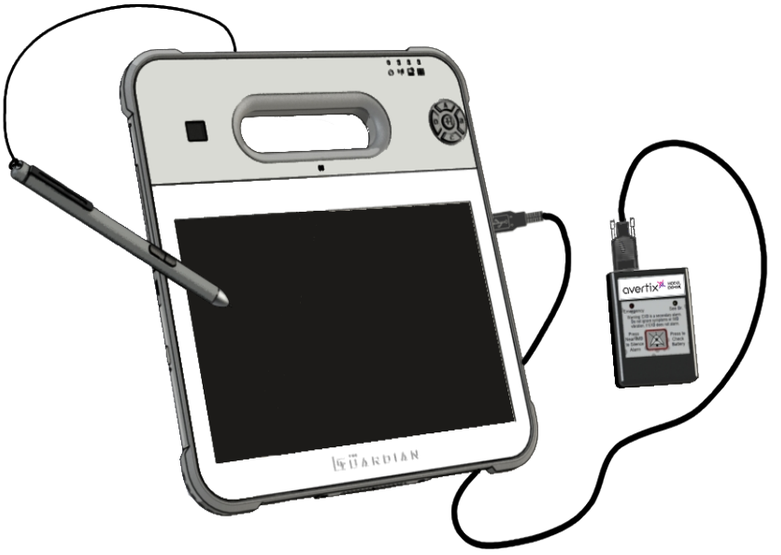
Avertix GUARDIAN™ Programmer
Application User's Manual
Programmer Software Release: 3.7



GUARDIAN

Preface

What's New in this Release?

Programmer release *3.7* includes the following new features.

New Programmer hardware
An all new, rugged tablet features hot-swappable batteries, MVA LED display, and medical grade PCAP touchscreen with Corning® Gorilla® Glass.

Digitizer stylus with tether cord
The stylus allows for easy use of the Programmer's touchscreen interface. The convenient tether cord prevents the stylus from getting lost or dropped.

Improved input options
The Windows-style on-screen keyboard provides predictive results as you touch with your finger or tap with the stylus.

Convenient hand strap
An adjustable hand strap provides convenient carrying capability and helps to prevent accidental dropping of the Programmer. The hand strap is also removable.

About this Document

This manual provides a detailed description of the Guardian Programmer software and describes how to accomplish specific Programmer tasks. This document is organized as follows:

1– Introduction	A basic description of the Programmer and other components of the Guardian System.
2– Pre-Implant Check	Procedure to check IMD operation before implantation.
3– Implant Verification	Verification procedures to perform immediately after implantation, but prior to closing the surgical pocket.
4– Pre-Discharge Setup	Setup procedures to perform prior to patient discharge.
5– Initial IMD Programming	Comprehensive information about setting IMD parameters and training the patient.
6– Follow-Up Visits	Procedures for checking IMD battery status, retrieving and reviewing data, checking vibration strength, and reviewing patient instructions.
7– Programmer Backup and Restore	Procedures for backing up and restoring patient data.
8– Troubleshooting	Procedures to follow if you encounter a problem.
A– IMD Parameters	All programmable parameters for the IMD, including default values and possible ranges.
B– Changing Heart Rate Bins using Edit Implant Parameters	Describes how to change IMD heart rate bins values using the Edit Implant Parameters window.
C– Patient Training Script	Provides the script that we recommend using when training

	the patient during Initial Programming.
Index	A topical index of the manual.

Conventions

This manual employs the following conventions:

Normal text	The standard text used in the manual.
"Semi-bold text in quotes and box"	Used to identify the suggested patient training instructions. (Ex. **"What would you do if this alarm occurs?"**)
Italics text	• Identifies user interface window names as well as their buttons and options, and menu item names. (Ex. Select *Browse* on the *Save As* window.) • Used for referencing section and chapter names, and also the titles of other manuals or documents. (Ex. See *Open the Patient Record* on page 17.)
Command1→ *Command2*	The arrow (→) indicates a command sequence from the menu bar. For example, *Admin* →*Backup* means "Select *Admin* and then select *Backup*."
Note:	Notes provide ancillary information about a topic or procedure.
Caution:	Caution statements include information regarding any special care to be exercised by the practitioner and/or the patient for the safe and effective use of the Guardian System.
Warning:	Warning statements describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Service & Support

Service

For service or maintenance of your Guardian Programmer, contact your *Avertix* representative.

Technical Support

For technical support, contact your *Avertix* representative.

Avertix Medical, Inc.

40 Christopher Way, Suite 201

Eatontown, NJ 07724 (USA)

Phone: *+1 (800) 508-5206* (USA toll-free)

Related Documentation

- *Guardian™ Programmer Model Prog-004 Setup & Operations Guide*
- *Guardian™ External Device (EXD) User's Manual*
- *Guardian™ Implantable Medical Device (IMD) Model AMSG3 User's Manual*
- *Guardian™ Implantable Medical Device (IMD) Model AMSG3-E User's Manual*
- *Patient Manual for the Guardian™ System*

Contents

1 Introduction

The Guardian™ system is designed to detect and warn patients about a variety of changes in their cardiac electrogram. It also stores baseline electrograms and, in the event of a warning, both pre- and post-event electrograms for later review.

This chapter provides an overview of the Guardian system and the detection algorithm that it relies upon. Topics include:

How the System Works

The fundamental goal of the Guardian system is to:

- Detect a rapid and significant change – a shift – in the ST deviation (the ST segment to PQ segment voltage difference) of a patient's electrogram.
- Warn the patient to seek medical help immediately if an ST shift occurs.

To detect an ST shift, the ST deviation is compared to baseline patient electrogram data using a specific detection algorithm. In addition to ST shift, the system detects other types of electrogram changes, such as low, high, and irregular heart rates. Each type of electrogram change is called an event. The physician can specify the type of warning, if any, that is associated with each event.

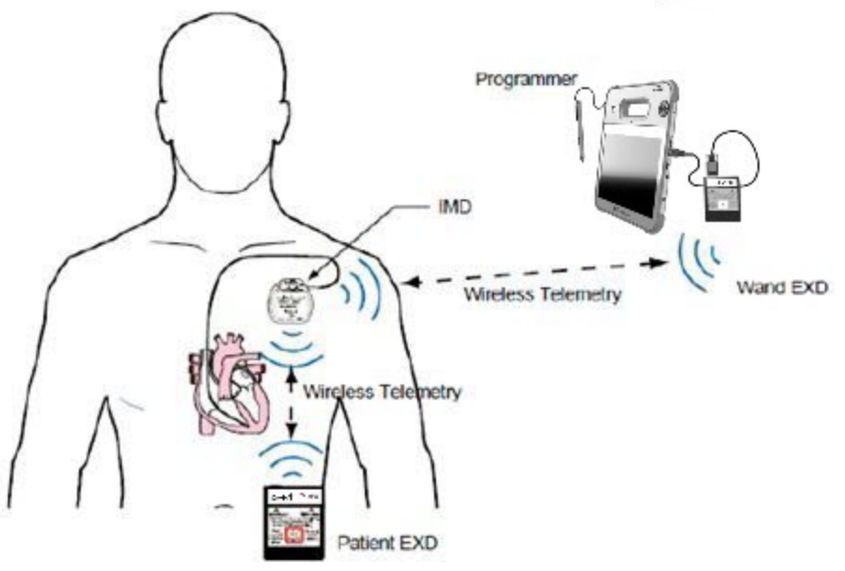
Notes:
The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes needs to be determined by a clinician.

Two levels of warning are possible: Emergency alarms, for significant events that require immediate medical attention, and See Doctor alerts, for less-significant events, where the patient calls their doctor in the next 1 or 2 days to make an appointment. The Emergency alarm and See Doctor alert produce distinguishable vibratory patterns in the Implantable Medical Device (IMD) and different audible patterns and visual indicators in the External Device (EXD).

Guardian System Architecture

The Guardian system comprises the following main components:

- Implantable Medical Device (IMD):
  - Collects and analyzes the patient's electrograms via an endocardial lead
  - Stores them for subsequent retrieval by a physician via wireless telemetry
  - Vibrates to warn the patient of an Emergency alarm or See Doctor alert
- External Device (EXD): A hand-held telemetry device that warns the patient of alarms and alerts via beeps and flashing LEDs. The Programmer has a Wand, which is used for communication between the Programmer and the IMD.
- Programmer: A computer workstation used to configure the IMD and, when desired, retrieve data from the IMD.

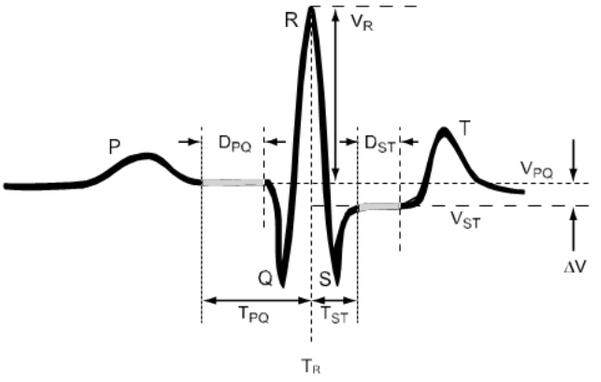


Detection Algorithm Basics

The Guardian IMD detects a shift in the ST deviation (the ST segment to PQ segment voltage difference) of a patient's electrogram. Using the patented *Avertix Medical, Inc.* detection algorithm, the IMD continually compares the ST deviation of each heartbeat to the patient's average ST deviation. The rest of this section provides a basic understanding of how the algorithm works.

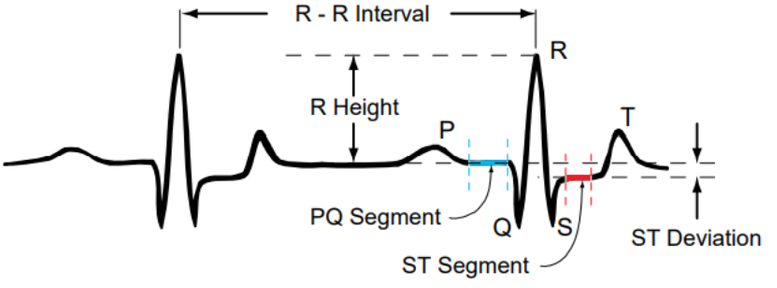
Algorithm Diagrams and Definitions

The detection algorithm analyzes a patient's cardiac waveform. To better understand the detection algorithm, consider the following diagram of a typical ECG waveform and the component definitions that follow.



Algorithm Element	Definition
R-Wave	R denotes the R-wave peak and VR denotes the voltage of the R-wave peak. The time where the R-wave peak occurs (used to determine the PQ and ST segments defined below) is defined as TR.
PQ Segment	That isoelectric portion of the electrogram that starts just after the end of the P wave and ends at the beginning of the QRS complex. The PQ segment can be customized for each patient. TPQ defines the start of the PQ segment and is measured (in milliseconds) from the Q-wave peak, or, if the size of the Q-wave is negligible, the R-wave peak. DPQ is the duration (in milliseconds) of the PQ segment. The PQ voltage (VPQ) is the average voltage of the PQ segment.
QRS Height	The difference between the maximum and minimum voltage values of the QRS complex. The QRS complex is defined as the deflections in the tracing of the electrogram, comprising the Q, R, and S waves, which represent the ventricular activity of the heart (the depolarization of the ventricles).
ST Segment	Starts at the end of the QRS complex and ends just before the T wave. The ST segment can be customized for each patient. TST defines the start of the ST segment and is measured (in milliseconds) from the S-wave peak, or, if the size of the S-wave is negligible, the R-wave peak. DST is the duration (in milliseconds) of the ST segment. The ST voltage (VST) is the average voltage of the ST segment.
ST Deviation	The ST Deviation (ΔV) of a beat is defined as the voltage difference between the average ST segment voltage (VST) and the average PQ segment voltage (VPQ). Stated mathematically: ST Deviation (ΔV) = VST – VPQ
R Height	The R-Height value (RPQ) is the difference between the R-Peak voltage (VR) and the average PQ segment voltage (VPQ).
ST Shift	The ST shift of a beat is the difference between the ST deviation of a beat and the average ST deviation of the beats in a baseline segment.
ST Shift Threshold	The percentage of the average baseline R height at which the ST shift is deemed to be excessive.

The following figure provides another illustration of an ECG waveform, with detection algorithm notations.



Legend:
R Height = R Peak - PQ Segment
ST Deviation = ST Segment - PQ Segment

Segment and ST Shift Characterization

The IMD supports two basic data acquisition modes: normal and post-emergency alarm, which is described later. In normal data acquisition mode, the IMD collects a 10-second electrogram segment every 30 or 90 seconds, depending on the characterization of the previous segment. If the previous segment is normal, which is defined as similar to the patient's baseline segment, the collection period is set to 90 seconds; otherwise, it is set to 30 seconds. Examples of the reasons for shorter collection periods are low, elevated, high, and irregular heart rates, or heartbeats that exhibit some degree of ST shift.

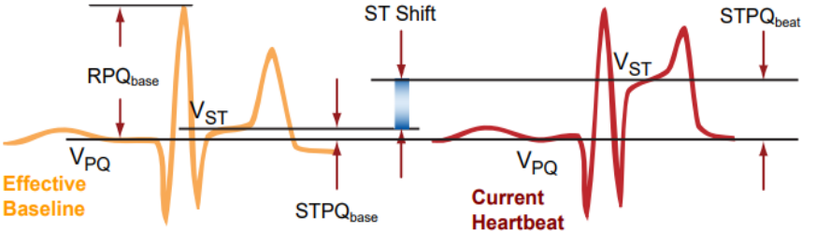
Heart Rate Characterization

Once a 10-second segment has been collected, the segment is characterized by heart rate and ST shift, regardless of the data acquisition mode. First, the times of all of the R waves are determined. Using this information, the average heart rate for the 10-second segment is determined and classified as being low, normal, elevated, high, or irregular.

ST Shift Characterization

ST shift characterization of a segment is done by characterizing regular beats (e.g., not PVCs) as either ST shifted or not. For each segment, the IMD analyzes up to eight regular beats. If the IMD finds six regular ST-shifted beats, the segment is classified as shifted; otherwise, it is classified as non-shifted. The IMD does not characterize the ST shift of segments that are classified as having a high heart rate. If the IMD does not detect enough regular beats to determine the ST shift classification, the segment is classified as too short (TS), and the results are saved and used during the next segment characterization.

ST shift determination for a regular beat is accomplished by first finding its ST deviation (i.e., the average ST segment voltage minus the average PQ segment voltage ($STPQ_{beat} = V_{ST} - V_{PQ}$)). Then, the detection algorithm calculates the ST shift (i.e., the ST deviation of the beat minus the average ST deviation of the effective baseline segment (ST Shift = $STPQ_{beat} - STPQ_{base}$)). A beat is declared to be ST shifted if its ST shift is greater than the physician-settable ST shift threshold. Otherwise, it is declared to be not ST shifted.



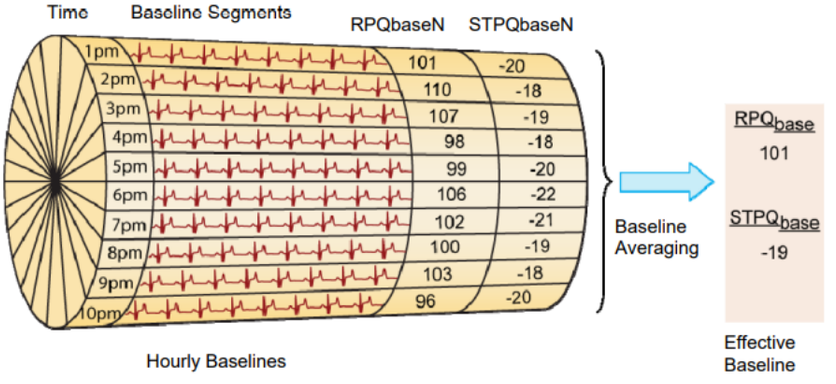
ST Shift = $STPQ_{beat}$ - $STPQ_{base}$
ST Shift Threshold = % R height where ST Shift is deemed excessive (ST Shift/ RPQ_{base})

The ST shift thresholds express the shift as a percentage of the baseline segment's average R height (RPQ_{base}). In the above figure, the ST shift is about 40% because

the size of the ST shift is about 40% of the R wave height of the effective baseline. The IMD provides separate thresholds for positive shifts and negative shifts at different heart rates.

Baseline Collection and Averaging

ST shift determination for a regular beat is based on a comparison to the effective baseline segment. Baseline segments are collected on an hourly basis. The IMD stores 24 baseline segments, one for each hour of the day. Only segments that are in the normal heart rate range with a low average ST shift are used as baseline segments. Each hour, the IMD evaluates up to 40 segments for possible use as a baseline segment. Once it finds a suitable segment, the IMD stops evaluating baseline candidates for the remainder of that hour. If after 40 attempts, no baseline segments are found that meet the criteria for baseline segments, baseline evaluation stops for that hour, and the IMD continues to use the previous baseline that was valid for that hour. When the next hour begins, the IMD again resumes baseline evaluation for that hour.



For each baseline, the IMD determines the R wave height of each beat and calculates the average height for that baseline segment (i.e.,$RPQ_{base}N$). It also determines the ST deviation of each beat and calculates the average ST deviation for the segment (i.e., $STPQ_{base}N$). At the top of each hour, the IMD establishes a new effective baseline by calculating the average R wave height (i.e.,RPQ_{base}) and ST deviation (i.e., $STPQ_{base}$) from all 24 baselines. In other words, the effective baseline is an average of all 24 baselines and is recalculated at the top of each hour.

Stale and Default Baselines

As previously stated, the IMD attempts to collect a new baseline up to 40 times every hour. If no suitable segment is collected, the IMD keeps the baseline that was previously in effect for that hour and uses it when calculating the effective baseline. An hourly baseline can remain valid for up to 72 hours if it has not been replaced. After three days, the IMD marks the hourly baseline stale and no longer uses that baseline when calculating the effective baseline. Instead, the IMD substitutes the values of the default baseline in place of the stale hourly baseline information.

Like all other baselines, the default baseline comprises two numbers: in this case RPQnormal which is the average height of the default baseline R waves, and STPQnormal which is the average ST deviation of the default baseline beats. On every IMD data retrieval, the Programmer updates the default baseline using the values of the effective baseline. In addition, IMDs with version 0.6.13.2 (or higher) firmware automatically update the default baseline when the IMD successfully collects 24 consecutive hourly baselines. When this occurs, the IMD sets the default baseline values equal to those of the effective baseline.

The IMD continues to use the default baseline for any hour where the baseline is stale until such time that the IMD can successfully collect a baseline for that hour.

Segment Classification

Using the heart rate ranges and ST shift classifications described previously, the algorithm classifies the segment into exactly one of the following groups.

Segment Classification	Abbreviation
High heart rate	HI
Elevated heart rate with an ST shift	EL-S
Elevated heart rate, not shifted	EL-NS
Normal heart rate with an ST shift	N-S
Normal heart rate, not shifted	N-NS
Low heart rate with an ST shift	LO-S
Low heart rate, not shifted	LO-NS
Irregular heart rate with an ST shift	IR-S
Irregular heart rate, not shifted, with many irregular beats	IR-NS>P
Irregular heart rate, not shifted, with a few irregular beats	IR-NS<P
Too short; not enough beats to make a classification. Save this information and use in the next segment analysis.	TS

Determining Events

After the segment has been characterized, the IMD checks the characterizations of the last several segments to determine if it should declare an event. Typically, several consecutive segments of a given classification type are required before the IMD declares an event. Examples of such events are:

- Positive ST Shift & Non-Elevated HR
- Negative ST Shift & Non-Elevated HR
- Negative ST Shift (Recovery)
- ST Shift & Elevated HR
- ST Shift & Elevated HR Persists
- High Heart Rate
- Low Heart Rate
- Irregular Heart Rate
- Flat Line
- Not Enough Beats
- Cannot Get Baseline

If an event is detected, the IMD determines what alarm type is mapped to the event. Although there are default mappings, the physician has control over which alarm type is generated for each event. The system defines the following alarm types:

- Emergency – Save data and alert the patient with an Emergency alarm
- See Doctor – Save data and alert the patient with a See Doctor alert
- None – Save data but don't alert the patient
- Ignore – Don't save any data and don't alert the patient

ST Shift Events as They Relate to Heart Rate

The primary function of the IMD is to detect ST shifts as they occur. As noted previously, there are four ST shift events. This section describes the conditions under which these events are detected and how the IMD notifies the patient.

Positive/Negative ST Shift & Non-Elevated HR

The Positive and Negative ST Shift & Non-Elevated HR events each represent the situation where the ST deviation of the patient's heartbeat has shifted, relative to the effective baseline, by an amount that exceeds the physician-set threshold for a low, normal, or irregular heart rate. These events are typically mapped to Emergency alarms.

Negative ST Shift (Recovery)

The Negative ST Shift (Recovery) event is declared when the patient's ST shift exceeds the negative ST shift threshold set for that patient at a time when the heart rate is significantly decreasing. This event is typically mapped to a See Doctor alert.

For at least some people, the electrophysiological response (i.e., negative ST shift) of the heart lags the actual ischemia introduced by a burden, such as exercise. Therefore, when a patient exerts him or herself (e.g., stress test), the heart rate typically climbs at the time of demand; however, an ST segment response may lag the heart rate change. Conversely, when the exertion lessens, the heart rate decreases; however, for patients that have chronic ischemia, the ST segment may remain depressed for several minutes after peak activity.

During that time, the heart rate will have decreased, typically to the Normal heart rate range, where if the patient's ST shift still exceeded the negative threshold, the Negative ST Shift & Non-Elevated HR event would be declared, resulting in the See Doctor alert. If the excessive shift continues even after the heart rate stabilizes in the Normal range, another Negative ST Shift & Non-Elevated HR event is generated; however, this time the event is mapped to the alarm type (e.g., Emergency alarm) chosen by the physician.

ST Shift & Elevated HR

The ST Shift and Elevated HR event occurs when the patient's ST shift, either positive or negative, exceeds the patient's defined ST shift threshold at a time when the patient's heart rate is elevated. This event is typically mapped to a See Doctor alert.

ST Shift & Elevated HR Persists

The ST Shift and Elevated HR Persists event is declared when the conditions that give rise to an ST Shift and Elevated HR event continue for a prolonged time period (i.e., 10 minutes by default). This condition indicates that neither the patient's heart rate nor ST shift has normalized. This event is typically mapped to a See Doctor alert.

Data Collection When an Emergency Alarm Occurs

When an event that is mapped to an Emergency alarm is detected, the IMD saves some already-collected data for future retrieval and switches to post-emergency alarm data acquisition mode. In this mode, the IMD temporarily changes the time interval between segment acquisition. The post-emergency alarm data acquisition mode lasts for 6 hours, 24 minutes and comprises two phases:

- The first phase consists of 24 segments, which are collected on one-minute intervals.
- The second phase consists of 24 segments, which are collected on 15-minute intervals.

When the last segment is collected, the IMD automatically reverts to its normal mode of operation. The sole purpose of post-emergency alarm mode is to collect data; event detection is suspended for the duration.

An Emergency alarm collects the following data:

Pre-Alarm Data

- 8 consecutive segments leading up to the event. These segments are collected over an approximate 10 minute time span.
- 16 additional segments that were collected prior to these 8 segments. The 16 segments typically span a time period ranging up to 9 to 27 hours prior to the event. The actual time span will vary and depends on the number of 30-second or 90-second acquisition cycles the IMD performed during that period.
- The current hourly baseline segment. This is the baseline that was collected for the hour in which the event occurred.

Post-Alarm Data

- 48 segments collected during the post-emergency alarm mode – after the event was detected.

Data Collection When a See Doctor Alert Occurs

When an event that is mapped to a See Doctor alert or None is detected, the IMD saves some already-collected data for future retrieval and then continues in its normal mode of operation. The data saved includes:

- The three segments leading up to the event being detected.
- The current hourly baseline segment. This is the baseline that was collected for the hour in which the event occurred.

A See Doctor alert, when it occurs, suppresses the signaling of any subsequent See Doctor alert event for a 24-hour period; although if they occur, they are recorded and will be downloaded at the next data retrieval. This feature gives the patient time to see the physician without being subject to numerous and repeated See Doctor alerts if they occur. Note that a See Doctor alert does not similarly suppress the signaling of a subsequent Emergency alarm.

Histogram Information

During segment characterization, the IMD collects ST deviation histogram information. Detailed histogram information is saved for 14 days. The histogram information for each day is also summarized (number of beats, median value, and some statistical spread information) and stored as ST deviation trending data for up to 192 days. These data can be useful for assessing long-term trending changes.

Using this trending data, the Guardian system provides an additional event called ST Trending, which is used to alert the patient to long-term changes in their ST deviation. This event is generated if the difference between the maximum daily ST deviation median value and minimum daily ST deviation median value exceeds a threshold set by the physician. As with the other events described previously, the physician can establish the alarm type mapping for the ST trending event.

Internal IMD Events

Independent of segment characterization, the IMD provides two additional events that signal internal problems within the IMD itself: watchdog timer and low IMD battery. Both events are hard-mapped to See Doctor alerts and cannot be configured otherwise. A watchdog timer event signals the occurrence of a general malfunction within the IMD. If this event occurs, you should contact *Avertix* for further assistance.

A low IMD battery event is the elective replacement indicator (ERI) that indicates the IMD battery power is low and that the estimated remaining usable battery life is less than 1 month. For further details on battery longevity and device replacement, see the model- specific *Guardian™ Implantable Medical Device (IMD) User's Manual*.

2 Pre-Implant Check

Before implanting the IMD, create a new patient record and test the IMD to ensure that it's in proper working order. If you are replacing an IMD – explanting an existing IMD and implanting a replacement – you still need to perform this same procedure, including the creation of a new patient record.

Procedures

- Create a New Patient Record
- Open the Patient Record
- Establish a Communication Session
- Run Pre-Implant Check
- Implant the IMD

Necessary Equipment & Information

The following equipment and information are required to perform Pre-Implant Check:

- The patient's IMD, sealed in its sterile package
- The Programmer and Wand, interconnected by the Serial cable
- The patient information (i.e., Name, Patient ID, Birth date (optional))

Other Implant-Related Documents

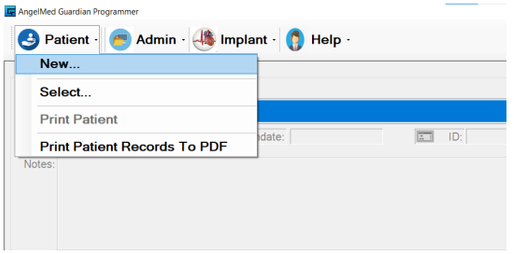
You will need the following additional manuals to complete the IMD implant:

- *Guardian™ Implantable Medical Device (IMD) User's Manual*
- *Instructions for Use* or other documentation supplied with the lead to be implanted with the IMD

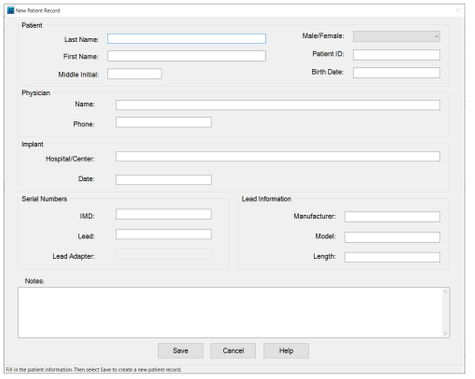
Create a New Patient Record

To create a new patient record:

1. Select *Patient* → *New* from the Main Programmer window.



2. Enter the relevant details in the *New Patient Record* window as defined below.



Patient	
Last Name (required)	Type the patient's last name (up to 30 characters). **Note:** The First/Middle/Last Name combination for any patient must be unique on a given Programmer.
First Name (required)	Type the patient's first name (up to 20 characters).
Middle Initial	Type the patient's middle initial (up to 10 characters).
Male/Female (required)	Select the patient's sex.
Patient ID (required)	Type the patient's ID number (up to 15 characters). The ID number must be unique. **Note:** The Patient ID cannot be changed after it has been entered. If you make a mistake, you must delete the record with the mistake, and create a new patient record. For further details, see *Patient ID Number Must be Changed* on page 103.
Birth Date	Type the patient's birth date (up to 10 characters).
Physician	
Name	Type the doctor's name (up to 50 characters).
Phone	Type the doctor's phone number (up to 20 characters).
Implant	
Hospital/Center	Type the name of the hospital or center where the IMD will be implanted (up to 50 characters).
Date	Type the date that the IMD will be implanted (up to 10 characters).
Serial Numbers	
IMD	The system automatically enters the IMD serial number (up to 15 characters) when you run Pre-Implant Check. We recommend that you do not enter the serial number manually now. **Note:** The IMD serial number cannot be changed after it has been entered. If you enter the serial number manually and make a mistake, you must delete the record with the mistake and create a new patient record. For further details, see *IMD Serial Number Must Be Changed* on page 96.
Lead	Type the serial number of the lead (up to 15 characters).
Lead Adapter	This is a read-only field and is only applicable for patients implanted with the Model AG101 IMD.

Lead Information	
Manufacturer	Type the name of the lead manufacturer (up to 50 characters).
Model	Type the model designation of the lead (up to 20 characters).
Length	Type the length of the lead (up to 20 characters).
Notes	
Notes	Type any additional notes about the patient (up to 4000 characters). You can add patient notes at any time.

3. Verify that the *Patient ID* and *IMD* serial number are correct because they cannot be changed once the record is saved.
4. Select *Save* to add the new record to the Programmer.
5. Continue with the next procedure, *Open the Patient Record*.

> **Caution:**
> To preserve the newly created patient record in the event of a Programmer failure, we recommend you back up the Programmer data to the Programmer flash drive at this time. For further details, see *Backing Up Programmer Data* on page 88.

Open the Patient Record

The Programmer provides two means of opening the patient record:

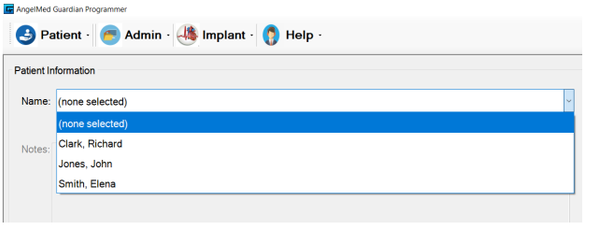
- from the *Name* list
- from the menu bar

From the Name List

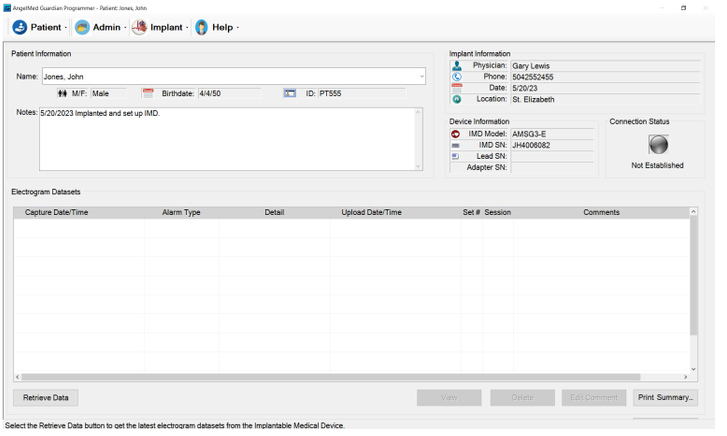
Selecting the patient from the *Name* list offers the most direct way to open a patient record.

To open a patient record from the Name list:

- From the Main Programmer window, select the name of the desired patient from the *Name* field.



In response, the Main Programmer window fills with information relevant to that patient.

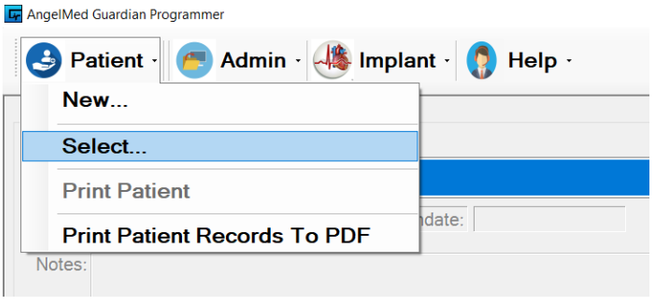


From the Menu Bar

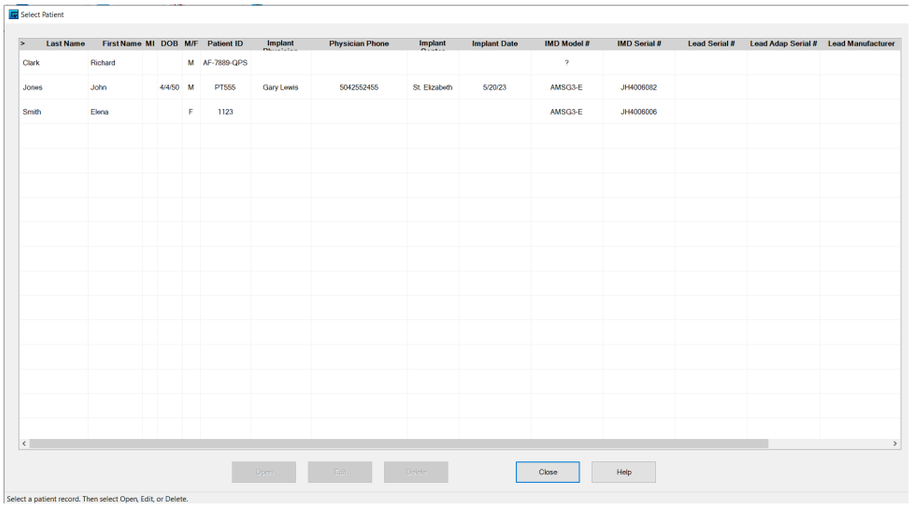
This method of opening a patient record allows you to view other patient details, such as patient ID or physician name, before opening the patient record.

To open a patient record from the menu bar:

1. From the Main Programmer window, select *Patient* → *Select*.



2. From the *Select Patient* window, select the row of the patient whose record you want to open and select *Open*. (You can also touch the patient row twice (i.e., double tap) with the stylus.)



   In response, the Main Programmer window fills with information relevant to that patient. You can sort patients by *Last Name*, *Patient ID*, and *IMD Serial #* by selecting the column header.

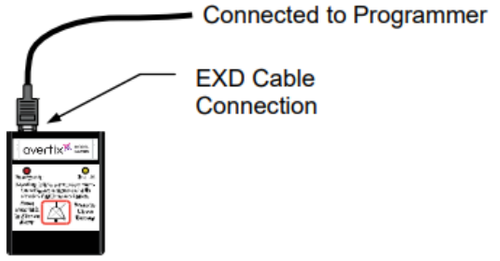
3. Continue with the next procedure, *Establish a Communication Session*.

Establish a Communication Session

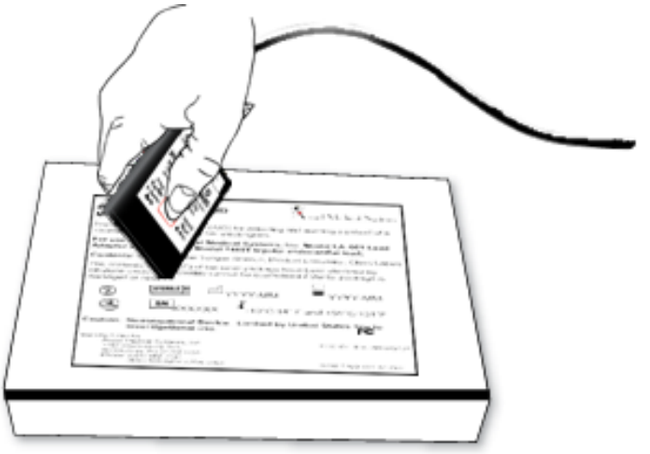
Once the patient record is open, you need to establish a communication session between the Programmer and the IMD. Doing so enables you to check the status of the IMD. Note that since the IMD is still in its sterile package, this procedure is performed through the IMD's outer box.

To establish a communication session with the IMD:

1. Ensure that your Wand is connected to the Serial cable, and the USB end of the Serial cable is connected to the Programmer. (If necessary, consult your Programmer Online Help, Programmer Setup and Operations Guide, or contact your *Avertix* representative for details on connecting the Serial cable to the Programmer.)

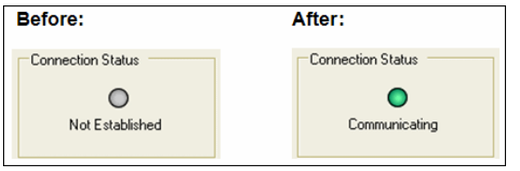


2. Wand within 2in (5cm) of the IMD.
3. Push the Silence Alarm/Check Battery button on the Wand.



Communications with the IMD is confirmed when:

- the Wand beeps twice immediately after pressing the button
- the *Connection Status* indicator in the Main Programmer window changes from *Not Established* to *Communicating*.



If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 102.

Warning:
Do not implant the IMD if you cannot establish a communication session. Obtain another IMD for implantation and return the non-functioning IMD to your *Avertix* representative.

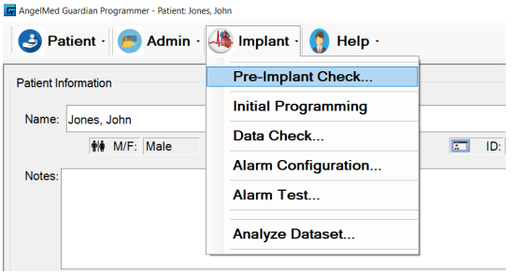
4. Once the communication session starts, you can set the Wand down, but keep it near the IMD in the following manner:
   - For Model AMSG3 and AMSG3-E IMDs, the maximum distance is 6ft (1.8m).
   - For Model AG101 IMDs, the maximum distance is 12in (.3m). The distance is less because the IMD is not connected to the lead adapter, which contains the far- field antenna for this IMD model.
5. Continue with the next procedure, *Run Pre-Implant Check*.

Run Pre-Implant Check

The Programmer's *Pre-Implant Check* window allows you to review the IMD's basic operating status.

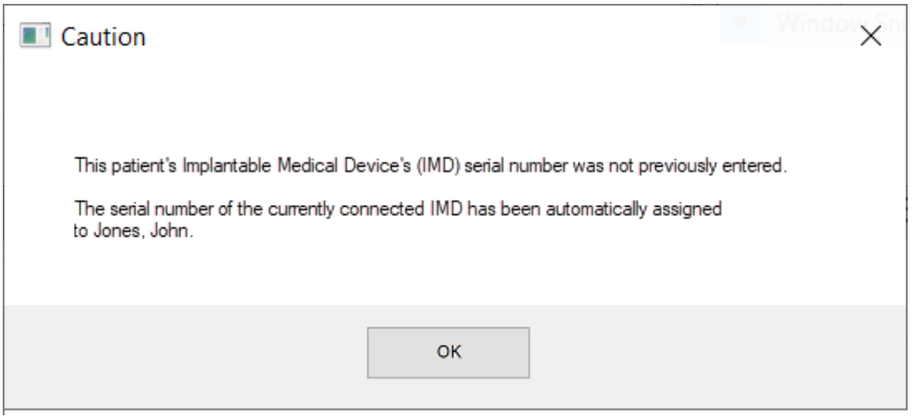
To run Pre-Implant Check:

1. Select *Implant* → *Pre-Implant Check* from the Main Programmer window.

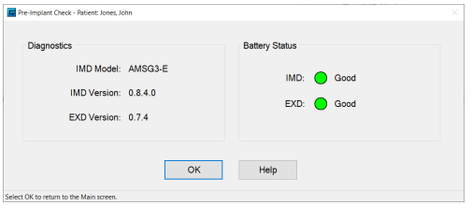


2. The system automatically detects the IMD serial number and adds it to the patient's record (assuming it was not previously entered).

   Select *OK* in the following window to accept the serial number.



3. The Programmer displays the Pre-Implant Check window.



4. Check IMD and EXD Battery Status and use the following table for the appropriate course of action, if any is necessary.

Battery Status	Meaning	
	EXD	IMD
Good (Green)	Battery voltage is within range for normal operation.	Battery voltage is within range for normal operation.
Low (Yellow)	Battery is low. Replace the battery.	Battery is low. Do not implant the IMD.
Replace (Red)	Battery is depleted. Replace the battery.	Battery is depleted. Do not implant the IMD.

Warning:
If the IMD battery status indicator is yellow (*Low*) or red (*Replace*), do not implant the IMD. Obtain another IMD for implantation and return the non-functioning IMD to your *Avertix* representative. Note that you need to create another patient record for the new IMD. For additional details, see *IMD Serial Number Must Be Changed* on page 96.

5. Continue with the next procedure, *Implant the IMD*.

Implant the IMD

At this point, you've successfully:

- Created the New Patient record
- Verified the operation of the IMD

You should now implant the IMD. See the Guardian™ Implantable Medical Device (IMD) User's Manual for IMD implant guidance.

Caution:
Do not suture the surgical pocket closed until you have first verified IMD operation. If the IMD does not function properly and the pocket is closed, you will have to re-open the pocket to determine the cause of failure.

After implanting the IMD, but before closing the surgical incision, you need to verify the IMD senses the cardiac signal as described in *3 Implant Verification* on page 23.

3 Implant Verification

After the IMD has been placed in the pocket, you need to ensure the IMD can sense the cardiac signal and can communicate with the Programmer through the skin. This phase of the process is called Implant Verification.

Procedures

After placing the IMD in the surgical pocket:

- Verify IMD Operation
- Close the Surgical Pocket
- Verify Transdermal Communication

Necessary Equipment & Information

- To complete these tasks, you need access to the Programmer and Wand, connected by the Serial cable. Be sure to use the same Programmer that was used during Pre-Implant Check for the patient.

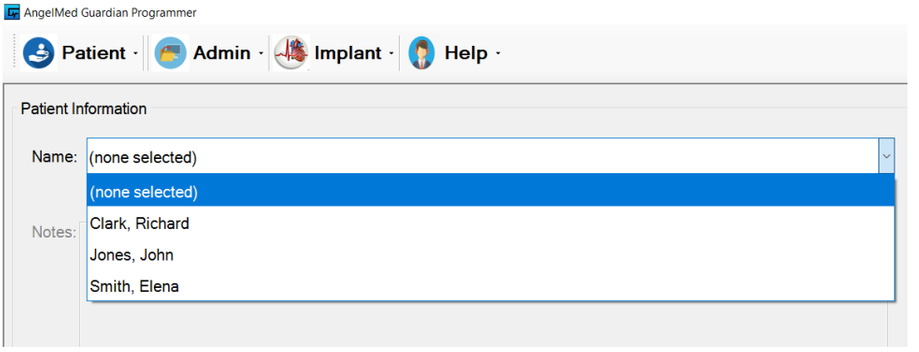
Verify IMD Operation

After implanting the IMD and the IMD has remained undisturbed in the pocket for at least 1 ½ minutes, establish a communication session with the IMD and then retrieve data. You will then quickly review the data to ensure the IMD is sensing the patient's cardiac signal.

To verify the IMD can sense the patient's cardiac signal:

> **Warning:**
> Because the IMD is in the sterile field, you need to place the Wand inside a sterile bag.

1. From the Main Programmer window, open the patient record by selecting the name of the desired patient from the *Name* field.



2. Holding the EXD over the IMD and within 2in (5cm) of the implant site, establish a communication session by pressing the Wand's Silence Alarm/Check Battery button.

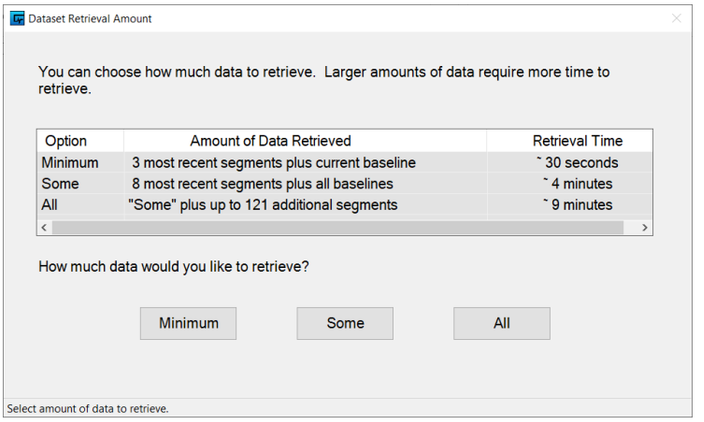
   Communications with the IMD is confirmed when:

   - the Wand beeps twice immediately after pressing the button
   - the *Connection Status* indicator in the Main Programmer window changes from *Not Established* to *Communicating*.

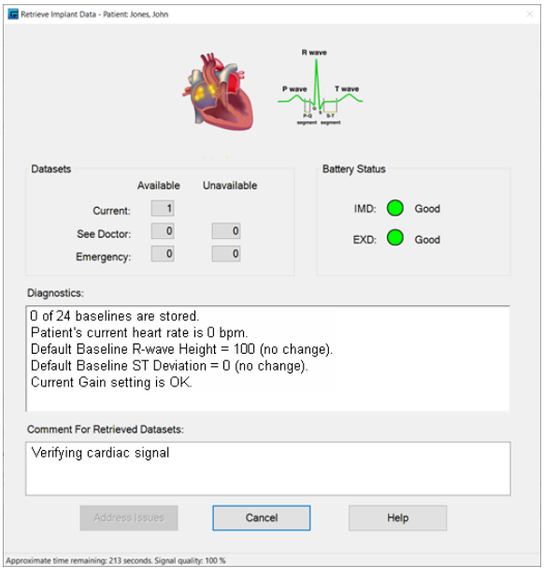
   If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 102*Connection Problems between the Programmer and IMD* on page 102.

3. Once the communication session starts, set the Wand down, but keep it within 6ft (1.8m) of the IMD.
4. Select the *Retrieve Data* button on the Main Programmer window to retrieve data.

5. From the *Dataset Retrieval Amount* window, select *Minimum*.



6. Observe the progress of the data retrieval from the *Retrieve Implant Data* window. The expected remaining time and the telemetry signal quality are displayed at the bottom of the window.

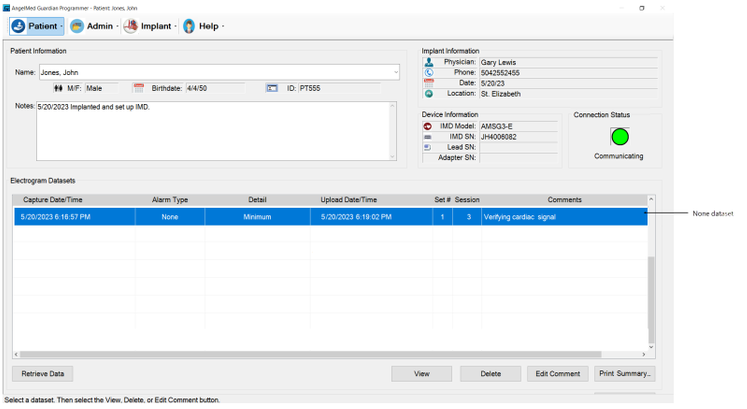


> **Note:**
> After initiating a retrieval, keep the Wand within 6ft (1.8m) of the patient. If telemetry signal quality dips below 95%, as indicated on the bottom of the window, move the Wand closer. If you lose communication, reestablish the session. The data retrieval process will continue where it stopped.

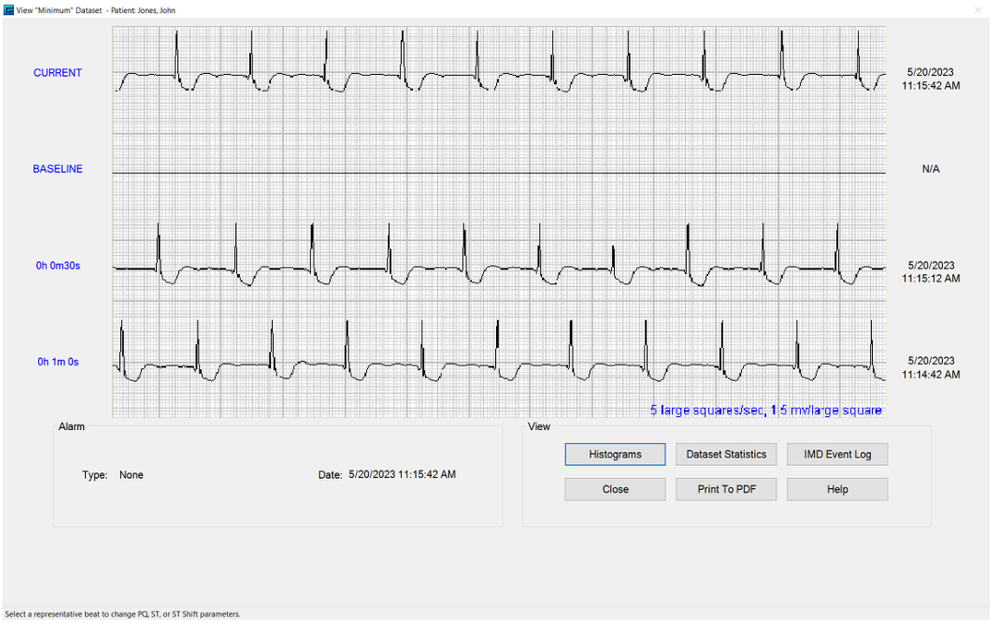
7. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, replace the IMD.
8. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Verifying cardiac signal*".

9. After the data retrieval completes, close the window by selecting the *Close* button. The retrieved data are automatically saved to the Programmer.
10. From the Main Programmer window, locate and select the None dataset, which is displayed in the top row, and then select View to open the dataset. (You can also touch the dataset twice with the stylus.)

> **Note:**
> Depending on how recently you performed Pre-Implant Check relative to this data retrieval, the Programmer may also retrieve one or more See Doctor alerts. If the See Doctor alerts are present, you should ignore them because they contain no patient data.

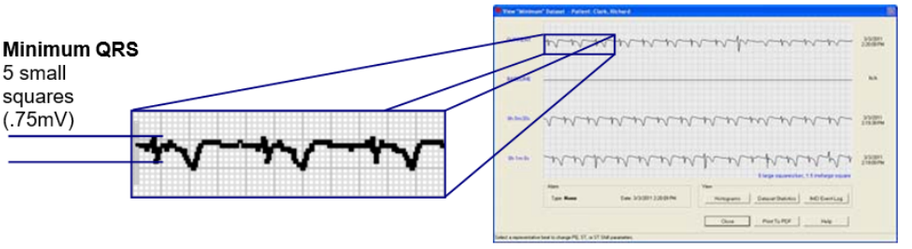


The *View Minimum Dataset* window opens and displays the electrogram segments that were just retrieved from the IMD.



Note:
At this point in the implant process, the cardiac signal will likely be distorted due to injury current. In addition, the baseline segment will likely appear as a flat line. This is expected because up to this time, the IMD was unable to acquire baselines.

11. Look at the most recent segment, which appears along the top of the window, and check for the following:
    a. The segment shows a continuous cardiac signal that has no gaps.
    b. The signal's QRS complex is at least five small squares (0.75mV) in height. An example is shown in the following figure.



12. Do one of the following:
    - If the *View Minimum Dataset* window shows a continuous cardiac signal, with proper minimum amplitude proceed to the next section, Close the Surgical Pocket.
    - If the *View Dataset* window does not show a continuous cardiac signal with adequate amplitude, refer to the following table.

Programmer displays:	Recommended actions
No cardiac signal (i.e., flat line)	• Recheck the lead, lead adapter (if present), and IMD header connections. • Verify the IMD has good contact with the surrounding pocket tissue.
Non-continuous cardiac signal	• Recheck the lead, lead adapter (if present), and IMD header connections. • Verify the IMD has good contact with the surrounding pocket tissue. • Ensure the lead tip is securely fixated, rather than loosely fixated, to the endocardium.
Low-amplitude cardiac signal	• Use PSA testing to verify the fidelity of the lead and lead adapter (if present). • Reposition the lead tip.

Wait at least 30 seconds. Then retrieve and review the segments again by repeating this procedure starting with Step 2.

Note:
If after retrieving data again the Programmer still displays no cardiac signal (i.e., flat line) or if you cannot re-establish a communication session with the IMD, you should exchange the IMD for another one.

Note:
If you need to exchange the IMD for another one, you will also need to delete the existing patient record and create a new record with the new IMD serial number. For further information, see *IMD with a Different Serial Number Must Be Implanted* on page 98.

Close the Surgical Pocket

Once you've established that the IMD is properly sensing the patient's cardiac signal, you can close the surgical pocket. Then continue with the next section, Verify Transdermal Communication.

Warning:
To prevent migration, suture the IMD securely within the pocket, using the two suture holes in the IMD header.

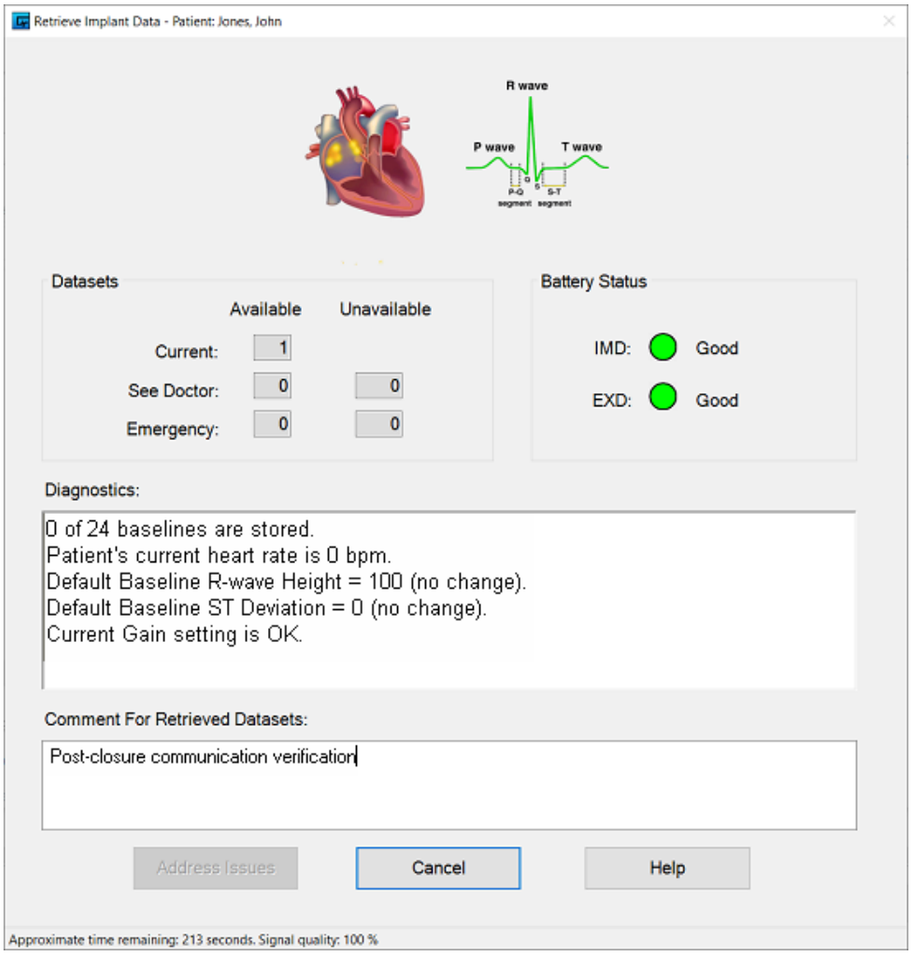
Verify Transdermal Communication

To ensure that you can communicate with the IMD through the skin, establish a final communication session with the IMD and then retrieve data.

To verify communications through the skin:

1. Ensure the patient's record in the Programmer is open.
2. Open a communication session with the IMD.

   If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 102.
3. Once the communication session starts, you can set the Wand down, but keep it within 6ft (1.8m) of the IMD.
4. Select the *Retrieve Data* button on the Main Programmer window to retrieve data.
5. From the *Dataset Retrieval Amount* window, select *Minimum*.
6. Observe the progress of the data retrieval from the *Retrieve Implant Data* window.



7. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, explant and replace the IMD.
8. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Post-closure communication verification*".
9. After the data retrieval completes, select *Close* on the *Retrieve Implant Data* window.

> **Note:**
> Under some circumstances, it is possible for the Retrieve Implant Data window to display some messages about anomalies being detected in the retrieved data. These messages are in red type. If they appear during this phase of Implant Verification, you can ignore them.

The data retrieval process verifies that you can communicate with the IMD through the skin. If you cannot retrieve data, contact your *Avertix* representative.

4 Pre-Discharge Setup

After the IMD is implanted and its operation verified, you need to establish preliminary values for a few of the IMD's operational parameters. This phase is called Pre-Discharge Setup.

Pre-Discharge Setup typically occurs on the day following implantation because you need to provide sufficient recovery time for the patient.

Procedures

- Retrieve IMD Data and Adjust Gain
- Set Heart Rate Bins
- Concluding the Pre-Discharge Setup

Necessary Equipment & Information

- To complete these tasks, you need access to the Programmer. Be sure to use the same Programmer that was used during Pre-Implant Check for the patient.

Retrieve IMD Data and Adjust Gain

In this step, you will:

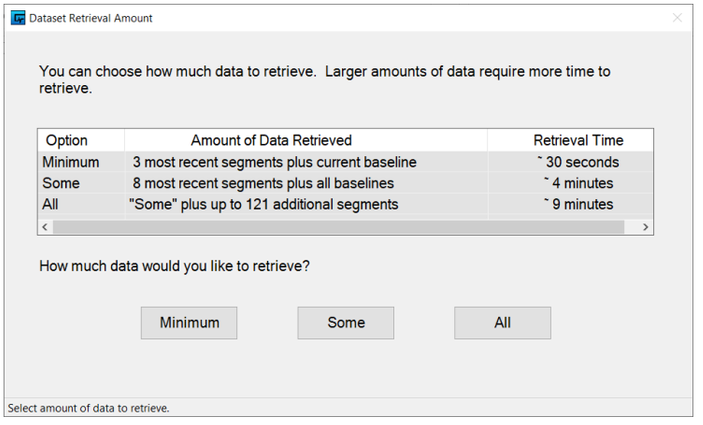
- Retrieve data from the IMD
- Adjust the IMD's amplifier gain if the Programmer indicates that a change is needed

To retrieve IMD data and, if prompted, adjust the gain:

1. Open the patient record from the Main Programmer window.
2. Establish a communication session with the patient's IMD.

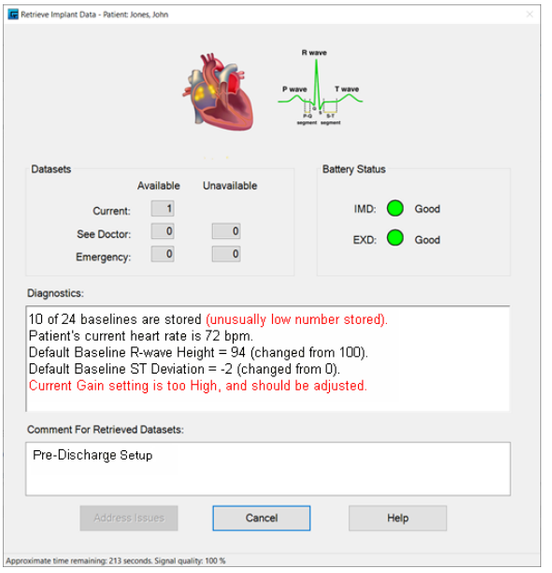
   If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 102.
3. From the Main Programmer window, select the *Retrieve Data* button.
4. From the *Dataset Retrieval Amount* window, select Some to retrieve all the hourly baselines plus the eight most recent segments.

> **Note:**
> Do not select *Minimum* for this data retrieval. A gain change, if one is indicated, deletes all the hourly baselines from the IMD. The *Minimum* data retrieval obtains only one baseline while the *Some* retrieval gets all the hourly baselines. By selecting Some, you will retrieve all the baselines from the IMD, making them available for inspection, if desired, in the event they are deleted by an IMD gain adjustment.



5. Observe the progress of the data retrieval from the *Retrieve Implant Data* window. The expected remaining time and the telemetry signal quality are

displayed at the bottom of the window.



6. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, contact your representative.
7. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Pre-Discharge Setup*".
8. Once the data are retrieved and automatically saved by the Programmer, check the status messages in the *Diagnostics* pane. Expect to see:

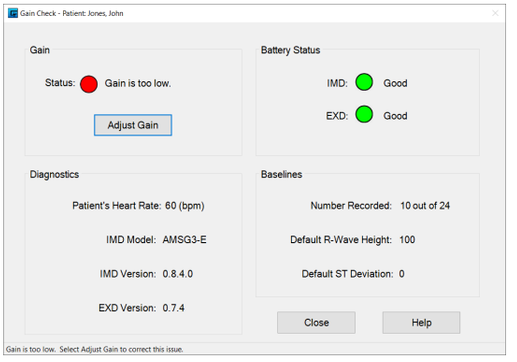
- *Number of baselines stored* – In most cases, Pre-Discharge Setup occurs the day after implantation. Consequently, the Programmer usually reports fewer than 24 recorded baselines and often issues the "*unusually low number stored*" message. Check that the IMD has recorded the number of baselines roughly equal to the number of hours that has transpired since the implant. For example, if the IMD was implanted at 3:30pm yesterday and the current time is 9:20am there should be about 18 baselines recorded. If there are much fewer, contact your representative.
- *Patient's current heart rate* – This should match the patient's actual heart rate. If the detected heart rate is not about the same as that measured by the usual means, see *Heart Rate Does Not Match Patient's Heart Rate* on page 95 to determine the cause of the problem, and then proceed to the next step.
- *Default Baseline R-Wave Height/ST Deviation* – Upon retrieving data, the Programmer sets the R wave height and ST deviation values of the default baseline using the corresponding values of the most recently retrieved segment. For more information on the default baseline and its function, see *Stale and Default Baselines* on page 7.

If the window displays “The segment used to update Default baseline values had unusual characteristics”, do another data retrieval, this time using the Minimum retrieval option. If the window displays the same message again, contact your representative.

- *Current Gain Setting* – During a data retrieval, the Programmer checks the amplitude of the cardiac signal from the lead to determine if the IMD amplifier gain is set appropriately. The window reports the gain as either:
  - *properly set*
  - *too high*
  - *too low*

> **Note:**
> Depending on the circumstances, the *Retrieve Implant Data* window may display several other warning messages, which appear in red type. If they are displayed during Pre-Discharge Setup, do not address them.

9. Do one of the following:
   - If the gain setting is good (*Current gain setting is properly set.*), select either *Defer Issues* or *Close* (whichever is available) and then proceed to *Set Heart Rate Bins* on page 36.
   - If the gain setting requires adjusting (*Current gain setting is too High/Low.*), select *Address Issues* and continue to the next step.
10. From the *Gain Check* window, select the *Adjust Gain* button.



11. Observe the progress bar in the *Evaluating Gain Change* window.
12. When the progress bar completes, re-establish a communication session with the IMD and select *OK*.
13. Again, check the gain status in the *Gain Check* window and do one of the following:

- If the gain setting is good (*Current gain setting is properly set.*), click *Close* and then proceed to *Set Heart Rate Bins* on the next page.
- If the gain setting still requires adjusting (*Current gain setting is too High/Low.*), perform Step 10 in this procedure.

> **Note:**
> Depending on the magnitude of the heart signal, the Programmer may need more than one opportunity to adjust the gain setting.

> **Note:**
> It is possible for the gain setting to be at its limit and still report that the gain is either too high or low. If this condition occurs, the Programmer will display an explanatory message and you should contact *Avertix* for assistance.

14. Continue with the next procedure, *Set Heart Rate Bins*.

Set Heart Rate Bins

There are three main heart rate thresholds (i.e., *Low*, *Normal*, and *High*), which the IMD uses when characterizing a segment.

- *Low* specifies the upper boundary of the Low heart rate bin. Heart rates at and below this rate should be considered low for the patient at rest. An event is triggered if the patient's heart rate falls to or below this rate.
- *Normal* specifies the upper boundary of the Normal heart rate bin. Heart rates at and below this rate, but above the specified Low rate, should be considered normal for the patient at rest. The upper and lower limits of this bin should bracket the normal resting heart rate of the patient.

> **Note:**
> It is important to establish an accurate range for the Normal bin because segments must be classified as normal to be used as baseline segments for ST shift detection.

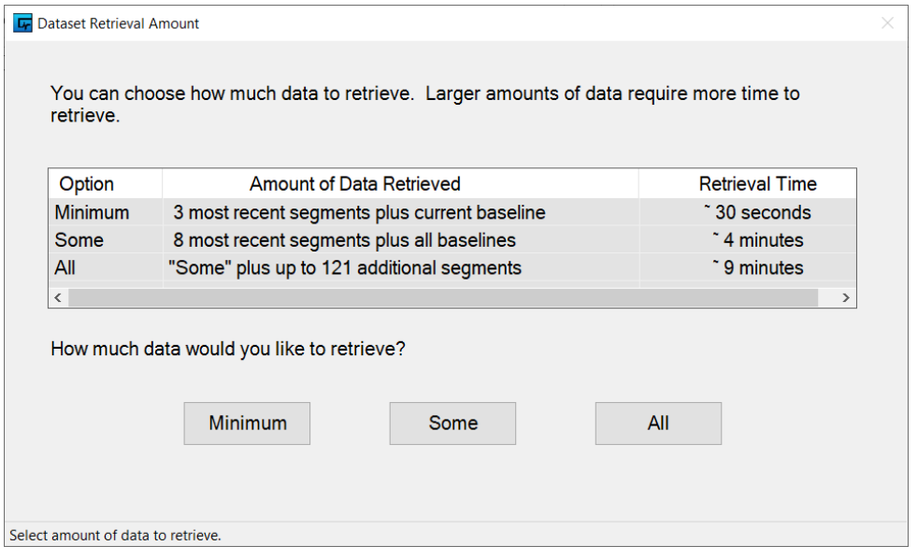
- *High* specifies the heart rate above which the patient should go to an Emergency room because the heart rate is potentially life-threatening. An event is triggered if the patient's heart rate rises above this rate.

The Normal threshold is particularly significant, because only electrograms characterized as Normal can be used as baselines. If you set the normal threshold too high, the distinction of a normal heart rate relative to elevated heart rates loses its significance. Set the threshold too low where it's lower than most of the patient's normal heartbeats, and the IMD may not be able to reliably acquire baselines.

To set the patient's heart rate bins:

1. Do one of the following:
   - If you changed the IMD's gain setting as described in the previous section, proceed to Step 2.
   - If you did not need to change the IMD's gain setting, skip to Step 8.
2. Retrieve data by selecting the *Retrieve Data* button on the Main Programmer window.

3. From the *Dataset Retrieval Amount* window, select *Minimum* for the fastest retrieval.

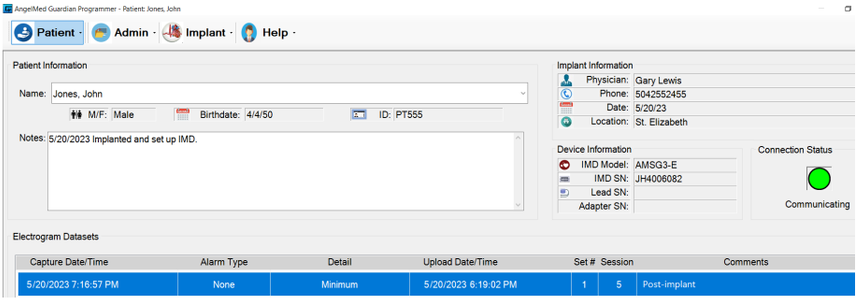


4. Observe the progress of the data retrieval from the *Retrieve Implant Data* window. The expected remaining time and the telemetry signal quality are displayed at the bottom of the window.

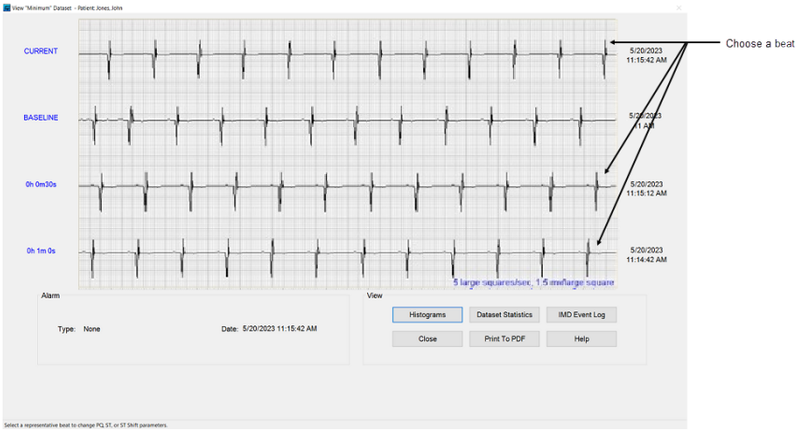
> **Note:**
> After initiating a retrieval, keep the EXD within 6ft (1.8m) of the patient. If the telemetry signal quality dips below 95%, as indicated on the bottom of the window, move the EXD closer. If you lose communication, reestablish the session. The data retrieval process will continue where it stopped.

5. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, contact your *Avertix* representative.
6. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Pre-Discharge Setup*".
7. After the data retrieval completes, close the window by selecting the *Close*, *Defer Issues*, or *Address Issues* button. The retrieved data are automatically saved to the Programmer.

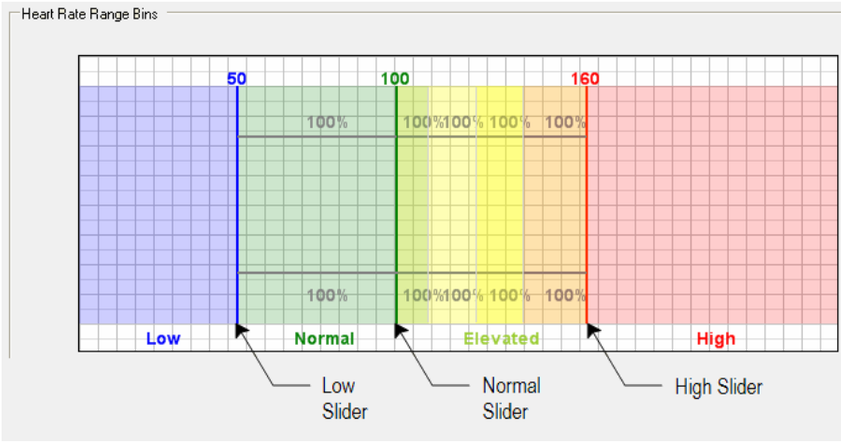
8. From the Main Programmer window, select the None dataset that you just retrieved and then select the View button. (You can also touch the dataset twice with the stylus.)



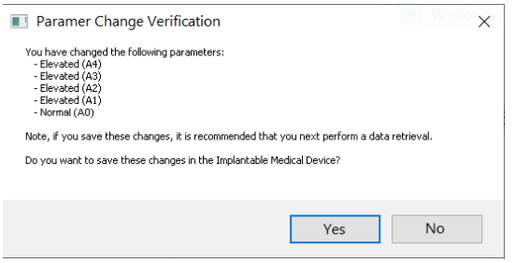
9. The Programmer displays the *View Minimum Dataset* window, showing four electrogram segments. Select any beat from the first, third, or fourth segments by touching one with your stylus.



10. From the *Edit Implant Parameters* window, review the current settings and change them as is appropriate for the patient by moving the sliders left or right.

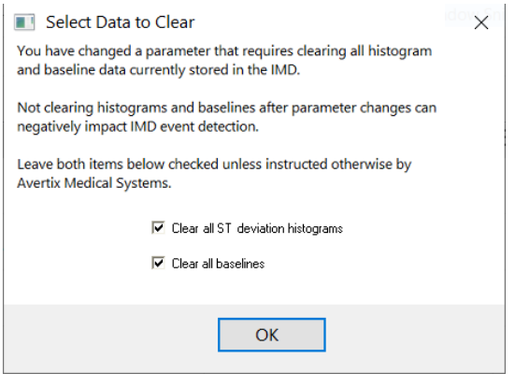


11. Save the new heart rate bin settings by selecting the *Save* button. (If you have elected to keep the original settings, select *Cancel* and then go to Step 17.)
12. The Programmer identifies the parameters that you have changed. Acknowledge these changes by selecting *Yes*.



Note:
Changing either the *Normal* or *High* sliders causes the Programmer to reapportion the boundaries of the internal Elevated bins (A1 – A4), which it then displays in the *Parameter Change Verification* box.

13. The Programmer may display the *Select Data to Clear* window. If it does, leave all items checked and select *OK*.



Note:
Leave all items checked on the *Select Data to Clear* window unless instructed otherwise by an *Avertix* representative.

14. The Programmer saves the heart rate parameter settings to the patient's IMD.
15. Re-establish a communication session with the patient's IMD.
16. Retrieve IMD data again by selecting *Retrieve Data* from the Main Programmer window, using the *Minimum* retrieval option.

> **Note:**
> You should always perform a data retrieval when you change any IMD parameter. Doing so ensures that the Programmer has a dataset that contains the most recent parameter values.

17. Continue with the next procedure, *Concluding the Pre-Discharge Setup*.

Concluding the Pre-Discharge Setup

The Pre-Discharge Setup process has concluded.

- Be sure to complete the *Guardian™ Patient Identification Card* and review its contents with the patient. Tell him or her to keep it close by at all times in a convenient place, such as a wallet.
- Ask the patient to return in 7 to 14 days for Initial Programming.

5 Initial IMD Programming and Patient Training

Initial IMD programming and patient training should be performed 7 to 14 days after implanting the IMD. This will allow enough time for the system to collect the baseline data needed to set the patient's remaining IMD parameters appropriately.

Following are the procedures that need to be completed for Initial Programming and Patient Training.

Procedures

- Retrieve Data from the IMD
- Open the Initial Programming Window
- Train the Patient
- Set the IMD Alarm Configuration
- Set IMD Parameters
- Set ST Segment Trending Parameters

Retrieve Data from the IMD

You need to retrieve the electrogram data that the IMD has collected from the patient. These data allow you to modify various IMD parameters to optimize electrogram characterization and event detection.

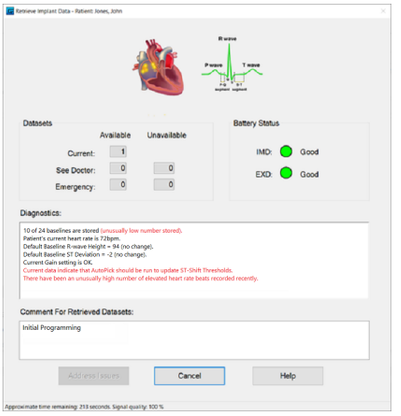
To retrieve data from the IMD:

1. Open the patient's record on the Programmer.
2. Establish a communication session with the patient's IMD.

   If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 102.
3. From the Main Programmer window, select the *Retrieve Data* button.
4. From the *Dataset Retrieval Amount* window, select *Some* to retrieve all the hourly baselines plus the eight most recent segments.

> **Note:**
> Do not select Minimum for this data retrieval. The Minimum data retrieval does not retrieve all the baselines and electrograms necessary for Initial Programming. If you retrieve data using the Minimum retrieval option, perform another retrieval, but use the Some option instead.

5. Observe the progress of the data retrieval from the Retrieve Implant Data window. The expected remaining time and the telemetry signal quality are displayed at the bottom of the window.



6. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, contact your *Avertix* representative.
7. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Initial Programming*".

8. When the retrieval completes, the Programmer automatically saves the data. From the *Retrieve Implant Data* window, select either *Close* or *Defer Issues*, whichever is available.

> **Note:**
> Because the IMD has not yet been fully programmed, it is common for the Programmer to report some data anomalies at this time, which appear in red type in the *Diagnostics* pane in the *Retrieve Implant Data* window. For now, you should ignore any that are reported.

9. Continue with the next procedure, *Open the Initial Programming Window*.

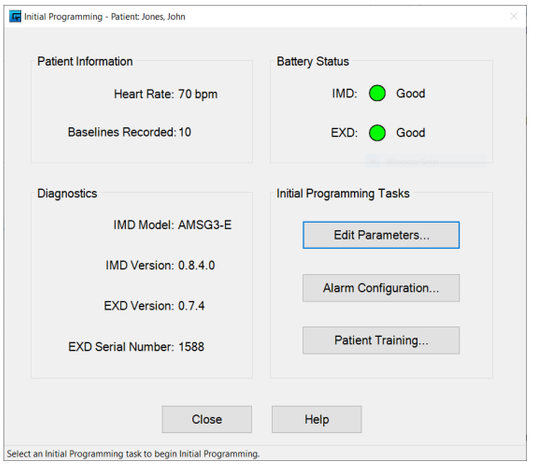
Open the Initial Programming Window

The *Initial Programming* window provides basic diagnostic information on the IMD and patient. It also serves as the launch point for performing the three primary tasks that comprise Initial Programming, specifically:

- Patient training
- Setting alarm configuration
- Setting IMD parameters

You can perform these tasks in any order.

> **Note:**
> The *Initial Programming* window checks that you have performed all three Initial Programming tasks. If you close the window before performing all the tasks, the Programmer displays an advisory message, which allows you to either continue to exit the window or re-enter the window to accomplish the remaining activities.
>
> If you close the window and then open it later to complete the tasks, you will need to visit all the task windows including any whose tasks you previously completed (e.g., *Alarm Configuration*). For those tasks, you can enter the task window and then exit it without making changes.

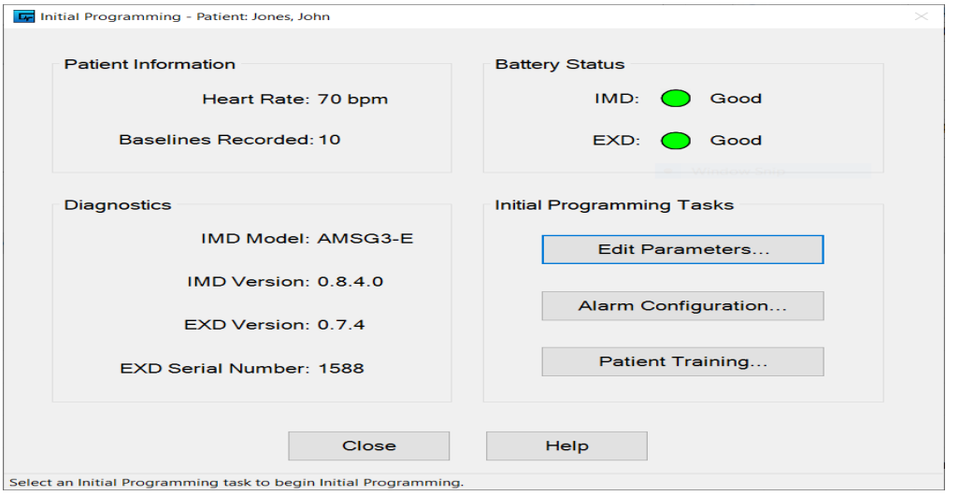


Begin by checking the device and patient status information from the *Initial Programming* window.

- Check Patient Information
- Check IMD and EXD Battery Status

Check Patient Information

1. Ensure that a communication session is established with the patient's IMD.
2. Open the *Initial Programming* window by selecting *Implant* → *Initial Programming* from the Main Programmer window.



> **Note:**
>
> The *Initial Programming* window checks the status of the most recently retrieved None dataset. If the dataset is no longer current, the Programmer displays an advisory message, informing you that you need to retrieve new IMD data. If you get this message, retrieve the data and then re-open the Initial Programming window.

3. From the *Patient Information* area, verify the *Heart Rate* detected by the IMD agrees with the patient's actual heart rate. If the displayed heart rate is incorrect, see *Heart Rate Does Not Match Patient's Heart Rate* on page 95.
4. Check *Baselines Recorded*. The IMD should have recorded 24 hourly baselines. If there are fewer than 24 baselines, the IMD parameter settings may not be appropriate for this patient. Note however, that you will be setting IMD parameters later in the Initial Programming process, which should resolve any baseline acquisition problem.

   (For information on resolving baseline acquisition problems, see *Problems with Collecting Baselines* on page 104.)

Check IMD and EXD Battery Status

1. Verify the status of the EXD and IMD batteries and, if necessary, take the appropriate corrective measure. (EXD battery replacement is described in *Replace the EXD Battery* on page 79.)

Battery Status	Meaning	
	EXD	IMD
Good (Green)	Battery voltage is within range for normal operation.	Battery voltage is within range for normal operation.
Low (Yellow)	Battery is low. Replace the battery.	Battery is low. Do not implant the IMD.
Replace (Red)	Battery is depleted. Replace the battery.	Battery is depleted. Do not implant the IMD.

2. Perform the three main Initial Programming tasks:

- *Train the Patient* on the facing page
- *Set the IMD Alarm Configuration* on page 49
- *Set IMD Parameters* on page 53

You can complete them in any order.

Train the Patient

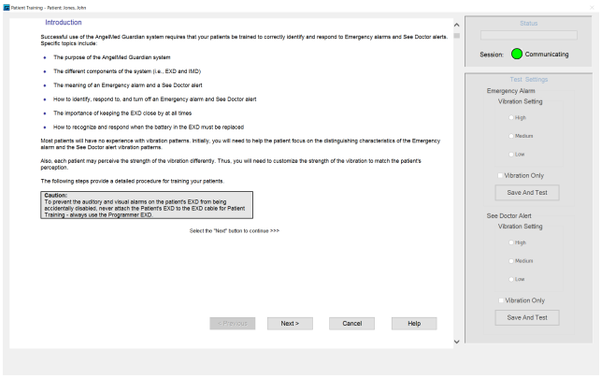
Successful use of the Guardian system requires that the patient be trained to correctly identify and respond to Emergency alarms and See Doctor alerts. Specific training topics include:

- An overview of the Guardian system
- The meaning of Emergency alarms and See Doctor alerts
- Setting the vibration level of Emergency alarms and See Doctor alerts
- How to identify, respond to, and turn off Emergency alarms and See Doctor alerts
- The importance of keeping the EXD close by at all times
- How to recognize and respond when the battery in the EXD must be replaced

Training is conducted using the Patient Training wizard. The wizard provides step-by- step instructions and provides the alarm testing controls that you use to demonstrate the alarms and alerts, and to set their vibration levels.

To start patient training:

1. Display the *Patient Training* window by selecting the *Patient Training* button on the *Initial Programming* window.



Follow the instructions that are displayed in the Patient Training window for each step in the training process. When you finish a step, select the Next button at the bottom of the window to go to the next training step. A copy of the entire training script is also provided in *C Patient Training Script* on page 115.

2. Do one of the following:
   - If you have not completed all three Initial Programming tasks, continue with:
     - *Set the IMD Alarm Configuration* on the facing page or
     - *Set IMD Parameters* on page 53
   - If you have completed all three Initial Programming tasks, select *Done* on the *Initial Programming* window and continue with the next procedure, *Set ST Segment Trending Parameters* on page 63.

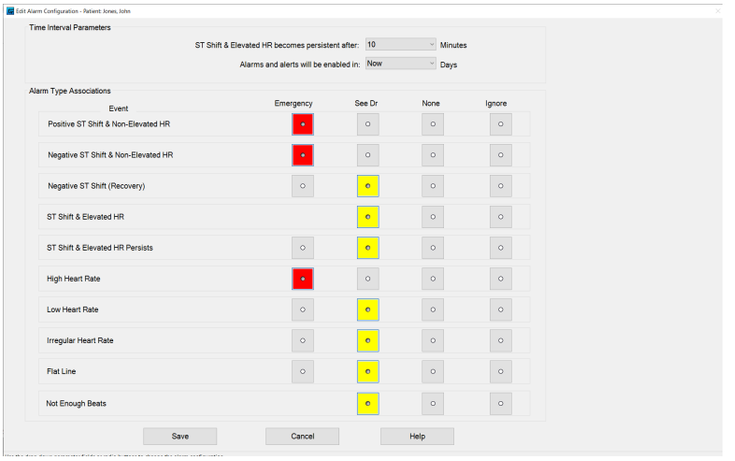
Set the IMD Alarm Configuration

The IMD detects a variety of cardiac-related events. Initially, all events are set to either *None* or *Ignore*. At this time, you should review the detectable events and assign each an appropriate alarm type – generally either Emergency alarm or See Doctor alert.

To set the IMD alarm configuration:

1. Select the *Alarm Configuration* button on the *Initial Programming* window. In response, the Programmer displays the *Edit Alarm Configuration* window.

> **Warning:**
> Be sure to reassign the *Alarm Type Associations*; otherwise, the patient's IMD will never signal an alarm or alert. Initially, all events are assigned to either *None* or *Ignore*, which will not warn the patient of an event. The following figure shows the generally recommended *Alarm Type Associations*.



> **Note:**
> This window is shown with generally recommended Alarm Type settings. Settings may differ for individual patients.

2. Set the *Time Interval Parameters* for this patient.

ST Shift and Elevated heart rate becomes persistent after:	Specifies the number of minutes after which the *ST Shift and Elevated HR* event is considered persistent. You can choose *3*, *5*, *10*, *15*, or *20* minutes. The default setting is *10* minutes.
Alarms and alerts will be enabled in:	During Initial Programming, this field is programmatically set to *Now* so that alarms and alerts are enabled when the alarm configuration changes have been saved.

3. In the *Alarm Type Associations* area, do the following:
   a. Review the various events the IMD is capable of triggering. The events are:

Positive ST Shift & Non-Elevated HR	Indicates three consecutive shifted and/or high heart rate segments where the last segment has a positive ST shift and low, normal, or irregular heart rate. The recommended setting for this event is *Emergency*.
Negative ST Shift & Non-Elevated HR	Indicates three consecutive shifted and/or high heart rate segments where the last segment has a negative ST shift and low, normal, or irregular heart rate. The recommended setting for this event is *Emergency*.
Negative ST Shift (Recovery)	Indicates a Negative ST Shift & Non-Elevated HR event has occurred during a period of time in which the patient's heart rate has decreased significantly. For further details, see *Negative ST Shift (Recovery)* on page 9.
ST Shift & Elevated HR	Indicates three consecutive shifted and/or high heart rate segments where the last segment has an ST shift (i.e., positive or negative) and an elevated heart rate. This event may be indicative of an exercise-induced ischemia. The recommended setting for this event is *See Dr*. In addition, *Emergency* cannot be selected for this event.
ST Shift & Elevated HR Persists	Indicates "n" continuous minutes of an *ST Shift & Elevated HR* event. By default, "n" is 10 minutes, but can be changed using the *ST Shift and Elevated heart rate becomes persistent after* parameter, which is also available in this window. The recommended setting for this event is *See Dr*.
High Heart Rate	Indicates three consecutive shifted and/or high heart rate segments where the last segment has a heart rate at or above the Elevated (A4) threshold. The recommended setting for this event is *Emergency*.
Low Heart Rate	Indicates three consecutive non-ST shifted segments where the heart rate is at or below the Low (LO) threshold. The recommended setting for this event is *See Dr*.
Irregular Heart Rate	Indicates 20 consecutive non-ST shifted irregular heart rate segments. The recommended setting for this event is *See Dr*.

Flat Line	Indicates 12 consecutive segments where the IMD could not detect enough beats for analysis. (When it occurs, this event succeeds two *Not Enough Beats* events. The *Not Enough Beats* event is then set to the Ignore *Alarm Type* to prevent recurrence.) The recommended setting for this event is *See Dr*.
Not Enough Beats	Indicates four consecutive segments where the IMD did not detect enough beats for analysis. If the *Not Enough Beats* event occurs three times over consecutive segments, the IMD declares a *Flat Line* event instead. The recommended setting for this event is *See Dr*.
Cannot Get Baseline	Indicates the IMD could not establish a new baseline segment for either 6, 12, or 24 consecutive hours, with the number of hours determined by a Programmer option set by your *Avertix* representative. The recommended setting for this event is *See Dr*.
ST Deviation Trending	Generated if the difference between the maximum daily median ST deviation value and minimum daily median ST deviation exceeds the threshold set by the physician. The recommended setting for this event is *See Dr*.

b. Review the various events the IMD is capable of triggering. The events are:

Emergency	Triggers an Emergency alarm when the assigned event is detected. Upon detection, the IMD saves the 24 electrogram segments leading to the Emergency alarm, the 48 segments recorded after the alarm, and the baseline segments against which they were compared.
See Doctor	Triggers a See Doctor alert when the assigned event is detected. For most See Doctor alerts, the IMD saves the three electrogram segments leading to the alert and the baseline segment against which the last segment was compared. The IMD does not save electrogram segments for See Doctor alerts triggered by *Cannot Get Baseline* and *ST Deviation Trending* events.
None	Triggers no alarm/alert but records the event as a See Doctor alert and saves the data accordingly. Use this option to save data for events you wish to be aware of, but that don't require the patient to contact you.
Ignore	Triggers no alarm/alert and does not record the event or any electrograms.

4. When you have reviewed the options and made your changes in the *Edit Alarm Configuration* window, select *Save*.
5. Select *Yes* when the Programmer prompts you to confirm your changes and return you to the *Initial Programming* window.

6. Do one of the following:
   - If you have not completed all three Initial Programming tasks, continue with:
     - *Train the Patient* on page 47 or
     - *Set IMD Parameters* on the facing page
   - If you have completed all three Initial Programming tasks, select *Done* on the *Initial Programming* window and continue with the next procedure, *Set ST Segment Trending Parameters* on page 63.

Set IMD Parameters

To set the patient's IMD parameters, conduct the following procedures, which are explained in the rest of this chapter:

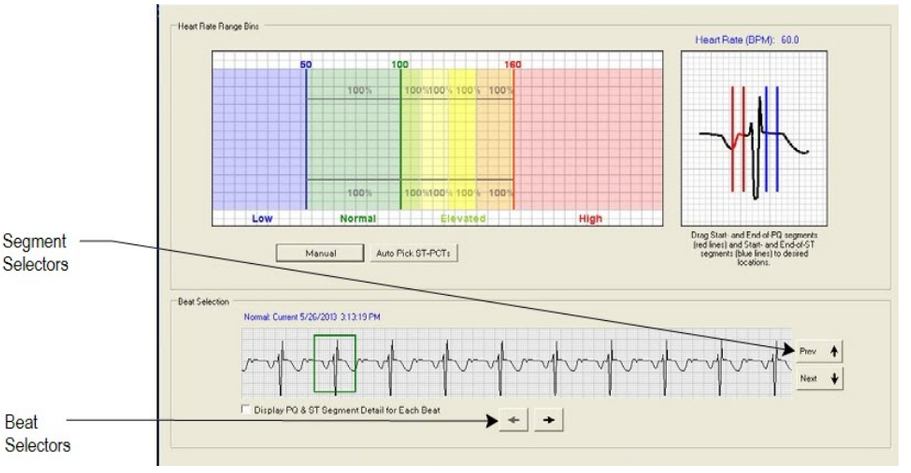
- Open the *Edit Implant Parameters* window
- Review and set the heart rate ranges
- Review the PQ and ST start and duration boundaries
- Set the ST shift thresholds

Open the Edit Implant Parameters window

The *Edit Implant Parameters* window is the main window from which you will review and change the main IMD parameters. Note that when setting the ST Shift thresholds and PQ/ST segment boundaries, you can use only heartbeats from the eight most recent segments of a None (i.e., no *Emergency* alarm or *See Dr* alert) dataset. In addition, the segment containing the beat(s) must be characterized as Normal heart rate and not shifted.

To open the Edit Implant Parameters window:

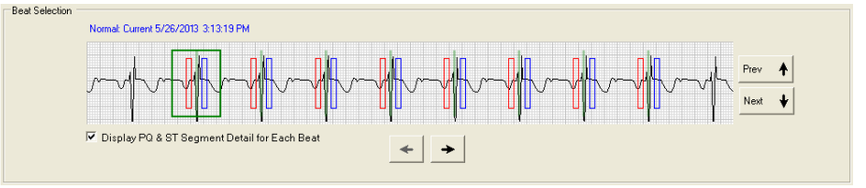
1. From the *Initial Programming* window, select the *Edit Parameters* button.
2. The Programmer displays the *Edit Implant Parameters* window, with the first heartbeat of the most recently retrieved electrogram highlighted by a green box in the *Beat Selection* area on the bottom of the window.



Use the Segment Selectors and Beat Selectors to view other segments and beats within the dataset.

> **Note:**
> Some segments consist entirely of high heart rate beats, which are unsuited for setting IMD parameters. If the highlighted beat belongs to such a segment,

Note:
the Programmer displays an explanatory message. In this case, you should perform another data retrieval and again attempt to set IMD parameters. If you subsequently receive the same message, you should select a beat from a different segment.



To display beat characteristics, check *Display PQ & ST Segment Detail for Each Beat*.

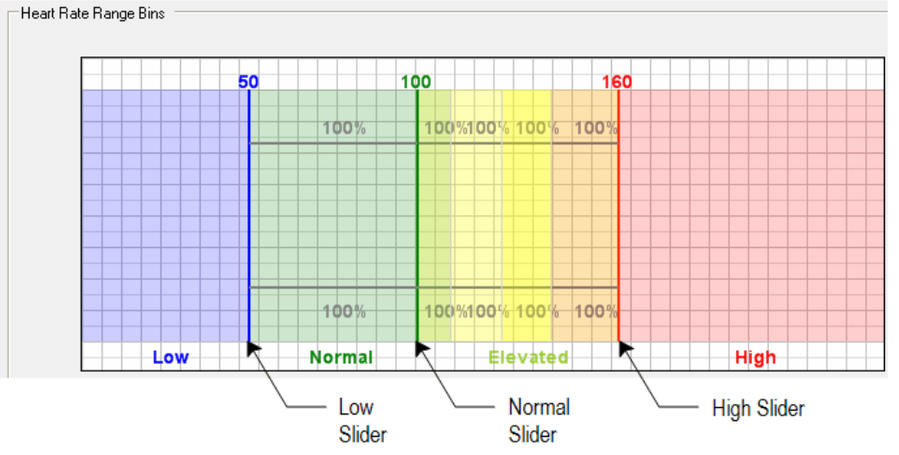
In response, the Programmer reveals additional heartbeat details:

- Green lines identify the R waves detected by the Programmer
- Red boxes indicate PQ segment boundaries
- Blue boxes indicate ST segment boundaries
- A purple box, if present, identifies an invalid beat - a beat that was not analyzed for ST shift characterization

  Note that the Programmer omits the beat details from the first and last beats because their sample data may not be complete.

Set Heart Rate Boundaries

Heart rate bins are an essential part of the detection algorithm. Each bin can have specific settings associated with it to indicate where the IMD will measure PQ and ST segments. This, in turn, is what enables the IMD to detect ST shifts in those segments. (For more information, see *Detection Algorithm Basics* on page 4.)



This area provides three sliders that allow you to change the following bins:

- *Low* specifies the upper boundary of the Low heart rate bin. Heart rates at and below this rate should be considered low for the patient at rest. An event is triggered if the patient's heart rate falls to or below this rate. If such an event occurs, the IMD automatically lowers the LO by the specified *Low HR decrement* value, which is available on the manual version of the *Edit Implant Parameters* window.
- *Normal* specifies the upper boundary of the Normal heart rate bin. Heart rates at and below this rate, but above the specified Low rate, should be considered normal for the patient at rest. The upper and lower limits of this bin should bracket the normal resting heart rate of the patient.

> **Caution:**
> It is important to establish an accurate range for the *Normal* bin because segments must be classified as normal to be used as baseline segments for ST shift detection.

- *High* specifies the heart rate above which the patient should go to an Emergency room because the heart rate is potentially life-threatening. An event is triggered if the patient's heart rate rises above this rate.

To change the heart rate bin values:

1. Determine which bin(s) you wish to change (i.e., *Low*, *Normal*, or *High*).

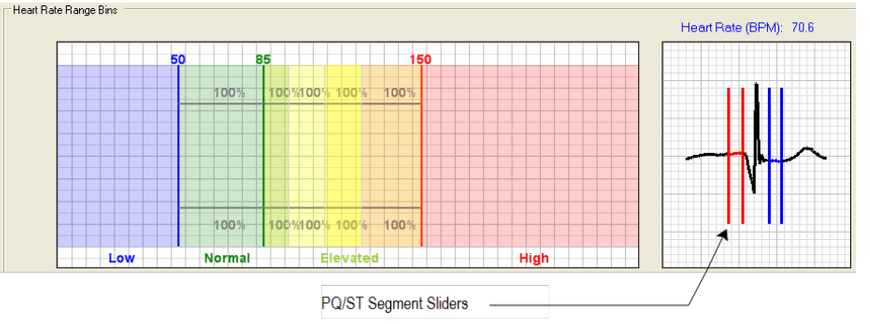
2. Drag the appropriate slider(s) to the desired value(s).

Review PQ and ST Start and Duration

The PQ and ST segment start and duration parameters are the means by which the IMD determines the temporal boundaries of the PQ and ST segments. These parameters help the IMD to characterize the ST shift of a heartbeat. For more information about PQ and ST segment start and duration parameters, see *Detection Algorithm Basics* on page 4.

The default values for these parameters are generally appropriate for most patients; however, you should perform a visual inspection of the boundaries to verify that no adjustment is needed.

You can review the PQ and ST segment boundaries from the *Edit Implant Parameters* window, as shown in the next figure. The red and blue vertical lines mark the boundaries of the current PQ and ST segments.

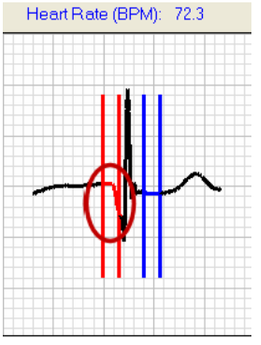


To review the PQ and ST segment boundaries:

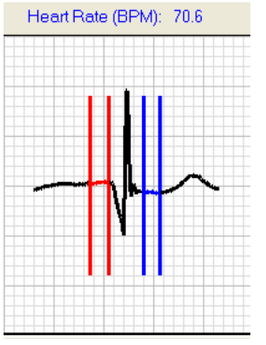
1. Visually inspect the selected heartbeat and verify the following:
   - The PQ segment ends before the beginning of the QRS complex.
   - The ST segment starts after the QRS complex and ends before the T wave.

   The following figures provide examples of PQ and ST segment boundaries that required adjustment.

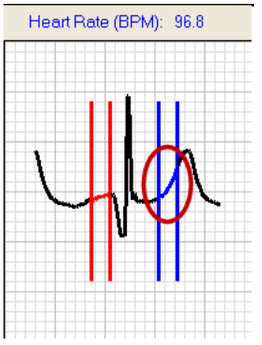
PQ Segment Needs Adjustment - The end of the PQ intrudes on the QRS complex.



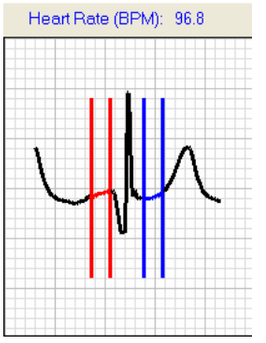
Corrected PQ Segment



ST Segment Needs Adjustment -Most of this ST segment overlaps the T wave.



Corrected ST Segment



2. Assess the PQ and ST segment boundaries against other beats in the dataset by using the Segment and Beat Selectors.
3. If you think any of the boundaries need adjustment, contact your *Avertix* representative.

> **Caution:**
> Do not adjust the PQ and ST segment boundaries without first contacting *Avertix* because changing them incorrectly can affect ST Shift characterization and detection.

Set ST Shift Thresholds

Two ST shift thresholds, positive and negative, mark the boundaries beyond which a sampled heartbeat is considered ST shifted. Three consecutive segments with enough beats that exceed either ST shift threshold, trigger an ST shift-related event. For more information about ST shift detection, see *Detection Algorithm Basics* on page 4.

You set ST shift thresholds using AutoPick, a Programmer feature that analyzes previously collected patient histogram data and then sets the thresholds to recommended values. Note that each heart rate bin has its own positive and negative thresholds.

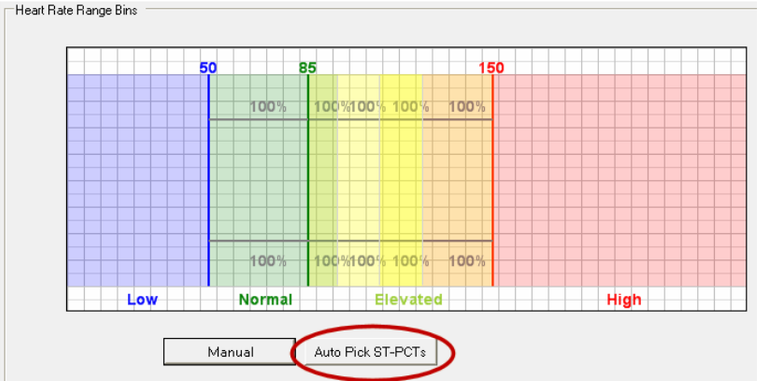
> **Caution:**
> You can also set the ST Shift thresholds manually from the manual version of the *Edit Implant Parameters* window. Do not use the manual method unless advised to do so by *Avertix* as this will affect ST Shift characterization and detection.

AutoPick Requirements

AutoPick's statistical analysis requires that the IMD sample at least two days of heartbeat (i.e., 14-day histogram) data. Ordinarily, this requirement is easily met since Initial Programming occurs roughly one to two weeks after implantation. If, however, the PQ and ST segment boundaries or the heart rate bin thresholds were recently changed, the histogram data would have been deleted at that time. If AutoPick cannot produce a result, it advises you with a message.

To set the ST shift thresholds using AutoPick:

1. Select the *AutoPick ST-PCTs* button on the *Edit Implant Parameters* window.



2. From the *Select AutoPick Days* dialog box, select the days upon which you want AutoPick to base its ST shift analysis and then select OK.

The Select AutoPick Days dialog box allows you to select any combination of days ranging back to 14 days ago. Days for which there are no valid beats for AutoPick to use are unavailable and cannot be selected.

By default, all available days are selected. Generally, you should keep this selection, except for any day where the heart rhythm may be significantly abnormal.
Consequently, you should deselect:

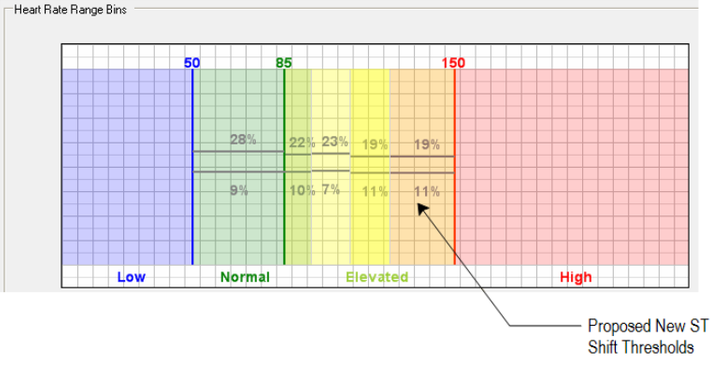
- The date of implantation Any date where the patient had an ST Shift event Any date where the patient underwent a heart bypass or stenting procedure
- If you deselect too many days (i.e., such that AutoPick does not have a sufficient number of valid beats with which to complete its analysis), the Programmer displays an explanatory message and gives you an opportunity to either cancel AutoPick or select additional days from the *Select AutoPick Days* dialog box.

Note:
To calculate the most appropriate ST Shift settings, AutoPick needs to analyze a sample of heartbeats that are typical for the patient. This is why we recommend omitting any days in which the patient's electrogram is likely to be atypical.

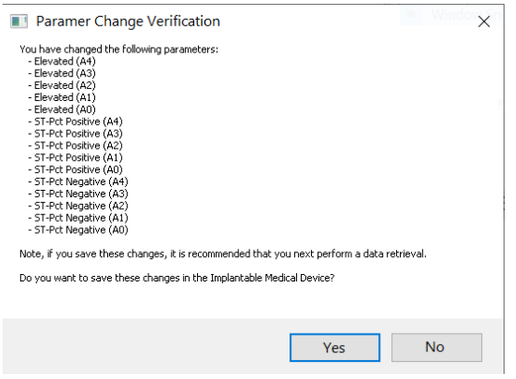
- If you deselect too many days (i.e., such that AutoPick does not have a sufficient number of valid beats with which to complete its analysis), the Programmer displays an explanatory message and gives you an opportunity to either cancel AutoPick or select additional days from the *Select AutoPick Days* dialog box.
- If you have selected all the available days and there are still an insufficient number of valid beats, AutoPick displays a message, explaining that AutoPick cannot be run at this time.

3. Do one of the following:

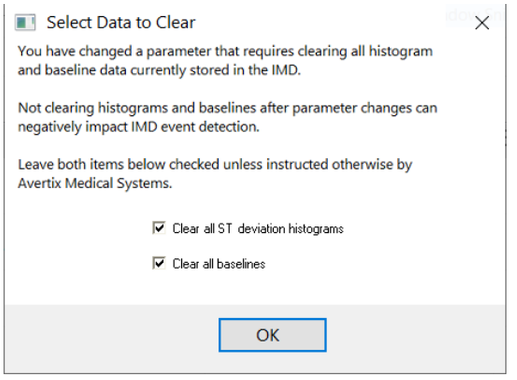
- If you cannot run AutoPick at this time, do not attempt to set the ST shift thresholds now. Instead, save any other changes that you have made by selecting *Save* and then see the patient in three or more days' time. When the patient returns, use AutoPick to set the ST shift thresholds. Note that you can perform the *Set ST Segment Trending Parameters* on page 63 now if you wish.
- If there are enough data for AutoPick to calculate the ST shift thresholds, the Programmer displays the new ST shift threshold values on the *Edit Implant Parameters* window. Proceed to the next step.



4. Save the IMD parameter settings by selecting *Save* on the *Edit Implant Parameters* window.
5. Select *Yes* on the *Parameter Change Verification* window, which identifies the parameters that you have changed since opening the *Edit Implant Parameters* window.



6. The Programmer may display the *Select Data to Clear* window. If it does, leave all items checked and select *OK*.



> **Note:**
> Leave all items checked on the *Select Data to Clear* window unless instructed otherwise by an *Avertix* representative.

The Programmer saves all IMD parameter changes to the patient's IMD.

7. Do one of the following:

- If you have not completed all three Initial Programming tasks, continue with:
  - *Train the Patient* on page 47 or
  - *Set the IMD Alarm Configuration* on page 49
- If you have completed all three Initial Programming tasks, select Done on the Initial Programming window and continue with the next procedure, *Set ST Segment Trending Parameters* on the facing page.

Set ST Segment Trending Parameters

Two ST Trending parameters, Check Hour and Ignore Data, govern when and how an ST Trending event is evaluated. This trending event is discussed in *Histogram Information* on page 11.

Check Hour Parameter

The *Check Hour* parameter specifies the daily time that the IMD checks its historical histogram data to determine whether a trending event has occurred. If an event did occur, the IMD signals the patient with the associated alarm or alert. The default *Check Hour* time is 9:00 am; however, you can set it to other times as well. The goal here is to select an hour when the patient is most likely to be awake.

Note that the IMD's current time (i.e., its internal clock) is set automatically to match the Programmer's current time-of-day. Because the IMD does not sense its own locality, you may want to inform your patient that if they travel frequently to other time zones and an event occurs, it will occur at the specified time relative to the time zone in which it was programmed.

Also, the IMD does not adjust its time-of-day between Daylight Savings time and Standard time. Therefore, you should choose an hour in the local Standard time when the patient will be awake even in Daylight Savings time.

> **Note:**
> The Programmer time-of-day clock is always set to the standard time of the time zone in which it is located. It does not adjust for Daylight Savings time.

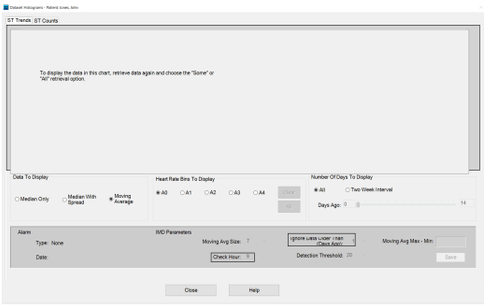
Ignore Data Parameter

The *Ignore Data* parameter establishes a starting calendar date for the period of time over which ST deviation trending analysis is evaluated up to the present time. Valid values range from *1* to *192* days. Therefore, a value of 10 would cause the IMD to evaluate the trending data starting from the calendar date that occurred 10 days ago. When setting this parameter during Initial Programming, you should set this parameter to 1 to exclude all ST deviation trending analysis prior to yesterday.

To set the ST Trending parameters:

1. Ensure that a communications session with the IMD is established.
2. From the Main Programmer window, select *Retrieve Data* using the *Minimum* retrieval option.
3. From the Main Programmer window, select the recently retrieved *None* dataset and select *View*.
4. From the *View Dataset* window, select the *Histograms* button.

5. From the Dataset Histograms window, select the ST Trends tab.



6. In the *Check Hour* field select an appropriate time of day; a time when the patient is most likely to be awake. Be sure to get proper input from the patient. Available times are: 12:00 (midnight), 3:00am, 6:00am, 9:00am, 12:00 (noon), 3:00pm, 6:00pm, and 9:00pm. All times are in the local standard time in which the Programmer is located. The values in this field represent an offset, in hours, from midnight.
7. Set the *Ignore Data Older Than (Days Ago)* field to *1* (1 day).
8. Select the *Save* button to save your values and then select *Yes* when prompted for confirmation.
9. Close the window by selecting the *Close* button.
10. Retrieve IMD data again using the *Minimum* retrieval option.

> **Note:**
> You should always perform a data retrieval when you change any IMD parameter. Doing so ensures that the Programmer has a dataset that contains the most recent parameter values.

6 Follow-Up Visits

This chapter describes the procedures to follow when patients come in for routine follow- up visits or in response to an Emergency alarm or See Doctor alert.

Procedures

Retrieve Data and Check IMD Battery Status

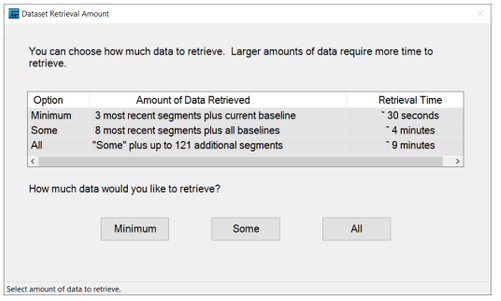
To check IMD battery status and evaluate the data that the IMD has collected, you must first retrieve the data from the IMD.

To retrieve data from the IMD:

1. Open the patient record on the Programmer.
2. Establish a communication session with the patient's IMD.

   If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 102
3. Select the *Retrieve Data* button on the Main Programmer window.
4. Do one of the following:
   - **Normal Data Acquisition Mode**

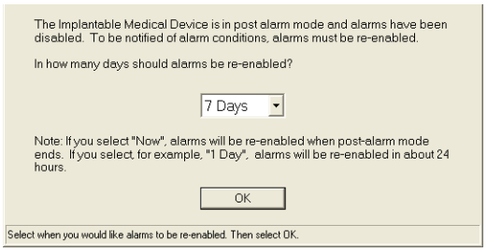
     If the IMD is in normal data acquisition mode, the Programmer displays the *Dataset Retrieval Amount* window.



     Select the *Some* option to begin a data retrieval.

> **Note:**
> We recommend using the Some retrieval option for the first retrieval of any office visit because it retrieves the full complement of IMD data (i.e., electrograms plus all IMD parameter values, histograms, and baselines) in the shortest retrieval time. The Minimum option does not retrieve all baselines nor does it retrieve the trending histogram data. Alternatively, you can use the All option; however, that retrieval option takes a considerably longer time to complete.

- **Post Emergency Alarm Data Acquisition Mode**



If the IMD is in post Emergency alarm data acquisition mode, the Programmer displays the Alarm Enable window.

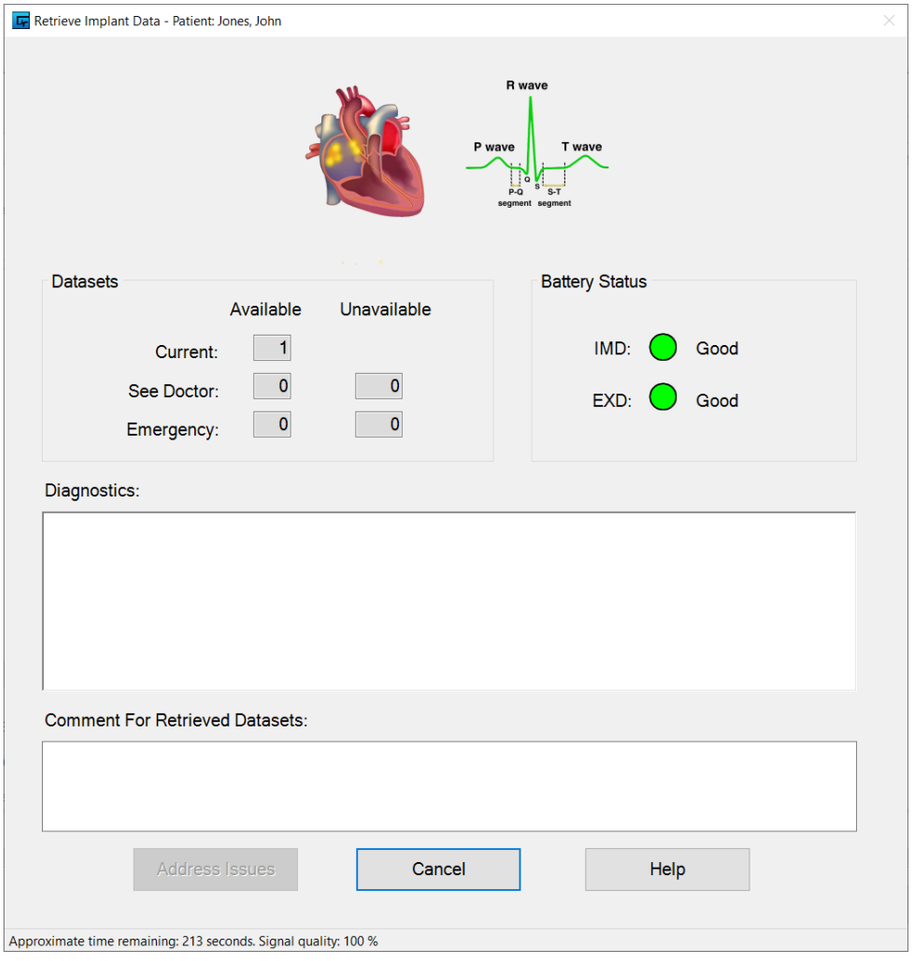
This window allows you to specify the time at which IMD alarming and alerting are re-enabled. Alarming and alerting are automatically disabled while the IMD is in post-Emergency alarm data acquisition mode.

> **Warning:**
> Setting a delay value disables alarming and alerting for the specified time period. Although the IMD still monitors and analyzes the cardiac signal, the IMD will not inform the patient of an event while alarms are disabled.

Select the time at which you want to re-enable IMD alarming and alerting and select *OK*.

- If you choose *Now*, alarms and alerts are re-enabled as soon as normal data acquisition resumes.
- If you choose *1-7 Days*, alarms and alerts are re-enabled in the number of days from when normal data acquisition resumes.

5. The Programmer displays the *Retrieve Implant Data* window, which provides *Datasets* and *Battery Status* information. A message bar on the bottom of the window tells you approximately how much time remains for the retrieval process and the strength of the telemetry signal.



The *Datasets* portion displays the number of datasets that are *Available* for retrieval and the number of datasets that have been discarded (i.e., *Unavailable*) for the following dataset types.

- *Current*: When the IMD is in normal data acquisition mode, this field shows a 1, indicating that one current dataset is being retrieved and that the dataset is a None (i.e., No alarm) dataset.
- *See Doctor*: The IMD can store up to six See Doctor alert datasets. The number in the *Available* box indicates how many, *0* to *6*, are being retrieved. If more than six See Doctor alerts occurred since the last time you retrieved data, only the six most recent datasets are saved by the IMD. Any See Doctor alerts that occurred prior to the most recent six are discarded; however, their number is noted in the *Unavailable* box.
- *Emergency*: The IMD can store up to two Emergency alarms. The number in the *Available* box indicates how many, 0 to 2, are being retrieved. If more than two Emergency alarms occurred since the last time you retrieved data, only the oldest and the most recent are saved by the IMD. Any segments associated with Emergency alarms that occurred between

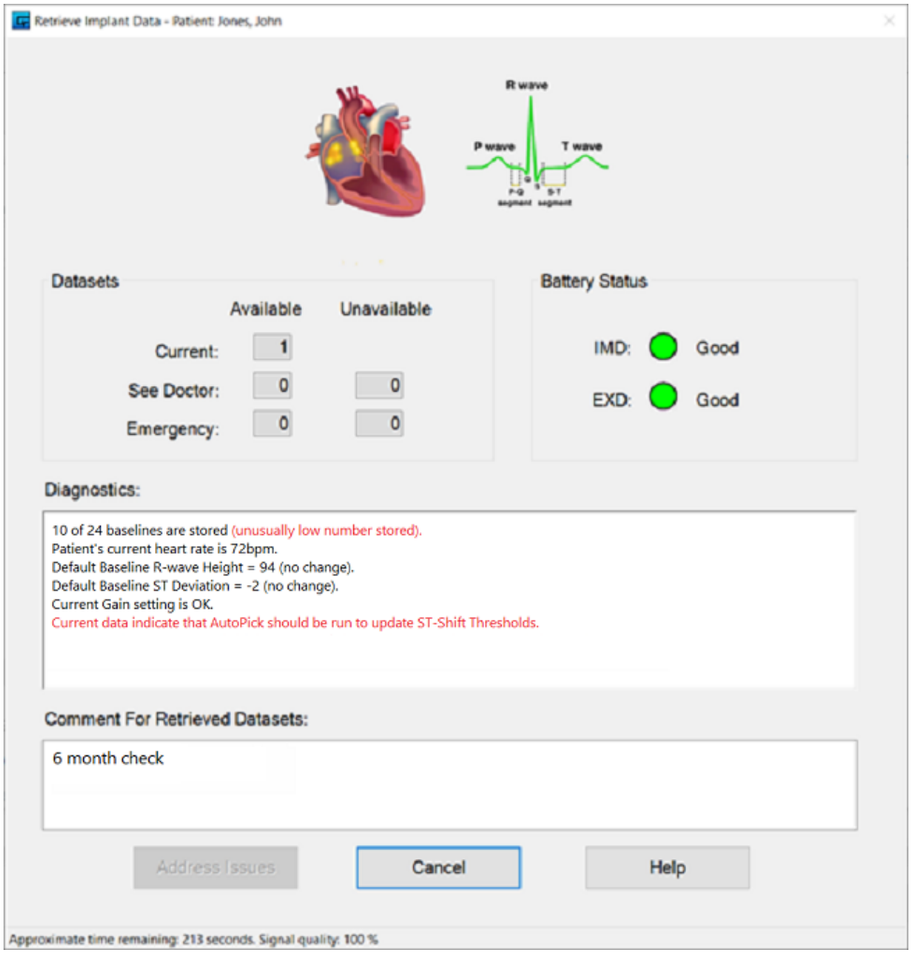
the oldest and the most recent are discarded. The number in the *Unavailable* box indicates how many alarms were discarded.

6. While the Programmer retrieves the IMD data, check the IMD battery status which is displayed in the *Battery Status* area.
   - If the IMD battery status is *Low*, the elective replacement indicator (ERI) flag is set and you should explant and replace the patient's IMD within one month.
   - If the IMD battery status is *Replace*, the IMD is no longer functioning normally and should be explanted and replaced as soon as possible.

     Explant instructions are provided in the *Guardian™ Implantable Medical Device (IMD) Model AMSG3-E User's Guide*.

> **Warning:**
> If the IMD battery status is *Replace*, the IMD is no longer functioning and is not monitoring the patient. It should be replaced as soon as possible.

7. If desired, type a comment in the *Comment for Retrieved Datasets* field. This comment will be applied to all of the datasets retrieved.
8. Once the data retrieval process concludes, the Programmer automatically saves the data and either the *Close* or *Address Issues* button becomes enabled, depending on the circumstances.



Do one of the following:

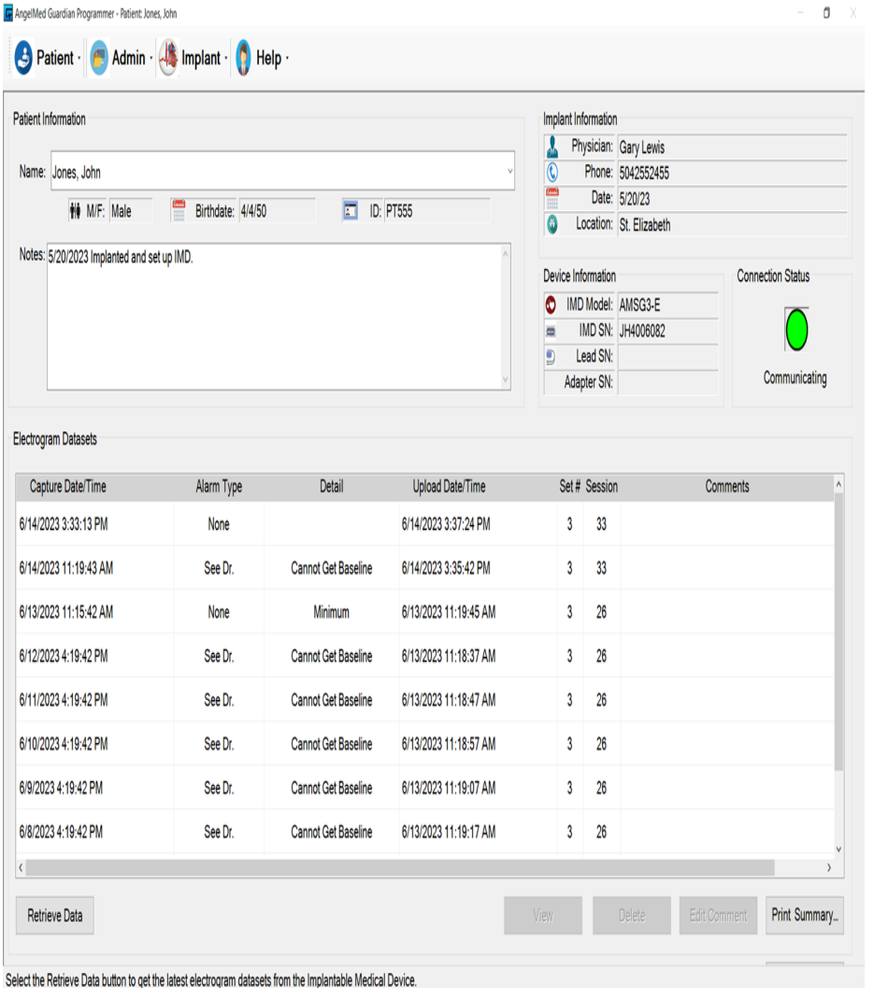
- If the *Address Issues* and *Defer Issues* buttons are available, the Programmer has detected some anomalies in the retrieved dataset, which are displayed in red. Generally, we recommend that you select the Address Issues button to correct the data issues. The Programmer will guide you through the process. You can however, select the *Defer Issues* button if you do not want to address the data issues at this time.
- If the *Close* button is available, the retrieved data is okay and you should select *Close* to dismiss the window.

Review the Datasets

After retrieving data from the patient's IMD, you can view the retrieved electrogram datasets. The *Alarm Type* column displays the alarm type (i.e., None, Emergency, or See Doctor). The *Alarm Detail* column displays the event that triggered the alarm, if any.

To view datasets:

1. Select the desired dataset on the *Electrogram Datasets* list and then select *View*. (You can also touch the dataset twice (i.e., double tap) with the stylus.)



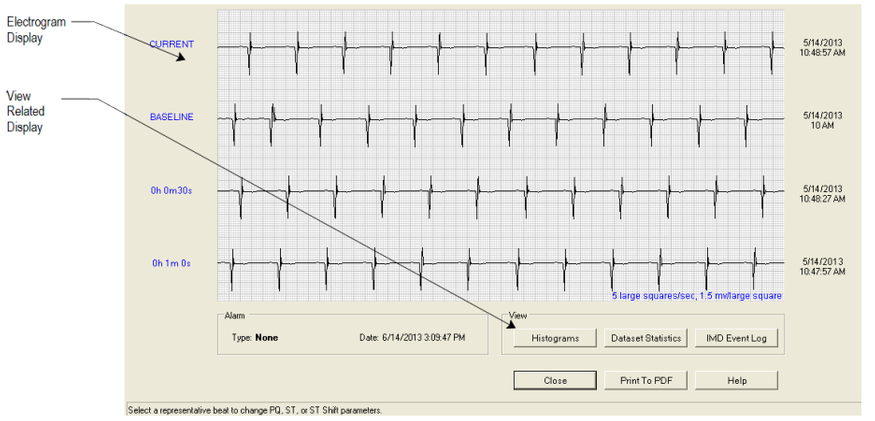
Note:
All electrogram and dataset timestamps are based on the local standard time of the Programmer that retrieves the data. The timestamps never adjust for Daylight Savings Time (DST), even in localities that observe DST.

2. The information displayed in the resulting window varies based on the nature of the *Alarm Type* and the *Alarm Detail*. The major characteristics of None, Emergency alarm, and See Doctor alert datasets are described in the following sections.

Reviewing "None" Datasets

Typically, when a patient comes in for a routine exam, the alarm type of the retrieved electrogram datasets will be *None*. (If there is no *None*, it means that the IMD is in post- emergency alarm mode.)

The next figure shows the View Minimum Dataset window. (If you retrieved data using the Some or All options, the Programmer would display the View Dataset window instead, which enables you to view all the hourly baselines and ST Trends histogram as well.)



The *View Minimum Dataset* window shows four electrogram segments where:

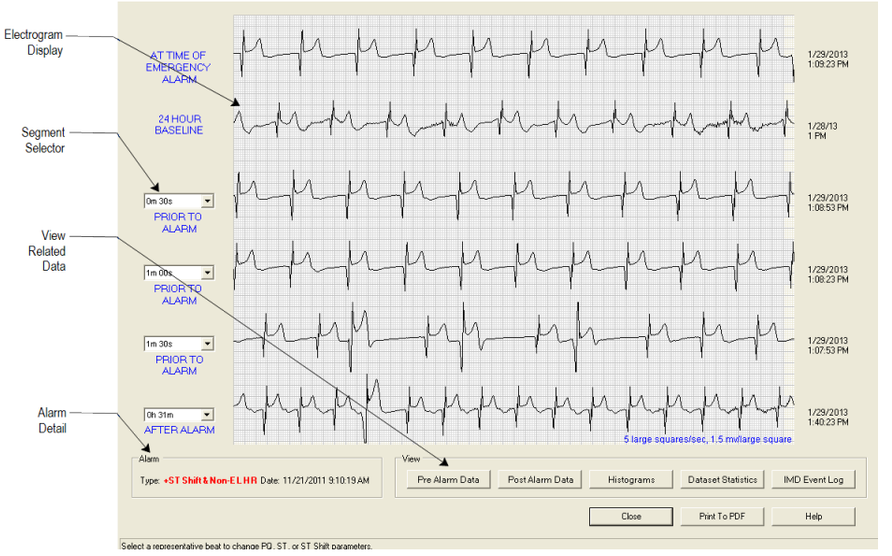
- The top segment (*CURRENT*) is the most recent electrogram
- The second segment is the hourly baseline associated with the *CURRENT* segment
- The third and fourth segments are the next most recently recorded electrograms

Reviewing Emergency Alarm Datasets

Emergency alarm datasets are collected when an event has occurred that is associated with an Emergency alarm. The event that triggered the Emergency alarm is shown in the *Alarm Detail* column in the *Electrogram Datasets* area of the Main Programmer window. It is also shown (in red letters) near the bottom left of the *View "Emergency Alarm" Dataset* window, along with the date and time of the alarm.

Emergency alarm datasets contain both pre- and post-alarm segments as described in *Data Collection When an Emergency Alarm Occurs* on page 10. If you retrieve data while the IMD is in post Emergency alarm mode, the dataset will contain the data collected up to that time. If you then retrieve data after the IMD has returned to normal data acquisition mode, the dataset will contain all the post-emergency alarm data.

The *View "Emergency Alarm" Dataset* window is shown in the next figure. You can select other segments using the drop-down boxes to the left of the electrogram segments. You can also view pre-alarm data, post-alarm data, histograms, and dataset statistics, by selecting the appropriate button on the bottom right side of the window.



The *View "Emergency Alarm" Dataset* window shows six electrogram segments.

- The top electrogram segment was taken at the time of the Emergency alarm.
- The second segment is the associated hourly baseline segment, taken nominally 24 hours before the Emergency alarm segment.
- The third, fourth, and fifth segments are, by default, the first, second, and third electrogram segments, respectively, recorded before the Emergency alarm segment. Use the *Segment Selectors* to select other pre-alarm segments.

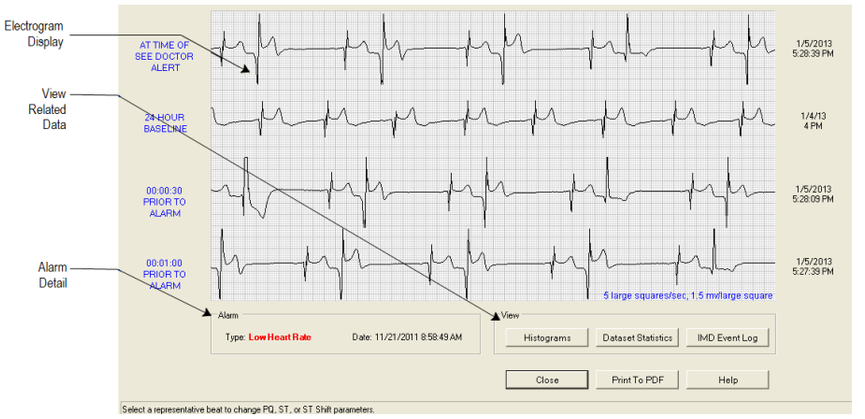
- The sixth electrogram segment is any of the 48 segments taken after the Emergency alarm. The default is the post-alarm segment with the largest average ST shift, positive or negative.

Reviewing See Doctor Alert Datasets

See Doctor alert datasets are collected when an event occurs that is associated with either a See Doctor alert or None alarm type. You can review the electrograms associated with the alert(s) and determine the cause and appropriate action. The event that triggered the See Doctor alert is shown in the *Alarm Detail* column in the *Electrogram Datasets* area of the Main Programmer window. It is also shown (in red letters) near the bottom left of the *View "See Doctor Alert" Dataset* window, along with the date and time of the alert.

> **Note:**
> Do not confuse a None dataset with a None alarm type. A None alarm type is used to save an event without alerting the patient. For more details, see ***Set the IMD Alarm Configuration* on page 49 on page 1**.

The *View "See Doctor Alert" Dataset* window is shown in the next figure. You can view histogram data or dataset statistics by selecting the appropriate button on the bottom right side of the window.



The *View "See Doctor Alert" Dataset* window shows four electrogram segments.

- The top electrogram segment was taken at the time of the See Doctor alert.
- The second segment is the associated hourly baseline segment, taken nominally 24 hours before the See Doctor alert.
- The third segment is the first segment taken before the See Doctor alert.
- The fourth segment is the second segment taken before the See Doctor alert.

Information on Some Additional Events

Four events deserve a little more explanation: Cannot Get Baseline, ST Trend, Negative ST Shift (Recovery), and Watchdog Reset.

Cannot Get Baseline Event

A Cannot Get Baseline event indicates that the IMD failed to find a baseline segment for either 6, 12, or 24 consecutive hours. The exact number of hours is determined by a Programmer option that is set by your *Avertix* representative. The *View Bad Baselines Event Log* window, available by viewing the associated dataset, presents detailed information about the reasons why segments were rejected as baselines.

The Cannot Get Baseline event can have a variety of causes, such as:

- The patient's average heart rate is not within the range specified for the Normal bin.
- The ST Shift of the electrograms is consistently too high, causing the IMD to reject them for use as a baseline.
- Other anomalies can disqualify a segment to be used as a baseline

See *Problems with Collecting Baselines* on page 104 for information on resolving baseline acquisition problems.

ST Trend Event

An ST Trend event indicates a relatively large long-term drift in the ST deviations of the patient's electrogram. When an *ST Trend* dataset is selected, the Programmer displays the *Dataset Histograms: ST Trends* window. (See *Histogram Information* on page 11 for more information.)

Negative ST Shift (Recovery)

The Recovery event occurs when the IMD detects a Negative ST Shift at Non-Elevated Heart Rate event during a time that the patient's heart rate is decreasing. (See *Negative ST Shift (Recovery)* on page 9 for more information.)

Watchdog Reset Event

A Watchdog Reset event indicates a problem with IMD operation. If you receive an alert for a watchdog reset, contact your *Avertix* representative immediately.

The Programmer displays the following message when retrieving a dataset that contains a Watchdog Reset event:

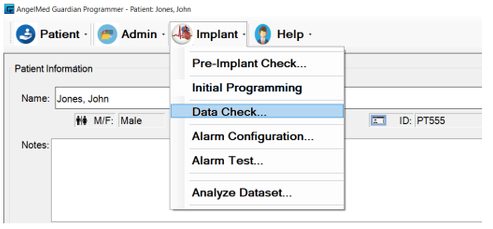
A device reset has occurred. Please contact Avertix immediately.

Checking Data for Issues

Recall that when you retrieve data from the IMD, the Programmer checks that data for anomalies and, if found, displays them in the *Retrieve Implant Data* window. You can choose to address the issues then or defer addressing them until a later time so that you can complete the immediate task. If you chose to defer addressing the issues, you can address them at a more convenient time by using the Data Check feature on the Programmer.

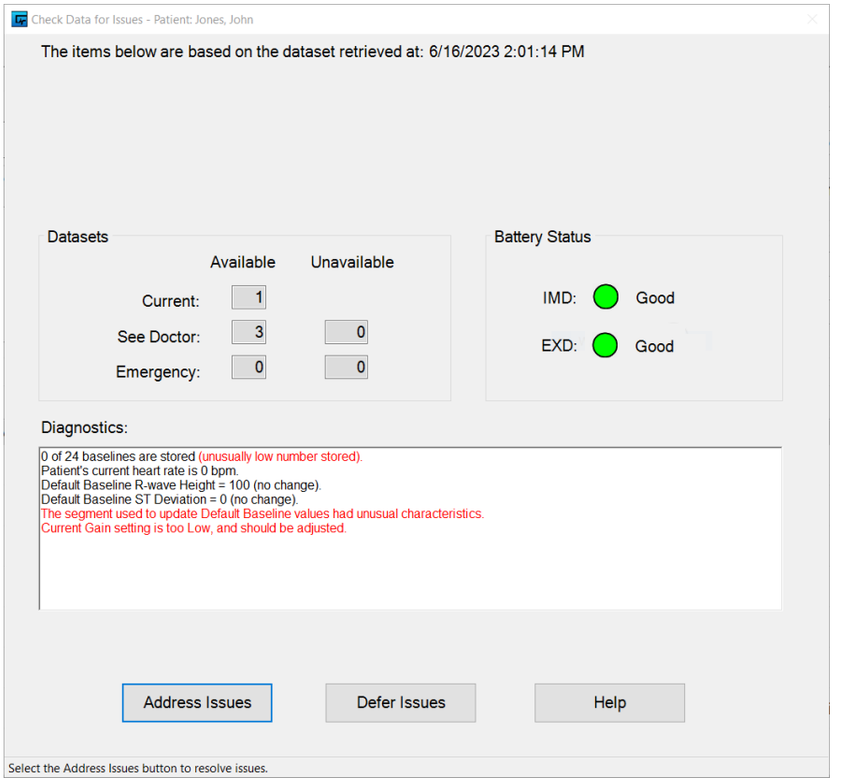
To check data for issues:

1. Open the patient's record on the Programmer.



2. Select the *Implant* →Data Check on the Main Programmer window.
3. Do one of the following:
   - If the Programmer issues an advisory message stating that you need to perform a new data retrieval, you should do so and address any issues that the new data retrieval suggests. (Note that the Programmer displays the advisory message if the most recent dataset is no longer current (e.g., older than 24 hours or does not match the current IMD parameter settings)).

- If the Programmer displays the *Check Data for Issues* dialog box, do the following:
  - If any of the entries in the Diagnostics area are red, select the *Address Issues* button and follow the instructions provided by the Programmer.
  - If none of the entries are red, there are no data issues and you should select *Close* to close this window.



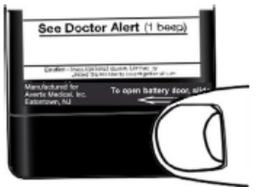
Replace the EXD Battery

The service life of the EXD battery is 6 months. We therefore recommend that you replace the EXD battery whenever a patient comes in for a visit. Be sure to replace the EXD battery at least every 6 months.

> **Caution:**
> Only use the EXD batteries supplied by *Avertix*. Never use "AA" sized batteries in the battery compartment, as the EXD will not function properly if they are used.

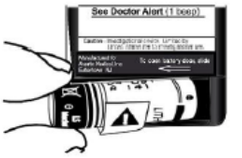
To replace the EXD battery:

1. Open the EXD's battery compartment by pushing down on the right-side of the battery cover and sliding it to the left.



2. Gently pull the tab to lift the negative (-) end of the old battery.
   Note: If the pull-tab is under the battery or missing, use a small screwdriver to gently lift the battery.

3. Insert the positive (+) end of the new battery into the battery compartment and then push down on the battery's negative (-) end. Be sure that the tab is exposed for subsequent removal.



4. Close the battery compartment by sliding the battery cover completely to the right.

5. To confirm that the EXD is working, press the EXD's Silence Alarm/Check Battery button repeatedly until you hear the EXD beep.

> **Note:**
> When you replace the EXD battery, you may need to press the button up to 20 times before the EXD beeps. This is due to a common characteristic of the battery's chemistry. If after 20 attempts the EXD still fails to beep, replace the new battery.

6. Discard the depleted battery according to local environmental regulations.

Review Alarms and Patient Instructions

During the follow-up visit, it is essential to reinforce the training the patient received on their previous office visit. When retraining the patient, you will:

- Confirm IMD vibration strength settings
- Verify that the patient can identify Emergency alarms and See Doctor alerts, and understands their meanings
- Remind the patient to check the EXD's battery power once a week
- Remind the patient to keep the EXD close by at all times
- Ensure the patient still has a copy of the Patient Manual and the Guardian system Patient ID card

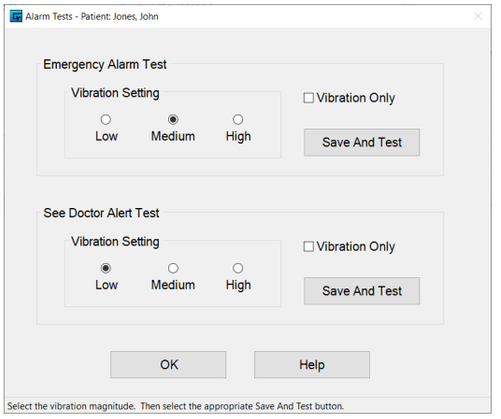
Confirm Vibration Settings and Verify Patient's Understanding of Alarms and Alerts

A patient's sensitivity to vibration may change over time – especially during the time between initial IMD programming (shortly after device implantation) and the first follow- up visit. Whenever the patient comes in for a follow-up visit, the appropriateness of the vibration strength setting should be confirmed while also ensuring that the patient can still identify the Emergency alarm and See Doctor alert and knows what to do if either occurs.

To confirm the vibration settings and review alarm/alert identification:

1. Establish a communication session between the Programmer and the patient's IMD.
2. From the Main Programmer window, select *Implant* → Alarm Test.
3. The Programmer displays the *Alarm Tests* window.

> **Note:**
> The vibration settings shown on the *Alarm Tests* window are the vibration settings that are currently stored on the patient's IMD.



The *Alarm Tests* window has the following features.

Vibration Setting	Selects the strength of Emergency alarm or See Doctor alert vibration that is appropriate for this patient. You can choose *Low*, *Medium*, or *High*. When a patient comes in for a follow-up visit, the selected strength indicates the patient's current vibration setting.
Vibration Only	Limits the test alarm or alert to IMD vibration only; the EXD auditory alarm does not play.
Save and Test	Saves a vibration strength to the patient's IMD and plays it to determine its appropriateness for the patient. To silence the alarm/alert, press the *Silence Alarm/Check Battery* button on the EXD. **Note:** The vibration strength that is played last is saved to the IMD. Be certain to play the desired strength last.
OK	Closes this window and terminates the session. **Note:** To save a vibration strength, select *Save And Test* and play the alarm/alert for the patient.
Help	Displays the online Help page for this window.

4. Tell the patient that you are going to play either an Emergency alarm or a See Doctor alert, and that you want the patient to tell you which one it is and what the patient will do if it occurs.
5. In the *Emergency Alarm Test* area, leave the current vibration setting selected. This is the setting currently stored in the patient's IMD.
6. Select *Vibration Only*.
7. Select *Save And Test*. This will play the Emergency alarm.
8. Ask the patient to identify the alarm and tell you what he or she will do if it occurs. Ensure the patient can identify the alarm and understands its meaning.
9. Then ask the patient if the strength of the alarm is "too weak," "about right," or "too strong."
10. After the patient has answered, give your EXD that is attached to the Programmer to the patient and ask the patient to turn off the alarm. Ensure the patient knows how to stop the alarm.
11. If the patient said the alarm is "about right," go to the next step. If the patient said the alarm is "too weak" or "too strong," play other strengths to find the most appropriate strength.

> **Note:**
> The last vibration strength played is saved in the IMD. After finding the appropriate strength, be sure to play it last.

12. Now tell the patient that you are going to play another alarm, and that you want the patient to tell you which one it is and what the patient will do if it occurs.
13. In the *See Doctor Alert Test* area, leave the current vibration strength selected. This is the strength currently stored in the patient's IMD.
14. Select *Vibration Only*.
15. Select *Save And Test*. This will play the See Doctor alert.
16. Ask the patient to identify the alert and tell you what he or she will do if it occurs. Ensure the patient can identify the alert and understands its meaning.
17. Then ask the patient if the strength of the alert is "too weak," "about right," or "too strong."
18. After the patient has answered, ask the patient to turn off the alert using your EXD that is attached to the Programmer.
19. If the patient said the alert is "about right," go to the next step. If the patient said the alert is "too weak" or "too strong," play other strengths to find the most appropriate strength.

> **Note:**
> The last vibration strength played is saved in the IMD. After finding the appropriate strength, be sure to play it last.

20. Leave the *Alarm Tests* window open and proceed to the next step, Play the Alarms and Alerts on the IMD and EXD.

Play the Alarms and Alerts on the IMD and EXD

To play the alarms and alerts on the IMD and EXD:

1. From the *Alarm Tests* window, verify that the alarm and alert vibration settings are set at the levels to which you and the patient agreed and that the *Vibration Only* checkboxes are unchecked.
2. Play an Emergency alarm (on both the IMD and EXD) at the selected strength by selecting *Save And Test* for the Emergency alarm. Ask the patient what he or she would do if it occurs.

> **Warning:**
> Ensure that both the IMD and EXD are alarming. If the EXD is not alarming, ensure that the *Vibration Only* checkbox for Emergency alarms is cleared and then select *Save And Test*. Also, verify the EXD is connected to the cable.

3. Play a See Doctor alert (on both the IMD and EXD) at the selected strength by selecting *Save And Test* for the See Doctor alert. Ask the patient what he or she would do if it occurs.

> **Warning:**
> Ensure that both the IMD and EXD are alarming. If the EXD is not alarming, ensure that the *Vibration Only* checkbox for Emergency alarms is cleared and then select *Save And Test*. Also, verify the EXD is connected to the cable.

4. Close the *Alarm Tests* window by selecting *OK*.

Remind the Patient to Check EXD Battery Power Weekly

Ask patients how they check battery power. Confirm the patient's correct understanding or provide the following information to the patient.

- Once a week the patient should check EXD battery power by pushing the Silence Alarm/Check Battery button on the EXD.
  - If the battery is working, the EXD will beep one time.
  - If the battery is not working, the EXD will not beep and he or she should call you for a replacement battery.
- The battery is a custom battery and can be obtained only from you.
- When the battery nears the end of its service life, the EXD will start the Low EXD Battery warning, where it beeps every 30 seconds. The patient can temporarily silence this warning by pressing the Silence Alarm/Check Battery button. After 12 hours, the warning starts again. When the Low EXD Battery warning occurs, the patient should call you for a replacement battery.

Stress the Importance of Keeping the EXD Close by

"You must keep your EXD within 6 feet (1.8 meters) at all times; otherwise, it may not beep and flash when an alarm occurs. As you saw when we played the sample alarms, the EXD provides a secondary alarm (the beeps and lights). This makes it easier to identify the type of alarm (Emergency or See Doctor) you are experiencing. Also, at night, the beeps may wake you even if the vibration alone doesn't.

And finally - if you don't have your EXD close by, you won't be able to turn off the IMD vibration (it will stop on its own after 5 minutes). You should carry your EXD with you during the day and keep it by your bed at night."

Ensure the Patient Has the Patient Manual and Guardian System Patient ID Card

Ask if the patient still has a copy of the *Patient Manual for the Guardian™ System*, and the *Guardian System Patient Identification* card. If not, provide these items to the patient.

Review Contact Info and Instructions on EXD and Patient ID Card

Take a moment to review the contact information (e.g., phone numbers, names) and any instructions written on the back of the patient's EXD and Patient ID Card. This information was originally written at the time of the patient's implant and should be reviewed to ensure it is still accurate and appropriate.

7 Programmer Backup and Restore

The Programmer comes equipped with a USB flash drive. The flash drive serves as secondary data storage that can be used to recover patient data in the event of a hardware failure on the Programmer.

The sections that follow describe how to backup data to and restore data from the flash drive.

> **Caution:**
> Do not use generic USB flash drives. Only *Avertix* flash drives are certified for use with the Guardian Programmer.

Procedures

Backing Up Programmer Data

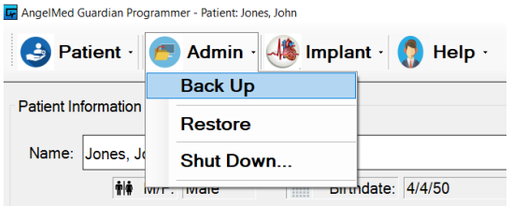
The backup process copies Programmer data from the Programmer to the flash drive, thereby ensuring the Programmer data remain safe even if the Programmer workstation experiences a hardware failure. We recommend that you back up Programmer data:

- At least twice a week
- Any time that you create a new patient record

> **Caution:**
> Do not use the flash drive of one Programmer to back up another Programmer. A Programmer can only use the flash drive with which it was shipped or its replacement from *Avertix*.

To back up Programmer data:

1. Make sure that an *Avertix* flash drive is plugged into the Programmer. (If necessary, consult your Programmer Setup Guide or contact your *Avertix* representative to identify the proper port.)
2. From the Main Programmer window, select Admin → *Backup*.



3. If there is a problem with the backup operation, one of the following messages displays.

- *Backup requires the USB drive to be connected. Please connect the USB drive. Then select the Retry button.*

  Insert an *Avertix* flash drive into the Programmer. Then select *Retry*.

- *Some files could not be backed up. Please contact Avertix.*

  The flash drive is either faulty or not properly seated in the Programmer's flash drive port. Remove the flash drive from the port, re-insert it, and then select *Retry*. If the same error occurs contact *Avertix* for a replacement drive. In the meantime, you can back up the data to the alternate flash drive that was supplied with your Programmer.

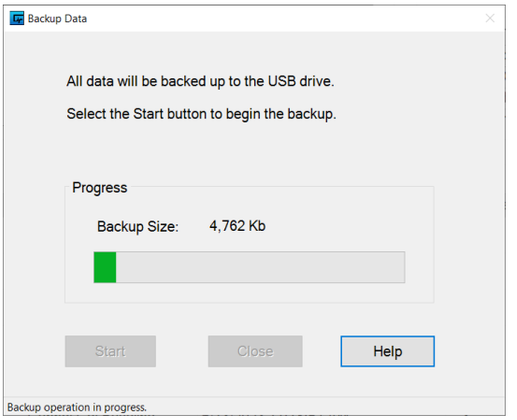
- *Data cannot be backed up due to insufficient space on the USB drive. Please connect a USB drive with at least <xxxxxxxx> bytes of free space.*

  (The <xxxxxxxx> is a dynamic number that changes depending on the amount of information that actually needs to be backed up.)

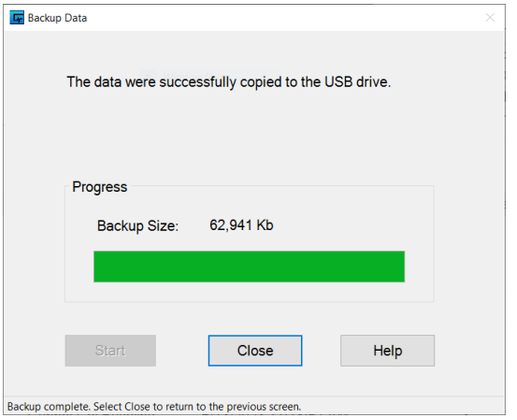
  Contact your *Avertix* representative for assistance.

4. The Programmer displays the *Backup Data* window. Select *Start* to begin the backup.

   The Programmer displays a progress bar, indicating the completion status of the backup.



5. When the backup successfully completes, the Programmer displays the following confirmation. Select *Close* to dismiss the window.



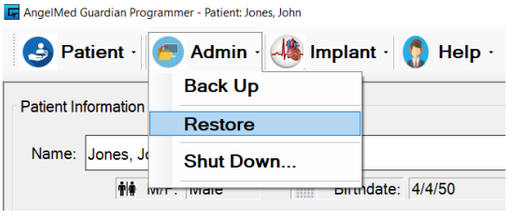
Restore Programmer Data

The Restore feature allows you to restore data from the flash drive to the Programmer's main data storage repository (i.e., Programmer's internal disk drive). This feature is typically used to restore data to a new Programmer, such as in a disaster recovery situation, or to copy patient data from one Programmer to another.

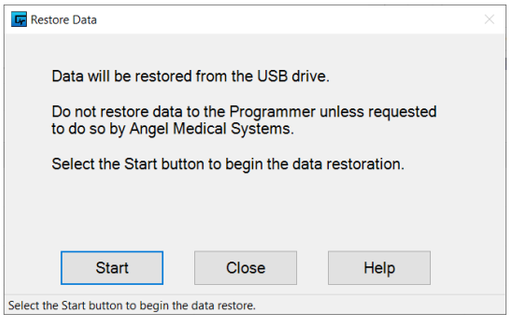
Caution:
Do not restore data to the Programmer unless requested to do so by *Avertix*. Restoring data to the Programmer can cause data on that Programmer to be overwritten.

To restore data from the flash drive to the Programmer:

1. Make sure that the appropriate *Avertix* flash drive is plugged into the Programmer. (If necessary, consult your *Programmer Setup Guide* or contact your *Avertix* representative to identify the proper port.)
2. From the Main Programmer window, select Admin → *Restore*.

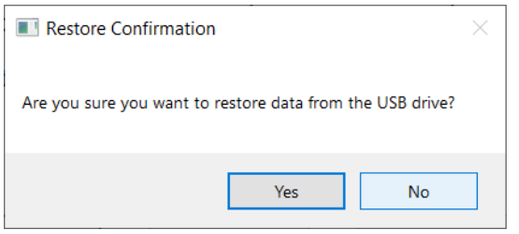


3. From the *Restore Data* window, select *Start* to start the data recovery process.



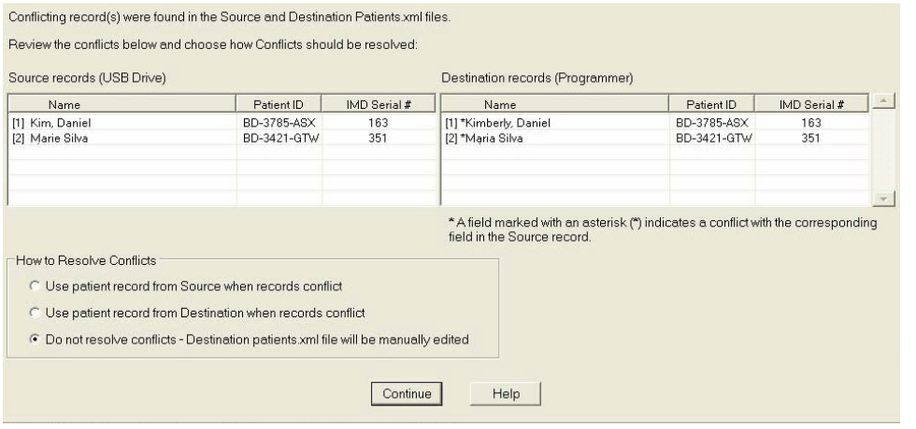
Note:
The time required to restore data depends on the amount of data to be restored and may take several minutes.

4. The Programmer prompts you to confirm that you want to restore data from the *Avertix* flash drive. Select *Yes* to restore the data.



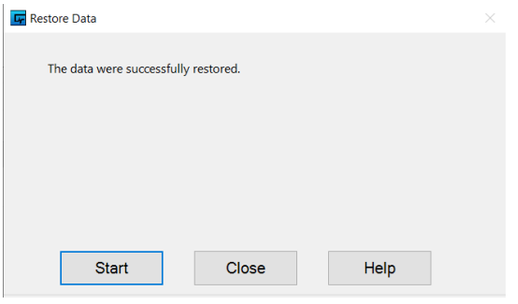
   The Programmer displays an hourglass icon while the data are being retrieved.

5. As the Programmer restores the data, it may encounter patient records that are in conflict. On a Programmer, patient records must comprise a unique name, patient ID and IMD serial number. If a patient record on the source flash drive shares some but not all of these fields in common with a record on the destination Programmer, a conflict exists and the Programmer displays the *Patient Record Conflicts* dialog box.



   Additional information on resolving records conflicts can be found in the Programmer online Help.

6. When the data are fully restored, the Programmer displays the following window. Select *Close* to dismiss the window.



Safeguarding Your Data for Disaster

Backing up your Programmer data to the flash drive as described previously is fine for securing the data in the event of a Programmer failure. But, how secure would your patient's data be if:

- The office where the Programmer is located suffered severe damage due to a fire or some other calamity?
- The Programmer was lost or stolen?

Because such events, though rare, do occur, it's essential that you not only back up your data, but safeguard your backed up data as well. Doing so ensures that your patient's electrograms and other Programmer data can be recovered should the need arise.

The Programmer is supplied with two flash drives, which allow you to store one of them in a secure location while the other is inserted into the Programmer workstation. The secure location should be a reasonable distance from the Programmer itself so that the data are sufficiently isolated. You may also find it convenient to use an archiving service that specializes in secure data storage. We suggest you archive your backed up Programmer data at least twice a week.

The following procedure describes how to archive your backed up Programmer data. Using this procedure, the two flash drives switch between the alternating roles of current flash drive and archived flash drive.

To archive your backed up Programmer data:

1. Get the archived flash drive from the secure location.
2. Remove the current flash drive from the Programmer.
3. Store the current flash drive in the secure location.
4. Plug the archived flash drive into the Programmer.
5. Perform a backup as described previously in *Backing Up Programmer Data* on page 88.

8 Troubleshooting

This chapter discusses possible Programmer problems and ways to resolve them. For help with any other questions or problems, please contact your *Avertix* representative.

This chapter addresses the following issues:

Data Backup or Restoration Problems

Cannot Backup or Restore Data

Verify that the USB flash drive is plugged into the Programmer. See *7 Programmer Backup and Restore* on page 87 for additional details.

Heart Rate Does Not Match Patient's Heart Rate

The IMD is implanted, but the patient's heart rate as displayed by the Programmer does not agree with the patient's true heart rate. Possible causes are:

- Mechanical problem, such as:
  - The IMD may not be properly grounded.
  - Connections in the lead system to the IMD header or endocardium may be faulty.
  - The lead system may be broken or damaged.
  - The lead may be implanted in the wrong place.
- Excessive injury current, which is caused by the newly implanted lead and may temporarily impede heartbeat detection.
- Inappropriate IMD amplifier gain setting. For checking and setting the gain, see *Retrieve IMD Data and Adjust Gain* on page 32.
- Other factors including some anomalous heartbeats and arrhythmias.

To determine why the IMD's measured heart rate is inaccurate:

1. Establish a communication session with the IMD.
2. Retrieve data by selecting *Retrieve Data* from the Main Programmer window. Use the *Minimum* retrieve option.
3. View the retrieved dataset by opening it from the Main Programmer window.
4. Do one of the following:
   a. If the signal displayed in the current segment is a flat line, then there is probably a mechanical problem. Do one of the following.
      - If the IMD has just been implanted and the surgical pocket is open, ensure that the IMD is making good contact with the surrounding tissue and recheck all lead system and IMD header connections. Then, retrieve and review the heart rate again. If the heart rate is still incorrect, contact your *Avertix* representative.
      - If the IMD has already been implanted and the surgical pocket is closed, contact your *Avertix* representative.

   b. If the signal displayed is not a flat line but rather indicates a cardiac signal, the IMD is probably not detecting the heartbeats properly. This can be caused for a variety of reasons. Contact your *Avertix* representative for assistance.

IMD Serial Number Must Be Changed

The IMD serial number for a patient record cannot be changed after it has been entered and saved. This section provides workarounds for situations wherein the IMD serial number must be changed because:

- An incorrect serial number was entered during new patient record creation
- A different IMD must be implanted
- An IMD must be explanted and replaced

Incorrect Serial Number Entered During New Patient Record Creation

During new patient record creation, you entered an incorrect IMD serial number and saved the patient record. You will need to delete the patient record and create a new patient record with the correct serial number.

To delete the current patient record:

1. As a precaution, back up the Programmer by selecting Admin → *Backup* from the Main Programmer window. (For specific details, see *Backing Up Programmer Data* on page 88.)
2. When the backup concludes, select *Patient* → *Select* from the Main Programmer window.
3. From the *Select Patient* window, select the name of the patient whose record you want to delete and then select *Delete*.

> **Caution:**
> Ensure you have selected the correct patient record to delete. Deleting a patient record also deletes any datasets associated with that patient.

4. Select *Yes* on the deletion confirmation prompt, which causes the Programmer to delete the record.
5. Re-create the patient record and consider allowing the IMD to automatically populate the IMD serial number. See *Create a New Patient Record* on page 14 for additional details.

IMD with a Different Serial Number Must Be Implanted

You cannot complete implantation of the intended IMD. Instead, you must implant a different IMD, which has a different serial number.

You will need to delete the patient record and create a new patient record with the serial number of the replacement IMD.

To delete the current patient record:

1. As a precaution, back up the Programmer by selecting *Admin → Backup* from the Main Programmer window. (For specific details, see *Backing Up Programmer Data* on page 88.)
2. When the backup concludes, select *Patient → Select* from the Main Programmer window.
3. From the *Select Patient* window, select the name of the patient whose record you want to delete and then select *Delete*.

> **Caution:**
> Ensure you have selected the correct patient record to delete. Deleting a patient record also deletes any datasets associated with that patient.

4. Select *Yes* on the deletion confirmation prompt, which causes the Programmer to delete the record.
5. Re-create the patient record, allowing the new IMD to automatically populate the IMD serial number. See *Create a New Patient Record* on page 14 for additional details.

IMD Must Be Explanted and Replaced

You must explant a patient's current IMD and implant a different one.

You will need to create a new patient record to be associated with the new IMD. As a consequence, this patient record will specify the new IMD serial number. Also, when creating the new record, be sure to specify a different:

- Patient ID number
- First/Middle/Last Name combination. For example, you might add a "-2" to the last name.

The Programmer does not permit patient records to share the same IMD serial number, Patient ID, or First/Middle/Last Name combination.

Caution:
Do not delete the original patient record. If you do, you will lose all of the patient's data that are currently stored on the Programmer.

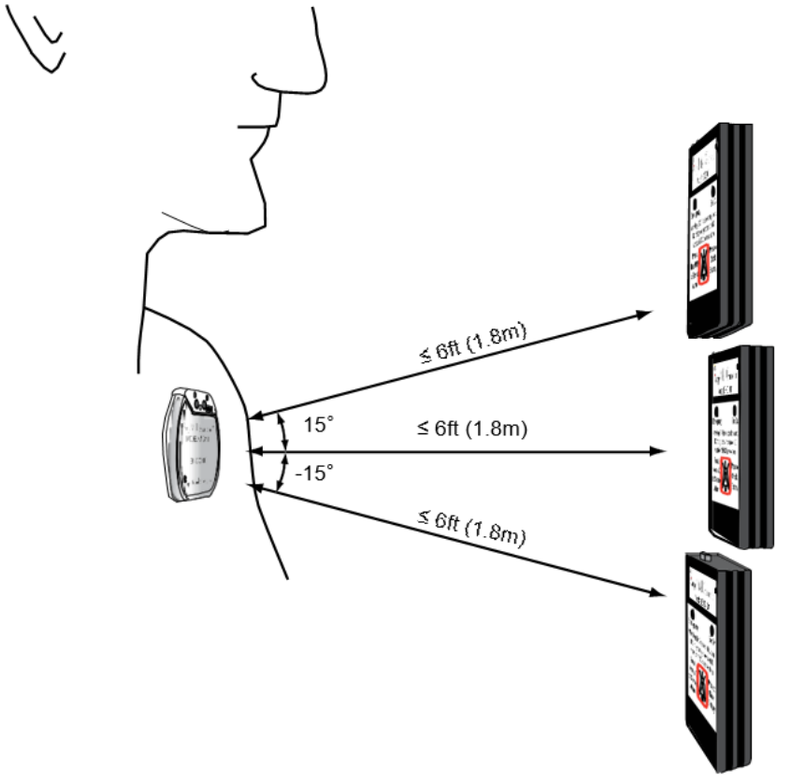
Data Retrieval from IMD is Suspended

While retrieving data from the patient's IMD, the Programmer displays a message informing you that the retrieval has been suspended and that you need to restart the retrieval. When restarting the data retrieval, you should first reposition the Wand to ensure more reliable communications. Once restarted, the Programmer resumes the data transfer at the point of suspension.

Positioning the Wand

Most IMD data retrievals are suspended because of communication problems between the IMD and Wand. These problems are generally caused by the position of the doctor's Programmer Wand: specifically, the distance between the Wand and IMD and the orientation of the Wand with respect to the IMD.

For any data retrieval, the Wand must be placed no further than 6 ft (1.8 m) from the implanted IMD. If possible, move the Wand even closer. Orientation of the Wand can also matter. Generally, the most reliable data retrievals occur when the Wand and IMD face each other and are ±15° in the same vertical plane as shown in the following figure.



To re-start a data retrieval:

1. Observe the *Connection Status* indicator on the Main Programmer window.

2. Do one of the following:

- If it indicates *Not Established*,

    a. Re-establish a communication session with the patient's IMD.

    b. Place the Wand within 6 ft (1.8m) of the IMD. If possible, move the Wand closer to the IMD and orient it as described previously.

- If it indicates *Communicating*, place the EXD within 6 ft (1.8m) of the IMD. If possible, move the Wand closer to the IMD and orient it as described previously.

3. Select the *Retry* button on the message window that was displayed when the data retrieval was suspended.
4. Observe the status of the resumed data retrieval on the *Retrieve Implant Data* window.

Connection Problems between the Programmer and IMD

You must open a communication session between the Programmer and IMD whenever you want to program, retrieve data from, or check the status of an IMD. A communication session is established using near-field communications. This requires that you hold the Programmer Wand to within 2in (5cm) of the IMD when attempting to start a session. You know the session has started when the Wand beeps twice and the *Connection Status* indicator in the Main Programmer window changes to *Communicating*.

If you are unable to start a communication session, perform the following checks before your next attempt:

1. Ensure the patient record is open.
2. Move the Wand to a slightly different position over the IMD and keep it within 2in (5cm) of the IMD.
3. Ensure that the Wand is connected to the Serial cable, and that the cable is connected to the Programmer's USB port. (If necessary, consult the *Programmer Setup* section of the Programmer online Help, *Programmer Setup and Operations Guide* or contact your *Avertix* representative for details on connecting the EXD cable to the Programmer.)
4. Ensure that the Wand battery is in good condition by clicking the Silence Alarm/Check Battery button. If the battery is good, you will hear a beep. If you do not hear a beep, you need to replace the Wand (EXD) battery.

   If you still cannot establish a communication session, contact your *Avertix* representative.

Patient ID Number Must be Changed

During new patient record creation, you entered an incorrect patient identification number. After it has been saved, the Patient ID cannot be changed.

You will need to delete the patient record and create a new patient record with the correct Patient ID Number.

To delete and re-create the current patient record:

1. As a precaution, back up the Programmer by selecting Admin → *Backup* from the Main Programmer window. (For specific details, see *Backing Up Programmer Data* on page 88.)
2. When the backup concludes, select *Patient* → *Select* from the Main Programmer window.
3. From the *Select Patient* window, select the name of the patient whose record you want to delete and then select *Delete*.

> **Caution:**
> Ensure you have selected the correct patient record to delete. Deleting a patient record also deletes any datasets associated with that patient.

4. Select *Yes* on the deletion confirmation prompt, which causes the Programmer to delete the record.
5. Re-create the patient record with the correct patient ID. See *Create a New Patient Record* on page 14 for additional details.

Problems with Collecting Baselines

The IMD has been implanted for over 24 hours; however, it has acquired or kept fewer than 24 baselines.

The IMD collects a baseline nominally once every hour. Regular baseline acquisition is essential for obtaining optimal ST shift characterization. If the IMD does not consistently collect a baseline each hour, you should determine the cause of the problem and correct it.

To resolve the problem with collecting baselines:

1. Verify that the patient's resting heart rate and rhythm are medically acceptable.
   - If they are, proceed to the next step.
   - If they are not acceptable (e.g., too high, low, irregular), do not complete this procedure, but rather regulate the heart rate such that is it acceptable and stable.

   > **Note:**
   > Baselines are segments that the IMD has judged to be super-normal for the patient. Certain drugs, particularly those that affect cardiac rate and rhythm, may significantly change a patient's heartbeat such that the IMD can no longer find a segment normal enough to be acceptable as a baseline. Before adjusting any IMD parameters, check the patient's resting heart rate and rhythm to ensure they are medically acceptable and therefore not the cause of IMD's inability to collect baselines.

2. Retrieve data from the patient's IMD. Use the *Some* retrieval option so that you recover all the recorded baselines.
3. From the Main Programmer window, open the retrieved dataset.
4. Do one of the following:
   - If there is a *See Doctor – Cannot Get Baseline* dataset among those retrieved, select it for viewing and then proceed to Step 5.
   - If not, perform the following steps:
     a. Select the None dataset.
     b. From the *View Dataset* window, select the *Baselines* button.
     c. On the *View Baselines* window, use the up and down arrows on the left of the window to find an hour for which no baseline is displayed. Note the number of *Hours Prior* in the left column.
     d. Select the *Bad Baselines Log* button.

5. From the *View Bad Baselines Event Log* window, scroll, if necessary, to the *Hours Ago* row that corresponds to the hour(s) for which there is no baseline.
6. Note the column with the largest number in it. If that column is:
   - *HI*, *EL-S*, *EL-N*,*LO-S*, or *LO-NS*, it is likely that the normal heart rate bin has not been set appropriately. See *Set Heart Rate Boundaries* on page 55.
   - *N-S* or *N-NS Shift Too High*, it is likely that the PQ and/or ST segment definition and/or ST Shift Threshold parameter values need to be adjusted. For instructions, see *Review PQ and ST Start and Duration* on page 57 and *Set ST Shift Thresholds* on page 59.
   - If any other column has the largest number in it, contact your *Avertix* representative.

EXD Does Not Beep When IMD Alarms

The patient states that when the IMD last issued an alarm or alert, the EXD did not beep at all or started beeping noticeably later than when the IMD started vibrating.

There may be a few reasons for this behavior:

- The EXD battery power may be depleted and therefore unable to beep.
- There may have been a temporary communication problem between the IMD and EXD; for example, the EXD may have been out of radio range (i.e., 6ft (1.8m)).

Background Information

When the IMD detects an event, it sends a radio message to the EXD, specifying whether to issue an alarm or alert and when to start beeping. When the EXD receives the message, it responds with an acknowledgment back to the IMD, signaling that it has received the message. Most times this handshaking protocol occurs as intended and the EXD and IMD both alarm at the same time. If, however, the EXD doesn't receive the initial message or the IMD doesn't receive the acknowledgment, the IMD starts vibrating on its own. If the EXD becomes in-range under these circumstances, it will begin to beep; however, it will start after the IMD has already started vibrating.

To resolve this problem:

1. Check the battery power of the patient's EXD by pressing the EXD Silence Alarm/Check Battery button. If it beeps, the battery is OK; otherwise, the battery is depleted.
   - If the battery is depleted, replace the battery.
   - Even if the battery is OK, you should still replace the battery as a prudent measure to ensure the current battery does not become depleted before the next office visit.
2. In case the problem was also due to the EXD being out of range, review the EXD range requirements with your patient.
   - Try to learn the circumstance under which the event happened. For example, where was the EXD at the time the IMD started to vibrate? Was it within 6ft (1.8m) of the IMD? Did the patient get their EXD? Were the EXD LEDs flashing?
   - Review the range requirements of the EXD with your patient to ensure that the EXD is always within 6ft (1.8m) of the IMD, day and night.

A IMD Parameters: Defaults and Ranges

IMD parameters are set from the Programmer. This chapter tabularizes the default values and the possible ranges for each parameter.

Edit Implant Parameters Window

HR-Max (BPM)

Heart Rate Bin	Min	Max	Default
Elevated (A4)	110	220	160
Elevated (A3)	90	190	140
Elevated (A2)	70	160	125
Elevated (A1)	55	130	110
Normal (A0)	40	115	100
Low (LO)	25	95	50

Start of PQ (milliseconds)

Heart Rate Bin	Min	Max	Default
Elevated (A4)	70	200	75
Elevated (A3)	70	200	85
Elevated (A2)	70	200	95
Elevated (A1)	70	200	105
Normal (A0)	70	200	150
Note: Start of PQ ≥ (Duration of PQ + 30)			

Duration of PQ (milliseconds)

Heart Rate Bin	Min	Max	Default
Elevated (A4)	40	90	40
Elevated (A3)	40	90	45
Elevated (A2)	40	90	50
Elevated (A1)	40	90	55
Normal (A0)	40	90	80
Note: Duration of PQ ≤ (Start of PQ – 30)			

Start of ST (milliseconds)

Heart Rate Bin	Min	Max	Default
Elevated (A4)	40	160	40
Elevated (A3)	40	160	45
Elevated (A2)	40	160	50
Elevated (A1)	40	160	55
Normal (A0)	40	160	80
Note: Start of ST ≤ (200 – Duration of ST)			

Duration of ST (milliseconds)

Heart Rate Bin	Min	Max	Default
Elevated (A4)	40	90	55
Elevated (A3)	40	90	60
Elevated (A2)	40	90	65
Elevated (A1)	40	90	70
Normal (A0)	40	90	80
Note: Duration of ST ≤ (200 – Start of ST)			

ST-Pct Positive/Negative (ST Shift Thresholds) (%)

Heart Rate Bin	Min	Max	Default
Elevated (A4)	0	127	100
Elevated (A3)	0	127	100
Elevated (A2)	0	127	100
Elevated (A1)	0	127	100
Normal (A0)	0	127	100

LO HR Decrement (BPM)

Min	Max	Default
0	7	5

Edit Alarm Configuration Window

Time Interval Parameters

Parameter	Min	Max	Default
ST Shift and Elevated HR becomes persistent after (minutes)	3	20	10
Alarms and alerts will be enabled in (days) *	Now	7	Never**
* Now means immediately or upon re-entering normal data acquisition mode **The Programmer automatically changes this parameter to Now at Initial Programming The value Never disables alarming and can only be set by an *Avertix* representative.			

Alarm Type Association (Recommended Settings)

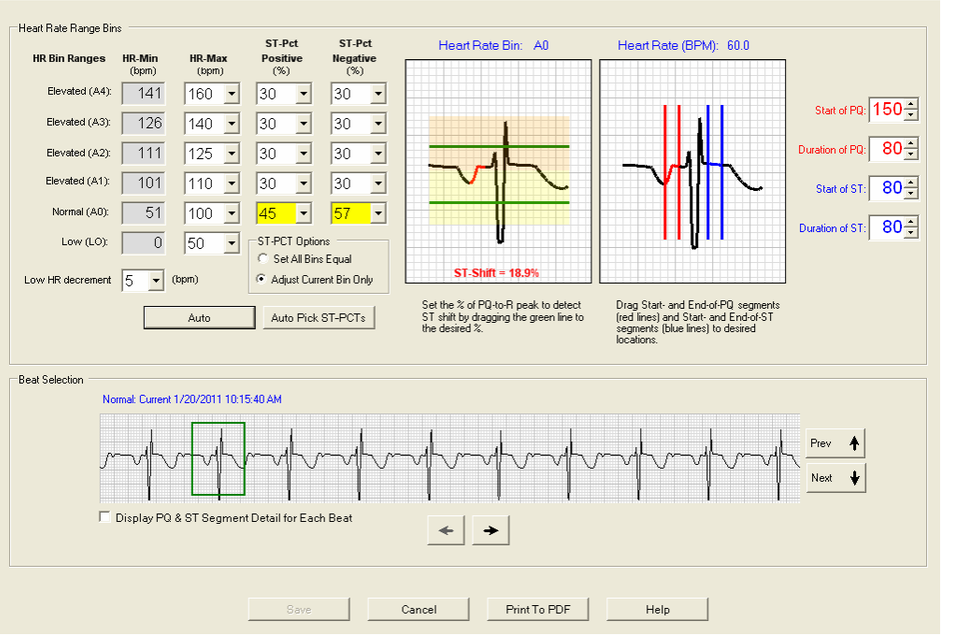
Event	Emergency	See Dr	None	Ignore
Positive ST Shift & Non-El HR	✓		*	
Negative ST Shift & Non-El HR	✓		*	
Negative ST Shift (Recovery)		✓	*	
ST Shift & Elevated HR	N/A	✓	*	
ST Shift & Elevated HR Persists		✓	*	
High Heart Rate	✓		*	
Low Heart Rate		✓	*	
Irregular Heart Rate		✓	*	
Flat Line		✓	*	
Not Enough Beats	N/A	✓	*	
Cannot Get Baseline	N/A	✓	*	
ST Deviation Trending	N/A	✓	*	
* Denotes the factory setting of each event. (✓ is the recommended setting.)				

Dataset Histograms: ST Trends Window

Parameter	Min	Max	Default
Moving Average Size (Days)	1	14	7
Check Hour*	0	23	9
Ignore Data Older Than (Days Ago)	1	192	1
Detection Threshold	10	50	20
*Hour of the day			

B Changing Heart Rate Bins Using Edit Implant Parameters

The *Heart Rate Bin* setup area of the manual version of the *Edit Implant Parameters* window allows you to review and specify the maximum number of beats per minute (bpm) for each heart rate bin.



- Significance of Heart Rate Bins
- How to Adjust Heart Rate Bins

Significance of Heart Rate Bins

Heart rate bins are an essential part of the detection algorithm. Each bin can have specific settings associated with it to indicate where the IMD will measure PQ and ST segments. This, in turn, is what enables the IMD to detect ST shifts in those segments. (For more information, see *Detection Algorithm Basics* on page 4.)

The three most important heart rate boundaries to set are *Low*, *Normal*, and *Elevated A4*. It is especially important to define these three settings accurately for the patient.

- *Low (LO)* specifies the upper boundary of the Low heart rate bin. Heart rates at and below this rate should be considered low for the patient at rest. An event is triggered if the patient's heart rate falls to or below this rate. If such an event occurs, the IMD automatically lowers the *LO* value by the amount specified by the *Low HR decrement* parameter, which is available on the manual version of the *Edit Implant Parameters* window.)
- *Normal (A0)* specifies the upper boundary of the Normal heart rate bin. Heart rates at and below this rate, but above the specified *Low* rate, should be considered normal for the patient at rest. The upper and lower limits of this bin should bracket the normal resting heart rate of the patient.

> **Caution:**
> It is important to establish an accurate range for the *Normal (A0)* bin because segments must be classified as normal to be used as baseline segments for ST shift detection.

- *Elevated (A4)* specifies the heart rate above which the patient should go to an Emergency room because the heart rate is potentially life-threatening. An event is triggered if the patient's heart rate rises above this rate.
- The other Elevated settings (*A1*, *A2*, and *A3*) are dependent on the *A0* and *A4* settings and must be set in accordance with prescribed values shown in the following table.

Changing Heart Rate Bins Using Edit Implant Parameters

		Bins	Elevated (A4)															
			110	115	120	125	130	135	140	145	150	160	170	180	190	200	210	220
NORMAL (A0)	40	A1	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55
		A2	70	70	70	70	70	70	70	70	70	70	70	70	70	70	70	70
		A3	90	90	90	90	90	90	90	90	90	90	95	95	100	100	100	105
	45	A1	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55	55
		A2	70	70	70	70	70	70	70	70	70	70	70	70	70	70	70	70
		A3	90	90	90	90	90	90	90	95	95	100	100	105	105	105	110	110
	50	A1	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60	60
		A2	70	70	70	70	70	75	75	75	75	75	75	80	80	80	80	80
		A3	90	90	90	90	95	95	95	100	100	105	105	110	110	115	115	120
	55	A1	65	65	65	65	65	65	65	65	65	65	65	65	65	65	65	70
		A2	70	75	75	75	75	80	80	80	80	80	85	85	85	85	85	90
		A3	90	90	95	95	95	100	100	105	105	110	110	115	120	120	125	125
	60	A1	70	70	70	70	70	70	70	70	70	70	70	70	70	75	75	75
		A2	80	80	80	80	80	85	85	85	85	85	90	90	90	90	95	95
		A3	90	95	95	100	100	105	105	105	110	115	115	120	125	125	130	130
	65	A1	70	75	75	75	75	75	75	75	75	75	75	75	80	80	80	80
		A2	80	85	85	85	85	90	90	90	90	90	95	95	95	100	100	100
		A3	95	95	100	100	105	105	115	110	115	115	120	125	130	130	135	140
	70	A1	75	80	80	80	80	80	80	80	80	80	80	85	85	85	85	85
		A2	85	85	90	90	90	90	95	95	95	95	100	100	100	105	105	105
		A3	95	100	100	105	105	110	110	115	115	120	125	130	135	135	140	140
	75	A1	80	80	85	85	85	85	85	85	85	85	85	90	90	90	90	90
		A2	90	90	90	95	95	95	100	100	100	100	105	105	110	110	110	110
		A3	100	100	105	105	110	115	115	120	120	125	130	135	135	140	140	150
	80	A1		85	85	90	90	90	90	90	90	90	90	95	95	95	95	95
		A2		95	95	100	100	100	100	105	105	105	110	110	115	115	115	115
		A3		105	105	110	110	115	120	120	125	130	135	135	140	150	150	150
	85	A1			90	90	95	95	95	95	95	95	95	100	100	100	100	100
		A2			100	100	105	105	105	105	110	110	115	115	115	120	120	125
		A3			110	110	115	120	120	125	125	130	135	140	150	150	150	160
	90	A1				95	100	100	100	100	100	100	100	105	105	105	105	105
		A2				105	105	110	110	110	115	115	120	120	120	125	125	130
		A3				115	115	120	125	125	130	135	140	140	150	150	160	160
	95	A1					100	105	105	105	105	105	105	110	110	110	110	110
		A2					110	110	115	115	115	120	120	125	125	130	130	130
		A3					120	120	125	130	130	135	140	150	150	160	160	170
	100	A1						105	110	110	110	110	110	115	115	115	115	115
		A2						115	115	120	120	125	125	130	130	130	140	140
		A3						125	125	130	135	140	140	150	160	160	160	170
	105	A1							110	115	115	115	115	115	120	120	120	120
		A2							120	120	125	125	130	130	140	140	140	140
		A3							130	130	135	140	150	150	160	160	170	170
	110	A1								115	120	120	120	120	125	125	125	125
		A2								125	125	130	130	140	140	140	140	150
		A3								135	140	140	150	160	160	170	170	180
	115	A1									120	125	125	125	130	130	130	130
		A2									130	130	140	140	140	150	150	150
		A3									140	150	150	160	160	170	170	180

How to Adjust Heart Rate Bins

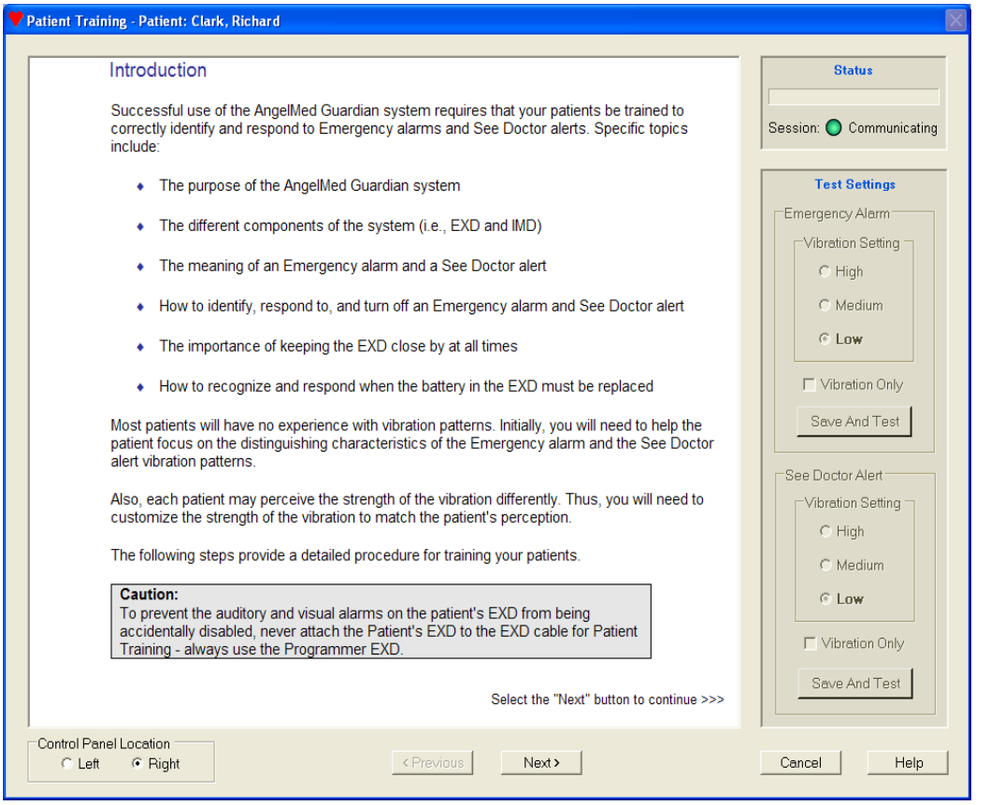
In general, the direction you intend to adjust the bins indicates the best way to start. If you wish to raise the boundary values, you should start at the *Elevated (A4)* bin, raise it, and then work your way down through the other bins. This prevents overlaps as you change each bin. If you wish to lower the boundary values, you should start at the *Low (LO)* bin and work your way up through the other bins.

To adjust the heart rate bins:

1. Review the heart rates in the *LO*, *A0* and *A4* heart rate bins. (For now, you can ignore the A1, A2, and A3 bins.)
2. If changes are needed, change the corresponding *LO*, *A0* and *A4* bin values.
3. Set the A1, A2, and A3 bins to the values specified in the preceding table for the corresponding *A0/A4* values that you chose. (The *A0* values are listed down the side and the *A4* values are listed along the top.)
4. Select *Save* to save your changes and close the window.

C Patient Training Script

Patient training is conducted using a wizard, shown in the following figure, which provides the recommended script and the controls used to manage the practice alarms. This appendix provides the script that appears in the training wizard.



Training Script

Introduction

Successful use of the Guardian system requires that your patients be trained to correctly identify and respond to Emergency alarms and See Doctor alerts. Specific topics include:

- The purpose of the Guardian system
- The different components of the system (i.e., EXD and IMD)
- The meaning of an Emergency alarm and a See Doctor alert
- How to identify, respond to, and turn off an Emergency alarm and See Doctor alert
- The importance of keeping the EXD close by at all times
- How to recognize and respond when the battery in the EXD must be replaced

Most patients will have no experience with vibration patterns. Initially, you will need to help the patient focus on the distinguishing characteristics of the Emergency alarm and the See Doctor alert vibration patterns.

Also, each patient may perceive the strength of the vibration differently. Thus, you will need to customize the strength of the vibration to match the patient's perception.

The following steps provide a detailed procedure for training your patients.

Caution:
To prevent the auditory and visual alarms on the patient's EXD from being accidentally disabled, never attach the Patient's EXD to the EXD cable for Patient Training - always use the Programmer EXD

Describe the Guardian System

1. Ask the patient to sit near the Programmer - during much of this training session, the patient will use the EXD to turn off alarms and alerts. The patient should not be able to see this screen from where they are sitting.
2. Tell the patient about the IMD and EXD and their functions.

   "Your Guardian system has two major parts:

   1. the Implantable Medical Device, called the IMD, which has been implanted in your chest,

   2. the External Device, or EXD, which you should carry with you at all times.

   The IMD monitors and records your heart's electrical signals 24 hours a day, 7 days a week. The IMD uses this information to vibrate and alert you if problems are detected."

   Show the EXD to the patient and explain its purpose.

   "This is the EXD. You should keep the EXD within 6 feet (1.8 meters) at all times. If your EXD is close by when the IMD starts vibrating, the EXD also starts beeping and a light flashes to indicate the type of alarm. So, keep your EXD with you during the day and near your bed at night."

Discuss Alarms and Alerts

1. Tell the patient about the two types of alarms and what to do when each occurs.

   "There are two types of alarms - an Emergency alarm and a See Doctor alert. The Emergency alarm means that you should seek help immediately by calling an ambulance to take you to the hospital. The See Doctor alert means that you should make an appointment to see the doctor in the next 1 or 2 days."

2. Explain the vibratory pattern for the Emergency alarm.

> **"The Emergency alarm and the See Doctor alert are very different so you can tell them apart. Also, the Emergency alarm feels much more urgent than the See Doctor alert.**
>
> **The Emergency alarm is 5 short vibrations and a short pause, and the See Doctor alert is only 1 short vibration with a long pause between vibrations. Some people think of the Emergency alarm as "fast" and the See Doctor alert as "slow".**
>
> **Let me tell you about the Emergency alarm first.**
>
> **When there is an Emergency alarm, your IMD will vibrate with five short vibrations and a short pause and then five more short vibrations, and so on. The EXD will also beep, but I want to teach you to feel the vibrations first. Most people have never really felt vibration patterns before, but it's easy to learn to feel them.**
>
> **The Emergency alarm was designed so that it will feel urgent and prompt you to take immediate action. The vibration will be in a 3-2, 3- 2 pattern, like this:**
>
> **Brr Brr Brr Brr Brr Brr Brr Brr Brr Brr "**

Demonstrate an Emergency Alarm (IMD Only)

The goal of this section is to teach the patient how the vibration pattern for the Emergency alarm feels.

1. Ensure that the *Session* status (in the "Status" panel) is "Communicating" (green indicator). If not, establish a session.
2. Tell the patient that you are going to play an Emergency alarm.

> **"Now I'm going to play an Emergency alarm on the IMD only. When I play the Emergency alarm, you'll feel the five short vibrations in a 3-2 pattern, then a short pause, and then the five short vibrations again, and so on.**
>
> **If a real Emergency alarm occurs, you can turn it off after 30**
>
> **seconds. We want you to wait 30 seconds to be sure you can identify which alarm you're experiencing before you turn it off - if you don't turn it off, it will play for 5 minutes.**
>
> **First I want you simply to pay attention to the pattern of the five short vibrations."**

3. Select *Save And Test* (in the "Test Settings" panel under *Emergency Alarm*) to play the vibratory alarm.
4. While the alarm is still playing (you will turn it off as part of the next step), ask the patient the following questions.

> **"Do you feel the five short vibrations?"**
>
> **"Do you think you'll be able to recognize this Emergency alarm when it occurs?"**

5. Reinforce the following points.

   "Remember, the five short vibrations with a short pause is an Emergency alarm."

   "If an Emergency alarm occurs, you should immediately call for an ambulance."

   "The five short vibrations and short pauses are intended to feel urgent, so that you know to immediately call for an ambulance."

6. Ensure that the patient can describe the alarm, knows that it is an Emergency alarm, and knows to call an ambulance for an Emergency alarm. It is very important to have the patient describe the pattern of the Emergency alarm, and state the appropriate response (e.g., the pattern is five vibrations in a 3-2 pattern, and I must call an ambulance immediately.) This verbalization helps the patient remember the alarm.

   "Now, you tell me, what does an Emergency alarm feel like and what do you do when it occurs?"

7. Ask the patient to turn off the alarm by pressing the Silence Acclamation Battery button on the EXD.

   "Now, I want you to turn off the alarm. You do this by holding the EXD just over the IMD and pressing the Silence Alarm/Check Battery button."

   "You should hear two beeps. If you hear only one beep, move the EXD a little and try again .The EXD needs to be within 2 in (5 cm) of the IMD."

Set the Emergency Alarm Strength

The goal of this section is to select a vibration strength that will alert the patient, but not be uncomfortable. You will play the Emergency alarm at each of the three strengths, each time asking how the alarm feels to the patient.

"Now I'm going to play the Emergency alarm at three different strengths, and I'd like for you to select the strength that is right for you. Our goal is to select a strength that will alert you, even wake you when you are sleeping, but that will not be too uncomfortable.

After the alarm has played for about 30 seconds, I would like for you to tell me if the alarm is "too weak", "about right", or "too strong"."

When you play the alarm (next step), you will start with the *Medium* strength, but do not tell the patient the strength that's selected because that may influence the patient's rating.

1. Play an Emergency alarm for about 30 seconds at *Medium* strength.
   a. Ensure that the *Session* status (in the Status panel) is *Communicating* (green indicator). If not, establish a session.
   b. Select *Save And Test* to play the alarm.

< Wait 30 Seconds >

c. Ask the patient for a strength rating.

"Is the alarm "too weak", "about right", or "too strong"?"

If the patient expresses difficulty in answering the question, you might rephrase it:

"Would you like for the alarm to be a little stronger or a little weaker or is it about right?"

d. Ask the patient to turn off the alarm.

2. Play an Emergency alarm for about 30 seconds at *Low* strength.

a. Ensure that the *Session* status (in the Status panel) is *Communicating* (green indicator).If not, establish a session.

b. Select *Save And Test* to play the alarm.

< Wait 30 Seconds >

c. Ask the patient for a strength rating.

"Is the alarm "too weak", "about right", or "too strong"?"

If the patient expresses difficulty in answering the question, you might rephrase it:

"Would you like for the alarm to be a little stronger or a little weaker or is it about right?"

d. Ask the patient to turn off the alarm.

3. Play an Emergency alarm for about 30 seconds at *High* strength.

a. Ensure that the *Session* status is still *Communicating* (green indicator).If not, establish a session.

b. Select *Save And Test* to play the alarm.

< Wait 30 Seconds >

c. Ask the patient for a strength rating.

"Is the alarm "too weak", "about right", or "too strong"?"

If the patient expresses difficulty in answering the question, you might rephrase it:

"Would you like for the alarm to be a little stronger or a little weaker or is it about right?"

d. Ask the patient to turn off the alarm.

4. Consulting with the patient, decide which strength is most appropriate. You may have to replay the alarm at different strengths to find the one most appropriate strength. If so, be sure to silence any alarms you play before changing to a new vibration level.
5. Finally, play the alarm at the patient's chosen strength once again to confirm the appropriateness of the vibration strength and to make certain that the selected strength is the last one played.

   Note:
   The last vibration setting played is saved to the IMD. Ensure that you have selected *Save And Test* to save the patient's chosen vibration strength.

6. Record the patient's chosen vibration strength so that you will remember it.

Explain the See Doctor alert to the patient.

"Now I want to tell you about the See Doctor alert. When you have a See Doctor alert, you should make an appointment to see the doctor in the next 1 or 2 days."

"The See Doctor alert is very different from the Emergency alarm. It was designed to get your attention, but to seem much less urgent than the Emergency alarm.

The See Doctor alert has just one short vibration and then a long pause, another short vibration and a long pause, and so on. It is a pattern like this:

Brrr (7 second pause) Brrr "

"You turn off the See Doctor alert the same way you turn off the Emergency alarm - you hold the EXD over the IMD and press the Silence Alarm/Check Battery button.

Like the Emergency alarm, you can turn off the See Doctor alert after it has played for 30 seconds. Again, we want you to wait 30 seconds to be sure you can identify which alarm you're experiencing before you turn it off.

When you turn off the alert, you will hear two short beeps. If you do not turn off the alert, it will play for 5 minutes."

Demonstrate a See Doctor Alert (IMD Only)

The goal of this section is to teach the patient how the vibration pattern for the See Doctor alert feels.

1. If the *Session* indicator in the upper right corner of this window is not Green (*Communicating*), establish a communication session with the patient's IMD.
2. Tell the patient that you are going to play a See Doctor alert.

   "Now I'm going to play a See Doctor alert on the IMD only. First I want you to just pay attention to the pattern - one short vibration and then a long pause, then another short vibration and a long pause, and so on."

3. Select *Save And Test* (in the *Test Settings* panel under *See Doctor Alert*) to play the See Doctor alert.

4. While the alert is still playing (you will turn it off as part of the next step), ask the patient the following questions.

   "Do you feel the one short vibration and the long pause?"

   "Do you think you'll be able to recognize the See Doctor alert when it occurs?"

   "Can you tell that it feels less urgent than the Emergency alarm?"

5. Reinforce the following points.

   "Remember, the See Doctor alert has one short vibration followed by a long pause."

   "When you feel the See Doctor alert, you should make an appointment to see the doctor in the next 1 or 2 days."

   Ensure that the patient can describe the alert, knows that it is a See Doctor alert, and knows to make an appointment to see the doctor in the next 1 or 2 days. It is very important to have the patient describe the pattern of the See Doctor alert and state the appropriate response (e.g., "the pattern is one vibration and a long pause and so on, and I must make an appointment to see the doctor in the next 1 or 2 days "). The verbalization helps the patient remember the alert.

   "Now, you tell me, what does a See Doctor alert feel like and what do you do when it occurs?"

6. Ask the patient to turn off the alert by pressing the Silence Alarm/Check Battery button on the EXD.

Set the See Doctor Alert strength

In this section, we set the vibration strength of the See Doctor alert using the same procedure as that used to set the Emergency alarm strength.

"Now I'm going to play the See Doctor alert at three different strengths, and I'd like for you to select the strength that is right for you. Our goal is to select a strength that will alert you, even wake you when you are sleeping, but that will not be too uncomfortable.

After the alert has played for about 30 seconds, I would like for you to tell me if the alert is "too weak", "about right", or "too strong"."

When you play the alert (next step), you will start with the *Medium* strength, but do not tell the patient the strength that's selected because that may influence the patient's rating.

1. Play a See Doctor alert for about 30 seconds at *Medium* strength.
   a. Ensure that the *Session* status is still *Communicating* (green indicator).If not, establish a session.
   b. Select *Save And Test* to play the alert.

< Wait 30 Seconds >

c. Ask the patient for a strength rating.

"Is the alert "too weak", "about right", or "too strong"?"

If the patient expresses difficulty in answering the question, you might rephrase it:

"Would you like for the alert to be a little stronger or a little weaker or is it about right?"

d. Ask the patient to turn off the alarm.

2. Play a See Doctor alert for about 30 seconds at *Low* strength.

a. Ensure that the *Session* status is still *Communicating* (green indicator). If not, establish a session.

b. Select *Save And Test* to play the alert.

< Wait 30 Seconds >

c. Ask the patient for a strength rating.

"Is the alarm "too weak", "about right", or "too strong"?"

If the patient expresses difficulty in answering the question, you might rephrase it:

"Would you like for the alert to be a little stronger or a little weaker or is it about right?"

d. Ask the patient to turn off the alarm.

3. Play a See Doctor alert for about 30 seconds at *High* strength.

a. Ensure that the *Session* status is still *Communicating* (green indicator). If not, establish a session.

b. Select *Save And Test* to play the alert.

< Wait 30 Seconds >

c. Ask the patient for a strength rating.

"Is the alert "too weak", "about right", or "too strong"?"

If the patient expresses difficulty in answering the question, you might rephrase it:

"Would you like for the alert to be a little stronger or a little weaker or is it about right?"

d. Ask the patient to turn off the alarm.

4. Consulting with the patient, decide which strength is most appropriate. You may have to replay the alert at different strengths to find the one most appropriate for this patient. If so, be sure to silence any alerts you play before changing to a new vibration level.
5. Finally, play the alert at the patient's chosen strength once again to confirm the appropriateness of the vibration strength and to make certain that the selected strength is the last one played.

   Caution:
   The last vibration setting played is saved to the IMD. Ensure that you have selected Save And Test to save the selected vibration strength.

6. Record the patient's chosen vibration strength so that you will remember it.

Tell the patient about the EXD and its auditory and visual indicators

This part of the training discusses the purpose of the EXD and its alarm and alert signals.

"Now that you can recognize the Emergency alarm and See Doctor alert when the IMD vibrates, I want to tell you about the EXD auditory alarms and alerts. Before you leave, I will give you an EXD to take home with you."

"You should keep the EXD with you at all times. It should not be farther away from you than 6 feet (1.8 meters). You should carry it with you during the day and keep it by your bed at night."

Explain that the EXD has both auditory and visual alarm/alert indicators and show the patient where the lights and their labels are located on the EXD.

"When your IMD detects a change in your heart signal and vibrates, it communicates with the EXD, and then the EXD beeps and a light on the EXD flashes."

"There are two lights on the EXD. It is very important to pay attention to the lights. The color and labels provide you with another way to tell which alarm you are experiencing. The red light is labeled Emergency, and the yellow light is labeled See Doctor."

Demonstrate the Emergency alarm on the IMD and EXD together

1. Explain the EXD auditory Emergency alarm.

   "Now, I will play an Emergency alarm where the IMD vibrates and the EXD beeps. This is what an Emergency alarm is like when you have the EXD close by. The Emergency alarm was designed to feel and sound urgent so that you know to immediately call for an ambulance."

   "In addition, the red light labeled Emergency flashes, so you can always look at the light to see what the alarm is."

   Point to the Emergency Alarm light on the EXD.

   "After the alarm has been on for 30 seconds, you can turn it off with the EXD. If

you don't turn it off, it will stay on for 5 minutes - but the red Emergency light will flash for 25 hours, or until your doctor turns it off."

Note:
The patient may notice that the red light does not remain on after you silence the alarm. This is because the EXD behaves differently when cabled to the Programmer.

2. Play an Emergency alarm on both the IMD and the EXD.
   a. Ensure that the *Session* status is still *Communicating* (green indicator).If not, establish a session.
   b. Ensure that the patient's chosen vibration strength is selected in the *Test Settings* panel, under *Emergency Alarm*.
   c. Select *Save And Test* to play the alarm.

      When you select *Save And Test*, the IMD vibrates. In addition, the EXD beeps in synchrony with the IMD, and the red light on the EXD flashes. Let the patient experience this alarm for about 30 seconds Be sure the patient notices the flashing light on the EXD.
   d. Ask the patient to turn off the alarm.
   e. Ask the patient what he or she would do if this alarm occurs to ensure that the patient knows to call for an ambulance immediately.

Explain the reminder alarm

When an emergency alarm occurs and is silenced, the IMD and EXD play the Emergency alarm again, about 15 minutes later. This reminder alarm is intended to remind the patient to call for an ambulance.

"After you have turned off the Emergency alarm, there will be another alarm in about 15 minutes. This is called the reminder alarm.

The IMD will vibrate and the EXD will beep again if it is within range. This is to remind you to call for an ambulance if you haven't already.

You can turn off the reminder alarm after it has been on for at least 30 seconds. It will play for about two and a half minutes if you don't turn it off."

"The reminder alarms will continue every 15 minutes for up to 2 hours unless you turn off the alarms twice. This is to make sure you're aware of the alarm. It is also a good reason to keep the EXD with you at all times so you can turn off the alarms."

"Now you tell me about the Emergency alarm and the reminder alarms, and how you turn them off."

Note:

Make certain the patient is aware that Emergency alarms must be turned off twice.

Demonstrate the See Doctor alert on the IMD and EXD together

1. Explain the See Doctor alert on the EXD.

   "This is what a See Doctor alert would be like if you have the EXD close by. The See Doctor alert was designed to feel and sound less urgent than the Emergency alarm."

   "In addition, the yellow light labeled See Doctor flashes, so you can always look at the light to see what the alarm is."

   Point to the See Doctor Alert light on the EXD.

   "After the alert has been on for 30 seconds, you will be able to turn it off with the EXD. If you don't turn it off, it will stay on for 5 minutes.

   The yellow See Doctor light will flash for 25 hours or until your doctor turns it off. This is to remind you to make an appointment with your doctor."

   Note:
   The patient may notice that the yellow light does not remain on after you silence the alert. This is because the EXD behaves differently when cabled to the Programmer.

2. Play a See Doctor alert on both the IMD and the EXD.
   a. Ensure that the *Session* status is still *Communicating* (green indicator).If not, establish a session.
   b. Ensure that the patient's chosen vibration strength is selected in the *Test Settings* panel, under *See Doctor Alert*.
   c. Select *Save And Test* to play the alert.

      When you select *Save And Test* for the See Doctor alert, the IMD will vibrate. The EXD will beep in synchrony with the IMD, and the yellow light on the EXD will flash. Let the patient experience this alarm for about 30 seconds Be sure the patient notices the flashing light on the EXD.
3. Ask the patient to turn off the alarm.
4. Explain that there are no Reminder alarms for a See Doctor alert.

   "There won't be any reminder alarms for the See Doctor alert. But the yellow See Doctor light will flash for 25 hours or until a doctor turns it off."

5. Make sure the patient knows to make an appointment to see the doctor in the next 1 or 2 days.

Test the Patient: See Doctor alert, IMD only

It is important to play the alarms on the IMD only again to ensure that the patient can identify them. Since you're testing the patient's recognition of the alarms, do not tell him or her which alarm/alert you're playing.

1. Play the See Doctor alert on the IMD only, using the vibration strength already chosen by the patient.

   "Now I'm going to play an alarm on the IMD only again, and I'd like for you to tell me what you would do if the alarm occurs."

   a. Ensure that the *Session* status is still *Communicating* (green indicator).

   b. Ensure that the patient's chosen vibration strength is selected in the *Test Settings* panel, under *See Doctor Alert*.

   c. Select *Save And Test* to play the vibratory alert.

   d. After the See Doctor alert has played for about 30 seconds, ask the patient to turn off the alarm.

2. Ask the patient what he or she would do if the alarm occurs.

   "What would you do if this alarm occurs?"

   Ensure that the patient knows to make an appointment to see the doctor in the next 1 or 2 days if the See Doctor alert occurs.

Test the Patient: Emergency Alarm, IMD only

1. Play the Emergency alarm on the IMD only using the vibration strength already chosen by the patient.

   "Here's another one."

   a. Ensure that the *Session* status is still *Communicating* (green indicator).

   b. Ensure that the patient's chosen vibration strength is selected in the *Test Settings* panel, under *Emergency Alarm*.

   c. Select *Save And Test* to play the vibratory alarm.

   d. After the Emergency alarm has played for about 30 seconds, ask the patient to turn off the alarm.

2. Ask the patient what he or she would do if the alarm occurs.

   "What would you do if this alarm occurs?"

   Ensure that the patient knows to call for an ambulance immediately.

3. If the patient does not know what to do when each alarm occurs, provide more training with IMD-only alarms (you can use *Previous* and *Next* to switch between the two IMD-only alarm types).

Test the Patient: Emergency Alarm, IMD and EXD

Play both an Emergency alarm and a See Doctor alert on the IMD and EXD to confirm again that the patient can respond appropriately to the alarms. Do not tell the patient which alarm you're playing.

1. Ensure that the *Session* status is still *Communicating* (green indicator). If not, establish a session.
2. Play an Emergency alarm at the patient's desired strength by selecting *Save And Test*.
   a. Ask the patient what he or she would do if this alarm occurs.
   b. Hand the EXD to the patient and ask the patient to turn off the alarm.

Test the Patient: See Doctor alert, IMD and EXD

1. Play a See Doctor alert at the patient's desired strength by selecting *Save And Test*.
   a. Ask the patient what he or she would do if this alert occurs.
   b. Hand the EXD to the patient and ask the patient to turn off the alert.
2. If the patient does not know what to do when each of the alarms occur, provide more training (you can use *Previous* and *Next* to switch between the two alarm types).

Tell the patient to call for an ambulance if uncertain about the alarm

If the patient is not certain which alarm is being played, the patient should call for an ambulance. Ensure that the patient can repeat this back to you.

"If you are not sure whether the alarm is an Emergency alarm or a See Doctor alert, you should always call for an ambulance. You should treat the situation as an Emergency.

For example, when the alarm goes off, you might be confused or stressed and not know for certain what the alarm is. If you don't know which alarm it is, you should call for an ambulance."

"So, what do you do if you're not sure what the alarm is?"

Tell the patient to call for an ambulance if symptoms of a heart attack arise

Tell the patient to call for an ambulance if the patient experiences symptoms of a heart attack even if the IMD is not vibrating and/or the EXD is not beeping.

Prepare the Patient's EXD

1. Insert the battery in the patient's EXD if you haven't done so already.
2. Press the EXD's Silence Alarm/Check Battery button repeatedly until you hear the EXD beep. This is necessary due to a common characteristic of the battery's chemistry.

   Note:
   Continue pressing the button until the EXD beeps. If after 20 attempts the EXD still fails to beep, replace the battery.

3. Stress the importance of keeping the EXD close by.

> **"You must keep your EXD within 6 feet (1.8 meters) at all times; otherwise, it may not beep and flash when an alarm occurs.**
>
> **As you saw when we played the sample alarms, the EXD provides a secondary alarm (the beeps and lights). This makes it easier to identify the type of alarm (Emergency or See Doctor) you are experiencing.**
>
> **Also, at night, the beeps may wake you even if the vibration alone doesn't.**
>
> **And finally - if you don't have your EXD close by, you won't be able to turn off the IMD vibration (it will stop on its own after 5 minutes). You should carry your EXD with you during the day and keep it by your bed at night."**

Tell the patient about the EXD battery

> **"Only your doctor can replace the EXD battery because a special type of battery is required. The EXD will not work with a standard AA battery. In addition, using the wrong battery could damage the EXD - so don't try to replace the battery yourself."**

> **"If the EXD battery has low power, you will get a Low EXD Battery warning. The EXD will chirp every 30 seconds but the IMD will not vibrate. If you hear the low battery warning, see your doctor in the next day or two to replace your battery."**
>
> **"You can turn off the Low EXD Battery warning for 12 hours by pressing the Silence Alarm/Check Battery button on the EXD. You don't have to hold the EXD near the IMD to turn off the low battery warning.**
>
> **After 12 hours, the low battery warning will start again, and you can turn it off again by pressing the button on the EXD."**

> **"Check the battery power once a week by pressing the Silence Alarm/Check Battery button on the EXD. It will beep once if the battery is working properly. If the EXD does not beep, call your doctor to get a replacement."**

Give the Patient's EXD to the patient

Write instructions on the back label of the EXD to tell the patient what to do if an Emergency alarm or a See Doctor alert occurs. For example, you might write the number to call and medications to take if an Emergency alarm occurs, and the number to call if a See Doctor alert occurs.

Show the patient the EXD neck cord/belt case and demonstrate how to use them

Instructions for attaching the neck cord to the EXD are provided in the *Patient Manual for the Guardian™ System*.

Give the patient the Guardian™ System Patient Identification Card and Patient Manual

- Complete the *Guardian™ Patient Identification Card* and review its content with the patient.

- Tell him or her to keep the card close by at all times in a convenient place, such as a wallet.
- Give the patient the *Patient Manual for the Guardian™ System*.
- Using the Patient Manual, review with the patient the information on potential electromagnetic interference, the use of cell phones, what to do when going through security systems, and medical precautions.

Training Complete!

The vibration settings that have been saved in the IMD are shown in the *Test Settings* panel.

Select the *Finish* button below to close this window.

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