Reveal LINQ™ LNQ11

Insertable Cardiac Monitor and Patient Assistant PA96000

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1 Introduction

This manual describes the insertion, operation, and intended use of the Medtronic Reveal LINQ Model LNQ11 Insertable Cardiac Monitor (ICM).

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

To enter Reveal LINQ ICM patient information, to program device data collection and arrhythmia detection parameters, and to interrogate the device, you need to use a Medtronic programmer and associated instructions. If you are using the Medtronic CareLink Model 2090 programmer or the CareLink Encore programmer, use this manual for programming instructions specific to the Reveal LINQ ICM and also use the general programmer interface instructions provided with your programmer. If you are using a programmer that supports the Reveal LINQ ICM other than the Medtronic CareLink Model 2090 programmer or the CareLink Encore programmer, use the instructions provided with that programmer. The programming instructions provided in this manual use these conventions:

- The names of on-screen buttons are shown within brackets. For example, “After entering all Patient Information, select the [PROGRAM] button”.

- Navigation paths are provided for screens with programmable parameters. For example, “To enter patient first name, select Patient > Patient Details > First Name”.

1.1 Product literature

Before inserting the device, it is recommended that you take the following actions:

- Read the product literature for information about prescribing, inserting, and using the device and for information about conducting a patient follow-up session.

- The Reveal LINQ ICM and PA96000 Clinician Manual provides an overview of the system and associated product literature. It also provides instructions on inserting the ICM, programming the device, monitoring the patient’s condition, and viewing the collected data; product specifications; precautions; and instructions for patient use of the Patient Assistant model PA96000. The Clinician Manual and other associated product literature are provided in your device package or are available electronically at www.medtronic.com/manuals.

- Discuss the device and insertion procedure with the patient and any other interested parties, and give them any patient information materials packaged with the device, including the Reveal ICM Device Identification Card.

The following documents provide additional information about the device and associated components:
Explanation of symbols – This insert defines the symbols that appear on the device package.

Reveal LINQ Medical Procedure and EMI Precautions Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on Reveal LINQ patients. The manual also provides patient education information related to sources of electromagnetic interference (EMI) in the home, at work, and in other environments. As appropriate, Medtronic recommends that you provide this information to other health care professionals who treat patients who have this device.

Reveal LINQ Insertable Cardiac Monitor MRI Technical Manual – This manual provides warnings, precautions, and guidance for health care professionals who intend to perform magnetic resonance imaging (MRI) scans on patients who have this device.

CareLink Model 2090 Programmer Reference Guide – This manual is a guide for setting up and using the CareLink Model 2090 programmer.

CareLink Encore Model 29901 Programmer Reference Guide – This manual is a guide for setting up and using the CareLink Encore programmer.

CareLink Encore Model 29901 Clinician Manual Supplement – This manual highlights the major differences between the CareLink Encore programmer and the CareLink 2090 programmer.

Technical manuals are available at www.medtronic.com/manuals.

1.2 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.
1.3 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.
2 System overview

2.1 System description
The Medtronic Reveal LINQ 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 activation.

The device is designed to record the occurrence of an arrhythmia in a patient automatically. Arrhythmias may be classified as tachyarrhythmia, bradyarrhythmia, pause, atrial tachyarrhythmia, or atrial fibrillation. In addition, while experiencing or immediately after a symptomatic event, the patient can activate the recording of cardiac information in the ICM.

The Reveal LINQ system consists of 4 main components.

**Medtronic Reveal LINQ Model LNQ11 Insertable Cardiac Monitor (ICM)** – The Reveal LINQ ICM is a small, leadless device that is inserted under the skin, in the chest. The device has 2 electrodes that monitor the patient's subcutaneous ECG continuously. The device memory can store up to 27 min of ECG recordings from automatically detected arrhythmias and up to 30 min of ECG recordings from patient-activated episodes. The system provides 3 options for segmenting the patient-activated episode storage: up to four 7.5 min recordings, up to three 10 min recordings, or up to two 15 min recordings. Arrhythmia detection parameters are set to pending automatically, based on patient information entered on the programmer during pre-insertion device setup: the patient's Date of Birth and the clinician’s Reason for Monitoring the patient. Arrhythmia detection parameters can also be programmed manually by the clinician.

The Reveal LINQ 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 Reveal LINQ ICM MRI Technical Manual.

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

**Medtronic programmer** – The programmer is used to set up the device to detect arrhythmias. It also allows you to view, save, or print the information stored by the device.

**Medtronic Patient Assistant Model PA96000** – The Patient Assistant is a hand-held, battery-operated telemetry device that enables the patient to activate the recording of cardiac information in the Reveal LINQ 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 patient monitor** – The Medtronic patient monitor can gather information automatically from the patient’s inserted device and communicates the information to the patient’s physician over a cellular telephone connection to the Medtronic CareLink Network. This daily wireless audit transmission is scheduled by the clinic and is usually set for a time when the patient is asleep. At other times, if requested to do so by their physician or clinic, the patient can use their monitor to perform a manual device interrogation to gather information from their inserted device and communicate it to their physician.

Patient interaction with their monitor includes the initial setup procedure, performing physician-requested data gathering, and responding to physician-specified notifications on the monitor screen. Refer to the literature that is included with the Medtronic patient monitor for connection and usage information.

### 2.2 Indications and contraindications

#### 2.2.1 Indications

The Reveal LINQ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated 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

The device has not been tested specifically for pediatric use.

#### 2.2.2 Contraindications

There are no known contraindications for the insertion of the Reveal LINQ 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 Avoiding effects of electrical interference in the home, work, and other environments

The Reveal LINQ ICM is designed to monitor and store ECG data and to receive radio signals from the programming head and the Patient Assistant. Since the device communicates with the programming head and Patient Assistant by means of radio frequency telemetry, 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 2.3.3). 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 electrical equipment such as cell phones, household appliances, electrical machine shop tools, microwave ovens, spark-ignited internal combustion engines, radio frequency transmitting systems, or microwave frequency transmitting systems. Although most interference is filtered out, there are some signals in the environment that have similar characteristics to the signals emitted by the programming head or the Patient Assistant, or which could otherwise interfere with device function.

For information to share with Reveal LINQ 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 Reveal LINQ Medical Procedure and EMI Precautions Manual for Health Care Professionals.

2.3.2 Warnings, precautions, and guidance for clinicians performing medical procedures on Reveal LINQ 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, always interrogate the device and save data before the procedure, and check device function afterwards.

**Magnetic Resonance Imaging (MRI)** – Although the Reveal LINQ 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 *Reveal LINQ Insertable Cardiac Monitor 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 Reveal LINQ patient can undergo an MRI scan and for precautions related to the procedure, see the *Reveal LINQ Insertable Cardiac Monitor MRI Technical Manual*. 
For information about additional medical procedures that are likely to be sources of interference or to be hazardous, see the Medtronic Medical Procedure and EMI Precautions 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.

2.3.3 Device reset

Certain conditions (including, but not limited, to device malfunction, EMI, electrocautery, or external defibrillation) may cause an electrical reset of the Reveal LINQ 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. You will be informed that a reset has occurred by a pop-up message that appears at the start of the next patient session. Always interrogate the device at the beginning and end of each patient session to document the programmed status. If a reset does occur, interrogate the device, reprogram the desired parameters after the source of interference is removed, and notify your Medtronic representative.

2.4 Pre-insertion considerations

Before inserting the Reveal LINQ ICM, consider whether mammography exams, breast implants, or concomitant device implants may be 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 Reveal LINQ device between the plates could cause tissue trauma, vascular trauma, or pain, or 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 device manipulation or angular stress that a mammography procedure can cause, allow sufficient time for the Reveal LINQ device pocket and incision to heal before performing a mammography procedure.

Breast implants – Breast implant or augmentation refers to the surgical procedure that changes the appearance of the breasts with liquid or gel-filled implants. Due to the implant locations for the Reveal LINQ device and their closeness to the breast, caution should be maintained during tunneling and insertion of the device to not damage the breast implant.

Concomitant cardiac monitor and cardiac pacemaker or defibrillator device implants – To minimize the possibility of the programming head 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 programming head
directly above an implanted device not manufactured by Medtronic while the Reveal LINQ application is active.

**Note:** If the Reveal LINQ 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.

### 2.5 Potential adverse events

Potential adverse events include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.
3 Inserting the Reveal LINQ Insertable Cardiac Monitor

3.1 Handling and disposal

Shipping and transport – The recommended transient temperature limits for shipping and transport are –18 °C (0 °F) to 55 °C (131 °F). Ship and transport the package in a dry place away from direct sunlight.

Storage – The recommended temperature limits for storage are 5 °C (41 °F) to 40 °C (104 °F). Store the package in a dry place away from direct sunlight.

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

Handling – Normal handling is unlikely to damage the device, but do not insert it under the following circumstances:

- The device has been dropped on a hard surface from a height of 30 cm (12 in) or more, which could damage device components.
- Upon inspection, the storage package appears to have been pierced, damaged, warped, or otherwise altered, which could render the device or insertion tools nonsterile.

Use by date – Before opening the sterile pack, check the “Use by” date shown on the package. Do not insert the device after the indicated “Use by” date. Inserting the device after the “Use by” date could adversely affect device longevity.

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. Removing the device from the pocket, reloading the device in the insertion tool, and repositioning the device in a new pocket is acceptable if the device and the insertion tools are retained in the sterile field. The device and insertion tools cannot be resterilized once removed from the sterile field. For additional information, see Section 3.2.7, “Repositioning the Reveal LINQ Insertable Cardiac Monitor”, page 24.
**Insertion tool disposal** – Dispose of the single-use insertion tools according to local environmental requirements.

**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.

- 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 reinset 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.

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### 3.2 Preparation, positioning and insertion

The following figure shows the Reveal LINQ insertion tool components. The Reveal LINQ ICM is preloaded in the insertion tool.

**Figure 1.** Reveal LINQ insertion tool components
3.2.1 Pre-insertion device setup

To enter Reveal LINQ ICM patient information, to program device data collection and arrhythmia detection parameters, and to interrogate the device, you need to use a Medtronic programmer and associated instructions. If you are using the Medtronic CareLink Model 2090 programmer or the CareLink Encore programmer, use this manual for programming instructions specific to the Reveal LINQ ICM and also use the general programmer interface instructions provided with your programmer. If you are using a programmer that supports the Reveal LINQ ICM other than the Medtronic CareLink Model 2090 programmer or the CareLink Encore programmer, use the instructions provided with that programmer.

Medtronic recommends that you set up the Reveal LINQ ICM with required patient information while it is still in the sterile package, a short time before the patient is prepared for the insertion procedure. Patient information is included in some reports and, if the patient has a Medtronic patient monitor, it is used for Medtronic CareLink Network patient enrollment.

To set up the device for insertion, take the following steps:

1. Turn on the programmer, position the programming head on the label side of the tray containing the device, and press the [Find Patient...] button.

2. After Reveal LINQ FullView software Model SW026 is started and telemetry is established, you will be prompted to enter patient information. If the Patient Information screen is not displayed, select Patient > Patient Information.

3. On the Patient Information screen, enter Implant Date, Patient Details, Physician Details, and patient History. Required fields are marked with an asterisk.

**Note:** The patient Date of Birth enables arrhythmia detection parameters to be set to pending automatically.

4. After entering patient information, select the [PROGRAM] button.

5. The Device Data Collection window opens automatically after Patient Information is programmed. Select the [OK] button without entering the information. Medtronic recommends that Device Data Collection information be entered after the device is inserted.

6. Select the Quick Look icon on the programmer screen and verify that the Battery Status is Good. If the Battery Status is not Good, select a different Reveal LINQ ICM to insert, if one is available. Contact Medtronic Technical Services (1-800-505-4636), your local Medtronic representative, or contact Medtronic at the appropriate telephone number or address listed on the back cover regarding the devices.

7. Insert the device immediately or at a later time:
   - If you plan to insert the device immediately, move the programming head away from the tray containing the device and proceed with the insertion procedure. You can reestablish telemetry with the device after it is inserted.
• If you plan to insert the device at a later time, select the [End Session] button and move the programming head away from the tray containing the device. You can start a new programming session with the device after it is inserted.

**Note:** If you have activated data collection in a device that you do not intend to insert at the present time, contact your Medtronic representative for assistance. Putting the device back on the shelf will cause false diagnostics to be collected, some of which cannot be cleared from the device.

### 3.2.2 Recommended insertion locations

The device may be inserted in either of 2 recommended locations without conducting pre-insertion surface mapping to determine if the location provides reliable signal quality and R-wave amplitude sensing (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 required for all insertion locations. For more information, see Section 3.2.6, “Programming device Reason for Monitoring and verifying sensing performance”, page 22.

**Best** – The device is positioned 45 degrees relative to the sternum over the 4th 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 4th 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.
3.2.3 Optional insertion locations

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

**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 5th 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 *Reveal LINQ 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.
3.2.4 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 or with a Medtronic programmer.

- 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 when viewed on the programmer or a minimum of 0.3 mV when viewed on a strip chart (see Figure 8).
- 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.

3.2.5 Inserting the Reveal LINQ Insertable Cardiac Monitor

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**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. Pull 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 fills 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).
3.2.6 Programming device Reason for Monitoring and verifying sensing performance

Before closing the incision, program Device Data Collection parameters and verify that the device sensing performance is acceptable.

1. Place a sterile programming head sleeve over the Medtronic programming head, or use a sterilized programming head. Move the Medtronic programming head over the device. 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, interrogate the device.

2. From the Quick Look screen, select Params > Device Data Collection….

3. Select Reason for Monitoring. The Reason for Monitoring the patient enables arrhythmia detection parameters to be set to pending automatically.

4. Enter Device Date/Time. For the daily wireless audit transmission to take place at the intended time, Device Date/Time must be programmed to the patient’s time zone.
5. Select Wireless Transmission Time. Set the hour of the daily wireless audit transmission to a time when the patient will be within 2 m of their MyCareLink Patient Monitor, if they have one. This is usually a time when the patient is asleep.

**Note:** Daily wireless audit transmission begins after the first successful device interrogation by the patient’s MyCareLink Patient Monitor. If the patient is not using a monitor, the device daily wireless audit is not turned on and the device must be interrogated during an in-clinic patient session.

6. Select Wireless Data Priority. Wireless Data Priority defines what data (Brady, Pause, or Tachy) is given priority in the daily wireless audit transmission. This priority is set to pending automatically when you enter patient Date of Birth and Reason for Monitoring. It can also be set manually if preferred.

**Note:** AT/AF data is prioritized separately by the device and does not need to be set by the clinician.

7. Verify that Device Data Collection is set to On. If not, select Device Data Collection > On and then select the [OK] button.

8. Examine the R-wave amplitude when the live rhythm is displayed.

**Figure 8. R-wave amplitude**

- The R-wave amplitude should be a minimum of 0.2 mV when viewed on the programmer or a minimum of 0.3 mV when viewed on a strip chart (see Figure 8).
- The peak-to-peak R-wave amplitude should be at least twice the peak T-wave or P-wave amplitude, whichever is greater.

9. If device sensing performance requirements are met, complete programming of remaining parameters, if any, and select the [PROGRAM] button.

10. Close the incision using your preferred method. If deemed necessary, use the suture hole on the device header to secure the device to the underlying tissue.

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.
3.2.7 Repositioning the Reveal LINQ 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.

**Note:** Medtronic recommends conducting surface mapping to determine a new insertion location that provides reliable signal quality and R-wave amplitude sensing. See Section 3.2.4 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 suture hole is closest to the opening and the header electrode is facing down. See Figure 9. In this orientation, the Reveal LINQ device name is facing up and the Medtronic name is facing down.
3. Slide the device back into the insertion tool body.

**Figure 9.** 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 3.2.5 for information about the insertion procedure. Some steps do not apply if you are reusing the previous incision.

3.3 Completing the insertion procedure

After successfully inserting the device, clear data registered during the insertion procedure, verify that Patient Information is complete and correct, confirm device data collection and sensing parameters, and instruct the patient in using the Reveal LINQ system.
For instructions for using the programmer and parameter setup, see Chapter 4, “Using the programmer”, page 27.

### 3.3.1 Clear data registered during insertion

If data collection was inadvertently activated before the insertion procedure, the device may record arrhythmic episodes (bradycardia or pause, for example). After insertion it is therefore important to clear all recorded episodes to prevent erroneous data from being stored in the device memory. Be aware that this action only clears the recorded episodes. For this reason, Cardiac Compass Trends may show inaccurate information on the day of insertion.

To clear data registered during device insertion, select Params > Device Data Collection… > [Clear Data…] > [Clear Data] > [Clear Now].

### 3.3.2 Patient information

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

From the Quick Look screen, select Patient > Patient Information.

On the Patient Information screen, verify Implant Date, Patient Details, Physician Details, and History.

**Note:** For arrhythmia detection parameters to be set to pending automatically, you must enter patient Date of Birth.

### 3.3.3 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 adjust the criteria for detecting arrhythmia episodes and the sensing parameters to optimize R-wave sensing:

- To adjust arrhythmia episode detection criteria, select Params > Detection.
- To optimize R-wave sensing, select Params > Additional Settings > Sensing…

For additional information about detection and sensing parameters, see Chapter 6, “Setting up sensing and arrhythmia detection”, page 63.
3.3.4 Patient instruction

**Patient Assistant** – Give the patient the Patient Assistant Model PA96000 Patient Manual, and the PA96000 Quick Reference Card. Instruct the patient on how to use the Patient Assistant, explaining which symptoms he or she should record.

The Patient Assistant PA96000 Quick Reference Card includes abbreviated instructions on using the Patient Assistant that can be carried in a purse or wallet.

For more information on instructing patients to use and troubleshoot the Patient Assistant, clinics can refer to Appendix B, “Using the Patient Assistant PA96000”, page 95.

**Reveal LINQ Insertable Cardiac Monitor Patient Manual** – Give the patient the *Reveal LINQ Insertable Cardiac Monitor Patient Manual*. This manual provides an overview of the cardiac monitor, precautions regarding items that may temporarily interfere with the data collection abilities of the ICM, and precautions regarding certain types of medical procedures.

**Medtronic patient monitor** – To enable stored device data to be transmitted to the physician or clinic via cellular telephone connection, give the patient the Medtronic patient monitor. Explain the function of the patient monitor and instruct the patient to set up the monitor according to the patient manual provided with the patient monitor. Provide additional instructions if necessary. For example, consider advising the patient to consult with you before traveling for an extended period of time outside their home time zone because you may need to adjust device transmission time for the time zone differences by using the Device Date/Time programmable parameter.

**Reveal ICM Device Identification Card** – This card is included in the device package. Complete the card and provide it to the patient. The patient can carry the card in a purse or wallet so that it is always available. The card is especially helpful if the device sets off a metal detector or security system. When completing the 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 programmer

4.1 Starting a patient follow-up session

You can use the Medtronic programmer to program the device settings and read out information collected by the device. For general information about the programmer and programming head, see the Medtronic CareLink Programmer Reference Guide or Medtronic CareLink Encore Programmer Reference Guide and, if necessary, the Medtronic CareLink Encore 29901 Clinician Manual Supplement. If you are not using either the Medtronic CareLink Model 2090 programmer or the CareLink Encore programmer, for information about how to use the programmer user interface, refer to the information provided with your Medtronic programmer.

**Note:** The red Emergency button on the programmer is intended for use with therapeutic devices and does not work for the Reveal LINQ diagnostic device.

4.1.1 How to interrogate the device

Turn on the programmer. Place the programming head over the device and press [Find Patient…]. The programmer interrogates data from the Reveal LINQ device memory. You then see the Reveal LINQ screen, which initially displays the most important information about the status of the device and data collected since the last patient session. If you want information about episodes from previous data collection periods, interrogate the device again by pressing [Interrogate…] and select the All option.

**Notes:**

- The first time you interrogate a new Reveal LINQ ICM, you see the Patient Information window. This enables you to enter patient information, including Date of Birth and Reason for Monitoring information that is used to set detection parameters to pending automatically.
- Start a new session for each patient. The programmer collects and stores data on a session-by-session basis.
**How to improve telemetry** – When the programming head is placed over the device and telemetry is established, the amber light on the programming head turns off, and one or more of the green indicator lights on the programming head illuminate. You can find the optimal position for the programming head by moving it around the inserted device until the greatest number of green lights illuminate. Position the programming head so at least 2 of the green lights illuminate to ensure proper telemetry has been established. If the programming head slides off the patient, the session does not terminate. Place the programming head back over the device to resume programming or interrogating the device.

**4.1.2 How to end a patient follow-up session**

Before you end a patient session, you can review or print a list of changes made during the current session. Select the Session icon and choose “Changes This Session”.

1. To end the patient session, press [End Session…].
2. To save the session data to a diskette or USB flash drive, select the [Save To Media...] option (see Section 4.4).

3. Confirm that you want to end the session by pressing [End Now]. To continue with the current programming session press [Cancel].

### 4.2 Programming parameters

The Parameters window allows you to view and program parameters that control data collection. All parameters that can be programmed have “active fields” in the window. Active fields, which appear as unshaded boxes next to parameter names, respond to the touch pen. Some active fields pertain to only one parameter, while other fields provide access to groups of parameters. If a parameter cannot be programmed, no active field appears next to its name.

When you change a parameter value, the new value is shown as pending with a dashed rectangle as its border. You can change several parameter values together. The values remain pending until you press [PROGRAM]. All the pending values are then programmed to device memory. If you want to cancel all pending values in the current window, press [Undo Pending].

The symbols that may appear in the parameters windows are explained in Table 1.
Table 1. Parameter programming symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Nominal symbol" /></td>
<td><strong>Nominal</strong> – Indicates the Medtronic nominal value for a parameter.</td>
</tr>
<tr>
<td><img src="image" alt="Programmed symbol" /></td>
<td><strong>Programmed</strong> – Indicates the value currently programmed in the device for a parameter.</td>
</tr>
<tr>
<td><img src="image" alt="Information symbol" /></td>
<td><strong>Information</strong> – Indicates additional information associated with the selected values. You can program these values, but the programmer provides information for you to consider when you press the icon.</td>
</tr>
<tr>
<td><img src="image" alt="Warning symbol" /></td>
<td><strong>Warning</strong> – Indicates that a value has an associated warning about possible undesirable interaction with other parameters, or a caution about using an option. You can still program this value, but the programmer will display the warning. Press the icon for an explanation of the warning or caution.</td>
</tr>
<tr>
<td><img src="image" alt="Interlock symbol" /></td>
<td><strong>Interlock</strong> – Appears when one selected value is incompatible with another value. You cannot program the device to this setting until you resolve the parameter interlock.</td>
</tr>
</tbody>
</table>

4.2.1 How to access parameters

**How to access parameters with 2 values** – If a parameter has only 2 values (for example, Off or On), touch the parameter field to switch to the alternate value.

**How to access parameters with more than 2 values** – If a parameter has more than 2 values, a window opens when you touch the parameter field and displays a set of values available for that parameter. Select a new value from this window. This new value is displayed as a pending value, and the window showing available values for that parameter closes. Also, you can press [Close] to close the window without changing the original value of the parameter (see Figure 12).
**Figure 12. Accessing parameters with more than 2 values**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Sensing...</th>
<th>Device Data Collection...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom</td>
<td>Three 10 min Episodes</td>
<td>On</td>
</tr>
</tbody>
</table>

### How to access a group of related parameters

If a parameter name is followed by 3 dots (…), selecting the parameter field opens a secondary window displaying a group of related parameter fields. Select new values for the desired secondary parameters. New values display as pending values. Press [OK] to close the secondary parameters window. You return to the main Parameters window, where you can press [PROGRAM] to save the new values to the device memory (see Figure 13).

**Figure 13. Accessing a group of related parameters**
4.2.2 How to save a set of parameter values

With the exception of Tachy detection parameters, sets of parameter values can be saved on the programmer hard drive and retrieved either in the current patient session or in subsequent patient sessions. This allows you to save and quickly access a custom set of parameter values for a particular clinical situation. For example, you may want to save a set of parameter values for an initial device insertion setting, or for a specific patient condition.

You can retrieve a previously saved custom parameter set, a parameter set of Medtronic nominal values, or the parameter values that were in effect at initial interrogation.

Tachy detection parameters are not included in the saved parameter set because they are based on patient Date of Birth.

Note: If you only turned on Device Data Collection at the start of the session, no initial interrogation values are available.

How to save a set of parameter values – When you have entered the desired values in the Parameters window, press [Save…] to open the Parameter Set Name window. Type a name for the parameter set and press [OK]. A saved parameter set can include both programmed and pending values.

How to retrieve a set of parameter values – In the Parameters window, press [Get…] to open the Get Parameter Set window. Select the parameter set you want to retrieve and press [Set Pending]. The parameter values in this set are displayed in the Parameters window. You can make any changes required before pressing [PROGRAM] to save the values to device memory.

If you want to remove an unneeded parameter set from the list in the Get Parameter Set window, select it and press [Delete].

You can select the following options from the Get Parameter Set window:

- Medtronic Nominals: the values chosen as nominal values for the device by Medtronic. The Medtronic Nominals cannot be customized or deleted.
- Initial Interrogation Values: the permanently programmed parameter values that were in effect at the first interrogation of the device during the patient session.
- Custom sets of values: all custom sets of values that were saved previously.
### 4.3 Entering patient information

The Reveal LINQ ICM stores patient-related information that you can view and print during a patient session. This information is typically programmed into the device a short time before the patient is prepared for device insertion, but it can be revised at any time. The patient's name and ID and the device serial number are printed on all full-size and strip chart reports. In addition, if the patient is using a Medtronic patient monitor, Patient Information is provided to the Medtronic CareLink Network automatically.

Select the Patient icon to see the Patient Information window. Select each text field to enter, change, or view its content.

**Figure 14. Patient Information window**

![Patient Information window](image)

**Table 2. Description of patient information**

<table>
<thead>
<tr>
<th>Information field</th>
<th>Description and required action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Date</td>
<td>Enter the date the device was inserted (implanted).</td>
</tr>
<tr>
<td>Serial Number (not selectable)</td>
<td>Displays the serial number of the inserted device.¹</td>
</tr>
<tr>
<td>Patient Details…</td>
<td></td>
</tr>
<tr>
<td>Name, Phone, and Address</td>
<td>Enter the patient's name, phone number, and address (Secondary Phone and Address 2 are optional).</td>
</tr>
<tr>
<td>ID</td>
<td>Enter the patient ID (optional, up to 15 characters).</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>Select the patient’s date of birth.²</td>
</tr>
<tr>
<td>Gender</td>
<td>Select the patient’s gender or “None Selected”.</td>
</tr>
</tbody>
</table>
Table 2. Description of patient information (continued)

<table>
<thead>
<tr>
<th>Information field</th>
<th>Description and required action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Details…</td>
<td>Select the physician’s name and phone number from a list. If they are not listed, add them to the list and select them.</td>
</tr>
<tr>
<td>Physician Phone</td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>Select the hospital name from a list. If it is not listed, add it to the list and select it.</td>
</tr>
<tr>
<td>Physician Specialty</td>
<td>Select the physician’s specialty from the list or select Other.</td>
</tr>
<tr>
<td>Implant Facility</td>
<td>Select the device insertion (implant) facility from the list or select Other.</td>
</tr>
<tr>
<td>History</td>
<td>Enter notes about the patient’s history (optional, up to 80 characters).</td>
</tr>
</tbody>
</table>

a The Serial Number prefix “RLA” indicates that the interrogated device is a Medtronic Reveal LINQ Model LNQ11 Insertable Cardiac Monitor. For additional information about identifying an implanted device, see Section A.2.
b The patient’s Date of Birth enables arrhythmia detection parameters to be set to pending automatically.
c To add new information to a list, press [Modify List…] and [Add…]. Type in your addition and press [OK].

4.4 Saving and retrieving session data

You can save device data from a patient session to a diskette or USB flash drive. Later, while no patient session is in progress, you can use the Read From Media application on the programmer to retrieve and view the saved data and to print reports.

Session data includes device data at interrogation and all parameter values that were in effect at the moment the session data was saved.

Caution: Do not modify the session data file in other applications because the file will become unreadable to the Read From Media application. Medtronic is not responsible for the inappropriate use of data saved to a diskette or USB flash drive.

To ensure the integrity and security of patient health information, it is recommended that you use USB flash drives and diskettes that are dedicated to storing Medtronic CareLink programmer data only.

4.4.1 How to save session data to a diskette or USB flash drive

To save session data to a diskette or USB flash drive, select Session icon > Save To Media… > Save, or select End Session… > Save To Media… > Save.

A diskette must be a formatted, IBM-compatible, 90 mm (3.5 inch) diskette.
The programmer saves the data it interrogated at the start of the current programmer session. If you want to save a record of all the information from the device, including previous data collection periods, press [Interrogate…] and select the All option from the Interrogate window. The All option provides more data for analysis if an issue needs to be investigated. The programmer automatically generates a file name using the current date and time.

Cautions:

- Make sure only virus-free diskettes and USB flash drives are used!
- Keep the programming head and any other electromagnetic devices away from diskettes. These devices may erase data stored on the diskettes.
- If you save data to a diskette that is corrupt or is not IBM-formatted or to a corrupt USB flash drive, the programmer may become unresponsive. If this occurs, remove the diskette or USB flash drive and turn the programmer off and on again. Normal operation should resume.

4.4.2 How to retrieve session data from a diskette or USB device

If you are in a patient session, end the session. Start a Read From Media session by selecting the “Reveal LINQ – Read From Media” option from the Select Model screen. Then, select [Start]. When the Read From Media – Warning window opens, press [OK]. To retrieve the session data, select Open File… > select the file for the patient and session > Open File.

After the programmer has read data that was saved during a patient session, it presents the information in a read-only view, similar to the way it presents real-time information during a patient session. In this read-only mode, no ECG traces can be shown because this is not a real-time session. The ECG window is replaced with the device model name and the words “Read From Media”.

In the read-only mode, the programmer allows you to view the saved data, print reports, and display all programmed parameter values. In the read-only mode, you cannot change the contents of the file on the diskette or USB flash drive.

To end the Read From Media session, press [End Session…].

4.5 Printing reports

The programmer provides flexibility in managing system report printing. You can:

- print reports on the programmer’s strip printer (if available) or on a full-size, external printer.
- set printing preferences to meet your needs.
• print immediately or later from a print queue.
• print an Initial Interrogation Report.
• print a custom selection of reports during a patient session.
• print a summary report for the patient session.
• manage the print queue.
• print segments of a selected ECG.
• print the information that appears in most windows.

4.5.1 Printer selection
You can print a report on the programmer's strip printer (if available) or on a full-size, external printer.

Strip printer – If you print a report on the strip printer, Medtronic recommends that you make a photocopy. The quality of printing on thermal paper diminishes with time.

External printer – For information about setting up an external full-size printer, see the Medtronic CareLink Programmer Reference Guide or Medtronic CareLink Encore Programmer Reference Guide and, if necessary, the Medtronic CareLink Encore 29901 Clinician Manual Supplement. If you are not using either the Medtronic CareLink Model 2090 programmer or the CareLink Encore programmer, for information about how to use the programmer user interface, refer to the information provided with your Medtronic programmer.

4.5.2 How to set general printing preferences
To set general printing preferences, select Reports icon > Preferences… > Printing.

Printing preferences allow you to select print options, such as number of copies, printer type, and whether to print now or later.
Printing preferences are applied automatically whenever you press a [Print…] button. If you prefer to set print preferences each time you print a report, select the check box next to “Pop up these options when any Print button is selected”.

4.5.3 How to set initial interrogation report printing preferences

To set initial interrogation report printing preferences, select Reports icon > Preferences… > Initial Report.

The programmer automatically prints certain reports after the first interrogation in a patient session if you set Initial Report preferences to do so. The reports that print automatically after the first interrogation in a patient session are collectively called the Initial Interrogation Report. The Quick Look Report is always a part of the Initial Interrogation Report. You can also select other reports to print as part of the Initial Interrogation Report.
Select the check box next to “Print Initial Interrogation Report after first interrogation”.

**Printing an Initial Interrogation Report for a patient session that is in progress** – To print an Initial Interrogation Report for a patient session that is in progress, you must first end and restart the patient session. The Initial Interrogation Report prints automatically after interrogation. Initial Report preferences take effect at the start of a new session and remain in effect until you change them and start a new session.

### 4.5.4 How to print reports during a patient session

To print reports during a patient session, select Reports icon > Available Reports...

To print the information that currently appears in a window, select the [Print...] button, if available. Printing can be selected from the Arrhythmia Episodes, Parameters, Patient Information, Quick Look, and Session windows.

From the Available Reports window, you can also print a customized set of reports chosen from the list of available reports.
Figure 17. Available Reports window

Select the reports you want to print. Press [Print Now] for immediate printing, or press [Print Later] to add the print request to the print queue. Reports that are not available for printing are displayed in lighter text.

To choose the number of copies or change the printer, press [Print Options…].

4.5.5 How to print a summary report for the patient session

To print a summary report for the patient session, select Reports icon > Final Report.

You can print a summary report at the end of a patient session. The Session Summary report contains information about the device and battery status, as well as a list of parameters and their current values. The report also shows any parameter values that you have changed during the current session.

4.5.6 How to manage the print queue

To manage the print queue, select Reports icon > Print Queue.

The Print Queue window shows the printing status of reports that you have chosen to print during the patient session. You can print or delete a print job from the queue. A report cannot be deleted if its status is “printing” or “waiting”.

Select the reports you want to print. Press [Print Now] for immediate printing, or press [Print Later] to add the print request to the print queue. Reports that are not available for printing are displayed in lighter text.

To choose the number of copies or change the printer, press [Print Options…].

4.5.5 How to print a summary report for the patient session

To print a summary report for the patient session, select Reports icon > Final Report.

You can print a summary report at the end of a patient session. The Session Summary report contains information about the device and battery status, as well as a list of parameters and their current values. The report also shows any parameter values that you have changed during the current session.

4.5.6 How to manage the print queue

To manage the print queue, select Reports icon > Print Queue.

The Print Queue window shows the printing status of reports that you have chosen to print during the patient session. You can print or delete a print job from the queue. A report cannot be deleted if its status is “printing” or “waiting”.

Select the reports you want to print. Press [Print Now] for immediate printing, or press [Print Later] to add the print request to the print queue. Reports that are not available for printing are displayed in lighter text.

To choose the number of copies or change the printer, press [Print Options…].
“Hold-Later” in the status column indicates that a report is on hold. You can print it from the print queue by pressing [Print]. A Hold-Later status can also mean that the printing of a report was interrupted by the start of a recording or that the printer is not operational (because it is out of paper, for example).

**Note:** The Print Queue window lists any reports held during the current patient session. If you end the patient session, any reports currently printing or pending in the print queue will be canceled.

### 4.5.7 Printing segments of the selected ECG

To help you locate portions of the currently selected ECG that may be of interest, the system enables you to print the currently displayed ECG segment plus 30 s, 60 s, or 120 s ECG segments from immediately before the episode you are currently viewing.

To print an ECG segment from the currently selected episode, select Print… > Selected Episode > Displayed ECG Include prior (0 s, 30 s, 60 s, or 120 s).

**Figure 18.** Print options window

### 4.6 Working with the ECG window

The ECG window displays ECG traces and a Marker Channel with annotations on the programmer screen. You can view real-time ECGs, freeze ECGs, record real-time ECGs, and recall any saved ECG strips before ending a patient session.
By default, the ECG window appears in partial view. You can expand this window to its full size by selecting the small square button in the upper-right corner of the window. In the expanded view, you can rearrange the ECGs or superimpose the Marker Channel annotations over an ECG. Simply press the touch pen on the ECG or Marker Channel trace and drag it to the desired position.

**Note:** When the Marker Channel is superimposed on an ECG trace, or an ECG trace is superimposed on another, only one of the trace names appears. Tap the name of the superimposed trace to reveal the hidden name.

### 4.6.1 Viewing real-time ECGs

The ECG window can display up to 4 real-time ECG traces during a patient session. The ECG Reveal trace displays the subcutaneous ECG signal from the Reveal LINQ device. ECG Lead I, II, and III traces can display surface ECG signals that are detected using skin electrodes attached to the patient. The ECG cable attached to these electrodes must be connected to the programmer. The window displays the current R-wave amplitude in the upper left corner.

**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.

**How to adjust the ECG with the button bar** – You can use the adjustment button bar to change the appearance of the ECGs.
**Figure 19. The ECG adjustment button bar**

1. The up arrow increases the size of the ECG.
2. The normalize button automatically resizes the ECG.
3. The down arrow decreases the size of the ECG.
4. Use the source button to choose which ECG to display.
5. The print selection button enables or disables the ECG for printing. You can select up to 2 ECGs for printing.

---

**How to adjust the ECG with the Adjust window** – You can use the Adjust window to make additional changes to the ECG display.
Figure 20. The ECG Adjust window

1 [Adjust…] displays the full screen ECG window and the Adjust window.
2 Adjust the size, source, and print selection options for each ECG.
3 The color options change the color of a trace.
4 The Clipping option truncates the tops and bottoms of traces at a 22 mm boundary. ECG Filter changes the bandwidth of traces to improve the clarity of the displayed ECG in the presence of interference. (Select the check box to enable (0.5 to 40 Hz) or disable (0.05 to 100 Hz) this option.) Show Artifacts displays pacing artifacts superimposed over ECGs.
5 Sweep Speed (12.5; 25; 50; 100 mm/s).
6 [Normalize] equalizes the spacing between the ECG traces and resizes each trace to its default setting.
7 The calibrate button adds a reference signal to the analog output (if available), the screen, and the real-time strip recorder (if available).
8 When you have finished, press [OK].

How to interpret Marker Channel annotations – Marker Channel annotations appear as 1 or 2 characters above or below the Marker Channel baseline. These annotations indicate events such as sensing and detection. The Marker Channel can be displayed as a separate trace, or superimposed over one of the ECGs.
<table>
<thead>
<tr>
<th>Marker</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>VS</td>
<td>Ventricular sense</td>
</tr>
<tr>
<td>AD</td>
<td>Asystole detection (marks the first event in a detected pause episode)</td>
</tr>
<tr>
<td>B</td>
<td>Brady sense</td>
</tr>
<tr>
<td>BD</td>
<td>Brady detection (marks the first event in a detected brady episode)</td>
</tr>
<tr>
<td>TS</td>
<td>VT (Tachy) sense</td>
</tr>
<tr>
<td>TD</td>
<td>VT (Tachy) detection (marks the first event in a detected VT episode) (below the baseline)</td>
</tr>
<tr>
<td>FS</td>
<td>FVT (Tachy) sense</td>
</tr>
<tr>
<td>FD</td>
<td>FVT (Tachy) detection (marks the first event in a detected FVT episode) (below the baseline)</td>
</tr>
<tr>
<td>TD</td>
<td>AT detection (marks the end of at least 2 min of atrial arrhythmia) (above the baseline)</td>
</tr>
<tr>
<td>FD</td>
<td>AF detection (marks the end of at least 2 min of atrial arrhythmia) (above the baseline)</td>
</tr>
<tr>
<td>Δ</td>
<td>Patient-activated symptom (only marked in a stored ECG recording)</td>
</tr>
<tr>
<td>S</td>
<td>Ignored event^a</td>
</tr>
</tbody>
</table>
Table 3. Marker Channel annotations (continued)

<table>
<thead>
<tr>
<th>Marker</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Asystole rejection (marks a pause that is determined to not be asystole)</td>
</tr>
<tr>
<td>F</td>
<td>FVT (Tachy) rejection (marks an event that would have been detected as FVT but was rejected due to noise)</td>
</tr>
</tbody>
</table>

a An event that ends a noise interval.

Notes:

- Any interruption in telemetry with the Reveal LINQ device may result in missing marker annotations on the ECG display.
- Changing the value of any sensing parameter may result in a missed marker on the ECG display when you press [PROGRAM].

4.6.2 How to freeze real-time ECG traces

You can freeze the last 15 s of all real-time ECG traces that are displayed in the expanded ECG window. Press [Freeze] at the top of the tool palette to capture the previous 15 s of ECG trace signals and to open the frozen strip viewing window.

You can use controls in the frozen strip viewing window to perform the following functions:

- View earlier or later portions of the strip by using the horizontal scroll bar.
- See frozen strips not visible in the window by using the vertical scroll bar.
- Measure a time interval with on-screen calipers.
Figure 21. Interpreting the frozen strip viewing window

1 [Freeze] freezes a real-time ECG and displays it in the frozen strip viewing window.
2 [Adjust...] opens the Adjust window with display options for the strip viewer.
3 Adjustment button bar allows you to normalize the trace, resize the trace, and change the source.
4 Arrow buttons move the on-screen calipers to show the beginning and the end of a time interval.
5 Calipers measurement: the time interval between the on-screen calipers.
6 [Strips...] opens a list of other frozen strips.
7 [Save] saves the on-screen frozen strip.
8 [Delete] deletes the on-screen frozen strip (if it was saved).
9 [Print...] prints the on-screen frozen strip.
10 [Close] closes the frozen strip viewing window.

Note: Saved ECG strips are not included in session data saved to a USB flash drive or to a diskette.

4.6.3 How to recall a saved ECG

Before ending the patient session, you can recall any ECG strip collected and saved during the session to view, adjust, and print the strip.
To view a previously collected ECG, press the [Strips...] button in the ECG control panel or the [Strips...] button in the strip viewer. Select a strip and press [Open]. The selected strip appears in the strip viewing window.
5 Monitoring the patient’s condition

5.1 Using the Reveal LINQ 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 Reveal LINQ 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 through the day. You can use this information to build a diagnostic picture of the patient’s condition.

The Reveal LINQ ICM can be implanted for several months or years, enabling you to monitor the patient’s condition continuously, without interfering with his or her daily activities.

Information recorded in the Reveal LINQ 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, to assess whether medical treatment is necessary or should be adjusted.
- Monitor the patient’s ventricular rhythm during atrial arrhythmia episodes, to assess whether a rate control therapy is having the desired effect or needs to be adapted.
- Record incidents of symptomatic events to correlate symptoms with cardiac rhythm and aid diagnosis.
- Continuously record other patient information that may help you to assess the patient’s condition, such as heart rate variability or patient activity.

When you have turned on data collection, the device detects arrhythmia episodes automatically based on detection criteria related to the patient’s age and the programmed Reason for Monitoring, or based on manually programmed detection parameters. (see Section A.1). You can also use the device together with the Patient Assistant by instructing the patient to record cardiac information while experiencing or immediately after a symptomatic event.

5.1.1 Recording episodes automatically

The Reveal LINQ ICM continuously senses the patient’s subcutaneous ECG, and analyzes the timing of ventricular events to detect possible episodes of arrhythmia.
The Reveal LINQ ICM can classify the following 4 types of arrhythmia episodes:

**Tachy (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 or 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 threshold.

**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 Reveal LINQ 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 6.4).

**Reveal LINQ episode data and ECG storage** – The device stores episode data and ECGs for each episode type where Detection is programmed On:

- Arrhythmia episode data is stored in an episode log. This includes up to 30 episodes each for brady, pause, AT, and AF, and up to 60 episodes for tachy. When the log is full, data from the most recent episode may overwrite the oldest stored episode data of that type.

- ECGs, recorded before and during an episode, can be stored in device memory. For each AT/AF episode the device stores an ECG of the first 2 min of the episode. For each tachy, brady, or pause episode, the ECG recording consists of 30 s of ECG before the episode and up to 27 s of ECG before the end of the episode.

- The Reveal LINQ ICM reserves 27 min of ECG storage per day for automatically detected episodes. When the available memory for automatically detected episodes is full, a new ECG recording will overwrite the oldest stored ECG recording, provided that a minimum number of episodes of each type remain in memory.
Notes:

- If AT/AF Recording Threshold is programmed to Only Longest Episode, an AT/AF episode of 10 min or greater duration is required to store an episode log and ECG. Until the device is interrogated, each subsequent AT/AF episode that is of greater duration overwrites the previously recorded shorter episode.

- After the device has accumulated 27 min of ECG storage on any given day, new episodes will not be stored if 3 episodes of a type (tachy, brady, pause, or AT) or 4 episodes of a type (AF) have been stored. On the next day, the device will resume recording episodes, overwriting the oldest episodes, until that day’s maximum of 27 min of accumulated episodes has been reached.

- If detection for an arrhythmia type is turned off after episode data for that type has already been stored, up to 3 episodes each for brady, tachy, and pause, and 1 episode for AT/AF are retained in device memory. These episodes are not subject to being overwritten unless detection is later turned back on for the particular arrhythmia type.

5.1.2 Recording episodes using the Patient Assistant

When the patient experiences symptoms, he or she can hold the Patient Assistant over the implanted Reveal LINQ ICM and press the record symptoms button to record a symptom episode. In this way, the patient manually activates the storage of an ECG.

The Reveal LINQ ICM can store up to 10 patient-activated (symptom) episodes in the episode log. When the log is full, data from the most recent episode will overwrite the oldest stored episode data.

The Reveal LINQ ICM reserves up to 30 min of ECG storage for ECG recordings of either the 4 most recent 7.5 min episodes, 3 most recent 10 min episodes, or 2 most recent 15 min episodes in the episode log. Each stored symptom episode contains 6.5 min, 9 min, or 14 min, respectively, of ECG recorded before the activation and 1 min after the activation. After the device has accumulated 30 min of ECG storage on any given day, new patient-activated episodes will not be stored. On the next day, the device will resume recording patient-activated episodes, overwriting the oldest episodes, until that day’s maximum of 30 min of accumulated patient-activated episodes has been reached.

5.2 Conducting a patient follow-up session

After device insertion, it is important to schedule regular patient follow-up sessions to read collected data and, if necessary, to adjust sensing and episode detection parameters.
Medtronic recommends that you schedule the first patient follow-up session 3 months after device insertion. The frequency of subsequent sessions depends on the patient's condition and the number of arrhythmia episodes that occur. To ensure that you do not miss episode information by overwriting of older episodes, schedule a session before the device memory is full. You can also instruct the patient to contact you when he or she has activated the Patient Assistant to record symptoms.

Perform the following checks and adjustments with the programmer during a follow-up patient session. For information on interrogating the device, see Section 4.1.

**Check battery status** – Check the device battery status in the initial Quick Look window.

- If the battery status is “RRT” (Recommended Replacement Time) the device is nearing the end of its battery life. From that date onward, the Reveal LINQ device is projected to operate for a minimum of 30 days, at which time the End of Service (EOS) status will be displayed.
- The device may be replaced or removed once the battery status reaches EOS.

**Notes:**
- If a battery status of RRT is observed through Medtronic CareLink Network remote monitoring, it is recommended that a manual device interrogation be scheduled prior to the device reaching EOS.
- When the device reaches EOS, daily wireless audits are discontinued.

**Read collected data** – The initial Quick Look window shows the AT/AF burden and the number of episodes recorded since the last patient session. You can look at detailed information about individual arrhythmia episodes, including ECG recordings if available. Printed reports help you to correlate episode data with other patient information. Using these diagnostic tools, you can follow developments in the patient's clinical condition over the short and long-term. For more information, see Chapter 7.

**Save collected data** – When the device memory reserved for automatically detected episodes and patient-activated episodes is full, details of the oldest episodes will be overwritten. Medtronic recommends that you save the data collected in each session to a USB flash drive or to a diskette. You can then look at the data later on the programmer (see Section 4.4).

**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 period. For more information about optimizing sensing, see Section 6.3.

**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 6.4.

If you are only interested in certain types of episodes, you can switch Detection off 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.

5.3 Monitoring the patient through the Medtronic CareLink Network

If the patient is enrolled in the Medtronic CareLink Network, alerts and diagnostic reports based on automatic daily wireless audits and manual device interrogations are available through a secure Internet website.

5.3.1 Transmitting patient and device information to the Medtronic CareLink Network

Daily wireless audits – The device transmits summary information each day to the patient’s Medtronic patient monitor. The automatic transmission starts at a time that has been programmed during device insertion or at a subsequent patient follow-up session. It is usually scheduled for midnight, when the patient is likely to be asleep and within 2 m of their monitor. The transmission is repeated several times over the course of 5 hours to improve the chance of transmission success. If a transmission is unsuccessful during this time period, the device waits until the next day’s transmission start time to retransmit. When the daily wireless audit data is successfully received by the monitor, it is transmitted via cellular telephone connection to the Medtronic CareLink Network.

Each daily wireless audit transmission includes episode counters, 10 s of the current ECG, 30 s of the ECG and rate plot for 1 episode (based on wireless episode data priority) if any new episodes have been detected, 10 s of the longest AF episode, up to 8 min of rate plot from a symptom (patient-activated) episode, battery status, ventricular Rate Histograms, and the previous 14 days of Cardiac Compass trend data.

Note: A single episode may be retransmitted for up to 14 days if no new events have occurred. In such a case, only the initial instance of the episode is reported.

Manual device interrogation – If instructed to do so, the patient can use their Medtronic patient monitor to interrogate their device and transmit complete information to the Medtronic CareLink Network.
5.3.2 Monitoring the patient and the device

Monitoring the patient through the Medtronic CareLink Network enables both exception-based and schedule-based care.

**CareAlert Notifications** – When the daily wireless audit transmission is received by the Medtronic CareLink Network, a Medtronic CareAlert Notification is generated automatically if CareAlert criteria are met and CareAlert Notifications are configured on the Medtronic CareLink Network website. For information about configuring CareAlert Notifications, see Section 5.4, “Medtronic CareAlerts and notifications”, page 55, and the Medtronic CareLink Network website.

**Event Report** – When the daily wireless audit transmission is received by the Medtronic CareLink Network, an Event Report is generated automatically if CareAlert criteria are met. It includes a 30 s ECG summary of 1 event and a list of other findings for the day. Trends (Cardiac Compass, Histograms, and Longest AF) information for AF monitoring can optionally be configured for inclusion in this report.

**Summary Report** – A Summary Report is generated automatically every 31 days. It includes a summary of all event information from the daily wireless audit transmissions that have occurred since the previous Summary Report, plus Trends (Cardiac Compass, Histograms, and Longest AF) information.

**Full Report** – A Full Report is generated automatically when the patient uses their Medtronic patient monitor to interrogate their device and transmit complete information to the Medtronic CareLink Network. The report includes all available ECGs since the last transmission from the patient, plus Trends (Cardiac Compass, Histograms, and Longest AF) information.

**Current Report** – Current Reports are clinician-generated, as needed, from the Transmission Details section of the Medtronic CareLink Network website. The Current Report selections available for each transmission include Quick Look, Trends, Episodes, and Comments Reports.

**Note:** For additional information about Report Preferences, see the Medtronic CareLink Network website.
5.3.3 Managing device functions and CareAlert monitoring

Device programming and CareAlert Notification configuration 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.

- If programming adjustments to device data collection, R-wave sensing, episode detection, symptomatic episode duration, or reason for monitoring parameters are required, they are made on the programmer when the patient is in the clinic for a follow-up session. For additional information, see Chapter 6, “Setting up sensing and arrhythmia detection”, page 63.

- If configuration adjustments to CareAlert monitoring and Notifications are required, they are made on the Medtronic CareLink Network website. For additional information, see Section 5.4, “Medtronic CareAlerts and notifications”, page 55, and the Medtronic CareLink Network website.

Battery status check – Battery status is configured automatically as a CareAlert Notification on the CareLink Network website. If desired, it can be configured as a Red or Yellow Alert condition. In addition, you can check the battery status in Patient Details on the CareLink Network website or in a Reveal LINQ 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 Reveal LINQ device is projected to operate for a minimum of 30 days, at which time the End of Service (EOS) status will be displayed.

- The device may be replaced or removed once the battery status reaches EOS.

Notes:

- It is recommended that a manual device interrogation be scheduled prior to the device reaching EOS. Manual device interrogation can be scheduled on the CareLink Network website. Actual device interrogation is then performed by the patient, at clinic instruction.

- When the device reaches EOS, daily wireless audits are discontinued.

Patient travel considerations – If the patient plans to travel outside their home time zone for an extended period of time, daily wireless audit transmissions and manual device interrogation transmissions to the Medtronic CareLink Network may still be available:

- The patient must take their Medtronic patient monitor with them.
- The patient must take their Patient Assistant with them.
- Cellular telephone service must be available at the patient’s travel destination. Encourage the patient to contact Medtronic to confirm availability of coverage.
• Schedule an in-office patient session just before the patient travels so that Wireless Transmission Time can be programmed to best fit their travel destination time zone by using the Device Date/Time programmable parameter.

• Schedule an in-office patient session just after the patient travels to reset Wireless Transmission Time to the patient’s home time zone.

### 5.4 Medtronic CareAlerts 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 Reveal LINQ 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 and the patient is using a Medtronic patient monitor, the system responds in the following ways:

- **Wireless signal and network transmission of event summary information**
  
The device sends a daily wireless audit transmission to the patient’s monitor. This transmission includes a summary of clinical management and system performance events that have occurred in the previous 24 hours. Upon receiving the signal, the monitor transmits the data to the Medtronic CareLink Network over a cellular telephone connection. For additional information about the daily wireless audit transmissions, see Section 5.3, “Monitoring the patient through the Medtronic CareLink Network”, page 52.

- **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, email message, and live phone call can also be configured.

  **Note:** If the patient’s monitor has not had communication with the Medtronic CareLink Network for 14 days, the patient is added to the Disconnected Monitors list on the Medtronic CareLink Network website so that the patient can be contacted, if desired.

- **Patient notifications**
  
  Each time data is successfully transmitted from the patient’s monitor to the Medtronic CareLink Network, a confirmation message is sent back to the patient’s monitor. This message indicates that the transmission was successfully received by the Medtronic CareLink Network and includes the date of the transmission.
If an alert notification is configured for AT/AF Daily Burden > Threshold, the Medtronic CareLink Network website can optionally be configured to also trigger a patient notification. The notification is sent to the patient’s monitor and includes the display of the clinic’s contact phone number for the patient to call.

### 5.4.1 Clinical management alerts

#### 5.4.1.1 Clinician-defined alerts

Reveal LINQ clinical management alerts are available on the Medtronic CareLink Network website, based on data transmitted from the device to the Medtronic patient monitor and then on to the Medtronic CareLink Network. 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**

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom (Patient Activated) Episode</td>
<td>This alert indicates that the patient pressed the Patient Assistant button to store a symptom episode.</td>
</tr>
<tr>
<td>Symptom (Patient Activated) + Detected Episode</td>
<td>This alert indicates that an auto-detected episode was detected within 20 min before the patient pressed the Patient Assistant button.</td>
</tr>
<tr>
<td>Tachy Episode</td>
<td>This alert indicates that a Tachy episode was detected when the sensed rate exceeded the programmed Tachy Detection Rate.</td>
</tr>
<tr>
<td>Pause Episode</td>
<td>This alert indicates that a Pause episode was detected when the time between sensed events exceeded the programmed Pause Detection Duration.</td>
</tr>
<tr>
<td>Brady Episode</td>
<td>This alert indicates that a Brady episode was detected when the sensed rate fell below the programmed Brady Detection Rate.</td>
</tr>
<tr>
<td>AF Episode</td>
<td>This alert indicates that an AF episode was detected.</td>
</tr>
<tr>
<td>AT Episode</td>
<td>This alert indicates that an AT episode was detected.</td>
</tr>
<tr>
<td>AT/AF Daily Burden &gt; Threshold</td>
<td>This alert indicates that the patient's cumulative time in AT/AF exceeded the threshold configured on the Medtronic CareLink Network website.</td>
</tr>
<tr>
<td>Average Ventricular Rate during AT/AF &gt; Threshold</td>
<td>This alert indicates that the patient's average ventricular rate during AT/AF exceeded the threshold configured on the Medtronic CareLink Network website.</td>
</tr>
</tbody>
</table>

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.

The configurable average ventricular Rate during AT/AF values are 90, 100, 110, 120, 130, 140 and 150 bpm.
Maximum Episode Count Met
This alert indicates that the maximum number of auto-detected episodes is stored on the device. If additional episode(s) are auto-detected, the oldest stored auto-detected episode(s) may be overwritten.

Maximum Symptom (Patient Activated) Count Met
This alert indicates that the maximum number of Symptom (Patient Activated) episodes is stored on the device. If additional episode(s) are patient-activated, the oldest stored patient-activated episode(s) may be overwritten.

Low Battery Voltage Recommended Replacement Timea
This alert indicates that the daily automatic battery voltage measurement has reached the recommended replacement time (RRT) voltage.

Electrical Reseta
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 Medtronic 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.

5.4.2 Operation of Medtronic CareAlert Monitoring and Medtronic CareAlert Notifications

The device sends a daily wireless audit transmission to the patient’s monitor. This transmission starts at a time you program, usually when the patient is expected to be asleep, and is repeated several times over the course of 5 hours to improve the chance of transmission success. If a transmission is unsuccessful during this time period, the device waits until the next day’s transmission start time to retransmit.

Note: If detection is programmed off for an arrhythmia type (Tachy, Pause, Brady, or AT/AF), the episode data for that arrhythmia type are not transmitted to the Medtronic CareLink Network. Without episode data, CareAlert Notifications for that arrhythmia type are not available on the Medtronic CareLink Network website, even if CareAlert notifications are configured.

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.
**Figure 22.** Process for transmitting Medtronic CareAlert Notifications

1. The device transmits a daily wireless audit signal to the patient's monitor.
2. The monitor sends the data to a secure server via a cellular telephone connection.
3. In the Medtronic CareLink Network configuration, the clinician can choose to be notified by one or more of the following methods: website, voice message, pager, text message, email message, and live call. The clinician can then consult the Medtronic CareLink Network website for detailed information.

### 5.4.3 Operation of Medtronic CareAlert patient notification

Individual patient notification is configured on the Medtronic CareLink Network website by selecting a patient and then overriding the clinic’s Alert Groups to customize notification for that patient.

Patient notification is available for AT/AF Daily Burden alerts. You can enable the patient to be notified when their cumulative Time in AT/AF exceeds the threshold you configured on the Medtronic CareLink Network website. If enabled, the clinic’s contact phone number is displayed on the patient's monitor for them to call.

Patient confirmation is provided for successful data transmission from their monitor to the Medtronic CareLink Network. This includes automatic transmission of the daily wireless audit data and transmission of physician-requested device interrogation data. If enabled, the date that the device data was successfully transmitted is displayed on the patient's monitor, helping to assure them that the system is working properly and that it is not necessary for them to call their clinic.

For additional information, see Section 5.4.4.4.

#### 5.4.3.1 Instructing the patient

It is important that patients understand that they may see an alert notification on their monitor screen. When they see this notification, they should follow the instructions you have provided, including calling the clinic at the number displayed on the monitor.
When you give the patient the Medtronic patient monitor, instruct them about the monitor display as follows:

1. The monitor screens are shown and described in the Reveal LINQ Patient Manual.
2. If the patient sees the orange notification screen on the monitor (see Figure 23), they should call the displayed phone number so that you can determine if they experienced a heart-related event.

**Figure 23.** Medtronic patient monitor notification screen

3. If the patient sees the blue confirmation screen on the monitor (see Figure 24), it’s an indication that the data from their cardiac monitor was successfully transmitted to the Medtronic CareLink Network as of the indicated date. The patient does not need to contact their clinic.

**Figure 24.** Medtronic patient monitor confirmation screen
5.4.4 Configuring alerts

When planning Medtronic CareAlerts for the Reveal LINQ 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 with the Medtronic programmer during device insertion or when the patient is in the clinic for a follow-up session.

**Note**: The Medtronic CareLink Network descriptions and screen image are subject to change and to clinic customization and are provided for reference only. See the Medtronic CareLink Network website for additional details regarding actual screens and reports for your clinic and your Reveal LINQ patients.

**Figure 25. Medtronic CareLink Network website**
5.4.4.1 Alert groups

Alert conditions can be prioritized by configurable alert group settings: Red Alerts, Yellow Alerts, Website-Only Alerts, and No Alerts. For each alert condition you can configure clinic alert groups that apply to all patients. 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 4. CareLink alert group features

<table>
<thead>
<tr>
<th>Alert features</th>
<th>Red Alert</th>
<th>Yellow Alert</th>
<th>Website-only Alert</th>
<th>No Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td>A color-coded website notification in the Alerts column on the alert transmission list</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>A website notification in the Alerts column on the alert transmission list</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>A description in the Event Summary column of the transmission list</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>Voice message</td>
<td>Optional</td>
<td>Optional</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pager</td>
<td>Optional</td>
<td>Optional</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Text message</td>
<td>Optional</td>
<td>Optional</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Email message</td>
<td>Optional</td>
<td>Optional</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Auto-generated event reports</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>-</td>
</tr>
</tbody>
</table>

5.4.4.2 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 > Display Alert Group Conditions for Reveal LINQ Wireless Devices.

2. For each Clinical Management Alert listed, select Red Alerts, Yellow Alerts, Website-only Alerts, or No Alerts.

3. For AT/AF Daily Burden, enter the threshold for cumulative Time in AT/AF.

4. For Average Ventricular Rate during AT/AF, enter the threshold for cumulative Time in AT/AF above a specified average rate.
5.4.4.3 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 Method 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.

5.4.4.4 Configuring patient-specific alerts

1. To configure patient-specific CareAlert condition groups on the Medtronic CareLink Network website, select MANAGE MY PATIENTS > patient name > CareAlert Notification > Override Clinic's Alert Groups and customize for this patient.

2. For each Clinical Management Alert listed, select Red Alerts, Yellow Alerts, or Website-only Alerts.

   Note: Patient Notification is not available if No Alerts is selected.

3. For AT/AF Daily Burden, enter the threshold for cumulative Time in AT/AF.

4. If appropriate for the patient, select Enable notification on patient home monitor; also, enter a phone number for the patient to call when notified.

5. For Average Ventricular Rate during AT/AF, enter the threshold for cumulative Time in AT/AF above a specified average rate.
6 Setting up sensing and arrhythmia detection

6.1 Introduction

This chapter describes how the Reveal LINQ 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.

6.2 Setting arrhythmia detection parameters automatically

The Reveal LINQ 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.

The selections for Reason for Monitoring include Syncope, Palpitations, Seizures, Ventricular Tachycardia, Suspected AF, AF Ablation, AF Management, Cryptogenic Stroke, and Other. These selections control parameter settings for AF detection sensitivity, Ectopy rejection, AT/AF recording threshold, and Wireless data priority. 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 Table 9.

For information about setting sensing and arrhythmia detection parameters manually, see Section 6.4.
6.3 Adjusting R-wave sensing

The automatic detection of arrhythmias by the Reveal LINQ ICM is based on R-wave sensing. For proper functioning of the device, it is important that all R-waves are reliably sensed, while other events like P-waves and T-waves are not marked as ventricular events. The Reveal LINQ 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 Reveal LINQ 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 26).

**Figure 26.** Auto-adjusting the sensing threshold

1. After a sensed R-wave, a programmable blanking period 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 Sensing Threshold Decay Delay period.
3. After the Sensing Threshold Decay Delay period 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 period 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 Reveal LINQ ICM uses blanking to reject noise due to EMI and myopotentials. The device starts a programmable blanking period with each R-wave. An event that occurs during the blanking period is not used for automatic episode detection.

6.3.1 Optimizing sensing

To optimize sensing:

- Select Params > Sensing > Sensitivity
- Select Params > Sensing > Blank after Sense
- Select Params > Sensing > Sensing Threshold Decay Delay

You can optimize the sensing of R-waves by adjusting the parameters Sensitivity, Blank after Sense, and Sensing Threshold Decay Delay.

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 – Select the length of the blanking period that is started after the detection of a sensed R-wave. During the blanking period, sensing is inhibited to prevent the multiple sensing of the R-wave due to a broad QRS complex. If the blanking period is programmed too long, tachy events may be blanked.
Sensing Threshold Decay Delay – Select the length of the period 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 Sensing Threshold Decay Delay at or longer than the Blank after Sense period. If the Blank after Sense period is programmed to an interval longer than the Sensing Threshold Decay Delay, the Sensing Threshold Decay Delay will be made equal to the Blank after Sense interval. If the Reveal LINQ device is placing a VS marker under the T-wave (commonly called T-wave oversensing), extending the Sensing Threshold Decay Delay may overcome the issue.

6.3.2 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 blanking period or the sensing threshold decay delay 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 sensing threshold decay delay may resolve oversensing. Extending the blanking period may also be used to resolve oversensing if extending the sensing threshold decay delay is unsuccessful.

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

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

6.3.3 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.
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.

6.4 Setting up automatic episode detection

The automatic detection and ECG storage of tachy (FVT and VT), pause (asystole), brady, and AF episodes is turned on when you activate Device Data Collection. An automatically detected episode starts when it 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 6.2, “Setting arrhythmia detection parameters automatically”, page 63.
Figure 27. Parameters window

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Detection</th>
<th>Interval (Rate)</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom</td>
<td>Tachy</td>
<td>340 ms (176 bpm)</td>
<td>16 beats</td>
</tr>
<tr>
<td></td>
<td>Brady</td>
<td>2000 ms (30 bpm)</td>
<td>4 beats</td>
</tr>
<tr>
<td></td>
<td>Pause</td>
<td></td>
<td>3 sec</td>
</tr>
<tr>
<td></td>
<td>AT/AF...</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Settings

- Sensing...
- Device Data Collection...

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.

6.4.1 Tachy episodes

To program tachy detection:

- Select Params > Tachy Detection
- Select Params > Tachy Interval (Rate)
- Select Params > Tachy Duration

You can adjust the criteria by which an increased ventricular rhythm is classified as a Tachy (ventricular tachyarrhythmia) episode.
The Reveal LINQ 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 ventricular tachyarrhythmia 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.

### 6.4.2 Brady episodes

To program brady detection:

- Select Params > Brady Detection
- Select Params > Brady Interval (Rate)
- Select Params > Brady Duration

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.

### 6.4.3 Pause (asystole) episodes

To program pause detection:

- Select Params > Pause Detection
- Select Params > Pause Duration

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, with one exception: if the sensitivity is programmed to 0.025 mV, 0.035 mV, or 0.050 mV and the sensed R-waves preceding the suspected pause are very low amplitude, the suspected pause episode is rejected because of probable undersensing. 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.

### 6.4.4 AT/AF episodes

To program AT/AF detection:

- Select Params > AT/AF… > AT/AF Detection
- Select Params > AT/AF… > Type
- Select Params > AT/AF… > AF Detection
- Select Params > AT/AF… > Ectopy Rejection
- Select Params > AT/AF… > AT/AF Recording Threshold
- Select Params > AT/AF… > Detect Very Regular AT Rhythms (when AT Detection is on)
The Reveal LINQ 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 28, Figure 29, and Figure 30). 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 Reveal LINQ 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 28.** Lorenz plot of an AF episode
Figure 29. Lorenz plot of an AT episode

Figure 30. Lorenz plot of sinus rhythm
In the Lorenz plots the difference between 2 consecutive R-wave intervals ($\Delta R_{RN}$) is plotted on the horizontal axis. The preceding R-wave interval difference ($\Delta R_{RN-1}$) 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 Reveal LINQ 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 Reveal LINQ device will store information and an ECG recording for both types of episodes.
7 Viewing the collected data

7.1 Introduction

The Medtronic CareLink programmer offers several ways to view and analyze the collected data in the Reveal LINQ device. This may help you to monitor the patient’s condition. You can assess the episode data and ECGs recorded since device insertion and since the last patient session, and you can follow 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 7.2). 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 7.3). 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 7.4). Rate histograms provide information about the heart rates recorded between patient sessions, and can be used to monitor the effectiveness of rate or rhythm control therapies (see Section 7.5).

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).

7.1.1 How to clear collected data

You can clear all diagnostic data stored in the device, except for the long-term Cardiac Compass data, and the lifetime episode counters. It is not normally necessary to clear the collected data because the oldest stored episodes are overwritten by newer episodes when the device memory is full.

To clear device data, select Params > Device Data Collection > Clear Data… > Clear Data > Clear Now.

7.2 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 Reveal LINQ ICM.

The Quick Look window provides battery information, a summary of the arrhythmia episodes recorded since the last follow-up appointment, parameter settings, and system observations. These observations inform you about important events. The Quick Look window includes links to more detailed information about the recorded episodes, parameter settings, and observations.
You can print the information presented in the Quick Look window in the Quick Look report.

**Note:** Quick Look shows information collected since the last patient session. Programming changes made during the current session may also affect the Quick Look observations.

### 7.2.1 Information provided by Quick Look

The Quick Look window automatically appears after the patient session is started\(^1\). You can also access the Quick Look window through the Quick Look icon. In the first patient session after device insertion, the Parameters window is displayed first to enable activation of Device Data Collection.

The Quick Look window shows information in 4 sections. Links via the [>>] button take you to more detailed information.

**Figure 31. Quick Look window**

<table>
<thead>
<tr>
<th>Battery Status</th>
<th>Parameter Settings</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Episodes (3)</strong></td>
<td><strong>Detection</strong></td>
<td><strong>Observations (0)</strong></td>
</tr>
<tr>
<td>Symptom</td>
<td>Interval (Rate)</td>
<td>Duration</td>
</tr>
<tr>
<td>Tachy</td>
<td>On</td>
<td>16 beats</td>
</tr>
<tr>
<td>Pause</td>
<td>On</td>
<td>3 sec</td>
</tr>
<tr>
<td>Brady</td>
<td>On</td>
<td>4 beats</td>
</tr>
<tr>
<td>AT</td>
<td>300 ms (200 bpm)</td>
<td>Only Longest Episode</td>
</tr>
<tr>
<td>AF</td>
<td>2000 ms (30 bpm)</td>
<td></td>
</tr>
</tbody>
</table>

**Battery status** – At the start of the patient session, the programmer presents 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.

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\(^1\) During pre-insertion device setup, the Patient Information screen is displayed first to enable patient information entry. This includes Date of Birth and Reason for Monitoring information used to program detection settings automatically. In the first patient session after insertion, the Parameters window opens first to enable activation of Device Data Collection.
Episodes – The arrhythmia episode information shows the number of automatically detected and patient-activated (symptom) episodes since the last patient session. Press [>>] to review details of all arrhythmia episodes. For more information, see Section 7.3. The “% of time AT/AF” information shows the percentage of time that the device detected AT/AF in the period since the last patient session, which can help you to assess the need to initiate or adjust the patient’s rate or rhythm control therapies.

Parameter Settings – The parameter settings show how the automatic recording of arrhythmia episodes is programmed. Press [>>] to review details of the parameter settings.

Quick Look Observations – Observations are based on the analysis of programmed parameters and data collected since the last patient session. If there is more information about an observation, you can press [>>] to look at relevant details.

The following types of observations may occur:

- Device status observations inform you about the status of the Reveal LINQ 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. Conditions that prevent data from being collected effectively are also reported, for example, when the device memory is full.
- Parameter observations warn of any inconsistencies in the programming of device parameters, for example, if a parameter value is still pending and must be programmed.

7.2.2 Printing the Quick Look report

To print the Quick Look report, select Reports > Available Reports… > Quick Look.

The Quick Look report prints the battery information, episode summary, and observations as presented in the Quick Look window. It also prints graphs showing long-term trends in arrhythmias (see Section 7.4).

7.3 Viewing arrhythmia episode data

To view arrhythmia episode data, select Episodes > Arrhythmia Episodes.

The Arrhythmia Episodes window enables you to view summary and detailed data for arrhythmia episodes. The Arrhythmia 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.

You can access the Arrhythmia Episodes window by selecting the Episodes icon or by pressing [>] in the Episodes section of the Quick Look window.

### 7.3.1 Viewing the episode log

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

- 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
Figure 32. Episode log

1 Use the scroll buttons on the right to go through the list of stored episodes.
2 Use the SYMPTOM, Tachy, Pause, Brady, AT, and AF check boxes to control the types of episodes that appear.
3 Use the [Sorted by] drop-down menu to sort the episodes by Date/Time, Type, or Duration.

Notes:

- If an episode starts before the interrogation and is still in progress during the interrogation, the device records “Episode in progress” in the episode text.
- Episodes that occur during a patient follow-up session are not included in the episode records, unless an interrogation is performed after the episode has ended.

7.3.2 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)
Figure 33. Arrhythmia episode record

At follow-up, 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 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 interval plot** – The episode interval plot displays a graph that plots the R-R intervals versus time, and indicates the following information:

- programmed detection intervals (Tachy detection intervals are only shown when a Tachy episode is selected)
- start of episode detection or end of episode detection

**Figure 34. Episode interval plot**

1 Use this option to switch the y-axis between Interval (ms) and Rate (bpm).

**Viewing the episode ECG** – If an ECG is available for this episode, the stored ECG is shown when you select the ECG option.
**Figure 35. Episode ECG**

1. The Marker Channel displays the annotated events.
2. The decision channel displays an annotation if an episode is detected.
3. Use the horizontal scroll bar to view all of the episode ECG data.
4. Use this option to switch the y-axis between Interval (ms) and Rate (bpm).
5. The calibration pulse provides an indication of the amplitudes of the R-waves in the episode.
6. The up arrow increases the size of the ECG. The down arrow decreases the size of the ECG. The normalize button automatically resizes the ECG.

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 5.1.

**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.
7.3.3 Printing episode data

To print episode data:

- Select Reports > Available Reports… > Episode Counters
- Select Reports > Available Reports… > AT/AF Summary
- Select Reports > Available Reports… > Episode List
- Select Reports > Available Reports… > Last Tachy with ECG
- Select Reports > Available Reports… > Last AT/AF with ECG

You can print the data of a selected episode in the episode log by pressing the [Print] button on the screen. More printed reports are available when you select the Reports icon.

**Episode Counters** – The Episode Counters report presents the following information for each type of arrhythmia episode:

- the number of episodes since the last patient session
- the number of episodes since device insertion (Device Lifetime Total)

The report also indicates if the incidence of a certain type of episode has increased or decreased since the last patient session by showing an up or down symbol.
**AT/AF Summary** – The AT/AF summary report gives an overview of the incidence of atrial arrhythmias in the patient. You can assess the AT/AF burden of the patient in the period prior to the last session and since the last session, and investigate how the AT/AF episodes are distributed over the day. The distribution of the duration of AT/AF episodes can show you if the patient suffers from short or long periods of atrial tachyarrhythmia.

**Episode List** – The Episode List shows the episode log of all episodes detected prior to the last patient session and since the last patient session.

**Last Tachy with ECG** – You can print detailed information about the last Tachy (FVT or VT) episode with ECG that was recorded before the current patient session. The information includes the interval plot, episode text, and the complete ECG recording of the episode.

**Last AT/AF with ECG** – You can print detailed information about the last AT/AF episode with ECG that was recorded before the current patient session. The information includes the interval plot, episode text, and the complete ECG recording of the episode.

**Note**: The time annotations that appear on the reports are based on the Reveal LINQ device clock.

**Printing segments of the selected ECG** – To help you locate portions of the currently selected ECG that may be of interest, the system enables you to print the currently displayed ECG segment plus 30 s, 60 s, or 120 s ECG segments from immediately before the episode you are currently viewing.

To print an ECG segment from the currently selected episode, follow these steps:
- Select Print… > Selected Episode
- Select Print… > Displayed ECG Include prior (0 s, 30 s, 60 s, or 120 s)

This Print - Options window is illustrated in Figure 18, page 40.

### 7.4 Viewing long-term clinical trends

To view long-term clinical trends, select Reports > Cardiac Compass Trends…

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 Cardiac Compass Trends report provides a picture of the patient’s condition over the last 14 months. Graphs show trends in the occurrence of arrhythmias, the amount of physical activity, 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.

Cardiac Compass Trends data is available only as a printed report.
The Cardiac Compass Trends report is based on data and measurements collected daily. The Reveal LINQ ICM begins storing data after it is inserted and data collection is programmed on. 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.
7.4.1 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.
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.

**Remote interrogations** – The Cardiac Compass Report records an underscored “I” symbol for a day on which the patient interrogates the device remotely.

**Patient symptoms** – A patient may experience symptoms of a possible cardiac event and record this occurrence using a 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.

**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.

**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 Reveal LINQ clock).
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.

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).

7.5 Viewing rate histograms to assess heart rates

To view rate histograms, select Reports > Available Reports… > Rate Histograms.

Rate histogram data is available only as a printed report. The Rate Histograms report is based on a continuous recording of ventricular rates in the period after the last patient session. The Rate Histograms report presents heart rate data in 2 types of histograms: ventricular rate and ventricular rate during AT/AF. The report includes data from the current (since last session) collection period.

Figure 38. Rate Histograms report example
Rate histograms show the percentage of time that the ventricular rate was recorded within each rate range.

**Ventricular rate histogram** – The ventricular rate histogram shows the rate distribution of ventricular events as the percentage of total time. The histogram shows 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.

**Ventricular rate during AT/AF histogram** – The ventricular rate during AT/AF histogram shows ventricular events that occurred during automatically detected AT/AF episodes. The histogram shows 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 total time that the patient spent in AT/AF (AT/AF burden). This histogram may be used to monitor the effectiveness of ventricular rate control therapy and drug titration.
A Product specifications

A.1 Reveal LINQ 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.

Table 5. Programmable parameters: Device Data Collection

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
<th>Shipped value</th>
<th>Reset value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason for Monitoring(^a)</td>
<td>Syncope; Palpitations; Seizures; Ventricular Tachycardia; Suspected AF; AF Ablation;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AF Management; Cryptogenic Stroke; Other(^a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Date/Time(^b)</td>
<td>(Enter current date and time)</td>
<td>—</td>
<td>1 Jan 1994</td>
</tr>
<tr>
<td>Wireless Transmission Time(^c)</td>
<td>00:00; 01:00; 02:00 ... 11:00; 12:00; 13:00 ... 23:00</td>
<td>00:00 (midnight)</td>
<td>00:00 (midnight)</td>
</tr>
<tr>
<td>Wireless Data Priority</td>
<td>Brady, Tachy, Pause; Brady, Pause, Tachy; Tachy, Brady, Pause; Tachy, Pause, Brady;</td>
<td>Pause, Tachy,</td>
<td>Pause, Tachy,</td>
</tr>
<tr>
<td></td>
<td>Pause, Brady, Tachy, Brady; Pause, Brady, Tachy</td>
<td>Brady</td>
<td>Brady</td>
</tr>
<tr>
<td>Device Data Collection(^d)</td>
<td>On(^a)</td>
<td>Off</td>
<td>On</td>
</tr>
</tbody>
</table>

\(^a\) Reason for Monitoring is used to set arrhythmia detection parameters to pending automatically.
\(^b\) The times and dates stored in episode records and other data are determined by the Device Date/Time clock.
\(^c\) Wireless Transmission Time programming is based on the Device Date/Time clock.
\(^d\) Turning on Device Data Collection enables sensing and data collection (all episode types). After being turned on, Device Data Collection cannot be turned off.

Table 6. Programmable parameters: R-wave sensing

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
<th>Shipped value</th>
<th>Reset value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.025; 0.035; 0.05; 0.075;</td>
<td>0.035 mV</td>
<td>0.035 mV</td>
</tr>
<tr>
<td></td>
<td>0.1; ... 0.2 mV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blank after Sense</td>
<td>130; 150; 170; 200; 250; 300;</td>
<td>150 ms</td>
<td>150 ms</td>
</tr>
<tr>
<td></td>
<td>400 ms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensing Threshold</td>
<td>130; 150; 200; 300; 400; 500</td>
<td>150 ms</td>
<td>150 ms</td>
</tr>
<tr>
<td>Decay Delay</td>
<td>ms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 7. Programmable parameters: episode detection

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
<th>Shipped value</th>
<th>Reset value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tachy Detection</td>
<td>On; Off</td>
<td>Off</td>
<td>On</td>
</tr>
<tr>
<td>Tachy Detection Interval (Rate)</td>
<td>270; 280; … 520 ms 220; 214; … 115 bpm</td>
<td>340 ms 176 bpm</td>
<td>340 ms 176 bpm</td>
</tr>
<tr>
<td>Tachy Duration</td>
<td>5; 12; 16; 24; 32; 48 beats</td>
<td>16 beats</td>
<td>16 beats</td>
</tr>
<tr>
<td>Brady Detection</td>
<td>On; Off</td>
<td>Off</td>
<td>On</td>
</tr>
<tr>
<td>Brady Interval (Rate)</td>
<td>1000; 1200; 1500; 2000 ms 60; 50; 40; 30 bpm</td>
<td>2000 ms 30 bpm</td>
<td>2000 ms 30 bpm</td>
</tr>
<tr>
<td>Brady Duration</td>
<td>4; 8; 12 beats</td>
<td>4 beats</td>
<td>4 beats</td>
</tr>
<tr>
<td>Pause Detection</td>
<td>On; Off</td>
<td>Off</td>
<td>On</td>
</tr>
<tr>
<td>Pause Duration</td>
<td>1.5; 3.0; 4.5 s</td>
<td>3.0 s</td>
<td>3.0 s</td>
</tr>
<tr>
<td>AT/AF Detection</td>
<td>On; Off</td>
<td>Off</td>
<td>On</td>
</tr>
<tr>
<td>Type</td>
<td>AT/AF; AF Only</td>
<td>—</td>
<td>AF Only</td>
</tr>
<tr>
<td>AF Detection</td>
<td>Least Sensitive; Less Sensitive; Balanced Sensitivity; More Sensitive</td>
<td>Less Sensitive</td>
<td>Less Sensitive</td>
</tr>
<tr>
<td>Ectopy Rejection</td>
<td>Off; Nominal; Aggressive</td>
<td>Off</td>
<td>Off</td>
</tr>
<tr>
<td>AT/AF Recording Threshold</td>
<td>All Episodes; ≥6 min; ≥10 min; ≥20 min; ≥30 min; ≥60 min; Only Longest Episode</td>
<td>≥10 min</td>
<td>≥10 min</td>
</tr>
<tr>
<td>Detect Very Regular AT Rhythms</td>
<td>Off; On - Rates ≥67 bpm; On - Rates ≥100 bpm; On - All Rates</td>
<td>Off</td>
<td>—</td>
</tr>
</tbody>
</table>

\(a\) Asystole.

Table 8. Programmable parameters: Symptomatic Episode Duration

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
<th>Shipped/Nominal/Reset value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic Episode Duration</td>
<td>Four 7.5 min Episodes; Three 10 min Episodes; Two 15 min Episodes</td>
<td>Four 7.5 min Episodes</td>
</tr>
</tbody>
</table>

Table 9. Parameters set to pending automatically according to the selected Reason for Monitoring the patient

<table>
<thead>
<tr>
<th>Reason for Monitoring(ab)</th>
<th>AF detection sensitivity(c)</th>
<th>Ectopy rejection(c)</th>
<th>AT/AF recording threshold(c)</th>
<th>Wireless data priority(c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syncope</td>
<td>Least Sensitive</td>
<td>Aggressive</td>
<td>Only Longest Episode</td>
<td>Pause, Tachy, Brady</td>
</tr>
<tr>
<td>Palpitations</td>
<td>Less Sensitive</td>
<td>Nominal</td>
<td>Episodes ≥6 min</td>
<td>Tachy, Pause, Brady</td>
</tr>
<tr>
<td>Seizures</td>
<td>Least Sensitive</td>
<td>Aggressive</td>
<td>Episodes ≥10 min</td>
<td>Pause, Tachy, Brady</td>
</tr>
</tbody>
</table>
Table 9. Parameters set to pending automatically according to the selected Reason for Monitoring the patient (continued)

<table>
<thead>
<tr>
<th>Reason for Monitoring ab</th>
<th>AF detection sensitivity c</th>
<th>Ectopy rejection c</th>
<th>AT/AF recording threshold c</th>
<th>Wireless data priority c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventricular Tachycardia</td>
<td>Least Sensitive</td>
<td>Aggressive</td>
<td>Episodes ≥10 min</td>
<td>Tachy, Pause, Brady</td>
</tr>
<tr>
<td>Suspected AF</td>
<td>Less Sensitive</td>
<td>Nominal</td>
<td>Episodes ≥6 min</td>
<td>Tachy, Pause, Brady</td>
</tr>
<tr>
<td>AF Ablation</td>
<td>Balanced Sensitivity</td>
<td>Nominal</td>
<td>All Episodes</td>
<td>Tachy, Pause, Brady</td>
</tr>
<tr>
<td>AF Management</td>
<td>Balanced Sensitivity</td>
<td>Nominal</td>
<td>All Episodes</td>
<td>Tachy, Pause, Brady</td>
</tr>
<tr>
<td>Cryptogenic Stroke</td>
<td>Balanced Sensitivity</td>
<td>Aggressive</td>
<td>All Episodes</td>
<td>Tachy, Pause, Brady</td>
</tr>
<tr>
<td>Other®</td>
<td>Less Sensitive</td>
<td>Aggressive</td>
<td>Episodes ≥10 min</td>
<td>Pause, Tachy, Brady</td>
</tr>
</tbody>
</table>

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 Patient Date of Birth.

b For all Reasons for Monitoring, AT/AF Detection Type is set to AF Only.

c AF detection sensitivity, Ectopy rejection, AT/AF recording threshold, and Wireless data priority parameters are set to pending automatically according to the selected Reason for Monitoring.

Table 10. Available counters a

<table>
<thead>
<tr>
<th>Counter</th>
</tr>
</thead>
<tbody>
<tr>
<td>AF episodes</td>
</tr>
<tr>
<td>AT episodes</td>
</tr>
<tr>
<td>Brady episodes</td>
</tr>
<tr>
<td>Pause (asystole) episodes</td>
</tr>
<tr>
<td>Symptom (patient-activated) episodes</td>
</tr>
<tr>
<td>Tachy episodes</td>
</tr>
</tbody>
</table>

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.
### Table 11. Available reports

<table>
<thead>
<tr>
<th>Report name</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT/AF Summary</td>
<td>AT/AF episode summary</td>
</tr>
<tr>
<td></td>
<td>AT/AF durations</td>
</tr>
<tr>
<td></td>
<td>AT/AF episode start time</td>
</tr>
<tr>
<td>Cardiac Compass</td>
<td>Programming and interrogation events</td>
</tr>
<tr>
<td></td>
<td>AT/AF total time per day</td>
</tr>
<tr>
<td></td>
<td>Ventricular rate during AT/AF</td>
</tr>
<tr>
<td></td>
<td>Average ventricular rate</td>
</tr>
<tr>
<td></td>
<td>Patient activity</td>
</tr>
<tr>
<td></td>
<td>Heart rate variability</td>
</tr>
<tr>
<td>Episode Counters</td>
<td>Number of episodes since last session</td>
</tr>
<tr>
<td></td>
<td>Device lifetime total number of episodes</td>
</tr>
<tr>
<td>Episode List</td>
<td>Episode log since last session</td>
</tr>
<tr>
<td>Last AT/AF with ECG</td>
<td>Episode summary</td>
</tr>
<tr>
<td></td>
<td>Parameter settings</td>
</tr>
<tr>
<td></td>
<td>Interval plot</td>
</tr>
<tr>
<td></td>
<td>ECG recording</td>
</tr>
<tr>
<td>Last Tachy with ECG</td>
<td>Episode summary</td>
</tr>
<tr>
<td></td>
<td>Parameter settings</td>
</tr>
<tr>
<td></td>
<td>Interval plot</td>
</tr>
<tr>
<td></td>
<td>ECG recording</td>
</tr>
<tr>
<td>Parameters: All Settings</td>
<td>Parameters</td>
</tr>
<tr>
<td></td>
<td>AT/AF Detection</td>
</tr>
<tr>
<td></td>
<td>Sensing</td>
</tr>
<tr>
<td></td>
<td>Device Data Collection</td>
</tr>
<tr>
<td></td>
<td>Device information</td>
</tr>
<tr>
<td>Parameters: Changes This Session</td>
<td>Parameters</td>
</tr>
<tr>
<td></td>
<td>Session Start value</td>
</tr>
<tr>
<td></td>
<td>Current value</td>
</tr>
<tr>
<td>Patient Information</td>
<td>see Section 4.3, “Entering patient information”, page 33</td>
</tr>
<tr>
<td>Initial Interrogation</td>
<td>Quick Look</td>
</tr>
<tr>
<td></td>
<td>Device status</td>
</tr>
<tr>
<td></td>
<td>Episode summary (since last session)</td>
</tr>
<tr>
<td></td>
<td>Observations</td>
</tr>
<tr>
<td></td>
<td>Cardiac Compass trends</td>
</tr>
<tr>
<td>Rate Histograms</td>
<td>Ventricular rate histogram (since last session)</td>
</tr>
<tr>
<td></td>
<td>Ventricular rate during AT/AF histogram (since last session)</td>
</tr>
<tr>
<td>Session Summary</td>
<td>Device information</td>
</tr>
<tr>
<td>Final: Session Summary</td>
<td>Device status</td>
</tr>
<tr>
<td></td>
<td>Parameter changes this session</td>
</tr>
<tr>
<td></td>
<td>Current value of parameters</td>
</tr>
</tbody>
</table>
A.2 Reveal LINQ ICM technical specifications

Table 12. Physical characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>1.2 cm³</td>
</tr>
<tr>
<td>Mass</td>
<td>2.5 g</td>
</tr>
<tr>
<td>Dimensions H x W x D</td>
<td>44.8 mm x 7.2 mm x 4.0 mm</td>
</tr>
<tr>
<td>Surface area of device can electrode</td>
<td>75.0 mm²</td>
</tr>
<tr>
<td>Surface area of device header electrode</td>
<td>9.0 mm²</td>
</tr>
<tr>
<td>Distance between the electrodes, edge-to-edge</td>
<td>37.7 mm</td>
</tr>
</tbody>
</table>

Table 13. Device identification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device identification code</td>
<td>Serial Number prefix “RLA”</td>
</tr>
<tr>
<td></td>
<td>The device manufacturer and model can be identified by the Serial Number displayed when the implanted device is interrogated with a Medtronic programmer. Serial Number prefix “RLA” indicates that the interrogated device is a Medtronic Reveal LINQ Model LNQ11 ICM. To view the Serial Number, select the Patient icon on the programmer screen.</td>
</tr>
<tr>
<td>Device X-ray image</td>
<td>An X-ray image of the implanted device can be used to identify that a patient has a Reveal LINQ device (typically implanted in the left chest area). See Figure 39.</td>
</tr>
</tbody>
</table>

Figure 39. Front and side view X-ray images of an implanted Reveal LINQ device
Table 14. Device materials in contact with human tissue

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can</td>
<td>Titanium</td>
</tr>
<tr>
<td>Electrodes</td>
<td>Titanium nitride</td>
</tr>
<tr>
<td>Header</td>
<td>Polyurethane, silicone</td>
</tr>
<tr>
<td>Coating</td>
<td>Parylene</td>
</tr>
</tbody>
</table>

Table 15. Insertion tools materials in contact with human tissue

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision tool</td>
<td>Polycarbonate, stainless steel</td>
</tr>
<tr>
<td>Insertion tools</td>
<td>Polycarbonate</td>
</tr>
</tbody>
</table>

Table 16. Battery characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Greatbatch Medical</td>
</tr>
<tr>
<td>Model/type</td>
<td>Reveal LINQ</td>
</tr>
<tr>
<td>Chemistry</td>
<td>Lithium carbon monofluoride</td>
</tr>
<tr>
<td>Projected longevity</td>
<td>3 years</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Average of 1 auto-detected episode per day.</td>
</tr>
<tr>
<td></td>
<td>Average of 1 patient-activated episode per month.</td>
</tr>
<tr>
<td></td>
<td>Less than or equal to 6 months shelf life (between device manufacture and insertion).</td>
</tr>
<tr>
<td><strong>Note:</strong></td>
<td>At the maximum shelf storage time of 12 months, longevity is reduced by approximately 3 months.</td>
</tr>
</tbody>
</table>
B Using the Patient Assistant PA96000

B.1 Using the Patient Assistant

B.1.1 What is the Patient Assistant?

The Patient Assistant model PA96000 is used by the patient to record (mark) heart rhythm data in their Reveal LINQ ICM. They should carry the Patient Assistant with them at all times. Tell the patient to use the Patient Assistant while, or just after, having symptoms, according to your instructions. Examples of symptoms (sometimes called “events”) include fainting, palpitations, dizziness, and shortness of breath.

The following information is also provided to the patient in the Patient Assistant PA96000 Patient Manual. The patient manual includes instructions on using, handling, maintaining, and other information about the Patient Assistant. The cardiology nurse or doctor may want to review this information with the Reveal LINQ patient. If you or the patient has questions or concerns about Patient Assistant use, contact a Medtronic representative or contact Medtronic Patient Services at 1-800-551-5544.

B.1.2 Patient Assistant button and lights

The Patient Assistant has a button and two lights. Figure 40 shows the button and lights, as well as the connection slot you can use to attach the Patient Assistant to a key chain, lanyard, or other personal item. The lights do not turn on until you press the button.
B.1.3 Instructions for using the Patient Assistant

You or a helper should follow these steps while you are having symptoms or as soon as possible afterward, as directed by your doctor.

1. Press and release the Record Symptom button. The Searching light will start flashing blue.

   Figure 41. Record Symptom button

2. Quickly hold the Patient Assistant flat against your chest, directly over your cardiac device. (Your cardiac device may be in a different location than shown in this figure.)
3. When a symptom is successfully marked, the Success tone will sound and the Success light will illuminate green. This means you have successfully recorded an event in your cardiac device. It usually takes just a few seconds for the Patient Assistant and cardiac device to communicate. If the success signals do not occur within 15 seconds, repeat steps 1-2.

Note: If the Symptom button is pressed within 5 minutes after a successfully recorded event, the Patient Assistant will return a response as if the command was processed, but the cardiac device will not record the additional event.

B.1.4 Troubleshooting

If you have difficulty using your Patient Assistant, see Table 17 to determine if one of the described problems occurred and follow the corrective action provided. If you still have trouble, your Patient Assistant may not be working correctly. Contact your doctor or clinic to replace the Patient Assistant.
Table 17. Problems and possible causes and solutions

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause and solution</th>
</tr>
</thead>
</table>
| You pressed the Record Symptom button, but the blue Searching light does not flash. | • Electromagnetic interference. Move away from the source of the interference (an electrical or magnetic item), press the button again, and wait for a response.  
• The Patient Assistant may have been in an environment that was too cold or hot. Allow it to come to room temperature, and then press the button again and wait for a response. |
| You pressed the Record Symptom button and the blue Searching light flashes, but no Success tone sounds and no green Success light illuminates. | • Insufficient telemetry; the Patient Assistant did not communicate with the cardiac device. Reposition the Patient Assistant directly over the cardiac device, press the button again, and wait for a response.  
• Electromagnetic interference. Move away from the source of interference (an electrical or magnetic item), press the button again, and wait for a response. |
| You pressed the Record Symptom button, the blue Searching light flashes, and the green Success light illuminates, but no Success tone sounds. | • Your current environment is too loud to hear the Success tone. Move to a quieter environment, press the button again, and wait for a response. |
| You pressed the Record Symptom button, the blue Searching light flashes, the Success tone sounds, but the green Success light does not illuminate. | • Your current environment is too bright to see the green Success light. Move to a darker environment, press the button again, and wait for a response. |

B.1.5 Handling your Patient Assistant

The Patient Assistant is designed for daily use. Precautions should be taken to avoid damaging it.

- Do not immerse the Patient Assistant in liquid or spill fluid on it.
- Do not drop or mishandle the Patient Assistant in any way that might cause damage. Contact your doctor or clinic if the Patient Assistant has been dropped and does not function.
- Do not open the Patient Assistant. The batteries cannot be replaced.
- Do not carry the Patient Assistant directly in front of your cardiac device, such as in a shirt or coat pocket, to avoid accidental recordings.
- Keep the Patient Assistant at room temperature. Optimal conditions for use are 5 °C (41 °F) to 43 °C (110 °F) with relative humidity up to 93%.
B.1.6 Cleaning
Regularly inspect the Patient Assistant for damage or defects. If it is damaged or if you cannot troubleshoot the problem, contact your doctor or clinic for assistance.

Be careful to prevent moisture from entering the Patient Assistant. The Patient Assistant is moisture resistant but not waterproof. Clean the outside of the Patient Assistant with a soft, slightly damp cloth, as needed. Do not clean the Patient Assistant with solvents (for example, nail polish remover) or chlorine-based cleansers (for example, bleach).

B.1.7 Patient Assistant disposal
Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. The Patient Assistant contains materials that can harm the environment, such as batteries.

B.1.8 Warnings and precautions
Warning: The Patient Assistant is not intended to be used as an alarm system for situations where medical attention is needed. Seek medical attention immediately if you are feeling ill and think you might need to go to the hospital. If there is an emergency, call your local emergency number. If your doctor has provided other instructions, follow them. Waiting to seek medical attention could be dangerous to your health.

Caution: To prevent the risk of infection, do not place the Patient Assistant in direct contact with your incision site until it is completely healed.

Caution: Do not modify this equipment. Modifications may impair the effectiveness of the Patient Assistant.

Caution: Use the Patient Assistant only as directed by your doctor. Do not “play” with your Patient Assistant, including unnecessarily pressing the Record Symptom button, because doing so can cause inappropriate data to be recorded.

Caution: Do not take the Patient Assistant into the MRI-controlled room (magnet room). Doing so can damage the Patient Assistant or the MR scanner.

B.1.9 Indications
The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant is used to initiate recording of cardiac event data in the device memory of the ICM.
B.1.10 Contraindications
There are no known contraindications for the use of this device.

B.1.11 Patient Assistant specifications
- Dimensions: Approximately 10 cm x 4 cm x 1 cm (4 in x 1.5 in x 0.4 in)
- Power source: Non-replaceable lithium coin cell battery
- Battery longevity (service life): When used at room temperature, a Patient Assistant button can be pressed a minimum of 200 times before the battery is depleted.

B.1.12 FCC Compliance information
This device complies with Part 15 of the FCC Rules respectively. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

B.1.13 Transport and storage conditions
- Keep the Patient Assistant at -25 °C (-13 °F) to 50 °C (122 °F) and less than 93% relative humidity when transporting it for 24 hours or less.
- Keep the Patient Assistant at 15 °C (59 °F) to 30 °C (86 °F) and less than 93% relative humidity when storing it for greater than 24 hours.
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