Angel Medical Systems

AngelMed Guardian®

External Device

(EXD)

User's Manual

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1   Introduction

The AngelMed Guardian® **External Device (EXD)**, a battery-operated hand-held telemetry device, is one of five primary components of the Guardian System. This manual describes how to use and maintain the EXD.

2   Guardian System Overview

The 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, 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 five components:

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.

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.

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

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

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 in response to alarms and alerts.

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

2.3   Intra-System Communication

Figure 1 shows the Guardian System communication architecture. The following points can be seen:

- The EXD is the "hub" of communication between the IMD and Programmer. The EXD is used to set up communication sessions between the IMD and Programmer, in order to retrieve IMD data and set IMD parameters. It is also used to silence alarms and alerts.

- The EXD uses both near field and far field telemetry. Near-field telemetry (maximum distance of 5 cm or 2 inches) is used to silence alarms and alerts and to establish communication sessions between the IMD and Programmer. Far-field telemetry (maximum distance of 1.8 meters or 6 feet) is used for communication between the IMD and EXD after a session has been established and to initiate synchronous alarms and alerts on the EXD and IMD.

- The EXD and Programmer each contain a serial port that allows them to be connected via cable.
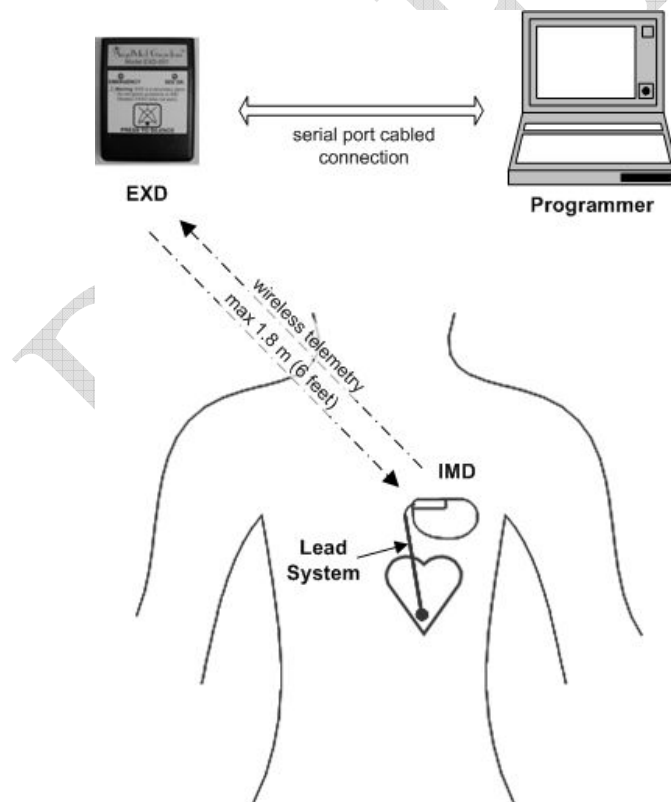

Fig. 1: Guardian System Communication Architecture

2.4 Available Literature

- AngelMed Guardian® Clinical Study Protocol

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

- AngelMed Guardian® Lead Adapter Instructions for Use

- AngelMed Guardian® Programmer Manual

- Patient Manual for the AngelMed Guardian® System

- Product Information Manual for the AngelMed Guardian® External Device (EXD)

- St. Jude Medical Tendril® SDX Model 1488T/TC/K Endocardial Steroid-Eluting Active Fixation Pacing Leads User's Manual

3   EXD Device Description

3.1   How Supplied

The EXD is packaged with a neck cord and a belt case.
Batteries are supplied separately.

3.2   Appearance

Front – The front of the EXD contains the emergency and
"see doctor" LEDs, and the "Press to Silence" button.

The **Emergency** LED flashes red during alarms.

The **See Doctor** LED flashes yellow during alerts.

The **Press to Silence** button can be used to silence alarms and alerts and to check EXD battery power.
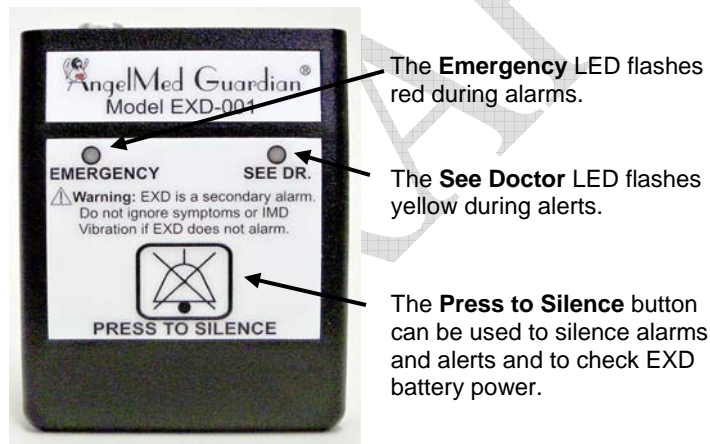
Fig. 2 Front of EXD

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.

The neck cord **attachment ring** allows patients to carry the EXD around their neck.

Two **instruction fields** provide space to write phone numbers and other instructions.

The **battery compartment door** provides access to the custom AngelMed battery.
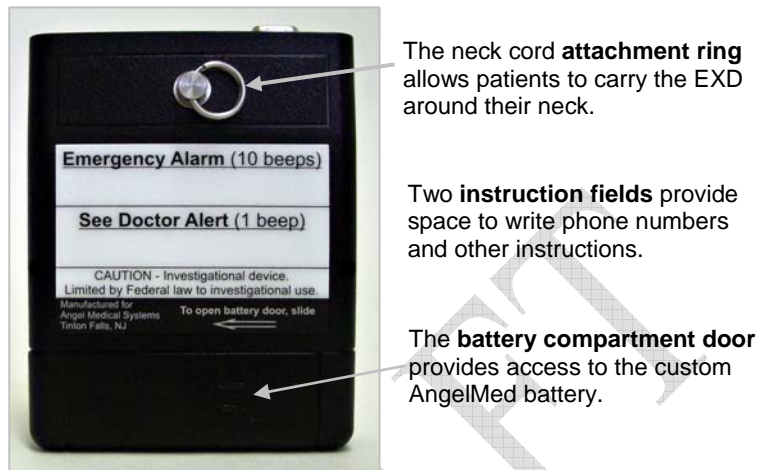
Fig. 3 Back of EXD

Battery Compartment – The battery compartment contains the EXD's serial number.

EXD **serial number**

Fig. 4 Battery Compartment

Top – The top of the EXD contains a serial interface port.

The **serial port** allows the EXD to be connected to the Programmer's docking station.

The green LED flashes slowly when a session is established between the EXD and the Programmer.

Fig. 5   Top of EXD

3.3   Neck Cord & Belt Case

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

> **Important:** Patients should keep their EXD within 1.8 m (6 feet) 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.

The belt case has an integral belt clip.

Fig. 6 Neck Cord

Fig. 7 Belt Case
(Belt clip not shown.)

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.

The neck cord is attached to the EXD by inserting the string loop at the end of the neck cord through the EXD's metal attachment ring and then inserting the neck cord through the string loop.

Fig. 8 Neck Cord Attached to EXD

3.4   Alarm & Alert Functionality

Emergency Alarm

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

During an **emergency alarm**, the IMD vibrates in a pattern of 10 short vibrations, like this:

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

If the patient's EXD is within 1.8 m (6 feet) of the IMD, the

red LED will flash. At the same time, the EXD will beep like this:

Beep-Beep-Beep   Beep-Beep   Beep-Beep-Beep   Beep-Beep

See Doctor Alert

When a "see doctor" alert occurs, the patient should seek medical attention as soon as possible, e.g., in 1-2 days.

During a "**see doctor" alert**, the IMD vibrates 1 time, pauses, vibrates again, and so on. If the EXD is within 1.8 m (6 feet) of the IMD, the EXD will beep and the yellow LED will flash.

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 5 cm (2 inches) of the patient's IMD and push the **Press to Silence** button:

Fig. 9: How to Silence an Alarm or Alert

If the EXD beeps twice, the alarm/alert has been silenced. If it beeps only once, readjust the position of 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 Parameters

The following table provides additional information about emergency alarms and "see doctor" alerts, including: the **duration** of the alarm/alert, characteristics of the **reminder alarm**, and characteristics of the EXD's flashing **LED**.

Note that there is a reminder alarm for the emergency alarm, but not for the "see doctor" alert.

Table 1. **Additional Parameters of Alarms and Alerts**

	Alarm/Alert Duration	**Reminder Alarm**	**EXD Flashing LED**
Emergency Alarms	Alarm/alert repeats for 5 minutes, or until it is silenced.	2.4-minute alarm that plays every 15 minutes for 2 hours, or until 2 separate alarms are silenced.	Red LED flashes for 24 hours, or until a communi-cation session is established between the Programmer and the IMD.
"See Doctor" Alerts	Alarm/alert repeats for 5 minutes, or until it is silenced.	None	Yellow LED flashes for 24 hours, or until a communication session is established between the Programmer and the IMD.

3.5 Certifications

FCC Compliance Statement (Part 15.19)

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

1. This device may not cause harmful interference, and

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

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

FCC ID: THL-000AG101

UL Certification

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

SAR

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

4 Setup

Follow these checklists to set up the EXD for physicians and patients:

Physician's EXD:

☑ Insert the battery.

☑ Connect the EXD to the Programmer's docking station, as shown in Figure 10, below.

- Attach the smaller end of the AngelMed cable to the EXD's serial port.

- Attach the larger end of the cable to the docking station's serial port.

Fig. 10 EXD Connected to Programmer's Docking Station

Patient's EXD:

☑ Insert the battery.

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

☑ Show the neck strap and belt case to the patient.

☑ Attach the neck strap, if the patient plans to use it.

5 Care & Maintenance

5.1 Battery Power

The EXD uses a custom battery that lasts about 6 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.

When the battery is close to reaching the end of its service
life, the EXD will beep every 30 seconds until it runs out of
power.

Physicians should replace the patient's EXD battery during every follow-up visit.

Patients should check their EXD's battery power once per week. If the battery needs to be replaced, they should contact their physician as soon as possible.

How to Check Battery Power

Battery power can be checked in two ways:

1. Push the **Press to Silence** button on the EXD.

    - If the battery is **working**, the EXD will beep 1 time.

    - If the battery is **not working**, the EXD will not respond.

2. Look at the "Battery Status" sections on the Programmer's Initial Setup or Initial Programming screens. A green indicator means the battery voltage is within range for normal operation. A yellow or red indicator means the battery should be replaced.
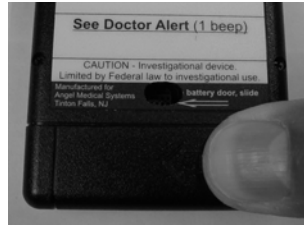
How to Replace the Battery

Caution

EXD batteries should be replaced only by trained medical personnel.

Do the following to replace the EXD battery:

1. To open the battery compartment, push down on the right-side end of the battery cover and slide it to the left.

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

3. Insert the positive (+) end of the new battery into the battery compartment, then push down on the battery's negative (-) end. **Important:** Only use batteries supplied by Angel Medical Systems.

4. To close the battery compartment, slide the battery cover completely to the right.

Fig. 11a – d. Replacing the Battery

5. To confirm that the battery was correctly inserted and is working, push the **Press to Silence** button. The EXD will beep 1 time if the battery is working.

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

5.2 General Care & Maintenance Items

- 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, tub, or similar place, replace it.

- 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. If the EXD is dropped from a height of more than .9 m (3 feet), replace it. If it is dropped from a height of less than .9 m (3 feet), push the **Press to Silence** button to verify functioning. If the device beeps 1 time, it is still functioning; if not, replace it.

- Protect the EXD from extreme temperatures. Don't expose the EXD to temperatures below 0°C (32° F) or above 50°C (122° F).

- Replace the EXD if it is damaged.

6 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.

6.1 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.

6.2   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 EXD. If the cell phone transmits above 3 watts, patients should hold the phone at least 30 cm (12 inches) away from the EXD.

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

6.3   Security System Precautions

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

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

7   Troubleshooting

Problem	Possible Causes	What to Do
EXD does not beep when the **Press to Silence** button is pushed.	Battery has run out of power.	Replace battery.
	Battery has been inserted backwards.	Reinsert battery.
	Wrong battery has been installed.	Replace battery with the custom AngelMed Guardian EXD battery.
EXD beeps 1 time, every 30 seconds.	Battery power is low.	Replace battery.

8   Service & Support

8.1   Service

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

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

8.2 Technical Support

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

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

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9   Specifications

Item	Specification
Power Source	3.6 volt lithium battery supplied only by Angel Medical Systems Non-rechargeable
Dimensions	Height: 7 cm (2.76 in) Width: 5.5 cm (2.17 in) Depth: 1.6 cm (0.63 in)
Drop Height Limit	.9 m (3 feet)
Electric shock Classification Protection	 ?? ??
Materials	??
Operating Conditions Temperature Humidity Atmospheric pressure	 0°C to 50°C (32°F to 122°F) 10% to 95% non-condensing 10.20 psi to 15.58 psi
Storage Conditions Temperature Humidity Atmospheric pressure	 -20°C to +55°C (-4°F to 131°F) 5% to 95% non-condensing 7.35 psi to 15.58 psi
Weight	141 grams (5 oz) with battery

Item	Specification
Telemetry Near field Far field	 5 cm (2 inches) 1.8 m (6 feet)

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