AngelMed Guardian®
Programmer
Model Prog-003

Setup & Operations Guide

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AngelMed®

Fold Line

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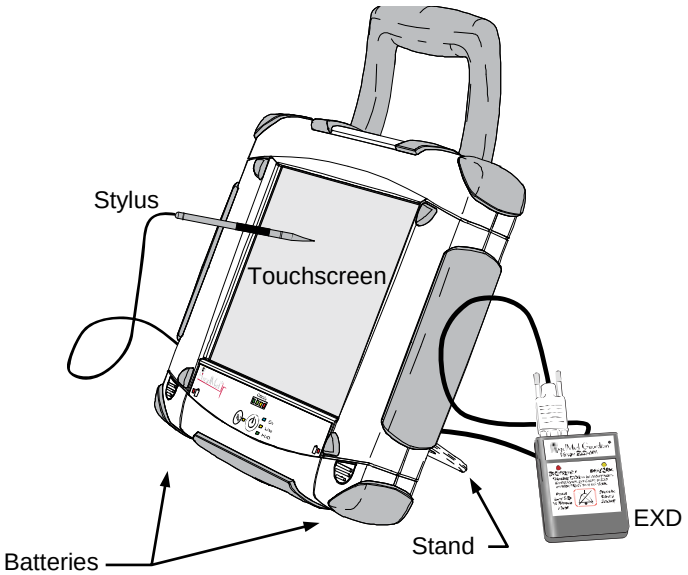
1 Introduction

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.

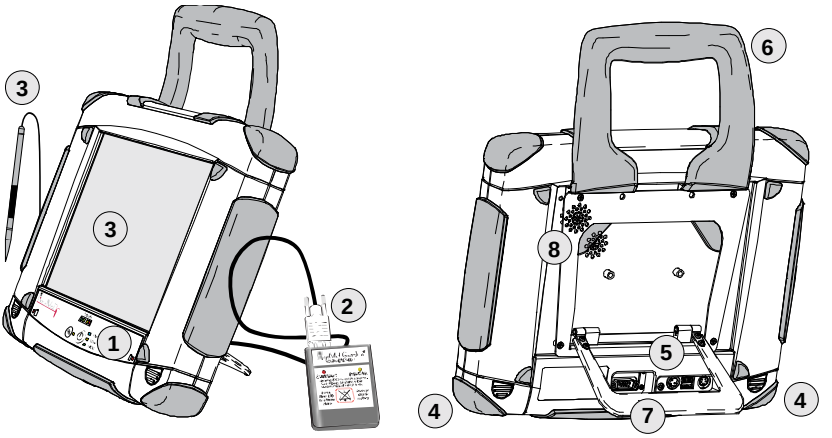
Caution:
Do not use generic USB flash drives or the flash drive of another Programmer. A Programmer can only use the flash drive it was shipped with or its replacement from Angel Medical Systems.

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

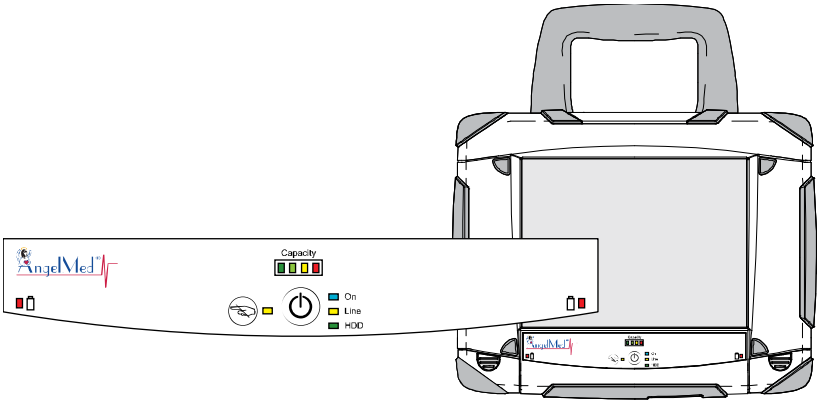
The Programmer is equipped with the following key features.

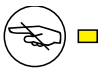


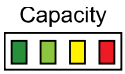
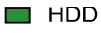
1.	Power switch and front panel	To control and monitor the Programmer
2.	EXD and cable	For communicating with patients' IMDs
3.	Touchscreen and stylus	For selecting program options
4.	Batteries	For operating the Programmer in battery mode
5.	Connector panel	For connecting the EXD, flash drive, and AC 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.

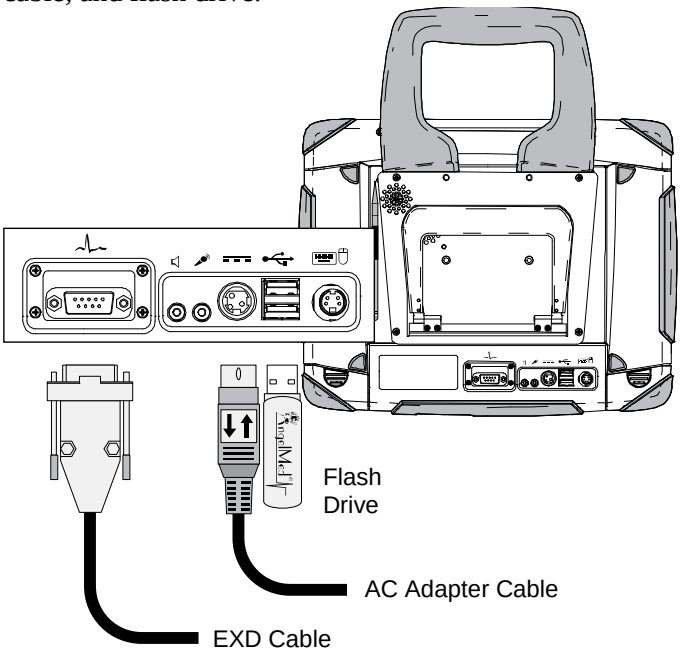


	Power On/Off – Press this button for about 1 second to start the Programmer
	Touchscreen On/Off – Press to temporarily disable the Programmer touchscreen. Press again to enable it. When lit, the yellow LED indicates that the touchscreen is disabled.

	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.
	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.
	Power indicator – means the Programmer is powered-on.
	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
	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.



	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.

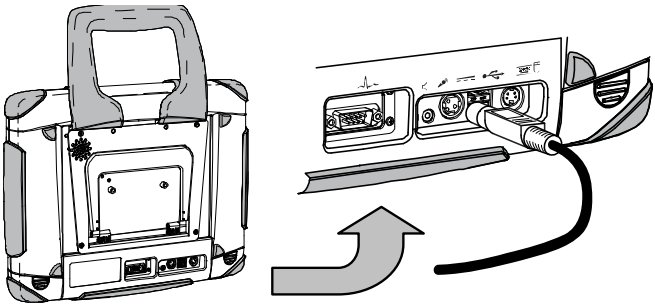
To charge the Programmer batteries:

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 (⎓) as shown in the following figure.



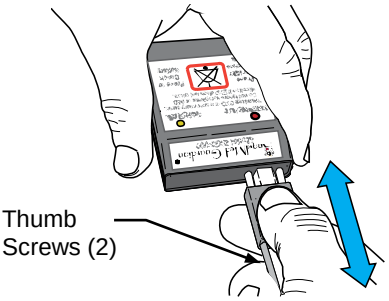
5. Leave the Programmer plugged in until it is fully charged as indicated by the Capacity indicator on the front panel.

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.

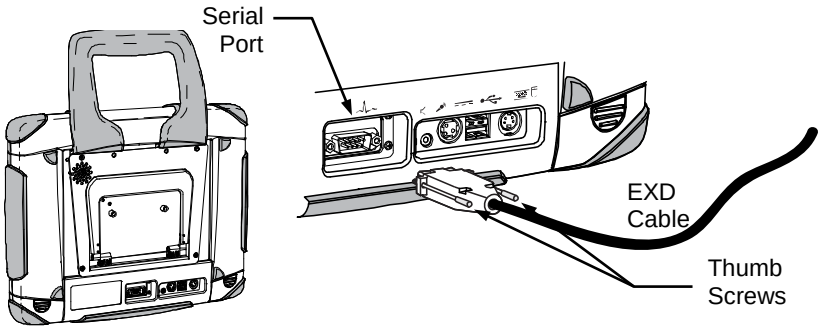
2. Connect the EXD to the Programmer's EXD cable. Use the two thumb screws on the EXD cable to secure it to the EXD.



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.



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

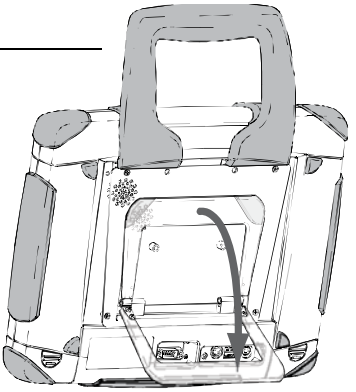
> **Caution:**
> Always secure the EXD cable to the Programmer using the thumb screws. Failure to do so can allow the EXD cable to become disconnected during a communication session with the IMD.

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

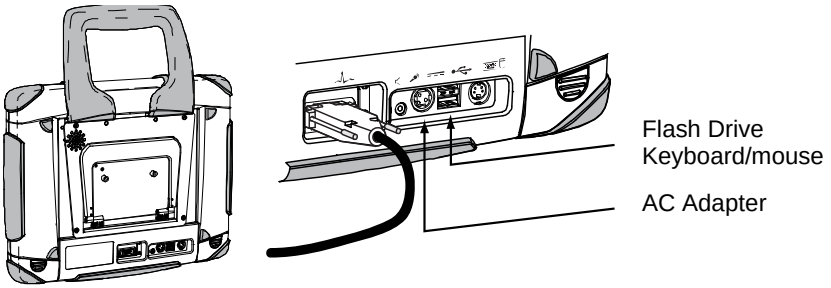
To support the Programmer at a convenient viewing angle, lower the stand and place the Programmer on a flat, horizontal surface.



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



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

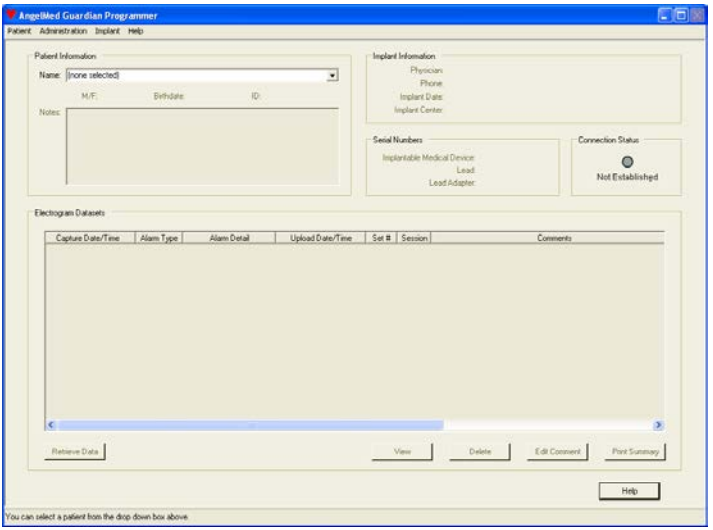
To start the Programmer:

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

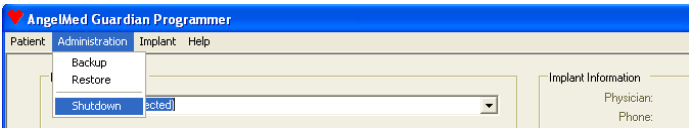
To ensure that patient data are not corrupted, you need to shut down the Programmer properly as described in the following procedure.

To shut down the Programmer:

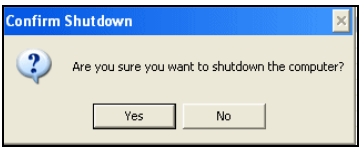
1. Complete or cancel any task that you are currently performing.

> **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

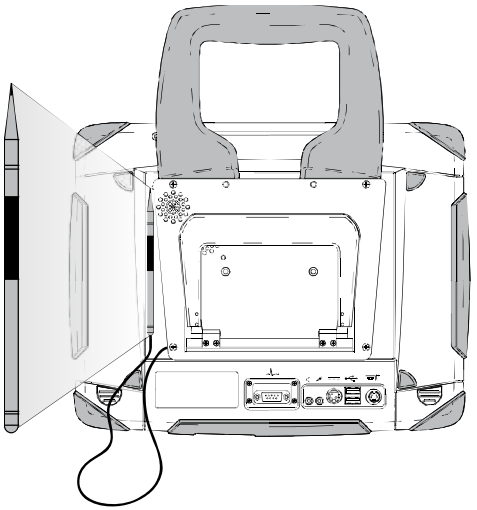
The Programmer's touchscreen and stylus allow you to select program controls and enter data. An on-screen keyboard is displayed when necessary to enter information such as patient and physician names, serial numbers, and notes.

Using the Stylus

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

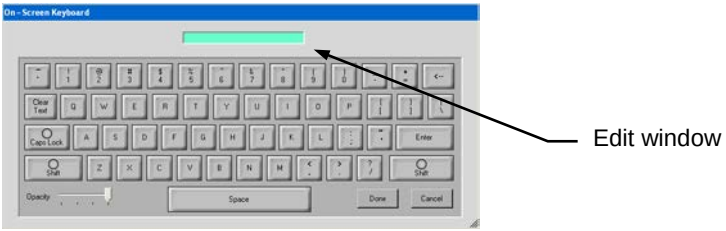
Caution:
The touchscreen only operates with the stylus or your fingers. Use of other devices can damage or destroy your touchscreen.

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.

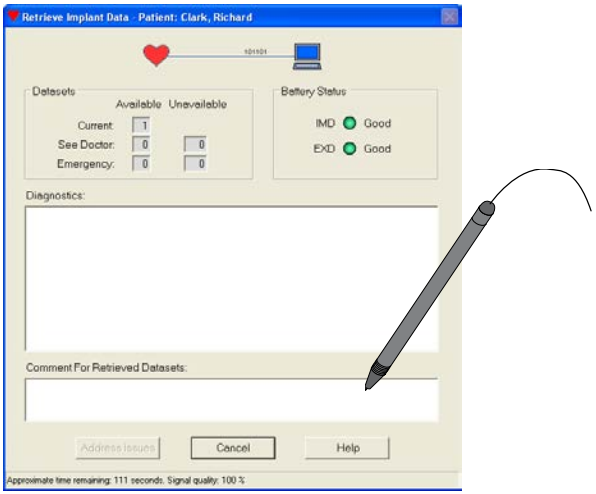


The keyboard has the following controls and features:

<--	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:

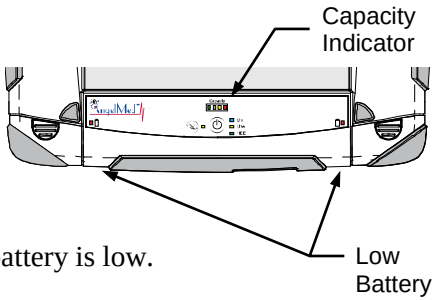
- From a window that has an edit field, use the stylus to touch the edit field in which you want to type the information. The following figure shows the stylus touching the edit field of the *Retrieve Implant Data* window.



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.

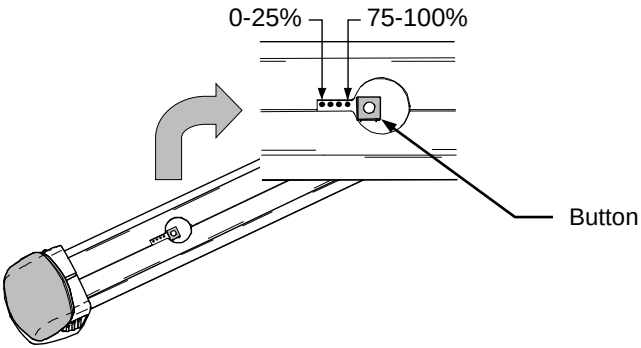
Low battery indicator

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 (≈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 (≈ 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.
40 Christopher Way, Suite 201
Eatontown, NJ 07724 USA
Phone: (800) 508-5206 (USA toll-free)

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 (max)	19VDC at 3.2A

Environmental Specifications

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

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**	**Compliance 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: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 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: 

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