Angel Medical Systems

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

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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 five 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 pre- and post-implant setup procedures. For detailed information on pre- and post-implant setup procedures, see the *AngelMed Guardian® Programmer User's Manual.*

2 Guardian System Overview

The 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 that require immediate medical attention, and "**see doctor" alerts**, for less-significant events that require medical attention as soon as possible (e.g., in 1-2 days.)

2.1 System Components

The Guardian System has the following components in addition to the IMD:

Lead – a standard bipolar cardiac lead (St. Jude Medical Model 1488T) that is attached to the apex of the right ventricle.

Lead Adapter – an adapter that connects the lead to the IMD and houses the antenna.

External Device (EXD) – a hand-held telemetry device that warns the patient of alarms and alerts via beeps and a red or yellow flashing LED, 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.

2.2 Indications & Contraindications

The Guardian System is contraindicated when neither the patient nor patient caregiver can take appropriate action for alarms and alerts.

Indications and contraindications for the EXD and IMD, individually, are discussed in the *AngelMed Guardian® Clinical Study Protocol*.

3 IMD Device Description

The fundamental purpose of the IMD is twofold:

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

2) 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 heart rate and initial ischemia. Each type of electrogram change is called a "condition." The physician can specify the type of warning (emergency alarm or "see doctor" alert) that is associated with each condition.

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

3.1 Data Acquisition, Characterization, and Storage

3.1.1 Data Acquisition Modes

The IMD supports two data acquisition modes: normal and post-emergency alarm.

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

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.

Post-emergency alarm data acquisition occurs after the IMD has detected an emergency alarm. In this mode, the IMD collects a 10-second segment every 5 minutes for 2 hours, and then every 15 minutes for 6 hours thereafter. The IMD does not try to detect any additional conditions. After 8 hours, the IMD reverts to normal data acquisition mode.

3.1.2 Data Characterization and Detection of Alarm Conditions

After an electrogram segment has been collected, it is characterized by heart rate and ST shift:

The **average heart rate** for the segment is determined, and the segment is categorized into one of 6 heart rate "bins."

The **ST shift** categorization is made by comparing this electrogram segment to a baseline segment collected 24 hours prior. (The physician sets a threshold for designating a beat as "shifted.")

Using the heart rate and ST shift categorizations, the segment is classified into 1 of 11 possible classifications. The classifications of the last several segments are then checked to determine if an alarm condition has been detected. If, for example, 3 consecutive segments are classified as "normal heart rate with an ST shift," then an alarm condition has been detected. Examples of alarm conditions include positive or negative ST shifts, high heart rate, initial ischemia, and low heart rate.

Overall, there are 10 conditions that can be mapped to one of four alarms: emergency, "see doctor," none (i.e., save data but don't alert the patient), and ignore (neither save data nor alert the patient). The physician can specify which alarm type is generated for each condition. For a detailed description of alarm type configuration, see the *AngelMed Guardian® Programmer User's Manual.*

3.1.3 Data Storage

The IMD stores electrogram signals, device parameters and patient data. electrogram signals are recorded and stored in 10-second segments. In addition to current data, data for up to two emergency alarms and up to three "see doctor" alerts is saved.

Stored segments may include:

- Current Data – the 9 most-recent electrogram segments that were captured prior to data retrieval;
- Pre-Emergency Alarm Data – the 8 electrogram segments that led up to detection of the emergency alarm condition and the baseline segments against which those segments were compared;
- Post-Emergency Alarm Data – segments that occurred after the detection of an emergency alarm condition;
- Pre-"See Doctor" Alert Data – the 3 electrogram segments that led up to the detection of a "see doctor" alert and the baseline segment against which those segments were compared;
- Baseline Segment Memory – 24 electrogram segments, one for each hour of the preceding 24 hours; and

- Histogram Information – histogram information for ST deviation and QRS height.

3.2 Vibration Patterns

The IMD vibration pattern is different for emergency alarms than for "see doctor" alerts.

For **emergency alarms**, the pattern is a repeating sequence of 10 short vibrations, followed by a 3-second pause:

Brrrr-Brrrr-Brrrr Brrrr-Brrrr Brrrr-Brrrr-Brrrr Brrrr-Brrrr

For **"see doctor" alerts**, the pattern is a repeating sequence of a half-second vibration, followed by a 7-second pause.

Vibration magnitudes are configurable in the Programmer. For more information, see the *AngelMed Guardian®* *Programmer User's Manual*.

3.3 Wireless Telemetry

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

3.3.1 Near-Field Telemetry

Near-field telemetry is used to establish communication sessions between the IMD and EXD. The EXD initiates all such communication sessions. Near-field telemetry is

unidirectional (the IMD is receive only) with a communication distance of at least 5 cm (2 inches).

3.3.2 Far-Field Telemetry

Far-field telemetry is used for sending an alarm or alert from the IMD to the EXD, for retrieving stored IMD data, and for sending parameters from the Programmer to the IMD. The maximum far-field communication distance is at least 1.8 m (6 feet). The IMD uses an antenna in the lead adapter for far-field communication.

3.4 Radiopaque Identifier

Each IMD has an X-ray absorptive marker for non-invasive identification.

3.5 Certifications

3.5.1 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

3.5.2 UL Certification

The IMD has been classified by Underwriters Laboratories, Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 2601-1.

3.5.3 SAR

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

4 Storage, Handling & Resterilization

Device storage. Store the device in a clean area, between -10°C to 55°C (14°F to 131°F), and away from sources of electromagnetic interference.

Drop limits.

- **Packaged IMD.** If the packaged IMD is dropped from a height of .9 m (3 feet) or more, contact your local Angel Medical Systems representative for a replacement.
- **Unpackaged IMD.** If the unpackaged IMD is dropped from a height of 30 cm (12 inches) or more

onto a hard surface (i.e., a concrete floor), contact your local Angel Medical Systems representative for a replacement.

If package is damaged. 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 local Angel Medical Systems representative.

No resterilization. Angel Medical Systems has sterilized the IMD with ethylene oxide prior to shipment. Do not resterilize the device. Contact your local Angel Medical Systems representative if resterilization is necessary.

Single-use only. Do not re-implant explanted IMDs.

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 before" date. Do not implant the device after the "use before" date because battery longevity may be reduced.

5 Precautions

5.1 General

Co-implantation. This device is not designed to be co-implanted with a pacemaker or defibrillator.

Lead system. The AngelMed Guardian IMD is intended for use ONLY with the AngelMed Guardian Lead Adapter Model LA-001 in combination with the St. Jude Model 1488T Bipolar Cardiac Lead.

WARNING

Do not connect the St. Jude cardiac lead directly to the AngelMed IMD.

Rather, connect the St. Jude lead to the AngelMed Guardian Lead Adapter. Then connect the lead adapter to the AngelMed IMD.

5.2 Medical Therapy Precautions

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 groundplate as far away from the IMD and lead system as possible.

External defibrillation. External defibrillation may damage the IMD and myocardium near the lead. Minimize current flowing through the IMD and lead system by following these precautions: Position defibrillation paddles as far as possible from the IMD and lead system (minimum of 13 cm [5 inches]), and use the lowest clinically appropriate energy output. Confirm that the IMD still functions following external defibrillation.

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 and confirm its function after treatment.

Lithotripsy. Lithotripsy may permanently damage the IMD. Avoid it unless the therapy site is not near the IMD, lead, and lead adapter.

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. RF ablation may damage the IMD or cause it to malfunction. To minimize RF ablation risks:

- Power off the IMD from the Programmer's Initial Setup screen;
- Avoid direct contact between the ablation catheter and the IMD, lead, and lead adapter;
- Position the groundplate so that the current pathway does not pass through or near the IMD and lead system. The current pathway should be a minimum of 15 cm (6 inches) away from the device and lead system.

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.

Ultrasound therapy. Avoid exposure of the IMD to therapeutic ultrasound because it could damage the device.

5.3 Electromagnetic Interference Precautions

The 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.

5.3.1 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.

5.3.2 Cell Phone Precautions

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

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

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

5.3.3 Security System Precautions

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

The IMD and EXD have metal inside that may set off an airport security system alarm. If this happens, patients should show their 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 IMD.

6 Implant & 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'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 setup procedure.
2) Implant the lead.
3) Connect the lead to the lead adapter.
4) Connect the lead adapter to the IMD.
5) Implant the IMD (and lead adapter).
6) Conduct the post-implant setup procedure.
7) Suture the pocket incision closed.

6.1 Conduct the Pre-Implant Setup Procedure

Notes:

These procedures should be performed with the IMD in its sealed sterile tray.

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

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1. Create a new patient record in the Programmer.

2. Select the new patient on the main Programmer screen.

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 local Angel Medical Systems representative.

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4. Run **Initial Setup**.

    - Automatically populate the IMD serial number into the Patient Record (if it was not manually entered in Step 1 above).

- When the Gain Change dialog displays, click “No”.
- The diagnostics area of the Initial Setup screen will correctly indicate that the heart rate is “0”, the gain is “too low”, and “0” baselines have been recorded.
- Verify that the IMD battery status indicator is green (“Good”).

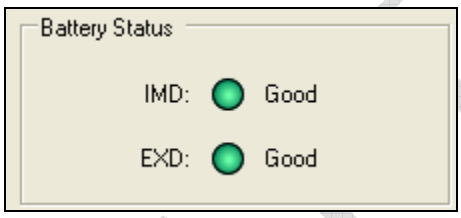

Figure 1: Programmer's Battery Status Information

WARNING

If the Programmer’s IMD battery status indicator is yellow (“Low”), or red (“Replace”), do not implant the IMD. Obtain another IMD for implantation. Return the IMD with the low battery to your local Angel Medical Systems representative.

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5. Review the heart rate bin boundaries, and modify them if necessary.

6.2 Implant the Lead

WARNING

Ensure that an external defibrillator is immediately available.

1. Implant the lead, ensuring that the lead tip is placed into the **apex** of the right ventricle. This location is necessary for proper functioning of the IMD. Conduct the appropriate lead testing procedure to confirm proper placement and fixation.

   For detailed instructions, see the *St. Jude Medical Tendril® SDX Model 1488T/TC/K Endocardial Steroid-Eluting Active Fixation Pacing Leads User's Manual*.

WARNING

Improper lead placement may affect the AngelMed Guardian Systems's ability to function as intended.

6.3 Connect the St. Jude Lead to the AngelMed Guardian Lead Adapter

WARNING

Do not connect the St. Jude cardiac lead directly to the AngelMed IMD.

1. Connect the implanted lead to the AngelMed Guardian lead adapter.

   For detailed instructions, see the *AngelMed Guardian® Lead Adapter Instructions for Use*.

WARNING

Verify that the connection between the lead and lead adapter is secure. A loose lead connection may result in inappropriate sensing and may affect the functionality of the Guardian IMD.

6.4 Connect the Lead Adapter 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.

INSERT DRAWING HERE – Fig 1 (IMD and its key components)

1. Insert the torque wrench through the IMD header septum and turn the lead tip connection setscrew (i.e., the innermost setscrew) clockwise until it stops and the torque wrench clicks once.

INSERT DRAWING HERE – Fig 2

2. Turn the setscrew counterclockwise 6 full rotations to provide clearance for the lead adapter connector pin. Watch the black line on the handle of the torque wrench to tell when 6 full rotations have occurred. Remove the torque wrench.

3. Repeat Steps 1 and 2 for the antenna connection setscrew (i.e., the outer setscrew).

4. Wipe off any body fluids on the connector pin of the lead adapter before inserting it into the IMD header receptacle.

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

5. Insert the lead adapter connector pin into the IMD header receptacle until the connector pin tip is fully seated inside the header. You will be able to see the end of the connector pin through the transparent 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.

INSERT DRAWING HERE – Fig 3

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

7. Repeat Step 6 for the other setscrew.

8. Test the connection by gently pulling on the header while holding the lead adapter. If there is movement, loosen

the setscrews and reinsert the lead adapter as described in Steps 1 through 8.

6.5 Implant the IMD and Lead Adapter

WARNING

The IMD is implanted on the left side of the patient only. Other locations have not been tested and may affect the device's functionality.

WARNING

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

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

2. The IMD's lead adapter houses a 7.62 cm (3 inch) antenna, which should not be hidden behind the device in the implant pocket. To take up excess length in the lead system, **rotate the device** to wrap the excess length around it or coil the excess length around the device. Do not kink the lead or lead adapter body.

INSERT DRAWING HERE – Fig 4

3. Implant the IMD into the pocket.

- To facilitate reliable data transmission, face the "front" of the device (the side engraved with the Angel Medical Systems logo) towards the skin.

4. To prevent migration, suture the device to the pectoral muscle, using the suture holes on the IMD.

6.6 Conduct the Post-Implant Setup Procedure

Note: Detailed information for these procedures is provided in the "Post-Implant Setup" chapter of the *AngelMed Guardian® Programmer User's Manual.*

Prior to closing the incision, establish a communication session between the IMD and Programmer and ensure proper functioning of the lead, lead adapter and IMD assembly. To do this, perform the following steps.

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

2. Establish a session between the Programmer and the IMD.

3. Run **Initial Setup**.
   - If the Gain Change dialog appears, click "Yes" to adjust the gain.
   - Verify that the IMD detected heart rate is about the same as that measured by usual means.

WARNING

If the bpm displayed is 0, and a communication session was successfully established between the Programmer and the IMD, it's likely that there is a mechanical problem. For example, the lead may not be connected to the lead adapter correctly, or the lead adapter may not be connected to the IMD correctly. It is also possible that the lead is broken or located in the wrong place (not in the apex of the right ventricle).

- Check IMD battery status.

WARNING

If the Programmer's IMD battery status indicator is yellow ("Low"), or red ("Replace"), do not complete implantation of the IMD. Remove the IMD attached to the lead adapter, and obtain another IMD to implant. Return the IMD with the low battery to your local Angel Medical Systems representative.

- Review and, if necessary, modify heart rate bin boundaries.

6.7 Suture the Pocket Incision Closed

7 Patient Follow-up

7.1 Follow-Up Frequency

After implant, patients should return to their physician in 3 to 7 days for initial programming. (For initial programming procedures, see the *AngelMed Guardian® Programmer User's Manual*.)

Patients should be seen for follow-up every 3 months for the first 6 months, and every 6 months thereafter. As the battery approaches the time for elective replacement (3.5 years assuming a typical use scenario), the follow-up frequency should be increased to every 3 months.

Patients who have an emergency alarm should call for an ambulance immediately.

Patients who have a "see doctor" alert should see their doctor within 1-2 days after the alert.

7.2 Follow-Up Tasks

During follow-up visits, physicians should do the following, at a minimum:

- 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 (which is displayed during data retrieval) is “yellow” or “red”.

For details on these procedures, see the “Retrieving and Responding to Data” chapter of the *AngelMed Guardian*® *Programmer User’s Manual*.

8 Pre- and Post-Explanting Procedures

WARNING

Always explant the IMD before cremation.

IMDs contain sealed chemical power cells and capacitors that may explode if incinerated.

Before or after explanting the IMD, do the following:

- Retrieve any stored data;
- From the Programmer’s Initial Setup screen, power off the device.

After explanting the IMD, do the following:

- Clean the IMD with disinfectant solution, but do not submerge it. Fluid in the lead receptacles of the IMD or adapter impedes analysis of the device.

- Return the IMD to your local Angel Medical Systems representative. Include an Out-of-Service/Explant/Patient Death form and, if possible, a printout of the programmed IMD settings.

9 Available Literature

- AngelMed Guardian® Clinical Study Protocol
- AngelMed Guardian® Programmer User's Manual
- AngelMed Guardian® Lead Adapter Instructions for Use
- St. Jude Medical Tendril® SDX Model 1488T/TC/K Endocardial Steroid-Eluting Active Fixation Pacing Leads User's Manual
- AngelMed Guardian® Implantable Medical Device (IMD) User's Manual
- AngelMed Guardian® External Device (EXD) User's Manual
- Patient Manual for the AngelMed Guardian® System

10 Service & Support

10.1 Service

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

10.2 Technical Support

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

Angel Medical Systems, Inc.
1 Sheila Drive
Tinton Falls, NJ 07724 (USA)
Phone: 732-212-1888 (USA)

11 Specifications

11.1 Physical & Mechanical Specifications

Item	Specification
Dimensions Length (Horizontal) Width (Vertical) Depth	 60 mm (2.36 in) 54 mm (2.13 in) 11 mm (0.43 in)
Displacement Volume	???
Drop Limit Packaged IMD Unpackaged IMD	 .9 m (3 ft) 30 cm (12 inches)
Lead Compatibility	AngelMed Guardian Lead Adapter (connected to the IMD) St Jude Model 1488T Bipolar Cardiac Lead (connected to the AngelMed Guardian Lead Adapter)
Materials in contact with human tissue Can Header Septum	 Titanium Epoxy Silicone
Weight	60 grams (5 oz)

11.2 Environmental Specifications

Item	Specification
Operating Conditions Temperature Humidity Atmospheric pressure	 25°C to 45°C (77°F to 113°F) N/A 10.20 psi to 15.58 psi
Storage Conditions Temperature Humidity Atmospheric pressure	 -10°C to +55°C (14°F to 131°F) N/A 7.35 psi to 15.58 psi

11.3 Battery Type and Longevity Specifications

Item	Specification
Battery Type	3.6V lithium
Battery Longevity	3.5 years, assuming nominal program parameters and typical use scenario (described in XX)

11.3.1 Device Longevity

Steve is writing this section.

11.4 Programmable Parameters: Defaults and Ranges

Programmable parameters are set from the Programmer. The following tables below show the default values and the possible ranges.

11.4.1 Edit Implant Parameters Screen

HR-Max (BPM)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	110	220	140
Elevated (A3)	90	190	120
Elevated (A2)	70	160	100
Elevated (A1)	55	130	90
Normal (A0)	40	115	80
Low (LO)	25	95	50

Start of PQ (milliseconds)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	50	315	75
Elevated (A3)	50	315	90
Elevated (A2)	50	315	105
Elevated (A1)	50	315	115
Normal (A0)	50	315	150
Notes and additional constraints: Start of PQ ≥ Duration of PQ + 25			

Duration of PQ (milliseconds)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	25	290	50
Elevated (A3)	25	290	60
Elevated (A2)	25	290	70

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A1)	25	290	75
Normal (A0)	25	290	100
Notes and additional constraints: Duration of PQ ≤ Start of PQ - 25			

Start of ST (milliseconds)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	25	290	40
Elevated (A3)	25	290	50
Elevated (A2)	25	290	55
Elevated (A1)	25	290	60
Normal (A0)	25	290	70
Notes and additional constraints: Start of ST ≤ 315 - Duration of ST			

Duration of ST (milliseconds)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	25	290	
Elevated (A3)	25	290	
Elevated (A2)	25	290	
Elevated (A1)	25	290	
Normal (A0)	25	290	
Notes and additional constraints: Duration of ST ≤ 315 - Start of ST			

ST-Pct Positive (%)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	0	127	50
Elevated (A3)	0	127	50
Elevated (A2)	0	127	50
Elevated (A1)	0	127	50
Normal (A0)	0	127	50

ST-Pct Negative (%)

Heart Rate Bin	Minimum	Maximum	Default
Elevated (A4)	0	127	50
Elevated (A3)	0	127	50
Elevated (A2)	0	127	50
Elevated (A1)	0	127	50
Normal (A0)	0	127	50

Lo HR Decrement (BPM)

Minimum	Maximum	Default
0	7	5

11.4.2 Alarm Configuration Screen

Parameter	Min	Max	Default
Turn Emergency Alarm Off After (Minutes)	1	5	5
Turn See Doctor Alert Off After (Minutes)	1	5	5
Elevated Heart Rate and ST Shift Becomes Persistent after (Minutes)	3	20	10

Alarm Type Association (Defaults)

Event	Emergency	See Dr	None	Ignore
Positive ST Shift & HR Normal	X			
Negative ST Shift & HR Normal	X			
Exercise Induced Ischemia		X		
Exercise Induced Ischemia Persists	X			
High Heart Rate	X			
Low Heart Rate		X		
Irregular Heart Rate		X		
Not Enough Beats		X		
Cannot Get Baseline		X		

Event	Emergency	See Dr	None	Ignore
ST Deviation Trending		X		
QRS Height Trending		X		

11.4.3 ST Trend Histogram Screen

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

11.4.4 QRS Trend Histogram Screen

Parameter	Min	Max	Default
Collection Start Hour*	0	23	0
Collection End Hour*	0	23	5
Check Hour*	0	23	9
Consecutive Days Needed to Detect	1	14	2
A0 QRS Baseline	0	255	0
EL QRS Baseline	0	255	0
Detection Threshold (%)	87	97	92

*****Hour of the day.

12 Index

[Back Cover]