



Wearable Cardioverter Defibrillator Model 5100

Patient Manual



Contact toll free (USA and Canada): 1-800-543-3267

WEAR

THE FOUR MOST IMPORTANT THINGS FOR YOU TO KNOW

- Wear the assembled electrode belt and garment with the monitor connected.
- Every 24 hours, change and recharge the battery.
- Act quickly for SIREN alerts. Press the response buttons.
- Read the display for GONG alerts and follow the instructions on the screen.

For more information, see the LifeVest WCD 5100 Patient Manual.

Wearing the LifeVest WCD

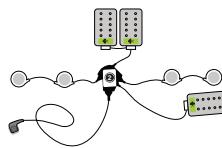
Gathering components



Monitor + Holster



Garment



Electrode Belt



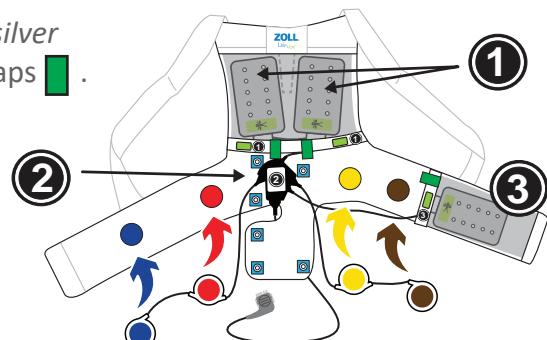
Battery



Charger

Assembling the electrode belt to the garment

- 1 Lay the garment on a flat, solid surface with the colored hook and loop fasteners, snaps, and the silver fabric facing up.
- 2 Lay the electrode belt with the silver sides of the therapy pads facing up.
- 3 Insert the rear therapy pads into the silver pockets with *silver facing silver* at ①. Secure the pockets by closing the snaps ④.
- 4 Place the vibration box ② on the garment position labeled with ②. Place the flap over the vibration box and secure the snaps ⑤.
- 5 Insert the front therapy pad into the front silver pocket with *silver facing silver* at ③. Secure the pockets by closing the snaps ⑥.
- 6 Match and attach colored hook and loop fasteners ⑦ ⑧ ⑨ ⑩ on round electrodes to the garment.



Wearing the garment assembly on your bare skin

- 1 Before putting on the garment, remove all clothing and undergarments.
- 2 Put on the garment and secure the garment by connecting the garment ends together in the front.
- 3 Make sure:
 - Round electrodes touch your skin.
 - Nothing is between the round electrodes and your skin.
 - Garment fits snugly.

See the LifeVest WCD 5100 Patient Manual for more information.



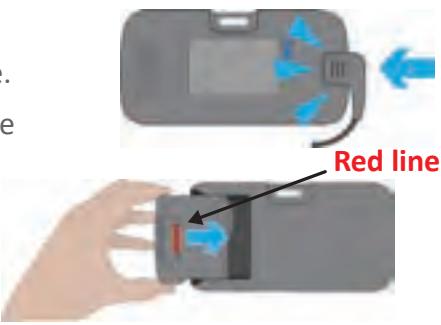
Questions? Call ZOLL 24 hours a day at 1-800-543-3267

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Starting the monitor

- 1 Gently connect the electrode belt to the monitor until it locks in place.
- 2 Push a fully charged battery into the monitor until it locks in place. The battery is firmly in place when you hear a click sound and the **red line** on the battery is **not** visible.

The startup screen displays followed by the “Press response buttons” voice prompt.



Changing and recharging the battery every 24 hours

- 1 Plug the power supply into the charger then into a standard power outlet. The blue light **●** on the charger turns on.
- 2 Insert the second battery into the charger and push the battery in firmly. The battery is firmly in place when you hear a click sound and the **red line** is **not** visible on the battery.
- 3 Look at the battery status on the charger. Battery should be charging or charged **■**.



Respond to any alerts

There are three types of alerts:

Vibration



A vibration is felt on your back on startup or to warn you that you are about to receive a siren alert.

Your Action: Press and release the response buttons to stop this alert.

Siren



The siren is a high-pitched two-tone sound that occurs when an abnormal heart rhythm is detected.

Your Action: Quickly press and release the response buttons to delay the treatment. You will receive a treatment if you do not respond.

Gong



The gong is a low-pitched repeating sound that alerts you to an issue on the monitor screen that requires your attention.

Your Action: Read the monitor screen to see what action you need to take.

Monitor indicator lights

Light located on the top of the monitor.

Normal operation.
Green light fades in and out.

Look at monitor screen for instruction. Blinking yellow light.

Immediate attention.
Look at monitor screen for instruction. Blinking red light.



For the Indications for Use statement and a complete list of warnings, refer to the LifeVest WCD 5100 Patient Manual.

If you have any questions, contact ZOLL LifeVest.

24 hours a day, 7 days a week: Toll free (USA) 1-800-543-3267

ZOLL **LifeVest**[®]

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Restricted distribution and use

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

Effectivity

This manual applies to the LifeVest wearable cardioverter defibrillator 5100 system.

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Patent

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Manuals for physician reference

Field Manual 20B0099 Rev C; Clinical Manual 20B0098 Rev D

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About this manual

This manual:

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

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1: Meet the LifeVest® WCD system

This section provides general information about the LifeVest WCD system including:

- Introduction to the LifeVest WCD system components
- Essential performance
- Indications for use
- Contraindications
- Intended use locations
- Safety information, such as warnings and cautions
- Information for non-patient/bystander
- Known residual risks
- Environmental considerations related to noise and vibration
- Electromagnetic interference
- Wireless interference
- Operator profiles

1: Meet the LifeVest® wearable cardioverter defibrillator system

The LifeVest wearable cardioverter defibrillator (WCD) is worn by a patient at risk for sudden cardiac arrest and who is not a candidate for or refuses an implantable defibrillator. It is lightweight and easy to wear, allowing patients to return to their activities of daily living.

The LifeVest WCD monitors the patient's heart continuously. If the patient goes into a life-threatening, rapid heart rhythm, the LifeVest WCD delivers a defibrillating treatment in an attempt to restore the patient's heart to normal rhythm. The treatment is automatic and does not require bystanders to help.

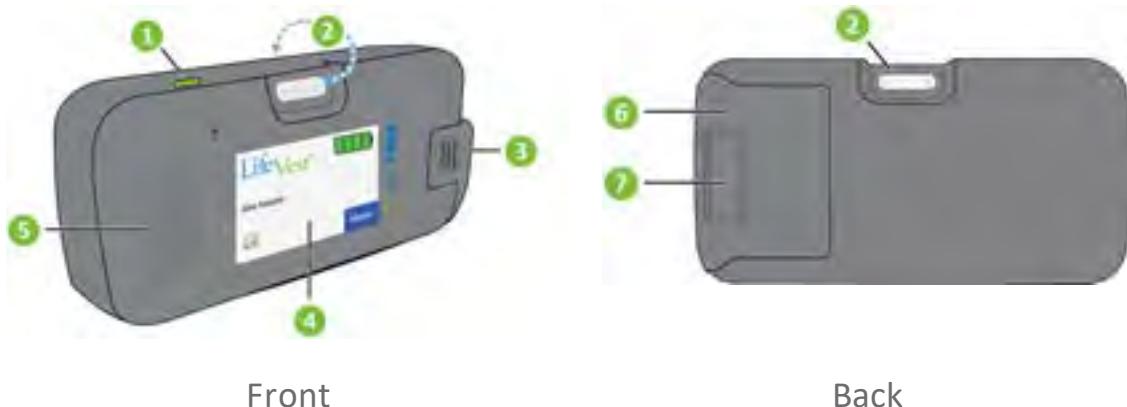
The LifeVest WCD does not treat all types of abnormal heart rhythms.

See "Safety information" on page 1-10 for general warnings and cautions.

LifeVest® WCD system components



Item	Description
1 Monitor	The main unit of LifeVest WCD system. The monitor connects to the electrode belt for the purposes of monitoring your heart rhythm and delivering defibrillating treatment, if needed. In the image, the electrode belt is shown connected, and the monitor is powered on. See “LifeVest® monitor” on page 1-3.
2 Garment and electrode belt	The assembled garment and electrode belt fits around your body and the electrode belt connects to the monitor. See “Garment and electrode belt” on page 1-5.
3 Holster	The holster allows you to carry the monitor. See “Placing the monitor in its holster” on page 3-33.
4 Charger and battery	The charger recharges the battery. The battery supplies power to the LifeVest WCD. In the image, a battery is shown in the charger. See “Charger and battery” on page 1-4.

LifeVest® monitor

Item	Description
1 Monitor status indicator light	Displays status of the monitor. See “Reading the monitor indicator light” on page 3-10.
2 Response buttons	Two buttons, located front and back. See “Using the LifeVest® WCD” on page 3-1.
3 Receptacle	The electrode belt connects to the monitor opening. See “Connecting the electrode belt to the monitor” on page 3-32.
4 Touchscreen	Displays messages about LifeVest WCD operation, and allows you to interact with the LifeVest WCD. See “Using the monitor screen” on page 3-12.
5 Speaker	Allows you to hear voice prompts and audible alerts.
6 Battery	Supplies power to the LifeVest WCD. See “Charging and changing batteries” on page 3-15.
7 Latch	Latch on the battery that helps insert and remove the battery.

Charger and battery

Note: The combination of the charger and power supply form a medical electrical system.

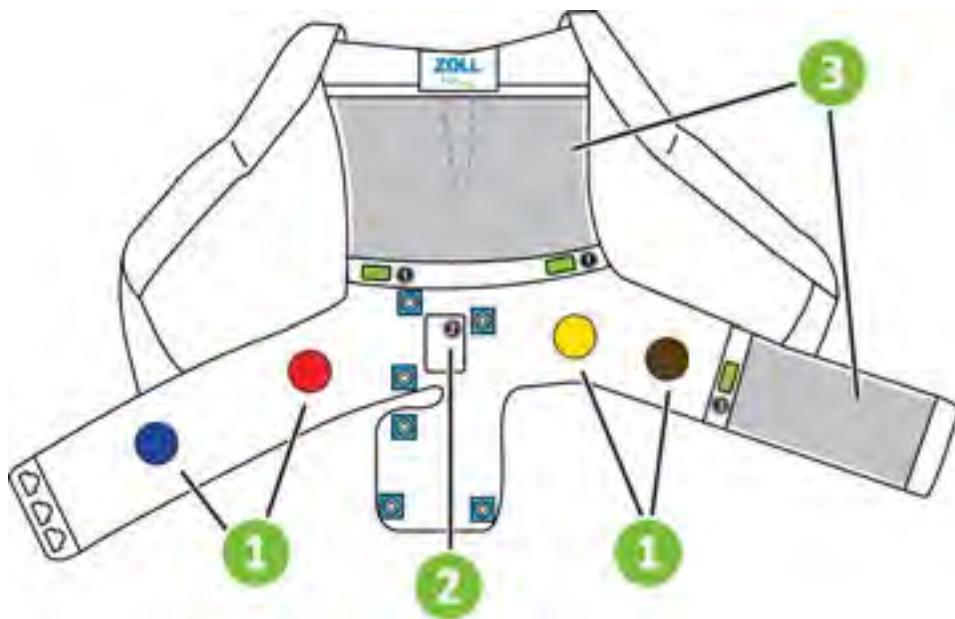


Item	Description
1 Battery	Supplies power to the LifeVest WCD. See “Charging and changing batteries” on page 3-15.
2 Charger base	Holds the battery for recharging. See “Charging and changing batteries” on page 3-15.
3 Indicator lights	Show the status of the charger and battery. See “Reading battery status icons on the monitor” on page 3-14.
4 Power supply	Plugs into a wall outlet to provide power to the charger. See “Charging and changing batteries” on page 3-15.

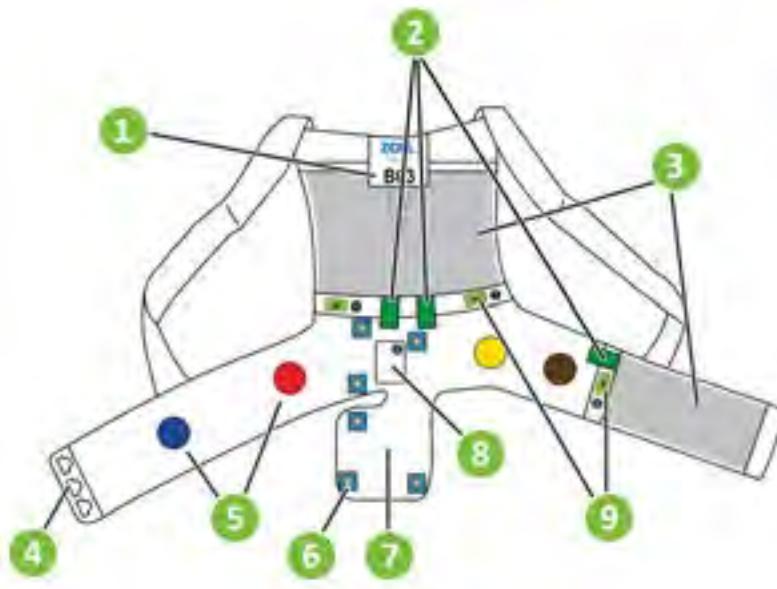
Garment and electrode belt

The garment is worn under your clothing to hold the electrode belt (which consists of the vibration box, round electrodes, and therapy pads) against your chest and back.

Garment

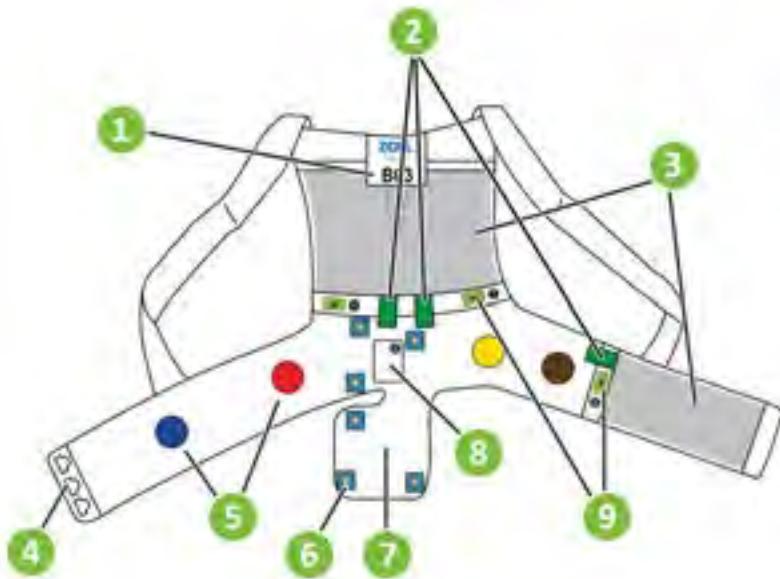


Item	Description
1 Colored hook and loop fasteners	Correspond to the colored fasteners on the electrode belt and are used to attach the electrode belt to the garment.
2 Vibration box position	The vibration box is placed in this area.
3 Silver fabric pockets	Therapy pads are inserted into the pockets in the back of the garment and on the right side when the garment is laying flat like the image above.

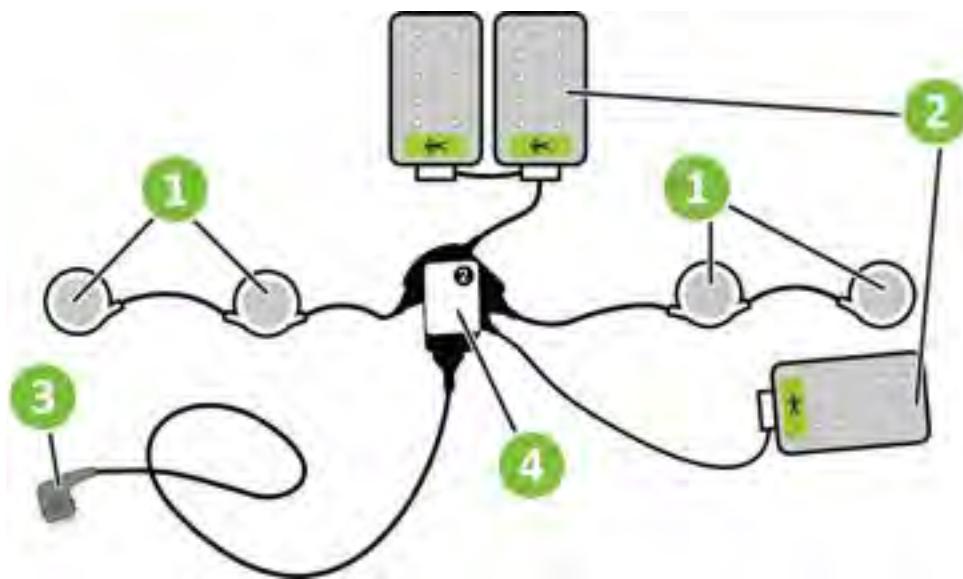
Garment detail

Item	Description
1 Size and care label	The size and care label shows the size of the garment, and symbols indicate how to care for the garment. For details about these symbols, see “Symbols glossary” on page A-1.
2 Therapy pads pocket snaps	Therapy pad pockets are snapped closed to secure the therapy pads in place.
3 Silver fabric pockets	Therapy pads are inserted into the pockets in the back of the garment and on the right side when the garment is laying flat like the image above.
4 Clasp	The front clasp keeps the garment securely in place on the body.
5 Colored hook and loop fasteners	The colored fasteners on the garment correspond to the colored fasteners on the electrode belt and are used to attach the electrode belt to the garment.
6 Vibration box flap snaps	The fabric flap is snapped closed to secure the vibration box in place.

Item	Description
7 Vibration box fabric flap	The fabric flap is folded over to secure the vibration box.
8 Vibration box position	The vibration box is placed in this area.
9 Therapy pad label	The therapy pads are placed in the pockets with the green labels.



Electrode belt



Item	Description
1 Round electrodes	Sense your heart's electrical signal for the monitor.
2 Therapy pads	Deliver a treatment to your heart. Blue™ gel disperses from the therapy pads before treatment is delivered. Additional Blue™ gel is provided in packets with the LifeVest WCD (not pictured).
3 Connector	Connects the electrode belt to the monitor.
4 Vibration box	Notifies you the LifeVest WCD is preparing to give a treatment. The vibration box also vibrates during the normal startup routine.

Essential performance

The essential performance of the LifeVest WCD is that it detects ventricular fibrillation or ventricular tachycardia, then delivers a defibrillating shock.

Indications for use

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

Contraindications

The LifeVest WCD is contraindicated for use on patients with an active implantable defibrillator.

Intended use locations

The LifeVest WCD is intended for users in a home, small clinic, hospital, and transport environment. Daily access to electrical power is required. Users should assess their changing environment to be sure they can hear alerts, see the screen, and access the LifeVest WCD. See “Environmental conditions” on page D-1 for specifications and details related to using the LifeVest WCD in these environments.

Safety information

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

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

General warnings and cautions are covered in this section. Component- and feature-specific warnings are in relevant sections throughout this manual.

Warnings warn you of possible serious injury or death that can be caused by misuse of the LifeVest WCD. This includes failures that could lead to you not being protected by the LifeVest WCD. Warning text is in a box with an orange border like the example below.



Warning text displays here.

Cautions advise you of possible minor injury that can be caused by misuse of the LifeVest WCD. Cautions also advise you of a problem with the LifeVest WCD. Such problems include damage to the LifeVest WCD or other property, or minor injury. Caution text is in a box with a yellow border like the example below.



Caution text displays here.

Before use

WARNING

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

Do not use the LifeVest WCD in the presence of flammable agents or in an oxygen enriched atmosphere. This could present an explosion and fire hazard, which may result in serious injury or death.

Tell your health care professional about all of your medical conditions and current treatments. Always wear the LifeVest WCD when instructed to do so by a health care professional. Inappropriate use of the LifeVest WCD may damage it and/or cause the system to malfunction, possibly resulting in serious injury or death. If you do not wear the LifeVest WCD, you are not protected, which may result in serious injury or death. Ask your health care professional to explain any parts that you do not understand.

Health care professionals should use appropriate caution when prescribing a LifeVest WCD to a patient who is dependent on a pacemaker. All patients who have pacemakers should be examined for proper pacemaker function after a treatment. Failure to examine a patient with a pacemaker may result in serious injury or death.

Some ventricular assist devices can be damaged or reprogrammed by external defibrillation. Therefore, patients wearing ventricular assist devices may not be suitable candidates for the LifeVest WCD as potential serious injury or death may occur.

 **WARNING**

If you do not hear the gong upon receiving the prompt to activate the LifeVest WCD, the LifeVest WCD may have malfunctioned. If you were to enter into a life-threatening arrhythmia, a system malfunction may result in serious injury or death. If you suspect the audio is not working properly on the LifeVest WCD, see “Troubleshooting issues with no screen message” on page 8-1 for details on a solution.

If the monitor indicator light is not blinking, the LifeVest WCD may have malfunctioned. If you were to enter into a life-threatening arrhythmia, a system malfunction may result in serious injury or death. If you suspect the monitor indicator light is not working properly on the LifeVest WCD, see “Troubleshooting issues with no screen message” on page 8-1 for details on a solution.

Receiving a treatment

 **WARNING**

If a treatment is delivered while your heart is beating normally, the treatment may cause an abnormal heart rhythm to occur. There is a small possibility that the abnormal heart rhythm may not be detected and may result in serious injury or death. If you get an alert sound and you are awake, press and release both response buttons to prevent receiving a treatment. If you fail to press and release both response buttons, you will get a treatment, which may result in serious injury or death.

Bystanders must not touch the patient while a treatment is being delivered. Anyone touching the patient during a treatment may be shocked, which may cause injury to the bystander.

 **WARNING**

CPR can be performed, but bystanders must not touch the patient while a treatment is being delivered. Anyone touching the patient during a treatment may be shocked, which may result in injury to the bystander. If external defibrillation is available, a decision can be made by a health care professional to remove the LifeVest WCD to treat the patient with external equipment. However, using an external defibrillator while the LifeVest WCD is worn could damage the LifeVest WCD, which may result in serious injury or death.

Receiving alerts

 **WARNING**

If you receive an alert sound and are awake, always press both response buttons to prevent receiving a treatment. If you fail to press both response buttons, you will get a treatment, which may result in serious injury or death.

Only the patient should press the response buttons. The patient's ability to press both response buttons lets the LifeVest WCD know whether or not the patient is conscious and is critical in deciding when to give the patient a treatment. If anyone other than the patient presses the response buttons, needed therapy may not be delivered, which may result in serious injury or death.

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 is disconnected from the monitor, or the garment is loosened, needed treatment may not be delivered, possibly resulting in serious injury or death.

Using the LifeVest® WCD

WARNING

Always operate the system within its environmental ranges. Operating the LifeVest WCD outside of these ranges may damage it and/or cause the system to malfunction, which may result in serious injury or death. See “Environmental conditions” on page D-1.

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

The electrode belt and holster strap may become entangled, which may result in serious injury. Be alert when wearing the LifeVest WCD and while using the holster with the strap.

Do not stack or place the LifeVest WCD next to other devices. Doing so could expose the LifeVest WCD to electromagnetic interference (EMI) disturbance that may cause the system to malfunction, which may result in serious injury or death.

Make sure the electrode belt is properly connected to the monitor. If the electrode belt is not properly connected, it may disconnect and you will not be protected, which may result in serious injury or death.

Make sure the battery is fully inserted and latched into the monitor. The red line on the battery should not be visible. If the battery is not fully inserted and latched, it may disconnect and you will not be protected, which may result in serious injury or death.

 **WARNING**

If the charger or power supply makes unusual noises, sparks, starts to smoke, or emits a burning smell, unplug it immediately from the wall outlet. The only way to completely remove power is by unplugging the AC power plug from the wall outlet. Place the charger so that the power plug is accessible in case you need to unplug it. If these precautions are not followed, serious injury or death may occur.

If you see Blue™ gel other than during a treatment, this may indicate a damaged electrode belt and may cause the system to malfunction, which may result in serious injury or death. Call ZOLL immediately at 1-800-543-3267. Inspect the LifeVest WCD for damage. See “Inspecting the LifeVest® WCD equipment” on page 2-2.

When you are performing a WalkTest® session, do not continue if the monitor broadcasts an alert sound. Stop and press and release both response buttons. If you continue, you may be at risk for a sudden cardiac arrest, which may result in serious injury or death.

When performing a WalkTest session, do not continue if you experience symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop and sit or lie down. If the symptoms continue or get worse, immediately call your health care professional or emergency help. If you continue or ignore the symptoms, you may be at risk for a sudden cardiac arrest or other health problems, which may result in serious injury or death.

Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 21.2 cm (8.35 inches) to any part of the LifeVest WCD, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result which may result in serious injury or death.

 **WARNING**

Ensure the electrode belt connector is aligned with the monitor receptacle before pushing it in. Do not force the connector. Forcing the connector may damage it. Inspect the LifeVest WCD for damage. See “Inspecting the LifeVest® WCD equipment” on page 2-2.

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

 **CAUTION**

If Blue gel gets into your eyes, flush your eyes immediately with water and contact your health care professional. Your eyes may become irritated from the Blue gel.

Caring for LifeVest® WCD components

 **WARNING**

Do not tamper with, alter, drop, or abuse any part of the system or labeling. Do not put fingers or foreign objects, such as paper clips or hair pins, into any connectors or openings. Altering the equipment in any way may damage it and/or cause the system to malfunction, which may result in serious injury or death. Changes or modifications to this device not authorized by ZOLL could void the radio frequency energy (RF) compliance and negate your authority to operate the device. Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.

Do not put the monitor, electrode belt, battery, or charger in or near water. Water entering a component may damage it and/or cause the system to malfunction, which may result in serious injury or death. Inspect the LifeVest WCD for damage. See “Inspecting the LifeVest® WCD equipment” on page 2-2.

⚠️ WARNING

Conductive parts of round electrodes and therapy pads and associated connectors should not contact other conductive parts including the earth. If this should occur, it could affect the ability of the LifeVest WCD to function properly, which may result in serious injury or death.

Do not steam, autoclave, or gas sterilize any part of the LifeVest WCD system. Do not use abrasive or flammable cleaning agents.

Inappropriate cleaning methods may damage the system and/or cause the system to malfunction, which may result in serious injury or death.

Do not use chlorine bleach, bleach alternatives, fabric softener, dryer sheets, anti-static sprays, or detergents that include bleach or fabric softener additives when washing and drying the garment. Do not use the high heat setting when drying the garment. Using bleach or any of these other prohibited agents to wash and dry the garment and/or using high heat to dry the garment may damage it and cause the system to malfunction, which may result in serious injury or death.

Interactions with other medical equipment

⚠️ WARNING

The LifeVest WCD is magnetic resonance (MR) unsafe. Do not use it in a magnetic resonance imaging (MRI) environment. If the LifeVest WCD is used in an MRI environment, the MRI could affect the ability of the LifeVest WCD to function properly, which could result in serious injury or death.

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

Information for non-patients/bystanders

WARNING

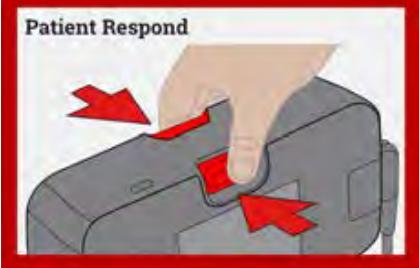
Only the patient should press the response buttons. The patient's ability to press both response buttons lets the LifeVest WCD know whether or not the patient is conscious and is critical in deciding when to give the patient a treatment. If anyone other than the patient presses the response buttons, needed therapy may not be delivered, which may result in serious injury or death.

Bystanders must not touch the patient while a treatment is being delivered. Anyone touching the patient during a treatment may be shocked, which may cause injury to the bystander.

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

Anyone other than the patient is considered a bystander, and anyone associated with the patient should understand the treatment sequence and be aware of the following information associated with a patient who is receiving a treatment.

Note: A label on the front of the garment instructs medical personnel to open the garment before giving the patient conventional external defibrillation.

Screen	Non-patient/bystander actions	DO NOT
	<p>Do not do anything.</p> <p><i>Note: The LifeVest WCD will direct a conscious patient to respond to messages and alerts. A patient who has lost consciousness due to their abnormal heart rhythm will be unable to respond. This lack of response prompts the LifeVest WCD to deliver a treatment.</i></p>	<p>Do not respond to messages and alerts in place of the patient.</p> <p>Do not press the response buttons for the patient.</p> <p>Do not touch the patient when a treatment is being delivered.</p>
	<p>If the patient is unconscious, call for help and then start CPR. Continue CPR until help arrives, however, do not touch the patient when a treatment is being delivered.</p> <p>If the patient remains conscious, check the electrode belt to make sure all electrodes are pressing against the patient's skin.</p>	<p>Do not touch the patient when a treatment is being delivered.</p>

Known residual risks

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

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

Environmental considerations related to noise and vibration

Certain environments or situations you encounter that are loud and have high vibration could affect the LifeVest WCD. A loud environment could make it difficult for you to hear an alert to be able to appropriately respond. A high vibration environment may result in an inappropriate treatment. For example, riding a motorcycle 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 WCD, be attentive to your LifeVest WCD, responding to any alerts. In the unlikely event that vibration causes you to receive a siren alert, press and release both response buttons to prevent receiving a treatment and move away from the source of vibration. For more information on the siren alert, see “Types of alerts” on page 4-1.

Electromagnetic interference

WARNING

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



The LifeVest WCD is magnetic resonance (MR) unsafe. Do not use it in a magnetic resonance imaging (MRI) environment. If the LifeVest WCD is used in an MRI environment, the MRI could affect the ability of the LifeVest WCD to function properly, which could result in serious injury or death.

Do not stack or place the LifeVest WCD next to other devices. Doing so could expose the LifeVest WCD to electromagnetic interference (EMI) disturbance that may cause the system to malfunction, which may result in serious injury or death.

The LifeVest WCD system was designed and developed in accordance with IEC 60601-1-2 and complies with the associated standards.

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

In the unlikely event that electromagnetic disturbance causes you to receive abnormal heart rhythm alerts, press and release both response buttons to prevent being treated and move away from the source of the disturbance. The LifeVest WCD should return to normal monitoring mode in approximately 5 seconds.

Wireless interference

WARNING

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

Do not tamper with, alter, drop, or abuse any part of the system or labeling. Do not put fingers or foreign objects, such as paper clips or hair pins, into any connectors or openings. Altering the equipment in any way may damage it and/or cause the system to malfunction, which may result in serious injury or death. Changes or modifications to this device not authorized by ZOLL could void the radio frequency energy (RF) compliance and negate your authority to operate the device. Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.



The LifeVest WCD is magnetic resonance (MR) unsafe. Do not use it in a magnetic resonance imaging (MRI) environment. If the LifeVest WCD is used in an MRI environment, the MRI could affect the ability of the LifeVest WCD to function properly, which could result in serious injury or death.

Do not stack or place the LifeVest WCD next to other devices. Doing so could expose the LifeVest WCD to electromagnetic interference (EMI) disturbance that may cause the system to malfunction, which may result in serious injury or death.

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

- **Monitor use** – The monitor contains a cell phone module for data transmissions. Generally, these data transmissions occur

once per day, for a short period of time. If you experience interference in proximity to another device, move that device at least 27 centimeters (10.6 inches) away from the monitor.

If you wear the monitor in an area where cell phones are restricted (such as in a hospital or other facility sensitive to RF emissions), the monitor should be placed in airplane mode, preventing transmission. Data will be stored in the monitor's memory and transmitted when airplane mode is turned off in a location that is not restricted

- **Cell phone use** – When using a cell phone, keep it at least 27 centimeters (10.6 inches) away from the round electrodes 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.
- **General precaution** – If you experience any interference with the LifeVest WCD when in the presence of any other wireless device, move away from the device or stop using it. **If you continue to have problems, call ZOLL at 1-800-543-3267.**

Operator profiles

The operator profile is a summary of the mental, physical, and demographic traits of the intended user populations.

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

- Patient wears and interacts with the LifeVest WCD on a daily basis. The patient profile is described below.
- ZOLL-authorized representative fits patients with the equipment and trains patients. The ZOLL-authorized representative profile is described in “ZOLL-authorized representative profile” on page 1-26.
- Health care professional prescribes the LifeVest WCD for the patient. The health care professional profile is described in “Health care professional profile” on page 1-27.

Patient profile

The LifeVest WCD is appropriate for patients who are at risk for sudden cardiac arrest and meet the requirements described in the LifeVest WCD 5100 Clinical Manual. The patient wears the LifeVest WCD at all times (except when showering or bathing); changes and charges the batteries every 24 hours; responds to alerts; and presses the response buttons, if conscious, if there is a treatment alert in order to prevent inappropriate treatment from occurring.

While using the LifeVest WCD, the patient is expected to do minimal maintenance, including periodically cleaning and inspecting the system, as instructed in “Cleaning the LifeVest® WCD system” on page 3-43.

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

ZOLL-authorized representative profile

ZOLL-authorized representatives are ZOLL-trained professionals. Their job

is to program the equipment according to the patient's prescription, measure and fit patients with the LifeVest WCD equipment, train patients and family members, and provide follow-up assistance if necessary. Information for ZOLL-authorized representatives is provided in the LifeVest WCD 5100 Field Manual.

ZOLL-authorized representatives must have the cognitive capabilities to understand training given by ZOLL that covers programming the LifeVest WCD, measuring and fitting patients, and training patients in the daily use of the LifeVest WCD.

Health care professional profile

Health care professionals evaluate the patient and prescribe the LifeVest WCD. Health care professionals also access patient data in ZOLL Patient Management Network. Health care professionals can prescribe settings for the LifeVest WCD. Information for health care professionals is provided in the LifeVest WCD 5100 Clinical Manual.

Patient training

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

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

In addition, the patient section of the LifeVest website at www.lifevest.zoll.com/patients provides educational videos and phone support is available by calling ZOLL at 1-800-543-3267.

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2: Getting started

This section provides information about getting started with the LifeVest WCD system including:

- At home with your LifeVest WCD system
- Inspecting the LifeVest WCD equipment
- Getting help with the LifeVest WCD

2: Getting started

WARNING

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

The LifeVest WCD is a prescribed medical device only for the patient for whom it was prescribed and only for the use for which it was intended.

Keep LifeVest WCD system components away from pets, pests, and children. Keep the LifeVest WCD system components away from continuous direct sources of heat, such as heaters.

At home with your LifeVest® WCD system

It is important you understand and complete the following steps when you are at home with your LifeVest WCD system. If you need assistance, call ZOLL at 1-800-543-3267.

Always

- Ensure you are wearing the electrode belt and garment correctly. See “Putting on the assembled electrode belt and garment” on page 3-28.
- Ensure a battery is fully inserted into the monitor, and the electrode belt is connected to the monitor. See “Connecting the electrode belt to the monitor” on page 3-32.
- Press and release both response buttons when you feel vibration or hear a siren alert. See “Understanding alerts” on page 4-1.
- Check the monitor screen when you hear a gong alert. See “Receiving a gong alert” on page 4-8.

First 24 hours

- Plug in the charger in a safe, convenient location, and recharge the second battery. See “Charging and changing batteries” on page 3-15.
- Read this entire manual.

Daily

- Change and recharge battery. See “Charging and changing batteries” on page 3-15.
- Inspect the system. See “Inspecting the LifeVest® WCD equipment” on page 2-2.
- Check electrode placement. All electrodes must be against your skin, ends of garment must be fastened together, and the clasp must be centered on your torso. See “Putting on the assembled electrode belt and garment” on page 3-28.
- Remove battery before taking off system to shower or bathe. See “Charging and changing batteries” on page 3-15.
- When you remove the LifeVest WCD for any reason, remove the battery first. When you put the LifeVest WCD back on, put the battery in last. See “Charging and changing batteries” on page 3-15.
- Follow normal startup routine when changing the battery. See “Daily routine and normal startup” on page 3-1.

Every one or two days

- Change to a clean garment. See “Wearing the LifeVest® WCD” on page 3-5.
- Wash the previously worn garment. See “Garment care” on page 3-45.

Inspecting the LifeVest® WCD equipment

Inspect the LifeVest WCD equipment daily. If you should notice any of the following conditions, call ZOLL immediately at 1-800-543-3267. You are

not expected to do any service on the LifeVest WCD. Only ZOLL is to perform service on the LifeVest WCD.

- Cracks in the housing of the monitor, battery, or charger.
- Cracks in the therapy pads.
- Garment damage, such as tears or degradation of snaps and colored hook and loop fasteners.
- Cracks in the holster.
- Cracks or cuts in electrode belt cables.
- Cracks or separation at connection points.
- Buildup of lint or dust in the monitor receptacle or electrode belt connector.
- Blue™ gel on the therapy pads at any time other than when treatment is about to occur or has just occurred.

Getting help with the LifeVest® WCD

If you experience an issue with any part of the LifeVest WCD system, call ZOLL immediately at 1-800-543-3267.

See “Troubleshooting issues with no screen message” on page 8-1 for possible solutions to some issues you may experience.

Getting help with LifeVest® WCD screen instructions

Some LifeVest WCD monitor screens include a Help button . Tap the Help button for more specific help for that screen's message.

To hear the help message, tap the message on the screen. The message is spoken in the language displayed.

Note: The speak option only works if enabled. See “Configuring help screen audio options” on page 6-8 for details on enabling this feature.

3: Using the LifeVest® WCD system

This section provides information about using the LifeVest WCD system including:

- Daily routine and normal startup
- Wearing the LifeVest WCD, including assembling the electrode belt to the garment, putting it on, connecting the electrode belt to the monitor, using the monitor's indicator lights and response buttons, and using the batteries and charger.
- Disconnecting the electrode belt from the monitor
- Removing the LifeVest WCD before you shower or bathe
- Disassembling the electrode belt from the garment
- Removing the monitor from its holster
- Cleaning the LifeVest WCD system

3: Using the LifeVest® WCD

Daily routine and normal startup

WARNING

If you do not hear the gong upon receiving the prompt to activate the LifeVest WCD, the LifeVest WCD may have malfunctioned. If you were to enter into a life-threatening arrhythmia, a system malfunction may result in serious injury or death. If you suspect the audio is not working properly on the LifeVest WCD, see “Troubleshooting issues with no screen message” on page 8-1 for details on a solution.

This section provides an overview of the daily routine along with the normal startup routine.

1 Inspect the LifeVest WCD equipment.

See “Inspecting the LifeVest® WCD equipment” on page 2-2.

2 Wear the assembled electrode belt and garment.

See “Wearing the LifeVest® WCD” on page 3-5.



- 3 Put a fully charged battery into the monitor until it clicks ensuring the battery is fully inserted into the monitor. The red line on the battery should not be visible.

See “Inserting a charged battery into the LifeVest® WCD” on page 3-9.

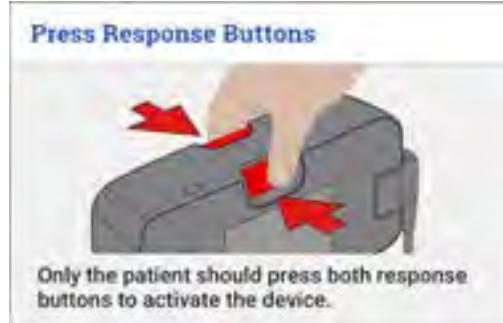


The startup screens display, and the monitor indicator light illuminates green, yellow, and red.



- 4 When you hear the gong and feel the vibration on your back, press and release both response buttons.

If you do not hear the gong or feel the vibration, call ZOLL immediately at 1-800-543-3267.



- 5 Ensure the monitor indicator light is green, fading in and out.

See “Reading the monitor indicator light” on page 3-10.



- 6 Check the monitor; it should display your name and the battery level.

If your name is not displayed, call ZOLL immediately at 1-800-543-3267.



For details on the battery status icons on the monitor, see "Reading the monitor indicator light" on page 3-10.

- 7 Change and recharge the battery every 24 hours.

See "Charging and changing batteries" on page 3-15 for details.



- 8 Wear the monitor in its holster. See "Placing the monitor in its holster" on page 3-33.



- 9 Respond to any alerts. See "Understanding alerts" on page 4-1 for details.



10 When you shower or bathe, remove the battery and completely remove the LifeVest WCD. See “Removing the LifeVest® WCD when you shower or bathe” on page 3-36 for details.



11 Change and wash the garment every 1 or 2 days. Follow the instructions in “Garment care” on page 3-45.



Wearing the LifeVest® WCD

The garment is worn directly against your skin under your clothing to hold the round electrodes and therapy pads against your upper body.

The electrode belt is connected to the monitor. The monitor is placed in its holster and worn around your waist, over your shoulder, or across your torso using the adjustable strap.



Wearing the monitor in its holster

Your LifeVest WCD holster comes with one adjustable piece and two extension pieces.



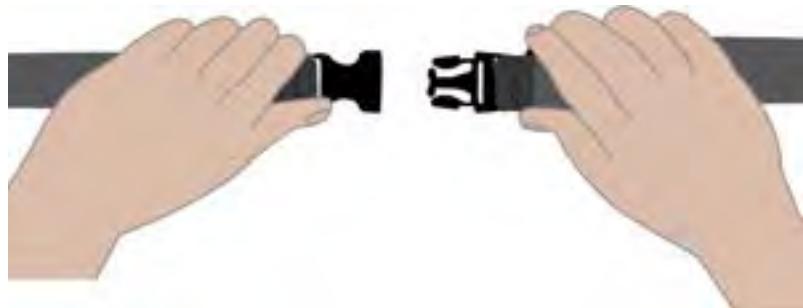
The adjustable piece and your selected extension piece form the strap you attach to the holster so you can wear the monitor around your waist, over your shoulder, or across your torso.

To wear the monitor in its holster:

- 1 Place the monitor in its holster. See “Placing the monitor in its holster” on page 3-33.
- 2 Select your desired extension piece.



- 3 Hold the buckle of the extension piece in one hand and the buckle of the adjustable piece in the other.



4 Connect the buckles.



5 Press the clasp open on one end of the strap.



6 Hook the clasp onto one of the monitor's strap rings.



7 Release the clasp.

- 8 Repeat steps 6 and 7 with the other side of the strap.



- 9 Adjust the strap as needed for your desired fit.



Inserting a charged battery into the LifeVest® WCD

Insert a fully charged battery into the LifeVest WCD every 24 hours or when you are putting on the LifeVest WCD. When you put the LifeVest WCD on, put the battery in last.

To insert a battery into the LifeVest WCD:

- 1 Pull the battery latch to remove the fully charged battery from the charger.
- 2 Push the battery firmly into the monitor until it clicks, ensuring the battery is fully inserted into the monitor.

The red line on the battery latch should not be visible.

The monitor indicator light illuminates green, yellow, and red.



The LifeVest WCD begins normal startup as described in “Daily routine and normal startup” on page 3-1.

Reading the monitor indicator light

WARNING

If the monitor indicator light is not blinking, the LifeVest WCD may have malfunctioned. If you were to enter into a life-threatening arrhythmia, a system malfunction may result in serious injury or death. If you suspect the monitor indicator light is not working properly on the LifeVest WCD, see “Troubleshooting issues with no screen message” on page 8-1 for details on a solution.

The monitor indicator light shows the status of the monitor. The indicator light is located on the top of the monitor.



Indicator	What it means	What to do
	Normal operation	Nothing
Green, fading in and out		
	Monitor has an urgent issue. You are still protected.	Read the monitor screen for instruction.
Yellow, blinking		
	Monitor has an urgent issue. Act immediately.	Read the monitor screen for instruction.
Red, blinking		

Using the response buttons

If you receive the siren alert, you should, if conscious, press and release both response buttons to stop from getting a defibrillating treatment. You do not have to hold the response buttons to stop treatment.

During normal monitoring, the monitor touchscreen may display a dark screen. If the screen is dark, press and release both response buttons to activate the screen.

The response buttons are also used during startup. See “Daily routine and normal startup” on page 3-1.

Using the monitor screen

The monitor screen displays information, messages, and menus related to LifeVest WCD operation, and allows you to interact with the LifeVest WCD.

On certain screens, you can play audio associated with the screen by tapping the monitor screen. See “Configuring help screen audio options” on page 6-8.

See “Monitor screen glossary” on page B-1 for descriptions of the graphics, indicators, and icons you will see on the monitor screen, as well as screens you may encounter and actions you should take.

Screen buttons

One way you interact with the LifeVest WCD is by using buttons on the screen. The following table describes the buttons you see most often. Other functions of the buttons are described in relevant sections in this manual.

Button	Name	Description
	Help	Tap to see additional information.
	Close	Tap to close the screen.
	Menu	Tap to see the menu.
	Back	Tap to go to the previous step when there is more than one step.
	OK	Tap to acknowledge you have read the screen. If any selections or changes were made on the screen, those selections or changes take effect.
	Next	Tap to go to the next step when there is more than one step.
	Save	Tap to save the information on the screen. If any selections or changes were made on the screen, they take effect.
	Translate	Tap to change the language in which the help screen audio is spoken.

Reading battery status icons on the monitor



A battery status icon is always displayed on the monitor's screen. It indicates the battery's status.

To view the battery power percentage remaining, tap the battery status icon on the monitor touchscreen.

Icon	What it means
A battery icon consisting of four solid green horizontal bars of equal length.	Battery level. Number of green bars indicates battery level.
A battery icon consisting of four horizontal bars. The first bar is red, and the other three are green.	Battery is low, a critical situation. The LifeVest WCD may or may not be able to deliver a treatment. Change battery as soon as possible and recharge battery. See "Charging and changing batteries" on page 3-15.
A yellow rectangular box containing a black question mark.	Battery may be defective: LifeVest cannot determine battery condition. Call ZOLL at 1-800-543-3267.

Charging and changing batteries

WARNING

Make sure the battery is fully inserted and latched into the monitor. The red line on the battery should not be visible. If the battery is not fully inserted and latched, it may disconnect and you will not be protected, which may result in serious injury or death.

If the charger or power supply makes unusual noises, sparks, starts to smoke, or emits a burning smell, unplug it immediately from the wall outlet. The only way to completely remove power is by unplugging the AC power plug from the wall outlet. Place the charger so that the power plug is accessible in case you need to unplug it. If these precautions are not followed, serious injury or death may occur.

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

The LifeVest WCD includes two batteries. While one battery is in the monitor, keep the second battery in the charger. Use only the batteries and charger supplied with the LifeVest WCD.

Change and recharge the batteries every 24 hours. Continue to wear the LifeVest WCD and keep the electrode belt connected during this procedure. You can also leave the monitor in the holster while changing the battery.

Charger setup

To set up the charger:

- 1 Place the charger so you can easily get to the side of the unit to insert and remove the battery. Make sure you can easily view the indicator lights.

The charger should be placed in a safe, convenient location where you can leave it plugged into a standard power outlet that stays on all the time and is not controlled by a switch.

The battery and charger may get warm. This is normal. Place the charger in a well-ventilated place.

- 2 Plug the power supply into the back of the charger.
- 3 Plug the power supply directly into a standard power outlet. Do not use an extension cord, surge protector, or adapter.



The yellow and green charger indicator lights flash three times, and the blue indicator light lights up and stays on. The charger beeps three times.

If you ever need to unplug the charger, unplug it from the power outlet first. Then, if necessary, unplug the power supply from the back of the charger. The charger does not have a power switch.

Removing the battery

Remove the battery to change batteries or when you remove the LifeVest WCD.

To remove the battery from the monitor:

- 1 Pull the battery latch.
- 2 Slide the battery out of the monitor.



Charging the battery

It is recommended you change and recharge the battery every 24 hours.

Note: Recharging the battery typically takes less than 6 hours but can take up to 16 – 18 hours. ZOLL recommends you establish a battery charging routine and do not allow a battery to drain completely of all charge before charging the battery.

To put the battery in the charger:

- 1 Ensure the charger is set up properly. See “Charger setup” on page 3-16.
- 2 Push the battery firmly into the charger until it clicks, ensuring the battery is fully inserted into the charger. The red line on the battery should not be visible.



The green indicator lights up. It may blink or light solid.



- 3 Read the battery status on the charger to confirm the battery status is either charging or charged.

For details on how to read the charger indicator lights, see “Reading the charger indicator lights” on page 3-19.

Reading the charger indicator lights

Charger indicator lights show the status of the battery and charger.

Indicator	What it means	What to do
 Yellow, lit solid, with audible alarm	Alarm condition 1. There is a problem, but the battery might still charge.	Battery can be used, but should be replaced. This condition will be accompanied by two beeps at the start of the alarm. Call ZOLL at 1-800-543-3267.
 Yellow, blinking, with audible alarm	Alarm condition 2. There is a problem, and the battery cannot charge.	Battery cannot charge. This condition will be accompanied by three beeps every 15 seconds. Call ZOLL immediately at 1-800-543-3267.
 Green, lit solid	Battery is fully charged, ready for use in monitor.	Leave the battery in the charger until you are ready to exchange the battery.
 Green, blinking	Battery is charging.	Leave the battery in the charger. Charging the battery typically takes less than 6 hours.

Indicator	What it means	What to do
 Blue, lit solid	Power is being applied to the charger. This light will continue to stay lit when the other indicators light.	Make sure this indicator lights up when you plug in the charger.

In the event of a power outage

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

- Notify your electrical provider to let them know you have a medical device that requires power. Determine if they believe the power will be out for 24 hours or more.

If the power will be out for 24 hours or more, seek alternative locations for powering the batteries, such as a neighbor, friend, or family member not affected by the outage; your local emergency medical services; or a source of backup power, such as a generator.

- **If help is not available, and you expect power to be out for more than 24 hours, call ZOLL 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.

Assembling the electrode belt to the garment

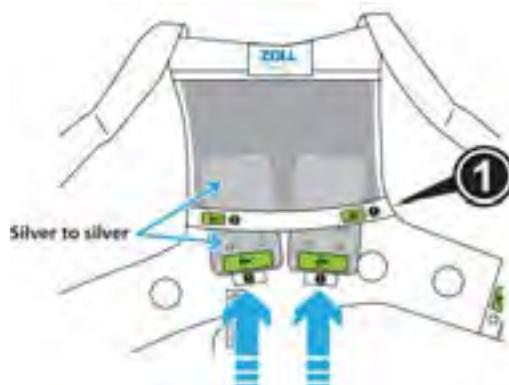
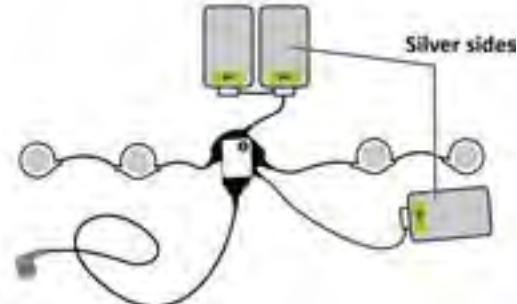
To assemble the electrode belt to the garment:

- 1 Lay the garment on a flat, solid surface with the colored hook and loop fasteners, snaps, and silver fabric pockets facing up.

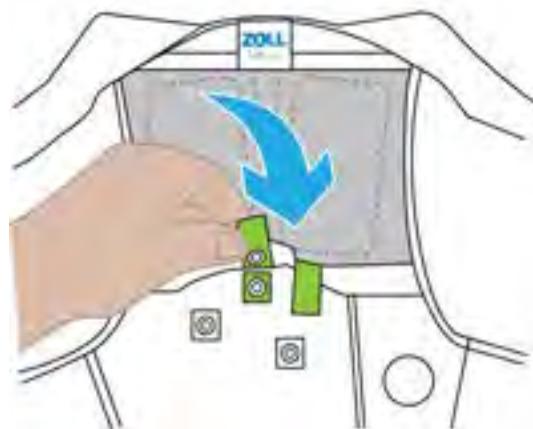


- 2 Lay the electrode belt with the silver sides of the therapy pads facing up.
- 3 Insert the rear therapy pads into the garment's rear pockets labeled 1.

Note: The therapy pads must match silver to silver. The silver sides of the therapy pads (with the green labels) must face the silver fabric on the pockets.



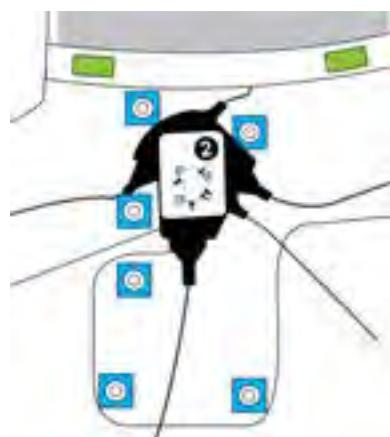
- 4 Secure the silver fabric pockets with the snaps. Make sure the snaps are securely fastened.



- 5 Position the vibration box on the garment in the position labeled 2.



The vibration box side labeled 2 must face up.



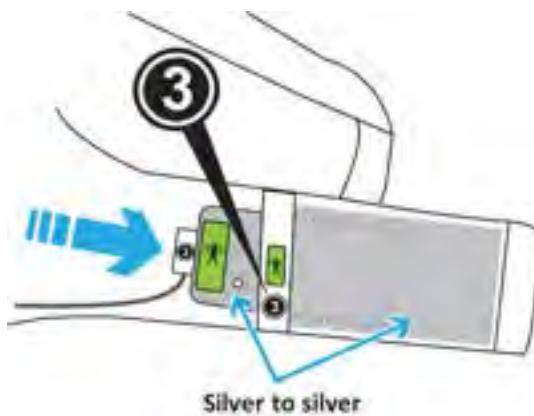
- 6 Secure the flap over the vibration box with the snaps. Make sure all snaps are securely fastened.

Note: At least one cable should be coming out of each of the four sides of the flap.

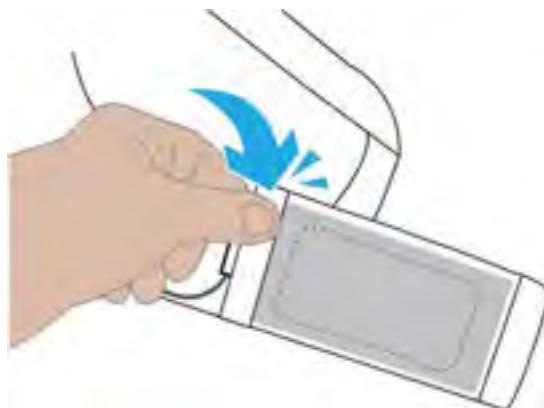


- 7 Insert the front therapy pad into the front pocket labeled 3.

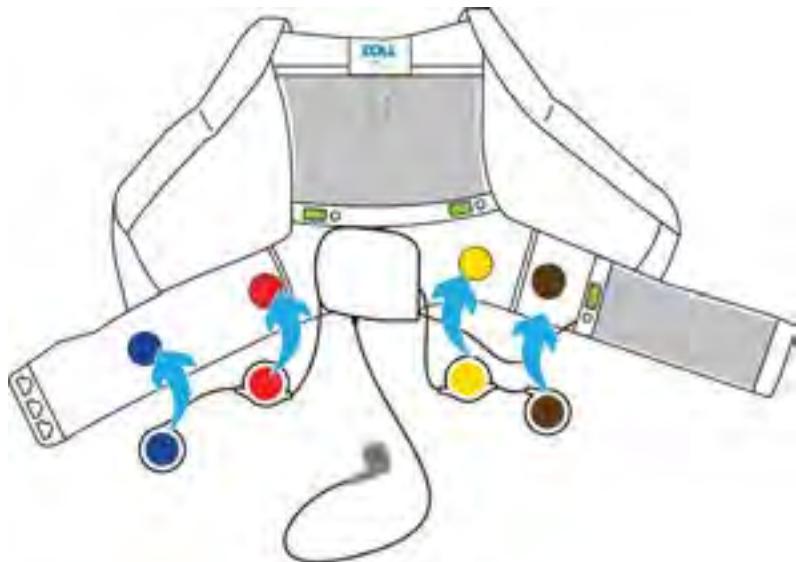
Note: The therapy pad must match silver to silver. The silver side of the therapy pad (with the green labels) must face the silver fabric on the pocket.



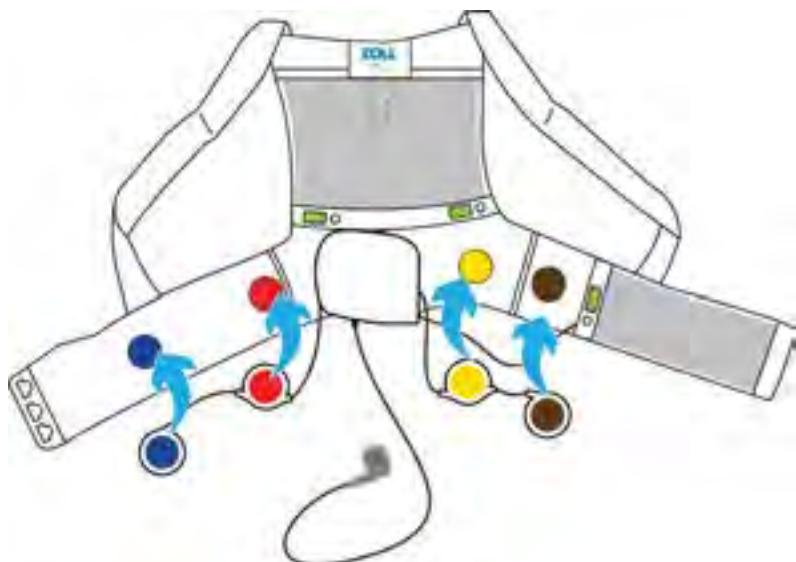
- 8 Secure the silver fabric pocket with the snap. Make sure the snap is securely fastened.



- 9 Match the colors on the backs of the round electrodes to the colors of the fasteners on the garment.



- 10 Attach the round electrodes to the garment.

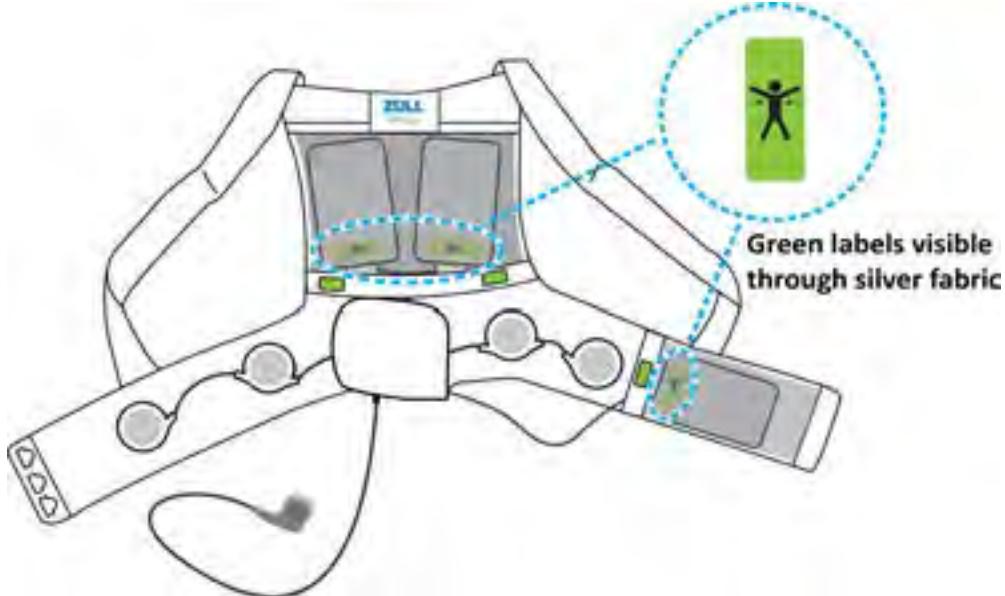


- 11 Verify your garment and electrode belt are assembled correctly.
See the following figures.



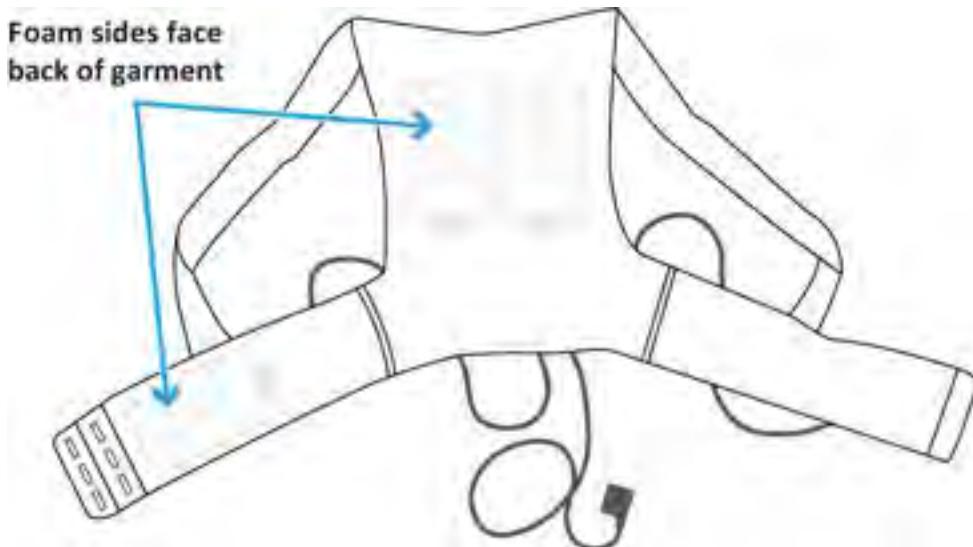
Inside of garment

The inside of the garment faces your body when worn, with the silver fabric pockets against your skin.



Outside of garment

The outside faces away from your body when worn. The foam sides of the therapy pads face the back of the garment.



Putting on the assembled electrode belt and garment

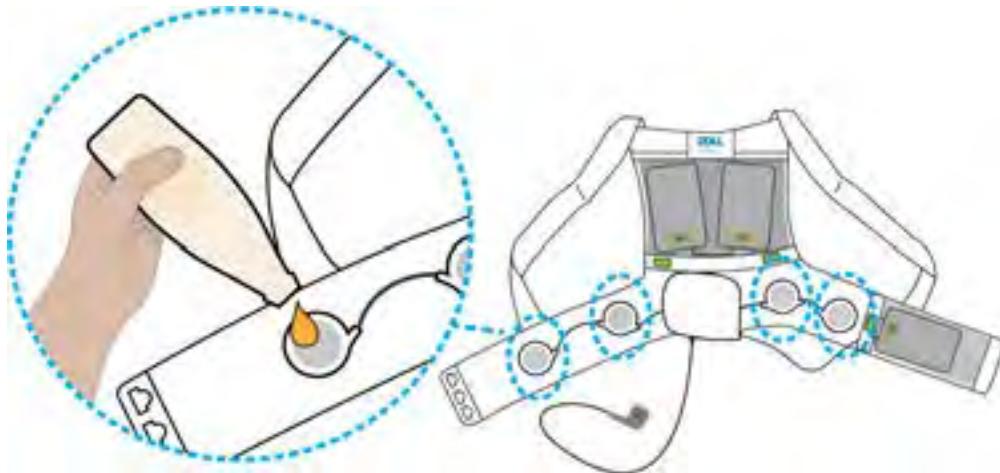
Follow these instructions to put on the assembled garment, then make sure you are wearing it properly. The garment and electrode belt must be worn against your bare skin.

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

Note: All clothing, including undergarments and bra, must be worn over the LifeVest WCD, not under it.



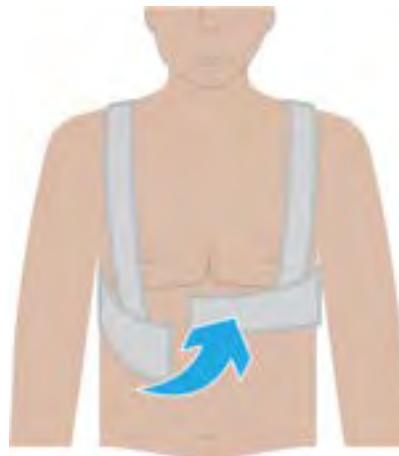
- 2 If desired, apply unscented lotion to the four round electrodes.



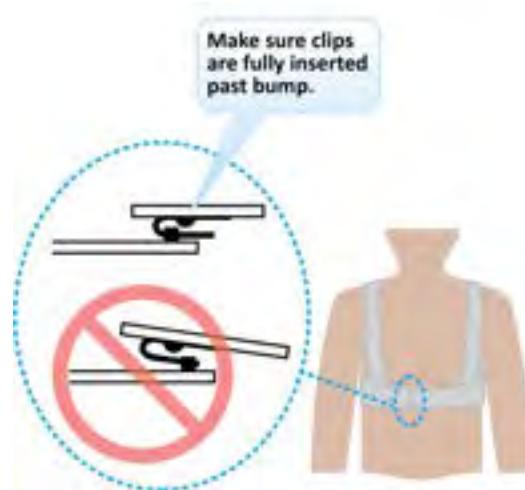
- 3 Put on the garment, making sure:

- The garment does not get twisted.
- The silver fabric pockets touch your bare skin.
- The garment and round electrodes touch your bare skin.
- The silver side of the front therapy pad is pressing against your torso rather than the underside of your left breast.

- 4 Secure the garment by connecting the garment ends together in the front.



Make sure the clips are fully inserted past the bump.



- 5 Check the position of the garment on your body and make sure it is 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

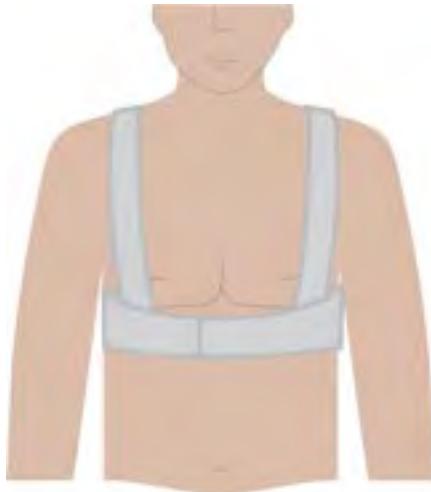
Too low

6 Make sure that:

- The garment is not twisted, and the straps are flat against your skin.
- The round electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green labels) must touch your body for the LifeVest WCD to work properly.
- The electrode belt cables do not interfere with the electrodes.
- The garment is properly secured.
- The garment is being worn snugly.

Note: It may help to look in a mirror to determine proper fit.

Your garment should look like the figures below.



- 7 Connect the electrode belt to the monitor. See “Connecting the electrode belt to the monitor” on page 3-32.

Connecting the electrode belt to the monitor

WARNING

Make sure the electrode belt is properly connected to the monitor. If the electrode belt is not properly connected, it may disconnect and you will not be protected, which may result in serious injury or death.

Ensure the electrode belt connector is aligned with the monitor receptacle before pushing it in. Do not force the connector. Forcing the connector may damage it. Inspect the LifeVest WCD for damage. See “Inspecting the LifeVest® WCD equipment” on page 2-2.

To connect the electrode belt:

- 1 Line up the connector with the monitor. The cable should face down.



- 2 Push the connector straight in until it locks securely into place.



Placing the monitor in its holster

The monitor should always be worn in its holster.

To place the monitor in its holster:

- 1 Put on the LifeVest WCD. See “Wearing the LifeVest® WCD” on page 3-5.

- 2 Place the holster flat on a solid surface with the cut-out portion facing up.



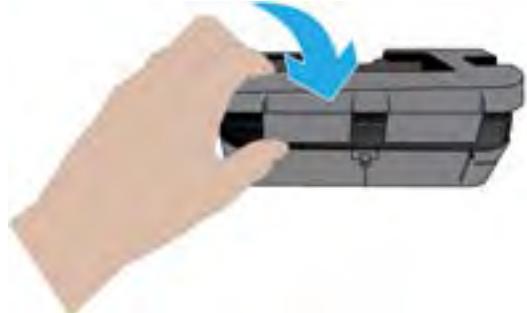
- 3 Open the holster by lifting the latch on the bottom to lift the top up.



- 4 Place the monitor completely in the holster with the attached electrode belt cable facing to the right.



- 5 Close the lid of the holster until it clicks.



- 6 If necessary, place the electrode belt cable in the cable guides on the holster.



- 7 Wear the monitor in its holster. See “Wearing the monitor in its holster” on page 3-6.

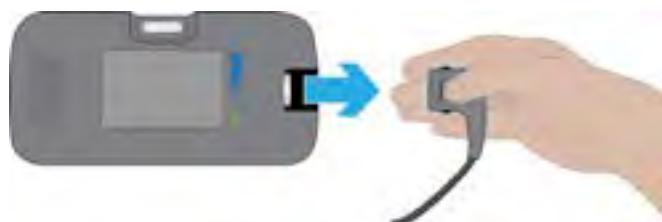
Disconnecting the electrode belt from the monitor

To disconnect the electrode belt:

- 1 Press the button on the electrode belt connector.



- 2 Pull the connector straight out of the monitor.



Removing the LifeVest® WCD when you shower or bathe

WARNING

Do not put the monitor, electrode belt, battery, or charger in or near water. Water entering a component may damage it and/or cause the system to malfunction, which may result in serious injury or death. Inspect the LifeVest WCD for damage. See “Inspecting the LifeVest® WCD equipment” on page 2-2.

- Completely remove the LifeVest WCD when you shower or bathe. Do not put the monitor, electrode belt, or battery in or near water.
- When you remove the LifeVest WCD to bathe or shower, you are not protected by the LifeVest WCD. Bathe or shower preferably when someone else is home with you.
- When you remove the LifeVest WCD for any reason, remove the battery first. When you put the LifeVest WCD back on, put the battery in last.

To remove the LifeVest WCD before you bathe or shower:

Note: You can keep the electrode belt connected to the monitor during this process.

- 1 Remove the battery from the monitor.

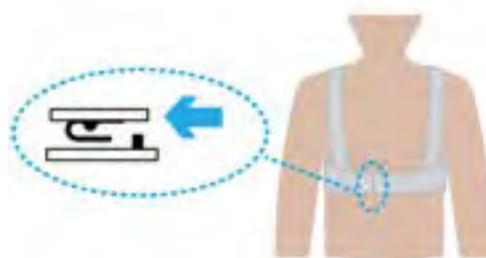
See “Charging and changing batteries” on page 3-15.



- 2 Unfasten the garment by disconnecting the garment ends in the front.



Make sure the clips are fully removed.



- 3 Remove the LifeVest WCD (garment and monitor in holster, if applicable) from your body.

If you plan to change the garment, see “Disassembling the electrode belt and garment” on page 3-38.

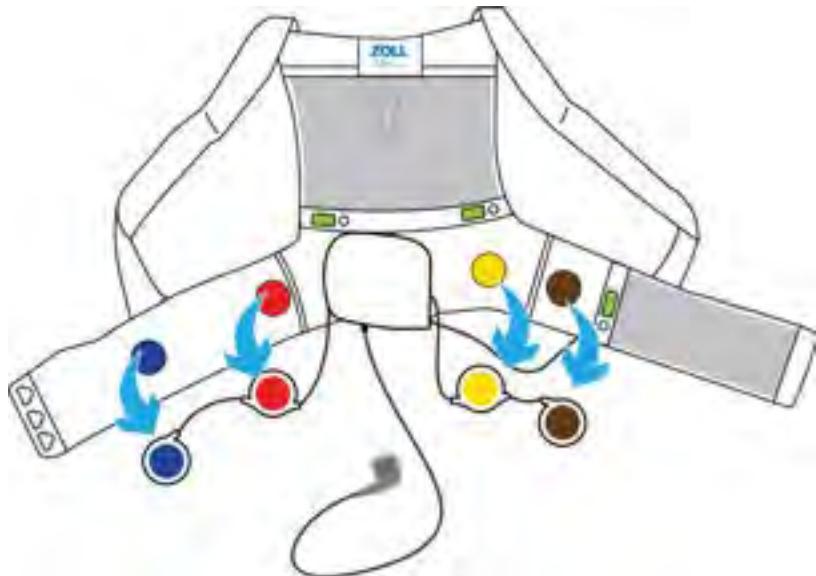


Disassembling the electrode belt and garment

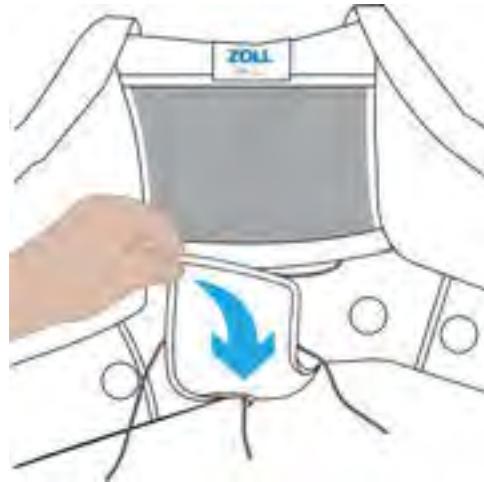
To remove the electrode belt from the garment:

Note: You can keep the electrode belt connected to monitor during this process.

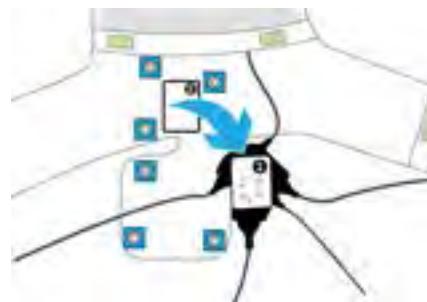
- 1 Remove the battery from the monitor. See “Removing the battery” on page 3-17.
- 2 Remove the four round electrodes from the garment. Hold the round electrodes when you remove them. Do not pull on the cables.



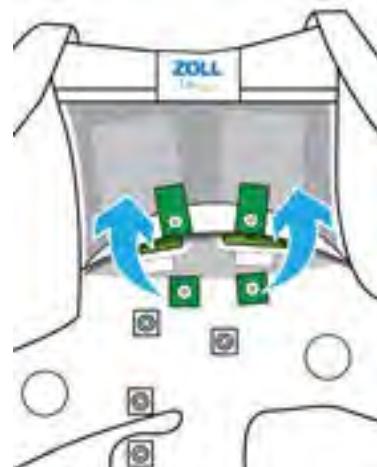
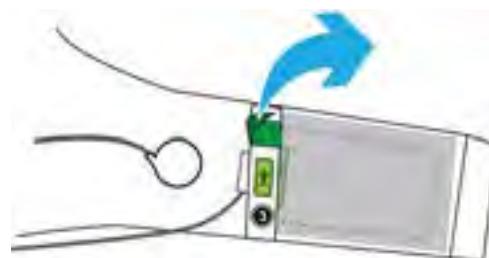
- 3 Unsnap and open the vibration box flap.



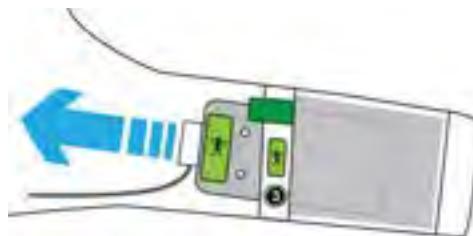
4 Remove the vibration box from the garment.



5 Unsnap the therapy pad pockets.



- 6 Remove the therapy pads from their pockets. Do not pull on the cables.



- 7 If necessary, clean the electrode belt and surfaces of the round electrodes and therapy pads. See “Cleaning the non-washable items” on page 3-43.
- 8 Reassemble the garment and electrode belt as described in “Assembling the electrode belt to the garment” on page 3-22.
- 9 Put on the assembled garment and electrode belt as described in “Putting on the assembled electrode belt and garment” on page 3-28.
- 10 Insert a battery into the monitor. See “Inserting a charged battery into the LifeVest® WCD” on page 3-9.

Removing the monitor from its holster

To remove the monitor from its holster:

- 1 Place the holster with the monitor in it flat on a solid surface with the screen of the monitor facing up.



- 2 If necessary, remove the electrode belt cable from the cable guides on the holster.



- 3 Open the holster by lifting the latch on the bottom to lift the top off.



- 4 Remove the monitor from its holster.



- 5 Close the lid of the holster until it clicks.



Cleaning the LifeVest® WCD system

WARNING

Do not tamper with, alter, drop, or abuse any part of the system or labeling. Do not put fingers or foreign objects, such as paper clips or hair pins, into any connectors or openings. Altering the equipment in any way may damage it and/or cause the system to malfunction, which may result in serious injury or death. Changes or modifications to this device not authorized by ZOLL could void the radio frequency energy (RF) compliance and negate your authority to operate the device. Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.

Do not steam, autoclave, or gas sterilize any part of the LifeVest WCD system. Do not use abrasive or flammable cleaning agents.

Inappropriate cleaning methods may damage the system and/or cause the system to malfunction, which may result in serious injury or death.

Clean the LifeVest WCD system as necessary.

Cleaning the non-washable items

The non-washable items are the monitor, battery, charger, holster, and electrode belt.

Before cleaning:

- Remove the battery from the monitor. See “Removing the battery” on page 3-17.
- Unplug the charger and disconnect the power cord.
- Disconnect the electrode belt from the monitor. See “Disconnecting the electrode belt from the monitor” on page 3-35.
- Remove the monitor from its holster. See “Removing the monitor from its holster” on page 3-41.
- Inspect the system. See “Inspecting the LifeVest® WCD equipment” on page 2-2.

- Review the following list on what to do and not do while cleaning the non-washables.



Do

- Before cleaning, remove the battery from the monitor.
- For all components except the round electrodes, use a bleach cleaning wipe or a soft cloth sparingly dampened with soap and water. Wipe clean with a cloth dampened with clean water.
- You may use isopropyl alcohol on the metal surfaces of the round electrodes.
- Wipe the components with a dry, clean cloth after cleaning to dry.



Do not

- 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 isopropyl alcohol on the therapy pads.
- Do not reconnect any components until they are completely dry.
- Do not soak the monitor, any accessory, or cable in any solution. An exception is the garment, which can be laundered. See "Garment care" on page 3-45.

Garment care

WARNING

Do not use chlorine bleach, bleach alternatives, fabric softener, dryer sheets, anti-static sprays, or detergents that include bleach or fabric softener additives when washing and drying the garment. Do not use the high heat setting when drying the garment. Using bleach or any of these other prohibited agents to wash and dry the garment and/or using high heat to dry the garment may damage it and cause the system to malfunction, which may result in serious injury or death.

Washing and drying the garment

Before washing the garment,

- Remove the electrode belt as described in “Disassembling the electrode belt and garment” on page 3-38.
- Attach the ends of the garment together as described in “Putting on the assembled electrode belt and garment” on page 3-28.
- Review the following list on what to do and not do while washing the garment.



Do

- Wash and dry the garment every 1 or 2 days.
- Wash and dry the garment by itself with no other laundry.
- Use the clothes washing detergent provided or a free and clear or fragrance-free clothes washing detergent only.



Do not

- Do not wash the electrode belt, monitor, or any other accessories.
- Do not use chlorine bleach, bleach alternatives, fabric softener, dryer sheets, anti-static sprays, or detergents that include bleach or fabric softener additives when washing and drying the

garment.

- Do not use the high heat setting to dry the garment.

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).

It is recommended you use a clothes dryer, set to a warm or medium setting, to dry the garment. Do not use the high heat setting. You can also lay the garment flat to dry.

Garment care symbols

The symbols on the back of the garment tag indicate specific care instructions that must be followed for the garment.



	Laundering symbol. Indicates to machine wash on normal cycle with a maximum water temperature of 40°C (104°F). (ASTM D5489, 5.4)
	Laundering symbol. Indicates to use only non-chlorine bleach when needed. (ASTM D5489, 5.4)
	Laundering symbol. Indicates to tumble dry on permanent press with a medium heat setting. (ASTM D5489, 5.4)
	Safety sign. Indicates that the instruction manual must be read. (ISO 7010, M002) Review this section for garment care.
	Laundering symbol. Indicates to iron when needed with a low heat setting of 110°C (230°F). (ASTM D5489, 5.4)

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4: Understanding alerts

This section provides information about alerts you may receive.

4: Understanding alerts

Types of alerts

How you respond to an alert depends on the type of alert you get.

There are three types of alerts:

- siren
- vibration
- gong

Siren alert



The siren alert is a high-pitched two-tone sound that means an abnormal heart rhythm has been detected. The monitor screen displays a message with a red border.

Press and release both response buttons at the same time to stop this alert. If you don't respond to this alert, you may receive a treatment within the next minute.

Follow the instructions in "Receiving a siren alert with a Patient Respond display message" on page 4-3 or "Receiving a siren alert with an If Patient is Not Responsive display message" on page 4-6.

Vibration alert



If you feel a vibration on your back from the electrode belt's vibration box, you are being warned you are about to receive a siren alert.

Follow the same instructions as for the siren alert in “Receiving a siren alert with a Patient Respond display message” on page 4-3.

You will also feel a short vibration every time you change the battery.

Press and release both response buttons at the same time to stop this alert.

Gong alert

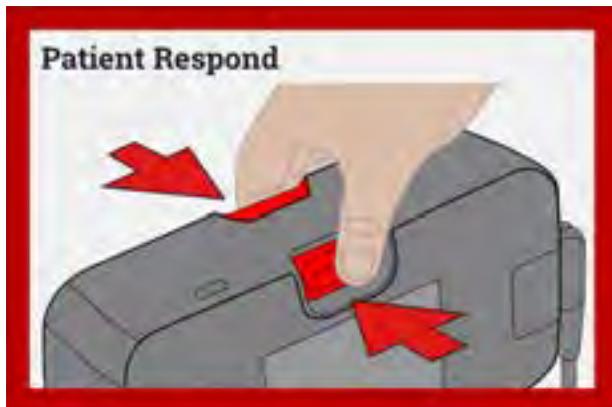


The gong alert is a low-pitched sound that repeats about once a second. The monitor indicator light will blink yellow or red. The monitor screen displays a message with a yellow or red border.

Read the message to see what action needs to be taken. If available, press the Help button on the screen for specific help.

Follow the instructions in “Receiving a gong alert” on page 4-8.

Receiving a siren alert with a *Patient Respond* display message



WARNING

If you receive an alert sound and are awake, always press both response buttons to prevent receiving a treatment. If you fail to press both response buttons, you will get a treatment, which may result in serious injury or death.

Only the patient should press the response buttons. The patient's ability to press both response buttons lets the LifeVest WCD know whether or not the patient is conscious and is critical in deciding when to give the patient a treatment. If anyone other than the patient presses the response buttons, needed therapy may not be delivered, which may result in serious injury or death.

If a treatment is delivered while your heart is beating normally, the treatment may cause an abnormal heart rhythm to occur. There is a small possibility that the abnormal heart rhythm may not be detected and may result in serious injury or death. If you get an alert sound and you are awake, press and release both response buttons to prevent receiving a treatment. If you fail to press and release both response buttons, you will get a treatment, which may result in serious injury or death.

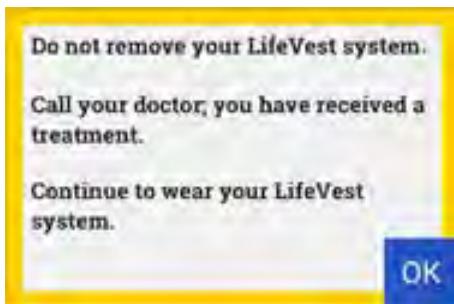
If you are conscious, press and release both response buttons to stop the treatment from occurring.

- The siren alert stops and a voice prompts that the treatment has been stopped. The response buttons change from flashing to solid red once pressed and the vibration stops.
- **No one else** should press the response buttons. Only you, the patient, should press and release the response buttons.
- If you feel dizzy, find a place to sit or lie down.
- Press and release both response buttons each time you feel the vibration box or hear the siren alert.

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

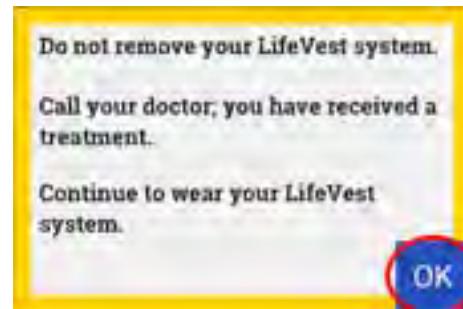
- This allows the LifeVest WCD to deliver a treatment.
- Voice prompts alert bystanders not to touch you.
- Voice prompts also alert bystanders to call for help after you have been given a treatment.
- **No one else** should press and release the response buttons. Only you, the patient, should press and release the response buttons.

After receiving a treatment



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

- 1 Continue to wear the LifeVest WCD system unless your health care professional tells you otherwise.
 - Leave the electrode belt connected to the monitor. Do not remove the electrode belt or garment.
 - Leave the battery in the monitor. Continue to change and recharge the batteries as normal.
 - Leave Blue gel under the therapy pads. Do not wipe them dry.
- 2 Call your health care professional's emergency number immediately to report your treatment.
- 3 Tap **OK** to resume normal monitoring.
- 4 Check the display for any messages and take the action indicated.
- 5 Call ZOLL and arrange to get a new electrode belt. See "Responding to Call ZOLL message" on page 4-15.



Receiving a siren alert with an *If Patient is Not Responsive* display message



⚠️ WARNING

If you receive an alert sound and are awake, always press both response buttons to prevent receiving a treatment. If you fail to press both response buttons, you will get a treatment, which may result in serious injury or death.

Only the patient should press the response buttons. The patient's ability to press both response buttons lets the LifeVest WCD know whether or not the patient is conscious and is critical in deciding when to give the patient a treatment. If anyone other than the patient presses the response buttons, needed therapy may not be delivered, which may result in serious injury or death.

If a treatment is delivered while your heart is beating normally, the treatment may cause an abnormal heart rhythm to occur. There is a small possibility that the abnormal heart rhythm may not be detected and may result in serious injury or death. If you get an alert sound and you are awake, press and release both response buttons to prevent receiving a treatment. If you fail to press and release both response buttons, you will get a treatment, which may result in serious injury or death.

If you (the patient) are awake and feel OK and you get this message:



- Press and release both 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 LifeVest WCD.
- **If you continue to get this message, call ZOLL immediately at 1-800-543-3267.**

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

Voice prompts and messages will alert bystanders to call for help.

Receiving a gong alert

If you get a gong alert, there is something that needs attention. The gong alert is accompanied by a message on the LifeVest WCD screen, and the monitor indicator light illuminates.

When you hear the gong alert:

1. Read the message on the monitor's display.
2. Consult the following subsections for information on what the message means and how to respond.

Responding to electrode belt problem message



This screen shows which round electrodes are causing problems.

The icons help you to determine the problem.

You may get any combination of these icons:



Good signal: Situation normal, no action required.



Round electrode off skin: Round electrode is not making good contact with skin.



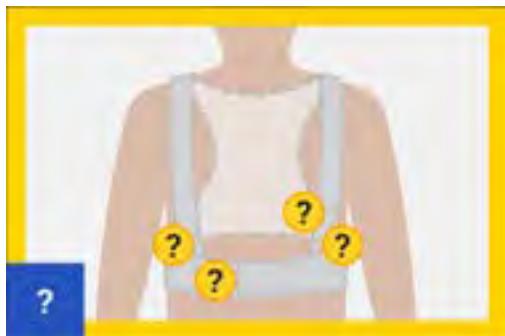
Poor signal: Could be muscle noise, electrical noise, weak signal, lost signal, or interference.

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

- The round electrodes indicated by the yellow or red icons are touching the skin.
- Nothing is between the round electrodes and the skin, such as clothing or one of the cables.
- Garment and electrode belt fit snugly, with the round electrodes pressing against the skin.
- You have cared for the LifeVest WCD system correctly. See “Cleaning the LifeVest® WCD system” on page 3-43.
- **If problems continue, call ZOLL at 1-800-543-3267.**

Tap **OK** to return to normal operation.

Responding to check electrodes message



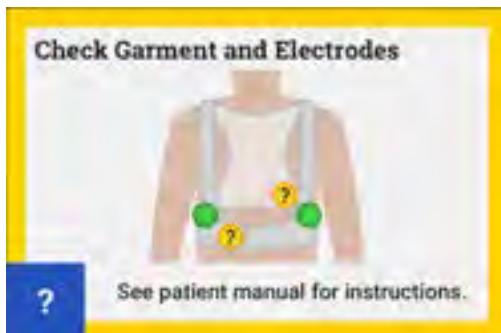
This screen displays when there may be a problem with the signal from the round electrodes.

If you get this message and you are conscious and feel OK, make sure:

- All four round electrodes are touching the skin, not flipped over or pulled away from the skin.
- Nothing is between the round electrodes and the skin, such as clothing or one of the cables.
- Garment and electrode belt fit snugly, with the round electrodes pressing against the skin.
- Electrode belt cable is securely connected to the monitor.

If you continue to get this message, call ZOLL immediately at 1-800-543-3267.

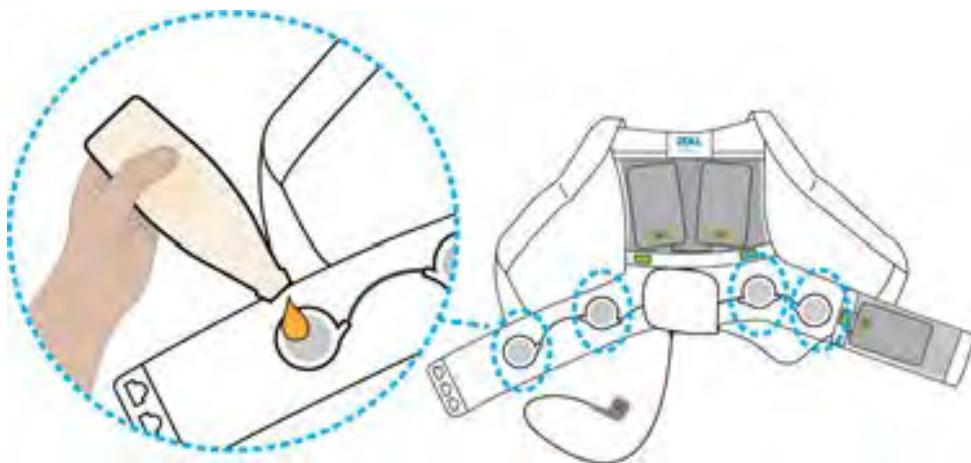
Responding to *Check Garment and Electrodes* message



After you get a number of electrode belt problem messages, 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 Remove the battery. See “Charging and changing batteries” on page 3-15.
- 2 Disconnect the electrode belt from the monitor. See “Disconnecting the electrode belt from the monitor” on page 3-35.
- 3 Take off the garment and make sure that nothing is covering the metal surfaces of the round electrodes.
- 4 Put a very small amount of unscented lotion on the metal surface of each round electrode, not on the therapy pads.



- 5 Put the garment on and connect the electrode belt to the monitor.
- 6 Insert the battery into the monitor.

If problems continue, call ZOLL at 1-800-543-3267.

Responding to therapy pad problem message



This screen displays when the therapy pads are not making good contact with the 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 icon.

The icons help you to determine the problem:

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

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

If you get red icons, make sure:

- Therapy pads and silver fabric pockets are pressing against your skin. See “Putting on the assembled electrode belt and garment” on page 3-28.
- Garment and electrode belt fits snugly. If the garment seems loose, make sure you are washing and drying the garment every 1 or 2 days as described in “Garment care” on page 3-45.
- Therapy pads are inserted correctly into their pockets, with the silver sides (with the green labels) facing the silver fabric pockets. See “Assembling the electrode belt to the garment” on page 3-22.
- **If problems continue, call ZOLL at 1-800-543-3267.**

Tap **OK** to return to normal operation.

Responding to *Add Gel to Therapy Pads* message

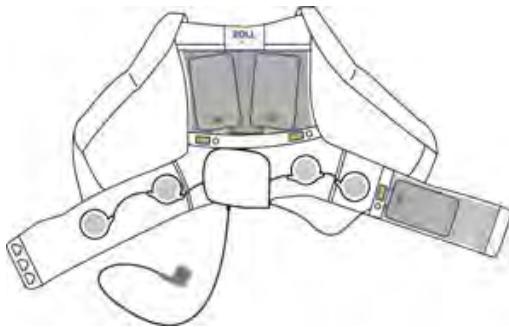


After you receive a treatment to correct an abnormal heart rhythm, you may see this message telling you to add gel.

Add Blue™ gel to the therapy pads or replace the electrode belt.

To add Blue™ gel:

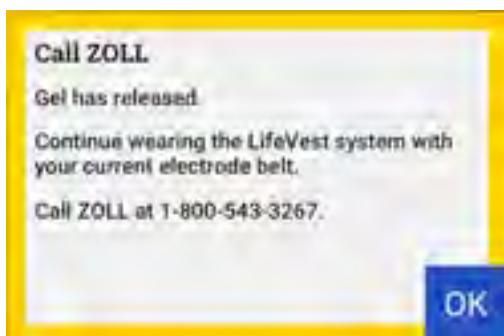
- 1 Locate the packets of Blue gel you got with the LifeVest WCD system.
- 2 Remove the battery from the monitor.
- 3 Remove the garment from your body.
 - Leave the therapy pads in the pockets.



- 4 Apply one half of a Blue gel packet onto the silver fabric of the front therapy pad and each rear therapy pad.
 - Do not apply to the round electrodes.
 - Blue gel packets can be disposed of in your trash can.

- 5 Put on the garment with electrode belt. See “Putting on the assembled electrode belt and garment” on page 3-28 for details.
 - Ensure there is no Blue gel on the left side of your body between the front and rear therapy pads. Blue gel should not extend between the two areas.
- 6 Insert the battery into the monitor and follow the normal startup routine. “Daily routine and normal startup” on page 3-1.

Responding to *Call ZOLL* message



After Blue™ gel is released, you may see this message telling you to call ZOLL. Call ZOLL at 1-800-543-3267.

- 1 Continue to wear the LifeVest WCD system unless your health care professional tells you otherwise.
 - Leave the electrode belt connected to the monitor. Do not remove the electrode belt or garment.
 - Leave the battery in the monitor. Continue to change and recharge the batteries as normal.
 - Leave Blue gel under the therapy pads. Do not wipe them dry.
- 2 Call your health care professional's emergency number immediately to report your treatment.
- 3 Tap **OK** to resume normal monitoring.
- 4 Check the display for any messages and take the action indicated.
- 5 Call ZOLL and arrange to get a new electrode belt.

Responding to *Too Much Gel, Clean Skin* message



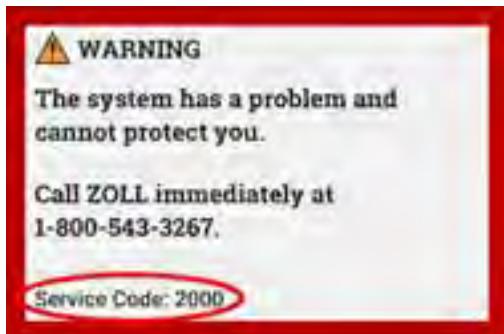
After you receive a treatment or after you add Blue™ gel to the therapy pads, you may see this message telling you there is too much Blue gel on your skin.

Remove excess Blue gel.

To remove excess Blue™ gel:

- 1 Remove the battery from the monitor.
- 2 Keep the electrode belt and garment on your body.
- 3 Use a towel or soft cloth to wipe the skin on your left side between the front and rear therapy pads.
 - Blue gel should not extend between the front and rear therapy pads.
 - Do not remove Blue gel under the therapy pads.
- 4 Insert the battery into the monitor and follow the normal startup routine. “Daily routine and normal startup” on page 3-1.

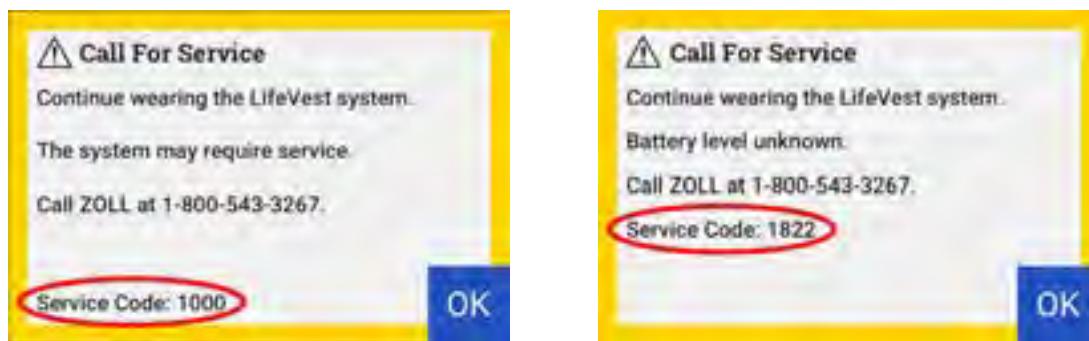
Responding to **WARNING** message



System has a severe service problem.
You cannot use the LifeVest WCD.

You must write down the Service Code number and call ZOLL immediately at 1-800-543-3267.

Responding to *Call For Service* message

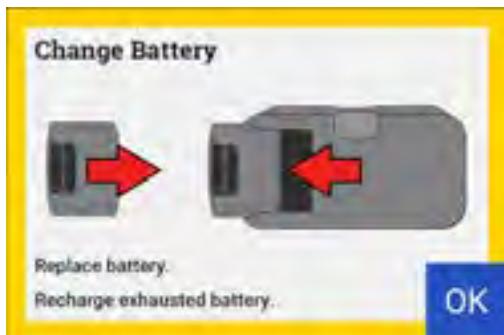


System has a problem that requires service. Continue to use the system, and change and recharge battery as normal.

You must write down the Service Code number and call ZOLL at 1-800-543-3267.

Tap **OK** to return to normal operation.

Responding to *Change Battery* message



Battery needs to be changed.

Change to a fully charged battery and place discharged battery into the charger. See “Charging and changing batteries” on page 3-15.

Tap **OK** to return to normal operation.

Responding to *Electrode Belt Not Connected* message

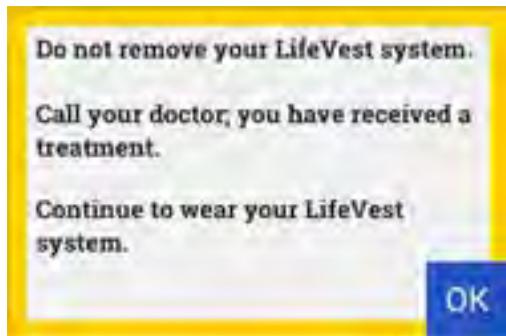


Electrode belt is not connected to monitor.

Connect the electrode belt to the monitor.

See “Connecting the electrode belt to the monitor” on page 3-32.

Responding to *Do not remove your LifeVest® system* message



You have received a treatment.

Call your health care professional's emergency number immediately.

Continue to wear your LifeVest WCD as normal.

Leave the electrode belt connected to the monitor. If necessary, change the battery as you normally would.

Follow instructions about what to do after receiving a treatment in "After receiving a treatment" on page 4-5.

Tap **OK** to return to normal operation.

Responding to *Press Response Buttons* message



You are to press both response buttons to test their function every time the battery is installed.

Press both response buttons as a reminder of what to do when a siren alert sounds.

Responding to *Release Response Buttons* message

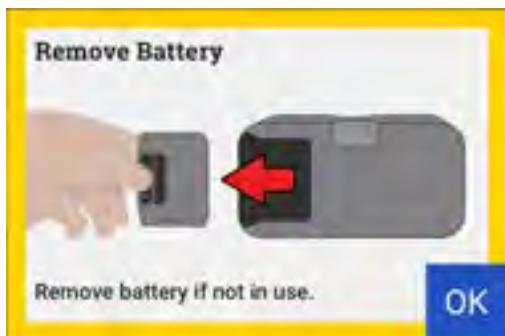


This message may appear at startup. You may be holding both response buttons instead of pressing and releasing them.

Release both response buttons.

If you are not holding both response buttons, call ZOLL immediately at 1-800-543-3267.

Responding to *Remove Battery* message



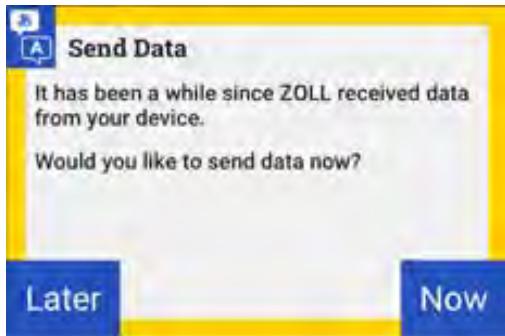
This message appears if the battery has been left in the monitor when not in use.

If you are not wearing the LifeVest WCD, tap **OK** and remove the battery from the monitor.

If you are wearing the LifeVest WCD, make sure the battery is firmly inserted into the monitor and check the electrode belt connection.

If you continue to get this message with the battery fully inserted, call ZOLL immediately at 1-800-543-3267.

Responding to *Send Data* message



The monitor has data that has not been transmitted for some time. This does not affect the device's ability to treat you.

Data should be sent manually as soon as possible. See "Sending data manually" on page 6-4.

5: Performing activities

This section provides information about using the activities options on the LifeVest WCD system including:

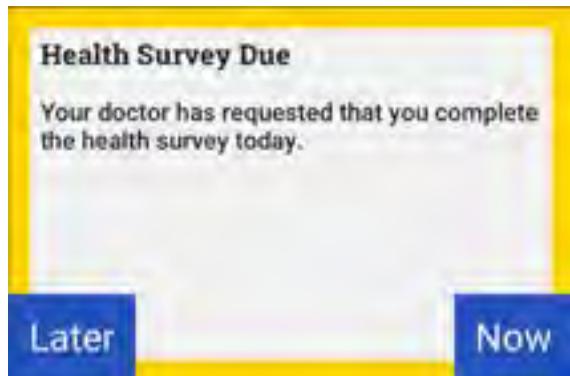
- Health survey activity
- WalkTest® activity

5: Performing activities

Note: If your health care professional did not request the activities options on your LifeVest WCD, you will not be able to access these options.

If enabled, the activities options allow the LifeVest WCD to provide some additional information to your health care professional. Your health care professional may then use that information to help evaluate your condition.

Health survey activity



If the *Health Survey Due* message displays, you should take the health survey.

You may tap **Later** to take the health survey later. When ready, see “Taking a delayed health survey” on page 5-5.

The health survey is one of the ways the LifeVest WCD can gather information about your condition. While wearing the LifeVest WCD, you may get requests to take a health survey. Your health care professional determines whether you receive these requests.

During the health survey, a series of questions is displayed. It is very important you answer these questions honestly. The health survey should take no more than 10 minutes. Continue wearing the LifeVest WCD throughout this process.

During the next scheduled data upload, the LifeVest WCD sends your health survey information to the cloud where ZOLL’s remote data management system allows your health care professional to review the results.

It is important that you wear the LifeVest WCD the entire time that you are taking the health survey so it can monitor and protect you.

If you have any questions, please contact your health care professional.

To take the health survey immediately when you receive the *Health Survey Due* message, see "Taking the health survey" below.

To take it another time, when ready, see "Taking a delayed health survey" on page 5-5.

Taking the health survey

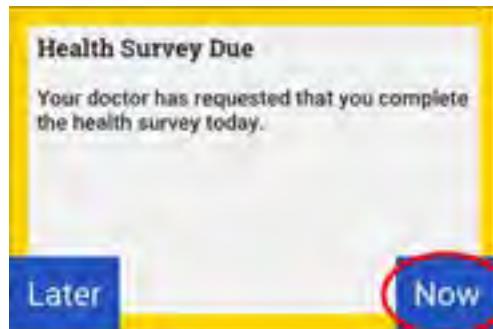
ZOLL suggests you read through all the steps below before you answer the questions for the first time. Your health care professional decides which questions you are to answer.

Note: The questions and answers shown in these instructions may not be the questions and answers you will see on your LifeVest WCD.

To take the health survey:

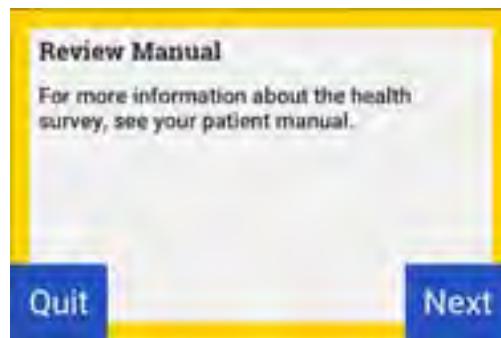
- 1 On the **Health Survey Due** screen, tap **Now**.

If you want to take the health survey later, tap **Later**. When ready, see "Taking a delayed health survey" on page 5-5.

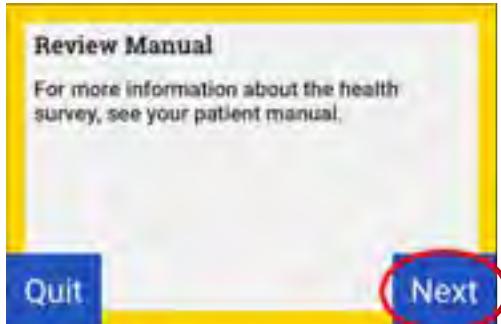


The **Review Manual** screen for the health survey displays.

- 2 Read the message on the screen, and perform any actions before continuing.

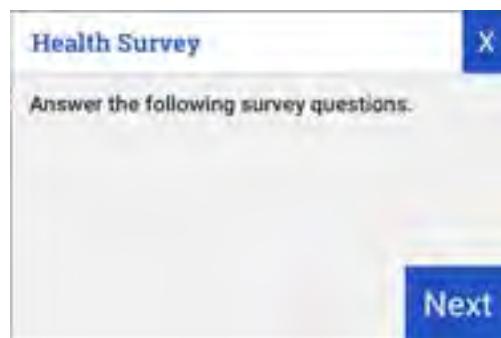


- 3 Tap **Next**.

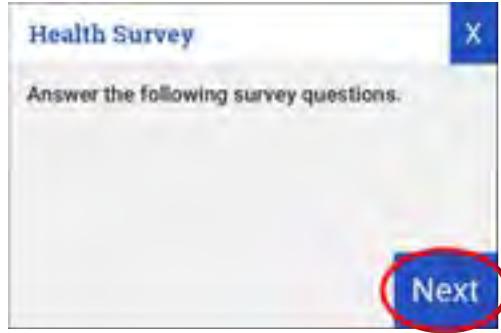


The **Health Survey** screen displays.

- 4 Read the message on the screen.



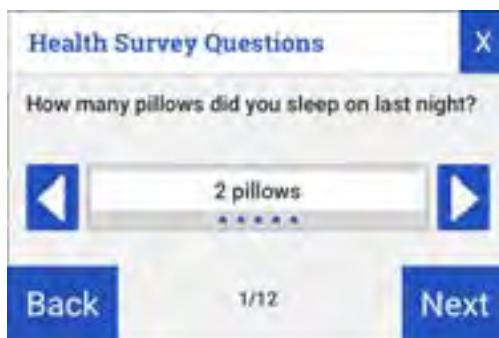
- 5 Tap **Next**.



The **Health Survey Questions** screen displays.

6 Read the question.

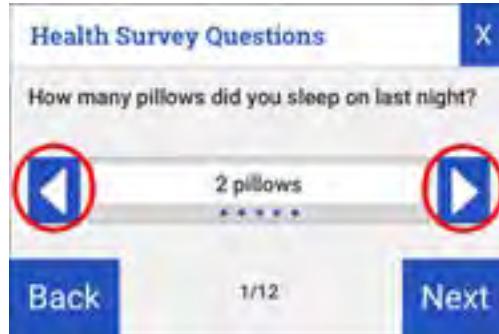
Note: You can tap the screen to hear the audio of the text.



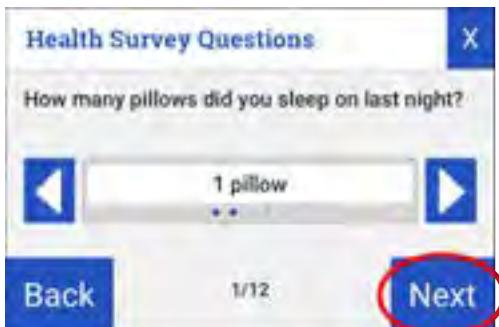
7 Select the answer that most closely describes your situation or the way you feel.

If necessary, tap the arrows to select your answer.

Note: You can tap the screen to hear the audio of the text.

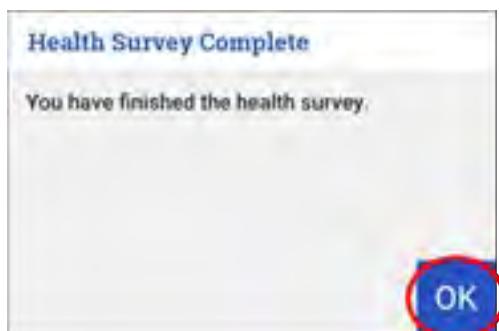


8 Tap **Next**.



9 Continue to answer the questions in the health survey.

10 When the **Health Survey Complete** screen displays, the health survey is complete. Tap **OK**.



Taking a delayed health survey

Follow this procedure if you chose **Later** on the **Health Survey Due** screen.

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

- 1 On the monitor, tap **Menu**.

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



The **Patient Menu** screen displays.

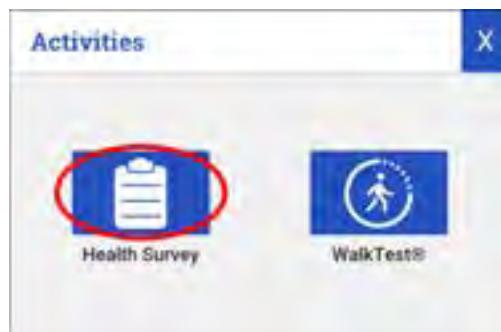
- 2 Tap **Activities**.

Note: If your health care professional did not request that you take any of the activities, you will not see the Activities option on your screen.



The **Activities** screen displays.

- 3 Tap **Health Survey**.



The **Review Manual** screen for the health survey displays.

See “Taking the health survey” on page 5-2 starting at step 2 for the rest of this process.

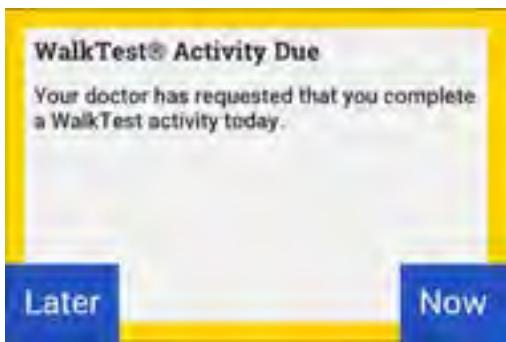
WalkTest® activity

WARNING

When you are performing a WalkTest® session, do not continue if the monitor broadcasts an alert sound. Stop and press and release both response buttons. If you continue, you may be at risk for a sudden cardiac arrest, which may result in serious injury or death.

When performing a WalkTest session, do not continue if you experience symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop and sit or lie down. If the symptoms continue or get worse, immediately call your health care professional or emergency help. If you continue or ignore the symptoms, you may be at risk for a sudden cardiac arrest or other health problems, which may result in serious injury or death.

When you are performing a WalkTest® session, do not continue if the monitor broadcasts an alert sound. Stop and press and release both response buttons. If you continue, you may be at risk for a sudden cardiac arrest, which may result in serious injury or death.



If the *WalkTest® Activity Due* message displays, you should perform the WalkTest activity.

You may tap **Later** to perform the WalkTest activity later. When ready, see “Performing a delayed WalkTest® session” on page 5-16.

The WalkTest activity is one of the ways to use the LifeVest WCD to gather information about your condition. While wearing the LifeVest WCD, you may get requests to perform a WalkTest activity. Your health care professional determines whether you receive these requests.

Note: If you have any movement issues, or if you have an abnormal gait

(such as foot dragging, shuffling, or limping), or if you need assistance while moving (such as by using a cane, walker, or crutches), please tell your health care professional as it may produce inaccurate results.

During the WalkTest activity, you will be asked a series of questions, directed to perform a WalkTest session while the LifeVest WCD monitors your heart and counts your steps, and then asked the same series of questions after the WalkTest session. It is very important you answer the questions honestly, choosing the answer that most closely describes how you feel at that moment. The WalkTest activity should take no more than 10 minutes. If possible, have someone with you while you perform the WalkTest activity. Continue wearing the LifeVest WCD throughout this process.

During the WalkTest session, the LifeVest WCD monitors your heart and counts your steps. Try to move at a pace you feel you can comfortably maintain for the six-minute session. Do not run or jog. You should wear comfortable shoes, and perform the WalkTest activity on a flat, level, preferably hard surface in a clear, unobstructed area. Do not use a treadmill. If you are prompted to perform multiple WalkTest sessions, perform them in the same place, the same way for the most accurate results. Do not listen to music, talk on the phone, or engage in any other activity that might distract you while performing the WalkTest activity. It is OK if you need to stop and rest at any time. After resting, continue the WalkTest session when you are able.

While you are performing a WalkTest session, the monitor voice prompts inform you of how much time remains in the session. It will also prompt you to stop. Stop when the monitor prompts you to.

During the next scheduled data upload, the LifeVest WCD sends your WalkTest activity information to the cloud where ZOLL's remote data management system allows your health care professional to review the results.

It is important that you wear the LifeVest WCD the entire time that you are performing the WalkTest activity so it can monitor and protect you.

If you have any questions, please contact your health care professional.

To perform the WalkTest activity immediately when you receive the *WalkTest® Activity Due* message, see “Performing the WalkTest® activity” on page 5-10.

To perform it another time, when ready, see “Performing a delayed WalkTest® session” on page 5-16.

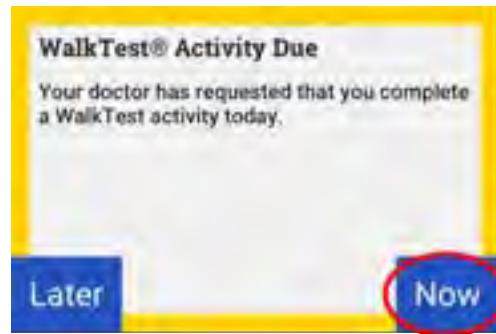
Performing the WalkTest® activity

To perform a WalkTest activity:

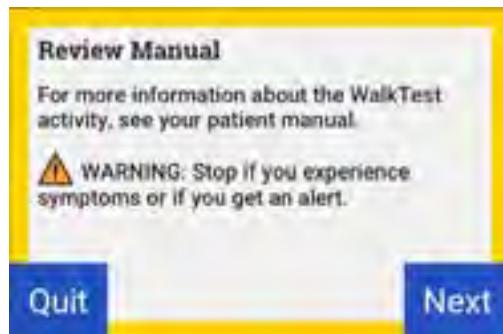
- 1 On the **WalkTest Activity Due** screen, tap **Now**.

If you want to complete the WalkTest activity later, tap **Later** to return to normal operation. When ready, see “Performing a delayed WalkTest® session” on page 5-16.

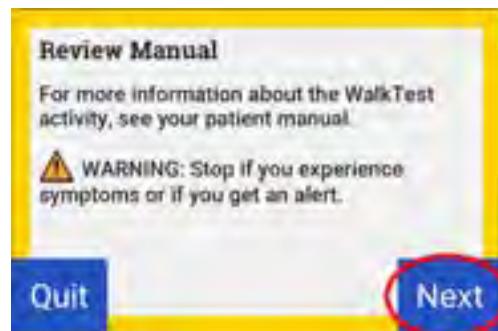
You will be prompted to complete the WalkTest activity at a later time if you do not complete on your own.



- 2 Read the message on the screen, and perform any actions before continuing.

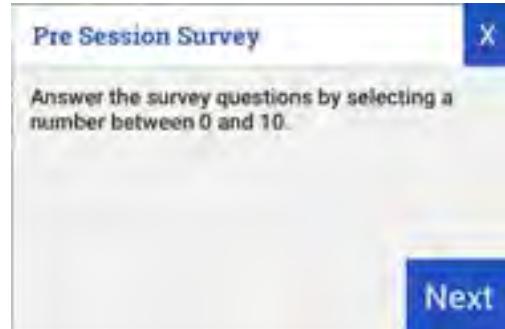


3 Tap **Next**.

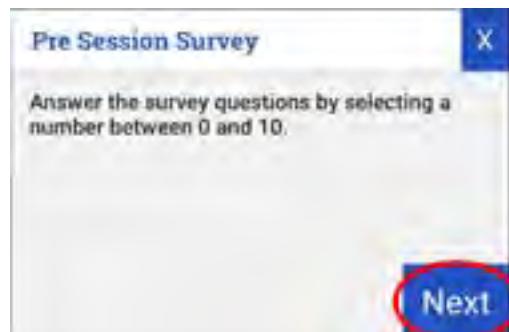


The **Pre Session Survey** screen displays.

4 Read the message on the screen.



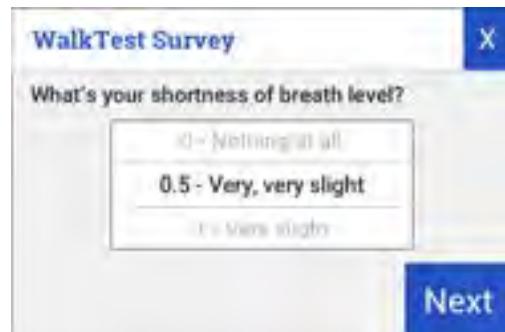
5 Tap **Next**.



The **WalkTest Survey** screen displays.

6 Read the question.

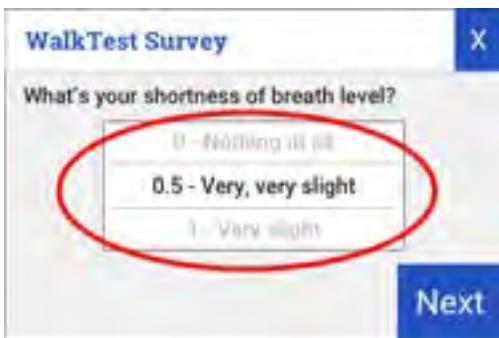
Note: You can tap the screen to hear the audio of the text.



7 Select the answer that most closely describes your situation or the way you feel.

If necessary, use your finger to scroll through the answers.

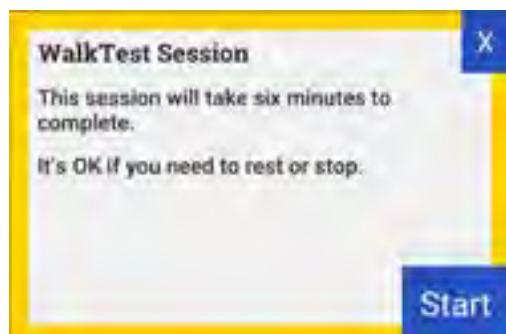
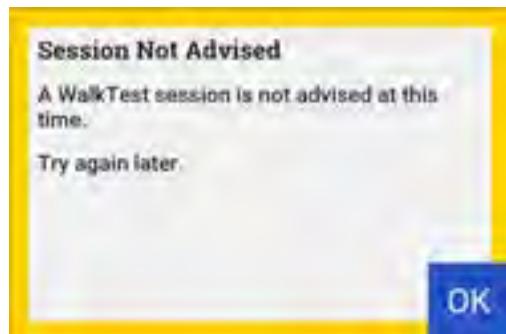
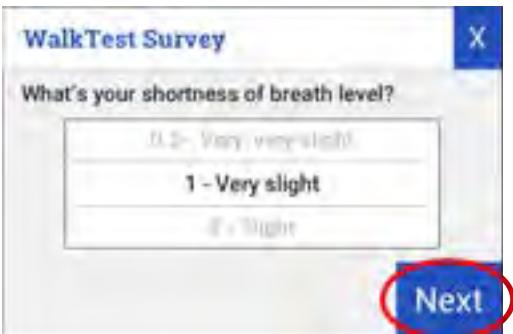
8 Tap **Next**.



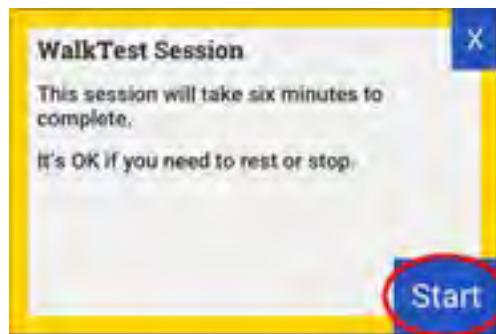
9 Continue to answer the questions in the WalkTest survey.

Note: If you receive the Session Not Advised message, you cannot proceed with this WalkTest session. At a later time, you will be asked to complete another WalkTest session.

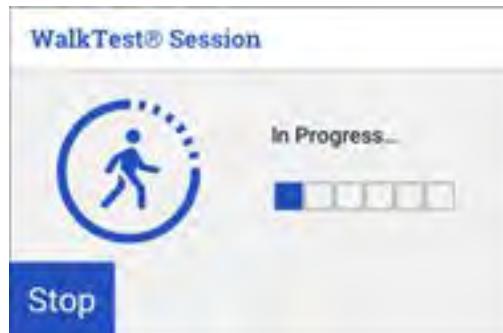
10 Read the message on the screen



- 11 If you are ready to start the WalkTest session, tap **Start**.



The **WalkTest Session** progress screen displays, and a voice will prompt you to start the WalkTest session.

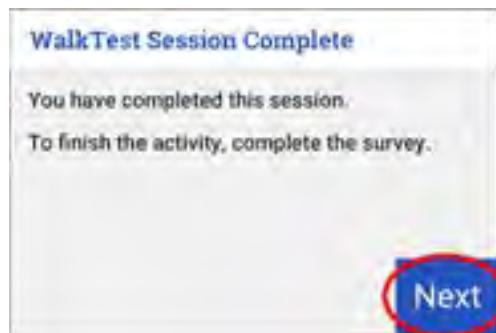


- 12 Continue for 6 minutes.

The progress bar shows how far you are in the WalkTest session.

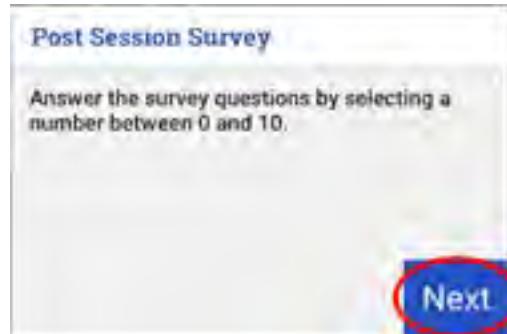
If you need to cancel the WalkTest session, tap **Stop**. At a later time, you will be asked to complete another WalkTest session.

- 13 When the **WalkTest Session Complete** screen displays, the WalkTest session is complete. Tap **Next**.



The **Post Session Survey** screen displays.

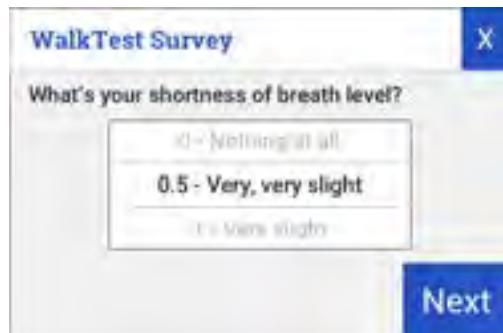
14 Read the message on the screen. Tap **Next**.



The **WalkTest Survey** screen displays.

15 Read the question.

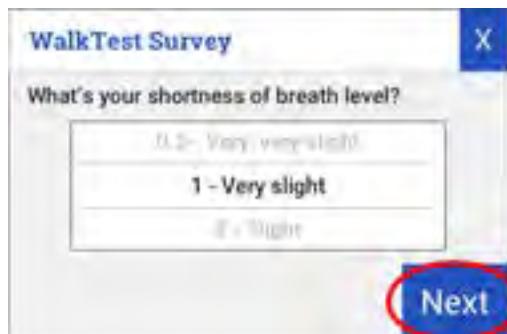
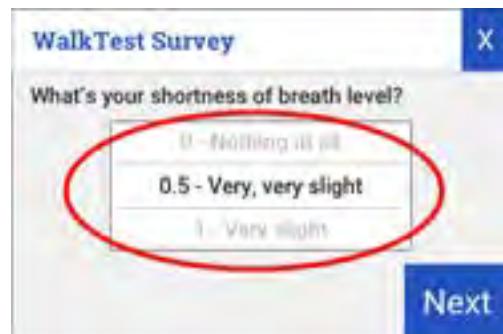
Note: You can tap the screen to hear the audio of the text.



16 Select the answer that most closely describes your situation or the way you feel.

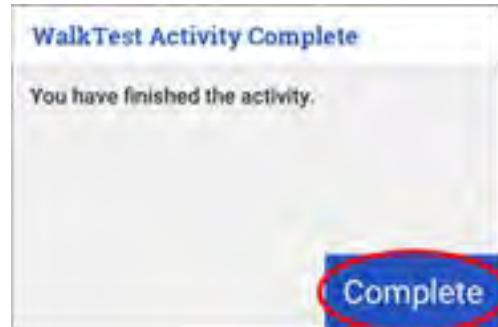
If necessary, use your finger to scroll through the answers.

17 Tap **Next**.



18 Continue to answer the questions in the WalkTest survey.

19 When the **WalkTest Activity Complete** screen displays, the WalkTest session is complete. Tap **Complete**.



Performing a delayed WalkTest® session

Follow this procedure if you chose **Later** on the **WalkTest® Activity Due** screen.

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

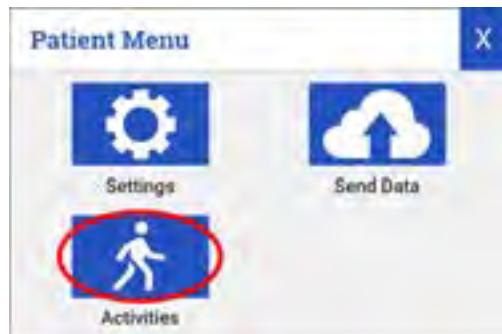
- 1 On the monitor, tap **Menu**.

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

The **Patient Menu** screen displays.

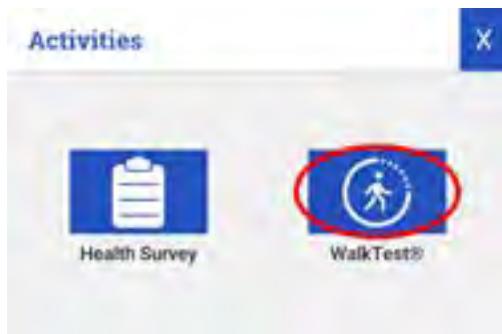


- 2 Tap **Activities**.



The **Activities** screen displays.

- 3 Tap **WalkTest®**.



The **Review Manual** screen displays.

See “Performing the WalkTest® activity” on page 5-10 starting at step 2 for the rest of this process.

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6: Using the monitor's functions

This section provides information about the other functions of the LifeVest WCD system including:

- Manually recording your heart rhythm
- Sending data to ZOLL
- Receiving updates to settings
- Configuring help screen audio options
- Enabling and disabling airplane mode

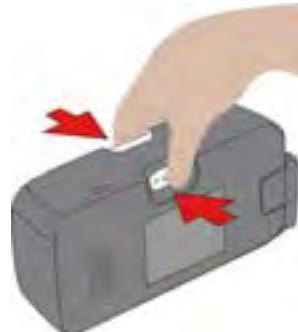
6: Using the monitor's functions

Manually recording your heart rhythm

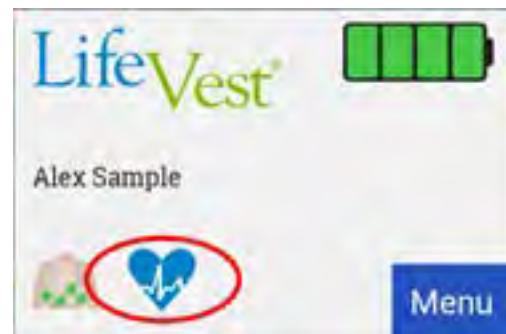
At times, you may want to record your heart rhythm for your health care professional to review. Recording your heart rhythm should take about 15 seconds. Recordings include data 30 seconds prior to buttons being pressed plus 15 seconds of real-time data.

To record your heart rhythm:

- 1 Press and hold both response buttons at the same time.



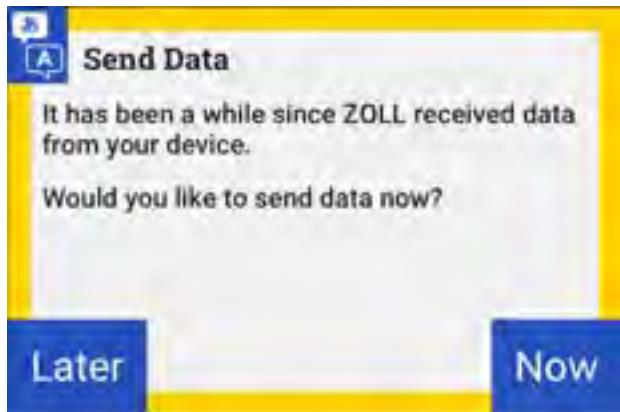
- 2 Release both response buttons when you see the heart rhythm recording icon and hear a single gong.



When the recording is complete, the heart rhythm recording icon is no longer displayed.

Sending data and receiving updates to settings

There may be times you need to send data, such as activity information and heart rhythm data, for your health care professional to review. You may also need to receive an update to settings on your LifeVest WCD from ZOLL.



If the **Send Data** message displays, you should send data.

You may tap **Later** to send data later. When ready, see “Sending data manually” on page 6-4.

Continue wearing the LifeVest WCD throughout this process.

Reading signal strength indicator

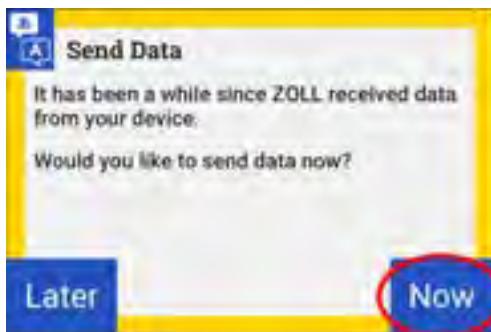
Data is sent either from the monitor to a cell tower or from a cell tower to the monitor. Indicators on the monitor show the strength of the cellular signal.

Symbol	What it means	What to do
	<p>The LifeVest WCD is connected to a cellular network.</p> <p>Signal strength is shown by the number of bars on the bottom right corner of certain screens. The more bars, the better.</p>	<p>To get a stronger signal, try moving the monitor to a different part of the house, possibly to a higher location or near a window.</p>
	<p>The LifeVest WCD is not connected to a cellular network.</p> <p>You may see this symbol until the LifeVest WCD finds a signal. That is normal.</p>	<p>If you get this symbol all the time, try relocating the monitor to another part of the house in order to get a signal.</p> <p>If you continue to see this symbol, call ZOLL at 1-800-543-3267.</p>

Sending data manually

To send data manually:

- 1 On the **Send Data** screen, tap **Now**.



- 2 The **Connecting** screen displays.



- 3 When the process starts, the monitor shows that data is being sent.

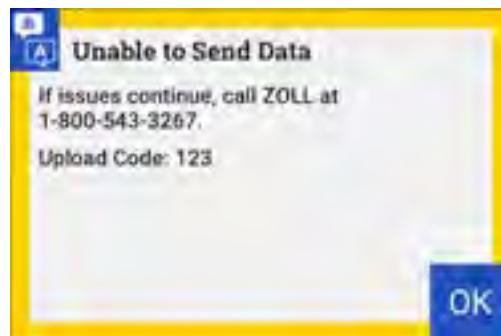
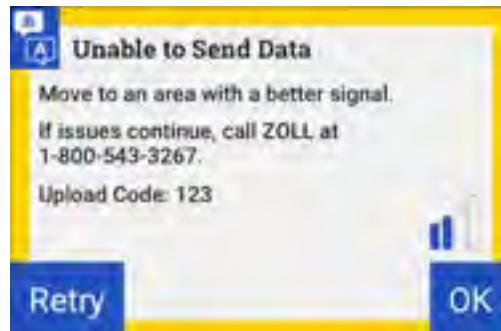


- 4 The monitor shows when the data transfer is complete.



5 If the monitor is unable to send data, one of the **Unable to Send Data** screens displays. Tap **Retry**, and try again, or Tap **OK**.

If you continue to have a problem sending data, call ZOLL at 1-800-543-3267.



Sending delayed data

Follow this procedure if you chose **Later** on the Send Data screen.

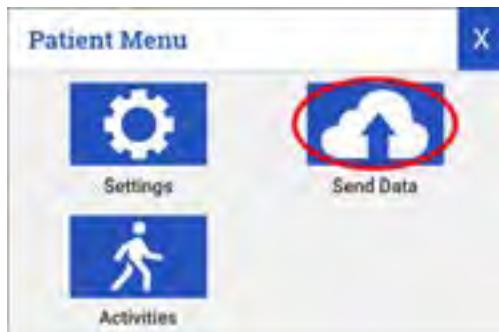
- 1 On the monitor, tap **Menu**.

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



The **Patient Menu** screen displays.

- 2 Tap **Send Data**.



The **Connecting** screen displays.



When the process starts, the monitor shows that data is being sent.

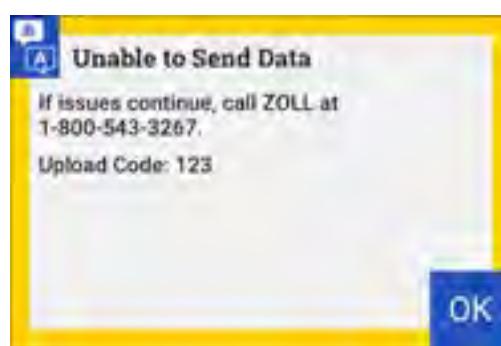
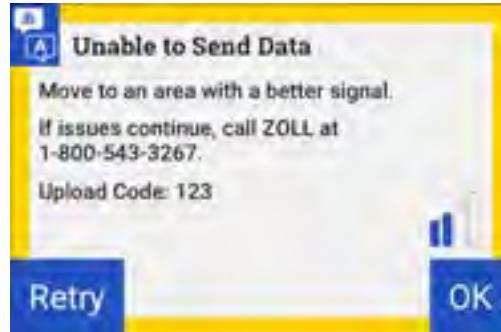


The monitor shows when the data transfer is complete.



If the monitor is unable to send data, one of the **Unable to Send Data** screens displays. Tap **Retry**, and try again, or Tap **OK**.

If you continue to have a problem sending data, call ZOLL at 1-800-543-3267.



Configuring help screen audio options

You can change the mode and volume of the help screen audio.

The mode sets how the help screen text is spoken. See “Changing the help screen audio mode” on page 6-11.

You can change the volume of spoken messages. This does not affect the volume of the treatment prompts, which are always delivered at full volume. To change the volume of the help screens, see “Changing the help screen audio volume” on page 6-9.

Changing the help screen audio volume

To change the help screen audio volume:

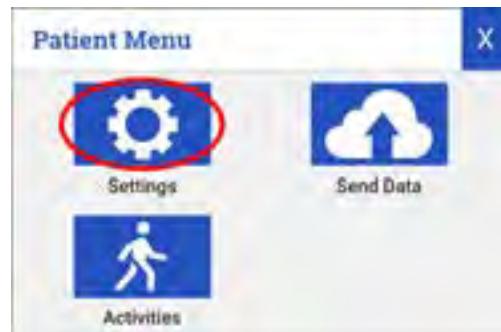
- 1 On the monitor, tap **Menu**.

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



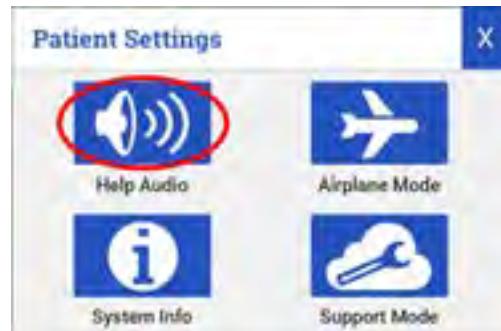
The **Patient Menu** screen displays.

- 2 Tap **Settings**.



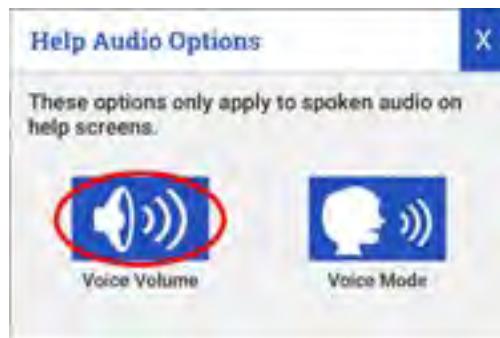
The **Patient Settings** screen displays.

- 3 Tap **Help Audio**.



The **Help Audio Options** screen displays.

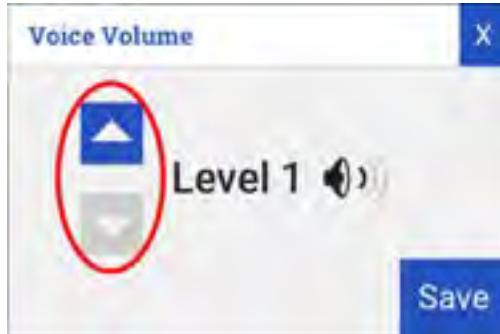
4 Tap Voice Volume.



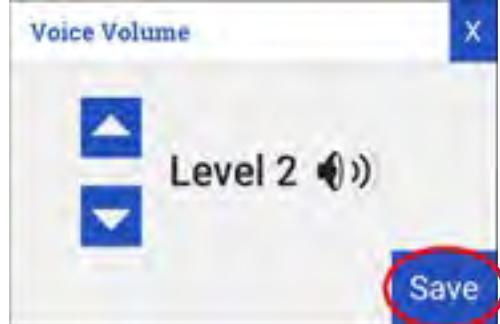
The Voice Volume screen displays.

5 Tap the up or down arrows to select the desired volume level.

Note: Level 3 is the loudest.



6 When the desired volume level is selected, tap Save.



The volume level is saved.

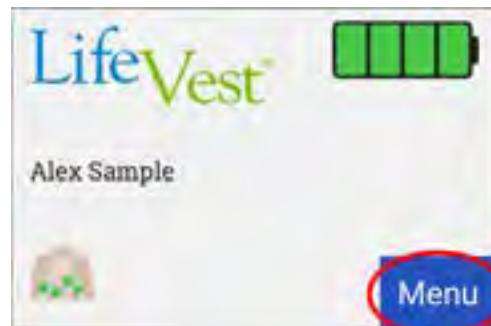
Changing the help screen audio mode

You can set the LifeVest WCD help screen audio to speak the help text when the help screen displays, when you tap the help screen, or not at all.

To change the help screen audio mode:

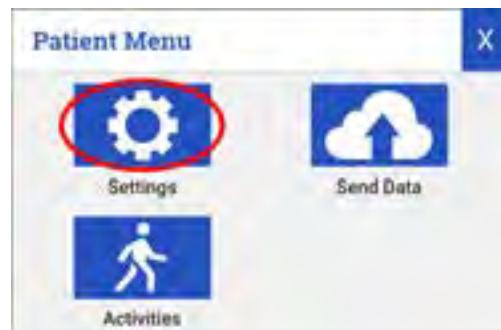
- 1 On the monitor, tap **Menu**.

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



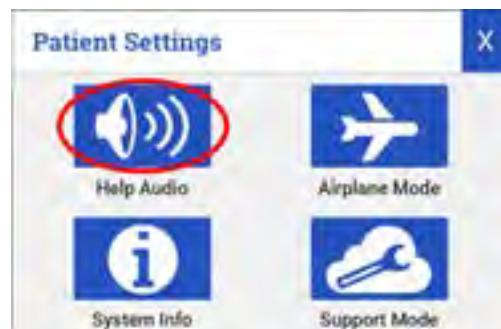
The **Patient Menu** screen displays.

- 2 Tap **Settings**.



The **Patient Settings** screen displays.

- 3 Tap **Help Audio**.



The **Help Audio Options** screen displays.

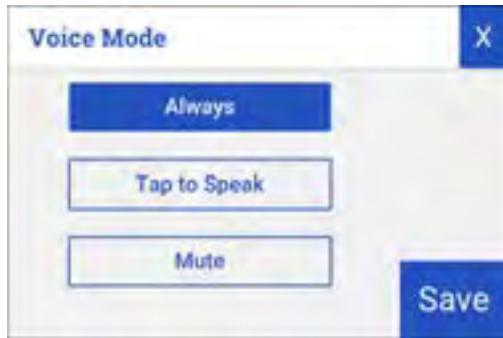
4 Tap Voice Mode.



The Voice Mode screen displays.

5 Tap the desired mode.

- **Always:** Audio automatically speaks the help text every time you enter a help screen.
- **Tap to Speak:** Audio speaks the help text when you tap the text area of the help screen.
- **Mute:** Audio does not speak the text with the help screens.



6 Tap Save.



The mode is saved.

Changing the LifeVest® WCD audio language

Note: This functionality is only available if there is a secondary language available on your LifeVest WCD.

If a secondary language is available on your LifeVest WCD, you will see

the Translate button  displayed in the upper left corner of help screens. Tap this button to temporarily change the language of the help screen and the spoken text.

Enabling and disabling airplane mode

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

Note: If you remove and reinsert the battery when airplane mode is enabled, upon startup airplane mode is automatically disabled. After startup, enable airplane mode again if necessary.

Enabling airplane mode

To enable airplane mode on the LifeVest WCD:

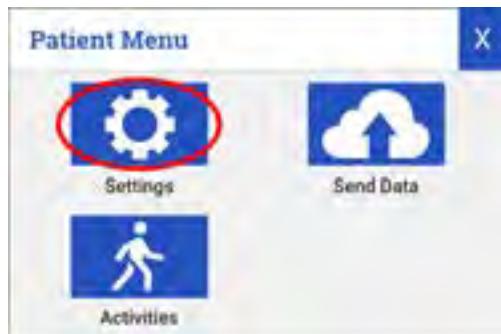
- 1 On the monitor, tap **Menu**.

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



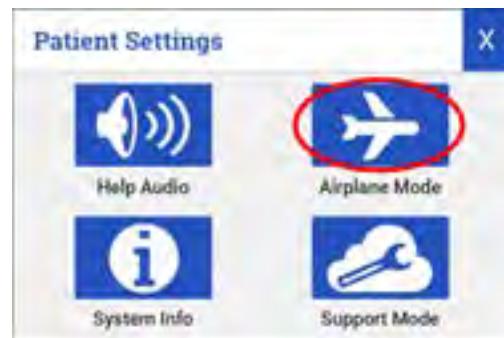
The **Patient Menu** screen displays.

- 2 Tap **Settings**.



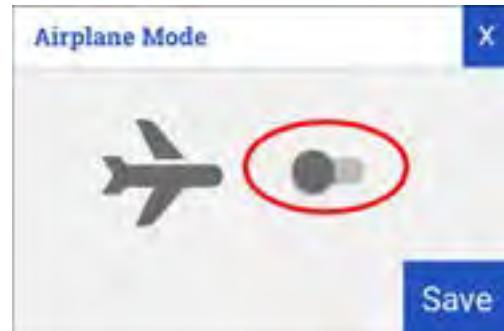
The **Patient Settings** screen displays.

3 Tap Airplane Mode.

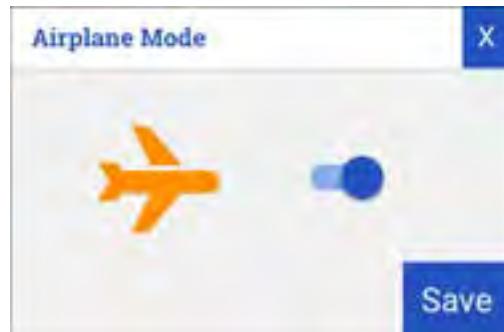


The Airplane Mode screen displays.

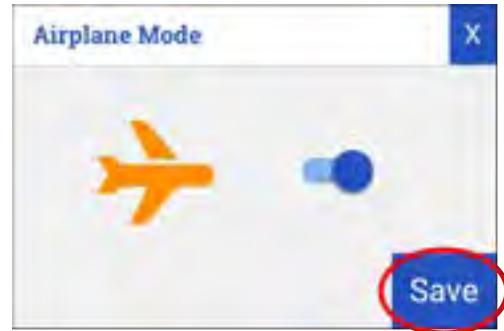
4 Tap the toggle switch to enable airplane mode.



The airplane mode indicator switches to on, and the airplane's color changes to orange.



5 Tap Save.



Airplane mode is enabled. No signals are transmitted from LifeVest WCD. You are still protected.

The Home screen displays the airplane mode indicator when airplane mode is enabled.



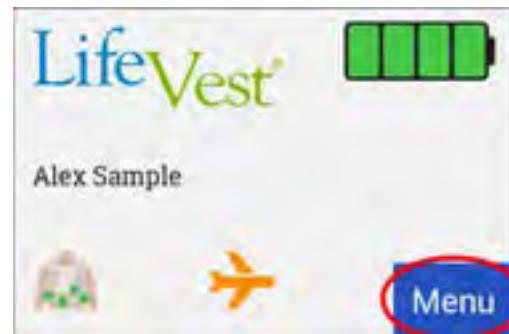
Disabling airplane mode

Note: If airplane mode was previously enabled, the monitor will automatically disable airplane mode the next time you change the battery.

To disable airplane mode manually on the LifeVest WCD:

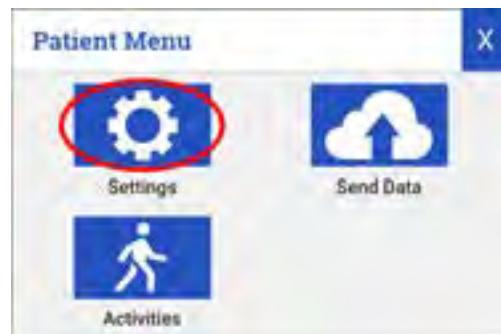
- 1 On the monitor, tap **Menu**.

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



The **Patient Menu** screen displays.

- 2 Tap **Settings**.



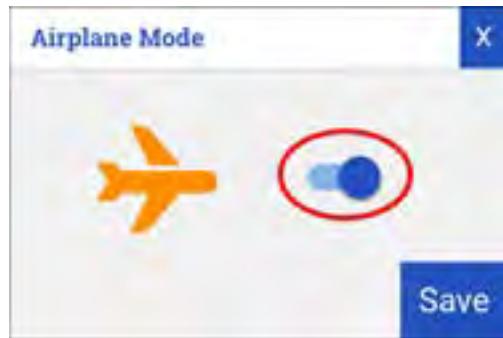
The **Patient Settings** screen displays.

- 3 Tap **Airplane Mode**.



The **Airplane Mode** screen displays.

4 Tap the toggle switch to disable airplane mode.



The airplane mode indicator switches to off, and the airplane's color changes to gray.



5 Tap **Save**.



Airplane mode is disabled. The device is able to transmit data again.

The Home screen does not display the airplane mode indicator.



Updating LifeVest® WCD settings using support mode

The support mode feature is not currently active.

ZOLL may reach out to you to update LifeVest WCD settings using support mode. Do not perform this process without assistance from ZOLL. Continue to wear the LifeVest WCD.

To update the LifeVest WCD settings, with assistance from ZOLL:

- 1 If you are able, ensure you are in a location with good cell coverage. This feature requires cell coverage. See “Sending data and receiving updates to settings” on page 6-2.

- 2 On the monitor, tap **Menu**.

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



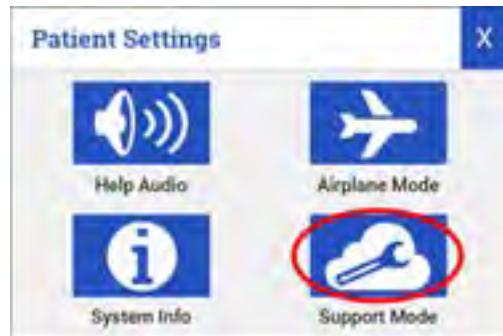
The **Patient Menu** screen displays.

- 3 Tap **Settings**.



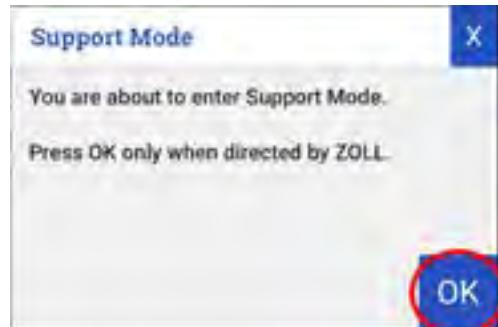
The **Patient Settings** screen displays.

4 Tap **Support Mode**.



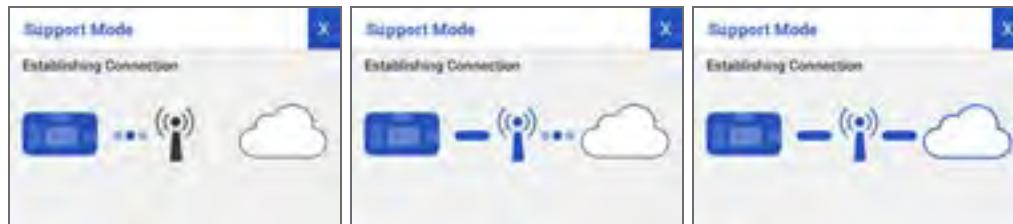
The **Support Mode** screen displays.

5 When directed to by ZOLL,
tap **OK**.

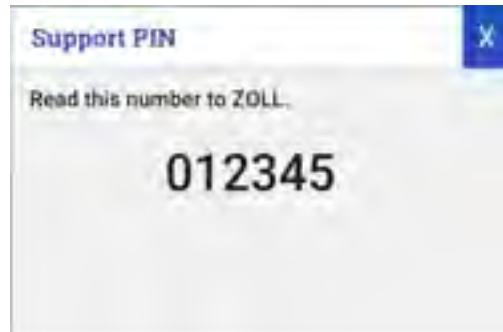


The **Support Mode** screen displays.

This screen displays the connection to ZOLL for the update.



Once the connection is established, the **Support PIN** screen displays.

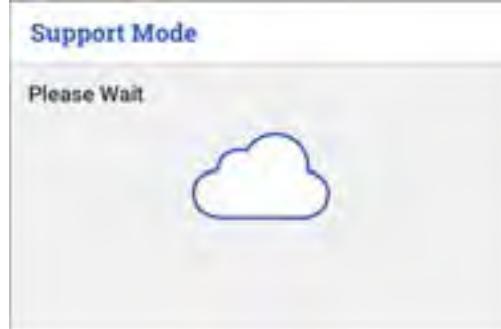


6 Read the number to ZOLL.

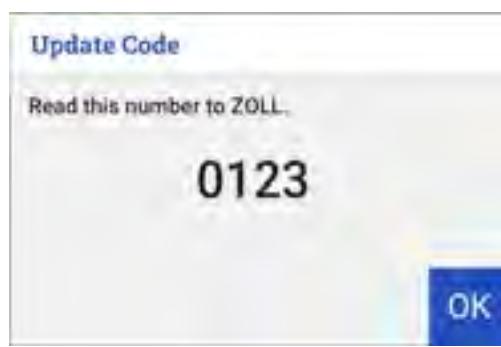
ZOLL uses this number to access your LifeVest WCD.



The update begins.



Once the update process is complete, the **Update Code** screen displays.



7 Read the number to ZOLL.

ZOLL uses this number to determine if the update was successful.

If the update was not successful, ZOLL instructs you what to do next, which may include repeating this process.



8 When directed to by ZOLL, tap **OK**.



The **Patient Settings** screen displays.

9 When directed to by ZOLL, tap the **Close** button on each screen until you return to the Home screen.



7: Ending use of the LifeVest® WCD system

This section provides information about what to do when ending use of the LifeVest WCD system.

7: Ending use of the LifeVest® WCD

WARNING

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

Two weeks before you are finished with the LifeVest WCD, call ZOLL and arrange to return the LifeVest WCD system. In the US and Canada, call 1-800-543-3267.

Do not dispose of the LifeVest WCD system. ZOLL will send packaging for the equipment and return instructions.

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

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8: Troubleshooting and FAQs

This section provides information about troubleshooting the LifeVest WCD system and addresses frequently asked questions you may have while using the LifeVest WCD.

8: Troubleshooting

Troubleshooting issues with no screen message

See “Understanding alerts” on page 4-1 if you received an alert with an on-screen message.

If you have problems with the LifeVest WCD and there is no message on the screen, consult the following chart to determine how to fix the problem.

Problem	Action
You cannot find the problem below	Continue to wear the LifeVest WCD.
OR	Call ZOLL immediately at 1-800-543-3267 to replace a defective monitor. System may require service.
You cannot resolve the issue with the actions below	
Monitor will not turn on (no display, no sounds, no illuminated indicator)	Ensure the battery is fully inserted into the monitor. The red line on the battery should not be visible. If the battery is fully inserted, exchange it with a fully charged battery, and recharge the depleted battery. See “Charging and changing batteries” on page 3-15.
	Remove and reinsert the battery, making sure to fully insert the battery. The red line on the battery should not be visible. See “Charging and changing batteries” on page 3-15.

Problem	Action
Cannot insert battery, or battery will not stay inserted	Try another battery. Call ZOLL immediately at 1-800-543-3267.
Cannot read display (shows random letters on screen or is otherwise unreadable)	Continue to wear the LifeVest WCD. Call ZOLL immediately at 1-800-543-3267 to replace a defective monitor.
Battery will not charge in charger	Unplug the charger and plug it back into the power outlet. Try a different power outlet. Check power supply connections. See “Charging and changing batteries” on page 3-15.
Data sending failure	Remove and reinsert the battery into the monitor. See “Charging and changing batteries” on page 3-15. If you are able, ensure you are in a location with good cell coverage. This feature requires cell coverage. See “Sending data and receiving updates to settings” on page 6-2. To get a stronger signal, try moving the monitor to a different part of the house, possibly to a higher location or near a window.

Problem	Action
Pressing the response buttons does not work	<p>Remove and reinsert the battery into the monitor. See “Charging and changing batteries” on page 3-15.</p> <p>Press the response buttons more firmly.</p> <p>If this problem persists, call ZOLL immediately at 1-800-543-3267.</p>
Vibration alert is not felt during startup	<p>Remove and reinsert the battery into the monitor. See “Charging and changing batteries” on page 3-15.</p> <p>Check the electrode belt connection to the monitor. See “Connecting the electrode belt to the monitor” on page 3-32.</p>

Frequently asked questions

When am I protected?

As long as you are wearing the LifeVest WCD, the battery is inserted, the garment with electrode belt is on your body correctly, the electrode belt is connected to the monitor, and the monitor is on, you are protected from sudden cardiac arrest.

See “Using the LifeVest® WCD” on page 3-1.

How many garments do I get and when do I get them?

Two. You receive one during the fitting. A second garment is shipped to the address confirmed during your fitting within 2 to 3 days of your fitting.

How do I put the LifeVest WCD together and put the garment on?

See “Wearing the LifeVest® WCD” on page 3-5.

What do I do if the garment feels too loose?

Fasten the garment on the tightest clasp setting. If the garment is still too loose, **call ZOLL at 1-800-543-3267**.

What do I do if the garment feels too tight?

Fasten the garment on a looser clasp setting. If the garment is still too tight, **call ZOLL at 1-800-543-3267**.

What if my weight changes?

Call ZOLL at 1-800-543-3267.

What do I do if the electrodes are causing irritation?

Clean the electrodes, and apply a small amount of unscented lotion on the surface of each electrode. Also, see “Known residual risks” on page 1-20 and the next FAQ item: “How do I clean the system?”.

How do I clean the system?

See “Cleaning the non-washable items” on page 3-43 for details on cleaning non-washable parts of the system. See “Garment care” on page 3-45 for details on caring for the garment.

What are these alerts I’m hearing?

See “Understanding alerts” on page 4-1.

I’m traveling. What do I need to do?

Take the entire LifeVest WCD system, including the charger and its power supply, second battery, and second garment, with you when traveling. Ensure you will have power to charge a battery for 6 hours every 24 hours.

If you are traveling by airplane, **call ZOLL at 1-800-543-3267** to obtain a travel letter and enable airplane mode when necessary. See “Enabling and disabling airplane mode” on page 6-14. Also, review “Electromagnetic interference” on page 1-22 so you understand how the LifeVest WCD system may interact with electromagnetic equipment you may come into contact with, such as metal detectors.

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Appendices

This manual has the following appendices:

- Appendix A: Symbols glossary: describes all the graphics, symbols, and icons you may see on the LifeVest WCD labels and packaging.
- Appendix B: Monitor screen glossary: describes the graphics, indicators, and icons you may see on the monitor screen.
- Appendix C: Charger indicator glossary: describes the indicators on the charger.
- Appendix D: Technical information: describes the technical aspects of the LifeVest WCD system.
- Appendix E: Software licensing statement.

Appendix A: Symbols glossary

This appendix includes all the graphics, symbols, and icons you may see on the LifeVest WCD labels and packaging.

Where applicable, specific standards related to the use of a graphic, symbol, or icon are listed in parentheses.

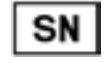
For details on specific monitor screens, see Appendix B: Monitor screen glossary.

LifeVest® WCD system component symbols

The following symbols can be found on the specified component.

Monitor

Symbol	Description
	Safety sign. Identifies an item which poses unacceptable risks to the patient, medical staff or other persons within the MR: magnetic resonance imaging environment. (ASTM F2503, 7.3.3)
	Safety sign. Indicates that the instruction manual must be read. (ISO 7010, M002)
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. (ISO 15223-1, 5.4.4)
	Indicates the item is a medical device.
IP66/IP67	Immersion protection indicates the device is dust-tight, and has protection against powerful water jets and the effects of temporary immersion in water. (IEC 60529, 4)

Symbol	Description
	<p>Symbol to indicate the device was put on the European Market after August 13, 2005, and do not dispose of via the municipal waste collection system of any member state of the European Union. [In accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union.]</p>
	<p>Identifies a defibrillator proof type BF (body float) applied part complying with IEC 60601-1. (IEC 60417, 5333)</p>
Rx Only	<p>Caution. Federal law restricts this device to sale by or on the order of a physician.</p>
	<p>Indicates the authorized representative in the European Community.</p>
	<p>Indicates the medical device manufacturer. (ISO 15223-1, 5.1.1)</p>
	<p>Indicates the manufacturer's catalogue number so that the medical device can be identified. (ISO 15223-1, 5.1.6)</p>
	<p>Indicates the manufacturer's serial number so that a specific medical device can be identified. (ISO 15223-1, 5.1.7)</p>

Electrode belt

Symbol	Description
	<p>Indicates the authorized representative in the European Community.</p>
	<p>Indicates the medical device manufacturer. (ISO 15223-1, 5.1.1)</p>

Symbol	Description
IP66/IP67	Immersion protection indicates the device is dust-tight, and has protection against powerful water jets and the effects of temporary immersion in water. (IEC 60529, 4)
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. (ISO 15223-1, 5.4.4)
	Indicates the need for the user to take care to avoid coming into contact with electricity with a risk of electric shock. (ISO 7010, W012)
	Indicates the item is a medical device.
	Symbol to indicate the device was put on the European Market after August 13, 2005, and do not dispose of via the municipal waste collection system of any member state of the European Union. [In accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union.]
	Indicates the manufacturer's catalogue number so that the medical device can be identified. (ISO 15223-1, 5.1.6)
	Indicates the manufacturer's serial number so that a specific medical device can be identified. (ISO 15223-1, 5.1.7)
	Indicates the date after which the medical device is not to be used. (ISO 15223-1, 5.1.4)

Symbol	Description
	Instructional icon. On the garment, this symbol indicates where to place the therapy pads in the garment. This symbol on the electrode belt indicates which side of the therapy pad should be next to your skin.
	Instructional icon. Indicates where to insert the therapy pads in the rear pockets of the garment.
	Instructional icon. Indicates the position of the vibration box on the garment.
	Instructional icon. Indicates where to insert the therapy pad in the side pocket of the garment.

Charger

For charger indicators, see “Charger indicator glossary” on page C-1.

Symbol	Description
	Safety sign. Indicates that the instruction manual must be read. (ISO 7010, M002)
	CE marking; indicates conformance with applicable European Directives and/or Regulations.
	Indicates the authorized representative in the European Community.
	Indicates the medical device manufacturer. (ISO 15223-1, 5.1.1)

Symbol	Description
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. (ISO 15223-1, 5.4.4)
	Indicates the manufacturer's catalogue number so that the medical device can be identified. (ISO 15223-1, 5.1.6)
	Indicates the manufacturer's serial number so that a specific medical device can be identified. (ISO 15223-1, 5.1.7)
	Symbol to indicate the device was put on the European Market after August 13, 2005, and do not dispose of via the municipal waste collection system of any member state of the European Union. [In accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union.]
	Indicates the item is a medical device.
	Indicates the device is dust-protected, and has protection against splashing water. (IEC 60529, 4)

Battery

Symbol	Description
	Indicates the manufacturer's catalogue number so that the medical device can be identified. (ISO 15223-1, 5.1.6)
	Indicates the manufacturer's serial number so that a specific medical device can be identified. (ISO 15223-1, 5.1.7)

Symbol	Description
	CE marking; indicates conformance with applicable European Directives and/or Regulations.
	Indicates the authorized representative in the European Community.
	Indicates the item is a medical device.
	Indicates the medical device manufacturer. (ISO 15223-1, 5.1.1)
IP66/IP67	Immersion protection indicates the device is dust-tight, and has protection against powerful water jets and the effects of temporary immersion in water. (IEC 60529, 4)
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. (ISO 15223-1, 5.4.4)
	Indicates on the rating plate that the equipment is suitable for Direct Current (DC) only. (IEC 60417, 5031)
	Symbol for do not dispose of in unsorted trash. Return to a collection site intended for waste electrical and electronic equipment. (accordance with the European Directives Waste Electrical and Electronic Equipment (WEEE) Directive and Battery Directive)

Garment

Symbol	Description
	Safety sign. Indicates that the instruction manual must be read. (ISO 7010, M002)

Symbol	Description
	Safety sign. Indicates general warning sign. (ISO 7010, W001)
	Safety sign. Warns the medical personnel to open the garment before giving the patient conventional external defibrillation. (IEC 60601-1, 7.5)
	Laundering symbol. Indicates to machine wash on normal cycle with a maximum water temperature of 40°C (104°F). (ASTM D5489, 5.4)
	Laundering symbol. Indicates to tumble dry on permanent press with a medium heat setting. (ASTM D5489, 5.4)
	Laundering symbol. Indicates to use only non-chlorine bleach when needed. (ASTM D5489, 5.4)
	Laundering symbol. Indicates to iron when needed with a low heat setting of 110°C (230°F). (ASTM D5489, 5.4)
	Instructional icon. On the garment, this symbol indicates where to place the therapy pads in the garment. This symbol on the electrode belt indicates which side of the therapy pad should be next to your skin.
	Instructional icon. Indicates where to insert the therapy pads in the rear pockets of the garment.
	Instructional icon. Indicates the position of the vibration box on the garment.

Symbol	Description
	Instructional icon. Indicates where to insert the therapy pad in the side pocket of the garment.
B01	Size of the garment.
B02	
B03	
B04	
B05	

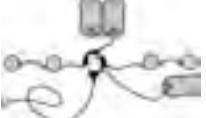
Blue™ gel packets

Symbol	Description
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. (ISO 15223-1, 5.4.4)
	Indicates the date after which the medical device is not to be used. (ISO 15223-1, 5.1.4)

Packaging symbols

Symbol	Description
	Indicates the medical device manufacturer. (ISO 15223-1, 5.1.1)
	Indicates the date after which the medical device is not to be used. (ISO 15223-1, 5.1.4)
	Indicates the manufacturer's catalogue number so that the medical device can be identified. (ISO 15223-1, 5.1.6)

Symbol	Description
	Indicates the manufacturer's serial number so that a specific medical device can be identified. (ISO 15223-1, 5.1.7)
	Indicates the manufacturer's batch code so that the batch or lot can be identified. (ISO 15223-1, 5.1.5)
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. (ISO 15223-1, 5.4.4)
	CE marking; indicates conformance with applicable European Directives and/or Regulations.
	Indicates the item is a medical device.
	Symbol to indicate the device was put on the European Market after August 13, 2005, and do not dispose of via the municipal waste collection system of any member state of the European Union. [In accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union.]
	Indicates a medical device that should not be used if the package has been damaged or opened. (ISO 15223-1, 5.2.8)
	Indicates a medical device that needs to be protected from moisture. (ISO 15233-1, 5.3.4)
	Indicates a medical device that needs protection from light sources. (ISO 15223-1, 5.3.2)

Symbol	Description
	Indicates a medical device that can be broken or damaged if not handled carefully. (ISO 15223-1, 5.3.1)
	Indicates the range of humidity to which the medical device can be safely exposed. (ISO 15223-1, 5.3.8)
	Indicates the temperature limits to which the medical device can be safely exposed. (ISO 15223-1, 5.3.7)
	Indicates the authorized representative in the European Community.
	Battery image on packaging.
	Charger image on packaging.
	Monitor image on packaging.
	Electrode belt image on packaging.
	Garment on packaging. May not appear on all packaging.

Appendix B: Monitor screen glossary

This appendix includes the graphics, indicators, and icons you may see on the monitor screen.

It also describes some screens you may see. Instructions on using all screens are included in the appropriate sections of this manual.

Indicators

Indicator	Description
	Battery level. Number of green bars indicates battery level.
	Battery is low, a critical situation. The LifeVest WCD may or may not be able to deliver a treatment. Change battery as soon as possible and recharge battery. See "Charging and changing batteries" on page 3-15.
	Battery level unknown. Call ZOLL at 1-800-543-3267.
	Round electrode good signal. Normal, no action required.
	Round electrode poor signal. Check round electrode for cause of poor signal and fix problem.
	Round electrode off skin. Check round electrode that is off skin and fix problem.
	Back therapy pads on skin. Normal, no action required.
	Front therapy pad on skin. Normal, no action required.
	Back therapy pads off skin. Check therapy pad that is off skin and fix problem.

Indicator	Description
	Front therapy pad off skin. Check therapy pad that is off skin and fix problem.
	Cellular signal strength. Strength is shown by the number of blue bars on the bottom right corner of certain screens.
	No cellular signal strength.

Buttons

Button	Name	Description
	Help	Tap to see additional information.
	Close	Tap to close the screen.
	Menu	Tap to see the menu.
	Back	Tap to go to the previous step when there is more than one step.
	OK	Tap to acknowledge you have read the screen. If any selections or changes were made on the screen, those selections or changes take effect.
	Next	Tap to go to the next step when there is more than one step.
	Save	Tap to save the information on the screen. If any selections or changes were made on the screen, they take effect.
	Translate	Tap to change the language in which the help screen audio is spoken.

Graphics

Graphic	Description
	Airplane mode on. Displays on the Home screen when airplane mode is enabled. Monitor will not transmit data. See “Enabling and disabling airplane mode” on page 6-14.
	Monitoring mode. Animated on the Home screen to show that LifeVest WCD is in monitoring mode. Situation normal, no action required.
	Belt Disconnected. Animated on the Home screen to show the electrode belt is not connected to the monitor and is not monitoring the patient’s ECG.
	Recording. Displays on the Home screen when LifeVest WCD is recording your ECG signal (manually activated).
	Training mode. Displays on screens when the LifeVest WCD is in training mode.

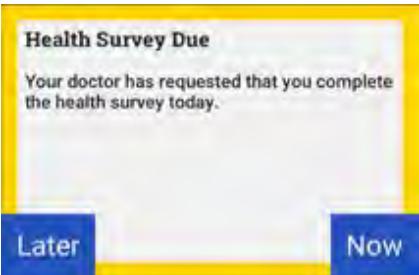
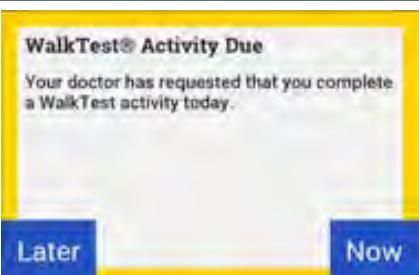
Screens

Screens that display upon start

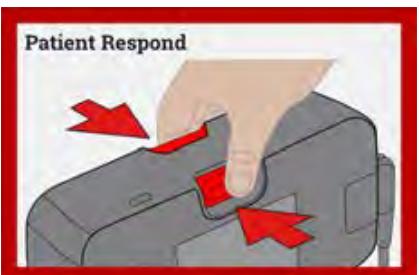
Screen	Description
	Startup screen. Displays on the monitor screen after you insert a battery into the monitor. See “Daily routine and normal startup” on page 3-1.

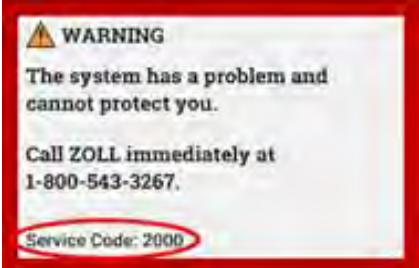
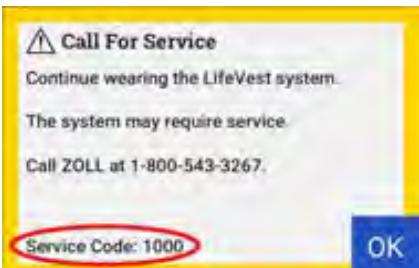
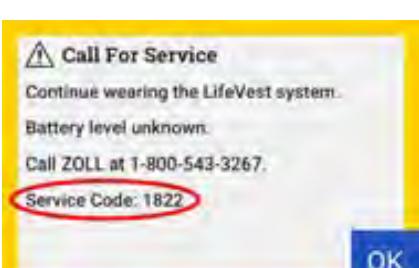
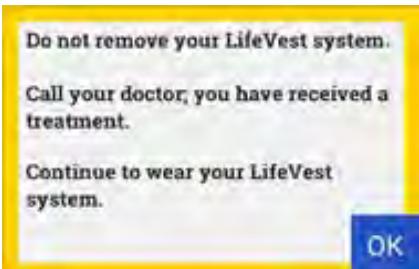
Screen	Description
	<p>Startup screen. Displays on the monitor screen after you insert a battery into the monitor.</p> <p>See “Daily routine and normal startup” on page 3-1.</p>
	<p>Startup screen. Displays on the monitor screen after you insert a battery into the monitor.</p> <p>See “Daily routine and normal startup” on page 3-1.</p>
 <p>Only the patient should press both response buttons to activate the device.</p>	<p>Displays after the startup screens along with the gong sound and vibration alert.</p> <p>See “Daily routine and normal startup” on page 3-1.</p>
	<p>Home screen. This Home screen is an example of a LifeVest WCD that has a fully charged battery and is monitoring normally.</p>

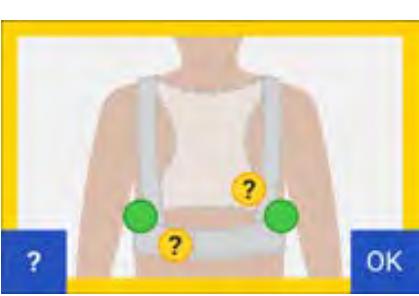
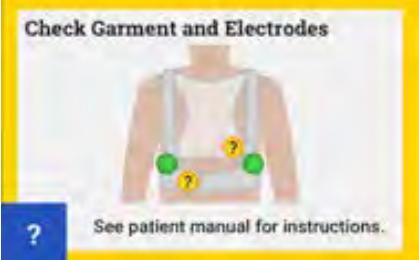
Activity screens

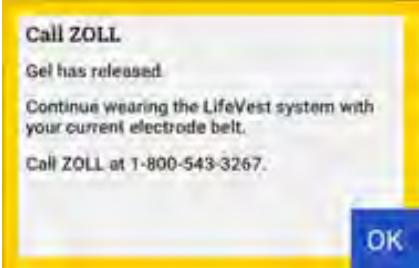
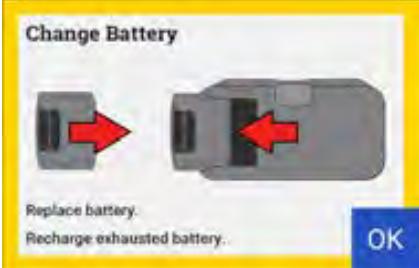
Screen	Description
 <p>Health Survey Due Your doctor has requested that you complete the health survey today.</p> <p>Later Now</p>	<p>Health Survey Due. Indicates you are due to take the health survey.</p> <p>See “Health survey activity” on page 5-1.</p>
 <p>WalkTest® Activity Due Your doctor has requested that you complete a WalkTest activity today.</p> <p>Later Now</p>	<p>WalkTest® Activity Due. Indicates you are due to perform the WalkTest activity.</p> <p>“WalkTest® activity” on page 5-7.</p>

Alert screens

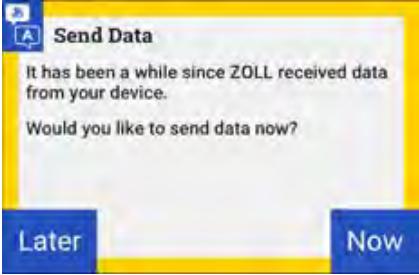
Screen	Description
 <p>Patient Respond</p> <p>A hand is shown pressing a grey LifeVest WCD device. Red arrows point to the device.</p>	<p>Patient Respond message. Displays when the LifeVest WCD is about to deliver a treatment. It is accompanied by the siren alert.</p> <p>See “Receiving a siren alert with a Patient Respond display message” on page 4-3</p>
 <p>If Patient is Not Responsive</p> <p>Two icons are shown: a blue phone with a signal and a red heart with hands.</p> <p>1 Call for Help 2 Perform CPR</p>	<p>If Patient is Not Responsive message.</p> <p>Indicates you have received a treatment or the LifeVest WCD cannot detect a heart rhythm.</p> <p>See “Receiving a siren alert with an If Patient is Not Responsive display message” on page 4-6.</p>

Screen	Description
 <p>WARNING The system has a problem and cannot protect you. Call ZOLL immediately at 1-800-543-3267. Service Code: 2000</p>	<p>WARNING message. You must write down the Service Code number and call ZOLL immediately at 1-800-543-3267.</p>
 <p>Call For Service Continue wearing the LifeVest system. The system may require service. Call ZOLL at 1-800-543-3267. Service Code: 1000</p>	<p><i>Call For Service</i> message. The LifeVest WCD may require service.</p> <p>You must write down the Service Code number and call ZOLL at 1-800-543-3267.</p>
 <p>Call For Service Continue wearing the LifeVest system. Battery level unknown. Call ZOLL at 1-800-543-3267. Service Code: 1822</p>	
 <p>Do not remove your LifeVest system. Call your doctor, you have received a treatment. Continue to wear your LifeVest system.</p>	<p><i>Do not remove your LifeVest system</i> message. Indicates you have received a treatment.</p> <p>See “After receiving a treatment” on page 4-5.</p>

Screen	Description
	<p>Electrode belt problem messages. Monitor is not receiving a clear signal from the round electrodes. The round electrodes as indicated with an X 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.</p> <p>See “Responding to check electrodes message” on page 4-10.</p>
	<p>Check electrodes message. Monitor is not receiving a signal from the round electrodes.</p> <p>This message is accompanied by a voice prompt telling you to <i>Check electrodes</i>.</p> <p>See “Responding to check electrodes message” on page 4-10.</p>
	<p><i>Check Garment and Electrodes</i> message.</p> <p>After multiple attempts to adjust the electrode belt, monitor is still not receiving a good signal from the electrode belt.</p> <p>See “Responding to Check Garment and Electrodes message” on page 4-11.</p>

Screen	Description
	<p>Therapy pad problem message. One or more therapy pads are not making contact with your skin.</p> <p>See “Responding to therapy pad problem message” on page 4-12.</p>
	<p><i>Add Gel to Therapy Pads</i> message. You have received a treatment and Blue gel is drying out.</p> <p>See “Responding to Add Gel to Therapy Pads message” on page 4-13.</p>
	<p><i>Call ZOLL</i> message. Blue gel has been released.</p> <p>See “Responding to Call ZOLL message” on page 4-15.</p>
	<p><i>Too Much Gel, Clean Skin</i> message. Too much Blue gel is on your skin.</p> <p>See “Responding to Too Much Gel, Clean Skin message” on page 4-16.</p>
	<p><i>Change Battery</i> message.</p> <p>Battery needs to be changed.</p> <p>See “Charging and changing batteries” on page 3-15.</p>

Screen	Description
 <p>Electrode Belt Not Connected</p>	<p><i>Electrode Belt Not Connected</i> message. The electrode belt is not connected to the monitor.</p> <p>See “Connecting the electrode belt to the monitor” on page 3-32.</p>
 <p>Press Response Buttons</p> <p>Only the patient should press both response buttons to activate the device.</p>	<p><i>Press Response Buttons</i> message. Instructs you to press both response buttons.</p>
 <p>Release Response Buttons</p>	<p><i>Release Response Buttons</i> message. Instructs you to release both response buttons.</p> <p>If you are not holding both response buttons, call ZOLL immediately at 1-800-543-3267.</p>
 <p>Remove Battery</p> <p>Remove battery if not in use.</p>	<p><i>Remove Battery</i> message. Indicates to remove the battery when you are not wearing the LifeVest WCD.</p> <p>See “Charging and changing batteries” on page 3-15.</p> <p>If you continue to get this message with the battery fully inserted, call ZOLL immediately at 1-800-543-3267.</p>

Screen	Description
 The image shows a digital display screen for a medical device. At the top, there is a blue icon of a computer monitor with a 'Send Data' message. Below the icon, the text 'Send Data' is displayed. The main message on the screen reads: 'It has been a while since ZOLL received data from your device.' followed by 'Would you like to send data now?'. At the bottom of the screen, there are two blue buttons: 'Later' on the left and 'Now' on the right. The 'Now' button is highlighted with a yellow background.	<p><i>Send Data</i> message. Indicates to send data to ZOLL.</p> <p>See “Sending data manually” on page 6-4.</p>

Appendix C: Charger indicator glossary

This appendix includes the indicators on the charger.

Indicator	What it means	What to do
	Alarm condition 1. There is a problem, but the battery might still charge.	Battery can be used, but should be replaced. This condition will be accompanied by two beeps at the start of the alarm. Call ZOLL at 1-800-543-3267.
	Alarm condition 2. There is a problem, and the battery cannot charge.	Battery cannot charge. This condition will be accompanied by three beeps every 15 seconds. Call ZOLL immediately at 1-800-543-3267.
	Battery is fully charged, ready for use in monitor.	Leave the battery in the charger until you are ready to exchange the battery.
	Battery is charging.	Leave the battery in the charger. Charging the battery typically takes less than 6 hours.
	Power is being applied to the charger. This light will continue to stay lit when the other indicators light.	Make sure this indicator lights up when you plug in the charger.

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Appendix D: Technical information

Environmental conditions

Operating environment

Monitor, electrode belt, and battery temperature range	0°C to 50°C (32°F to 122°F) <i>Note: The electrode belt, which is worn in direct contact with the skin, operates to a maximum of 43°C (109.4°F). In accordance with IEC 60601-1, 3rd Edition, Clause 11.1.2, the electrode belt does not generate any additional heat, and provided the skin does not exceed 43°C, the maximum surface temperature of the electrode belt will not exceed 43°C.</i>
Charger temperature range	0°C to 40°C (32°F to 104°F)
Humidity range (all components)	5% to 95% relative humidity, non-condensing
Altitude (all components)	500 m (1,640 ft) below sea level to 3,050 m (10,006 ft) above sea level

Storage and transportation environment

Temperature range (all components)	-5°C to 55°C (23°F to 131°F)
Humidity range (all components)	5% to 95% relative humidity, non-condensing
Altitude (all components)	500 m (1,640 ft) below sea level to 4,572 m (15,000 ft) above sea level

Specifications

Monitor dimensions	20.3 x 9.7 x 5.3 centimeters (8.0 x 3.8 x 2.1 inches)
Monitor weight (with battery)	861 grams (1.9 pounds)
Electrode belt and garment weight	540 grams to 563 grams (1.19 to 1.24 pounds) Dependent on garment size.
Monitor power source	3-cell lithium-ion battery, 10.8 Volts  , 3.3 Amp-hours, 36.2 Watt-hours or 3-cell lithium-ion battery, 11.1 Volts  , 2.8 Amp-hours, 31.1 Watt-hours
Charger	Input: 18 to 24 Volts  60 Watts
Charger power supply Manufacturer: Delta Electronics, Inc. Part number: MDS-060BAS19A or Manufacturer: EDAC (Wall Industries, Inc.) Part number: DTEM10682P-19-ZL	AC Input: 100 to 240 Volts  , 50-60 Hertz, 1.5 Amps
Battery charging time	3 to 6 hours average under normal conditions
Charger dimensions	17.8 x 14.5 x 7.4 centimeters (7 x 5.7 x 2.9 inches)
Charger weight (without the battery)	458 grams (1 pound)

Wireless RF Information – Monitor

Operational RF Frequency Bands

US Frequency Bands		
LTE Band Name	Uplink Frequency (MHz)	Downlink Frequency (MHz)
LTE Band 2	1850 – 1910	1930 – 1990
LTE Band 4	1710 – 1755	2110 – 2155
LTE Band 12	699 – 716	729 – 746
Maximum radio frequency transmit power: +23 dBm		

EU Frequency Bands		
LTE Band Name	Uplink Frequency (MHz)	Downlink Frequency (MHz)
LTE Band 1	1920 – 1980	2110 – 2170
LTE Band 3	1710 – 1785	1805 – 1880
LTE Band 8	880 – 915	925 – 960
LTE Band 20	832 – 862	791 – 821
LTE Band 28	703 – 748	758 – 803
Maximum radio frequency transmit power: +23 dBm		

Standards for PTCRB Compliance:

- CTIA Total Radiated Power for LTE CAT-M1 v3.9.3 September 2021
- CTIA Isotropic Sensitivity for LTE CAT-M1 v3.9.3 September 2021
- PTCRB UICC Electrical PTCRB v3.2, NAPRD03 v6.6 GCF-cc v3.83
- Radiated Spurious Emissions
 - PVG.04
 - 3GPP TS 51.010-1 (TC 12.2.2)
 - 3GPP TS 34.124 (TC 8.2)
 - 3GPP TS 36.124 (TC 8.2)

Standards for FCC Wireless Certification:

- FCC CFR47 Part 2 – Frequency allocation and Radio Treaty Matters; General Rules and Regulations
- FCC CFR47 Part 24 - Personal Communications Services
- FCC CFR47 Part 27 - Miscellaneous Wireless Communications Services

Standards for US SAR compliance of a body worn device

- FCC 47 CFR 2.1093 - Radiofrequency radiation exposure evaluation: portable devices
- IEEE Standard 1528-2013 IEEE Recommended Practice for Determining Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Head from Wireless Communications Devices: Measurement Techniques

Wireless technology incorporated in the device:

- LTE Category M1 cellular radio

Wireless technology operating characteristics:

US Frequency Bands				
	Effective RF radiated power	Operation range in MHz (Uplink)	Modulation	Bandwidth of receiving section in MHz (Downlink)
LTE Band 2	Complies with FCC 27.50c(10)	1850 – 1910	OFDM*	1930 – 1990
LTE Band 4	Complies with FCC 24.232c	1710 – 1755	OFDM*	2110 – 2155
LTE Band 12	Complies with FCC 27.50d(4)	699 – 716	OFDM*	729 – 746

*Orthogonal frequency division multiplex

System life expectancy

Monitor	3 years of monitoring and defibrillating service The LifeVest WCD is designed to be used continuously with infrequent defibrillation, which is defined in IEC 60601-2-4 as a defibrillator designed to endure less than 2,500 discharges.
Battery	At least 1 year (about 200 charge/discharge cycles)
Charger	3 years
Electrode belt (excluding therapy pads)	3 years of monitoring and defibrillating service
Therapy pads	2 years during normal humidity storage in the absence of a treatment
Garment	4 months per patient when part of a two garment distribution
Holster	Maximum of 1 year, and/or 1 patient

Auditory alert signal information

This section contains details about the LifeVest WCD monitor and charger auditory alert signals.

Note: Monitor sound pressure was measured with the monitor in its holster.

Monitor gong alert

Alert signal	Description	Type	Priority	Sound pressure (dB @ 1 m)
Gong Soft	Gong	Informative	Low	59.5 dBA +/- 3 dBA
Gong Medium	Gong	Technical	Medium	67.0 dBA +/- 3 dBA
Gong High	Gong	Technical	Medium	71.5 dBA +/- 3 dBA

Monitor siren alert

Alert signal	Description	Type	Priority	Sound pressure (dB @ 1 m)
Siren Medium	Siren	Physiological	High	80.9 dBA +/- 3 dBA
Siren High	Siren	Physiological	High	86.0 dBA +/- 3 dBA

Monitor whistle alert

Alert signal	Description	Type	Priority	Sound pressure (dB @ 1 m)
Whistle Soft	Whistle	Informative	Medium	63.0 dBA +/- 3 dBA
Whistle Medium	Whistle	Informative	Medium	71.3 dBA +/- 3 dBA
Whistle High	Whistle	Informative	Medium	76.7 dBA +/- 3 dBA

Charger alert

Alert signal	Description	Type	Priority	Sound pressure (dB @ 1 m)
Beep – Power On	3 pulses per burst, no repeat	Informative	n/a	56 dBA +/- 3dBA
Beep – Low Priority	2 pulses per burst, no repeat	Technical	Low	62 dBA +/- 3dBA
Beep – Medium Priority	3 pulses per burst, 15 second burst interval	Technical	Medium	62 dBA +/- 3dBA

Monitor spoken alert

Alert signal	Description	Type	Priority	Sound pressure (dB @ 1 m)
Spoken Message High	"Bystanders, do not interfere."	Technical	High	73.6 dBA +/- 3dBA

Alert system reminder signals and intervals

The chart below lists reminder signals, the nature of the alerts, and the intervals between reminder signals.

Reminder signal condition	Alert	Interval
Low battery	Replace battery	15 minutes
Post treatment notification	Continue to wear	15 seconds (alert is repeated two times after treatment)
Treatment previously delivered	Treatment delivered, call health care professional	Each time monitoring operations begin
Therapy pad impedance too high	Add Blue gel	13 minutes
Therapy pad impedance too low	Too much Blue gel	13 minutes
Therapy pad falloff	Therapy pad falloff	13 minutes
Escalated electrode belt not connected	Remove battery if not in use	6 minutes
Electrode belt not connected	Connect electrode belt	5 minutes

Alert delays

The following charts list the delays from the onset of alert conditions until the alert signals are generated.

Monitor alerts, high priority

Alert condition	Alert condition delay	Alert signal generation delay	Notes
Device problem — loss of ability to detect and/or treat	none	Immediate	2000 level service code
Treatable cardiac arrhythmia present	Approx. 3 – 5 seconds	Approx. 10 seconds	
Treatable cardiac arrhythmia present – maximum treatment delivered	Five pulses delivered	Immediate	Continues until non-treatable rhythm detected
Asystole detected (30 seconds no response)	none	Immediate	Continues until non-asystolic rhythm detected

Monitor alerts, medium priority

Note: Alerts delayed if higher priority alert is active.

Alert condition	Alert condition delay	Alert signal generation delay	Notes
Low battery	≤ 60 seconds	Immediate	
Post treatment notification	none	Immediate	
Normal sinus rhythm to asystole detected	< 20 seconds	Immediate	
Treatment electrode impedance too high/low	10 minutes	3 minutes	
ECG signal contamination – single channel	< 5 seconds	30 minutes	If condition sustains over 30 minutes.
ECG signal contamination – dual channel	< 5 seconds	5 minutes	If condition sustains over 5 minutes.
Response buttons activated	15 seconds	Immediate	
Treatment electrode falloff	2 minutes at power-up, 10 minutes after power-up	3 minutes	
Response buttons activated after treatment no longer needed	< 1 second	Immediate	
Escalated electrode belt not connected	none	18 minutes	If condition sustains over 18 minutes.
Device problem — still able to detect and treat	none	Immediate	1000 level service code

Monitor alerts, low priority

Alert condition	Alert condition delay	Alert signal generation delay	Notes
Electrode belt not connected – level 1	none	Immediate	

Electromagnetic compatibility

The LifeVest WCD was tested by an independent EMC test laboratory to demonstrate compliance to the emissions and immunity requirements of the applicable standards. Results are shown in “Classification for use” on page D-13.

Classification of applied part

The LifeVest system applied part classification is Type BF. The LifeVest system patient connections are isolated from other parts of the device to such a degree that no current higher than the allowable patient leakage current flows if an unintended voltage originating from an external source is connected to the patient, and thereby applied between the patient connection and the earth.

Classification for use

Type of protection against electric shock	Monitor, electrode belt: Internally powered Charger: Class II Isolated Power supply that does not rely on protective earthing. <i>Note: The combination of the charger and power supply form a Medical Electrical Equipment system (ME System).</i>
Degree of protection against electric shock	Monitor, electrode belt, and battery: Type BF applied parts, shown by this symbol  See "Classification of applied part" on page D-12.
Degree of protection against water	Charger: IP54 Power Supply: IP21 Monitor, electrode belt, and battery: IP66/IP67 See "Symbols glossary" on page A-1 for details on these ratings.
Mode of operation	Monitor: Continuous Charger: Continuous

FCC regulatory information



WARNING

Do not tamper with, alter, drop, or abuse any part of the system or labeling. Do not put fingers or foreign objects, such as paper clips or hair pins, into any connectors or openings. Altering the equipment in any way may damage it and/or cause the system to malfunction, which may result in serious injury or death. Changes or modifications to this device not authorized by ZOLL could void the radio frequency energy (RF) compliance and negate your authority to operate the device. Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.

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: W56LV51C1BW0

The available scientific evidence does not show that any health problems are associated with using low-power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low-power wireless devices emit low levels of RF in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research. The LifeVest WCD 5100 has been tested and found to comply with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET65.

FCC Supplier's Declaration of Conformity

LifeVest LV 5100

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.

ZOLL Medical Corporation, 121 Gamma Drive, Pittsburgh PA 15238 (USA)
Contact 24 hours a day, 7 days a week: 1-800-543-3267

Aircraft use

The LifeVest WCD was tested to demonstrate compliance to the emissions and immunity requirements of the following standard: RTCA DO-160, 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.

See “Enabling and disabling airplane mode” on page 6-14 for information on enabling airplane mode on the LifeVest WCD.

IEC 60601-1-2 specifications

Electromagnetic emissions declaration

Unless noted otherwise, all of the following information applies to versions of the LifeVest wearable cardioverter defibrillator 5100 using the compatible electrode belt and charger.

Guidance and manufacturer's declaration — electromagnetic emissions		
The LifeVest WCD 5100 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The LifeVest WCD 5100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The LifeVest WCD 5100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
*Harmonic emissions IEC 61000-3-2	Class A	The LifeVest WCD 5100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
*Voltage fluctuations/flicker emissions EN 61000-3-3	Complies	
*Applies only to LifeVest WCD 5100 Charger.		

Electromagnetic immunity declaration

Unless noted otherwise, all of the following information applies to versions of the LifeVest WCD 5100 and Charger

Guidance and manufacturer's declaration — electromagnetic immunity			
The LifeVest WCD 5100 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2kV, ±4kV, ±8kV, ±15 Air	±2kV, ±4kV, ±6kV, ±8 kV Contact ±2kV, ±4kV, ±8kV, ±15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
*Electrical fast transient IEC 61000-4-4	±2kV power line	±2kV power line	Mains power quality should be that of a typical home environment.
*Surge IEC 61000-4-5	±1kV differential	±1kV differential	Mains power quality should be that of a typical home environment.

Guidance and manufacturer's declaration — electromagnetic immunity			
The LifeVest WCD 5100 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
*Voltage dips IEC 61000-4-11	0% U_T , 0.5 cycle; tested at 0, 45, 90, 135, 180, 225, 270, 315 degrees phase angle 0% U_T , 1 cycle; tested at 0 degrees phase 70% U_T , 25 cycles (50 Hz) or 30 cycles (60 Hz); tested at 0 degrees phase	0% U_T , 0.5 cycle; tested at 0, 45, 90, 135, 180, 225, 270, 315 degrees phase angle 0% U_T , 1 cycle; tested at 0 degrees phase 70% U_T , 25 cycles (50 Hz) or 30 cycles (60 Hz); tested at 0 degrees phase	Mains power quality should be that of a typical home environment. If the user of the LifeVest wearable cardioverter defibrillator 5100 requires continued operation during power mains interruptions, it is recommended that the LifeVest wearable cardioverter defibrillator 5100 charger be powered from an uninterruptible power supply.
*Voltage Interrupts IEC 61000-4-11	0% U_T , 250 cycles (50 Hz) or 300 cycles (60 Hz)	0% U_T , 250 cycles (50 Hz) or 300 cycles (60 Hz)	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment.
*Applies only to LifeVest WCD 5100 Charger Note: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic immunity declaration

 **WARNING**

Portable and mobile RF communications equipment should be used no closer to any part of the LifeVest WCD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

This information applies to the LifeVest WCD 5100 Charger

Guidance and manufacturer's declaration — electromagnetic immunity

The LifeVest WCD 5100 Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 Charger should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Recommended separation distance:			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	$d = 1.2\sqrt{P}$
	6Vrms 150kHz to 80 MHz in Amateur radio bands ^a	6 Vrms	$d = 2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	$d = 1.2\sqrt{P}$

^aThe ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Guidance and manufacturer's declaration — electromagnetic immunity

The LifeVest WCD 5100 Charger is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 Charger should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	<p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^c, should be less than the compliance level in each frequency range.^d Interference may occur in the vicinity of</p>  <p>equipment marked with the symbol.</p>
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	8 A/m 65 A/m 7.5 A/m	

^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifeVest 5100 is used exceeds the applicable RF compliance level above, the LifeVest 5100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LifeVest 5100.

^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

This information applies to the LifeVest WCD 5100

Guidance and manufacturer's declaration — electromagnetic immunity			
The LifeVest WCD 5100 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Recommended separation distance:			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^e	3 Vrms *30 MHz to 80 MHz outside ISM bands ^f	$d = 1.2\sqrt{P}$
	6Vrms 150kHz to 80 MHz in Amateur radio bands ^e	6 Vrms	$d = 2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^e	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz

^eThe ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

^fThe ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Guidance and manufacturer's declaration — electromagnetic immunity

The LifeVest WCD 5100 is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest WCD 5100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 60601-2-4	20 V/m 80 MHz to 2.7 Ghz	20 V/m	$d = 0.6 \sqrt{P}$ 80 MHz to 800 MHz $d = 1.15 \sqrt{P}$ 80 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^g Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^h , should be less than the compliance level in each frequency range. ⁱ Interference may occur in the vicinity of equipment marked with the  symbol.
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	8 A/m 65 A/m 7.5 A/m	

^gThe compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

^hField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifeVest 5100 is used exceeds the applicable RF compliance level above, the LifeVest 5100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LifeVest 5100.

ⁱOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Test specifications for enclosure port immunity to RF wireless communications equipment

This information applies to the LifeVest WCD 5100 Charger

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
1500 ¹	1500	WCDMA Band 11, LTE Band 11,21	Pulse Modulation 217 Hz	Not applicable	See footnote ²	Not applicable	40
2100 ¹	2100	WCDMA Band 1, LTE Band 1	Pulse Modulation 217 Hz	Not applicable	See footnote ²	Not applicable	40
385	380-390	TETRA 400	Pulse modulation 18 MHz	1.8	0.3	27	27
450	430-470	GMRS 460, FRS 460	FM 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GMS 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28

¹Additional frequencies not outlined in IEC 60601-1-2:2014 tested per outcome of risk analysis.

²For a calculation of the minimum separation distance from RF equipment see Separation distance from RF equipment table.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFIF 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9

Test specifications for enclosure port immunity to RF wireless communications equipment

This information applies to the LifeVest WCD 5100

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
1500 ¹	1500	WCDMA Band 11, LTE Band 11, 21	Pulse Modulation 217 Hz	Not applicable	See footnote ²	Not applicable	40
2100 ¹	2100	WCDMA Band 1, LTE Band 1	Pulse Modulation 217 Hz	Not applicable	See footnote ²	Not applicable	40
385	380-390	TETRA 400	Pulse modulation 18 MHz	1.8	0.3	27	40
450	430-470	GMRS 460, FRS 460	FM 5 kHz deviation 1 kHz sine	2	0.3	28	40
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	40
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	40
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GMS 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	40

¹Additional frequencies not outlined in IEC 60601-1-2:2014 tested per outcome of risk analysis.

²For a calculation of the minimum separation distance from RF equipment see Separation distance from RF equipment table.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFIF 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	40
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	40

Test specifications for enclosure port immunity to Radio Frequency Identification Readers (RFID)

RFID Specification	Frequency	Test Level (rms)	Compliance Level (rms)	Electromagnetic Environment Guidance
				Recommended separation distance between any part of the LifeVest WCD 5100 or LifeVest WCD Charger
ISO 14223	134.2 kHz	65 A/m	65 A/m	2.5 cm
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m	7.5 A/m	
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m	7.5 A/m	
ISO/IEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m	5 A/m	
ISO 18000-3 Mode 3	13.56 MHz	12 A/m	12 A/m	
ISO/IEC 18000-7	433 MHz	3 V/m	3 V/m	20cm
ISO/IEC 18000-63 Type C	860-960 MHz	54 V/m	54 V/m	20 cm
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m	54 V/m	20 cm

Separation distances from RF equipment

This Information applies to the LifeVest WCD 5100

The LifeVest WCD 5100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifeVest WCD 5100 can help prevent the electromagnetic interference by maintaining a minimum distance of at least 21.2 cm (8.35 in) between portable and mobile RF communications equipment (transmitters) and the LifeVest WCD 5100 as calculated below, according to IEC 60601-1-2 (2014).

$$d = \frac{6}{E} \sqrt{P}$$

where:

d = minimum separation distance in centimeters

E = immunity test level = 40 V/m for LifeVest

P = maximum power of the transmitter = 2 W for LifeVest 5100

Solving for **d** yields 21.2 cm (8.35 inches)

As noted elsewhere in this document, the recommended separation distance is 27 cm (10.6 inches) as required by the US FDA.

Recommended separation distances from RF equipment

This information applies to the LifeVest WCD 5100 Charger

Recommended separation distances between portable and mobile RF communications equipment and the LifeVest WCD 5100 Charger					
Rated maximum output power of transmitter, in watts	Separation distance according to frequency of transmitter, in meters				
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz Amateur radio bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.7GHz
	$d = 1.2\sqrt{P}$	$d = 2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.2	0.12	0.12	0.23
0.1	0.38	0.63	0.38	0.38	0.73
1	1.2	2	1.2	1.2	2.3
10	3.8	6.3	3.8	3.8	7.3
100	12	20	12	12	23

This information applies to the LifeVest WCD 5100

Recommended separation distances between portable and mobile RF communications equipment and the LifeVest WCD 5100

The LifeVest WCD 5100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifeVest WCD 5100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifeVest WCD 5100 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, in watts	Separation distance according to frequency of transmitter, in meters						
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz Amateur radio bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.7GHz	80 MHz to 800 MHz*	800 MHz to 2.7 GHz
	$d = 1.2\sqrt{P}$	$d = 2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	$d = 0.6\sqrt{P}^*$	$d = 1.15\sqrt{P}^*$
0.01	0.12	0.06	0.12	0.12	0.23	0.06	0.12
0.1	0.38	0.19	0.38	0.38	0.73	0.19	0.36
1	1.2	0.6	1.2	1.2	2.3	0.6	1.15
10	3.8	1.9	3.8	3.8	7.3	1.9	3.63
100	12	6	12	12	23	6	11.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: The Amateur bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Note 4: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz. This is to decrease the likelihood that mobile/portable

communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 5: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

**IEC 60601-2-4 requirement*

Appendix E: Software licensing statement

Certain software components (referred to herein as “Open Source Components”) that are used by the LifeVest WCD are licensed by ZOLL Medical Corporation (referred to herein as “ZOLL Medical”) under various open source license agreements. As required by the terms of these open source license agreements, ZOLL Medical offers to make the source code corresponding to the Open Source Components, and any ZOLL Medical modifications thereof, available upon request. Information regarding the Open Source Components is available at .

NO WARRANTY

TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE OPEN SOURCE COMPONENTS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY AGAINST INFRINGEMENT OR ANY VIOLATION OF INTELLECTUAL PROPERTY RIGHTS COVERING THE OPEN SOURCE COMPONENTS. IN NO EVENT UNLESS REQUIRED BY APPLICABLE LAW WILL ANY PARTY, INCLUDING ZOLL MEDICAL, BE LIABLE FOR DAMAGES, INCLUDING ANY GENERAL, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR INABILITY TO USE THE OPEN SOURCE COMPONENTS (INCLUDING BUT NOT LIMITED TO LOSS OF DATA OR DATA BEING RENDERED INACCURATE OR LOSSES SUSTAINED BY ANY PARTY FOR A FAILURE OF THE OPEN SOURCE COMPONENTS TO OPERATE WITH ANY OTHER PROGRAMS).

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