Medtronic

REVEAL® PLUS 9526

Insertable Loop Recorder System:

Product Information Manual

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

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Contents

1 Prescribing the Reveal® Plus ILR

1.1 System Description

The Reveal® Plus Insertable Loop Recorder (ILR) is designed to improve the capture of subcutaneous electrocardiograms (ECG) during a symptomatic episode. The ILR provides storage of both patient-activated and automatically detected (auto-activated) events. Auto activation may help to detect abnormal heart rhythms in patients who fail to activate the ILR.

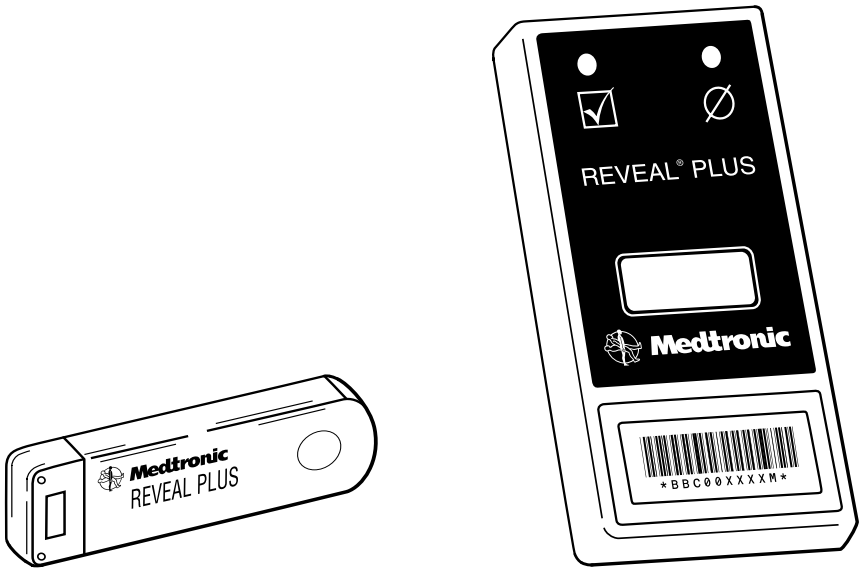
Note: The subcutaneous ECG of the ILR may differ from a surface ECG due to differences in electrode separation, ILR placement position in the body, and the difference between subcutaneous and surface contact impedance.

The ILR system has three primary components:

Insertable Loop Recorder – An implantable, single-use, programmable device containing two electrodes on the body of the device for continuous (i.e., looping) recording of the patient's subcutaneous ECG.

Activator – A hand-held, battery-operated telemetry device used by the patient during or after a symptomatic event to store an event into the ILR memory.

Programmer – A Medtronic Model 9790 and 2090 programmers, programming head (excluding Model 9766), and Model 9809 Software are used to enable ILR operations, and view, save, or print stored data.



Insertable Loop Recorder Activator

Figure 1. *Model 9526 Reveal Plus Insertable Loop Recorder and Model 6191 Activator*

1.2 Indications and Contraindications

1.2.1 Indications

The Reveal Plus ILR is an implantable patient-and automatically- activated monitoring system that records subcutaneous ECG and is indicated for

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias.
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia.

1.2.2 Contraindications

There are no known contraindications for the implantation of the Reveal Plus ILR. 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 Activator Environmental Precautions

The Model 6191 Activator has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. Precaution should be taken to avoid damage to the Activator, including (but not limited to) those listed herein.

Do not drop or mishandle the Activator in a way that might physically damage it. Avoid spilling fluid on the Activator. Do not submerge in liquid. Do not open the Activator. Do not sterilize the Activator by gamma radiation or by steam (e.g., autoclave) (see “Cleaning and Care” on page 46 for more information). Do not use the Activator in the presence of flammable anesthetics. Other environmental factors may impact proper performance of the Activator. Use of good electronic device practices will help to prevent environmental damage to the Activator.

Avoid exposing the Activator to temperatures below 48 °F (9 °C) for extended periods of time. Although the Activator will operate at temperatures as low as 5 °F (–15 °C), exposure to cold temperatures will shorten Activator battery life, and may have an adverse effect on Activator reliability (see also “Activator Specifications” on page 51).

If the Activator is dropped from a height of less than 1 meter, verify proper function by pressing the white button (while holding Activator away from implant site) and observing the flashing amber light above the ∅symbol.

If the Activator is dropped from a height of greater than 1 meter, do not continue to use it (see “Service” on page 46).

1.3.2 Cellular Phones

There may be a potential interaction between cellular phones and Reveal Plus ILR operation. Potential effects may include corruption of the data stored in memory or inappropriate device operation. The following information provides a general guideline to patients having an ILR who desire to operate a cellular phone.

- Maintain a minimum separation of 15 centimeters between a hand-held personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power compared to hand-held models. For phones transmitting above three watts, a minimum separation of 30 centimeters between the antenna and the implanted device is advised.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over, or within 15 centimeters of, the implanted device, because some phones emit signals when they are turned on but not in use (i.e., in the Listen or Standby mode). Storing the phone in a location opposite the side of the implant is recommended.

1.3.3 Diathermy

Therapeutic diathermy should not be used at the implant site on patients who have a Reveal Plus ILR because of possible damage to the circuitry due to heating effects.

1.3.4 Electrocautery and Radio Frequency (RF) Ablation

Electrocautery or RF ablation may cause corruption of the data stored in memory, and/or cause electrical reset of the Reveal Plus ILR. Verify device function after electrocautery or radio frequency energy has been used.

1.3.5 Electromagnetic Interference (EMI)

Since the Reveal Plus ILR communicates with the programmer and Activator by means of radio frequency telemetry, electromagnetic interference (EMI) may cause short telemetry interruptions, or temporarily affect the recorded electrocardiogram. The ILR will function properly after exposure to such EMI signals.

1.3.6 External Defibrillation

The Reveal Plus ILR may be damaged if defibrillation paddles are placed directly over the device. In addition, defibrillation discharges may result in the corruption of the stored ECG data. Defibrillation paddles placed at least 13 cm from the implanted ILR should not damage the device. Verify ILR function after defibrillation.

1.3.7 Electronic Article Surveillance (EAS)

Many retail stores are equipped with EAS gates as a security measure against theft. Magnetic and radio frequency (RF) fields produced by EAS gates may trip the low battery indicator flag on the Reveal Plus ILR. The device will continue to operate normally if this occurs. To minimize the possibility of tripping the low battery indicator flag, avoid prolonged exposure while passing through these gates.

1.3.8 Home or Job Environment

The Reveal Plus ILR should not be affected by the normal operation of electrical equipment such as household appliances, electrical machine shop tools, microwave ovens, spark-ignited internal combustion engines, radio frequency transmitting systems, or microwave frequency transmitting systems. (See also “Cellular Phones” on page 6.)

1.3.9 Implanted Pacemakers and Defibrillators

To minimize the possibility of the programming head and telemetry interfering with implanted pacemakers and defibrillators, the Reveal Plus ILR should be implanted at least 7.5 cm away from any other implanted device.

Do not hold the Model 6191 Activator or programming head directly above another implanted device while the Reveal Plus application is active.

1.3.10 Irradiation

The Reveal Plus ILR should not be directly irradiated by therapeutic levels of ionizing radiation (such as that produced by cobalt machines or linear accelerators used for cancer treatment) because of the risk of permanent damage to the ILR circuitry. If such therapy is required in the vicinity of the implanted ILR, shield the device and confirm its function after treatment.

1.3.11 Lithotripsy

Permanent damage to the Reveal Plus ILR may occur if the device is at the focal point of the lithotripsy beam. Since this situation is easily avoided, lithotripsy may be used safely if the ILR is kept at least 2.5 to 5 cm away from the focal point of the lithotripsy beam.

1.3.12 Magnetic Resonance Imaging (MRI)

Magnetic and radio frequency (RF) fields produced by MRI may adversely affect the data being stored by the Reveal Plus ILR.

Also, since the ILR contains ferromagnetic components, the strong magnetic field of the MRI system may apply a mechanical force on the ILR. The patient may be able to feel this magnetic force on the ILR. While this does not represent a safety hazard, the patient must be made aware of this possibility to avoid undue patient concern.

1.3.13 Power-On Reset (POR)

Certain conditions (including but not limited to EMI, electrocautery, or transthoracic defibrillation) may cause an electrical reset, (also defined as a POR) of the Reveal Plus ILR, which may cause loss of stored data. Always interrogate the ILR at the beginning and end of each patient session to verify and document the desired programmed status of the ILR.

If a POR has occurred, interrogate the ILR, reprogram the ILR to desired parameters after the source of interference is removed, and notify your Medtronic representative.

1.3.14 Random Failure

All battery-operated devices will ultimately cease to function due to normal depletion of the battery and may also fail at any time due to random component or battery failure which cannot be predicted prior to their occurrence.

1.3.15 Sterile Package

The sterile package should be inspected prior to opening. If the seal or package is damaged, contact your local Medtronic representative.

1.3.16 X-Ray and Fluoroscopy

Exposure to normal diagnostic levels of X-ray and fluoroscopic radiation should not affect the Reveal Plus ILR.

1.4 Potential Adverse Events

Potential adverse events include, but are not limited to, the following:

- Body tissue rejection phenomena, including local tissue reaction,
- Infection,
- Device migration,
- Erosion of the device through the skin.

1.5 Storage, Handling, and Resterilization

1.5.1 Storage and Handling

The temperature range for transportation and storage of the Reveal Plus ILR is from 0 to 131 °F (–18 to 55 °C).

The temperature range for transportation and storage of the Activator is from –40 to 158 °F (–40 to 70 °C).

Do not implant the ILR if the package is damaged.

Dropping the ILR onto a hard surface (e.g., from a height of 30 cm or more onto a concrete floor) could damage the ILR. Should this occur, do not implant the ILR.

1.5.2 Resterilization

Medtronic has sterilized the device package contents with ethylene oxide prior to shipment. Resterilization is necessary only if the seal on the sterile package is broken. (Resterilization does not affect the “Use By” date.) If necessary, resterilize with ethylene oxide using a validated sterilization process, observing the following precautions:

- Do not resterilize using an autoclave, gamma radiation, organic cleaning agents (such as alcohol, acetone, etc.), or ultrasonic cleaners.
- Do not exceed 55 °C (131°F) or 103 kPa when sterilizing.

1.6 ILR Longevity

Projected longevity for the ILR from implant to a low battery condition is 14 months.[1] When a low battery condition is reached, the ILR will continue to operate normally for a projected one month until an end of life condition is reached.

1.6.1 Battery Status

The battery status is displayed in the Device Status window after an interrogation and in pop-up messages.

Table 1. ILR Battery Status

Battery Status Message	Suggested Action
Ok	None
Low	Interrogate the ILR (All Events and Settings). If clinically appropriate, consider replacing the ILR.
End of life[a]	Remove ILR. If clinically appropriate, replace ILR.
Not Available[b]	Start recording, and interrogate device to obtain current status.
Being Updated	Wait one minute and re-interrogate.

[a] It is not possible to store events or retrieve data from the ILR when the battery has reached end of life.

[b] The battery status may be unavailable when the device is in shipping mode. To obtain the battery status in this case, start recording, wait one minute, and then interrogate the ILR. IMPORTANT! Starting a recording session erases all stored events from the ILR memory.

[1] Projected longevity based on a six-month shelf life.

2 Implant, Initial Programming, and Operation

2.1 Implant Procedure

The Reveal Plus ILR can be inserted in a single-incision procedure using aseptic technique. A subcutaneous pocket should be created, which is slightly smaller than the width of the ILR. The ILR should be inserted into the pocket with the electrodes facing outward (toward the skin). When inserted into the pocket, the ILR should enlarge the pocket to make a tight fit. It is important to keep movement of the ILR within the pocket to a minimum for good auto-activation performance. Suture the device in place using the suture holes to help minimize movement of the device.

For patients with an ILR programmed to patient activation only mode, an implantation anywhere in the subcutaneous area of the left anterior thorax should provide adequate signal amplitude.

For patients with an ILR programmed to manual mode plus the auto-activation mode, choose implant locations and orientations that provide the following requirements to help ensure a successful setup of the auto-activation feature, and to help minimize inappropriate auto-activation:

- R-wave to T-wave and R-wave to P-wave peak-to-peak amplitude ratios (R/T and R/P ratios), which are as large as possible (preferably greater than 2:1 for R/T and 5:1 for R/P).
- Minimal device movement due to body and arm movement, and changes in posture. Implantation closer to the sternum and away from the lower half of the pectoral region and breast area may help minimize device movement.
- The largest possible R-wave signal amplitudes considering the two preceding requirements.
- Implantation in an orientation more parallel to midline may help to minimize device movement and may help to provide a larger R-wave.

Suitable implant locations and orientations can be determined before implant with surface ECG measurements in the locations and orientations of interest. This can be done using standard surface ECG electrodes and placing them approximately four centimeters apart to roughly match the subcutaneous electrode spacing of the ILR. These measurements can be done using standard ECG measurement systems such as the Medtronic programmer (using accompanying ECG cables and Lead II on the Select Model Screen).

Before closing, verify that the ECG signal quality and amplitude are adequate.

Note: The ILR should be explanted when it is no longer clinically necessary, or when the battery is depleted.

2.1.1 Identification Card and Registration Form

An Implanted Device Identification Card is included in the shipping package. The information on this card should be filled out by the clinician, and the card given to the patient.

A Device Registration Form is also included in the shipping package. Upon completion by the clinician, this form serves as a permanent record of the facts related to the implanted ILR. A copy of this form should be returned to Medtronic.

Establishing a Patient Record – At the time of implant, the clinician should establish a record of the patient's ILR. The registration form should not serve this purpose, as this form is intended for registering the patient and device with Medtronic.

2.2 Starting the ILR Application

How to Start the ILR Application

Use the following steps to prepare the ILR for programming.

1. From the Select Model screen select **[OTHER]** and then **Reveal Plus Model 9526**. At the bottom of the screen, press **[Start]**. The programmer displays the Main screen.
2. The ILR is shipped with factory settings as shown in the table on page 49. Press **[Interrogate...]** on the Main screen and select **[Settings Only]**. A Device Status Warning notifies you that the ILR is in its shipping mode. To begin operation, a message on the Warning screen instructs you to select **[Setup...]** from the Main screen.
3. Press **[Continue]** at the bottom of the warning message. The Device Status window displays a message indicating that the ILR is in its shipping mode. Press **[OK]** at the bottom of the status window. A Setup Reminder message is displayed. The ILR is ready for programming and ECG recording.
4. Select **[Setup...]** from the Main Screen to program the device.

2.3 ILR Main Screen

The Main screen has the following attributes (see Figure 2):

- Displays real-time ECG waveform with sense markers when the programming head is positioned over the implanted ILR.
- Provides function and menu buttons (see “Main Screen Button Descriptions” on page 14).
- Displays heart rate summary graphs[1], representing both patient-activated and auto-activated stored events.
  - Heart rate summary graphs appear as a series of vertical bars. Each bar represents the minimum and maximum heart rate in an ECG event segment.
  - Arrow buttons scroll the heart rate summary graph to display other stored events.
  - ECG waveform details are displayed by tapping the touch pen on the heart rate summary graph display.

[1] Heart rate summary graphs are not of diagnostic quality. Refer to event waveforms for diagnostic information.

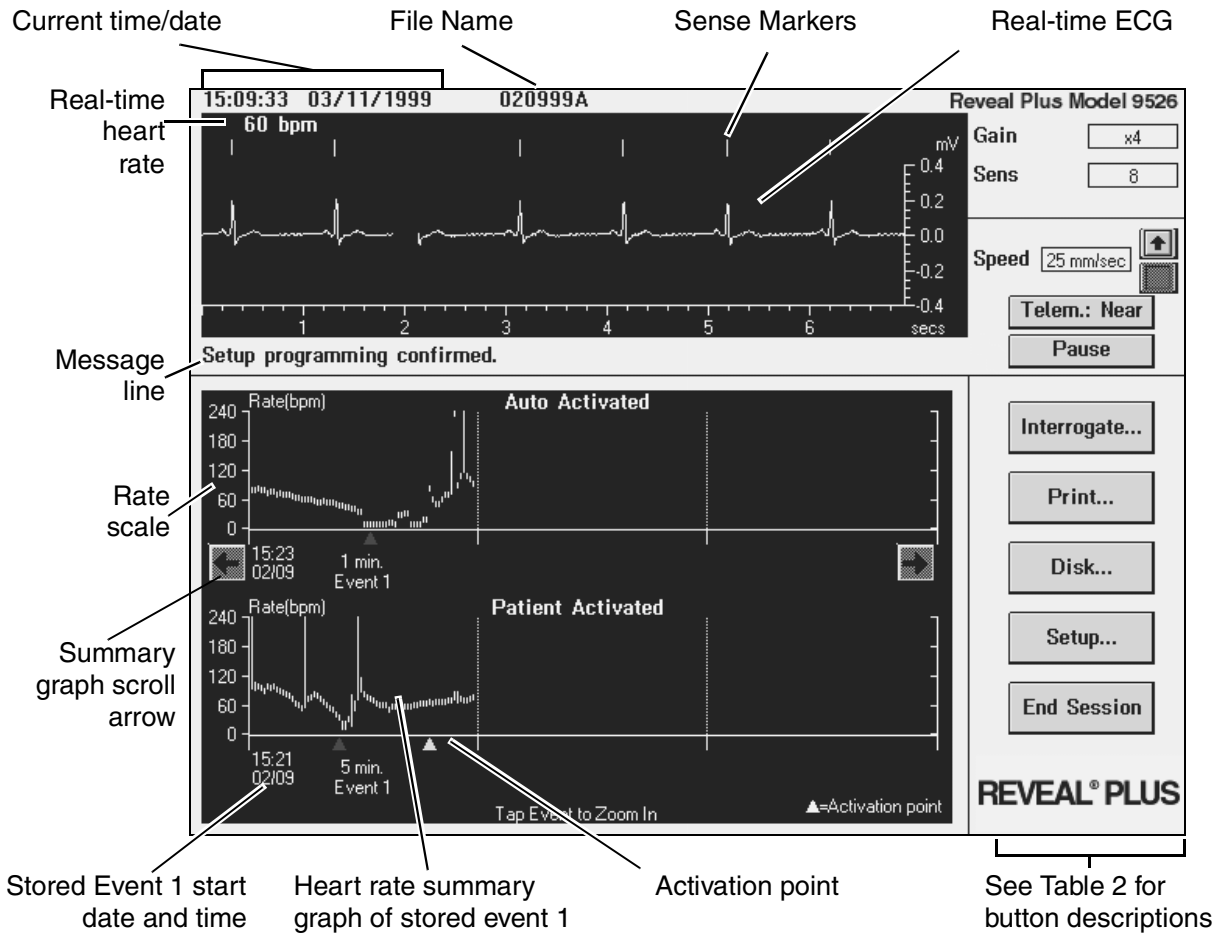


Figure 2. *Main Screen*

Table 2. ***Main Screen Button Descriptions***

Button	Description
	Displays ECG gain and sensitivity settings.
	Adjusts real-time ECG sweep speed. Speed is programmable to 25 or 50 mm/sec using the up/down buttons.
	Toggle button with which you select the telemetry range (**Near** or **Far**) (see page 15).
	Toggle button that pauses the real-time ECG display. (**Continue** restarts it.)
	Opens Interrogate window from which you select events or settings to retrieve from device memory (see page 33).
	Opens Print window from which you select printing options (see page 40).
	Opens Disk window from which you save data to disk, or read data from disk (see page 43).
	Opens the Setup window from which you program patient and auto-activated stored event modes, ECG storage capacity, automatic activation parameters, and gain/sensitivity setup (see page 16).
	Ends the current patient session (see page 44).

2.4 Telemetry

The programmer and the ILR communicate via telemetry. Telemetry is possible only when the programming head is correctly positioned over the implanted ILR such that the yellow light on the programming head turns to green.

2.4.1 Telemetry Range

You can set the Telemetry range to **Near** or **Far** using the toggle switch on the ILR Main screen. The **Near** setting should be appropriate for most patients.

2.4.2 Verifying Proper Telemetry

A successful interrogation or programming operation verifies proper communication between the ILR and the programmer.

Under conditions that adversely affect telemetry, it may be difficult to program the ILR even when the green light indicates that telemetry should be possible. If this occurs, reposition the programming head slightly in one direction or the other over the ILR, and/or change the Telemetry range setting. If you encounter further difficulties establishing telemetry, contact your Medtronic representative.

2.5 Real-Time ECG[1]

A real-time ECG waveform appears at the top of the main menu after establishing telemetry with the device. Vertical bars above the real-time ECG indicate device sense markers.

You can select 25 or 50 mm/sec real-time ECG sweep speed using the up/down buttons on the Main screen.

The real-time ECG display is paused temporarily during ILR interrogation.

2.5.1 Printing the Real-Time ECG Waveform

You can print the patient's real-time ECG any time during a patient session using the programmer's strip chart printer.

1. To start printing a real-time ECG, press the desired paper speed button on the programmer.
2. To stop printing, press the paper speed button again.
3. Press the paper advance button to advance the paper to a perforation before tearing off a printout.

2.5.2 Real-Time ECG Waveform Interruption

The real-time ECG waveform is momentarily interrupted while interrogating or programming the ILR. Interruptions may result in short periods of missing real-time ECG waveform data.

2.5.3 Markers on Real-Time ECG Printouts

A "down" arrow (▾) above the ECG trace on the printout indicates the transmission of a telemetry command from the programmer to the ILR. An "up" arrow (▴) indicates the reception of the telemetry response from the ILR.

[1] Real-Time ECG is subcutaneous ECG in this device.

2.6 Setup Procedure for Programming the ILR

To program the ILR, press **[Setup...]** from the Main screen and follow the steps indicated on the Setup screen (see Figure 3).

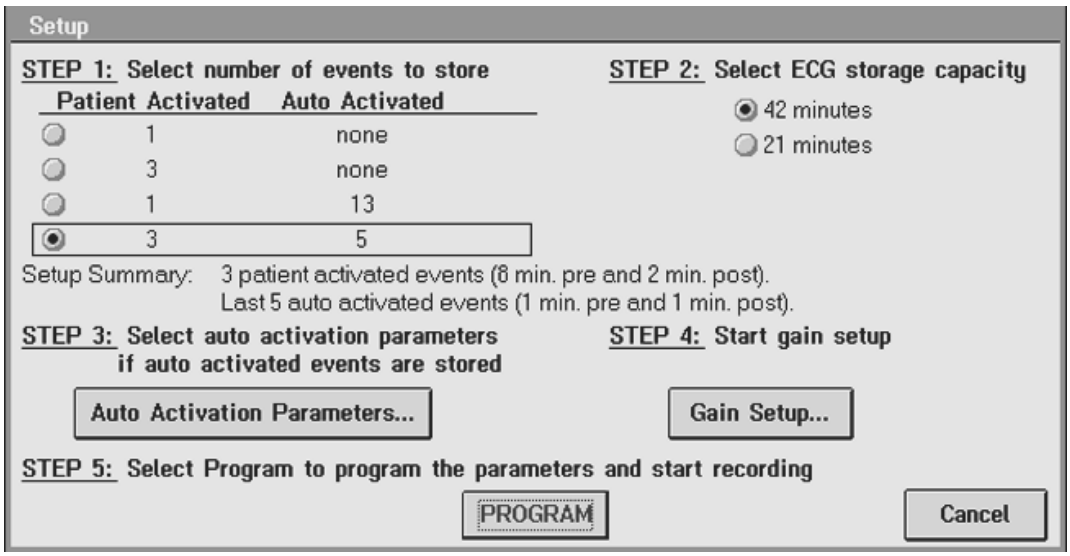


Figure 3. *Setup Screen*

Note: With the Reveal Plus ILR, the **P** (Program) button on the programming head is functional only during patient posture tests.

2.6.1 Step 1: Select number and type of events to store

Select the number of patient-activated and auto-activated events.

2.6.2 Step 2: Select ECG storage capacity

Select the ECG storage capacity.

2.6.3 Step 3: Select auto-activation parameters

Note: Skip this step if you did *not* select an auto-activated event mode in step 1.

a. Press **[Auto-Activation Parameters...]**. The Auto-Activation Parameters screen is displayed (see Figure 4).

b. From the Auto-Activation Parameters screen, select from the following options, and then press **[Accept]**.

- Brady option (<30 or <40 bpm). An auto-activated event will be recorded after 4 consecutive bradycardia beats.
- Asystole option (> 3 secs or >4.5 secs).
- Tachy options: (Off, >115,... >230 bpm), and the number of consecutive beats (16 or 32).
- Event storage option (to store either the last 5 or 13, or the first 6 or 14, auto-activated events).

Store the last auto-activated events from the Auto-Activation Parameters screen to assist in documenting the most recent events.

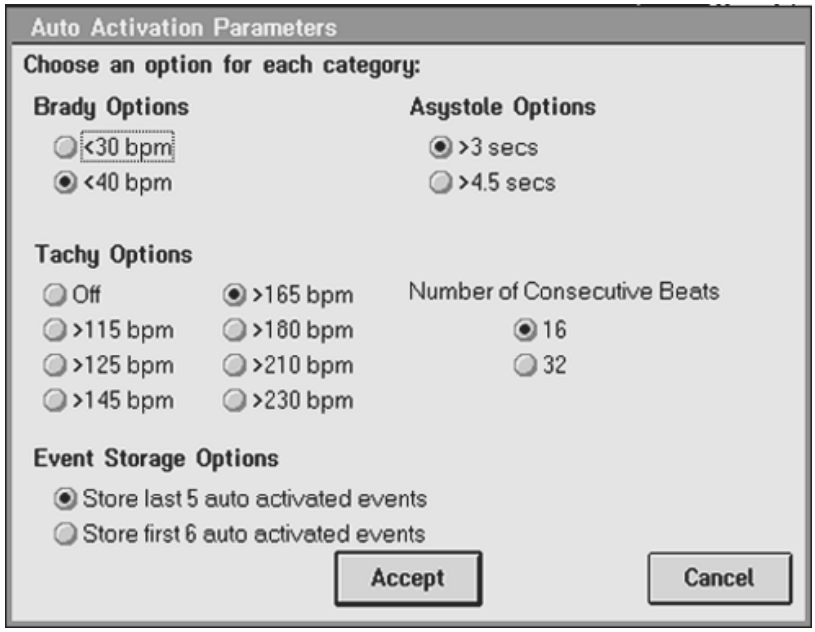


Figure 4. *Auto-Activation Parameters Screen*

Note: Once an auto-activation has occurred, a subsequent auto-activation cannot occur until four consecutive normal intervals have been sensed and either 1.5 minutes (for a 21-minute storage capacity), or 3 minutes (for a 42-minute storage capacity) has elapsed. The ILR may not store an entire continuous event or a subsequent event until the post auto-activation criteria have been met. However, patient activation is still possible during this period.

2.6.4 Step 4: Start Gain Setup

This step defines the procedure for establishing the gain and sensitivity settings. From the Setup screen (Figure 3) press the **[Gain Setup...]** button to display the Gain and Sensitivity Setup screen (see Figure 5).

You can manually program the gain and sensitivity settings; however, the Auto-Setup procedure is recommended. Refer to page 29 for the Manual Gain and Sensitivity setup procedure.

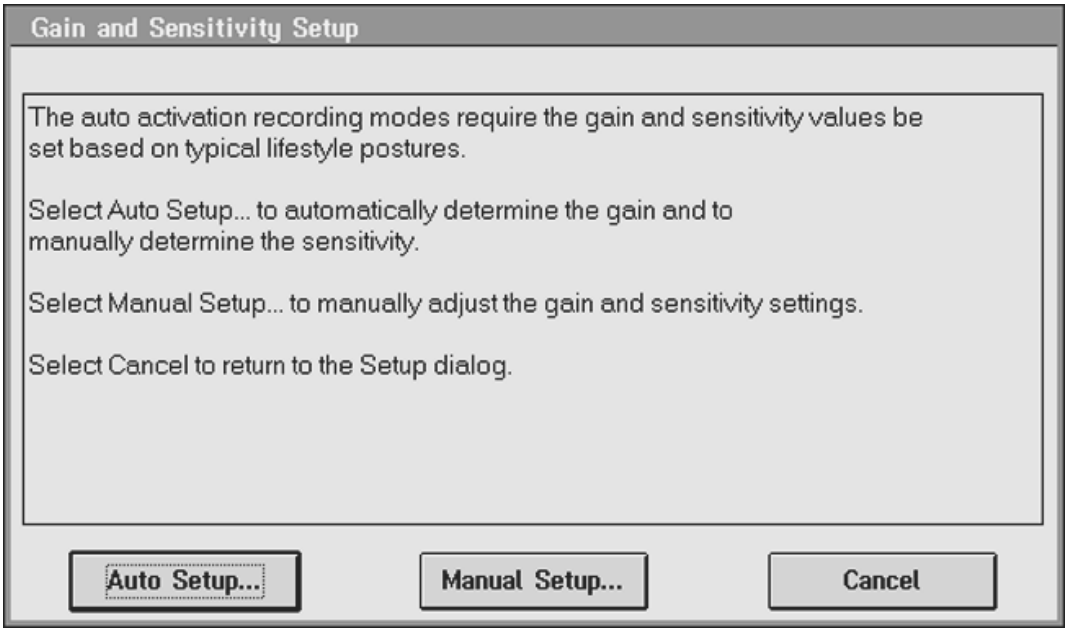


Figure 5. *Gain and Sensitivity Setup Screen*

2.6.5 Automatic Gain Setup Procedure

This procedure determines a recommended gain setting by monitoring R-wave amplitude during patient lifestyle posture tests. Depending on the value of the derived recommended gain setting, one of two guided setup methods is used to define the sensitivity setting.

1. From the Gain and Sensitivity Setup screen (Figure 5), press **[Auto-Setup...]**. The “Automatic Gain Setup” screen is displayed (see Figure 6).

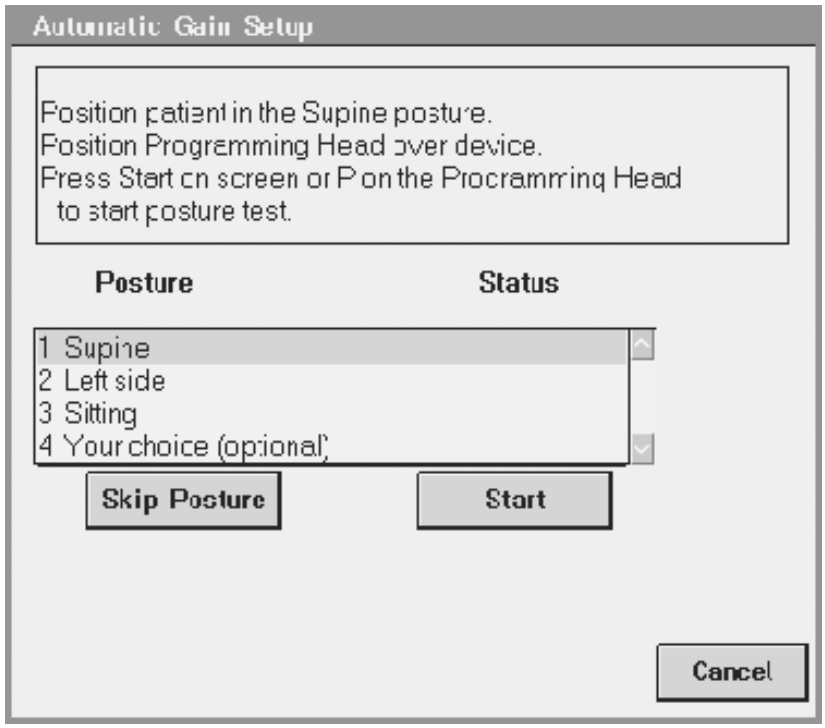


Figure 6. *Automatic Gain Setup*

Notes:

- It is recommended that data be gathered for at least three different patient postures. You may add an optional, patient-specific posture to the three recommended postures.
- If necessary, you may skip any posture selection by pressing **[Skip Posture]**.
- Ensure that the programming head is positioned properly over the ILR throughout each posture test.
- If the message “Insufficient signal amplitude to perform gain test” appears on the Automatic Gain Setup screen, reposition the programming head and restart the test.

2. Place the patient in the selected posture and press **[Start]**. A bar graph at the bottom of the screen indicates the progress of the data collection process.
3. Repeat the procedure for each selected posture.

Note: When the data collection process is complete, the programmer displays the “Sensitivity Setup” screen and the recommended gain and posture for establishing the ILR sensitivity setting (see Figure 7).

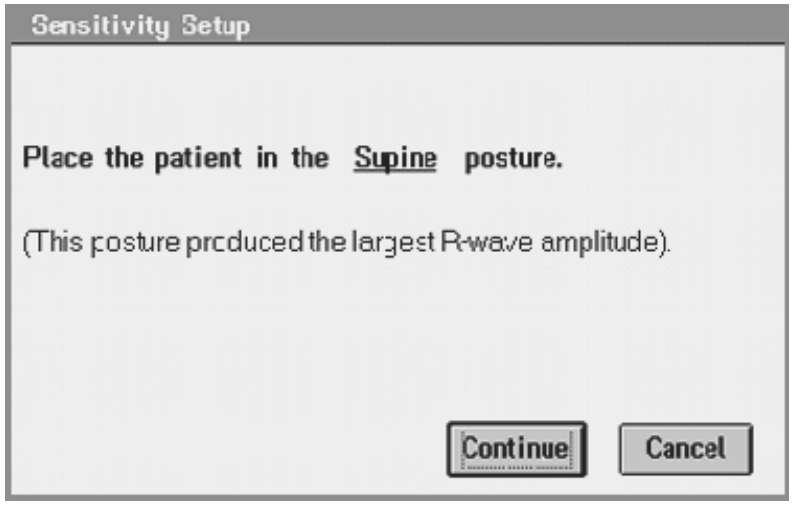


Figure 7. *Sensitivity Setup - Patient Posture*

4. Place the patient in the recommended posture.
5. Press **[Continue]**. The programmer displays a new “Sensitivity Setup” screen that indicates the recommended posture and gain setting (see Figure 8).

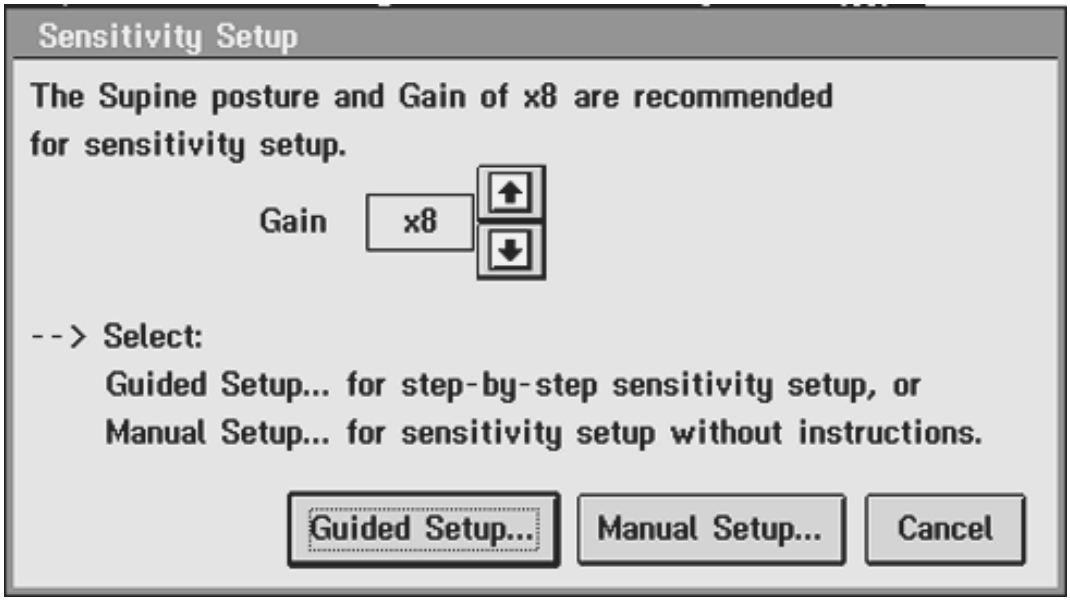


Figure 8. *Sensitivity Setup Selection - Guided or Manual*

You may select either the *guided* or *manual* sensitivity setup procedure. The guided procedure directs the operator step-by-step to define the sensitivity setting. The manual sensitivity setup procedure allows an experienced operator to access the ILR gain and sensitivity settings, without assistance from the programmer.

For the manual procedure, press the **[Manual Setup...]** button, and refer to the “Manual Adjustment of Sensitivity” instructions beginning on page 24.

6. Press the **[Guided Setup...]** button. If the recommended gain setting is either x4 or x8, the programmer uses the “Guided Method 1” procedure (see below) to establish the sensitivity setting. For gain values of x1 or x2, the programmer uses the “Guided Method 2” procedure (see page 22).

Guided Sensitivity Setup Method 1 Procedure

1. The “Sensitivity Setup - Guided - Method 1” screen indicates that the programmer has temporarily adjusted the gain setting. Follow the instructions on the screen (see Figure 9) to adjust the sensitivity appropriately. Then press **[Continue]**.
   a. Use the arrow button to increase the sensitivity setting until the R-wave sense markers are visible above the real-time ECG waveform (see Figure 2).

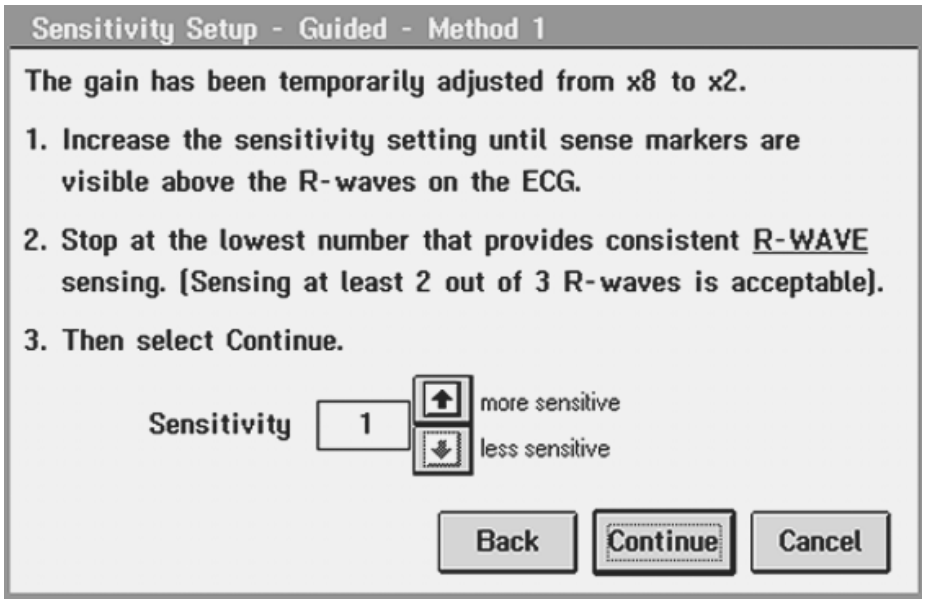


Figure 9. *Sensitivity Setup - Guided - Method 1*

2. From the “Sensitivity Setup - Guided” screen, the programmer indicates that it has restored the recommended gain setting and has temporarily adjusted the sensitivity setting to check for a safety margin of two sensitivity settings (see Figure 10).

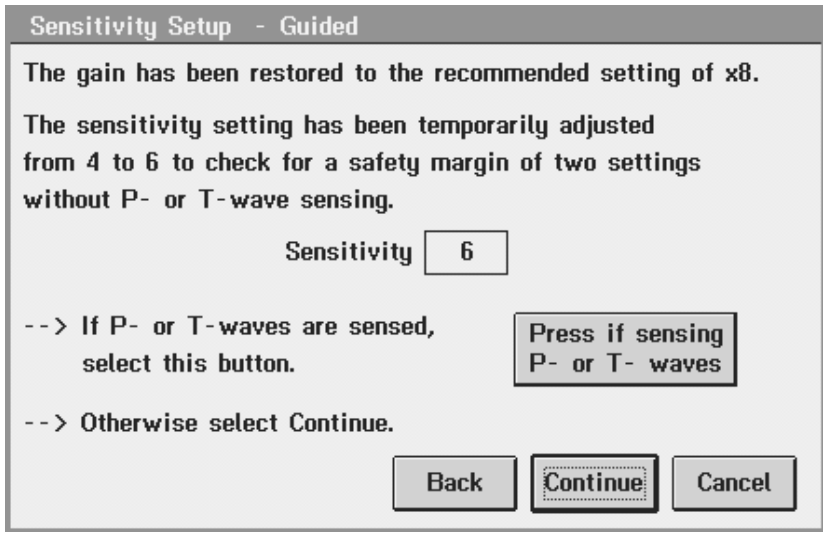


Figure 10. *Sensitivity Setup - Guided (Margin Test)*

If sense markers are present above P- or T-waves in the ECG waveform, press **[Press if sensing P- or T-waves]**.

a. If you pressed **[Press if sensing P- or T-waves]** in the previous step, the programmer displays the same screen with the sensitivity setting decremented by one. (If the safety margin cannot be maintained, see page 24.)

b. Observe the real-time ECG waveform. If sense markers still appear above the P- or T-waves in the ECG waveform, press **[Press if sensing P- or T-waves]** again.

c. Repeat this sequence until the sense markers no longer appear above the P- or T-waves in the ECG waveform.

3. Press **[Continue]**. The “Sensitivity Setup - Guided - Results” screen is displayed, indicating the recommended ILR gain and sensitivity settings (see Figure 11).
   a. If possible, verify that there is normal R-wave sensing, but no P- and T-wave sensing in all postures. A message on the screen instructs you how to perform the verification.
   b. Press **[Accept]** to return to the Setup screen (Figure 3). From the Setup screen, press “PROGRAM” to complete step 5 of the setup procedure.

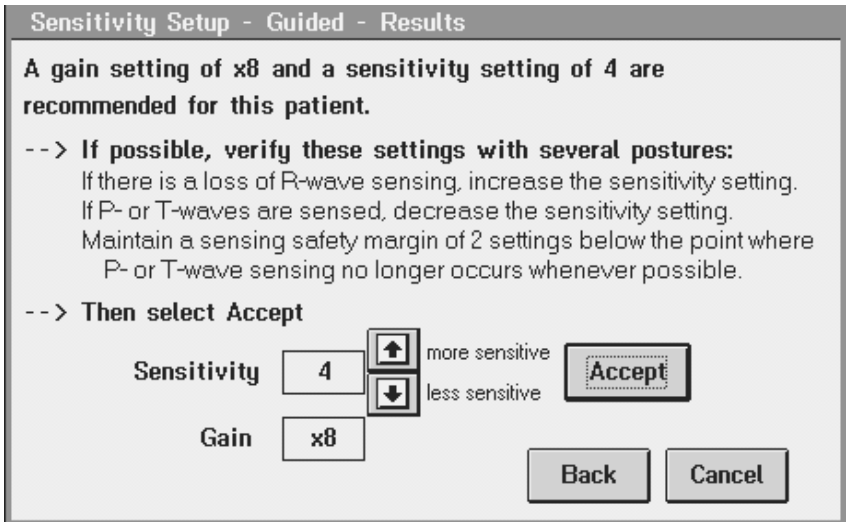


Figure 11. *Recommended Sensitivity and Gain Setting – Results*

Guided Sensitivity Setup Method 2 Procedure

1. The “Sensitivity Setup - Guided - Method 2” indicates that the programmer has temporarily adjusted the gain setting (see Figure 12). Follow the instructions on the screen.

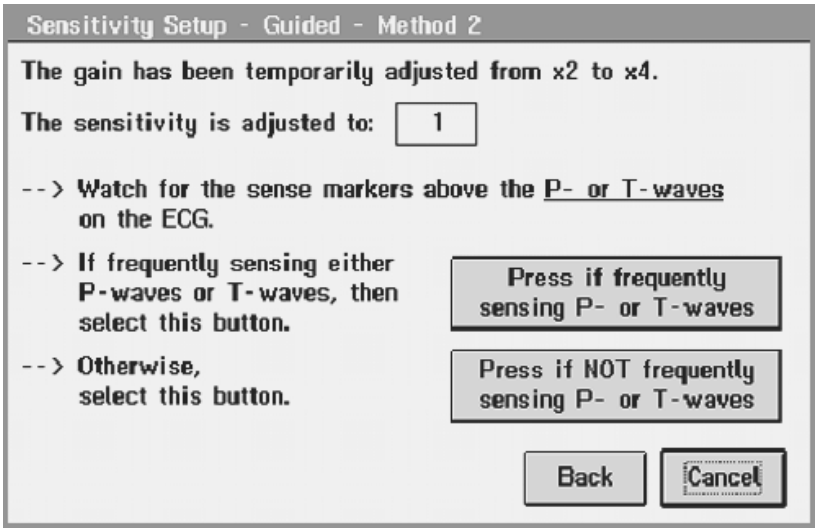


Figure 12. *Sensitivity Setup - Guided - Method 2*

2. If sense markers do not appear above the P- or T-waves, press the **[Press if NOT frequently sensing P-or T-waves]** button once. Repeat this step until sense markers appear above the P- or T-waves.

3. Press the **[Press if frequently sensing P- or T-waves]** button. The “Sensitivity Setup - Guided” screen is displayed indicating that the programmer has restored the recommended gain setting and has temporarily adjusted the sensitivity setting to check for a safety margin of two sensitivity settings (see Figure 13).

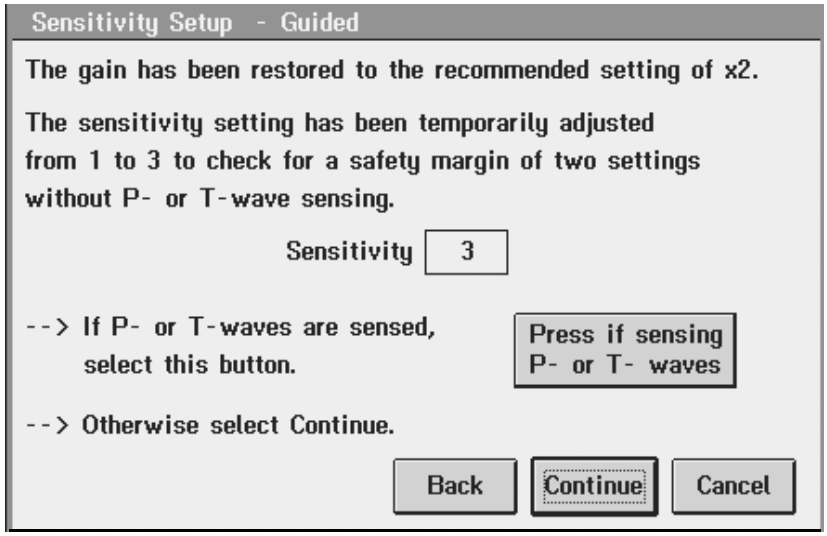


Figure 13. *Sensitivity Setting - Guided - Method 2 (Margin Test)*

Note: A sensitivity safety margin less than recommended may increase the likelihood of inappropriate auto-activation.

4. Press the **[Press if sensing P- or T-waves]** button if any sense markers appear above the P- or T-waves. Otherwise, press **[Continue]** to proceed to the next step. (If the safety margin cannot be maintained, see page 24.)
5. Press **[Continue]**. The “Sensitivity Setup - Guided - Results” screen is displayed, indicating the recommended ILR gain and sensitivity settings (see Figure 14).
   a. If possible, verify normal R-wave sensing and no P- and T-wave sensing in all postures. A message on the screen instructs you how to perform the verification.
   b. Press **[Accept]** to return to the Setup screen (Figure 3). From the Setup screen, press **[PROGRAM]** to complete step 5 of the setup procedure.

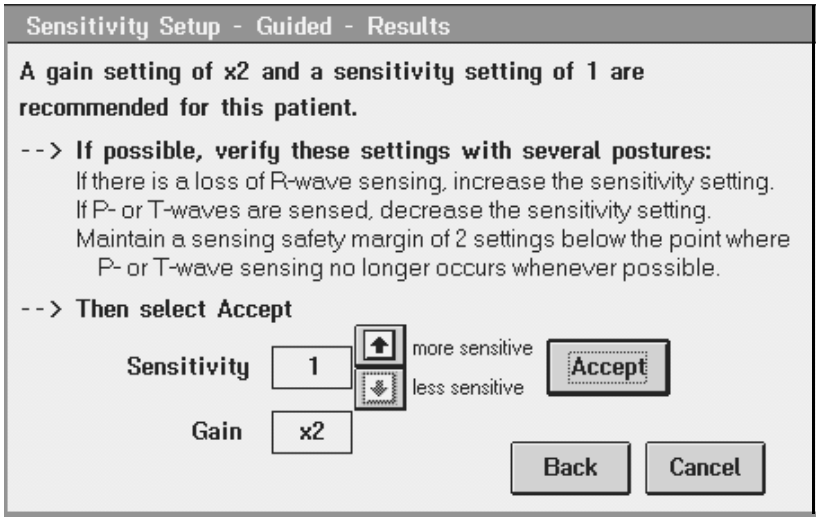


Figure 14. *Recommended Sensitivity and Gain*

Safety Margin Cannot be Maintained

This message applies to both Method 1 and Method 2 for the Sensitivity Setup. If the following screen appears (Figure 15) when determining the appropriate sensitivity, refer to the instructions on the screen. Press **[Repeat Setup]** to start over, or **[Cancel]** to exit the ILR programming procedure.

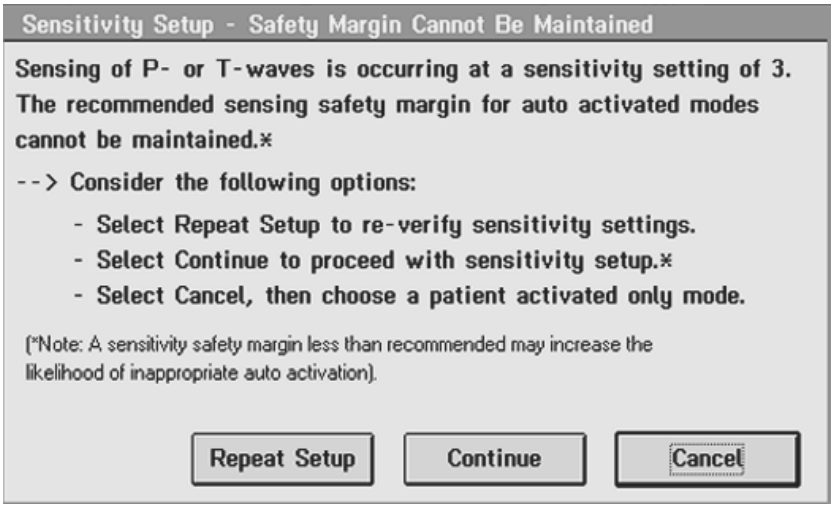


Figure 15. *Safety Margin Cannot be Maintained*

Manual Adjustment of Sensitivity (After an automatic gain setup)

To manually adjust the sensitivity setting after the automatic gain setup procedure:

1. Select **[Manual Setup...]** from the Sensitivity Setup screen (Figure 8). The screen shown in Figure 16 is displayed.
2. Place the patient in the posture indicated on the screen.
3. Use the arrow buttons to adjust the sensitivity for optimum R-wave detection following the instructions beginning on page 25.

4. Press **[Accept]** to return to the Setup screen (Figure 3). From the Setup screen, press **[PROGRAM]** to complete step 5 of the setup procedure.

Note: You can also alter the gain setting from the Manual Sensitivity Setup Screen.

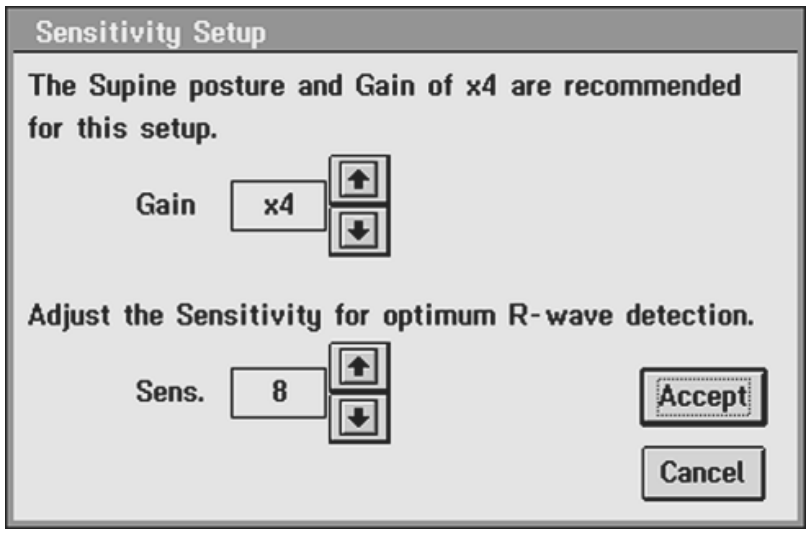


Figure 16. *Manual Sensitivity Setup Screen*

Manually Adjusting the Sensitivity Setting

The ILR sensitivity setting represents a fixed sensing threshold voltage. Increasing the setting lowers the sensing threshold voltage (see Figure 17).

Increasing sensitivity setting decreases the threshold voltage.

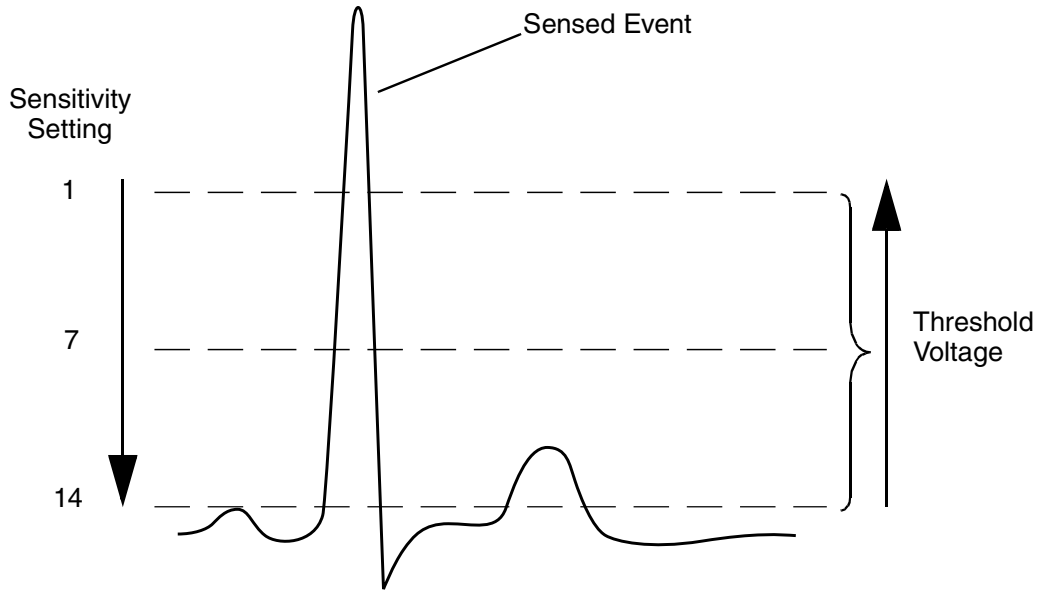


Figure 17. *Relationship of Sensitivity Setting to Threshold Voltage*

The following conditions can cause the ILR to over-sense P-waves, T-waves, and noise, or under-sense R-waves:

- Amplitude changes due to posture variations

- Muscle noise
- Low R/T or R/P ratios

Note: The sense markers may disappear when the sensitivity setting is too high as a result of special noise rejection techniques.

How to Determine the Optimum Sensitivity Setting

Use the following procedure to determine the *optimum sensitivity setting*. This setting maintains good R-wave sensing by the ILR, while minimizing the sensing of P-waves, T-waves, and noise.

1. Position the patient in a posture that produces the largest peak-to-peak R-wave amplitude. Use the recommended posture and gain setting if the Auto Setup was selected.
2. Use Method 1 or 2 below to find an *initial sensitivity setting.* Refer to the following table to determine which method to use.

Recommended Gain	Method to Use	Temporary Gain
x8	Method 1	x2
x4	Method 1	x1
x2	Method 2	x4
x1	Method 2	x2

Method 1 – This method finds an *initial sensitivity setting* that maintains good R-wave sensing for up to a 4x drop in amplitude (see Figure 18).

Note: Method 1 can only be used for recommended gain settings of x4 or x8.

a. Adjust the gain to the temporary gain setting in step 2 above.
b. View the sense markers on the real-time ECG screen while doing step c.
c. Adjust the sensitivity to the **lowest** setting (highest sensing threshold voltage) that maintains consistent R-wave sensing (at least two out of three R-waves). This is the *initial sensitivity setting*.
d. Adjust the gain back to the recommended gain setting.
e. Proceed to step 3 (refer to page 28).

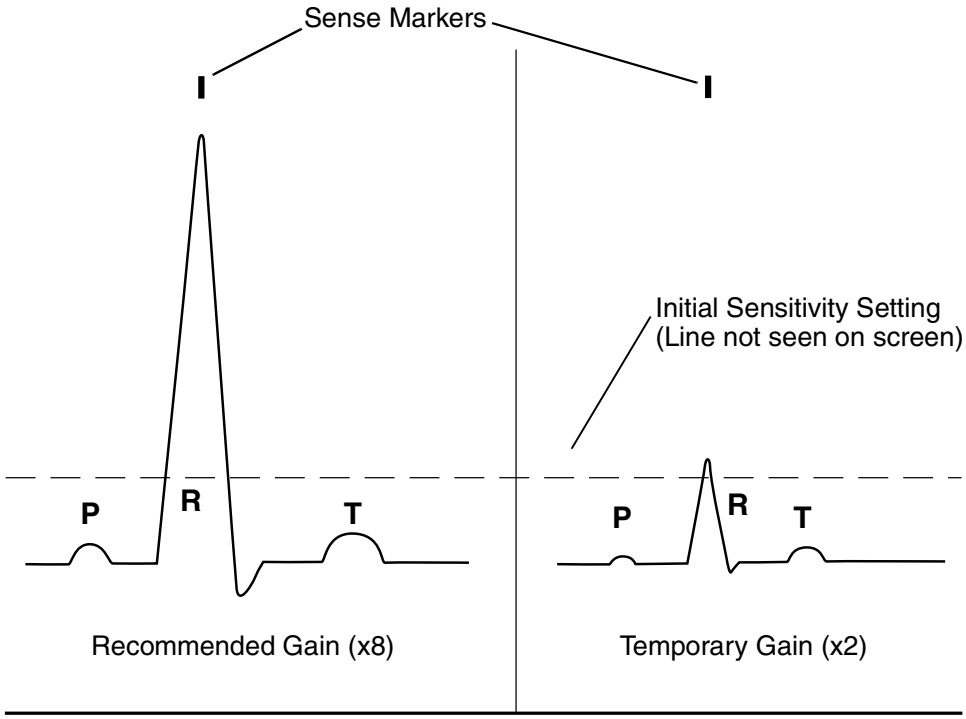


Figure 18. *Initial Sensitivity Setting - Method 1 Example*

Method 2 – This method finds an *initial sensitivity setting* that provides a threshold voltage margin of 2x from over-sensing of P-waves or T-waves (see Figure 19).

Note: This method should be used for recommended gain settings of x1 or x2.

a. Adjust the gain to the temporary gain setting in step 2 above.

b. View the sense markers on the real-time ECG screen while doing step c.

c. Start at a setting of 1, and adjust the sensitivity to the **lowest** setting (highest sensing threshold voltage) that maintains consistent sensing of P-waves or T-waves. This is the *initial sensitivity setting.*

Note: If it is not possible to sense P-waves or T-waves at any setting, an *initial sensitivity setting* of 14 is recommended.

d. Adjust the gain back to the recommended gain setting.

e. Proceed to step 3 (refer to page 28).

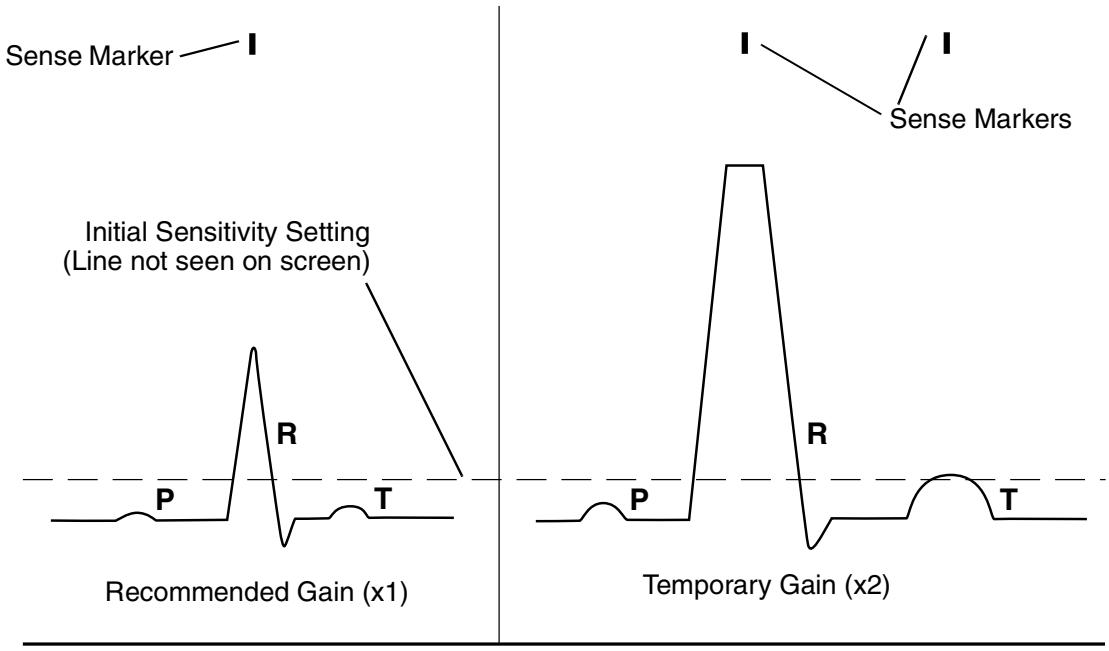


Figure 19. *Initial Sensitivity Setting - Method 2 Example*

3. Verify that the *initial sensitivity setting* provides a safety margin of at least two settings without P-wave or T-wave oversensing. To do this:
   a. Increase the sensitivity by two settings to lower the sensing threshold voltage, and view the sense markers.
   b. If there is no oversensing, the *initial sensitivity setting* is the *optimum sensitivity setting.*
   c. If necessary, adjust the sensitivity from the *initial sensitivity setting* to provide the desired margin of safety.

Note: A safety margin of less than two sensitivity settings may be appropriate for some patients.

Refer to the following examples.

Example 1. *Initial sensitivity setting* is 6 with no oversensing of T-waves or P-waves – You increase the setting by two, and at a sensitivity setting of 8, there is still no oversensing. The *optimum sensitivity setting* is 6.

Example 2. *Initial sensitivity setting* is 5 with no oversensing of T-waves or P-waves – You increase the setting until T-waves or P-waves are first sensed, which happens at 7. To obtain a safety margin of two settings, the *optimum sensitivity setting* is 4.

Example 3. *Initial sensitivity setting* is 7 with oversensing of T-waves or P-waves – You decrease the sensitivity setting until T-waves or P-waves are no longer sensed, which happens at a setting of 3. To obtain a safety margin of two settings, the *optimum sensitivity setting* is 1.

How to Verify the Optimum Sensitivity Setting Over Postures

If possible, verify the *optimum sensitivity setting* over postures as follows:

1. Place the patient in a number of typical postures, and view the sense markers on the real-time ECG screen to ensure that no undersensing or oversensing occurs.
2. If there is a loss of sensing, increase the sensitivity setting.

3. If there is consistent oversensing, decrease the sensitivity setting while maintaining a safety margin of two settings.

Manual Adjustment of Gain and Sensitivity

Notes:

- The following setup procedure applies only when both patient-activated and auto-activated storage are selected.
- It is recommended that you use the automatic gain setting as described on page 18.

You can set up gain and sensitivity manually at any time during a patient session. You must press **[Accept]** to proceed to program the device.

To manually adjust the gain and sensitivity settings:

1. Press **[Gain Setup...]** on the Setup screen (refer to Figure 3).
2. Press **[Manual Setup...]** on the Gain and Sensitivity screen (refer to Figure 5).
3. Adjust the gain and sensitivity manually, and press **[Accept]**. Adjust the gain before adjusting the sensitivity.
   - If possible, adjust the gain for the posture that produces the largest signal amplitude.
   - Use the arrow keys to adjust the gain setting so that the signal on the real-time ECG display is as large as possible without going out of range. Some minor “clipping” or flattening of the signal peaks is permissible since the heart rhythm will still be visible.
   - Adjust the sensitivity setting only after the desired gain setting has been selected. A different gain setting will always require a different optimum sensitivity setting. To adjust the sensitivity manually, first choose the best gain setting and then follow the procedure that starts on page 25.

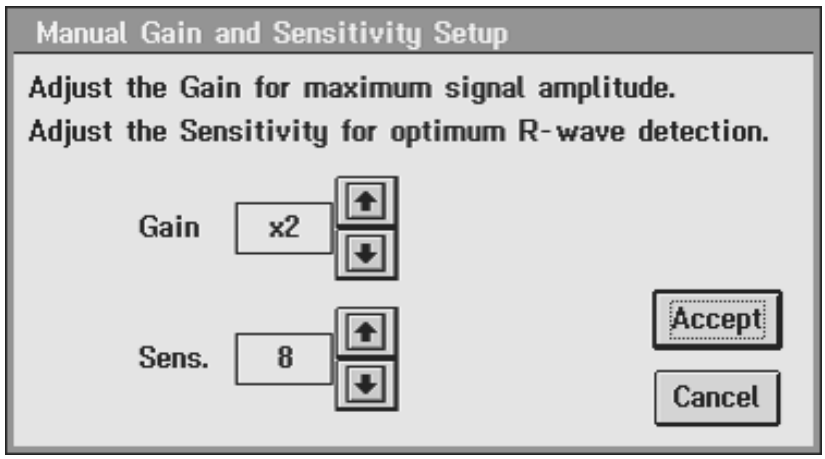


Figure 20. *Manual Gain and Sensitivity Setup Screen*

4. Press **[Accept]**.
5. Press **[PROGRAM]** from the Setup screen (refer to Figure 3).

2.7 Storing an Event

Follow these steps to store a patient-activated event in the ILR memory:

1. Lay the Activator flat over the implant.
2. Press the white button one time.
3. Immediately remove the Activator from over implant and observe the lights.
   – A flashing **green** light above the ☑ symbol indicates that the ILR successfully received the signal from the Activator.
   – A flashing **yellow** light above the ∅ symbol indicates that the ILR did *not* receive the signal from the Activator. Reposition the Activator and repeat steps 2 and 3 until a flashing green light is observed.

2.7.1 Storing an Event in a Clinical Setting

Additional consideration is required when storing an event while interacting with the programmer and programming head. You must follow a sequence of events, which involves particular timing relationships between starting to record, using the Activator, and interrogating the device to properly store an event. Failure to wait the recommended times can result in incomplete, non-contiguous, or no data being stored.

Note: If the ILR has already been programmed and the patient-activated memory is not full, proceed to step 3.

1. Select **[PROGRAM]** on the Setup screen to program the device (see page 16).

Note: At this point, you may remove the programming head. However, removing the program head while storing an event is optional for the Reveal Plus ILR.

2. Wait the minimum recommended Pre time after pressing **[PROGRAM]**. (See Table 3 to determine the recommended waiting time, which depends on the type and number of events, and the storage capacity.)
3. Store an event with the Activator (see page 46).[1]
4. Wait the minimum recommended Post time (after a successful activation) depending on the programmed storage capacity.
5. Place the programming head over the ILR and interrogate the device to retrieve the stored data (see page 33).

Table 3. *Recommended Minimum Waiting Time*

Number of Events		Storage Time	Time Wait Period for Patient-Activated Events (minutes)	
Patient-activated	**Auto-activated**	**Minutes**	**Pre**	**Post**
1	0	21	20	1.5
3	0	21	6	1.5
1	0	42	40	2.5
3	0	42	12	2.5
1	13/14[a]	21	6	1.5
3	5/6[b]	21	4	1.5
1	13/14[a]	42	12	2.5
3	5/6[b]	42	8	2.5

[a] The ILR stores the last 13 auto-activated events or the first 14 auto-activated events.

[b] The ILR stores the last 5 auto-activated events or the first 6 auto-activated events.

[1] If the activation is performed before the recommended storage time has elapsed, a longer than normal post-activation time will be seen in the stored data.

2.8 Clearing Memory Without Changing Gain and Sensitivity Settings

To save time during a follow-up procedure, you may use the following short-cut to clear the ILR memory without changing its gain and sensitivity settings.

Note: If an unacceptable number of false auto-activated events have been recorded, verify that the gain and sensitivity settings are optimized.

To clear memory storage without changing the gain and sensitivity settings, perform the following steps:

1. Select **[Setup]** from the Main screen.
2. On the Setup screen, select **[Auto-Activation Parameters...]**.
3. Choose **[Accept]** on the Auto-Activation Parameters screen.
4. Select **[Gain Setup]**.
5. On the Gain and Sensitivity Setup screen, choose **[Manual Setup]**.
6. Choose **[Accept]**.
7. On the Setup screen, select **[PROGRAM]**.
8. Select **[Yes]**.

3 Conducting a Patient Session

3.1 Starting a Patient Session

See page 12 for instructions on starting the application for the Reveal Plus ILR on the programmer.

3.1.1 Interrogating the ILR

When you perform an interrogation, the ILR transmits data from memory to the programmer via telemetry. The data are then available for viewing, printing, or saving to disk.

When you select **[Interrogate...]** from the Main screen, the programmer opens the Interrogate window from which you specify the data to interrogate. There are two options:

- **All Events and Settings:** All stored events and device settings (number of stored events, storage mode, gain, sensitivity, auto activation parameters, battery status, and any status messages) are displayed.
- **Settings Only:** Device settings (number of stored events, storage mode, gain, sensitivity, auto activation parameters, battery status, and any status messages) are displayed.

When the interrogation is completed, information is displayed in the Device Status window (See Figure 21).

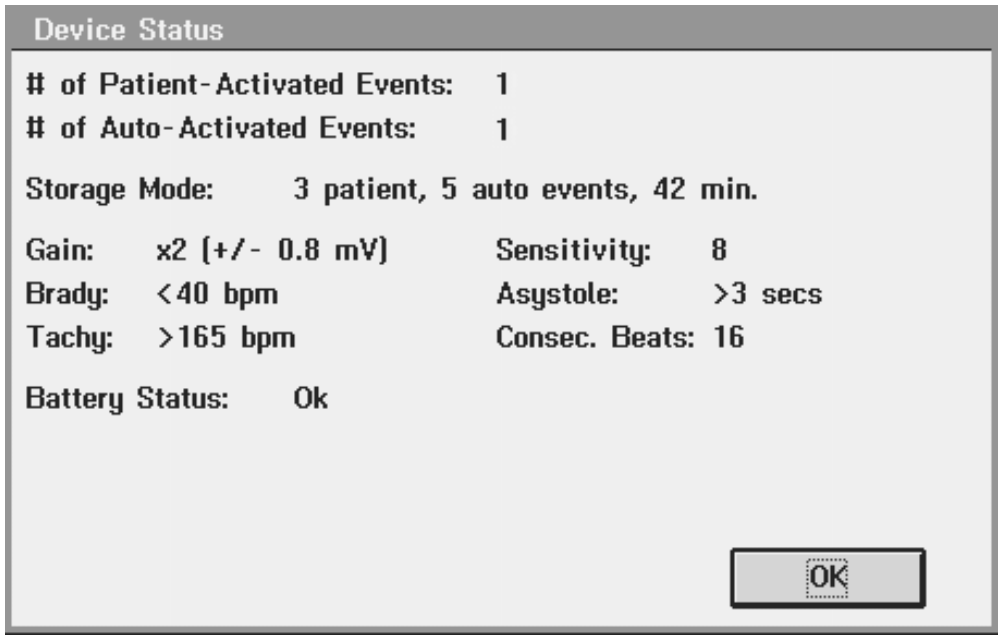


Figure 21. *Device Status Window*

3.1.2 How to Interrogate the ILR

1. Position the programming head over the ILR. (The yellow light must turn green.)
2. Select **[Interrogate...]** from the ILR Main screen (the Interrogate window opens).
3. Select **All Events and Settings** or **Settings Only**, and then **[OK]**.

   The retrieval of stored events may take several minutes. A status gauge shows the progress of the interrogation – you may select **[Stop]** to terminate the interrogation at any time.
4. When the interrogation is completed, select **[OK]** in the Device Status window.

   If you used the **All Events and Settings** option, the heart rate summary graph(s) representing the event(s) retrieved from memory are displayed on the Main screen.

Notes:

- During device interrogation, the real-time ECG display is paused. The display resumes when the interrogation is complete.
- **Interrogate stored events before adjusting any settings. If you do not interrogate first, you will lose the data.**

See page 30 for information on timing considerations when interrogating stored events.

- Event date and time are calculated based on the programmer clock. Verify that the displayed current date and time are correct before interrogating the ILR (see “Setting the Programmer Clock” on page 52).
- The battery status may be unavailable if you interrogate a device in shipping mode.

  To obtain the battery status in this case, start recording, wait one minute, and then interrogate the ILR.

  IMPORTANT! Selecting **[PROGRAM]** from the Setup screen starts a recording and erases all stored events.
- Upon interrogation, the programmer displays messages regarding the status of the ILR in the Device Status window and/or pop-up windows. Table 4 lists these messages, as well as suggested actions to take.

Table 4. *Device Status Messages*

Message	Explanation / Suggested Actions
Power-on Reset Occurred.	An electrical reset of the ILR has occurred. Device reset to Power-on Reset settings (see “Power-on Reset Settings” on page 50), and memory is cleared. • Press **[Reset Status].** (Programmed parameters are reset to default values.) • Press **[Setup...]** on the Main screen, and perform the setup procedure (see page 16). • Contact a Medtronic representative.
Low battery condition detected.	• Interrogate ILR (All Events and Settings). • Print or save event data. • If clinically appropriate, consider replacing the ILR. • Contact a Medtronic representative.
Battery at end of life. Recording and retrieval cannot be performed.	ILR is unable to record or store ECG. The software will confirm the battery status. • Remove ILR. • If clinically appropriate, replace ILR. • Contact a Medtronic representative.
Device in shipping mode.	ILR is not set up to record ECG. • Perform the setup procedure (see page 16).
Patient or automatic recording stopped. Device memory full.	ILR memory is full. Device is unable to store more events until recording is restarted. • Interrogate ILR (All Events and Settings). • View, print, and/or save data to disk, as appropriate. • Perform the setup procedure (see page 16).

3.2 Viewing Events

You may view events retrieved from the ILR memory and events read from disk.

3.2.1 *How to View Stored Events*

1. To retrieve events from the device, interrogate the ILR (All Events and Settings), if you have not already done so (see page 33).

   -or-

2. To retrieve events previously saved to disk, perform a Read from Disk (see page 44).
3. On the Main screen, tap the screen with the touch pen on the area of the heart rate summary graph that you wish to view in more detail. This takes you to the first zoom level of the event ECG waveform data and centers the area of the event you tapped (see Figure 22).
   - Use the scroll bar at the bottom of the screen to move through the stored event (see “How to Use the Scroll Bar” on page 39). To view the event in greater detail, tap the screen over the ECG of interest. This takes you to the second zoom level and centers the area of the event you tapped (see Figure 23). Tap the screen again over the ECG of interest to move to the third zoom level (see Figure 24).
   - To zoom out or return to the Main screen, select **[Zoom Out].**

First zoom level:
30 seconds of ECG per line.
5 minutes of ECG per screen.

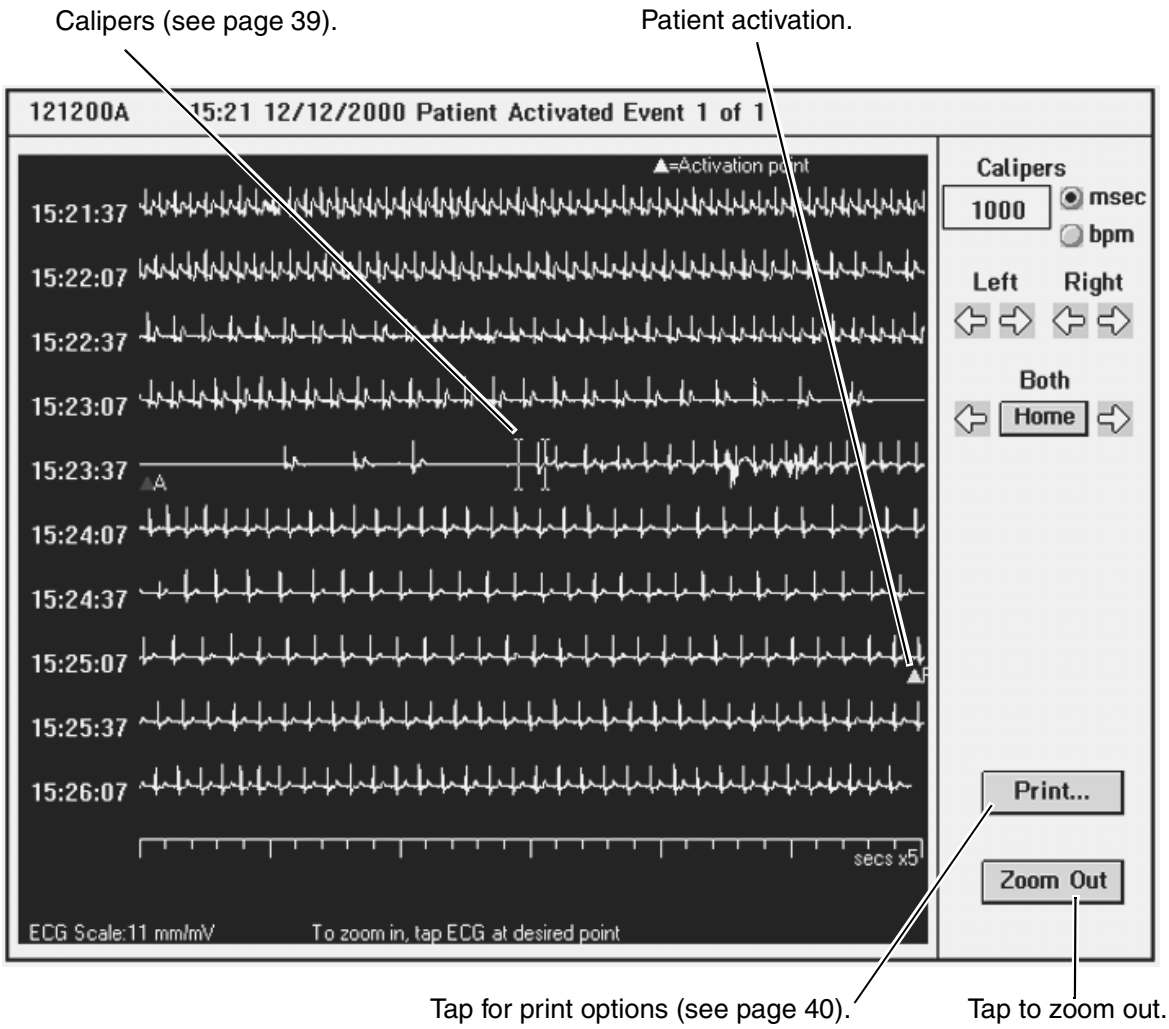


Figure 22. *First Zoom Level*

Second zoom level:
8 seconds of ECG per line.
24 seconds ECG per screen.

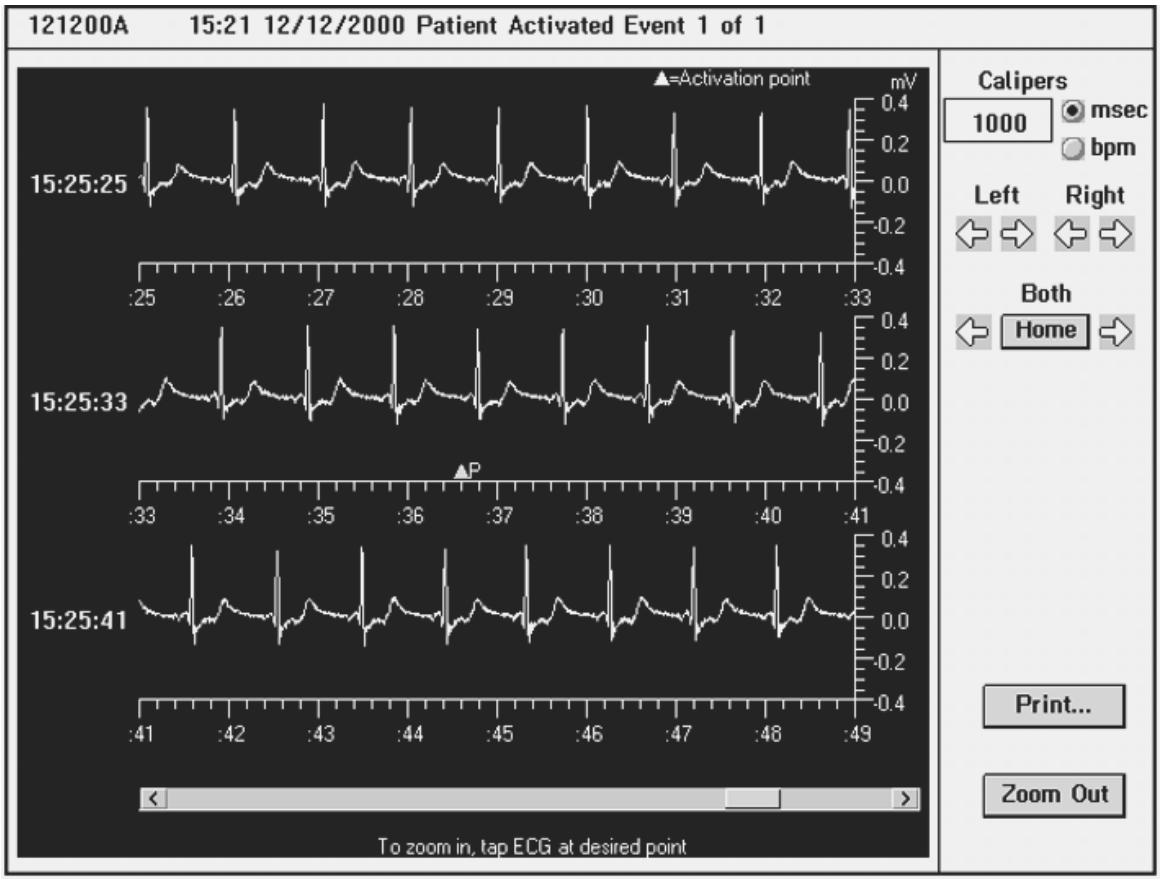


Figure 23. *Second Zoom Level*

Third zoom level:
4 seconds of ECG per screen.

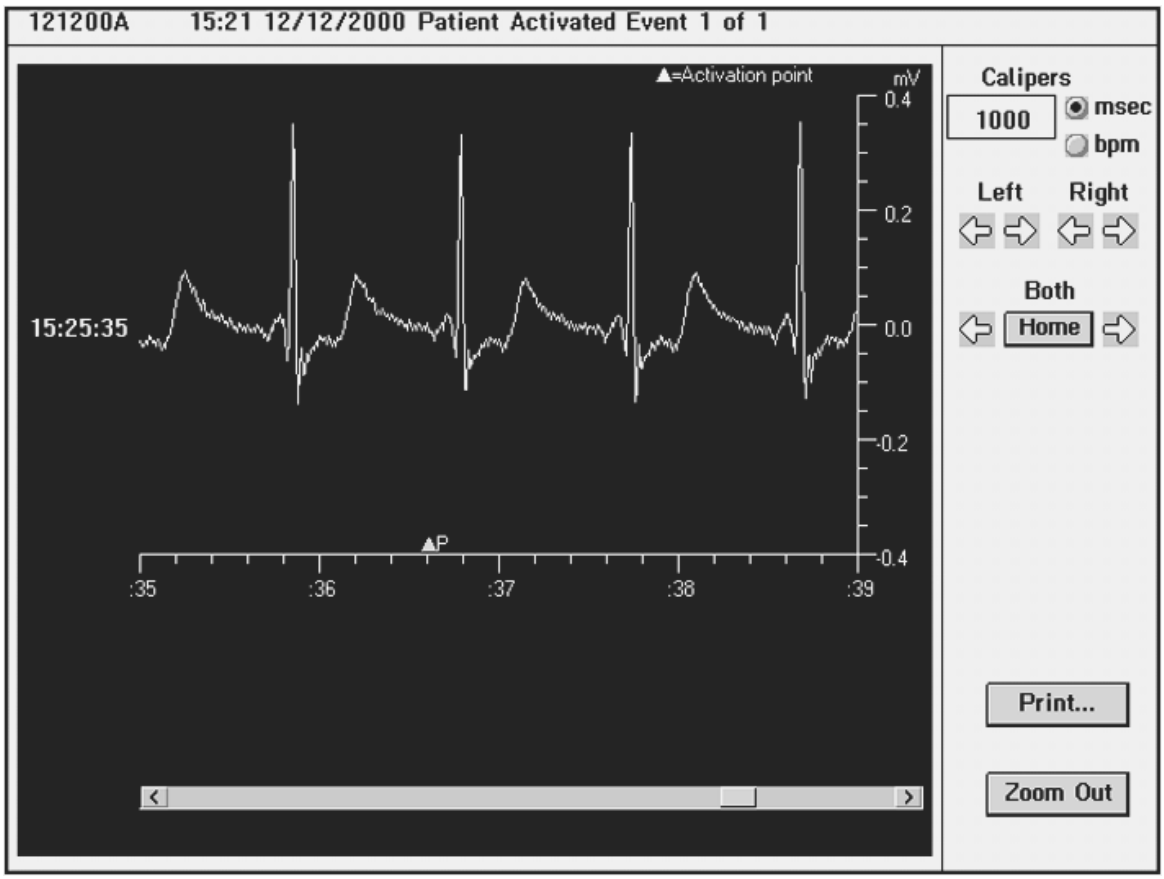


Figure 24. *Third Zoom Level*

3.2.2 *How to Use the On-Screen Calipers*

The on-screen calipers are available at every zoom level to measure cycle length (after you have selected an event to view from the Main Screen).

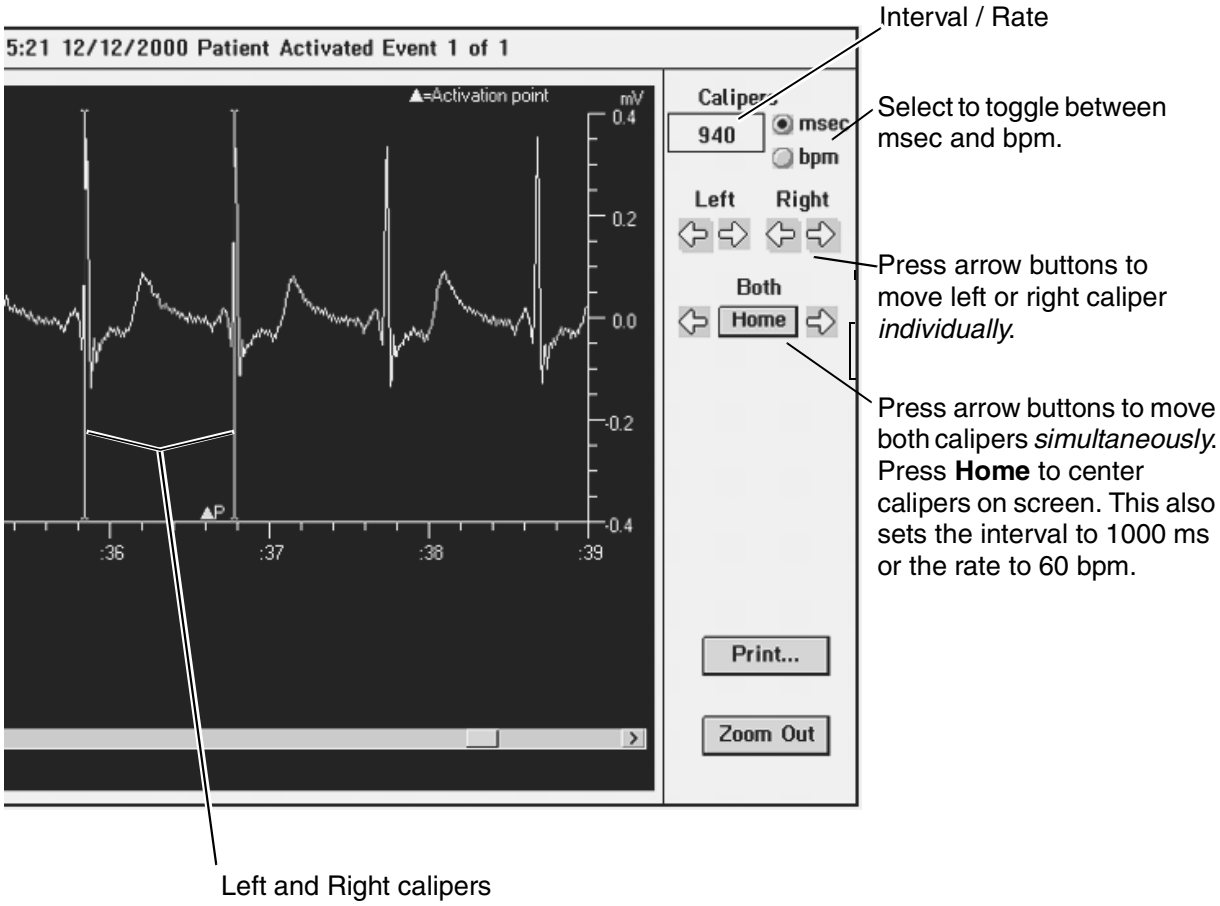


Figure 25. *On-Screen Calipers*

3.2.3 *How to Use the Scroll Bar*

The Scroll Bar is available at the bottom of each zoom level screen.

You may scroll through a stored event by using the Scroll Box, or the Page Left and Page Right arrows (Figure 26).

- Tap the Page Left or Page Right arrow to move one page at a time. Tap and hold to scroll continuously.
- The Scroll Box shows the relative position of the ECG displayed on the programmer screen within the stored event. Touch and drag the Scroll Box to the right or left to view a different area of the event.

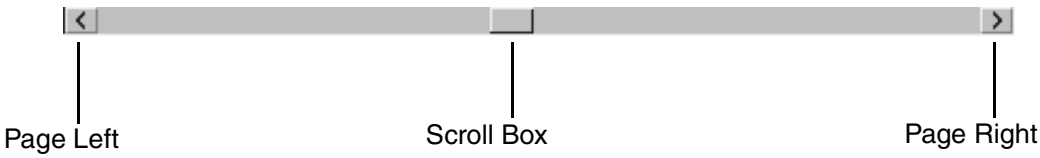


Figure 26. *Scroll Bar*

3.3 Printing Events, Settings, and Screens

3.3.1 Print Options

There are five print options available. These options are only available after reading data from a disk or interrogating a device.

- **All Events:** Prints all stored events and the associated device settings.
- **Single Event:** Prints a single stored event and the associated device settings.
- **Summary Graph(s):** Prints the heart rate summary graph(s) displayed on the Main Screen.
- **Current Device Settings:** Prints the current device settings.
- **Paused Waveform:** If the real-time ECG waveform is paused, prints up to 10 seconds of ECG prior to the pause. For more information, see “Printing the Real-Time ECG Waveform” on page 15.

  Note: The real-time ECG must already be paused for this option to be selectable.

3.3.2 Printers

Data may be printed to either the programmer strip chart printer, or to an external printer:

- **Programmer Strip:** Prints to the programmer strip chart printer.
- **Full Size:** Prints to an external printer (see “Connecting an External Printer” on page 41).

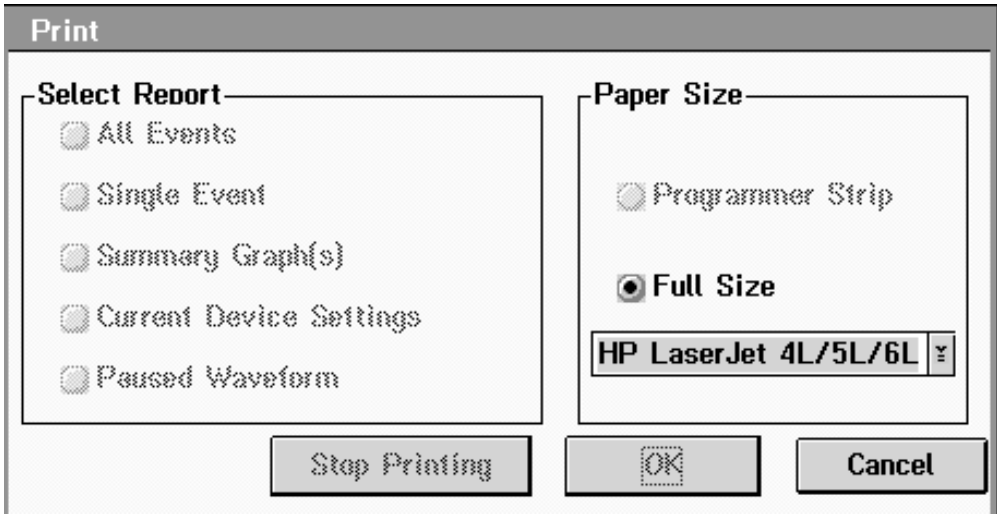
3.3.3 *How to Print Events and Settings*

You may print events retrieved from the ILR memory and events read from disk.

1. To retrieve events from the device, interrogate the ILR (All Events and Settings), if you have not already done so (see page 33).

   -or-

2. To retrieve events previously saved to disk, perform a Read from Disk (see page 44).
3. Select **[Print...]** from the Main Screen (the Print window opens).



4. Select **Report** and **Paper Size** options and then [**OK**]. If you choose **Full Size**, select a compatible print driver from the pull-down menu.
5. Select the **[Stop Printing]** button to stop printing during the current print job after the first page has printed.

Notes:

- While printing data, the programmer is operational for other tasks, including starting other print jobs.
- It is possible when printing and interrogating a device for all events and settings at the same time, that the telemetry may be interrupted during the interrogation.
- Using the programmer strip chart printer, printing 21 minutes of stored data will take approximately 4 minutes. Printing 42 minutes of stored data will take approximately 8 minutes.

3.3.4 *How to Print Screen-View of Events*

You may print the event data displayed on the first, second, and third zoom levels.

1. Select **[Print...]** from one of the zoom levels.
2. Select **All Pages of Event** or **Current Page of Event** as appropriate.

   Use the print option **Current Page of Event** from the second or third zoom level to print a more detailed waveform printout.

   Note: Only these two options are available for printing from a zoom level.
3. Select **Full Size** or **Programmer Strip** as appropriate.

3.4 Connecting an External Printer

Only printers listed by this software should be connected to the programmer. All printers supported by this software are certified to IEC 950, except the Canon BubbleJet 230 (U.S. use only). It is the responsibility of the user to keep the printer at least 2 meters from the patient.

By connecting a compatible printer to the programmer, you are able to print ILR data onto full-size pages (see “External Printers” on page 51).

Printer Compatibility – The printer you connect to the programmer must be compatible with one of the printer drivers. Refer to Appendix A for a list of printers which are compatible with the programmer software.

Materials You Will Need – To connect a printer to the programmer, you will need a Parallel Interface printer cable. One end of the cable must fit the parallel interface port on your printer; the other end must be a standard 25-pin male D-connector to fit into the parallel port on the programmer.

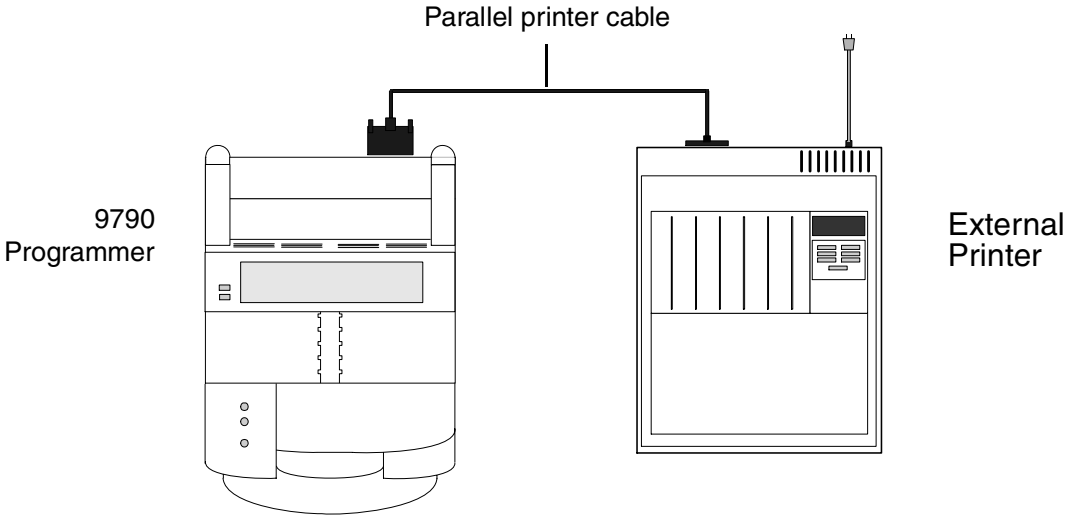
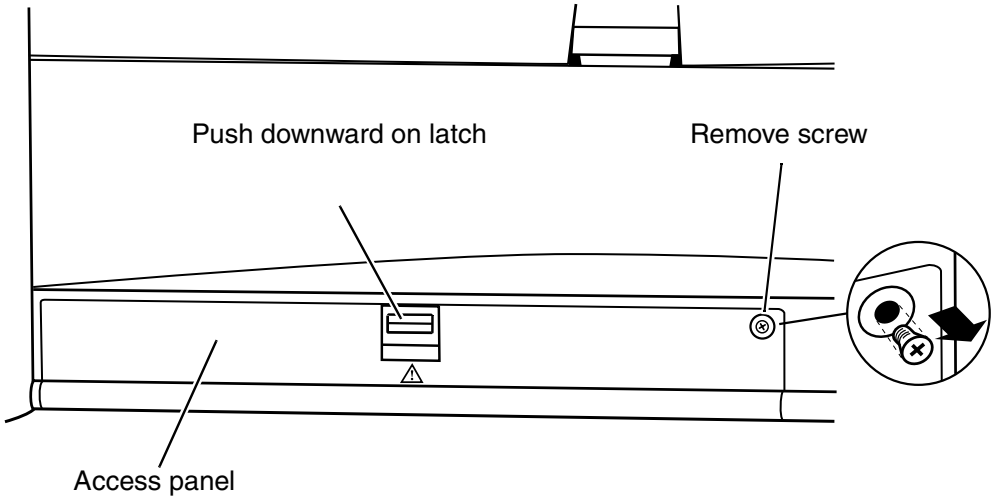


Figure 27. *Printer Connection*

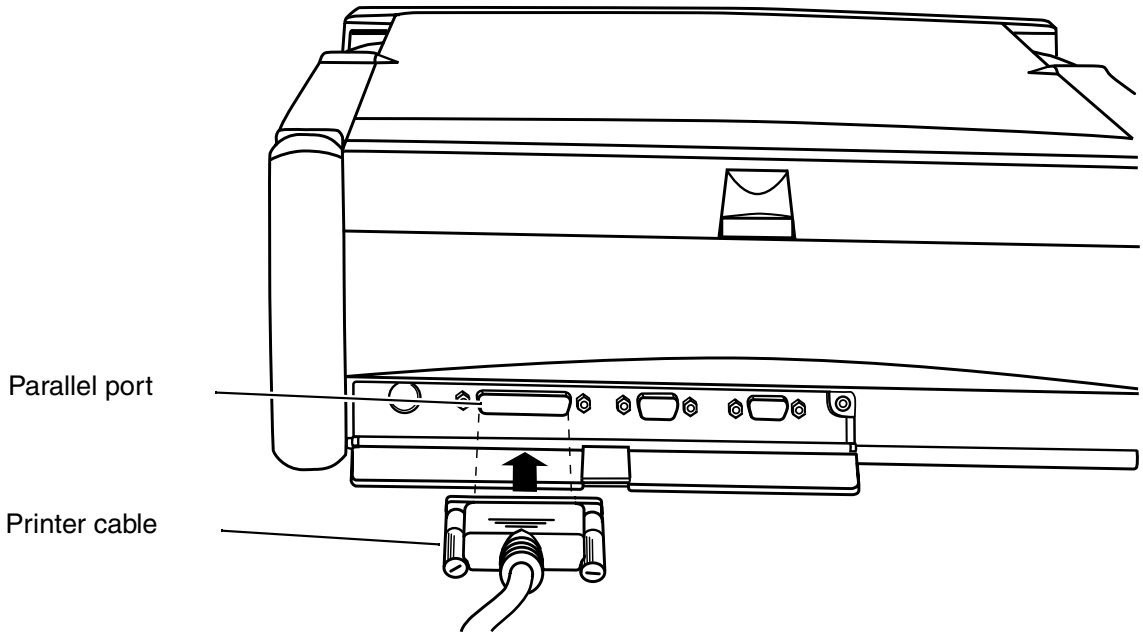
3.4.1 *How to Connect an External Printer*

Note: Prior to connecting a printer to your programmer, you should end the ILR session and turn the programmer off.

1. Open the access panel on the back of the programmer by pushing downward on the small latch at the top center of the panel. If necessary, remove the Phillips head screw in the upper right corner of the panel. (Instructions continued on following page.)



2. Connect the printer cable to the parallel port on the programmer.



3. Connect the other end of the cable (if it is not already connected) to the printer. Connect the printer power cord to an appropriate power outlet and turn the printer on. Verify that the printer is on-line and has been loaded with paper.

3.5 Disk Operations

You may save the most recently interrogated events and associated device settings to a disk for future reference. At a later time, you may read ILR data saved to disk onto the programmer in order to view and/or print it.

See page 43 for instructions on saving ILR data to disk, and page 44 for instructions on reading ILR data from disk.

Diskette Requirements – Use formatted (IBM compatible) 3.5 inch, 720 KB (DS, DD) or 1.44 MB (DS, HD) diskettes.

Data Filenames – Saved files are automatically named with a filename representing the date the file was saved. The naming convention is as follows:

MMDDYYXX	(e.g., 041701A)
MM	month (01 – 12)
DD	day (01 – 31)
YY	year (01, 02)
XX	suffix (A – Z, AA – ZZ)

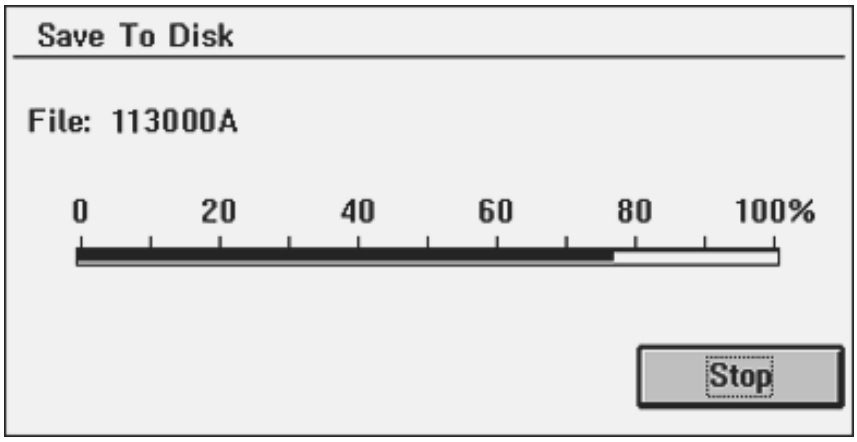
Notes:

- Do not place disks near the programming head. Doing so could erase data.
- Do not use diskettes containing ILR data in other computers.

3.5.1 *How to Save To Disk*

1. Interrogate the ILR (All Events and Settings), if you have not already done so (see page 33).
2. Select **[Disk...]** from the Main Screen (the Disk window opens).
3. Select **Save to Disk**.
4. Insert a diskette into disk drive and select **[OK]**.

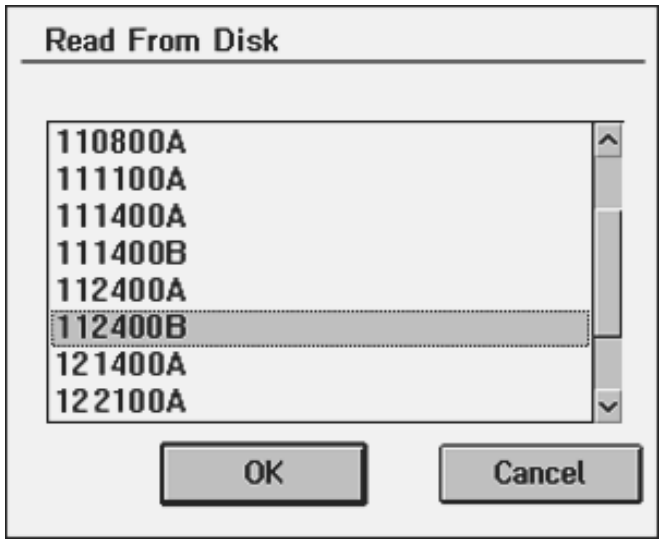
   The programmer automatically generates a filename. The filename is displayed in the Save to Disk window (see below), at the top of the Main Screen or zoom screens, and also on any printed reports (except the Current Settings report). Write down the filename to identify the file with the patient.



5. When the operation is complete, remove diskette from the disk drive. Label diskette with the filename and any other pertinent information.

3.5.2 *How to Read from Disk*

1. Select **[Disk...]** from the Main Screen (the Disk window opens).
2. Select **Read from Disk**.
3. Insert disk containing the ILR event data you wish to view into the disk drive and select **[OK].**
4. Select the file you wish to open and select **[OK]**. If necessary, use the ^ and v buttons to scroll through the list of filenames.



5. When the operation is complete, data read from disk are displayed on the Main Screen, zoom level screens, and printed reports.

   See page 35 for instructions on viewing events, and page 40 for instructions on printing events.

3.6 Ending A Patient Session

IMPORTANT! Before you end a patient session you should restart recording if you have not already done so. If you wish to save any event data stored in device memory for future reference, you must either print it (see page 40) or save it to disk (see page 43) before you restart recording. **By pressing [Program] at the bottom of the Setup screen, you erase all stored events and start recording.**

3.6.1 *How to End a Patient Session*

1. Select **[End Session]** from the Main Screen. The programmer displays the message, "**Exit this session?**"
2. Select **[Yes]** to end the session; select **[No]** to cancel.

3.7 Follow-up Visits

If a post-implant one week wound check is scheduled, interrogate the ILR to view auto-activated events. This may help determine the frequency of future follow-up visits.

Schedule periodic follow-up visits for patients who may be incapable of manually activating the ILR, to view auto-activated events.

Periodic interrogation of auto-activated events may uncover recorded events for which the patient was unaware.

Schedule a final follow-up visit prior to device end-of-life (see page 9 for longevity).

To clear data but retain the same programmed gain and sensitivity settings that were set at a previous time, review programming short-cut, page 31. This can be used after a patient practice session or at a follow-up visit. This programming short-cut can be used if the current settings are adequate to keep the number of inappropriate auto-activations to a minimum.

4 Activator

4.1 Description

The Reveal Plus Activator is a hand-held, battery-operated telemetry device used by the patient during or after a symptomatic event to store an episode into the ILR memory.

A green light above the ☑ symbol on the Activator flashes for approximately ten seconds if the ILR received the signal from the Activator.

A yellow light above the ∅ symbol flashes for approximately ten seconds if the ILR did *not* receive the signal from the Activator.

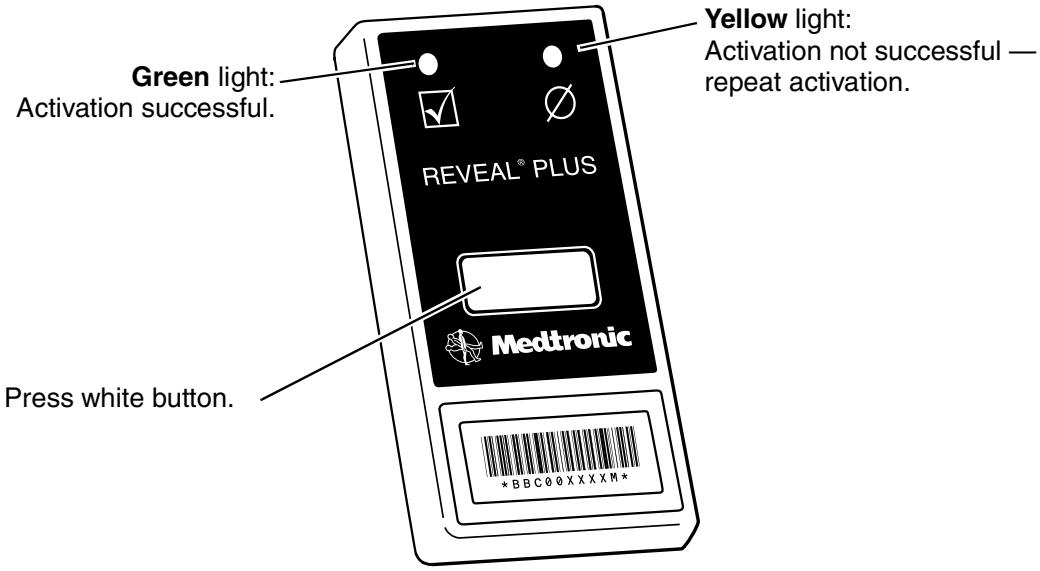


Figure 28. *Model 6191 Activator (Front)*

4.1.1 Intended Use

The Activator is intended for use in combination with the Model 9525 Reveal, and Models 9526 Reveal Plus Insertable Loop Recorders.

4.1.2 FCC Statement

The Model 6191 Activator complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1) This device may not cause harmful interference, and 2) this device must accept interference received, including interference that may cause undesired operation.

The FCC identifier for the Model 6191 Activator is FCC ID: LF56190.

Note: The user must not make changes or modifications to the Model 6191 Activator without the prior approval of Medtronic, Inc.

UL/CUL Certification

The Model 6191 Activator has been classified by Underwriters Laboratories, Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 2601-1 and CAN/CSA C22.2 No. 601.1-M90.

4.1.3 Activator Environmental Precautions

See page 6.

4.2 Cleaning and Care

Clean the outside of the Activator with a slightly damp cloth. Mild household cleaners will not damage the case or labels. The Activator is water-resistant, but not waterproof.

The Activator is not designed to operate in environments where it would remain wet for extended periods of time. Be careful to prevent moisture from entering the Activator. If the Activator needs to be used in a wet environment, take measures to prevent exposure of the device to moisture.

Do not immerse the Activator in liquid, or clean it with aromatic or chlorinated hydrocarbons or acetone (e.g., bleach or nail polish remover).

4.3 Service

The Activator is not field-repairable. If service of the Activator is necessary, contact your local Medtronic representative.

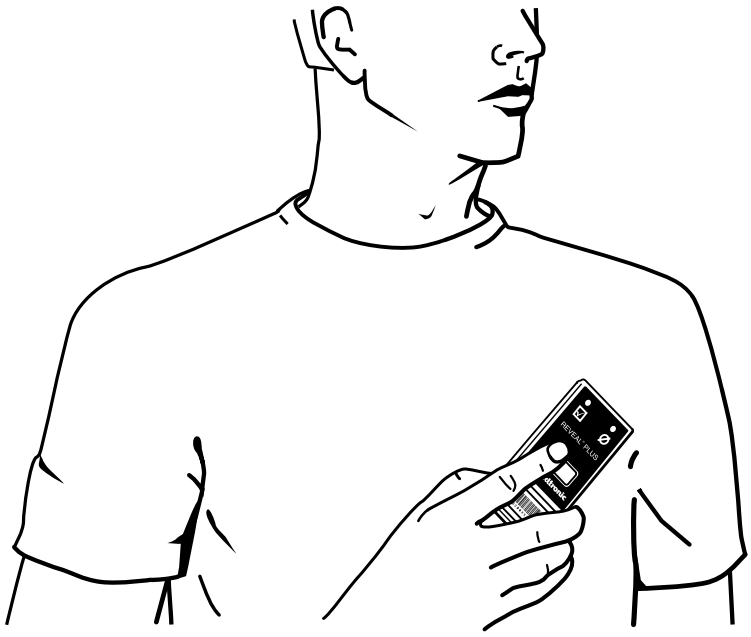
4.4 Longevity

The projected longevity for the Activator is 24 months and 2,000 activations.

4.5 Operation

During or after a symptomatic event, the patient should perform the following steps to store an event into the ILR memory:

1. Lay the Activator flat over the implant.



2. Press the white button one time.
3. Immediately remove the Activator from over the implant site and observe the lights.
   – When the ILR has received the signal from the Activator, a **green** light flashes above the ☑ symbol.
   – A flashing **yellow** light above the ∅ symbol indicates that the ILR did *not* receive the signal from the Activator. Reposition the Activator and repeat steps 2 and 3 until you see a flashing green light.

Notes:

- Instructions for use are printed on the back of the Activator.
- After using the Activator to store an event, patients should contact their physician or clinic to arrange for a follow-up visit, as appropriate.

4.6 Activator Pouch

A small pouch and cord are packaged with the Activator to allow you to wear it around your neck. The pouch also has a clip mounted on the back, which provides you with the option to attach it to a belt or a suitable pocket.

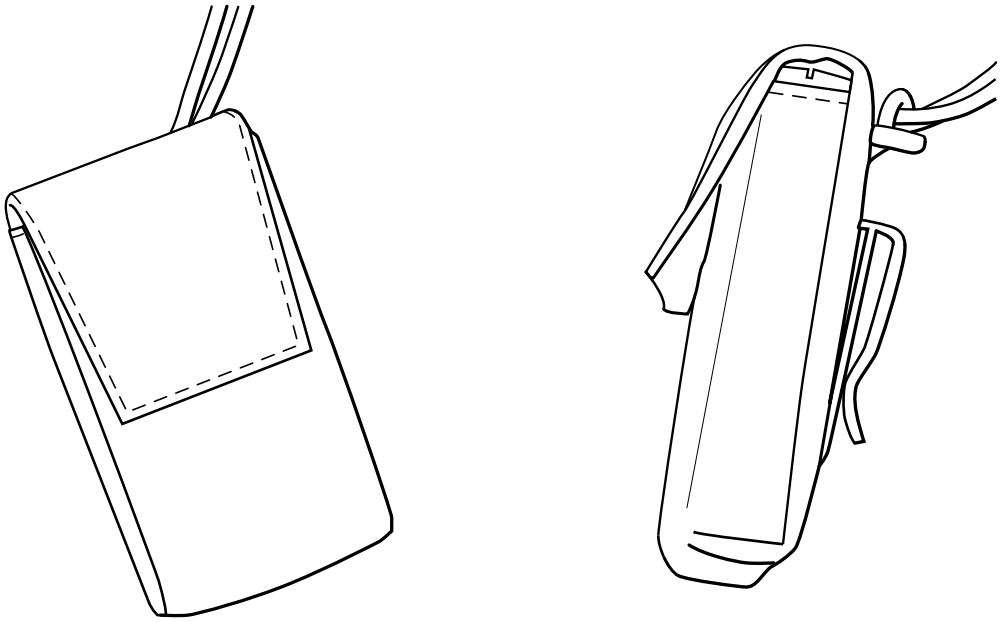


Figure 29. *Activator Pouch*

5 Appendix A

5.1 ILR Specifications

5.1.1 Materials

Component	Material Used
Case and external electrode	Titanium
Header	Polyurethane, silicone
Coating	Parylene

5.1.2 Dimensions / Radiopaque ID

Parameter	Value
Volume	8 cm^3
Length	61 mm
Width	19 mm
Thickness	8 mm
Mass	17 g
Radiopaque ID	AAB
Electrode spacing	38.5 mm

5.1.3 Factory Shipped Settings

Parameter	Factory Shipped Setting
ECG Recording	OFF
Gain	x2
Sensitivity	8
Storage Mode	3 patient-activated events (12 minutes pre/2 minutes post)
Brady Setting[a]	<40 bpm
Tachy Setting[a]	>165 bpm
Tachy NID[a,b]	16
Asystole[a]	>3.0 seconds
Auto Roll[a]	ON

[a] The default setting when auto activation is enabled.
[b] Number of consecutive intervals detected.

5.1.4 Power-on Reset Settings

Parameter	Power-on Reset Setting (Default Values)
ECG Recording	ON
Gain	x2
Sensitivity	8
Storage Mode	3 patient-activated events (6 minutes pre/1 minute post)
Brady Setting[a]	<40 bpm
Tachy Setting[a]	>145 bpm
Tachy NID[a,b]	16
Asystole[a]	>3.0 seconds
Auto Roll[a]	OFF

[a] The default setting when auto activation is enabled.
[b] Number of consecutive intervals detected.

5.1.5 Electrical Specifications

Parameter	Value
Sampling Rate	100 Hz[a]
Resolution (calculated)	1.5 μV at Gain of x8 2.9 μV at Gain of x4 5.9 μV at Gain of x2 11.7 μV at Gain of x1
Bandwidth (-3db points)	0.85 – 32 Hz

[a] In compressed storage modes, data sampled at 100 Hz is stored at 50 Hz.

5.1.6 Battery Information

Parameter	Value
Model	LTC-3PN-S2
Manufacturer	Eagle Picher
Battery type	Lithium thionyl chloride
Initial voltage	3.67 V
Effective voltage at “Low Battery” condition	3.30 V
Effective voltage at “Battery at end of life” condition	3.00 V
Deliverable capacity	BOL to LBI = 0.250 Ah LBI to EOL = 0.025 Ah BOL to EOL = 0.275 Ah
Estimated minimum capacity following “Low Battery” condition message [a]	0.014 Ah
Projected longevity	14 months[b]

[a] The nominal value is 0.025 Ah. The 0.1% minimum capacity is estimated at 0.014 Ah.
[b] Projected longevity based on a six-month shelf life.

5.2 Activator Specifications

Parameter	Value
Power Source	3 V coin-type lithium battery (type CR2032); non-rechargeable
Operating Temperature Range[a]	48 to 110 °F (9 to 44 °C)
Operating Humidity Range	30-75%
Transportation and Storage	
Ambient Temperature Range	–40 to 158 °F (–40 to 70 °C)
Relative Humidity	10 to 95%
Atmospheric Pressure	500 to 1060 hPa
Classification with respect to electric shock	Internally powered
Protection from electric shock	Type B
Protection from ingress of liquids	Ordinary equipment
Mode of operation	Continuous operation
Physical Specifications	
Length	85 mm
Width	45 mm
Thickness	16 mm
Mass	40 g

[a] The extended operational temperature range is 5 to 158 °F (-15 to 70 °C). Battery life is compromised, and Activator reliability is adversely affected, if device is operated in the extended range.

5.3 External Printers

Printer	Model (s)
HP LaserJet	4ML
HP LaserJet	4L, 5L, 6L
Canon	BJ-230
HP DeskJet	320, 500, 500C, 510, 520, 540, 550C, 560C

5.4 Setting the Programmer Clock

Displayed or printed time stamps for data stored in the Reveal Plus ILR memory are based on the programmer clock. For this reason, resetting the programmer time and date will have corresponding effects in the time stamps interrogated from the ILR. This may also cause the displayed or printed time stamps to change slightly as a result of being interrogated by different programmers.

5.4.1 *How to Set the Programmer Clock*

1. Display the Select Model screen and select the Programmer icon from the tool palette.
2. Select **[TIME AND DATE]**.
3. Use the [^] and [v] buttons to select Month, Day, Year, Hours, and Minutes values.
4. Select **[Apply]** to save your changes and select the desired tool palette icon to close the Programmer Time and Date window.

5.5 Special Notice

The Medtronic® Reveal Plus Insertable Loop Recorder (ILR) is implanted in the extremely hostile environment of the human body. This environment places severe limitations on the design and function of the ILR. These limitations unavoidably reduce the effectiveness and longevity of the ILR despite the exercise of due care in design, component selection, manufacture, and testing prior to sale. The ILR includes a power source that will ultimately cease to function due to exhaustion or premature failure, possibly necessitating removal of the ILR before its expected explantation. Other reasons for failure of the ILR include but are not limited to: body rejection phenomena; physiological variations in patients; fibrotic tissue formation; erosion of the ILR through the skin; infection; random component failure; or interference from transmitters, tools, appliances, instruments, equipment, electrocautery, external defibrillators, or other equipment that use electricity, ionizing radiation, or electromagnetic wave transmission. Consequently, no representation or warranty is made that failure or cessation of function of the ILR will not occur, that the body will not react adversely to the implantation of the ILR, or that medical complications will not follow the implantation of the ILR.

5.6 Technical Support

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

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise.

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

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