Medtronic

REVEAL® XT 9529

Insertable Cardiac Monitor

Clinician Manual

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

Contents

1 System overview

1.1 System description

The Medtronic Reveal XT Insertable Cardiac Monitor is a programmable device that continuously monitors a patient's ECG and other physiological parameters. The Reveal XT records cardiac information in response to automatically detected arrhythmias and patient activation.

The Reveal XT is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial tachyarrhythmia/atrial fibrillation (AT/AF), bradyarrhythmia, asystole, or (fast) ventricular tachyarrhythmia. In addition, the Reveal XT can be activated by the patient to record cardiac rhythm during symptomatic episodes.

The Reveal XT system consists of 3 main components.

Figure 1. System components
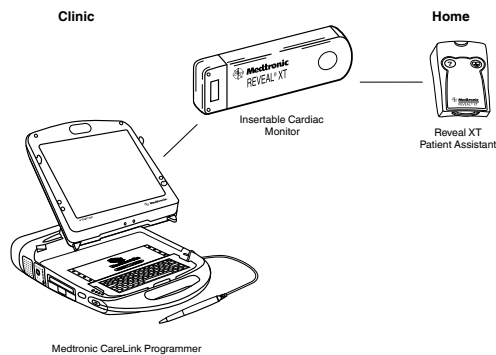
Medtronic Reveal XT Model 9529 Insertable Cardiac Monitor – The Reveal XT is a small, leadless device that is typically implanted under the skin, in the chest. The device uses two electrodes on the body of the device to continuously monitor the patient's subcutaneous ECG. The device memory can store up to 27 min of ECG recordings from automatically detected arrhythmias and up to 22.5 min of ECG recordings from patient-activated episodes. The system provides options to segment the patient-activated episode storage: up to three 7.5 min recordings, up to two 10 min recordings, or up to one 15 min recording.

Medtronic CareLink Model 2090 programmer with FullView software Model SW007 – The programmer is used to set up the Reveal XT to detect arrhythmias. It also allows you to view, save, or print the stored information.

Reveal XT Patient Assistant Model 9539 – The Patient Assistant is a hand-held, battery-operated telemetry device that enables the patient to record cardiac information in the Reveal XT after experiencing symptoms of a possible cardiac event. A query function enables the patient to check his or her device and receive notification when an arrhythmia has occurred or when the device status has changed.

Note: If you consider use of the 2–button Patient Assistant to be too complicated for a particular patient, the single-button Reveal Patient Assistant Model 9538 (without the query function) is also compatible with the Reveal XT.

Cautions:

- The Reveal XT cannot be used as an alarm system to alert the patient to emergency situations.
- Before performing an MRI procedure, refer to Section D.1 for important information about procedures and MRI-specific contraindications, warnings, and precautions.

Note: The Reveal XT 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.

1.2 Indications and contraindications

1.2.1 Indications

The Reveal XT Insertable Cardiac Monitor is an implantable patient-activated and automatically-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.

1.2.2 Contraindications

There are no known contraindications for the implant of the Reveal XT Insertable Cardiac Monitor. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

1.3 Precautions

1.3.1 Effects of electrical interference

The Reveal XT is designed to monitor and store ECG data and to receive radio signals from the programming head and the Patient Assistant. Since the Reveal XT 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 Reveal XT (see Section 1.4). The device will function normally as soon as the patient moves away from the source of interference. The Reveal XT 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 Reveal XT function.

Potential sources of interference in home and work environments include the following equipment:

Airport security systems – Airport security systems are unlikely to interfere with monitoring and data collection. However, the metal case of the Reveal XT could set off a metal detector. Before walking through security systems patients should therefore inform security personnel that they have an implanted metal device. Also, the use of a hand-held screening wand by a security operator may trigger inappropriate episode detection.

Electronic Article Surveillance (EAS) equipment – EAS equipment should not affect data collection, although inappropriate episode detection could be triggered. Patients should be advised not to linger near or lean against theft prevention systems, but to walk through them at a normal pace.

Induction cooktops – The electromagnetic pulses emitted by induction cooktops can be sensed by the Reveal XT and could temporarily interfere with data collection. To minimize the risk of interference, the patient should be advised to only switch the heating zones on and off when an induction-compatible pan is in place.

Industrial equipment – Patients who use or work near electric arc welding equipment, broadcasting antennas, power plants, transmission lines, high-voltage equipment or other sources of high electrical current, should initially be monitored to check for interference with Reveal XT function.

Radio transmitters – For items that transmit through an antenna, it is recommended that a minimum distance be kept between the antenna and the Reveal XT. Types of radio transmitter that may affect data collection include 2-way transmitters (keep 15 cm (6 in)

away), portable transmitters (keep 30 cm (12 in) away) and HAM transmitters (keep 2.75 m (9 feet) away).

Wireless communication equipment – There may be a potential interaction between wireless communication equipment (for example, cordless or mobile phones, pagers, PDAs, Wi-Fi enabled laptop computers, and Bluetooth devices) and Reveal XT operation. Potential effects may include telemetry interruptions, triggering of inappropriate episode detection or corruption of the data stored in memory. The following information provides a general guideline to patients who use wireless communication equipment:

- Keep 15 cm (6 in) between the equipment and the implanted device. When using portable and mobile cellular phones be aware that they generally transmit at higher power compared to hand-held models. For phones transmitting above 3 W, a minimum distance of 30 cm (12 in) between the antenna and the implanted device is advised.

- Hold a mobile phone to the ear that is furthest from the implanted device.

- Do not carry a phone or other transmitting device in a breast pocket or on a belt over, or within 15 cm (6 in) of, the implanted device, because some devices emit signals when they are turned on but not in use (for example, mobile phones in the Listen or Standby mode). Store the device in a location opposite the side of the implant.

1.3.2 Hospital and medical therapy hazards

The influence of medical equipment on device performance 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. The following medical procedures are likely to be sources of interference or to be hazardous:

Computed tomographic x-ray (CT scan) – If the patient undergoes a CT scan procedure and the device is exposed to the CT scan beam, oversensing may occur for the duration of time the device is in the beam.

Diathermy – Therapeutic diathermy should not be used at the implant site on patients who have a Reveal XT because of possible tissue damage due to heating effects.

Electrocautery and Radio Frequency (RF) Ablation – Electrocautery or RF ablation may temporarily affect data collection, or cause electrical reset of the Reveal XT (see Section 1.4).

- Avoid direct contact of the cautery equipment with the implanted device. Direct contact may damage the device.

- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

External defibrillation – Do not place defibrillation paddles directly over the device, and try to avoid having the device between the paddles when defibrillating. Defibrillation may lead to tissue damage, device reset, or result in the loss of stored data. It is advisable to check device function after defibrillation.

Implanted pacemakers and defibrillators – To minimize the possibility of the programming head and telemetry interfering with a pacemaker or defibrillator, the Reveal XT should be implanted 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 XT application is active.

Note: If the patient has a co-implanted pacemaker or defibrillator, the automatic detection of arrhythmia episodes in the Reveal XT may be affected by the paced heart rhythm.

Lithotripsy – Lithotripsy can permanently damage the Reveal XT if it is at the focal point of the lithotripsy beam. If lithotripsy is required keep the focal point of the lithotripsy beam at least 5 cm (2 in) from the Reveal XT. It is advisable to check device function after lithotripsy.

Magnetic Resonance Imaging (MRI) – The Reveal XT is MR Conditional. It has been demonstrated to pose no known hazards in a specified MR environment with the conditions of use specified in Section D.1.

Radiation therapy – Exposing the device to therapeutic levels of ionizing radiation (such as that produced by cobalt machines or linear accelerators used for cancer treatment) may trigger inappropriate episode detection or corrupt the data stored in memory. It is advisable to check device function after radiation therapy. Cumulative radiation levels above 5 Gy may permanently damage the device.

Radiotherapy and device operational errors – Exposing the device to direct or scattered neutrons may cause electrical reset of the device, errors in device functionality, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of the neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. An electrical reset requires reprogramming of device parameters. Electron beam treatments do not cause electrical reset of the device.

Therapeutic ultrasound – Medtronic recommends that the Reveal XT should not be exposed to therapeutic ultrasound, because it may permanently damage the device. Refer specific concerns about particular patient conditions to your local Medtronic representative.

Transcutaneous Electrical Nerve Stimulators (TENS) – The effects of TENS used in close proximity to the Reveal XT depend on the type of pulse train employed. Because of the possible effects on device function, patients should not be allowed to use TENS at home

before it has been clearly established that the device does not interfere with Reveal XT function.

X-Ray and fluoroscopy – Exposure to normal diagnostic levels of x-ray (for example, an x-ray or CT scan) and fluoroscopic radiation should not damage or cause an electrical reset of the Reveal XT.

1.4 Device reset

Certain conditions (including, but not limited, to device malfunction, EMI, electrocautery, or external defibrillation) may cause an electrical reset of the Reveal XT. 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 B.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.

1.5 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.

2   Implanting the Reveal XT

2.1   Handling and disposal

Storage – The recommended temperature limits for storage and handling are 5 °C (41 °F) to 40 °C (104 °F). Store the package in a dry place away from direct sunlight. The operating temperature range is 22 °C (72 °F) to 45 °C (113 °F).

Handling – Normal handling is unlikely to damage the Reveal XT, but do not implant it under the following circumstances:

- The device has been dropped on a hard surface from a height of 30 cm (12 in) or more. This could damage the device components.

- The storage package has been pierced or altered. This could render the device non-sterile.

- The "Use by" date has expired. This could adversely affect the longevity.

Use by date – Check the "Use by" date shown on the package before opening the sterile pack.

Checking sterility – Before shipment, the device was sterilized as shown on the package. The sterile pack cover carries an illustration of the opening instructions. 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 the sterility, do not implant the device. Return non-sterile devices to Medtronic.

Caution: The device is protected by a single sterile barrier, which should not be opened before the sterile pack is in a sterile field.

Explant and disposal – Remove the Reveal XT when it is no longer needed, when the battery is depleted, or before burial or cremation.

In some countries, the removal of battery-operated implantable devices is mandatory because of environmental concerns. Please check the local regulations. In addition, the cremation process could cause the battery to explode.

- Medtronic implantable devices are for single use only. Do not resterilize and reimplant explanted devices.

- Dispose of explanted devices according to local regulations or return them to Medtronic for analysis and disposal.

2.2 Preparation, positioning and implant

2.2.1 Contents of the package

The Reveal XT package contains the following items:

- Reveal XT Insertable Cardiac Monitor
- Patient Assistant
- conductive patches
- wrist strap for the Patient Assistant
- carrying case for the Patient Assistant
- product documentation

2.2.2 Preparing for implant

The Reveal XT package is fitted with the Reveal XT Vector Check measuring tool, which helps to simplify device positioning. The Vector Check helps you to confirm reliable sensing and to determine the preferred implant site and device position. Even slight changes in implant site or device position can have a significant influence on signal quality and R-wave amplitude.

The Vector Check tool is attached to the blister package and allows you to test sensing characteristics while the device is still in the sterile package. Because the Reveal XT is not removed from the sterile package, the Vector Check can be used in a non-sterile area. The Vector Check has 2 electrodes that are approximately 4 cm apart, and which match the electrode spacing of the device. These electrodes make contact with the device electrodes at one end and with the patient's skin at the other (see Figure 2).

Figure 2. The Vector Check tool
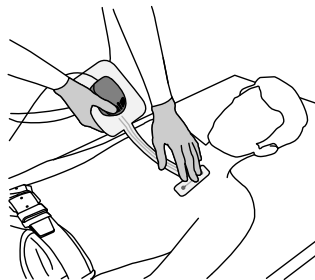
Make sure you have a Medtronic CareLink Model 2090 programmer available, on which Reveal XT FullView software has been installed. The programmer is needed to activate data collection and monitor device sensing.

To prepare for implant, take the following steps:

1. Before starting, thoroughly clean the implant zone (abrading the skin may help in getting good ECG signals). The recommended implant zone is between the first intercostal space and fourth rib, from a parasternal line to a midclavicular line. The lower chest V3 area, between the fourth and fifth rib, is an alternative implant site (see Figure 3).

2. Attach 2 conductive patches to the electrodes (see Figure 4). This ensures that reliable contact with the patient's skin is maintained during the procedure.

Figure 3. The Vector Check and implant zone

1	Mid-clavicular line	3	4th rib
2	1st rib	4	V3 implant site
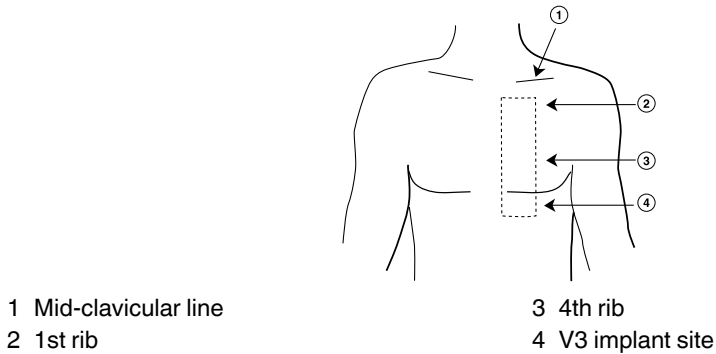
Figure 4. Attaching conductive patches
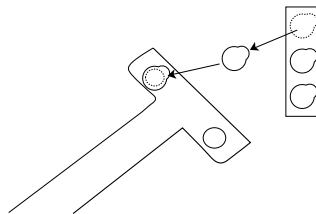
2.2.3 Determining the implant site and device positioning

To determine the preferred implant site and device position, take the following steps:

1. Turn on the programmer, position the programming head on the blister pack label, and press [Find Patient…]. Reveal XT FullView software is then started and telemetry established.

2. Turn on Device Data Collection. (The Reveal XT is shipped with data collection turned off. Data collection must be activated before starting the Vector Check.) As soon as telemetry with the device is established, you are automatically prompted to activate data collection. At this point you can check the device date and time and adjust if necessary. The correct device date and time are important for data collection and lifetime calculations. Press [OK] and [PROGRAM] to activate data collection.

3. Attach the Vector Check electrodes to the patient's skin using the conductive patches. Applying conductive ECG spray may help to improve contact with the skin. The position and orientation of the electrodes should correspond with the desired implant site and orientation. During the measurement, it is important to maintain good contact between the electrodes and the skin, so keep the electrodes firmly pressed against the skin (see Figure 2).

4. Apply light pressure to the programming head, ensuring good contact between the electrodes on the other side of the lid and the device itself. Monitor the signal strength using the Reveal XT ECG shown on the programmer. You can also print the ECG using the programmer strip printer and then measure the signal amplitude manually.

5. Check different programming head positions to verify R-wave amplitude. Use the real time R-wave amplitude display in the upper left of the programming screen to find a position with the highest and most stable R-wave amplitude possible. The R-wave amplitude should be at least 0.2 mV when viewed on the programmer screen (or 0.3 mV when viewed on the programmer strip chart). Also, the peak-to-peak R-wave amplitude must be at least twice the peak T-wave and P-wave amplitudes. If the measured signals are of sufficient amplitude, mark the implant site and proceed with the implant. If these conditions are not met, repeat the procedure as often as necessary until a suitable position (with the best possible peak-to-peak R-wave amplitude) is found and marked.

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

2.2.4 Implanting the Reveal XT

Caution: The sterile blister package containing the device 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 into the sterile field.

Implant the Reveal XT in a single-incision procedure using normal aseptic techniques.

1. Create a subcutaneous pocket that is **slightly smaller** than the width of the device.

2. Insert the Reveal XT into the pocket with the electrodes facing outward. The device should enlarge the pocket to make a tight fit.

3. To ensure good sensing and episode detection, it is important to minimize device movement in the pocket. Use the suture holes on the device header to secure it to the underlying tissue and minimize rotation and migration of the device after implant.

Clearing data registered during implant – During the positioning and implant procedure, the Reveal XT may record arrhythmic episodes (bradycardia or asystole, for example), caused by detaching and reattaching the electrodes. After implant 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, the Cardiac Compass report may show inaccurate information on the day of implant.

2.3 Completing the implant procedure

When the Reveal XT has been implanted, set up the device sensing and data collection, and instruct the patient in using the Reveal XT system.

Turn on the programmer and interrogate the Reveal XT (see Section 3.1).

Activating data collection – If you have not already done so during the implant procedure, turn on data collection in the Reveal XT. Check the device date and time and adjust if necessary.

Select Params icon
    ⇒ Device Data Collection…
        ⇒ On
            ⇒ Device Date/Time…
                ⇒ OK

Setting up sensing and data collection – To prepare the device for collecting data, take the following steps:

1. Fill in patient information in the implanted device (see Section 3.3).

2. Adjust the sensing parameters to optimize R-wave sensing (see Section 5.2)

3. Adjust the criteria for detecting arrhythmia episodes, if necessary (see Section 5.3).

Using the Patient Assistant – To enable symptom recording and, if appropriate, to use the query function, give the patient the Patient Assistant. For more information on using and maintaining the Patient Assistant, see the *Reveal Patient Assistant 9538/9539 Clinician Manual*.

Instruct the patient on how to use the Patient Assistant, explaining which symptoms he or she should record. The *Reveal XT Patient Manual* provides a place for you to write instructions in the section, "Instructions from your doctor".

Program the notification criteria in the Reveal XT as appropriate for the patient (see Section 5.4). If the query function is enabled, instruct the patient when to use the query button and what to do when a response is received.

Patient Manual – Give the patient a copy of the *Reveal XT Patient Manual*, which includes instructions for using the Patient Assistant.

Reveal ICM Device Identification Card – This card is attached to the *Reveal Patient Assistant Quick Reference Card*. The patient can carry the Quick Reference Card/device identification card in the Patient Assistant carrying case or in a purse or wallet so that it is always available. The identification card is especially helpful if the Reveal XT sets off a metal detector or security system. When completing the identification card, print all relevant details with a ballpoint pen (black is preferred). Use the enclosed stickers to indicate the serial number.

Device Registration Form – A device registration form is included in the package. When completed, this form serves as a permanent record of the facts related to the implanted Reveal XT. Please ensure that a copy of the completed form is returned to Medtronic.

3   Using the programmer

3.1   Starting a patient follow-up session

You can use the Medtronic CareLink Model 2090 programmer with Reveal XT FullView software 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*.

Notes:

- The red Emergency button on the programmer is intended for use with therapeutic devices and does not work for the Reveal XT device.

- Programmers other than those listed in the System Description (see Section 1.1) are not compatible with the Reveal XT.

3.1.1   How to interrogate the device

Turn on the programmer. Place the programming head over the Reveal XT and press [Find Patient…]. The programmer interrogates data from the Reveal XT device memory. You then see the Reveal XT 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 XT, you see the Device Data Collection activation window.

- Because the programmer collects and stores data on a session-by-session basis, you need to start a new session for each patient.

Figure 5. Reveal XT screen
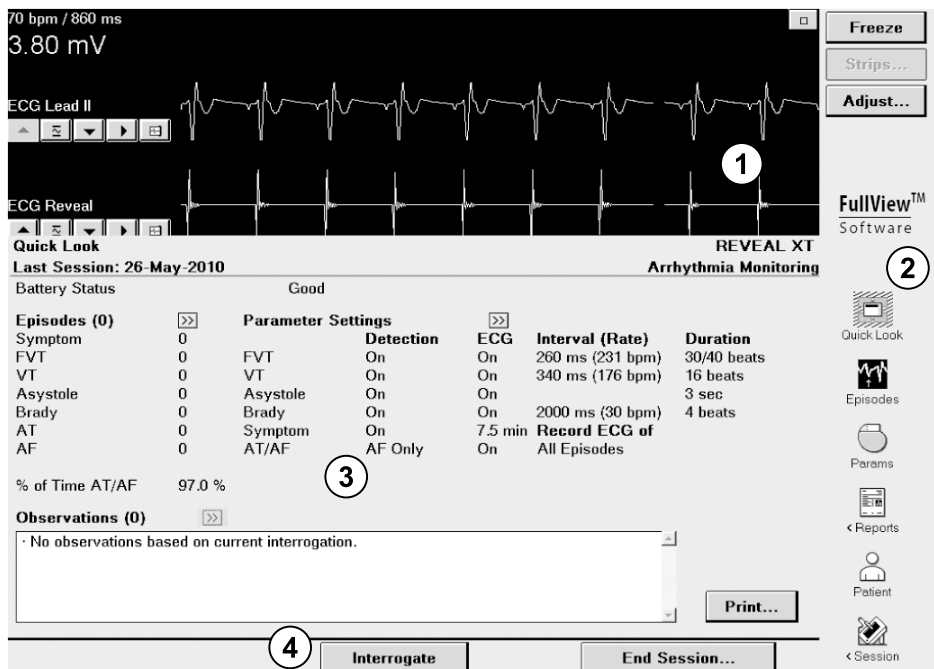
1 ECG window and controls   3 Main window
2 Control panel   4 Button line

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 implanted 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.

3.1.2 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…].

Figure 6. End session
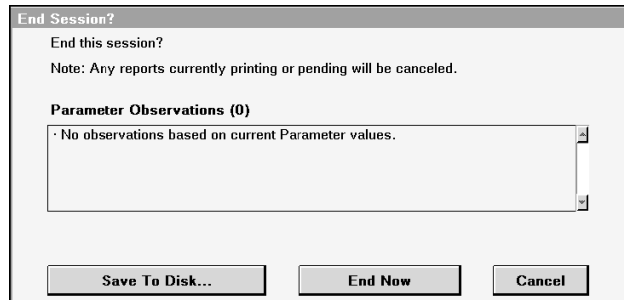
2. To save the session data to a diskette or USB flash drive, select the [Save To Disk…] option (see Section 3.4).

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

3.2 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

Symbol	Description
◇ⁿ (Nominal symbol)	**Nominal –** Indicates the Medtronic nominal value for a parameter.
▣P (Programmed symbol)	**Programmed –** Indicates the value currently programmed in the device for a parameter.
ⓘ (Information symbol)	**Information –** 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.
⚠ (Warning symbol)	**Warning –** 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.
🚫 (Interlock symbol)	**Interlock –** Appears when one selected value is incompatible with another value. You cannot program the device to this setting until you resolve the parameter interlock.

3.2.1 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.

Figure 7. Accessing parameters with more than 2 values
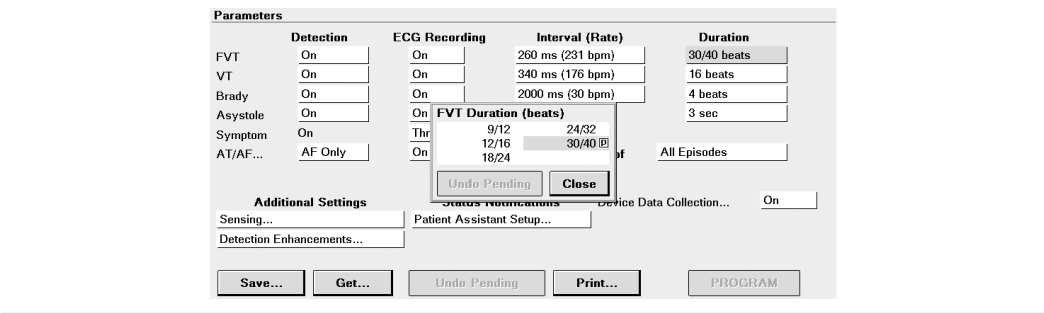
How to access a group of related parameters – If a parameter name is followed by 3 dots (…), selecting the parameter field opens a secondary window displaying a group of related parameter fields. Select new values for the desired secondary parameters. New values display as pending values. Press [OK] 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.

Figure 8. Accessing a group of related parameters
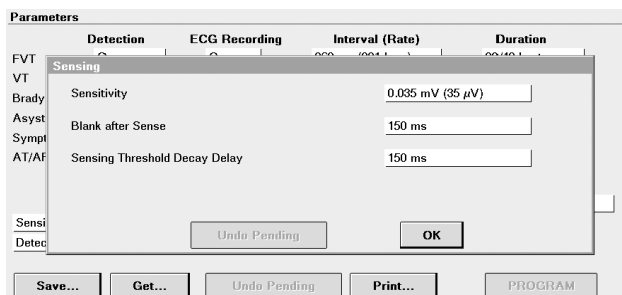
3.2.2 How to save a set of parameter values

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 implant 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.

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 Reveal XT during the patient session.

• Custom sets of values: all custom sets of values that were saved previously.

3.2.3 Programming instructions in this manual

Programming instructions in this manual are often represented by a programming block, which describes the path through the Reveal XT FullView software to specific screens or parameters. The following conventions are used in programming blocks:

• The "⇒" symbol precedes the screen text you can select to navigate to a new screen.

• The "▷" symbol precedes the name of a parameter you can program for a feature.

An example of a programming block using these conventions is as follows:

Select Params icon
  ⇒ Asystole
    ▷ Detection
    ▷ ECG Recording
    ▷ Duration

3.3 Entering patient information

The Reveal XT stores patient-related information that you can view and print during a patient session. This information is typically programmed into the device at the time of implant, 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.

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

Figure 9. Patient Information window

Table 2. Description of patient information

Information field	Description and required action
Implant Date	Enter the date the device was implanted.
Serial Number (not selectable)	Displays the serial number of the implanted device.
Patient	Enter the patient's name (up to 30 characters).
ID	Enter the patient ID (up to 15 characters).
Date of Birth	Select the patient's date of birth.
Notes	Enter notes about the patient or other information (up to 80 characters).
Last Update (not selectable)	Displays the date of the last Patient Information update.
Physician Phone	Select the physician's name and phone number from a list. If they are not listed, add them to the list[a] and select them.
Hospital	Select the hospital name from a list. If it is not listed, add it to the list[a] and select it.

[a] To add new information to a list, press [Modify List…] and [Add…]. Type in your addition and press [OK].

3.4 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 Disk 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 Disk application. Medtronic is not responsible for the inappropriate use of data saved to a diskette or USB flash drive.

Note: The device application may use the terms "disk" or "diskette" in the context of saving and retrieving device data. When a USB flash drive is connected to the 2090 Programmer to store device data, the terms disk or diskette should be interpreted as applying to the USB flash drive, rather than the diskette.

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 2090 Programmer data only.

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

Select Session icon
  ⇒ Save To Disk…
    ⇒ Save

Select End Session…
  ⇒ Save To Disk…
    ⇒ Save

A diskette must be a formatted, IBM-compatible, 3.5-inch diskette with a capacity of 720 KB (DS, DD) or 1.44 MB (DS, HD).

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.

3.4.2 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 Disk session by selecting the "Reveal XT/Reveal DX – Read From Disk" option from the Select Model screen. Then, select [Start]. When the Read From Disk – Warning window opens, press [OK]. To retrieve the session data, follow these steps:

> ⇒ 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 Disk".

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.

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

3.5 Printing reports

You can print a report on the programmer's thermal strip printer or on a full-size, external printer.

Notes:

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

- For information about setting up an external full-size printer, see the *Medtronic CareLink Programmer Reference Guide*.

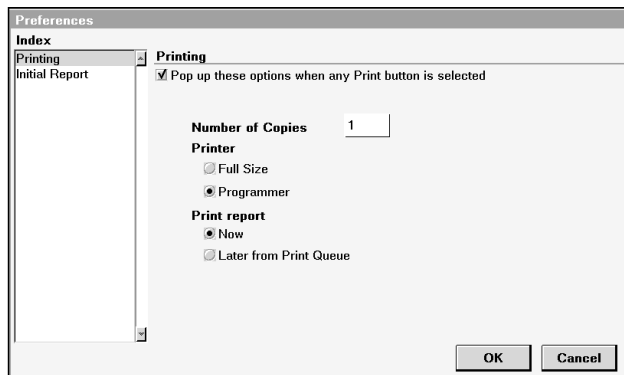### 3.5.1 How to set printing preferences

Select Reports icon
⇒ Preferences…
⇒ Index (Printing)

Printing preferences allow you to select print options, such as number of copies, printer type, and whether to print now or later.

Figure 10. Printing Preferences window

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".
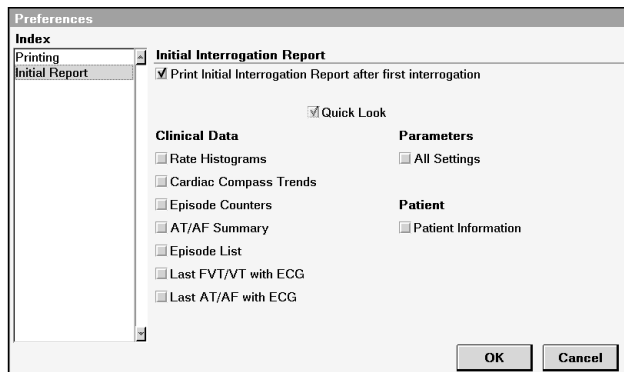
3.5.2 How to print an initial interrogation report

Select Reports icon
> ⇒ Preferences…
>> ⇒ Index (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.

Figure 11. Initial Interrogation Report window

Select the check box next to "Print Initial Interrogation Report after first interrogation".

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.
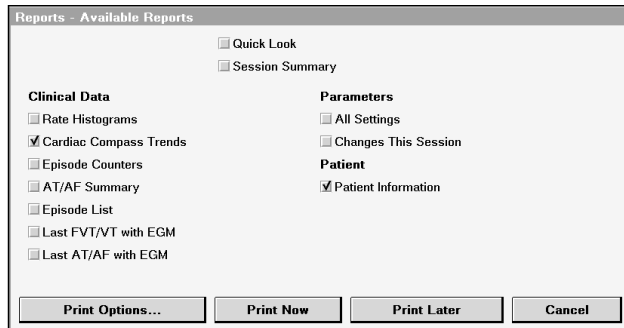
3.5.3 How to print reports during a patient session

Select Reports icon
> ⇒ Available Reports…

In most windows, you can press the [Print…] button to print the information that currently appears in the window.

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

Figure 12. 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. The window shows reports not available for printing in lighter or faded text.

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

3.5.4 How 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.

3.5.5 How 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".

"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: To display the Print Queue window when you are not in a patient session, select the Print Queue icon from the Select Model screen. This Print Queue window lists any reports held from previous sessions.

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 30 s, 60 s, and 120 s ECG segments from the episode you are currently viewing.

To print an ECG segment from the currently selected episode, follow these steps:

ECG
   ⇒ Print..
      ▷ Selected Episode
      ▷ Displayed ECG Include Prior (30 s, 60 s, or 120 s)

Figure 13. Print options window

3.6 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 from the programmer's strip chart recorder, 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.

3.6.1 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 XT 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.

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

Figure 14. The ECG adjustment button bar
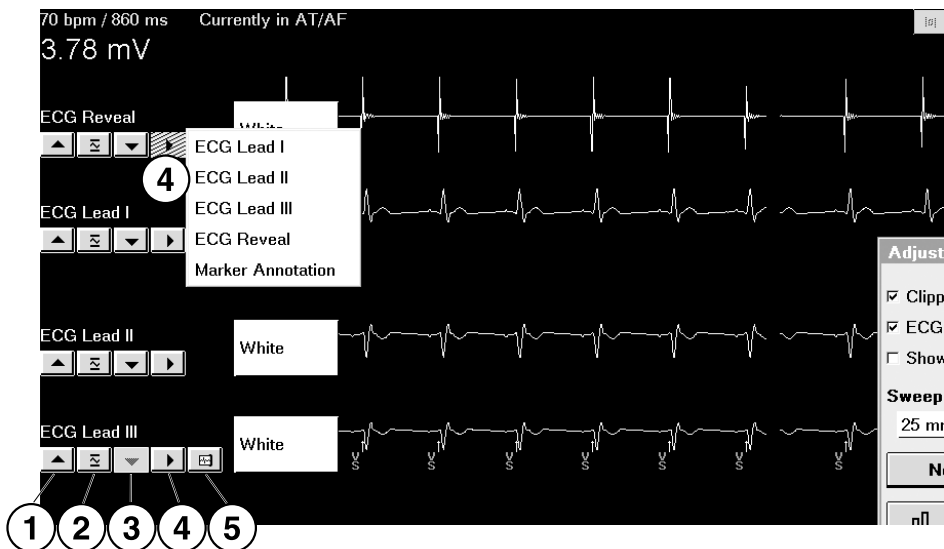
1 The up arrow increases the size of the ECG.
2 The normalize button automatically resizes the ECG.
3 The down arrow decreases the size of the ECG.
4 Use the source button to choose which ECG to display.
5 The print selection button enables or disables the ECG for printing. You can select up to 2 ECGs 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 15. 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, the screen, and the real-time strip recorder.
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 3. Marker Channel annotations

Marker	Explanation
V S	Ventricular sense
A D	Asystole detection (marks the first event in a detected asystole episode)
B	Brady sense
B D	Brady detection (marks the first event in a detected brady episode)
T S	VT sense
T D (below the baseline)	VT detection (marks the first event in a detected VT episode)
F S	FVT sense
F D (below the baseline)	FVT detection (marks the first event in a detected FVT episode)
T D (above the baseline)	AT detection (marks the end of at least 2 min of atrial arrhythmia)
F D (above the baseline)	AF detection (marks the end of at least 2 min of atrial arrhythmia)
Δ	Patient-activated symptom (only marked in a stored ECG recording)
V̶ S	Ignored event[a]

Table 3. Marker Channel annotations (continued)

| Marker	Explanation
A ~~D~~	Asystole rejection (marks a pause that is determined to not be asystole)
T ~~D~~	VT rejection (marks an event that would have been detected as VT but was rejected due to noise)
F ~~D~~	FVT rejection (marks an event that would have been detected as FVT but was rejected due to noise)

[a] An event that ends a noise interval.

Notes:

- Any interruption in telemetry with the Reveal XT 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].

3.6.2 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 16. Interpreting the frozen strip viewing window
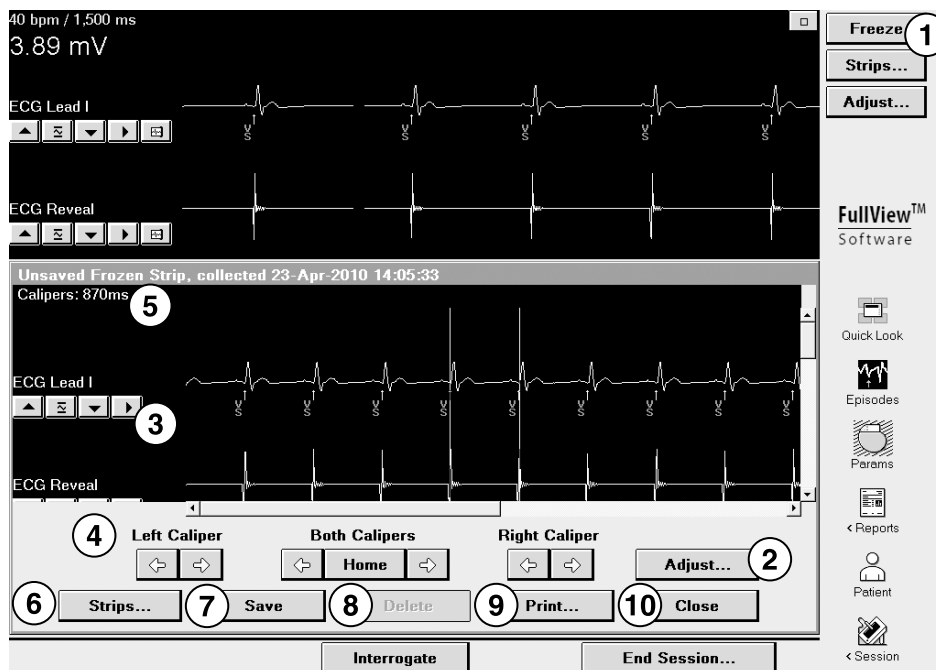
1 [Freeze] freezes a real-time ECG and displays it in the frozen strip viewing window.
2 [Adjust…] opens the Adjust window with display options for the strip viewer.
3 Adjustment button bar allows you to normalize the trace, resize the trace, and change the source.
4 Arrow buttons move the on-screen 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 diskette.

3.6.3 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.

4   Monitoring the patient's condition

4.1   Using the Reveal XT 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 XT 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 XT 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 XT 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 automatically detects arrhythmia episodes based on default detection criteria (see Section B.1). You can also use the Reveal XT together with the Patient Assistant by instructing the patient to record information when he or she experiences symptoms.

4.1.1   Recording episodes automatically

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

The Reveal XT can classify the following 5 types of arrhythmia episodes:

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

FVT (fast ventricular tachyarrhythmia or ventricular fibrillation) – The patient's heart rate increases to a rate that is higher than the programmable FVT threshold.

Bradyarrhythmia – The patient's heart rate falls to a rate that is lower than the programmable brady threshold.

Asystole – No ventricular events are sensed for a programmable period of time.

AT/AF or AF only – The patient has an atrial tachyarrhythmia or atrial fibrillation. You can also choose to record atrial fibrillation only. The Reveal XT 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 5.3).

The Reveal XT stores up to 30 arrhythmia episodes of each type in an episode log. When the log is full, data from the most recent episode will overwrite the oldest stored episode data of that type.

The Reveal XT can also store the ECG recorded before and during the episode in device memory. For each AT/AF episode the Reveal XT stores an ECG of the first 2 min of the episode. For each VT, FVT, brady or asystole 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 XT reserves 27 min of ECG storage 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. The system will only overwrite a recording if at least 3 episodes of that type remain in memory.

4.1.2 Recording episodes using the Patient Assistant

When the patient experiences symptoms, he or she can hold the Patient Assistant over the implanted Reveal XT 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 XT 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 XT reserves up to 22.5 min of ECG storage for ECG recordings of either the 3 most recent 7.5 min episodes, 2 most recent 10 min episodes, or 1 most recent 15 min episode 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. When the memory space for symptom episodes is full, the ECG of the oldest stored episode will be overwritten by a new episode.

4.1.3 Checking the status using the Patient Assistant query

The Patient Assistant query function enables the patient to check if the Reveal XT has detected important device status information, such as low battery or that the memory space for automatically detected arrhythmia episodes is full. You can set up the interaction between the Reveal XT and the Patient Assistant by programming the notification criteria in the Reveal XT. Notification criteria determine which types of arrhythmia episodes or changes in device status will trigger a response when the patient presses the query button. For information on setting up the Patient Assistant notification criteria, see Section 5.4.

The Reveal XT Patient Manual provides a place for you to record instructions for the patient about using the Patient Assistant. This information should indicate when the patient should press the record symptoms button and the query button. The instructions should also include when and how the patient should contact you.

Note: The Patient Assistant is not intended to detect or indicate the presence or absence of medical conditions. If the patient is feeling ill, he or she should seek immediate medical attention, regardless of indications from the Patient Assistant.

4.2 Conducting a patient follow-up session

After implant, 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 implant. 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, or has received notification to contact you after pressing the Patient Assistant query button.

Perform the following checks and adjustments with the programmer during a follow-up patient session. For information on interrogating the device, see Section 3.1.

Check battery status – Check the Reveal XT battery status in the initial Quick Look window.

• If the battery status is "Ageing", Medtronic advises you to schedule the next patient follow-up session within 3 months.

- If the battery status is "RRT" (Recommended Replacement Time) you should schedule the next patient follow-up session within 3 months of the date the device reached RRT. From that date onwards, 99% of the Reveal XT devices have sufficient battery capacity to operate for at least 90 days before the battery reaches the End of Service (EOS) status.

- The Reveal XT should be replaced or removed before the battery status reaches EOS.

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 6.

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 since the previous session to diskette. You can then look at the data later on the programmer (see Section 3.4).

Check sensing – Assess ventricular sensing by comparing the Reveal 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 5.2.

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 5.3.

If you are only interested in certain types of episodes, you can switch ECG Recording off for the other episode types to save memory space. These episodes will still be stored in the episode log, without an ECG recording.

Program the Patient Assistant query function – If you want the patient to contact you when an arrhythmia episode has been detected or the device status has changed, you can adjust the Patient Assistant notification criteria (see Section 5.4).

Note: If the battery status is "RRT", Medtronic advises you to switch off the Device Battery Low Patient Assistant query option to avoid repeated notifications.

# 5   Setting up sensing and arrhythmia detection

5.1 Introduction

This chapter describes how the Reveal XT senses R-waves, automatically detects cardiac arrhythmias, and interacts with the Patient Assistant. You can program the parameters to adjust sensing and set up automatic episode detection and the Patient Assistant query function. This chapter also provides advice for programming the parameters. For the programmable ranges and nominal settings of the parameters, see Section B.1.

5.2 Adjusting R-wave sensing

The automatic detection of arrhythmias by the Reveal XT is based on R-wave sensing. For proper functioning of the Reveal XT, 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 XT 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 XT 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 17).

Figure 17. Auto-adjusting the sensing threshold
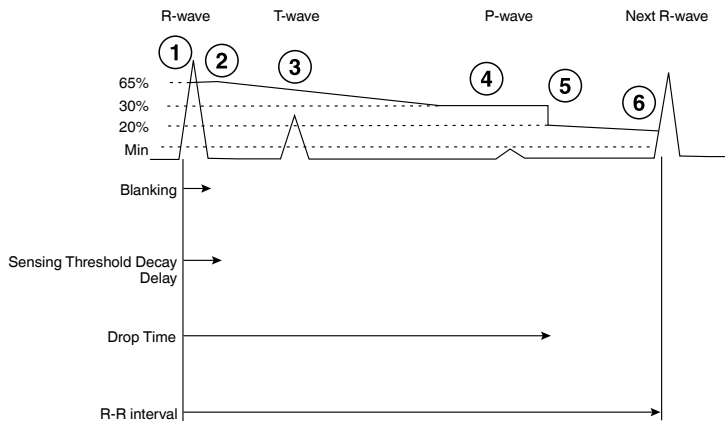
1 After a sensed R-wave, a programmable blanking period is started and the sensing threshold is set to 65% of the ECG peak.
2 The sensing threshold stays at this level during the programmable Sensing Threshold Decay Delay period.
3 After the Sensing Threshold Decay Delay period is finished, the sensing 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 XT 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.

5.2.1 Optimizing sensing

Select Params icon
> ⇒ Sensing…
>> ▷ Sensitivity
>> ▷ Blank after Sense
>> ▷ 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, FVT or VT 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 longer than the Blank after Sense period.

5.2.2 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 blanking period or the sensing threshold decay delay may resolve oversensing.

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.

5.2.3 Preventing false detections of asystole

The device may falsely detect occurrences of asystole in some circumstances. False detections of asystole 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 asystole detections are loss of contact between the device electrodes and the pocket or muscle tissue, and loss of ventricular sensing due to diminishing 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, a lack of observable changes in the heart rhythm and rate before and after an asystole event, and observable "micro-signals" occurring at a regular interval of approximately 160 ms (the telemetry frequency of the device). False detections of asystole typically occur within the first few weeks after implant and are usually prevented by creating a tight pocket for the device.

Loss of ventricular sensing due to diminishing R-wave amplitudes may result from programming the device to a less sensitive setting. If you suspect that diminishing 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.

5.3 Setting up automatic episode detection

The automatic detection and ECG storage of FVT, VT, 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 FVT, VT, 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 an asystole 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 and data collection function of the device. This enables you to specify the types episodes that are detected and those 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 device memory being filled with episodes that are not relevant for monitoring the patient's condition. To save memory space, Medtronic recommends that you adjust the detection criteria for classifying cardiac arrhythmias or to turn off ECG recording for certain types of episodes. For example, to make the Reveal XT less sensitive for the detection of FVT episodes, you can program the FVT duration parameter to a higher value.

Figure 18. Parameters window

Notes:

- VT, FVT, brady, and asystole 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 (VT, FVT, brady, or asystole). If this occurs, the device stores information for each detected episode.

- If an automatically detected episode occurs simultaneously with a patient-activated episode, both episodes are recorded.

5.3.1 FVT episodes

Select Params icon
  ⇒ FVT
    ▷ Detection
    ▷ ECG Recording
    ▷ Interval (Rate)
    ▷ Duration

You can adjust the criteria by which fast ventricular rhythm is classified as a Fast Ventricular Tachyarrhythmia (FVT) episode.

The Reveal XT marks a possible FVT event when the ventricular interval is shorter than the programmed FVT interval length. If the number of FVT events exceeds the programmed duration and the ECG noise level is not excessive, an FVT episode is stored. If the noise level is excessive, as indicated by the presence of very short ventricular intervals and high frequency content in the ECG, the FVT is rejected. The FVT 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 VT interval.

- The median ventricular interval is equal to or longer than the programmed VT interval during a period of 20 s.

- No R-wave is detected during a period of 10 s.

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

Detection – Program FVT Detection to "Off" to prevent automatic detection of FVT episodes.

ECG Recording – Program ECG Recording to "Off" to prevent automatic ECG storage for each FVT episode.

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

Duration – Select how many FVT events out of the most recent events must occur before the episode is classified as an FVT episode. For example when the duration is programmed to 30/40, it means that the 40 most recent events must consist of at least 30 FVT events to classify the episode as FVT.

Note: Program the FVT interval at least 40 ms shorter than the VT interval, to allow for normal variations in the patient's tachycardia interval.

5.3.2 VT episodes

Select Params icon
> ⇒ VT
>> ▷ Detection
>> ▷ ECG Recording
>> ▷ Interval (Rate)
>> ▷ Duration

You can adjust the criteria by which an increased ventricular rhythm is classified as a Ventricular Tachyarrhythmia (VT) episode.

The Reveal XT marks a possible VT event when the ventricular interval is shorter than the programmed VT interval length (but longer than the programmed FVT interval length). If the number of such VT events exceeds the programmed duration, a VT episode is stored unless FVT detection is off and the ECG noise level is excessive. The VT 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 VT interval.
- The median ventricular interval is equal to or longer than the programmed interval during a period of 20 s.
- No R-wave is detected during a period of 10 s.

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

Detection – Program VT Detection to "Off" to prevent automatic detection of VT episodes.

ECG Recording – Program ECG Recording to "Off" to prevent automatic ECG storage for each VT episode.

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

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

Note: Program the VT interval at least 40 ms longer than the FVT interval, to allow for normal variations in the patient's tachycardia interval.

5.3.2.1 VT detection enhancements

Select Params icon
⇒ Detection enhancements…
▷ VT Stability
▷ VT Onset
▷ VT Onset Percent (when VT Onset On)

To avoid the detection of unstable ventricular rhythms during rapidly conducted AT/AF or sinus tachycardia, you can enhance VT detection using the VT Stability and VT Onset parameters. Atrial fibrillation is typically associated with a fast and unstable (irregular) ventricular rate. Sinus tachycardia can generally be distinguished from ventricular tachycardia by the speed of ventricular rate increase (onset). Typically, ventricular tachycardia exhibits a sudden rate increase, while sinus tachycardia is characterized by a gradual rate increase.

VT Stability – VT Stability may help to avoid VT episodes from being detected as a result of single ventricular events at high rates. An R-wave that may be the start of a VT episode is compared with the 3 previous VT or FVT intervals. If the difference between the current interval and any of the 3 previous intervals is greater than the programmed VT Stability interval, the R-wave is not classified as a VT event.

For example, a suspected R-wave interval of 360 ms is compared with 3 previous R-wave intervals of 350, 290, and 330 ms. The difference between the suspected interval of 360 ms and the smallest previous interval of 290 ms is greater than the programmed VT Stability interval of 50 ms (in this case). As a result the R-wave interval is classified as unstable and will not start a new VT episode.

Note: Medtronic advises you to program the VT Stability interval long enough to allow for normal VT interval variation. A short VT Stability interval may decrease the sensitivity of the device to detect VT.

VT Onset – VT Onset limits the VT episodes detected to those where the ventricular rate increases rapidly. VT Onset compares the 4 most recent R-wave intervals with the previous 4 intervals. You can define a rapid increase with the VT Onset Percent parameter. If the average length of the 4 most recent R-wave intervals is shorter than the average length of the

4 previous R-wave intervals multiplied by the programmed Onset Percent, the next 4 R-waves are classified as VT events.

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

Notes:

- Programming VT Onset to "On" may delay detection of true ventricular tachyarrhythmia in patients who experience exercise-induced ventricular tachyarrhythmia.

- If you program VT Onset Percent to a lower setting, sinus tachyarrhythmia episodes are less likely to be inappropriately detected as ventricular tachyarrhythmia. However, there may be a reduced likelihood of detecting true ventricular tachyarrhythmia.

5.3.2.2 Combined count detection

Because FVT and VT events are counted separately, a ventricular rhythm with variable interval lengths may delay the detection of an FVT or VT episode. The Reveal XT uses a combined count detection algorithm to track the combined number of FVT and VT events. When the combined count detection criterion is met, the episode is marked as an FVT episode if one or more of the last 8 events is an FVT event. The episode is marked as a VT episode if none of the last 8 events is an FVT event.

5.3.3 Brady episodes

Select Params icon
⇒ Brady
▷ Detection
▷ ECG Recording
▷ Interval (Rate)
▷ 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.

ECG Recording – Program ECG Recording to "Off" to prevent automatic ECG storage for each brady episode.

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.

5.3.4 Asystole episodes

Select Params icon
    ⇒ Asystole
       ▷ Detection
       ▷ ECG Recording
       ▷ Duration

The device detects an 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 Asystole 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 asystole are very low amplitude, the suspected asystole episode is rejected because of probable undersensing. An asystole episode terminates after 12 ventricular sensed events have occurred.

Detection – Program Asystole Detection to "Off" to prevent automatic detection of asystole episodes.

ECG Recording – Program ECG Recording to "Off" to prevent automatic ECG storage for each asystole episode.

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

5.3.5 AT/AF episodes

Select Params icon
    ⇒ AT/AF…
        ▷ AT/AF Detection
        ▷ Type
        ▷ AF Detection
        ▷ Ectopy Rejection (when AF Detection is on)
        ▷ AT Detection
        ▷ Detect Very Regular AT Rhythms (when AT Detection is on)

    ⇒ ECG Recording
        ▷ Record ECG of

The Reveal XT 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 19, Figure 20, and Figure 21). 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 XT 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 19. Lorenz plot of an AF episode
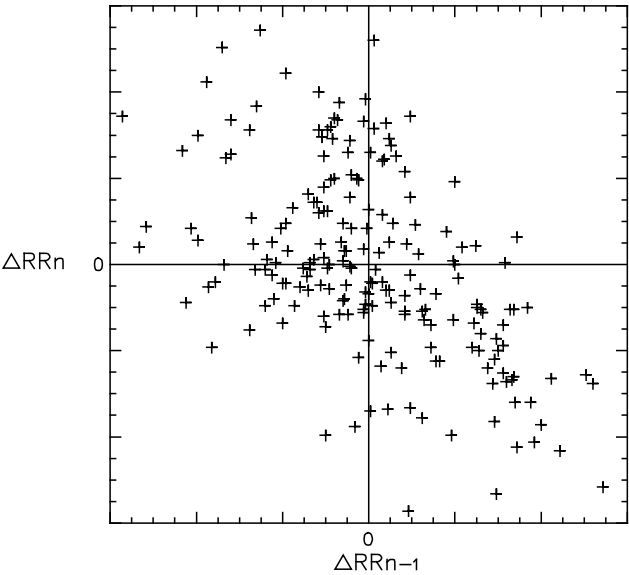
Figure 20. Lorenz plot of an AT episode
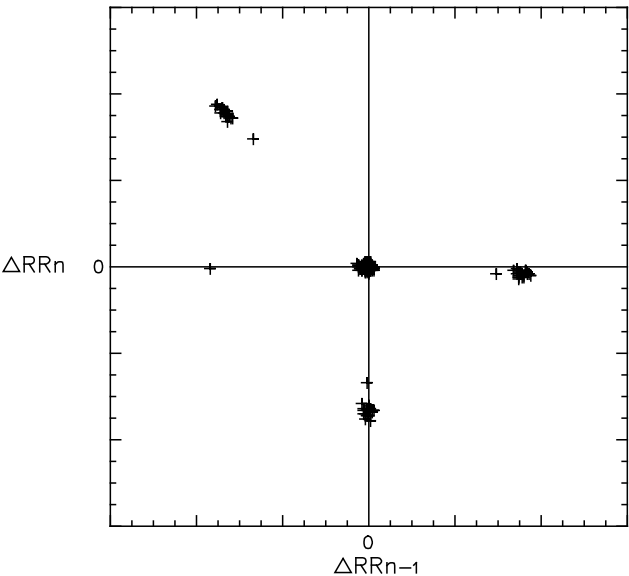
Figure 21. Lorenz plot of sinus rhythm
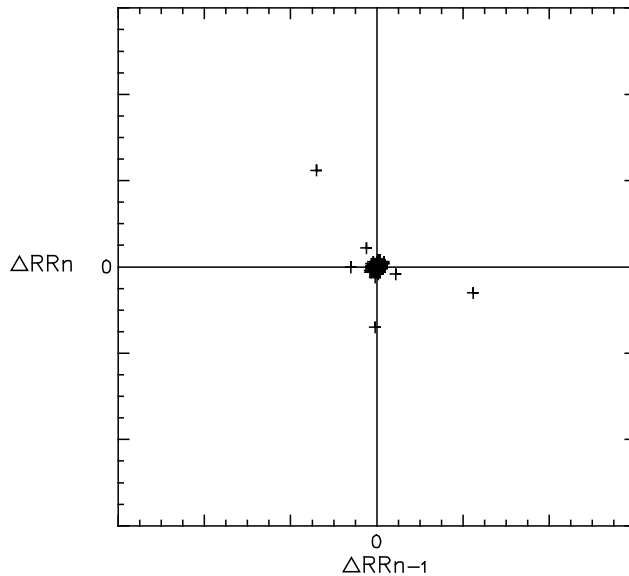
In the Lorenz plots the difference between 2 consecutive R-wave intervals (ΔRR_n) is plotted on the vertical axis. The preceding R-wave interval difference (ΔRR_{n-1}) is plotted on the horizontal axis

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, AT 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 XT may continuously detect AT episodes and record ECGs of those episodes (if ECG recording is programmed on). 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 detections are runs of ectopy (PACs or PVCs) with irregular coupling intervals caused by underlying sinus variability. The

Ectopy Rejection algorithm recognizes these patterns of ectopy by the density of points in the Lorenz Plot. When Ectopy Rejection is enabled, the device will not detect AF when the algorithm detects evidence of ectopy during any 2 min period.

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

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.

ECG Recording – Program ECG Recording to "Off" to prevent the automatic ECG storage for AT/AF episodes.

Note: An AT/AF episode can occur simultaneously with one of the other types of episodes. If this occurs, the Reveal XT will store information and an ECG recording (if programmed on) for both types of episodes.

When ECG Recording is programmed on, you can conserve memory space by avoiding the storage of ECGs of short "AF only" episodes.

If you select "All Episodes", an ECG of the first 2 min of each "AF only" episode is stored. If you select a minimum length for "AF only" episodes, no ECG will be stored for shorter "AF only" episodes. The records of all "AF only" episodes will still be stored in the episode log (see Section 6.3.1).

Note: If many successive short "AF only" episodes are stored in the episode log without ECG, there may be fewer than 3 ECG recordings stored in memory.

Record ECG of – Select the minimum length of "AF only" episodes for automatic ECG storage, or select all episodes.

5.4 Setting up the Patient Assistant query function

The Patient Assistant can be used to inform the patient about the status of the Reveal XT or the occurrence of an episode that you should be informed about. When the patient presses the query [?] button on the Patient Assistant, the event indicator lights up if a status change or episode has occurred since the last patient follow-up session. The OK indicator lights up if no status change or episode has occurred. The Patient Assistant query function notifications are not automatically switched on when you program Device Data Collection to "On". You can select which changes or episodes will be notified and program the conditions that must be met before the notification is given.

Figure 22. Patient Assistant Setup window

Notes:

- If the patient presses the query [?] button on the Patient Assistant when no events are programmed for the query function, the OK indicator will light up.

- The Patient Assistant query setup does not affect the automatic detection of episodes in the Reveal XT (see Section 5.3).

5.4.1 Device Battery Low

Select Params icon
   ⇒ Patient Assistant Setup…
      ⇒ Device Battery Low
         ▷ Enable

Enable – You can enable the Reveal XT to notify the patient when the battery of the Reveal XT has reached the Recommended Replacement Time (RRT).

Note: If the battery status is RRT, Medtronic advises you to switch off the Device Battery Low query option to avoid repeated notifications.

5.4.2 Maximum Symptom (Patient mark) Episodes Reached

Select Params icon
- ⇒ Patient Assistant Setup…
  - ⇒ Maximum Symptom (Patient mark) Episodes Reached
    - ▷ Enable

Enable – You can enable the Reveal XT to notify the patient when the memory space for patient-activated episodes is full. This means that a new patient-activated episode will overwrite an episode recorded since the last patient follow-up session.

5.4.3 Maximum Auto Detection Episodes Reached

Select Params icon
- ⇒ Patient Assistant Setup…
  - ⇒ Maximum Auto Detection Episodes Reached
    - ▷ Enable

Enable – You can enable the Reveal XT to notify the patient when the memory space for automatically activated episodes is full. This means that a new, automatically detected episode will overwrite an episode recorded since the last patient session.

5.4.4 FVT/VT episodes

Select Params icon
- ⇒ Patient Assistant Setup…
  - ⇒ FVT/VT
    - ▷ Enable
    - ▷ Duration for Notification
    - ▷ V. Rate

Enable – You can enable the Reveal XT to notify the patient when an episode of ventricular tachyarrhythmia (VT) or fast ventricular tachyarrhythmia (FVT) has occurred. You can choose to get a notification for all FVT/VT episodes, or you can set up criteria for notifying certain episodes. The patient is notified of a single FVT/VT episode if the episode lasts longer than the programmed duration and the rate exceeds the programmed rate.

Duration for Notification – Select the minimum episode length (in s) before episode notification.

Note: An FVT or VT episode that does not meet the detection criteria for automatically detected FVT or VT episodes, will not result in a notification. The minimum episode length of the automatically detected FVT or VT episode can be calculated by multiplying the Interval and Duration parameter settings.

V. Rate – Select the minimum ventricular rate for episode notification. The patient is notified if the average rate of 4 consecutive R-wave intervals exceeds this programmed rate.

5.4.5 Asystole episodes

Select Params icon
 ⇒ Patient Assistant Setup…
  ⇒ Asystole
   ▷ Enable
   ▷ Duration for Notification

Enable – You can enable the Reveal XT to notify the patient when an asystole episode has occurred. You can choose to get a notification for all asystole episodes, or you can set up criteria for notifying certain episodes. The patient is notified of a single asystole episode if the episode lasts longer than the programmed duration.

Duration for Notification – Select the minimum episode length (in s) before notification

5.4.6 Brady episodes

Select Params icon
 ⇒ Patient Assistant Setup…
  ⇒ Brady
   ▷ Enable
   ▷ Duration for Notification

Enable – You can enable the Reveal XT to notify the patient when a bradyarrhythmia episode has occurred. You can choose to get a notification for all bradyarrhythmia episodes, or you can set up criteria for notifying certain episodes. The patient is notified of a single bradyarrhythmia episode if the episode lasts longer than the programmed duration.

Duration for Notification – Select the minimum episode length (in s) before notification.

Note: A brady episode that does not meet the detection criteria for automatically detected brady episodes, will not result in a notification. The minimum episode length of the automatically detected brady episode can be calculated by multiplying the Interval and Duration parameter settings.

5.4.7 AT/AF Daily Burden

Select Params icon
⇒ Patient Assistant Setup…
⇒ AT/AF Daily Burden
▷ Enable
▷ Burden

Enable – You can enable the Reveal XT to notify the patient when the total amount of AT/AF in one day has exceeded the programmed burden. The total amount of AT/AF is measured over a 24-hour period, starting at midnight.

Burden – Select the minimum amount of AT/AF per day (in hours) before notification.

Note: The Reveal XT will not notify the patient about the AT/AF Daily Burden within 1 day of the last patient follow-up session, because the AT/AF episodes may have occurred shortly before or during the patient session.

5.4.8 V. Rate During AT/AF

Select Params icon
⇒ Patient Assistant Setup…
⇒ V. Rate During AT/AF
▷ Enable
▷ Burden
▷ V. Rate

Enable – You can enable the Reveal XT to notify the patient when there has been an extended period of elevated ventricular rate while in AT/AF. The patient is notified when the average ventricular rate during AT/AF exceeds the programmed V. Rate for a duration greater than the programmed burden. The burden is measured over a 24 hour period, starting at midnight

Burden – Select the minimum amount of time per day (in hours) of elevated ventricular rate during AT/AF before notification.

V. Rate – Select the minimum ventricular rate for notification.

6 Viewing the collected data

6.1 Introduction

The Medtronic CareLink Model 2090 programmer offers several ways to view and analyze the collected data in the Reveal XT. This may help you to monitor the patient's condition. You can assess the episode data and ECGs recorded since implant 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 6.2). 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 6.3). For long-term monitoring of the patient's condition, Cardiac Compass graphs show trends in data collected over a longer period of time (see Section 6.4). 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 6.5).

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).

6.1.1 How to clear collected data

You can clear all diagnostic data stored in the Reveal XT, 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.

Select Params icon
⇒ Device Data Collection…
    ⇒ Clear Data…
        ⇒ Clear Data

6.2 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 XT.

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.

6.2.1 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.

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

Figure 23. Quick Look window
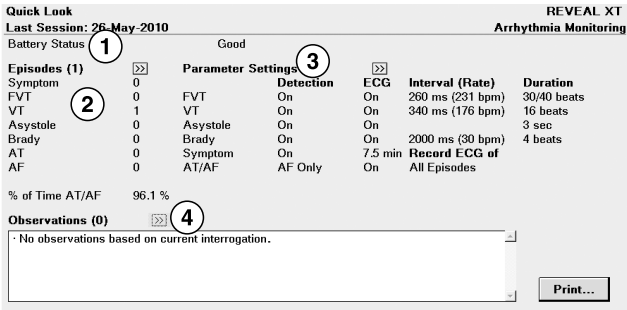
| 1 | Battery status | 3 | Parameter settings |
| 2 | Arrhythmia episode information | 4 | Observations |

Battery status – At the start of the patient session, the programmer presents the Reveal XT battery status. The battery status can be "Good", "Ageing", "RRT", or "EOS". If the battery status shows RRT (Recommended Replacement Time), the date when the battery reached RRT is indicated.

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 6.3. The

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[1] In the first patient session after implant, the Parameters window is displayed first to enable activation of Device Data Collection.

"% 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. Quick Look observations also show the events that have met the notification criteria of the Patient Assistant query function. 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 XT, for example, when the Reveal XT 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 one hour 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.

6.2.2 Printing the Quick Look report

Select Reports icon
   ⇒ 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 6.4). The Patient Assistant summary shows which events have met the notification criteria of the Patient Assistant query function since the last patient session.

6.3 Viewing arrhythmia episode data

Select Episodes icon
   ⇒ 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.

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

Episode data collected before previous sessions can also be shown, if available, and interrogated at the start of the patient follow-up session. At initial interrogation, the programmer reads data collected by the device 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.

6.3.1 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 24. Episode log
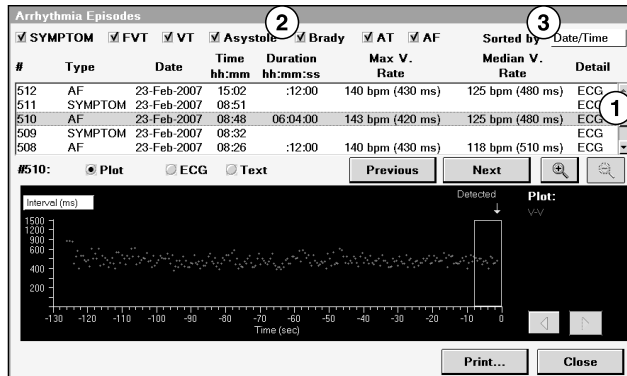
1 Use the scroll buttons on the right to go through the list of stored episodes.

2 Use the SYMPTOM, FVT, VT, Asystole, 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 Reveal XT 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.

6.3.2 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 25. Arrhythmia episode record
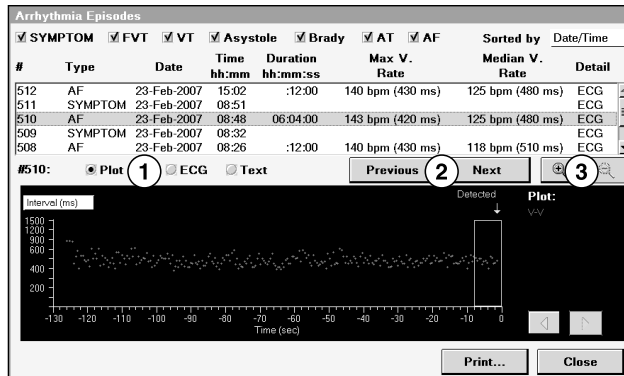
1 Use the Plot, ECG, and Text option buttons to display the selected episode data in one of the available formats.
2 Use the [Previous] and [Next] buttons to navigate from record to record.
3 Use the [+] button to maximize the display, and the [-] button to minimize it.

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 mark) 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 (FVT and VT detection intervals are only shown when an FVT or VT episode is selected)

- start of episode detection or end of episode detection

Figure 26. Episode interval plot
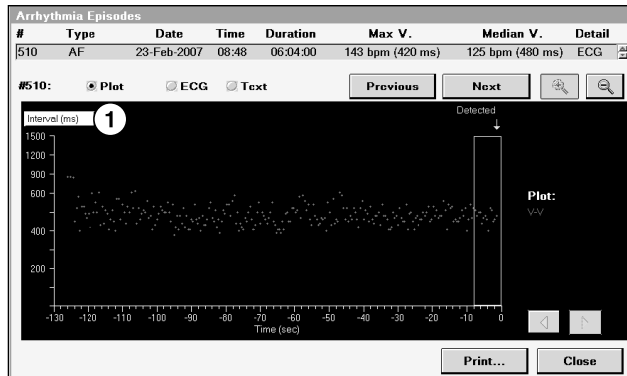
1 Use this option to switch the y-axis between Interval (ms) and Rate (bpm).

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

Figure 27. Episode ECG
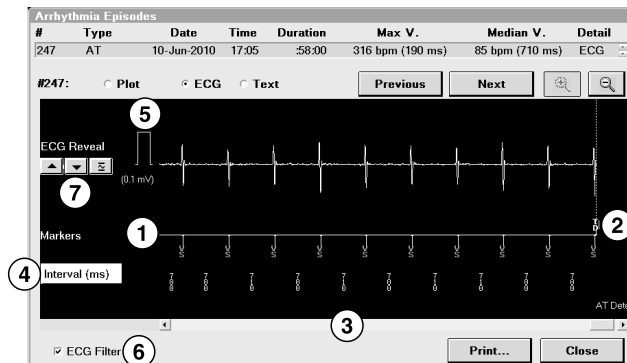
1 The Marker Channel displays the annotated events.
2 The decision channel displays an annotation if an episode is detected.
3 Use the horizontal scroll bar to view all of the episode ECG data.
4 Use this option to switch the y-axis between Interval (ms) and Rate (bpm).
5 The calibration pulse provides an indication of the amplitudes of the R-waves in the episode.
6 Use the ECG Filter option to improve the clarity of the displayed ECG.
7 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 4.1.

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.

Figure 28. Episode text
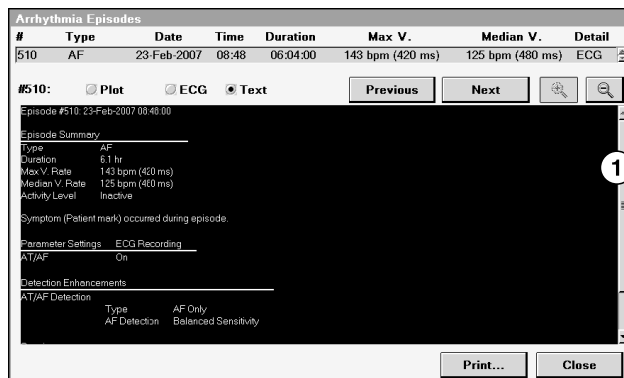
1 Use the vertical scroll bar to scroll through the episode text.

6.3.3 Printing episode data

Select Reports icon
  ⇒ Available Reports…
     ▷ Episode Counters
     ▷ AT/AF Summary
     ▷ Episode List
     ▷ Last FVT/VT with ECG
     ▷ 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 prior to the last patient session

• the number of episodes since the last patient session

• the number of episodes since implant (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 FVT/VT with ECG – You can print detailed information about the last FVT or VT episode with ECG that was recorded before the current patient session. The information includes the interval plot 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 and the complete ECG recording of the episode.

Note: The time annotations that appear on the reports are based on the Reveal XT 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 30 s, 60 s, and 120 s ECG segments from the episode you are currently viewing.

To print an ECG segment from the currently selected episode, follow these steps:

ECG
  ⇒ Print..
    ▷ Selected Episode
    ▷ Displayed ECG Include Prior (30 s, 60 s, or 120 s)

Figure 29. Print options window

6.4 Viewing long-term clinical trends

Select Reports icon
⇒ 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 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 trend data is available only as a printed report.

The Cardiac Compass report is based on data and measurements collected daily. The Reveal XT begins storing data after the device is implanted and data collection for the device is programmed on. Each day thereafter, the Reveal XT 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 Reveal XT device clock.

• You cannot manually clear the Cardiac Compass trend data.

6.4.1 Cardiac Compass trend graphs

Figure 30. Cardiac Compass trend graphs
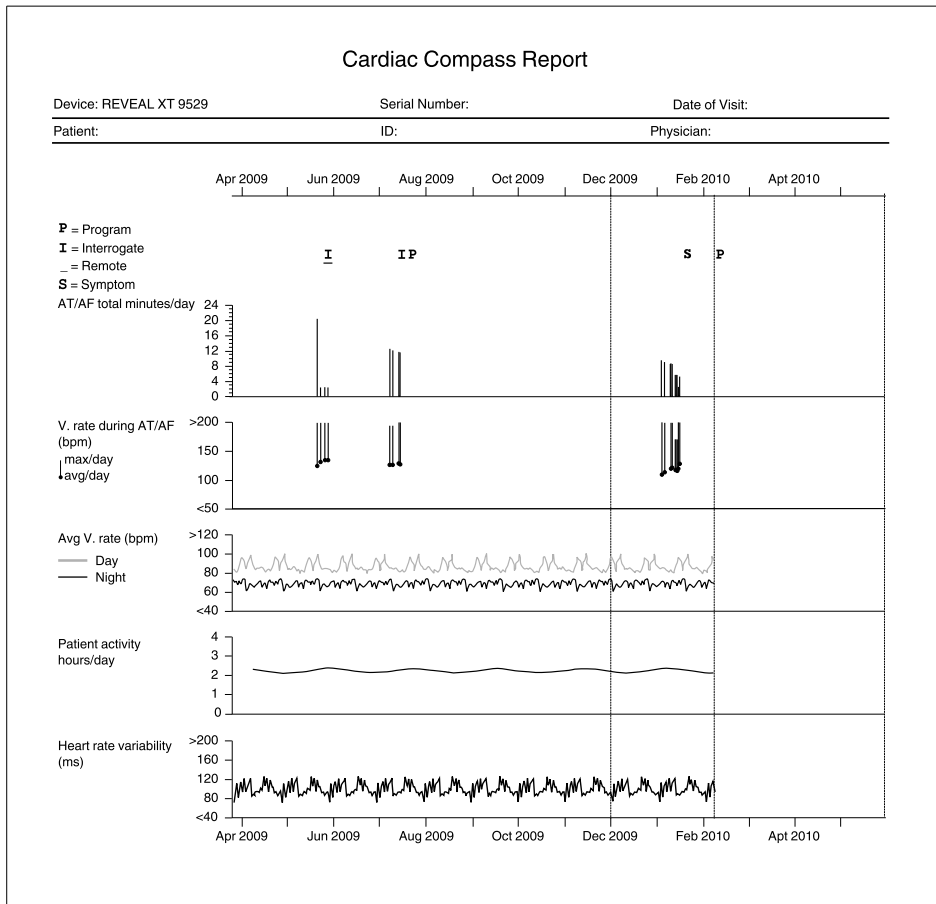
Programming and interrogation events – The report shows when the Reveal XT was interrogated or reprogrammed, to allow possible correlations between device parameter changes and other clinical trends.

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 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 XT 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 Reveal XT 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 Reveal XT 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, VT, or FVT).

6.5 Viewing rate histograms to assess heart rates

Select Reports icon
>   ⇒ 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 before and 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) and previous (prior to last session) collection periods.
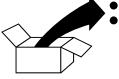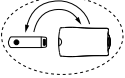
Figure 31. Rate Histograms report example
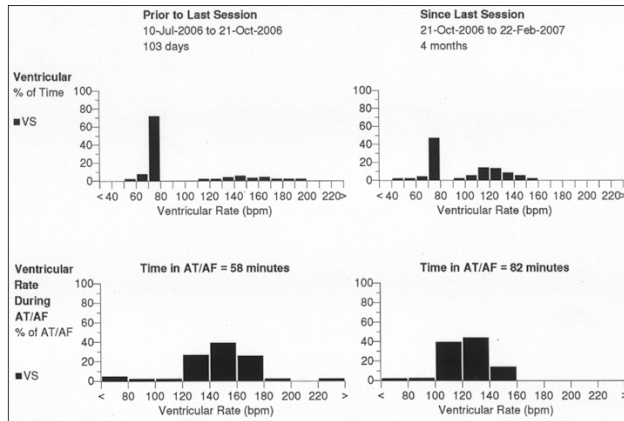
Rate histograms show the percentage of time that the ventricular rate was recorded within each rate range.
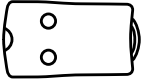
Ventricular rate histogram – The ventricular rate histogram shows the rate distribution of ventricular events as the percentage of total time. The histogram shows 20 rate ranges that are each 10 bpm wide. Rates slower than 40 bpm are included in the <40 bpm range; rates faster than 220 bpm are included 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 9 rate ranges that are each 20 bpm wide. Rates slower than 80 bpm are included in the <80 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   Explanation of symbols

Symbol	Explanation
SN	Serial number
	Date of manufacture
	Use by
STERILE EO	Sterilized using ethylene oxide
+ XX °C / + XXX °F / − XX °C / − XX °F	Temperature limitation
2	Do not reuse
	Open here
i	Consult instructions for use
	Package contents
+	Accessories
	Product documentation
	Insertable Cardiac Monitor
	Insertable Cardiac Monitor system

Symbol	Explanation
1	Single sterile barrier
	Patient Assistant Model 9539
MR	MR Conditional
	Recording

B   Product specifications

B.1   Reveal XT programmable parameters

Note: Tolerances for programmable parameter values are valid when the device temperature is between 22 °C and 45 °C (72 °F to 113 °F).

Table 4. Programmable parameters: data collection

Parameter	Programmable values	Shipped value	Nominal/Reset value
Device Data Collection[a]	On	Off	On
Device Date/Time…[b]	(Enter current date and time)	Current time (manufacturing time zone)	1 Jan 1994

[a] Turning on Device Data Collection enables sensing and data collection (all episode types).
[b] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

Table 5. Programmable parameters: R-wave sensing

Parameter	Programmable values	Shipped value	Nominal/Reset value
Blank after Sense	130; 150; 170; 200; 250; 300; 400 ms	150 ms	150 ms
Sensing Threshold Decay Delay	130; 150; 200; 300; 400; 500 ms	150 ms	150 ms
Sensitivity	0.025; 0.035; 0.05; 0.075; 0.1; … 0.2 mV[a]	0.035 mV	0.035 mV

[a] Sensitivity at nominal conditions as measured at 37 °C (98.6 °F) can vary by ±1% per °C from 22 °C to 45 °C (72 °F to 113 °F).

Table 6. Programmable parameters: episode detection

Parameter	Programmable values	Shipped value	Nominal/Reset value
Asystole Detection	On; Off	On	On
Asystole Duration	1.5; 3.0; 4.5 s	3.0 s	3.0 s
Asystole ECG Recording	On; Off	On	On
AT/AF Detection	On; Off	On	On
AT/AF AF Detection	Least Sensitive; Less Sensitive; Balanced Sensitivity; More Sensitive; Most Sensitive	Balanced Sensitivity	Balanced Sensitivity
AT/AF AT Detection	Least Sensitive; Most Sensitive	Least Sensitive	Least Sensitive

Table 6. Programmable parameters: episode detection (continued)

Parameter	Programmable values	Shipped value	Nomi-nal/Reset value
AT/AF Detect Very Regular AT Rhythms	Off; On-Rates ≥ 67 bpm; On-Rates ≥ 100 bpm; On-All Rates	On-All Rates	On-All Rates
AT/AF Detection Type	AT/AF; AF Only	AF Only	AF Only
AT/AF ECG Recording	On; Off	On	On
AT/AF Record ECG of	All Episodes, Episodes ≥ 6 min, Episodes ≥ 10 min, Episodes ≥ 20 min, Episodes ≥ 30 min, Episodes ≥ 60 min	All Episodes	All Episodes
Brady Detection	On; Off	On	On
Brady Duration	4; 8; 12 beats	4 beats	4 beats
Brady ECG Recording	On; Off	On	On
Brady Interval (Rate)	1000; 1200; 1500; 2000 ms	2000 ms	2000 ms
Ectopy Rejection	On; Off	Off	Off
FVT Detection	On; Off	On	On
FVT Duration	9/12; 12/16; 18/24; 24/32; 30/40 beats	30/40 beats	30/40 beats
FVT ECG Recording	On; Off	On	On
FVT Interval (Rate)	240; 250; … 400 ms	260 ms	260 ms
Symptom ECG Recording	Three 7.5 min Episodes; Two 10 min Episodes; One 15 min Episode	Three 7.5 min Episodes	Three 7.5 min Episodes
VT Detection	On; Off	On	On
VT ECG Recording	On; Off	On	On
VT Duration	5; 12; 16; 24; 32; 48 beats	16 beats	16 beats
VT Interval (Rate)	250; 260; … 520 ms	340 ms	340 ms
VT Onset	On; Off	Off	Off
VT Onset Percent	72; 75; 78; 81; 84; 88; 91; 94; 97%	81%	81%
VT Stability	Off; 30; 40; … 100 ms	Off	Off

Table 7. Programmable parameters: Patient Assistant query setup

Parameter	Programmable values	Shipped/Nomi-nal/Reset value
Asystole Enable	On; Off	Off
Asystole Duration for Notification	5; 7.5; 10; 15; 20 s, All Asystole Episodes	All Asystole Episodes
AT/AF Burden	Any; 1; 2; 3; 4; 6; 12; 18; 24 hours	6 hours
AT/AF Daily Burden Enable	On; Off	Off

Table 7. Programmable parameters: Patient Assistant query setup (continued)

Parameter	Programmable values	Shipped/Nomi-nal/Reset value
Brady Enable	On; Off	Off
Brady Duration for Notification	10; 15; … 40; 50; 60; 120; 180; 240 s; All Brady Episodes	All Brady Episodes
Device Battery Low Enable	On; Off	Off
FVT/VT Enable	On; Off	Off
FVT/VT Duration for Notification	5; 10; … 60 s; All FVT/VT Episodes	All FVT/VT Episodes
FVT/VT V. Rate	Any; 240; 250; … 520 ms	Any
Maximum Auto Detected Episodes Reached	On; Off	Off
Maximum Symptom (Patient mark) Episodes Reached	On; Off	Off
V. Rate During AT/AF Burden	Any; 1; 2; 6; 12; 18; 24 hours	6 hours
V. Rate During AT/AF Enable	On; Off	Off
V. Rate During AT/AF	90; 100; … 150 bpm	100 bpm

Table 8. Device and patient information

Data field
Date of Birth
Hospital
ID
Implant Date
Last Update
Notes
Patient
Physician
Phone
Serial Number

Table 9. Available counters[a]

Counter
Asystole episodes
AF episodes
AT episodes

Table 9. Available counters^a (continued)

Counter
Brady episodes
FVT episodes
Symptom (patient-activated) episodes
VT episodes

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

Table 10. Available reports

Report name	Contents
AT/AF Summary	AT/AF episode summary (before prior session and before last session) AT/AF durations AT/AF episode start time
Cardiac Compass	Programming and interrogation events AT/AF total time per day Ventricular rate during AT/AF Average ventricular rate Patient activity Heart rate variability
Episode Counters	Number of episodes since last session Number of episodes prior to last session Device lifetime total number of episodes
Episode List	Episode log since last session Episode log prior to last session
Last AT/AF with ECG	Episode summary Parameter settings Interval plot ECG recording
Last FVT/VT with ECG	Episode summary Parameter settings Interval plot ECG recording
Parameters: All Settings	Parameters Sensing Detection enhancements Patient Assistant setup Device Data Collection Device information
Parameters: Changes This Session	Parameters Session Start value Current value
Patient Information	see Table 8

Table 10. Available reports (continued)

Report name	Contents
Initial Interrogation: Quick Look	Device status Episode summary (since last session) Observations Patient Assistant summary Cardiac Compass trends
Rate Histograms	Ventricular rate histogram (since last session and prior to last session) Ventricular rate during AT/AF histogram (since last session and prior to last session)
Session Summary	Device information Device status Parameter changes this session Current value of parameters

B.2 Reveal XT technical specifications

Table 11. Physical characteristics

Parameter	Value
Volume	9 cm^3
Mass	15 g
Dimensions H x W x D	62 mm x 19 mm x 8 mm
Surface area of device can electrode	43 mm^2
Surface area of device header electrode	43 mm^2
Distance between the electrodes	40 mm
Radiopaque ID	RAB

Table 12. Materials in contact with human tissue

Parameter	Value
Can and external electrode[a]	Titanium
Header	Polyurethane, silicone
Coating	Parylene

[a] Traces of silver from the Vector Check electrodes may remain on the device.

Table 13. Battery characteristics

Parameter	Value
Manufacturer	Eagle Picher
Model/type	LTC-3PN-S36
Chemistry	Lithium Thionyl Chloride

Table 13. Battery characteristics (continued)

Parameter	Value
Nominal voltage	3.6 V
Effective voltage at RRT[a]	>3.1 V
Mean capacity to RRT[a]	0.25 Ah
Estimated residual capacity at RRT[a]	0.02 Ah
Projected longevity[b]	3 years

[a] RRT = Recommended Replacement Time
[b] After 12 months shelf life

Table 14. Sensing characteristics

Parameter	Value
Input impedance	≥150 kΩ
ECG gain	50 x
Sampling rate	256 Hz
Sampling resolution	16 bits/sample
Bandwidth	0.5 – 95 Hz

C   Sensing and detection performance

C.1 Reveal XT sensing and detection performance

There was no prospective clinical testing of the device.

C.1.1 R-wave sensing

The R-wave sensing performance was assessed with a desktop emulation of the device using previously collected Reveal Plus electrocardiograms (3588 recordings from 600 patients) from 3 clinical studies. The electrocardiograms tested were comprised of the following:

- All patient-activated recordings (974 recordings from 431 patients) collected during each study.

- A single, randomly-selected, automatically activated recording from each patient at each follow-up of the clinical studies (selected from the available recordings by an automated, unbiased method). This amounted to 2614 automatically activated recordings from 533 patients, which represented 11% of all 23,810 automatically activated recordings collected.

This predefined subset of Reveal Plus electrocardiograms from the 3 studies was used to approximate the kind of tracings expected in real-life use of Reveal XT. Reveal XT performance in particular patients may vary when automatically activated recordings occur more or less frequently than occurred in the clinical studies.

These recordings contained 1.5 million opportunities to sense R-waves. Reveal XT correctly identified 99.1%[2] of all R-waves, with 1.6%[3] of all sensed R-waves being inappropriate detections.

C.1.2 Asystole detection

Asystole detection performance was evaluated on a database of 463 asystole episodes, detected in 50 patients with previously implanted Reveal XT devices.[4] Of those asystole episodes that were detected inappropriately, 44.5% (GEE Adjusted) were now rejected, while continuing to detect 98.9% (GEE Adjusted) of those asystole episodes that were detected appropriately.

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[2] Median per patient sensitivity for all patients.
[3] Median per patient positive predictive value for all patients.
[4] Clinical Trial Registration Information ID number: NCT00680927. Clinical Trial Registration URL: http://www.clinicaltrials.gov/ct2/show/NCT00680927

C.1.3 FVT detection

FVT detection performance was evaluated on a database of 208 FVT episodes, detected in 50 patients with previously implanted Reveal XT devices.[4] Of those FVT episodes that were detected inappropriately, 99.3% (GEE Adjusted) were now rejected as noise, while continuing to detect 96.4% (GEE Adjusted) of those FVT episodes that had true heart rates in the programmed FVT zone.

C.1.4 AT/AF detection

C.1.4.1 AT/AF databases

The performance of the AT/AF detection algorithm was assessed using the following standard published arrhythmia databases[5]:

- 1984 monitoring hours in 153 patients

- 92.9 hours of AF, 1.6 hours of AT

- 148 AF episodes, 3 AT episodes

C.1.4.2 AT/AF duration detection performance

AT/AF duration detection performance was assessed in "AF only" and AT/AF mode.

AF only mode – Reveal XT correctly identified 98%[6] of the total time in true AF (that is, detected AF and true AF occurred at the same time), with 7%[7] of total duration of AF detection being inappropriate (that is, detected AF did not overlap with true AF episodes).

AT/AF mode – Reveal XT correctly identified 98%[8] of the total time in true AT/AF (that is, detected AT/AF and true AT/AF occurred at the same time), with 19%[9] of total duration of AT/AF detection being inappropriate (that is, detected AT/AF did not overlap with true AT/AF episodes).

The Reveal XT AT/AF duration detection performance translates into accurate Daily Burden estimates. In the "AF only" mode, Reveal XT detected the daily AF burden within 25% of the actual AF burden in 91% of patients having more than 10 min of AF per day (21/23 patients). For the 130 patients with less than 10 min of daily AF burden, Reveal XT also detected less than 10 min of daily burden in 96% of patients. The equivalent figures for the algorithm set to AT/AF mode are 78% (18/23 patients) and 87% (113/130 patients), respectively.

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[5] Only AT/AF episodes >2 min in duration were considered from standard, published databases. The device was optimized to detect episodes longer than 2 min.
[6] Duration sensitivity for "AF only" mode.
[7] Duration positive predictive value for "AF only" mode.
[8] Duration sensitivity for AT/AF mode.
[9] Duration positive predictive value for AT/AF mode.

C.1.4.3 AT/AF episode detection performance

AT/AF episode detection performance was assessed in "AF only" and AT/AF mode.

AF only mode – Reveal XT correctly identified 99%[10] of all the true AF episodes, with 24%[11] of all detected AF episodes being inappropriate.

AT/AF mode – Reveal XT correctly identified 98%[12] of all the true AT/AF episodes, with 68%[13] of all detected AT/AF episodes being inappropriate.

C.1.5 AT/AF detection clinical performance

C.1.5.1 Clinical database

The performance of the AT/AF detection algorithm was also assessed using data from a clinical performance database, which contained data from 1 clinical study.[14] This database contained data recorded simultaneously over a 45 hour period[15] by the Reveal XT and surface Holters of the following groups of patients:

- Patients who are scheduled to undergo pulmonary vein ablation or surgical rhythm control intervention.
- Patients who have undergone pulmonary vein ablation within the last 6 months and still have symptoms attributable to AF.
- Patients who have documented frequent AF or frequent symptoms attributable to AF.

AT/AF detection performance was assessed using only AF episodes ≥ 2 min in duration. The clinical performance database contained the following information:

- 5937 monitoring hours in 150 patients
- 752 hours of AF
- 303 AF episodes

This specific patient group from the clinical study was used to approximate the AT/AF detection performance of the Reveal XT. Reveal XT performance may vary for particular patients.

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[10] Mean per patient episode sensitivity for "AF only" mode for all patients.
[11] Mean per patient episode positive predictive value for "AF only" mode for all patients.
[12] Mean per patient episode sensitivity for AT/AF mode for all patients.
[13] Mean per patient episode positive predictive value for AT/AF mode for all patients.
[14] Clinical Trial Registration Information ID number: NCT00680927. Clinical Trial Registration URL: http://www.clinicaltrials.gov/ct2/show/NCT00680927
[15] Median recording time

C.1.5.2 AT/AF episode and duration detection performance

Nominal mode of operation – The nominal mode of operation for the device is with AT/AF Detection Type set to AF-only and AF Detection set to Balanced Sensitivity.

The Reveal XT correctly identified 98%[16] of the total time in true AF (that is, detected AF and true AF occurred at the same time), 97%[17] of total time of non-AF periods (that is, periods without AF detection and true non-AF periods occurred at the same time), with 15%[18] of total duration of AF detection being inappropriate (that is, detected AF did not overlap with true AF episodes).

The Reveal XT correctly identified an average of 92%[19] of true AF episodes per patient, with an average of 33%[20] of detected AF episodes being inappropriate per patient. The Reveal XT correctly identified 82%[21] of all true AF episodes, with 77%[22] of all detected AF episodes being inappropriate. The difference between average percentage of inappropriate detections per patient and percentage of inappropriate detections of all episodes is large because only a few patients contributed a large number of inappropriate detections.

The following table summarizes the performance results for the Reveal XT in the nominal mode of operation.

Table 15. Performance Metrics for Nominal Mode of Operation

	All episodes	Patient average
Duration Detection Sensitivity	98%	91%
Duration Detection Specificity	97%	93%
Duration Detection Positive Predictive Value	85%	68%
Episode Detection Sensitivity	82%	92%
Episode Detection Positive Predictive Value	23%	67%

The Reveal XT AF duration detection performance translates into accurate AF burden estimates (% AF measured over 45 hour period). The Reveal XT detected the AF burden within 25% of the actual AF burden in 94% of the patients having more than 10 min of AF (48/51 patients). For the 99 patients with less than 10 min of AF burden, Reveal XT also detected less than 10 min of burden in 86% of patients.

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[16] Duration Detection Sensitivity (All episodes)
[17] Duration Detection Specificity (All episodes)
[18] 100% - Duration Detection Positive Predictive Value (All episodes)
[19] Episode Detection Sensitivity (Patient average)
[20] 100% - Episode Detection Positive Predictive Value (Patient average)
[21] Episode Detection Sensitivity (All episodes)
[22] 100% - Episode Detection Positive Predictive Value (All episodes)

The table below summarizes the AF algorithm performance with respect to total true AF episodes and duration. There were a total of 248 appropriately detected AF episodes in 51 patients and a total appropriately detected AF duration of 737 hours. There were a total of 739 inappropriately detected AF episodes in 33 patients and a total inappropriately detected duration of 136 hours. The inappropriately detected AF episodes tended to be much shorter in duration than appropriately detected AF episodes. Note that, in a given category, there may be different numbers of patients which contribute to episode and durations totals since 1) a single detected AF episode can span a true AF period and a non-AF period and 2) a single detected AF episode need not span the entire duration of a true AF episode to be counted as a correctly identified episode.

Table 16. AF episode and duration detection performance

		Actual AF (≥ 2 min)	
		Yes	**No**
Detected AF	Yes	248 episodes (51 patients) 737 hrs (51 patients)	739 episodes (33 patients)[a] 136 hrs (60 patients)
	No	55 episodes (8 patients) 15 hrs (50 patients)	N/A 5049 hrs (141 patients)

[a] 81% of these episodes came from 7 patients with frequent and prolonged ectopy resulting in irregularly irregular ventricular rates in the absence of AF.

Programmable options - AF-only mode (nominal) – The following table summarizes the performance results for the Reveal XT for different AF Detection settings with AT/AF Detection Type set to AF-only. The percent of detected AF episodes being inappropriate per patient decreases from 49% to 22% from the Most Sensitive to the Least Sensitive setting.

	AF Detection settings				
	Most sensitive	**More sensitive**	**Balanced sensitivity (nominal)**	**Less sensitive**	**Least sensitive**
Total Duration Sensitivity	98%	98%	98%	98%	97%
Total Duration Specificity	95%	97%	97%	98%	99%
Average Episode Detection Sensitivity per patient	97%	94%	92%	92%	90%
Average Episode Detection Positive Predictive Value per patient	51%	59%	67%	71%	78%

Programmable options – AT/AF mode – The following table summarizes the performance results for the Reveal XT for AT/AF Detection Type set to AT/AF and different settings of Detect Very Regular AT Rhythms. The Detect Very Regular AT Rhythms option allows for choosing the ventricular rate limit for the detection of regular AT, such as for atrial flutter that is conducted with a fixed conduction ratio. For example, the Rates >= 100 bpm

setting will only detect regular AT with ventricular rate that is faster than 100 bpm. This will limit regular AT detection to atrial flutter with a 2:1 conduction ratio.

	Detect Very Regular AT Rhythms settings			
	All Rates	**Rates >= 67 bpm**	**Rates >= 100 bpm**	**OFF**
Total Duration Sensitivity	99%	99%	99%	99%
Total Duration Specificity	92%	94%	95%	95%
Average Episode Detection Sensitivity per patient	96%	96%	96%	96%
Average Episode Detection Positive Predictive Value per patient	26%	31%	42%	43%

D   MRI procedure

D.1 Performing a Magnetic Resonance Imaging (MRI) procedure

It is important to read the information in this chapter before conducting an MRI scan on a patient with an implanted Reveal XT. Contact your Medtronic representative if you have any questions about the information provided.

D.1.1 MRI conditions for use

⚠ /MR\	**MR Conditional –** The Reveal XT has been demonstrated to pose no known hazards in a specified MR environment with the conditions of use specified in this section.

Non-clinical testing has demonstrated that the Reveal XT is safe for use in the MRI environment when used according to the instructions provided in this section.

The Reveal XT can be safely scanned in patients under the following conditions:

- Closed bore, cylindrical magnet with static magnetic field must be 1.5 T or 3.0 T.

- Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s.

- Whole body Specific Absorption Rate (SAR) as reported by the MRI equipment must be ≤2.0 W/kg; head SAR as reported by the MRI equipment must be ≤3.2 W/kg.

- The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 30 min. If additional chest scans beyond 30 min are necessary, a waiting period of at least 10 min is required.

In non-clinical testing, the device produced a temperature rise of less than 4 °C (7.2 °F). A maximum whole body average SAR was used for a 30 min scanning period. In the 1.5 T device (manufacturer Philips, model Intera, software version 2.1.3.2, Field strength B1 of 4.5 µT), the maximum SAR level of 4.0 W/kg was used, which was displayed on the MRI scanner console. In the 3 T device (manufacturer Philips, model Achieva, software version 2.1.3.2, Field strength B1 of 1.6 µT) a maximum level of 0.9 W/kg was used, which was displayed on the MRI scanner console.

D.1.2 General information on MRI procedures

D.1.2.1 Types of electromagnetic fields generated by MRI systems

An MRI system produces 3 types of electromagnetic fields that may interact with implanted devices. All 3 of these fields are necessary to produce an MRI image.

Static magnetic field – This is a steady state, non-varying magnetic field that is normally always on, even when no scan is in progress. The spatial gradient (dB/dz) of the static magnetic field is at its maximum near the entrance to the bore of the MRI equipment. In non-clinical testing the spatial gradient (dB/dz) values for the 1.5 T and 3 T machines were 2.5 and 4.6 T/m respectively.

Gradient magnetic fields – These low-frequency, pulsed magnetic fields are present only during a scan. MRI equipment uses 3 orthogonal gradient magnetic fields to form the image. These gradient magnetic fields vary linearly within the bore. In non-clinical testing the 1.5 T machine had a spatial gradient field of 21 mT/m and the 3 T machine had 80 mT/m.

RF field – This is a pulsed RF field that is present only during a scan. The RF field can be produced by a variety of transmission RF coils, such as a whole body transmit coil or an extremity coil (for example, a transmit head coil).

D.1.2.2 Potential interactions for implanted Reveal XT devices in the MRI environment

The Reveal XT design and the conditions for use (see Section 2.1) limit the potential interactions described in this section. The effects described might be experienced by the patient but will not harm the patient or damage the device.

Magnetic and RF field interactions – The magnetic material of an implanted device may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner.

The gradient magnetic field and modulated RF field may induce currents and voltages in the device. This could lead to tissue heating, nerve stimulation and electrical stress on device components.

The gradient magnetic field and modulated RF field may induce voltages in the sensing circuitry. This may affect sensing and event detection and thus could lead to inappropriate data recorded by the Reveal XT. Pre-MRI and post-MRI operation precautions are described to prevent potentially misleading information.

Image artifacts and distortion – The Reveal XT causes image distortion for areas in the image that surround the implanted device. Image artifacts and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters (see Section D.1.5.3).

D.1.3 MRI contraindications

Although the Reveal XT is considered conditionally safe for use in the MRI environment when used under the specified conditions, other implanted devices or the patient's individual medical condition might have an impact on safety and might require additional examination. If applicable, user manuals for the other implanted devices, including abandoned leads, should be consulted before conducting the MRI scan.

Patients with a Reveal XT that has been implanted for less than 6 weeks are contraindicated for an MRI procedure. The 6-week post-implant waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of "tugging" on the device caused by the magnetic fields.

Patients with a Reveal XT implanted in sites other than the subcutaneous region of the chest are contraindicated for an MRI procedure.

D.1.4 MRI potential adverse events

An implanted Reveal XT may be subject to interactions in the MRI environment. The device design minimizes the potential adverse effects that may result from these interactions to an acceptable level. However, patients may experience minor discomfort, due to tissue heating or "tugging".

The MRI environment may interfere with the device's capability to detect irregular heart rhythms, and therefore, diagnostic information collected during the MRI procedure may be corrupted.

D.1.5 Radiology-specific MRI warnings and precautions

D.1.5.1 MRI equipment requirements

The MRI equipment requirements listed in this section must be satisfied during all MRI procedures performed on patients with a Reveal XT. If you are unsure of the capabilities of your MRI machine, contact the MRI manufacturer.

Compatible MRI equipment classifications – The safety and reliability of Reveal XT devices have been evaluated in vitro using MRI equipment that has the following operating characteristics:

- hydrogen proton magnetic resonance imaging equipment with a static magnetic field of 1.5 T and 3.0 T
- RF excitation frequency that is approximately 64 MHz in a 1.5 T static magnetic field and approximately 128 MHz in a 3 T static magnetic field
- closed bore, cylindrical magnet systems

- whole body gradient systems with a gradient slew rate specification of 200 T/m/s or less[23]

D.1.5.2 MRI procedure requirements

MRI RF power – The whole body SAR as reported by the MRI equipment must be ≤2.0 W/kg. The head SAR as reported by the MRI equipment must be ≤3.2 W/kg.

Local or surface coils – If local or surface coils are needed, adhere to the following requirements:

- Do not use a local, interventional, extremity volume, or surface transmit coil over or near the chest, trunk, or shoulder region of the patient. A local or surface receive-only coil is permissible.

Total scan duration over the chest – The uninterrupted duration of active scanning over the chest during MRI (when RF and gradients are on) must not exceed 30 min. If additional chest scans beyond 30 min are necessary, a waiting period of at least 10 min is required.

Total scan duration outside of the chest region – There are no scan duration limitations when imaging areas outside of the chest region, provided the Reveal XT is not in the RF field.

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

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[23] The true limitation for gradient magnetic fields necessary to safely scan patients is that the maximum gradient magnetic field time rate of change (dB/dt) the patient is exposed to is in the range of 30-60 T/s. The Reveal XT has been evaluated in vitro using test equipment with a gradient magnetic field time rate of change of 100 T/s. The maximum gradient magnetic field (dB/dt) that the gradient system will produce during a scan may not be reported via the MRI console or MRI equipment specifications. Therefore, the above MRI equipment requirement that restricts scans to whole body gradient systems with a gradient slew rate specification of 200 T/m/s or less is an alternative means of ensuring that the gradient system cannot produce gradient magnetic field levels that could potentially harm the patient. Using a whole body gradient system that exceeds the gradient slew rate specification of 200 T/m/s, or any type of special purpose gradient system, is allowed only if the maximum gradient magnetic field (dB/dt) the device is exposed to can be verified to be 100 T/s or less.

D.1.5.3 Image quality

MRI image quality may be compromised if the area of interest is at or near the implanted Reveal XT. The figures below show the image artifacts (top view) of 2 Reveal XT devices placed on a grid. The device on the right was placed vertically on the grid, and the one on the left was placed horizontally. Figure 32 and Figure 33 show the artifacts for the 1.5 T machine (spinEcho and gradientEcho images respectively) and Figure 34 and Figure 35 show the same artifacts for the 3 T machine. The images show worst-case artifacts of about 6 cm (2.5 in) around the Reveal XT. For both the 1.5 T closed bore device (manufacturer Philips, model Intera, software version 2.1.3.2), and the 3 T closed bore device (manufacturer Philips, model Achieva, software version 2.1.3.2), the results are summarized in Table 17. The gradient field is expressed as a percentage of the maximum peripheral nerve stimulation (PNS).

Figure 32. Image artifacts at 1.5 T (spinEcho)
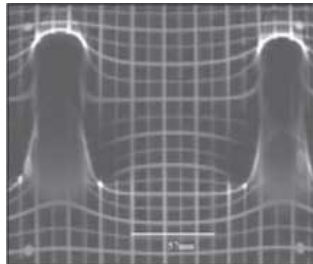
Figure 33. Image artifacts at 1.5 T (gradientEcho)
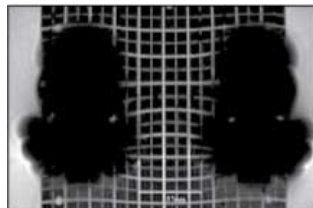
Figure 34. Image artifacts at 3 T (spinEcho)
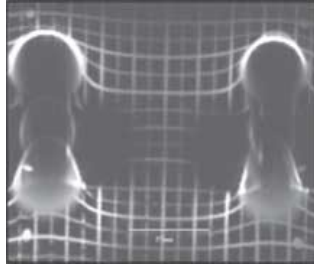
Figure 35. Image artifacts at 3 T (gradientEcho)
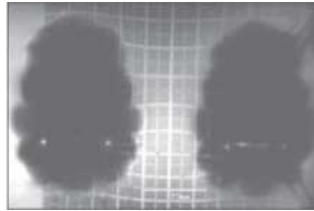
Table 17. MRI scan, effects on image quality

Figure	B0 (T)	Scan type	Flip angle (°)	B1 (µT)	Percentile of max PNS (%)
Figure 32	1.5	spinEcho	70	2.28 (25%)	8
Figure 33	1.5	gradientEcho	30	0.49 (1%)	15
Figure 34	3.0	spinEcho	70	1.57 (94%)	23
Figure 35	3.0	gradientEcho	30	0.77 (23%)	54

D.1.6 Cardiology-specific MRI warnings and precautions

System information and patient records – All pertinent information about the implanted Reveal XT, such as model name, model number, and serial number, should be recorded in the patient record. This will help communicate to referring physicians that a patient has a Reveal XT.

Patient identification (ID) card requirements – Reference materials, such as a Device Identification Card, should be provided to all patients with an implanted Reveal XT. These materials indicate that the patient may have an MRI procedure, and help to communicate to referring physicians that a patient has a Reveal XT.

D.1.7 Pre-MRI operation

Identifying the Reveal XT – There are 2 ways to verify that a patient has a Reveal XT:

- There is a radiopaque symbol on all implanted Reveal XT devices. An x-ray of the implanted system can verify whether the device is a Reveal XT. The radiopaque symbol (RAB) is located in the header of the device. See Figure 36 for the device radiopaque symbol and its location. An x-ray can also indicate whether the patient has any additional implanted devices.

- The patient records or device identification cards, if applicable, must be complete and accurate if they are to be used to verify that the patient has a Reveal XT or that the patient has no additional implanted devices.

Figure 36. Location of the radiopaque symbol
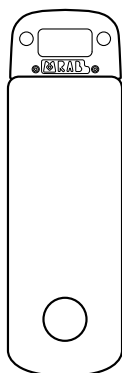
Preparing a Reveal XT for an MRI procedure – The following tasks must be completed before performing an MRI procedure on a patient with a Reveal XT:

1. Check that the system has been implanted for more than 6 weeks. The 6-week post-implant waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of "tugging" on the device caused by the magnetic fields.

2. Check that additional implantable devices are not present. Interactions with all other implanted devices have not been tested by Medtronic.

3. Check that abandoned leads are not present. Interactions with abandoned leads have not been tested by Medtronic.

4. Check that the data in the Reveal XT has been saved. Before the MRI procedure is started, the data stored in the Reveal XT must be read out and saved to a diskette using the programmer. The MRI procedure might corrupt the recorded data in the Reveal XT.

5. Make sure that the patient does not bring the Patient Assistant into the MRI controlled room (magnet room).

Caution: Do not bring the Medtronic CareLink Model 2090 programmer into the MRI controlled room (magnet room). It is not MRI safe.

D.1.8 During MRI operation

Radiology considerations during the MRI scan: image artifact and distortion – The Reveal XT causes image distortion for areas in the image that surround the implanted device (see Section D.1.5.3). Image artifacts and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

D.1.9 Post-MRI operation

After the MRI procedure is complete, check the programmed parameters of the Reveal XT using the programmer. Clear the data collected during the MRI procedure because the MRI procedure might temporarily have affected the event detection and recording of the Reveal XT.

Note: The Cardiac Compass trend data cannot be cleared and might show irregularities at the time of the MRI operation.

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