Medtronic

LINQ II™ LNQ22

MR Insertable Cardiac Monitor

Clinician Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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1.1 Explanation of packaging and product symbols

Table 1. Explanation of symbols

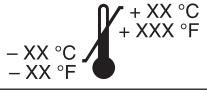
Symbol	Explanation
	MR Conditional
	Caution
	Consult instructions for use.
	Package contents
	Sterilization: Ethylene Oxide Gas
	Single sterile barrier system
	Product documentation
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.
	Reorder number
	Serial number
	Temperature limitations

Table 1. Explanation of symbols (continued)

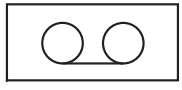
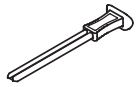
Symbol	Explanation
	Humidity limitation
	Manufacturer
	Date of manufacture
	Authorized representative in the European Community
	Do not reuse.
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	ACMA (Australian Communications and Media Authority and the New Zealand Ministry of Economic Development Radio Spectrum Management standards) symbol for Australia and New Zealand
	Storage temperature
	Transit temperature
	Follow instructions for use (blue).
	Model number
	Do not use if package is damaged.
	Recording

Table 1. Explanation of symbols (continued)

Symbol	Explanation
	Insertion tool handle
	Insertion tool plunger
	Incision tool
	LINQ II insertable cardiac monitor
	Implantable device (coated)
	Machine-readable serial number

1.2 Introduction

This manual describes the insertion, operation, and intended use of the Medtronic LINQ II Insertable Cardiac Monitor (ICM).

Throughout this manual, “device” refers to the LINQ II ICM.

Use the Reveal LINQ Mobile Manager clinician app to enter patient information, program data-collection and arrhythmia-detection parameters, and interrogate the device. Instructions for setting detection and sensitivity parameters are provided with the Reveal LINQ Mobile Manager clinician app.

Before inserting the device, take the following actions:

- Read the product literature for the clinician app, patient app, and Patient Assistant. This product literature is available electronically at www.medtronic.com/manuals. It provides the following information:
  - Information about how all the parts of the LINQ II system interact
  - Product specifications
  - Precautions

  - Instructions on monitoring the patient's condition and viewing the collected data
  - Instructions and information for patients on the LINQ II ICM, the patient app, and the Patient Assistant
- Discuss the device and insertion procedure with the patient. Give the patient any patient materials packaged with the device.

1.2.1 Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users.

For more information, contact your local Medtronic representative or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

1.2.2 Notice

The Patient Information screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the patient information that end users enter into the Patient Information screen. MEDTRONIC SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY THAT RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

1.2.3 Data security

Medtronic has designed safeguards to protect patient information and device data for the Model LNQ22 device.

Bluetooth® communication system[1] – The device uses Bluetooth wireless technology to communicate with the clinician app, the patient app, and the home communicator. Critical data accepted or sent through the Bluetooth communication from the device is encrypted by the device before it is sent over the Bluetooth channel. The device responds only to authorized commands.

[1] The Bluetooth® word mark is a registered trademark of Bluetooth SIG, Inc. Any use of the word mark by Medtronic is under license.

2 System overview

2.1 System description

The Medtronic LINQ II ICM is a programmable device that continuously monitors a patient's ECG and other physiological parameters. The device records cardiac information in response to automatically detected arrhythmias and patient-initiated activation or markings.

The device is designed to automatically record the occurrence of an episode of arrhythmia in a patient. (Arrhythmias are classified as tachyarrhythmia, bradyarrhythmia, pause, atrial tachyarrhythmia, or atrial fibrillation.)

In order to manually record symptoms, the patient will also need either the patient app or the Patient Assistant. The patient can use the patient app or the Patient Assistant to manually record his or her cardiac rhythm while experiencing or immediately after a symptomatic event.

In order to remotely monitor your patient's device, give your patient either the patient app or the home communicator. The home communicator and patient app transmit recorded data from the device to the CareLink Network. The clinician app allows the health care provider to interrogate and monitor the device as well as edit the monitoring parameters.

Medtronic LINQ II Model LNQ22 insertable cardiac monitor (ICM) – The LINQ II ICM is a small, leadless device that is inserted under the skin, in the chest. The device uses 2 electrodes on the body of the device to monitor the patient's subcutaneous ECG continuously. The arrhythmia-detection parameters' initial settings are based on information entered in the Reveal LINQ Mobile Manager clinician app: the patient's date of birth and the clinician's reason for monitoring the patient. The parameters are pending and editable, allowing the clinician to always be able to customize each parameter before programming parameters into the device. Clinicians can also program arrhythmia-detection parameters manually.

The device provides up to 30 min of patient-activated episodes per day, and up to 27 min of ECG storage for automatically detected episodes. The system provides 2 options for segmenting the patient-activated episode storage: a 10 min recording (9 min before and 1 min after a symptom mark) or a 15 min recording (14 min before and 1 min after a symptom mark). For more information about episode storage, see *Section 6.1.3, LINQ II episode-data and ECG storage, page 33*.

The LINQ II ICM is MR Conditional. It has been shown to pose no known hazards in a specified MR environment with specified conditions of use. For more information, see the *LINQ II MRI Technical Manual.*

Caution: The device cannot be used as an alarm system to alert the patient to emergency situations.

Note: The device subcutaneous ECG may differ from a surface ECG due to differences in electrode separation and device placement in the body, as well as the differences between subcutaneous and surface contact impedances.

Reveal LINQ Mobile Manager clinician app – The Reveal LINQ Mobile Manager clinician app (called the "clinician app" from now on) is an application downloaded onto the clinic's tablet. The clinician app allows the clinician both to set up the device prior to insertion and to conduct the follow-up procedures for monitoring the device. The clinician app provides the operator an interface to change device settings (programming), interrogate the collected data, and display real-time data such as ECG and Marker Channel information.

Patient connector – The model 24967 patient connector telemetry head communicates with the device, which enables clinicians to interrogate and program the implantable device during insertion or patient follow-up sessions.

Refer to the literature included with the Medtronic patient connector for connection and usage information.

MyCareLink Heart mobile app – The MyCareLink Heart mobile app (called the "patient app" from now on) is an application downloaded onto the patient's Internet-connected mobile device such as a smartphone or tablet. The patient interacts with the patient app for initial setup, viewing status information, and recording symptoms. The ability to record symptoms must be enabled on the device in order for the patient to activate the recording of cardiac information while experiencing or immediately after a symptomatic event. The clinician uses the recorded information to determine if the symptoms were associated with a cardiac event.

Medtronic Patient Assistant PA97000 – The Patient Assistant is a hand-held, battery-operated device that uses Bluetooth Low Energy. A patient uses the Patient Assistant to activate recording of cardiac information in the LINQ II ICM while experiencing or immediately after a symptomatic event. The clinician uses the recorded information to determine if the symptoms were associated with a cardiac event.

Medtronic MyCareLink Relay home communicator – The MyCareLink Relay home communicator (called the "home communicator" from now on) can automatically gather information from patients' implanted devices and can communicate that information to patients' physicians by connecting via cellular phone or wireless Internet to the Medtronic CareLink Network. The home communicator will transmit available data to the CareLink Network whenever the device is within range of the home communicator.

Refer to the literature that is included with the Medtronic home communicator for connection and usage information.

2.2 Indications and contraindications

2.2.1 Indications

The LINQ II ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

2.2.2 Contraindications

There are no known contraindications for the insertion of the LINQ II ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

2.3 Precautions

2.3.1 General warnings and precautions

Battery depletion – Carefully monitor device longevity by checking the replacement indicators. Battery depletion eventually causes the device to stop functioning.

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents.

Device damage during explant or repositioning – Do not grip the device by the edges of its clear sapphire surface, which extend slightly beyond the titanium case. Gripping the sapphire edges may damage the device.

For more information on explanting the device, see *Chapter 5*.

Device storage – Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference. Exposing the device to magnets or electromagnetic interference may damage the device.

Dropped device – Do not implant the device if it is dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

If the package is damaged – A single sterile barrier protects the device and the insertion tools. Do not use the device or accessories if the packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Storage temperature – Store and transport the package between –18 °C and +55 °C (0 °F and 131 °F). Device reset may occur at temperatures below –18 °C (0 °F). Device longevity may decrease and performance may be affected at temperatures above +55 °C (131 °F).

"Use-by" date – Do not implant the device after the "Use-by" date because the battery longevity could be reduced.

2.3.2 Avoiding effects of electromagnetic interference in the home, work, and other environments

The LINQ II ICM is designed to monitor and store ECG data and to receive data through Bluetooth® Low Energy communication from the patient connector, patient's mobile device, home communicator, and the Patient Assistant.

Because the device communicates with the patient connector, patient's mobile device, the clinician's mobile device, home communicator, and Patient Assistant by means of Bluetooth Low Energy, certain types of electromagnetic interference (EMI) may cause temporary telemetry interruptions, trigger inappropriate episode detection, corrupt the data stored in memory, or result in an electrical reset of the device (see *Section 2.4*). The device will function normally as soon as the patient moves away from the source of interference. The device should not be affected by the normal operation of household electrical equipment. Although most interference is filtered out, there are some signals in the environment that have similar characteristics to the signals emitted by the patient connector, home communicator, or the Patient Assistant, or which could otherwise interfere with device function.

For information to share with LINQ II patients about sources of electromagnetic interference (EMI) in the home, at work, and in other environments that patients may need to avoid, see the Medtronic *LINQ II Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals*.

2.3.3 Warnings, precautions, and guidance for clinicians performing medical procedures on LINQ II patients

The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, Medtronic recommends interrogating the device and saving data before the procedure, and checking device function afterwards.

Magnetic Resonance Imaging (MRI) – Although the LINQ II ICM is considered conditionally safe for use in the MRI environment when used under specified conditions, other implanted devices or the patient's individual medical condition might have an impact on safety and might require additional examination. Medtronic recommends that cardiologists/radiologists validate any already implanted devices or leads by using the

LINQ II MRI Technical Manual. We also recommend referencing the Medtronic MRI Resource Library website located at www.medtronic.com/mri.

For detailed information on determining if a LINQ II patient can undergo an MRI scan and for precautions related to the procedure, see the *LINQ II MRI Technical Manual.*

For information about additional medical procedures that are likely to be sources of interference or to be hazardous, see the Medtronic *LINQ II Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals*. This manual provides warnings, precautions, and guidance for health care providers who perform medical therapies and diagnostic procedures on patients with cardiac devices.

Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are provided in the manual that is packaged with the device or on the Medtronic Manual Library website (www.medtronic.com/manuals).

2.4 Device reset

Certain conditions (such as device malfunction, EMI, electrocautery, or external defibrillation) may cause an electrical reset of the LINQ II ICM. This can result in the loss of stored data and changes in the settings of some programmed parameters. For an overview of the reset parameter settings see *Section A.1.2*.

In the clinician app, you will be informed that a reset has occurred by a pop-up message that appears at the start of the next patient session. If a reset does occur, interrogate the device, save the session, reprogram the desired parameters, and notify your Medtronic representative.

In the CareLink Network website, you will be informed that a reset has occurred by a message at the top of the **Patient Detail** page for the patient. Click **Acknowledge Device Reset** in the warning and notify your Medtronic representative. The reset must be acknowledged before you can remotely reprogram the device. Use the **Device Settings** tab to remotely reprogram the device.

2.5 Pre-insertion considerations

Before inserting the Medtronic LINQ II Model LNQ22 ICM, consider whether mammography requirements or concomitant device implants are factors that affect your decision on whether to insert the device or your decision on insertion location.

Mammography – Mammography involves compressing the breast between two plates in order to take various x-ray views. During the mammography procedure, manipulation or angular stress of the LINQ II device between the plates could cause tissue trauma, vascular trauma, or pain, or could affect device sensing. Before scheduling a mammogram, the

cardiologist and mammography clinician should weigh the potential risks against the benefits and evaluate other diagnostic options. To minimize risks related to device manipulation or angular stress that a mammography procedure can cause, allow sufficient time for the LINQ II device pocket and incision to heal before performing a mammography procedure.

Concomitant cardiac monitor and cardiac pacemaker or defibrillator device implants – To minimize the possibility of the patient connector and telemetry interfering with a pacemaker or defibrillator, the device should be inserted at least 7.5 cm (3 in) away from any other implanted device. Do not hold the Patient Assistant or the patient connector directly above an implanted device not manufactured by Medtronic.

Note: If the LINQ II patient has an implanted pacemaker or defibrillator, the automatic detection of arrhythmia episodes by the device may be affected by the paced heart rhythm.

Concomitant neurostimulator and cardiac device implants – Some patients have medical conditions that require the implant of both a neurostimulator and a cardiac device (for example, pacemaker, defibrillator, or monitor). In this case, physicians (for example, neurologist, neurosurgeon, cardiologist, and cardiac surgeon) involved with either device should contact Medtronic Technical Services or their Medtronic representative before implanting or inserting a second device in the patient. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant or insertion procedure. For information about how to contact Medtronic, see the telephone numbers and addresses provided on the back cover of this manual.

2.6 Potential adverse events

The following are known potential adverse events associated with the use of this product.

Note: Implant and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions.

- acute tissue trauma
- discomfort/pain
- device migration
- erosion through the skin
- excessive fibrotic tissue growth
- fever
- hematoma

- hemorrhage
- infection
- pneumothorax
- seroma
- skeletal-muscle twitching sensation
- tissue damage due to heating of device
- toxic/allergic reaction, including device rejection phenomenon and local tissue reaction

The LINQ II ICM and implant-tool materials that come into contact with human tissue are listed in *Table 12* and *Table 13*.

3 Inserting the LINQ II Insertable Cardiac Monitor

3.1 Handling and disposal

Shipping and transport – Ship and transport the package in a dry place away from direct sunlight. Ensure that the package temperature remains within the range defined in *page 12*.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Operation – The operating temperature range is 17 °C (63 °F) to 45 °C (113 °F).

Checking sterility – Before shipment, the device was sterilized as shown on the package. An illustration of opening instructions is included on the cover of the sterile pack. Before opening the sterile pack, check for any signs of damage that might invalidate the sterility of the contents. If there is any uncertainty about sterility, do not insert the device. Return nonsterile devices to Medtronic.

Caution: A single sterile barrier protects the device and the insertion tools. Do not open the cover of the sterile pack until it is in a sterile field.

Repositioning the device during insertion – During insertion, it may be necessary to reposition the device if the initial insertion location does not meet sensing performance requirements. The device and insertion tools cannot be resterilized once removed from the sterile field. For additional information, see *Section 3.2.8, Repositioning the LINQ II Insertable Cardiac Monitor, page 25*.

Incision and Insertion tools disposal – Dispose of the single-use incision and insertion tools according to local environmental requirements.

Cautions:

- Biohazard: The incision tool and insertion tool come into contact with blood and present a biohazard.
- Sharp-edge hazard: The incision tool has a sharp edge.

Removal and disposal – Consider the following information related to device removal and disposal:

- Remove the device when it is no longer needed, when the battery is depleted, or before burial or cremation.

- When using surgical tools to handle the device, avoid gripping the edges of its clear sapphire surface, which extend slightly beyond the edges of the titanium case. For more information on explanting the device, see *Chapter 5*.
- In some countries, the removal of battery-operated, insertable or implantable devices is mandatory because of environmental concerns. Check local regulations. In addition, the cremation process could cause the battery to explode.
- Medtronic insertable and implantable devices are for single-patient use only. Do not resterilize and reinsert devices that have been removed.
- Contact Medtronic for Return Mailer Kits to return removed devices for analysis and disposal. See the back cover for addresses. **Note:** Disposal of removed devices or leads is subject to local, state, and federal regulations.

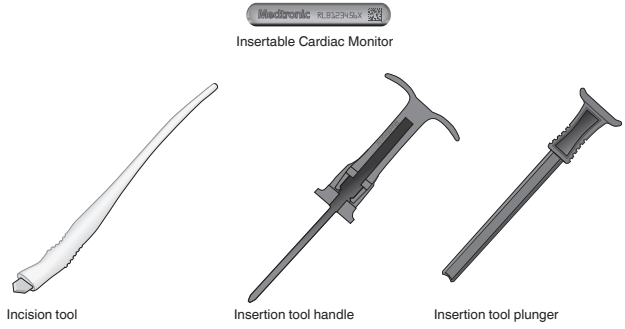
3.2 Preparation, positioning, and insertion

3.2.1 Contents of package

The LINQ II package contains the following items:

- LINQ II Insertable Cardiac Monitor (preloaded in the included insertion tool handle)
- Incision tool
- Insertion tool plunger
- Insertion tool handle
- Product documentation

Figure 1. LINQ II components



3.2.2 Pre-insertion device setup

Make sure that you have the clinician app available. The clinician app is needed to enter patient information, activate the device, program the device's detection parameters, and to verify device sensing. For instructions on setup and entering patient information, follow instructions in the clinician app.

Note: The device is automatically activated when you insert the device and complete the Insert Device workflow in the clinician app.

3.2.3 Recommended insertion locations

The device may be inserted in either of 2 recommended locations without conducting pre-insertion surface mapping (see *Figure 2*).

If the device is inserted in a different location, Medtronic recommends that you conduct pre-insertion surface mapping to verify that signal quality and R-wave amplitude sensing are reliable.

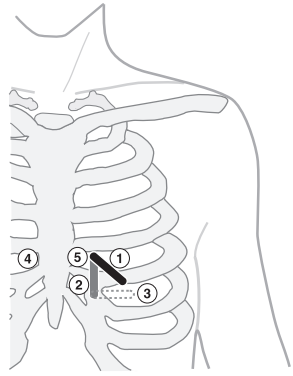
Note: Post-insertion verification of sensing performance is recommended for all insertion locations. For more information, see *Section 3.2.7, Programming device Reason for Monitoring and verifying sensing performance, page 24*.

Best – The device is positioned 45 degrees relative to the sternum over the fourth intercostal space (V2-V3 electrode orientation). The superior end of the device is positioned approximately 2 cm (±1 cm) left lateral from the sternal border.

Good – The device is positioned over the fourth intercostal space approximately 2 cm (±1 cm) parallel to the sternal border.

Note: The incision for the insertion pocket may be located at either end of these recommended insertion locations, based on clinician preference and on patient anatomy, comfort, and cosmetic considerations. To achieve standard ECG R-wave polarity, make the incision at the superior end of the locations shown.

Figure 2. Insertion locations



1 Best recommended insertion location
2 Good recommended insertion location
3 Optional inframammary fold insertion location
4 V1 ECG electrode location
5 V2 ECG electrode location

3.2.4 Optional insertion locations

If the recommended insertion locations are not suitable, optional insertion locations may be considered. Lesser signal quality may be observed in the optional insertion locations. Medtronic recommends conducting pre-insertion surface mapping of optional insertion locations to determine whether they provide reliable signal quality and R-wave amplitude sensing. Surface mapping may be conducted with clinic ECG equipment.

Optional inframammary fold insertion location – If applicable for the patient, the device may optionally be positioned in subcutaneous tissue above the inframammary fold. The device is positioned 90 degrees relative to the sternum in the region of the fifth intercostal space. The end of the device is positioned approximately 2 cm (±1 cm) left lateral from the sternal border. See *Figure 2*.

Before selecting this insertion location, consider whether the device location will interfere with mammography or with the position of a wire support bra. For precautions related to mammography, see the *LINQ II Medical Procedure and EMI Precautions Manual for Health Care Professionals.*

Additional optional insertion locations – The insertion zone is between the first intercostal space and the inframammary fold, from the left parasternal line to the midclavicular line.

3.2.5 Surface mapping to qualify an optional insertion location

If an optional insertion location is considered, Medtronic recommends conducting surface mapping to determine if the insertion location provides reliable signal quality and R-wave amplitude sensing.

Surface mapping considerations – Conduct surface mapping with clinic ECG equipment.

- Use pediatric-size ECG conductive patches to approximate the device electrode size.
- Space the ECG conductive patches 4 cm apart, center-to-center, to approximate the device electrode spacing.
- Position and orient the ECG electrodes to correspond with the desired insertion site and orientation.

Signal quality and R-wave amplitude sensing requirements – Examine the R-wave amplitude from available insertion locations to find a position with the highest and most stable R-wave amplitude possible.

- The R-wave amplitude should be a minimum of 0.2 mV.
- The peak-to-peak R-wave amplitude should be at least twice the peak T-wave or P-wave amplitude, whichever is greater.

If the measured signals are of sufficient amplitude, mark the site with a sterile pen and proceed with the insertion. If these conditions are not met, repeat the surface mapping procedure until a suitable insertion location (with the best possible peak-to-peak R-wave amplitude) is found and marked.

3.2.6 Inserting the LINQ II Insertable Cardiac Monitor

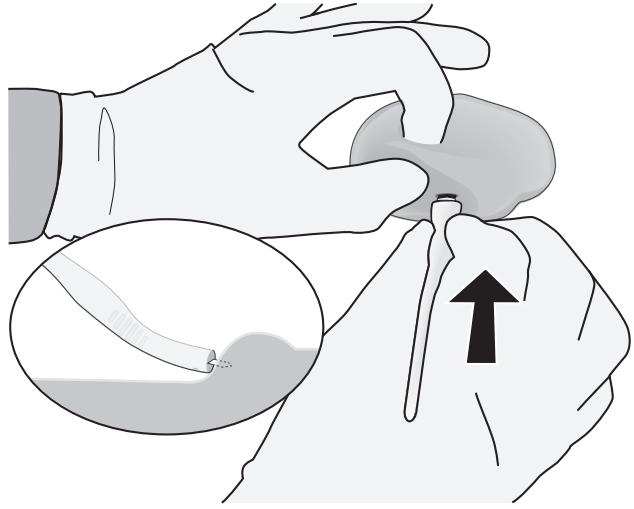
Caution: The sterile blister package containing the device and the insertion tools is a “single barrier” system. There is no additional barrier covering the inner tray, so do not peel back the cover of the outer tray until you are ready to pass the device and insertion tools into the sterile field.

Insert the device in the selected location using normal aseptic techniques and using the insertion tools provided with the device.

Note: Medtronic recommends retaining the insertion tools in the sterile field during the procedure in case device repositioning is required.

1. Prepare the insertion site, using conventional antiseptic and local anesthetic procedures, to maintain sterility, reduce infection risk, and minimize patient discomfort.
2. Pinch the skin adjacent to the selected incision location to tent it and then, at an angle of approximately 90 degrees to the pinched tissue, push the blade of the supplied incision tool in to its full depth. It is not necessary to cut laterally (see *Figure 3*).

Figure 3. Pinch the skin and make an incision

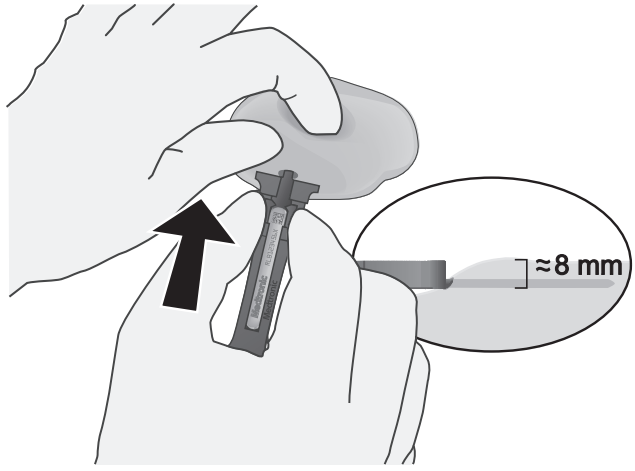


3. Orient the supplied insertion tool so that the side with the large slot in the tool body is facing up. The device is preloaded in the insertion tool and is visible through the slot.

   Note: Do not insert the supplied insertion tool plunger at this time.

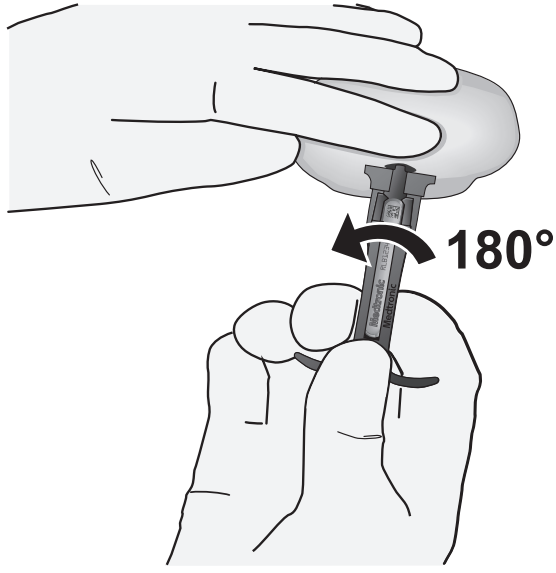
   If necessary, pinch the skin adjacent to the incision and then insert the tool to create a pocket approximately 8 mm under the skin (see *Figure 4*).

Figure 4. Pinch the skin and insert the tool



4. Rotate the insertion tool 180 degrees to open the incision, create the correct pocket size, and correctly position the device for insertion (see *Figure 5*).

Figure 5. Rotate the insertion tool

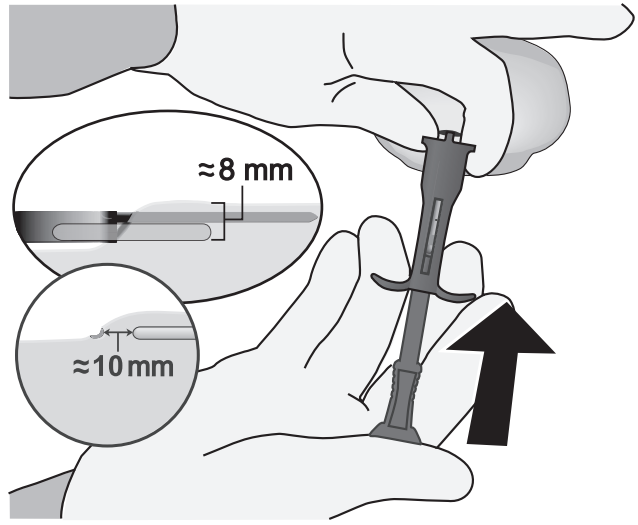


5. Push the insertion tool toward the incision so that the tool body is pressed against the incision.
6. Insert the supplied plunger into the insertion tool and then push the plunger in completely (see *Figure 6*).

   The preloaded device is delivered into the pocket created by the insertion tool, approximately 10 mm past the incision and 8 mm under the skin.

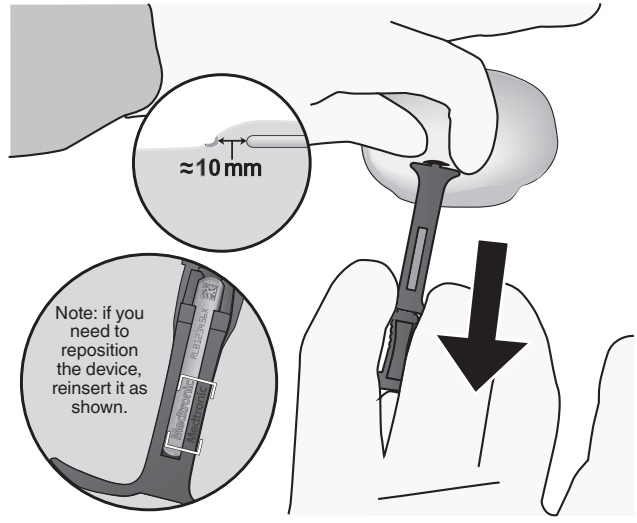
   Note: The window in the insertion tool handle fills with the insertion tool plunger as the device is inserted.

Figure 6. Plunger insertion



7. Use pressure to hold the device in place, approximately 10 mm from the incision, and then remove the insertion tools. The insertion tool and plunger may be removed together or separately (see *Figure 7*).

Figure 7. Insertion tools removal



3.2.7 Programming device Reason for Monitoring and verifying sensing performance

Before closing the incision, verify that the device sensing performance is acceptable.

1. Ensure that the patient connector is within 2 m of both the tablet and the inserted device during interrogation. If you entered patient information just before starting the insertion procedure, continue the session that is already in process. If that session has been ended, use the clinician app and restart the workflow for inserting the device.

   If you need to move the patient connector into the sterile field in order to establish a connection with the device, first place the patient connector in a sterile sleeve.
2. Using the clinician app, examine the R-wave amplitude when the live rhythm is displayed.
   - The R-wave amplitude should be a minimum of 0.2 mV.
   - The peak-to-peak R-wave amplitude should be at least twice the peak T-wave or P-wave amplitude, whichever is greater.
3. If device sensing performance requirements are met, complete programming of any remaining parameters.

If device sensing performance requirements are not met, reposition the device and then retest device sensing performance. Repeat the procedure as necessary until an insertion location is found that provides appropriate device sensing performance. Failure to meet sensing performance requirements may result in degraded automatic episode detection performance.

3.2.8 Repositioning the LINQ II Insertable Cardiac Monitor

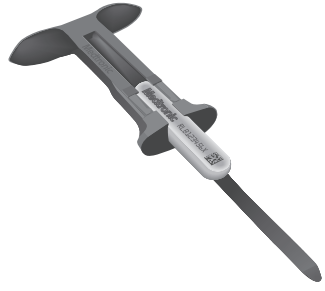
If device sensing performance requirements are not met, the device may be removed from the previous insertion location and repositioned. If the insertion tools have been retained within the sterile field, they may be reused, with the device reloaded in the insertion tool. When using surgical tools to handle the device, avoid gripping the edges of its clear sapphire surface. For more information on how to grip the device with surgical tools, see *Chapter 5*.

Note: If you are inserting the device in a position that is not one of the recommended positions, Medtronic recommends conducting surface mapping to determine a new insertion location that provides reliable signal quality and R-wave amplitude sensing. See *Section 3.2.5* for information about surface mapping.

To reload the device in the insertion tool, take the following steps:

1. Orient the supplied insertion tool so that the side with the large slot in the tool body is facing up.
2. Orient the device at the tool body opening so that the end with the Medtronic name is closest to the opening and the Medtronic name is facing up. See *Figure 8*.
3. Slide the device back into the insertion tool body.

Figure 8. Reloading the device in the insertion tool



When repositioning the device, Medtronic recommends reusing the previous incision and changing the angle of the tool insertion. Change the angle of insertion by at least 22 degrees. For example, see the difference in insertion angle between the Best and Good recommended insertion locations shown in *Figure 2*.

After reloading the device in the insertion tool, see *Section 3.2.6* for information about the insertion procedure. If you are reusing the previous incision, some steps do not apply.

3.2.9 Closing the incision site

ICM insertion has been associated with a small risk of device migration and loss through the incision.

After verifying that the device sensing performance is acceptable, close the incision using your preferred method (such as Dermabond, sutures, or staples). Dress the wound according to clinic preferences.

3.3 Completing the insertion procedure

After successfully inserting the device, verify that the patient's information is complete and correct, confirm sensing parameters, and instruct the patient in using the LINQ II system.

For instructions for using the clinician app and parameter setup, see the information included in the clinician app.

3.3.1 Patient information

Before completing the insertion procedure, it may be appropriate to verify that patient information is complete and correct.

To view and edit patient information, navigate to the Device & Patient Settings tab in the clinician app.

The date of birth that is entered for the patient during device set up is used to set arrhythmia detection parameters to pending automatically.

3.3.2 Device parameters

Detection and sensing parameters – When patient Date of Birth and Reason for Monitoring are entered during device setup and activation, arrhythmia detection parameters are set to pending automatically.

If necessary, you can use the clinician app to adjust the criteria for detecting arrhythmia episodes and the sensing parameters to optimize R-wave sensing.

For additional information about detection and sensing parameters, see *Chapter 7, Setting up sensing and arrhythmia detection, page 41*.

3.3.3 Patient instruction

Using the patient app – The patient app transmits stored device data to the physician or clinic via an internet connection. The patient app can be installed on the patient's mobile device. The patient can use the patient app to record symptoms. Instruct the patient on how to use the patient app, explaining which symptoms the patient should record. Instructions for using the app are available in the app help included in the app.

Using the Patient Assistant – The Patient Assistant PA97000 is used by the patient to record symptoms. The Patient Assistant is an optional instrument and is not required. The Patient Assistant is available for patients who cannot use the patient app or for patients who choose to use the home communicator. Instruct the patient on how to use the Patient Assistant, explaining which symptoms the patient should record. For more information, see the instructions that accompany the Patient Assistant.

Patient Manual – Give the patient a copy of the *LINQ II Insertable Cardiac Monitor Patient Manual*. This manual provides an overview of the cardiac monitor.

Using the home communicator – If the patient does not have the patient app, the home communicator may be used to transmit stored device data to the physician or clinic via an Internet connection. Explain the function of the home communicator and instruct the patient to set it up according to the information provided with it.

Device manipulation (Twiddler's syndrome) – Educate the patient about the consequences of device manipulation.

Warning: Excessive manipulation of the device can cause the device to migrate, which could either reduce the communication range of the device, or cause erosion and loss of contact between the skin and the device electrodes, which could lead to reduced detection.

3.3.4 Device identification card

LINQ II ICM Device Identification Card – This card is found in the LINQ II ICM packaging. The patient can carry the identification card in a purse or wallet so that it is always available. The identification card is especially helpful if the device sets off a metal detector or security system. When completing the identification card, print all relevant details with a ballpoint pen (black is preferred). To determine the serial number of the patient's device, refer to the serial number stickers included in the device package.

4 Using the clinician app

4.1 Connecting the device with the clinician app

You can use the clinician app to program the device settings and view information collected by the device. For general information about the clinician app, refer to the information provided with clinician app.

5 Explanting the LINQ II Insertable Cardiac Monitor

Due to the development of fibrotic tissue, it may be difficult to remove the device.

If you cannot locate the device by using manual palpation, fluoroscopy or x-ray could help to determine the device's location and orientation.

Use conventional antiseptic and local anesthetic procedures when you access the device.

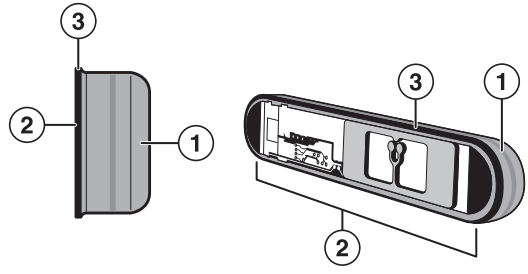
When using surgical tools to remove the device, take care to avoid damaging the device:

- Use the minimum amount of force necessary.
- A clear sapphire coating covers the length of one side of the device. This clear sapphire surface partially overlaps the titanium case, creating an edge. Avoid gripping the device by this edge, which extends slightly beyond the titanium case. (See *Figure 9* and *Figure 10*.)
- Instead, grip the device by the flat sapphire surface and the titanium case. (See *Figure 11*.)
- Avoid using mosquito forceps and other high-leverage forceps that may damage the device.
- Instead, use a tool that grips a larger surface area of the device. These tools more evenly distribute force across the gripped device surfaces. (See *Figure 11*.)

Caution: Do not grip the device by the edges of its clear sapphire surface, which extend slightly beyond the titanium case. Gripping the sapphire edges may damage the device.

Note: The edges of the clear sapphire surface as shown in the following figures are not drawn to scale.

Figure 9. LINQ II device components (cross-section view on the left)



1 Titanium case
2 Clear sapphire surface
3 Edge of clear sapphire surface

Figure 10. Do not grip the device by the edges of its clear sapphire surface

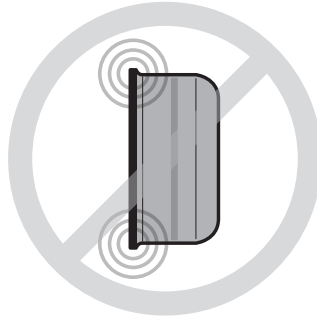
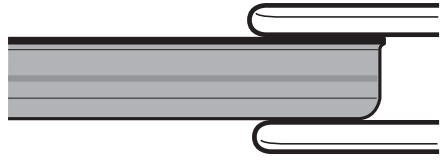


Figure 11. Recommended method of handling the device with a surgical tool



For additional information on removing and disposing the device, see *Section 3.1*.

6 Monitoring the patient's condition

6.1 Using the LINQ II system

For patients with known or suspected cardiac arrhythmias, it is important to monitor the cardiac rhythm over a long period of time under ambulatory conditions. Information about the cardiac rhythm may help you to identify if patient symptoms are related to arrhythmias, or to detect asymptomatic arrhythmias. Continuous and long-term cardiac monitoring may help you to make informed decisions about the patient's need for medication, cardioversion, or other rate or rhythm control therapy.

The LINQ II ICM stores detailed information about the occurrence of cardiac arrhythmia episodes. It also records other information about the patient, such as average heart rates, heart rate variability, and activity throughout the day. You can use this information to build a diagnostic picture of the patient's condition.

The LINQ II ICM can be implanted for up to 4.5 years, enabling you to monitor the patient's condition continuously without interfering with his or her daily activities.

Information recorded in the LINQ II ICM may help you to monitor and assess the patient's condition in the following ways:

- Monitor the patient's AT/AF burden and the occurrence of asymptomatic episodes of AT/AF and assess whether medical treatment is necessary or needs to be adjusted.
- Monitor the patient's ventricular rhythm during atrial arrhythmia episodes and assess whether rate control therapy is having the desired effect or needs to be adapted.
- Correlate symptomatic events with the patient's cardiac rhythm in order to do the following:
  - Rule out cardiac behavior as the cause of symptoms.
  - Help diagnose neurological or psychosomatic causes.
- Continuously record other patient information that may help you to assess the patient's condition, such as heart rate variability or patient activity.

When data collection is enabled in the device, the device detects arrhythmia episodes automatically based on detection criteria entered into the clinician app. See the instructions included in your clinician app for more information. You can also use the device together with the Patient Assistant or patient app by instructing the patient to record cardiac information while experiencing or immediately after a symptomatic event.

6.1.1 Recording episodes automatically

The LINQ II ICM continuously senses the patient's subcutaneous ECG, and analyzes the timing of ventricular events to detect possible episodes of arrhythmia.

The LINQ II ICM can classify the following types of arrhythmia episodes:

VT (ventricular tachyarrhythmia) – The patient's heart rate increases to a rate that is higher than the programmable tachy rate (interval) threshold for the programmable tachy duration.

FVT (fast ventricular tachyarrhythmia) – The patient's heart rate increases to a rate that is higher than 231 bpm (intervals lower than 260 ms) for 30 of the last 40 beats.

Brady (bradyarrhythmia) – The patient's heart rate falls to a rate that is lower than the programmable brady rate (interval) threshold for the programmable brady duration.

Pause (asystole) – No ventricular events are sensed for a programmable period of time.

AF only or AT/AF (atrial fibrillation only or atrial tachyarrhythmia/atrial fibrillation) – The patient has an atrial tachyarrhythmia or atrial fibrillation. You can also choose to record atrial fibrillation only. The LINQ II device detects an episode of conducted AT or AF by analyzing the irregularity of ventricular rhythm using an automatic algorithm.

You can adjust the criteria for classifying cardiac arrhythmias to suit the individual patient's condition. For more information see *Section 7.4*.

6.1.2 Recording episodes using the Patient Assistant or patient app

The patient can activate the LINQ II ICM to record symptoms using either the Patient Assistant or the patient app.

When the patient experiences symptoms, he or she should press the Record Symptom button on the Patient Assistant or patient app. This activates the device to create and store a patient-activated episode. The Patient Assistant should be held over the device when the patient presses the Record Symptom button, but the patient app only needs to be within 1.5 m (5 feet) of the device for recording symptoms.

When the patient records a symptom, that information is shown in the **Symptom details** field in the clinician app and the Medtronic CareLink Network website.

Note: The Patient Assistant will not work when the clinician is conducting a session.

6.1.3 LINQ II episode-data and ECG storage

The LINQ II ICM stores arrhythmia episode data, including ECGs, for episode types that are programmed On and for patient-activated episodes. Episode data is stored in episode logs and episode records.

Episode logs – An episode log includes the following information:

- The type of episode
- A unique episode ID
- The time, date, and duration of the episode
- Additional heart-rate data

The device stores up to 10 episode logs daily for each episode type, up to a total of 30 episode logs for each episode type. (Additional episode logs may be available if their associated episode records have not been overwritten.) When the device storage is full, the most recent episode log may overwrite the oldest stored episode log of that type.

Episode records – An episode record includes an ECG waveform and event markers. For each AT/AF episode the LINQ II ICM stores an ECG of the first 2 min of the episode. An episode record is also associated with an episode log. For each tachy, brady, or pause episode, the device stores 30 s of ECG before the episode and up to 27 s of ECG before the end of the episode. The device reserves 27 min of ECG storage for automatically detected episodes.

The device stores up to 3 episode records daily for each type (VT, FVT, AT, AF, Brady, Asystole). If more than 3 episodes of a specific episode type occur in a day, the longest episode record overrides the most recent episode record of that type. Up to 2 additional episode records may be recorded if the episodes occur within 20 min prior to a patient-activated episode.

Patient-activated symptom episodes – The LINQ II ICM can store up to 3 patient-activated episode logs daily, up to a total of 10 patient-activated episode logs. When the device storage is full, the most recent patient-activated episode log will overwrite the oldest patient-activated episode log. Patient-activated episode logs include the type of episode, a unique episode ID, and the time and date of the activation.

The system provides 2 options for segmenting ECG storage for patient-activated symptom episodes: either 10 min recordings (9 min before and 1 min after an activation) or 15 min recordings (14 min before and 1 min after an activation). The device can store up to a total of 30 min of ECG data for patient-activated symptom episodes: either the 3 most recent 10 min episodes or the 2 most recent 15 min episodes. After the device has accumulated 30 min of ECG storage on any given day, new ECGs from patient-activated symptom episodes will not be stored. On the next day, the device will resume recording ECGs, overwriting the oldest ECGs from patient-activated symptom episodes, until that day's

maximum of 30 min of accumulated ECG storage from patient-activated symptom episodes has been reached.

6.2 Monitoring the patient through the Medtronic CareLink Network

If the patient is enrolled in the Medtronic CareLink Network, alerts and diagnostic reports based on wireless device transmissions are available through the CareLink Network. This section provides details on the daily transmissions and how to access the information using the secure Medtronic CareLink Network website.

6.2.1 Transmitting patient and device information to the Medtronic CareLink Network

Wireless transmissions – The device transmits data to the CareLink Network when it is connected to either the home communicator or the patient app. When the LINQ II ICM has data to transmit, it will begin broadcasting to the home communicator or the patient app and will transmit the data when connected.

6.2.2 Conducting a patient follow-up session remotely

After device insertion, you can monitor the patient remotely through the CareLink Network. If you choose remote monitoring through the CareLink Network, the following conditions must be met before the patient's data can be sent to the CareLink Network:

- The patient is successfully enrolled into your CareLink Network clinic
- The patient has set up the home communicator or patient app

Review the patient's first transmission to ensure that the device is properly configured for the patient's condition. You may also adjust sensing and episode detection parameters. This section discusses how to conduct a follow-up session using the CareLink Network. For information on using the clinician app to interrogate the device and conduct a follow-up session, see the app help included in the clinician app.

Check battery status – You can check the device battery status on the CareLink Network.

- If the battery status is "RRT" (Recommended Replacement Time) the device is nearing the end of its battery life. From that date onward, the LINQ II device is projected to operate for a minimum of 30 days. The End of Service (EOS) status indicator will be displayed no later than 60 days after RRT.

Note: End of Service is the point at which an individual prolonged service period has elapsed and performance to design specification cannot be ensured. For example, the device may eventually reset, experience data loss, and lose the ability to communicate.

Check sensing – Assess ventricular sensing by comparing the device ECG trace with the annotations in the Marker Channel. If marked events do not correspond to the ventricular events displayed on the ECG, adjust the sensitivity threshold setting or blanking interval. For more information about optimizing sensing, see *Section 7.3*.

Check episode detection – Compare details in the episode log with the ECG recording of an episode to verify that episodes are being detected properly. You can adjust the detection criteria for each type of episode to optimize detection. For more information, see *Section 7.4*.

If you are only interested in certain types of episodes, you can switch off detection for the other episode types to save memory space. Episode data and ECG recordings for these episode types will not be stored by the device.

6.2.3 Remote programming

The Medtronic CareLink Network website allows you to change device settings and parameters without the patient being present. You can access patient and device data by selecting **MANAGE MY PATIENTS** and then selecting the patient's name. The **Device Settings** tab is where you can edit episode detection and sensing settings. New parameter settings will be updated on the patient's device within 72 hours as long as the device is connected to the Medtronic CareLink Network through the home communicator or the patient app. The other tabs are where you can edit patient demographic data, equipment information, set CareAlert notifications, write comments and notes, and view patient history.

6.2.4 Monitoring the patient and the device

The CareLink Network allows you to remotely access and monitor patient data. For more information about viewing patient data through the CareLink Network, see *Chapter 8*.

Note: The CareLink Network is not a real-time emergency notification system.

6.2.5 Managing device functions and CareAlert Monitoring

Programming the device and configuring CareAlert Notifications are separate but interrelated operations. In order to receive CareAlert Notifications for a specific arrhythmia type (Tachy, Pause, Brady, or AT/AF), detection must be programmed On for that arrhythmia type. You may program the device remotely using the CareLink Network or during a follow-up session using the clinician app. CareAlert Notifications are configured using the CareLink Network.

Battery status check – Battery status is configured automatically as a CareAlert Notification on the CareLink Network website. You can check the battery status in Patient Details on the CareLink Network website or in a LINQ II report.

- If the battery status is “RRT” (Recommended Replacement Time) the device is nearing the end of its battery life. From that date onward, the LINQ II device is projected to operate for a minimum of 30 days. The End of Service (EOS) status indicator will be displayed no later than 60 days after RRT. For more information, see *page 34*.

Patient travel considerations – If the patient plans to travel for an extended period, wireless transmissions to the CareLink Network may still be available:

- The patient must take their home communicator and Patient Assistant or patient app with them.
- Cellular telephone or Wi-Fi (if using the patient app) service must be available at the patient’s travel destination. Encourage the patient to contact Medtronic to confirm availability of coverage.

Note: Episodes recorded on the device are time-stamped according to the patient’s home time zone.

6.3 Medtronic CareAlert events and notifications

Important clinical management and system performance events may occur between scheduled patient sessions. These events may relate to clinical management data stored in device memory or to system issues that should be investigated. The early detection and notification of these events, should they occur, enables you to intervene promptly with appropriate care for your patient.

The LINQ II device continuously monitors for a specified set of clinical management and system performance events that may occur between scheduled follow-up sessions. If the device detects that such an event has occurred, the system responds in the following ways:

- **Wireless signal and network transmission of event summary information**

The device sends the record of the event to the CareLink Network either through the patient app or the home communicator. For additional information about wireless transmissions, see *Section 6.2, Monitoring the patient through the Medtronic CareLink Network, page 34*.

- **Clinician notifications of alert events**

  Medtronic CareAlert Notifications are displayed on the Medtronic CareLink Network Clinician Website, if available. Notification by voice message, pager, text message, and email message can also be configured.

  Note: If the patient's home communicator or patient app has not transmitted data to the Medtronic CareLink Network for 15 days, the patient is added to the Disconnected Monitors list on the Medtronic CareLink Network website.

6.3.1 Clinical management alerts

6.3.1.1 Clinician-defined alerts

LINQ II clinical management alerts are available on the Medtronic CareLink Network website. CareLink Network alerts allow clinics to define the events for which they want notification and assign an urgency level. Alerts are based on data transmitted to the Medtronic CareLink Network from the patient's home communicator or patient app. Notifications for each alert condition are clinician-configurable on the Medtronic CareLink Network website and do not require the patient to be present.

Clinical Management Alerts	
Symptom (Patient Activated) Episode	The alert indicates that a patient-activated symptom episode was stored in the device with either the patient app or the Patient Assistant.
Symptom (Patient Activated) + Detected Episode	This alert indicates that an episode was detected automatically within 20 min before a patient-activated symptom episode was stored in the device with either the patient app or the Patient Assistant.
Tachy Episode	This alert indicates that a Tachy episode was detected when the sensed rate exceeded the programmed Tachy Detection Rate and Duration.
Pause Episode	This alert indicates that a Pause episode was detected when the time between sensed events exceeded the programmed Pause Detection Duration.
Brady Episode	This alert indicates that a Brady episode was detected when the sensed rate fell below the programmed Brady Detection Rate and Duration.
AF Episode	This alert indicates that an AF episode was detected.
AT Episode	This alert indicates that an AT episode was detected.

AT/AF Daily Burden > Threshold	This alert indicates that the patient's cumulative time in AT/AF exceeded the threshold configured on the CareLink Network website. The configurable Time in AT/AF values are Any time, 1, 2, 3, 4, 6, 12, 18, and 23 hrs/day. In addition to the clinic alert, patient notification can be enabled. Patient notification includes the display of the clinic's contact phone number for the patient to call.
Average Ventricular Rate during AT/AF > Threshold	This alert indicates that the patient's average ventricular rate during AT/AF exceeded the threshold configured on the CareLink Network website. The configurable Time in AT/AF values are Any time, 1, 2, 3, 4, 6, 12, 18, and 23 hrs/day. The configurable average ventricular Rate during AT/AF values are 90, 100, 110, 120, 130, 140 and 150 bpm.
Low Battery Voltage Recommended Replacement Time[a]	This alert indicates that the LINQ II ICM has reached the recommended replacement time (RRT).
Electrical Reset[a]	This alert indicates that the device has been electrically reset and may require reprogramming. Contact your Medtronic representative.

[a] Low Battery Voltage and Electrical Reset alerts cannot be configured on the CareLink Network website as "No Alert".

For details about programmable settings for a particular arrhythmia detection parameter, see *Section A.1*.

For details about configurable settings for a particular alert condition, see the Medtronic CareLink Network Clinician Website.

For general information about the Medtronic CareLink Network, see www.medtronic.com/carelink.

6.3.2 Operation of Medtronic CareAlert Monitoring and Medtronic CareAlert Notifications

The CareAlert Notification methods (any one or a combination of voice message, text message, pager, email, or website-only) are set on a per-clinic basis according to alert urgency and time of day. You then can assign the level of urgency to each alert for individual patients, so that the same alert can be high urgency for one patient and low urgency for another patient.

When planning Medtronic CareAlerts for the LINQ II device, consider that alert notification configuration and device arrhythmia detection programming are separate but interdependent operations: CareAlerts are configured on the Medtronic CareLink Network website at any time and do not require the patient to be present. Device arrhythmia detection parameters are programmed remotely using the CareLink Network website or with the clinician app during device insertion or a follow-up session.

6.3.3 Alert groups

Alert conditions can be prioritized by configurable alert group settings: Red Alerts, Yellow Alerts, Website-Only Alerts, and No Alerts. For each reason for monitoring, you can use the default Medtronic settings or configure alert defaults for your clinic for each of the **Clinical Management Alert** categories. To view the default settings for each reason for monitoring, click **MANAGE MY CLINIC** > **Alert Groups** > **LINQ II Wireless Device Alert Conditions** and make a selection in the **Reason for Monitoring** list. For individual patients you can then override the clinic alert groups, as needed, with customized alerts for individual patients.

CareAlert Notification methods are configured for Red Alerts and Yellow Alerts while setting clinic alert groups. These notification methods are also used for customized patient alerts.

Table 2. CareLink alert group features

Alert features	Red Alert	Yellow Alert	Website-only Alert	No Alert
A color-coded website notification in the Alerts column on the alert transmission list	X	X	-	-
A website notification in the Alerts column on the alert transmission list	-	-	X	-
A description in the Event Summary column of the transmission list	X	X	X	-
Voice message	Optional	Optional	-	-
Pager	Optional	Optional	-	-
Text message	Optional	Optional	-	-
Email message	Optional	Optional	-	-

6.3.4 Configuring clinic-wide alert groups

1. To configure clinic-wide CareAlert condition groups on the Medtronic CareLink Network website, select **MANAGE MY CLINIC** > **Alert Groups** and expand **Display Alert Group Conditions** in the LINQ II Wireless Device Alert Conditions section.
2. Select **Create Clinic Default Alert Groups**.
3. For each Clinical Management Alert listed, select Red Alerts, Yellow Alerts, Website-only Alerts, or No Alerts.
4. For AT/AF Daily Burden, enter the threshold for cumulative Time in AT/AF.
5. For Average Ventricular Rate during AT/AF, enter the threshold for cumulative Time in AT/AF above a specified average rate.

6.3.5 Configuring notification methods

1. To configure CareAlert Notifications on the Medtronic CareLink Network website, select **MANAGE MY CLINIC** > **Red Alert Clinic Notification** or **Yellow Alert Clinic Notification**.
2. Select notification methods for both daytime hours and for after-hours and holidays.
3. Select **Notification Hours** to configure when and how your clinic is notified when the Medtronic CareLink Network receives a CareAlert Transmission.

7 Setting up sensing and arrhythmia detection

7.1 Introduction

This chapter describes how the LINQ II device parameters can be set pending automatically based on the selected Reason for Monitoring the patient and the patient's age. It also describes how the device senses R-waves and automatically detects cardiac arrhythmias, and it provides advice for programming the parameters to adjust sensing and set up automatic episode detection. For the programmable ranges and nominal settings of the parameters, see *Section A.1*.

7.2 Setting arrhythmia detection parameters automatically

The LINQ II device enables you to set arrhythmia detection parameters to pending automatically, based on your Reason for Monitoring the patient and on the patient's Date of Birth. Programming of both of these parameters is required during the device insertion process. After these parameters have been set to pending automatically, they can be programmed or you can modify individual parameters according to your preference. The Reason for Monitoring and individual parameters can be changed during later patient follow-up sessions or during remote programming.

The selections for Reason for Monitoring include Syncope, Cryptogenic Stroke, Large or Small Vessel Stroke, Suspected AF, AF Ablation, AF Management, Palpitations, Ventricular Tachycardia, Seizures, and Other. These selections control the default settings for parameters. In addition, Tachy Detection Interval is programmed automatically to 230 bpm minus the patient's age and rounded to the nearest programmable value, as calculated from the information entered in Patient Date of Birth, for all Reasons for Monitoring.

For more information, see *Section A.1.1*.

For information about setting sensing and arrhythmia detection parameters manually, see *Section 7.4*.

7.2.1 MyCareLink Heart Mobile App Optimization

The MyCareLink Heart Mobile App Optimization parameter can be set using the clinician app or the CareLink Network Website. Refer to the product literature for the clinician app for more information about the Mobile App Optimization parameter.

When MyCareLink Heart Mobile App Optimization is enabled, patients may experience faster connectivity when marking a symptom with the patient app. However, this parameter will affect the battery longevity of the LINQ II ICM.

With Mobile App Optimization set to Off, the battery is projected to last 4.5 years. With Mobile App Optimization set to On, the battery is projected to last 2.5 years. For more information about battery longevity, see *Section A.2.2*.

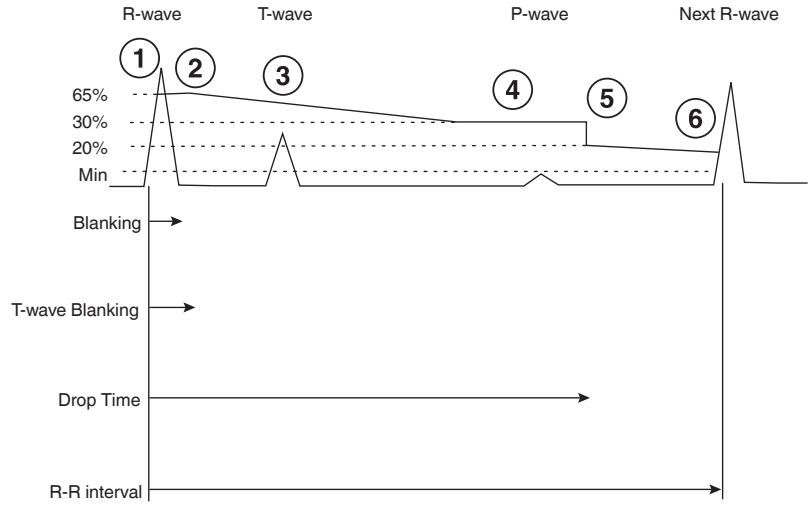
The Mobile App Optimization parameter is disabled by default. For more information, see *Section A.1*.

7.3 Adjusting R-wave sensing

The automatic detection of arrhythmias by the LINQ II ICM is based on R-wave sensing. For proper functioning of the device, it is important both that all R-waves are reliably sensed and that other events like P-waves and T-waves are not marked as ventricular events. The LINQ II ICM filters the ECG signal to reduce noise and to reduce the number of sensed P-waves and T-waves. The filtered ECG signal is compared against the sensing threshold.

The sensing threshold defines the minimum electrical amplitude that is recognized as a sensed event. Only signals that are higher than the sensing threshold are sensed as R-waves. The LINQ II ICM has a dynamic sensing threshold. It automatically adjusts the sensing threshold after a sensed R-wave to help reduce oversensing from P-waves and T-waves, while ensuring a reliable sensing of the next R-wave (see *Figure 12*).

Figure 12. Auto-adjusting the sensing threshold



1 After a sensed R-wave, a programmable blanking interval is started and the sensing threshold is set to 65% of the ECG peak.
2 The sensing threshold stays at this level during the programmable T-wave Blanking Interval.
3 After the T-wave Blanking Interval is finished, the sensing threshold decreases to 30% of the ECG peak within 1 s.
4 The sensing threshold stays at this level until 1.5 s has elapsed since the R-wave was sensed.
5 The sensing threshold then drops to 20% of the ECG peak.
6 The sensing threshold continues to decrease until a new R-wave is sensed or the minimum threshold is reached. The minimum threshold is the programmed sensitivity setting.

After a sensed R-wave, a blanking interval starts and the sensing threshold is set to a level related to the measured amplitude. The sensing threshold stays at this value for a certain period of time to prevent T-wave sensing. When no new R-wave has been sensed during this delay, the sensing threshold starts to decrease. The sensing threshold decreases at such a rate that oversensing of T-waves and P-waves is avoided, but the sensing of an early R-wave is still possible. The sensing threshold will never drop below the programmed sensitivity setting to avoid the sensing of noise or P-waves.

Notes:

- The maximum sensing threshold is 65% of 1 mV. If the R-wave amplitude is higher than 1 mV, the threshold is set to 0.65 mV.
- The LINQ II ICM uses blanking to reject noise due to EMI and myopotentials. The device starts a programmable blanking interval with each R-wave. An event that occurs during the blanking interval is not used for automatic episode detection.

7.3.1 Optimizing sensing

You can optimize the sensing of R-waves by adjusting the parameters Sensitivity, Blank after Sense, and T-wave Blanking Interval.

Note: Medtronic recommends that you check for proper R-wave sensing when you change the sensing parameters.

Sensitivity – You can program the sensitivity to set the minimum threshold for R-wave sensing. You should program the sensitivity with care. Programming the sensitivity to a higher setting decreases the number of sensed ventricular events with lower amplitudes. Programming the sensitivity to a lower setting increases the number of sensed ventricular events, but may result in the oversensing of EMI, myopotentials, P-waves, and T-waves.

Note: Medtronic recommends that you program the sensitivity to a setting slightly above the P-wave amplitude.

Blank after Sense – You can select the length of the Blank after Sense interval, which starts after the detection of a sensed R-wave. During the Blank after Sense interval, sensing is inhibited to prevent the multiple sensing of the R-wave due to a broad QRS complex. If the Blank after Sense interval is programmed too long, tachy events may be blanked.

T-wave Blanking Interval – You can select the length of the interval during which the sensing threshold remains at its initial value after the detection of an R-wave. To ensure proper sensing of R-waves, you should program the T-wave Blanking Interval at or longer than the Blank after Sense interval. If the Blank after Sense interval is programmed to an interval longer than the T-wave Blanking Interval, the T-wave Blanking Interval will be made equal to the Blank after Sense interval. If the LINQ II device is placing a VS marker under the T-wave (commonly called T-wave oversensing), extending the T-wave Blanking Interval may overcome the issue.

7.3.2 Preventing undersensing and oversensing

You can use the surface ECG trace with marker annotations in the ECG window to assess ventricular sensing. Undersensing should be suspected when distinct R-waves are not being marked as ventricular senses (VS) in the Marker Channel. Oversensing can be investigated by checking the Marker Channel for sensed ventricular events that are not due to sensed R-waves.

Undersensing R-waves – Programming the sensitivity to a lower setting may increase the number of sensed R-waves, but you should check that this does not result in the false detection of P-waves. If R-waves are being missed during high ventricular rates, shortening the Blank after Sense interval or the T-wave Blanking Interval may resolve undersensing.

Oversensing P-waves – If P-waves are marked as ventricular senses, programming the sensitivity to a higher setting may reduce oversensing.

Oversensing T-waves – If T-waves are marked as ventricular senses, extending the T-wave Blanking Interval may resolve oversensing. Extending the Blank after Sense interval may also be used to resolve oversensing if extending the T-wave Blanking Interval is unsuccessful.

Oversensing R-waves – If broad QRS complexes result in the oversensing of R-waves, increasing the blanking interval may reduce the number of oversensed R-waves.

Note: Check the ECG trace for the effect of the reprogrammed settings.

7.3.3 Preventing false pause (asystole) detections

The device may falsely detect pause (asystole) occurrences in some circumstances. False pause detections may make it more difficult to diagnose whether the underlying arrhythmia is the cause of a patient's symptomatic or syncopal events. The most common causes of false pause detections are loss of contact between the device electrodes and the pocket or muscle tissue, and loss of ventricular sensing due to transient R-wave amplitudes. To prevent false positive pause episodes, ensure that the R-wave amplitude is a minimum of 0.2 mV at insertion. For information, see *Section 3.2.7*.

Loss of contact between the device electrodes and pocket or muscle tissue may be indicated by a sharp deflection of the ECG signal followed by a gradual return to baseline and a lack of observable changes in the heart rhythm and rate before and after a pause event.

If you suspect that transient R-wave amplitudes are the cause of a loss of sensing, consider programming the device to a more sensitive setting, while still ensuring that the Sensitivity value is greater than the amplitude of the patient's P-waves.

7.4 Setting up automatic episode detection

Activating the device turns on the automatic detection and ECG storage of the following episodes:

- Tachy (FVT and VT)
- Pause (asystole)
- Brady
- AF

An automatically detected episode starts when the cardiac rhythm meets the detection criteria for that episode type. The detection criteria for tachy and brady episodes are based on the length of the ventricular interval of the suspected R-wave and the number of such R-waves that have occurred (duration). The detection of a pause episode is based on the duration of the event. The detection of AT/AF episodes is based on the R-wave variability within 2-minute periods. The system provides independent on/off control for each arrhythmia detection function of the device. This enables you to specify the episode types that are detected and for which data is stored.

Note: The nominal settings of the detection criteria are chosen to ensure the detection of episodes of all types. This may result in the device memory being filled with episodes that are not relevant for monitoring the patient's condition. While detection parameters may be set manually, the preferred alternative is to select a Reason for Monitoring that is appropriate for the patient's condition. This will set arrhythmia parameters to pending automatically that will result in episode data being stored that is relevant to the selected patient's condition. Parameters set to pending may be programmed as is or changed if preferred. For additional information, see *Section 7.2, Setting arrhythmia detection parameters automatically, page 41*.

Notes:

- Tachy, brady, and pause episodes cannot occur simultaneously. Only one type of episode can be in progress at a time.
- An AT/AF episode can be in progress at the same time as one of the other types of episodes (tachy, brady, or pause). If this occurs, the device stores information for each detected episode.
- If an automatically detected episode and a patient-activated episode occur simultaneously, each episode is recorded separately.

7.4.1 Tachy episodes

You can adjust the criteria by which an increased ventricular rhythm is classified as a Tachy episode.

The LINQ II device marks a possible Tachy event when the ventricular interval is shorter than the programmed Tachy interval length. If the number of such Tachy events exceeds the programmed duration and the ECG noise level is not excessive, a Tachy episode is stored. Additionally, very fast rates will cause a Tachy episode to be stored when 30 of the last 40 ventricular events have an interval shorter than 260 ms. If the noise level is excessive, as indicated by the presence of very short ventricular intervals and high frequency content in the ECG, the Tachy episode is rejected. The Tachy episode ends when one of the following criteria is met:

- Eight consecutive R-waves are detected with an interval equal to or longer than the programmed Tachy interval.
- The median ventricular interval is equal to or longer than the programmed Tachy interval during a period of 20 s.
- No R-wave is detected during a period of 10 s.

If Tachy detection is programmed off, the device stops detection and recording of the episode is terminated.

Detection – Program Tachy Detection to “Off” to prevent automatic detection of Tachy episodes.

Interval – Select the ventricular interval length of the rate that will be classified as ventricular tachyarrhythmia.

Duration – Select the number of Tachy events that must occur before the episode is classified as a Tachy episode.

Tachy: Require Rapid Onset – Sinus tachycardia can generally be distinguished from ventricular tachycardia by the speed of ventricular rate increase (onset). Typically, ventricular tachycardia exhibits a sudden rate increase, while sinus tachycardia is characterized by a gradual rate increase. Tachy: Require Rapid Onset limits the tachy episodes detected to those in which the ventricular rate increases rapidly. Tachy: Require Rapid Onset compares the 4 most recent R-wave intervals with the previous 4 intervals. If the average length of the 4 most recent R-wave intervals is shorter than the average length of the 4 previous R-wave intervals multiplied by 81%, then the next 4 R-waves are classified as Tachy events.

For example, the average of 4 most recent R-wave intervals of 410, 370, 340, and 300 ms is 355 ms. The average of the 4 preceding R-wave intervals of 480, 450, 510, and 470 ms is 478 ms. Because the average value of 355 ms is less than 387 ms (81% of 478 ms), the Tachy: Require Rapid Onset criteria are met and the next 4 R-waves are classified as Tachy events.

Note: Programming Tachy: Require Rapid Onset to “On” may delay detection of true tachy episodes in patients who experience exercise-induced ventricular tachycardia.

7.4.2 Brady episodes

A bradyarrhythmia episode starts when the number of R-waves with a ventricular interval longer than the programmed interval length exceeds the programmed duration. The bradyarrhythmia episode ends when one of the following criteria is met:

- Four consecutive R-waves are detected with a ventricular interval equal to or shorter than the programmed interval.
- No R-wave is detected during a period of 10 s.

Detection – Program Brady Detection to “Off” to prevent automatic detection of brady episodes.

Interval – Select an interval that represents a heart rate lower than the patient’s normal rate at rest.

Duration – Select the number of brady intervals that must occur before the episode is classified as a bradyarrhythmia episode.

7.4.2.1 Brady: Nighttime ECGs Stored

Brady: Nighttime ECGs Stored is used to set user preferences for the number of Brady ECGs stored between midnight and 6:00 AM.

If you select **None** to be stored, Brady episodes will still be detected and the brady episode counter will be incremented on the **Quick Look** tab. But no corresponding episode logs or episode records will be stored during this time period.

If you select **1 ECG** to be stored, the ECG of the first detected Brady episode during this time period will be stored.

If you select **Up to 3 ECGs** to be stored, the device will function normally: the ECGs for the first three episodes will be stored. If a longer episode is detected, then it will overwrite the last stored episode.

7.4.3 Pause (asystole) episodes

The device detects a pause (asystole) episode when the interval from the previous ventricular sense to the current event (either a ventricular sense, escape time-out, or an overrange ECG signal) exceeds the programmed Pause Duration. A pause episode terminates after 12 ventricular sensed events have occurred.

Detection – Program Pause Detection to “Off” to prevent automatic detection of pause episodes.

Duration – Select the length of the pause interval that must occur before the episode is classified as a pause episode.

7.4.4 AT/AF episodes

The LINQ II ICM detects the occurrence of AT/AF episodes from variations in the ventricular rhythm. AT/AF episodes are detected using an automatic algorithm based on the pattern of R-wave interval variability within 2-minute periods. The differences between consecutive R-wave intervals are plotted in a Lorenz plot (for examples, see *Figure 13*, *Figure 14*, and *Figure 15*). Pattern recognition is used to identify the AT and AF episodes; R-wave intervals during AF episodes are highly irregular and uncorrelated, whereas more regular R-wave patterns are expected during AT episodes. A clinical AT rhythm with some irregularity may be classified as AF.

The LINQ II ICM might classify a clinical AT rhythm with some irregularity as AF. This means that “AF only” episodes may show the occurrence of some AT events.

Figure 13. Lorenz plot of an AF episode

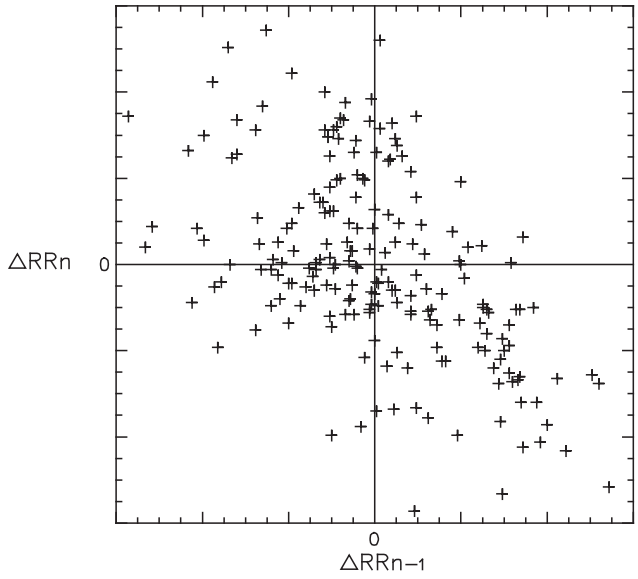


Figure 14. Lorenz plot of an AT episode

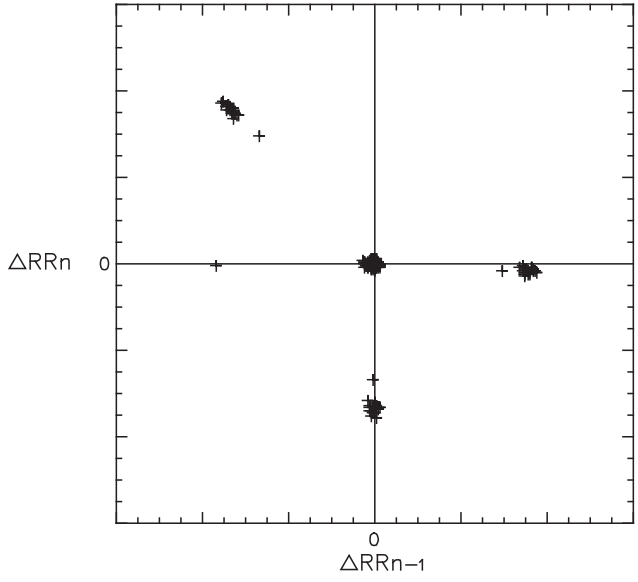
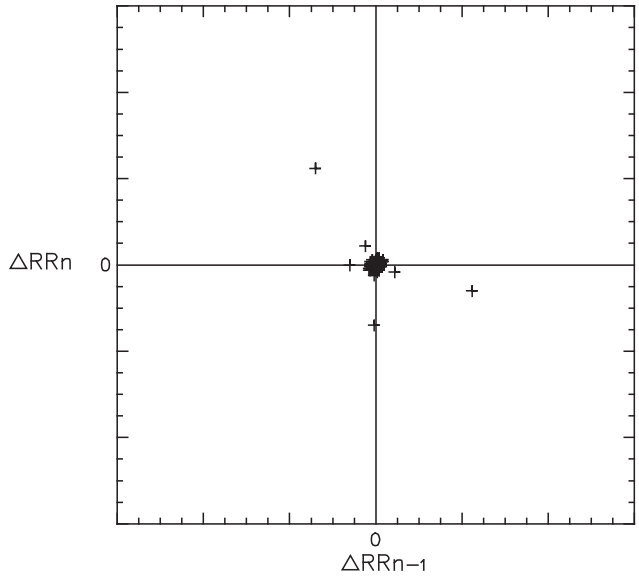


Figure 15. Lorenz plot of sinus rhythm



In the Lorenz plots the difference between 2 consecutive R-wave intervals (ΔRR_n) is plotted on the horizontal axis. The preceding R-wave interval difference (ΔRR_{n-1}) is plotted on the vertical axis

AT/AF Detection – Program AT/AF Detection to “Off” to prevent automatic detection of AT/AF episodes.

You can choose to monitor combined AT/AF episodes or episodes where AF events are predominant. The detection of these episodes can be enhanced by programming the parameters AF Detection and Detect Very Regular AT Rhythms.

Type – Select the type of episodes you want to monitor.

Note: In patients with a low heart rate variability the LINQ II device may continuously detect AT episodes and record ECGs of those episodes. Medtronic recommends that you select “AF only” for these patients to avoid filling the device memory.

AF Detection – The default setting of this parameter ensures optimal performance of AF detection in most patients. In some instances, the parameter may be reprogrammed to suit individual patients.

Ectopy Rejection – A primary cause of false positive AF detection is runs of ectopy (PACs or PVCs) with irregular coupling intervals caused by underlying sinus variability. Two rejection algorithms exist to block false detections. The Ectopy Rejection algorithm

recognizes patterns of ectopy by the density of points in the Lorenz Plot. Additionally, a P-wave presence algorithm looks for evidence of a P-wave between two R-waves. When Ectopy Rejection is set to Nominal the P-wave presence algorithm is enabled. When Ectopy Rejection is set to Aggressive, both the P-wave presence and the Ectopy Rejection algorithms are enabled. The device will not detect AF when the algorithm detects evidence of ectopy during any 2 min period. When Ectopy Rejection is set to Off, both the P-wave presence and the Ectopy Rejection algorithms are disabled.

Detection of very regular AT rhythms – The system also discriminates AT episodes by the regularity of the patient's rate. If the rate during an AT episode is less than the programmed Detect Very Regular AT Rhythms parameter setting, the AT Episode is not detected. If the Detect Very Regular AT Rhythms parameter setting is set to On – All Rates, the system detects all AT episodes. If the Detect Very Regular AT Rhythms parameter setting is set to Off, very regularly conducted atrial tachycardias such as consistent 2:1 or 3:1 atrial flutter will not be detected.

Note: An AT/AF episode can occur simultaneously with one of the other types of episodes. If this occurs and detection is programmed On, the LINQ II device will store information and an ECG recording for both types of episodes.

8 Viewing the collected data with the CareLink Network

8.1 Introduction

The CareLink Network website offers several ways to view and analyze the collected data in the LINQ II device. This may help you to monitor the patient's condition. You can assess the episode data and ECGs received since device insertion and you can monitor for long-term trends.

A patient session starts with a quick overview of the battery status and the episodes recorded since the last patient session (see *Section 8.2*). More detailed information, including ECGs, about the most recently recorded episodes may help you to diagnose the patient's symptoms or investigate the patient's heart rhythm (see *Section 8.3*). For long-term monitoring of the patient's condition, Cardiac Compass Report graphs show trends in data collected over a longer period of time (see *Section 8.5*). Rate histograms provide information about the heart rates recorded for a duration of 30 days, 90 days, or 14 months. Rate histograms can be used to monitor the effectiveness of rate or rhythm control therapies (see *Section 8.5*).

Note: When AT/AF is mentioned in a report, it refers to information about "AT/AF" or "AF only" episodes (depending on the programmed episode type).

8.2 Viewing a summary of recently stored data

At the start of a patient follow-up session, it is useful to view a summary of the patient's condition and the battery status of the LINQ II ICM.

You can access the Quick Look window by selecting TRANSMISSIONS and then selecting the date of the patient's most recent transmission.

You can print the information presented in the Quick Look window in the Quick Look report.

Note: Quick Look shows information collected from the last time the patient's information was viewed. Programming changes made during the current session may also affect the Quick Look observations.

8.2.1 Information provided by Quick Look

You can access the Quick Look window by selecting TRANSMISSIONS and then selecting the date of the patient's most recent transmission.

The Quick Look window provides Battery Status, a summary of the arrhythmia episodes recorded within the monitoring period, parameter settings, and system observations.

Patient data – The top of the Quick Look window displays the patient's data, including Phone, Date of Birth, Follow-up Physician, device serial number, Implant Date, and Reason for Monitoring. You can edit patient data by selecting MANAGE MY PATIENTS.

Comments about patient – You can view or make any comments or notes about the patient by selecting **Edit** in the **Comments about patient** box. Comments are shared notes across the CareLink Network for this patient and are edited by selecting the Comments and Notes tab.

Arrhythmia episode information – The arrhythmia episode information shows the number of automatically detected and patient-activated (symptom) episodes from the Current transmission, those episodes that have occurred over the Lifetime of the device, and the detection parameters.

- The "% of time AT/AF" information shows the percentage of time that the device detected AT/AF in the period from the Current transmission and over the Lifetime of the device, which can help you to assess the need to initiate or adjust the patient's rate or rhythm control therapies.
- The "PVCs (% beats)" information shows the percent of beats that are detected as PVCs. The LINQ II ICM is designed to detect single PVCs between two normal sinus beats and does not count any beats that are part of a couplet or triplet PVC series.

Battery status – The Quick Look window displays the device battery status. The battery status can be "Good", "RRT", or "EOS". If the battery status shows RRT (Recommended Replacement Time), the date when the battery reached RRT is indicated.

Observations – Observations are based on the analysis of programmed parameters and data collected since the last patient session.

The following types of observations may occur:

- Device status observations inform you about the status of the LINQ II ICM, for example, when the device is approaching the Recommended Replacement Time (RRT) or End of Service (EOS). An observation is also reported if a device reset has occurred.
- Diagnostic data observations report notable arrhythmia episodes, for example when a patient-activated (symptom) episode has been recorded within 20 min of an automatically detected episode.

Episode List – The Episode List displays the history of episodes recorded by the patient's device within the monitoring period including the Assessment, type of episode, Date, time detected, duration of the episode, maximum ventricular rate, median ventricular rate, and Episode Details.

Current ECG – The Current ECG displays the ECG reading from the patient's device at the time of the most recent transmission.

Episode ECGs – ECG readings from recorded symptom episodes are shown in the episode ECG section of the **Quick Look** window. Select **View Full ECG** for a more detailed report on a symptom episode. From the **Assessment** drop-down menu, you may make an assessment of the episode as **Appropriate**, **Indeterminate**, or **Inappropriate**. When you have assessed all of the episodes select **Save Assessments**.

8.3 Viewing arrhythmia episode data

To view arrhythmia episode data, select the Episodes tab.

The Episodes window enables you to view summary and detailed data for arrhythmia episodes. The Episodes window shows data of both the automatically detected and patient-activated (symptom) episodes. Episode information is available in several formats, including interval plot diagrams, ECG recordings, and text summaries.

Note: If detection is programmed to Off for an episode type, episode data and ECGs for that type are not stored.

8.3.1 Viewing the episode log

The episode log is a list of stored episode records that can be viewed in the upper part of the Episodes window. The log lists all episodes currently stored in device memory. The log includes the following summary information:

- Assessment of the episode
- Type of episode
- The date, time, and duration of the episode
- The highest ventricular rate (automatically detected episodes only); for brady episodes the lowest ventricular rate is shown
- The median ventricular rate at detection (automatically detected episodes only)
- Whether ECG data is available for the episode

8.3.2 Viewing episode details

Detailed information about the episode currently selected in the episode log appears in the lower portion of the window and can be maximized for better viewing. For a particular episode, you can display the following information:

- An interval (or rate) plot
- A strip chart of the stored ECG (if available)
- A text summary (automatically detected episodes only)

During a follow-up session, you may be able to correlate patient-activated (symptom) episodes and automatically detected episodes. This may help to show a possible relationship between patient symptoms and cardiac rhythm.

Notes:

- If the patient uses the patient app or Patient Assistant while an automatically detected episode is in progress, both episodes are stored. The device records “Symptom (Patient Activated) occurred during episode” in the text of the automatically detected episode.
- During long episodes, the device may not record the whole ECG to conserve memory. The last 27 s of ECG before the end of the episode is always included in the ECG recording, but during a longer episode, ECG storage may be suspended in the middle of the episode.
- The device records extra marker and interval data from the period before the automatic detection of an episode. This data is shown in the episode interval plot and episode ECG. Intervals longer than 2000 ms are shown as “> 2000 ms” and may affect the time scale of the plot or ECG.

Viewing the episode ECG – If an ECG is available for this episode, ECG will be displayed in the Episode Details column.

The length of the stored ECG depends on the type of episode. For information about ECG data storage of patient-activated or automatically detected episodes, see *Section 6.1*.

Viewing the episode text – The episode text summary includes more information than the episode log. This option is not available for patient-activated (symptom) episodes.

8.4 Printing and sending a report

You can print or send a report using the following icons on the **TRANSMISSIONS** tab.

 To print a report, select the Open PDF Report icon.
 To save a report, select the Send to Reports List icon.

Printing a report – To print a report, select one of 3 types of reports from the menu: Clinic Preferred Reports, Current Report, or Custom Reports.

Sending a report to the Reports List – You can create a report for later use that will be saved in the Reports List. To save a report, select one of 3 types of reports from the menu: Clinic Preferred Reports, Current Report, or Custom Reports.

Clinic Preferred Reports – Allows you to create a reusable customized report for your clinic. You can customize the information that will be included in all Clinic Preferred Reports. To customize your clinic's Clinic Preferred Reports, navigate to **MANAGE MY CLINIC** > **Report Preferences** > **ICMs**.

You can configure the following information for your Clinic Preferred Reports:

- Include Trends (Cardiac Compass, Histograms, and Longest AF)
- Include Device Parameter Settings
- Include Full Episode ECG
- Remove Episodes Marked as Inappropriate

Current Report – The Current Report will include all of the information in the tab you are viewing. For example, if you are viewing the **Episodes** tab and **Current Report** is selected, then the report that is generated will contain information from the **Episodes** tab.

Custom Reports – A custom report allows you to configure the following information in a report:

- Include Trends (Cardiac Compass, Histograms, and Longest AF)
- Include Device Parameter Settings
- Include Full Episode ECG
- Remove Episodes Marked as Inappropriate

8.5 Viewing long-term clinical trends

To view long-term clinical trends, select the Trends tab.

An analysis of clinical information collected over a long term may help you to follow changes in a patient's condition and correlate these changes with variations in therapy, patient activity, or symptoms.

The Trends window provides a picture of the patient's condition. You can change the duration of the observation period by selecting 30 days, 90 days, or 14 months in the drop-down menu on the Trends tab. Graphs show trends in the occurrence of arrhythmias, average daytime and nighttime ventricular rates, the amount of physical activity, PVCs, and heart rate variability. Dates and event annotations allow you to correlate trends from different graphs. The report may also help you to assess whether rate or rhythm control therapies are effective.

The Trends window is based on data and measurements collected daily. The LINQ II ICM begins storing data after it is inserted and data collection is enabled. Each day thereafter, the device stores a set of Cardiac Compass data. Storage continues until the 14-month storage capacity is filled. At that point, the oldest stored data is overwritten with new data.

Notes:

- The time annotations displayed on the report are based on the device clock.
- You cannot manually clear the Cardiac Compass Trends data.

8.5.1 Cardiac Compass trend graphs

Programming and interrogation events – The report shows when the device was interrogated or reprogrammed, to allow possible correlations between device parameter changes and other clinical trends.

When the patient is evaluated during a patient session, the report records an "I" for a day on which the device is interrogated and a "P" for a day on which any programmable parameter is changed (except for temporary changes). If the device is interrogated and programmed on the same day, only a "P" appears. The report shows a "_" under an "I" or "P" for instances when the patient's device was remotely interrogated or remotely programmed.

Two dashed vertical lines run through all the graphs to indicate the beginning of the current patient session and the beginning of the last session, if applicable.

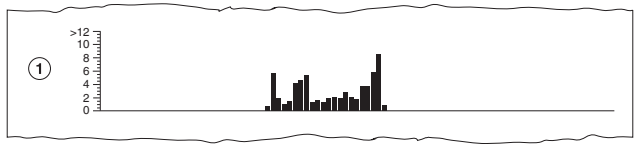
Patient symptoms – A patient may experience symptoms of a possible cardiac event and record this occurrence using the patient app or Patient Assistant. The Cardiac Compass Report records an "S" for a day on which the patient marks cardiac symptoms. If multiple events are recorded per day, one symbol is displayed per day according to system priorities.

For example, if the device is programmed or interrogated on the same day as the patient marks a symptom, the program or interrogate event will display rather than the “S”.

AT/AF total time per day – This trend may help you to assess the need to initiate or adjust the patient’s rate or rhythm control therapies. It may also reveal the presence of asymptomatic episodes of AT/AF.

The device records a daily total for the time (burden) the patient spent in atrial arrhythmia. This trend may be reported in hours or minutes per day depending on the maximum (total) atrial arrhythmia duration per day.

Figure 16. AT/AF total time per day



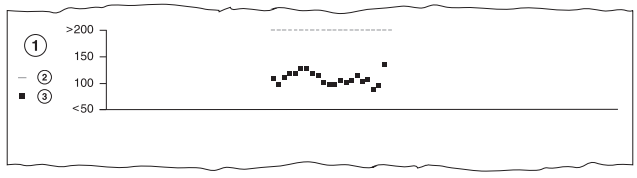
1 Total time per day

Ventricular rate during AT/AF – You may use this trend to perform the following assessments:

- Correlate patient symptoms to rapid ventricular responses to AT/AF.
- Prescribe or titrate antiarrhythmic and rate control drugs.
- Assess the efficacy of an AV node ablation or modification procedure.

The graph plots daily median ventricular rates during episodes of atrial arrhythmia. The vertical lines show the daily difference between the median rate and the maximum sensed ventricular rate. Multiple points on one day represent multiple episodes with different median rates.

Figure 17. Ventricular rate during AT/AF



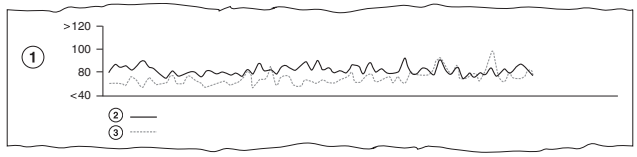
1 Beats per minute
2 Max
3 Average

Average ventricular rate – The day and night heart rates provide information that may have the following clinical uses:

- Objective data to correlate with patient symptoms
- Indications of autonomic dysfunction or symptoms of heart failure
- Information regarding diurnal variations

For this trend, “day” is defined as the 12-hour period between 8:00 AM and 8:00 PM and “night” as the 4-hour period between midnight and 4:00 AM (as indicated by the LINQ II clock).

Figure 18. Average ventricular rate



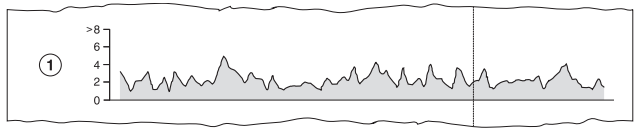
1 Beats per minute
2 Day
3 Night

Patient activity – The patient activity trend may help you to obtain the following types of information:

- A way to monitor a patient’s exercise regimen
- An early indicator of progressive diseases like heart failure, which cause fatigue and a consequent reduction in patient activity

The device uses data derived from the built-in accelerometer to determine weekly patient activity.

Figure 19. Patient activity

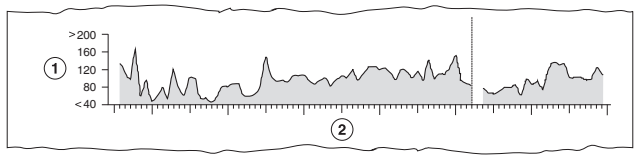


1 Hours per day

Heart rate variability – Reduced variability in the patient’s heart rate may help you to identify heart failure decompensation. The device measures each ventricular interval and calculates the median ventricular interval every 5 min. It then calculates and plots a variability value (in ms) for each day.

Note: The heart rate variability calculation does not include events that occur during automatically detected arrhythmia episodes (AT/AF or Tachy).

Figure 20. Heart rate variability

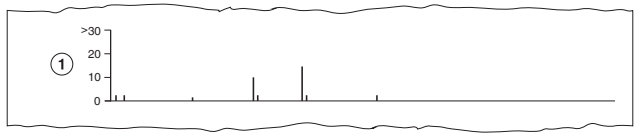


1 Milliseconds

2 Date

PVC – This trend displays the percent of beats that are detected as PVCs per day.

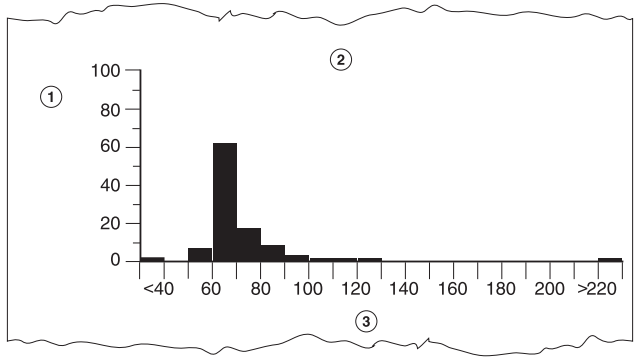
Figure 21. PVC



1 Percentage of beats

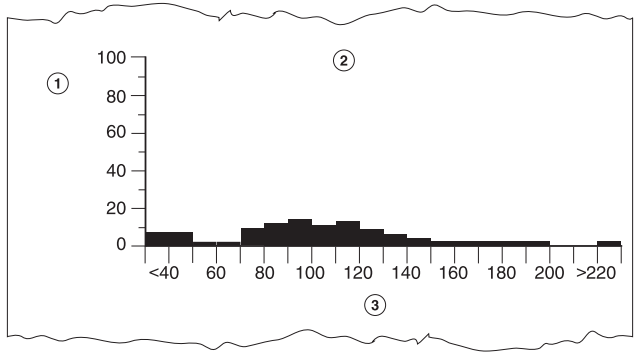
Ventricular rate during AT/AF histogram (time in or out of AT/AF) – The Time out of AT/AF and Time in AT/AF histograms show ventricular events that occurred during automatically detected AT/AF episodes. The histograms show 20 rate ranges that are each 10 bpm wide. Rates slower than 40 bpm are included in the <40 bpm range; rates faster than 220 bpm are included in the >220 bpm range. The information includes the AT/AF burden expressed in both the percentage of time and the total time that the patient spent in or out of AT/AF.

Figure 22. Time out of AT/AF



1 Percentage of time out of AT/AF
2 Total time
3 Rate (bpm)

Figure 23. Time in AT/AF



1 Percentage of time in AT/AF
2 Total time
3 Rate (bpm)

A Product specifications

A.1 LINQ II ICM programmable parameters

Notes:

- Tolerances for programmable parameter values are valid when the device temperature is between 17 °C and 45 °C (63 °F to 113 °F).
- The symbol ◈ in parameter tables indicates the Medtronic nominal value for that parameter.

A.1.1 Parameters based on Reason for Monitoring

The default settings for each Reason for Monitoring setting are shown in *Table 3* and *Table 4*. The settings described in these two tables are followed by both the clinician app and the CareLink Network for remote programming. When the Reason for Monitoring is set, it will in turn set other settings to the pending values reflected in these tables.

Table 3. Parameters automatically set to pending according to Reason for Monitoring: Syncope, Cryptogenic Stroke, Large or Small Vessel Stroke, Suspected AF, AF Ablation

Parameter	Syncope	Cryptogenic Stroke	Large or Small Vessel Stroke	Suspected AF	AF Ablation
Tachy Detection Enable	ON	ON	ON	ON	ON
Tachy Rate[a]	230 bpm – age	230 bpm – age	230 bpm – age	230 bpm – age	230 bpm – age
Tachy Duration	16	16	16	16	16
Tachy: Require Rapid Onset	ON	ON	ON	ON	ON
Brady Detection Enable	ON	ON	ON	ON	ON
Brady Rate	30	30	30	30	30
Brady Duration	4	12	12	12	12
Brady: Nighttime ECGs Stored	1 ECG	None	None	None	None

Table 3. Parameters automatically set to pending according to Reason for Monitoring: Syncope, Cryptogenic Stroke, Large or Small Vessel Stroke, Suspected AF, AF Ablation (continued)

Parameter	Syncope	Cryptogenic Stroke	Large or Small Vessel Stroke	Suspected AF	AF Ablation
Pause Detection Enable	ON	ON	ON	ON	ON
Pause Duration	3	5	5	5	5
PVC Detection Enable	ON	ON	ON	ON	ON
AT/AF Detection Enable	AF only	AF only	AF only	AF only	AF only
Symptom (Patient Activated Storage Mode)	Two 15 min episodes	OFF	OFF	OFF	OFF
AF: Detection Sensitivity	Least	Balanced	Balanced	Less	Balanced
AT/AF: Ectopy Rejection	Aggressive	Aggressive	Aggressive	Nominal	Nominal
AT/AF: Recording Threshold	≥ 10 min	All	All	≥ 6 min	≥ 6 min
Mobile App Optimization	OFF	OFF	OFF	OFF	OFF

[a] For all Reasons for Monitoring, Tachy Detection Interval is programmed automatically to the closest value less than or equal to 230 bpm minus the patient's age, as calculated from the information entered in the patient's Date of Birth.

Table 4. Parameters automatically set to pending according to Reason for Monitoring: AF Management, Palpitations, Ventricular Tachycardia, Seizures, Other

Parameter	AF Management	Palpitations	Ventricular Tachycardia	Seizures	Other
Tachy Detection Enable	ON	ON	ON	ON	ON
Tachy Rate[a]	230 bpm – age	230 bpm – age	230 bpm – age	230 bpm – age	230 bpm – age
Tachy Duration	16	16	16	16	16

Table 4. Parameters automatically set to pending according to Reason for Monitoring: AF Management, Palpitations, Ventricular Tachycardia, Seizures, Other (continued)

Parameter	AF Management	Palpitations	Ventricular Tachycardia	Seizures	Other
Tachy: Require Rapid Onset	ON	ON	OFF	ON	ON
Brady Detection Enable	ON	ON	ON	ON	ON
Brady Rate	30	30	30	30	30
Brady Duration	12	12	12	12	12
Brady: Nighttime ECGs Stored	None	None	None	None	None
Pause Detection Enable	ON	ON	ON	ON	ON
Pause Duration	5	5	5	5	5
PVC Detection Enable	ON	ON	ON	ON	ON
AT/AF Detection Enable	AF only	AF only	AF only	AF only	AF only
Symptom (Patient Activated Storage Mode)	OFF	Two 15 min episodes	Two 15 min episodes	Two 15 min Episodes	OFF
AF: Detection Sensitivity	Balanced	Less	Least	Least	Less
AT/AF: Ectopy Rejection	Nominal	Nominal	Aggressive	Aggressive	Aggressive
AT/AF: Recording Threshold	≥ 6 min	≥ 6 min	≥ 10 min	≥ 10 min	≥ 10 min
Mobile App Optimization	OFF	OFF	OFF	OFF	OFF

[a] For all Reasons for Monitoring, Tachy Detection Interval is programmed automatically to the closest value less than or equal to 230 bpm minus the patient's age, as calculated from the information entered in the patient's Date of Birth.

A.1.2 Parameter shipped and reset values

Table 5. Monitoring information parameters

Parameter	Programmable values	Shipped value	Reset value
Reason for Monitoring	Syncope	-	-
	Cryptogenic Stroke		
	Large or Small Vessel Stroke		
	Suspected AF		
	AF Ablation		
	AF Management		
	Palpitations		
	Ventricular Tachycardia		
	Seizures		
	Other		
Patient Local Date and Time	Month, Date, Year Hour, Minute, AM, PM	This field defaults to the tablet's date and time.	Jan 01, 1994
Mobile App Optimization **Note:** Tap **ADVANCED SETTINGS** to access this parameter setting.	ON[a] OFF	OFF	OFF

[a] When the **Mobile App Optimization** is turned **ON**, the LINQ II ICM battery longevity is reduced.

Table 6. Sensing parameters

Parameter	Programmable Values	Shipped Value	Reset Value
Sensitivity	0.025 mV (25 µV)	0.035 mV (35 µV)	0.035 mV (35 µV)
	0.035 mV (35 µV)		
	0.05 mV (50 µV)		
	0.075 mV (75 µV)		
	0.1 mV (100 µV)		
	0.125 mV (125 µV)		
	0.15 mV (150 µV)		
	0.175 mV (175 µV)		
	0.2 mV (200 µV)		

Table 6. Sensing parameters (continued)

Parameter	Programmable Values	Shipped Value	Reset Value
Blank after Sense	130; 150; 170; 200; 250; 300; 400 ms	150 ms	150 ms
T-Wave Blanking Interval	130; 150; 200; 300; 400; 500 ms	150 ms	150 ms

A.1.3 Demographic parameters and available counters

Table 7. Required demographics parameters

Parameter	Editable values
First Name	Confirm or edit the patient's first name as you would like it to appear in the patient's record.
Last Name	Confirm or edit the patient's last name as you would like it to appear in the patient's record.
Date of Birth	Confirm or edit the patient's date of birth from the picker. This setting is used to calculate the nominal Tachy Detection Interval setting.
Gender	Confirm or edit the patient's gender from the drop menu.
Phone Number	Confirm or edit the patient's phone number.

Table 8. Optional patient demographics information

Parameter	Editable values
Address	Confirm or edit the patient's address.
City	Confirm or edit the city where the patient lives.
State/Region	Confirm or edit the state or region where the patient lives.
Postal Code	Confirm or edit the patient's postal code.
Country	Confirm or edit the patient's country of residence.
Patient ID	Confirm or edit the patient's ID number from the patient ID card

Table 9. Available episode counters[a]

Counter
Symptom (patient-activated episodes)
Tachy

Table 9. Available episode counters[a] (continued)

Counter
Pause
Brady
AT
AF
Time in AT/AF
PVCs (% beats)

[a] The episode counters are maintained for the current patient session and the lifetime of the device. Lifetime counters are only available on the Episode Counters report.

A.2 LINQ II ICM technical specifications

A.2.1 Device specifications

Table 10. Physical characteristics

Parameter	Value
Volume	◈1.4 cm^3
Mass	◈3.4 g
Dimensions H x W x D	◈45.1 mm x ◈8.0 mm x ◈4.2 mm
Surface area of device electrode	◈16.0 mm^2
Distance between the electrodes, centroid-to-centroid	◈40 mm

The ◈ symbol indicates a nominal value for that parameter.

Table 11. Device identification

Parameter	Value
Device identification code	Serial Number prefix “RLB” The device manufacturer and model can be identified by the Serial Number displayed when the implanted device is interrogated with the clinician app. Serial Number prefix “RLB” indicates that the interrogated device is a Medtronic LINQ II Model LNQ22 ICM. To view the Serial Number, select the Patient icon in the clinician app.
Device X-ray image	An X-ray image of the implanted device can be used to identify that a patient has a LINQ II device (typically implanted in the left chest area). See *Figure 24*.

Figure 24. Front and side view X-ray images of an implanted LINQ II device

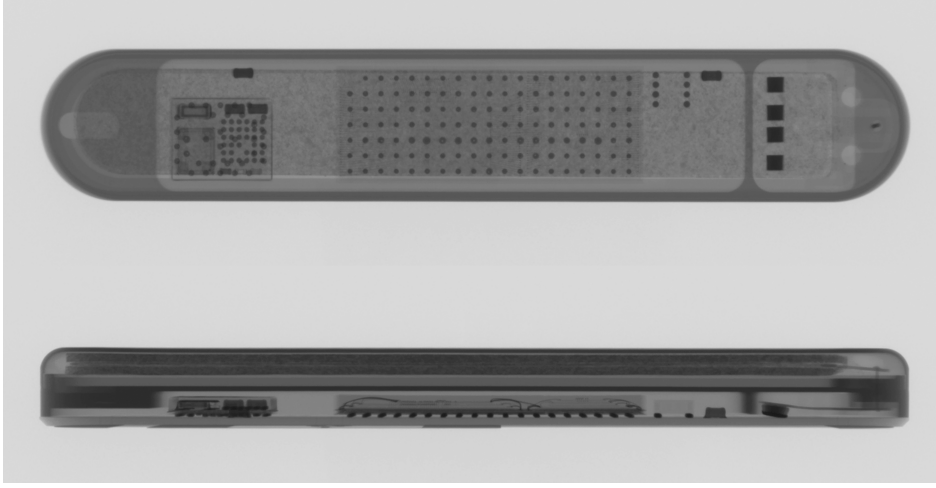


Table 12. Device materials in contact with human tissue

Parameter	Value
Device	Titanium, sapphire
Electrodes	Titanium nitride
Coating	Parylene

Table 13. Insertion tools materials in contact with human tissue

Parameter	Value
Incision tool	Polycarbonate, stainless steel
Insertion tools	Polycarbonate

A.2.2 Battery specifications

Table 14. Battery characteristics

Parameter	Value
Manufacturer	Medtronic
Model/type	LINQ II
Chemistry	Lithium anode Silver vanadium oxide (SVO) and fluorinated carbon (CFx) cathode

A.2.2.1 Projected longevity

When Mobile App Optimization is disabled for the life of the device, the projected longevity of the LINQ II ICM is 4.5 years. When Mobile App Optimization is enabled for the life of the device, the projected longevity is 2.5 years. By default, Mobile App Optimization is disabled for each Reason for Monitoring.

Table 15. The following table shows the estimated longevity of the device if Mobile App Optimization was initially enabled but is now being disabled.

Length of time with Mobile App Optimization enabled	Estimated longevity remaining if Mobile App Optimization is disabled
1 year	2.7 years
2 years	0.9 years

Table 16. The following table shows the estimated longevity of the device if Mobile App Optimization was initially disabled but is now being enabled.

Length of time with Mobile App Optimization disabled	Estimated longevity remaining if Mobile App Optimization is enabled
1 year	1.9 years
2 years	1.4 years
3 years	0.8 years
4 years	0.3 years

Note: The maximum shelf-storage time of 18 months reduces battery longevity by approximately 10%.

These longevity projections are based on the following usage scenario:

- An average of 1 auto-detected episode per day
- An average of 1 patient-activated episode per month
- A shelf-storage time of 6 months or less between device manufacture and insertion
- PVC Detection enabled

A.2.3 Algorithm performance data

Atrial fibrillation detection algorithm – *Table 17* shows episode-detection performance data for the LINQ II AF detection algorithm. *Table 18* shows episode-duration performance data for the algorithm.

Data from the Reveal LINQ Usability Study was used to test the LINQ II AF detection algorithm's performance. The study enrolled 151 patients; 83.4% had a history of AF and 16% had a history of atrial flutter. AF ablation or AF management was the indication provided for 81% of the patients. Recorded data was excluded if it was incomplete or uninterpretable, resulting in a final data set of ECG recordings from 138 patients, out of which 108 true AF episodes were observed in 37 patients[2,3].

Table 17. Episode-detection performance metrics for the AF detection algorithm

	Gross	Patient Average	GEE (95% confidence bound)[a]
Sensitivity	97.2%	99.7%	94.2% (94.1% - 94.2%)
Positive predictive value	84.9%	95.3%	95.1% (83.2% - 98.7%)

[a] Generalized Estimating Equation (GEE) estimates and the 95% confidence bound are shown to adjust for multiple episodes per subject. An exchangeable correlation structure was utilized in the GEE model to account for multiple observations per subject.

Table 18. Duration-detection performance metrics for the AF detection algorithm

	Gross	Patient Average
Sensitivity	98.9%	96.7%
Specificity	99.8%	99.8%

[2] Pürerfellner H, et al. Adapting detection sensitivity based on evidence of irregular sinus arrhythmia. *Europace*. 2018 Nov 1;20(FI_3):f321-f328.

[3] Sanders P, et al. Performance of a new AF detection algorithm in a miniaturized insertablecardiac monitor: results from the Reveal LINQ Usability Study. *Heart Rhythm*. 2016;13:1425–1430.

Table 18. Duration-detection performance metrics for the AF detection algorithm (continued)

	Gross	Patient Average
Positive predictive value	99.0%	95.4%
Negative predictive value	99.8%	98.8%

Pause detection algorithm – *Table 19* shows performance data for the LINQ II pause detection algorithm. Reveal LINQ data was used to test the algorithm's performance[5]. The data was taken from the de-identified Medtronic CareLink data warehouse.

An independent non-development validation set was also created. It comprised 1222 device-detected pause episodes from 90 consecutive patients with unexplained syncope who had been implanted with Reveal LINQ devices without TruRhythm. Of these 1222 episodes, 194 episodes from 33 patients were true asystole episodes; 1028 episodes from 70 patients were inappropriate episode detections.

Table 19. Performance metrics for the pause detection algorithm

	Gross	Patient Average	GEE (95% confidence bound)[a]
Relative sensitivity[b]	96.4%	96.0%	94.6% (87.2% - 97.8%)
Positive predictive value	59.6%	41.6%	41.6% (31.1% - 53.0%)

[a] Generalized Estimating Equation (GEE) estimates and the 95% confidence bound are shown to adjust for multiple episodes per subject. An exchangeable correlation structure was utilized in the GEE model to account for multiple episodes per subject.
[b] Compared to the Reveal LINQ algorithm

Bradycardia detection algorithm – *Table 20* shows performance data for the LINQ II bradycardia detection algorithm. Reveal LINQ data from 663 consecutive Reveal LINQ devices implanted in patients with palpitations was used to test the algorithm's performance[4]. The data was taken from the de-identified Medtronic CareLink data warehouse. Stored device episodes collected over 12 months were adjudicated and run through the enhanced bradycardia algorithm.

[4] Passman RS et al. Development and validation of a dual sensing scheme to improve accuracy of bradycardia and pause detection in an insertable cardiac monitor. *Heart Rhythm*. 2017;14(7):1016–1023.

Table 20. Performance metrics for the bradycardia detection algorithm

	Gross	Patient Average	GEE (95% confidence bound)[a]
Relative sensitivity[b]	98.3%	94.6%	97.7% (96.0% - 98.7%)
Positive predictive value[c]	96.5%	85.8%	86.9% (79.3% - 92.0%)

[a] Generalized Estimating Equation (GEE) estimates and the 95% confidence bound are shown to adjust for multiple episodes per subject. An exchangeable correlation structure was utilized in the GEE model to account for multiple episodes per subject.
[b] Compared to the Reveal LINQ without Dual Sense algorithm.
[c] Using the Reveal LINQ Dual Sense algorithm approved for use with Reveal LINQ with TruRhythm.

PVC detection algorithm – *Table 21* shows performance data for the LINQ II PVC detection algorithm. Reveal XT data was used to test the algorithm's performance. The PVC detection algorithm was evaluated with real-world clinical data from the de-identified Medtronic CareLink data warehouse[5]. An independent validation data set comprised 787 episodes from 134 patients who were implanted with Reveal LINQ ICMs for unexplained syncope.

Table 21. Performance metrics for the PVC detection algorithm

	Gross	Patient Average	GEE (95% confidence bound)[a]
Sensitivity	75.2%	69.9%	72.5% (65.8% - 78.3%)
Specificity	99.6%	99.4%	99.4% (99.2% - 99.6%)
Positive predictive value	75.9%	40.6%	40.6% (33.6% - 48.0%)
Negative predictive value	99.5%	99.6%	99.6% (99.3% - 99.7%)

[a] Generalized Estimating Equation (GEE) estimates and the 95% confidence bound are shown to adjust for multiple episodes per subject. An exchangeable correlation structure was utilized in the GEE model to account for multiple episodes per subject.

[5] Medtronic data on file.

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