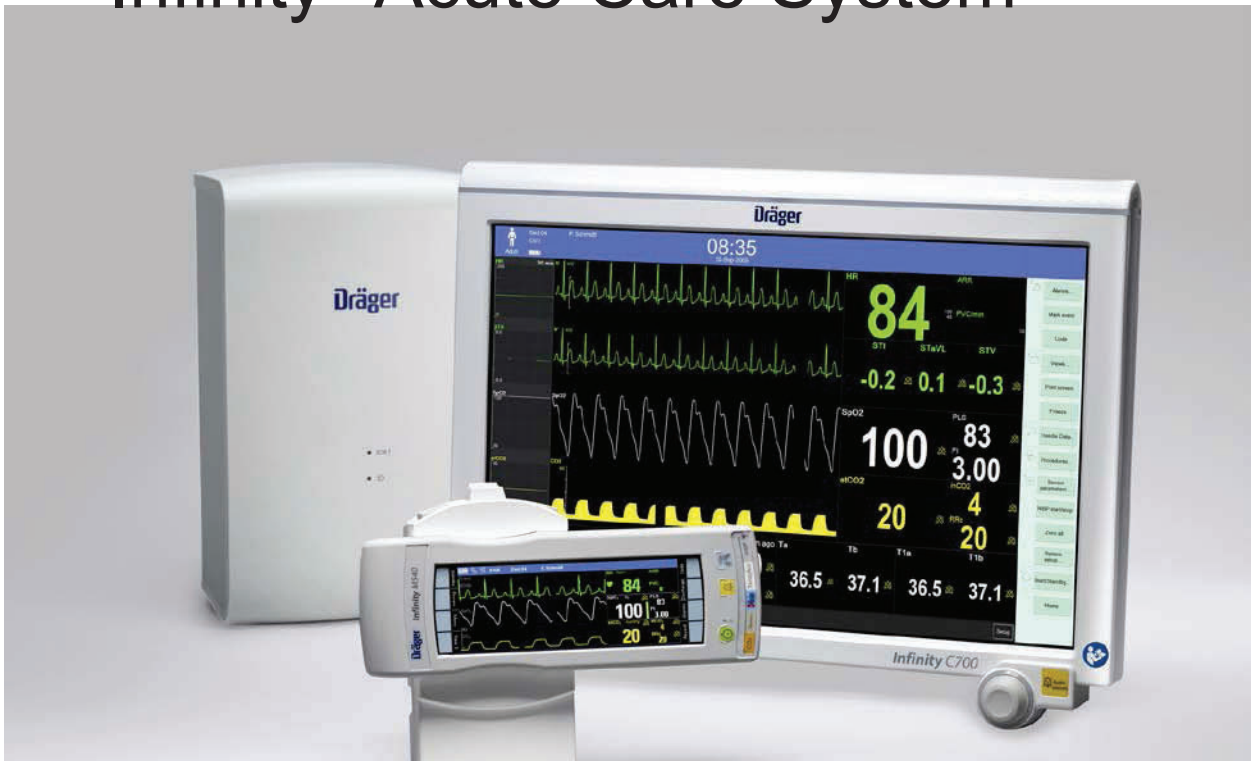


End-user Software Release Notes

Infinity® Acute Care System



Software VG7.1

End-user Software Release Notes for Infinity® Acute Care System (IACS) VG7.1

This document describes the VG7.1 software version for the Infinity Acute Care System (IACS) patient monitoring platform. Software version VG7.1 adds software enhancements, performance enhancements, and addresses limitations identified in preceding software versions.

- A. Software enhancements
- B. Algorithm enhancements
- C. Corrected defects
- D. Known limitations
- E. Hardware and software compatibility
- F. System compatibility
- G. Recommendations for training

A. Software Enhancements:

QR code: IACS now offers a QR code illustrated in Figure 1. This allows the user to access device's information directly by scanning it. It is available in the System setup menu and the Service menu.

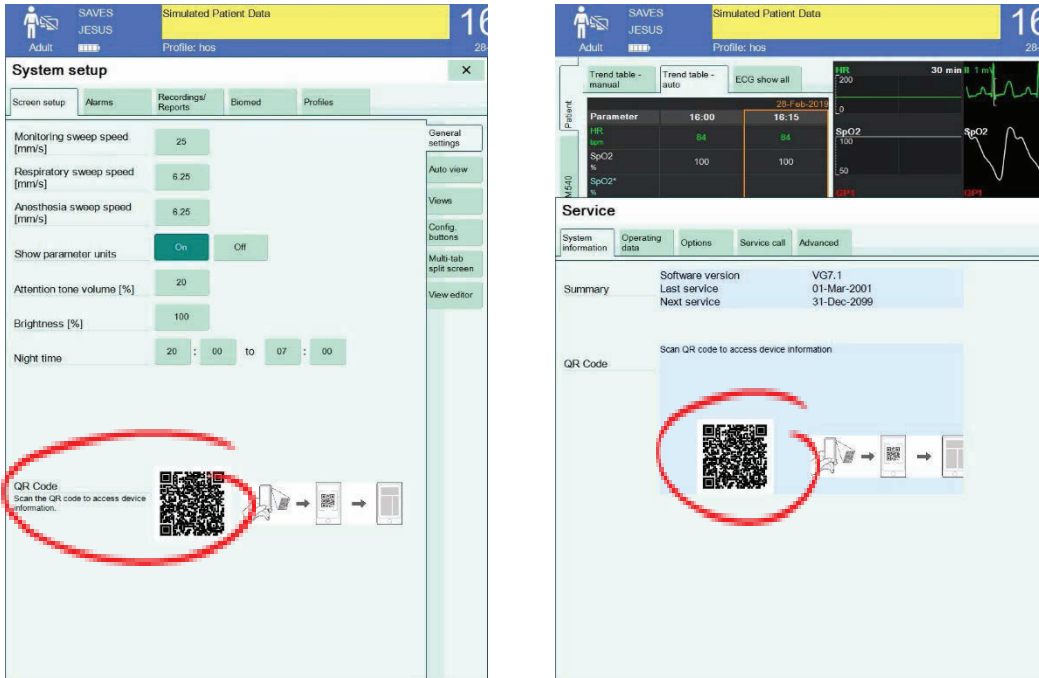


Figure 1: QR Code in System Setup Menu and Service Menu

Hybrid alarm tone set: IACS now offers the ability to have a fourth alarm tone set, called hybrid, which is a combination of IEC low-grade and medium-grade tones and Draeger Infinity high-grade tone. This user feedback has been implemented to make high grade alarms more alerting while reducing alarm fatigue by using softer tones for medium and low grade alarms. The setting is available in the current Alarms menu in System setup behind password protection, illustrated in Figure 2.

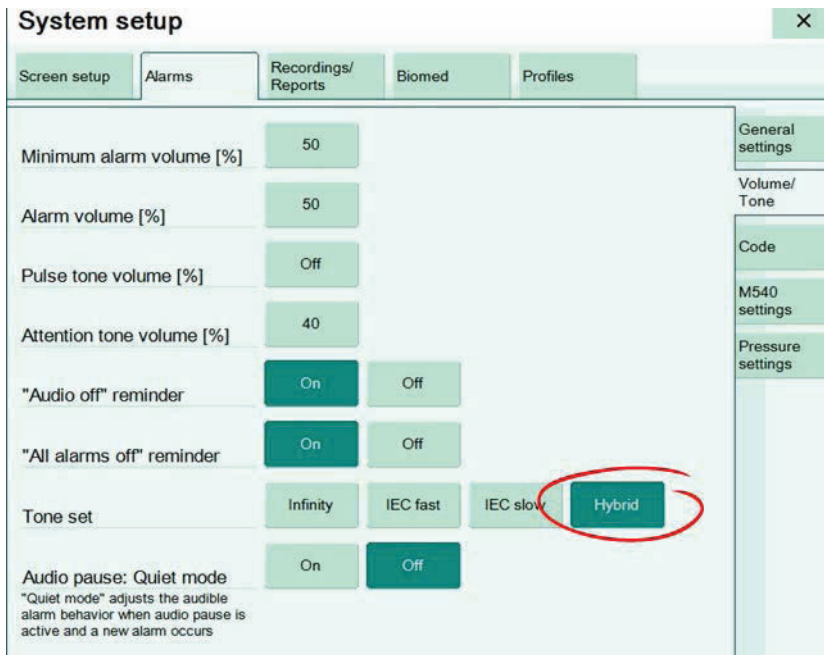


Figure 2: Hybrid Alarm tone setup

Impedance respiration: IACS now offers the ability to configure, in manual mode, the respiration threshold independently from the waveform size. The enhancement includes the display of a bracket on the waveform channel illustrated in Figure 3. This allows users to clearly set the threshold according to the amplitude of the waveform and thus avoid false apnea alarms, illustrated in Figure 4. The Respiration menu has been slightly modified to accommodate for this change. In parallel, enhancements in the filtering of the respiration signal has allowed to reduce the number of false positive apnea alarms.

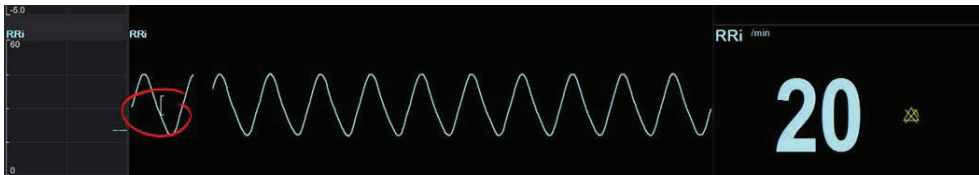


Figure 3: Threshold bracket on the respiration waveform when in manual mode

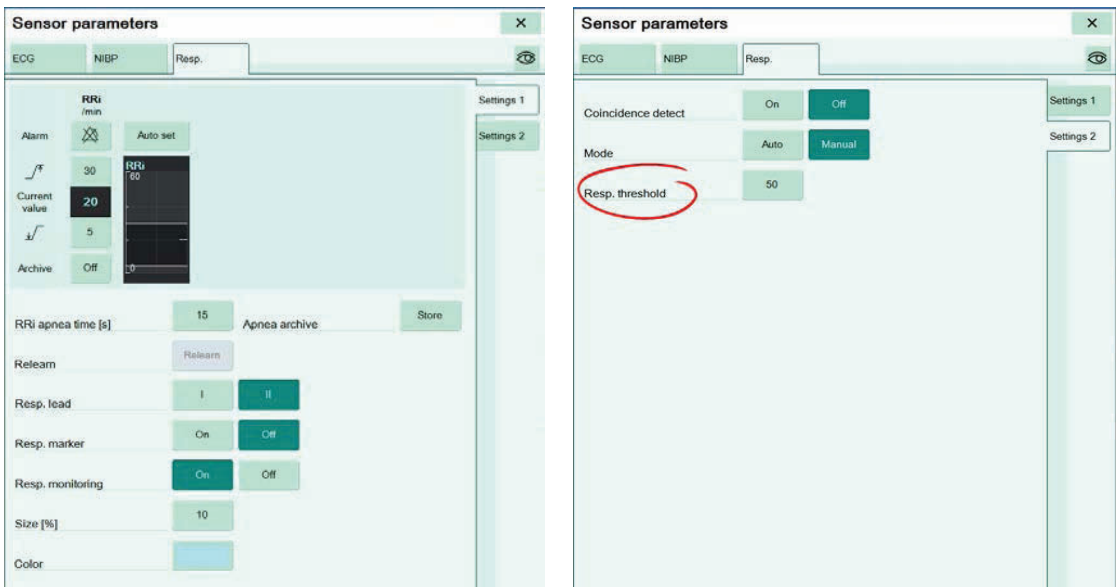


Figure 4: Impedance respiration menu

Split screen – tabular trend auto update: IACS now offers the ability to have the tabular trend in the split screen to update automatically. The user can therefore now choose between automatic or manual trend tables in the split screen, illustrated in Figure 5 and 6.

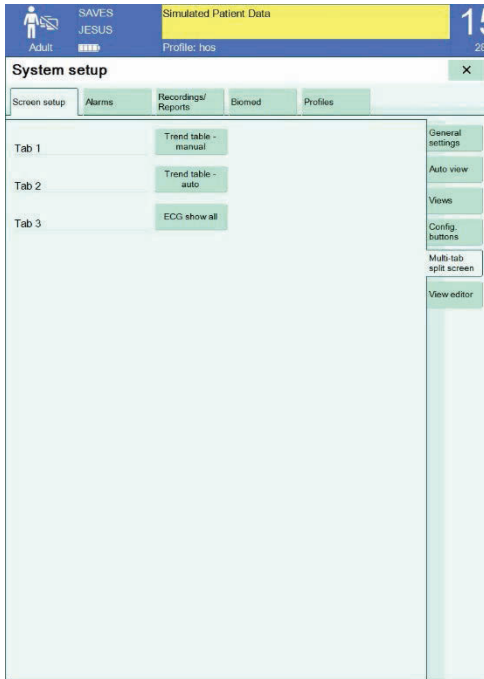


Figure 5: Available configurations

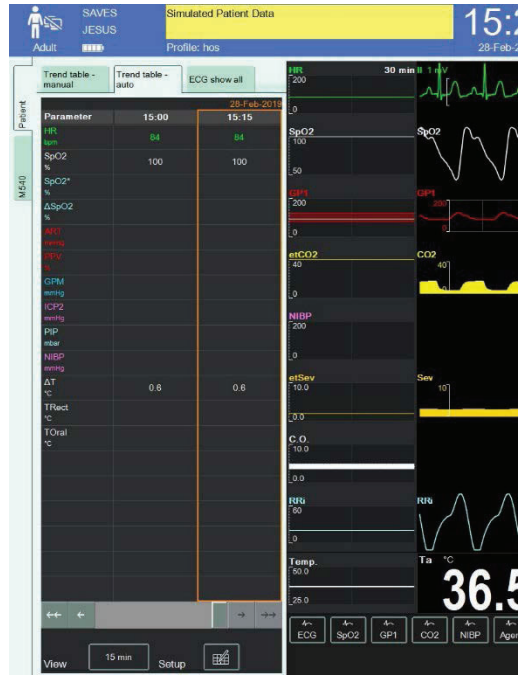


Figure 6: The last column will update automatically

External device Reconnect button: IACS now offers the ability to reconnect third party devices when one or several are digitally disconnected. The user therefore does not have to physically disconnect and reconnect the devices and/or powercycle the cockpit to get the devices connected again. This functionality needs to be enabled in the Biomed menu and is accessible in the Screen setup menu, illustrated in Figure 7.

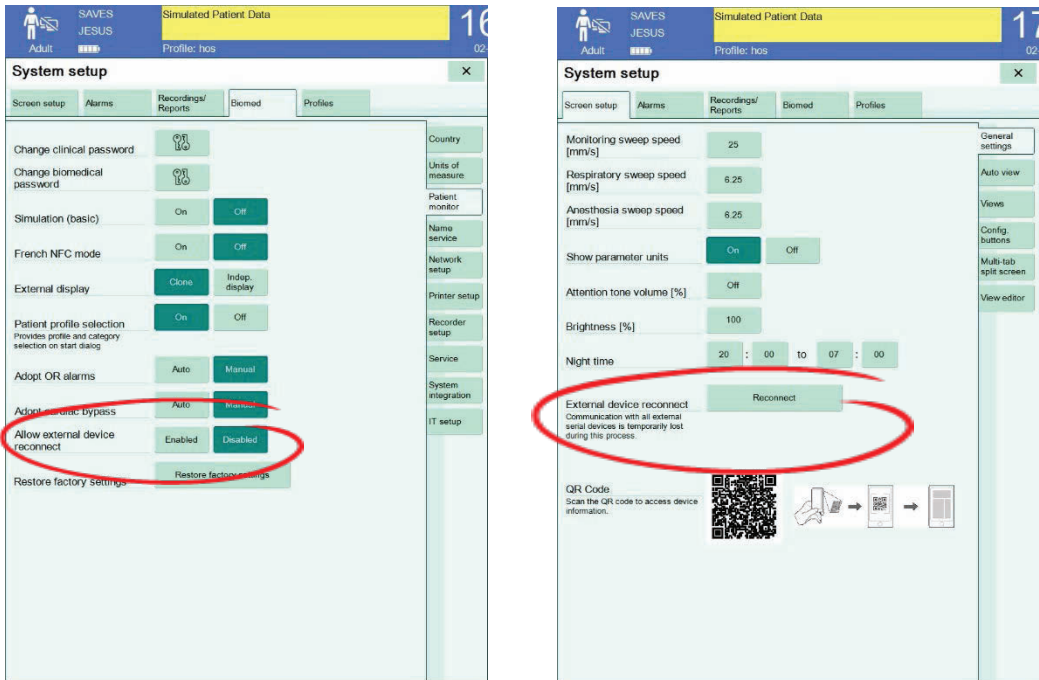


Figure 7: External device Reconnect button setup and access

B. Algorithm enhancements:

Ventricular Fibrillation detection: The algorithm has been improved to increase sensitivity to ventricular fibrillation detection.

Improvement of the ECG beat classification: The ECG beat classification has been enhanced for dual processing lead by introducing cross-checking between both leads. This change has led to higher PVC detection sensitivity, positive predictivity and a lower PVC detection false positive rate.

C. Corrected defects, performance limitations or change requests:

1. M540 reset when the ECG cable is not well inserted. (corrected in M540 VG7.0.2)
2. M540 reset due to relay test failure. (corrected in M540 VG7.0.2)
3. Sporadic cockpit reboots due to queue/timing issues with Recordings
4. IBP alarm suppression timer when stuck does not get cleared when connecting and disconnecting the Hemopod.
5. With Bis Aspect device connected, EMG bar graph is always orange regardless of EMG value.
6. Erroneous Scio Reduced accuracy alarm.
7. Infinity Central Station (ICS) does not display surveillance alarms from a stand-alone M540.
8. Desaturation alarm randomly turns on when resuming monitoring even though it is set to Off in the profile.
9. Desaturation alarm randomly turns off when resuming monitoring even though it is set to On in the profile.
10. Loss of device connectivity in the OR after the room is shut down overnight.
11. Citrix Disconnect button does not activate when connecting to an already existing session.
12. Patient category buttons do not grey out in the Start menu just after a patient category change.
13. Primary agent waveform is not displayed on M540 stand-alone after patient category change.

14. M540 alarm volume may not go to 100% when optical lens is blocked on M500 and M540 shows Offline message.
15. On SPV/PPV tool, RRI label is displayed but not the corresponding waveform after a power cycle.
16. Intermittent freeze of the cockpit and waveform gaps with active Citrix tab.
17. Secure M540 updates when not using service tools.
18. Brief loss of monitoring on Cockpit due to memory availability.
19. Incorrect color sent by the M540 stand-alone for the Heart Rate (HR) parameter when pulse is the heart rate source.
20. Cockpit does not synchronize with M540 anymore when a discharge has been performed immediately after the M540 dock – discharge button on M540 and cockpit will be greyed out until synchronization between both devices has ended.
21. M540 stand-alone may flood the network with frames not intended to be on the network.
22. Print ECG filter settings on strip recorder.
23. Address the M540 not connecting to the Cockpit issue due to a software defect in the Operating System.
24. Recorder configuration changed to a different one outside of the monitoring unit.

D. Known limitations:

1. When the Scio is connected to the M500, it is recommended not to connect any other CO₂ source to the M540 until the Scio has been disconnected from the M500 or the M540 is undocked.
2. Rarely the M540 Stand Alone stops being recognized by Innovian. If wireless is available on that M540, it is recommended to undock the M540, wait a couple of minutes and then dock it back to the M500.
3. IACS cockpit will only accept a maximum of 17 characters for the custom service password.
4. ALT+F10 combination to activate the mouse cursor will not work if a Citrix session is connected. To make this shortcut available again, exit the Citrix session.

E. Hardware and software compatibility

Hardware components and corresponding software versions for Cockpit VG7.1 / M540 VG7.1.

- Infinity C500/C700 Cockpit VG7.1
(2nd generation Kontron Cockpit with 4 GB RAM minimum).
- Infinity C500/C700 Cockpit VG7.1
(3rd generation Kontron Cockpit with 8 GB RAM and i5 processor)
- Infinity M540 patient monitor VG7.1
- Infinity PS250/P2500 1.49/1.16
- Infinity M500 3.6, 4.0, 4.2, 4.3

HW compatibility with 3rd generation cockpit: Due to HW modifications, the third generation C500 MK32500 and third generation C700 MK32700 cockpits will be moving to Revision Index RI03. RI03 requires VG7.1 software version and is not compatible with any revision below VG7.1.

Complementary software versions for compatibility with Cockpit VG7.1 / M540 VG7.1 features by data consumers:

- Infinity CentralStation VG2.1.1, VG2.1.2
- Infinity Gateway VF7.2

F. System compatibility

Minimum software versions for Dräger Infinity patient monitoring devices, basic compatibility with Cockpit VG7.1 / M540 VG7.1:

- Infinity Delta/Delta XL/Kappa series ≥VF9.x
- Infinity OMEGA/OMEGA S series ≥VF9.x
- Infinity CentralStation ≥ VG1.1.2
- Infinity M300 telemetry monitor ≥ VG2.2.x

Note: IACS is no longer compatible with any Infinity CentralStation VF version, with IACS VG6.0 software and higher.

Cockpit VG7.1 / M540 VG7.1 software IS NOT COMPATIBLE with to the following Dräger systems:

- 1st Generation (Advantech) C500/C700 Cockpits not compatible
- Infinity MVWS CentralStation not compatible
- Infinity MVVS View Station not compatible
- Infinity Kappa XLT not compatible

Compatible Dräger systems and corresponding minimum requirement software versions:

- Innovian Web ≥VF7.1
- Infinity Gateway ≥VF7.1
- Dräger Evita 2 Dura ventilator 1.00
- Dräger Evita 4 ventilator 1.00
- Dräger Evita XL ventilator 5.00
- Dräger V500 ventilator 2.51
- Dräger V300 ventilator 2.42
- Dräger VN500 ventilator 2.51
- Dräger Carina ventilator 3.21
- Dräger Savina ventilator 4.21
- Dräger Oxylog ventilator 1.06
3000+
- Dräger Perseus A500 anesthesia machine 2.01
- Dräger Primus anesthesia machine family 4.53.x
- Dräger Apollo anesthesia machine 4.53
- Dräger Zeus IE anesthesia machine 2.0.x
- Dräger Fabius anesthesia machine family 3.35b

Compatible systems from other manufacturers and corresponding minimum requirement software versions:

- Maquet SERVO-i 7.0
- Edwards Vigilance II all software versions
- Edwards EV1000 software version 1.5
- Covidien BIS Complete software version 3.0
- IDMed ToFScan software version 1.5.8
- Nellcor PM1000N all software versions
- Masimo Radical 7 all software versions
- Citrix ICA Citrix XenApp server (versions 5, 6 and 6.5)
- Citrix StoreFront Server $\geq 7.x$
- Citrix client 4.7

G. Dräger's training recommendation for Cockpit VG7.1 / M540 VG7.1:

Dräger, the manufacturer of IACS, recommends that clinicians as well as those responsible for setting up and servicing devices read all "Instructions for Use: Infinity Acute Care System VG7.1" manuals prior to employing the system in the care of patients.

Dräger will provide product training specific to the software enhancements and upgrades referenced in this letter, enabling your organization to fulfil the requirements of local regulations. Contact your Dräger representative for details.