

LifeVest[®]

Wearable Cardioverter Defibrillator Model 4000

Patient Manual

Using TruVector™ Detection Algorithm



ZOLL[®]

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Restricted distribution and use

Federal (USA) law restricts this device to distribution and use by or on the order of a physician.

Effectivity

This manual describes the LifeVest 4000 wearable defibrillator system.

Disclaimer

Information, operation, specifications, and product appearance may change without notice. Names and data used in examples are fictitious.

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Patents

Patent: www.zoll.com/patents

Summary of Safety and Clinical Performance: Basic UDI-DI 0855778005P010030VM

The Summary of Safety and Clinical Performance (SSCP) is available in the European Database on Medical Devices (EUDAMED, <https://ec.europa.eu/tools/eudamed>). The SSCP is linked to the Basic UDI-DI of the device (0855778005P010030VM).

Clinical manual for physician reference

20B0049_EUK_REVT

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1: Introduction

About the LifeVest® WCD system

The LifeVest® wearable cardioverter defibrillator (WCD) continuously monitors your heart. If it detects a life threatening rhythm that is too fast, the device delivers treatment to restore normal rhythm. If you are conscious, you can prevent a treatment by using the response buttons when the device alerts you that a treatment is coming.

About this manual

This manual:

- is for patients who are using the LifeVest wearable defibrillator.
- gives you instructions on the use and care of the device.
- is intended to supplement the training you received when you were fitted with the LifeVest device.

What's in this manual

Here's how to use this manual:

- The next few pages contain safety information, intended use locations, essential performance, and electromagnetic compatibility guidance.
- **Meet the LifeVest® WCD system** tells you about the components, what they're called, and basically how they work.
- **Using the LifeVest® WCD system** suggests a daily routine, tells you how to use and care for the device, and tells you what to tell your family members.
- **Assembling and putting on the garment** goes into the specific details about how to assemble the electrode belt to the garment, then how to put on the assembled belt and garment. This section also covers connecting and disconnecting the electrode belt, removing the garment when you shower or bathe, as well as disassembling and laundering the garment.
- **Responding to alarms** explains the types of alarms and tells you what to do if you get an alarm.
- **Using the activities options** covers options that can be prescribed by your doctor while you're wearing the LifeVest WCD.
- Appendixes include **Quick charts**, a **Glossary**, a **Graphics glossary**, and a **Software licensing statement**. The quick charts are particularly helpful as reminders of how to do things. The glossary defines terms and abbreviations. The list of symbols defines icons on the components, in this manual, and on the packaging.
- Use the **Index** at the back of the manual to find what you're looking for quickly.

Safety information

This information helps you safely operate the LifeVest device. Read and understand these warnings, cautions, and symbols before using the device.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Terms used



WARNING: Warns you of possible injury or death that can be caused by misuse of the device. This includes device failure that could lead to you being not protected by the device.



CAUTION: Advises you of a possible problem with the device. Such problems include damage to the device or other property, or minor injury.



WARNINGS

Do not use the LifeVest system until you receive training and understand the manual. If you do not understand how to use the system, you may damage it, cause the system to malfunction, and/or cause injury or death.

Tell your medical professional about all of your medical conditions and current treatments. Always wear the LifeVest WCD when instructed to do so by a medical professional. Inappropriate use of the LifeVest WCD may damage it and/or cause the system to malfunction. Ask your medical professional to explain any parts that you do not understand.

Make sure the battery is fully inserted and latched into the monitor. If the battery is not fully inserted and latched, it may disconnect and you will not be protected.

Make sure the electrode belt is properly connected to the monitor. If the electrode belt is not properly connected, it may disconnect and you will not be protected.

Do not tamper with, alter, drop or abuse any part of the system or labeling. Do not put fingers or foreign objects, such as paper clips or hair pins, into any connectors or openings. Altering the equipment in any way may damage it and/or cause the system to malfunction. Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.

Do not put the monitor, electrode belt, battery or charger in or near water. Water entering the device may damage it and/or cause the system to malfunction.

**WARNINGS**

Always operate the system within the range of 0°C to 50°C (32°F to 122°F), up to 95% relative humidity (non-condensing), and up to 3,048 meters (10,000 feet) in altitude. Operating the device outside of this range may damage it and/or cause the system to malfunction.

Do not use the device in the presence of flammable agents or in an oxygen enriched atmosphere. This could present an explosion and fire hazard.

If you see Blue™ gel other than during a treatment, this may indicate a damaged electrode belt and cause the system to malfunction. Call your device provider immediately.

If the therapy pad Blue gel gets into your eyes, flush your eyes immediately with water and contact your physician. Your eyes may become irritated from the Blue gel.



The LifeVest WCD is magnetic resonance (MRI) unsafe. Do not use it in a MR imaging environment.

Do not stack or place the LifeVest WCD next to other devices. Doing so could expose the device to EMI disturbance that may cause the system to malfunction.

Only the patient should press the response buttons. The patient's ability to press the response buttons lets the device know whether or not the patient is conscious and is critical in deciding when to give the patient a shock. If anyone other than the patient holds the response buttons, needed therapy may not be delivered, possibly resulting in serious injury or death.

Do not touch the patient while a shock is being delivered. Anyone touching the patient during a treatment may be shocked.

Do not remove the battery, do not disconnect the electrode belt from the monitor, and do not loosen the garment while the monitor is broadcasting alert sounds and/or voice prompts. If the battery is removed, the electrode belt disconnected from the monitor, or the garment is loosened, needed therapy may not be delivered, possibly resulting in serious injury or death. CPR can be performed as long as the monitor is not broadcasting alerts sounds and/or voice prompts. If external defibrillation is available, a decision can be made by a medical professional to remove the device and monitor/treat the patient with external equipment.

Do not dispose of or incinerate the batteries. The batteries contain lithium ion and must be disposed of properly by ZOLL.



WARNINGS

Do not force the connector. Allow the connector to align before pushing it in. Forcing the connector may damage it and cause the system to malfunction.

Do not use chlorine bleach, bleach alternatives, fabric softener, anti-static sprays or detergents that include bleach or fabric softener additives when laundering the garment. Using bleach or any of these other prohibited agents to launder the garment may damage it and cause the system to malfunction.

If you get an alert sound and you are awake, always hold the response buttons to prevent receiving a treatment. If you fail to hold the response buttons, you will get a treatment.

If you receive a treatment while your heart is beating normally and you did not use the response buttons, the treatment may cause an abnormal rhythm to occur. There is a small possibility that the abnormal heart rhythm may not be detected and death may result.

When performing the WalkTest® activity, do not continue with the activity if the monitor broadcasts an alert sound. Stop the activity and press the response buttons as you normally would. If you continue with the activity, you may place yourself at risk for a cardiac arrest, possibly resulting in serious injury or death.

When performing the WalkTest activity, do not continue the activity if you experience symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop the activity and sit or lie down. If the symptoms continue or get worse, immediately call your doctor or emergency help. If you continue the activity or ignore the symptoms, you may place yourself at risk for a cardiac arrest or other health problems, possibly resulting in serious injury or death.

Conductive parts of electrodes and associated connectors should not contact other conductive parts including earth.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. If this should occur, it could affect the ability of the LifeVest WCD to function properly, which may result in serious injury or death.

**CAUTIONS**

If the charger or power supply makes unusual noises, sparking, starts to smoke, or emits a burning smell, unplug it immediately from the wall outlet. The only way to completely remove power is by unplugging the AC power plug from the wall outlet. Place the charger so that the power plug is accessible in case you need to unplug it.



Any medical electrical equipment connected to the patient at the same time as the LifeVest must be defibrillator proof, as shown by this symbol. If the equipment is not defibrillator proof, the equipment may be damaged if the LifeVest delivers a treatment shock. Disconnect any non-defibrillator proof equipment from the patient while the patient is wearing the LifeVest.

Environment considerations related to noise and vibration

Certain environments or situations you encounter that are loud and have high vibration could affect the LifeVest WCD. A loud environment could make it difficult for you to hear an alert to be able to appropriately respond. A high vibration environment may result in an inappropriate treatment. For example, riding a motorcycle may cause vibration and make it difficult for some patients to hear an alert which may result in an inappropriate treatment.

If you encounter a loud, high vibration environment while wearing the LifeVest WCD, you should be attentive to your device to ensure you respond to any alerts. In the unlikely event that vibration causes you to receive a siren alert, hold the response buttons to prevent receiving a treatment and move away from the source of vibration.

Residual risks/undesirable side effects

A rash or skin irritation is a potential risk with use of the LifeVest WCD. If you experience skin irritation, which may include redness, itching, or swelling, and you believe that medical attention is required, consult your health care provider.

An inappropriate treatment may be delivered while the heart is beating normally if the patient is awake during a treatment alert but does not press the response buttons. In a small percentage of cases, this treatment may cause an abnormal heart rhythm to occur.

The LifeVest WCD may not detect every treatable, life-threatening rapid heart rhythm due to ventricular arrhythmia rates below the prescribed programmed threshold, ventricular arrhythmia morphology, or noise contamination.

General defibrillation residual risks/undesirable side effects

A treatment shock from any defibrillator may cause skin burn. The LifeVest WCD uses Blue™ gel to reduce the chance of burn.

Defibrillation does not treat all heart problems or conditions such as a dangerously slow heart rate or a complete stoppage of the heart. Delivery of a treatment shock under such conditions provides no clinical benefit.

In a small percentage of cases, a treatment shock may not convert a rapid heart rhythm to a normal rhythm.

Post-shock asystole can occur with defibrillation. Post-shock asystole is a known and potentially adverse outcome of defibrillation therapy.

Intended Purpose

The intended purpose of the LifeVest Wearable Defibrillator, Model 4000 is to detect ventricular fibrillation or ventricular tachycardia and deliver a defibrillating shock without patient or bystander interaction.

Indications

The LifeVest Wearable Defibrillator, Model 4000 is indicated for patients 18 years of age and older who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

Contraindications

The LifeVest Wearable Defibrillator, Model 4000 is contraindicated for use on patients with an active implantable defibrillator.

Intended User

The LifeVest Wearable Defibrillator, Model 4000 is intended for the following user groups:

- **Patient:** The patient is the primary intended user of the LifeVest 4000. The patient wears and interacts with the system daily.
- **ZOLL Authorized Representative:** ZOLL authorized representatives are trained by ZOLL to fit and train patients with the LifeVest 4000. These representatives are responsible for programming the equipment per the patient's prescription, fitting patients, and providing training to patients and their families.

- **Healthcare Professionals:** Healthcare professionals prescribe the LifeVest 4000 for the patient, including identifying device settings. Healthcare professionals can also access patient data in the ZOLL Patient Management Network.

Intended Patient Population

The following list summarizes the typical patient conditions and situations that create a risk for SCA and for which the LifeVest Wearable Defibrillator, Model 4000 is appropriate therapy.

- Primary prevention (Ejection Fraction (EF) \leq 35% and either myocardial infarction (MI) or dilated cardiomyopathy (DCM)) including:
 - After recent MI
 - Before and after Coronary Artery Bypass Grafting (CABG) or Percutaneous transluminal coronary angioplasty (PTCA)
 - Listed for cardiac transplant
 - Recently diagnosed nonischemic cardiomyopathy
 - Class IV heart failure
 - Terminal disease with life expectancy of less than 1 year
- ICD indications when patient condition delays or prohibits ICD implantation
- ICD explantation

Vulnerable Populations

ZOLL does not make specific claims regarding use of the LifeVest 4000 in vulnerable populations.

Intended use locations

The intended electromagnetic environments for the LifeVest[®] 4000 are home, small clinic, hospital, and transport.

Essential performance

The essential performance of the LifeVest WCD is that it detects ventricular fibrillation or ventricular tachycardia, then delivers a defibrillating shock. Unacceptable risks include loss of detection and treatment functionality.

Aircraft use

The LifeVest® 4000 was tested to demonstrate compliance to the emissions and immunity requirements of the following standard: RTCA DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 20 (RF immunity) and Section 21 (RF emissions).

Check with your airline for any special restrictions on using personal electronic equipment when making your flight reservations.

Reconditioning

The LifeVest device can be reused only if it is reconditioned under the responsibility of ZOLL.

Operator profile

As defined by IEC 60601-1-6, the operator profile is a summary of the mental, physical, and demographic traits of the intended user population.

According to the IEC definition, the operator is defined as the person interacting with the device. In the case of the LifeVest WCD, there are three operators:

- The patient wears and interacts with the LifeVest WCD on a daily basis. The patient profile appears below.
- ZOLL authorized representatives fit patients with the equipment, and train patients. The ZOLL authorized representative profile appears below.
- Healthcare professionals prescribe the LifeVest WCD for the patient. The healthcare professional profile appears below.

Patient profile

The device is appropriate for patients who are at risk for sudden cardiac arrest and meet the requirements described in the Patient Manual. The patient wears the LifeVest WCD at all times (except when showering or bathing), changes and charges the batteries every 24 hours, responds to alarms, and presses the response buttons if there is a treatment alarm in order to prevent inappropriate shocks from occurring.

While a patient is using the device, the patient is expected to do minimal maintenance, including periodically cleaning and inspecting the system, as instructed in section 3, page 3-32.

The patient is not expected to do any service on the device. Only ZOLL is to perform service on the device. The device is to be returned to ZOLL for service.

ZOLL authorized representative profile

ZOLL authorized representatives are ZOLL-trained professionals. Their job is to program the equipment according to the patient's prescription, measure and fit patients with the LifeVest equipment, train patients and family members, and provide follow-up assistance if necessary.

ZOLL authorized representatives must have the mental and physical capabilities to understand training given by ZOLL that covers programming the device, measuring and fitting patients, and training patients in the daily use of the device.

Healthcare professional profile

Healthcare professionals evaluate and prescribe the patient. (Clinical information is provided in the Operator's Manual.) Healthcare professionals also monitor the patient. (ZOLL Patient Management Network, formerly known as LifeVest Network, is described in the Operator's Manual.) Healthcare professionals can perform advanced programming of the device.

Patient training

It is essential that all patients receive training before wearing the LifeVest WCD. This training is given by ZOLL authorized representatives. These representatives deliver the LifeVest training in the patient's home or in a clinical setting.

Patient training consists of instructions for garment and electrode belt assembly and disassembly; alarm response, including the use of the response buttons; and how to change and recharge the batteries.

After completing the training, patients sign an agreement that documents receipt of training in the use and care of the LifeVest WCD.

In addition, phone support is available for patients by calling ZOLL or a ZOLL representative.

Electromagnetic interference



WARNING

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Many common devices, including motors and electronic equipment, could produce electromagnetic interference, also known as EMI, in the LifeVest device that could affect its operation. The LifeVest device has been tested with a number of common sources of electromagnetic disturbance, including cellular telephones, airport security systems, and anti-theft detection systems. This testing, along with clinical trial testing, has demonstrated that in everyday use the LifeVest device is not normally affected by commonly encountered electromagnetic disturbances.

Anti-theft detection systems, also known as electronic article surveillance systems, are often used in department stores and libraries to prevent theft by electronically sensing a special tag on a piece of merchandise when the tag passes through a detector gate. In the USA, these detector gates are commonly located near the doorways. In Europe, the detector gates may be positioned near the checkout areas.

To prevent possible disturbance with the LifeVest device, follow these simple guidelines when passing through airport security gates or anti-theft detection gates:

- Walk through the gate at a normal pace.
- Avoid lingering near or leaning on the gate.

In some occupational and hospital environments, unusually high levels of electromagnetic disturbance could be encountered. Examples of possible sources of such disturbance include: Magnetic resonance (MR) imaging equipment, communication equipment such as microwave transmitters, arc welding equipment, high voltage transmission lines, electrocautery systems, and electronic muscle stimulators. These environments should be avoided while wearing the LifeVest device.

In the unlikely event that electromagnetic disturbance causes you to receive arrhythmia alarms, hold the response buttons to prevent being shocked and move away from the source of the disturbance. The LifeVest device should return to normal monitoring mode in approximately 5 seconds.

Wireless interference



WARNING

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The LifeVest WCD can be susceptible to or cause wireless interference. Follow these instructions:

- **Cell phone use** – When using a cell phone, keep it at least 27 centimeters (10.6 inches) away from the sensing electrodes (the round ones) on the electrode belt. If you experience noise alarms while using a cell phone, move the cell phone away from the electrode belt or stop using the cell phone.
- **Charger with touchscreen use** – The charger with touchscreen contains a cell phone for data transmissions. Keep the charger with touchscreen at least 27 centimeters (10.6 inches) away from your body to prevent interference. If you experience interference near the charger with touchscreen, move away from the charger. If you take the charger with touchscreen to a hospital, be sure that the use of cell phones is permitted. If not, do not use the charger with touchscreen while in the hospital. If you need to transmit data, use the wired modem connection.
- **Hotspot use** – The hotspot contains a cell phone for data transmissions. Keep the hotspot at least 27 centimeters (10.6 inches) away from your body to prevent interference. If you experience interference near the hotspot, move away from the hotspot. If you take the hotspot to a hospital, be sure that the use of cell phones is permitted. If not, do not use the hotspot while in the hospital.
- **General precaution** – If you experience any interference with the LifeVest WCD when in the presence of any other wireless device, move away from the device or stop using the device that is causing the interference. If you continue to have problems, call ZOLL.

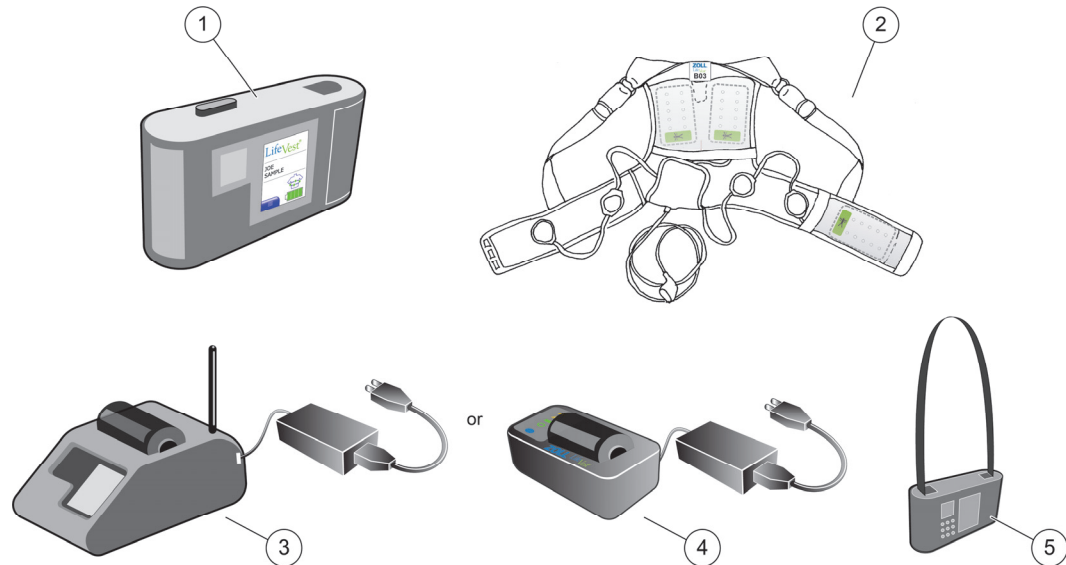
Ingress protection

The LifeVest device, when worn in its holster, is rated IP22. The first number of the IP (ingress protection) rating designates protection against solid foreign objects. The second number designates protection against water.

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2: Meet the LifeVest® WCD system

Components



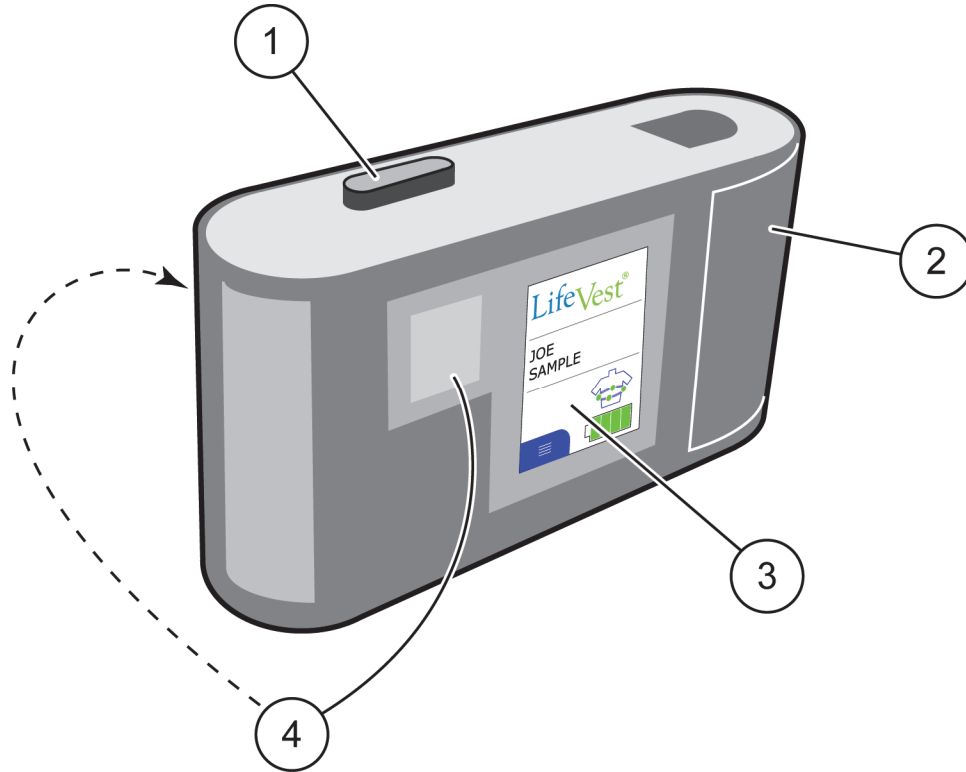
Item	Description
1 Monitor	Main unit of LifeVest system. Connects to electrode belt. Monitors your heart rhythm and delivers defibrillating treatment. See details on page 2-2.
2 Garment and electrode belt	Fits around your body and connects to the monitor. Different style garments may be provided. See details on page 2-3.
3 Charger with touchscreen	Recharges the battery, communicates wirelessly with the monitor, and transmits data for doctor review. See details on page 2-4.
4 Charger with indicator lights	Recharges the battery. See details on page 2-5.
5 Holster	Lets you carry around the monitor.



If the package for your LifeVest WCD system or any of its components has been damaged, or opened by anyone other than you or your ZOLL authorized representative, do not use the system or component. Contact ZOLL immediately.

Monitor

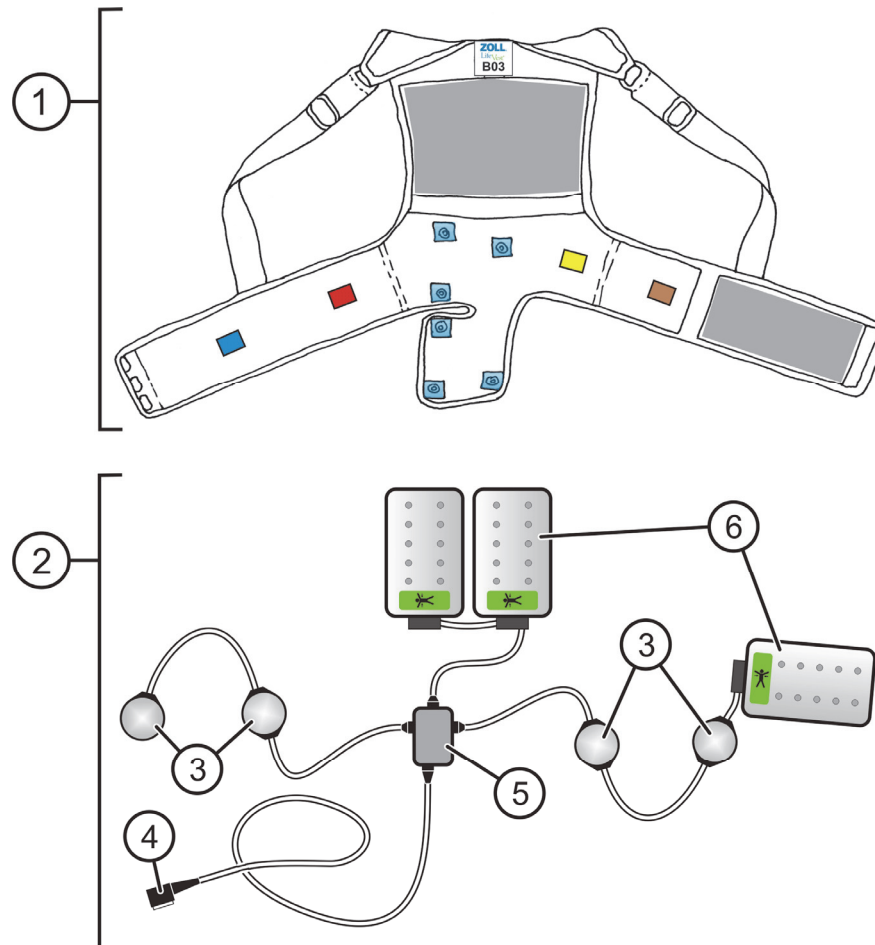
For details about operating and caring for the monitor, see section 3. For details about responding to alarms, see section 5.



Item	Description
1 Connector	Connects to electrode belt.
2 Battery	Powers the monitor. To recharge the battery, use the charger; see page 2-4.
3 Touchscreen	<p>Displays messages about device operation, and allows patient to interact with device. When you turn the monitor upside-down, the display flips for reading by the patient who is wearing the device.</p> <p>During normal monitoring, most of the time the LifeVest monitor displays a dark screen. To see the display, press and release the response buttons.</p> <p>For more on the monitor touchscreen, see page 2-6.</p>
4 Response buttons	Two buttons, located front and back, that light solid red when the device senses that your heart is in a rapid life-threatening rhythm. You should, if conscious, press both response buttons to stop from getting a defibrillating treatment. You can press and release the response buttons; you don't have to hold them continuously.

Garment and electrode belt

Your garment may be white or gray in color, depending on your region or country. All colors and styles of garment perform the same function: to hold the round electrodes and therapy pads against your chest. For details on assembling, wearing, and caring for the garment and electrode belt, see section 4.



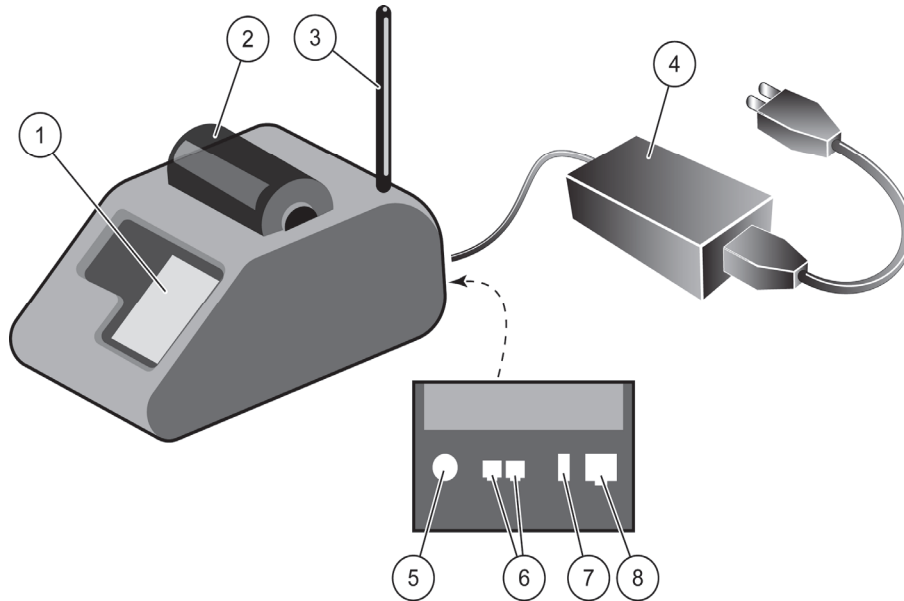
Item	Description
1 Garment	Worn under your clothing to hold the heart sensors and therapy pads against your chest.
2 Electrode belt	Assembles to garment and contains heart sensors, vibration box, and therapy pads.
3 Heart sensors	Sense your heart's electrical signal for the monitor. Also called electrodes.
4 Connector	Connects to the monitor.
5 Vibration box	Notifies you that the device is preparing to give you a treatment.
6 Therapy pads	Deliver a treatment to your heart.

Charger

The LifeVest system includes two batteries so that the monitor can run continuously on battery power. For details on battery care, see section 3.

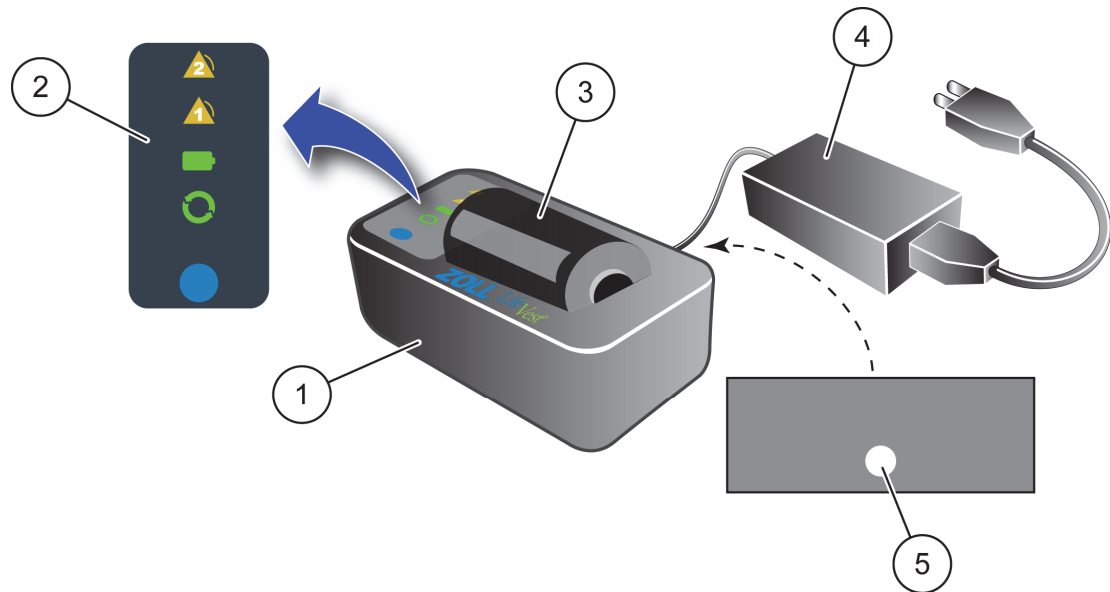
There are two types of chargers: One has a touchscreen and is described below. The other has indicators and is described on the next page. You will receive one or the other. The charger with touchscreen charges the battery and transmits data. The charger with indicator lights charges the battery, and the hotspot transmits data.

Charger with touchscreen



Item	Description
1 Touchscreen	Displays messages about device operation and allows patient to interact with device. For more on the charger touchscreen, see page 2-7.
2 Battery	Shown charging in charger while other battery is in monitor.
3 Antenna	Raise the antenna for best reception for transmitting data.
4 Power supply	Plugs into a standard power outlet to provide power to the charger. Manufacturer: SL Power Part Number: CENB1060A1849N02
5 Power supply connector	Connects the power supply to the charger.
6 Phone jacks	Connects the charger to a phone line. Only use if instructed by ZOLL.
7 USB connector	Do not use. Do not connect anything to this connector.
8 Ethernet connection	Do not use. Do not connect anything to this connector.

Charger with indicator lights



Item	Description
1 Charger base	Accepts the battery for recharging.
2 Indicator lights	Show the status of the charger. For the details on charger operation, see section 3.
3 Battery	Shown charging in the charger while the other battery is in the monitor.
4 Power supply	Plugs into a standard power outlet to provide power to the charger. Manufacturer: Delta Electronics, Inc. Part number: MDS-060BAS19A Or Manufacturer: EDAC (Wall Industries, Inc.) Part number: DTEM10682P-19-ZL
5 Power supply connector	Connects the power supply to the charger.

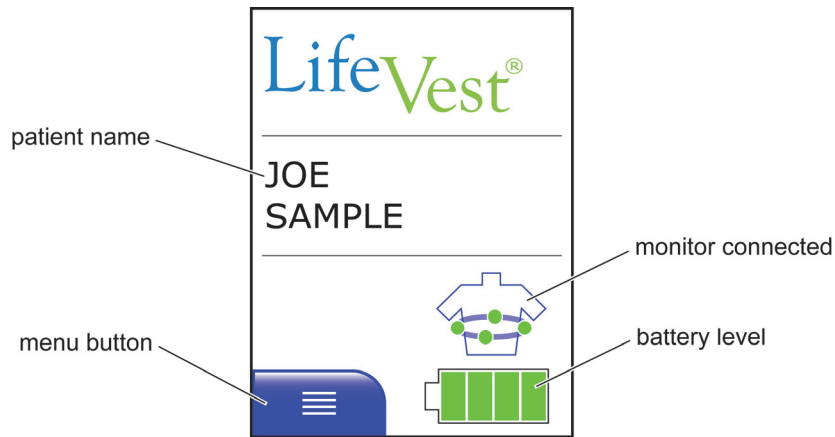
Monitor touchscreen


Shown below is an example of the monitor screen during normal monitoring.

Not all of the symbols, controls, and indicators are shown in this example. Some symbols are shown only at certain times.

As situations change, the screen will change to advise you and suggest an action to take. Screens that require you to take some action will have a help screen associated with them. For more on help screens, see page 2-8.

For a complete description of how to use the touchscreen in the daily use of the LifeVest WCD, see section 3.



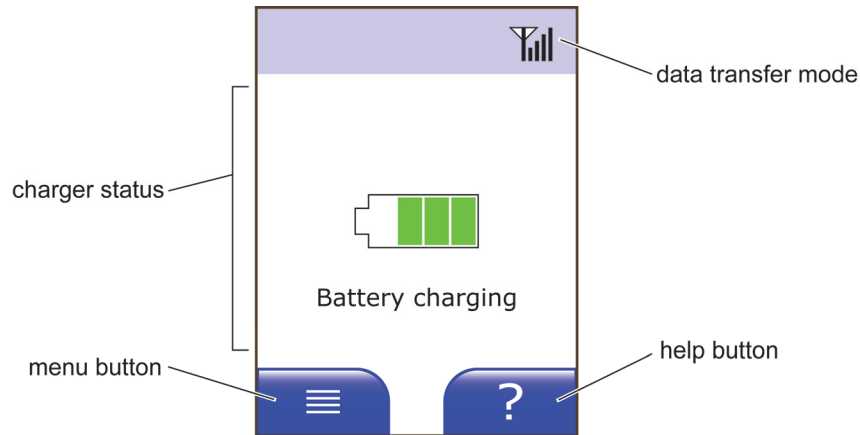
Item	What it means and how to use it
Patient name	Displays your name so you know this device was programmed for you.
Menu button	Tap to display the patient menu, where you can select various options. See details in section 3.
Monitor connected	Shows that the monitor is connected to the patient and is in normal monitoring mode. <div style="text-align: center;">  </div> If you see this symbol instead of the monitor connected symbol, the electrode belt is not connected. See details in section 3.
Battery level	Shows amount of charge remaining in battery. Also shows when the battery is discharged or is defective. See details in section 3.





Charger touchscreen

Shown below is an example of what you might see on the charger screen during normal use.


Not all of the symbols, controls, and indicators are shown in this example. Some symbols are shown only at certain times.

For a complete description of how to use the touchscreen in the daily use of the LifeVest WCD, see section 3.

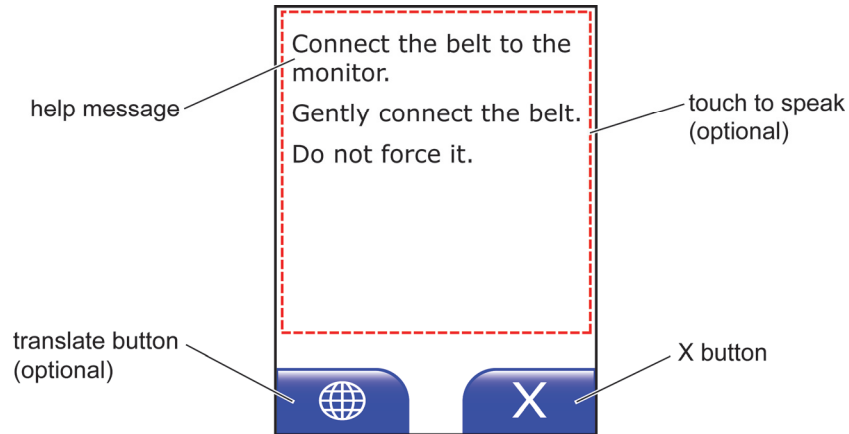


Item	What it means and how to use it
Data transfer mode	Shows how data will be transmitted to your health care provider. You will see one of these symbols: <ul style="list-style-type: none">  LifeVest WCD is set up for a wireless connection. The number of bars indicates the signal strength.  LifeVest WCD is set up for a wireless connection, but there is no signal. Try relocating the charger to improve the signal. If you continue to see this symbol, call ZOLL.  Charger communication may not be functioning properly. Charger can still be used to charge battery. Call ZOLL.  LifeVest WCD is set up for a land line phone.
Charger status	Shows what is going on with the charger. If a battery is inserted into the charger, the battery status is shown here. If there is no battery inserted, you'll get a message telling you to insert the battery.
Menu button	Tap to display the menu where you can select various options. During normal operation, you can ignore this button.
Help button	Tap for help related to the charger status being displayed.

Help screens

If you press a help button  on the monitor or charger, you'll get a help screen.

Shown below is an example of a help screen.

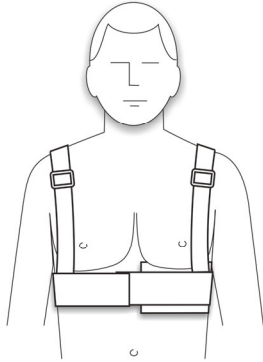


Item	What it means and how to use it
Help message	Brief message telling you what to do based on the present condition.
Translate button	Tap to see the help message in the secondary language. When you leave the screen, the display returns to the primary language. This button appears only if a secondary language has been programmed.
Touch to speak	If the speak option is enabled, touch the message area of the screen to hear the help message. The message will be spoken in the language displayed. The area to press is shown by the dashed line in the example above; the dashed line will not be visible on screen. To enable this feature, see section 3.
X button	Tap to close the screen.

3: Using the LifeVest® WCD system

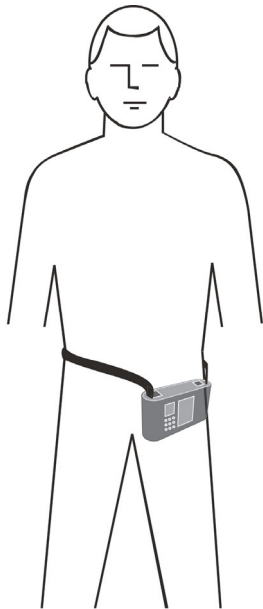
Daily routine

This is an overview of the steps involved in the daily use of the LifeVest WCD. Some details are found elsewhere in this manual.

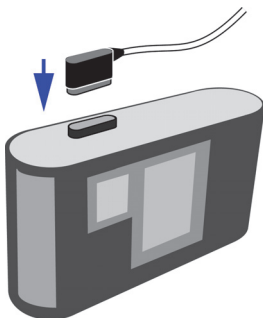
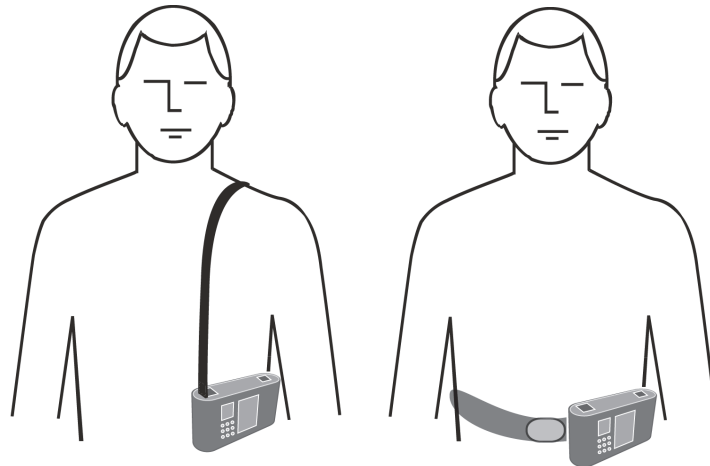


- 1 Wear the assembled electrode belt and garment.

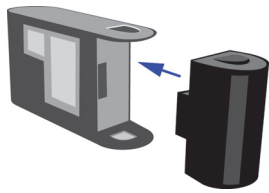
For details about assembling and putting on the electrode belt and garment, see section 4.



- 2 Wear the monitor in its holster. The holster strap is adjustable to give you several options for comfortably wearing the system. There is also a belt clip on the back of the holster.



- 3 Connect electrode belt.



- 4 Put a fully-charged battery into the monitor and follow the normal startup routine. See page 3-3.

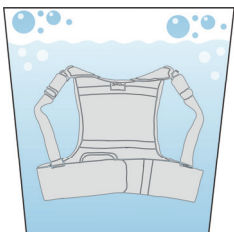
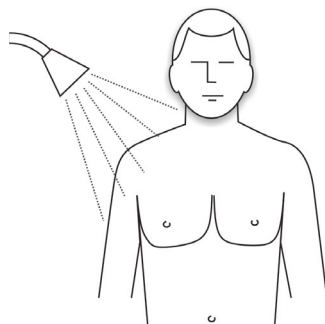
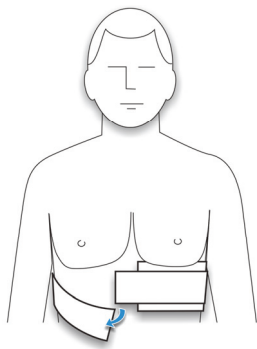


- 5 Change and recharge the battery every 24 hours. See page 3-6.



- 6 Respond to any alarms. See section 5.

- 7 Completely remove the LifeVest WCD when you shower or bathe. See section 4.

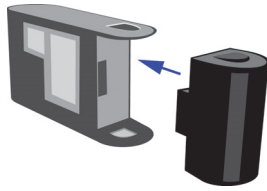


- 8 Change and wash the garment every 1 or 2 days.

Wash only the garment. Do not wash the electrode belt, monitor, or any other accessories.

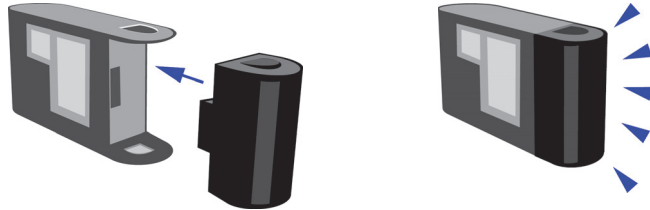
Follow the instructions in section 4 for laundering the garment.

Normal startup routine

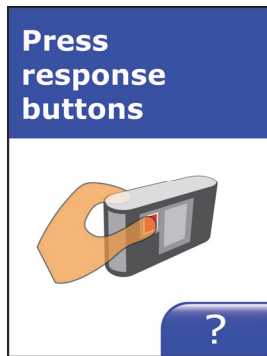


1 Put a fully-charged battery into the monitor. Make sure the battery is completely inserted.

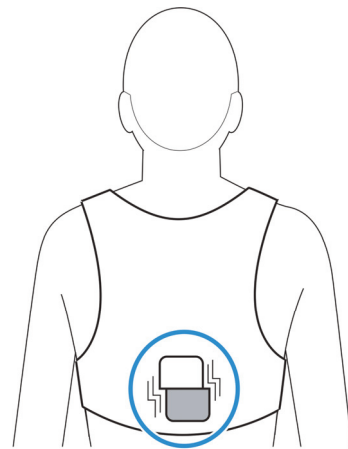
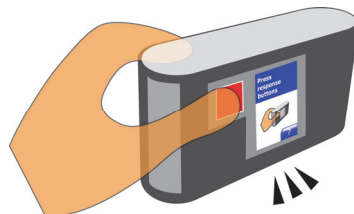
- Push the battery firmly into the monitor until it clicks.
- Make sure the battery is fully inserted and latched into the monitor.



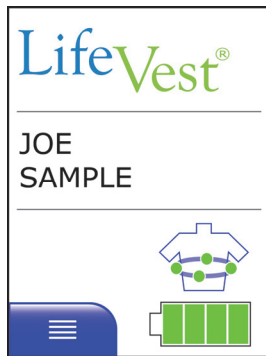
2 Startup screens appear.



3 When you hear the gong and feel the vibration in your back, press the response buttons.



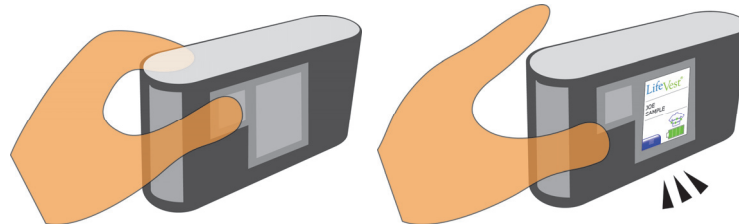
If you do not hear the gong or feel the vibration within 30 seconds, remove the battery. Reinsert the battery and try again. If the monitor still does not operate normally, contact ZOLL.



- 4 The monitor displays your name and battery level.

Make sure your name appears on the monitor. If your name does not appear, contact ZOLL immediately.

During normal monitoring, most of the time the LifeVest monitor displays a dark screen. To see the display, press and release the response buttons.

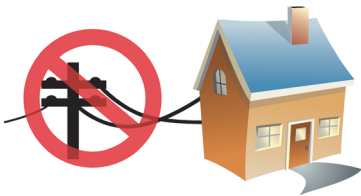


Taking care of the batteries

What you need to know

- There are two types of chargers: One with a touchscreen, and one with indicator lights. You will receive one or the other. Battery care and charging is the same with either type of charger.
- You have two batteries so you can use one while charging the other. Change and recharge batteries every 24 hours.
- Recharging the battery can take up to 16 hours.
- Place the charger in a safe place where you can leave it plugged in. Keep the second battery in the charger while you use the monitor.
- The battery and charger may get warm. This is normal. Place the charger in a well ventilated place.
- Use only the batteries, charger, and power supply provided with the LifeVest system.
- Remove the battery from the monitor whenever you're not wearing the device. For example, when you remove the device to take a shower, remove the battery first, to ensure the device is not active when you are not wearing it.

In the event of a power outage



If power is interrupted for any reason, you need to take steps to keep your batteries charged.

- Notify your electric company to let them know you have a medical device that needs power. Determine if they believe the power will be out for 24 hours or more. If so, seek alternatives for powering the batteries, such as a neighbor, friend, or family member not affected by the outage.
- Notify your local emergency medical services and see if they can help.
- Locate a source of backup power if possible, such as a generator. Plug the battery charger into the backup power and charge the spare battery continuously. Change the batteries every 24 hours.

If help is not available, and you expect power to be out for more than 24 hours, contact ZOLL immediately to have spare batteries sent to you.

When the power is restored, plug in your charger as normal. Continue charging and changing batteries every 24 hours.

Change and recharge batteries daily

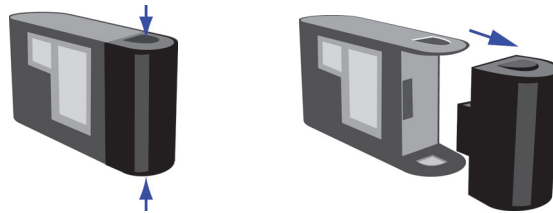


WARNING

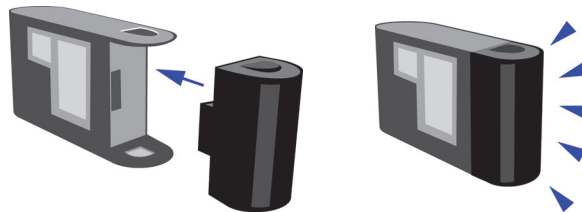
Make sure the battery is fully inserted and latched into the monitor. If the battery is not fully inserted and latched, it may disconnect and you will not be protected.

While you are wearing the device, change and recharge the batteries every 24 hours. Leave the electrode belt connected during this procedure.

- 1 Remove the existing battery from the monitor.
 - You can leave the monitor in the holster with the electrode belt connected.
 - Open the holster end flap, then push the battery latches and slide the battery out of the monitor.



- 2 Remove the fully-charged battery from the charger and put it into the monitor.
 - Push the battery firmly into the monitor until it clicks.
 - Make sure the battery is fully inserted and latched into the monitor.
 - Close the holster end flap.
 - Make sure the device follows the startup routine on page 3-3.



- 3 Put the used battery from the monitor into the battery charger.
 - Push the battery in firmly.
 - Read the battery status on the charger. Battery should be charging, testing or charged.
- 4 If you ever need to unplug the charger, unplug it from the wall outlet first. Then, if necessary, unplug the power supply from the back of the charger.

Charger setup and use, charger with touchscreen



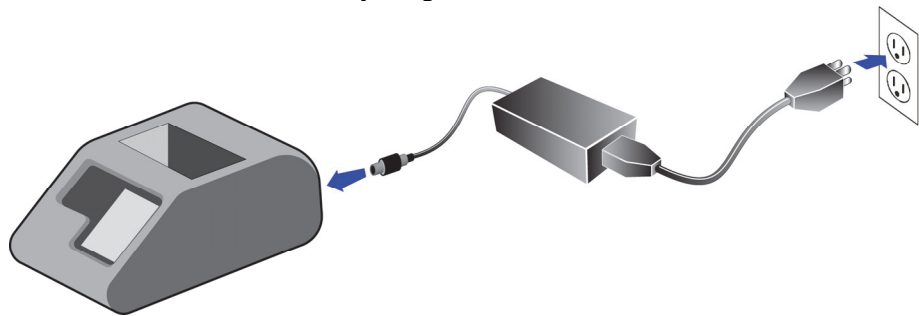
WARNING

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

There are two types of chargers: One with a touchscreen, and one with indicator lights. You will receive one or the other. If you have the charger with a touchscreen, continue below. If you have the charger with the indicator lights, see page 3-13.

Initial setup

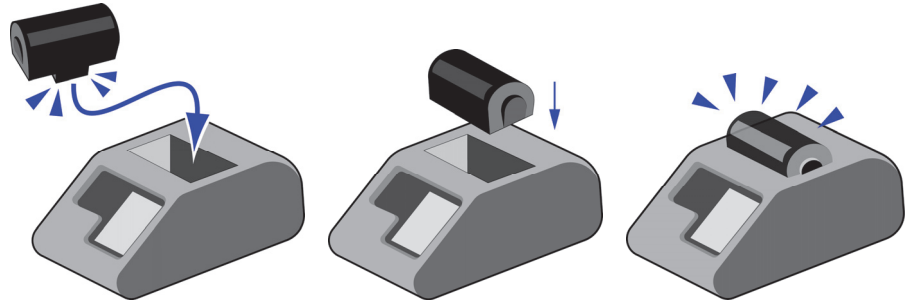
- 1 Place the charger in the room where you sleep, on a nightstand or end table, near a power outlet.
 - Place the charger so you can easily get to the top of the unit to insert and remove the battery.
 - The charger can be placed anywhere in the house, but we recommend the room where you sleep so it's convenient to use every day.
- 2 Plug the power supply into the back of the charger, then plug the power supply into a power outlet. Make sure the outlet stays on all the time and is not controlled by a light switch.



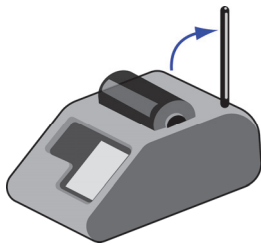
CAUTION: If the charger or power supply makes unusual noises, sparking, starts to smoke, or emits a burning smell, unplug it immediately from the wall outlet. The only way to completely remove power is by unplugging the AC power plug from the wall outlet. Place the charger so that the power plug is accessible in case you need to unplug it.

Note: Use only the power supply provided with the LifeVest system.

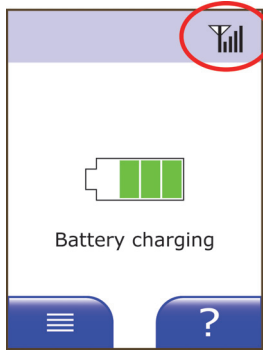
- 3 Insert the spare battery into the charger.
 - Orient the battery with its connector facing the rear of the charger.
 - Push the battery in firmly.



- On the charger's screen, read the battery status. Battery should be charging, charged, or testing.
- For details about reading the battery status on the charger, see page 3-11.



- 4 Raise the antenna on the charger.



5 Look for a symbol along the top of the charger's display:



- Charger is set up for the cellular network.
 - Signal strength is shown by the number of bars. The more bars, the better.
 - If you have at least one bar, charger setup is finished.
-



- You may see this signal at power-up until the charger finds a signal. That is normal.
 - If you get this symbol all the time, charger is not getting a signal.
 - Try relocating the charger to another part of the house in order to get a signal.
 - If the problem continues, call ZOLL.
-



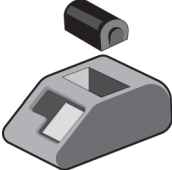



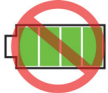

- Charger communication may not be functioning properly.
 - Charger can still be used to charge battery.
 - Call ZOLL.
-



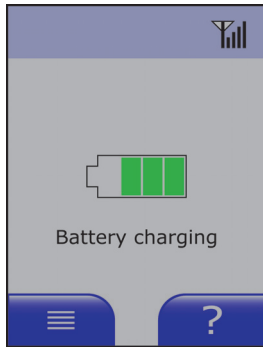
- Charger is set up for a land line phone connection.
 - Charger cannot be used in this mode.
 - If you see this symbol, call ZOLL.
-

How to read the charger touchscreen

If your charger has a touchscreen, the screen shows the status of the battery and charger. When the room gets dark, the charger display gets dim; see next page.

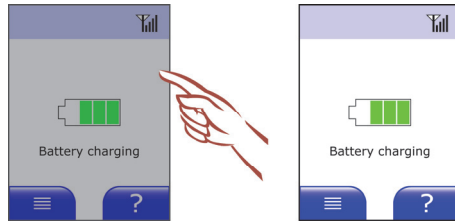
Screen shows	What it means	What to do
 <p>Insert battery</p>	There is no battery in the charger	Insert the battery into the charger. Leave one battery in the charger while you use the other battery.
 <p>Battery charging</p>	Battery is charging	Let the battery charge. This can take up to 4 hours.
 <p>Battery charged</p>	Battery is fully charged, ready for use in monitor	Leave battery in the charger until ready to exchange battery.
 <p>Battery testing</p>	Battery is being tested	<p>Let the test run, which can take up to 12 hours. Test verifies battery function as part of normal routine. After test, battery will be charged, which can take another 4 hours. So the whole process can take up to 16 hours.</p> <p>If you need to use the battery sooner, remove battery from charger as soon as you see this on the screen. Then put the battery back into the charger to skip the test and charge the battery. The test will be performed the next time the battery is plugged into the charger.</p>
 <p>Battery problem</p>	Battery has a problem, but still might hold a charge	<p>The battery may charge, but will take longer than normal. Battery can be used, but should be replaced. Call ZOLL for a replacement battery.</p>
 <p>Charger problem</p>	Charger has a problem, and cannot charge the battery.	<p>Do not leave a battery in the charger. Battery is not being charged.</p> <p>If the problem continues, call ZOLL.</p>

Charger display dims in the dark

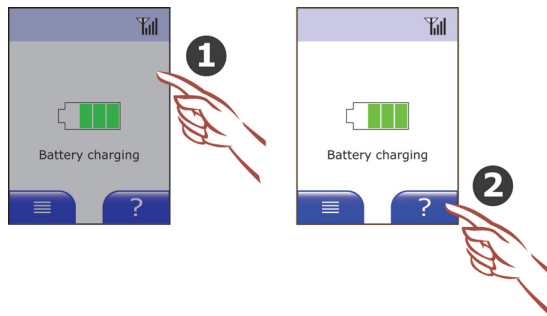


When the room gets dark, the charger display gets dim.

To return the display to full brightness, either turn on the light in the room or tap the screen.



If you want to press a button and the screen is dim, first tap the screen to make it bright. Then tap the button.



Charger setup and use, charger with indicator lights



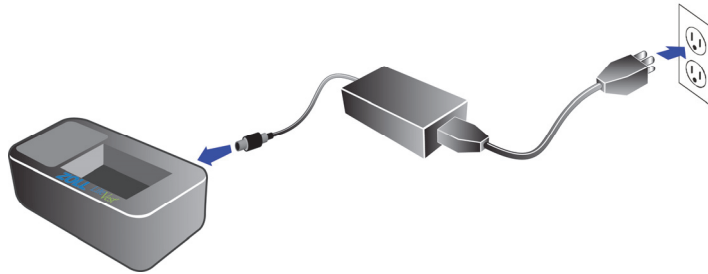
WARNING

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

There are two types of chargers: One with a touchscreen, and one with indicator lights. You will receive one or the other. If you have the one with the indicator lights, continue below. If you have the one with a touchscreen, see page 3-8.

Initial setup

- 1 Place the charger in the room where you sleep, on a nightstand or end table, near a power outlet.
 - Place the charger so you can easily get to the top of the unit to insert and remove the battery.
 - The charger can be placed anywhere in the house, but we recommend the room where you sleep so it's convenient to use every day.
- 2 Plug the power supply into the back of the charger, then plug it into a standard power outlet. Make sure the outlet stays on all the time, and is not controlled by a light switch.



CAUTION: If the charger or power supply makes unusual noises, sparking, starts to smoke, or emits a burning smell, unplug it immediately from the wall outlet. The only way to completely remove power is by unplugging the AC power plug from the wall outlet. Place the charger so that the power plug is accessible in case you need to unplug it.







Note: Use only the power supply provided with the LifeVest system.



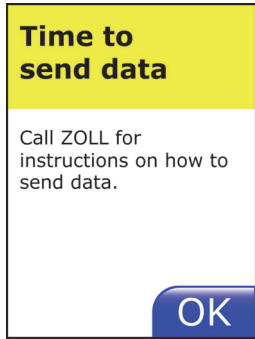
- 3 Insert the battery into the charger.
 - Orient the battery with its connector facing the front of the charger.
 - Push the battery in firmly.
 - Read the battery status on the charger. Battery should be charging, testing, or charged.
 - For details on how to read the charger indicator lights, see next page.

How to read the charger indicator lights

If your charger has indicator lights, those indicators show the status of the battery and charger.

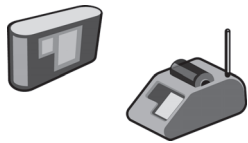
Indicator	What it means	What to do
 Yellow, blinking, with audible alarm	Alarm condition 2. Charger has a problem, and cannot charge the battery.	Call ZOLL immediately. Battery is not being charged. This condition will be accompanied by three beeps every 15 seconds.
 Yellow, lit solid, with audible alarm	Alarm condition 1. Battery has a problem, but still might hold a charge.	Call ZOLL. Battery has a problem, and may charge, but will take longer than normal. Battery can be used, but should be replaced. This condition will be accompanied by two beeps at the start of the alarm.
 Green, lit solid	Battery is fully charged, ready for use in monitor.	Leave the battery in the charger until you are ready to exchange the battery.
 Green, blinking	Battery is charging.	Leave the battery in the charger. Charging typically takes up to 4 hours.
 Blue, lit solid	Power is being applied to the charger.	Make sure this indicator lights when you plug in the charger. This light will continue to stay lit when the other indicators light. To remove power from the charger, unplug it from the wall outlet. There is no power switch.
 Three icons are blue, lit solid	Battery is being tested.	Let test run. Test verifies battery function as part of normal routine. Testing can take up to 14 hours. After the test, the battery will charge as normal. This whole process, of testing and charging, can take up to 18 hours. If you need to use the battery sooner, remove the battery from the charger as soon as the indicator lights blue, then reinstall the battery into the charger. It will skip the testing and go right to charging, for a shorter cycle time.

Sending data manually

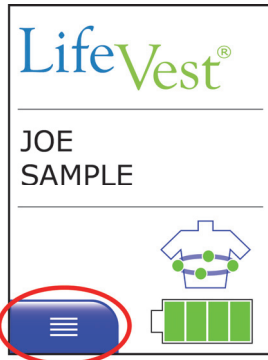



If you get this message, you need to send data manually.

Call ZOLL, then follow along with this procedure.

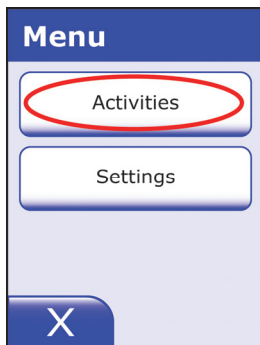
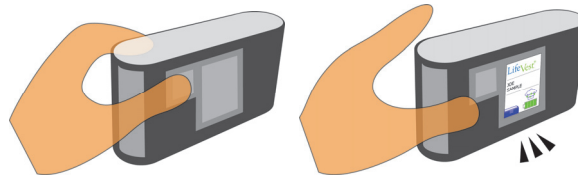


1 Go into the same room where the charger is located.



2 On the monitor, tap the menu button .

If the screen is dark, press and release the response buttons to activate the screen.




3 Tap **Activities**.





4 Tap **Send data**.




5 On the monitor's display, look at the symbols  above the charger antenna.

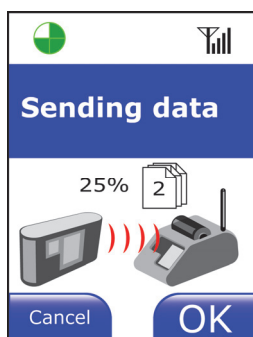
- Signal strength is shown by the number of segments. The more segments, the better.
- To get a stronger signal, try moving closer to the charger.

• You may see this symbol  while the device seeks a connection. This is normal.

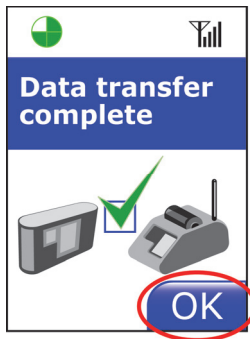
• If this symbol  does not go away after several minutes, you cannot send data. Press **Cancel** and try again later.



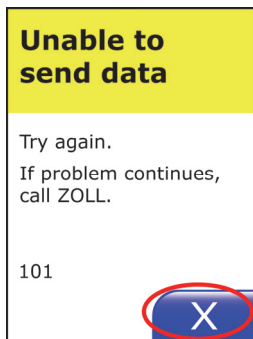
6 When you see at least one green segment on the signal strength symbol  tap **OK**.



7 The monitor shows that data is being sent. Stay near the charger until the transfer is complete.



8 The monitor shows when data transfer is complete. Tap **OK**.



If the monitor is unable to send data, you'll get this message.

Tap **X** and try again.

If you continue to have a problem sending data, you will get additional instructions from ZOLL.

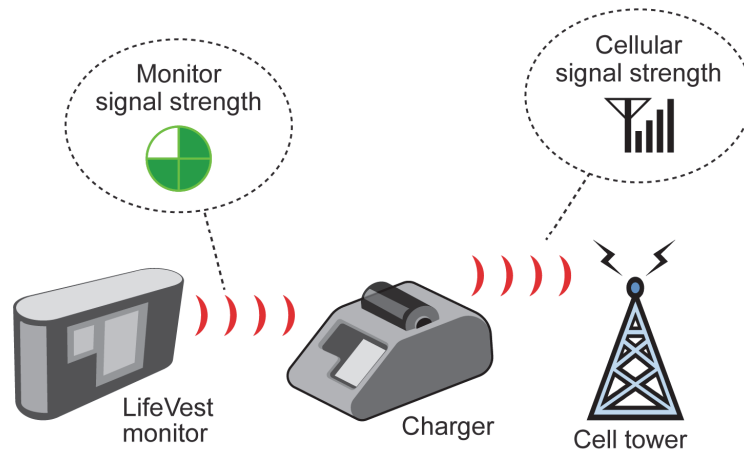
How to read the signal strength symbols

Data gets sent from the monitor to the charger or the hotspot then to the cell tower.

Symbols on the devices show the signal strength. One symbol shows the strength of the monitor signal, the other shows the strength of the cellular signal.



Depending on which type of charger you have, you may see these symbols on the charger or monitor.

These symbols are explained on the next two pages.






Monitor signal strength symbol

This symbol shows the strength of the signal from the monitor. Depending on which type of charger you have, you may see this symbol on the charger or monitor.

Symbol	What it means	What to do
	<p>Monitor is connected to the charger.</p> <p>Signal strength is shown by the number of green segments. The more segments, the better.</p>	<p>To get a stronger signal, try moving the monitor closer to the charger.</p> <p>If you have at least one green segment, data can be sent.</p>
	<p>The monitor is not connected to the charger.</p> <p>You may see this signal while the monitor finds a signal. That is normal.</p>	<p>If you get this symbol all the time, monitor is not connected.</p> <p>Try relocating the monitor and charger to another part of the house.</p> <p>Monitor and charger can still be used normally.</p> <p>If you continue to see this symbol, call ZOLL.</p>

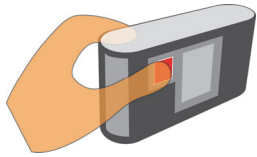
Cellular signal strength symbol

This symbol shows the strength of the signal from the charger to the cellular network. Depending on which type of charger you have, you may see this symbol on the charger or monitor.

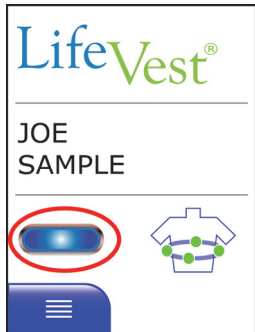
Symbol	What it means	What to do
	<p>The device is connected to a cellular network.</p> <p>Signal strength is shown by the number of bars. The more bars, the better.</p>	<p>To get a stronger signal, try moving the charger to a different part of the house, possibly to a higher location or near a window.</p> <p>If you have at least one bar, data can be sent.</p>
	<p>The device is not connected to a cellular network.</p> <p>You may see this signal until the device finds a signal. That is normal.</p>	<p>If you get this symbol all the time, device is not getting a signal.</p> <p>Try relocating the charger to another part of the house in order to get a signal.</p> <p>Monitor and charger can still be used normally.</p> <p>If you continue to see this symbol, call ZOLL.</p>
 <p>(only on some chargers)</p>	<p>Device is set up for a land line phone connection or is connected to a secondary device.</p> <p>Charger functions normally, but uses a land line to transfer data.</p>	<p>In this mode, a phone line can be plugged into the back of the charger or the LifeVest WCD may be connected to a secondary device.</p>


Recording your heart rhythm

At times, you may want to record your heart rhythm for your doctor to review. Follow this procedure to record your heart rhythm.



- 1 Hold the response buttons for 3 seconds.



- 2 Release response buttons when you see the recording indicator  and hear a single gong.

Speak options

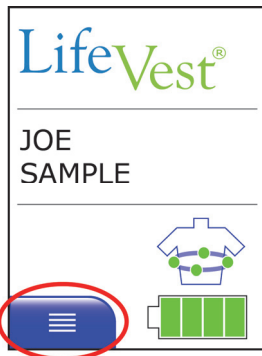
There are three speak options associated with the help screens:


- Speak when you tap the text area of the help screen.
- Speak with every help screen.
- Don't speak with the help screens.

You can also change the volume of these messages. This does not affect the volume of the treatment prompts, which are always delivered at full volume.

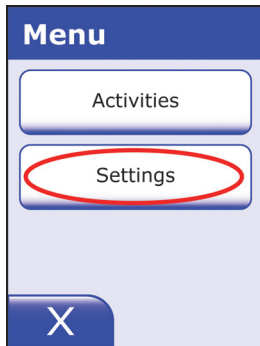
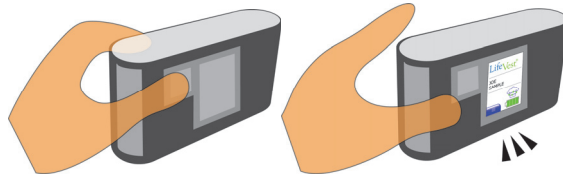
Screens speak in the language displayed.

Follow this procedure to change the speak mode or volume.

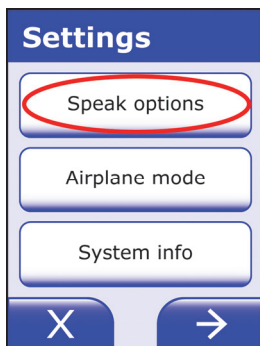


- 1 On the monitor, tap the menu button .

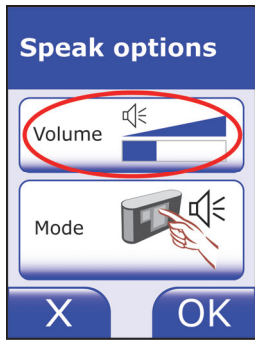
If the screen is dark, press and release the response buttons to activate the screen.



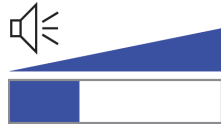
- 2 Tap **Settings**.



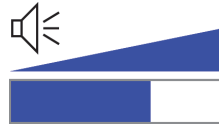
- 3 Tap **Speak options**.



4 Tap **Volume** until you hear the desired volume.



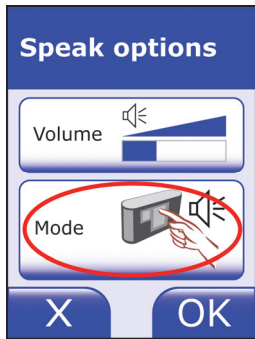
Volume level 1.



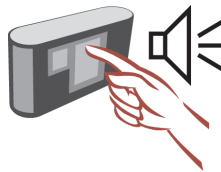
Volume level 2.



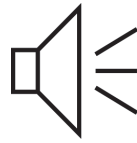
Volume level 3.



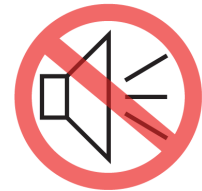
5 Tap **Mode** until you see the speak mode you want.



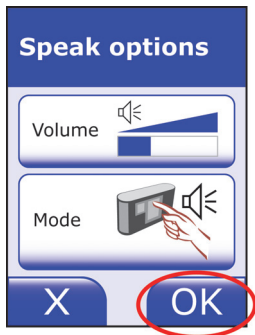
LifeVest monitor speaks when you tap the text area of the screen.



LifeVest monitor speaks with every help screen. You don't have to tap it.



LifeVest monitor does not speak.



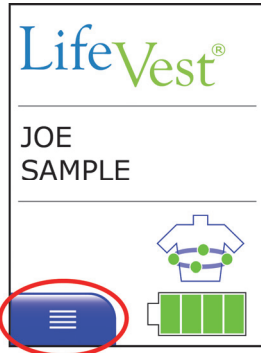
6 When you are finished with the speak options, tap **OK**.


To close the screen without making any changes, tap **X**.

Airplane mode

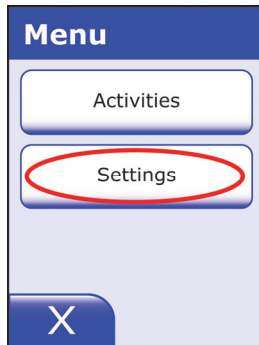
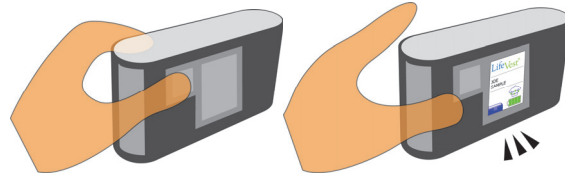
Airplane mode disables the LifeVest WCD from wirelessly transmitting data to avoid interfering with aircraft operation and other electrical equipment.

Follow this procedure to set the LifeVest WCD for airplane mode.

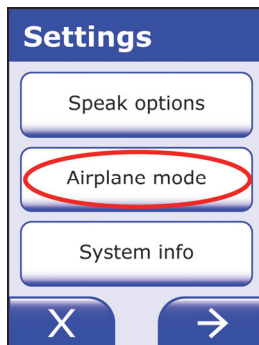


- 1 On the monitor, tap the menu button .

If the screen is dark, press and release the response buttons to activate the screen.



- 2 Tap **Settings**.



- 3 Tap **Airplane mode**.

When the airplane symbol appears on the button, airplane mode is selected. Each time you tap **Airplane mode**, it toggles between on and off.

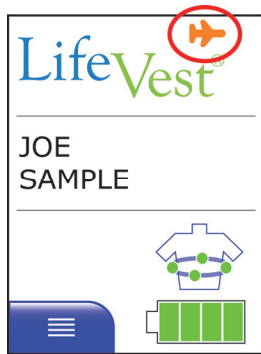


Airplane mode **ON**. No signals are transmitted from LifeVest WCD.



Airplane mode **OFF**. This is the normal position.

Tap **X** to save your changes and close this screen.



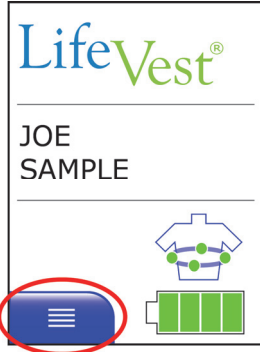
- 4 On the home screen, if you see the airplane symbol in the upper right corner, the LifeVest WCD is in airplane mode.


When you see the airplane symbol, no signals will be transmitted from LifeVest WCD.

The monitor will go out of airplane mode the next time you change the battery, or if you attempt to manually send data.

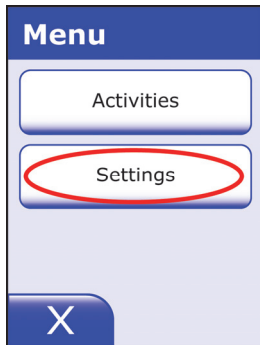
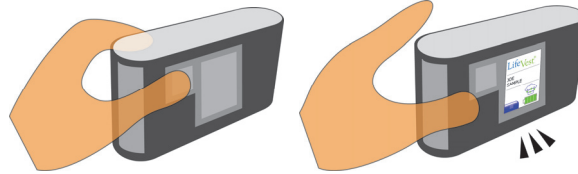
System information screens

If you ever call for service or support, you may be asked for information about your LifeVest WCD. You may be instructed to go into the system information screens.



- 1 On the monitor, tap the menu button .

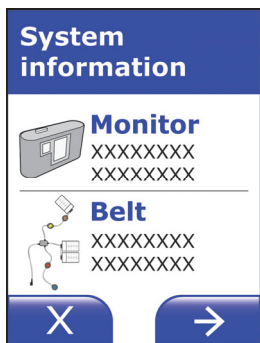
If the screen is dark, press and release the response buttons to activate the screen.




- 2 Tap **Settings**.



- 3 Tap **System info**.



- 4 System information will be shown.

- To go from one screen to another, tap the next page  button.
- To close either screen, tap **X**.

Support mode

Introduction

This feature lets ZOLL update your LifeVest® 4000 while you remain at home.

It's a simple process that should take just a few minutes.

If your LifeVest WCD needs to be updated

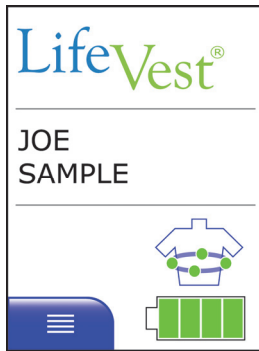
If your LifeVest WCD needs to be updated, here's what will happen and what we need you to do:

- ZOLL will call and explain that your LifeVest WCD needs to be updated.
- You will be talked through a simple updating process.
- You are to remain on the phone with ZOLL until this entire process has been completed.
- You need to continue to wear the device during this process.
- You will interact with the screen, pressing buttons and reading back what the display says.
- If you are unable or uncomfortable doing this, have someone with you who can talk with ZOLL and interact with the LifeVest device.
- Follow along with the procedure starting on the next page.

To enter support mode

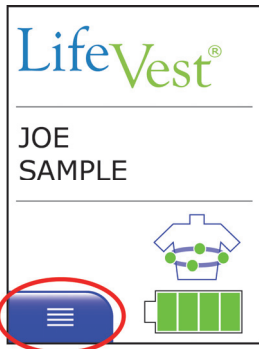
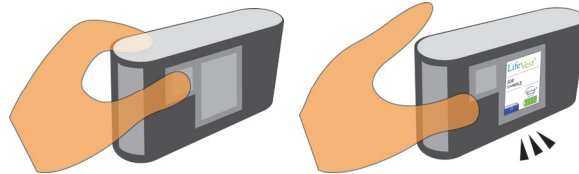
If you are to enter support mode:

- You will be contacted by ZOLL and they will guide you through this process.
- Refer to these instructions to follow along as you remain in contact with ZOLL.
- As you respond to each step, tell ZOLL what you see on the screen.

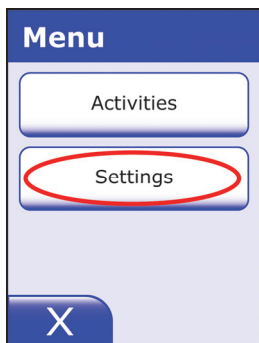


- 1 During normal monitoring, the LifeVest screen should display the “home” screen, as shown at left.

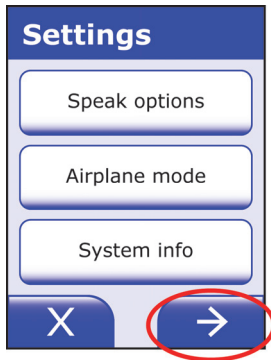
If the screen is dark, press and release the response buttons to activate the screen.




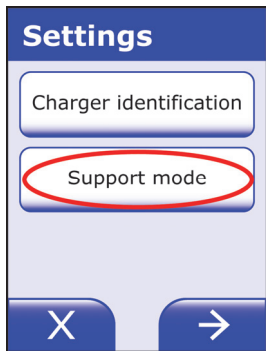
- 2 Tap the menu button .



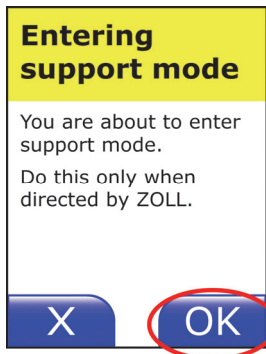
- 3 Tap **Settings**.



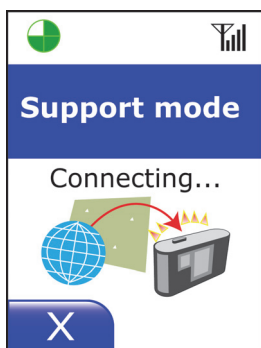
4 Tap the next page button .



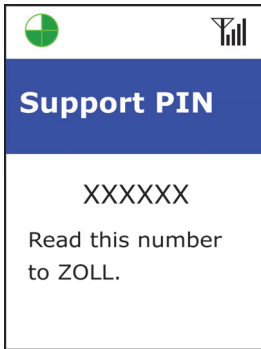
5 Tap **Support mode**.



6 Tap **OK**.

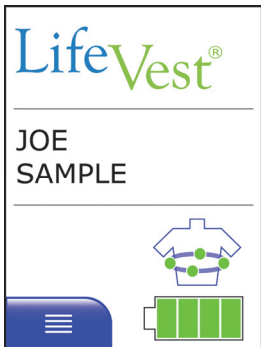
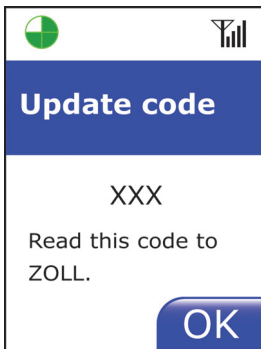


7 You'll see the support mode screen for a few moments.



8 You'll then see either a support PIN or an update code.

Tell ZOLL which screen you see, then read the number to ZOLL and wait for further instructions.



9 When ZOLL tells you that the update has been completed, tap **OK**, then tap **X** until you return to the home screen.

Periodically clean and inspect the system

How to clean the garment

Specific details about laundering the garment are in section 4.

How to clean the non-washable items

Unplug the battery charger and disconnect the power cord before cleaning.

Non-washable items such as the battery, charger, cables, ECG electrodes, and therapy pads may be cleaned using a soft cloth sparingly dampened with an all-purpose cleaner or equivalent cleaning solution. Wipe off any remaining cleaning solution before putting the device back on.

When you clean these items, keep in mind:

- Don't apply liquids directly to any of the non-washable items, as they contain electronic components that can be damaged.
- Don't attempt to clean any electrical contacts or connectors.
- Do not put fingers or foreign objects into any connectors or openings. Doing so may result in electrical shock.
- Don't use any cleaning solution on the garment.

Inspection

Inspect your system periodically. If you should notice any of the following conditions, please notify ZOLL as soon as possible:

- Cracks in the housing of the monitor, battery, or charger.
- Cracks in the therapy pads.
- Tears in the garment or holster.
- Blue™ gel leaking from the therapy pads at any time other than when defibrillation is about to occur or has just occurred.

What family members need to know



WARNINGS

Only the patient should press the response buttons. The patient's ability to press the response buttons lets the device know whether or not the patient is conscious and is critical in deciding when to give the patient a shock. If anyone other than the patient holds the response buttons, needed therapy may not be delivered, possibly resulting in serious injury or death.

Do not touch the patient while a shock is being delivered. Anyone touching the patient during a treatment may be shocked.

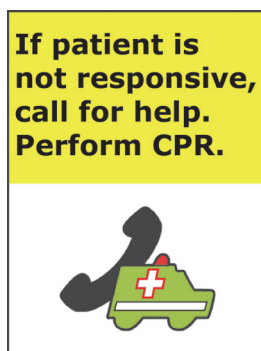
Do not remove the battery, do not disconnect the electrode belt from the monitor, and do not loosen the garment while the monitor is broadcasting alert sounds and/or voice prompts. If the battery is removed, the electrode belt disconnected from the monitor, or the garment is loosened, needed therapy may not be delivered, possibly resulting in serious injury or death. CPR can be performed as long as the monitor is not broadcasting alerts sounds and/or voice prompts. If external defibrillation is available, a decision can be made by a medical professional to remove the device and monitor/treat the patient with external equipment.

Information for family members

Since your family member or friend may be wearing the LifeVest device for a period of time, you may want to understand the daily routine involving the device, as well as warnings and cautions directed to the patient. In that case you should read this entire manual.

Anyone associated with the patient should be aware of the following information:

- If the LifeVest treatment does not revive the patient and the patient is unconscious, call for help and then start CPR.
- If the patient gets the alarm message shown below and the patient is unconscious, call for help and then start CPR. If the patient remains conscious, check the belt to make sure all electrodes are pressing against the patient's skin.



- A label on the front of the garment reminds medical personnel to open the garment before giving the patient conventional external defibrillation.
- Keep the LifeVest device out of the reach of children.
- The LifeVest WCD will direct a conscious patient to respond to messages and alerts. A patient who has lost consciousness due to their arrhythmia will be unable to respond, letting the device know it is time to deliver a treatment shock. The bystander should not respond to messages and alerts in place of the patient.

When you are finished with the device



Call ZOLL and arrange to return the LifeVest system.

Battery recycling



WARNING

Do not dispose of or incinerate the batteries. The batteries contain lithium ion and must be disposed of properly by ZOLL.

The lithium-ion batteries used with the LifeVest device are recyclable and should be returned to ZOLL.

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4: Assembling and putting on the garment

About this chapter

This chapter contains instructions for:

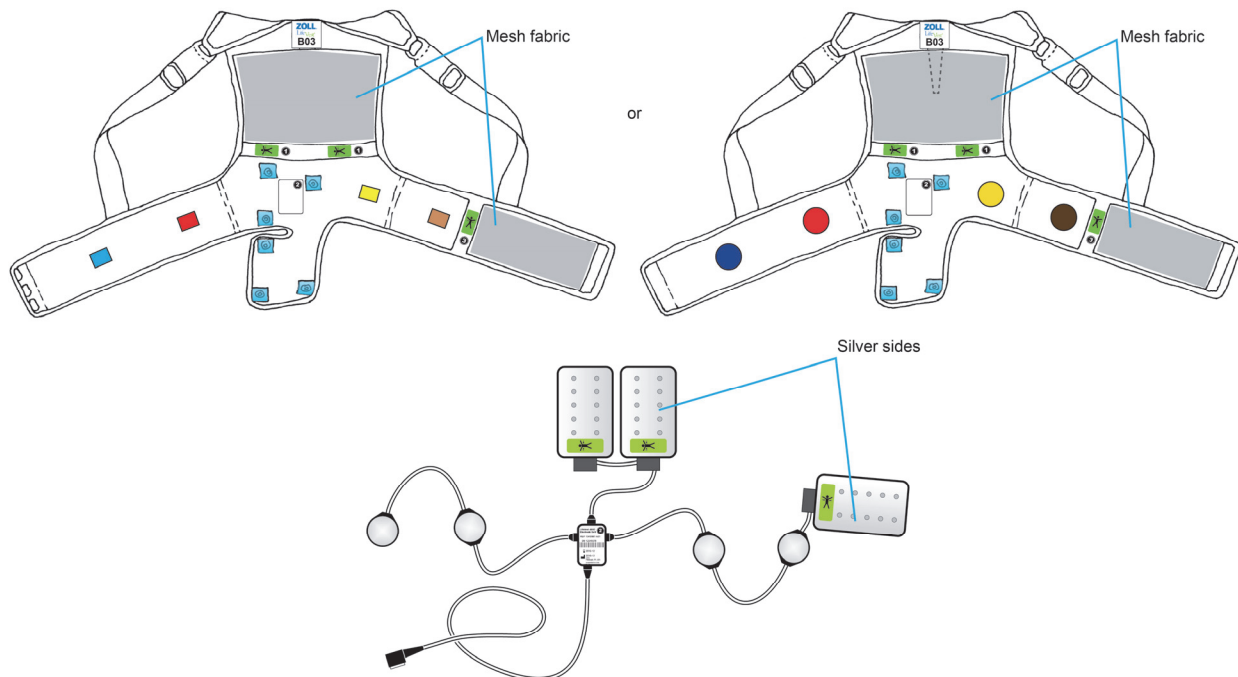
- Assembling the electrode belt to the garment
- Putting on the assembled electrode belt and garment
- Connecting and disconnecting the electrode belt
- Removing the garment when you shower or bathe
- Disassembling and laundering the garment

Assembling the electrode belt to garment

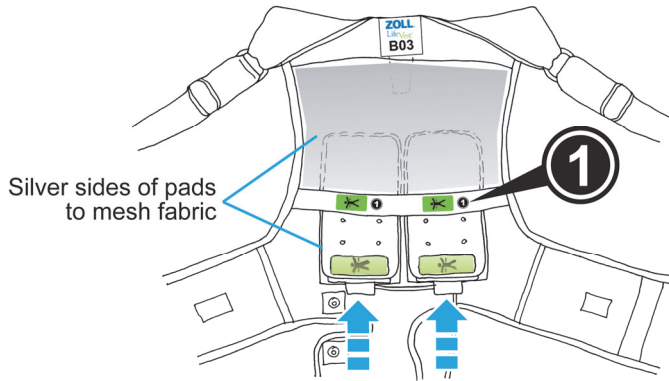
Your garment may be white or gray in color, depending on your region or country. The instructions for assembling the electrode belt and garment are the same.

Lay the electrode belt and garment on a flat surface as shown below.

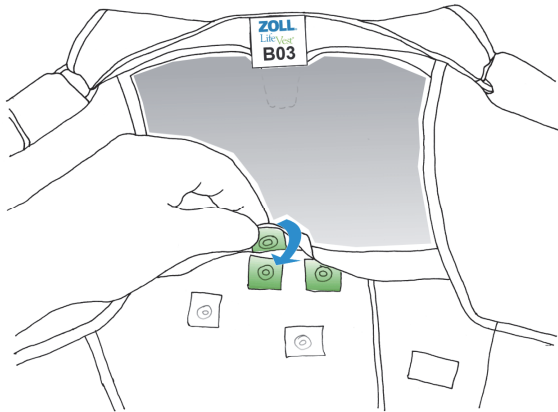
- Place the garment with the mesh fabric facing up.
- Place the electrode belt with the silver sides of the therapy pads facing up.



1 Insert the rear therapy pads into the garment's rear pockets.

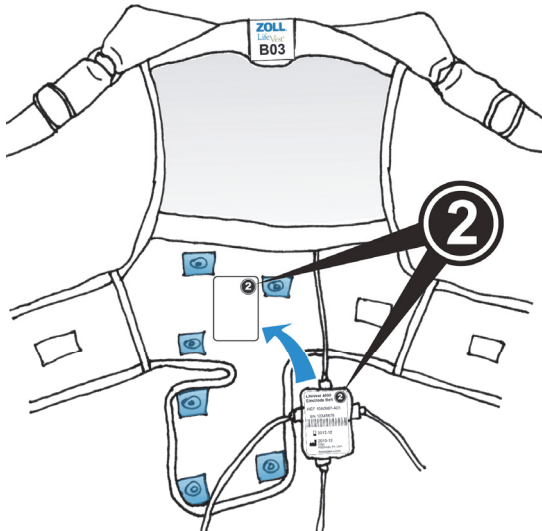


- The rear pockets are numbered 1.
- Find the pads numbered 1. Insert the pads with the silver sides of the pads facing the mesh fabric of the pockets. Confirm that the green stickers on the pads are facing up.

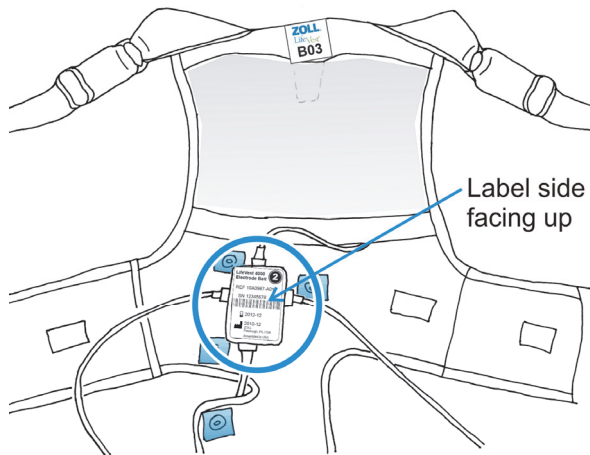


- Snap the green tabs to secure the pockets.
- Make sure the snaps are securely fastened.

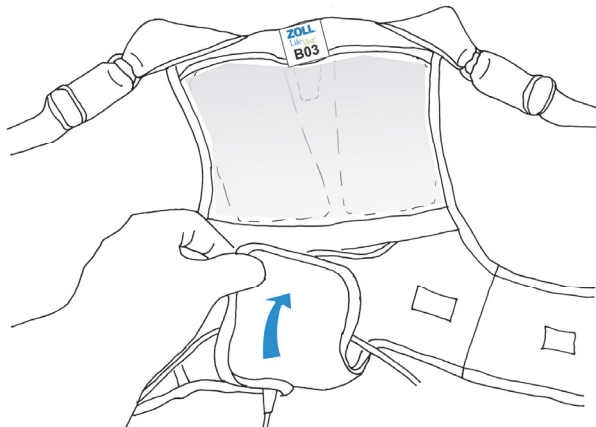
2 Position and secure the vibration box to the garment.



- The vibration box goes in the position numbered 2.

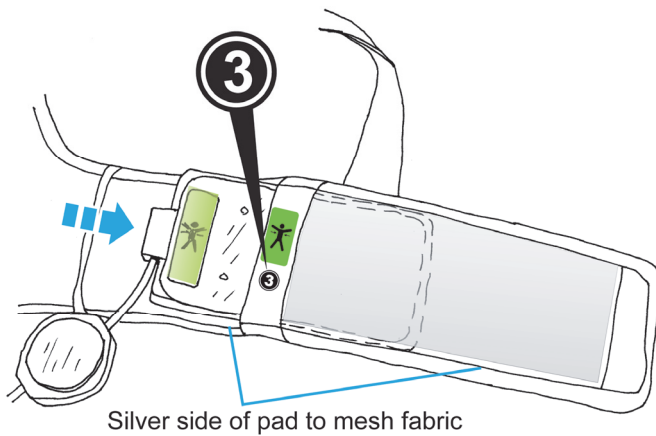


- Place the vibration box with the label side facing up.

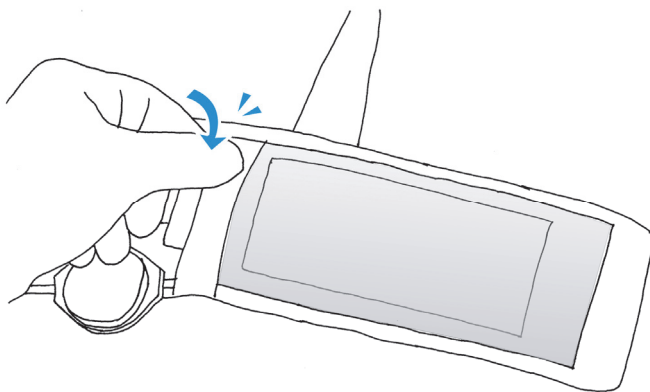


- Snap the flap over the vibration box to the blue tabs.
- Make sure all three snaps are securely fastened.

3 Insert the front therapy pad into the front pocket.

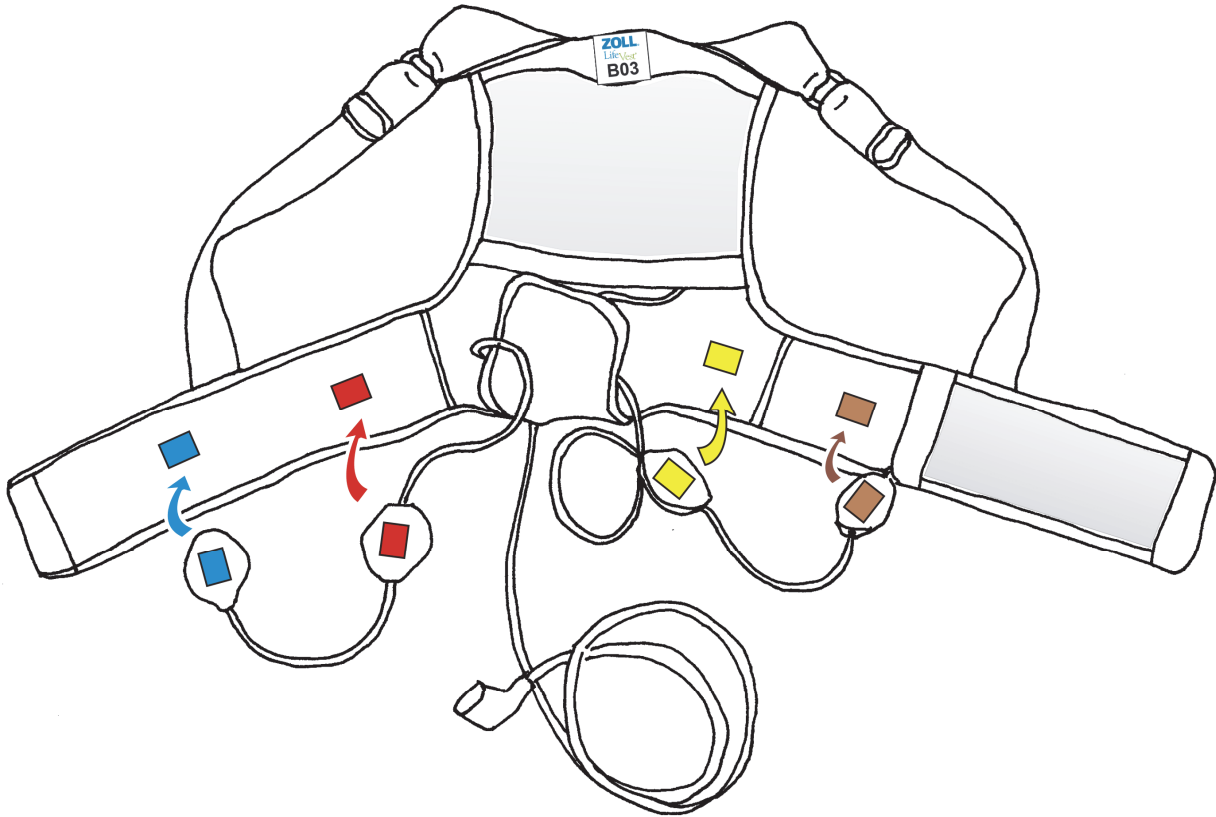


- The front pocket is numbered 3.
- Find the pad numbered 3. Insert the pad with the silver side of the pad facing the mesh fabric of the pocket. Confirm that the green sticker on the pad is facing up.



- After the therapy pad is fully inserted, snap the pocket closed.
- Make sure the snap is securely fastened.

- 4 Attach the ECG electrodes to the garment. Match the colors on the backs of the electrodes to the colors of the Velcro on the garment.



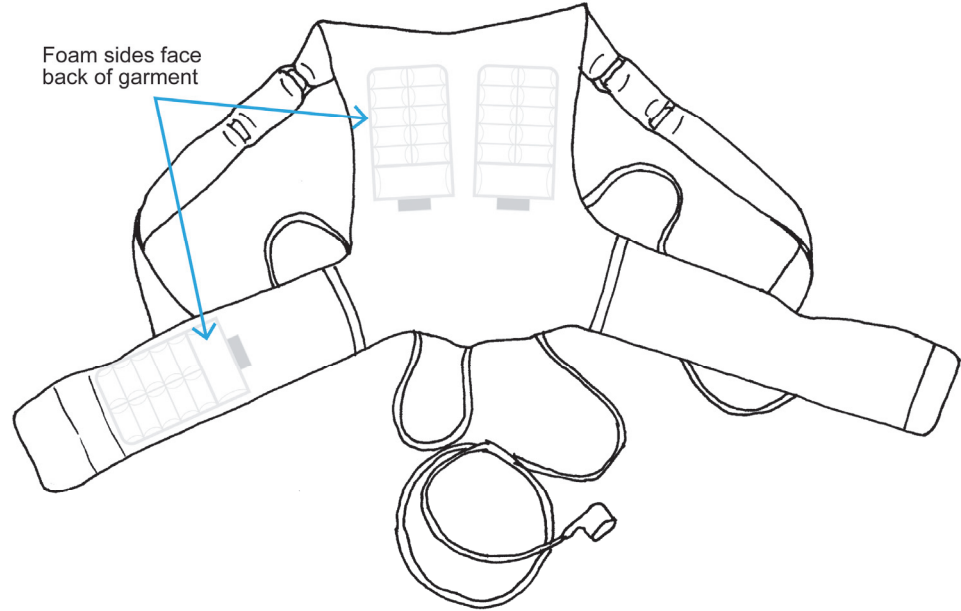
- 5 Make sure that you have properly assembled the electrode belt to the garment. See next page.
- 6 Then put on the assembled garment. See page 4-7.

Assembled electrode belt and garment

The assembled electrode belt and garment should look like the following figures.

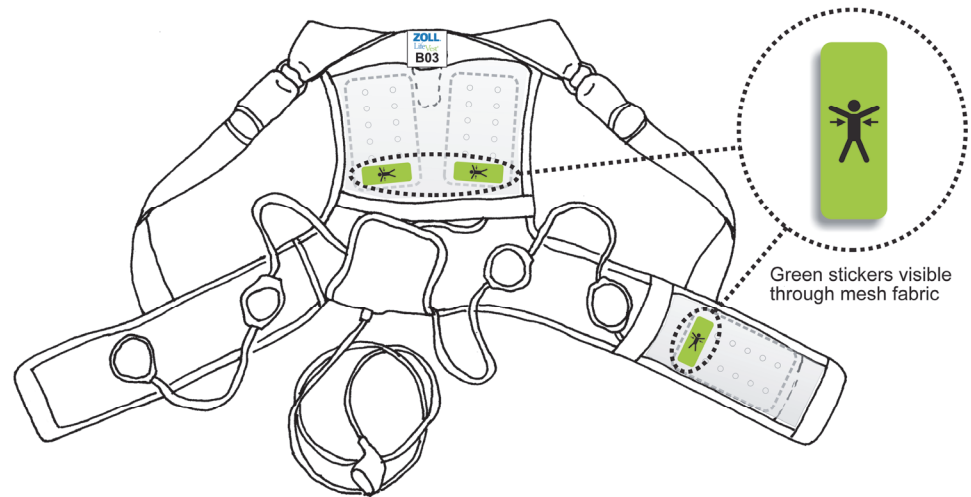
Outside view

This side faces away from your body when worn. The foam sides of the electrodes face the back of the garment.



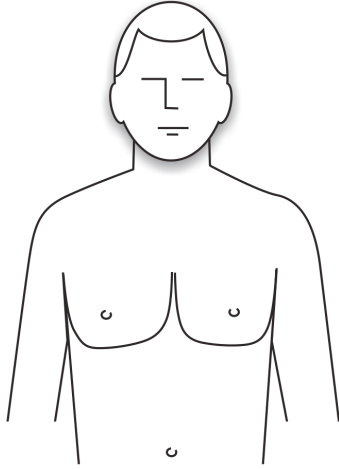
Inside view

This side faces toward your body when worn, with the mesh fabric pockets against your skin. Look for the green stickers visible through the mesh fabric.



Putting on the assembled electrode belt and garment

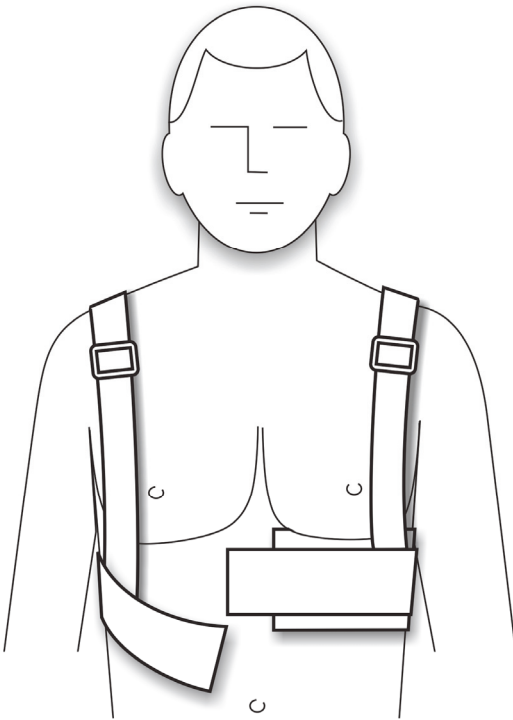
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 1 Before putting on the garment, remove all clothing and undergarments from your upper body.

All clothing, including underwear must be worn **OVER** the device, **NOT** under it.

- 2 If desired, apply unscented hand lotion or skin cream to the four ECG (round) electrodes.

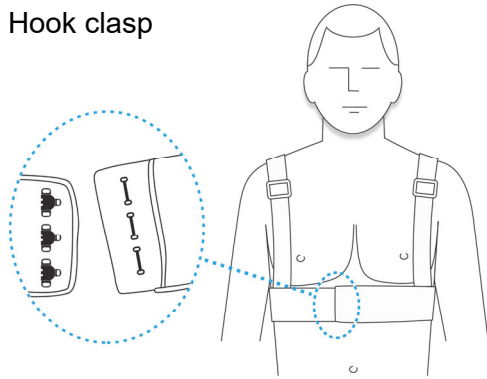


- 3 Put on the garment, making sure:
 - The garment doesn't get twisted.
 - The silver sides of the therapy pads in their mesh fabric pockets touch your bare skin.

If you are a female:

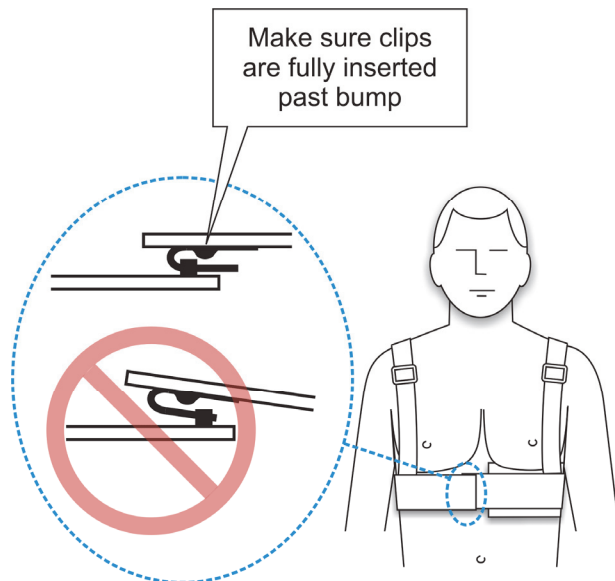
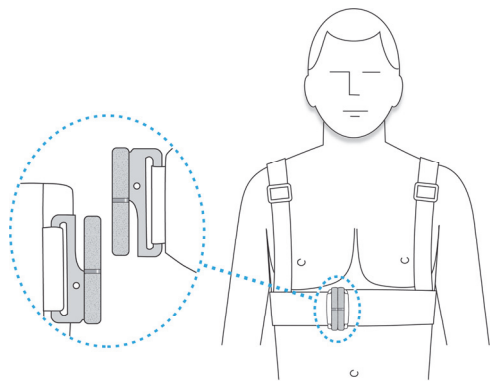
- Wear a bra **OVER** the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad in its mesh pocket is pressing against your body rather than the underside of your left breast.

Hook clasp



- 4 Connect the garment ends together in the front. Your garment has either a hook clasp or a butterfly clasp. This action is different depending on the type of clasp on your garment. Instructions for each clasp follow. Choose which applies.

Butterfly clasp



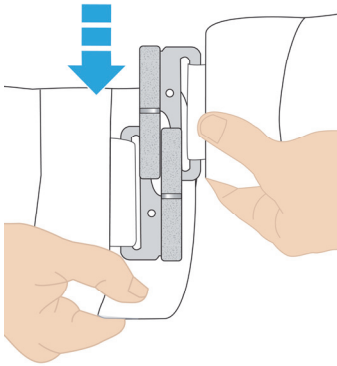
If your garment has a hook clasp:

- a. Slide the hooks into the clips.
- b. Ensure the hooks are fully inserted past the slight bumps in the clips.

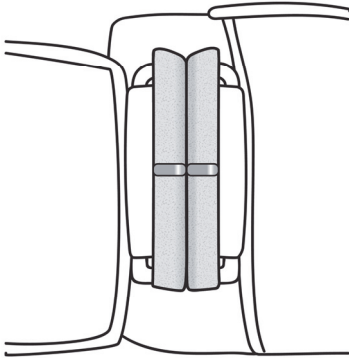
If your garment has a butterfly clasp, see the next page.

If your garment has a butterfly clasp:

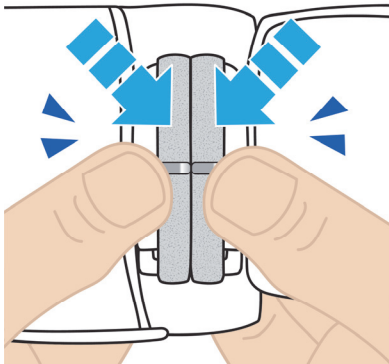
- a. Insert the left side of the clasp straight into the right side.



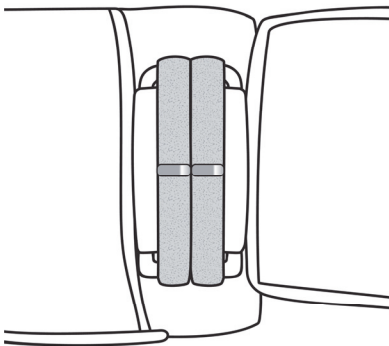
- b. Slide the left side down completely until both sides are level with each other and the raised bumps are aligned.



- c. Press the two sides down to secure. The clasp clicks into place.

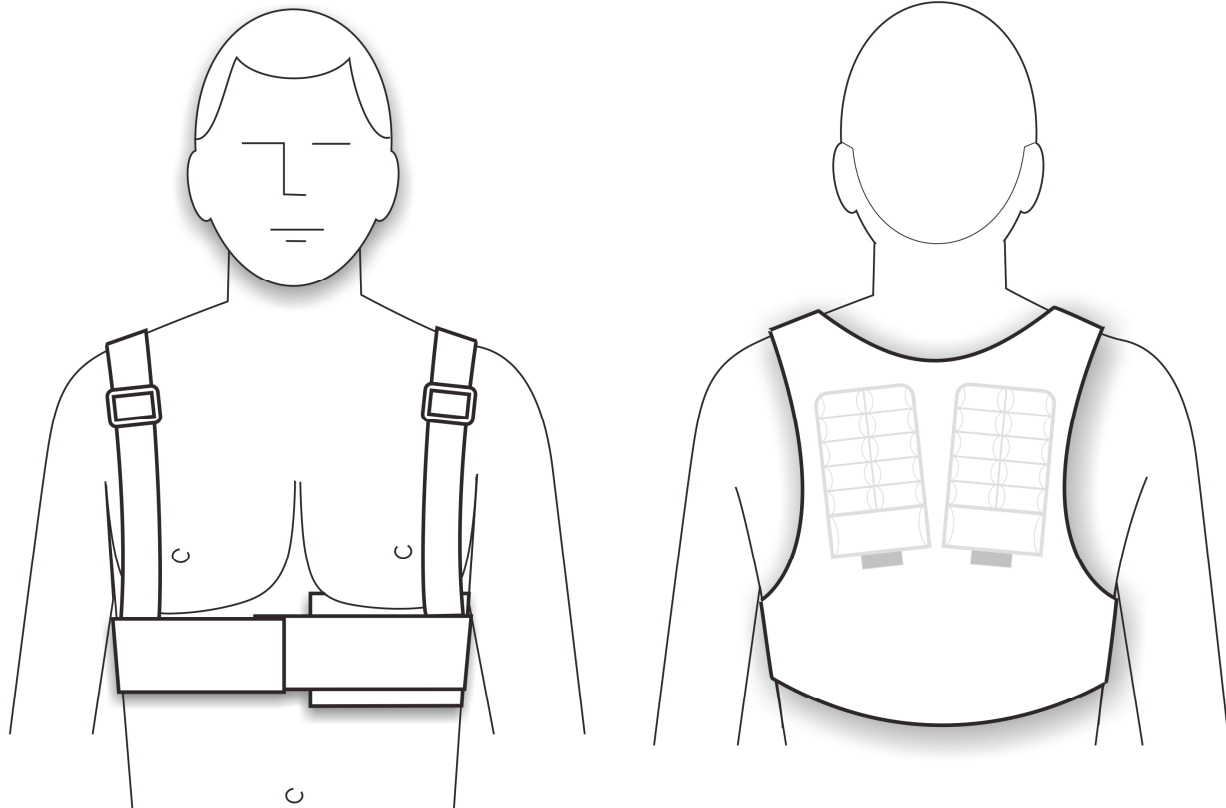


The secured garment clasp should lie flat.



5 Look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against your skin.
- The electrodes and therapy pads are pressing against bare skin. The mesh fabric pockets and silver sides of the therapy pads (with green stickers) **MUST TOUCH YOUR BODY** for the device to work properly.
- None of the cabling interferes with the electrodes.
- The garment is being worn correctly. Your garment should look like the figures below.

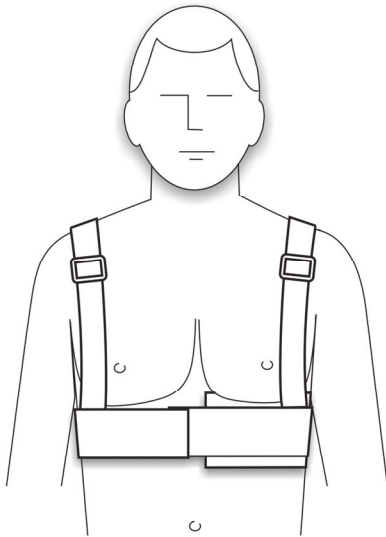
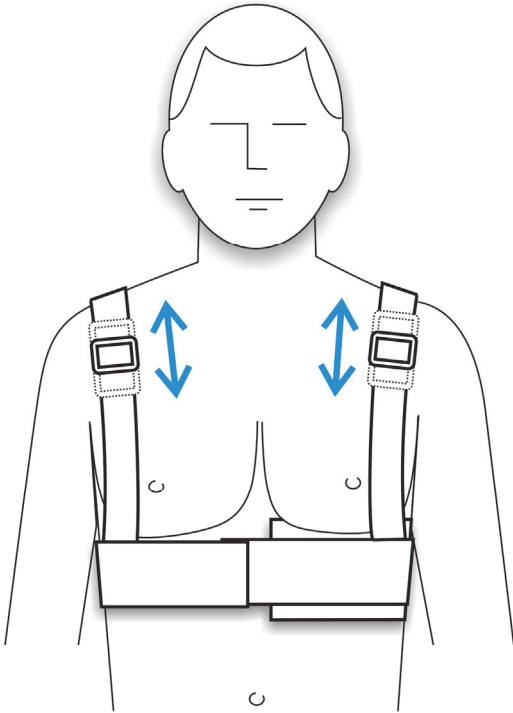


- 6 Check the position of the garment on your body and make sure it's not too high or too low.

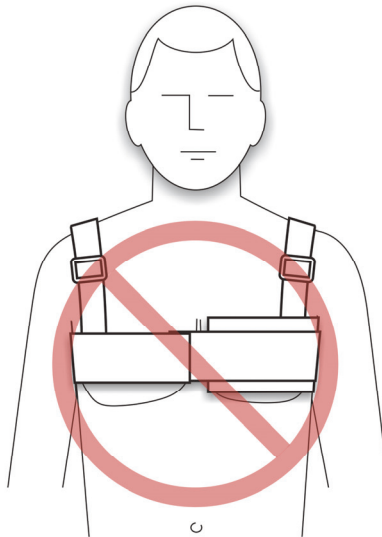
To position the garment properly, you may need to adjust the shoulder straps.

Move the sliders to position the garment properly, and for a snug fit.

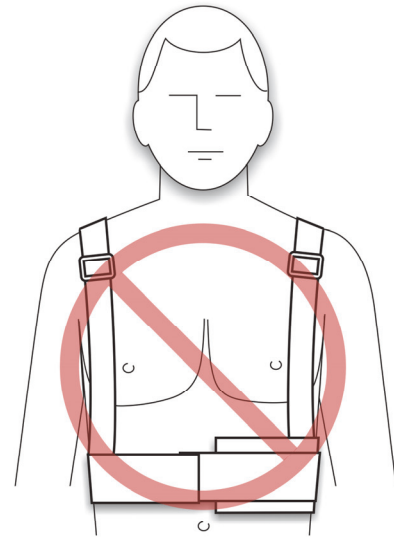
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



Too low

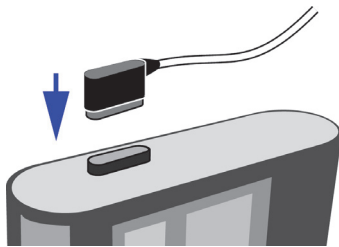
Connecting and disconnecting the electrode belt

To connect the belt

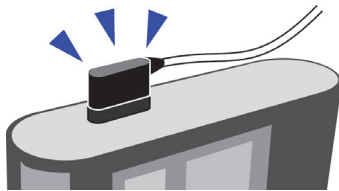


WARNING

Do not force the connector. Allow the connector to align before pushing it in. Forcing the connector may damage it and cause the system to malfunction.

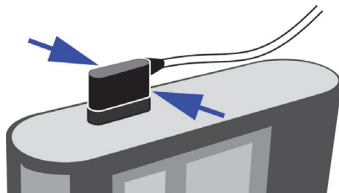


- 1 Line up the connector with the monitor. The cable should face toward the center of the monitor.

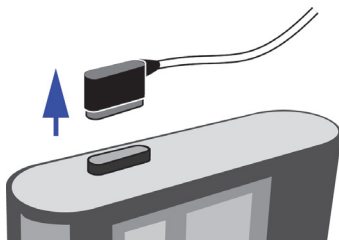


- 2 Gently push the connector straight in until it locks in place.

To disconnect the belt

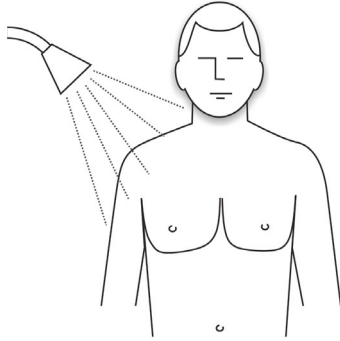


- 1 Squeeze the sides of the connector as you pull it away from the monitor.



- 2 Pull the connector straight out of the monitor.

Removing when you shower or bathe

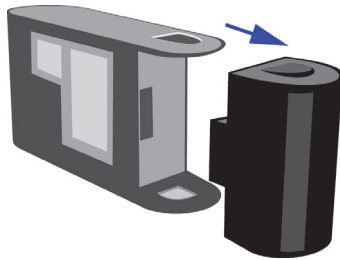


When you remove the device to bathe or shower, you are not protected by the device. Bathe or shower in the evening, preferably when someone else is home with you.

When you remove the device for any reason, remove the battery first. When you put the LifeVest® device back on, put the battery in last.

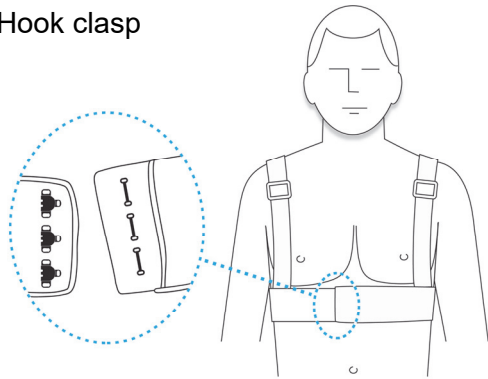
Completely remove the LifeVest device when you shower or bathe. Don't put the monitor, electrode belt, or battery in or near water.

To remove the LifeVest® device before you bathe or shower



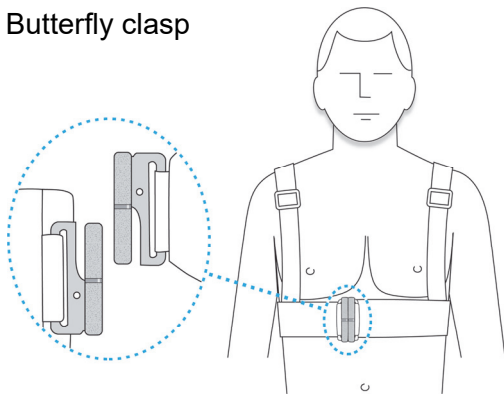
- 1 Remove the battery from the monitor. Keep the belt connected to monitor.

Hook clasp



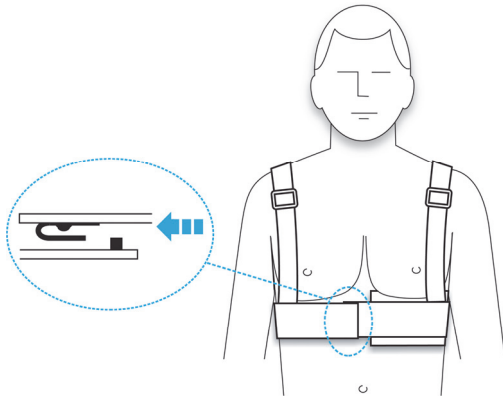
- 2 Unfasten and remove the garment from your body. Your garment has either a hook clasp or a butterfly clasp. This action is different depending on the type of clasp on your garment. Instructions for each clasp follow. Choose which applies.

Butterfly clasp



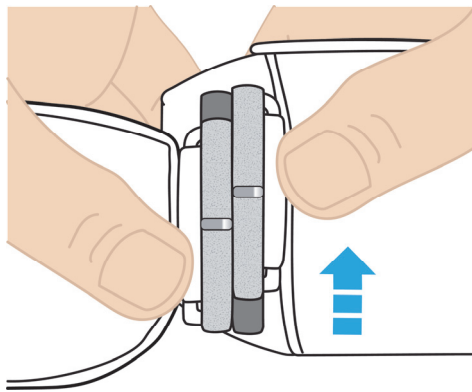
If your garment has a hook clasp, slide the hooks out of the clips completely.

If your garment has a butterfly clasp, see below.

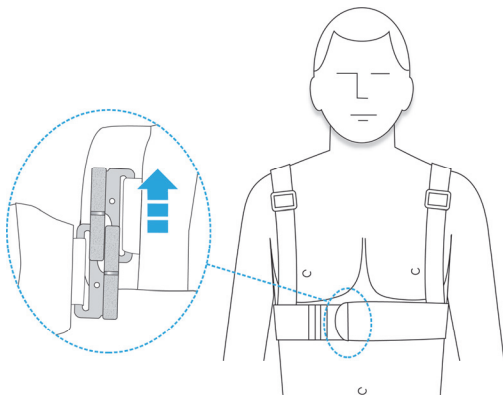


If your garment has a butterfly clasp:

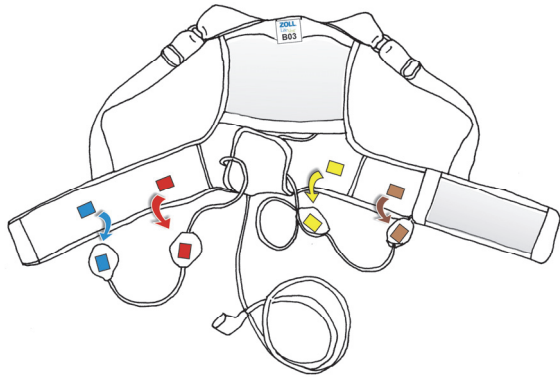
- a. Push on the back of the clasp.
- b. Slide the left side of the clasp up.



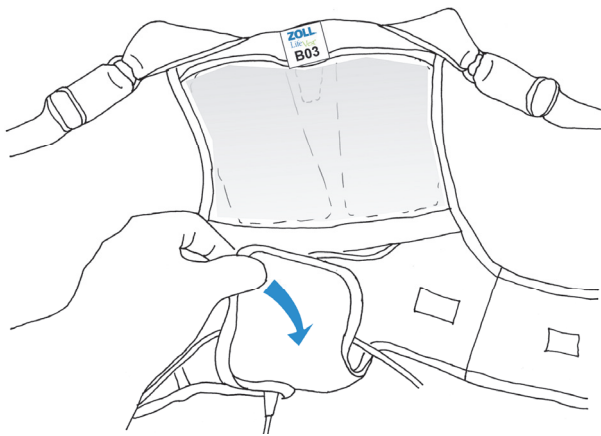
3 Remove the garment from your body. If you plan to change the garment, follow the procedure on page 4-16 to disassemble the electrode belt from the garment.



Disassembling the electrode belt and garment



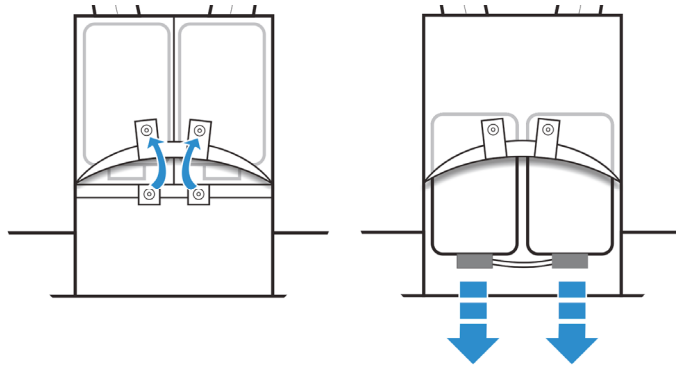
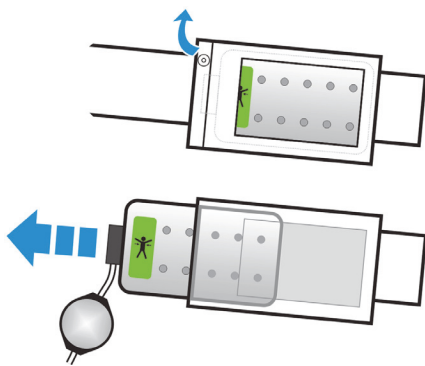
- 1 Remove the four ECG electrodes from garment. Pull on the electrodes, not on the wires.



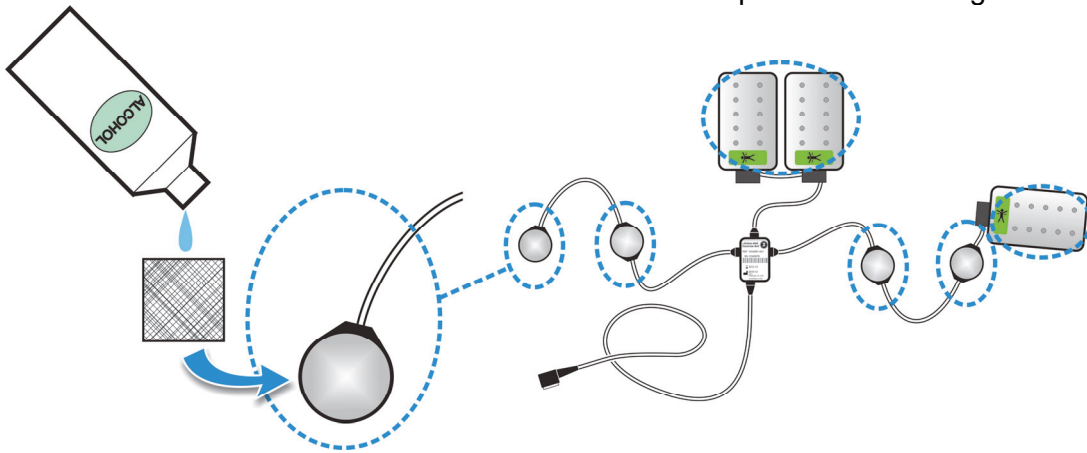
- 2 Remove the vibration box from the garment.

Do not use the vibration box as a handle to pull or lift the electrode belt. Pulling on the vibration box can damage the internal wiring and cause the system to malfunction.

- 3 Unsnap and remove the therapy pads from their pockets.



- 4 Wipe the metallic surfaces of the electrodes and therapy pads with a soft cloth dampened with rubbing alcohol.



- 5 Reassemble the garment and electrode belt as described on page 4-1.
- 6 Put on the assembled garment and electrode belt as described on page 4-7.

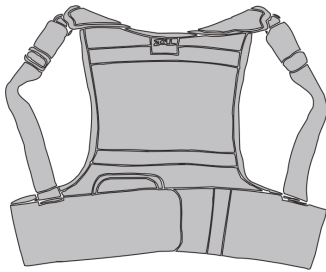
For instructions on laundering the dirty garment, see next page.

Laundering the garment



CAUTION

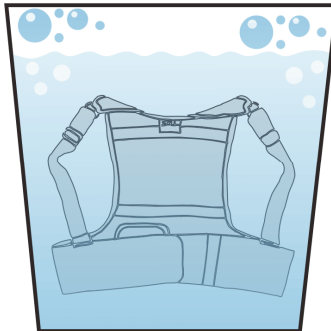
Do not use chlorine bleach, bleach alternatives, fabric softener, anti-static sprays or detergents that include bleach or fabric softener additives when laundering the garment. Using bleach or any of these other prohibited agents to launder the garment may damage it and cause the system to malfunction.



Launder the garment every 1 or 2 days.

Before washing the garment:

- Remove the electrode belt to protect it from damage. **Do not wash the electrode belt.**
- Attach the ends of the garment together.

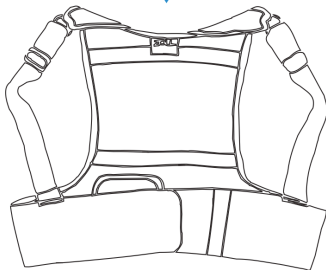


Wash the garment by itself. Do not wash it with other laundry.

The garment may be hand-washed or machine washed, using a normal wash cycle and warm water, with a maximum water temperature of 45°C (113°F).

Use only commercially available mild detergent.

Use a clothes dryer to dry the garment. Set the clothes dryer to a warm or medium setting. Do not use the high heat setting.



5: Responding to alarms

How this chapter is organized

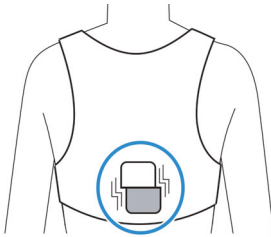
This chapter is organized by the types of alarms you can have while wearing the LifeVest® WCD:

- **Physiological alarms**, such as in response to a treatment or asystole. See below.
- **Technical alarms**, such as a service code. See page 5-5.
- **Informative alarms**, such as a reminder to change the battery or respond to electrode noise. See page 5-7.

Physiological alarms

These alarms are in response to a physiological condition in the patient wearing the LifeVest WCD.

Vibration alarm



If you get a vibration in the back of the electrode belt, you are being warned that you're about to get a siren alarm. You will also get a short vibration alarm every time you change the battery.

Press the response buttons to stop this alarm.

Follow the same instructions as for the siren alarm; see page 5-2.

Siren alarm



The siren alarm is a high-pitched two-tone sound that means an abnormal rhythm has been detected.

Press the response buttons to stop this alarm. If you don't respond to this alarm, you will probably receive a treatment within the next minute.

If this alarm is accompanied by the "respond" message, see page 5-2.

If this alarm is accompanied by the "call for help" message, see page 5-4.

Siren with respond message



WARNINGS

If you get an alert sound and you are awake, always hold the response buttons to prevent receiving a treatment. If you fail to hold the response buttons, you will get a treatment.

If you receive a treatment while your heart is beating normally and you did not use the response buttons, the treatment may cause an abnormal rhythm to occur. There is a small possibility that the abnormal heart rhythm may not be detected and death may result.



If you are conscious, hold the response buttons to stop the treatment from occurring.

- The siren stops and a voice prompt alerts bystanders that the treatment has been stopped.
- **NO ONE ELSE** should hold the response buttons. Only you, the patient, should hold the response buttons.
- If you feel dizzy, find a place to sit or lie down.
- Hold the response buttons each time you feel the vibration alarm or hear the siren alarm.




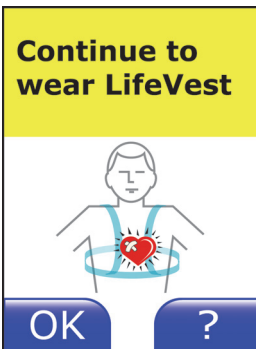
If you are not conscious, naturally you will not be able to press the response buttons.

- This allows the device to deliver a treatment.
- Voice prompts alert bystanders not to touch you.
- Voice prompts also alert bystanders to call for help after you have been given a treatment.

If you get a treatment

After getting a treatment, you may feel wetness on your back, sides, and chest. This is Blue™ gel that was released just before the first treatment was delivered. You might also have some chest soreness.

When any of these messages appear, tap the help button  for reminders about what to do.




- 1 Call your doctor's emergency number immediately to report your treatment.
- 2 **Unless your doctor tells you otherwise**, continue to wear the LifeVest system.
 - Leave the belt connected. Do not remove the electrode belt or garment, and do not disconnect the electrode belt from the monitor.
 - Leave the battery in the monitor. Do not remove the battery. Continue to change and recharge the batteries as normal.
 - Leave the gel under the therapy electrodes. Do not wipe them dry.
 - Tap **OK** after reading the message.



- 3 Call ZOLL and arrange to get a new belt.
Tap **OK** to resume normal monitoring.



- 4 Check the display for any messages and take the action indicated.
 - For help with specific messages, tap the help button .
 - For general instructions for any message accompanied by a gong, see pages 5-5 and 5-7.

Siren with call for help message

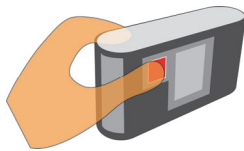
If patient is not responsive, call for help. Perform CPR.



If you are awake and feel OK and you get this message:

- Press the response buttons to stop the message and siren alarm.
- If the alarm continues even after you press the response buttons, remove and replace the battery to reset the device.
- If you continue to get this message, call ZOLL.

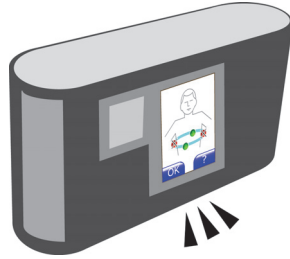
If you are not conscious, naturally you will not be able to press the response buttons.



Voice prompts and messages alert bystanders to call for help.

Technical alarms


These alarms typically indicate a problem with the device.


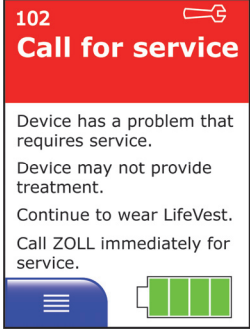
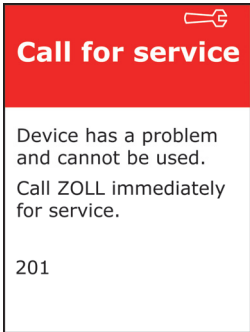


Technical alarms are accompanied by a low-pitched “gong” sound that repeats about once a second.

If you get a technical alarm, there is a problem that needs your attention. Take the following action:

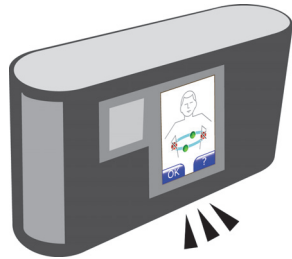
- Read the message on the monitor’s display.
- Use this chart to see what the message means and what to do.

Message	What it means	What to do
	<p>System has a problem that requires servicing. You can continue to use the device.</p> <p>Note the code beginning with the number 1.</p>	<p>Write down code number and call ZOLL.</p> <p>Tap OK to return to normal operation.</p>

Message	What it means	What to do
	<p>System may have a more severe service problem.</p> <p>System may not provide needed treatment.</p> <p>You should continue to use the device.</p> <p>Note the code 102 on the screen.</p>	<p>Write down code 102 and call ZOLL immediately.</p> <p>Continue using the device.</p>
		
	<p>System has a more severe service problem.</p> <p>You CANNOT use the device.</p> <p>Note the code beginning with the number 2.</p>	<p>Write down the code number and call ZOLL immediately.</p>


Informative alarms

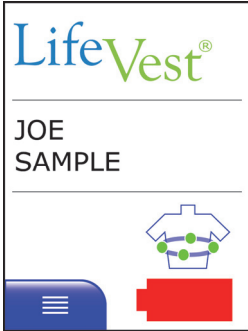
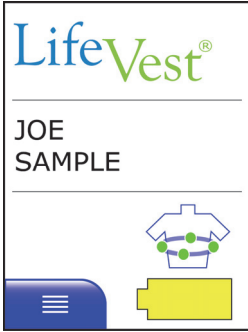
These alarms are for information purposes.

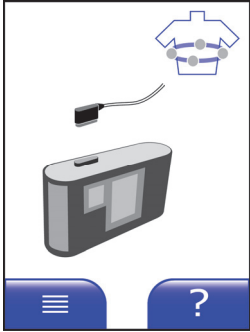
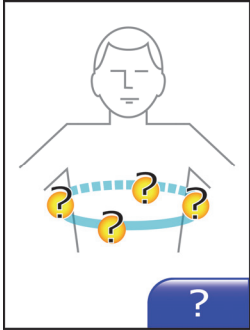
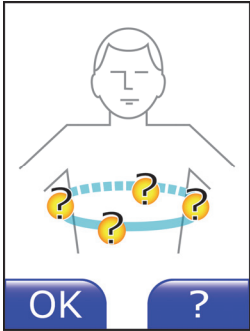

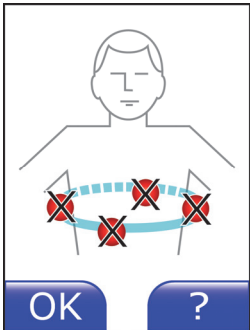



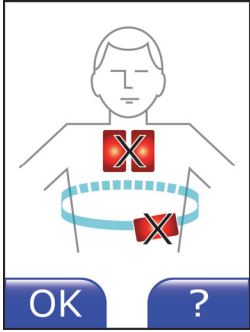
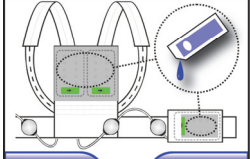
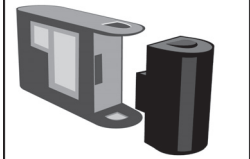
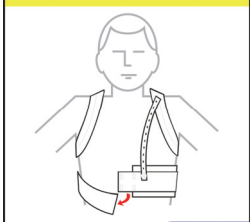
Informative alarms are accompanied by either a low-pitched “gong” sound that repeats about once a second, or a high-pitched “train whistle” type of sound.

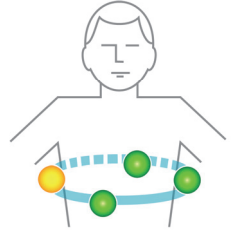



If you get an informative alarm, there is a problem that needs your attention. Take the following action:

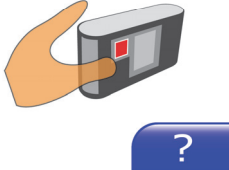
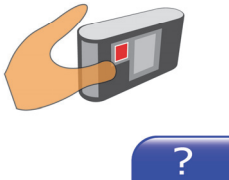

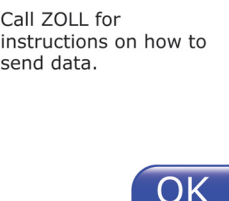
- Read the message on the monitor’s display.
- For specific help with any message, tap the help button  if one is available on screen.
- Use this chart to see what the message means and what to do.


Message	What it means	What to do
 <p>LifeVest®</p> <p>JOE SAMPLE</p>	<p>Red battery symbol means that battery has discharged and needs to be changed.</p>	<p>Change to a fully-charged battery and place discharged battery into the charger.</p>
 <p>LifeVest®</p> <p>JOE SAMPLE</p>	<p>Yellow battery symbol means that battery condition cannot be determined, but battery may continue to function normally.</p>	<p>Continue to use and recharge battery as normal. Call ZOLL for a replacement battery.</p>

Message	What it means	What to do
	<p>Electrode belt is not connected to monitor.</p>	<p>Connect the electrode belt to the monitor.</p>
	<p>Monitor is not receiving a signal from the electrode belt. This message is accompanied by a voice prompt telling you to <i>Check electrodes</i>.</p>	<p>Adjust your garment and electrode belt so that each ECG electrode is touching your skin. For more details about this message, see page 5-14.</p>
	<p>Monitor is receiving a poor signal or no signal from the electrode belt. Electrode icons can be any combination of green, yellow, or red to show specific conditions. Tap the help button  for details.</p>	<p>Adjust your garment and electrode belt so that each ECG electrode is touching your skin. Pay particular attention to the electrode icons that show yellow or red on screen. Tap OK to return to normal operation. For more details about this message, see page 5-13.</p>
	<p>Monitor is not receiving a clear signal from the electrode belt. Electrodes are probably not in good contact with skin. Electrode icons can be any combination of green, yellow, or red to show specific conditions. Tap the help button  for details.</p>	<p>Adjust your garment and electrode belt so that each ECG electrode is touching your skin. Pay particular attention to the electrode icons that are yellow or red. Tap OK to return to normal operation. For more details about this message, see page 5-13.</p>

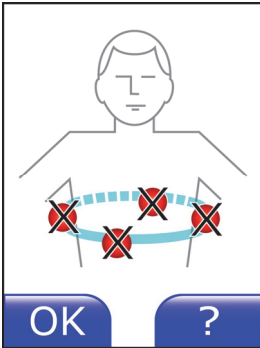
Message	What it means	What to do
	<p>Therapy pad is not making contact with your skin.</p>	<p>Make sure the therapy pads are inserted correctly, with their metal sides (with green stickers) against your skin.</p> <p>Make sure the therapy pads and mesh pockets are pressing against your skin.</p> <p>Tap OK to return to normal operation.</p> <p>For more details, see page 5-16.</p>
<p>Add gel to therapy pads</p> 	<p>You have received a treatment and the gel is drying out.</p>	<p>Add gel to the therapy pads or replace electrode belt.</p> <p>Tap OK to return to normal operation.</p> <p>See details on page 5-19.</p>
<p>Change battery</p> 	<p>Battery has discharged and needs to be changed.</p>	<p>Change to a fully-charged battery and place discharged battery into the charger.</p> <p>Tap OK to return to normal operation.</p>
<p>Check belt</p> 	<p>After multiple attempts to adjust the belt, monitor is still not receiving a good signal from the electrode belt.</p>	<p>See details on page 5-15.</p>

Message	What it means	What to do
<p>Checking...</p> 	<p>Device is checking to see if the belt is sending a clear signal.</p>	<p>No action required. Just wait while this screen is displayed.</p>
<p>Continue to wear LifeVest</p> 	<p>You have received a treatment.</p>	<p>Continue to wear the LifeVest device. Call your doctor's emergency number immediately.</p> <p>Leave the electrode belt connected; change and recharge the battery as normal until you receive a replacement belt.</p> <p>Follow instructions about what to do after receiving a treatment on page 5-3.</p> <p>Tap OK to return to normal operation.</p>
<p>Performing belt maintenance</p>  <p>25%</p> <p>Please wait.</p>	<p>The system is performing maintenance on the belt.</p>	<p>No action required. Just wait while this screen is displayed.</p>
<p>Press response buttons</p> 	<p>You are to press the response buttons to test their function every time the battery is installed.</p>	<p>At startup, press the response buttons as a reminder of what to do when a siren alarm sounds.</p>

Message	What it means	What to do
<p>Release response buttons</p> 	<p>This message may appear at startup. You may be holding the response buttons instead of pressing and releasing them.</p>	<p>Release the response buttons. If you are not holding the response buttons, device may be defective. Call ZOLL.</p>
<p>Release response buttons</p> 	<p>This message may appear after a detection. You may be holding the response buttons and you are no longer having a treatable heart rhythm.</p>	<p>Release the response buttons. If you are not holding the response buttons, device may be defective. Call ZOLL.</p>
<p>Remove battery</p> <p>If LifeVest is not in use, remove battery.</p> 	<p>This message appears if the battery has been left in the monitor when not in use.</p>	<p>If you are not wearing the LifeVest WCD, remove the battery from the monitor. If you are wearing the LifeVest WCD, make sure the electrode belt is firmly connected. If you continue to get this message with the belt connected, call ZOLL.</p>
<p>Time to send data</p> <p>Call ZOLL for instructions on how to send data.</p> 	<p>Data should be sent manually as soon as possible. Either a treatment was delivered or the monitor has data that has not been transmitted for some time.</p>	<p>Contact ZOLL for instructions about how to send data. Tap OK to return to normal operation. See details in section 3.</p>

Message	What it means	What to do
	Too much gel is on your skin.	Leave the gel that is under the therapy pads, but wipe the gel from the skin that is not under the therapy pads. Tap OK to return to normal operation. See details on page 5-21.

Belt problem message



This screen shows which ECG electrodes (the round ones) are causing problems.

If you get this message with yellow icons, along with a voice prompt stating to *Check electrodes*, see page 5-14.

The symbols help you to determine the problem. You may get any combination of these symbols:



Electrode off skin: Electrode is not making good contact with skin.




Poor signal: Could be muscle noise, electrical noise, weak signal, lost signal, or interference.



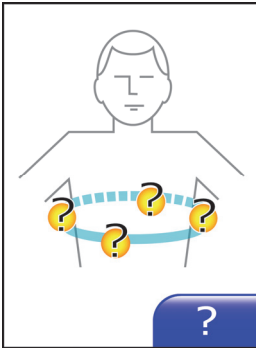
Good signal: Situation normal, no action required.

If you get one or more of the yellow or red symbols, make sure:

- The electrodes indicated by the yellow or red symbols are touching your skin.
- Nothing is between the ECG electrodes and your skin, such as clothing or one of the cables.
- Garment and belt fit snugly, with the electrodes pressing against your skin.

While you're wearing the LifeVest WCD, tap the help button  for reminders about what to do.

Check electrodes message



You may get this screen with this voice prompt:

Check electrodes.

If you are awake and feel OK, follow the instructions below.

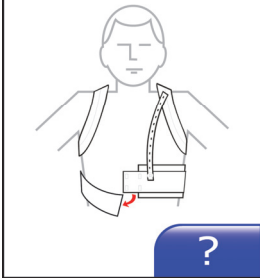
If you get this message and you're conscious

The problem may be with the signal from the ECG electrodes (the round ones). Follow this procedure to correct the problem.

- 1 Check your electrode belt and garment. Make sure:
 - All four ECG electrodes are touching your skin, not flipped over or pulled away from your skin.
 - Nothing is between the ECG electrodes and your skin, such as clothing or one of the cables.
 - Garment and belt fit snugly, with the electrodes pressing against your skin.
 - Electrode cable is securely connected into the monitor.
- 2 If you continue to get this message, call ZOLL.

Check belt message

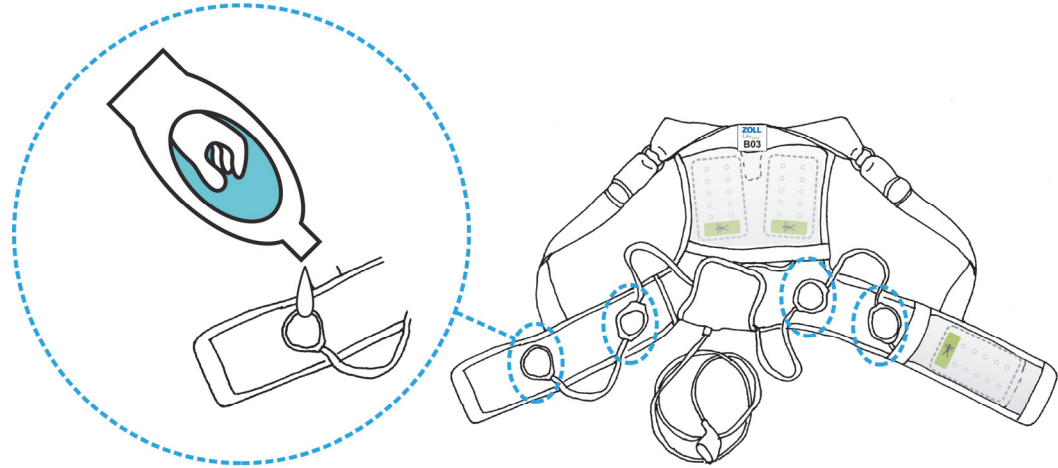
Check belt




After you get a number of belt problem screens, you may get this message. It means that the monitor is still not receiving a good signal from the electrode belt.

If you get this message:

- 1 Disconnect the electrode belt from the monitor.
- 2 Take off the garment and make sure that nothing is covering the metal surfaces of the ECG electrodes.
- 3 Put a dab of unscented hand lotion, skin cream, or moisturizer on the surface of each ECG electrode (the round ones, not on the therapy pads).

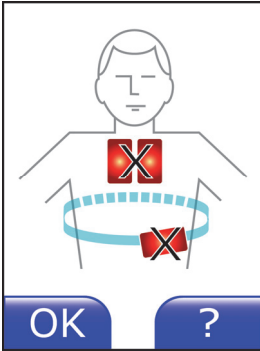


- 4 Put the garment on and connect the electrode belt to the monitor.

While you're wearing the LifeVest WCD, tap the help button  for reminders about what to do.

If problems continue, call ZOLL.

Therapy pad problem message



This screen shows when the therapy pads (the large rectangular ones) are causing problems by not making good contact with your skin.

Remember that there are three therapy pads: one in front and two in back. Any one of them could be causing the problem, so be sure to check all three if you get a red symbol.

The symbols help you to determine the problem:




Therapy pad off skin: Metal side is not making good contact with skin. Check all three therapy pads, front and back.



Therapy pad on skin: Situation normal, no action required.

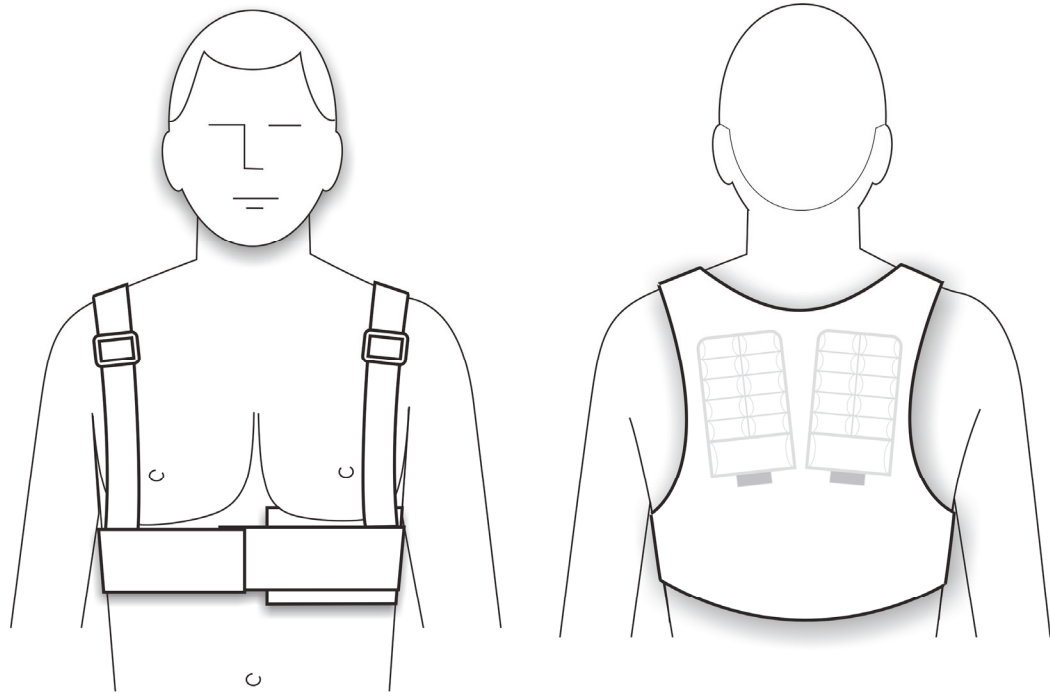
If you get red symbols, make sure:

- Therapy pads and mesh pockets are pressing against your skin. For details, see page 5-17.
- Therapy pads are inserted correctly into their pockets, with the silver sides (with the green stickers) facing the mesh fabric. For details, see page 5-18.
- Garment and belt fits snugly, with the mesh fabric pockets holding the therapy pads pressing against your skin.

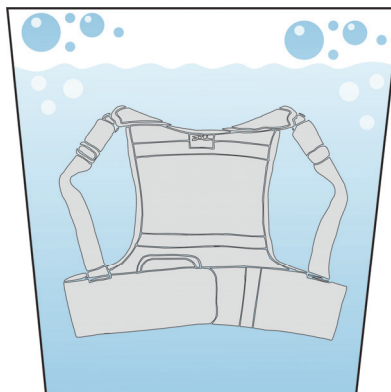
While you're wearing the LifeVest WCD, tap the help button  for reminders about what to do.

Therapy pad and mesh pocket may not be pressing against your skin

- 1 Change your body position and make sure that the garment is not twisted or loose.
- 2 Make sure that the mesh fabric pockets and the therapy pads are pressing against your bare skin. For details about putting on the garment and electrode belt, see section 4.



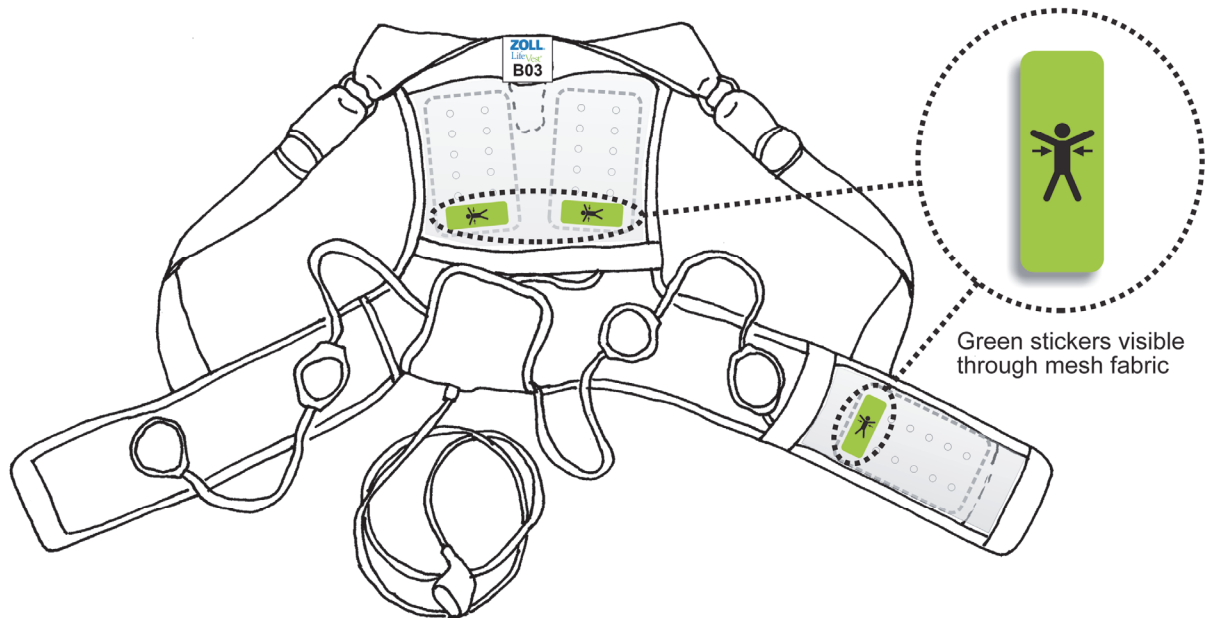
- 3 To help prevent stretching, launder the garment every 1 or 2 days. Follow the instructions for how to launder the garment in section 4.



- 4 If problems continue, call ZOLL.

Therapy pad may not be inserted correctly into its pocket

- 1 Remove the battery from the monitor, then remove the garment and electrode belt from your body.
- 2 Make sure the therapy pads are inserted correctly, with their silver sides (with green stickers) facing the mesh fabric, which faces your body.



- 3 Put on the garment and electrode belt, then put the battery into the monitor to resume normal operation.
- 4 If problems continue, call ZOLL.

Add Blue™ gel



After you receive a treatment to correct an abnormal rhythm, you may see this message telling you to add gel.

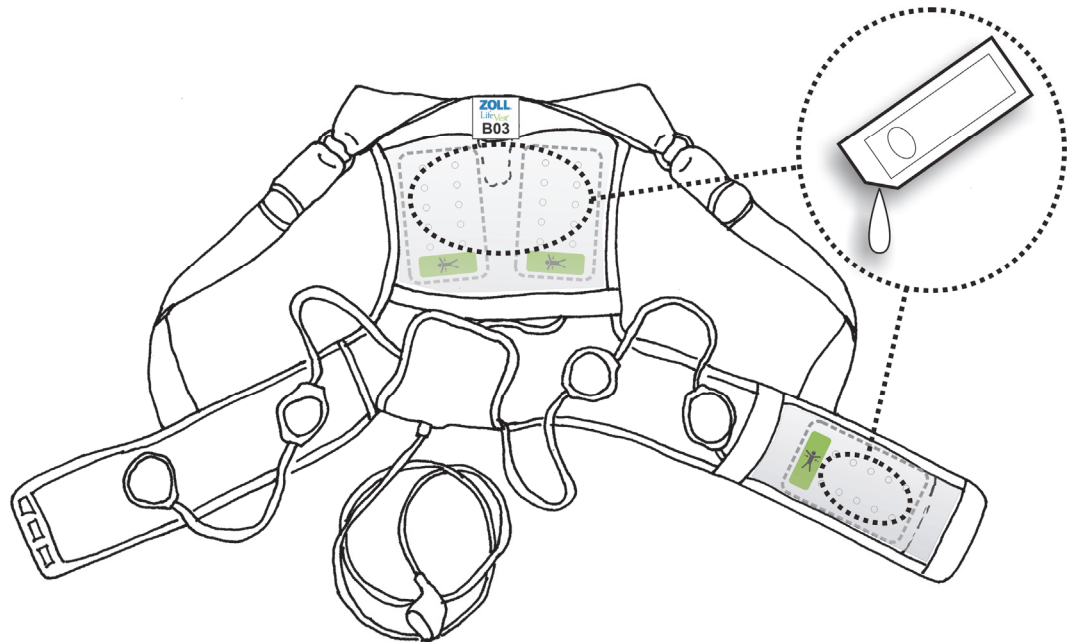
Follow the instructions below to add gel.

While you're wearing the LifeVest WCD, tap the help button **?** for reminders about what to do.

Tap **OK** to resume normal monitoring.

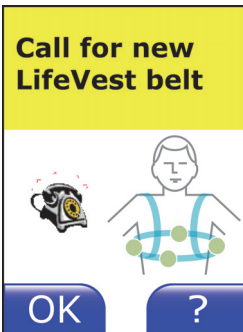
To add gel

- 1 Remove the battery from the monitor, then remove the electrode belt and garment from your body.
- 2 Locate the packets of Blue gel you got with the LifeVest system. Add one-half packet of gel to each therapy pad, directly onto the mesh material of each pocket. Apply to the rear pads and the front pad (but not to the ECG electrodes.)



- 3 Put on the electrode belt and garment. Refer to section 4.
- 4 Put the battery into the monitor and follow the normal startup routine.


Replace belt



After you receive a treatment to correct an abnormal rhythm, you may see this message telling you to replace the belt.

Continue to wear the belt until you get the replacement belt. The belt is still functional and can provide additional treatment if needed.

When you receive the new belt, follow the instructions below to replace the belt.

While you're wearing the LifeVest WCD, tap the help button  for reminders about what to do.

Tap **OK** to resume normal monitoring.

To replace the electrode belt


- 1 Remove the battery from the monitor.
- 2 Disconnect the electrode belt from the monitor.
- 3 Remove the electrode belt and garment from your body.
- 4 Disassemble the electrode belt from the garment, assemble the new electrode belt into a clean garment, and put on the assembled electrode belt and garment. Refer to section 4.
- 5 Connect the electrode belt to the monitor.
- 6 Put the battery into the monitor and follow the normal startup routine.

Too much gel



After you add gel to the electrode belt, you may see this message telling you there is too much gel between the therapy electrodes.

Follow the instructions below to remove the excess gel.

While you're wearing the LifeVest WCD, tap the help button  for reminders about what to do.

Tap **OK** to resume normal monitoring.

To remove excess gel

- 1 Remove the battery from the monitor.
- 2 With the electrode belt and garment on your body, and using a towel or soft cloth, wipe your skin between the front and back therapy pads on the left side of your body. Be careful not to remove the gel under the therapy pads.
- 3 Reinstall the battery into the monitor.

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6: Using the activities options

Introduction

This section covers two activities options that your prescriber can request while you're wearing the LifeVest® WCD. These options are the health survey and WalkTest® activity. Before you do either of these options for the first time, read through and understand this section of the manual.

If your prescriber did not request the health survey or WalkTest activity, you will not be able to access these options.

Your prescriber ordered the LifeVest WCD to protect you because you are at risk of sudden cardiac arrest. With the activities options, the LifeVest WCD allows you to provide some additional information to your prescriber. Your prescriber may then use that information to help evaluate your condition.

For more about the **health survey** option, see page 6-2.

For more about the **WalkTest** option, see page 6-10.

Health survey option

Your prescriber may request that you take the health survey as another way to use the LifeVest WCD to gather information about your condition.

How does it work?

The purpose of the health survey is to have the LifeVest WCD display a series of questions about your health and allow you to answer on the monitor. On the screen, you'll see the possible answers. You can touch the screen to have the questions read to you. Pick the one answer that most closely describes how you feel.

You will then go on to the next question and repeat this until you are finished. The health survey should take no more than 10 minutes.

The LifeVest WCD stores your answers and, during your next download, will send the results to a secure website where your prescriber can choose to review the results. Your prescriber may have you repeat the health survey once a day or once a week. The LifeVest device will remind you when you are scheduled to take the health survey.

What do I have to do?

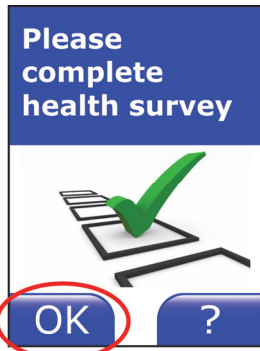
You need to answer the health survey questions honestly.

It is important that you wear the LifeVest WCD the entire time that you are taking the health survey so that it can monitor and protect you. While taking the health survey, follow the on-screen directions.

Why is it important that I do the health survey?

It is very important that you indicate how you really feel when you answer the questions. Your prescriber may use the information from the health survey to help evaluate your condition.

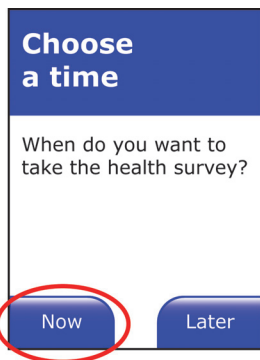
How to know if you are to take the health survey



- 1 If you get this message when you change the battery, you are to take the health survey.

If you have any questions, please contact your prescriber.

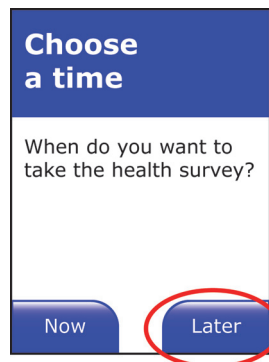
Tap **OK**.



- 2 To take the health survey right now, tap **Now**.

You will be taken to the screens for taking the health survey.

Continue with the steps on page 6-4.



If you want to take the health survey later, tap **Later**.

This screen goes away and the LifeVest device continues with normal operation.

You will be reminded to take the health survey in about 15 minutes.

If you want to take the health survey at any other time, see the steps on page 6-7.

Answering the health survey questions

During the health survey, the LifeVest WCD will ask you questions about your health, and you will enter your answers on the LifeVest monitor.

The LifeVest WCD steps you through the process. As you are taking the health survey, the LifeVest device prompts you as to what to do next. You enter your answers to the questions by using the screen on the LifeVest monitor.

We suggest that you read through all the steps in this manual before you answer the questions for the first time.

Your prescriber will decide which questions you are to answer. The questions and answers shown in these instructions may not be the questions and answers you will see on your LifeVest monitor.



- 1 When you choose to take the health survey, you will be presented with the first question.

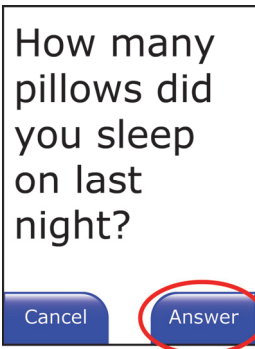
The question shown here is just an example. Your screen may show a different question.

Read the first question.

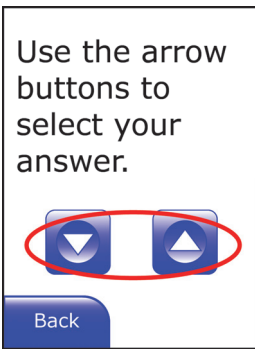
If you want to hear the question spoken to you, tap the screen in the question area.



Note: You can change the speak option so you hear each question screen as soon as it appears, without tapping the screen. You can also change the speak volume. For the details about changing the speak settings, see *Speak options* on page 3-23.

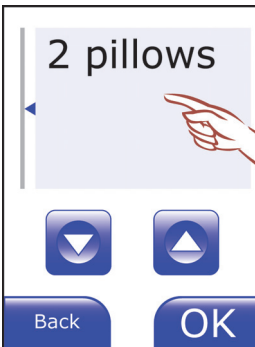
Note: If you want to cancel taking the health survey at any time, tap **Cancel**.



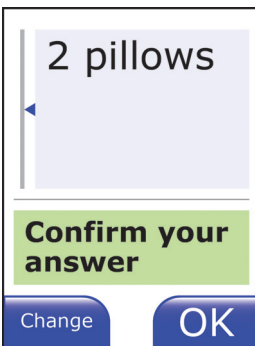
- 2 When you are ready to answer the question, tap **Answer**.



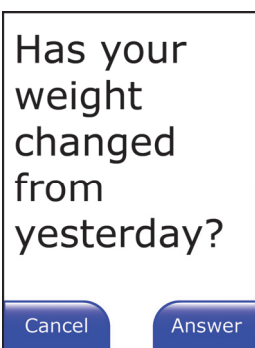
- 3 Use the  and  buttons to scroll through the answers.



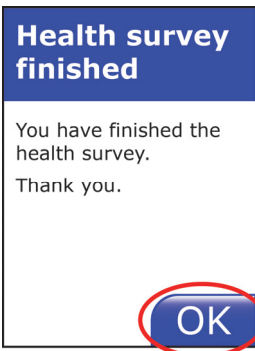
- 4 Choose an answer.
- The answers shown here are just examples. Your screens may show different answers.
 - To hear an answer, tap the screen in the answer area.
 - Select the answer that most closely describes your situation or the way you feel.
 - If you need to see the question again, tap **Back**.
 - To choose an answer, tap **OK**.



- 5 Confirm your answer.
- If the answer shown is correct, tap **OK**.
 - If you want to go back and change your answer, tap **Change**.



- 6 Repeat for the remaining questions.

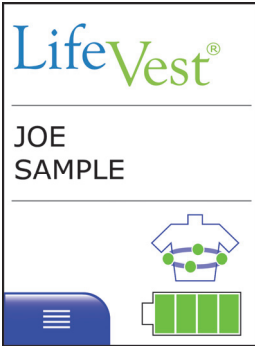


- 7 When you get this message, you have finished the health survey.
Tap **OK**.

Taking the health survey later

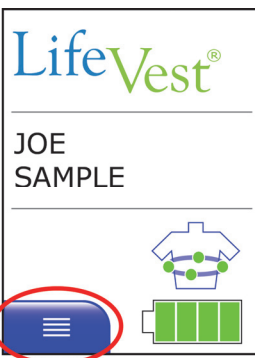
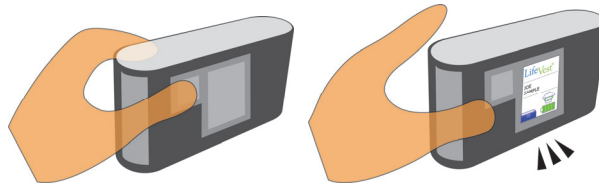
Follow this procedure if you chose “later” when you got the message telling you to complete the health survey.


Note that your menus might look slightly different than what is shown here. The procedure and buttons that you are to tap are the same.

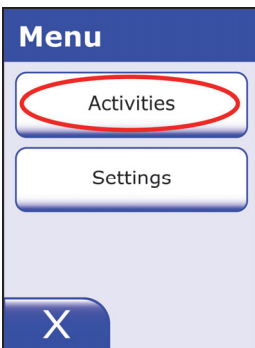


- 1 During normal monitoring, the LifeVest screen should look like the one at left.

If the screen is dark, press and release the response buttons to activate the screen.



- 2 Tap the menu button .

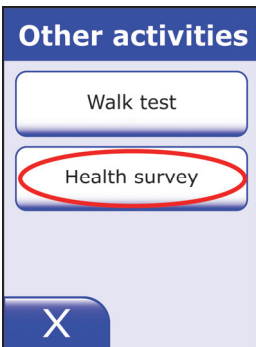


- 3 Tap **Activities**.



4 Tap **Other activities**.

Note: If your prescriber did not request that you take any of the activities, you will not see the “other activities” option on your screen.



5 Tap **Health survey**.

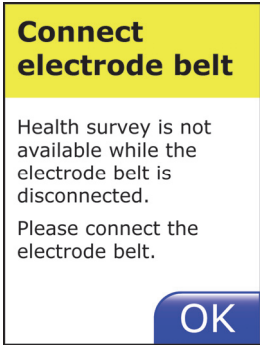
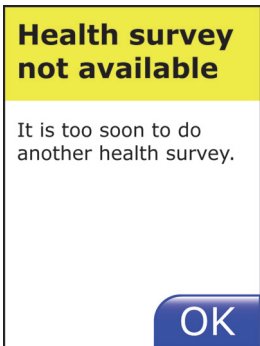

You're now ready to take the health survey.

Continue with the steps on page 6-4.

Health survey messages

As you take the health survey, you may get one of these messages. If so, here is what the message means and what you should do.

If you get any other messages, see *Section 5, Responding to alarms*.

Message	What it means	What to do
 <p>Connect electrode belt</p> <p>Health survey is not available while the electrode belt is disconnected.</p> <p>Please connect the electrode belt.</p> <p>OK</p>	<p>You are attempting to take the survey with the electrode belt disconnected.</p> <p>The belt needs to be connected to take the health survey.</p>	<p>Wear the LifeVest WCD and connect the electrode belt to the monitor.</p> <p>After connecting the electrode belt, the message goes away.</p> <p>Try again to take the health survey.</p>
 <p>Health survey not available</p> <p>It is too soon to do another health survey.</p> <p>OK</p>	<p>You are attempting to take the health survey more frequently than scheduled.</p>	<p>Tap OK to clear the message.</p> <p>Wait until you get this message:</p>  <p>Please complete health survey</p> <p>OK ?</p>

WalkTest® option

Your physician prescriber may order the WalkTest activity as one of the ways to use the LifeVest WCD to gather information about your condition.

How does it work?

The purpose of the WalkTest activity is for the LifeVest device to monitor your heart and count your steps for 6 minutes.

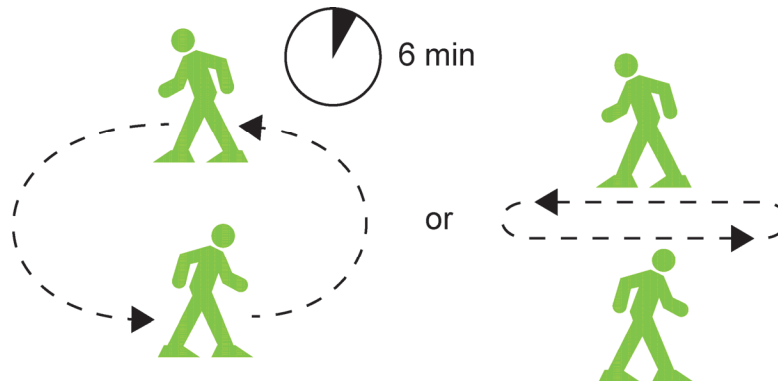
Before and after the activity, you'll be asked two questions. One about your shortness of breath level, another about your fatigue level (how tired you feel). After the walk, you'll answer the same two questions again. You'll look at the screen for the possible answers and pick the one that most closely describes how you feel at that moment.

During the next scheduled data download, the LifeVest device sends your WalkTest activity information to a secure website. From there your physician prescriber can review the results.

Your physician prescriber may have you repeat the WalkTest activity once a day or once a week. The LifeVest device will remind you when you are scheduled to take the walk test.

What do I have to do?

Try to perform the WalkTest activity at a pace you feel you can comfortably maintain for 6 minutes. You can carry out the session in a circle or oval, such as on an athletic track. You can also conduct your WalkTest activity in a square or rectangle, such as within a room. You can also move in a straight line, turning as you reach the ends, such as going back and forth in a hallway or narrow room.



It is important that you wear the LifeVest WCD the entire time that you're doing the WalkTest session so that it can monitor your progress and protect you.

While you are doing the WalkTest activity, LifeVest will give you audible prompts about how much longer the session will last. It will also tell you when to stop the activity.

It is also important that you do the WalkTest session for only 6 minutes. Listen for the voice prompt that tells you to “stop walking” after 6 minutes. When you hear this voice prompt, please stop the activity.

During the WalkTest activity, it is OK if you need to stop and rest at any time. After resting, continue the session when you are able to.

Why is it important that I do the WalkTest® activity?

Your physician prescriber may use the information from the WalkTest session to help evaluate your condition.

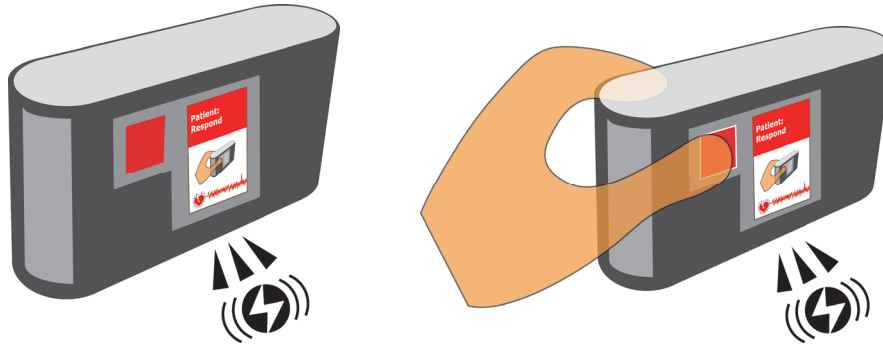
It is very important that you indicate the true state of your condition when you answer the questions. Your physician prescriber may review your answers and use this information to help evaluate your condition.

Warnings specific to the WalkTest® activity



WARNINGS

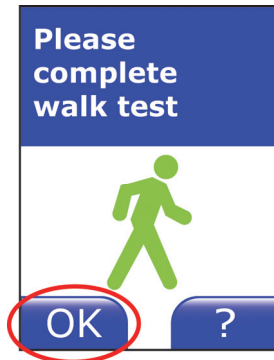
If you get the siren alert, stop the WalkTest® session and press the response buttons.



When performing the WalkTest activity, do not continue with the activity if the monitor broadcasts an alert sound. Stop the activity and press the response buttons as you normally would. If you continue with the activity, you may place yourself at risk for a cardiac arrest, possibly resulting in serious injury or death.

When performing the WalkTest activity, do not continue the activity if you experience symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop the activity and sit or lie down. If the symptoms continue or get worse, immediately call your doctor or emergency help. If you continue the activity or ignore the symptoms, you may place yourself at risk for a cardiac arrest or other health problems, possibly resulting in serious injury or death.

How to know if you are to take a WalkTest® session

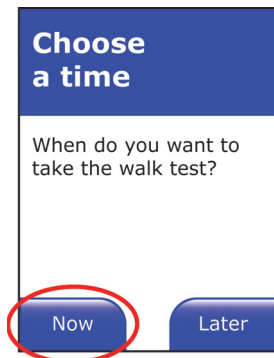


- 1 If you get this message when you change your battery, your physician prescriber has asked that you perform a WalkTest session.

Throughout the WalkTest procedure, you must wear the LifeVest WCD, with it connected normally.

If you have any questions, please contact your physician.

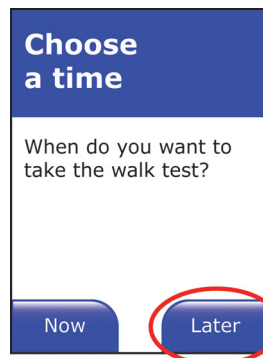
Tap **OK**.



- 2 If you are prepared to take the WalkTest session when you receive the message, tap **Now**.

You will be taken to the screens for the WalkTest activity.

Continue with the pre-activity questions; see page 6-14.



If you want to perform the WalkTest session later, tap **Later**.

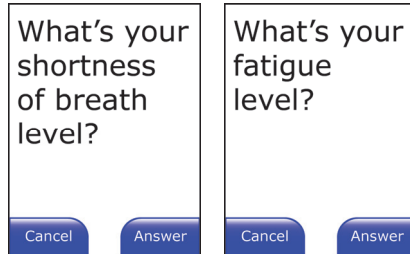
This screen goes away and the LifeVest WCD continues with normal operation.

You will be reminded to perform the WalkTest session in about 15 minutes.

If you want to perform the WalkTest session at any other time, see page 6-23.

WalkTest® session: answering the pre-activity questions

Before you take the WalkTest activity, you'll be asked two questions about how you feel. One about your shortness of breath level, another about your level of tiredness. After the WalkTest activity, you'll answer the same two questions again.

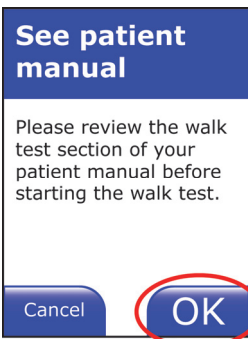


The questions will appear on the LifeVest monitor screen. With each question, choose the answer that best describes how you feel.

It is very important that you indicate the true state of your condition when you answer the pre- and post-activity questions. Your physician prescriber may review your answers and use this information to help evaluate your condition.

If you get a message while performing the WalkTest session, follow the instructions on the screen. For more information, see page 6-25.

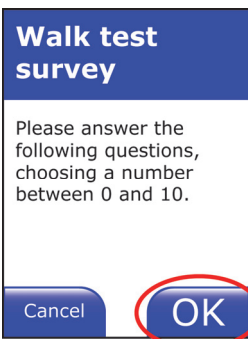
When you're ready to answer the questions, follow this procedure.



- 1 When you choose to take the WalkTest activity, you will be presented with this screen.

This screen reminds you to review the WalkTest section of the patient manual before taking the WalkTest session.

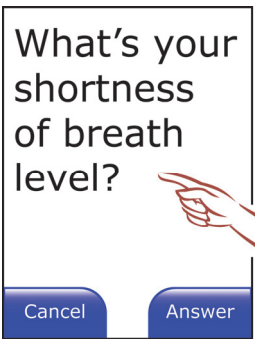
After reviewing the patient manual, tap **OK**.



- 2 This screen reminds you that you're going to be asked two questions before you start the activity.

Tap **OK** to continue.

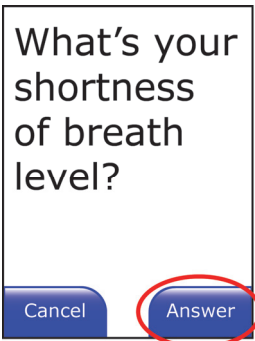
Note: If you want to cancel the WalkTest activity at any time, tap **Cancel**.



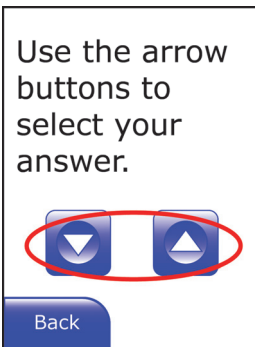
3 Read the question.



If you want to hear the question spoken, tap the screen in the question area.

Note: You can change the speak option so you hear each question screen as soon as it appears, without tapping the screen. You can also change the speak volume. For the details about changing the speak settings, see *Speak options* on page 3-23.



4 When you are ready to answer the question, tap **Answer**.



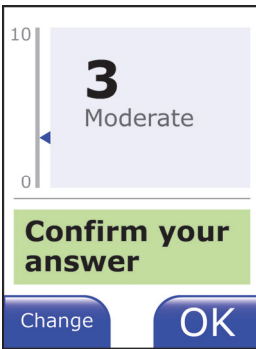
5 Use the  and  buttons to scroll through the answers.



6 Choose an answer.

- To hear an answer spoken, tap the screen in the answer area.
- You can select an answer from zero through 10, according to the answer scale shown on the next page.
- Select the answer that most closely describes how you feel.
- When your desired answer is shown, tap **OK**.
- If you need to see the question again, tap **Back**.

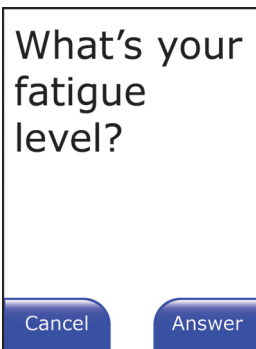
Answer scale	
0	Nothing at all
0.5	Very, very slight
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	
10	Very, very severe



7 Confirm your answer.

If the answer shown is correct, tap **OK**.

To go back to the previous screen and change your answer, tap **Change**.



8 Repeat for the second question.

The LifeVest device may tell you not to perform the WalkTest session based on your answers to the pre-activity questions.

After answering the two questions, continue with the active portion of the WalkTest activity. See page 6-17.

WalkTest® session: taking the active portion

After answering the two questions, you're ready to do the active portion of the WalkTest session.

You will move actively for 6 minutes while wearing the LifeVest WCD. You should be as comfortable as possible while performing the WalkTest session. Wear comfortable shoes. Perform the WalkTest session on a flat, level surface, preferably a hard surface, in a clear, unobstructed area so that you will not be prevented from moving normally. Do not use a treadmill. If your physician prescriber asks you to perform multiple WalkTest activities, doing the activity in the same location will give the most accurate results.

This test observes you while moving at a normal pace. Please do not run or jog.

If you have any walking problems (if you have an abnormal gait, such as foot dragging, shuffling, or limping; or if you need assistance while moving around, such as by using a cane, walker, or crutches) please tell your prescriber as it may produce inaccurate results.

Be aware that the LifeVest WCD will be giving you voice prompts throughout the WalkTest session, so you may prefer to perform it in a private location. So that you can hear the voice prompts, do not listen to music, talk on the phone, or engage in any other activity that might distract you while completing the WalkTest session.

During the WalkTest session, it is OK if you need to stop and rest at any time. After resting, continue the session when you are able.

During the WalkTest activity, you'll be advised about how much time remains. Then, after the walk, you'll answer the two questions again.

If possible, have someone with you while you do the WalkTest activity.

When you are ready to take the WalkTest activity, follow this procedure.



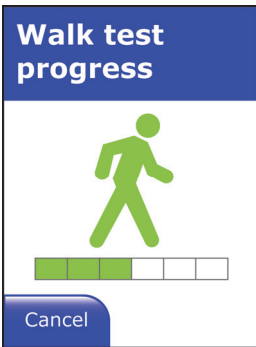
- 1 After answering the pre-activity questions, you will get this screen.

Stand up and get ready to start the activity.

When you are ready to start, tap the screen where indicated.



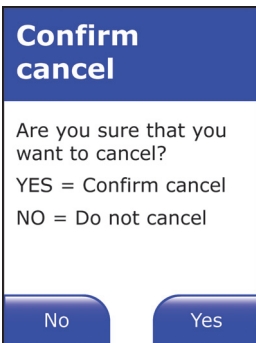
- 2 You will get a voice prompt to start the WalkTest activity.
Begin moving around your chosen course.
Continue for 6 minutes.



- 3 You will get a voice prompt after each minute of the WalkTest activity.
The progress bar shows how far along you are in the WalkTest activity.



- 4 If you need to cancel the WalkTest activity, tap the **Cancel** button.



If you tap **Cancel**, you will be asked to confirm that you really want to cancel.

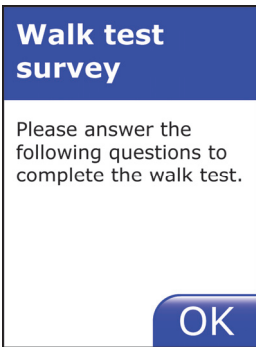
- If you do indeed want to cancel the WalkTest activity, tap **Yes**.
- If you do not want to cancel, and you want to return and complete the WalkTest activity, tap **No**. Choose this option if you are resting and plan to resume the activity.



- 5 After 6 minutes, you will get this message, along with a voice prompt telling you to stop walking.

When you hear the voice prompt telling you to stop, the WalkTest session has ended and you can stop moving around.

Tap **OK**.



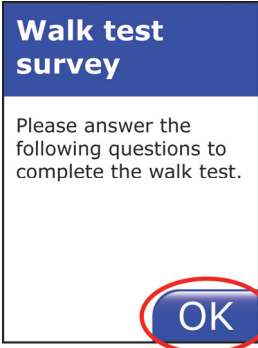
- 6 Proceed to answer the two questions again.

After answering the two questions, you can resume your normal activity.

See page 6-20.

WalkTest® session: answering the post-activity questions

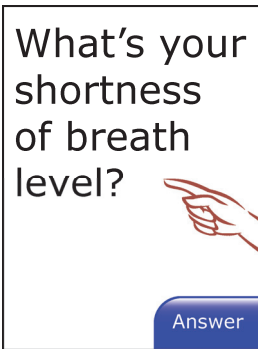
You will be asked two questions after the WalkTest session. The questions will appear on the LifeVest monitor. With each question, choose the answer that best describes how you feel.



- 1 You'll see this screen after the active portion of the WalkTest activity. This screen reminds you that you will be asked two questions after performing the WalkTest session.

These are the same questions you answered before the active portion of the test. Your answers should reflect how you feel now that you have completed the WalkTest session. Your answers do not need to match your previous answers.

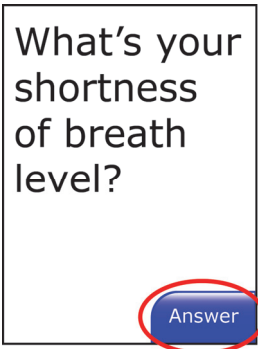
Tap **OK**.



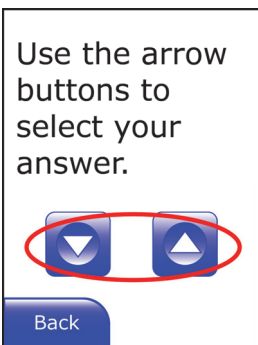
- 2 Read the question.

Tap the screen in the question area to hear the question.

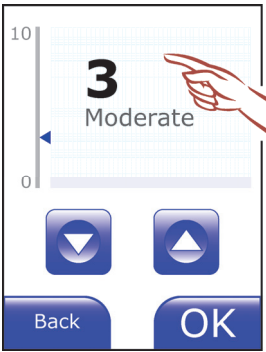
Note: You can change the speak option so you hear each question screen as soon as it appears, without tapping the screen. You can also change the speak volume. For the details about changing the speak settings, see *Speak options* on page 3-23.



- 3 When you are ready to answer the question, tap **Answer**.



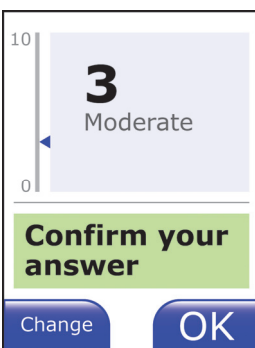
- 4 Use the  and  buttons to scroll through the answers.



5 Choose an answer.

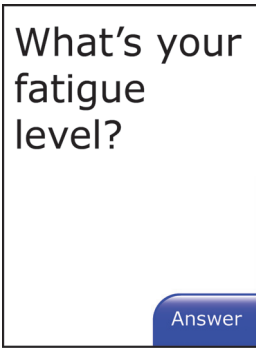
- To hear an answer spoken, tap the screen in the answer area.
- You can select an answer from zero through 10, according to the answer scale below.
- Select the answer that most closely describes how you feel.
- When your desired answer is shown, tap **OK**.
- If you need to see the question again, tap **Back**.

Answer scale	
0	Nothing at all
0.5	Very, very slight
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	
10	Very, very severe

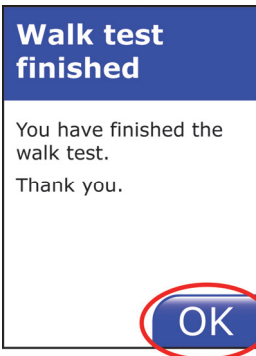


6 Confirm your answer.

- If the answer shown is correct, tap **OK**.
- If you want to go back and change your answer, tap **Change**.



7 Repeat for the second question.



8 You have now finished the WalkTest session.

After answering the two questions, you can resume your normal activity.

Tap **OK**.

Follow any additional instructions your prescriber gives you regarding when and how to perform the WalkTest activity.

After completing the WalkTest activity, sit down and rest before resuming your normal activities.

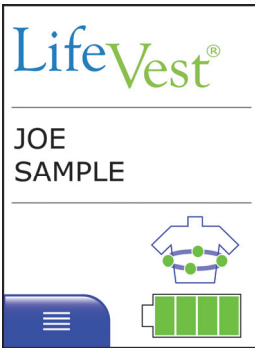
If you have any questions about these instructions, call ZOLL.

If you have any questions about your medical condition, call your health care provider.

Taking the WalkTest® session later

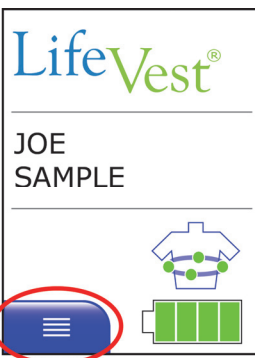
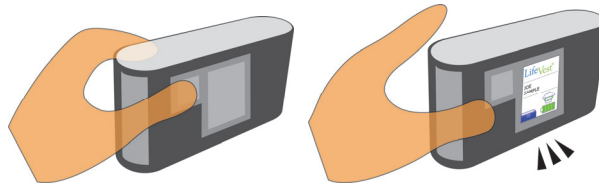
Follow this procedure if you chose “later” when you got the message telling you to complete the WalkTest activity.


Note that your screens might look slightly different than what’s shown here. The procedure is the same.

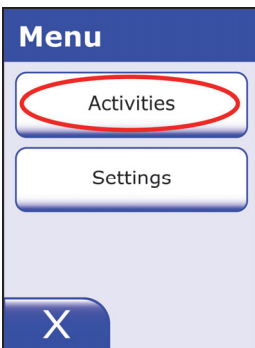


- 1 During normal monitoring, the LifeVest screen should look like the one at left.

If the screen is dark, press and release the response buttons to activate the screen.



- 2 Tap the menu button .

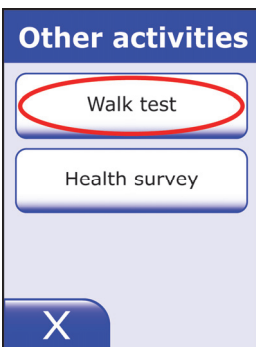


- 3 Tap **Activities**.



4 Tap **Other activities**.

Note: If your physician prescriber did not request that you take any of the activities, you will not see the “other activities” option on your screen.



5 Tap **Walk test**.

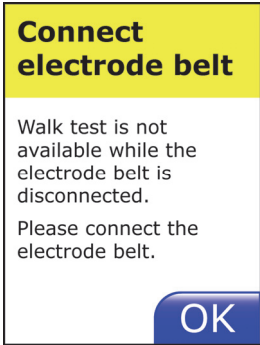
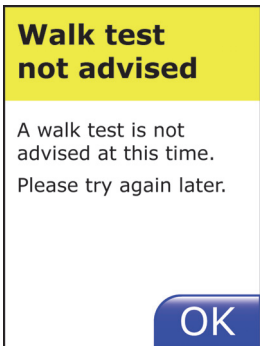
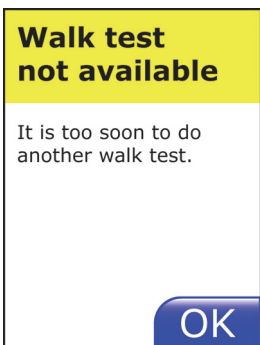

You're now ready to take the WalkTest activity.

Start with the pre-activity questions on page 6-14.

WalkTest® messages

As you take the WalkTest session, you may get one of these messages. If so, here is what the message means and what you should do.

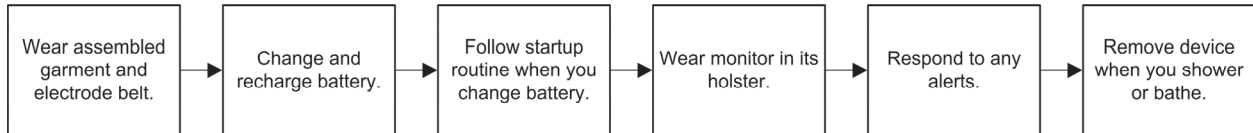
If you get any other messages, see *Section 5, Responding to alarms*.

Message	What it means	What to do
 <p>Connect electrode belt</p> <p>Walk test is not available while the electrode belt is disconnected.</p> <p>Please connect the electrode belt.</p> <p>OK</p>	<p>You are attempting to perform the WalkTest activity with the electrode belt disconnected.</p> <p>The belt needs to be connected to perform the WalkTest activity.</p>	<p>Wear the LifeVest WCD and connect the electrode belt to the monitor.</p> <p>After connecting the electrode belt, the message goes away.</p> <p>Try again to perform the WalkTest activity.</p>
 <p>Walk test not advised</p> <p>A walk test is not advised at this time.</p> <p>Please try again later.</p> <p>OK</p>	<p>You are attempting to perform the WalkTest activity and the LifeVest is advising you not to perform the WalkTest session at this time.</p>	<p>Tap OK to clear the message.</p> <p>Try again later (or wait until tomorrow).</p>
 <p>Walk test not available</p> <p>It is too soon to do another walk test.</p> <p>OK</p>	<p>You are attempting to perform the WalkTest activity more frequently than scheduled.</p>	<p>Tap OK to clear the message.</p> <p>Wait until you get this message:</p>  <p>Please complete walk test</p> <p>OK ?</p>

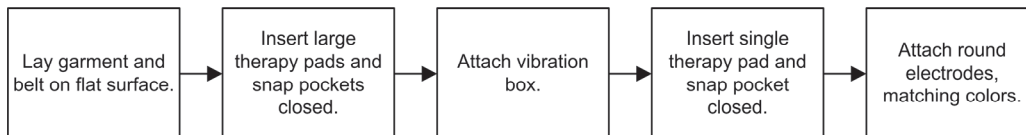
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Appendix A: Quick charts

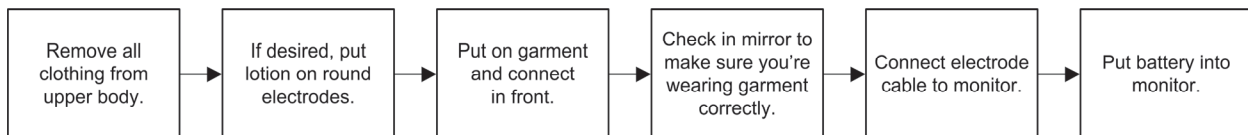
Daily routine



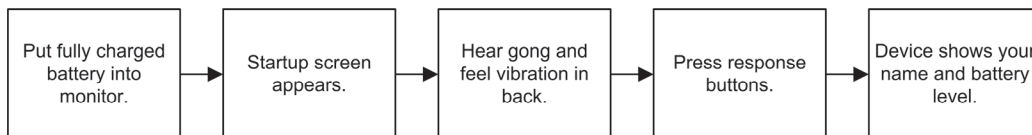
Assemble electrode belt and garment



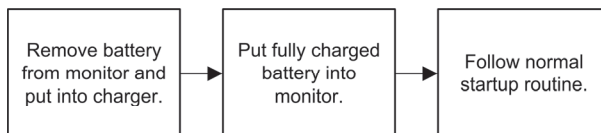
Put on LifeVest® system



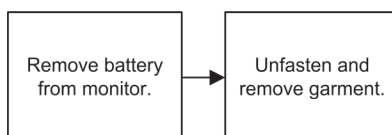
Normal startup routine



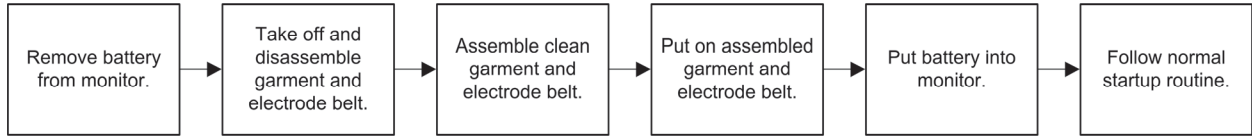
Recharge batteries daily



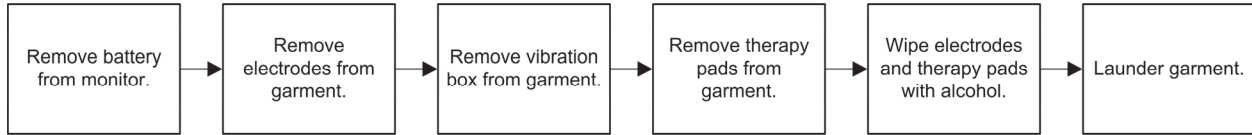
Remove LifeVest® system before bathing or showering



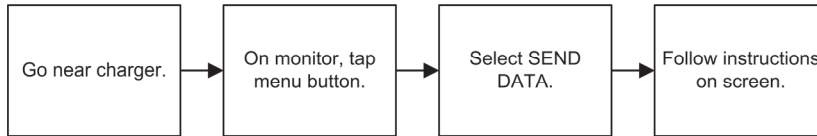
Change garment as needed



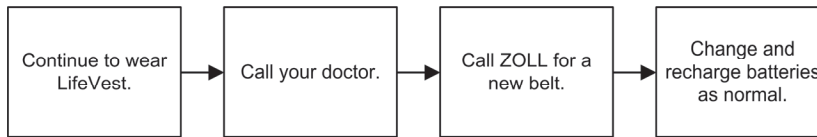
Disassemble electrode belt and garment



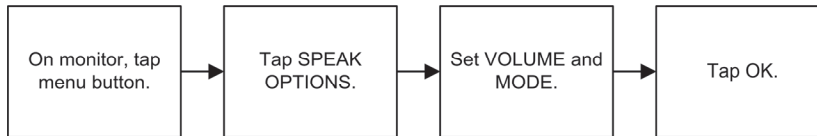
Manually send data to your doctor



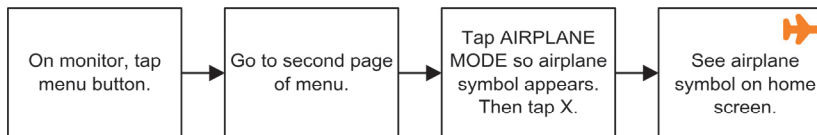
If you get a treatment



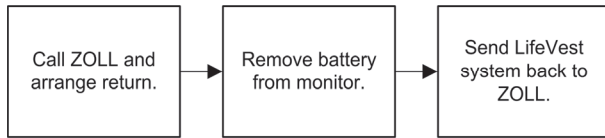
Change speak options



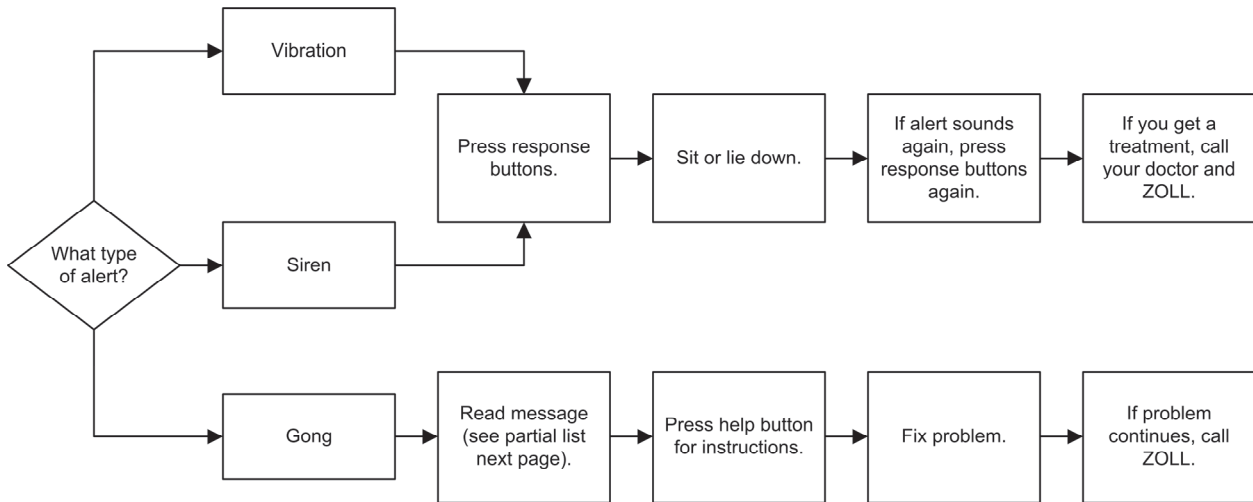
Airplane mode



When you're finished with device

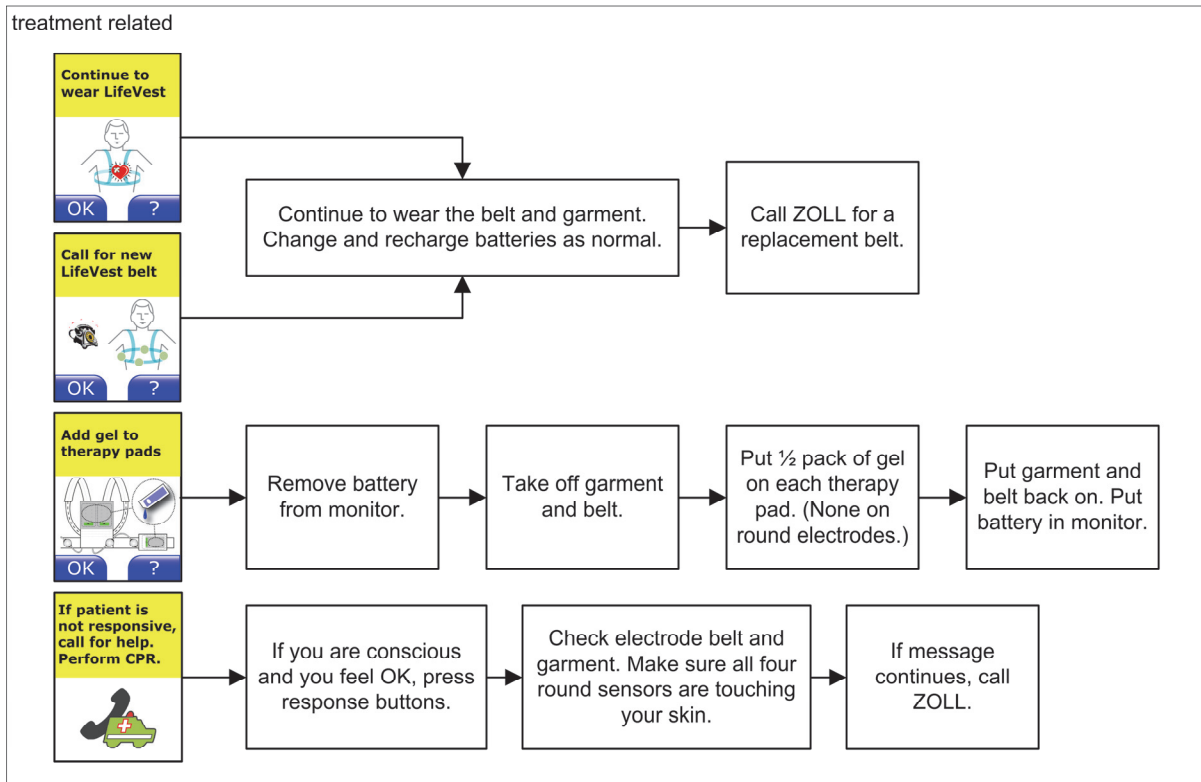
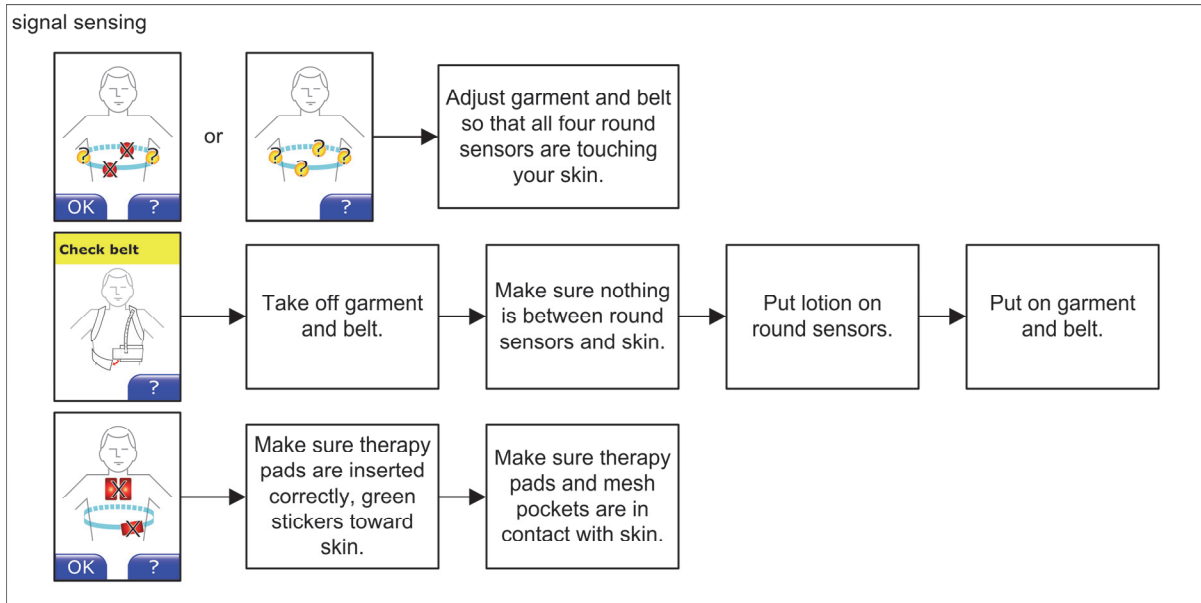


If you get an alert



Responding to a gong alert

This is just a partial list. For complete list and further details, see section 5.



Appendix B: Glossary









Arrhythmia	Abnormal heart rhythm.
Asystole	Heart stops beating.
Cardioversion defibrillation	Restoration of normal heart rhythm by electrical treatment.
ECG electrodes	Electrocardiogram electrodes, used to monitor heart rate.
Electrode	A solid electrical conductor through which an electric current enters and leaves a body.
Electrode belt	The belt that contains the ECG electrodes, the therapy pads, the vibration box, connector, and cables.
Electromagnetic interference (EMI)	Electrical or magnetic interference caused by sources such as motors, transformers, welding equipment, and speakers, that can interfere with device performance.
Fibrillation	Rapid, uncoordinated contractions of the heart muscle.
Garment	The cloth that holds the electrode belt in place against the patient's skin.
ICD	Implantable cardioverter defibrillator. Is implanted in the chest and is used to treat abnormal heart rhythms.
Joules	Units of measurement of shock energy.
MI	Myocardial infarction or heart attack. The damaging or death of a region of heart muscle usually resulting from a blocked blood supply to that area.
SCA	Sudden cardiac arrest.
SCD	Sudden cardiac death. Usually follows SCA.
Therapy pads	The large electrodes (one pad in front; two pads in back) that deliver defibrillating energy to treat SCA.
Ventricular fibrillation (VF)	Rapid, uncoordinated, and ineffective beating of the ventricles (lower portion) of the heart. Can be fatal if untreated.
Ventricular tachycardia (VT)	The lower portion of the heart muscle beats at a fast, abnormal rate. This can lead to VF if untreated.
VT/VF	Ventricular tachycardia/ventricular fibrillation. Primary abnormal heart rhythms responsible for SCA.

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Appendix C: Graphics glossary






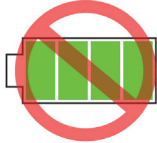









This appendix includes all the graphics, symbols, and icons you will see on your LifeVest® 4000 wearable defibrillator and accessories. This includes indicators and navigation buttons on the monitor and charger; symbols and safety signs on the device components and accessories; and graphics on the device, accessories, and packaging.
















C1: Navigation Buttons

	Menu button: Tap to see menu.
	OK button: Tap to acknowledge that you have read the screen. If any selections or changes were made on the screen, they take effect.
	Cancel button: Tap to back out of the screen. If any changes were made, they are disregarded.
	Translate button: Tap to change the language on the screen to the secondary language. Only shown when there is a secondary language.
	Help button: Tap to see help screen.
	X button: Tap to close the screen.
	Next page button: Tap to go to the next page when there is more than one.
	Previous page button: Tap to go to the previous page when there is more than one.

C2: Indicators

	Cell modem selected: Cellular modem is selected. Device is in range of the cell network and can transmit data. Number of bars indicates signal strength.
	No cell signal: No data can be sent via cell network.

	Monitor signal strength: Indicates strength of signal being sent from monitor. Number of pie pieces indicates signal strength. Signal must be present in order to send data.
	No monitor signal: No data can be sent from monitor.
	Battery level (on monitor): Number of bars indicates battery charge. Battery charging (on charger with touchscreen only): Animated to show that battery is charging.
	Battery empty (on monitor): Battery is discharged. Battery will still operate for a while but should be changed.
	Battery testing: Animated to show that battery is being tested. Charger with touchscreen only.
	Battery problem: Battery has a problem and may need to be replaced. Call ZOLL. Charger with touchscreen only.
	Power is being applied to the charger. Charger with indicator lights only.
	Battery is charging. Charger with indicator lights only.
	Battery is fully charged, ready for use in the monitor. Charger with indicator lights only.
	Alarm condition 1. Battery has a problem but still might hold a charge. Call ZOLL. Charger with indicator lights only (IEC TR 60878, 5307).
	Alarm condition 2. Charger has a problem and cannot charge the battery. Call ZOLL immediately. Charger with indicator lights only (IEC TR 60878, 5307).
	Battery testing. Charger with indicator lights only.
	Battery low: Battery is low, a critical situation. Change battery as soon as possible and recharge battery. Tap for help.
	Battery may be defective: LifeVest monitor cannot determine battery condition. Call ZOLL for service. Tap for help.
	Charger problem: Charger has a problem and cannot be used. Call ZOLL immediately. Charger with touchscreen only.

	ECG sensor good signal: Situation normal, no action required.
	ECG sensor poor signal: Check sensor for cause of poor signal and fix problem.
	ECG sensor off skin: Check sensor that is off skin and fix problem.
	Therapy pad on skin: Situation normal, no action required.
	Therapy pad off skin: Check electrode that is off skin and fix problem.
	Land line dialing mode: Shows that LifeVest device is connected to a land line phone or is connected to a secondary device. Charger with touchscreen only.
	Monitor transmitting: Monitor is transmitting data to the charger.
	Monitor trying to connect: Monitor is trying to connect to the charger.
	Airplane mode: Monitor will not transmit data.
	Monitoring mode: Animated to show that LifeVest WCD is in monitoring mode. Situation normal, no action required.
	Belt Disconnected: Animated to show that the electrode belt is not connected to the monitor and is not monitoring the patient's ECG. Connect belt to monitor so that LifeVest WCD can resume normal monitoring mode.
	Recording: LifeVest monitor is recording your ECG signal (manually activated).
	Service required: Device has a problem and requires service. Call ZOLL.
	Icon for health survey on patient setup menu.
	Icon for WalkTest® on patient setup menu.



Icon for trends on patient setup menu.

C3: Symbols



Indicates to machine wash on normal cycle with a maximum water temperature of 40°C (105°F) (ASTM D5489, 5.4).



Indicates to tumble dry on delicate/gentle with a low heat setting (ASTM D5489, 5.4).



Indicates to tumble dry on permanent press with a medium heat setting (ASTM D5489, 5.4).



Indicates to use only non-chlorine bleach when needed (ASTM D5489, 5.4).



Indicates to iron when needed with a low heat setting of 110°C (230°F) (ASTM D5489, 5.4).



Indicates the date when the medical device was manufactured (ISO 15223-1, 5.1.3).



Indicates the medical device manufacturer (ISO 15223-1, 5.1.1). Note: May also include manufacturing date.



Indicates the date after which the medical device is not to be used (ISO 15223-1, 5.1.4).



Identifies a defibrillation-proof type BF applied part complying with IEC 60601 (IEC 60417, 5334).















Identifies a type BF applied part complying with IEC 60601-1 (IEC 60417, 5333).









Indicates on the rating plate that the equipment is suitable for Alternating Current (AC) only; to identify relevant terminals (IEC 60417, 5032).











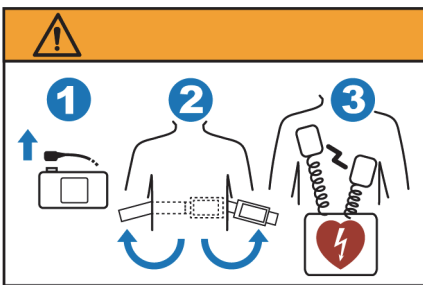
Indicates on the rating plate that the equipment is suitable for Direct Current (DC) only (IEC 60417, 5031).

	Indicates the manufacturer's catalogue number so that the medical device can be identified (ISO 15223-1, 5.1.6).
	Indicates the manufacturer's serial number so that a specific medical device can be identified (ISO 15223-1, 5.1.7).
	Indicates the manufacturer's batch code so that the batch or lot can be identified (ISO 15223-1, 5.1.5).
	Indicates a medical device that needs to be protected from moisture (ISO 15223-1, 5.3.4).
	Indicates a medical device that needs protection from light sources (ISO 15223-1, 5.3.2).
	Indicates a medical device that should not be used if the package has been damaged or opened (ISO 15223-1, 5.2.8).
	Indicates the range of humidity to which the medical device can be safely exposed (ISO 15223-1, 5.3.8).
	Indicates the temperature limits to which the medical device can be safely exposed (ISO 15223-1, 5.3.7).
	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment (IEC 60417, 5140).
	Identifies equipment meeting the safety requirements specified for Class II (IEC 60417, 5172).
IP21	Indicates the device is protected against solid foreign objects of ≥ 12.5 mm (0.5 inches) diameter, and has protection against vertically falling water drops (IEC 60529, 4).
IP22	Indicates the device is protected against solid foreign objects of ≥ 12.5 mm (0.5 inches) diameter, and has protection against vertically falling water drops when the enclosure is tilted up to 15°.
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself (ISO 15223-1, 5.4.4).
	Indicates the need for the user to consult the instructions for use (ISO 15223-1, 5.4.3).
CE ₀₁₂₃	CE marking with Notified Body designation.

	CE marking; indicates conformance with applicable European Directives and/or Regulations.
	UK Conformity Assessed marking; indicates conformance with applicable Directives and/or Regulations of Great Britain.
	Indicates the authorized representative in the European Community (ISO 15223-1, 5.1.2).
	Indicates the item is a medical device.
	Symbol for do not dispose of in unsorted trash. Return to a collection site intended for waste electrical and electronic equipment.
	Indicates a medical device that has not been subjected to a sterilization process ISO 15223-1, 5.2.7).

C4: Safety Signs

	Laundering symbol: No anti-static spray.
	Laundering symbol: No fabric softener.
	Battery: Do not incinerate.
	Battery: Do not short circuit.
	Identifies an item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment (ASTM F2503, 7.3.3).
	Indicates that the instruction manual must be read (ISO 7010, M002).
	Indicates general warning sign (ISO 7010, W001).
	Indicates the need for the user to take care to avoid coming into contact with electricity with a risk of electric shock (ISO 7010, W012).

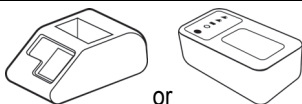


Warns the medical personnel to open the garment before giving the patient conventional external defibrillation (IEC 60601-1, 7.5).

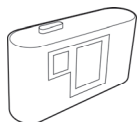
C5: Graphics



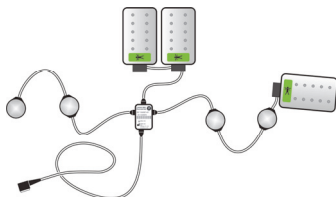
Packaging: Battery.



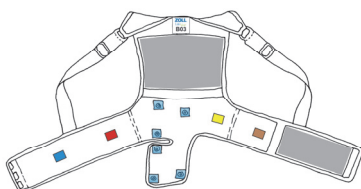
Packaging: Charger.



Packaging: Monitor.



Packaging: Electrode belt.



Packaging: Garment. May not appear on all packaging.



Therapy pad label: Place this side (silver side) of the therapy pad next to your skin.

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a physician (21 CFR 801.15, (c)(1)(i)(F)).

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Appendix D: Software licensing statement

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