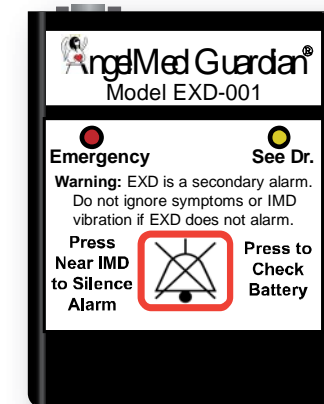


AngelMed Guardian®  
External Device (EXD)  
Model EXD-001

User's Guide



Angel Medical Systems®  
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June 2018  
P/N 0203-2100-005#P10 Rev D





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The AngelMed Guardian system is protected by U.S. patents. For more information, please see the Help/About page on the AngelMed Guardian Programmer.

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# 1 Introduction

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

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

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

## 2 System Overview

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

Two levels of warnings are possible:

- ◆ Emergency alarms, for significant events that require immediate medical attention
- ◆ See Doctor alerts, for less-significant events where the patient makes an appointment to see the doctor in the next 1 or 2 days

### System Components

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The AngelMed Guardian system comprises the following components:

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

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

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



## Indications & Contraindications

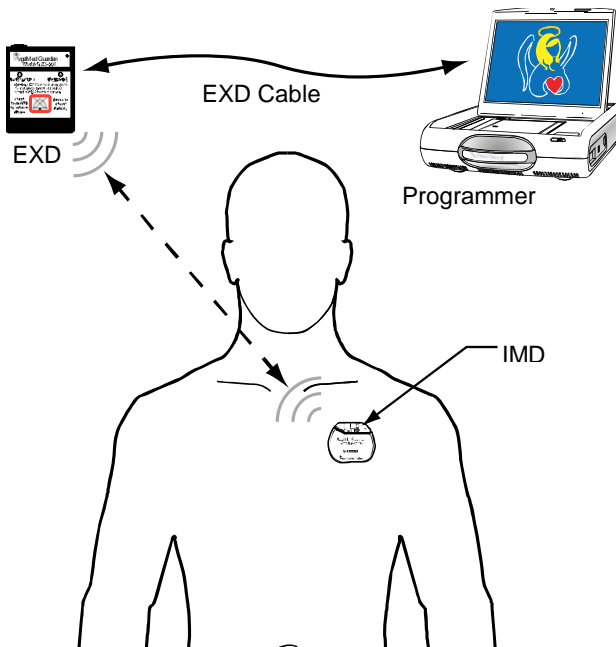
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See the *AngelMed Guardian® Implantable Medical Device (IMD) User's Manual* for indications and contraindications relevant to the AngelMed Guardian system.

## Intra-System Communication

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The following figure shows the AngelMed Guardian system communication architecture.



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

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

The EXD and Programmer are connected via cable.

## **Available Literature**

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

- ◆ *AngelMed Guardian<sup>®</sup> Implantable Medical Device (IMD) User's Manual*
- ◆ *AngelMed Guardian<sup>®</sup> Programmer User's Manual*
- ◆ *Patient Manual for the AngelMed Guardian<sup>®</sup> System*

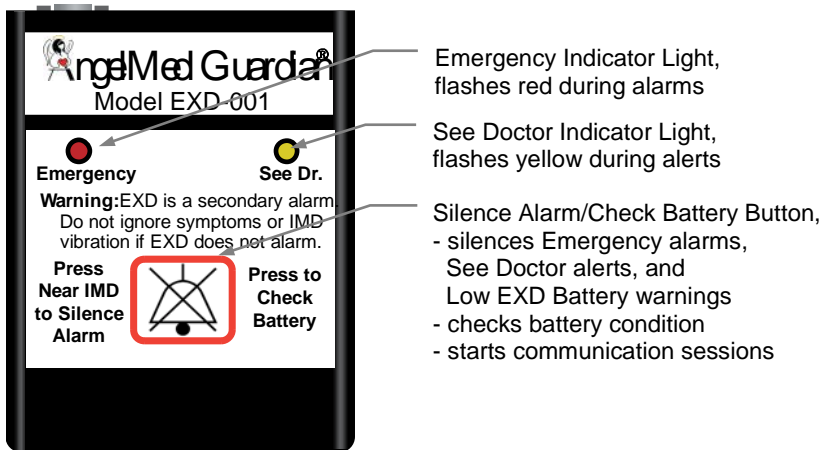
# 3 EXD Device Description

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## Appearance

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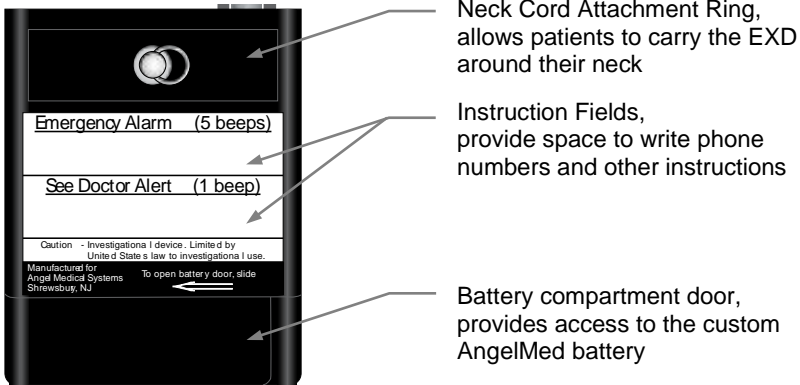
**Front** – The front of the EXD contains the Emergency and See Doctor indicator lights, and the Silence Alarm/Check Battery button.



## EXD Device Description

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**Back** – The back of the EXD contains a metal ring for attaching the neck cord, two instruction fields, and the door to the battery compartment.



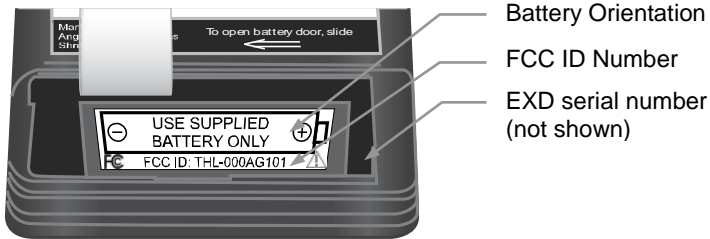
**Top** – The top of the EXD contains a serial interface port and an unlabeled green indicator light.

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

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



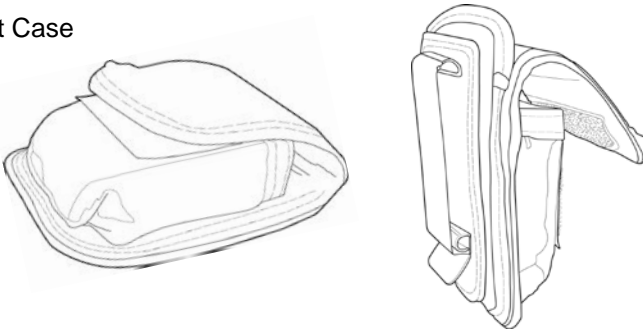
**Battery Compartment** – The battery compartment shows the proper battery orientation, the EXD’s serial number, and the FCC ID number.



## Neck Cord & Belt Case

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

### Belt Case



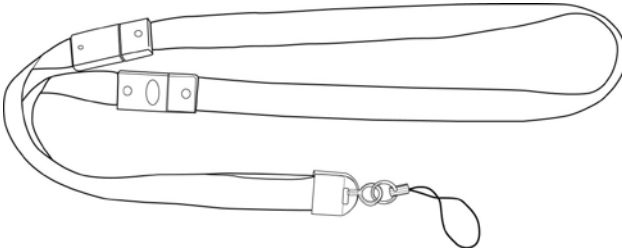
The belt case has an integrated belt clip.

### **Warning:**

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

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

Neck Cord



**Warning:**

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

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## **Emergency Alarms and See Doctor Alerts**

### ***Emergency Alarm Functionality***

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

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

***Brrrr–Brrrr–Brrrr***

***Brrrr–Brrrr***

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

***Beep–Beep–Beep***

***Beep–Beep***

### **See Doctor Alert Functionality**

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

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

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

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

**Beep** ←———— 7 sec —————→ **Beep**

### **How to Silence an Emergency Alarm or See Doctor Alert**

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

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



Silencing an Alarm or Alert

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

**Additional Alarm and Alert Information**

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

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

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

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

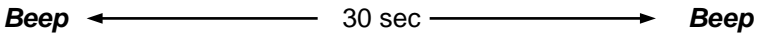
\*\* A See Doctor alert suppresses the signaling of any subsequent See Doctor alert for a 24-hour period. This feature gives the patients time to see the physician without being subject to repeated See Doctor alerts should they occur. Emergency alarms are not suppressed.



## Low EXD Battery Warning

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

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

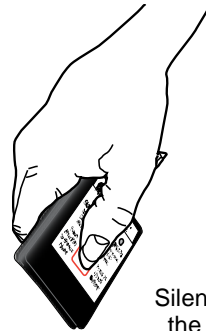


The Low EXD Battery warning beeps continually until either:

- ◆ The battery power is depleted
- ◆ The warning is silenced

### How to Silence a Low EXD Battery Warning

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



Silencing the Low EXD Battery Warning

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

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

## **Certifications**

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### ***FCC Compliance Statement (Part 15.19)***

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

- 1.** This device may not cause harmful interference, and
- 2.** This device must accept any interference received, including interference that may cause undesired operation.

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

FCC ID: THL-000AG101

### **SAR**

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

# 4 Setup

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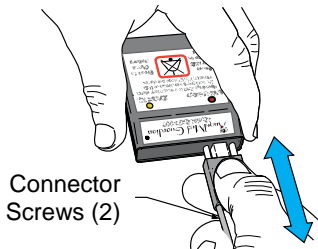
Use these steps to set up the EXD for the Programmer and patients.

## Programmer EXD

---

### *To connect the EXD to the EXD Cable:*

1. Insert the battery as described on page 16.
2. Connect the EXD to the Programmer's EXD cable. Use the two connector screws on the EXD cable to secure it to the EXD.



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

- ◆ See your Programmer user documentation.

## **Patient's EXD**

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- 1.** Insert the battery as described on page 16.
- 2.** Write instructions on the back of the EXD. Instructions may include emergency telephone numbers and medical advice.
- 3.** Show the neck cord and belt case to the patient.
- 4.** Attach the neck cord to the EXD, if the patient plans to use it. (See the *Patient Manual for the AngelMed Guardian<sup>®</sup> System* for neck cord attachment instructions.)

# 5 Care and Maintenance

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## Battery Power

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

### **Caution:**

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

When the battery nears the end of its service life, the EXD issues the Low EXD Battery warning as described on page 11. Physicians should replace the patient’s EXD battery at least every six months.

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

### ***How to Check Battery Power***

Battery power can be checked in two ways:

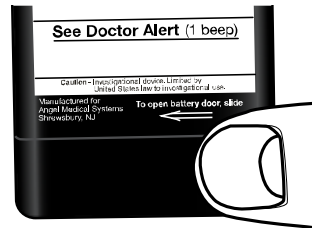
- ◆ Push the Silence Alarm/Check Battery button on the EXD.
  - If the battery is working, the EXD will beep one time.
  - If the battery is not working, the EXD will not respond.

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

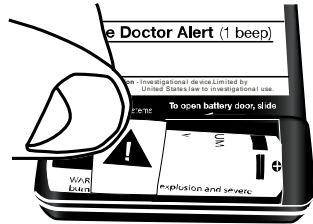
## How to Replace the Battery

To replace the EXD battery:

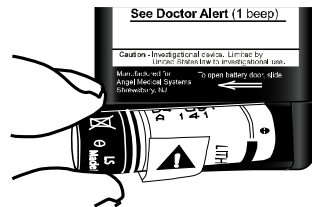
1. Open the EXD's battery compartment by pushing down on the right-side of the battery cover and sliding it to the left.



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



3. Insert the positive (+) end of the new battery into the battery compartment, then push down on the battery's negative (-) end. **Caution:** Only use batteries supplied by Angel Medical Systems. **Caution:** Check the expiration date on the battery shipping box to ensure the battery is fresh.



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



5. To confirm that the battery was correctly inserted and is working, push the Silence Alarm/Check Battery button. The EXD will beep one time if the battery is working.
6. Discard the depleted battery according to local environmental regulations.

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## General Care & Maintenance

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- ◆ Check the EXD's battery power once a week.
- ◆ Do not sterilize the EXD.
- ◆ Keep the EXD dry. The EXD is not waterproof, so getting it wet may damage its electronics. If the EXD is accidentally dropped into a sink or similar place, return it for service or replacement.
- ◆ Never use strong cleaners or solvents to clean the EXD. If the surface of the EXD needs to be cleaned, wipe it gently with a cloth lightly dampened in clean water.
- ◆ Observe the drop limit as documented in *EXD Specifications* on page 22. If the EXD is dropped from a height that exceeds the drop limit, replace it. If it is dropped from a height that is less than the drop limit, push the Silence Alarm/Check Battery button to verify operation. If the device beeps one time, it is still functioning; if not, replace it.
- ◆ Protect the EXD from extreme temperatures. For applicable temperature ranges, see *EXD Specifications* on page 22.
- ◆ Replace the EXD if it is damaged.

# 6 EMI Precautions

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

## Sources of Strong EMI

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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.



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## Cell Phone Precautions

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

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

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

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

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## Security System Precautions

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

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

# 7 Troubleshooting

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

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

# 8 Service and Support

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## Service

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

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

## Technical Support

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For technical support, contact your Angel Medical Systems 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)

# 9 EXD Specifications

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Item	Specification
Dimensions	Height: 2.8 in (70 mm) Width: 2.2 in (55 mm) Depth: 0.6 in (16 mm)
Operating Conditions Temperature Humidity Atmospheric pressure	32°F to 122°F (0°C to 50°C) 10% to 95% non-condensing 10.20 psi to 15.58 psi (703 hPa to 1074 hPa)
Storage Conditions Temperature Humidity Atmospheric pressure	-4°F to 131°F (-20°C to +55°C) 5% to 95% non-condensing 7.35 psi to 15.58 psi (507 hPa to 1074 hPa)
Weight	2.1 oz (58 grams) with battery
Power Source	3.6 V lithium thionyl chloride battery. Replacement is available only from Angel Medical Systems. Battery is non-rechargeable
Drop Limit	3 ft (0.9 m)
Telemetry Distance (max) Near-field Far-field	2 in (5 cm) 6 ft (1.8 m)

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# Notes



