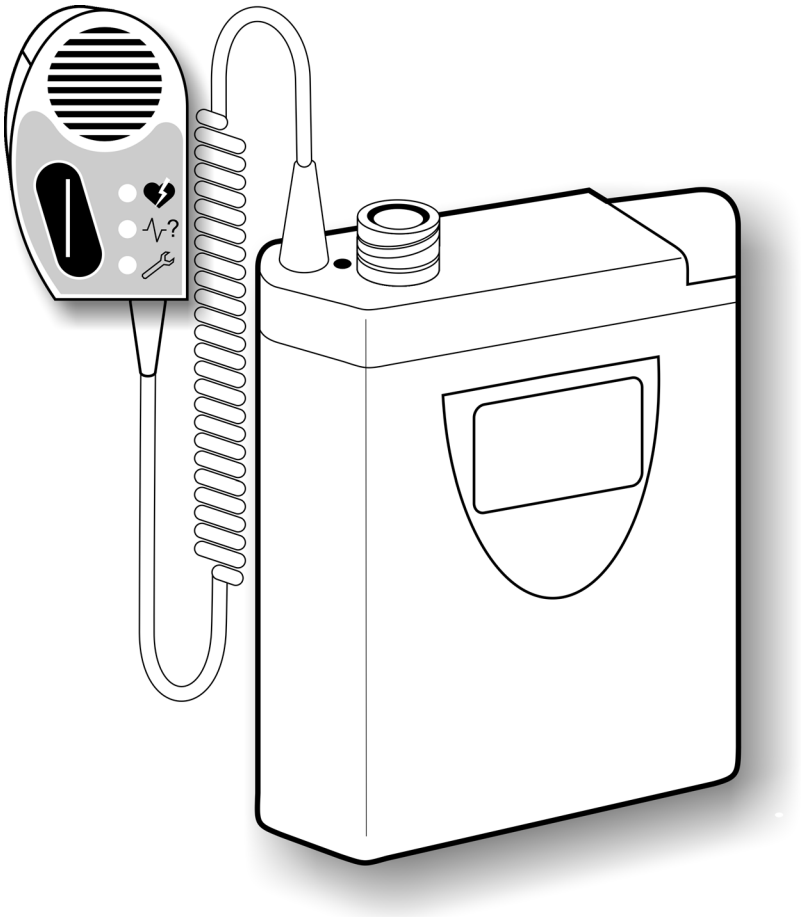
LifeVest®

Model WCD 3000

Operator's Manual



ZOLL®

PN 20B0028 Rev P3

Restricted sale

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

Effectivity

This manual describes the LifeVest WCD 3000 wearable defibrillator system.

Disclaimer

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

Trademarks

ZOLL and LifeVest are registered trademarks of ZOLL Medical Corporation in the United States of America. All other product names mentioned herein are the trademarks of their respective owners.

Copyright notice

Patents

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

Software nonexclusive license

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

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Contents

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Important information

Symbols

An exclamation point is used to indicate a group of warnings and cautions.

Warnings are indicated by:  **WARNING**

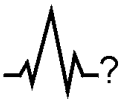
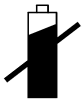
A **Warning** is a statement that alerts the patient to possible injury or death caused by misuse of the device. This includes device failure that could lead to the patient being unprotected by the device.

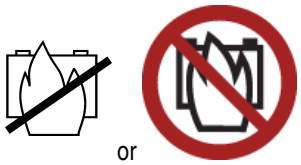
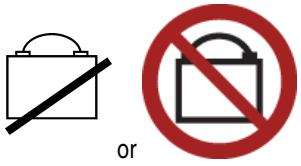
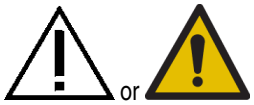
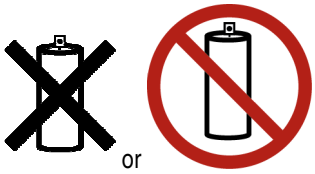
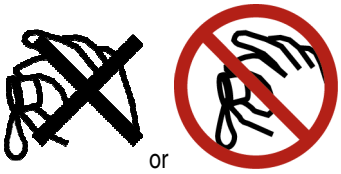
Cautions are indicated by:  **CAUTION**

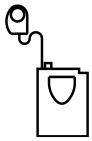
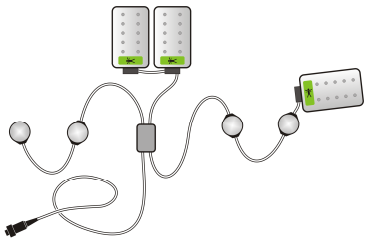
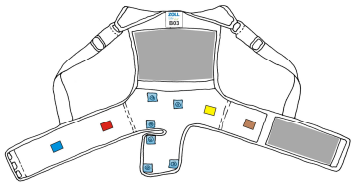
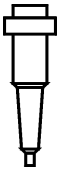
A **Caution** is a statement that alerts the patient to a possible problem with the device. Such problems include damage to the device or other property.

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

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

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

	Battery pack: Do not incinerate.
	Battery pack: Do not short circuit.
	Caution: Consult accompanying documents.
	Monitor connector: Type BF defibrillator-proof connector.
	Laundering symbol: Normal cycle in warm water.
	Laundering symbol: Tumble dry warm.
	Laundering symbol: Only non-chlorine bleach, when needed.
	Laundering symbol: Iron on low temperature.
	Laundering symbol: No anti-static spray.
	Laundering symbol: No fabric softener.
	Manufacturing date.

	Manufacturing location.
	Packaging: Monitor.
	Packaging: Modem.
	Packaging: Electrode belt.
	Packaging: Garment.
	Power supply electrical information: Alternating current (AC).
	Power supply electrical information: Direct current (DC).
	Therapy pad label: Place this side (foil side) of the therapy pad next to your skin.
	Packaging: Serial cable.
	Packaging: Test plug.

For assistance with the device

ZOLL hotline in USA

For questions concerning the LifeVest system 24 hours a day, 7 days a week, call:

1-800-543-3267

Outside of the USA, call the device provider.

Clinical center code

Your clinical center code is:

Recycling information

Battery packs

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

Dispensed therapy pads

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

Chapter 1: Device Description

The ZOLL LifeVest Wearable Cardioverter Defibrillator, or LifeVest device, is a microprocessor based and programmable patient-worn defibrillator that electrocardiographically monitors the patient's heart function and automatically delivers electrical therapy to treat syncopal ventricular tachyarrhythmias or sudden cardiac arrest (SCA).

The LifeVest device is comprised of the wearable components of the LifeVest system, including the Monitor in the Holster, the Battery Pack, the Alarm Module, the Electrode Belt, and the Garment. The LifeVest system is comprised of the LifeVest device, the Battery Charger, a second Battery Pack, and the modem. An approved test device and a serial cable are also supplied, to set up a patient and test the system.

The LifeVest device is worn continuously by the patient except when bathing. The device consists of a small defibrillator unit which connects to a patient-worn garment and electrode belt around the patient's chest. Unlike conventional ECG sensing and defibrillation electrodes, the LifeVest device electrodes are dry and non-adhesive to provide patient comfort. If the LifeVest device detects ventricular tachycardia above a programmable pre-set heart rate or ventricular fibrillation, it notifies the patient through various alarms and voice messages and instructs the patient to press response buttons that are on the device. Only if the patient fails to press the response buttons, indicating loss of consciousness, is electrical therapy delivered to treat the abnormal condition. The LifeVest device is specified to deliver a defibrillation pulse within 60 seconds from the onset of ventricular tachycardia or ventricular fibrillation (VT/VF), and can treat repeatedly up to five times if necessary.

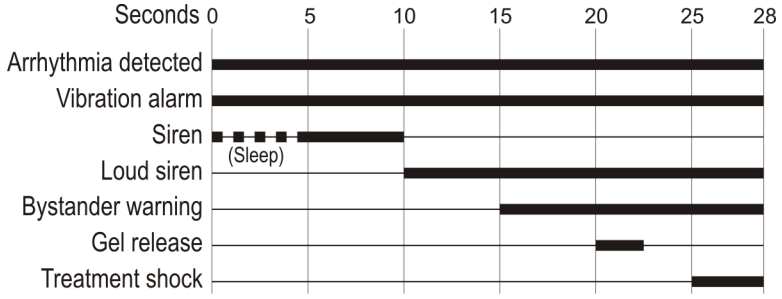
The LifeVest device also records the patient's electrocardiogram (ECG) prior to and during treatment or near treatment events. This feature allows physicians to review the ECG documentation of the SCA event. ECG recordings also allow the detection of nonsustained ventricular tachycardia (NSVT), which is often considered a risk indicator for SCA. On a weekly basis, or as needed, the patient downloads the memory contents of the device by telephone to ZOLL's computer server. Physicians then can monitor patient weartime compliance, NSVT events, and the record of any treatment events.

Treatment sequence

After identifying VT/VF, there is a response time of 25 seconds (programmable up to 55 seconds) to allow the patient time to respond to the alarms, as shown below. VF identification can be set from 120 to 250 beats per minute (bpm), with a default of 200 bpm.

If the system identifies VT, there is a response time of 60 seconds (programmable up to 180 seconds). VT identification can be set from 120 to 250 bpm, with a default setting of 150 bpm.

Typical treatment sequence during ventricular fibrillation



During normal operation, the vibration alarm gets activated first, then the siren alarm. If an arrhythmia is detected during the sleep interval, the vibration and siren alarms are activated together. Programming the sleep interval is discussed in Chapter 12, **Programming the Monitor**, and Chapter 16, **Monitor Setup Using Alarm Module**.

The LifeVest device can deliver up to 5 defibrillating pulses during an arrhythmic episode. The energy of the pulses can be programmed to between 75 and 150 joules (±5%), with a default setting of 150 joules.

Chapter 2: Clinical Information

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 18.75 kilograms (41.3 pounds) or greater. See *Device use for patients under 18 years of age* on page 2-2.

Device use in patients under 18 years of age

According to the 2010 AHA guidelines,[1] 2-4 J/kg is the recommended energy level for effective defibrillation therapy for pediatric patients including patients under 18 years of age. In order for these patients to be treated with an appropriate amount of energy with the LifeVest device, which is programmable between 75 and 150 joules, they must meet the minimum required weight of 18.75 kg. At the minimum energy setting of 75 J, a minimum weight patient of 18.75 kg would receive the maximum dose of 4 J/kg. In order to meet the AHA's minimum recommendation of 2 joules per kg, patients weighing over 37 kg should be programmed to receive more than 75 joules. Appropriate dosage is determined and prescribed by the physician.

As of November 8, 2012, the company registry contained 248 pediatric patients, aged 3-17, including those in the literature publications.

Retrospectively collected data has shown the ability of the LifeVest to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as 13. Four patients in the 3-17 age group experienced SCA during LifeVest use that was successfully converted to a life sustaining rhythm. The following table provides further detail on the pediatric patients receiving an appropriate treatment with the LifeVest.

Patient	Age	Wear duration (days)	Indication for LifeVest use	Treatment summary	Energy delivered (Joules)	Reason for ending LifeVest use
1	13	78	Congenital heart disease	1 appropriate treatment	151	Heart transplant
2	14	3	Cardiomyopathy	1 appropriate treatment	150	Received ICD
3	15	55	Wolf-Parkinson-White syndrome	1 appropriate treatment	150	Received ICD
4	16	60	Tetralogy of Fallot	4 appropriate treatments	152-154	Improved ejection fraction

There are three peer-reviewed articles on the use of the LifeVest specifically in the pediatric population. One paper describes four pediatric patients prescribed a wearable defibrillator from a single site.[2] All carried a diagnosis of anthracycline-induced cardiomyopathy. While no patients received an appropriate treatment in this study, no patients received an inappropriate treatment despite the inappropriately detected rhythm caused by ECG noise. Two patients had documented noncompliance with wear, which resulted in failure to detect and treat a life-threatening arrhythmia in one. The paper concluded that the wearable defibrillator is a short-term alternative for children at risk for SCD, who can be

[1] Link M, et al. *Part 6: Electrical Therapies: Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing - 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.* Circulation. 2010;122[suppl 3]:S706–S719.
[2] Everitt MD, Saarel EV. Use of the wearable external cardiac defibrillator in children. *Pacing and Clinical Electrophysiology.* 2010;33(6):742-746.

properly fit with the wearable defibrillator, where the risk of ICD use is greater than the benefit.

In a paper by Collins et al., 81 multi-site wearable defibrillator patients from 9-18 years old, and 103 patients aged 19-21, were retrospectively reviewed.[3] In patients ≤18 years of age, there was one inappropriate therapy, due to sinus tachycardia and artifact, and one withholding of therapy due to a device-device interaction. Compliance was generally similar to adults among these younger patients, with an average daily use of 19 hours, and non-compliance or comfort issues only being recorded for 7-11% of patients. This paper concluded that the wearable defibrillator could be an appropriate therapy for pediatric patients who are at risk for SCA, as they had two appropriate treatments in their young adult population (age 19-21). However, they had no appropriate treatments in their pediatric population (age 9-18).

The third paper by LaPage et al., published prior to the two papers discussed above, detailed the fatal device-device interaction between the wearable defibrillator and a unipolar epicardial pacemaker.[4] Such interactions are not unique to pediatric patients nor are they unique to wearable defibrillators, being copiously described in the ICD and AED literature. LifeVest manuals have specific warnings about pacemaker interactions; please see Chapter 4: Warnings and Precautions. These warnings advise physicians to use appropriate caution when prescribing the LifeVest device to a patient who is dependent on a pacemaker.

The rate of inappropriate treatments per patient days of use for patients under 18 years of age is similar to that of patients 18 years of age and older. Inappropriate treatments can be prevented by pressing the response buttons. Only one serious adverse event has been reported for pediatric patients using the device. This event is described in the paper by LaPage et al, which summarizes the withholding of therapy caused by a pacemaker interacting with the wearable defibrillator.

[3] Collins KK, Silva JN, Rhee EK, Schaffer MS. Use of a wearable automated defibrillator in children compared to young adults. *Pacing and Clinical Electrophysiology.* 2010;33(9):1119-1124.
[4] LaPage MJ, Canter CE, Rhee EK. A fatal device-device interaction between a wearable automated defibrillator and a unipolar ventricular pacemaker. *Pacing Clin Electrophysiol.* Jul 2008;31(7):912-915.

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Chapter 3: Contraindications

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

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Chapter 4: Warnings and Precautions

Warnings

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

Prescription

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

Shock Hazard

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

Rescue Defibrillation

- Remove the LifeVest device from the patient or disconnect the Monitor prior to conventional defibrillation. Failure to do so could interfere with conventional defibrillation and damage the LifeVest device. The LifeVest device’s ECG electrodes are rated for a 2000 volt defibrillating pulse and are not intended for use with any other external defibrillator, which could produce a 5000 volt defibrillating pulse.

Pacemaker Use

- Use appropriate caution when prescribing a LifeVest device to a patient who is dependent on a pacemaker. ZOLL recommends that all patients who have pacemakers be examined for proper pacemaker function after a defibrillation. (See Chapter 5, **Individualization of Treatment**.)

Warnings

- A complete understanding of the manual is necessary before prescribing or training a patient to use the LifeVest System. Failure to understand how to use the system could lead to an inappropriately assembled or misused device resulting in a device that is unable to deliver treatment or delivers inappropriate treatment.
- Before prescribing, the healthcare professional should consider whether the patient will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The healthcare professional should consider mental, visual, physical and auditory limitations that may impact a patient’s ability to successfully interact with the system. Failure of the patient to successfully interact with the system may result in device alarms, failure to deliver treatment, or delivery of inappropriate treatment.

Possible Improper System Performance

Environment

- Do not operate or store the LifeVest system outside of the environmental ranges listed in Chapter 15, **System Specifications**, of this manual. To do so could cause the system to fail.

Battery Pack

- Completely insert the Battery Pack into the Monitor. If the Battery Pack is only partially inserted, the LifeVest device cannot detect an abnormal rhythm or deliver a treatment shock.
- Use ONLY the WCD 3000 Battery Pack with the WCD 3000 Monitor. Use ONLY the WCD 3000 Battery Charger when charging the WCD 3000 Battery Pack. To use any other battery pack or charger could cause the device to fail.
- Charge Battery Packs at least once every 3 months during prolonged storage. Failure to recharge could result in Battery Packs becoming unusable. Charge Battery Packs before giving them to a patient. Charge Battery Packs when re-stocking them after patient use.

Electromagnetic Interference

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

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

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

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

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

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

Precautions

A “precaution” is a statement that alerts the patient to a possible problem with the device. Such problems include damage to the device or other property.

Travel

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

Shock Hazard

- Be certain the LifeVest device assigned to a particular patient goes to that patient. There exists the potential for false shocks if the patient wears the wrong device. Make certain that the patient name that appears on the Monitor’s display is correct.

Possible Improper System Performance

- Do not drop the Monitor. If you do, call for a replacement and return the Monitor that was dropped to your ZOLL representative.
- Do not put foreign objects, such as fingers, paper clips, or hair pins into any of the LifeVest system connectors or openings. Doing so may cause the system to fail.
- Protect the LifeVest device from moisture and extreme sunlight when outdoors. To protect the device, the patient should always wear clothing over the Garment and keep the Monitor in the Holster.
- Do not put the Monitor, Battery Pack, Electrode Belt, Alarm Module, Battery Charger, or modem in or near water. The patient should not bathe or shower while wearing the LifeVest device. Also, before washing the Garment and Holster, be sure to remove the Electrode Belt, the Battery Pack, and the Monitor. The Electrode Belt, the Battery Pack, Battery Charger, Alarm Module, Monitor, and modem must not touch water. Doing so may cause the system to fail.
- Do not allow food or liquid to splash or drip on the LifeVest system. Doing so may cause the system to fail.
- Do not expose the LifeVest system to direct sunlight, excessive heat, or excessive cold for prolonged periods of time. Doing so may damage the system.
- Do not interrupt the Monitor’s diagnostic test. Disconnecting the test device during the test could damage the device.

Risk of Fire

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

Warnings and Cautions for the Patient

This section reviews the Warnings and Cautions given to the patient in Chapter 1 of the Patient Manual. Please make certain the patient has read and understands these warnings and cautions.

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

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

Warnings

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

Patient Protection

- Wear the Electrode Belt directly against skin. Do not wear clothing underneath the Garment and Electrode Belt. Make sure when putting on the assembled Garment and Electrode Belt, that the Garment Belt doesn't become twisted. Look in a mirror to make sure the Garment is being worn correctly.
- Check to make sure that the metallic side of both front and rear Therapy Pads make contact with your bare skin before closing the belt buckle, or a defibrillating pulse cannot be delivered. If you are a female patient, it is best to wear a bra over the assembled Garment and Electrode Belt. If a bra is not worn, a safety feature for detecting a reversed Therapy Pad could be defeated in large-breasted women.
- Always wear the LifeVest device and make sure the Electrode Belt and Battery Pack are properly connected to the Monitor. The device cannot detect an abnormal rhythm or deliver a treatment shock if not worn and properly connected.
- Do not let another individual wear your LifeVest device. The LifeVest device recognizes your heart rhythm pattern. If it detects an unfamiliar heart rhythm, it may shock that person.
- Remove the Battery Pack from the Monitor whenever the device is not being worn. For example, when you remove the device to take a shower, be sure to

remove the Battery Pack first, to ensure the device is not active when you are not wearing it.

Shock Hazard

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

Rescue Defibrillation

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

Possible Improper System Performance

Environment

- Do not operate or store the LifeVest system outside of the environmental ranges listed in Chapter 15, **System Specifications**. To do so may damage the system.

Battery Pack

- Completely insert the Battery Pack into the Monitor. If the Battery Pack is only partially inserted, the LifeVest device cannot detect an abnormal rhythm or deliver a treatment shock.
- Use ONLY the WCD 3000 Battery Pack with the WCD 3000 Monitor. Use ONLY the WCD 3000 Battery Charger when charging the WCD 3000 Battery Pack. To use any other battery pack or charger could cause the device to fail.
- Charge Battery Packs at least once every 3 months during prolonged storage. Failure to recharge could result in Battery Packs becoming unusable. Charge Battery Packs before giving them to a patient. Charge Battery Packs when re-stocking them after patient use.

Electromagnetic Interference

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

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

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

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

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

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

Cautions

Shock Hazard

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

Possible Improper System Performance

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

Monitor, and the modem must not touch water. Doing so may cause the system to fail.

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

Risk of Fire

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

Travel

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

Gel Release

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

Bathing and Showering

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

To Help Ensure Proper Operation

- Make sure the metal surface of each therapy pad is facing your skin. If the metal side is not facing your skin, you will not receive treatment shock(s) if needed.
- Press and hold both response buttons on the Alarm Module at the same time if you hear alarms, feel a vibration, and receive a message telling you to “RESPOND.” If you do not, you may receive a defibrillating electrical shock while conscious. To avoid receiving a defibrillating electrical shock while conscious, remember to always press and hold both response buttons when the device indicates that you should. If you receive a shock while conscious, it will be painful.
- If you receive a treatment while your heart is beating normally and you did not use the response buttons, the treatment may cause an abnormal rhythm to occur. There is a small possibility that the abnormal heart rhythm may not be detected and death may result.
- Do not press the response buttons by artificial means or by having another person press them for you. This would defeat the purpose of the response buttons.

- Do not let another individual wear your LifeVest device. The LifeVest device recognizes your heart rhythm pattern. If it detects an unfamiliar heart rhythm, it may shock that person.
- If you do not hear a tone or feel a vibration when you first turn the device on, disconnect the Battery Pack and the Electrode Belt from the Monitor and reconnect them. If it still does not operate normally, contact your device provider for a replacement.
- Do not put anything other than the Monitor and Message Manual into the Holster. The extra weight may pull the Electrode Belt from the body.
- Keep out of the reach of children.* The device may be damaged by improper handling.
- Use the LifeVest system only after understanding all training and instructions from authorized personnel to help ensure proper operation.

 **CAUTION:** Do not push Record and Transmit buttons during the start-up sequence unless you specifically want to enter the programming mode (see Chapter 16, **Monitor Setup Using Alarm Module**). Remove and reinsert the battery to return to the normal operating mode.

* See indication for patients under 18 years of age.

Chapter 5: Individualization of Treatment

Specific patient population

Patient groups expected to use the LifeVest device are those whose SCD risk is temporary (hours to months) or those who have limited expected life span (less than one year). Patients who have an elevated SCD risk include the following:

- Patients awaiting cardiac transplant or patients having equivalent heart status (New York Heart Association Class III or IV heart failure) and an ejection fraction below 30%.
- Patients having an acute myocardial infarction (MI), or patients immediately post coronary artery bypass graft surgery with any of the following: a VT/VF event within 48 hours of the MI or surgery, an ejection fraction below 30% at least three days after MI or surgery, or patients having a sudden cardiac arrest or syncopal VT event at least 48 hours after MI or surgery and not receiving an ICD. Also included are patients having an acute MI and are Killip Class III or IV at least three days after the MI.
- Patients having viral, chemical, or metabolic cardiomyopathy who are expected to recover.
- Patients beginning pro-arrhythmic medications.

Patient groups not expected to use the LifeVest device are:

- Patients with mental, visual, physical, or auditory deficits that could impair their ability to properly interact with the LifeVest device.
- Patients taking medication that would significantly impair their ability to activate the response buttons.
- Patients who are unwilling or unable to comply with usage requirements such as wearing the device continuously, except when bathing or showering.
- Patients, who for anatomic or other non-correctable reasons, have excessive amounts of electrode noise corrupting the detection algorithm.
- Female patients who are pregnant, breast-feeding, or who are not taking adequate contraceptive measure if they are of childbearing age.
- Patients under 18 years of age.[*]
- Any patient with an advance directive prohibiting resuscitation.

[*] See indications for patients under 18 years of age.

Interaction with pacemakers

Several interactions with pacemakers are possible.

First, if patient goes into a ventricular arrhythmia and the pacemaker continues to pace, the pacemaker's pulses may be the dominant signal. This may potentially cause the LifeVest device to lock on the pacemaker's signal as the cardiac rhythm and prevent the LifeVest device from detecting the arrhythmia. This interaction has been documented between ICDs and pacemakers[†], although no such interaction has yet occurred between the LifeVest device and pacemakers. The risk varies according to the type of pacemaker and the programmed mode of the pacemaker.

Second, if the patient is baselined with the pacemaker active, an unpaced QRS complex may be interpreted by the LifeVest device as a change in the QRS morphology. As a result, if the rate goes above the arrhythmia rate threshold, the LifeVest device may then declare the unpaced rhythm a treatable arrhythmia and begin the treatment alarm sequence. As long as the patient uses the response buttons of the LifeVest device, the device will not deliver a treatment shock. However, be aware that an increased potential for an unnecessary shock does exist.

Recommendations for patients with pacemakers

- If the pacemaker does pace during ventricular fibrillation, there is a risk that the pacemaker stimulus artifact would be tracked by the LifeVest device as a valid heart rate during ventricular fibrillation. In order for this to occur, the pacemaker stimulus artifact must be greater than the ventricular fibrillation signal. ZOLL therefore recommends that patients whose pacemaker stimulus artifact is greater than 0.5 mV in any ECG lead should not be enrolled.
- Because of the risk that the patient's unpaced ECG signal may be interpreted as a ventricular tachycardia if it exceeds the arrhythmia rate threshold, ZOLL recommends setting the VT rate threshold to 200 when a patient is baselined while being paced.

[†] Glikson, et al, "Importance of Noise Reversion as a Potential Mechanism of Pacemaker-ICD Interactions," *PACE*, May 1998, 21: 1111-1121.

Other articles of interest:

Altamura, et al., "Transthoracic DC Shock May Represent a Serious Hazard in Pacemaker Dependent Patients," *PACE*, January 1995, 18 (Part II): 194-198

Brode, et al, "ICD-Antiarrhythmic Drug and ICD-Pacemaker Interactions," *Journal of Cardiovascular Electrophysiology*, July 1997, 8:830-842.

Geiger, et al, "Interactions Between Transvenous Nonthoracotomy Cardioverter Defibrillator Systems and Permanent Transvenous Pacemakers," *PACE*, March 1997, 20 (Part I): 624-630.

Recommendation for double counting of a normal rhythm

Double counting of a normal rhythm is known to occur with ICDs and other rhythm analysis devices.

There is at present no method of determining which patients are likely to experience false arrhythmia declarations due to this condition. If a patient does experience such false arrhythmia declarations, there are two actions which may help: increasing the arrhythmia rate threshold and/or lengthening the patient's responsiveness test. Increasing the arrhythmia rate threshold should reduce the frequency of false arrhythmia declarations due to double counting, while lengthening the patient's responsiveness test gives the patient additional time to respond to the alarms if a shock is not necessary.

Asystole detection

The LifeVest monitors the ECG signal and declares asystole when the amplitude of the ECG input signal falls below 100 microvolts for at least 16 seconds.

When the device declares asystole, it generates the following voice messages to notify bystanders: "Device disabled. Call ambulance."

To silence the alarms and restore the device to normal operation, remove and reinsert the battery.

Interaction with ventricular assist devices

WARNING: Some ventricular assist devices can be damaged by external defibrillation. Therefore, patients wearing ventricular assist devices may not be suitable candidates for the LifeVest.

If you have a patient who is a candidate for the LifeVest, and that patient is using a ventricular assist device, check the manufacturer's instructions regarding whether the device could be damaged by external defibrillation. If the ventricular assist device could be damaged by external defibrillation, that patient is not a candidate for the LifeVest.

For example, instructions provided with the Thoratec HeartMate XVE left ventricular assist system (LVAS) state to remove the connection between the percutaneous tube and the XVE system controller before using a defibrillator, or the XVE LVAS could be permanently damaged.

Individualization of patient treatment

Patient capability assessment

The following questions may be used as a screening tool to aid in assessing a patient's ability to use the device.

Do you know how to use a remote control?	☐Yes ☐No ☐Somewhat ☐Only if I have to
Do you ever sleep through your alarm?	☐Frequently ☐Sometimes ☐Never
Do you consider yourself to be a nervous person?	☐Yes ☐No ☐Somewhat
Do you startle easily?	☐Yes ☐No ☐Somewhat
Would you be able to feel a vibration in your right mid-back?	☐Yes ☐No ☐Somewhat
Are you able to read the display message?	☐Yes ☐No ☐Somewhat ☐With glasses ☐Without glasses
Was the patient able to hear the audio tone?	☐Yes ☐No ☐Somewhat
Was the patient able to access the response buttons?	☐Easy ☐Somewhat difficult ☐Difficult
Was the patient able to hold the response buttons for 30 seconds?	☐Comfortably ☐Somewhat difficult ☐Difficult

Memory assessment

Read to patient:

> "Sometimes people have trouble remembering things. If you do not know the answers to some of the next questions, that's okay. It's very normal. If you do know the answers, the questions may seem obvious."

What is the date today? (month/day/year)	☐Correct ☐Incorrect/Not answered
What day of the week is it?	☐Correct ☐Incorrect/Not answered
What is the name of this place?	☐Correct ☐Incorrect/Not answered
What is your telephone number?	☐Correct ☐Incorrect/Not answered
What is your street address? (Ask only if patient does not have a phone)	☐Correct ☐Incorrect/Not answered
How old are you?	☐Correct ☐Incorrect/Not answered
When were you born?	☐Correct ☐Incorrect/Not answered
Who is the President of the U.S. now?	☐Correct ☐Incorrect/Not answered
Who was the past President before him?	☐Correct ☐Incorrect/Not answered
What was your mother's maiden name?	☐Correct ☐Incorrect/Not answered
Subtract 3 from 20, and keep subtracting from each new number all the way down. (20-17-14-11-8-5-2)	☐Correct ☐Incorrect/Not answered
	Total Number of Errors:
	(More than 3 errors may indicate memory loss.)

Note: The subject's reading, hearing, fine motor skills, dexterity, and mental/emotional status should be assessed visually while interviewing. These assessments as well as the answers to the above questions will determine whether a subject is capable of wearing the LifeVest device.

Chapter 6: Patient Counseling Information

Patient training is explained in Chapter 11, **Patient Training**.

Warnings and cautions to review with the patient are explained in Chapter 4, **Warnings and Precautions**.

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Chapter 7: Conformance to Standards

The following Standards were used during the design and development of the LifeVest System. Compliance with the applicable portions of these standards was verified in nonclinical lab tests.

- IEC 60601-1:1988, Am. 1 (1991), Am. 2 (1995) Medical electrical equipment - Part 1: General requirements for safety
- UL 2601-1:2nd Ed. Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2:1993 Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4: Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
- IEC 60601-2-4:2002 Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors
- IEC 60601-2-27:1994 Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
- CISPR 11:1990 Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement
- EN55011:1993 Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement
- EN61000-3-2:1995 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16A per phase)
- EN61000-3-3:1994 Electromagnetic compatibility (EMC) - Part 3: Limits - Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤16 A
- EN61000-4-2:1995 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- EN61000-4-3:1997 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- EN61000-4-4:1995 Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 4: Electrical fast transient/burst immunity test.
- EN61000-4-5:1995 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
- EN61000-4-6:1996 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

- EN61000-4-8:1993 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- EN61000-4-11:1994 Electromagnetic Compatibility (EMC), Part 4: Testing and Measuring Techniques - Section 11: Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
- IEC 801-3: 1984 Electromagnetic Compatibility (EMC), Part 3: Radiated Electromagnetic Field Requirements, Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment
- MIL-STD-810E Environmental Engineering Considerations and Laboratory Tests
- UL 94: 5th Ed. Test for Flammability of Plastic Materials for Parts in Devices and Appliances
- ASTM D4169-82 Standard Practice for Performance Testing of Shipping Containers and Systems

Chapter 8: System Overview

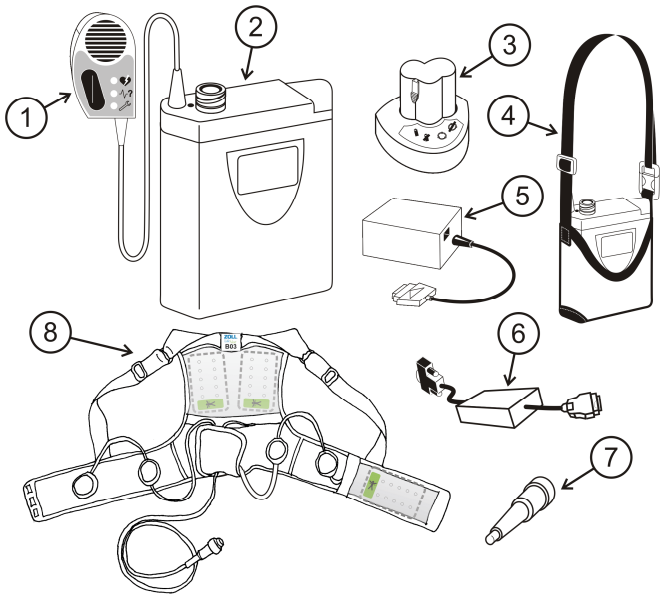
This chapter briefly describes the components and operation of the LifeVest system.

System description

Components of the LifeVest system are shown below.

To set up a patient and test the system, you are supplied with an approved test device and a serial cable.

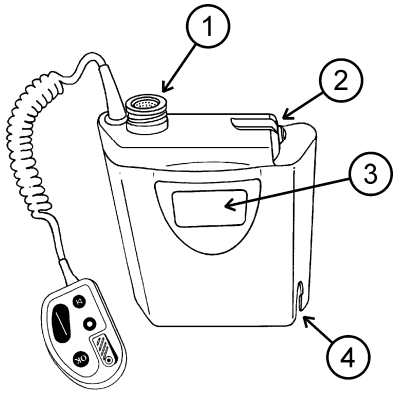
For a list of system components and accessories with their ZOLL part numbers, see page 8-16.



1 Alarm module
2 Monitor
3 Battery charger with battery pack inserted
4 Monitor inserted into holster
5 Modem
6 Serial cable
7 Test Plug
8 Assembled garment and electrode belt

Monitor

The Monitor, illustrated below, contains the diagnostic circuitry and the defibrillation circuitry.



1 Electrode belt connector.

2 Communications port (under rubber cover).

3 Display panel.

4 Battery pack insertion point.

The Monitor has two external connectors: the Electrode Belt connector and the Communication Port connector. The Electrode Belt connector is where the Electrode Belt cable attaches to the Monitor. The Communication Port connector is where the serial cable attaches to the Monitor. (When not being used to program the Monitor or send data through the modem, the Communication Port should be covered with the rubber cover.)

The Battery Pack is inserted at the bottom of the Monitor.

The Monitor's digital and analog circuitry provide ECG analysis, arrhythmia detection, programmed treatment sequences, timekeeping, and background operation such as self-monitoring/test routines for the hardware and software. Memory capacity allows storage of:

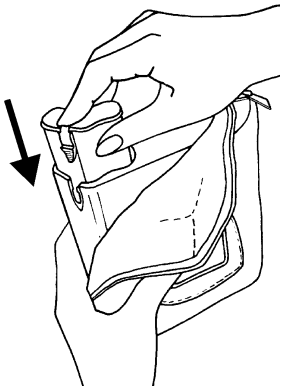
- The arrhythmia detection algorithm and treatment table.
- Seventy-five minutes of ECG recordings.
- Time tags and device status indicators.
- All applications software needed to perform self-monitoring/test routines and operational functions.

Nonvolatile storage is capable of maintaining device memory containing programmable parameter data (for example, electronic patient ID and treatment parameters).

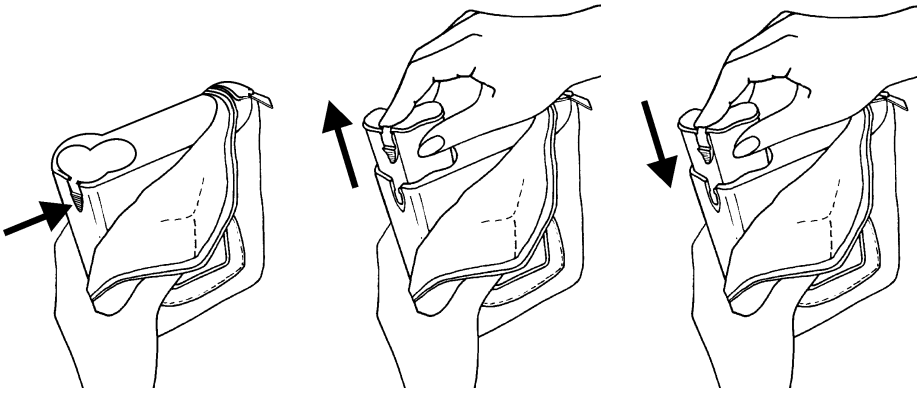
When the Battery Pack is fully charged, it should provide power to monitor the patient for 24 hours with sufficient reserve capacity to deliver at least one 5-pulse defibrillating sequence at 150 joules. The Monitor can usually charge its capacitors for a 150 joules shock within the minimum response alarm time of 25 seconds.

Battery Pack

The patient starts the device by inserting the Battery Pack into the Monitor.



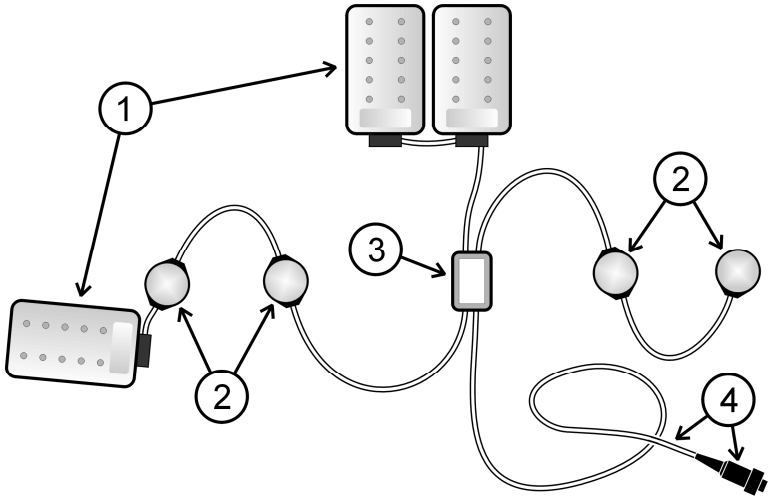
When the Battery Pack is depleted, the patient removes it by pressing the release latch, pulling the Battery Pack out, and replacing it with a fully-charged Battery Pack.



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

Electrode Belt

The Electrode Belt consists of the ECG monitoring electrodes, the therapy electrodes (referred to as "therapy pads"), and a vibration box, all of which is interconnected by electrical wiring.



1 Therapy pads.

2 ECG electrodes.

3 Vibration box.

4 Electrode belt cable and connector.

For operation in Europe:

The Electrode Belt is the "Applied Part" in accordance with subclause 2.1.5 of IEC 60601-1.

ECG monitoring electrodes

Four ECG electrodes are designed to provide continuous body-surface ECG monitoring through two ECG leads, side-to-side and front-to-back. The ECG electrodes are of capacitive design, allowing constant contact between the electrode surface and the skin, without the electrolytic gel or adhesives that may cause skin irritation.

Therapy electrodes

The therapy electrodes are designed to deliver the cardioverting/defibrillating energy through the patient's chest in the apex-posterior configuration. (In the LifeVest System Patient Manual the therapy electrodes are referred to as therapy pads.)

A small quantity of electrolytic gel is contained in each therapy electrode of a number of formed blisters, which are protected by an outer shell. In the event of prolonged arrhythmia detection, an activation signal is sent to a gas generating device sealed inside each therapy electrode. Activation of the gas generating device should result in dispersal of the electrolytic gel to the patient's skin. The Garment is designed to provide for therapy electrode placement and therapy electrode conformance to the patient's body.

Other features

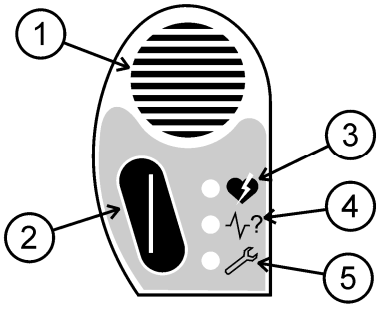
The Electrode Belt also includes the following features:

- A vibration box, designed to provide notification of impending electrical treatment.
- The ECG electrode system, designed to provide an electronic fall-off sensing mechanism to indicate proper electrode contact with the patient's skin.

Alarm Module

The Alarm Module clips onto the patient's belt or shirt pocket. It is designed to alert the patient to certain conditions through lights and voice messages.

The front of the module contains:



1 Speaker.

2 One of the two response buttons.

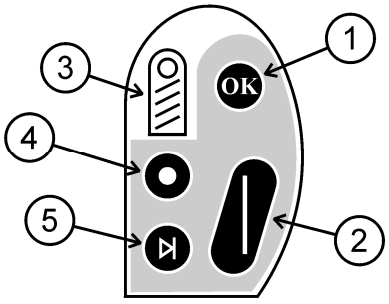
3 Red light and a symbol of a heart receiving a shock to indicate an abnormal rhythm.

4 Yellow light and the symbol of a heart rhythm and question mark to indicate that the patient ECG signal is suspect due to either noise or electrode fall-off.

5 Flashing yellow light and the symbol of a wrench to indicate that the device requires attention or service.

The patient should check the Monitor's display panel to see if a message accompanies any light.

The rear of the Alarm Module contains:



1 OK button.

2 One of the two response buttons.

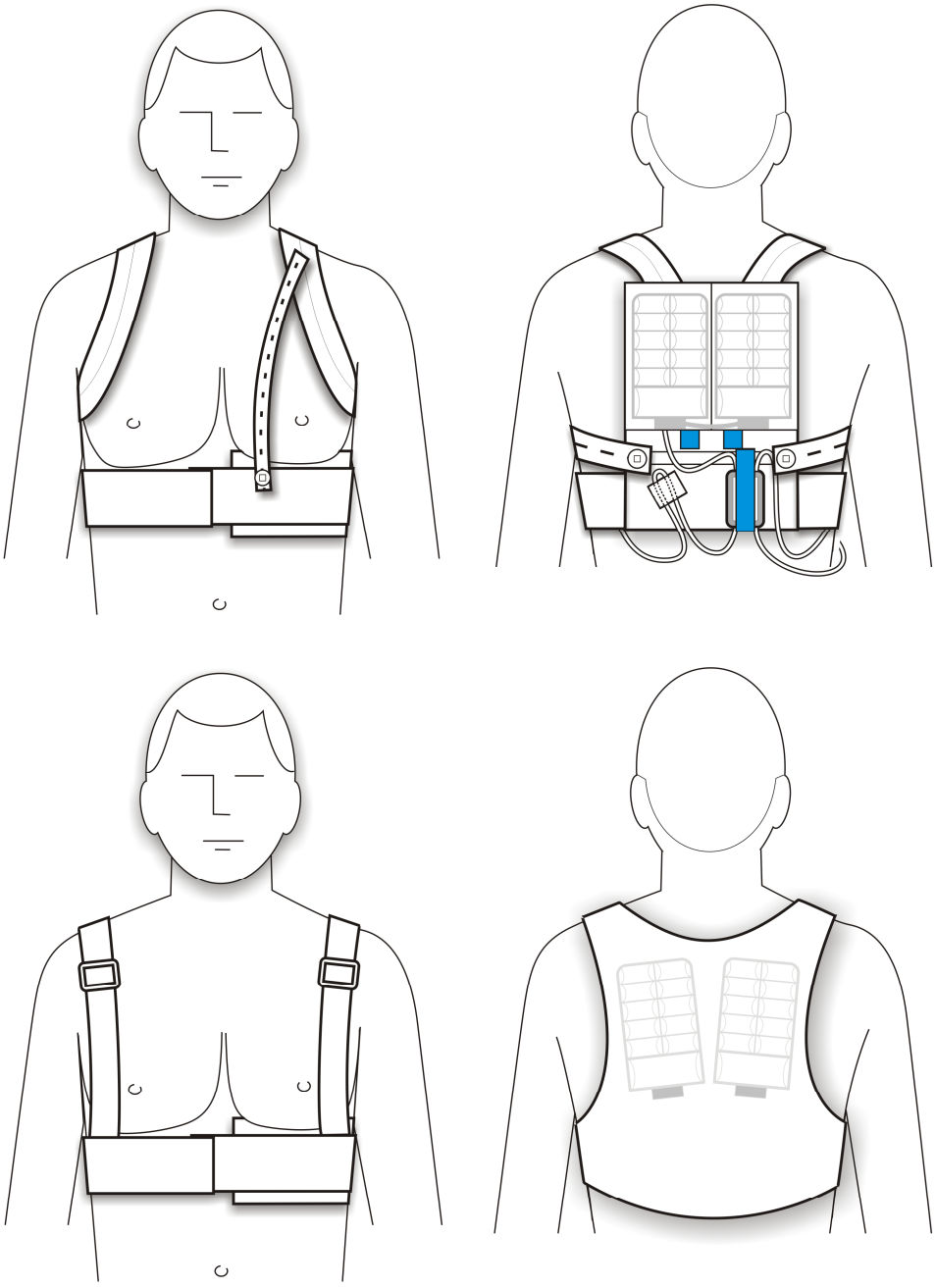
3 Clip to attach the module to the patient's belt, shirt, or jacket.

4 Record button.

5 Transmit button (for modem transfer).

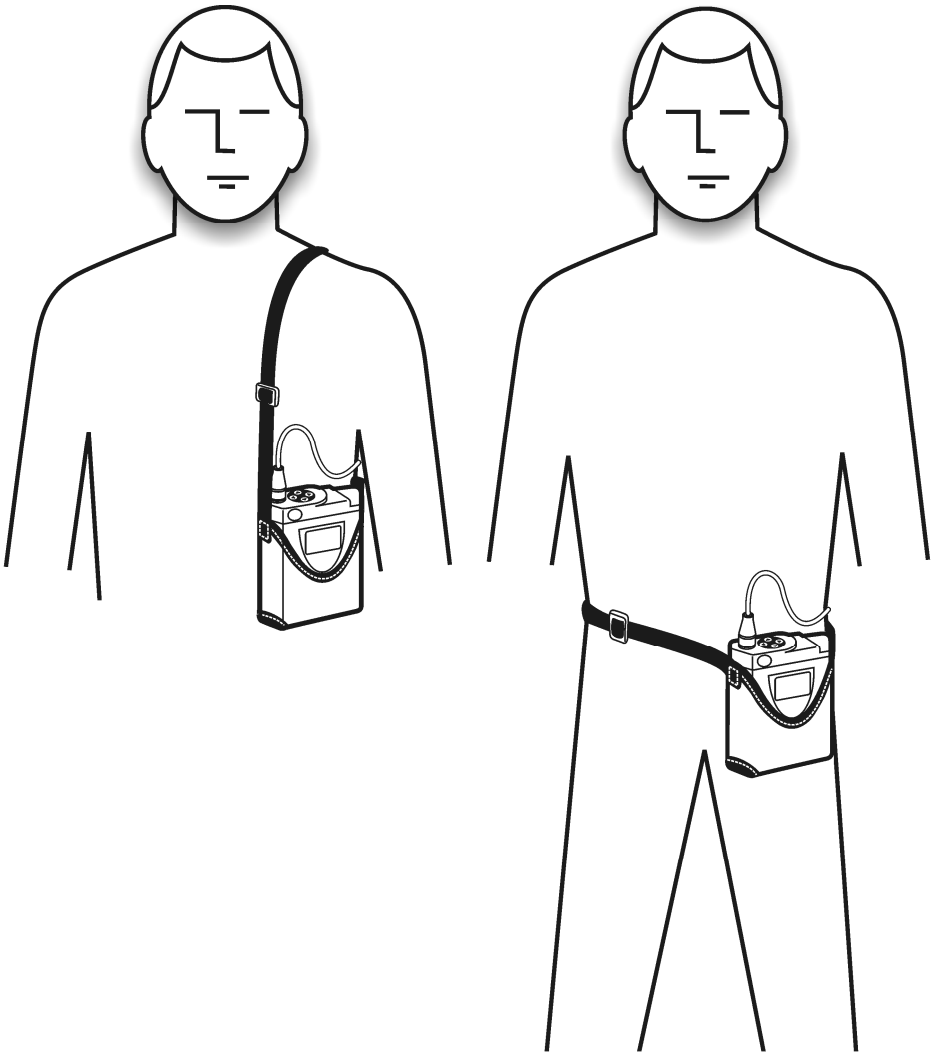
Garment

The Garment is worn under the patient's clothing. It positions the electrodes and therapy pads against the patient's chest, next to the skin. A bra or T-shirt may be worn over the Garment.



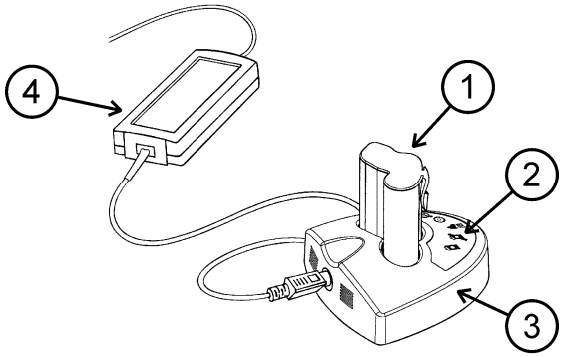
Holster

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



Battery Charger

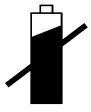
The Battery Charger, shown below, is designed to charge the Battery Pack after 24 hours of use. Its circuitry is designed to monitor the battery temperature, the battery voltage, and the charge time to protect the Battery Pack from over-charge.



1 Battery pack
2 Battery status display
3 Battery charger
4 Power supply

The Battery Charger has lights and symbols on its top panel to indicate the status of the charger and Battery Pack.

Battery charger functions

Symbol	Function	Light	Meaning
	Battery charging	Solid orange	Battery is charging.
	Battery testing	Flashing orange	Battery is being tested.
	Battery ready	Green	Battery is charged and ready.
	Charger fault	Flashing red	Problem with battery pack or battery charger. Reconnect and try again. If it fails, switch battery packs and try again. If problem continues, call device provider.
	Battery pack fault	Flashing red	Problem with battery pack or battery charger. Reconnect and try again. If it fails, switch battery packs and try again. If problem continues, call device provider.

For more information on the Battery Pack and Charger, see the Patient Manual.

System Operation

The LifeVest device delivers cardioverting/defibrillating shocks through the therapy electrodes. The time to detect, charge, and deliver a maximum energy shock is designed to be one minute or less. The appropriate energy level is determined by a treatment table, with parameters preset at the factory and/or programmed by the physician.

When the device determines that a treatable arrhythmia is in progress, it is designed to administer a responsiveness test. During the responsiveness test, a conscious patient should be able and is expected to prevent shock delivery by holding the pair of response buttons located on the Alarm Module. This action is confirmed by an appropriate message and the silencing of the alarms. If the detection criteria return to normal, the system should automatically terminate the shock sequence. If the arrhythmia continues and the patient loses consciousness, the subsequent release of the response buttons allows the device to proceed with the shock sequence.

To reduce the transthoracic impedance through the patient's chest prior to cardioverting/defibrillating energy delivery, each therapy electrode releases conductive electrolytic gel. The biphasic defibrillator is designed to deliver 150 joules into an impedance of 150 ohms. The device has no upper limit on impedance, however, at 200 ohms the device is designed to deliver over 90% of the requested energy. Impedance over 200 ohms may have less energy delivered.

The LifeVest device attempts to synchronize to the R wave of the patient's ECG and deliver the pulse within 60 ms of the R wave. If synchronization is not achieved within 3 seconds, the LifeVest device delivers an unsynchronized shock.

Cardioverting/defibrillating shocks delivered by the LifeVest device are designed to have the following characteristics. (The complete list of cardioverting/ defibrillating shock criteria are listed in Chapter 17, **System Specifications**.)

Shock Parameters	Value
Waveform	Biphasic truncated exponential
Delivered Energy Range	75-150 joules (± 5%)

For operation in Europe:

IPS 10.8V DC classified as BF but passes the leakage current requirement for CF rating except while charging for pulse delivery.

Patient notification

Patient messages

Visual and audible messages notify the patient of system status and expected responses via voice and display messages.

The LifeVest device communicates by voice with bystanders when shock delivery is imminent.

Patient alarms

Audible alarms are generated to alert the patient that device interaction is required. Most audible alarms should be accompanied by a message instructing the patient to take appropriate action.

Vibration box

The Electrode Belt's vibration box is a vibrating device that alerts the patient of impending medical treatment. It should be accompanied by a message instructing the patient to take appropriate action.

Self-monitoring and test routines

By the LifeVest device

The LifeVest device is designed to monitor its own functions and perform testing routines to confirm operational status. The Monitor is designed to perform periodic self-monitoring/test routines, which include:

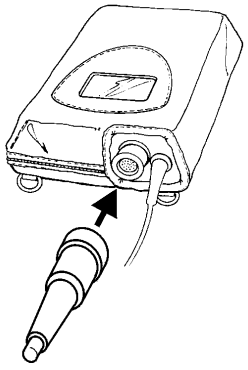
- Monitoring battery functionality, with the patient being notified if the battery is low.
- Continuity test of the Electrode Belt shocking electrode wiring.
- Notifying the patient by an appropriate visual and/or audible message if the ECG monitoring signal deteriorates due to excessive noise.

Upon actuation, the Monitor is designed to perform a self-test to confirm operational status. This self-test includes verifying ECG signal integrity, confirming detection algorithm parameters, and assessing battery status.

In addition to periodic self-monitoring/testing, when an arrhythmia is detected, the Monitor is designed to supervise charging the capacitors and measuring the transthoracic impedance. Failures that would prevent or make improper pulse delivery should result in inhibition of the shocking circuit, accompanied by appropriate visual and/or audible messages.

Test Plug

The Test Plug tests the monitor's ability to generate and deliver a shock.



Recording

The LifeVest Device automatically time tags and records system changes, including the following:

- Battery status.
- Device activation/deactivation.
- Change in status of ECG electrode contact.
- Any detectable errors during operation.

An arrhythmia recording includes the following data:

At a minimum, the ECG before, during, and after an arrhythmia should be recorded. The lengths of the recording both before and after the event are preset to a pre-buffer of 30 seconds and a post-buffer of 15 seconds. During an arrhythmic event, ECG recording is continuous until the primary detection criteria indicate a return to normal sinus rhythm.

- ECG channel and gain setting.
- Actual transthoracic impedance at time of pulse delivery.
- Response button activation.
- Changes in arrhythmia diagnosis/status.
- Pulse delivery timing and energy delivered.

The patient is also able to record the ECG by pressing the Record button on the Alarm Module.

Recharging

The depleted Battery Pack is recharged when the patient inserts it into the Battery Charger. Charging normally takes up to 3½ hours, but the patient should leave the Battery Pack in the charger until it is needed. The Battery Charger should remain plugged in at all times. It should be plugged into an outlet not controlled by a wall switch.

Periodically, testing occurs when the Battery Pack is inserted into the Battery Charger. Testing and charging may take up to 16 hours.

 **WARNING:** Use ONLY the WCD 3000 Battery Pack with the WCD 3000 Monitor. Use ONLY the WCD 3000 Battery Charger when charging the WCD 3000 Battery Pack. To use any other battery pack or charger could cause the system to fail.

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

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

Battery pack

- Completely insert the Battery Pack into the Monitor. If the Battery Pack is only partially inserted, the LifeVest device cannot detect an abnormal rhythm or deliver a treatment shock.
- Use ONLY the WCD 3000 Battery Pack with the WCD 3000 Monitor. Use ONLY the WCD 3000 Battery Charger when charging the WCD 3000 Battery Pack. To use any other battery pack or charger could cause the device to fail.
- Charge Battery Packs at least once every 3 months during prolonged storage. Failure to recharge could result in Battery Packs becoming unusable. Charge Battery Packs before giving them to a patient. Charge Battery Packs when re-stocking them after patient use.

Communication functions

Serial cable

The Serial Cable is designed to provide the LifeVest device with a standard RS232C serial port connection. This allows the device to be initialized and programmed via a computer.

Modem

The Modem transfers data to the LifeVest Network for storage and review.

To transfer data using the home dialer settings, the patient connects the Modem to the Monitor, then presses the Transmit button on the Alarm Module. Refer to Chapter 8 of the Patient Manual for more detail.

To transfer data using the hospital dialer settings, hold the Response Buttons while pressing the Transmit button.

Security traceability

Once the Monitor has been properly initialized, a programmed electronic device ID ensures proper patient identification.

The LifeVest Network web site allows access to relevant patient data via the Internet. The website is secured and also offers password protection.

WCD 3000 system components and accessories

Description	ZOLL Part Number
WCD 3000 Programmed Monitor	10A0893-A0x
Battery Pack	10A0894-A01
Battery Charger with Power Supply	11B0009-A01
Modem	10A0924-A0x
Test Plug	10A0922-A01
Serial Cable	10A0897-A01
Holster	10B0800-A01
Electrode Belt	10A0889-A01
Garment	10A0991-A0x or or 10A1004-B0x
Tote Bag	10B0822-A01
WCD 3000 Patient Manual	20B0027
WCD 3000 Operator's Manual	20B0028
WCD 3000 Message Reference	20B0029
WCD 3000/3100 Patient Video	20B0046

Chapter 9: Unpacking System

Upon receipt of the LifeVest system, check every package for damage. Note the serial number of any damaged item and call your device provider to report the problem.

Contents should be checked against the items listed on the packing slip. Report any discrepancies immediately to your device provider.

Parts list

Each patient should receive:

- LifeVest system (Monitor, Electrode Belt, Garments, two Battery Packs, Battery Charger, Modem, and Holster)
- Patient Manual and Message Manual

You should also have:

- A serial cable to set up patients
- An approved test device to test the Monitor

Also required, but not supplied:

- A computer for programming the Monitor and viewing patient data. This computer must have a serial port, terminal emulator software (HyperTerminal or equivalent), Internet access, and web browser software. (See page 9-3 for additional computer requirements.)
- An analog phone line nearby for downloading patient data from the Monitor to the ZOLL server.

Setup

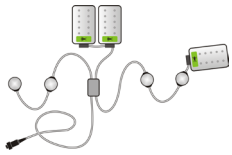
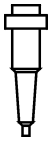
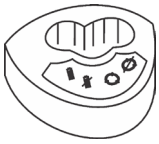
To set up the LifeVest system and initialize a patient, refer to Chapter 12, **Programming the Monitor**, and Chapter 13, **LifeVest Network**.

Inspection

For inspection of the system during a patient's visit, see Chapter 14, **LifeVest System Inspection**.

Package labeling symbols

The contents of the shipment should be indicated by a circle drawn around the symbol of the component enclosed. The symbols are:

	Packaging: Electrode belt.
	Packaging: Garment.
	Packaging: Modem.
	Packaging: Monitor.
	Packaging: Serial cable.
	Packaging: Test plug.
	Packaging: Battery charger
	Packaging: Battery Pack

All other system symbols can be found in the Preface.

Computer system minimum requirements for using LifeVest Network

This information represents minimum requirements for using the LifeVest Network. For better performance, a faster computer, additional disk space, higher RAM configurations, and a high-speed connection are recommended. Please note that you should obtain, install, and test the listed software on your computer prior to using the LifeVest Network.

Computer	MS-DOS Pentium (75 MHz or faster)
Web Browser	Microsoft Internet Explorer 5.0 and abov
Software	Adobe Acrobat Reader 4.0 or above (obtain free reader at www.adobe.com)
Monitor	S-VGA color monitor with at least 800 x 600 resolution
Other requirements	Standard keyboard
	Internet connection
	Printer

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Chapter 10: Patient Fitting

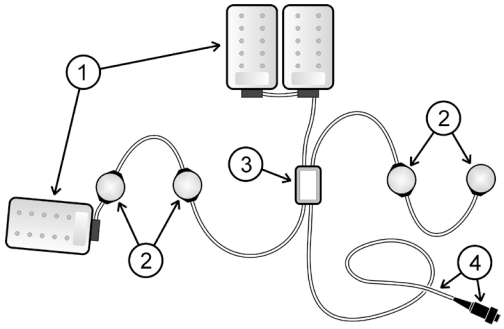
This chapter explains how to fit a patient and assemble the components of the LifeVest belt.

Before you start

- Gather the electrode belt and garment.
- Read through these procedures completely.
- Familiarize yourself with the components and what they're called.
- Have a clean, flat area to lay out and assemble the components, such as a table or counter. You might want to put a towel or cloth on the table to protect the components as you assemble them.

Components of the LifeVest belt assembly

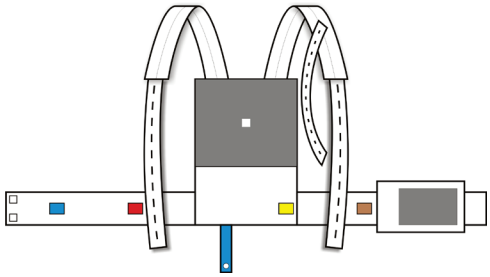
Electrode Belt

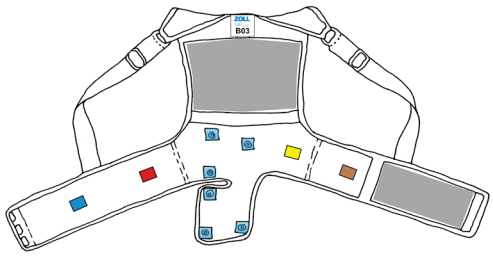


The belt comes in one size and fits any patient. The parts of the electrode belt are as follows:

1 Therapy pads
2 ECG electrodes (also called ECG sensors)
3 Vibration box
4 Connector

Garment





The garment comes in a variety of sizes to suit the patient.

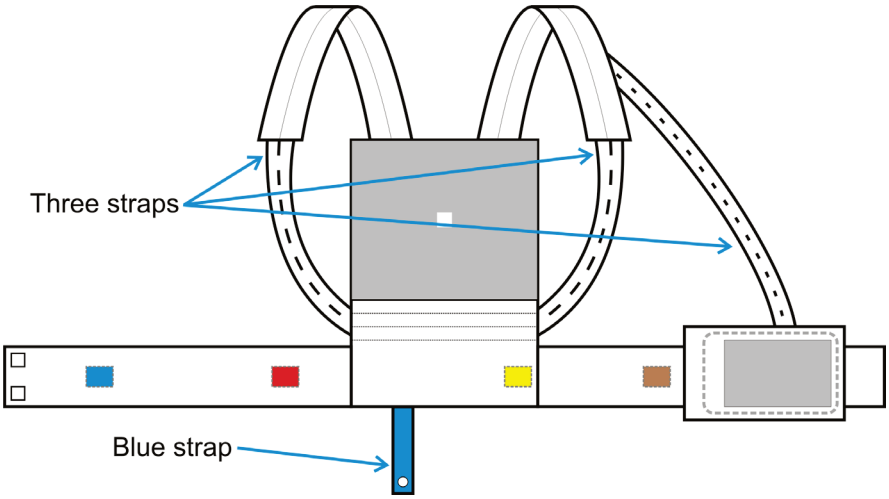
In this chapter, you will measure the patient to determine what size garment to use.

There are two style garments, with slight variations in fit and assembly. See next page to determine which garment you have.

Which style garment do you have?

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

Garment A

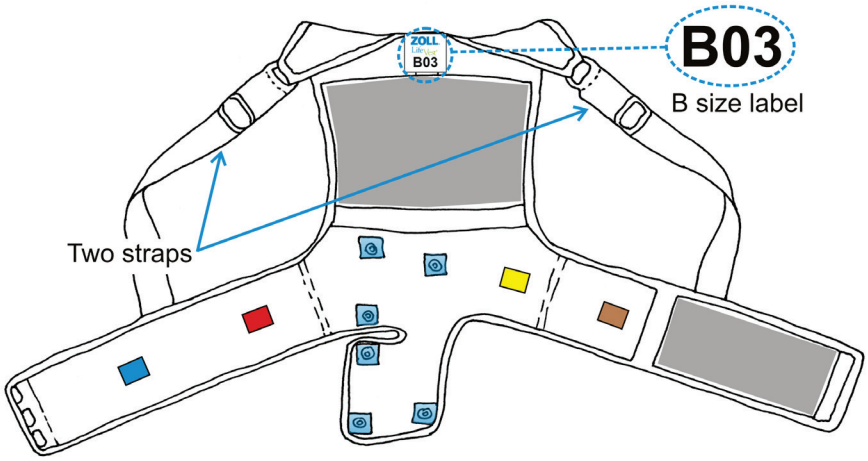


This style garment has three straps at the top, and a small blue strap at the bottom.

We call this garment style A.

If you have this style garment, see page 10-3.

Garment B



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

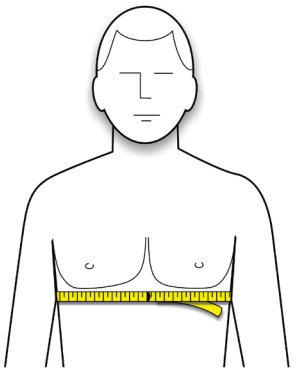
We call this garment style B.

If you have this style garment, see page 10-12.

Measuring the patient for garment A

Measure the patient to determine what size garment A to use.

If you are using garment B, see page 10-12.

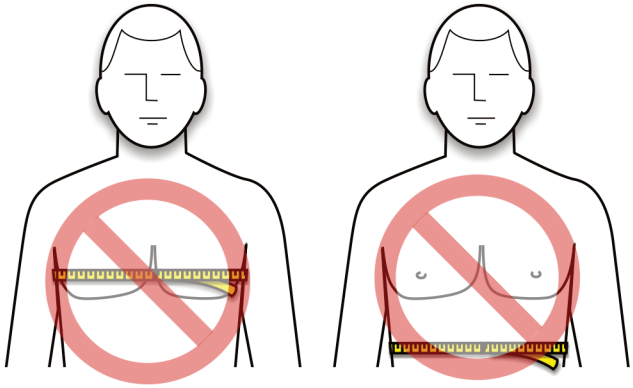


1 Have patient stand and remove all upper body clothing, including undergarments.

2 Place a measuring tape around the patient's chest, centered at the xiphoid.

Measure to the closest inch or centimeter.

Don't measure too high or too low across the patient's torso.



3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement		Garment
inches	centimeters	10A0991-A0X
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit the patient.

Example measurement

Chest measurement inches	Chest measurement centimeters	Garment 10A0991-A0X
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

As an example, let's say the patient measures 44 inches.

According to the chart, a patient measuring 44 inches needs garment size A06.

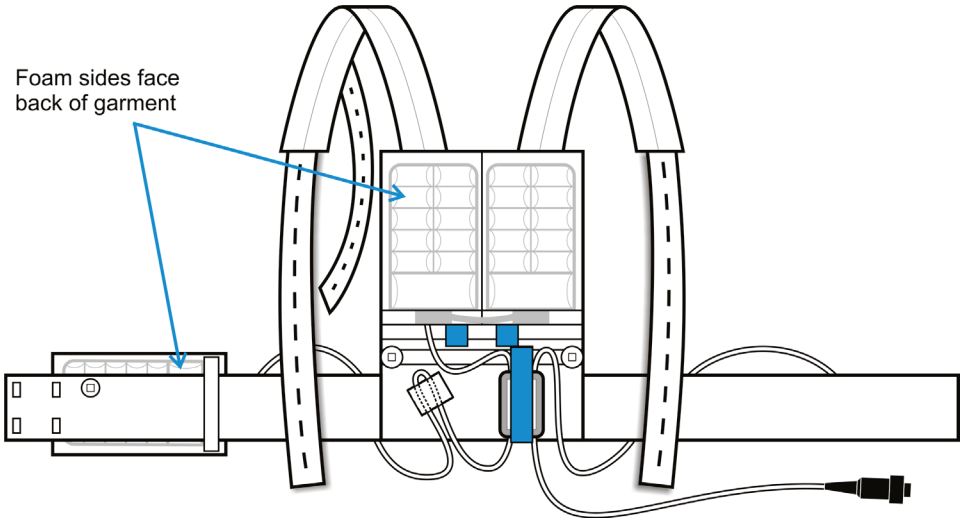
Assembling the electrode belt to garment A

Refer to this section for garment A. If you have garment B, see page 10-14.

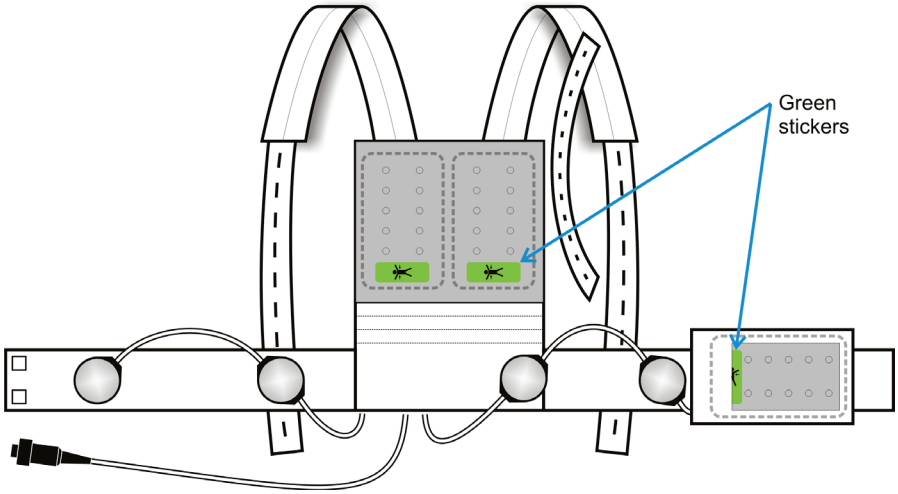
Assemble the belt and garment as described in the Patient Manual, but do not fasten the straps.

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

Outside view
This side faces away from the patient's body when worn. The foam sides of the electrodes face the back of the garment.



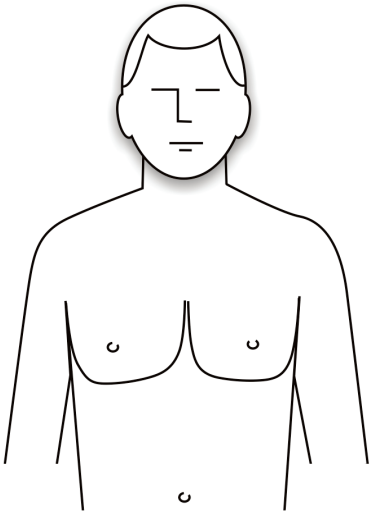
Inside view
This side faces toward the patient's body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting garment A on the patient and finalizing assembly

Refer to this section for garment A. If you have garment B, see page 10-15.

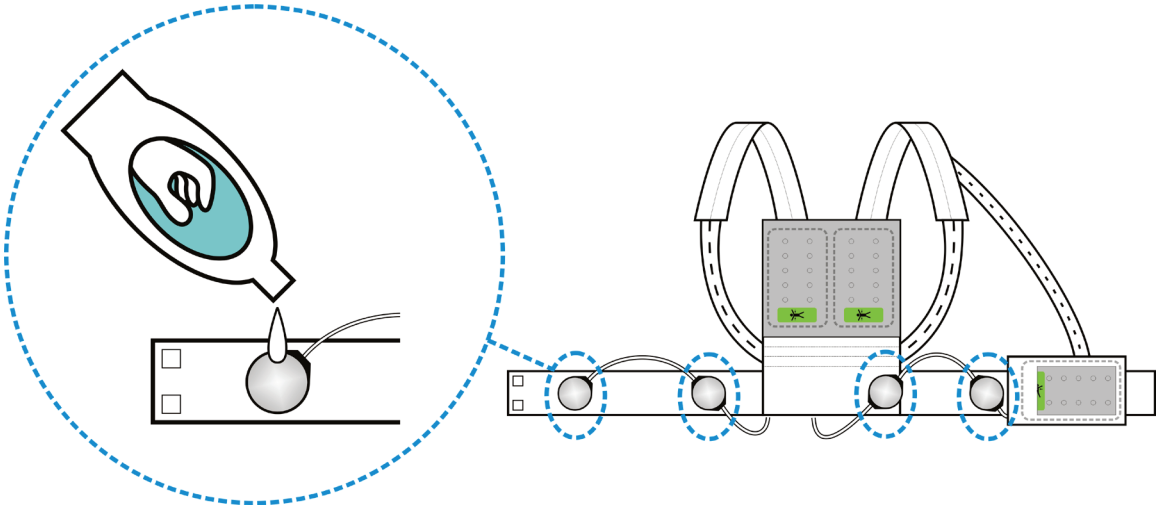
Follow these instructions to help the patient put on the assembled garment, then adjust the garment for a proper fit.

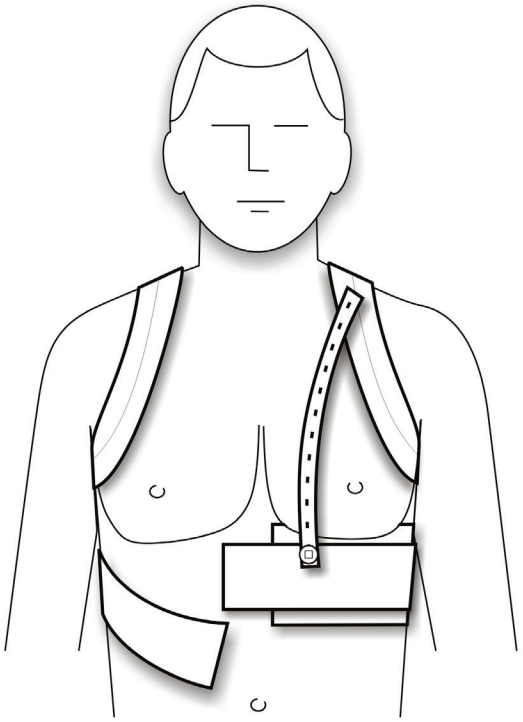


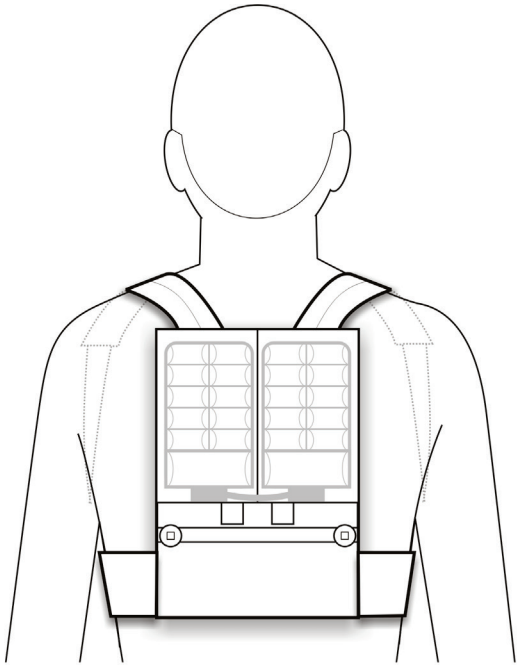
1 Have the patient remove all clothing and undergarments from the upper body before putting on the garment.

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

2 Apply unscented hand lotion or skin cream to the four ECG (round) electrodes.





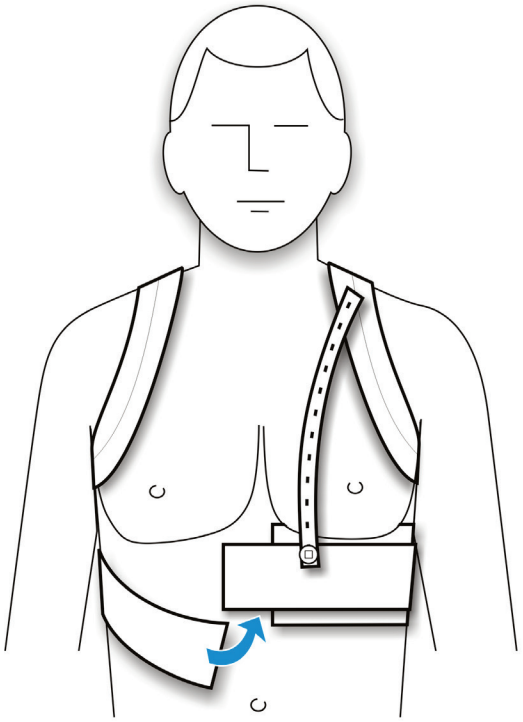


3 Help the patient put on the garment, making sure:

- The garment doesn't get twisted as the patient puts it on.
- The silver fabric pockets touch the patient's bare skin.

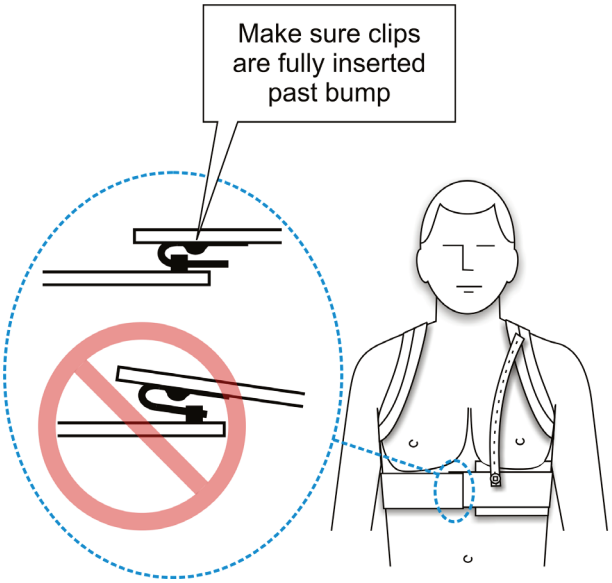
If patient is a female:

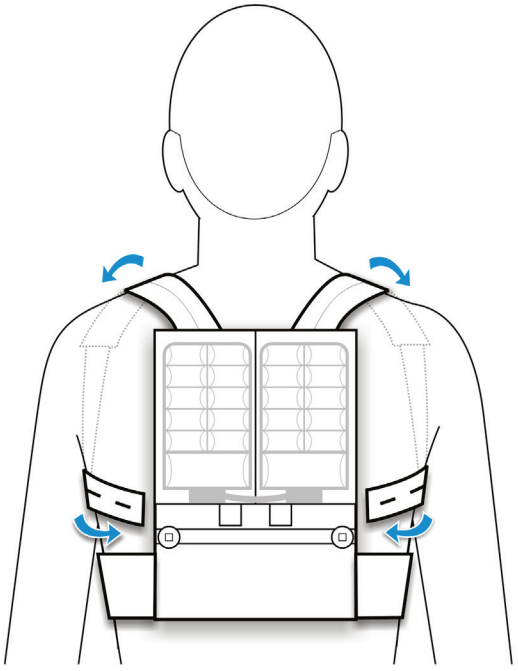
- Patient should wear a bra OVER the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against the patient's body rather than the underside of the patient's left breast.



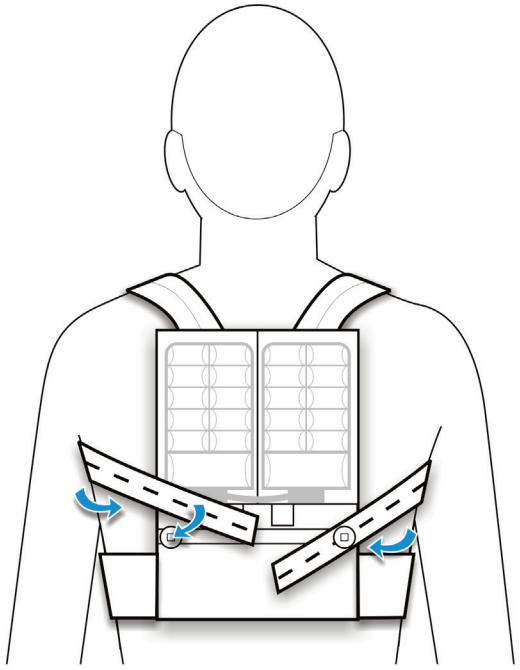
4 Connect the garment ends together in the front.

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



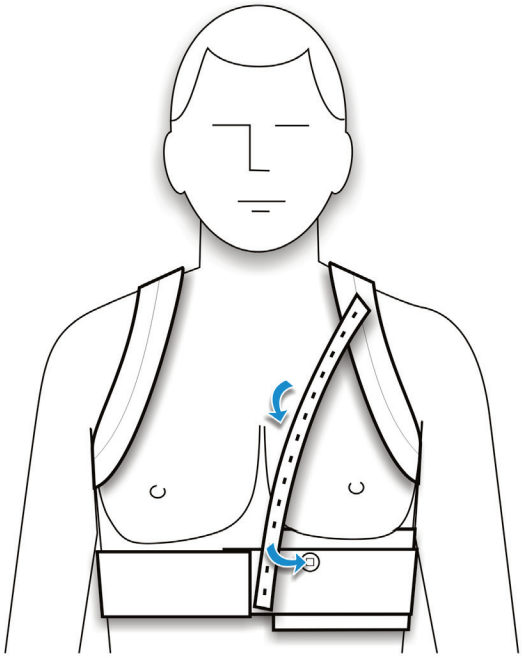


5 Position straps over the patient's shoulders and bring them under the patient's arms around to the patient's back.



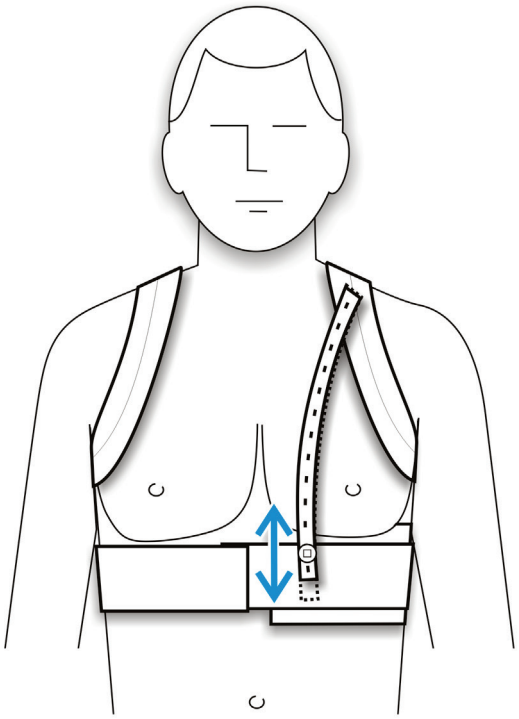
6 Without stretching the strap, find the hole that lines up with the button. Then stretch the strap slightly and attach the button to the next hole.

- Do not cut the strap.
- Excess strap can be folded over and buttoned again.
- Repeat for each of the two long straps.
- Adjust the garment for a good fit.



7 Bring the remaining strap down the front of the patient's chest and button it to the front of the garment.

- Do not cut the strap.
- Excess strap can be folded over and buttoned again.

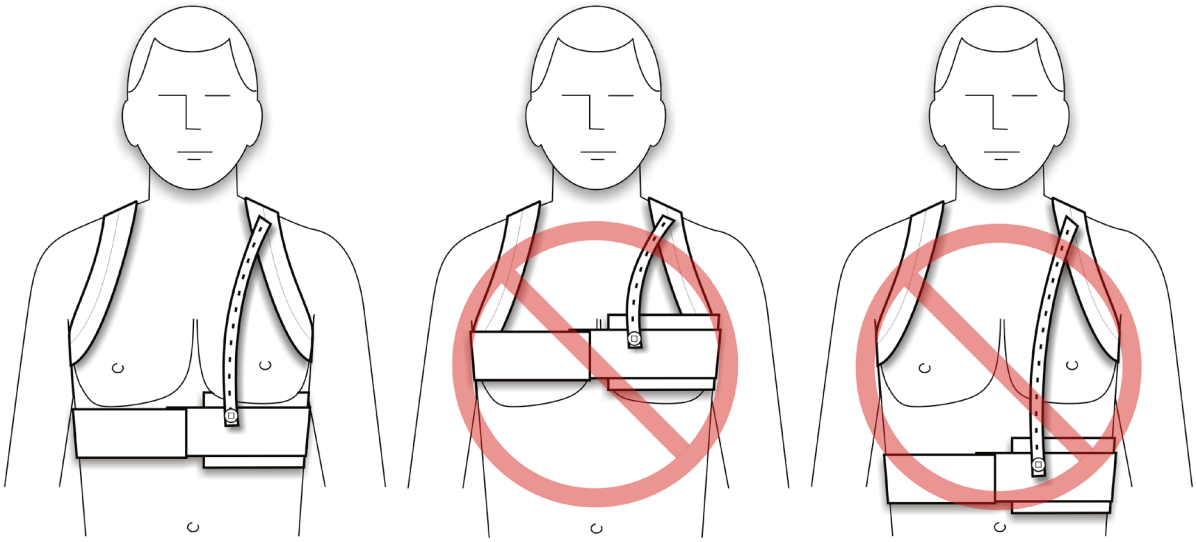


8 Check the position of the garment on the patient's body and make sure it's not too high or too low.

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

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

- The garment **should** cross the patient's body just below the breastbone.
- The garment **should not** be as high as the patient's nipples.
- The garment **should not** be as low as the patient's belly button.



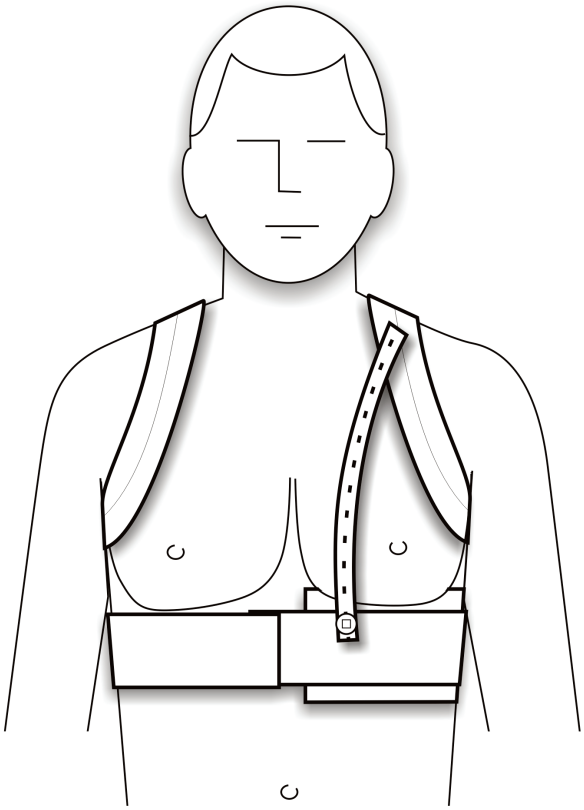
Positioned properly

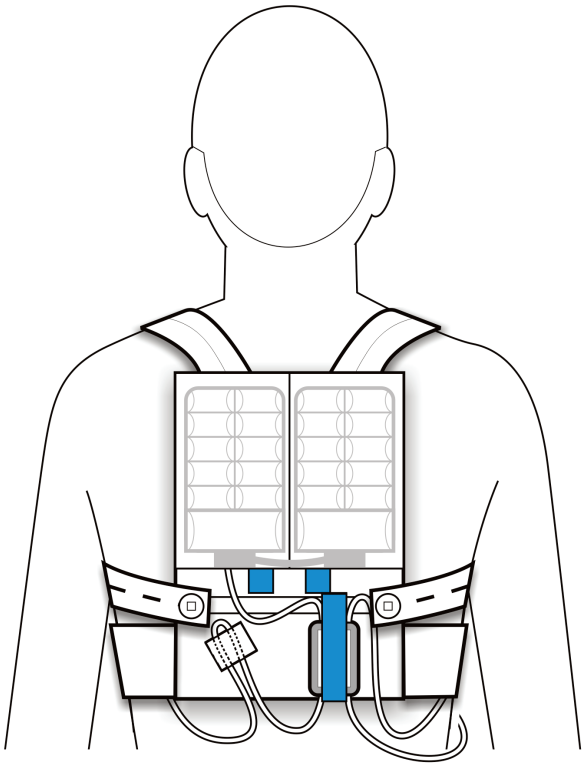
Too high

Too low

9 Have the patient look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against patient's skin.
- The ECG electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green stickers) MUST TOUCH THE PATIENT'S BODY for the device to work properly.
- None of the cabling interferes with the ECG electrodes or therapy pads.
- The garment is being worn correctly. It should look like the figures below.

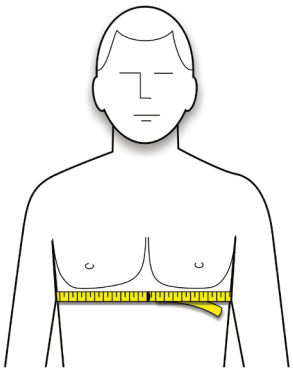




Measuring the patient for garment B

Measure the patient to determine what size garment A to use.

If you are using garment A, see page 10-3.

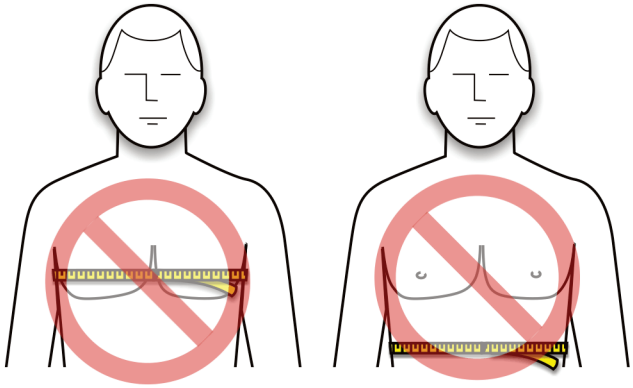


1 Have patient stand and remove all upper body clothing, including undergarments.

2 Place a measuring tape around the patient's chest, centered at the xiphoid.

Measure to the closest inch or centimeter.

Don't measure too high or too low across the patient's torso.



3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement		Garment
inches	centimeters	10A1004-B0X
26-31	66-80	B01
32-37	81-95	B02
38-44	96-112	B03
45-51	113-130	B04
52-56	131-142	B05

The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit the patient.

Example measurement

Chest measurement		Garment
inches	centimeters	10A1004-B0X
26-31	66-80	B01
32-37	81-95	B02
38-44	96-112	B03
45-51	113-130	B04
52-56	131-142	B05

As an example, let's say the patient measures 44 inches.

According to the chart, a patient measuring 44 inches needs garment size B03.

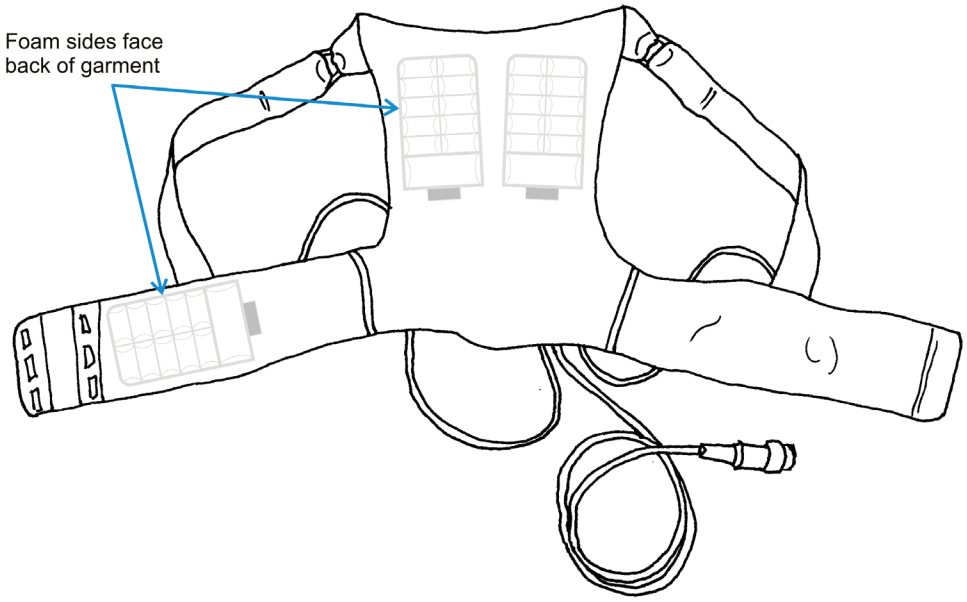
Assembling the electrode belt to garment B

Refer to this section for garment B. If you have the garment A, see page 10-5.

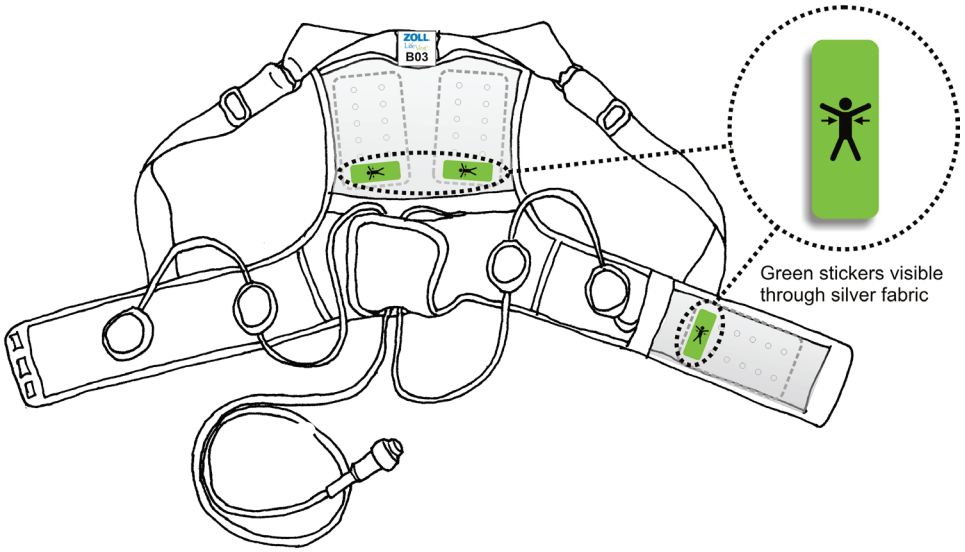
Assemble the belt and garment as described in the Patient Manual.

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

Outside view
This side faces away from the patient's body when worn. The foam sides of the electrodes face the back of the garment.



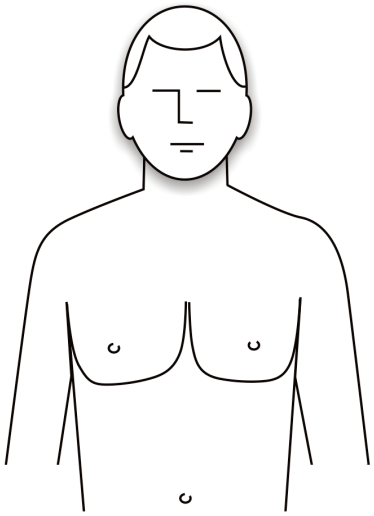
Inside view
This side faces toward the patient's body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting garment B on the patient and finalizing assembly

Refer to this section for garment B. If you have garment A, see page 10-6.

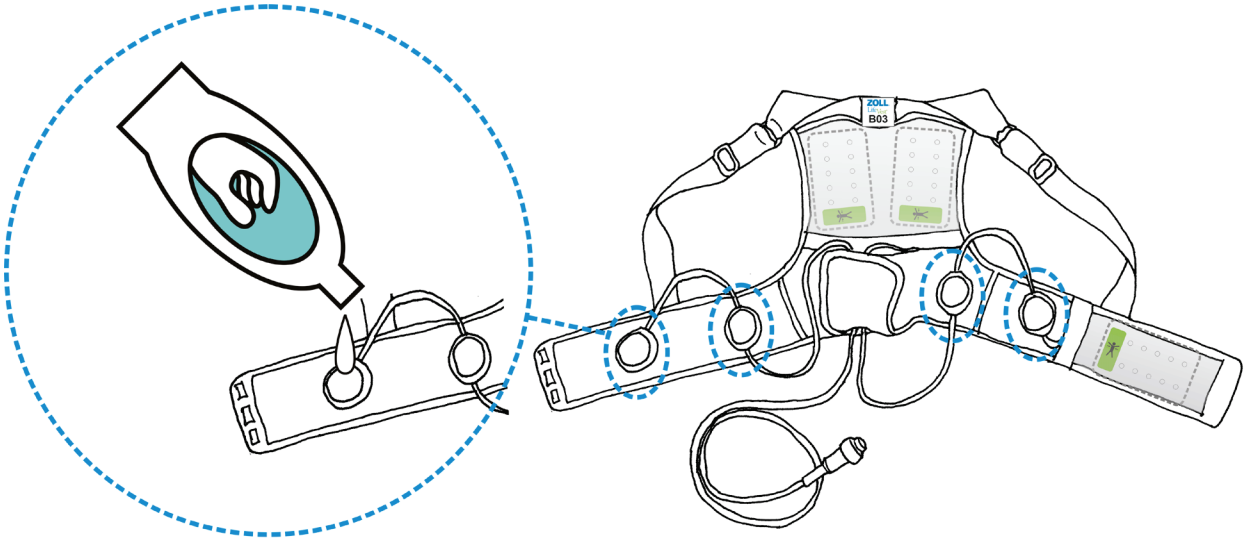
Follow these instructions to help the patient put on the assembled garment, then adjust the garment for a proper fit.

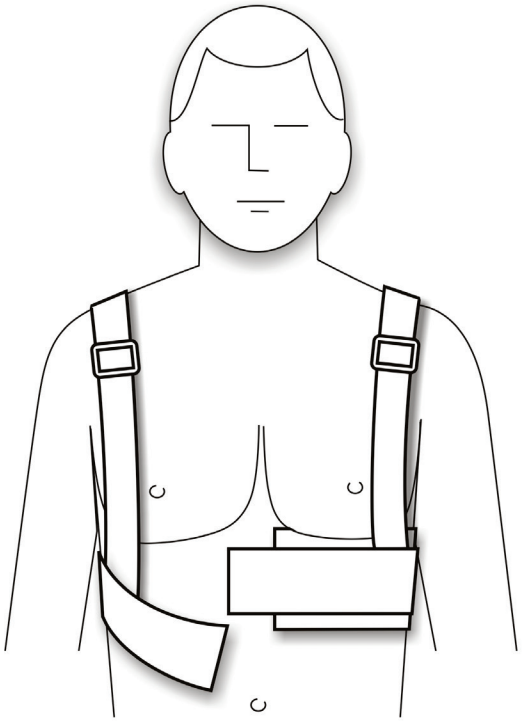


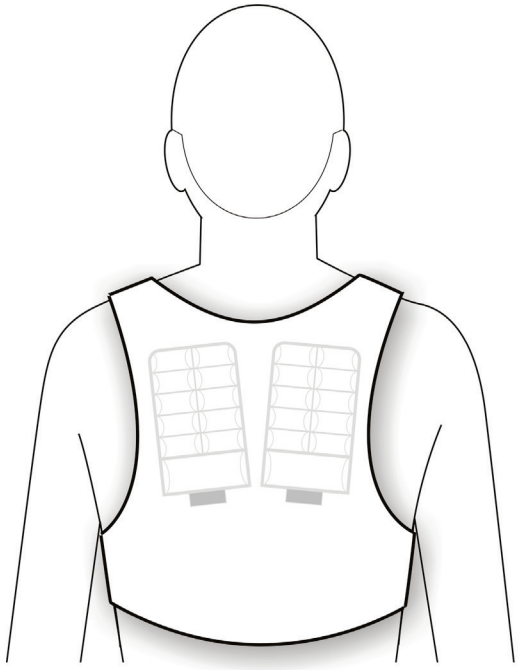
1 Have the patient remove all clothing and undergarments from the upper body before putting on the garment.

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

2 Apply unscented hand lotion or skin cream to the four ECG (round) electrodes.





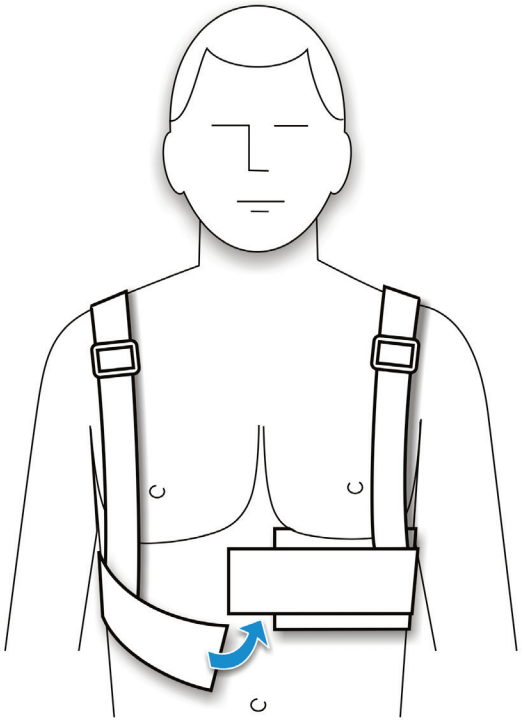


3 Help the patient put on the garment, making sure:

- The garment doesn't get twisted as the patient puts it on.
- The silver fabric pockets touch the patient's bare skin.

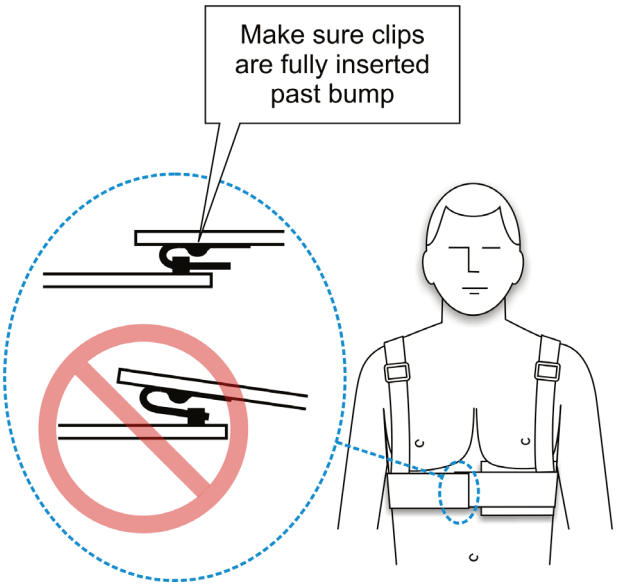
If patient is a female:

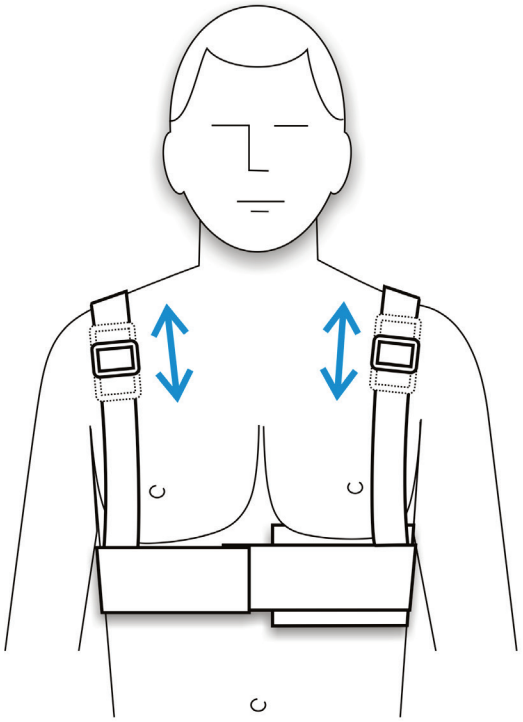
- Patient should wear a bra OVER the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against the patient's body rather than the underside of the patient's left breast.



4 Connect the garment ends together in the front.

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



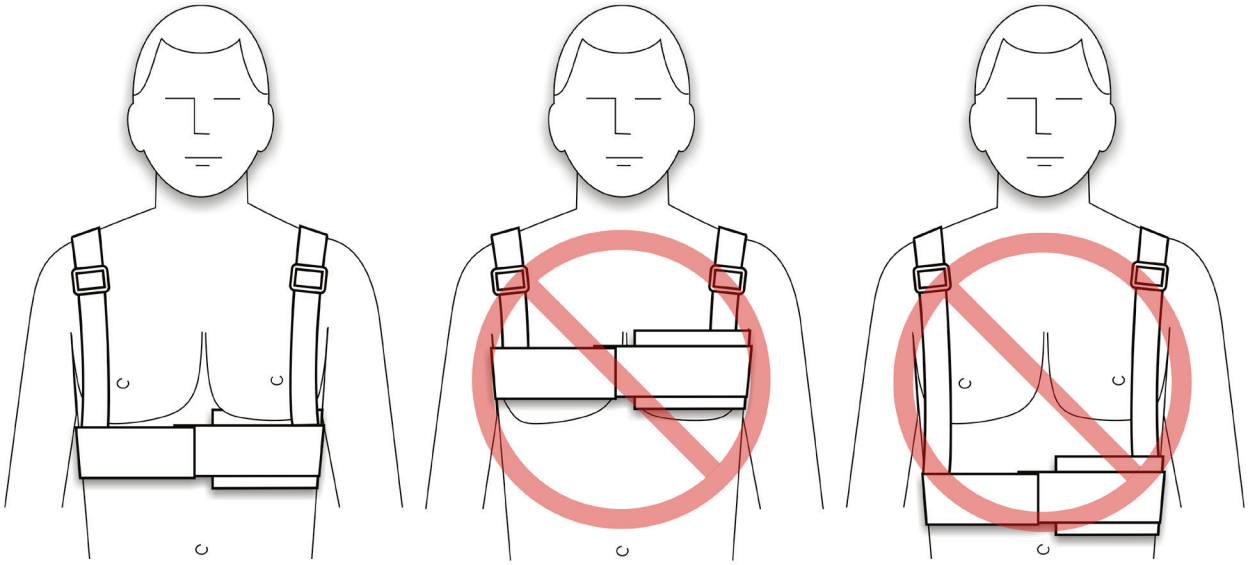


5 Check the position of the garment on the patient's body and make sure it's not too high or too low.

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

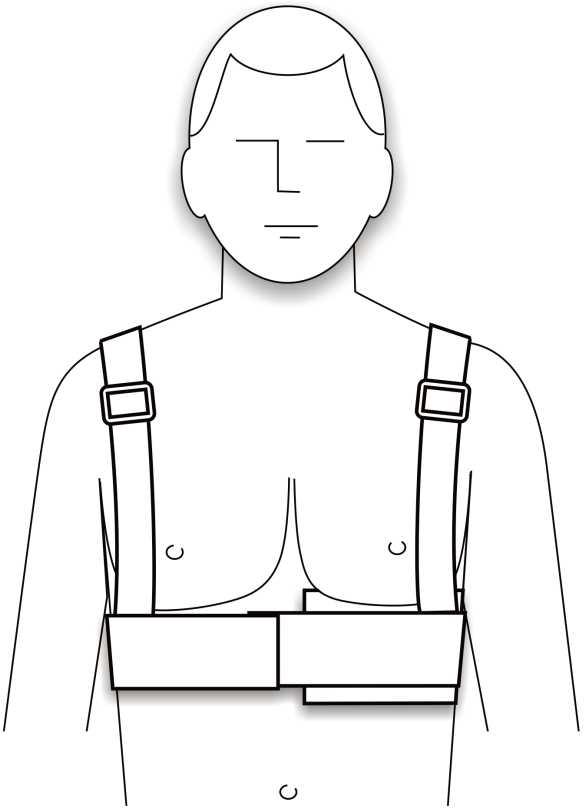
Move the buckles to position the garment properly, and for a snug fit.

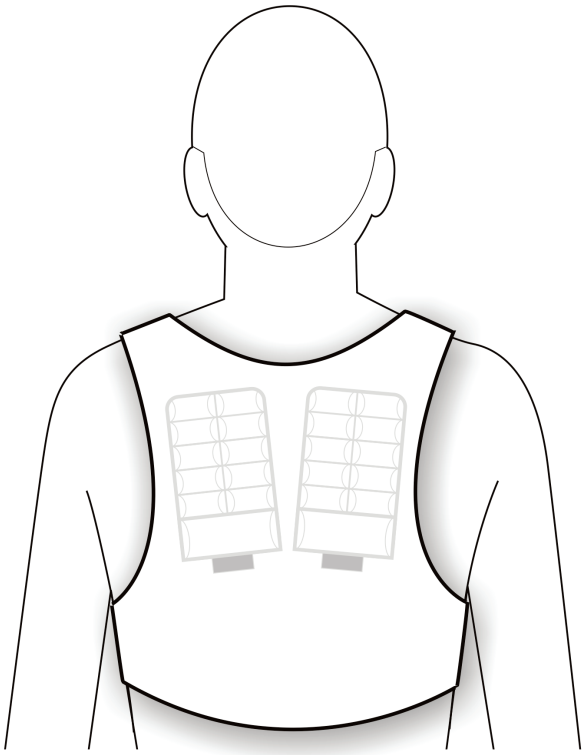
- The garment **should** cross the patient's body just below the breastbone.
- The garment **should not** be as high as the patient's nipples.
- The garment **should not** be as low as the patient's belly button.



6 Have the patient look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against patient's skin.
- The ECG electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green stickers) MUST TOUCH THE PATIENT'S BODY for the device to work properly.
- None of the cabling interferes with the ECG electrodes or therapy pads.
- The garment is being worn correctly. It should look like the figures below.





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Chapter 11: Patient Training

Description

This chapter explains how to use the Monitor's training mode to introduce the patient to LifeVest device operation.

In the LifeVest System Patient Manual, Chapter 3, How do you make the LifeVest Device Part of your Daily Routine, explains how to assemble, wear, and operate the LifeVest device.

Preparation

Make sure that the patient has been properly fitted and supplied with a LifeVest system, as described in the previous chapter. Then review the procedures given in the Patient Manual, allowing the patient to demonstrate understanding. See the Patient Manual for information concerning:

- Chapter 1: Introduction information, including warnings and cautions (listed in Chapter 4 of this manual as well)
- Chapter 2: Who Should Wear This, Who Should Not?
- Chapter 3: How do you make the LifeVest Device Part of your Daily Routine?
- Chapter 4: What do the Messages Mean?
- Chapter 5: How do you Maintain Clear ECG Signals to the Monitor?
- Chapter 6: What if you Experience an Abnormal Heart Rhythm?
- Chapter 7: How do you Record ECGs?
- Chapter 8: How do you Communicate by Modem?
- Chapter 9: How do you Maintain the System?
- Chapter 10: What is the Operating Environment of the System?
- Chapter 11: What do Family Members Need to Know?

Make clear to the patient that he or she is at risk of SCD if unprotected by the LifeVest device, and to call the prescribing physician and/or ZOLL when problems arise with the system.

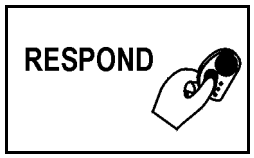
Make sure to write the physician's office number and emergency number in Chapter 1 of the Patient Manual. In the USA, ZOLL can be contacted 24 hours a day, 7 days a week at 1-800-543-3267. Outside of the USA, the patient must contact the prescribing physician.

Patient training mode

After fitting the patient with the device and reviewing the patient manual with him/her, have the patient demonstrate understanding of the material by using the device in the training mode, as described next.

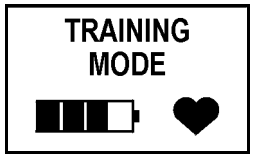
Training mode

The Monitor is shipped already in the training mode. When the Battery Pack is connected for the first time, before the patient information has been entered, the patient should see:



The patient must press both response buttons, just as the patient would for normal startup, to see:

Then the patient must press OK to see:



In the training mode, the monitor should simulate normal operation, whether or not the Electrode Belt is connected. In the training mode, the device can simulate a treatment sequence for an abnormal heart rhythm or a noise notification sequence (described in the next section).

To exit the training mode, you must use the terminal program to baseline or rebaseline the Monitor, or set it up for a new patient.

Treatment sequence simulation

To begin a treatment sequence simulation, press the Record button on the Alarm Module.

- The patient should see and hear the messages and hear the alarms, as described in the Patient Manual (Chapter 6, **What if you Experience an Abnormal Heart Rhythm?**). The patient should also feel the vibration box if wearing the Electrode Belt during training.
- Some messages should also display TRAINING MODE at the bottom of the display.
- The patient should experience what occurs during the delivery of two pulses if the patient does not press the response buttons. Of course, a shock will not actually be delivered.
- After two simulated shocks, the patient should hear "*Device disabled. Call ambulance*." Normally this would occur after the fifth shock.
- If the response buttons are pressed, the patient should see and hear the "*Treatment stopped by response buttons. Bystanders, do not touch device*."
- The patient should hear "*Call ambulance*" if a simulated treatment shock was given.
- To turn off the treatment sequence simulation, press the Record button again.

Noise notification simulation

To begin a noise notification simulation, press the Transmit button on the Alarm Module.

- The patient should see and hear the messages described in the Patient Manual (Chapter 5, **How do you Maintain Clear ECG Signals to the Monitor**).
- Some messages should also display TRAINING MODE at the bottom of the display and alternately display the PRESS OK message.
- The patient should experience what occurs when the ECG electrodes are not sending clear ECG signals to the Monitor.
- To turn off the noise notification simulation, press the Transmit button again.

Warnings and cautions to review with the patient

Refer to Chapter 4 for the warnings and cautions to review with the patient. These are also included in Chapter 1 of the Patient Manual.

Chapter 12: Programming the Monitor

About this chapter

- This chapter covers monitor setup procedures using a computer.
- This description applies to software version 2.9 and up. Previous versions do not have some of the features shown.
- You will need an IBM-compatible computer that has an RS-232 serial port. The serial port should be a DB-9 connector. If your computer has any other connector, you will need an adapter so that the computer will work with the serial cable supplied with the LifeVest.
- Some laptop computers may not have an RS-232 serial port. In that case you will need an adapter card that provides a serial port. Contact your computer manufacturer for details.
- The computer used for this setup does not need to have an Internet or phone connection. You will be communicating only between the computer and the LifeVest monitor.
- Your screens may look slightly different than what's shown in this manual. Operational procedures should remain the same.
- This setup requires the serial cable supplied with the LifeVest system.
- This setup also requires that the computer is running a terminal emulator program such as HyperTerminal, a piece of software provided with Windows. Details about setting up HyperTerminal are provided on page 12-25.
- With software version 2.9 and up, you can also set up the monitor without a computer, by using the alarm module buttons. See Chapter 16, **Monitor Setup Using Alarm Module**.

How to connect the monitor to your computer

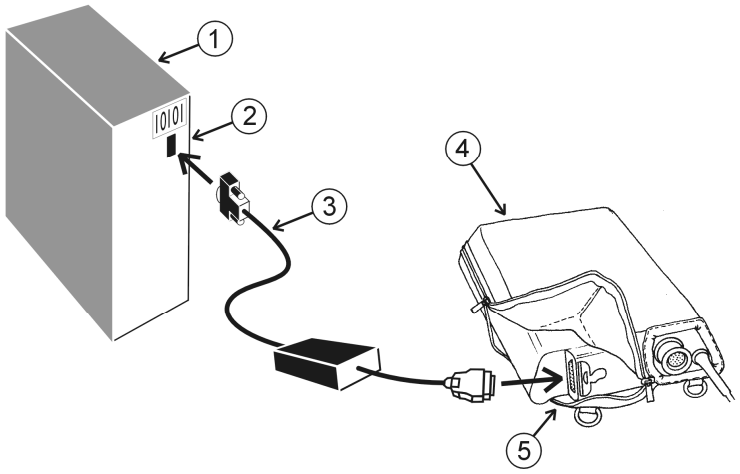
For this procedure, you will need the serial cable supplied with the WCD 3000 system.

Depending on your computer's serial port, you may need an adapter in order to mate the cable plug to the computer.

If your computer does not have a serial port, you may need an adapter card in order to provide the serial port.

1 Have the monitor powered up and operating normally. Disconnect the electrode belt from the monitor.

2 Connect the monitor to the computer with the serial cable as shown.



1 Computer
2 Serial port
3 Serial cable
4 Monitor
5 Communication port

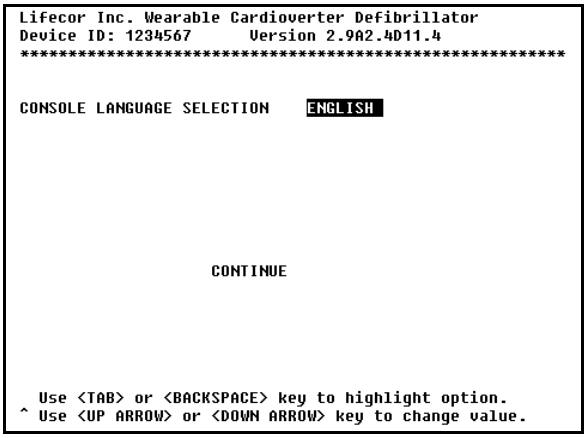
How to enter the setup mode

1 Have the monitor powered up and connected to your computer through the serial cable.

2 Start HyperTerminal or other terminal emulator from your computer (details about HyperTerminal are on page 12-25).

3 When the blank terminal screen appears on your computer, press the **ESC** key three times.

The menu below appears, showing that the computer is now communicating with the monitor.

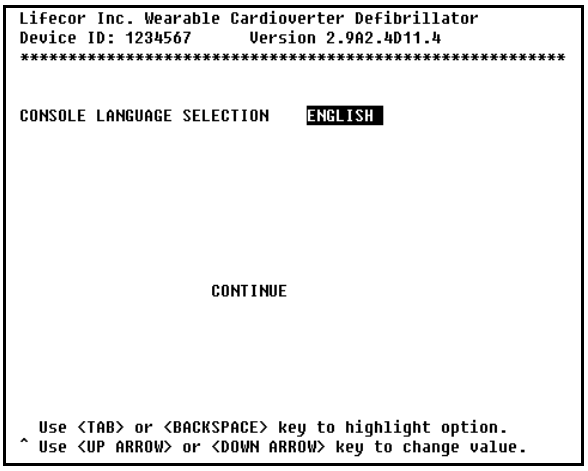


If you do not get the startup screen

- Click on the **X** in the upper right corner of the HyperTerminal screen to close the program.
- Remove the battery from the monitor, then reinstall it and allow the monitor to power up normally.
- Make sure the serial cable is securely plugged into the monitor and your computer.
- Repeat the procedure above.
- If you continue to have problems, check the communications port settings (see page 12-26).
- Make sure the COM port you are using is not assigned to any other purpose, such as for a modem or a hand-held computer interface. If you suspect any other use, choose COM2 or COM3.
- If you continue to have problems, call ZOLL for help.

How to select a setup language

1 Have the console language selection menu displayed:

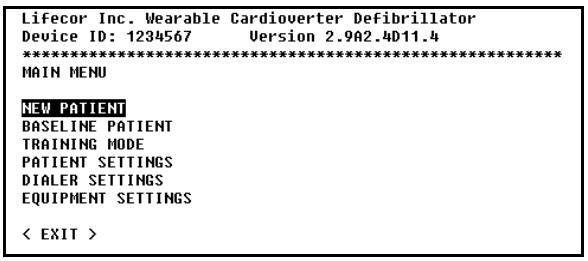


Notice the instructions for navigation at the bottom of the page. Some screens have symbols in front of the options that correspond with the symbols in front of the instructions.

2 Use the up and down arrow keys to see the language choices available. When your language is displayed, press the **Tab** key to highlight **CONTINUE**, then press **Enter**.

Note: The language you choose is used only in the setup mode. This will not be the language for the patient messages (which you can set through the patient settings option, discussed later).

Main menu displays:



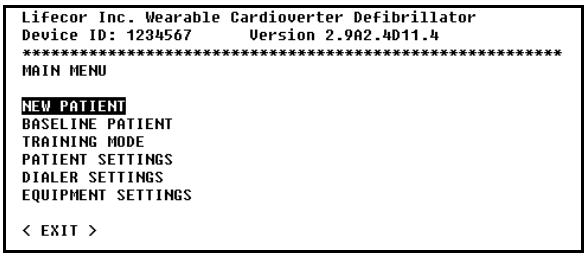
3 From this menu, you can enter or change any of the choices displayed. Continue with the procedures in the rest of this section.

Menu options

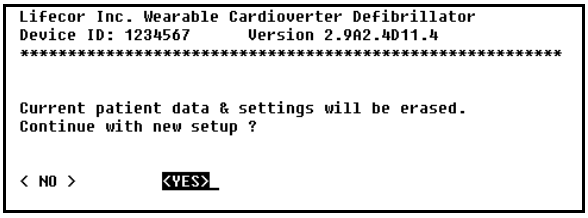
Menu option	What it lets you select or enter	When to use it
New patient	Patient's name and dialing number (if more than one number is available).	To set up a new patient.
Baseline patient	When you choose this option, the monitor goes into the baseline mode when you exit the setup mode.	To baseline a patient after the initial setup, such as during a follow-up visit.
Training mode	When you choose this option, the monitor goes into the training mode when you exit the setup mode.	To train the patient in the monitor's basic operation regarding the treatment sequence and noise sequence.
Patient settings	Patient's name and languages for the displayed messages and voice prompts. Defaults and options for rate thresholds (in beats per minute), response time (how many seconds until the device delivers the defibrillating shock), pulse energy (in joules), and other treatment options.	To change or correct a patient's name. When setting up a new patient, use this menu to set the patient's language for the displays and voice prompts. A secondary language can also be selected for bystanders. Check or set the treatment options when setting up a new patient, or during a follow-up visit.
Dialer settings	Phone number dialing modes (touch tone or pulse) and dialing prefixes (any numbers that need to be dialed in front of the phone number) for dialing from the patient's home and the hospital.	When setting up a new patient, enter the details about the phone system. Update this menu if the patient has any changes to their phone system that require updates to the dialing mode or prefix.
Equipment settings	New country, locality settings, and connectivity settings (see below).	See individual options below.
New country	Country where the patient lives.	Country will be defined by your device provider. If you need to change the country, contact your device provider.
Locality settings	Clinical center code and name that the patient is associated with. Time zone and daylight savings time (on or off) for the locality where the patient lives.	When setting up a new patient, or if patient moves to another location.
Connectivity settings	Details associated with the modem and phone dialing.	When setting up a new patient, to define the connection method, phone number build code, and modem type (if different from defaults). Remaining settings (overrides) are normally not used. However, ZOLL may ask you to enter a value for service purposes.

How to set up a new patient

1 From the **Main Menu**, Tab to **NEW PATIENT**, then press **Enter**.



A warning states that the current patient data and settings will be erased if you continue.

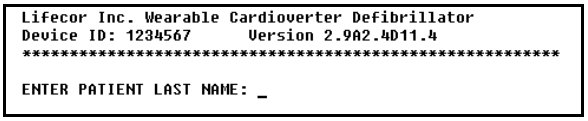


2 Tab to **YES**, then press **Enter**.

First name screen displays:

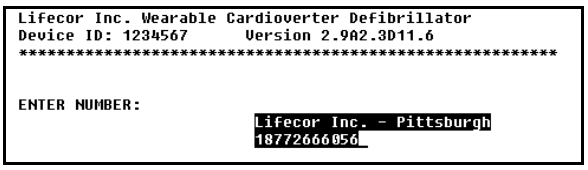
3 Type the patient's first name, then press **Enter**.

Last name screen displays:



4 Type the patient's last name, then press **Enter**.

Dialing number screen may display, showing the phone number exactly as it will be dialed from the monitor:



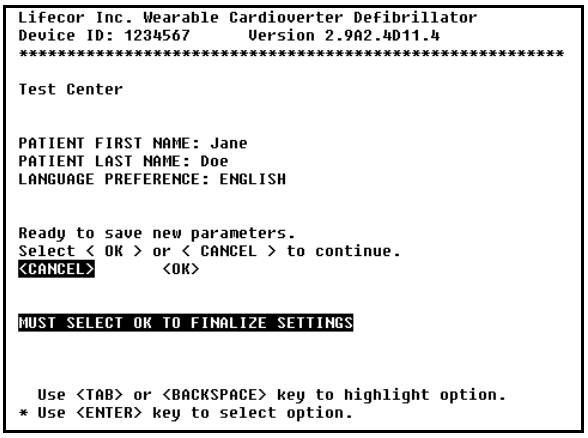
Note: The dialing number screen will not be shown if a single phone number serves the whole country, or if a patient dialing override is selected.

- If the dialing number screen displays, continue with step 5 below.
- If the dialing number screen does not display, continue with step 6 below.

5 With the dialing number screen displayed, select the number that corresponds with the city or area where the patient lives.

- To change the city, press the up and down arrow keys. When the correct city is displayed, press **Enter**.
- Holding an arrow button down makes the selections scroll faster.
- You can also type the first letter of the city, then use the arrow keys to scroll to the selected city.

6 The patient setup verification screen displays:



Review the information to make sure you have entered it properly, then do one of the following:

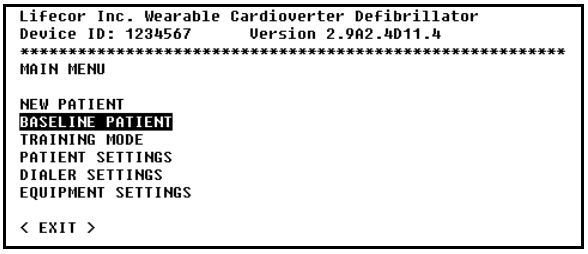
- To save the information as displayed, Tab to **OK**, then press **Enter**.
- If any information needs to be changed, Tab to **CANCEL**, then press **Enter**.

How to set up the monitor to baseline a patient

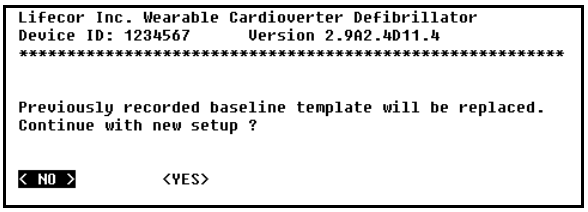
When you set up a new patient, the monitor automatically goes into the baseline mode after you exit the setup mode. You will not need to do this procedure as a separate step.

Use the procedure below to re-baseline a patient, such as during a follow-up visit.

1 From the **Main menu**, Tab to **BASELINE PATIENT**, then press **Enter**.



You will be asked if you want to continue:



2 Tab to **YES**, then press **Enter**.

3 When the **Main menu** displays, Tab to **EXIT**, then press **Enter** to log out.

The monitor will be in baseline mode.

Disconnect the monitor from the computer.

You can then baseline the patient as described on the next page.

How to baseline a patient

When you set up a new patient, or when you select Baseline, the monitor goes into baseline mode when you exit the setup mode. You then record the patient's baseline heart rhythm.

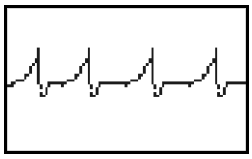
1 Assemble the electrode belt and attach it to the patient.

2 Connect the electrode belt to the monitor. (Don't press OK until the patient is ready.)

3 Have the patient sitting down, relaxed, and not talking or moving around.

4 When the patient is ready, press OK.

Messages show the sequence of recording the patient's baseline:

PRESS OK TO RECORD	Press OK button to start recording baseline.
RECORDING BASELINE	Monitor is preparing to record baseline.
	Baseline is being recorded. Baseline recording time will vary depending on the patient, strength of the ECG signal, and the amount of noise on ECG signal. Total time may take from 45 seconds to 5 minutes.

If you have any problems baselining patient, see next page.

5 When you see the baseline complete message, press OK button.

BASELINE COMPLETE

PRESS OK

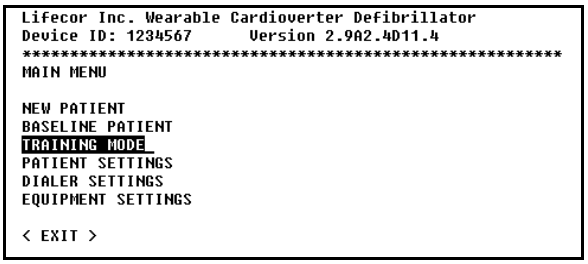
The monitor returns to normal operation.

If you have problems baselining a patient

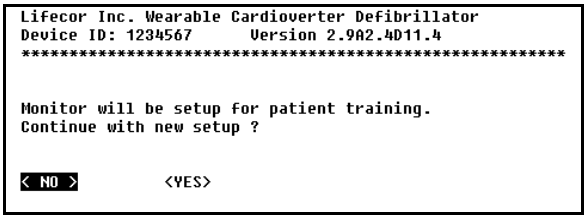
Message	What it means	What to do
BASELINE FAILED	Monitor could not learn the patient's baseline.	Verify that the ECG electrodes are clean and contacting the patient's skin. Also verify that the electrode belt is fitting properly. Apply unscented hand lotion to the ECG electrodes. Then try to baseline the patient again. If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, discontinue attempting to baseline the patient. If problems continue, call ZOLL or your device provider.

How to place the monitor in training mode

1 From the **Main menu**, Tab to **TRAINING MODE**, then press **Enter**.



You will be asked if you want to continue:



2 To enter the training mode, Tab to **YES**, then press **Enter**.

3 When you exit the setup mode, the monitor will be in training mode.

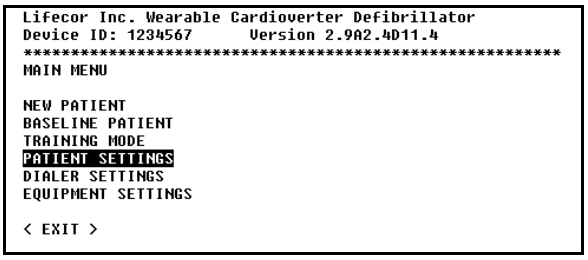
You can then train the patient as described in Chapter 11, **Patient Training**.

4 To exit from training mode, return to the setup mode, go to the main menu and select BASELINE PATIENT, then exit and perform a baseline on the patient. See **How to baseline a patient** on page 12-9.

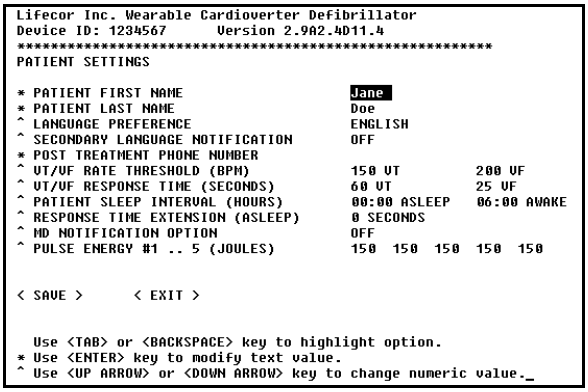
After baselining, the monitor will go into its normal monitoring mode.

How to change patient settings

1 From the Main menu, **Tab** to **PATIENT SETTINGS**, then press **Enter**.



Patient settings menu shows what you can change. A chart showing the details of patient settings is on page 12-14.



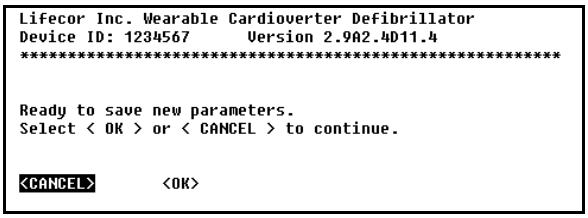
2 Change settings as follows:

- To change any text value (such as the patient's name), Tab to the field, then press **Enter**.
- To change a numeric value (such as the VT/VF rate threshold), Tab to the field, then use the up and down arrow keys to change the value.
- To select a value from a list of choices (such as the language preference), Tab to the field, then use the up and down arrow keys to make a selection.

3 Review the information to make sure you have entered it properly, then do one of the following:

- To save the changes you have made, Tab to **SAVE**, then press **Enter**.
- To leave this menu without saving any of your changes, Tab to **EXIT**, then press **Enter**. Another screen will confirm that you want to exit without saving.

4 If you chose **SAVE** from the **Patient settings** menu, you will see a reminder screen:



Do one of the following:

- To save the changes, Tab to **OK**, then press **Enter**.
- To exit without saving any changes, Tab to **CANCEL**, then press **Enter**.

How to print patient settings

1 From the **Main menu**, Tab to **PATIENT SETTINGS**, then press **Enter**.

2 With the **Patient settings** menu displayed, click on **File**, then choose **Print**.

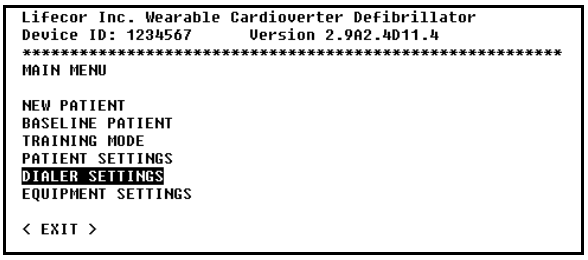
3 To return to the **Main menu**, tab to **Exit**, then press **Enter**.

Patient settings

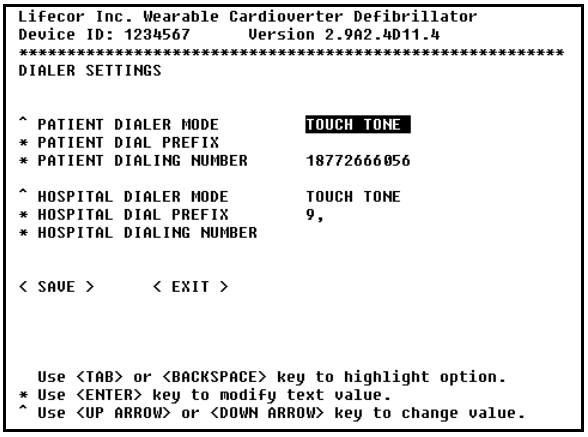
Patient setting	What it means	How to select
Patient first name	Patient's first name.	Enter patient's name that will be used on patient records.
Patient last name	Patient's last name.	Enter patient's name that will be used on patient records.
Post treatment phone number	Phone number displayed for patient to call after receiving a treatment shock.	Set to the phone number you want the patient to call after receiving treatment.
Patient language	Language that monitor will use for display messages and spoken alarms.	Select from list of languages.
Second language	Second language that will be used for spoken alarms to advise bystanders.	Select from list of languages or select none.
VT/VF rate threshold	Heart rate that must be sustained before VT or VF is declared.	Range: 120-250 beats per minute Defaults: VT=150 beats per minute, VF=200 beats per minute
VT/VF response time	Elapsed time before treatment delivered.	Range: VT=60-180 seconds, VF=25-55 seconds Defaults: VT=60 seconds, VF=25 seconds
Patient sleep interval	Time the patient normally sleeps. If an arrhythmia is detected during the sleep interval, the tactile and arrhythmia alarm are activated together (unlike normal operation when the tactile alarm gets activated first, then the arrhythmia alarm). This setting is used in conjunction with the response time extension.	Range: Any two times during a 24-hour clock Default: Asleep at 00:00 (midnight) and awake at 06:00 (6:00 a.m.)
Response time extension	Time to be added to the response time during the patient sleep interval.	Range: 0-30 seconds Default: 0
MD notification	Determines if patient receives "call doctor" message after stopping a treatment.	Default: Off Can be set to repeat message every 5 minutes for up to 1 hour
Pulse energy 1...5	Energy level of each of the five shocks. Each shock can be set to a different level.	Range: 75-150 joules Default: 150 joules

How to change dialer settings

1 From the **Main menu**, Tab to **DIALER SETTINGS**, then press **Enter**.



Dialer settings menu shows what you can change. A chart showing the details of dialer settings is on page 12-16.

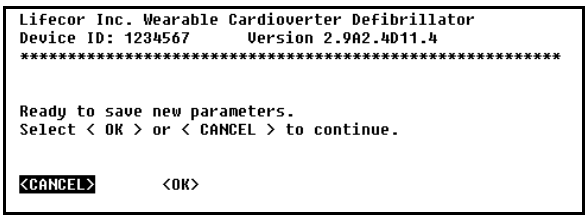


2 Change settings as follows:

- To select a value from a list of choices (such as the patient dialer mode), Tab to the field, then use the up and down arrow keys to make a selection.
- To change any text value (such as the patient dial prefix), Tab to the field, then press **Enter**.

3 Tab to **SAVE**, then press **Enter**.

Confirmation screen displays:

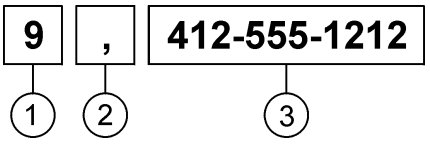


4 Tab to **OK**, then press **Enter**.

Dialer settings

Dialer setting	What it means	How to select
Patient dial prefix	Prefix number that may be required to dial out from patient's home (see example below). For example, you may need to dial 9 to reach an outside line. That number 9 is the dial prefix and it is dialed before the dialing number.	Select any number, based on what is required. If any pauses are required, each comma equals 1 second.
Patient dialing number	Phone number that will be called to transmit data from monitor when patient calls from home. This is a complete number with area code and phone number.	Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Patient dialer mode	Type of phone patient has at home.	Touch tone or pulse, based on what patient has at home.
Hospital dial prefix	Prefix number that may be required to dial out from hospital (see example below). For example, you may need to dial 9 to reach an outside line. That number 9 is the dial prefix and it is dialed before the dialing number.	Select any number, based on what is required. If any pauses are required, each comma equals 1 second.
Hospital dialing number	Phone number that will be called to transmit data from monitor when patient calls from hospital. This is a complete number with area code and phone number.	Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Hospital dialer mode	Type of phone used to send data from hospital.	Touch tone or pulse, based on what is available at hospital.

Phone number example



1 Dial prefix (precedes any phone numbers)

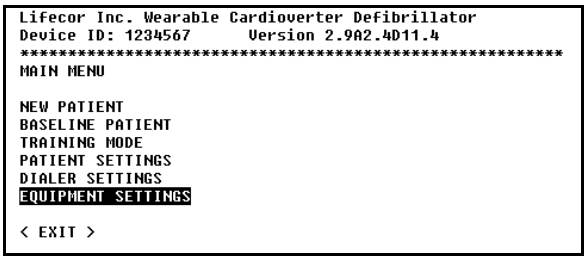
2 Pause (each comma equals 1 second)

3 Dialing number

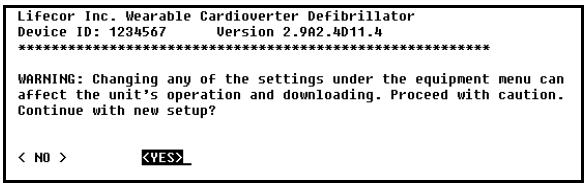
How to change country

WARNING: The country is set by device provider and does not normally need to be changed. Changing the country affects a number of communication settings and could affect the unit's operation and downloading. Contact your device provider for assistance if you need to change this setting.

1 From the **Main menu**, Tab to **EQUIPMENT SETTINGS**, then press **Enter**.

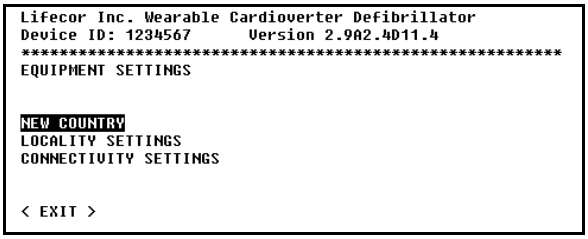


Warning screen displays:

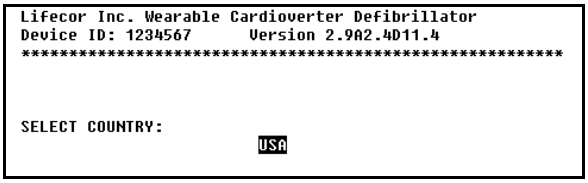


2 Tab to **YES**, then press **Enter**.

3 Tab to **NEW COUNTRY**, then press **Enter**.



Select country menu displays:



4 Use the up and down arrow keys to select the country, then press **Enter**.

Depending on how the monitor was set up by your device provider, the country you want to select may not be available in the list displayed. If you want to select a country that is not on the list, contact your device provider to have the monitor reprogrammed.

Confirmation screen displays:

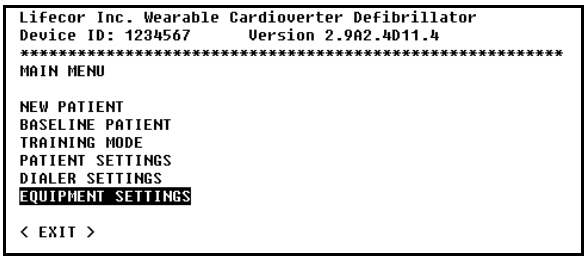
5 Tab to **YES**, then press **Enter**.

After changing the country (and after entering a new patient and selecting the patient's city if the country is served by more than one phone number), check the locality and connectivity settings.

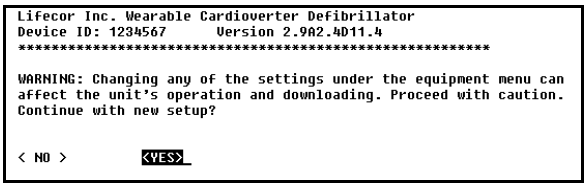
How to change locality settings

WARNING: Locality settings are set by device provider and do not normally need to be changed. Changing the locality settings could affect the unit's operation and downloading. Contact your device provider for assistance if you need to change any of these settings.

1 From the **Main menu**, Tab to **EQUIPMENT SETTINGS**, then press **Enter**.

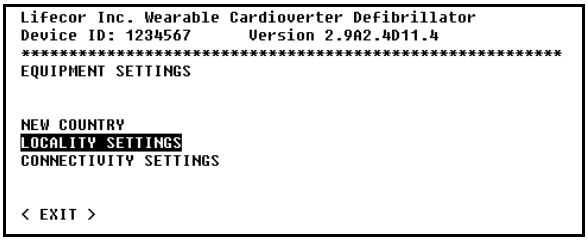


Warning screen displays:

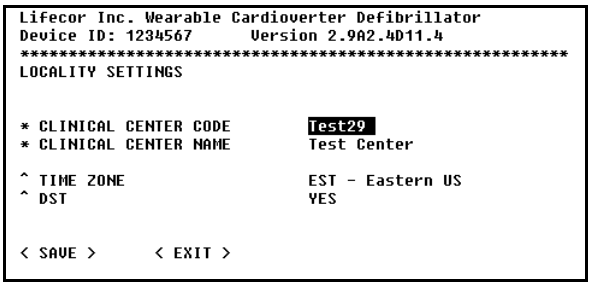


2 Tab to **YES**, then press **Enter**.

3 Tab to **LOCALITY SETTINGS**, then press **Enter**.



Locality settings menu displays. A chart showing the details of locality settings is on page 12-20.

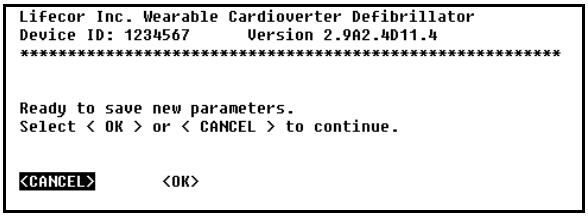


4 Change settings as follows:

- To change any text value (such as the clinical center name), Tab to the field, then press **Enter**.
- To select a value from a list of choices (such as the time zone setting), Tab to the field, then use the up and down arrow keys to make a selection.

5 Tab to **SAVE**, then press **Enter**.

Confirmation screen displays:



6 Tab to **OK**, then press **Enter**.

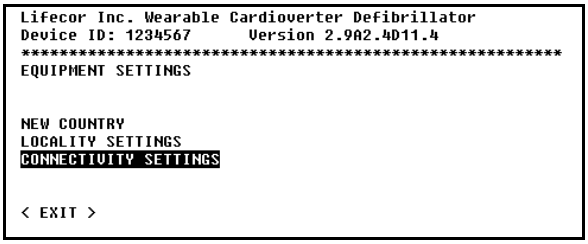
Locality settings

Locality setting	What it means	How to select
Clinical center code	Code assigned to your clinical center.	Use the code number for your clinical center. Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Clinical center name	Name of your clinical center.	Can be any combination of letters and number, limited to 75 characters. Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Time zone	Allows choosing patient's time zone in countries where there are multiple time zones.	Select from the list of time zones.
Daylight savings time (DST)	Selects whether or not location follows daylight savings time.	Select Yes or No.

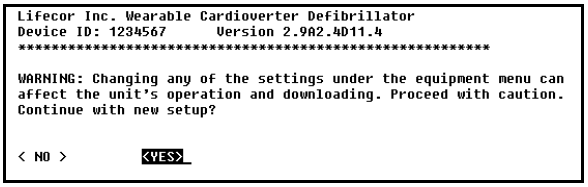
How to change connectivity settings

WARNING: Connectivity settings are set by device provider and do not normally need to be changed. Changing the connectivity settings could affect the unit's operation and downloading. Contact your device provider for assistance if you need to change these settings.

1 With the Equipment settings menu displayed, Tab to **CONNECTIVITY SETTINGS**, then press **Enter**.

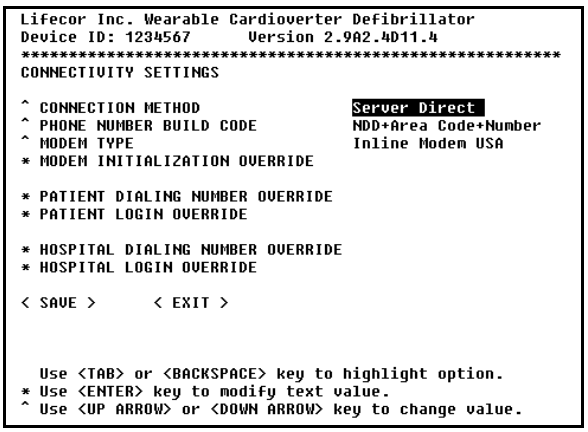


Warning screen displays:



2 Tab to **YES**, then press **Enter**.

Connectivity settings menu displays. A chart showing the details of connectivity settings is on page 12-23.

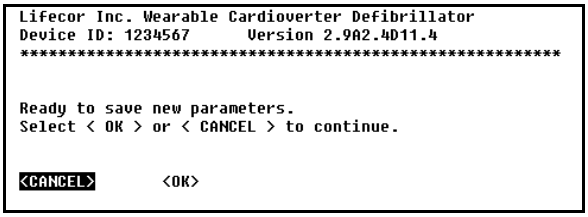


3 Change settings as follows:

- To select a value from a list of choices (such as the connection method), Tab to the field, then use the up and down arrow keys to make a selection.
- To change any text value (such as the dialing number override), Tab to the field, then press **Enter**.

4 Tab to **SAVE**, then press **Enter**.

Confirmation screen displays:

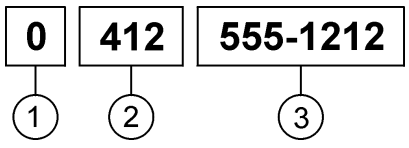


5 Tab to **OK**, then press **Enter**.

Connectivity settings

Connectivity setting	What it means	How to select
Connection method	Determines how monitor accesses the ZOLL database, whether through server direct numbers or Internet service provider numbers.	Select the type of dialing method to be offered during patient setup. Defaults to the type of connection numbers most likely to be used in the selected country. Does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Phone number build code	Describes how phone number is constructed for the country and locality (see example below).	Select how phone number gets dialed, whether to include a national direct dialing (NDD) number and area code. The NDD number is the access code used to make a call within a country from one city to another. The NDD is followed by the area/city code for location being called. When calling another city in the same vicinity, the NDD may not be necessary. Does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Patient dialing number override	Allows you to enter manual dialing information.	Normally not used. For service purposes, we may ask you to enter a value.
Patient login override		
Hospital dialing override		
Hospital login override		
Modem type	Type of modem used to transfer data.	Select type of modem being used, based on country where it will be used. Does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Modem initialization string override	Allows you to enter manual dialing information.	Normally not used. For service purposes, we may ask you to enter a value.

Phone number build example



1 National direct dialing (NDD)

2 Area/city code

3 Phone number

How to log out of the setup mode

1 From the **Main menu**, Tab to **EXIT**, then press **Enter**.

2 Log out of HyperTerminal by doing one of the following:

- Click on the **X** in the upper right corner of the screen.
- Click on **File**, then **Exit**.

3 Disconnect the serial cable from the monitor and computer.

HyperTerminal setup

Setup and logging in the first time

Before connecting the computer to the monitor, you need to set up the computer so that it can communicate with the monitor. After this initial setup, you'll save the settings to simplify the procedure of communicating with the monitor in the future.

After you set up the computer, you can communicate with any monitor, not just the one you initially set it up with. The computer doesn't save patient information; that information is stored and saved by the monitor.

To log in after you have set up the communications software, see **Logging in after the initial setup** on page 12-29.

Procedure

1 If you haven't already done so, turn on your computer and have Windows running.

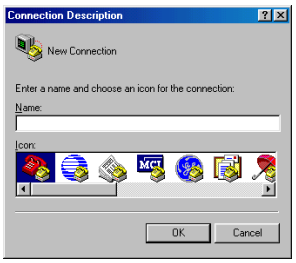
2 Connect the computer to the communications port on the monitor as described in page 12-2. Have the battery installed into the monitor.

3 On the computer, click **Start**, select **Programs**, then **Accessories**, **Communications**, then **HyperTerminal**.

Note: With some computers, the HyperTerminal program may not be located as listed above. Search through Programs, Accessories, Communications, and other folders to find HyperTerminal. You're looking for a program called Hypertrm.exe. If you continue to have trouble locating the software, call your computer services department for assistance.

4 Double click the HyperTerminal icon (yours may look different).

Connection Description menu appears:



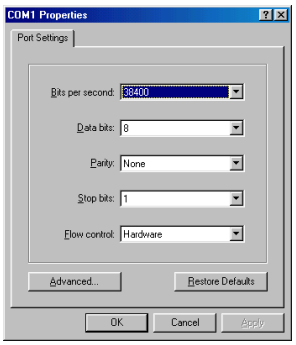
5 In the Name text box, enter a name such as **WCD setup**. Click **OK**.

Connect To menu appears.

6 In the **Connect using** field, choose **Direct to Com 1**, then click **OK**.

Note: If you know that your computer is using Com 1 for another purpose, choose another connection, such as Com 2 or 3. But in most cases, you want to choose Com 1.

COM1 Properties menu appears.



7 Set the Port Settings to these values:

Bits per second:	38400
Data bits:	8
Parity:	None
Stop bits:	1
Flow control:	None

8 Click **OK**. HyperTerminal displays a blank screen.

9 Press the **ESC** key three times. The Console Language Selection menu appears, showing that the computer is now communicating with the monitor.

If you have problems, see page 12-30.

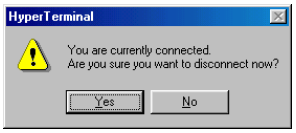
Logging out of HyperTerminal

1 From the main menu, choose

The monitor will resume normal operation.

2 Choose **File**, then **Exit**.

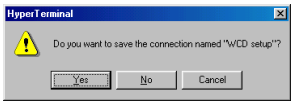
Disconnect menu appears:



3 Click **Yes** to end this session.

The first time you log out, you will be asked if you want to save the setup parameters.

Save session menu appears:



4 Click **Yes** to save your setup parameters and assign an icon to this setup.

This saves the communications settings, not the patient information. Patient setup and other information is saved in the monitor.

By saving the communications setup, the next time you log in to the computer, your port settings will be recalled.

To simplify future logins, create a shortcut to the WCD setup on your desktop. Follow the instructions on the next page.

5 Disconnect the monitor from the computer.

Creating a setup shortcut

To simplify log in, particularly if you plan to use the computer to program other monitors on a regular basis, you should create a shortcut on your computer's desktop.

Follow this procedure to create a shortcut. This procedure presumes that you have already set up the communication protocol and have set up a setup icon in the HyperTerminal program.

1 Have your computer turned on and operating, with the Windows desktop screen displayed.

2 Click on **Start**, select **Programs**, then **Accessories**, **Communications**, then **HyperTerminal**.

3 From the HyperTerminal menu displayed, click on the **WCD setup** icon (yours may look different) with the right mouse button.

4 From the drop down menu, hover over **Send To**, then choose **Desktop (create shortcut)** from the expanded menu. (Click with the left mouse button as normal.)

5 When the verification menu appears, click **OK**.

6 To log in from now on, double click on the shortcut icon on your desktop:

You will be taken directly to the HyperTerminal startup screen. You can then resume with the normal setup procedure.

Note: Your WCD setup icon may look different than this example, depending on what icon you selected when you first set up HyperTerminal.

Logging in after the initial setup

After you log in for the first time, subsequent logins are simpler because the communication protocol is already set up.

Follow this procedure to log in the terminal program after it has been set up.

1 Make sure the computer is turned on and running. Have the battery installed in the monitor.

2 Connect the serial cable between the computer's serial port and the monitor's communication port.

3 On your computer's desktop, double click on the **WCD setup** shortcut.

4 When the terminal menu appears, press **ESC** three times.

5 When the Console Language Selection menu appears, choose a setup language.

6 When the main menu displays, select the action that you want to take from the choices displayed.

If you have problems

Follow these suggestions (in this order) if you have trouble getting HyperTerminal to work on your computer.

1 If you can start HyperTerminal, but you can't seem to connect, click on the **X** in the upper right corner of the HyperTerminal screen to close the program.

2 Remove the battery from the monitor, then reinstall it and allow the monitor to power up normally.

3 Make sure the serial cable is securely plugged into the monitor and your computer.

4 Try to log in again.

5 If you continue to have problems, check the communications port settings. See page 12-26.

6 If you continue to have problems, make sure the COM port you are using is not assigned to any other purpose, such as for a modem or hand-held computer interface. If you suspect that COM1 is being used for any purpose, choose COM2 or COM3 for the LifeVest port. See page 12-26.

7 If you continue to have problems, call ZOLL or your device provider for help.

Chapter 13: LifeVest Network

About LifeVest Network

LifeVest Network is a secure Internet Web site for viewing data related to the LifeVest wearable defibrillator.

From LifeVest Network, you can view ECG recordings, treatment events, and compliance data.

You can view and print a number of reports related to the LifeVest.

For more information about LifeVest Network, and to set up your LifeVest Network account, contact ZOLL.

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Chapter 14: System Inspection

This chapter explains:

- Inspecting system during visit
- Inspecting and refurbishing between patients
- Testing the Monitor
- Troubleshooting problems that may occur during baseline or wear

LifeVest System inspection during patient visit

When the patient returns for a scheduled visit, or after having received a defibrillating shock, perform the following inspection of the LifeVest System.

Garment inspection

Inspect the garment for:

- Loose stitching which might affect the fit.
- Deterioration of elastic portions of the garment.
- Permanent stretching of material.
- Deterioration of fasteners.

Electrode Belt inspection

Check the Electrode Belt for:

- Cables pulled out of normal position.
- Cables cracked or split.
- Evidence of tampering with ECG electrodes or therapy electrodes.
- Bends and creases in the therapy electrode surface that may have caused a split in the surface.
- Intentional or inadvertent gel extrusion evidenced by blue dye visible on fabric.

Monitor inspection

Use an approved test device to test the Monitor. Also, check the Monitor for:

- Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.
- Evidence of tampering, such as fasteners exposed through a torn label.

Alarm Module inspection

Check Alarm Module for:

- Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.
- Evidence of tampering, such as a torn label.

Battery Pack inspection

- Evidence of having been dropped, such as dents, cracked finish, cracked housing or cracked latch.

Battery Charger inspection

- Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.
- Evidence of tampering, such as contacts being distorted.

Modem inspection

- Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.
- Evidence of tampering, such as screws exposed through a torn label.

Serial Cable inspection

- Evidence of cables cracked or split.
- Evidence of broken or cracked connectors.

Compliance and noise review

When the patient returns for a scheduled visit, review the compliance and noise records. If the patient's wear time is less than 23 hours a day, discuss possible reasons for non-compliance.

If dual-lead noise is greater on average than 15 minutes a day, check for causes of noise, such as fit of garment or activities of patient. Review the following checklist.

Troubleshooting multiple "adjust belt" alarms checklist

Questions and actions to assist in resolving the problem:

- Is belt assembled correctly to garment?
- Is garment belt twisted?
- Are ECG electrodes attached to garment?
- Are all electrodes touching the skin?
- Is there a change in garment—too loose or too tight?
- Is there a change in patient's weight?
- Apply more lotion to the electrodes.
- Note noise relationship to exercise, sleeping, waking, and startup.
- Take apart after three "adjust belt" warnings and reassemble.
- Note time of alarm start.
- Note date of last baseline.
- Make a manual recording.
- Download after call-in.

After the inspection is complete, rebaseline the patient.

LifeVest System inspection and reconditioning between patients

When inspecting the system before it is transferred to another patient, follow the inspection instructions of the previous section with these exceptions:

- Discard the Garment.
- Recondition the Electrode Belt as described below.
- Recondition the Monitor and accessories (such as the modem and battery charger) as described on page 14-5.

Electrode belt reconditioning

Materials needed:

- Cleaning and disinfecting solution containing alkyl dimethyl benzyl ammonium chloride, such as Formula 409 Commercial Solution (made by Clorox Company)
- Lint-free wipes
- Toothbrush
- Protective gloves and safety glasses

Step 1: Inspect all electrode belt components

- Look for any defect that could affect operation, such as cracks, cuts, or other signs of damage.
- Check therapy pads for any sign of blue gel.
- If there is any damage, do not use the belt on another patient.

Step 2: Clean all components

- Use only recommended cleaning solution and lint-free wipes. Follow directions on cleaning solution.
- Do not clean with alcohol. Do not soak in alcohol or any other solution.
- Use toothbrush for small spaces and to remove stubborn deposits.
- Allow to air dry.

Step 3: Store belt

- Place clean, dry belt in a plastic bag and store in a clean, dry place.

Monitor and accessories reconditioning

Materials needed:

- Cleaning and disinfecting solution containing alkyl dimethyl benzyl ammonium chloride, such as Formula 409 Commercial Solution (made by Clorox Company)
- Lint-free wipes
- Toothbrush
- Protective gloves and safety glasses

Step 1: Inspect the monitor and accessories

- Look for evidence that the Monitor or accessory was dropped, such as dents, cracked finish, or cracked housing parts.
- Look for evidence of tampering, such as fasteners exposed through a torn label.
- If there is any damage to the Monitor, do not use it on another patient.
- If any accessory is damaged, replace it.

Step 2: Clean the monitor and accessories

- Remove the Battery Pack from the Monitor before cleaning.
- Unplug and disconnect all accessories before cleaning.
- Use only recommended cleaning solution and lint-free wipes. Follow directions on cleaning solution.
- Do not soak the Monitor or any accessory in any solution.
- Use toothbrush for small spaces and to remove stubborn deposits.
- Allow to air dry.

Step 3: Test the monitor

- Use an approved test device to test the Monitor.

Step 4: Store the monitor and accessories

- Wrap and bag all accessories in clean, dry plastic bags.
- Store the Monitor and accessories in a clean, dry place.

LifeVest device inspection checklist

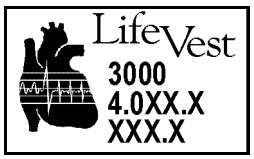
Note: For convenience, make copies of this checklist and use for inspections.

Yes	No	
☐	☐	Loose stitching which might affect the fit.
☐	☐	Deterioration of elastic portions of the garment.
☐	☐	Permanent stretching of fabric.
☐	☐	Deterioration of fasteners.
☐	☐	Cables pulled out of normal position.
☐	☐	Cables cracked or split.
☐	☐	Evidence of tampering with ECG electrodes or therapy electrodes.
☐	☐	Bends and creases in a therapy electrode surface that may cause a split in the surface.
☐	☐	Intentional or inadvertent gel extrusion evidenced by blue dye visible on fabric.
☐	☐	Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.
☐	☐	Evidence of tampering, such as fasteners exposed through a torn label.
☐	☐	Service code failure or monitor failed test conducted with approved test device.
☐	☐	Data transfer malfunction.
☐	☐	Malfunction of the Alarm Module buttons or messages.
☐	☐	Defective ECG.
☐	☐	Defective vibration box.
☐	☐	Bent pins in belt connector.

Testing the monitor

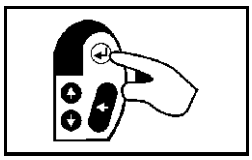
Follow this procedure to test the monitor's ability to generate and deliver a shock. To perform this test, you will need the test plug. We suggest that you test the monitor every 6 months.

How to test the monitor

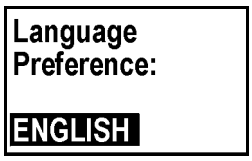


1 Disconnect the electrode belt from the monitor.

2 Put a fully-charged battery into the monitor. During power up (while LifeVest is displayed), press and hold both the record and transmit buttons.

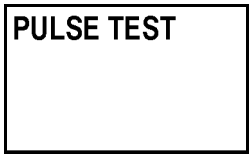


3 Continue to hold both buttons down until the monitor displays the alarm module icon, then release the buttons. Press OK button.



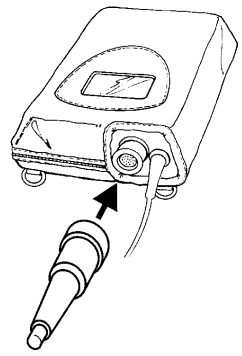
4 Using the up and down buttons (record and transmit), select a language, then press OK button.

5 Select **DIAGNOSTIC**, then press OK button.



6 With **PULSE TEST** displayed, press OK button.

Connect Test Plug Then Press OK



7 Connect the test plug to the monitor. Then press OK button.

Leave the test plug connected until the test is complete.

If you want to stop the test before completion, press both response buttons.

If you have problems testing the system, see page 14-9.

TESTING... TIME LEFT XX:XX

A message advises you that the test is being conducted and shows the time remaining to complete the test.

The monitor sounds a loud alarm near the end of the test.

When the test is complete, one of the following messages displays:

TESTING COMPLETE PASS

Use the monitor only if you receive the **PASS** message.

TESTING COMPLETE FAIL

If you receive the **FAIL** message, do not use the monitor. Contact ZOLL or your device provider for a replacement.

8 Disconnect the test plug from the monitor.

9 Remove and reinstall the battery pack before using the monitor.

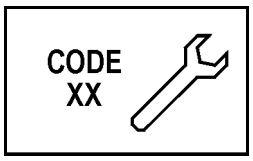
If you have problems testing the system

If you get an error message while testing the system, use this chart to determine what it means and how to correct the problem.

Message	What it means	What to do
NOT ENOUGH RUNTIME TO COMPLETE TEST	Battery doesn't have enough reserve power to run test.	Disconnect the test plug. Remove battery and insert a fully-charged battery. Reconnect the test plug and attempt to run the test again.
TESTING ABORTED	You pressed a button on the Alarm Module, stopping the test.	To start the test again, disconnect the test plug, then reconnect it. Don't press any buttons during the test.
CODE XX 	System has a problem that requires servicing. The monitor is inoperable and cannot be used.	Download data via modem. Then contact your service provider or ZOLL to report problem and arrange to have monitor replaced.

System service codes

Service codes seen in the following message are designed to give the ZOLL Service Department information concerning the system.



Refer error codes to the device provider.

Troubleshooting

This section explains the most likely difficulties you may encounter during patient setup and/or during the patient's period of wear.

Problem	Solution
Difficulty obtaining baseline	If after 3 minutes, the "Baseline Failed" message appears, the patient may have a rhythm that is difficult to auto learn, such as multiple pre-ventricular contractions (PVCs). Check the Electrode Belt ECG electrodes for good contact and then try again. If problems continue, discontinue using the LifeVest.
Monitor too noisy during baseline	Check to be certain all fasteners are fastened and that no cloth is covering the ECG electrodes. Apply more lotion and try again. If the problem continues, switch to another belt. If that does not solve the problem, contact the device provider.
Electrode Belt problems	Be sure the Electrode Belt is securely fastened in the front. If the patient receives the "Connect Electrode Belt" message while wearing the device, the patient should disconnect the Electrode Belt and the battery from the Monitor, and then reconnect them both. If the problem continues, the patient must bring the device in for evaluation. If the patient receives the "Check Therapy Pads" message while wearing the device, Therapy Pads are not making good contact with the patient's skin. Make sure the Therapy Pads are inserted correctly, metal sides (with green stickers) against the patient's skin. Make sure Therapy Pads and mesh pockets are pressing against the patient's skin. If problems continue, call ZOLL or your device provider.
Patient receiving excessive "adjust belt" alarms	Have patient download data via modem. If there is more than 15 minutes of notified noise, bring the patient in to measure for proper fit. Check that all fasteners are fastened and that cloth is not covering ECG electrodes. Investigate the time of day or night the patient is receiving the alarms. Investigate patient's sleeping position to determine if a change in position increases or decreases noise. If noise does not seem to be due to fit or patient positioning, switch to another belt and evaluate continuance of noise. Check on the noise level each day until the noise lessens and reaches an acceptable level. If the noise remains the same, discontinue using the device. There are two different noise alarms: Dual lead noise results in an alarm after 5 minutes. Single lead noise results in an alarm after 30 minutes.
Miscellaneous problems	If the patient develops a rash while wearing the device, it should be evaluated by the attending physician and treated. If the severity does not preclude wearing the device, the device should be worn.
Inspection failure	If any part of the LifeVest device fails the inspection, replace that part of the patient's system. Return the part to your device provider.

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Chapter 15: System Specifications

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

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

Cardioverting/defibrillating shock criteria

Design criteria	Value
Waveform	Biphasic truncated exponential.
Delivered energy	From 75 to 150 joules (±5%) at 20°C (68°F) when discharged into a 50 ohm resistive load. Settings within that range are programmable in 25 joule increments.
Charging/delivery time	Maximum joule shock in 22 seconds at 20°C (68°F) ambient temperature.
Defibrillating peak output current	Not greater than 35 A for a maximum joule defibrillating shock delivered into a 50 ohm load.
Pulses per cardioverting/ defibrillating sequence	Five. Conversion of the arrhythmia after a shock automatically precludes delivery of remaining shocks in the sequence.
Reset	Following successful arrhythmia conversion, the software resets the pulse sequence, thereby enabling a new treatment sequence in the event of another detected arrhythmia.

Programmable parameters

Refer to Chapter 12, **Programming the Monitor**, for programmable parameters, ranges, and default values.

Operating environment

This section lists the environmental ranges in which the LifeVest system should operate.

LifeVest Device: Monitor, Battery Pack, Alarm Module, Electrode Belt, Garment, and Holster

Temperature range	0 to 50°C (32 to 122°F) **Note:** The Electrode Belt, which is worn in direct contact with the skin, operates to a maximum of 41°C (105.8°F). In accordance with IEC 60601-1, Clause 42.3, it does not generate any additional heat, and provided the skin does not exceed 41°C, the maximum surface temperature of the Electrode Belt will not exceed 41°C.
Humidity range	0% to 95% relative humidity, non-condensing
Altitude	To 10,000 feet

Battery Charger

Temperature range	0 to 50°C (32 to 122°F)
Humidity range	0% to 95% relative humidity, non-condensing
Altitude	To 10,000 feet

Serial Cable and Modem

Temperature range	0 to 50°C (32 to 122°F)
Humidity range	0% to 95% relative humidity, non-condensing
Altitude	To 10,000 feet

Test Plug

Temperature range	0 to 50°C (32 to 122°F)
Humidity range	0% to 95% relative humidity, non-condensing
Altitude	To 10,000 feet

Device specifications

Monitor dimensions	5.1 x 6.125 x 1.6 inches 13 x 16 x 4 centimeters
Monitor weight (with battery and holster)	1.87 pounds 0.85 kilograms
Electrode belt weight	1 pound 0.5 kilograms
Power source	3-cell lithium-ion battery pack 10.8 VDC, 1.8 Ah
Battery charger	Input: 18.0 VDC, 2 A Output: 18.0 VDC, 2 A
Battery charger power supply	Phihong Model PSS-45W-180 Class II ITE/LPS Power Unit AC Input: 100-240 VAC, 1.6 A max, 60/50 Hz DC Output: 18 VDC, 2.8 A, 51 W max

UL 2601-1 classification for use

Type of protection against electric shock	Internally powered
Degree of protection against electric shock	Type BF applied parts
Degree of protection against ingress of water	Ordinary
Mode of operation	Continuous

Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Storage environment

LifeVest Device: Monitor, Alarm Module, Electrode Belt, Garment, and Holster

Temperature range	-5 to 55°C (23 to 131°F)
Humidity range	5% to 95% non-condensing
Altitude	To 10,000 feet

Battery Pack

Temperature range	-5 to 55°C (23 to 131°F)
Humidity range	5% to 95% non-condensing
Altitude	To 10,000 feet

Battery Charger

Temperature range	-5 to 55°C (23 to 131°F)
Humidity range	10% to 90% non-condensing
Altitude	To 10,000 feet

Serial Cable and Modem

Temperature range	-5 to 55°C (23 to 131°F)
Humidity range	5% to 95% non-condensing
Altitude	To 10,000 feet

Test Plug

Temperature range	-5 to 55°C
Humidity range	5% to 95% non-condensing
Altitude	To 10,000 feet

System life expectancy

The life expectancy of the LifeVest system is as follows:

Monitor including alarm module	3 years of monitoring and defibrillating service
Battery pack	1 year (~200 charge/discharge cycles) in use every other day
Battery charger	3 years
Electrode belt/therapy electrodes	24 months during normal humidity storage
Garment	6 months per patient when part of a three garment distribution
Holster	12 months per patient
Serial cable	3 years
Test plug	3 years
Modem	3 years

Battery pack information

The battery pack contains lithium-ion batteries and circuitry to protect the batteries and provide diagnostics to the Monitor.

Device accuracy

The LifeVest device meets the applicable portions of the AAMI standards for Automatic External Cardioverter Defibrillators (ANSI/AAMI DF2-1989 and AAMI DF39-1/93), which specify that the sensitivity for detecting VF should be greater than 90%, the sensitivity for detecting VT should be greater than 75%, and the specificity should be greater than 95%.

ZOLL testing using an arrhythmia database demonstrated a sensitivity of 95% to all ventricular tachyarrhythmias and specificity of 100% to non-ventricular rhythms.

Electromagnetic interference

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

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

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

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

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

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

Environmental testing

Electromagnetic compatibility (EMC) testing results in accordance with:

- EN 55011 1991, Radiated and Conducted Emissions Amendments A1: 1997 and A2: 1996
- CISPR 11 for Class B ISM, Limits and methods of measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio Frequency Equipment
- EN 60601-1-2 Collateral Standard for Electro Magnetic Compatibility
- EN 61000-4-2 Electrostatic Discharge Immunity Test
- EN 61000-4-3 Radiated, Radio-Frequency, Electromagnetic Field Immunity Test

The LifeVest system was tested by an independent EMC test laboratory to demonstrate compliance to the emissions and immunity requirements of the tests listed in IEC 60601-1-2. The following performance criteria were met:

- EN 55011: The Monitor, Alarm Module, and Electrode Belt met the Group 1, Class B requirements of EN 55011 for radiated emissions within the frequency range of 30-1000 MHz at a distance of 10 meters.
- EN 61000-4-2: The Monitor, Alarm Module, and Electrode Belt met the Class A performance criteria for ESD immunity when subjected to air discharges of 2, 4, 6, and 8 kV at multiple test points, and contact discharges of 2, 4, and 6 kV at multiple test points.
- EN 61000-4-3: The Monitor, Alarm Module, and Electrode Belt met the Class A performance criteria for amplitude modulated RF (80% AM at 1 kHz) at 3 V/m from 80-800 MHz, and at 10 V/m from 800-2000 MHz. In addition, the Monitor, Alarm Module, and Electrode Belt met the Class A performance criteria for pulse modulated RF at 10 V/m at 900 MHz with a repetition frequency of 200 Hz.

Mechanical strength

IEC 60601-1, subclause 21a: The Monitor and Alarm Module were subjected to an inward directed force of 45 Newtons over an area of 625 square millimeters. No appreciable damage or reduction of creepage distances or air clearances occurred.

IEC 60601-1, subclause 21b: The Monitor and Alarm Module were subjected to mechanical blows of an energy of 0.5 joules using an impact test apparatus. No live parts were exposed which could create a safety hazard.

IEC 60601-1, subclause 21.5: The Monitor and Alarm Module were dropped from height of 1 meter onto a 50 mm thick hardwood board, once from 3 different attitudes. No live parts were exposed which could create a safety hazard.

Ingress of liquids

IEC 60601-2-4, subclause 44.3: The Monitor and Alarm Module were subjected to an artificial rainfall of 3 mm/min falling vertically from a height of 0.5 meters above the top of the equipment for 30 seconds. The rainfall was directed in the least favorable position of normal use.

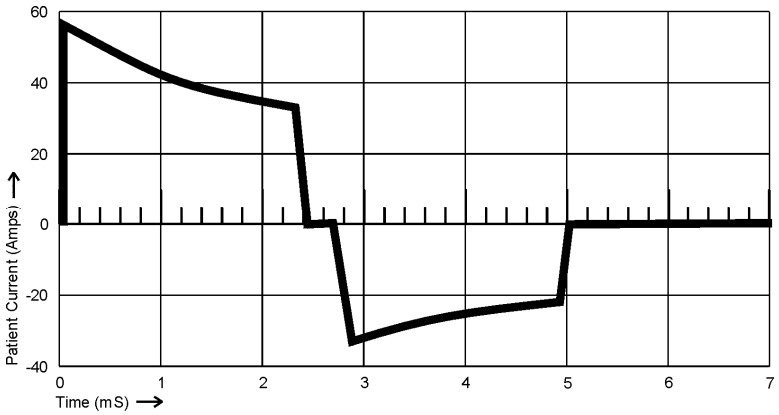
The Monitor and Alarm Module functioned normally, did not present a safety hazard, and met the dielectric strength tests required for defibrillators.

Defibrillating pulse waveforms

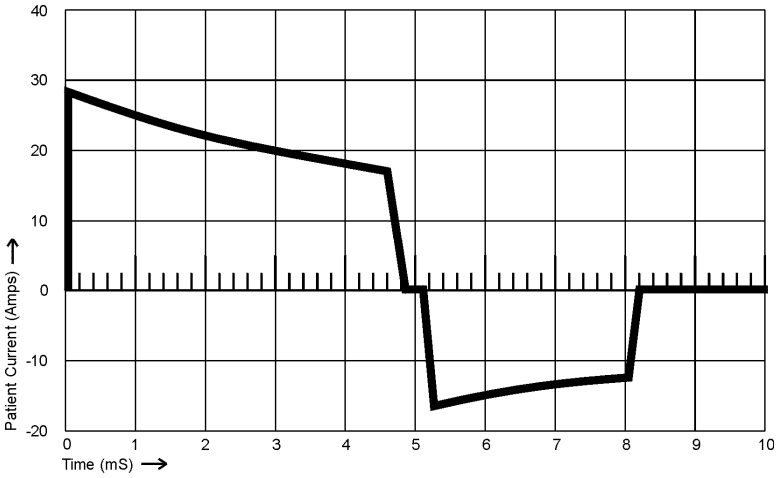
This section provides the technical details of the LifeVest therapy, as required by IEC 60601-2-4 clause 6.8.3.

Pulses were delivered into resistive loads of 25, 50, 100, and 150 ohms using the maximum energy setting of the Monitor.

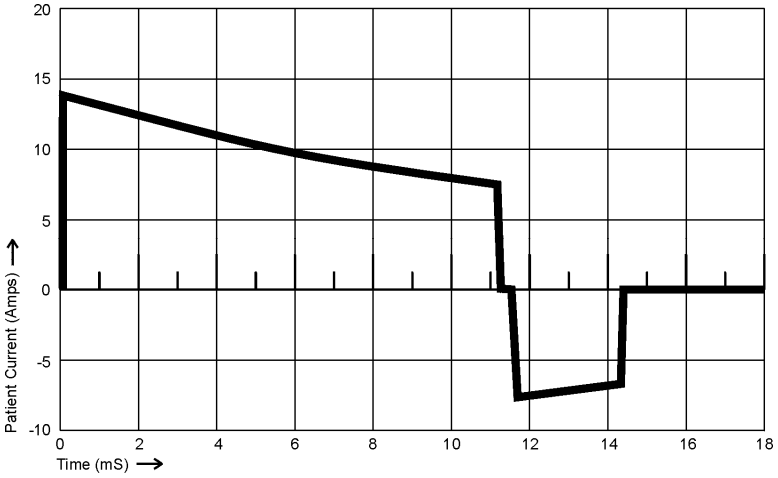
150 joules at 25 ohms



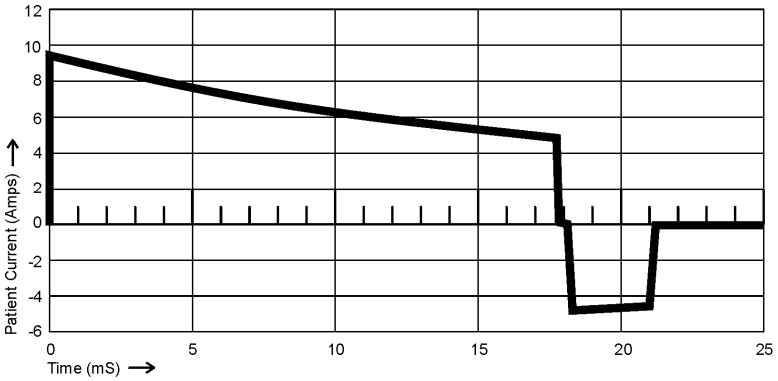
150 joules at 50 ohms



150 joules at 100 ohms



150 joules at 150 ohms



Pulse delivery synchronization

There is no indicator of the status of the synchronizer function because the Monitor software is always in the synchronous delivery mode. The software should attempt to deliver the therapy pulse within 60 milliseconds of the R wave. If a synchronized pulse cannot be delivered within 3 seconds, an unsynchronized pulse should be delivered.

VF threshold

The VF rate threshold can be set within the range of 120-250 beats per minute (BPM). The default setting is 200 BPM.

VF response time, which is the elapsed time before treatment is delivered, can be set within the range of 25-55 seconds. The default setting is 25 seconds.

VT threshold

The VT rate threshold can be set within the range of 120-250 BPM, not to exceed the VF threshold. The default setting is 150 BPM.

If the patient's heart rate exceeds the VT rate threshold and the patient holds the Response Buttons after the alarm sequence has continued for 30 seconds, the alarms stop and the system increases the VT rate threshold by 10%. If VT continues and the higher rate threshold is exceeded, the alarm sequence starts again. This can continue until the VF rate threshold is exceeded, at which time the device goes into the VF alarm sequence. When the patient's heart rate falls below the original VT rate threshold, the VT rate threshold resets to the initial setting.

VT response time can be set within a range of 60-180 seconds. The default setting is 60 seconds.

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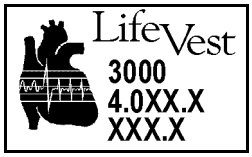
Chapter 16: Monitor Setup Using Alarm Module

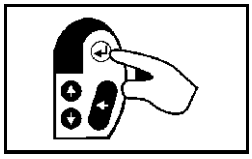
About this chapter

- This chapter covers monitor setup procedures using the alarm module, which is an alternative to using a computer and serial cable.
- This chapter applies to software version 4.0 and up.
- You can also set up the monitor with a computer. For the details, see Chapter 12, **Programming the Monitor**.

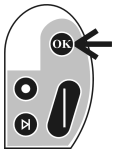
How to enter setup mode



1 Insert the battery into the monitor. During power up (while LifeVest is displayed), press and hold both the record and transmit buttons.



2 Continue to hold both buttons down until the monitor displays the alarm module icon, then release the buttons.



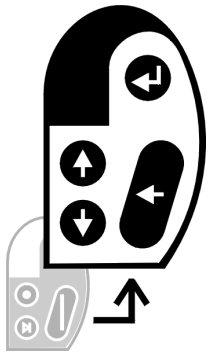
3 Press OK button.

The monitor is now in setup mode. Continue by selecting a setup language (see next page).

Note: If you do not select a language within 30 seconds, the monitor resumes normal operation. However, once you get to the main menu, the monitor remains in setup mode until you exit or remove the battery.

Alarm module button functions

When you enter the setup mode using the alarm module, the buttons function as follows:

Alarm Module	Button	Icon	Function	What it does
	● Record		up	Selects previous menu item or option in a list of options. With text entries, scrolls through letters or numbers.
	▶▌ Transmit		down	Selects next menu item or option in a list of options. With text entries, scrolls through letters or numbers.
	OK		OK or enter	Selects current menu item. Used as an enter key to select current highlighted choice on menu item.
	Response		backspace	Goes back to previous selection screen or to opening menu. Also used as a backspace key with text entries.

How to select a menu language

The setup menus can be displayed in a variety of languages. This language will be used only with the setup menus.

This is not the patient's language preference used to display messages and alarms on the monitor (which can be set up through the Language menu).

1 Using the up and down buttons (record and transmit), select a language.

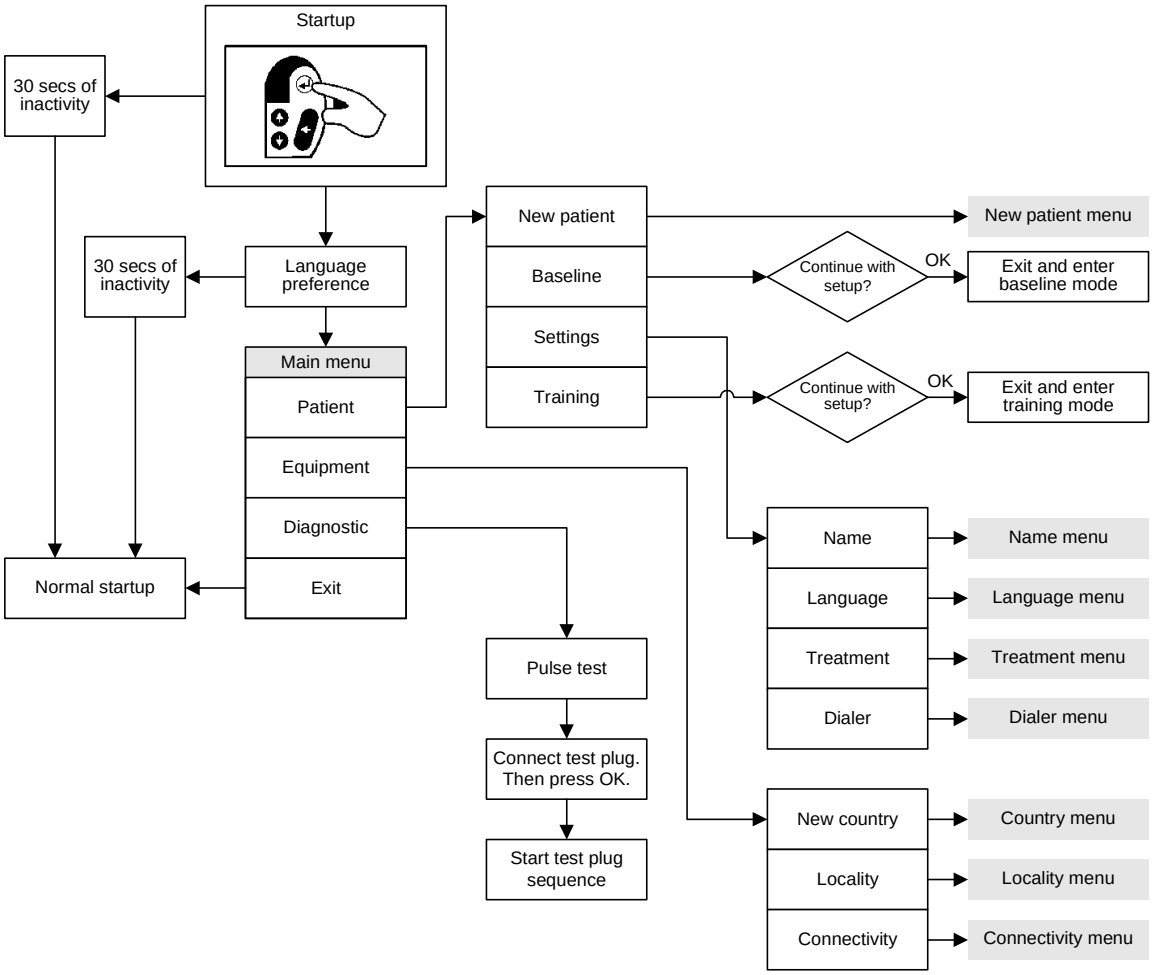
2 Press OK button.

Monitor displays the main menu.

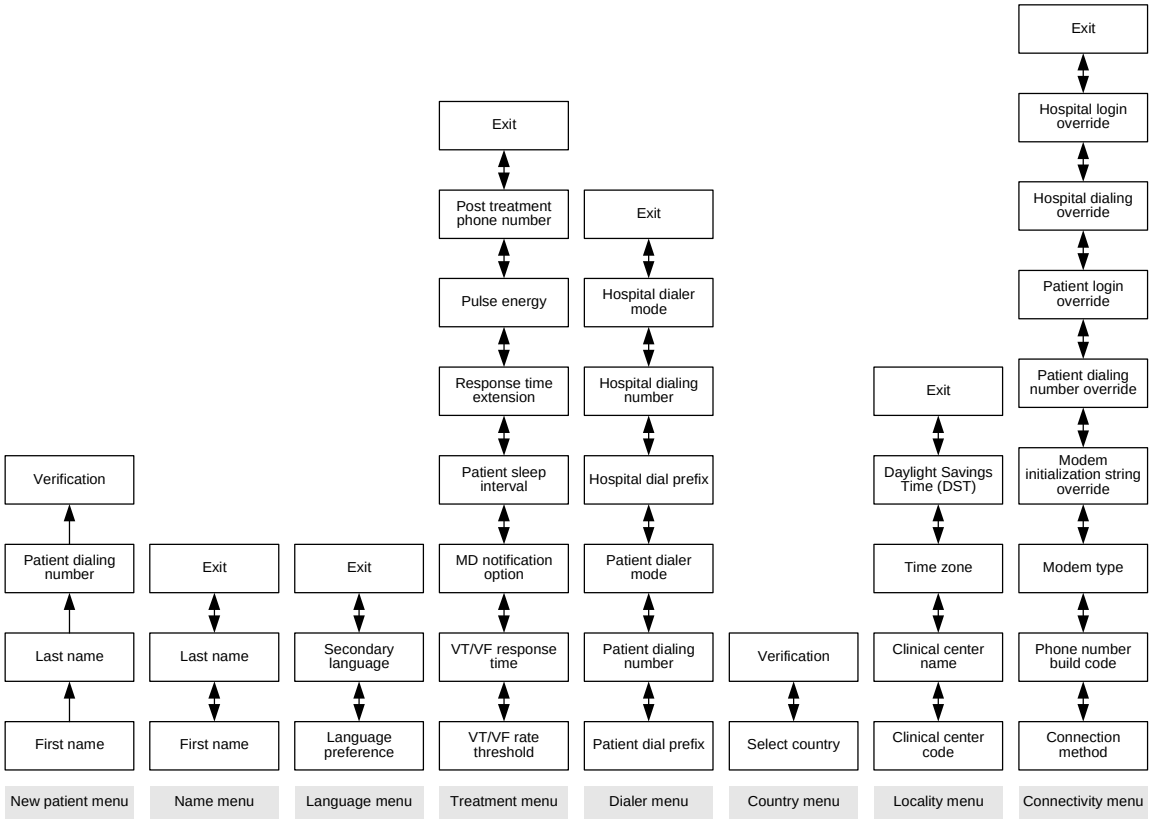
From here you can make further selections and set up the system. Procedures are explained in the rest of this section.

Setup menu

Menu structure



Submenus

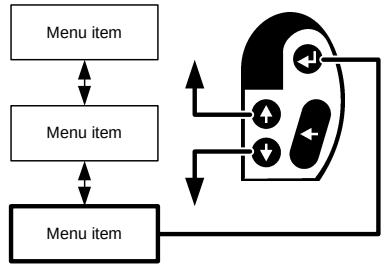

Verification
Patient dialing number
Last name
First name
New patient menu
Exit
Last name
First name
Name menu
Exit
Secondary language
Language preference
Language menu
Exit
Post treatment phone number
Pulse energy
Response time extension
Patient sleep interval
MD notification option
VT/VF response time
VT/VF rate threshold
Treatment menu
Exit
Hospital dialer mode
Hospital dialing number
Hospital dial prefix
Patient dialer mode
Patient dialing number
Patient dial prefix
Dialer menu
Verification
Select country
Country menu
Exit
Daylight Savings Time (DST)
Time zone
Clinical center name
Clinical center code
Locality menu
Exit
Hospital login override
Hospital dialing override
Patient login override
Patient dialing number override
Modem initialization string override
Modem type
Phone number build code
Connection method
Connectivity menu

About the menus and options

Menu or option	What it lets you select or enter	When to use it
New patient menu	Patient's name and dialing number (if more than one number is available).	To set up a new patient. Be sure to select country before setting up a new patient.
Baseline option	When you choose this option, the monitor goes into the baseline mode when you exit the setup mode.	To baseline a patient after the initial setup, such as during a follow-up visit.
Training option	When you choose this option, the monitor goes into the training mode when you exit the setup mode.	To train the patient in the monitor's basic operation regarding the treatment sequence and noise sequence.
Name menu	Patient's name displayed on the device and used when transmitting patient data.	To change or correct a patient's name.
Language menu	Languages for the displayed messages and voice prompts.	When setting up a new patient, use this menu to set the patient's language for the displays and voice prompts. A secondary language can also be selected for bystanders.
Treatment menu	Defaults and options for rate thresholds (in beats per minute), response time (how many seconds until the device delivers the defibrillating shock), pulse energy (in joules), and other treatment options.	When setting up a new patient, and to change a patient's treatment settings, such as during a follow-up visit.
Dialer menu	Phone number dialing modes (touch tone or pulse) and dialing prefixes (any numbers that need to be dialed in front of the phone number) for dialing from the patient's home and the hospital.	When setting up a new patient, enter the details about the phone system. Update this menu if the patient has any changes to their phone system that require updates to the dialing mode or prefix.
Country menu	Country where the patient lives.	Select the country before setting up a new patient, or if patient moves to another country. The country affects all of the communication settings, so it must be selected first. The country selected also defines whether you must select a dialing number when setting up a new patient.
Locality menu	Clinical center code and name that the patient is associated with. Time zone and daylight savings time (on or off) for the locality where the patient lives.	When setting up a new patient, or if patient moves to another location.
Connectivity menu	Details associated with the modem and phone dialing.	When setting up a new patient, to define the connection method, phone number build code, and modem type (if different from defaults). Remaining settings (overrides) are normally not used. However, ZOLL may ask you to enter a value for service purposes.

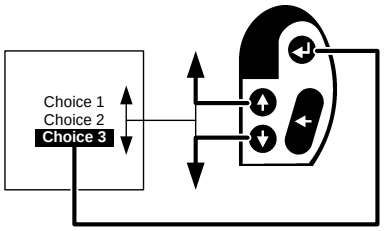
Menu navigation

How to select a menu item



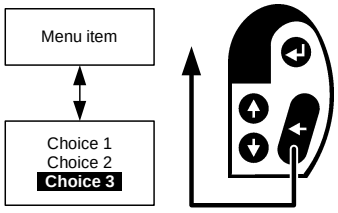
- Use the up and down arrow keys to scroll through menus.
- Go to the menu containing the setting or option you want to change.
- Press OK to select the menu item, causing it to be highlighted.

How to make a choice within a menu



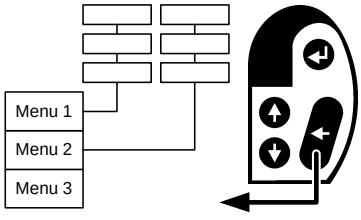
- If a list of choices is presented, use the up and down arrow keys to select your choice.
- When your choice is highlighted, press OK.

How to undo before saving



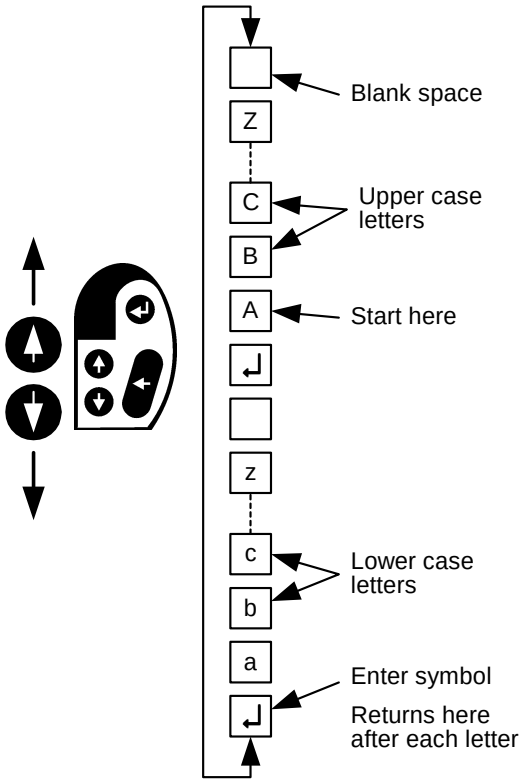
- If you're in the middle of changing something and you realize that you do not want to change it, **do not** press OK.
- Press the backspace button to back out of the change and restore the previous setting.

How to exit the current menu



- To exit the current menu and return to a selection menu, press the backspace button.
- Each time you press the backspace button, you will go back one menu level until you reach the main menu.

How to enter a text field

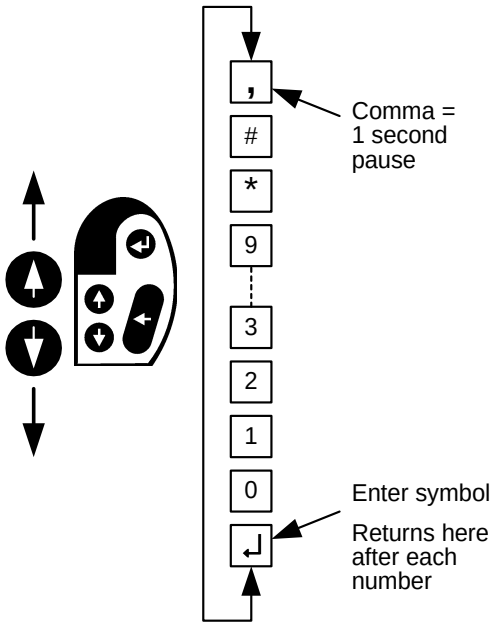


- When you are in a menu that requests that you enter text, such as the patient's first or last name, use the up and down arrow buttons to scroll through the alphabet.
- The display starts with the upper case A. Each time you press the up arrow, you will scroll through the upper case letters A through Z. If you continue pressing the up arrow, you will then see a blank space, then the enter symbol. Then the letters scroll again with lower case letters a through z.
- Each time you reach a letter you want to insert, press OK.
- After you enter each letter, you'll return to the enter symbol at the bottom of the list shown at left.
- When you are finished with an entry, have the enter symbol displayed and press OK.

Hints

- You may press either the up or down arrow key to move through the alphabet in either direction.
- Hold down one of the arrow keys to move through the letter quickly.
- If you need a blank space between words, use the blank that appears right after the letter Z (upper or lower case).

How to enter a number field

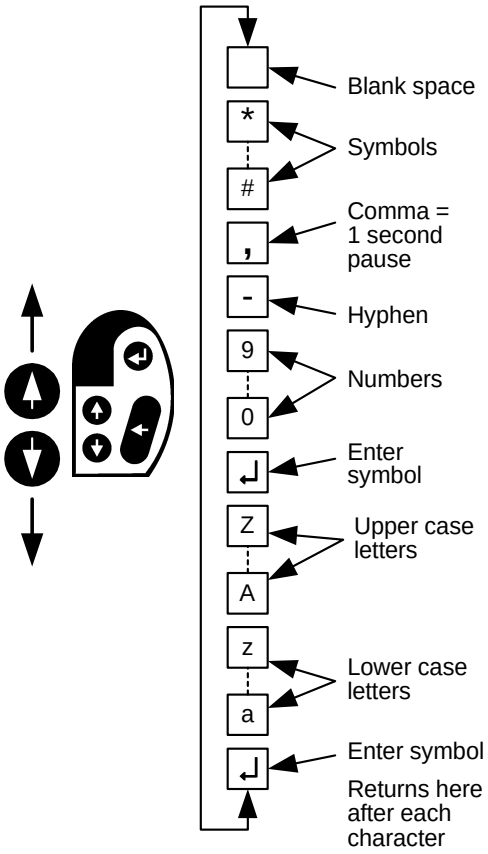


- When you are in a menu that requests that you enter a number, use the up and down arrow buttons to scroll through the numbers.
- The display starts with the number 0. Each time you press the up arrow, you will scroll through the numbers 0 through 9. If you continue pressing the up arrow, you will then see symbols, a comma, then the enter symbol.
- Each time you reach a number you want to insert, press OK.
- After you enter each number, you'll return to the enter symbol at the bottom of the list shown at left.
- When you are finished with an entry, have the enter symbol displayed and press OK.

Hints

- You may press either the up or down arrow key to move through the numbers in either direction.
- Hold down one of the arrow keys to move through the numbers quickly.
- If you need to insert a pause, use the comma. Each comma inserts a 1-second pause. You can insert multiple commas if you need more pauses.

How to enter an alphanumeric field



- When you are in a menu that accepts letters and numbers, such as the post-treatment phone number, the up and down arrow buttons scroll through both letters and numbers.
- Each time you press the up arrow, you will scroll through the lower case letters a through z, then upper case A through Z, then the numbers 0 through 9. There are also two enter symbols, symbols, and a blank space.
- Each time you reach a letter or number you want to insert, press OK.
- After you enter each number, you'll return to the enter symbol at the bottom of the list shown at left.
- When you are finished with an entry, scroll to one of the enter symbols, then press OK.

Hints

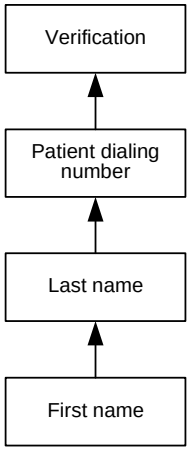
- You can press either the up or down arrow key to move through the letters and numbers in either direction.
- Hold down one of the arrow keys to move through the letters and numbers quickly.
- If you need to insert a pause into a phone number, use the comma. Each comma inserts a 1-second pause. You can insert multiple commas if you need more pauses.

How to set up a new patient

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **NEW PATIENT**, then press OK button.

This takes you to the new patient menu, starting with First Name, shown at the bottom of the diagram. As you enter data, you will move up through the menu structure.



New patient menu

3 Enter patient's first name, then press OK button.

For instructions on how to enter text, see **How to enter a text field** on page 16-7.

4 Enter patient's last name, then press OK button.

5 Select the patient dialing number, then press OK button.

Note: The patient dialing number menu will not be shown if a single phone number serves the whole country, or if a patient dialing override is selected.

- If more than one number is available for the country selected, the numbers will be shown along with the area or city served by that number.
- To change to another area or city, use the up and down arrow buttons. Holding an arrow button down makes the numbers scroll faster.
- To enter the first letter of the city, press the backspace button (response), then use the arrow keys. Press the OK button twice to complete your entry and display cities that begin with that letter. Continue scrolling with the arrow keys.

6 Verification menu appears.

Review the patient settings and make any changes required.

- If settings are correct, select **OK**, then press OK button.
- To change the patient's name, see **How to set up or change patient name** on page 16-16.
- If you need to change the clinical center, contact your device provider.

7 With the menu displayed, press the backspace button once.

8 With the main menu displayed, select **EXIT**, then press OK button.

The monitor will exit the setup mode and be in baseline mode. Follow the normal startup routine.

Continue with the baseline procedure on page 16-13.

How to set up the monitor to baseline a patient

When you set up a new patient, the monitor automatically goes into the baseline mode after you exit the setup mode. You will not need to do this procedure as a separate step.

Use the procedure below to re-baseline a patient, such as during a follow-up visit.

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **BASELINE**, then press OK button.

3 Select **OK**, then press OK button.

4 The monitor will exit the setup mode and be in baseline mode. Follow the normal startup routine.

Continue with the baseline procedure on the next page.

How to baseline a patient

When you set up a new patient, or when you select Baseline, the monitor goes into baseline mode when it exits the setup mode. You then record the patient's baseline heart rhythm.

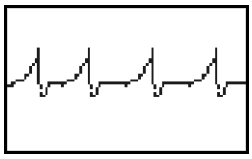
1 Assemble the electrode belt and attach it to the patient.

2 Connect the electrode belt to the monitor. (Don't press OK until the patient is ready.)

3 Have the patient sitting down, relaxed, and not talking or moving around.

4 When the patient is ready, press OK to start recording the patient's baseline.

Messages show the sequence of recording the patient's baseline:

PRESS OK TO RECORD	Press OK button to start recording baseline.
RECORDING BASELINE	Monitor is preparing to record baseline.
	Baseline is being recorded. Baseline recording time will vary depending on the patient, strength of the ECG signal, and the amount of noise on ECG signal. Total time may take from 45 seconds to 5 minutes.

5 When you see the baseline complete message, press OK button.

BASELINE COMPLETE

PRESS OK

The monitor returns to normal operation.

If you have problems baselining a patient

Message	What it means	What to do
BASELINE FAILED	Monitor could not learn the patient's baseline.	Verify that the ECG electrodes are clean and contacting the patient's skin. Also verify that the electrode belt is fitting properly. Apply unscented hand lotion to the ECG electrodes. Then try to baseline the patient again. If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, discontinue attempting to baseline the patient. If problems continue, call ZOLL or your device provider.

How to place the monitor in training mode

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **TRAINING**, then press OK button.

3 Select **OK**, then press OK button.

4 The monitor will exit the setup mode and be in training mode.

You can then train the patient as described in Chapter 11, **Patient Training**.

To leave training mode, remove and reinstall the battery pack.

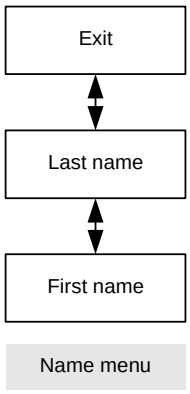
How to set up or change patient name

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **SETTINGS**, then press OK button.

3 Select **NAME**, then press OK button.

This takes you to the name menu.



4 Press up and down buttons to see menu settings.

The chart below lists name settings, what they mean, and how to select them.

5 When you reach a menu that displays what you want to change, press the OK button. This highlights the selection.

- Change the setting using the alarm module buttons.
- Press OK to save your changes and return the display to normal. If the selection remains highlighted, it has not been saved. You may need to press OK again.

Name setting	What it means	How to select
First name	Patient's first name.	Enter patient's first name that will be used on patient records.
Last name	Patient's last name.	Enter patient's last name that will be used on patient records.

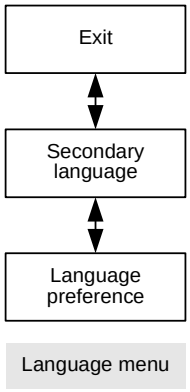
How to set up or change language

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **SETTINGS**, then press OK button.

3 Select **LANGUAGE**, then press OK button.

This takes you to the language menu.



4 Press up and down buttons to see menu settings.

The chart below lists language settings, what they mean, and how to select them.

5 When you reach a menu that displays what you want to change, press the OK button. This highlights the selection.

- Change the setting using the alarm module buttons.
- Press OK to save your changes and return the display to normal. If the selection remains highlighted, it has not been saved. You may need to press OK again.

Langauge setting	What it means	How to select
Language preference	Language that monitor will use for display messages and spoken alarms.	Select from list of languages.
Secondary language	Second language that will be used for spoken alarms to advise bystanders.	Select from list of languages or select none.

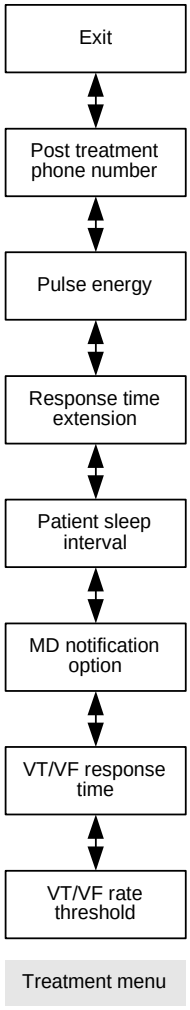
How to set up or change treatment settings

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **SETTINGS**, then press OK button.

3 Select **TREATMENT**, then press OK button.

This takes you to the treatment menu.



4 Press up and down buttons to see menu settings.

The chart on the next page lists treatment settings, what they mean, and how to select them.

5 When you reach a menu that displays what you want to change, press the OK button. This highlights the selection.

- Change the setting using the alarm module buttons.
- Press OK to save your changes and return the display to normal. If the selection remains highlighted, it has not been saved. You may need to press OK again.

Treatment setting	What it means	How to select
VT/VF rate threshold	Heart rate that must be sustained before VT or VF is declared.	Range: 120-250 beats per minute Defaults: VT=150 beats per minute, VF=200 beats per minute
VT/VF response time	Elapsed time before treatment delivered.	Range: VT=60-180 seconds, VF=25-55 seconds Defaults: VT=60 seconds, VF=25 seconds
MD notification	Determines if patient receives “call doctor” message after stopping a treatment.	Default: Off Can be set to repeat message every 5 minutes for up to 1 hour
Patient sleep interval	Time the patient normally sleeps. If an arrhythmia is detected during the sleep interval, the tactile and arrhythmia alarm are activated together (unlike normal operation when the tactile alarm gets activated first, then the arrhythmia alarm). This setting is used in conjunction with the response time extension.	Range: Any two times during a 24-hour clock Default: Asleep at 00:00 (midnight) and awake at 06:00 (6:00 a.m.)
Response time extension	Time to be added to the response time during the patient sleep interval.	Range: 0-30 seconds Default: 0
Pulse energy 1...5	Energy level of each of the five shocks. Each shock can be set to a different level.	Range: 75-150 joules Default: 150 joules
Post treatment phone number	Phone number displayed for patient to call after receiving a treatment shock.	Set to the phone number you want the patient to call after receiving treatment.

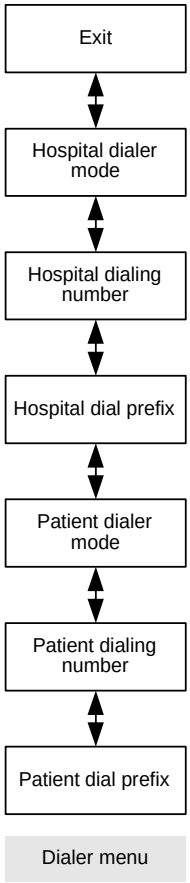
How to set up or change dialer settings

1 From the main menu, select **PATIENT**, then press OK button.

2 Select **SETTINGS**, then press OK button.

3 Select **DIALER**, then press OK button.

This takes you to the dialer menu.



4 Press up and down buttons to see menu settings.

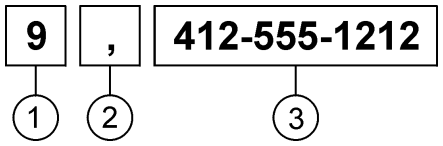
The chart on the next page lists dialer settings, what they mean, and how to select them.

5 When you reach a menu that displays what you want to change, press the OK button. This highlights the selection.

- Change the setting using the alarm module buttons.
- Press OK to save your changes and return the display to normal. If the selection remains highlighted, it has not been saved. You may need to press OK again.

Dialing setting	What it means	How to select
Patient dial prefix	Prefix number that may be required to dial out from patient's home (see example below). For example, you may need to dial 9 to reach an outside line. That number 9 is the dial prefix and it is dialed before the dialing number.	Select any number, based on what is required. If any pauses are required, each comma equals 1 second.
Patient dialing number	Phone number that will be called to transmit data from monitor when patient calls from home. This is a complete number with area code and phone number.	Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Patient dialer mode	Type of phone patient has at home.	Touch tone or pulse, based on what patient has at home.
Hospital dial prefix	Prefix number that may be required to dial out from hospital (see example below). For example, you may need to dial 9 to reach an outside line. That number 9 is the dial prefix and it is dialed before the dialing number.	Select any number, based on what is required. If any pauses are required, each comma equals 1 second.
Hospital dialing number	Phone number that will be called to transmit data from monitor when patient calls from hospital. This is a complete number with area code and phone number.	Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Hospital dialer mode	Type of phone used to send data from hospital.	Touch tone or pulse, based on what is available at hospital.

Phone number example



1 Dial prefix (precedes any phone numbers)

2 Pause (each comma equals 1 second)

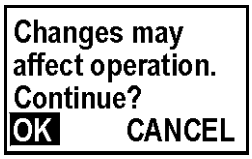
3 Dialing number

How to change country

WARNING: The country is set by device provider and does not normally need to be changed. Changing the country affects a number of communication settings and could affect the unit's operation and downloading. Contact your device provider for assistance if you need to change this setting.

1 From the main menu, select **EQUIPMENT**, then press OK button.

WARNING: Changing any of the settings under the equipment menu can affect the unit's operation and downloading. Proceed with caution.



2 Select **OK**, then press OK button.

3 Select **NEW COUNTRY**, then press OK button.

4 Select the country where the patient lives, then press OK button.

If you want to select a country that is not shown as one of the options, contact your device provider for assistance.

5 Select **OK**, then press OK button.

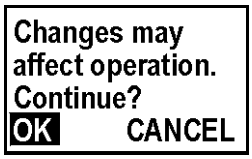
After changing the country (and after entering a new patient and selecting the patient's city if the country is served by more than one phone number), check the locality and connectivity settings.

How to change locality settings

WARNING: Locality settings are set by device provider and do not normally need to be changed. Changing the locality settings could affect the unit's operation and downloading. Contact your device provider for assistance if you need to change any of these settings.

1 From the main menu, select **EQUIPMENT**, then press OK button.

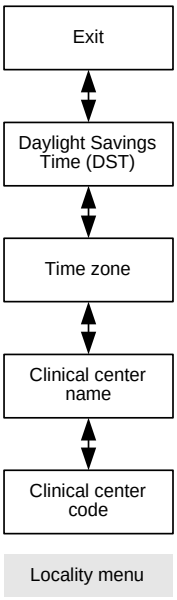
WARNING: Changing any of the settings under the equipment menu can affect the unit's operation and downloading. Proceed with caution.



2 Select **OK**, then press OK button.

3 Select **LOCALITY**, then press OK button.

This takes you to the locality settings menu.



4 Press up and down buttons to see menu settings.

The chart on the next page lists locality settings, what they mean, and how to select them.

5 When you reach a menu that displays what you want to change, press the OK button. This highlights the selection.

- Change the setting using the alarm module buttons.
- Press OK to save your changes and return the display to normal. If the selection remains highlighted, it has not been saved. You may need to press OK again.

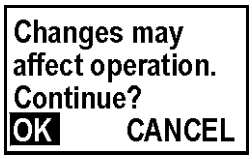
Locality setting	What it means	How to select
Clinical center code	Code assigned to your clinical center.	Use the code number for your clinical center. Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Clinical center name	Name of your clinical center.	Can be any combination of letters and numbers, limited to 75 characters. Determined by device provider and does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Time zone	Allows choosing patient's time zone in countries where there are multiple time zones.	Select from the list of time zones.
Daylight savings time (DST)	Selects whether or not location follows daylight savings time.	Select Yes or No.

How to change connectivity settings

WARNING: Connectivity settings are set by device provider and do not normally need to be changed. Changing the connectivity settings could affect the unit's operation and downloading. Contact your device provider for assistance if you need to change these settings.

1 From the main menu, select **EQUIPMENT**, then press OK button.

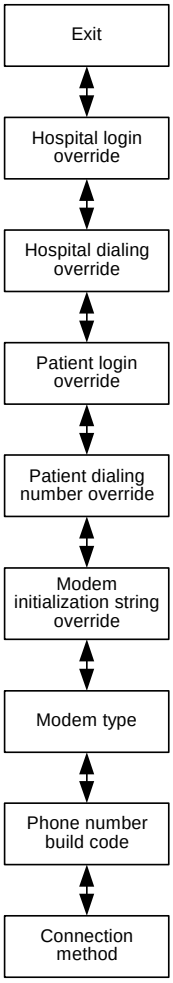
WARNING: Changing any of the settings under the equipment menu can affect the unit's operation and downloading. Proceed with caution.



2 Select **OK**, then press OK button.

3 Select **CONNECTIVITY**, then press OK button.

This takes you to the connectivity settings menu.



Connectivity menu

4 Press up and down buttons to see menu settings.

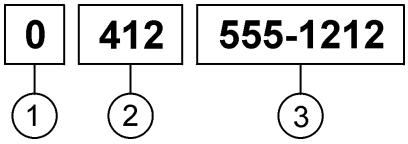
The chart on the next page lists connectivity settings, what they mean, and how to select them.

5 When you reach a menu that displays what you want to change, press the OK button. This highlights the selection.

- Change the setting using the alarm module buttons.
- Press OK to save your changes and return the display to normal. If the selection remains highlighted, it has not been saved. You may need to press OK again.

Connectivity setting	What it means	How to select
Connection method	Determines how monitor accesses the ZOLL database, whether through server direct numbers or Internet service provider numbers.	Select the type of dialing method to be offered during patient setup. Defaults to the type of connection numbers most likely to be used in the selected country. Does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Phone number build code	Describes how phone number is constructed for the country and locality (see example below).	Select what gets dialed in front of phone number if anything, including a national direct dialing (NDD) number and area code. The NDD number is the access code used to make a call within a country from one city to another. The NDD is followed by the area/city code for location being called. When calling another city in the same vicinity, the NDD may not be necessary. Does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Modem type	Type of modem used to transfer data.	Select type of modem being used, based on country where it will be used. Does not normally need to be changed. Contact your device provider for assistance if you need to change this setting.
Modem initialization string override	Allows you to enter manual dialing information.	Normally not used. For service purpose, we may ask you to enter a value.
Patient dialing number override		
Patient login override		
Hospital dialing override		
Hospital login override		

Phone number build example



1 National direct dialing (NDD)

2 Area/city code

3 Phone number

How to leave setup mode

1 Press the backspace button until the main menu displays.

2 From the main menu, select **EXIT**, then press OK button.

3 Monitor resumes normal operation. Follow screen messages.

Note: If the monitor is placed in setup mode and left unattended, it will return to normal operation after 15 minutes of inactivity.

Chapter 17: Adverse Events

Patient deaths

Within the enrolled population of 289 patients, 12 deaths were reported in the study (see Table 1 below).

In only one case was the death judged to be device-related. The patient had a VT/VF event that was detected by the device. However, the front therapy electrode was incorrectly placed (reversed) by the patient. Because of this, the device detected an abnormally high electrical circuit impedance through the patient and did not deliver the shock. Subsequent to this event, the device has been modified so that the therapy electrodes can only be placed in the patient-worn chest garment the correct way.

Table 1. Description of patient deaths that occurred in the study (n=289 patients)

Description	Frequency of occurrence	Cardiac/ Non-cardiac	Device related?
Incorrect placement of front therapy electrode	1	Cardiac	Yes
Died while hospitalized and not wearing the device	4	Cardiac	No
Died while at home and not wearing the device	7*	Cardiac	No

*Two patients were no longer routinely wearing the device. One patient died while removing the device to shower. The cause of death in the other patient was determined to be a non-sudden cardiac event. One patient left the hospital against medical advice and died before resuming device use. The circumstances of the remaining two patient deaths are unknown.

Reported adverse events

The adverse events that occurred during the study are listed according to their frequency of occurrence (Table 2).

Adverse events are classified as either Complications (which required device-related hospitalization), or Observations (which required minimum intervention and no hospitalization).

Table 2. Adverse events tabulated by frequency (n=289 patients)

Adverse Event (AE)	# Patients with AEs	% Patients with AEs	# of AEs	AE/Patient Years	Device Related?
Complications Total	0	0	0	0	NA
Observations Total	33	11.4%	36	0.48	
Skin rashes	17	5.9%	20	0.27	Yes
Inappropriate defibrillation	6	2%	6	0.08	Yes
60 cycle interference	2	0.69%	2	0.03	Yes
Pacemaker interaction	1	0.3%	1	0.013	Yes
Loss of contact between battery and monitor	1	0.3%	1	0.013	Yes
Left jugular thrombosis	1	0.3%	1	0.013	No
No shock delivery	1	0.3%	1	0.013	Yes
Discomfort at front therapy pad	1	0.3%	1	0.013	Yes
Arrhythmia detection aborted	1	0.3%	1	0.013	Yes
Device disabled during arrhythmia detection	1	0.3%	1	0.013	Yes

Potential adverse events

- Potential adverse events are listed in order of seriousness:
- Failure to sense and detect a treatable arrhythmia resulting in death.
- Unsuccessful cardioversion or defibrillation resulting in death or disability.
- Inappropriate shock causing abnormal heart rhythms, including fatal rhythms.
- Improper, ineffective, or non-operation of the device due to external causes such as electromagnetic interference.
- Failure resulting from random component failure.
- Ineffective cardioversion/defibrillation by another external defibrillator if the LifeVest device is not removed from patient as advised by the chest belt label.
- Fire hazard in the presence of a high oxygen concentration.
- Bystander shock from patient contact during a treatment event.
- Superficial skin burns resulting from defibrillation.
- Skin ulcers and allergic dermatitis due to constant and continual electrode/skin interactions.

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Chapter 18: Clinical Studies

Electrophysiology laboratory study—October 1996 to September 1997

This chapter refers to the WCD 2000, which is an earlier version of LifeVest device. Ten patients were electively induced into VT or VF, and all ten were converted or defibrillated with the first 230 joule WCD 2000 device delivered shock. There were no post-shock arrhythmias or skin burns. The average time from induction to treatment was 28 ±15 seconds. The average patient impedance was 54 ±13 ohms.

In-hospital feasibility study—April 1997 to January 1998

The objective of the study was to evaluate the risk of an unnecessary shock and to obtain, if possible, documentation of a full automatic detection and defibrillation of spontaneous VT/VF events. Fifteen patients wore the WCD 2000 device in the hospital for a total of 58 days with no automatic treatments or unnecessary shocks. Eleven patients stated they felt comfortable using the device, and twelve patients reported that the device was easy to use. Ten patients reported that they would feel comfortable going home with the device.

Definitive clinical trial—February 1998 to July 2001

Objective

The objective of the study was to demonstrate safety and effectiveness of the WCD 2000 device. The safety objective was to demonstrate less than 2.3% false shocks per patient-month with 90 percent confidence A minimum of 500 patient months of weartime experience was required. The effectiveness objective was to demonstrate greater than 25% resuscitation success with 90 percent confidence.

Method

A prospective, non-randomized, multi-national trial involving 16 centers (15 U.S. centers and one European center) evaluated the safety and effectiveness of the WCD 2000 device with patients at risk of sudden cardiac death. Historical controls of Emergency Medical Services, sudden cardiac arrest survivorship, and reported ICD unnecessary shock frequency were used to establish comparative success criterion for WCD 2000 device safety and effectiveness. Two populations at SCA risk were chosen for the investigation. The first population (WEARIT) consisted of patients waiting for heart transplant or patients having an equivalent cardiac status, namely New York Heart Association Class III or IV heart failure and an ejection fraction below 30 percent. Typically, these patients used the WCD 2000 device until they received a heart transplant, a circulatory assist device, or an ICD. The second patient population (BIROAD) included

acute myocardial infarction (MI) patients and patients immediately following a coronary artery bypass graft procedure. Additional requirements for both the MI and bypass patients included VT/VF within the first 48 hours or a left ventricular ejection fraction of less than 30 percent. A Killip Class III or IV 72 hours following the MI and syncopal VT/VF after 48 hours post-MI also qualified patients for WCD 2000 device use. The post-MI patients used the WCD 2000 device for approximately four months. Patient characteristics are summarized in Table 1.

Table 1. Patient demographics

	Total Study	**BIROAD**	**WEARIT**
Ejection fraction	23% ±10, n=282	30% ±10, n=107	19% ±7, n=175
QRS width (msecs)	121 ±33, n=261	109 ±20, n=109	128 ±38, n=152
Age (years)	55 ±12, n=288	59 ±11, n=111	52 ±11, n=177
Male	82%, n=236/289	83%, n=93/112	81%, n=143/177
History of smoking	66%, n=288	67%, n=112	65%, n=176
History of hypertension	59%, n=288	81%, 112	44%, n=176
History of nonsustained ventricular tachycardia	52%, n=267	71%, n=105	40%, n=162
History of sustained ventricular tachycardia	32%, n=259	51%, n=102	20%, n=157
Beta-blocker medications	57%, n=285	70%, n=111	49%, n=174
Anti-arrhythmia drugs	22%, n=285	18%, n=111	25%, n=174
Inotropic medications	16%, n=285	3%, n=111	25%, n=174

Study results

The study population consisted of 289 patients with 901 patient months (75.1 years) of patient device experience, an exposure mean of 94 days (ranging from 1-1032 days) for individual patient exposures, and an average daily wear time of 19.1 hours (see Table 2).

The device successfully treated six of eight correctly diagnosed spontaneous events of sudden cardiac arrest (see Table 3).

Table 2. Average daily device wear time

	Total Study (n=289)	BIROAD (n=112)	WEARIT (n=177)
Average use (hours/day)	19.1 ±5.7	20.1 ±6.3	18.7 ±5.3

Table 3. Summary of study results (n=289 patients)

Event Description	Number or Events
SCA events with device being worn	8
SCA events correctly diagnosed	8
SCA events successfully treated*	6
Unnecessary shock episodes**	6

*Two out of 8 events were not treated because the patient incorrectly inserted the therapy electrodes in the chest garment. Changes were subsequently implemented to prevent these human failures from re-occurring.

**No deaths, arrhythmia inductions, or injury resulted from these unnecessary shocks. Using the ECG recordings that documented the unnecessary shocks, algorithm software changes were implemented to reduce the future probability of unnecessary shocks.

Safety results

The most frequent adverse event reported is temporary skin rash. There were six unnecessary shock episodes during 901 months of accumulated patient use. The unnecessary shock rate per patient-month is 0.69% (90% confidence interval: 0.30 to 1.35%). No arrhythmias were induced from the unnecessary shocks. Two failures must occur for an unnecessary shock to happen. First, the detection algorithm must falsely declare an arrhythmia to exist for the duration of the alarm sequence (at least 25 seconds). Second, the patient must fail to use the response buttons despite the alarms.

Modifications were made to the WCD 2000 device after carefully reviewing the circumstances during which the unnecessary shocks occurred. The modifications included changes to the design in the noise and arrhythmia alarms as well as, modifications to the detection algorithm. These changes were implemented during the last year of the study. During that time, no false shock episodes occurred.

Effectiveness results

The device successfully detected and treated 5 sudden cardiac arrest episodes. The device detected but was unable to treat two other sudden cardiac arrest episodes resulting in a 71 percent successful resuscitation rate.

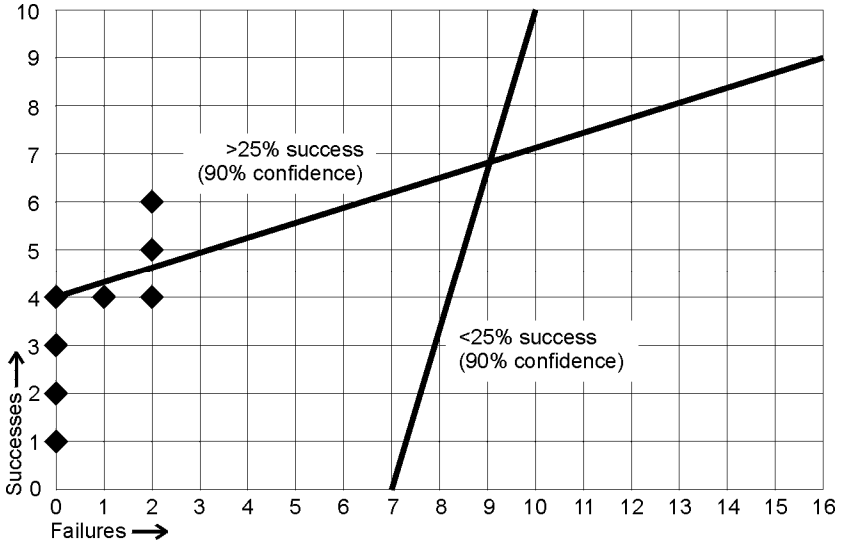
The hypothesis for the efficacy objective was that the successful resuscitation rate using the WCD 2000 device would be at least 25% (see Objective and Method sections on page 18-1). A confidence level of 90% was chosen for the minimum boundary of acceptance or rejection. An additional requirement of the study design was that the power must be at least 50% if the true successful resuscitation rate was 43%. The true successful resuscitation rate was estimated to be between 43% and 90% based on a ventricular detection success rate of 85% to 95 % and a defibrillation success rate of 50% to 95%. From these requirements, the trial was designed as a sequential evaluation of SCA events occurring while the device was worn. The results were evaluated by stopping rules to determine if the hypothesis could be accepted or rejected.

The stopping rules were (s is a successful resuscitation event, f is an unsuccessful resuscitation event):

- Stop with a favorable conclusion whenever $s \geq 4 + f/3$
- Stop with an unfavorable conclusion whenever $f \geq 7 + s/7$

This design met the power requirement of at least 50% if the true WCD 2000 device successful resuscitation rate was only 43% and would have a power over 90% for true rates over 60%. A graph of the resuscitation successes versus failures is shown in the figure below.

Resuscitation successes versus failures



Biphasic animal study—WCD 3000 Monitor

Animal testing was performed using a porcine model to demonstrate successful defibrillation by the biphasic waveform used in the WCD 3000 device, prior to human testing. Using a modified down-up threshold test sequence in seven preparations (average weight 37.4 kg), the average estimated defibrillation threshold was 75 joules. During the first six preparations, problems were identified with the detection algorithm dropping out of detection due to noise artifacts, device stopping after pulse delivery, and false arrhythmia alarms. Subsequent design changes were made to hardware and software. In the seventh preparation, three WCD 3000 devices successfully detected and delivered therapy a total of seven times.

Biphasic animal study—WCD 3000 Electrode Belt

Animal testing was performed using a porcine model to demonstrate successful defibrillation by the biphasic waveform using the WCD 3000 Electrode Belt. Using a modified down-up threshold test sequence in seven preparations (average weight 32.4 kg), the average estimated defibrillation threshold was 58 joules. Three WCD 3000 Electrode Belts successfully detected and delivered therapy a total of 14 times.

Biphasic Electrophysiology Laboratory Sub-Study—March 2001 to November 2001

Twelve patients were electively induced into VT or VF, and all twelve were converted or defibrillated with the first biphasic shock (either 70 or 100 joules). A total of 23 successful biphasic shocks were delivered. There were no post-shock arrhythmias or skin burns. The average patient impedance was 68 ±8 ohms.

WCD 3000 Clinical sub-study—September 2001 to April 2002

The objective of the sub-study was to demonstrate the safety of the WCD 3000 device by comparing the incidence of false arrhythmia declarations (false alarms) with the WCD 3000 device to the WCD 2000 device. The study would be considered successful if the incidence of false arrhythmia declarations was less than, or equal to, the WCD 2000 device. A minimum of 10 patients and 100 weeks of cumulative device use would be required.

A prospective, non-randomized, multi-national trial involving 4 centers (3 U.S. centers and 1 European center) evaluated the safety of the WCD 3000 device with patients at risk of sudden cardiac death. Two populations at SCA risk were chosen for the sub-study. The first population (WEARIT) consisted of patients waiting for heart transplant or patients having an equivalent cardiac status, namely New York Heart Association Class III or IV heart failure and an ejection fraction below 30 percent. The second patient population (BIROAD) included acute myocardial infarction (MI) patients and patients immediately following a coronary artery bypass graft procedure. Additional requirements for both the MI

and bypass patients included VT/VF within the first 48 hours or a left ventricular ejection fraction of less than 30 percent. A Killip Class III or IV 72 hours following the MI and syncopal VT/VF after 48 hours post-MI also qualified patients for WCD 3000 device use.

Table 4. Patient demographics

Parameter	Total Study (n=13)	BIROAD (n=6)	WEARIT (n=7)
Ejection fraction	21% ±7, n=11	25% ±5, n=4	18% ±6
QRS width (msecs)	105 ±15, n=9	104 ±12, n=4	106 ±18, n=5
Age (years)	56 ±11	57 ±9	56 ±13
Male	69%	67%	71%
History of smoking	83%, n=12	100%	67%, n=6
History of hypertension	83%, n=12	80%, n=5	86%
History of NSVT	89%, n=9	100%, n=4	80%, n=5
History of VT	44%, n=9	50%	33%, n=3
Beta-blocker medication	82%, n=11	100%, n=5	67%, n=6
Anti-arrhythmia medication	9%, n=11	20%, n=5	0%, n=6
Inotropic medications	0%, n=11	0%, n=5	0%, n=6

The study population consisted of 13 patients with 105 patient weeks of patient device experience. There were 214 false arrhythmia detections during that time. The rate of false detections using the WCD 3000 device was 2.0 per patient week of use as compared to 4.5 per patient week using the WCD 2000 device. There were no treatable tachyarrhythmic events during the study. There were four true arrhythmias recorded during the study, all four resolved spontaneously. There were no inappropriate defibrillations during the study.

One adverse event was reported during the study. This event involved a patient who received an asystole alarm due to incompletely connecting the electrode belt to the monitor. The patient called an ambulance to take her to the hospital as the device directed. She was hospitalized as a precaution and transferred from this local hospital to the investigational site where she was examined and discharged to home. No injury resulted from this event. The patient continued to wear the device.

Index

G

H

I

L

M

N

O

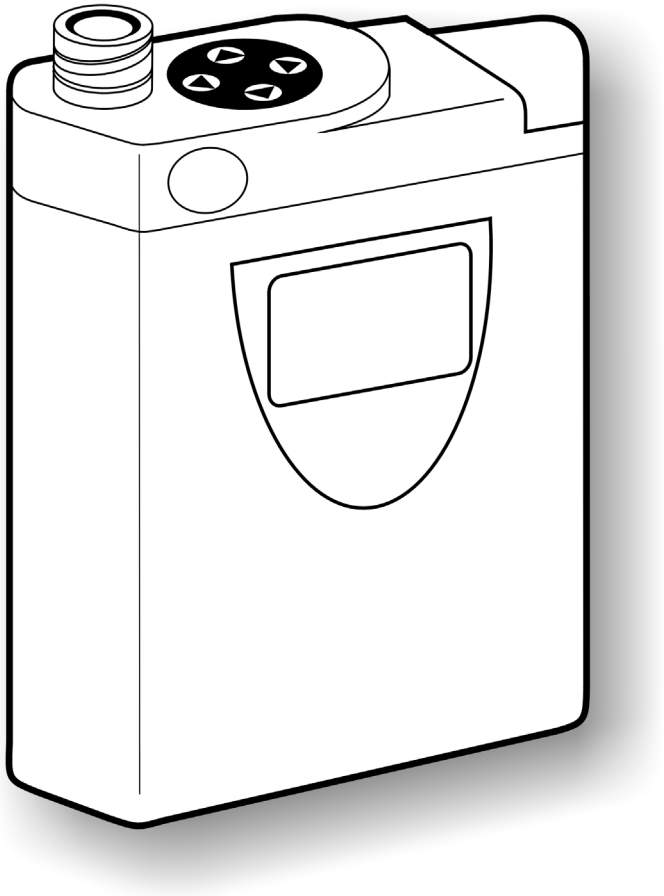
P

Z

LifeVest®

Model WCD 3100

Operator's Manual



ZOLL®

PN 20B0040 Rev G3

Restricted sale

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

Effectivity

This manual describes the LifeVest WCD 3100 wearable defibrillator system.

Disclaimer

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

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Copyright notice

Patents

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

Software nonexclusive license

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Contents

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1: Introduction

About this manual

This manual:

- is for operators of the LifeVest wearable defibrillator.
- gives you instructions on how to fit patients, as well as instruct patients in the use and care of the device.
- supplements the patient manual, which gives patient instructions on the use and care of the LifeVest device.

What's in this manual

Here's how to use this manual:

- The next few pages contain details about the LifeVest system, plus safety information.
- **Patient fitting** explains how to fit a patient and assemble the components of the LifeVest belt.
- **Patient training** gives guidelines for instructing the patient about the LifeVest system and how to respond to alerts.
- **Monitor setup for a new patient** covers the basic procedures and menus for setting up the monitor before use by a new patient. (If you need to change other settings, see the programming section of the Service Manual.)
- **LifeVest Network** tells how to view patient data on the LifeVest Network using a computer with Internet access.
- **Clinical information** contains indications, contraindications, a summary of the clinical studies, and other clinical details.
- Appendixes include **Quick charts**, **Part numbers**, and **Symbols**. The quick charts are particularly helpful as reminders of how to do things.
- Use the **Index** at the back of the manual to find what you're looking for quickly.

About the LifeVest system

The LifeVest is a cardioverter defibrillator worn by a patient at risk for sudden cardiac arrest (SCA). It monitors the patient's heart continuously and, if the patient goes into a life-threatening arrhythmia, can deliver a shock treatment to restore the patient's heart to normal rhythm.

Two main components

The LifeVest system consists of two main components: (1) an electrode belt and garment that surrounds the patient's chest, and (2) a monitor that the patient wears around the waist or from a shoulder strap.

Washable garments are available in sizes to suit most patients. The LifeVest device's electrodes are dry and non-adhesive to provide patient comfort.

The monitor weighs about 1.8 pounds, making it the lightest external defibrillator available. The device contains pushbuttons and indicators for the user, as well as a speaker for sounding alerts and voice prompts.

Treatment cycle less than a minute

When the device detects a treatable arrhythmia, an alert sequence begins, giving a conscious patient time to stop the treatment. This keeps inappropriate arrhythmia detections from becoming inappropriate shocks, a key difference between the wearable defibrillator and an implanted defibrillator.

If the patient holds the two "response" buttons at any time during the treatment sequence, the alerts stop and no shocks will be delivered.

If the patient does not respond or releases the response buttons, the device continues to give alerts and spoken warnings to bystanders that a treatment shock is about to be delivered.

Gel within the electrodes is released just prior to delivering the treatment shock in order to deliver the shock most efficiently.

The entire event, from arrhythmia detection to delivery of the shock treatment, typically takes less than one minute.

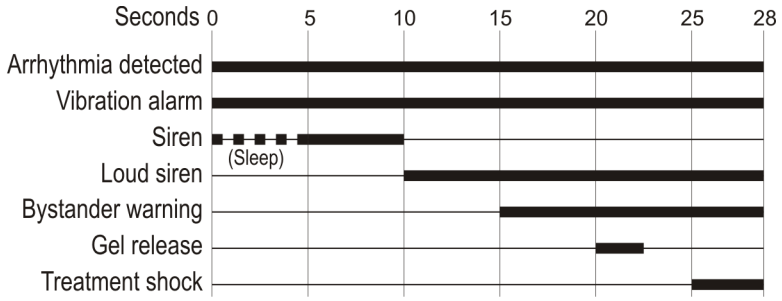
If the arrhythmia continues after the first shock, up to 5 shocks may be given.

Treatment sequence

After identifying VF, there is a response time of 25 seconds (programmable up to 55 seconds) to allow the patient time to respond to the alerts, as shown below. The lower threshold for VF identification can be set from 120 to 250 beats per minute (bpm), with a default of 200 bpm.

If the system identifies VT, there is a response time of 60 seconds (programmable up to 180 seconds). The lower threshold for VT identification can be set from 120 to the VF threshold, with a default setting of 150 bpm.

Typical treatment sequence during ventricular fibrillation



During normal operation, the vibration alert gets activated first, then the siren alert. If an arrhythmia is detected during the sleep interval, the vibration and siren alerts are activated together. Programming the sleep interval is discussed in the Service Manual.

The LifeVest device can deliver up to 5 defibrillating pulses during an arrhythmic episode. The energy of the pulses can be programmed individually to between 75 and 150 joules (±5%), with a default setting of 150 joules.

ECG recording of events

The patient's electrocardiogram (ECG) is recorded for all detected arrhythmias, including before and after treatment. The patient can also manually record an ECG at any time by pressing the response buttons on the device.

Patients transmit information from their devices by telephone to the LifeVest Network. Physicians can then access their patient's information from virtually any computer with an Internet connection. LifeVest Network allows physicians to view ECG recordings, patient use, ECG interference, and other device-related information.

Biphasic waveform delivers efficient energy

The LifeVest device delivers its defibrillating energy in a biphasic truncated exponential waveform, whereby the signal goes positive, then negative very quickly. This type of waveform has been shown to be effective defibrillating at lower energy levels.

The amplitude and width of the phases of the energy waveform are automatically adjusted to deliver a precise energy amount regardless of the patient's body impedance.

Reliable detection algorithm

The LifeVest has proved to be effective at detecting ventricular tachycardia (VT) and ventricular fibrillation (VF). The detection algorithm was 100% sensitive for VF and 95% sensitive for VT in bench testing. The algorithm uses the patient's baseline vectorcardiogram as a template for detecting changes in cardiac signal morphology in addition to standard rate determination of arrhythmias.

Safety information

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

Terms used


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


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

Warning

- A complete understanding of the manual is necessary before prescribing or training a patient to use the LifeVest System. Failure to understand how to use the system could lead to an inappropriately assembled or misused device resulting in a device that is unable to deliver treatment or delivers inappropriate treatment.
- Before prescribing, the healthcare professional should consider whether the patient will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The healthcare professional should consider mental, visual, physical and auditory limitations that may impact a patient's ability to successfully interact with the system. Failure of the patient to successfully interact with the system may result in device alarms, failure to deliver treatment, or delivery of inappropriate treatment.

Rescue defibrillation

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

Shock hazard

- Do not attempt to open the monitor, battery, battery charger, or modem. This may expose you to high voltage and damage the system.

To help ensure proper operation

- Use only the cables, batteries, and accessories specified in this manual. If you use any other items, the system may not operate correctly.
- Operate the system within the range of 0°C to 50°C (32°F to 122°F), up to 95% relative humidity (non-condensing), and up to 10,000 feet in altitude.

2: Patient fitting

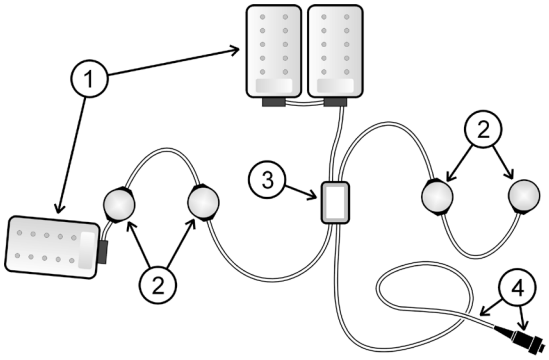
This section explains how to fit a patient and assemble the components of the LifeVest belt.

Before you start

- Gather the electrode belt and garment.
- Read through these procedures completely.
- Familiarize yourself with the components and what they're called.
- Have a clean, flat area to lay out and assemble the components, such as a table or counter. You might want to put a towel or cloth on the table to protect the components as you assemble them.

Components of the LifeVest belt assembly

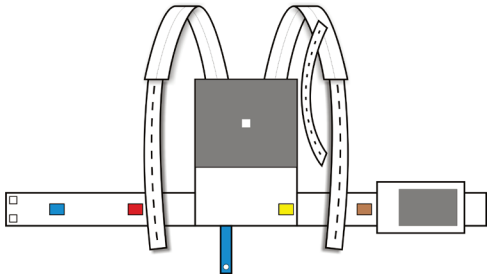
Electrode Belt

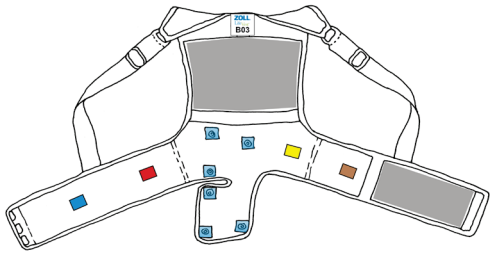


The belt comes in one size and fits any patient. The parts of the electrode belt are as follows:

1 Therapy pads
2 ECG electrodes (also called ECG sensors)
3 Vibration box
4 Connector

Garment





The garment comes in a variety of sizes to suit the patient.

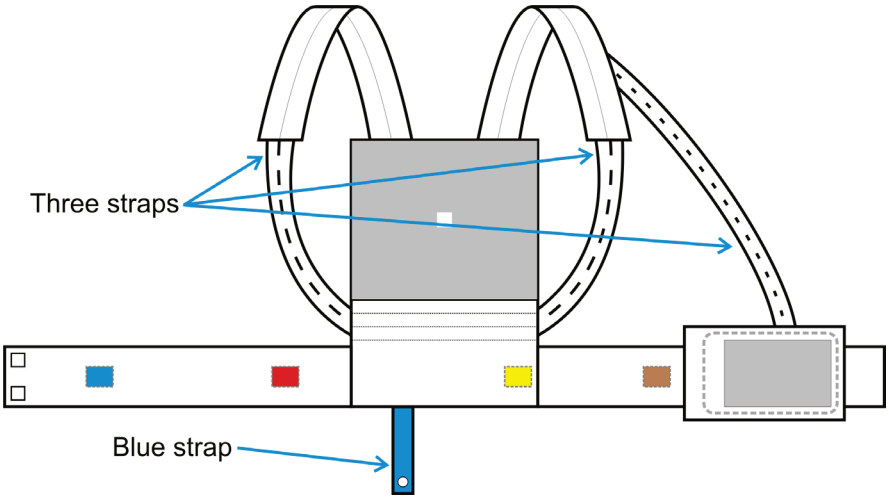
In this chapter, you will measure the patient to determine what size garment to use.

There are two style garments, with slight variations in fit and assembly. See next page to determine which garment you have.

Which style garment do you have?

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

Garment A

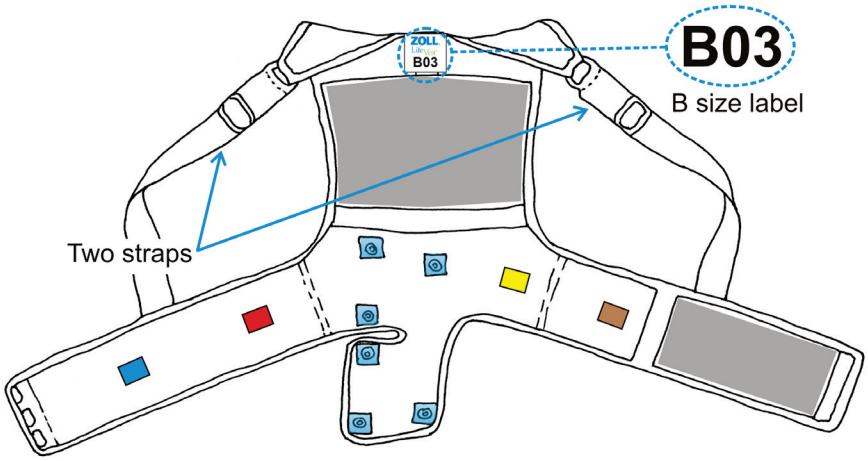


This style garment has three straps at the top, and a small blue strap at the bottom.

We call this garment style A.

If you have this style garment, see page 2-3.

Garment B



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

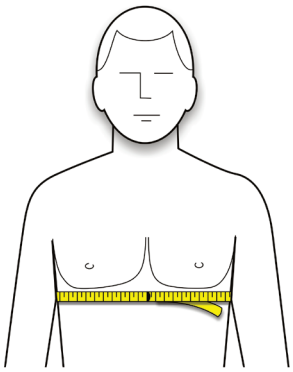
We call this garment style B.

If you have this style garment, see page 2-12.

Measuring the patient for garment A

Measure the patient to determine what size garment A to use.

If you are using garment B, see page 2-12.

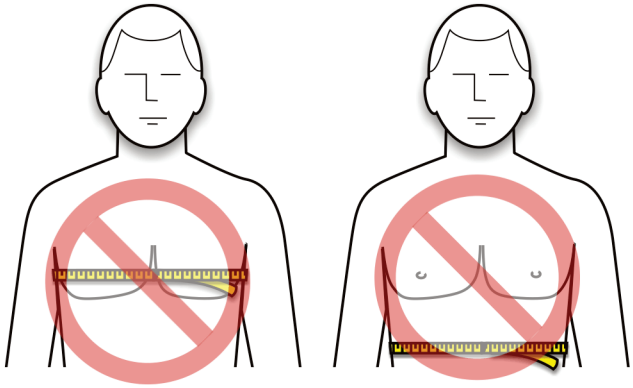


1 Have patient stand and remove all upper body clothing, including undergarments.

2 Place a measuring tape around the patient's chest, centered at the xiphoid.

Measure to the closest inch or centimeter.

Don't measure too high or too low across the patient's torso.



3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement		Garment
inches	centimeters	10A0991-A0X
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit the patient.

Example measurement

Chest measurement inches	Chest measurement centimeters	Garment 10A0991-A0X
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

As an example, let's say the patient measures 44 inches.

According to the chart, a patient measuring 44 inches needs garment size A06.

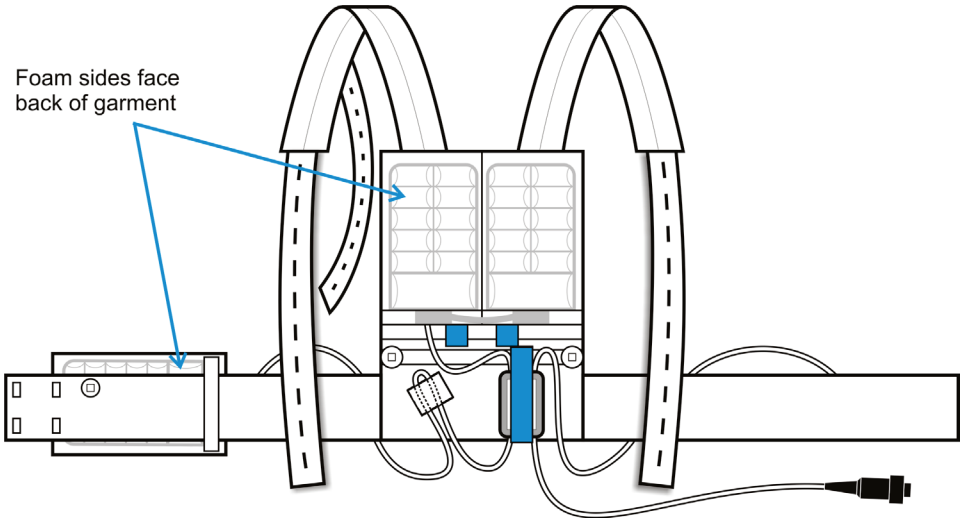
Assembling the electrode belt to garment A

Refer to this section for garment A. If you have garment B, see page 2-14.

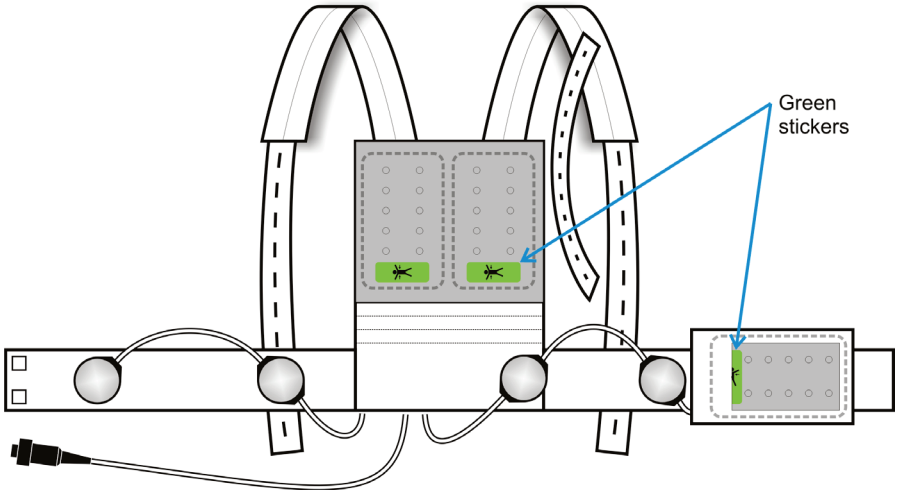
Assemble the belt and garment as described in the Patient Manual, but do not fasten the straps.

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

Outside view
This side faces away from the patient's body when worn. The foam sides of the electrodes face the back of the garment.



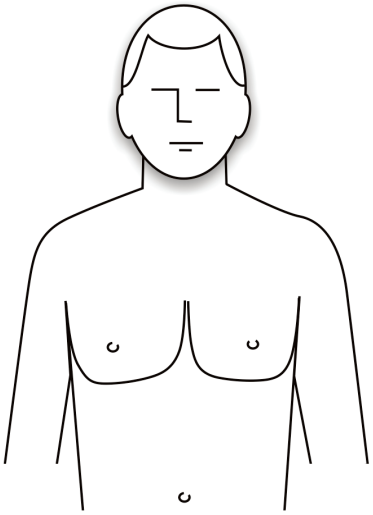
Inside view
This side faces toward the patient's body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting garment A on the patient and finalizing assembly

Refer to this section for garment A. If you have garment B, see page 2-15.

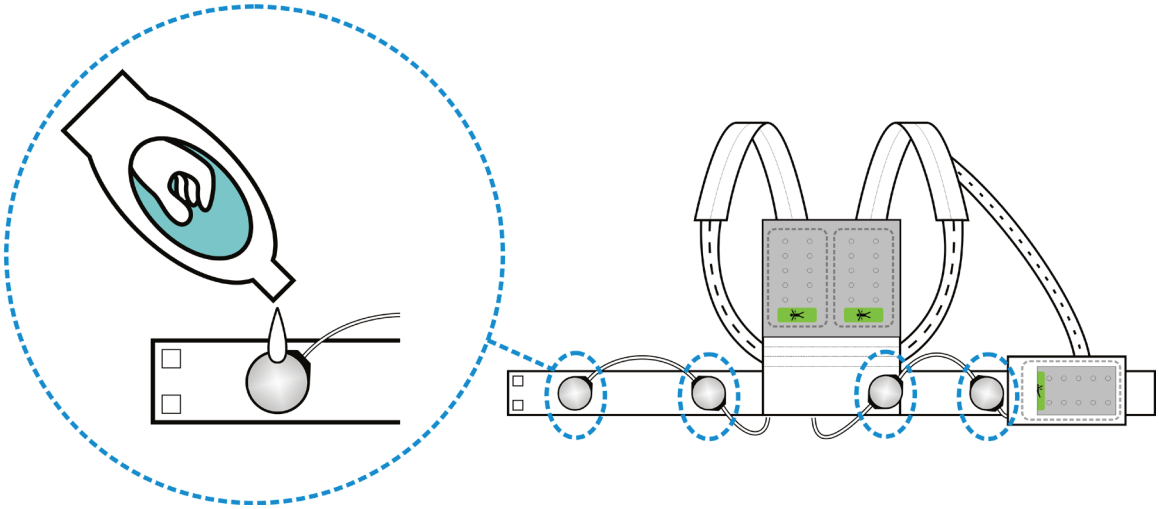
Follow these instructions to help the patient put on the assembled garment, then adjust the garment for a proper fit.

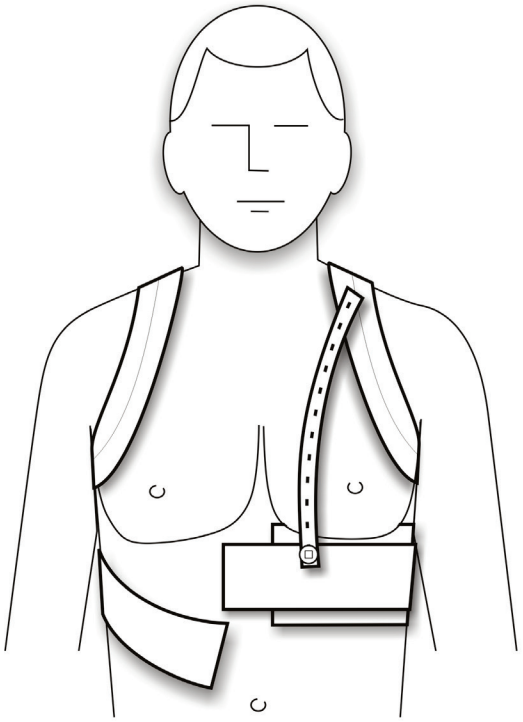


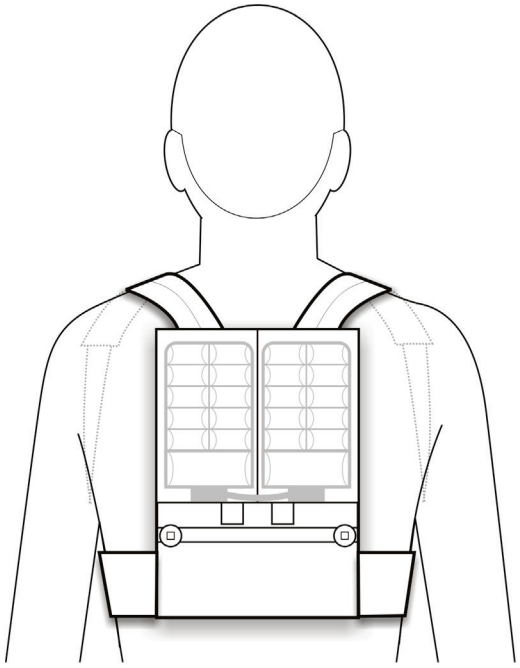
1 Have the patient remove all clothing and undergarments from the upper body before putting on the garment.

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

2 Apply unscented hand lotion or skin cream to the four ECG (round) electrodes.





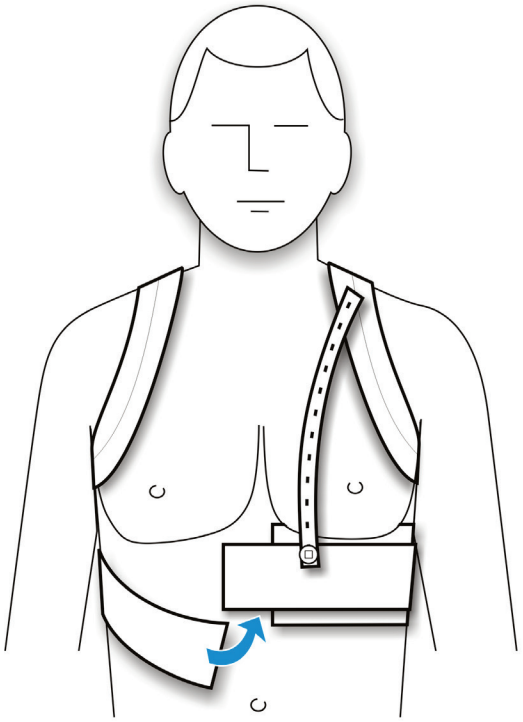


3 Help the patient put on the garment, making sure:

- The garment doesn't get twisted as the patient puts it on.
- The silver fabric pockets touch the patient's bare skin.

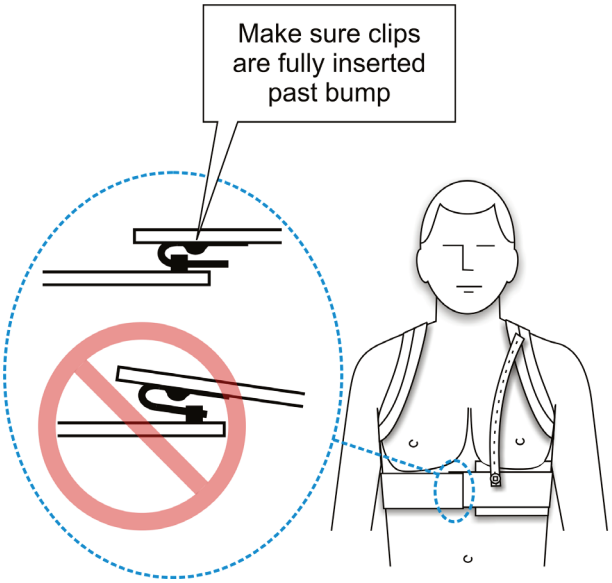
If patient is a female:

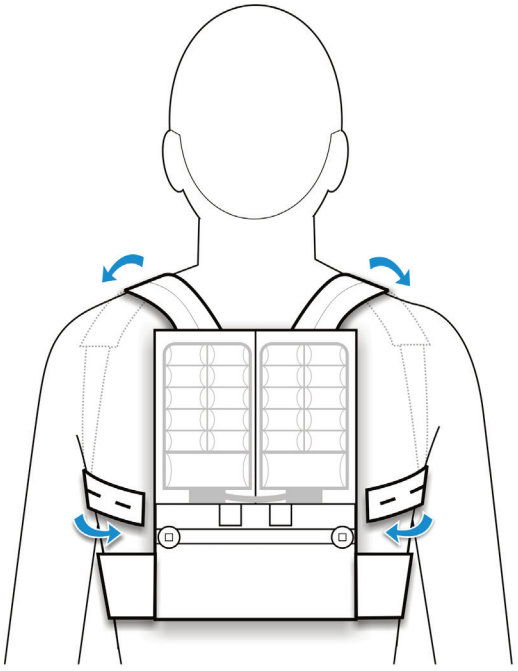
- Patient should wear a bra OVER the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against the patient's body rather than the underside of the patient's left breast.



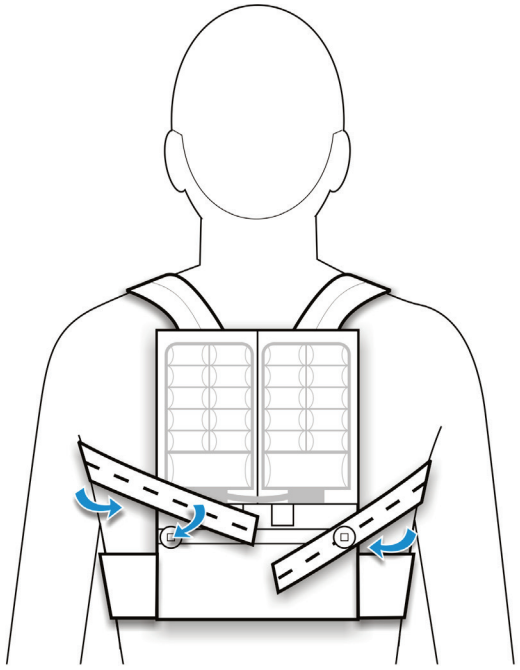
4 Connect the garment ends together in the front.

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



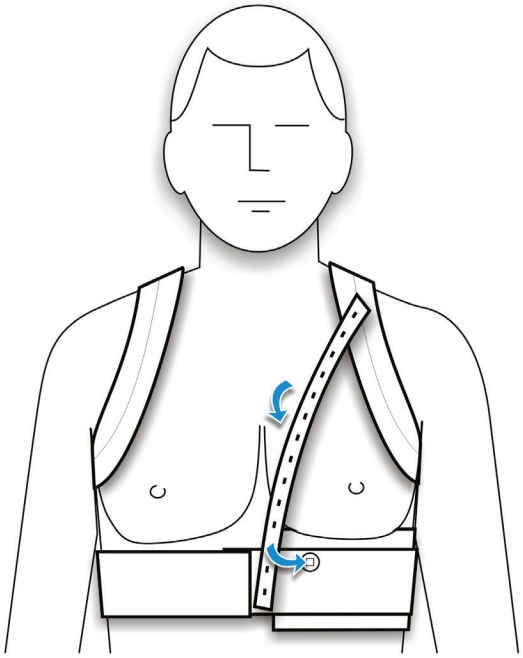


5 Position straps over the patient's shoulders and bring them under the patient's arms around to the patient's back.



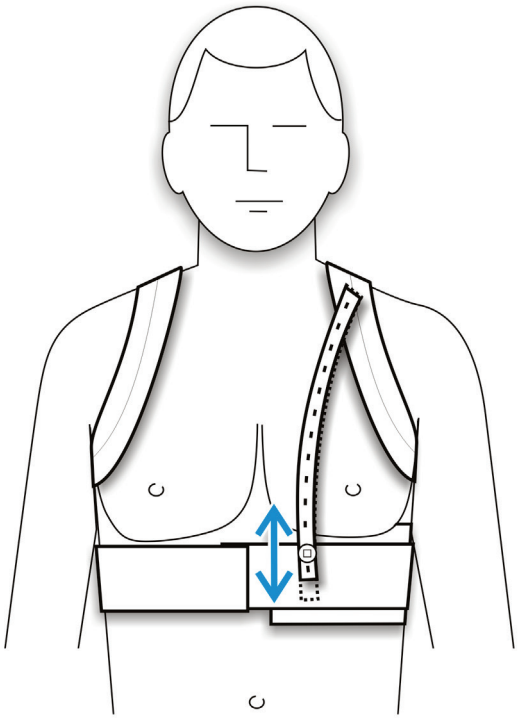
6 Without stretching the strap, find the hole that lines up with the button. Then stretch the strap slightly and attach the button to the next hole.

- Do not cut the strap.
- Excess strap can be folded over and buttoned again.
- Repeat for each of the two long straps.
- Adjust the garment for a good fit.



7 Bring the remaining strap down the front of the patient's chest and button it to the front of the garment.

- Do not cut the strap.
- Excess strap can be folded over and buttoned again.

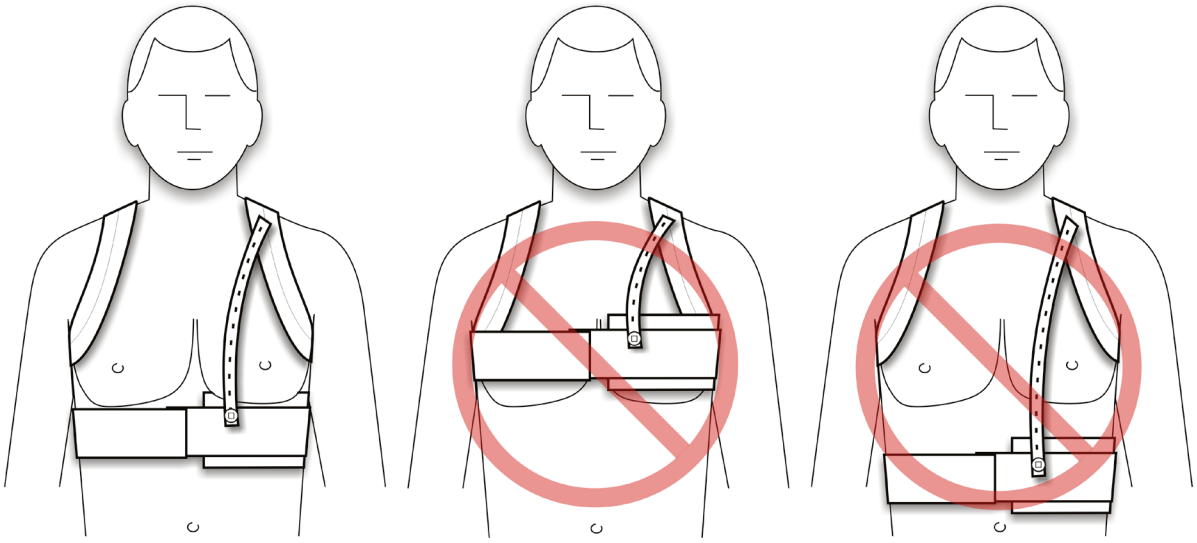


8 Check the position of the garment on the patient's body and make sure it's not too high or too low.

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

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

- The garment **should** cross the patient's body just below the breastbone.
- The garment **should not** be as high as the patient's nipples.
- The garment **should not** be as low as the patient's belly button.



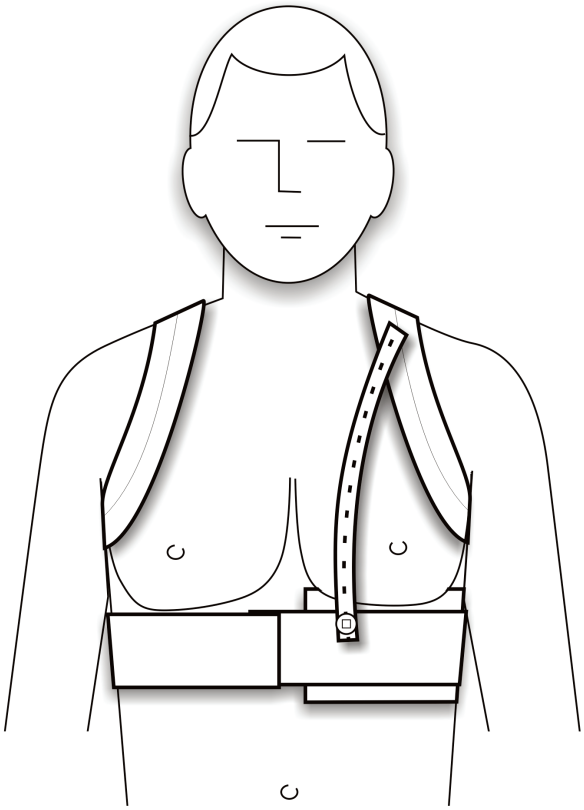
Positioned properly

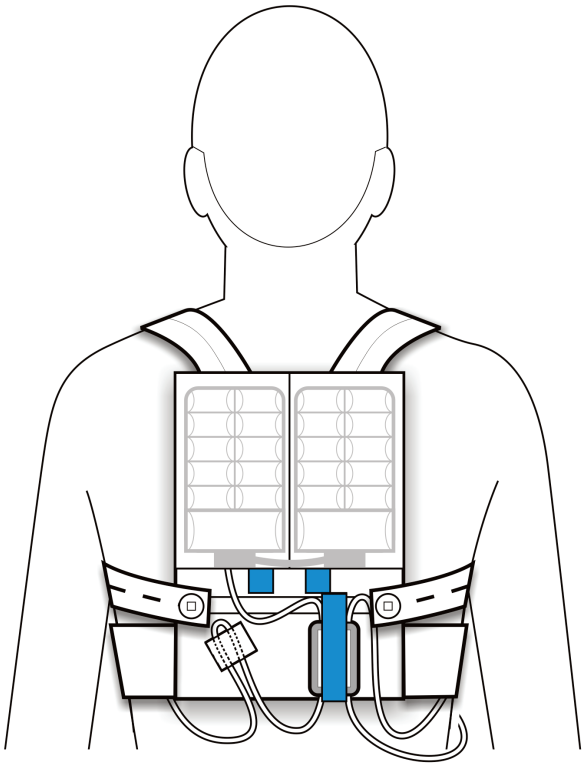
Too high

Too low

9 Have the patient look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against patient's skin.
- The ECG electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green stickers) MUST TOUCH THE PATIENT'S BODY for the device to work properly.
- None of the cabling interferes with the ECG electrodes or therapy pads.
- The garment is being worn correctly. It should look like the figures below.

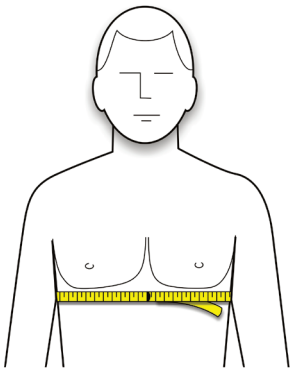




Measuring the patient for garment B

Measure the patient to determine what size garment A to use.

If you are using garment A, see page 2-3.

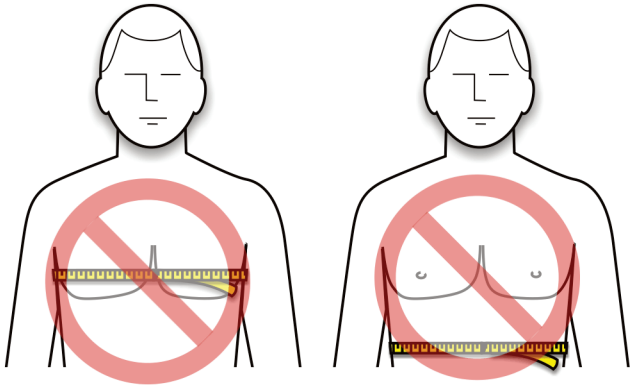


1 Have patient stand and remove all upper body clothing, including undergarments.

2 Place a measuring tape around the patient's chest, centered at the xiphoid.

Measure to the closest inch or centimeter.

Don't measure too high or too low across the patient's torso.



3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement		Garment
inches	centimeters	10A1004-B0X
26-31	66-80	B01
32-37	81-95	B02
38-44	96-112	B03
45-51	113-130	B04
52-56	131-142	B05

The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit the patient.

Example measurement

Chest measurement		Garment
inches	centimeters	10A1004-B0X
26-31	66-80	B01
32-37	81-95	B02
38-44	96-112	B03
45-51	113-130	B04
52-56	131-142	B05

As an example, let's say the patient measures 44 inches.

According to the chart, a patient measuring 44 inches needs garment size B03.

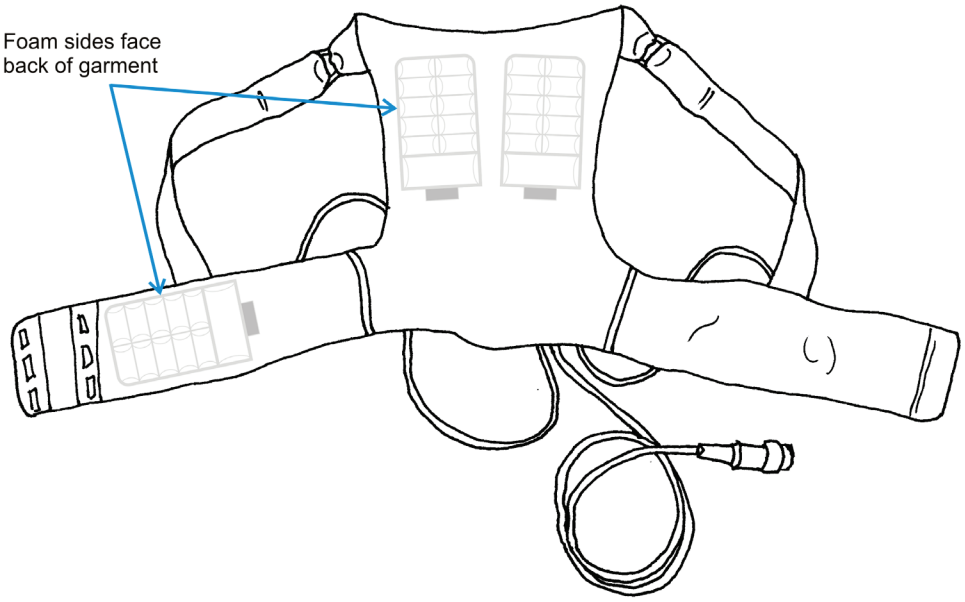
Assembling the electrode belt to garment B

Refer to this section for garment B. If you have the garment A, see page 2-5.

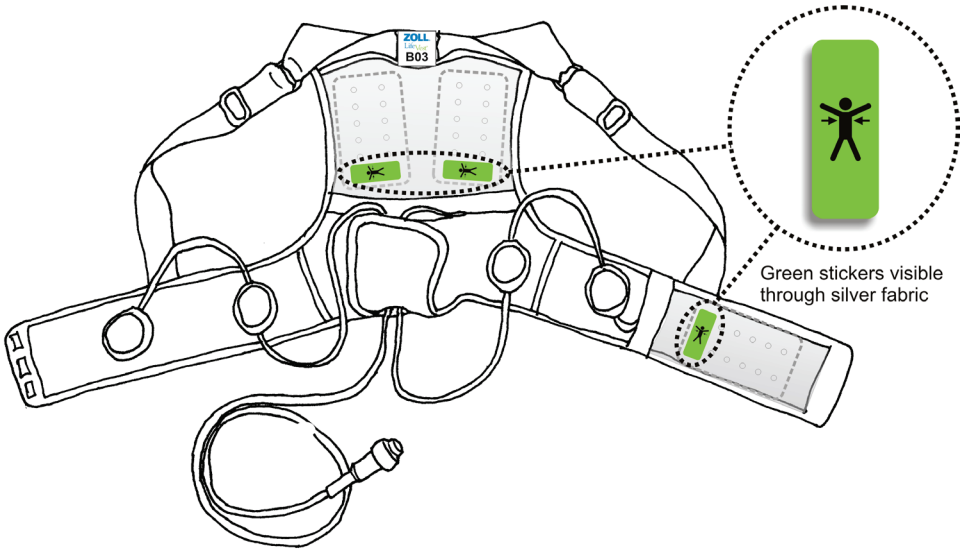
Assemble the belt and garment as described in the Patient Manual.

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

Outside view
This side faces away from the patient's body when worn. The foam sides of the electrodes face the back of the garment.



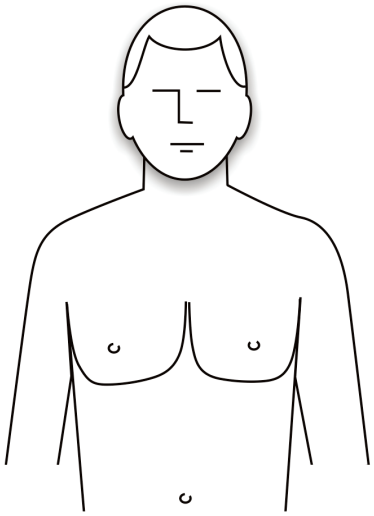
Inside view
This side faces toward the patient's body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting garment B on the patient and finalizing assembly

Refer to this section for garment B. If you have garment A, see page 2-6.

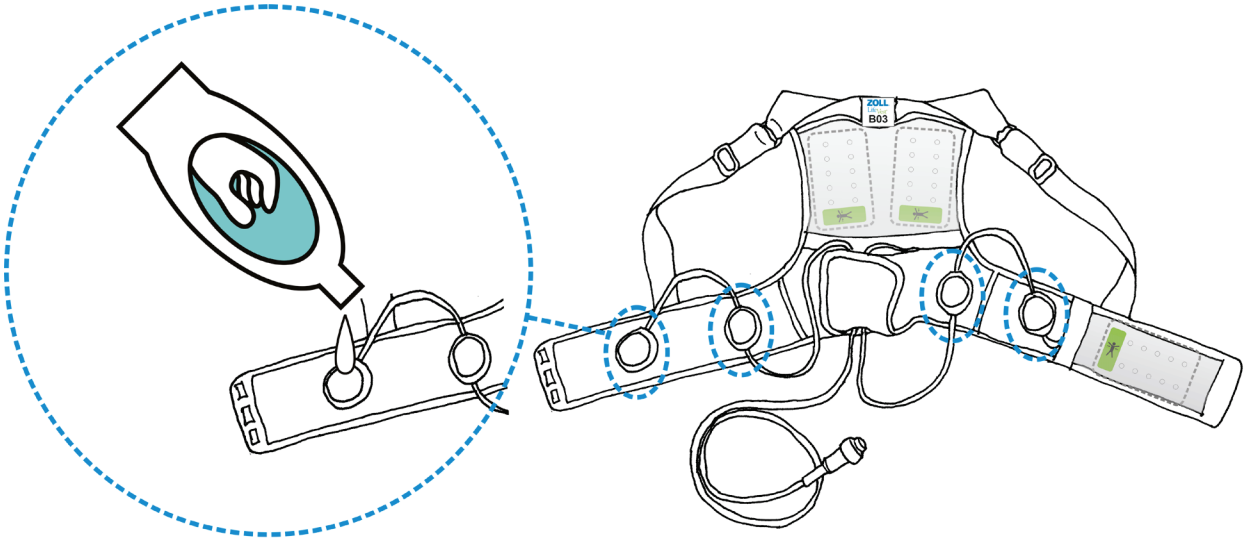
Follow these instructions to help the patient put on the assembled garment, then adjust the garment for a proper fit.

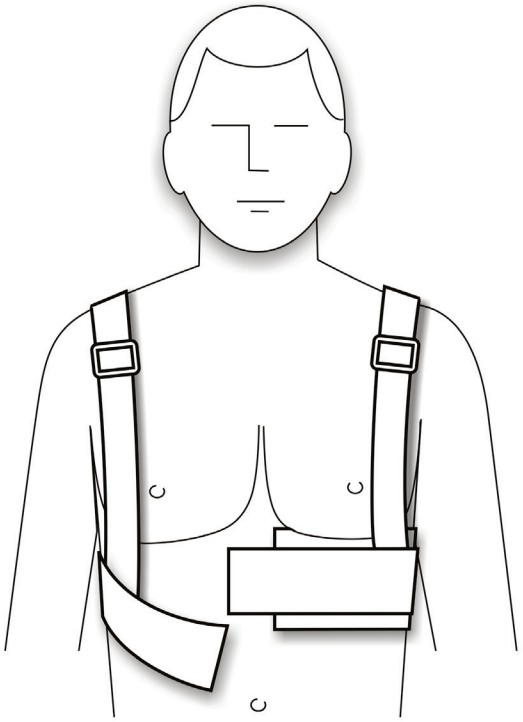


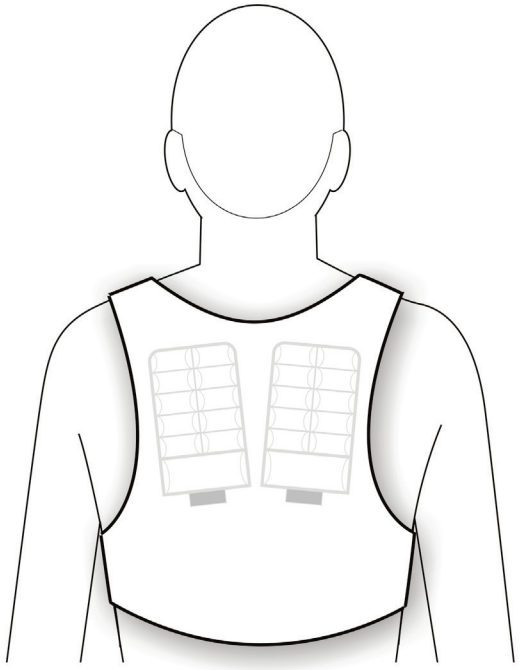
1 Have the patient remove all clothing and undergarments from the upper body before putting on the garment.

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

2 Apply unscented hand lotion or skin cream to the four ECG (round) electrodes.





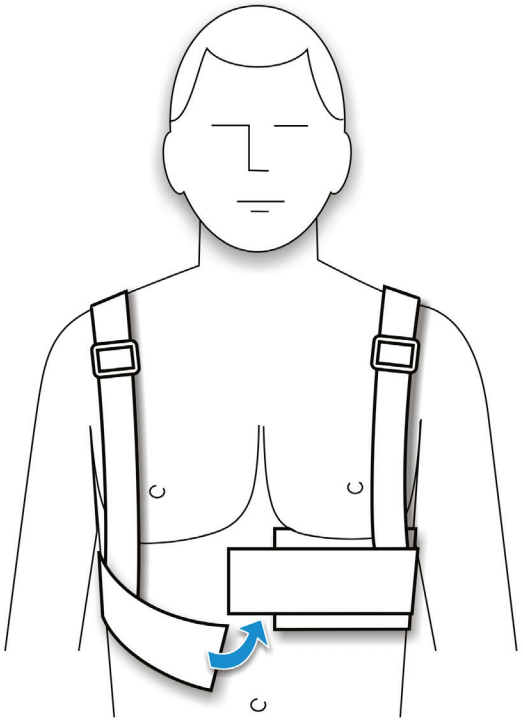


3 Help the patient put on the garment, making sure:

- The garment doesn't get twisted as the patient puts it on.
- The silver fabric pockets touch the patient's bare skin.

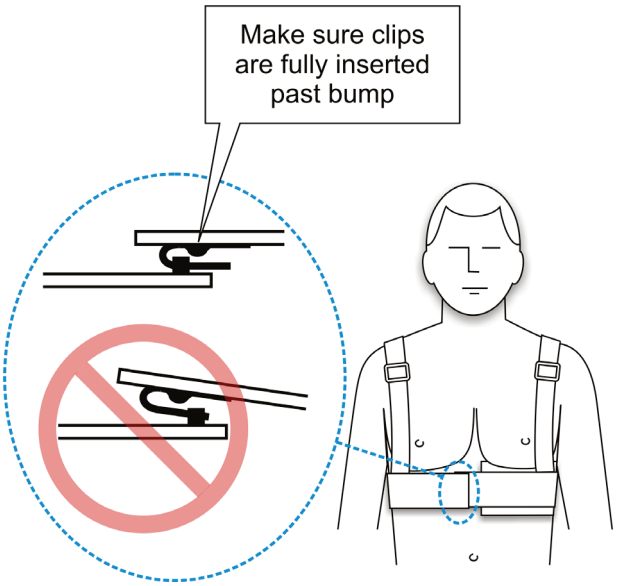
If patient is a female:

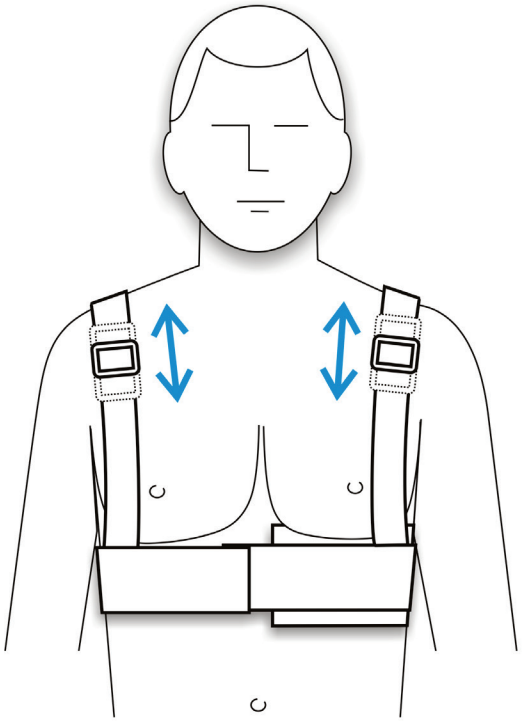
- Patient should wear a bra OVER the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against the patient's body rather than the underside of the patient's left breast.



4 Connect the garment ends together in the front.

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



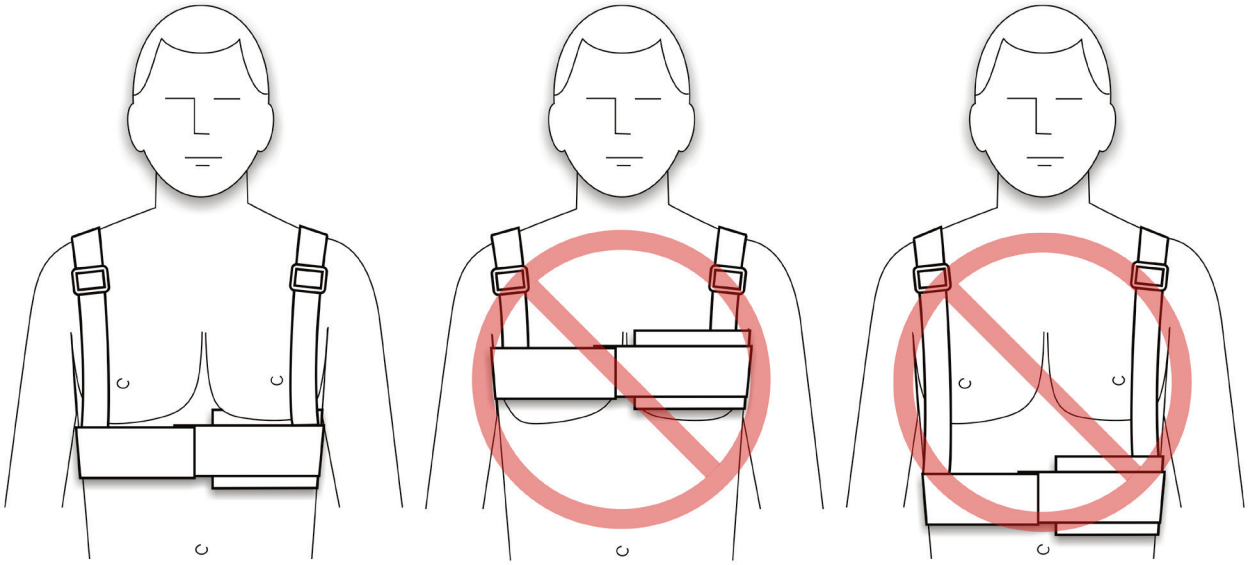


5 Check the position of the garment on the patient's body and make sure it's not too high or too low.

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

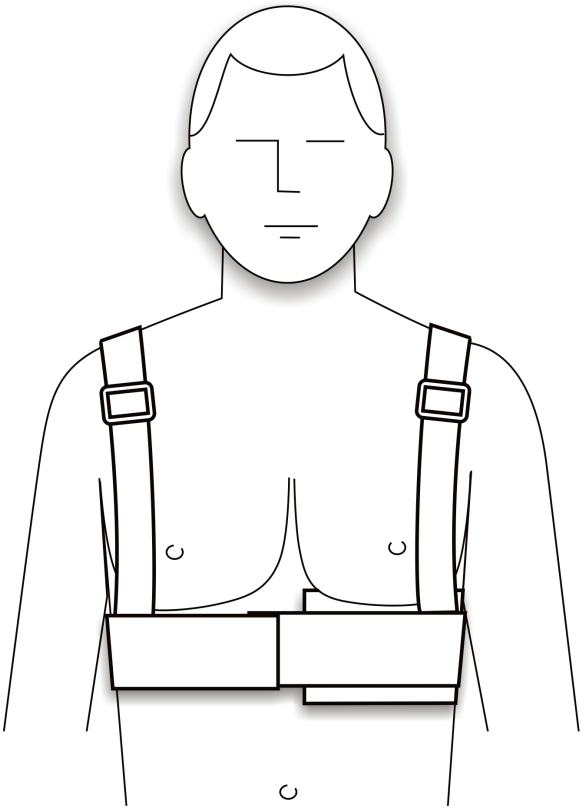
Move the buckles to position the garment properly, and for a snug fit.

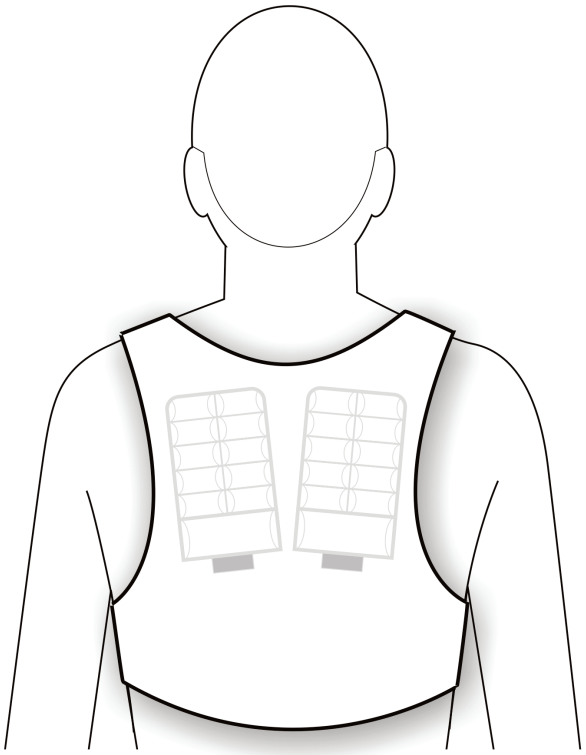
- The garment **should** cross the patient's body just below the breastbone.
- The garment **should not** be as high as the patient's nipples.
- The garment **should not** be as low as the patient's belly button.



6 Have the patient look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against patient's skin.
- The ECG electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green stickers) MUST TOUCH THE PATIENT'S BODY for the device to work properly.
- None of the cabling interferes with the ECG electrodes or therapy pads.
- The garment is being worn correctly. It should look like the figures below.





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3: Patient training

This section gives guidelines for instructing the patient about the LifeVest system and how to respond to alerts.

We suggest that you:

1 Go over the main points below.

2 Explain the operating modes and alerts as described on page 3-3.

3 Demonstrate the types of alerts that can occur as described on page 3-4.

Main points to teach the patient

When you instruct the patient, stress the following points, explained below and on the following page:

- If you get a siren alert, hold the response buttons.
- If you get a gong alert, read the message.
- If you get shocked, call your doctor and send data.
- Review the Patient Manual so that the patient is familiar with its contents and where to find things.

If you get a siren alert, hold the response buttons

- The response buttons will light red when you are to press them so they will be easy to find, even in the dark.
- As long as you are able to, hold the response buttons to stop a treatment. As long as you remain conscious and hold the response buttons, you are in no danger of receiving a treatment shock.
- If you lose consciousness, of course you will not be able to hold the response buttons. In this case, and if the lethal heart rhythm continues, the device will go through the treatment cycle and deliver a treatment shock.
- It is very important that only you (the patient) hold the response buttons. This is how the monitor knows whether or not you are conscious. DO NOT let anyone else hold the response buttons for you.

If you get a gong alert, read the message

- Read the display and do what it says to fix the problem. Check the Patient Manual (section 5) for reminders about what to do for various messages.
- Keep in mind that the monitor gives alerts, messages, and voice prompts to guide you in what to do.

If you have an event, call your doctor and send data

- If you have any kind of cardiac event, even if you manage to stay conscious and hold the response buttons, you should contact your physician and report the incident.
- Any cardiac event is recorded by the monitor so you can send the data later.
- As soon as possible after any cardiac event, you should send data using the modem.

Review the contents of the Patient Manual

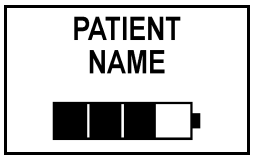
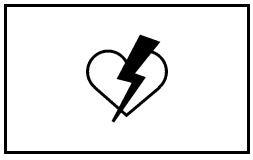
Review how to:

- change and charge the battery
- change the garment
- disassemble and reassemble the garment and electrode belt
- send data using the modem

Also be sure to review the warnings and cautions located in the Patient Manual.

Summary of operating modes

As you instruct the patient, keep in mind that the device has basically three operating modes:

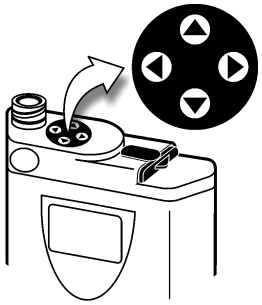
Mode	Message	What it means	What the patient needs to do
Normal monitoring – no alerts		Monitor is operating normally.	Nothing.
Gong alert	Various messages can appear, for example:   	Patient needs to take action.	Read monitor and do what it says. Check Patient Manual for more information. See section 5, *Responding to alerts*.
Siren alert	 and 	An arrhythmia is being detected.	Press and hold the response buttons if conscious. Check Patient Manual for more information. See section 5, *Responding to alerts*.

Demonstrating the alerts

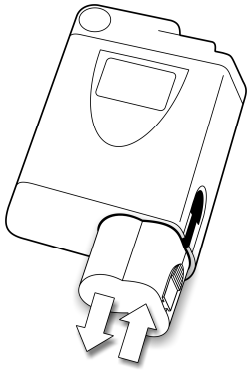
Demonstrate the alerts to help the patient learn how to respond. Follow the procedures below to:

- Place the system in training mode, then
- Simulate alert conditions.

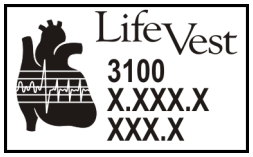
How to enter training mode

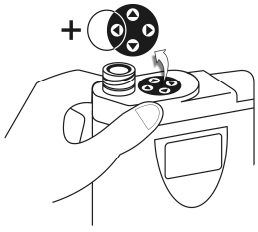


View the navigation buttons from the top of the monitor with the display facing you.



1 Remove and reinsert the battery.

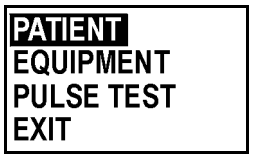




2 While the opening screen is displayed, hold the response buttons and hold ◄ at the same time. Continue holding these buttons until the screen changes.

This screen may be displayed for more than 10 seconds.

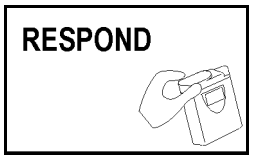
3 Press ▲ or ▼ to choose a language, then press ►.



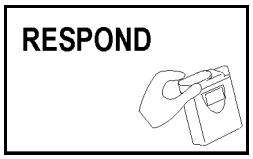
4 With **PATIENT** selected, press ►.

5 Press ▲ or ▼ to select **TRAINING**, then press ►.

6 Press ► to select **OK**, then press the response buttons.

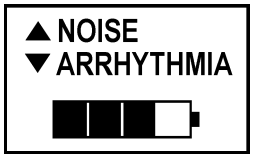


7 Press the response buttons again.



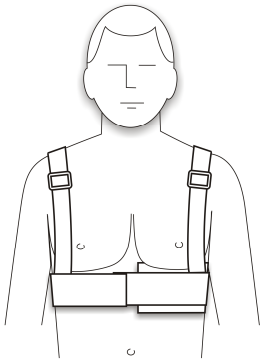
8 The monitor is now in training mode, with these messages alternating.

Press the response buttons to silence the gong alert.

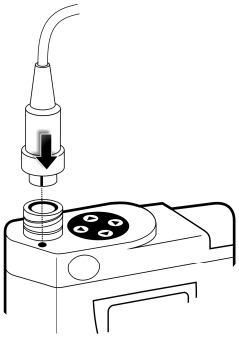


9 The monitor is ready to demonstrate the noise and arrhythmia alerts.

Connect patient for training mode

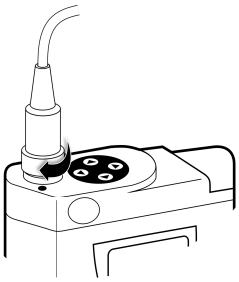


1 Outfit the patient with the electrode belt and garment.

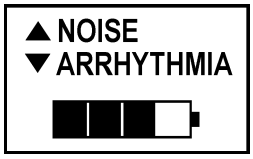


2 Connect the electrode belt to the monitor.

3 Continue with the procedures on the next page.



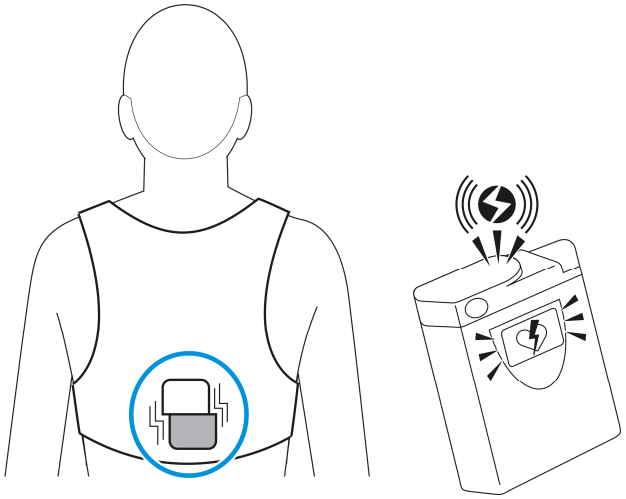
How to demonstrate the arrhythmia alerts

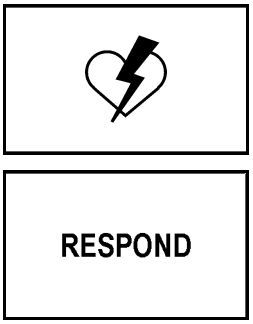


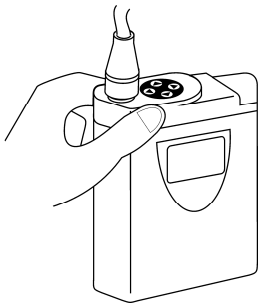
1 With this screen displayed, press ▼.

The device runs through the alert sequence that will occur if an arrhythmia is detected:

- Vibration alert activates and response buttons light red.
- Siren alert sounds.
- Display shows that an arrhythmia has been detected and tells patient to press response buttons.
- Voice prompts announce to bystanders that that patient is going to be shocked.







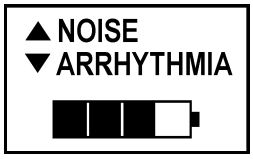
2 Tell the patient to press and hold the response buttons during the alerts.

The alerts stop as long as the patient holds the response buttons.

Tell the patient to release the response buttons to show that the alert sequence resumes.

3 To stop the arrhythmia demonstration, press ▼.

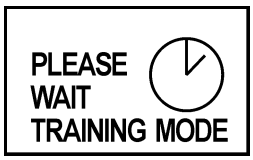
How to demonstrate a noise alert



1 With this screen displayed, press ▲.

2 Tell the patient what to do when the gong alert sounds:

- Read the display. This particular message states that ECG signal is not clear. The ECG electrodes are not sending a good signal to the monitor.
- Take action to correct problem. In this case, adjust the belt so that the ECG electrodes make better contact with the skin.
- Press response buttons if display so states. This stops the gong alert.



3 With a noise alert, when you press the response buttons, the monitor checks for an improvement in the ECG signal.

For the demonstration, the ADJUST BELT message returns.

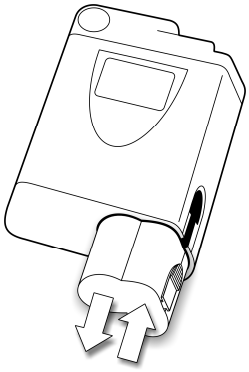
4 After three cycles, the monitor displays this message.

When this happens, the patient is expected to check the belt as described in the Patient Manual.

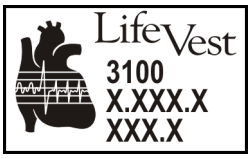
Pressing the response buttons does not make this message go away.

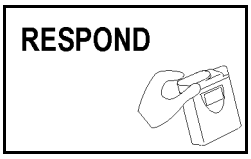
5 To stop the noise alert demonstration, press ▲.

How to exit training mode

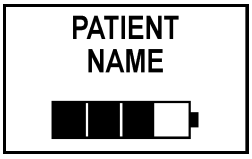


1 Remove and reinsert the battery.





2 Press the response buttons as normal.



3 Monitor resumes normal operation.

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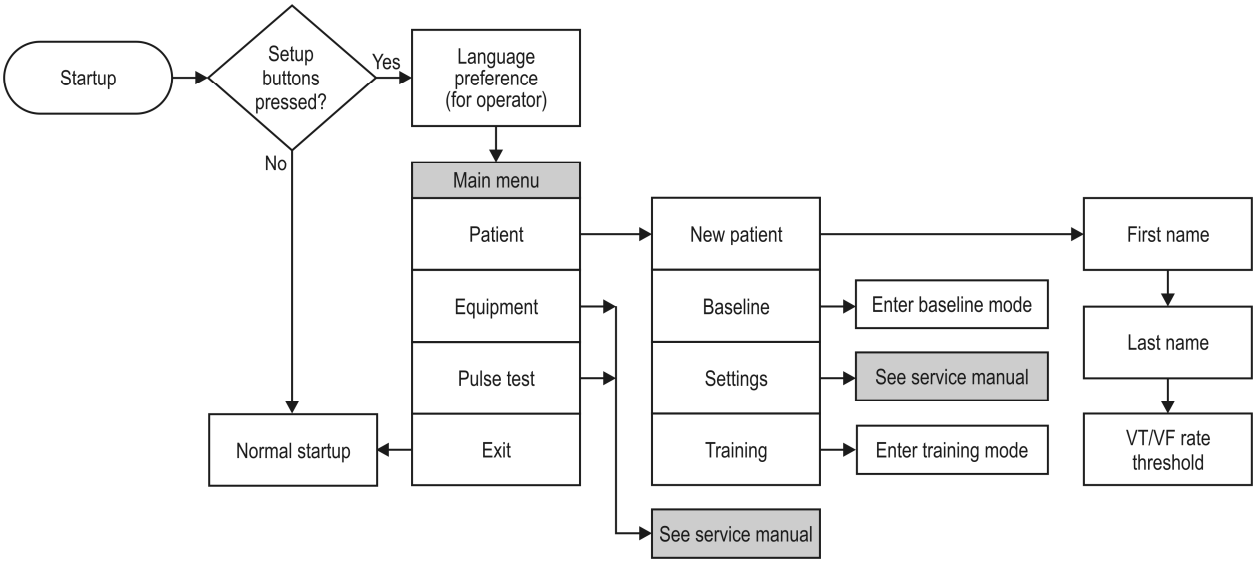
4: Monitor setup for a new patient

About this section

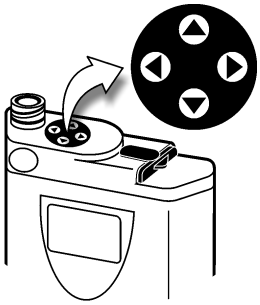
- This section covers the basic procedures and menus for setting up the monitor before use by a new patient.
- If you need to change any other settings, see the programming section of the Service Manual.

Menu structure

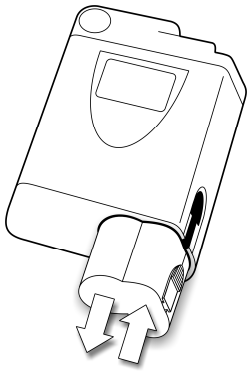


How to put the monitor in setup mode

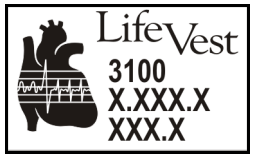
Before entering new patient information, follow this procedure to place the monitor in setup mode.

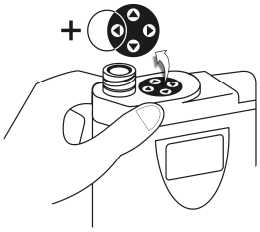


View the navigation buttons from the top of the monitor with the display facing you.



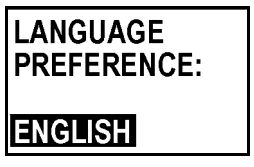
1 Remove and reinsert the battery.





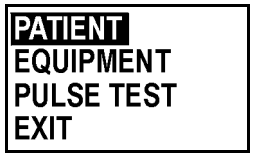
2 While the opening screen is displayed, hold the response buttons and hold ◄ at the same time. Continue holding these buttons until the screen changes.

This screen may be displayed for more than 10 seconds.



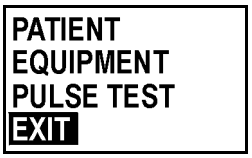
3 Press ▲ or ▼ to choose a language, then press ►.

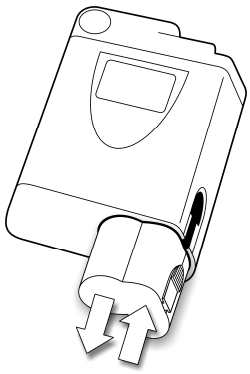
Note: The language you choose only affects the setup screens and will not affect the patient screens.



4 The main menu displays, showing that the monitor is in setup mode.

You may now proceed to program the monitor. See page 4-4 for details on setting up a new patient.



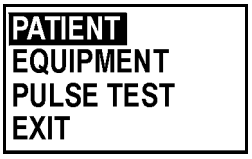


5 When you are finished programming the monitor, do one of the following to return to normal operation:

- Navigate back to the main menu, select **EXIT**, then press ►.
- Wherever you are in any menu, remove and reinsert the battery.

How to set up a new patient

New patient setup consists of entering the patient's name and the rate thresholds for ventricular tachycardia and ventricular fibrillation.



1 With the monitor in setup mode (see page 4-2), and with **PATIENT** selected, press ►.

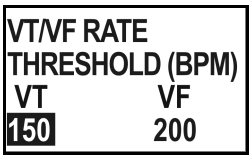
2 With **NEW PATIENT** selected, press ►.

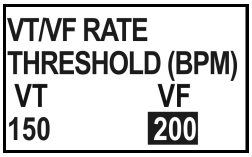
Note that the response buttons light red to show you are in edit mode.

3 Enter patient's first name as follows:

- Press ▲ and ▼ to select characters.
- To advance to next character, press ►. To go back, press ◄.
- To save the name, press the response buttons.

4 Enter patient's last name. Follow same procedure as with first name.





5 To accept the values shown for the rate thresholds without changing them, press the response buttons.

To change one or both values:

- Use ► or ◄ to select the threshold you want to change.
- Then press ▲ or ▼ to change the value.
- Repeat to change the other value.
- To save the new values, press the response buttons.

6 Press ► or ◄ to select **OK**, then press the response buttons.

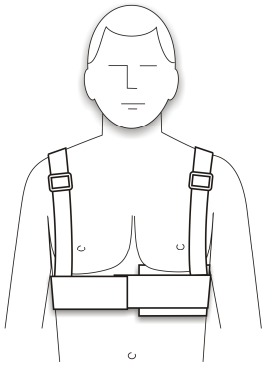
Baseline the patient as described on the next page.

How to baseline a patient

The monitor's arrhythmia detection algorithm uses the patient's baseline ECG as a template to help determine if a treatable arrhythmia exists.

When you set up a new patient, the monitor automatically goes into the baseline mode when you exit the setup mode or the next time the system powers up.

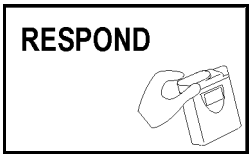
Follow this procedure to baseline the patient.



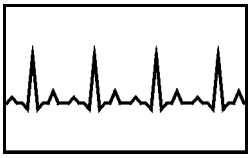
1 Prepare the patient, attach the garment and electrode belt, and connect the electrode cable to the monitor.

Have the patient sitting or lying down, relaxed, and not talking or moving around.

Put a fully-charged battery into the monitor.

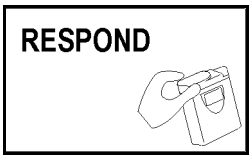


2 When you see the **READY TO RECORD** message, press the response buttons.



This message displays while the monitor records the baseline. The monitor also shows the patient's ECG.

Baseline recording time will vary depending on the patient, strength of the ECG signal, and the amount of noise on the ECG signal. Recording the baseline may take up to 5 minutes.



3 When you see the **BASELINE COMPLETE** message, press the response buttons.

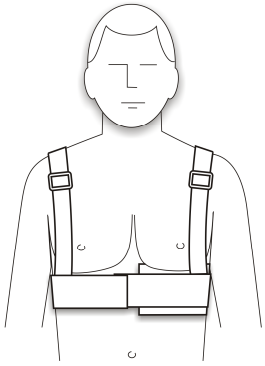
The monitor returns to normal operation.

If you get the **BASELINE FAILED** message, the monitor could not learn the patient's baseline. Do the following:

- Verify that the ECG electrodes are properly contacting the patient's skin. You may need to clean the skin or clip excessive hair before fitting the patient with the electrode belt and garment.
- Try to baseline the patient again. Remove the battery and repeat this procedure starting on the previous page.
- If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, discontinue attempting to baseline the patient and call ZOLL.

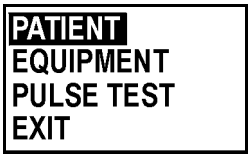
How to manually re-baseline a patient

Use this procedure if you need to manually re-baseline a patient.



1 Prepare the patient, attach the garment and electrode belt, and connect the electrode cable to the monitor.

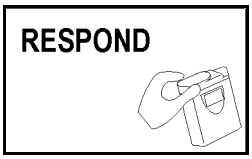
Have the patient sitting or lying down, relaxed, and not talking or moving around.



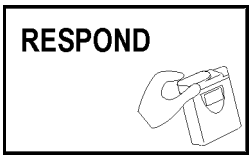
2 With the monitor in setup mode (see page 4-2), press ▲ or ▼ to select **PATIENT**, then press ►.

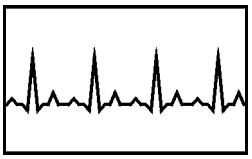
3 Press ▲ or ▼ to select **BASELINE**, then press ►.

4 Press ► or ◄ to select **OK**, then press the response buttons.



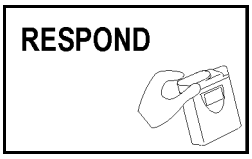
5 When you see the **READY TO RECORD** message, press the response buttons.





This message displays while the monitor records the baseline. The monitor also shows the patient's ECG.

Baseline recording time will vary depending on the patient, strength of the ECG signal, and the amount of noise on the ECG signal. Recording the baseline may take up to 5 minutes.



6 When you see the **BASELINE COMPLETE** message, press the response buttons.

The monitor returns to normal operation.

If you get the **BASELINE FAILED** message, the monitor could not learn the patient's baseline. Do the following:

- Verify that the ECG electrodes are properly contacting the patient's skin. You may need to clean the skin or clip excessive hair before fitting the patient with the electrode belt and garment.
- Try to baseline the patient again. Remove the battery and repeat this procedure starting on the previous page.
- If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, discontinue attempting to baseline the patient and call ZOLL.

5: LifeVest Network

About LifeVest Network

LifeVest Network is a secure Internet Web site for viewing data related to the LifeVest wearable defibrillator.

From LifeVest Network, you can view ECG recordings, treatment events, and compliance data.

You can view and print a number of reports related to the LifeVest.

For more information about LifeVest Network, and to set up your LifeVest Network account, contact ZOLL.

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6: Clinical information

Indications

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 18.75 kilograms (41.3 pounds) or greater. See *Device use for patients under 18 years of age* on page 6-5.

Contraindications

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

WARNING: Before prescribing, the healthcare professional should consider whether the patient will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The healthcare professional should consider mental, visual, physical and auditory limitations that may impact a patient's ability to successfully interact with the system. Failure of the patient to successfully interact with the system may result in device alarms, failure to deliver treatment, or delivery of inappropriate treatment.

Physician information to instruct patient caregivers

The LifeVest should only be prescribed to patients who will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The physician should consider mental, visual, physical and auditory limitations that may impact a patient's ability to successfully interact with the system.

When the patient does not meet all of these criteria, physicians use medical judgment to determine that a patient caregiver can assist the patient in certain responsibilities, such as assembling/disassembling the device. The patient's ability to press the response buttons is a test of the patient's consciousness and is part of the device's process to decide whether and when to deliver treatment. If anyone other than the patient holds the response buttons, needed therapy may not be delivered, possibly resulting in serious injury or death.

Interaction with pacemakers

WARNING: Always use appropriate caution when prescribing a LifeVest device to a patient who is dependent on a pacemaker. All patients who have pacemakers should be examined for proper pacemaker function after a defibrillation.

Several interactions with pacemakers are possible:

- If a patient goes into a ventricular arrhythmia and the pacemaker continues to pace, the pacemaker's pulses may be the dominant signal.[1] This may potentially cause the LifeVest device to lock on the pacemaker's signal as the cardiac rhythm and prevent the LifeVest device from detecting the arrhythmia. The risk varies according to the type of pacemaker and the programmed mode of the pacemaker.
- If the patient is baselined with the pacemaker active, an unpaced QRS complex may be interpreted by the LifeVest device as a change in the QRS morphology. As a result, if the rate goes above the arrhythmia rate threshold, the LifeVest device may then declare the unpaced rhythm a treatable arrhythmia and begin the treatment alert sequence. As long as the patient uses the response buttons of the LifeVest device, the device will not deliver a treatment shock. However, be aware that an increased potential for an unnecessary shock does exist.
- After the shock is delivered, the pacemaker may have difficulty capturing the myocardium[2] or may be reset to a default mode.

[1] Glikson, et al, "Importance of Noise Reversion as a Potential Mechanism of Pacemaker-ICD Interactions," *PACE*, May 1998, 21: 1111-1121.
[2] Altamura, et al., "Transthoracic DC Shock May Represent a Serious Hazard in Pacemaker Dependent Patients," *PACE*, January 1995, 18 (Part II): 194-198

Other articles of interest:

Brode, et al, "ICD-Antiarrhythmic Drug and ICD-Pacemaker Interactions," *Journal of Cardiovascular Electrophysiology*, July 1997, 8:830-842.

Geiger, et al, "Interactions Between Transvenous Nonthoracotomy Cardioverter Defibrillator Systems and Permanent Transvenous Pacemakers," *PACE*, March 1997, 20 (Part I): 624-630.

Recommendations for patients with pacemakers

If the pacemaker does pace during ventricular fibrillation, there is a risk that the pacemaker stimulus artifact would be tracked by the LifeVest device as a valid heart rate during ventricular fibrillation. In order for this to occur, the pacemaker stimulus artifact must be greater than the ventricular fibrillation signal. Patients whose pacemaker stimulus artifact is greater that 0.5 mV in any ECG lead should not use the LifeVest device.

Because of the risk that the patient's unpaced ECG signal may be interpreted as a ventricular tachycardia if it exceeds the arrhythmia rate threshold, set the VT rate threshold above the maximum paced rated when a patient is baselined while being paced.

After shock delivery, check the pacemaker's programming and ability to capture.

Recommendation for double counting of a normal rhythm

Double counting of a normal rhythm is known to occur with ICDs and other rhythm analysis devices.

Patients likely to experience double counting declarations may have high T waves and/or low QRS amplitudes. If a patient does experience such false arrhythmia declarations, there are two actions which may help: increasing the arrhythmia rate threshold and/or lengthening the response time. Increasing the arrhythmia rate threshold should reduce the frequency of false arrhythmia declarations due to double counting, while lengthening the response time gives the patient additional time to respond to the alerts if a shock is not necessary.

Asystole detection

The LifeVest monitors the ECG signal and declares asystole when the amplitude of the ECG input signal falls below 100 microvolts for at least 16 seconds. The following conditions can occur:

- If the normal sinus rhythm changes directly to asystole, the patient is prompted to check electrodes. If there is no response and the condition does not change after 30 seconds, the LifeVest displays a message and voice prompt that if the patient is not responsive to call for help and to perform CPR.
- If the normal sinus rhythm changes to bradycardia, then to asystole, the LifeVest displays a message and voice prompt for bystanders that if the patient is not responsive to call for help and to perform CPR.

Interaction with ventricular assist devices

WARNING: Some ventricular assist devices can be damaged or reprogrammed by external defibrillation. Therefore, patients wearing ventricular assist devices may not be suitable candidates for the LifeVest.

If you have a patient who is a candidate for the LifeVest, and that patient is using a ventricular assist device, check the manufacturer's instructions regarding whether the device could be damaged or reprogrammed by external defibrillation. If the ventricular assist device could be damaged by external defibrillation, that patient is not a candidate for the LifeVest.

For example, instructions provided with the Thoratec HeartMate XVE left ventricular assist system (LVAS) state to remove the connection between the percutaneous tube and the XVE system controller before using a defibrillator, or the XVE LVAS could be permanently damaged.

Device use in patients under 18 years of age

According to the 2010 AHA guidelines,[1] 2-4 J/kg is the recommended energy level for effective defibrillation therapy for pediatric patients including patients under 18 years of age. In order for these patients to be treated with an appropriate amount of energy with the LifeVest device, which is programmable between 75 and 150 joules, they must meet the minimum required weight of 18.75 kg. At the minimum energy setting of 75 J, a minimum weight patient of 18.75 kg would receive the maximum dose of 4 J/kg. In order to meet the AHA's minimum recommendation of 2 joules per kg, patients weighing over 37 kg should be programmed to receive more than 75 joules. Appropriate dosage is determined and prescribed by the physician.

As of November 8, 2012, the company registry contained 248 pediatric patients, aged 3-17, including those in the literature publications.

Retrospectively collected data has shown the ability of the LifeVest to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as 13. Four patients in the 3-17 age group experienced SCA during LifeVest use that was successfully converted to a life sustaining rhythm. The following table provides further detail on the pediatric patients receiving an appropriate treatment with the LifeVest.

Patient	Age	Wear duration (days)	Indication for LifeVest use	Treatment summary	Energy delivered (Joules)	Reason for ending LifeVest use
1	13	78	Congenital heart disease	1 appropriate treatment	151	Heart transplant
2	14	3	Cardiomyopathy	1 appropriate treatment	150	Received ICD
3	15	55	Wolf-Parkinson-White syndrome	1 appropriate treatment	150	Received ICD
4	16	60	Tetralogy of Fallot	4 appropriate treatments	152-154	Improved ejection fraction

There are three peer-reviewed articles on the use of the LifeVest specifically in the pediatric population. One paper describes four pediatric patients prescribed a wearable defibrillator from a single site.[2] All carried a diagnosis of anthracycline-induced cardiomyopathy. While no patients received an appropriate treatment in this study, no patients received an inappropriate treatment despite the inappropriately detected rhythm caused by ECG noise. Two patients had documented noncompliance with wear, which resulted in failure to detect and treat a life-threatening arrhythmia in one. The paper concluded that the wearable defibrillator is a short-term alternative for children at risk for SCD, who can be

[1] Link M, et al. *Part 6: Electrical Therapies: Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing - 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.* Circulation. 2010;122[suppl 3]:S706–S719.
[2] Everitt MD, Saarel EV. Use of the wearable external cardiac defibrillator in children. *Pacing and Clinical Electrophysiology.* 2010;33(6):742-746.

properly fit with the wearable defibrillator, where the risk of ICD use is greater than the benefit.

In a paper by Collins et al., 81 multi-site wearable defibrillator patients from 9-18 years old, and 103 patients aged 19-21, were retrospectively reviewed.[1] In patients ≤18 years of age, there was one inappropriate therapy, due to sinus tachycardia and artifact, and one withholding of therapy due to a device-device interaction. Compliance was generally similar to adults among these younger patients, with an average daily use of 19 hours, and non-compliance or comfort issues only being recorded for 7-11% of patients. This paper concluded that the wearable defibrillator could be an appropriate therapy for pediatric patients who are at risk for SCA, as they had two appropriate treatments in their young adult population (age 19-21). However, they had no appropriate treatments in their pediatric population (age 9-18).

The third paper by LaPage et al., published prior to the two papers discussed above, detailed the fatal device-device interaction between the wearable defibrillator and a unipolar epicardial pacemaker.[2] Such interactions are not unique to pediatric patients nor are they unique to wearable defibrillators, being copiously described in the ICD and AED literature. LifeVest manuals have specific warnings about pacemaker interactions; please see *Interaction with pacemakers* on page 6-2 and *Recommendations for patients with pacemakers* on page 6-3. These warnings advise physicians to use appropriate caution when prescribing the LifeVest device to a patient who is dependent on a pacemaker.

The rate of inappropriate treatments per patient days of use for patients under 18 years of age is similar to that of patients 18 years of age and older. Inappropriate treatments can be prevented by pressing the response buttons. Only one serious adverse event has been reported for pediatric patients using the device. This event is described in the paper by LaPage et al, which summarizes the withholding of therapy caused by a pacemaker interacting with the wearable defibrillator.

[1] Collins KK, Silva JN, Rhee EK, Schaffer MS. Use of a wearable automated defibrillator in children compared to young adults. *Pacing and Clinical Electrophysiology.* 2010;33(9):1119-1124.
[2] LaPage MJ, Canter CE, Rhee EK. A fatal device-device interaction between a wearable automated defibrillator and a unipolar ventricular pacemaker. *Pacing Clin Electrophysiol.* Jul 2008;31(7):912-915.

Clinical studies

Initial FDA-approved study[1]

Conducted between 1990 and 2001, the objective of the FDA-approved trial was to demonstrate safety (low false shock rate) and efficacy (survival after sudden cardiac arrest). There were 289 high SCA risk patients who used the device an average of 3 months. Of 8 SCA events that occurred during the trial, 6 were successfully converted. There were 6 appropriate shocks during the trial. The trial design was to demonstrate superiority of the wearable defibrillator to reliance on the EMS system for SCA treatment.

Biphasic electrophysiology laboratory sub-study[2]

This study was conducted between March 2001 and November 2001. Twelve patients were electively induced into VT or VF, and all 12 were converted or defibrillated with the first biphasic shock (either 70 or 100 joules). A total of 23 successful biphasic shocks were delivered. There were no post-shock arrhythmias or skin burns. The average patient impedance was 68 ±8 ohms.

WCD 3000 clinical evaluation

This study was conducted between September 2001 and April 2002. The objective was to demonstrate the safety of the LifeVest WCD 3000 device by comparing the incidence of false arrhythmia declarations (false alerts) with the WCD 3000 device to the WCD 2000 device. The study would be considered successful if the incidence of false arrhythmia declarations was less than, or equal to, the WCD 2000 device. A minimum of 10 patients and 100 weeks of cumulative device use would be required.

A prospective, non-randomized, multi-national trial involving four centers (three U.S. centers and one European center) evaluated the safety of the WCD 3000 device with patients at risk of sudden cardiac death. Two populations at SCA risk were chosen:

- The first population consisted of patients waiting for heart transplant or patients having an equivalent cardiac status, namely New York Heart Association Class III or IV heart failure and an ejection fraction below 30 percent.
- The second patient population included acute myocardial infarction (MI) patients and patients immediately following a coronary artery bypass graft procedure. Additional requirements for both the MI and bypass patients included VT/VF within the first 48 hours or a left ventricular ejection fraction of less than 30 percent. A Killip Class III or IV 72 hours following the MI and syncopal VT/VF after 48 hours post-MI also qualified patients for WCD 3000 device use.

[1] Feldman et al., “Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patient at High Risk for Sudden Death: Results of WEARIT/BIROAD,” *PACE*, 2004, 27:4-9.
[2] Reek et al., “Clinical Efficacy of a Wearable Defibrillator in Acutely Terminating Episodes of Ventricular Fibrillation Using Biphasic Shocks”, *PACE*, 2003, 26:2016-2022.

Patient demographics

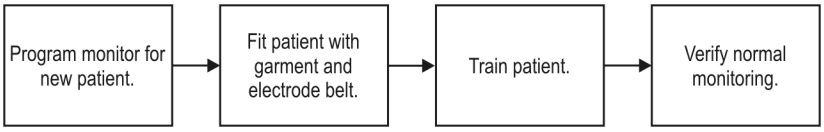
Parameter	Total Study (n=13)	WEARIT (n=7)	BIROAD (n=6)
Ejection fraction	21% ±7, n=11	18% ±6	25% ±5, n=4
QRS width (msecs)	105 ±15, n=9	106 ±18, n=5	104 ±12, n=4
Age (years)	56 ±11	56 ±13	57 ±9
Male	69%	71%	67%
History of smoking	83%, n=12	67%, n=6	100%
History of hypertension	83%, n=12	86%	80%, n=5
History of NSVT	89%, n=9	80%, n=5	100%, n=4
History of VT	44%, n=9	33%, n=3	50%
Beta-blocker medication	82%, n=11	67%, n=6	100%, n=5
Anti-arrhythmia medication	9%, n=11	0%, n=6	20%, n=5
Inotropic medications	0%, n=11	0%, n=6	0%, n=5

The study population consisted of 13 patients with 105 patient weeks of patient device experience. There were 214 false arrhythmia detections during that time. The rate of false detections using the WCD 3000 device was 2.0 per patient week of use as compared to 4.5 per patient week using the WCD 2000 device. There were no treatable tachyarrhythmic events during the study. There were four true arrhythmias recorded during the study, all four resolved spontaneously. There were no inappropriate defibrillations during the study.

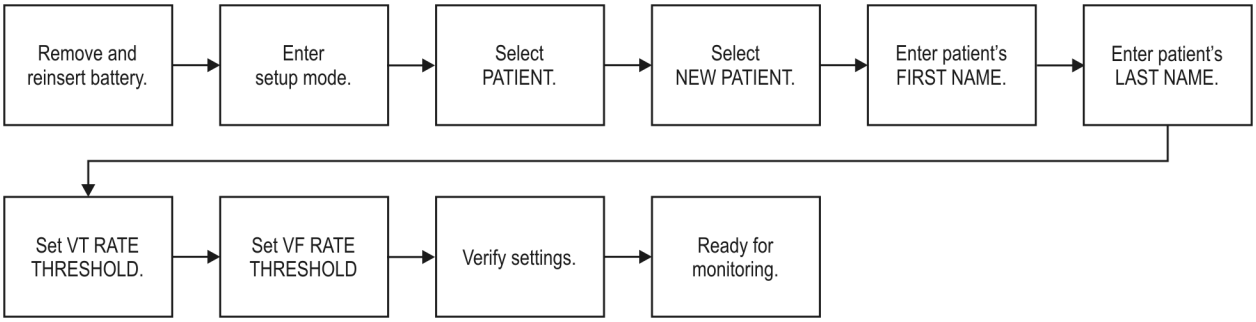
One adverse event was reported during the study. This event involved a patient who received an asystole alert due to incompletely connecting the electrode belt to the monitor. The patient called an ambulance to take her to the hospital as the device directed. She was hospitalized as a precaution and transferred from this local hospital to the investigational site where she was examined and discharged to home. No injury resulted from this event. The patient continued to wear the device.

Appendix A: Quick charts

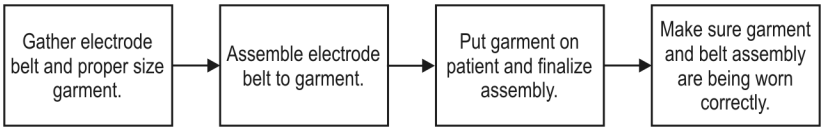
Overview of new patient setup



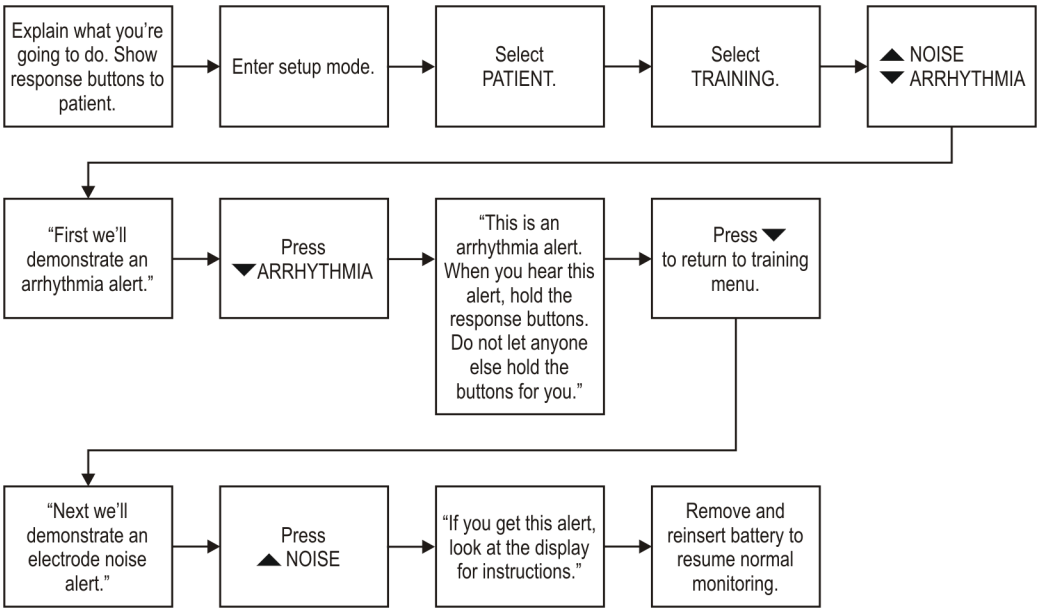
Program monitor for new patient



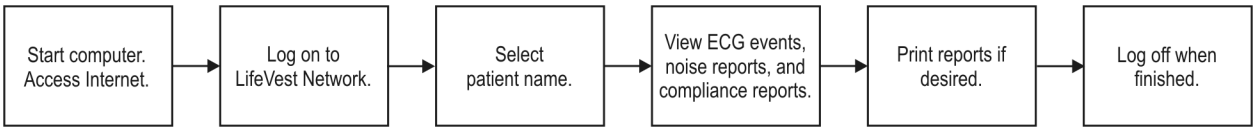
Fit patient with garment and electrode belt



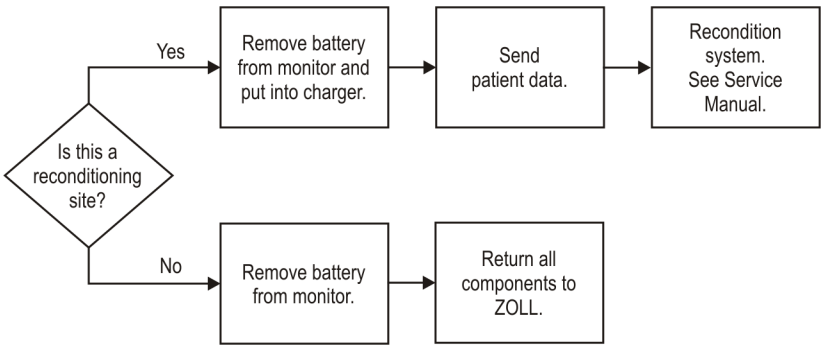
Train patient



To view patient data



When patient is finished with device



Appendix B: Part Numbers

Description	ZOLL Part Number
WCD 3100 Programmed Monitor	10A0967-Axx
Battery	10A0894-A01
Battery Charger with Power Supply	11B0009-A01
Modem	10A0924-A0x or 10A0903-A01
Test Plug	10A0922-A01
Holster	10B0844-A01
Electrode Belt	10A0889-A01
Garment	10A0991-A0x or or 10A1004-B0x
Tote Bag	10B0822-A01
WCD 3100 Patient Manual	20B0039
WCD 3100 Quick Guide	20B0042
WCD 3100 Operator's Manual	20B0040
WCD 3100 Service Manual	20B0041
WCD 3100 Patient Checklist	20B0043
WCD 3000/3100 Patient Video	20B0046

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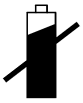
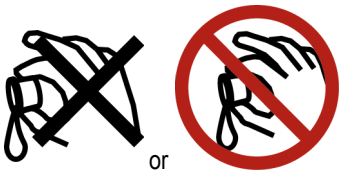
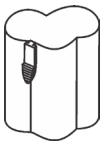
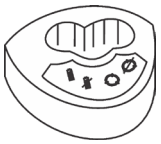
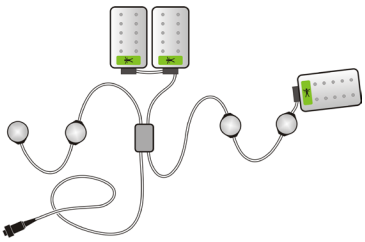
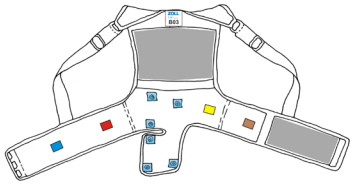
Appendix C: Symbols

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

	Laundering symbol: No anti-static spray.
	Laundering symbol: No fabric softener.
	Manufacturing date.
	Manufacturing location.
	Monitor connector: Type BF defibrillator-proof connector.
	Packaging: Battery
	Packaging: Battery charger
	Packaging: Monitor.
	Packaging: Modem.
	Packaging: Electrode belt.

	Packaging: Garment.
	Power supply electrical information: Alternating current (AC).
	Power supply electrical information: Direct current (DC).
	Therapy pad label: Place this side (foil side) of the therapy pad next to your skin.
EC REP	Symbol for EC representative next to name and address of authorized EC rep.

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Index

O

P

Q

R

S

T

U

V

W

Z

LifeVest®

Model 4000

Operator's Manual

ZOLL®

PN 20B0048 Rev E4

Contents

Restricted sale

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

Effectivity

This manual describes the LifeVest 4000 wearable defibrillator system.

Disclaimer

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

Trademarks

ZOLL, LifeVest, and Blue are trademarks or registered trademarks of ZOLL Medical Corporation in the United States of America. All other trademarks and registered trademarks are property of their respective owners.

Copyright notice

Patents

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

Software nonexclusive license

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

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1: Introduction

About this manual

This manual:

- is for operators of the LifeVest wearable defibrillator.
- gives you instructions on how to fit patients, as well as instruct patients in the use and care of the device.
- supplements the *Patient Manual*, which gives patient instructions on the use and care of the LifeVest device.

What's in this manual

Here's how to use this manual:

- The next few pages contain safety information, details about the LifeVest system, and electromagnetic compatibility guidance.
- **Patient fitting** explains how to fit a patient and assemble the components of the LifeVest belt.
- **Patient training** gives guidelines for instructing the patient about the LifeVest system and how to respond to alerts.
- **Monitor setup for a new patient** covers the basic procedures and menus for setting up the monitor before use by a new patient. (If you need to change other settings, see the programming section of the *Service and Programming Manual*.)
- **Activities programming** covers programming the LifeVest options, including a health survey, walk test, and trends. This section explains how to enable, set up, change, or disable these options.
- **LifeVest Network** tells how to view patient data on the LifeVest Network using a computer with Internet access.
- **Clinical information** contains indications, contraindications, a summary of the clinical studies, and other clinical details.
- Appendixes include **Quick charts**, **Symbols,** and **Patient training all modes**. The quick charts are particularly helpful as reminders of how to do things. Use the list of symbols to help identify the meaning of icons on the components, in this manual, and on the packaging. Refer to the appendix on patient training for a full guide on using the various training modes.
- Use the **Index** at the back of the manual to find what you're looking for quickly.

Safety information

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

Terms used

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

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

WARNINGS

Do not prescribe or train a patient to use the LifeVest System until you understand the manual. If you do not understand how to use the system, it may result in damage and/or cause the system to malfunction.

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

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

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.

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

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

WARNINGS

Before prescribing the LifeVest, the healthcare professional should consider whether the patient will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The healthcare professional should consider mental, visual, physical and auditory limitations that may impact a patient's ability to successfully interact with the system. Failure of the patient to successfully interact with the system may result in system malfunction, possibly resulting in serious injury or death.

Always use appropriate caution when prescribing a LifeVest device to a patient who is dependent on a pacemaker. All patients who have pacemakers should be examined for proper pacemaker function after a defibrillation.

Always take precautions with a patient wearing a ventricular assist device. Some ventricular assist devices can be damaged or reprogrammed by external defibrillation. Therefore, patients wearing ventricular assist devices may not be suitable candidates for the LifeVest.

About the LifeVest system

The LifeVest is a cardioverter defibrillator worn by a patient at risk for sudden cardiac arrest (SCA). It monitors the patient's heart continuously. If the patient goes into a life-threatening arrhythmia, the LifeVest delivers a treatment shock to restore the patient's heart to normal rhythm.

Two main components

The LifeVest system consists of two main components: (1) an electrode belt and garment that surrounds the patient's chest, and (2) a monitor that the patient wears around the waist or from a shoulder strap.

Washable garments are available in sizes to suit most patients. The LifeVest device's electrodes are dry and non-adhesive to provide patient comfort.

The monitor contains a touchscreen for the user, as well as a speaker for sounding alerts and voice prompts.

Treatment cycle less than a minute

When the device detects a treatable arrhythmia, a sequence begins, giving a conscious patient time to stop the treatment. This keeps inappropriate arrhythmia detections from becoming inappropriate shocks, a key difference between the wearable defibrillator and an implanted defibrillator.

If the patient presses the two "response" buttons at any time during the treatment sequence, the alerts stop and the treatment shock is delayed.

If the patient does not respond, the device continues to give alerts and voice prompts to the patient and bystanders.

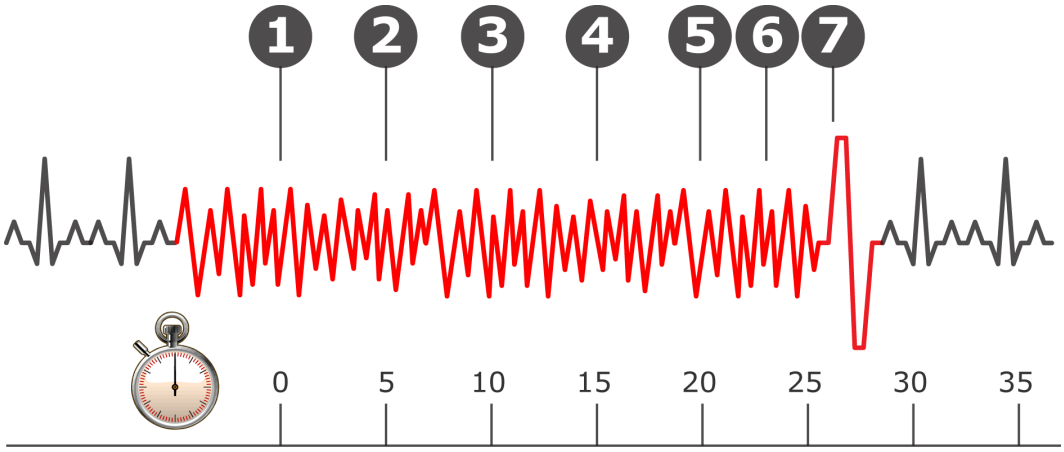
Gel within the electrodes is released just prior to delivering the treatment shock in order to deliver the shock most efficiently.

The entire event, from arrhythmia detection to delivery of the treatment shock, typically takes less than one minute.

If the arrhythmia continues after the first treatment shock, up to 5 shocks may be given.

Typical treatment timeline during ventricular fibrillation

This is a hypothetical example of a treatment timeline for VF during an awake cycle when the patient does not press the response buttons.



Event	
1	Arrhythmia detected, activating vibration alert, which continues throughout sequence. If an arrhythmia is detected during the sleep interval, the vibration and siren alerts are activated together (unlike normal operation when the vibration alert gets activated first, then the siren alert). For the details about setting the sleep interval, see the programming section of the Service and Programming Manual.
2	Siren alerts begin (except during sleep interval; see event 1 above).
3	Siren alerts get louder.
4	Patient audible prompt: “Press response buttons to delay treatment.” You can give the patient more time to respond while sleeping by setting the response time extension up to 30 seconds. For the details about setting the response time extension, see the programming section of the Service and Programming Manual.
5	Gel released.
6	Bystander audible prompt: “Bystanders, do not interfere.”
7	Treatment shock.

Treatment sequence

After identifying VF, there is a response time of 25 seconds (programmable up to 55 seconds) to allow the patient time to respond to the alerts. The lower threshold for VF identification can be set from 120 to 250 beats per minute (bpm), with a default of 200 bpm.

If the system identifies VT, there is a response time of 60 seconds (programmable up to 180 seconds). The lower threshold for VT identification can be set from 120 to the VF threshold, with a default setting of 150 bpm.

The LifeVest device can deliver up to 5 defibrillating pulses during an arrhythmic episode. The energy of the pulses can be programmed individually to between 75 and 150 joules, with a default setting of 150 joules.

ECG recording of events

The patient's electrocardiogram (ECG) is recorded for all detected arrhythmias, including before and after treatment. The patient can also manually record an ECG at any time by pressing the response buttons on the device.

Information gets transmitted from the LifeVest to LifeVest Network. Physicians can then access their patient's information from virtually any computer with an Internet connection. LifeVest Network allows physicians to view ECG recordings, patient use, ECG interference, and other device-related information.

Biphasic waveform delivers efficient energy

The LifeVest device delivers its defibrillating energy in a biphasic truncated exponential waveform, whereby the signal goes positive, then negative very quickly. This type of waveform has been shown to be effective defibrillating at lower energy levels.

The amplitude and width of the phases of the energy waveform are automatically adjusted to deliver a precise energy amount regardless of the patient's body impedance.

Reliable detection algorithm

The LifeVest has proved to be effective at detecting ventricular tachycardia (VT) and ventricular fibrillation (VF). The detection algorithm was 100% sensitive for VF and 95% sensitive for VT in bench testing. The algorithm uses the patient's baseline vectorcardiogram as a template for detecting changes in cardiac signal morphology in addition to standard rate determination of arrhythmias.

Intended use locations

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

Essential performance

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

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 anti-theft detection systems. This testing, along with clinical trial testing, has demonstrated that in everyday use the LifeVest device is not normally affected by commonly encountered electromagnetic disturbances.

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

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

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

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

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

Wireless interference

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

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

FCC regulatory information

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

The monitor contains:

FCC-ID POOWML-C40

The charger contains:

FCC-ID POOWML-C40
FCC-ID AU792U05E06800

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

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

IEC 60601-1-2 specifications

Electromagnetic emissions declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The LifeVest 4000 wearable defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest 4000 wearable should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions EN 55011 (2009), Amendment 1 (2010)	Group 1	The LifeVest 4000 wearable defibrillator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions EN 55011 (2009), Amendment 1 (2010)	Class B	The LifeVest 4000 wearable defibrillator is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2 (2005), Amendment 2 (2009)	Class A	
Voltage fluctuations/flicker emissions EN 61000-3-3 (2008)	Complies	

Electromagnetic immunity declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The LifeVest 4000 wearable defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest 4000 wearable defibrillator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2 (2008)	±6 kV Contact ±8 kV Air	±8 kV Contact ±15 kV Air	No precautions necessary.
Electrical fast transient IEC 61000-4-4 (2004), Amendment 1 (2010)	±2kV power line ±1kV I/O lines	±2kV power line ±1kV I/O lines	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5 (2005)	±1kV differential ±2kV common	±1kV differential ±2kV common	Mains power quality should be that of a typical home environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11 (2004)	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% dip U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% dip U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home environment. If the user of the LifeVest 4000 requires continued operation during power mains interruptions, it is recommended that the LifeVest 4000 charger be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 (2009)	3.0 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic immunity declaration for life-supporting equipment

Guidance and manufacturer's declaration – electromagnetic immunity			
The LifeVest 4000 wearable defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeVest 4000 wearable defibrillator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 (2008)	3 Vrms 150 kHz to 80 MHz outside ISM bands[1]	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the LifeVest 4000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[1]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3 (2006)	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[2] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[3] should be less than the compliance level in each frequency range.[4] Interference may occur in the vicinity of equipment marked with the following symbol: 

[1] The ISM (industrial, scientific, and medical) bands between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[2] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[3] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifeVest 4000 is used exceeds the applicable RF compliance level above, the LifeVest 4000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LifeVest 4000.

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

Recommended separation distances from RF equipment for the LifeVest 4000

Recommended separation distances between portable and mobile RF communications equipment and the LifeVest 4000 wearable defibrillator

The LifeVest 4000 wearable defibrillator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifeVest 4000 wearable defibrillator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifeVest 4000 wearable defibrillator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, in watts	Separation distance according to frequency of transmitter, in meters			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

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

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

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

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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2: Patient fitting

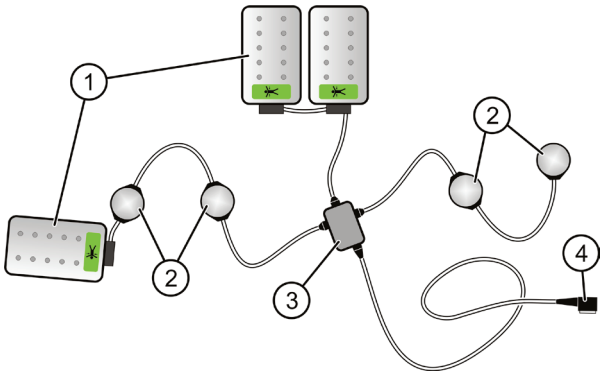
This section explains how to fit a patient and assemble the components of the LifeVest belt.

Before you start

- Gather the electrode belt and garment.
- Read through these procedures completely.
- Familiarize yourself with the components and what they're called.
- Have a clean, flat area to lay out and assemble the components, such as a table or counter. You might want to put a towel or cloth on the table to protect the components as you assemble them.

Components of the LifeVest belt assembly

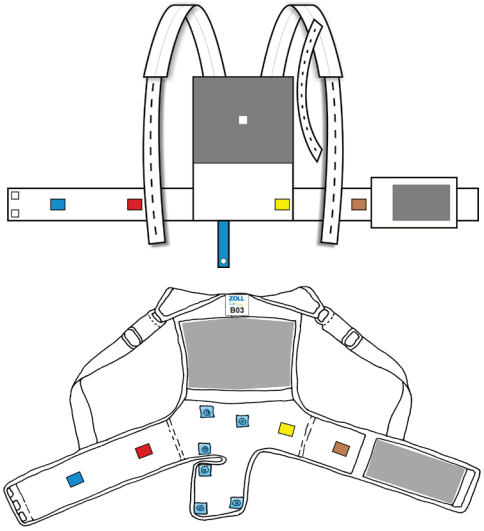
Electrode Belt



The belt comes in one size and fits any patient. The parts of the electrode belt are as follows:

1 Therapy pads
2 ECG electrodes (also called ECG sensors)
3 Vibration box
4 Connector

Garment



The garment comes in a variety of sizes to suit the patient.

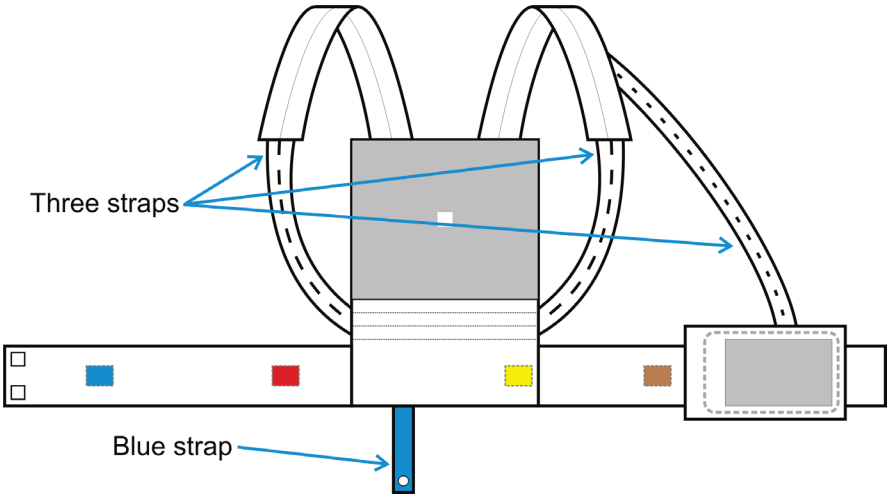
In this chapter, you will measure the patient to determine what size garment to use.

There are two style garments, with slight variations in fit and assembly. See next page to determine which garment you have.

Which style garment do you have?

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

Garment A

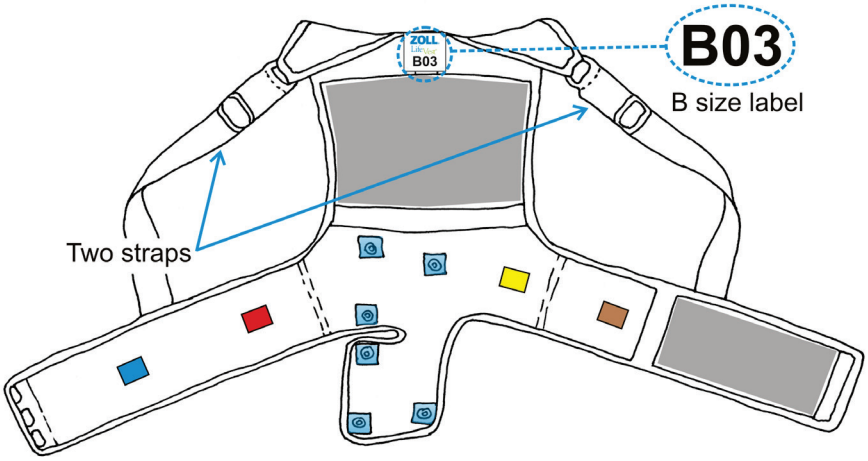


This style garment has three straps at the top, and a small blue strap at the bottom.

We call this garment style A.

If you have this style garment, see page 2-3.

Garment B



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

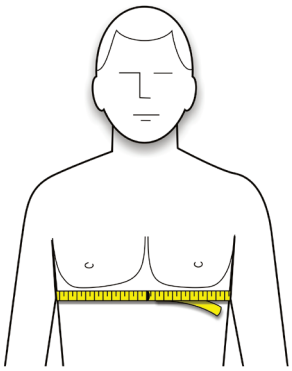
We call this garment style B.

If you have this style garment, see page 2-12.

Measuring the patient for garment A

Measure the patient to determine what size garment A to use.

If you are using garment B, see page 2-12.

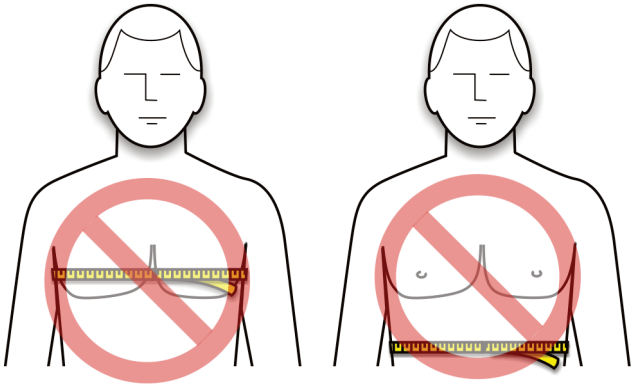


1 Have patient stand and remove all upper body clothing, including undergarments.

2 Place a measuring tape around the patient's chest, centered at the xiphoid.

Measure to the closest inch or centimeter.

Don't measure too high or too low across the patient's torso.



3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement inches	Chest measurement centimeters	Garment 10A0991-A0X
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit the patient.

Example measurement

Chest measurement inches	Chest measurement centimeters	Garment 10A0991-A0X
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

As an example, let's say the patient measures 44 inches.

According to the chart, a patient measuring 44 inches needs garment size A06.

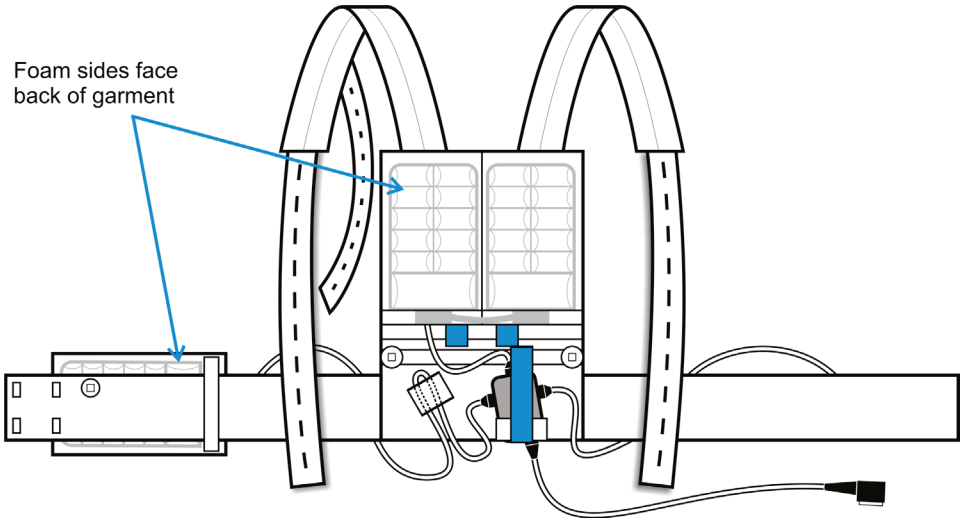
Assembling the electrode belt to garment A

Refer to this section for garment A. If you have garment B, see page 2-14.

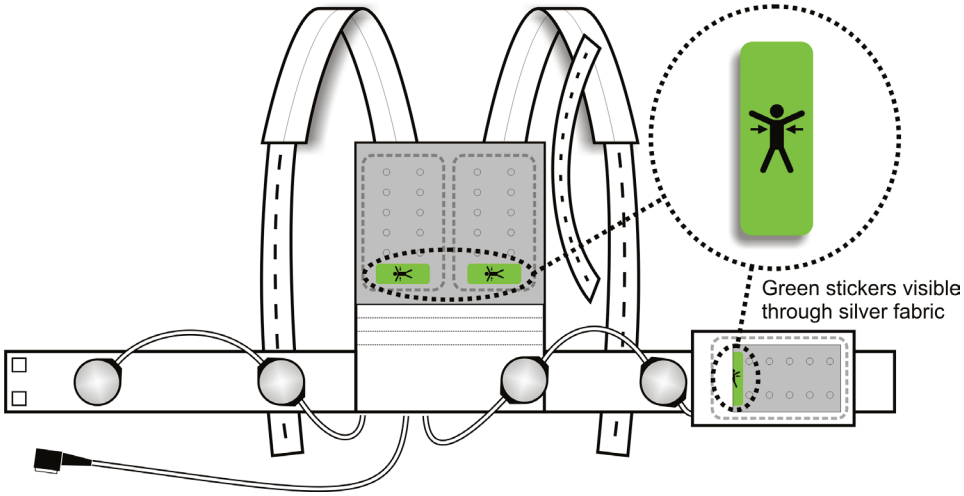
Assemble the belt and garment as described in the Patient Manual, but do not fasten the straps.

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

Outside view
This side faces away from the patient's body when worn. The foam sides of the electrodes face the back of the garment.



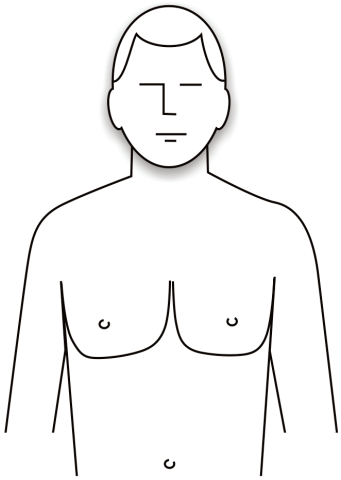
Inside view
This side faces toward the patient's body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting garment A on the patient and finalizing assembly

Refer to this section for garment A. If you have garment B, see page 2-15.

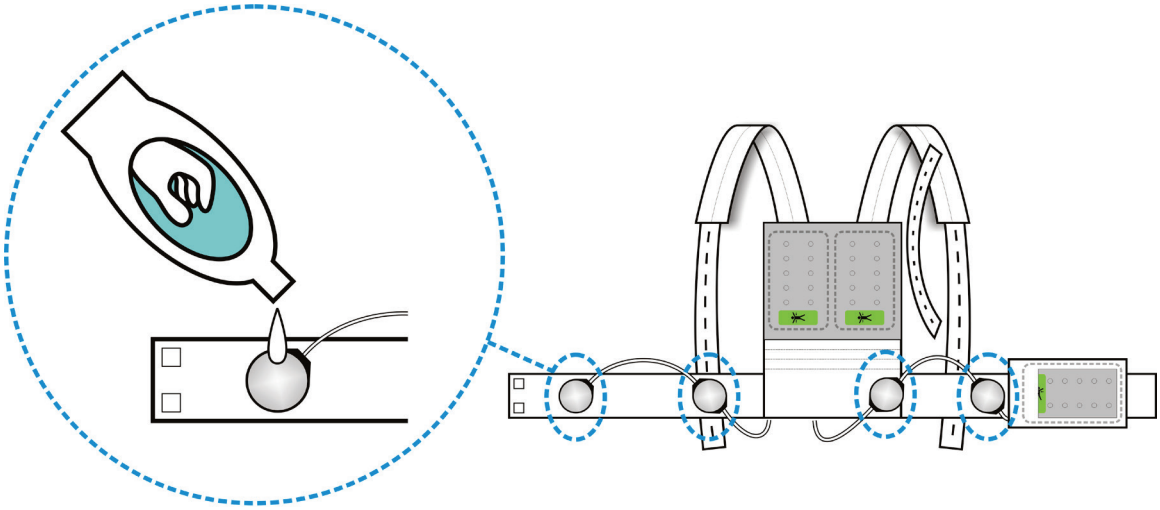
Follow these instructions to help the patient put on the assembled garment, then adjust the garment for a proper fit.

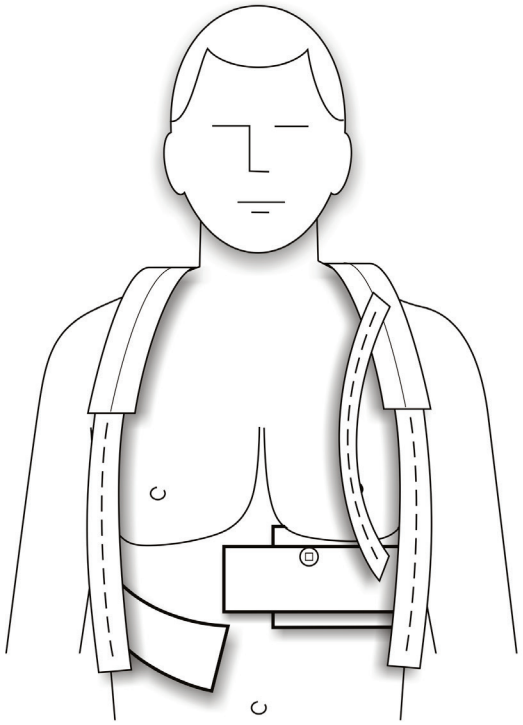


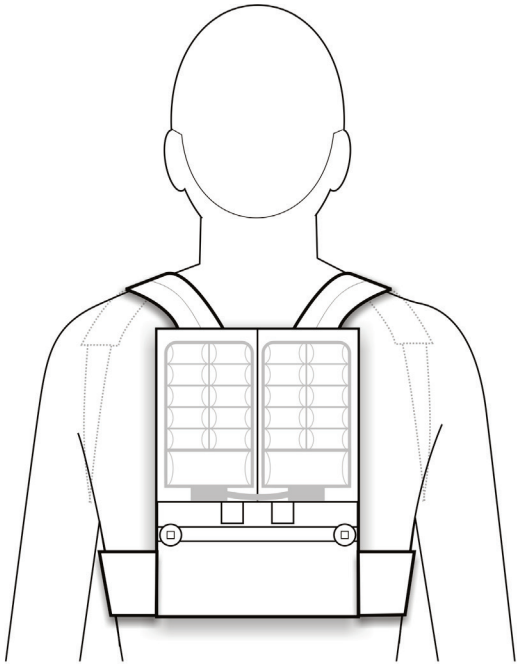
1 Have the patient remove all clothing and undergarments from the upper body before putting on the garment.

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

2 Apply unscented hand lotion or skin cream to the four ECG (round) electrodes.





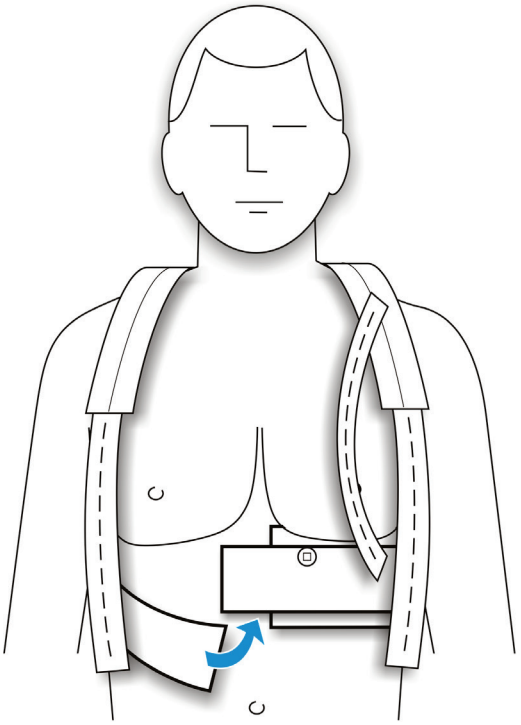


3 Help the patient put on the garment, making sure:

- The garment doesn't get twisted as the patient puts it on.
- The silver fabric pockets touch the patient's bare skin.

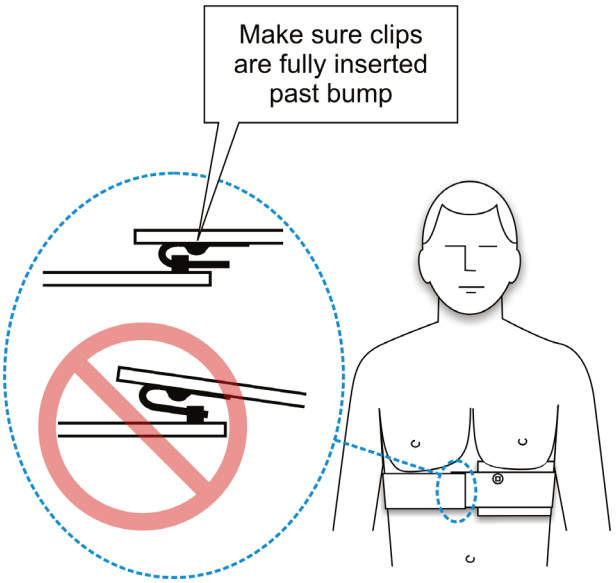
If patient is a female:

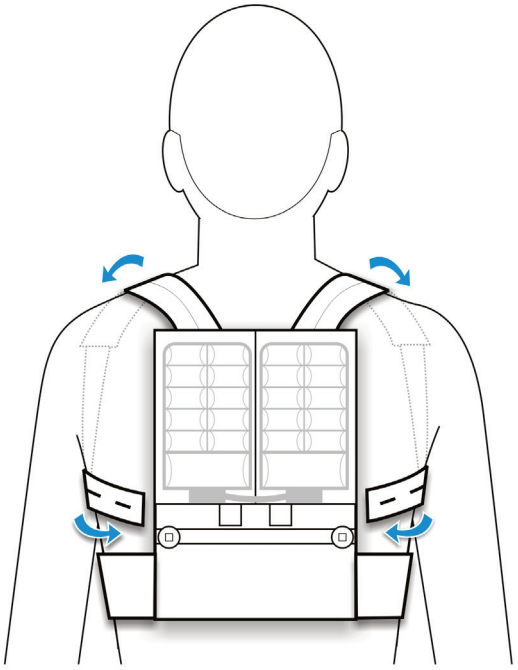
- Patient should wear a bra OVER the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against the patient's body rather than the underside of the patient's left breast.



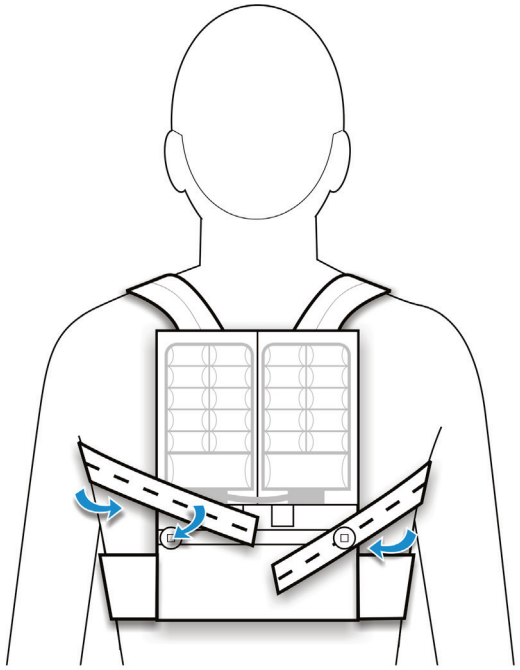
4 Connect the garment ends together in the front.

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



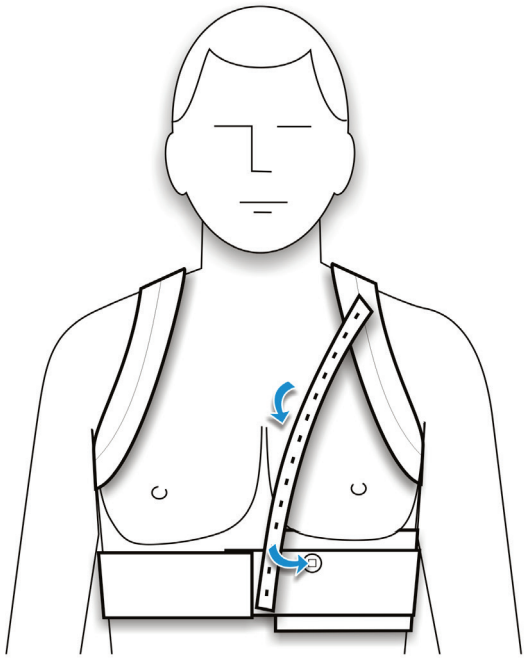


5 Position straps over the patient's shoulders and bring them under the patient's arms around to the patient's back.



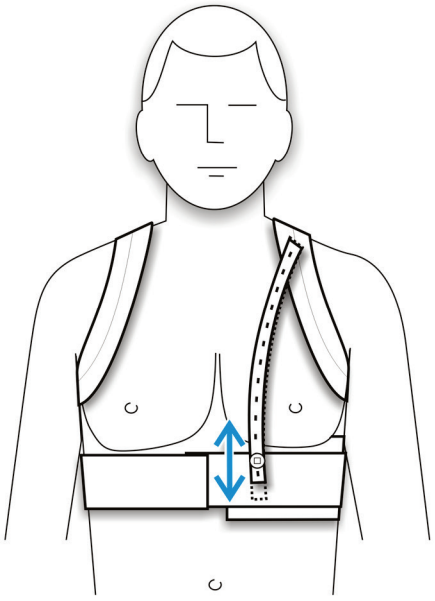
6 Without stretching the strap, find the hole that lines up with the button. Then stretch the strap slightly and attach the button to the next hole.

- Do not cut the strap.
- Excess strap can be folded over and buttoned again.
- Repeat for each of the two long straps.
- Adjust the garment for a good fit.



7 Bring the remaining strap down the front of the patient's chest and button it to the front of the garment.

- Do not cut the strap.
- Excess strap can be folded over and buttoned again.

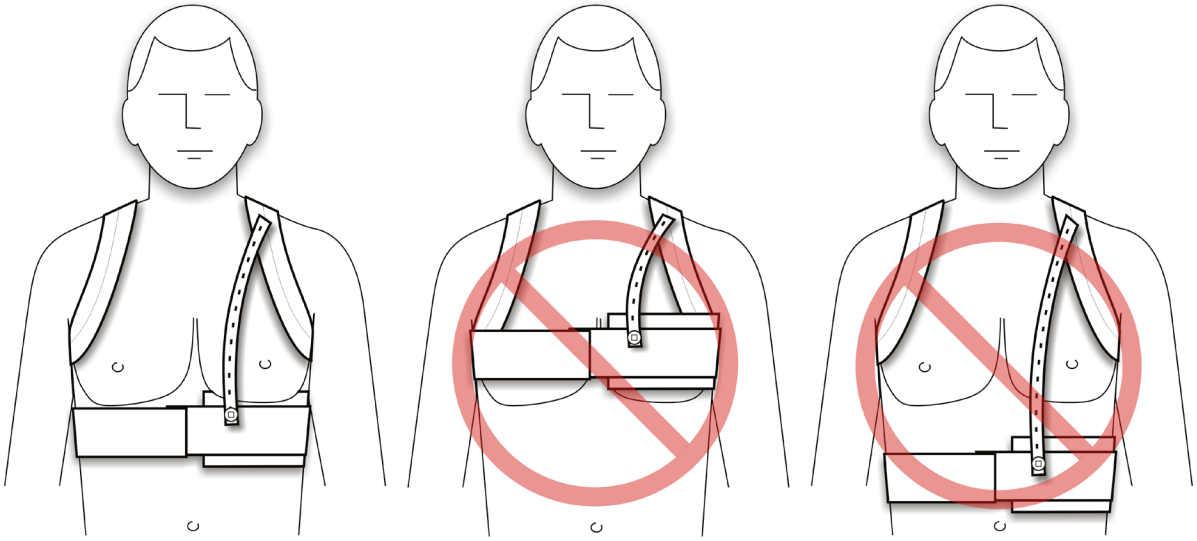


8 Check position of garment on the patient's body and make sure it's not too high or too low.

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

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

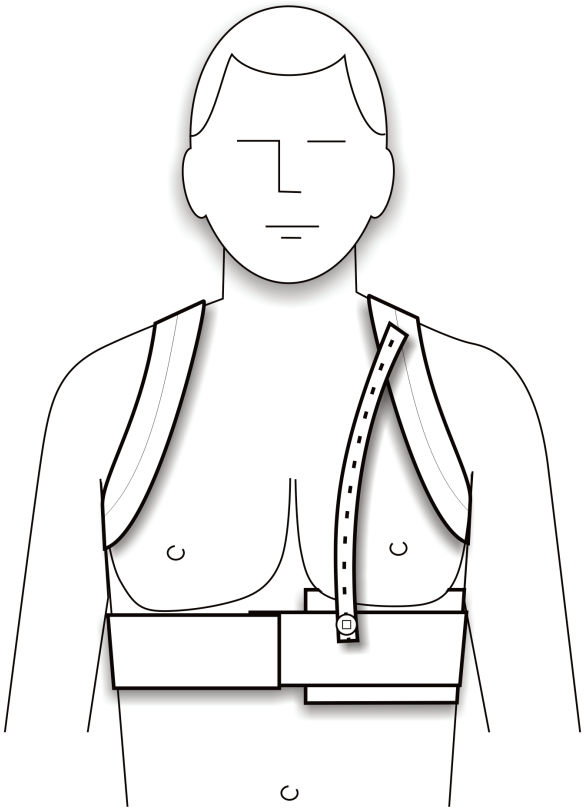
- The garment **should** cross the patient's body just below the breastbone.
- The garment **should not** be as high as the patient's nipples.
- The garment **should not** be as low as the patient's belly button.

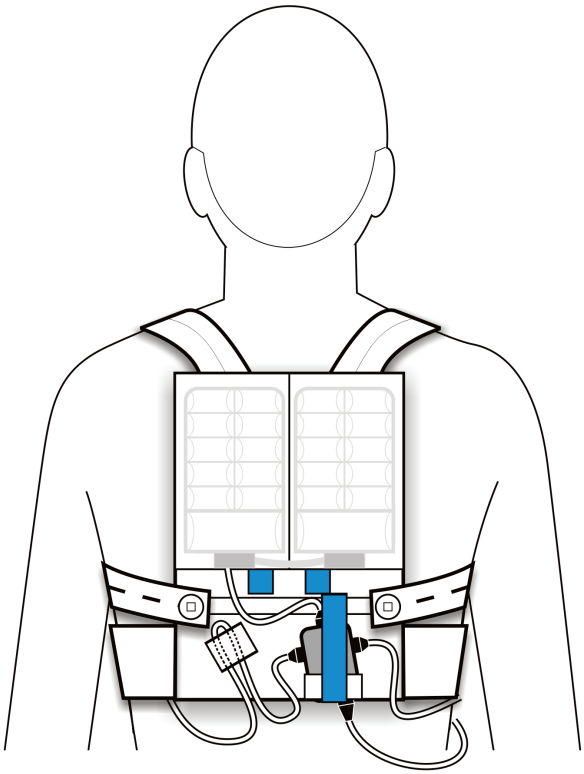


Positioned properly | Too high | Too low

9 Have the patient look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against patient's skin.
- The ECG electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green stickers) MUST TOUCH THE PATIENT'S BODY for the device to work properly.
- None of the cabling interferes with the ECG electrodes or therapy pads.
- The garment is being worn correctly. It should look like the figures below.

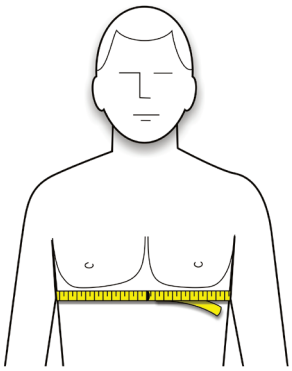




Measuring the patient for garment B

Measure the patient to determine what size garment B to use.

If you are using garment A, see page 2-3.

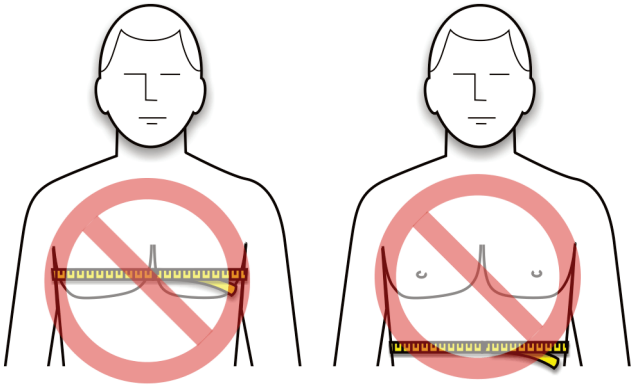


1 Have patient stand and remove all upper body clothing, including undergarments.

2 Place a measuring tape around the patient's chest, centered at the xiphoid.

Measure to the closest inch or centimeter.

Don't measure too high or too low across the patient's torso.



3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement		Garment
inches	centimeters	10A1004-B0X
26-31	66-80	B01
32-37	81-95	B02
38-44	96-112	B03
45-51	113-130	B04
52-56	131-142	B05

The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit the patient.

Example measurement

Chest measurement		Garment
inches	centimeters	10A1004-B0X
26-31	66-80	B01
32-37	81-95	B02
38-44	96-112	B03
45-51	113-130	B04
52-56	131-142	B05

As an example, let's say the patient measures 44 inches.

According to the chart, a patient measuring 44 inches needs garment size B03.

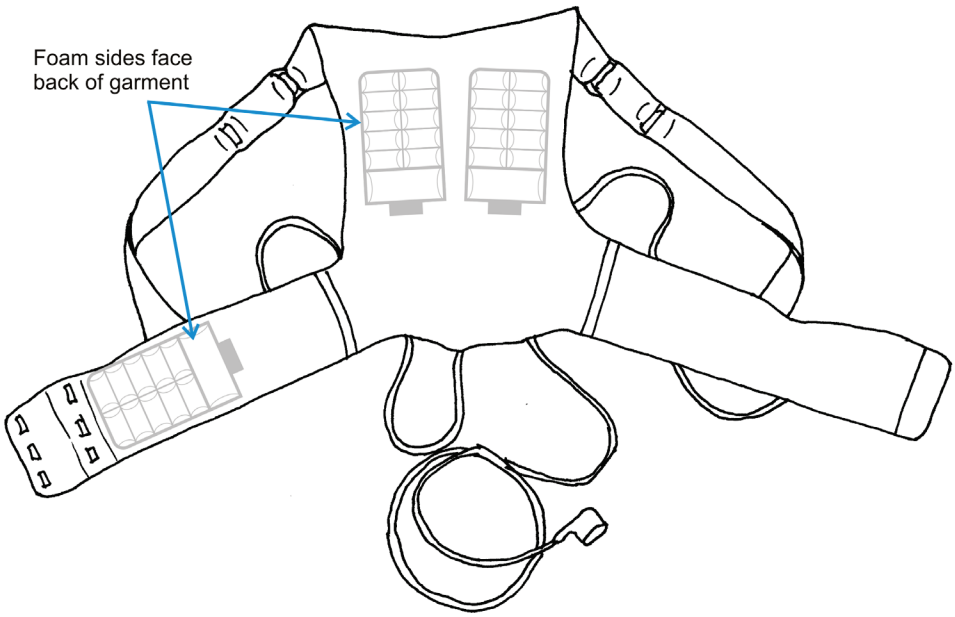
Assembling the electrode belt to garment B

Refer to this section for garment B. If you have the garment A, see page 2-5.

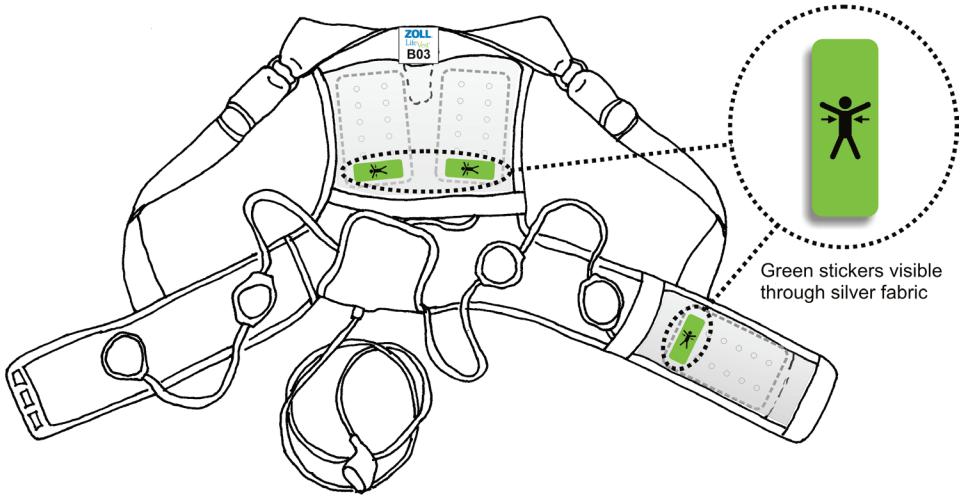
Assemble the belt and garment as described in the Patient Manual.

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

Outside view
This side faces away from the patient's body when worn. The foam sides of the electrodes face the back of the garment.



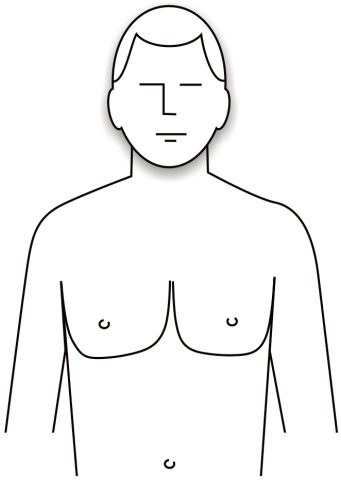
Inside view
This side faces toward the patient's body when worn, with the silver pockets against your skin. Look for the green stickers visible through the silver fabric.



Putting garment B on the patient and finalizing assembly

Refer to this section for garment B. If you have garment A, see page 2-6.

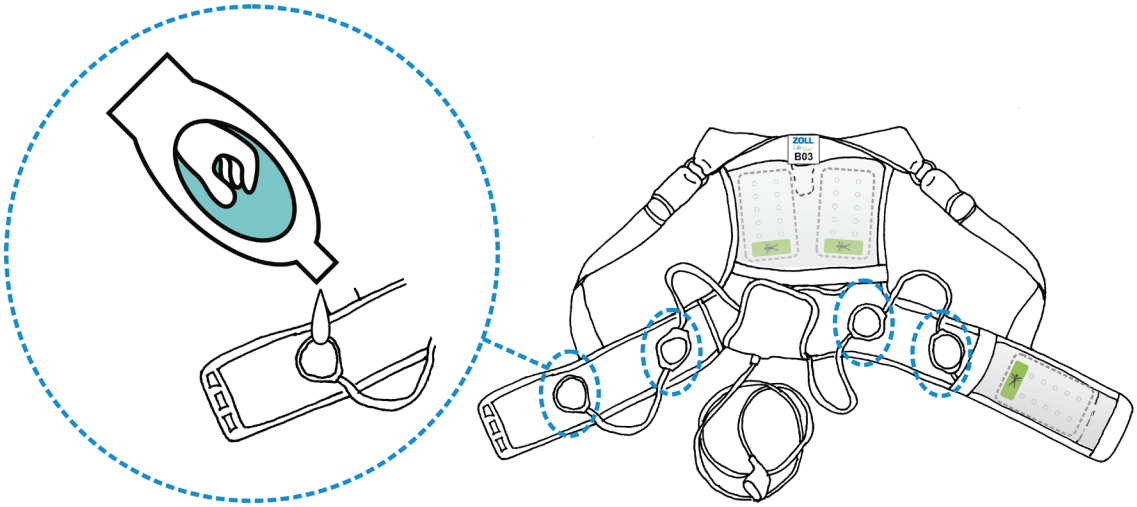
Follow these instructions to help the patient put on the assembled garment, then adjust the garment for a proper fit.

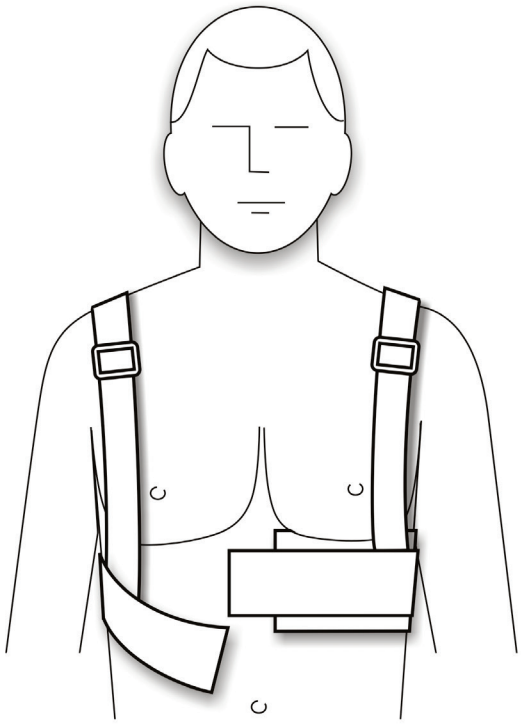


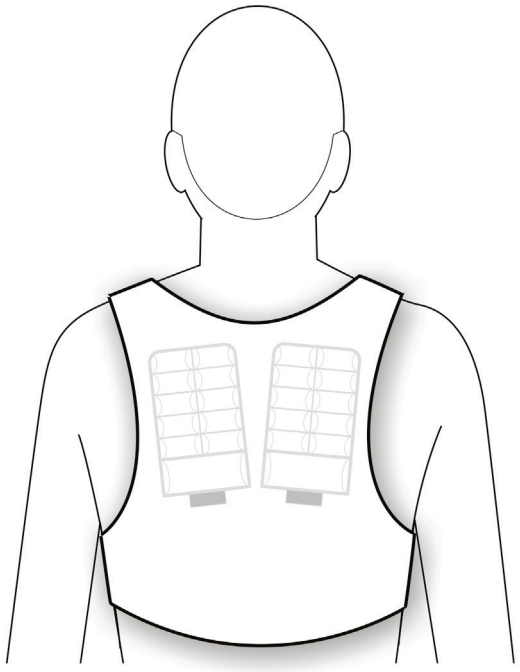
1 Have the patient remove all clothing and undergarments from the upper body before putting on the garment.

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

2 Apply unscented hand lotion or skin cream to the four ECG (round) electrodes.





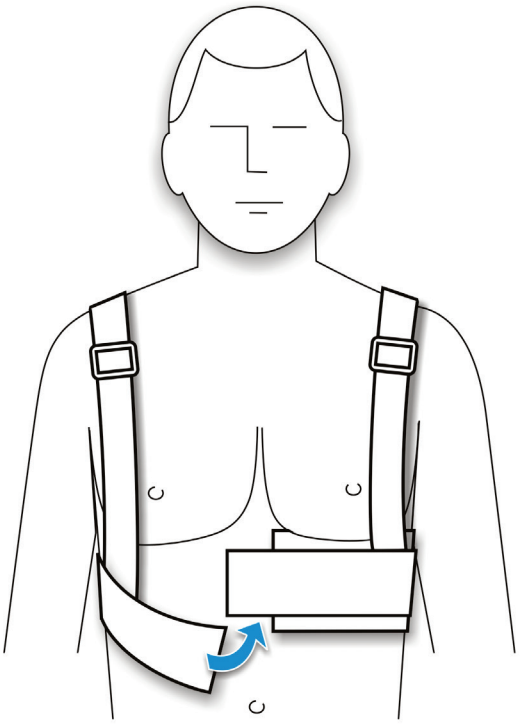


3 Help the patient put on the garment, making sure:

- The garment doesn't get twisted as the patient puts it on.
- The silver fabric pockets touch the patient's bare skin.

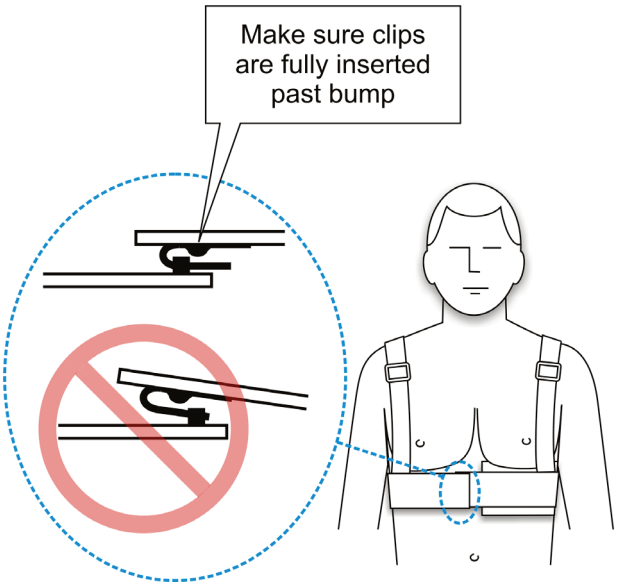
If patient is a female:

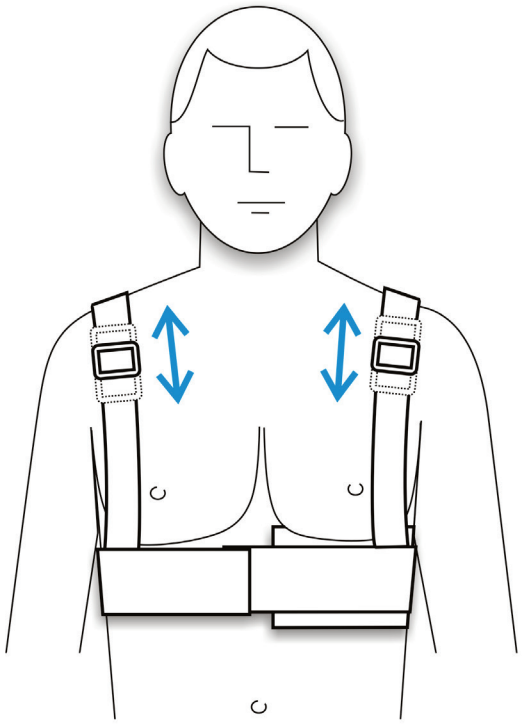
- Patient should wear a bra OVER the assembled electrode belt and garment.
- Make sure that the silver side of the front therapy pad is pressing against the patient's body rather than the underside of the patient's left breast.



4 Connect the garment ends together in the front.

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



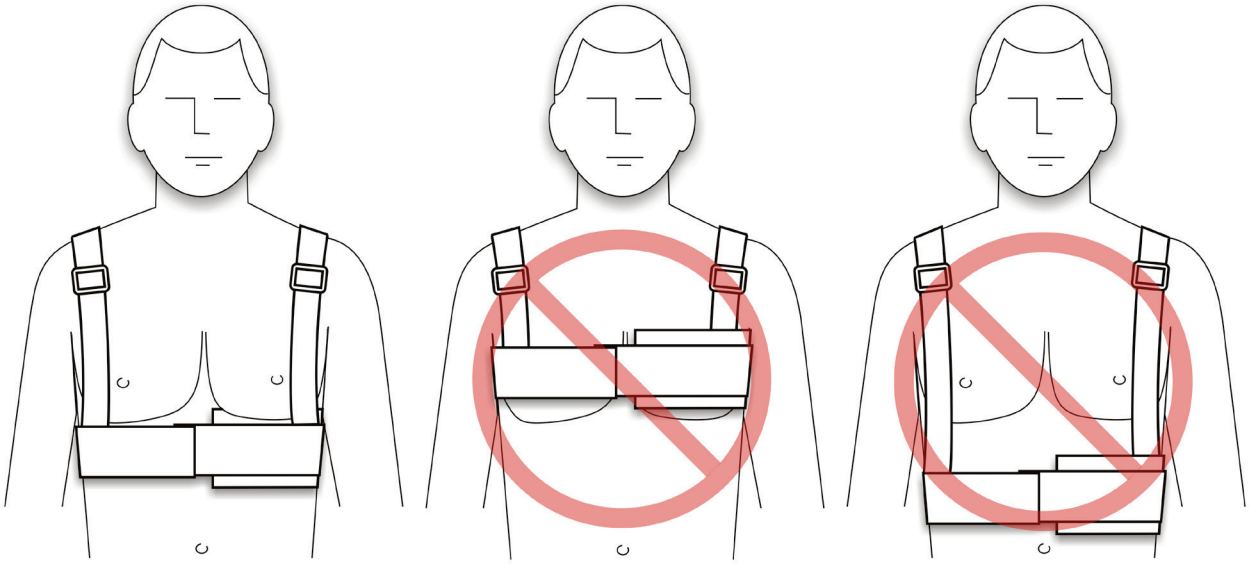


5 Check position of garment on the patient's body and make sure it's not too high or too low.

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

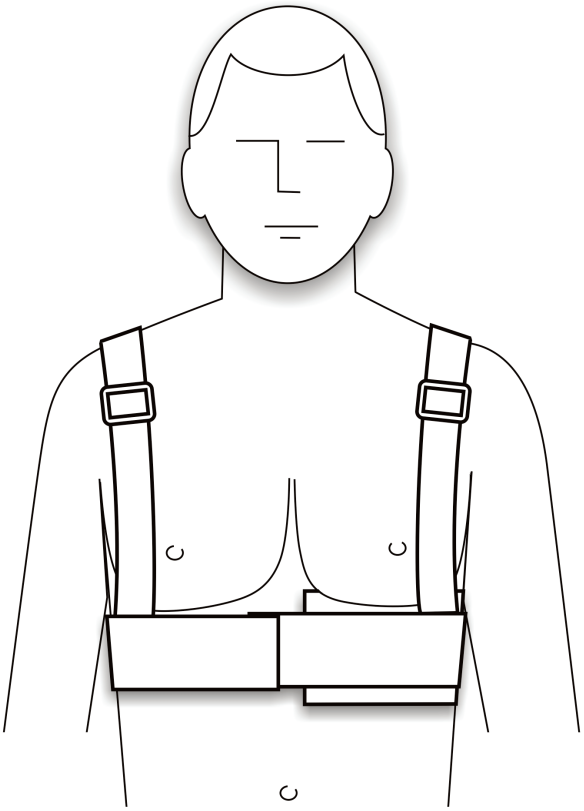
Move the buckles to position the garment properly, and for a snug fit.

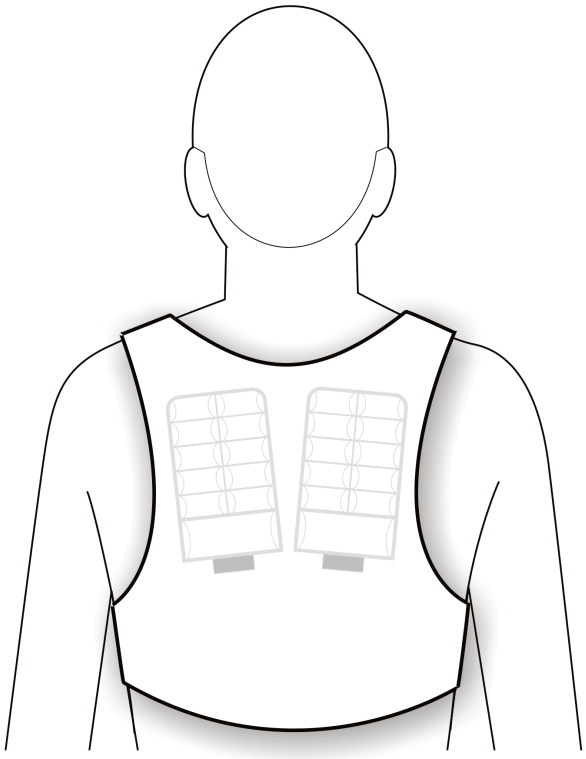
- The garment **should** cross the patient's body just below the breastbone.
- The garment **should not** be as high as the patient's nipples.
- The garment **should not** be as low as the patient's belly button.



6 Have the patient look in a mirror to make sure that:

- The garment is not twisted. Straps are flat against patient's skin.
- The ECG electrodes and therapy pads are pressing against bare skin. The silver fabric pockets and silver side of the therapy pads (with green stickers) MUST TOUCH THE PATIENT'S BODY for the device to work properly.
- None of the cabling interferes with the ECG electrodes or therapy pads.
- The garment is being worn correctly. It should look like the figures below.





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3: Patient training

This section gives guidelines for instructing the patient about the LifeVest system and how to respond to alerts.

We suggest that you:

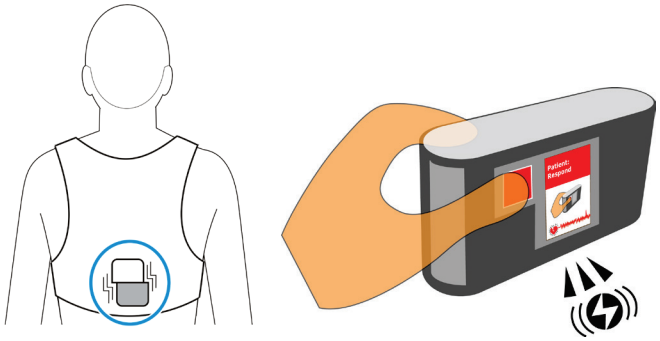
1 Go over the main points below, continued on the next page.

2 Explain the operating modes and alerts as described on page 3-4.

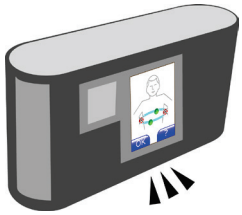
3 Demonstrate the types of alerts that can occur as described on page 3-5.

Main points to teach the patient

When you instruct the patient, stress the following points, explained on the following pages:



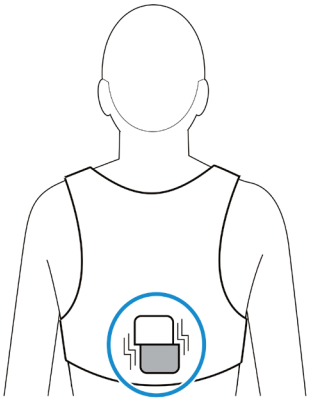
If you get a vibration or siren alert, press the response buttons.

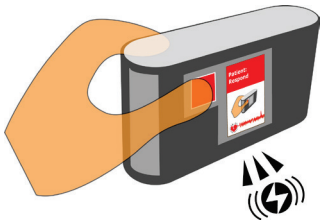


If you get a gong alert, read the message and take action to fix the problem.

If you get a treatment, continue wearing the LifeVest and call your doctor.

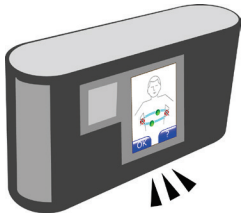
If you get a vibration or siren alert, press the response buttons





- The response buttons will light red when you are to press them so they will be easy to find, even in the dark.
- As long as you are able to, press the response buttons to stop a treatment. You don't have to hold them continuously. You can press and release them. If you get the siren alert again, press the buttons again.
- As long as you remain conscious and press the response buttons, you are in no danger of receiving a treatment.
- If you lose consciousness, of course you will not be able to press the response buttons. In this case, and if the siren alert continues, the device will go through the treatment cycle and deliver a treatment.
- It is very important that only you (the patient) press the response buttons. This is how the monitor knows whether or not you are conscious. DO NOT let anyone else press the response buttons for you.

If you get a gong alert, read the message



- Read the display and fix the problem.
- Tap the help button ? for brief instructions.
- You can set the monitor to speak when a help screen is displayed (see Patient Manual, section 3).
- For more complete instructions about what to do for various messages, check the Patient Manual, section 5.
- Keep in mind that the monitor gives alerts, messages, and voice prompts to guide you in what to do.

If you have an event, call your doctor

- If you have any kind of cardiac event, even if you manage to stay conscious and press the response buttons, you should contact your physician and report the incident.
- Any cardiac event is recorded by the monitor so your doctor can review the data later.

Review the contents of the Patient Manual

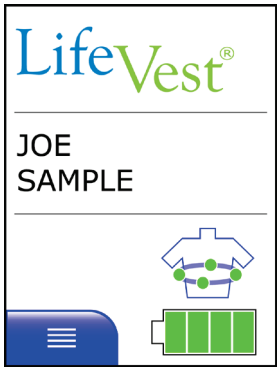
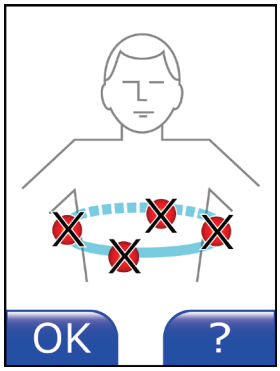
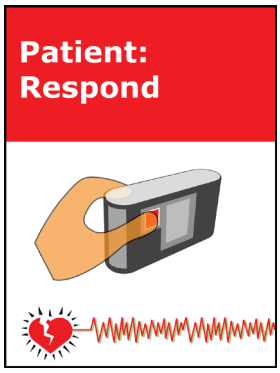
As part of the patient's training, review with the patient how to:

- change and recharge the battery
- change the garment
- disassemble and reassemble the garment and electrode belt

Also be sure to review the warnings and cautions located in the Patient Manual.

Summary of operating modes

As you instruct the patient, keep in mind that the device has basically three operating modes:

Mode	Message	What it means	What the patient needs to do
Normal monitoring – no alerts		Monitor is operating normally.	Nothing.
Gong alert	Various messages can appear, for example: 	Patient needs to take action.	Read screen. Tap help ? for instructions. Check Patient Manual for more information. See section 5, *Responding to alerts*.
Siren alert		An arrhythmia is being detected.	Press the response buttons if conscious. If unconsious, you'll get a treatment. Check Patient Manual for more information. See section 5, *Responding to alerts*.

Demonstrating the LifeVest to the patient

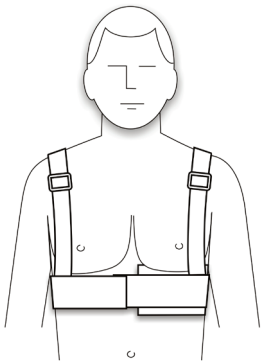
Demonstrate the alerts to help the patient learn how to respond.

You should now connect the electrode belt and have the patient wearing the garment and belt assembly as normal.

At a minimum, you should demonstrate the treatment sequence and belt alerts. Those demonstrations are explained on the following pages.

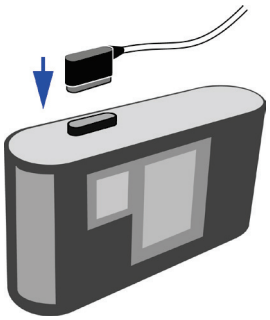
Optionally, you can demonstrate other functions, and you can have the monitor narrate the demonstrations. Those features are covered in Appendix D of this manual.

Connect patient for training mode



1 Outfit the patient with the electrode belt and garment.

2 Enter training mode.

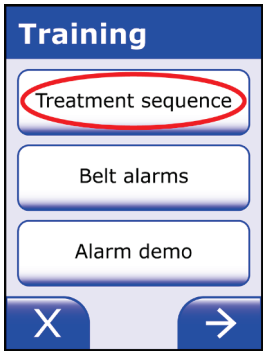


3 Connect the electrode belt to the monitor.

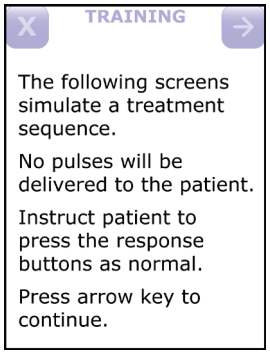
4 Continue with the procedure on the next page.

Demonstrating the treatment sequence

1 From the **Training mode** menu, tap **Select sections**.



2 From the **Training** menu, tap **Treatment sequence**.

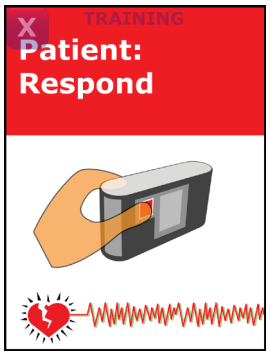


3 This screen reminds you that the LifeVest is going to simulate a treatment sequence.

Since the LifeVest is in training mode, the word **TRAINING** appears at the top of the screen.

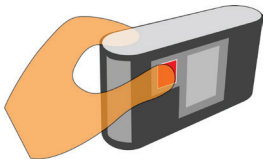
To advance to the next screen, tap the next page button in the upper right corner. As you proceed through the training, some screens will not have this button, forcing the patient to take the action indicated on screen.

To stop the training sequence, tap the **X** button in the upper left corner.



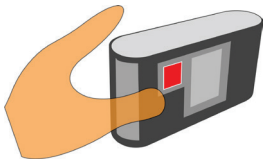
4 The device runs through the alert sequence that will occur if an arrhythmia is detected:

- Vibration alert activates and response buttons light red.
- Siren alert sounds (during training the siren is not as loud as it will be during an actual alert).
- Display shows that an arrhythmia has been detected and tells patient to press response buttons.
- Voice tells patient to press response buttons and tells bystanders not to interfere.



5 Tell the patient to hold the response buttons, not to just press and release them.

Note that the treatment is delayed while the buttons are held.



6 Next tell the patient to release the response buttons.

This message shows that treatment is being delayed because the response buttons were pressed and released.

Note the timing bar at the bottom of the screen. Alerts resume when the timing bar gets to the end.

Patient can press and release the response buttons again to delay treatment.

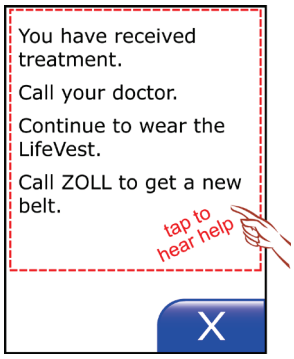
Allow the treatment sequence to continue so the patient can hear the alerts and voice prompts.

7 This screen shows that treatment has been given.

Note that we're only showing this screen during the demonstration; it will not normally be seen.

8 This screen tells the patient to continue to wear the device after receiving treatment.

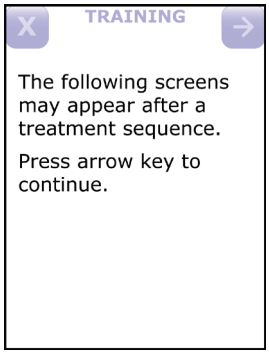
Tell the patient to tap the help button ? to show the patient an example of the type of help screens that are available.



9 This is an example of a help screen.

Tap the top half of the screen to demonstrate the speak option. This option works with any help screen.

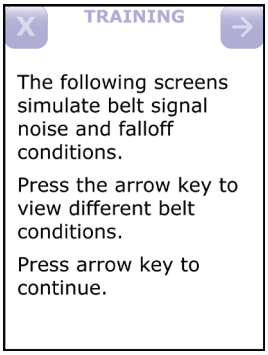
Tap the **X** button X to close any help screen.



10 Tap the next page button → to see additional screens, or tap the **X** button X to end the demonstration.

Demonstrating a belt alert

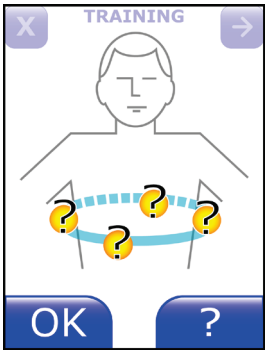
1 From the **Training** menu, select **Belt alarms**.



2 This screen reminds you that the LifeVest is going to simulate belt signal noise and falloff conditions.

To advance to the next screen, tap the next page button in the upper right corner.

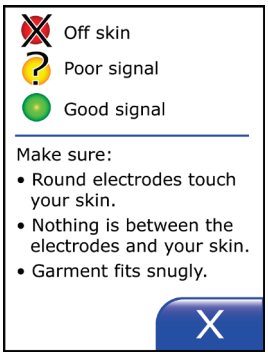
To stop the simulation, tap the **X** button in the upper left corner of any screen.



3 A series of screens show what the patient might see to indicate belt problems.

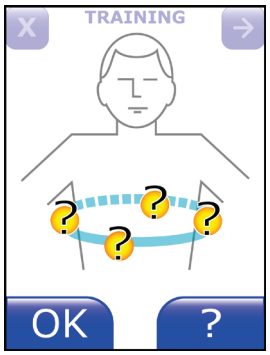
Each time you tap the next page button you'll see another screen.

Tap the help button ? to show the patient the help screen for belt problems.



4 This help screen shows what the symbols mean, and gives short instructions about what to do to fix the problem.

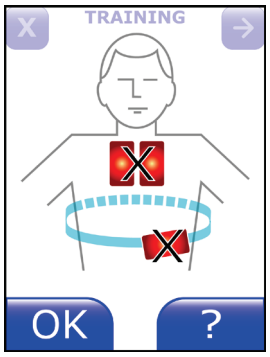
Tap the **X** button X to close the help screen.



5 Tell the patient what to do when the gong alert sounds:

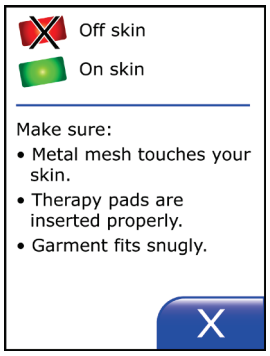
- **Read the display.** This particular message states that there is a problem with the belt. The round electrodes are sending a poor signal to the monitor.
- **Take action to correct problem.** In this case, you would adjust the belt so that the round electrodes make better contact with the skin.

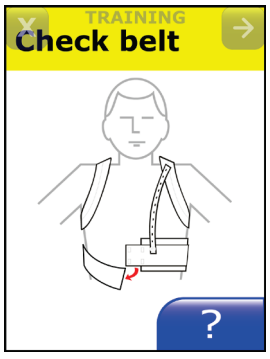
Press **OK** after you fix the problem. This stops the gong alert.



6 Keep tapping the next page button until you get to the therapy pad problem screens.

Again, you can tap the help button ? to show the patient the type of help associated with this screen.



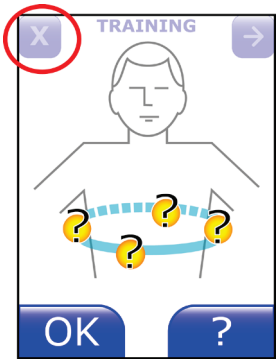


7 Tap the next page button until the monitor displays this message.

When this happens, the patient is expected to remove and check the belt.

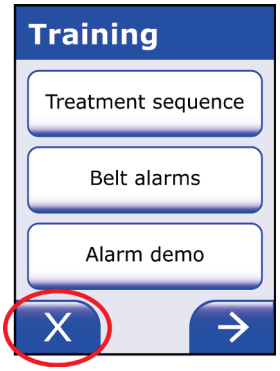
8 Tap the **X** button X to end the demonstration.

Exiting training mode

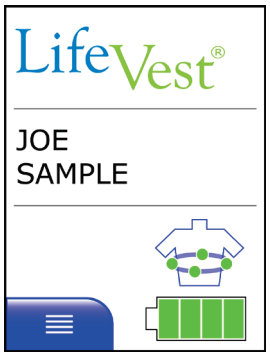


1 If you're in the middle of any training simulation, with the word **TRAINING** at the top of the screen, tap the **X** button  in the upper left corner of the screen.

This returns you to the training menu.



2 From any of the training menus, tap the **X** button until you return to the home screen.



3 When you reach the home screen, the LifeVest resumes normal operation.

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4: Monitor setup for a new patient

About this section

- This section covers the basic procedures for setting up the monitor before use by a new patient.
- If you need to enable, set up, change, or disable any of the activities options, see section 5, *Activities programming*.
- If you need to change any other settings on the monitor or charger, see the programming section of the Service and Programming Manual.

Summary of settings

The chart below shows all of the settings that can be programmed on the LifeVest.

Some settings are considered part of the basic setup for a new patient, and those settings are covered on the following pages.

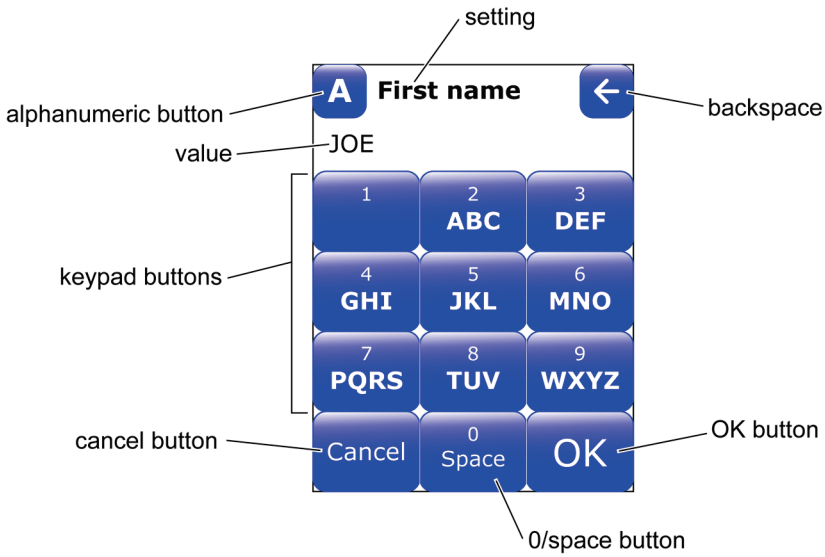
Other settings are considered advanced programming. Those settings are covered in the Service and Programming Manual.

All settings return to their default values when you set up a new patient.

Setting	Range	Default	Basic or advanced
Patient name	Any alphanumeric name	(blank)	Part of basic setup covered in this manual
VT rate threshold	120-250 beats per minute	150 beats per minute	
VF rate threshold	120-250 beats per minute	200 beats per minute	
Clinical center code	Any alphanumeric code	Determined by ZOLL	
Time zone	Selected from list	Time zone where patient resides	
Pulse energy	75-150 joules	150 joules for 5 shocks	Part of advanced setup covered in Service and Programming Manual
VT response time	60-180 seconds	60 seconds	
VF response time	25-55 seconds	25 seconds	
Patient sleep interval	Any two times during the day	Start: 11:00 PM, End: 6:00 AM	
Response time extension	0-30 seconds	0 seconds	
Patient language	Select from list	English	
Secondary language	Select from list	Off	
Operator language	Select from list	English	
Lead preference	Side-to-side or front-to-back	Side-to-side	

About the keypad

Some settings require using the keypad to enter the value. The buttons and displays on the keypad are described below.



Item	What it means and how to use it
Alphanumeric button	Tap to put the keypad in alpha or numeric mode: A = alpha mode, for entering names and words. Letters will be entered first with each key tap. 2 = numeric mode, for entering numbers. Numbers will be entered first with each key tap.
Setting	Shows the programmed setting that is currently being entered through the keypad.
Backspace button	Tap to back up and erase one character at a time. Continue tapping to erase more characters.
Value	Shows value being entered using the keypad.
Keypad buttons	For entering alpha characters or numbers. In alpha mode, tap the keypad to enter the desired characters. With the first key tap, the letters will be entered. Tap the button repeatedly to cycle through its characters. For example, you would rapidly tap the 2ABC button one time to enter A, two times to enter B, three times to enter C, and four times to enter 2. In numeric mode, tap the keypad to enter the desired numbers. With the first key tap, the number will be entered. If you rapidly tap a key, it will cycle through the letters also. After 2 seconds, the character is accepted and the cursor moves to the next position.
Cancel button	Tap to back out of the screen. If any changes were made, they are disregarded.
0/Space button	Tap to enter a 0 (zero) or space.
OK button	Tap to accept the value displayed and to exit the screen.

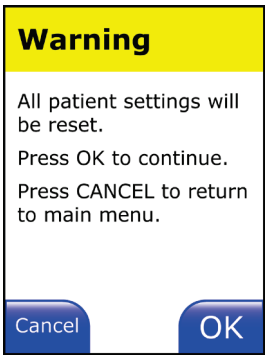
Programming mode

To perform any of the procedures in this section, the monitor needs to be in programming mode. Generally programming is performed by ZOLL personnel. If you need to have the device reprogrammed, please contact ZOLL.

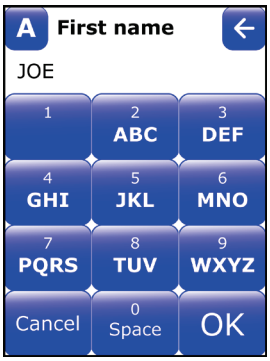
Programming the monitor for a new patient

New patient programming consists of entering the patient's name and the rate thresholds for ventricular tachycardia (VT) and ventricular fibrillation (VF).

1 With the main menu displayed, tap **New patient**.

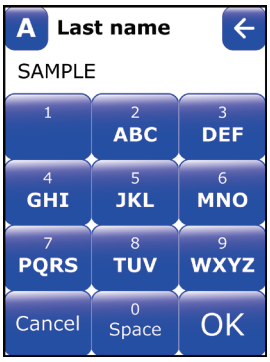


2 Read the warning message, then tap **OK**.

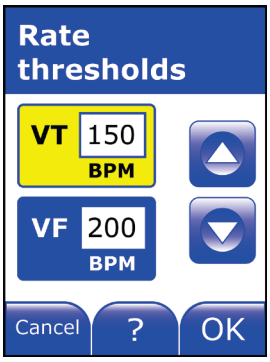


3 Enter patient's first name, then tap **OK**.

For help in using the keypad, see page 4-2.



4 Enter patient's last name, then tap **OK**.



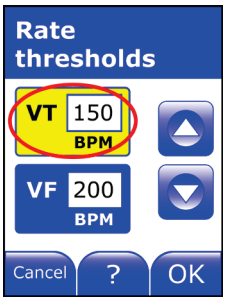
5 This screen shows the values for the rate thresholds. Review these values and change if needed.

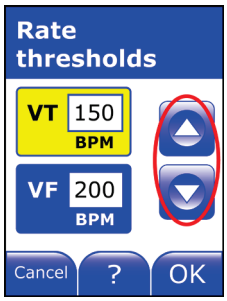
To accept the values shown, tap **OK**.

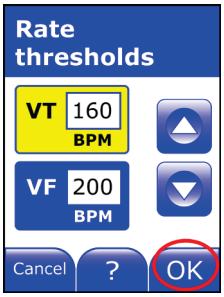
To see the range and defaults, tap the help button ?.

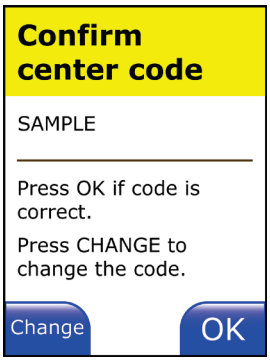
To change one or both values:

- Tap the threshold you want to change so its window is yellow.
- To change the value, tap ▲ or ▼.
- Repeat to change the other value if desired.
- To save the new values, tap **OK**.
- To leave this screen without changing the values, tap **Cancel**.







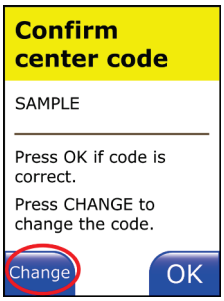


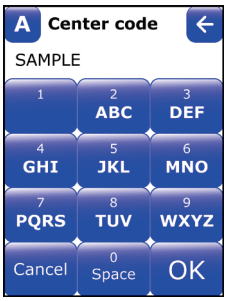
6 Confirm center code and change if needed.

To accept the code shown, tap **OK**.

To change the code:

- Tap **Change**.
- Use the keypad to enter a new code, then tap **OK**.



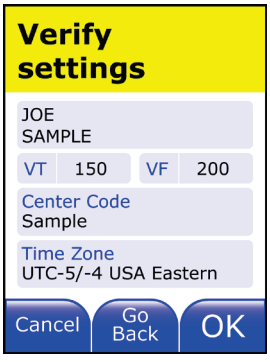


7 Set time zone.

To accept the time zone shown, tap **OK**.

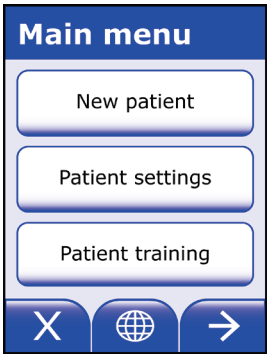
To change the time zone:

- Tap  to go west,  to go east.
- Tap **OK**.



8 Verify all of the settings.

- To accept the changes, tap **OK**.
- To change any of the settings, tap **Go Back**. Then enter the correct values.
- On any screen, to accept the value shown without changing it, tap **OK**.
- To cancel this setup, tap **Cancel**.



9 From the main menu, tap **X** to close the screen and exit programming.

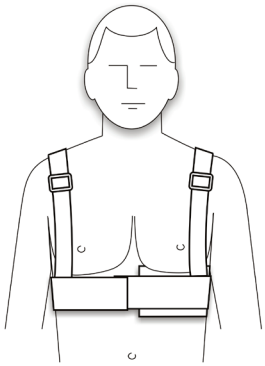
Continue to set up the patient as described on the next page.

Setting up a patient

The monitor's arrhythmia detection algorithm uses the patient's normal ECG as a template to help determine if a treatable arrhythmia exists.

After you program the monitor for a new patient, the monitor automatically goes into the setup mode.

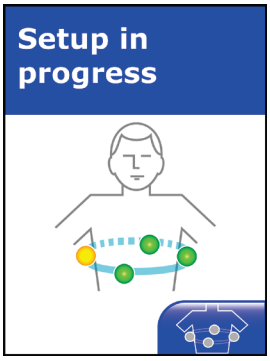
Follow this procedure to set up the patient.



1 Have the patient put on the garment and electrode belt, and connect the electrode cable to the monitor.

Have the patient sitting or lying down, relaxed, and not talking or moving around.

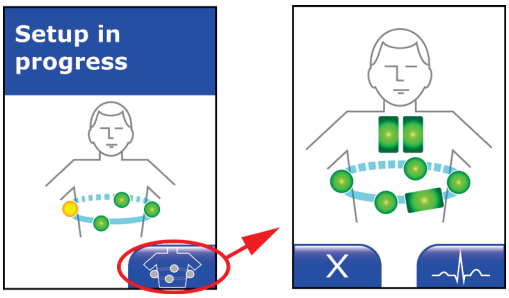
2 When you see this message, tap **OK**.

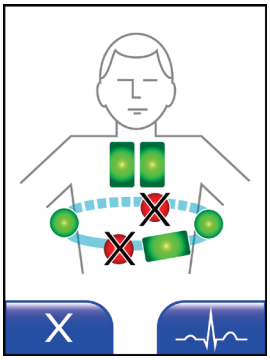


3 This message displays while the monitor records the patient's ECG.

Setup time will vary depending on the patient, strength of the ECG signal, and the amount of noise on the ECG signal. Setup may take up to 5 minutes.

4 During setup, tap  to see the status of the belt sensors.

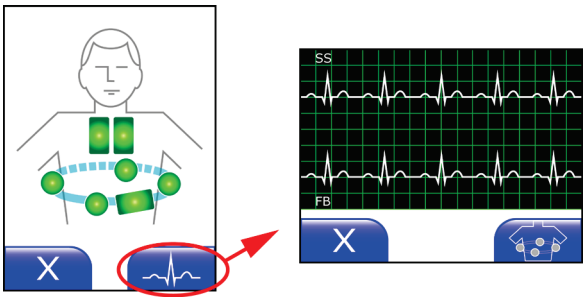


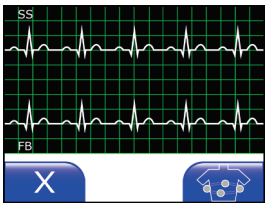


This screen shows the status of the belt sensors.

- Good sensors are shown as  or  .
- Problem sensors are shown as  or  or  . If you have any of these, make sure the sensor is in good contact with the patient's skin.

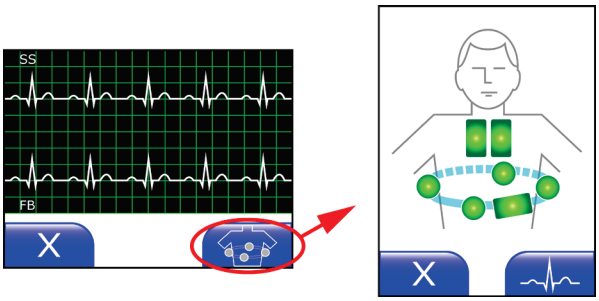
To see the patient's ECG, tap  .



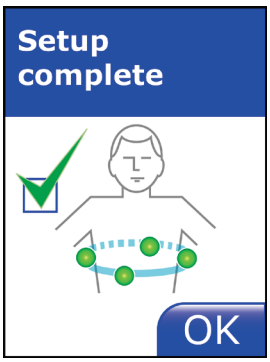


This screen shows the patient's ECG. Rotate the monitor for easier viewing. The top line shows the side-to-side (SS) channel, the lower line shows the front-to-back (FB) channel.

To return to the screen that shows the belt sensors, tap  .

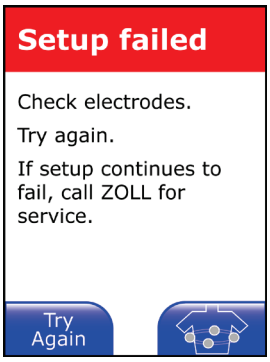


To close either of these screens, tap 
.



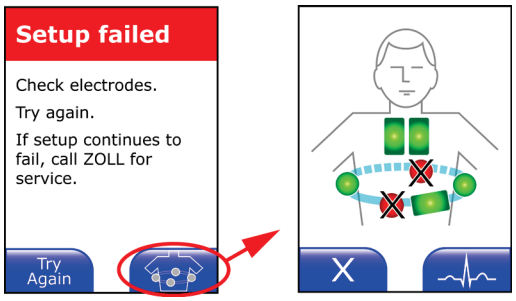
5 When you see this message, setup is complete.

Tap **OK** and the monitor operates normally.



If you get this message, the monitor failed the setup. Do the following:

- Verify that the sensors are properly contacting the patient's skin. Tap  to see if any sensors may be causing the problem.

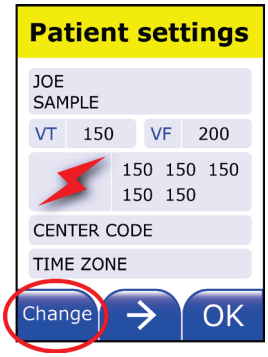


- If any sensors are not contacting the skin, they will be shown in red. Check these sensors for good contact with skin. You may need to clean the skin or clip excessive chest hair.
- Try to setup the patient again. From the **Setup failed** screen, tap **Try Again** and repeat this procedure.
- If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. Call ZOLL.

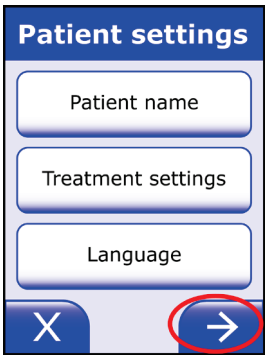
Rebaselining a patient

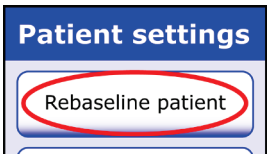
Use this procedure if you need to rebaseline a patient.

1 On the **Main menu**, select **Patient settings**.

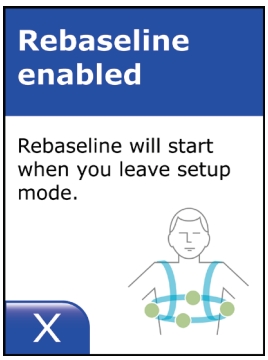


2 On the **Patient settings** summary screen, tap **Change**.





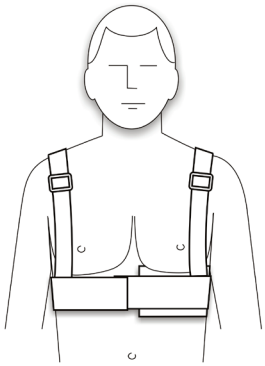
3 On the **Patient settings** menu, tap the arrow button → to go to the second page, then select **Rebaseline patient**.



4 You will get this screen verifying that the rebaseline will start when you leave setup mode.

Tap the **X** button.

Tap the **X** button again on the patient settings screen, and on the menu screen.

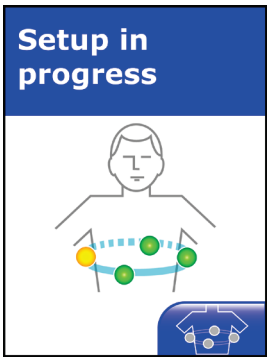


5 Prepare the patient as follows:

- Have the patient put on the garment and electrode belt, and connect the electrode cable to the monitor.
- Have the patient sitting or lying down, relaxed, and not talking or moving around.

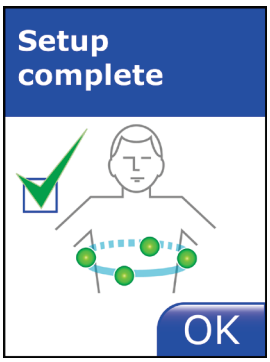
6 When you see this message, the LifeVest is ready to rebaseline.

When the patient is ready, tap **OK**.



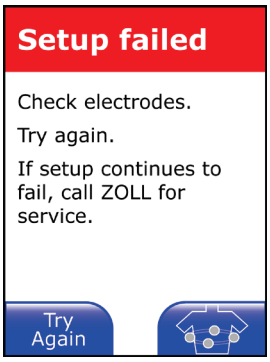
7 This message displays while the monitor rebaselines the patient.

The time for this process will vary depending on the patient, strength of the ECG signal, and the amount of noise on the ECG signal. Total time may be up to 5 minutes.



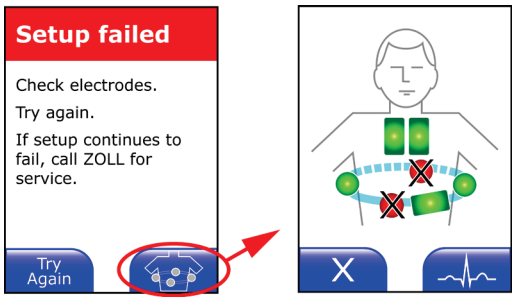
8 When you see this message, setup is complete.

Tap **OK** and the monitor operates normally.



If you get this message, the monitor failed the setup. Do the following:

- Verify that the sensors are properly contacting the patient's skin. Tap  to see if any sensors may be causing the problem.



- If any sensors are not contacting the skin, they will be shown in red. You may need to clean the skin or clip excessive hair before fitting the patient with the electrode belt and garment.
- Try to setup the patient again. From the **Setup failed** screen, tap **Try Again** and repeat this procedure.
- If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, call ZOLL.

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5: Activities programming

Overview of activities

The LifeVest offers a number of options for displaying patient activities, including a health survey, walk test, and trends.

You can enable, set up, change, or disable these options by programming the LifeVest monitor.

To view the present status of the activities options on the LifeVest monitor, see *Viewing activities* on page 5-5.

About the health survey

The LifeVest has the ability to ask the patient a series of prescriber selected health- related questions. The patient is to answer the questions in a way that most closely describes how they feel. The patient proceeds to answer each question until all questions are answered.

The LifeVest stores the patient's answers and, during the next download, sends the results to a secure website where the prescriber can choose to review the results.

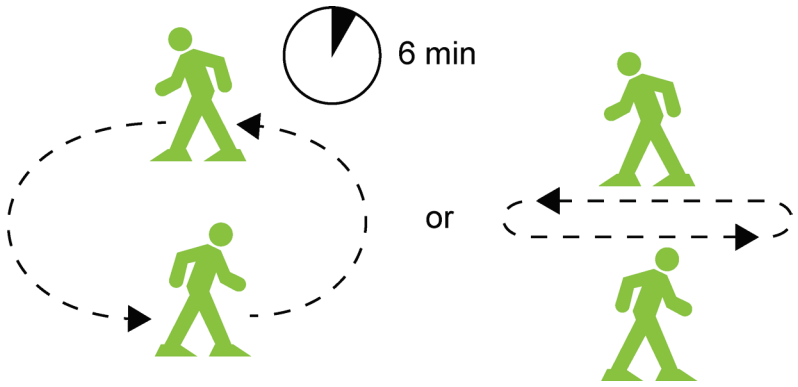
It is possible to program the device for a health survey through the monitor screens. A health survey can be enabled for different schedules, either daily or weekly, and the number of times the survey is to be taken. Questions to be included in the health survey are selected from a list.

To enable, disable, or set up a health survey, see *Health survey programming* on page 5-8.

About the walk test

The purpose of the walk test is to have the patient walk for 6 minutes while the LifeVest monitors the patient's heart and counts the number of steps taken.

The patient is to walk at a comfortable pace for 6 minutes. The patient can walk in a circle or oval, such as walking a track. The patient can walk in a square or rectangle, such as walking around a room. The patient can also walk in a straight line, turning at the ends, such as walking back and forth in a hallway or narrow room.



While the patient is walking, audible prompts indicate how much longer to walk, and when to stop walking.

Before and after the walk test, the patient will be asked the same two questions: One about the patient's shortness of breath level and another about the patient's fatigue level. The patient's responses to the questions will determine whether the walk test can be taken. The threshold for allowing the patient to take the walk test must be set by the clinician.

The LifeVest records the answers to the questions as well as the number of steps taken during the walk test and, during the next download, sends the results to a secure website where the prescriber can choose to review the results.

The LifeVest should be programmed according to the patient's physician prescriber. It is possible to program the device for a walk test through the monitor screens. A walk test can be enabled for different schedules, either daily or weekly, and the number of times the walk is to be taken. You also set the threshold for answering the pre-walk questions. If the patient answers the questions above a certain threshold, the LifeVest will not permit the patient to take the walk test.

As part of setting up a patient's monitor for the walk test, measure and enter the patient's step length. Entering the step length will give an approximation of the distance covered during the walk test. See page 5-19.

To enable, disable, or set up a walk test, see *Walk test programming* on page 5-14.

About the trends

Trends is another option that displays data while a patient is wearing the LifeVest, including heart rate, activity, and body position.

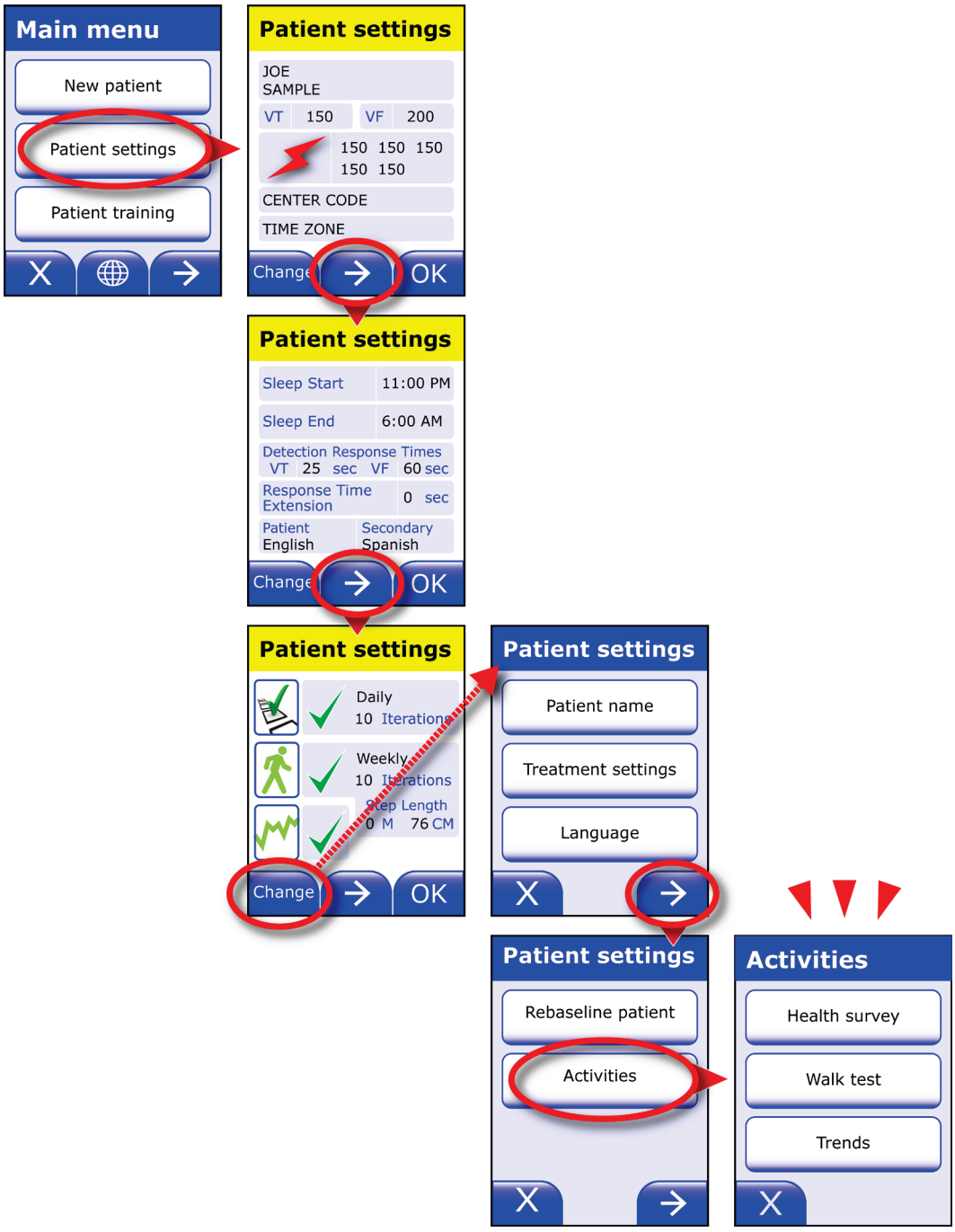
There are no programming settings for trends, just whether the option is enabled or disabled.

Trends are enabled on every monitor by default. Data delivery is determined by LifeVest Network.

If you need to disable the trends, see *Trends programming* on page 5-25.

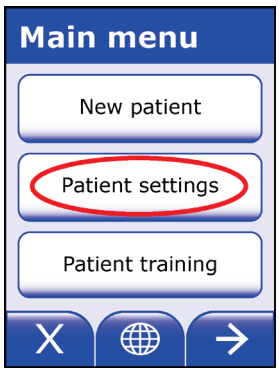
Activities programming menu map

Use this map to help navigate to the activities menus on the monitor. From the activities menu, you can select the programmable settings for the health survey, walk test, and trends.

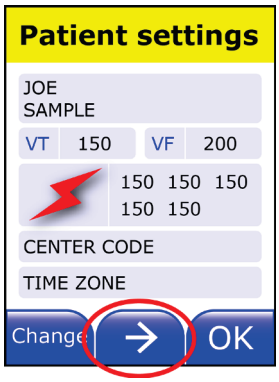


Viewing activities

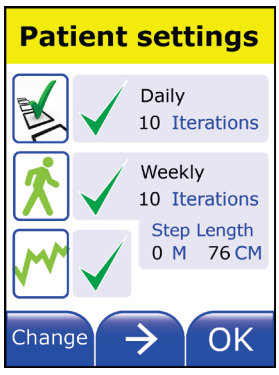
You can view the present status of the activities on the patient settings screen. Follow these instructions to view the activities options:



1 After entering programming mode, and with the main menu displayed, select **Patient settings**.



2 Tap → to get to the third page.

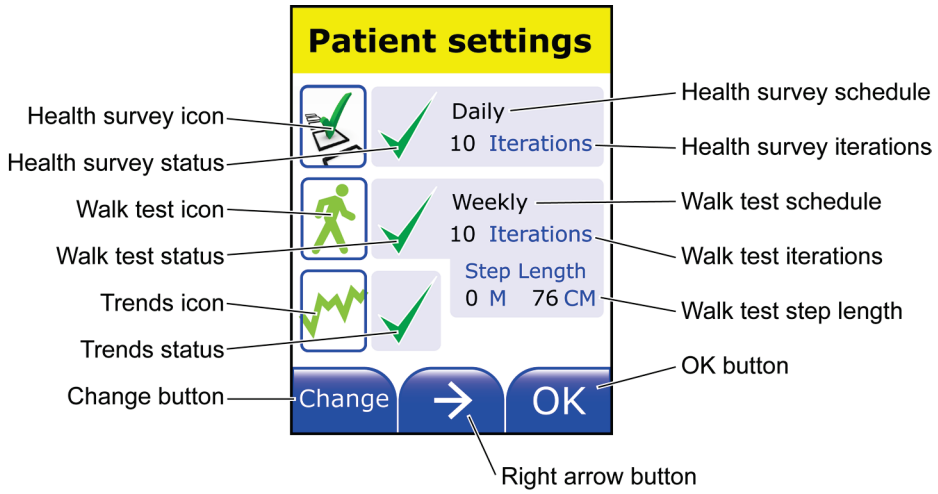


The third page shows the status of the activities.

Details on how to read this screen are on the next page.

How to read the activities settings

You can view the activities settings on the patient settings screen.



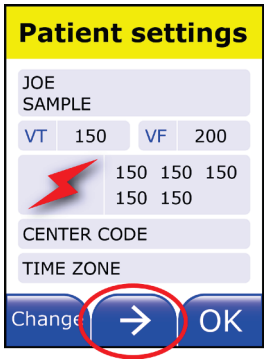
Item	What it means and how to use it
Health survey icon 	The settings to the right of this icon give you the status and settings of the health survey. To review the questions selected for the survey or make any changes, tap **Change**. See details on page 5-8.
Health survey status	 Health survey option is enabled.
	 Health survey option is disabled.
Walk test icon 	The settings to the right of this icon give you the status and settings of the walk test. To make any changes, tap **Change**. See details on page 5-14.
Walk test status	 Walk test option is enabled.
	 Walk test option is disabled.

Item	What it means and how to use it
Trends icon 	The check or X to the right of this icon gives you the status of the trends. To make any changes, tap **Change**. See details on page 5-25.
Trends status	 Trends option is enabled.
	 Trends option is disabled.
Health survey schedule	Daily or weekly, this indicates whether the patient will be instructed to take the health survey once a day or once a week.
Health survey iterations	This is the number of times the patient will be instructed to take the health survey. For example, if the screen shows 10, the patient will be instructed to take the health survey 10 times. The infinity symbol ∞ means that the health survey will be repeated indefinitely as scheduled.
Walk test schedule	Daily or weekly, this indicates whether the patient will be instructed to take the walk test once a day or once a week.
Walk test iterations	This is the number of times the patient will be instructed to take the walk test. For example, if the screen shows 10, the patient will be instructed to take the walk test 10 times. The infinity symbol ∞ means that the walk test will be repeated indefinitely as scheduled.
Walk test step length	Indicates the step length setting for this patient. Regardless of whether the step length was entered in FT and IN or M and CM, this screen displays the setting in M and CM. To change the step length, tap **Change**. See details on page 5-19.
Change button	Tap this button to change any of the patient settings.
Right arrow button	Tap this button to see the other patient settings screens.
OK button	Tap this button to leave the patient settings screen without making any changes.

Health survey programming

Follow these instructions to enable the health survey from the monitor.

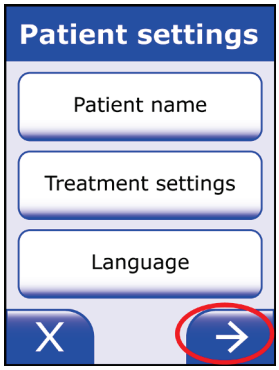
1 In programming mode, and with the main menu displayed, select **Patient settings**.



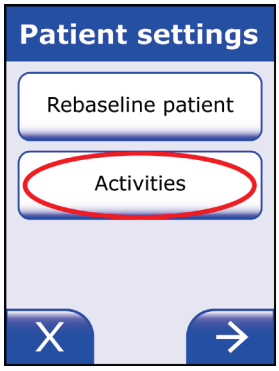
2 Tap → to get to the third page, so you can see the existing activities settings.

Review the existing activities settings.

To change any of the activities settings, tap **Change**.

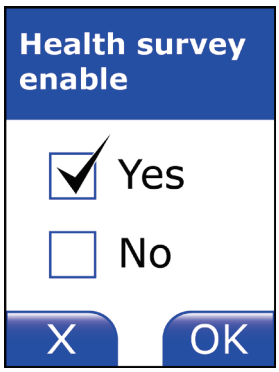


3 Tap → to get to the second page.



4 Select **Activities**.

5 Select **Health survey**.

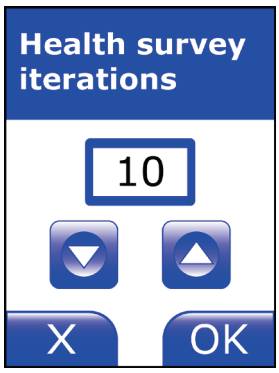


6 To enable the health survey, tap **Yes** so it's checked, then tap **OK**.

To disable the health survey, tap **No** so it's checked, then tap **OK**. Skip the remaining steps of this procedure.

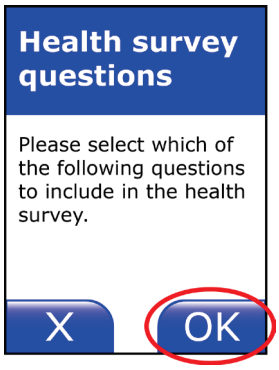
7 Select when to schedule the health survey, checking either **Daily** or **Weekly**.

- If you select **Daily**, the patient will be prompted to take the health survey once a day.
- If you select **Weekly**, the patient will be prompted to take the health survey once a week.
- After making your selection, tap **OK**.



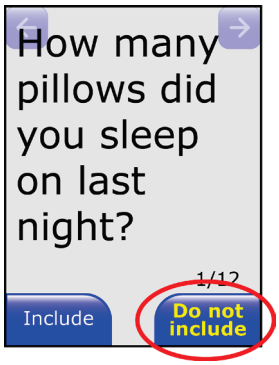
8 Select the number of health survey iterations using and .

- This setting is used in conjunction with the schedule you selected the previous step.
- For example, if you selected **Daily** in the previous step, now select the number of days to repeat the health survey.
- If you selected **Weekly**, select the number of weeks to repeat the health survey.
- If you want to repeat the health survey for the foreseeable future, enter ∞ (the infinity symbol). Infinity is the default, and it is located below the number 1. If you tap the button, the numbers advance from infinity to 1, 2, 3, and so on. To return to the infinity setting, use the button to count down below the number 1.
- After making your selection, tap **OK**.



9 Next you will select the questions to include in the health survey.

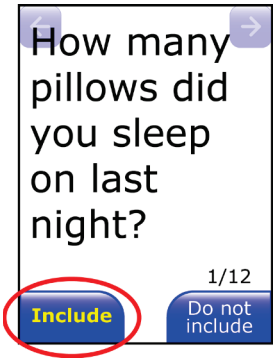
To proceed, tap **OK**.



10 You will be shown each of the possible questions.

Before we explain how to select which questions to include in the patient survey, here's what you need to know:

- If a question *is not* to be included, the **Do not include** button is highlighted yellow and the screen background is gray.

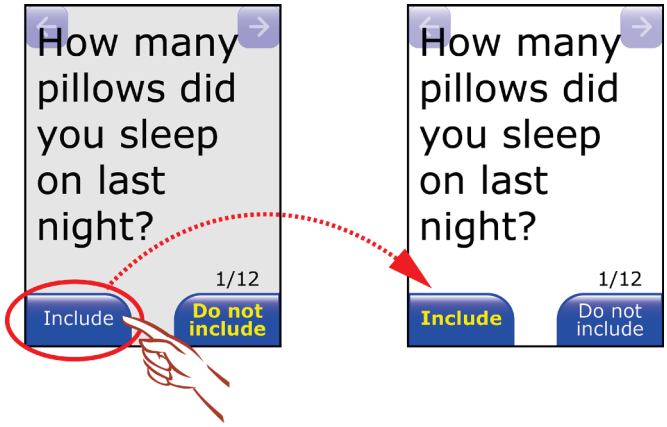


- If a question *is* to be included, the **Include** button is highlighted yellow and the screen background is white.

Now select which questions to include in the survey.

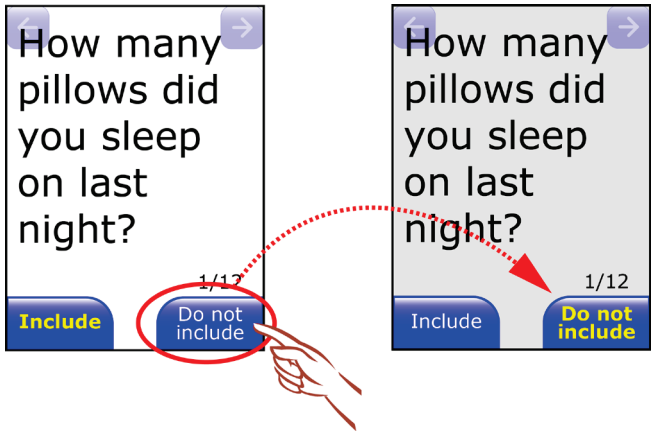
To **include a question** on the survey, tap **Include** while the question is displayed.

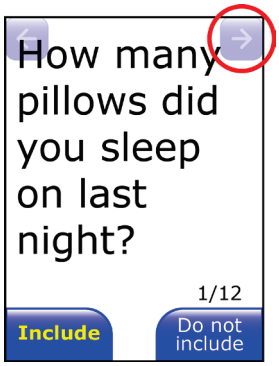
Notice that the **Include** button becomes highlighted yellow, and the screen background changes to white.



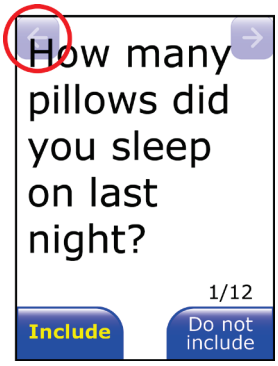
To **not include a question** on the survey, tap **Do not include** while the question is displayed.

Notice that the **Do not include** button becomes highlighted yellow, and the screen background changes to gray.

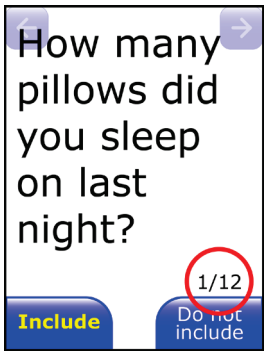




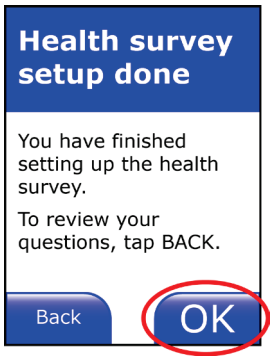
To go to the next question, tap the right arrow button in the top right corner.



To go back to a previous question, tap the left arrow button in the top left corner.



The question number is shown in the lower right corner of the screen.



11 After the last question, you will get this screen.

- To review your questions, tap **Back**. Then you can go through the questions by using the arrow buttons at the top of the screens.
- For each question, either **Include** or **Do not include** will be highlighted depending on your selection.
- When you get to the last question and tap either **Include** or **Do not include**, you will see this screen, indicating that you have seen all of the questions.
- When you are finished setting up the health survey, tap **OK**.

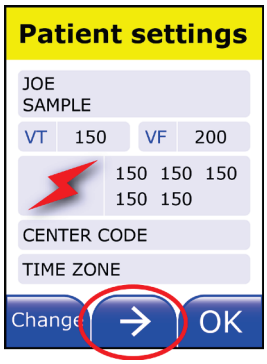
This completes the procedure for setting up the health survey.

Walk test programming

If you have not already measured and entered the patient's step length, see page 5-19.

After entering step length, follow these instructions to set up the walk test.

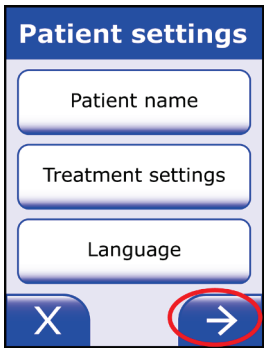
1 In programming mode, and with the main menu displayed, select **Patient settings**.



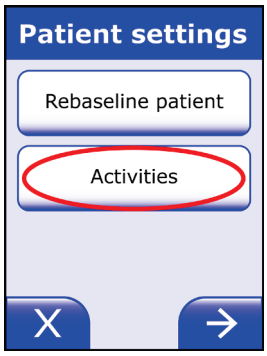
2 Tap → to get to the third page, so you can see the existing activities settings.

Review the existing activities settings.

To change any of the activities settings, tap **Change**.

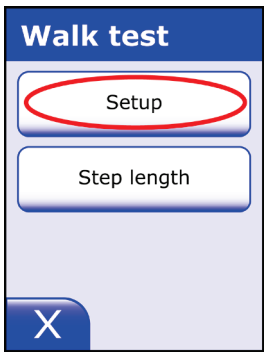


3 Tap → to get to the second page.

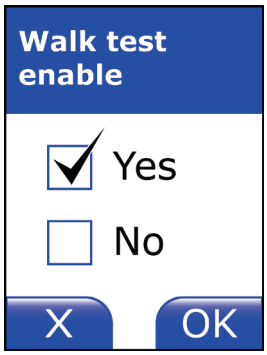


4 Select **Activities**.

5 Select **Walk test**.

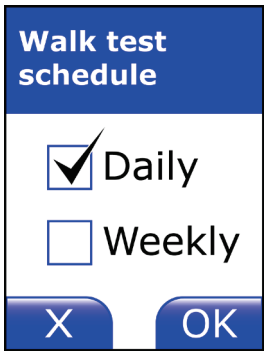


6 Select **Setup**.



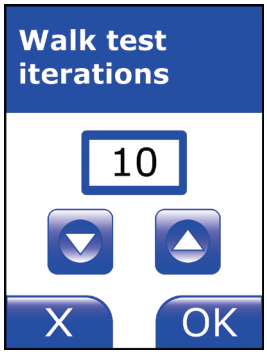
7 To enable the walk test, tap **Yes** so it is checked, then tap **OK**.

To disable the walk test, tap **No** so it is checked, then tap **OK**. Skip the remaining steps of this procedure.



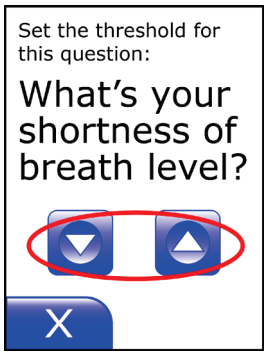
8 Select when to schedule the walk test, checking either **Daily** or **Weekly**.

- Remember that this setting comes from the physician prescriber.
- If you select **Daily**, the patient will be prompted to take the walk test once a day.
- If you select **Weekly**, the patient will be prompted to take the walk test once a week.
- After making your selection, tap **OK**.



9 Select the number of walk test iterations using and .

- This setting is used in conjunction with the schedule you selected in the previous step.
- For example, if you selected **Daily** in the previous step, now select the number of days to repeat the walk test.
- If you selected **Weekly**, select the number of weeks to repeat the walk test.
- If you want to repeat the walk test for the foreseeable future, enter ∞ (the infinity symbol). Infinity is the default, and it is located below the number 1. If you tap the button, the numbers advance from infinity to 1, 2, 3, and so on. To return to the infinity setting, use the button to count down below the number 1.
- After making your selection, tap **OK**.



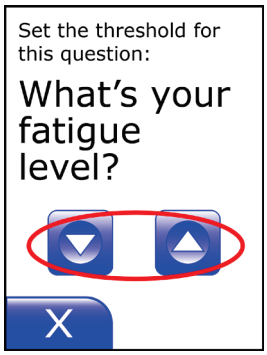
10 Set the threshold for the first pre-walk question.

- Remember that this setting comes from the physician prescriber.
- When you are ready to enter a value, tap either the ▼ or ▲ button.

Enter the threshold using this screen.

- Questions will be answered using the scale shown below.
- If a patient answers above this level, the patient will not be permitted to take the walk test.
- Tap the ▼ and ▲ buttons to change the value, then tap **OK**.

Threshold scale	
0.5	Very, very slight
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	
10	Very, very severe

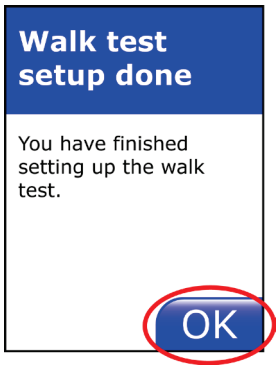


11 Set the threshold for the second pre-walk question.

- Remember that this setting comes from the physician prescriber.
- When you are ready to enter a value, tap either the ▼ or ▲ button.

Enter the threshold by tapping the and buttons, then tap **OK**.

Set the second pre-walk question threshold, as you did in step 10.



12 When you get this screen, tap **OK**.

This completes the procedure for setting up the walk test.

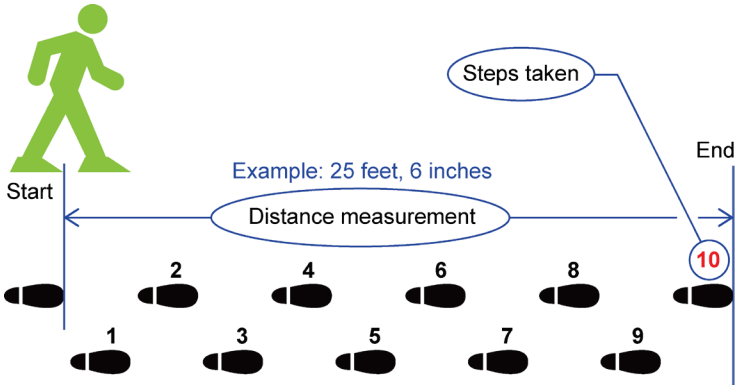
Measuring step length

As part of setting up a patient's monitor for the walk test, measure the patient's step length as follows. You'll need to have a tape measure or some other measuring device that can measure up to 35 feet (11 meters), as well as some way of marking the floor (such as tape) with a starting and ending point.

1 Mark a starting point. Have the patient use this starting point for their toe, as shown below.

2 Have the patient walk 10 steps as shown below. The patient should walk in their normal fashion, taking their normal gait, not stretching or running. Mark the end point.

3 Measure the total distance covered from the starting point to the end point, in feet and inches, or meters and centimeters.



Steps taken	10			
Distance measurement	25	FT	6	IN
		M		CM

4 Write down the number of steps taken and distance measurement. In the example shown above, the number of steps taken is 10, and the distance measurement is 25 feet, 6 inches.

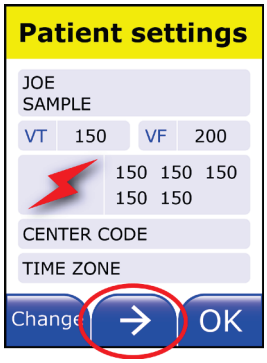
Steps taken		
Distance measurement	**FT**	**IN**
	M	**CM**

This is one method of estimating the step length. Other methods may be used.

Entering step length

After measuring the patient's steps and distance (see page 5-19), enter those values as follows:

1 In programming mode, and with the main menu displayed, select **Patient settings**.

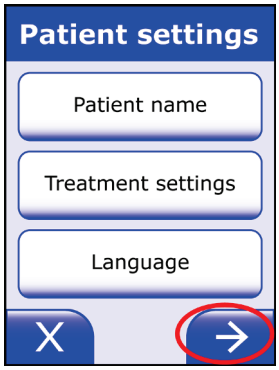


2 Tap → to get to the third page, so you can see the current activities settings.

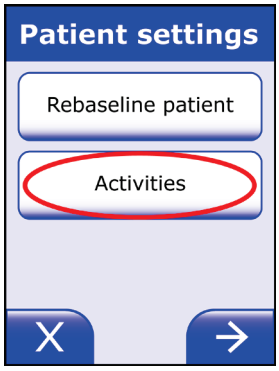
Verify that you want to change the step length.

To change the step length, tap **Change**.

Note that step length is converted into M and CM if entered in FT and IN when displayed on the patient settings screen.

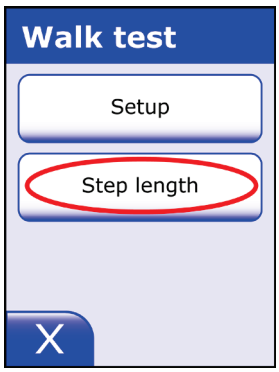


3 Tap → to get to the second page.

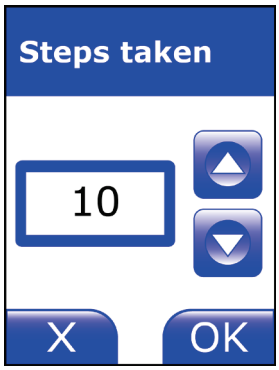


4 Select **Activities**.

5 Select **Walk test**.



6 Select **Step length**.



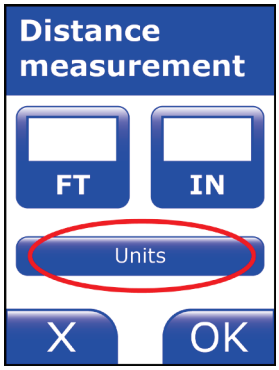
7 Enter the number of steps the patient walked, then tap **OK**.

In the example, the patient walked 10 steps.

Steps taken	10			
Distance measurement	25	**FT**	6	**IN**
		M		**CM**

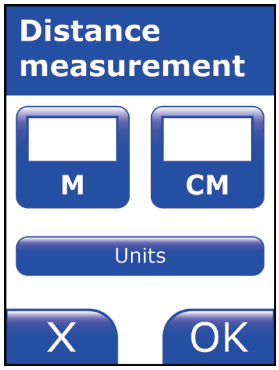
8 Remember the total distance covered by the number of steps the patient took?

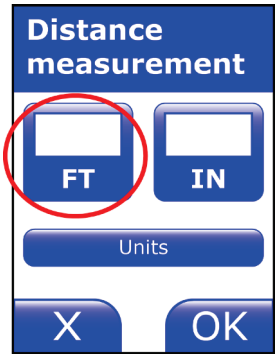
For the following steps, we'll presume you measured the distance in feet and inches.



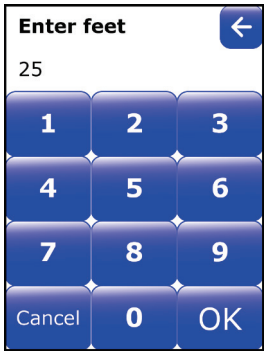
If, however, you measured your distance in meters and centimeters, tap the **Units** bar to change the windows to **M** (meters) and **CM** (centimeters).

If you change the units, enter the values as described in the next steps using the windows marked **M** (meters) and **CM** (centimeters) instead of **FT** (feet) and **IN** (inches).





9 Tap the **FT** (feet) window.



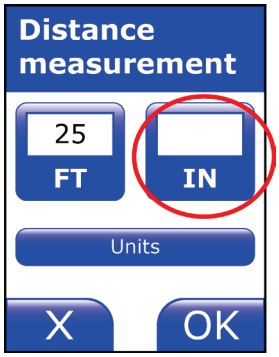
Enter the number of feet in your distance measurement.

In the example we've been using, you'd enter the number 25.

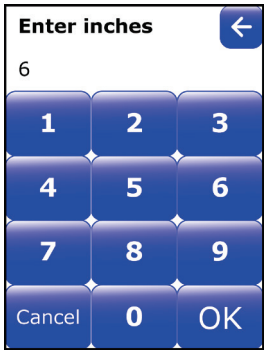
Steps taken	10			
Distance measurement	25 **FT**		6 **IN**	
	M		**CM**	

To correct an entry, use the back arrow button .

After you enter your number, tap **OK**.



10 Next, tap the **IN** (inches) window.

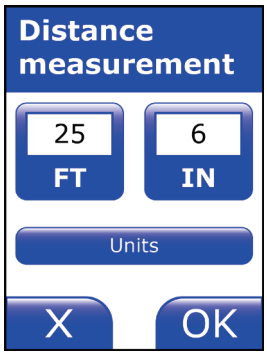


Enter the number of inches in your distance measurement.

In the example, you'd enter the number 6.

Steps taken	10			
Distance measurement	25 **FT**		6 **IN**	
	M		**CM**	

Then tap **OK**.



11 The screen shows the total distance you entered.

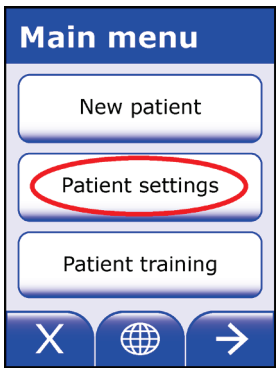
Confirm that you entered the correct value.

- If the value is correct, tap **OK**.
- If you need to change the value, tap the **FT** or **IN** window and re-enter the value.

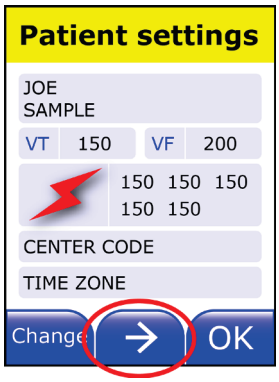
This completes the procedure for entering step length.

Trends programming

Follow these instructions to change the status of the trends (enabled or disabled) from the monitor.



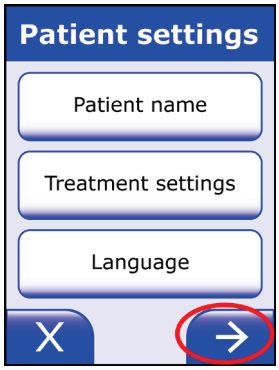
1 In programming mode, and with the main menu displayed, select **Patient settings**.



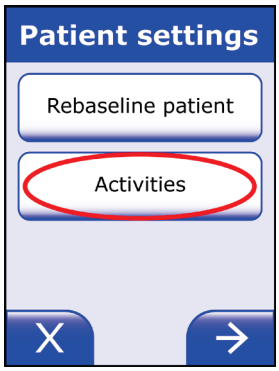
2 Tap → to get to the third page, so you can see the existing activities settings.

Review the existing activities settings.

To change any of the activities settings, tap **Change**.



3 Tap → to get to the second page, then select **Activities**.



4 Select **Trends**.

5 Select a status for the trends:

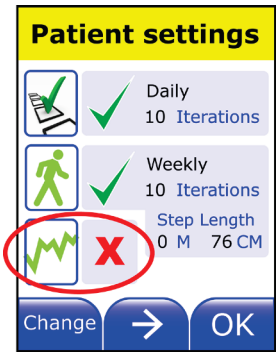
- To enable trends, tap **Yes** so it's check, then tap **OK**.
- To disable trends, tap **No** so it's checked, then tap **OK**.

6 If you selected **Yes** in step 5, this screen appears when you tap **OK**.

Tap **OK**.

If you selected **No** in step 5, you are taken directly to the **Patient settings** screen. See next step.

There are no other programmable settings for the trends.



7 The **Patient settings** screen shows the status of the trends:

Trends option is **enabled**.

Trends option is **disabled**.

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6: LifeVest Network

About LifeVest Network

LifeVest Network is a secure Internet Web site for viewing data related to the LifeVest wearable defibrillator.

From LifeVest Network, you can view ECG recordings, treatment events, and compliance data.

You can view and print a number of reports related to the LifeVest.

For more information about LifeVest Network, and to set up your LifeVest Network account, contact ZOLL.

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7: Clinical information

Indications

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 18.75 kilograms (41.3 pounds) or greater. See *Device use for patients under 18 years of age* on page 7-5.

Contraindications

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

WARNING

Before prescribing the LifeVest, the healthcare professional should consider whether the patient will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The healthcare professional should consider mental, visual, physical and auditory limitations that may impact a patient's ability to successfully interact with the system. Failure of the patient to successfully interact with the system may result in system malfunction, possibly resulting in serious injury or death.

Physician information to instruct patient caregivers

The LifeVest should only be prescribed to patients who will be able to successfully interact with the system, including understanding the manual and training, assembling/disassembling the device, and using the response buttons. The physician should consider mental, visual, physical and auditory limitations that may impact a patient's ability to successfully interact with the system.

When the patient does not meet all of these criteria, physicians use medical judgment to determine that a patient caregiver can assist the patient in certain responsibilities, such as assembling/disassembling the device. The patient's ability to press the response buttons is a test of the patient's consciousness and is part of the device's process to decide whether and when to deliver treatment. If anyone other than the patient holds the response buttons, needed therapy may not be delivered, possibly resulting in serious injury or death.

Interaction with pacemakers

WARNING

Always use appropriate caution when prescribing a LifeVest device to a patient who is dependent on a pacemaker. All patients who have pacemakers should be examined for proper pacemaker function after a defibrillation.

Several interactions with pacemakers are possible:

- If a patient goes into a ventricular arrhythmia and the pacemaker continues to pace, the pacemaker's pulses may be the dominant signal.[1] This may potentially cause the LifeVest device to lock on the pacemaker's signal as the cardiac rhythm and prevent the LifeVest device from detecting the arrhythmia. The risk varies according to the type of pacemaker and the programmed mode of the pacemaker.
- If the patient is baselined with the pacemaker active, an unpaced QRS complex may be interpreted by the LifeVest device as a change in the QRS morphology. As a result, if the rate goes above the arrhythmia rate threshold, the LifeVest device may then declare the unpaced rhythm a treatable arrhythmia and begin the treatment alert sequence. As long as the patient uses the response buttons of the LifeVest device, the device will not deliver a treatment shock. However, be aware that an increased potential for an unnecessary shock does exist.
- After the shock is delivered, the pacemaker may have difficulty capturing the myocardium[2] or may be reset to a default mode.

[1] Glikson, et al, "Importance of Noise Reversion as a Potential Mechanism of Pacemaker-ICD Interactions," *PACE*, May 1998, 21: 1111-1121.
[2] Altamura, et al., "Transthoracic DC Shock May Represent a Serious Hazard in Pacemaker Dependent Patients," *PACE*, January 1995, 18 (Part II): 194-198

Other articles of interest:

Brode, et al, "ICD-Antiarrhythmic Drug and ICD-Pacemaker Interactions," *Journal of Cardiovascular Electrophysiology*, July 1997, 8:830-842.

Geiger, et al, "Interactions Between Transvenous Nonthoracotomy Cardioverter Defibrillator Systems and Permanent Transvenous Pacemakers," *PACE*, March 1997, 20 (Part I): 624-630.

Recommendations for patients with pacemakers

If the pacemaker does pace during ventricular fibrillation, there is a risk that the pacemaker stimulus artifact would be tracked by the LifeVest device as a valid heart rate during ventricular fibrillation. In order for this to occur, the pacemaker stimulus artifact must be greater than the ventricular fibrillation signal. Patients whose pacemaker stimulus artifact is greater than 0.5 mV in any ECG lead should not use the LifeVest device.

Because of the risk that the patient's unpaced ECG signal may be interpreted as a ventricular tachycardia if it exceeds the arrhythmia rate threshold, set the VT rate threshold above the maximum paced rate when a patient is baselined while being paced.

After shock delivery, check the pacemaker's programming and ability to capture.

Recommendation for double counting of a normal rhythm

Double counting of a normal rhythm is known to occur with ICDs and other rhythm analysis devices.

Patients likely to experience double counting declarations may have high T waves and/or low QRS amplitudes. If a patient does experience such false arrhythmia declarations, there are two actions which may help: increasing the arrhythmia rate threshold and/or lengthening the response time. Increasing the arrhythmia rate threshold should reduce the frequency of false arrhythmia declarations due to double counting. Lengthening the response time gives the patient additional time to respond to the alerts if a shock is not necessary.

Asystole detection

The LifeVest monitors the ECG signal and declares asystole when the amplitude of the ECG input signal falls below 100 microvolts for at least 16 seconds. The following conditions can occur:

- If the normal sinus rhythm changes directly to asystole, the patient is prompted to check electrodes. If there is no response and the condition does not change after 30 seconds, the LifeVest displays a message and voice prompt that if the patient is not responsive to call for help and to perform CPR.
- If the normal sinus rhythm changes to bradycardia, then to asystole, the LifeVest displays a message and voice prompt for bystanders that if the patient is not responsive to call for help and to perform CPR.

Interaction with ventricular assist devices

WARNING

Always take precautions with a patient wearing a ventricular assist device. Some ventricular assist devices can be damaged or reprogrammed by external defibrillation. Therefore, patients wearing ventricular assist devices may not be suitable candidates for the LifeVest.

If you have a patient who is a candidate for the LifeVest, and that patient is using a ventricular assist device, check the manufacturer's instructions regarding whether the device could be damaged or reprogrammed by external defibrillation. If the ventricular assist device could be damaged by external defibrillation, that patient is not a candidate for the LifeVest.

Device use in patients under 18 years of age

According to the 2010 AHA guidelines,[1] 2-4 J/kg is the recommended energy level for effective defibrillation therapy for pediatric patients including patients under 18 years of age. In order for these patients to be treated with an appropriate amount of energy with the LifeVest device, which is programmable between 75 and 150 joules, they must meet the minimum required weight of 18.75 kg. At the minimum energy setting of 75 J, a minimum weight patient of 18.75 kg would receive the maximum dose of 4 J/kg. In order to meet the AHA's minimum recommendation of 2 joules per kg, patients weighing over 37 kg should be programmed to receive more than 75 joules. Appropriate dosage is determined and prescribed by the physician.

As of November 8, 2012, the company registry contained 248 pediatric patients, aged 3-17, including those in the literature publications.

Retrospectively collected data has shown the ability of the LifeVest to successfully convert a sudden cardiac arrest to a life-sustaining rhythm in patients as young as 13. Four patients in the 3-17 age group experienced SCA during LifeVest use that was successfully converted to a life sustaining rhythm. The following table provides further detail on the pediatric patients receiving an appropriate treatment with the LifeVest.

Patient	Age	Wear duration (days)	Indication for LifeVest use	Treatment summary	Energy delivered (Joules)	Reason for ending LifeVest use
1	13	78	Congenital heart disease	1 appropriate treatment	151	Heart transplant
2	14	3	Cardiomyopathy	1 appropriate treatment	150	Received ICD
3	15	55	Wolf-Parkinson-White syndrome	1 appropriate treatment	150	Received ICD
4	16	60	Tetralogy of Fallot	4 appropriate treatments	152-154	Improved ejection fraction

There are three peer-reviewed articles on the use of the LifeVest specifically in the pediatric population. One paper describes four pediatric patients prescribed a wearable defibrillator from a single site.[2] All carried a diagnosis of anthracycline-induced cardiomyopathy. While no patients received an appropriate treatment in this study, no patients received an inappropriate treatment despite the inappropriately detected rhythm caused by ECG noise. Two patients had documented noncompliance with wear, which resulted in failure to detect and treat a life-threatening arrhythmia in one. The paper concluded that the wearable defibrillator is a short-term alternative for children at risk for SCD, who can be

[1] Link M, et al. *Part 6: Electrical Therapies: Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing - 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.* Circulation. 2010;122[suppl 3]:S706–S719.
[2] Everitt MD, Saarel EV. Use of the wearable external cardiac defibrillator in children. *Pacing and Clinical Electrophysiology.* 2010;33(6):742-746.

properly fit with the wearable defibrillator, where the risk of ICD use is greater than the benefit.

In a paper by Collins et al., 81 multi-site wearable defibrillator patients from 9-18 years old, and 103 patients aged 19-21, were retrospectively reviewed.[1] In patients ≤18 years of age, there was one inappropriate therapy, due to sinus tachycardia and artifact, and one withholding of therapy due to a device-device interaction. Compliance was generally similar to adults among these younger patients, with an average daily use of 19 hours, and non-compliance or comfort issues only being recorded for 7-11% of patients. This paper concluded that the wearable defibrillator could be an appropriate therapy for pediatric patients who are at risk for SCA, as they had two appropriate treatments in their young adult population (age 19-21). However, they had no appropriate treatments in their pediatric population (age 9-18).

The third paper by LaPage et al., published prior to the two papers discussed above, detailed the fatal device-device interaction between the wearable defibrillator and a unipolar epicardial pacemaker.[2] Such interactions are not unique to pediatric patients nor are they unique to wearable defibrillators, being copiously described in the ICD and AED literature. LifeVest manuals have specific warnings about pacemaker interactions; please see *Interaction with pacemakers* on page 7-2 and *Recommendations for patients with pacemakers* on page 7-3. These warnings advise physicians to use appropriate caution when prescribing the LifeVest device to a patient who is dependent on a pacemaker.

The rate of inappropriate treatments per patient days of use for patients under 18 years of age is similar to that of patients 18 years of age and older. Inappropriate treatments can be prevented by pressing the response buttons. Only one serious adverse event has been reported for pediatric patients using the device. This event is described in the paper by LaPage et al, which summarizes the withholding of therapy caused by a pacemaker interacting with the wearable defibrillator.

[1] Collins KK, Silva JN, Rhee EK, Schaffer MS. Use of a wearable automated defibrillator in children compared to young adults. *Pacing and Clinical Electrophysiology.* 2010;33(9):1119-1124.
[2] LaPage MJ, Canter CE, Rhee EK. A fatal device-device interaction between a wearable automated defibrillator and a unipolar ventricular pacemaker. *Pacing Clin Electrophysiol.* Jul 2008;31(7):912-915.

Clinical studies

Initial FDA-approval study[1]

Conducted between 1990 and 2001, the objective of the FDA-approval trial was to demonstrate safety (low false shock rate) and efficacy (survival after sudden cardiac arrest). There were 289 high SCA risk patients who used the device an average of 3 months. Of 8 SCA events that occurred during the trial, 6 were successfully converted. There were 6 appropriate shocks during the trial. The trial design was to demonstrate superiority of the wearable defibrillator to reliance on the EMS system for SCA treatment.

Biphasic electrophysiology laboratory sub-study[2]

This study was conducted between March 2001 and November 2001. Twelve patients were electively induced into VT or VF, and all 12 were converted or defibrillated with the first biphasic shock (either 70 or 100 joules). A total of 23 successful biphasic shocks were delivered. There were no post-shock arrhythmias or skin burns. The average patient impedance was 68 ±8 ohms.

WCD 3000 clinical evaluation

This study was conducted between September 2001 and April 2002. The objective was to demonstrate the safety of the LifeVest WCD 3000 device by comparing the incidence of false arrhythmia declarations (false alarms) with the WCD 3000 device to the WCD 2000 device. The study would be considered successful if the incidence of false arrhythmia declarations was less than, or equal to, the WCD 2000 device. A minimum of 10 patients and 100 weeks of cumulative device use would be required.

A prospective, non-randomized, multi-national trial involving four centers (three USA centers and one European center) evaluated the safety of the WCD 3000 device with patients at risk of sudden cardiac death. Two populations at SCA risk were chosen:

- The first population consisted of patients waiting for heart transplant or patients having an equivalent cardiac status, namely New York Heart Association Class III or IV heart failure and an ejection fraction below 30 percent.
- The second patient population included acute myocardial infarction (MI) patients and patients immediately following a coronary artery bypass graft procedure. Additional requirements for both the MI and bypass patients included VT/VF within the first 48 hours or a left ventricular ejection fraction of less than 30 percent. A Killip Class III or IV 72 hours following the MI and syncopal VT/VF after 48 hours post-MI also qualified patients for WCD 3000 device use.

[1] Feldman et al., “Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patient at High Risk for Sudden Death: Results of WEARIT/BIROAD,” *PACE*, 2004, 27:4-9.
[2] Reek et al., “Clinical Efficacy of a Wearable Defibrillator in Acutely Terminating Episodes of Ventricular Fibrillation Using Biphasic Shocks”, *PACE*, 2003, 26:2016-2022.

Patient demographics

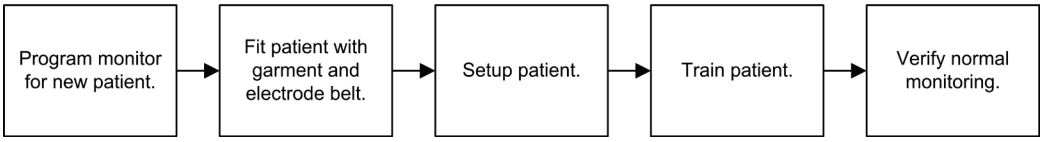
Parameter	Total Study (n=13)	WEARIT (n=7)	BIROAD (n=6)
Ejection fraction	21% ±7, n=11	18% ±6	25% ±5, n=4
QRS width (msecs)	105 ±15, n=9	106 ±18, n=5	104 ±12, n=4
Age (years)	56 ±11	56 ±13	57 ±9
Male	69%	71%	67%
History of smoking	83%, n=12	67%, n=6	100%
History of hypertension	83%, n=12	86%	80%, n=5
History of NSVT	89%, n=9	80%, n=5	100%, n=4
History of VT	44%, n=9	33%, n=3	50%
Beta-blocker medication	82%, n=11	67%, n=6	100%, n=5
Anti-arrhythmia medication	9%, n=11	0%, n=6	20%, n=5
Inotropic medications	0%, n=11	0%, n=6	0%, n=5

The study population consisted of 13 patients with 105 patient weeks of patient device experience. There were 214 false arrhythmia detections during that time. The rate of false detections using the WCD 3000 device was 2.0 per patient week of use as compared to 4.5 per patient week using the WCD 2000 device. There were no treatable tachyarrhythmic events during the study. There were four true arrhythmias recorded during the study, all four resolved spontaneously. There were no inappropriate defibrillations during the study.

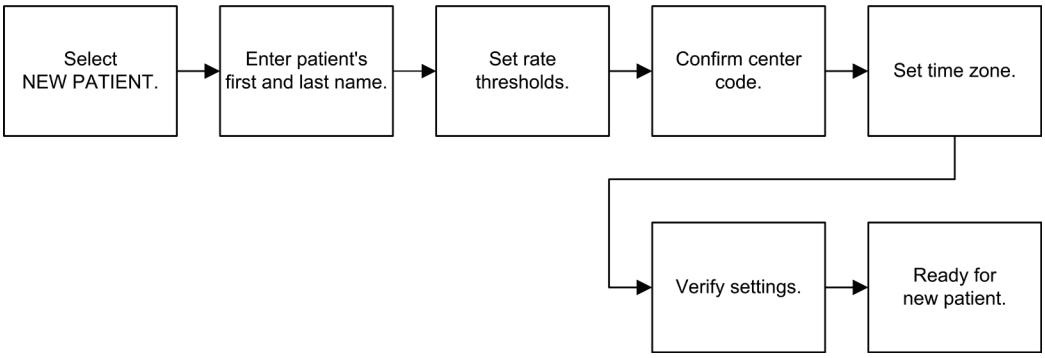
One adverse event was reported during the study. This event involved a patient who received an asystole alert due to incompletely connecting the electrode belt to the monitor. The patient called an ambulance to take her to the hospital as the device directed. She was hospitalized as a precaution and transferred from this local hospital to the investigational site where she was examined and discharged to home. No injury resulted from this event. The patient continued to wear the device.

Appendix A: Quick charts

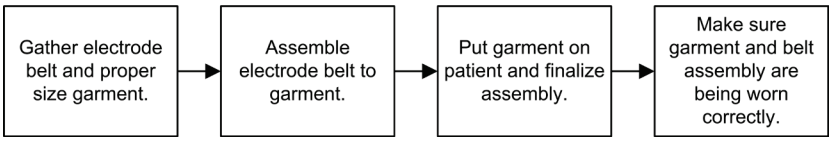
Overview of new patient setup



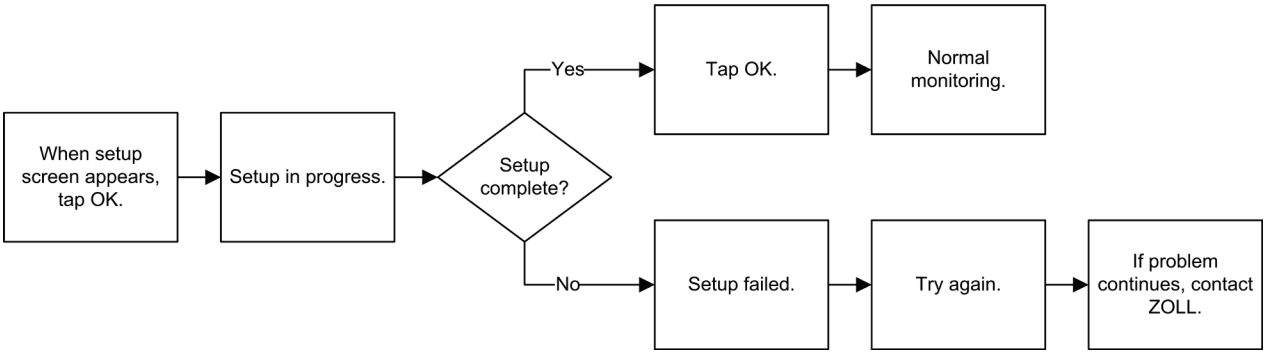
Programming monitor for new patient



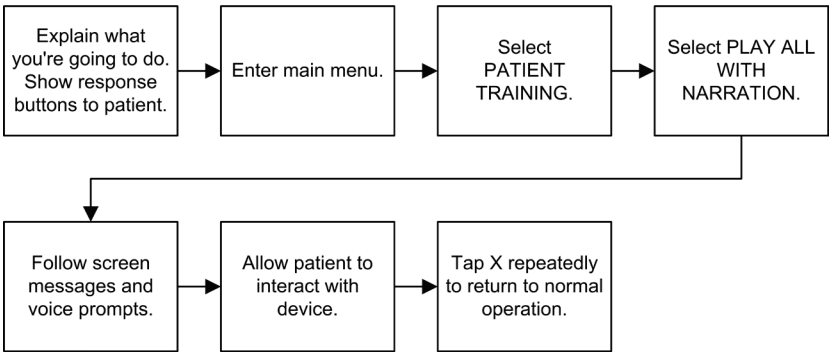
Fitting patient with garment and electrode belt



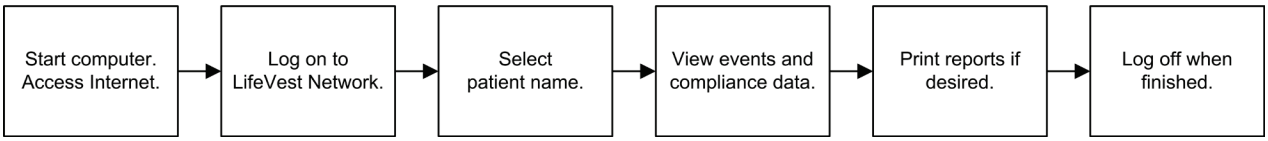
Setting up new patient



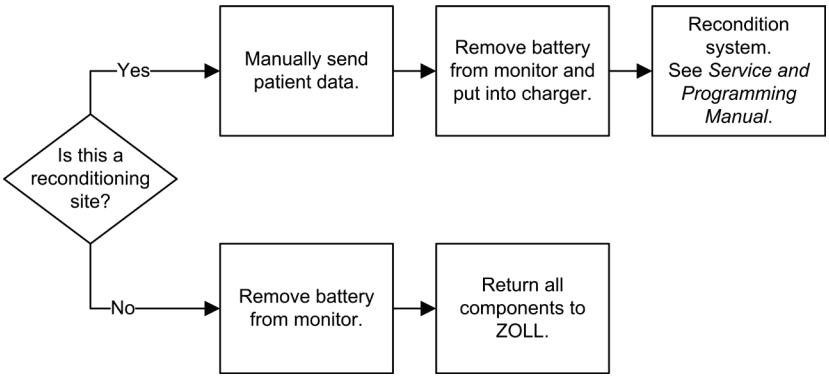
Training patient



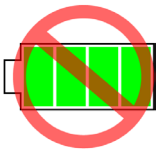
Viewing patient data

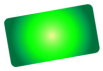
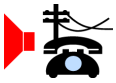


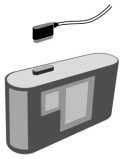
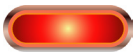
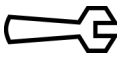
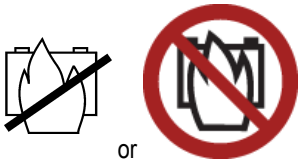
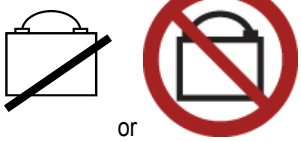
When patient is finished with device

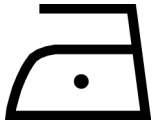
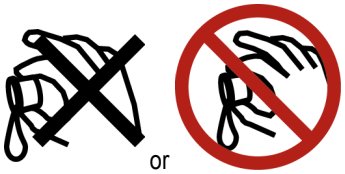
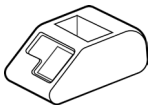
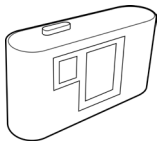


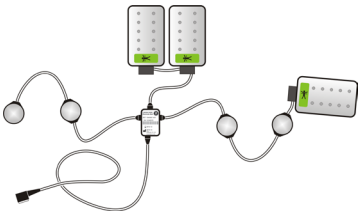
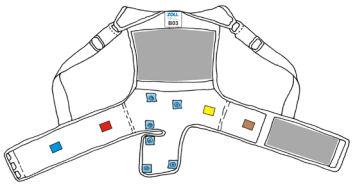
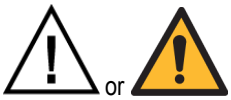
Appendix B: Symbols

	Cell modem selected: Cellular modem is selected.
	No cell signal: No data can be sent via cell network.
	Cell modem is not functioning.
	Bluetooth signal strength: Indicates signal strength from charger. Number of pie pieces indicates signal strength. Signal must be present in order to send data from monitor to charger.
	No Bluetooth signal: No data can be sent between monitor and charger.
	Battery level (on monitor): Number of bars indicates battery charge. Battery charging (on charger): Animated to show that battery is charging.
	Battery empty (on monitor): Battery is discharged.
	Battery testing: Animated to show that battery is being tested.
	Battery problem: Battery has a problem and may need to be replaced. Call ZOLL.
	Battery low (red battery symbol): Battery is getting low. Change battery as soon as possible and recharge battery. Tap for help.
	Battery may be defective (yellow battery symbol): LifeVest cannot determine battery condition. Call ZOLL for service. Tap for help.
	Menu button: Tap to see menu.
	OK button: Tap to acknowledge that you have read the screen. If any selections or changes were made on the screen, they take effect.
	Cancel button: Tap to back out of the screen. If any changes were made, they are disregarded.
	Translate button: Tap to change the language on the screen to the secondary language. Only shown when there is a secondary language.

	Help button: Tap to see help screen.
	X button: Tap to close the screen. Used with help screens.
	Next page button: Tap to go to the next page when there is more than one.
	Previous page button: Tap to go to the previous page when there is more than one.
	Charger problem: Charger has a problem and cannot be used. Call ZOLL immediately.
	ECG electrode good signal: Situation normal, no action required.
	ECG electrode poor signal: Check electrode for cause of poor signal and fix problem.
	ECG electrode off skin: Check electrode that is off skin and fix problem.
	Therapy electrode on skin: Situation normal, no action required.
	Therapy electrode off skin: Check electrode that is off skin and fix problem.
	Land line dialing mode: Shows that LifeVest is connected to a land line phone.
	Land line dialing mode with sound: Shows that LifeVest is connected to a land line phone and that sound will be heard when phone connection is attempted.
	Monitor transmitting: Monitor is transmitting data to the charger.
	Monitor connected: Monitor is set to manually send data.
	Airplane mode: Monitor will not transmit data.
	Monitoring mode: Animated to show that LifeVest is in monitoring mode. Situation normal, no action required.

	Standby mode: Animated to show that LifeVest is in standby, not monitoring. Connect belt to monitor so that LifeVest can resume normal monitoring mode.
	Recording: LifeVest is recording your ECG signal.
	Service required: Device has a problem and requires service. Call ZOLL.
	Symbol for health survey on patient setup menu.
	Symbol for walk test on patient setup menu.
	Symbol for trends on patient setup menu.
 or	Battery: Do not incinerate.
 or	Battery: Do not short circuit.
CE 0297	CE marking, indicates conformance with European Medical Device Directive.
	Laundering symbol: Normal cycle in warm water.
	Laundering symbol: Tumble dry warm.

	Laundering symbol: Only non-chlorine bleach, when needed.
	Laundering symbol: Iron on low temperature.
 or	Laundering symbol: No anti-static spray.
 or	Laundering symbol: No fabric softener.
	Manufacturing date.
	Manufacturing location.
	Expiration date.
	Monitor connector: Type BF defibrillator-proof connector.
	Monitor connector: Type BF non defibrillator-proof connector.
	Packaging: Battery
	Packaging: Charger.
	Packaging: Monitor.

	Packaging: Electrode belt.
	Packaging: Garment.
	Power supply electrical information: Alternating current (AC).
	Power supply electrical information: Direct current (DC).
	Therapy pad label: Place this side (foil side) of the therapy pad next to your skin.
	Caution: Read and follow the caution text next to this symbol. If on a product, consult accompanying documents.
	Symbol: See instructions for use.
	Symbol: Automated external defibrillator.
	Symbol: Dangerous voltage. Surface could become hazardous for bystanders to touch when the device is in use.
	Symbol for catalog number, accompanied by number.
	Symbol for serial number, accompanied by serial number.
	Symbol for lot number, accompanied by lot number.
	Symbol for EC representative next to name and address of authorized EC rep.
	Symbol for keep dry.
	Symbol for keep away from sunlight.

	Symbol for do not use if package is damaged.
	Symbol for temperature limitation. Upper and lower limits of temperature are indicated next to the horizontal lines.
	Symbol for emits RF energy.
	Symbol for magnetic resonance (MR) unsafe.

Appendix C: Patient training all modes

This appendix explains all of the training modes, gives the details about the sequence that training is presented in the automatic mode, and gives the procedure for training in the manual mode.

About training modes

There are three training modes of operation:

- Automatic with narration
- Automatic without narration
- Manual, where you select what parts to see (no narration).

Order of automatic training

In automatic mode, this is the order that things are presented:

1) treatment sequence

2) belt noise problems (ECG first, then therapy electrodes)

3) battery conditions

4) standby mode

Training narration

When you choose the training mode with narration, the screens are accompanied by narration that tells the patient what is being demonstrated, and what to do in each situation.

Training narration is in a female voice so that it is different than the normal operation prompts and help narrations.

Operation narration (such as “press response buttons”) is in a male voice and functions as normal during training; it cannot be turned off.

Help narrations (press to speak) also function the same as normal, and they are also in the same voice as the operational messages (male voice), so that the patient learns what is normal operation.

Operation screens get training banner

In training mode, the operation screens have the TRAINING banner at the top of the screen in the patient's language. Otherwise the screens are the same as when the unit is operating normally.

Help screens and the "please wait" screen do not display the training banner.

Help screens work as normal

Help screens work just like normal in training mode. The difference is that even with training narration turned off, help screens function as normal. Help screens speak when touched, the same as they normally do when the speak option is enabled.

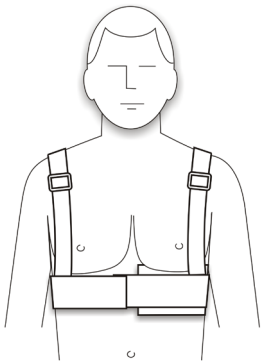
These narrations speak in the language programmed for the patient. If a secondary language was programmed, the translate button will be present on the help screens. Pressing the translate button plays the narration in the secondary language.

Programming mode

To perform any of the procedures in this section, the monitor needs to be in programming mode. Please contact ZOLL.

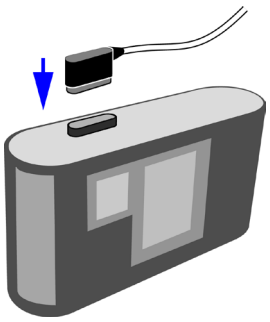
Connecting patient for training mode

In order to get the full effect of the demonstration, you should connect the electrode belt and have the patient wearing the garment and belt assembly as normal.



1 Outfit the patient with the electrode belt and garment.

2 Enter training mode.



3 Connect the electrode belt to the monitor.

4 Continue with one of the procedures on the following pages:

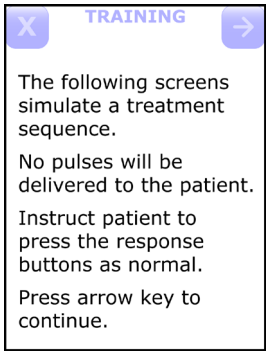
- To play all with or without narration, see page C-4.
- To select sections, see page C-12.

Play all: treatment sequence

1 From the **Training mode** menu, tap **Play all** or **Play all with narration**.

- **Play all** goes through the training screens without any narration.
- **Play all with narration** adds narration to the screens.

Help screens function as normal in both modes.

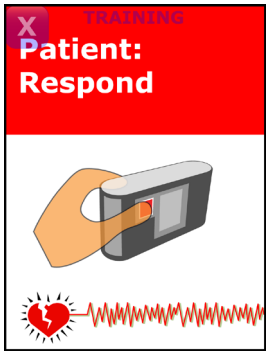


2 The screen (and vocal narration in narration mode) tell you that the LifeVest is going to simulate a treatment sequence.

Since the LifeVest is in training mode, the word **TRAINING** appears at the top of the screen.

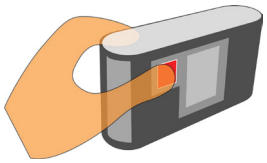
Tap the next page button in the upper right corner when you're ready to move on to the next screen. Some screens will not have this button, forcing you to take the action indicated on screen before moving on.

At any time you can tap the **X** button in the upper left corner to stop the training sequence.



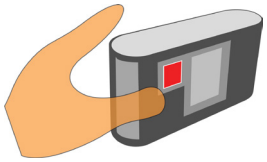
3 The device runs through the alert sequence that will occur if an arrhythmia is detected. Vocal narration (in narration mode) explains what is happening to the patient, and says what action to take.

- Vibration alert activates and response buttons light red.
- Siren alert sounds (during training the siren is not as loud as it will be during an actual alert).
- Display shows that an arrhythmia has been detected and tells patient to press response buttons.
- Voice prompts tell patient to press response buttons and bystanders not to interfere.



4 For this first demonstration, tell the patient to hold the response buttons, not to just press and release them.

Note that the treatment stays delayed while the buttons are held.



5 Next tell the patient to release the response buttons.

The message shows that treatment is being delayed because the response buttons were pressed and released.

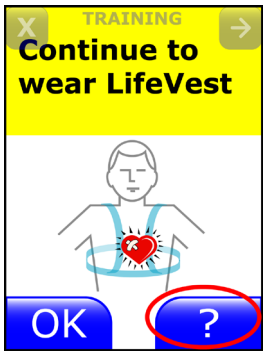
Note the timing bar at the bottom of the screen. Alerts resume when the timing bar gets to the end.

Patient can press and release the response buttons again to delay treatment.

Allow the treatment sequence to continue so the patient can hear the alerts and voice prompts.

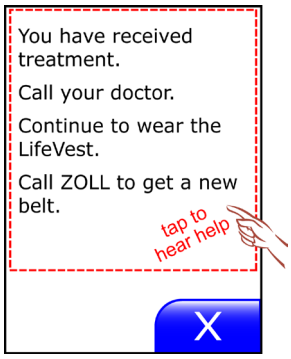
6 This screen shows that treatment has been given.

Note that we're only showing this screen during the demonstration; it will not normally be seen.



7 This screen tells the patient to continue to wear the device after receiving treatment.

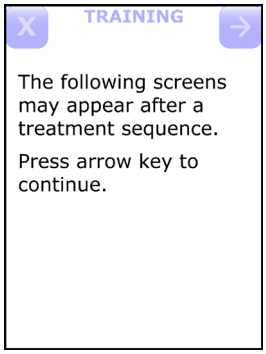
Tell the patient to tap the help button ? to show the patient an example of the type of help screens that are available.



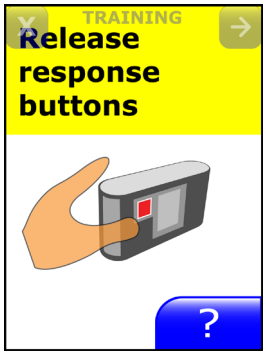
8 This is an example of a help screen.

Tap the top half of the screen to demonstrate the speak option. This option works with any help screen.

Tap the **X** button X to close the help screen.



9 Tap the next page button → to see additional screens that you might see after a treatment.



10 This screen appears if the patient's heartbeat returns to normal rhythm and the patient is still holding the response buttons.

This serves as a reminder to let go of the response buttons.

11 This screen appears after a treatment to remind the patient to replace the belt.

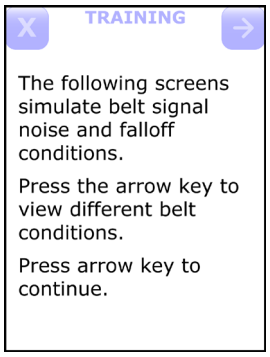
The patient should continue wearing the belt until the replacement belt arrives.

12 This screen tells the patient to add gel to the therapy pads.

Gel that was released during treatment has dried out. Add the gel from the packets provided with the LifeVest.

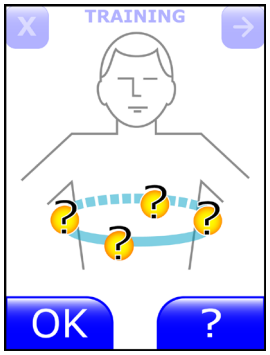
Automated training continues with the belt noise sequence. See next page.

Play all: belt alert



1 This screen reminds you that the LifeVest is going to simulate belt signal noise and falloff conditions.

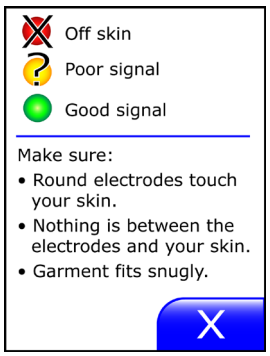
Tap the **X** button X in the upper left corner of any screen if you want to stop the simulation.



2 Repeatedly tap the next page button → in the upper right corner to see screens that indicate belt problems.

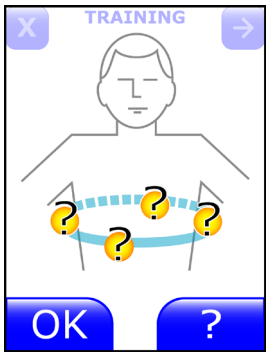
Each time you tap the next page button → you'll see another screen.

On any of these screens, tap the help button ? to see the help screen associated with belt problems.



3 The help screen shows what the symbols mean, and gives short instructions about what to do to fix the problem.

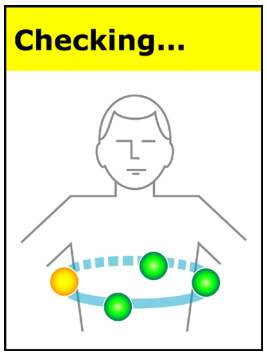
Tap the **X** button X to close the help screen.



4 Tell the patient what to do when the gong alert sounds:

- **Read the display.** This particular message states that there is a problem with the belt. The round electrodes are sending a poor signal to the monitor.
- **Take action to correct the problem.** In this case, you would adjust the belt so that the round electrodes make better contact with the skin.

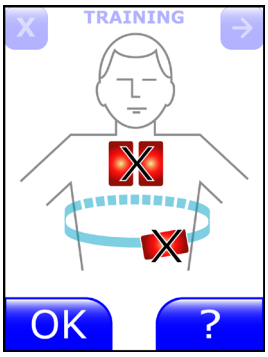
Press **OK** after you fix the problem. This stops the gong alert.



5 When you press **OK**, this screen shows that the device is checking for a good signal from the belt.

Since this is a training simulation, after a few seconds, the screen returns to the belt noise screen.

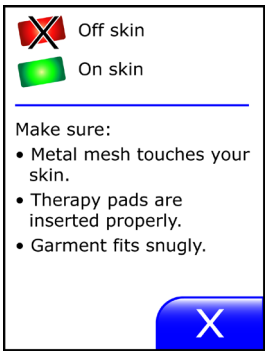
In normal operation, the noise screen will be redisplayed if the problem remains. If there is no problem, the home screen is displayed.

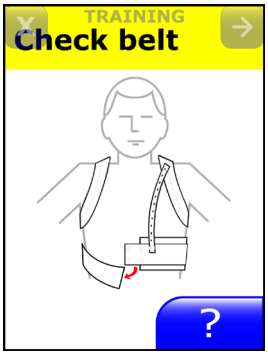


6 Keep tapping the next page button → until you get to the therapy pad problem screens.

Again, you can tap the help button ? to show the patient the help screen.

Tap the **X** button X to close the help screen.





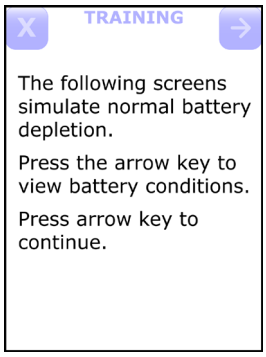
7 Tap the next page button → until the monitor displays this message.

When this happens, the patient is expected to remove and check the belt.

Tap the next page button → to simulate that the patient has corrected the problem.

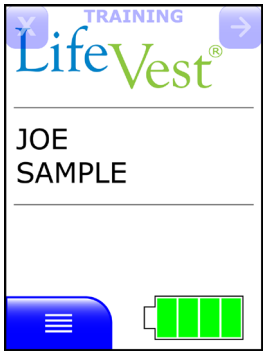
Automated training continues with the battery conditions. See next page.

Play all: battery conditions



1 This screen reminds you that the LifeVest is going to simulate battery conditions.

Tap the **X** button in the upper left corner of any screen if you want to stop the simulation.

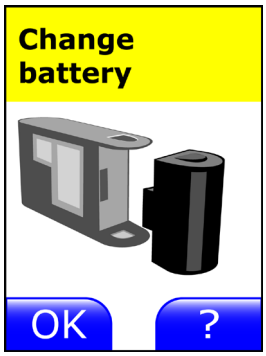


2 Tap the next page button repeatedly to show how the battery icon changes to simulate battery depletion.

3 Keep tapping the next page button until you get to the red battery. This means that the battery needs to be changed.

When the battery gets near the end of its charge, you will get the red battery symbol and the next screen as a reminder to change the battery.

Tap the red battery symbol to show the reminder screen (next step, below).

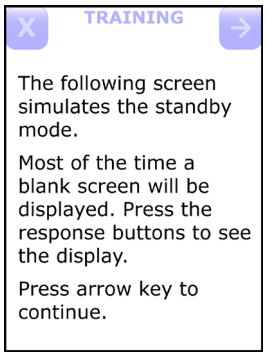


4 This screen appears when it's time to change the battery, or when you tap the red battery symbol.

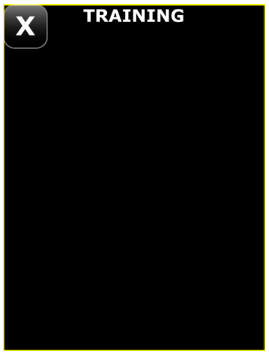
Tap the help button to see the help screen associated with changing the battery.

Automated training continues with the standby mode. See next page.

Play all: standby mode



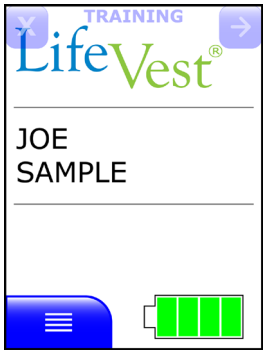
1 This screen reminds you that the LifeVest is going to simulate the standby mode.



2 Tap the next page button to see the standby screen.

Most of the time the LifeVest displays a dark screen like this.

To see the display, press the response buttons.

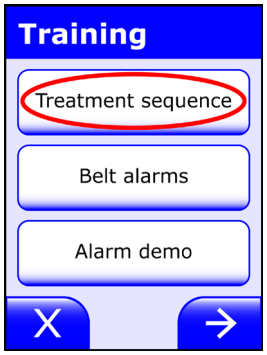


3 To end the training session, tap the **X** button or the next page button .

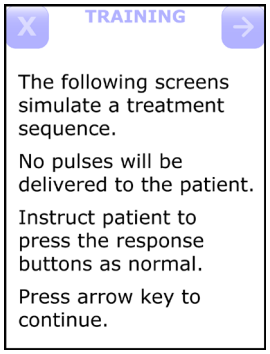
This ends the play all training.

Select sections: demonstrating the treatment sequence

1 From the **Training mode** menu, tap **Select sections**.



2 From the **Training** menu, tap **Treatment sequence**.

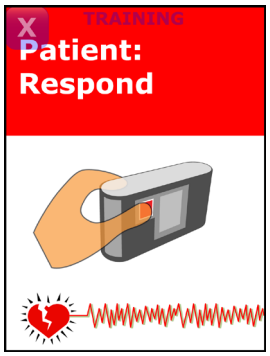


3 This screen reminds you that the LifeVest is going to simulate a treatment sequence.

Since the LifeVest is in training mode, the word **TRAINING** appears at the top of the screen.

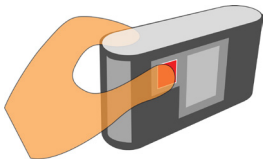
Tap the next page button in the upper right corner to advance to the next screen. Some screens will not have this button, forcing you to take the action indicated on screen.

Tap the **X** button in the upper left corner when you want to stop the training sequence.



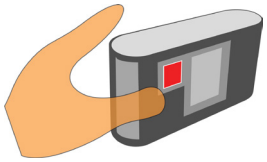
4 The device runs through the alert sequence that will occur if an arrhythmia is detected:

- Vibration alert activates and response buttons light red.
- Siren alert sounds (during training the siren is not as loud as it will be during an actual alert).
- Display shows that an arrhythmia has been detected and tells patient to press response buttons.
- Voice prompts patient to press response buttons and bystanders not to interfere.



5 Tell the patient to hold the response buttons, not to just press and release them.

Note that the treatment stays delayed while the buttons are held.



6 Next tell the patient to release the response buttons.

The message shows that treatment is being delayed because the response buttons were pressed and released.

Note the timing bar at the bottom of the screen. Alerts resume when the timing bar gets to the end.

Patient can press and release the response buttons again to delay treatment.

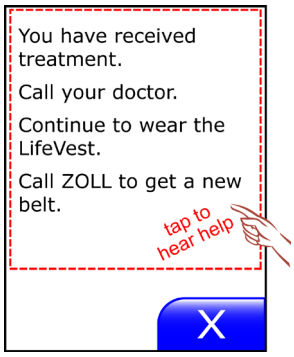
Allow the treatment sequence to continue so the patient can hear the alerts and voice prompts.

7 This screen shows that treatment has been given.

Note that we're only showing this screen during the demonstration; it will not normally be seen.

8 This screen tells the patient to continue to wear the device after receiving treatment.

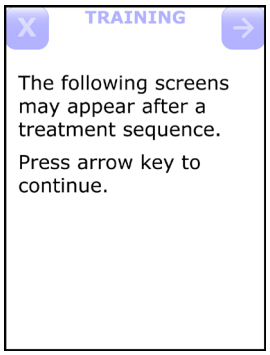
Tell the patient to tap the help button ? to show the patient an example of the type of help screens that are available.



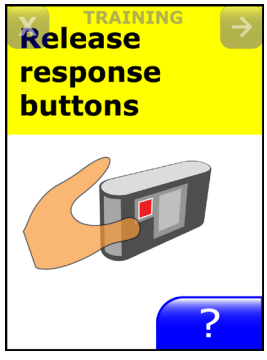
9 This is an example of a help screen.

Tap the top half of the screen to demonstrate the speak option. This option works with any help screen.

Tap the **X** button X to close the help screen.



10 Tap the next page button → to see additional screens.



11 This screen appears if the patient's heartbeat returns to normal rhythm and the patient is still holding the response buttons.

12 This screen appears after a treatment to remind the patient to replace the belt.

The patient should continue wearing the belt until the replacement belt arrives.

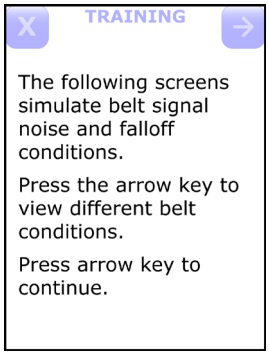
13 This screen tells the patient to add gel to the therapy pads.

Gel that was released during treatment has dried out. Add the gel from the packets provided with the LifeVest.

To end the training session, tap the **X** button or the next page button .

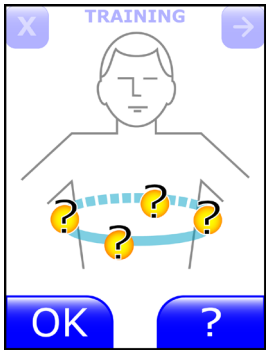
Select sections: demonstrating a belt alert

1 From the **Training** menu, select **Belt alarms**.



2 This screen reminds you that the LifeVest is going to simulate belt signal noise and falloff conditions.

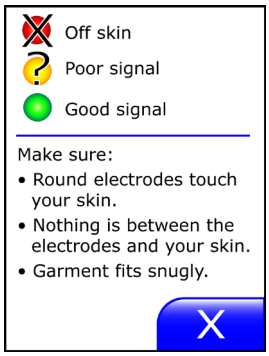
Tap the **X** button X in the upper left corner of any screen if you want to stop the simulation.



3 Repeatedly tap the next page button → in the upper right corner to see screens that indicate belt problems.

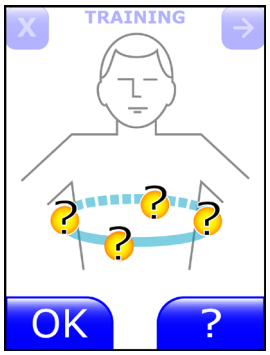
Each time you tap the next page button → you'll see another screen.

On any of these screens, tap the help button ? to see the help screen associated with belt problems.



4 The help screen shows what the symbols mean, and gives short instructions about what to do to fix the problem.

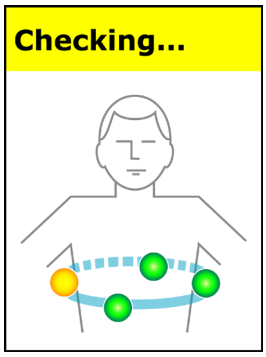
Tap the **X** button X to close the help screen.



5 Tell the patient what to do when the gong alert sounds:

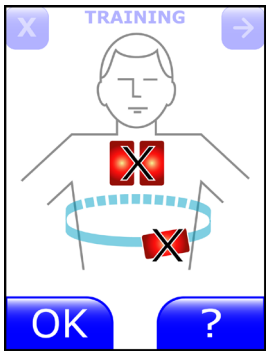
- **Read the display.** This particular message states that there is a problem with the belt. The round electrodes are sending a poor signal to the monitor.
- **Take action to correct the problem.** In this case, you would adjust the belt so that the round electrodes make better contact with the skin.

Press **OK** after you fix the problem. This stops the gong alert.



6 When you press **OK**, this screen shows that the device is checking for a good signal from the belt.

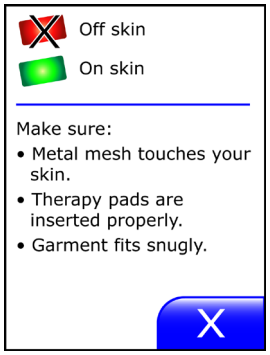
After a few seconds, the screen returns to the belt noise screen.

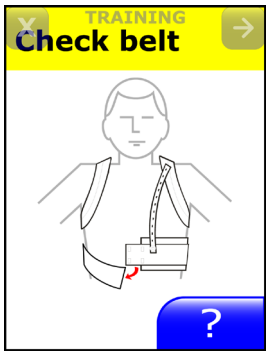


7 Keep tapping the next page button → until you get to the therapy pad problem screens.

Again, you can tap the help button ? to show the patient the help screen.

Tap the **X** button X to close the help screen.





8 Tap the next page button until the monitor displays this message.

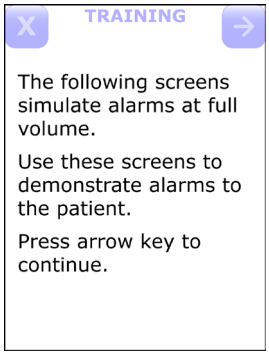
When this happens, the patient is expected to remove and check the belt.

Tap the next page button to simulate that the patient has corrected the problem.

Tap the **X** button or next page button to end the demonstration.

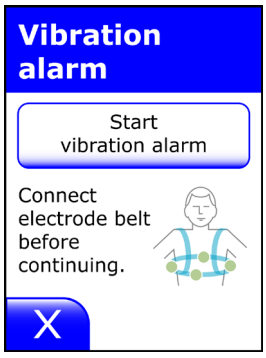
Select sections: demonstrating the alerts

1 From the **Training** menu, select **Alarm demo**.

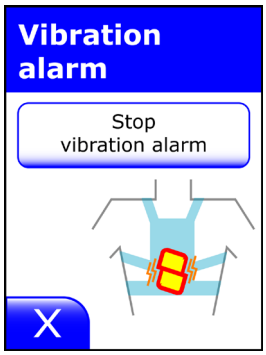


2 This screen reminds you that the LifeVest is going to simulate the alerts. Tap the next page button to continue.

3 From the **Alarm demo** screen, select **Vibration alarm**.



4 Have the patient wearing the electrode belt and garment, and connect the electrode belt before continuing.



5 Tap **Start vibration alarm**. The patient will feel the vibration alert in the back of the garment.

Tap **Stop vibration alarm** to stop the alert.

Tap **X** to return to the **Alarm demo** screen.

6 From the **Alarm demo** screen, tap **Tone alarms**.

7 Tap **Gong alarm** to hear the gong alert.

Tap **Siren alarm** to hear the siren alert.

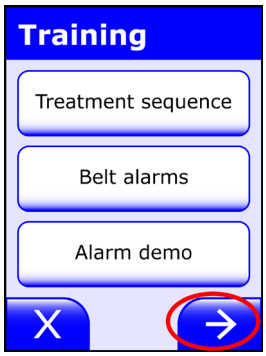
Tap **X** to return to the **Alarm demo** screen.

8 From the **Alarm demo** screen, tap **Voice prompts**.

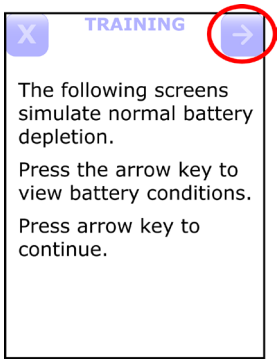
9 Tap the button to hear the first message. Repeat to hear each of the messages.

Tap **X** to return to the **Alarm demo** screen.

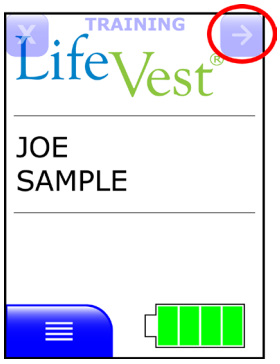
Select sections: demonstrating battery condition



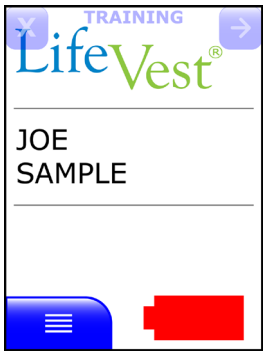
1 From the **Training** menu, tap the next page button to go to the next page, then select **Battery demo**.



2 This screen reminds you that the LifeVest is going to simulate battery depletion. Tap the next page button to continue.



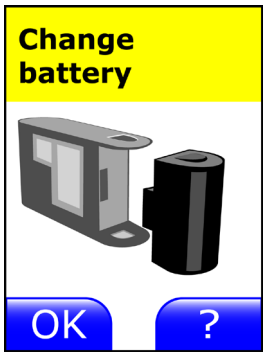
3 Tap the next page button repeatedly to show how the battery icon changes to simulate battery depletion.



4 Keep tapping the next page button until you get to the red battery. This means that the battery needs to be changed.

When the battery gets near the end of its charge, you will get the red battery symbol as a reminder to change the battery.

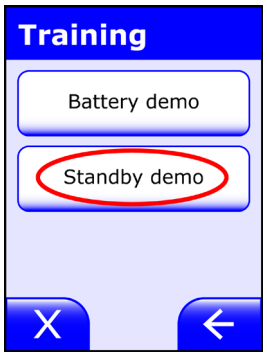
Tap the red battery symbol to show the reminder screen (next step, below).



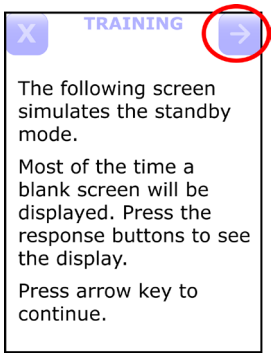
5 This screen appears when it's time to change the battery, or when you tap the red battery symbol.

Tap the help button ? to see the help screen associated with changing the battery.

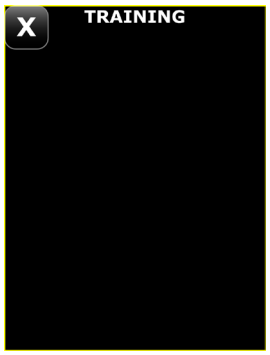
Manual mode: demonstrating standby condition



1 From the **Training** menu, tap the next page button to go to the next page, then select **Standby demo**.

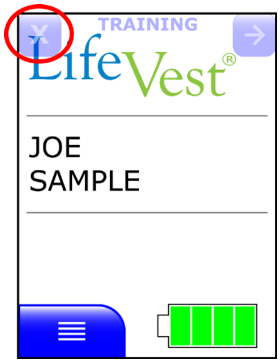


2 This screen reminds you that the LifeVest is going to simulate the standby mode. Tap the next page button to see the standby screen.



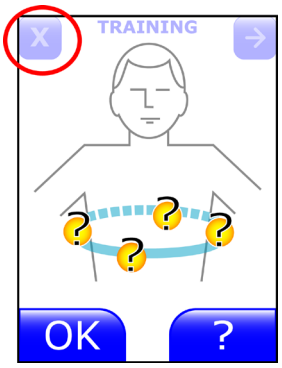
3 Most of the time the LifeVest displays a dark screen like this.

To see the display, press the response buttons.



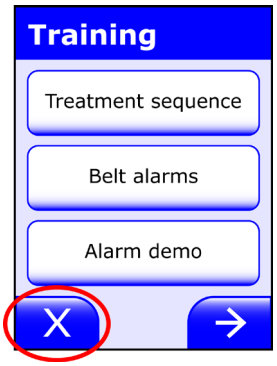
4 To end the training session, tap the **X** button.

Exiting training mode

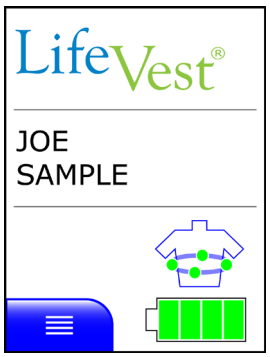


1 When you want to stop a training session:

- On any screen with the word **TRAINING** at the top of the screen, tap the **X** button  in the upper left corner of the screen.
- From any other screen, tap the **X** button in the lower corner.



2 If any other screens appear, tap the **X** button along the bottom until you return to the home screen.



3 When you reach the home screen, the LifeVest resumes normal operation.

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Index

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

X

Y

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