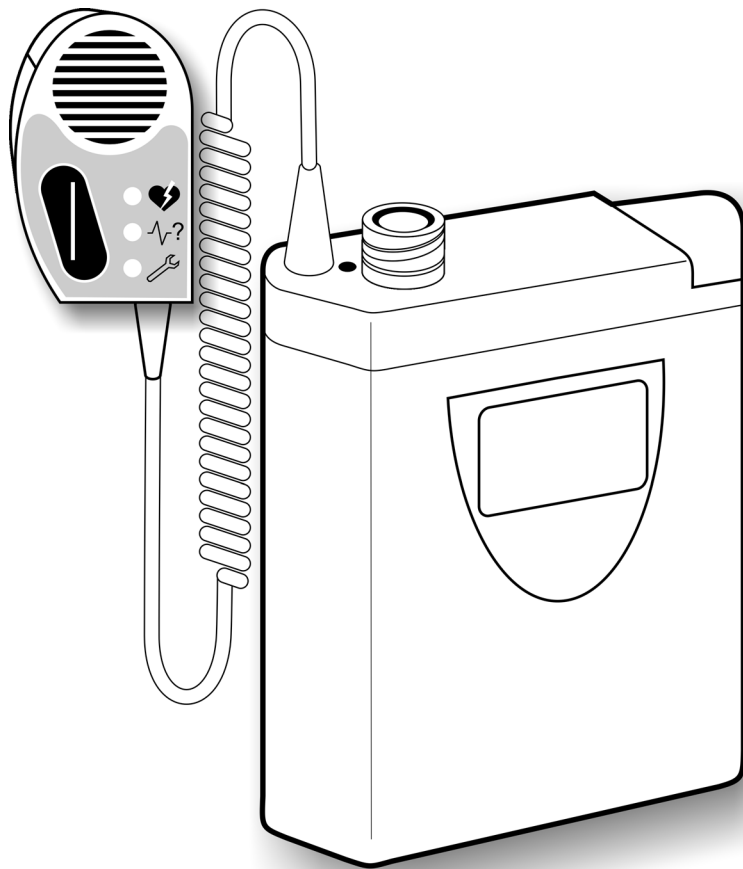


LifeVest[®]

Model WCD 3000

Patient Manual



ZOLL[®]

PN 20B0027 Rev M proposed

Restricted sale

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

Effectivity

This manual describes the LifeVest WCD 3000 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

US patents: 6,681,003; 6,280,461; 6,253,099; 6,169,387; 6,097,982; 6,065,154; 5,944,669; 5,929,601; 5,741,306; others pending.

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Glossary

Alarm Module	The module connected to the Monitor that contains the response buttons, OK button, Record button, Transmit button, speaker, and lights.
Arrhythmia	Abnormal heart rhythm.
Asystole	Heart stops beating.
Battery Charger	Charges the Battery Pack.
Battery Pack	Rechargeable batteries that power the Monitor.
Cardioversion Defibrillation	Restoration of normal heart rhythm by electrical shock.
Electrode	A solid electrical conductor through which an electric current enters and leaves a body.
ECG electrodes	Electrocardiogram electrodes, used to monitor heart rate.
Electrode Belt	The belt that contains the ECG electrodes, the therapy pads, the vibration box, electrode belt connector, and connecting 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.
LifeVest device	Wearable components of the LifeVest System: Electrode Belt, Garment, Battery Pack, Monitor, and Alarm Module. Device is worn to detect and treat sudden cardiac arrest (SCA).
LifeVest system	LifeVest device, Battery Charger, and Modem.
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.
Modem	Connects to telephone line. When Monitor is connected to the modem, patient information can be sent to doctor.

Monitor	Monitors the patient's heart activity, and delivers a shock to treat an abnormal heart rhythm if needed.
Response Buttons	The buttons patient presses to respond to certain messages. Most importantly, the patient presses and holds response buttons to prevent a shock treatment from being delivered.
SCA	Sudden cardiac arrest.
SCD	Sudden cardiac death. Usually follows SCA.
Therapy Pads	The large electrodes (one pad in front; double-pad 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. This 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.

Preface

Recycling information

Battery packs

LifeVest Battery Packs contain lithium-ion batteries and are recyclable. Battery Packs should be recycled according to national, regional, and local governmental regulations. If recycling is not possible, contact your device provider. Do not dispose of Battery Packs in the trash. Do not incinerate batteries since they might explode.

Dispensed therapy pads

LifeVest therapy pads are not user recyclable. After use, the entire electrode belt should be returned to a ZOLL authorized service center.

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Chapter 1: Introduction

Chapter overview

This chapter describes the LifeVest System Wearable Cardioverter Defibrillator.

It explains:

- The purpose of the device and who should be wearing it.
- The party to contact if a problem arises.
- System components.
- Symbols used on the system and in the patient manuals.
- Warnings and cautions.
- An introduction to the system.

Please read this entire manual before wearing the device. Be sure to ask your doctor about anything you do not understand. Please read this chapter carefully. It contains warnings and cautions of which you must be aware.

This manual is a reference document. After reading it thoroughly, keep it on hand to refer to as needed.

Why did your doctor recommend the LifeVest System for you?

Your doctor recommended that you wear the device because you have a condition that puts you at risk for sudden cardiac arrest (SCA).

Are there alternatives to the LifeVest System?

There are several alternative practices and procedures:

- Sudden cardiac arrest treatment by emergency medical services (EMS) or by calling 911
- Automatic external defibrillators (AEDs) in the community
- Implantable cardioverter defibrillators (ICDs)
- Antiarrhythmic medication

If you need assistance

If you are experiencing health problems call your physician or clinic.

Call your prescribing physician (device provider) or ZOLL when problems arise with the system. In the USA, ZOLL can be contacted 24 hours a day, 7 days a week.

Outside of the USA, you must contact the prescribing physician.

Important phone numbers

Please fill in the following numbers if not already provided:

Doctor's Phone Number:

Doctor's Emergency Number:

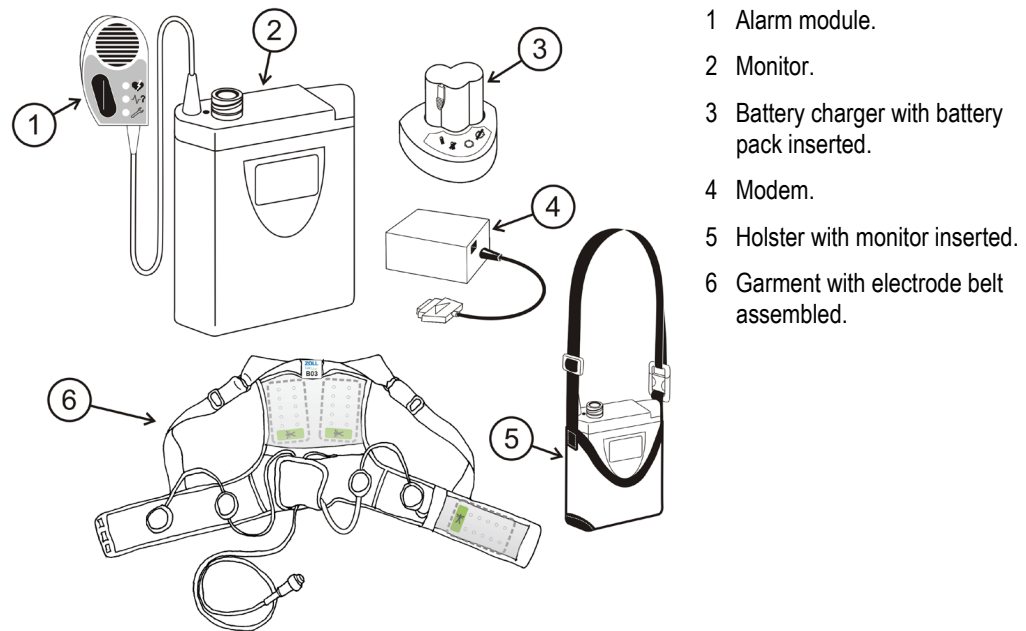
ZOLL in USA: 1-800-543-3267

Outside of USA, call prescribing physician:

LifeVest System components

The LifeVest device consists of the Monitor inserted into a Holster, an Alarm Module connected to the Monitor, a Battery Pack, an Electrode Belt, and a Garment.


The LifeVest system consists of the LifeVest device, a second Battery Pack, the modem, and the Battery Charger, which charges the Battery Pack.




Symbols



In the manuals, this symbol indicates warnings and cautions.

Warnings are indicated by:  **WARNING**








A **Warning** is a statement that alerts you to possible injury or death caused by misuse of the device.

Cautions are indicated by:  **CAUTION**

A **Caution** is a statement that alerts you to a possible problem or condition of operation. Such problems include possible device malfunction, device failure, or damage to the device or other property.

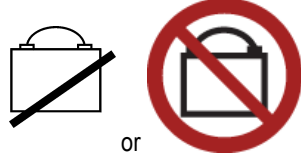
Throughout this manual, xx in a message represents a number such as heart rate. For example, xxx in the message Heart Rate xxx represents the heart rate in beats per minute.

Additional device and manual symbols are explained on the next pages.

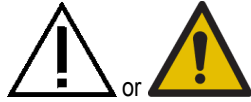
	Alarm module symbol: Abnormal heart rhythm.
	Alarm module symbol: monitor is receiving an unclear ECG signal.
	Alarm module symbol: Device needs attention or service.
	Battery charger is charging and/or testing battery pack.
	Battery charger needs service.
	Battery pack charged.
	Battery pack needs service.



Battery pack: Do not incinerate.



Battery pack: Do not short circuit.



Caution: Consult accompanying documents.



Monitor connector: Type BF defibrillator-proof connector.



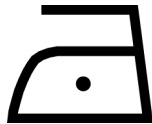
Laundering symbol: Normal cycle in warm water.



Laundering symbol: Tumble dry warm.



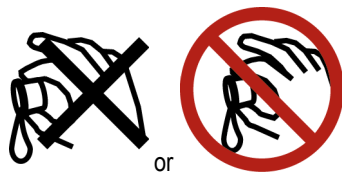
Laundering symbol: Only non-chlorine bleach, when needed.



Laundering symbol: Iron on low temperature.



Laundering symbol: No anti-static spray.



Laundering symbol: No fabric softener.



Manufacturing date.



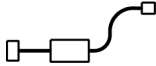
Manufacturing location.



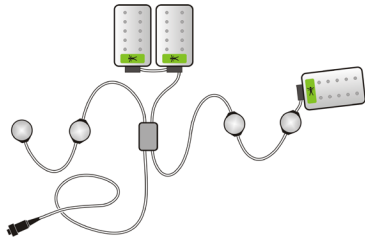
Packaging: Monitor.



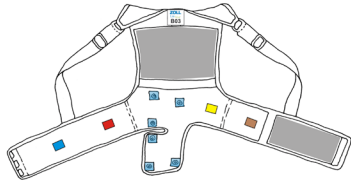
Packaging: Modem.



Packaging: Electrode belt.



Packaging: Garment.



Power supply electrical information: Alternating current (AC).



Power supply electrical information: Direct current (DC).



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

Warnings and cautions for patient



This section reviews the Warnings and Cautions. Please make certain that you read and understand these warnings and cautions.

A **Warning** is a statement that alerts you to possible injury or death caused by misuse of the device. This includes device failure that could lead to you being unprotected by the device.

A **Caution** is a statement that alerts you to a possible problem with the device. Such problems include damage to the device or other property, or minor injury.

Warnings

- A complete understanding of the manual and patient training is necessary before using the LifeVest System. If you do not understand how to use the system you could inappropriately assemble or misuse the device resulting in a device that is unable to deliver treatment or delivers inappropriate treatment.

Patient protection:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Wear the device directly against skin. Do not wear clothing underneath the device. Make sure when putting on the assembled Garment and Electrode Belt, that the Garment doesn't become twisted. Check to make sure that the metallic sides of both front and rear Therapy Pads makes contact with your bare skin when you wear the Garment, or a defibrillating pulse cannot be delivered. If you are a female patient, make sure that you wear a bra over the assembled Garment and Electrode Belt. Look in a mirror to make sure the Garment is being worn correctly.
- Always wear the LifeVest device and make sure the Electrode Belt and Battery Pack are properly connected to the Monitor. The device cannot detect an abnormal rhythm or deliver a treatment shock if not worn and properly connected.
- Do not let another individual wear your LifeVest device. The LifeVest device recognizes your heart rhythm pattern. If it detects an unfamiliar heart rhythm, it may shock that person.
- Remove the Battery Pack from the Monitor whenever the device is not being worn. For example, when you remove the device to take a shower, be sure to remove the Battery Pack first, to ensure the device is not active when you are not wearing it.

Shock hazard:

- Do not attempt to open the Monitor, the Battery Pack, the Alarm Module, the Battery Charger, or the modem. Doing so may expose you to high voltage, and damage the system.

Rescue defibrillation:

- If you should require conventional defibrillation, a warning label on the Garment informs medical personnel to unfasten and lay open the Garment, thus removing the front therapy pad from your chest. If they fail to do so, the LifeVest device may interfere with the defibrillation, and the conventional defibrillator may damage the LifeVest device.

Possible improper system performance

Environment:

- Do not operate or store the LifeVest system outside of the environmental ranges listed in Chapter 10, **What is the Operating Environment of the System**. To do so may damage the system.

Battery Pack:

- Completely insert the Battery Pack into the Monitor. If the Battery Pack is only partially inserted, the LifeVest device cannot detect an abnormal rhythm or deliver a treatment shock.
- Use ONLY the WCD 3000 Battery Pack with the WCD 3000 Monitor. Use ONLY the WCD 3000 Battery Charger when charging the WCD 3000 Battery Pack. To use any other battery pack or charger could cause the device to fail.

Electromagnetic interference:

Many common devices, including motors and electronic equipment, may produce electromagnetic interference that can affect the operation of the LifeVest device. The LifeVest device has been tested with a number of common sources of such interference, 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 interference.

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 U.S., these detector gates are commonly located near the doorways. In Europe, the detector gates may be positioned near the checkout areas.

To prevent possible interference 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 interference may be encountered. Examples of possible sources of such interference include: 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 interference causes you to receive arrhythmia alarms, press the response buttons to prevent being shocked and move away from the source of the interference. The LifeVest device should return to normal monitoring mode in approximately 5 seconds.

Cautions

Travel:

- This device has not been tested or approved for use on aircraft.

Shock hazard:

- Check the Monitor's display panel when you first turn on the LifeVest device to make certain that you have received the Monitor that has been programmed specifically for you. There is a chance of a false shock if you wear the wrong device. If the name is not correct, call your device provider immediately.

Possible improper system performance:

- Do not drop the LifeVest device. To do so may cause serious damage. If you do drop one of the device components, inform your device provider immediately.
- Do not put foreign objects, such as fingers, paper clips, or hair pins into any of the LifeVest system connectors or openings. Doing so may cause the system to fail.
- Protect the LifeVest device from moisture and extreme sunlight when wearing it outdoors. To protect the device, always wear clothing over the Garment and keep the Monitor and Battery Pack in the Holster.
- Do not put the Monitor, Battery Pack, Electrode Belt, Alarm Module, Battery Charger, or modem in or near water. Do not bathe or shower while wearing the LifeVest device. Also, before washing the Garment and Holster, be sure to remove the Electrode Belt and the Monitor with Battery Pack. The Electrode Belt, the Battery Pack, Battery Charger, Alarm Module, Monitor, and modem must not touch water. Doing so may cause the system to fail.

- Do not allow food or liquid to splash or drip on the LifeVest system. Doing so may cause the system to fail.
- Do not expose the LifeVest system to direct sunlight, excessive heat, or excessive cold for prolonged periods of time. Doing so may damage the system.

Risk of fire:

- Use appropriate caution in an oxygen-rich environment. As with any defibrillator, there exists the risk of a spark and fire during defibrillation.

Gel release:

- The therapy pads should not release gel unless a treatment shock is about to be given. Gel seepage at any other time indicates a damaged Electrode Belt. If this occurs, call your device provider immediately.
- Flush your eyes immediately with water and contact your physician if the therapy pad gel gets into your eyes. Your eyes may become irritated from the gel.

Bathing and showering:

- Bathe or shower in the evening, preferably when someone else is at home. Several studies indicate sudden cardiac death (SCD) occurs more often in the early morning.

To help ensure proper operation:

- Make sure the metal surface of each therapy pad is facing your skin. If the metal side is not facing your skin, you will not receive treatment shock(s) if needed.
- Press and hold both response buttons on the Alarm Module at the same time if you hear alarms, feel a vibration, and receive a message telling you to “Respond.” If you do not, you may receive a defibrillating electrical shock while conscious. To avoid receiving a defibrillating electrical shock while conscious, remember to always press and hold both response buttons when the device indicates that you should. If you receive a shock while conscious, it will be painful.
- 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.
- Do not press the response buttons by artificial means or by having another person press them for you. This would defeat the purpose of the response buttons.
- If you do not hear a tone or feel a vibration when you first turn the device on, disconnect the Battery Pack and the Electrode Belt from the Monitor and reconnect them. If it still does not operate normally, contact your device provider for a replacement.

- Do not put anything other than the Monitor and Message Manual into the Holster. The extra weight may pull the Electrode Belt from the body.
- Keep out of the reach of children.¹ The device may be damaged by improper handling.
- Use the LifeVest system only after understanding all training and instructions from authorized personnel to help ensure proper operation.
- Do not kink the cables. Kinking the cables may damage them and cause the system to malfunction.

Environment considerations related to noise and vibration

Certain environments or situations you encounter that are loud and have high vibration could affect the LifeVest. 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 or using some lawnmowers 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, 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.

¹ See indications for patients under 18 years of age.

What is the LifeVest device and how does it work?

The remainder of this chapter will introduce each part of the LifeVest system: the Electrode Belt, the Alarm Module, the Monitor, the Battery Pack, the Garment, the Holster, and the Battery Charger.

The following chapters describe the system in more detail.

Electrode Belt

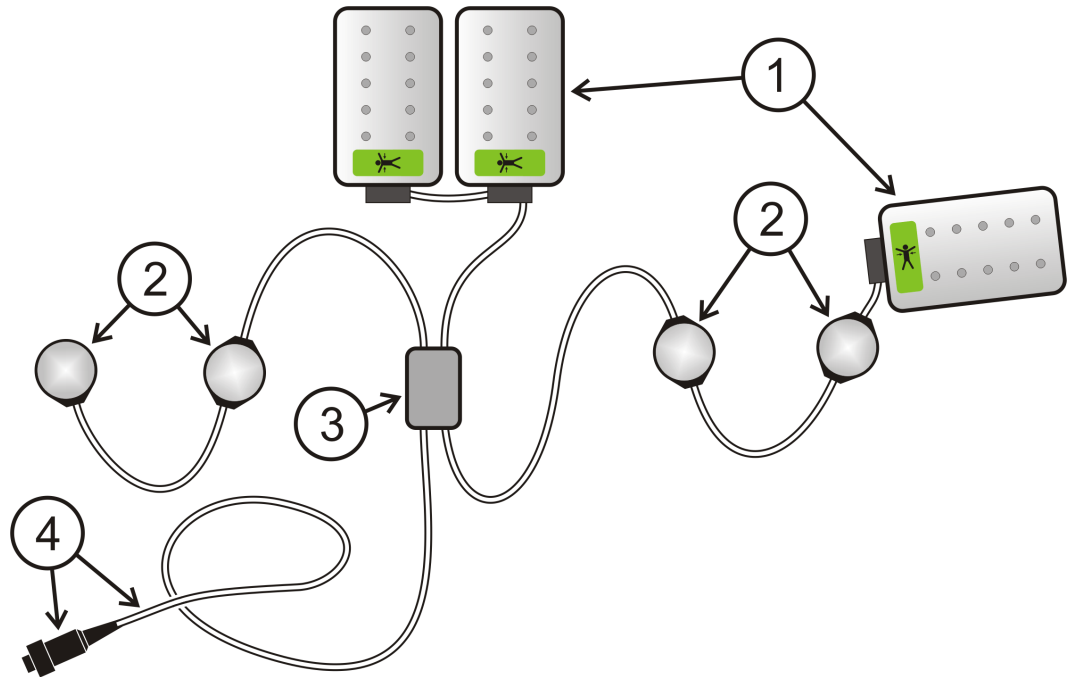
The Electrode Belt contains:

-
- 1 Therapy pads, which are the electrodes that deliver a shock to your heart to correct an arrhythmia.

 - 2 ECG electrodes, which are the electrodes that monitor your heart's rhythm.

 - 3 Vibration box notifies you of a possible shock delivery.

 - 4 Electrode belt cable and connector.

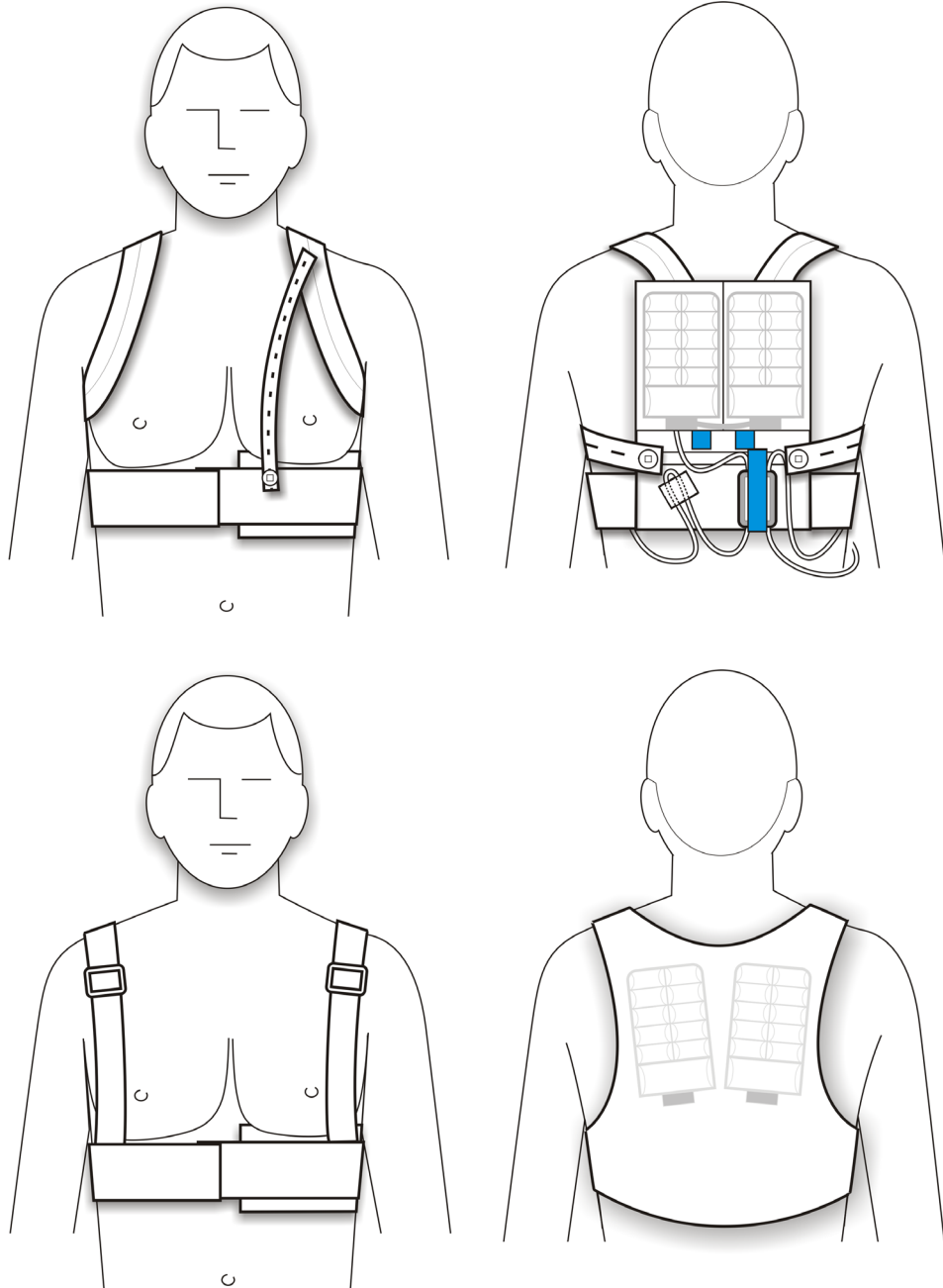


Garment

The Garment is worn under your clothing and holds the electrode belt in place. (A bra or T-shirt may be worn over the Garment.)

The Garment positions the electrodes and therapy pads against your chest, next to your skin.

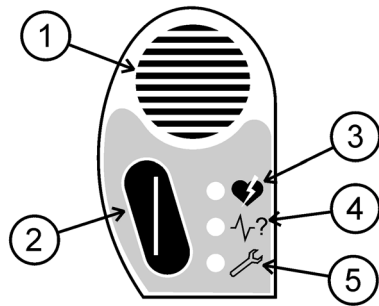
Proper positioning of the Electrode Belt is over the rib cage, just under the breast area, as shown below:



Alarm Module

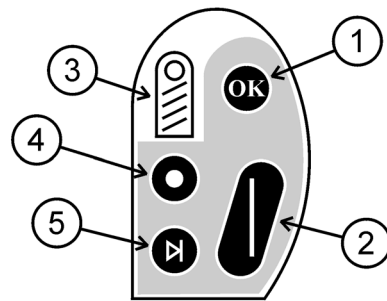
The Alarm Module, which is connected to the Monitor, can clip onto your belt or breast pocket. It alerts you to certain conditions with lights and voice messages. Check the Monitor's display panel to see if a message accompanies the light.

The front of the module features:



- 1 Speaker.
- 2 One of the two response buttons.
- 3 Red light and a symbol of a heart receiving a shock to indicate an abnormal rhythm.
- 4 Yellow light and the symbol of a heart rhythm and question mark to indicate that one or more of the ECG signals are not clear.
- 5 Flashing yellow light and the symbol of a wrench to indicate that the device requires attention or service.

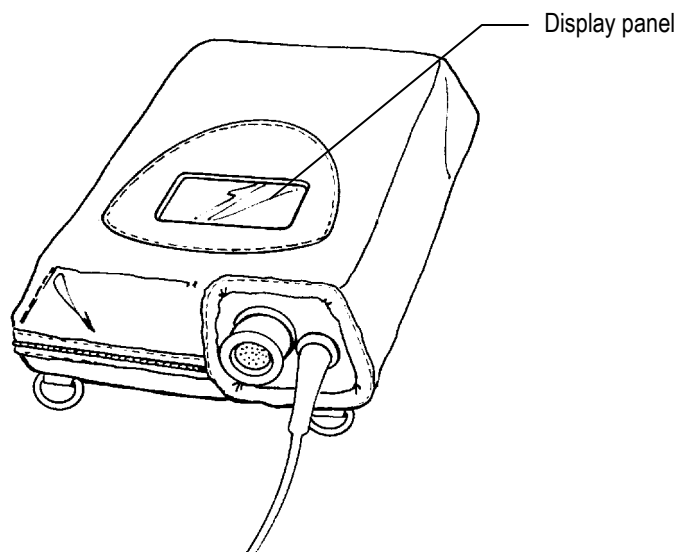
The rear of the Alarm Module features:



- 1 OK button.
- 2 One of the two response buttons.
- 3 Clip to attach the module to your belt, shirt, or jacket.
- 4 Record button.
- 5 Transmit (modem) button.

Monitor

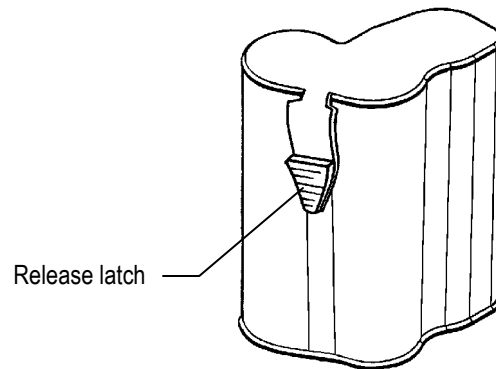
The battery-operated Monitor, shown below, monitors your heart's activity, and, if needed, delivers a shock to treat an abnormal heart rhythm. The Monitor also features a display panel to give you messages when necessary.



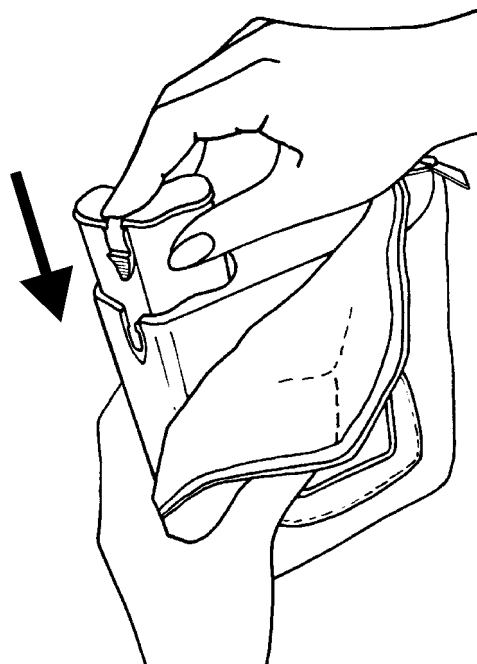
To operate the Monitor, slide the monitor out of the holster to expose the Battery Pack port. Insert the Battery Pack into the Monitor as shown on the next page. See Chapter 3, **How do you make the LifeVest Device Part of your Daily Routine**, for details.

Battery Pack

The Battery Pack, shown below, is a sealed plastic case that contains rechargeable batteries. To operate the Monitor, insert the Battery Pack into the Monitor. To recharge a depleted Battery Pack, insert it into the Battery Charger.

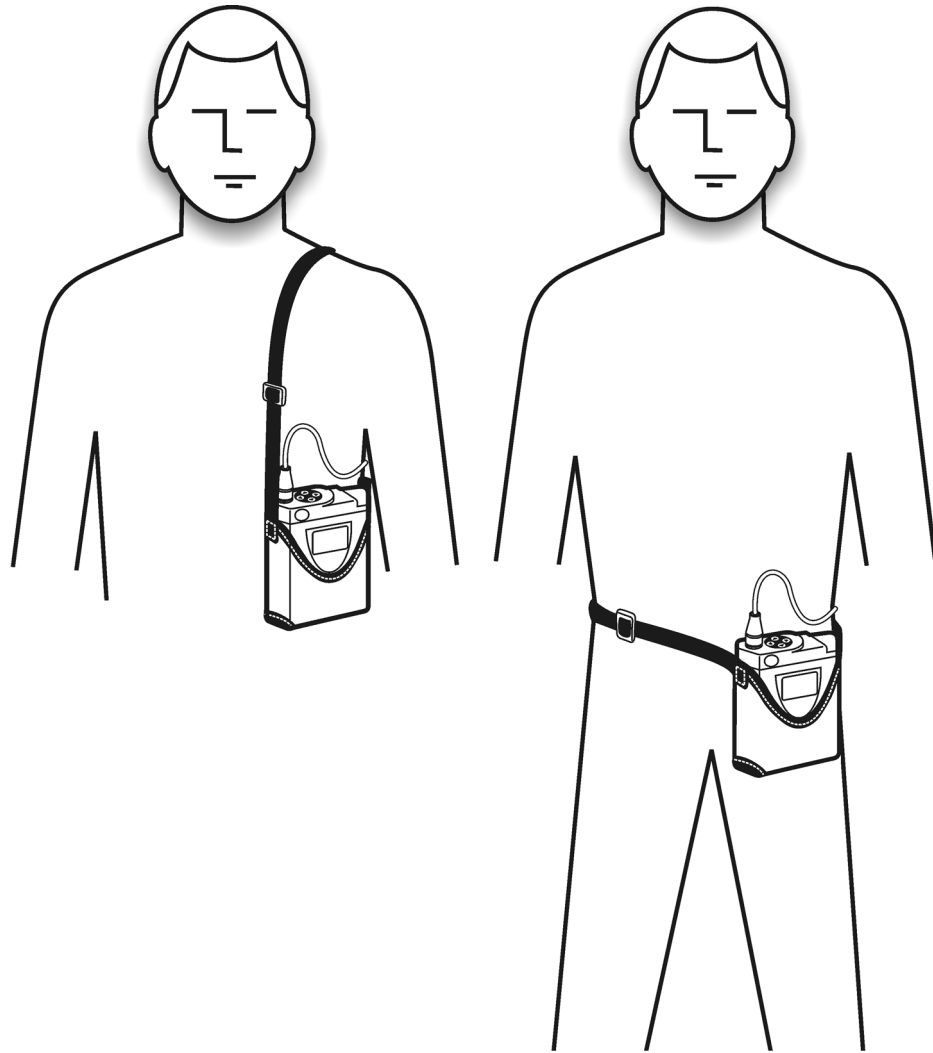


Connecting Battery Pack to Monitor:



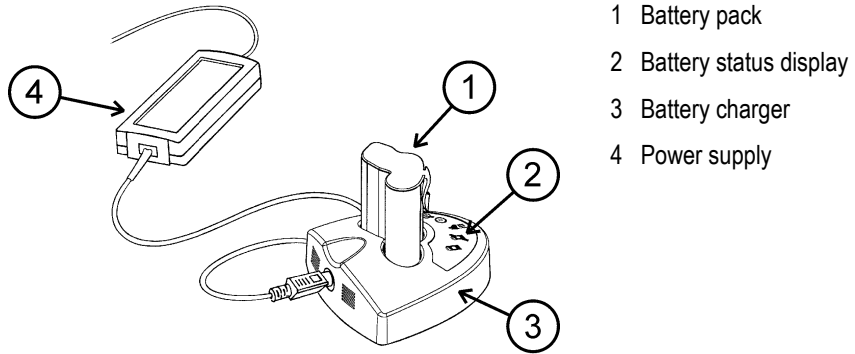
Holster

The Holster holds the Monitor in a comfortable position on your body. The holster strap is adjustable to give you several options for comfortably wearing the system.



Battery Charger

The Battery Charger charges the Battery Pack after approximately 24 hours of use.



Patient training

You will receive training at the hospital or at your doctor's office. In addition, you will receive a training video, a message manual, and this patient manual. Review these training materials and be certain to ask the training personnel if you have any questions about the LifeVest system.



Make sure that you read and understand all warnings and cautions given in this manual.

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Chapter 2: Who Should Wear This, Who Should Not?

Your physician has prescribed the ZOLL Wearable Cardioverter Defibrillator, or LifeVest device, for you because you are at risk of having an abnormal heart rhythm that may endanger your life. The LifeVest device is an automatic externally-worn defibrillator. Before wearing the LifeVest device, be certain that you have been told and that you understand its risks and benefits. If you have additional questions, ask your physician.

The LifeVest device is designed to monitor your heart for abnormal rhythms. Abnormal rhythms are detected by sensing your heart's electrical activity (similar to an ECG or electrocardiogram) on the skin surface of your chest. Because the LifeVest device is built into a comfortable garment, you can continue your normal day-to-day activities as your heart is being monitored.

If you have an abnormally fast heart rhythm and lose consciousness, the LifeVest device is designed to detect the abnormal rhythm and deliver a shock that, in most instances, should restore your heart rhythm to normal. However, if you remain conscious, you can and should stop the shock. If you do not, you will be conscious when a treatment shock is delivered. Shock delivery is described in Chapter 6, **What if you Experience an Abnormal Heart Rhythm?**

The LifeVest device should be used by patients who are at risk for sudden cardiac death (SCD), but who cannot or will not use an implantable defibrillator. You might need to wear the LifeVest device if:

- You are waiting for a heart transplant.
- You have had a heart attack or bypass surgery.
- You have heart disease or congestive heart failure.
- You are beginning pro-arrhythmic medications.

You should not wear the LifeVest device if:

- You have an active implantable cardioverter defibrillator (ICD).
- You have a mental, physical, vision, or hearing problem that could interfere with understanding the LifeVest device messages.
- You take medication that would slow down your ability to properly press the response buttons.
- You are unwilling or unable to wear the device continuously, except when bathing or showering.
- You have excessive electrode noise that makes the device unable to tell if you are having an abnormal heartbeat.
- You are a female patient who is pregnant, breast-feeding, or if you are not taking adequate birth-control measures if of childbearing age.
- You are under 18 years of age with a chest circumference of less than 26 inches (66 centimeters) and a weight of less than 18.75 kilograms (41.3 pounds).
- You have an advance directive prohibiting resuscitation.
- You have a pacemaker—consult your physician.

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Chapter 3: How do you make the LifeVest Device Part of your Daily Routine?

Chapter overview

Each day you should insert the Electrode Belt into a clean garment and insert a fully-charged Battery Pack into the Monitor. This chapter explains:

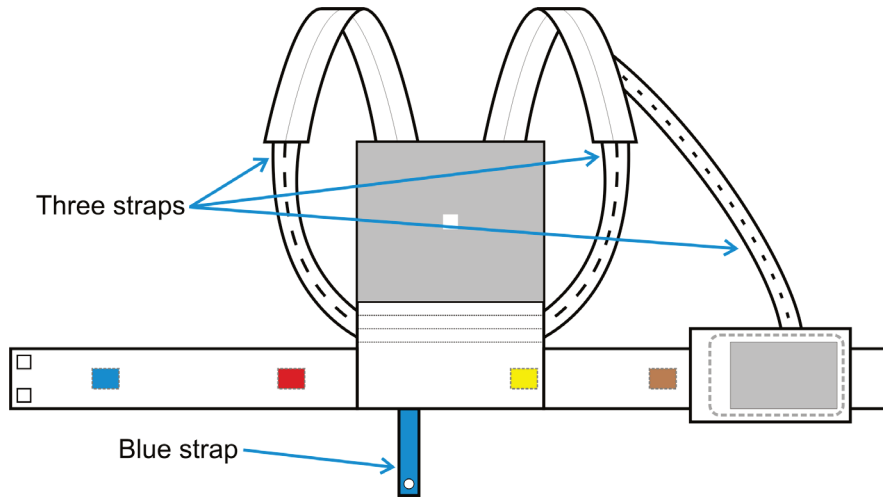
- How to assemble the Electrode Belt and Garment.
- How to use the Holster containing the Monitor.
- How to connect the Electrode Belt to the Monitor.
- How to insert a fully-charged Battery Pack into the Monitor.
- How to respond to messages.
- How to operate the Battery Charger.
- How to remove the device.

See the end of this chapter for a summary of the LifeVest device assembly and startup. You can also refer to Appendix A for a flowchart of the assembly and startup.

Which style garment do you have?

The first thing to do is figure out which style garment you have. Then refer to the instructions for the style you have.

Garment A

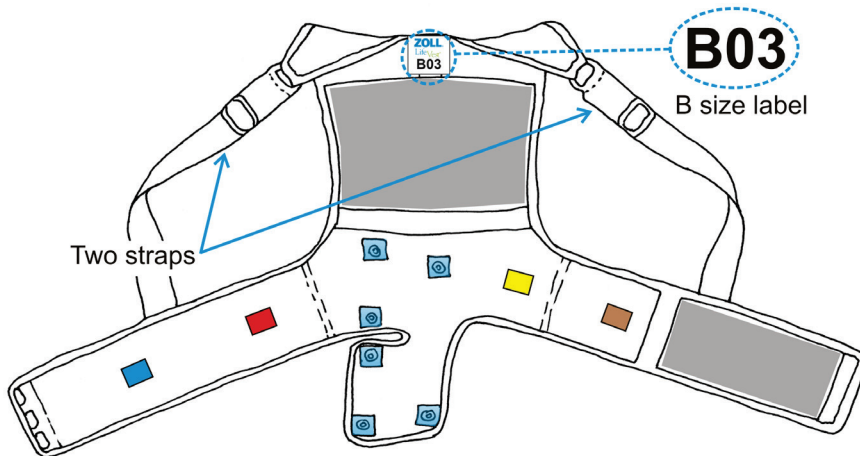


This style garment has three straps at the top, and a small blue strap at the bottom.

We call this garment style A.

If you have this style garment, see page 3-3.

Garment B



This style garment has two straps and a label showing the B size of the garment.

We call this garment style B.

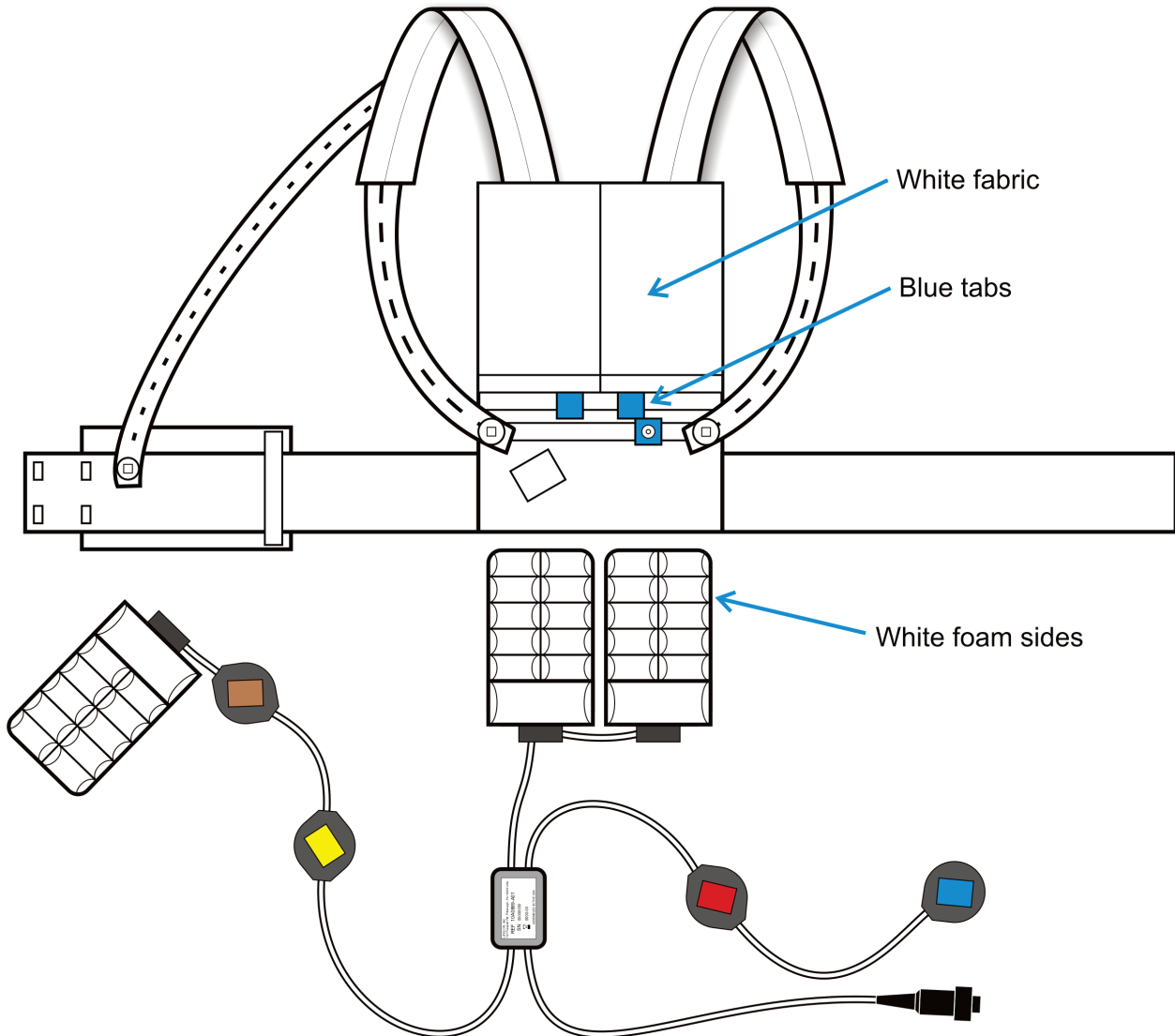
If you have this style garment, see page 3-13.

Assembling the electrode belt to garment A

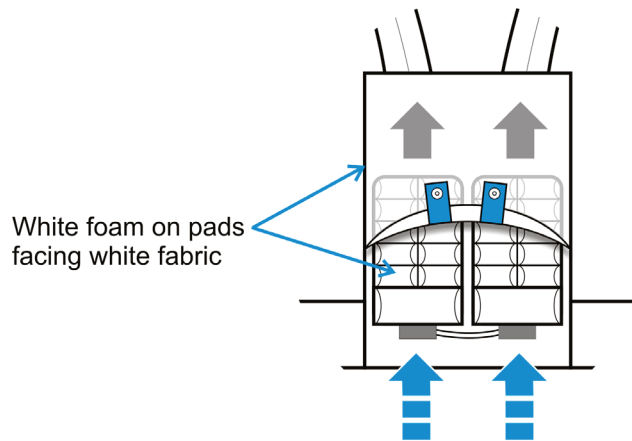
Refer to this section for garment A. If you have garment B, see page 3-13.

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

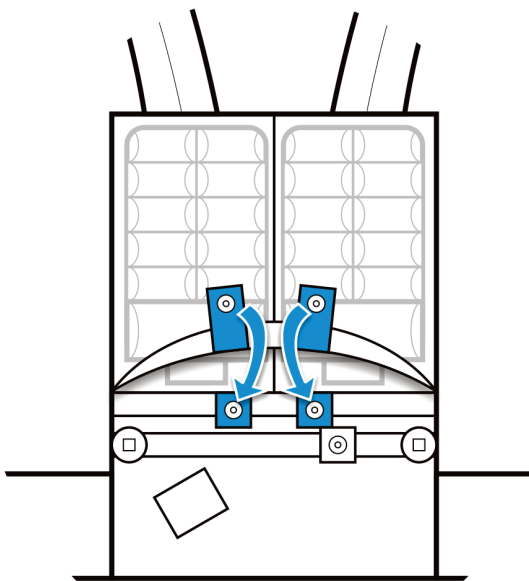
- Place the garment with the white fabric and blue tabs on the back pockets facing up.
- Place the electrode belt with the white foam sides of the therapy pads facing up.



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

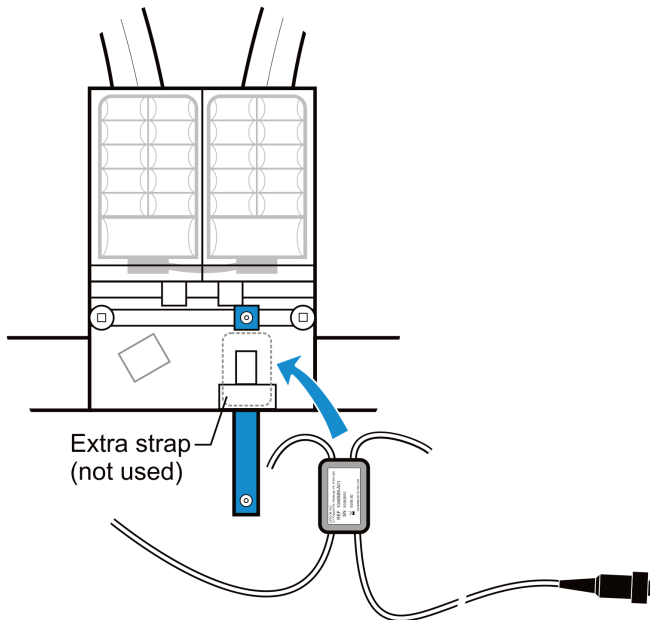


- Insert the pads with the white foam facing up, toward the white fabric.

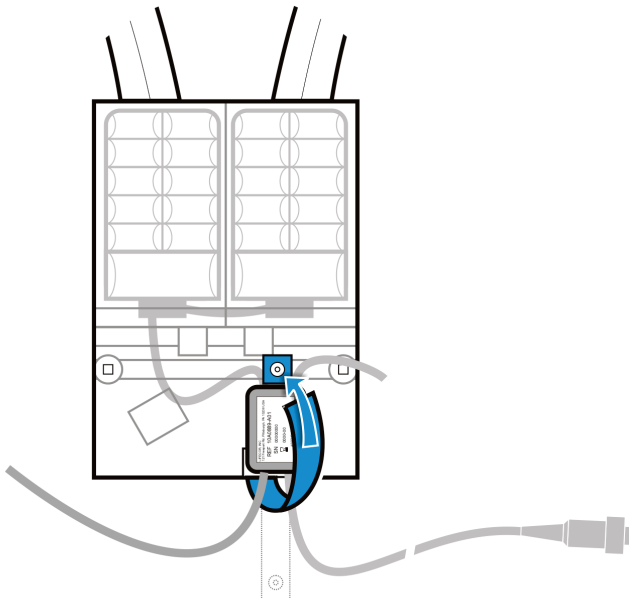


- Snap the blue tabs to secure the pockets.
- Make sure the snaps are securely fastened.

2 Position and secure the vibration box to the garment.

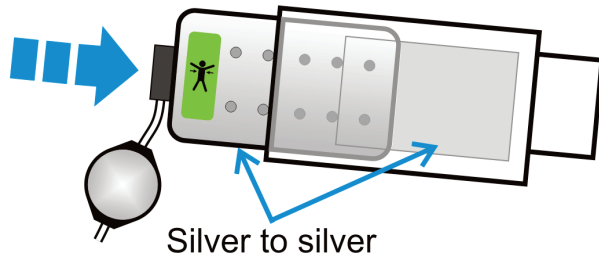


- Position the vibration box with the label side facing toward you.
- Position the box with the wires going up and down (not sideways), and with the connector cable exiting down.
- Your garment may have an extra strap (see figure to the left). This strap is not used with your electrode belt. Place the vibration box over the extra strap.

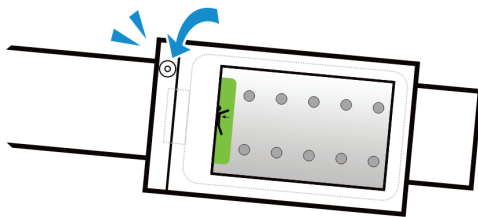


- Pull the blue strap up between the wires.
- Snap the blue strap over the vibration box.
- Make sure the snap is securely fastened.

3 Insert the front therapy pad into the front pocket.

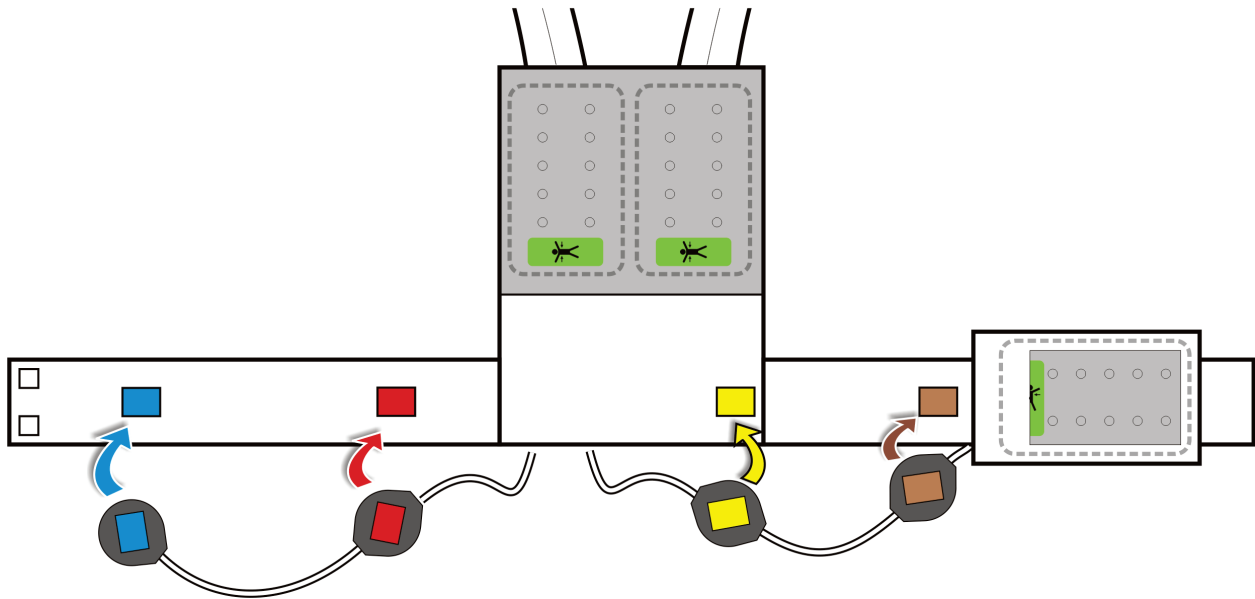


- Turn the garment over.
- Insert the pad with silver to silver. By that we mean to have the silver side of the pad (with the green sticker) facing the silver fabric on the pocket.



- 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 3-9.

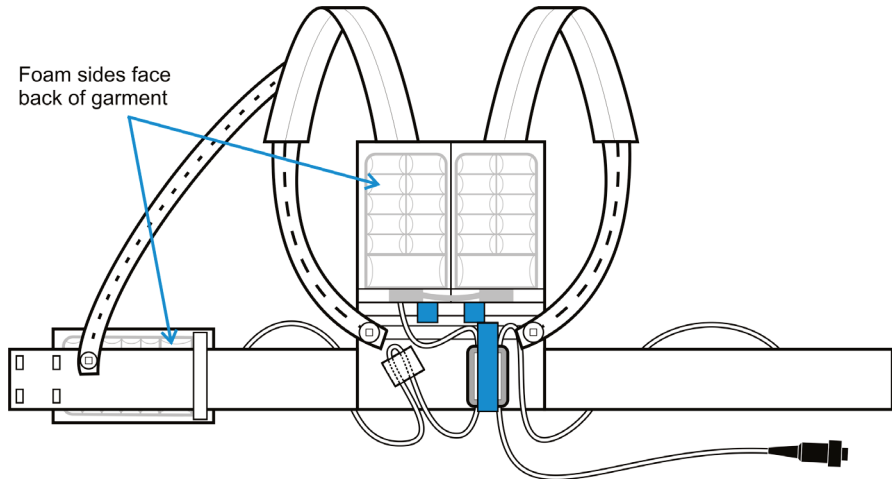
Assembled electrode belt and garment A

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

If the straps are not buttoned, button them now.

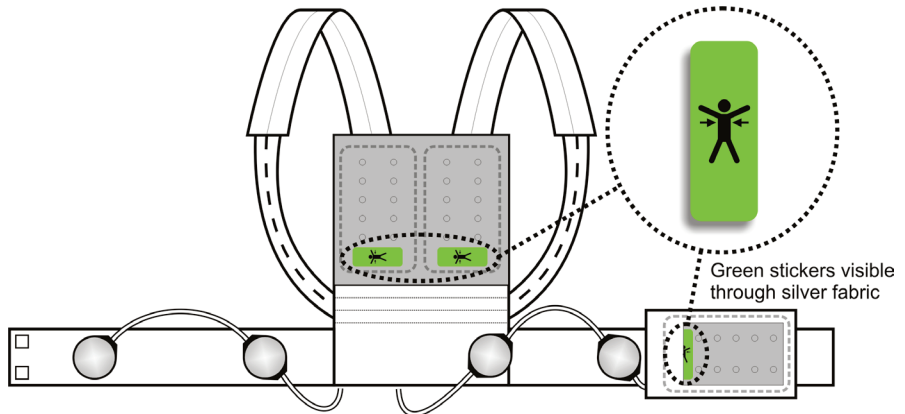
Outside view

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



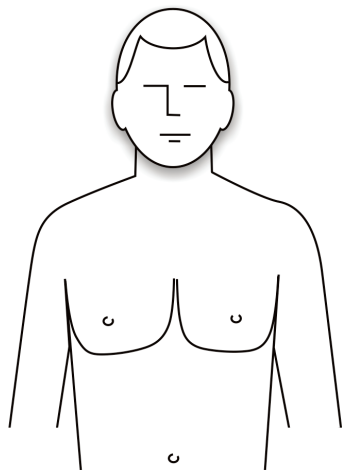
Inside view

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



Putting on the assembled electrode belt and garment A

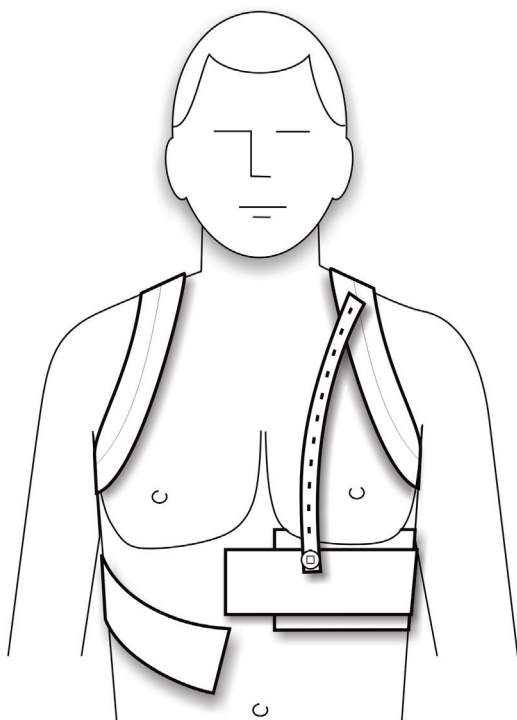
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 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:

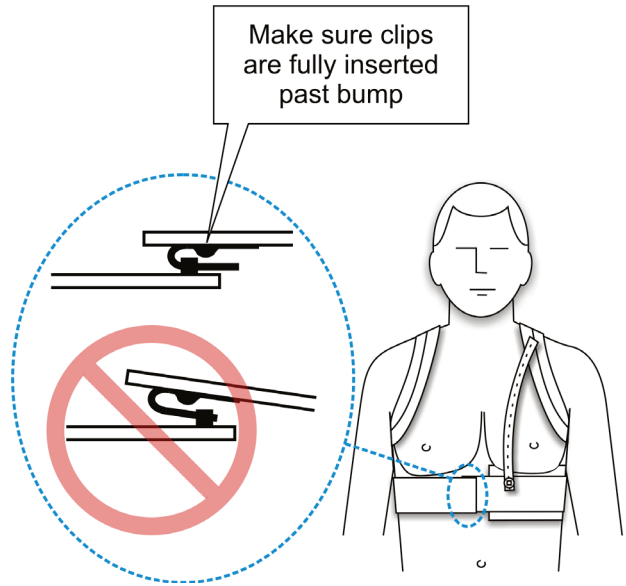
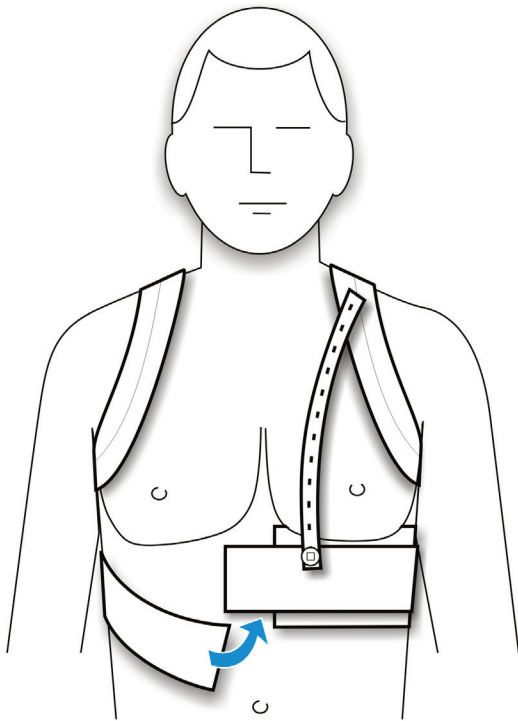
- The garment doesn't get twisted.
- The silver fabric pockets touch your bare skin.

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 is pressing against your body rather than the underside of your left breast.

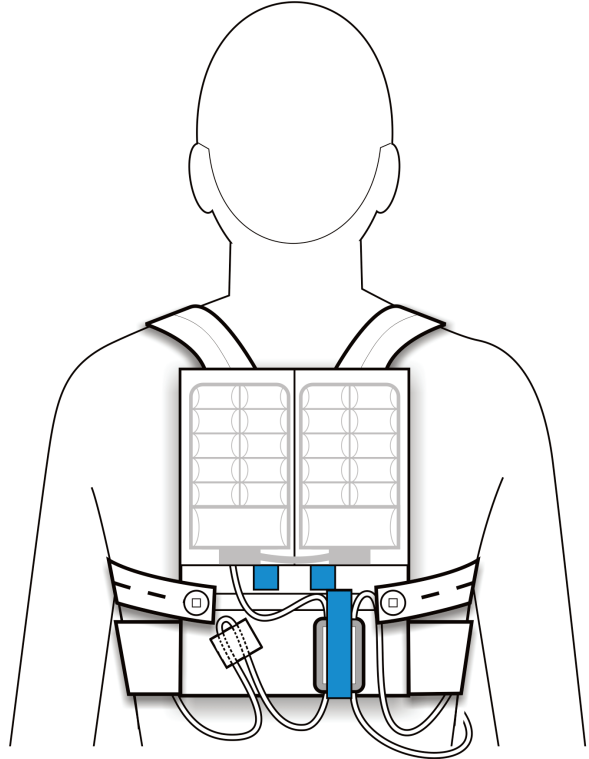
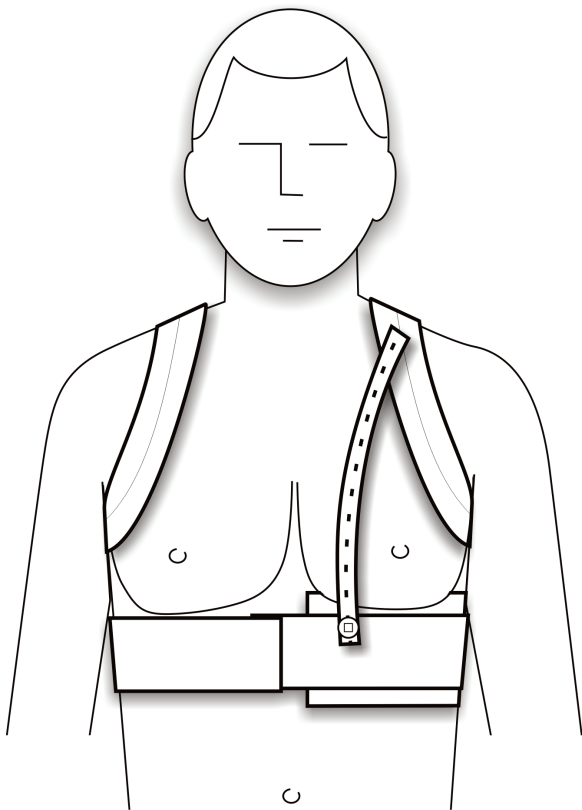
- 4 Connect the garment ends together in the front.

Make sure that the clips are fully inserted past the slight bumps in the clips.



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 silver fabric pockets and silver side 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 or therapy pads.
- The garment is being worn correctly. Your garment should look like the figures below.

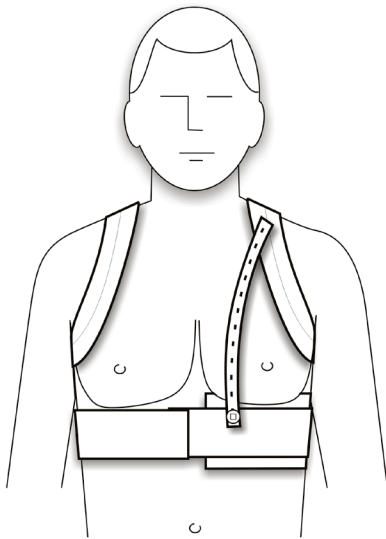
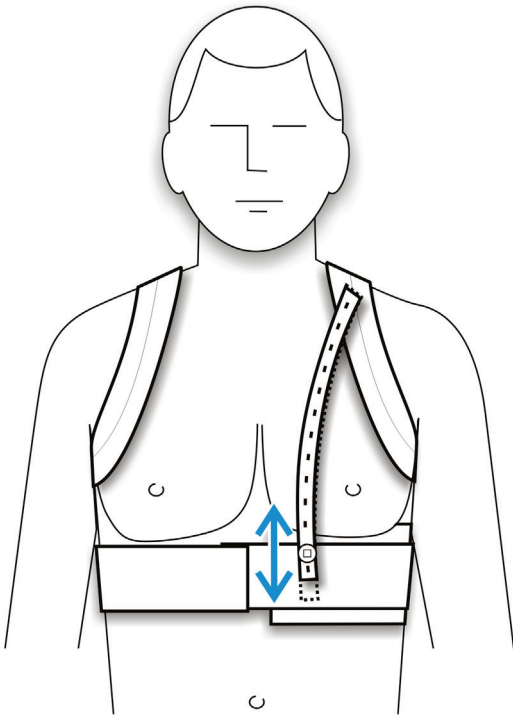


- 6 Check the position of the garment on your body and make sure it's not too high or too low.

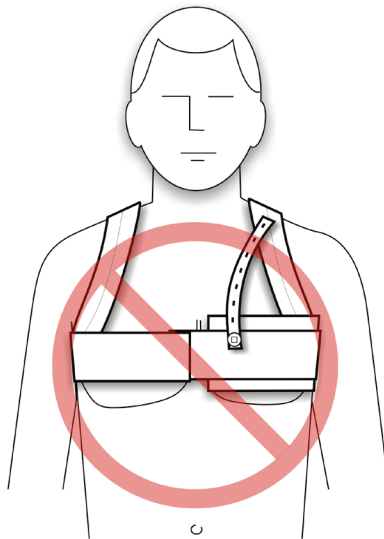
To position the garment properly, you may need to adjust the front strap.

Move the strap to the button hole that positions the garment properly, and for a snug fit.

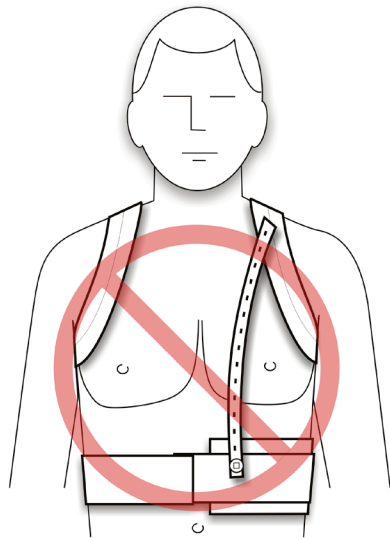
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



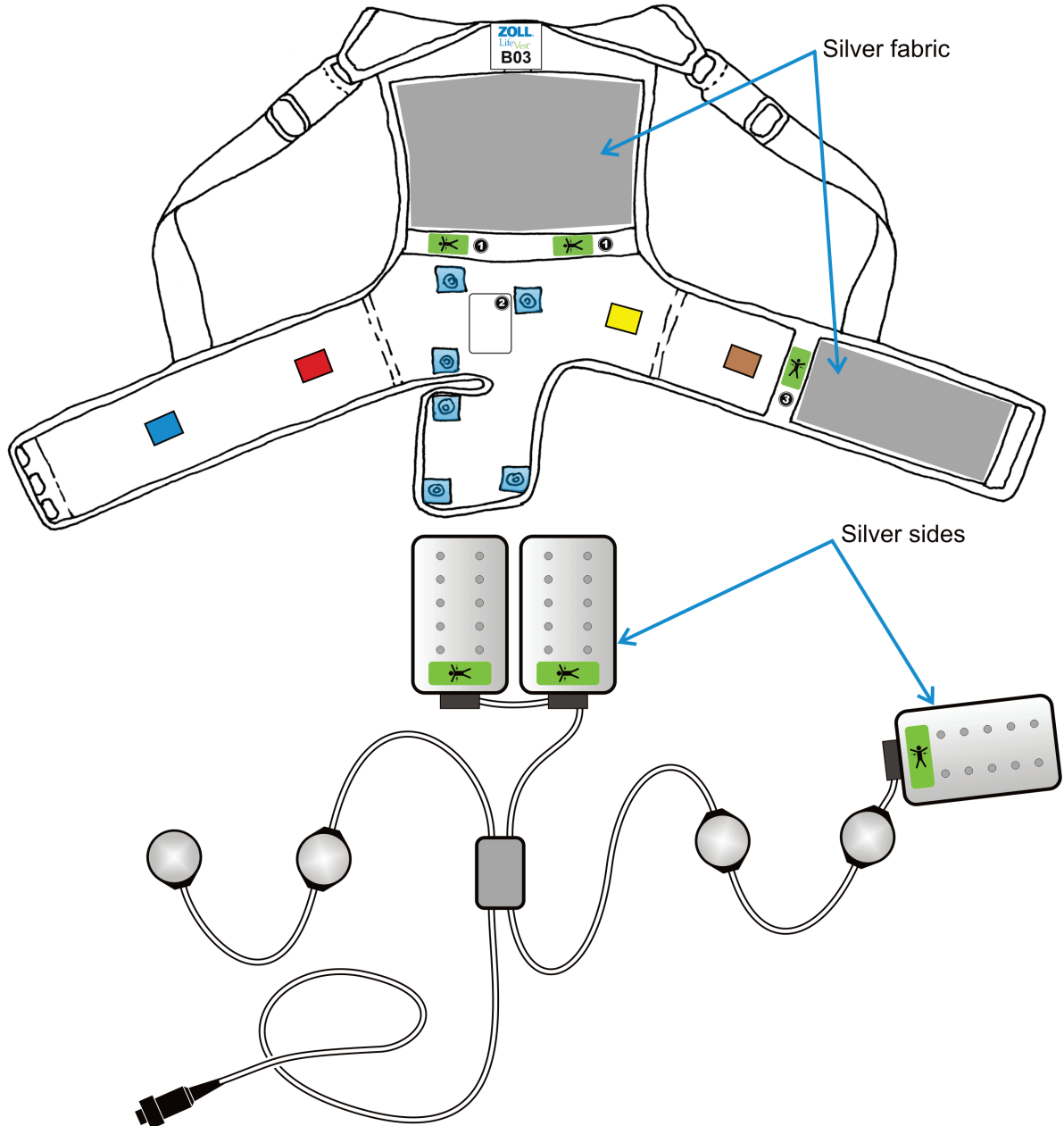
Too low

Assembling the electrode belt to garment B

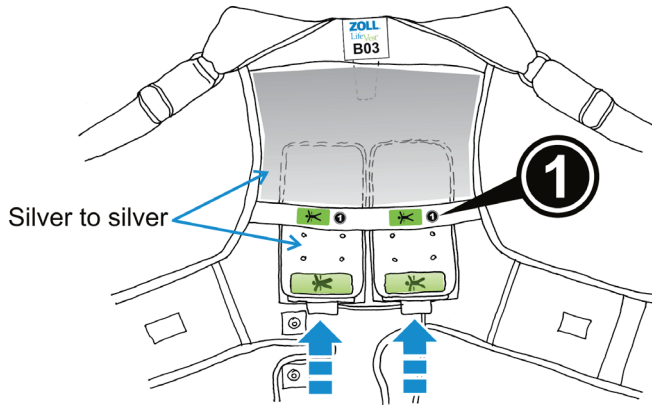
Refer to this section for garment B. If you have garment A, see page 3-3.

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

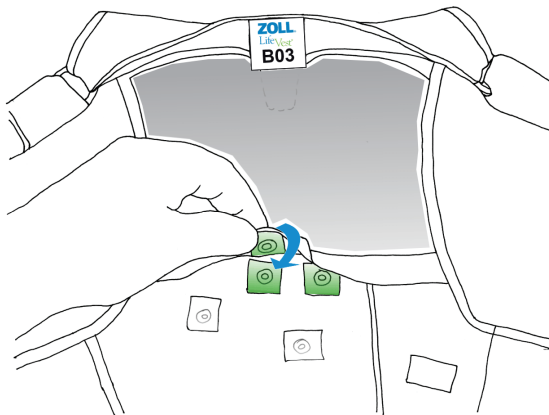
- Place the garment with the silver fabric facing up.
- Place the electrode belt with the silver sides of the therapy pads facing up.



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

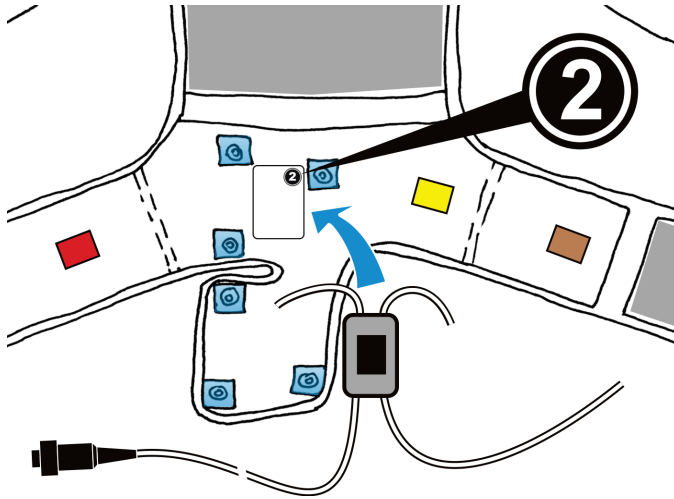


- The rear pockets are numbered 1.
- Insert the pads with silver to silver. By that we mean to have the silver sides of the pads (with the green stickers) facing the silver fabric on the pockets.

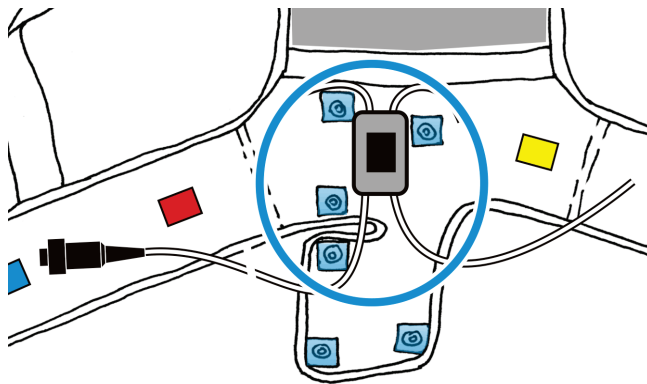


- Snap the green tabs to secure the pockets.
- Make sure the snaps are securely fastened.

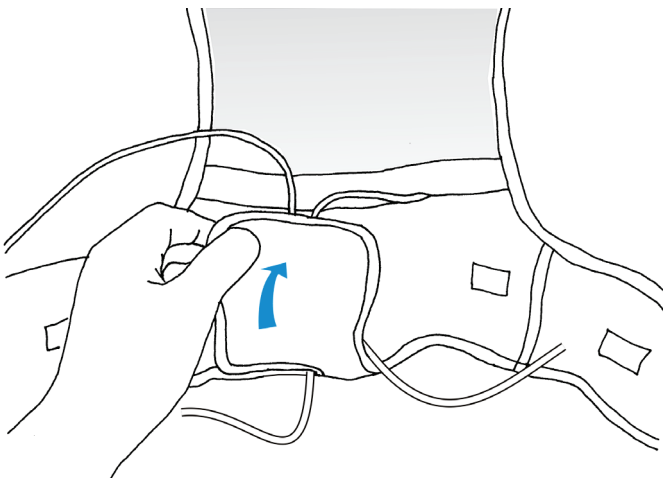
2 Position and secure the vibration box to the garment.



- The vibration box goes in position numbered 2.
- Position the vibration box with the label side facing toward the garment.

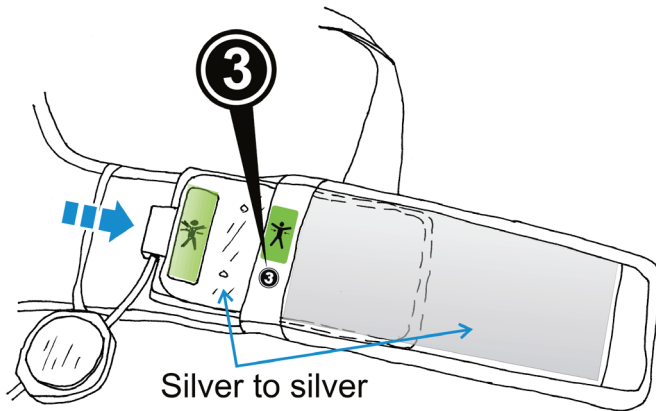


- Place the vibration box with the wires going up and down (not sideways), and with the connector cable exiting down.

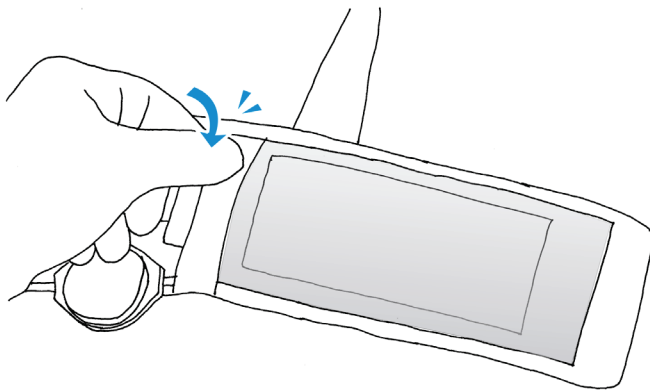


- Bring the flap up between the wires.
- Snap the flap over the vibration box to the blue tabs.
- Make sure all three snaps are securely fastened.

3 Insert the front therapy pad into the front pocket.

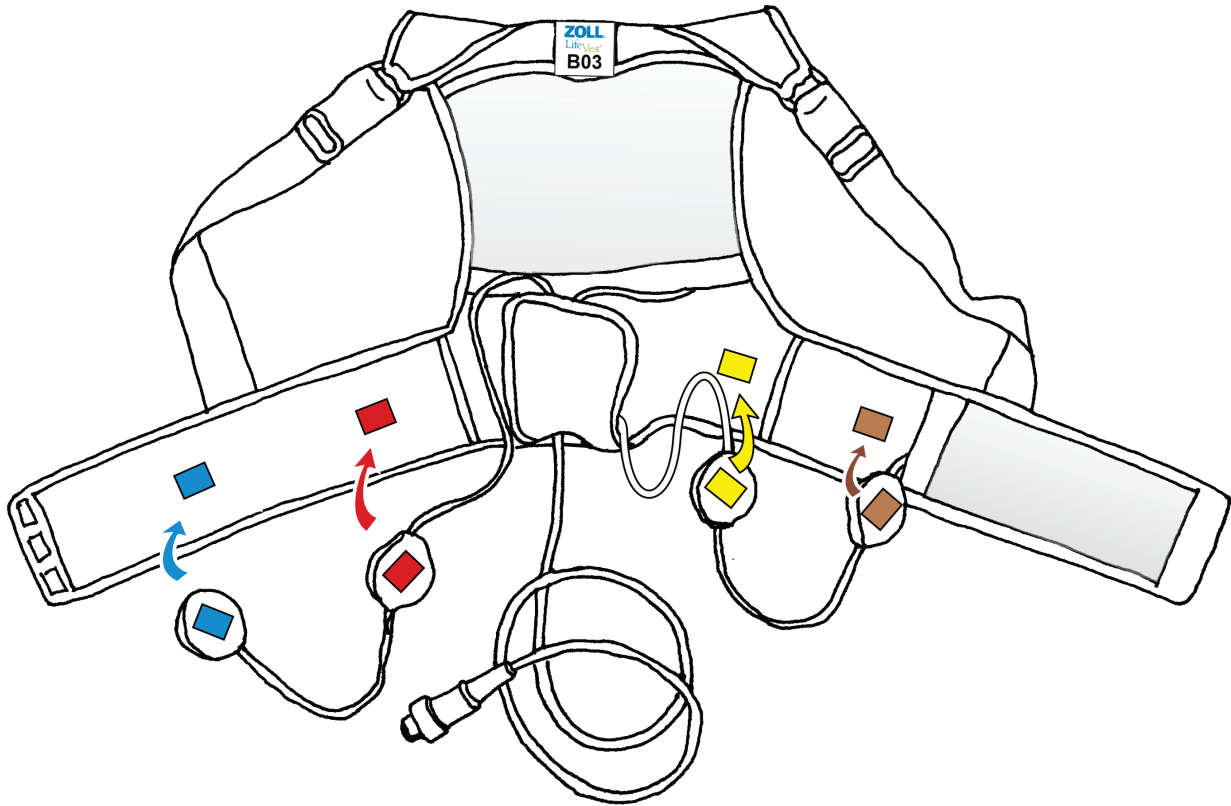


- The front pocket is numbered 3.
- Insert the pad with silver to silver. By that we mean to have the silver side of the pad (with the green sticker) facing the silver fabric on the pocket.



- 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.



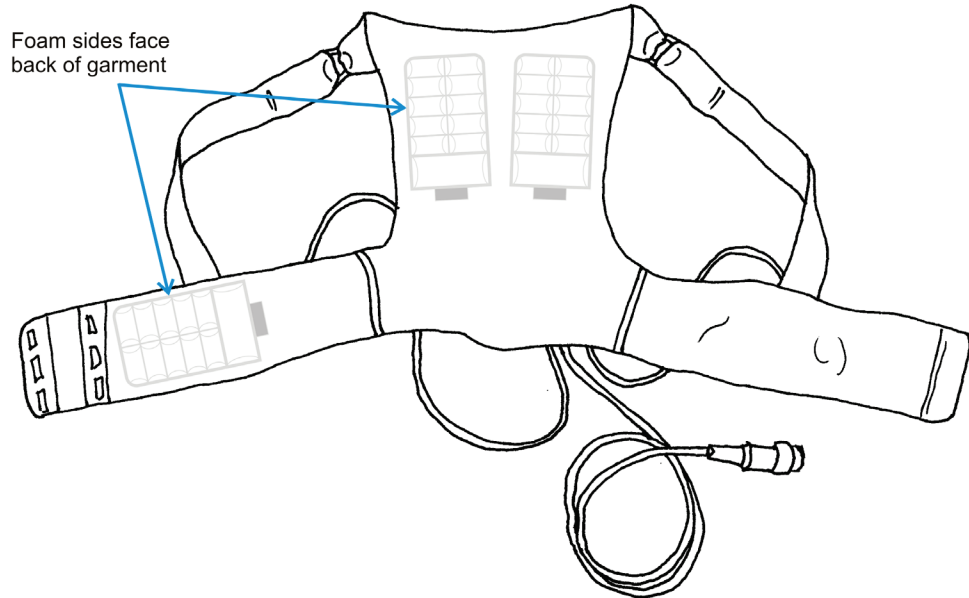
- 5 Make sure that you have properly assembled the electrode belt to the garment. See next page.
- 6 Then put on the assembled garment. See page 3-19

Assembled electrode belt and garment B

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

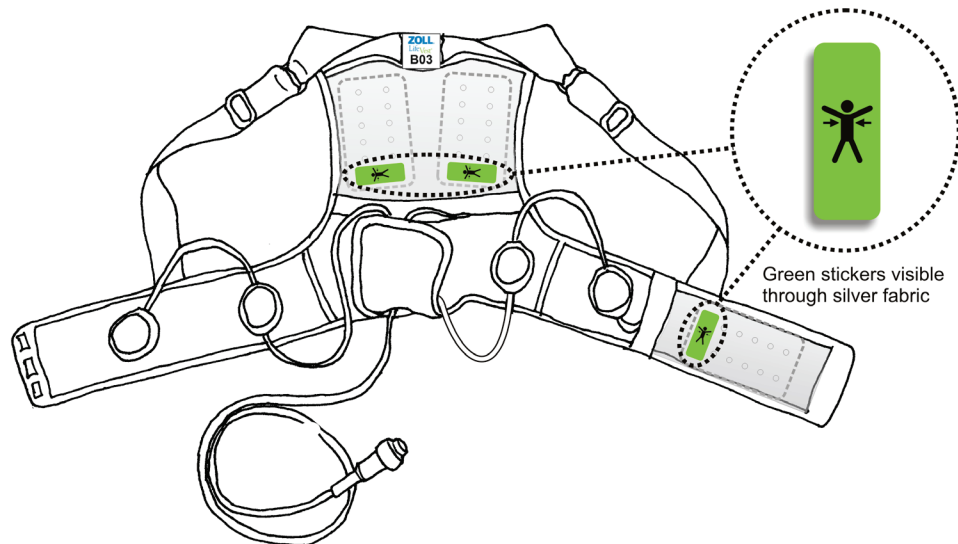
Outside view

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



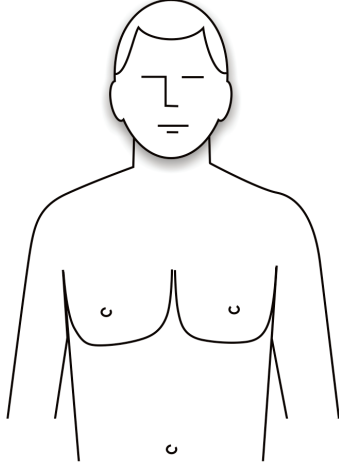
Inside view

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



Putting on the assembled electrode belt and garment B

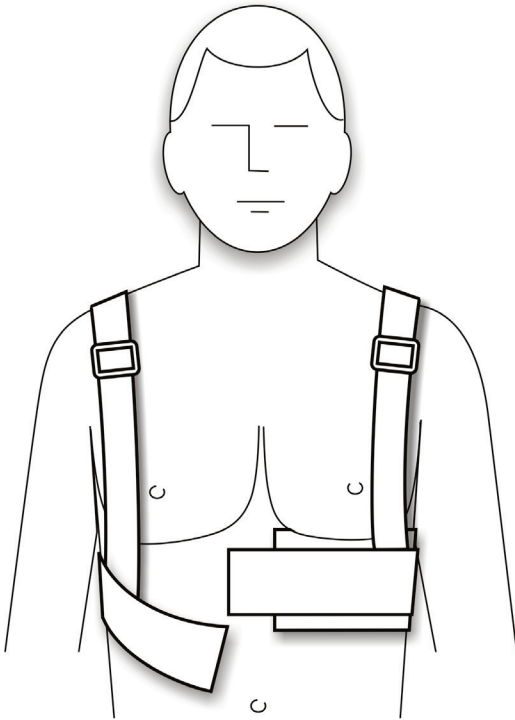
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 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:

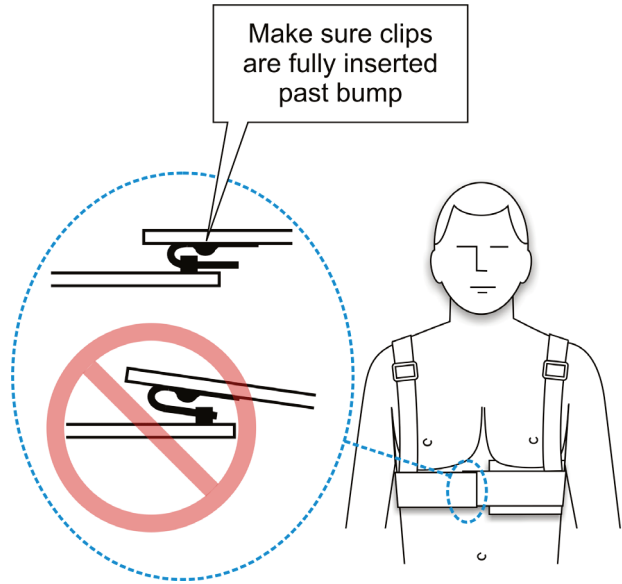
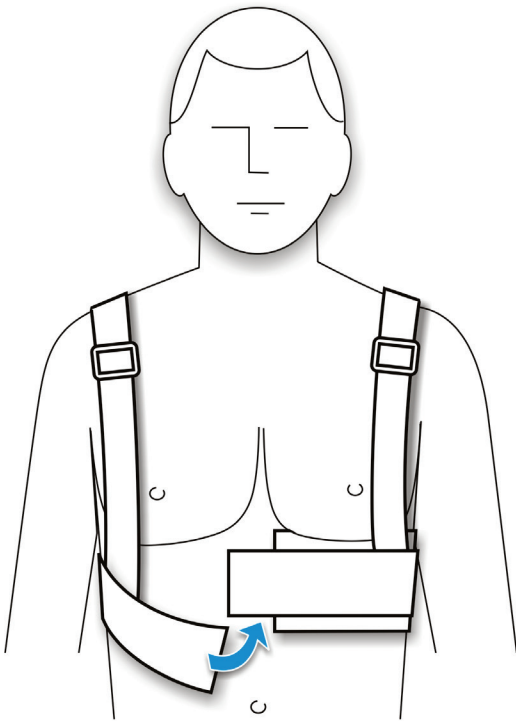
- The garment doesn't get twisted.
- The silver fabric pockets touch your bare skin.

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 is pressing against your body rather than the underside of your left breast.

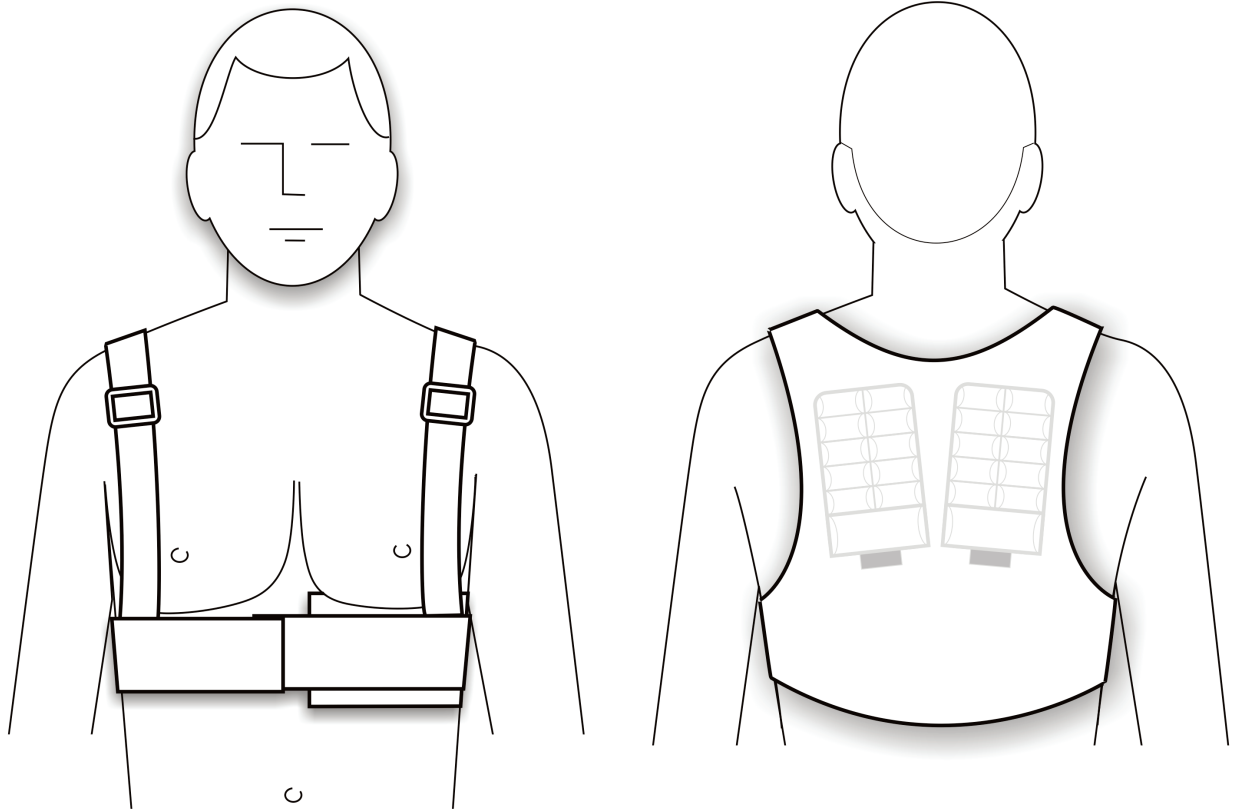
- 4 Connect the garment ends together in the front.

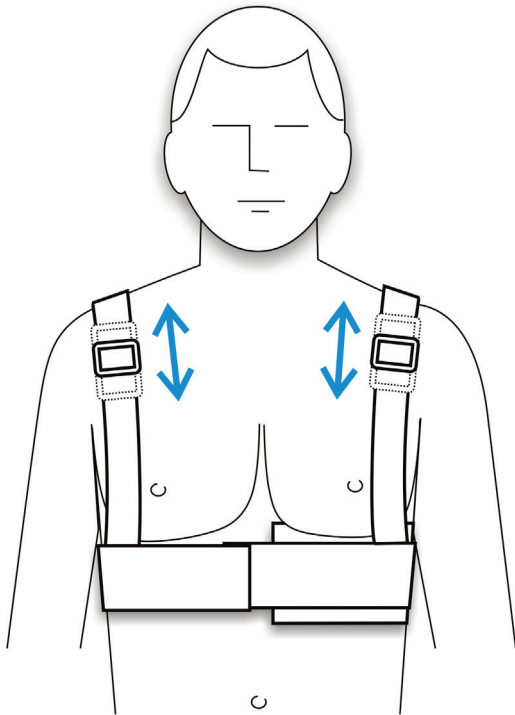
Make sure that the clips are fully inserted past the slight bumps in the clips.



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 silver fabric pockets and silver side 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.



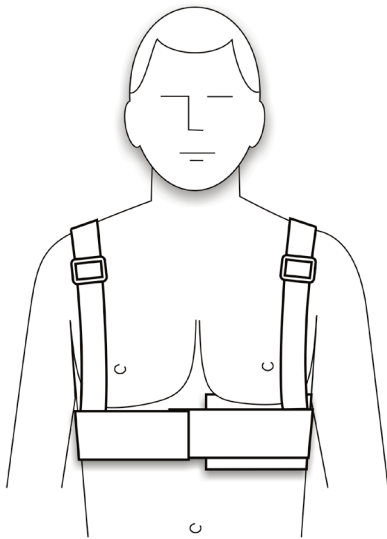


- 6 Check the position of the garment on your body and make sure it's not too high or too low.

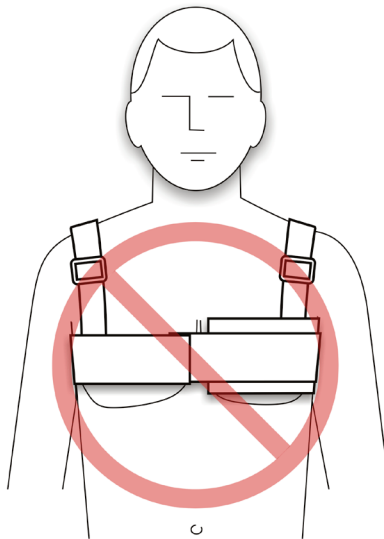
To position the garment properly, you may need to adjust the shoulder straps.

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

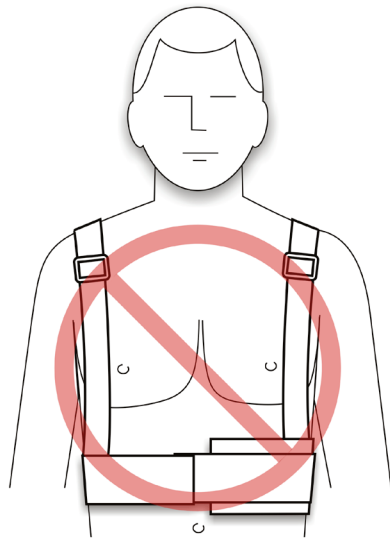
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



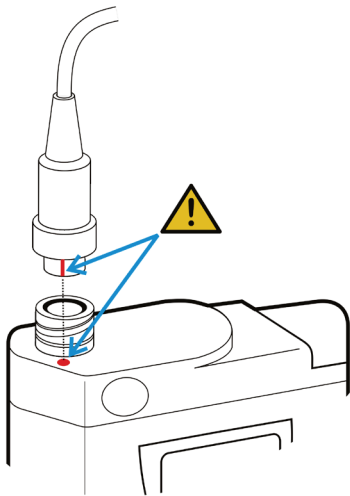
Too low

Connecting the electrode belt to the monitor

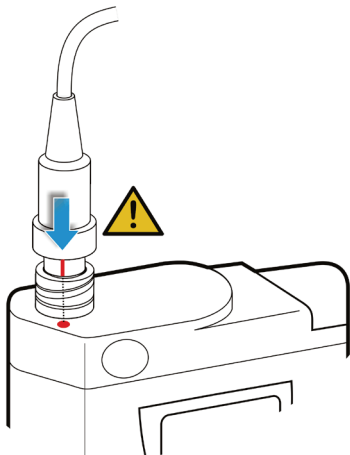
Normal daily use does not require disconnecting the electrode belt from the monitor. However, if you do need to disconnect the electrode belt, follow this procedure to reconnect the electrode belt to the monitor.



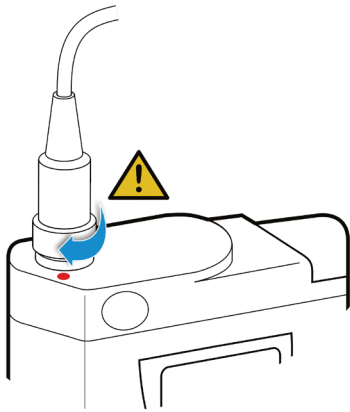
WARNING: Do not force the connector. Allow the connector to align before tightening. Forcing the connector may damage it and cause the system to malfunction. Failure to connect the electrode belt properly, or damaging the connector by bending the pins, can result in device malfunction. The device won't protect you because it won't be able to deliver a treatment.



- 1 Line up the mark on the connector with the mark on the top of the monitor.
 - The connector must be lined up before you push it into the monitor.
 - Don't turn the whole connector in order to line it up.
 - Don't force the connector.

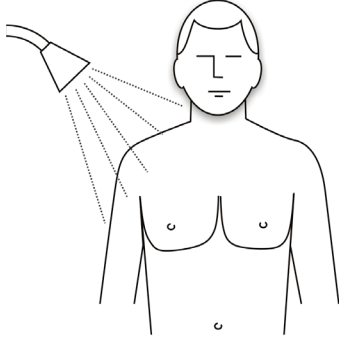


- 2 Push the connector in gently. Don't force it or try to steer it into position. Let it self align.
 - Gently push down on connector until it stops.
 - It should be seated on the connector far enough so that rotating ring contacts with the threads of the connector.
 - Don't force the connector into the monitor or you'll bend the pins.



- 3 Turn the connector ring clockwise to tighten. It should tighten in one to two turns.
- If you can turn the connector (the whole connector, not just the ring), it's not seated properly.
 - If you fail to line up the connector properly before turning the ring, the connector may not be threaded properly. You can tell because the connector ring doesn't tighten properly, or the connector isn't straight when it is connected.
 - To solve this problem, turn the connector ring counterclockwise until it spins freely. Then gently turn it clockwise to tighten.

Remove device when you shower or bathe



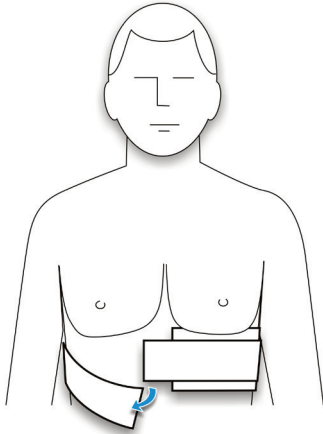
When you remove the device to bathe or shower, you are not protected by the device. Bathe or shower in the evening, preferably when someone else is home with you.

When you are not wearing 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

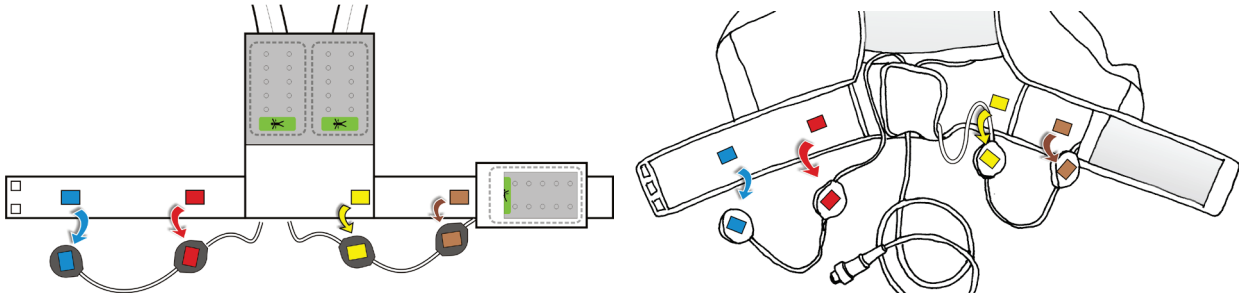
- 1 Remove the battery from the monitor.
- 2 Unbuckle and remove the holster. Keep electrode belt connected to monitor.
- 3 Unfasten and remove the garment from your body.



If you plan to change the garment, follow the procedure on the next page to disassemble the electrode belt from the garment.

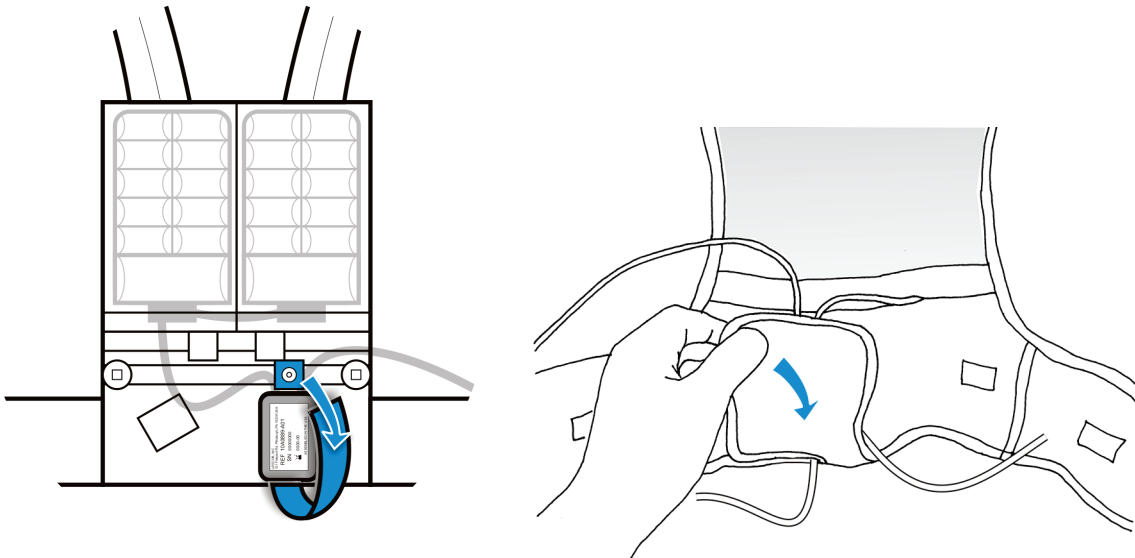
Disassembling the electrode belt and garment

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

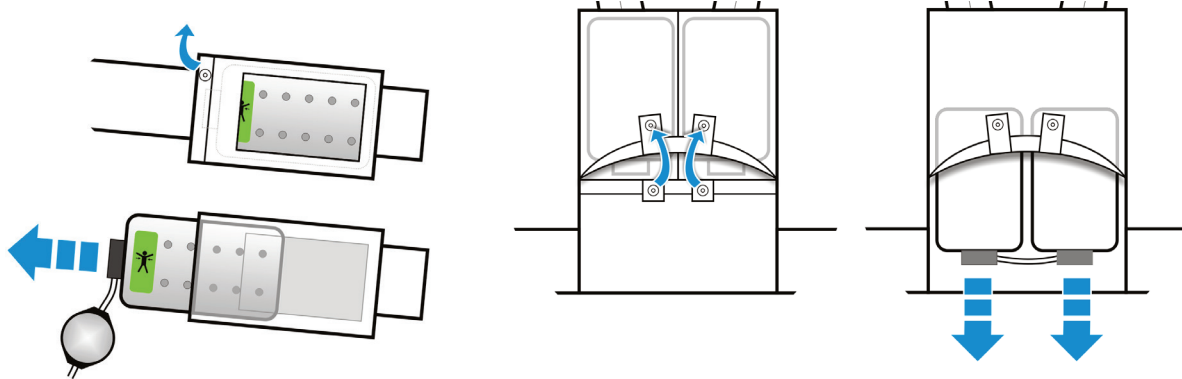


- 2 Remove the vibration box from the garment.

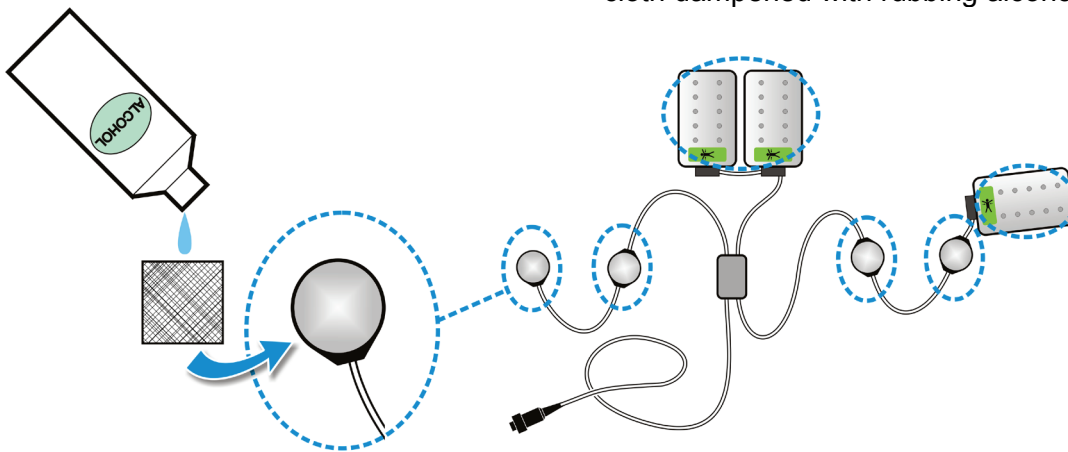
Do not use the vibration box as a handle to pull or lift the electrode belt. Pulling on the vibration box can damage the internal wiring and cause the system to malfunction.



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



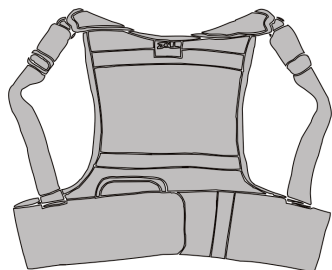
- 4 Wipe the metallic surfaces of the electrodes and therapy pads with a soft cloth dampened with rubbing alcohol.



- 5 Reassemble the garment and electrode belt as described on page 3-3 (garment A) or page 3-13 (garment B).
- 6 Put on the assembled garment and electrode belt as described on page 3-9 (garment A) or page 3-19 (garment B).

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

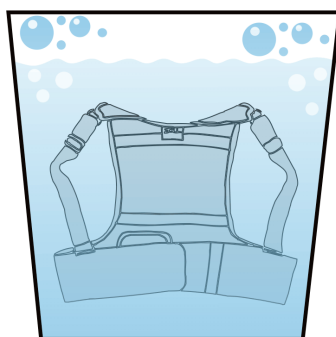
Laundering the garment



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.
- With garment A, leave the straps buttoned.



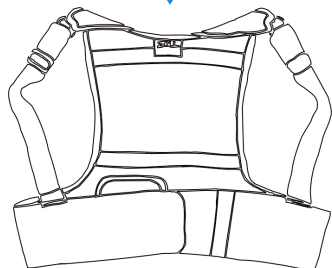
Wash the garment by itself. Do not wash it with other laundry.

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 clothes washing detergent only, such as Woolite® Original, Tide®, Purex® After the Rain, Fab® Spring Magic, or Arm & Hammer® for sensitive skin.



CAUTION: Do not use chlorine bleach, bleach alternatives, fabric softener, or anti-static sprays. Do not use detergents that include bleach or fabric softener additives.



Use a clothes dryer or hang the garment to dry. If you use a clothes dryer, set it to a warm or medium setting. Do not use the high heat setting.

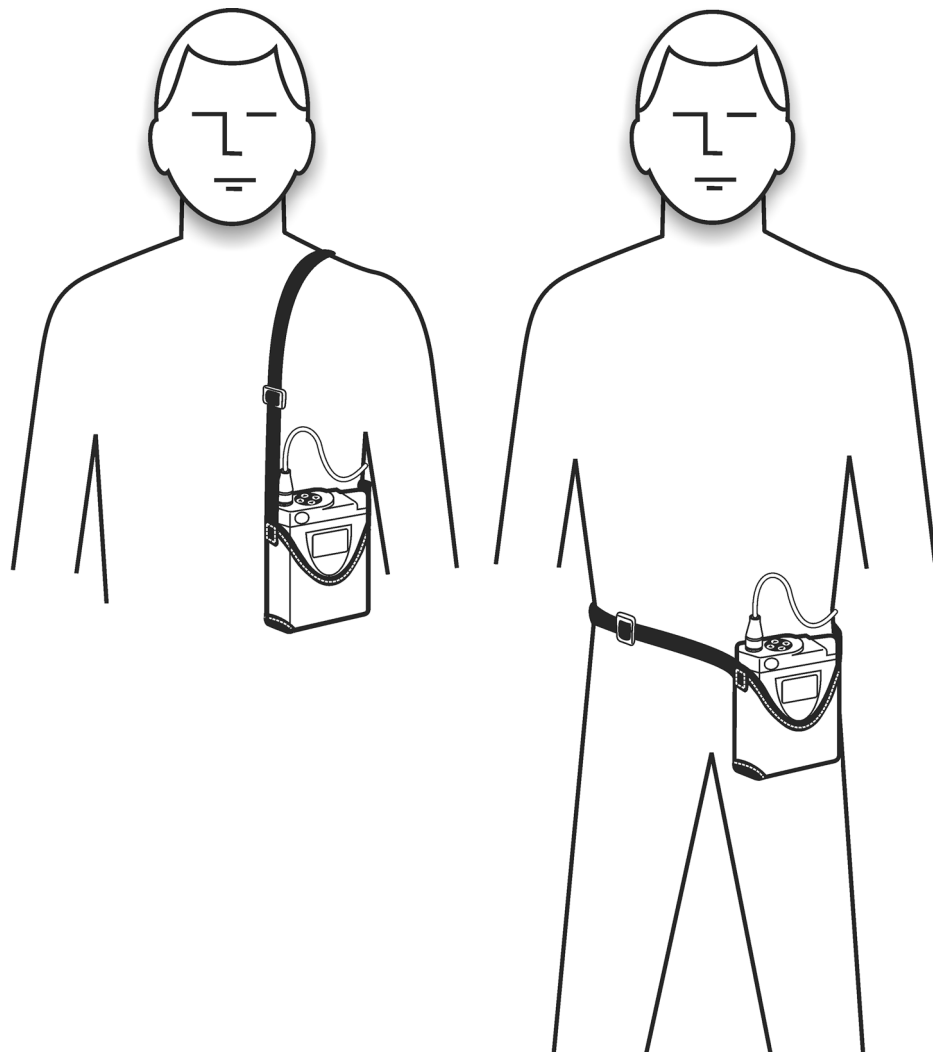
Using the holster

You may use the holster so that you can wear the monitor when moving around.


The holster strap is adjustable to give you several options for comfortably wearing the system.

To use the holster:

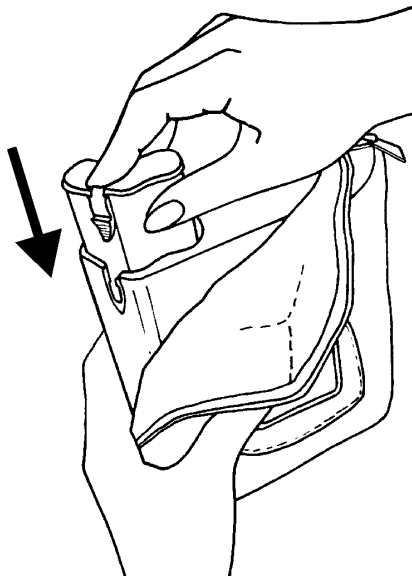
- 1 Put the monitor into the holster.
- 2 Wrap the Holster belt around your waist or place the strap over your shoulder.
- 3 Close the belt buckle and adjust for fit.



Inserting the Battery Pack

 **WARNING:** Insert ONLY a WCD 3000 Battery Pack into the Monitor. Using any other battery could cause the device to fail.

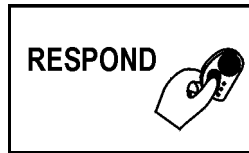
- 1 Unzip the bottom portion of the Holster to expose the battery compartment.
- 2 Insert the Battery Pack into the bottom of the Monitor.
 - Push the Battery Pack firmly into the Monitor.
 - Make sure the Battery Pack is fully inserted into the Monitor.



- 3 Zip the Holster closed.
- 4 Respond to the startup messages, as described next.

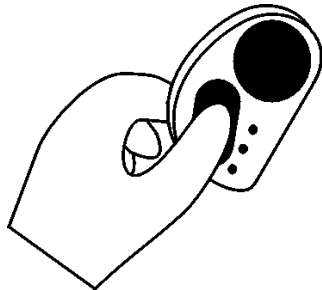
Startup messages

After the ZOLL logo displays, this message displays:



This is the response button test.

Press both response buttons on the Alarm Module at the same time to respond.



If you do not press the response buttons, after a few seconds you should hear a voice message telling you to press the response buttons to activate the device:

To activate device, press response buttons.

But if you hold the response buttons for too long, this message displays:



Respond by releasing the response buttons.

Normal monitoring message

After startup, the normal monitoring message displays, which shows your name, the battery level, and a flashing heart symbol:



This message displays during normal monitoring. To illuminate the display, press the OK button.

As the battery charge goes down, the normal monitoring message shows a decrease in the battery's capacity. For example:

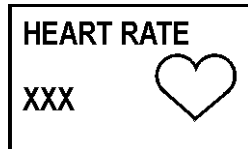
 Approximately 50% charged

 Approximately 25% charged

The time left on a freshly charged battery varies, and the given level is only an estimate. It may vary according to usage.

To view your heart rate

To view your heart rate at any time, press the response buttons. This message displays:



(xxx indicates the heart rate in digits).

If you get a CHECK THERAPY PADS message

If you get this message, the Therapy Pads are not making good contact with your skin.

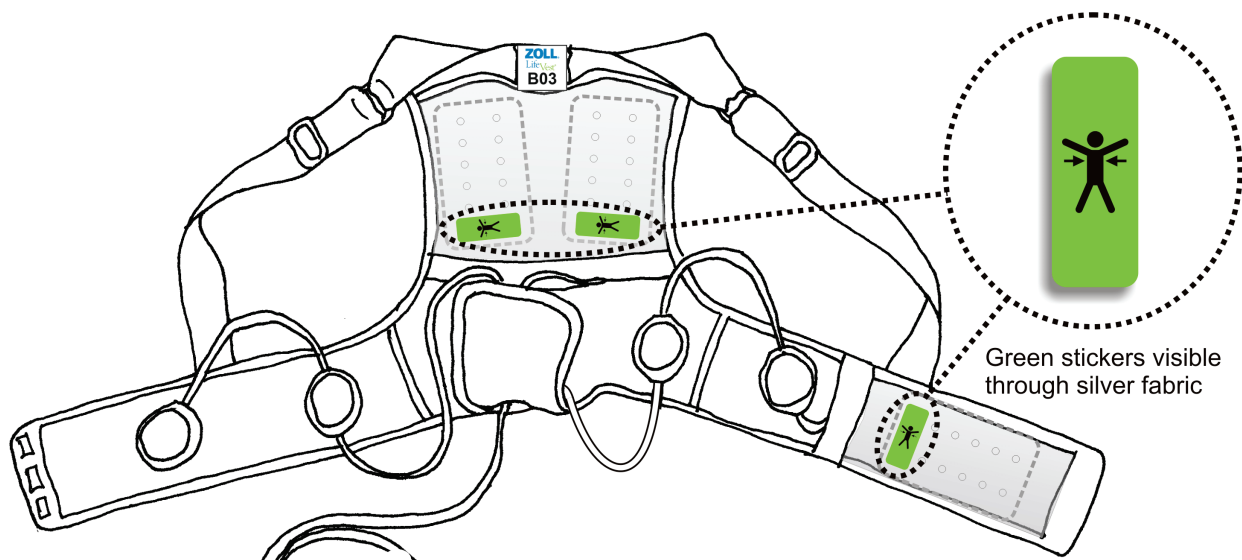
**CHECK THERAPY
PADS
PRESS OK**

This could be caused by:

- Therapy Pad may not be inserted correctly into its pocket.
- Therapy Pad and mesh pocket may not be pressing against your skin.

Therapy Pad may not be inserted correctly into its pocket

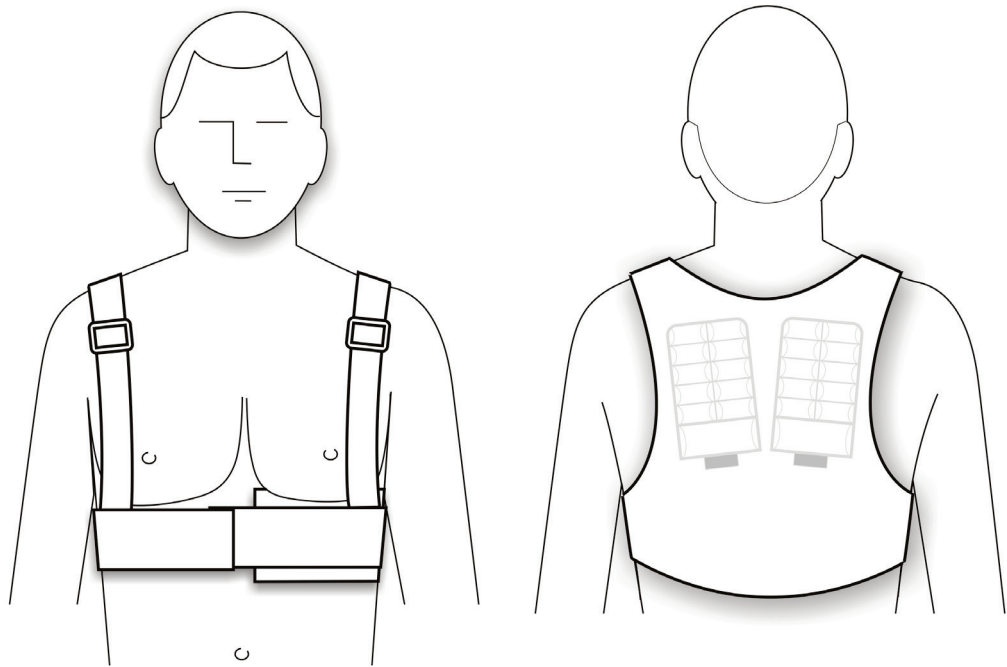
- 1 Remove the battery from the monitor, then remove the Garment and Electrode Belt from your body.
- 2 Make sure the therapy pads are inserted correctly, their metal sides (with green stickers) facing your body.



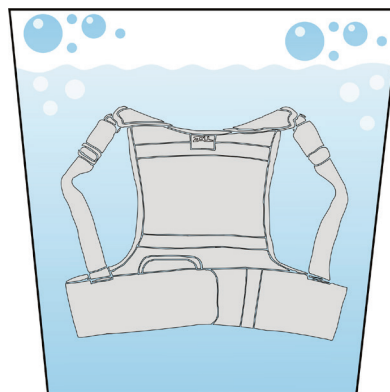
- 3 Put on the Garment and Electrode Belt, then put the battery into the monitor to resume normal operation.
- 4 If problems continue, call ZOLL or your device provider for assistance.

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 metal mesh pockets and the therapy pads are pressing against your bare skin. For details about putting on the garment and electrode belt, see page 3-9 for garment style A, page 3-19 for garment style B.



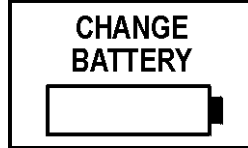
- 3 To help prevent stretching, launder the garment every 1 or 2 days. Follow the instructions for how to launder the garment on page 3-28.



- 4 If problems continue, call ZOLL or your device provider for assistance.

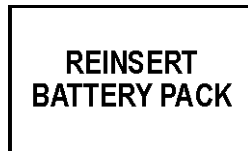
Battery messages

When the Battery Pack is depleted, this message displays along with a gong alarm:

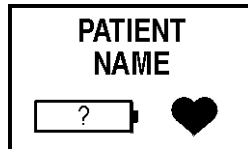


Exchange Battery Packs, wearing one and charging the other.

If the Battery Pack is improperly connected, this message displays:



Remove and reinsert the Battery Pack. If this message reappears, or if you see the following message:



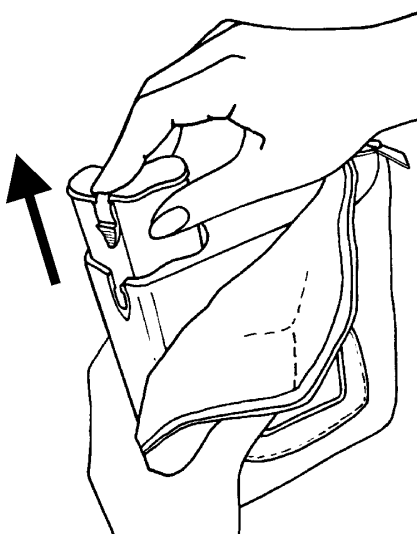
Call your device provider to report the problem. You may insert the other Battery Pack when it is fully charged.

Charging the Battery Pack

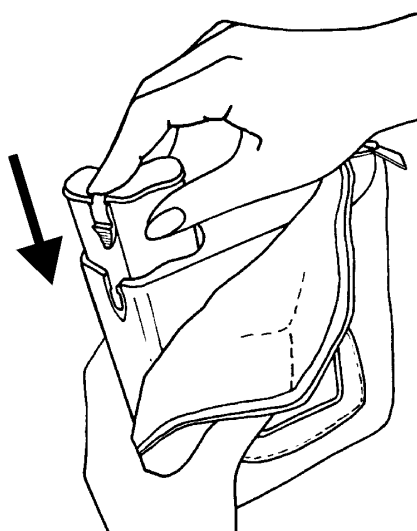
Charge the Battery Pack after a 24-hour maximum period of use, even if the battery symbol shows that it is not completely depleted. You have two Battery Packs, one to wear and one to charge. Once a day, or whenever you receive a “Change Battery” message, exchange Battery Packs, wearing one and charging the other.

To charge:

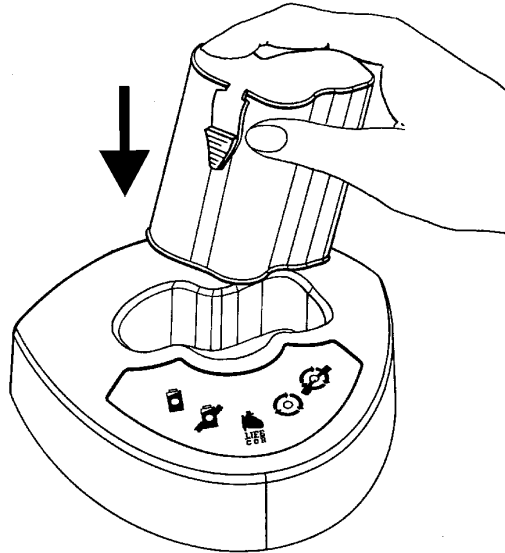
- 1 Unzip the Holster to expose the Battery Pack.
- 2 Remove the depleted Battery Pack by grasping the Monitor, pushing down on the Battery Pack latch, and pulling the Battery Pack from the Monitor.




- 3 Insert the fresh Battery Pack into the Monitor.




- 4 Insert the used Battery Pack into the Battery Charger, as shown next. (Make sure that the Battery Pack is completely inserted into the Battery Charger.)



Once the Battery Pack is fully charged, the green light should be lit. The Battery Pack should remain in the Battery Charger until it is needed. Keep the Battery Charger plugged into an electrical outlet at all times. Make sure that this electrical outlet is not controlled by a wall switch.


 **WARNING:** Charge the WCD 3000 Battery Pack with the WCD 3000 Battery Charger ONLY. To use any other charger could cause the system to fail.


 **WARNING:** Press the Battery Pack firmly into the Battery Charger when inserting. If the Battery Pack is not pressed firmly into the charger, charging may not take place.


See the next section to learn about operating the Battery Charger.

Battery Charger

The WCD 3000 Battery Charger is designed to charge and test the WCD 3000 Battery Pack.

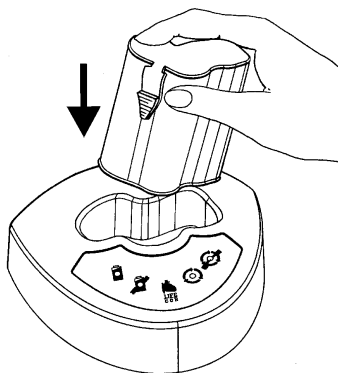
 **WARNING:** Use this charger only with authorized power supplies. Using other power supplies may cause personal injury or damage to equipment.

 **WARNING:** Unplug the charger from the outlet before attempting to clean it to reduce risk of electrical shock.

 **WARNING:** Do not disassemble, incinerate, modify or short circuit the Battery Pack, Battery Charger, or other device components.

Operation

- 1 Place the Battery Charger in a well-ventilated area.
- 2 Connect the power supply to the Battery Charger before plugging the AC power cord into an electrical outlet.
- 3 Make sure the Battery Charger is properly connected to the power supply before inserting a Battery Pack.
- 4 Insert the Battery Pack firmly into the Battery Charger as shown. (It fits only one way; with improper fit, turn it until it lines up.)







- 5 When the Battery Pack is inserted, check the battery status lights (explained next) for about 10 seconds to see that neither “Fault” light lights up.

Charging can take up to 3½ hours. The “Ready” light turns solid green when fully charged. A fully-charged Battery Pack should remain on the charger until it is needed. Keep the Battery Charger plugged into the electrical outlet at all times. Choose an outlet not controlled by a wall switch.

Battery status lights

The Battery Charger has four lights to let you know the status of the Battery Pack and/or Battery Charger. They are:

	Ready	Solid green when battery is ready.
	Battery charging Battery testing	Solid orange if charging. Flashing orange if testing.
	Charger fault	Flashing red.
	Battery fault	Flashing red.

Charging/testing battery pack

During and shortly after charging or testing, the Battery Pack and Battery Charger may be warm to the touch. This is normal.

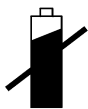


If the “Charge” light is solid orange following insertion of the Battery Pack, the charger is in rapid-charge mode. Rapid charge of a fully depleted battery can take up to 3½ hours. When charging has completed, the orange “Charge” light should turn off and the green “Ready” light should turn on.

If the “Charge” light flashes orange following insertion of the Battery Pack, the charger is testing the Battery Pack. Testing of a fully depleted Battery Pack can take up to 12½ hours, for a total of up to 16 hours. When testing, the “Charge” light should flash orange. When charging, it should be solid orange. When finished, the solid green “Ready” light should light.

If the testing cycle starts (indicated by the flashing orange “charge” light) and you must use the Battery Pack sooner than testing would allow, pull the Battery Pack from the charger and then reinsert. It will skip the testing and begin charging.

Battery fault



A “Battery Fault” light is designed to indicate a charging problem with either the battery or the charger. If the “Battery Fault” light flashes, the charger will continue to charge the battery. In this case, up to 10 hours may be required to charge the battery.

If the “Battery Fault” light flashes while charging the Battery Pack, refer to the “Troubleshooting the Battery Charger/Battery Pack” section of Chapter 9. If the problem persists, remove the Battery Pack in question and install another Battery Pack into the charger. Note whether or not the “Battery Fault” light flashes. Reinstall the Battery Pack in question and allow it to charge. Contact your device provider to explain the problem.


If the “Battery Fault” light does not flash until the “Ready” light appears, the Battery Pack has reached the end of its useful life. It may not last a full 24 hours, but the battery can be used. Contact your device provider immediately to explain the problem.


Charger fault




A “Charger Fault” light should notify of charging problems with either the Battery Pack or Battery Charger. If the light flashes, the charger will NOT charge the Battery Pack. Refer to the “Troubleshooting the Battery Charger/Battery Pack” section of Chapter 9. If the problem persists, install the other battery into the charger. Note whether or not the “Charger Fault” light flashes. Contact your device provider immediately to explain the problem.

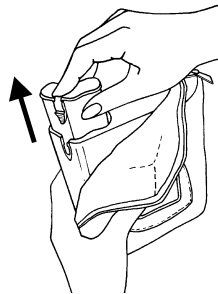
Removing device

 **WARNING:** COMPLETELY REMOVE the LifeVest device when you shower or bathe! Do not put the Monitor, Electrode Belt, Alarm Module, or Battery Pack in or near water. To do so may cause the device to fail.

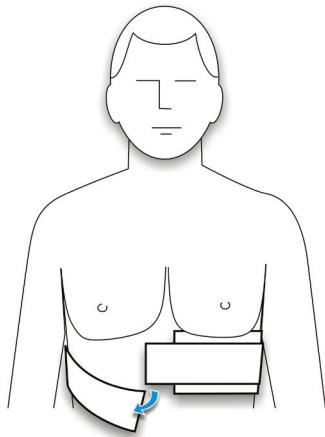
 **WARNING:** Remove the Battery Pack from the Monitor whenever the device is not being worn. For example, when you remove the device to take a shower, be sure to remove the Battery Pack to ensure the device is not active when you are not wearing it.

 **WARNING:** When you do not wear the device, or anytime the Electrode Belt or Battery Pack is disconnected from the Monitor, you are not protected by the device. ZOLL recommends that you bathe or shower when someone else is home with you.

To remove the LifeVest device before you bathe or shower:



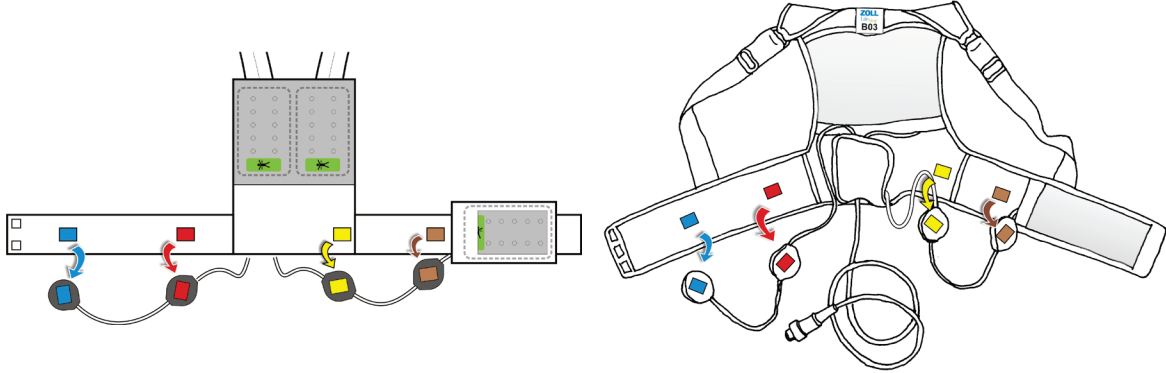
- 1 Remove the Battery Pack from the Monitor.
- 2 Unbuckle and remove the Holster. Keep electrode belt connected to Monitor.



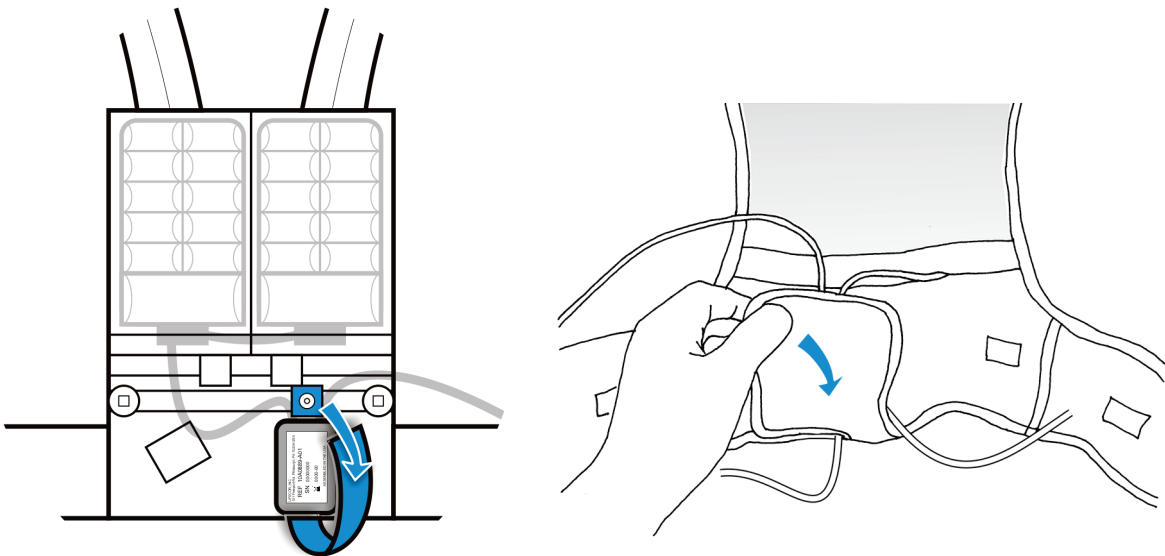
- 3 Unfasten and remove the Garment from your body.

If you plan to launder the Garment at this time:

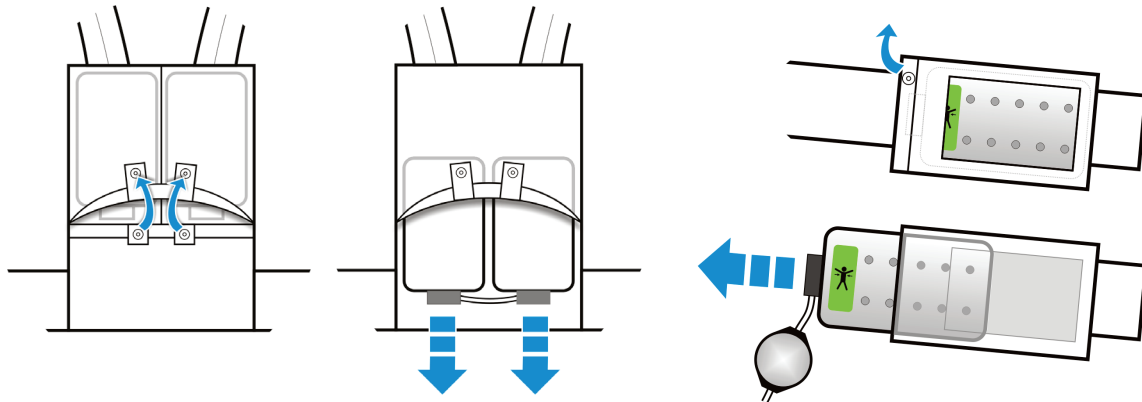
- 4 Remove Electrodes from Garment. Pull on the electrodes, not on the wires.



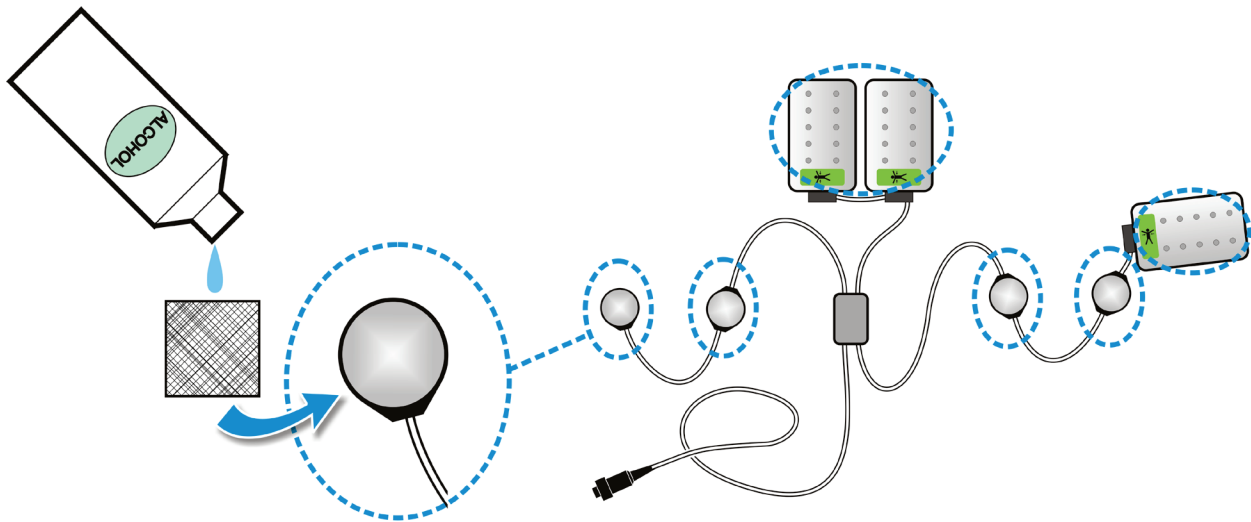
- 5 Remove the Vibration Box from the Garment.



6 Unsnap and remove the Therapy Pads from their pockets.



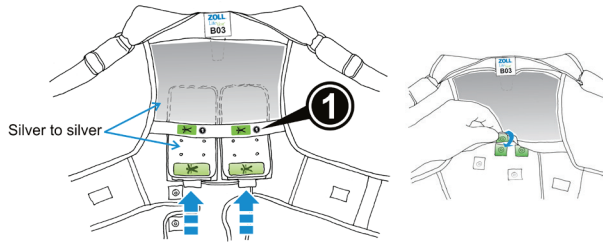
7 Wipe the Electrodes and Therapy Pads with a soft cloth dampened with rubbing alcohol.



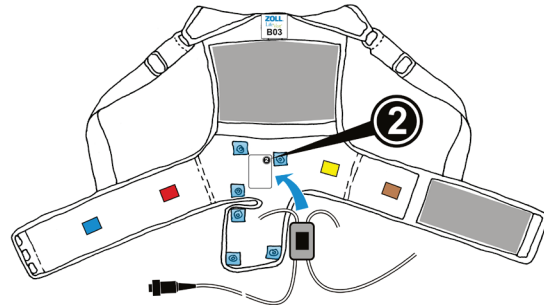
8 Launder the worn Garment as described on page 3-28.

Summary: Assembly and startup

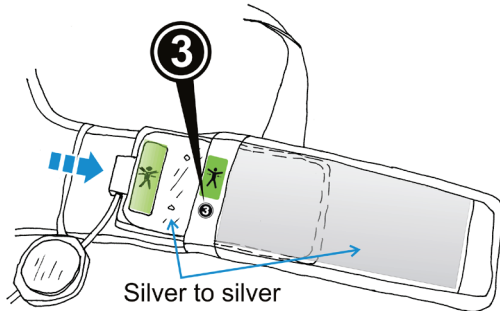
1 Insert rear therapy pads and snap closed.



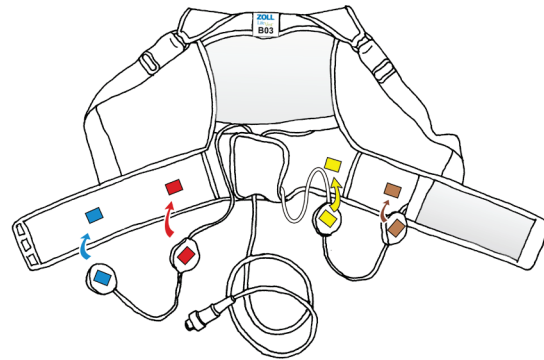
2 Position Vibration Box and snap to secure.



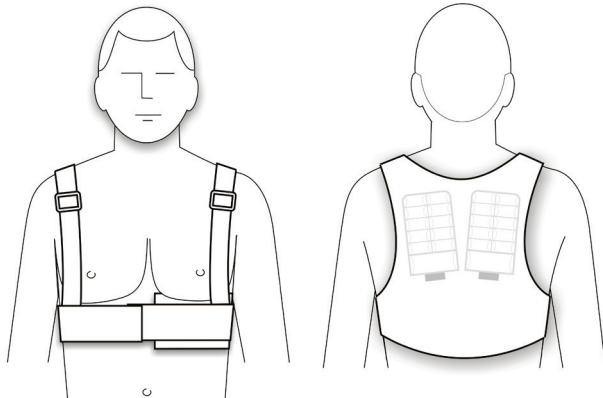
3 Insert front therapy pad and snap closed.



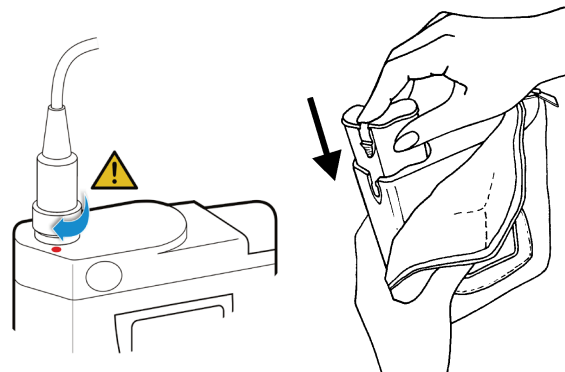
4 Attach electrodes to the garment; match colors.



5 Put on garment and belt.



6 Connect belt and insert Battery Pack.

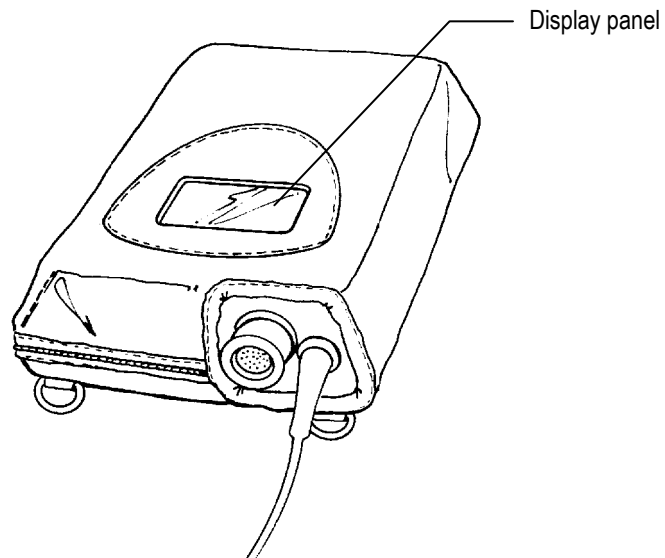


Chapter 4: What do the Messages Mean?

Chapter overview




The LifeVest device communicates with you through voice messages and display messages (see Monitor's display panel below). These messages are designed to tell you what to do. Some messages are accompanied by an Alarm Module light.

When you receive a message, respond by following its instructions. A response may include pressing Alarm Module button(s) or performing a task. This chapter will explain the lights, buttons, messages, and expected responses. Most messages are grouped according to function. (At the end of this chapter there is also a list of the spoken and written messages.)

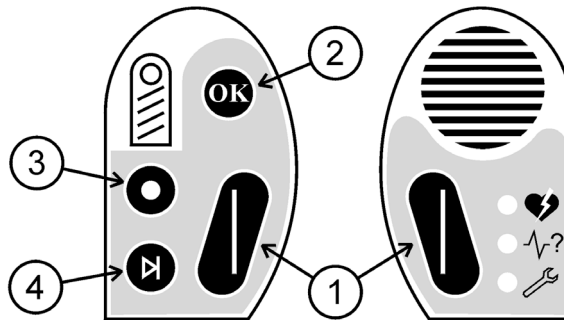


Alarm Module

The Alarm Module has the following lights, each accompanied by a symbol:

	Red	Indicates an abnormal heart rhythm.
	Yellow	Indicates unclear or "noisy" ECG signals being received by the Monitor.
	Flashing yellow	Indicates that the device requires attention or service.

The Alarm Module also has the following buttons:



-
- 1 Two Response Buttons: Press BOTH response buttons when the message tells you to, or any time you want to see your heart rate.
 - 2 OK: Press the OK button when the message tells you to, or any time you wish to see the battery level.
 - 3 Record: Press and hold for 3 seconds to record an ECG. Your doctor may review this recording when you download information via the modem.
 - 4 Transmit: Press this button to download information via the modem.
-

Responding to messages

The LifeVest device is designed to get your attention with:

- Lights.
- The vibration of the vibration box against your skin.
- Alarms.

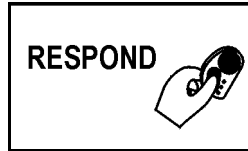
When you see, feel, or hear any of these cues:

- 1 Press both response buttons.
- 2 Read and/or listen to the message.
- 3 Follow any message instructions.

Normal operation

If you receive a message on the display panel during normal operation, it should be one of those listed in this section.

When the LifeVest device powers up, you should see a logo, followed by:



This message should be accompanied by an alarm and vibration. Press both response buttons until the message disappears.

If you do not press the response buttons, you should hear the voice message:

To activate device press response buttons.

However, if you hold the response buttons for too long a period of time, you should see the flashing yellow light and the message:



Release the response buttons if you see this message.

If one of the Therapy Pads is not making contact with your skin, this message displays:




Make sure Therapy Pads are inserted correctly, metal sides (with green stickers) against your skin. Make sure Therapy Pads and mesh pockets are pressing against your skin.

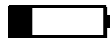
After start-up, the normal monitoring message displays, showing your name, the battery level, and a flashing heart symbol:



This message displays during normal monitoring. To backlight the display, press the OK button.

As the battery charge goes down, the normal monitoring message should show a decrease in the battery's capacity. For example:

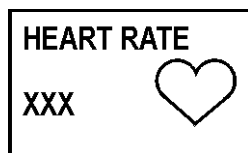
 Approximately 50% charged.

 Approximately 25% charged. (When approximately 25% is left, be prepared to change batteries within 2 hours.)

Keep in mind that the battery level on a freshly charged battery varies. Also, the level may vary according to usage.

(See the Service Messages section of this chapter for the "Change Battery" and "Reinsert Battery Pack" messages.)

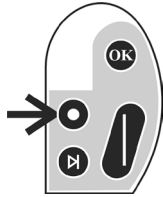
During normal monitoring, any time you press the response buttons you should see your heart rate:



(xxx indicates the heart rate)

Recording ECGs

Press the Record button to record an ECG and store it in the Monitor's memory.



When you press Record, this message displays:

**HOLD BUTTON
FOR 3 SECONDS
TO RECORD**

Hold the Record button until the message disappears or the alarm sounds. The following message displays with the date and time:

**RECORDING...
mm/dd/yy
hh:mm**

(mm/dd/yy indicates date and hh:mm indicates time)

Abnormal heart rhythms

When the device detects an abnormal heart rhythm, you should see the red light on the Alarm Module light up, feel a vibration on your back, and see these display messages:



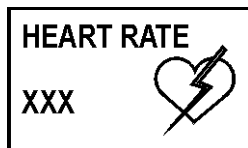
You should also hear the alarm. When this occurs, you should PRESS AND HOLD BOTH RESPONSE BUTTONS to prevent a treatment shock while you are conscious.

If you should lose consciousness, a shock may be necessary. NO ONE ELSE SHOULD HOLD THE RESPONSE BUTTONS FOR YOU.

If you feel dizzy, find a place to sit or lie down. When you press and hold the response buttons, you will hear this voice prompt:

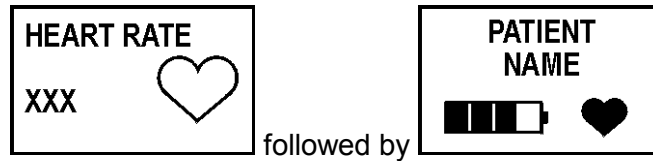
***Treatment stopped by response buttons.
Bystanders, do not touch device.***

And the following message displays:



⚠ WARNING: If you fail to press and hold both response buttons on the Alarm Module at the same time, after you have received a message telling you to do so, you may receive a defibrillating electrical shock while conscious. If you receive a shock while conscious, it will be painful. To avoid receiving a defibrillating electrical shock while conscious, remember to always press and hold both response buttons when the device tells you to. Also, if you receive a shock while the heart is beating normally, the shock 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 remain conscious and your heart rhythm remains constant, you will see the following messages:



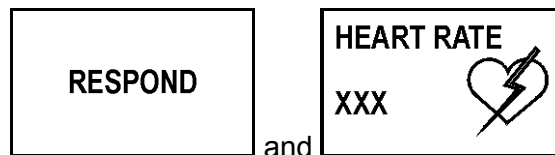
If you lose consciousness, voice messages should warn others that you are about to receive a shock and that they should not touch you. These voice messages are:

Electrical shock possible. Do not touch patient.

After the delivery of each shock, bystanders will hear:

Call ambulance.

When you regain consciousness, if your heart rhythm still appears abnormal, these messages display:

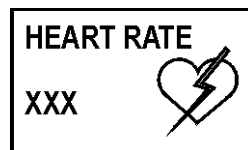


Press and hold the response buttons.

You will hear this voice prompt:

***Treatment stopped by response buttons.
Bystanders, do not touch device.***

and see:

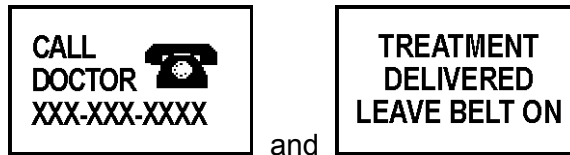


If this occurs, you should call an ambulance while holding both response buttons.



WARNING: If a shock occurs, call your doctor as soon as possible!

If your heart rhythm returns to normal after receiving a treatment shock, these messages display:



accompanied by the voice message:

Contact physician.

Until you change the Battery Pack, the “Call Doctor” message should appear each time you press OK or the response buttons.

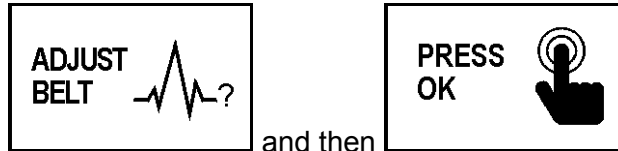
If you are still unconscious after the delivery of a five-shock sequence, bystanders will hear:

Device disabled, call ambulance.

Unclear ECG signals

If unclear ECG signals are received by the Monitor, the yellow light on the Alarm Module should light. The symbol of a heart rhythm with a question mark and one of the following messages should display.

If the ECG signal is poor, you should see the message:



Adjust the Electrode Belt, making sure that each ECG electrode is in complete contact with your skin. Then press OK.

While the device rechecks the ECG signal clarity, you should see:



If the signals are clear, the message should disappear. If not, the “Adjust Belt” message again displays.

If the problem continues after you have made three attempts to adjust the belt, this message displays:



At this point:

- 1 Disconnect and remove the Electrode Belt.
- 2 Check the Electrode Belt to make sure that nothing is covering the ECG electrodes.
- 3 Rub unscented hand lotion, skin cream, or moisturizer on the surface of each ECG electrode, but not on the therapy pads.
- 4 Put the Electrode Belt back on and reconnect it to the Monitor.

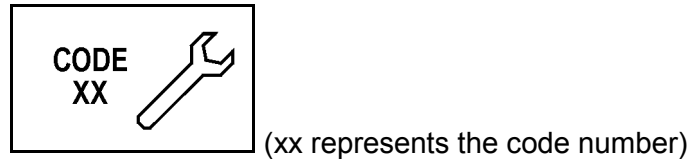
If the problem continues, call your device provider to report the problem.

If the poor ECG signal is due to an unusual motion, such as exercise, discontinue the motion as soon as possible.

Service Messages

If the device needs service, you should see the yellow light on the Alarm Module flash, and see a message on the display.

One type of service message displays a wrench symbol and a code number.



When you see this type of message, call your device provider to report the code number. You should be instructed what to do next.

The second type of service message is designed to give you a direct instruction or information. The following subsections list these messages.

Press button(s)

When the device requires you to press the response buttons or the OK button, you should see:



Respond by pressing the appropriate button(s).

Release response buttons

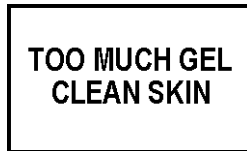
When the device requires you to release the response buttons, you should see:



To respond, release the response buttons.

Too much gel, clean skin

After receiving a shock, you may see:



If so, you should leave the gel on the skin under the therapy pads, but wipe away the gel on the skin not under the therapy pads.

Add gel or replace belt

After you receive a therapy shock to correct an abnormal rhythm, you may see:



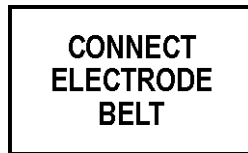
Do not ignore this message or proper treatment may not be delivered when needed. Add extra gel (supplied) to the therapy pads (but not to ECG electrodes). To add gel, follow the instructions in Chapter 6, **What if you Experience an Abnormal Heart Rhythm?**, or Chapter 9, **How do you Maintain the System?**

If you have not added enough gel, you should see the “Add Gel or Replace Belt” message again. Repeat the steps for applying gel.

(To change the belt when you see this message, following the instructions in Chapter 6, **What if you Experience an Abnormal Heart Rhythm?**, or Chapter 9, **How do you Maintain the System?**)

Electrode belt connection

If the Electrode Belt is not connected, you should see:

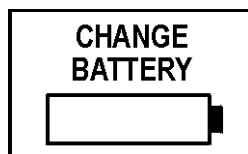


This message appears whenever the Electrode Belt is disconnected. It should reappear every five minutes until it is properly connected.

If you receive this message when the Electrode Belt is connected, disconnect and then reconnect the Monitor and the Electrode Belt. If the message continues, call your device provider immediately to report the problem.

Change battery

If the battery is depleted, the yellow light should flash, and you should receive the message:



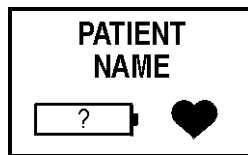
This message means that you must replace the depleted Battery Pack with the fully-charged one. Then insert the depleted Battery Pack into the Battery Charger to recharge.

Reinsert battery

If the battery is not connected properly, the yellow light should flash, and you should receive the message:



This message means that you must reinsert the Battery Pack to restart the device. If the message appears again, reinsert again. If it appears again, or you see the message:



Call your device provider to explain the problem. You may insert the other Battery Pack when it's fully charged.

Communication messages

Your doctor should tell you how often to send Monitor information through the modem. Normally it should be about once a week. To do so, connect the modem to the Monitor's communication port (as detailed in Chapter 8, **How do you Communicate by Modem**).

When you press the transmit button to send data, you may see the following messages, unless the device is busy. If the device is busy, the information will still be sent, but you may not see these messages.




While downloading, you should see the percentage that has already been sent (xx indicates percentage).

When transmission is complete, you should see the display message:







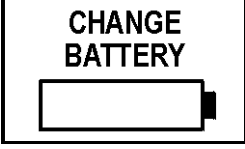



Disconnect from the modem as described in Chapter 8.



If transmission failed, you may see one of the following service messages.








Message	What it means	What to do
BUSY SIGNAL PRESS OK TO CONTINUE	Phone line is busy.	Press OK. Wait a few minutes. Then press and hold the Transmit button to try sending data again.
CHECK MODEM PRESS OK TO CONTINUE	Data could not be transmitted.	Check modem connections. Press OK, then press and hold Transmit button to try sending data again.
NO ANSWER PRESS OK TO CONTINUE	There was no answer at the receiving end.	Press OK, then press and hold the Transmit button to try sending data again.
 XX	Data could not be transmitted. An error code will appear.	Press OK, then try again. If problem continues, contact your device provider and report the error code.
TRY AGAIN LATER PRESS OK TO CONTINUE	Transmission was interrupted.	Press OK, then press and hold the Transmit button to try sending data again. If problems continue, wait a few minutes and try again.
TIME TO CONNECT MODEM & SEND DATA	Either it has been more than a week since data was sent, or for some other reason the system has determined that you should send data.	Press OK to delete the message. Send data at your earliest convenience. If you do not send data, you will see the message each time you power up the monitor.



Message list


All messages (both display and voice) are listed in this section. Next to each message is the associated alarm module light, what it means, and what to do.

Message	Alarm module light	What it means, what to do
	Yellow light	Your ECG is unclear. Adjust belt and press OK.
	Flashing yellow light	Add gel to the therapy pads or replace Electrode Belt. (See Chapter 6 or 9 for instructions.)
	Flashing yellow light	Press the Transmit button to try again, or disconnect modem and try again later.
Call ambulance. (voice message)	Red light	Indicates to bystanders that they should call an ambulance for you.
	No light	Call doctor's emergency number immediately.
	Flashing yellow light	Remove used battery, replace with new one, and insert used one into Battery Charger.
	Yellow light	Disconnect and remove the Electrode Belt. Check to make sure that nothing is covering the ECG electrodes. Rub unscented hand lotion, skin cream, or moisturizer on the surface of each ECG electrode. Put the belt back on and reconnect it to the monitor. If problem persists, call device provider.
	Flashing yellow light	Make sure modem is connected to phone line. Check modem connections and then press the Transmit button to try again.
	No light	Modem is preparing to send data. No action required.

Message	Alarm module light	What it means, what to do
CHECK THERAPY PADS PRESS OK	No light	Therapy Pads are not making good contact with your skin. Make sure Therapy Pads are inserted correctly, metal sides (with green stickers) against your skin. Make sure Therapy Pads and mesh pockets are pressing against your skin.
CODE XX 	Flashing yellow light	Call device provider with code information.
DATA TRANSFER COMPLETE PRESS OK 100% ■■■■■■■■	No light	Data has been sent over modem. Disconnect modem as described in Chapter 8.
DATA TRANSFER IN PROGRESS XX% ■■■□□□□□	No light	Indicates that data is being sent over modem. No action is required.
<i>Device disabled. Call ambulance.</i> (voice message)	Red light	Indicates to bystanders that they should call an ambulance for you.
DIALING... X, XXXXXXXXXX	No light	Modem is preparing to send data. No action required.
<i>Do not touch patient.</i> (voice message)	Red light	Tells bystanders that they should not touch you.
<i>Electrical shock possible.</i> (voice message)	Red light	Tells bystanders that you are about to receive a shock and that they should not touch you.
CONNECT ELECTRODE BELT	No light	Indicates Electrode Belt is not connected to Monitor.
HEART RATE XXX 	No light	Indicates heart rate in beats per minute. No response required.

Message	Alarm module light	What it means, what to do
<p>HEART RATE XXX </p>	Red light	Indicates abnormal heart rate. Hold both response buttons and follow any other instructions.
<p>HOLD BUTTON FOR 3 SECONDS TO RECORD</p>	No light	Hold Record button until display message disappears (3 seconds) or alarm sounds.
<p>HOLD BUTTON FOR 3 SECONDS TO SEND DATA</p>	No light	Hold Transmit button until display message disappears (3 seconds) or alarm sounds.
<p>PATIENT NAME </p>	No light	Displays patient name and the battery level. No response required.
<p>NO RATE </p>	No light	Can be caused by noise on a single ECG electrode, or from a changing heart rate. No response required.
<p>NO RATE </p>	Red light	Indicates abnormal rhythm is being detected, even though no rate is displayed. Hold both response buttons and follow any other instructions.
<p>PATIENT NAME </p>	No light	Call device provider to report that battery symbol displays a question mark.
<p>PRESS OK </p>	Yellow or flashing yellow	Follow instructions and then press OK.
<p>PLEASE WAIT </p>	Yellow light	Wait while device checks ECG signal clarity.

Message	Alarm module light	What it means, what to do
RECORDING... mm/dd/yy hh:mm	No light	Indicates ECG is being recorded. Shows date and time of recording.
REINSERT BATTERY PACK	Flashing yellow light	Remove Battery Pack from Monitor, and reinsert it. If message reappears, insert other charged Battery Pack.
RELEASE RESPONSE BUTTONS 	Flashing yellow light	Release response buttons.
RESPOND 	Flashing yellow light	Appears at startup. Press response buttons to perform response button test. Press buttons until message disappears.
RESPOND	Red light	Hold both response buttons and follow any other instructions.
TIME TO CONNECT MODEM & SEND DATA	Flashing yellow light	If it is time to send data over the modem, this message will appear when you turn the device on and press the response buttons. Connect Monitor to modem and press Transmit button to send data.
To activate device, press response buttons. (voice message)	Flashing yellow light	Press both response buttons.
TOO MUCH GEL CLEAN SKIN	Flashing yellow light	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.
Treatment stopped by response buttons. Bystanders, do not touch device. (voice message)	Red light	Hold response buttons and follow additional instructions.

Message	Alarm module light	What it means, what to do
<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>TREATMENT DELIVERED LEAVE BELT ON</p> </div>	No light	You have been given a shock treatment. Continue to wear the LifeVest. Call your doctor as soon as possible.
<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>TRY AGAIN LATER PRESS OK TO CONTINUE</p> </div>	Flashing yellow light	There is no answer, or data transfer has been interrupted. Press the Transmit button to try again, or disconnect and try again later.
<div style="border: 1px solid black; padding: 5px; text-align: center;">  <p>XX</p> </div>	No light	Data could not be transmitted. An error code will appear. Press OK, then try again. If problem continues, contact your device provider and report the error code.

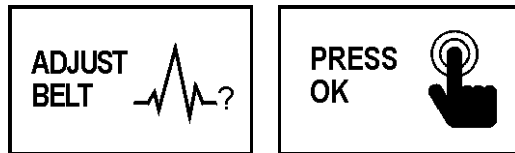
Chapter 5: How do you Maintain Clear ECG Signals to the Monitor?

Chapter overview

This chapter describes what you should do if one or more ECG electrodes are not sending clear ECG signals to the Monitor.

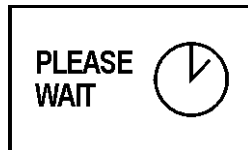
Unclear ECG signal

If the LifeVest device detects an unclear (“noisy”) signal, it will wait for the signal to become clear before notifying you, because it is designed to lessen the frequency of “Adjust Belt” messages you receive. If an ECG signal remains unclear, you should see the Alarm Module yellow light turn on, hear the single-tone alarm, and see the messages described in this chapter. The first time a poor ECG signal occurs, you should see the messages:



These two messages will alternate, letting you know that an ECG electrode is not sending a clear signal to the Monitor. If you see this message, you must readjust your Electrode Belt so that each ECG is touching your skin. Then press OK.

While the device checks to see if the ECG signals are clear, you should see:



After a period of time, the “please wait” message should disappear. If there is still an unclear signal, the “Adjust Belt” message should reappear.

If the problem continues after three attempts to adjust the Electrode Belt, you should see the following message:



When this occurs, you should:

- 1 Disconnect the Electrode Belt from the monitor.
- 2 Take off the Garment and check to make sure that nothing is covering the ECG electrodes.
- 3 Rub unscented hand lotion, skin cream, or moisturizer on the surface of each ECG electrode, but not on the Therapy Pads.
- 4 Put the garment on and connect the Electrode Belt to the Monitor.

If the problem continues, call your device provider to report the situation.

If you see the message:



It does not necessarily mean the device is not monitoring you. This message may result from an unclear signal on a single ECG electrode, or from a changing heart rate.

Possible Reasons for Poor Signal Quality

During the Day

During the daytime, poor signal quality may be due to unusual arm motion, such as that involved with exercise. If this should occur, do not continue such motion for an extended period of time.

During Sleep

During the night, poor signal quality may be due to one or more of the electrodes lifting from your skin. If this is the case, move to a relaxed position where all electrodes can make good contact with your skin. If the alarms continue, readjust your position again.

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Chapter 6: What if you Experience an Abnormal Heart Rhythm?

Chapter overview

This chapter describes what you might expect if experiencing an abnormal heart rhythm.

Description

If you have an abnormally fast heart rhythm, you may remain conscious and/or become light headed, or you may lose consciousness.

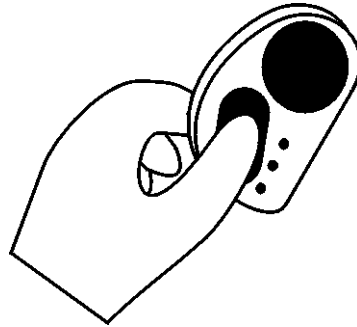
The LifeVest device is designed to detect an abnormally fast rhythm and alert you with vibrations, alarms, and messages. If this happens, find a safe place to sit or to lie down.

An abnormal heart rhythm may or may not prove to be life threatening. However, you are not in any immediate danger from the abnormal heart rhythm as long as you remain conscious. It's important to know that you can and should stop any impending treatment shock by pressing and holding both response buttons on the Alarm Module at the same time. This should silence the dual-tone alarm and stop the vibration.

When an abnormal rhythm occurs

Holding Response Buttons

When the message tells you to hold the response buttons, be sure to press and hold both response buttons on the Alarm Module at the same time.



If you are holding both response buttons, the LifeVest device is designed to recognize you are conscious and therefore not deliver a treatment.

Remember, an abnormal heart rhythm may or may not prove to be life threatening, but you should not be in any immediate danger from the abnormal rhythm as long as you remain conscious.

When you press the response buttons, the dual-tone alarm and the vibration against your skin should stop.

(If you lose consciousness, you will naturally release the response buttons; the voice messages should tell any bystanders what is happening and what to do to help you.)

What to expect

When the device detects an abnormal heart rhythm, you should see the red light on the Alarm Module light up, feel a vibration on your back, and see the following message:



When this occurs, you should **PRESS AND HOLD BOTH RESPONSE BUTTONS** to prevent a treatment shock.

(You should see your heart rate when you press the response buttons.)

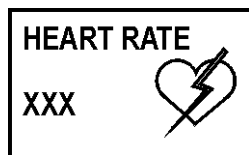
If you should lose consciousness, a shock may be necessary. Therefore, **NO ONE ELSE SHOULD HOLD THE RESPONSE BUTTONS FOR YOU.**

Switch hands if your hand becomes tired from holding the response buttons.

If you feel dizzy, find a place to sit or lie down. When you press and hold the response buttons, you should hear:

***Treatment stopped by response buttons.
Bystanders, do not touch device.***

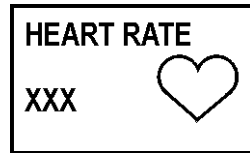
The following message displays:



! WARNING: If you fail to press and hold both response buttons on the Alarm Module at the same time, after you have received a message telling you to do so, you may receive a defibrillating electrical shock while conscious. If you receive a shock while conscious, it will be painful. To avoid receiving a defibrillating electrical shock while conscious, remember to always press and hold both response buttons when the device tells you to. Also, if you receive a shock while the heart is beating normally, the shock 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.

! WARNING: Do not press the response buttons by artificial means or by having another person press them for you. This would defeat the purpose of the response buttons.

If your heart rhythm returns to normal, your heart rate displays:

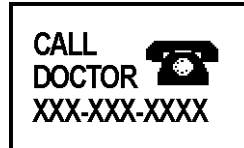


(xxx indicates heart rate in beats per minute)

But if you must hold the response buttons for more than two minutes because of an abnormal heart rhythm, these messages display:



and



If this happens, call your doctor while holding both response buttons.

What happens if you lose consciousness?

If you lose consciousness, voice messages should warn others that you are about to receive a shock and that they should not touch you. These voice messages are:

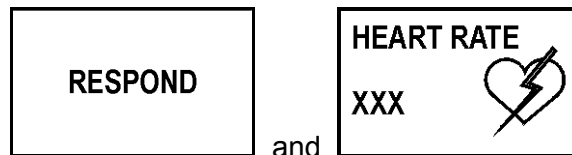
Electrical shock possible. Do not touch patient.

After the delivery of each shock, bystanders should hear:

Call ambulance.

Regaining consciousness

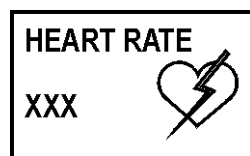
When you regain consciousness, if your heart rhythm still appears abnormal, these messages display:



Press and hold the response buttons. You should hear:

***Treatment stopped by response buttons.
Bystanders, do not touch device.***

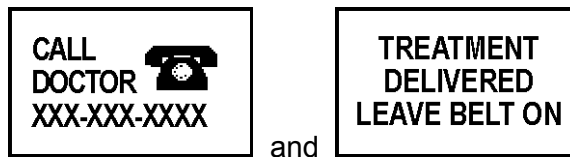
and see:



If this occurs, you should call an ambulance while continuing to hold the response buttons.

IF A SHOCK OCCURS, CALL YOUR DOCTOR AS SOON AS POSSIBLE!

If your heart rhythm returns to normal after receiving a treatment, these messages display:



accompanied by the voice message:

Contact physician.

You should then see the battery level message before the display goes blank. Until you change the Battery Pack, the “Call Doctor” message should appear each time you press “OK” or the response buttons.

When you regain consciousness, you may feel wetness on your back, sides, and chest. This is gel that is released just before the first shock is delivered. You might also have some chest soreness. Also:

- 1 Do not remove your Garment unless you receive a message telling you to “Add Gel or Replace Belt” (see next section). You may experience more abnormal rhythms and shocks, which would require the use of the gel under the therapy pads.
- 2 Check the display for any messages. Follow any additional instructions on the Monitor’s message panel.
- 3 Call your doctor’s emergency number immediately to report your shock treatment. He or she will want to see you at the hospital or office.

Adding gel or replacing belt

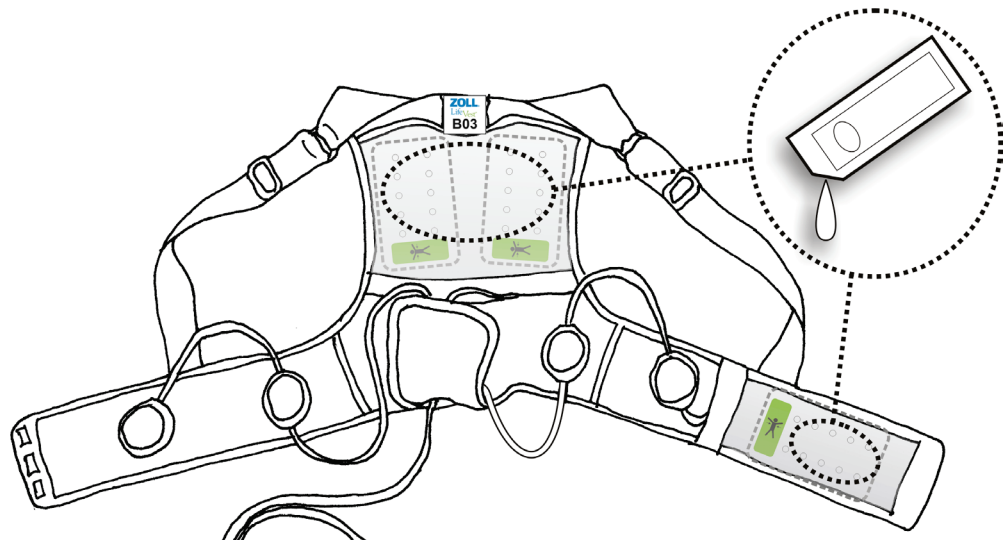
After you receive a therapy shock to correct an abnormal rhythm, you may see:

**ADD GEL OR
REPLACE BELT**

Do not ignore this message or proper treatment may not be delivered when needed.

To add gel

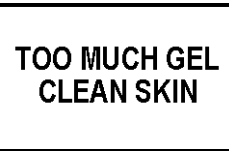
- 1 Remove the Battery Pack from the Monitor.
- 2 Remove the Electrode Belt from your body.
- 3 You've been supplied with two packets of gel. Add one-half packet of gel to each therapy pad (directly onto the mesh material of each pocket). Apply to the rear pads and the front pad (but not to the ECG electrodes.)



- 4 Put the Electrode Belt on again. Reinstall the Battery Pack.

If you have not added enough gel, you should see the message “Add Gel or Replace Belt” message again. If so, repeat the steps for applying gel.

If you’ve added too much gel, this message displays:



If you see this message, wipe the gel from the skin that is not under the therapy pads, leaving the gel on the skin that is under the therapy pads.

To change the Electrode Belt

- 1 Put the extra Electrode Belt into a clean Garment, and put lotion on the ECG electrodes of the new belt. (This is described in Chapter 3 of this manual.) Do not apply lotion to the Therapy Pads.
- 2 Disconnect the worn Electrode Belt from the Monitor.
- 3 Remove the worn Electrode Belt from your body.
- 4 Put on the clean Electrode Belt and fasten it.



WARNING: Before connecting the belt to the monitor: Do not force the connector. Allow the connector to align before tightening. Forcing the connector may damage it and cause the system to malfunction.

- 5 Connect the Electrode Belt to the Monitor, turning the connector ring clockwise to tighten it.

What happens if you remain unconscious?

If you are still unconscious after the delivery of a five-shock sequence, bystanders should hear:

Device disabled. Call ambulance



WARNING: If you should require conventional defibrillation, a warning label on the Garment informs medical personnel to unfasten and lay open the Garment, thus removing the front therapy pad from your chest. If they fail to do so, the LifeVest device may interfere with the defibrillation, and the conventional defibrillator may damage the LifeVest device.

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Chapter 7: How do you Record ECGs?

Chapter overview

This chapter describes how to record an ECG.

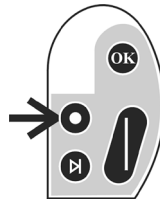
Description

At times, you may want to record your heart rhythm (ECG) for your doctor to review when you send information over the modem or when you go for a doctor visit.

Recording an ECG

To record an ECG:

- 1 Press the Record button on the Alarm Module for 3 seconds.



- 2 You should see the message:

**HOLD BUTTON
FOR 3 SECONDS
TO RECORD**

- 3 Hold the Record button until the message disappears or an alarm sounds. If you release the Record button before three seconds elapse, the ECG will not be recorded. While the ECG is recording, you should see the message:

**RECORDING...
mm/dd/yy
hh:mm**

which disappears when recording is done.

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Chapter 8: How do you Communicate by Modem?

Chapter overview

This chapter describes:

- How to hook up the WCD 3000 modem to your telephone.
- How to connect your Monitor to the modem.
- How to use the modem to send information to your doctor's facility.

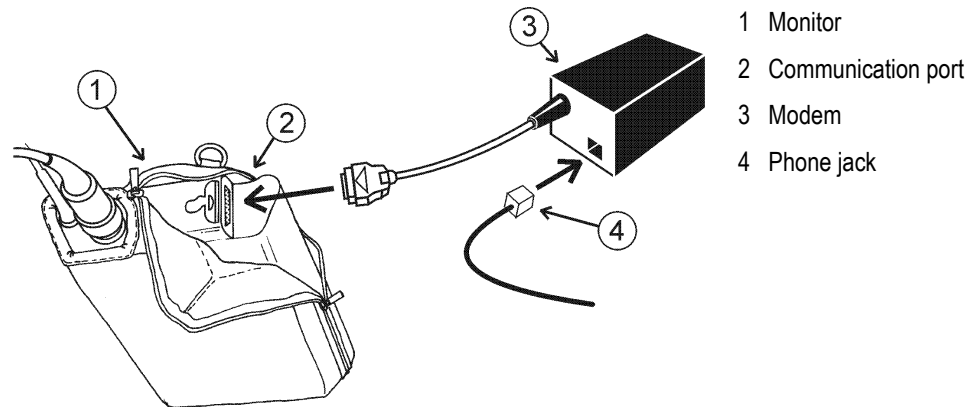
Description

Your physician may want Monitor information to be periodically sent from your home to the clinic or hospital. You will be able to do this by:

- 1 Connecting the Monitor to the modem.
- 2 Pressing the transmit button to begin sending data.

How to connect the modem

- 1 Unplug the phone jack from your phone and plug it into the modem.
- 2 Insert the modem connector into the Monitor's communication port as shown below. Make sure the arrow label on the top of the modem connector is facing up when you insert it into the Monitor.



How to send data

Once a week you should send Monitor information through the modem. To do so:

- 1 Connect the modem as described on the previous page.
- 2 Press the Transmit button for 3 seconds to start sending data.



You should see this message:

**HOLD BUTTON
FOR 3 SECONDS
TO SEND DATA**

If you release the Transmit button before three seconds elapse, the data will not be sent.

When you press the transmit button to send data, you may see the following messages, unless the device is busy. If the device is busy, the information will still be sent, but you may not see these messages.

CHECKING MODEM

**DIALING...
X,
XXXXXXXXXX**

**DATA TRANSFER
IN PROGRESS**

XX% ■■■□□□□□□□

While downloading, you should see the percentage that has already been sent (xx indicates percentage). When transmission is complete, you should see the display message:


**DATA TRANSFER
COMPLETE
PRESS OK
100% ■■■■■■■■■■**

Once transmission is complete, disconnect from the modem. To disconnect:

- 1 Disconnect the Monitor from the modem. Make sure the rubber cover is closed over the Monitor's communication port before closing the zipper.
- 2 Remove the phone jack from the modem.
- 3 Reconnect the phone jack to the phone.

If transmission failed

If transmission failed, you may see one of the following service messages.

Message	What it means	What to do
BUSY SIGNAL PRESS OK TO CONTINUE	Phone line is busy.	Press OK. Wait a few minutes. Then press and hold the Transmit button to try sending data again.
CHECK MODEM PRESS OK TO CONTINUE	Data could not be transmitted.	Check modem connections. Press OK, then press and hold Transmit button to try sending data again.
NO ANSWER PRESS OK TO CONTINUE	There was no answer at the receiving end.	Press OK, then press and hold the Transmit button to try sending data again.
 XX	Data could not be transmitted. An error code will appear.	Press OK, then try again. If problem continues, contact your device provider and report the error code.
TRY AGAIN LATER PRESS OK TO CONTINUE	Transmission was interrupted.	Press OK, then press and hold the Transmit button to try sending data again. If problems continue, wait a few minutes and try again.
TIME TO CONNECT MODEM & SEND DATA	Either it has been more than a week since data was sent, or for some other reason the system has determined that you should send data.	Press OK to delete the message. Send data at your earliest convenience. If you do not send data, you will see the message each time you power up the monitor.

Chapter 9: How do you Maintain the System?

Chapter overview

This chapter describes:

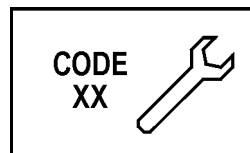
- Service messages.
- Replacing Battery Pack.
- Charging Battery Pack.
- Troubleshooting Battery Pack and Battery Charger.
- Laundering washable items.
- Cleaning non-washable items.
- General maintenance.
- Traveling with the system.

Service messages

A service message and a flashing yellow light on the Alarm Module are designed to let you know that the device needs attention or service.

Coded service messages

One type of service message displays a wrench symbol and a code number.



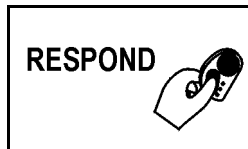
(xx represents the code number)

When you see this type of message, call your device provider.

The second type of message is designed to give you a direct instruction or information. The rest of this section lists these messages.

Response button test

When the device starts up, you will be asked to perform a response button test by pressing both response buttons on the Alarm Module. The yellow light should flash, and you should see the message:



This message should be accompanied by an alarm sequence. Press both response buttons until the message disappears.

The device should then display the battery level message before beginning normal operation.

If you do not press the response buttons, you should hear the voice message:

To activate device press response buttons.

Release Response Buttons message

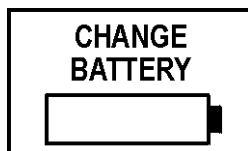
If you hold the response buttons for too long a period of time, you should see a flashing yellow light and the message:



To resume normal operation, release the response buttons when you see this message.

Change Battery message

If the battery is depleted, the yellow light should flash, and the following message should automatically appear:



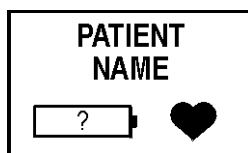
This message means that you must replace the depleted Battery Pack with the fully-charged one. Then insert the depleted Battery Pack into the Battery Charger to recharge.

Reinsert Battery Pack message

If the battery is not inserted correctly, you should see the message:



This message means that you must disconnect and then reinsert the Battery Pack. If the message reappears, or if you see:



Call your device provider to report the problem. You may insert the other Battery Pack if it is charged.

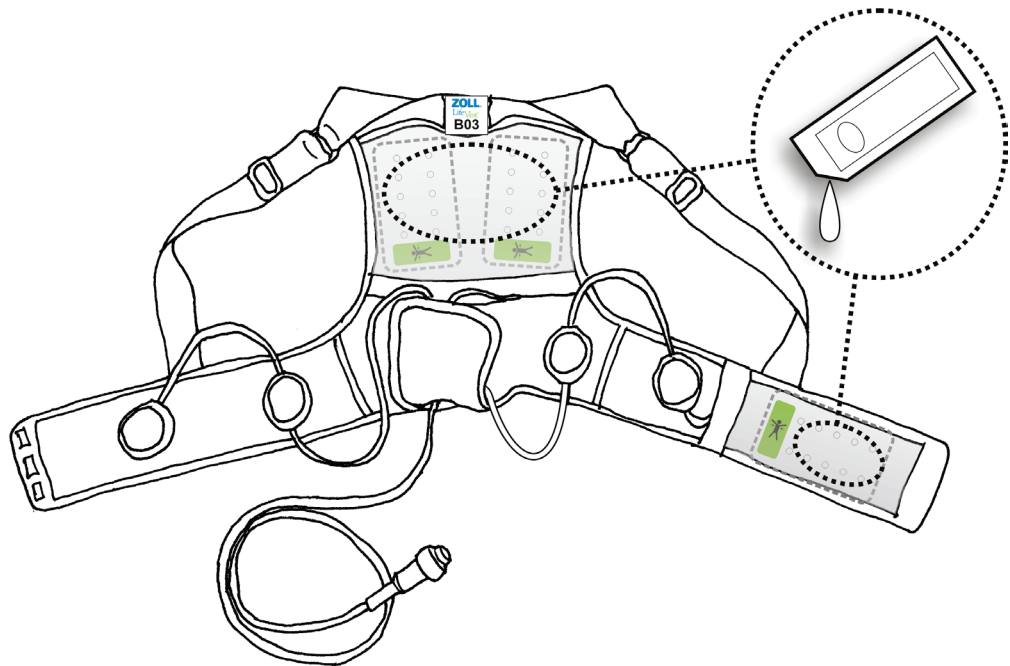
Add Gel or Replace Belt message

After you receive a therapy shock to correct an abnormal rhythm, you may see:

**ADD GEL OR
REPLACE BELT**

To add gel:

- 1 Remove the Battery Pack from the Monitor.
- 2 Remove the Electrode Belt from your body.
- 3 You should receive two packets of gel. Add a half packet of gel to each therapy pad (apply to front and rear pads), applying directly to the mesh pockets:



Do not apply gel to ECG electrodes.

- 4 Put the Electrode Belt on again. Reinstall the Battery Pack.

If you have not added enough gel, you should see the Add Gel or Replace Belt message again. If so, repeat the steps for applying gel.

To change the Electrode Belt:

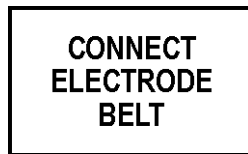
- 1 Put the extra Electrode Belt into a clean Garment, and put lotion on the ECG electrodes of the new belt. (This is described in Chapter 3 of this manual.) Do not apply lotion to the Therapy Pads.
- 2 Disconnect the worn Electrode Belt from the Monitor.
- 3 Remove the worn Electrode Belt from your body.
- 4 Put on the clean Electrode Belt and fasten it.



WARNING: Before connecting the belt to the monitor: Do not force the connector. Allow the connector to align before tightening. Forcing the connector may damage it and cause the system to malfunction.

- 5 Connect the Electrode Belt to the Monitor, turning the connector ring clockwise to tighten it.

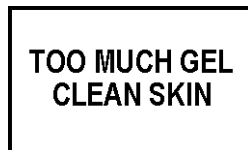
If the Electrode Belt is not properly connected, you should see:



If you see this message when the Electrode Belt is connected, disconnect the Electrode Belt from the Monitor, and then reconnect it. If the message reappears, call your device provider immediately to report the problem.

Too Much Gel, Clean Skin message

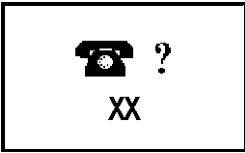
If there is too much gel on your skin, you should see:



Leaving the gel that is under the therapy pads, wipe it from the skin that is not under the therapy pads.

Communication error messages

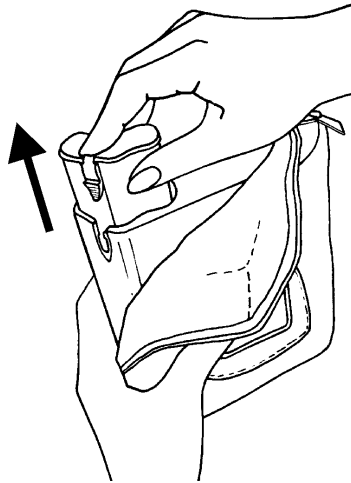
If transmission failed, you may see one of the following service messages.

Message	What it means	What to do
BUSY SIGNAL PRESS OK TO CONTINUE	Phone line is busy.	Press OK. Wait a few minutes. Then press and hold the Transmit button to try sending data again.
CHECK MODEM PRESS OK TO CONTINUE	Data could not be transmitted.	Check modem connections. Press OK, then press and hold Transmit button to try sending data again.
NO ANSWER PRESS OK TO CONTINUE	There was no answer at the receiving end.	Press OK, then press and hold the Transmit button to try sending data again.
	Data could not be transmitted. Phone dialing programming may be incorrect. An error code will appear that defines the problem.	Press OK, then try again. If problem continues, contact your device provider and report the error code.
TRY AGAIN LATER PRESS OK TO CONTINUE	Transmission was interrupted.	Press OK, then press and hold the Transmit button to try sending data again. If problems continue, wait a few minutes and try again.
TIME TO CONNECT MODEM & SEND DATA	Either it has been more than a week since data was sent, or for some other reason the system has determined that you should send data.	Press OK to delete the message. Send data at your earliest convenience. If you do not send data, you will see the message each time you power up the monitor.

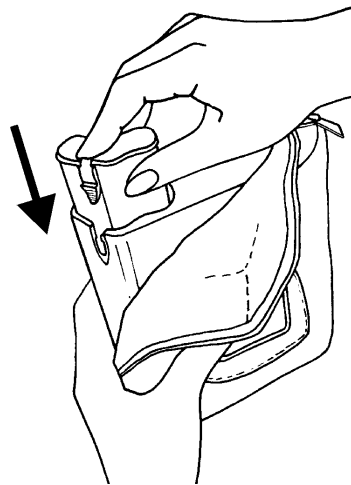
Replacing the battery pack


To replace the depleted Battery Pack with the freshly charged one:

- 1 Disconnect the depleted Battery Pack by grasping the Monitor, pressing down on the Battery Pack latch, and pulling the Battery Pack from the Monitor.



- 2 Connect the freshly charged one to the Monitor:

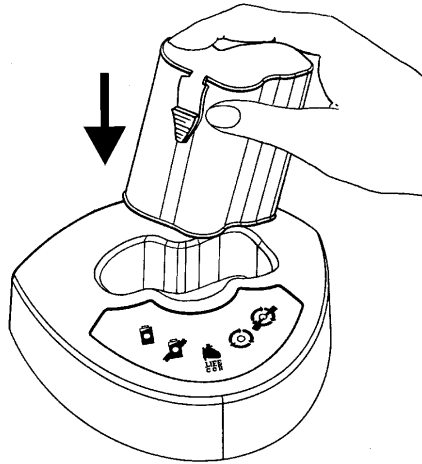


 **WARNING:** Make sure to completely insert the Battery Pack into the Monitor. If you only partially insert it, the LifeVest device cannot detect an abnormal rhythm or deliver a treatment shock.

Charging the battery pack

The Battery Charger should be plugged into a properly grounded outlet that is not controlled by a wall switch. The Battery Charger should be left on at all times.

To charge the depleted Battery Pack, insert it into the Battery Charger as shown:



Make sure that the Battery Pack is completely inserted into the Battery Charger.

The Battery Charger's orange light should light up while the Battery Pack is charging, and flash while the Battery Pack is going through a test cycle. Charging can take up to 3½ hours, the test cycle can take up to 12½ hours, for a total of up to 16 hours. Once the Battery Pack is fully charged, the green light should light. Leave the Battery Pack in the charger until it is needed.



WARNING: Press the Battery Pack firmly into the Battery Charger when charging. If the Battery Pack is not pressed firmly into the charger, charging may not take place.

Battery charger specifications

Battery charger	Input: 18.0 VDC, 2 A Output: 18.0 VDC, 2 A
Battery charger power supply	Phihong Model PSS-45W-180 Class II ITE/LPS Power Unit AC Input: 100-240 VAC, 1.6 A max, 60/50 Hz DC Output: 18 VDC, 2.8 A, 51 W max


Troubleshooting battery pack and battery charger

Problem	Solution
Battery is placed on charger, but no charger lights light up.	<ol style="list-style-type: none">1 Check power supply connections.2 Remove Battery Pack and then reinsert.3 Try the other Battery Pack.4 Contact device provider for a replacement.
Battery fault indicator lights.	Replace battery and call device provider to report problem.
Charger fault indicator lights.	Replace battery and call device provider to report problem.

Battery Charger status lights are explained in Chapter 2 of this manual.

How to launder the garment

 **CAUTION:** Before washing the Garment, remove the Electrode Belt to protect it from damage.

 **CAUTION:** Use clothes washing detergent only. Do not use chlorine bleach, bleach alternatives, fabric softener, or anti-static sprays.


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).

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

You may use a clothes dryer or hang the Garment to dry. If you use a clothes dryer, set it to a warm or medium setting. Do not use the high heat setting.

Leave the straps buttoned on the Garment when laundering.

How to clean the non-washable items

 **WARNING:** Unplug battery charger and disconnect the power cord before cleaning to reduce risk of electrical shock.

Non-washable items such as the Alarm Module, Battery Pack, Battery Charger, Modem, cables, ECG electrodes, and therapy pads may be cleaned using a soft cloth sparingly dampened with Formula 409 all-purpose cleaner (made by Clorox Company) or equivalent cleaning solution.

Do not apply liquids directly to any of the non-washable items, as they contain electronic components that can be damaged.

Do not attempt to clean any electrical contacts or connectors.

Do not use any cleaning solution on the garment.

Inspection

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

- Cracks in the housing of the Monitor, Alarm Module, Battery Pack, or Battery 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.

General maintenance information

To make sure that dirt and strain do not shorten the life of your LifeVest system:

- Do not splash or spill food or liquid on the system.
- Do not hang items such as a radio or tape player from the Garment, Electrode Belt, or Holster.
- Do not expose the system to rain, snow, extreme direct sunlight, extreme heat, or extreme cold.
- Do not attempt to open the case of the Monitor, the Alarm Module, the Battery Pack, or the Battery Charger.
- Do not kink the cables. Kinking the cables may damage them and cause the system to malfunction.

Traveling with the LifeVest System

When traveling, be certain to take the Battery Charger, spare Battery Pack, and the Patient Manual.

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Chapter 10: What is the Operating Environment of the System?

Chapter overview

This chapter lists the temperature, humidity, and altitude ranges within which the LifeVest system must be operated.

Operating environment

LifeVest Device

Temperature range 0°C to 50°C (32°F to 122°F)

Note: The Electrode Belt, which is worn in direct contact with the skin, operates to a maximum of 41°C (105.8°F). It does not generate any additional heat, and provided the skin does not exceed 41°C, the maximum surface temperature of the Electrode Belt will not exceed 41°C.

Humidity range 0% to 95% relative humidity, non-condensing

Altitude To 10,000 feet

Battery Charger

Temperature range 0°C to 50°C (32°F to 122°F)

Humidity range 0% to 95% relative humidity, non-condensing

Altitude To 10,000 feet

Modem

Temperature range 0°C to 50°C (32°F to 122°F)

Humidity range 0% to 95% relative humidity, non-condensing

Altitude To 10,000 feet



WARNING: Do not operate or store the LifeVest system outside of the recommended ranges. To do so could cause the system to fail.

Environment considerations related to noise and vibration

Certain environments or situations you encounter that are loud and have high vibration could affect the LifeVest. 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 or using some lawnmowers 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, 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.

Chapter 11: What do Family Members Need to Know?

Chapter overview

This chapter gives important information for the family and friends of the person wearing the LifeVest device.

Important information

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. If so, you should probably read this entire manual. However, this chapter is specifically for you. It contains several warnings and cautions that all family members and friends should know.



WARNING: If someone touches the patient when he or she is receiving a defibrillating treatment shock, that person will be shocked also. **DO NOT TOUCH THE PATIENT WHEN THE TREATMENT SHOCK IS ABOUT TO OCCUR.**



WARNING: If someone other than the patient wears the device, it will not recognize the unfamiliar heart rhythm and may shock that person.



WARNING: KEEP OUT OF REACH OF CHILDREN!¹



WARNING: Do not hold the response buttons for an unconscious patient. The patient's ability to press the response buttons lets the device know whether or not the patient is still conscious. Based on this information, the device is designed to decide whether or not the patient should receive treatment shock(s).

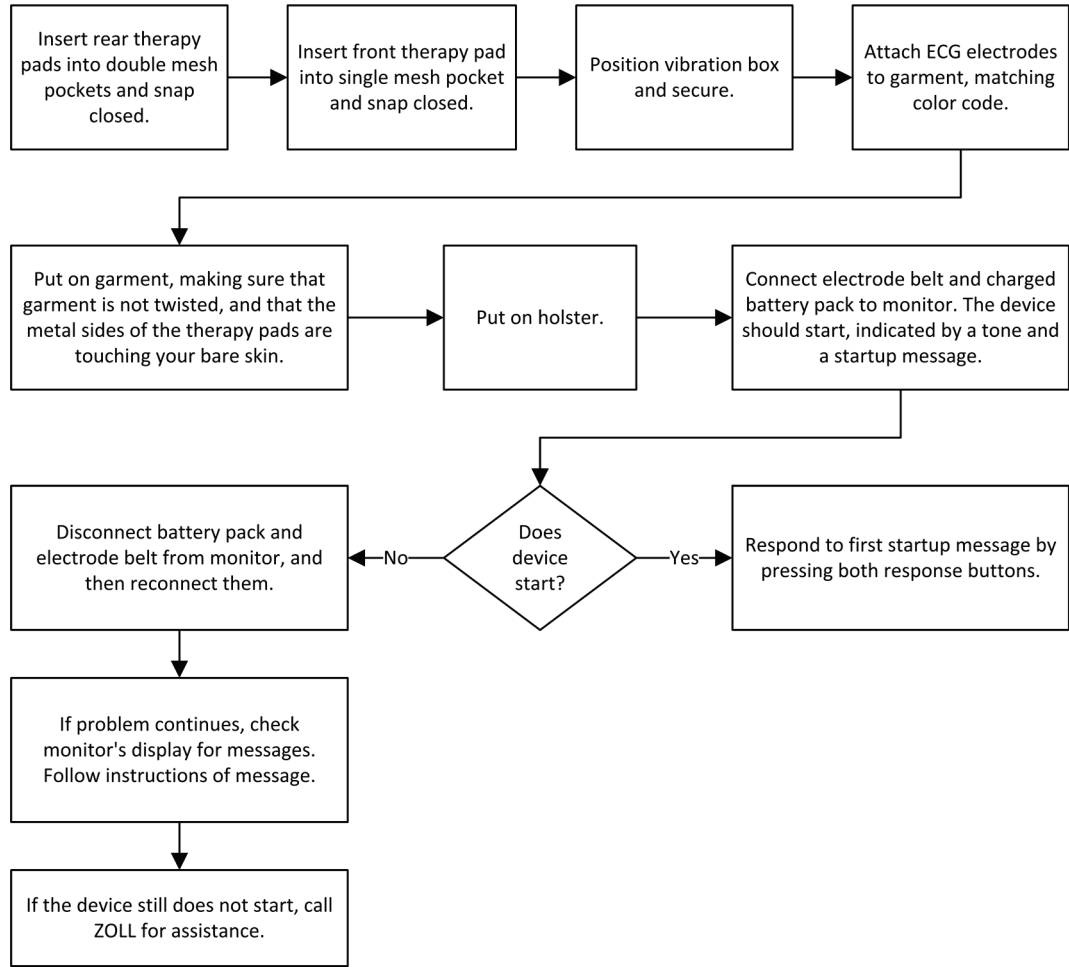
You may also notice a label on the front of the Garment stating that medical personnel must open the Electrode Belt before conventional external defibrillation. This only applies in the case of conventional external defibrillation administered by trained personnel.

The LifeVest 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.

¹ See indication for patients under 18 years of age.

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Appendix A: Flowchart of Assembly and Startup



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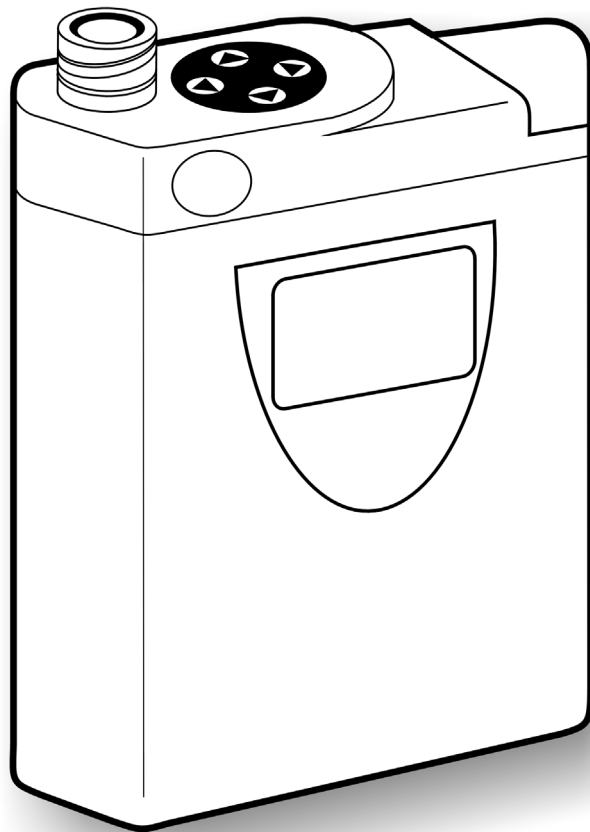
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LifeVest[®]

Model WCD 3100

Patient Manual



ZOLL[®]

PN 20B0039 Rev D Proposed

Restricted sale

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

Effectivity

This manual describes the LifeVest WCD 3100 wearable defibrillator system.

Disclaimer

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

Trademarks

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Patents

US patents: 6,681,003; 6,280,461; 6,253,099; 6,169,387; 6,097,982; 6,065,154; 5,944,669; 5,929,601; 5,741,306; others pending.

Software nonexclusive license

The LifeVest device includes certain software ("Software"). ZOLL grants you a nonexclusive license to use the Software solely for diagnostic and treatment purposes as part of use of the LifeVest device. You are prohibited from: (i) reproducing the Software; (ii) removing or destroying any proprietary markings, copyright notices or other legends which are part of the Software; (iii) modifying or reverse engineering the Software; or (iv) removing the Software from the LifeVest device. Title to the Software will remain at all times with ZOLL. You must keep the Software confidential.

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1: Introduction

About the LifeVest system

The LifeVest device continuously monitors your heart. If it detects a life threatening rhythm that is too fast, the device delivers a 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.
- **Meet the LifeVest system** tells you about the components, what they're called, and basically how they work.
- **Using the LifeVest device** 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 alerts** explains the types of alerts and tells you what to do if you get an alert.
- Appendixes include **Quick charts**, a **Glossary**, and **Symbols**. 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.

Terms used



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



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

Warning

- A complete understanding of the manual and patient training is necessary before using the LifeVest System. If you do not understand how to use the system you could inappropriately assemble or misuse the device resulting in a device that is unable to deliver treatment or delivers inappropriate treatment.

Shock hazard

- Always wear the LifeVest device and make sure the electrode belt and battery are properly connected to the monitor. The device cannot detect an abnormal rhythm or deliver a treatment shock if not worn and properly connected.
- Do not let another person wear your LifeVest device. Because the device has been programmed to recognize your specific heart rhythm pattern, if it detects an unfamiliar heart rhythm, it may shock that person.
- Do not attempt to open the monitor, battery, battery charger, electrode belt, or modem. This may expose you to high voltage and damage the system.

Rescue defibrillation

- If you should require conventional defibrillation, a warning label on the garment informs medical personnel to unfasten and lay open the garment, thus removing the front therapy pad from your chest. If the garment remains fastened and connected, the LifeVest device may interfere with the defibrillation, and the conventional defibrillator may damage the device.

To help ensure proper operation

- Use the LifeVest device only after you understand all training and instructions.

- Do not put anything other than the monitor into the holster. The extra weight may pull the electrode belt from the body.
- Keep the device out of the reach of children.* The device may be damaged by improper handling.
- Do not kink the cables. Kinking the cables may damage them and cause the system to malfunction.
- Do not drop the device. If you do drop one of the device components, inform ZOLL immediately.
- Do not put foreign objects, such as fingers, paper clips, or hair pins into any connectors or openings.
- Protect the device from moisture and extreme sunlight when wearing it outdoors. To protect the device, always wear clothing over the garment and keep the monitor and battery in the holster.
- Do not put the monitor, electrode belt, battery, battery charger, or modem in or near water. Do not bathe or shower while wearing the LifeVest device. Also, before washing the garment and holster, be sure to remove the electrode belt and the monitor.
- Do not allow food or liquid to splash or drip on the LifeVest device.
- Do not expose the device to direct sunlight, excessive heat, or excessive cold for prolonged periods of time.
- Use only the cables, batteries, and accessories specified in this manual. If you use any other items, the system may not operate correctly.
- 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 10,000 feet in altitude.

Risk of fire

- Use appropriate caution in an oxygen-rich environment. As with any defibrillator, there is a risk of sparking during defibrillation.

Gel release

- The therapy pads should not release gel unless a treatment shock is about to be given. Gel seepage at any other time indicates a damaged electrode belt. If this occurs, call your device provider immediately.
- If the therapy pad gel gets into your eyes, flush your eyes immediately with water and contact your physician. Your eyes may become irritated from the gel.

* See indication for patients under 18 years of age.

Travel

- The LifeVest device has not been tested or approved for use in aircraft. Check with your airline for any special restrictions on using personal electronic equipment when making your flight reservations.

Electromagnetic interference

Many common devices, including motors and electronic equipment, may produce electromagnetic interference, also known as EMI, that can affect the operation of the LifeVest device. The LifeVest device has been tested with a number of common sources of such interference, 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 interference.

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

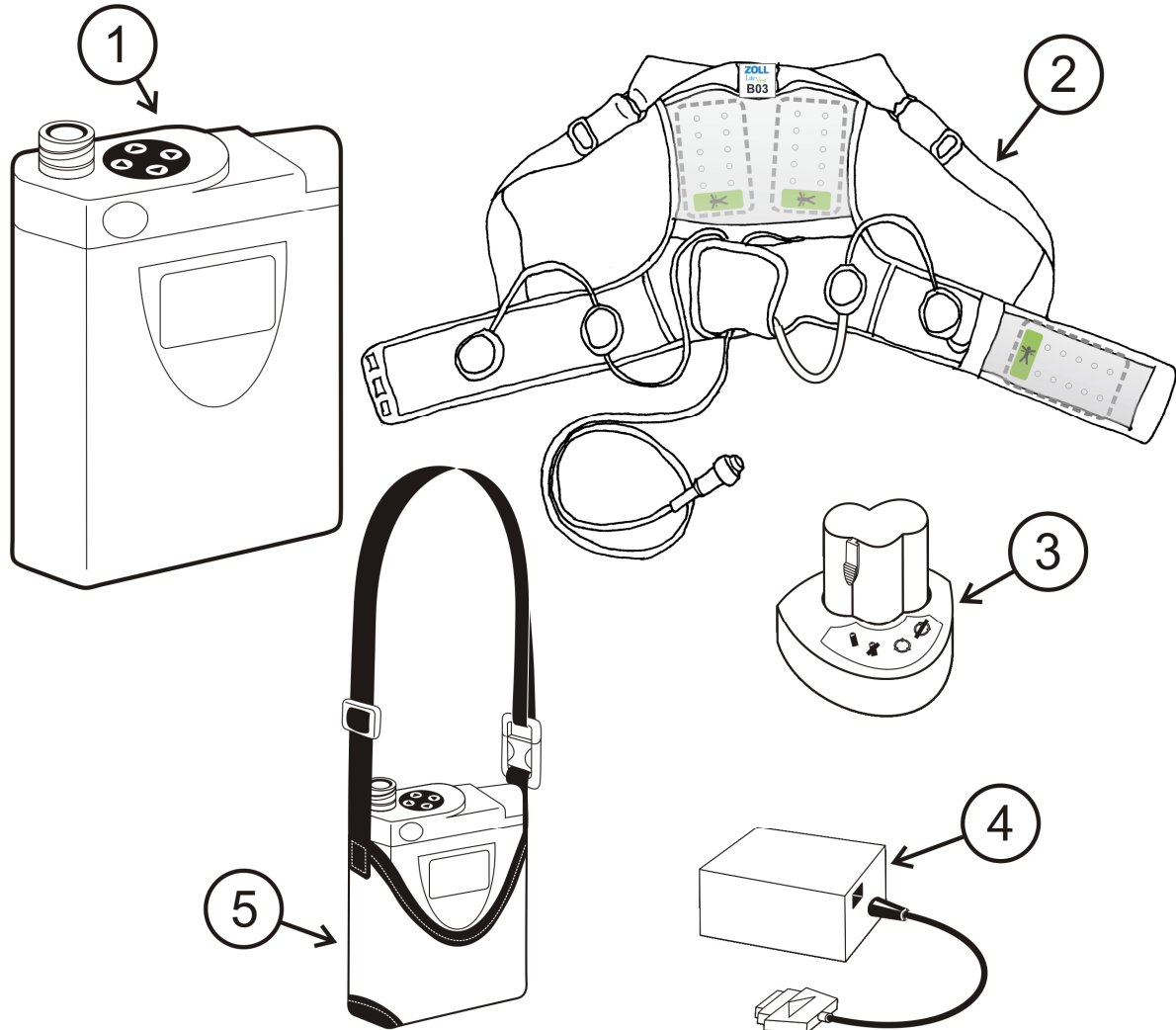
- Walk through the gate at a normal pace.
- Avoid lingering near or leaning on the gate.

In some occupational and hospital environments, unusually high levels of electromagnetic interference may be encountered. Examples of possible sources of such interference include: 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 interference causes you to receive arrhythmia alerts, hold the response buttons to prevent being shocked and move away from the source of the interference. The LifeVest device should return to normal monitoring mode in approximately 5 seconds.

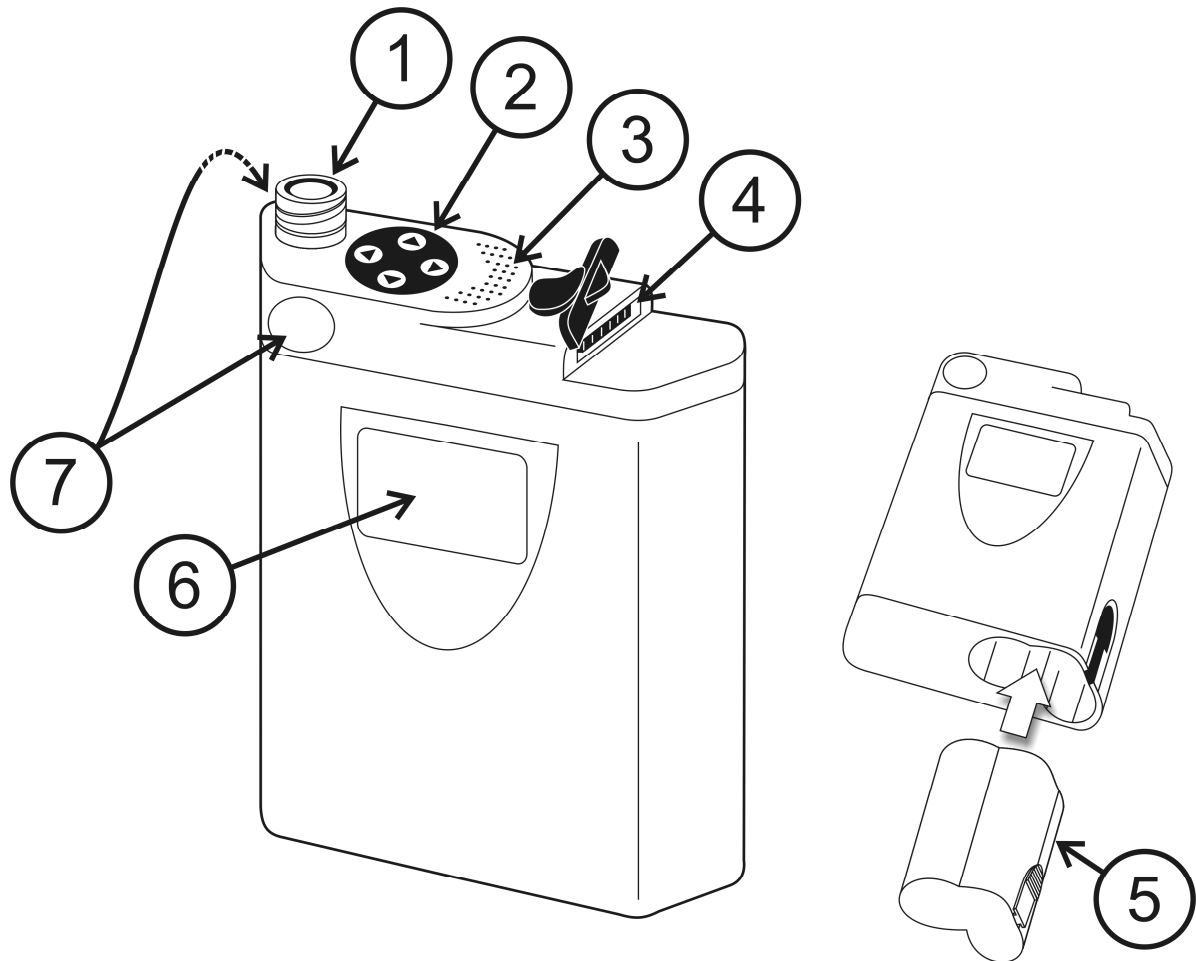
2: Meet the LifeVest system

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. See details on page 2-3.
3 Battery charger	Recharges a second battery while the monitor is being worn. See details on page 2-4.
4 Modem	Connects the monitor to a phone line to transmit data for doctor review. See details on page 2-4.
5 Holster	Lets you carry around the monitor.

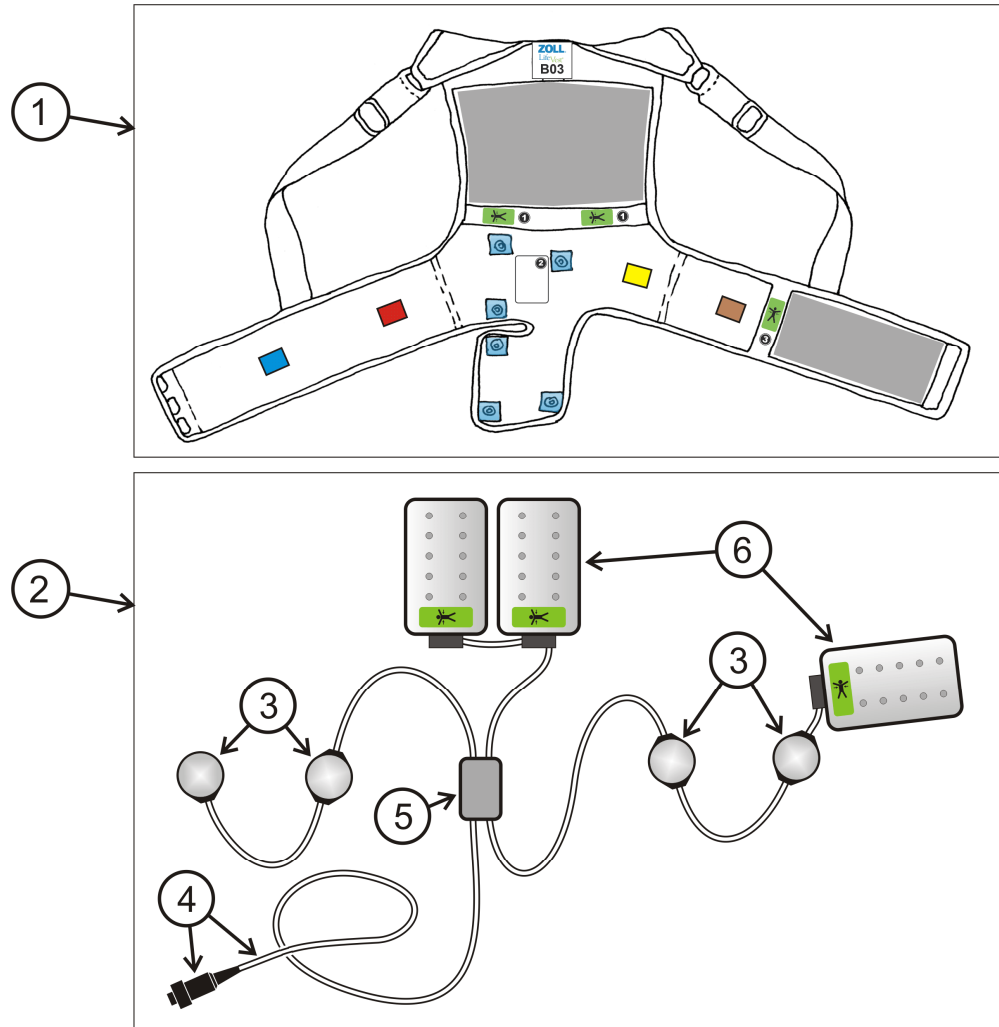
Monitor



Item	Description
1 Electrode connector	Connects to electrode belt.
2 Navigation buttons	Used by operator to program the device.
3 Speaker	Where sound comes from for alerts and voice prompts.
4 Communication port	Connector for attaching accessories (such as the modem) to the monitor.
5 Battery	Powers the monitor.
6 Display	Displays messages about device operation. In normal operation, the display is upside-down for reading by the patient who is wearing the device.
7 Response buttons	Two buttons, located front and back, that light red when the device senses that your heart is in a rapid life-threatening rhythm. You should, if conscious, hold <i>both</i> response buttons to stop from getting a defibrillating shock. You may also be prompted to press the response buttons with some messages. For details about responding to alerts, see section 5.

Garment and electrode belt

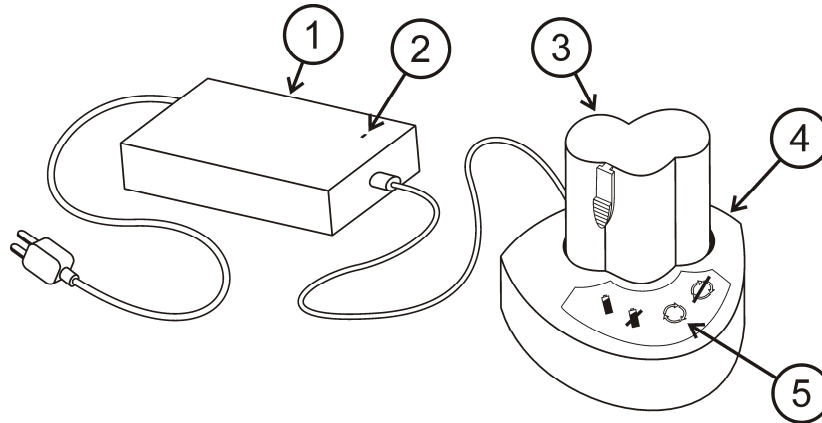
For details on assembling, wearing, and caring for the garment and electrode belt, see section 4.



Item	Description
1 Garment	Worn under your clothing to hold the ECG electrodes and therapy pads against your chest.
2 Electrode belt	Assembles to garment and contains ECG electrodes, vibration box, and therapy pads.
3 ECG electrodes	Sense your heart's electrical signal for the monitor.
4 Connector and cable	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.

Battery charger

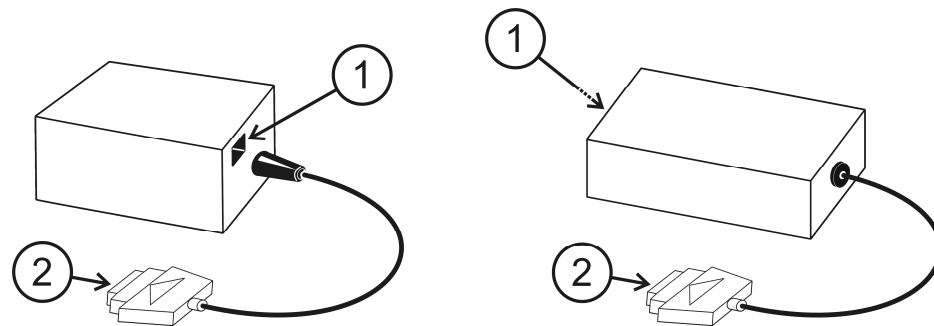
The LifeVest system includes two batteries and a charger so that the monitor can run continuously on battery power. For details on battery care, see section 3.



Item	Description
1 Power unit	Converts AC line power into a level suitable for the battery charger.
2 Power indicator	Comes on to show AC line power is being supplied to battery charger.
3 Battery	Shown charging in charger base.
4 Charger base	Accepts the battery for recharging.
5 Charger indicators	Show operating mode of charger. For details, see section 3.

Modem

The modem sends data from the monitor so your doctor can view it. For details about sending data, see section 3. There are two versions of the modem.

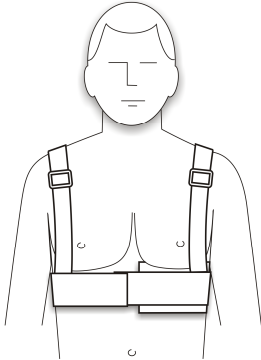


Item	Description
1 Phone jack	Accepts phone plug cable that connects to a normal analog phone line.
2 Monitor connector	Plugs into communication port on monitor.

3: Using the LifeVest device

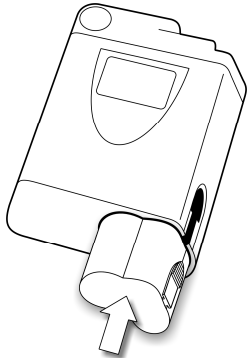
Daily routine

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

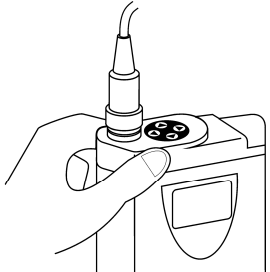
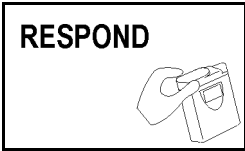
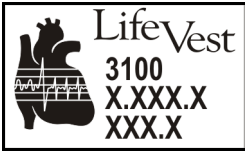


- 1 Wear the assembled electrode belt and garment.

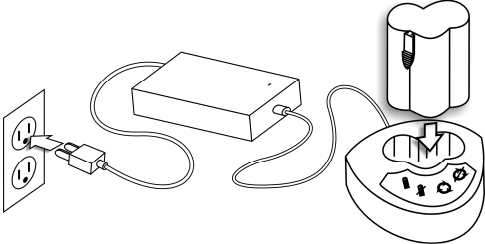
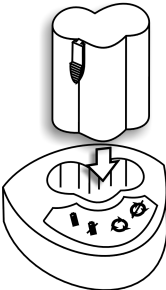
For details about assembling and putting on the electrode belt and garment, see section 4.

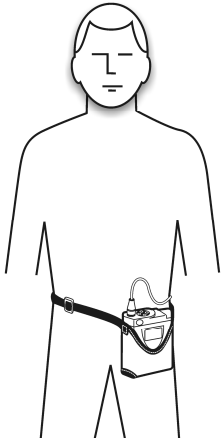


- 2 Put a fully-charged battery into the monitor and follow the normal startup routine. See page 3-3.

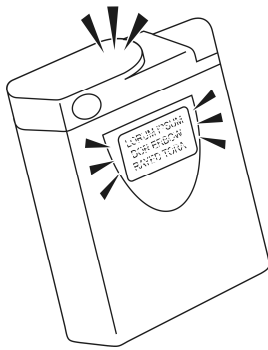
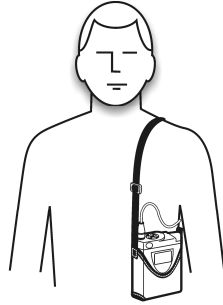


- 3 Change and recharge the battery every 24 hours. See page 3-4.



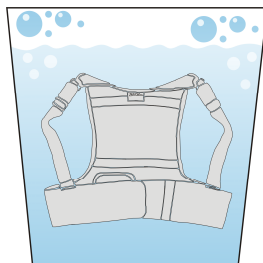
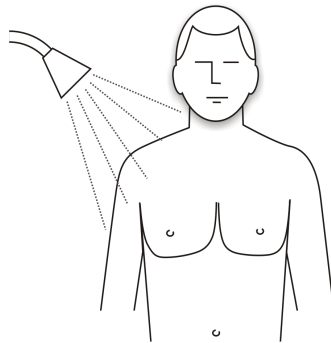
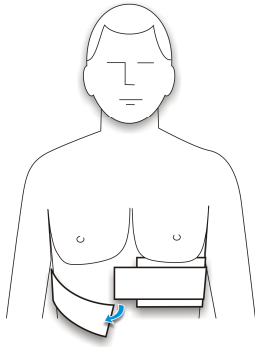


- 4 Wear the monitor in its holster. The holster strap is adjustable to give you several options for comfortably wearing the system.



- 5 Respond to any alerts or messages. See section 5.

- 6 Completely remove the LifeVest device when you shower or bathe. See section 4.

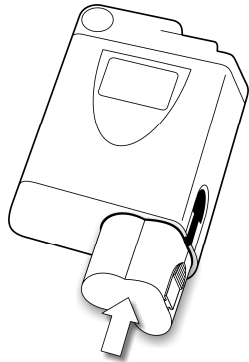


- 7 Change and wash the garment every 1 or 2 days.

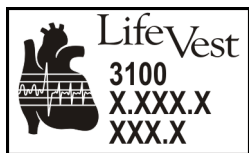
Wash only the garment. Do not wash the electrode belt, monitor, or any other accessories.

Follow the instructions in section 4 for laundering the garment.

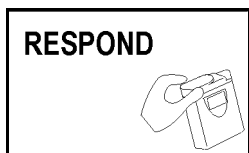
Normal startup routine



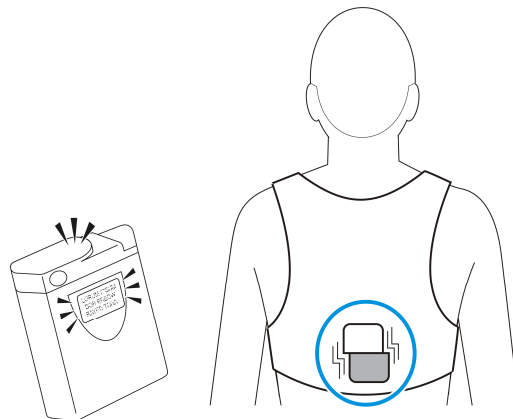
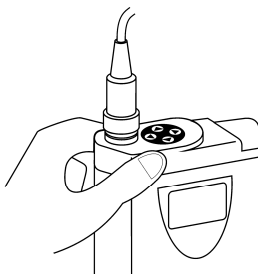
- 1 Put a fully-charged battery into the monitor. Make sure the battery is completely inserted.



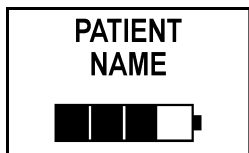
- 2 Startup screen appears.



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



If you do not hear the gong alert or feel the vibration alert 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 condition.

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

Taking care of the batteries

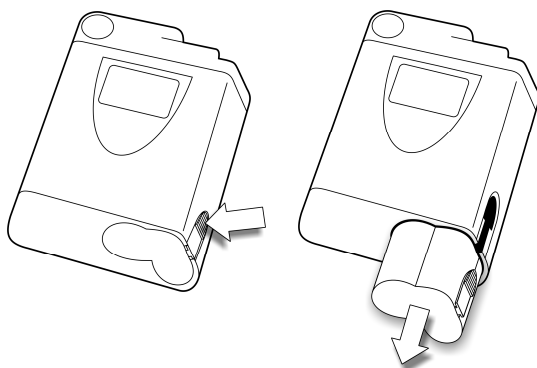
What you need to know

- 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 charged 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 and charger supplied with the LifeVest system.
- Remove the battery from the monitor whenever the device is not being worn. For example, when you remove the device to take a shower, be sure to remove the battery first, to ensure the device is not active when you are not wearing it.

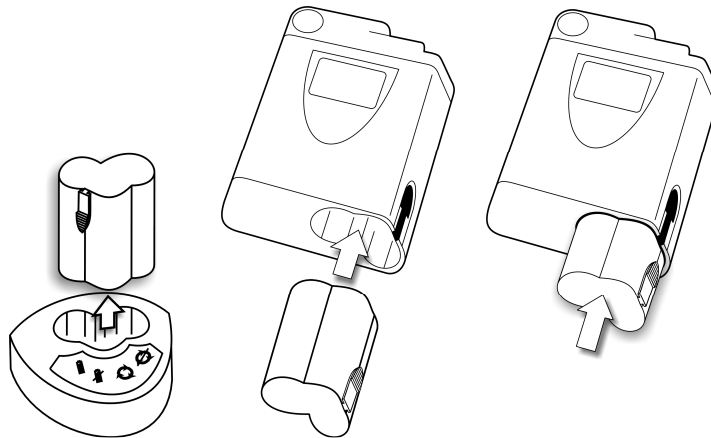
Change and recharge batteries daily

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

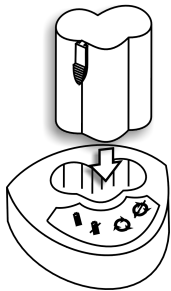
- 1 Remove the existing battery from the monitor.
 - Slide the monitor out of the holster to expose the battery compartment.
 - Push the battery latch, then slide the battery out of the monitor.




- 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 into the monitor.
 - Make sure the device follows the startup routine on page 3-3.



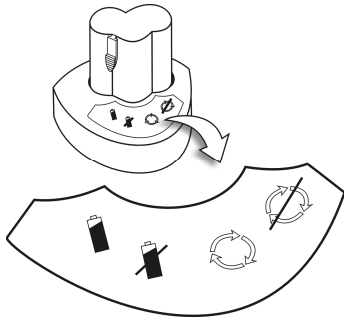
- 3 Put the monitor back into the holster.



- 4 Put the used battery from the monitor into the battery charger.


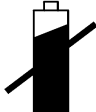


- Push the battery in firmly.
- Verify that the battery is being charged, shown by  lit steady or flashing.
- For details about the charger lights, see next page.

How to read battery charger lights



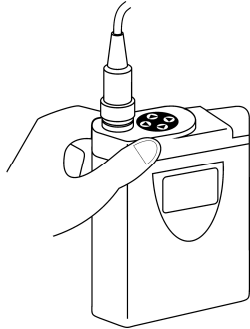
These indicators show you the status of the battery and charger.

Check them with the battery charger plugged in and a battery installed in the charger.

Icon	Light	What it means	What to do
	Green solid	Battery is fully charged, ready for use in monitor	Leave battery in charger until ready to exchange battery.
	Red flashing	Battery showing a fault, but still might hold a charge	<p>If light flashes when you first connect battery, remove the battery and reinsert it firmly. If the light continues to flash, the battery may charge, but will take longer than normal.</p> <p>If light flashes at end of charge cycle, battery is reaching the end of its life and can be used, but should be replaced.</p> <p>If problems continue, call ZOLL.</p>
	Orange solid	Battery is charging	Let battery charge. Can take up to 3.5 hours.
	Orange flashing	Battery is being tested	<p>Let test run. Can take up to 12.5 hours. Test verifies battery function as part of normal routine. After test, battery will be charged, for a total of up to 16 hours.</p> <p>If you need to use battery sooner, remove battery from charger as soon as light starts flashing, then put the battery back into the charger to skip test and charge battery.</p>
	Red flashing	Charger showing a fault, not charging	<p>Do not leave a battery in the charger with this light on. Battery is not being charged.</p> <p>Remove the battery and reinsert it firmly. If the light continues to flash, call ZOLL.</p>

How to record 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 at any time.



- 1 Hold the response buttons for 3 seconds.

**HOLD BUTTONS
FOR 3 SECONDS
TO RECORD**

**RECORDING...
MM/DD/YY
HH:MM**

- 2 Release response buttons when you see this message. Your heart rhythm is being recorded.

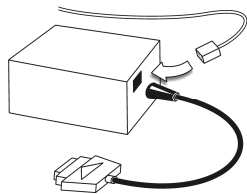
How to send data to your doctor

You will need the modem supplied with the LifeVest system.

The monitor needs to be operating, with a battery installed. You can leave the electrode belt connected to the monitor so the device can continue to monitor your heart during this procedure.

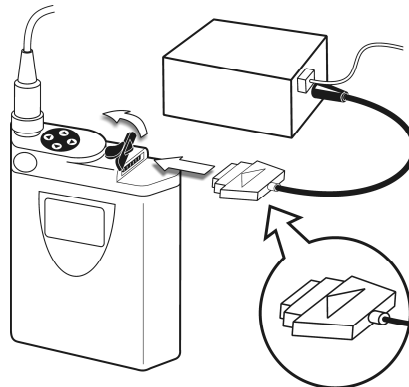
You must connect the phone line to the modem first, then connect the modem to the monitor, as described below.

To connect the modem and send data



- 1 Plug your phone line into the modem. Connect directly from the wall to the modem, not through phones or answering machines.

- 2 Connect the modem to the monitor's communication port. Make sure the white triangle on top of the modem connector faces up.



- 3 Data will be sent and you will see these messages.


CHECKING MODEM	DIALING... X, XXXXXXXXXX	DATA TRANSFER IN PROGRESS XX% ■■■■■■■■■■	DATA TRANSFER COMPLETE 100% ■■■■■■■■■■
---------------------------	---------------------------------------	--	--

If you get an error message, see the chart on the next page.

- 4 When the transfer is complete, disconnect the modem from the monitor. Disconnect the phone line from the modem.

The monitor resumes normal operation.

If you get an error message when sending data

Message	What it means	What to do
BUSY SIGNAL	Phone line is busy.	Disconnect the modem connector from the monitor. Wait a few minutes. Then reconnect the monitor.
CHECK MODEM	Data could not be sent.	Check modem connections. Disconnect the modem. Then reconnect the modem in the order described: Connect the phone first, then the monitor. If you continue to get this message, make sure your phone service is working.
NO ANSWER	There was no answer at the receiving end.	Disconnect the modem from the monitor. Wait a few minutes. Then reconnect the modem. If you continue to get this message, make sure your phone service is working.
TRY AGAIN LATER	Data transfer was interrupted.	Disconnect the modem from the monitor. Wait a few minutes. Then reconnect the modem. If problems continue, wait a few minutes and try again.
 XX	Data could not be sent. An error code will appear.	Disconnect the modem from the monitor. Wait a few minutes. Then reconnect the modem. If problem continues, write down the error code, then contact ZOLL.

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, battery charger, modem, cables, ECG electrodes, and therapy pads may be cleaned using a soft cloth sparingly dampened with Formula 409[®] all-purpose cleaner or equivalent cleaning solution.

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.
- 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 battery 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

Who this information is for

This information is for the family and friends of the person wearing the LifeVest device.

What you need to know

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 probably read this entire manual.

Information for family members

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

- **Don't hold the response buttons for the patient.** 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 still conscious and is critical in deciding when to give the patient a shock.



WARNING: If anyone other than the patient holds the response buttons, needed therapy may not be delivered, possibly resulting in serious injury or death.

- **Don't touch the patient when the treatment shock is about to occur.** If anyone touches the patient when the patient receives a defibrillating shock, the person touching the patient will be shocked also.
- **Don't remove the battery, don't disconnect the electrode belt from the monitor, and don't loosen the garment unless you are prepared to do CPR (cardiopulmonary resuscitation) on the patient.**
- **Don't let anyone else wear the LifeVest device.** If someone other than the patient wears the device, it will not recognize the unfamiliar heart rhythm and may shock that person.
- If the LifeVest treatment does not revive the patient and the patient is unconscious, call 911 (or your emergency medical service) and then start CPR.

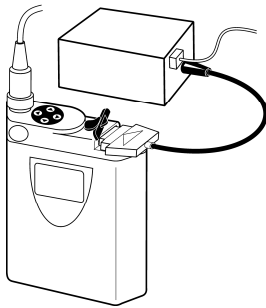
- If the patient gets the alert messages shown below and the patient is unconscious, call 911 (or your emergency medical service) and then start CPR. If the patient remains conscious, check the belt to make sure all electrodes are pressing against the patient's skin.



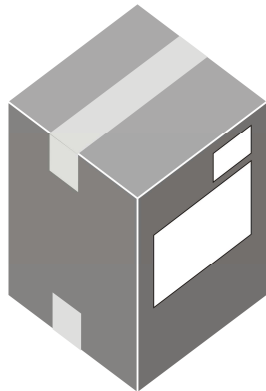
- A label on the front of the garment reminds medical personnel to open the garment before giving the patient conventional external defibrillation.
- Keep the LifeVest device out of the reach of children.*

* See indications for patients under 18 years of age.

When you are finished with the device



1 Connect the modem and send data. See page 3-8.



2 Call ZOLL and arrange to return the LifeVest system.

Battery recycling

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



WARNINGS:

- Do not dispose of the batteries in the trash.
- Do not incinerate the batteries since they might explode.

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4: Assembling and putting on the garment

About this chapter

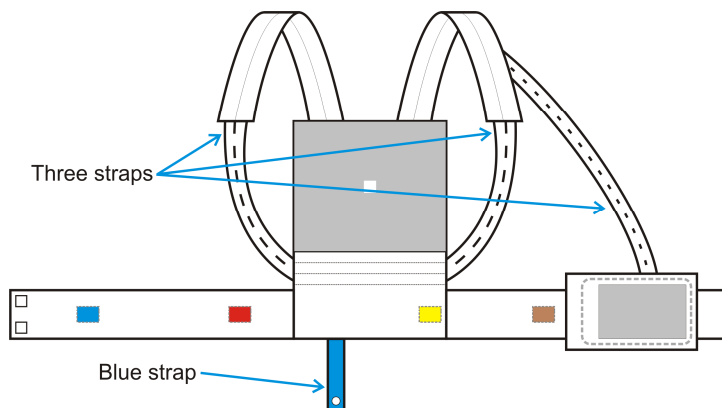
This chapter contains instructions for:

- Identifying which style garment you have
- 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

Which style garment do you have?

The first thing to do is figure out which style garment you have. Then refer to the instructions for the style you have.

Garment A

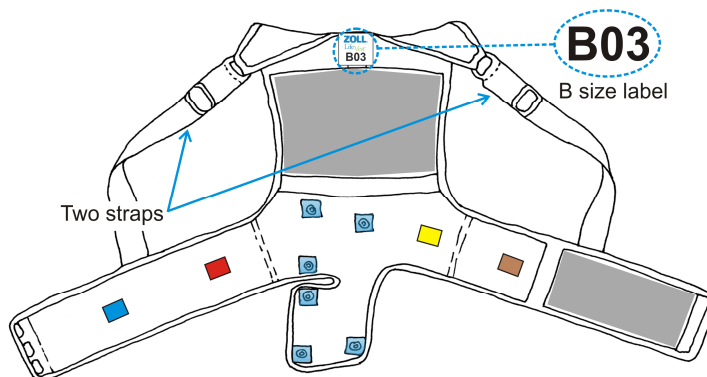


This style garment has three straps at the top, and a small blue strap at the bottom.

We call this garment style A.

If you have this style garment, see page 4-2.

Garment B



This style garment has two straps and a label showing the B size of the garment.

We call this garment style B.

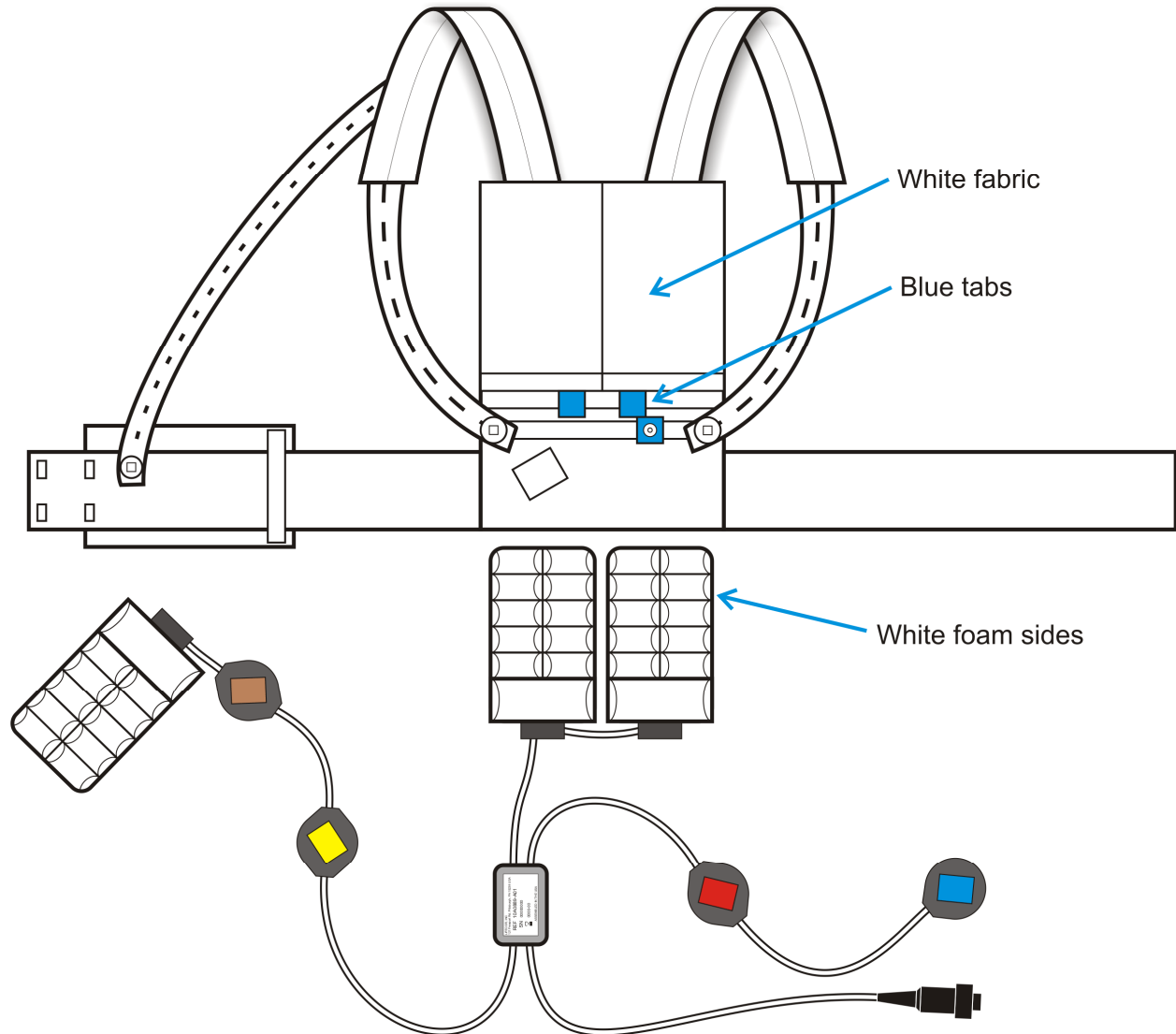
If you have this style garment, see page 4-12.

Assembling the electrode belt to garment A

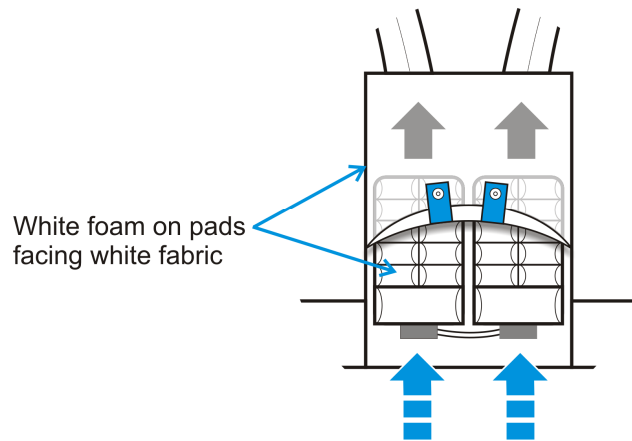
Refer to this section for garment A. If you have garment B, see page 4-12.

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

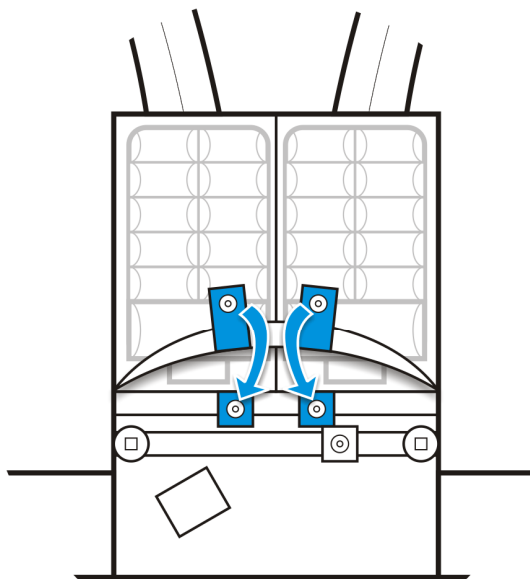
- Place the garment with the white fabric and blue tabs on the back pockets facing up.
- Place the electrode belt with the white foam sides of the therapy pads facing up.



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

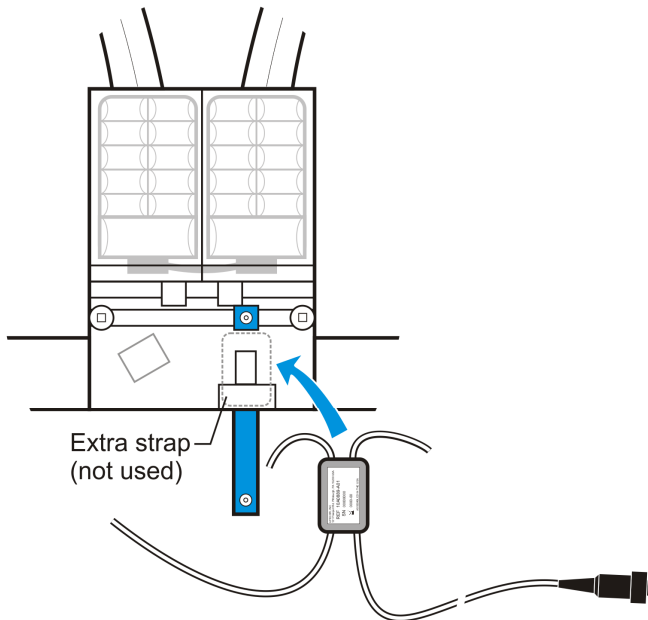


- Insert the pads with the white foam facing up, toward the white fabric.

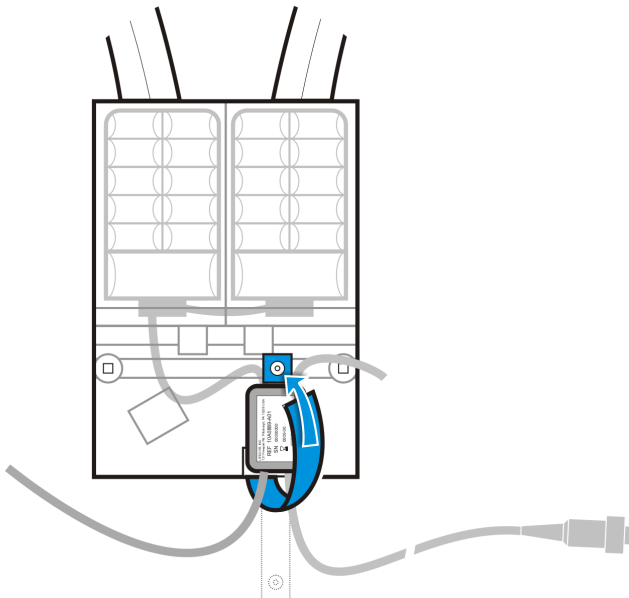


- Snap the blue tabs to secure the pockets.
- Make sure the snaps are securely fastened.

2 Position and secure the vibration box to the garment.

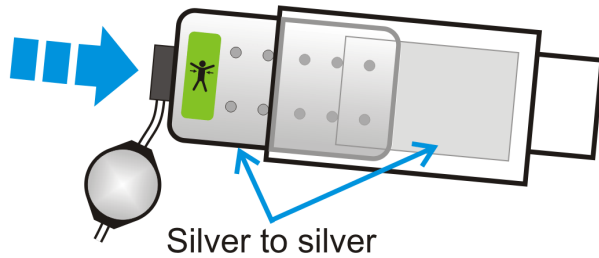


- Position the vibration box with the label side facing toward you.
- Position the box with the wires going up and down (not sideways), and with the connector cable exiting down.
- Your garment may have an extra strap (see figure to the left). This strap is not used with your electrode belt. Place the vibration box over the extra strap.

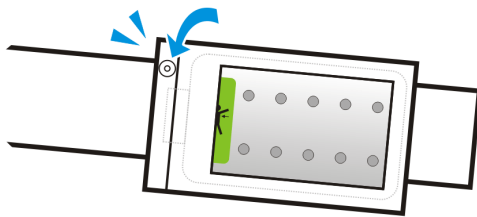


- Pull the blue strap up between the wires.
- Snap the blue strap over the vibration box.
- Make sure the snap is securely fastened.

3 Insert the front therapy pad into the front pocket.

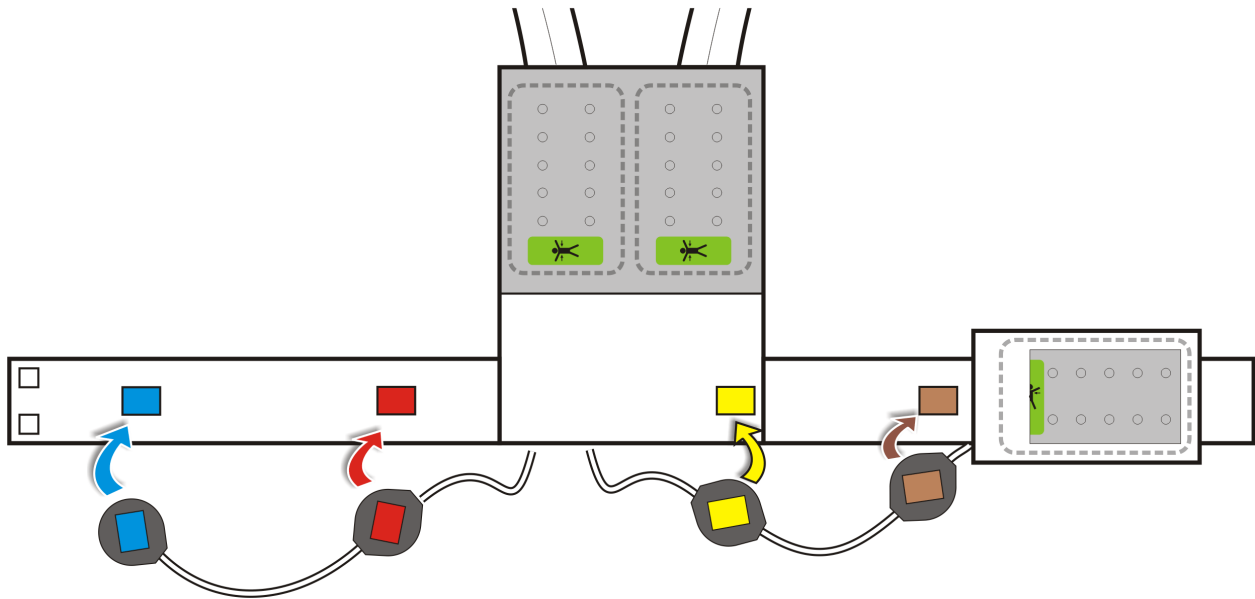


- Turn the garment over.
- Insert the pad with silver to silver. By that we mean to have the silver side of the pad (with the green sticker) facing the silver fabric on the pocket.



- 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 4-8.

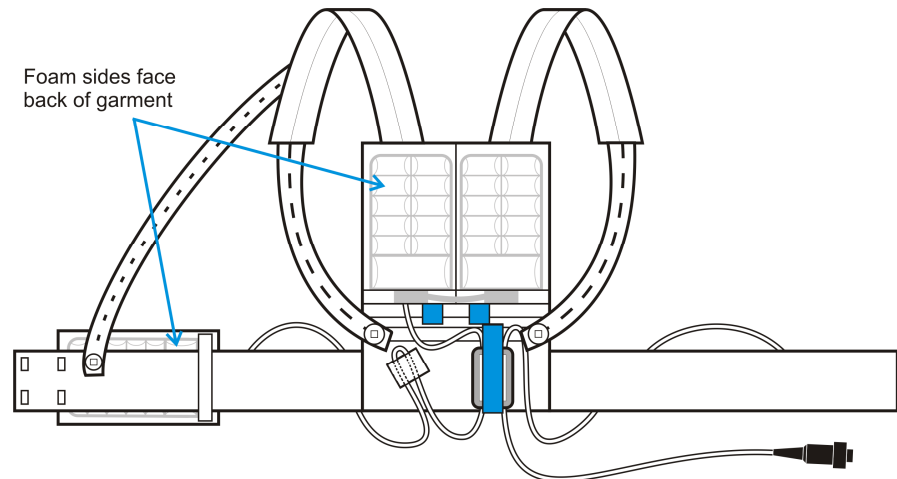
Assembled electrode belt and garment A

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

If the straps are not buttoned, button them now.

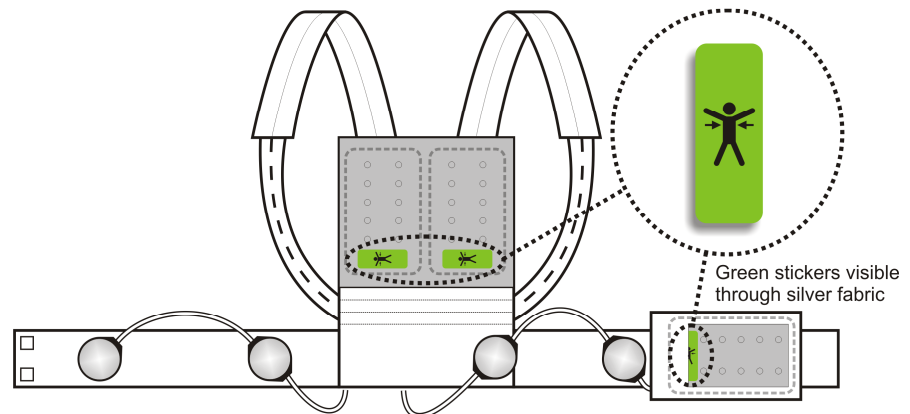
Outside view

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



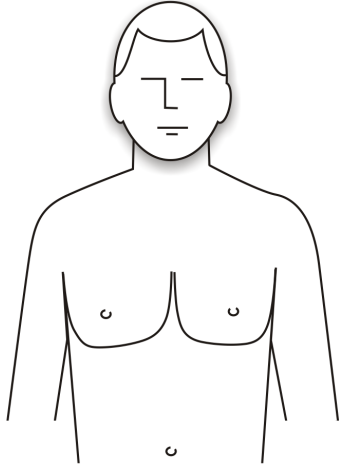
Inside view

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



Putting on the assembled electrode belt and garment A

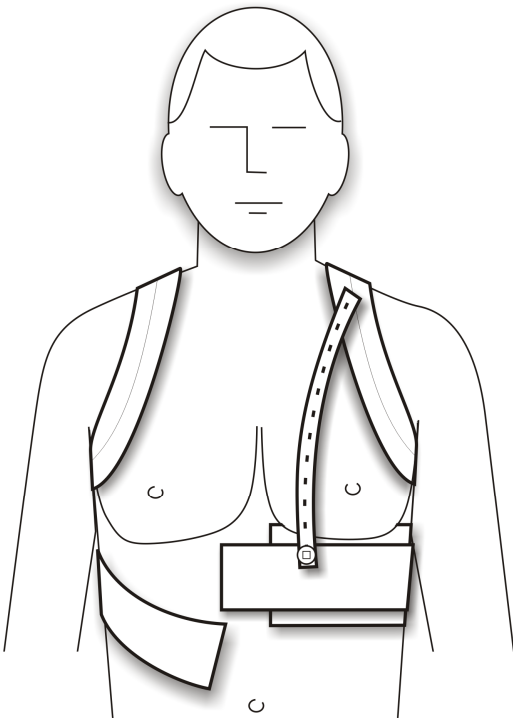
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 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:

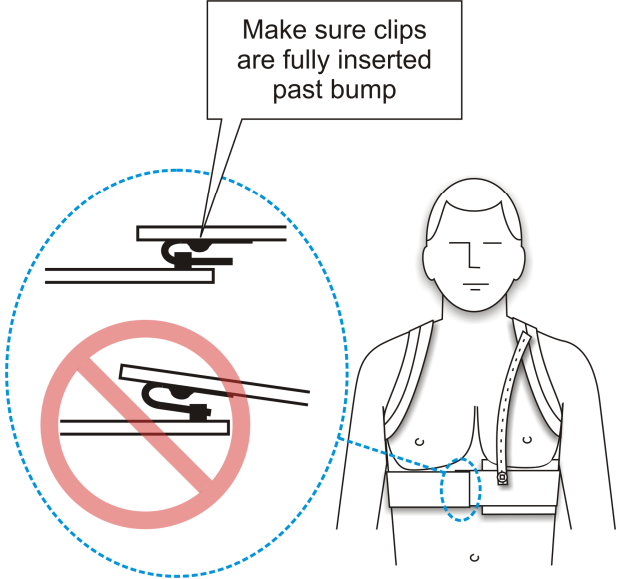
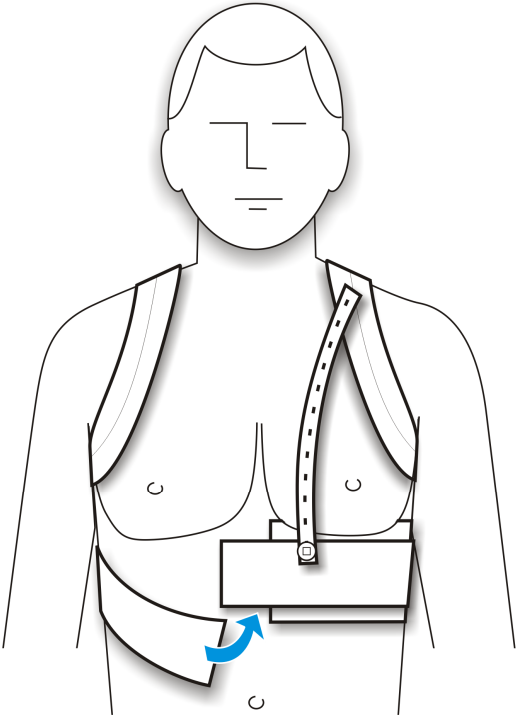
- The garment doesn't get twisted.
- The silver fabric pockets touch your bare skin.

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 is pressing against your body rather than the underside of your left breast.

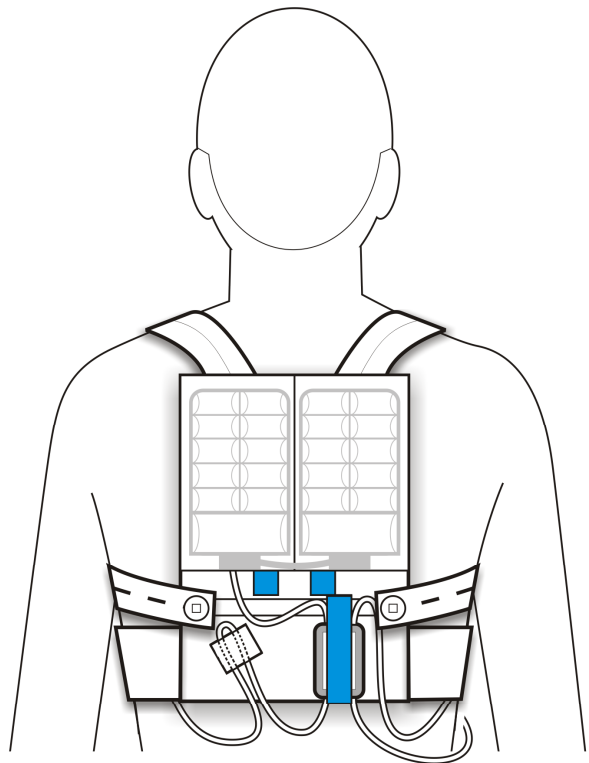
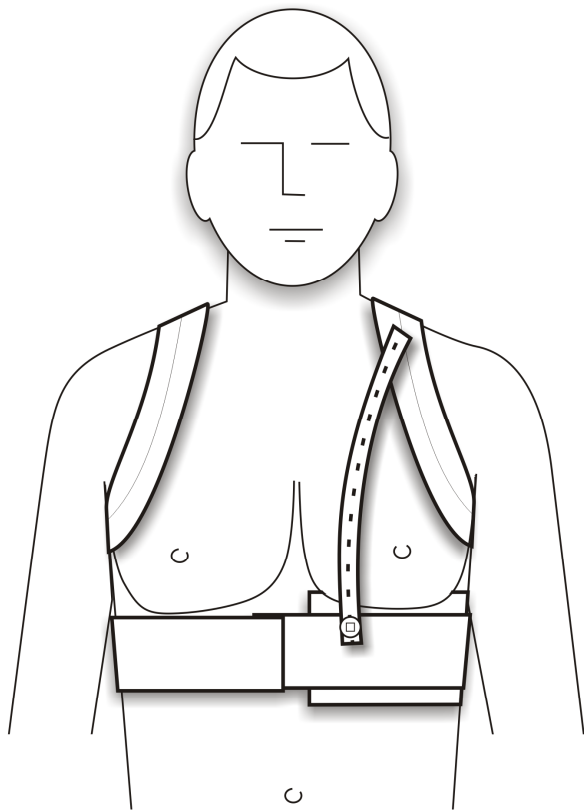
- 4 Connect the garment ends together in the front.

Make sure that the clips are fully inserted past the slight bumps in the clips.



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 silver fabric pockets and silver side 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 or therapy pads.
- The garment is being worn correctly. Your garment should look like the figures below.

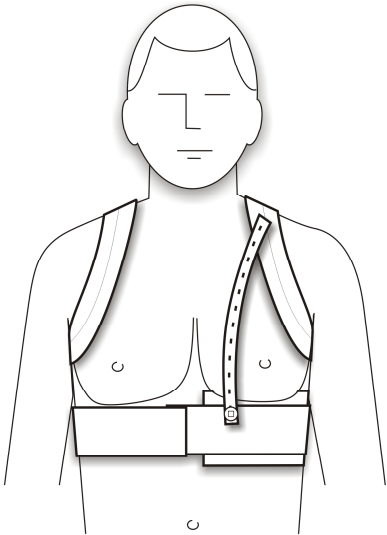
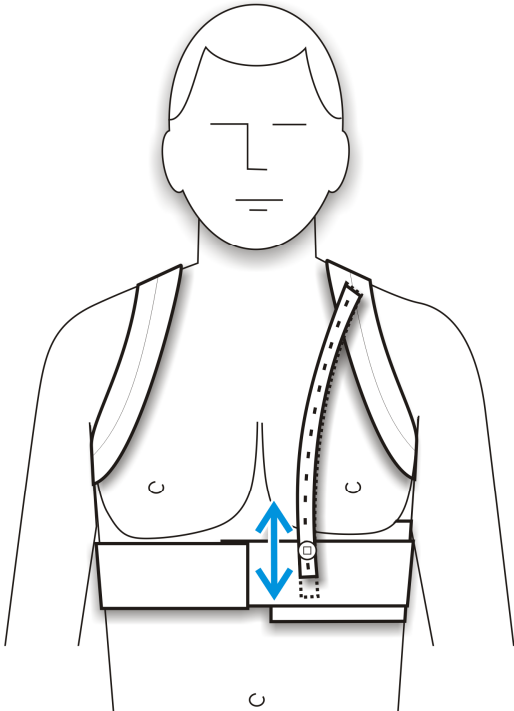


6 Check the position of the garment on your body and make sure it's not too high or too low.

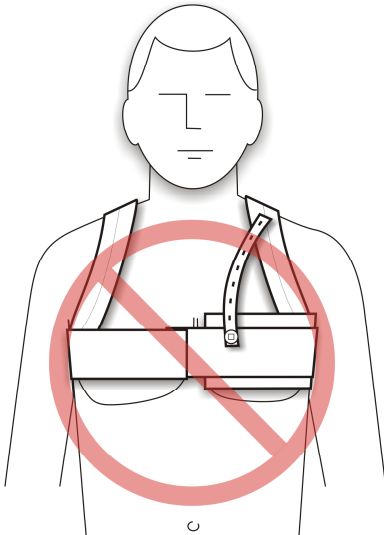
To position the garment properly, you may need to adjust the front strap.

Move the strap to the button hole that positions the garment properly, and for a snug fit.

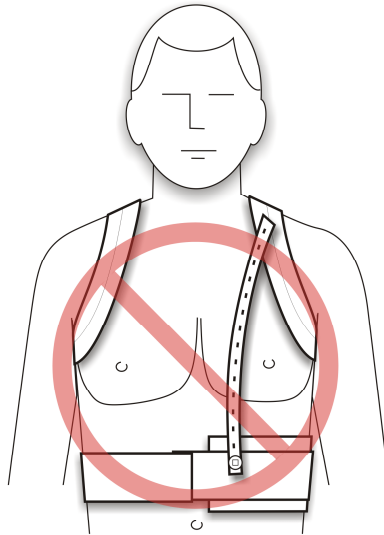
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



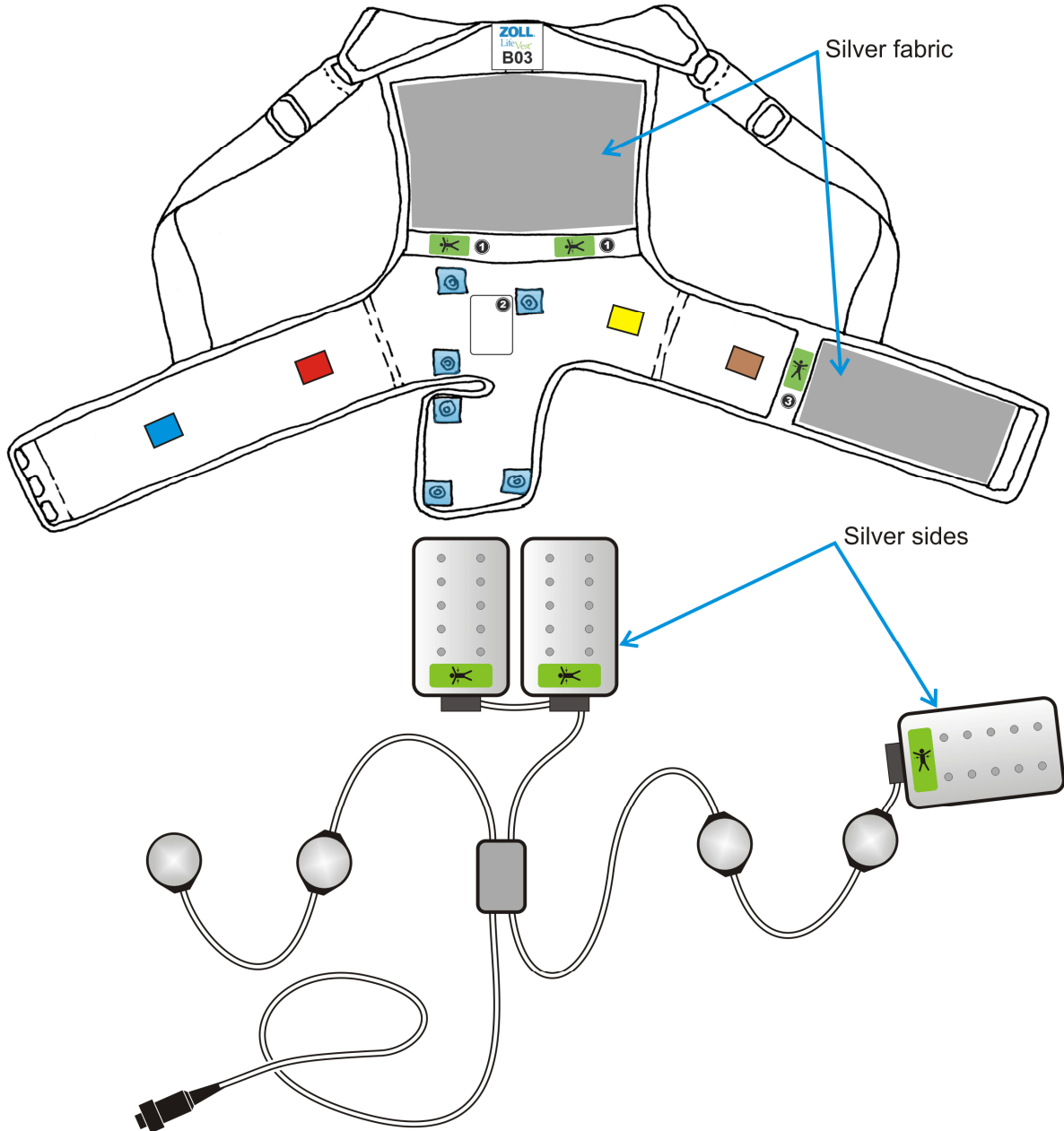
Too low

Assembling the electrode belt to garment B

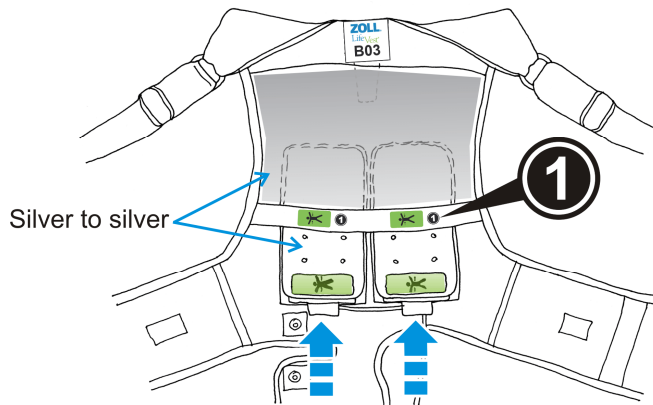
Refer to this section for garment B. If you have garment A, see page 4-2.

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

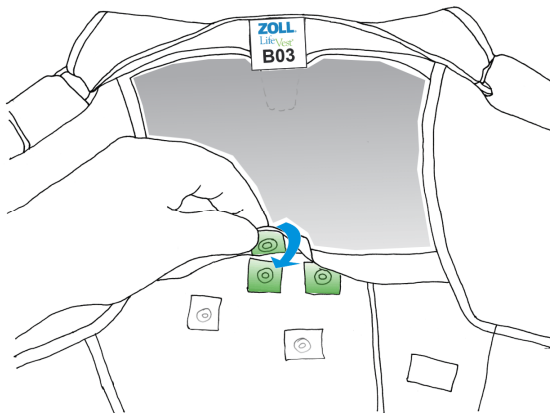
- Place the garment with the silver fabric facing up.
- Place the electrode belt with the silver sides of the therapy pads facing up.



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

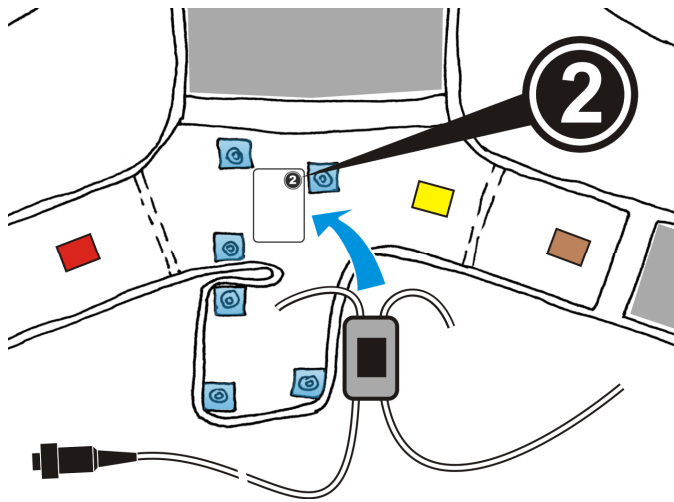


- The rear pockets are numbered 1.
- Insert the pads with silver to silver. By that we mean to have the silver sides of the pads (with the green stickers) facing the silver fabric on the pockets.

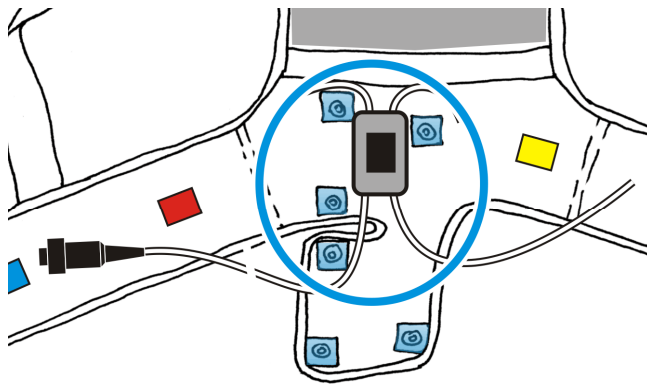


- Snap the green tabs to secure the pockets.
- Make sure the snaps are securely fastened.

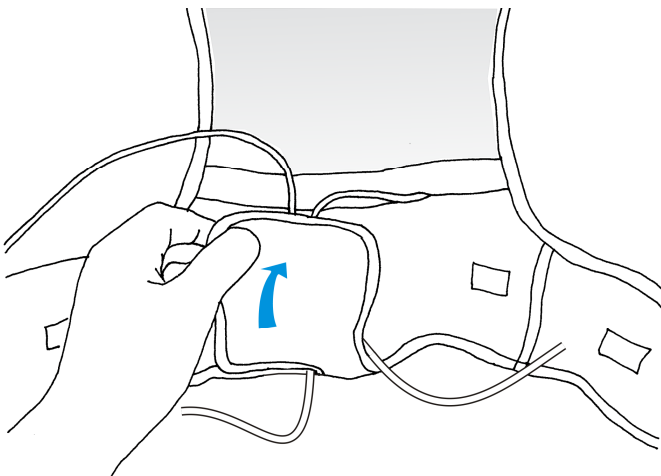
2 Position and secure the vibration box to the garment.



- The vibration box goes in position numbered 2.
- Position the vibration box with the label side facing toward the garment.

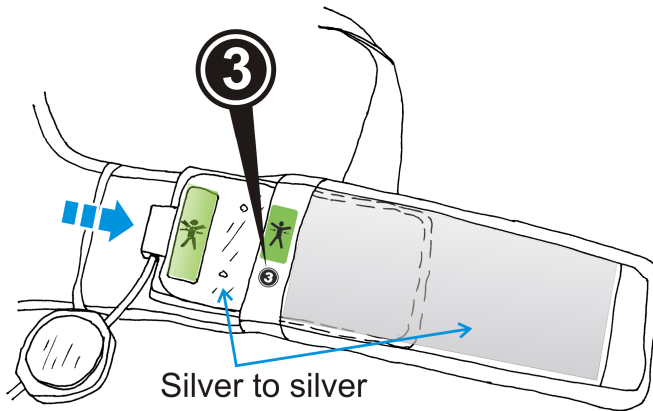


- Place the vibration box with the wires going up and down (not sideways), and with the connector cable exiting down.

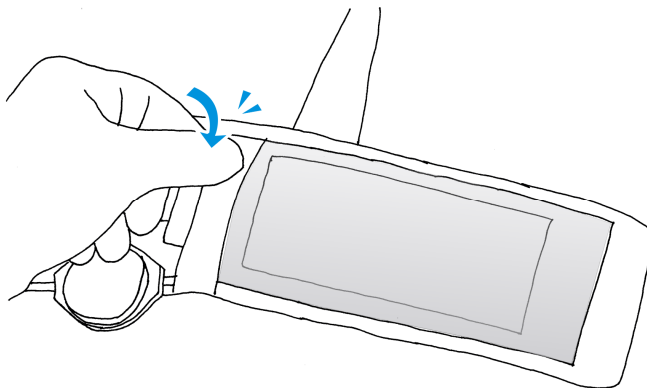


- Bring the flap up between the wires.
- Snap the flap over the vibration box to the blue tabs.
- Make sure all three snaps are securely fastened.

3 Insert the front therapy pad into the front pocket.

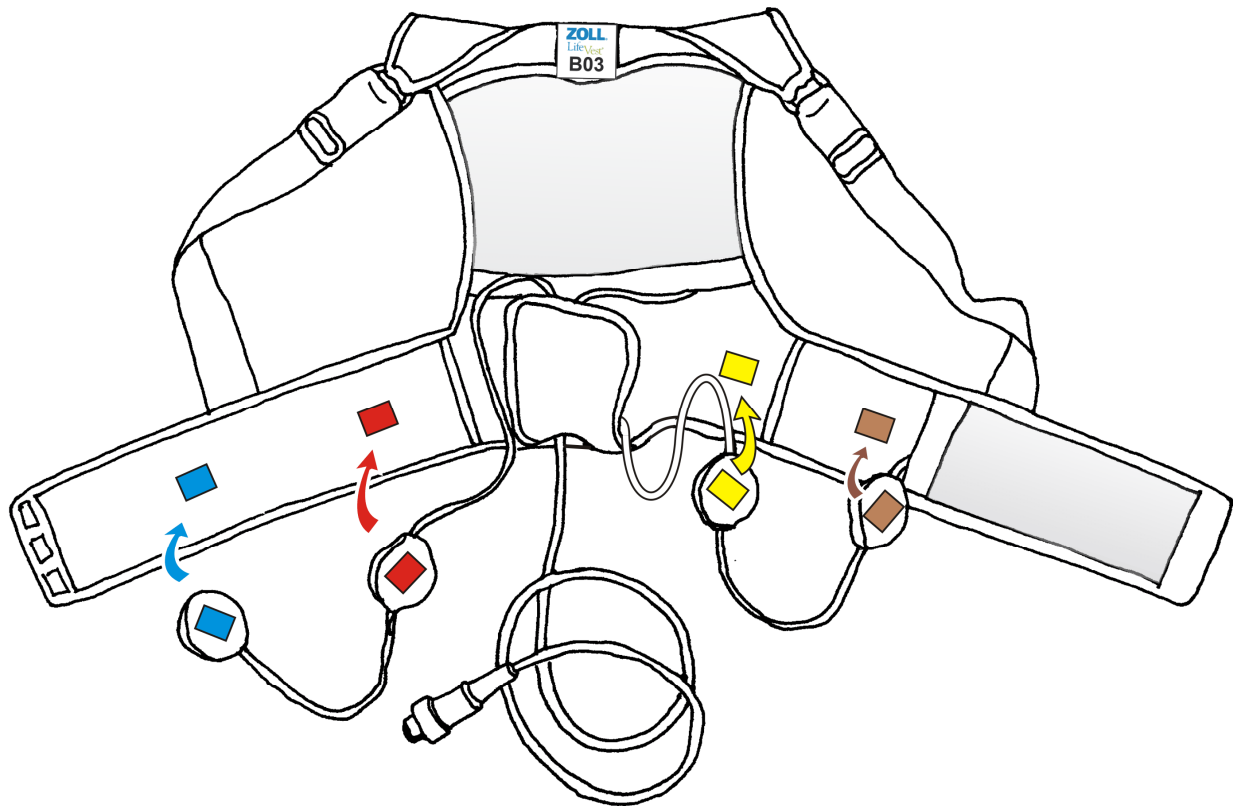


- The front pocket is numbered 3.
- Insert the pad with silver to silver. By that we mean to have the silver side of the pad (with the green sticker) facing the silver fabric on the pocket.



- 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.

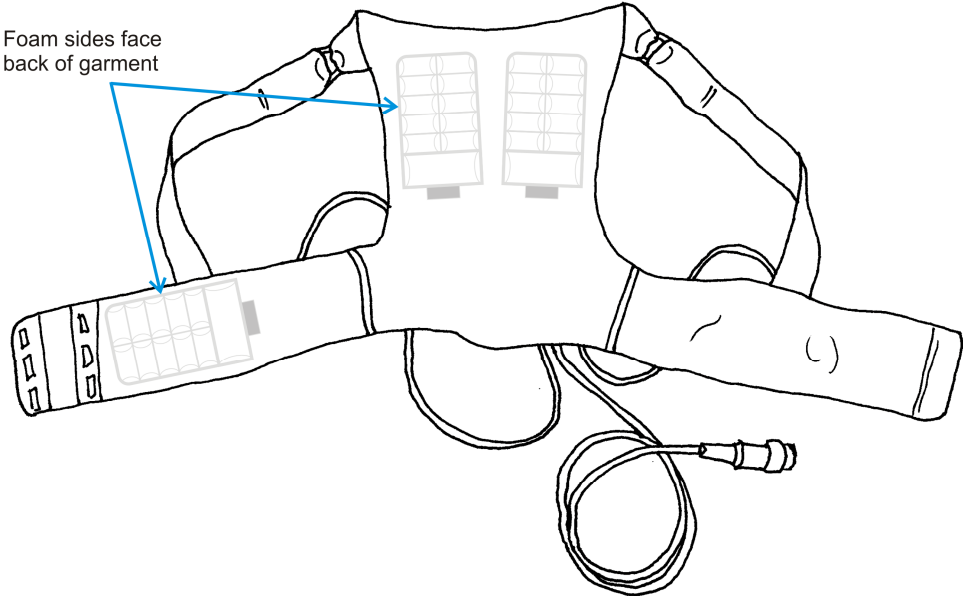


- 5 Make sure that you have properly assembled the electrode belt to the garment. See next page.
- 6 Then put on the assembled garment. See page 4-18

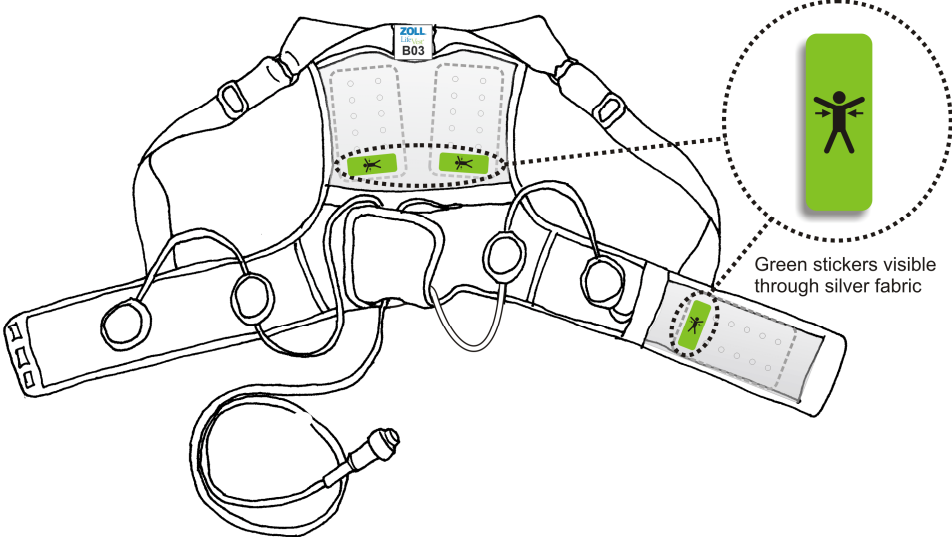
Assembled electrode belt and garment B

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.

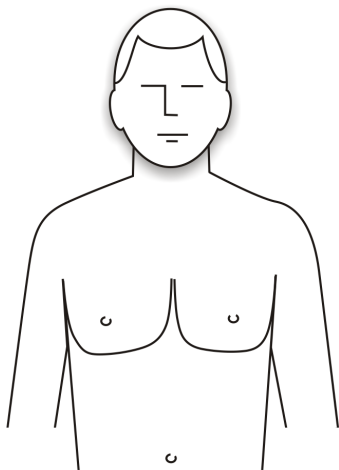


Inside view
This side faces toward your body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting on the assembled electrode belt and garment B

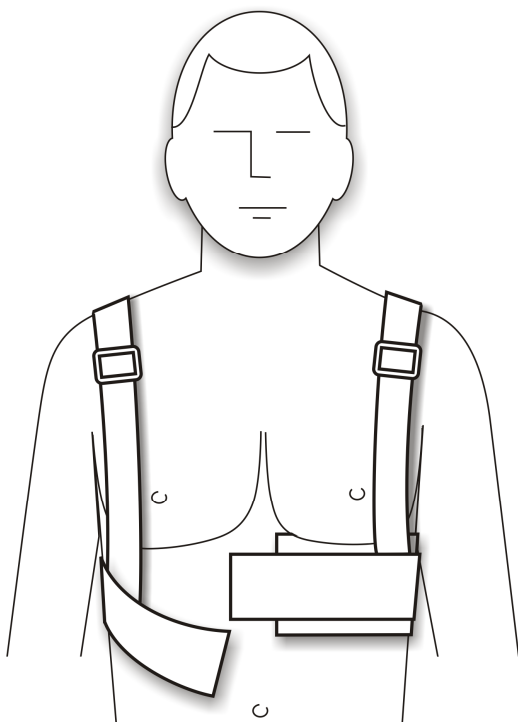
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 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:

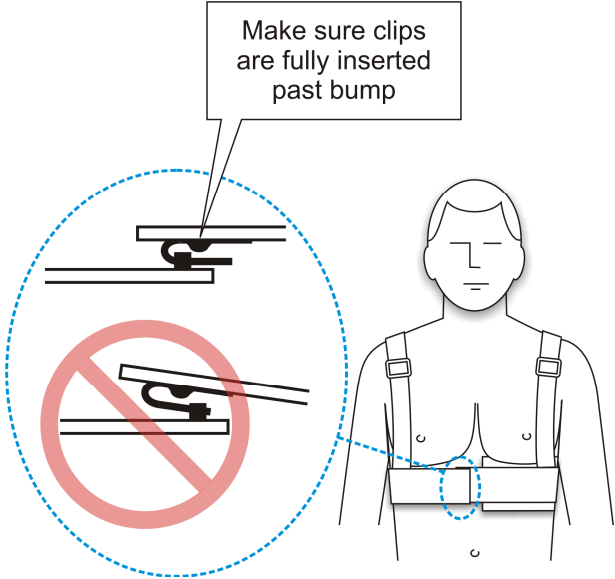
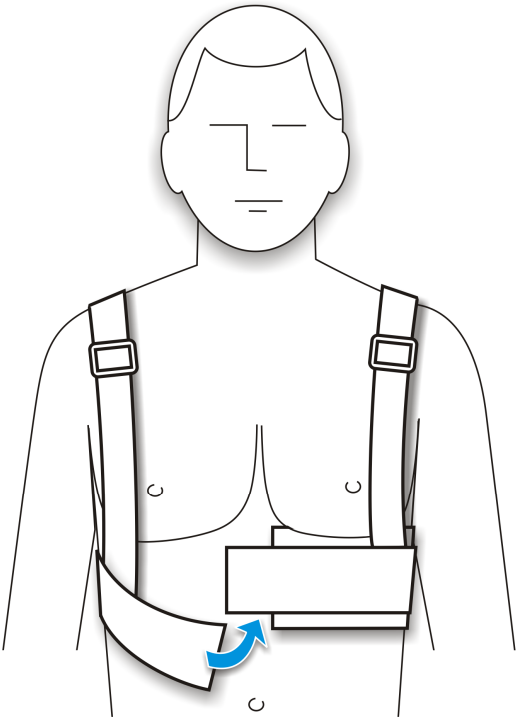
- The garment doesn't get twisted.
- The silver fabric pockets touch your bare skin.

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 is pressing against your body rather than the underside of your left breast.

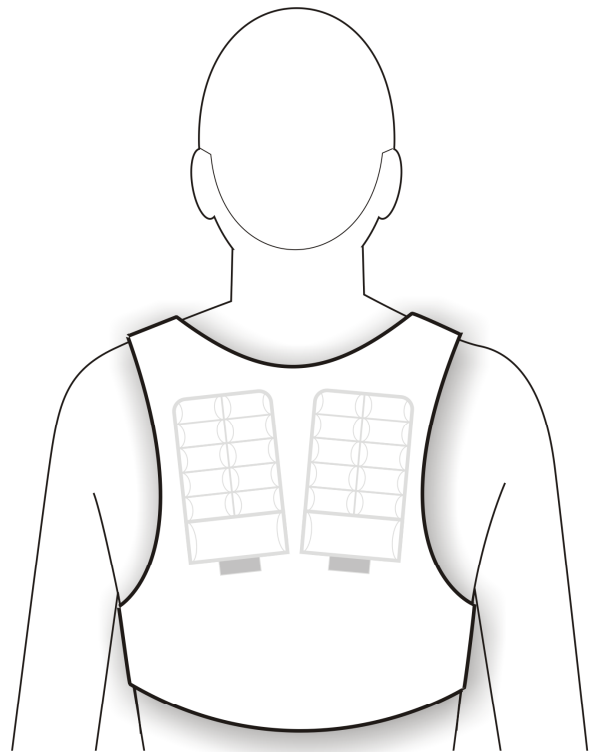
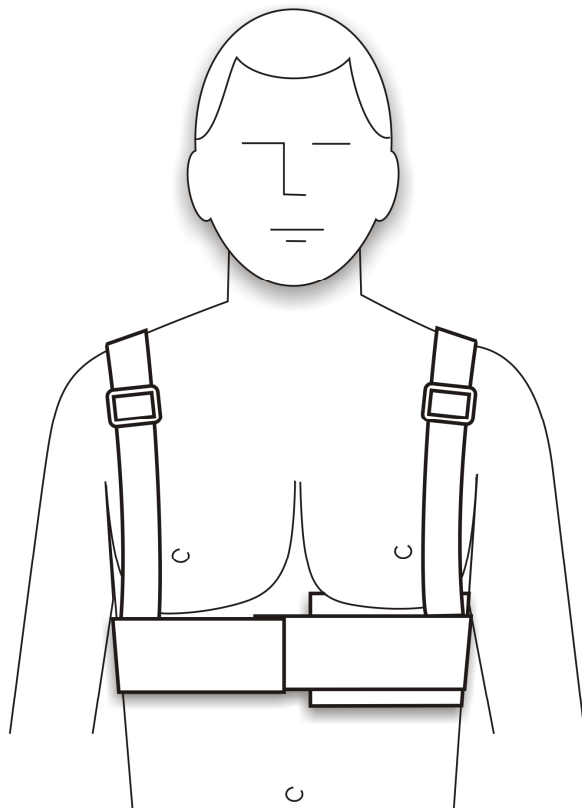
- 4 Connect the garment ends together in the front.

Make sure that the clips are fully inserted past the slight bumps in the clips.



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 silver fabric pockets and silver side 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.

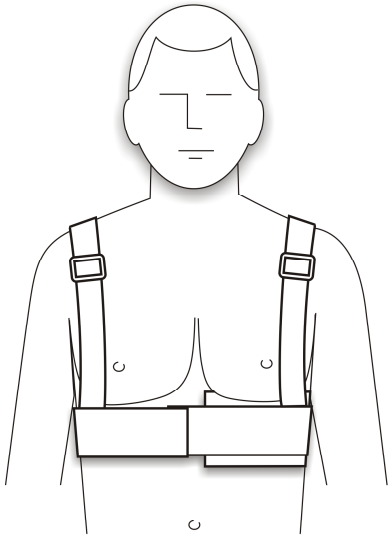
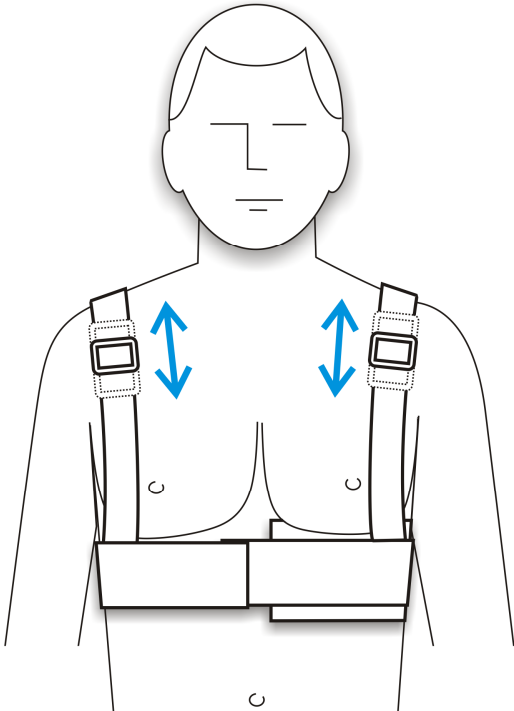


6 Check the position of the garment on your body and make sure it's not too high or too low.

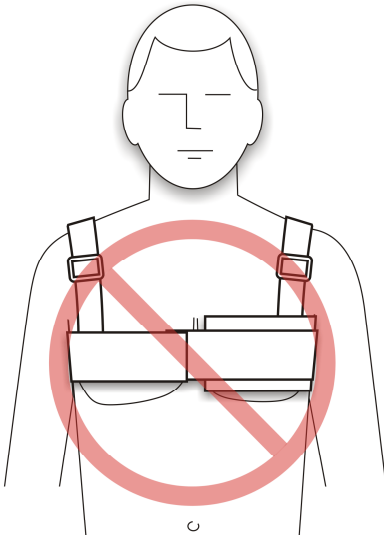
To position the garment properly, you may need to adjust the shoulder straps.

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

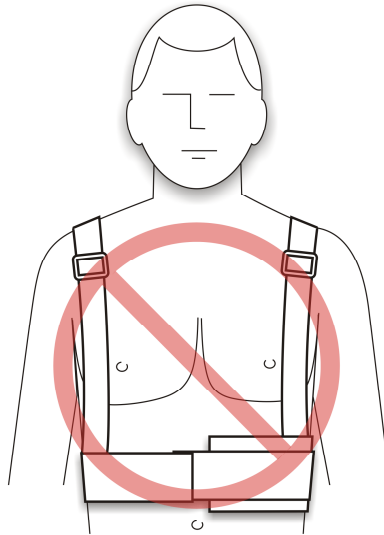
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



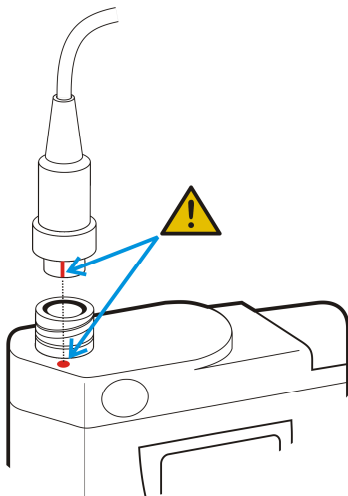
Too low

Connecting the electrode belt to the monitor

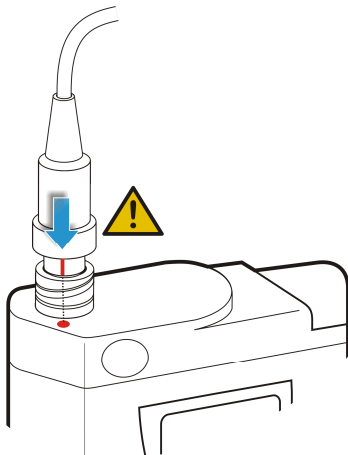
Normal daily use does not require disconnecting the electrode belt from the monitor. However, if you do need to disconnect the electrode belt, follow this procedure to reconnect the electrode belt to the monitor.



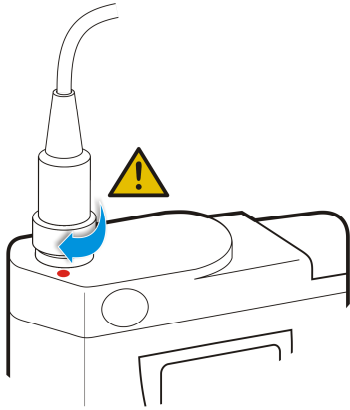
WARNING: Do not force the connector. Allow the connector to align before tightening. Forcing the connector may damage it and cause the system to malfunction. Failure to connect the electrode belt properly, or damaging the connector by bending the pins, can result in device malfunction. The device won't protect you because it won't be able to deliver a treatment.



- 1 Line up the mark on the connector with the mark on the top of the monitor.
 - The connector must be lined up before you push it into the monitor.
 - Don't turn the whole connector in order to line it up.
 - Don't force the connector.

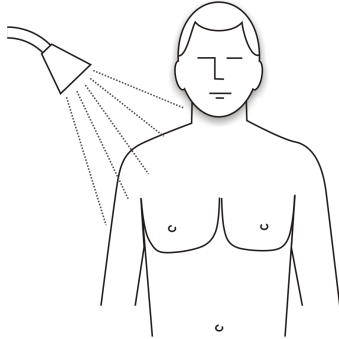


- 2 Push the connector in gently. Don't force it or try to steer it into position. Let it self align.
 - Gently push down on connector until it stops.
 - It should be seated on the connector far enough so that rotating ring contacts with the threads of the connector.
 - Don't force the connector into the monitor or you'll bend the pins.



- 3 Turn the connector ring clockwise to tighten. It should tighten in one to two turns.
- If you can turn the connector (the whole connector, not just the ring), it's not seated properly.
 - If you fail to line up the connector properly before turning the ring, the connector may not be threaded properly. You can tell because the connector ring doesn't tighten properly, or the connector isn't straight when it is connected.
 - To solve this problem, turn the connector ring counterclockwise until it spins freely. Then gently turn it clockwise to tighten.

Remove device when you shower or bathe

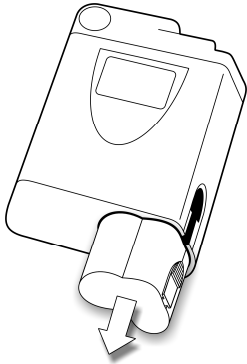


When you remove the device to bathe or shower, you are not protected by the device. Bathe or shower in the evening, preferably when someone else is home with you.

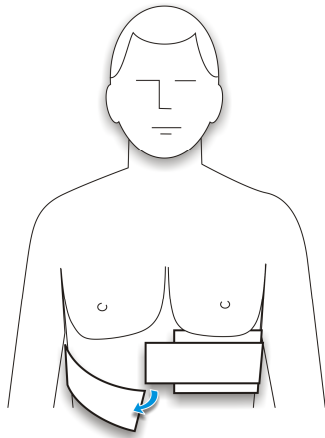
When you are not wearing the device for any reason, remove the battery first. When you put the LifeVest device back on, put the battery in last.

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.
- 2 Unbuckle and remove the holster. Keep electrode belt connected to monitor.

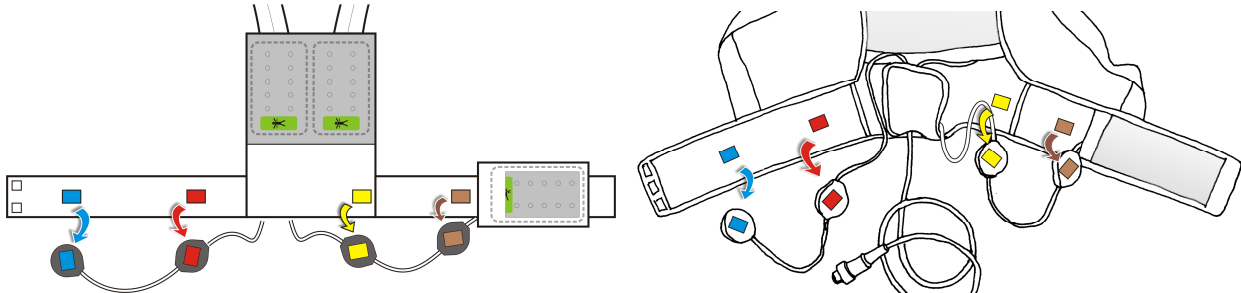


- 3 Unfasten and remove the garment from your body.

If you plan to change the garment, follow the procedure on the next page to disassemble the electrode belt from the garment.

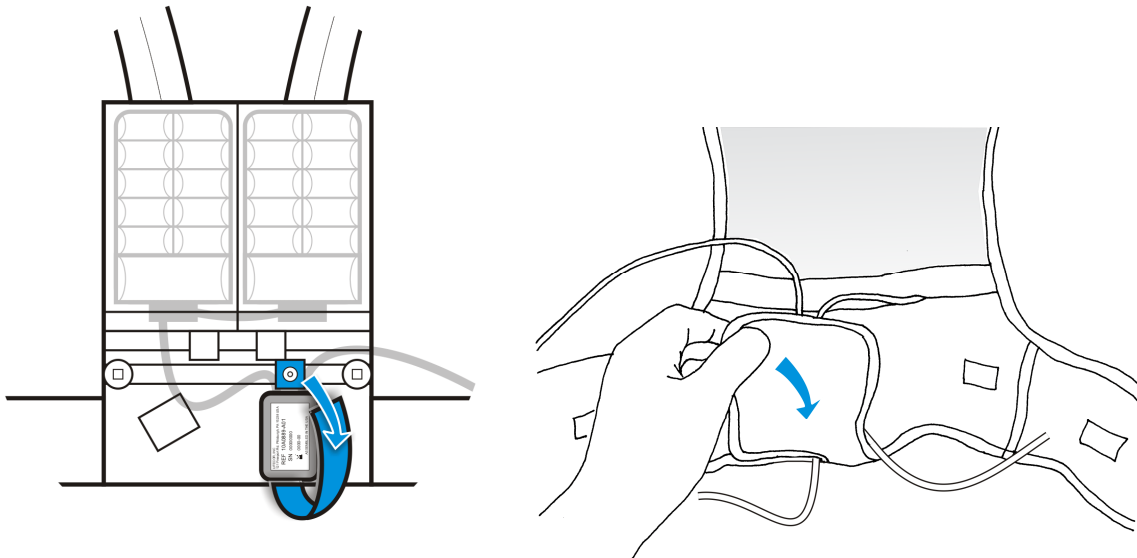
Disassembling the electrode belt and garment

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

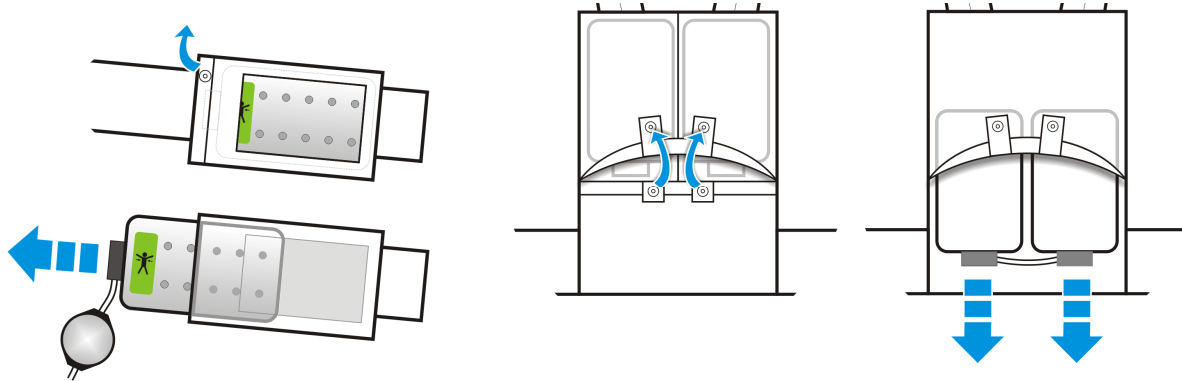


- 2 Remove the vibration box from the garment.

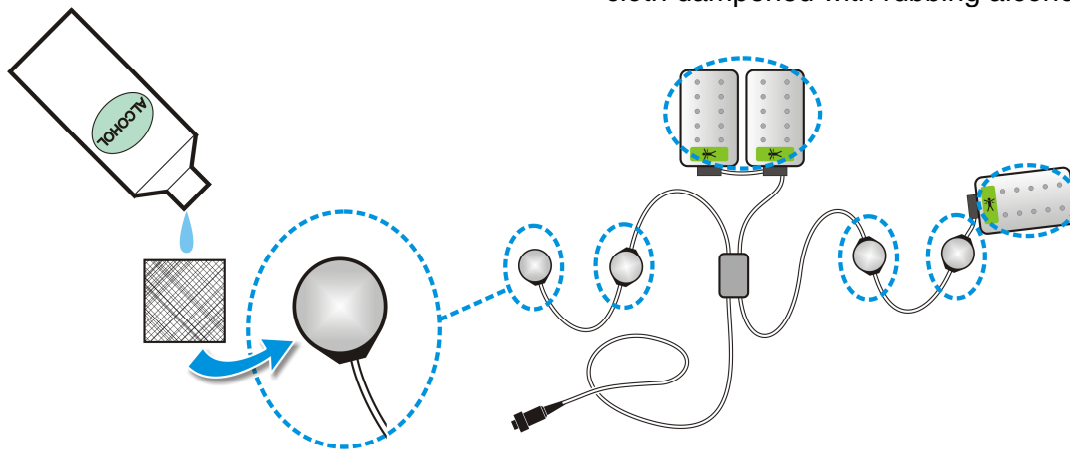
Do not use the vibration box as a handle to pull or lift the electrode belt. Pulling on the vibration box can damage the internal wiring and cause the system to malfunction.



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



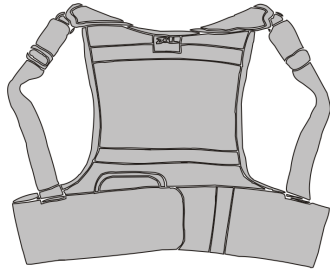
- 4 Wipe the metallic surfaces of the electrodes and therapy pads with a soft cloth dampened with rubbing alcohol.



- 5 Reassemble the garment and electrode belt as described on page 4-2 (garment A) or page 4-12 (garment B).
- 6 Put on the assembled garment and electrode belt as described on page 4-8 (garment A) or page 4-18 (garment B).

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

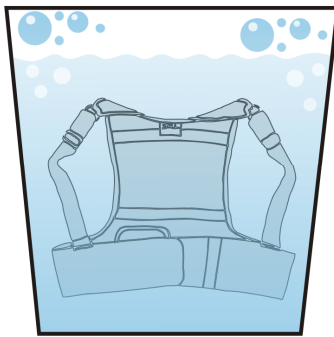
Laundering the garment



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.
- With garment A, leave the straps buttoned.



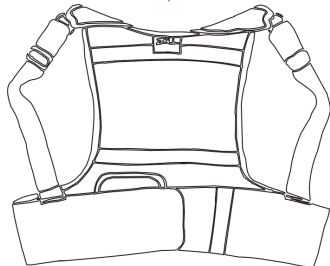
Wash the garment by itself. Do not wash it with other laundry.

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 clothes washing detergent only, such as Woolite® Original, Tide®, Purex® After the Rain, Fab® Spring Magic, or Arm & Hammer® for sensitive skin.



CAUTION: Do not use chlorine bleach, bleach alternatives, fabric softener, or anti-static sprays. Do not use detergents that include bleach or fabric softener additives.



Use a clothes dryer or hang the garment to dry. If you use a clothes dryer, set it to a warm or medium setting. Do not use the high heat setting.

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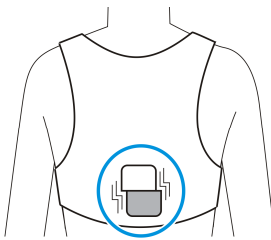
5: Responding to alerts

Types of alerts

How you respond to an alert depends on the type of alert you get. There are three types of alerts:

- vibration
- siren
- gong

Vibration alert

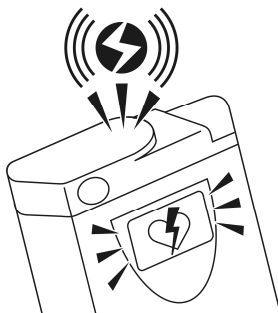


If you get a vibration in the back of the electrode belt, you are being warned that you're about to get a siren alert.

Hold the response buttons to stop this alert.

See details on page 5-2 for siren alert.

Siren alert

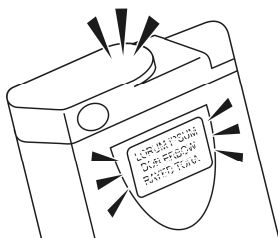


The siren alert is a high-pitched two-tone sound that means an abnormal rhythm has been detected.

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

See details on page 5-2.

Gong alert

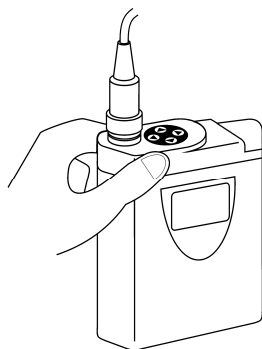
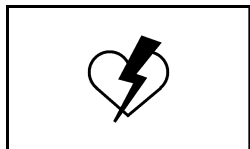


The gong alert is a low-pitched “gong” sound that repeats about once a second.

This type of alert is accompanied by a message stating a problem that needs your attention. Read the message, fix the problem, and then press the response buttons to clear the message.

See details on page 5-5.

Siren with respond message



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.
- Change hands if your hand becomes tired from holding the response buttons.
- If you feel dizzy, find a place to sit or lie down.

If you are not conscious, naturally you will not be able to hold 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 an ambulance after you have been given a treatment.



WARNINGS:

- During a siren alert, if you fail to hold both response buttons when you are awake, you may receive a treatment, which will be painful. That is why you need to hold both response buttons if you get the siren alert.
- 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.
- Do not hold the response buttons by artificial means or by having another person hold them for you. 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 remove the battery from the monitor when you get alerts. The device needs to be powered up in order to continue to function.

If you get a treatment

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

When any of these messages appear, here's what to do:



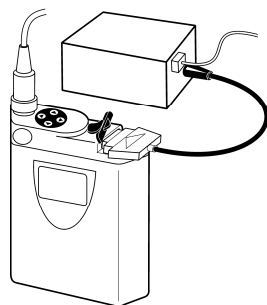
- 1 Call your doctor's emergency number immediately to report your treatment.



- 2 **Unless your doctor tells you otherwise**, continue to wear the LifeVest system.
 - Do not remove the electrode belt or garment, and do not disconnect the electrode belt from the monitor.
 - Continue to change and charge batteries as needed.
 - Leave the gel under the therapy electrodes. Do not wipe them dry.



- 3 Check the display for any messages and take the action indicated. See details on page 5-5.

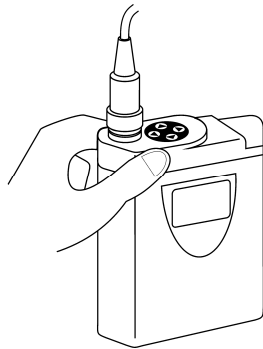


- 4 Send data to your doctor. See details in chapter 3.
- 5 Call ZOLL and arrange to get a replacement belt.

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 these messages:






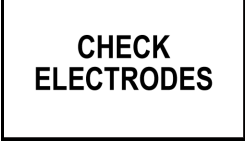

- Press the response buttons to stop the messages and siren alert.
- If the alert continues even after you press the response buttons, remove and replace the battery to stop the alert.
- If you continue to get these messages, call ZOLL.

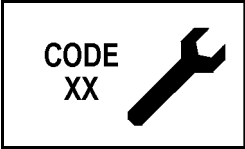
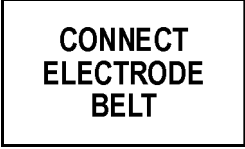

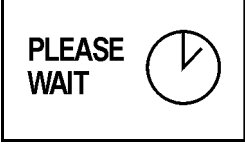



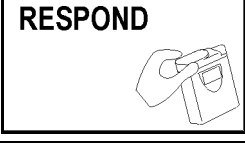

If you are not conscious, naturally you will not be able to press the response buttons. Voice prompts and messages alert bystanders to call for help.

Gong alerts

If you get a gong alert, there is a problem that needs your attention.

- 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
	You have received a treatment shock and the gel is drying out.	Add gel to the therapy pads or replace electrode belt. See details on page 5-13.
	Monitor is not receiving a clear signal from the electrode belt.	Adjust your garment and electrode belt so that each ECG electrode is touching your skin. For more details, see page 5-8.
	You have received a treatment shock. Notify your doctor immediately.	Call doctor's emergency number immediately. Follow instructions about what to do after receiving a treatment shock on page 5-3.
	Battery has discharged and needs to be changed.	Change to a fully-charged battery and place discharged battery into the charger.
	After three attempts to adjust the belt, monitor is still not receiving a clear signal from the electrode belt.	See details on page 5-8.
	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> .	Adjust your garment and electrode belt so that each ECG electrode is touching your skin. For more details about this message, see page 5-10.
	Therapy pad is not making contact with your skin.	Make sure the therapy pads are inserted correctly, with their metal sides (with green stickers) against your skin. Make sure the therapy pads and mesh pockets are pressing against your skin. For more details, see page 5-11.

Message	What it means	What to do
	System has a problem that requires servicing.	Write down code number and call ZOLL.
	Electrode belt is not connected to Monitor.	Connect the electrode belt to the monitor.
	Battery condition cannot be determined, but battery may continue to function normally.	If battery holds a charge, continue to use and recharge battery as normal. Call ZOLL.
	Device is processing information.	Wait while device processes.
	Battery has not been inserted properly.	Remove battery, then put it back into the monitor, being sure to fully insert the battery.
	You may be holding the response buttons instead of pressing and releasing them.	At startup, press the response buttons momentarily, then release them. If you are not holding the response buttons, device may be defective. Call ZOLL.
	This message appears if the battery has been left in the monitor when not in use.	If you are not wearing the LifeVest, remove the battery from the monitor. If you are wearing the LifeVest, make sure the electrode belt is firmly connected. If you continue to get this message with the belt connected, call ZOLL.
	You are to press the response buttons to test their function every time the battery is installed.	At startup, press the response buttons as a reminder of what to do when an alert sounds.
	Device is waiting for you to respond.	Hold both response buttons and follow any other instructions.

Message	What it means	What to do
<p style="text-align: center;">TIME TO CONNECT MODEM AND SEND DATA</p>	<p>Data should be sent because either a treatment shock was delivered or the monitor has data that should be viewed.</p>	<p>Connect the modem and send data. See details in section 3.</p>
<p style="text-align: center;">TOO MUCH GEL CLEAN SKIN</p>	<p>Too much gel is on your skin.</p>	<p>Leave the gel that is under the therapy pads, but wipe the gel from the skin that is not under the therapy pads. See details on page 5-15.</p>
<p style="text-align: center;">TREATMENT DELIVERED LEAVE BELT ON</p>	<p>You have received a treatment shock.</p>	<p>Continue to wear the LifeVest device. Leave the electrode belt connected and change the battery as normal until you receive a replacement belt. Call your doctor as soon as possible. See details on page 5-3.</p>

Belt problem messages



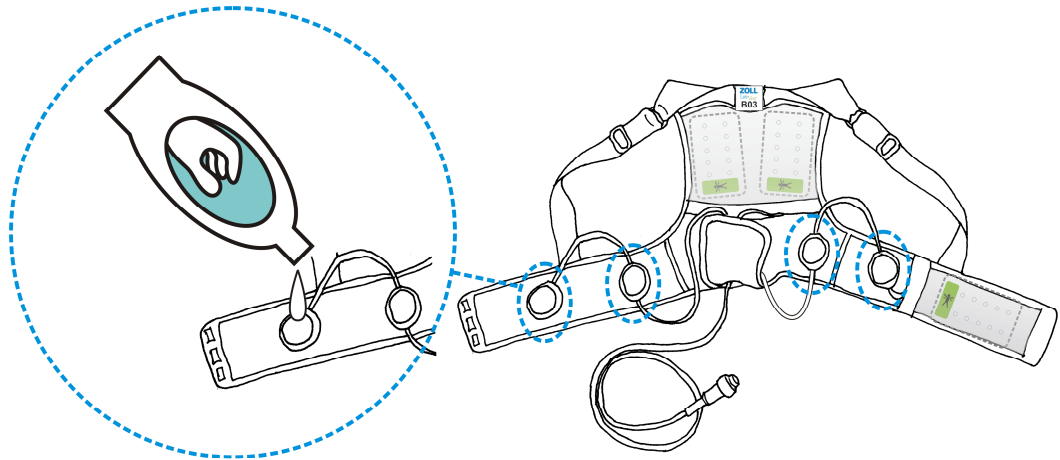
Press the response buttons, then adjust the garment and electrode belt by following these guidelines:

- Make sure the electrode belt fits snugly, with the ECG electrodes (the round ones) touching your skin.
- Make sure all fasteners are connected, with the garment ends fastened and centered in front.
- Make sure nothing is between the ECG electrodes and your skin.



If the problem continues, you may see this message. If so:

- 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 the four round ECG electrodes.



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

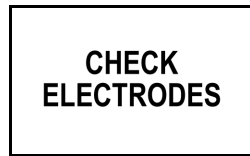
If problems continue, call ZOLL.

Possible reasons for a poor ECG signal

During the Day – May be due to unusual arm motion, such as that involved with exercise. Do not continue such motion for an extended period of time.

During Sleep – May be due to one or more of the electrodes lifting from your skin. Move to a relaxed position where all electrodes can make good contact with your skin. If the alerts continue, readjust your position again. Check to make sure that the garment is not too loose.

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 therapy pads message

**CHECK
THERAPY
PADS**

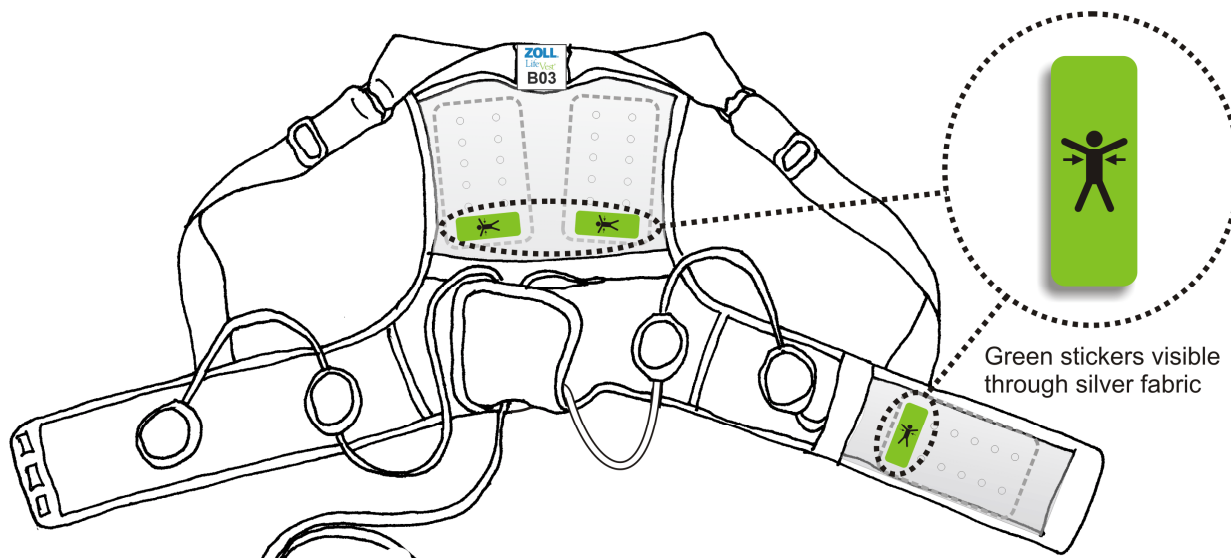
If you get this message, the therapy pads are not making good contact with your skin.

This could be caused by:

- Therapy pad may not be inserted correctly into its pocket.
- Therapy pad and mesh pocket may not be pressing against your skin.

Therapy pad may not be inserted correctly into its pocket

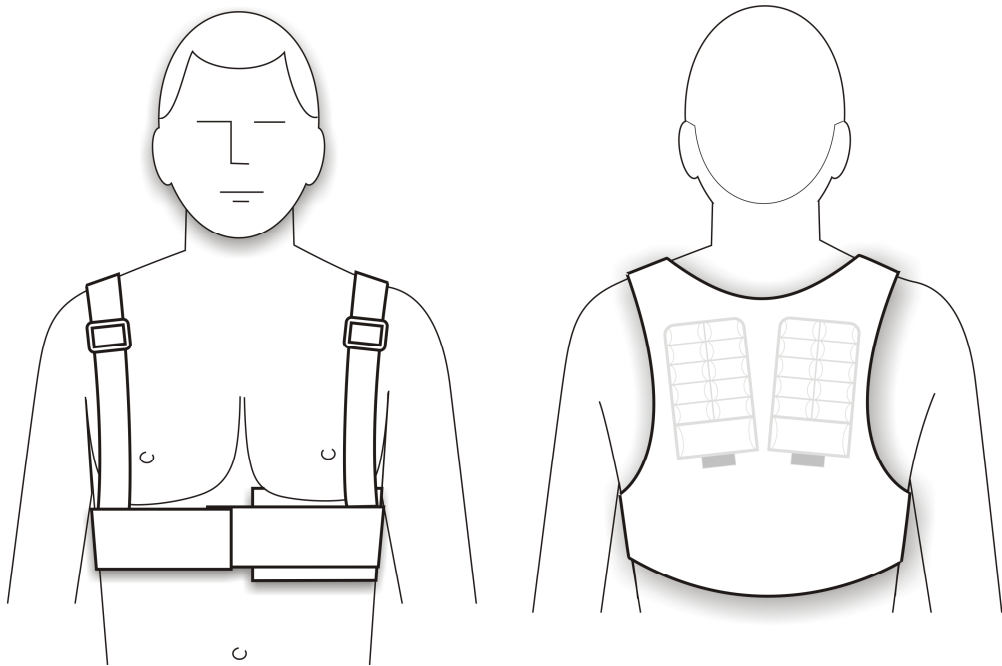
- 1 Remove the battery from the monitor, then remove the garment and electrode belt from your body.
- 2 Make sure the therapy pads are inserted correctly, their metal sides (with green stickers) facing your body.



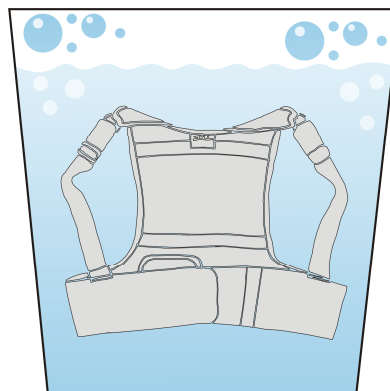
- 3 Put on the garment and electrode belt, then put the battery into the monitor to resume normal operation.
- 4 If problems continue, call ZOLL.

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 metal mesh 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.

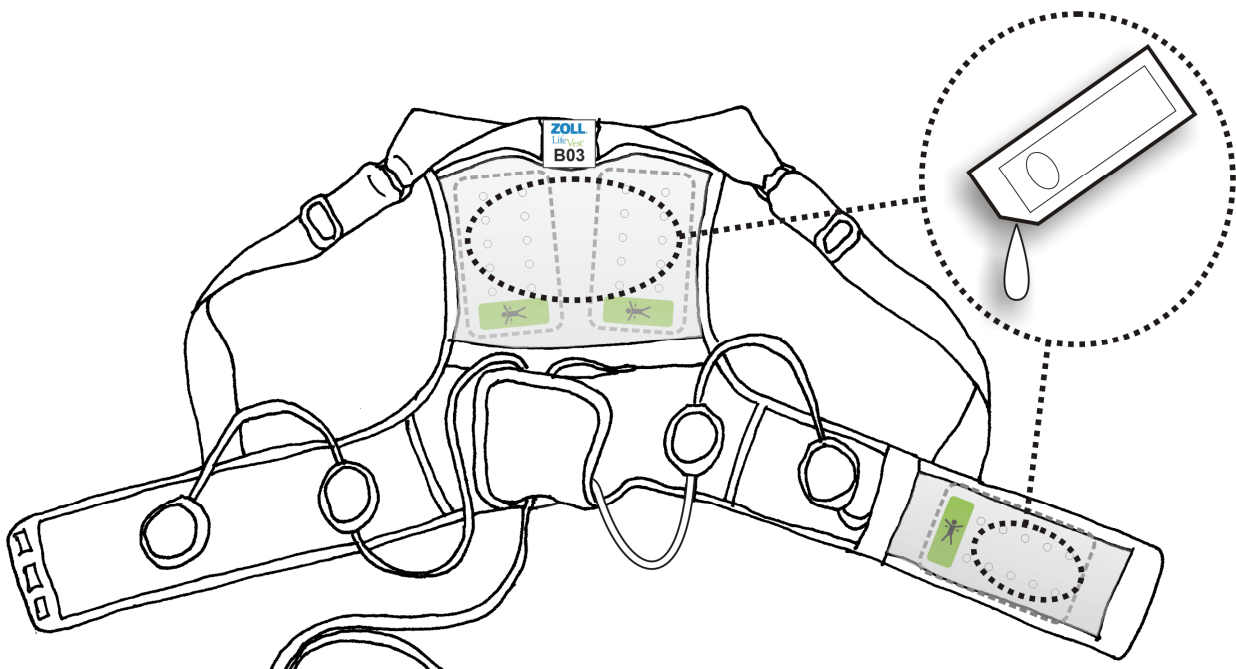
Add gel or replace belt message

**ADD GEL OR
REPLACE BELT**

After you receive a therapy shock to correct an abnormal rhythm, you may see this message telling you to add gel or replace the electrode belt.

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 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.

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 into a clean garment, and put on the assembled electrode belt and garment. Refer to section 4.
- 5 Put the battery into the monitor and follow the normal startup routine.

Too much gel message



**TOO MUCH GEL
CLEAN SKIN**

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

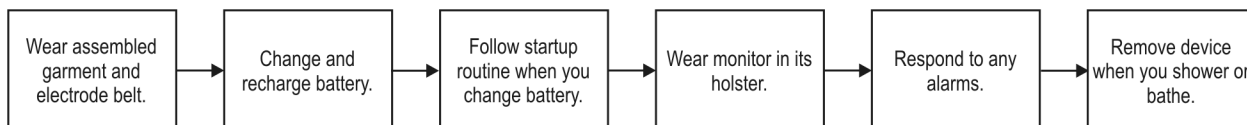
To remove excess gel

- 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 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.

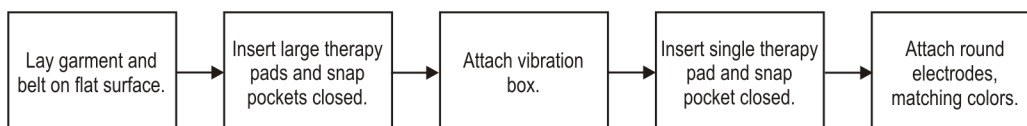
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Appendix A: Quick charts

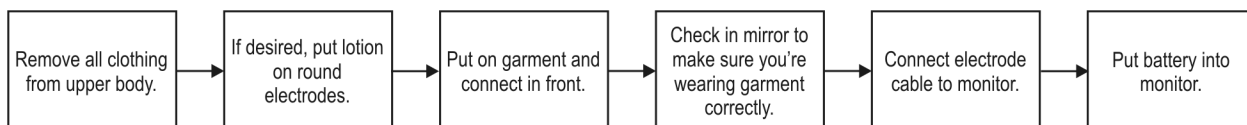
Daily routine



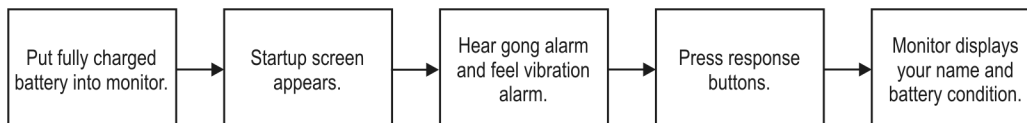
Assemble electrode belt and garment



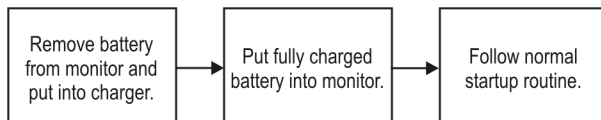
Put on LifeVest system



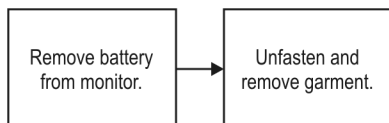
Normal startup routine



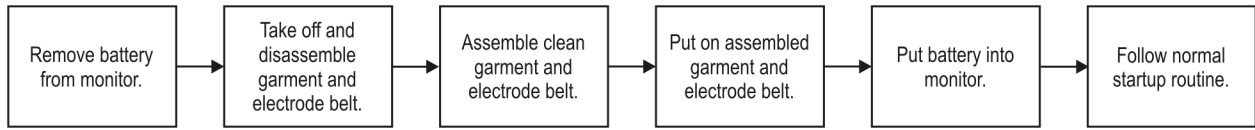
Recharge batteries daily



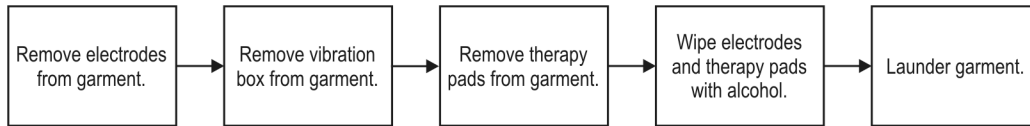
Remove LifeVest system before bathing or showering



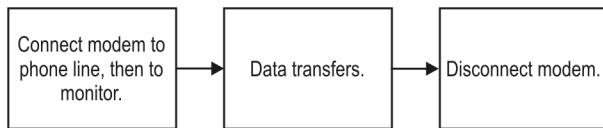
Change garment as needed



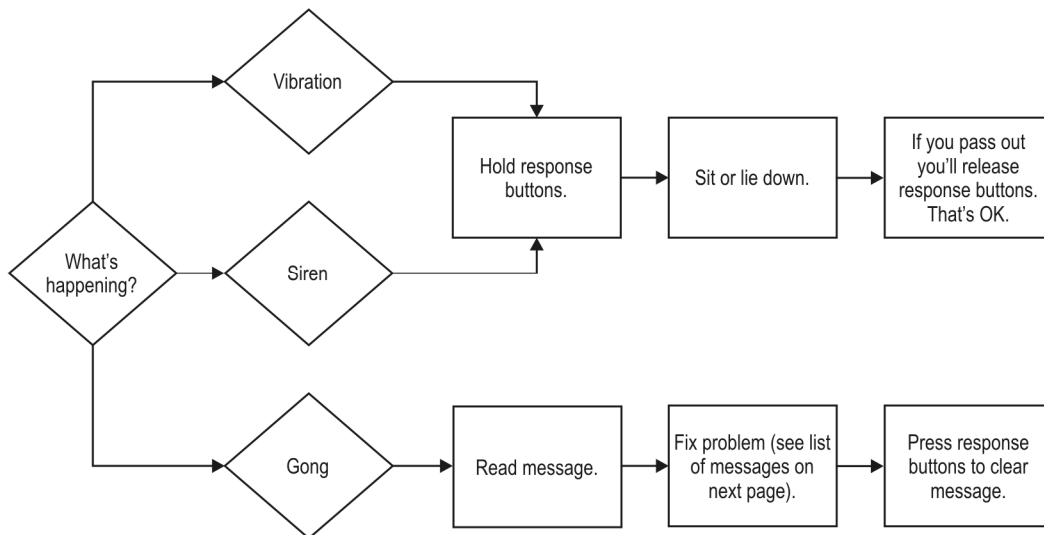
Disassemble electrode belt and garment



Send data to your doctor

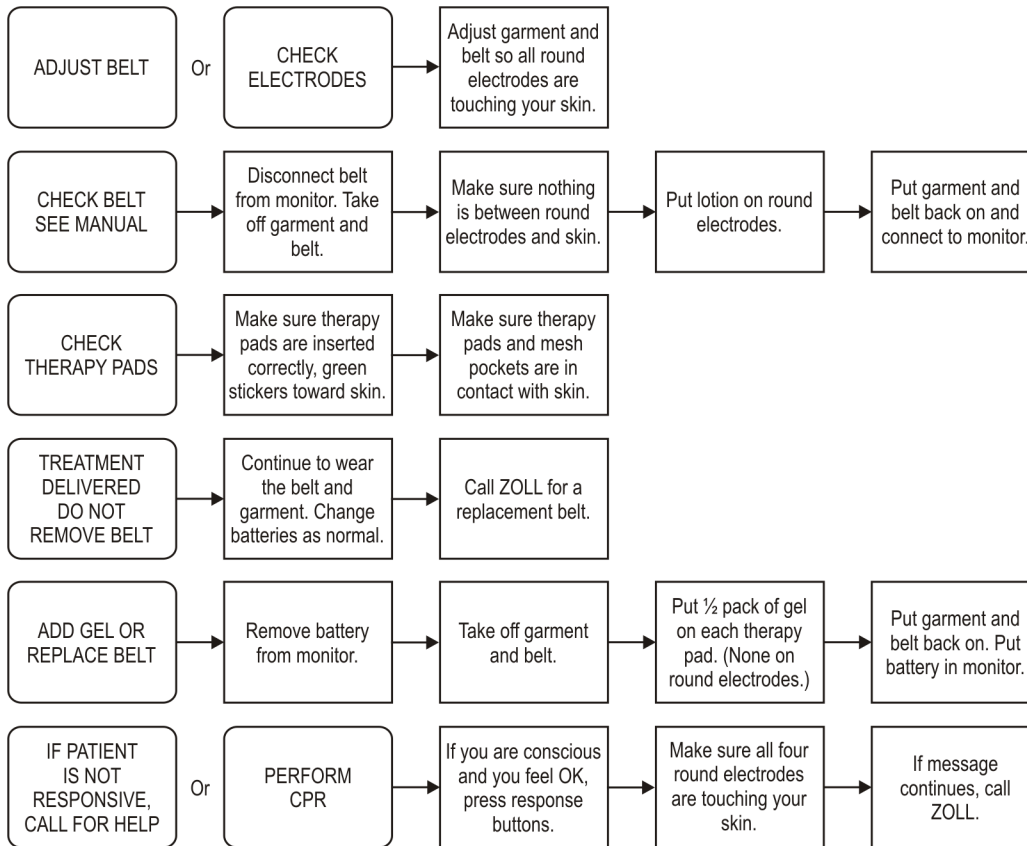


If you get an alert

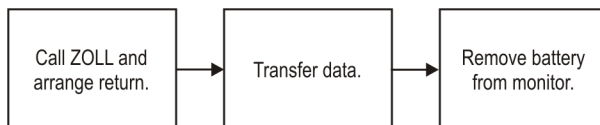


If you get a gong alert

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



When you're finished with device








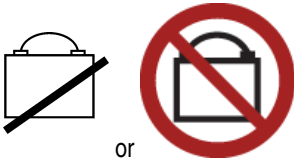






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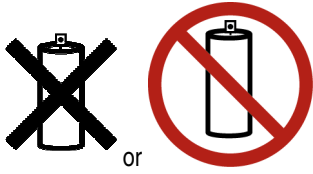
Appendix B: Glossary

Arrhythmia	Abnormal heart rhythm.
Asystole	Heart stops beating.
Cardioversion defibrillation	Restoration of normal heart rhythm by electrical shock.
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.
Modem	Connects to telephone line. Allows you to send data from the monitor for your doctor to view.
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.

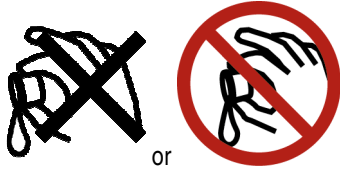
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Appendix C: Symbols

	Battery charger: Battery charged.
	Battery charger: Battery charger is charging or testing battery.
	Battery charger: Battery charger needs service.
	Battery charger: Battery needs service.
	Battery: Do not incinerate.
	Battery: Do not short circuit.
	Caution: Consult accompanying documents.
	CE marking, indicates conformance with European Medical Device Directive.
	Laundry symbol: Normal cycle in warm water.
	Laundry symbol: Tumble dry warm.
	Laundry symbol: Only non-chlorine bleach, when needed.
	Laundry symbol: Iron on low temperature.



Laundrying symbol: No anti-static spray.



Laundrying symbol: No fabric softener.



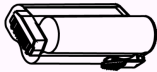
Manufacturing date.



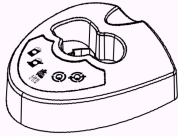
Manufacturing location.



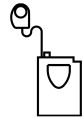
Monitor connector: Type BF defibrillator-proof connector.



Packaging: Battery



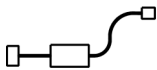
Packaging: Battery charger



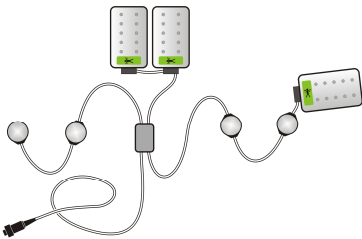
Packaging: Monitor.



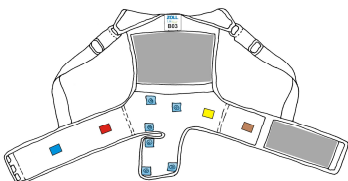
Packaging: Modem.



Packaging: Electrode belt.

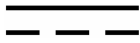


Packaging: Garment.





Power supply electrical information: Alternating current (AC).



Power supply electrical information: Direct current (DC).



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

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LifeVest[®]

Model 4000

Patient Manual



ZOLL[®]

PN 20B0047 Rev D Proposed

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Index

Restricted sale

Federal (USA) law restricts this device to sale 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.

Trademarks

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Patents

US patents: 6,681,003; 6,280,461; 6,253,099; 6,169,387; 6,097,982; 6,065,154; 5,944,669; 5,929,601; 5,741,306; others pending.

Software nonexclusive license

The LifeVest device includes certain software ("Software"). ZOLL grants you a nonexclusive license to use the Software solely for diagnostic and treatment purposes as part of use of the LifeVest device. You are prohibited from: (i) reproducing the Software; (ii) removing or destroying any proprietary markings, copyright notices or other legends which are part of the Software; (iii) modifying or reverse engineering the Software; or (iv) removing the Software from the LifeVest device. Title to the Software will remain at all times with ZOLL. You must keep the Software confidential.

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1: Introduction

About the LifeVest system

The LifeVest device 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 location, essential performance, and electromagnetic compatibility guidance.
- **Meet the LifeVest system** tells you about the components, what they're called, and basically how they work.
- **Using the LifeVest device** 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 alerts** explains the types of alerts and tells you what to do if you get an alert.
- **Using the activities options** covers options that can be prescribed by your doctor while you're wearing the LifeVest.
- Appendixes include **Quick charts**, a **Glossary**, **Symbols**, 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.

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 and/or cause the system to malfunction.

Always wear the LifeVest when instructed to do so by a medical professional. Make sure the electrode belt is properly connected to the monitor. Inappropriate use of the LifeVest may damage it and/or cause the system to malfunction.

Do not tamper, alter, drop or abuse any part of the system or labeling. Altering the equipment in any way may damage it and/or cause the system to malfunction.

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.

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 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.

**WARNINGS**

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

Do not stack or place the LifeVest 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.

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.



WARNINGS

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

When performing the walk test, do not continue walking if you experience symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop walking and sit or lie down. If the symptoms continue or get worse, immediately call your doctor or emergency help. If you continue walking 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.

Intended use location

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

Essential performance

The essential performance of the LifeVest 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-160F, 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.

Electromagnetic interference

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 such 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 alerts, 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

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

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

FCC regulatory information

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The monitor contains:

FCC-ID POOWML-C40

The charger contains:

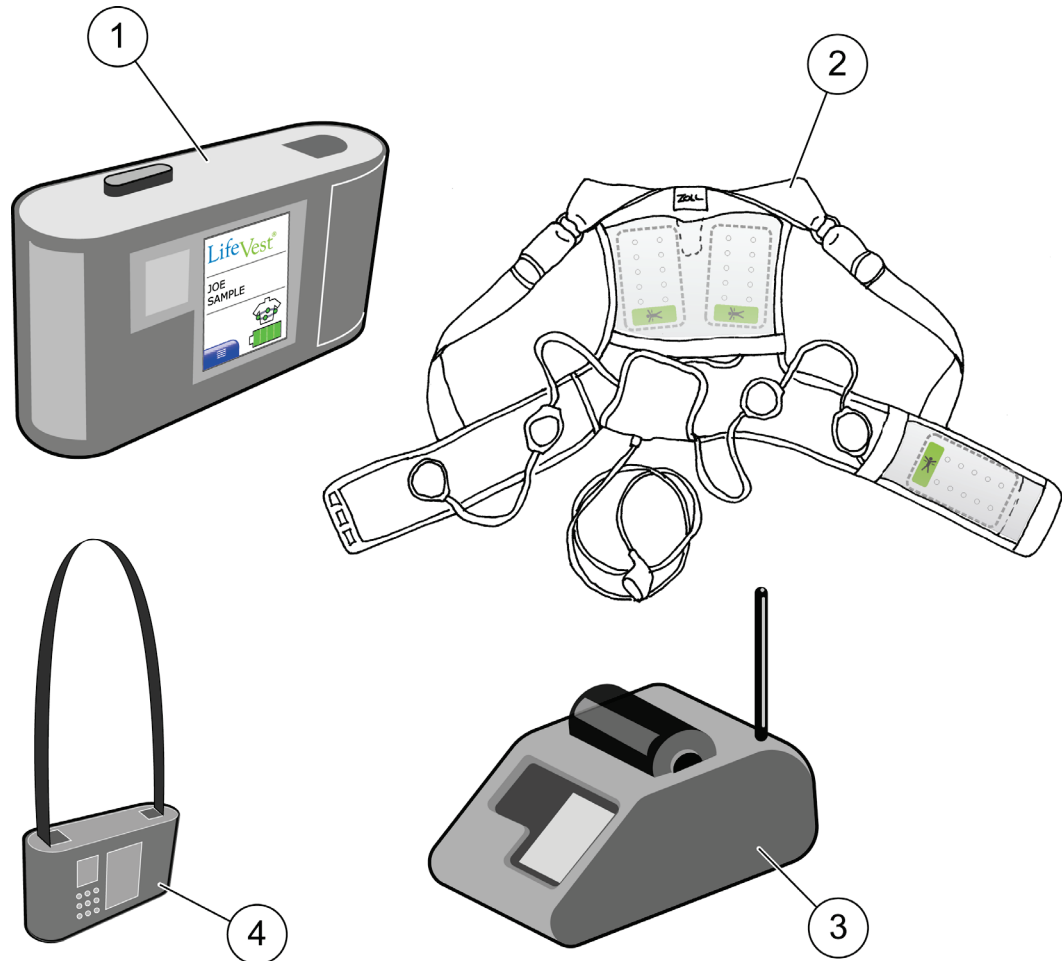
FCC-ID POOWML-C40
FCC-ID AU792U05E06800

To comply with FCC RF exposure requirements, a minimum separation distance of 10.6 inches (27 centimeters) must be maintained between the user's or bystander's body and the antenna on the charger. With a separation distance of 10.6 inches (27 centimeters) or more, the charger produces RF exposure that is well below the maximum permissible exposure limits.

Changes or modifications to this device not authorized by ZOLL could void the RF compliance and negate your authority to operate the device.

2: Meet the LifeVest system

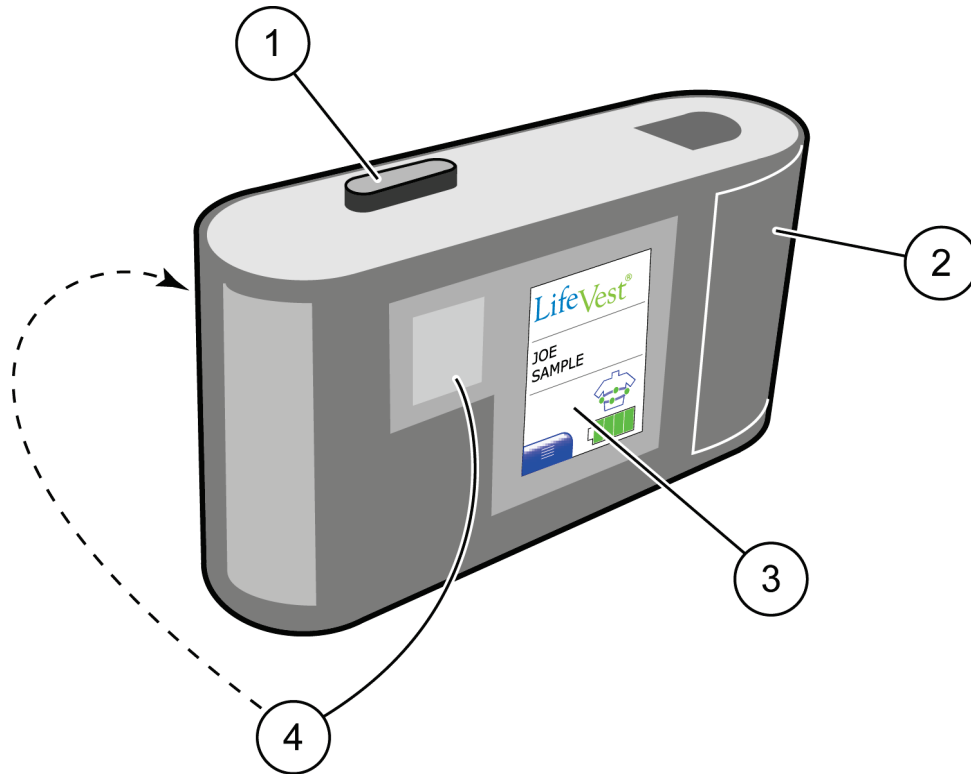
Components



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	Recharges the battery, communicates wirelessly with the monitor, and transmits data for doctor review. See details on page 2-4.
4 Holster	Lets you carry around the monitor.

Monitor

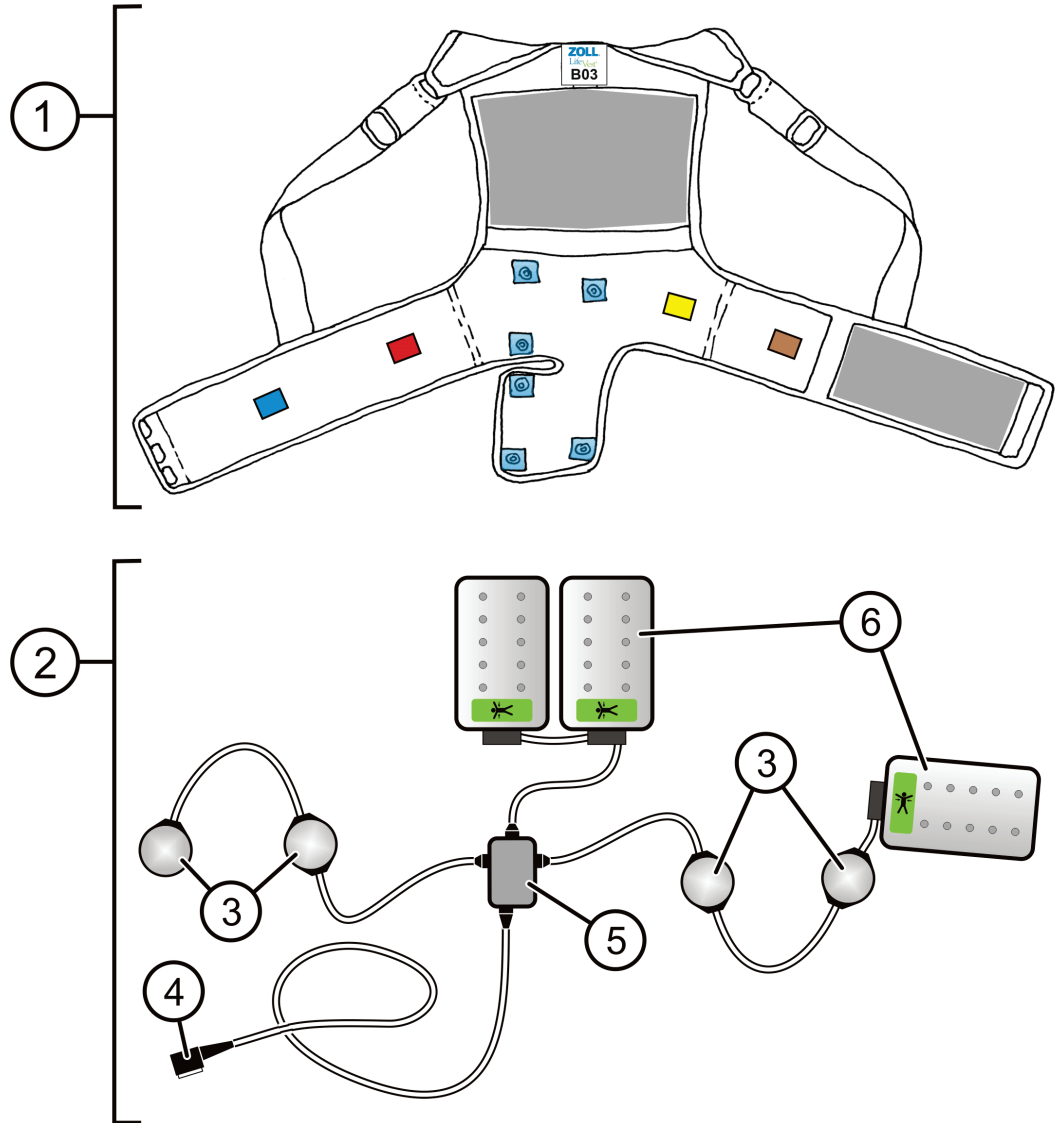
For details about operating and caring for the monitor, see section 3. For details about responding to alerts, see section 5.



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 displays a dark screen. To see the display, press and release the response buttons.</p> <p>For more on the monitor touchscreen, see page 2-5.</p>
4 Response buttons	<p>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.</p> <p>During normal monitoring, the front response button flashes red about once every six seconds.</p> <p>If the LifeVest detects an abnormal rhythm, the response buttons light solid, not flashing.</p>

Garment and electrode belt

For details on assembling, wearing, and caring for the garment and electrode belt, see section 4.

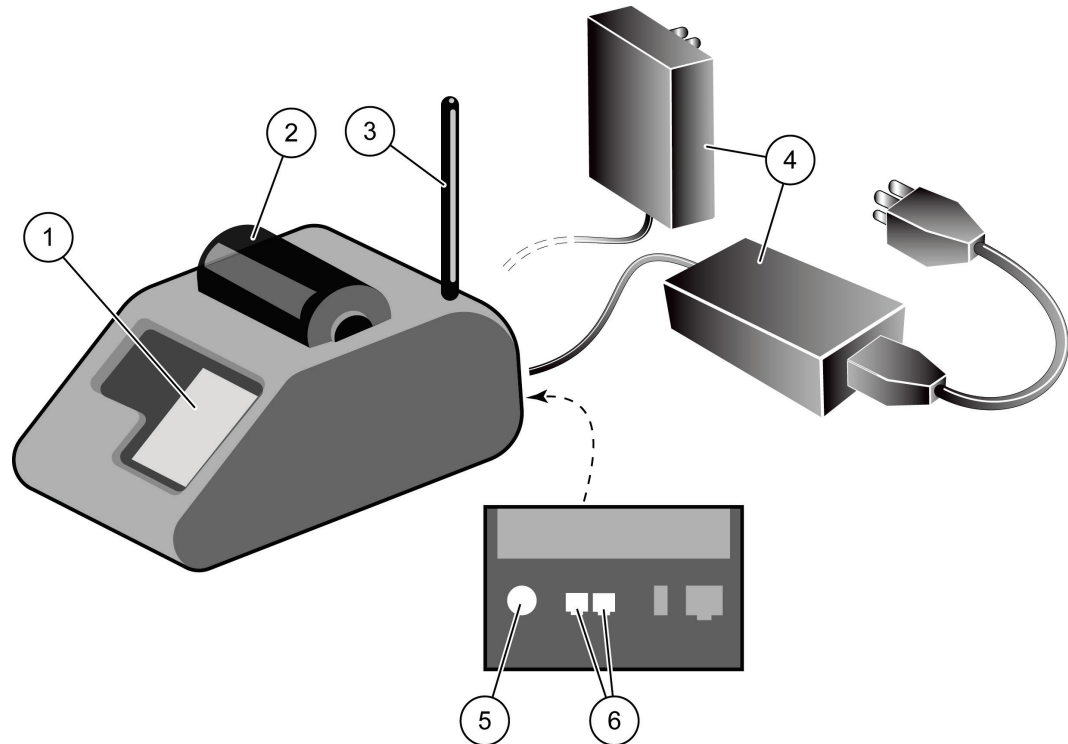


Item	Description
1 Garment	Worn under your clothing to hold the heart sensors and therapy pads against your chest.
2 Electrode belt	Assembles to garment and contains heart sensors, vibration box, and therapy pads.
3 Heart sensors	Sense your heart's electrical signal for the monitor. Also called electrodes.
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 charger recharges the battery, communicates wirelessly with the monitor, and transmits data for your doctor to review.

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



Item	Description
1 Touchscreen	Displays messages about device operation, and allows patient to interact with device. For more on the charger touchscreen, see page 2-6.
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. Different types of power supplies may be provided: One plugs directly into the outlet, the other has a detachable power cable.
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.

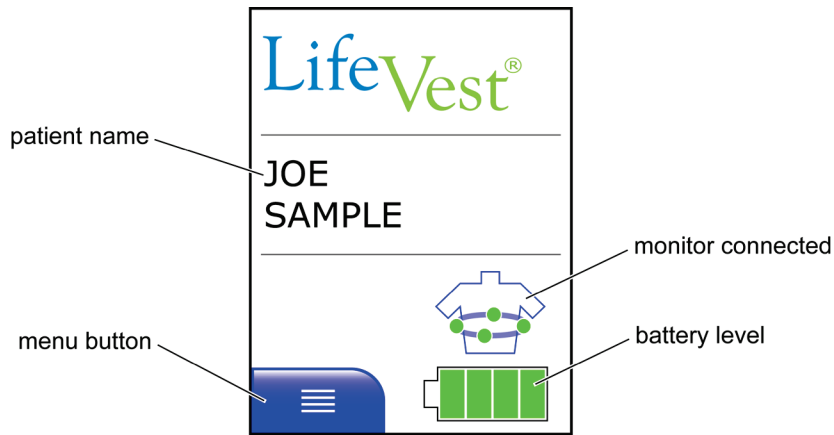
Monitor touchscreen


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 2-7.

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



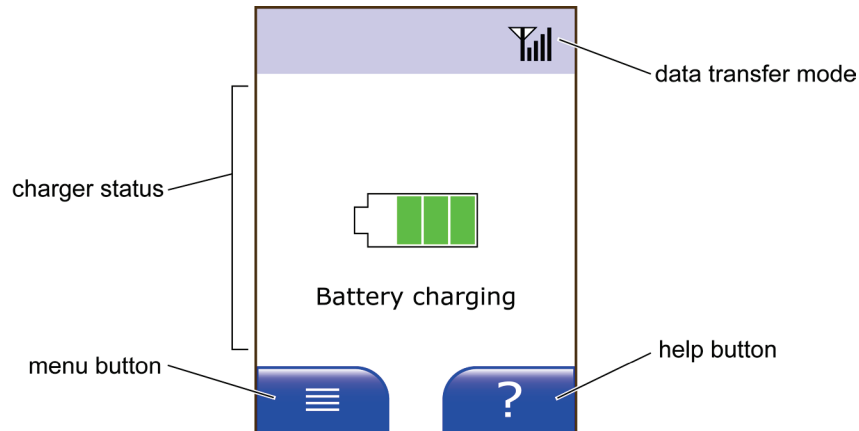
Item	What it means and how to use it
Patient name	Displays your name so you know this device was programmed for you.
Menu button	Tap to display the patient menu, where you can select various options. See details in section 3.
Monitor connected	Shows that the monitor is connected to the patient and is 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, see section 3.

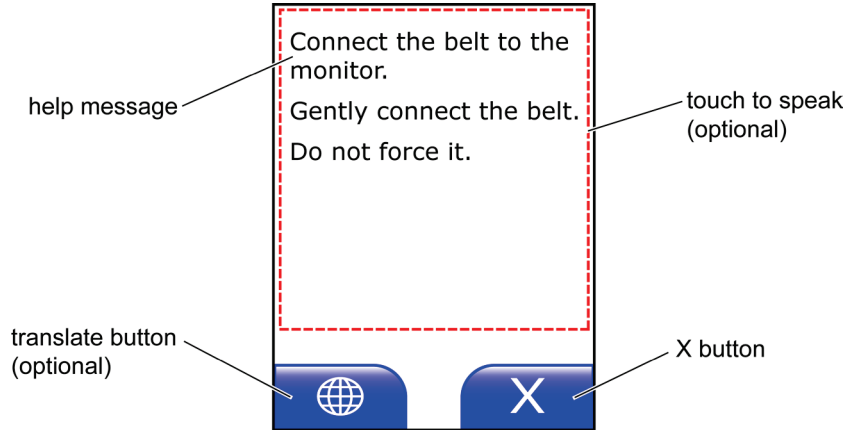


Item	What it means and how to use it
Data transfer mode	Shows how data will be transmitted to your health care provider. You will see one of these symbols: <ul style="list-style-type: none">  LifeVest is set up for a wireless connection. The number of bars indicates the signal strength.  LifeVest is 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 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.



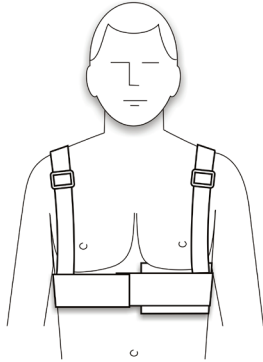
Item	What it means and how to use it
Help message	Brief message telling you what to do based on the present condition.
Translate button	Tap to see the help message in the secondary language. When you leave the screen, the display returns to the primary language. This button appears only if a secondary 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.

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3: Using the LifeVest

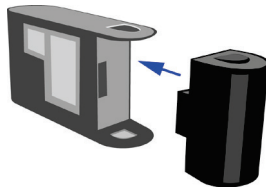
Daily routine

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



- 1 Wear the assembled electrode belt and garment.

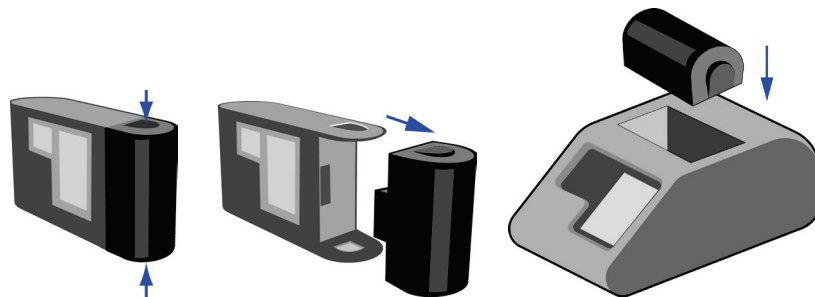
For details about assembling and putting on the electrode belt and garment, see section 4.



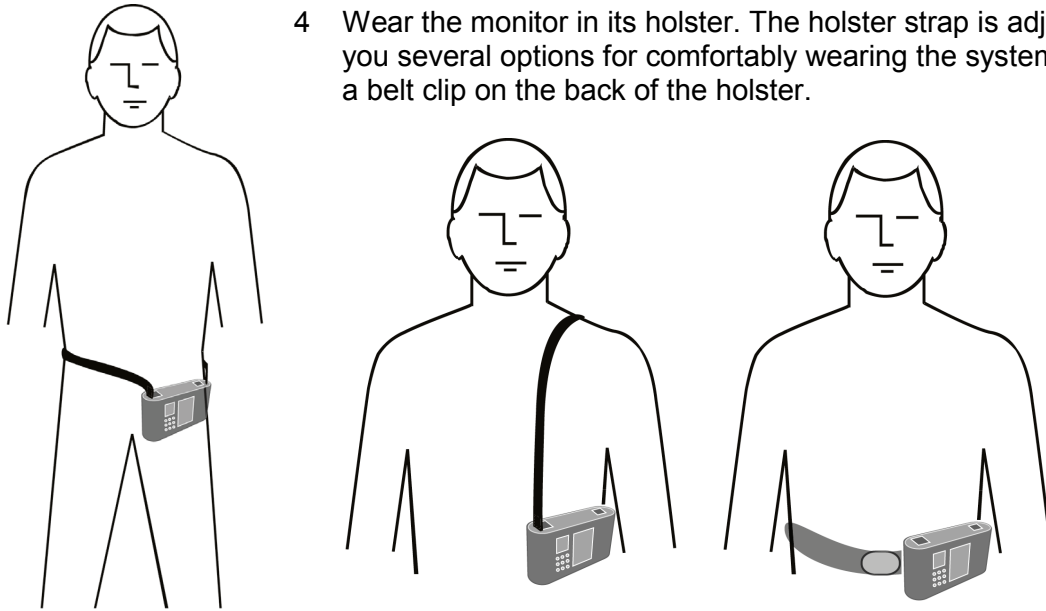
- 2 Put a fully-charged battery into the monitor and follow the normal startup routine. See page 3-3.



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



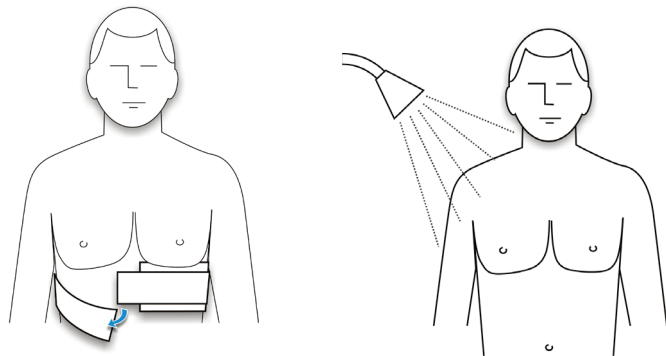
- 4 Wear the monitor in its holster. The holster strap is adjustable to give you several options for comfortably wearing the system. There is also a belt clip on the back of the holster.



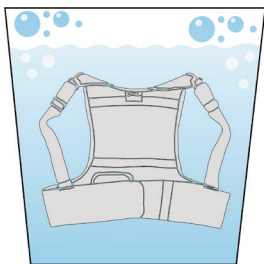
- 5 Respond to any alerts. See section 5.



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



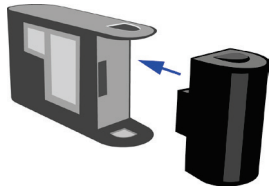
- 7 Change and wash the garment every 1 or 2 days.



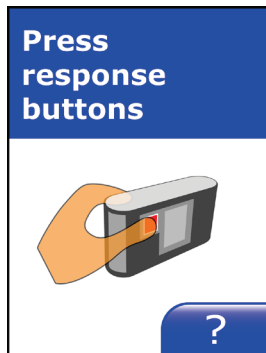
Wash only the garment. Do not wash the electrode belt, monitor, or any other accessories.

Follow the instructions in section 4 for laundering the garment.

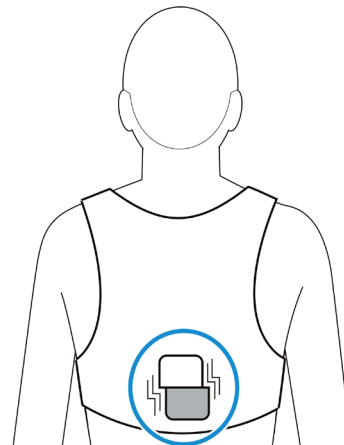
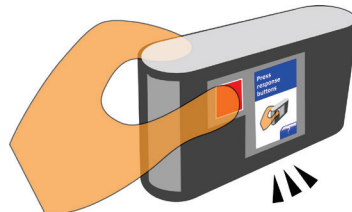
Normal startup routine



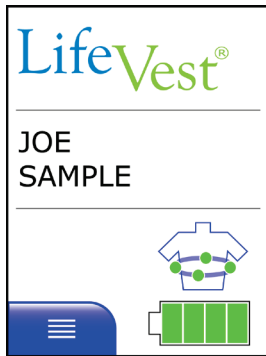
- 1 Put a fully-charged battery into the monitor. Make sure the battery is completely inserted.
- 2 Startup screens appear.



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



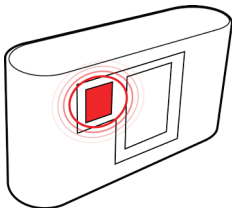
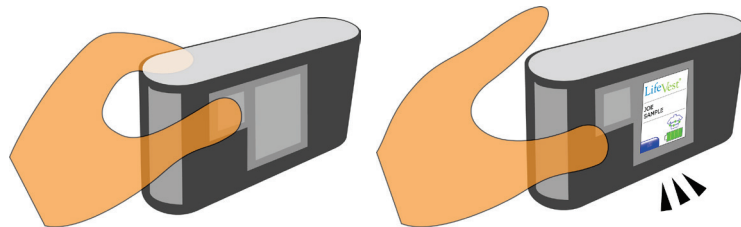
If you do not hear the gong or feel the vibration within 30 seconds, remove the battery. Reinsert the battery and try again. If the monitor still does not operate normally, contact ZOLL.



- 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.

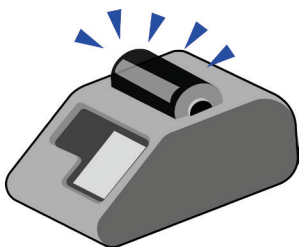
During normal monitoring, most of the time the LifeVest displays a dark screen. To see the display, press and release the response buttons.



Also during normal monitoring, the response buttons flash red about once every six seconds.

Taking care of the batteries

What you need to know



- 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 and charger supplied 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.

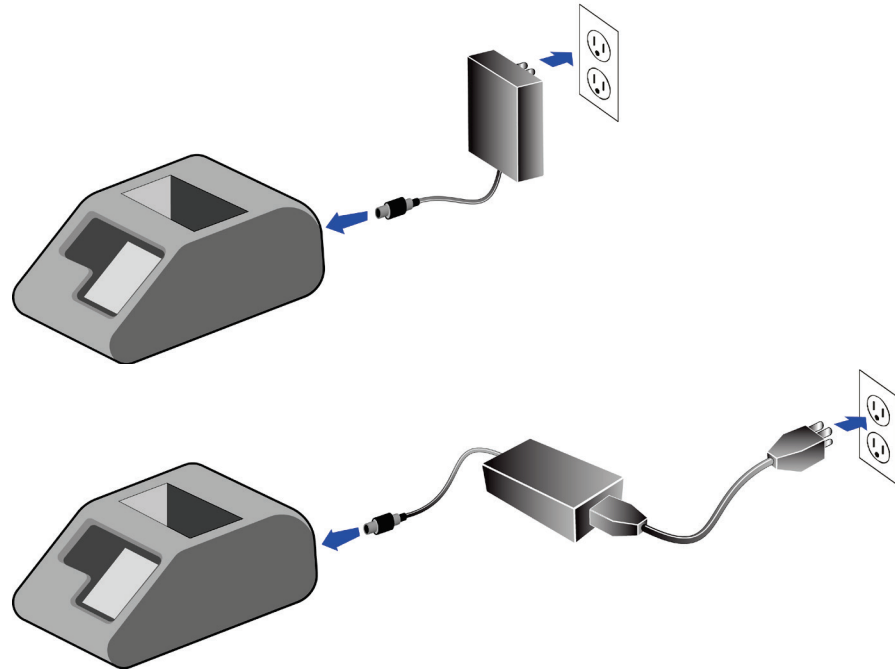
If help is not available, and you expect power to be out for more than 24 hours, contact ZOLL immediately at 1-800-543-3267 to have spare batteries sent to you.

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

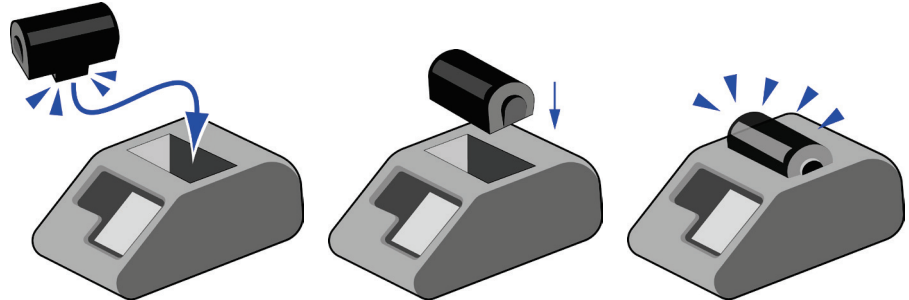
Charger setup

- 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 actually 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 lightswitch.

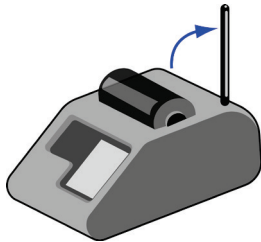
Different types of power supplies may be provided: One plugs directly into the outlet, the other has a detachable power cord.



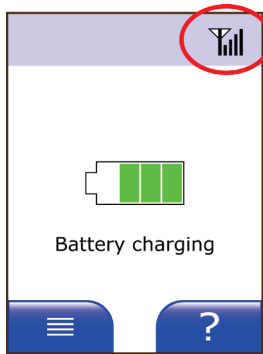
- 3 Insert the spare battery into the charger.
 - Orient the battery with its connector facing the rear of the charger.
 - Push the battery in firmly.



- 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.
-

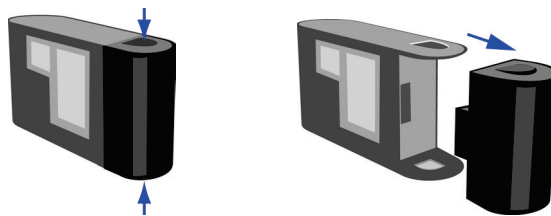


- Charger is set up for a land line phone connection.
 - Charger functions normally, but uses a land line to transfer data.
 - In this mode, a phone line must be plugged into the back of the charger.
-

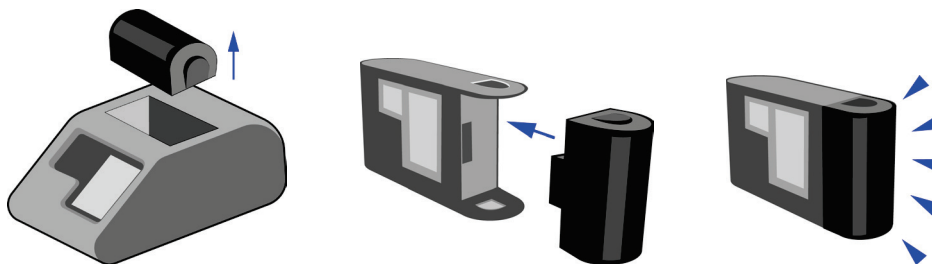
Change and recharge batteries daily

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

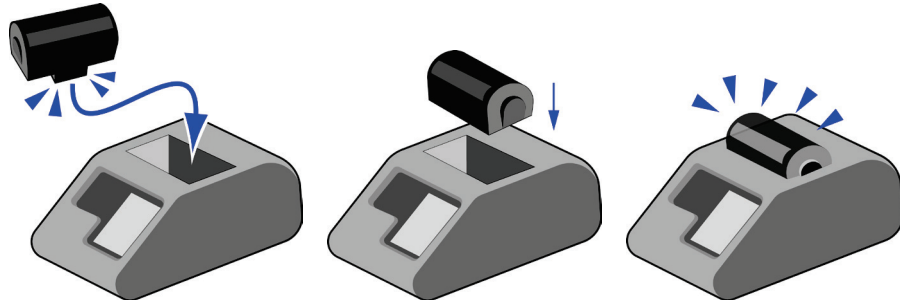
- 1 Remove the existing battery from the monitor.
 - You can leave the monitor in the holster with the electrode belt connected.
 - Open the holster end flap, then push the battery latches and slide the battery out of the monitor.



- 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 into the monitor.
 - Make sure the device follows the startup routine on page 3-3.

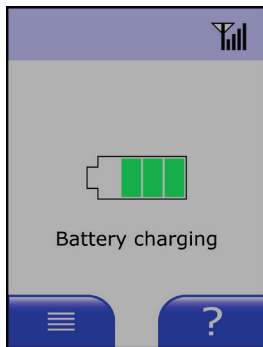


- 3 Put the used battery from the monitor into the battery charger.
 - Orient the battery with its connector facing the rear of the charger.
 - Push the battery in firmly.



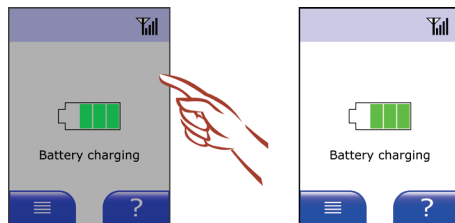
- Read the battery status on the charger. See page 3-11.
- Verify that the battery is being charged.

Charger display dims in the dark

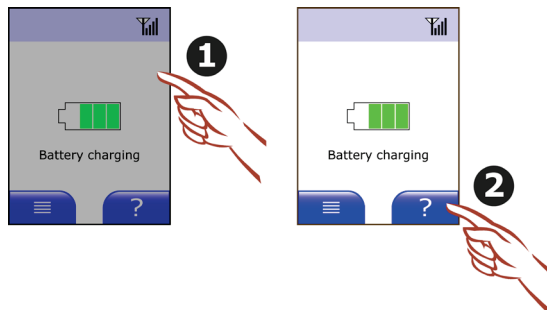


When the room gets dark, the charger display gets dim.

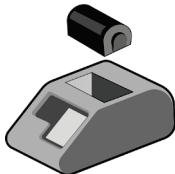



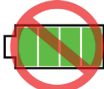

To return the display to full brightness, either turn on the light in the room or tap the screen.



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

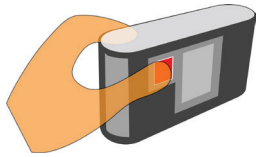


Battery status indicators

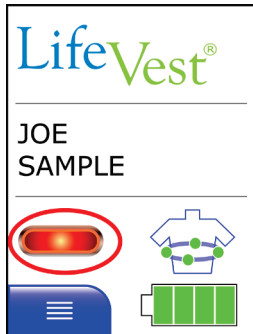
Screen shows	What it means	What to do
 <p>Insert battery</p>	There is no battery in the charger	Insert the battery into the charger. Leave one battery in the charger while you use the other battery.
 <p>Battery charging</p>	Battery is charging	Let the battery charge. This can take up to 4 hours.
 <p>Battery 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.</p> <p>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>


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.

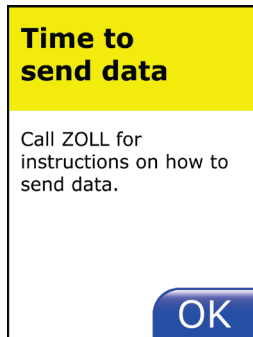


1 Hold the response buttons for 3 seconds.



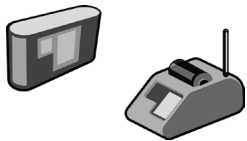
2 Release response buttons when you see the recording indicator  and hear a single gong.

Sending data manually

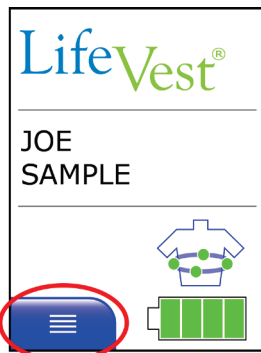



If you get this message, you need to send data manually.

Call ZOLL, then follow along with this procedure.

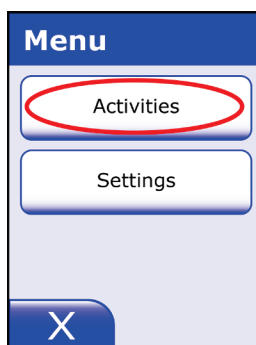
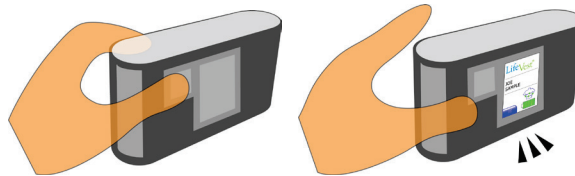


1 Go into the same room where the charger is located.



2 On the monitor, tap the menu button .

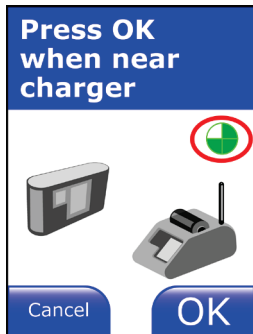
If the screen is dark, press and release the response buttons to activate the screen.




3 Tap **Activities**.




4 Tap **Send data**.




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

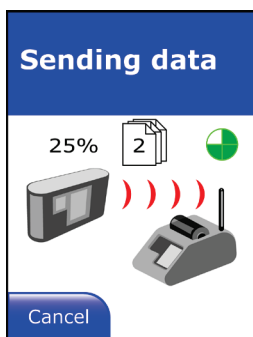
- Signal strength is shown by the number of segments. The more segments, the better.
- To get a stronger signal, try moving closer to the charger.

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

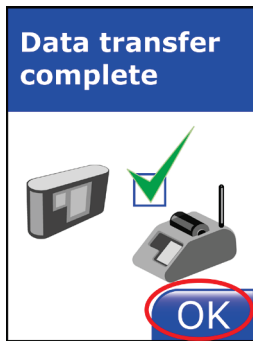
• If this symbol  does not go away after several minutes, you cannot send data. Press **Cancel** and try again later.



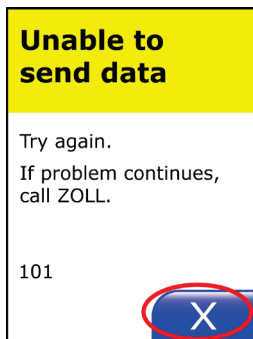
6 When you see at least one green segment on the signal strength symbol  tap **OK**.



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.

Speak options

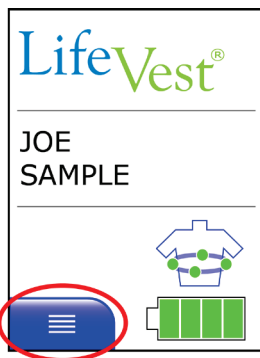
There are three speak options associated with the help screens:


- 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.

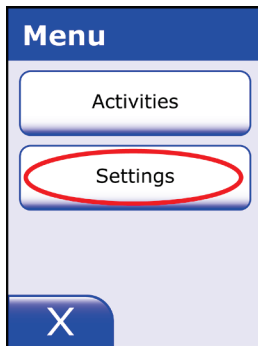
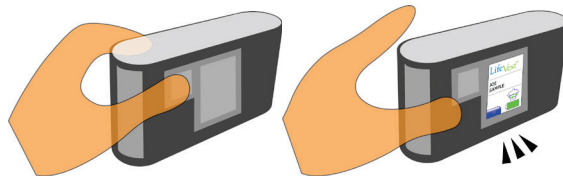
Screens speak in the language displayed.

Follow this procedure to change the speak mode or volume.

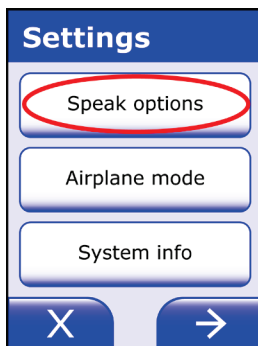


- 1 On the monitor, tap the menu button .

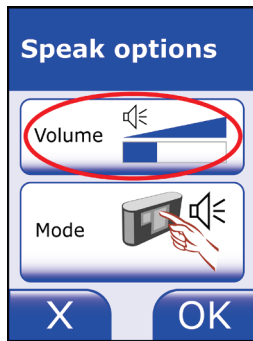
If the screen is dark, press and release the response buttons to activate the screen.



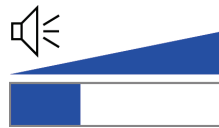
- 2 Tap **Settings**.



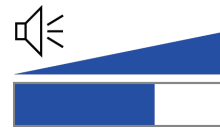
- 3 Tap **Speak options**.



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



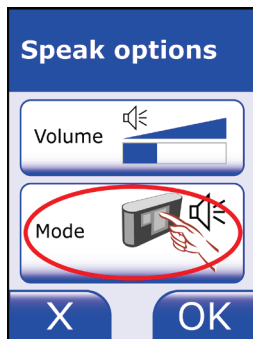
Volume level 1.



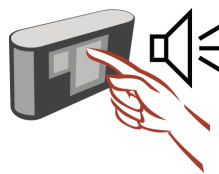
Volume level 2.



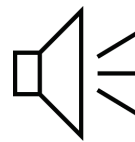
Volume level 3.



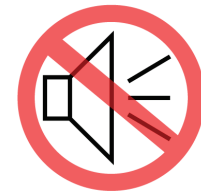
5 Tap **Mode** until you see the speak mode you want.



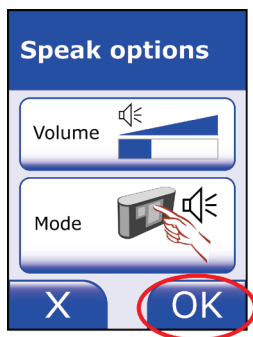
LifeVest speaks when you tap the text area of the screen.



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



LifeVest does not speak.



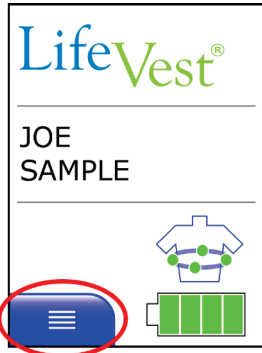
6 When you are finished with the speak options, tap **OK**.


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

Airplane mode

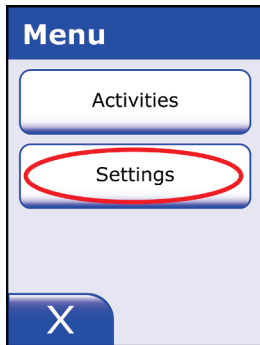
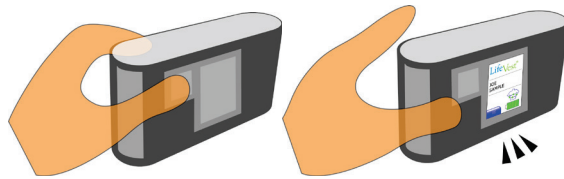
Airplane mode disables the LifeVest from wirelessly transmitting data to avoid interfering with aircraft operation and other electrical equipment.

Follow this procedure to set the LifeVest for airplane mode.

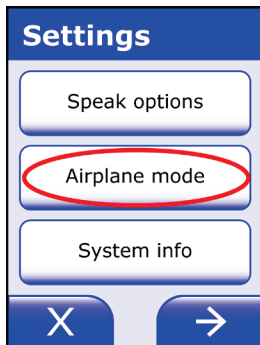


- 1 On the monitor, tap the menu button .

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

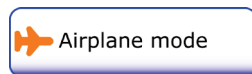


- 2 Tap **Settings**.



- 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.

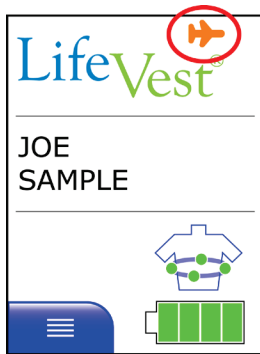


Airplane mode **ON**. No signals are transmitted from LifeVest.



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

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



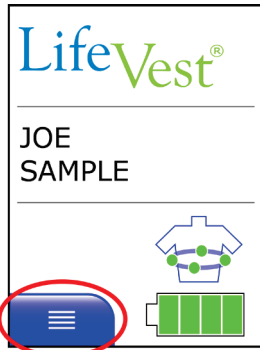
- 4 On the home screen, if you see the airplane symbol in the upper right corner, the LifeVest is in airplane mode.


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

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

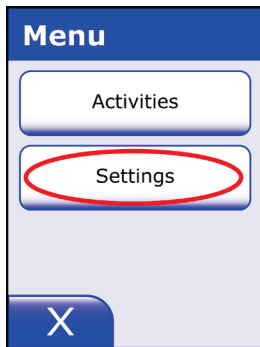
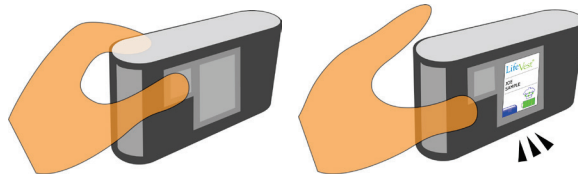
System info screens

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

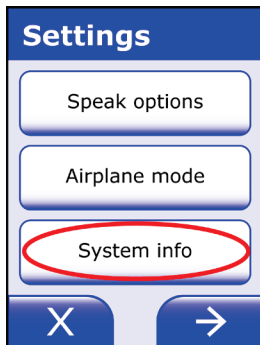


- 1 On the monitor, tap the menu button .

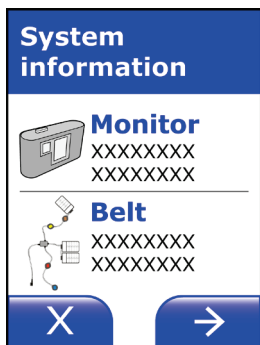
If the screen is dark, press and release the response buttons to activate the screen.




- 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 needs to be updated

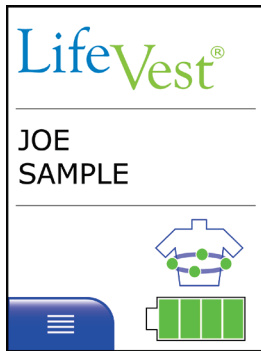
If your LifeVest needs to be updated, here's what will happen and what we need you to do:

- ZOLL will call and explain that your LifeVest 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

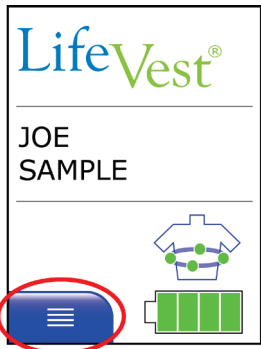
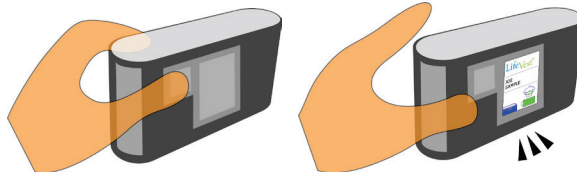
If you are to enter support mode:

- 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.

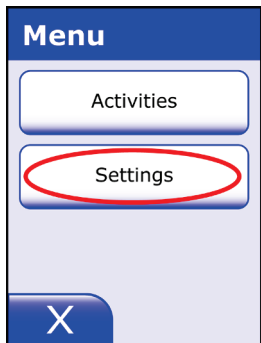


1 During normal monitoring, the LifeVest screen should display the “home” screen, as shown at left.

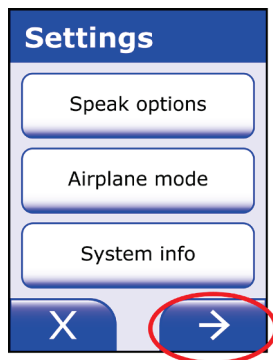
If the screen is dark, press and release the response buttons to activate the screen.




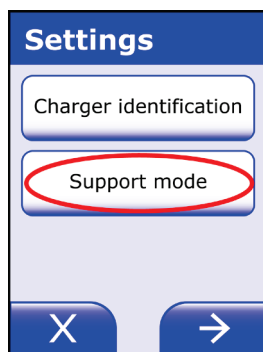
2 Tap the menu button .



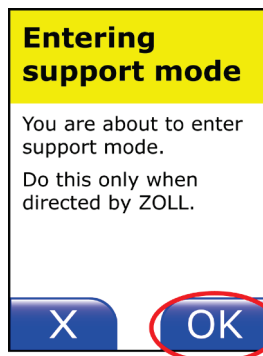
3 Tap **Settings**.



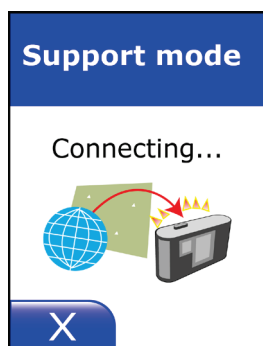
4 Tap the next page button .



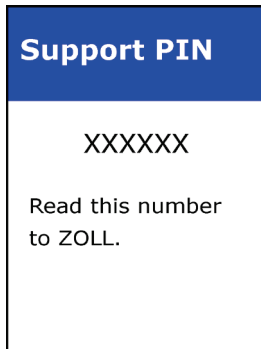
5 Tap **Support mode**.



6 Tap **OK**.

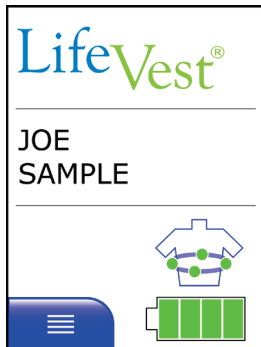
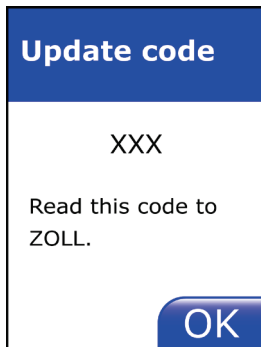


7 You'll see the support mode screen for a few moments.



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 Formula 409[®] all-purpose cleaner or equivalent cleaning solution.

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.
- 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.

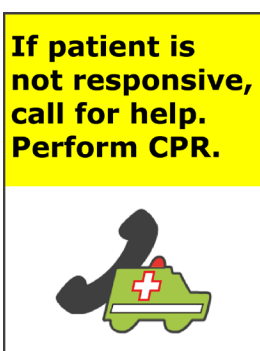
Do not remove the battery, do not disconnect the electrode belt from the monitor, and do not loosen the garment while the monitor is broadcasting alert sounds and/or voice prompts. If the battery is removed, the electrode belt disconnected from the monitor, or the garment is loosened, needed therapy 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:

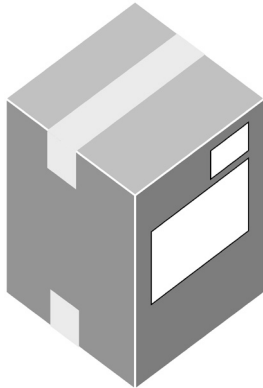
- If the LifeVest treatment does not revive the patient and the patient is unconscious, call for help and then start CPR.
- If the patient gets the alert message shown below and the patient is unconscious, call for help and then start CPR. If the patient remains conscious, check the belt to make sure 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.*

* See indication for patients under 18 years of age.

When you are finished with the device



Call ZOLL and arrange to return the LifeVest system.

In the USA, call 1-800-543-3267.

Battery recycling

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



WARNINGS

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

4: Assembling and putting on the garment

About this chapter

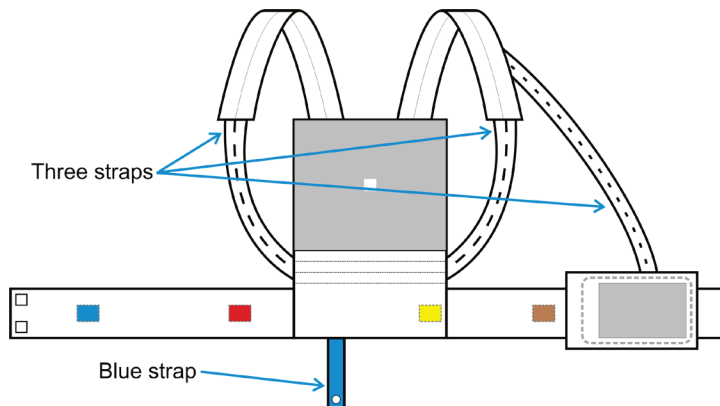
This chapter contains instructions for:

- Identifying which style garment you have
- 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

Which style garment do you have?

The first thing to do is figure out which style garment you have. Then refer to the instructions for the style you have.

Garment A

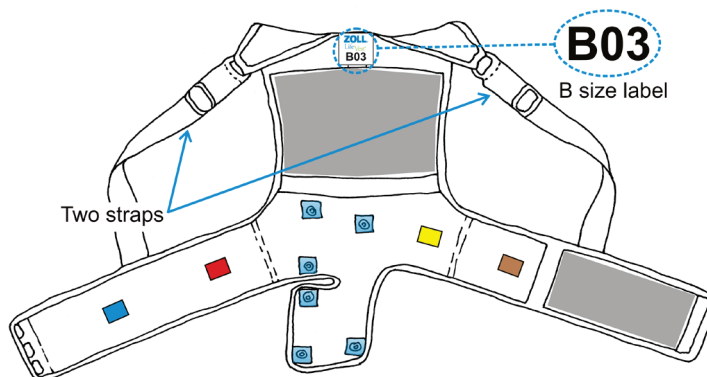


This style garment has three straps at the top, and a small blue strap at the bottom.

We call this garment style A.

If you have this style garment, see page 4-2.

Garment B



This style garment has two straps and a label showing the B size of the garment.

We call this garment style B.

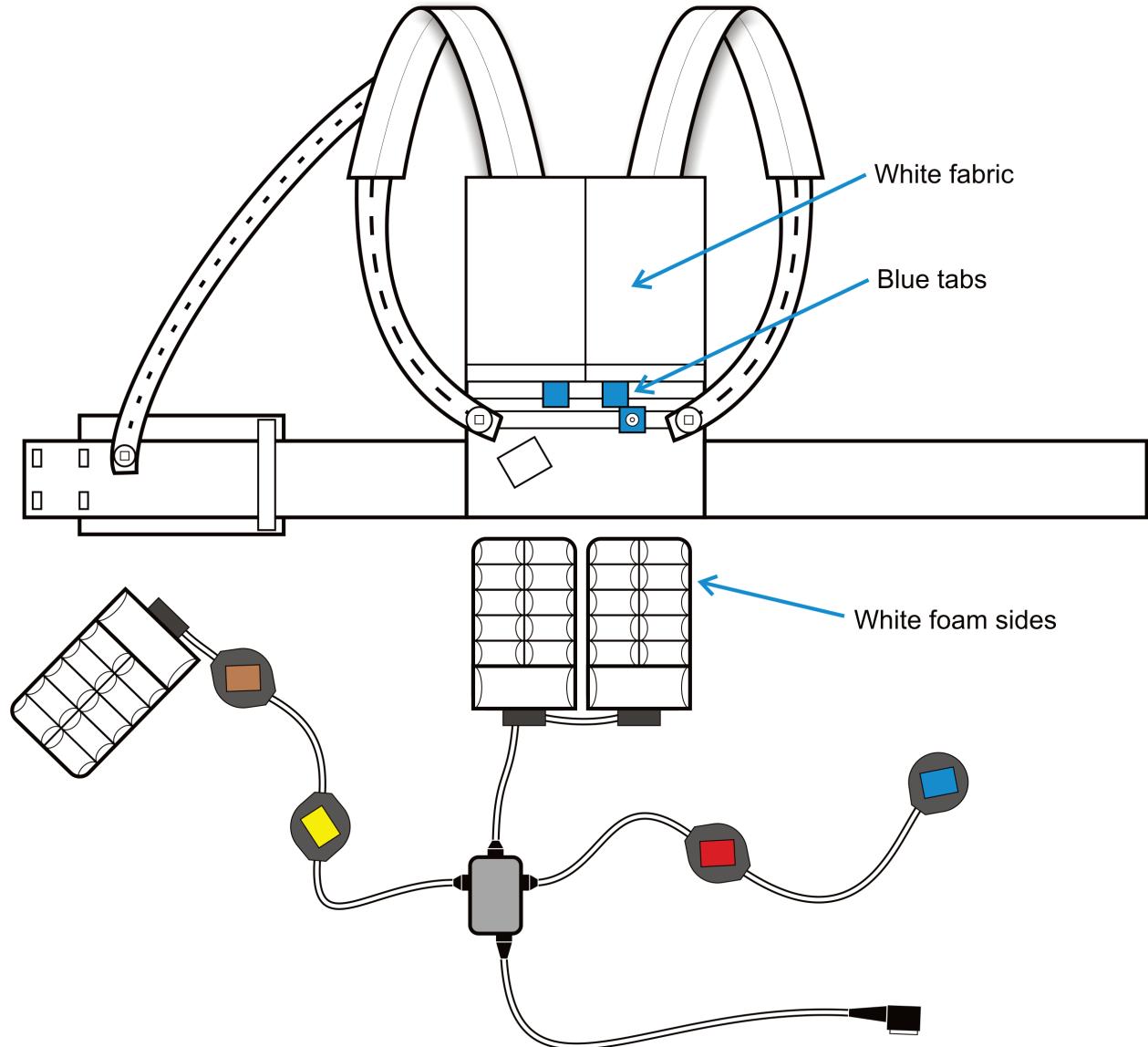
If you have this style garment, see page 4-12.

Assembling the electrode belt to garment A

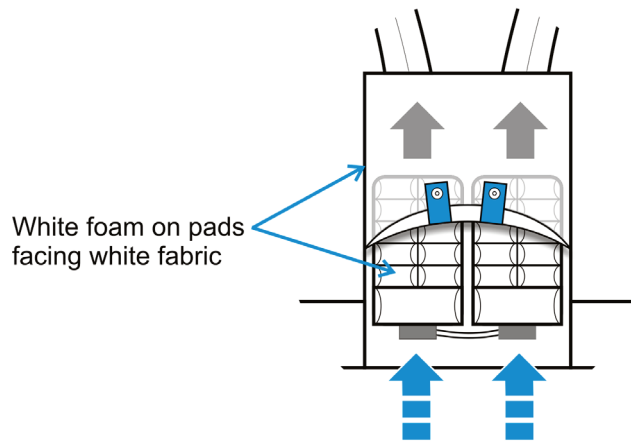
Refer to this section for garment A. If you have garment B, see page 4-12.

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

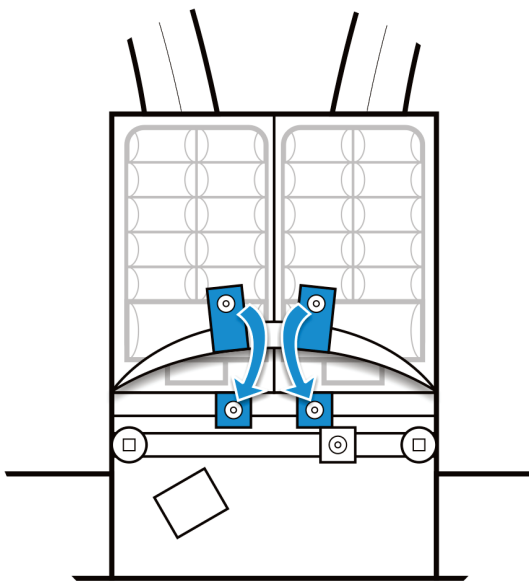
- Place the garment with the white fabric and blue tabs on the back pockets facing up.
- Place the electrode belt with the white foam sides of the therapy pads facing up.



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

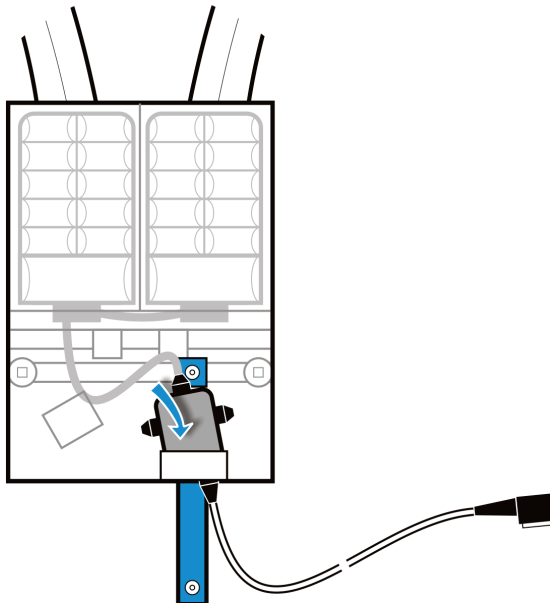


- Insert the pads with the white foam facing the white fabric.

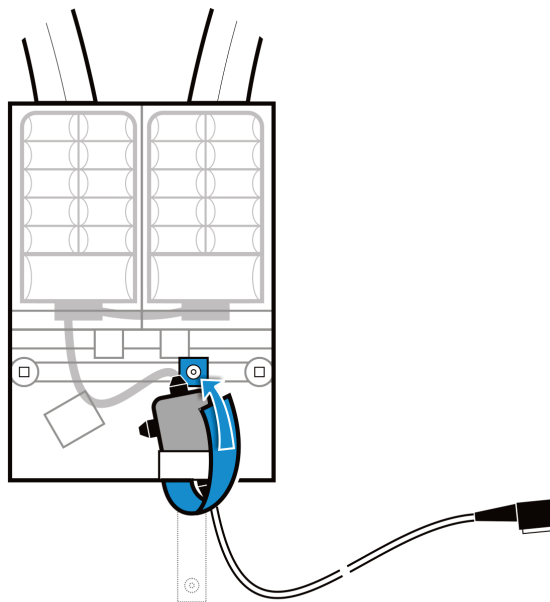


- Snap the blue tabs to secure the pockets.
- Make sure the snaps are securely fastened.

2 Attach the vibration box to the garment.

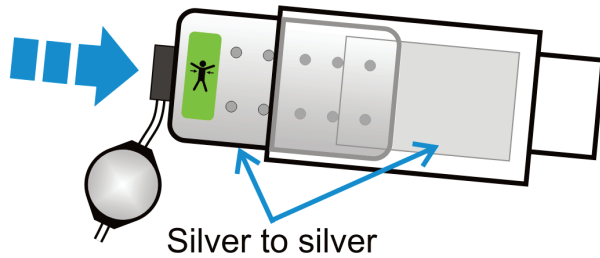


- Position the vibration box with the label side facing toward the garment, and with the connector cable facing down.
- Insert the connector cable under the strap along the edge of the garment.
- Slide the vibration box under the strap.

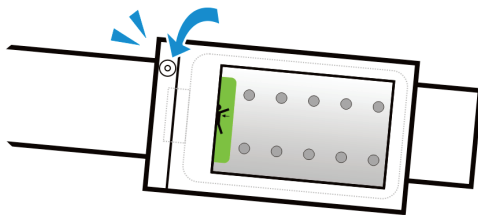


- Snap the blue strap over the vibration box.
- Make sure the snap is securely fastened.

3 Insert the front therapy pad into the front pocket.

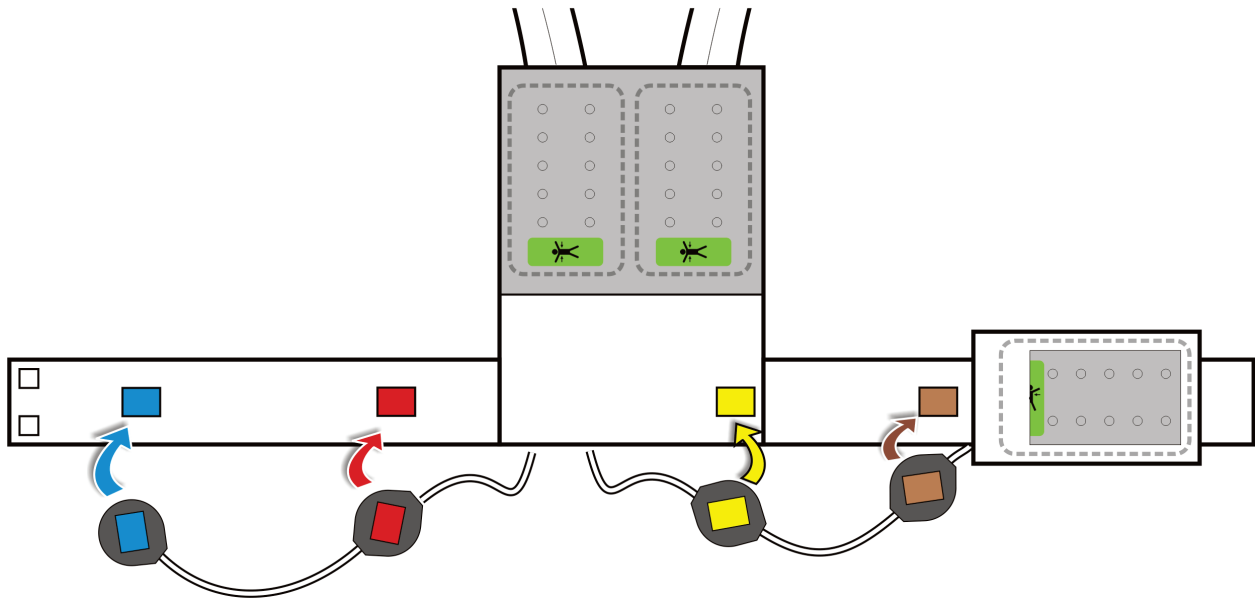


- Turn the garment over.
- Insert the pad with silver to silver. By that we mean to have the silver side of the pad (with the green sticker) facing the silver fabric on the pocket.



- 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 4-8.

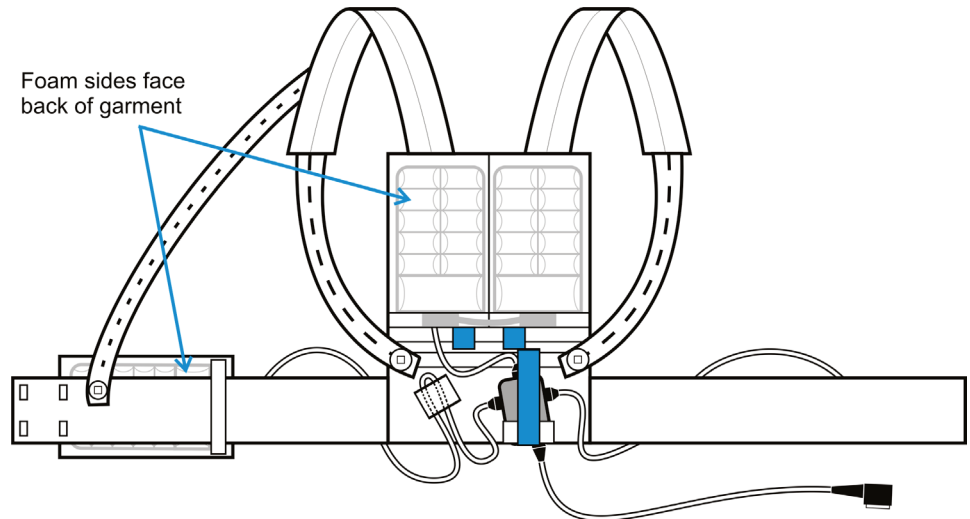
Assembled electrode belt and garment A

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

If the straps are not buttoned, button them now.

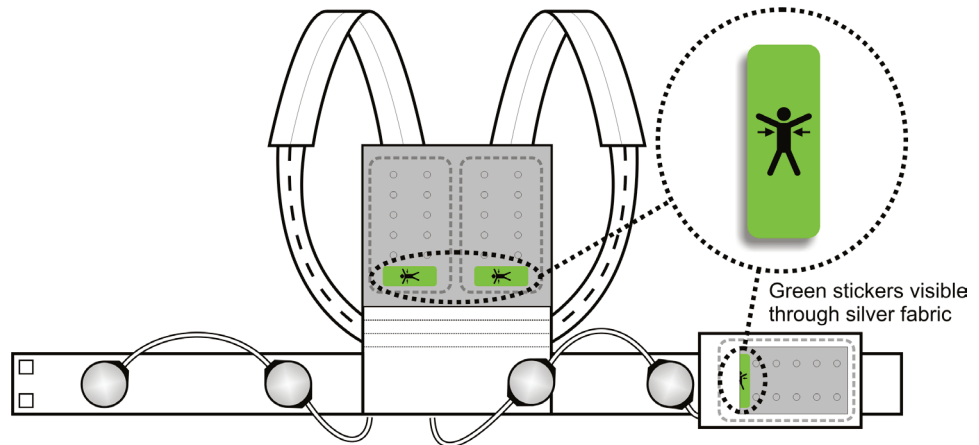
Outside view

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



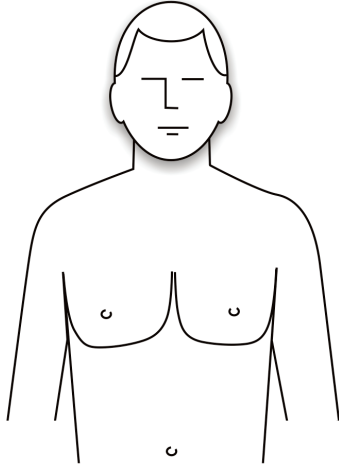
Inside view

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



Putting on the assembled electrode belt and garment A

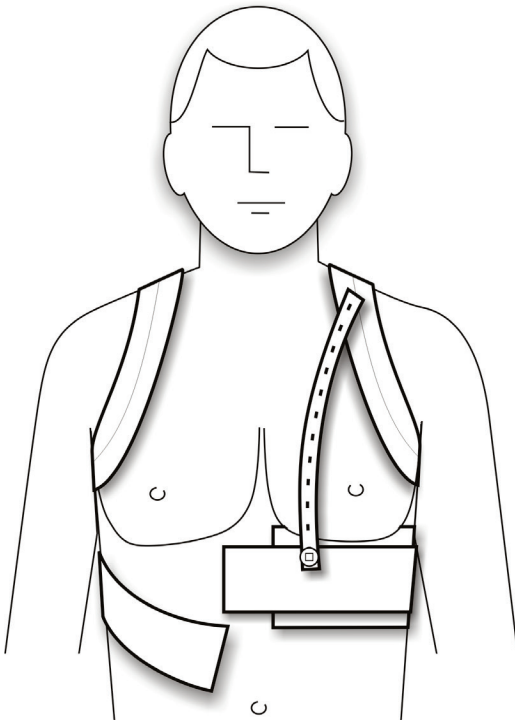
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 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.



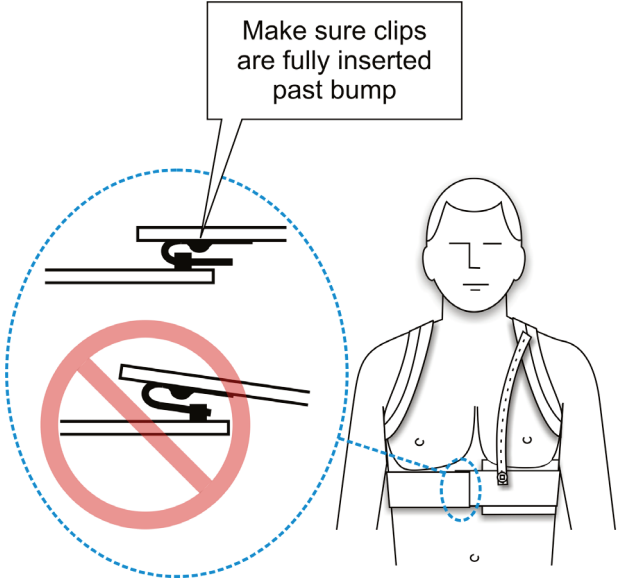
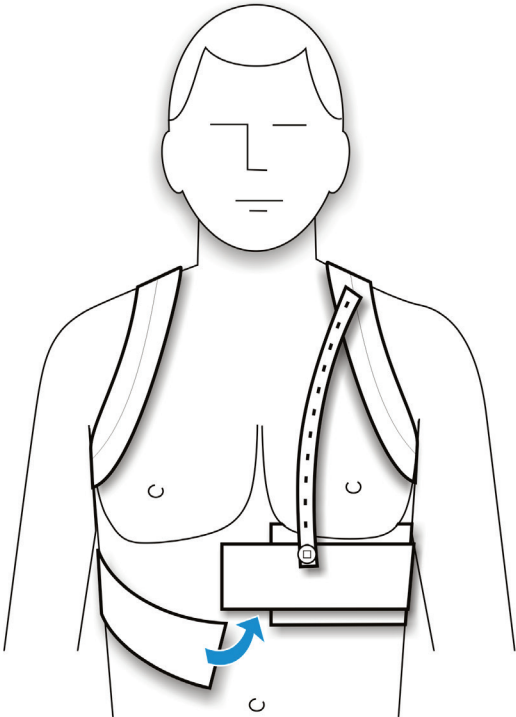
- 3 Put on the garment, making sure:
 - The garment doesn't get twisted.
 - The silver fabric pockets touch your bare skin.

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 is pressing against your body rather than the underside of your left breast.

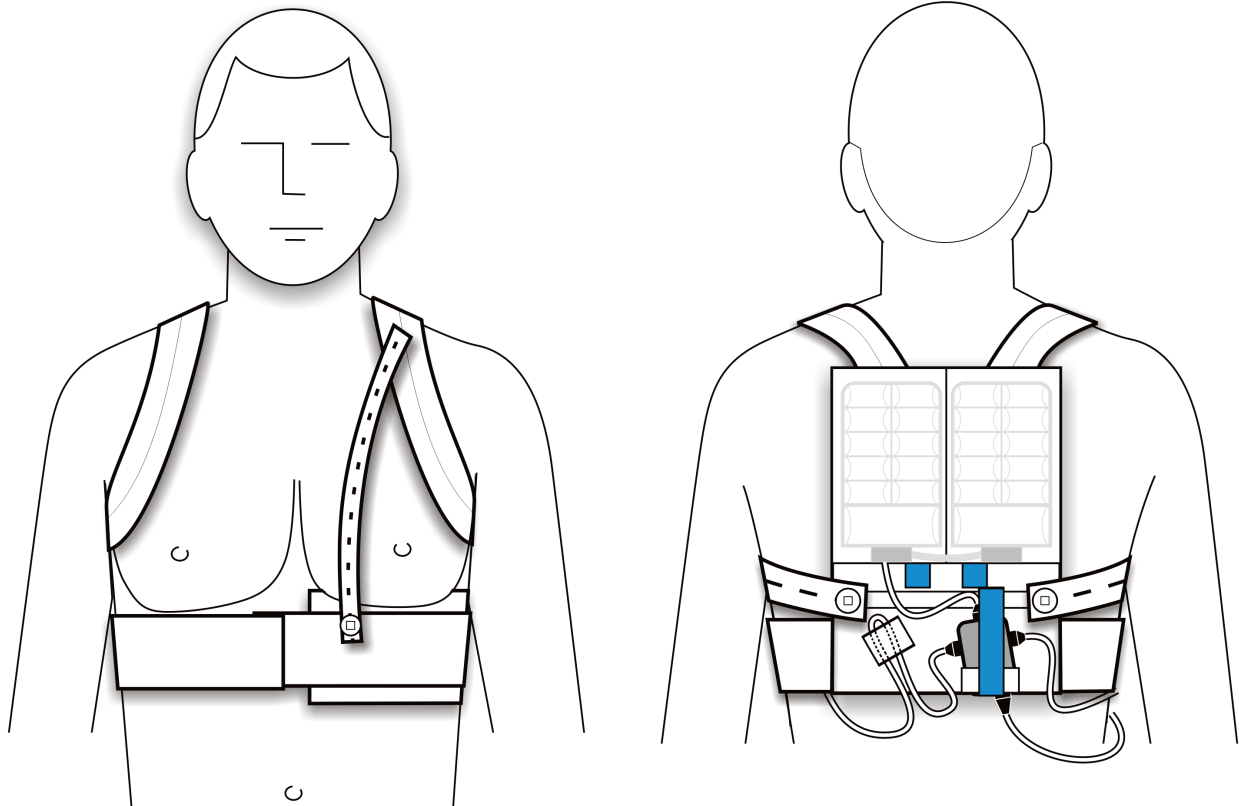
- 4 Connect the garment ends together in the front.

Make sure that the clips are fully inserted past the slight bumps in the clips.



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 silver fabric pockets and silver side 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 or therapy pads.
- The garment is being worn correctly. Your garment should look like the figures below.

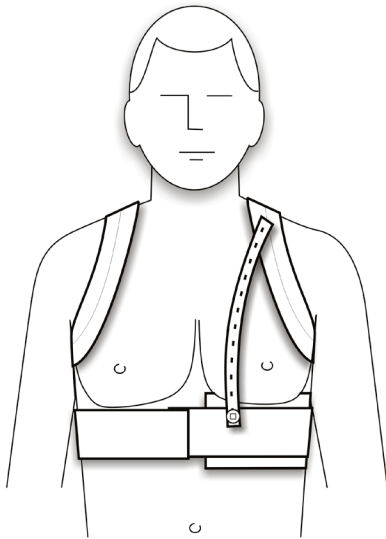
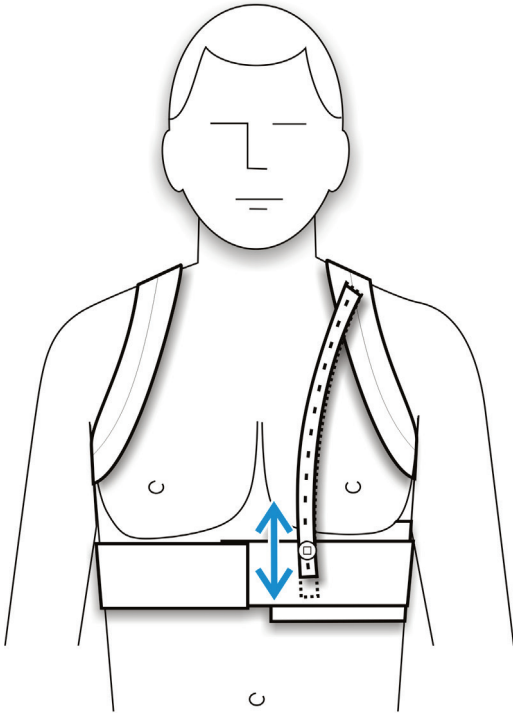


- 6 Check the position of the garment on your body and make sure it's not too high or too low.

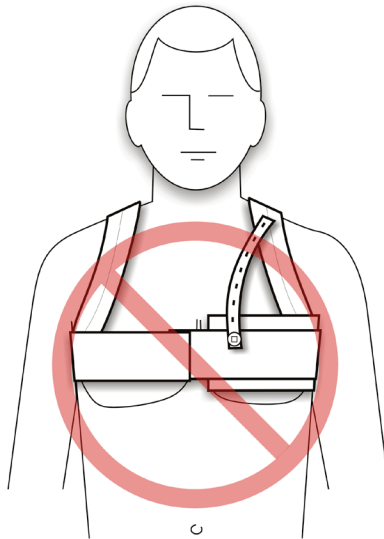
To position the garment properly, you may need to adjust the front strap.

Move the strap to the button hole that positions the garment properly, and for a snug fit.

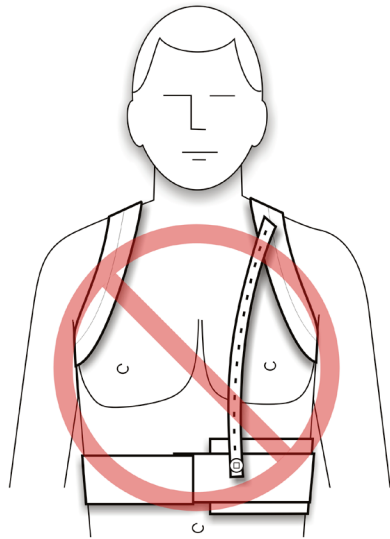
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



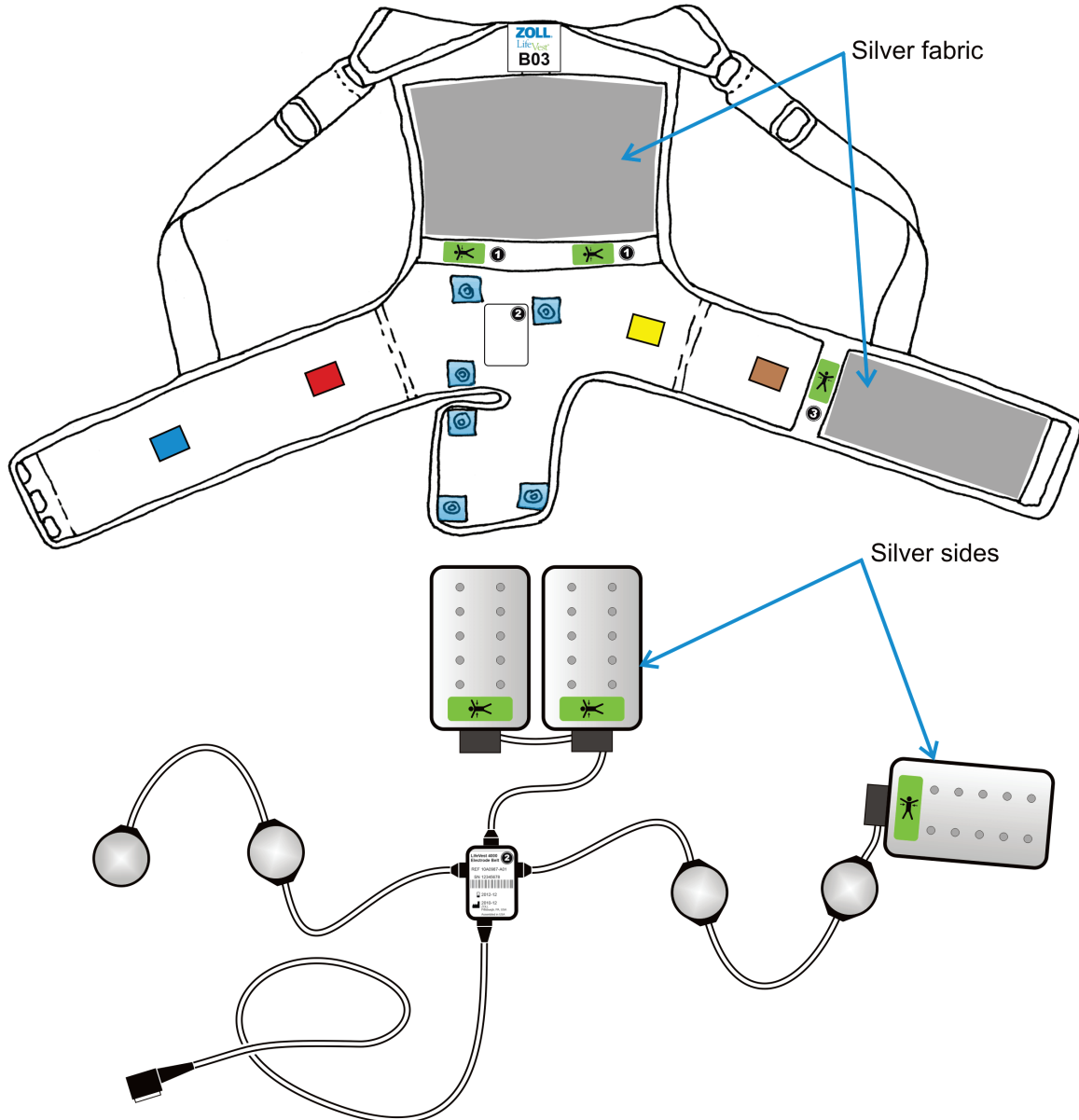
Too low

Assembling the electrode belt to garment B

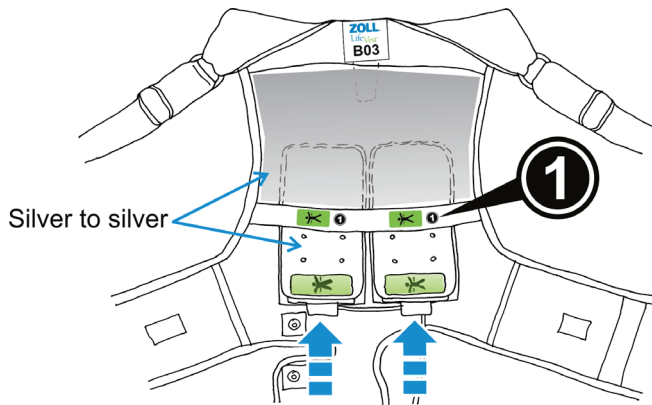
Refer to this section for garment B. If you have garment A, see page 4-2.

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

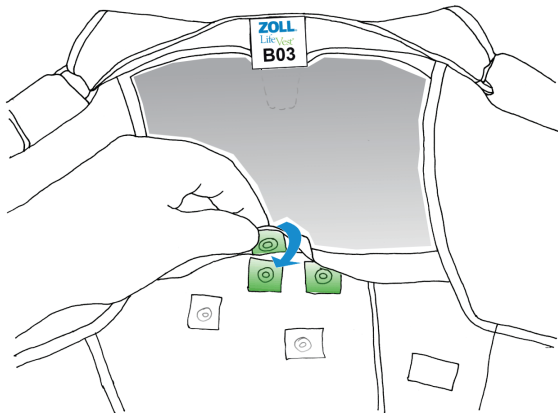
- Place the garment with the silver fabric facing up.
- Place the electrode belt with the silver sides of the therapy pads facing up.



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

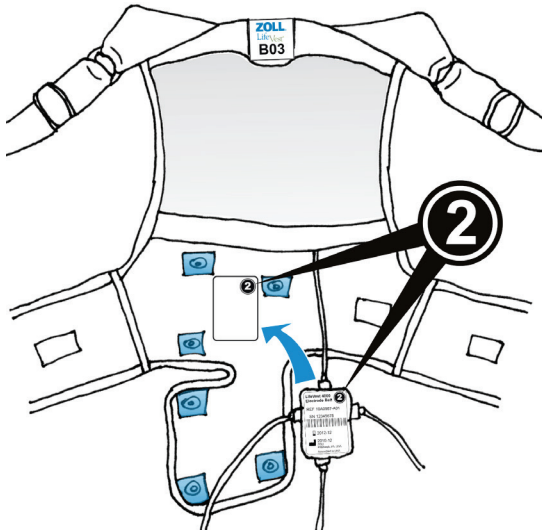


- The rear pockets are numbered 1.
- Insert the pads with silver to silver. By that we mean to have the silver sides of the pads (with the green stickers) facing the silver fabric on the pockets.

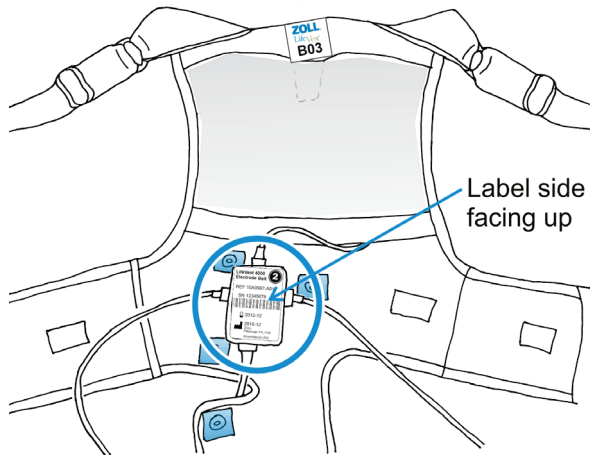


- Snap the green tabs to secure the pockets.
- Make sure the snaps are securely fastened.

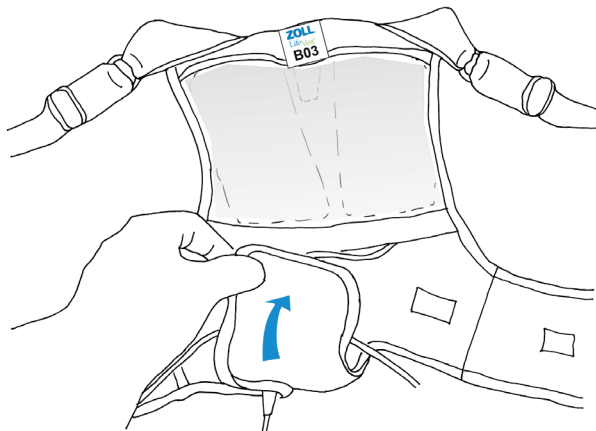
2 Position and secure the vibration box to the garment.



- The vibration box goes in position numbered 2.

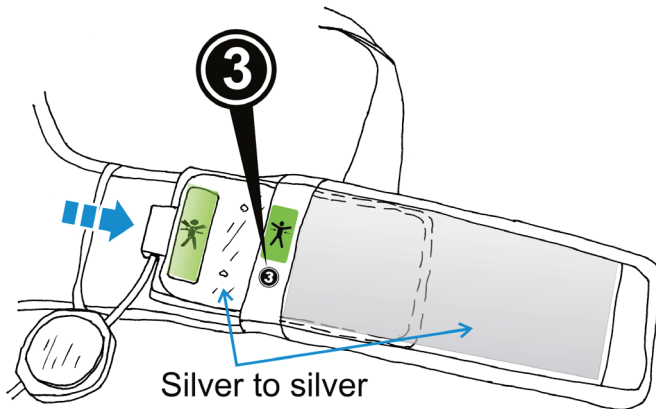


- Place the vibration box with the label side facing up.

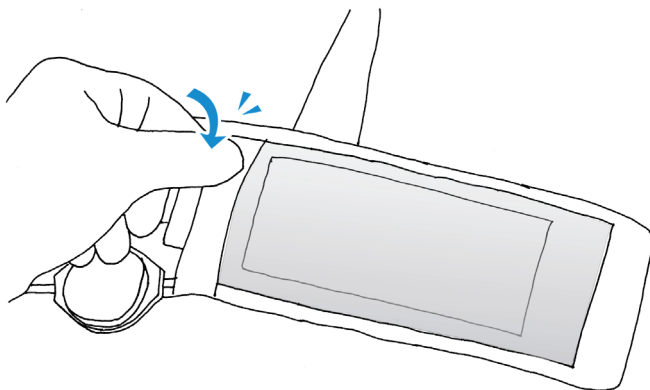


- Snap the flap over the vibration box to the blue tabs.
- Make sure all three snaps are securely fastened.

3 Insert the front therapy pad into the front pocket.

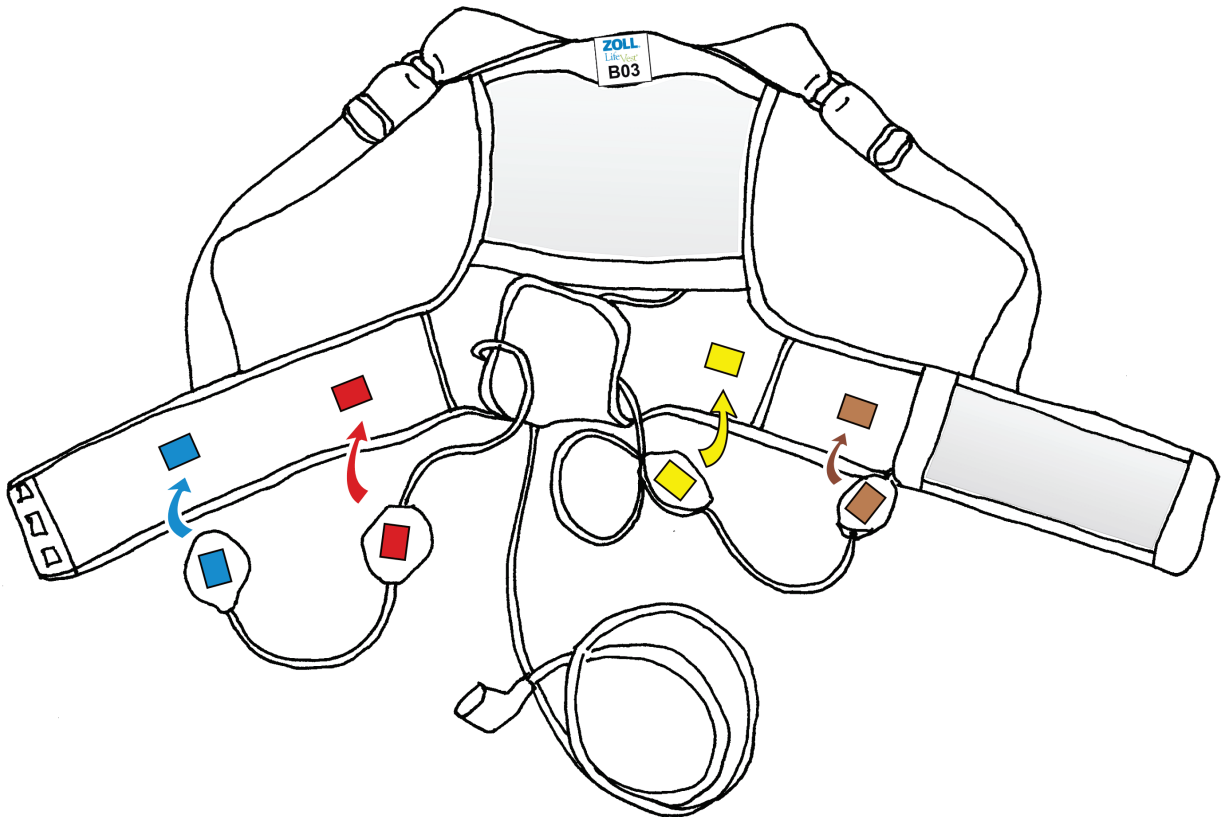


- The front pocket is numbered 3.
- Insert the pad with silver to silver. By that we mean to have the silver side of the pad (with the green sticker) facing the silver fabric on the pocket.



- 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.



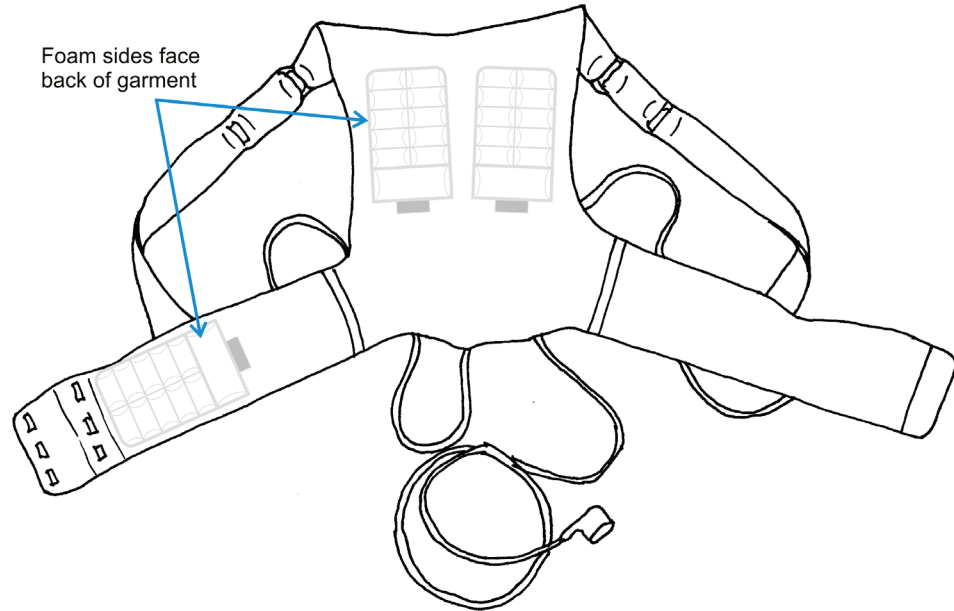
- 5 Make sure that you have properly assembled the electrode belt to the garment. See next page.
- 6 Then put on the assembled garment. See page 4-18

Assembled electrode belt and garment B

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

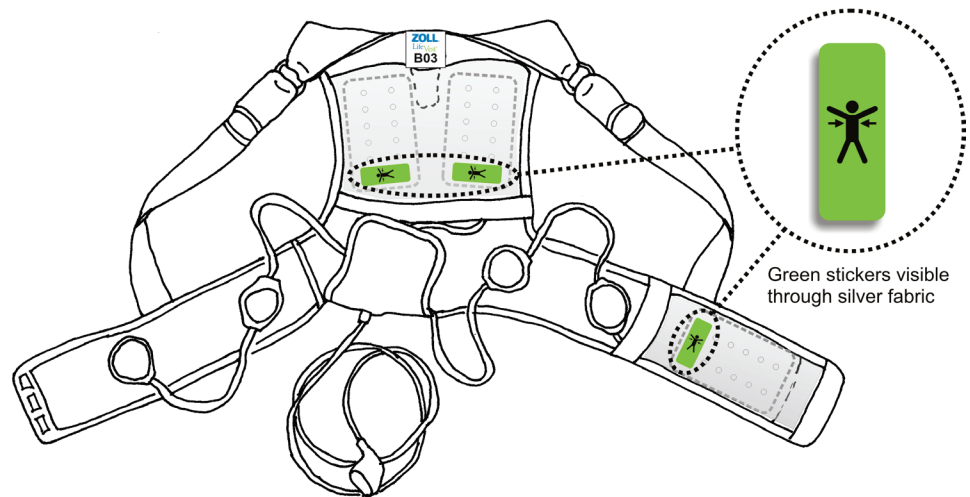
Outside view

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



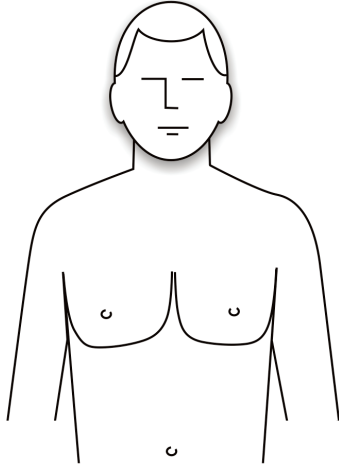
Inside view

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



Putting on the assembled electrode belt and garment B

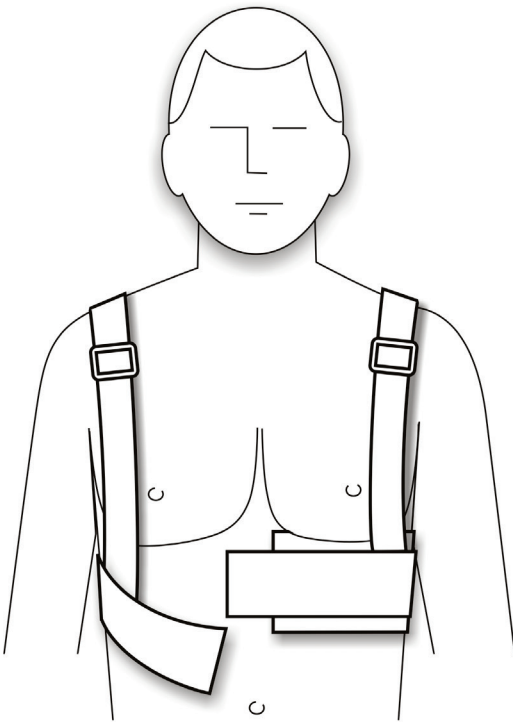
Follow these instructions to put on the assembled garment, then make sure you're wearing it properly.



- 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:

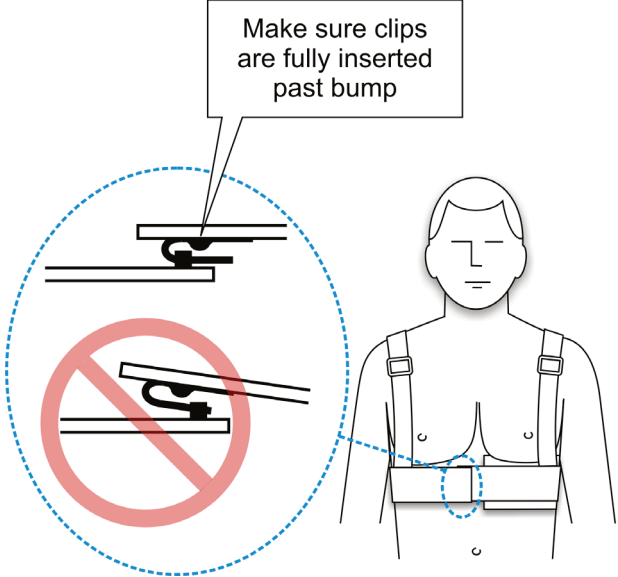
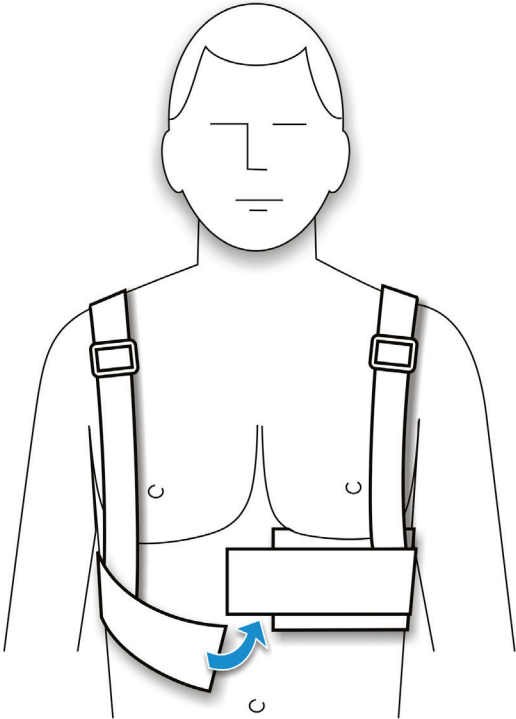
- The garment doesn't get twisted.
- The silver fabric pockets touch your bare skin.

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 is pressing against your body rather than the underside of your left breast.

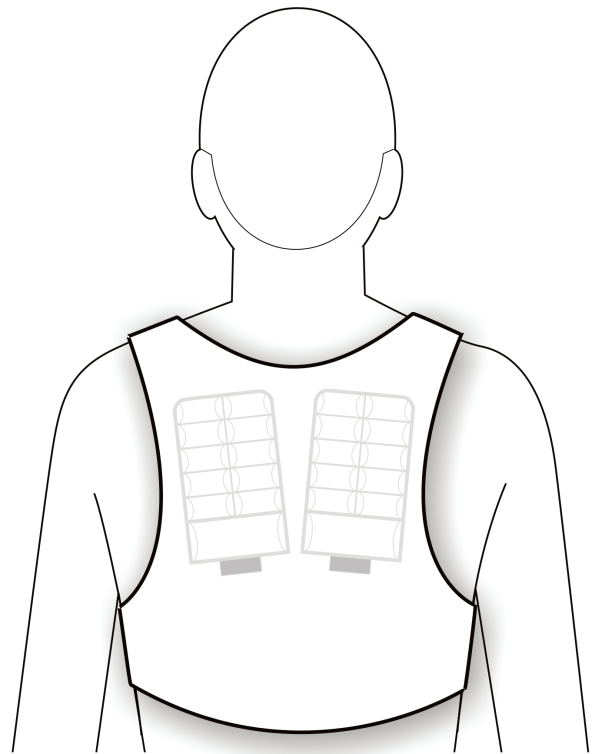
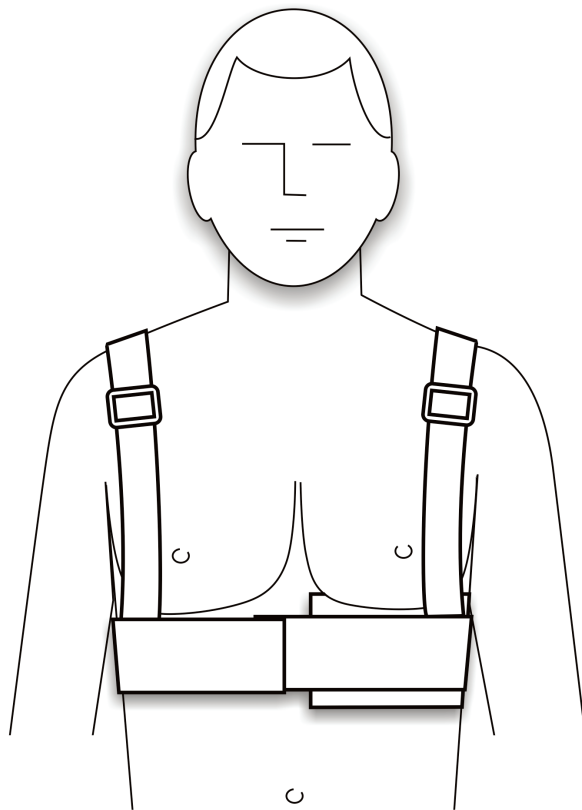
- 4 Connect the garment ends together in the front.

Make sure that the clips are fully inserted past the slight bumps in the clips.



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 silver fabric pockets and silver side 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.

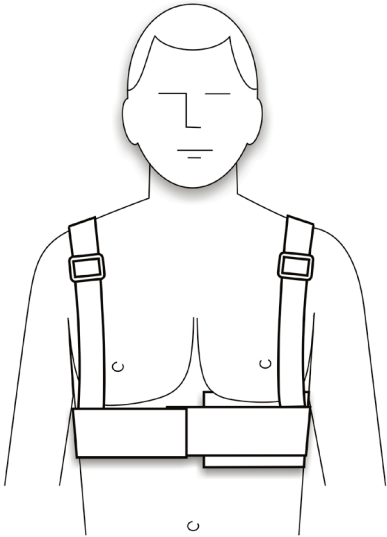
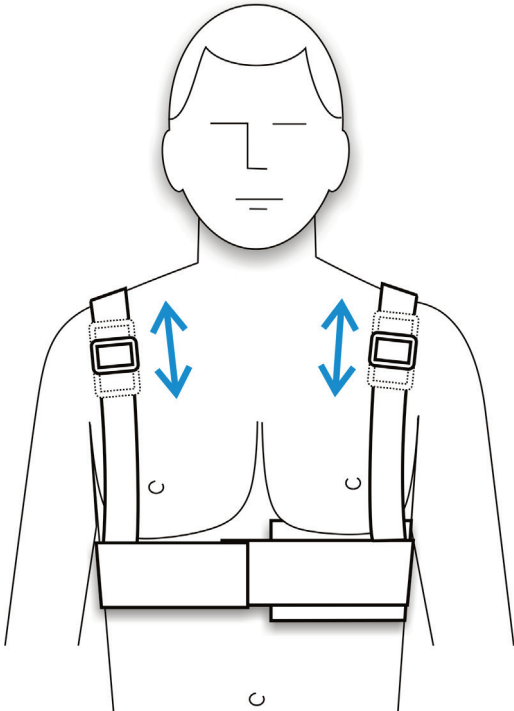


6 Check the position of the garment on your body and make sure it's not too high or too low.

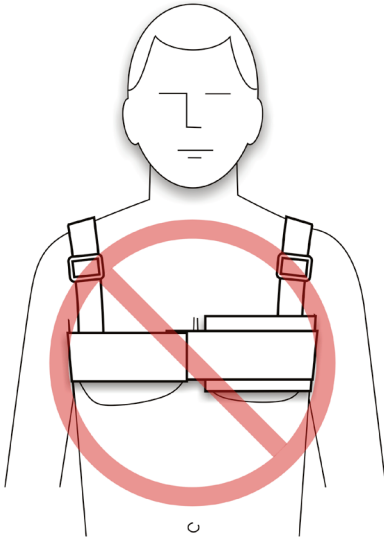
To position the garment properly, you may need to adjust the shoulder straps.

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

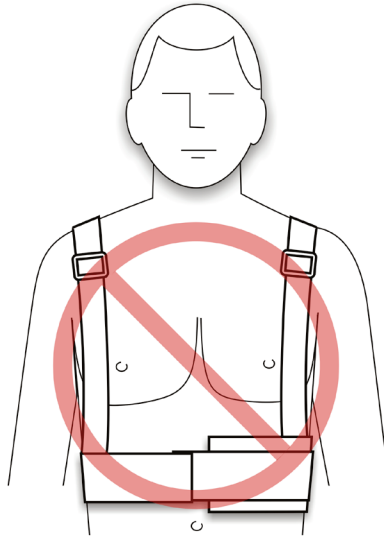
- The garment **should** cross your body just below your breastbone.
- The garment **should not** be as high as your nipples.
- The garment **should not** be as low as your belly button.



Positioned properly



Too high



Too low

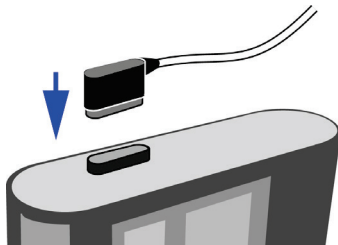
Connecting and disconnecting the electrode belt

To connect the belt

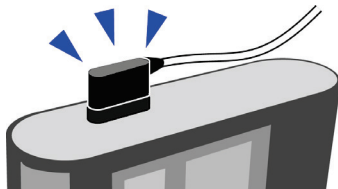


WARNING

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.

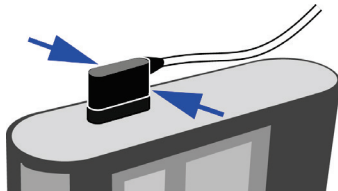


- 1 Line up the connector with the monitor. The cable should face toward the center of the monitor.

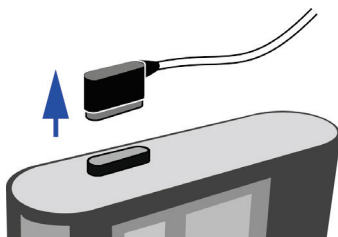


- 2 Gently push the connector straight in until it locks in place.

To disconnect the belt

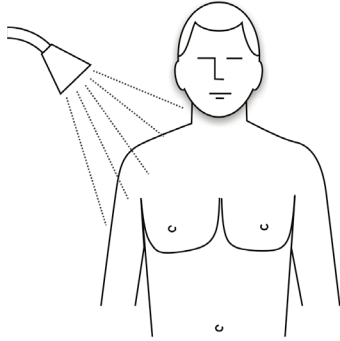


- 1 Squeeze the sides of the connector as you pull it away from the monitor.



- 2 Pull the connector straight out of the monitor.

Removing when you shower or bathe

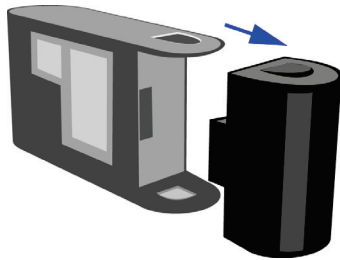


When you remove the device to bathe or shower, you are not protected by the device. Bathe or shower in the evening, preferably when someone else is home with you.

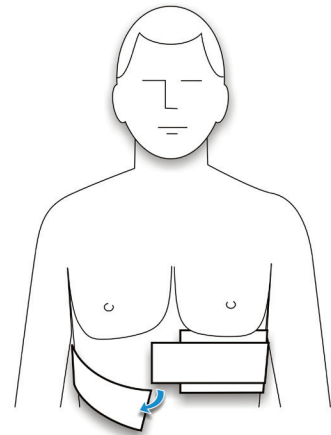
When you remove the device for any reason, remove the battery first. When you put the LifeVest device back on, put the battery in last.

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.

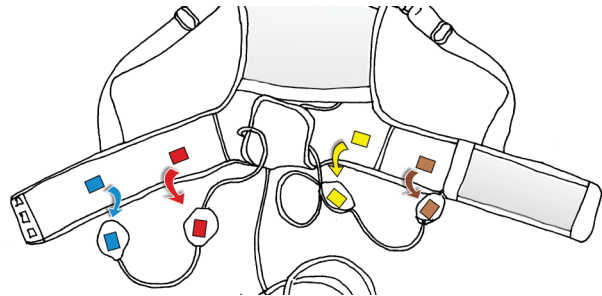
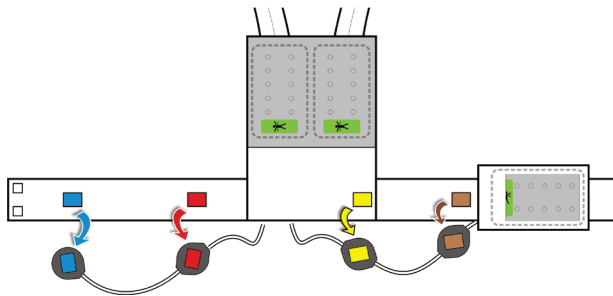


- 2 Unfasten and remove the garment from your body.

If you plan to change the garment, follow the procedure on the next page to disassemble the electrode belt from the garment.

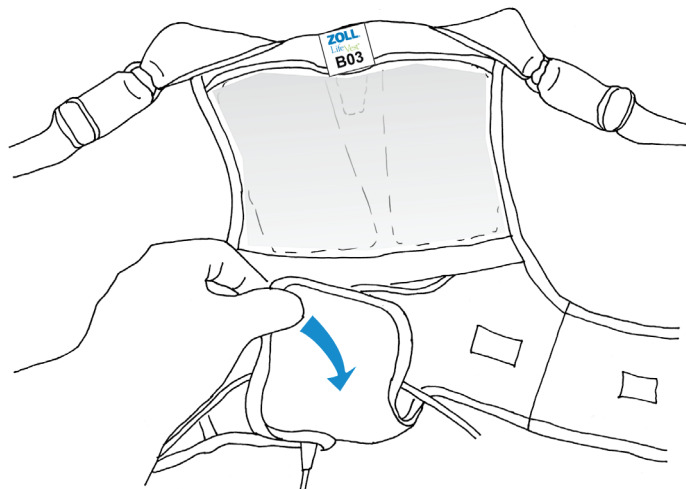
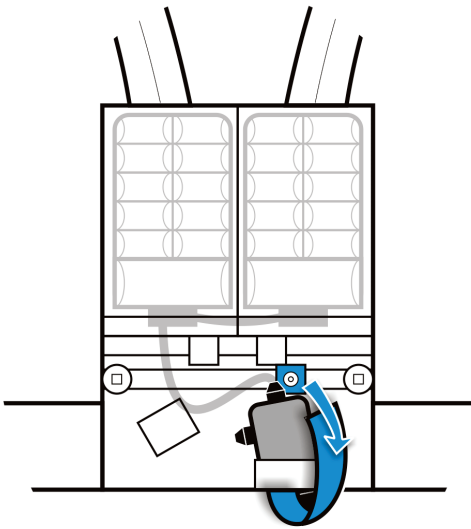
Disassembling the electrode belt and garment

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

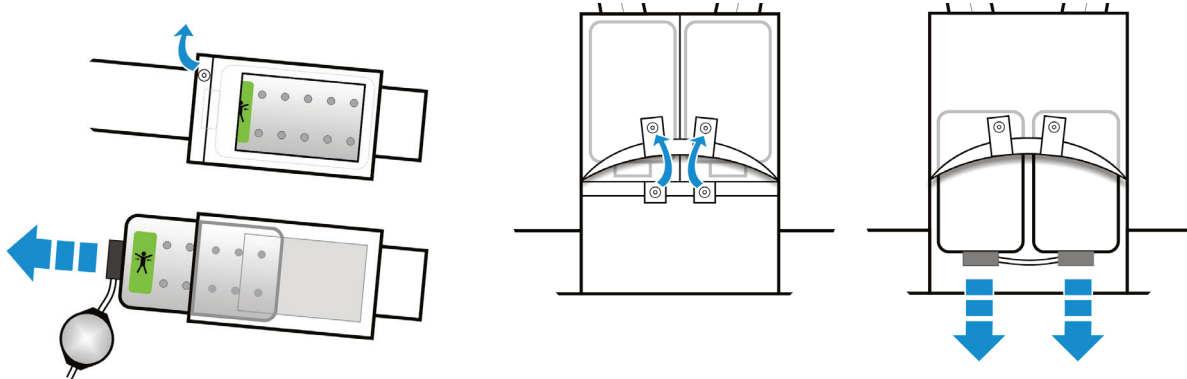


- 2 Remove the vibration box from the garment.

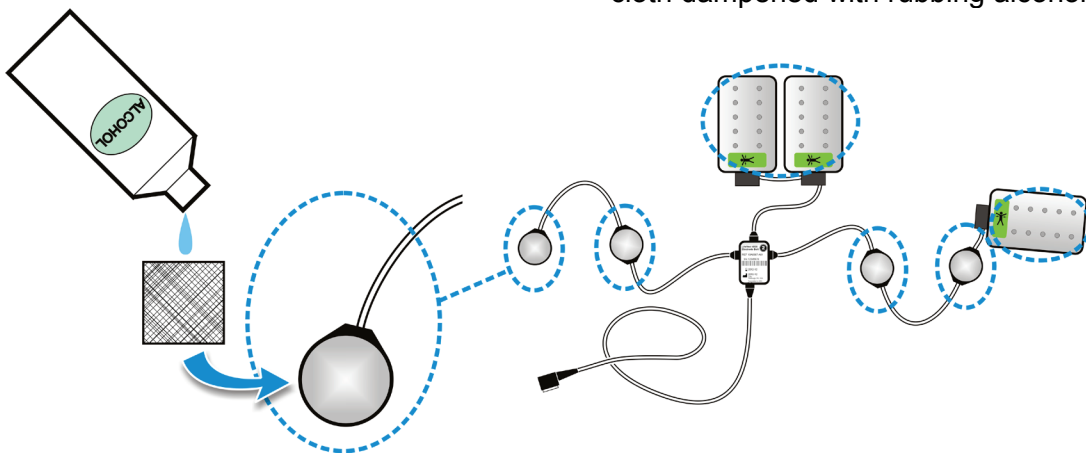
Do not use the vibration box as a handle to pull or lift the electrode belt. Pulling on the vibration box can damage the internal wiring and cause the system to malfunction.



- 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 4-2 (garment A) or page 4-12 (garment B).
- 6 Put on the assembled garment and electrode belt as described on page 4-8 (garment A) or page 4-18 (garment B).

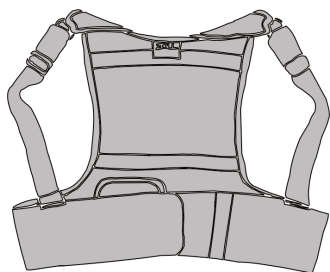
For instructions on laundering the dirty garment, see next page.

Laundering the garment



CAUTION

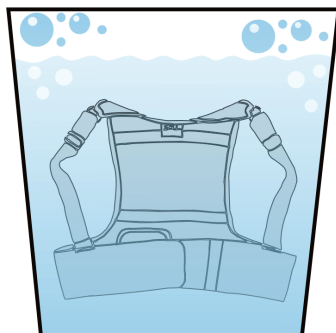
Do not use chlorine bleach, bleach alternatives, fabric softener, anti-static sprays or detergents that include bleach or fabric softener additives when laundering the garment. Using bleach or any of these other prohibited agents to launder the garment may damage it and cause the system to malfunction.



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.
- With garment A, leave the straps buttoned.

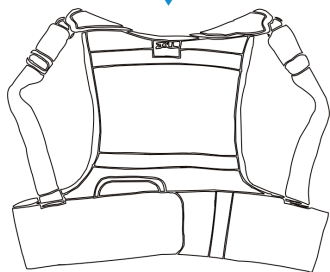


Wash the garment by itself. Do not wash it with other laundry.

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 clothes washing detergent only, such as Woolite® Original, Tide®, Purex® After the Rain, Fab® Spring Magic, or Arm & Hammer® for sensitive skin.

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.



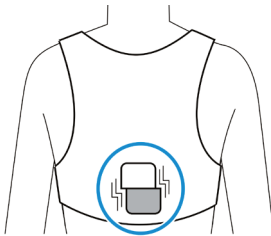
5: Responding to alerts

Types of alerts

How you respond to an alert depends on the type of alert you get. There are three types of alerts:

- vibration
- siren
- gong

Vibration alert



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

Press the response buttons to stop this alert.

Follow the same instructions as for the siren alert on page 5-2.

Siren alert

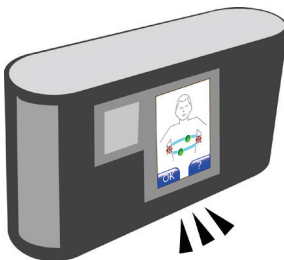


The siren alert is a high-pitched two-tone sound that means an abnormal rhythm has been detected.

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

Follow the instructions on page 5-2.

Gong alert

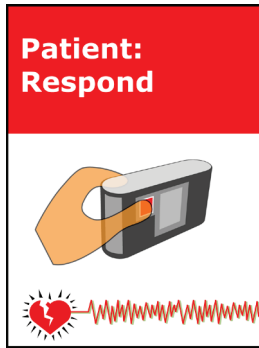


The gong alert is a low-pitched "gong" sound that repeats about once a second.

This type of alert is accompanied by a message stating a problem that needs your attention. Read the message to see what action needs to be taken. For specific help, press the help button on the screen.

Follow the instructions on page 5-5.

Siren with respond message



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 alert or hear the siren alert.



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.




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 get a treatment

After getting a treatment, you may feel wetness on your back, sides, and chest. This is 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.



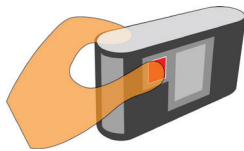
- 3 Call ZOLL and arrange to get a new belt.
Tap **OK** to resume normal monitoring.



- 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 page 5-5.

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 alert.
- If the alert 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.

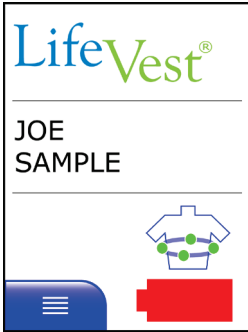
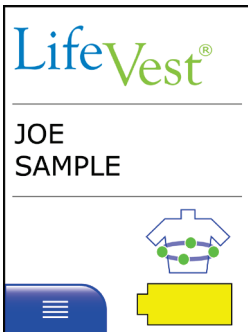
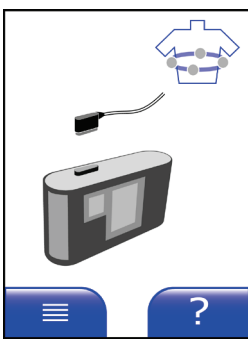
If you are not conscious, naturally you will not be able to press the response buttons.

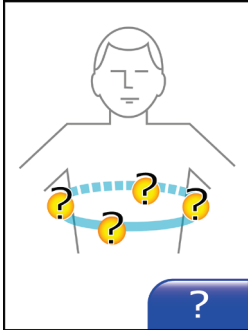
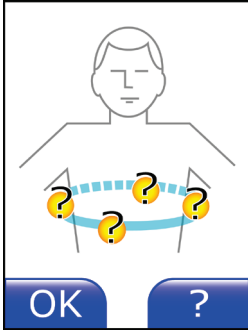

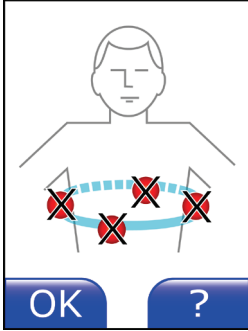

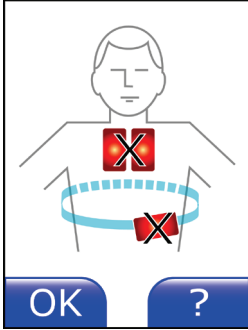
Voice prompts and messages alert bystanders to call for help.




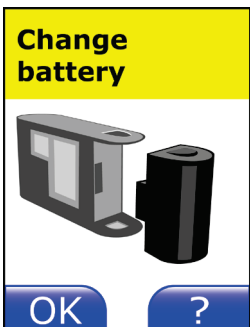
Gong alerts

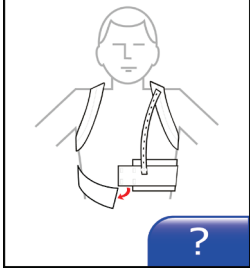
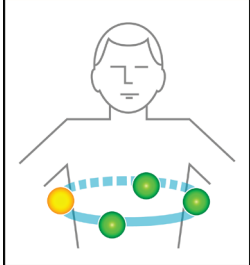

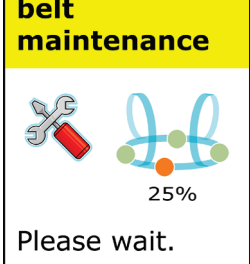
If you get a gong alert, there is a problem that needs your attention.


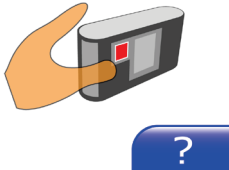
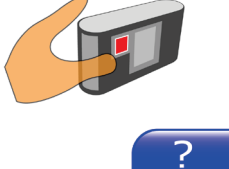

- Read the message on the monitor's display.
- For specific help with any message, tap the help button .
- Use this chart to see what the message means and what to do.

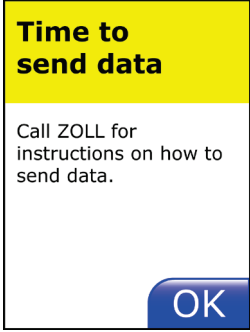

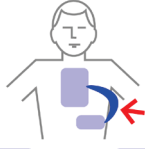
Message	What it means	What to do
 <p>The screenshot shows the LifeVest logo at the top, followed by the name 'JOE SAMPLE'. Below the name is a small icon of a vest with electrodes. At the bottom right, there is a red battery icon. A blue help button with a question mark is visible in the bottom right corner of the screen.</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>The screenshot shows the LifeVest logo at the top, followed by the name 'JOE SAMPLE'. Below the name is a small icon of a vest with electrodes. At the bottom right, there is a yellow battery icon. A blue help button with a question mark is visible in the bottom left corner of the screen.</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>
 <p>The screenshot shows a monitor with a disconnected electrode belt. The belt is shown as a separate component with a cable, not attached to the monitor. A blue help button with a question mark is visible in the bottom right corner of the screen.</p>	<p>Electrode belt is not connected to monitor.</p>	<p>Connect the electrode belt to the monitor.</p>

Message	What it means	What to do
	<p>Monitor is not receiving a signal from the electrode belt.</p> <p>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.</p> <p>For more details about this message, see page 5-12.</p>
	<p>Monitor is receiving a poor signal or no signal from the electrode belt.</p> <p>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.</p> <p>Pay particular attention to the electrode icons that show yellow or red on screen.</p> <p>Tap OK to return to normal operation.</p> <p>For more details about this message, see page 5-11.</p>
	<p>Monitor is not receiving a clear signal from the electrode belt. Electrodes are probably not in good contact with skin.</p> <p>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.</p> <p>Pay particular attention to the electrode icons that are yellow or red.</p> <p>Tap OK to return to normal operation.</p> <p>For more details about this message, see page 5-11.</p>
	<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 5-14.</p>

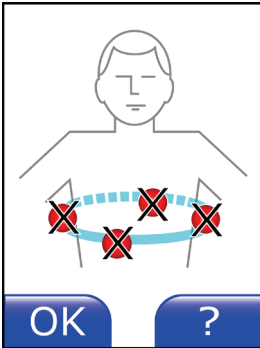
Message	What it means	What to do
 <p>Add gel to therapy pads</p>	<p>You have received a treatment and the gel is drying out.</p>	<p>Add gel to the therapy pads or replace electrode belt. Tap OK to return to normal operation. See details on page 5-17.</p>
 <p>Call for service</p> <p>Device has a problem that may require service. Call ZOLL for service.</p> <p>101</p> <p>OK</p>	<p>System has a problem that requires servicing. You can continue to use the device. Note the code beginning with the number 1.</p>	<p>Write down code number and call ZOLL. Tap OK to return to normal operation.</p>
 <p>Call for service</p> <p>Device has a problem and cannot be used. Call ZOLL immediately for service.</p> <p>201</p>	<p>System has a more severe service problem. You CANNOT use the device. Note the code beginning with the number 2.</p>	<p>Write down the code number and call ZOLL immediately.</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. Tap OK to return to normal operation.</p>

Message	What it means	What to do
<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 5-13.</p>
<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. Leave the electrode belt connected; change and recharge the battery as normal until you receive a replacement belt. Follow instructions about what to do after receiving a treatment on page 5-3. Tap OK to return to normal operation.</p>
<p>Performing belt maintenance</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>

Message	What it means	What to do
<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 alert sounds.</p>
<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, remove the battery from the monitor. If you are wearing the LifeVest, make sure the electrode belt is firmly connected. If you continue to get this message with the belt connected, call ZOLL.</p>

Message	What it means	What to do
 <p>Time to send data</p> <p>Call ZOLL for instructions on how to send data.</p> <p>OK</p>	<p>Data should be sent manually as soon as possible.</p> <p>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.</p> <p>Tap OK to return to normal operation.</p> <p>See details in section 3.</p>
 <p>Too much gel. Clean skin.</p>  <p>OK ?</p>	<p>Too much gel is on your skin.</p>	<p>Leave the gel that is under the therapy pads, but wipe the gel from the skin that is not under the therapy pads.</p> <p>Tap OK to return to normal operation.</p> <p>See details on page 5-19.</p>

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 5-12.

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.



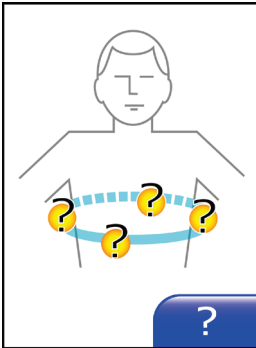
Good signal: Situation normal, no action required.

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, 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.

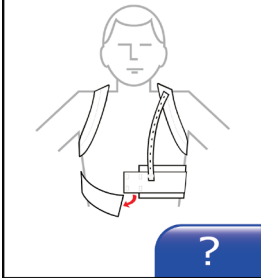
If you get this message and you're conscious

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

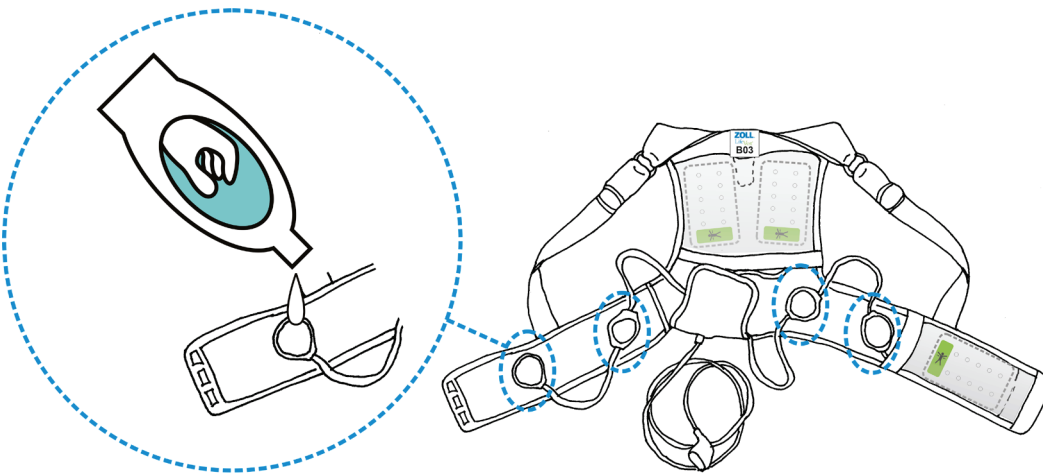
Check belt



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).

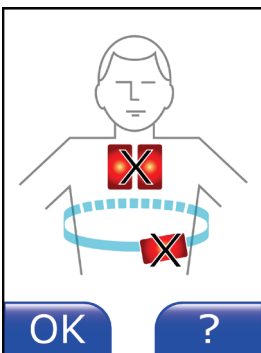


- 4 Put the garment on and connect the electrode belt to the monitor.

While you're wearing the LifeVest, 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.

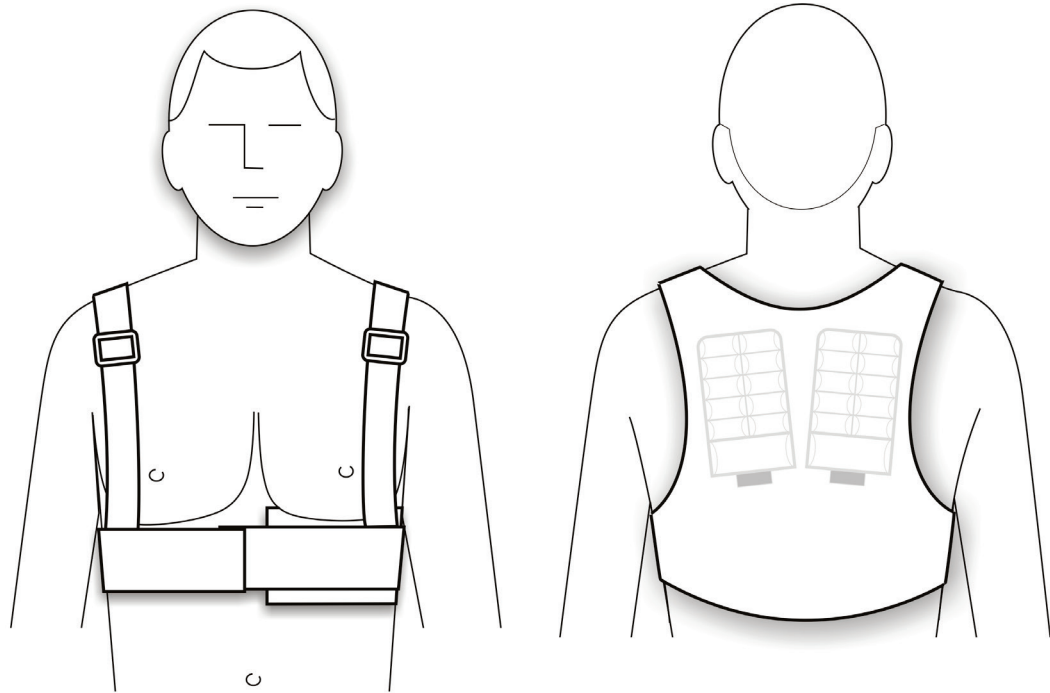
If you get red symbols, make sure:

- Therapy pads and mesh pockets are pressing against your skin. For details, see page 5-15.
- Therapy pads are inserted correctly into their pockets, with the metal sides (with the green stickers) facing the metal mesh. For details, see page 5-16.
- Garment and belt fits snugly, with the metal mesh of the therapy pads pressing against your skin.

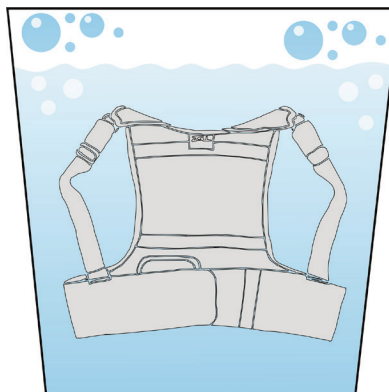
While you're wearing the LifeVest, tap the help button  for reminders about what to do.

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 metal mesh pockets and the therapy pads are pressing against your bare skin. For details about putting on the garment and electrode belt, see section 4.



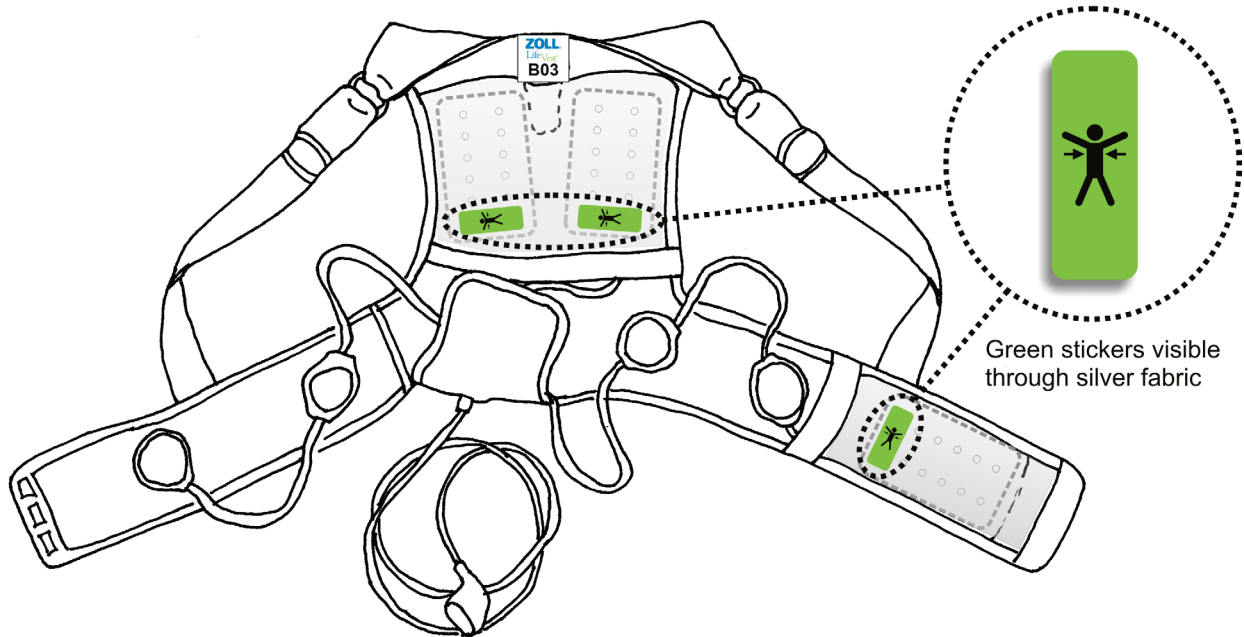
- 3 To help prevent stretching, launder the garment every 1 or 2 days. Follow the instructions for how to launder the garment in section 4.



- 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, their metal sides (with green stickers) facing the metal mesh, 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 gel



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

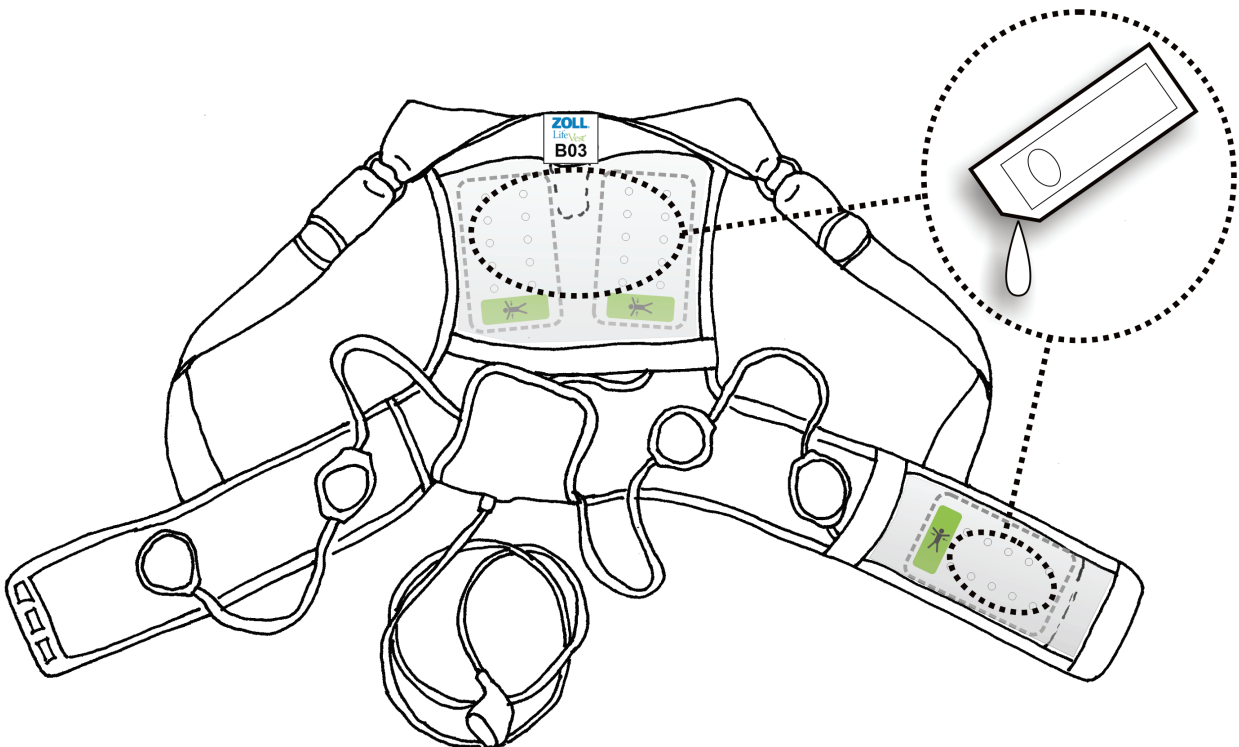
Follow the instructions below to add gel.

While you're wearing the LifeVest, 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 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, 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 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, 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. These options are the health survey and walk test. 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 walk test, you will not be able to access these options.

Your prescriber ordered the LifeVest to protect you because you are at risk of sudden cardiac arrest. With the activities options, the LifeVest 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 **walk test** 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 to gather information about your condition.

How does it work?

The purpose of the health survey is to have the LifeVest 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 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 will remind you when you are scheduled to take the health survey.

What do I have to do?

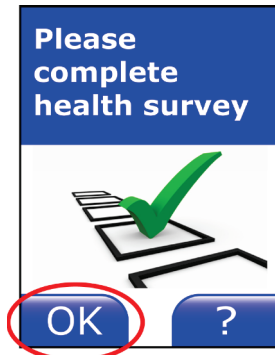
You need to answer the health survey questions honestly.

It is important that you wear the LifeVest 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.

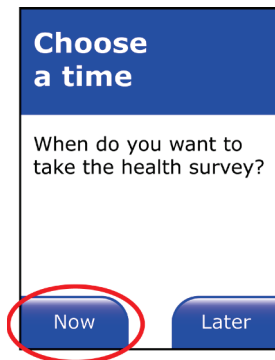
How to know if you are to take the health survey



- 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.

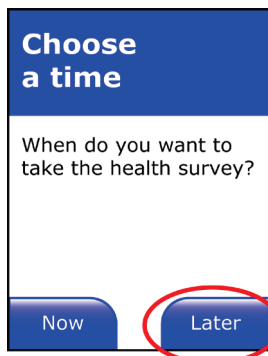
Tap **OK**.



- 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 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.

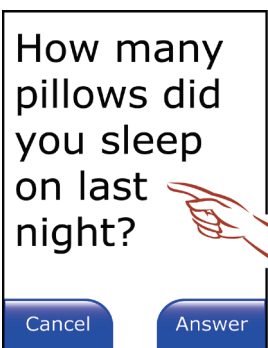
Answering the health survey questions

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

The LifeVest steps you through the process. As you are taking the health survey, the LifeVest 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.



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

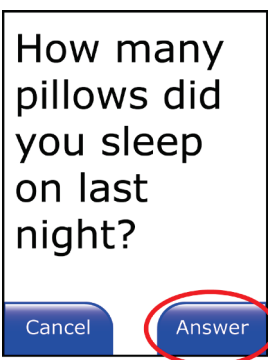
The question shown here is just an example. Your screen may show a different question.

Read the first question.

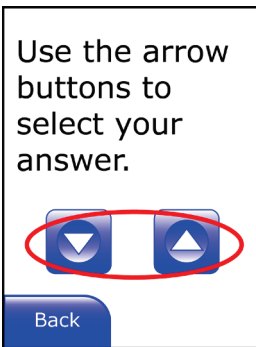
If you want to hear the question spoken to you, tap the screen in the question area.



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 3-16.

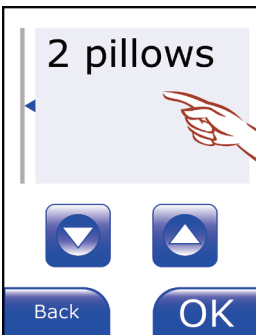
Note: If you want to cancel taking the health survey at any time, tap **Cancel**.



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

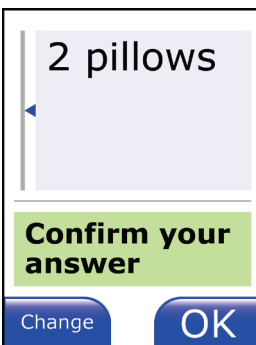


3 Use the  and  buttons to scroll through the answers.



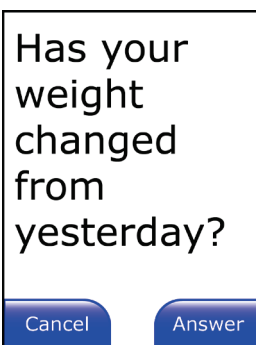
4 Choose an answer.

- 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**.

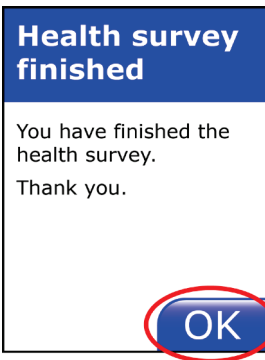


5 Confirm your answer.

- 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.

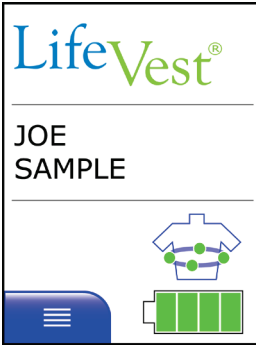


- 7 When you get this message, you have finished the health survey.
Tap **OK**.

Taking the health survey later

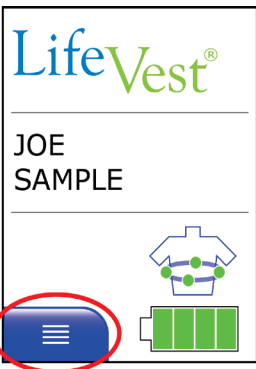
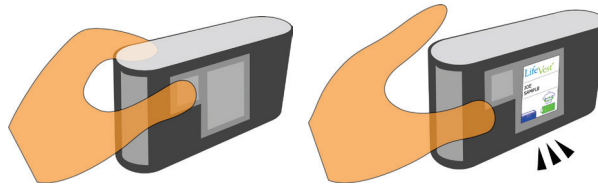
Follow this procedure if you chose “later” when you got the message telling you to complete the health survey.

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.

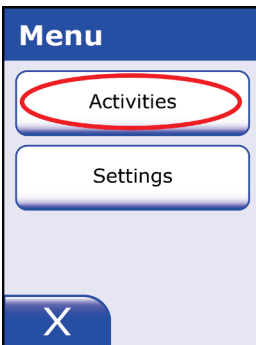


- 1 During normal monitoring, the LifeVest screen should look like the one at left.

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



- 2 Tap the menu button .

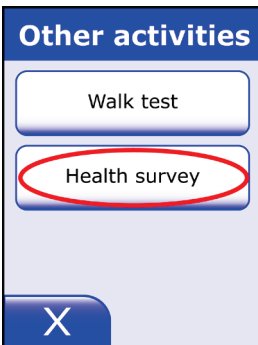


- 3 Tap **Activities**.



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**.

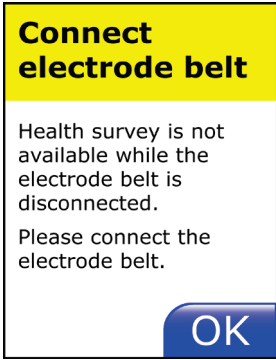
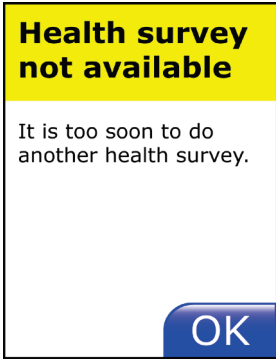

You're now ready to take the health survey.

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 alerts*.

Message	What it means	What to do
 <p>Connect electrode belt</p> <p>Health survey is not available while the electrode belt is disconnected. 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 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>

Walk test option

Your physician prescriber may order the walk test as one of the ways to use the LifeVest to gather information about your condition.

How does it work?

The purpose of the walk test is to walk for 6 minutes while the LifeVest monitors your heart and counts your steps.

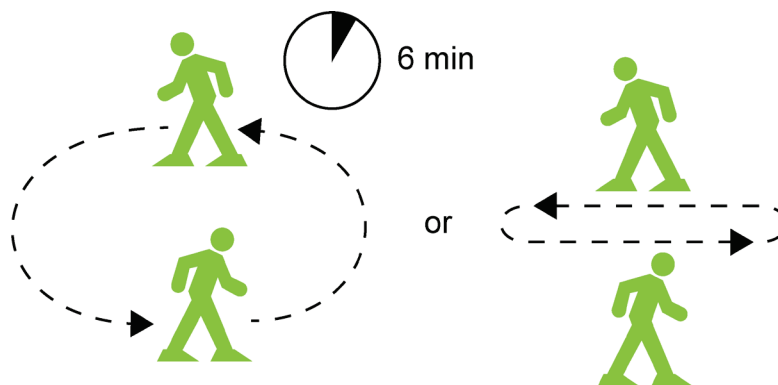
Before and after the walk, you'll be asked two questions. One about your shortness of breath level, another about your fatigue level (how tired you feel). After the walk, you'll answer the same two questions again. You'll look at the screen for the possible answers and pick the one that most closely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

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

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

What do I have to do?

Try to walk at a pace you feel you can comfortably maintain for 6 minutes. You can walk in a circle or oval, such as walking a track. You can walk in a square or rectangle, such as walking around a room. You can also walk in a straight line, turning as you reach the ends, such as walking back and forth in a hallway or narrow room.



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

While you are walking, the LifeVest will give you audible prompts about how much longer you are to walk. It will also tell you when to stop walking.

It is also important that you only walk for 6 minutes as part of this walk test. Listen for the voice prompt that tells you to “stop walking” after 6 minutes. When you hear this voice prompt, please stop walking.

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

Why is it important that I do the walk test?

Your physician prescriber may use the information from the walk test to help evaluate your condition.

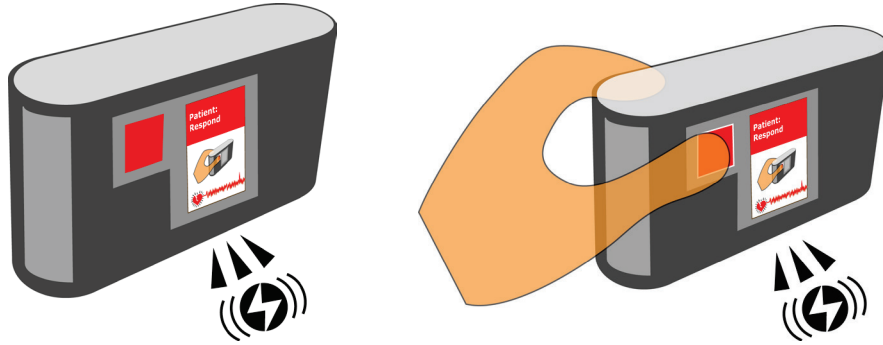
It is very important that you indicate the true state of your condition when you answer the questions. Your physician prescriber may review your answers and use this information to help evaluate your condition.

Warnings specific to the walk test



WARNINGS

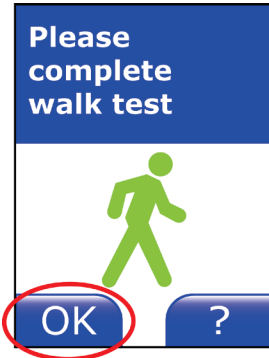
If you get the siren alert, stop walking and press the response buttons.



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

When performing the walk test, do not continue walking if you experience symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop walking and sit or lie down. If the symptoms continue or get worse, immediately call your doctor or emergency help. If you continue walking 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 the walk test

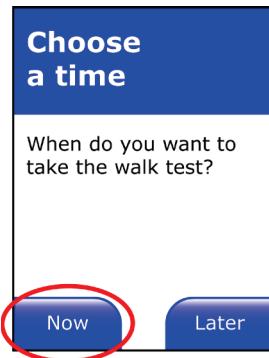


- 1 If you get this message when you change your battery, your physician prescriber has asked that you perform a walk test.

Throughout the walk test procedure, you must wear the LifeVest, with it connected normally.

If you have any questions, please contact your physician.

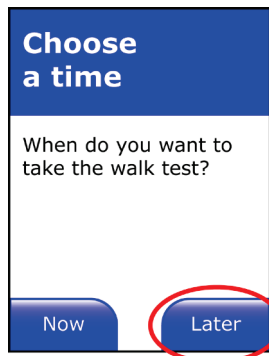
Tap **OK**.



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

You will be taken to the screens for taking the walk test.

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



If you want to take the walk test later, tap **Later**.

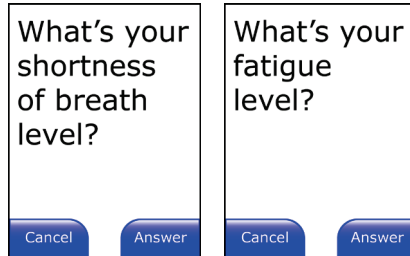
This screen goes away and the LifeVest continues with normal operation.

You will be reminded to take the walk test in about 15 minutes.

If you want to take the walk test at any other time, see page 6-23.

Answering the pre-walk questions

Before you take the walk test, 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 walk, you'll answer the same two questions again.

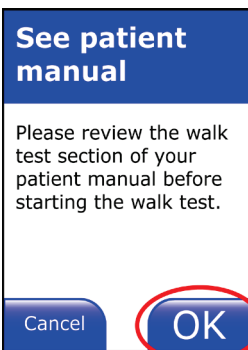


The questions will appear on the LifeVest monitor screen. With each question, choose the answer that best describes how you feel.

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

If you get a message while taking the walk test, follow the instructions on the screen. For more information, see page 6-25.

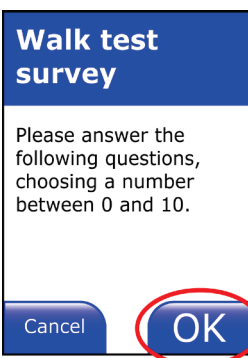
When you're ready to answer the questions, follow this procedure.



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

This screen reminds you to review the walk test section of the patient manual before taking the walk test.

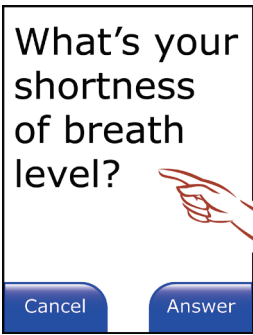
After reviewing the patient manual, tap **OK**.



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

Tap **OK** to continue.

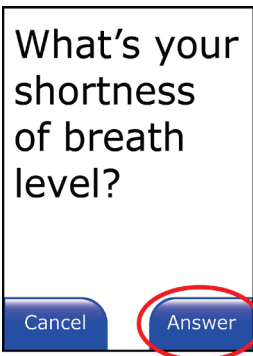
Note: If you want to cancel taking the walk test at any time, tap **Cancel**.



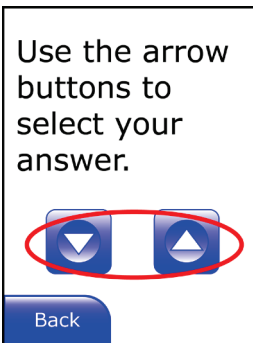
3 Read the question.



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

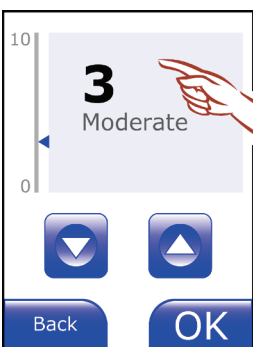
Note: You can change the speak option so you hear each question screen as soon as it appears, without taping the screen. You can also change the speak volume. For the details about changing the speak settings, see *Speak options* on page 3-16.



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



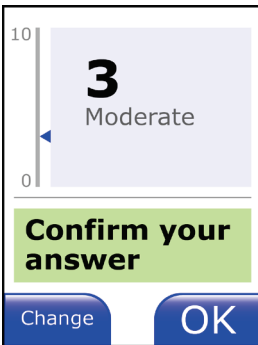
5 Use the  and  buttons to scroll through the answers.



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**.

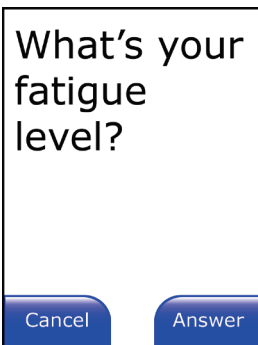
Answer scale	
0	Nothing at all
0.5	Very, very slight
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	
10	Very, very severe



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 may tell you not to take the walk test based on your answers to the pre-walk questions.

After answering the two questions, continue with the walking portion of the walk test. See page 6-17.

Taking the walking portion of the walk test

After answering the two questions, you're ready to do the actual walking portion of the walk test.

You will walk for 6 minutes while wearing the LifeVest. You should be as comfortable as possible while walking. Wear comfortable shoes. Walk on a flat, level surface, preferably a hard surface. Walk in a clear, unobstructed area so that you will not be prevented from walking normally. Do not walk on a treadmill. If your physician prescriber asks you to do multiple walk tests, doing the walk in the same location will give the most accurate results.

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

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

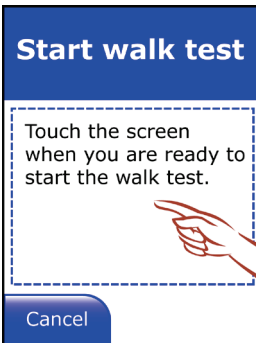
Be aware that the LifeVest will be giving you voice prompts throughout the walk test, so you may prefer to do the walk test in a private location. So that you can hear the voice prompts, do not listen to music, talk on the phone, or engage in any other activity that might distract you while doing the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

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

During the walk, 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 walk test.

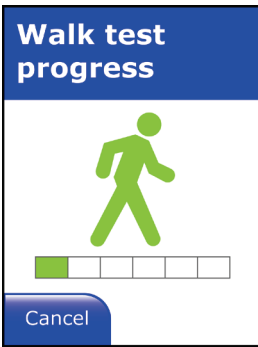
When you are ready to take the walk test, follow this procedure.



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

Stand up and get ready to start walking.

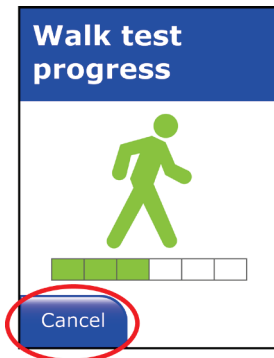
When you are ready to start walking, tap the screen where indicated.



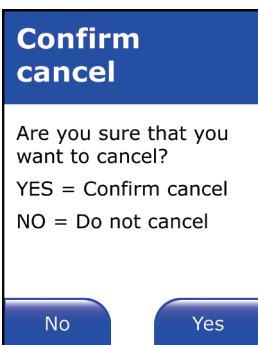
- 2 You will get a voice prompt to start the walk test.
- Begin walking.
- Continue walking for 6 minutes.



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



- 4 If you need to cancel the walk test, tap the **Cancel** button.



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

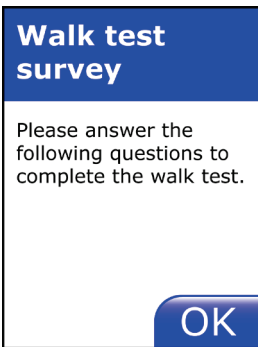
- If you do indeed want to cancel the walk test, tap **Yes**.
- If you do not want to cancel, and you want to return and complete the walk test, tap **No**. Choose this option if you are resting and plan to resume the walk.



- 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 walking, the walk test has ended and you can stop walking.

Tap **OK**.



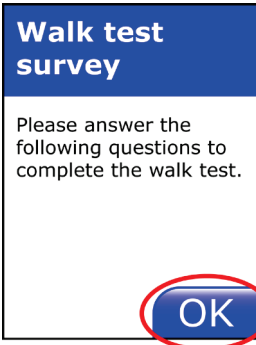
- 6 Proceed to answer the two questions again.

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

See page 6-20.

Answering the post-walk questions

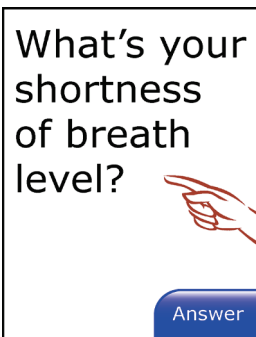
You will be asked two questions after the walk test. The questions will appear on the LifeVest. With each question, choose the answer that best describes how you feel.



- 1 You'll see this screen after the walking portion of the walk test. This screen reminds you that you will be asked two questions after taking the walk test.

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

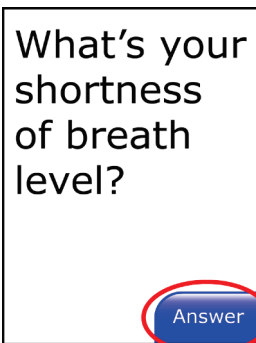
Tap **OK**.



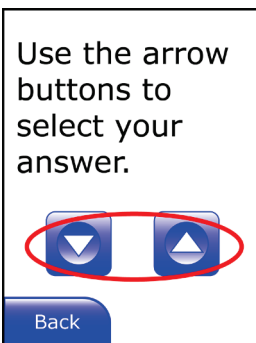
- 2 Read the question.


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

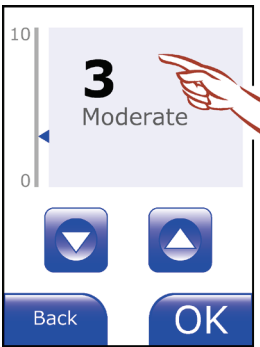
Note: You can change the speak option so you hear each question screen as soon as it appears, without taping the screen. You can also change the speak volume. For the details about changing the speak settings, see *Speak options* on page 3-16.



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



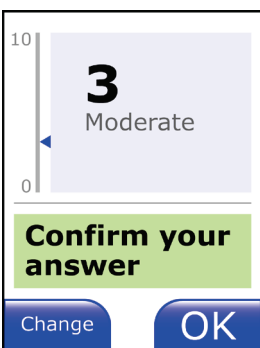
- 4 Use the  and  buttons to scroll through the answers.



5 Choose an answer.

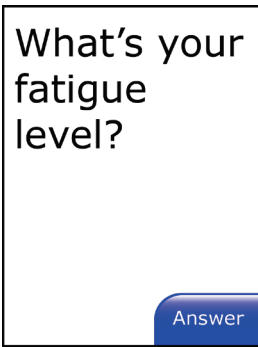
- To hear an answer spoken, tap the screen in the answer area.
- You can select an answer from zero through 10, according to the answer scale below.
- Select the answer that most closely describes how you feel.
- When your desired answer is shown, tap **OK**.
- If you need to see the question again,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

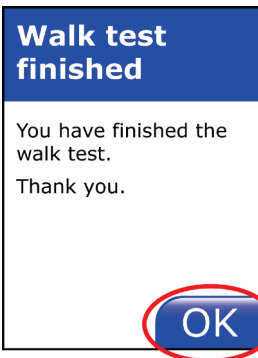


6 Confirm your answer.

- 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 walk test.

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 take the walk test.

After completing the walk test, sit down and rest before resuming your normal activities.

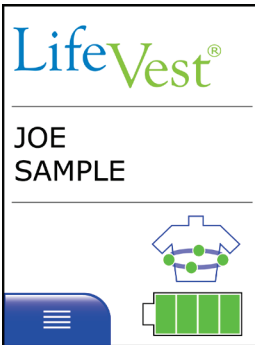
If you have any questions about these instructions, call ZOLL.

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

Taking the walk test later

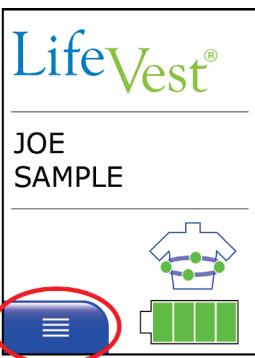
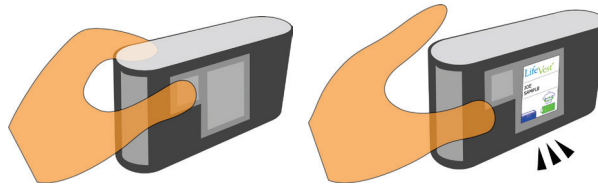
Follow this procedure if you chose “later” when you got the message telling you to complete the walk test.

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

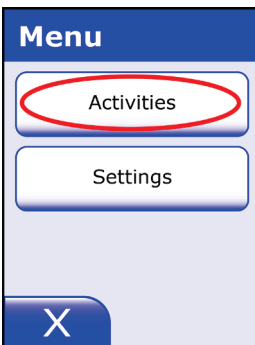


- 1 During normal monitoring, the LifeVest screen should look like the one at left.

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



- 2 Tap the menu button .

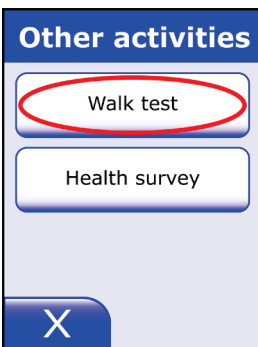


- 3 Tap **Activities**.



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**.

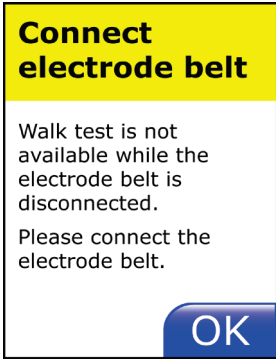
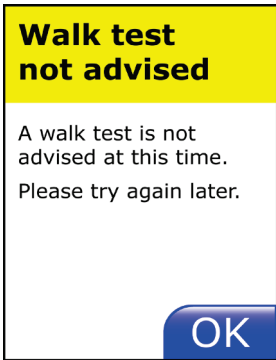
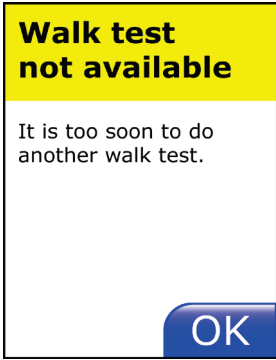
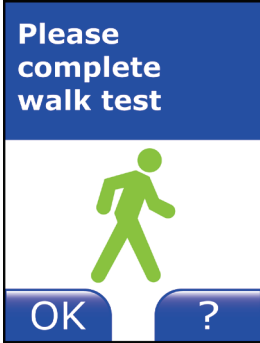
You're now ready to take the walk test.

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

Walk test messages

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

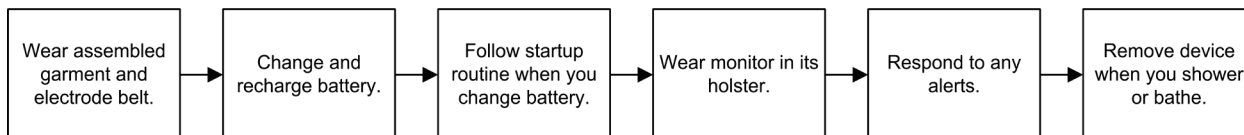
If you get any other messages, see *Section 5, Responding to alerts*.

Message	What it means	What to do
 <p>Connect electrode belt</p> <p>Walk test is not available while the electrode belt is disconnected. Please connect the electrode belt.</p> <p>OK</p>	<p>You are attempting to take the walk test with the electrode belt disconnected.</p> <p>The belt needs to be connected to take the walk test.</p>	<p>Wear the LifeVest 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 walk test.</p>
 <p>Walk test not advised</p> <p>A walk test is not advised at this time. Please try again later.</p> <p>OK</p>	<p>You are attempting to take the walk test and the LifeVest is advising you not to take the walk test 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 take the walk test 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>

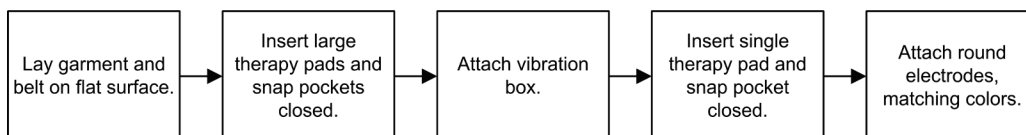
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Appendix A: Quick charts

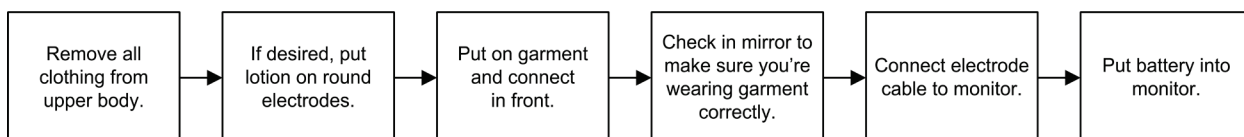
Daily routine



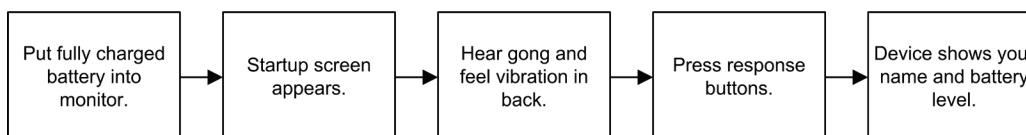
Assemble electrode belt and garment



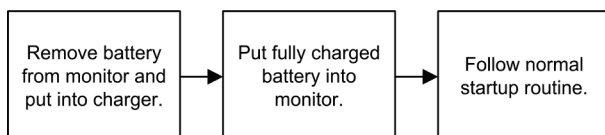
Put on LifeVest system



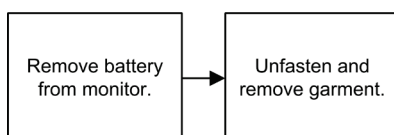
Normal startup routine



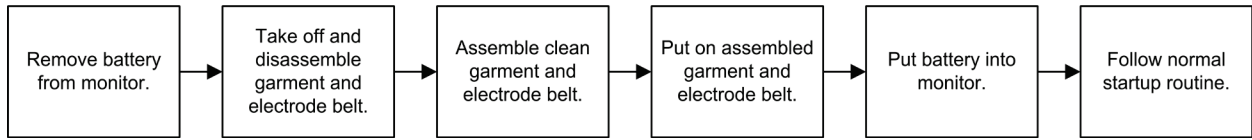
Recharge batteries daily



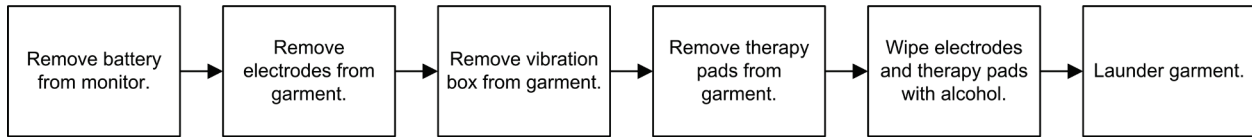
Remove LifeVest system before bathing or showering



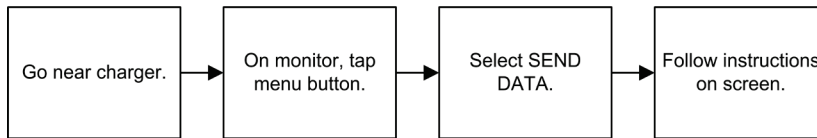
Change garment as needed



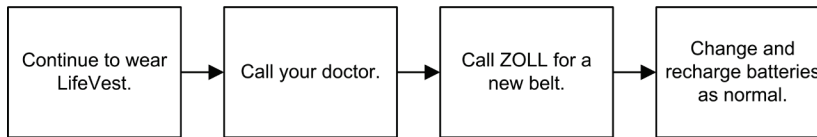
Disassemble electrode belt and garment



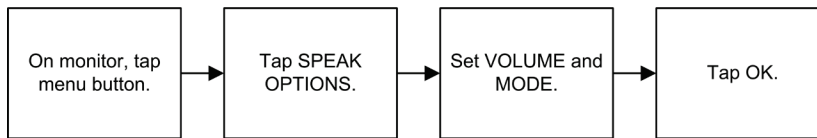
Manually send data to your doctor



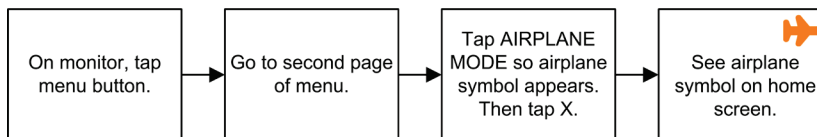
If you get a treatment



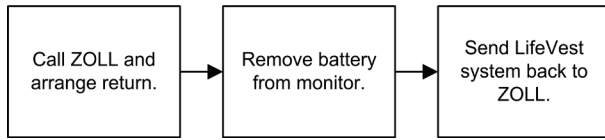
Change speak options



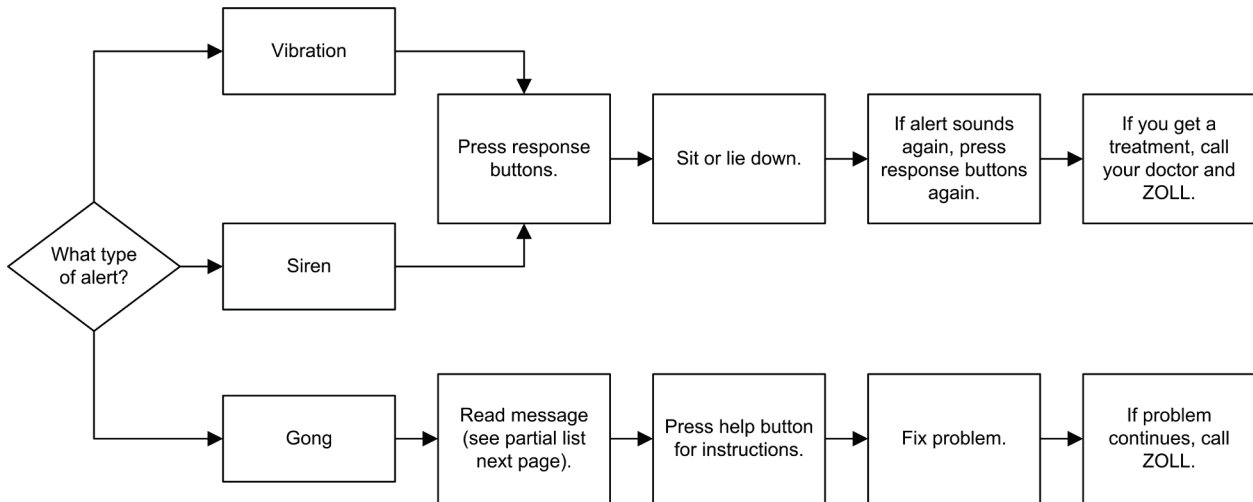
Airplane mode



When you're finished with device

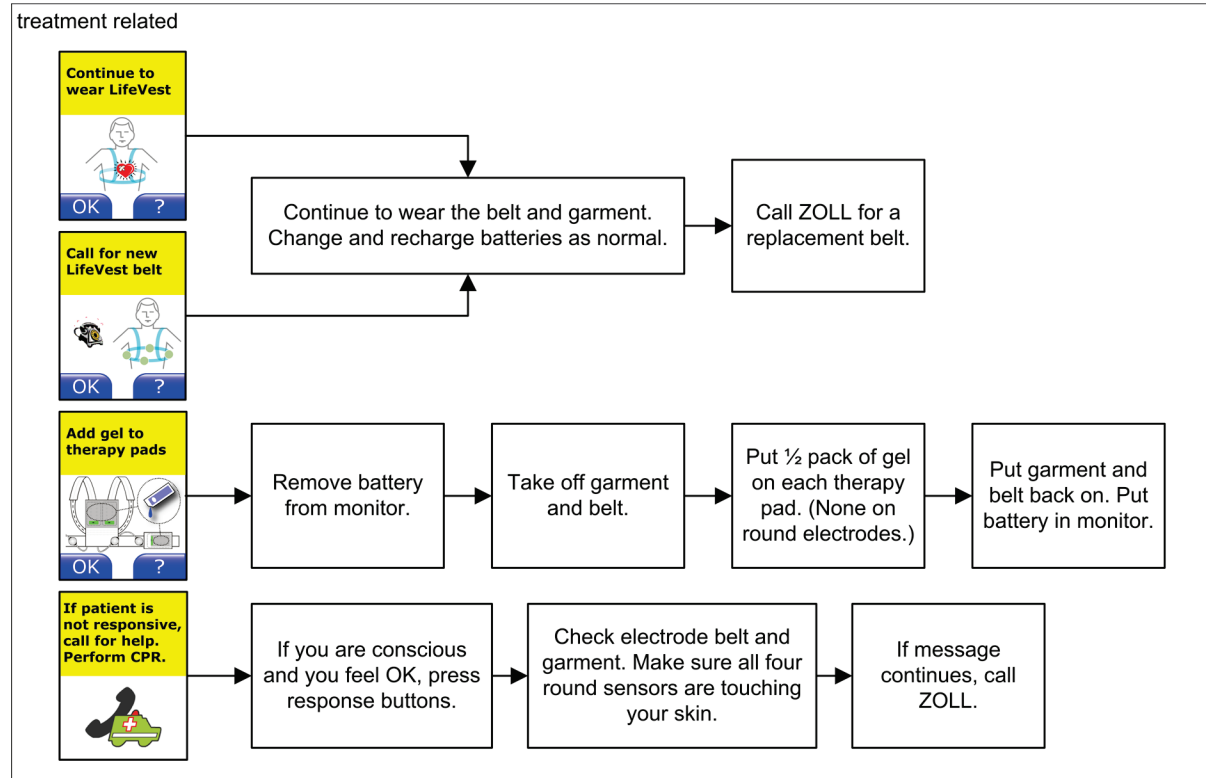
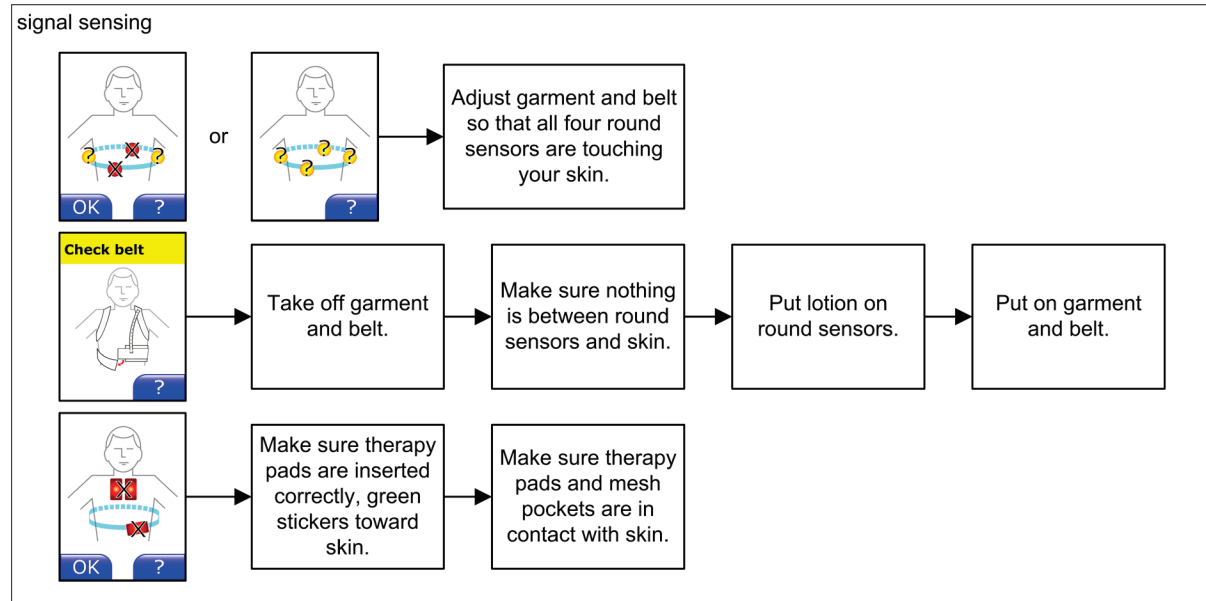


If you get an alert



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: Symbols

	Cell modem selected: Cellular modem is selected. LifeVest 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.
	Cell modem is not functioning.
	Bluetooth signal strength: Indicates signal strength from charger. Number of pie pieces indicates signal strength. Signal must be present in order to send data from monitor to charger.
	No Bluetooth signal: No data can be sent between monitor and charger.
	Battery level (on monitor): Number of bars indicates battery charge.
	Battery charging (on charger): 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.
	Battery problem: Battery has a problem and may need to be replaced. Call ZOLL.
	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 cannot determine battery condition. Call ZOLL for service. Tap for help.
	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.
	Charger problem: Charger has a problem and cannot be used. Call ZOLL immediately.
	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 is connected to a land line phone.
	Land line dialing mode with sound: Shows that LifeVest is connected to a land line phone and that sound will be heard when phone connection is attempted.
	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 is in monitoring mode. Situation normal, no action required.

	<p>Standby mode: Animated to show that LifeVest is in standby, not monitoring. Connect belt to monitor so that LifeVest can resume normal monitoring mode.</p>
	<p>Recording: LifeVest is recording your ECG signal (manually activated).</p>
	<p>Service required: Device has a problem and requires service. Call ZOLL.</p>
	<p>Battery: Do not incinerate.</p>
	<p>Battery: Do not short circuit.</p>
	<p>CE marking, indicates conformance with European Medical Device Directive.</p>
	<p>Laundering symbol: Normal cycle in warm water.</p>
	<p>Laundering symbol: Tumble dry warm.</p>
	<p>Laundering symbol: Only non-chlorine bleach, when needed.</p>
	<p>Laundering symbol: Iron on low temperature.</p>
	<p>Laundering symbol: No anti-static spray.</p>
	<p>Laundering symbol: No fabric softener.</p>



Manufacturing date.



Manufacturing location.



Expiration date.



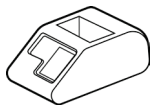
Monitor connector: Type BF defibrillator-proof connector.



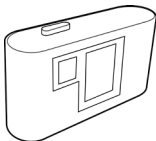
Monitor connector: Type BF non defibrillator-proof connector.



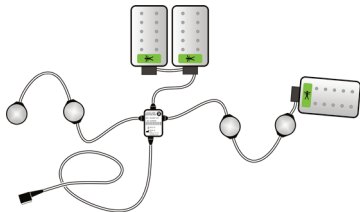
Packaging: Battery



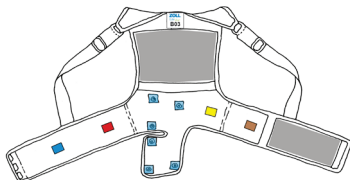
Packaging: Charger.



Packaging: Monitor.



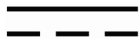
Packaging: Electrode belt.



Packaging: Garment.



Power supply electrical information: Alternating current (AC).



Power supply electrical information: Direct current (DC).



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



Caution: Read and follow the caution text next to this symbol. If on a product, consult accompanying documents.

	Symbol: See instructions for use.
	Symbol: Automated external defibrillator.
	Symbol: Dangerous voltage. Surface could become hazardous for bystanders to touch when the device is in use.
	Symbol for catalog number, accompanied by number.
	Symbol for serial number, accompanied by serial number.
	Symbol for lot number, accompanied by lot number.
	Symbol for EC representative next to name and address of authorized EC rep.
	Symbol for keep dry.
	Symbol for keep away from sunlight.
	Symbol for do not use if package is damaged.
	Symbol for temperature limitation. Upper and lower limits of temperature are indicated next to the horizontal lines.
	Symbol for emits RF energy.
	Symbol for magnetic resonance (MR) unsafe.

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Appendix D: Software licensing statement

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