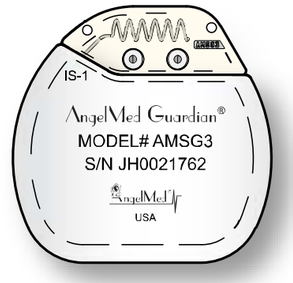
AngelMed Guardian® Implantable Medical Device (IMD) Model AMSG3

User's Guide



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AngelMed®

Fold Line

Caution - Investigational device. Limited by United States law to investigational use.

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 with either of the following Programmers:

- AngelMed Guardian Model Prog-002 Programmer running software version 3.6 or higher.
- 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 system is an implantable cardiac event recorder with ST segment measurement and alarms. It is indicated for use when the clinician decides to monitor for ST segment deviations on a continuous basis. The AngelMed Guardian system signals a visible, audible, and vibrotactile alarm to the patient if it detects electrogram parameters that are preset by the clinician. It also records events matching electrogram parameters preset by the clinician for later analysis by the clinician.

> **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 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.
- Patients who cannot feel the IMD vibration when the IMD is placed on top of the skin and just under the left clavicle.

See *Precautions* on page 13 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.

[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 (indicative of initial ischemia), 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)

While reasonable defaults are provided, 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 51. 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 – the 24 electrogram segments that led up to 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.

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

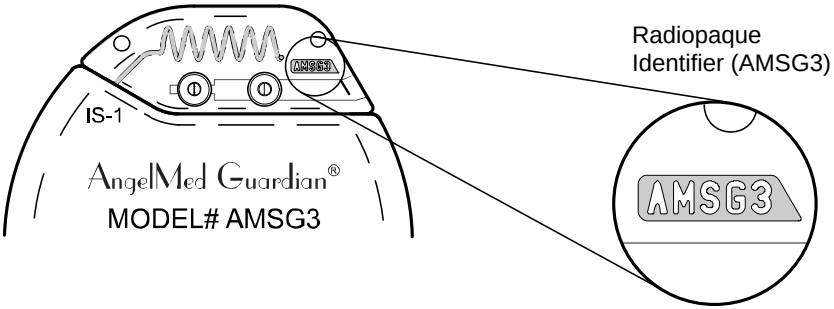
Near-field telemetry is used to silence IMD alarms and establish far-field communication sessions between the IMD and EXD. The EXD initiates all communication sessions. Near-field telemetry is unidirectional (the IMD can only receive) with a communication distance of approximately 2 in (5 cm).

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 46.

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.

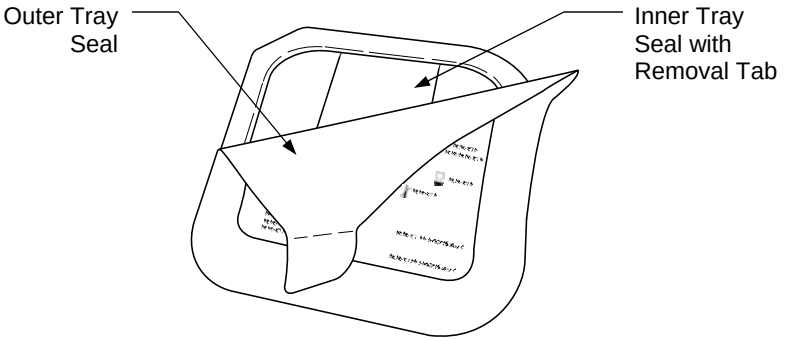
No resterilization. Angel Medical Systems has sterilized the IMD with ethylene oxide prior to shipment. Do not resterilize the device.

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 Setup inspection, which is discussed on page 22, 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.



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 3 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 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 16 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 13 for information on the implant site.

Warning:
Ensure that an external defibrillator is immediately available.

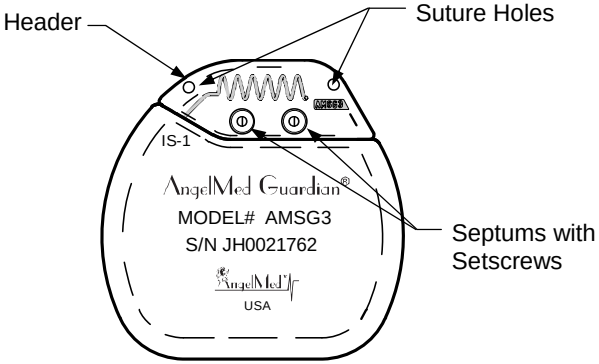
1. Implant the endocardial lead using standard lead implantation techniques, ensuring that the lead tip is actively fixated into the apex of the right ventricle. This location is necessary for proper functioning of the IMD.

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.

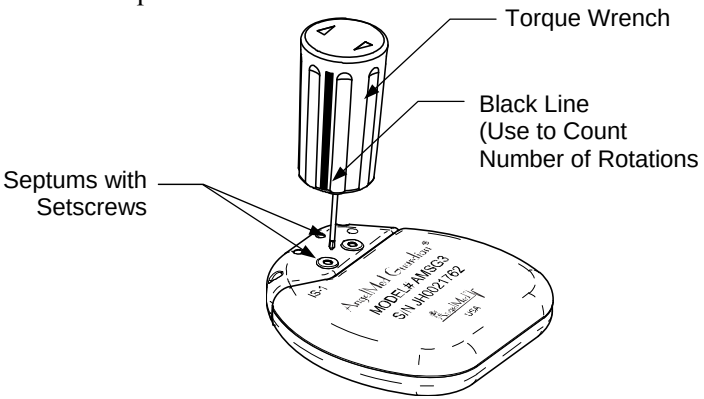
3. Connect the Lead to the IMD

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



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.



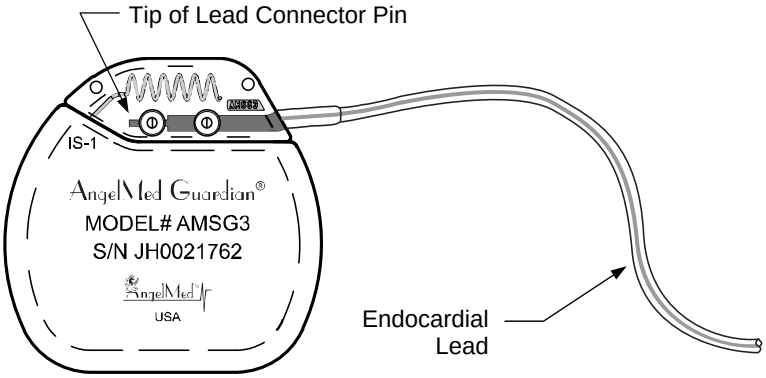
2. Observing the black line on the torque wrench handle, turn the same setscrew counterclockwise six full rotations to provide clearance for the lead connector pin.

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.



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.

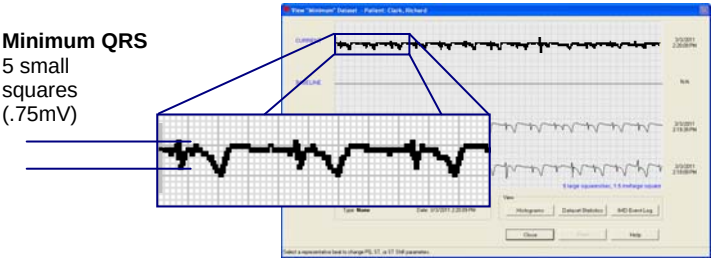
   Note:
   If the Programmer reports any dataset anomalies in the *Retrieve Implant Data* window, you should ignore them at this time.

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.

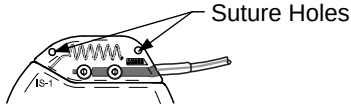


8. Do one of the following:

- 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.



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 32.
- 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 EXD battery every 6 months and/or when the EXD battery status indicator is yellow (Low) or red (Replace).
- Confirm 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 the ID card and knows where the 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 47.) 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 43.

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 22.

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:

> **Note:**
> If the Programmer you are using has a printer, you do not need to write the values. Instead, you can print the parameter values by selecting the *Print Parameters* button from the *Edit Implant Parameters* window.

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				

Event	Emer-gency	See Dr	None	Ignore
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.

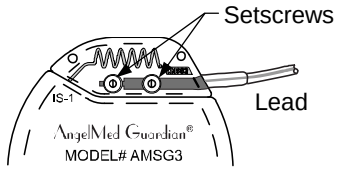
9. Do one of the following:

– **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.



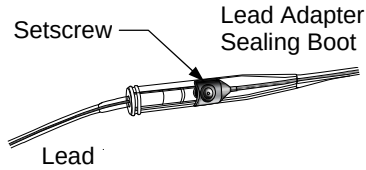
c. Set the IMD aside for now so that it can be later returned to Angel Medical Systems. Then proceed to Step 10.

– **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.



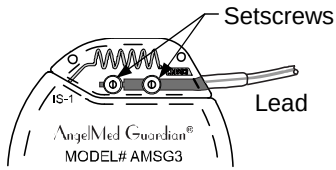
c. Set the IMD and lead adapter aside for now so that they can be later returned to Angel Medical Systems. (The AMSG3 IMD does not use a lead adapter.) Then proceed to Step 10.

– **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 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 43.

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 24 through 30.

a. Attach the lead to the header of the replacement IMD. (See *Connect the Lead to the IMD*, page 24.)

b. Place the new IMD and lead into the surgical pocket. (See *Implant the IMD*, page 26.)

c. Using the Programmer, conduct the Implant Verification procedure for the replacement IMD. (See *Conduct the Implant Verification Procedure*, page 27.)

d. Suture the IMD securely within the pocket and close the incision. (See *Secure the IMD and Close the Incision*, page 29.)

e. Verify that you can still communicate with the IMD through the skin. (See *Verify Transdermal Communication*, page 29.)

f. Conduct a Post-Implant Setup. (See *Conduct the Post-Implant Setup Procedure*, page 30.) 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 or printed in Step 5 starting on page 38. 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 or printed 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: (800) 508-5206 (USA toll-free)
(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
$\text{Voltage}_{\text{(Beginning of Life(BOL))}}$	3.6V
$\text{Voltage}_{\text{(ERI)}}$	3.4V
$\text{Voltage}_{\text{(EOS)}}$	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 ≥ (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.

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