

# Instructions for use Infinity<sup>®</sup> Acute Care System



#### WARNING

To properly use this medical device, read and comply with these instructions for use. Infinity<sup>®</sup> M540 patient monitor Software VG7.1

## **Typographical conventions**

- 1 Consecutive numbers indicate steps of action, with the numbering restarting with 1 for each new sequence of actions.
- Bullet points indicate individual actions or different options for action.
- Dashes indicate the listing of data, options, or objects.
- (A) Letters in parentheses refer to elements in the related illustration.
- A Letters in illustrations denote elements referred to in the text.
- > The greater-than symbol indicates the navigation path in a dialog.

Bold, italicized text indicates labels on the device and texts that are displayed on the screen.

#### **Figures**

Images of products and screen content in this document may differ from the actual products depending on configuration and design.

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## Microstream® MicroPod® External Capnography Module patents

The capnography component of this product is covered by one or more of the following US patents: 6,437,316; 6,428,483; 6,997,880; 7,488,229; 8,414,488; 8,412,655 and their foreign equivalents. Additional patent applications pending.

#### **Open-source software**

Dräger devices that use software may use open-source software, depending on their setup. Open-source software may be subject to different terms of license. Additional information regarding the open-source software used in this device is available at the following web page: *www.draeger.com/opensource* 

## Safety information definitions

#### WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

#### CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

#### NOTE

A NOTE provides additional information intended to avoid inconvenience during operation.

#### Duties of the operating organization

The tasks described in this document specify the requirements that have to be met by each respective target group.

The operating organization of this product must ensure the following:

The target group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).

The target group has been trained to perform the task.

The target group has read and understood the chapters required to perform the task.

#### **Description of target groups**

The target groups may only perform the following tasks if they meet the corresponding requirements.

#### User

Task	Requirement
Use of the product in accordance with the intended use	Specialist medical knowledge in the use of the product

#### **Reprocessing personnel**

Task	Requirement
Reprocessing	Specialist knowledge in the reprocessing of medical devices

#### Service personnel

Task	Requirement						
Installation	Specialist knowledge in						
Basic service activities (inspection, maintenance according to "Maintenance" on page 377).	electrical engineering and mechanics Experience in the servicing of medical devices						

#### Specialized service personnel

Task	Requirement
Installation	Specialist knowledge in
Basic and complex service activities	electrical engineering and mechanics
(inspection, maintenance, repair)	Experience in the servicing of medical devices
	Training in service activities on this product

A service contract with Dräger is recommended.

# Abbreviations and symbols

For explanations, refer to the sections "Abbreviations" on page 36 and "Symbols" on page 33.

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#### Mandatory reporting of adverse events

Serious adverse events with this product must be reported to Dräger and the responsible authorities.

#### Strictly follow these instructions for use

#### NOTE

The Infinity Acute Care System provides the following additional instructions for use:

- Infinity Acute Care System Monitoring applications (describes the Cockpit user interface of the IACS)
- Infinity Acute Care System Medical Cockpit (describes the hardware of the Cockpit)
- Infinity Acute Care System Monitoring accessories (describes all of the IACS accessories).

Please refer to these additional instructions for use for device-specific information.

#### WARNING

Risk of incorrect operation and of incorrect use.

Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under "Application," and in conjunction with appropriate patient monitoring.

Strictly observe all WARNING and CAUTION statements throughout these instructions for use and all statements on medical device labels. Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

#### Storing the instructions for use

WARNING

Risk of incorrect use

Instructions for use must be kept accessible for the user.

#### Training

Training for users is available from the responsible Dräger organization, see *www.draeger.com*.

#### Maintenance

#### WARNING

Risk of medical device failure and of patient injury.

The medical device must be inspected and serviced regularly by service personnel. Repair and complex maintenance carried out on the medical device must be performed by experts.

If the above is not complied with, medical device failure and patient injury may occur. Observe chapter "Maintenance."

A service contract with Dräger is recommended. It is recommended that original Dräger parts are used for repairs and that Dräger performs these repairs.

#### WARNING

Any modification of this device or any use different from the one specified in these instructions for use may cause interference with other equipment or result in injury to the patient or the user, including electric shock, burns or death.

#### Safety checks

The medical device must be subject to regular safety checks. See chapter "Maintenance".

#### Accessories

#### WARNING

Risk due to incompatible accessories.

Dräger has only tested the compatibility of accessories listed in the current list of accessories. If other accessories are used, there is a risk of patient injury due to medical device failure. Dräger recommends that the medical device is only used with accessories listed in the current list of accessories.

#### CAUTION

The MPods and associated accessories that have patient contact are not manufactured with natural rubber latex.

#### Installing accessories

#### CAUTION

Risk of device failure

Install accessories to the basic device in accordance with the instructions for use of the basic device. Make sure that there is a safe connection to the basic device.

Strictly observe instructions for use and assembly instructions.

#### Sterile accessories

#### CAUTION

Risk of medical device failure and of patient injury.

Do not use sterile-packaged accessories if the packaging has been opened, is damaged, or if there are other signs of non-sterility. Single-use accessories must not be reused, reprocessed, or resterilized.

#### **Restrictions for use**

#### WARNING

To avoid electric shock, the equipment should only be connected to a power source that is properly grounded (protective earth ground).

#### CAUTION

Device for use in healthcare facilities only and exclusively by persons as defined in the target groups (see page 6).

#### **Restriction of distribution**

Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

#### **Connected devices**

#### WARNING

Risk of electric shock and of device malfunction

Any connected devices or device combinations not complying with the requirements mentioned in these instructions for use can compromise the functional integrity of the medical device and lead to electric shock. Before operating the medical device, strictly comply with the instructions for use of all connected devices and device combinations.

# Safe connection with other electrical equipment

#### WARNING

**Risk of patient injury** 

Electrical connections to equipment not listed in these instructions for use should only be made following consultation with the respective manufacturers. Equipment malfunction may result and pose a risk of patient injury.

#### WARNING

The leakage current increases when multiple medical devices are connected to a patient. Make sure that the galvanic isolation of each device is suitable for the intended application. Connect only equipment to the analog and digital signal inputs and outputs that is setup and tested according to IEC standards.

To protect the patient from possible injury due to electrical shock, peripheral devices should only be connected to a monitor within the same room. The installer or service provider should verify that the leakage current of the interconnected system meets the electrical safety requirements of IEC 60601-1.

#### **Connection to hospital network**

Many medical devices manufactured by Dräger use networks to transmit patient data in real-time and to notify clinical users of alarm conditions. Hospitals should refer to IEC 80001-1 before attempting to connect such medical devices to their IT networks.

#### Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to persons familiar with the most important inherent characteristics of the medical device. Instructions and WARNING and CAUTION statements are therefore largely limited to the specifics of the Dräger medical device.

These instructions for use do not contain any information on the following points:

- Risks that are obvious to users
- Consequences of obvious improper use of the medical device
- Potentially negative effects on patients with different underlying diseases

Medical device modification or misuse can be dangerous.

#### CAUTION

Risk of patient injury

Do not make therapeutic decisions based solely on individual measured values and monitoring parameters.

#### **Patient monitoring**

The user of the medical device is responsible for choosing a suitable patient monitoring system that provides appropriate information on medical device performance and patient condition.

Patient safety may be achieved by a wide variety of means ranging from electronic surveillance of medical device performance and patient condition to direct observation of clinical signs.

The responsibility for selecting the best level of patient monitoring lies solely with the user of the medical device.

# General safety information

The following WARNING and CAUTION statements apply to general operation of the medical device.WARNING and CAUTION statements specific to subsystems or particular features of the medical device appear in the respective sections of these instructions for use or in the instructions for use of another product being used with this medical device.

#### WARNING

Risk of explosion and of chemical burns.

Improper handling of batteries can result in explosions and chemical burns.

Do not throw batteries into fire. Do not force batteries open.

#### WARNING

Never use equipment that has been damaged or compromised for patient monitoring.

#### WARNING

To avoid electric shock, inspect all cables before use. Never use cables that appear cracked, worn, or damaged in any way (doing so may compromise performance or put the patient at risk).

#### WARNING

To avoid risk of electric shock, this equipment must only be connected to a main power source with a protective earth ground.

#### WARNING

Do not cover the device with blankets or bed sheets. To prevent burns to the patient, avoid direct contact between external surfaces and the patient.

#### WARNING

To avoid patient injury as the result of a falling monitor when using a rolling trolley, universal bed hook, or handle hook mount, do not apply excessive force to the monitor or mount when entering or exiting elevators, or passing over thresholds or uneven surfaces.

#### CAUTION

To avoid injuring the patient, disconnect all sensors that will not be used during transport, before moving the patient.

#### CAUTION

Read all cleaning instructions (for example, originating from the disinfectant manufacturer and the hospital) carefully *before* cleaning the device. Refer to the chapter entitled "Reprocessing" on page 365 for device-specific cleaning instructions. Moisture may damage the circuits, compromise critical performance and present a safety risk.

#### WARNING

Dräger recommends using the Infinity Acute Care System or the M540 for primary diagnosis and the ICS (Infinity CentralStation) for patient viewing only.

#### WARNING

To prevent restriction of air flow to the device and also prevent potential overheating, do not allow the patient to come into direct contact with system components for extended periods of time.

# For countries subject to the EU directive 2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device.

To initiate collection or for further information, visit Dräger on the Internet at www.draeger.com. Use the Search function with the keyword "WEEE" to find the relevant information. If access to Dräger's website is not possible, contact the local Dräger organization.

#### Not for use in areas of explosion hazard

#### WARNING

**Risk of explosion** 

This medical device is neither approved nor certified for use in areas where oxygen concentrations greater than 25% (combustible or explosive gas mixtures) are likely to occur.

#### WARNING

When placing the device, make sure that adequate airflow exists. To prevent overheating, position the device with at least 5 cm (2 in) of space all around.

# Information on electromagnetic compatibility

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided in the Electromagnetic compatibility section in the *Technical data* chapter. Portable and mobile radio frequency communications equipment can affect medical electrical equipment.

#### WARNING



Do not connect connectors with an ESD warning symbol and do not touch their pins without implementing ESD protective measures. Such protective

measures may include antistatic clothing and shoes, touching a potential equalization pin before and during connection of the pins, or using electrically insulating and antistatic gloves. All users concerned must be instructed in these ESD protective measures.

#### **Operating location**

Only use devices (monitor, MPod, MCable, and accessories) in areas that meet the environmental requirements outlined in the technical data section.

#### WARNING

To avoid interfering with device operation, do not operate devices (monitor, MPod, MCable, and accessories) close to equipment that emits microwave or other high-frequency emissions.

#### WARNING

Periodically make sure that the device is properly mounted and secured to prevent injury. Make sure the requirements for maximum load and slope of floor are met. Consult the documentation of the mounting manufacturer for detailed information.

#### WARNING

To minimize the risk of patient strangulation, carefully position and secure sensor cables. Also position the sensor cables to minimize inductive loops.

#### CAUTION

To prevent overheating, do not place the device in direct sunlight or near heaters.

#### CAUTION

After extended exposure in a cold environment, acclimate the device carefully so that condensation does not form on the electronic parts and damage the device.

#### CAUTION

To avoid damaging the touch-sensitive screen, do not allow sharp instruments to touch the front of the devices.

#### CAUTION

To avoid short-circuiting and otherwise damaging the device, Dräger recommends that no fluids come in contact with the IACS devices when they are connected to a power socket. If fluids are accidentally spilled on the equipment, remove the affected device from service as soon as possible and have service personnel verify that patient safety is not compromised.

#### **Defibrillator precautions**

The M540 and the peripheral devices are protected against high-frequency interference from defibrillators and electrosurgical units and against 50- and 60-Hz power line interference.

#### WARNING

To protect the patient during defibrillation and to ensure accurate ECG information, use only ECG electrodes and cables specified by Dräger. Removal of applied parts that are not rated defibrillation-proof, such as disposable SpO2 sensors, may be required to prevent sensor breakdown and energy shunting.

#### CAUTION

To prevent burns and electric shock due to the rerouting of electrical current through electrodes, do not position the defibrillator pads near any electrodes or sensors.

#### CAUTION

Only defibrillate across the chest.

#### Electrosurgery

Observe the following precautions during electrosurgery to reduce electrosurgical unit (ESU) interference and improve operator and patient safety.

#### WARNING

For better performance and to reduce the hazard of burns during surgery, always use accessories designed for ESU environments. Do not use skin temperature sensors.

#### WARNING

To reduce the hazard of burns during electrosurgery, keep the sensor or transducer (e.g., ECG, SpO2 pressure) and their associated cables away from the surgical site, the ESU return electrode, and earth ground.

#### NOTE

Cover internally placed reusable temperature sensors with temperature sensor sheaths.

#### WARNING

To reduce the hazard of burns during electrosurgery, do not use four-lead extension cables in electrosurgical environments.

#### Security recommendations

Dräger makes the following security recommendations:

- Physical security of the patient monitors is recommended and is the responsibility of the operating organization.
- Physical security of the telecommunications closet is recommended and is the responsibility of the operating organization.
- Dräger recommends that operating organizations restrict physical access to unused ethernet ports on the IACS.
- Dräger recommends that operating organizations restrict physical access to unused USB and serial ports on the IACS.
- Dräger relies on the medical device isolation mechanism of the VLANs and the proper configuration, implementation, and use of the operating organization's security measures to prevent the introduction of malware onto the Infinity network.

#### CAUTION

Dräger recommends that all documents opened for viewing within a hospital LAN must come from a secure source. This page has been left blank intentionally.

# Application

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## Intended use

The Infinity M540 is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patients in environments where patient care is provided by trained health care professionals.

The M540 obtains physiological data from connection to optional accessory devices. The transfer of this data is accomplished by the Infinity network.

The M540 is intended to monitor one patient at a time.

The M540 and any connected hardware are not intended for use in the following hospital environments:

- Hyperbaric chambers
- Environments containing MRI equipment

The Infinity MCable Microstream, when connected to the M540, provides continuous sidestream measurements of carbon dioxide (CO2) for intubated and non-intubated patients.

The Infinity MCable Microstream is intended for use with adult, pediatric, and neonatal patients.

## Indications for use

The M540 monitors the following parameters:

- Heart rate
- Arrhythmia (adult and pediatric patients only)
- 12-lead analysis
- ST segment analysis including TruST<sup>®</sup> (adult and pediatric patients only)
- Apnea
- Impedance respiratory rate (RRi)
- Invasive pressure (IP)
- Non-invasive blood pressure (NIBP)
- Temperature
- Cardiac output, only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
- Arterial oxygen saturation (SpO2)
- Pulse rate
- Perfusion index (PI)
- Total arterial hemoglobin (SpHb) (adult and pediatric patients only)
- Total oxygen content (SpOC) (adult and pediatric patients only)
- Carboxyhemoglobin saturation (SpCO) (adult and pediatric patients only)
- Methemoglobin saturation (SpMet)
- Pleth variability index (PVI)
- Carbon dioxide (CO2)
- Oxygen (O2) (adult and pediatric patients only)
- Nitrous oxide (N2O) (adult and pediatric patients only)
- Anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, Enflurane) (adult and pediatric patients only)
- xMAC (adult and pediatric patients only)

The IACS is also capable of connecting to third party devices to display physiologic, multi-parameter data, store trends, and send the data across a network. This page has been left blank intentionally.

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# Overview

These instructions for use describe the M540 patient monitor. This monitor is a rugged, light-weight, hand-held, transportable patient monitor with a touchscreen and independent user interface.

When the M540 is docked in the Infinity M500 and is part of an Infinity Acute Care System (IACS) configuration, the M540 is the signal acquisition and data processing module for the Infinity C500/C700. The M540 can also be used as a standalone monitor docked in an Infinity M500.

The M540 also provides seamless patient monitoring when it is undocked from the M500 for patient transport (see page 82).

The M540 comes with a wireless option that allows it to transmit patient data to the ICS (Infinity CentralStation) during transport.

#### NOTE

Because the M540 is also part of an IACS configuration, some of the IACS components are also described here. For specific information regarding the IACS, refer to the instructions for use *Infinity Acute Care System – Monitoring Applications*.

Some terms used in these instructions for use:

- Cockpit refers to the Infinity C700 Medical Cockpit or the Infinity C500 Medical Cockpit which is the display module of the Infinity Acute Care System
- M540 refers to the Infinity M540 patient monitor
- M500 refers to the Infinity M500 that secures the M540 and charges the internal battery of the M540
- Docking the M540 refers to placing the M540 on the M500.
- Patient and user default settings (referred to as profiles) are stored on the M500. For more information, refer to the chapter *Operating Concept* page 47.

The M540 docked on an M500 can be set up as a stand-alone configuration to charge the battery when the M540 is not part of an IACS configuration.

The following diagram shows an M540 stand-alone configuration. In addition, you can connect various hardware to expand the monitoring capabilities.



- **A** The M540
- **B** The M500
- C Y-cable/Y-adapter
- D Power supply
- E Power cable

#### Front view of the M540



- A 8 function keys (see page 59)
- **B** Header bar (see page 60)
- C Parameter field (see page 62)
- D NIBP start/stop key
- E Alarm bar
- F Power on/off key
- G Battery LED symbol
- H Audio pause key
- I Parameter field in alarm
- J Waveform area (see page 62)

#### M540 Keys

The M540 has the following keys:

Key/LED	Function					
	On/off key					
$\odot$	Turns the M540 on or off.					
	The button LED flashes when the M540 is undocked; it lights up when the M540 is docked.					
	Battery LED symbol					
	This symbol lights up when the M540 is docked to indicate the battery is being charged; it does not light up when the M540 is undocked.					
	Audio pause key Pauses acoustic alarm signals for two minutes.					
NBP	NIBP start/stop key Starts/stops non-invasive blood pressure measurements.					

#### Back view of the M540

# A B C C Porton

- A Charging contact points
- B Labels
- C Optical ethernet links

#### CAUTION

Do not affix any labels inside the shaded areas of the M540. Doing so may interfere with charging the device or with communicating with the M500. It may also prevent the M540 from physically docking to the M500.

#### Side view of the M540



- A Non-invasive blood pressure connector
- B Temp (2) / Aux connector
- C SpO2 connector
- D Hemo connector
- E CO2 connector
- F ECG connector

## M500 docking station

The M500 is the device that mechanically secures and powers the M540. The M500 also charges the battery of the M540. If the M540 is part of an IACS configuration, the M500 controls the communication between the M540 and the Cockpit through an optical Ethernet link.

When used in a standalone configuration, the M500 facilitates patient transport by allowing the M540 to be undocked from one M500 and redocked in another M500 while maintaining all patient monitor connections. In addition to powering the M540, the M500 stores network information, connects the M540 to the Infinity network and stores default profile settings that can be adopted upon docking. For detailed information see "Profiles" on page 67.

#### Front view of the M500



- A Locking mechanism secures the M540 (for more detailed information, see "Locking/unlocking the M540" on page 42)
- **B** Release button for undocking the M540 (you only need to press one button to release the M540)
- C Optical Ethernet links
- D Pins for charging the M540 battery; the pins also provide power to the M540 when it is docked

#### Back view of the M500



- **E** Nurse call connector (not available in a standalone configuration)
- F Network LED lights up green when connected to the network
- G System cable connector

#### NOTE

A cable hook can be attached on the bottom of the M500 docking station. For more information about the hook and other hardware options, refer to the *Infinity Acute Care System – Monitoring Accessories Instructions for use.* 

#### M540 docked in the M500

The following diagram shows the M540 when it is docked in the M500 docking station.



Additional hardware

The following table lists the additional devices that can be connected to the M540.

Device	Description	Connection
Infinity MCable – Masimo SET	Measures the percentage of functional hemoglobin saturated with oxygen ( <i>SpO2</i> ) and reports the perfusion index ( <i>PI</i> ), and the pulse rate ( <i>PLS</i> ).	Connects directly to the <b>SpO2</b> connector of the M540 (see page 186 and page 200).
Infinity MCable – Masimo rainbow SET	Measures the percentage of functional hemoglobin saturated with oxygen ( <i>SpO2</i> ) and reports the perfusion index ( <i>PI</i> ), and the pulse rate ( <i>PLS</i> ). In addition, it measures total hemoglobin ( <i>SpHb</i> ), total oxygen content ( <i>SpOC</i> ), pleth variability index ( <i>PVI</i> ), carboxyhemoglobin saturation ( <i>SpCO</i> ), methemoglobin saturation ( <i>SpMet</i> )	

- A M540 patient monitor
- **B** M500 docking station

Device	Description	Connection
Infinity MCable – Nellcor OxiMax	Measures the percentage of functional hemoglobin saturated with oxygen (% <i>SpO2</i> ) and the pulse rate ( <i>PLS</i> ).	Connects directly to the <b>SpO</b> <sup>2</sup> connector of the M540 (see page 186 and page 200).
Hemo4 pod Infinity MPod – Quad Hemo	Measures up to four pressures, cardiac output, core and body surface temperature.	Connects directly to the Hemo connector of the M540 (see information starting on
Hemo2 pod	Measures up to two pressures, cardiac output, core and body surface temperature.	page 229).
Infinity MCable – DualHemo	Measures up to two pressures.	
Infinity MCable – Mainstream CO2	Measures mainstream CO2.	Connects directly to the CO2 connector of the M540 (see page 254).
Infinity MCable – Analog/Sync	Provides a sync pulse to synchronize defibrillators to the heart beat of the patient during cardioversion. The cable's analog out function provides an <i>ECG</i> and arterial blood pressure signal to a device such as intra- aortic balloon pump.	Connects to the Temp/Aux connector of the M540 (see page 207) or to the CO2 connector with a Y-cable.
Infinity MCable – Microstream CO2	Measures Microstream CO2	Connects directly to the CO2 connector of the M540 (see page 268).

Device	Description	Connection
Scio Four	Measures the concentration of CO2, N2O, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	Connects directly to the CO2 connector of the M540 or the M500 docking station (see page 280).
Scio Four Oxi	Measures the concentration of CO2, N2O, O2, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	
Scio Four plus	Measures the concentration of CO2, N2O, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	
Scio Four Oxi plus	Measures the concentration of CO2, N2O, O2, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	

# Symbols

淤	Keep away from sunlight	Not made with natural rubber latex	Not made with natural rubber latex
LATEX	Caution: This product contains natural rubber latex which may cause an allergic reactions	X	Alarm monitoring deactivated temporarily
<b>(</b>	Warning! Strictly follow these instructions for use	Â	Caution! Observe the accompanying documentation!
ŢŢ	Consult instructions for use	Not made with natural rubber latex	Not made with natural rubber latex
	ESD warning	$\bigotimes$	Alarm monitoring deactivated permanently
(8888)	Battery status (when the battery is fully charged, all segments in the symbol are filled in)		Acoustic alarm signal paused temporarily
) L	Function/setting is unlocked	$\bigotimes$	Acoustic alarm signal turned off permanently
Ĥ	Function/setting is locked		Lung symbol that pulsates with each detected breath
	Manufacturer		Heart blip that flashes with each detected pulse
M	Date of manufacture	P	Pacer detection is activated; the heart symbol flashes with each detected paced pulse

IPXx	Degree of protection against solid particle and liquid ingress, e.g., IPX1, IPX4, etc.	Ċ	Power on/off
<u> </u>	Lower alarm limits		WEEE - dispose electrical-electronic equipment properly
	Upper alarm limits	REF	Component number and revision
¥ *	Autoset alarm limits	SN	Device serial number
+)	Battery charging LED	÷.	Adult patient category
X	The speaker is deactivated	Ň	Pediatric patient category
<u> </u>	The M540 is docked and connected to the network	•	Neonatal patient category
F©	Federal communications commission declaration of conformity number	R	Japanese radio wave law certification
LATEX FREE	Not manufactured with natural rubber latex	┥♥⊦	Defibrillation-proof Type CF equipment
$\rightarrow$	Gas in	╡╋	Defibrillation-proof Type BF equipment
	Gas out	Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician.
Do not re-use	Do not re-use, single patient use	<b>(51)</b>	China RoHs marking for Control of pollution caused by Electronic Information Products.

Use by:	Symbol indicates shelf life. YYYY- mm-dd indicates date by which device needs to be used to remain safe.	MD	Medical device
yyyy-mm-dd			
DEHP	Contains DEHP		

#### Wireless symbols

The following symbols appear in the header bar of the M540 only when it is on wireless transport.

(((•)))	White wireless symbol indicating the M540 has optimum association with a wireless access point.	(( <b>●</b> )) ■	White wireless symbol indicating the M540 has good association with a wireless access point
	This symbol also appears on the back of the M540 when the wireless option is activated.		
( <b>•</b> )	White wireless symbol indicating the M540 has adequate association with a wireless access point	1	The symbol appears white when the M540 is still associated with a wireless access point but no data is transmitted to the ICS.
			The symbol appears red when the M540 is no longer associated with a wireless access point.

# Abbreviations

The following table lists the abbreviations in these instructions for use and those abbreviations that are displayed on the M540.

Abbreviation	Description
ABD	Abdominal pressure
AHA	American Heart Association
AIVR	Accelerated idioventricular rhythm
AOR	Aortic arterial blood pressure
APP	Abdominal perfusion pressure
ARR	Arrhythmia
ART	Arterial blood pressure
ART D	Diastolic arterial blood pressure
ART M	Mean arterial blood pressure
ART S	Systolic arterial blood pressure
ARTF	Artifact
ASY	Asystole
AXL	Axillary arterial blood pressure
BDP	Bladder pressure
BGM	Bigeminy
BPP	Bladder perfusion pressure
BRA	Brachial arterial blood pressure
BRADY	Bradycardia
CISPR	International Special Committee on Radio Interference
CO2	Carbon dioxide
CPP	Cerebral perfusion pressure
CPP2	Cerebral perfusion pressure 2
CPP3	Cerebral perfusion pressure 3
CPP4	Cerebral perfusion pressure 4
CPT	Ventricular couplet
CVP	Central venous blood pressure
ECG	Electrocardiogram

Abbreviation	Description
ECGaVF, ECGaVL, ECGaVR	ECG leads
ECGdV1 to ECGdV6	Derived chest leads
ECGV	Chest lead from a 5- or 6-wire lead set.
ECGV+	Second chest lead from a 6-wire lead set
ECGV1 to ECGV6	ECG chest leads ECGV1 to ECGV6
ESO	Esophageal pressure
etCO2	Endtidal CO2
F	Left leg electrode (IEC)
FEM	Femoral arterial blood pressure
FEMV	Femoral venous blood pressure
GPM	Mean general pressure
GP1 D to GP4 D	General pressure 1 to 4, diastolic value
GP1 M to GP4 M	General pressure 1 to 4, mean only value
GP1 S to GP4 S	General pressure 1 to 4, systolic value
GP1 to GP4	General pressure 1 to 4
GP5 to GP8	General pressure 5 to 8
HR	Heart rate
I, II, III	ECG leads
IACS	Infinity Acute Care System
IP	Invasive pressure
ICP	Intracranial pressure
ICP2	Intracranial pressure 2
ICP3	Intracranial pressure 3
ICP4	Intracranial pressure 4
ICS	Infinity CentralStation
r	
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Abbreviation	Description
IEC	International Electrotechnical Commission
inCO2	Inspiratory CO2 concentration
ISO	International Organization for Standardization
L	Left arm electrode (IEC)
LA	Left arm electrode (AHA)
LA	Left atrial blood pressure
LL	Left leg electrode (AHA)
LV	Left ventricular blood pressure
LV D	Diastolic left ventricular blood pressure
LV M	Mean left ventricular blood pressure
LV S	Systolic left ventricular blood pressure
N	Right leg electrode (IEC)
NIBP	Non-invasive blood pressure
NIBP D	Diastolic non-invasive blood pressure
NIBP M	Mean non-invasive blood pressure
NIBP S	Systolic non-invasive blood pressure
PA	Pulmonary arterial blood pressure
PA D	Diastolic pulmonary arterial blood pressure
PA M	Mean pulmonary arterial blood pressure
PA S	Systolic pulmonary arterial blood pressure
PI	Perfusion index (SpO2)
PLS	Pulse rate from SpO2
PLS CO-Ox	Pulse CO-Oximetry
PVC/min	Rate of premature ventricular contractions per minute

Abbreviation	Description
PVI	Pleth variability index
R	Right arm electrode (IEC)
RA	Right arm electrode (AHA)
RA	Right atrial blood pressure
RAD	Radial arterial blood pressure
RL	Right leg electrode (AHA)
RRc	Respiratory rate (CO2)
RRi	Respiratory rate (impedance)
RUN	Ventricular run
RV	Right ventricular blood pressure
RV D	Diastolic right ventricular blood pressure
RV M	Mean right ventricular blood pressure
RV S	Systolic right ventricular blood pressure
SpCO	Carbon monoxide bound to hemoglobin
SpHb	Total hemoglobin levels in arterial or venous blood
SpHbv	Total hemoglobin (venous)
SpMet	Methemoglobin saturation
SpO2	Pulse oxygen saturation
SpOC	Total oxygen concentration
STCVM	Change in vector magnitude
STdV1 to STdV6	ST-segment deviation of derived leads (ECGdV1 to ECGdV6)
STI, STII, STIII, STV, STV1 to STV6	ST deviation leads
STVM	ST vector magnitude
SVT	Supraventricular tachycardia
TACH	Tachycardia

Abbreviation	Description
TruST	Algorithm that provides a TruST- 12-lead-ECG (including derived chest leads ECGdV1, ECGdV3, ECGdV4, ECGdV6) using a 6- wire lead set that provides leads ECGI, ECGII, ECGIII, ECGaVL, ECGaVR, ECGaVF, ECGV2, ECGV5.
UAP	Umbilical arterial blood pressure
UVP	Umbilical venous pressure
VESA	Video Electronics Standards Association
VF	Ventricular fibrillation
VTACH	Ventricular tachycardia

# Assembly and preparation

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# Overview

This section describes the following basic assembly tasks:

- Docking/undocking the M540 from the M500
- Locking/unlocking the M540 into the M500
- Connecting/disconnecting the system cables

# Commercially available M500 mounting solutions

Various mounting solutions are available. It is the responsibility of the hospital to install, test, and ensure the proper and safe operation of any mounting solution. Contact a Dräger representative for specific approved mounting solutions.

#### CAUTION

Check the weight ratings of the commercially available mounts to avoid injuring the patient or damaging the device.

#### CAUTION

Avoid mounting solutions that could impede air flow since the M500 requires adequate airflow to dissipate heat.

# Docking/undocking the M540

The following diagram shows the side and front of the M500 which holds the M540 in place.

#### Front view of the M500 with M540 docked



### Side view of the M500 (M540 undocked)



- A M500 locking tab
- B M540 patient monitor
- **C** M500
- D Swivel mount (optional) and mounting clamp
- E Release button

#### To dock the M540

- 1 Align the curved portion of the M540 with the curved portion of the M500.
- 2 Press the M540 (B) into the M500 (C) until it 'clicks' into place.
- 3 Push the locking tab (A) of the M500 toward the front, to the locked position <sup>∩</sup><sub>⊥</sub>, to fasten the M540 into place.

To lock the M540 into place permanently, see page 42.

#### To undock the M540

- Push the locking tab (A) of the M500 toward the back. If the locking tab does not move, it has been locked. To unlock the M540, see page 42.
- 2 Hold the M540 firmly and press one of the M500 release buttons (E see arrow).
- 3 Pull the M540 (B) out of the M500 (C).



# Locking/unlocking the M540

You can lock the M540 in the M500 to prevent anyone from undocking it.

#### To lock the M540

- 1 Push the locking tab (D) of the M500 toward the front. This prevents anyone from undocking the M540. Pushing the locking tab back, allows anyone to undock the M540 again.
- 2 Insert the 2 mm Allen key (A) into the middle hole (B) on the locking tab and turn it clockwise to the locked position 1. The locking tab is now fixed and the M540 cannot be unlocked unless it is first 'unlocked' using the hex wrench tool.



- A Allen key
- B Center hole on locking tab for locking/unlocking the M540
- **C** Release buttons for undocking the M540
- D Locking tab

#### To unlock the M540

- Insert the 2 mm Allen key (A) into the middle hole (B) on the locking tab and turn it counterclockwise to the unlocked position 1.
- 2 Push the locking tab (D) back to unlock the release buttons (C) on the M500 to undock the M540.

# Connecting the system cables in an IACS configuration

For details on connecting the IACS system cables, refer to the Instructions for use *Infinity Acute Care System – Monitoring Applications*.

# Connecting the system cable in an M540 stand-alone configuration

1 Connect one end of the M540 Y-cable/Yadapter to the M500 system connector (A).



- **2** Connect the power supply to the M540 system cable.
- 3 Connect the power cable to the power supply.

# Additional M540 accessories

The M540 patient monitor supports a variety of accessories that include transport hardware, clamps, cable hooks, trolleys, and so forth. For more information about these specialized accessories, refer to the *Infinity Acute Care System* – *Monitoring Accessories Instructions for use*.

# Mounting the Infinity MCable – Masimo SET and Masimo rainbow SET/Nellcor OxiMax

The following diagram shows how a Masimo MCable and a Nellcor OxiMax can be mounted to the M540.



- **A** M540
- **B** Tabs of the MCable mount adapter that lock into the side of the M540.
- C MCable housing
- D MCable

- E Blue SpO2 connector
- F Indentations for locking the MCable mount adapter
- **G** Intermediate cable or reusable SpO<sub>2</sub> sensor which connects directly to the MCable

#### To attach the MCable mount adapter

Follow these steps to attach the MCable to the M540:

- 1 Make sure the cable end of the MCable (D) mount adapter (C) points in the same direction as the connector side of the M540.
- 2 Align the tabs on the mount adapter (B) with the indentations on the M540 and push firmly until the mount adapter clicks in place.
- **3** Connect the MCable (D) to the blue SpO2 connector on the M540.

#### To remove the MCable mount adapter

- Insert a flat head screwdriver (or equivalent tool) between the indentations for locking the MCable mount adapter (F).
- **2** Gently lift to unhinge the adapter.

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# Operating concept

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# Overview

The M540 is a portable patient monitor that accompanies the patient from the bedside to anywhere in the hospital. This small, lightweight, splash-resistant monitor makes transporting less disruptive to the patient, reducing the risks of undetected events, and improving the efficiency of the clinician. The M540 is available in the following configurations:

- As a transport module in an IACS setup. When docked, the M540 communicates with the Infinity network through the Cockpit.
- As a standalone monitor docked in an M500 that is connected to the Infinity network. When docked, the M540 is in wired mode and communicates with the Infinity network through the M500.

If the wireless option is activated and configured, the M540 switches to wireless mode automatically when undocked. If the wireless option is not activated when the M540 is undocked, monitoring continues but the M540 no longer communicates with the network.

#### NOTE

The M540 can also be docked to an M500 that is only connected to power and is used for charging the M540 battery.

An M540 standalone configuration consists of the following components:

- M540 patient monitor
- M500 (docking station)
- Y-cable/Y-adapter for power and/or network connection
- Power supply
- MPod and MCable devices for monitoring specific parameters and associated accessories.

An M540 in an IACS configuration consists of all of the above listed components and the following:

- C500/C700 display module
- P2500 power supply or the PS250 power supply

#### NOTE

For detailed information on how the M540 functions in an IACS configuration, refer to the Instructions for use *Infinity Acute Care System* – Monitoring Applications.

An M540 can be mounted in an M500 on a trolley, or in a traditional wall mounting.

### M540 in standalone / wireless mode

An M540 standalone monitor communicates with the Infinity network through the M500. For information on configuring the wired option (for example, setting up IP addresses, and so on, see page 308).

When the wireless option is activated and configured, a standalone M540 communicates wirelessly with the Infinity network when undocked. When docked, a wireless M540 transitions back to a wired connection, and the wireless symbol is replaced by the network symbol  $\square_{r}$ .

For detailed information on configuring the wireless option (for example, setting up IP addresses, activating and deactivating wireless mode), see page 308.

For information how the M540 behaves in an IACS configuration, see page 52.

#### NOTE

Speaker volume reverts to its default after it is power-cycled. Speaker volume can be changed manually.

#### Configuration changes while on wireless transport

Any changes to the M540 profile settings while on transport (including remote changes) are maintained when the user redocks the M540 to the M500 where it was previously docked. However, if the user docks the M540 on a different M500, the configuration settings of the M500 determine if the M540 adopts the profile of the M500 or if it retains the transport settings when it is docked.

For detailed information on configuring the profile adoption behavior, see page 81.

#### Transport tone volume settings

When an M540 monitor is undocked, the following transport settings are activated. These transport settings are initially configured under the password-protected **Volume/ Tones** tab (see page 303).

 The setting *Transport pulse tone* determines the pulse tone volume for SpO2 and heart rate when the M540 is undocked. While undocked the user can adjust the pulse tone volume manually in the parameter-specific SpO2 or heart rate setup menu.  The transport volume determines the speaker volume of the M540 when it undocks for patient transport.

When used in an IACS configuration, the M540 is responsible for issuing all acoustic alarm signals when it is undocked. The Cockpit no longer issues acoustic alarm signals while the M540 is undocked.

While undocked, the user can adjust the *Transport volume* setting manually by pressing the *Alarms* function key then the *Alarm volume* button. If the M540 docks on an M500 in an IACS configuration, the speaker is deactivated and the Cockpit assumes primary alarm annunciation.

Because these transport settings are part of a profile, the profile adoption setting determines what happens to any changes that occur during transport when the M540 docks to the M500. For more information, see page 81.

#### Bed label setting

If the *Keep bed label* setting on the M540 is set to *Yes*, the M540 adopts the bed label that was configured on the previous device (IACS or M500).

If the *Keep bed label* setting on the M540 is set to *No*, the M540 adopts the bed label that was configured on the M540. The other settings that were configured in the *Name service* dialog on the previous device will be maintained (for example: *Mon. unit*).

If the *Keep bed label* setting is set to *No* and the bed label is modified while the M540 is wireless, the bed label is automatically updated on the M540 and the update is transmitted over the network.

If the M540 reports an offline message, the *Keep* **bed label** setting has not been configured on the M500. In this case the M540 automatically reverts to the default setting **Yes** when it is undocked. For more information about the offline message, see page 324.

Contact specialized service personnel to configure this setting appropriately. For more information, see page 314.

If the wireless mode is disabled, the *Keep bed label* setting appears grayed out.

#### Network status symbol

The following table lists the symbols that appear on the M540 header bar to indicate whether the M540 is in wireless mode or not and how robust the wireless connection is.

<u>_</u>	The M540 is docked on an M500 and is communicating with the Infinity network through a wired connection.
((( 🖕 )))	The M540 is communicating wirelessly and has optimum association with a wireless access point.
((•)) •	The M540 is communicating wirelessly and has good association with a wireless access point.
( <b>•</b> )	The M540 is communicating wirelessly and has adequate association with a wireless access point.
1	The symbol appears white when the M540 is still associated with a wireless access point but no data is transmitted to the ICS.
	The symbol appears red when the M540 is no longer associated with a wireless access point.

# M540 in an IACS configuration

In addition to operating as a standalone device, the M540 can also function as the signal acquisition component for an IACS configuration. When docked on the M500, the M540 remains at the bedside and communicates all patient data to the Infinity Medical Cockpit, the main display component of the IACS. When disconnected ("undocked") from the M500 for patient transport, the M540 continues to monitor the patient.

When the wireless option is activated and configured, the M540 switches to wireless mode automatically within 10 seconds of being undocked from the M500. When the M540 is on wireless transport, the network symbol  $\Box$  is replaced by a wireless symbol (see page 51) until the M540 returns to an M500.

Once redocked on the M500, the M540 transmits the data that was collected during patient transport to the Cockpit. For more detailed information on how the M540 functions in an IACS configuration, refer to the Instructions for use *Infinity Acute Care System – Monitoring Applications*.

# Configuration changes while on wireless transport

Any changes (including remote changes) to the patient profile while the M540 was on wireless transport are reset to the profile settings of the Cockpit once the M540 is docked. For information how the M540 behaves as a standalone device, see page 49.

# Communicating with the Infinity network

An M540 communicates with the Infinity network wirelessly when the wireless option is unlocked and configured. An M540 also communicates with the network when it is docked on an M500 that is connected to the Infinity network. An M540 that communicates with the Infinity network is Infinity OneNet compatible.

The following data are made available to the Infinity network while the M540 is communicating with the Infinity network:

- All real-time parameter and waveform information.
- All alarm information in case of multiple alarms, the alarm condition with the highest grade alarm is sent to the network.
- M540 trend data (up to 72 hours of trend data for each parameter).
- ST complexes can be viewed from the ICS and the Symphony application.

- Alarm messages of high, medium, and low priority from devices on the network within the configured monitoring unit and the selected alarm group.
- The following messages: All alarms off,
   All alarms paused (with timer), HR Limits
   Off, the patient category identifier (adult, pediatric, neonate), Pacer off, Pacer fusion
- 🛛 Alarm limits off symbol 🖄
- Patient name

See "Device communication messages / general device messages" on page 324 for network-related messages.

#### NOTE

If an NIBP measurement was taken more than 24 hours ago, and the M540 is undocked and re-docked to a Cockpit or stand-alone docking station, the data displays on the ClusterView and the ICS BedView without a time stamp.

#### Loss of connection to the network

When the M540 loses its connection to the Infinity network and the feature *Offline detection* is activated at the Cockpit, the following happens:

- A single notification alarm of low alarm priority sounds once within 25 seconds of the offline condition. The single notification tone annunciates even if alarms are paused or the alarm volume has been deactivated.
- The alarm volume is automatically adjusted to 100% until the condition clears. Once the M540 re-establishes communication with the network, the previous alarm volume is restored.

 The message *Offline* appears on cyan background in the network message area until the connection to the network is restored.

The alarm condition clears when communication between the M540 and the network is re-established.

When the setting *Offline detection* is not activated at the Cockpit or at an M540 in a standalone configuration, the above messages and alarm tone behaviors are not supported.

**Offline detection** is a Service setting which is configured by Service personnel.

# ICS (Infinity CentralStation) communication

Each M540 that is connected to the network can be associated with an ICS.

#### NOTE

# The IACS is compatible with ICS software VGx.

An M540 is represented on the ICS with a viewport and a BedView. Depending on the layout of the ICS, a viewport may consist of several waveforms and parameters. Regardless of the selected ICS layout, the top M540 waveform and the associated parameter field always appear in the viewport. The parameter data and waveforms appear in the assigned ICS viewport within 40 seconds after the M540 has been undocked from the M500. The wireless symbol <sup>(()</sup>) appears next to the bed label in the ICS viewport. The wireless symbol disappears as soon as the M540 is docked on the M500.

Refer to the instructions for use *Infinity CentralStation* for information on how to assign a patient to an ICS.

#### ICS BedView waveform/parameter assignment

The ICS also provides a BedView window which displays the content of the M540 in greater detail. A BedView contains up to seven waveforms and associated parameter fields. Up to four additional parameter fields can be allocated to appear along the bottom. The BedView screen is populated with waveforms and parameter fields from the five available M540 Views. These Views determine how many waveforms and parameter fields are displayed on the M540.

Specifically, the ICS uses the following rules to populate the BedView window with waveforms and parameter fields from the M540:

 The top waveform of View 1 of the M540 becomes channel 1 on the ICS BedView.

- No waveform and no parameter field are repeated more than once. Therefore, the next unique waveform becomes channel 2 on the ICS BedView. This waveform could originate from the same View or, if no unique waveform is available, from the next View. For example, if the *ECGII* waveform occupies the top channel in View 1 and the *ECGII* waveform is repeated in View 2, the *ECGII* waveform in View 2 is skipped because it has the same label as the top waveform in View 1 and is therefore not unique.
- The remaining available slots on BedView continue to be populated by other unique waveforms on the M540 in the same way.
- Once the waveforms are assigned to the BedView, the associated parameter fields are assigned next to their respective waveforms.
- Lastly, the four available parameter slots located at the bottom of the BedView are filled with unique parameter fields (no waveforms) starting with the right-most parameter field which appears along the bottom of the M540.
- If you are using PatientWatch, part of the Infinity Gateway product suite, ECG III, ECG aVF, and ECG aVL will not display, but these leads are still available at the patient monitor and the ICS.
- If an NIBP measurement was taken more than 24 hours ago, and the M540 is undocked and re-docked to a Cockpit or stand-alone docking station, then the NIBP measurement data is sent and displayed without a time stamp on the Main screen and the BedView on the ICS.

#### NOTE

When the M540 is placed in standby or discharge mode, ECG and IP waveform scales appear in the viewport. However, waveforms do not appear in the viewport.

#### NOTE

When Bed View 1 is the only view enabled on the M540, the ICS Bed View does not draw correctly.

#### Wireless M540 and the ICS

If the *Keep bed label* setting on the M540 is set to *Yes,* the patient data of a wireless M540 continue to display in the same viewport of the ICS even after it is undocked.

If the *Keep bed label* setting is set to *No*, the M540 uses the bed label configured in the M540 wireless menu when it undocks. In this case the patient data are removed from the ICS viewport. A message appears in the viewport that the M540 is disconnected because the ICS no longer recognizes the patient due to the new bed label. To display the patient data on the ICS, the patient must be admitted again at the ICS. If not readmitted, the patient will no longer appear in the ClusterView of the ICS.

If the user docks a different M540 on an M500, the data of the original wireless M540 continues to be displayed in the same ICS viewport. In addition, the ICS alarm surveillance function monitors the new patient if configured to do so. The data of the new M540 are made available to the Infinity network and the patient can be manually assigned to an empty viewport at the ICS.

While a M540 is on the Infinity network, any events that occur are sent to the ICS event disclosure data base.

The M540 also supports the full disclosure application on the ICS which stores waveforms continuously.

#### NOTE

PatientWatch does not display ECG III, ECG aVF, and ECG aVL in the ECG show all screen. However, these leads are still available at the patient monitor and at the ICS.

#### NOTE

An alarming M540 wireless parameter is only stored in the ICS Event Disclosure database if the parameter appears on the BedView of the ICS.

#### Trend data

After docking/undocking the M540, one minute of trend data collected during this transition period may not be displayed at the ICS equipped with software version VG1. However, these trends are visible at the Cockpit.

The ICS also displays trend data for a M540 that is on the Infinity network. The trend history and tabular trend windows on the ICS only display parameters that have trend data available. Parameters with no trend data do not appear at the ICS.%Paced values originating from the M540 do not appear in the trends of an ICS equipped with software version VG1. These values do appear when the M540 is docked in an IACS configuration.

For more detailed information regarding the windows and functions on the ICS, refer to the instructions for use *Infinity CentralStation*.

#### Audio pause feature

The Infinity network supports an audio pause of alarm tones from the ICS (see *Pausing acoustic alarm signals* in the Alarms chapter for more information).

#### Network communication interruptions

#### Wireless interruptions

If the communication between a wireless M540 and the ICS is interrupted because the M540 is outside the range of the wireless access points, the following happens:

- The wireless symbol appears red in the M540 header bar.
- A message indicating that the M540 is offline appears at the ICS in the viewport of the patient.
- The M540 sounds an error tone and displays the message *Network error*.
- The alarm volume behaves differently for a wireless or a wired M540.

Wireless	Wired
The M540 alarm volume is automatically set to 100% and you can no longer deactivate the volume setting. Once the communication between the M540 and the ICS is restored, the previous alarm volume setting is restored.	The M540 alarm volume is automatically set to 100% if the alarm volume was set to <b>Off</b> . You can no longer deactivate the volume setting. Once the communication between the M540 and the ICS is restored, the previous alarm volume setting is restored. If the alarm volume was set to any other setting than <b>Off</b> when the network interruption occurred, the alarm volume remains
	unchanged.

#### WARNING

Interruptions to network communication can limit parameter information and alarm annunciation to the bedside. Respond to network alarm errors immediately to ensure continued monitoring from areas remote to the bedside.

#### NOTE

For detailed information about the configuration and operation of wireless components in the Infinity network, contact your Dräger representative.

#### **Network interruptions**

When the M540 is connected to the network, but the communication with the ICS is interrupted, the following occurs:

- The message *Not monitored by central* appears in the viewport of the ICS and in the M540 header bar.
- The privacy mode is canceled.

- A single notification alarm of low alarm priority sounds once within 25 seconds of the start of the offline condition. The single notification tone annunciates even if alarms are paused or the alarm volume has been deactivated.
- The alarm volume is automatically adjusted to 100%. Once the M540 re-establishes communication with the ICS, the previous alarm volume is restored.

#### Network data transfer

The IACS network supports the transfer of patient data from a source device, such as an Infinity Delta, Delta XL/Kappa (software version VF7 to VF9.x) or

an IACS Cockpit, to another Cockpit. For more information about how to transfer data, refer to the instructions for use entitled *Monitoring applications*.

During a network transfer, the M540 displays the message *Transferring data...*.

#### CAUTION

Do not touch the screen or undock the M540 during the data transfer. Doing so can cause a network failure and result in an incomplete transfer.

After a successful transfer the M540 returns to the last monitoring screen before the transfer started. A message appears at the Cockpit to confirm that the transfer is complete.

# Remote view and remote control

The user can remotely view the data of any M540 that is connected to the Infinity network from the following devices:

- IACS Cockpits
- ICS
- Patient monitors Delta/Delta XL/Kappa, Vista XL, and Gamma XXL

The user can also execute certain remote functions from the above devices for any M540 that is connected to the Infinity network provided the *Remote control* and *Remote silence* settings are enabled. These settings are located in the *Service* menu. For more information, contact specialized service personnel.

If the M540 is on wireless transport, any remote changes to the patient profile are reset to the profile settings of the Cockpit once the M540 is docked.

When the M540 is in a standalone configuration, the profile adoption setting determines if remote changes that affect profile settings are reset to the default profile of the M500 or not (see "Profile behavior in a standalone configuration" on page 81).

If multiple devices try to execute a remote function simultaneously, the M540 always accepts the latest remote request.

The following table lists which functions can be performed remotely for an M540.

#### NOTE

When viewing the patient monitor in Remote View, the HR label displays instead of the PLS label. The value reported is the PLS value.

Remote function	Remote control from the ICS?	Remote control from other patient monitors?
Pausing the alarm tone for 2 minutes	Yes	Yes

Remote function	Remote control from the ICS?	Remote control from other patient monitors?
Pre-silencing alarms for 2 minutes. This function suppresses acoustic alarm signals for possible alarm conditions so that the user can concentrate on a procedure without being interrupted. Optical alarm signals are still reported for any alarm condition.	Yes	Yes
Requesting continuous/timed recordings for M540 used in an IACS configuration and on wireless transport	Yes	Yes
The recording requests are stored on the M540 and transferred to the Cockpit once the M540 is docked. The user can review a stored event at the Cockpit and request a manual recording.		
Requesting continuous/timed recordings for standalone M540.	No	No
Activate/deactivate the alarm function for a parameter	Yes	No
Activate/deactivate the alarm <b>Archive</b> function. The following happens for each setting of the <b>Archive</b> function:	Yes	No
<ul> <li>If the M540 is in an IACS configuration and on wireless transport and a parameter whose <i>Archive</i> function is set to <i>Str/Rec</i> or <i>Store</i> goes into alarm, that event is stored at the M540 and in the Event Disclosure database of the ICS. Once the M540 is docked, the event is transferred to the Cockpit where you can view it on the alarm history page and request a manual recording.</li> </ul>		
If the M540 is in standalone mode, the alarming parameter causes an event to be stored in the Event Disclosure database of the ICS and in the <i>Event recall</i> dialog of the M540 (see <i>Event recall</i> in the Alarms chapter.		
If the M540 is in an IACS configuration and on wireless transport a parameter whose <i>Archive</i> function is set to <i>Record</i> goes into alarm, the recording request is stored at the M540 but no recording is generated. Once the M540 is docked, the request is transferred to the Cockpit where the user can view it on the alarm history page and request a manual recording.		
If the M540 is in standalone mode, the alarming parameter causes an event to be stored in the Event Disclosure database of the ICS and in the <i>Event recall</i> dialog of the M540 (see <i>Event recall</i> in the Alarms chapter.		
Configuring alarm limits	Yes	No
Auto setting alarm limits	Yes	No
Configuring arrhythmia settings	Yes	No

Remote function	Remote control from the ICS?	Remote control from other patient monitors?
Configuring <b>ST</b> settings	No	No
Reviewing trend data	Yes	No
Initiate relearning	Yes	No
Change the demographic data of the patient	Yes	No

# **Function keys**

A total of eight function keys are located on the front of the M540 (4 on the right and 4 on the left side).

The function keys in positions 2, 3, 4 and 7 are permanently assigned to the functions *Review, Menu* (Main), *View 1*, and *Alarms*.

The function keys in positions 1, 5, 6 and 8 carry default assignments, but they can be reprogrammed (see page 60). The current function key assignments (key names) are displayed next to the function keys.

The following diagram shows where the function keys are located on the M540.



### Default function key assignments

	Function Key	Function
1	<i>Standby</i> (default)	Places the M540 into standby mode (see page 83). When the M540 is docked in an IACS configuration, pressing this function key also places the Cockpit in standby mode.
2	Review	Opens the <b>Event recall</b> dialog (see Event recall in the Alarms chapter).

	E	From etting
	Function	Function
3	Menu	Opens the <i>Main</i> dialog. It also closes any open dialog and returns the user to the monitoring view.
4	View 1 to View 5	Scrolls through five pre- configured screen layouts (see page 66).
5	<b>Code</b> (default)	Invokes the Code function at the Cockpit when the M540 is docked in an IACS configuration. For more information, refer to the <i>instructions for use Infinity</i> <i>Acute Care System –</i> <i>Monitoring Applications</i> .
6	<i>Discharge</i> (default)	Discharges the patient (see page 90).
7	Alarms	Opens the <i>Alarm settings</i> dialog.
8	<b>Record</b> (default)	Records an event which can be viewed in the <i>Event recall</i> dialog.
		When the M540 is docked in an IACS configuration, pressing the <b>Record</b> function key notifies the Cockpit to start/stop a timed recording.
		Press and hold the function key for two seconds to start a continuous recording.

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#### Alternate function key assignments

Key	Function
Privacy	Places the M540 into privacy mode (see page 83). This mode is only available when the patient is admitted at the ICS.
Mark	Stores an event in the <i>Event recall</i> dialog.
Patient	Opens the <b>Patient setup</b> dialog (see page 89).
Rest ECG report	Prints a Rest ECG report

#### To program a function key

- 1 Touch the *Menu* function key.
- 2 Touch the *Screen setup* tab > *Function keys* tab.
- 3 Touch one of the programmable setup keys (Setup key 1, Setup key 2, Setup key 3, or Setup key 4) and then touch the desired function.
- 4 Touch **X** to close the dialog.

The new key assignment is retained until manually reset to the factory default or until another key is assigned as described above. Because the function key assignments are also part of the profile, the position of these keys might change if the M540 is docked on an M500 with a profile whose stored function key setup is different.

# Monitoring area

The monitoring area of the M540 screen contains a header bar, waveforms, and parameter fields that report the current vital signs of the patient. The appearance of the monitoring area depends on the selected view, which controls the layout and content of the screen (see page 66).

#### Header bar

The blue header bar appears along the top of the screen. It is always visible and displays the following information:

- Remaining battery charge symbol ••••• (when the battery is fully charged, all segments in the symbol are filled in; the segments appear empty as the battery charge is depleting)
- Network connection symbol M540 is connected to the network
- Patient category (adult, pediatric, neonate)
- Bed label

- Patient name and alarm message field
- Current time
- Wireless symbol ((1)) appears when the M540 is on wireless transport.
- The alarm message symbol, when applicable.

#### The alarm status field

The following are some examples of alarm-related symbols and messages that can appear in the alarm status field.

Symbol	Label	Description
Â	Audio paused	Appears with a timer and disappears when the user presses the yellow key on the front of the M540 patient monitor.
X	Audio off	Indicates that the alarm volume is set to off.
À	All alarms paused	Indicates that all alarms have been paused for the amount of time specified in the <i>Alarms</i> menu.
	Alarms	Indicates that all alarms have been set to off.

For a complete list of supported messages see page 323.

For more detailed information on alarm monitoring see "Alarms" on page 93.

#### **Parameter fields**

Each parameter field contains real-time values of a parameter and a combination of the following information:

- Parameter labels (including dynamic pressure labels)
- Crossed triangle symbols when alarms are turned off
- Units of measure
- ECG heart blip (and pacer blip for paced pulses), RRi blip, and SpO2 blip
- Timers for non-invasive blood pressure
- Special source labels (for example, PLS for heart rate signal source for pulse oximetry)

#### Waveforms

The main screen of the M540 displays up to three waveforms simultaneously. Waveforms are drawn from left to right and can contain the following information:

- Signal scales
- Units of measure
- Parameter labels
- Pacer spikes
- QRS synchronization markers
- Respiration waveform markers to indicate breath detection

#### NOTE

If the acquired signal does not fit in the waveform channel, the top of the waveform may appear clipped. When a parameter is in alarm, the parameter field flashes in the color of the alarm priority (see *Alarm priorities* in the Alarms chapter), and a corresponding alarm message appears in the header bar. Each parameter chapter describes the parameter fields for the corresponding parameter in greater detail.

When a dialog is open, the parameter fields appear along the right side of the screen. This display behavior prevents the vital signs from being obscured while the user is performing setup tasks.

The **X** in the upper right corner of any window closes the open dialog and returns the user to the main screen.

#### To configure the waveforms

- 1 Touch the waveform area to open the waveform channel dialog.
- 2 Touch the *Channel 1*, *Channel 2*, or *Channel 3* tab to configure the desired channel.
- **3** Touch *Waveform* and select the desired parameter in the *Waveform* dialog.
- 4 Touch *Size* and then select the desired amplitude.
- 5 Touch X to close the dialog.

#### Dialogs

The following diagram shows how the monitoring area appears when accessing a dialog. The left side is reserved for the dialog while the right side displays the parameter fields. A dialog contains horizontal and vertical tabs that open additional dialogs. To access dialogs, touch the function keys on the front of the M540. To access parameter-specific setup pages directly, touch the corresponding parameter fields on the main screen.



- A Horizontal tabs the selected tab appears light blue
- B Button that closes the dialog
- C Parameter fields displaying real-time values

# Adjusting the display

If the orientation of the device changes during patient transport, the Auto flip function allows the screen to flip by 180°. This feature can be turned on or off.

#### NOTE

Operate the touchscreen with finger presses only. Do not use sharp objects.

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#### To turn the auto flip function on/off

- 1 Touch the *Menu* function key.
- 2 Touch the Screen setup tab > Settings tab.
- 3 Touch *Autoflip* until the desired choice is selected (*Yes* or *No*).
- 4 Touch **X** to close the dialog.

#### To flip the screen manually

- 1 Touch the *Menu* function key.
- 2 Touch the Screen setup tab > Settings tab.
- 3 Touch *Flip screen*. The screen flips automatically and flips back if the user selects the button again.
- 4 Touch **X** to close the dialog.

### Calibrating the touchscreen

If the touchscreen is out of alignment, the user can calibrate it at any time.

#### To calibrate the touchscreen

- 1 Touch the *Menu* function key.
- 2 Touch the Screen setup tab > Settings tab > Touch calib.
- **3** Touch each cross appearing successively in each corner of the screen.

or

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- Push and hold the following two keys simultaneously: <a href="https://www.eys.simultane-ously-complexity-c
- 2 Touch each cross appearing successively in each corner of the screen.

# **Battery power**

The M540 automatically switches to battery power for up to 3 hours when it is undocked or if there is a loss of power to the M500. The M540 displays low battery messages as applicable and then performs a safe shutdown that preserves the integrity of the patient data and the user settings. A shutdown is accompanied by an audible tone. When the M540 is docked, the M500 continuously charges the internal battery. The battery charge symbol on the front of the M540 lights up green when the battery is being charged.

To continue monitoring during a loss of power or during patient transport, the battery of the M540 should be fully charged at all times. The battery charge indicator **IIIII** in the header bar indicates the remaining battery charge.

#### **Charging times**

The following table indicates the required time to charge a depleted battery:

Capacity	Approximate charging time
70%	4 hours
90%	5.5 hours
100%	6.5 hours

#### **Battery operating times**

The following table lists the operating times of a fully charged internal battery powering an M540 that is monitoring with ECG, SpO2, Temp continuously, and NIBP in 15-minute interval mode.

Mode	Approximate operating time		
Regular bedside mode	3 hours		
Power save	4 hours		

#### NOTE

Connecting any additional parameters other than the configuration specified in the instructions for use, may diminish the battery life of the M540.

### Low battery conditions

When the message *Low battery* appears, 10 minutes of battery runtime remains before the M540 shuts down automatically. The message remains on display for 5 minutes and is accompanied by an acoustic alarm signal of low priority. The battery charge indicator **\_\_\_** in the header bar appears red.

After the 5-minute period, the message **Recharge battery** appears in the message area of the header bar indicating that 5 minutes of battery life remain. This message is accompanied by an acoustic alarm signal of medium priority. The battery charge indicator **• •** in the header bar appears red.

When the battery of an M540 is depleted, it can still monitor a patient as soon as the user docks it on an M500 that is receiving power.

#### WARNING

When the M540 shuts down due to a depleted battery, M540 configured settings are preserved for up to 60 hours. To avoid the loss of configured settings, Dräger recommends docking the M540 back into the M500 prior to 60 hours.

# Power-saving mode

When the M540 is not docked, the power save mode conserves battery charge while continuing to monitor a patient.

When power save mode is activated, the display of the M540 is turned off. The display of the M540 automatically turns back on when:

- The user docks the M540 on the M500
- The user touches the screen or any key
- The M540 detects an alarm condition of medium- or high-priority

#### To activate/deactivate power save mode

- 1 Touch the *Menu* function key.
- 2 Touch the Screen setup tab > Settings tab.
- 3 Touch *Power save* until the desired choice is selected (*Off*, 1, 2, 3, 4, 5 min).
- 4 Touch **X** to close the dialog window.

#### Views

Each M540 supports five pre-configured views, which control the content and the appearance of the screen. The user can switch to a different view to adjust the screen layout to the needs of the current monitoring session.

#### Selecting a view

The following table lists the pre-configured views and the associated defaults. Once selected, the user can change the parameter assignments as needed.

Selected view	Default parameters	Default waveforms
One waveform and three parameter fields (vital signs display)	HR, SpO2, and NIBP	ECG lead II
One waveform and four parameter fields	HR, SpO2, NIBP, and RRi	ECG lead II
One waveform and seven parameter fields	HR, SpO2, RRi, NIBP, GP1, GP2 and Temperature. If no IP sensor is connected the corresponding parameter labels may not be displayed.	ECG lead II
Two waveforms and five parameter fields	HR, SpO2, RRi, Temperature, and NIBP	ECG lead II and SpO2
Three waveforms and three parameter fields	HR, SpO2, and RRi	ECG lead II, SpO2, and RRi

#### To select a view

• Touch the currently selected function key several times (for example, *View 5*) to scroll through the available view labels.

#### To deactivate a view

The user can deactivate up to four views.

- 1 Touch the *Menu* function key.
- 2 Touch the *Screen setup* tab > *Screen views* tab.
- 3 Touch View 1, View 2, View 3, View 4, or View 5, > Off.
- 4 Touch **X** to close the dialog.

#### To assign a pre-configured view to a view key

- 1 Touch the *Menu* function key.
- 2 Touch the *Screen setup* tab > *Screen views* tab.
- 3 Touch *View 1*, *View 2*, *View 3*, *View 4*, or *View 5* and then touch the desired configuration.
- 4 Touch X to close the dialog.

# **Profiles**

A profile consists of pre-defined settings. Profiles eliminate time-consuming setup tasks that would otherwise have to be repeated for each monitoring session.

A profile includes patient and user defaults. Patient defaults can be customized for each patient category separately. User defaults are the same across all patient categories. The user can save the current profile settings as a default profile and/or restore the default profile under a password-protected menu (see page 311).

The following sections describe which settings are included in a profile and which are not and how profiles behave in an IACS configuration and in standalone mode.

# Settings included in a profile

The following table illustrates which settings are included in a profile. The table also identifies which settings are patient defaults and which are user defaults.

Setting	Patient default	User default	Comments (if applicable)			
	Screen views dialog					
(Press the M	enu function key > .	Screen setup tab	> Screen views)			
View 1	х		The view that is active when the user saves the profiles, will become			
View 2	х					
View 3	х					
View 4	х					
View 5	х					
(Press the I	Settings in Fun Wenu function key >	ction keys dial Screen setup >	log Function keys)			
Setup key 1		х				
Setup key 2		х				
Setup key 3		х				
Setup key 4		Х				
	Alarm pro	file settings				
The alarm pro	ofile settings are c	onfigured in the	following dialogs			
Alarm settings dialog (Press the Alarms function key)						
Speaker volume		х				
	Alarm set	<i>tings</i> dialog				
(Press the <i>Menu</i> function key > <i>System setup</i> > <i>Alarm setup</i> > enter password > <i>Alarm setup</i> )						
<i>All alarms paused</i> (Time selection)		х				
Alarm validation		х				
SpO2 alarm delay		х	This selection is only available if the <b>SatSeconds</b> setting is set to <b>Off</b> .			
Alarm group		х				
NIBP/SpO2 interlock		х				
ASY/VF alarms		х				
Pacer mode	x					
Alarm bar		Х				
Battery alarm		х				

Setting	Patient default	User default	Comments (if applicable)		
Pressures paused	х				
Pressures off	х				
	Alarm set	tings dialog			
(Press the <i>Menu</i> function key	> System setup >	• Alarm setup > e	enter password > <i>Volume/ Tones</i> )		
Minimum alarm vol.		Х			
Transport volume		х			
Transport pulse tone		х			
Alarm pattern		х			
Reminder: all alarms off		х			
Reminder: audio off		х			
	SpO2 sensor of	f dialog (Masim	o)		
(Press the <i>Menu</i> function key	> System setup >	Alarm setup > er	nter password > <b>SpO2 sensor off</b> )		
Alarm	х				
(alarm priority setting)					
Archive	X				
	SpO2 check sen	<b>isor</b> dialog (Nell	lcor)		
(Press the <i>Menu</i> function key	> System setup >	Alarm setup > er	nter password > <b>SpO2 sensor off</b> )		
<i>Alarm</i> (Alarm priority setting)	Х				
Archive	х				
CO2 profile settings					
The CO2 pro	file settings are co	onfigured in the f	ollowing dialogs.		
	CO2 lin	<i>iit</i> s dialog			
	(Touch the CO	2 parameter field)			
<i>Alarm</i> (On/off setting)	Х		These settings can be configured separately for each of the following		
Upper and lower alarm limits	х		parameters: etCO2, inCO2, RRc.		
Archive	х				
Mainstream dialog					
(Touch the CO2 parameter field > <i>Mainstream</i> )					
RRc apnea time	х				
Apnea archive	х				
Size [mV/cm] (size of the waveform)	х		Touch the CO <sub>2</sub> waveform to set the scale of the waveform.		
Atm. pressure		х			
Gas compens.		Х			

Setting	Patient default	User default	Comments (if applicable)	
Airway adapter		х		
<b>Color</b> (Color of the waveform and parameter)	x			
·	Microstr	eam dialog		
(10	uch the CO2 param	eter field > <i>Micro</i>	stream)	
Anne a sus hiss	X			
Apnea archive	X			
Size [mV/cm] (size of the waveform)	Х		Touch the CO2 waveform to set the scale of the waveform (see page 62).	
Averaging	х			
<b>Color</b> (color of the waveform and parameter)	x			
	Scio	dialog		
	(Touch the CO2 pa	arameter field > S	cio)	
RRc apnea time	x			
Apnea archive	x			
Size [mV/cm] (size of the waveform)	X		Touch the CO <sub>2</sub> waveform to set the scale of the waveform (see page 62).	
<b>Color</b> (color of the waveform and parameter)	x			
	Scio prot	file settings		
The Scio profile settings are config	gured in the followin	ng dialogs. For CC	2 settings, see CO2 profile settings in this table.	
	O2 lim	its dialog		
	(Touch the O2 pa	rameter field > S	Scio)	
Alarm (On/off setting)	x		These settings can be configured separately for each of the following	
Upper and lower alarm limits	x		parameters: FiO2, etCO2	
Archive	x			
Agents limits dialog				
(Touch the Agent parameter field > Scio)				

Setting	Patient default	User default	Comments (if applicable)		
<i>Alarm</i> (On/off setting)	x		These settings can be configured separately for each of the following		
Upper and lower alarm limits	х		parameters: FiO2, etCO2		
Archive	х				
	Agent	settings			
	A	gent			
	Touch <b>Prim. ag</b>	<b>ent</b> parameter fiel	d		
	Touch Sec. and	OR <b>ont</b> parameter field	4		
Sec. agent alarm	x		These settings can be configured		
Agent	×		separately for each of the following		
xMAC archive	x		parameters: inSev, etSev, inDes,		
			inEnf, etEnf		
Heart rate and arrhythmia profile settings					
The heart rate and arrh	ythmia profile sett	ings are configu	red in the following dialogs		
	HR lim	its dialog			
(То	uch the heart rate pa	arameter field > <i>H</i>	R limits)		
Alarm	х		These settings can be configured		
Upper and lower alarm limits	×		parameters: HR, Brady (only in		
	×		neonatal mode); PVC (only in adult		
			and pediatric mode).		
(Tou	<b>מור אמת</b> ch the heart rate par	rameter field > AI	RR limits)		
Alarm	x		The availability of the parameters,		
(Alarm priority setting)			depends on the selected arrhythmia		
Count and Rate	х		mode (see page 157).		
Archive	х				
ECG 1 dialog					
	ne neart rate param	eter liela > Settir	lgs > ECG 1)		
(For pulse tone)	X				
Tone source	x				
(For pulse tone)					
ECG filter	Х				

Setting	Patient default	User default	Comments (if applicable)		
HR source	х				
<b>Color</b> (Color of the waveform and parameter)	x		This setting affects ECG, ARR, and ST		
Size [mV/cm] (Size of the waveform)	X		Touch the heart rate waveform to set the scale of the waveform (see page 62).		
(Touch t	<b>ECG</b> he heart rate param	<b>2 dialog</b> leter field > <b>Settir</b>	ngs > ECG 2)		
Pacer detection	x		This setting is not available when the ESU filter is activated.		
QRS sync marker	x				
Cable type	x				
ARR lead 1	x				
ARR lead 2	x				
ARR processing	x				
ST profile settings					
The ST prof	file settings are co	nfigured in the f	ollowing dialogs		
	<b>ST lim</b> (Touch the ST	<b>its dialog</b> <sup>-</sup> parameter field)			
Alarm (On/off setting)	x		These settings can be changed for all ST parameters (STI, STII, STIII, STAN, STAN, STAN, STAN, STAN,		
Upper and lower alarm limits	х		STAVR, STAVL, STAVF, STV, STV+, STV1, STV2, STV3, STV4, STV5		
Archive	x		STV6, STVM, STCVM, STdV1, STdV3, STdV4, STdV6).		
	<b>Setting</b> (Touch the ST para	<b>gs dialog</b> meter field > <b>Sett</b>	ings)		
ST lead 1	x				
ST lead 2	x				
ST monitoring	x				
Event duration	x				
STV1	x		This setting is only available with 6- lead cable.		
Setting	Patient default	User default	Comments (if applicable)		
--	------------------------------------	--------------------	--	--	
R	Respiration (RRi) profile settings				
The respiration	profile settings are	e configured in t	he following dialogs		
	Resp. lii	nits dialog			
	(Touch the RR	i parameter field)	1		
<i>Alarm</i> (On/off setting)	Х				
Upper and lower alarm limits	х				
Archive	х				
	Settin	gs dialog			
(	Touch the RRi para	meter field > Sett	lings)		
Resp. lead	х				
Mode	x				
Marker	х				
Monitoring	х				
Apnea time	х				
Apnea archive	х				
<b>Color</b> (Color of the waveform and parameter)	х				
Coincidence	х				
Size [mV/cm] (Size of the waveform)	x		Touch the <b><i>RRi</i></b> waveform to set the scale of the waveform (see page 62).		
	SpO2 (Masimo	) profile sett	ings		
The SpO2 profile settings are configured in the following dialog					
<b>SpO2 limits dialog</b> (Touch the SpO2 parameter field)					
Alarm (On/off setting)	x		These settings can be configured separately for <b>SpO</b> 2, <b>Desat.</b> , and		
Upper and lower alarm limits	x		PLS.		
Archive	x				

Setting	Patient default	User default	Comments (if applicable)		
	Settings dialog				
	(Touch the SpO2 parameter field > Settings)				
	~				
Por graph	×				
	X				
Averaging time	X				
Sensitivity mode	X				
Fast SAT mode	X				
<b>Color</b> (Color of the waveform and parameter)	X				
Size [mV/cm] (Size of the waveform)	x		Touch the <b>SpO2</b> waveform to set the scale of the waveform (see page 62).		
Puls	e CO-Ox (Mas	imo) profile	settings		
The Pulse CO-Ox profile settings are configured in the following dialogs					
Two separate <i>Pulse CO-Ox limits</i> dialog window (Touch the Pulse CO-Ox parameter field)					
Alarm (On/off setting)	x		These settings can be configured for the following parameters in two		
Upper and lower alarm limits	х		separate <b>Pulse CO-Ox limits</b>		
Archive	Х		SpMet, PVI.		
(Touch the F	<b>Setting</b> Pulse CO-Ox param	<b>s 1 dialog</b> eter field > <b>Settir</b>	ngs > Settings 1)		
Pulse CO-Ox 1 x					
Pulse CO-Ox 2	x				
Pulse CO-Ox 3	x				
SpHb Averaging	х				
<b>Color</b> (Color of the waveform and parameter)	x				

Setting	Patient default	User default	Comments (if applicable)	
Settings 2 dialog				
	CO-Ox parameter field > Settings > Settings 2 > enter password)			
	X			
PVIAveraging				
	SpO2 (Nelicor	) profile setti	ngs	
The SpO2 pro	ofile settings are c	onfigured in the	following dialogs	
	SpO2 lir (Touch the SpO	<i>nits</i> dialog D2 parameter field	)	
<i>Alarm</i> (On/off setting)	x		These settings can be configured separately for <b>SpO</b> 2, <b>Desat.,</b> and	
Upper and lower alarm limits	x		PLS.	
Archive	x			
Settings dialog (Touch the SpQ2 parameter field > Settings)				
Tone volume	x			
Tone source	x			
Bar graph	x			
Response mode	x			
SatSeconds	x			
<b>Color</b> (Color of the waveform and parameter)	x			
Size [mV/cm] (Size of the waveform)	x		Touch the <b>SpO2</b> waveform to set the scale of the waveform (see page 62).	
Non-inv	Non-invasive blood pressure profile settings			
The non-invasive blood	pressure profile se	ettings are config	gured in the following dialogs	
(Touch	NIBP lin the non-invasive bl	<b>nits dialog</b> ood pressure para	ameter field)	
Alarm (On/off setting)	х		These settings can be configured separately for NIBP S, NIBP D, and	
Upper and lower alarm limits	x		NIBP M.	
Archive	x			

Setting	Patient default	User default	Comments (if applicable)	
Settings dialog				
( louch the n	on-invasive blood pi	ressure paramete	r field > <i>Settings</i> )	
Interval time	x			
Inflation mode	х			
Chime	х			
<b>Color</b> (Color of the waveform and parameter)	x			
	Temperature	profile settin	igs	
The temperature	profile settings a	re configured in	the following dialogs	
	<b>Temp lin</b> (Touch the temper)	<b>nits dialog</b> ature parameter fi	eld)	
Alarm (On/off setting)	х		These settings can be configured separately for Ta, Tb, $\Delta$ T, T1a, T1b,	
Upper and lower alarm limits	х		ΔΤ1	
Archive	х			
(Tou	Setting	<b>gs dialog</b> parameter field >	Settings)	
<b>Color</b> (Color of the waveform and parameter)	x			
Ta label	х		Parameter labels can be changed to	
Tb label	х		TOral, TEso, TNasal, TRect, TBlad, Tcore, TBld1, TBlnkt, TSkin, TR, TL	
T1a label	х		Parameter labels can be changed	
T1b label	x		to: T1Oral, T1Eso, T1Nasal, T1Rect, T1Blad, T1core, T1Bld1, T1Blnkt, T1Skin, T1R, T1L	
			NOTE: These selections are available only when using an MPod – Quad Hemo.	

Setting	Patient default	User default	Comments (if applicable)		
Invas	Invasive blood pressure profile settings				
The invasive blood pre	essure profile setti	ngs are configu	ed in the following dialogs		
Invasive blo (Tou	od pressure limi ch the invasive bloo	<b>ts dialog (exan</b> d pressure param	n <b>ple: <i>CVP limits</i>)</b> eter field)		
Alarm (On/off setting)	X		These settings can be configured separately for ART D, ART M,		
Upper and lower alarm limits	x		ART S, PA D, PA M, PA S, LV D,		
Archive	x		- LV M, LV S, GP1 D, GP1 M, GP1 S GP2 D, GP2 M,GP2 S GP3 D, GP3 M, GP3 S, GP4 D, GP4 M, GP4 S, RA, LA, RV, CVP, ICP, CPI		
<b>Settings dialog</b> (Touch the invasive blood pressure parameter field > <b>Settings</b> )					
Edit label	x				
Filter	x				
<b>Color</b> (Color of the waveform and parameter)	x				
Size [mV/cm] (Size of the waveform)	x		Touch the invasive blood pressure waveform to set the scale of the waveform (see page 62).		
<i>Edit label</i> (For <i>Pod 1A label</i> through <i>Pod</i> <i>1D label</i> and <i>Pod 2A label</i> through <i>Pod 2D label</i> )	x		Parameter labels can be changed to: <i>GP1</i> to <i>GP8</i> , <i>ART</i> , <i>LV</i> , <i>LA</i> , <i>PA</i> , <i>CVP</i> , <i>ICP</i> , <i>RA</i> , <i>RV</i> , <i>AXL</i> , <i>BRA</i> , <i>FEM</i> , <i>RAD</i> , <i>AOR</i> , <i>UAP</i> , <i>ABD</i> , <i>BDP</i> , <i>ESO</i> , <i>FEMV</i> , <i>UVP</i> , <i>GPM</i>		

# **Monitor settings**

The following list contains the monitor settings which are a subset of the profile settings. When the **Profile settings** is set to **Monitor**, only these settings are adopted when the M540 is docked.

- Key configuration
- Alarm volume
- All alarms paused
- Alarm validation
- Alarm pattern
- Alarm bar
- ASY/VF alarms
- SpO2 alarm delay
- NIBP/SpO2 interlock
- Pacer mode
- Alarm group
- Parameter color
- HR source

- Tone source (ECG and SpO2)
- Tone volume (ECG and SpO2)
- Size [mV/cm] (ECG and SpO2 waveform)
- ECG filter
- Pacer detection
- QRS sync marker
- ARR processing
- Bar graph (SpO2)
- PVI Averaging
- SpHb Cal
- Gas compens. (CO2 compensation)
- Waveform scale (CO2, O2 and IP)
- Scio anesthetic agent selection
- Chime (non-invasive blood pressure)
- *Filter* (invasive blood pressure)
- Transport volume
- Transport pulse tone

# Settings not included in a profile

The following settings are not included in a profile and must be configured separately. These settings remain unchanged until they are manually changed again by the user.

Dialog	Setting	
Screen setup dialog (Press the <i>Menu</i> function key > Screen setup)		
Screen setup	Autoflip	
	Power save	
ARR dialog (Touch the heart rate parameter field > Settings > ARR)		
ARR	ARR mode	

Dialog	Setting	
Service d	ialogs	
(Press the Menu function	key > System setup >	
Service > enter password > select dialog)		
Service	ECG baseline	
	Data collection	

Dialog	Setting	Dialog	Setting
Network setup	Network mode	Wireless network	Wireless mode
	Bed label		SSID
	Care unit		Channels
	Mon. unit		Encryption
	Hospital		Keep bed label <sup>1)</sup>
	Mon. unit ID		Bed label
	IP address	Alarm setup	Quiet mode <sup>1)</sup>
	Net mask	<sup>1)</sup> <i>Note:</i> These M500 c	onfiguration settings are
	Default gateway	not part of the profile	and must be configured
	Duplicate IP Check	automatically adopte	d by the M540 regardless
	IP Check Interval	of the profile adoption	n setting.
Biom (Press the Menu fund Biomed > enter pa	ed dialogs ction key > System setup > issword > select dialog)		
Biomed	Language		
	French NFC		
	Line frequency		
	SpO2 sensor type		
Units	Тетр		
	etCO2		
	Pressures		
	ST		
	SpHb		
	Height		
	Weight		
Docking station	IP address <sup>1)</sup>		
	Net mask <sup>1)</sup>		
	Default gateway 1)		
	Bed label <sup>1)</sup>		
	Care unit <sup>1)</sup>		
	Mon. unit <sup>1)</sup>		
	Load profile <sup>1)</sup>		
	Profile settings 1)		

# Saving a profile

The user can save the current profile settings as a default device profile (see page 311). In a standalone configuration, the profile is saved on the M540 and on the M500. If the profile cannot be saved, the message **Save profile failed** appears.

## CAUTION

If the profile save function fails, the previously stored profile on the M500 is deleted. Therefore, if the message **Save profile failed** appears, save the profile again.

Whenever a patient is discharged, units of measure are changed, or a new patient is admitted, the userconfigurable profile is restored automatically. The user can also request to restore the default profile manually at any time (see page 311).

# Profile behavior in an IACS configuration

When the M540 is docked in an IACS configuration, the profile of the connected Cockpit overwrites any profile settings of the M540. The M540 itself provides the following profile settings to the Cockpit:

- ECG cable type
- Heart rate source
- SpO2 alarm delay, SpO2 sensitivity mode for Masimo, SpO2 sensitivity mode for Nellcor
- Ambient pressure value
- IP labels
- Patient category (adult, pediatric, neonatal)

After a patient discharge, all patient data are deleted and the default profile of the Cockpit is restored.

## NOTE

To save a stored profile during a software upgrade, the user can copy the profile onto a USB flash drive by using the import/export feature of an IACS Cockpit. After the upgrade, the user can reimport the profile from the USB flash drive back onto the M540. In addition, the user can use the same feature to export a profile to multiple M540 devices. However, this feature is only possible when the M540 is docked on an M500 in an IACS configuration. For detailed information, refer to the Instructions for use *Infinity Acute Care System* – *Monitoring Applications*.

# Profile behavior in a standalone configuration

The ability to store the profile settings on the M500 in a standalone configuration allows the M540 to accompany the patient to different care areas of the hospital. By uploading the default profile from the M500 at the new care area, the monitor adapts to its new clinical environment (OR, ICU, CCU, and so on) while retaining the patient data.

How profiles are handled when an M540 is docked, depends on the configuration settings of the M540 and the M500. The *Load profile* setting of the M500 determines if the M540 adopts the M500 profile or if it uses its current profile settings.

The **Profile settings** feature determines if the entire profile is adopted (patient and user settings) or only a subset (monitor settings only).

## **Profile adoption**

The configuration of the M500 determines whether or not the M540 adopts the profile settings stored on the M500.

The following table illustrates how the profiles are managed under different circumstances.

Action	M500 <i>Load profile</i> settings:	M500 Profile settings:	Result
Docking the M540	Off	(Not used)	The M540 uses its current profile settings.
	Automatic	All	The M540 adopts the profile stored on the M500. See page 68 for a list profile settings.
	Automatic	Monitor	The M540 adopts only the monitor settings which are a subset of the profile stored on the M500. See page 78 for a list of monitor settings.
Discharging the M540	Off	(Not used)	The profile stored on the M500 is restored.
	Automatic	All	The profile stored on the
	Automatic	Monitor	M500 is restored. See page 68 for a list profile settings.

# Different profile configurations

The following happens when an M540 with a newer software version and newer profile settings docks on an M500 with an outdated profile:

- If the *Load profile* settings on the M500 is set to *Automatic*, the M540 adopts the settings stored on the M500.
- Any M540 settings that are not part of the profile setup stored on the M500, remain unchanged on the M540.

## NOTE

Contact specialized service personnel to make sure the M500 is updated with the latest profile.

The following happens when an M540 with an older software version that does not support new settings docks on an M500 with an updated profile:

- If the *Load profile* settings on the M500 is set to *Automatic*, the M540 adopts the recognized settings stored on the M500.
- Any M500 profile settings that are not supported on the M540 are ignored.

# Use-case scenario

The following scenario describes how profiles are handled when the patient is moved to different clinical areas:

Step 🕨	Action	Result
1	The M540 is docked to the ICU M500 whose <i>Load profile</i> settings are configured to <i>Automatic</i> and whose <i>Profile settings</i> feature is set to <i>All</i> .	The M540 adopts the profile settings defined for the ICU that are stored on the M500.
2	The M540 is undocked for transport.	The M540 continues to use the adopted ICU profile settings.
3	During transport, the alarm limits are changed on the M540.	The M540 continues to use the adopted ICU profile settings with the modified alarm limits.
4	The M540 is docked to the same M500 in the ICU.	The M540 does not readopt the profile but continues to use the ICU profile settings with the modified alarm limits.
5	The M540 is undocked and accompanies the patient to the OR where it is docked to an M500.	The M540 adopts the profile settings defined for the OR that are stored on the M500.
6	The M540 is undocked from the OR M500.	The M540 continues to use the adopted OR profile settings.
7	The M540 is redocked to the same ICU M500.	The M540 adopts the profile settings defined for the ICU that are stored on the M500.

# Standby mode

The user can temporarily interrupt patient monitoring by placing the M540 in standby mode.

Standby mode has the following effect:

- All patient data are removed from the screen
- All monitoring (including acoustic and optical alarm signals) is suppressed
- Active alarms are considered acknowledged by the user
- All recordings are canceled
- The M540 displays Standby, Touch screen to resume monitoring

When the M540 is docked in an IACS configuration, selecting standby mode automatically activates standby mode on the Cockpit and vice versa. For more information, refer to Instructions for use *Infinity Acute Care System – Monitoring Applications*.

#### To place the M540 in standby mode

Press the *Standby* function key (if available for display, see page 59).

or

- 1 Press the *Menu* function key.
- 2 Touch the *Main* tab, if not already selected.
- 3 Touch Standby.

The message *Standby*, appears in the center of the M540 screen.

#### To take the M540 out of standby mode

• Touch the screen to resume monitoring.

# **Privacy mode**

Privacy mode is available when the M540 is docked in an IACS or a standalone configuration provided the patient is admitted at the Infinity CentralStation (ICS). In privacy mode, patient monitoring continues but the patient data are removed from the screen and appear only at the ICS BedView.

When the M540 is part of an IACS configuration, Selecting privacy mode on the M540 automatically activates privacy mode on the Cockpit and vice versa. Likewise, taking a patient out of privacy mode on the M540 does the same on the Cockpit. Privacy mode is canceled when the connection to the Infinity network is disrupted. Activating privacy mode has the following effect:

- All patient data are removed from the display of the M540, but continue to display at the ICS in BedView mode.
- The alarm bar is deactivated
- Acoustic alarm signals are only provided at the ICS
- The M540 displays *Privacy*, *Touch screen to resume monitoring*

## To place the M540 into privacy mode

Press the *Privacy* function key (if available for display, see page 59).

or

- 1 Press the *Menu* function key.
- 2 Touch the *Main* tab, if not already selected.
- 3 Touch Privacy mode.

The message *Privacy*, *Touch screen to resume monitoring* appears in the center of the M540 screen.

## To take the M540 out of privacy mode

• Touch the screen to resume monitoring.

# **Recordings/reports**

The following recordings and reports can be requested from an M540.

# Timed, continuous, and stored recordings

The *Record* function key located on the front of the M540 (see page 59) executes different commands:

 In an IACS configuration – pressing the *Record* function key notifies the Cockpit to start/stop a timed recording on the assigned network recorder.

Press and hold the same function key for at least two seconds to start a continuous recording.

 On wireless transport or in standalone mode – pressing the *Record* function key stores an event which can be viewed in the *Event recall* dialog (see *Event recall* in "Alarms" on page 93).

## NOTE

In standalone mode, the M540 does not support timed or continuous recordings.

# **Rest ECG reports**

A diagnostic 12-lead Rest ECG report can only be requested from the M540 when the patient is also admitted at the ICS and the 12-lead locked option is unlocked on the M540 and on the ICS. If either of those two pre-requisites are not met, the function key is not available for requesting this report.

### NOTE

Rest ECG report is only available for adult and pediatric patients.

To obtain an optimal automatic diagnostic interpretation of an Rest ECG report, make sure the following settings are configured appropriately for the patient before the report is generated:

- Birth date in the *Patient setup* dialog of the M540 (see page 89)
- Gender and Race in the *Rest ECG setup* dialog of the M540 (see page 148)
- Height, weight these settings must be entered at the Cockpit when the M540 is docked in an IACS configuration. If the M540 is in standalone mode, the same settings must be entered at the ICS.

#### To generate a Rest ECG report

Press the *Rest ECG report* function key (if available for display, see page 59).

or

- 1 Press the *Menu* function key.
- 2 Touch the *Main* tab, if not already selected.
- 3 Touch the Rest ECG report button.

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# Getting started

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# Overview of monitoring a patient

This chapter describes the necessary steps to start monitoring a patient on the M540.

Specifically, this section describes how to:

- Turn the M540 on/off
- Admit/discharge a patient on the M540
- Change the patient category

# Turning the M540 on/off

### To turn the M540 on

• Press the on/off switch (A) of the M540.



The M540 emits a high-pitched tone followed by two power-up tones, performs a self-test, and displays the **New patient?** prompt. Touch **Discharge** to delete the patient data or **Cancel** to continue monitoring the patient and append the new data to the previous data set. The main screen appears.

#### To turn the M540 off

- Press and hold the on/off switch (A).
   A dialog appears and asks if you want to shut down the monitor.
- 2 Touch Shutdown.

# Admitting a patient

You can admit a patient at the M540 manually by entering the demographic data in the *Patient setup* tab.

You can also admit a patient over the network by pulling the data from an HL7/ADT interface. This is either possible if the M540 is part of an IACS configuration that is connected to the Infinity network, the patient data can be retrieved over the network and transferred to the M540.

#### WARNING

Monitors in a care area may seem identical but may use different default alarm settings because of different profile assignments. After admitting a patient, always verify that the set alarm limits are appropriate for the patient.

#### To admit the patient manually

## NOTE

Avoid using dashes in patient identification numbers, as the monitor could cut off part of the number.

- 1 Press the *Menu* function key.
- 2 Touch the Patient setup tab.
- 3 Touch *Patient category* and then touch the appropriate category (*Adult, Pediatric, Neonate*). The message *Changing category will change alarm settings and algorithmic processing* appears. For more details on the categories, see page 91.
- 4 Touch OK. The Patient setup dialog closes.
- 5 Press the *Menu* function key.
- 6 Touch the *Patient setup* tab.
- 7 Touch *Name* and use the keyboard to enter the name (up to 25 characters)
- 8 Touch Confirm.

- 9 Touch *ID* and use the keyboard to enter the ID number (up to 12 characters) and then touch *Confirm*.
- 10 Touch Admit date, then touch each of the following: Day, Month, and Year to enter the appropriate date.
- 11 Touch OK to confirm the data entry.

Use the arrows to scroll up or down to change the data. To scroll faster through the data (for example, the year), touch and hold the arrow.

12 Touch *Birth date*, then touch each of the following: *Day*, *Month*, and *Year* to enter the appropriate date.

Use the arrows to scroll up or down to change the data. To scroll faster through the data (for example, the year), touch and hold the arrow.

- 13 Touch OK to confirm the data entry.
- 14 Touch *Physician* and use the keyboard for entering the name of the physician (up to 12 characters).
- 15 Touch *Confirm* to confirm the data entry.

#### NOTE

The height and weight of the patient must be entered at the Cockpit when the M540 is docked in an IACS configuration. When the M540 is on wireless transport or in standalone mode, the height and weight can be entered at the ICS.

# Admitting a patient using the hospital information system

You can populate the *Patient setup* page automatically, by pulling the demographic data of a patient from the network. The prerequisite for this network data transfer is the Infinity gateway with an interface to the hospital Admit, Discharge, Transfer (ADT) system. The Hospital Information System (HIS) searches the database for the demographic data of the patient by using the patient ID.

# **Discharging a patient**

A patient discharge has the following effect at the M540:

- All demographic data are removed from the screen
- Any active recordings are canceled at the Cockpit if the M540 is docked in an IACS configuration
- Factory or user default limit settings are restored
- The message Discharged, Touch screen to resume monitoring appears

#### To discharge a patient

Press the *Discharge* function key (if available for display, see page 59).

or

- 1 Press the *Menu* function key.
- 2 Touch the *Main* tab.
- 3 Touch *Discharge*. The message *Caution discharge will delete patient data* appears.
- 4 Touch Discharge.

#### WARNING

Risk: Mixing of patient data

Before monitoring a patient, always press the function key *Discharge* to make sure that any previous patient data does not get appended to the new patient data.

#### WARNING

Pressing the *Discharge* function key unintentionally could lead to loss of data.

# **Patient categories**

Each patient category has a specific profile associated with it. Profiles are a set of patient and user settings that have been pre-configured by the factory or the hospital. The M540 supports the following patient categories:

Patient category	Typical age range	Weight	Height
Adult	12 to 140 years	0.1 to 350.0 kg (0.1 to 772.0 lbs)	10 to 250 cm (5 to 100 in)
Pediatric	0 to 16 years	0.1 to 350.0 kg (0.1 to 772.0 lbs)	10 to 250 cm (5 to 100 in)
Neonate	0 to 2 years	1 to 10,000 g (0 oz to 351 oz)	10 to 250 cm (5 to 100 in)

## Selecting a new patient category

After selecting the patient category, the new patient category label appears in the header bar (see page 60).

A patient category change does not affect the following settings: the patient and physician names, patient ID, birth date, admit date, height, and weight.

#### To select a new patient category

- 1 Press the *Menu* function key.
- 2 Touch the *Patient setup* tab.
- 3 Touch *Patient category* and then select the appropriate category (*Adult, Pediatric, Neonate*). The message *Changing category will change alarm settings and algorithmic processing* appears.
- 4 Touch OK.

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# Alarms

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# **Overview of alarms**

The M540 produces acoustic and optical alarm signals to alert you to alarm conditions ranging from alarm limits violations, arrhythmia calls, and battery issues.

Persistent alarms generate acoustic and optical alarm signals that require user intervention to cease. One-shot alarms are only reported once and do not require any user intervention.

Each alarm condition is assigned one of three alarm priorities:

- high (life-threatening)
- medium (serious)
- low (advisory)

Each alarm priority has unique acoustic and optical alarm signals.

In addition to the visual and acoustic alarm signals, alarm messages appear in the alarm message field of the M540. All alarm conditions and associated alarm messages are described in detail in the chapter "Troubleshooting" on page 323. The color of an alarm message corresponds to the priority of the associated alarm condition (see "Alarm priorities" on page 94).

The alarm settings for a patient can be set up to store alarms for later event review in the event recall dialog. A physiological alarm can also activate an external alarm device such as nurse call.

When the M540 is docked in an IACS configuration, special monitoring modes (see page 100), such as cardiac bypass mode, affect the regular alarming behavior.

## WARNING

The user must remain within the hearing distance of the acoustic alarm signal to ensure quick detection and the appropriate response. The distance of the user to the medical device must be appropriate for the volume of the alarm signal.

### WARNING

Alarm volume levels that are less than ambient noise levels can impede the user's recognition of alarms.

# **Alarm priorities**

Every alarm condition is assigned to one of three priorities: high (life-threatening), medium (serious), or low (advisory). Visual and acoustic alarm signals indicate the level of the alarm priority. For more information on how alarm priorities affect alarm reporting, see "Optical alarm signals" on page 97 and "Acoustic alarm signals" on page 98.

## High-priority alarm conditions

All high-priority alarms are physiological alarm conditions that can be life-threatening and require immediate intervention.

An example of a high-priority alarm condition is asystole.

# Medium-priority alarm conditions

Most medium-priority alarms report physiological or technical alarm conditions that require prompt attention but may not be life-threatening.

An example of a medium-priority physiological alarm condition is a respiratory rate limit violation. An example of a medium-priority technical alarm condition is a hardware failure in a pressure transducer.

## Low-priority alarm conditions

All low-priority alarms alert you to technical issues that may compromise the ability of the system to monitor the patient.

An example of a low-priority alarm condition is an artifact on the *ECG* waveform.

# Alarm processing

The M540 provides acoustic and optical alarm signals for all parameters except for the following ones:

- Cardiac output (C.O.)
- Injectate temperature (Tinj)
- Pulmonary wedge pressure (PWP)
- Paced beats (%paced)
- Perfusion index (PI) for Masimo SET MCable and Masimo rainbow SET MCable
- Total oxygen content (SpOC) for the Masimo rainbow SET MCable

# Latching and non-latching alarm behavior

When an alarm condition no longer exists, the associated acoustic and optical alarm signals behave in one of two ways:

- The alarm signals automatically stop when the alarm condition ceases to exist. This type of alarm is called a non-latching alarm condition.
- The alarm signals continue until you acknowledge the alarm even though the alarm condition has ceased to exists. This type of alarm is called a latching alarm condition.

In general, high-priority alarms are latching alarm conditions while low-priority alarm conditions are non-latching. Exceptions to this alarm behavior are listed on page 100.

The alarm priority of a latching alarm condition determines how the alarm signals behave after the alarm condition ceases to exist:

- A latched alarm condition of high-priority is identified by the standard acoustic and optical alarm signals (see "Optical alarm signals" on page 97).
- A latched alarm condition of medium-priority is downgraded to a status message which appears in the header bar. The background of the alarm message and the parameter field no longer flash in the alarm color, and there are no acoustic alarm signals.

## To acknowledge a latched alarm condition

- Press the following key on the M540:



or

- 1 Select *All alarms off /All alarms pause* (the name and function of the button depends on the M540 configuration see page 317). To access the button, press the *Alarms* function key.
- 2 Change the alarm limits.

The latched alarm signals are cleared and all acoustic and visual latched alarm signals disappear.

# Multiple alarm conditions

During multiple alarm conditions, the M540 reports the most recently detected highest-priority alarm condition. When several alarm conditions occur simultaneously, the parameter fields flash for all alarming parameters. The alarm condition with the highest priority determines which acoustic alarm signal is generated, how the alarm bar and the parameter field appear, and what alarm message appears in the header bar. Messages for active alarms rotate in the header bar.

# Activating or deactivating alarm validation

When alarm validation is activated (see page 303), an alarm condition must exist for a certain time before acoustic and optical alarm signals are triggered. This feature reduces nuisance alarms.

When alarm validation is activated, the time between the detection and annunciation of a parameter falling outside the set alarm limits equals the time of detection plus the assigned alarm validation delay. For heart rate, adding the delay time may exceed the maximum of 10 seconds allowed by ASI/AAMI/IEC 60601-2-27. The following table lists which parameters have an alarm validation time. Parameters that do not appear in the table have no validation times and acoustic and optical alarm signals are triggered almost immediately.

Parameter	Upper alarm limit	Lower alarm limit
ECG/Heart rate (HR)	6 s	6 s
Pulse rate (PLS)	6 s	10 s
ST segment analysis (ST)	off, 15 s to 60 s (in increments of 15 s – selectable) $^{1)}$	off, 15 s to 60 s (in increments of 15 s – selectable) $^{1)}$
Respiratory rate (RRi)	14 s	14 s
Respiratory rate (RRc)	8 s	10 s
Pulse oximetry (SpO2) 2)	6 s	10 s
Invasive blood pressure	10 s	4 s
Total hemoglobin (SpHb and SpHbv)	6 s	10 s
Carboxyhemoglobin saturation (SpCO)	6 s	10 s
Pleth variability index (PVI)	6 s	10 s

Parameter	Upper alarm limit	Lower alarm limit	
Methemoglobin saturation (SpMet)	6 s	10 s	

# NOTE

1) Select the validation period for the ST limit alarm in the ST dialog (see page 166).

2) For Nellcor OxiMax: the **SatSeconds** alarm time overrides the alarm validation setting (see page 204).

# **Optical alarm signals**

Each alarm priority has its own distinct optical alarm signals.

The alarm message in the header bar is the only optical alarm signal if an alarming parameter is not included in the current screen view and the alarm bar is deactivated. For more information on alarm messages, see page 98.

Alarm priority	Parameter field	Alarm message field <sup>1)</sup> in header bar	Alarm bar (if activated, see page 304)	Alarm message in header bar (refer to "Messages" on page 326)
High (life-threatening) (for example, asystole, ventricular fibrillation)	Flashing red background	Red background	Flashing red	White alarm message on red background
Medium (serious) (for example, alarm limit violations)	Flashing yellow background	Yellow background	Flashing yellow	Black alarm message on yellow background
Low (advisory) (for example, disconnected lead)	Solid cyan background	Cyan background	No optical alarm signal	Black alarm message on cyan background

#### NOTE

<sup>1)</sup>M540 alarm messages are designed to be legible at arm's length.

Optical alarm signal indicators on the M540



- A Alarm message field in the blue header bar
- B Alarming parameter field
- C Alarm bar

# Acoustic alarm signals

During an alarm, the M540 provides distinct acoustic alarm signals for each alarm priority in addition to optical alarm signals (see page 97). The specific characteristics of these acoustic alarm signals depend on the selected alarm tone pattern. The available alarm tone patterns are: *IEC fast*, *IEC slow*, *Infinity*, and *Hybrid*.

When acoustic alarm signals are paused, the alarm bar and the parameter field stop flashing but remain lit up in the respective alarm color.

If multiple alarm conditions exist simultaneously, an acoustic alarm signal sounds for the alarm condition with the highest priority.

# Alarm bar

The alarm bar on the M540 visually announces high- and medium-priority alarm conditions (see page 94).

However, the alarm bar is inactive when:

- Only low-priority alarm conditions exist
- The alarm bar is deactivated (see page 304)
- Cardiac bypass is activated (see page 102) and the M540 is docked in an IACS configuration
- Privacy mode is activated
- Alarm monitoring is deactivated (see page 109)

# NOTE

Normally, in an IACS configuration, acoustic alarm signals only sound at the Cockpit not at the M540. Therefore, all acoustic alarm signals are transferred automatically from the M540 to the Cockpit once you dock the M540. However, if you want alarms to sound at both devices, select the alarm volume at the M540 manually. For more information refer to the *Infinity Acute Care System* – *Monitoring Applications* Instructions for use.

Alarm priority	IEC fast	IEC slow	Infinity	Hybrid
High	The following acoustic alarm signal is repeated every 4.5 s:	The following acoustic alarm signal is repeated every 8 s:	Continuous two-tone sequence	Continuous two-tone sequence
	Three beeps > one beep > one beep with higher pitch > short pause.	Three beeps > one beep > one beep with higher pitch > short pause.		
Medium	The following acoustic alarm signal is repeated every 7 s: Two beeps > one lower pitched beep	The following acoustic alarm signal is repeated every 15 s: Two beeps > one lower pitched beep	Two tones > short pause	The following acoustic alarm signal is repeated every 7 s: Two beeps > one lower pitched beep
Low	Two beeps repeated every 16 s	Two beeps repeated every 30 s	Low tone repeated every 30 s	Two beeps repeated every 16 s

# Attention tones

The M540 also provides an attention tone to alert you to special information such as:

- Start of venous stasis
- End of zeroing of a transducer
- CO2 calibration is required
- CO2 MCable maintenance is due

An attention tone annunciates once as a chime which consists of two tones at the same pitch. Unlike attention tones, pulse tones for ECG or SpO<sub>2</sub> consist of a single tone.

# Adjusting the alarm volume

The volume of the alarm tone is adjustable. Set the volume of the alarm tone so it can be heard during the noisiest times.

Be aware of the following conditions when adjusting the alarm volume:

- The available settings for alarm volume depend on the configured *Minimum alarm vol.*. For example, if the selected *Minimum alarm vol.* setting is 10%, then the *Alarm volume* settings below this value are grayed out.
- The setting for *Minimum alarm vol.* does not affect the *Transport pulse tone* or the *Tone volume*.

When an M540 is undocked, it uses the speaker volume configured under the *Transport volume* setting (see page 305) in the password-protected Service menu to generate acoustic alarm signals. The available settings are: 50% to 100% (adjustable in increments of 10%).

When the M540 is docked to the Cockpit, the Cockpit assumes primary alarm annunciation and the M540 speaker is deactivated.

When the M540 is docked to an M500, the profile speaker volume is restored provided the *Load profile* setting is activated. If the *Load profile* setting was not activated, the previously configured speaker volume setting is maintained.

#### NOTE

When the M540 is in Power Save mode, speaker volume reverts to its default setting. Speaker volume can be changed manually.

During patient transport, you can change the alarm tone/speaker volume of the M540.

### To adjust the alarm volume

- 1 Press the *Alarms* function key.
- 2 Touch the *Alarm volume* button and select the desired volume level (*Off*, 5%, 10 to 100% in increments of 10%).

### NOTE

The M540 speaker volume can only be turned off when the M540 is docked in an IACS configuration or when it is connected to the ICS.

The X symbol appears in the M540 header bar when the alarm volume is deactivated.

When the M540 is on wireless transport in an IACS configuration or in standalone mode and it loses its connection to the ICS, the alarm volume setting is automatically set to 100%. The setting **Off** is no longer available until the connection to the ICS is restored.

# Testing visual and acoustic alarm signals

At startup, the M540 alarm bar illuminates and two speaker tones sound separately. These two distinct tones help the user identify if a speaker is malfunctioning. The user should also test the visual and acoustic alarm signals by creating an alarm condition (for example, by lowering the upper heart rate alarm limits of the heart rate). To end the test, restore the alarm limits to the previous setting (see page 110). Make sure that the volume of the alarm tone is above the ambient noise.

## NOTE

If the M540 speakers fail, all alarm patterns are generated by the M540's power-up/power-down alert tone mechanism. Contact specialized service personnel.

# Special alarm behavior

Activating any of the following features alters the normal alarm annunciation behavior:

- ASY/VF alarms
- SpO2 Desat alarm feature

- NIBP/SpO2 interlock feature
- Zeroing invasive blood pressures
- Privacy mode

- Cardiac bypass mode and OR alarms (only available when the M540 is docked in an IACS configuration)
- Standby mode
- French NFC mode
- ECMO mode
- Pressures pause and Pressures off functions

# Arrhythmia/ventricular fibrillation alarms

You can control the alarming behavior for ventricular fibrillation (VF) and asystole (ASY) alarms.

Alarm signals are not generated for ventricular fibrillation and asystole events when the following conditions are met:

- The ASY/VF alarms setting is set to Always on or Follow HR (see page 304)
- The ARR mode is set to Off
- The *HR source* is set to *Arterial* or *SpO2* with ECG available as a heart rate source

## NOTE

When *Arterial* is selected as the HR source, the first valid pressure is derived from the following list in priority order: ART, AOR, FEM, AXL, RAD, UAP, BRA.

To make sure that asystole and ventricular fibrillation alarms are always reported do one of the following:

– Turn arrhythmia monitoring on

or

 Set the *HR source* to *ECG* (see page 147) when the *ARR mode* setting is set to *Off* (see page 160)

The ASY, VF off message appears when arrhythmia monitoring is deactivated, the ASY/VF **alarms** selection is set to **Follow HR**, and heart rate alarms are deactivated.

# SpO2 desaturation alarm feature

The alarm priority is upgraded to high-priority if the SpO2 value falls below the desaturation alarm limit. Deactivating the SpO2 alarm automatically deactivates the desaturation alarm. The desaturation alarm can be activated only if SpO2 alarms are activated (see page 204 for the Nellcor sensor and page 192 for the Masimo SET MCable). When using the Infinity MCable – Nellcor OxiMax this feature is only available if the **SatSeconds** function is set to **Off** (see page 204).

# NIBP/SpO2 interlock alarm feature

To avoid *SpO2* nuisance alarms when the blood pressure cuff and the *SpO2* sensor are placed on the same limb during an active non-invasive blood pressure measurement, select *NIBP/SpO2 interlock On* in the *Alarm setup* dialog (see page 304).

When the feature is activated, all *SpO2* alarms are deactivated during an active non-invasive blood pressure measurement. To activate or deactivate this feature, see page 304.

# Zeroing invasive pressures

Zeroing all invasive pressures using the zero key (>0<) on the hemodynamic pods has the following effects:

 All invasive blood pressure limit alarms and static alarms are suppressed from the time the key is pressed until 30 seconds after the zeroing procedure is completed.

Zeroing an individual invasive blood pressure from the M540 (see page 238) has the following effects:

 The invasive blood pressure limit alarm and static alarm for that parameter are suppressed from the time the button is pressed until 30 seconds after the zeroing procedure is completed.  If the zeroed parameter is *ICP* or *ART*, the *CPP* limit alarm is also suppressed from the time the button is pressed until 30 seconds after the zeroing procedure is completed.

The following alarm conditions cancel the suppression of alarms caused by zeroing invasive blood pressures:

- Invasive blood pressure parameter is outside of the measuring range (too high/low)
- Pressure transducer failure due to a hardware failure, such as an open circuit or short circuit within the cable.
- Unplugged transducers
- Disconnected hemodynamic pods
- A wedge pressure measurement that ends before the 30-second zeroing period ends, activates the alarm limit for the parameter *PA M* only.

# **Privacy mode**

Privacy mode is available when the M540 is docked in an IACS configuration, on wireless transport, or in standalone mode provided the patient is admitted at the ICS. When privacy mode is activated, the following happens at the M540:

- All patient data are removed from the M540, but continues to display at the ICS
- The alarm bar is deactivated
- Acoustic alarm signals are only provided at the ICS
- The M540 displays *Privacy, Touch screen to* resume monitoring

You can activate privacy mode only if the patient is also admitted at the ICS. To activate or deactivate this feature, see page 83.

# Standby mode

When Standby mode is activated, the following happens at the M540:

- All patient data are removed from the screen
- All monitoring (including acoustic and optical alarm signals) is suppressed
- Active alarms are considered acknowledged by the user
- All recordings are canceled at the Cockpit (provided the M540 is docked in an IACS configuration)
- The M540 displays Standby, Touch screen to resume monitoring

# OR alarms

OR alarms are only available on the M540 when it is docked in an IACS configuration. When OR alarms are activated at the Cockpit, alarm messages for medium- and high-priority alarms clear when the alarm condition no longer exists.

## NOTE

**RRi** and 12-lead ECG monitoring are unavailable when the M540 is set to OR alarms and the ECG filter is set to **Monitor**.

# Cardiac bypass mode

Cardiac bypass mode is only available when the M540 is docked in an IACS configuration, and the Cockpit is set to OR alarms. When cardiac bypass mode is activated, the following happens at the M540:

- All alarm monitoring (including arrhythmia alarms), and the alarm bar are deactivated
- The message *All alarms off: Bypass* appears in the upper right corner of the screen

Cardiac bypass mode is not available if *French NFC* mode is activated.

# French NFC mode

When *French NFC* mode is activated, the following happens at the M540:

- Heart rate alarms cannot be deactivated
- The alarm pause period cannot last longer than 3 minutes
- You cannot activate cardiac bypass mode when *French NFC* mode is activated. If cardiac bypass mode was activated before *French NFC* mode was turned on, cardiac bypass mode is deactivated.

To activate or deactivate this feature, see page 311.

# ECMO mode

When a patient undergoes ECMO (extracorporeal membrane oxygenation), pressure tracings change from pulsatile to non-pulsatile. ECMO mode supports the pressure transition from pulsatile to non-pulsatile by disabling systolic, diastolic, static pressure, and arterial catheter disconnected alarms. Mean pressure alarms remain enabled.

ECMO mode supports a patient undergoing the ECMO procedure by suppressing diastolic, systolic, static pressure, and arterial catheter disconnect alarms. Mean pressure alarms continue to function.

#### To activate ECMO mode on the M540

- 1 Press the *Alarms* button on the M540 to open the Alarm settings dialog.
- Press the ECMO mode key to activate (toggles to On/Off).

At the M540:

- Systolic alarms are disabled
- Diastolic alarms are disabled
- Static pressure alarms are disabled

 Art. cath. disconnect alarms are disabled; however, these alarms can be manually turned on (re-enabled).

When ECMO mode is on, the following banner appears on the M540 indicating that systolic and diastolic alarms are disabled.



#### To deactivate ECMO mode

#### WARNING

All systolic, diastolic, static pressure, and *Art. cath. disconnect* alarms are disabled in ECMO mode, which reduces the number of invasive pressure alarms to mean pressure limit alarms only.

- 1 Press the *ECMO mode* button (toggles to On/Off).
  - The disabled systolic and diastolic banner on the Cockpit and M540 is removed. All arterial pressure alarms are enabled.

# Pressures paused and Pressures off functions

The user can set pressure alarms to *Pause*, configure pause durations, and set pressure alarms to *Off*.

To configure the **Pressures pause** button and the **Pressures off** button, do the following:

- 1 Press *Menu* on the M540.
- 2 Press System setup.
- 3 Press Alarm setup.
- 4 Enter the clinical password.
- 5 Press Settings 2.
- 6 Press Pressures off.
- 7 Select Enable.

## To configure pause durations

The user can configure pause durations when the *Pressures pause* key is available for selection in the *Alarm settings* dialog.

- 1 Press the *Menu* key on the M540.
- 2 Press the System setup key.
- 3 Press the *Alarm setup* key.
- 4 Enter the clinical password in the *Alarm setup* dialog.
- 5 Press Settings 2.
- 6 Press the *Pressures paused* key.
- 7 Select one of the following increments for pausing alarms:
  - 1 min
  - 2 min (default)
  - 3 min
  - 4 min
  - 5 min
  - Disable

#### To pause pressure alarms

- 1 Press the *Alarms* key on the M540 to open the *Alarm settings* dialog.
- 2 On the M540, press *Pressures pause*.

## WARNING

Selecting *Pressures pause* impacts all invasive pressure alarms including the *Art. cath. disconnect* alarm.

# To set pressure alarms Off

- 1 On the main screen, press *Alarms*.
- 2 Press Pressures off.

The following banner is displayed in a red banner on the M540:

Pressures off

3 Press *Pressures off* again to cancel the function.

## CAUTION

The **Pressures off** setting will remain in effect until canceled by the user.

### WARNING

Selecting *Pressures off* impacts all invasive pressure alarms including the *Art. cath. disconnect* alarm.

## NOTE

Audio paused has priority over Pressure paused. Initiating Audio pause during Pressure pause will automatically cancel Pressure pause.

# **Pre-silencing alarms**

This function allows you to pre-silence (audio pause in advance) potential alarm conditions before they occur. Pre-silencing allows you to concentrate on a procedure without being interrupted by continuous acoustic alarm signals arising from potential alarm conditions. A presilence period lasts two minutes.

Pre-silencing alarms has the following effect:

- Any alarm conditions are reported visually by a corresponding alarm message and a blinking parameter field (see page 97).
- A single acoustic alarm signal is generated for the first occurrence of an alarm condition of low, medium or high priority.
- The alarm message *Audio paused* appears in the far right field of the header bar along with a timer and the following symbol:
- If multiple alarm conditions arise during an active pre-silence period, the M540 triggers a single acoustic alarm signal for the highestgrade alarm event.

#### NOTE

Pre-silencing alarms is not possible when the quiet mode is deactivated.

## Initiating a pre-silence period

You can initiate a pre-silence in several ways:

- From an M540 in standalone mode or on wireless transport
- From an ICS
- From the remote view of another Infinity monitor within the same monitoring unit
- From the Cockpit when the M540 is docked in an IACS configuration

To initiate a pre-silence period remotely is only possible when the remote control setting of the remote device is also activated. Refer to the corresponding instructions for use for information on how to activate the remote control feature.

#### To pre-silence alarms at the M540

Press the following key on the M540:



The pre-silence state can be canceled by pressing the same key again that initiated the pre-silence period. All alarm events are again reported as usual.

#### To pre-silence alarms remotely

 Press the following key on the main menu bar of the ICS to pre-silence alarms for all assigned patients:



Press the same key in the viewport area to pause alarm tones for an individual patient. For more information, refer to the ICS instructions for use.

• Refer to the instructions for use of any remote device within the same monitoring unit for instructions on how to initiate an audio pause.

The pre-silence state can be canceled by pressing the same key again that initiated the pre-silence period. All alarm events are again reported as usual.

# Pausing acoustic alarm signals (audio pause)

Active alarms can be paused, or silenced, at the M540 for two minutes. In addition to pausing alarms, the setting of the quiet mode feature determines how subsequent alarm conditions are announced.

You can initiate an audio pause in several ways:

- From an M540 in standalone mode or on wireless transport
- From an ICS
- From the remote view of another Infinity monitor within the same monitoring unit
- From the Cockpit when the M540 is docked in an IACS configuration
- From a remote device when remote control and remote silence are activated at the remote device and the Cockpit (refer to the IACS Monitoring Applications IFU)
- When first turning on the device.

# Quiet mode

This feature gives you the flexibility to decide if you want restricted or full annunciation of future alarm conditions after you have already paused alarms. This feature affects the audio pause behavior of the IACS and the ICS. When this mode is activated (see page 303), the number of acoustic alarm signals is reduced to eliminate unnecessary noise while still alerting the clinician to important alarm conditions.

## Activated quiet mode

If a new alarm condition with a priority higher than the currently paused alarm occurs, a truncated alarm tone sounds. In addition, the alarm is represented by optical alarm signals corresponding to the alarm priority. If the new alarm is of equal or lower priority than the paused alarm, the new alarm condition is only represented by an optical alarm signal. No acoustic alarm signal is issued.

If the patient is also admitted at the ICS, any highpriority alarm condition will sound at the ICS. For any subsequent alarm condition of equal or lesser priority, no further alarm tones sound.

## Deactivated quiet mode

Any new alarm condition breaks through the audio pause period with full acoustic and optical alarm signal annunciation. The audio pause message is no longer displayed. The same is true if the patient is admitted at the ICS.

# Pausing alarms at the M540

The following happens at the M540 when you pause active alarms:

- All acoustic alarm signals are paused for a maximum of about two minutes.
- The Audio paused message appears in the alarm message header of the Cockpit along with the timer and the following symbol:
- The alarm message appears in the color corresponding to the alarm priority.
- The parameter field no longer flashes in the color corresponding to the alarm priority. It appears in solid color.
- The alarm bar no longer flashes for high-priority and medium-priority alarm conditions.

## NOTE

If the alarm condition remains unchanged after the alarm pause period expires, the acoustic and optical alarm signals are reactivated. The only exception are single notification (one-shot) alarms which are only reported once. The behavior of new alarm condition while the systems is in an audio pause state is determined by the *Quiet mode* setting.

#### To initiate an audio pause at the M540

Press the yellow key on the M540:



Pressing the key again cancels the audio pause period and all alarm events are reported as usual.

#### To initiate an audio pause remotely

 Press the following key on the main menu bar of the ICS to audio pause alarms for all assigned patients:



Press the same button in the viewport area to pause alarm tones for an individual patient. For more information, refer to the instructions for use of the ICS.

 Refer to the instructions for use of any remote device within the same monitoring unit for instructions on how to initiate an audio pause.

Pressing the key again cancels the audio pause period and all alarm events are reported as usual.

# Pausing alarm monitoring temporarily

If the password-protected alarm pause feature is activated (see page 303), you can pause alarm monitoring temporarily. The alarm pause duration is adjustable from 1 minute to 5 minutes.

## NOTE

If the *French NFC* mode is activated (see page 311), you cannot pause alarm monitoring for more than 3 minutes.

The following happens when you pause alarm monitoring:

- Acoustic and optical alarm signals for new alarm conditions are suppressed for all parameters until alarm monitoring begins again
- Alarm signals for any active alarm condition stop immediately
- The alarming parameter field and alarm bar return to the pre-alarm state
- Alarm messages are removed from the alarm message field in the header bar
- The far right field of the header bar turns yellow and displays the alarm message *All alarms pause*, a timer, and the following symbol:



## To pause alarm monitoring temporarily

- 1 Press the *Alarms* function key.
- 2 Touch All alarms pause.

As soon as the alarm pause period ends, the M540 generates acoustic and optical alarm signals as needed.

### To activate alarm monitoring after pausing

- 1 Press the *Alarms* function key.
- 2 Touch *All alarms pause* before the alarm pause period ends to cancel the alarm pause.
## Activating or deactivating alarm monitoring

#### WARNING

If *No timeout* is assigned to the alarm off period, no counter appears and alarms remain deactivated until you enable them again.

#### WARNING

Never leave a patient unattended when alarm monitoring is permanently deactivated. Always activate alarm monitoring again as soon as possible.

If the password-protected alarm pause feature is set to **No timeout** (see page 303), the following happens when you deactivated alarm monitoring:

- All acoustic and optical alarm signals for new alarm conditions are suppressed for all parameters until alarm monitoring is manually activated again
- Acoustic alarm signals for any active alarm condition stop immediately
- The alarming parameter field and alarm bar return to the pre-alarm state
- Alarm messages are removed from the alarm message field of the header bar
- The far right field of the header bar turns yellow and displays a message that all alarms are off and the following symbol appears:



#### To deactivate alarm monitoring

- 1 Press the *Alarms* function key.
- 2 Touch All alarms off.

#### To activate alarm monitoring after deactivating

- 1 Press the *Alarms* function key.
- 2 Touch All alarms off.

The M540 provides acoustic and optical alarm signals again when it detects a new alarm condition.

# Configuring a patient's alarm settings

The following section describes the alarm features and settings available for each patient. When setting alarm limits, make sure they are appropriate for the patient's condition. Each parameter has its own dialog for configuring parameter-specific alarm functions. For composite parameters such as non-invasive blood pressure, there are alarm settings for each parameter (systolic, diastolic, and mean).

### Setting the upper and lower alarm limits

You can configure the upper and lower alarm limits of a parameter manually to trigger acoustic and optical alarm signals if a parameter goes above or below the set limits.

#### WARNING

Setting alarm limits to extreme values may prevent certain alarm conditions from being detected and from being annunciated with acoustic and optical alarm signals.

#### WARNING

To ensure authorized changes are made to alarm settings, make the clinical, biomedical, and service passwords only available to appropriately trained individuals.

#### To set an individual parameter's alarm settings

- 1 Touch the parameter field (for example, *HR*) to access that parameter's dialog.
- 2 Touch the tab for configuring the parameter limits (for example, *HR limits*).
- 3 Touch the upper or lower alarm limit.
- 4 Touch the up or down arrow to change the alarm limit setting.
- 5 Touch OK.

### Using the Auto set function

The *Auto set* function allows you to adjust alarm limits quickly based on preset percentages listed in the following table:

Parameter	Upper limit	Lower limit
Ta, Tb, T1a, T1b Blood temperature is	≤107% of current value	≤93% of current value
also adjusted at the M540, but the value displays only at the Cockpit.		
$\Delta T$ , $\Delta T1$ , PVC/min, inCO <sub>2</sub>	Not affected	Not affected
SpO2	Adult/pediatric: 100% saturation	Current value –((value)*(5%))
	Neonate: 98% saturation	
ST	Current value +2.0 mm	Current value –2.0 mm
FiO2 (via Scio)	100%	21%
etO2 (via Scio)	100%	18%
inHal etHal inIso etIso inEnf etEnf inSev etSev inDes etDes	5% (+/- 0.1) above parameter value	5% (+/- 0.1) below parameter value
etCO2	Current value +25%	Current value –20%
all others	Alarm limit that is closest to but not more than 25% above the current value of the parameter	Alarm limit that is closest to but not more than 20% below the current value of the parameter

#### To use the Auto set function

- 1 Touch the parameter field of the parameter whose alarm limits you wish to set (for example, *HR*).
- 2 Touch the tab for configuring the parameter limits (for example, *HR limits*).
- 3 Touch Auto set.

#### NOTE

If the **Auto set** function forces the alarm limits of a parameter outside the allowable limit range of the monitor, the alarm limits remain unchanged.

## Activating/deactivating alarms

Except for the following parameters, you can activate or deactivate the alarm function for individual parameters:

- Asystole and ventricular fibrillation (for these arrhythmia events you cannot deactivated alarms unless the ASY/VF alarms selection is set to Follow HR, see page 101)
- Pulmonary wedge pressure
- Perfusion index (PI)
- Total oxygen content (SpOC) for the Masimo rainbow SET MCable

When you deactivate alarms, no acoustic and optical alarm signals are triggered for that parameter. When alarm monitoring is deactivated, a crossed out triangle (A) appears in the parameter field.



When you activate the alarm function for a parameter, the crossed out triangle disappears.

## Archive function

The archive function setting determines what happens in response to an alarm limit violation. The available settings are:

- Off no event is stored and no recording is generated.
- Store stores the event for later review (see page 113).
- Record stores the event for later review (see page 113) when in standalone mode or on wireless transport. Once the M540 is docked, any stored event is transferred to the alarm history of the IACS where you can request a manual recording of the event.
- Str/Rec generates a timed recording for an M540 docked in an IACS configuration and stores the event.

When the M540 is in standalone mode or on wireless transport, this setting stores an event for later review (see page 113). Once the M540 is docked, any stored event is transferred to the alarm history of the IACS where you can request a manual recording of the event.

# To configure an individual parameter's archive function

- 1 Touch the parameter field to access that parameter's dialog (for example, *HR*).
- 2 Touch the tab for configuring the parameter limits (for example, *HR limits*).
- 3 Touch *Archive* and toggle to one of the following settings: *Off*, *Store*, *Record*, *Str/Rec*.
- 4 Touch **X** to close the dialog.

## **Event recall**

The *Event recall* dialog is an electronic record of the patient's alarm history. It records alarm messages and stores the waveforms of the events. The *Event recall* dialog records an entry under the following circumstances:

 When an alarm occurs for a parameter (including heart rate and *ST*) whose alarm feature is activated and archive function is set to *Store* or *Str/Rec* (see page 112).

Whenever an arrhythmia event occurs (even when the alarm function is deactivated). For an event to be stored, only the archive function must be set to *Str/Rec* or *Store*, *Record*.

In standalone mode, the archive function can be set to *Record*, *Str/Rec* or *Store* and an event will be stored.

 When you press the *Mark* function key on the front of the M540 (see page 59). These alarm events are labeled *BED TIMED* and can be viewed in greater detail (see page 115).

- When you press the *Record* function key (see page 59) on the M540 when the M540 is either in standalone mode or on transport. These alarm events are labeled *BED TIMED* and can be viewed in greater detail (see page 115).
- When the M540 on transport or in standalone mode and an alarm occurs for a parameter whose alarm archive function is set to *Record*.

The alarm history stores up to 150 events. When the storage capacity of 150 events is reached, new events replace the oldest events.

#### NOTE

On the M540, if multiple events occur together, (less than 5 seconds), only the first event may be available in the *Event recall* dialog.

If a higher priority alarm occurs less than 5 seconds from a previous alarm, the higher priority alarm event is stored while the previous one is deleted.

The alarm history is maintained until the patient is discharged. If the M540 is turned off and turned back on, the patient's alarm history is not affected; however, the history will not record the time of the shutdown.

### **Viewing stored events**

The following diagram shows the *Event recall* dialog. When you select any field on the table, a frame highlights the selected row. For information on what conditions prompt an entry to be stored in the *Event recall* dialog, see page 112.

#### To access stored events

Select the *Review* function key. The following diagram shows the *Event recall* dialog.



- A Event list with date, time, and cause of each event.
- **B** Arrow buttons for scrolling through the event list.
- **C** *View* button for viewing a single event in greater detail.
- D Delete button for deleting an event.
- E *Lock* button for locking an event (if the M540 is docked in an IACS configuration, pressing this button has no effect on events at the Cockpit).

## Viewing a snapshot of a single event

Twenty seconds of waveform and parameter data are stored automatically in the *Event recall* dialog under the following circumstances:

- When a parameter whose alarm feature is activated and archive feature is set to *Store* or *Str/Rec* (see page 112) violates set alarm limits.
- Whenever an arrhythmia event occurs (even when the alarm function is deactivated). For an event to be stored, only the archive function must be set to *Str/Rec* or *Store*, *Record*.
- You press the *Mark* function key (see page 59).
- When you press the *Record* function key (see page 59) on the M540 when the M540 is on transport or in standalone mode.

Events with stored waveform and parameter data are identified in the *Event recall* dialog by the label *BED TIMED* for manually stored events or the alarm string (for example, HR > 120) for a limit violation. Such an event consists of a snapshot of two waveforms at the time of the event. The two waveforms follow the setting for *Channel 1* and *Channel 2* except in the case of a limit violation where the first waveform is replaced by the alarming parameter waveform. Of the 20-second event capture, 10 seconds were recorded before and 10 seconds were recorded after the event occurred.

The following diagram shows a snapshot of a single event.



- A Waveform data
- B Prev button scrolls to the previous event
- C Next button scrolls to the next event
- D Status bar with date and time stamp the event was stored and arrow buttons for scrolling through 20-second portions of waveform data

#### To view a snapshot of a stored event

- 1 Press the *Review* function key.
- 2 Select the event that you wish to view.
- **3** Touch *View* to display the waveforms associated with the event.

# Configuring the SpO2 alarm priority

The following two SpO2 alarm messages can be configured for the alarm priority that is most appropriate for your care environment. When the M540 is docked in an IACS configuration, the Cockpit controls these settings.

Depending on which MCable is used, the message reporting the underlying alarm condition differs:

- Masimo rainbow SET or Masimo SET: SpO2 sensor off
- Nellcor: SpO2 check sensor

Both settings are saved as part of the patient profile.

# Configuring the alarm priority for a disconnected Masimo sensor

This alarm setting is for configuring the alarm priority and the alarm archiving behavior of certain Masimo SpO<sub>2</sub> parameters. The **SpO<sub>2</sub> sensor off** message appears when the MCable detects that the sensor is no longer attached to the patient. This setting can be configured separately for each patient category. It is available for the following SpO<sub>2</sub> cables:

- Masimo rainbow SET MCable
- Masimo SET MCable

For information on how to configure the alarm priority for the setting *SpO2 sensor off*, see page 307.

On the Cockpit and the M540, the following SpO2 parameters can generate this alarm message according to the selected alarm priority:

Masimo rainbow SET MCable	Masimo SET MCable
SpO2	SpO2
PLS	PLS
SpHbv or SpHb	
SpOC	
PVI	
SpMet	

# Configuring the alarm condition for a disconnected Nellcor sensor

This alarm feature is for configuring the alarm priority and the alarm archiving behavior of certain Nellcor SpO2 parameters. The **SpO2 check sensor** message appears when the Nellcor OxiMax MCable detects that the sensor is no longer attached to the patient or other technical issues that interfere with the functional integrity of the sensor. This feature can be configured separately for each patient category. For information on how to configure the alarm priority for the setting **SpO2 check sensor**, see page 307.

The following SpO2 parameters generate an alarm message according to the selected alarm priority:

- SpO2
- PLS

## Alarm management setup (password-protected)

The password-protected alarm setup is only accessible to authorized personnel. For details on available setup functions, see page 317.

## The Code function key

If the M540 is connected to the IACS you can activate a set of monitoring functions at the IACS during emergency care by selecting the *Code* 

function key on the M540. For specific information, refer to the Instructions for use *Infinity Acute Care System – Monitoring Applications*.

## Alarm groups

You can configure the M540 and other monitors as members of an alarm group. This feature makes sure that any alarms that occur at any of the monitors within the alarm group are broadcast to all other members in the alarm group (see page 304) for remote viewing of alarm conditions.

When the M540 is docked in a IACS configuration, the alarm group of the M540 is adjusted to the alarm group ID set on the Cockpit device.

#### NOTE

On the M540, if you change the default value of the alarm group to any other value, then the default value will not come back after a discharge.

To resolve this issue:

- Change the alarm group ID, or
- Perform another discharge, or
- Undock and then redock the M540

# Alarm ranges and defaults

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
HR adult Increment: 5 bpm	On	Upper: 25 to 300 bpm Lower: 20 to 295 bpm	<ul> <li>– 120 (adult)</li> <li>– 150</li> <li>(pediatric)</li> </ul>	<ul> <li>45 (adult)</li> <li>50</li> <li>(pediatric)</li> </ul>	<i>Str/Rec</i> (adult, pediatric)
			– 170 (neonate)	– 80 (neonate)	<b>Off</b> (neonate)
STVM/STCVM Increment: 0.1 mm or 0.01 mV	2	Upper: 0.1 to 45.0 mm 0.01 to 4.50 mV Lower: 0.0 to 44.9 mm 0.00 to 4.49 mV	1.0 mm (0.1 mV)	0.0 mm (0 mV)	Off
Increment: 0.1 mm or 0.01 mV	2	Upper: -14.9 to +15.0 mm -1.49 to +1.50 mV Lower: -15.0 to +14.9 mm -1.50 to +1.49 mV	1.0 mm (0.1 mV)	–1.0 mm (–0.1 mV)	Off
<b>RRi</b> (adult) Increment: 1	$\bigotimes$	Upper: 6 to 100 Lower: 5 to 99 (adult)	30	5	Off
<b>RRi</b> pediatric, neonate <i>Increment: 1</i>	~	Upper: 6 to 145 Lower: 5 to 144	80	20	Off
PLS Increment of 5	2	Upper: 35 to 235 Lower: 30 to 230	<ul> <li>120 (adult)</li> <li>150 (pediatric)</li> <li>180 (neonate)</li> </ul>	<ul> <li>45 (adult)</li> <li>50 (pediatric)</li> <li>80 (neonate)</li> </ul>	Off

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
<b>SpO</b> 2 <sup>1)</sup>	On	Upper: 21 to 100%	<ul> <li>100% (adult,</li> </ul>	85%	Off
Increment: 1%		Lower: 20 to 99%	pediatric) - 95% (neonate)		NOTE: Changing this setting automati cally changes the <i>Desat.</i> archive setting to the same setting.
Desat. Increment: 1 NOTES: - The Desat. alarm status is set to off when Nellcor SatSeconds is set to any value other than Off. - The Desat. alarm status is set to off when the SpO2 alarm is turned off.	(Adult/ pediatric) <b>On</b> (neonate)	Lower: 19 to (SpO2 lower limit - 1)% (within the maximum measurement range of 19 to 98%) If the SpO2 low alarm limit is lowered to or below the SpO2 desat alarm limit, then the SpO2 desat alarm automatically adjusts to 1% less than the SpO2 low alarm limit. The SpO2 desat alarm limit cannot be raised to or above the SpO2 low alarm limit	N/A	75%	Off NOTE: Changing this setting automati cally changes the SpO2 archive setting to the same setting.
PVI		Upper: 1 to 100	100	0	Off
Increment: 1		Lower: 0 to 99			

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
SpHb / SpHbv	$\times$	Upper: 1.2 to 25.0 g/dL	17.0 g/dL	7.0 g/dL	Off
Increment	<i>4</i> <del>2</del>	(0.7 to 15.5 mmol/L)	(10.6 mmol/L)	(4.3 mmol/L)	
0.2 g/aL (0.1 mmol/L)		(0.6 to 15.4 mmol/L)			
SpCO	××	Upper: 1 to 99	10	0	Off
Increment: 1		Lower: 0 to 98			
SpMet	~~~	Upper: 0.1 to 99.9	3.0	0	Off
Increment: 0.1		Lower: 0.0 to 99.8			
NIBP S adult	On	Upper: 11 to 250 mmHg	160 mmHg	90 mmHg	Off
Increment: 1		1.4 to 33.3 kPa	(21.3 kPa)	(12.0 kPa)	
mmHg or 0.1 kPa		Lower: 10 to 249 mmHg			
		1.3 to 33.2 kPa			
NIBP S pediatric	On	Upper: 11 to 170 mmHg	120 mmHg	50 mmHg	Off
Increment: 1		1.4 to 22.7 kPa	(16 kPa)	(6.7 kPa)	
mmHg or 0.1		Lower: 10 to 169 mmHg			
		1.3 to 22.6 kPa			
NIBP S neonate	On	Upper: 11 to 130 mmHg	80 mmHg	50 mmHg	Off
Increment: 1		1.4 to 17.3 kPa	(10.7 kPa)	(6.7 kPa)	
mmHg or 0.1		Lower: 10 to 129 mmHg			
		1.3 to 17.2 kPa			
NIBP D adult	On	Upper: 11 to 250 mmHg	110 mmHg	50 mmHg	Off
Increment: 1		1.4 to 33.3 kPa	(14.7 kPa)	(6.7 kPa)	
mmHg or 0.1 kPa		Lower: 10 to 249 mmHg			
		1.3 to 33.2 kPa			
NIBP D pediatric	On	Upper: 11 to 170 mmHg	80 mmHg	35 mmHg	Off
Increment: 1		1.4 to 22.7 kPa	(10.7 kPa)	(4.7 kPa)	
mmHg or 0.1		Lower: 10 to 169 mmHg			
		1.3 to 22.6 kPa			

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
NIBP D neonate	On	Upper: 11 to 130 mmHg	60 mmHg	25 mmHg	Off
Increment: 1		1.4 to 17.3 kPa	(8 kPa)	(3.3 kPa)	
mmHg or 0.1 kPa		Lower: 10 to 129 mmHg			
		1.3 to 17.2 kPa			
NIBP M adult		Upper: 11 to 250 mmHg	125 mmHg	60 mmHg	Off
Increment: 1		1.4 to 33.3 kPa	(16.7 kPa)	(8.0 kPa)	
mmHg or 0 1 kPa		Lower: 10 to 249 mmHg			
		1.3 to 33.2 kPa			
NIBP M pediatric	On	Upper: 11 to 170 mmHg	85 mmHg	40 mmHg	Off
Increment: 1 mmHg or 0.1 kPa		1.4 to 22.7 kPa	(11.3 kPa)	(5.3 kPa)	
		Lower: 10 to 169 mmHg			
0.7 17 0		1.3 to 22.6 kPa			
NIBP M neonate	On	Upper: 11 to 130 mmHg	70 mmHg	40 mmHg (5.3 kPa)	Off
Increment: 1		1.4 to 17.3 kPa	(9.3 kPa)		
mmHg or 0 1 kPa		Lower: 10 to 129 mmHg			
0.7 1.7 0		1.3 to 17.2 kPa			
Δ <b>T</b> / Δ <b>T1</b>	×2%	Upper: 0.1 to 39.0 °C	1.0 °C	0.0 °C	Off
Increment:	<u> </u>	0.2 to 70.2 °F	(3.6 °F)	(0.0 °F)	
0.1 °C or 0.1 + 0.2 °F		Lower: 0.0 to 38.9 °C			
± 0.2 T		0.0 to 70.0 °F			
Ta/T1a/Tb/T1b	×3x	Upper: 0.1 to 50.0 °C	39.0 °C	34.0 °C	Off
Increment:		32.2 to 122.0 °F	(102.2 °F)	(93.2 °F)	
0.1 °C or 0.1 °F		Lower: 0.0 to 49.9 °C			
		32.0 to 121.8 °F			

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
IP S adult Increment: 1 mmHg or 0.1 kPa	(GP1 S to GP8 S, LV S, RV S) <b>On</b> (systolic arterial pressure, PA S)	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa	<ul> <li>160 mmHg (21.3 kPa) for <i>GP1 S</i> to <i>GP8 S</i>, systolic arterial pressure, <i>LV</i> <i>S</i></li> <li>35 mmHg (4.7 kPa) for <i>PA S</i>, <i>RV S</i></li> </ul>	<ul> <li>90 mmHg (12.0 kPa) for <i>GP1 S</i> to <i>GP8 S</i>, systolic arterial pressure</li> <li>75 mmHg (10.0 kPa) for <i>LV S</i></li> <li>10 mmHg (1.3 kPa) for <i>PA S</i>, <i>RV S</i></li> </ul>	Off
IP S pediatric/ neonate Increment: 1 mmHg or 0.1 kPa	(GP1 S to GP8 S, LV S, RV S) <b>On</b> systolic arterial pressure, PA S)	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa	<ul> <li>120 mmHg (16.0 kPa) for <i>GP1 S</i> to <i>GP8 S</i>, systolic arterial pressure, <i>LV</i> <i>S</i></li> <li>35 mmHg (4.7 kPa) for <i>PA S</i>, <i>RV S</i></li> </ul>	<ul> <li>75 mmHg (10.0 kPa) for <i>GP1 S</i> to <i>GP8 S</i>, systolic arterial pressure</li> <li>50 mmHg (6.7 kPa) for <i>LV S</i></li> <li>10 mmHg (1.3 kPa) for <i>PA S</i>, <i>RV S</i></li> </ul>	Off

Parameter	Alarm default status	Alarm limit range		Upper limit Lo defaults de		wer limit faults	Archive default setting
IP D adult Increment: 1 mmHg or 0.1 kPa	(GP1 D to GP8 D, LV D, RV D)	Upper: –49 to +400 mmHg –6.5 to +53.3 kPa Lower: –50 to +399 mmHg –6.6 to +53.2 kPa	-	110 mmHg (14.7 kPa) for <i>GP1 D</i> to <i>GP8 D</i> , diastolic arterial pressure	_	50 mmHg (6.7 kPa) for <i>GP1 D</i> to <i>GP8 D</i> , diastolic arterial pressure	Off
	<b>On</b> (diastolic arterial pressure PA D)		_	25 mmHg (3.3 kPa) for <i>LV D</i> 13 mmHg (1.7 kPa) for <i>PA D</i> , <i>RV D</i>	_	2 mmHg (0.3 kPa) for <b>PA D</b> , <b>LV D</b> , <b>RV D</b>	
IP D pediatric Increment: 1 mmHg or 0.1 kPa	(GP1 D to GP8 D, LV D, RV D) <b>On</b> (diastolic arterial pressure PA D)	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa	_	80 mmHg (10.7 kPa) for <i>GP1 D</i> to <i>GP8 D</i> , diastolic arterial pressure 25 mmHg (3.3 kPa) for <i>LV D</i> 13 mmHg (1.7 kPa) for <i>PA D</i> , <i>RV</i>	_	35 mmHg (4.7 kPa) for <i>GP1 D</i> to <i>GP8 D</i> , diastolic arterial pressure 2 mmHg (0.3 kPa) for <i>PA D</i> , <i>LV D</i> , <i>RV D</i>	Off
IP D neonate Increment: 1 mmHg or 0.1 kPa	(GP1 D to GP8 D, LV D, RV D) <b>On</b> (diastolic arterial pressure PA D)	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa	_	80 mmHg (10.7 kPa) for <i>GP1 D</i> to <i>GP8 D</i> , diastolic arterial pressure 25 mmHg (3.3 kPa) for <i>LV D</i> 13 mmHg (1.7 kPa) for <i>PA D</i> , <i>RV D</i>	_	30 mmHg (4.0 kPa) for <i>GP1 D</i> to <i>GP8 D</i> , diastolic arterial pressure 2 mmHg (0.3 kPa) for <i>PA D</i> , <i>LV D</i> , <i>RV D</i>	Off

Parameter	Alarm default status	Alarm limit range	Up de	oper limit faults	Lo de	ower limit faults	Archive default setting
IP M adult Increment: 1 mmHg or 0.1 kPa	On	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa	-	125 mmHg (16.7 kPa) for <i>GP1 M</i> to <i>GP8 M</i> , mean arterial pressure 80 mmHg (10.7 kPa) for <i>LV M</i> 20 mmHg (2.7 kPa) for <i>LA</i> , <i>ICP</i> , <i>CVP</i> , <i>ABD</i> , <i>BDP</i> , <i>ESO</i> , <i>FEMV</i> , <i>UVP</i> , <i>GPM</i> 17 mmHg (2.3 kPa) for <i>PA M</i> , <i>RV M</i> 12 mmHg (1.6 kPa) for <i>RA</i>	_	60 mmHg (8.0 kPa) for <i>GP1 M</i> to <i>GP8 M</i> , mean arterial pressure 40 mmHg (5.3 kPa) for <i>LV M</i> 7 mmHg (0.9 kPa) for <i>PA M</i> , <i>RV M</i> 2 mmHg (0.3 kPa) for <i>RA</i> , <i>ICP, ABD,</i> <i>BDP,</i> <i>ESO,</i> <i>FEMV,</i> <i>UVP</i>	Off
					_	(0.0 kPa) for <i>LA</i> , <i>CVP, GPM</i>	

Parameter	Alarm default status	Alarm limit range	Upp defa	per limit aults	Lower lim defaults	it Archive default setting	ţ
IP M pediatric Increment: 1 mmHg or 0.1 kPa	On	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa		85 mmHg (11.3 kPa) for <i>GP1 M</i> to <i>GP8 M</i> , mean arterial pressure, <i>LV</i> <i>M</i> 20 mmHg (2.7 kPa) for <i>LA</i> , <i>ICP</i> , <i>CVP</i> , <i>ABD</i> , <i>BDP</i> , <i>ESO</i> , <i>FEMV</i> , <i>UVP</i> , <i>GPM</i> 17 mmHg (2.3 kPa) for <i>PA</i> , <i>RV M</i> 12 mmHg (1.6 kPa) for <i>RA</i>	<ul> <li>50 mm (6.7 kP for <i>GP</i> to <i>GP8</i> mean arterial pressu</li> <li>40 mm (5.3 kP for <i>LV</i></li> <li>7 mmH (0.9 kP for <i>PA</i>, <i>RV M</i></li> <li>2 mmH (0.3 kP for <i>RA</i>, <i>ICP</i>, <i>A</i> <i>BDP</i>, <i>ESO</i>, <i>FEMV</i>, <i>UVP</i></li> <li>0 mmH (0.0 kP for <i>LA</i>, <i>CVP</i> (0</li> </ul>	Hg Off Pa) 1 M 8 M, re Hg Pa) M Ig Pa) BD, BD, BD,	

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
IP M neonate Increment: 1 mmHg or 0.1 kPa	On	Upper: -49 to +400 mmHg -6.5 to +53.3 kPa Lower: -50 to +399 mmHg -6.6 to +53.2 kPa	<ul> <li>80 mmHg (10.7 kPa) for <i>GP1 M</i> to <i>GP8 M</i>, mean arterial pressure, <i>LV</i> <i>M</i></li> <li>20 mmHg (2.7 kPa) for <i>LA</i>, <i>ICP</i>, <i>CVP</i>, <i>ABD</i>, <i>BDP</i>, <i>ESO</i>, <i>FEMV</i>, <i>UVP</i>, <i>GPM</i></li> <li>17 mmHg (2.3 kPa) for <i>PA</i>, <i>RV M</i></li> <li>12 mmHg (1.6 kPa) for <i>RA</i></li> </ul>	<ul> <li>40 mmHg (5.3 kPa) for <i>GP1 M</i> to <i>GP8 M</i>, mean arterial pressure, <i>LV M</i></li> <li>7 mmHg (0.9 kPa) for <i>PA</i>, <i>RV M</i></li> <li>2 mmHg (0.3 kPa) for <i>RA</i>, <i>ICP, ABD</i>, <i>BDP</i>, <i>ESO</i>, <i>FEMV</i>, <i>UVP</i></li> <li>0 mmHg (0.0 kPa) for <i>CVP</i>, <i>GPM</i></li> </ul>	Off
CPP, BPP, APP Increment: 1 mmHg or 0.1 kPa FiO2	On On	Upper: -24 to +300 mmHg -3.2 to +40.0 kPa Lower: -25 to +299 mmHg -3.3 to +39.9 kPa Upper: 19 to 100%	100 mmHg (13.3 kPa) 100%	70 mmHg (9.3 kPa) 20%	Off Store
Increment of 1%		Lower: 18 to 99%			
etO2 Increment of 1%	2	Upper: 11 to 100% Lower: 10 to 99%	100%	10%	Off
inN2O	On (fixed)	Fixed at 82%	82%	Not applicable	Store (fixed)

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
<b>RRc</b> Increment of 1/min	(Adult/ pediatric) <b>On</b> (neonate)	Upper: 6 to 150 /min (when no CO2 device is connected) 6 to 100 /min (when Scio is connected) Lower: 5 to 149 /min (when no CO2 device is connected) 5 to 99 /min (when Scio is connected)	<ul> <li>30 /min (adult)</li> <li>60 /min (pediatric, neonate)</li> </ul>	<ul> <li>5 /min (adult)</li> <li>20 /min (pediatric, neonate)</li> </ul>	Off
		NOTE Scio is not available in neonate mode.			
<i>inCO</i> 2 <i>Increment of</i> <i>1 mmHg,</i> <i>0.1 kPa, or 0.1%</i>	On	Upper: 2 to 10 mmHg 0.3 to 1.3 kPa 0.3 to 1.3% Lower: not user-selectable	4 mmHg (0.5 kPa, 0.5%)	Not applicable	Off
etCO2 Increment of 1 mmHg, 0.1 kPa, or 0.1%	On	Upper: 6 to 100 mmHg 0.8 to 13.3 kPa 0.8 to 13.3% Lower: 5 to 99 mmHg 0.7 to 13.0 kPa 0.7 to 13.0%	50 mmHg (6.7 kPa, 6.6%)	30 mmHg (4.0 kPa, 3.9%)	Off
PVC/min	On	Upper: 1 to 50	10	Not applicable	Off
inHal Increment of 0.1 kPa or 0.1%	On	Upper: 0.1 to 8.6 kPa 0.1 to 8.5% Lower: 0.0 to 8.5 kPa 0.0 to 8.4%	1.6 kPa, 1.6% (adult) 1.9 kPa, 1.9% (pediatric)	0.0 kPa, 0.0%	Store

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
etHal Increment of 0.1 kPa or 0.1%	×	Upper: 0.1 to 8.6 kPa 0.1 to 8.5% Lower: 0.0 to 8.5 kPa 0.0 to 8.4%	8.5 kPa, 8.5%	0.0 kPa, 0.0%	Off
inlso Increment of 0.1 kPa or 0.1%	On	Upper: 0.1 to 8.6 kPa 0.1 to 8.5% Lower: 0.0 to 8.5 kPa 0.0 to 8.4%	2.4 kPa, 2.4% (adult) 2.8 kPa, 2.8% (pediatric)	0.0 kPa, 0.0%	Store
etlso Increment of 0.1 kPa or 0.1%	2	Upper: 0.1 to 8.6 kPa 0.1 to 8.5% Lower: 0.0 to 8.5 kPa 0.0 to 8.4%	8.5 kPa, 8.5%	0.0 kPa, 0.0%	Off
inEnf Increment of 0.1 kPa or 0.1%	On	Upper: 0.1 to 10.1 kPa 0.1 to 10.0% Lower: 0.0 to 10.0 kPa 0.0 to 9.9%	3.6 kPa, 3.6% (adult) 4.1 kPa, 4.1% (pediatric)	0.0 kPa, 0.0%	Store
etEnf Increment of 0.1 kPa or 0.1%	2	Upper: 0.1 to 10.1 kPa 0.1 to 10.0% Lower: 0.0 to 10.0 kPa 0.0 to 9.9%	10 kPa, 10%	0.0 kPa, 0.0%	Off

Parameter	Alarm default status	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default setting
inSev Increment of 0.1 kPa or 0.1%	On	Upper: 0.1 to 10.1 kPa 0.1 to 10.0% Lower: 0.0 to 10.0 kPa 0.0 to 9.9%	4.4 kPa, 4.4% (adult) 5.1 kPa, 5.1% (pediatric)	0.0 kPa, 0.0%	Store
etSev Increment of 0.1 kPa or 0.1%	2	Upper: 0.1 to 10.1 kPa 0.1 to 10.0% Lower: 0.0 to 10.0 kPa 0.0 to 9.9%	10 kPa, 10%	0.0 kPa, 0.0%	Off
inDes Increment of 0.1 kPa or 0.1%	On	Upper: 0.1 to 20.3 kPa 0.1 to 20.0% Lower: 0.0 to 20.2 kPa 0.0 to 19.9%	12.5 kPa, 12.5% (adult) 14.5 kPa, 14.5% (pediatric)	0.0 kPa, 0.0%	Store
etDes Increment of 0.1 kPa or 0.1%	2	Upper: 0.1 to 20.3 kPa 0.1 to 20.0% Lower: 0.0 to 20.2 kPa 0.0 to 19.9%	20 kPa, 20%	0.0 kPa, 0.0%	Off
Inspiratory xMAC high	On	The user can not configure the xMAC limits.	Not applicable	Not applicable	Store

### NOTE

1) If the low alarm limit is set to  $\leq$  the factory default value of 85, the SpO<sub>2</sub> high and low alarm limits are displayed in the SpO<sub>2</sub> parameter field.

# Arrhythmia ranges and defaults

Parameter	Alarm priority default	Rate (default)	Count (default)	Alarm archive factory default
ASY	High	Not adjustable	Not adjustable	Str/Rec
VF	High	Not adjustable	Not adjustable	Str/Rec
VTACH	High	≥100 to 200 (≥120)	≥5 to 15 (≥10)	Str/Rec
		Increments of 10	Increments of 1	
ARTF	Off	Not adjustable	Not adjustable	Off
RUN	Medium	not adjustable (Rate = <b><i>VTACH</i></b> )	3 to VT count – 1 (3 to 9) changes based on <i>VTACH</i>	Str/Rec
AIVR	Medium	Not adjustable = <i>VTACH</i> rate −1 (≤119)	Not adjustable (≥3)	Off
SVT	Medium	≥120 to 200 (≥150)	≥3 to 10 (≥3)	Str/Rec
		Increments of 10	Increments of 1	
CPT	Low	Not adjustable	Not adjustable	Str/Rec
BGM	Low	Not adjustable	Not adjustable	Str/Rec
ТАСН	Off	≥100 to 200 (≥130)	≥5 to 15 (≥8)	Off
		Increments of 10	Increments of 1	
BRADY	Off	≤30 to 105	Not adjustable	Off
		(adult ≤ 50; pediatric ≤60)	(≥8)	
		Increment of 5		
Pause	Off	1 to 3.5 (2.5)	Not adjustable	Off
		Increments of 0.5		

# ECG, arrhythmia, and ST segment

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# Overview of ECG and heart rate monitoring

The M540 calculates and displays the heart rate, identifies paced beats, reports arrhythmia conditions, measures ST deviations. ECG and heart rate monitoring is for adult, pediatric, and neonatal patients.

The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.

3-, 5-, 6-, and 10-wire lead sets are available for adult and pediatric ECG monitoring (including TruST). A neonatal ECG adapter cable is available for connecting individual ECG leads for neonatal monitoring.

Normal ECG monitoring (including 12-lead ECG monitoring) is not of diagnostic quality. The only report of diagnostic quality is an optional Rest ECG report which is generated from a 12-lead ECG. This report can be generated when the required options are activated, and the patient is admitted at the Infinity CentralStation. For more information on how to generate such a report, refer to page 85.

The ECG monitoring functions are configurable in the ECG pages (see page 145).

Before performing any monitoring functions, refer to the chapter "For your safety and that of your patients"on page 11.

## ECG signal processing and display

The M540 identifies QRS complexes of certain amplitudes and QRS widths for adult, pediatric, and neonatal patients (see the ECG section of the Technical data chapter in the M540 instructions for use for detailed parameter specifications). It calculates heart rates within a range of 15 beats to 300 beats per minute, using the R-R intervals of the last 10 seconds. This calculation excludes the two longest and the two shortest R-R intervals. The M540 averages the remaining intervals and displays the result as the current heart rate in the heart rate parameter field. For adult and pediatric patients, the QRS threshold is adjustable (see page 148).

During dual-channel processing, a weight is assigned to each channel depending on its level of artifact. The channel with less artifact always receives the greater weight. When a channel exceeds a certain level of artifact, it is excluded from the composite signal, and the M540 shifts to single-channel processing. If both channels experience excessive artifact, the message **ECG artifact** appears until at least one channel is sufficiently free of artifact.

During artifact, asterisks (\* \* \*) replace the heart rate value. When the artifact clears, QRS processing resumes without initiating a relearning phase.

Arrhythmia monitoring and the selected arrhythmia mode affect the display of the heart rate parameter field. For detailed information, see "Arrhythmia processing" on page 156.

Parameter-specific error messages are listed in the chapter "Troubleshooting" starting on page 323.

## Supported parameters

- ECG: HR (heart rate),
- ST: STI, STII, STIII, STAVR, STAVL, STAVF, STV, STV+, STV1 to STV6, STVM, STCVM, STdV1, STdV3, STdV4, STdV6
- Arrhythmia: ARR (ASY), VF, ARTF, VTACH, RUN, AIVR, SVT, CPT, BGM, TACH, Brady, Pause; (see page 157 for a description of these arrhythmia modes) and PVC/min

#### NOTE

In addition to stored events, the two high priority alarms ASY and VF are also stored and displayed in the ICS trends.

# **ECG precautions**

Refer to the following sections for general precautions:

- "Safe connection with other electrical equipment" on page 14
- "Electrosurgery" on page 18
- "Defibrillator precautions" on page 18

#### WARNING

Do not select TruST leads for ECG signal processing. If the QRS morphology of a TruST lead differs from that of its equivalent conventional lead, always refer to the conventional lead.

#### WARNING

To prevent patient injury, always verify the timing of the QRS synchronization pulse before attempting cardioversion using the Infinity MCable – Analog/Sync.

#### WARNING

Do not rely solely on the ECG when monitoring seizure-prone patients. Electrical artifacts of non-cardiac origin, such as seizure, may prevent detection of certain arrhythmias.

#### NOTE

Use of the rest ECG report is required for an ECG signal quality that is compliant with IEC 60601-2-25 diagnostic high frequency specifications.

# Connecting the 3-, 5-, 6-wire lead sets for ECG monitoring



The ECG lead sets connect directly to the M540.

- A M540 ECG port
- B Lead set
- C Port cover

#### To connect the ECG lead sets

 Insert the 3-, 5-, or 6-wire lead wire set (B) into the recessed ECG port (A) on the side of the M540.

Orient the lead set (B) so the exposed pins face towards you as you push it firmly into the ECG connector.

#### NOTE

An ECG lead set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead sets are pushed firmly into the ECG connector of the M540.

Almost every MonoLead features a number on the lead set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

- 2 Insert the port cover (C) to protect the unused ECG lead pins.
- 3 Connect the lead wires to the patient. For information on applying the electrodes to the patient, refer to the illustrations starting on page 141.

## Connecting the lead sets for 12-lead ECG monitoring

The ECG lead sets connect directly to the M540.



- A M540 ECG port
- **B** 6-wire lead set
- C 4-wire lead set

#### To connect the ECG lead sets

 Insert the 6-wire lead set (B) and the 4-wire lead set (C) into the ECG port (A) on the side of the M540.

Orient lead sets (B and C) so the exposed pins face towards you as you push them firmly into the channel.

#### NOTE

An ECG lead set can rest in the ECG port of the M540 without actually being connected. Make sure that all ECG lead sets are pushed firmly into the ECG port of the M540.

Almost every MonoLead features a number on the lead set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

2 Connect the lead wires to the patient. For information on applying the electrodes to the patient, refer to the illustrations starting on page 141.

#### NOTE

When using a 12-lead ECG wire set where the lead wires are coiled, it is recommended that the 6-wire lead set is coiled in the same direction as the 4-wire lead set to prevent artifact. For example, both lead sets are either coiled towards the patient or away from the patient.

# Connecting the lead sets for neonatal ECG monitoring



The ECG lead sets connect directly to the M540.

- A M540 ECG port
- B Neonatal ECG adapter cable
- C Neonatal ECG electrodes
- D Port cover

#### To connect the ECG lead set

1 Insert the neonatal ECG adapter cable (B) into the ECG port (A) on the side of the M540.

Orient the neonatal ECG adapter cable (B) so the exposed pins face towards you as you push them firmly into the channel.

#### NOTE

An ECG lead set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead sets are pushed firmly into the ECG connector of the M540.

- 2 Insert the port cover (D) to protect the unused ECG lead pins on the M540.
- Connect the individual neonatal ECG electrodes (C) to the neonatal ECG adapter cable (B).

For information on applying the electrodes to the patient, refer to the illustrations starting on page 141.

# Patient preparation for ECG monitoring

The following tips provide optimal ECG monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

Follow hospital procedures for proper skin preparation. Dräger recommends Ag/AgCl disposable electrodes. Never use disposable electrodes after their expiration date and make sure that there is enough gel and that the gel has not dried out.

P and T waves with amplitudes exceeding 0.2 mV can be interpreted as QRS complexes. To allow detection of low heart rate conditions under these circumstances, place the lead with the highest R wave in channel *ECG1*. If P and T waves continue to be misinterpreted, reposition the electrodes or use an SpO2 sensor to monitor the pulse rate.

To maintain a clear signal, change electrodes every 24 to 48 hours or more often when the following occurs:

- ECG signal degradation
- Excessive patient perspiration
- Skin irritation

Consider the following when selecting electrode sites:

- Surgery keep electrodes as far from the surgical site as possible, while maintaining a clinically useful lead configuration. Place the cable and lead wires as far from the ESU as possible and perpendicular to the ESU cables.
- Burn Patients use sterile electrodes. Clean the equipment thoroughly and follow hospital infection control procedures.
- Incorrect placement of electrodes affects the signal quality.

#### Electrosurgery

Integrated ESU suppression improves the performance of the monitor during electrosurgery, reduces noise on ECG waveforms, and protects the patient from burns.

# To minimize interference from the electrosurgical unit

The ESU filter setting can only be activated when the M540 is docked in an IACS configuration.

- 1 Touch the heart rate parameter field to select the ECG dialog box directly.
- 2 Touch the Settings 2 tab > ECG 2 tab.
- 3 Select ECG filter until it toggles to ESU.
- 4 Touch X to close the dialog.

#### NOTE

12-lead monitoring is not available when the ECG filter is set to *ESU*. Likewise, the *ESU* filter selection is not available when you are using 12-lead monitoring. If the *ECG filter* is set to *ESU* and you switch to 12-lead, the filter setting automatically changes to *Monitor*.

#### NOTE

ESU mode provides better HR performance in the presence of electrosurgical interference, but with possible ECG R-wave amplitude reduction on narrow complexes.

# ECG display

On the M540, the ECG display consists of:

- ECG parameter field
- ECG waveforms
- Show all leads dialogs containing up to 12 leads

The ECG parameter field appears differently when you activate arrhythmia monitoring. For more detail, see page 159.

## ECG Parameter field

The ECG parameter field contains the following elements:



- A Parameter label
- B Units of measure
- **C** Crossed triangle symbol when alarms are turned off
- D Heart rate value
- E Heart blip that flashes with each detected ECG complex (if pacer detection is activated, the symbol appears as <sup>P</sup>♥ when a paced beat is detected)

## ECG waveforms

The ECG waveform contains the following elements:



- A Lead label
- B Selected waveform scale
- C Message field indicating the filter and pacer setting. For example, the message *Pacer off* appears when you deactivate pacer detection.

If pacer detection is activated (see page 147), blue pacer spikes identify paced beats. Pacer spikes are printed on strip recordings.

Lead set	Available ECG leads
Three electrodes	I, II, or III
Five electrodes	I, II, III, aVR, aVL, aVF, V <sup>1)</sup>
Six electrodes	Standard: I, II, III, aVR, aVL, aVF, V, V+ <sup>1)</sup>
	TruST: I, II, III, aVR, aVL, aVF, dV1, V2, dV3, dV4, V5, dV6 <sup>2)</sup>
6 + 4 electrodes	I, II, III, aVR, aVL, aVF, V1 to V6 <sup>3)</sup>

#### NOTE:

- <sup>1)</sup> V and V+ are chest leads
- <sup>2)</sup> The letter 'd' indicates a derived lead

# <sup>3)</sup> Using a 6-wire lead set and a 4-wire lead set provides a 12-lead ECG

To select the number of leads and the lead set, see page 145.

# ECG electrode colors

Lead wire connectors to the electrodes are labeled and color-coded according to IEC and AHA.

IEC		AHA/US	
L	Yellow	LA	Black
F	Green	LL	Red
R	Red	RA	White
C/C2	White/white and yellow	V/V2	Brown/brown and yellow
Ν	Black	RL	Green
C+/C5	Gray and white/white and black	V+/V5	Gray and brown/brown and orange
C6	White and violet	V6	Brown and violet
C4	White and brown	V4	Brown and blue
C3	White and green	V3	Brown and green
C1	White and red	V1	Brown and red

# Electrode placement for adult and pediatric patients



## Standard configuration, three electrodes (IEC/AHA)



## Standard configuration, five electrodes (IEC/AHA)



## Pacer configuration, five electrodes (IEC/AHA)



# Standard configuration, six electrodes (IEC/AHA)





12-lead configuration, ten electrodes for 12-lead Rest ECG monitoring (AHA)

## 12-lead configuration, ten electrodes for 12-lead Rest ECG monitoring (IEC)



## **Electrode placement for neonates**

For neonates, place the RA and LA electrodes at the midaxillary line. Position the LL electrode below the diaphragm and umbilicus. Avoid the liver area and ventricles of the heart to prevent blood flow artifact.



# 12-lead monitoring

Standard 12-lead monitoring is only available when you use a 6-lead and a 4-wire lead set. 12-lead monitoring using a 10-wire lead set is a locked option that must be purchased separately. Place the chest electrodes in positions 1 through 6 as shown on page 143. TruST 12-lead monitoring offers real-time assessment of ST segment deviations with only six electrodes. TruST uses the conventional 6-lead standard electrode placement (see page 142), measuring 8 leads and interpolating 4 chest leads. TruST is available for adult and pediatric patients, but not for neonatal patients.You can view all ECG waveforms, including TruST, on the **Show all** page (see page 147). For information on how to activate TruST, see page 167.

#### WARNING

Do not select TruST leads for ECG signal processing. If the QRS morphology of a TruST lead differs from that of its equivalent conventional lead, always refer to the conventional lead.

# Accessing the ECG dialog

- 1 Touch the heart rate parameter field.
- 2 Touch the Settings tab, or if the parameter is not displayed touch any parameter field > Settings tab > Change parameter.
- **3** Touch the desired parameter label to display it on the main screen.
- 4 Touch the parameter field > **Settings** tab.
All ECG parameter setup functions take place in the *ECG* dialog (see page 143).

#### NOTE

If excessive line frequency artifact is seen on the ECG waveform, confirm that the correct *Line frequency* has been set in the *Biomed* dialog. For more information, refer to "Configuring the biomed settings" on page 310.

The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

#### WARNING

When the setting *HR* source is set to *Auto*, no acoustic alarm signal is issued and no message appears in the header bar when an ECG lead wire is disconnected from the patient.

When the HR source is set to ECG and changed to Auto, if the actual HR source is still ECG but becomes invalid, then the HR parameter field remains blank instead of looking for another HR source (such as SpO2 or ART if available). When due to disconnected ECG electrodes, there will be a technical condition whose alarm grade is user configurable. Select an unavailable source and change it back to Auto.

For the Cockpit and the M540, a bradycardia (BRADY) alarm in neonatal mode only annunciates when an HR alarm is set to **On**. If the HR alarm is set to **Off**, the BRADY alarm will be Off, but displays as On. When the **ASY/VF alarms** setting is set to **Always on** or **Follow HR alarm**, the BRADY alarm also annunciates, even if HR alarms are still Off. Deactivate the BRADY alarm by manually turning it Off.

When the HR source on the M540 is set to *ECG* and is then changed to *Auto*, if the actual HR source is still ECG but at some point the ECG signal becomes invalid, then the HR parameter field remains blank instead of looking for another HR source (such as *SpO2* or *Arterial pressure* if available). If this is due to ECG electrodes being disconnected, then there will be a technical condition whose alarm grade is user configurable. As a workaround, select an unavailable source and then change it back to *Auto*.

Selection	Available settings	Description		
Settings – ECG 1 page				
Tone volume <sup>1)</sup>	<i>Off</i> , 5, 10 (default) to 100% in increments of 10%	Selects the volume of the pulse tone. If you dock the M540 in an IACS configuration, this setting is replaced by the pulse tone volume setting of the Cockpit. When you undock the M540, this setting is replaced by the <i>Transport pulse tone</i> setting configured under the <i>Alarm</i> <i>setup</i> tab (see page 317).		
Tone source 1)	ECG (default), PI	Selects the source of the pulse tone.		
<sup>1)</sup> This setting is a patient of	default which may be unique for each patient category;	it is part of the profile.		
ECG filter <sup>1)</sup>	<ul> <li>Off – provides the greatest sensitivity to noise or artifact (the message <i>Filter off</i> appears in the waveform channel) Passband: 0.08 - 40Hz</li> <li><i>Monitor</i> (default) – recommended for standard monitoring; reduces wandering isoelectric line, muscle artifact, and power line interference. No message appears in the waveform channel.</li> <li>Passband: 0.5 - 40Hz</li> <li><i>ESU</i> – reduces signal distortion during electrosurgery (the message <i>Filter ESU</i> appears in the waveform channel). This selection is not available when the M540 is in standalone mode.</li> <li>Passband: 0.5 - 16Hz</li> <li>12-lead monitoring is not available when the ESU filter is enabled. Likewise, the ESU filter selection is not available when you are using 12-lead monitoring.</li> </ul>	Controls the sensitivity to various artifact sources. When the M540 is set to OR alarms and the filter selection is set to <i>Monitoring</i> ,: - the hardware low pass ESU filter is activated. - <i>RRi</i> is unavailable - 12-lead ECG monitoring is unavailable None of these settings are of diagnostic quality.		

Selection	Available settings	Description		
HR source <sup>1)</sup>	<ul> <li>ECG (default) – derives the heart rate from the ECG signal.</li> </ul>	Selects a different source for the heart rate when the ECG channel is unavailable due to artifact resulting from surgical procedures.		
	<ul> <li>Arterial pressure         derives the heart         rate from the arterial blood pressure         signal. The heart rate parameter field         label changes to APR and appears in         the color of ART.</li> </ul>			
	<ul> <li>SpO2 – derives the heart rate from the pulse oximetry signal. The heart rate parameter field label changes to PLS and appears in the color of SpO2.</li> </ul>			
	<ul> <li>Auto – derives the heart rate either from the ECG signal or other available sources. If an ECG signal is not available, the M540 switches to Arterial pressure, and then to SpO2.</li> </ul>			
Show all leads	None	Shows all ECG waveforms. Press anywhere in the waveform area to access additional ECG waveforms. Press <i>Menu</i> to close all the ECG waveforms.		
Size all ECG <sup>1)</sup>	0.25, 0.5, 1 (default), 2, 4, 8 mV/cm	Sets the amplitude of ALL displayed ECG leads.		
<sup>1)</sup> This setting is a patient of	lefault which may be unique for each patient category;	it is part of the profile.		
Color <sup>1)</sup>	Red, White, Yellow, Green (default), Light blue, Blue, Purple, Orange	Determines the color of the ECG waveforms, and the arrhythmia/ST parameter labels and values.		
Settings – ECG 2 page				
Pacer detection	- <b>On</b> (default)	Determines whether pacer		
(Not available in neonatal mode)	<ul> <li>Off – the message Pacer off appears in the waveform channel</li> </ul>	impulses are detected. See "Pacer fusion mode" on page 152 for precautions before you start		
	<ul> <li>Fusion – the message Pacer fusion appears in the waveform channel</li> </ul>	this mode.		
QRS sync marker	<ul> <li>On– displays QRS synchronization markers</li> <li>Off (default)</li> </ul>	Determines whether vertical white markers appear on the waveform to identify QRS complexes. The markers help determine when it is safe to perform synchronized cardioversion.		

Selection	Available settings	Description	
Cable type <sup>1)</sup> (TruST is only available with a 6- wire lead set)	<ul> <li>Auto (default)</li> <li>3, 5, 6, and 12 leads (if activated)</li> <li>When using the ECG extension cable, the system always assumes the cable is a 6-wire lead set.</li> </ul>	When set to <i>Auto</i> , it detects the number of connected lead wires automatically. If auto mode does not detect the connected lead set, it allows you to select the cable type manually. "12" denotes a combination of a 6- wire lead set and 4-wire lead set for 12-lead monitoring.	
ARR lead 2 <sup>1)</sup>	ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV (arrhythmia lead 2 default), ECGV+, ECGV1 to ECGV6	processing.	
ARR processing <sup>1)</sup>	<i>ECG1</i> , <i>ECG1&amp;2</i> (default) The <i>ECG1&amp;2</i> selection is not available if the neonatal patient category is selected.	<b>ECG1</b> setting – arrhythmia processing occurs only on the lead selected as arrhythmia lead 1. <b>ECG1&amp;2</b> setting – arrhythmia processing occurs on the leads selected as arrhythmia lead 1 and arrhythmia lead 2.	
<sup>1)</sup> This setting is a patient of	default which may be unique for each patient category;	it is part of the profile.	
QRS threshold	<ul> <li>Normal (default)</li> <li>Low</li> </ul>	This function is only available for adult and pediatric patients. <b>Normal</b> – detects QRS complexes >0.5 mV	
	WARNING Risk of inaccurate HR value If the QRS setting is set to Low in the presence of HR artifact, the associated HR value may be inaccurate.	<i>Low</i> – detects QRS complexes ≥0.2 mV.	
	To avoid an inaccurate HR value for adult and pediatric patients, it is recommended to set the QRS threshold setting to Normal.		
	Rest ECG setup page		
Gender	<ul> <li>Unknown (default)</li> <li>Male</li> <li>Female</li> </ul>		

Selection	Available settings	Description
Race	<ul> <li>Unknown (default)</li> </ul>	
	– Caucasian	
	– Asian	
	– African	
	– Other	

# Monitoring paced patients

When pacer detection is activated, the M540 uses the following specifications to identify a pulse as a pacer pulse:

- Amplitude (a<sub>p</sub>):  $\pm 2$  to  $\pm$  700 mV
- Width (dp): 0.2 to 2.0 ms
- A paced beat is identified in the heart rate parameter field by the letter P that appears next to the flashing heart symbol when a pacer pulse is detected.
- On the ECG waveform, blue spikes appear to identify pacer spikes.

#### NOTE

When the M540 is docked, pacer detection is deactivated automatically in neonatal mode or when the ESU filter is activated. When the M540 is undocked, the M540 automatically activates the pacer detection.

When pacer detection is deactivated, the message **Pacer off**, appears in the top ECG channel.

To optimize pacer monitoring, follow the guidelines "Optimizing pacer processing" on page 154.

#### To turn pacer detection on/off

- 1 Touch the heart rate parameter field to select the ECG dialog directly.
- 2 Touch the Settings tab > ECG 2 tab.
- 3 Touch *Pacer detection* until it toggles to *On* or *Fusion* (see page 304).
- 4 Touch X to close the dialog.

# **Pacemaker precautions**

The M540 has been tested for pacemaker pulse detection. However, it is impossible to anticipate every clinically possible waveform characteristic. For paced patient, the M540 could therefore miscount heart rates and misinterpret rate-dependent arrhythmias.

False low-rate alarms can result under the following conditions:

- 700-mV pacer pulses followed by QRS complexes smaller than 0.5 mV
- Asynchronous pacemaker pulses with overshoot
- Asynchronous pacemaker with large amplitude pace pulses with no overshoot and at low heart rate (30 bpm)

False low-rate and asystole alarms can result in the following conditions:

 Fused beats and asynchronous pacemakers, when coupling intervals are in the range of +10 to –90 ms

As well, false high-rate alarms can result under the following condition:

- Asynchronous pacemaker with large pace pulse tails and at low heart rate (30 bpm)
- Large atrial pacemaker pulse preceded by a large ventricular pacemanker pulse with overshoot (both having identical amplitude and durations)

#### WARNING

Make sure pacer detection is deactivated for patients without pacemakers. Make sure it is activated for patients with pacemakers. Deactivating pacer detection for paced patients may result in pacemaker pulses being counted as regular QRS complexes, which could prevent an asystole alarm from being detected. Always verify that the pacer detection status is correct for the patient. Be aware that setting the ECG filter option to ESU deactivates pacemaker detection automatically.

#### WARNING

Interference from a monitor may cause some rate-adaptive implantable pacemakers to pace at unnecessarily high rates. Be extra vigilant with patients when using these types of pacemakers.

#### WARNING

Always keep pacemaker patients under close surveillance and monitor their vital signs carefully.

- Do not assess the patient's condition exclusively from the heart and respiratory rate values the monitor displays and the rate alarms that are generated. Heart rate meters may continue to count the pacemaker rate during cardiac arrest or some arrhythmias.
- Some pacemakers (especially external pacemakers with body surface electrodes) emit pulses with amplitudes far exceeding the 700 mV maximum amplitude specified for the M540. The M540 may incorrectly detect these large pacemaker pulses as valid QRS complexes and may fail to detect cardiac arrest.

#### WARNING

Impedance respiration and pacemaker detection are inoperative when the ESU filter is selected. Refer to "Electrosurgery" on page 18 for general safety precautions.

#### NOTE

Full arrhythmia processing does not occur on detected paced beats.

#### Pacer fusion mode

Pacer fusion mode offers increased detection sensitivity to fused paced beats, thereby reducing false asystole and low heart rate alarms.

#### WARNING

Pay close attention to pacemaker patients being monitored in Fusion mode because this mode may increase the risk of falsely counting pacemaker spikes as QRS complexes, thus failing to detect cardiac arrest.

#### CAUTION

*Fusion* mode pacer detection is not intended for use with large-signal, unipolar pacemakers. It is intended for use only with bipolar pacemakers. Observe the following:

- Select *Fusion* mode only in situations where it becomes necessary to suppress repeated false asystole and/or false low heart rate alarms.
- Before selecting *Fusion* mode, be certain that the patient has a bipolar pacemaker (external or implanted) and that it is accurately programmed as appropriate for that patient.
- Do not use *Fusion* mode if you are uncertain as to what type of pacemaker is being used.

#### NOTE

The displayed heart rate may be incorrect if the pacemaker pulse wanders through the ECG waveform (ineffective pacing). During the wandering pacemaker test required by AAMI/ANSI/IEC 60601-2-27, the displayed heart rate varied between 15 and 30 bpm (rather than consistently being 30 bpm).

# Device interference with pacemaker monitoring

The following devices can interfere with pacemaker monitoring.

#### Impedance-derived rate response pacemakers

These pacemakers emit pulses that adjust the pacemaker rate to the respiratory rate. These pulses could be falsely interpreted as pacer pulses. For impedance-derived rate response pacemakers, modify the electrode placement until the blue spikes on the waveform disappear since they are not related to real pacer impulses.

#### WARNING

Wireless monitoring could lead to possible interference with pacemaker monitoring due to WLAN (wireless local area network).

#### Infusion or roller bypass pumps

Interference from these devices can cause pacer spikes to appear on the waveform although the ECG appears normal. To determine if the pump is the cause of the artifact, turn it off, if possible. To minimize the artifact, choose the lead with the best signal or replace the electrodes. Rerouting invasive pressure tubing away from the infusion tubing can also improve the ECG signals.

#### Line isolation devices

To minimize the effect of line isolation devices, which can cause temporary disturbances in the ECG signal, follow these precautions:

- Choose the lead with the best signal for ECG monitoring.
- Check the ECG electrodes; replace them, if necessary.

# Transcutaneous Electrical Nerve Stimulators (TENS)

Signals from transcutaneous electrical nerve stimulators (TENS) often resemble pacer signals and can be labeled as such. The M540 can reject valid QRS complexes, which follow misinterpreted TENS signals. If TENS signals continue to register as pacer spikes, deactivate pacer detection (see page 147).

# **Optimizing pacer processing**

You can minimize interference and optimize ECG signal acquisition and processing for paced patients.

#### To optimize pacer processing

- Touch the heart rate parameter field to select the ECG dialog directly.
- 2 Touch the **Settings** tab > **ECG 1** tab.

- 3 Touch *ECG filter* until it toggles to *Monitor* or *Off* and determine which setting provides the clearest signal.
- 4 Touch **X** to close the dialog.

## Arrhythmia monitoring overview

#### WARNING

When HR alarm and arrhythmia monitoring are deactivated and the *ASY/VF alarms* setting is set to *Follow HR alarm*, the monitor does not generate asystole or ventricular fibrillation alarms. To make sure that ASY/VF alarms are always generated, set the *ASY/VF alarms* setting to *Always on*.

The M540 performs arrhythmia monitoring on adult and pediatric patients. Arrhythmia monitoring is not available for neonates. To make sure that asystole and ventricular fibrillation alarms are reported even when the heart rate alarm monitoring and arrhythmia monitoring functions are deactivated, set the **ASY/VF alarms** selection in the **Alarm setup** dialog to **Always on** (see Configuring a patient's alarm settings in the Alarms chapter). The selected arrhythmia mode (see page 157) controls which arrhythmia parameters are monitored and how they are displayed. Each occurrence of an arrhythmia event is stored in the *Event recall* page provided the archive setting is configured (see page 156).

The arrhythmia monitoring functions have configurable parameter-specific setup pages (see page 160).

#### NOTE

The message  $\bigotimes$  **HR Alarms Off** appears in the right most field in the header bar whenever you turn heart rate alarms off.

The AR, ASY, VF off message appears when arrhythmia monitoring is deactivated, the ASY/VF alarms feature is set to Follow HR, and heart rate alarms are deactivated.

#### NOTE

If French NFC mode is activated (see page 311), you cannot deactivate heart rate alarms.

Before performing any monitoring functions, see the *For your safety and that of your patients* chapter. Appropriate lead selection is essential for accurate arrhythmia monitoring. It is ideal to assign the two best ECG leads as the arrhythmia monitoring leads. The following two options are available:

- ECG1 (single channel selection) dedicates processing to the lead selected as arrhythmia lead 1.
- ECG1&2 (dual channel selection) determines the heart rate and arrhythmia based on the leads selected as arrhythmia lead1 and arrhythmia lead 2.

#### NOTE

When the M540 is docked in an IACS configuration, the top two ECG waveform channels on the Cockpit are arrhythmia lead 1 and arrhythmia lead 2.

When the M540 is in standalone mode or on wireless transport, the selected arrhythmia leads and waveform channel may be different. Make sure that the waveform channel and arrhythmia channels are configured appropriately.

#### To select arrhythmia leads

- 1 Touch the heart rate parameter field to select the *ECG* dialog directly.
- 2 Touch the Settings tab > ECG 2 tab.
- 3 Touch the ARR lead 1 or ARR lead 2 tab.
- 4 Touch the appropriate lead and then touch **X** to close the dialog.

# Arrhythmia processing

Arrhythmias are identified using an internal detection process. This process does the following:

- Filters out ECG signal artifacts
- Detects the beat pattern
- Classifies the beat pattern
- Detects the rhythm

When arrhythmia analysis is enabled, multiple arrhythmia alarm conditions may occur simultaneously. Announcing all the alarm conditions could result in alarm fatigue and prevent the clinician from addressing the most serious condition. For this reason, priorities are set for the arrhythmia conditions so that only the highest priority alarm event annunciates. Although the priority of arrhythmia events cannot be modified, the clinician can modify the alarm grade to allow enabled alarms of lower priority to annunciate.

The priority for arrhythmia events is:

- 1 Asystole
- 2 VF (ventricular fibrillation)
- **3** VTACH (ventricular tachycardia)
- 4 RUN (ventricular run)
- 5 AIVR (accelerated idioventricular rhythm)
- 6 SVT (supraventricular tachycardia)

- 7 CPT (ventricular couplet)
- 8 BGM (bigeminy)
- 9 TACH (tachycardia)
- 10 BRADY (bradycardia)
- 11 PAUSE (user selectable interval)
- 12 ARTF (artifact, background rhythm)

For a description of the arrhythmias and associated events, see page 157.

#### NOTE

In addition to stored events, the two high priority alarms ASY and VF are also stored and displayed in the ICS trends.

An arrhythmia with a high grade alarm configuration has a higher priority than an arrhythmia with a medium, low or disabled alarm grade configuration. An arrhythmia with a medium grade alarm configuration has a higher priority than an arrhythmia with a low or disabled alarm grade configuration. An arrhythmia with a low grade alarm configuration has a higher priority than an arrhythmia with a disabled alarm configuration. The priority for arrhythmia events configured with the same alarm grade follows the arrhythmia hierarchy list. When arrhythmia artifact is present (ARTF) at 100% artifact level, no arrhythmia events are recognized except for bradycardia and ventricular fibrillation. If sinus tachycardia and ventricular tachycardia are configured at the same alarm grade, a ventricular tachycardia will take priority if the rate is high enough and the beats are classified as ventricular beats.

#### NOTE

Arrhythmia processing does not occur on detected paced beats.

# Arrhythmia modes

If arrhythmia monitoring is activated, the selected arrhythmia mode determines how many events are monitored. The available arrhythmia modes are: *Basic*, *Advanced*, and *Off*.

#### NOTE

The *Advanced* arrhythmia mode is only available when the full arrhythmia option is activated.

When the **ASY/VF alarms** setting is set to **Always on**, asystoles and ventricular fibrillation events are always reported, even when arrhythmia monitoring is deactivated.

The following table lists the events that are reported with each arrhythmia mode.

Arrhythmia monitoring off (the following events are detected, if at least one ECG is displayed)				
ASY	Asystole	ole 4 s pass without the detection of a valid QRS complex		
VF	Ventricular fibrillation	Sinusoidal waveform with fibrillation characteristics <sup>1)</sup>		
Arrhythm	ia monitoring mode Ba	<i>sic</i> (the following additional events are detected)		
VTACH	Ventricular Tachycardia	N or more PVCs are detected in an interval T = (60 * (N - 1)) / R, where N is the VTACH count and R is the VTACH rate $^{2}$ , $^{4)}$		
PVC	Premature Ventricular Contraction	PVC alarm limit exceeded. The PVC parameter value represents the number of QRS complexes classified as PVCs over a 1-minute interval.		
ARTF	Artifact	More than 50% of beats in the last minute were classified as questionable.		
Advanced events)	Advanced arrhythmia monitoring mode (includes <i>Basic</i> mode events plus the following additional events)			
RUN	Ventricular RUN	Series of 3 to N–1 consecutive PVCs with a beat-to-beat rate $\geq$ the VTACH rate $^{2)}$		
AIVR	Accelerated Idioventricular Rhythm	Series of 3 or more PVCs with a rate less than the VTACH rate.		
SVT	Supraventricular Tachycardia	N or more consecutive normal beats, with a beat-to-beat rate greater than or equal to the SVT setting <sup>2)</sup>		
CPT	Ventricular Couplet	Sequence of beats with the pattern: normal, PVC, PVC, normal.		
BGM	Ventricular bigeminy	Sequence of beats with the pattern: normal, PVC, normal, PVC, normal.		
TACH	Tachycardia	N or more consecutive normal beats, with a beat-to-beat rate $\geq$ TACH rate setting. <sup>2) 4)</sup>		
BRADY	Bradycardia	Eight or more consecutive normal beats, with an average rate ≤ bradycardia rate setting. <sup>3)</sup>		
PAUSE	Pause	Sequence of two beats classified as normal or PVC, with an interval ≥ pause rate value in seconds (±100 ms).		

<sup>1)</sup> Certain ventricular tachycardias have sinusoidal waveforms closely resembling ventricular fibrillation. Because of the similarities between these waveforms, such types of ventricular tachycardia can be classified as ventricular fibrillation, the more serious of the two conditions.

<sup>2)</sup> N is the event count set in the count column of the arrhythmia setup table (see page 160).

<sup>3)</sup> For the Cockpit and the M540, a bradycardia (BRADY) alarm in neonatal mode only annunciates when an HR alarm is set to On. If the HR alarm is set to Off, the BRADY alarm will be Off, but displays as On. When the ASY/VF alarms setting is set to Always on or Follow HR alarm, the BRADY alarm also annunciates, even if HR alarms are still Off. Deactivate the BRADY alarm by manually turning it Off.

In neonatal mode, you set alarm limits for **BRADY** in the alarm setup page. The M540 alarms for this event as a limit violation.

<sup>4)</sup> A PVC or another abnormal beat breaks the analysis sequence and restarts analysis.

#### To select the arrhythmia mode

- 1 Touch the heart rate parameter field to select the *ECG* dialog directly.
- 2 Touch the **Settings** tab > **ARR** tab.
- 3 Touch *ARR mode* and toggle to one of the following modes:

– Off

- Basic
- Advanced (locked option)
- 4 Touch X to close the dialog.

# Arrhythmia display

When arrhythmia monitoring is activated, arrhythmia events appear in the heart rate parameter field.

When arrhythmia monitoring is turned off (see page 159) and at least one ECG waveform is displayed, asystole and ventricular fibrillation events are still reported.

#### NOTE

To make sure that asystole *and* ventricular fibrillation alarms are reported even when heart rate monitoring is turned off, set the *ASY/VF alarms* selection in the *Alarm setup* dialog to *Always on* (see page 304).

#### Arrhythmia basic parameter field

If the heart rate parameter field is displayed and arrhythmia monitoring is activated, all arrhythmia values and labels appear in the heart rate parameter field. The arrhythmia parameter field contains the following elements:



- A Heart rate parameter label
- B Unit of measurement
- C Arrhythmia label
- **D** Crossed triangle symbol when alarms are turned off
- E Number of Premature Ventricular Contractions (*PVC*) per minute
- F PVC label
- G LRN message
- H Heart rate
- I Heart blip that pulsates with each detected beat (if pacer detection is turned on, the symbol appears as <sup>P</sup>♥ when a paced beat is detected)

# Accessing the arrhythmia dialog

- **1** Touch the heart rate parameter field.
- 2 Touch the Settings tab.
- 3 Touch the ARR tab, or if the parameter is not displayed touch any parameter field > Settings tab > Change parameter.
- 4 Touch the desired parameter label to display on the main screen.
- 5 Touch the parameter field > *Settings* tab > *ARR* tab.

# Arrhythmia parameter setup functions

All arrhythmia parameter setup functions take place in the arrhythmia dialog (see "Accessing the arrhythmia dialog"page 160). The limits dialog contains the *Auto set* and *Alarm* buttons for configuring the alarm functions.

Selection	Available settings	Description
ARR mode	Off, Basic (default), Advanced	Selects which events are reported (see page 157 for more detail).
Relearn	None	Establishes a new QRS templates

# **Monitoring ST overview**

ST analysis examines normal QRS complexes from up to 12 ECG leads. The M540 learns each ST lead, combines the measurements into an average QRS complex, and derives the ST segment deviation. ST monitoring is available for adult and pediatric patients.

The ST segment deviation is defined as the displacement (in mm or mV) above or below the isoelectric line. The deviation measurement compares the isoelectric point to the ST measurement point. The following illustration identifies the measured elements of a QRS complex.



- A Fiducial point
- B ST level
- C ST measurement point
- D QRS offset
- E QRS onset
- F Isoelectric point

#### NOTE

ST analysis is always performed using a dedicated filter which ensures diagnostic quality. The ECG filter settings (*ESU*, *Monitor*, and *Off*) are not of diagnostic quality, and as a result, the ST segment of the ECG waveform may appear differently from the ST segment of the ST complex. An ECG report is not of diagnostic quality. Therefore, the ST segment of the ECG waveform on the report may appear differently from the ST segment of the ST complex. The only report of ECG diagnostic quality is a Rest ECG report.

The ST monitoring functions are configurable on parameter-specific setup pages (see page 168).

Before performing any monitoring functions, see the *For your safety and that of your patients* chapter.

### Standard ST monitoring

The 6-wire lead set monitors eight ECG electrodes, of which two are chest electrodes V and V+ (C and C+). 12-lead ST analysis provides the most comprehensive view of a patient's condition. However, with optimal placement of the V and V+ leads and using only eight leads, you can achieve an ST analysis that is almost as comprehensive but with fewer electrodes.

# TruST 12-lead monitoring

This feature offers real-time assessment of 12 ST segment deviations, with only six electrodes, which provide eight measured ECG leads and four derived chest leads. The derived leads are identified by adding the letter 'd' before the lead label. When TruST monitoring is activated, the ECGV lead defaults to ECGV2 and the ECGV+ lead defaults to ECGV5. Although you can select derived leads for display, they are excluded from arrhythmia and QRS processing.

#### NOTE

ST values and complexes of derived leads will be missing after discharging and entering the bedside with truST turned on, and when ECG cable type is not set to **Auto**. You can either set the cable type to **Auto** or unplug the ECG cable.

# 12-lead ST monitoring

During 12-lead ST monitoring, the M540 acquires 12 ST leads in addition to the following:

- ST Vector Magnitude (STVM) the magnitude (mm or mV) of the ST vector. It is a summary vector, combining the ST values from all 12 leads. STVM is trended and has its own alarm limits.
- ST Change in Vector Magnitude (STCVM) the change of magnitude (mm or mV) between the current ST vector and the ST vector at the time of the last reference. STCVM values also show a change in the location of the ST vector over time.

#### To activate or deactivate ST monitoring

You can turn ST monitoring on or off at any time.

- 1 Touch the ST parameter field.
- 2 Touch the Settings tab.
- 3 Touch *ST monitoring* until it toggles to *On* or *Off*.

# Connecting lead sets for ST monitoring

ST monitoring uses the following lead configurations for each available ST monitoring mode:

- Standard ST monitoring uses the standard 3-5-, and 6-wire lead sets. For more information see the diagrams starting on page 141.
- TruST provides 12-lead ST monitoring with a 6-lead wire set (see page 135).
- 12-lead ST monitoring uses the standard 12lead ECG configuration with a 6-lead plus a 4wire lead set (see page 135).

# ST display

When ST alarms are activated, the M540 alarms for all ST leads whether they are displayed or not. In either case, the ST parameter field flashes and the alarming lead is identified in the header bar.

When ST monitoring is activated, current ST values display in a separate parameter field. You can select which two ST leads are displayed in the parameter field.

The ST parameter field contains the following elements:



- A Selected ST lead labels
- **B** Unit of measurement
- C Crossed triangle indicating alarms are off for the selected ST leads
- D Selected ST deviation values

# ST complex dialogs

The number of displayed ST complexes depends on the connected lead set. You can view all ST complexes or zoom in on a single ST complex to view it in greater detail. The following functions are available in the single ST complex dialog:

- Changing the isoelectric point
- Changing the ST measuring point

# To access the general ST complex dialog

- 1 Touch the ST parameter field.
- 2 Touch the Settings tab.
- 3 Touch ST complex.

### Zooming in on a single ST complex

The following diagram shows a single ST complex when you zoom in on one ST complex.



- **A** ST label (unique for each ST lead)
- B Single complex window
- C When *ISO:* or *ST:* button is selected, left and right arrows allow you to move the ISO/ST measuring point
- D Confirm button
- E ST: button
- F ISO: button

#### To zoom in on a single STcomplex

- 1 Touch the ST parameter field.
- 2 Touch the Settings tab.
- **3** Touch *ST complex*. The general ST complexes dialog displays.
- 4 Touch a single ST complex window.

# ST measuring points

You can change the ST measuring points and isoelectric point from the single ST complex dialog. The setup buttons for changing the measuring points are located on the left side of the screen. Changing the measuring point for one complex adjusts the measuring points for all ST complexes.

#### Adjusting ST measuring points

Whenever you adjust the isoelectric and ST measuring points, the ST deviation is recomputed.

#### To change ST measuring points

- 1 Touch the ST parameter field to access the ST dialog directly.
- 2 Touch the Settings tab.
- **3** Touch **ST** complex to display the general ST complexes dialog.
- **4** Touch an individual ST panel to zoom in on a single ST complex.
- 5 Touch *ISO:* and use the arrows to move cursor and adjust isoelectric point.
- 6 Touch *ST:* and use the arrows to move cursor and adjust ST point.
- 7 Touch Confirm to accept the settings and to close the ST complex panel or touch X to close the ST complex panel without saving changes.

# ST reference

You can save ST reference complexes as a reference point for future ST deviation measurement comparisons. The first time you relearn QRS complexes, the current ST data are saved as a reference data. This original ST reference data is updated each time you save ST references.

#### Saving ST reference

You can save the ST reference from the **Settings** tab. Saving the ST reference saves all current ST complexes as the new reference.

# Accessing the ST dialog

- **1** Touch the ST parameter field.
- 2 Touch the Settings tab.

Or, if the parameter is not displayed

- 1 Touch any parameter field > *Settings* tab > *Change parameter*.
- **2** Touch the desired parameter label to display it on the main screen.
- 3 Touch the parameter field > **Settings** tab.

# ST setup functions

All ST parameter setup functions take place in the ST dialog (see "Accessing the ST dialog" on page 166).

The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description
Settings		
<b>Relearn</b> (Not available if ECG is not connected, in neonatal mode, or ST monitoring is turned off)	None	Purges stored average ST complexes, blanks displayed average ST complexes, and learns the arrhythmia and dominant QRS pattern.
ST lead 1 <sup>1)</sup>	<ul> <li>Three electrodes: STI, STII, STIII</li> </ul>	Selects an ST lead for analysis
ST lead 2 <sup>1)</sup>	<ul> <li>Five electrodes: STI, STII, STIII, STaVR, STaVL, STaVF, STV</li> </ul>	and display.
	<ul> <li>Six electrodes: STI, STII, STIII, STaVR, STaVL, STaVF, STV, STV+</li> </ul>	
	<ul> <li>Six electrodes (with TruST activated): STI, STII, STIII, STaVR, STaVL, STaVF, STdV1, STV3, STdV3, STdV4, STV5, STdV6</li> </ul>	
	<ul> <li>Ten electrodes: STI, STII, STII, STAVR, STaVL, STaVF, STV1, STV2, STV3, STV4, STV5, STV6, STCVM, and STVM</li> </ul>	
	<ul> <li>Default for ST lead1: STII</li> </ul>	
	<ul> <li>Default for ST lead2: STV for 5-/6-wire lead set STV2 for TruST or 10-wire lead set</li> </ul>	

Selection	Available settings	Description
ST monitoring <sup>1)</sup>	<i>Off</i> , <i>On</i> (default)	Turns ST monitoring on/off.
ST complex	None	Views ST complexes.
Event duration <sup>1)</sup>	<i>Off</i> , 15, 30, 45, 60 (default) seconds	Defines a period an alarm condition must persist, before alarm signals are generated.
<i>TruST</i> <sup>1)</sup> ( <i>TruST</i> is only available with a 6- wire lead set.)	<i>On</i> , <i>Off</i> (default)	Turns TruST monitoring on or off.
Save:	None	Saves the current ST complexes as references (see page 165).
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.

<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.

# Learning/relearning QRS pattern

The M540 creates a reference template by learning the dominant QRS pattern of a patient. The reference template is stored for reference and all subsequent beats and rhythms are compared against it and classified either as normal or irregular.

The M540 can only learn the QRS pattern of the leads that are selected for arrhythmia processing. If only one lead is available, the M540 only learns on one lead. If no lead set is connected, the M540 cannot perform a learning phase. In this case, an error message is displayed.

The M540 starts a learning phase automatically when:

- Exiting discharge or standby
- Patient category is changed to Adult or Pediatric
- Arrhythmia monitoring is activated

#### NOTE

During the learning phase, only ASY and VF arrhythmia events are reported.

- A different arrhythmia mode is selected
- Different ECG leads are selected for arrhythmia processing

#### NOTE

The relearn is initiated only on the available assigned lead(s).

- The ARR processing setting is changed from ECG1 to ECG1&2, if the leads selected for processing are available
- The ARR lead 1 setting is changed to an available lead
- The ARR lead 2 setting is changed to an available lead, if the ARR processing setting is ECG1&2

- A lead-off condition of a processed lead is resolved
- The neutral lead is changed
- A lead set is physically connected, if that lead set provides the neutral or processed lead(s)
- The cable type is changed
- The *ECG filter* setting is changed to or from *ESU*
- The OR Alarm setting is changed
- The M540 is docked in an IACS configuration whose profile has a different ECG lead configuration
- A standalone M540 is docked on an M500 whose profile has a different ECG lead configuration

During the learning phase, which lasts approximately 30 to 40 seconds, the message *ARR relearning* appears in the message field. In addition, and message *LRN* appears in the ECG parameter field.

If ST monitoring is turned on, ST deviations are also recomputed during the learning phase.

#### Manual relearning

Relearn the QRS pattern of a patient when:

- Leads are reconnected or electrodes are repositioned
- Eight hours have passed since the last learning phase
- Questionable arrhythmia calls appear on the ECG
- Other significant changes appear on the ECG

You can initiate a relearning phase from the arrhythmia and the ST dialogs.

#### To relearn from the arrhythmia dialog

- 1 Touch the heart rate parameter field to select the ECG dialog.
- 2 Touch the **Settings** tab > **ARR** tab > **Relearn**.

#### To relearn from the ST dialog

- 1 Touch the ST parameter field to select the ST dialog.
- 2 Touch the **Settings** tab > **Relearn**.

# Impedance respiration (RRi)

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# Overview of respiration monitoring

The M540 measures respiratory rate derived from passing a harmless high-frequency current between two ECG electrodes on the patient's chest. Electrical resistance (impedance) between the electrodes varies with the expansion and contraction of the chest during inspiration and expiration. The M540 displays a respiration waveform and respiratory rate value from these impedance changes.

The M540 uses ECG leads I or II regardless of the lead selected for 5-, 6-, and 12-lead configurations. RRi processing is dependent on the QRS processing lead for 3-lead configurations. RRi works only on leads I and II. Respiration monitoring is for adult, pediatric, and neonatal patients. The M540 can use the respiration signal for central apnea monitoring.

The respiration monitoring functions are configurable in the parameter-specific dialog (see page 177). Before performing any monitoring functions, refer to the section "For your safety and that of your patients" starting on page 11. Parameter-specific error messages are listed on page 333.

#### Supported parameters

RRi – respiratory rate measured by impedance (respiration values are not displayed when the ESU filter is activated – see page 146).

#### NOTE

**RRi** and 12-lead ECG monitoring are unavailable when the M540 is set to OR alarms and the ECG filter is set to **Monitor**.

# **RRi** precautions

#### WARNING

The safety and effectiveness of the respiration measurement method in apnea detection, particularly the apnea of prematurity and apnea of infancy, has not been established.

#### WARNING

This device does not monitor obstructive apnea. Patients at risk for respiratory crises should be observed closely.

#### WARNING

Large amplitude pacemaker pulses (100 mV or greater) may interfere with the monitor's ability to measure or detect respiration.

#### WARNING

The monitor reports an apneic event when no breaths are detected within the established apnea alarm time period. Therefore, do not rely on impedance respiration monitoring as the sole method for detecting cessation of breathing. Dräger recommends the monitoring of additional parameters that indicate the patient's oxygenation status, such as etCO<sub>2</sub> and SpO<sub>2</sub>. Heart rate limit alarms should also be enabled and set appropriately.

#### WARNING

*RRi* and pacemaker detection are inoperative when the ESU filter is selected. Refer to "Electrosurgery" on page 18 for general safety precautions.

# Connecting the 3-, 5-, 6-wire lead sets for respiration monitoring



The ECG lead sets connect directly to the M540:

- A ECG connector
- B Lead set
- C Port cover

#### To connect the ECG lead sets

 Insert the 3-,5-, or 6-wire lead set (B) into the recessed ECG connector (A) on the side of the M540.

Orient the ECG lead set (B) so the exposed pins face toward you as you push it firmly into the channel.

#### NOTE

An ECG lead set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead sets are pushed firmly into the ECG connector of the M540.

Almost every MonoLead features a number on the lead set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

- 2 Insert the port cover (C) to protect the unused ECG lead pins.
- 3 Connect the lead to the patient.

For information on applying the electrodes to the patient, refer to the illustrations starting on page 174.

# Connecting the lead sets for 12-lead respiration monitoring

The ECG lead sets connect directly to the M540:



- A ECG connector on the M540
- B 6-Wire lead set
- C 4-Wire lead set

#### To connect the ECG lead sets

 Insert the 6-wire lead set (B) and the 4-wire lead set (C) into the recessed ECG connector (A) on the side of the M540.

Orient the ECG lead sets (B and C) so the exposed pins face toward you as you push it firmly into the ECG channel.

#### NOTE

An ECG lead set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead sets are pushed firmly into the ECG connector of the M540.

Almost every MonoLead features a number on the lead set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

2 Connect the lead wires to the patient. For information on applying the electrodes to the patient, refer to the illustrations starting on page 174.

#### NOTE

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When using a 12-lead ECG wire set where the lead wires are coiled, it is recommended that the 6-wire lead set is coiled in the same direction as the 4-wire lead set to prevent artifact. For example, both lead sets are either coiled toward the patient or away from the patient.

# Connecting the lead wires for neonatal respiration monitoring



The ECG lead sets connect directly to the M540:

- A ECG connector on the M540
- B ECG adapter cable
- C Port cover
- D Neonatal ECG adapter cable
- E Neonatal ECG lead wires

#### To connect the ECG lead set

 Insert the ECG adapter cable (B) into the recessed ECG connector (A) on the side of the M540.

Orient the neonatal ECG adapter cable (B) so the exposed pins face toward you as you push it firmly into the channel.

#### NOTE

An ECG lead set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead sets are pushed firmly into the ECG connector of the M540.

- 2 Insert the port cover (C) to protect the unused ECG lead pins on the M540.
- Connect the individual neonatal ECG electrodes (E) to the neonatal ECG adapter cable (D).

For information on applying the electrodes to the patient, refer to the illustrations starting on page 174.

# Patient preparation for respiration monitoring

The following tips regarding skin preparation and proper electrode placement provide strong signals with minimal artifact but must never replace hospital-approved practices or manufacturer's recommendations. Because ECG electrodes are used for respiration monitoring, see illustrations starting on page 135 for information on electrode placement. Follow the same precautions for respiratory monitoring as for ECG monitoring (see page 134) and observe the following general recommendations:

- Place the electrodes so they generate the clearest possible signals with minimal artifact.
- Electrodes that adhere tightly and have a large conductive area provide the best results. Use a 5-wire lead set to improve the respiration signal (where the N electrode for IEC or RL electrode for AHA is the neutral electrode).
- Incorrect placement of electrodes affects the signal quality.

- For adult and pediatric patients, position the electrodes to span the maximum expansion and contraction of the lungs. This is especially important in the case of deep abdominal breathers.
- For neonates, place the RA and LA electrodes at the midaxillary line. Position the LL electrode below the diaphragm and umbilicus. Avoid the liver area and ventricles of the heart to prevent blood flow artifact.



# **Respiration display**

On the M540, the respiration display consists of:

- Respiration parameter field
- Respiration waveform

#### **Respiration parameter field**

The respiration parameter field contains the following elements:



- A Impedance respiratory rate label (RRi)
- B Crossed triangle symbols if alarms are turned off
- C Lung symbol that blinks with each detected breath
- D Respiratory rate value

#### **Breath markers**

The following diagram shows how white vertical markers on the respiration waveform can identify each detected breath.



If an M540 is in an IACS configuration, respiration markers are not sent to the Infinity network.

Respiration markers indicate the time of breath detection, not the beginning or end of respiration. If respiration markers also appear during artifact, set the respiration measuring mode to manual and adjust the breath detection threshold so only valid breaths are counted.

#### To turn the respiration markers on

- 1 Touch the respiration parameter field to select the Respiration dialog directly.
- 2 Touch the Settings tab.
- 3 Touch *Marker > On*.

#### NOTE

Respiration waveform markers are not sent to the network from wireless M540s.

The following respiration measuring modes are available:

- Auto (default) appropriate for patients with regular breathing patterns. It uses the optimal breath-detection threshold calculated at the beginning of respiration monitoring.
- Manual appropriate for adult or pediatric patients whose breathing patterns show excessive variation. Also appropriate for neonates with irregular breathing rhythms whose respiration signals may otherwise not be reliably evaluated. The M540 does not set a breath-detection threshold at the beginning of respiration monitoring. Instead, adjustments made alter the breath detection sensitivity of the monitor. When manual mode is selected, a vertically centered respiration threshold bracket is displayed on the waveform to indicate the threshold at which a breath is detected.

To select the desired respiration mode, see page 178.

#### WARNING

If the respiration waveform size is set too low in manual mode, shallow breaths may not be counted. If it is set too high, cardiac artifact will be counted as breaths. Therefore, always use the respiration marker to verify breath detection at the desired amplitude.

#### NOTE

In manual mode, the threshold is represented by two horizontal lines. When the detection threshold exceeds in amplitude the waveform channel, these horizontal lines will disappear.

# Accessing the respiration dialog

- 1 Touch the respiration parameter field.
- 2 Touch the Settings tab.

Or, if the parameter is not displayed

- Touch any parameter field > Settings tab > Change parameter.
- **2** Touch the desired parameter label to display it on the main screen.
- 3 Touch the parameter field > Settings tab.

# **Respiration parameter setup functions**

All respiration parameter setup functions take place in the respiration dialog (see "Accessing the respiration dialog" on page 177). The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description		
Settings 1 page				
Resp. lead 1)	I, II (default)	Selects the lead for respiration monitoring.		
Relearn	None	Initiates a relearning of the respiration signal, only in Auto mode.		
Marker <sup>1)</sup>	<i>On</i> , <i>Off</i> (default)	Superimposes a vertical line on the respiration waveform when a breath is detected (see page 176).		
Monitoring <sup>1)</sup>	<ul> <li>On (default in neonatal mode)</li> </ul>	Turns respiration monitoring on		
	<ul> <li>Off (default in adult/pediatric mode)</li> </ul>			
Apnea time <sup>1)</sup>	<i>Off</i> , 10, 15 (default), 20, 25, 30 s	Determines how long an apnea has to last before an alarm is triggered.		
Apnea archive <sup>1)</sup> Color <sup>1)</sup>	<ul> <li>Off</li> <li>Str/Rec – a recording as well as an event storage is triggered automatically in response to an apnea.</li> <li>Store (default) – a waveform segment is stored in response to an apnea.</li> <li>Record – a recording is triggered automatically in response to an apnea.</li> <li>Red, White, Yellow, Green, Light blue (default). Blue, Purple, Orange</li> </ul>	Determines what happens in response to an apnea. In case of false apnea alarms, it is advised to observe the patient's breathing pattern (belly or chest), and reposition electrodes accordingly, or to adjust the detection threshold manually. Determines the color of the waveforms, and the parameter		
	(uolauli), blue, l'alpie, orange	labels and values.		
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.		
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.				
Settings 2 page				

Selection	Available settings	Description
Mode <sup>1)</sup>	<i>Auto</i> (default), <i>Manual</i>	Determines the processing mode for the breath-related impedance change.
Coincidence <sup>1)</sup>	<i>On</i> , <i>Off</i> (default)	Determines whether you are alerted when the respiratory rate is within 20% of the heart rate, which is an indication that the M540 is counting heart beats as respiration.
Resp. threshold	10% to 100% (in 10% increments) – default: 50%	Adjusts the breath detection threshold.
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.		

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# SpO2 and Pulse CO-Ox monitoring with Masimo SET MCable

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### **Overview of SpO2 monitoring**

SpO2 and Pulse CO-Ox monitoring is only possible with the corresponding SpO2 MCable. The following hardware is available for monitoring SpO2 and Pulse CO-Ox parameters:

- Infinity MCable Masimo SET (Masimo SET MCable)
- Infinity MCable Masimo rainbow SET (Masimo rainbow SET MCable)

The values and the waveform are displayed on the M540 and on the Cockpit if the M540 is docked in an IACS configuration.

The Masimo SET MCable and Masimo rainbow SET MCable support motion tolerant pulse oximetry using Signal Extraction Technology (SET). This technology enhances the quality of SpO2 monitoring and also measures the percentage of functional hemoglobin saturated with oxygen (SpO2) in the arterial blood of the patient accurately and effectively.

A sensor applied to the patient measures the absorption levels of red and infrared light. The Masimo SET MCable or Masimo rainbow SET MCable uses the difference between the two measurements to calculate the percentage of saturated hemoglobin (SpO2). Because light absorption varies with blood volume and blood volume varies with pulse rate, both types of Masimo SET MCable can also derive a pulse rate (PLS).

In addition, the Masimo SET MCable also provides a perfusion index (PI) value. PI is the ratio of the pulsatile blood flow to the non-pulsatile blood flow in peripheral tissue. The PI value provides information regarding the perfusion status of the selected application site. This provides a means to select the most optimal site.

The Infinity MCable – Masimo rainbow SET measures additional parameters that continuously and non-invasively measure blood constituents.

SpO2 and Pulse CO-Ox measurements are for adult, pediatric, and neonatal patients (with the following exceptions).

### NOTE

The Masimo rainbow SET parameters SpHb and SpOC are not approved for neonatal monitoring.

### NOTE

Information about wavelength range may be useful during photodynamic therapy. For details, see the Technical data chapter.

The SpO2 monitoring functions are configurable in the parameter-specific dialog (see page 191).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 11.

Parameter-specific error messages are listed on page 333.

#### NOTE

This device is covered under one or more of the following USA patents: 5,758,644, 6,011,986, 6,699,194, 7,214,986, 7,254,433, 7,530,955 and other applicable patents listed at: www.masimo.com/patents.htm.

### Supported parameters

The parameters SpO<sub>2</sub>, PLS, and PI are available and displayed regardless of which Masimo sensor and which Masimo SET MCable is being used.

The availability of additional Masimo rainbow SET parameters depends on the sensor type that is being used and which parameters are activated on the Masimo rainbow SET MCable.

#### NOTE

SpO2 monitoring may be compromised by the patient's condition such as low perfusion, low hematocrit level, high hemoglobin concentration, high CO, elevated levels of Bilirubin, and excessive motion.

#### Standard parameter set

The Infinity MCable – Masimo SET and the Infinity MCable – Masimo rainbow SET always support the following parameters:

- Functional oxygen saturation (SpO2). The unit of measurement is%.
- Pulse rate (PLS). The unit of measurement is beats/min.
- Perfusion index (PI) which indicates the arterial pulse signal strength. The measurement range is 0.0 to 20.0%.

#### Expanded parameter set

In addition to the above standard parameters, the Masimo rainbow SET MCable provides the following additional optional parameters:

- Total hemoglobin (SpHb) measures the total hemoglobin levels in arterial or venous blood. The unit of measurement is selectable (see page 312).
- Total oxygen content (SpOC) measures the total blood oxygen content; this value is calculated from the SpHb and the SpO2 values. The unit of measurement is mL/dL.
- Pleth variability index (PVI) measures peripheral perfusion changes secondary to respiration or the PI amplitude over a respiration. PVI may be closely related to intrathoracic pressure changes, circulating blood volume and vascular tone. The unit of measurement is %.
- Carboxyhemoglobin saturation (SpCO) measures the amount of carbon monoxide that is bound to hemoglobin. The unit of measurement is %.

 Methemoglobin saturation (SpMet) measures the methemoglobin concentration in arterial blood. The unit of measurement is %.

Various sensors are available for the Masimo rainbow SET MCable. The availability of the parameters depends on the selected sensor type.

Each sensor provides certain parameters which must also be activated on the Masimo rainbow SET MCable.

- CO sensor; this type of sensor provides the following parameters: SpO2, PLS, PI, SpCO, SpMet, PVI.
- M-LNCS sensor; this type of sensor provides the following parameters: SpO<sub>2</sub>, PLS, PI.
- Hb sensor; this type of sensor provides the following parameters: SpO2, PLS, PI, SpHb, SpOC, SpMet, PVI.

#### NOTE

A color band on the Masimo rainbow SET MCable indicates which parameters are activated on the MCable. If an MCable does not have a label, the supported parameters are by default SpO2, PLS, and PI.

The following illustration shows the multi-color band which appears on the side of the Masimo rainbow SET MCable (see page 191 for more information).



If you connect a sensor but the parameter is not activated on the MCable, the parameter label appears in the parameter field without a value.

### SpO2 and Pulse CO-Ox precautions

Interfering substances: Carboxyhemoglobin may erroneously increase measurement values. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes that change arterial pigmentation, may cause erroneous measurement values.

### WARNING

High oxygen levels may predispose a premature baby to retinopathy of prematurity. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off. Transcutaneous pO2 monitoring is recommended for premature babies receiving supplemental oxygen.

### WARNING

An SpO2 sensor should not be used as an apnea monitor.

### WARNING

Use only Masimo-specified sensors. Other sensors may not provide adequate protection against defibrillation and may put the patient at risk.

### WARNING

A Pulse CO-Oximeter should be considered an early warning device. If a trend toward patient hypoxemia is observed, blood samples should be analyzed by laboratory instruments to completely understand the condition of the patient.

#### WARNING

The pulsations from an intra-aortic balloon support can elevate the pulse rate. Verify the pulse rate of the patient against the heart rate.

#### WARNING

Elevated levels of methemoglobin (MetHb) may lead to inaccurate SpO2 and SpCO measurements.

Elevated levels of total bilirubin may lead to inaccurate SpO<sub>2</sub>, SpMet, SpCO, SpHb, and SpOC measurements.

Motion artifact may lead to inaccurate SpMet, SpCO, SpHb, and SpOC measurements.

Very low arterial oxygen saturation (SaO<sub>2</sub>) levels may cause inaccurate SpCO and SpMet measurements.

Hemoglobin synthesis disorders may cause erroneous SpHb readings.

### WARNING

To reduce the hazard of burns during surgery, keep the sensor or transducer and their associated cables away from the surgical site, the electro-surgical unit return electrode, and earth ground.

#### WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours to ensure a high quality signal. Incorrectly applying the SpO2 sensor using excessive pressure for prolonged periods of time can result in a pressure injury.

#### CAUTION

Do not immerse the sensor or patient cable in any liquid. Moisture may present a safety risk.

### CAUTION

When using the maximum sensitivity setting, the performance of the sensor off detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, false readings may occur due to environmental noise' such as light, vibration and excessive air movement. In addition, when a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

#### NOTE

An **SpO2** sensor can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

### NOTE

Possession or purchase of the Masimo SET MCable or the Masimo rainbow SET MCable does not convey any expressed or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

### NOTE

Purchase of this device confers no express or implied license under any Masimo patent to use this instrument with any oximetry sensor that is not manufactured or licensed by Masimo. For a list of approved sensors, see the Instructions for use *Infinity Acute Care System – Monitoring Accessories.* 

### NOTE

Do not use a functional tester to assess the accuracy of an **SpO2** sensor probe or an **SpO2** sensor monitor. Since SpO2 sensor measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ±A rms of a CO-Oximeter's measured value.

### NOTE

A functional tester can be used to measure the total error of an **SpO2** sensor monitor-probe system if a particular calibration curve has been independently demonstrated to be accurate for that system. The functional tester can then measure how accurately a particular **SpO2** sensor is in reproducing the calibration curve.

### **Connecting the Masimo SET MCable**

The Masimo SET MCable connects directly to the M540. The logo on the MCable identifies if you are using a Masimo rainbow SET or a Masimo SET MCable.



### To connect the Masimo SET MCable

- Attach the Masimo SET MCable connector (B) to the blue SpO2 port (A) of the M540.
- 2 Attach the sensor intermediate cable (D) to the Masimo SET MCable 14-pin connector (C).
- 3 Attach the appropriate Masimo -sensor to the end of the sensor cable (E).

- A SpO2 port on the M540
- B MCable connector
- C MCable 14-pin connector
- D Intermediate cable connector to MCable
- E Connector for various sensors (3 options)

### **Connecting the Masimo rainbow SET MCable**

The Masimo rainbow SET MCable connects directly to the M540. The logo on the MCable identifies if you are using a Masimo rainbow SET or a Masimo SET MCable.

A color band located on the side of the Masimo rainbow SET MCable indicates which parameters are activated.



- Fields appearing in color represent parameters that are already activated
- Fields with the letteX' denote parameters that are not activated
- Fields that appear empty denote parameters that might be activated later

A Masimo MCable can be mounted to the back of an M540 (see page 44).

### To connect the Masimo rainbow SET MCable

- 1 Attach the MCable connector (B) to the blue SpO2 port (A) of the M540.
- **2** Attach the intermediate cable (D) to the 20-pin connector of the MCable (C).
- **3** Attach the appropriate Masimo sensor to the end of the intermediate cable (E).

For detailed information on which sensors support which parameters, refer to the supported parameter sections in the Instructions for use *Infinity Acute Care System – Monitoring Accessories.* 



- A SpO2 port on the M540
- B MCable connector
- C MCable 20-pin connector
- D Masimo rainbow SET intermediate cable connector to MCable
- E Connector for various sensors (3 options)

### **Patient preparation**

The following tips provide optimal SpO2 monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

The accuracy of SpO2 monitoring depends largely on the strength and quality of the SpO2 signal.

If a finger is used as a monitoring site, remove any nail polish. Cut the finger nails of the patient, if necessary.

The signal may vary due to the following conditions:

- Placement of a sensor that is too tight
- Patient experiences hypotension, severe vasoconstriction, severe anemia, or hypothermia
- Arterial occlusion proximal to the sensor
- Patient is in cardiac arrest or is in shock.
- Bright light causing erratic measurement or missing values. Cover the sensor with opaque material if it is likely to be exposed to direct bright light.
- Significant levels of dysfunctional hemoglobins (carboxyhemoglobin and methemoglobin)
- Intravascular dyes such as indocyanine green or methylene blue
- Excessive patient movement
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

The maximum sensitivity mode for a Masimo MCable is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion.

The message *SpO2 low perfusion* appears when the monitor detects low amplitude arterial pulsations. In this case, do the following:

- 1 Check the patient and treat if necessary.
- 2 Move the sensor to a site that is more adequately perfused.
- **3** Select maximum sensitivity mode.

### Applying the sensor

### NOTE

Only use Masimo sensors with the Masimo SET MCable and the Masimo rainbow SET MCable. Read the instructions provided with the sensor for optimal application techniques and for safety information. Never use damaged sensors.

If you are using a reusable sensor, make sure it is clean before applying it to the patient. Follow the recommendations of the manufacturer.

#### To apply the sensor

- 1 Select the size and type of sensor that is best suited for your patient. Follow the recommendations of the manufacturer.
- 2 Position the sensor correctly and attach it to your patient.



3 Connect the sensor to the Masimo SET MCable or the Masimo rainbow SET MCable.

#### NOTE

After connecting the sensor, if the sensor-LED does not light up:

- observe the monitor for any message and act accordingly, or
- replace the sensor

### SpO2 and Pulse CO-Ox display

On the M540, the SpO2 display consists of:

- SpO2 parameter field displaying SpO2, PLS, and PI values
- A user-configurable Pulse CO-Ox parameter field when a Masimo rainbow SET MCable with additional parameters is connected. If the Masimo rainbow SET MCable supports only the standard parameter set (SpO2, PLS, PI), the regular parameter field appears instead.
- SpO2 pulse plethysmogram waveform

### NOTE

The pulse plethysmogram waveform is directly proportional to the strength of the pulse amplitude.

The following table lists the maximum times the M540 requires to report the parameter values after connecting the sensor to the MCable.

Parameter	Maximum time
SpO2, PLS, PI	up to 35 s
SpMet, PVI, SpCO	up to 60 s
SpHb, SpOC	up to 90 s
PVI	up to 150 s

### SpO2 parameter field (Masimo SET MCable)

The SpO<sub>2</sub> parameter field contains the following elements:



- A SpO2 label
- B Units of measure
- **C** Crossed triangle symbol when the SpO2 alarm is turned off.
- D PLS (pulse) label
- E PLS value
- **F** Crossed triangle symbol when the PLS alarm is turned off.
- G Perfusion index value
- H Perfusion index label
- I Pulse bar graph can be turned on/off (see page 192)
- J SpO2 saturation value
- K Upper and lower limit

# PLS CO-Ox parameter field (Masimo rainbow SET MCable)

The PLS CO-Ox parameter field appears in addition to the regular SpO2 parameter field when a Masimo rainbow SET MCable is connected that supports parameters in addition to the standard parameter set (SpO2, PLS, PI). The parameter content of the parameter field is configurable (see page 194).

The display of PLS CO-Ox parameters (SpHb/SpHbv, SpOC, SpMet, PVI, SpCO) is affected by the following conditions:

- Blanks appear instead of parameter values if a sensor is connected but the parameter is not activated on the MCable.
- Asterisks (\*\*\*) replace the parameter values under the following circumstances:
  - A parameter is activated but an incompatible sensor is connected
  - A parameter is activated but no sensor is connected
  - A technical failure exists (for example, an unplugged sensor)

#### NOTE

The parameter SpHb changes to SpHbv (if *Venous* was selected for the blood source setting SpHb Cal – see page 192).

 You can select up to three parameters to be displayed in the parameter field (see page 194). Units of measure appear next to the parameter label if applicable and can be activated/deactivated (see page 312). The Pulse CO-Ox parameter field contains the following elements:



- A Parameter 1
- B Unit of measurement for parameter 1
- **C** Upper/lower alarm limits or crossed triangle symbols when alarms are deactivated (for the parameters SpOC there are no alarm limits)
- D Parameter 2
- E Parameter 2 value
- F Parameter 3 value
- G Parameter 3
- H Parameter 1 value

### Accessing the SpO<sub>2</sub> dialog

- 1 Touch the SpO2 parameter field.
- 2 Touch the Settings tab.

Or, if the parameter is not displayed

- 1 Touch any parameter field > Settings tab > Change parameter.
- 2 Touch the desired parameter label to display it on the main screen.
- 3 Touch the parameter field > **Settings** tab.
- 4 Touch the *Change parameter* button.
- 5 Select the desired parameter
- 6 Repeat steps 1 and 2.

To access the PLS CO-Ox dialogs, see page 194.

### SpO2 parameter setup functions

All SpO2 parameter setup functions take place in the SpO2 dialog (see "Accessing the SpO2 dialog" on page 191).

The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description
Tone volume <sup>1)</sup> Off, 5, 10 (default), 20, 30, 40, 50, 60, 70           80, 90, 100%	Adjusts the volume of the pulse tone. If you dock the M540 in an IACS configuration, this setting is replaced by the pulse tone volume setting of the Cockpit.	
		When you undock the M540, this setting is replaced by the <i>Transport pulse tone</i> setting configured under the <i>Alarm setup</i> tab (see page 317).
Tone source 1)	<ul> <li><i>ECG</i> (default) – the heart blip pulsates with each detected pulse.</li> <li><i>SpO2</i></li> </ul>	Selects the source of the pulse tone which affects the ECG and SpO2 parameter field display (see page 189). For the <b>SpO2</b> selection, the higher the pitch of the tone, the higher the SpO2 saturation percentage.
Bar graph <sup>1)</sup>	<b>On</b> , <b>Off</b> (default)	Displays a bar graph that is proportional to the pulse rate and strength.
Averaging time 1)	2 to 4, 4 to 6, 8 (default), 10, 12, 14, 16 s	Determines how quickly the reported SpO2 value responds to changes in the patient's oxygen saturation.
		A longer averaging time provides a more accurate result. However, in clinical situations where rapid physiological changes have to be monitored, use a shorter averaging time

Selection	Available settings	Description	
Sensitivity	<ul> <li>Normal (default) – standard mode</li> </ul>	Determines the level of detection	
mode <sup>1)</sup>	<ul> <li>APOD (adaptive probe off detection) – the least sensitive mode for detecting a reading on patients with low perfusion.</li> <li>Provides the best detection for detached sensors. This mode is useful for patients at particular risk for sensors becoming detached such as children or patients who are restless.</li> </ul>	sensitivity.	
	Max. – provides maximum sensitivity for poor signals (this mode is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed in APOD or Normal sensitivity mode. Max. mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion.)		
Fast SAT mode 1)	<b>On</b> , <b>Off</b> (default)	Activates rapid tracking of arterial	
	When the <b>Averaging time</b> setting is set to 2 to 4 s or 4 to 6 s, the <b>Fast SAT mode</b> selection is grayed out.	oxygen saturation changes.	
	Red, White (default), Yellow, Green, Light blue, Blue, Purple, Orange	Determines the color of the waveforms, and the parameter labels and values.	
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.	
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.			

### NOTE

The password-protected alarm setting *SpO2 sensor off* pro vides additional SpO2 alarm configuration. For more detailed information see *Configuring the SpO2 alarm priority* in the Alarms chapter.

### Accessing the Pulse CO-Ox dialog

General Masimo rainbow SET setup functions take place in the *SpO2* and *Pulse CO-Ox limits* dialogs.

To access the *Pulse CO-Ox limits* dialog, proceed as follows:

- 1 Touch the *Pulse CO-Ox limits* parameter field if it is displayed on the main screen.
- 2 Touch the Settings tab.

Or, if the parameter is not displayed

- 1 Touch any parameter field > **Settings** tab > **Change parameter**.
- **2** Touch the desired parameter label to display it on the main screen.
- **3** Touch the parameter field > **Settings** tab.
- 4 Touch the *Change parameter* button.
- 5 Select the desired parameter
- 6 Repeat steps 1 and 2.

### Pulse CO-Ox parameter setup functions

All Pulse CO-Ox parameter setup functions take place in the Pulse CO-Ox dialog.

The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description
Pulse CO-Ox 1 <sup>1)</sup>	SpHb <sup>1)</sup> (default), SpOC, SpMet, SpCO, PVI	Selects the parameter for the parameter 1 location the <i>Pulse CO-Ox limits</i> parameter field. The associated parameter label and value have the largest font.
		With an Hb sensor, the default parameter is SpHb. With a CO-sensor, the default parameter for the parameter 1 location in the parameter field changes automatically to SpCO.
		Changes to the parameter selection are retained if the same sensor is disconnected and then reconnected. The parameter selection changes to the default selection, if another Masimo rainbow SET sensor type is connected.

Selection	Available settings	Description	
Pulse CO-Ox 2 <sup>1)</sup>	SpHb <sup>1)</sup> , SpOC (default), SpMet, SpCO, PVI	Selects the parameter for the parameter 2 location in the Pulse CO-Ox parameter field.	
		With an Hb sensor, the default parameter is SpOC. With a CO-sensor, the default parameter for the parameter 2 location in the parameter field changes automatically to SpMet.	
		Changes to the parameter selection are retained if the same sensor is disconnected and then reconnected. The parameter selection changes to the default selection, if another Masimo rainbow SET sensor type is connected.	
Pulse CO-Ox 3 <sup>1)</sup>	SpHb <sup>2)</sup> , SpOC, SpMet, SpCO, PVI (default)	Selects the parameter for the parameter 3 location in the <i>Pulse CO-Ox limits</i> parameter field.	
		PVI is the default parameter for the parameter 3 location in the parameter field for both CO and Hb sensors.	
		Changes to the parameter selection are retained if the same sensor is disconnected and then reconnected. The parameter selection changes to the default selection, if another Masimo rainbow SET sensor type is connected.	
SpHb Averaging <sup>1), 2)</sup>	<ul> <li>Long – approximately 6 minutes</li> <li>Medium (default) –</li> </ul>	Determines how responsive the monitor is to rapid physiological changes while tracking blood hemoglobin values.	
<ul> <li>approximately 3 minutes</li> <li>Short – approximately 1 minute</li> </ul>	A longer averaging time provides a more accurate result. However, in clinical situations where rapid physiological changes have to be monitored, use a shorter averaging time.		
Color <sup>1)</sup>	Red, White (default), Yellow, Green, Light blue, Blue, Purple, Orange	Determines the color of the waveforms, and the parameter labels and values.	
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.	
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.			
<sup>2)</sup> If the venous blood blood source) to S	<sup>2)</sup> If the venous blood source was selected for SpHb Cal, the parameter label changes from SpHb (arterial blood source) to SpHbv.		

### Password-protected Masimo rainbow SET setup functions

Additional Masimo rainbow SET setup functions take place in the **Settings 2** page which is protected by a clinical password.

Selection	Available settings	Description
SpHb Cal <sup>1)</sup>	<ul> <li>Arterial (default)</li> <li>Venous</li> </ul>	Selects the blood sampling source which is used to calculate the <i>SpHb</i> value. The <i>SpHb</i> value changes to <i>SpHbv</i> when the <i>SpHb Cal</i> setting <i>Venous</i> is selected.
PVI Averaging <sup>1)</sup>	<ul> <li>Short</li> <li>Long (default)</li> </ul>	Determines how responsive the monitor is to rapid physiological changes while tracking pleth variability index. A longer averaging time provides a more accurate result. However, in clinical
<sup>1)</sup> This setting is a pat	ient default which may be unique for each patien	situations where rapid physiological changes have to be monitored, use a shorter averaging time.

## SpO2 and pulse rate monitoring with Nellcor OxiMax MCable

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### **Overview of SpO2 monitoring**

SpO2 monitoring is only possible with an SpO2 MCable. The M540 uses the Infinity MCable – Nellcor OxiMax (Nellcor OxiMax MCable) to measure the percentage of functional hemoglobin saturated with oxygen (SpO2) and derive a pulse rate (PLS) continuously. The values and waveform display on the M540.

A sensor, applied to the patient, measures the absorption levels of red and infrared light. The Nellcor OxiMax MCable uses the difference between the two measurements to calculate the SpO2. Because light absorption varies with blood volume and blood volume varies with pulse rate, the Nellcor OxiMax MCable can also derive a PLS value.

SpO2 measurements are for adult, pediatric, and neonatal patients.

### NOTE

Information about wavelength range may be useful during photodynamic therapy. For details, see the Technical data chapter.

The SpO2 monitoring functions are configurable in the parameter-specific dialog (see page 203).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients"on page 11.

Parameter-specific error messages are listed on page 333.

### Supported parameters

- Saturation (SpO2)
- Pulse rate (PLS)

#### NOTE

SpO2 monitoring may be compromised by the patient's condition such as low perfusion, low hematocrit level, high hemoglobin concentration, high CO, elevated levels of Bilirubin, and excessive motion.

### SpO<sub>2</sub> precautions

Interfering Substances: Carboxyhemoglobin may erroneously increase measurement values. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes that change arterial pigmentation, may cause erroneous measurement values.

### WARNING

High oxygen levels may predispose a premature baby to retinopathy of prematurity. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off. Transcutaneous pO2 monitoring is recommended for premature babies receiving supplemental oxygen.

### WARNING

An SpO2 sensor should not be used as an apnea monitor.

### WARNING

Use only Nellcor- and Dräger-specified sensors. Other sensors may not provide adequate protection against defibrillation and may put the patient at risk.

### WARNING

To reduce the hazard of burns during surgery, keep the sensor or transducer and their associated cables away from the surgical site, the electro-surgical unit return electrode, and earth ground.

### WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours to ensure a high quality signal. The misapplication of a SpO2 sensor with excessive pressure for prolonged periods can induce pressure injury.

#### CAUTION

Do not immerse the sensor or patient cable in any liquid. Moisture may present a safety risk.

### NOTE

An SpO2 sensor can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

### NOTE

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized consumable products which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device and/or consumable products. For a list of approved sensors, see the Instructions for use *Infinity Acute Care System – Accessories*.

### NOTE

Do not use a functional tester to assess the accuracy of an SpO2 sensor probe or an SpO2 sensor monitor. Since SpO2 sensor measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within  $\pm A$  rms of a CO-Oximeter's measured value.

### NOTE

A functional tester can be used to measure the total error of an SpO2 sensor monitor-probe system if a particular calibration curve has been independently demonstrated to be accurate for that system. The functional tester can then measure how accurately a particular SpO2 sensor is in reproducing the calibration curve.

### Connecting the Nellcor OxiMax MCable

The Nellcor OxiMax MCable connects directly to the M540.



### To connect the Nellcor OxiMax MCable

- 1 Connect the Nellcor OxiMax MCable (B) to the blue SpO2 port (A) of the M540.
- 2 Attach the sensor cable (D) to the Nellcor Oxi-Max MCable connector (C).
- 3 Attach the appropriate sensor cable to the end of the SpO<sub>2</sub> cable (E) – see page 202 for more information.

- A SpO2 port on the M540
- B MCable connector
- C MCable 14-pin connector
- D Intermediate cable connector to MCable
- E Intermediate cable connector to sensor

### Patient preparation for SpO2 monitoring

The following tips provide optimal SpO2 monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

The accuracy of SpO2 monitoring depends largely on the strength and quality of the SpO2 signal.

If a finger is used as a monitoring site, remove any nail polish. Cut the finger nails of the patient, if necessary, for better sensor placement.

Pulses may be counted erroneously due to the following conditions:

- Placement of a sensor that is too tight
- Patient experiences hypotension, severe vasoconstriction, severe anemia, or hypothermia
- Arterial occlusion proximal to the sensor
- Patient is in cardiac arrest or is in shock
- Bright light causing erratic measurement or missing values. Cover the sensor with opaque material if it is likely to be exposed to direct bright light.
- Significant levels of dysfunctional hemoglobins (HbCO or MetHb)
- Intravascular dyes such as indocyanine green or methylene blue
- Excessive patient movement
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

### Applying the sensor

If you are using a reusable sensor, make sure it is clean before applying it to the patient. Follow the recommendations of the manufacturer.

#### NOTE

Read the instructions provided with the sensor for optimal application techniques and for safety information. Never use damaged sensors. Doing so may compromise performance.

#### To apply the sensor

- 1 Select the size and type of sensor that is best suited for your patient. Follow the recommendations of the manufacturer.
- 2 Position the sensor correctly and attach it to your patient.



3 Connect the sensor to the Nellcor OxiMax MCable.

### NOTE

After connecting the sensor, do the following if the sensor-LED does not light up:

- Observe the monitor for any message and act accordingly, or
- Replace the sensor

### SpO<sub>2</sub> display

On the M540, the SpO2 display consists of:

- SpO2 parameter field
- SpO2 pulse plethysmogram waveform

### NOTE

The pulse plethysmogram waveform is directly proportional to the strength of the pulse amplitude.

The SpO<sub>2</sub> parameter field contains the following elements:



- A SpO2 label
- B Units of measure
- **C** Crossed triangle symbol when the SpO<sub>2</sub> alarm is turned off.
- D PLS (pulse) label
- E PLS value
- **F** Crossed triangle symbol when the PLS alarm is turned off.
- **G** Pulse bar graph can be turned on/off, see page 203
- H SpO2 saturation value
- I Upper and lower SpO2 limit

### Accessing the SpO<sub>2</sub> dialog

- 1 Touch the SpO2 parameter field.
- 2 Touch the Settings tab,

or, if the parameter is not displayed

touch any parameter field > **Settings** tab > **Change parameter**.

- **3** Touch the desired parameter label to display it on the main screen.
- 4 Touch the parameter field > **Settings** tab.
- 5 Touch the *Change parameter* button.

- 6 Select the desired parameter.
- 7 Repeat steps 1 and 2.

### SpO2 parameter setup functions

All SpO2 parameter setup functions take place in the SpO2 dialog (see "Accessing the SpO2 dialog" on page 202).

The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description	
Tone volume 1)	<i>Off</i> , 5, 10 (default), 20, 30,	Sets the volume of the pulse tone.	
	40, 50, 60, 70, 80, 90, 100%	<ul> <li>If you dock the M540 in an IACS configuration, this setting is replaced by the pulse tone volume setting of the Cockpit.</li> </ul>	
		<ul> <li>When you undock the M540, this setting is replaced by the <i>Transport pulse tone</i> setting configured under the <i>Alarm setup</i> tab (see page 317)</li> </ul>	
Tone source <sup>1)</sup>	<ul> <li><i>ECG</i> (default) – the heart rate blip pulsates with each detected pulse.</li> <li><i>SpO2</i></li> </ul>	Selects the source of the pulse tone which affects the ECG and SpO <sub>2</sub> parameter field display (see page 202). For the SpO <sub>2</sub> selection, the higher the pitch of the tone, the higher the SpO <sub>2</sub> saturation percentage.	
Bar graph <sup>1)</sup>	<b>On</b> , <b>Off</b> (default)	Displays a bar graph that is proportional to the pulse rate and strength.	
Response mode <sup>1)</sup>	<ul> <li>Normal (default) – 90% change within 5 to 7 seconds</li> </ul>	Establishes the frequency the oximeter uses to calculate, record, and display SpO2 saturation levels.	
	– <b><i>Fast</i></b> – 90% change	<ul> <li>Normal mode responds to changes in blood oxygen saturation in 5 to 7 seconds</li> </ul>	
	within 2 to 4 s	<ul> <li>Fast mode responds to changes in blood oxygen saturation levels in 2 to 4 seconds when calculating %SpO2.</li> </ul>	

Selection	Available settings	Description	
SatSeconds 1)	<b>Off</b> (default), 10, 25, 50, 100	This selection does the following:	
	<b>NOTE:</b> When <b>SatSeconds</b> is set to any value other than <b>Off</b> , the <b>Desat</b> alarm status is set to <b>Off</b> .	<ul> <li>Analyzes desaturation events by multiplying their duration (seconds) by the number of percentage points the patient exceeds the alarm limit.</li> </ul>	
		<ul> <li>Eliminates nuisance alarms caused by brief and numerous violations of lower and upper alarm limits.</li> </ul>	
		<ul> <li>Overrides the alarm validation setting and the SpO2 high priority desaturation alarm for neonatal patients.</li> </ul>	
Color <sup>1)</sup>	<i>Red, White</i> (default), Yellow, Green, Light blue, Blue, Purple, Orange	Determines the color of the waveforms, and the parameter labels and values.	
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.	
<sup>1)</sup> This setting is a pat	ient default which may be unio	que for each patient category; it is part of the profile.	

### NOTE

The password-protected alarm setting *SpO2 check sensor* provides additional SpO2 alarm configuration. For more detailed information see *Event recall* in the Alarms chapter.

# Temperature

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### Overview of temperature monitoring

The M540 measures and displays the following temperature values:

- Surface body temperature
- Core temperature

Temperature monitoring is intended for adult, pediatric, and neonatal patients. All clinical thermometer readings are a direct measurement.

#### NOTE

The temperature functions and associated probes should be calibrated every two years by qualified personnel to maintain an accuracy of  $\pm0.1$  °C (±0.2 °F).

The temperature monitoring functions are configurable in the parameter-specific dialog (see page 211).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 11.

Parameter-specific error messages are listed on page 343.

### **Supported parameters**

- *Ta*, *Tb*, *∆T*: absolute temperature values, temperature difference values
- *T1a*, *T1b*, *∆T1* absolute temperature values, delta temperature values

### Precautions

### WARNING

Protective covers for general purpose probes contain latex.

#### NOTE

Cover internally placed reusable temperature sensors with temperature sensor sheaths.

#### NOTE

After starting the body temperature measurement, it takes some time until the monitor displays the actual value. This time period depends on the difference in temperature between environment and body.

### Connecting the temperature sensors

You can connect temperature sensors directly to the M540 or to one of the following hemodynamic pods:

- MPod QuadHemo
- Hemo4 pod
- Hemo2 pod

### Connecting the sensors to the M540

You can connect a single sensor or two sensors to the M540 directly using the dual temperature adapter cable. The dual temperature sensor cable monitors two temperatures simultaneously.

### To connect two temperature sensors

- Connect the temperature sensors (D) to the sensor ports (C) of the dual temperature Ycable.
- Connect the connector (B) of the dual temperature cable to the M540 Temp/Aux port (A).

#### To connect a single temperature sensor

Connect a temperature sensor (E) directly to the M540 temperature port (A).



- A M540 temperature port
- B Dual temperature cable connector
- C Dual temperature sensor port
- D Temperature sensors
- E Temperature sensor connecting directly to the M540

### Connecting the temperature sensors to the hemodynamic pods

You can connect a single temperature sensor to the following devices:

- Hemo4 pod
- Hemo2 pod
- MPod QuadHemo

# To connect temperature cables to the MPod – QuadHemo

 Connect the temperature sensor connector (A) to the MPod – QuadHemo Temp B port (C) or Temp A port (D).





2 Connect the connection cable to the monitor connector (B) of the MPod – QuadHemo and to the gray hemo port on the M540.

# To connect temperature cables to the Hemo2 pod and the Hemo4 pod

 Connect the temperature sensor connectors (E) to the Temp A port (H) and/or the Temp B port (G) of the Hemo4 or the Hemo2 pod.



2 Connect the connection cable to the monitor port (F) of the Hemo2 or the Hemo4 pod and to the gray hemo port on the M540 (see page 207).

### **Temperature display**

On the M540, the temperature display consists of a parameter field (see page 211).

Any temperature values originating from the MPod – QuadHemo, the Hemo2 pod, or the Hemo4 pod are labeled T1a, T1b, and  $\Delta$ T1. Any temperature values originating from a single or dual temperature cable that is connected to the M540 temperature port are labeled Ta, Tb, and  $\Delta$ T.

When a single temperature sensor is connected, only one temperature value displays. The values for the second temperature and temperature difference appear blank.

### Temperature parameter field

The following diagram shows a temperature parameter field.



- A Direct temperature label
- B Units of measure
- **C** Crossed triangle symbol when the temperature alarms are turned off
- D Delta temperature parameter label or second direct temperature label
- E Direct temperature value
- F Calculated temperature parameter

### Accessing the temperature dialog

- **1** Touch the temperature parameter field.
- 2 Touch the **Settings** tab.

Or, if the parameter is not displayed

- 1 Touch any parameter field > **Settings** tab > **Change parameter**.
- 2 Touch the desired parameter label to display it on the main screen.
- **3** Touch the parameter field > **Settings** tab.

### Temperature parameter setup functions

All temperature parameter setup functions take place in the temperature dialog (see "Accessing the temperature dialog" on page 210).

### NOTE

On the M540, changing the color of one temperature parameter changes the color of all the temperature parameters.

### CAUTION

Do not connect a Tcore<sup>®</sup> sensor to the Cardiac Output (C.O.) Tb port on an MPod — Quad Hemo.

The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description
Ta Th	– TOral – TEso	<i>Ta</i> configures the first temperature value on the
	<ul> <li>TNasal</li> <li>TRect</li> <li>TBlad</li> <li>Tcore</li> <li>TBld1</li> <li>TBlnkt</li> </ul>	M540. <i>Tb</i> configures the second temperature value on the M540.
ΔΤ	– TSkin – TR – TL	Difference <b>Ta-Tb</b>
<b>T</b> 4	TAOrol	The configures the third
T1b	– 110rai – T1Eso	temperature value.
	– T1Nasal – T1Rect	temperature value.
	– T1Blad	
	– T1core – T1Bld1	
	– T1Blnkt	
	– T1Skin – T1R	
	– T1L	

Selection	Available settings	Description
<b>∆T1</b>		Difference <b>T1a</b> – <b>T1b</b>
Color <sup>1)</sup>	Red, White (default), Yellow, Green, Light blue, Blue, Purple, Orange	Determines the color of the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.		

# Non-invasive blood pressure (NIBP)

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### Overview

The M540 uses the oscillometric method to acquire and process non-invasive blood pressure (NIBP) signals. Blood pressure measurements use the oscillometric method and are equivalent to those obtained by intra-arterial methods, within the limits prescribed by the Association for Advancement of Medical Instrumentation, Electronic Automated Sphygmomanometers.

The M540 inflates and then deflates a blood pressure cuff wrapped around the arm or the leg of a patient. A hose connects the cuff to the monitor which determines the systolic, diastolic and mean pressures for adult, pediatric and neonatal patients.

To protect the patient from excessive inflation limits, the blood pressure cuff automatically deflates when:

- A measurement exceeds two minutes in adult and pediatric mode
- A measurement exceeds 90 seconds in neonatal mode

### NOTE

The non-invasive blood pressure functionality should be calibrated every two years by technically qualified personnel as described in the Service manual.

The non-invasive blood pressure monitoring functions are configurable in the parameter-specific setup page (see page 224).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 11.

Parameter-specific error messages are listed on page 340.

### Supported parameters

- NIBP S Systolic non-invasive blood pressure
- NIBP D Diastolic non-invasive blood pressure
- NIBP M Mean non-invasive blood pressure

### Non-invasive blood pressure precautions

### WARNING

Rapid, prolonged cycling of non-invasive blood pressure measurements have on occasion been associated with petechiae, ischemia, purpura, or neuropathy. Make sure that the cuff is properly attached and check the cuff site regularly to prevent the cuff pressure from impeding the blood flow.

### WARNING

Obstructions may cause the cuff to inflate and deflate improperly and result in inaccurate measurement values. Check the hose and cuff for damage and soiling. Do not allow the hose and cuff to come in contact with fluids, and make sure that they are not compressed or kinked.

### WARNING

Do not place the cuff on injured or breached skin because cuff compression could further damage the tissue.

#### WARNING

Do not place the cuff on a limb with either an intra-arterial line or a vascular prosthesis because cuff compression will impede perfusion.

### WARNING

Do not perform a blood pressure measurement on the upper arm of the side of a mastectomy to prevent patient injury.

### WARNING

When measuring the non-invasive blood pressure while monitoring another parameter simultaneously on the same limb, the measurement of the other parameter can be temporarily interrupted.

#### WARNING

Accurate non-invasive blood pressure measurements depend on the correct size and type of the blood pressure cuff in relation to the patient's arm circumference. The wrong sized cuff, or cuffs outside the range or size manufactured by Dräger, can cause inaccurate measurements. Use only Dräger approved cuffs and make sure that the correct size is used for each patient.

### WARNING

To reduce the possibility of pumping air into the patient's blood vessels, never connect pneumatic connectors to an intravascular system.

### WARNING

Before monitoring neonates and infants:

- Select the correct cuff size and hose.
- Select the neonatal or pediatric patient category, if not already selected. This provides the appropriate inflation for neonates, infants, and pediatric patients and protects neonatal patients from excessive cuff pressures and longer cuff cycle time.

Failure to follow the above actions could result in extreme discomfort, petechiae, ischemia, purpura, or neuropathy.

### NOTE

The effectiveness of non-invasive blood pressure monitoring has not been established in pregnant patients, including pre-eclamptic patients.

### NOTE

The accuracy of the oscillometric blood pressure signal can decrease (up to loss of measurement) under the following conditions:

- weak pulses
- irregular pulses
- patient movement artifacts
- tremor artifacts
- respiratory artifacts
- pulses generated from a ventricular assist device

### NOTE

A systolic blood pressure higher than the current high inflation limit may trigger a message that the non-invasive blood pressure inflation limit is low. When this message appears, manually check the blood pressure of the patient.

### Connecting the non-invasive blood pressure hose and cuff

The following diagram shows where the noninvasive blood pressure hose connects to the noninvasive blood pressure hose connector (A) on the side of the M540.



- A Non-invasive blood pressure connector on the M540
- B Non-invasive blood pressure hose
- C Blood pressure cuff

### To connect the hose and cuff

- 1 Select a blood pressure cuff (C) size that is appropriate for the patient.
- 2 Connect the blood pressure cuff (C) to the hose (B).
- Connect the non-invasive blood pressure hose (B) to the non-invasive blood pressure connector (A) of the M540.
## Patient preparation for non-invasive blood pressure monitoring

The following tips provide optimal non-invasive blood pressure monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

Accurate non-invasive blood pressure measurements depend on the correct size and type of the blood pressure cuff in relation to the arm circumference of the patient. The wrong sized cuffs, or cuffs outside the range or size manufactured by Dräger, can cause inaccurate measurements. Use only Dräger approved cuffs and make sure that the correct size is used for each patient.

### Applying the blood pressure cuff

Weak or irregular pulses, patient movement, tremors, or respiratory artifacts can affect the accuracy of non-invasive blood pressure measurements and even cause them to fail. Before applying the cuff, read the non-invasive blood pressure precautions.

We recommend that you do not apply the cuff on a limb that is already used for other measurements. Make sure that other patient connections do not interfere with each other.

The following diagram depicts a typical Dräger cuff.

- A Index line
- B Artery marker
- C Range labels
- D Size indicator

# Correct patient positioning for patients with hypertension

For a patient with hypertension who is not in a supine position, perform the resting blood pressure measurement as follows:

- Place the patient in a comfortable seated position.
- Make sure the legs are not crossed.
- Make sure the feet are flat on the floor.
- Make sure the patient leans back and the arms are at rest.
- Apply the center of the cuff at the level of the right atrium.
- Make sure the patient is relaxed and does not talk during the measurement.
- Wait for 5 minutes before performing the first measurement, if possible.

#### NOTE

The accuracy of the blood pressure measurement can be affected by the following conditions:

- The measuring site, the position and the physiological condition of the patient, patient movement.
- Cuffs that are stored or used outside of the specified environmental conditions. For acceptable conditions, refer to the Technical data chapter.

#### NOTE

Blood pressure measurements can be affected by arrhythmias (for example, atrial and premature ventricular contraction), atrial fibrillation, low perfusion, diabetes, renal diseases, trembling and shivering. In the presence of implausible measurement values check the above-mentioned conditions and repeat the measurement. If possible, wait for a few minutes before performing another measurement at the same measuring site.

#### To apply the cuff

- Place the cuff 2 to 5 cm (1 to 2 inches) above the elbow (or around the middle of the thigh).
   Place the cuff label "this side to patient" against the skin.
- 2 Place the artery marker (B) over the artery pointing to the hand or the foot. Place the cuff label 'index' (A) so that it falls within the range labels (C) to ensure the correct fit. If the cuff does not fall within the indicated range, select a cuff that better accommodates the limb circumference.
- 3 Wrap the deflated cuff snug around the limb without impeding blood flow. Make sure there is a finger's width of space between the cuff and the upper arm or thigh, then fasten.

## Non-invasive blood pressure display

On the M540, the non-invasive blood pressure parameter field displays the latest readings for mean, systolic, and diastolic pressure (in mmHg or kPa).

The appearance of the non-invasive blood pressure parameter field depends on the selected non-invasive blood pressure mode (see page 220). If a measurement is invalid, the non-invasive blood pressure parameter field replaces the non-invasive blood pressure values with asterisks (\*\*\*).

When a measurement is in progress, the background of the lower part of the parameter field turns white.

During low systolic or diastolic pulse amplitudes or significant motion artifacts, the parameter field may only display a mean value. If the M540 is in venousstasis mode, the cuff pressure and the label **Venous stasis** appears in the non-invasive blood pressure parameter field.

If you cannot apply the cuff at heart level, adjust the displayed systolic and diastolic non-invasive blood pressure values as follows: add 8 mmHg (1.1 kPa) for each 10 cm (4 in) above the heart; subtract 8 mmHg (1.1 kPa) for each 10 cm (4 in) below the heart.

# Non-invasive blood pressure parameter field

The non-invasive blood pressure parameter field contains the following elements:



- A Non-invasive blood pressure parameter label
- B Unit of measurement
- C Systolic and diastolic pressure value
- D Crossed triangle symbol when the NIBP D (diastolic) alarm is turned off.
- E Crossed triangle symbol when the NIBP M (mean) alarm is turned off.
- F Mean pressure value
- **G** Crossed triangle symbol when the NIBP S (systolic) alarm is turned off.

The inflation pressure value and the label *Inflation pressure* appear when a measurement is in progress.

#### NOTE

An interval timer bar appears in the parameter field between interval measurements.

## Non-invasive blood pressure measurement modes

#### WARNING

Press the NIBP start/stop key to deflate the cuff rapidly if an adverse effect occurs on the patient.

The following non-invasive blood pressure measurement modes are available:

- Single
- Interval
- Continuous
- Venous stasis

The selected mode affects the appearance of the non-invasive blood pressure parameter field (see page 219).

Before taking any non-invasive blood pressure measurements, read the precautions on see page 215.

At the beginning of a measurement, the M540 inflates the cuff to a pressure that is 25 mmHg (3.3 kPa) for adult/pediatric and 30 mmHg (4 kPa) for neonate above the previously detected systolic value. If the M540 cannot obtain a valid measurement, it reinflates the cuff to the maximum inflation pressure provided the measurement cycle has not timed-out. If the M540 cannot obtain a measurement within the measurement cycle, no further attempts are made until the next scheduled interval or until you initiate a single measurement. Error messages identify the cause of failed measurements (see page 340).

The last non-invasive blood pressure measurement value is displayed in the parameter field until the new measurement is completed. New values appear at the end of a measurement at which point a chime sounds if the corresponding function was activated (see page 224).

#### Single-measurement mode

Single-measurement mode allows you to start measurements when needed. You can start and stop a single measurement any time.

#### To start a single measurement

Press the **NIBP** start/stop key on the M540. Pressing the key again stops the measurement.

#### Interval mode

#### WARNING

Because non-invasive blood pressure measurements occur intermittently, a patient's condition may change between measurements. Therefore, do not rely on noninvasive blood pressure alarms alone to notify you of a patient's changing condition.

In interval mode, the M540 initiates measurements at set intervals. Changing the interval setting during a measurement resets the interval timer. If you select another interval setting after interval mode was deactivated, you must press the *NIBP* start/stop key on the front of the M540 for interval measurements to start.

#### NOTE

A safety timer ensures that a cuff remains deflated for at least 30 seconds before the end of a measurement and the beginning of a new one. This precaution avoids prolonged impeded blood flow which could be harmful. The safety timer overrides any interval setting and is of particular importance in the 1 and 2-minute intervals.

You can still take single measurements during an interval cycle.

Interval measurements are not possible during:

- Venous-stasis mode the measurements resume immediately after the cuff deflates.
- Cardiac bypass mode press the *NIBP* start/stop key to resume interval measurement after exiting cardiac bypass mode.
- Standby mode press the *NIBP* start/stop key to resume interval measurement after exiting standby mode.
- Activated Continuous mode.

#### To activate or deactivate interval mode

- 1 Touch the non-invasive blood pressure parameter field.
- 2 Touch the Settings tab.
- **3** Touch the *Interval time* button and select the desired time (*Off*, 1, 2, 2.5, 3, 5, 10, 15, 20, 25, 30, 45, 60, 120, or 240 min).

For any interval setting of 5 minutes and up, the following time alignment occurs. After the first measurement is completed, all subsequent measurements align with the next natural time boundary that corresponds to the selected interval. For example, if a 5-minute interval is selected at 10:03, the next interval starts at 10:05, 10:10 and so on. If a 10-minute interval is selected at 10:07, the next interval starts at 10:10, 10:20, and so forth.

4 Touch **X** to close the dialog.

#### To start interval measurements

Press the NIBP start/stop key on the M540.

#### To stop interval measurements

Press the NIBP start/stop key on the M540.

#### NOTE

Pressing the *NIBP* start/stop key longer than two seconds suspends interval mode and sets the *Interval time* to *Off*.

If the M540 is power cycled while in interval mode, you must press the *NIBP* start/stop key to resume interval measurements.

#### **Continuous measurements**

#### WARNING

When using continuous mode, observe the patient closely and verify limb perfusion clinically. Be extra vigilant when using continuous mode on neonates or hemodynamically compromised patients.

In continuous mode, the M540 continuously initiates the non-invasive blood pressure measurements over a 5-minute period.

A 10 second ( $\pm$ 1 second) minimum interval between the end of one measurement and the start of another provides minimal perfusion of the limb.

#### To activate or deactivate continuous mode

- 1 Touch the non-invasive blood pressure parameter field.
- 2 Touch the Settings tab.
- **3** Make sure venous stasis is not activated (see page 222).
- 4 Touch the *Continuous mode* button until it toggles to *On* or *Off*.
- **5** Touch **X** to close the dialog.

#### NOTE

Continuous mode prevents you from enabling venous stasis.

#### To stop continuous measurements

Do one of the following:

Press the NIBP start/stop key on the M540,

or

Touch the non-invasive blood pressure parameter field > Settings > Continuous mode button until it toggles to Off.

## Venous stasis

By maintaining a constant cuff pressure, the M540 stops the blood flow to the lower extremity of the cuffed limb long enough to cannulate a patient. In this mode, the cuff occludes the limb for about as long as a non-invasive blood pressure measurement takes (approximately two minutes for adults and approximately one minute for neonates).

#### WARNING

Do not use venous stasis on a limb that is unsuitable for non-invasive blood pressure measurements (for example, an arm with a catheter). If the patient experiences adverse reactions, immediately press the *NIBP* start/stop key to deflate the cuff.

During venous stasis the monitor determines the initial and maximum cuff inflation pressure and inflation time based on the patient category.

Inflation	Adult	Pediatric	Neonatal
Initial and maxi- mum inflation pressure (mmHg)	80 ±5	60 ±4	40 ±3
Inflation time (s)	120 ±5	120 ±5	60 ±2.5

#### Activating or deactivating venous stasis

#### NOTE

Make sure continuous mode is not enabled (see page 221) because it prevents you from using venous-stasis mode.

#### To activate or deactivate venous stasis

- 1 Touch the non-invasive blood pressure parameter field.
- 2 Touch the Settings tab.
- 3 Make sure continuous mode is not activated (see page 221).
- 4 Touch the *Venous stasis* button until it toggles to *On* or *Off*.
- 5 Touch X to close the dialog.

#### NOTE

When the venous-stasis mode begins, an attention tone sounds.

Interval measurements are suspended during venous stasis but resume immediately after the cuff deflates.

## Accessing the non-invasive blood pressure dialog

- 1 Touch the non-invasive blood pressure parameter field.
- 2 Touch the **Settings** tab,

or, if the parameter is not displayed

Touch any parameter field > **Settings** tab > **Change parameter**.

- **3** Touch the desired parameter label to display it on the main screen.
- 4 Touch the parameter field > **Settings** tab.

## Non-invasive blood pressure parameter setup functions

All non-invasive blood pressure parameter setup functions take place in the non-invasive blood pressure dialog (see "Accessing the non-invasive blood pressure dialog" on page 223). The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description	
Settings			
Interval time <sup>1)</sup> (Cardiac bypass mode automatically deactivates interval measurements)	<b>Off</b> (default), 1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 25 min, 30 min, 45 min, 60 min, 120 min, 240 min	Defines intervals for the non-inva- sive blood pressure measure- ments.	
Inflation mode	Adult (default), Pediatric, Neonate	Sets a threshold for maximum cuff inflation.	
Continuous mode <sup>1)</sup>	<b>On</b> , <b>Off</b> (default)	Initiates successive non-invasive blood pressure measurements for 5 min.	
Chime <sup>1)</sup>	<b>On</b> , <b>Off</b> (default)	Determines if a tone sounds at the end of a completed non-invasive blood pressure measurement.	
Venous stasis 1)	<b>On</b> , <b>Off</b> (default)	Stops blood flow to the lower part of the cuffed limb for a fixed time.	
Color <sup>1)</sup>	Red, White (default), Yellow, Green, Light blue, Blue, Purple, Orange	Determines the color of the pa- rameter labels and values.	
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.	
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.			

## Invasive pressures (IP)

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## Overview of invasive pressure monitoring

The M540 acquires, processes, and displays invasive pressure signals and relays the data to the Cockpit. Several pods are available for monitoring invasive pressure. Monitoring more than two pressures simultaneously requires the Multi-IP option.

IP measurements are for adult, pediatric, and neonatal patients.

The IP monitoring functions are configurable in the parameter-specific dialog (see page 242).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 11.

Parameter-specific error messages are listed on page 344.

#### Supported parameters

See page 236 for available IP pressure labels.

- If both an arterial blood pressure and ICP are connected, the algorithm computes the difference between ICP and mean arterial blood pressure and reports it as CPP (applicable to ICP, ICP2, ICP3, and ICP4).
- If both an arterial blood pressure and BDP are connected, the algorithm computes the difference between BDP and mean arterial blood pressure and reports it as BPP.
- If both an arterial blood pressure and ABD are connected, the algorithm computes the difference between ABD and mean arterial blood pressure and reports it as APP.

#### Hemodynamic pods

Invasive pressure signals originate from the following hemodynamic pods:

- Hemo4 pod
- Hemo2 pod
- Infinity MPod Quad Hemo (MPod Quad Hemo)
- Infinity MCable Dual Hemo (Dual Hemo MCable)

#### Hemo4 pod

This pod measures up to four pressures, cardiac output, and temperature.



- A Key →0< for zeroing all pressures simultaneously (see page 238)
- **B** Key for starting a cardiac output measurement
- **C** Wedge button for starting wedge pressure measurements
- D Pressure label windows
- E Transducer slots

#### NOTE

The connectors for temperature and cardiac output are located on the side of the hemodynamic pod.

#### Hemo2 pod

This pod measures up to two pressures, cardiac output, and temperature.



- A Key →0< for zeroing all pressures simultaneously (see page 238)
- B Key for starting a cardiac output measurement
- **C** Key button for starting wedge pressure measurements
- D Pressure label windows
- E Transducer slots

#### NOTE

The connectors for temperature and cardiac output are located on the side of the hemodynamic pod.

#### MPod – Quad Hemo

This pod measures up to four pressures, cardiac output, and temperature.



- F Key →0< for zeroing all pressures simultaneously (see page 238)
- G Key for starting a cardiac output measurement
- H Key for starting wedge pressure measurements
- I Intermediate cables for attaching the transducers.

#### NOTE

The connectors for temperature and cardiac output are located on the side of the hemodynamic pod.

#### **Dual Hemo MCable**

This Dual Hemo MCable measures up to two pressures.



- A Dual Hemo MCable connector that connects to the M540.
- **B** Intermediate cables for attaching the transducer adapter cables.

## Invasive pressure precautions

#### WARNING

To prevent patient injury, never reuse a single-use transducer.

#### WARNING

Do not zero all pressures simultaneously using the >0< key if any pressure waveform is flat (nearly static).

## Connecting the Hemo4 and Hemo2 pods

The Hemo4 and Hemo2 pods connect directly to the M540. The following diagram shows where the gray hemodynamic port (A) is located on the side of the M540.



- A Hemodynamic port on the M540
- **B** Hemodynamic port on the pod
- C Pod connection cable
- D Transducer cable
- E Transducer slot
- F Transducer adapter cable
- G Invasive pressure adapter block

#### To connect the Hemo4 and Hemo2 Pod

- 1 Attach the invasive pressure adapter (G) to the bottom of the Hemo4/Hemo2 pod.
- 2 Connect one end of the connection cable (C) to the Hemo4/Hemo2 port (B).



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- 3 Connect the other end of the connection cable(C) to the gray hemodynamic port of the M540(A).
- 4 Attach the transducers to the transducer slot (E).
- 5 Connect the transducer adapter cables (F) to the transducer cable (D).

## Connecting the MPod – Quad Hemo

The MPod – Quad Hemo connects directly to the M540.



### To connect the MPod – Quad Hemo

- Connect one end of pod connection cable (C) to the connector located on the right side of the MPod – Quad Hemo (B).
- 2 Connect the other end of the connection cable (E) to the gray Hemo connector of the M540 (A).
- **3** Insert the transducers into the transducer slots (D).
- 4 Connect the transducer cables (F) to the transducer adapter cable (G).

The transducer adapter cables are permanently fastened to the back of the MPod – Quad Hemo.

- A Hemodynamic port on the M540
- B MPod Quad Hemo
- C Red connector of the pod connection cable
- D Transducer slot
- E Gray connector of the pod connection cable
- F Transducer cable
- G Transducer adapter cable

## Connecting a second MPod – Quad Hemo

Connecting a second MPod – Quad Hemo to the first MPod – Quad Hemo provides support for an additional four invasive pressure measurements.



- A Hemodynamic port on the M540
- B MPod Quad Hemo
- C Transducer
- D Red connector of the pod connection cable
- E Gray connector of the pod connection cable
- F Transducer cable
- **G** Gray connector of the pod-to-pod connection cable
- H Red connector of the pod-to-pod connection cable

#### To connect a second MPod – Quad Hemo

- Connect the gray connector of the pod connection cable (E) to the hemodynamic port on the M540 (A).
- Connect the red connector of the pod connection cable (D) to the connector located on the right side of the first MPod – Quad Hemo (B).
- Connect the gray connector of the pod-to-pod connection cable (G) to the first MPod – Quad Hemo (B).
- 4 Connect the red connector of the pod-to-pod connection cable (H) to the second MPod Quad Hemo.

#### NOTE

An audible tone annunciates when zeroing succeeds.

#### NOTE

Cardiac output measurements can only be performed on the first MPod – Quad Hemo.

#### NOTE

The C.O. Start key on the second MPod – Quad Hemo is disabled.

#### NOTE

The Temp A and C.O./Temp B connections are disabled on the second MPod – Quad Hemo.

#### NOTE

Unplugging the second MPod – Quad Hemo will automatically power-cycle the first MPod – Quad Hemo. This erases the zero reference for all existing invasive pressure channels.

After unplugging the second MPod – Quad Hemo:

- Re-zero all existing invasive pressure channels.
- If you are using the arterial invasive pressure signal with the MCable – Analog/Sync, re-zero the arterial invasive pressure channel.

#### NOTE

If two MPod – Quad Hemos are daisy-chained, then the second MPod – Quad Hemo's temperature ports will not provide a temperature reading.

## **Connecting the Dual Hemo MCable**

The Dual Hemo MCable connects directly to the M540.



#### To connect the Dual Hemo MCable

- 1 Attach the transducers (D) to the transducer adapter cables (C). The transducer adapter cables are permanently fastened to the Dual Hemo MCable.
- 2 Connect the Dual Hemo MCable connector (B) to the gray hemodynamic port (A) on the M540.

### **Preventing fluid ingress**

Refer to the following figure to correctly position the Dual Hemo MCable to prevent fluids from entering the ports where the transducer cables are attached.



- A Hemodynamic port on the M540
- B Dual Hemo MCable connector
- C Transducer adapter cable
- D Transducer
- E Transducer cables

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## Patient preparation for invasive pressure monitoring

#### NOTE

If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubbles may lead to wrong pressure measurement values.

The following tips provide optimal invasive pressure monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

- When preparing the patient, make sure there are no air bubbles in the sensor or the stopcock.
- For maximum signal strength, choose the shortest possible length of high-pressure tubing. Shorter tubing reduces signal attenuation but is more susceptible to motion artifacts. High-pressure tubing limits signal dampening.
- Position the transducer so that it is level with the appropriate anatomical reference point for each monitored pressure.

## Invasive pressure display

On the M540, the invasive pressure display consists of:

- Invasive pressure parameter field
- Invasive pressure waveform

#### Invasive pressure parameter field

The content of the invasive pressure parameter fields depends on whether the parameter is pulsatile or non-pulsatile. Parameter fields for pulsatile pressures (GP1, GP2, GP3, GP4, ART, AOR, FEM,GP5, GP6, GP7, GP8, AXL, RAD, UAP, BRA, LV, PA, RV,) display systolic, diastolic, and mean pressure values.

Parameter fields for non-pulsatile pressures (LA, RA, CVP, ICP, ICP2, ICP3, ICP4, ABD, BDP, ESO, FEMV, UVP, GPM) display only the mean pressure value.

If the M540 detects a static pressure, the algorithm computes only the mean pressure. A static pressure condition occurs when the maximum and minimum values of a pulsatile pressure signal differ by less than 3 mmHg (0.4 kPa).

An invasive pulsatile pressure parameter field contains the following elements:



An invasive non-pulsatile pressure parameter field contains the following elements:



- A Invasive pressure parameter label
- B Unit of measurement
- C Systolic/diastolic pressure values
- **D** Crossed triangle symbol when the diastolic invasive pressure alarm is turned off.
- **E** Crossed triangle symbol when the mean invasive pressure alarm is turned off.
- F Mean pressure value
- **G** Crossed triangle symbol when the systolic invasive pressure alarm is turned off.

- A Invasive pressure parameter label
- B Unit of measurement
- C Mean pressure value
- **D** Crossed triangle symbol when the diastolic invasive pressure alarm is turned off.

## Labeling Invasive pressure channels

The invasive pressure label determines how a signal is analyzed and reported. The M540 takes the pressure labels from the connected pod or MCable provided the transducers are connected. When a new label is assigned to a pressure channel, the M540 clears the parameters and conditions set for the previous label (including alarms and waveform scales) and replaces them with the settings of the new label.

The following rules apply to labeling pressure channels:

 If no pressure labels are assigned, the labels GP1 to GP8 are automatically assigned depending on how many pressures are connected

#### NOTE

If the M540 displays the generic pressure labels (GP1, GP2, GP3, GP4...), the displays on the Hemo2 and Hemo4 pods are labeled (P1a, P1b, P1c, P1d...).

 The zero value, the date, and time are associated with the pressure channel remain unchanged even if a new label is assigned

#### To assign a pressure label manually

- 1 Touch the invasive pressure parameter field.
- 2 Touch the Settings tab.
- 3 Touch Edit label.
- 4 Touch the appropriate pod label *Pod 1A label, Pod 1B label*, and so on.
- 5 Touch the new pressure label.
- 6 Touch X to close the dialog.

Or

- 1 Touch the *Menu* function key.
- 2 Touch Label IP.

## Standard pressure labels

The M540 detects the labels automatically from the hemodynamic pod, provided a transducer is connected. The M540 transfers the labels to the Cockpit.You can also label pressure channels manually. The following table lists the available invasive pressure labels.

Invasive pressure labels			
Label	Pressure type	Measured pressures	Measurement range
ART	Arterial blood pressure	Systolic, diastolic, mean	-50 to +400 mmHg
AOR	Aortic arterial blood pressure		–6.6 to +53.3 kPa
FEM	Femoral arterial blood pressure		
AXL	Axillary arterial blood pressure		
RAD	Radial arterial blood pressure		
UAP	Umbillical arterial blood pressure		
BRA	Brachial arterial blood pressure		
LV	Left ventricular blood pressure		
PA	Pulmonary arterial blood pres- sure		
RV	Right ventricular blood pressure		
CVP	Central venous blood pressure	Mean	
FEMV	Femoral venous blood pressure		
ESO	Esophageal pressure		
UVP	Umbilical venous pressure		
RA	Right atrial blood pressure		
LA	Left atrial blood pressure		
ICP	Intracranial pressure		
CPP <sup>1)</sup>	Cerebral perfusion pressure		
ICP2	Intracranial pressure 2		
CPP2 <sup>1)</sup>	Cerebral perfusion pressure 2		
ICP3	Intracranial pressure 3		
CPP3 <sup>1)</sup>	Cerebral perfusion pressure 3		
ICP4	Intracranial pressure 4		
CPP4 <sup>1)</sup>	Cerebral perfusion pressure 4		
ABD	Abdominal pressure		
APP <sup>1)</sup>	Abdominal perfusion pressure		
BDP	Bladder pressure		
BPP <sup>1)</sup>	Bladder perfusion pressure		
Generic labels			
GP1 to GF	28	Systolic, diastolic, mean	
GPM	Mean general pressure	Mean	

Invasive pressure labels			
Label	Pressure type	Measured pressures	Measurement range
<sup>1)</sup> The perfusion pressure value is only calculated when ICP/ABD/BDP and arterial blood pressure values are available.			

## Pressure label conflicts

Each pressure label is assigned to one location. If you try to reuse a label, you must confirm it. The M540 assigns the label to the currently selected parameter field and places an automatic pressure label (GP1 to GP8) in the previous location. When the M540 is docked in an IACS configuration, the pressure labels are saved as part of the M540 profile.

#### Pod-M540 label conflicts

The hemodynamic pods store pressure labels like the M540. When a pod with previously stored labels is connected, different pressure labels may exist for the same channel, thus causing a conflict.

The label stored in the M540 has priority over the label stored in the pod. When a patient monitored by a standalone M540 is discharged, the label from the M500 patient profile then takes priority over the label stored in the M540.

## Zeroing a pressure transducer

To establish accurate invasive pressure values, zero the transducer according to the hospital's protocol at least once a day. Perform additional zeroing under the following circumstances:

- After introducing a catheter into the vascular system of the patient
- Before each monitoring session
- Each time you use a new transducer or tubing
- Whenever you connect the transducer cable to the monitor
- If the reported pressure values seem incorrect
- When the message check zero appears

For zeroing to be successful, a pressure must be stable for at least 3 seconds. Messages report the status of the zeroing process. The time and date of the last successful zero is recorded on the invasive pressure page. Check the invasive pressure waveform and repeat the zeroing procedure if the zeroing fails because the pressures are not static. If the procedure fails after two attempts, replace the transducer or consult specialized service personnel.

#### Zeroing a specific transducer

This procedure allows you to select a specific transducer for zeroing.

#### To zero a specific sensor

- 1 Touch the appropriate invasive pressure parameter field.
- 2 Touch the Settings tab.

- **3** Align the transducer to the level of the heart (phlebostatic axis point, fifth intercostal space and midaxillary line).
- 4 Close the transducer stopcock to the patient and open it to air.
- 5 Touch Zero on the M540.

If the zeroing of the transducer is successful, the message **Zero accepted** appears. If zeroing fails, the message **did not zero** appears. In that case, repeat steps three to five.

6 Touch **X** to close the dialog.

#### Zeroing all pressure transducers

This procedure zeroes all pressure transducers simultaneously.

Zeroing all pressures simultaneously from the Hemo4 pod, the Hemo2 pod, and the MPod – Quad Hemo automatically zeroes all transducers open to air simultaneously.

# To zero all pressure transducers from the hemodynamic pods

- 1 Align the transducer to the level of the heart (phlebostatic axis point, fifth intercostal space and midaxillary line).
- 2 Close the stopcocks to the patient, and open them to air.
- 3 Press the >0< key (A) on the Hemo4, Hemo2, or the MPod Quad Hemo.



#### WARNING

Using the >0< key on the hemodynamic pods zeroes all static invasive pressures < 3 mmHg.

Certain invasive pressure alarms are suppressed while pressures are being zeroed. For detailed information, see *Zeroing invasive blood pressures* in the Alarms chapter.

#### WARNING

Do not zero all pressures simultaneously using the >0< key if any pressure waveform is flat (nearly static).



4 Verify that the transducers have been zeroed. If zeroing failed, repeat steps two and three.

#### CAUTION

Pressing the zero key on either MPod – Quad Hemo will zero all available invasive pressures from both MPod – Quad Hemos.

## Pulmonary wedge pressure

You cannot request pulmonary wedge pressures directly from the M540. For more information on requesting pulmonary wedge pressures when the

M540 is part of IACS, refer to the Instructions for use *Infinity Acute Care System – Monitoring Applications*.

### Accessing the invasive pressure dialog

- 1 Touch the invasive pressure parameter field.
- 2 Touch the Settings tab.

Or, if the parameter is not displayed

- 1 Touch any parameter field > **Settings** tab > **Change parameter**.
- 2 Touch the desired parameter label to display it on the main screen.
- 3 Touch the parameter field > **Settings** tab.

## Invasive pressure parameter setup functions

All invasive pressure setup functions take place in the invasive pressure dialog (see "Accessing the invasive pressure dialog" on page 241). The limits dialog contains the **Auto set** and **Alarm** buttons for configuring the alarm functions. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

Selection	Available settings	Description
	Settings	
Zero	None	Zeroes only the pressure indicated on the invasive pressure page and displays the time and date of the last zeroing (see page 239).
Edit label <sup>1)</sup>	ART, AOR, FEM, AXL, RAD, UAP, BRA, LA, LV, PA, RV, RA, ABD, BDP, CVP, ESO, FEMV, ICP, ICP2, ICP3, ICP4, LA, GPM, RAD, UVP, GP1 to GP8	Allows the user to assign a label to each pressure channel 1 through 8.
	The defaults are as follows:	
	– Channel 1: <i>GP1</i>	
	– Channel 2: <b>GP2</b>	
	– Channel 3: GP3	
	– Channel 4: <i>GP4</i>	
	– Channel 5: <b>GP5</b>	
	– Channel 6: <b>GP6</b>	
	– Channel 7: GP7	
	– Channel 8: GP8	
Filter <sup>1)</sup>	8 and 16 Hz (default)	Selects the filter setting applied to the invasive pressure signal.

Selection	Available settings	Description	
Color <sup>1)</sup>	Red, White, Yellow, Green, Light blue, Blue, Purple, Orange	Determines the color of the waveforms, and the parameter	
	The various invasive pressure parameters have the following defaults:		
	<ul> <li>ART, AOR, FEM, AXL, RAD, UAP, BRA, GP1 to GP4 = Red</li> </ul>		
	- PA, LV, BDP = Yellow		
	<ul> <li>CVP, ABD, ESO, FEMV, GPM, UVP</li> <li>Blue</li> </ul>		
	- ICP, ICP2, ICP3, ICP4, LA = Purple		
	<ul> <li>RA, RV, GP5 to GP8 = Orange</li> </ul>		
Change parameter	A list of currently available parameters.	Changes the parameter field to a different parameter.	
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.			

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## Cardiac output

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## Overview of cardiac output monitoring

The M540 uses the thermodilution method to compute cardiac output for adult and pediatric patients. Cardiac output monitoring is not intended for neonatal patients.

The MPod – QuadHemo, the Hemo4 and Hemo2 pods connect to the M540 and acquire the blood, and the injectate temperatures which are used to compute the cardiac output value.

Although the M540 processes the cardiac output algorithms, you can only view the data and execute cardiac output functions on the Cockpit when the M540 is docked in an IACS configuration. For more information, refer to the Instructions for use *Infinity Acute Care System – Monitoring Applications*.

#### Cardiac output measurement method

A solution of known temperature and volume is injected into the blood stream in the right atrium. A thermistor in the catheter tip continuously measures the temperature of the blood as it leaves the heart. The injectate mixes with and cools the surrounding blood. The blood reaches its minimum temperature relatively quickly and then warms up slowly until it returns to the baseline blood temperature. The total drop in blood temperature is inversely related to the cardiac output of the patient. The lower the cardiac output value, the more the injectate cools the blood. When computing cardiac output, the M540 takes the following factors into account:

- Injectate volume, temperature, density, and specific heat of the fluid that is being injected
- Baseline blood temperature, density, and specific heat
- Temperature changes of the blood injectate mixture
- Area under the temperature curve

Before performing any monitoring functions, refer to the section "For your safety and that of your patients"on page 11.

Parameter-specific error messages are listed on page 346.

#### Supported parameters

The following parameters are available on the Cockpit when the M540 is docked:

- C.O. Cardiac output
- Tblood Blood temperature
- Tinj Injectate temperature

## **Cardiac output precautions**

#### WARNING

An incorrect computation constant may yield incorrect cardiac output measurements and put the patient at risk. Confirm that the manually entered computation constant is correct for the catheter you are using.

#### WARNING

Verify that you enter the patient's current weight (not his or her 'admit' weight). Failure to enter an accurate weight value can result in inaccurate calculations and put the patient at risk.

#### NOTE

C.O. monitoring is only supported on the first MPod – QuadHemo in a daisy-chained configuration.

## Connecting the cardiac output hardware

You can connect the hemodynamic cable to one of the following devices:

- MPod QuadHemo
- Hemo4 pod
- Hemo2 pod

#### NOTE

Cardiac output is only supported from the first MPod in a daisy-chain configuration.

The intermediate cable from any of the above devices connects directly to the M540.



- A M540 hemodynamic port
- B Gray connector of the hemodynamic cable
- **C** Red connector of the hemodynamic cable
- D MPod QuadHemo hemodynamic port
- **E** Pod connector of the cardiac-output intermediate cable
- **F** Cardiac output port of the MPod QuadHemo
- **G** Thermistor port of the cardiac-output intermediate cable
- H Catheter cable and thermistor cable

# To connect the cardiac output hardware to the MPod – QuadHemo

- 1 Connect the gray connector of the hemodynamic cable (B) to the gray hemodynamic port (A) of the M540.
- 2 Connect the red connector of the hemodynamic cable (C) to the MPod QuadHemo hemody-namic port (D).
- 3 Connect the pod connector of the cardiac-output intermediate cable (E) to the cardiac output port of the MPod – QuadHemo (F).
- 4 Connect the catheter and the thermistor cables (H) to the thermistor port of the cardiac-output intermediate cable (G).



- A M540 hemodynamic port
- B Gray connector of the hemodynamic cable
- **C** Red connector of the hemodynamic cable
- D MPod Quad Hemo hemodynamic port
- E Pod connector of the cardiac-output intermediate cable
- F Cardiac-output port of the MPod Quad Hemo
- **G** Thermistor port of the cardiac-output intermediate cable
- H Catheter cable and thermistor cable

## To connect the cardiac output hardware to the Hemo4 and the Hemo2 pods

- 1 Connect the hemodynamic cable connector (B) to the gray hemo connector (A) of the M540.
- 2 Connect the red connector of the hemodynamic cable (C) to the Hemo4/Hemo2 connector (D).
- 3 Connect the pod connector of the cardiac-output intermediate cable (F) to the cardiac output connector of the Hemo4/Hemo2 pod (E).
- 4 Connect the catheter and the thermistor cables (H) to the thermistor port of the cardiac-output intermediate cable connector (G).

## Patient preparation for cardiac output monitoring

The following tips provide optimal cardiac output monitoring results but must never replace hospitalapproved practices or manufacturer's recommendations.

- Follow the recommendations of the manufacturer. Dräger recommends that you place prefilled syringes or the closed injectate delivery system into an ice bath.
- Check the ice bath regularly and add ice to maintain a temperature between 0 °C (32 °F) and 5 °C (41 °F). The accuracy of measurements done with the thermodilution method increases as the temperature of the injectate approaches 0 °C (32 °F).

#### NOTE

For the most accurate results when using an injectate at room temperature, use a 10 cc injectate volume unless clinically contraindicated.

- Verify the injectate volume.
- Verify the proper selection of catheter type and size or computation constant if **Other** is chosen for the catheter type.

- Use an in-line injectate system. Systems that measure the injectate temperature in the ice bath can introduce errors. These errors happen because the injectate temperature changes between its removal from the ice bath and the injection.
- If you fill your syringes manually, fill them with the same volume each time. The recommended amount is 10 cc for adults and 5 cc for pediatric patients. Do not touch the body of the syringe to avoid warming the injectate.
- Inject the entire volume in one swift, continuous motion.
- Perform the injection at the end of expiration. Taking successive cardiac output measurements at different points in the respiratory cycle provides different measurements, especially for patients on mechanical ventilators.
- Discard results that are widely different from the general trend, and results associated with irregularly shaped waveforms.

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## Mainstream CO2 monitoring

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## Overview of mainstream CO2 monitoring

The M540 provides fast and continuous mainstream measurements of carbon dioxide concentrations (CO<sub>2</sub>) in the airway of intubated patients. The M540 acquires signals from a CO<sub>2</sub> sensor (Infinity MCable – Mainstream CO<sub>2</sub>) which fits over a mainstream airway adapter. The lightweight, reusable CO<sub>2</sub> mainstream sensor provides sensitive and accurate measurements. It uses non-dispersive infrared technology to measure CO<sub>2</sub> in breathing gases.

CO<sub>2</sub> monitoring is available for adult, pediatric, and neonatal patients.

As respiration gases flow through the airway adapter, the sensor analyzes the expired and inspired air of the patient by sending a beam of infrared light through transparent ports in the airway adapter while detecting changes in CO<sub>2</sub> absorption levels.

Before performing any monitoring functions, refer to the section "For your safety and that of your patients"on page 11.

Parameter-specific error messages are listed on page 346.

#### Supported parameters

- etCO2 (end-tidal CO2 concentration)
- inCO2 (inspiratory CO2 concentration)
- *RRc* (respiratory rate derived from CO<sub>2</sub> measurement)

## **CO2 precautions**

#### WARNING

RRc apnea alarms are NOT reported if the setting *RRc apnea time* is set to *Off* in the CO<sub>2</sub> setup page and the RRc alarm feature is deactivated. To generate RRc apnea alarms, activate the RRc alarms and select an RRc apnea alarm time.

#### WARNING

The safety and effectiveness of the respiration measurement method in apnea detection, particularly the apnea of prematurity and apnea of infancy, has not been established.

### WARNING

Patient monitors that measure CO<sub>2</sub>, anesthetic agents, and/or respiratory mechanics are not intended to be used as an apnea monitor and/or recording device. While these products provide an apnea alarm, that alarm condition is initiated based on the elapsed time since the last breath was detected. Clinical diagnosis of a true apneic event, however, requires multiple physiological signals.

#### WARNING

CO2 alarms do not activate until the first breath is detected after turning on the monitor or discharging a patient.
#### WARNING

The surface temperature of the sensor may rise to 43 °C (109 °F). Prolonged exposure to the patient's skin may result in a burn.

#### CAUTION

Leaks in the breathing circuit (for example, an uncuffed endotracheal tube or a damaged airway adapter) may significantly affect CO<sub>2</sub> measurement values.

### CAUTION

To avoid accidental disconnections, do not apply excessive tension to any sensor cable.

### CAUTION

To prevent leakage, make sure the airway adapter is firmly connected to the breathing circuit.

### CAUTION

Check the CO<sub>2</sub> mainstream sensor for damage before use. A damaged CO<sub>2</sub> sensor may impair galvanic isolation or may introduce debris into the breathing circuit.

### NOTE

Dräger CO<sub>2</sub> accessories that come in contact with the patient do not contain natural rubber latex.

### WARNING

For premature babies, do not carry out CO2 measurements because the CO2 cuvette significantly increases the dead space.

# Connecting the CO<sub>2</sub> sensor

Before connecting any CO<sub>2</sub> hardware, make sure the airway adapter in use matches the airway adapter setting of the M540 (see page 259). For example, do not use a disposable airway adapter if the M540 is configured for a reusable airway adapter (and vice versa). Not aligning the adapter with the configuration setting at the M540 compromises the displayed CO<sub>2</sub> value.

The M540 is only compatible with the CO<sub>2</sub> sensors 6871950 revision 5 or higher. Previous revisions are not compatible.





- D Y-piece
- E Airway adapter
- F Endotracheal tube adapter

### CAUTION

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Always position the sensor windows of the airway adapter vertically to prevent patient secretions from obscuring the adapter windows.

### To connect the CO<sub>2</sub> hardware

- 1 Connect the end of the CO<sub>2</sub> sensor cable (B) to the yellow CO<sub>2</sub> connector (A) on the M540.
- 2 Select a suitable adult or pediatric mainstream airway adapter (C) whose windows are clean and dry (replace the adapter if necessary).
- 3 Insert the airway adapter (E) between the endotracheal tube adapter (F) and the ventilator Y-piece (D).
- 4 Snap the CO<sub>2</sub> mainstream airway adapter (A) firmly on the airway adapter and make sure that the cable is directed away from the patient.

- A CO2 connector on the M540
- B CO2 sensor cable connector
- C Mainstream airway adapter

# Patient preparation for CO2 monitoring

The following tips provide optimal CO<sub>2</sub> monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

A default O<sub>2</sub> concentration of 21% (the percentage of oxygen in ambient air) for all CO<sub>2</sub> measurements is assumed. If the patient is receiving supplemental oxygen or N<sub>2</sub>O or Heliox, select the gas that is being administered in the CO<sub>2</sub> setup page. Make sure to adjust the ambient pressure to the actual measurement value manually. Automatic ambient pressure compensation is not provided. Failure to compensate for supplemental gases results in inaccurate CO<sub>2</sub> measurement values.

When switching adapter types (from reusable to disposable or adult to pediatric, or vice versa), there is no need to re-zero a Dräger sensor. If the sensor window is clean and the correct sensor type is selected under the *Airway adapter* in the CO2 dialog, only zero a Dräger sensor when the measurement value is suspect or when prompted to re-zero.

# CO<sub>2</sub> display

On the M540, the CO2 display consists of:

- CO2 parameter field
- CO2 waveform

## CO<sub>2</sub> parameter field

The CO<sub>2</sub> parameter field contains the following elements:



- A etCO2 label
- B Unit of measurement
- **C** Crossed triangle symbol when the etCO<sub>2</sub> alarm is turned off
- D inCO2 label
- E inCO2 value the level of CO2 in the airway during inspiration, taken as the minimum value during the previous measurement interval
- **F** Crossed triangle symbol when inCO<sub>2</sub> alarms are turned off
- **G** Crossed triangle symbol when RRc alarms are turned off
- H *RRc* value respiratory rate derived from the CO2 signal
- I RRc (respiratory rate derived from CO2 measurement) parameter label
- J etCO2 value highest average CO2 in the airway during expiratory phase

# CO2 waveform

The M540 also displays an instantaneous CO2 waveform.



- A Expiratory or alveolar plateau (level of CO<sub>2</sub> in lungs ceases to increase significantly)
- **B** Endtidal concentration point (end of expiratory phase, where CO<sub>2</sub> is measured)
- C Onset of inspiratory phase
- D Onset of expiratory phase
- E Baseline during inspiration

# Troubleshooting

In addition to evaluating the clinical status of a patient, CO<sub>2</sub> waveforms can help troubleshoot problems with equipment. The following table shows how CO<sub>2</sub> waveforms can be used to identify common problems.

Description	Cause	CO2 waveform								
Alveolar plateau showing a downward slope that merges with a descending limb.	<ul> <li>Inadequate seal around the endotracheal tube</li> </ul>	$\square$ $\land$ $\land$								
	<ul> <li>Leaky or deflated endotracheal or tracheostomy cuff</li> </ul>									
	<ul> <li>Artificial airway that is too small for the patient</li> </ul>									
Elevated waveform base- line with corresponding in- crease in CO <sub>2</sub> level.	<ul> <li>Rebreathing due to one of the following causes:</li> <li>Disposable airway adapter is used although the Cockpit is configured for the reusable adapter type</li> <li>Contaminated airway adapter (dirty window)</li> <li>CO2 zero drift</li> <li>Insufficient expiratory time</li> <li>Faulty expiratory valve</li> <li>Inadequate inspiratory flow</li> </ul>									
	<ul> <li>Malfunction of a CO<sub>2</sub> absorber system</li> </ul>									
	<ul> <li>Partial rebreathing circuits</li> </ul>									
Change in slope of ascend- ing limb. Possible absence of an alveolar plateau.	Obstruction caused by one of the following:	$\square \square \square$								
	limb of breathing circuit									
	- Foreign matter in upper airway									
	<ul> <li>Partially kinked or occluded ar- tificial airway</li> </ul>									
	<ul> <li>Herniated endotracheal or tra- cheostomy tube cuff</li> </ul>									
	<ul> <li>Bronchospasm</li> </ul>									
Elevated baseline, with	<ul> <li>Faulty ventilator circuit valve</li> </ul>									
pronounced slope on descending limb	<ul> <li>Rebreathing (see above)</li> </ul>	SVV								

# Using the CO<sub>2</sub> dialog

Setup for all CO<sub>2</sub> parameters takes place in the CO<sub>2</sub> dialog. This dialog contains the following tabs:

- CO2 limits used to set up upper alarm limits and lower alarm limits
- Mainstream used to set up associated CO2 parameters
- Calibration check used to perform a Mainstream sensor calibration check. For information about the Calibration check tab, see "Performing a calibration check"on page 261.

If the CO<sub>2</sub> MCable is not connected to the M540 patient monitor, then the *Microstream* tab also displays in the CO<sub>2</sub> dialog.

#### To access the Mainstream settings

If the parameter displays on the M540 patient monitor:

- 1 Touch the CO2 parameter field.
- 2 Touch the *Mainstream* tab.

Or, if the parameter field is not displayed:

- 1 Touch the parameter field > **Settings** tab > **Change parameter**.
- 2 Touch the desired parameter label to display it on the main screen.

### CO<sub>2</sub> limits

Setup for all CO2 alarm limit functions takes place in the **CO2 limits** dialog within the CO2 dialog. The *CO2 limits* dialog displays tabs on the right-side of the window for etCO2, inCO2, and RRc settings.

etCO2 and RRc allow adjustment of the alarm limits, use of the *Archive* feature, and use of *Auto set.* For inspiratory CO2 concentration, only the upper alarm limit and *Archive* can be used. For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

#### NOTE

The sensor must be removed from the airway adapter before zeroing. The sensor is zeroed in room air. Do not breathe on the airway adapter during zeroing. CO2-related alarms are disabled whenever the sensor is zeroing; however, active alarms continue to display during zeroing.

#### NOTE

CO2 limits settings apply to both Mainstream and Microstream.

# CO<sub>2</sub> parameter setup

All setup functions for CO<sub>2</sub> parameters take place in the CO<sub>2</sub> dialog.

For detailed information on alarm setup, see *Configuring a patient's alarm settings* in the Alarms chapter.

### NOTE

When a Scio module is connected, parameter controls for Scio are available only in the CO2 setup menu.

Selection	Available settings	Description			
<b>Zero</b> (only available if a CO2 device is con- nected)	None	Zeroes the CO <sub>2</sub> sensor if necessary. The CO <sub>2</sub> sensor stores a new zero point for CO <sub>2</sub> measurements.			
Atm. pressure <sup>1)</sup>	570 to 800 mmHg 760 mmHg (default)	Determines the ambient pressure setting of the sensor and compensates for pressure effects. Failure to compensate for pressure can cause inaccurate measurements.			
Gas compens. <sup>1)</sup>	<i>Air</i> (default), <i>№0/02</i> , O2 > 50%, <i>HeliOx</i>	Compensates for supplemental oxygen or N2O or <i>HeliOx</i> . Failure to compensate for supplemental oxygen can cause inaccurate measurements.			
<i>RRc apnea time</i> <sup>2)</sup>	<b>Off</b> (default), 10, 15, 20, 25, 30 s	Specifies the time the M540 waits before re- porting a cessation of breathing as an apnea event.			
Apnea archive <sup>2)</sup>	Off, Store (default), Str/Rec, Record	Determines what happens in response to an apnea.			
Airway adapter	<b>Reusable</b> (default), <b>Disposable</b>	Determines the type of airway adapter used for CO2 monitoring.			
		Compensates for the type of airway adapter that is being used.			
		Requires the user to match the adapter with the configuration setting at the M540; if the adapters do not match, the CO2 value displayed is compromised.			
Color <sup>2)</sup>	Red, White, Yellow (default), Green, Light blue, Blue, Purple, Orange	Determines the color of the waveforms, and the parameter labels and values.			

Selection	Available settings	Description						
Change parameter	CO2 (default)	Changes the parameter field to a different						
	Examples: HR, SpO2, PLS CO- Ox, CO2, NIBP, RRi, T, T1, GP1, GP2, GP3, GP4, ST	parameter.						
<sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.								

<sup>2)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.

# Performing a calibration check

The *Calibration check* tab is used to do the following tasks:

- View the date of the last calibration
- Perform a calibration check

A calibration check verifies that the CO2 sensor is within the acceptable calibration limits. If successful, the message **CO2 calibration check successful** displays on the M540. For descriptions of additional message conditions, see "Calibration and maintenance" on page 349. Perform a calibration check according to the healthcare facility's guidelines.

## **Required accessories**

Test filter (attached to the CO2 sensor and shown in the following figure).



Contact the biomed or service personnel for the required accessories, if needed.

#### To perform a calibration check

- 1 Select the Calibration check tab.
- 2 Follow the instructions as they display on the *Calibration check* window.
- 3 If the calibration check fails, follow the instructions that display on the M540 monitor or contact specialized service personnel.

### WARNING

**Risk of inaccurate patient results** 

A Microstream MCable that is out of calibration may provide inaccurate results.

If calibration does not take place as instructed, the Microstream MCable may be out of calibration.

Ensure the proper calibration of the Microstream MCable.

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# Microstream CO<sub>2</sub> monitoring

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# **Overview of Microstream CO2 monitoring**

The Infinity Microstream MCable, when connected to the *M540*, provides continuous sidestream measurements of carbon dioxide (CO<sub>2</sub>) concentrations for intubated and non-intubated patients.

The Microstream MCable is intended for use with adult, pediatric, and neonatal patients with the appropriate accessories.

The *M540* acquires signals from the *Infinity MCable – Microstream CO2* (subsequently referred to as the *Microstream MCable* and shown in the following figure): Before performing any monitoring functions, refer to the chapter "For your safety and that of your patients" on 11.

### Supported parameters

- etCO2 (end-tidal CO2 concentration)
- *inCO2* (inspiratory CO2 concentration)
- *RRc* (respiratory rate derived from CO<sub>2</sub>)

Parameter-specific error messages are listed on page 350.



The Microstream MCable enables the clinician to monitor CO<sub>2</sub> on the M540. It uses non-dispersive infrared technology to measure CO<sub>2</sub> in breathing gases. The Microstream MCable analyzes the expired and inspired air as the respiration gases flow through the sample line. It automatically compensates for ambient pressure within the defined operating ranges.

## Use models

The Microstream MCable can be used in numerous ways to monitor the CO<sub>2</sub> concentrations of a patient. The Microstream MCable docks to the back of the M540 or is used with a specialized clamp for mounting at the bedside or on a pole.

Refer to the following figures for examples of various setup options and the associated accessories. For a complete list of mounting and patient accessories, refer to the *Instructions for use* – *Infinity Acute Care System Monitoring Accessories*.

The following figure shows the Microstream MCable on the M540.



- A M540 patient monitor
- B SpO2 pod mount
- C Microstream MCable in the Microstream MCable holder

The following figure shows the Microstream MCable attached to a pole during transport or at the bedside.



- A Universal pole mount
- B Interface plate
- C Sample line
- D Microstream MCable in the Microstream MCable holder
- **E** Microstream extension cable (0.9 m)

The following figure shows the Microstream MCable during transport attached to a bedrail:



- A Microstream MCable in the Microstream MCable holder
- B Bed rail

Microstream extension cable (0.9 m) (not visible in photo)

C Sample line

## Accessories

Refer to the *Infinity Acute Care System Instructions* for use, Monitoring Accessories for available accessories used during Microstream CO2 monitoring.

# Precautions

### WARNING

**Risk of flammability** 

The sample line may ignite in the presence of O2 when directly exposed to laser, ESU devices, or high heat.

When performing head and neck procedures involving a laser, electrosurgical devices, or high heat, use the sample line with caution to prevent the sample line or surrounding surgical drapes from igniting.

### WARNING

Risk of blockage in sample line

Excessive moisture in the sample line may cause blockage due to the ambient humidity or breathing of unusually humid air.

If too much moisture enters the sample, the message *Sample line blocked* displays on the M540. Replace the sample line when this message appears.

### CAUTION

Risk due to leakage

Air leakage may cause inaccurate parameter readings.

To prevent leakage, make sure the airway adapter is firmly connected to the breathing circuit.

### CAUTION

Risk of blockage in the sample line

Do not immerse the Microstream MCable.

To prevent leakage, make sure the airway adapter is firmly connected to the breathing circuit.

### CAUTION

Risk due to high altitudes

In high-altitude environments, etCO2 values may be lower than values observed at sea level.

When using the Microstream MCable in high-altitude environments, consider adjusting etCO2 alarm settings accordingly.

#### WARNING

**Risk of electrical shock** 

Servicing by unauthorized personnel may cause electric shock.

To protect against electric shock, only qualified service personnel should remove the Microstream MCable cover. There are no userserviceable parts inside the device.

### WARNING

**Risk of flammability** 

Use of the Microstream MCable in a combustible atmosphere, such as in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide may increase the risk of flammability.

Do not use the Microstream MCable in a combustible atmosphere.

#### WARNING

Risk of air-quality contamination

Gas leakage may contaminate the air.

When using the Microstream MCable for a patient with anesthetics, nitrous oxide, or high concentrations of oxygen, connect the gas outlet to a scavenger system to contain these gases from being released to the surrounding atmosphere.

#### WARNING

**Risk of incorrect CO2 measurements** 

Electromagnetic interference may result in incorrect measurements in the Microstream MCable.

Operating high frequency electrosurgical equipment in the vicinity of the Microstream MCable can produce interference in the module resulting in incorrect measurements.

### WARNING

**Risk of patient injury** 

Unintentionally disconnecting the Microstream MCable from the device may injure the patient.

To prevent patient injury, do not lift the M540 by the CO<sub>2</sub> cable since the Microstream MCable could disconnect from the device and injure the patient.

# Connecting the Microstream MCable

This topic describes the steps to connect the Microstream MCable and its holder to the M540 patient monitor for CO<sub>2</sub> monitoring.

### **Required components**

- Microstream MCable
- Sample line (see Choosing a sample line on page 272)
- Accessories: Microstream MCable holder. SpO<sub>2</sub> mount

Refer to the Infinity Acute Care System Instructions for use, Monitoring Accessories for available Microstream MCable accessories.

#### To connect the Microstream MCable

This procedure describes how to attach the Microstream MCable to the M540 using the appropriate accessories. The SpO2 mount should already be attached to the M540 device. If this is not the case, contact specialized service personnel for assistance.

1 Slide the MCable holder (A) onto the SpO2 pod mount. The holder slides in only one direction:



2 Insert the Microstream MCable (B) into the flexible MCable holder (C) with the CO<sub>2</sub> port (D) facing as shown:



- 3 Connect the cable of the Microstream MCable to the yellow CO<sub>2</sub> connector on the M540.
- 4 Select the appropriate sample line according to the monitoring needs of the patient (see "Choosing a sample line"on page 272).
- **5** Open the door (E) on the Microstream MCable that covers the CO<sub>2</sub> port.
- 6 Insert the sample line connector into the CO<sub>2</sub> port while being careful to avoid releasing the door and catching the sample line.



- 7 Turn the connector clockwise to secure it in place. This placement ensures that gas does not leak from the connection point and provides accurate measurements.
- 8 Connect the sample line to the patient as described in the instructions for use supplied with the sample line.

#### CAUTION

Risk of damage to the Microstream MCable.

Sample lines are intended for single-patient use only.

Do not reprocess sample lines.

- 9 Check that the CO2-related information appears on the M540. If the CO2 information does not display, refer to the Troubleshooting" chapter on page 323 for message conditions. The M540 patient monitor begins to search for breaths and provides alarms only after a valid breath occurs. The Microstream MCable automatically compensates for ambient pressure within the defined operating ranges.
- **10** After completing the CO<sub>2</sub> monitoring procedure, detach the sample line.

**11** Discard the sample line as required by the healthcare facility protocols.

## Connecting to a scavenger system

The Microstream MCable provides an exhaust port (A) for a scavenger system, if needed.



# Additional Microstream MCable mounting options

The Microstream MCable can be mounted to the patient's bed rail or on an IV pole.

For more information on the Microstream MCable adapter kit, refer to the *Infinity Acute Care System Instructions for use, Monitoring Accessories.* 

### **Required accessories**

- Universal pole mount
- Interface plate
- Microstream MCable holder
- Extension cable (0.9 m, 2 ft 11 in) (optional)

# To mount the Microstream MCable to a pole or bed rail

1 Attach the universal pole mount (A) to the desired location on the pole or bed rail.



- 2 Pull up and turn the release knob (B) either horizontally or vertically to the desired position for the Microstream MCable.
- 3 Attach the interface plate (C) by sliding the plate between the two grooves on the universal pole mount.



4 Insert the Microstream MCable into the flexible holder.

5 Slide the Microstream MCable unit into the interface plate as shown:



Connect the extension cable to the MCable unit and the M540, if the cable is being used.

# **Detaching Microstream MCable and components**

The Microstream MCable and its components can be detached for storage or cleaning. For reprocessing recommendations, refer to "Reprocessing"on page 365.

# To detach the Microstream MCable from the M540 patient monitor

- 1 Disconnect the Microstream MCable connector from the M540 patient monitor.
- 2 Slide the Microstream MCable (A) out of the MCable holder (B).



3 Slide the Microstream MCable holder (C) off the SpO2 pod mount.



4 Reprocess or complete maintenance, as required by the healthcare facility.

# To detach the Microstream MCable from the IV pole or the bed rail

- 1 Disconnect the Microstream MCable connector from the M540.
- 2 Slide the Microstream MCable (A) out of the flexible holder (B).
- 3 Slide the Microstream MCable holder off the interface plate (C).
- 4 Slide the interface plate off the universal pole mount.



able\_onPole\_BW

# Choosing a sample line

Microstream monitoring requires Microstream sample lines. For additional information about Microstream FilterLines, other sample lines, or additional sizing, refer to the *Infinity Acute Care System Instructions for use, Monitoring Accessories* and refer to the sample line IFU.

To select the appropriate sample line for the patient, keep in mind the following conditions when choosing a sample line:

 Consider if the patient is ventilated or not ventilated to determine if an airway adapter or a cannula should be used.

- If ventilated, consider if the patient is humidified or non-humidified.
- Consider the size and weight of the patient in order to select the most appropriate sample line for the patient.
- Consider the probability that the patient could switch between oral and nasal breathing since certain accessories are appropriate for either situation.
- Consider the length of time the patient requires
   CO2 monitoring.

# CO<sub>2</sub> display

On the M540, the CO2 display consists of:

- CO2 parameter field
- CO2 waveform

## CO<sub>2</sub> parameter field

The CO<sub>2</sub> parameter field contains the following elements:



### A etCO2 label

- B Unit of measurement
- **C** Crossed triangle symbol when the etCO<sub>2</sub> alarm is turned off
- D inCO2 label
- E *inCO2* value the level of *CO2* in the airway during inspiration, taken as the minimum value within the measurement interval
- F Crossed triangle symbol when *inCO2* alarms are turned off
- **G** Crossed triangle symbol when *RRc* alarms are turned off
- **H** *RRc* value respiratory rate derived from the CO<sub>2</sub> measurement.
- I RRc parameter label
- J etCO2 value highest CO2 in the airway during expiratory phase within the measurement interval

## CO<sub>2</sub> waveform

The M540 also displays an instantaneous CO2 waveform.



- A Expiratory or alveolar plateau (level of CO<sub>2</sub> in lungs ceases to increase significantly)
- **B** Endtidal concentration point (end of expiratory phase, where CO<sub>2</sub> is measured)
- **C** Onset of inspiration phase
- **D** Onset of expiratory phase
- E Baseline during inspiration

# Troubleshooting

In addition to evaluating the clinical status of a patient, CO<sub>2</sub> waveforms help troubleshoot equipment problems. The following table shows how CO<sub>2</sub> waveforms can be used to identify common problems.

Description	Cause	CO2 waveform
Alveolar plateau showing a downward slope that merg-	<ul> <li>Inadequate seal around the endotracheal tube</li> </ul>	$\square$ $\land$ $\land$
es with a descending limb.	<ul> <li>Leaky or deflated endotracheal or tracheostomy cuff</li> </ul>	
	<ul> <li>Artificial airway that is too small for the patient</li> </ul>	
Elevated waveform base-	Rebreathing due to one of the fol-	
line with corresponding in-	lowing causes:	
crease in CO2 level.	<ul> <li>Insufficient expiratory time</li> </ul>	
	<ul> <li>Faulty expiratory valve</li> </ul>	
	<ul> <li>Inadequate inspiratory flow</li> </ul>	
	<ul> <li>Malfunction of a CO<sub>2</sub> absorber system</li> </ul>	
	<ul> <li>Partial rebreathing circuits</li> </ul>	

Change in slope of ascend-	Obstruction caused by one of the								
ing limb. Possible absence	following:	$\square$ $\land$ $\land$							
of an alveolar plateau.	<ul> <li>Partial obstruction in expiratory limb of breathing circuit</li> </ul>								
	<ul> <li>Foreign matter in upper airway</li> </ul>								
	<ul> <li>Partially kinked or occluded ar- tificial airway</li> </ul>								
	<ul> <li>Herniated endotracheal or tra- cheostomy tube cuff</li> </ul>								
	<ul> <li>Bronchospasm</li> </ul>								
Elevated baseline, with	<ul> <li>Faulty ventilator circuit valve</li> </ul>								
pronounced slope on de- scending limb	<ul> <li>Rebreathing (see above)</li> </ul>	$ \$							

# Using the CO<sub>2</sub> dialog box

Setup functions for CO<sub>2</sub> parameters take place in the CO<sub>2</sub> dialog. This dialog contains the following tabs:

- CO2 limits sets upper and lower limits
- Microstream sets associated CO2 parameters
- Calibration check performs a Microstream MCable calibration. For information about the Calibration tab, see "Calibration check"on page 276.

If the M540 patient monitor is not set up for CO<sub>2</sub> monitoring, then the *Mainstream* tab also displays in the CO<sub>2</sub> dialog.

### To access the Microstream settings

If the CO<sub>2</sub> parameter displays on the M540 device:

- 1 Touch the CO2 parameter field.
- 2 Touch the *Microstream* tab.
- Or, if the parameter field is not displayed:

- 1 Touch the parameter field > **Settings** tab > **Change parameter**.
- **2** Touch the desired parameter label to display it on the main screen.

### CO<sub>2</sub> limits

Setup functions for CO<sub>2</sub> parameters take place in the **CO<sub>2</sub> limits** dialog within the **CO<sub>2</sub>** dialog.

The **CO2** *limits* dialog displays tabs on the right side of the window for **etCO2**, *inCO2*, and **RRc** settings.

etCO2 and RRc allow adjustment of the upper and lower alarm limits, use of the Archive feature, and use of Auto set. For inspiratory CO2, only the upper limit and Archive can be used.

# CO<sub>2</sub> parameter setup

Setup functions for CO<sub>2</sub> parameters take place in the CO<sub>2</sub> dialog within the *Microstream* tab.

For detailed alarm setup information, see *Configuring a patient's alarm settings* in the Alarms chapter.

### NOTE

When a Scio module is connected, parameter controls for Scio are available only in the CO<sub>2</sub> setup menu.

Selection	Available settings	Description						
<i>RRc apnea time</i> <sup>1)</sup>	Off (default) 10 s, 15 s, 20 s, 25 s, 30 s	Specifies how long the M540 waits before re- porting a cessation in breathing as an apnea event.						
Apnea archive <sup>1)</sup>	Off, Store (default), STr/Rec	Determines what happens in response to an apnea event.						
Next service in:	Informational only (settings are not applicable)	The remaining number of hours until mainte- nance is required.						
Averaging	Instantaneous Last valid breath 10 s, 20 s (default), 30 s	Controls the specific time or the interval used to select the maximum measured <b>etCO2</b> and the minimum measured <b>inCO2</b> .						
Change parameter	CO <sub>2</sub> (default) ECG, ST, NIBP, etc.	Changes the current parameter to another pa- rameter.						
Color <sup>1)</sup>	Red, White, Yellow (default), Green, Light blue, Blue, Pur- ple, Orange	Determines the color of the CO2 waveform, and the parameter labels and values.						
<i>Last calibration:</i> Informational only Displays the date of the last calibration.								
<sup>1)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.								

# **Calibration check**

The *Calibration check* tab is used to perform the following tasks:

- Viewing the hours remaining until the next service check is due for the Microstream MCable
- Viewing the date of the last calibration
- Performing a calibration check

A calibration check verifies that the Microstream MCable is within the acceptable calibration limits. If the check is successful, the message *CO<sub>2</sub> calibration check successful* displays on the M540. For descriptions of additional message conditions, see "Calibration and maintenance"on page 349. Perform a calibration check according to the healthcare facility's schedule guidelines.

### **Required accessories**

- A gas canister (with a mix of 5% CO2, 21% O2, Balance: N2)
- Sample line

Contact the biomed or service personnel for the required accessories if needed.

### To perform a calibration check

- 1 Select the Calibration check tab.
- 2 Follow the instructions as they display on the *Calibration check* window. If the calibration check is unsuccessful, see "*Calibration and maintenance*" on page 349 or contact specialized service personnel.

#### WARNING

Risk of inaccurate patient results

A Microstream MCable that is out of calibration may provide inaccurate results. If calibration does not take place as instructed, the Microstream MCable may be out of calibration.

Ensure the proper calibration of the Microstream MCable.

# Scio Monitoring

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# **Overview of Scio monitoring**

The Scio Four module samples gas from the breathing gas of pediatric patients and adults. It continuously measures the concentration of CO<sub>2</sub>, N<sub>2</sub>O, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, Enflurane) in the breathing gas as well as the O<sub>2</sub> concentration (optional). All measured values as well as derived values are communicated to a patient monitor.

#### WARNING

Risk of inaccurate gas measurement values

During warm-up, reported values may not be accurate. Wait until the gas analyzer has completed initialization and warm-up. Refer to the Technical Data appendix in the gas analyzer supplement for further information regarding gas analyzer accuracy.

#### WARNING

**Risk due to defective sensors** 

If the gas analyzer is not ready for operation, the patient will not be adequately monitored. Before using the medical device, ensure a suitable substitute monitoring.

#### WARNING

**Risk of patient safety** 

The multigas information displayed is intended to be used by trained and authorized health care professionals only.

#### NOTE

The M540 does not backfill secondary agent trends on the network. The secondary agents are sent in real-time to the network.

#### NOTE

In this chapter, all Scio Four modules (Scio Four, Scio Four Oxi, Scio Four plus, and Scio Four Oxi plus) are referred to as "gas analyzer." The gas analyzer is available in four variants with different functions as listed below.

	<b>O</b> 2	CO2, N2O	Agent	Agent ID	Mixtures
Scio Four	No	Yes	1 out of 5	No	No
Scio Four Oxi	Yes	Yes	1 out of 5	No	No
Scio Four plus	No	Yes	2 out of 5	Yes	Yes
Scio Four Oxi plus	Yes	Yes	2 out of 5	Yes	Yes

The M540 patient monitor automatically detects the variant of gas analyzer connected and adjusts all context-sensitive menus for the gas analyzer variant.

At start-up, the gas analyzer warms up and displays the low-priority alarm **Scio warming up: Accur. Iow** on the M540 monitor. During this time, concentrations for certain gases may not be available and the anesthetic agent may not be identified.

The following alarms are supported prior to the detection of a valid breath:

- Use third agent detected
- %0 out of range high
- Agent reduced accuracy
- Agent value temporarily unavail.
- Check water trap/sample line
- Gas sensor failure
- CO2 out of range
- CO2 reduced accuracy
- CO2 sensor failure
- Gas sensor reduced accuracy
- inlso >
- inN2O >
- inO2 low
- Inspiratory xMAC high
- O2 out of range high
- O2 reduced accuracy

- O2 sensor failure
- O2 value temporarily unavail.
- N2O out of range high
- N2O reduced accuracy
- N2O sensor failure
- N2O value temporarily unavail.
- Sample line occluded
- Scio is not connected
- Scio unavailable for neonates
- Scio warming up: Accur. low
- Second agent detected
- Water trap is full

All other O2 alarms, CO2 alarms, N2O alarms, and anesthetic gas alarms are active only after one breath has been detected.

Supported parameters -									
Th	The following parameters are supported:								
_		-	etDes						
_	inCO2	-	inlso						
	etCO2	-	etlso						
_	EiO2	-	inHal						
_	etO2	-	etHal						
	inN2Q	-	inEnf						
_	otN2O	-	etEnf						
_	env20	-	xMAC						
-	IIIJEV								

# Connecting and disconnecting the Scio module

This topic describes the required components and steps necessary to connect and disconnect the Scio module to the M540 patient monitor or the M500 docking station. 1 Connect the RS-232 end of the Scio connection cable into one of the RS-232 ports on the back panel of the Scio module. Tighten the mounting screws to secure the cable to the module.

# **Required components**

- Scio module
- Scio connection cable

Refer to the *Infinity Acute Care System Instructions for use, Monitoring Accessories* for available Scio modules and cables.

### To connect the Scio module to the M540

This procedure describes how to connect the Scio module to the M540 using the appropriate accessories.



2 Connect the other end of the Scio connection cable to the yellow CO<sub>2</sub> connector on the M540.



### To disconnect the Scio module from the M540

This procedure describes how to disconnect the Scio module from the *M540*.

- 1 Remove the Scio connection cable from the yellow CO<sub>2</sub> connector on the *M540*.
- 2 Loosen the mounting screws on the RS-232 end of the Scio connection cable. Remove the Scio connection cable from the RS-232 port on the back panel of the Scio module.

# To connect the Scio module to the M500 docking station

The *M500* docking station supports a cable connection for interfacing and communicating with the Scio gas module. When the Scio gas module is connected to the *M500*, it enables communication with the docked *M540*.

- 1 Connect the RS-232 end of the Scio connection cable into one of the RS-232 ports on the back panel of the Scio module. Tighten the mounting screws to secure the cable to the module.
- 2 Connect the USB end of the Scio connection cable to an *M500* with a compatible USB port.

### To disconnect the Scio module from the M500

- 1 Remove the Scio connection cable from the USB port on the back of the *M500*.
- 2 Loosen the mounting screws on the RS-232 end of the Scio connection cable. Remove the Scio connection cable from the RS-232 port on the back panel of the Scio module.

#### WARNING

The USB port on the M500 is a Scio-only connection. Do not connect any other device to the USB port on the M500.



### NOTE

When the Scio is connected to the M500, the M540 CO2 port becomes disabled when it is docked. Consequently, CO2 (Mainstream and Microstream) is not available from the M540. You must disconnect the Scio from the M500 or undock the M540 to activate the M540 CO2 port, which requires a transition time of less than one minute.

# **Accessing Scio settings**

Setup for Scio parameters takes place through the parameter fields for the following gases:

- CO2
- **O**2
- N2O
- Prim. agent
- Sec. agent

### To access the Scio settings

If the CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, primary agent, or secondary agent parameter field displays on the M540:

• Touch the desired parameter field.

Or, if the CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, primary agent, or secondary agent parameter field is not displayed:

- 1 Touch a parameter field > Settings tab > Change parameter.
- 2 Touch the desired agent parameter label to display the parameter field on the main screen.
- **3** Touch the desired parameter field.

# CO<sub>2</sub> settings

### CO<sub>2</sub> alarm limits

Setup for all CO2 alarm functions takes place in the *CO2 limits* dialog within the *CO2* dialog. The *CO2 limits* dialog displays tabs on the right side of the window for *etCO2*, *inCO2*, and *RRc* settings.

etCO2 and RRc allow adjustment of the upper and lower alarm limits, use of the Archive feature, and use of Auto set. For inCO2, only the upper limit and Archive can be used.

## CO<sub>2</sub> parameter setup functions

Setup functions for CO<sub>2</sub> parameters take place in the **Scio** dialog within the **CO<sub>2</sub>** dialog.

#### NOTE

When a CO<sub>2</sub> mainstream sensor or *Microstream* MCable is connected, parameter controls for Scio are unavailable.

Selection	A١	vailable settings	Description						
RRc apnea time	-	<b>Off</b> (default)	Specifies the time the M540 waits before						
	-	10	reporting a cessation of breathing as an appea event.						
	-	15							
	-	20							
	-	25							
	-	30							
Apnea archive	-	Off	Determines what happens in response to an						
	-	Store (default)	apnea.						
	-	Str/Rec							
	-	Record							
Color	-	Red	Determines the color of the waveforms, and						
	-	White	the parameter labels and values.						
	-	Yellow (default)							
	-	Green							
	-	Light blue							
	-	Blue							
	-	Purple							
	-	Orange							
Change parameter	_	A list of currently available parameters	Changes the parameter field to a different parameter.						

# O<sub>2</sub> settings

### O2 alarm limits

For gas analyzers with O2 monitoring, setup for all O2 alarm functions takes place in the **O2 limits** dialog within the **O2** dialog. The **O2 limits** dialog displays tabs on the right side of the window for **etO2** and **FiO2** alarm limit settings.

etO2 and FiO2 allow adjustment of the upper and lower alarm limits, use of the Archive feature, and use of Auto set.

### NOTE

When a gas analyzer without O2 monitoring is connected, the parameter field for O2 will not available in the Scio setup menu.

### O2 parameter setup functions

Setup functions for O<sub>2</sub> parameters take place in the **Settings** tab within the **O**2 dialog.

Selection	Available settings	Description
Change parameter	<ul> <li>A list of currently available parameters</li> </ul>	Changes the parameter field to a different parameter.

# N<sub>2</sub>O settings

### N<sub>2</sub>O alarm limits

The inN2O alarm status is always set to "On" and cannot be changed.

The inN2O high alarm limit is fixed at 82% and cannot be changed. The inN2O low alarm limit is not required.

There are no alarms for etN2O.

### N2O parameter setup functions

Setup functions for **N2O** parameters take place in the **Settings** tab within the **N2O** dialog.

Selection	Available settings	Description
Change parameter	<ul> <li>A list of currently available parameters</li> </ul>	Changes the parameter field to a different parameter.

# Agent settings

## Agent alarm setup

Setup for agent alarms take place in the agent dialogs. The *Prim. agent* dialog and *Sec. agent* dialog allow the following to be adjusted for all agent alarms:

- Alarm status (on/off)
- Lower limit
- Upper limit
- Archive status

When a secondary agent is used, alarm limit violations trigger alarms only for the primary agent. Although the alarm limits on the secondary agent can be set, the alarms will not annunciate for the secondary agent until it is changed to the primary agent.

### NOTE

The M540 does not backfill secondary agent trends on the network. The secondary agents are sent in real-time to the network.

#### To access the agent alarm settings

If an agent parameter field displays on the M540 device:

1 Touch the *Prim. agent* parameter field or *Sec. agent* parameter field.

### NOTE

On gas analyzers with automatic agent identification:

- If no agent is automatically detected, the user can adjust all alarm limit settings from either the *Prim. agent* dialog or the *Sec. agent* dialog.
- If a primary agent is automatically detected, the user can adjust the alarm limit settings for only the corresponding gas from the *Prim. agent* dialog.
- If a secondary agent is automatically detected, the user can adjust the alarm limit settings for only the corresponding gas from the Sec. agent dialog.
- If a secondary agent is not automatically detected, the user can adjust all alarm limit settings from the **Sec. agent** dialog.
- 2 Touch the *inAgent limits* tab or *etAgent limits* tab.

Or, if an agent parameter field is not displayed:

- Touch a parameter field > Settings tab > Change parameter.
- **2** Touch the desired agent parameter label to display it on the main screen.

#### WARNING

Setting alarm limits to extreme values may prevent certain alarm conditions from being detected and from being annunciated with acoustic and optical alarm signals.

#### To configure agent alarm settings

#### NOTE

For more information on agent alarm settings, see the Alarm ranges and defaults section in the *Alarms* chapter.

- 1 Touch the *Alarm* on/off button to activate or deactivate alarm monitoring. A crossed-out triangle appears in the parameter field when alarm monitoring is deactivated.
- 2 Touch the button displaying the limit to be adjusted. Touch the up or down arrow to change the alarm limit setting. Touch *OK* to confirm the setting.
- 3 Touch the *Archive* button repeatedly to select one of the following settings to determine what happens in response to an alarm:
  - Off no event is stored and no recording is generated.
  - Store stores the event for later review (see page 284).

- Record generates a timed recording
- Str/Rec generates a timed recording and stores the event.

Touch the *Auto set* button (J), to auto adjust the alarm limits of all parameters. For more information, see *Using the Auto set function* in the Alarms chapter.

### Agent parameter setup functions

Setup functions for Agent parameters take place in the **Settings** tab within the **Prim. agent** dialog or **Sec. agent** dialog.

Selection	Available settings	Description
Sec. agent alarm	<ul><li>On (default)</li><li>Off</li></ul>	Indicates a change of the anesthetic agent during monitoring. Only occurs on gas analyzers with automatic
<i>Agent</i> (Scio Four Oxi and Scio Four only)	<ul> <li>Desflurane</li> <li>Enflurane</li> <li>Halothane</li> <li>Isoflurane</li> <li>Sevoflurane (default)</li> </ul>	<ul> <li>Configures the Scio Four or Scio Four Oxi module to measure the concentration levels of a user-specified anesthetic agent.</li> <li>WARNING:         <ul> <li>Use care when selecting the agent manually. Measurements are inaccurate if the wrong agent is selected.</li> <li>Scio Four Oxi and Scio Four cannot recognize anesthetic gas mixtures. Measurements are inaccurate if anesthetic gases are mixed.</li> </ul> </li> </ul>
xMAC archive	<ul> <li>Off</li> <li>Store (default)</li> <li>Str/Rec</li> <li>Record</li> </ul>	Determines what happens in response to an Inspiratory xMAC high alarm. <b>NOTE:</b> The <i>Agent</i> button is grayed out when a gas analyzer with automatic agent identification is connected (Scio Four Plus, Scio Four Oxi Plus).
Change parameter	<ul> <li>A list of currently avail- able parameters</li> </ul>	Changes the parameter field to a different parameter.

# CO<sub>2</sub> display

On the M540, the CO2 display consists of:

- CO2 parameter field
- CO2 waveform

## CO<sub>2</sub> parameter field

The CO<sub>2</sub> parameter field displays the current values for:

- Inspired CO2 (inCO2) the level of CO2 in the airway during inspiration phase.
- End-tidal CO2 (etCO2) the level of CO2 in the airway at the end of expiration.
- Respiratory Rate (RRc) the patient's respiratory rate, derived from the etCO2 signal.



- A etCO2 label
- B Unit of measurement
- **C** Crossed triangle symbol when the etCO<sub>2</sub> alarm is turned off
- D inCO2 label
- E *inCO*<sub>2</sub> value the level of *CO*<sub>2</sub> in the airway during inspiration, taken as the minimum value within the measurement interval
- F Crossed triangle symbol when *inCO*<sub>2</sub> alarms are turned off

- G Crossed triangle symbol when *RRc* alarms are turned off
- **H** *RRc* value respiratory rate derived from the CO<sub>2</sub> measurement.
- I RRc parameter label
- J etCO2 value highest CO2 in the airway during expiratory phase within the measurement interval

### CO<sub>2</sub> waveform

The M540 also displays an instantaneous CO2 waveform.



- A Expiratory or alveolar plateau (level of CO<sub>2</sub> in lungs ceases to increase significantly)
- **B** End-tidal concentration point (end of expiratory phase, where CO<sub>2</sub> is measured)
- C Onset of inspiratory phase
- D Onset of expiratory phase
- E Baseline during inspiration
## Troubleshooting

In addition to evaluating the clinical status of a patient, CO<sub>2</sub> waveforms can help troubleshoot problems with equipment. The following table shows how CO<sub>2</sub> waveforms can be used to identify common problems.

Description	Cause	Capnogram
Alveolar plateau showing a downward slope that	<ul> <li>Inadequate seal around the endotracheal tube</li> </ul>	$\square$ $\land$ $\land$
merges with a descending limb.	<ul> <li>Leaky or deflated endotracheal or tracheostomy cuff</li> </ul>	
	<ul> <li>Artificial airway that is too small for the patient</li> </ul>	
Elevated waveform	Rebreathing due to one of the	
baseline with	following causes:	
COrresponding increase in CO2 level.	<ul> <li>Disposable airway adapter is used although the Cockpit is configured for the reusable adapter type</li> </ul>	
	<ul> <li>Contaminated airway adapter (dirty window)</li> </ul>	
	<ul> <li>CO2 zero drift</li> </ul>	
	<ul> <li>Insufficient expiratory time</li> </ul>	
	<ul> <li>Faulty expiratory valve</li> </ul>	
	<ul> <li>Inadequate inspiratory flow</li> </ul>	
	<ul> <li>Malfunction of a CO<sub>2</sub> absorber system</li> </ul>	
	<ul> <li>Partial rebreathing circuits</li> </ul>	

Description	Cause	Capnogram
Change in slope of ascending limb. Possible absence of an alveolar plateau.	Obstruction caused by one of the following: – Partial obstruction in expiratory limb of breathing circuit	$\frown \frown \frown$
	<ul> <li>Foreign body in upper airway</li> </ul>	
	<ul> <li>Partially kinked or occluded artificial airway</li> </ul>	
	<ul> <li>Herniated endotracheal or tracheostomy tube cuff</li> </ul>	
	– Bronchospasm	
Elevated baseline, with	<ul> <li>Faulty ventilator circuit valve</li> </ul>	
pronounced slope on descending limb	<ul> <li>Rebreathing (see above)</li> </ul>	$\sum$

## O<sub>2</sub> display

### NOTE

O2 monitoring is available only with Scio Four Oxi and Scio Four Oxi plus.

On the M540, the O2 display consists of:

- O2 parameter field
- O2 waveform

The unit of measure for O2 is %.

### O2 parameter field

The O<sub>2</sub> parameter field displays the current values for:

- Inspired O2 (inO2/FiO2) the level of O2 in the airway during inspiration phase.
- End-tidal O2 (etO2) the level of O2 in the airway at the end of expiration.



- A inO2 label
- **B** Crossed triangle symbol when the inO2 alarm is turned off
- C etO2 label
- **D** Crossed triangle symbol when the etO2 alarm is turned off

- E etO2 value highest level of O2 in the airway during the expiratory phase within the measurement interval
- **F** inO2 (FiO2) value the level of O2 in the airway during inspiration, taken as the minimum value within the measurement interval

## N<sub>2</sub>O display

### N<sub>2</sub>O parameter field

The N2O parameter field displays the current values for:

- Inspired N2O (inN2O) the level of N2O in the airway during inspiration, taken as the minimum value within the measurement interval
- End-tidal N2O (etN2O) the highest level of N2O in the airway during the expiratory phase within the measurement interval

The unit of measure for N2O is %.



- A inN2O label
- B etN2O label
- **C** etN2O value the highest level of N2O in the airway during the expiratory phase within the measurement interval
- **D** inN2O value the level of N2O in the airway during inspiration, taken as the minimum value within the measurement interval

## Agent display

The agent waveforms and parameters can be identified by color as follows:

- Sevoflurane = yellow
- Desflurane = blue
- Isoflurane = purple
- Halothane = red
- Enflurane = orange

The appearance of the agent parameter field varies depending on the number of identified agents. Typical agent parameter field displays are shown below.

## Agent parameter fields

The M540 can display both a Primary Agent parameter field and a Secondary Agent parameter field. These Agent parameter fields display the current values for:

- Inspired agent (e.g., inSev) the level of anesthetic agent in the airway during the inspiration phase
- Expired agent (e.g., etSev) the level of anesthetic agent in the airway during the expiration phase
- xMAC (Primary Agent parameter field only) the MAC multiple calculated from the current expiratory measured values and the agedependent MAC values

#### Parameter field for primary agent



- A Abbreviation for inspired primary anesthetic agent (may display *Agent*? during agent identification for gas analyzers with automatic identification)
- **B** Unit of measurement
- **C** Crossed triangle symbol when the inspired agent alarm is turned off
- **D** Abbreviation for expired primary anesthetic agent (may display *Agent?* during agent identification for gas analyzers with automatic identification)
- E Expired primary agent value the level of anesthetic agent in the airway during the expiration phase
- **F** Crossed triangle symbol when the expired agent alarm is turned off
- G xMAC multiple
- H xMAC label
- I Inspired primary agent value the level of anesthetic agent in the airway during the inspiration phase

### Parameter field for secondary agent



- A Abbreviation for inspired secondary anesthetic agent (may display *Agent?* during agent identification for gas analyzers with automatic identification)
- B Unit of measurement
- **C** Crossed triangle symbol when the inspired agent alarm is turned off
- **D** Abbreviation for expired secondary anesthetic agent (may display *Agent?* during agent identification for gas analyzers with automatic identification)
- E Crossed triangle symbol when the expired agent alarm is turned off
- F Expired secondary agent value the level of anesthetic agent in the airway during the expiration phase
- **G** Inspired secondary agent value the level of anesthetic agent in the airway during the inspiration phase

### Manual agent identification

Manual agent identification is available only for gas analyzers without automatic agent identification: Scio Four and Scio Four Oxi.

### WARNING

Risk due to inaccurate gas measurement values

Use care when selecting the agent manually. Measurements are inaccurate if the wrong agent is selected.

### WARNING

Risk due to inaccurate gas measurement values

Measurements using a gas analyzer without automatic agent recognition are inaccurate if anesthetic gases are mixed.

To configure manual agent identification, refer to "Agent parameter setup functions" on page 287.

## Automatic agent identification

Automatic agent identification setup is available only for the following gas analyzers: Scio Four Plus and Scio Four Oxi plus.

These gas analyzers automatically identify up to two anesthetic agents, even in mixtures.

If the gas analyzer has not yet identified or cannot identify an agent, or has detected a mixture of three or more anesthetic agents (for example, due to too low agent concentrations, a leaking vaporizer, or traces of disinfectants), the agent parameter field is blank and the Agent label displays **Agent?** 

## xMAC (MAC multiple)

The **xMAC** value is a simple navigation aid for anesthetic agent delivery.

IACS displays the inspiratory and expiratory measured values for O2, N2O, anesthetic gases, and the *xMAC*.

The **xMAC** is the MAC multiple calculated from the current expiratory measured values and the agedependent MAC values. If no respiratory phase is detected, expiratory values and **xMAC** cannot be displayed.

The integrated *xMAC* algorithm is based on the MAC values shown in the following table. These values are guiding values only. The binding values are specified on the package information leaflet of the anesthetic agent.

The MAC values are dependent upon the age of the patient. The values specified in the table (according to ISO 80601-2-55) apply to a patient age of 40 years.

IACS provides age-corrected xMAC if the user has entered a birth date for the patient. If no birth date is entered, IACS uses 40 years as the age.

Agent	MAC corresponds to: (in 100% O2)
Desflurane	6.0 Vol%
Enflurane	1.7 Vol%
Halothane	0.77 Vol%
Isoflurane	1.15 Vol%
Nitrous oxide	105 Vol%
Sevoflurane	2.1 Vol%

The age-corrected MAC values are calculated using an equation developed by W. W. Mapleson (British Journal of Anaesthesia 1996, pp. 179-185).

The equation applies to patients older than 1 year.

MACage corrected = MAC1 x 10<sup>(-0.00269 x (age -40))</sup>

<sup>1 40</sup> years

For gas mixtures, the respective multiples for N<sub>2</sub>O and anesthetic agents are added according to the following equation:

 $xMAC = \frac{\text{exp. conc. Anesth}_{1}}{\text{MAC}_{\text{age-corrected}} \text{ Anesth}_{1}} + \frac{\text{exp. conc. Anesth}_{2}}{\text{MAC}_{\text{age-corrected}} \text{ Anesth}_{2}} + \frac{\text{exp. conc. N}_{2}O}{\text{MAC}_{\text{age-corrected}} \text{ N}_{2}O}$ 

#### Example:

exp. lso. = 0.65 Vol%; exp. N2O = 69%; age = 32 years

MACage-corrected from Iso.: MAC1 = 1.21 Vol% MACage-corrected from N2O: MAC<sup>\*\*</sup> = 110 Vol%

*xMAC* = 0.54 + 0.63 = 1.2

The influence of other drugs (opiates or intravenous hypnotics) is not considered in the *xMAC* calculation.

1 32 years

## Zeroing the gas analyzer

The gas analyzer automatically purges and zeroes itself and does not require any interaction by the user.

If the IACS has been in Standby or Discharge for less than two hours, the gas analyzer is available without zeroing for at least the first 90 minutes of monitoring.

However, if the IACS and/or gas analyzer has been powered down or has been in Standby or Discharge for more than two hours, a warm-up procedure occurs when the IACS begins monitoring. The warm-up procedure includes zeroing and can take up to 7.5 minutes. During this time, accuracy is reduced.

During zeroing:

Waveforms flatline

- The status bar displays the message Scio zeroing is in progress
- Active Scio alarms continue to display

During the first 25 seconds of zeroing, the Sciorelated parameter fields (CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, Agents) display the last valid values. If zeroing takes longer than 25 seconds, those parameter fields display *CAL*.

# System configuration

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## Overview

This chapter describes the *Menu* and *Alarm settings* dialogs. The *Menu* dialog consists of several dialogs for configuring the M540. Some of these dialogs are password-protected and are only accessible to authorized personnel.

## Service tab

The Service tab is password-protected and includes features such as factory defaults, service and test modes. It also includes remote control settings which enables the M540 to be controlled by ICS. For more information about service-related features, refer to the repair instructions. The *Menu* dialog consists of the following dialogs:

- *Main* (see page 299)
- Patient setup (see page 301)
- System setup (see page 302)
  - **Biomed** button (see page 310)
  - Service tab
  - **System information** tab (see page 308)
  - Alarm setup tab (see page 317)
- Screen setup (see page 316)
  - **Settings** tab (see page 316)
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  - Function keys tab (see page 316)

## **Configuring general settings**

This section describes the setup functions of the *Main* dialog.

### To access the Main dialog

- 1 Press the *Menu* function key.
- 2 Touch the *Main* tab.

<i>Main</i> dialog		
Selection	Available settings	Description
<i>All alarms pause</i> or <i>All alarms off</i>	None	When the <b>All alarms pause</b> button is selected, all alarm functions are temporarily suppressed for a selected time. The alarm function is automatically activated when the alarm pause timer times out.
		When the <b>All alarms off</b> button is selected, all alarm functions are suppressed until you select the button again to activate the alarm function.
		To configure this button, see page 299.
Show all leads	None	Displays waveforms for all ECG leads.
Label IP	Available channels:	Assigns a label name to the IP labels.
	Pod 1A label, Pod 1B label, Pod 1C label, Pod 1D label, Pod 2A label, Pod 2B label, Pod 2C label, Pod 2D label	
	Pressure labels: GP2, ART, LV, LA, PA, CVP, ICP, RA, RV, AXL, BRA, FEM, RAD, AOR, UAP, ABD, BDP, ESO, FEMV, UVP, GPM	
	Generic labels: <i>GP1</i> through <i>GP8</i>	

<i>Main</i> dialog		
Selection	Available settings	Description
Rest ECG report	None	Prints a 12-lead ECG report for an adult or pediatric patient during 12-lead monitoring when the M540 is in wireless mode.
		When the M540 is docked, the feature is deactivated. In this case a 12-lead ECG report can only be printed from the Cockpit.
		The report can be configured to include the following demographic data (refer to page 301):
		– Gender
		– Race
		If the <i>ECG filter</i> is set to <i>ESU</i> , the report cannot be generated.
Standby	None	Enters standby mode.
Privacy mode	None	Enters privacy mode. This mode is only available when the M540 is docked in an IACS configuration or when it is on wireless transport and the patient is admitted at the ICS.
		If the patient is not admitted at the ICS, the button is displayed but it is not activated. For more information, see page 83.
Discharge	– Cancel	Discharges a patient and deletes all the
	– Discharge	patient's data.
M540 Audio	<ul> <li>On</li> <li>Off (default)</li> </ul>	When the M540 is initially docked to a Cockpit, the <i>M540 Audio</i> setting is <i>Off</i> and the speaker off symbol displays. This setting can be turned <i>On</i> and if needed, the alarm volume and pulse tone volume can also be adjusted.
		When the M540 is on transport, in wireless mode or in standalone configurations, this setting is always activated.

## Configuring the patient settings

This section describes the setup functions of the *Patient setup* dialog. The dialog configures the M540 for the patient.

#### To access the Patient setup dialog

- 1 Press the *Menu* function key.
- 2 Touch the *Patient setup* tab.

Patient setup dialog		
Selection	Available settings	Description
	Demog	graphic Data
Patient category	– Adult	Selects the type of patient.
	– Pediatric	
	– Neonate	
Name	Keyboard	Allows you to enter the name of the patient.
ID	Keyboard	Allows you to enter the ID number of the patient.
Admit date	– Day	Allows you to enter the admit date of the
	– Month	patient.
	– Year	
Birth date	– Day	Allows you to enter the birth date of the patient.
	– Month	
	– Year	
Physician	Keyboard	Allows you to enter the name of the physician of the patient.
Race	– Unknown	Allows you to enter a race for the patient.
	– Caucasian	
	– Asian	
	– African	
	– Other	
Gender	– Unknown	Allows you to enter a gender for the patient.
	– Male	
	– Female	

## Configuring the system settings

This section describes the setup functions of the *System setup* dialog from where you can access biomed and service settings and system information. In addition the *Alarm setup* tab provides access to various alarm settings.

## Accessing the system information

The **System setup** dialog provides access to password-protected dialog and the current system information.

#### WARNING

Do not service the M540 while monitoring a patient.

#### To access the system information

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Select one of the following actions:
  - Touch the *Biomed* button to access the *Biomed* dialog (see page 310).
  - or
  - Touch the Service button to access the Service dialog (refer to the service instructions).

or

 Touch the System information button to access the System information dialog (see page 308).

or

- Touch the *Alarm setup* button to access the *Alarm setup* tab (see page 303).
- 4 Enter the password and touch OK.

## Accessing the Alarm setup dialog

The *Alarm setup* dialog provides access to password-protected alarm settings.

#### To access the Alarm setup dialog

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.

- 3 Touch the *Alarm setup* or the *Volume/ Tones* tab.
- 4 Enter the required password and touch OK.

Refer to the following table for available selections:

Selection	Available settings	Description
Alarm setup tab (passwo		sword required)
All alarms paused <sup>1)</sup>	1, 2 (default), 3, 4, 5 min	Selecting one of these settings changes the alarm button on the <i>Main</i> dialog to <i>All alarms paused</i> .
All alarms off		When selected:
		<ul> <li>All alarm functions are temporarily suppressed for the selected time.</li> </ul>
		<ul> <li>The alarm function is automatically activated when the alarm pause timer times out.</li> </ul>
		<ul> <li>The message <i>All alarms paused</i> with the remaining time and the symbol X appears on the M540.</li> </ul>
	No timeout	Selecting this setting changes the alarm button on the <i>Main</i> dialog to <i>All alarms off</i> .
		When selected:
		<ul> <li>All alarm functions are suppressed until you select the button again to activate the alarm function again.</li> </ul>
		<ul> <li>The message <i>All alarms off</i> and the symbol X appears on the M540.</li> </ul>
	Disable	Selecting this setting deactivates (grays out) the <i>All alarms off</i> button (depending on its previous configuration) on the <i>Main</i> dialog (see page 299). You cannot temporarily or permanently deactivate alarm monitoring.
Alarm validation <sup>1)</sup>	<ul> <li>On</li> <li>Off (default)</li> </ul>	When activated, alarm conditions are verified for a certain time before triggering acoustic and optical alarm signals (see <i>Activating or</i> <i>deactivating alarm validation</i> in the Alarms chapter). This reduces nuisance alarms.

Selection	Available settings	Description
SpO2 alarm delay <sup>1)</sup>	<b>On</b> (default)	An SpO2 lower alarm limit violation must persist for 10 seconds before triggering acoustic and optical alarm signals.
		This function is not possible if the Nellcor <b>SatSeconds</b> feature is set to any value other than <b>Off</b> (see page 204).
		The alarm validation feature must be activated.
	Off	An SpO2 lower alarm limit violation triggers an alarm immediately.
Alarm group <sup>1)</sup>	0 (default) to 255	You can configure the M540 and other monitors as members of an alarm group. This feature allows each member of an alarm group to view each other's alarm conditions remotely.
NIBP/SpO2 interlock <sup>1)</sup>	On	The SpO2 alarm function is deactivated during non-invasive blood pressure and PLS CO-Ox measurements (for more details, see <i>NIBP/SpO2 interlock alarm feature</i> in the Alarms chapter.
	Off (default)	The SpO2 alarm function is activated during non-invasive blood pressure and PLS CO-Ox measurements.
ASY/VF alarms <sup>1)</sup>	Follow HR	ASY and VF alarm settings follow the setting of the heart rate alarms.
		WARNING: If you select <i>Follow HR</i> , ASY, and VF alarms are not reported if the heart rate and arrhythmia alarm functions are turned off.
	Always on (default)	ASY and VF alarm functions are always activated.
Pacer mode <sup>2)</sup>	<ul> <li>Basic (default)</li> </ul>	Fusion mode is not selectable.
	– Advanced	Fusion mode is selectable in the <i>ECG</i> setup page (see page 152).
Alarm bar <sup>1)</sup>	<ul> <li>On (default)</li> <li>Off</li> </ul>	Determines whether the alarm bar flashes during an alarm.
Battery alarm	See "Configuring the battery alarm" on page 320.	

Selection	Available settings	Description
Volume/ Tones tab (clinical password required)		
Minimum alarm vol.	<ul> <li>Off (not available if connection to the ICS is unavailable)</li> <li>5, 10, 20, 30, 40, 50 (default), 60, 70, 80, 90, 100%</li> </ul>	Determines which alarm volume settings are available under the <i>Alarm volume</i> button. This setting does not affect the volume of the attention or the pulse tone.
Transport volume	50% (default), 60%, 70%, 80%, 90%, 100%	Determines the alarm volume of the M540 while it is on patient transport.
Transport pulse tone	<ul> <li>Off (default)</li> <li>5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100%</li> </ul>	Determines the volume of the heart rate and the SpO2 pulse tone while the M540 is on patient transport.
Alarm pattern	<ul> <li>IEC slow</li> <li>IEC fast (default)</li> <li>Infinity</li> </ul>	Determines the type of alarm tone pattern in use (for more information, see <i>Acoustic alarm signals</i> on the Alarms chapter).
Quiet mode – On – Off (default)	<ul> <li>On – Only alarm conditions of higher priority override an active audio pause. The appropriate parameter field flashes. Alarm conditions of equal or lower alarm priority will not be reported with an alarm tone.</li> </ul>	
		<ul> <li>Off – Any new alarm condition, regardless of its alarm priority, overrides an already active audio pause state at the Cockpit and at the ICS if the patient is admitted there. All optical and acoustic signals are reported fully for any new alarm condition.</li> </ul>
		For detailed information how quiet mode affects the audio pause behavior, see <i>Quiet</i> <i>mode</i> in the Alarms chapter.

Selection	Available settings	Description
Reminder: audio off	<ul> <li>On (default)</li> <li>Off</li> </ul>	Sounds an alarm tone every 30 seconds at the at the M540 to remind you that the alarm tone is deactivated during an active alarm condition. This alarm tone is suppressed if you initiate an audio pause.
		When the M540 is set to OR alarms, the volume of the alarm tone corresponds to the <i>Alarm volume</i> setting of 10%. When OR alarms are not activated, the volume equals to 50%.
		<ul> <li>On – a truncated acoustic alarm signal sounds every 30 seconds for an alarm condition of medium priority or high priority. Low-priority alarms tones are not truncated.</li> </ul>
		During multiple alarm conditions, the reminder tone adjusts itself to always report the alarm condition with the highest alarm priority.
		<ul> <li>Off – No alarm tone sounds when the alarm volume is deactivated and an alarm occurs.</li> </ul>
		<b>Reminder: audio off</b> is not supported on the ICS or any other such device in remote view mode.
<sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.		
<sup>2)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.		

### Accessing the configurable SpO2 alarm features

The *Alarm setup* dialog provides access to password-protected SpO2 alarm settings. Depending on the configuration of the M540, one of the following two tabs appears.

- The SpO2 sensor off tab when the M540 is configured for Masimo.
- The SpO2 check sensor tab when the M540 is configured for Nellcor.

#### To access the *Alarm setup* dialog

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the *Alarm setup* tab.
- 4 Enter the required password and touch OK.
- 5 Touch the **SpO2 sensor off** tab (Masimo).

or

6 Touch the SpO2 check sensor tab (Nellcor)

Selection	Available settings	Description
Alarm	– High – Medium	Assigns an alarm priority to the sensor alarm or deactivates the sensor alarm. The selected alarm priority affects how the alarm event is reported.
		The event is treated as a persistent alarm. The message appears in the header bar of the M540 until the condition disappears. The acoustic alarm signal can be audio paused but will resume if the condition persists beyond the two minute audio pause time.
	<i>Low</i> (default)	The event is treated as a one-shot alarm. The message appears briefly in the header bar. Once you acknowledge the alarm by pressing the yellow audio pause key, the message disappears and the acoustic alarm signal stops.
	(off)	No visual or acoustic alarm signals are triggered.
Archive	<b>Off</b> (default)	Determines what happens when the corresponding alarm occurs:
		<ul> <li>No event is stored and no recording is generated.</li> </ul>
	Store	<ul> <li>Stores the event for later review.</li> </ul>
	Record	<ul> <li>Generates a timed recording (except for standalone mode).</li> </ul>
	Str/Rec	Generates a timed recording and stores the event.

## Viewing the system information

This section describes how to review the various system information which is located in different menus under the **System information** dialog.

### NOTE

When the wireless option is not installed, the *Wireless* tab does not appear and the information is not available.

#### To view the system information

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the **System information** button. This menu displays general system information.
- 4 Touch one of the following tabs to view the additional system information: *Name service*, *Docking station*, *Wireless*.

Dialog	Available information	
System information	Serial number	
	H/W interface	
	S/W revision	
	S/W checksum	
	Boot loader	
	FPGA revision	
	SpO2 sensor type	
Name service	IP address	
	Subnet mask	
	Default gateway	
	Bed label	
	Care unit	
	Hospital	
	Mon. unit	
	Mon. unit ID	
Docking station	DS revision	
	MAC address	

Dialog	Available information	
Wireless	WLAN MAC address	
	Multicast address	
	Signal strength	
	BSSID	
	SSID	
	Encryption	
	Channel number	
	Regulatory domain	

## Configuring the biomed settings

This section describes the setup functions of the *Biomed* dialogs.

### To access the Biomed dialog

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the *Biomed* button.
- 4 Enter the password and touch OK.
- 5 Touch the Settings 1 or the Settings 2 button.

Biomed dialogs		
Biomed > Settings 1 dialog		
Selection	Available settings	Description
Language	English, German, Spanish, French, Italian, Port.(Br), Port (EU), Russian, Japanese, Swedish, Norweg., Danish, Dutch, Turkish, Polish, Finnish, Greek, Chinese, Hungarian,Czech	Selects the language of the M540 screen text.
Date	– Day – Month – Year	Allows you to enter the date.
Time	– Hour – Minute	Allows you to enter the time.
Simulation	– Cancel – OK	Activates simulation mode. Select the <b>Discharge</b> function key to exit.
Save profile	– Cancel – OK	Saves and replaces the profile (including the current views) for the current patient category. Be aware that saving profiles must be done separately for each patient category.

Biomed dialogs		
Biomed > Settings 1 dialog		
Selection	Available settings	Description
Restore Profile	– Cancel – OK	Restores the saved profile settings and up to five available views on the M540. In standalone mode, if docked on an M500 that has a saved profile, selecting this button will restore the M500 default profile.
Line frequency	50, 60 Hz (default)	Selects the line frequency.
	Biomed > Setting	gs 2 dialog
French NFC	<ul><li><i>Off</i> (default)</li><li><i>On</i></li></ul>	When activated, heart rate alarms cannot be turned off, and the <i>All alarms pause</i> period cannot exceed 3 minutes.
Test pulse	None	Generates 1 mm test pulse.
SpO2 sensor type	<ul> <li>Masimo (default)</li> <li>Nellcor</li> </ul>	Selects the type of sensor.
Change clinical password Change biomedical password	Use the keypad to enter the new password (up to 4 numbers)	Configures a new password for the M540. When an M540 whose password has been changed docks to a Cockpit with a different password, the Cockpit password overrides the M540 password. CAUTION Be sure to record the new password because it cannot be retrieved once it is lost. For further assistance, contact DrägerService.

## Configuring units of measure

### To access the Biomed dialog

- 1 Press the *Menu* function key.
- 2 Touch the **System setup** tab.
- 3 Touch the *Biomed* button.
- 4 Enter the password and touch *OK*.
- 5 Touch the *Units* tab.

Changing the units of measure discharges the patient.

Biomed > Units dialogs		
Selection	Available settings	Description
Тетр	<ul> <li>°C (Celsius) default</li> </ul>	Assigns the selected unit of measurement to
	<ul> <li><i>°F</i> (Fahrenheit)</li> </ul>	the parameter. Whenever you change a unit of measurement. the M540 discharges the
CO2	<ul> <li><i>mmHg</i> (default)</li> </ul>	patient.
	– kPa	
	- %	
Pressures	<ul> <li><i>mmHg</i> (default)</li> </ul>	
	– kPa	
ST	<ul> <li><i>mm</i> (default)</li> </ul>	
	– <i>mV</i>	
SpHb (SpHbv)	<ul> <li>g/dL (default)</li> </ul>	
	– mmol/L	
Height	<ul> <li><i>cm</i> (default)</li> </ul>	
	– in	
Weight	– Ib/oz	
	<ul> <li>kg/g (default)</li> </ul>	
Agent	– kPa	
	- %	

## Configuring the M500 setup

The following setup features are intended for a wired M500. These settings are stored on the M500 and are adopted by an M540 when it is docked.

### NOTE

When the wireless option is activated on the M540 or the M540 is used in an IACS configuration, the **Docking station** tab is grayed out and no configuration is possible.

#### To access the Biomed dialog

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the *Biomed* button.
- 4 Enter the password and touch OK.
- 5 Touch the *Docking station* tab.
- 6 Touch the following tabs: *Network setup*, *Name service*, *Other*.

Selection	Available settings	Description
	Network setup	<b>o</b> dialog
IP address	User selectable; the default setting is: 0.0.0.0	Allows you to configure the IP address on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is grayed out.
Net mask	User selectable; the default setting is: 255.255.0.0 NOTE: The Net mask cannot be 255.255.255.128.	Allows you to configure the subnet mask on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is grayed out.
Default gateway	User selectable; the default setting is: 0.0.0.0	Allows you to configure the default gateway on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is grayed out.
	Name service	e dialog
Bed label	User selectable; the default setting is blank	Allows you to enter the bed label on the alphanumeric keypad (limited to 7 characters).
Mon. unit	User selectable; the default setting is blank	Allows you to enter the monitoring unit on the alphanumeric keypad (limited to 7 characters).
Care unit	User selectable; the default setting is blank	Allows you to enter the care unit on the alphanumeric keypad (limited to 7 characters).
Hospital	User selectable; the default setting is blank	Allows you to enter the name of the hospital on the alphanumeric keypad (limited to 7 characters).
Mon. unit ID	User selectable from 1 – 255; the default setting is: 1	Allows you to enter the monitoring unit ID on the alphanumeric keypad (limited to 7 characters).

Selection	Available settings	Description
	<b>Other</b> dia	log
Load profile NOTE: The Load profile button appears grayed out until at least one profile has been saved.	<b>Off</b> (default)	After docking, the M540 does not adopt the profile of the M500 but uses its own settings instead.
	Automatic	After docking, the M540 adopts the profile of the M500.
Profile settings	All	Patient and monitor settings are downloaded to the M540.
	<i>Monitor</i> (default)	Only monitor settings are downloaded to the M540.

## Configuring the wireless network setup

#### To access the *Biomed* dialog

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the *Biomed* button.
- 4 Enter the password and touch OK.
- 5 Touch the *Wireless network* tab.

#### NOTE

When the wireless option is not installed, the *Wireless network* tab is grayed out and the information is not available.

Biomed > Wireless network dialogs		
Selection	Available settings	Description
Wireless mode	– On	Activates/deactivates the wireless option.
	- Off (default)	
SSID	Keyboard for entering a passphrase with alphanumeric values	This selection is only available when you choose <i>WPA2-PSK</i> for the <i>Encryption</i> menu selection.
Channels	1 to 13	The available channel selections are determined by the regulatory domain.
Encryption	<ul> <li>None (default)</li> <li>WPA2-PSK</li> </ul>	Activates/deactivates wireless encryption. If <b>None</b> is selected, the <b>SSID</b> setting changes to <b>SSID</b> .

Keep bed label	<b>Yes</b> (default)	<ul> <li>In an IACS configuration: The M540 retains the bed label of the Cockpit when it undocks. Any changes to the M540 bed label do not have any effect. If the patient is also monitored by the ICS, the data continue to display in the same viewport when the M540 is undocked.</li> <li>In standalone mode: The M540 retains the bed label configured on the M500.</li> </ul>
	No	The M540 retains the bed label configured in the <i>Wireless network</i> dialog when it is undocked. If the wireless bed label is changed while wireless, the bed label is automatically updated at the M540 and over the network.
		If the patient is monitored by the ICS, the data are removed from the viewport. A message appears in the viewport that the M540 is disconnected. An offline message appears if the wireless bed label has not been configured.
Bed label	User selectable; the default setting is blank	Allows you to enter the bed label on the alphanumeric keypad (limited to 7 characters).
		The <i>Keep bed label</i> setting determines what happens to the bed label – see above for detailed information.

## Configuring the screen layout

This section describes the setup functions of the *Screen setup* dialog.

### To access the Screen setup dialog

- 1 Press the *Menu* function key.
- 2 Touch the Screen setup tab.

Screen setup dialog		
Selection	Available settings	Description
	Settings di	alog
Touch calib.	None	Calibrates the touchscreen.
Flip screen	None	Flips the screen 180 degrees.
Autoflip	<ul><li>Yes (default)</li><li>No</li></ul>	Activates/deactivates automatic flipping of the screen.
Power save	<b>Off</b> (default), 1, 2, 3, 4, 5 min	Selects the amount of time in minutes until the M540 goes into power save mode (see page 66).
	Screen views	dialog
View 1	– 1wav 4pbox	Selects a predefined view or deactivates the
View 2	– 1wav 7pbox	view by selecting <b>Off</b> (except View 1).
View 3	– 2wav 5pbox	
View 4	– 3wav 3pbox	
View 5	– 1wav 3pbox	
	– Off	
Function keys dialog		
Setup key 1	Standby, Code, Discharge,	Assigns a function to the user configurable
Setup key 2	Record, Privacy, Mark, Patient Rest ECG report	function keys.
Setup key 3		
Setup key 4		

## **Configuring alarm settings**

This section describes the setup functions of the *Alarms* dialog.

### To access the Alarm settings dialog

- 1 Press the *Alarms* function key.
- 2 Touch the *Alarm settings* tab.

Alarms dialog		
Selection	Available settings	Description
	Alarm sett	ings
Alarm volume <sup>1)</sup>	Off, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100% (default)	Sets the overall monitor volume and supersedes alarm volume.
		The setting <i>Off</i> is not available if there is no connection to the ICS.
		While the M540 is in transport, the full range of volume settings are available.
<i>All alarms pause</i> or <i>All alarms off</i>	None	When the <b>All alarms pause</b> button is selected, all alarm functions are temporarily suppressed for a selected time. The alarm function is automatic ally activated once the alarm pause timer times out.
		When the <b>All alarms off</b> button is selected, all alarm functions are suppressed until you select the button again to activate the alarm function.
		To configure this button, see page 299.
Pressures pause	1 min, 2 min, (default), 3 min, 4 min, 5 min, Disabled	Determines the duration and availability of the <b>Pressures pause</b> function.
Pressures off	Enabled, Disabled	Determines the availability of the <b>Pressures off</b> function.

Alarms dialog		
Selection	Available settings	Description
	Config. alarm	is window
SpO2 sensor off	<ul> <li><i>High</i></li> <li><i>Medium</i></li> <li><i>Low</i> (default for Nellcor)</li> <li><i>One-shot</i></li> <li></li></ul>	<ul> <li>Assigns an alarm priority to the sensor alarm or deactivates the sensor alarm.</li> <li><i>High</i>: The event is treated as a high-priority alarm.</li> <li><i>Medium</i>: The event is treated as a medium-priority alarm.</li> <li><i>Low</i>: The event is treated as a persistent low-priority alarm.</li> <li><i>One-shot</i>: The event is treated as a low-priority, single notification alarm.</li> <li><u>X</u>: No visual or acoustic alarm signals are triggered; however, if the sensor is no longer attached to the patient, a corresponding message appears in the SpO2 parameter field.</li> </ul>
ECG leads off	<ul> <li>High</li> <li>Medium</li> <li>Low (default)</li> <li>One-shot</li> <li>⋌ (off)</li> </ul>	<ul> <li>Determines what happens when the corresponding alarm occurs. The selected alarm priority affects how the alarm event is reported visually and acoustically – generates a timed recording and stores the event.</li> <li><i>High:</i> The event is treated as a latching alarm.</li> <li><i>Medium</i>: The event is treated as a medium-priority alarm.</li> <li><i>Low</i>: The event is treated as a persistent low alarm.</li> <li><i>One-shot</i>: The event is treated as a low grade, single notification. The message <i>ECG leads off</i> appears briefly in the header bar until the user acknowledges the condition or the condition disappears.</li> <li><i>X</i>: No visual or acoustic alarm signals are triggered.</li> </ul>

Alarms dialog				
Selection	Available settings	Description		
RRi lead off	<ul> <li>High</li> <li>Medium</li> <li>Low (default)</li> </ul>	Assigns an alarm priority to the RRi lead-off alarm or deactivates it. The selected alarm priority affects how the alarm event is reported visually and acoustically.		
	<ul> <li>— One-shot</li> <li>— ∑ (off)</li> </ul>	<ul> <li>High: The event is treated as a high- priority alarm.</li> </ul>		
		<ul> <li>Medium: The event is treated as a medium-priority alarm.</li> </ul>		
		<ul> <li>Low: The event is treated as a persistent low-priority alarm.</li> </ul>		
		<ul> <li>One-shot: The event is treated as a low- priority, single notification alarm. The message <i>RRi lead off</i> appears briefly in the header bar until the user acknowledges the condition or the condition disappears.</li> </ul>		
		<ul> <li>– X : No visual or acoustic alarm signals are triggered.</li> </ul>		
ART cath. disconnected?	<ul> <li><i>High</i> (default)</li> <li>→ ☆ (off)</li> </ul>	Assigns an alarm priority to the <b>ART cath</b> . <b>disconnected?</b> alarm or deactivates it. The selected alarm priority affects how the alarm event is reported visually and acoustically.		
		<ul> <li>High: The event is treated as a high- priority alarm condition.</li> </ul>		
		<ul> <li>A is no visual or acoustic alarm signals are triggered.</li> </ul>		
<sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.				

## Configuring the battery alarm

A battery alarm alerts you to a low battery charge when the M540 is undocked. The priority of the accompanying battery alarm tone is configurable.

#### To configure the battery alarm:

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the *Alarm setup* tab.
- 4 Enter the password.

- 5 Select one of the following settings:
  - Medium (default) a persistent tone of medium priority sounds when the battery has approximately 5-10 minutes of the remaining charge left.
  - High a tone of high priority sounds when the battery has approximately 5 minutes of the remaining charge left. Also, the message *Recharge battery* appears in the alarm area. Refer to *Alarm priorities* in the Alarms chapter.

## Options

The M540 supports the following options which are automatically unlocked:

- Full arrhythmia option
- 12-lead monitoring option
- Multi-IP option for measuring more than two invasive blood pressures

The M540 also supports the wireless (WiFi) locked option which can be unlocked using a password. The *Wireless* tab under *System information* tab and the *Biomed* menu is available when the wireless option is unlocked. The wireless tabs do not appear when the wireless option is locked.

### To unlock the wireless option

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the Service button.
- 4 Enter the password > OK.
- 5 Touch the *Locked options* tab.
- 6 Touch the Wireless button.
- 7 Enter the password.

The label inside the *Wireless* button changes to *Unlocked*.

Once unlocked, options remain activated even under the following circumstances:

- When the M540 is turned on or off
- When software is downloaded
- When factory defaults are restored
- When another language is selected

#### To lock the wireless option

- 1 Press the *Menu* function key.
- 2 Touch the System setup tab.
- 3 Touch the Service button.
- 4 Enter the password > OK.
- 5 Touch the *Locked options* tab.
- 6 Touch the *Wireless* button. A dialog box with the following message appears:

#### Disabling this option disables wireless functionality. A passcode is required to re-enable the option.

7 Touch the *Lock* button. The label inside the *Wireless* button changes to *Locked.* 

### **Temporary options**

Temporary options make it possible for an M540 in an IACS configuration to perform the intended functions together with the Cockpit when the devices do not share the same option setup. For example, when an M540 with permanent options docks to an IACS Cockpit that does not have the same options activated, the M540 options temporarily loans these options to the Cockpit. Temporary options are deactivated when a patient is discharged. However, they are retained if you turn the Cockpit or the M540 off and on. This page has been left blank intentionally.

# Troubleshooting

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## Overview

Multiple alarm messages cycle in the alarm message field of the header bar.

For example, if two faults are detected simultaneously, the more urgent of the two is displayed.

The exclamation marks in the following tables indicate the priority level of the alarm messages (see page 94 for definitions). The exclamation marks are not in the actual alarm messages.

Warning = !!! Message of high priority Caution = !! Message of medium priority Advisory = ! Message of low priority If no priority level is assigned, the message is informational and no action is required.

In the following tables, messages are listed in alphabetical order. These tables identify possible alarm causes and provides corrective action. The various causes and remedies should be worked through in the order listed until the problem has been resolved.

#### NOTE

If the M540 speakers fail, all alarm patterns are generated by the M540's power-up/power-down alert tone mechanism. Contact specialized service personnel.

## Device communication messages / general device messages

Priority	Message	Cause	Remedy
None	Audio paused by remote	M540 alarms were paused by a remote device.	Informational message – no action required.
None	Check IP address	Duplicate PDS or Multicast address.	Ensure the fourth octet of the IP address is unique within the monitoring unit.
None	Duplicate IP address	The IP address is already in use.	Assign a unique IP address.
None	Duplicate device name	The domain name is already in use (i.e., a duplicate monitoring unit label, care unit label, device label, and hospital name).	Assign a unique domain name.
None	Not monitored by central	The communication between the ICS and the M540 is interrupted.	<ul> <li>Return the M540 within the range of the wireless access point.</li> </ul>
		A wireless M540 is out of range of the access point.	<ul> <li>Check the network connections.</li> </ul>
			<ul> <li>Make sure the M540 is assigned correctly to an ICS.</li> </ul>
Priority	Message	Cause	Remedy
----------	-------------------------	--	--
None	Offline	A wireless M540 is undocked and does not have a bed label assignment.	<ul> <li>Check the network connections.</li> <li>Assign a bed label to the M540.</li> </ul>
		Disconnected network cable.	
None	Recording stored	A recording was requested but no recorder is available for printing the recording.	Dock the M540 to an the M500 in an IACS configuration so the recording request can be processed by the Cockpit.
None	Remote relearn	The indicated function was initiated from the central station.	Informational message – no action required.
None	Remote limit change	The indicated function was initiated from the central station.	Informational message – no action required.
None	Restore Profile Failed	The profile could not be restored.	Try to restore the profile again before contacting specialized service personnel.
None	Save profile failed	The profile could not be saved on the M540 and/or the M500.	Try to save the profile again before contacting specialized service personnel.
None	Profile transfer failed	The profile failed to load on the M540 upon docking.	Undock and redock the M540 before contacting specialized service personnel.

#### M540 battery messages

Priority	Message	Cause	Remedy
!	Low battery	The M540 is undocked and the battery charge has ten minutes of run time remaining.	Return the M540 to the M500 to recharge the battery.
		An advisory tone sounds every 20 seconds.	
!!	Recharge battery	The M540 is undocked and the battery charge has five minutes of run time remaining.	For information on how to configure the priority of the alarm tone that accompanies this message, see page 320.

#### Messages

Priority	Message	Cause	Remedy
!!!	All alarms off	The <i>All alarms off</i> function is set to <i>No</i> <i>timeout</i> (see page 317) and you select the <i>All</i> <i>alarms off</i> button.	Select the <i>All alarms off</i> button again to remove the message.
111	All alarms paused with timer	The <i>All alarms paused</i> function is set to a time (see page 317) and you select the <i>All alarms</i> <i>paused</i> button.	Select the <i>All alarms paused</i> button again to remove the message.
!!	All alarms paused with timer	The yellow All alarms paused key was pressed.	Press the key again to remove the message.
	2nd HemoPod unplugged <sup>1)</sup>	The second invasive pressure device is disconnected.	Check the equipment and replace if necessary.
None	HemoPod incompatible	An incompatible invasive pressure device has been connected.	Remove the incompatible invasive pressure pod.
<sup>1)</sup> In the pa	arameter field the parameter valu	ie is replaced by * * *	•

Priority	Message	Cause	Remedy
!!	Audio off	This message appears in the alarm message field when the alarm volume is deactivated on a standalone M540 and the patient is also admitted at the ICS.	Activate the alarm volume.
		When the M540 is in an IACS configuration, this message appears when the alarm volume of the Cockpit is deactivated.	
!!!	All alarms off: Bypass	This message appears in the alarm message field when you activate cardiac bypass mode (see page 317).	Deactivate the feature to remove the message.
None	Discharged Touch screen to resume monitoring	This message appears in the center of the M540 screen when the patient has been discharged (see page 90).	Touch the screen to resume monitoring and admit a new patient.
!	Duplicate IP Address	This message appears in the alarm message field when a duplicate IP address is detected anywhere on the Infinity network. The M540 goes offline within 10 seconds of a <b>Duplicate IP Address</b> alarm condition.	<ul> <li>Configure a new IP address</li> <li>Power-cycle the M540</li> <li>Re-dock the M540</li> <li>The M540 then immediately tries to rejoin the Infinity network. If the address is already used, the same steps provided above will repeat.</li> </ul>
None	Filter ESU	This message appears above the ECG waveform when set to <i>Filter off</i> (see page 146).	Select another filter setting to change or remove the message.
None	Filter off	This message appears above the ECG waveform when set to <i>Filter off</i> (see page 146).	Activate the function to remove the message.

## ECG

Priority	Message	Cause	Remedy
!!!	ASY	The reported arrhythmia was	Check the patient and
!!!	Brady	detected.	treat if necessary.
	(neonatal patient category)		
!!!	VF		
111	ASY, VF OFF	This message appears in the alarm message field under the following circumstances:	The message disappears under the following circumstances:
		<ul> <li>Heart rate alarms are activated.</li> </ul>	<ul> <li>The <i>HR source</i> is</li> </ul>
		<ul> <li>HR source is set to Arterial or</li> </ul>	changed to <i>ECG</i> , or
		SpO2.	<ul> <li>The ARR mode is changed to Basic or</li> </ul>
		<ul> <li>ARR mode (arrhythmia) is deactivated.</li> </ul>	Advanced.
!!!	HR, ASY, VF off	This message appears in the alarm message field when specific settings are configured as follows:	Reconfigure the setting to remove the message.
		<ul> <li>Heart rate alarms are deacti- vated.</li> </ul>	
		<ul> <li>ASY/VF alarms feature is set to Follow HR (see page 304).</li> </ul>	
		<ul> <li>Arrhythmia monitoring is de- activated.</li> </ul>	
		The same message also appears under the following circumstances:	
		<ul> <li>Heart rate alarms are deacti- vated.</li> </ul>	
		<ul> <li>ASY/VF alarms feature is set to Always on (see page 304).</li> </ul>	
		<ul> <li>Arrhythmia monitoring is de- activated.</li> </ul>	
		<ul> <li>The selected <i>HR source</i> is activated and is either <i>Arterial</i> or <i>SpO2</i>.</li> </ul>	

Priority	Message	Cause	Remedy
!!	HR Alarms Off	<ul> <li>This message appears in the alarm message field under the following circumstances.</li> <li>When the alarm limits for heart rate are deactivated and the <i>ASY/VF alarms</i> function is set to <i>Always on</i> (see page 304).</li> <li>When the alarm limits for heart rate are deactivated, the basic arrhythmia function is activated and the <i>ASY/VF alarms</i> function is set to <i>Follow HR</i> (see page 304).</li> </ul>	
!	ECG artifact <sup>2)</sup>	<ul> <li>Patient movement (shivering, tremors)</li> <li>Bad electrode contact</li> <li>Excessive signal noise interference from auxiliary equipment</li> </ul>	<ul> <li>Check the electrodes and reapply if necessary.</li> <li>Make sure that the patient's skin is properly prepped.</li> <li>Isolate the patient from auxiliary equipment, if possible.</li> </ul>
!	ECG leads off <sup>2)</sup>	Lead-off condition detected due to: – Broken cable(s) – Disconnected ECG lead wires – Loose lead wire(s) – Wrong lead selected – Dried out electrode gel	<ul> <li>Replace faulty cable(s).</li> <li>Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes.</li> <li>Select another ECG</li> </ul>
!	ECG unplugged <sup>2)</sup>	ECG cable(s) disconnected from the M540.	<ul> <li>If monitoring augmented leads, verify that the number of selected leads in the <i>ECG</i> setup page is correct.</li> <li>Check cable(s) and connection(s).</li> <li>Replace cable(s) if necessary.</li> </ul>

<sup>2)</sup> In the parameter field the parameter value is replaced by \*\*\*

Priority	Message	Cause	Remedy	
!!	HR > (alarm limit)The parameter value is above/belowHR < (alarm limit)	<ul> <li>Check the patient and treat if necessary.</li> </ul>		
			<ul> <li>Change the alarm limits.</li> </ul>	
!!	HR out of range high <sup>1)</sup>	The parameter value is above the measurement range of the monitor.	Check the patient and treat if necessary.	
None	xx <sup>3)</sup> Lead off	The indicated lead wire is no longer attached to the patient.	Reattach the electrode to the patient.	
<sup>1)</sup> In the parameter field the parameter value is replaced by +++				
<sup>3)</sup> xx repre	esents LA, LL, RA, RL, V, V	1 to V6, or V+		

#### NOTE

**RRi** and 12-lead ECG monitoring are unavailable when the M540 is set to OR alarms and the ECG filter is set to **Monitor**.

## ST

Priority	Message	Cause	Remedy		
!	Cannot analyze ST <sup>3)</sup>	The algorithm cannot determine ST values due to artifact, the	<ul> <li>Perform a relearn.</li> <li>Check electrodes; re-apply if necessary.</li> </ul>		
		beats, or invalid leads.	<ul> <li>Make sure the patient's skin is properly prepared.</li> </ul>		
			<ul> <li>Isolate the patient from auxiliary equipment if possible.</li> </ul>		
			<ul> <li>Inspect and replace faulty lead sets.</li> </ul>		
			<ul> <li>Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes.</li> </ul>		
			<ul> <li>Reapply the electrode(s).</li> <li>Make sure the patient's skin is properly prepared.</li> </ul>		
			<ul> <li>If a lead wire or electrode cannot be replaced, select another ST lead.</li> </ul>		
<sup>3)</sup> In the pa	rameter field the parameter value	is replaced by ***			
!!	ST <label><sup>4)</sup> &gt; (alarm limit) ST<label><sup>4)</sup> &lt; (alarm limit)</label></label>	The parameter value is above/below the set	<ul> <li>Check the patient and treat if necessary.</li> </ul>		
		upper /lower alarm limits.	<ul> <li>Change the alarm limits.</li> </ul>		
!!	ST <label> <sup>4)</sup> out of range high <sup>2)</sup></label>	The parameter value is above/below the	<ul> <li>Check the patient and treat if necessary.</li> </ul>		
!!	ST <label> <sup>4)</sup> out of range low<sup>1)</sup></label>	measurement range of the monitor.	<ul> <li>Check the placement of electrodes and change their position if necessary.</li> </ul>		
None	ST relearning	ST relearn is in progress	Informational message – no action required.		
<sup>1)</sup> In the parameter field the parameter value is replaced by					
<sup>2)</sup> In the parameter field the parameter value is replaced by +++					
<sup>4)</sup> <label> represents I, II, III, aVR, aVL, aVF, V, V1 to V6, or V+</label>					

## Arrhythmia

Priority	Message	Cause	Remedy
!!! !!!	ASY Asystole VF Ventricular fibrillation	The indicated arrhythmia was detected.	<ul> <li>Check the patient and treat if necessary.</li> <li>Some messages only</li> </ul>
!!!	VTACH <sup>1)</sup> Ventricular Tachycardia		appear when the full arrhythmia option is installed.
!!	RUN <sup>1)</sup> Ventricular RUN		
!!	AIVR <sup>1)</sup> Accelerated Idioventricular Rhythm		
!!	SVT <sup>1)</sup> Supraventricular Tachycar- dia		
!	CPT <sup>1)</sup> Ventricular Couplet		
!	BGM <sup>1)</sup> bigeminy		
Off	TACH <sup>1)</sup> Tachycardia		
Off	Brady <sup>1)</sup> Bradycardia		
Off	Pause <sup>1)</sup> user selectable interval		
Off	ARTF <sup>1)</sup> artifact, background rhythm		
None	<i>ARR cannot learn</i> (arrhythmia lead)	After 100 beats, the M540 cannot determine the dominant normal complex on any lead selected for QRS processing.	<ul> <li>Check the electrode preparation.</li> <li>Reapply electrodes if necessary.</li> </ul>
None	ARR relearning	The M540 is learning the patient's QRS complex to establish a reference template.	Informational message – no action required.
!!	<i>PVC/min</i> > (alarm limit)	PVC value is above the upper alarm limit.	<ul> <li>Check the patient and treat if necessary.</li> <li>Reapply electrodes if necessary.</li> </ul>
<sup>1)</sup> These arr listed in	 hythmia events can have one of three alarm pr n this table is the default. For these arrhythmia	l riorities assigned (high, medium, a events, you can disable alarms	or low.) or is turned off. The priority

## Respiration (RRi)

Priority	Message	Cause	Remedy
!!	<b>RRi &gt;</b> (alarm limit) <b>RRi &lt;</b> (alarm limit)	The parameter value is above/below the set	<ul> <li>Check the patient and treat if necessary.</li> </ul>
			<ul> <li>Check the alarm limits.</li> </ul>
!!!	RRi apnea	Neonatal apnea condition was detected.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
!!	RRi apnea	Adult or pediatric apnea condition was detected.	<ul> <li>Check the placement of electrodes. Change their position if necessary.</li> </ul>
			<ul> <li>Initiate a relearn or reset breath-detection sensitivity in manual mode.</li> </ul>
!	RRi artifact <sup>2)</sup>	Persistent artifact was detected.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
!	RRi high impedance <sup>2)</sup>	A high respiration impedance was	<ul> <li>Make sure the patient's skin is prepared properly.</li> </ul>
!	RRi lead off <sup>2)</sup>	The respiration lead has been invalid for 10	<ul> <li>Isolate the patient from any auxiliary equipment, if possible.</li> </ul>
!	RRi lead unavailable <sup>2)</sup>	Faulty or disconnected electrodes.	<ul> <li>Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes.</li> </ul>
			<ul> <li>Inspect and replace faulty lead sets.</li> </ul>
			<ul> <li>If a lead wire or electrode cannot be replaced, select another lead for processing (in the RRi setup page).</li> </ul>
!!	RRi coincidence	The heart rate and respiratory rate fall within 20% of each other.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
			<ul> <li>Check and change the electrode placement if you receive a coincidence message until you obtain a clear respiration signal.</li> </ul>

Priority	Message	Cause	Remedy	
!!	RRi out of range high <sup>1)</sup>	The respiratory rate is higher than 150 breaths per minute.	<ul> <li>Check the patient and treat if necessary.</li> <li>Check the placement of</li> </ul>	
		The M540 may be counting artifacts as valid breaths.	electrodes. Change their position if necessary.	
		The M540 may be counting interference caused by faulty equipment.	from the source of interference.	
None	RRi relearning	Relearn is in progress.	Informational message – no action required.	
<sup>1)</sup> In the parameter field the parameter value is replaced by +++				
<sup>2)</sup> In the pa	arameter field the parameter v	alue is replaced by ***		

#### NOTE

*RRi* and 12-lead ECG monitoring are unavailable when the M540 is set to OR alarms and the ECG filter is set to *Monitor*.

#### SpO2

# The following messages originate from three different hardware devices (Masimo SET, Masimo rainbow SET, and Nellcor OxiMax).

Priority	Message	Cause	Remedy
None Masimo rainbow SET only	Learning Pulse CO-Ox <sup>3)</sup>	The Masimo rainbow SET- specific parameters are being calculated (only the parameters for SpO2, PLS, and PI are available).	Wait until the Masimo rainbow SET parameters are calculated.
None Any Masimo MCable	Low SpO2 SIQ	MCable detects a low signal quality for the indicated parameter.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
None Masimo rainbow SET only	Low SpHb SIQ Low SpHbv SIQ Low SpOC SIQ		<ul> <li>Make sure the SpO2 sensor is attached properly to the patient.</li> </ul>
	Low SpMet SIQ Low SpCO SIQ Low PVI SIQ		<ul> <li>Check all cable connections.</li> </ul>
!!	<i>PLS</i> > (alarm limit) <i>PLS</i> < (alarm limit)	The pulse rate above/below the set upper/lower alarm limits.	<ul> <li>Check the patient and treat if necessary.</li> <li>Change the alarm limits.</li> </ul>
!!	PLS out of range high <sup>1)</sup> PLS out of range low <sup>2)</sup>	The parameter value is above/below the measurement range of the monitor.	<ul> <li>Check the patient and treat if necessary.</li> <li>Change the alarm limits.</li> </ul>

Priority	Message	Cause	Remedy
!!	<b>SpHb</b> > (alarm limit)	The parameter value is	<ul> <li>Check the patient</li> </ul>
	<b>SpHbv</b> < (alarm limit)	lower alarm limits.	and treat if necessary.
	<b>PVI</b> > (alarm limit)		<ul> <li>Change the alarm</li> </ul>
	<b>PVI</b> < (alarm limit)		limits.
	<b>SpCO</b> > (alarm limit)		
	<b>SpCO</b> < (alarm limit)		
	<b>SpMet</b> > (alarm limit)		
	<b>SpMet</b> < (alarm limit)		
!!	<b>SpO</b> 2 > (alarm limit)	The parameter value is	<ul> <li>Check the patient</li> </ul>
	<b>SpO</b> 2 < (alarm limit)	lower alarm limits.	and treat if necessary.
		The priority changes to high (!!!) if the SpO2 value falls more than 10% below the lower limit. This does not occur when using <b>SatSeconds</b> time with the Nellcor OxiMax MCable.	<ul> <li>Change the alarm limits.</li> </ul>
!	SpO2 cable expired <sup>3)</sup>	Cable expired.	Replace the cable.
Any Masimo MCable			
!	SpO2 cable expires soon	Cable near expiration.	Replace the cable.
Any Masimo MCable			
!	SpO2 cable failure <sup>3)</sup>	The Masimo rainbow SET	Replace the
Masimo rainbow SET only		or has expired.	Intermediate cable.
! Nellcor OxiMax MCable only	SpO2 check sensor <sup>3)</sup>	SpO2 sensor is detecting too much ambient light.	<ul> <li>Make sure the SpO2 sensor is attached properly to the patient.</li> </ul>
			<ul> <li>Check all cable connections.</li> </ul>

Priority	Message	Cause	Remedy
None Masimo rainbow SET only	SpO2 Sensor Calibrating <sup>3)</sup>	The sensor is being checked for functional integrity.	<ul> <li>Wait until the message disappears.</li> </ul>
			This message appears right before the message <b>SpO</b> 2 <b>searching</b> .
III Any SpO2 MCable	Desat. < (alarm limit)	The parameter value is below the set lower alarm limit.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
			<ul> <li>Change the alarm limit.</li> </ul>
! Any SpO2	SpO2 H/W failure <sup>3)</sup>	Masimo SET MCable or Nellcor OxiMax MCable	<ul> <li>Check for a faulty MCable.</li> </ul>
MCable		nardware failure.	<ul> <li>Power cycle the M540 to clear the message.</li> </ul>
			<ul> <li>Contact specialized service personnel.</li> </ul>
! Any Masimo MCable	SpO2 interference detected <sup>3)</sup>	Interference such as artifact was detected.	<ul> <li>Make sure the sensor is properly attached.</li> </ul>
			<ul> <li>Make sure that no nail polish or some other substance is blocking the light.</li> </ul>
			<ul> <li>Change the sensor location.</li> </ul>
None Any Masimo MCable	SpO2 low perfusion	Arterial pulsations with low amplitudes were detected.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
			<ul> <li>Move the sensor to a site that is more adequately perfused.</li> </ul>
			<ul> <li>Select the maximum sensitivity mode (see page 193).</li> </ul>

Priority	Message	Cause	Remedy
! Any SpO2 MCable	<b>SpO2 MCable unplugged</b> <sup>3)</sup> In the parameter field the parameter value is replaced by blanks for the Masimo rainbow SET parameter PI.	The SpO2 MCable is disconnected from the M540.	Check connections to the M540.
Masimo rainbow SET only	<i>SpO2 only mode</i> Parameter values are displayed for <i>SpO2</i> , <i>PLS</i> , and <i>PI</i> ; the Masimo rainbow SET parameter values are replaced by ***	The device cannot calibrate the Masimo rainbow SET parameters and is attempting to display the standard Masimo parameters.	Remove and reapply the sensor. If the problem persists, contact specialized service personnel.
! Any Masimo MCable	SpO2 replace cable next pt.	Cable expired.	Replace the cable.
! Any Masimo MCable	SpO2 replace sensor next pt.	<ul> <li>SpO2 sensor expired</li> <li>Adhesive sensor expired</li> </ul>	Replace the sensor.
None Any SpO2 MCable	SpO2 searching <sup>3)</sup>	The sensor is searching for valid pulses to compute a measurement value.	Verify proper sensor application.
! Any Masimo MCable	SpO2 sensor expired <sup>3)</sup>	<ul> <li>SpO2 sensor expired</li> <li>Adhesive sensor expired</li> </ul>	Replace the sensor.
! Any Masimo MCable	SpO2 sensor expires soon	<ul> <li>SpO2 sensor near expiration</li> <li>Adhesive sensor near expiration</li> </ul>	Replace the sensor.
! Any SpO2 MCable	SpO2 sensor failure 3)	The MCable has detected a hardware failure with the SpO2 sensor.	<ul> <li>Make sure the SpO2 sensor is properly attached to the patient and all cables are properly connected.</li> <li>Replace sensor.</li> <li>Contact specialized service personnel.</li> </ul>

Priority	Message	Cause	Remedy	
! Any Masimo MCable	SpO2 sensor off <sup>3)</sup>	The Masimo MCable has detected that the SpO2 sensor is no longer attached to the patient.	Reattach the SpO2 sensor.	
!	<i>SpO2 sensor unplugged</i> In the parameter field the parameter value is replaced by the following depending on which MCable is used: *** for the parameters SpO2, PLS, SpHb/SpHbv, PVI, SpCO, SpOC, SpMet; blanks for the parameter PI.	The SpO2 intermediate cable or sensor is unplugged.	<ul> <li>Verify that the cable and the sensor are properly connected.</li> <li>Check for faulty sensor.</li> </ul>	
! Any Masimo MCable	SpO2 unrecognized cable <sup>3)</sup>	An incompatible Masimo MCable is connected.	<ul> <li>Connect the right type of cable.</li> <li>Contact specialized service personnel.</li> </ul>	
! Any SpO2 MCable	SpO2 unrecognized sensor <sup>3)</sup>	<ul> <li>The MCable does not recognize the connected sensor.</li> <li>A reusable SpHb sensor is connected to a Masimo rainbow SET MCable that does not support this parameter.</li> </ul>	<ul> <li>Connect the right type of sensor.</li> <li>Contact specializedservice personnel.</li> </ul>	
<ul> <li><sup>1)</sup> In the parameter field the parameter value is replaced by</li> <li><sup>2)</sup> In the parameter field the parameter value is replaced by +++</li> </ul>				
<sup>o</sup> in the pa	arameter field the parameter value is	s replaced by """		

## Non-invasive blood pressure

Priority	Message	Cause	Remedy
!!	NIBP D > (alarm limit) $^{1)}$ NIBP D < (alarm limit) $^{1)}$ NIBP M > (alarm limit) $^{1)}$ NIBP M < (alarm limit) $^{1)}$ NIBP S > (alarm limit) $^{1)}$ NIBP S < (alarm limit) $^{1)}$	The parameter value is above/below the set upper /lower alarm limits.	<ul> <li>Check the patient and treat if necessary.</li> <li>Change the alarm limits.</li> </ul>
11	NIBP blocked line <sup>1)</sup>	The inflation rate is too high or the time to evacuate residual cuff pressure at the end of the deflation cycle is too short.	<ul> <li>Select a different cuff.</li> <li>Check the hose and cuff for damage.</li> <li>Restart the measurement. If the message does not clear, contact specialized service personnel.</li> </ul>
!	NIBP cannot measure 1)	The pulse profile is too poor to establish a reliable measurement (usually due to persistent motion artifact)	<ul> <li>Check the patient and treat if necessary.</li> <li>Move the cuff to a limb with less movement.</li> <li>Restart the measurement. If the message does not clear, contact specialized service personnel.</li> </ul>
!	NIBP cuff leak <sup>1)</sup>	The drop in cuff pressure at the end of the inflation cycle is too great.	<ul> <li>Check the hose and cuff for leaks. Replace if necessary.</li> <li>Restart the measurement. If the message does not clear, contact specialized service personnel.</li> </ul>

Priority	Message	Cause	Remedy
!!	NIBP H/W failure <sup>1)</sup>	<ul> <li>Non-invasive blood pressure measurement circuit failure</li> <li>Non-invasive blood pressure zero out of</li> </ul>	<ul> <li>Check all hardware, and contact specialized service personnel.</li> <li>Power cycle the M540 to clear this message.</li> </ul>
		range or faulty transducer	
!!	NIBP low inflation limit <sup>1)</sup>	The pressure of the patient is greater than the maximum allowed cuff inflation pressure.	Select the next higher inflation limit setting.
!	NIBP mean only <sup>1) 2)</sup>	The pulse amplitude is too small or too high for the M540 to derive systolic and diastolic pressure values but sufficient to report a mean pressure value.	<ul> <li>Check the patient and treat if necessary.</li> <li>Check the hose and cuff.</li> <li>Check the size and the placement of the cuff.</li> </ul>
!	NIBP measurement timeout <sup>1)</sup>	An non-invasive blood pressure measurement has exceeded time-out limit.	Repeat the measure- ment.
!	NIBP open line <sup>1)</sup>	There was no significant increase in cuff pressure during the inflation cycle.	Make sure that the hose and cuff are properly connected to the moni- tor.
!!	NIBP out of range high NIBP out of range low	The parameter value is above/below the measurement range of the monitor.	Check the non-invasive blood pressure inflation limits and adjust them if necessary (for exam- ple, if the wrong patient category is selected).
!	NIBP overpressure <sup>1)</sup>	The cuff pressure has exceeded the overpressure threshold.	<ul> <li>Check the patient and treat if necessary.</li> <li>Check the cuff for obstructions.</li> <li>Repeat the measurement.</li> </ul>
None	NIBP pneumatic char needed	Non-invasive blood pressure hardware failure in the M540.	Contact specialized service personnel and take the M540 out of service.

Priority	Message	Cause	Remedy
None	NIBP pneumatic char failed	Technical hardware failure.	Contact specialized service personnel and take the M540 out of service.
None	Venous stasis started	Message reports the start of venous stasis.	Informational message – no action required).
None	Venous stasis ended	Message reports the end of venous stasis.	Informational message – no action required).
None	Venous stasis ending	Message reports that venous stasis is ending in less than 10 seconds.	Informational message – no action required).
<sup>1)</sup> In the parameter field the parameter value is replaced by ***			
<sup>2)</sup> In the pa	arameter field the systolic and diastoli	c parameter values are re	placed by ***

## Cardiac output

Although the M540 processes the cardiac output algorithm, you can only view the messages on the Cockpit, when the M540 is docked in an IACS configuration. For more information, refer to the Instructions for use *Infinity Acute Care System – Monitoring Applications*.

## Temperature

Priority	Message	Cause	Remedy		
!	Cannot derive $\Delta T^{(3)(4)}$	One of the cables is either unplugged or faulty, or the	<ul> <li>Check the equipment and replace it if necessary.</li> </ul>		
	Cannot derive ΔT2	value is out of range.	<ul> <li>Connect the second temperature sensor.</li> </ul>		
!!	$T > {}^{4)} > (alarm limit)$	The parameter value is	<ul> <li>Check the patient and treat</li> </ul>		
	<b>T &lt;</b> ⁴) < (alarm limit)	upper/lower alarm limits.	<ul> <li>Freessary.</li> <li>Change the alarm limits.</li> </ul>		
!	T H/W Failure <sup>3)</sup>	The hardware reference	Contact specialized service		
	T1 H/W Failure 3)	values do not meet the	personnel.		
	T2 H/W Failure <sup>3)</sup>				
!!	Temp out of range high <sup>2)</sup>	The parameter value is	<ul> <li>Check the patient and treat</li> </ul>		
!!	Temp out of range low <sup>1)</sup>	above/below the measurement range of the	If necessary.		
		monitor.	<ul> <li>Check the equipment and replace, if necessary.</li> </ul>		
!	T unplugged <sup>3)</sup>	The temperature sensor is unplugged.	Reapply the temperature sensor.		
<sup>1)</sup> In the parameter field the parameter value is replaced by					
<sup>2)</sup> In the parameter field the parameter value is replaced by +++					
<sup>3)</sup> In the parameter field the parameter value is replaced by ***					
<sup>4)</sup> Value ca	an be for <b>Ta/T1a, Tb/T1b, ΔT</b> /	′ <b>⊿T1</b>			

## Invasive pressure

Priority	Message	Cause	Remedy
!!!	ART cath. disconnected?	The arterial catheter could be dislodged, or there could be a leak in the tubing.	<ul> <li>Assess the catheter insertion site.</li> <li>Inspect the tubing for leaks or the presence of blood.</li> <li>Check the patient and treat, if necessary.</li> </ul>
!!	transducer failure	Hardware failure in the pressure transducer.	Check the transducer and replace, if necessary.
!! !!	CPP > (alarm limit) CPP < (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	<ul> <li>Check the patient and treat if necessary.</li> <li>Change the alarm limits.</li> </ul>
!! !!	<b>CPP out of range high</b> <sup>2)</sup> <b>CPP out of range low</b> <sup>1)</sup>	The pressure rate falls outside the measuring range of the monitor.	<ul> <li>Check the patient and treat if necessary.</li> <li>Check the equipment and replace, if necessary.</li> </ul>
!	HemoPod unplugged <sup>3)</sup>	The hemodynamic pod is disconnected.	Check the equipment and replace if necessary.
!	2nd HemoPod unplugged <sup>3)</sup>	The second invasive pressure device is disconnected.	<ul> <li>Check the equipment and replace if necessary.</li> </ul>
None	HemoPod incompatible	An incompatible invasive pressure device has been connected.	<ul> <li>Remove the incompatible invasive pressure pod.</li> </ul>
!! !!	IP x <sup>4)</sup> > (alarm limit) IP x <sup>4)</sup> < (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	<ul> <li>Check the patient and treat if necessary.</li> <li>Change the alarm limits.</li> </ul>
 	IP x <sup>4)</sup> > out of range high IP x <sup>4)</sup> < out of range low	The pressure signal falls outside the measuring range of the monitor.	<ul> <li>Check the patient and treat if necessary.</li> <li>Check the equipment and replace, if necessary.</li> </ul>
None	<ip> check zero</ip>	The invasive blood pressure zero value stored in the M540 was lost and the transducer requires zeroing.	Zero the transducer.

Priority	Message	Cause	Remedy		
None	<ip> did not zero</ip>	Transducer zeroing failed because of:	<ul> <li>Keep all tubing motionless, then rezero.</li> </ul>		
		<ul> <li>excessive signal</li> </ul>	<ul> <li>Change the transducer.</li> </ul>		
		noise – a non-static wave- form	<ul> <li>Check stopcock, then rezero.</li> </ul>		
!	HemoPod H/W failure <sup>3)</sup>	Invasive pressure hardware failure.	<ul> <li>Check hardware and replace if necessary.</li> </ul>		
			<ul> <li>Call specialized service personnel.</li> </ul>		
!!	<ip> static pressure</ip>	Static pressure detected on a pulsatile signal, due to:	<ul> <li>Check the patient and treat if necessary.</li> </ul>		
		<ul> <li>a physiological condition such as an asystole</li> </ul>	<ul> <li>Open the system to the patient by turning the stopcock.</li> </ul>		
		<ul> <li>a transducer that is closed to the patient</li> <li>a catheter tip that is</li> </ul>	<ul> <li>Follow hospital procedures for dislodging catheters.</li> </ul>		
		lodged against a ves- sel wall – a clot on the catheter tip	<ul> <li>Follow hospital procedures for clotted catheters.</li> </ul>		
!	HemoPod unplugged <sup>1)</sup>	The pressure transducer for the specified parameter is either unplugged or faulty.	<ul> <li>During an active pressure: Reconnect or replace the cable.</li> </ul>		
			<ul> <li>During an inactive pressure: Turn off alarms.</li> </ul>		
None	<ip> Zero accepted</ip>	Transducer zeroing was successful.	Informational message – no action required.		
<sup>1)</sup> In the pa	arameter field the parameter valu	e is replaced by			
<sup>2)</sup> In the pa	arameter field the parameter valu	e is replaced by +++			
<sup>3)</sup> In the pa	arameter field the parameter valu	e is replaced by * * *			
<sup>4)</sup> x repres	<sup>4)</sup> x represents S (systolic), D (diastolic), or M (mean)				

#### Mainstream CO<sub>2</sub>

Priority	Message	Cause	Remedy
None	CO2 calibration check failed	The mainstream sensor calibration procedure failed.	<ul> <li>Ensure that the filter and sensor are clean.</li> </ul>
			<ul> <li>If failure persists, contact specialized service personnel.</li> </ul>
None	CO2 calibration check successful	The mainstream sensor calibration procedure was successful.	Informational message – no action required.
None	%0 calibration in progress	The mainstream sensor calibration procedure is in progress.	Informational message – no action required.
!	CO2 check airway adapter <sup>1)</sup>	<ul> <li>The mainstream sensor is not properly seated on the adapter</li> </ul>	<ul> <li>Make sure the mainstream sensor is attached properly to the adapter.</li> </ul>
<ul> <li>There are secretion the adapter</li> <li>There is sensor zer drift</li> </ul>	<ul> <li>There are secretions in the adapter</li> <li>There is sensor zero</li> </ul>	<ul> <li>If message persists, clean or replace the airway adapter.</li> </ul>	
		drift	<ul> <li>If message persists though the airway adapter is clean, zero the sensor.</li> </ul>
!	CO2 MCable failure <sup>1)</sup>	CO2 sensor hardware failure.	Contact specialized service personnel.

Priority	Message	Cause	Remedy
!	CO2 incompatible sensor <sup>1)</sup>	<ul> <li>The M540 has detected that the used mainstream sensor is not compatible with the selected sensor type setting (reusable/disposable)</li> </ul>	<ul> <li>Use the airway adapter type the system is configured for or adjust the airway adapter setting (see page 259).</li> <li>If the message persists, clean or replace the airway</li> </ul>
		<ul> <li>Secretions in the adapter</li> <li>Sensor zero drift</li> <li>High inspiratory CO2 concentration</li> </ul>	<ul> <li>If the message persists even though the correct airway adapter type is selected and the airway adapter is clean, zero the sensor.</li> </ul>
			<ul> <li>If the message persists, the inspiratory CO<sub>2</sub> value might not be accurate. Check the patient and ventilation.</li> </ul>
!!	CO2 out of range high <sup>1)</sup>	The parameter signal is outside the measuring	<ul> <li>Check the patient and treat if necessary.</li> </ul>
		range of the monitor.	<ul> <li>Check the equipment and replace if necessary.</li> </ul>
None	CO2 please zero	Instructional message for the mainstream sensor only.	Zero the mainstream sensor.
!	CO2 sensor too warm <sup>1)</sup>	The CO2 mainstream sensor is too warm due to ambient temperature.	<ul> <li>Unspecified accuracy at ambient temperatures above 40 °C (104 °F).</li> <li>The sensor will return to normal operation at ambient temperatures below 40 °C (104 °F). If not, replace the sensor and contact specialized service personnel.</li> </ul>
!	CO2 MCable unplugged <sup>1)</sup>	The CO2 sensor is disconnected.	Check the CO <sub>2</sub> connections.
!	CO <sub>2</sub> MCable failure	The CO <sub>2</sub> sensor hardware failed due to a corrupt EPROM (erasable programmable read-only memory) chip.	Contact specialized service personnel.

Priority	Message	Cause	Remedy
!!	CO2 warming up	The CO <sub>2</sub> sensor is completing its warm-up cycle.	<ul> <li>Wait for the CO2 sensor to warm up. During warm-up, the accuracy is reduced.</li> </ul>
			<ul> <li>If the message persists longer than 15 min. after the sensor has warmed up, and the ambient temperature is above 10 °C (50 °F), contact specialized service personnel.</li> </ul>
			<ul> <li>You cannot zero the sensor while this message is displayed and the ambient temperature is above 10 °C (50 °F).</li> </ul>
			<ul> <li>When the ambient temperature is below 10 °C (50 °F), the message can display longer than 15 minutes. In this case, it is possible to zero the sensor after the message has been displayed for at least 10 minutes.</li> </ul>
None	CO2 zeroing failed	Zeroing of the sensor has failed or the sensor is faulty.	<ul> <li>Try to zero the sensor again making sure not to breathe on the sensor and that the sensor is not blocked.</li> </ul>
			<ul> <li>If zeroing fails again, replace the sensor and contact specialized service personnel.</li> </ul>
None	CO2 zeroing in progress	The CO2 zeroing is in progress	Informational message – no action required.
!!	etCO2 > (alarm limit)	The parameter value is above/below the set	<ul> <li>Check the patient and treat if pecessary</li> </ul>
	etCO2 < (alarm limit) (except inCO2)	upper/lower alarm limits.	<ul> <li>Change the alarm limits.</li> </ul>
!!	RRc out of range high	The parameter signal is outside the measuring range of the monitor.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
		<u>.</u>	<ul> <li>Check the equipment and replace if necessary.</li> </ul>

Priority	Message	Cause	Remedy		
!!	RRc apnea	Apnea was detected	<ul> <li>Check the patient and treat if necessary.</li> </ul>		
			<ul> <li>Check the placement of sensor.</li> </ul>		
<sup>1)</sup> In the pa	<sup>1)</sup> In the parameter field the parameter value is replaced by ***				

#### Microstream CO<sub>2</sub>

#### Calibration and maintenance

Priority	Message	Cause	Remedy
None	CO <sub>2</sub> calibration check failed	The Microstream MCable calibration procedure failed.	Contact specialized service personnel.
None	CO2 calibration check successful	The Microstream MCable calibration procedure was successful.	Informational message – no action required.
None	%0 calibration in progress	The Microstream MCable calibration procedure is in progress.	Informational message – no action required.
None	CO <sub>2</sub> calibration required	The Microstream MCable calibration procedure is due.	Contact specialized service personnel.
None	CO2 MCable: Maintenance is due	Maintenance for Microstream MCable is due.	Contact specialized service personnel.
None	CO2 zeroing failed	Resetting the Microstream MCable to zero has failed the standard three attempts.	Contact specialized service personnel.
None	CO2 zeroing in progress	The Microstream MCable is being reset to zero.	Informational message – no action required.

#### CO<sub>2</sub> monitoring

Priority	Message	Cause	Remedy
!!	CO2 out of range high <sup>1)</sup>	The parameter signal is outside the measuring	<ul> <li>Check the patient and treat if necessary.</li> </ul>
		range of the monitor.	<ul> <li>Check the equipment and replace if necessary.</li> </ul>
!	CO2 sensor unplugged <sup>1)</sup>	The Microstream MCable is disconnected.	Check the CO <sub>2</sub> connections.
!	CO2 MCable unplugged	The Microstream MCable is disconnected from the monitor.	Reconnect the Microstream MCable to the monitor.
!	CO2 MCable failure	The Microstream MCable hardware has failed due to an internal issue including:	Contact specialized service personnel.
		<ul> <li>a corrupt EPROM (erasable programmable read- only memory) chip</li> </ul>	
		<ul> <li>a compromised flow rate that caused the auto- zero procedure to fail.</li> </ul>	
!	CO2 MCable: Gas outlet blocked	The Microstream MCable gas outlet is blocked.	<ul> <li>Ensure that the gas outlet is not blocked.</li> </ul>
			<ul> <li>Contact specialized service personnel.</li> </ul>

Priority	Message	Cause	Remedy
!!	CO2 warming up	The Microstream MCable is completing its warm-up cycle.	<ul> <li>Wait for the Microstream MCable to warm up. During warm-up, the accuracy is reduced.</li> </ul>
			<ul> <li>If the message persists longer than 15 min. after the sensor has warmed up, and the ambient temperature is above 10 °C (50 °F), contact specialized service personnel.</li> </ul>
			<ul> <li>You cannot zero the sensor while this message is displayed and the ambient temperature is above 10 °C (50 °F).</li> </ul>
			<ul> <li>When the ambient temperature is below 10 °C (50 °F), the message can display longer than 15 minutes. In this case, it is possible to zero the sensor after the message has been displayed for at least 10 minutes.</li> </ul>
None	CO2 zeroing in progress	The Microstream MCable is being reset to zero.	Informational message – no action required.
!!	etCO2 > (alarm limit) etCO2 < (alarm limit) (except inCO2)	The parameter value is above/below the set upper/lower alarm limits.	<ul> <li>Check the patient and treat, if necessary.</li> <li>Change the alarm limits.</li> </ul>
!!!	RRc apnea	Apnea was detected.	<ul> <li>Check the patient and treat, if necessary.</li> </ul>
			<ul> <li>Check the placement of sensor.</li> </ul>
!!	RRc out of range high	The parameter signal is outside the measuring range of the monitor.	<ul> <li>Check the patient and treat if necessary.</li> </ul>
			<ul> <li>Check the equipment and replace if necessary.</li> </ul>
<sup>1)</sup> In the pa	arameter field the parameter	value is replaced by ***	

#### Sample line

Priority	Message	Cause	Remedy
!	Sample line is being cleared	A sample line blockage occurred and the Microstream MCable is attempting to clear the sample line.	Informational message – no action required.
!	Sample line blocked	The sample line is blocked during the purging process.	Replace the sample line.
!	Sample line disconnected	The sample line is disconnected from the Microstream MCable.	Securely connect the sample line to the Microstream MCable.

#### Scio

#### CAUTION

Risk due to gas measurement failure

If gas measurement fails, the patient can no longer be adequately monitored.

- Ensure corresponding substitute monitoring.
- Check sample line and water trap for damage or blockage and resolve these as needed.
- Observe the prescribed exchange intervals.

#### Alarm - Cause - Remedy

If an alarm occurs, the table helps to quickly identify causes and remedies. The possible causes and remedial measures should be consulted in the order in which they are listed until the alarm is resolved.

The following table lists the alarm messages in alphabetical order.

Alarm Priority	Alarm	Cause	Remedy
Medium	[agent] out of range high	Agent concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh- gas settings, and ventilation
Low	Agent reduced accuracy	Accuracy of the Agent sensor cannot currently be guaranteed. <b>NOTE</b> This alarm occurs only on gas analyzers with manual agent identification.	<ul> <li>Ensure clean ambient air</li> <li>Check water trap and sample line.</li> <li>Change the water trap or sample line if necessary.</li> <li>Wait for automatic zeroing.</li> <li>Power cycle the gas analyzer.</li> <li>Call specialized service personnel.</li> </ul>
Low	Agent sensor failure	The Agent sensor measurement has failed due to: – Sample line occlusion.	<ul> <li>Check sample line.</li> <li>Remove radiating devices (e.g., telephone).</li> </ul>
		<ul> <li>Electrical disturbance.</li> <li>Internal failure.</li> </ul>	<ul> <li>Use alternative agent measurement system.</li> <li>Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	Agent value temporarily unavail.	Agent parameter has unknown accuracy or automatic identification is taking more time than usual, possibly due to: – Zeroing failure – Polluted ambient air during zeroing. – Electromagnetic disturbances. – Overheating.	<ul> <li>Ensure clean ambient air.</li> <li>Remove radiating devices (e.g., telephone).</li> <li>Check ambient temperature.</li> <li>Change the water trap or sample line if necessary.</li> <li>Power cycle Scio.</li> <li>Change vaporizer settings.</li> <li>Call specialized</li> </ul>
Low	Chock water	Sample line is blocked or	service personnel.
Low	trap/sample line	<ul> <li>Outline into its blocked of not connected.</li> <li>Water trap is full or not installed.</li> </ul>	<ul> <li>Check water trap.</li> </ul>
Medium	CO2 out of range high	CO <sub>2</sub> concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh- gas settings and ventilation.
Low	CO2 reduced accuracy	Accuracy of the CO <sub>2</sub> sensor cannot currently be guaranteed.	<ul> <li>Ensure clean ambient air</li> <li>Check water trap and sample line.</li> <li>Change the water trap or sample line if necessary.</li> <li>Wait for automatic zeroing.</li> <li>Power cycle the gas analyzer.</li> <li>Call specialized</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	CO2 sensor failure	The CO2 sensor in patient gas measurement module has failed due to: - Sample line occlusion.	<ul> <li>Check sample line.</li> <li>Remove radiating devices (e.g., telephone).</li> </ul>
		<ul><li>Electrical disturbance.</li><li>Internal failure.</li></ul>	<ul> <li>Use alternative CO2 measurement system.</li> </ul>
			<ul> <li>Call specialized service personnel.</li> </ul>
Low	<i>et[agent] &lt; #</i> NOTE This alarm occurs only for the primary agent.	<ul> <li>Expiratory anesthetic gas concentration has fallen below the lower alarm limit for more than 15 seconds.</li> <li>Soda lime is dried out.</li> </ul>	<ul> <li>Check vaporizer and fresh-gas settings.</li> <li>Check breathing system for large leaks.</li> <li>Exchange soda lime.</li> </ul>
Medium	et[agent] > # NOTE This alarm occurs only for the primary agent.	Expiratory anesthetic gas concentration has exceeded the upper alarm limit for more than 15 seconds.	Check vaporizer and fresh-gas settings
Medium	etCO2 < #	Expiratory CO2 has fallen below the limit for more than 15 seconds.	Check ventilation.
Medium	etCO2 > #	Expiratory CO <sub>2</sub> has exceeded the limit for more than 15 seconds.	Check ventilation.
Medium	etO2 < #	Expiratory O2 concentration has fallen below the lower alarm limit for more than 15 seconds.	<ul> <li>Check O2 concentration and fresh-gas settings</li> <li>Check breathing system for large leaks.</li> <li>Check O2 supply.</li> </ul>
Medium	etO2 > #	Expiratory O2 concentration has exceeded the upper alarm limit for more than 15 seconds.	Check O2 concentration and fresh-gas settings.

Alarm Priority	Alarm	Cause	Remedy
High	FiO2 < #	<ul> <li>Inspiratory O2 concentration has fallen below the lower alarm limit:</li> <li>At least 15 seconds (with respiratory phases).</li> <li>At least 30 seconds (without respiratory phases).</li> </ul>	<ul> <li>Check O2 concentration and fresh-gas settings</li> <li>Check breathing system for large leaks.</li> <li>Check O2 supply.</li> </ul>
Medium	FiO2 > #	Inspiratory O2 concentration has exceeded the upper alarm limit for more than 15 seconds.	Check O2 concentration and fresh-gas settings.
Medium	Gas sensor failure	<ul> <li>The patient-gas measurement has failed due to:</li> <li>Sample line occlusion.</li> <li>Electrical disturbance.</li> <li>Internal failure.</li> </ul>	<ul> <li>Check sample line.</li> <li>Remove radiating devices (e.g., telephone).</li> <li>Use alternative gas measurement system.</li> <li>Call specialized service personnel.</li> </ul>
Low	Gas sensor reduced accuracy	Accuracy of the gas measurements cannot be guaranteed.	<ul> <li>Ensure clean ambient air</li> <li>Check water trap and sample line.</li> <li>Change the water trap or sample line if necessary.</li> <li>Wait for automatic zeroing.</li> <li>Power cycle the gas analyzer.</li> <li>Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	<i>in[agent] &lt; #</i> <b>NOTE</b> This alarm occurs only for the primary agent.	<ul> <li>Inspiratory anesthetic gas concentration has fallen below the lower alarm limit for more than 15 seconds.</li> <li>Soda lime is dried out.</li> </ul>	<ul> <li>Check vaporizer and fresh-gas settings.</li> <li>Check breathing system for large leaks.</li> <li>Exchange soda lime.</li> </ul>
Medium	<i>in[agent]</i> > # NOTES This alarm occurs only for the primary agent.	<ul> <li>Inspiratory anesthetic gas concentration has exceeded the upper alarm limit:</li> <li>At least 15 seconds (with respiratory phases).</li> <li>At least 30 seconds (without respiratory phases).</li> </ul>	Check vaporizer and fresh-gas settings.
Medium	<ul> <li>inN2O &gt; 82</li> <li>NOTE This alarm is suppressed if any of the following alarms is active: <ul> <li>Scio is not connected</li> <li>Gas sensor failure</li> <li>N2O sensor failure</li> <li>Sample line blocked</li> </ul> </li> </ul>	<ul> <li>Inspired N2O is less than 82%:</li> <li>At least 15 seconds (with respiratory phases).</li> <li>At least 30 seconds (without respiratory phases).</li> </ul>	Check fresh-gas composition.

Alarm Priority	Alarm	Cause	Remedy
Medium	inCO2 > #	<ul> <li>Inspired CO<sub>2</sub> has exceeded the limit for more than 15 seconds possibly due to one of the following: <ul> <li>Soda lime is depleted.</li> <li>Leakage in breathing system.</li> </ul> </li> <li>Gas measurement is inaccurate due to high respiratory rate.</li> <li>Large dead space.</li> </ul>	<ul> <li>Check soda lime.</li> <li>Increase fresh-gas flow.</li> <li>Check fresh-gas settings.</li> <li>Replace the breathing system.</li> <li>Adjust alarm limits if necessary.</li> <li>Check ventilation settings</li> </ul>
Medium	Inspiratory xMAC high	<ul> <li>The inspiratory anesthetic gas concentration has exceeded 5 xMAC</li> <li>or, while the patient is breathing:         <ul> <li>The inspiratory anesthetic gas concentration has exceeded 3 xMAC for more than 30 seconds,</li> <li>The expiratory anesthetic gas concentration has exceeded 2.5 xMAC for more than 30 seconds.</li> </ul> </li> </ul>	Check vaporizer and fresh-gas settings.
High	Inspiratory xMAC high	<ul> <li>The inspiratory anesthetic gas concentration has exceeded 3 xMAC for more than 30 seconds,</li> <li>and         <ul> <li>while the patient is breathing, the expiratory anesthetic gas concentration has exceeded 2.5 xMAC for more than 30 seconds.</li> <li>The inspiratory anesthetic gas concentration has exceeded 5 xMAC.</li> </ul> </li> </ul>	Check vaporizer and fresh-gas settings.

Alarm Priority	Alarm	Cause	Remedy
Medium	N2O out of range high	N2O concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh- gas settings and ventilation.
Low	N2O reduced accuracy	Accuracy of the N2O sensor cannot currently be guaranteed.	<ul> <li>Ensure clean ambient air</li> </ul>
			<ul> <li>Check water trap and sample line.</li> </ul>
			<ul> <li>Change the water trap or sample line if necessary.</li> </ul>
			<ul> <li>Wait for automatic zeroing.</li> </ul>
			<ul> <li>Power cycle the gas analyzer.</li> </ul>
			<ul> <li>Call specialized service personnel.</li> </ul>
Low	N2O sensor failure	The N2O sensor in the patient- gas measurement module has failed due to:	<ul> <li>Check sample line.</li> </ul>
			<ul> <li>Remove radiating devices (e.g.,</li> </ul>
		<ul> <li>Sample line occlusion.</li> </ul>	telephone).
		<ul> <li>Electrical disturbance.</li> </ul>	<ul> <li>Use alternative N2O</li> </ul>
		<ul> <li>Internal failure.</li> </ul>	measurement system.
			<ul> <li>Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	N2O value temporarily unavail.	N2O parameter has unknown accuracy possibly due to:	<ul> <li>Ensure clean ambient air.</li> </ul>
		<ul> <li>Zeroing failure.</li> </ul>	<ul> <li>Remove radiating</li> </ul>
		<ul> <li>Polluted ambient air during zeroing.</li> </ul>	devices (e.g., telephone).
		<ul> <li>Electromagnetic disturbances</li> </ul>	<ul> <li>Check ambient temperature.</li> </ul>
		<ul> <li>Overheating.</li> </ul>	<ul> <li>Check water trap and sample line.</li> </ul>
			<ul> <li>Change the water trap or sample line if necessary.</li> </ul>
			<ul> <li>Power cycle the gas analyzer.</li> </ul>
			<ul> <li>Call specialized service personnel.</li> </ul>
Medium	O2 out of range high	O2 concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh- gas settings and ventilation.
Low	O2 reduced accuracy	Accuracy of the O2 sensor cannot currently be guaranteed.	<ul> <li>Ensure clean ambient air</li> </ul>
			<ul> <li>Check water trap and sample line.</li> </ul>
			<ul> <li>Change the water trap or sample line if necessary.</li> </ul>
			<ul> <li>Wait for automatic zeroing.</li> </ul>
			<ul> <li>Power cycle the gas analyzer.</li> </ul>
			<ul> <li>Call specialized service personnel.</li> </ul>
Alarm Priority	Alarm	Cause	Remedy
----------------	----------------------------------	---	--
Medium	O2 sensor failure	The O2 sensor in the patient- gas measurement module has failed due to:	<ul> <li>Use alternative O2 measurement system.</li> </ul>
Low	O2 value temporarily unavail.	<ul> <li>Sample line occlusion.</li> <li>Electrical disturbance.</li> <li>Internal failure.</li> <li>O2 parameter has unknown accuracy, possibly due to:</li> <li>Polluted ambient air during zeroing.</li> </ul>	<ul> <li>Call specialized service personnel.</li> <li>Ensure clean ambient air.</li> <li>Remove radiating devices (e.g.,</li> </ul>
		<ul> <li>Electromagnetic disturbances.</li> <li>Overheating.</li> </ul>	<ul> <li>telephone).</li> <li>Check ambient temperature.</li> <li>Check water trap and sample line.</li> <li>Change the water trap or sample line if necessary.</li> <li>Wait for auto zeroing to complete.</li> <li>Power cycle the gas analyzer.</li> <li>Change vaporizer settings.</li> <li>Call specialized service personnel.</li> </ul>
Medium	RRc > #	Respiratory rate has exceeded the limit.	Check ventilation.
Medium	RRc < #	Respiratory rate is below the limit.	Check ventilation.

Alarm Priority	Alarm	Cause	Remedy	
Medium	RRc apnea	No breathing or ventilation.	<ul> <li>Start manual ventilation.</li> </ul>	
			<ul> <li>Check ventilation settings.</li> </ul>	
			<ul> <li>Check spontaneous breathing ability of the patient</li> </ul>	
		Sample line is not connected.	Connect sample line to breathing circuit.	
Medium	RRc out of range high	RRc has exceeded the upper limit of the measurement range of the Scio.	Check vaporizer, fresh- gas settings and ventilation.	
Low	Sample line blocked	Sample line or patient-side filter is occluded.	Check sample line, water trap, and patient-side filter.	
Medium	Scio is not connected	Scio module disconnected or turned off.	Connect the Scio module or turn it on.	
Low	Scio unavailable for neonates	<ul> <li>Scio is plugged in while the M540 is already in neonate mode.</li> <li>M540 is switched to neonate mode while Scio is already plugged in.</li> </ul>	<ul> <li>Connect an alternate CO2 monitor (e.g., Mainstream or Microstream) if CO2 monitoring is desired in neonate mode.</li> <li>Switch the M540 out of neonate mode in order to continue Scio monitoring.</li> </ul>	
Low	Scio warming up: Accur. low	Accuracy is not guaranteed while Scio is warming up.	Wait for the Scio module to warm up.	
Low	Second agent detected NOTE This alarm occurs only on gas analyzers with outcomptio grant	A second anesthetic agent has been detected. <b>NOTE</b> This alarm could be an expected clinical behavior if	<ul> <li>Wait for the transition phase to end after changing anesthetic agents.</li> <li>Flush the system if necessary.</li> </ul>	
	identification.	two agents as part of the process.	<ul> <li>Check fresh-gas settings.</li> </ul>	

Alarm Priority	Alarm	Cause	Remedy	
Medium	<i>Third agent detected</i> <b>NOTE</b> This alarm occurs only on gas analyzers with automatic agent identification.	<ul> <li>A mixture of three or more anesthetic agents has been detected, possibly as a result of: <ul> <li>A change of the anesthetic agent during monitoring</li> <li>Electromagnetic interference</li> <li>The use of inhalants or sprays (e.g., albuterol)</li> </ul> </li> </ul>	<ul> <li>Wait for the transition phase to end after changing anesthetic agents.</li> <li>Flush the system if necessary.</li> <li>Check fresh-gas settings.</li> <li>Check for electromagnetic radiation in the vicinity.</li> </ul>	
Low	Water trap is full	<ul> <li>Water trap is full.</li> </ul>	<ul> <li>Check water trap.</li> </ul>	
		<ul> <li>Sample line is occluded.</li> </ul>	<ul> <li>Check sample line, water trap, and patient-side filter.</li> </ul>	
Medium	xMAC out of range high	<ul> <li>Indicates that the expiratory xMAC is out of range high when:</li> <li>Primary agent, secondary agent, and/or N2O are out of range high.</li> <li>or</li> <li>Expiratory xMAC exceeds 10.</li> </ul>	Check vaporizer, fresh- gas settings, and ventilation.	

## Status Messages

Message	Condition	Suggested action
Scio zeroing is in progress	Zeroing cycle in progress.	Wait for zeroing cycle to complete.

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# Reprocessing

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Cleaning and disinfecting temperature         sensors and cables.         Cleaning blood pressure cuffs         Cleaning and disinfecting pressure         transducers and hemodynamic pods         Cleaning and disinfecting mainstream CO2         sensors and airway adapters	

## **Reprocessing overview**

This chapter provides information for the reprocessing of M540 device-specific components and accessories.

For cleaning instructions regarding devices that connect to the IACS, refer to the instructions for use entitled *Infinity Acute Care System – Monitoring Applications* (Software VG7.1).

For specific cleaning instructions regarding the Cockpit, refer to the instructions for use entitled *Infinity Acute Care System – Infinity Medical Cockpits.* 

## Reprocessing of M540 device-specific components

### Disassembly

Observe before disassembly:

- 1 Switch off the device and all devices connected to it.
- 2 Disconnect the power cable.

### **Cleaning and disinfecting precautions**

#### WARNING

Because of the risk of electric shock, never remove the cover of any device while it is in operation or connected to power.

### WARNING

Do not immerse or rinse the device and its peripherals. If you spill liquid on the device (including the battery or accessories), or accidentally immerse it in liquid, disconnect the device from the power source and allow it to dry completely for at least 24 to 48 hours. Contact specialized service personnel regarding the continued safety of the device and its peripherals before placing it back in operation.

### CAUTION

To avoid damaging the device, do not use sharp tools or abrasives. Never immerse electrical connectors in water or other liquids.

### CAUTION

Do not autoclave accessories.

### CAUTION

Never immerse electrical connectors or the NIBP connector.

### Information on reprocessing

Instructions for reprocessing are based on internationally accepted guidelines, e.g., standard ISO 17664.

## Safety information

### WARNING

### **Risk of infection**

Reusable products must be reprocessed, otherwise there is an increased risk of infection and the products may no longer function correctly.

- Observe the infection prevention and reprocessing regulations of the healthcare facility.
- Observe national hygiene and reprocessing regulations.
- Use validated procedures for reprocessing.
- Reprocess reusable products after every use.
- Observe the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.

### CAUTION

Risk due to faulty products

Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reusable products.

Check the products for signs of wear and replace them if necessary.

## Information on disinfectants

Use disinfectants that are nationally approved and are suitable for the particular reprocessing procedure.

### **Surface Disinfectants**

Dräger recommends using a disinfectant from the following list. Other disinfectants are used at your own risk.

Class of active ingredient	Surface disinfectant	Manufacturer
Chlorine-releasing agents	Actichlor plus	Ecolab
	BruTab 6S	Brulin
	Clorox Professional Disinfecting Bleach Cleaner	Clorox
	Dispatch Hospital Cleaner Disin- fectant Towels with Bleach	
	Klorsept 17	Medentech
Oxygen-releasing agents	Descogen Liquid	Antiseptica
	Descogen Liquid r.f.u.	
	Dismozon plus	Bode Chemie
	Dismozon pur	
	Oxycide	Ecolab USA
	Perform	Schülke & Mayr
	Virkon	DuPont
Quaternary ammonium com-	Mikrozid sensitive liquid <sup>1)</sup>	Schülke & Mayr
pounds	Mikrozid sensitive wipes <sup>1)</sup>	
	Mikrozid alcohol free liquid <sup>1)</sup>	
	Mikrozid alcohol free wipes <sup>1)</sup>	
	Acryl-des <sup>1)</sup>	

Class of active ingredient	Surface disinfectant	Manufacturer
Aldehydes	Buraton 10 F	Schülke & Mayr

1) Virucidal against enveloped viruses

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

At the time of validation, the listed surface disinfectants showed good material compatibility.

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:

## **Classifications for reprocessing**

### **Classification of medical devices**

Medical devices and their components are classified according to the way they are used and the resulting risk.

- Bactericidal
- Yeasticidal
- Virucidal or virucidal against enveloped viruses

Observe the specifications from the disinfectant manufacturers.

Classification	Explanation
Non-critical	Components that come only into contact with skin that is intact
Semi-critical (A, B)	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin
Critical (A, B, C)	Components that penetrate skin or mucous membranes or come into contact with blood

### Classification of device-specific components - He

- Hemodynamic pods

Observe the instructions for use for the components.

The following classification is a recommendation from Dräger.

### Non-critical

- M540
- M500
- Power supply
- MCable
- MPod

### Semi-critical A

None

### Semi-critical B

– None

Components	Disinfection with clean- ing	Manual clean- ing followed by disinfection by immersion	Machine cleaning with thermal dis- infection	Steam steril- ization	Special re- processing measures
M540	Yes	N/A	N/A	N/A	N/A
M500	Yes	N/A	N/A	N/A	N/A
Power supply	Yes	N/A	N/A	N/A	N/A
MCable	Yes	N/A	N/A	N/A	N/A
MPod	Yes	N/A	N/A	N/A	N/A
Hemodynamic pods	Yes	N/A	N/A	N/A	N/A

## **Reprocessing procedures**

At the time of validation, the following reprocessing procedures showed good material compatibility and effectiveness:

### Validated reprocessing procedures

The effectiveness of the listed reprocessing procedures has been validated by independent laboratories that are certified to the standard ISO 17025.

Procedure	Agent	Manufacturer	Concentration	Contact time	Temperature
Surface Disinfection	Buraton 10 F	Schülke & Mayr	1%	30 min	N/A
with cleaning	Dismozon	BODE Chemie	1.5%	15 min	N/A

## **Reprocessing list**

Critical

None

### Surface Disinfection with cleaning

### WARNING

Risk of electric shock and device malfunction

Penetrating liquid may cause the following:

- Damage to the device
- Electric shock when switching on the device
- Device malfunctions

Ensure that no liquid penetrates the device.

- 1 Remove soiling immediately. Use a cloth dampened with cleaning agent to remove soiling.
- 2 Disinfect the surface.
- 3 After the product has been exposed to the disinfectant for the specified contact time, remove residual disinfectant.
- 4 Wipe with a cloth dampened with water (preferably drinking-water quality). Allow the product to dry.
- **5** Check the product for visible soiling. Repeat steps one through four if necessary.
- 6 Check the product for visible damage and replace if necessary.

## After Reprocessing

### Preparations before re-use

- Assemble and prepare the device so that it is ready for use. See "Assembly and preparation" in the appropriate IFU:
  - Instructions for use Infinity Acute Care System Monitoring Applications Software VG7.1 or higher
  - Instructions for use Infinity Acute Care System Infinity M540 patient monitor Software VG7.1 or higher
- 2 To check the operational readiness, see "Getting started" in the appropriate IFU.

## **Reprocessing of accessories**

Clean and disinfect the device or components before each maintenance step – and also when returning for repair.

Continuous exposure to moisture can damage peripheral devices. Please read the following instructions carefully before cleaning any device.

- Do not spray cleaning agents on peripheral devices. Wipe them with a cloth moistened with soapy water.
- Disinfect the surfaces with a gauze moistened with one of the approved agents (see page 371).
- Dry thoroughly with a lint-free cloth.

Before cleaning any device, read the general safety precautions in the *For your safety and that of your patients* chapter.

## Approved cleaning agents

Clean and disinfect the device or components per hospital approved protocol.

Agents tested by Dräger and shown to have no harmful effect at the time of testing include:

- Compliance<sup>™</sup> (7.35% hydrogen peroxide, 0.23 % peracetic acid, 92.42% inert ingredients)
- Sporox II (7.5% hydrogen peroxide, 0.85% phosphoric acid, and 91.65% inert ingredients)
- Dismozon<sup>®</sup> pur

### NOTE

Dräger makes no claims regarding the efficacy of the listed chemicals, their methods as a means for disinfecting, the ability of the agents to control infection, their environmental impact, safe handling, or any related precautions in their use. Refer to information provided by the manufacturer of the cleaning solution for more information in these areas.

### CAUTION

The use of cleaning agents or concentrations of agents other than those listed, may damage the device and will void warranty.

### To clean and disinfect a reusable SpO2 sensor

• Refer to the cleaning instructions and recommendations provided with the sensor.

## Cleaning and disinfecting patient cables

Use only the approved cleaning agents listed on page 371, unless otherwise specified. The following procedures apply to all patient cables.

### Patient cable precautions

### CAUTION

Do not immerse the patient cables in any liquid.

### CAUTION

Do not use excessive pressure or flex cables unnecessarily when cleaning. Excessive pressure can damage the cables.

### To clean patient cables

- 1 Disconnect the patient cable from the M540.
- 2 Clean the patient cables with a gauze pad moistened with soapy water or with an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

### To disinfect patient cables

- 1 Disconnect the patient cable from the M540.
- 2 Disinfect patient cables with a gauze pad using an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

# Cleaning and disinfecting reusable ECG lead wires

Use only the approved cleaning agents listed on page 371, unless otherwise specified.

### To clean ECG lead wire

- 1 Disconnect the lead wires from the M540.
- 2 Clean the reusable ECG electrodes. regularly with a toothbrush and water to remove any gel residue.
- 3 Wipe the ECG lead wires with a gauze pad moistened with soapy water or with an approved cleaning agent.
- 4 Dry thoroughly with a lint-free cloth.

### To disinfect ECG lead wire

- 1 Disconnect the ECG lead wires from the M540.
- 2 Disinfect the ECG lead wires with a gauze pad using an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

# Cleaning and disinfecting temperature sensors and cables

Use only the approved cleaning agents listed on page 371, unless otherwise specified.

### Temperature sensor and cable precautions

### CAUTION

Do not immerse the patient cables in any liquid.

### CAUTION

Do not use excessive pressure or flex cables unnecessarily when cleaning. Excessive pressure can damage the cables.

### CAUTION

Never boil or autoclave the cable. Vinyl can withstand temperatures up to 100 °C (212 °F) but begins to soften around 90 °C (194 °F). Handle gently when hot and wipe away from the tip, toward the cables.

### To clean temperature cables

- 1 Disconnect the temperature cable from the M540.
- 2 Clean the temperature cables with a gauze pad moistened with soapy water or with an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

#### To clean temperature sensors

- 1 Clean the temperature sensors with a gauze pad using an approved cleaning agent.
- 2 Dry thoroughly with a lint-free cloth.

### To disinfect temperature cables

- 1 Disconnect the temperature cable from the M540.
- 2 Disinfect temperature cables with a gauze pad using an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

### To disinfect temperature sensors

- 1 Disconnect the temperature sensor from the M540.
- 2 Disinfect the temperature sensor with a gauze pad using an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

### Cleaning blood pressure cuffs

### Non-invasive blood pressure precaution

### CAUTION

The blood pressure cuff can be immersed in cleaning solution, but do not allow the solution to enter the non-invasive blood pressure hose. The warranty is void if cleaning solution is allowed to enter the hose or the cuff.

#### To clean blood pressure cuffs

- 1 Disconnect the non-invasive blood pressure hose from the M540.
- 2 Wipe the blood pressure cuff with a cloth moistened with soapy water or using an approved cleaning agent.
- **3** Dry thoroughly with a lint-free cloth.

# Cleaning and disinfecting pressure transducers and hemodynamic pods

### Transducers

Always handle transducers and other pressure accessories with great care. Do not apply excessive pressure to a transducer diaphragm.

### CAUTION

Do not allow liquids to enter the connector.

### To clean and sterilize transducers

Refer to the cleaning instructions and recommendations provided with the transducer.

### To clean transducer plates

- 1 Remove the transducer mounting plate from the front of the hemodynamic pod.
- 2 Wash the plate with hot soapy water.

### To clean hemodynamic pods

- 1 Disconnect the hemodynamic pod from the M540.
- 2 Wipe the hemodynamic pod with a gauze pad moistened with an enzymatic cleaning agent or a solution of green tinctured soapy water.

### NOTE

Do not spray cleaning agents on the hemodynamic pod.

**3** Dry thoroughly with a lint-free cloth.

### To disinfect hemodynamic pods

- 1 Disinfect the surfaces with a gauze pad using an approved cleaning agent.
- 2 Dry thoroughly with a lint-free cloth.

# Cleaning and disinfecting mainstream CO<sub>2</sub> sensors and airway adapters

Mainstream sensors and airway adapters precaution

### WARNING

To reduce the risk of infection, remember that the disposable airway adapters are for singlepatient use only and cannot be sterilized.

# To clean and disinfect the mainstream sensor and reusable airway adapters

Refer to the Dräger Infinity MCable Mainstream CO<sub>2</sub> instructions for use for cleaning and disinfection instructions of the mainstream sensor and reusable airway adapters.

# Disposal

EU Directive 2002/96/EC (WEEE)	376
M540 and M500	376
Disposal of Accessories	376

This device is subject to EU Directive 2002/96/EC (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste of electrical and electronic equipment. Dräger has authorized a firm to dispose of this device in the proper manner. For more detailed information, please contact your local Dräger organization.

### M540 and M500

All materials must be disposed of or recycled properly and in accordance with local regulations. There are no known special disposal requirements for any accessories.

### **Disposal of Accessories**

When disposing accessories, observe the hospital infection prevention guidelines and the respective instructions for use.

## Maintenance

Overview
Definition of maintenance concepts
Inspection
Visual inspection
Inspection / safety checks
Scope of inspection/safety checks for the
M540
Metrological checks
Preventive maintenance

## Overview

This chapter describes the maintenance measures required to maintain the functional integrity of the medical device. Maintenance measures must be performed by the responsible personnel.

### WARNING

**Risk of infection** 

Users and service personnel can become infected with pathogens.

Disinfect and clean the device or the components before any maintenance measures and also before returning the medical device for repair.

### WARNING

**Risk of electric shock** 

Current-carrying components are located under the cover.

- Do not remove the cover.
- Maintenance measures must be performed by the responsible personnel. Dräger recommends specialized service personnel performs these measures.

### WARNING

If the device is mechanically damaged, or if it is not working properly, do not use it. Contact your hospital's service personnel.

### WARNING

Any modification of this device or any use different from the one specified in these instructions for use may cause interference with other equipment. It may also result in injury to the patient or the user, including electric shock, burns or death.

### CAUTION

This device must be inspected and serviced at regular intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with specialized service personnel through your vendor. For repairs we recommend that you contact specialized service personnel.

### CAUTION

When servicing devices from Dräger, always use spare parts that are qualified to Dräger standards. Dräger cannot warrant or endorse the safe performance of third-party spare parts for use with the devices.

### CAUTION

If you spill liquid on the equipment, battery or accessories or immerse these components in liquid, allow them to dry completely for at least 24 hours to 48 hours. Contact your hospital's service personnel to test any such component is fully operational before putting it back in clinical use.

### NOTE

Perform maintenance measures only when no patient is connected to the device.

### **Definition of maintenance concepts**

Concept	Definition
Maintenance	All measures (inspection, preventive maintenance, repair) intended to maintain and restore the functional integrity of a medical device.
Inspection	Measures intended to determine and assess the actual state of a medical device.
Preventive maintenance	Recurrent specified measures intended to maintain the functional integrity of a medical device.
Repair	Measures intended to restore the functional integrity of a medical device after a device malfunction.

## Inspection

Perform inspections of the system and all accessories at regular intervals and observe the following specifications to ensure safe operation of each device.

Checks	Interval	Personnel responsible
Inspection/safety checks	Every 2 years	Expert
Metrological checks	Every 2 years	Expert

## **Visual inspection**

Perform a visual inspection before every use and in accordance with your hospital's policy.

- Make sure that the housing is not cracked or broken and there are no signs of spilled liquids or damage.
- 2 Inspect all accessories (for example, sensors and cables). Do not use if there are any signs of damage.
- **3** Turn the monitor on and make sure the backlight is bright enough.

- 4 Examine all system cables, power plugs and discontinue use if there are any signs of damage.
- **5** Inspect all patient cables, lead wires and strain reliefs for general condition. Make sure the connectors are properly engaged at each end.

## Inspection / safety checks

Inspection and safety checks of devices must be performed according to the suggested intervals specified in the table on page 379.

### Scope of inspection/safety checks for the M540

Safety checks are no substitute for preventive maintenance measures (including preventive replacement of wearing parts) as identified by the manufacturer.

### WARNING

**Risk of medical device failure** 

If safety checks are not performed on a regular basis, the proper operation of the medical device can be compromised.

Perform safety checks at the indicated intervals.

- 1 Check accompanying documents:
  - Instructions for use are available.
- 2 Perform a functional test of the following features according to the instructions for use:
  - Verify the LEDs.
  - Perform a functional test of the internal battery
  - Perform system tests (for example, communication with the IACS and functional integrity of buttons, alarm bar, and monitored parameters).
- **3** Check that the device combination is in good condition:
  - All labels are complete and legible
  - There is no visible damage
  - Fuses which are accessible from the outside are in compliance with the specified values

- 4 Check the electrical safety requirements according to IEC62353 every two years by qualified DrägerService personnel.
- 5 Check the following safety features:
  - The power LED and the battery indicator LED function properly.
  - Check the functional integrity of the Infinity MCable – Nurse call.
  - Functional integrity of the visual and acoustic alarm signals.
  - Functional integrity of the <sup>1</sup>/<sub>4</sub> button located on the front of the device.
  - Functional integrity of the non-invasive blood pressure overpressure sensor (including the valves and the pump).
- 6 Replace the battery every two years and make sure the M540 runs on battery charge without fail for one minute as follows:
  - Undock the M540 from the M500.
  - Turn on the M540.
  - Wait for one minute and observe the M540.

If the battery fails, trained personnel must replace it.

### Metrological checks

If required by applicable regulations, the following measurement functions must be checked every two years by specializedservice personnel:

- Body temperature
- Non-invasive blood pressure

### WARNING

**Risk of faulty components** 

Device failure is possible due to wear or material fatigue of the components.

To maintain proper operation of all components, this device must undergo inspection and preventive maintenance at specified intervals.

### WARNING

**Risk of electric shock** 

Before performing any maintenance work, disconnect all electrical connectors from the power supply.

The following table shows the preventive maintenance intervals:

Component	Interval	Measure	Personnel responsi- ble
Two non-invasive blood pres- sure air inlet filters of the M540	Every two years	Replace	Expert
If the non-invasive blood pressure air inlet filter seems dirty or damaged, replace it before the recommended two years. The air inlet filter should be replaced, if the M540 was exposed to liquid. See <i>"Exchanging the ambient air filter"</i> in the Technical documentation which is available from Dräger.			
Internal M540 battery	Every two years	Replace	Hospital personnel
<b>NOTE:</b> For devices that have high transport or battery use, the battery must be checked more often.			

Technical documentation is available on request by contacting the Dräger representative.

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## **Technical data**

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## Overview

This chapter contains the technical data for the following devices of the Infinity Acute Care System:

- M540
- Infinity M500 MDock
- Power supply

- MPod and MCable
- Parameter specifications

For technical data regarding the C500/C700, refer to the Instructions for use entitled *Infinity Acute Care System – Infinity Medical Cockpit.* 

## System compatibility

In a stand-alone configuration, an M540 is compatible with the following devices and applications.

Device/Application	Compatible software version
ICS	VGx
IACS	VG7.x
Innovian	VF7 or higher
Symphony	VF7 or higher
Gateway	VF6 or higher

## **Device combinations**

This device can be operated in combination with other Dräger devices or with devices from other manufacturers. Observe the accompanying documents of the individual devices.

If a device combination is not approved by Dräger, the safety and the functional integrity of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices. Device combinations approved by Dräger meet the requirements of the following standards:

- IEC 60601-1, 3rd edition (general requirements for safety, device combinations, software-controlled functions)
- IEC 60601-1-2 (electromagnetic compatibility)
- IEC 60601-1-8 (alarm systems)

Or:

- IEC 60601-1, 2nd edition (general requirements for safety)
- IEC 60601-1-1 (device combinations)
- IEC 60601-1-2 (electromagnetic compatibility)
- IEC 60601-1-4 (software-controlled functions)
- IEC 60601-1-8 (alarm systems)

If a device combination is not approved by Dräger, proper operation of the devices can be compromised.

The operating organization must ensure that the device combination meets the applicable standards.

Strictly observe Instructions for use and assembly instructions of all connected devices.

### CAUTION

Combinations of Dräger devices and third-party devices that are not approved by Dräger may adversely affect operation of those devices and may put the patient at greater risk of injury.

### CAUTION

The medical device must only be used with software tested and approved by Dräger. Any modifications of the operating system settings can impair operating safety. Responsibility for any such modifications lies with the operating organization.

## Infinity M540

Physical specifications	
Dimensions (W x H x D)	259 x 89 x 43 mm (10.2 x 3.5 x 1.7 in)
Weight	916 g (2.0 lbs)
Cooling	Conduction (docked), Convection (undocked)
Materials	Enclosure: PC-ABS/TPU
	Lenses: polyamide
	Internal plastic: polyamide (PA)
	Printed circuits: glass/epoxy, lead/tin solder, copper etch
	Battery: lithium ion
	Heatsink: magnesium
	Non-invasive blood pressure assembly: plastic, stainless steel, copper wire
	Packing: corrugated cardboard, urethane foam
User interface	Touchscreen plus 3 keys

Connectors	
Input/output ports	<ul> <li>ECG</li> <li>NIBP</li> <li>Temperature/Auxillary</li> <li>SpO2</li> <li>Hemo CO2</li> <li>CO2</li> </ul>
Display attributes	
Display type	Color Liquid Crystal Display (LCD), advanced touchscreen
Display size	158.2 mm (6.2 in) diagonal
Viewing size	148.8 x 53.8 mm (5.9 x 2.1 in)
Resolution (pixels)	640 x 240 (1/2 VGA)
Luminance	80 cd/m <sup>2</sup> minimum during battery operation
	110 cd/m <sup>2</sup> minimum when powered by M500
Alarm bar	Integrated on the side of the front bezel; blinks red for high priority and yellow for medium-priority alarm conditions; does not blink for low-priority alarm conditions.
Acoustic attributes	
Minimum acoustic tone	45 dB(A)
Alarms	Alarm levels: high priority, medium priority, low priority
System alarm delay	<3 s
Electrical specifications	
Power source	Internal lithium-ion battery or external power from the M500, 24 V
Battery pack	Lithium: 7.2 V DC, 3200 mAh
Protection class	Internally powered (per IEC 60601-1)
Battery operating time	Normal operation: approximately 3 hours
	Power save mode: approximately 4 hours
	<b>NOTE:</b> Battery operating time varies with device configuration. The battery operating times specified above are under the following load conditions: wireless enabled; invasive pressure (IP) via the MPod Quad Hemo (4 invasive pressures); continuous 6-lead ECG; SpO2 with Nellcor MCable or Masimo SET MCable; two continuous temperature probes; non-invasive blood pressure (NIBP) with 15-minute interval mode enabled.

Battery recharging time	100% capacity: approximately 6.5 hours for a completely dis- charged battery
	90% capacity: approximately 5.5 hours for a completely dis- charged battery
	70% capacity: approximately 4 hours for completely dis- charged battery
Mode of operation	Continuous (with power coupling through the M500)
Environment	
Humidity (non condensing)	Operating: 10% to 95%
	Storage: 5% to 95%
Temperature	Operating: 0 °C to 40 °C (32 °F to 104 °F)
	<b>NOTE:</b> At ambient temperatures above 35 °C (95 °F) the battery may not be charging even while it is docked in the M500; however, the battery symbol still indicates the actual battery charge.
	Storage: –20 °C to 60 °C (–4 °F to 140 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (647 to 1060 hPa)
	Storage: 375 to 795 mmHg (500 to 1060 hPa)
Drop	IEC 60068-2-31: 2008 Procedure 1
	Drop once on each of six surfaces from a height of 1 m (3.2 ft)
Shock and vibration	Shock test in accordance with IEC 60068-2-27:2008
	Test type: Type 2: – peak acceleration: 300 m/s2 (30g); – duration: 6 ms; – pulse shape: half sine; – number of shocks: 3 shocks per direction per axis (18 total)
	Broad-band random vibration in accordance with IEC 60068-2-64:2008 using the following conditions:
	Acceleration amplitude: – 10 Hz to 100 Hz: 1,0 (m/s2) 2/Hz; – 100 Hz to 200 Hz: –3 db/octave; – 200 Hz to 2,000 Hz: 0,5 (m/s2) 2/Hz;
	Duration: 30 min per each perpendicular axis (3 total).
Transportation	Per International Safe Transit Association (ISTA)
Protection against liquid ingress	IPX4 (protected against splashing water) per IEC 60529

Communications	
Wired network	802.3 100BaseT Ethernet when connected to the M500. Optically isolated connection between the M540 and M500.
Wireless network	Complies with IEEE 802.11b/g WLAN standards (2.4GHz). Supports WPA2 security.
Radio power output	30mW (2.4 GHz)

## Sound pressure

Sound pressure levels for IEC alarm tones Measurements per ISO 3744, 5 to 100% volume setting			
Device	Low priority	Medium priority	High priority
M540	46 dB(A) to 66 dB(a)	46 dB(A) to 67 dB(a)	48 dB(A) to 68 dB(a)

## Infinity M500

Physical specifications			
Dimensions (W x H x D)	102 x 195 x 107 mm (4.0 x 7.7 x 4.2 in)		
Weight	1200 g (2.6 lbs)		
Cooling	Convection		
Materials	Enclosure: polyamide (PA) and ABS		
Mounting	VESA 75		
Connectors			
Input/output ports	<ul> <li>System cable connector</li> </ul>		
	<ul> <li>Nurse call connector</li> </ul>		
Electrical specifications	-		
DC input	24 V DC nominal, 1.5 A (18 to 30 V DC)		
Protection class	For use with specified Class I power supply		
Mode of operation	Continuous		
Power output	26 W nominal		
Environment			
Humidity (non condensing)	Operating: 10% to 95%		
	Storage: 5% to 95%		
Temperature	Operating: 0 °C to 40 °C (32 °F to 104 °F)		
	Storage: –20 °C to 60 °C (–4 °F to 140 °F)		
Atmospheric pressure	Operating: 485 to 795 mmHg (647 to 1060 hPa)		
	Storage: 375 to 795 mmHg (500 to 1060 hPa)		
Risk management			
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529		
Communications	•		
Internal network (M540)	802.3 100BaseT Ethernet (optically isolated)		

## Power supply (PS50)

Physical specifications		
Dimensions (W x H x D)	76 x 146 x 43 mm (2.99 x 5.75 x 1.69 in)	
Weight	400 to 550 g (0.88 to 1.2 lbs)	
Cable length (from power supply to DC output connec- tor)	1.82 m (71.7 in)	
Display attributes		
LED	Power (green)	
Environment		
Humidity (non-condensing)	Operating: 5 to 95%	
	Storage: 5 to 95%	
Temperature	Operating: 0 to 70 °C (32 to 158 °F)	
	Storage: –40 to +85 °C (–40 to +185 °F)	
Ambient pressure	Operating: 485 to 795 mmHg (64.7 to 106 kPa)	
	Storage: 375 to 795 mmHg (50 to 106 kPa)	
Electrical specifications		
Input voltage	100 to 240 V~	
Input frequency	47 to 63 Hz	
Input current	1.35 A	
Inrush current	15 A at 115 V AC or 30 A at 230 V AC at 25 °C (77 °F) cold start 1	
Leakage current	0.1 mA max at 230 V AC, 50 Hz	
Output voltage	24 V	
Maximum output power	50 W	
Protection Class	Class 1	
Total regulation	$\pm 5\%$ maximum at full load, includes tolerance Line and load regulation	

## 120 Watt desktop power supply (PS120)

The following power supply is for use with the M540 patient monitor.

### CAUTION

Always use a power cable with a hospital-grade plug and connect it to a hospital-grade or grounded receptacle as required by local regulation.

Physical specifications	
Connections	ODU Medi-Snap (3 pins)
Cooling	Convection non-vented case
Size (W x D x H)	174 x 82 x 40 mm (6.85 x 3.2 x 1.6 in)
Weight	684 grams (24 ounces) excluding the cord
Environment	
Temperature	Operating: 0 to 40 °C (32 to 104 °F)
	Storage: –20 to 85 °C (–4 to 185 °F)
Relative humidity	5 to 95% non-condensing
Height above sea level	0 to 3000m (10,000 feet)
Ambient pressure	70 to 106 kPa (10.15 to 15.37 psi)
Electrical specifications	
Input voltage	100 V AC to 240 V AC ( <u>+</u> 10%)
Input frequency	47 to 63 Hz
Input current	2 A max at 90 V AC input
Inrush current	30A at 115 V AC or 60A at 230 V AC
Leakage current	Less than 0.6 mA in fault condition (264 V/50 Hz)
Output voltage	24.5 V
Maximum output power	120W
Protection class	Class I
Mode of operation	Continuous
Standard compliance	
Protection against liquid ingress	IP41 (protected against vertically falling water drops and in- gress of e.g. wires or screws) per IEC 60529.

## Infinity MCable – Mainstream CO2

Physical specifications	
Size (W x H x D)	30 x 50 x 20 mm (1.18 x 1.97 x 0.79 in)
Weight (without cable)	30 g or less (0.066 lb or less)
Cable length	2.5 m (98.4 in)
Connections	Single cable connecting to the M540
Environment	
Humidity (non-condensing)	Operating: 5 to 95%
	Storage: 5 to 95%
Temperature	Operating: 10 to 40 °C (50 to 104 °F)
	Storage: -40 to 75 °C (-40 to +167 °F)
	Extended operating: -20 to 50 °C (-4 to 122 °F)
	<b>NOTE</b> : The measurement accuracy of the MCable and the time required to meet the specified accuracy can vary in the Extended operating range.
Ambient pressure	Operating: 428 to 825 mmHg (57 to 110 kPa)
	Storage: 86 to 825 mmHg (11.5 to 110 kPa)
Electrical specifications	
Power source	Powered directly from the M540
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type BF
Protection against liquid ingress	IP64 (dust tight and protected against splashing water) per IEC 60529
Defibrillator protection	Yes

## Infinity MCable – Microstream CO2

Physical specifications		
Infinity MCable Microstream	92 mm (height) x 70 mm (width) x 49 mm (depth)	
Infinity MCable Microstream weight	240 grams (0.52 pounds)	
MCable holder	105.8 mm (height) x 87.3 mm (width) x 69.9 (depth)	
MCable holder weight	100 grams (3.52 ounces)	
Storage		
Ambient pressure	88 mmHg to 795 mmHg	
Height above sea level	-381 m to 15,240 m (-1,250 feet to 50,000 feet)	
Temperature	–40 to 70 °C (–40 to 158 °F)	
Humidity	10 to 95%	
During operation		
Height above sea level	-1,250 to 15,000 feet	
Height above sea level change rate	500 feet/min maximum or ambient pressure change of 12.4 mmHg/min max.	
Ambient CO2 levels	0 to 700 ppm	
Ambient pressure	430 to 795 mmHg	
Humidity	10 to 95% non-condensing	
Maximum tolerable change rate of the units of ambient temperature	0.5 °C/min	
Operating pressure from a ventilation	Over pressure: +100 cmH2O	
system	Under pressure: –20 cmH2O	
Temperature	0 to 40 °C (32 to 104 °F)	
Electrical specifications		
Power source	Powered directly from the M540	
Mode of operation	Continuous	
Risk management		
Protection against electrical shock	Туре ВБ	
Protection against liquid ingress	IPX2	
Defibrillator protection	Yes	

## Infinity MCable – Masimo SET and Infinity MCable – Masimo rainbow SET

Physical specifications	
Size (W x H x D)	61 x 20 x 130 mm (2.4 x 0.8 x 5.1 in)
Weight	0.12 kg (0.26 lb)
Cable length	300 mm (11.8 in)
Connections	Single cable connecting to the M540
	Masimo cable connector for sensor cable
Environment	
Humidity (non-condensing)	Operating: 10 to 95%
	Storage: 10 to 95%
Temperature	Operating: 0 to 45 °C (32 to 113 °F)
	Storage: –40 to +70 °C (–40 to +158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa)
	Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	
Power source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	500 mW / 1 W
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Туре СҒ
Protection against liquid ingress	IPX2 (protected against vertically falling water drops with enclosure tilted up to $15^{\circ}$ ) per IEC 60529
Defibrillator protection	Yes

## Infinity MCable – Nellcor OxiMax

Physical specifications	
Size (W x H x D)	61 x 21 x 130 mm (2.4 x 0.8 x 5.1 in)
Weight	0.12 kg (0.26 lbs)
Cable length	300 mm (11.8 in)
Connections	Single cable connecting to the M540
	Nellcor cable connector for sensor cable
Environment	•
Humidity (non-condensing)	Operating: 10 to 95%
	Storage: 10 to 95%
Temperature	Operating: 0 to 45 °C (32 to 113 °F)
	Storage: –40 to +70 °C (–40 to +158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa)
	Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	•
Power source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	500 mW
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Туре СҒ
Protection against liquid ingress	IPX2 (protected against vertically falling water drops with enclosure tilted up to 15°) per IEC 60529
Defibrillator protection	Yes
### Infinity Hemo2 and Hemo4 pods

Physical specifications	
Size (W x H x D)	205 x 140 x 60 mm (8.1 x 5.5 x 2.3 in)
Weight	Hemo2: 0.7 kg (1.6 lbs)
	Hemo4: 0.9 kg (1.9 lbs)
	<b>NOTE:</b> Weight includes one (Hemo2) or two (Hemo4) trans- ducer adapter block(s) and excludes mounting clamp.
Connectors	
Input/output ports	Two (Hemo2) or four (Hemo4) invasive blood pressure chan- nels (IP), two temperatures, and C.O.
	Single cable connecting to the M540
Display attributes	
User controls	Keys (C.O. Start, IP zero, <i>Wedge</i> )
Displays	Two (Hemo2) or four (Hemo4) four-character LCDs
Environment	
Humidity (non-condensing)	Operating: 20 to 90%
	Storage: 10 to 95%
Temperature	Operating: 10 to 40 °C (50 to 104 °F)
	Storage: –20 to +50 °C (–4 to +122 °F)
Atmospheric pressure	Operating: 525 to 795 mmHg (70 to 106 kPa)
	Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	1 W for a single pod with connected pressure probes
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX0 (no specific protection) per IEC 60529
Defibrillator protection	Yes

### Infinity MPod – Quad Hemo

Physical specifications	
Size (W x H x D)	205 x 110 x 80 mm (8.1 x 4.3 x 3.2 in)
Weight	0.48 kg (1.1 lbs)
	<b>NOTE:</b> Weight includes four transducer cables but excludes the mounting clamp and rod.
Connections	Four invasive blood pressure channels, two temperatures, and C.O.
	Single cable connecting to the M540
Environment	•
Humidity (non-condensing)	Operating: 10 to 95%
	Storage: 10 to 95%
Temperature	Operating: 0 to 45 °C (32 to 113 °F)
	Storage: -40 to 70 °C (-40 to 158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa)
	Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	•
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	500 mW for a single pod with connected pressure probes
Mode of operation	Continuous
Risk management	-
Protection against electrical shock	Туре СҒ
Protection against liquid ingress	IPX2 (protected against vertically falling water drops with enclosure tilted up to 15°) per IEC 60529
Defibrillator protection	Yes

### Infinity MCable – Dual Hemo

Physical specifications	
Size (W x H x D)	61 x 25 x 125 mm (2.4 x 1.0 x 5.0 in)
Weight	0.20 kg (0.44 lb)
Cable length	2500 mm (98.4 in)
Connections	Two invasive blood pressure channels
	Single cable connecting to the M540
Environment	
Humidity (non-condensing)	Operating: 10 to 95%
	Storage: 10 to 95%
Temperature	Operating: 0 to 45 °C (32 to 113 °F)
	Storage: –40 to 70 °C (–40 to 158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa)
	Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	•
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	300 mW
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX4 (protected against vertically falling water drops) per IEC 60529
Defibrillator protection	Yes

### Infinity MCable – Analog/Sync

Physical specifications		
Size (W x H x D)	66 x 31 x 110 mm (2.6 x 1.3 x 4.4 in)	
Weight	0.19 kg (0.42 lb)	
Cable length	500 mm (19.7 in)	
Connections	Two connectors; one for analog output and one for QRS sync pulse cable	
	Single cable connecting to the M540	
Environment		
Humidity (non-condensing)	Operating: 10 to 95%	
	Storage: 10 to 95%	
Temperature	Operating: 0 to 45 °C (32 to 113 °F)	
	Storage: –40 to 70 °C (–40 to 158 °F)	
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa)	
	Storage: 375 to 795 mmHg (50 to 106 kPa)	
Analog output		
Signals	ECG, arterial blood pressure	
Maximum delay	≤ 25 ms	
Output range	±4.95 V ±5%	
Signal gain	ECG: 1000 (1 V/mV)	
	Arterial pressure:10 mV/mmHg	
Accuracy	ECG: ±100 mV or ±10%	
	Arterial pressure: $\pm 40$ mV or $\pm 4\%$	
ECG bandwidth	0.5 to 40 Hz	
Invasive blood pressure bandwidth	DC to 50 Hz	
Pacemaker pulses	Amplitude: 5 V (nominal)	
	Duration: 4 ms	
Maximum pressure offset	±10 mV	
Pressure range	–50 to +400 mmHg (1 V/100 mmHg)	
	–6.6 to +53.3 kPa (1 V/13.3 kPa)	
Output impedance	200 Ω ±5%	
Data rate	250 per second	

QRS sync pulse output	
Delay	≤35 ms
Output high (QRS detected):	Amplitude: 10 V ±5%
	Duration: 50 ms
	Output impedance: 5000 $\Omega$
Output low (no QRS)	<0.8 V
Pacemaker pulses	Not included
Electrical specifications	
Source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	≤325 mW under fault condition
	≤250 mW during normal operation
Mode of operation	Continuous
Risk management	
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529

### Infinity MCable – Nurse call

Physical specifications		
Size (W x H x D)	65 x 32 x 161 mm (2.6 x 1.36 x 6.3 in)	
Cable length	4500 mm (177.2 in)	
Connections	Single cable connection to the M500	
Cable signals during non-alarm state		
	Cable 1 (NO normally open): white	
	Cable 2 (COM common): brown	
	Cable 3 (NC normally closed): green	
Environment		
Humidity (non-condensing)	Operating: 10 to 95%	
	Storage: 10 to 95%	
Temperature	Operating: 0 to 45 °C (32 to 113 °F)	
	Storage: -20 to +60 °C (-4 to +140 °F)	
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa)	
	Storage: 375 to 795 mmHg (50 to 106 kPa)	
Electrical requirements		
Input voltage	24 V ±25%	
Relay contact	1 A DC, 24 V DC, 15 W maximum	
Mode of operation	Continuous	
Isolation voltage	1.5 k V AC	

### Parameter monitoring specifications

#### NOTE

The following parameters are not monitored in neonatal mode: Arrhythmia, Cardiac Output, and ST segment analysis.

#### ECG

Display	Up to 12 leads
Available leads	3-wire lead set: ECGI, ECGII, ECGIII (user-selectable)
	5-wire lead set: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV
	6-wire lead set: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV, ECGV+
	Optional 12-lead monitoring with 6-wire lead set and 4-wire lead set: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV1 to ECGV6
	TruST on: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGdV1, ECGV2, ECGdV3, ECGdV4, ECGV5, ECGdV6 ("d" prefix identifies derived lead)
Measurement range	15 bpm to 300 bpm (beats/min)
	<b>NOTE:</b> For heart rates of 300 bpm and greater, the monitor may display VF and not the expected +++ as the parameter value.
Accuracy	$\pm 2$ bpm or $\pm 1\%$ (whichever is greater)
Resolution	1 bpm
Sweep speed	25 mm/s ±2%
QRS detection	0.5 mV - 5.0 mV detected, $\leq$ 0.15 mV not detected, per IEC 60601-2-27.
Frequency band	Monitor filter: 0.5 to 40 Hz (0.5 to 16 Hz in OR alarms)
	Diagnostic filter: 0.05 to 150 Hz
	ESU filter: 0.5 to 16 Hz (pacer detection deactivated)
	Filter OFF: 0.08 to 40 Hz (M540 display is limited to 40 Hz)
ECG isoelectric line recovery	$\leq$ 3 s after the termination of the transient interference from a defibrillator or ESU device

Common mode rejection ratio (CMRR)	Diagnostic mode: >90 dB (with a 51 k $\Omega$ /47 nF imbalance) Filter mode: >110 dB (with a 51 k $\Omega$ /47 nF imbalance)	
Degree of protection against electric shock	Type CF	
Defibrillation protection	Yes	
Unit will detect pacers with the following characteristics:		
Pacer detection (adult/pediatric only)	Amplitude (a <sub>p</sub> ): ±2 to ±700 mV Width (d <sub>p</sub> ): 0.2 to 2.0 ms	
Rise/fall times (min)	0.1 dp, ≤100 μs	
Overshoot (min)	0.025 to 0.25 a <sub>p</sub> , <2 mV	
Recharge time constant	4 to 100 ms	

### ECG/Arrhythmia/ST supplemental information

QRS isoelectric components (Rest ECG report only)	Isoelectric components between the overall QRS onset and an individual lead onset are not included in a Q or R duration
Sample Frequency	Use of the Rest ECG report is required for an ECG signal quality that is compliant with the diagnostic high frequency specification of 500 Hz sampling rate in IEC 60601-2-25
Amplitude quantisation	2.5 μV/LSB
Respiration excitation waveform	Square wave signal, 50 μA, 39.896 kHz
Auxiliary current (leads off detection)	Active electrode: <100 nA
	Reference electrode: <900 nA
Noise suppression	Not applicable
Maximum alarm delay	<10 s according to ANSI/AAMI/IEC 60601-2-27
Time to alarm for tachycardia	Ventricular tachycardia 1 mV pp, 206 bpm
	Gain: 0.5, range: 3.0 to 3.5 s, average: 3.3 s Gain: 1.0, range: 2.9 to 3.3 s, average: 3.2 s Gain: 2.0, range: 2.8 to 3.5 s, average: 3.0 s
	Ventricular tachycardia 2 mV pp, 195 bpm
	Gain: 0.5, range: 2.2 to 4.0 s, average: 3.0 s Gain: 1.0, range: 1.9 to 2.5 s, average: 2.3 s Gain: 2.0, range: 2.0 to 2.9 s, average: 2.5 s
Tall T wave rejection capability	1.8 mV when the <i>ECG filter</i> is set to <i>Monitor</i>
	1.6 mV when the <i>ECG filter</i> is set to <i>Off</i>

Heart rate averaging method	Heart rate is normally based on the average R-R interval cal- culated over the last 10 seconds, however it updates more quickly to reflect changes to the patient's underlying rate.
Response time of heart rate meter to change in heart rate	Heart rate change from 80 to 120 bpm Range: 3.4 to 7.1 s average: 5.3 s Heart rate change from 80 bpm to 40 bpm: Range: 6.3 to 8.6 s average: 7.4 s
Heart rate meter accuracy and response to irregular rhythm	Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 60 bpm Rapid alternating ventricular bigeminy: 120 bpm Bidirectional systoles: 90 bpm

### Arrhythmia (ARR)

Basic arrhythmia detection	Asystole, ventricular fibrillation, artifact, ventricular tachycardia $^{\mbox{\tiny 1)}}$
Full arrhythmia detection	Adds the following calls on to basic arrhythmia: ventricular run, accelerated idioventricular rhythm, supraventricular tachycardia, couplet, bigeminy, tachycardia, bradycardia, pause, and PVC/min
PVC/min measurement range	0 to 300 bpm
PVC/min resolution	1 bpm
PVC/min accuracy	$\pm 5$ or $\pm 10\%$ of the rate (whichever is greater)
PVC/min response time	≤4 s
<sup>1)</sup> Bradycardia is available as a low heart rate alarm for neonates.	

### ST segment analysis

Sensing leads	3-wire lead set: ECGI, ECGII, ECGIII (user-selectable)
	5-wire lead set: (choice of 2 leads for display) ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV
	6-wire lead set: (choice of 2 leads for display) ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV, ECGV+
	Optional 12-lead monitoring with 6-wire lead set and 4-wire lead set: (choice of 2 leads for display) ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV1 to ECGV6, STCVM, STVM
	TruST on: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGdV1, ECGV2, ECGdV3, ECGdV4, ECGV5, ECGdV6 ("d" prefix identifies derived lead)
ST complex	Length: 828 ms (–260 to +568 ms from the fiducial point)
Isoelectric point	Setting range: start of ECG complex to fiducial point
	Default: QRS onset –28 ms
ST measurement point	Setting range: fiducial point to end of ECG complex
	Default: QRS offset +80 ms
ST update interval	15 s $\pm$ 1 s, 1 normal beat required
ST input accuracy	±0.5mm (0.05mV) or 15% of the measured value, whichever is greater, for STI, II, III, aVR, aVL, aVF, V, V+, V1 to V6, dV1, dV3, dV4, dV6
	$\pm$ 3.2 mm (0.32 mV) for STVM and STCVM
	CAUTION
	ST accuracy may be impacted if ECG double-counting occurs or with highly irregular heart rates.
ST measuring range	–15.0 to +15.0 mm (–1.5 to +1.5 mV) for STI, II, III, aVR, aVL, aVF, V, V+, V1 to V6, dV1, dV3, dV4, dV6
	0 to +45 mm (0 to +4.5mV) for STVM, STCVM
ST resolution	±0.1 mm (0.01 mV)

### NOTE

In an unlikely scenario where the heart rate is low (30 bpm, 45 bpm) and ST deviations are high ( $\geq$  +/-13mm), the claimed ST accuracy might not be met on one or two leads.

### **Respiration (RRi)**

Sensing leads	I or II (user-selectable)
Measuring method	Impedance pneumography
Auxiliary current	<10 μA for any active electrode
Respiration excitation waveform	Square wave signal, 50 μA, 39.896 kHz
Bandwidth (–3dB)	0.25 to 3.5 Hz
Detection threshold	Manual mode: 0.20 to 3.5 $\Omega$
	Auto mode: 0.25 to 2.75 Ω
Measurement range	0 to 150 bpm
Resolution	1 bpm
Measuring accuracy	The accuracy of respiration rate is: @ 0-100 breaths/minute: +/- 2 breaths/minute or +/- 2% of the rate value (whichever is greater) @ 101-150 breaths/minute: +/- 3 breaths/minute or +/- 3% of the rate value (whichever is greater)
Apnea detection intervals	Off, 10, 15, 20, 25, and 30 s

### Invasive pressure (IP)

Measuring method	Resistive strain gauge transducer
Resolution	1 mmHg (0.1 kPa)
Measurement range	–50 to 400 mmHg (–6.6 to +53.3 kPa) GP1 to 8, arterial pressures, PA, wedge pressure, CVP, LA, LV, RV, RA, ICP, ABD, BDP, ESO, FEMV, UVP, GPM
Dynamic range	Before zeroing: –250 to +600 mmHg (–33.3 to +79.9 kPa) After zeroing: –50 to +400 mmHg (–6.6 to +53.3 kPa)
Zero balance range	±200 mmHg (±26.6 kPa)
Filter settings	User selectable DC to 8 Hz, DC to 16 Hz
Accuracy	$\pm 1$ mmHg or $\pm 3\%$ (whichever is greater) excluding the transducer
IP update interval	4 s
Response time (at 90% of pressure change)	14 beats + 2 s (arterial pressures, LV, GP1 to GP8) 8 beats + 2 s (PA, RV) 16 s (CVP, ABD, BDP, ESO, FEMV, UVP, GPM, RA, LA, ICP)
Transducer specifications	Transducers with a resistance of 200 $\Omega$ to 3000 $\Omega$ and an equivalent pressure sensitivity of 5 $\mu$ V/V/mmHg $\pm10\%$

### Non-invasive blood pressure (NIBP)

Accuracy validation	Reference method: intra-arterial.
	Adult: the femoral artery Pediatric: the umbilical, brachial, radial or femoral arteries Neonate: the umbilical, brachial, radial or femoral arteries
	The associated NIBP readings were taken on the same limb.
Parameter display	Systolic, diastolic, mean values
Measuring method	Oscillometric through step-deflation. The cuff inflates to oc- clude blood flow through the patient's limb, and then the cuff is deflated in a controlled manner. As the cuff pressure de- creases, the oscillations increase in amplitude and then de- crease as blood returns to normal flow. From this change in amplitude, the mean arterial blood pressure can be directly determined and systolic (S) and diastolic (D) blood pressures derived.
Modes of operation	Manual (single measurement), interval, continuous, or ve- nous stasis
Interval times	Off, 1, 2, 2.5, 3, 5, 10, 15, 20, 25, 30, 45, 60, 120, and 240 min
Adult measurement range	Heart rate: 30 to 240 bpm Systolic: 30 to 250 mmHg (4 to 33.3 kPa) Mean: 30 to 230 mmHg (4 to 30.6 kPa) Diastolic: 10 to 210 mmHg (1.3 to 28 kPa)
Pediatric measurement range	Heart rate: 30 to 240 bpm Systolic: 30 to 170 mmHg (4 to 22.6 kPa) Mean: 30 to 150 mmHg (4 to 20 kPa) Diastolic: 10 to 130 mmHg (1.3 to 17.3 kPa)
Neonatal measurement range	Heart rate: 30 to 240 bpm Systolic: 30 to 130 mmHg (4 to 17.3 kPa) Mean: 30 to 110 mmHg (4 to 14.7 kPa) Diastolic: 10 to 100 mmHg (1.3 to 13.3 kPa)
Connector	Quick-release connector with single airway
Maximum inflation pressure	Adult: 265 mmHg, ±5 mmHg (35.3 kPa, ±0.66 kPa) Pediatric: 180 mmHg, ±5 mmHg (24 kPa, ±0.66 kPa) Neonate: 140 mmHg, ±5 mmHg (18.7 kPa, ±0.66 kPa)
Minimum inflation pressure	Adult: 110 mmHg, ±5 mmHg (14.7 kPa, ±0.66 kPa) Pediatric: 90 mmHg, ±5 mmHg (12 kPa, ±0.66 kPa) Neonate: 80 mmHg, ±5 mmHg (10.7 kPa, ±0.66 kPa)

Default inflation pressure	Adult: 160 mmHg, ±5 mmHg (21.3 kPa, ±0.66 kPa) Pediatric: 130 mmHg, ±5 mmHg (17.3 kPa, ±0.66 kPa) Neonate: 110 mmHg, ±5 mmHg (14.7 kPa, ±0.66 kPa)
Inflation pressure after a valid measure- ment	Adult: last systolic value plus 25 mmHg, ±5 mmHg (3.3 kPa, ±0.66 kPa) Pediatric: last systolic value plus 25 mmHg, ±5 mmHg (3.3 kPa, ±0.66 kPa) Neonate: last systolic value plus 30 mmHg, ±5 mmHg (4 kPa, ±0.66 kPa)
Inflation pressure after a technical alarm	Adult: 160 mmHg, ±5 mmHg (21.3 kPa, ±0.66 kPa) Pediatric: 130 mmHg, ±5 mmHg (17.3 kPa, ±0.66 kPa) Neonate: 110 mmHg, ±5 mmHg (14.7 kPa, ±0.66 kPa)
Maximum measurement time	Adult: 2 min, ±3 s Pediatric: 2 min, ±3 s Neonate 90 s, ±1 s
Maximum measurement time including a retry	Adult: 3 min Pediatric: 2 min Neonate: 90 s
Software safety cut-off SWh = value in specified range that last for at least 15 s SWi = instantaneous limit value	Adult (SWh): 265, to 290 mmHg (35.3, to 38.6 kPa) Pediatric (SWh): 185 to 215 mmHg (24.6 to 28.6 kPa) Neonate (SWh): 125 to 145 mmHg (16.6 to 19.3 kPa)
	Adult (SWi): >290 mmHg (38.6 kPa) Pediatric (SWi): >215 mmHg (28.6 kPa) Neonate (SWi): >145 mmHg (19.3 kPa)
Redundant safety cut-off	Adult: 300 mmHg (40 kPa) Pediatric: 300 mmHg (40 kPa) Neonate: 150 mmHg (20 kPa)
Static cuff accuracy	±3 mmHg (±0.4 kPa)
Calibration check range	0 to 260 mmHg, ±3 mmHg (0 to 34.6 kPa, ±0.4 kPa)
Resolution	1 mmHg (0.13 kPa)
Measurement accuracy	Maximum Standard Deviation: 8 mmHg (1.1 kPa) Maximum Mean Error: ±5 mmHg (±0.7 kPa)

### **Cardiac Output**

Parameter display	Cardiac output, blood temperature, injectate temperature
Measuring method	Thermodilution
Measurement range	Cardiac output:0.5 to 20 L/min Blood temperature: 25 to 43 °C (77 to 109 °F) Injectate temperature: –5 to +35 °C (23 to +95 °F)
Accuracy	Cardiac output: $\pm 5\%$ or 0.1 L/min, whichever is greater Blood temperature: $\pm 0.15$ °C ( $\pm 0.3$ °F) not including probe errors Injectate temperature: $\pm 0.25$ °C ( $\pm 0.45$ °F) not including probe errors)
Resolution	Cardiac output: 0.1 L/min Blood temperature: 0.1 °C (0.2 °F) Injectate temperature: 0.1 °C (0.2 °F)
Response time	Blood temperature: 3 s Injectate temperature: 3 s

# Pulse Oximetry (SpO<sub>2</sub>) Infinity MCable – Masimo SET and Infinity MCable – Masimo rainbow SET

Adult and pediatric sensors	LNCS DCI, LNCS DCIP, LNCS TC-I, LNCS TF-I, LNCS YI, LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, LNCS Pdtx-3, LNCS- DBI Adtx, LNCS Inf, LNCS Inf-3, Trauma LNCS Adtx, Trauma LNCS Inf/Pdtx
	RD-SET Adt, RD-SET Pdt, RD-SET Inf, RD-SET DC-I Adt, RD-SET DCIP Pdtx
	M-LNCS DCI Adtx, M-LNCS DCIP Pdtx, M-LNCS TC-I, M-LNCS TF-I Adtx, M-LNCS YI multi-site, M-LNCS DBI Adtx, M-LNCS Adtx-3, M-LNCS Pdtx-3, M-LNCS Adtx-3, M-LNCS Inf-3, Trauma M-LNCS Adtx, Trauma M-LNCS Inf/Pdtx
	R2-25a, R2-20a, R2-25, R2-20, R2-25r, R2-20r, R25-L, R20-L, R25, R20, rainbow DCI Adtx, rainbow DCIP Pdtx
Neonatal sensors	LNCS Inf, LNCS Inf-3, LNCS Neo, LNCS Neo-3, LNCS Ne- oPt-3, LNCS NeoPt, LNCS YI, LNCS SofTouch, Neo-Pt- 500m, Trauma LNCS Neo
	RD-SET Neo, RD-SET NeoPt
	M-LNCS NeoPt-3, M-LNCS Neo-3, Trauma M-LNCS Neo
Parameter display	Masimo SET MCable: Pulse oximetry (SpO2), pulse rate (PLS), perfusion index (PI))
	Masimo rainbow SET MCable: Pulse oximetry (SpO2), pulse rate (PLS), perfusion index (PI), SpHb (total hemoglobin), SpOC (total oxygen saturation), SpCO (carbon monoxide in hemoglobin), SpMet (methemoglobin saturation), PVI (pleth variability index)
Measuring method	Absorption-spectrophotometry
Measurement range (Infinity MCable – Masimo SET)	SpO2: 1 to 100% PLS: 26 to 239 bpm PI: 0.00 to 20%
Measurement range (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv: 0.0 to 25.0 g/dL (0.0 to 15.5 mmol/L) SpOC: 0 to 35 mL/dL PVI: 0 to 100% SpCO: 0 to 99% SpMet: 0 to 99.9%
Resolution (Infinity MCable – Masimo SET)	SpO2: 1% PLS: 1 bpm PI: 0.01%

Resolution (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv: 0.1 g/dL (0.1 mmol/L) SpOC: 1 mL/dL PVI: 1% SpCO: 1% SpMet: 0.1%
Maximum update interval	30 s
Accuracy (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv for 8 to 17 g/dL: $\pm 1$ g/dL SpCO accuracy for 1 to 40%: $\pm 3\%$ SpMet accuracy for 1 to 15%: $\pm 1\%$
PI accuracy	±10%
SpO2 accuracy with no motion adult, pediatric <sup>1) 2)</sup>	0 to 69% not specified 70 to 100%
	$\pm 2\%$ for: LNCS DCI, LNCS DCIP LNCS TF-I, LNCS YI, LNCS Adtx, LNCS Pdtx, LNCS Neo (finger) $^{\rm 6)}$
	±3.5% for: LNCS TC-I
SpO2 accuracy with no motion neonatal <sup>1) 2) 3)</sup>	0 to 69% not specified 70 to 100%
	±2% for: LNCS Inf
	$\pm 3\%$ for: LNCS Neo (foot) <sup>6)</sup> , LNCS NeoPt, LNCS YI <sup>7)</sup>
PLS accuracy with no motion 4)	±3 bpm
SpO2 accuracy with motion adult, pediatric <sup>1) 2) 3)</sup>	0 to 69% not specified 70 to 100%, ±3% for: LNCS DCI, LNCS DCIP, LNCS YI, LNCS Adtx, LNCS Pdtx
SpO2 accuracy with motion neonatal <sup>1) 2) 3) 5)</sup>	0 to 69% not specified 70 to 100%, ±3% for: LNCS Inf, LNCS Neo, LNCS NeoPt
PLS accuracy with motion <sup>4)</sup>	±5 bpm
SpO2 low perfusion accuracy adult, pediatric <sup>1) 2) 8)</sup>	±2% for: LNCS DCI, LNCS DCIP, LNCS TF-I, LNCS Adtx, LNCS Pdtx
	±3.5% for: LNCS TC-I
SpO2 low perfusion accuracy	±2% for: LNCS Inf, LNCS Neo (finger) 6)
neonatal <sup>1) 2) 3) 8)</sup>	$\pm$ 3% for: LNCS Neo (foot) <sup>6)</sup> , LNCS NeoPt
PLS low perfusion accuracy <sup>4)</sup>	±3 bpm
Interfering substances	Carboxyhemoglobin may erroneously increase measurement values. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any sub- stance containing dyes that change arterial pigmentation, may cause erroneous measurement values.

Nominal wavelength LNCS sensors	Red: IR:	Tip clip 653 nm 880 nm	Tip clip 653 nm 880 nm	All others 660 nm 905 nm	
Radiant flux at 50 mA pulsed	≤15 m	۱W			

#### NOTE

- <sup>1)</sup> Since SpO<sub>2</sub> sensor measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ±1 Arms of the value measured by a co-oximeter.
- <sup>2)</sup> The Infinity MCable Masimo SET SpO2 sensor with adult sensors has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 Arms of the value measured by a co-oximeter. Subjects were male (63%) and female (37%) between the ages of 18 and 38, with skin pigmentation ranging from light to dark.
- <sup>3)</sup> Accuracy of saturation measurements on neonates is decreased by ±1 digit as compared to accuracy on adult patients to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.
- <sup>4)</sup> The pulse rate accuracy has been validated on healthy adult volunteers during induced hypoxia studies in the range of 70 to100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 Arms of the pulse rate value measured by the ECG monitor.
- <sup>5)</sup> The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- <sup>6)</sup> Sensor accuracy depends on the weight of the patient. If the weight is less than 3 kg, the accuracy is  $\pm 3\%$ . For weights above 40 kg, the accuracy is  $\pm 2\%$ .
- <sup>7)</sup> Sensor accuracy depends on the weight of the neonate. If the weight exceeds 3 kg, the accuracy is  $\pm 2\%$ . For weights between 1 and 3 kg, the accuracy is  $\pm 3\%$  (if the sensor is applied on the foot).
- <sup>8)</sup> The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. 1% has been added to the saturation accuracy for neonatal sensors to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Adult and pediatric sensors	OxiMax MaxA, OxiMax MaxAL, OxiMax MaxA, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxR, OxiMax MaxFast, SoftCare SC-A, OxiCliq A, OxiCliq P, OxiBandOXI- A/N, OxiBandOXI-P/I, Durasensor DS-100A, Dura-Y D-YS
Neonatal sensors	OxiMax MaxN, OxiMax MaxI, SoftCare SC-NEO, SoftCare SC-PR, OxiCliq I, OxiCliq N, Oxi-A/N, Oxi-P/I
Parameter display	Pulse oximetry (SpO2), pulse rate (PLS)
Measuring method	Absorption-spectrophotometry
Measurement range	SpO2: 1 to 100% PLS: 26 to 239 bpm
Resolution	SpO2: 1% PLS: 1 bpm
Update interval	2 s, ±0.5 s
Maximum update interval	30 s
SpO2 measuring accuracy adult, pediatric <sup>1) 2)</sup>	0 to 60% not specified
	60 to 80% not specified: SoftCare SC-A, OxiMax MaxR, Oxi- Cliq A, OxiCliq P, OxiCliq N, OxiCliq I, D-YS, DS100A, Oxi- A/N, Oxi-P/I
	60 to 80%, ±3% for: OxiMax MaxA, OxiMax MaxAL, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxFast
	70 to 100%
	±2% for: OxiMax MaxA, OxiMax MaxAL, OxiMax MaxP, Ox- iMax MaxN, OxiMax MaxI, OxiMax MaxFast, SoftCare SC-A
	±2.5% for: OxiCliq A, OxiCliq P, OxiCliq N, OxiCliq I
	±3% for: D-YS, DS100A, Oxi-A/N, Oxi-P/I
	$\pm 3.5\%$ for: D-YS with D-YSE Ear Clip or D-YSPD Spot Clip
	80 to 100%, ±3.5% for: OxiMax MaxR

### Pulse oximetry (SpO<sub>2</sub>) Infinity MCable – Nellcor OxiMax

SpO2 measuring accuracy neonatal <sup>1) 2) 3)</sup>	0 to 60% not specified
	60 to 80% not specified: SoftCare SC-PR, SoftCare SC-NEO, OxiCliq N, D-YS, Oxi-A/N
	60 to 80%, ±3% for: OxiMax MaxN
	70 to 100%
	±2% for: OxiMax MaxN, SoftCare SC-PR, SoftCare SC-NEO
	±3.5% for: OxiCliq N
	±4% for: D-YS, Oxi-A/N
PLS measuring accuracy <sup>4)</sup>	PLS: $\pm 3$ bpm or $\pm 3\%$ (whichever is greater)
SpO2/PLS response time	Normal mode: 90% change within 5 to 7 s
	Fast mode: 90% change within 2 to 4 s
Nominal wavelength	Red: 660 nm
	IR: 910 nm
Radiant flux	≤15 mW

#### NOTE

- <sup>1)</sup> Since SpO<sub>2</sub> sensor measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ±1 Arms of the value measured by a co-oximeter.
- <sup>2)</sup> The Infinity MCable Nellcor OxiMax SpO2 sensor with adult sensors has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 to100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 Arms of the value measured by a co-oximeter. Subjects were male (45%) and female (55%) between the ages of 19 and 48, with skin pigmentation ranging from light to dark.
- <sup>3)</sup> Accuracy of saturation measurements on neonates is decreased by ±1 digit as compared to accuracy on adult patients to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.
- <sup>4)</sup> The pulse rate accuracy has been validated on healthy adult volunteers during induced hypoxia studies in the range of 70 to100% SpO<sub>2</sub> against a laboratory co-oximeter and ECG monitor. This variation equals ±1 Arms of the pulse rate value measured by the ECG monitor.

Measurement range	etCO2 and inCO2: 0 to 99 mmHg (0 to 13.3 kPa or 0 to 13.2 vol% at sea level)
	RRc: 03 to 150 breaths per minute
Measurement accuracy	Disposable cuvette and reusable cuvette:
	<ul> <li>±0.26 Vol% or ±5% rel.</li> </ul>
	− ±0.27 kPa or ±5% rel.
	<ul> <li>±2.00 mmHg or ±5% rel.</li> </ul>
	<b>NOTE</b> : For the above 3 values, choose whichever is the greater of the two values.
	Reusable cuvette in extended temperature range:
	- ±(0.43 Vol% + 8% rel.)
	− ±(0.44 kPa + 8% rel.)
	<ul> <li>±(3.30 mmHg + 8% rel.)</li> </ul>
Resolution	etCO2 and inCO2: 0.1 mmHg (0.1 kPa or 0.1%) RRc: 1 breath per minute
Warm up time needed to reach full oper-	At 20 to 40 °C (68 to 104 °F), approximately 2 min
ating specifications	At 10 °C (50 °F), approximately 10 min
Total system response time	<200 ms (rise time plus delay time)
	Rise time: <35 ms
	Delay time: <165 ms
Measurement accuracy drift	Over 6 hours is less than 0.03 Vol% at 5 Vol% CO2, drift of precision (noise).
How humidity/condensate affect perfor- mance	The airway adapter windows are indirectly heated through the sensor to prevent moisture condensation. Water droplets and other window contamination may slightly influence measurement bias, up to 0.3 Vol% at 5 Vol% CO <sub>2</sub> at worst (normally much less).
	If measurement light is blocked so the noise of the reading gets too high, an error message is sent by the CO <sub>2</sub> sensor in- dicating that the airway adapter has to be checked (cleaned or replaced) and such message is displayed by the host.
Adverse effects on performance of cycli- cal pressures up to 10 kPa (100 cmH2O)	No effects other than with static pressure. For more informa- tion see "The effect of ambient pressure on performance" on page 418.

### Mainstream Carbon dioxide concentrations (CO2)

Compensation	Atm. pressure: user-selectable; 540 to 800 mmHg (72-106.7 kPa)
	Gas: user-selectable; Air, N2O/O2, O2 > 50%, HeliOx
	<b>NOTE</b> : Selection for Gas Compensation must be made for the automatic correction of the influence of a balance gas.

#### The effect of ambient pressure on performance

The user has to manually set the total gas pressure (ambient or ambient pressure) in the monitor, which is used by the mainstream CO<sub>2</sub> sensor to automatically compensate for pressure effects.

The remaining bias error is less than 2% of reading (i.e., 2% relative) for ambient pressures between 57 and 110 kPa, which includes imperfection of foreign gas compensation (O2, N2O, He).

With user selection of atmospheric pressure, the Dräger mainstream CO<sub>2</sub> module incorporates compensation for pressure effects according to the following table:

#### NOTE

The following table applies to the Gas Compensation of "Air."

	Correction factors for atmospheric pressure					
CO <sub>2</sub> Value Prior to	Atm P	Atm P	Atm P	Atm P	Atm P	Atm P
Pressure	106.3 kPa	101.3 kPa	96.3 kPa	91.3 kPa	86.3 kPa	81.3 kPa
1 kPa (7.5 mmHg)	0.981	1	1.020	1.042	1.066	1.093
5 kPa (37.5 mmHg)	0.969	1	1.033	1.069	1.109	1.153
10 kPa (75.0 mmHg)	0.969	1	1.033	1.070	1.110	1.155

#### The effect of interfering gases and vapors on performance

The additional errors from interfering gases and vapors are not corrected automatically by the **Gas Compensation** selection.

Gas or Vapor, Concentration	CO2 reading in Vol% at 0 Vol% CO2
Halothane, 5 Vol%	0.02
Enflurane, 5 Vol%	0.03
Isoflurane, 5 Vol%	0.02
Sevoflurane, 5 Vol%	0.02
Desflurane, 20 Vol%	0.00
Ethanol, 4%	0.00
Isopropanol, 1 Vol%	0.00
Acetone, 1%	0.00
Methane, 3 Vol%	< 0.02
NO, 100 ppm	0.01
NO2, 50 ppm	0.00
CO, 4 Vol%	0.00
Freon R21, 100 Vol%	0.07
Freon R134a, 100 Vol%	0.19
Water vapor, 37 °C saturated	0.01

#### NOTE

Given readings are pure interfering gas effects, balance N2 (if applicable, without CO2 content). The CO2 reading of mixtures (for example, CO2, N2O, O2, anesthetic agent or CO2, O2, N2, water vapor) is within specified tolerance.

### Microstream carbon dioxide concentrations (CO<sub>2</sub>)

CO <sub>2</sub> units	mmHg or kPa or Vol% (as relevant to Microstream capnogra- phy)
etCO2, inCO2 range	0–99 mmHg (as relevant to the Microstream capnography)
CO2 waveform resolution	0.1 mmHg
etCO2, inCO2 resolution	1 mmHg
CO2 partial pressure accuracy	<ul> <li>0 to 38 mmHg ± 2 mmHg <sup>1</sup> (2) <sup>3</sup>)</li> <li>39 to 99 mmHg ± [5% of expected reading + 0.08 x (expected reading in mmHg - 39mmHg)] <sup>1</sup> (2) <sup>3</sup>)</li> </ul>
Accuracy in presence of interfering gas- es as required by ISO 80601-2-55	The accuracy in presence of interfering gases is within 4% of the accuracy values above; therefore:
	<ul> <li>0 to 38 mmHg: ± (2 mmHg + 4% of expected reading in mmHg)</li> </ul>
	<ul> <li>39-99 mmHg: ± [9% of expected reading in mmHg + 0.08 x (expected reading in mmHg – 39 mmHg)]</li> </ul>
	<ul> <li>0 to 38 mmHg ± (2 mmHg + 4% of expected reading in mmHg) in the presence of up to 80% helium with up to 15% oxygen</li> </ul>
	<ul> <li>39-99 mmHg: ± [9% of expected reading in mmHg + 0.08 x (expected reading in mmHg – 39 mmHg)] in the presence of up to 80% helium with up to 15% oxygen</li> </ul>
Waveform sampling	20 samples/s
Respiratory rate range	0 to 150 breaths per minute
Respiratory rate accuracy	$-$ 0 to 70 breaths per minute $\pm$ 1 breaths per minute
	$-$ 71 to 120 breaths per minute $\pm$ 2 breaths per minute
	$-$ 121 to 150 breaths per minute $\pm$ 3 breaths per minute
Flow rate	50 mL per minute (tolerance –7.5, +15), flow measured by volume
Leakage rate	Less than 40 mbar per minute when a 30% vacuum is in- voked on the flow system.
System Response	
Rise time	<190 ms.
Delay time	<2.7 sec.
	After the system warm up and during steady state Microst- ream MCable use: the maximum delay time between patient breath and its report on the CO <sub>2</sub> waveform is 2.9 sec.

Warm-up period	Includes power-up time (10 seconds maximum) and initializa- tion time (180 seconds).
	Total warm-up time 1 minute and 30 seconds maximum.
Compression	BTPS is the standard correction used by Microstream cap- nography during all measurement procedures for body, tem- perature, pressure, and saturation.

#### NOTE

<sup>1)</sup> Applies for respiratory rates up to 80 breaths per minute.

- $^{2)}$  For respiratory rates above 80 breaths per minute, accuracy is 4 mmHg or  $\pm$  12% of reading, whichever is greater, for etCO<sub>2</sub> values exceeding 18 mmHg.
- <sup>3)</sup> For respiratory rates above 60 breaths/minute, the Microstream FIIterLine H Set for Infant/Neonatal is required.

#### Temperature

Parameter display	Temperatures: Ta, Tb, $\Delta$ T, T1a, T1b, $\Delta$ T1 (or assigned labels)
Measurement range	Ta, Tb, T1a, T1b: 0 to 50 °C (32 to 122 °F)
	$\Delta$ T, $\Delta$ T1: 0 to 50 °C (32 to 122 °F)
Resolution	0.1 °C (0.1 °F)
Accuracy (exclusive of probe)	Ta, Tb, T1a, T1b: ±0.1 °C (±0.2 °F) ΔT, ΔT1: ±0.2 °C (±0.4 °F)
Probe accuracy	Reusable probe: ± 0.1 °C (±0.2 °F) at 0 °C to 50 °C (32 to 122 °F)
	Disposable probes:
	± 0.1 °C (±0.2 °F) at 25 °C to 45 °C (77 to 113 °F)
	± 0.2 °C (±0.4 °F) at 0 to 25 °C (32 to 77 °F)
Average update time	<2.5 s
Response time	23 to 44 °C (73.4 to 111.2 °F) ±0.2 °C (±0.4 °F) within 150 s
	2 °C (°F) temperature change (approximately):
	<ul> <li>reusable GP probes with cover: 60 s</li> </ul>
	<ul> <li>disposable GP probes: 30 s</li> </ul>
	<ul> <li>reusable and disposable skin temperature sensors: 15 s</li> </ul>
Degree of protection against electric shock	Туре СҒ
Defibrillation protection	Yes

#### Scio

For Scio Four/Scio Four Oxi/Scio Four plus/Scio Four Oxi plus modules, refer to the Supplements for information.

### Electromagnetic compatibility

#### CAUTION

The medical device must only be used with software tested and approved by Dräger. Any modifications of the operating system settings can impair operating safety. Responsibility for any such modifications lies with the operating organization.

The separation distances are written with regard to the M540. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment, and older equipment may be particularly susceptible to interference.

#### **General notes**

The M540 patient monitor and its radio are designed and manufactured in a way that ensures that the emission limits for RF (Radio Frequency) energy, as defined by the FCC (Federal Communications Commission), the RSS (Radio Standards Specifications), by ETSI and by IEC/EN 60601-1-2, will not be exceeded. These limits are part of international safety standards that are defined by international committees.

The radio in the M540 patient monitor complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not recommended. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

The equipment should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Low level signals such as ECG are particularly susceptible to interference from electromagnetic energy. While the equipment meets the testing described below, it is not a guarantee of perfect operation, the 'quieter' the electrical environment the better. In general, increasing the distance between electrical devices decreases the likelihood of interference.

#### NOTE

The equipment is intended for use in the electromagnetic environments specified below. The user of this equipment should assure that is used in such an environment.

Electromagnetic emissions				
Emissions	Compliance according to	Electromagnetic environment		
RF emissions (CISPR 11)	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
CISPR emissions classification	Class A	The equipment is suitable for use in		
Harmonic emissions (IEC 61000-3-2)	Class A	industrial areas and hospitals (CIS- PR 11 Class A). If it is used in a res-		
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	PR 11 Class B is normally required) this equipment might not offer ade- quate protection to radio frequency communication services. The user might need to take mitigation mea- sures such as relocating or reorient- ing the equipment.		

Electromagnetic immunity			
Immunity against	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: ±6 kV air discharge: ±8 kV	±6 kV ±8 kV	Floors should be wood, concrete or ceram- ic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/bursts (IEC 61000-4-4)	AC power lines: ±2 kV input / output lines: ±1 kV	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environ- ment.
Surges on AC mains lines (IEC 61000-4-5)	Common mode: ±2 kV differential mode: ±1 kV	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environ- ment.
Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	Equipment which emits high levels of pow- er line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference.
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95%, 0.5 periods dip 60%, 5 periods dip 30%, 25 periods dip >95%, 5 s	>95%, 0.5 pe- riods 60%, 5 peri- ods 30%, 25 peri- ods >95%, 5 s	Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions ensure that bat- teries are installed and charged. Ensure that battery life exceeds longest anticipat- ed power supply failures or provide an ad- ditional uninterruptible power supply.

Electromagnetic immunity				
Immunity against	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment	
Conducted RF	150 kHz to 80 MHz:	3 Vrms	Portable and mobile RF communications	
lines (IEC 61000-4-6) radiated RF (IEC 61000-4-3)	80 MHz to 2.5 GHz	3 V/m	part of the device, including cables, than the recommended separation distance cal- culated from the equation applicable to the frequency of the transmitter as below.	
			Recommended separation distance	
			$\mathbf{d} = \left[\frac{3.5}{\mathbf{V}_1}\right] \sqrt{\mathbf{P}}$	
		[ <i>V</i> 1] V	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P} \qquad \text{80 MHz to 800 MHz}$	
			$d = \left[\frac{7}{E_1}\right] \sqrt{P} \qquad \text{800 MHz to 2.5 GHz}$	
		[ <i>E</i> 1] V/m	where $P$ is the maximum output power rat- ing of the transmitter in watts (W) accord- ing to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).	
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a)</sup> , should be less than the compli- ance level in each frequency range <sup>b)</sup> .	
			Interference may occur in the vicinity of equipment marked with the following symbol:	
			(())	

#### NOTE

<sup>a)</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

<sup>b)</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### **Recommended separation distances**

Maximum PEIRP (Watts)	150 kHz to 800 MHz Distance <sup>1</sup> (m)	800 MHz to 2.5 GHz Distance <sup>1</sup> (m)	Comments (if applicable)	
0.001	0.04	0.07		
0.003	0.06	0.12		
0.010	0.12	0.23		
0.040	0.21	0.4	For example: WLAN 5250	
0.100	0.38	0.73	For example: WLAN 2440 (Europe), Bluetooth	
0.200	0.54	1.03	For example: WLAN 5250 (Europe)	
0.250	0.6	1.03	For example: DECT-devices	
1.000	1.2	2.3	For example: GSM 1800 / GSM 1900 / UMTS cellular phones, WLAN 5600 (not in Europe)	
2.000	1.7	3.25	For example: GSM 900 cellu- lar phones	
3.000	2.08	3.98		
10.00	3.8	7.27		
100.00	12	23		
<sup>1</sup> Information regarding separation distances (IEC 60601-1-2:2007, tables 4 and 6)				

#### NOTE

Avoid exposure to known sources of EMI (electromagnetic interference) with medical devices such as magnetic resonance imaging MRI systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors. Note that the presence of RFID devices may not be obvious.

#### **General information**

This device was tested for electromagnetic compatibility using accessories from the list of accessories. Other accessories may only be used if they do not compromise the electromagnetic compatibility. The use of non-compliant accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device. This device may be used in the direct vicinity of other devices only if Dräger has approved this device arrangement. If no approval has been given by Dräger, it must be ensured that this device functions correctly in the desired arrangement before use. The instructions for use for the other devices must be followed.

#### **Electromagnetic environment**

Emissions	Compliance
Radiated emissions	Class A, group 1 (30 MHz to 1 GHz)
Conducted emissions	Class A, group 1 (150 kHz to 30 MHz)

#### NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Immunity against	Test level and required electromagnetic environ- ment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±8 kV
	Air discharge: ±15 kV
Fast transient electrical disturbances (bursts)	Power cable: ±2 kV
(IEC 61000-4-4)	Longer signal input lines/output lines: ±1 kV
Impulse voltages (surges) (IEC 61000-4-5)	Voltage, external conductor – external conductor: ±1 kV
	Voltage, external conductor – protective ground con- ductor: ±2 kV

Immunity against	Test level and required electromagnetic environ- ment
Magnetic fields at mains frequency (IEC 61000-4-8)	30 A/m
Voltage dips and short interruptions in the supply	100 % drop, 0.5 period
voltage (IEC 61000-4-11)	100 % dip, 1 period
	30 % dip, 25/30 periods
	Voltage interruptions:
	100 % drop, 5 seconds
Radiated high-frequency disturbances (IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m
Conducted high-frequency disturbances (IEC 61000-4-6)	150 kHz to 80 MHz: 3 Vrms, ISM bands: 6 Vrms
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies from 385 MHz to 5785 MHz: 9 V/m to 28 V/m, with various pulse modulations

### Recommended separation distances from wireless communication devices

To ensure that the functional integrity of this device is maintained, there must be a separation distance of at least 1.0 m (3.3 ft) between this device and wireless communication devices.

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These instructions for use only apply to Infinity® Acute Care System -Infinity M540 - VG7.1

with the Serial No .:

If no Serial No. has been filled in by Dräger, these instructions for use are provided for general information only and are not intended for use with any specific machine or unit.

This document is provided for customer information only, and will not be updated or exchanged without customer request.



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# CE

The radio equipment in the Infinity M540 patient monitor complies with the Radio Equipment Directive (2014/53/EU). A copy of the Declaration of Conformity is available at the following Internet address: www.draeger.com/doc-radio

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