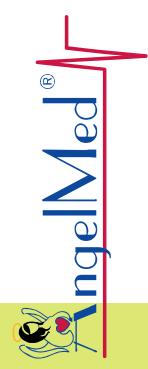


Reminders

- Emergency Alarms: The IMD vibrates and EXD beeps 5 times, and then repeats. Call for an ambulance immediately.
- See Doctor Alerts: The IMD vibrates and EXD beeps one time, pauses for 7 seconds, and then repeats. See your doctor in the next 1 or 2 days.
- EXD Low Battery Warning: The EXD makes a very short beep every 30 seconds. Replace the EXD battery.
- Heart Attack Symptoms: If you have heart attack symptoms, call for an ambulance immediately – even if your AngelMed Guardian system is not alarming.
- If you can't tell what the alarm is, call for an ambulance immediately.
- Keep your EXD within 6 feet (1.8m) of your IMD at all times.
- Check your EXD's battery power once a week.
- Carry your AngelMed Guardian System Patient Identification Card with you at all times.

Patient Manual for the AngelMed Guardian® System



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Heart Attack Symptoms

If you feel any **heart attack symptoms, call for an ambulance immediately**— even if your AngelMed Guardian System is not alarming.

Heart attack symptoms are¹:

- ◆ **Chest discomfort.** Most heart attacks involve discomfort in the center of the chest that lasts more than a few minutes, or that goes away and comes back. It can feel like uncomfortable pressure, squeezing, fullness or pain.
- ◆ **Discomfort in other areas of the upper body.** Symptoms can include pain or discomfort in one or both arms, the back, neck, jaw or stomach.
- ◆ **Shortness of breath.** May occur with or without chest discomfort.
- ◆ **Other signs.** These may include breaking out in a cold sweat, nausea or lightheadedness.

¹ From the American Heart Association (2007). *Know the Facts, Get the Stats.*

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DRAFT

1 Responding to Alarms and Heart Attack Symptoms

The next two pages provide a quick reference for

- ◆ How you know if you're getting an Emergency alarm and See Doctor alert – and what to do when each occurs
- ◆ What to do if you can't tell whether it's an Emergency alarm or See Doctor alert
- ◆ What to do if you experience heart attack symptoms

Heart attack symptoms are described on the inside front cover.

Important reminders on how to use your AngelMed Guardian system are summarized on the back cover.

Responding To Alarms and Alerts

If You Experience	Do This
<ul style="list-style-type: none">◆ A repeating pattern of<ul style="list-style-type: none">- 5 vibrations on IMD <p>Brrr Brrr Brrr Brrr Brrr</p> <ul style="list-style-type: none">◆ 5 beeps on EXD <p>Beep Beep Beep Beep Beep</p> <ul style="list-style-type: none">◆ A flashing red EXD light	<p>Call for an ambulance immediately.</p> <p>This is an Emergency alarm.</p> <p>See page 25 for more information.</p>
<ul style="list-style-type: none">◆ A repeating pattern of<ul style="list-style-type: none">- 1 vibration and a 7-second pause on IMD <p>Brrr (7 seconds) Brrr</p> <ul style="list-style-type: none">◆ 1 beep and a 7-second pause on EXD <p>Beep (7 seconds) Beep</p> <ul style="list-style-type: none">◆ A flashing yellow EXD light	<p>See your doctor in the next one or two days.</p> <p>This is a See Doctor alert.</p> <p>See page 28 for more information.</p>
<ul style="list-style-type: none">◆ A very short beep every 30 seconds (EXD) – and the IMD does not vibrate <p>Short Beep (30 seconds)</p>	<p>Replace your EXD battery or have your doctor replace it for you in the next 1 to 2 days.</p> <p>This is a Low EXD Battery warning.</p> <p>See pages 33 and 34 for more information.</p>

If you	Do this
Don't know which alarm it is (For example, you may be stressed and confused.)	Call for an ambulance immediately. Treat the alarm as an Emergency alarm.

Responding To Heart Attack Symptoms

If you	Do this
Have any heart attack symptoms like: <ul style="list-style-type: none">◆ Chest discomfort◆ Discomfort in the upper body◆ Shortness of breath	Call for an ambulance immediately. You may be having a heart attack – even if your AngelMed Guardian system isn't alarming. See the inside front cover for more information.

2 About the AngelMed Guardian System

Your doctor has prescribed the AngelMed Guardian® system to monitor and record your heart's electrical signals, 24 hours a day. This manual describes the system and provides instructions on how to use it.

Your heart is a muscular organ which pumps blood throughout your body. The pumping is controlled by electrical signals from within the heart. While these signals vary from person to person, they all share similar characteristics. It is these characteristics that the AngelMed Guardian system monitors.

A typical heart signal, shown here, can provide vital information on the heart's overall health.

Each area of the signal indicates a different part of the overall heart function. Using diagnostic equipment, doctors can identify many heart problems.



In a similar way, the AngelMed Guardian system continuously monitors your heart. It warns you of changes that may indicate that your heart is not getting enough oxygen – a condition called myocardial ischemia. Myocardial ischemia can lead to

a heart attack. It often occurs when a blockage develops in one of the heart arteries. Clinical studies suggest that this condition often changes the shape of the signal. If the signal shape changes too much, the AngelMed Guardian system warns you to seek medical help.

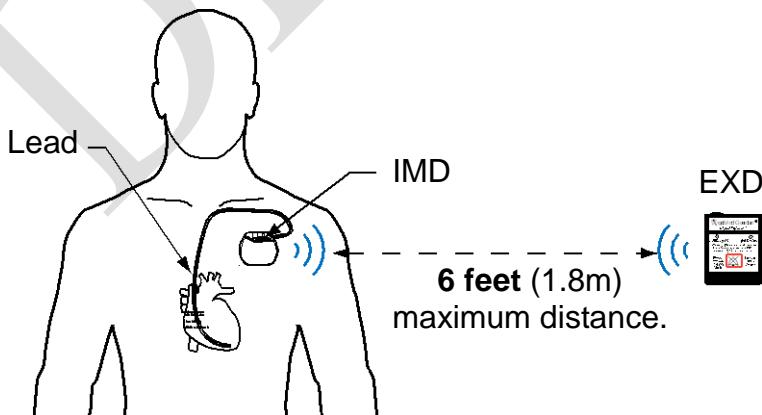
The AngelMed Guardian system also records your heart signals. These recordings can be reviewed by your doctor during office visits.

How the System Works

Your AngelMed Guardian system has two main parts:

- ♦ Implantable Medical Device (IMD, Model AG101 or Model AMSG3)
- ♦ External Device (EXD, Model EXD-001)

The IMD is surgically implanted just under the skin on the upper left side of your chest.



A lead is also implanted. One end of the lead is attached to the inside of your heart, and the other end connects to the IMD. The lead allows the IMD to monitor the electrical signals directly from your heart, 24 hours a day. The IMD gently vibrates if it detects specific changes in your heart signal.

When this occurs, the IMD communicates with the EXD, and the EXD beeps when the IMD vibrates. However, the EXD can only beep if it is within 6 feet (1.8 meters) of the IMD. That is why you must carry the EXD with you at all times. Note that your IMD will still beep even if your EXD is out of range.

As shown in the figure below, the EXD has Emergency and See Doctor lights, plus a *Silence Alarm/Check Battery* button. These features are described in detail later in this manual.



How Long Will Your IMD Last?

Your IMD is powered by an internal battery, which is expected to last about 3.5 years under normal conditions. However, excessive alarming and data retrievals (conducted by your doctor) may reduce IMD battery longevity. When the battery gets low, the IMD needs to be replaced. An incision is made where your current IMD is located, and your current IMD is replaced with a new one. The lead inside your heart remains in place.

Your IMD continuously monitors its own battery. When the IMD battery gets low, the IMD issues a See Doctor alert. Your doctor will then schedule a time to replace the IMD. The IMD is designed to last about 1 month after warning of low battery power. (The EXD has its own battery, which is discussed in *EXD Battery* on page 31.)

How the System Warns You of a Problem

Your AngelMed Guardian system provides three kinds of warnings.

- ◆ Emergency alarm
- ◆ See Doctor alert
- ◆ Low EXD Battery warning

An overview of each of these three alarms is provided in Section 1 – *Responding to Alarms and Heart Attack Symptoms* on page 1.

The AngelMed Guardian system signals an Emergency alarm or See Doctor alert when a change occurs in your heart's electrical signal. When these warnings occur, the IMD gently vibrates under your skin. In addition, the EXD warns you with beeps and a red or yellow flashing light.

Emergency alarms are used for life-threatening heart conditions, so you should call for an ambulance immediately. See Section 6 – *Emergency Alarms* on page 25 for more information.

See Doctor alerts are not as serious, but you should make an appointment to see your doctor in the next 1 or 2 days. See Section 7 – *See Doctor Alerts* on page 28 for more information.

Low EXD Battery warnings mean that the EXD battery power is low. The EXD beeps, but the IMD does not vibrate. You should either replace the EXD battery with the custom battery supplied by your doctor or call your doctor to replace the battery for you. The Low EXD Battery warning is described in Section 8 – *EXD Battery* on page 31. Battery replacement instructions are provided in Section 8 – *How to Replace the EXD Battery* on page 34.

3

When Not to Use this Product

The AngelMed Guardian system may not be implanted in the following circumstances:

- ◆ In patients who have previously been implanted with a device that regulates heart rhythm such as a pacemaker or cardioverter-defibrillator (ICD). The AngelMed Guardian system is not designed to monitor your heart if these devices are also implanted.
- ◆ In patients who cannot feel the IMD vibration when it is placed on top of the skin and just under the left collarbone.

4 Risks and Benefits

What are the Benefits?

The major benefit of the AngelMed Guardian system is that it constantly monitors the heart and warns you to seek medical help when it detects specific changes in your heart signal. Early treatment can save your life.

The AngelMed Guardian system also records your heart signal. This feature should help your doctor to manage your heart condition going forward.

What are the Risks?

Your doctor can best explain the risks involved with the AngelMed Guardian system. Some possible risks are as follows:

- ♦ Implanting the AngelMed Guardian IMD presents the same risks as any surgery. A small percentage of patients will develop a complication because of the implant surgery. These may include infection, reaction to a drug used during surgery, blood loss, or damage to a blood vessel, heart wall, or other organ.

- ◆ After surgery, you will feel some discomfort. This should lessen as you recover. Some patients however, continue to feel discomfort where the IMD is implanted.
- ◆ You should follow certain precautions with your AngelMed Guardian system. Your doctor will discuss them with you and many are discussed in this booklet. Please read this booklet completely. Pay close attention to sections that are labeled **Warning** or **Caution** because they contain important safety information.

Note that some coronary artery blockages may not cause your AngelMed Guardian system to warn you to get help. This is why you should **always get immediate medical attention if you experience heart attack symptoms**, even if your AngelMed Guardian system hasn't warned you.

5 General Warnings and Precautions

Your AngelMed Guardian system contains small electrical components. Under some circumstances, these parts can be affected and even damaged by external factors such as equipment that is used in medical settings, industry, and around the house.

This section explains the practices and environments that can adversely affect your AngelMed Guardian system. It covers:

- ◆ Medical therapy precautions
- ◆ Physical exercise precautions
- ◆ Interference from electrical devices and engines

Where possible, this section also explains steps that you or others can take to minimize any damaging effects.

Medical Therapy Precautions

Your AngelMed Guardian system will not be harmed by diagnostic x-rays (including fluoroscopy, dental and chest x-rays), computed tomography (CT) scans, mammographies, or ultrasonic dental cleaners.

However, some medical procedures can affect your IMD and the heart tissue near your lead. These procedures are listed in this section. Always tell the medical staff that you have an IMD and show them this booklet.

Diathermy is a medical procedure that uses microwaves or sound waves to heat body tissue. Do not have diathermy treatments. Diathermy may damage your IMD and injure the tissue near your implanted lead.

Electrosurgical cautery is a medical procedure that uses electrical currents to burn body tissue. Electrosurgical cautery may damage or interfere with your IMD. If electrosurgical cautery is necessary, medical personnel should keep the current path and groundplate as far away from the IMD and lead system as possible.

Because this treatment can cause your IMD to alarm, ask your doctor if alarms should be disabled prior to treatment. After treatment, see your doctor to confirm the IMD is operating properly.

Electrical therapies – Any treatment that uses therapeutic levels of electricity, like electro-acupuncture or electro-muscle stimulation, may damage or interfere with your IMD. If you undergo an electrical therapy, medical personnel should keep the current path as far away from the IMD and lead system as possible.

Because these treatments can cause your IMD to alarm, ask your doctor if alarms should be disabled prior to treatment. After treatment, see your doctor to confirm the IMD is operating properly.

External defibrillation uses external equipment to deliver an electrical shock to stop rapid heartbeats. External defibrillation may damage the IMD and heart tissue near the lead. Medical personnel should minimize current flowing through the IMD and lead system by:

- Positioning defibrillation paddles as far as possible from the IMD and lead system.
- Using the lowest clinically appropriate energy output.

After treatment, see your doctor to confirm the IMD is operating properly.

High radiation sources – High radiation sources such as cobalt 60 or gamma radiation should not be directed at the IMD. If you require radiation therapy near your IMD, medical personnel should put lead shielding over the device to prevent radiation damage. After radiation therapy, your doctor should periodically verify that your IMD is working properly since damage from radiation may not be immediately detectable.

Lithotripsy is a medical procedure that uses shock waves to break up hardened bodily secretions such as kidney stones. Lithotripsy may permanently damage the IMD. Avoid it unless the therapy site is not near your IMD or lead.

MRI (magnetic resonance imaging) is a diagnostic technique that uses radio waves to produce images of the body. Do not have an MRI. An MRI creates a very powerful magnetic field that can damage your IMD and injure the tissue near your implanted lead.

Radiofrequency (RF) ablation is a medical procedure that uses heat energy to destroy a small area of body tissue. RF ablation may damage your IMD or cause it to malfunction. To minimize RF ablation risks, medical personnel should avoid direct contact between the ablation catheter and your IMD and lead system. In addition, they should position the groundplate so that the current pathway does not pass through or near your IMD and lead system.

Because this treatment can cause your IMD to alarm, ask your doctor if alarms should be disabled prior to treatment. After treatment, see your doctor to confirm the IMD is operating properly.

Transcutaneous Electrical Nerve Stimulation (TENS)

(TENS) is the electrical stimulation of the skin to relieve pain. TENS may damage your IMD. If you need TENS, medical personnel should place the TENS electrodes close to one another and as far as possible from your IMD and lead system.

Because this treatment can cause your IMD to alarm, ask your doctor if alarms should be disabled prior to treatment. After treatment, see your doctor to confirm the IMD is operating properly.

Ultrasound therapy is a diagnostic technique that uses sound waves to produce images of the body. Ultrasound therapy, if directed at the IMD, may damage the device and cause you harm. If you need ultrasound therapy, the therapy should not be directed at the IMD. After treatment, see your doctor to confirm the IMD is operating properly.

Physical Activity Precautions

After surgery, the surgical site is likely to be sore. You need time to heal and you should keep this in mind whenever you exercise or stretch your upper body. Speak with your doctor about the kinds of physical activities you should avoid until you heal.

After you heal, you should be able to resume most of your usual activities. However, because you have an implanted device, avoid playing contact sports like football since the EXD, IMD or lead may get damaged. Also, consult your doctor before doing strenuous or repetitive upper-body exercise like weight lifting or softball.

Warning

Avoid contact sports after you get your IMD. Also, get your doctor's approval before starting an exercise program, especially if it involves upper-body activity. Strenuous activity may damage the implanted components, which may prevent the AngelMed Guardian system from warning you when it should.

Interference from Electrical Devices and Engines

All electrical devices generate some amount of electromagnetic interference (EMI). The AngelMed Guardian system protects against most sources of EMI. However, you should follow certain precautions as discussed in this section. Also, speak with your doctor if you want to learn more about these precautions.

What is Electromagnetic Interference?

Electromagnetic interference (EMI) is waves of energy from electrical equipment that interfere with the proper operation of nearby equipment. No doubt, you have already experienced EMI. For example, you may have heard static on the radio when you used an electrical appliance in the kitchen. This is an example of EMI.

Electrical equipment in good working order does not usually produce enough EMI to interfere with your IMD and EXD. This includes small and large kitchen appliances, stereo equipment, washers, dryers, computers, and similar items.

Sources of Strong EMI

Some types of equipment produce strong EMI. The following equipment can damage or interfere with your IMD and EXD:

Home appliances that are not in good working order.

High-voltage power lines.

Automobile ignition systems. Do not work under the hood of the car when the engine is running. However, it is okay to 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 limit your exposure to ignition-system parts.

Industrial equipment such as arc welders, large electro-magnets, induction furnaces, and very large or defective electric motors.

Radio transmitters and transmitters for radio-controlled equipment or toys.

Small motor-driven appliances like hair dryers, electric shavers, power tools. Do not hold small motor-driven appliances close to your IMD and EXD.

Some medical equipment such as MRIs. See *Medical Therapy Precautions* on page 12 for details.

Warning

Stay away from high-powered energy sources like MRIs and large industrial motors and generators. Getting too close can damage the IMD and injure the tissue near your implanted lead.

Warning

Be aware of any signs that warn those with pacemakers and other implanted devices to stay away. Such environments often have high-powered energy fields, which can interfere with the operation of the IMD. Speak with your doctor before entering such areas.

Cell Phones

Cell phones can safely be used with your AngelMed Guardian system, provided that you do the following:

- ◆ Hold the phone at least 6 inches (15 centimeters) away from your implanted IMD. Typically, that can be done by holding the phone on the right side of your body – opposite the IMD. If your cell phone transmits above 3 watts, hold the phone at least 12 inches (30 centimeters) away from your IMD.
- ◆ If you do not know the transmit power of your cell phone, check the cell phone manual. If you still do not know the transmit power, assume the cell phone transmits at the higher power and hold the phone at least 12 inches (30 centimeters) away from the IMD and EXD.
- ◆ Store the phone at least 6 inches (15 centimeters) away from the IMD. For example, store the phone on the right side of your body – opposite the IMD. This is important because some phones send signals when in the Listen or Standby mode.
- ◆ Never carry your phone in a shirt or breast pocket, which would place the device over the IMD.

Security Systems

Anti-Theft Systems (in Stores and Libraries)

Anti-theft systems that are used in stores, libraries and other places can interfere with your IMD and EXD if you stay within 2 feet of them. Please observe the following precautions.

- ◆ Pedestal systems are usually placed at store exits. Walk past the pedestals at a normal pace and do not linger.
- ◆ Tag deactivator systems are often used at stores and library checkout counters. Stay at least 2 feet away from them while conducting business.
- ◆ Do not work at the checkout counter of a store or library where such systems are used.
- ◆ Avoid self checkout counters where such systems are used. Store management should be able to tell you if the self checkout counters are equipped with an electronic security system.

Security Systems (in Airports and Other Public Buildings)

Security systems such as those used in airports and some public buildings will probably not interfere with your IMD and EXD. Walk through them at a normal pace, and do not linger near them.

The IMD and EXD have metal parts that may set off a security system alarm. If this happens, show your Identification Card to the security officers. If they use a handheld wand to perform a search, ask them to work quickly and avoid holding the wand over your IMD.

What Happens if IMD or EXD Operation is Impaired?

If you experience any of the conditions warned against in the previous sections, your IMD or EXD may be affected. When affected by these outside factors, the IMD or EXD may do the following:

- ◆ Issue a warning even if no medical problem exists
- ◆ Not issue a warning if a medical problem does exist

If the impairment is caused by electrical devices like cell phones, security systems, or sources of strong EMI (see page 19), the IMD or EXD generally returns to normal operation when the condition no longer exists. For example, when you step away from a store's security system or move away from the ignition system of a running automobile, the IMD and EXD will operate normally.

If you had one of the medical therapies discussed previously (see page 12) or if you sustained a physical shock or injury over the implant site, see your doctor to ensure the IMD is operating properly.

Warning

If you think your IMD or EXD may be damaged, call your doctor so that he or she can examine them. A damaged IMD or EXD may not warn you if a heart problem occurs.

6 Emergency Alarms

If you have an Emergency alarm, call for an ambulance immediately.

Alarm Pattern

During an Emergency alarm, the IMD vibrates in a repeating pattern of five short vibrations. The five vibrations are in a 3-2 pattern like this:

Brrrr- Brrrr- Brrrr Brrrr- Brrrr

If your EXD is within 6 feet (1.8 meters) of the IMD, the EXD will beep like this:

Beep-Beep-Beep Beep-Beep

Also, the **red light**, labeled "Emergency", on the EXD will flash.

These alarms will continue for up to 5 minutes, unless you turn them off with the EXD.

How to Respond

If you have an Emergency alarm, do the following:

1. Call for an ambulance immediately.

2. Look at the back of your EXD and follow any instructions written on the label.
3. Turn off the alarm by holding the EXD within 2 inches (5 centimeters) of your IMD. Then press the *Silence Alarm/Check Battery* button.
4. Take your EXD with you to the hospital.
5. At the Emergency room, tell the medical staff that you have an implanted device that vibrates when you have a heart problem. Also, show them your Patient ID card and this booklet, if available.

Turning Off an Emergency Alarm

You can turn off an Emergency alarm after it has been on for at least 30 seconds.

To turn off an Emergency alarm, hold the EXD within 2 inches (5 centimeters) of your IMD and push the *Silence Alarm/Check Battery* button on your EXD.



Turning Off an Emergency Alarm

If the EXD beeps twice, you have successfully turned off the alarm. If it beeps only once, move the EXD a little and try again. After the alarm has been turned off, your IMD will stop vibrating and the EXD will stop beeping.

Reminder Alarms

After 15 minutes, the IMD will vibrate again and the EXD will beep again with the pattern of five short vibrations. This is called a reminder alarm. It reminds you to call for an ambulance immediately, if you haven't done so already.

As before, you can turn off the reminder alarm after it has been on for at least 30 seconds. If you don't turn it off, the alarm will continue for about two minutes and then stop automatically.

For your safety, reminder alarms will recur every 15 minutes for up to 2 hours. They will stop after you have turned off two separate alarms.

Flashing Red Light Remains On

The EXD's red Emergency light will flash for 25 hours, unless your doctor turns it off. Your doctor is the only person who can turn off the EXD's flashing light.

7

See Doctor Alerts

If you have a See Doctor alert, make an appointment to see your doctor in the next one or two days.

Alert Pattern

The See Doctor alert is very different from the Emergency alarm. The IMD vibrates one time, pauses for about 7 seconds, vibrates again, and so on, like this:

Brrrr ← 7 sec → **Brrrr**

If your EXD is within 6 feet (1.8 meters) of the IMD, the EXD will beep like this:

Beep ← 7 sec → **Beep**

Also, the **yellow light**, labeled "See Dr.", on the EXD will flash.

These alerts will continue for up to 5 minutes, unless you turn them off with the EXD.

How to Respond

If you have a See Doctor alert, do the following:

1. Make an appointment to see your doctor in the next 1 or 2 days.
2. Look at the back of your EXD and follow any instructions written on the label.
3. Turn off the alert by holding the EXD within 2 inches (5 centimeters) of your IMD. Then press the *Silence Alarm/Check Battery* button.
4. Bring your EXD to your appointment.

Turning Off a See Doctor Alert

You turn off a See Doctor alert the same way you turn off an Emergency alarm.

You can turn off a See Doctor alert after it has been on for at least 30 seconds.

To turn off the alert, hold the EXD within 2 inches (5 centimeters) of your IMD and push the *Silence Alarm/Check Battery* button.



Turning Off a
See Doctor Alert

If the EXD beeps twice, you have successfully turned off the alert. If the EXD beeps only once, move the EXD a little and try again. After the alert has been turned off, your IMD will stop vibrating and the EXD will stop beeping.

No Reminder Alarm

There are no reminder alarms for the See Doctor alert. The vibrations and beeps will not restart after you turn them off.

Flashing Yellow Light Remains On

The EXD's yellow See Dr. light will flash for 25 hours, unless your doctor turns it off. Your doctor is the only person who can turn off the EXD's flashing See Dr. light.

8 EXD Battery

The EXD uses a custom battery that lasts about six months. This battery is available only from your doctor. Your doctor will provide you with a spare battery so that you can replace the battery between appoints should the need arise. If you don't feel comfortable changing the battery yourself, ask your doctor to replace it for you.

You should however check your EXD battery power once a week. If this check shows that the battery is dead (see page 32) or if you hear a low EXD battery warning (see page 33), either replace the battery yourself (see page 34) or have your doctor do it for you.

Warning

Use only the battery supplied by your doctor in your EXD. The EXD will not work with a different battery. Using a different battery can also damage your EXD. An EXD that isn't working properly cannot warn you when it should.

Checking EXD Battery Power

Check your EXD's battery power once a week.

To check battery power, press the *Silence Alarm/Check Battery* button on your EXD. You do not need to hold the EXD near your IMD when you press the button.

- ◆ If the battery is working, the EXD will make **one** very short beep (“chirp”) at the same time you press the button.
- ◆ If the battery is not working, the EXD will not beep when you press the button. Call your doctor to replace the battery.

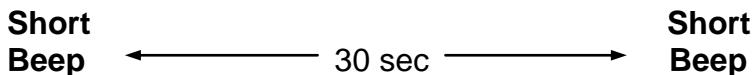
Warning

Check the EXD's battery power once a week to avoid losing power to your EXD. An EXD with a depleted battery cannot warn you when it should.

Low EXD Battery Warning

If you get a Low EXD Battery warning, see your doctor in the next day or two for a replacement battery.

If your EXD battery has low power, the EXD will make a very short beep (“chirp”) every 30 seconds, until it runs out of power or until you turn the warning off.



The IMD does not vibrate during a Low EXD Battery warning.

You can turn off a Low EXD Battery warning after it has been on for at least 30 seconds. When you turn it off, the Low EXD Battery warning remains off for 12 hours and then starts beeping again.

To turn off the Low EXD Battery warning for 12 hours, press the *Silence Alarm/Check Battery* button on the front of your EXD. You do not need to hold the EXD near the IMD to turn off the Low EXD Battery warning.

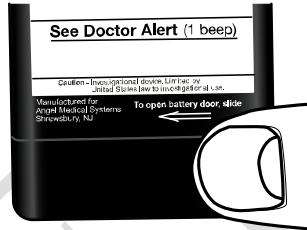
Turning Off
a Low
Battery
Warning



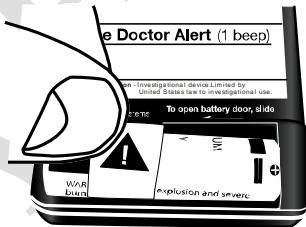
How to Replace the EXD Battery

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.

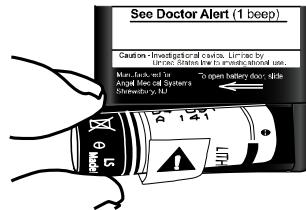


2. Gently pull the tab to lift the negative (-) end of the old battery. **Note:** If the pull-tab is under the battery or missing, use a small screwdriver to gently lift the battery.

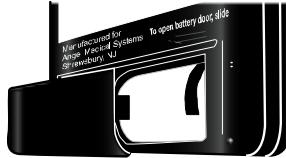


3. Insert the positive (+) end of the new battery into the battery compartment, then push down on the battery's negative (-) end.

Caution: Your EXD will only operate when you use the battery supplied by your doctor. Do not use a common household battery.



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.

Note: You may need to press the button up to 20 times before the EXD beeps. This is a characteristic of a new battery when it is being used for the first time.

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

Warning

If you replaced the EXD battery and the EXD no longer beeps when pressing the *Silence Alarm/Check Battery* button, perform the steps in the *Troubleshooting* section on page 44. If the EXD still does not beep, your EXD is not functioning properly and you should contact your doctor for assistance. Note however, that your IMD can still vibrate if it detects a heart problem even if your EXD is not working properly.

9 Keeping the EXD Close By

Keep the EXD within 6 feet (1.8 m)

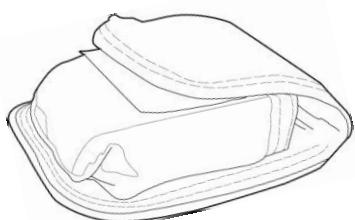
It is important for you to keep the EXD within 6 feet (1.8 meters) of your IMD at all times. You should carry it with you during the day, and keep it by your bed at night. Doing so allows the EXD to beep and flash if your IMD signals an Emergency alarm or See Doctor alert. Keeping the EXD close by also allows you to stop the EXD and IMD warnings if they occur.

Do not expose the EXD to extreme temperatures or water as these may interfere with its operation. For information on ways to care for your EXD, see *Care and Maintenance* on page 40.

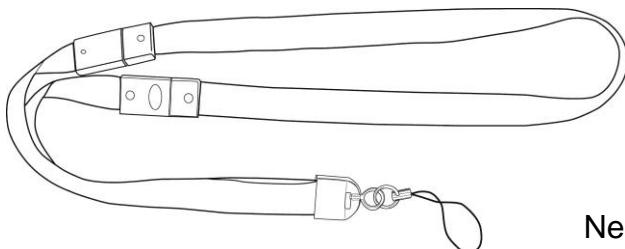
Belt Case and Neck Cord

Your AngelMed Guardian system includes a neck cord and a belt case for carrying the EXD. These accessories help you to keep the EXD close by at all times. The belt case has a built-in belt clip.

Belt Case



The neck cord has a breakaway safety feature. If you pull hard on the neck cord, it automatically opens and falls from your neck. This feature protects you if the neck cord or EXD gets caught on something.



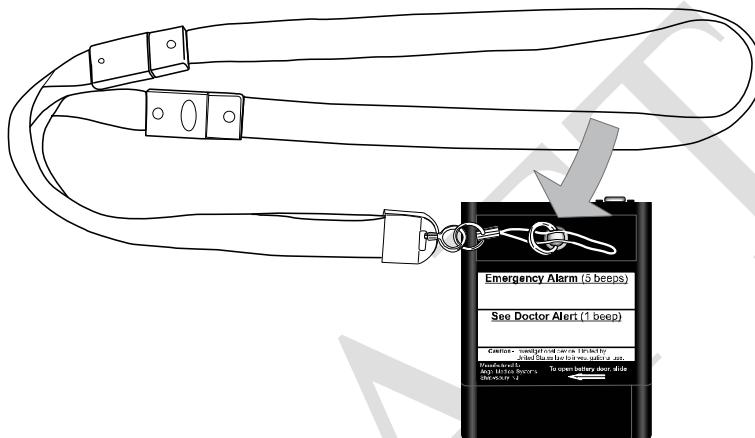
Neck Cord

Warning

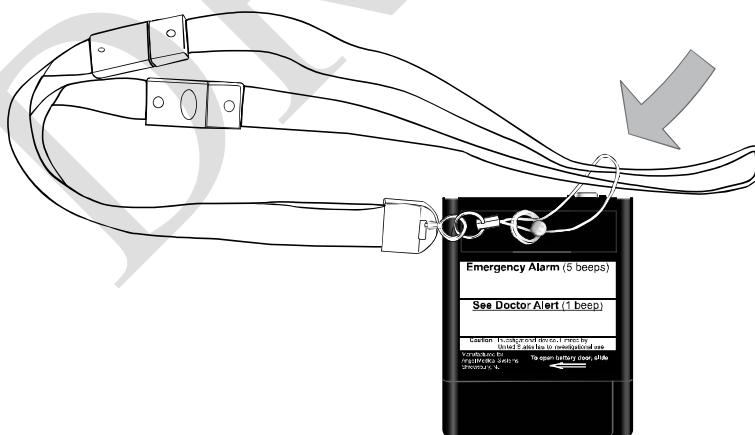
Do not use any neck cord except the one supplied by Angel Medical Systems. Many neck cords do not have a breakaway safety feature, which protects you from injury if your EXD or neck cord gets caught on something.

How to Attach the Neck Cord to the EXD

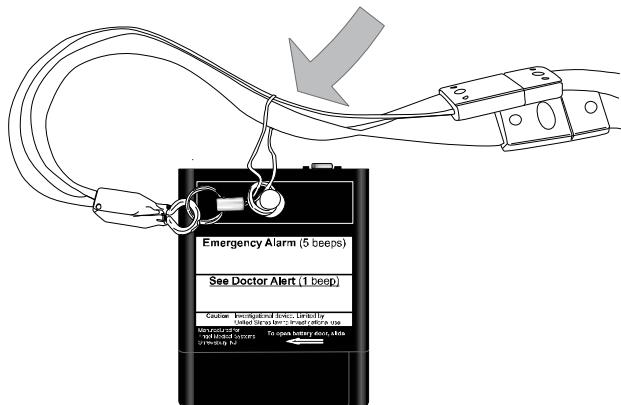
7. Insert the string loop at the end of the neck cord through the EXD's metal attachment ring.



8. Insert the neck cord through the string loop.



9. Slide the string loop down the neck cord.



10 Care and Maintenance

Warning

Contact your doctor if any of these statements are true:

- ◆ You sense any problems with your IMD.
- ◆ Your EXD is damaged.
- ◆ If after replacing the battery, you don't hear the short beep ("chirp") when you press the EXD's *Silence Alarm/Check Battery* button.
- ◆ Your EXD battery power is low and you need help replacing the EXD battery.

These conditions indicate your AngelMed Guardian system is not functioning properly and may fail to warn you when it should.

Take care of your AngelMed Guardian system as follows:

Check the EXD's battery power once a week See Section 8, *EXD Battery* on page 31 for details.

Keep the EXD dry. The EXD is not waterproof, so getting it wet may damage its electronics. If you accidentally drop the EXD into a sink, tub, or similar place, call your doctor.

Never use strong cleaners or solvents to clean the EXD. If the surface of the EXD gets dirty, you can clean it with a cloth lightly dampened in clean water.

Don't expose your EXD to extreme temperatures.
It may stop operating.

- In cold climates (below 32°F (0°C)), keep your EXD underneath your outer clothing so that it does not come into contact with the frigid air.
- In hot climates (above 122°F (50°C)), keep your EXD out of direct sunlight.

If the EXD is dropped from a height of greater than 3 feet (0.9 meters) or if it strikes another object sharply, see your doctor for a replacement EXD. If the EXD is dropped from a lesser height, push the *Silence Alarm/Check Battery* button. If the device beeps one time, it is okay; if it does not beep, see your doctor for a replacement.

Don't expose your IMD and EXD to atmospheric pressures below 10.2 psi (703 hPa) or above 15.58 psi (1074 hPa). Operation of these devices outside this range is not recommended.

11 Travel Information

Your AngelMed Guardian system is designed to go anywhere you go. With only a few of points to keep in mind, you can travel freely.

Travel Restrictions: Follow any travel restrictions that are recommended by your doctor.

EXD Temperature Ranges: Observe the EXD temperature ranges described on page 41 when visiting hot or cold climates.

Change the EXD Battery? Your EXD battery can work for about 6 months. Depending on when it was last replaced, the battery could run out of power while you are away. If you intend to travel for an extended time period, we recommend that you change the battery before you leave. It's also a good idea to take a spare battery along with you whenever you travel. For instructions on changing the battery, see *How to Replace the EXD Battery* on page 34. If you need help changing the battery, contact your doctor for assistance.

Security Systems: Your IMD may trigger security systems like those found at airports. Always carry your ID card, which you can show the security officer, if necessary. For more details on this topic, see *Security Systems* on page 22.

Patient Manual: Take this manual with you when you travel. It contains information that may be helpful to you as you come across places, environments, or circumstances that you don't normally encounter.

Different Time Zone: If you travel to another time zone, ask your doctor if your AngelMed Guardian system's trending check should be set for another time.

This check occurs every day at the same time and warns you if it finds a problem. Ideally, this check should occur when you are awake. If you travel to another time zone, this check may no longer occur when you are awake.

12 EXT Battery Troubleshooting

Problem	Possible Causes	What to Do
EXD does not beep when the <i>Silence Alarm/Check Battery</i> 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.

13 Glossary

Diathermy

A medical procedure that uses microwaves or sound waves to heat body tissue for therapeutic purposes.

Electromagnetic interference (EMI)

Waves of energy from electrical equipment that interfere with the proper operation of nearby equipment.

Electrosurgical cautery

A medical procedure that uses electrical currents to burn body tissue for surgical purposes.

External Device (EXD)

The pager-sized device that uses sound (i.e., beeps) and a flashing light to warn you to seek medical attention.

External defibrillation

The use of external equipment designed to stop rapid heartbeats.

Implanted cardioverter-defibrillator (ICD)

An implanted device used to stop rapid heartbeats.

Implantable Medical Device (IMD)

The device that is implanted under the skin to monitor your heart. It vibrates to warn you to seek medical attention.

Lithotripsy

A medical procedure that uses shock waves to break up hardened bodily secretions.

Magnetic resonance imaging (MRI)

A diagnostic technique that uses radio waves to produce images of internal body tissues.

Myocardial ischemia

A condition where a portion of the heart has insufficient blood flow. This can lead to a heart attack.

Pacemaker

An implanted device used to speed up a slow heartbeat.

Radiofrequency (RF) ablation

A medical procedure that uses heat energy to destroy a small area of body tissue.

Transcutaneous Electrical Nerve Stimulation (TENS)

The electrical stimulation of the skin to relieve pain.

Ultrasound therapy

A diagnostic technique that uses sound waves to produce images of internal body tissues.

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Patient Instructions

Physician:

Copy and write the EXD back label instructions here.

Emergency Alarm (5 beeps)

See Doctor Alert (1 beep)

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

Manufactured for
Angel Medical Systems
Shrewsbury, NJ

To open battery door, slide

