AngelMed Guardian® Implantable Medical Device (IMD) Model AMSG3

User's Guide

IS-1

AngelMed Guardian®
MODEL# AMSG3
S/N JH0021762
AngelMed
USA

AngelMed®

Fold Line

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Contents

1   Introduction

The AngelMed Guardian® Implantable Medical Device (IMD) is an implantable programmable device that monitors the patient's electrogram, vibrates to warn the patient of alarms and alerts, and stores electrogram signals and other data. The IMD is one of the primary components of the AngelMed Guardian system.

How supplied – The IMD is supplied in a sterile tray for introduction into the operating field. The tray contains one IMD and a torque wrench. The outer box contains literature.

About this manual – This document describes the IMD and provides implantation procedures, as well as an outline of the Pre-Implant Check and Post-Implant Setup procedures. For detailed information on these procedures using the Programmer, see the *AngelMed Guardian Programmer Application User's Manual.*

Available Literature

The following documents provide information relevant to the AngelMed Guardian system.

- ♦ *AngelMed Guardian® External Device (EXD) Model EXD-001 User's Manual*
- ♦ *AngelMed Guardian® Programmer Application User's Manual*
- ♦ *Patient Manual for the AngelMed Guardian® System*
- ♦ *User's Manual or Instructions for Use of the Angel Medical Systems-supplied pacing lead*

2   System Overview

The AngelMed Guardian system monitors and detects changes in patients' electrograms, using baseline electrograms from the previous day for comparison. If a change exceeds a pre-specified threshold, the system warns the patient and stores pertinent data for subsequent review. Two levels of warnings are possible:

♦ Emergency alarms, for significant events where the patient immediately calls for an ambulance

♦ See Doctor alerts, for less-significant events where the patient makes an appointment to see the doctor in the next 1 or 2 days

System Components

The AngelMed Guardian system consists of the IMD plus the following components:

Lead – an Angel Medical Systems-supplied IS-1, currently-marketed, active fixation, steroid eluding pacing lead that attaches to the apex of the right ventricle.

External Device (EXD) – a hand-held telemetry device that provides alarms and alerts via beeps and a red or yellow flashing indicator light, and is used to silence alarms and alerts. The EXD is also used for communication between the Programmer and the IMD.

Programmer – a customized computer that allows the physician to program IMD parameters and alarm settings for each patient. It also enables the physician to retrieve and review data collected by the IMD.

The IMD is programmed using the AngelMed Guardian Model Prog-003 Programmer running software version 3.6 or higher.

This booklet summarizes some of the tasks that can be performed with the Programmer. For detailed information on Programmer-related tasks, see the *AngelMed Guardian Programmer Application User's Manual*. You may also consult the Programmer online Help.

Indications & Contraindications

Indications: The AngelMed Guardian IMD is an implantable cardiac monitor indicated for use to alert patients at risk for acute coronary syndrome to ST segment shifts indicating coronary ischemia. The device is indicated to reduce the probability of death, a new Q wave MI, and late arrival at a medical facility (>2 hours following ST shift detection) for patients having a confirmed thrombotic closure of a coronary artery with or without associated symptoms.

Device alerting functionality following implantation is indicated to decrease the time-to-door following a confirmed coronary occlusion. In patients at risk for coronary ischemia, the AngelMed Guardian system alerts patients to coronary occlusion following a ruptured plaque, as well as high, low and irregular heart rhythms resulting in new arrhythmia diagnoses and improved beta-blocker management. Additional diagnoses that may result from the AngelMed Guardian system alerts include rate-induced bundle branch block and transient heart block that may require a therapeutic device.

The presence of the AngelMed Guardian system with alerting enabled has also demonstrated statistically and clinically significant improvements in patient quality-of-life using the Macnew validated quality-of-life instrument.

Note:
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.

Contraindications: Do not implant the IMD in:

♦ Patients with cognitive impairment that would prevent recognition of alarms

♦ Patients who cannot feel the vibration from the implanted device (IMD)

♦ Patients with implanted pacemaker, ICD or CRT devices

♦ Patients where a pacemaker lead cannot be placed safely

See *Precautions* on page 14 for additional considerations regarding IMD implantation and operation.

3 **IMD Device Description**

The IMD serves two fundamental functions:

♦ To detect an ST shift – in other words, a change in the ST deviation of a patient's electrogram[1]

♦ If an ST shift occurs, to warn the patient to seek immediate medical help, by vibrating in a recognizable pattern

In addition to ST shift, the IMD detects other types of electrogram changes, such as high or irregular heart rates. Each type of electrogram change is called an event. The physician can specify the type of warning – either Emergency alarm or See Doctor alert – that is associated with each event.

See the *AngelMed Guardian Programmer Application User's Manual* for detailed information.

Data Acquisition, Characterization, and Storage

Data Acquisition Modes

The IMD supports the following data acquisition modes:

♦ Normal data acquisition mode – The usual means by which the IMD collects patient data. The IMD collects a 10-second electrogram segment every 30 or 90 seconds, depending on the characterization of the previous segment.

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[1] ST deviation is the voltage difference between the ST and PQ segments. Mathematically: ST deviation = ST segment – PQ segment

♦ Post-emergency alarm data acquisition mode – Occurs after the IMD has detected an event associated with an emergency alarm. In this mode, the IMD collects a segment every minute for 24 minutes and then every 15 minutes for 6 hours. After 6 hours and 24 minutes, the IMD automatically reverts to normal data acquisition mode. The IMD does not try to detect additional events during this time period.

Data Characterization and Detection of Alarm Conditions

After an electrogram segment has been collected, it is characterized by heart rate and ST shift. The ST shift categorization is made by comparing this electrogram segment to a baseline segment collected nominally over the previous 24 hours. For each patient the physician sets the threshold for designating an ST shift event.

Using the heart rate and ST shift categorizations, the segment is classified, and the classifications of the last several segments are checked to determine if an event has been detected. If, for example, three consecutive segments are classified as "normal heart rate with a positive ST shift," then an event has been detected. Examples of events include positive or negative ST shifts, high heart rate, an ST shift at an elevated heart rate, and low heart rate.

With some exceptions, the events can be mapped to one of the following alarm types:

♦ Emergency

♦ See Doctor

♦ None (i.e., save data in the See Doctor manner but don't alert the patient)

♦ Ignore (i.e., neither save the data nor alert the patient)

The physician can customize which alarm type is generated for each kind of detected event. For a list of events and their default alarm type assignments, see the *Alarm Configuration Window* on page 52. For a detailed description of alarm type configurations, see the *AngelMed Guardian Programmer Application User's Manual.*

Data Storage

The IMD stores electrogram signals, IMD parameters, and patient data. Electrogram signals are recorded and stored in 10-second segments. In addition to current data, the IMD can save up to two Emergency alarms and up to six See Doctor alerts.

Stored segments may include:

♦ Current Data – up to 129 electrogram segments that were captured immediately prior to data retrieval

♦ Pre-Emergency Alarm Data – 24 electrogram segments that occurred prior to the detection of the Emergency alarm event and the hourly baseline segment for the hour in which the event occurred

♦ Post-Emergency Alarm Data – the 48 electrogram segments that occurred after the detection of an Emergency alarm event

♦ Pre-See Doctor Alert Data – the three electrogram segments that led up to the detection of a See Doctor alert and the hourly baseline segment for the hour in which the event occurred

♦ Baseline Segment Memory – 24 electrogram segments, one for each hour of the preceding 24 hours

♦ Histogram Information – ST deviation histogram information

For a detailed description of data collected by the IMD, see the *AngelMed Guardian Programmer Application User's Manual.*

Vibration Patterns

The IMD vibration pattern is different for emergency alarms than for See Doctor alerts.

Emergency alarms – consist of a repeating sequence of five short vibrations in a 3-2 sequence:

Brrrr–Brrrr–Brrrr   Brrrr–Brrrr

See Doctor alerts – consist of a repeating sequence of a half-second vibration, followed by a 7-second pause.

Brrrr ←——————— 7 sec ———————→ **Brrrr**

Vibration magnitudes can be set to one of three levels using the Programmer. For more information, see the *AngelMed Guardian Programmer Application User's Manual*.

Wireless Telemetry

The IMD communicates via wireless telemetry to and from the EXD. The IMD is capable of both near- and far-field telemetry.

Near-Field Telemetry

Near-field telemetry is used to silence IMD alarms and establish far-field communication sessions between the IMD and EXD. The EXD initiates all communication sessions. Near-field telemetry is unidirectional (the IMD can only receive) with a communication distance of approximately 2 in (5 cm).

Far-Field Telemetry

Far-field telemetry is bidirectional and is used for sending an alarm or alert from the IMD to the EXD, for retrieving stored IMD data, and for sending configuration parameters from the Programmer to the IMD. The maximum far-field communication distance is approximately 6 ft (1.8 m). The maximum distance for retrieving data and setting IMD parameters may be less depending on the distance and orientation of the EXD. The IMD's far-field communication is enabled by the helical antenna in the IMD header.

Radiopaque Identifier

Each IMD has a tungsten-stamped plate inside the header for non-invasive identification. This radiopaque identifier is the IMD model number, AMSG3.
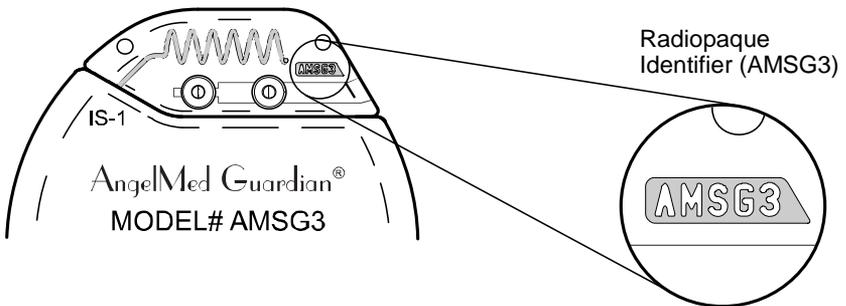
Certifications

FCC Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105(b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, the user is encouraged to try to correct the interference by one of the following measures:

◆ Reorient or relocate the receiving antenna.

◆ Increase the separation between the equipment and receiver.

◆ Consult the dealer or an experienced radio/TV technician for help.

(Part 95.1215(a))

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

(Part 95.1217(a)(1))

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services, and must accept any interference received, including interference that may cause undesired operation.

FCC ID: THL-IMDAMSG3

SAR

This portable transmitter with its antenna has shown compliance with FCC's SAR limits for general population / uncontrolled exposure.

The antenna used for this device must not be co-located or operating in conjunction with any other antenna or transmitter.

4 Storage, Handling, and Resterilization

Device storage. Store the device in a clean area, away from sources of electromagnetic interference. For additional details, see *Environmental Specifications* on page 47.

Drop limits

♦ **Packaged IMD.** If the packaged IMD is dropped from a height of 3 ft (0.9 m) or more, contact your AngelMed representative for a replacement.

♦ **Unpackaged IMD.**

    – If the unpackaged IMD is dropped outside the sterile operating field, contact your AngelMed representative for a replacement.

    – If the unpackaged IMD is dropped inside the sterile field, from a height of 12 in (30 cm) or more onto a hard surface, contact your AngelMed representative for a replacement.

Package integrity. Do not use the IMD if the packaging is wet, punctured, opened, or damaged, because the integrity of the sterile packaging may be compromised. Return the device to your AngelMed representative.

No resterilization. Angel Medical Systems has sterilized the IMD with ethylene oxide prior to shipment. Do not resterilize the device.

Single-use only. Do not re-implant an explanted IMD.

Temperature equilibration. After cold storage, allow the device to reach room temperature before programming or implanting the device. Cold storage temperatures may affect initial device function.

Use By date. Do not implant the device after the "Use By" date because battery longevity may be reduced.

Opening the Package. If the IMD passes its Pre-Implant Check inspection, which is discussed on page 23, you can remove it from its packaging. The package's outer tray can be opened in non-sterile surroundings. When opening the inner tray, you must observe standard sterile practices.

Outer Tray
Seal

Inner Tray
Seal with
Removal Tab
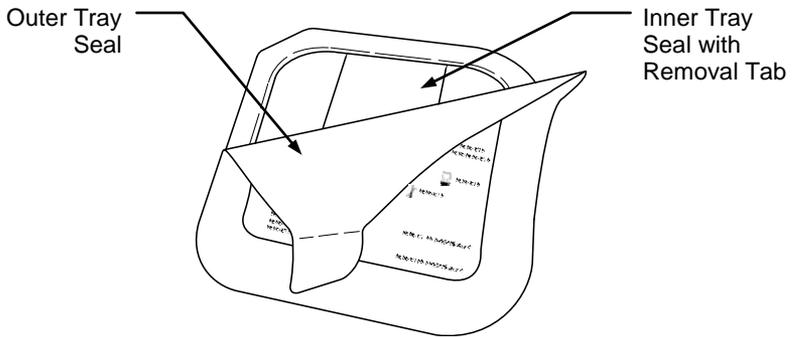
5   Precautions

General

Co-implantation: The AngelMed Guardian system is
contraindicated in patients who have previously been implanted
with a pacemaker or cardioverter-defibrillator. The AngelMed
Guardian system is not designed to monitor electrograms in the
presence of pacing signals generated by these devices.

The AngelMed Guardian system has not been evaluated for
implantation with other electronic implantable medical devices.

Patient compliance: The AngelMed Guardian system should not be
implanted in a patient in whom the physician lacks confidence in
the ability or desire of the patient to understand and
appropriately respond to the alerts and alarms from the device.

Lead: The IMD is intended for use only with the lead supplied by
Angel Medical Systems (i.e., a standard IS-1, currently-
marketed, active fixation, steroid eluding pacing lead).

Contraindications: The *Contraindications* section on page 4 lists
additional precautions that are associated with the AngelMed
Guardian system.

Implantation:

♦ The IMD is intended for subcutaneous implantation in a left
pectoral pocket. Do not implant the IMD in any other location.

♦ For reliable data transmission, implant the device within 2 in
(5 cm) of the surface of the skin.

♦ Implantation should not be attempted if venous access is inadequate to support placement of the endocardial lead in the apex of the right ventricle.

♦ The AngelMed Guardian system has not been evaluated for implantation in patients with non-sinus cardiac rhythm, 2nd and 3rd degree atrioventricular blocks, or right or left bundle-branch blocks.

Twiddler's Syndrome: Advise patients against manipulating the IMD since it may result in lead damage or lead displacement.

Adverse Environmental Conditions: Tell patients that they need to be mindful of the effects of adverse environmental conditions such as EMI and extreme temperatures. These topics are discussed in this manual as well as in the patient's manual.

Potential Adverse Effects

♦ Air embolism

♦ Bleeding

♦ Cardiac perforation

♦ Cardiac dissection

♦ Damage to the vessel at the catheter insertion site

♦ Device failure resulting in removal or replacement

♦ Erosion

♦ Extracardiac stimulation (phrenic nerve, diaphragm, chest wall)

♦ False positive ST shift alarm - device alarms when there is no clinically relevant ST shift

♦ Allergic reaction

♦ Body rejection phenomena including local tissue rejection

♦ Cardiac tamponade

♦ Chronic nerve damage

♦ Death

♦ Endocarditis

♦ Excessive fibrotic tissue growth

♦ Extrusion

♦ False negative ST shift alarm - risk of the device not detecting all ST shift events

- Formation of fibrotic tissue, local tissue reaction Fluid accumulation
- Induced ventricular ectopy
- Infection
- Keloid formation
- Lead migration/ dislodgment
- Myocardial irritability
- Nausea and vomiting
- Palpitations
- Pericardial rub
- Procedure related, random component failure
- Stroke (brain attack) from a clot being dislodged by the catheter
- Thrombosis
- Valve damage (particularly in fragile hearts)
- Venous perforation
- Ventricular fibrillation

- Formation of hematomas or cysts
- Ischemia
- Lead abrasion and discontinuity
- Loss of sensing due to dislodgement or mechanical malfunction of the lead
- Myocardial damage
- Pain in shoulder or arm
- Pericardial effusion
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thromboemboli
- Vascular complications, which may require vessel repair
- Venous occlusion
- Vein wall rupture
- Visible bump at implant site, may cause discomfort under clothing (e.g.,brassiere straps)

Medical Therapy Precautions

Note:
Therapies where electrical current passes through the body may interfere with IMD operation and cause it to alarm if there is no heart problem, or not alarm if there is a problem. At your discretion, you may advise your patients to visit your office so that you can temporarily disable IMD alarms if they need to undergo such therapy.
Alarms are temporarily disabled from the Programmer's *Edit Alarm Configuration* window. See the *AngelMed Guardian Programmer Application User's Manual* for more information.

Diathermy: Avoid diathermy. Diathermy may damage the IMD and injure the tissue near the implanted lead.

Electrosurgical cautery: Electrosurgical cautery may damage or interfere with the IMD. If electrocautery is necessary, keep the current path and ground plate as far away from the IMD and lead system as possible. Confirm IMD operation after treatment.

Electrical therapies: Any treatment that uses therapeutic levels of electricity, like electro-acupuncture or electro-muscle stimulation, may damage or interfere with your IMD. If electrical therapy is performed, medical personnel should keep the current path as far away from the IMD and lead system as possible. Confirm IMD operation after treatment.

External defibrillation: External defibrillation may damage the IMD and myocardium near the lead. Minimize current flowing through the IMD and lead system by observing the following:
  – Position defibrillation paddles as far as possible from the IMD and lead system
  – Use the lowest clinically appropriate energy output

Confirm IMD operation after treatment.

High radiation sources: Do not direct high radiation sources such as cobalt 60 or gamma radiation at the IMD. If a patient requires radiation therapy in the vicinity of the IMD, place lead shielding over the device to prevent radiation damage. After treatment, you should periodically verify IMD operation since damage from radiation may not be immediately detectable.

Lithotripsy: Lithotripsy may permanently damage the IMD. Avoid it unless the therapy site is not near the IMD or lead.

Magnetic resonance imaging (MRI): Do not use MRI on patients who have an IMD. MRI may damage the device and injure the myocardium near the implanted lead.

Radiofrequency (RF) ablation: The effect of RF ablation on the IMD has not been evaluated. RF ablation may damage the IMD or cause it to malfunction. To minimize RF ablation risks:

– Temporarily turn off all alarms using the Programmer's *Edit Alarm Configuration* window. See the *AngelMed Guardian Programmer Application User's Manual* for instructions.

– Avoid direct contact between the ablation catheter and the IMD and lead.

– Position the ground plate so that the current pathway does not pass through or near the IMD and lead.

– After completing the procedure, turn the alarms back on.

Confirm IMD operation after treatment.

Transcutaneous Electrical Nerve Stimulation (TENS): TENS may interfere with device function. To reduce interference, place the TENS electrodes close to one another and as far as possible from the IMD and lead system. Confirm IMD operation after treatment.

Ultrasound therapy: Avoid exposing the IMD to therapeutic ultrasound because it can damage the device and harm the patient. If the patient needs ultrasound therapy, medical personnel should not direct the therapy at the IMD.

Electromagnetic Interference Precautions

The AngelMed Guardian system is protected against most sources of electromagnetic interference (EMI). However, sources of strong EMI can damage the IMD and EXD, and interfere with the wireless communication between them.

Sources of Strong EMI

Home appliances that are not in good working order.

High-voltage power lines.

Automobile ignition systems. Patients should not work under the hood of a car when the engine is running. Patients can, however, drive or be a passenger in a car.

Ignition systems of other internal combustion engines, like gasoline-powered lawn mowers and leaf blowers. It's generally safe to work around running internal combustion engines, but patients should limit their exposure to ignition-system parts.

Industrial equipment such as arc welders, large electro-magnets, induction furnaces, and very large or defective electric motors.

Small motor-driven appliances like hair dryers, electric shavers, power tools, radio transmitters, and transmitters for radio-controlled equipment or toys. Patients should not hold small motor-driven appliances close to their IMD and EXD.

Some medical equipment such as MRIs. See *Medical Therapy Precautions* on page 17 for further details.

> **Warning:**
> Patients should stay away from high-powered energy sources like MRIs and large industrial motors and generators. Getting too close can damage the IMD and injure the myocardium near the implanted lead.

> **Warning:**
> Advise patients to be aware of any signage that warns those with pacemakers and other implanted devices to stay away. Such environments often have high-powered energy fields, which can interfere with the operation of the IMD.

Cell Phone Precautions

Cell phones emit EMI, but can safely be used with the AngelMed Guardian system provided that patients do the following:

♦ Hold the phone at least 6 in (15 cm) away from the IMD and EXD. If the cell phone transmits above 3 watts, patients should hold the phone at least 12 in (30 cm) away from the IMD and EXD.

 If the patient does not know the transmit power of the cell phone, the patient should assume that the cell phone transmits at the higher power and should hold the phone at least 12 in (30 cm) away from the IMD and EXD.

♦ Store the phone at least 6 in (15 cm) away from the IMD and EXD. This is important because some phones send signals when in the Listen or Standby mode.

♦ Patients should never carry the phone in a shirt or breast pocket, which would place the device over the IMD.

Anti-theft Systems

Anti-theft systems that are used in stores, libraries, and other places can interfere with the IMD and EXD if the patient stays within 2 feet of them. Patients should observe the following precautions.

♦ Pedestal systems are usually placed at store exits. Patients should walk past the pedestals at a normal pace and not linger.

♦ Tag deactivator systems are often used at stores and library checkout counters. Patients should stay at least 2 feet away from them while conducting business.

♦ Patients should not operate the checkout counter at a store or library where such systems are used.

Security Systems

Security systems such as those used in airports will probably not interfere with the IMD and EXD. Patients should walk through them at a normal pace, and not linger near them.

The IMD and EXD have metal parts that may set off an airport security system alarm. If this happens, the patient should show the Identification Card to the security officers. If they use a handheld wand to perform a search, the patient should ask them to work quickly and avoid holding the wand over the IMD.

Physical Activity Precautions

Patients should be advised to not engage in contact sports like football since the EXD, IMD, or lead may get damaged. Also, they should be encouraged to consult with you before doing strenuous or repetitive upper-body exercise like weight lifting or softball.

6   Implant and Setup Procedures

Proper surgical procedures and sterile techniques are the responsibility of the physician. The following procedures are provided for information only. Each physician must apply the information in these procedures according to professional medical training and experience.

Refer to the *AngelMed Guardian Programmer Application User's Manual* for detailed information about all of the implant and setup procedures performed using the Programmer. This *IMD User's Manual* provides only an outline of these procedures.

IMD implant and setup procedures include the following steps:

1. Conduct the Pre-Implant Check procedure.

2. Implant the lead.

3. Connect the lead to the IMD.

4. Implant the IMD.

5. Conduct the Implant Verification procedure.

6. Secure the IMD and close the incision.

7. Verify transdermal communication.

8. Conduct the Post-Implant Setup procedure.

9. Set an Appointment for Initial Programming.

1. Conduct the Pre-Implant Check Procedure

Note:

This procedure should be performed with the IMD in its sealed sterile tray.

Refer to the *Pre-Implant Check* chapter of the *AngelMed Guardian Programmer Application User's Manual* for detailed information about these procedures.

1. Create a new patient record in the Programmer and enter the relevant details in the *New Patient Record* window.

2. Select the new patient on the Main Programmer window.

3. With the IMD in its sealed sterile tray, establish a session between the Programmer and the IMD. The session may be established with the sterile tray still in the IMD's outer box.

Warning:

If you cannot establish a session between the Programmer and the IMD, do not implant the IMD. Obtain another IMD for implantation. Return the IMD to your AngelMed representative.

4. Select *Implant → Pre-Implant Check*.

– The Programmer automatically populates the IMD serial number into the patient record (if it was not manually entered in Step 1).

– Ensure the *Diagnostics* area of the *Pre-Implant Check* window indicates that the *IMD Diagnostics* have passed.

–   Verify that the IMD *Battery Status* indicator is green (i.e., Good).

> **Warning:**
> If the Programmer's IMD *Battery Status* indicator is yellow (i.e., Low) or red (i.e., Replace), do not implant the IMD. Obtain another IMD for implantation. Return the IMD with the low battery to your AngelMed representative.

2. Implant the Lead

> **Warning:**
> To ensure the proper operation of the IMD, you should review the *Precautions* section on page 14 for information on the implant site.

> **Warning:**
> Ensure that an external defibrillator is immediately available.

1. Implant the endocardial lead using standard lead implantation techniques, ensuring that the lead tip is actively fixated into the apex of the right ventricle. This location is necessary for proper functioning of the IMD.

2. Conduct both unipolar and bipolar lead testing to confirm proper placement and fixation. For detailed instructions, see the documentation that accompanies the endocardial lead.

> **Warning:**
> Improper lead placement may affect the AngelMed Guardian System's ability to function as intended.

3. Connect the Lead to the IMD

In this procedure, use the supplied torque wrench to connect the lead to the IMD.

Header — Suture Holes

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USA

Septums with
Setscrews
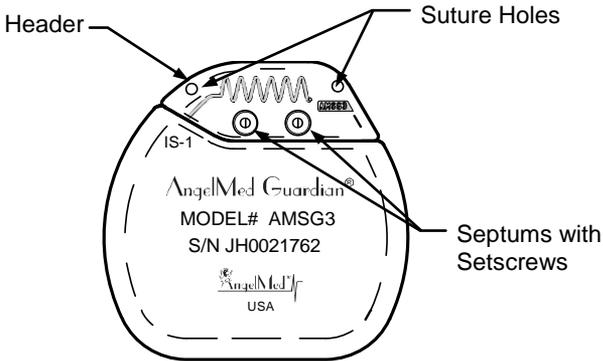
Caution:
Only use the torque wrench supplied with the IMD. This wrench is designed to prevent damage to the device from over-tightening a setscrew.

1. Insert the torque wrench through either of the IMD header septums and turn the corresponding setscrew clockwise until it stops and the torque wrench clicks once.

Torque Wrench

Black Line
(Use to Count
Number of Rotations

Septums with
Setscrews
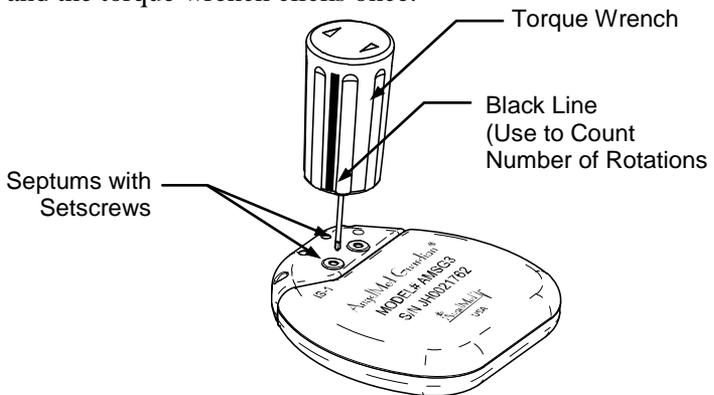
2. Observing the black line on the torque wrench handle, turn the same setscrew counterclockwise six full rotations to provide clearance for the lead connector pin.

3. Repeat Steps 1 and 2 for the other setscrew.

4. Wipe off any body fluids on the connector pin of the lead.

> **Note:**
> To facilitate insertion, sterile water may be used to lubricate the lead connector pin.

5. Insert the lead connector pin into the IMD header receptacle until the connector pin tip is fully seated inside the header. You can see the end of the connector pin through the header. Ensure that the end of the connector pin extends beyond the innermost setscrew and all the way to the end of the header cavity.

Tip of Lead Connector Pin

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AngelMed
USA

Endocardial Lead
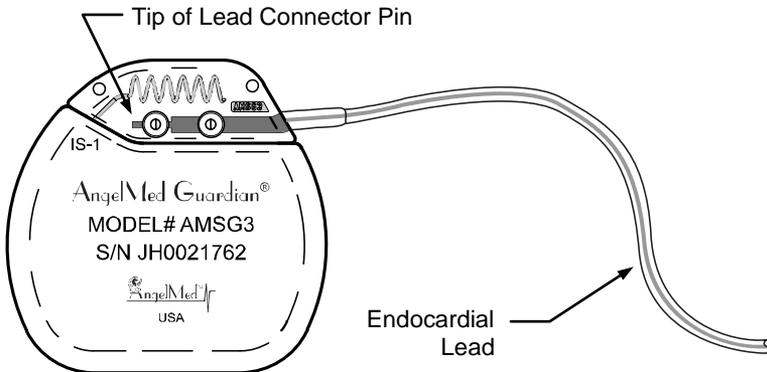
6. Insert the torque wrench through either IMD header septum and into a setscrew. Turn the setscrew clockwise until the torque wrench clicks once.

7. Repeat Step 6 for the other setscrew.

8. Test the connection by gently pulling on the header while holding the lead. If there is movement, loosen the setscrews and reinsert the lead as described in Steps 1 through 6.

4. Implant the IMD

1. Prepare a pocket subcutaneously or submuscularly in the left pectoral region. Ensure that the pocket will position the device header within 2 in (5 cm) of the surface of the skin.

2. Coil any excess lead length behind the IMD while inserting the IMD into the pocket. The IMD can be positioned with the etched label facing either toward or away from the skin surface; however, the IMD header should be proximal to the clavicle.

5. Conduct the Implant Verification Procedure

> **Note:**
> Detailed information for these procedures is provided in the *Implant Verification* chapter of the *AngelMed Guardian Programmer Application User's Manual.*

Prior to closing the incision, you need to ensure the IMD can sense the cardiac signal and can communicate with the Programmer through the skin. To do this, perform the following steps.

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

2. Establish a communication session with the IMD. Since the IMD will be in the sterile field, hold the EXD inside a sterile bag (e.g., video camera drape) while establishing the session.

3. Select the *Retrieve Data* button on the Main Programmer window to retrieve data.

4. From the *Dataset Retrieval Amount* window, select *Minimum* for the quickest data retrieval.

5. After the data retrieval completes, select *Close* on the *Retrieve Implant Data* window.

> **Note:**
> If the Programmer reports any dataset anomalies in the *Retrieve Implant Data* window, you should ignore them at this time.

6. From the Main Programming window, open the dataset that you just retrieved.

7. 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.
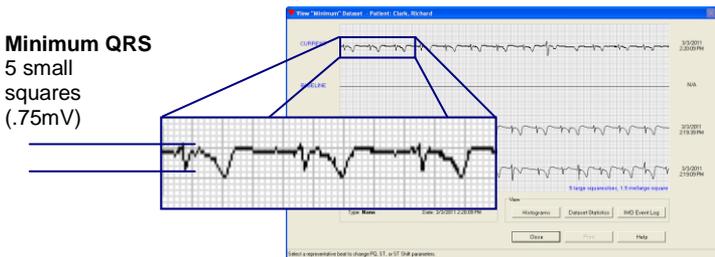
8. Do one of the following:
  – If the Programmer shows a continuous cardiac signal with the proper minimum amplitude, proceed to the next step to close the incision.
  – If the Programmer shows either no cardiac signal (i.e., flat line) or a cardiac signal that is not continuous:
    • Recheck the lead and IMD header connections. To obtain an adequate amplitude, you may need to reposition the lead tip.
    • Verify the IMD is making good contact with the surrounding tissue in the pocket.
    • Wait at least 30 seconds. Then retrieve and review the segments again. If you are still unable to obtain a continuous cardiac signal, exchange the IMD for another one and again verify the IMD senses the cardiac signal.

6. Secure the IMD and Close the Incision

1. To prevent migration, suture the IMD securely within the pocket, using the IMD suture holes.

Suture Holes

2. Suture the pocket incision closed.
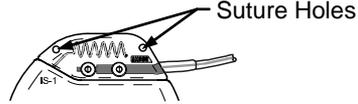
7. Verify Transdermal Communication

Establish a final communication session between the IMD and Programmer to ensure that you can communicate with the IMD through the skin.

1. Ensure the patient's record in the Programmer is open.

2. Establish a communication session with the IMD.

3. Select the *Retrieve Data* button on the Main Programmer window to retrieve data.

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

5. After the data retrieval completes, select *Close* on the *Retrieve Implant Data* window.

> **Caution:**
> 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 by selecting the *Defer Issues* button.

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

8. Conduct the Post-Implant Setup Procedure

Post-Implant Setup typically occurs on the day following
implantation because you need to provide sufficient time for the
patient's heart signal to stabilize. Post-Implant Setup comprises two
main tasks:

♦ Setting the IMD's signal gain

♦ Setting the heart rate bins

Setting the Signal Gain

1. Open the patient record in the Programmer.

2. Establish a communication session with the IMD.

3. Select the *Retrieve Data* button on the Main Programmer
window to retrieve data.

4. From the *Dataset Retrieval Amount* window, select *Some* to
retrieve all the hourly baselines plus the eight most recent
electrograms.

5. After the data retrieval completes, check the status messages in
the *Diagnostics* pane of the *Retrieve Implant Data* window.
Expect to see:

– *Number of baselines stored* – Check that the number of stored
baselines roughly equals the number of hours since the
implant.

– *Patient's current heart rate* – Verify that the indicated heart
rate matches the patient's actual heart rate

– *Default Baseline R-Wave Height/ST Deviation* – Indicates the
values used for the default baseline. No action on your part is
required.

– *Current Gain Setting* – Indicates the current IMD gain
setting.

6. Do one of the following:

- – If the gain setting is good (*Current Gain setting is OK.*), select either *Defer Issues* or *Close* (whichever is available) and then proceed to *Setting the Heart Rate Bins* on page 33.

- – If the gain setting requires adjusting (*Current Gain setting is too High/Low and should be adjusted.*), select *Address Issues* and continue to the next step.

7. From the *Gain Check* window, select the *Adjust Gain* button.

8. Observe the progress bar in the *Evaluating Gain Change* window.

9. When the progress bar completes, re-establish a communication session with the IMD and select *OK*.

10. Again, check the gain status in the *Gain Check* window and perform Step 6 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 your AngelMed representative for assistance.

---

11. Continue with the next task, *Setting the Heart Rate Bins*.

Setting the Heart Rate Bins

1. Retrieve data by selecting the *Retrieve Data* button on the Main Programmer window.

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

3. 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.

4. From the Main Programmer window, open the *None* dataset that you just retrieved.

5. From the *View Minimum Dataset* window, select any beat from the first, third, or fourth segments.

6. From the *Edit Implant Parameters* window, review the Low, Normal, and High heart rate bin current settings and change them if appropriate.

7. Save the new settings by selecting the *Save* button. (If you have elected to keep the original settings, select *Cancel* and then go to Step 12.)

8. 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 AngelMed representative.

9. The Programmer saves the heart rate parameter settings to the patient's IMD.

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

11. Retrieve IMD data again by selecting Retrie*ve 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.

12. The Post-Implant Setup process has concluded. Be sure to complete the *AngelMed Guardian IMD Patient Information 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.

9. Set an Appointment for Initial Programming

Establish a time for the patient to return for Initial IMD Programming. Initial Programming sets most of the IMD's operating parameters and is conducted about 7 to 14 days after Post-Implant Setup. (For further details, see the *AngelMed Guardian Programmer Application User's Manual*.)

7   Patient Follow-up

Follow-up Frequency

Patients should be seen for follow-up at 1, 3, 6, and 12 months after the implant, and every 6 months thereafter.

Follow-up Tasks

During follow-up visits, physicians should:

♦ Check IMD battery status.

♦ Retrieve and review stored electrograms.

♦ Confirm that IMD parameters are set appropriately and modify them if necessary.

♦ Replace the patient's EXD battery every 6 months if the patient has not already done so.

♦ Confirm the IMD vibration settings are still appropriate

♦ Review key instructions with the patient. For example:

– Responding to Emergency alarms and See Doctor alerts

– Checking EXD battery power

– Ensuring the patient has their ID card and knows where their Patient Manual is.

For details on these procedures, see the *AngelMed Guardian Programmer Application User's Manual*.

8   Explant Procedure

After about 3.5 years (typical use), the IMD sets the elective
replacement indicator (ERI) flag, indicating a low battery. When the
ERI flag is set, the IMD issues a See Doctor alert to the patient. At
this time, the patient must be scheduled to have his or her IMD
replaced within a month's time. (For additional details on the ERI
flag, see page 48.) You can also determine IMD battery status any
time you retrieve IMD data. The battery status is reported by the
Retrieve Implant Data window on the Programmer.

The IMD should also be explanted after the death of a patient.

> **Warning:**
> In the event of patient death, the IMD must be explanted for
> either or both of the following reasons.
> ♦ Some jurisdictions require that battery-operated devices
>   be explanted due to environmental concerns.
> ♦ IMDs contain sealed chemical power cells and
>   capacitors that may explode if incinerated.

Before you Begin

Ensure that you have the required tools and replacement devices
before starting the procedure.

If replacing an IMD, verify that you have a:

♦ Replacement IMD (sterile torque wrench supplied in package)

♦ Programmer to retrieve data from the old IMD and program the
  replacement IMD

If explanting an IMD without replacing it, verify that you have a:

♦ Sterile torque or hex wrench to loosen the connector screw that secures the lead to the IMD

♦ Lead cap to cover the proximal end of the lead (if the lead is to be abandoned)

♦ Programmer to retrieve data from the old IMD

Explanting the IMD

This section describes how to:

♦ Replace a Model AMSG3 IMD with another Model AMSG3 IMD

♦ Replace a Model AG101 IMD with a Model AMSG3 IMD

♦ Explant and not replace a Model AMSG3 IMD

For additional information on the Model AG101 IMD, see the *AngelMed Guardian® Implantable Medical Device (IMD) Model AG101 User's Guide*.

To replace an IMD, perform the following procedure in its entirety.

To explant an IMD without replacing it, you need only complete Steps 4 through 9.

Always return any explanted device(s) as discussed in *After Explanting the IMD* on page 44.

1. Prior to the date of explantation, contact Angel Medical Systems and identify the serial number of the IMD that you intend to replace. Angel Medical Systems uses this information to determine if any internal parameters have been set for the patient. If they have, an AngelMed representative will arrange to set these parameters in the replacement IMD.

2. On the date of explantation, create another patient record and conduct a Pre-Implant Check on the replacement IMD to prepare it for use.

> **Note:**
> When creating another patient record, the Programmer does not allow you to use the same first name-middle initial-surname combination. You will need to add one or more characters to make the name combination unique. For example, add -2 to the surname (e.g., Meyer-2). You will also need to specify a different patient ID.

Instructions for this step are provided in *Conduct the Pre-Implant Check Procedure* on page 23.

3. Leave the properly working replacement IMD in its sterile packaging and set it aside for now.

4. Retrieve data from the IMD using the following instructions:

a. From the Programmer, open the patient's original patient record and establish a communication session with the implanted IMD.

b. From the Main Programmer window, select the *Retrieve Data* button.

c. Select *All* on the *Dataset Retrieval Amount* dialog box.

d. When the data have been retrieved, select either *Close* or *Defer Issues* on the *Retrieve Implant Data* window.

5. Record the IMD parameter settings using the following instructions:

    a. Open a communication session with the IMD and record the following parameter values from the associated windows (in parentheses). These values need to be returned with the explanted device. They are also needed for programming the replacement IMD as described in Step 12. Use the provided tables to record the values.

- IMD Vibration settings (*Alarm Tests*)

Event	Low	Med	High
Emergency Alarm			
See Doctor Alert			

- Alarm mappings (*Edit Alarm Configuration*)

Event	Emer-gency	See Dr	None	Ignore
Positive ST Shift & Non-Elevated HR				
Negative ST Shift & Non-Elevated HR				
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				
ST Deviation Trending				

b. Open the dataset that you retrieved and record the following parameter values from the associated windows.

- Heart rate bin settings (*Edit Implant Parameters*)
  Low _____bpm
  Normal _____bpm
  High _____bpm

- PQ/ST Start and Duration values for Normal heart rate bin only (*Edit Implant Parameters*)

Heart Rate Bin	Start (ms)	Duration (ms)
Normal bin, PQ segment		
Normal bin, ST segment		

6. Turn off alarms on the IMD to be explanted or replaced using the following instructions:

a. From the Main Programmer window, select *Implant* → *Alarm Configuration*.

b. From the *Edit Alarm Configuration* window, set all *Events* to *Ignore* and then select *Save* to save your changes. Doing so ensures the IMD will not signal an alarm or alert when it detects an event. (Because the IMD will not be connected to the endocardial lead once it is explanted, events such as Flat Line will occur.)

7. Verify that a sterile torque or hex wrench is available, so that you can loosen the required setscrews.

> **Note:**
> A sterile torque wrench is provided in the replacement IMD packaging, but is also available separately from AngelMed.

8. Dissect the IMD and coiled lead from the surgical pocket, taking care not to damage the lead insulation.

9. Do one of the following:

– **If you are replacing a Model AMSG3 IMD with another Model AMSG3 IMD:**

> **Warning:**
> Do not twist the lead when disconnecting it from the IMD header. Doing so may rotate the lead's connector pin and helix.

a. Loosen the two setscrews in the IMD header.

b. Withdraw the lead from the header.

Setscrews

IS-1

Lead

AngelMed Guardian®
MODEL# AMSG3
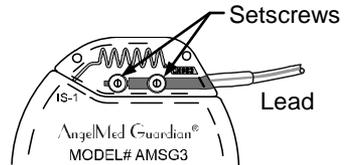
c. Set the IMD aside for now so that it can be later returned to Angel Medical Systems. Then proceed to Step 10.

– **If you are replacing a Model AG101 IMD with a Model AMSG3 IMD:**

> **Warning:**
> Do not twist the lead or lead adapter when disconnecting them. Doing so may rotate the lead's connector pin and helix.

a. Loosen the setscrew in the lead adapter sealing boot.

b. Withdraw the lead from the lead adapter sealing boot.

Setscrew

Lead Adapter
Sealing Boot

Lead

---
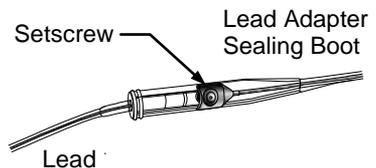
c. Set the IMD and lead adapter aside for now so that they can be later returned to Angel Medical Systems. (The AMSG3 IMD does not use a lead adapter.) Then proceed to Step 10.

– **If you are explanting and not replacing a Model AMSG3 IMD:**

> **Warning:**
> Do not twist the lead when disconnecting it. Doing so may rotate the lead's connector pin and helix.

a. Loosen the two setscrews in the IMD header.

b. Withdraw the lead from the header.
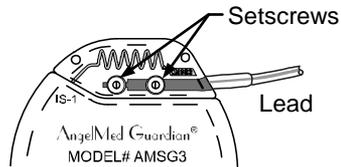
c. Set the IMD aside for now so that it can be later returned to Angel Medical Systems.

d. Cap the lead and secure with sutures.

> **Warning:**
> To prevent patient injury, cap any abandoned lead and secure the lead caps with sutures to prevent unwanted transmission of electrical signals from the electrode to the heart. Seal the remaining open end of any severed lead with medical adhesive and a lead cap. Suture the remnant to adjacent tissue using heavy, nonabsorbable suture to prevent migration of the lead fragment.

e. Suture the pocket incision closed.

f. Skip the remaining steps and proceed to *After Explanting the IMD* on page 44.

---

10. Inspect the connector pin on the lead and verify that it is free from corrosion or other physical damage.

> **Caution:**
> To ensure a proper connection between the lead and replacement IMD, clear the connector pin of any bodily fluids or tissue.

11. Finish the implantation by completing the following steps. These steps are the same as those for initial implantation and appear on pages 25 through 31.

  a. Attach the lead to the header of the replacement IMD. (See *Connect the Lead to the IMD*, page 25.)

  b. Place the new IMD and lead into the surgical pocket. (See *Implant the IMD*, page 27.)

  c. Using the Programmer, conduct the Implant Verification procedure for the replacement IMD. (See *Conduct the Implant Verification Procedure*, page 28.)

  d. Suture the IMD securely within the pocket and close the incision. (See *Secure the IMD and Close the Incision*, page 30.)

  e. Verify that you can still communicate with the IMD through the skin. (See *Verify Transdermal Communication*, page 30.)

  f. Conduct a Post-Implant Setup. (See *Conduct the Post-Implant Setup Procedure*, page 31.) Note that because you are leaving the original lead in place, you can perform this procedure anytime after re-implantation. You do not have to wait until the following day, although you may if you wish.

12. Enter the IMD parameter values of the original IMD into the replacement IMD. Refer to the values that you recorded in Step 5 starting on page 39. For assistance on entering the parameter values into the IMD, see the *Initial Programming* chapter of the *AngelMed Guardian Programmer Application User's Manual*.

13. Perform Initial Programming on the replacement IMD for long-term operation. (If necessary, see the *AngelMed Guardian Programmer Application User's Manual* for details on Initial Programming procedures.)

After Explanting the IMD

♦ Clean all explanted devices with disinfectant solution, but do not submerge the IMD. Fluid in the IMD header receptacle can impede analysis of the device.

♦ Return the explanted device(s) using the Product Return Kit. (Your AngelMed representative can provide the Product Return Kit if you do not have one.)

♦ When returning an IMD, please include a record of the IMD's Programmer settings that you recorded in Step 5.

9   **Service and Support**

Service

If the IMD does not operate correctly, contact your AngelMed representative.

Technical Support

For technical support, contact your AngelMed representative or Angel Medical Systems.

Angel Medical Systems, Inc.
1163 Shrewsbury Ave., Suite E
Shrewsbury, NJ 07702 USA
Phone: +1 800 508-5206 (USA toll-free)
            +1 561 962-2191

10 **IMD Specifications**

Physical & Mechanical Specifications

Item	Specification

Dimensions
   Height (Vertical)
   Width (Horizontal)
   Depth
	
	2.10 in (53 mm)
	2.13 in (54 mm)
	0.40 in (10 mm)

Weight	1.1 oz (32 grams)
Volume	23.4 cm3

Drop Limit
   Packaged IMD
   Unpackaged IMD
	
	3 ft (0.9 m)
	30 cm (12 in)

Lead Compatibility	Angel Medical Systems-supplied endocardial pacing lead

Materials in contact with human tissue
   Can
   Header
   Septum
	
	Titanium
	Tecothane® polyurethane resin*
	Silicone

* Tecothane is a registered trademark of Lubrizol Corporation.

Environmental Specifications

Item	Specification

Operating Conditions
    Temperature
    Humidity
    Atmospheric pressure
	
	77°F to 113°F (25°C to 45°C)
	N/A
	10.20 psi to 15.58 psi
	(703 hPa to 1074 hPa)

Storage Conditions
    Temperature
    Humidity
    Atmospheric pressure
	
	14°F to 131°F (-10°C to +55°C)
	N/A
	7.35 psi to 15.58 psi
	(507 hPa to 1074 hPa)

Battery Type and Longevity Specifications

Item	Specification
Battery Type	3.6V lithium thionyl chloride
Manufacturer	EaglePicher
Model	LTC-15MC-S7
Voltage$_{(Beginning of Life(BOL))}$	3.6V
Voltage $_{(ERI)}$	3.4V
Voltage $_{(EOS)}$	3.0V
Capacity (BOL to EOS)	1463mAh
Battery Longevity	3.5 years, assuming nominal program parameters and typical use

Device Longevity

There are three activities that affect the expected longevity of the IMD:

♦ Normal data collection and analysis
♦ Generating vibrations when alarms and alerts are detected
♦ Communicating with the Programmer

Battery capacity is constantly used to perform normal data collection and analysis. The rate of consumption is low, but somewhat variable, depending primarily on how often a patient's electrocardiogram is normal.

By contrast, battery capacity is used at a relatively high rate when the device is vibrating, but the device is expected to vibrate for a small percentage of time. Similarly, when communicating with the Programmer, the IMD uses battery capacity at a relatively high rate on an infrequent basis.

The IMD monitors its battery voltage and also maintains an estimate of cumulative battery capacity usage. Depending on these parameters, the IMD sets the following service flags:

♦ Elective replacement indicator (ERI) flag
♦ End of service (EOS) flag

ERI Flag

When the elective replacement indicator (ERI) flag is set, the IMD issues a See Doctor alert. The ERI flag is activated if the battery voltage falls below 3.4V, in which case the estimated time remaining before EOS is usually 30 days, but can range from 14 to 70 days.

EOS Flag

The end of service (EOS) flag is set if either the battery voltage falls below 3.0V or the estimated battery capacity has been used. The IMD does not operate when battery voltage is less than 3.0V.

11 Programmable Parameters: Defaults and Ranges

Programmable IMD parameters are set from the Programmer. The following tables show the possible ranges for these parameters and their default values where applicable.

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 (ms)

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 $\geq$ (Duration of PQ + 30)

Duration of PQ (ms)

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 (ms)

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 (ms)

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

ST Trends Histogram 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	192
Detection Threshold	10	50	20

*Hour of the day.

Alarm Tests Window (Vibration Settings)

Parameter	Min	Max	Default
Emergency Alarm Test	Low	High	Low
See Doctor Alert Test	Low	High	Low

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 AngelMed representative.

Alarm Type Association (Recommended Settings)

Event	Emergency	See Dr	None	Ignore
Positive ST Shift & Non-Elevated HR	X		*	
Negative ST Shift & Non-Elevated HR **	X		*	
ST Shift & Elevated HR	N/A	X	*	
ST Shift & Elevated HR Persists	X		*	
High Heart Rate	X		*	
Low Heart Rate		X	*	
Irregular Heart Rate		X	*	
Flat Line	X			*
Not Enough Beats	N/A	X		*
Cannot Get Baseline	N/A	X	*	
ST Deviation Trending	N/A	X	*	

*   Denotes the factory setting of each event. (X is the recommended setting.)
**If detected while the patient's heart rate is decreasing, the IMD automatically reclassifies the event as a Recovery event, which is internally mapped as a See Doctor alert.

A.   Clinical Investigations

There have been six human clinical studies related to the AngelMed Guardian system was developed to provide patient alerting for ischemia and heart rate related cardiac events. These are:

♦ A first Proof of Concept Study [1]

♦ Human Factors Studies to optimize alerting parameters [2]

♦ A First-in-Man Study in Brazil (CARDIOSAVER) [3-6]

♦ A US IDE Safety Study (DETECT) [3-4]

♦ A Prospective Randomized Pivotal IDE Study (ALERTS) [7]

♦ A Quality of Life sub-study in ALERTS subjects (AQOL)

The results of these studies follow.

First Proof of Concept and Human Factors Studies (2001-20040 [1,2]

The first study in humans used a temporary pacemaker lead to measure RV apical voltage (referenced to left pectoral region) during a two-minute occlusion obtained during scheduled balloon angioplasty of 17 lesions in 14 subjects (who were receiving the angioplasty for clinical reasons). This study demonstrated that the ST changes during coronary occlusion as seen from an intracardiac RV apical electrogram were larger than those seen on the skin surface.

It was recognized early in the development of the AngelMed Guardian system, that the primary function of the system would be to alert heart attack patients to take immediate action and quickly call 911 for transportation to a medical facility. Based on the premise that correct compliance to alerting was critical for the AngelMed Guardian system to providing patient benefit, the alerting

signals/protocols must be simple and robust, and instructions to patients must be clear. With this in mind, AngelMed developed the alerting functionality in the AngelMed Guardian system including vibration from the implanted device (IMD), and sound and flashing LEDs in a pager-sized external device (EXD). Studies using appropriate elderly subjects were conducted to identify and validate the triple-sensory modality alerting provided by the AngelMed Guardian system. The patterns and intensities of both the external and internal alerting were evaluated with respect to human factors issues and results used to determine the final alerting that would be appropriate for, and most effective in, the target patient population.

CARDIOSAVER [3-6]

In 2005, AngelMed initiated the CARDIOSAVER study in collaboration with the Dante Pazzanese Hospital of Cardiology in Sao Paulo, Brazil. The CARDIOSAVER study was designed to better understand the proper functioning of the AngelMed Guardian system as it responds to an occlusion of a human coronary artery. The study included 20 subjects at high risk for heart attack, with the added indications that they had 1) demonstrated ischemia on an exercise stress test and 2) had an angiogram showing a stenosed coronary artery and 3) had a clinical indication for angioplasty and/or stenting. The AngelMed Guardian IMD was implanted in these subjects and initial programming of the devices was done shortly after implant. Some of the subjects then underwent a repeat stress test with both intracardiac and surface ECG recordings used to assess ST-segment changes with elevated heart rate. Next, each subject underwent PCI. The PCI procedures included balloon occlusion of the target artery. These occlusions lasted up to three minutes in order to provide intracardiac recording of ST-segment changes associated with the resultant ischemia evoked by the balloon occlusion of the coronary artery.

The data collected during balloon occlusion clearly showed total coronary occlusion would cause significant intracardiac ST shifts if the vessel stenosis being opened by PCI did not have significant

collaterals. These data also showed that occlusion of a stenosis with good collateral flow would not cause significant ST shifts as the downstream tissue was still being fed oxygen by the collateral vessels.

After the implantation and balloon occlusion studies were completed, CARDIOSAVER subjects were sent home with daily ambulatory monitoring and alerting activated, and additional spontaneous coronary occlusive events were then detected. The results of this study were published in the Journal of the American College of Cardiology including data providing the first human examples of AngelMed Guardian alerting for real-life ischemic events that were caused by vulnerable plaque rupture in a coronary artery. These data were convincing and showed the potential of the AngelMed Guardian system to detect acute coronary occlusion in subjects to enable potentially life or heart muscle-saving early coronary intervention/revascularization.

DETECT [3-4]

In late 2006, AngelMed submitted an IDE to the FDA requesting approval to begin a US-based 20-subject safety study with two primary objectives:

♦ Show that the AngelMed Guardian system maintains a high safety profile when implanted in US patients and

♦ Demonstrate that the AngelMed Guardian Programmer AutoPick function would provide a reliable means for objectively selecting ST shift ischemia detection thresholds based upon statistical measures of each subject's normal daily range of ST segment variability.

The DETECT study proved the value of the Programmer AutoPick function. Using the subject's own data as a guide (subject acts as his or her real-time control) provides for greater ischemia detection specificity since what is normal for one patient may be quite abnormal for another. This approach also helps to normalize

thresholds for each individual, which may be particularly important in patients with some degree of incomplete revascularization of their coronary artery disease.

The inclusion and exclusion criteria for the US DETECT study were different from those used in Brazilian CARDIOSAVER study. The DETECT subjects were survivors of a prior ACS event or bypass with additional risk factors that increased their probability of having a heart attack. DETECT was successful in demonstrating that the IMDs could be implanted successfully and safely. Results from the DETECT and CARDIOSAVER studies provided the basis for the design of the ALERTS randomized prospective pivotal study with enrollment of 1020 subjects, conducted between 2008 and 2013. Multiple articles have been published describing the results from the CARDIOSAVER and DETECT studies showing the effectiveness of the AngelMed Guardian system in detecting ST segment changes from coronary blockages including thrombotic occlusions from ruptured plaques.

Of particular importance in the JACC publication was the evidence from three of the four Emergency alarm cases presented of a first transient occlusive event followed at a later time by a more significant event, all related to an IVUS confirmed ruptured plaque.

ALERTS [7]

ALERTS Clinical Study Design

The ALERTS randomized prospective clinical trial was approved under IDE (G060259) by the FDA to test the safety and efficacy of the AngelMed Guardian system. The study design compared the outcomes for subjects with and without the benefit of alerting following the detection of anomalous changes in the electrogram monitored by an IMD through a standard pacemaker lead. For the six-month randomized period, Treatment group subjects received alerts from IMD detections, Control group subjects did not. Control

subjects, however, had detection enabled, which allowed detection related data to be captured and saved for later review.

The ALERTS clinical study subject profile involved the following requirements:

♦ Advanced Multi-vessel Cardiac Disease

♦ An index ACS event (MI, Unstable Angina or CABG) within six months of subject enrollment.

♦ Additional risk factors/co-morbidities (diabetes, TIMI risk score >3, or renal insufficiency).

The reason for this profile was twofold. First, this subject profile had a high risk for a recurrent ACS event so they would derive the most potential benefit from alerting, and second, to provide a sufficient number of events within the ALERTS trial in order to demonstrate a significant benefit from alerting.

After enrollment but prior to the implantation, a first baseline 12-lead ECG was recorded. The IMD was implanted, using a procedure nearly identical to that used for a single chamber pacemaker, requiring virtually no additional physician education on the implant procedure itself. A single IS-1 active fixation pacemaker lead was positioned and then fixed at or near the apex of the right ventricle. Before discharge, data were retrieved from the IMD to check for proper performance and to configure the device for baseline electrogram collection. Any adverse events and complications were recorded.

Subjects were randomized 1:1 to the Treatment and Control groups when they returned to the site for programming of the AngelMed Guardian IMD 7-14 days after implantation. Both the Treatment and Control group subjects had ST shift detection enabled; however, only the Treatment group subjects had alerting turned "on", the Control subjects had alerting turned "off". The randomization was stratified by site with a blocking scheme that consists of blocks of randomly varying size. A second baseline 12-lead ECG was also collected at the time of randomization.

Following randomization, subjects who were randomized to the Treatment group had their IMDs programmed for both detection and alerting and were provided with an EXD. Using the physician Programmer to trigger both Emergency alarms and See Doctor alerts, Treatment group subjects were trained to recognize these alerts and silence them using the EXD. Treatment subjects were then instructed on how to respond to Emergency alarms and See Doctor alerts.

Subjects randomized to the Control group received the standard of care, per the treating physician and site. Both groups received the same education regarding the importance of seeking immediate medical attention should subjective symptoms of an ischemic event occur regardless of whether an alert was issued by the AngelMed Guardian system. Except for the difference in activating the alerting capability, the Control and Treatment subjects had their IMDs programmed in the same way with respect to event detection and collection of related cardiac data. It is important to note that the enabling ST shift detection and data capture in the Control group allowed the collection of the time and electrogram data associated with what would have been an Emergency alarm were alerts enabled. This information was essential in determining endpoints in our Control patients.

The protocol required all subjects to have follow-up visits at one, three, and six months, then every six months from that point onward. At each visit the subject's IMD event status was uploaded to the Programmer for review, and records of medications taken were updated. Further, subjects reviewed the ALERTS study protocol in order to reinforce the training on how to correctly respond to AngelMed Guardian system alerts and/or subjective symptoms that may be associated with a heart attack.

For the Control subjects, alerts were enabled at the 6-month follow-up visit, consistent with the parameters of the Treatment subjects' programming at 7-14 days (i.e., at six months the Control subjects transitioned to "alerting on"). At this time, former Control subjects were trained on the AngelMed Guardian system alerting protocols. At each subject visit, a 12-lead ECG was also obtained, data was

retrieved from the IMD, and AutoPick was typically evaluated to check/adjust ischemia threshold settings as necessary. Any adverse experiences or complications were recorded as well. For the first six months of follow-up, the Control group subjects and site staff were blinded to the ECG data that was transmitted to the Programmer, thus avoiding any influence on the treatment of the Control group subjects.

In the event of an Emergency alarm, upon presentation at a study site, subjects would have the time of symptom onset recorded as well as arrival time at the treatment facility. When no symptoms were present, the symptom onset time was recorded as "null". Regardless of whether chest pain was present, subjects having an Emergency alarm underwent a cardiac evaluation consistent with the standard of care for chest pain. This included serial cardiac enzymes, serial ECGs, recording of adverse events, summary of medications taken or delivered in response to the subject visit. If deemed necessary (or if the initial standard of care tests were inconclusive or ambiguous), the protocol requested the provision of more specific standard of care tests, including stress tests and/or angiography. This was done to obtain the most definitive results possible with respect to the occurrence of coronary artery occlusions and/or narrowing. Echocardiogram measurements of Left Ventricular Ejection Fraction (LVEF) were collected pre-implant and at the time of discharge for any confirmed thrombotic event.

Two methods are important to understand the analysis and results of the ALERTS Clinical Study. These relate to the components of the primary efficacy endpoint of the study.

There are three components of the primary efficacy objective for the ALERTS Clinical Study. These are:

♦ Cardiac or unexplained death,

♦ New Q Wave MI (a new Q wave in the six-month ECG that was not present before randomization of the subject), or

♦ Arrival at a medical facility for a confirmed thrombotic event more than two hours after detection of ST segment changes exceeding the detection threshold by the IMD.

The initial ALERTS Statistical Analysis Plan (SAP) approved by FDA in 2008 did not distinguish between the maximum allowable time between ST shift detection and the "late arrival" for a confirmed occlusive event for Control subjects versus Treatment subjects. For Treatment group subjects, a two-hour interval was simple to assess, because the IMD alert starts the interval and the ER arrival time ends the interval. However, Control group subjects get no such alert to start the interval, although detection is enabled. For Control group subjects, we began with an actual ER arrival time (the end of the interval) and then reviewed the IMD data, looking back in time to determine where the interval would have started had alerting been enabled – by looking for an IMD detection event.

Following an initial IDE supplement that limited the maximum time ("look-back" period) to seven days, additional publications in 2013 indicated that seven days was too short and that the presentation of subjects with no symptoms or unrecognized symptoms could be delayed until their next scheduled follow-up. In ALERTS follow-up schedule, that could be as long as 90 days (i.e. between the three and six-month follow-up visits).

Before unblinding, FDA agreed to allow the sponsor to submit endpoint data with multiple look-back periods. The data presented for primary and many secondary endpoints therefore are presented with maximum look-back periods of 7, 10, 30, 50, 70 and 90 days.

ALERTS Statistical and Clinical Analyses Considerations and Methodology

For the population studied in ALERTS, the predicted annual event rate for either reinfarction or sudden death after the index (enrolling) event was 4.8% for patients presenting with STEMI and 5.6% for patients presenting with non–ST-elevation MI/unstable angina. However, as with any new study, there was still uncertainty

regarding the rate of events to be expected in the Control population as well as uncertainty regarding the size of the treatment effect - i.e., the reduction in rate of events that might be observed in the Treatment group as compared to Control group. To account for this uncertainty, a Bayesian adaptive design was selected so that sample size could be dynamically determined during the course of the trial. The appropriateness of the sample size was to be evaluated at different time points during the trial, with Bayesian prediction of data values for subjects who had not yet reached their six-month follow-up visit. In order to determine whether to stop or to continue subject accrual, several planned analyses were specified. The first planned analysis was to occur after 600 subjects were enrolled and randomized, with subsequent analyses occurring at every 300 randomizations thereafter to a maximum of 3,000 subjects.

In 2005, while using an adaptive Bayesian statistical approach was very novel, the sponsor and our medical advisors thought it was appropriate. Over time, however, experience and practical reality demonstrated that for a device trial of this magnitude and complexity, the desired benefit of the specified Bayesian predictive model was not realistic, and the approach did not actually accomplish what was intended. Specifically, regarding the New Q wave component of the primary composite endpoint, the premise that an eECG core-lab-identified new Q wave in a one- or three-month visit would predict with certainty the presence of the new Q wave at six months was not true. In addition, the data used in the early interim analyses were often incomplete and in some cases incorrectly entered in the study database (both issues subsequently remedied through the monitoring process). Therefore, the predictive aspect that was specified in the design was neither accurate nor supportable, and the sponsor had to adjust accordingly.

As a result of this, the ALERTS study was stopped after reaching the FDA IDE approved enrollment target of 1020 enrolled subjects. At this point the database was frozen, and the ALERTS study data were statistically analyzed according to the FDA approved Statistical Analysis Plan (SAP).

For the purposes of clarification, Bayesian statistical methods use posterior probabilities instead of p-values to assess the level of evidence in support of a hypothesis. The study statistician provided support for use of a posterior probability of 0.975 or greater as the appropriate threshold for declaring statistical significance for the primary, secondary and other safety and efficacy endpoints of the ALERTS Clinical Study.

Primary and secondary efficacy endpoint measurements and adjudications were performed by a combination of independent adjudication committees and core laboratories, using pre-specified charters and processes, as follows:

♦ **The Adverse Events Committee (AC)** – an independent committee of physicians who adjudicated all adverse events entered by the clinical study sites.

♦ **Medpace** – served as the ALERTS clinical research organization (CRO) who was responsible for obtaining data from and interfacing between clinical sites, and allowing minimal interaction between, the sponsor, the Core Laboratories, the committees, and the study statistician.

♦ **The ALERTS Group for Endpoint Adjudication (AGEA)** – an independent committee of physicians who identified positive clinical events for inclusion as eligible confirmed thrombotic occlusive events for the Time-to-Door >2 hours component of the composite primary endpoint.

♦ **The eECG Core Laboratory at the Duke Clinical Research Institute** – a 12-lead ECG Core Lab that performed all 12-lead ECG analyses for ALERTS.

♦ **The Angiography Core Laboratory at The PERFUSE Study Group**, Harvard Medical School – an angiographic Core Lab that performed all analyses of angiograms obtained during cardiac catheterization procedures performed during ALERTS.

♦ **Data Safety Management Board (DSMB)** – an independent committee of experts from various disciplines who were responsible for monitoring the overall conduct of the study.

In accordance with the SAP and after adjudication of all events (by the AGEA Committee), angiograms by the PERFUSE Core Lab, and all ECGs by the eECG Core Laboratory at the Duke Clinical Research Institute (using serial review of pre-implant, at-randomization, one-, three-, and six-month ECGs), the results were reported as posterior probabilities by the ALERTS study statistician.

ALERTS Clinical Study Results - ALERTS Primary Safety Endpoint

The primary safety objective was to establish that the proportion of subjects free of system-related complications is > 90%, at six months (i.e. the incidence of system-related complications is < 10%).

The primary safety endpoint of greater than 90% freedom from system related complications was clearly met. In addition to meeting this objective, it is important to note that there was no lasting morbidity from any system-related complication in ALERTS, since all safety related issues were resolved over the course of the study.

Table A - 1 provides the statistical analysis showing a posterior probability of 0.9994, clearly demonstrating statistical significance for the primary safety endpoint.

Table A - 1 Analysis of Primary Safety Endpoint	
All Successfully Implanted Subjects (N=910)	
Status at six months: ♦ 25 subjects with events ♦ 870 event-free ♦ 15 unobserved (no event but insufficient follow-up) ♦ % Event-free = 870/(870+25) = 97.2%	
Posterior Probability Pr(R > 0.90 | data) at six months (with SAP-specified imputations for missing values)	0.9994

ALERTS Clinical Benefits: Reducing Time-to-Door

It is unanimous among the medical community that reducing time from coronary occlusion to treatment for heart attacks is clinically beneficial to a patient's overall outcome.

The ALERTS Clinical Study is the first study ever conducted that could capture the time delay from detection of coronary occlusion to arrival at a medical facility. For the Control subjects, as with all heart attack patients today, the only prompt to cause a patient to seek medical attention for a heart attack is the recognition of symptoms such as chest pain. The ALERTS study provides an excellent comparison showing the efficacy of an AngelMed Guardian Emergency alarm compared to recognition of such symptoms.

Specifically, Figure A - 1 presents the distribution of time-to-door from the detection of confirmed coronary occlusion to arrival at a medical facility. There were 52 such events, 34 arrivals in 27 Treatment subjects and 18 arrivals in 17 Control subjects. These data include subjects with and without reported symptoms. There were only five late arrival events (>2 hrs) in four Treatment subjects as compared with 18 late arrivals in 17 Control subjects, most of which arrived days or weeks after the detected occlusion.
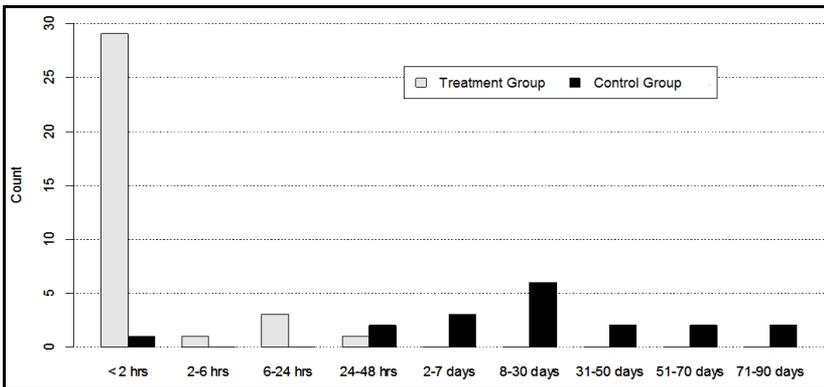
Figure A - 1 Distribution Of Subject Arrival Delays from AngelMed Guardian Detection for Confirmed Thrombotic Events During the 0-6 Month Randomized Period

Long delays (>7 days) have also been reported in the literature. [9] Specifically, Shelfer et al reported [10] with respect to myocardial infarctions, that "a substantial minority are accompanied by minimal or no discomfort. Consequently, many affected patients may not seek medical attention, and the diagnosis may be delayed for months or years." With 49.1% of ALERTS Control subjects being diabetic, the occurrence of silent MI is not surprising. [11,12]

Figure A - 2 and Figure A - 3 display this data as the cumulative percent of arrivals vs. time with the two-hour late arrival limit marked by the dashed vertical line. Figure A - 1, Figure A - 2, and Figure A - 3 the time elapsed between Emergency alarm and arrival for Treatment subjects and from the first IMD detection of ST shifts with data capture (which would have resulted in an Emergency alarm if enabled) to ER arrival for Control subjects.
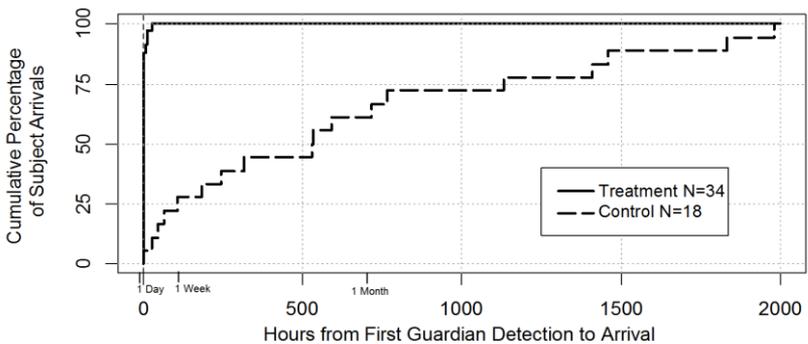
Figure A - 2   ALERTS cumulative distribution of all subject arrival delays
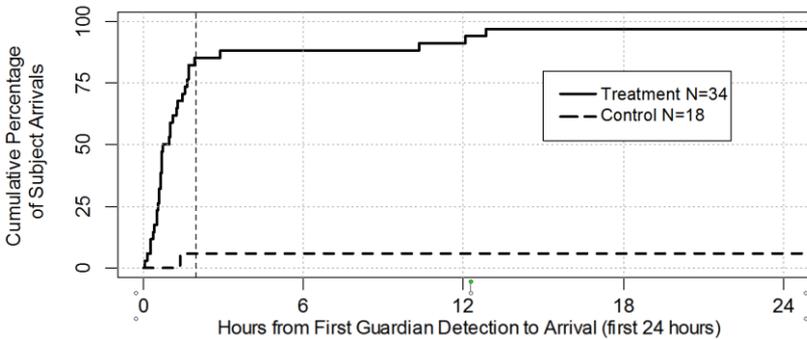
Figure A - 3 *Cumulative Distribution Of Subject Arrival Delays(First 24 Hours) Following Alert/Detection For Excessive ST Shift*

The efficacy of patient alerting is best shown in Figure A - 3 as 85% (29/34) of Treatment subject arrivals compared to only 6% (1/18) of Control subject arrivals were within two hours of detected, confirmed coronary occlusion. The recordings of ST shift events in the Control group, allows the ALERTS study to capture, for the first time, the presentation patterns for patients with no symptoms or unrecognized symptoms. This Control group behavior plus the clear effectiveness of alerting in prompting Treatment subjects to seek treatment quickly is the most remarkable outcome of the ALERTS Clinical Study.

Clinical Benefit: Primary Efficacy Endpoint

The primary efficacy objective was to evaluate the effectiveness of the AngelMed Guardian system in the detection of rapidly progressive ST-shift events, which are indicative of a coronary occlusive event (usually thrombotic). This objective was evaluated over a relatively brief, six-month follow-up period after randomization, and before the Control group transitioned to alerting. As specified, the primary efficacy endpoint was the composite of either:

♦ Cardiac or unexplained death,

♦ New Q-wave MI, or

♦ Time-to-door >2 hours for a confirmed thrombotic coronary occlusive event

Such a confirmed thrombotic event as defined in the study protocol is a detection of an ST shift event, followed by a positive standard of care test for coronary obstruction upon presentation at a medical facility.

In accordance with the SAP and after adjudication of all events (by the AGEA Committee), angiograms (by the PERFUSE Core Lab) and all ECGs (by the eECG Core Laboratory at the Duke Clinical Research Institute using serial review of ECGs at randomization, one, three and six months), the incidence of composite primary endpoint events and the posterior probability of a lower incidence in the Treatment group were computed. Results are shown in Table A - 2 using different look-back period windows for late arrival. A posterior probability at or above 0.975 is required to claim statistical significance. Table A - 2 shows the primary efficacy endpoint posterior probability vs. look-back interval. The change in the number of control subjects meeting the primary endpoint from 21 to 29, is due to the arrival of many of these control subjects more than seven days after event detection, as seen in Figure A - 1.

With all Control subject late arrivals counted (90 day look-back), and using the original single baseline primary endpoint data from Table A - 2, the posterior probability of 0.974 strongly suggests a positive trend indicating that alerting reduces the number of primary endpoint events in the Treatment group.

Table A - 2	Bayesian Posterior-Probabilities for the Composite Primary Objective Using Different "Look-Back" Intervals					
Look-back Window	Control Group (N=456)		Treatment Group (N=451)		95% BCI (ON - OFF)	Posterior Prob $P_r(R_{ON} < R_{OFF} \mid$ data)
	N	Patients (%)	N	Patients (%)	*(Completers only)*	(Completers only)
7-Day	428	21 (4.9%)	423	16 (3.8%)	(-3.93%, 1.67%)	0.7856
30-Day	428	25 (5.8%)	423	16 (3.8%)	(-5.02%, 0.84%)	0.9177
50-Day	428	27 (6.3%)	423	16 (3.8%)	(-5.55%, 0.43%)	0.9527
70-Day	428	28 (6.5%)	423	16 (3.8%)	(-5.82%, 0.24%)	0.9644
90-Day	428	29 (6.8%)	423	16 (3.8%)	(-6.06%, 0.03%)	0.9740

The more accurate dual baseline analysis of the primary endpoint that corrected the new Q wave MI quality control issues discussed above is shown in Table A - 3 from the statistician's report.

Table A - 3	Bayesian Posterior-Probabilities for the Composite Primary Objective Using Different "Look-Back" Intervals Adjusted for Q-Wave Quality Control Issues Using Dual Baselines					
Look-back Window	Control Group (N=456)		Treatment Group (N=451)		95% BCI (ON - OFF)	Posterior Prob $P_r(R_{ON} < R_{OFF} \mid$ data)
	N	Patients (%)	N	Patients (%)	*(Completers only)*	(Completers only)
7-Day	428	20 (4.7%)	423	13 (3.1%)	(-4.28%, 1.02%)	0.8833
30-Day	428	24 (5.6%)	423	13 (3.1%)	(-5.36%, 0.23%)	0.9637
50-Day	428	26 (6.1%)	423	13 (3.1%)	(-5.89%, -0.18%)	0.9812
70-Day	428	27 (6.3%)	423	13 (3.1%)	(-6.16%, -0.38%)	0.9870
90-Day	428	28 (6.5%)	423	13 (3.1%)	(-6.43%, -0.60%)	0.9908

The level of statistical significance of 0.975 is clearly surpassed when ECG Q wave quality issues were reduced using the dual baseline ECG analysis shown in Table A - 3. The posterior probability of 0.9908 with the 90 day look-back that includes all the late control subject arrivals shows that that this endpoint was highly statistically significant.

Secondary Endpoint: Reduction in Median Time to Arrival for All Subjects with "Confirmed Thrombotic Events"

Objective:
To determine that the AngelMed Guardian system reduces the time from the ST shift detection to presentation at a medical facility for a confirmed thrombotic or ACS event for Treatment subjects when compared to Control subjects.

Endpoint Result:
The median time from IMD detection to arrival at a medical facility was 51 minutes (0.85 hours) for Treatment subjects who received alerts and 30 hours 8 minutes for Control subjects. This was based on 43 events (which occurred in 35 subjects with arrival occurring within seven days post detection for confirmed positive tests including positive 12-lead ECG, positive cardiac enzyme test, positive stress test, positive angiogram, or new Q wave at six months). Control subjects had ST shifts detected and data captured but were not alerted, while Treatment subjects were alerted.

This difference as shown in Table A - 4 shows statistical significance (posterior probability > 0.9999).

Table A - 4	Summary of Times from Detection to Arrival for Confirmed Thrombotic Event						
Look-back Window	Group	Events (Subjects)	Mean ± SD (hours)	Min	Median (hours)	Max	$P_r(\mu_T < \mu_C \mid data)$
7-Day	OFF	9 (8)	52.33 ± 61.14	1.38	30.13	186.03	> 0.9999
	ON	34 (27)	2.66 ± 5.30	0.05	0.85	26.63	
90-Day	OFF	18 (17)	664.53 ± 640.46	1.38	532.71	1980.44	> 0.9999
	ON	34 (27)	2.66 ± 5.30	0.05	0.85	26.63	

If all Control subject late arrivals out to 90 days are included, the Treatment group remains unchanged at 0.85 hours while the Control group median arrival time increases from 30 hours to 532.71 hours (22 days). The posterior probability remains above 0.9999 for all look-back windows including those at of 10, 30, 50 and 70 days.

Secondary Endpoint: Reduction of Late Arrivals for "Confirmed Thrombotic Events" Where Late Arrivals are >2 hours Post Guardian ST Shift Detection

Objective:
To determine whether the AngelMed Guardian system reduced the time-to-door (defined >2 hours Emergency alarm-to-arrival time, measured from the time the IMD detected a rapidly progressive ST-shift event to the time that the subject presented at a medical facility) for a confirmed thrombotic coronary event.

Endpoint Result:
As one can see from Table A - 1 and Table A - 2 the arrival pattern for Control subjects and Treatment subjects are very different. Most Treatment subjects arrived before two hours while most Control subjects arrived more than seven days after AngelMed Guardian detection of a rapidly progressive ST shift event confirmed by one of the following: 12-lead ECG, cardiac enzymes, positive stress test, or angiography.

The posterior probability that the incidence of late arrivals (90 day maximum late arrival) is lower in the Treatment group is 0.9978, indicating a reduction that is highly statistically significant.

This is based on the 21 subjects with late arrival events shown in Table A - 1 with 17 subjects in the Control group vs. four in the Treatment group arriving after two hours.

Other Endpoint: Echocardiographic Ejection Fraction at Discharge Following Recurrent Event

This endpoint captures the echocardiographic ejection fraction at discharge after having a confirmed thrombotic occlusive event during the six-month randomization period. Ejection fraction data was obtained from the case report forms. Only subjects with a confirmed thrombotic occlusive event and documented echocardiographic ejection fraction value at discharge were included in this analysis.

Ejection fraction data was available at the time the ALERTS Clinical Study database was locked for a total of 64 events in 52 subjects qualified for this endpoint (25 events in 20 Control subjects and 39 events in 32 Treatment subjects). The individual data for this endpoint are presented in Table A - 5. All events are considered independent for statistical analysis. The relevant hypothesis is: H: $\mu_t > \mu_c$, where μ_t and μ_c represent the mean ejection fractions in the Treatment and Control groups, respectively.

Table A - 5 ALERTS Summary Statistics -- LVEF after discharge (%)							
Group	N	Mean ± SD	Min	Q1	Med	Q3	Max
Control	25	44.8 ± 14.6	20.0	33.0	45.0	55.0	69.0
Treatment	39	53.3 ± 10.3	30.0	45.0	55.0	60.0	70.0

Using the pre-specified analysis method (Bayesian version of a t-test), the posterior probability of H is 0.9857, with 95% BCI for ($\mu_t - \mu_c$) = (0.85, 14.49). It is also to be noted that the mean LVEF increased from pre-implant in the Treatment group and decreased in the Control group. With the time-to-door so very different between the two groups, this evidence further supports the clinically meaningful concept of "Time-is-muscle" in that the LVEF is higher at discharge in the Treatment group as compared to the Control group.

Additional Benefits – ALERTS STUDY

The ALERTS study showed the AngelMed Guardian system offers a number of important additional benefits not captured in the study endpoints, including:

♦ Core Lab confirmed alerts for silent ischemia in 38 subjects (23 thrombotic occlusions and 15 progressive coronary narrowing)

♦ Confirmed presentation due to alerts for arrhythmia and other medical conditions including transient heart block, bradycardia, tachycardia, atrial fibrillation, severe anemia, bundle branch block, hypokalemia, cardiomyopathy, and bigeminy

In addition, the Treatment group had 42.6% more cardiovascular medication adjustments and 60.9% more beta blocker medication adjustments compared to Control group subjects during the six-month randomized period.

Additional Benefits: Improvements in Quality of Life, AQOL Study

A patient's perspective on their health status has increasingly been recognized as an important and medically meaningful outcome. Measurement of health status and quality-of-life is increasingly being used and evaluated during assessment of coverage by payers [13] and large purchasers of healthcare [14] alike. It can also predict long-term outcomes in patients with coronary heart disease [15]. Poor health status is related to a worsening of prognosis [16]. Health status can also predict resource use and costs over time in patients with heart disease [17].

Health status can be measured through Quality of Life (QOL) instruments, which provide both quantitative and qualitative information related to patients' perception of how their disease and its treatment (e.g., stent, CABG, beta blockers) affects them over time. For example, QOL can relate to a patient's ability to function along several dimensions (e.g., socially, physically, and

emotionally). Treatment satisfaction, anxiety or depression levels may be measured in addition to the patient's overall feeling of well-being. An "instrument" refers to a constellation of items contained in a survey such as instructions to respondents, procedures for administration, scoring, interpretation of results, and other materials found in the respective user manuals [18].

While the ALERTS study measured the clinical endpoints, another important aspect of care in these high risk patients is the subjects' own perception of their disease and how this perception affects their physical and mental health status over time. The AQOL study was designed and run as an independent study using ALERTS study subjects during the final two years of the ALERTS study from 2012 thru 2014.

Methods

The AQOL study serves to measure aspects of the ALERTS subject lives which are not captured elsewhere by ALERTS (e.g., anxiety, productivity, use of emergency-department resources). The AQOL study uses two well established QOL instruments known as the EuroQOL EQ-5D [19-20] and MacNew. [21-23] These have been used and validated to evaluate medical interventions including heart-related therapies. The AQOL study also includes a third custom QOL survey designed in collaboration with Dr. Neil Oldridge the designer of MacNew. This custom study, the AngelMed Quality of Life - Frequency of Emergency Department Usage (AMQOL-FEDU), was designed to measure changes in quality-of-life that are related specifically to AngelMed Guardian heart-monitoring and alerting. All three surveys in the AQOL study were given to a subset of ALERTS subjects in order to prospectively examine changes in QOL by comparing the subject's quality-of-life during the year prior to implantation, to their quality-of-life at both six months ("Post-1") and 12 months ("Post-2") after their alerting features were activated.

Two versions of three surveys for the AQOL study were used. Version 1 was given to both Treatment and Control subjects prior to implant. Version 2 was given to Treatment subjects at six months (i.e., Post-1 time-point) and at 12 months (i.e., Post-2 time-point) after randomization which occurs 7-14 days after IMD implant. Version 2 was given to Control subjects at 12 and 18 months post-randomization since Control subjects did not have alerts enabled for the first six months. The statistical analysis of the QOL data was performed using SPSS version 22 software. Repeated measures analysis of variance (ANOVA) was carried out, with significant main effects followed-up using post-hoc t-tests. Chi-squared statistics were used to evaluate results that were reflected as percentage data.

Subject Enrollment

The study enrolled 157 subjects at 21 ALERTS study sites with 133 having Post-1 completion and 108 having Post-2 completion.

Results - Significant Improvements in Quality of Life

All three surveys showed a significant improvement in subject quality-of-life. Specifically:

♦ EuroQOL measures quality of life using the EuroQOL Visual Analog Scale (VAS). This survey is non-specific to cardiac studies and is used to show QOL changes that are valid for inclusion in cost-analysis studies. The VAS results indicate an improvement of 5.1, at both 6 ($p < 0.01$) and 12 ($p < 0.01$) months from 66.9 to 72 at six months and 72.1 at 12 months, post-implant. The 6- and 12-month EuroQOL VAS results indicate statistically significant benefit in quality of life.

♦ MacNew is specific to assessing QOL changes in cardiac studies. The minimum clinically important difference is 0.5 MacNew points. The AngelMed Guardian MacNew global improvement is 0.67 at 6mo and 0.53 at 1yr (compared to pre-implant baseline, $p < 0.0001$). Both 6- and 12-month MacNew results indicate clinically significant benefit in QOL.

♦ The results from the AMQOL-FEDU, showed that implanted subjects report extremely positive reactions to having the AngelMed Guardian system. Specifically, that the AngelMed Guardian system gives them "peace of mind." and makes them feel safer with less anxiety and an overall improvement in quality-of-life. Table A - 6 summarizes the AMQOL-FEDU survey questions and results.

Table A - 6 AMQOL-FEDU Survey Results								
	6 Months				1 Year			
	Pos	Neutral	Neg	Efficiency Pos:Neg	Pos	Neutral	Neg	Efficiency Pos:Neg
More Control Since Alarms on	90%	5%	5%	20.0	89%	8%	3%	32.0
Safer Since Alarms on	90%	6%	3%	30.0	90%	6%	5%	19.4
QOL Improved	69%	23%	6%	11.5	71%	20%	8%	8.6
More Productive	48%	38%	14%	3.6	55%	28%	18%	3.1
Less Depressed	47%	27%	11%	4.2	44%	29%	11%	4.0
Slept Better	50%	29%	12%	4.2	50%	22%	15%	3.4
Less Anxiety	73%	16%	8%	9.7	69%	12%	11%	6.3
Less Anxiety (symptoms)	62%	13%	7%	9.1	49%	14%	14%	3.5
Worried Less About Overdoing It	62%	20%	13%	4.9	66%	16%	12%	5.5
Exercise	56%	21%	8%	6.8	61%	20%	10%	6.0
Sexual Activity	34%	17%	14%	2.4	34%	15%	10%	3.4
Average	62%	20%	9%	6.8	62%	17%	11%	5.8

Seventy percent of the subjects reported an improvement in quality-of-life at six months after AngelMed Guardian system alerting was enabled. This includes a large variety of improvements in QOL, such as success in going back to work, resuming normal day-to-day recreational activities as well as other health issues. The table also shows that the important improvements in quality-of-life at six months after alerting were sustained at one year.

Study Conclusions

Effectiveness

The ALERTS Clinical Study demonstrated that the AngelMed Guardian system is effective and demonstrated that patients with confirmed thrombotic events will arrive more quickly in to a medical facility for standard of care evaluation. By itself, the occlusion-to-door median arrival time, following an alert, of under an hour dramatically surpasses the best results ever seen in any prior studies of patient symptom-to-door arrival times. The ALERTS Clinical Study for the first time demonstrated just how ineffective symptom recognition is in getting patients with confirmed thrombotic events to treatment quickly. In ALERTS the Control subjects, representing the current real world response to coronary occlusion, present days and sometimes weeks after the coronary blockage might have been detected and treated.

The ALERTS Clinical Study demonstrated efficacy by meeting the primary effectiveness endpoint when all late arriving control patients were included and the dual baseline analysis was used to improve quality in the Q wave MI component.

Additional efficacy was demonstrated by the Treatment group compared to the Control group having reduced time-to-door and late arrival secondary endpoints and higher left ventricular ejection fraction before discharge from a confirmed thrombotic event (another pre-specified endpoint.

Safety

Safety was demonstrated in the ALERTS Clinical Study as the study met its primary safety endpoint by surpassing the required safety threshold of 90% freedom from system related complications. The final result was a 97.2% freedom from system related complications with no lasting morbidity.

Risk Benefit Analysis

The ALERTS Clinical Study demonstrated that the risks associated with the AngelMed Guardian system are those associated with the implantation of the IMD and lead neither of which had lasting morbidity.

On the other hand, the list of benefits to subjects is extensive.

- Statistically significant benefit was shown in favor of the Treatment group for the dual baseline primary endpoint analyses, as well as a number of secondary and other endpoints including:
  - Reduction of death, new Q wave MI or late arrival for confirmed thrombotic events using the 90-day look-back and dual baseline.
  - Reduction of median time-to-door for confirmed thrombotic events of 51 minutes for treatment subjects as compared to 22 days for control subjects
  - Reduction of late arrivals for Treatment vs. Control groups.
  - Higher left ventricular ejection fraction before discharge from a confirmed thrombotic event.
- Additional benefits not captured in the study endpoints, include:
  - Core Lab confirmed alerts for silent ischemia
  - Confirmed presentation from alerts for arrhythmia and other medical conditions
  - Improved beta-blocker dose management
  - Statistically significant improvements in quality-of-life

There is also clear evidence that the AngelMed Guardian system can easily fit into the standard of care chest pain protocol used for the emergent evaluation of patients presenting with suspected AMI, adding value without introducing bias. The AngelMed Guardian system is the first implanted device to provide either ST segment monitoring or ST shift alerting in ambulatory subjects with advanced multi-vessel cardiac disease, and the ALERTS Clinical Study has shown that it can be done safely and effectively.

The AngelMed Guardian system enables a new ability to detect a disease process with high morbidity and mortality at an earlier stage, where earlier intervention can change the disease process, making an important impact on both individual patients and public health.

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Index

AngelMed Guardian® External Device (EXD) Model EXD-001

User's Guide

AngelMed Guardian®
Model EXD-001

Emergency
See Dr.

Warning: EXD is a secondary alarm. Do not ignore symptoms or IMD vibration if EXD does not alarm.

Press Near IMD to Silence Alarm

Press to Check Battery

Angel Medical Systems®
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AngelMed®

Fold Line

Contents

1   **Introduction**

The AngelMed Guardian® External Device (EXD) is a battery-operated telemetry device that assists in signaling the alarms and alerts generated by the AngelMed Guardian Implantable Medical Device (IMD). The EXD also enables communication between the IMD and AngelMed Guardian Programmer.

How supplied – The EXD is packaged with a neck cord and a belt case. Batteries are supplied by Angel Medical Systems and installed by the physician.

About this manual – This document describes the EXD, including the alarms and alerts that it signals. It also describes how to install the battery and provides general care information.

2 System Overview

The AngelMed Guardian system detects changes in patients'
electrograms, using baseline electrograms from the previous day for
comparison. If a change exceeds a pre-specified threshold, the system
warns the patient and stores pertinent data for subsequent review.
Two levels of warnings are possible:

♦ Emergency alarms, for significant events that require immediate
  medical attention

♦ See Doctor alerts, for less-significant events where the patient
  makes an appointment to see the doctor in the next 1 or 2 days

System Components

The AngelMed Guardian system comprises the following
components:

External Device (EXD) – a hand-held telemetry device that warns
  the patient of alarms and alerts via beeps and flashing indicator
  lights, and is used to silence alarms and alerts. The EXD also
  enables communication between the Programmer and the IMD.

Implantable Medical Device (IMD) – an implantable programmable
  device that vibrates to warn the patient of alarms and alerts, and
  stores electrogram signals and other data. Electrogram signals are
  obtained through an endocardial lead.

Programmer – a workstation the physician uses to program IMD
  parameters and alarm settings. It also enables the physician to
  retrieve and review data collected by the IMD.

Indications & Contraindications

See the *AngelMed Guardian® Implantable Medical Device (IMD) User's Manual* for indications and contraindications relevant to the AngelMed Guardian system.

Intra-System Communication

The following figure shows the AngelMed Guardian system communication architecture.
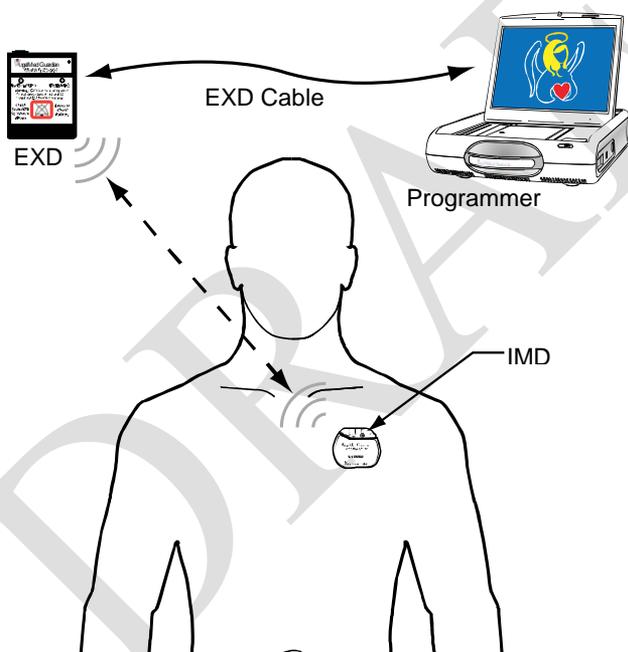
The EXD serves as the communication hub between the IMD and Programmer. Using the EXD, the physician establishes communication sessions between the IMD and Programmer, in order to retrieve IMD data and set IMD parameters. The EXD is also used by the patient to silence alarms and alerts.

The EXD uses both near-field and far-field telemetry to communicate with the IMD. Near-field telemetry, which allows a maximum distance of 2 in (5 cm), is used to silence alarms and alerts and to establish communication sessions between the IMD and Programmer. Far-field telemetry, which allows a maximum distance of 6 ft (1.8 m), is used for communication between the IMD and EXD after a session has been established and to initiate alarms and alerts on the EXD when the IMD has detected a coronary event.

The EXD and Programmer are connected via cable.

Available Literature

The following documents provide information relevant to the AngelMed Guardian system.

♦ *AngelMed Guardian® Implantable Medical Device (IMD) User's Manual*

♦ *AngelMed Guardian® Programmer User's Manual*

♦ *Patient Manual for the AngelMed Guardian® System*

3 EXD Device Description

Appearance

Front – The front of the EXD contains the Emergency and See Doctor indicator lights, and the Silence Alarm/Check Battery button.

AngelMed Guardian®
Model EXD-001

Emergency   See Dr.

Warning: EXD is a secondary alarm. Do not ignore symptoms or IMD vibration if EXD does not alarm.

Press Near IMD to Silence Alarm

Press to Check Battery

Emergency Indicator Light, flashes red during alarms

See Doctor Indicator Light, flashes yellow during alerts

Silence Alarm/Check Battery Button,
- silences Emergency alarms, See Doctor alerts, and Low EXD Battery warnings
- checks battery condition
- starts communication sessions

Back – The back of the EXD contains a metal ring for attaching the
neck cord, two instruction fields, and the door to the battery
compartment.
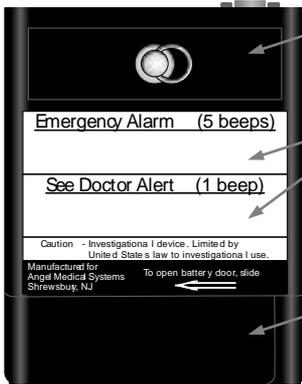
Neck Cord Attachment Ring,
allows patients to carry the EXD
around their neck

Instruction Fields,
provide space to write phone
numbers and other instructions

Battery compartment door,
provides access to the custom
AngelMed battery

Top – The top of the EXD contains a serial interface port and an
unlabeled green indicator light.

Serial Port, allows the
EXD to be connected to
the Programmer
workstation

Green Indicator Light
flashes slowly when a
session is established
between the IMD and
the Programmer

Battery Compartment – The battery compartment shows the proper battery orientation, the EXD's serial number, and the FCC ID number.

Battery Orientation

FCC ID Number

EXD serial number (not shown)
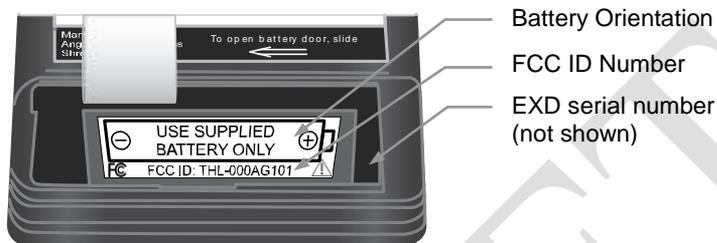
Neck Cord & Belt Case

The AngelMed Guardian system includes a belt case and neck cord for carrying the EXD. These accessories help patients to keep the EXD close by at all times.

Belt Case
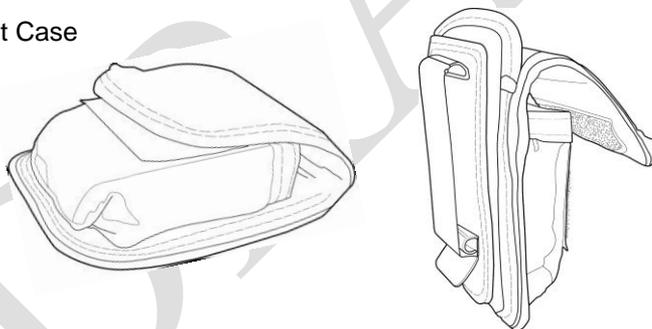
The belt case has an integrated belt clip.

> **Warning**:
> Patients should keep their EXD within 6 ft (1.8 m) of their IMD. This allows the EXD to beep and flash if the IMD signals an Emergency alarm or See Doctor alert.

The neck cord has a breakaway safety feature that enables it to automatically open under tension. For instructions on attaching the EXD to the neck cord, see the *Patient Manual for the AngelMed Guardian® System.*

Neck Cord
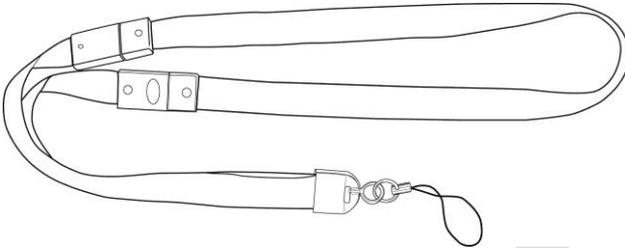
Warning:
Do not use any neck cord except the one supplied by Angel Medical Systems. Many neck cords do not have a breakaway safety feature.

Emergency Alarms and See Doctor Alerts

Emergency Alarm Functionality

When an Emergency alarm occurs, the patient should call for an ambulance immediately.

During an Emergency alarm, the IMD vibrates in a repeating pattern of five short vibrations, like this:

Brrrr–Brrrr–Brrrr   *Brrrr–Brrrr*

If the patient's EXD is within 6 ft (1.8 m) of the IMD, the red indicator light will flash. At the same time, the EXD will beep like this:

Beep–Beep–Beep   *Beep–Beep*

See Doctor Alert Functionality

When a See Doctor alert occurs, the patient should make an appointment to see the doctor in the next 1 or 2 days.

During a See Doctor alert, the IMD vibrates one time, pauses, vibrates again, and so on.

Brrrr ◄──────── 7 sec ────────► **Brrrr**

If the EXD is within 6 ft (1.8 m) of the IMD, the EXD will beep and the yellow indicator light will flash.

Beep ◄──────── 7 sec ────────► **Beep**

How to Silence an Emergency Alarm or See Doctor Alert

An Emergency alarm or See Doctor alert can be silenced after it has been on for at least 30 seconds.

To do so, hold the EXD within 2 in (5 cm) of the patient's IMD and push the Silence Alarm/Check Battery button.

Silencing an Alarm or Alert

If the EXD beeps twice, the alarm/alert has been silenced. If it beeps only once, re-position the EXD and try again. After an alarm or alert has been silenced, the IMD will stop vibrating and the EXD will stop beeping.

Additional Alarm and Alert Information

The following table provides additional information about Emergency alarms and See Doctor alerts.

Note that there is a reminder alarm for the Emergency alarm, but not for the See Doctor alert.

	Initial Alarm/Alert	Reminder Alarm	EXD Flashing Indicators
Emergency Alarms*	Repeats for up to 5 minutes or until it is silenced.	Plays for 2.5 minutes at 15-minute intervals for 2 hours or until silenced. Has the same pattern as the initial alarm.	Red light flashes for 25 hours or until a communication session is established between the Programmer and the IMD.
See Doctor Alerts**	Repeats for up to 5 minutes or until it is silenced.	No Reminder	Yellow light flashes for 25 hours or until a communication session is established between the Programmer and the IMD.

* Emergency alarms must be silenced twice. If the initial alarm is not silenced, but instead runs to completion, the patient must silence two reminder alarms.

** A See Doctor alert suppresses the signaling of any subsequent See Doctor alert for a 24-hour period. This feature gives the patients time to see the physician without being subject to repeated See Doctor alerts should they occur. Emergency alarms are not suppressed.

Low EXD Battery Warning

When the EXD battery power is low, the EXD issues the Low EXD Battery warning. This warning means that the EXD has one to two days of power left before the battery must be changed.

During a Low EXD Battery warning, the EXD beeps one time, pauses, beeps again, and so on. Unlike the Emergency alarm or See Doctor alert, the Low EXD Battery warning does not cause the IMD to vibrate.

Beep ⟵―――――――― 30 sec ―――――――⟶ **Beep**
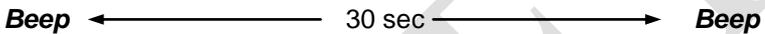
The Low EXD Battery warning beeps continually until either:

♦ The battery power is depleted

♦ The warning is silenced

How to Silence a Low EXD Battery Warning

You can silence a Low EXD Battery warning at any time. To do so, just push the Silence Alarm/Check Battery button. Note that unlike the Emergency alarm or See Doctor alert, you do not need to hold the EXD near an IMD to silence a Low EXD Battery warning.

When you silence the Low EXD Battery warning, the beeping stops for a period of 12 hours at which time the warning starts again. Restarting the warning serves to remind patients that the EXD battery needs replacement. You can silence the Low EXD Battery warning any number of times.

Silencing
the Low
EXD Battery
Warning

For information on the EXD battery and how to replace it, see *Battery Power* on page 15.

Certifications

FCC Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC ID: THL-000AG101

SAR

This portable transmitter with its antenna complies with FCC's RF exposure limits for general population/uncontrolled exposure.

4 Setup

Use these steps to set up the EXD for the Programmer and patients.

Programmer EXD

To connect the EXD to the EXD Cable:

1. Insert the battery as described on page 16.

2. Connect the EXD to the Programmer's EXD cable. Use the two connector screws on the EXD cable to secure it to the EXD.

Connector
Screws (2)

To connect/disconnect the EXD Cable to/from the Programmer:

♦ See your Programmer user documentation.

Patient's EXD

1. Insert the battery as described on page 16.

2. Write instructions on the back of the EXD. Instructions may include emergency telephone numbers and medical advice.

3. Show the neck cord and belt case to the patient.

4. Attach the neck cord to the EXD, if the patient plans to use it. (See the *Patient Manual for the AngelMed Guardian® System* for neck cord attachment instructions.)

5 Care and Maintenance

Battery Power

The EXD uses a custom battery that lasts about six months. This battery is available only from Angel Medical Systems.

> **Caution:**
> Use of a battery other than the EXD battery supplied by Angel Medical Systems may damage the EXD or cause it to malfunction. Although "AA" sized batteries will fit in the battery compartment, only the battery supplied by Angel Medical Systems allows proper functioning of the EXD.

When the battery nears the end of its service life, the EXD issues the Low EXD Battery warning as described on page 11. Patients should change their EXD battery every six months or any time the EXD issues a Low EXD battery warning. During follow-up visits, physicians should ask patients if their EXD battery is fresh and provide replacement batteries. Some patients may not feel comfortable replacing the battery to their EXD. For these patients, the physician should replace the battery for them.

Patients should check their EXD's battery power once per week. If the battery needs to be replaced, the patient should see his or her physician in the next day or two to replace the battery.

How to Check Battery Power

Battery power can be checked in two ways:

♦ Push 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 respond.

♦ Look at the Battery Status area of the Programmer's Retrieve Implant Data or Initial Programming windows. (This method requires the EXD to be connected to the Programmer.) A green indicator means the battery voltage is within range for normal operation. A yellow or red indicator means the battery should be replaced.

How to Replace the Battery

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.
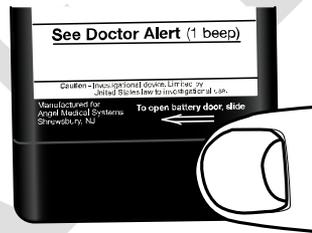
2. Gently pull the tab to lift the negative (−) end of the old battery. **Note:** If the pull-tab is under the battery or missing, use a small screwdriver to gently lift the battery.
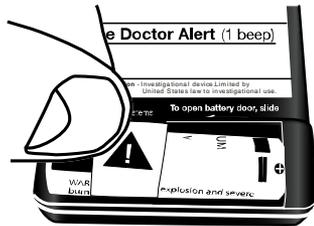
3. Insert the positive (+) end of the new battery into the battery compartment, then push down on the battery's negative (−) end. **Caution:** Only use batteries supplied by Angel Medical Systems. **Caution:** Check the expiration date on the battery shipping box to ensure the battery is fresh.
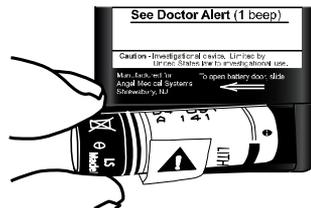
4. Close the battery compartment by
sliding the battery cover completely
to the right.

5. To confirm that the battery was correctly inserted and is working,
push the Silence Alarm/Check Battery button. The EXD will
beep one time if the battery is working.

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

General Care & Maintenance

♦ Check the EXD's battery power once a week.

♦ Do not sterilize the EXD.

♦ Keep the EXD dry. The EXD is not waterproof, so getting it wet
may damage its electronics. If the EXD is accidentally dropped
into a sink or similar place, return it for service or replacement.

♦ Never use strong cleaners or solvents to clean the EXD. If the
surface of the EXD needs to be cleaned, wipe it gently with a
cloth lightly dampened in clean water.

♦ Observe the drop limit as documented in *EXD Specifications* on
page 22. If the EXD is dropped from a height that exceeds the
drop limit, replace it. If it is dropped from a height that is less
than the drop limit, push the Silence Alarm/Check Battery button
to verify operation. If the device beeps one time, it is still
functioning; if not, replace it.

♦ Protect the EXD from extreme temperatures. For applicable
temperature ranges, see *EXD Specifications* on page 22.

♦ Replace the EXD if it is damaged.

6   EMI Precautions

The AngelMed Guardian system is protected against most sources of electromagnetic interference (EMI). However, sources of strong EMI can damage the EXD (and IMD), and interfere with the wireless communication between them.

Sources of Strong EMI

Sources of strong EMI include:

♦ Home appliances that are not in good working order.

♦ High-voltage power lines.

♦ Ignition systems of running automobile engines. Patients should not work under the hood of a car when the engine is running. Patients can, however, drive or be a passenger in a car.

♦ Ignition systems of other internal combustion engines, like gasoline-powered lawn mowers and leaf blowers. It's generally safe to work around running internal combustion engines, but patients should limit their exposure to ignition-system parts.

♦ Industrial equipment such as arc welders, induction furnaces, and very large or defective electric motors.

♦ Small motor-driven appliances like hair dryers, electric shavers, power tools, and transmitters for radio-controlled equipment or toys. Patients should not hold small motor-driven appliances close to their IMD and EXD.

Cell Phone Precautions

Cell phones also emit EMI, but can safely be used with the AngelMed Guardian system provided that patients do the following:

♦ Hold the phone at least 6 in (15 cm) away from the EXD. If the cell phone transmits above 3 watts, patients should hold the phone at least 12 in (30 cm) away from the EXD and IMD.

   If the patient does not know the transmit power of the cell phone, the patient should assume that the cell phone transmits at the higher power and should hold the phone at least 12 in (30 cm) away from the IMD and EXD.

♦ Store the phone at least 6 in (15 cm) away from the EXD and IMD. This is important because some phones send signals when in the Listen or Standby mode.

Security System Precautions

Security and anti-theft systems used in airports, stores, and other areas will probably not interfere with the EXD if patients walk past them at a normal pace and do not linger.

The EXD has metal inside that may set off an airport security system alarm. If this happens, patients should show their *AngelMed Guardian System Identification Card* to the security officers. If security officers use a handheld wand to perform a search, patients should ask them to work quickly and avoid holding the wand over their EXD.

7 Troubleshooting

Problem	Possible Causes	What to Do
EXD does not beep when the Silence Alarm/Check Battery button is pushed.	Battery power is depleted.	Replace the battery.
	Battery has been inserted backwards.	Reinsert the battery.
	Wrong battery has been installed.	Replace the battery with the AngelMed custom EXD battery.
EXD beeps once every 30 seconds.	Battery power is low.	Replace the battery.
EXD does not stop IMD vibratory alarms	IMD is not receiving the EXD radio signal.	Hold the EXD directly over and within 2 in (5 cm) of the implanted IMD and press the Silence Alarm/Check Battery
	EXD battery is depleted.	Check for bad EXD battery and replace if necessary.
Cannot establish a communication session between the IMD and Programmer.	IMD is not receiving the EXD radio signal.	Hold the EXD directly over and within 2 in (5 cm) of the implanted IMD and press the Silence Alarm/Check Battery
	EXD battery is depleted.	Check for bad EXD battery and replace if necessary.
	Loose EXD cable.	Verify the EXD cable connections are secure. (See Setup on page 13.)

See also the Programmer User's Manual for more troubleshooting.

8   Service and Support

Service

If the EXD does not operate correctly, contact your Angel Medical Systems representative.

For additional EXD batteries, contact your Angel Medical Systems representative.

Technical Support

For technical support, contact your Angel Medical Systems representative, or Angel Medical Systems.

Angel Medical Systems, Inc.
1163 Shrewsbury Ave., Suite E
Shrewsbury, NJ 07702 USA
Phone: (800) 508-5206 (USA toll-free)
        (561) 962-2191

9 EXD Specifications

Item	Specification
Dimensions	Height: 2.8 in (70 mm) Width: 2.2 in (55 mm) Depth: 0.6 in (16 mm)

Operating Conditions
   Temperature
   Humidity
   Atmospheric pressure
	32°F to 122°F (0°C to 50°C)
	10% to 95% non-condensing
	10.20 psi to 15.58 psi
	(703 hPa to 1074 hPa)

Storage Conditions
   Temperature
   Humidity
   Atmospheric pressure
	-4°F to 131°F (-20°C to +55°C)
	5% to 95% non-condensing
	7.35 psi to 15.58 psi
	(507 hPa to 1074 hPa)

Weight	2.1 oz (58 grams) with battery
Power Source	3.6 V lithium thionyl chloride battery. Replacement is available only from Angel Medical Systems. Battery is non-rechargeable
Drop Limit	3 ft (0.9 m)

Telemetry Distance (max)
   Near-field
   Far-field
	2 in (5 cm)
	6 ft (1.8 m)

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Notes

Notes

AngelMed Guardian® Programmer
Model Prog-003

Setup & Operations Guide

AngelMed®

Fold Line

Contents

Contents

1 Introduction

The Model Prog-003 Programmer is a compact and portable device that allows you to program and retrieve patient data from an AngelMed Guardian IMD. The Programmer comes equipped with:

♦ An External Device (EXD) for communicating with a patient's IMD

♦ A stylus and touchscreen for selecting programming options

♦ An integrated stand to provide a convenient viewing angle

♦ Two USB flash drives (not shown) for backing-up patient data

♦ Two batteries and AC adapter (not shown) for operating the Programmer either with or without an AC line source
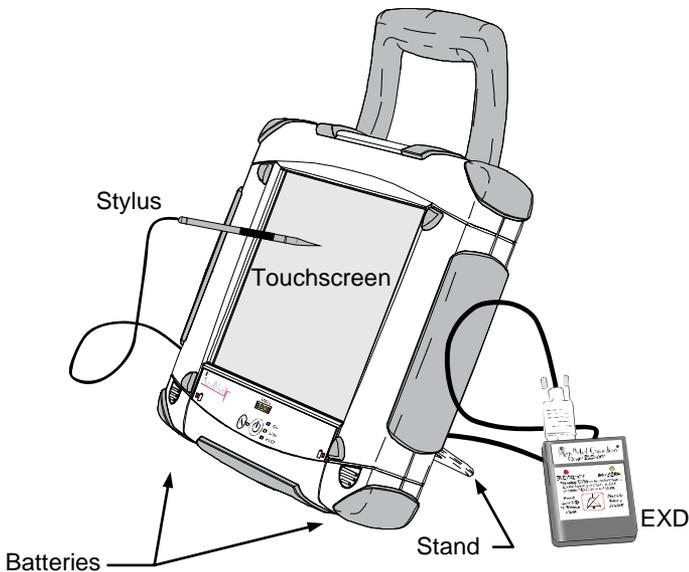
AC Operation

You can operate the Programmer indefinitely from standard AC line current by using the supplied AC adapter. The AC adapter can simultaneously power the Programmer and recharge the batteries.

Warning:
Do not use any AC adapter other than the one supplied with your Programmer. Use of another adapter can damage the Programmer and result in personal injury or property damage.

Battery Operation

The Programmer comes equipped with two batteries. The batteries are hot swappable, meaning that they can be removed and re-inserted even when the Programmer is operating.

The Programmer can operate in battery mode for up to 2 hours depending on the charge and condition of the batteries. You can operate the Programmer with only one battery; however, doing so reduces the time that the Programmer can run in battery mode. To operate the Programmer for longer time periods, plug-in the AC adapter.

Indicator lights on the Programmer front panel provide constant feedback on the state of the battery charge. For additional information on the batteries and the battery indicators, see:

♦ *Front Panel Controls and Indicators* on page 5
♦ *Checking the Battery State-of-Charge* on page 19
♦ *Recharging the Batteries* on page 20

USB Flash Drive

The Programmer is supplied with two USB flash drives: A and B. Only one flash drive is in use at a given time. Keep the other at a nearby location for disaster recovery purposes.

The flash drives are used only to back-up and restore Programmer data as discussed in the *AngelMed Guardian Programmer Application User's Manual.* You do not need to plug-in the flash drive for routine Programmer operation, such as retrieving and analyzing IMD data or IMD programming.

Caution:
Do not use generic USB flash drives or the flash drive of another Programmer. A Programmer can only use the flash drive it was shipped with or its replacement from Angel Medical Systems.

Optional Keyboard and Mouse

Although the Programmer is designed to be operated using the touchscreen and stylus, an optional keyboard and mouse are also available and can be obtained from your AngelMed representative.

Programmer Features and Controls

The Programmer is equipped with the following key features.
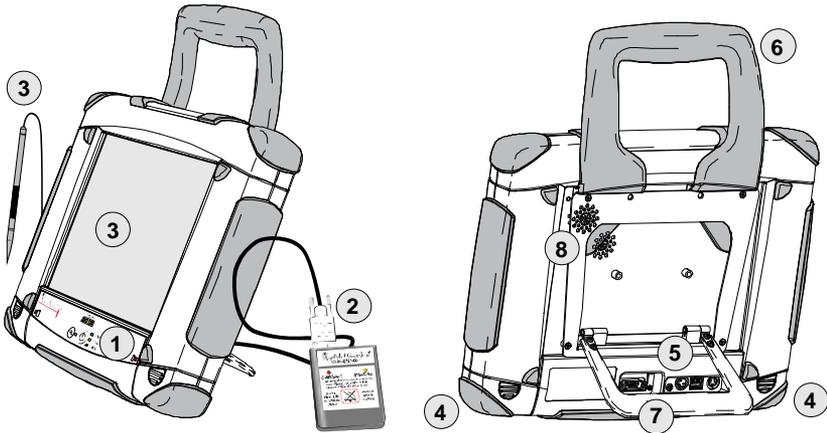
1.	Power switch and front panel	To control and monitor the Programmer
2.	EXD and cable	For communicating with patients' IMDs
3.	Touchscreen and stylus	For selecting program options
4.	Batteries	For operating the Programmer in battery mode
5.	Connector panel	For connecting the EXD, flash drive, and AC adapter
6.	Handle	To carry the Programmer
7.	Stand	To keep the Programmer upright
8.	Magnetic stylus storage area	To hold the stylus when not in use
9.	AC adapter (not shown)	To recharge the batteries and operate the Programmer from an AC line source

Front Panel Controls and Indicators

The front panel contains the power switch as well as indicators that allow you to monitor primary Programmer functions including battery charge.
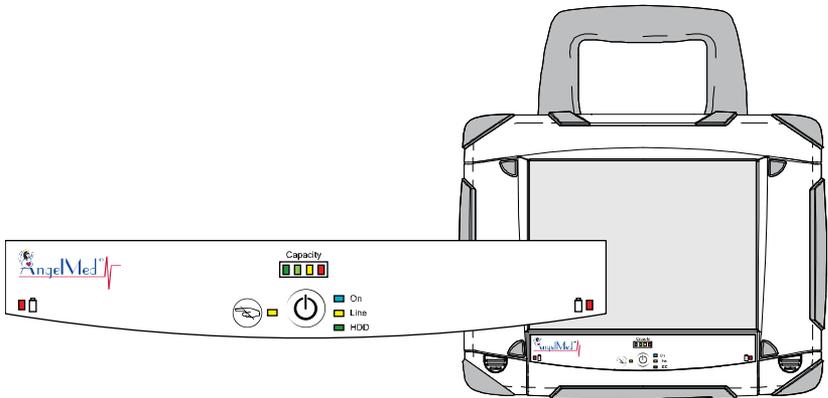
⏻	Power On/Off – Press this button for about 1 second to start the Programmer
	Touchscreen On/Off – Press to temporarily disable the Programmer touchscreen. Press again to enable it. When lit, the yellow LED indicates that the touchscreen is disabled.

■ ▯ ▯ ■	**Left/right Battery Low** – Recharge by connecting the AC adapter to the Programmer or replace the battery. ♦ Lights when the capacity of the corresponding battery drops below 10% ♦ Flashes when the capacity drops below 5% If the indicator starts to flash, plug-in the AC adapter as soon as possible to avoid automatic battery shutdown and possible Programmer shutdown. For more information, see *Automatic Battery Shutdown* on page 20.
Capacity ■ ■ ■ ■	**Total Battery Capacity** – Displays the available battery capacity in 25% increments, with red indicating approximately 0-25% capacity. This indicator is lit at all times except when the Programmer is both powered-off and in battery mode.
■ On	**Power indicator** – means the Programmer is powered-on.
■ Line	**Line mode indicator** – means the Programmer is receiving power from its AC adapter. This indicator: ♦ flashes when the batteries are charging ♦ is solidly lit during line mode when no batteries are inserted or when all batteries are fully charged
■ HDD	**Hard Disk Drive access indicator** – lights on every read/write access to the Programmer's hard disk drive

Connector Panel

The connector panel is located on the back of the Programmer. It contains connectors for the Programmer EXD cable, AC adapter cable, and flash drive.

Flash Drive

AC Adapter Cable
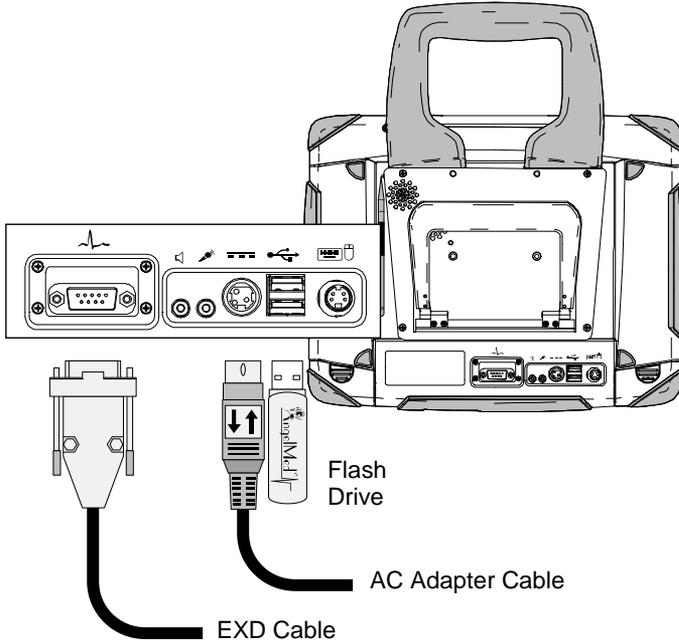
EXD Cable

∿	Serial port – Connect the EXD cable to this connector and secure it using the thumb screws.
===	Power In port – Connect the AC adapter to this port when you want to charge the batteries and/or run the Programmer in line mode.
⟜	USB ports – Connect the flash drive to either port when you want to back up the Programmer. You can also use either port to connect the optional keyboard.
◁ 🎤 ⌨ 🖱	Do not use. (The optional keyboard/mouse connects to a USB port.)

---

2   Setup

Use the following steps to set-up the Programmer.

Unpack the Programmer

1. Unpack the Programmer and any accessories from their shipping boxes.

2. Ensure that you have all the components and articles that have been specified on the packing list(s).

Contact your AngelMed representative if any items are missing.

Charge the Programmer Batteries

When the Programmer is shipped to your site, its batteries are not fully charged. We recommend charging them now, so that you can use the Programmer without having to plug it into an AC line outlet.

> **Caution:**
> If you do not intend to use the Programmer for 6 months or more, do not charge the batteries at this time. Storing completely charged batteries for long time periods (≈6 mo); can degrade battery life.

To charge the Programmer batteries:

1. Ensure both batteries are fully inserted into the Programmer.

2. Plug the AC Line cord into the receptacle on the AC Adapter.

3. Plug the other end of the AC line cord into the wall outlet.

4. Plug the DC power cord of the AC adapter into the Programmer's Power In port ($\equiv$) as shown in the following figure.
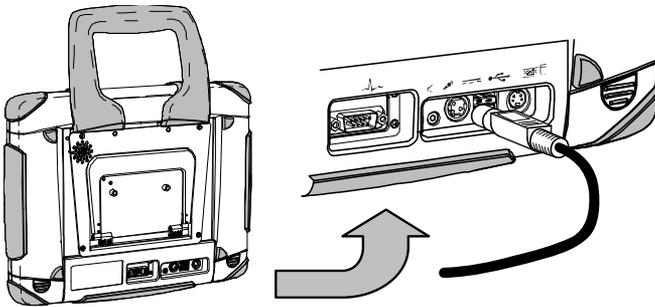
5. Leave the Programmer plugged in until it is fully charged as indicated by the Capacity indicator on the front panel.

Connect the EXD to the EXD Cable

1. Check the EXD battery compartment and, if necessary, insert the custom EXD battery.

> **Caution:**
> The EXD uses a custom battery supplied by Angel Medical Systems. Use of any other battery may damage the EXD or cause it to fail. Although "AA" sized batteries will fit in the battery compartment, only the battery supplied by Angel Medical Systems allows proper functioning of the EXD.

2. Connect the EXD to the Programmer's EXD cable. Use the two thumb screws on the EXD cable to secure it to the EXD.
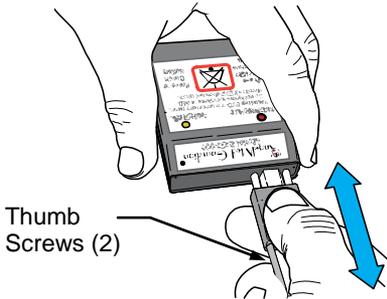
Thumb
Screws (2)

> **Caution:**
> Always secure the EXD to the cable using the thumb screws.
> Failure to do so can allow the EXD cable to become
> disconnected during a communication session with the IMD.

Connect the EXD Cable to the Programmer

1. Connect the EXD cable to the Programmer serial port (⋏⋏),
which is located on the back of the Programmer.

Serial Port

EXD
Cable
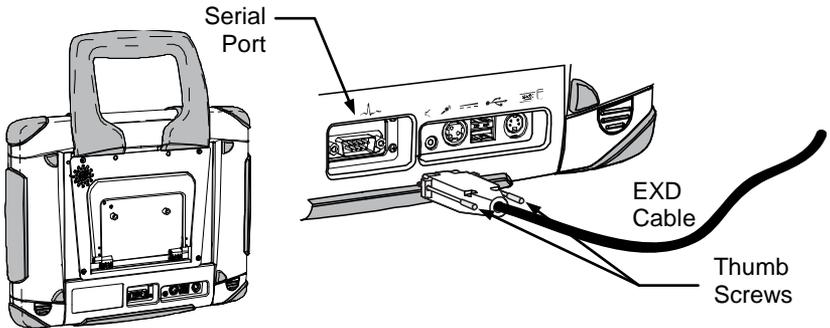
Thumb
Screws

2. Secure the cable connection by tightening the thumb screws.

Caution:
Always secure the EXD cable to the Programmer using the
thumb screws. Failure to do so can allow the EXD cable to
become disconnected during a communication session with the
IMD.

To disconnect the EXD cable from the Programmer:

♦ Loosen the thumb screws on the EXD connector and pull the
connector from the serial port.

Deploy the Stand

To support the Programmer at a
convenient viewing angle, lower the
stand and place the Programmer on
a flat, horizontal surface.
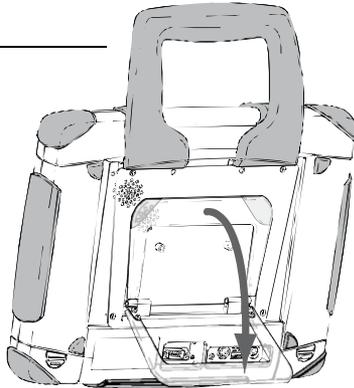
Attach Accessories as Needed

Attach the following accessories as the need arises:

♦ AC adapter – to recharge the batteries and operate Programmer in
line mode

♦ Flash drive – to back-up or restore the Programmer data

♦ Optional keyboard/mouse – to operate the Programmer using a
standard keyboard and mouse
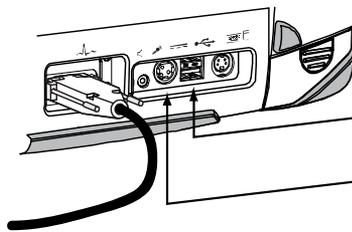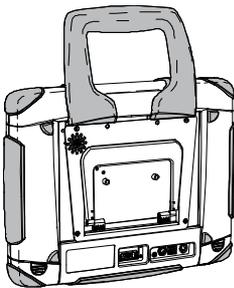
Flash Drive
Keyboard/mouse

AC Adapter

Note:
When using the optional keyboard and mouse, plug the
keyboard into either USB port on the Programmer and the
mouse into the USB port on the keyboard.

---

3 **Programmer Operations**

This section describes how to perform the most common Programmer activities, such as:

♦ Starting the Programmer

♦ Shutting Down the Programmer

♦ Using the Stylus and On-Screen Keyboard

♦ Checking the Battery State-of-Charge

♦ Recharging the Batteries

♦ Storing the Programmer

♦ System Maintenance

Starting the Programmer

To start the Programmer:

1. Verify that at least one charged battery is installed or plug the AC Adapter into the Programmer. (If you use the AC adapter be sure that it is plugged into a wall outlet.)

2. Start-up the Programmer by pressing the Power button ⏻ on the front of the Programmer for about 1 second.

The Programmer responds by lighting the On indicator.

3. The Programmer displays the Main Programmer window from which you will perform all of your Programmer-related activities.
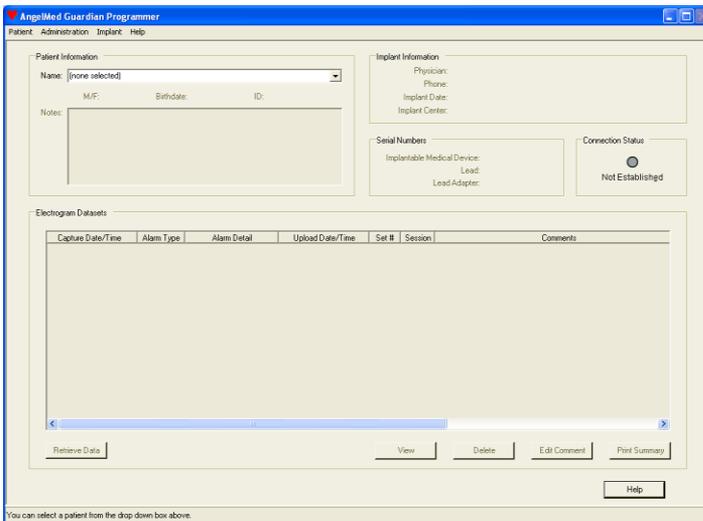
For information on performing Programmer-related tasks such as programming an IMD or retrieving patient IMD data, see the *AngelMed Guardian Programmer Application User's Manual* on your *AngelMed Guardian User Documentation* CD or consult the Programmer online Help.

Shutting Down the Programmer

To ensure that patient data are not corrupted, you need to shut down the Programmer properly as described in the following procedure.

To shut down the Programmer:

1. Complete or cancel any task that you are currently performing.

> **Note:**
> If the Programmer is unresponsive and cannot be shut-down in the prescribed manner, see "*Programmer is unresponsive*" in the *Troubleshooting* section on page 22

2. From the Main Programmer window, select *Administration → Shutdown*.

3. The Programmer displays a confirmation prompt. Select *Yes* to shut the Programmer down.
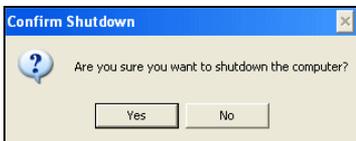
4. The Programmer shuts down shortly thereafter.

5. Return the stylus to the storage area, which is located to the left of the stand on the back plate. (See *Using the Stylus* on page 16 for more information.)

Using the Stylus and On-Screen Keyboard

The Programmer's touchscreen and stylus allow you to select
program controls and enter data. An on-screen keyboard is displayed
when necessary to enter information such as patient and physician
names, serial numbers, and notes.

Using the Stylus

The stylus works in concert with the Programmer touchscreen:
similar to other styluses that are used with many handheld digital
devices.

Caution:
The touchscreen only operates with the stylus or your fingers. Use
of other devices can damage or destroy your touchscreen.

The stylus is tethered to the Programmer. When you are done using
the Programmer, secure the stylus by placing it against the magnet,
which is embedded in the rear plate of the Programmer and to the left
of the stand.
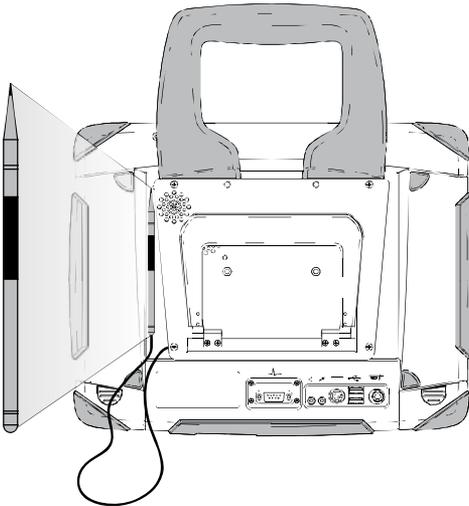
Using the On-Screen Keyboard

Most data entry occurs when you create a patient record; however, you can enter comments whenever you retrieve data from an implanted IMD. The on-screen keyboard, shown below, is not displayed on the Programmer until you need to use it: typically, from a window that has text entry fields.
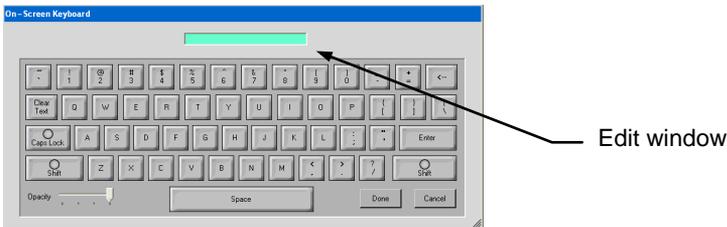
Edit window

The keyboard has the following controls and features:

`<--`	Is the Backspace key, used to clear one character at a time.
Clear Text	Clears all text in the edit window.
Enter	Used to open a new line for typing under the current line. Useful only for edit fields that accommodate multiple lines.
Shift	Used to type the next letter only in upper case.
Caps Lock	Used to type all following letters in upper case. To return to normal typing, touch this key again.
Opacity	Used to control the opacity of the keyboard. Move the slider to the left to view the underlying screen.
Done	Saves the typed text to the edit field of the current Programmer window and closes the keyboard.
Cancel	Closes the keyboard without saving the typed text.

To display the on-screen keyboard:

♦ From a window that has an edit field, use the stylus to touch the edit field in which you want to type the information. The following figure shows the stylus touching the edit field of the *Retrieve Implant Data* window.
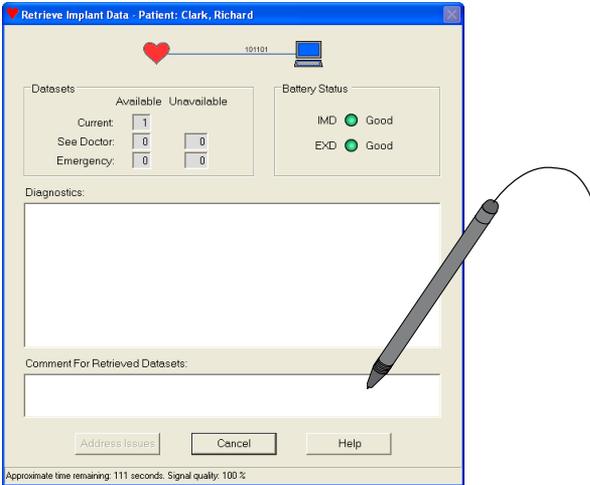
In response, the Programmer displays the on-screen keyboard.

Checking the Battery State-of-Charge

The Programmer provides several means of checking the batteries'
state of charge.

Capacity indicator
Displays the total battery
capacity available to the
Programmer.

Low battery indicator
Lights when the corresponding battery is low.
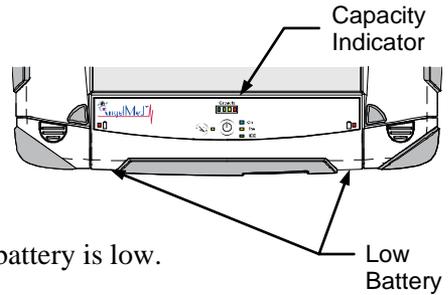
For additional details on these indicators, see
Front Panel Controls and Indicators on page 5.

On-Battery charge indicator
Displays the charge of an individual battery. To check the charge of
an individual battery, remove the battery from the Programmer and
press the button in the inspection window. Four LEDs indicate the
charge level in approximately 25% increments as shown in the
following figure.
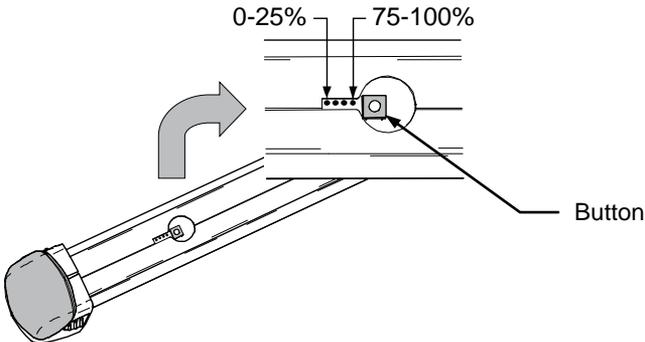
Note the 0-25% indicator flashes when the button is pressed and the
battery charge is below 5%.

Recharging the Batteries

The Programmer batteries charge automatically whenever the Programmer is operated using AC power. When the Programmer is operated in battery mode, the batteries provide power to the Programmer and slowly discharge over time.

> **Note:**
> Do not store batteries completely charged or discharged for long time periods ($\approx$6 mo); doing so can degrade battery life. For this purpose, discharge or charge batteries to between 40% and 60% of capacity prior to storage. Use the on-battery charge indicator described on page 19 to determine the charge level.

To charge the Programmer batteries:

♦ Plug the Programmer's AC adapter into the wall outlet and the Programmer's Power In port.

In response, the Line indicator lights and the Capacity indicator displays the total state of the charge of all inserted batteries.

Automatic Battery Shutdown

Each Programmer battery has an internal controller that shuts the battery down automatically, when it has discharged to a certain level. This feature helps to prevent a deep discharge state, which would then require a lengthy ($\approx 8 - 10$ hrs) recharge time.

> **Note:**
> To avoid a deep discharge state, be sure to recharge a completely discharged battery as soon as possible. The internal controller on each battery continues to use battery power even on discharged batteries. This can lead to a deep discharge condition and cause lengthy recharge times.

Storing the Programmer

When storing the Programmer, observe all environmental requirements, as stated in *Environmental Specifications* on page 25.

If you are storing the Programmer for 6 months or more, charge or discharge the batteries to between 40% to 60% as indicated by the on-battery charge indicator. You can discharge the batteries by operating the Programmer in battery mode or charge the batteries by plugging in the AC adapter.

> **Note:**
> Do not store batteries completely charged or discharged for long time periods (≈6 mo). Doing so can degrade battery life.

System Maintenance

The Programmer has no parts that require maintenance. You may however, want to clean the exterior of the Programmer from time to time.

To clean the Programmer, including the stylus and EXD, turn-off the Programmer and wipe them with a damp cloth moistened with a mild antimicrobial agent.

> **Caution:**
> Keep liquid out of the interior of the Programmer and EXD. Never spray liquid directly onto them.

> **Caution:**
> Do not open the Programmer housing. Doing so would expose internal electronic components, which can damage the Programmer. Contact your AngelMed representative if you need assistance with your Programmer.

4   Troubleshooting

Problem	Possible Cause	What to Do
Programmer does not start	Batteries not inserted.	Insert a charged battery into the Programmer or connect the AC adapter.
	Inserted batteries are depleted.	Connect the AC adapter to the Programmer.
No battery power	Batteries are depleted.	Insert batteries, connect the AC Adapter, and observe the Capacity indicator on the front panel.
Programmer is unresponsive	Touchscreen has been manually disabled.	Press the Touchscreen On/Off button ⊘ ▫ on the front panel to re-enable the touchscreen.
	Internal device error.	Turn-off the Programmer by pressing and holding the Power button ⏻ for about 5 seconds. Then restart the Programmer. If the condition persists, contact your AngelMed representative.
Battery will not hold a charge.	Battery is old or damaged.	Replace the battery.
Battery takes a long time to charge (8 – 10 hours)	Battery is in a deep discharge state.	Allow the battery to charge. You can avoid deep discharge state by promptly recharging discharged batteries.

Problem	Possible Cause	What to Do
EXD does not beep when the EXD's button is pushed.	Battery power is depleted.	Replace the EXD battery.
	Battery is inserted backwards.	Reinsert the EXD battery.
	Wrong battery is installed.	Replace the battery with the AngelMed custom EXD battery.
EXD beeps once every 30 seconds.	Battery power is low.	Replace the EXD battery.
EXD does not stop IMD vibratory alarms	Radio communication problem between the IMD and EXD.	Hold the EXD directly over and within 2 in (5 cm) of the IMD and press the Silence Alarm/Check Battery button on the EXD.
	EXD battery is depleted.	Check for bad EXD battery and replace if necessary.
Cannot establish a communication session with the IMD.	Communication problem between the IMD and EXD.	Hold the EXD directly over and within 2 in (5 cm) of the IMD and press the Silence Alarm/Check Battery button on the EXD.
	EXD battery is depleted.	Check for bad EXD battery and replace if necessary.
	Loose EXD cable.	Verify the EXD cable connections are secure.

See also the *AngelMed Guardian Programmer Application User's Manual* or online Help for more troubleshooting.

5   Service and Support

Service

If the Programmer does not operate correctly or if you need replacement parts (i.e., stylus, battery etc.), contact your AngelMed representative.

Technical Support

For technical support, contact your AngelMed representative, or Angel Medical Systems.

Angel Medical Systems, Inc.
1163 Shrewsbury Ave., Suite E
Shrewsbury, NJ 07702 USA
Phone: (800) 508-5206 (USA toll-free)
        (561) 962-2191

6 Specifications

Electrical Requirements

AC Adapter

Input power   100-240VAC, 47-63Hz, 3-wire grounded

Nominal output   4.4A @ 18VDC (80W)

Check AC Adapter label for additional specifications.

Base Unit Power Supply

Input power   19VDC at 3.2A
(max)

Environmental Specifications

Temperature	0° to 40°C (32° to 104° F) (Operating)
	0° to 55°C (32° to 131°F) (Storage)
Relative	10% to 90% (Operating)
Humidity	5% to 95% (Storage)
(non-condensing)	

Physical Specifications

Height	10.7in (272mm) (excluding flexible handle)
Width	13.5in (342mm)
Thickness	2.4in (61mm) (with stand collapsed)
Weight	4.2kg (9.3lbs) (includes EXD and cable, add 0.9kg (1.9lbs) for AC adapter)

Programmer Screen

Display	10.4in (264mm), thin-film transistor LCD
Color	18-bit (262,144 colors)
Size	10.4in (264mm) diagonal
Resolution	XGA (1024 x 768 pixels)

Battery

Standard	Smart Battery System (SBS) compliant
Technology	Prismatic Li-Ion
Weight per pack	280g
Output voltage (nominal)	+14.4V
Output current (nominal)	1.9A
Charge voltage (nominal)	+16.8V
Charge current (maximum)	1.2A
Pre-charge current (typical)	100mA
Capacity per pack	28Wh
Recommended ambient temp range, discharging	32° to 140°F (0° to +60°C)
Recommended ambient temp range, charging	+59° to +77°F (+15° to +25°C)
Recommended ambient temp range, storage	32° to 140°F (0° to +60°C)
Maximum ambient temp range, discharging	-4° to +140°F (-20° to +60°C)
Maximum ambient temp range, charging	32° to +113°F (0° to +45°C)

Telemetry

Standard	MICS (Medical Implant Communication Service) compliant as defined by:

♦ FCC Rules and Regulations, "MICS Band Plan", Part 95, Jan. 2003.

♦ 47 CFR 95.601-95.673 Subpart E, Federal Communications Commission, 1999.

♦ ETSI EN 301 839-1 "Electromagnetic compatibility and Radio spectrum Matters (ERM);Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods.", European Telecommunications Standards Institute, 2002.

Frequency	402MHz to 405MHz
Power	EIRP (Equivalent isotropically radiated power) = 25μW
Bandwidth	300kHz at any one time
Range	≈2m

A Explanations of Label Symbols

Battery label

Do not dispose of this device or parts of it. For more information, see:
Directive 2002/96/Ec Of The European Parliament And Of The Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

This device is rechargeable.

Device can be recycled, please return to vendor.

Signifies a warning; handle this device carefully.

Do not short-circuit this device.

Do not inflame and/or heat this device.

Do not scratch this device and/or (try to) open the housing.

Do not shock, hit, or smash this device.

Recommended temperature ranges for charging (blank area) and discharging (hatched area) this device.

Programmer serial number label

⊠	Do not dispose of this device or parts of it. For more information, see: Directive 2002/96/Ec Of The European Parliament And Of The Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)
((•))	This device uses a radio transmitter and emits non-ionizing radiation.
IP65	The Programmer is designed to meet the IP65 protection class.

Note:
The Programmer is designed to meet IP65 class specifications. These specifications are met only if all connector covers are mounted and both batteries are inserted and locked.

B Warnings, Notes, and Safety Instructions

Warning:
Do not use any AC adapter other than the one supplied with your Programmer. Use of another adapter can damage the Programmer and result in personal injury or property damage.

Caution:
Do not use generic USB flash drives or the flash drive of another Programmer. A Programmer can only use the flash drive it was shipped with or its replacement from Angel Medical Systems.

Caution:
The EXD uses a custom battery supplied by Angel Medical Systems. Use of any other battery may damage the EXD or cause it to fail. Although "AA" sized batteries will fit in the battery compartment, only the battery supplied by Angel Medical Systems allows proper functioning of the EXD.

Caution:
Always secure the EXD to the cable using the thumb screws. Failure to do so can allow the EXD cable to become disconnected during a communication session with the IMD.

Caution:
Always secure the EXD cable to the Programmer using the thumb screws. Failure to do so can allow the EXD cable to become disconnected during a communication session with the IMD.

Note:
When using the optional keyboard and mouse, plug the keyboard into either USB port on the Programmer and the mouse into the USB port on the keyboard.

Caution:
Generally, you should not use the Power On/Off button to shut-down
the Programmer because you may lose Programmer data. Instead,
select *Administration* → *Shutdown* from the main Programmer
window. Use the Power On/Off button only as a last resort, if the
Programmer becomes unresponsive.

Caution:
The touchscreen only operates with the stylus or your fingers. Use of
other devices can damage or destroy your touchscreen.

Note:
Do not store batteries completely charged or discharged for long time
periods (≈6 mo); doing so can degrade battery life. For this purpose,
discharge or charge batteries to between 40% and 60% of capacity
prior to storage. Use the on-battery charge indicator described on page
19 to determine the charge level.

Note:
To avoid a deep discharge state, be sure to recharge a completely
discharged battery as soon as possible. The internal controller on each
battery continues to use battery power even on discharged batteries.
This can lead to a deep discharge condition and cause lengthy recharge
times.

Caution:
Keep liquid out of the interior of the Programmer and EXD. Never
spray liquid directly onto them.

Caution:
Do not open the Programmer housing. Doing so would expose internal
electronic components, which can damage the Programmer. Contact
your AngelMed representative if you need assistance with your
Programmer.

Note:
The Programmer is designed to meet IP65 class specifications. These
specifications are met only if all connector covers are mounted and
both batteries are inserted and locked.

Caution:
Do not use accessories or cables with the Programmer other than those listed in *Components and Accessories* on page 41. Using other cables or accessories may result in increased emissions or decreased immunity of the Programmer.

Caution:
The Programmer is intended for use by healthcare professionals. Although it complies with the limits for medical devices contained in IEC/EN 60601-1-2:2007, the Programmer may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device or shielding the location.

C Compliance

FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

♦ This device may not cause harmful interference, and

♦ This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC ID: THL-000AG101

SAR

This portable transmitter with its antenna complies with FCC's RF exposure limits for general population/uncontrolled exposure.

Electromagnetic Compatibility

The Programmer requires special precautions with regard to
electromagnetic compatibility (EMC) and should be used in
accordance with the information provided in this manual.

The Programmer complies with the requirements of the international
EMC standard IEC 60601-1-2:2007 when used with the cables listed in
Components and Accessories on page 41.

Caution:
Do not use accessories or cables with the Programmer other than
those listed in *Components and Accessories* on page 41. Using other
cables or accessories may result in increased emissions or decreased
immunity of the Programmer.

The Programmer is intended for use in the electromagnetic
environment specified in Tables C-1 through C-4.

Caution:
The Programmer is intended for use by healthcare professionals.
Although it complies with the limits for medical devices contained in
IEC/EN 60601-1-2:2007, the Programmer may cause radio
interference or may disrupt the operation of nearby equipment. It may
be necessary to mitigate this effect by reorienting or relocating the
receiving device or shielding the location.

Table C-1: **Guidance and manufacturer's declaration —
electromagnetic emissions
(IEC 60601-1-2:2007 Table 1)**

Guidance and manufacturer's declaration – electromagnetic emission		
The Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emission CISPR 11	Group 1	The Programmer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Programmer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

**Table C-2:   Guidance and manufacturer's declaration —
electromagnetic immunity for all equipment
and systems (IEC 60601-1-2:2007 Table 2)**

Guidance and manufacturer's declaration – electromagnetic immunity			
The Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compli-ance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	N/A – The device is battery powered ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A – The device is battery powered	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compli-ance Level**	**Electromagnetic Environment - Guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95 % dip in U_T) for 0.5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70% U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 s	N/A – The device is battery powered	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Programmer requires continued operation during power mains interruptions, it is recommended that the Programmer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table C-3: **Guidance and manufacturer's declaration — electromagnetic immunity for equipment and systems that are not life-supporting (IEC 60601-1-2:2007 Table 4)**

Guidance and manufacturer's declaration – electromagnetic immunity			
The Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compli-ance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz outside ISM bands	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Recommended separation distance: $$d = 1.2\sqrt{P}$$ $$d = 1.2\sqrt{P} \quad \text{80MHz to 800MHz}$$ $$d = 2.3\sqrt{P} \quad \text{800MHz to 2.5GHz}$$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: $(((\cdot)))$

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Programmer is used exceeds the applicable RF compliance level above, the Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Programmer.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table C-4: Recommended separation distances between portable and mobile RF communications equipment and the Programmer (IEC 60601-1-2:2007 Table 6)

Recommended separation distances between portable and mobile RF communications equipment and the Programmer.

The Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Programmer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	.12	.12	.23
0.1	.37	.37	.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Disposal

Do not place the Programmer, its batteries, or other components in residential or commercial trash bins; instead, return them to Angel Medical Systems. Contact your AngelMed representative for assistance.

Components and Accessories

The Programmer is available with the following components and accessories.

♦ Stylus

♦ Battery

♦ AC Adapter

♦ AC power cord

♦ Flash drive

♦ EXD

♦ EXD cable, 6ft (1.8m)

♦ EXD cable, 10ft (3m) (optional)

♦ Carrying case (optional)

♦ Keyboard (optional)

♦ Mouse (optional)

If you need to order any of these components, contact your AngelMed representative for assistance. Also, be prepared to provide the model, serial, and part numbers of the Programmer. These numbers are printed on the device label, which is affixed to the bottom of the unit.

Notes
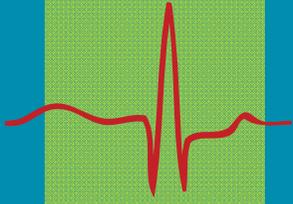
AngelMed Guardian® Programmer

Application User's Manual

Programmer Software Release: v3.6

AngelMed®

What's New in this Release?

Programmer release 3.6 contains the following new feature.

Programmer update to manage the new Model AMSG3 Implantable Medical Device (IMD)
The Model AMSG3 IMD is functionally equivalent to the current generation IMD, the Model AG101. The only difference is that the Model AMSG3 IMD does not use or connect to the lead adapter. This update enables the Programmer to recognize both IMD models.

About this Document

This manual provides a detailed description of the AngelMed 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 AngelMed 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 – Post-Implant Setup	Setup procedures to perform after the surgery is complete.
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.
Sans-serif text	Used to identify the suggested patient training instructions. (Ex. "Now, use the EXD to silence the alarm."
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 *Opening the Patient Record* on page 4-3.)
Command1 → *Command2*	The arrow (→) indicates a command sequence from the menu bar. For example, *Administration* → *Backup* means "Select *Administration* 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 AngelMed 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 Angel Medical Systems Programmer, contact your Angel Medical Systems (AngelMed) representative.

Technical Support

For technical support, contact your AngelMed representative, or Angel Medical Systems as follows:

Angel Medical Systems, Inc.
1163 Shrewsbury Ave. Suite E
Shrewsbury, NJ 07702 USA
Phone: 800 508 5206 (USA only)
         +1 561 962 2191

Related Documentation

♦ *AngelMed Guardian® Programmer Model Prog-003 Setup & Operations Guide*

♦ *AngelMed Guardian® External Device (EXD) User's Guide*

♦ *AngelMed Guardian® Implantable Medical Device (IMD) Model AMSG3 User's Guide*

♦ *Patient Manual for the AngelMed Guardian® System*

CONTENTS

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1

INTRODUCTION

The AngelMed 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 AngelMed Guardian system and the detection algorithm that it relies upon. Topics include:

- ♦ How the System Works
- ♦ AngelMed Guardian System Architecture
- ♦ Detection Algorithm Basics

1.1 How the System Works

The fundamental goal of the AngelMed 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 makes an appointment to see the doctor in the next 1 or 2 days. 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).

1.2 AngelMed Guardian System Architecture

The AngelMed 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 also has an EXD, 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.
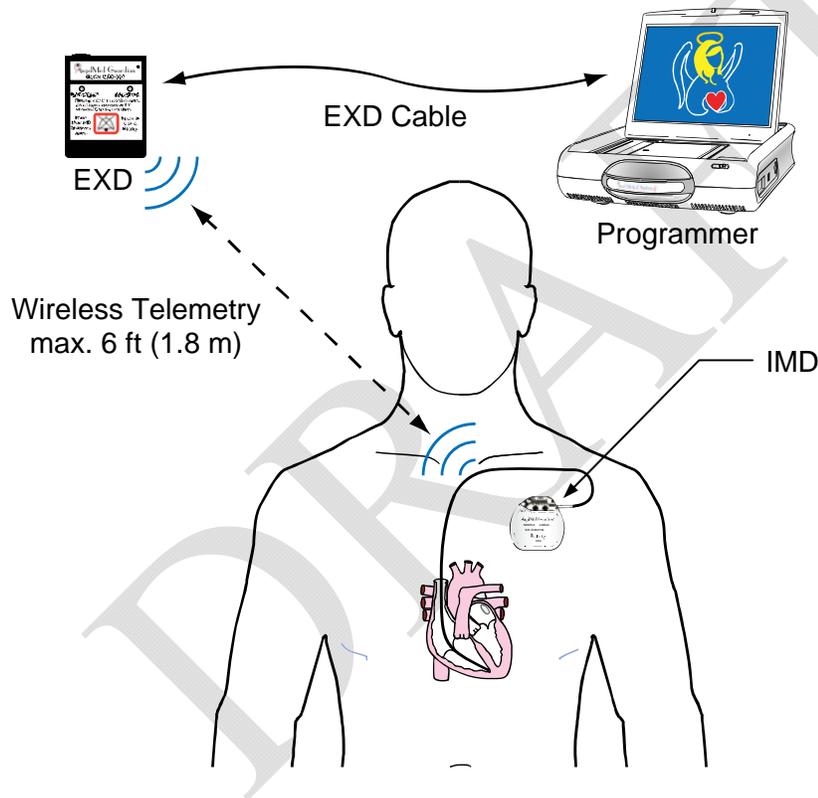
1.3 Detection Algorithm Basics

The AngelMed 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 Angel Medical Systems, 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.

1.3.1 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 V_R 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 T_R.
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. T_{PQ} 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. D_{PQ} is the duration (in milliseconds) of the PQ segment. The PQ voltage (V_{PQ}) is the average voltage of the PQ segment.

Algorithm Element	Definition
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. T_{ST} 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. D_{ST} is the duration (in milliseconds) of the ST segment. The ST voltage (V_{ST}) is the average voltage of the ST segment.
ST Deviation	The ST Deviation ($\triangle V$) of a beat is defined as the voltage difference between the average ST segment voltage (V_{ST}) and the average PQ segment voltage (V_{PQ}). Stated mathematically: ST Deviation ($\triangle V$) = $V_{ST} - V_{PQ}$
R Height	The R-Height value (RPQ) is the difference between the R-Peak voltage (V_R) and the average PQ segment voltage (V_{PQ}).
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.
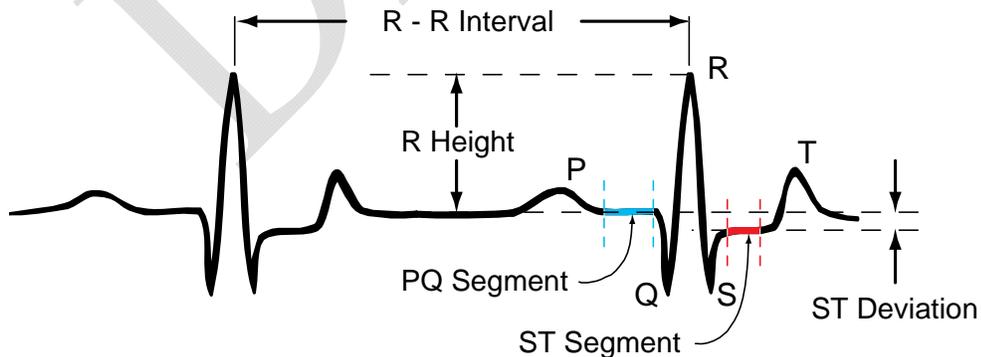
Legend:
R Height = R Peak - PQ Segment
ST Deviation = ST Segment - PQ Segment

1.3.2   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 a significant ST shift.

1.3.2.1   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.

1.3.2.2   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.
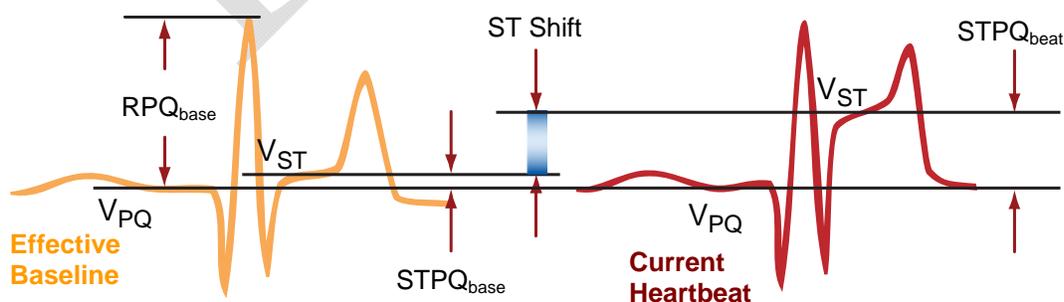
ST Shift = STPQbeat - STPQbase
ST Shift Threshold = % R height where ST Shift is deemed excessive (ST Shift/ RPQbase)

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.

1.3.2.3   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.
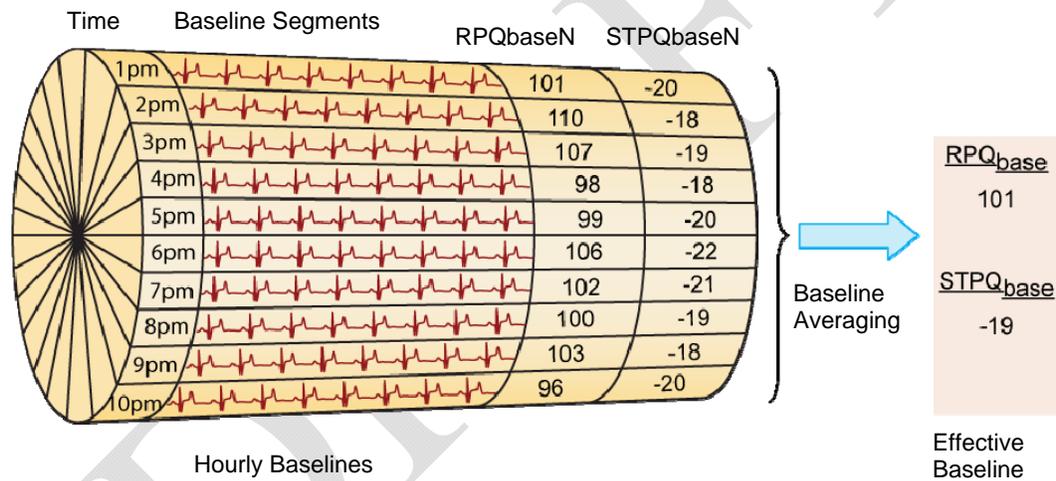
For each baseline, the IMD determines the R wave height of each beat and calculates the average height for that baseline segment (i.e.,RPQbaseN). It also determines the ST deviation of each beat and calculates the average ST deviation for the segment (i.e., STPQbaseN). At the top of each hour, the IMD establishes a new effective baseline by calculating the average R wave height (i.e.,RPQbase) and ST deviation (i.e., STPQbase) 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.

1.3.2.4 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, the IMD automatically updates 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.

1.3.2.5 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

1.3.3   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
- ♦ 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

1.3.3.1   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 ST Shift & Non-Elevated HR and 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.

For the Negative ST Shift & Non-Elevated HR event however, an additional set of circumstances can influence the alarm mapping. Specifically, if the event is detected at a time when the heart rate is significantly decreasing, the alarm type is automatically set 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 event.

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 an Emergency alarm.

1.3.3.2   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.

1.3.3.3 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.

1.3.3.4 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 AngelMed 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.

1.3.3.5 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 Angel Medical Systems 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 *AngelMed Guardian® Implantable Medical Device (IMD) User's Guide.*

PRE-IMPLANT CHECK 2

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 EXD, interconnected by the EXD 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:

♦ *AngelMed Guardian® Implantable Medical Device (IMD) User's Guide*
♦ *Instructions for Use* or other documentation supplied with the lead to be implanted with the IMD

2.1 Create a New Patient Record

⇒ **To create a new patient record:**

1. Select *Patient* → *New* from the Main Programmer window.
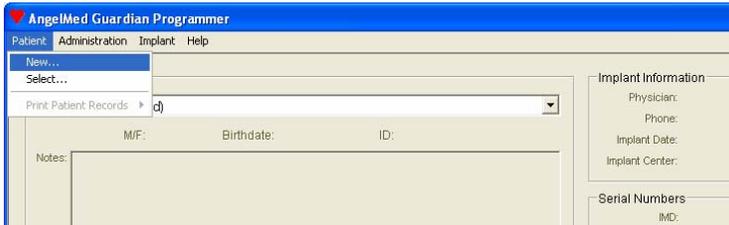
2. Enter the relevant details in the *New Patient Record* window as defined below.

Patient Information:

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 8-7.
Birth Date	Type the patient's birth date (up to 10 characters).

Physician Information:

Name	Type the doctor's name (up to 50 characters).
Phone	Type the doctor's phone number (up to 20 characters).

Implant Information:

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/Notes:

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 8-3.
Lead	Type the serial number of the lead (up to 15 characters).
Lead Adapter	Type the serial number of the lead adapter (up to 15 characters). **Note:** This field is not applicable for patients who are implanted with the Model AMSG3 IMD, which does not use the lead adapter; please leave blank.
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 7-2.

2.2 Open the Patient Record

The Programmer provides two means of opening the patient record:
♦ from the *Name* list
♦ from the menu bar

2.2.1 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.
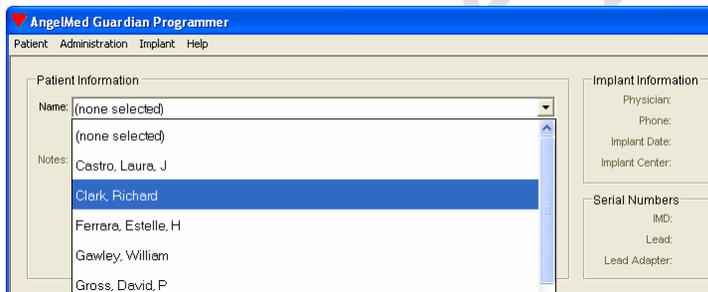
In response, the Main Programmer window fills with information relevant to that patient.
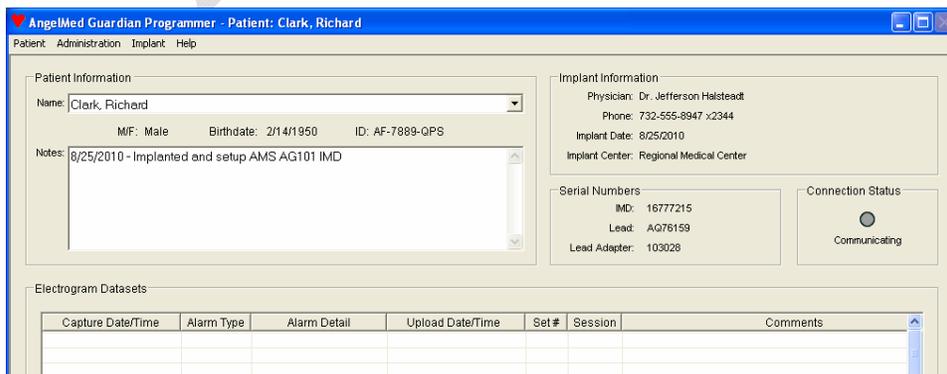
2.2.2 From the Menu Bar

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*.
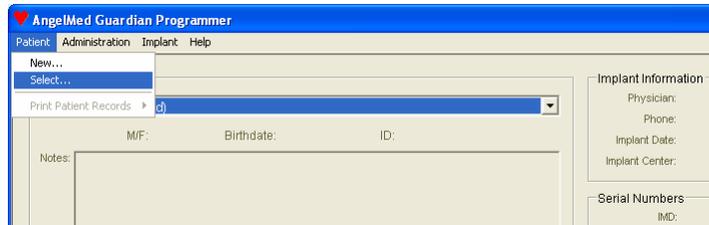
2. From the *Select Patient* window, select the row of the patient whose record you want to open and select *Open*. (You can also touch the patient row twice (i.e., double tap) with the stylus.)
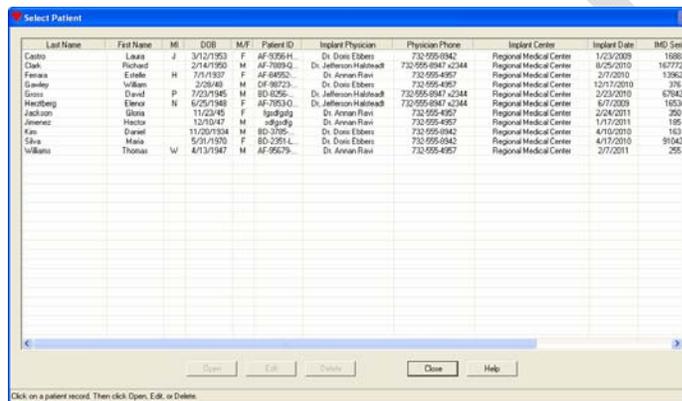
In response, the Main Programmer window fills with information relevant to that patient. You can sort patients by *Last Name*, *Patient ID*, and *IMD Serial #* by selecting the column header.

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

2.3 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 EXD is connected to the EXD cable, and the EXD cable is connected to the Programmer. (If necessary, consult your Programmer online Help, *Programmer Setup and Operations Guide,* or contact your AngelMed representative for details on connecting the EXD cable to the Programmer.)

Connected to Programmer

EXD Cable
Connection
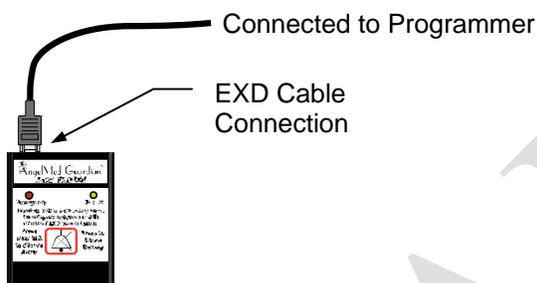
2. Place the EXD within 2in (5cm) of the IMD.

3. Push the Silence Alarm/Check Battery button on the EXD.
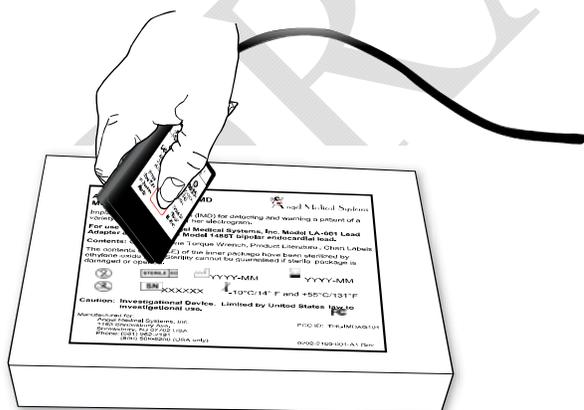
Communications with the IMD is confirmed when:
– the EXD beeps twice immediately after pressing the button
– the *Connection Status* indicator in the Main Programmer window changes from *Not Established* to *Communicating*.

Before:

Connection Status

Not Established

After:

Connection Status
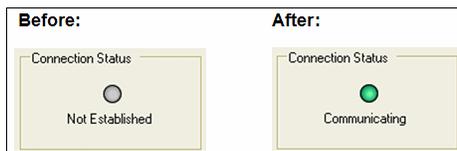
Communicating

If you cannot establish a session, see *Connection Problems between the Programmer and IMD* on page 8-6.

> **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 AngelMed representative.

4. Once the communication session starts, you can set the EXD down, but keep it within 6ft (1.8m) of the IMD to maintain communications.

5. Continue with the next procedure, *Run Pre-Implant Check*.

2.4 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.
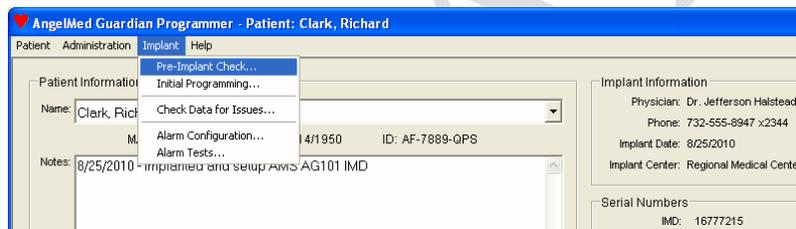
2. The system automatically detects the IMD serial number and adds it to the patient's record (assuming it was not previously entered).

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

3. The Programmer displays the *Pre-Implant Check* window.
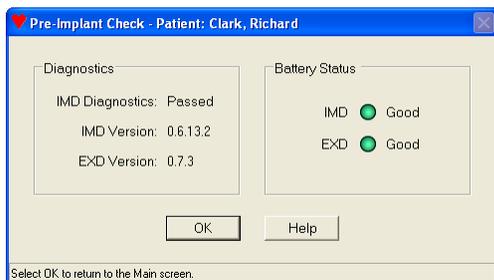
4. Check that the *IMD Diagnostics* have *Passed*.

> **Warning:**
> Do not implant an IMD that has not passed its IMD Diagnostics. Obtain
> another IMD for implantation and return the non-functioning IMD to your
> AngelMed 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 8-3.

5. 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 AngelMed 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 8-3.

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

2.5 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 *AngelMed Guardian® Implantable Medical Device (IMD) User's Guide* 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 *Implant Verification* on page 3-1.

IMPLANT VERIFICATION

3

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 EXD, connected by the EXD cable. Be sure to use the same Programmer that was used during Pre-Implant Check for the patient.

3.1 Verify IMD Operation

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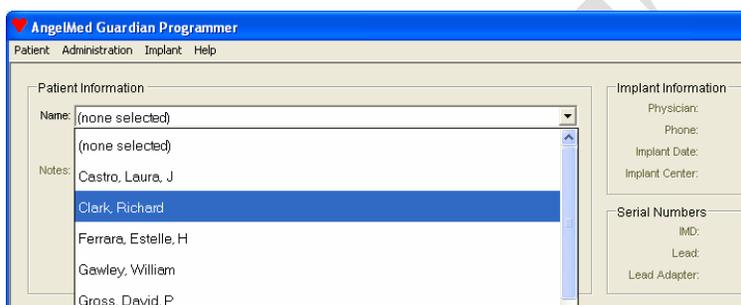
2. Holding the EXD over the IMD and within 2in (5cm) of the implant site, establish a communication session by pressing the EXD's Silence Alarm/Check Battery button.

Communications with the IMD is confirmed when:
– the EXD 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 8-6.

3. Once the communication session starts, set the EXD 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*.
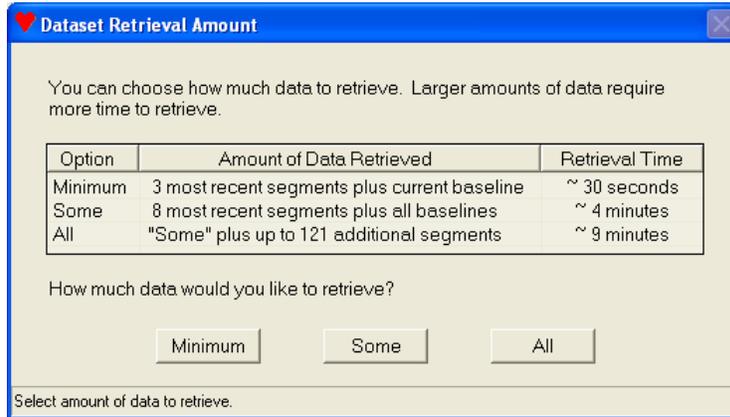
6. Observe the progress of the data retrieval from the *Retrieve Implant Data* window. The expected remaining time and the telemetry signal quality are displayed at the bottom of the window.
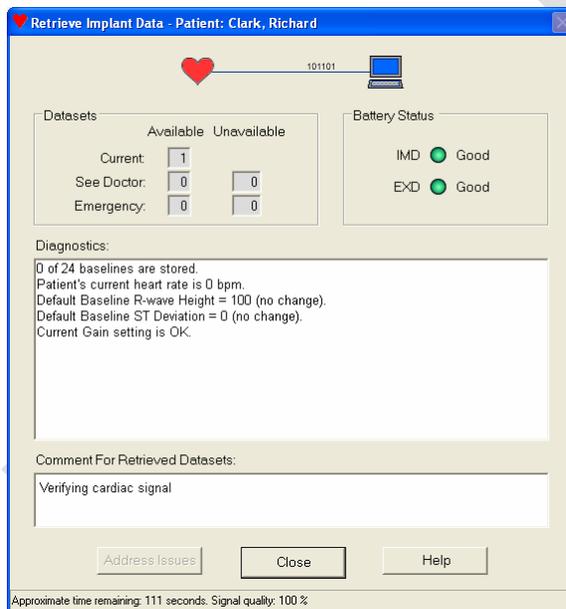
Note:
After initiating a retrieval, keep the EXD within 6ft (1.8m) of the patient. If telemetry signal quality dips below 95%, as indicated on the bottom of the window, move the EXD closer. If you lose communication, reestablish the session. The data retrieval process will continue where it stopped.

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 Programming 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.
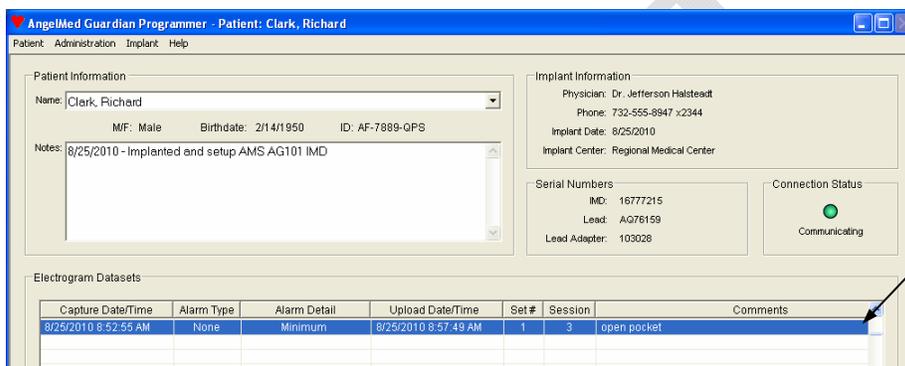
None Dataset

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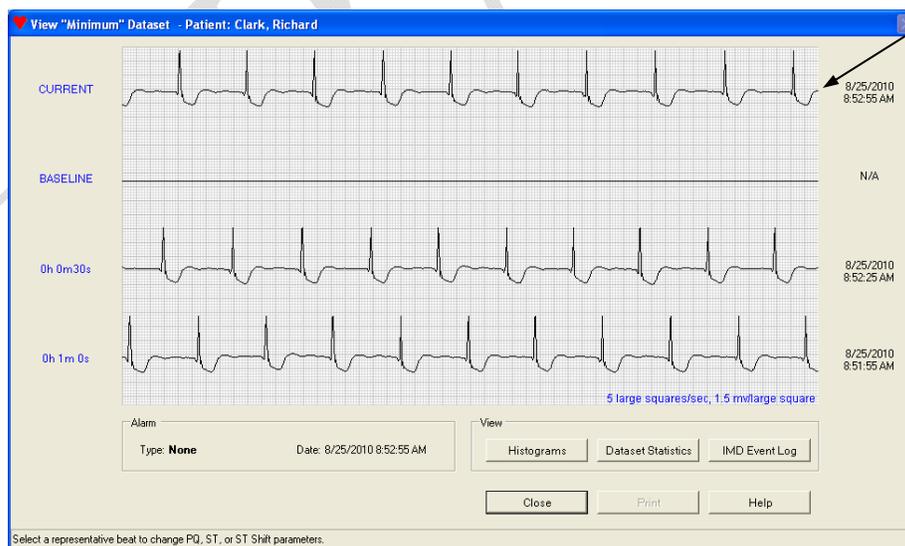
Most Recent Segment

> **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.

Minimum QRS
5 small
squares
(.75mV)
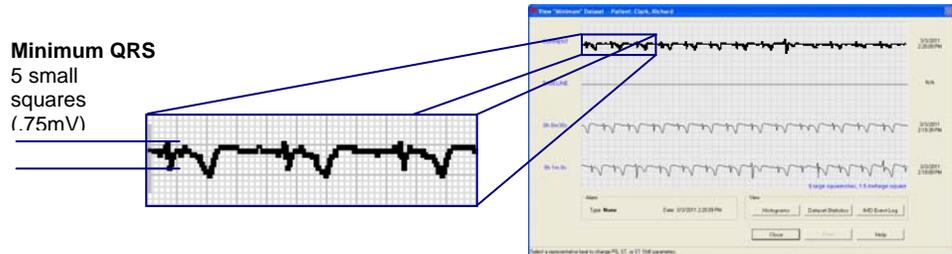
12. Do one of the following:

– 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/IMD header connection. ♦ Verify the IMD has good contact with the surrounding pocket tissue.
Non-continuous cardiac signal	♦ Recheck the lead/IMD header connection. ♦ 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. ♦ 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 8-3.

3.2 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.

3.3 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 8-6.

3. Once the communication session starts, you can set the EXD 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 AngelMed representative.

POST-IMPLANT SETUP

4

After the IMD is implanted and its operation verified, you need to perform a few follow-up activities to enable the IMD to collect baselines. This phase is called Post-Implant Setup.

Post-Implant Setup typically occurs on the day following implantation because you need to provide sufficient time for the patient's heart signal to stabilize.

Procedures

♦ Retrieve IMD Data and Adjust Gain

♦ Set Heart Rate Bins

♦ Concluding the Post-Implant 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.

4.1 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 8-6.

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 preserve all the baselines on the Programmer in the event the IMD gain needs adjustment.
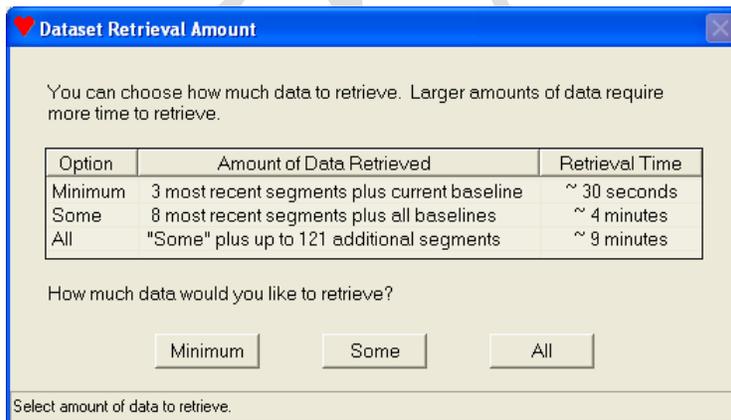
5. Observe the progress of the data retrieval from the *Retrieve Implant Data* window. The expected remaining time and the telemetry signal quality are displayed at the bottom of the window.
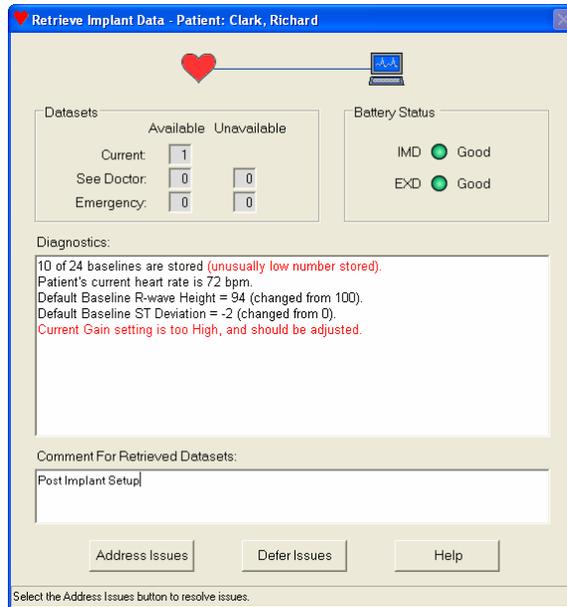
6. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, contact your AngelMed representative.

7. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Post-Implant 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, Post-Implant 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 AngelMed 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 8-2 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 1-8.

If the window displays "*The segment used to update Default baseline values had unusual characteristics*", do another data retrieval. If the window displays the same message again, contact your AngelMed 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:

o *properly set*

o *too high*

o *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 Post Implant 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 4-5.

– 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.
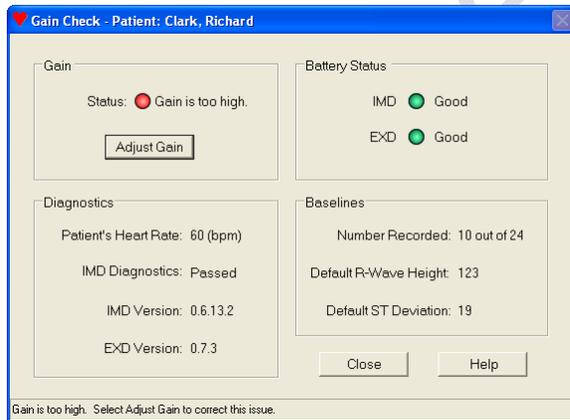
11. Observe the progress bar in the *Evaluating Gain Change* window.
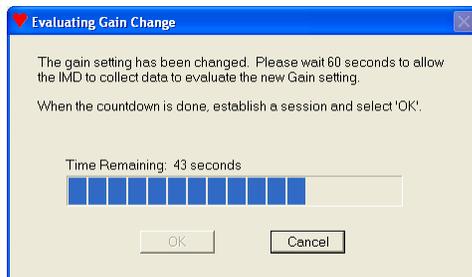
12. When the progress bar completes, re-establish a communication session with the IMD and select *OK*.

13. Again, check the gain status in the *Gain Check* window and perform Step 9 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 AngelMed for assistance.

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

4.2 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 looses 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. Retrieve data by selecting the *Retrieve Data* button on the Main Programmer window.

2. From the *Dataset Retrieval Amount* window, select *Minimum* for the fastest retrieval.
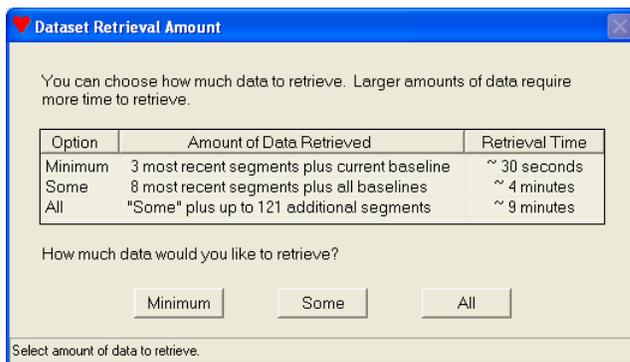
3. Observe the progress of the data retrieval from the *Retrieve Implant Data* window. The expected remaining time and the telemetry signal quality are displayed at the bottom of the window.

> **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.

4. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, contact your AngelMed representative.

5. If desired, type a meaningful comment about the retrieved data in the *Comment* field, for example "*Post-Implant Setup*".

6. 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.

7. 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.)
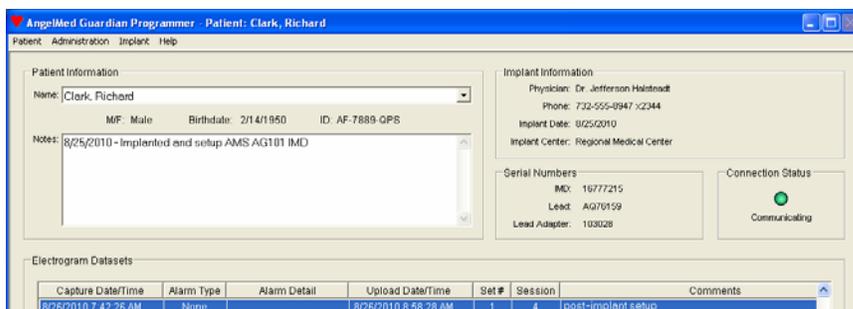
8. The Programmer displays the *View Minimum Dataset* window, showing four electrogram segments. Select any beat from the first, third, or fourth segments by touching one with your stylus.

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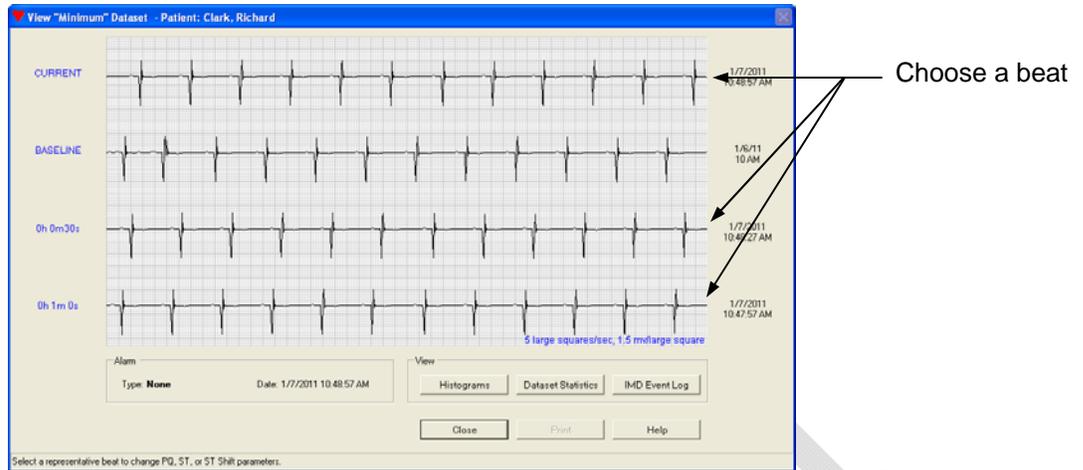
9. From the *Edit Implant Parameters* window, review the current settings and change them as is appropriate for the patient by moving the sliders left or right.

Low Slider   Normal Slider   High Slider
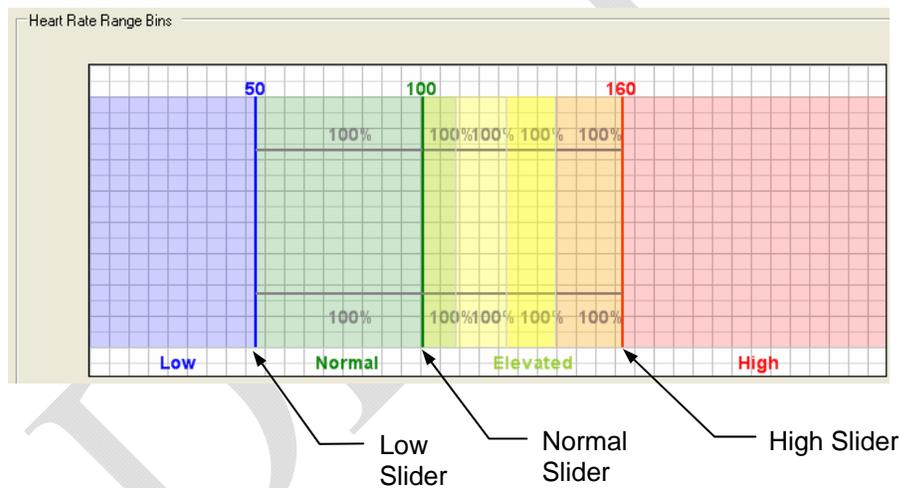
10. Save the new heart rate bin settings by selecting the *Save* button. (If you have elected to keep the original settings, select *Cancel* and then go to Step 16.)

11. 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.

12. The Programmer may display the *Select Data to Clear* window. If it does, leave all items checked and select *OK*.
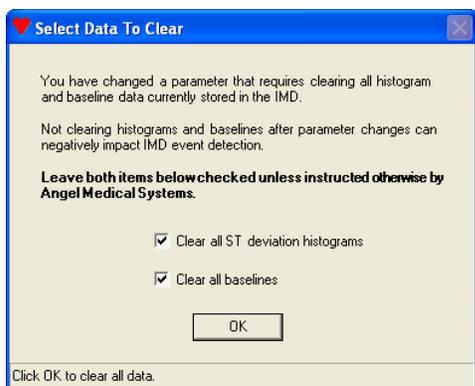
> **Note:**
> Leave all items checked on the *Select Data to Clear* window unless instructed otherwise by an AngelMed representative.

13. The Programmer saves the heart rate parameter settings to the patient's IMD.

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

15. Retrieve IMD data again by selecting Retrie*ve 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.

16. Continue with the next procedure, *Concluding the Post-Implant Setup*.

4.3 Concluding the Post-Implant Setup

The Post-Implant Setup process has concluded.

♦ Be sure to complete the *AngelMed Guardian IMD Patient Information 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

5.1 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 8-6.

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.
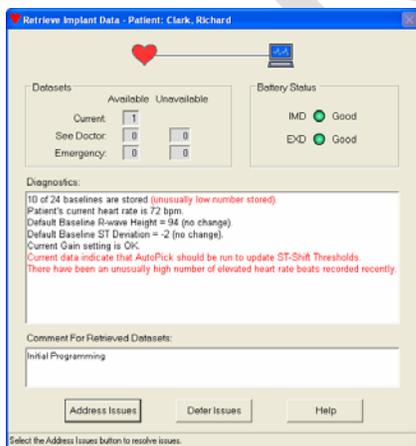
6. While the data are downloading to the Programmer, verify that the IMD battery status indicates *Good*. If it is not *Good*, contact your AngelMed representative.

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*.

5.2 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.
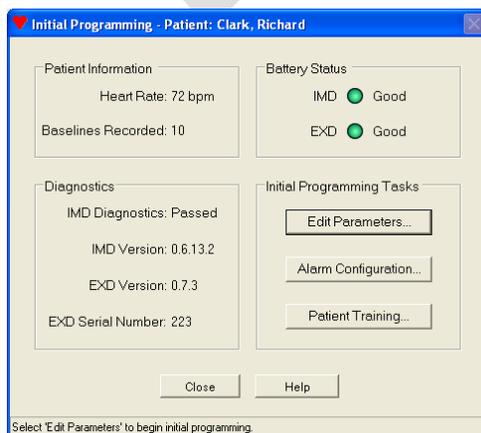
Begin by checking the device and patient status information from the *Initial Programming* window.

5.2.1 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.
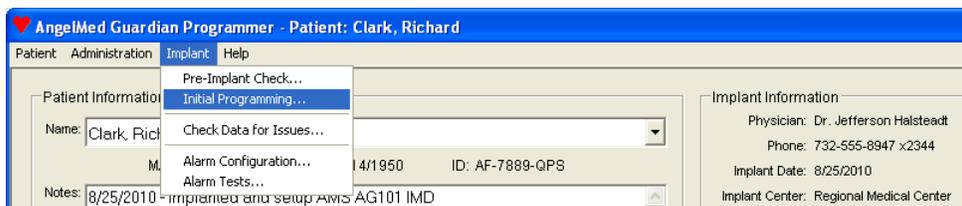
> **Note:**
> The *Initial Programming* window checks the status of the most recently retrieved None dataset. If the dataset is no longer current, the Programmer displays an advisory message, informing you that you need to retrieve new IMD data. If you get this message, retrieve the data and then re-open 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 8-2.

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 8-8.)

5.2.2 Check Diagnostic Results

♦ From the *Diagnostics* area of the *Initial Programming* window, verify *IMD Diagnostics* indicates *Passed*. If it does not indicate *Passed*, contact your AngelMed representative.

5.2.3 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 6-11.)

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. Explant and replace the IMD.
Replace (Red)	Battery is depleted. Replace the battery.	Battery is depleted. Explant and replace the IMD.

2. Perform the three main Initial Programming tasks:

- *Train the Patient* on page 5-6
- *Set the IMD Alarm Configuration* on page 5-7
- *Set IMD Parameters* on page 5-11

You can complete them in any order.

5.3 Train the Patient

Successful use of the AngelMed 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 AngelMed 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 EXD battery 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.
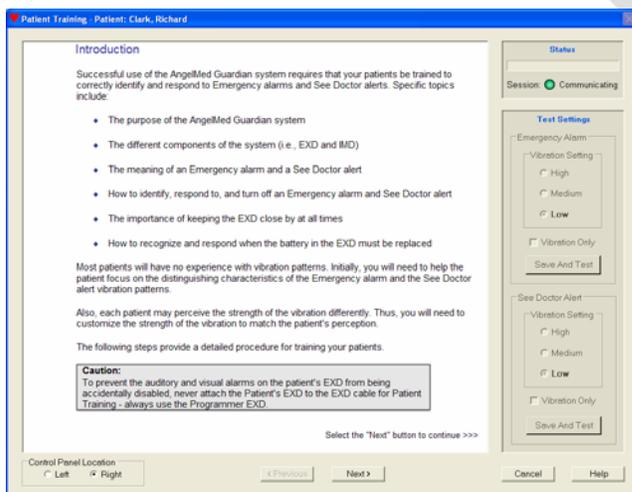
Follow the instructions that are displayed in the Patient Training window for each step in the training process. When you finish a step, select the *Next* button at the bottom of the window to go to the next training step. A copy of the entire training script is also provided in *Patient Training Script* on page C-1.

2. Do one of the following:

– If you have not completed all three Initial Programming tasks, continue with:

o *Set the IMD Alarm Configuration* on page 5-7 or

o *Set IMD Parameters* on page 5-11

– 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 5-19.

5.4 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*. Note that if this event is detected during a period of time in which the patient's heart rate has decreased significantly, the event is automatically mapped to a See Doctor event. For further details, see *Positive ST Shift & Non-Elevated HR and Negative ST Shift & Non-Elevated HR* on page 1-9.
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 *Emergency*.
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 24 consecutive hours. 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. Assign each event to one of the following *Alarm Types.*

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:
   o *Train the Patient* on page 5-6 or
   o *Set IMD Parameters* on page 5-11
   – 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 5-19.

5.5 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

5.5.1 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, 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.

5.5.2 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 1-4.)
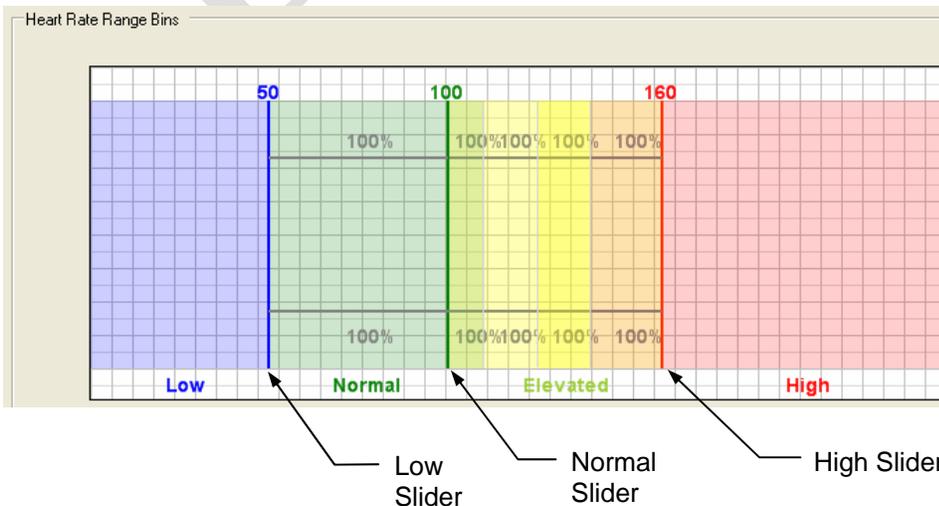
This area provides three sliders that allow you to change the following bins:

♦ *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).

5.5.3 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 1-4.

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.
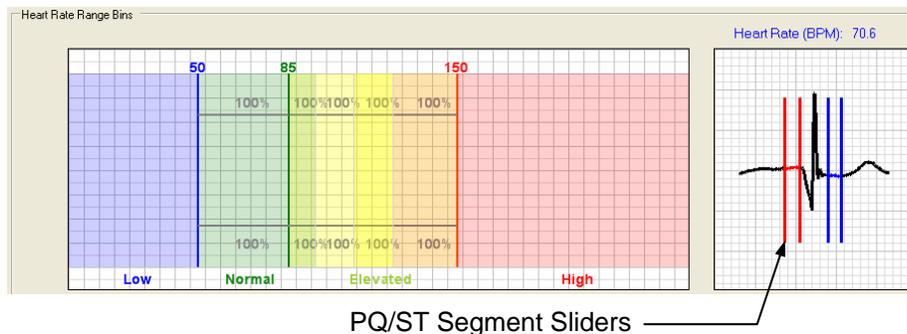

PQ/ST Segment Sliders

⇒ **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.
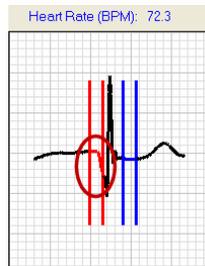
Corrected PQ Segment
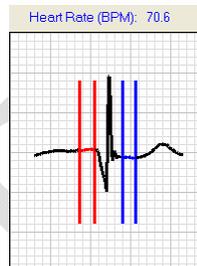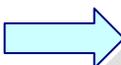
ST Segment Needs Adjustment -
Most of this ST segment overlaps the T wave.
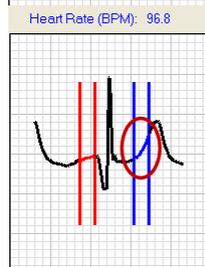
Corrected ST Segment
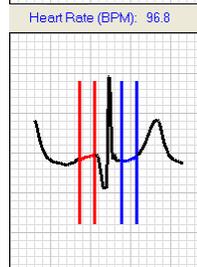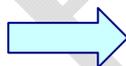
2. Assess the PQ and ST segment boundaries against other beats in the dataset by using the Segment and Beat Selectors.

3. If you think any of the boundaries need adjustment, contact your AngelMed representative.

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

5.5.4 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 1-4.

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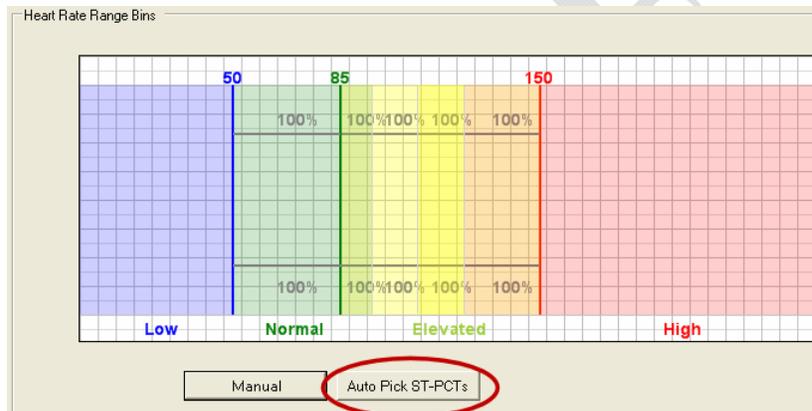
2. From the *Select AutoPick Days* dialog box, select the days upon which you want AutoPick to base its ST shift analysis and then select *OK*.

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


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 day's time. When the patient returns, use AutoPick to set the ST shift thresholds. Note that you can perform the *Set ST Segment Trending Parameters* procedure on page 5-19 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.


Proposed New ST Shift Thresholds
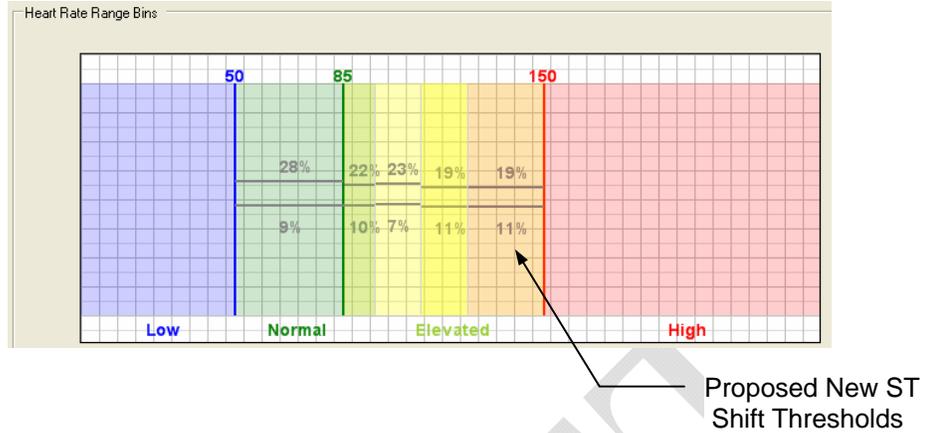
4. Save the IMD parameter settings by selecting *Save* on the *Edit Implant Parameters* window.

5. Select *Yes* on the *Parameter Change Verification* window, which identifies the parameters that you have changed since opening the *Edit Implant Parameters* window.
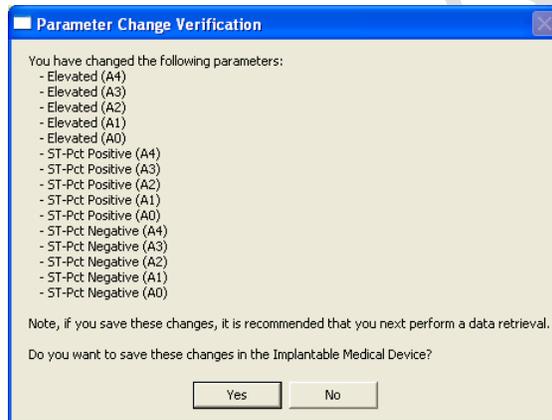
6. The Programmer may display the *Select Data to Clear* window. If it does, leave all items checked and select *OK*.
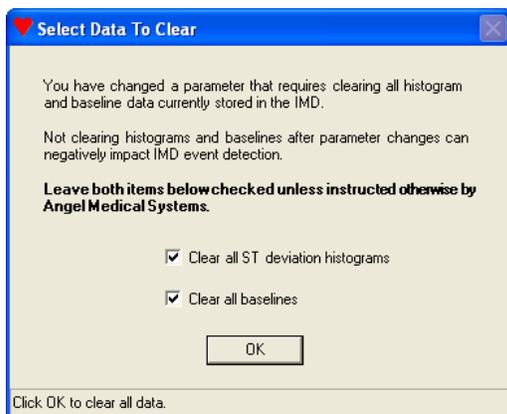
> **Note:**
> Leave all items checked on the *Select Data to Clear* window unless instructed otherwise by an AngelMed representative.

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:
  - o *Train the Patient* on page 5-6 or
  - o *Set the IMD Alarm Configuration* on page 5-7
- 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 5-19.

5.6 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 1-11.

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.
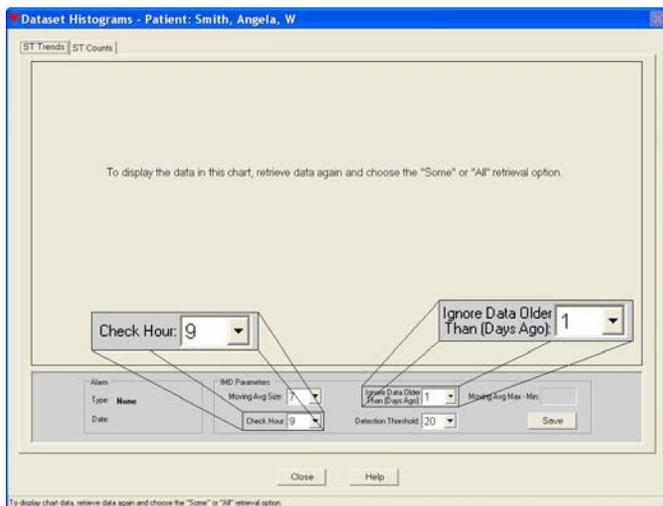
6. In the *Check Hour* field select an appropriate time of day; a time when the patient is most likely to be awake. Be sure to get proper input from the patient. Available times are: 12:00 (midnight), 3:00am, 6:00am, 9:00am, 12:00 (noon), 3:00pm, 6:00pm, and 9:00pm. All times are in the local standard 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.

FOLLOW-UP VISITS   6

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

♦ Review the Datasets

♦ Checking Data for Issues

♦ Replace the EXD Battery

♦ Review Alarms and Patient Instructions

6.1 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 8-6.

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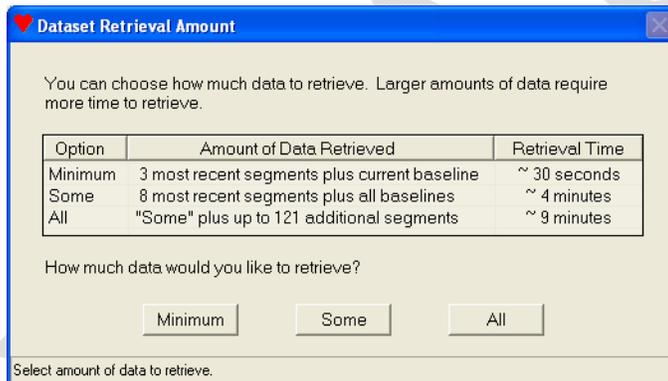
Select the *Some* option to begin a data retrieval.

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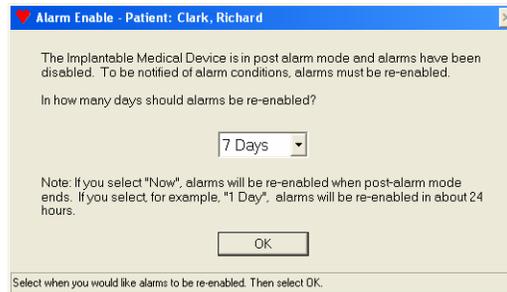
This window allows you to specify the time at which IMD alarming and alerting
are re-enabled. Alarming and alerting are automatically disabled while the IMD
is in post-Emergency alarm data acquisition mode.

> **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*.
o If you choose *Now*, alarms and alerts are re-enabled as soon as normal data
acquisition resumes.
o 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.
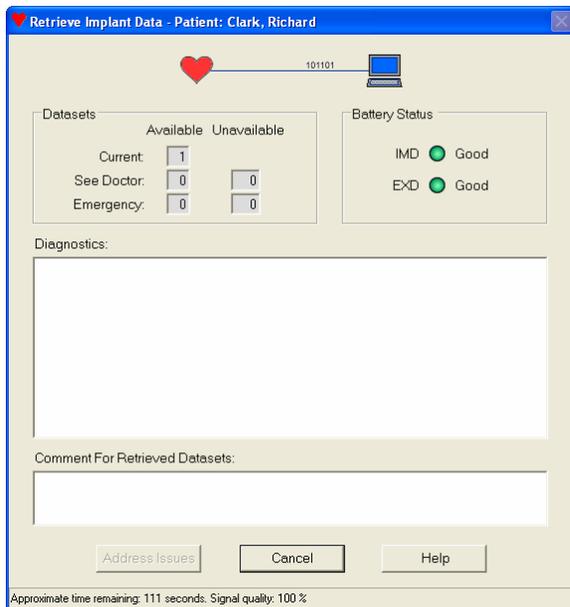
The *Datasets* portion displays the number of datasets that are *Available* for retrieval and the number of datasets that have been discarded (i.e., *Unavailable*) for the following dataset types.

–   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 *AngelMed Guardian® Implantable Medical Device (IMD) User's Manual*.

> **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.
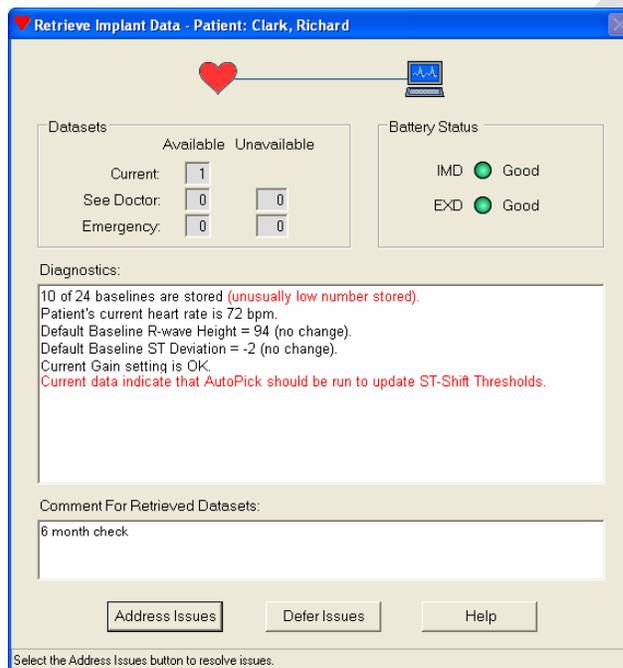
Do one of the following:

– 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.

6.2 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.)
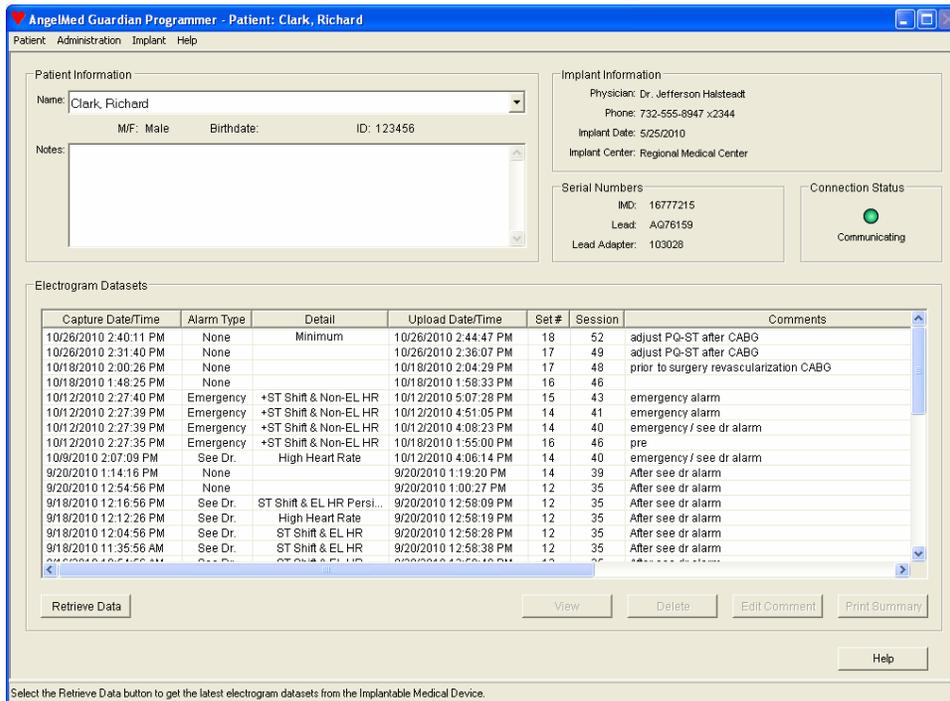
Note:
All electrogram and dataset timestamps are based on the local standard time of the Programmer that retrieves the data. The timestamps never adjust for Daylight Savings Time (DST), even in localities that observe DST.

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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.

6.2.1 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.)

Electrogram
Display
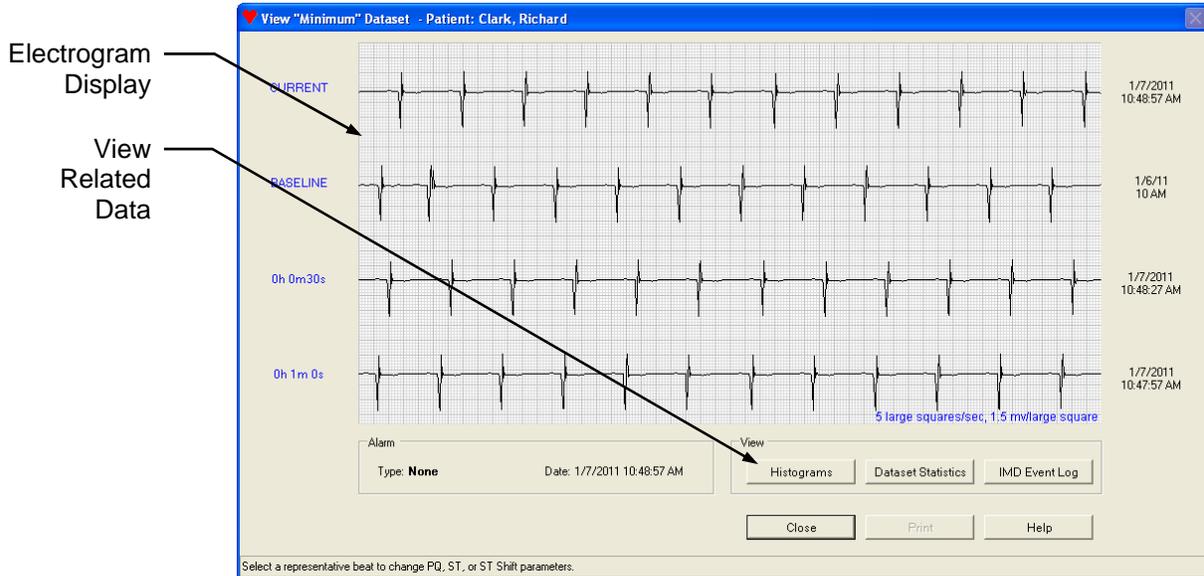
View
Related
Data

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

## 6.2.2 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 1-10. 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.

Electrogram
Display

Segment
Selector

View
Related
Data
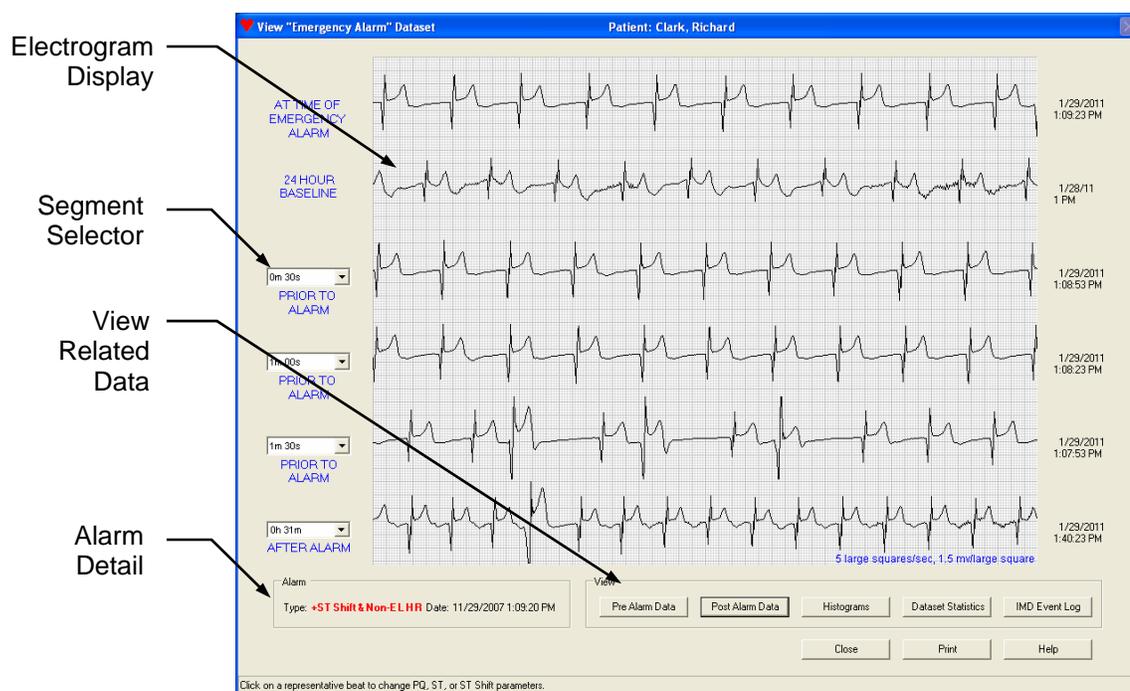
Alarm
Detail

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.

6.2.3 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 5-7.

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.

Electrogram Display

View Related Data

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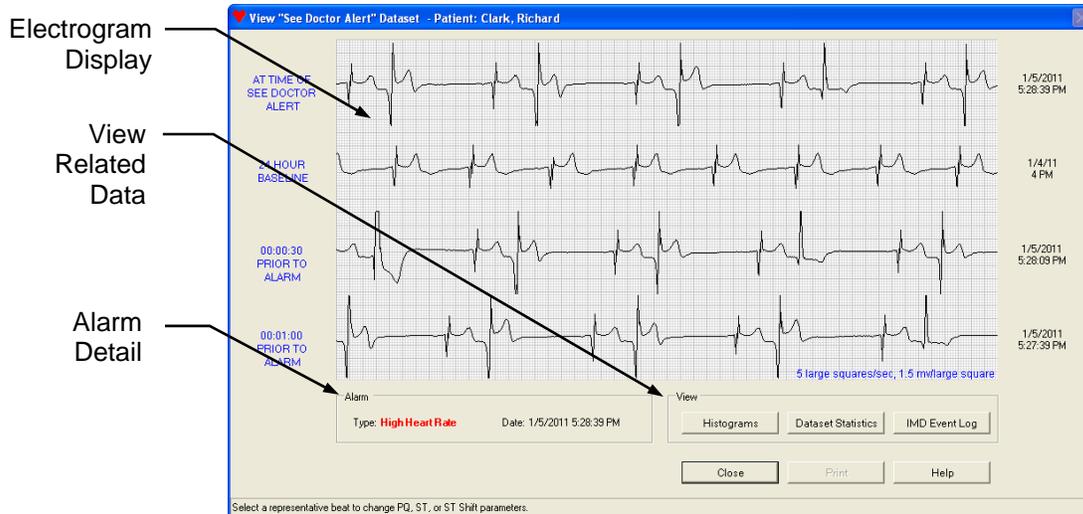
The *View "See Doctor Alert" Dataset* window shows four electrogram segments.

♦ 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.

6.2.3.1   Information on Some Additional Events

The following events deserve a little more explanation: Cannot Get Baseline, ST Trend, Recovery (-ST Shift & Non-EL HR), and Watchdog Reset.

Cannot Get Baseline Event

A Cannot Get Baseline event indicates that the IMD failed to find a baseline segment for 24 consecutive hours. 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 8-8 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 1-11 for more information.)

Recovery (-ST Shift & Non-EL HR)

The Recovery event occurs when the IMD detects a Negative ST Shift at Non-Elevated Heart Rate (-ST Shift & Non-EL HR) event during a time that the patient's heart rate is decreasing. (See *Positive ST Shift & Non-Elevated HR and Negative ST Shift & Non-Elevated HR* on page 1-9 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 AngelMed 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 Angel Medical Systems immediately.

6.3 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 *Check Data for Issues* feature on the Programmer.

⇒ **To check data for issues:**

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

2. Select the *Implant → Check Data for Issues* on the Main Programmer window.
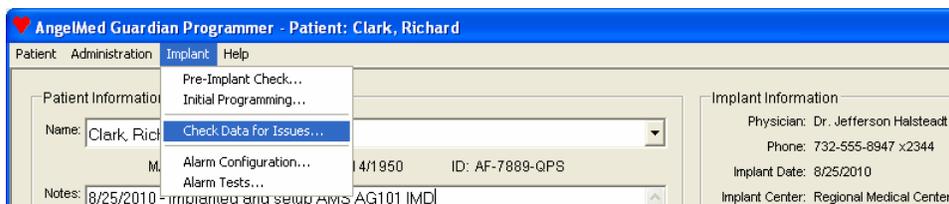
3. Do one of the following:

– 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:
  o If any of the entries in the Diagnostics area are red, select the *Address Issues* button and follow the instructions provided by the Programmer.
  o If none of the entries are red, there are no data issues and you should select *Close* to close this window.
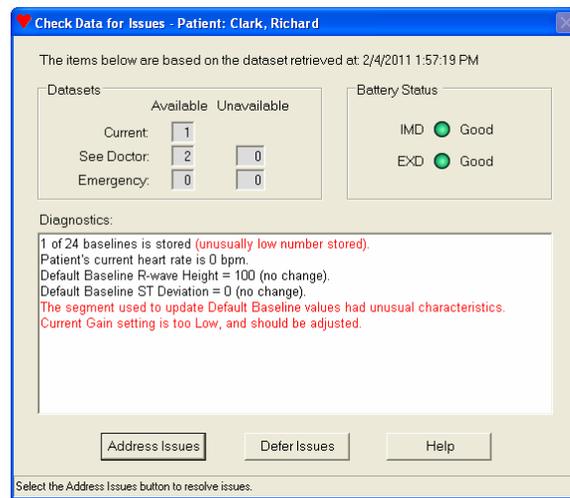
6.4 Replace the EXD Battery

The service life of the EXD battery is 6 months. At anytime that you consult with patients, be sure to ask when they last changed the EXD battery and, if necessary, change the battery for them. Also, verify that they have a spare EXD battery so they can change the battery at home when necessary. The EXD battery must be replaced every 6 months.

> **Caution:**
> Only use the EXD batteries supplied by Angel Medical Systems. Although conventional "AA" sized batteries will fit in the battery compartment, 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.
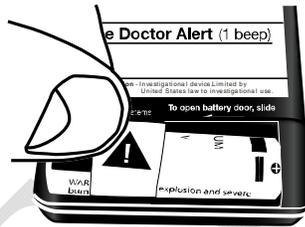
3. Insert the positive (+) end of the new battery into the battery compartment, and then push down on the battery's negative (-) end. Be sure that the tab is exposed for subsequent removal.

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 with another.

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

6.5 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 AngelMed Guardian system ID card

These procedures are explained in the following sections.

6.5.1 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 Tests*.

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.
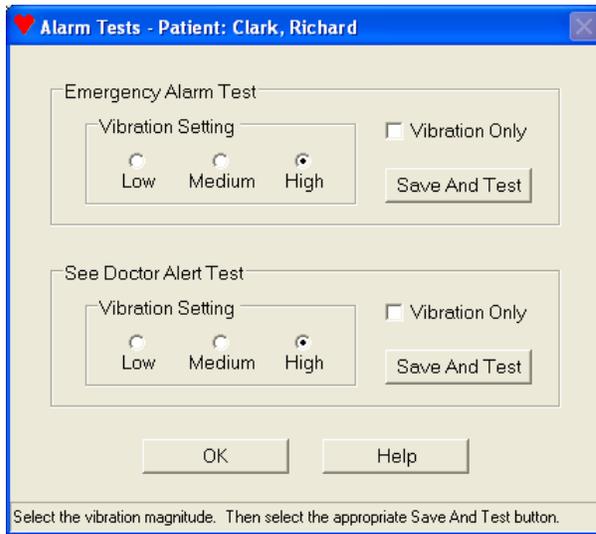
The *Alarm Tests* window has the following features.

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 on-line 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*.

6.5.2 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 See Doctor alerts 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*.

6.5.3 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 replace the battery or call your office for assistance.

6.5.4   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."

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

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

6.5.6 Review Contact Info and Instructions on EXD and System Information 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 System Information 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 and restore data from the flash drive.

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

Procedures

♦ Backing Up Programmer Data

♦ Restore Programmer Data

♦ Safeguarding Your Data for Disaster Recovery

7.1 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 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 Angel Medical Systems.

⇒ **To back up Programmer data:**

1. Make sure that an AngelMed flash drive is plugged into the Programmer. (If necessary, consult your Programmer Setup Guide or contact your Angel Medical Systems representative to identify the proper port.)

2. From the Main Programmer window, select *Administration* → *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 AngelMed flash drive into the Programmer. Then select *Retry*.
    –   *Some files could not be backed up. Please contact Angel Medical Systems.*

        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 Angel Medical Systems 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 AngelMed representative for assistance.

4. The Programmer displays the *Backup Data* window. Select *Start* to begin the backup.
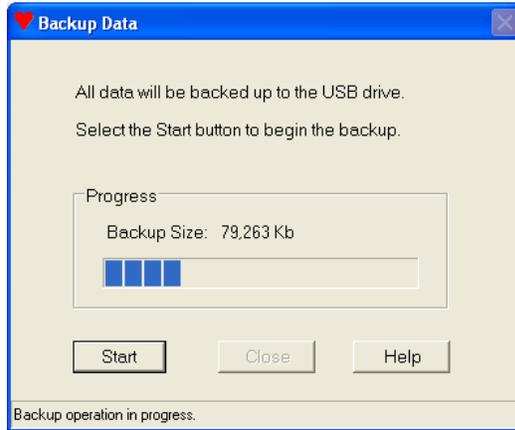
The Programmer displays a progress bar, indicating the completion status of the backup.

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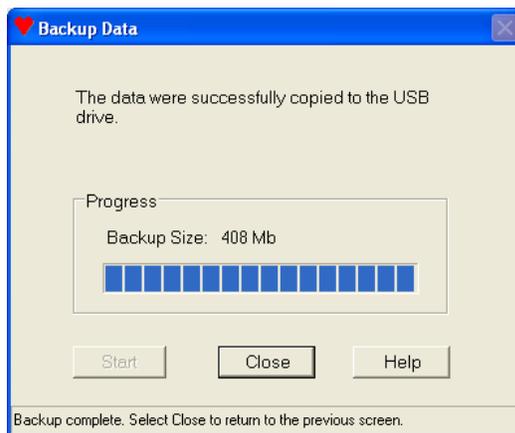
7.2 Restore Programmer Data

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 AngeMed. 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 AngelMed flash drive is plugged into the Programmer. (If necessary, consult your *Programmer Setup Guide* or contact your AngelMed representative to identify the proper port.)

2. From the Main Programmer window, select *Administration → Restore*.


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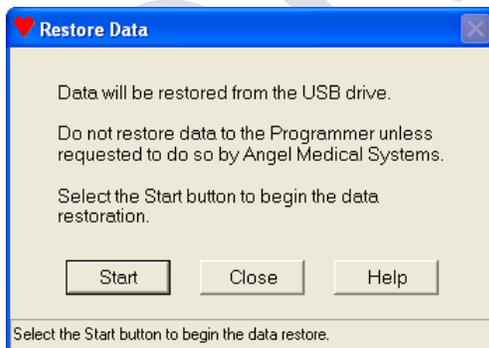

> **Note:**
> The time required to restore data depends on the amount of data to be restored and may take several minutes.

4. The Programmer prompts you to confirm that you want to restore data from the AngelMed flash drive. Select *Yes* to restore the data.
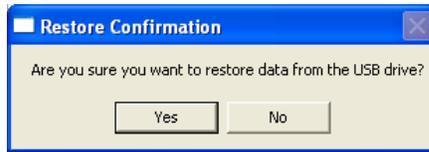
The Programmer displays an hourglass icon while the data are being retrieved.

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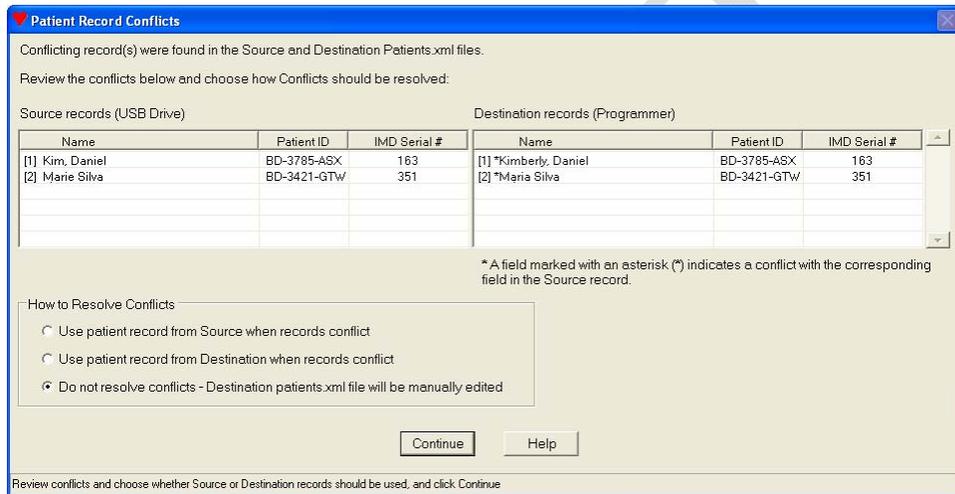
Additional information on resolving records conflicts can be found in the Programmer online Help.

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

7.3 Safeguarding Your Data for Disaster Recovery

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 7-2.

T ROUBLESHOOTING   8

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

This chapter addresses the following issues:

♦ Data Backup or Restoration Problems

♦ Heart Rate Does Not Match Patient's Heart Rate

♦ IMD Serial Number Must Be Changed

♦ Data Retrieval from IMD is Suspended

♦ Connection Problems between the Programmer and IMD

♦ Patient ID Number Must be Changed

♦ Problems with Collecting Baselines

♦ EXD Does Not Beep When IMD Alarms

8.1 Data Backup or Restoration Problems

Cannot Backup or Restore Data

Verify that the USB flash drive is plugged into the Programmer. See *Programmer Backup and Restore* on page 7-1 for additional details.

8.2 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 between the lead and IMD header or endocardium may be faulty.
  − The lead may be broken or damaged.
  − The lead may be implanted in the wrong place.

♦ Excessive injury current, which is caused by a 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 4-2.

♦ 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.

   o 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 AngelMed representative.

   o If the IMD has already been implanted and the surgical pocket is closed, contact your AngelMed 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 AngelMed representative for assistance.

8.3 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

8.3.1 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 *Administration → Backup* from the Main Programmer window. (For specific details, see *Backing Up Programmer Data* on page 7-2.)

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 2-2 for additional details.

8.3.2 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 *Administration* ➔ *Backup* from the Main Programmer window. (For specific details, see *Backing Up Programmer Data* on page 7-2.)

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 2-2 for additional details.

8.3.3 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.

8.4 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 EXD to ensure more reliable communications. Once restarted, the Programmer resumes the data transfer at the point of suspension.

Positioning the EXD

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

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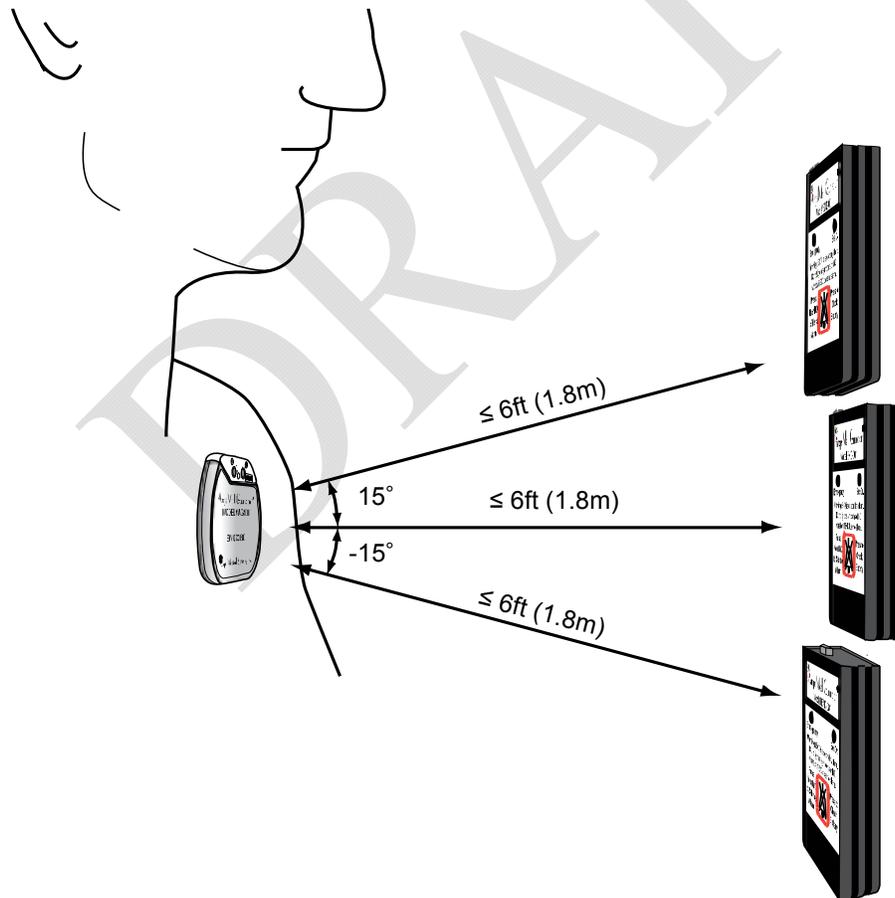
⇒ **To re-start a data retrieval:**

1. Observe the *Connection Status* indicator on the Main Programming 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 EXD within 6 ft (1.8m) of the IMD. If possible, move the EXD 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 EXD 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.

8.5 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 EXD to within 2in (5cm) of the IMD when attempting to start a session. You know the session has started when the EXD 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 EXD to a slightly different position over the IMD and keep it within 2in (5cm) of the IMD.

3. Ensure that the EXD is connected to the EXD cable, and the EXD cable is connected to the Programmer. (If necessary, consult the *Programmer Setup* section of the Programmer online Help, *Programmer Setup and Operations Guide* or contact your AngelMed representative for details on connecting the EXD cable to the Programmer.)

4. Ensure that the EXD 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 EXD battery.

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

8.6 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 *Administration* → *Backup* from the Main Programmer window. (For specific details, see *Backing Up Programmer Data* on page 7-2.)

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 2-2 for additional details.

8.7 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 5-12.
   - *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 5-13 and *Set ST Shift Thresholds* on page 5-14.
   - If any other column has the largest number in it, contact your AngelMed representative.

8.8 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 acknowledgement 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 in the near future.

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.

IMD PARAMETERS: DEFAULTS AND RANGES

<div style="text-align: right; font-size: large; font-weight: bold; color: #2e3192;">A</div>

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 $\geq$ (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 $\leq$ (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 $\leq$ (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 $\leq$ (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 Heart Rate 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 AngelMed representative.

Alarm Type Associations (Recommended settings)

Event	Emergency	See Dr	None	Ignore
Positive ST Shift & Non-El HR	✓			
Negative ST Shift & Non-El HR *	✓			
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	✓		

* Automatically mapped to See Doctor if event is detected with decreasing heart rate.

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	192
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

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 1-4.)

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.

NORMAL (A0)	Bins	Elevated (A4)															
		110	115	120	125	130	135	140	145	150	160	170	180	190	200	210	220
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	75	75	75	75
	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			N/A				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.

PATIENT TRAINING SCRIPT

C

Patient training is conducted using a wizard, shown in the following figure, that 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 AngelMed 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 AngelMed 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 AngelMed 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 AngelMed 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 Alarm/Check 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 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.

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. <u>Be sure the patient notices the flashing light on the EXD</u>.

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 AngelMed Guardian® System.*

Give the patient the System Information Card and Patient Manual

♦ Complete the *AngelMed Guardian® System Patient Information 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. This card replaces the IMD Information card that the patient received after Post-Implant Setup. If the patient has their IMD Information Card, you should ask him or her to return that card to you (to avoid any confusion).

♦ Give the patient the *Patient Manual for the AngelMed 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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Programmer Application User's Manual

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