



Model 000 Patient Manual



20B0060 Rev A-P1

Restricted sale

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

Effectivity

This manual describes the LifeVest 5000 wearable defibrillator system.

Disclaimer

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

Trademarks

ZOLL, LifeVest, Blue and the color Blue are trademarks and/or registered trademarks of L Medical Corporation in the United States and/or other countries.

Copyright notice

© 2016 ZOLL Medical Corporation. All rights reserved.

Patents

Patent: www.zoll.com/patents

Software nonexclusive license

The LifeVest device includes certain oftware ("Son. 20LL grants you a nonexclusive license to use the Software solely for diagnosic and patment purposes as part of use of the LifeVest device. You are prohibited from:

- (i) reproduci ware;
- (ii) remover or destroyle any proprietary markings, copyright notices or other legends which are part of the Softwal
- (iii) modify g or reverse g gineering the Software; or
- oving Softy e from the LifeVest device.

Title to the Software will remain at all times with ZOLL. You must keep the Software confidential.

Contact information



ZOLL Pittsburgh, PA 15238

USA

Phone toll free (USA and Canada)

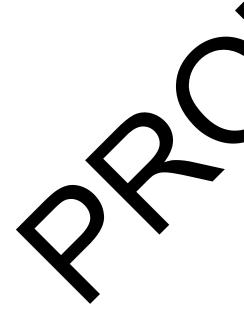
Phone outside USA 1-4

1-800-543-3267 1-412-968-3333

Fax

1-412-826-9485

Web www.zoll.com



Contents

: Introduction1-	1
About this manual	1-
1	
About the LifeVest system and cardiac defibrillation	A -
1	
How the LifeVest works	1-
1	
Safety information	1-
2	
Environment considerations related to noise and vibration	1
5	
Intended use locations	1-
5	
Essential performance	1-
5	
Aircraft use	1-
5	
Operator profile	1-
6	
Patient profile	1-
6	
ZOLL authorized representative profile	1-
6	
Patient training	1-
6	
Electromagnetic interfer	1-
7	
Wireless interfere	1-
8	
FCC regulator information	1-
8	
: Meet the Vest 00 sys2-	· 1
compone s	2-
Ga ent and electrode belt	2-
2	
Monitor front view	2-
3	
Monitor — back view	2-
4	
Monitor touchscreen	2-
5	
Help screens	2-
7	
Charger	2-
8	

3: Using	the LifeVest3-1	
	Daily routine3-	-
	1	
	Normal startup routine3-	-
	2	
	Battery care3-	-
	3	
	Charger setup3-	-
	4	
	Change and charge batteries daily 3-	-
	7	
	Record your heart rhythm (ECG) 3-	-
	8	
	Patient menu screen	-
	9	
	Voice options	
	10	
	Sending data manually	
	11	
	Airplane mode	
	13	
	WiFi	
	15	
	System information	
	23	
	Support mode	
	24	
	Periodically clean and inspect the system	
	26 What forsily reambors read to be out	
	What family members need to know	
	27 When you are finished with the device	
	28	
	28	
A. Carm	ent and electrode belt4-1	
4. Gaili	Assemble the garment and electrode belt	
	Assemble the garment and electrode beit	-
	Assembled garment and electrode belt 4-	_
	3	
	Putting on the assembled garment and electrode belt 4-	_
	4	
	Connecting and disconnecting the electrode belt4-	
	7	
	,	

	Remove when showering and bathing	4-8
	Disassembling the garment and electrode belt	
	Laundering the garment	4-10
5:	Responding to alerts	5-1
٥.	Overview of alerts	
	Physiological alerts: vibration or siren sound	
	Siren with call for help message	
	Technical alerts: gong sound	
	Informative alerts: gong or high-nitched "train whistle" sound	55
	Informative alerts: gong or high-pitched "train whistle" sound	
_		
6:	Using the activities options	<i></i>
	Introduction to activities	c
	Taking the health survey	6-2
	Taking the health survey now	6-3
	Taking the WalkTest™	6-7
	Taking the WalkTest™ now	6-9
Αp	ppendix A: Symbols and Icons	A-1
10		
۸n	ppendix B : Software Licensing Statement	D 1
Аþ	NO WARRANTY	 В-1

1: Introduction

About this manual

This manual:

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

About the LifeVest system and cardiac defibrillation

The LifeVest device continuously monitors your heart. If it detects a life hreatening shythm that is too fast, the device delivers treatment to restore normal rhythm. If you are conscisus, you can prevent a treatment by using the response buttons when the devices you that a treatment is coming.

How the LifeVest works

The round electrodes in the garment monitor your hout. Therefore, it is important to maintain a snug fit across your chest. If the LifeVe detects a possible life threatening rhythm, the device will first create a vibration in the middle if your back to carn you of a possible treatment. The siren alert then occurs to inform you that the LifeVest is bout to deliver a treatment, a therapeutic dose of electrical progry, in an alemnt to estore your normal heart rhythm.

If you are conscious:

To const a treatment from occurring, press the esponse is atons on the monitor. You may release the botons, but must repeat pressing them each ting the siren alert occurs. Pressing e buttons to is the device that you are



If you are up sonscious:

The response buttons will not be pressed, which tells the LifeVest to prepare to deliver a treatment. The monitor will then play an auditory message to inform bystanders to not interfere while the treatment is delivered.



Safety information

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

- Conductive parts of electrodes and associated connectors should not contact other conductive parts including earth.
- If the charger or power supply makes unusual noises, sparking, starts to smoke and emits a burning smell, unplug it immediately from the wall outlet. The only we to completely remove power is by unplugging the AC power plug from the wall outlet.
- Any medical electrical equipment connected to the patient of the samptime as the LifeVest must be defibrillator proof, as shown by this symbol. It is equipment is not defibrillator proof, the equipment may be damaged if the Livest or person treatment. Disconnect any non-defibrillator proof equipment from the patient while the patient is wearing the LifeVest.

Terms used

WARNING: Warns of possible injury or death that can be a sed by misuse of the device.

This includes device failure that result in the ability of the device to

protect you.

CAUTION: Advises of possible problems that include amage to the device or other

property, or minor Jury.

WARNINGS

Do not use the LifeVet System unit you receive training and understand the manual. If you do not understand how use the system, you may damage it and/or cause the system to malfunction.

Always your the eVest who instructed to do so by a medical professional. Make sure the electric event is connected to the monitor. Inappropriate use of the LifeVest may damage it and/or us are system to malfunction.

Joing ample alter, drop or abuse any part of the system or labeling. Altering the equipment in any will may dail ge it and/or cause the system to malfunction. Do not disassemble the unit. A show hazard exists. Refer all servicing to qualified personnel.

Depot put the monitor, electrode belt, battery or charger in or near water. Water entering the device may damage it and/or cause the system to malfunction.

WARNINGS

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

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

If you see Blue™ gel other than during a treatment, this may indicate a damaged elember and cause the system to malfunction. Call ZOLL LifeVest immediately.

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

The LifeVest is magnetic resonance (MRI) unsafe. Do not use the limaging environment.

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

Only the patient should press the response but to a satient's above to press the response buttons lets the device know whether or not the patient is anscious 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, possible resulting in second injury or death.

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

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

Do not a good of or measurate the batteries. The batteries contain lithium ion and must be add on aperly by ZOLL.

Do no sorce the ennector. Allow the connector to align before pushing it in. Forcing the connector may damage it and cause the system to malfunction.

that lude bleach, bleach alternatives, fabric softener, anti-static sprays or detergents that lude bleach or fabric softener additives when laundering the garment. Using bleach or any of these other prohibited agents to launder the garment may damage it and cause the system to malfunction.

WARNINGS

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

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

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

When performing the WalkTest™, do not continue walking if the monitor broad asts an alert sound. Stop walking and press the response buttons as you normally would. If you continue walking, you may place yourself at risk for a cardiac arrest, possibly resulting in selection or death.

When performing the WalkTest™, do not continue walking if you was ione symptoms such as shortness of breath, chest pain, or other pain or discomfort. Stop walking and sit or lie down. If the symptoms continue or get worse, immediately call your actor or emergency slp. If you continue walking or ignore the symptoms, you may place you lif at risk for a cardiac arrest or other health problems, possibly resulting in serious injury or dea



Indications for use

The LifeVest system 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.

The LifeVest system is indicated for patients under 18 years of age who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator. Patients must have a chest circumference of 26 inches (66 centimeters) or greater and a weight of 18.79 kilograms (41.3 pounds) or greater.

Environment considerations related to noise and vibration

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

If you encounter a loud, high vibration environment of the yearing the LifeVest, you should be attentive to your device to ensure you respond to any alert, at the unlikely event that vibration causes you to receive a siren alert, press the response buttons prevent receiving a treatment and move away from the source of vibration

Intended use locations

The intended electromagnetic extronments are home, small clinic, hospital and the sport.

Essential performance

The essential per primance of the LifeVest is that it detects ventricular fibrillation or ventricular tachycardia, then plivers a treament. Unacceptable risks include loss of detection and treatrant for tional

Aircraft u

The LifeVer 5000 was tested to demonstrate compliance to the emissions and immunity quirements of the following standard: RTCA DO-160F, Environmental Conditions and Test Procedures for Airborne Equipment, Section 20 (RF immunity) and Section 21 (RF emissions).

Sheck with the airline for any special restrictions on using personal electronic equipment when haking flight reservations.

The Airplane mode feature disables the LV5000 from communicating wirelessly. Use this option when on an airplane or in any environment where cellular phone use is prohibited.

Operator profile

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

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

- The patient wears and interacts with the LifeVest on a daily basis. The patient patient papears below.
- ZOLL authorized representatives fit patients with the equipment, and transfer tients the ZOLL authorized representative profile appears below.

Patient profile

The device is appropriate for patients who are at risk for sudd cardiac rrest and much the requirements described in the Patient Manual.

ZOLL authorized representative profile

ZOLL authorized representatives are ZOLL-transcripted fessionals. Sair job is to program the equipment according to the patient's pre-ription, may ure and fit patients with the LifeVest equipment, train patients and family members, and provide follow-up assistance if necessary.

ZOLL authorized representatives past has the mental old physical capabilities to understand training given by ZOLL that covers programme the disce, measuring and fitting patients, and training patients in the daily ase to the device.

Patient training

It is essential the all patients region training before wearing the LifeVest. This training is given by ZOLL authorized representatives. These representatives deliver the LifeVest training in the patient of the Clinical Atting.

Project training consists of instructions for garment and electrode belt assembly and discrement, and account including the use of the response buttons; and how to change and rechange the batteries.

A er competing the training, patients sign an agreement that documents receipt of training in a use and care of the LifeVest.

In addition, phone support is available for patients by calling ZOLL or a ZOLL representative. See age ii, for the ZOLL phone support number.

Electromagnetic interference

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

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

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

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

usually high In some occupational and hospital environment cels of electromagnetic disturbance could be encountered. Examp s of possi sources of such disturbance include: Magnetic resonance (MR) imaging equip ent, commun ation equipment such as microwave transmitters, arc welding equipment, high voltage transi ssion lines, electrocautery systems, and electronic muscle stimulator hese ironments hould be avoided while wearing the LifeVest device.

In the unlikely event that electromage etic disturbance causes you to receive arrhythmia alerts, press the response buttons to prevent ling shocked and move away from the source of the disturbance. The Livest success should recarn to normal monitoring mode in approximately 5 seconds.

Wireless interference

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

- **Cell phone use** When using a cell phone, keep it at least 10.6 inches (27 centimeters) away from the round electrodes on the electrode belt. If you experience noise alerts while using a cell phone, move the cell phone away the electrode belt or stop using the cell phone.
- Charger use The charger contains a cellular device for data transcriptions. Lep the charger at least 10.6 inches (27 centimeters) away from you body prevent interference. If you experience noise alerts while use the charger, move away from the charger. If you take the charger to a lospical busine that the use of cellular devices is permitted. If not, do not use the charge while in the hospital. If you need to transmit data, use your in-home of supported the pen WiFi network.
- **General precaution** If you experience are terference with the LifeVest when in the presence of any other wireless dece, here away from the device or stop using the other device. If you continue to have placems, call ZOLL.

FCC regulatory information

This device complies with part 15 of the Fu Rules. Operation is subject to the following two conditions: (1) This device may be cause have the following two any interference received a cludity interference that may cause undesired operation.

The monitor contains ECC-ID: W56MTA E-BW-A.

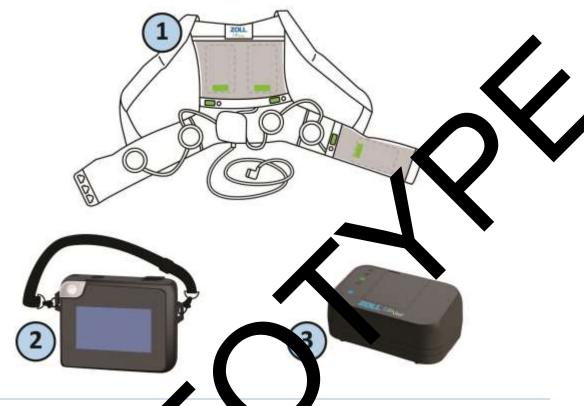
Refer to charger Jel for FCC

Changes or mode cations to this evice not authorized by ZOLL could void the RF compliance and negate your a shority to or rate the device.

The allable clientific councie does not show that any health problems are associated with using low prover wireless devices. There is no proof, however, that these low power wireless devices are absorbed. Safe. Low power Wireless devices emit low levels of radio frequency vergy. (E) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects assess 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 LV5000 has been tested and bound 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. The maximum SAR levels tested for the LV5000 has been shown to be 0.133 W/kg at Body.

2: Meet the LifeVest 5000 system

Components



<u>Item</u>

1

Garment and electrode belt



Monitor

Des a on

The garment, is around your body and the electrode belt connects to monitor. The lectrode belt contains the therapy pads, round electroles and the vibration box. See details on page 2-2.

Connect o the electrode belt. Monitors your heart rhythm and initiates treatment. See details on page 2-3 and 2-4.

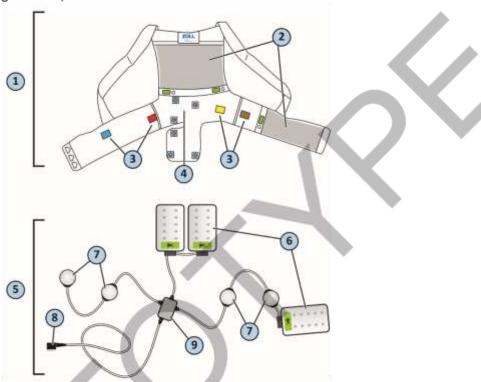
A strains attached to the monitor for easy mobility while wearing the device.

3 Ch. er s

Recharges the battery, communicates wirelessly with the monitor, and transmits data for prescriber review. The LifeVest system includes two batteries so that the monitor can run continuously on battery power. See details on page 2-8 and 2-9.

Garment and electrode belt

For details on assembling, wearing, and caring for the garment, see sections 3 and 4. For details about responding to alerts, see section 5.



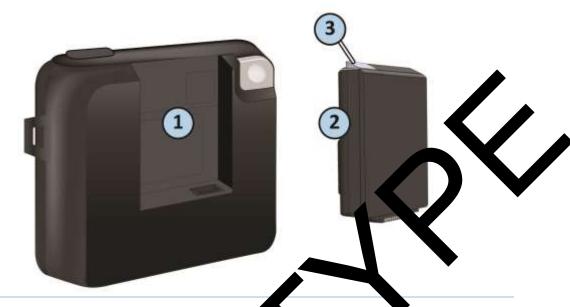
Item		Description
1	Garment	Worn under your clothing to hold the round electrodes and therapy pads against your chest.
2	Therapy pad pockets	The silver mesh pockets where the therapy pads are placed. There are two on the back of the garment and one on the front.
3	Round electrode Velcro attachment areas	These areas on the garment are color-coded Velcro to match the appropriate round electrode placement.
4	Vibration box area	This is the area of the garment where the vibration box is placed.
(5)	Electrode belt	Assembles into garment and contains the round electrodes, vibration box, and therapy pads.
6	Therapy pads	Deliver a treatment to your heart and contains Blue $^{\! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! $
7	Round electrodes	Sense your heart's electrical signal. Also called ECG electrodes or electrodes.
8	Connector	Connects the electrode belt to the monitor.
9	Vibration box	Notifies you that the device is preparing to give you a treatment. (Also vibrates on start-up after the battery is inserted.)

Monitor — front view



<u>Item</u>		Description
1	Response buttons	Two buttons, located of the front and lock of the monitor, that light solid red when the device sense that your heart has a life threatening, irregular rhythm. If you was conscious, press both response buttons to stop the LifeVest from delivering a treatment location and release the response buttons; you don't have shold them continuously.
2	Speaker	Audi <u>ble</u> voice prompt and alerts.
3	Status indicator lights	Indicate syst in status. Green: On soll during normal operation. Off during gong or siren alerts. Rllow: Flash during a gong alert to tell you that something requires your attitude seck monitor screen for any instructions.
4	nnector	Connection site for the electrode belt cable.
P	Strak tachin t	Two strap attachment areas on either side of the monitor. The strap is adjustable to give you two options to comfortably wear the system. For options on how to wear, see section 3.
V	Touchscreen	Displays messages about device operation, and allows you to interact by touch with the device. When the monitor is held upside down, the display flips so that you can read the screen.
	▼	Most of the time during normal monitoring, the touchscreen is dark. To view the display on the screen, press the response buttons.
		For details, see page 2-5.

Monitor — back view



<u>Item</u>		Description
1	Battery placement area	Location of battery placement in the nation.
2	Battery	Powers the moni r. To recharge the battery, use the charger; see page 2-8.
3	Battery release button	Press to a move the ottery from the monitor.

Monitor touchscreen

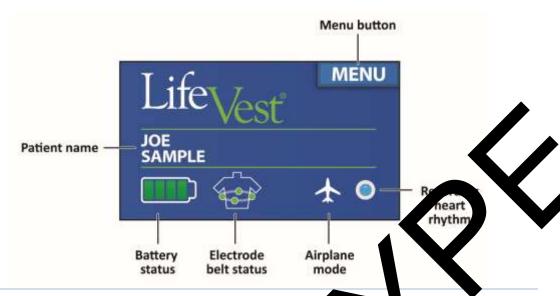
Shown on the following page is an example of the monitor screen during normal monitoring.

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

As situations change, the screen will change to advise you and suggest an action to take. So that require you to take some action will have a help screen associated with them. For me on help screens, see page 2-7.

Most of the time the monitor display screen is darkened to conserve battery power fyour the to view the Home screen or complete an action while wearing the LifeVest, pross the buttons.

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



Description Item Displays your name so you know this was programmed for you. **Patient name** Tap to display the Patient Menu, where you co elect various options. See Menu button details in section 3. **Electrode belt** cted to the patient and are in normal Round elec odes are con status monitoring ode. not connected. See details in section 5. of charge remaining in battery. hows amou

Shows amos of charge remaining in battery of charge remaining charge remain

Yellow indicates that the battery needs to be changed. Call ZOLL for a replacement.

Red indicates a depleted charge.

A syding heart Indicates that your heart rhythm is being recorded for your prescriber to review, see section 3.

Airplane mode is on. For details, see section 3.

mode

Airpla

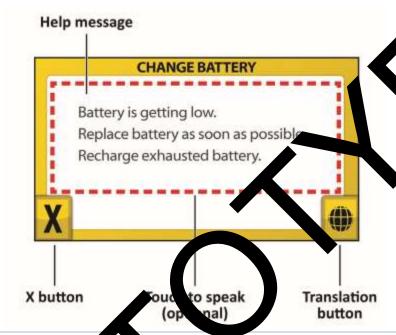
Help screens



For any screen on the monitor that has a question mark icon in the lower right corner, you can tap that icon and see a help screen.

Shown below is an example of a help screen.

Note: Not all screens will have a help button. This button also appears in different color such as on response button screens where the help button is blue.



Item	Description
Help message	Brief Jessas Alling you wat to do based on the present condition.
Touch to speak	If e speak optic is enabled, touch the message area of the screen to hear the he message. The message will be spoken in the language displayed. The area to tap he hown by the dashed line in the example above; the dashed line will not be isible on screen. To enable this feature, see section 3.
X button	se the screen.
fransla on butto	Only appears if more than one language is programmed.

Charger

The charger recharges the battery and communicates wirelessly with the monitor.

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



Item



Power supply

scription

Plugs has a standard power outlet to provide power to the charger. For the larger power supply, any 60601-1 or 60950-1 approved power supply providing an output of 18 VDC at 1.67 Amps (min) with a CULP A-2-35135-SG connector, see Charger setup in section 3 for a section

2

inu tra

Indicate charger status. See details on page 2-9.

త

ttery

Powers the monitor. To recharge the battery, use the charger.

7

Power supply connection area

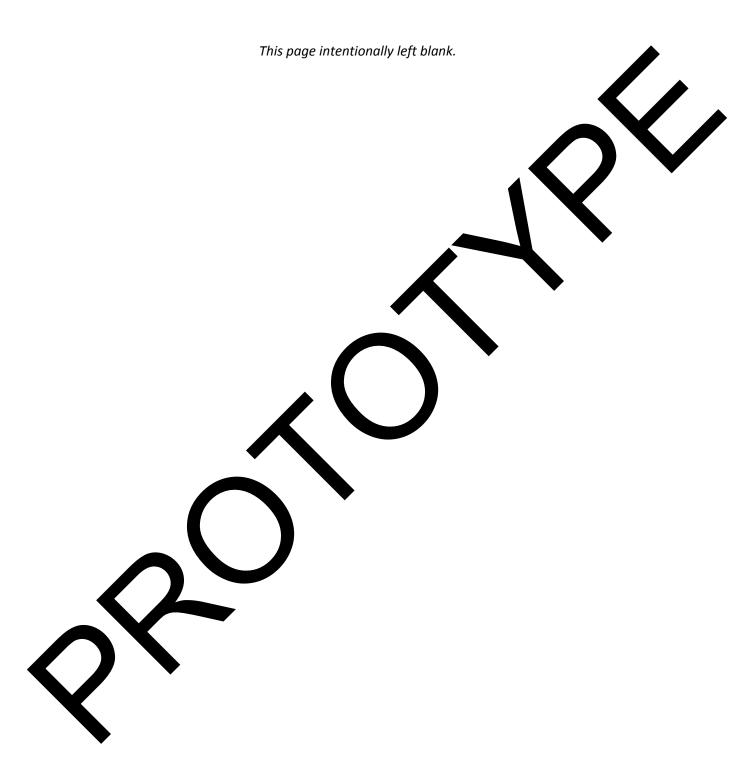
Connects the power supply to the charger.

Battery charger indicators

The battery charger indicators are located on the top of the charger. These indicate the charger status. For details, see section 3.



lcon		Description
1	Power	Charge s connected to a power source.
2	Charging	Poxery currently being charged. Light blinks until fully charged and then a go off.
3	Charge complete	tery has full ower.
4	Battery fault	Charger communication may not be functioning properly. Charger can so be used to charge battery. Solid light and a momentary beging sound occurs. Call ZOLL.
5	C'a ger faul	Problem with the charger. Light blinks and a beeping sound occurs. Call ZOLL.
) (

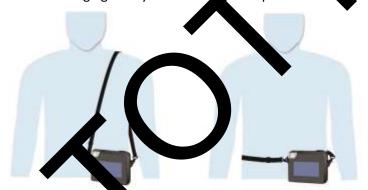


3: Using the LifeVest

Daily routine

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

- 1. Wear the assembled electrode belt and garment. For details on wearing the Life see section 4.
- 2. Put a fully-charged battery into the monitor and follow the normal cartup roune. See page 3-2.
- 3. Change and recharge the battery every 24 hours. See page 3-3, attery c
- 4. Wear the monitor with the strap fastened to the two same areas on the monitor. The strap is adjustable to give you two options to confortably we the system, either around your waist or hanging over your should take a purse.



- 5. Respond to any are. See section 5.
- 6. Remove he battery from the monitor and then completely remove the LifeVest from your bod when you shower or bathe. Do not reinsert the battery until you are wearing the fully attempted decide. See section 4.
 - Chan and wash the garment every 1 or 2 days. Wash only the garment. Do not wash the charge belt, monitor, or any other accessories. Follow the instructions in section 4 laundering the garment.

Normal startup routine



- **1.** Remove the depleted battery from the monitor.
- **2.** Insert a fully-charged battery into the monitor.
 - Make sure the battery is completely inserted



3. Startup screen appears.



- 4. When you ear the gong and it the vibration on your Jack press the response buttons.
 - If you do not have the gong or feel the
 via tion within seconds, remove the batter. Reinsert the battery and try again.
 - If the maitor still does not operate normally, contact OLL.



- **5.** The monitor displays your name and battery level.
 - Make sure your name appears on the monitor.
 If your name does not appear, contact ZOLL immediately.



- **6.** During normal monitoring, most of the time the LifeVest monitor screen displays a dark screen and the green status indicator is lit solid.
 - To see the display, press the response buttons.

Battery care

What you need to know



- You have two batteries, so you can use one while charging the other.
- Change and recharge batteries every 24 h
- Recharging the battery takes approximally 4 to 6 hours.
- Place the charger in a safe place where ou can leave it plugged in. Keep the second butery in the charger while you we the opport.
- Always have a battery in the charge even when fully charged.
- The battery and charger may get warm. This is normal. Place the charger in well ventilated place.
- Use only the batteries and charger supplied with the LifeVes stem.
- Remove the battery from the monitor when processing the device when showering, for example). Always remove the battery first to ensure the device is not active when you are not wearing it. A "whistle" alert will sound if the battery has been left in the monitor for over 20 minutes with the electrode belt disconnected.

In the event of a power out ge

If there is a power interruption you need to take teps to keep your batteries charged.



- Notify your electric company that you have a medical device that needs power. If they believe the power will be out for 24 hours or more seek alternatives for powering the batteries, such as a neighbor or family member not affected by the outage.
- Notify your local emergency medical services and see if they can help.

Locate a source of backup power if possible, such as a generator. Plug the battery charger into the backup power and charge the spare battery continuously. Change the batteries every 24 hours.

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

When the power is restored, continue charging and changing batteries every 24 hours.

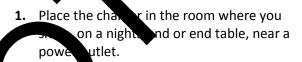
Charger setup

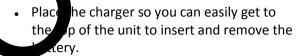
If the charger or power supply makes unusual noises, sparking, starts to smoke, or emits a burning smell, unplug it immediately from the wall outlet. The only way to completely remove power is by unplugging the AC power plug from the wall outlet.

Note: For the charger power supply, any 60601-1 or 60950-1 approved power supply providing an output of 18 VDC at 1.67 Amps (min) with a CUI PPM-2-35135-SG connector as detail below may be used.

Connection	Designation
Inner Contact	+V
Outer Ring	-V







- The charger can actually be placed anywhere in the house, but we recommend the room where you sleep so it is convenient to use every day.
- 2. Plug the power supply into the back of the charger, then plug it into a standard power outlet.
 - Make sure the outlet stays on all the time, and is not controlled by a light switch.
 - · Keep the charger plugged in at all times.
 - When you first plugin the charger, all of the icons will blink three times and you will hear a rapid, beeping sound.
 - When the charger is powered on, the blue icon remains on.





- **3.** Gently insert the spare battery into the charger.
 - Orient the battery with its connector facing into the base of the charger.
 - Push the battery in firmly.
 - It takes approximately 4 to 6 hours charge a battery.
 - Keep a battery in the charge even when fully charged



- 4. Look for a symbol along the left of the charger's display. These symbols in that the battery status
 - The backery should be arged or change.
 - nese s, bols are explained in the next section, Charger and battery status dicators.

Charger and battery status indicators



Icon	What it means	What to 19
1 Power	Power is on.	the power pply into the back of the larger, then plug it into a standard power butlet. Make sure the outlet stays on all he time, and is not controlled by a light witch. Always leave a battery in the charger, even when the battery is fully charged.
2 Charging	charging.	Let the battery charge. This can take 4 to 6 hours.
3 Charge complete	Battery is fully charged, ready for unin monitor.	Leave battery in the charger until ready to exchange battery even when the battery is fully charged.
4 Batt v fault	Battery has a problem.	Call ZOLL for a replacement battery.
Charter faut	Charger has a problem, and cannot charge the battery.	Do not leave a battery in the charger. Battery is not being charged. Call ZOLL for a replacement charger.

Change and charge batteries daily





Leave the elect ode belt connects during this procedure

- 1. Remove the exist, battery from the monitor by presing the release button on top of the battery, having it away from the monitor.
 - Leave the electrode belt connected to the monitor during this procedure.
- **2.** Remove the fully-charged battery from the charger and place it into the monitor.
 - Push the battery firmly into the monitor until it clicks to ensure it is fully inserted.





- **3.** Gently place the used battery from the monitor into the battery charger.
 - Properly orient the battery with the label side down and firmly push it into the charger base.
 - Check the battery status on the charger and verify that the battery is being charged. It takes approximately 4 to 6 hours to charge a battery.

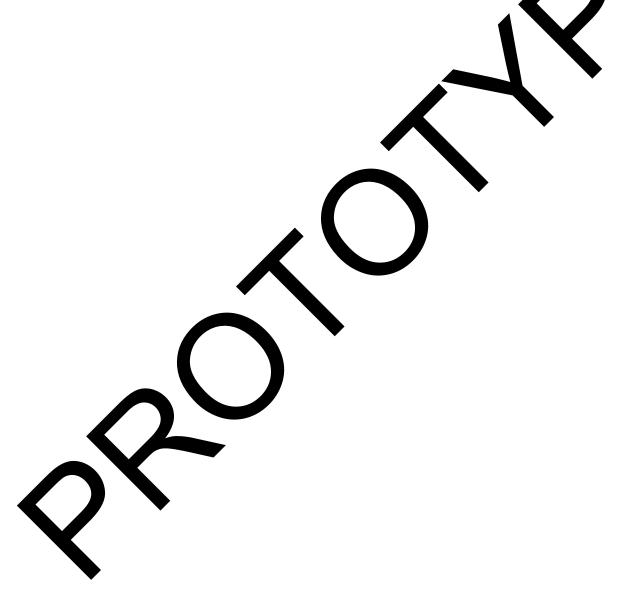
Record your heart rhythm (ECG)



At times, you may want to record your heart rhythm (ECG) for your prescriber to review.

- **1.** Hold the response buttons for 3 seconds.
- 2. Release response buttons when you see recording indicator and hear a single ang.

On the monitor the ECG recording indicator was appear in the bottom right corner of the recording will take 15 seconds.



Patient menu screen

Tap **MENU** on the Home screen to open the Patient Menu screen.





Note: Your prescriber may assign **ACTIVITIES** for you to perform. If the **CTIV** con is not displayed on your monitor your prescriber has not assigned you to do a y.

Settings menu



See more information starting on page 3-10.



Send data



See more information in on page 3-



Activities menu



more information in section 6, Using the virities options.

Note If the **ACTIVITIES** icon is not displayed on your monitor it is inactive. It is not necessary to have **ACTIVITIES** activated. This is at your prescriber's discretion.



Voice options

The LifeVest system provides the option of having Help screen messages spoken to you when they are displayed on the monitor. Help screens provide information and/or instructions about a specific topic or aid in resolving a problem. This section explains the voice options and how to set them so the monitor speaks Help messages.

Note: Voice options do not affect the volume level of physiological alerts or messages.





- 1. On the home screen, tax MENU.
- 2. On the Patient Menu, tax FTTINGS.
- 3. On the tings Menu, tap V EE
- **4.** On ZIP Vo. Options there are two options: Volume and Note.



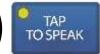
Use the row keys to increase or decrease the volume the messages.

Note olume is not affected for physiological alerts or messages.





If you want the mestages to automate ally speak appear, set and Alwar Speak option.



If you want the messages spoken to you only when you tap the screen when Help screens appear, select the Tap to Speak option.



If you do not want to hear the messages spoken to you, select Mute.

5. Tap **ACCEPT** to confirm your selections and return to the Settings screen.

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

Sending data manually

Normally, data transmission from the monitor to ZOLL occurs without you having to initiate it. However, if data is requested by ZOLL after a treatment or for another reason, the Send Data icon provides the means for you to send the data.



- 1. On the monitor home screen, tap **MENU**.
 - If the monitor screen is off, press the buttons to show the home screen.



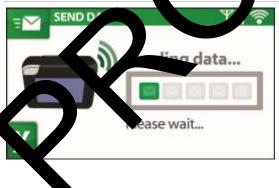
2. On the Patient Menu, tap IND DATA.



Tap **SEND** begin the data transfer.

icons for network availability. See details on page A-1.

If you experience problems sending data, call ZOLL.



- **4.** The device then connects through the charger or through WiFi to send your data.
 - The gray envelopes on the screen will turn green as data is successfully sent to ZOLL.



- **5.** Your download is complete once you see all envelopes turn green and hear a gong alert.
- **6.** Tap **ACCEPT** to close the Send Data screens and go to the Home screen.
- **7.** You have now successfully sent your data to ZOLL.



If data is unable to send, you will see this sch and hear a gong alert.

Tap **TRY AGAIN**.

If you continue to have a croblem adding data, write down the service coe (in the service right corner of the screen) and cell ZOLL.

To continue this task, airplane mode needs to be turned off.

Tap CONTINUE to turn off airplane mode and continue the task.

Tap X to exit this screen.

If airpla de is ON you will see this screen.

Tan **CONTINUE** to try airplane mode off and continue sending data.

For details ee Airplane mode page 3-13.

Airplane mode

Airplane mode disables transmitting data capabilities. Use Airplane mode in any situation where wireless transmission use is prohibited in order to avoid interference with aircraft operation and other electrical equipment.



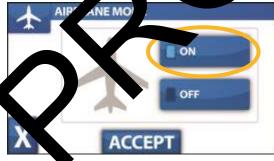
1. On the home screen, tap **MENU**.



2. On the Patient TTINGS.



3. On the Skings Menu, tap AIRPLANE.



4. Airplane mode is off by default. Tap **ON** to enable Airplane mode, then tap **ACCEPT** to confirm and close the screen.

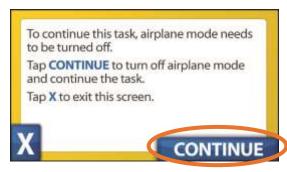
Note: The monitor will go out of airplane mode the next time you remove or change the battery.

Tap **X** to close the screen without making any changes.



5. The airplane symbol will appear and remain on the Home screen when airplane mode is enabled.

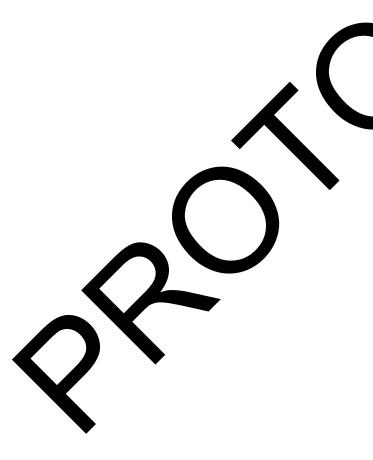
Note: The monitor will go out of airplane mode the next time you change the battery.



If you attempt to manually send data airplane mode, you will see this seen: le in

You have two choices:

- 1. To turn off airplane ode and ITINUE. with the tack tap CO
- 2. To leave airplane me turned on and sceed with the tax tap X.

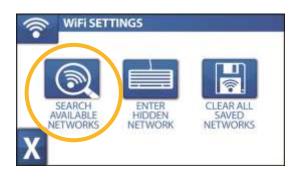


WiFi

WiFi allows you to transmit data to ZOLL from any location where wireless networks are available.



Searching for and accessing available WiFi networks

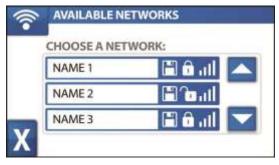


- 1. On the home screen, tap ENU.
- 2. On the Patient Menu, tap ETTINGS.
- 3. On the Settin Menu, tap 'Fi.
- 4. On WiFi strings, tap **SEARCH A AILABLE NETWORKS** browse for an available WiFi network.

are taking lace, the WiFi Settings screen displays.



nng message will appear while the device looks for an available network.





- 5. If networks are available they will appear for selection. Use the up and down arrows to navigate to additional networks in the list. Each network displays signal strength and security status (locked or unlocked). A locked network a closed network that is not accessible by the LifeVest.
- **6.** Tap on the network name you want to use. It wait screen may appear while you sele you is identified.

Tap X at any time to can

123



Encreted Network Pa word required: If a resword is equired when you select a network, a eyboard appears for entering the password for hat network.

Tap the shift key (up arrow) on the keypad to shift between uppercase and lowercase letters.

Tap the numeric button to access numbers and symbols.

Tap the cancel/backspace key to delete and retype the password.

After typing the password, tap **ACCEPT**.

A wait screen may appear while your password is being validated.



7. If the network is available, its name is displayed as connected.

Tap ACCEPT.



Password invalid: A screen is displeted If the password is invalid.

Tap **TRY AGAIN** and re-enter e pass d on the keypad screen.

Tap X to close.



A second isplays to into m you if the network is

this occurs, to ACCEPT to go back to the Search vailable Networks menu to choose a new ork.



If Previously Connected: If the device was previously connected to the WiFi network selected then the WiFi network information screen will appear.

Tap **CONNECT** to proceed to the Enter Password screen.

Tap **FORGET** for your device to forget all information for this WiFi network.

To close the screen without making any changes, tap \mathbf{X} .



Tapping **FORGET** on the previous screen displays the WiFi Network information screen.

Tapping **FORGET** a second time deletes all network information on this device.

To go back to the WiFi Network security screen, tap **X**.



If no networks are available, the "New ViFi networks are available" message is displayed

Tap ACCEPT to go back to the liFi Set smenu.



If you the st tap **ACCE**, after 30 seconds a timed of screen we display.



If you are already connected to a WiFi network or have previously connected you will bypass the password screens and go directly into this screen.

Network Connected: If you are connected to a network **DISCONNECT** appears on the WiFi Network screen.

Tap **DISCONNECT** to get back to the WiFi settings menu.

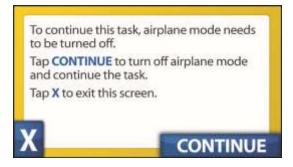
Tap **FORGET** to go to the WiFi Network Forget screen.

To go back to the WiFi Settings screen, tap X.

If you are not able to connect to WiFi Settings one of the next two screens will display.



If a download is in progress, this screen displays.



If airplane mode is on, this screen a lays

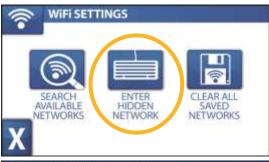
Tapping **CONTINUE** turns off a plane m

Tap **X** to close this screen and renain in airplane mode.

For details, see trplane mode on page 3-13.

Entering a hidden WiFi network







- 1. On the home screen, tap MENU,
- 2. On the Patient Menu, tap SET NGS
- 3. On the Settings Menu, to Wh.
- 4. On the WiFi Settings meet, tap EN SR HIDDEN NETWORK.

If **ENTER H DEN NETWOR** selected from the WiF a ttings screen, a key, ad screen appears to table entry of the network name.

5. After typing in a twork Name, tap ACCEPT.



6. If a Network is available, the Network Security screen appears, displaying security level options. If you are not sure of your network security, select WPA2 as your first option.

A "Please wait..." screen may then appear while your selected network option is being connected.

If you require assistance with the hidden network connection, contact ZOLL.



7. If a Password is required when you select a network from the list, a keyboard appears.

After typing the password, tap **ACCEPT**. If you do not tap **ACCEPT**, after 30 seconds a timed out screen displays.



If NO password is required, the connection is made. Tap **ACCEPT** to continue.



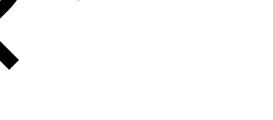
If the network is not available, a screen displayed to inform you of this.

Tap **TRY AGAIN** to try and connect to the atwork again. This takes you back to be English twork Name keypad screen.

Tap X to close. This woul ack to the Enter Network Name paper screen

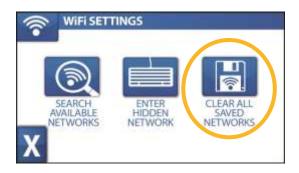
Try connect with the **WPA** security network option.

If you are still unable connect, contact ZOLL for sistance



Clearing all saved WiFi networks





- 1. On the home screen, tap **MENU**.
- 2. On the Patient Menu, tap SET AGS.
- 3. On the Settings Menu, ta WiF.
- 4. On the WiFi Settings men tap CLL SALL SAVED NETWORKS.



5. On the ALL SAVED NETWORKS screen, tap DeLETE to lete all saved WiFi networks or CANCEL to go bab.



6. Tap **DELETE** to confirm deleting all saved WiFi networks.

Tap **CANCEL** to go back to the WiFi Settings menu.



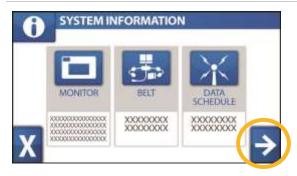
7. The last screen provides confirmation that all WiFi networks have been deleted.

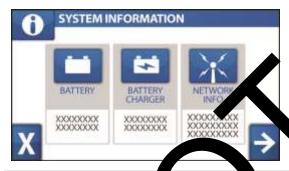
Tap **ACCEPT** to take you to the WiFi Settings menu screen.

System information

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







- 1. On the home screen, tap NU.
- 2. On the Patient Menu, tap STINGS.
- 3. On the Settings Mich. O
- **4.** The System commation screens isplay informations ociated with the system components.
 - Tap on the Net arrow to see more seem Information options.

Tap to close and return to the Settings Men

Support mode

This feature lets ZOLL update the settings in your LifeVest monitor while you remain at home.

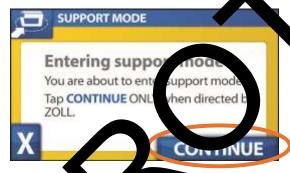
It is a simple process that should take just a few minutes.

Updating your LifeVest:

- ZOLL will call you to talk you through the updating process.
- Remain on the phone with ZOLL until this entire process has been completed.
- Continue to wear the device during this process.
- You will interact with the monitor screen, tapping icons and readily back who the display says.
- If you are unable or uncomfortable doing this, have someone veh you we can talk with ZOLL and interact with the monitor.
- Follow along with the procedure below.

Note: You need to have access to your charger or to update your settings.



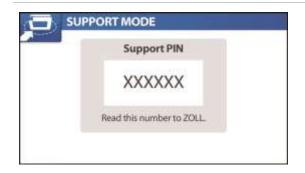


ZOLL will call you to assist you through this process.

- On the home screen, tap **MENU**.
- 2. On the Patient Menu, tap SETTINGS.
- **3.** On the Settings Menu, tap **SUPPORT**.
- **4.** On the Support Mode screen, tap **CONTINUE**.



5. A "Connecting" screen appears.

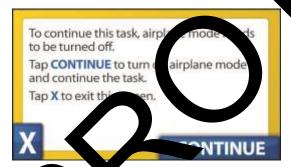


6. When this screen appears, read this number to the ZOLL representative.



7. A "Please wait..." screen appears





Lote: If you attempt to enter the support mode while in airplane mode, you will see this screen.

You have two choices:

- To turn off airplane mode and continue to enter support mode, tap **CONTINUE**.
- To leave airplane mode turned on and not enter support mode, tap X and return to the Settings Menu screen.

For information on Airplane mode, see page 3-13.

Periodically clean and inspect the system

WARNING

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

If you see Blue™ gel other than during a treatment, this may indicate a damaged electrode at and cause the system to malfunction. Call ZOLL LifeVest immediately.

Clean the electrode belt and inspect equipment when changing garments. Secific details about laundering the garment are in section 4.

Cleaning non-washable items

Unplug the battery charger and disconnect the power cord from the war putlet before cleaning.

If necessary non-washable items such as the charger, bat wies, cables, and herapy pads may be cleaned with a soft cloth. Do not use a damp cloth or such hing with water, chamicals or cleaning solutions.

If necessary, clean the monitor touchscreen by wining it with a ft cloth dampened with window or glass cleaner. Dampen the cloth arectly, not spray saything directly on the monitor.

The round electrode metallic surface may be cleaned will a soft cloth dampened with rubbing alcohol.

- Don't apply liquids pectato any of the non-washable items, as they contain electronic components that can be day ged.
- Don't atter to any electroal contacts or connectors.
- Do not use any cleaning olution on the garment. Specific details about laundering the garment are in section 4

Call ZQ' add anal cleaning is needed for the monitor or charger.

Inspection

Inspecture of the following system when changing garments. If you should notice any of the following please notify ZOLL as soon as possible:

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

What family members need to know

WARNINGS

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

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

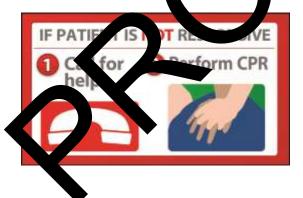
Do not remove the battery, do not disconnect the electrode belt from the months, and so not loosen the garment while the monitor is broadcasting alert sounds and/or pice pictus. If the battery is removed, the electrode belt disconnected from the monitor, or the tarment a posened, needed therapy may not be delivered, possibly resulting in serious injury or doubt. CPR can be performed as long as the monitor is not broadcasting alert sounds and one prompts. If external defibrillation is available, a decision can be made by a medical pofessional to recover the device and monitor/treat the patient with external equipment.

Information for family members

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

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

The LifeVest directs a conscious patient to respond to messages and alerts. A patient who has lost consciousness describe arrhythm will be unable to respond, letting the device know it is time to deliver areatment. The bystander should not respond to messages and alerts in place of the patient.



- If the LifeVest treatment does not revive the patient and the patient is unconscious, call for help and then start CPR.
- If the patient remains conscious, check the belt to make sure all round electrodes are pressing against the patient's skin.
- A label on the front of the garment reminds medical professionals to open the garment before giving the patient conventional external defibrillation.
- Keep the LifeVest device out of the reach of children.*1

^{*1} See indication for patients under 18 years of age.

When you are finished with the device



Call ZOLL and arrange to return the LifeVest system.

Battery recycling

WARNING

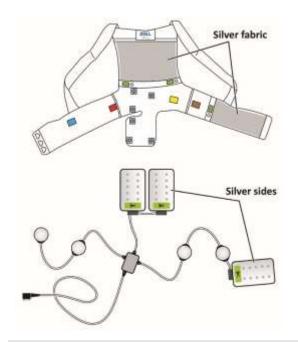
Do not dispose of or incinerate the batteries. The batteries contain lithium io and must disposed of properly by ZOLL.

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



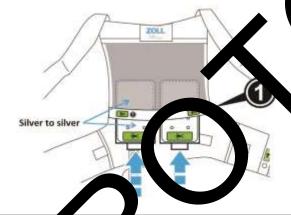
4: Garment and electrode belt

Assemble the garment and electrode belt



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

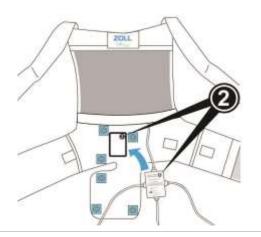
- Place the garment with the silver me fabric facing up.
- Place the electrode belt with the single sides of the therapy pads facing up.



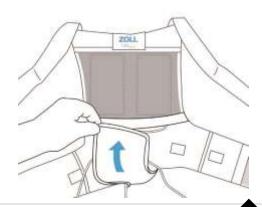
- 1. Insert the ear therapy pads into the garment rear pockets.
 - me rear pockets are numbered 1.
 - Insert the pads silver to silver, meaning place the silver sides of the pads (with the green labels) facing the silver mesh fabric on the pockets. Make sure the pads are flat against the silver mesh fabric.



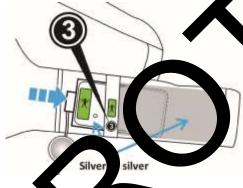
 Snap the green tabs to close the pockets, making sure they are securely fastened.



- **2.** Position and secure the vibration box to the garment.
 - The vibration box flap is numbered 2 on the garment.
 - Place the vibration box with the label side facing up.
 - Make sure wires are not crossed or twited.



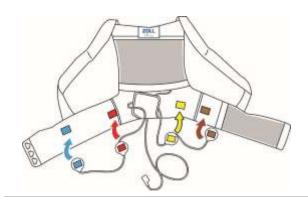
 Snap the flap over the dibration ax to the blue tabs, making sure II three snap are securely fastern.





Insert the front therapy pad into the front pocket.

- The front pocket on the garment is numbered 3.
- Insert the pad with silver to silver, meaning place the silver side of the pad (with the green labels) facing the silver mesh fabric on the pocket.
- After the therapy pad is fully inserted, snap the pocket closed, making sure it is fastened securely.



- **4.** Attach the round electrodes to the garment, matching the colors on the backs of the round electrodes to the colors of the Velcro on the garment. Make sure not to cross or twist the wires.
- **5.** Make sure that you have properly assembled the electrode belt to the garment.

Assembled garment and electrode belt

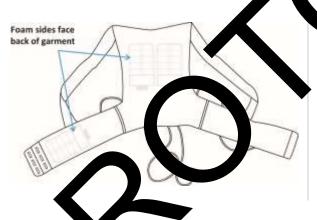
The assembled electrode belt and garment should look like the following figures:

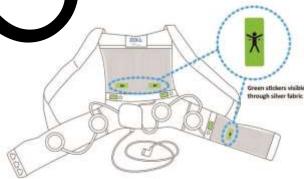
Outside view

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

Inside view

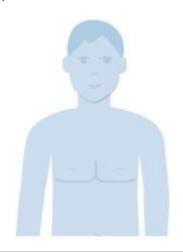
worn. The silver mesh fabric pockets are against your skin. The green labels are isible through the silver mesh fabric.





Putting on the assembled garment and electrode belt

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



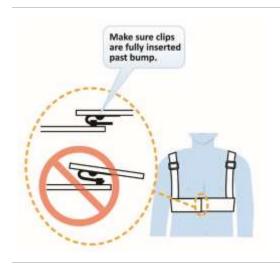
- Before putting on the garment, remove all clothing and undergarments from your upper body.
 - All clothing, including underwear muse worn OVER the device, NOT update.
- **2.** If desired, apply unscented has a lotion four round electrodes.



- 3. Put or arment, making sure:
 - The garmen loesn't get twisted.
 - The liver mesh poric pockets touch your bare skin.
 - The round electrodes are flat against the skin with crossed or twisted wires.

If you are a female:

- Wear a bra **OVER** the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against your body underneath your left breast.



- **4.** Connect the garment ends together in the front.
 - Make sure that the clips are fully inserted past the slight bumps in the clips.
 - There are two clip sets, a looser and tighter setting allowing for fitting adjustments

5. Look in a mirror to make sure that:

- The garment is being worn correctly, fitting snug to your torse.
- The garment is not twisted. Straps are flat against your sland tighteness
- The round electrodes and therapy pads are pressing a cost bare skin. The sixer mesh fabric pockets and silver side of the therapy pads (with grain lasts) MUST TOUCH YOUR BODY for the device to work properly.
- None of the cables are crossed, twisted together interfering to the round electrodes.

Your garment should look like these figures.





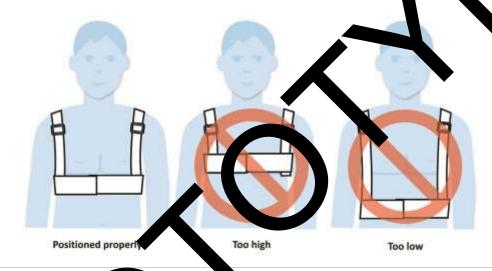


6. Check the position of the garment on your body and make sure it is not too high or too low.

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

Move the buckle sliders to position the garp of properly, and for a snug fit.

- The garment should cross your body below your breastbone.
- The garment should not be shigh a your nipples.
- The garment should not be a slove s your belly button.



Connecting and disconnecting the electrode belt

WARNING

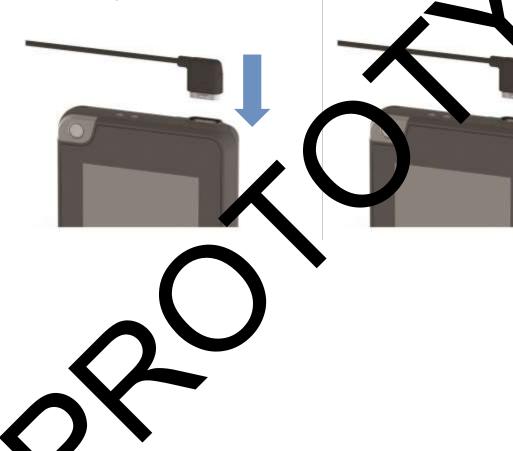
Do not force the connector. Allow the connector to align before pushing it in. Forcing the connect may damage it and cause the system to malfunction.

To connect the belt

Line up the connector with the monitor. The cable should face toward the center of the monitor. Gently push the connector straight in until it locks in place.

To disconnect the belt

Gently squeeze the sides of a connector as you pull it straight out on he maite



Remove when showering and bathing

WARNING

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



Always completely remove the LifeVest december y shower or bathe. Don't put the monitor electron belt, or battery in or near water.

When you remove the device for any reason, remove the battery first.

When you remove the trieve that the or shower, you are not protected by the device. Bath or shower preferably when the peone else is home. It is you.

When you put the Life st back on, put the battery in last.

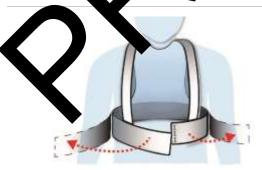
Note the batter should be removed if the LifeVest is not being used.

A loud whistle sound is activated to the Librest has been dle for 20 minutes or more with the electrode belt disconnected. The alerts you are more the battery.

Removing the LifeVest device before ou bathe or shower



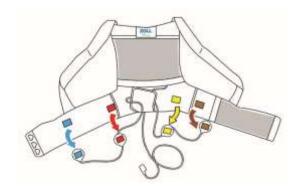
1. Remove the battery from the monitor. Keep the belt connected to the monitor.



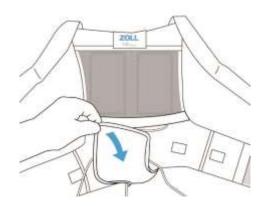
2. Unfasten and remove the garment from your body.

To change the garment, follow the procedure on page 4-9 and then 4-1.

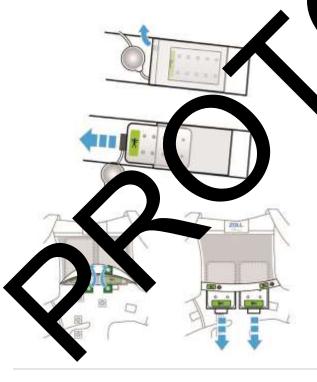
Disassembling the garment and electrode belt



1. Remove the four round electrodes from the garment by gently separating the Velcro from the garment. Do not pull on the wires.



- 2. Unsnap fasteners and remove the paration box from the garment.
 - Gently pull vibration by caway from the garment dilling on a sibration box wires can datage the internal using and cause the community of the cause



- Unsnap and remove the therapy pads from their process.
- **4.** Wipe the metallic surfaces of the round electrodes with a soft cloth dampened with rubbing alcohol.

Note for reference:

- Assembling the garment and electrode belt see page 4-1.
- Putting on the assembled garment and electrode belt see page 4-4.
- For laundering instructions, see page 4-10.

Laundering the garment

WARNING

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







Launder the garment every 1 or 2 days. Before washing the garment:

- Remove the electrode belt (round electrodes and prapy pads) to protect it from damage. Do not wash the electrode elt with the garment.
- Attach the clips of the general nent together.
- Wash the garment witself. not wash it with other laundry.
- The garment was a hand-washed or machine washed, using a normal way cycle and warm water, with a maximum water temperature of 45°C (11) F).
- Us a mile othes washing detergent only, such as varieties for insitive skin.
- Use clothes dryer on medium heat setting to dry the garment. Do not use the high heat setting. Do not use dryer sheets. (If a dryer is in available, the garment may be laid out on a flat urface to air dry.)



5: Responding to alerts

Overview of alerts

This section is organized by the types of alerts you can experience while wearing the LifeVest;

- Physiological alerts, such as in response to a treatment or asystole. See below.
- **Technical alerts** such as a service code. See page 5-4.
- Informative alerts, such as a reminder to change the battery or respond to round electrode noise. See page 5-6.

Physiological alerts: vibration or siren sound

These alerts are in response to a physiological condition or possible hear related active detected while wearing the LifeVest.



Vibration alert

During normal use, if you get a vibration in the back of the electrode belt, you are being warren but the siren art will sound within 5 seconds. You will also get a she wibration alert every time you change the battery.

Press the response attons to sto the siren alert and the vibration alert.



Siren alerts

The shalert is a high-pitched two-tone sound that means an abnormal heart rhy m has been detected. The response buttons will turn red during the alert.

response buttons to stop this alert. If you do not respond to this alert, you will probably receive a treatment within the next minute.

The siren alert is accompanied by screen messages and voice prompts.

There are two possible messages:

- **1.** If the alert is accompanied by a "respond" message follow instructions on the following page. This alert instructs you to respond.
- **2.** If this alert is accompanied by the "call for help" message it will audibly instruct bystanders to call for help.

Responding to a siren alert

WARNINGS

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

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





If you are conscious, press the response buttons to stop the treatment from occur ing. You was see these red bordered screek. The need to respond to a siren alert.

- The size stops and a voice pumpt indicates that are trustment is being delayed.
- NO ONE ELSE pauld press the response ps. Only you she patient, should press the response buttons.
- If you feeddizzy, find a place to sit or lie down.
- Press the response buttons each time you feel the viriation alert or hear the siren alert.

If you are set consious, you yet not be able to press the response buttons.

This allows the device to deliver a treatment.

Vol. pro pre are. standers not to touch you.

region unto scious.

If you receive a treatment



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

When any of the following messages appear, tap Help for additional information about where to do.



- Call your prescriber's emerged y named immediately to report your reatment
- 2. Unless your prescribe tells we herwise, continue to wear the feVest's tem.
 - Leave the anti-connected. Do now emove the electrode bence arment, and do not disconnect the electrode belt from the
 - Leave the attery in the monitor. Do not remove the attery. Continue to change a trecharge the batteries as normal.
 - Lea the Blue[™] gel under the therapy pag
 Do not wipe them dry.

ap ACCEPT after reading the message.



3. Call ZOLL and arrange to get a new belt.

Tap **ACCEPT** to acknowledge you have read the "Call ZOLL" message on the screen.



4. Check for any further instructions that may be displayed for you to follow.



For additional information, tap Help.

For more details, see page 5-19.

Siren with call for help message

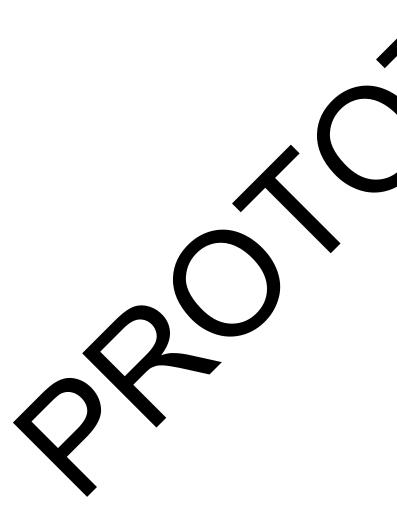


If you are awake and feel fine and the monitor shows this message:

- Press the response buttons to stop the message and siren alert.
- If the alert continues even after you pass the response buttons, remove and replace a battery to reset the device.
- If you continue to get this essage, c

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

Voice prompts and messages alert bystanders to call for help.



Technical alerts: gong sound

These alerts may indicate a problem with the device.

Technical alerts are accompanied by a low-pitched "gong" sound that repeats about once a second.



Note: This is the same gong sound that sounds for informative alerasee page 5-6.

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

Take the following action:

- Read the message on the monitor's display.
- Use the technical alerts list below to see that the manage means and what to do.

Message or icon on monitor

Call for service Device has a problem that may require service. Call ZOLL for service. ACCEPT

What it rea

Svet sa problem at require ervicing.

the device is sel able to used.

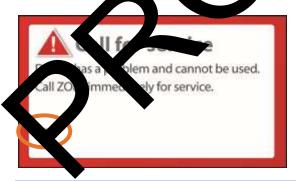
What to do

Continue using the device.

Find the code number (Example: 101) shown on the bottom left side of the monitor.

Write down the code number and call ZOLL.

Tap **ACCEPT** to return to Home screen.



System has a more severe service problem.

You **CANNOT** use the device.

Call ZOLL immediately.

Find the code number (Example: 202) shown on the bottom left side of the monitor.

Write down the code number and call ZOLL.

Informative alerts: gong or high-pitched "train whistle" sound

These alerts are for informational purposes.

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

If you get an informative alert there is a problem that needs your attention. Take the followage action:

- Read the message on the monitor's display.
- For specific help with any message, tap Help if it is available on the screen
- Use the following lists to see what the message means and what the property of th

Informative general gong alerts

The following screens occur along with a gong alera turing gener functioning of the device. These alerts may occur at the startup of the device after ball by replacement.

Message or icon on monitor

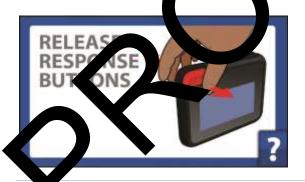
PRESS RESPONSE BUTTONS

What it means

ress the res, ase puttons to tes their action every time the base reliable.

What to do

At startup, press the response buttons as a reminder of what to do when a siren alert sounds.



This message may appear at startup.

You may be holding the response buttons instead of pressing and releasing them.

Release the response buttons.

If you are not holding the response buttons, the device may not be functioning properly.

Call ZOLL.

Message or icon on monitor



What it means

Electrode belt is not connected to the monitor.

Monitor is receiving a poor signal or no signal from the electrode belt.

What to do

Gently connect electrode belt to monitor.

If belt is already connected:

- 1. Remove by ary
- econnect and lectron pelt.
- 3. Re. all battery.

Note: Until you connect whelt, the monitor will interest tently toggle between this alert screen and the Home screen.



e system performing naintenance on the belt.

No action required.

Wait while this screen is displayed, usually about 30 seconds.



The monitor has not automatically sent data either after a treatment was delivered or after a routine specified length of time.

Send data manually as soon as possible.

For details, see page 3-11.

Message or icon on monitor

Unable to send data Try again. If problems continue, call ZOLL. TRY AGAIN 405

What it means

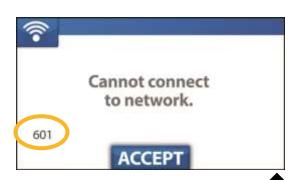
A connectivity issue is preventing the monitor from sending data to ZOLL.

What to do

Tap **TRY AGAIN** to attempt sending again or tap **X** to close and try again later.

Find the code number (Example: 405) shows the botton and side the monitor.

rite wyr de code mber a call ZOLL.

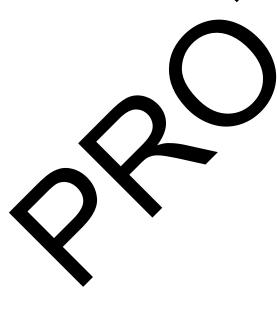


A connectivity issue is preventing the conitor from connection to the chosen provonk

ACCEPT to attempt contesting again.

If the connection fails a second time, find the code number (Example: 601) shown on the bottom left side of the monitor.

Write down the code number and call ZOLL.



Informative electrode belt gong alerts

The following screens occur along with a gong alert when the device detects electrode belt problems.

Message or icon on monitor



What it means

Monitor is not receiving a good signal from the round electrodes that are colored red on the screen.

A voice prompt will tell you to check round electrodes.

The system and their placement and their control by your skin.

What to do

Adjust your gard and electrode belt so the each row a encorode touching your son.

ean track and ceretrodes with alcohol and apply unsurpted to distinct the distinct of the dist

No action required.

Wait while this screen is displayed, usually about 30 seconds.



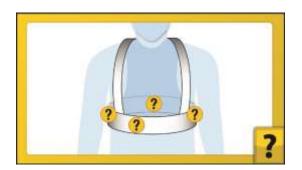


The therapy pads are not aking contact with your skin.

Make sure the therapy pads are inserted correctly, with the metal sides facing the silver mesh fabric on the pockets.

Make sure the therapy pads and mesh pockets are pressing against your skin.

Message or icon on monitor



What it means

Monitor is not receiving a signal from the electrode belt.

What to do

Adjust your garment and electrode belt so that each round electrode is touching your skin.

Make sure noth a is covering the metasurfaces and ound electrones.

nd lotic on the strace of each round each trode.



The monitor pot receiving good anal from the electrode at

Make wre the electrode belt is connected to the monitor.

Remove the battery from the monitor. Take off the garment and make sure nothing is covering the round electrodes or therapy pads.

Put a dab of unscented hand lotion on the surface of each round electrode.

Put the garment back on and reinsert the battery.

If problems continue, call ZOLL.

For details, see section 4.

Informative battery gong alerts

The following screens occur along with a gong alert when the device detects possible battery problems.

Message or icon on monitor

Battery charge level cannot be determined Call ZOLL for a new battery. Continue wearing the LifeVest.

What it means

Yellow battery: Battery charge level cannot be determined.

What to do

Remove the ball by and insert the fully charbattery from the charb into the monitor

ontine warring the eVest.

ZOLL for a represent battery.



Red batt y: Bat y needs to be change.

Replace with a fully-charged battery.

Place discharged battery into the charger.

Tap **ACCEPT** to return to Home screen.



gong sounds if the battery has been left in the monitor when not in

If the LifeVest has been idle for 20 minutes or more with the electrode belt disconnected a "train whistle" alert occurs.

Remove the battery when the LifeVest is not being used.

If the LifeVest is being used, ensure the electrode belt is properly connected to the monitor.

Call ZOLL if the alert persists.

Informative after treatment gong alerts

The following screens occur along with a gong alert after you have experienced an abnormal heart rhythm and received a treatment.

Message or icon on monitor



What it means

This message may appear after detection.

You may be pressing the response buttons and you are no longer having a treatable heart rhythm.

What to do

Release the res buttons.

re not p If you nctioning ay no pperly.

ZOLL.



You have re treatmen

Continue to wear the LifeVest device.

> Call your prescriber's emergency number immediately.

Leave the electrode belt connected; change and recharge the battery as normal.

Follow instructions about what to do after receiving a treatment, see page 5-3.

Tap **ACCEPT** to return to the Home screen.



You have received a eatment.

Message or icon on monitor



What it means

Blue™ gel has been released and the gel is drying out.

What to do

Add gel to the therapy pads.

Call ZOLL to get a replacement elect de belt.

Tap ACCF setup. Sonorman peratik

for deals, page 5-19.



Too much gel is on your skin.

Leave the Blue gel that it ander the therapy pads, but tipe the gel from the skin the is not under the therapy pads.

Tap **ACCEPT** to return to normal operation.

For details, see page 5-20.



Informative gong alerts: additional instructions on what to do

The following are expanded instructions on what to do when certain gong alerts occur.

Electrode belt message

This screen shows which round electrodes are causing problems.

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





Good signal: (Green) Situation non-land, no action required.



Poor signal: (Yellow Could Louische noise, electrical noise, wear signal, louisignal, or interference



Off skip (Red) Round actrode is not making good contact with skin. No signal is

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

- The round electrodes indicated by the yellow red symbols are touching your skin.
- Nothing is between the round electrodes and your skin, such as clothing or one of the cables.
- Garment and belt fit and w, with the ectrodes pressing against your skin.
- Round electrode cable is see ely connected into the monitor.

While you're wearing the Vest, tap H. for reminders about what to do.

Check round electrodes message

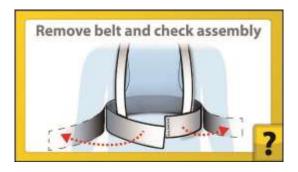


You may get this screen with this voice prompt: *Check electrodes*. The problem may with the signal from the round electrodes.

Follow this procedure to correct the problem.

- 1. Check your electrode belt and garment. Make sure:
 - All four round electrodes are touching your sky, not flipped to r or pulled away from your skin.
 - Nothing is between the round electrons and yer skin, such as clothing or one of the cables.
 - Garment and belt fit snugly, went the robe electrodes pressing against your skin.
 - Round electrode cable is sed tely connected into the monitor.
- 2. If you continue to get the message all ZOLL.

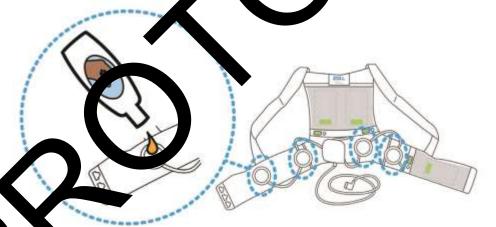
Check belt message



After you get a number of belt problem screens, you may get a remove belt od check ssemb message. It means that the monitor is still not receiving a good signal from the electrical belt.

If you get this message:

- **1.** Remove the battery from the monitor.
- 2. Disconnect the electrode belt from the monitor.
- **3.** Take off the garment and make sure that not leaves covering the metal surfaces of the round electrodes.
- **4.** Check that the therapy pads are in the paskets with the over side touching the silver mesh fabric.
- 5. Put a dab of unscented hand lot in on the surface of each round electrode (the round ones, not the therapy pads)



- **6.** Put be garment on, making sure it fits snugly, and connect the electrode belt to the monitor. Put the battery back into the monitor.
 - While you're wearing the LifeVest, tap Help for reminders about what to do.
- 7. If problems continue, call ZOLL.

Replace belt message



After you receive a treatment to correct an abnormal rhythm, you may see a sessage elling you to replace the belt.

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

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

While you're wearing the LifeVest, tap Help for reminder sout what to a

Tap **ACCEPT** to return to the Home screen.

To replace the electrode belt:

- 1. Remove the battery from the move or.
- 2. Disconnect the electrode belt from the monitor.
- 3. Remove the electrode by and galacent from your body.
- **4.** Disassemble the elegation the garment, assemble the new electrode belt into a clean garment, and put on the assembled electrode belt and garment, see section 4.
- **5.** Connect the seed belt to the onitor.
- **6.** Put the attery into the nonitor and follow the normal startup routine.

Therapy pad message



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

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

The symbols help you to determine the oblem.



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



Therapy pad coskin: Situation normal, no action required.

If you get red symbols, make sy

- Therapy pads and me pockets are pressing against your skin.
- Therapy pads are inserted correctly into their pockets, with the metal sides (with the grantsheads) facing the netal mesh.
- Gallent and belt is snugly, with the metal mesh of the therapy pads pressing aga st your skin.
- Make we to prozerly launder the garment, see page 4-10.

Whi you're earing the LifeVest, tap Help for reminders about what to do.

Add gel to therapy pads



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

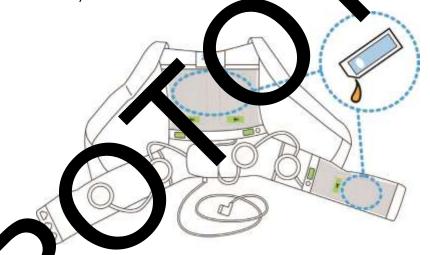
Follow the instructions below to add gel.

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

Tap **ACCEPT** to return to the Home scr

To add gel:

- 1. Locate the packets of gel you received with the LifeVest system
- **2.** Remove the battery from the monitor, then remove the from your body.
- 3. Add one-half packet of gel to all three therap pack directly onto the silver mesh material of each pocket. Apply to the rear pads and e front pad (but not to the round electrodes.)



- 4. Put the electrode belt and garment, see section 4.
- **5.** at the battery into the monitor and follow the normal startup routine.

Too much gel on therapy pads



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

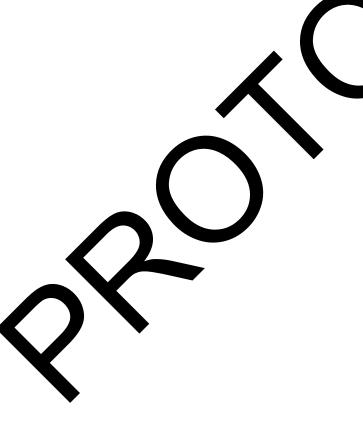
Follow the instructions below to remove the excess gel.

While you're wearing the LifeVest, tap Help or reminders about what to do.

Tap ACCEPT to return to the Hop screen

To remove excess gel:

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



6: Using the activities options

Introduction to activities

Your prescriber can request two activity options that are programmed into the system while you are wearing the LifeVest. These options are the health survey and the WalkTest™. Before y perform either of these activities for the first time, read this section of the manual.

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

These activities allow you to provide some additional information to your prescriber. Your prescriber may then use that information to help evaluate your condition.



For more about the health survey option see the health survey" section below.



For more about the Walk potion see king the WalkTest™", page 6:

Taking the health survey

If you get the message "Please complete health survey" when you change the battery, you are to take the health survey. You have the option of taking the health survey now or later.

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

If you have any questions, please contact your prescriber.

What do I have to do?

You need to answer the health survey questions honestly.

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

Why is it important that I do the health surve

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



Taking the health survey now

If the monitor displays the screen with the message "Please Complete Health Survey" when you change the battery, you are to take the health survey.

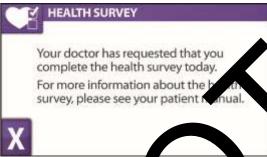
Read through all the health survey steps in this manual before you answer the questions for the first time.

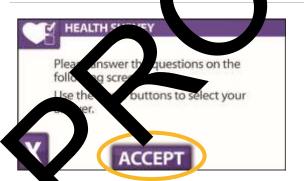
There are many health related questions that your prescriber can include in the survey the questions and answers shown in these instructions may not be the questions and answers you see on your monitor.

If any alerts are displayed during the health survey, see section 5.



Tap NOW to start the high lth st.
 Tap Help for details.





2. The message on the screen instructs you to use the arrow buttons to select your answers.

Tap **ACCEPT**.

Note: To cancel taking the health survey, tap **X** at any time.



- **3.** Read the first question.
- **4.** Use the arrow keys to scroll to the appropriate answer.
- **5.** Tap **ACCEPT** to choose your answer and continue to the next question.

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

Note: If you want to hear the question a poke to you, tap the screen in the question a la.

You can change the voice of an so you hear each question screen as pon as the pears, without tapping the screen. You also change the voice volume. For the details about changing the volume with see Voice options in section 3.



6. Repeat steps 5 for the remaining questions.



- Upon completion of the health survey you will see this screen.
- 8. Tap ACCEPT.

Taking the health survey later



If you tap **LATER**, the system returns to the Home screen instead of proceeding with the health survey.

When you decide to complete the health survey, access it by tapping **MENU** the Hone screen, then **ACTIVITIES**, and then **HEALTH SURVEY**.









Health survey messages

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

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

Message

HEALTH SURVEY CONNECT ELECTRODE BELT Health survey is not available while the electrode belt is disconnected. Please connect the electrode belt. ACCEPT

What it means

You are attempting to take the survey with the electrode belt disconnected.

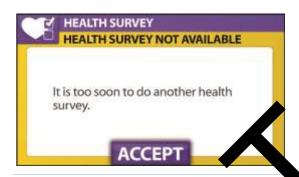
The belt needs to be connected to take the health survey.

What to do

Wear the trickless connect the electrod below the mountaing the electrod below the message grown away.

nessage go away.

y again to take the
howh survey.



You are attempt of to take the health survey uently than scheduled.

Tap **ACCEPT** to clear the message.

Wait until you get this message: "Please complete health survey."



Taking the WalkTest™

WARNINGS

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

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

When performing the WalkTest™, do not continue walking if you experience so aptoms so that shortness of breath, chest pain, or other pain or discomfort. Stop walking and so or lie chavn. If the symptoms continue or get worse, immediately call your doctor or emergancy has a you continue walking or ignore the symptoms, you may place yourself at risk for cardiac a jest or other health problems, possibly resulting in serious injury or death.

Your physician prescriber may order the WalkTest™ of the ways to use the LifeVest to gather information about your condition.

How does it work?

The purpose of the WalkTest™ is to monthly your heart and count your steps while you walk for 6 minutes.

Before and after the walk, you we've asked two questions: one about your shortness of breath level and another about your fatigut evel (how tired you feel). After the walk, you will answer the same two questions again. Look at the screen for the possible answers and pick the one that most closely describes how the feel at the moment.

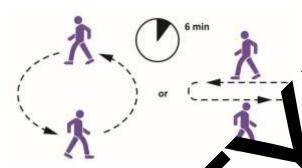
During the next heduled data pwnload, the LifeVest sends your WalkTest™ information to a secure website vere your physician prescriber can review the results.

Your projects pressure made you repeat the WalkTest™ once a day or once a week. The Life lest will to mind you when you are scheduled to take the WalkTest™.

What do I have to do?

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

If possible, have someone with you while you do the WalkTest™. Try to walk at a pace you can comfortably maintain for 6 minutes. You can walk in a circle or oval (as walking a track), in a square or rectangle (around a room), or in a straight line, turning as you reach the ends (wasking back and forth in a hallway).



While you are walking, the LifeVest will give you audible frompts about how such longer you are to walk. It will also tell you when to stop walking at is right if you need to stop and rest at any time. Continue walking when you are able. After the want you will answer the fatigue and shortness of breath questions again.

It is also important that you only walk for minutes as art of this WalkTest™. Listen for the voice prompt that tells you to "stop wall g" after 6 minutes. When you hear this voice prompt, please stop walking.

- Wear comfortable loes
- Walk on a hard-flat surface. Do at walk on a treadmill.
- Do not refor jog. This est monitors you while you are walking at a normal pace.
- If you have any walking problems, or if you have an abnormal gait, such as foot dragging, suffling, or lapping, or if you need assistance while walking, such as by using a call walks. These, please tell your physician prescriber as it may produce inact results.
 - The monitor gives you voice prompts throughout the WalkTest™, so you may prefer to the WalkTest™ in a private location. So that you can hear the voice prompts, do not the walk Test™ in a private location. So that you can hear the voice prompts, do not the walk Test™ in a private location. So that you can hear the voice prompts, do not the walk Test™ in a private location.
- If your physician prescriber asks you to do multiple WalkTests™, doing the walk in the same location gives the most accurate results.

Why is it important that I do the WalkTest™?

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

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

Taking the WalkTest™ now

If you get this message "Please Complete WalkTest™" when you change your battery, your pasicial prescriber has asked that you perform a WalkTest™.

Throughout the WalkTest™ procedure, you must wear the LifeVest, with it confected form ly.

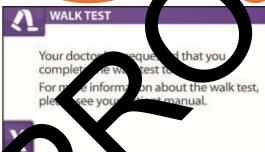
You have the option of taking the WalkTest™ now or later. Make sure the elect de belt connected to the monitor before starting the WalkTest™.

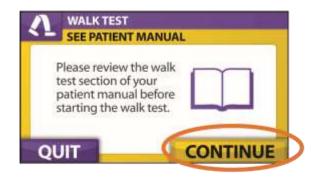
During the WalkTest™, the LifeVest monitors your heart and count your steps. It test takes six minutes to complete. If you receive an alert while walking, stop calking and press to response buttons.

If you have any questions, please contact your physician.



- Tap N V to begin.
 - Tap H p for details.



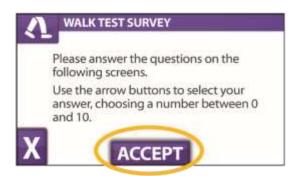


 When you tap NOW, a message to review the WalkTest™ in the manual is displayed.

Review the manual as needed.

Note: This screen times out. If you want to read, tap **QUIT**. If you already have read the manual, tap **CONTINUE**.

To get back to the WalkTest™ if you quit, see page 6-13.



A message appears prompting you to answer two questions.

Tap ACCEPT.

The questions ask you to select ratings on a scale that reflects your current shortness of breath and fatigue levels before the WalkTest™. Use the arrows on the screens to scroll to the most appropriate number. The following table displays the scale for questions.

Note: To cancel taking the WalkTest™, tap X.

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

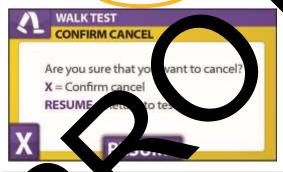




The monitor will display two pre-walk questions about your shortness of breath and fatigue levels (how tired you feel).

- **4.** Select your levels using the arrows to the left and right of the scale.
- **5.** Tap **ACCEPT** on each screen to confirm ar continue.





6. The WalkTest Start screen appears. Tap

RT when you're ready to begin the test.

A volumer of the start walking.

What you need to do during the WalkTest™ is described in the "What do I have to do?" section on page 6-8.

To cancel the WalkTest™, tap **X**. If you cancel the WalkTest™ you will be asked to confirm that you really want to cancel.

If you do want to cancel, tap X.

If you do not want to cancel, tap **RESUME**.



7. A progress bar is displayed during the WalkTest™.

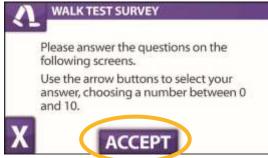
You will receive a voice prompt after each minute of the WalkTest™.

Continue walking for 6 minutes.



8. When the test is completed (after approximately 6 minutes), you are instructed to stop.

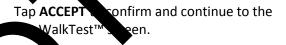
Tap ACCEPT.

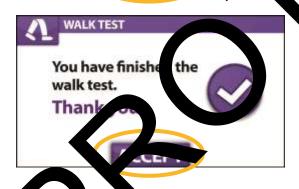




9. The shortness of breath and a gue to estion are displayed again with least rating a eens.

Select the numbers the best of your levels after the walk. Your answer DO NOT need to match your precious answer.





10. Tap ACCEPT on this screen to close the WalkTest™ and return to the Home screen.

After completing the WalkTest[™], sit down and rest before resuming your normal activities.

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

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

uring the data download, the LifeVest sends your WalkTest™ information to a secure website where your physician prescriber can review the results.

ur physician prescriber may have you repeat the WalkTest™ at certain intervals. The LifeVest will remind you when you are scheduled to take the WalkTest™ by displaying a message on the monitor.

Taking the WalkTest™ later



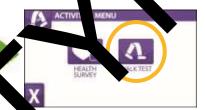
If you choose to complete the WalkTest $^{\text{\tiny M}}$ later, tap **LATER** to return to the Home screen.

If you tap **LATER** another WalkTest™ promp won't be displayed until you change the battery.

When you decide to complete the WalkTest™, access it by tapping **MENU** when Hornz screen, then **ACTIVITIES**, and then **WALKTEST™**.









WalkTest™ messages

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

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

Message

WALKTEST CONNECT ELECTRODE BELT Walk test is not available while the electrode belt is disconnected. Please connect the electrode belt. ACCEPT

What it means

You are attempting to take the WalkTest™ with the electrode belt disconnected.

The belt needs to be connected to take the WalkTest™.

What to do

Wear the tris-Vest connect the electrod below the mountor.

After any cing the electrod below the the message guaraway.

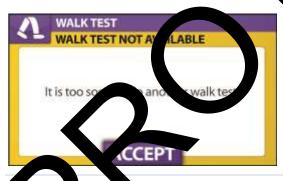
It is a supply to the the tribe the tribe to the tribe the tribe to the tribe the tribe to the tribe tribe. The tribe tribe



You are temping to take the WalkTest and the set is advising you not to ke the WalkTest™ a this time.

Tap **ACCEPT** to clear the message.

Try again later (or wait until tomorrow).



You are attempting to take the WalkTest™ more frequently than scheduled. Tap **ACCEPT** to clear the message.

Wait until you get this message: "Please complete WalkTest™."

Appendix A: Symbols and Icons

Cell signal strength: LifeVest is in range of a cell network and can transmit data. Number of bars indicates signal strength.

Note: These icons also appear on a different color background, such as green when sending data.

- Registered, connected, data can be transmitted, white bars indicate signal strength.
- Signal strength is too weak to send data.
- Cell modem is powered but not functioning properly.
- Not connected to ZOLL charger network server.







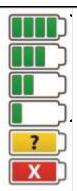


WiFi signal strength: WiFi networks are a mable transmitting data.

Note: These icons also appear on a different color back round, such as green when sending data.

- Connected to WiFi network, data can be ansmitted, white bars indicate signal strength.
- Signal stren is to weak to send data.
- Wif a power d/turned or but not connected to any access points.
- Vari is not functioning properly.

WiFi is not powered or turned off.



Battery levels that are displayed on the monitor.

Green segments: Depict how much charge is left in the battery.

Yellow battery: Call ZOLL for service.

Red battery: Battery is low, a critical situation. Change battery as soon as possible and recharge battery.

A-1 LifeVest 5000 Patient Manual



Electrode belt symbol shows that the electrode belt is connected to the monitor.



The electrode belt is not connected to the monitor. If not corrected, a gong alert sounds and the "belt not connected" screen is displayed.



Help button: Tap this icon to see help screen information.



X button: Tap this icon to close the screen.



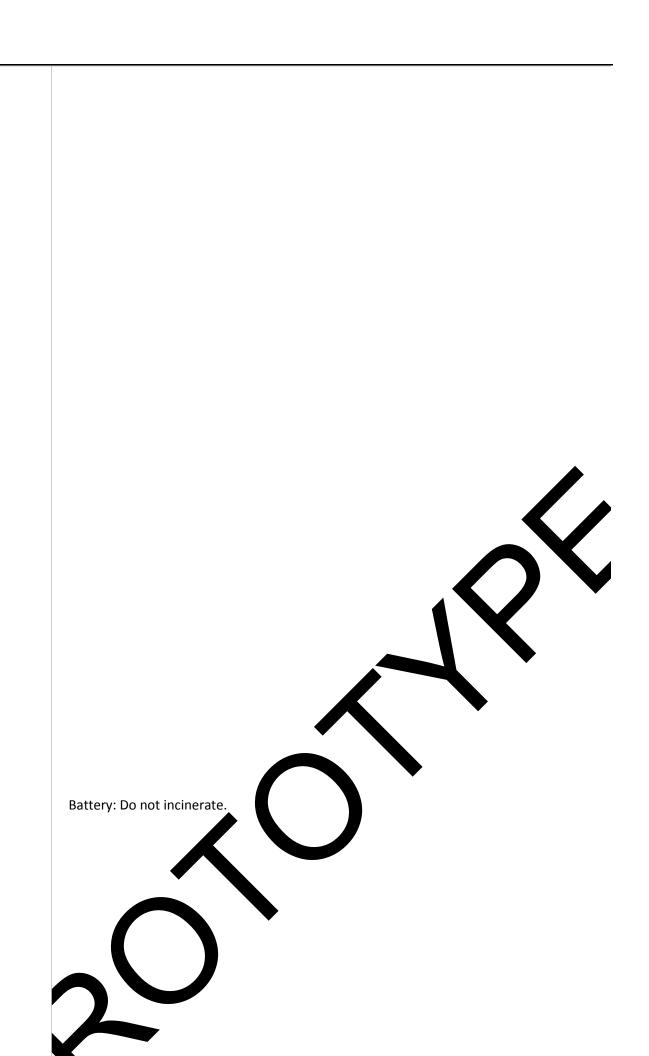
Round electrode good signal: Situation normal, no action required.



Round electrode poor signal: Check round electrodes for cause of poor signal to fix the problem.



Round electrode off skin: Round electrode is not making good contact with skin. No signal is detected. See Responding to alerts, section 5.

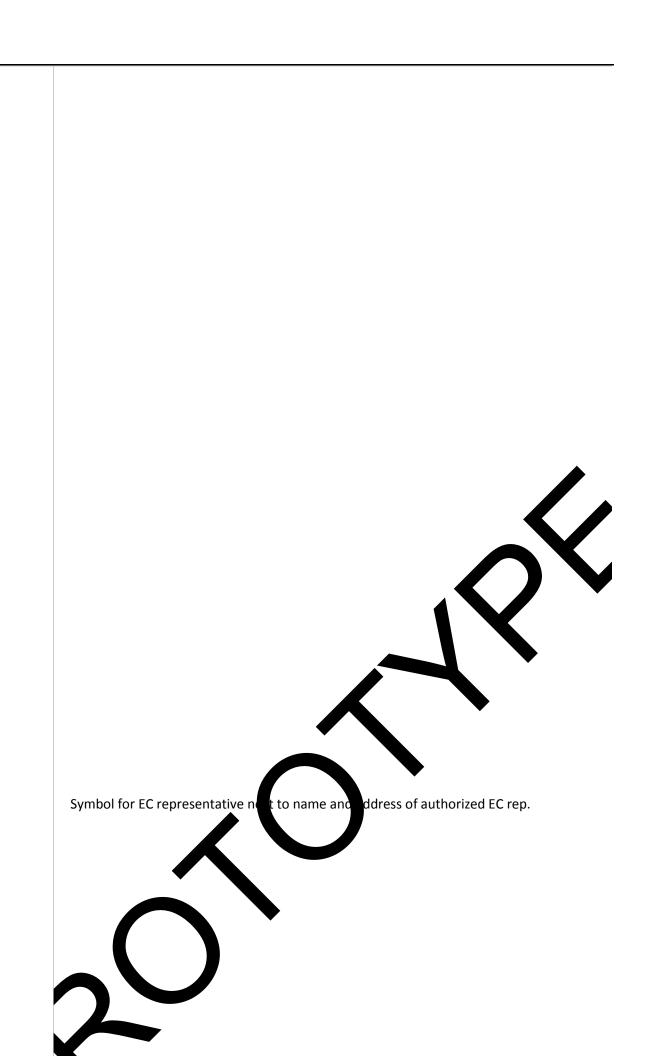


8	Battery: Do not short circuit.
MR	Magnetic resonance (MR) unsafe.
	Laundering symbol: Normal cycle in warm water.
0	Laundering symbol: Tumble dry warm.
	Laundering symbol: Only non-chlorine bleach, when needed.
$\overline{\Box}$	Laundering symbol: Iron on low temperature.
8	Laundering symbol: No anti-static spray.
	Laundering symbol: No fabric softener.

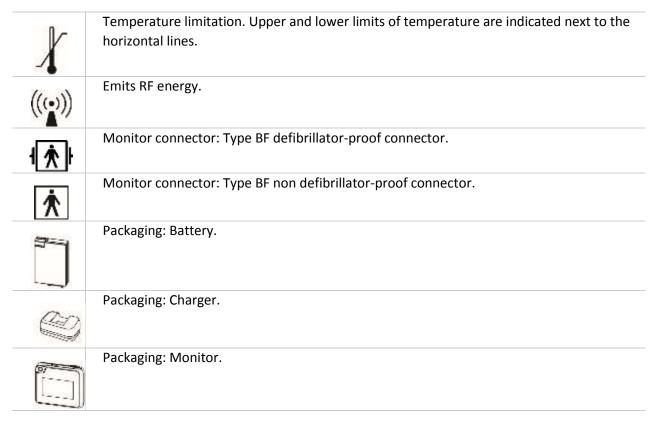
A-2

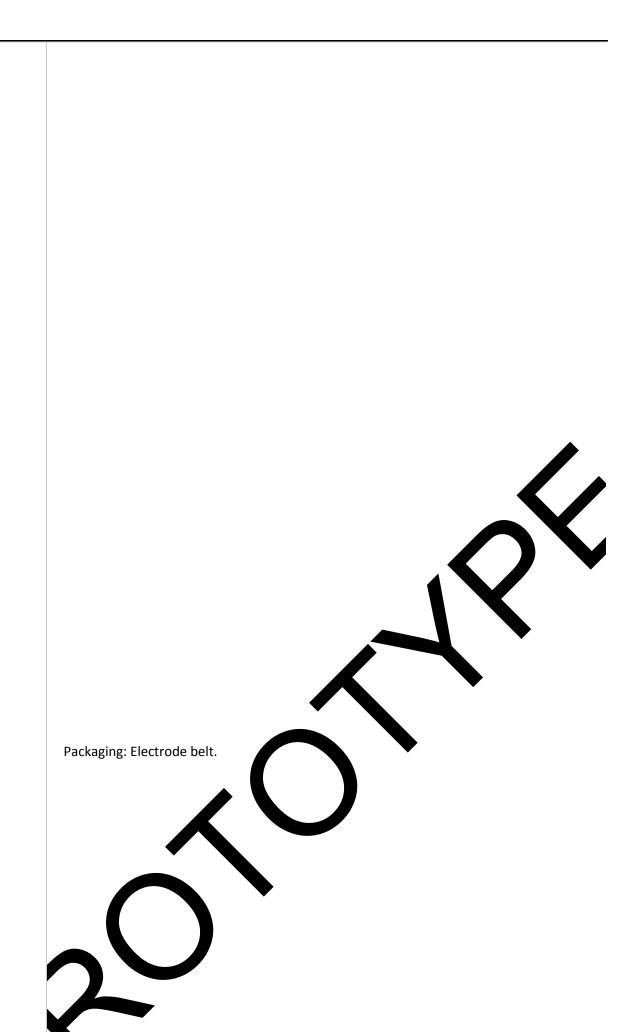
Appendix A: Symbols and Icons

M	Manufacturing date.
***	Manufacturing location.
\subseteq	Expiration date.
4	Automated external defibrillator.
4	Dangerous voltage. Surface could become hazardous for bystanders to touch when the device is in use.
C E.287	CE marking, indicates conformance with European Medical Device Directive.
REF	Symbol for catalog number, accompanied by number.
SN	Symbol for serial number, accompanied by serial number.
LOT	Symbol for lot number, accompanied by lot number.



	Power supply electrical information: Direct current (DC).
- -	Therapy pad label: Place this side (silver side) of the therapy pad next to your skin
	See instructions for use.
	Keep dry.
<	Keep away from sunlight.
7	Do not use if package is damaged.





	Packaging: Garment.
	WiFi icon. Tap this icon to find or access WiFi networks.
0	Information icon. Tap this icon to access serial number information about the LifeVest components.
(Voice icon. Tap this icon to access volume controls and speak options for Help screens.
	Support mode icon. Tap this icon to enter support mode when directed to do so by ZOLL.
1	WalkTest™ icon. Tap this icon on the Activities Menu screen to initiate the WalkTest™.
	Health survey icon. Tap this icon on the Activities Menu screen to initiate the Health Survey.
2	Settings Menu icon. Tap this icon to view Voice, Airplane, WiFi, Info and Support settings.



Send Data screen icon. Tap this icon to initiate sending data to ZOLL.



Activities Menu icon. Tap this icon to access the health survey and WalkTest™.



Airplane mode icon: Airplane mode disables the LifeVest's wireless transmission capabilities to avoid interfering with aircraft and other electrical equipment operation. Use Airplane mode in any situation where cell phone use is prohibited in order to eliminate electrical interference.



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



Therapy pad off skin: Check therapy pad that is of skin and fix palem. See Responding to alerts, section 5.





Appendix B: Software Licensing Statement

Certain software components (referred to herein as "Open Source Components") that are used by the LifeVest 5000 wearable defibrillator 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 there available upon request.

NO WARRANTY

TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE OPEN SOURCE COM PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRES INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MER FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY AGAINST IN VIOLATION OF INTELLECTUAL PROPERTY RIGHTS COVERING. URCE COMPONENTS. IN NO EVENT UNLESS REQUIRED BY APPLICABLE LAW WILL NY PARTY, II UDING ZOLL MEDICAL, BE LIABLE FOR DAMAGES, INCLUDING ANY ÉRAL, SPECIAL, IN CONSEQUENTIAL DAMAGES ARISING OUT OF THE U LABILITY TO USE THE OPEN SOURCE COMPONENTS (INCLUDING BUT NOT LIMITED TO LOSS OF D. A OR DATA BEING RENDERED INACCURATE OR LOSSES SUSTAINED BY ANY PARTY FOR A FAIL OF THE OPEN SOURCE COMPONENTS TO OPERATE WITH ANY OT





Index

Α	battery label symbols, A-2 blank screen, 2-3
about	Did II Screen, 2-3
LifeVest system, 1-1	C
manual, 1-1	C
activities	call for help message, 5-4
health survey, 6-1, 6-2	cardiac defibrillation
introduction, 6-1	definition, 1-1
taking the health survey, 6-3	care
WalkTest™, 6-1, 6-7	battery, 3-3
AED, A-3	caution, 4-10
aircraft use, 1-5	detergent, 4-10
airplane mode, 2-6, 3-13	dryer, 4-10
alerts	laundry, 4-10
add gel, 5-19	monitor, 3-2
after treatment, 5-12	non-was ble items,
battery, 5-11	warni ,3-26
check belt, 5-16	wa 10
check round electrodes, 5-15	car Jn
electrode belt, 5-9, 5-14	charger set 3-4
gong, 5-5, 5-9, 5-11, 5-12, 5-14	utions, 1-2
informative, 5-6, 5-11, 5-12, 5-14	a warnings, parent, 1-2
overview, 5-1	cell sign strength selected symbol, A-1
physiological, 5-1	charger, 8
remove excess gel, 5-20	batte charger indicators, 2-8
replace belt, 5-17	batt y indicator icons, 2-9
responding to, 5-2	scription, 2-1
siren, 5-1, 5-4	charger icons, 3-6
technical, 5-5	battery full, 3-6
therapy pads, 5-18	battery problem, 3-6
train whistle, 5-6	charger problem, 3-6
vibration and siren, 5-1	charging, 3-6
	no battery, 3-6
В	charger setup, 3-4
backup nower	change batteries, 3-7
backup power 3	daily, 3-7
battery, 2-A	recharge batteries, 3-7
charging, 3	clean
	caution, 4-10
recyclin 3-28	detergent, 4-10
warnin 3-28	dryer, 4-10
Wallin 3-28	laundry, 4-10
	monitor, 3-26
	non-washable items, 3-26
	warning, 3-26
▼	wash, 4-10
	close or x button
	icon, A-2

battery care, 3-3

components, 2-1	Н
conscious, 5-2	1 101
contact ZOLL, ii	health survey
cracks	messages, 6-6
housing, 3-26	take it later, 6-5
therapy pads, 3-26	take it now, 6-3
	what to do, 6-2
D	why important, 6-2 help
daily routine, 3-1	button icon, A-2
dark screen, 2-3	housing
dark screen, 2 3	cracks, 3-26
_	how the LifeVest works, 1-1
E	now the lifevest works, 1-1
ECG electrodes, 2-2	
electrode belt	
connecting, 4-7	icon
description, 2-1	activities menu, A-5
disconnecting, 4-7	airplane mo
warnings, 4-7	charger ettery indicate 2-9
electrodes, 2-2	healt drvey, A-4
EMI	he 2
electromagnetic interference, 1-7	formation, A-4
environment	round electable
noise and vibration, 1-5	green, A-2
essential performance, 1-5	d, A-2
	y vw, A-2
F	send ta, A-5
	settir s menu, A-4
family, 3-27	sur ort mode, A-4
warnings, 3-27	Jice, A-4
FCC regulatory information, 1-8	volume, A-4
finished with device, 3-28	WalkTest™, A-4
	WiFi, A-4
G	indications for use, 1-5
garment	informative alert, 5-6
description, 2-1	inspection, 3-26
position, 4-5	intended use, 1-5
garment and greatrode lt, 2-2,	interference wireless, 1-8
assemble 4-1	
assemble 4-3	L
disassemble	lavor daria = 4.40
and -4	laundering, 4-10
inside v v, 4-3	symbols, A-2
outside view, 4-3	warnings, 4-10
(ez. 1g, 4-4	
gel	M
ado, 19	meet the LifeVest, 2-1
remov. excess, 5-20	monitor, 2-3
gong, 5-5	battery, 2-3
gong alerts	battery release button, 2-3
general, 5-6	connector, 2-3

description, 2-1	recording heart rhythm, 2-6, 3-8
response buttons, 2-3	recycle, 3-28
speaker, 2-3	replace belt, 5-17
status indicators, 2-3	response buttons
touchscreen, 2-3	location, 2-3
monitor touchscreen, 2-5	return, 3-28
battery status icon, 2-6	battery, 3-28
electrode belt status icon, 2-6	round electrode, 2-2
menu button, 2-6	round electrode Velcro attachment areas
patient name, 2-6	description, 2-2
	routine
N	daily, 3-1
	normal, 3-2
non-washable items	
battery charger, 3-26	S
cables, 3-26	
monitor, 3-26	safety information, 1-2
round electrodes, 3-26	send data manually, 3-11
therapy pads, 3-26	showering and
normal startup routine, 3-2	warning 4-8
	siren
0	cz6 elp message, 5-4
	sirt, ralert, s
operator profile, 1-6	responding 5-2
	mode, 2-3
P	standa screen, 2-3
nationt	status il cators, 2-3
patient	support pde, 3-24
warnings and cautions, 1-2	symbol
patient age, 1-5	AP
patient menu screen, 3-9	Automated external defibrillator, A-3
activities menu, 3-9 send data, 3-9	battery
	call ZOLL, A-1
settings menu, 3-9 patient profile, 1-6	charging, A-1
patient training, 1-6	incinerate, A-2
_	level, A-1
phone number, ii	needs charged, A-1
power outage, 3-3	short circuit, A-2
power supply, 2-9 profile	BF, A-4
	BF non DP, A-4
operator 4-6 patient, 1	CE marking, A-3
ZOU suthol representative profile, 1-6	cell signal strength, A-1
zer solliok representative profile, 1-6	dangerous voltage, A-3
	DC power electrical, A-3
	Do not use if package damaged, A-3
de ription answer scale, 6-10	EC REP, A-3
red. Te	electrode belt, A-2
batt 12s, 3-7	electrode belt connector, A-2
5,5 .	expiration date, A-3
▼	Keep away from sunlight, A-3
	Keep dry, A-3
	laundry, A-2
	dryer, A-2
	• •

low temperature, A-2	normal startup routine, 3-2
no anti-static spray, A-2	
no fabric softener, A-2	V
LOT, A-3	
magnetic resonance, A-2	vibration, 5-1
manufacturing	vibration box area
date, A-3	description, 2-2
location, A-3	voice
MR unsafe, A-2	mode, 3-10
non chlorine bleach, A-2	options, 3-10
packaging	volume, 3-10
battery, A-4	
charger, A-4	W
electrode belt, A-4	
garment, A-4	WalkTest™
monitor, A-4	how it works, 6-7
power supply electrical, A-3	importance, 6-9
REF, A-3	messages, 6-14
RF energy, A-4	rate description as we cale, 6-10
See instructions for use, A-3	take it law, 6-13
SN, A-3	take iow, 6-9
temperature limitation, A-4	w-5, 6-7
WiFi signal strength, A-1	nat to 6-8
symbols and icons, A-1	warnings, 1-2, 4, 3-26, 3-27, 3-28, 4-7, 4-8, 4-10,
system information, 3-23	-7
	accautions, pawent, 1-2
т	siren ert, 5-2
	WiFi, 3-1
technical alerts, 5-5	acces ing available networks, 3-15
therapy pad pockets	clearing all saved networks, 3-22
description, 2-2	eleting networks, 3-22
therapy pads	entering a hidden network, 3-20
cracks, 3-26	searching for networks, 3-15
green, A-5	wireless interference, 1-8
label, A-3	
red, A-5	Z
treatment	7011
prevent, 1-1	ZOLL
	contact, ii
U	ZOLL authorized representative profile, 1-6
unconscious	
using VifeVs 3-1	
aily rolline, 3	
·	