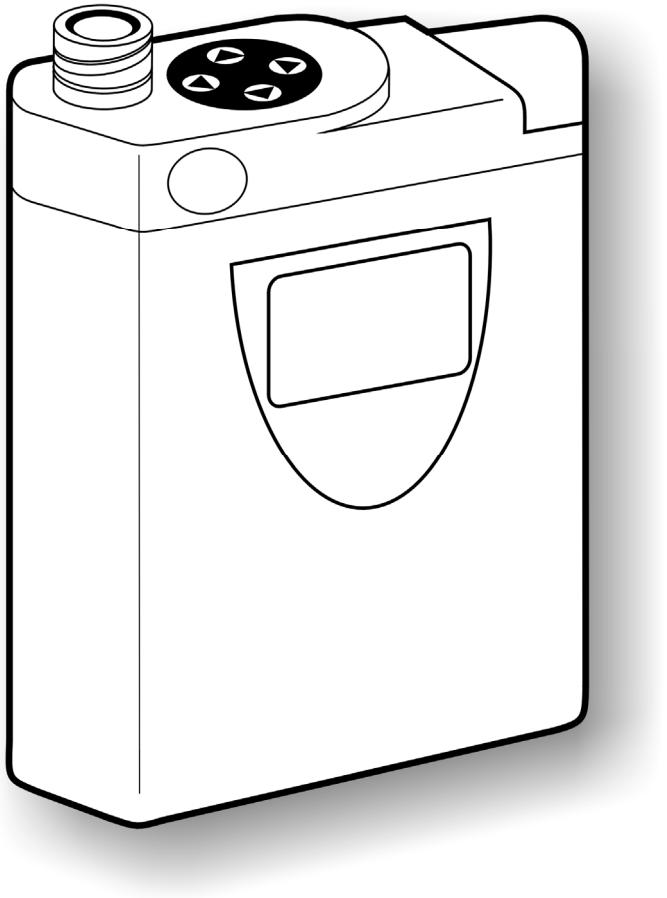
LifeVest®

LifeVest System
Model WCD 3100

Service Manual



LIFE COR

PN 20B0041 Rev FI

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 with software version 5.1 and up.

Disclaimer

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

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Patents

US patents: 6,681,003; 6,280,461; 6,253,099; 6,169,387; 6,097,982; 6,065,154; 5,944,669; 5,929,601; 5,741,306; 5,078,134; 4,928,690; others pending.

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Contents

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1: Introduction

About this manual

This manual:

- gives you instructions on how to program, maintain, and troubleshoot the device.
- contains technical information and other lesser-used information.
- supplements the Patient Manual and Operator's Manual.

What's in this manual

This manual is organized as follows:

- **Monitor programming** covers programming beyond the basic monitor setup. (For basic patient setup, see the Operator's Manual.)
- **Maintenance** tells you how to inspect, recondition, and test the system.
- **Troubleshooting** helps you to solve simple problems a patient may have with the system.
- **Technical information** includes specifications, standards that the system meets and has been tested for, and defibrillating pulse waveforms. This section also includes information about the pulse delivery synchonization and VF/VT thresholds.
- Appendixes include **Quick charts** and a **Maintenance checklist**. 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.

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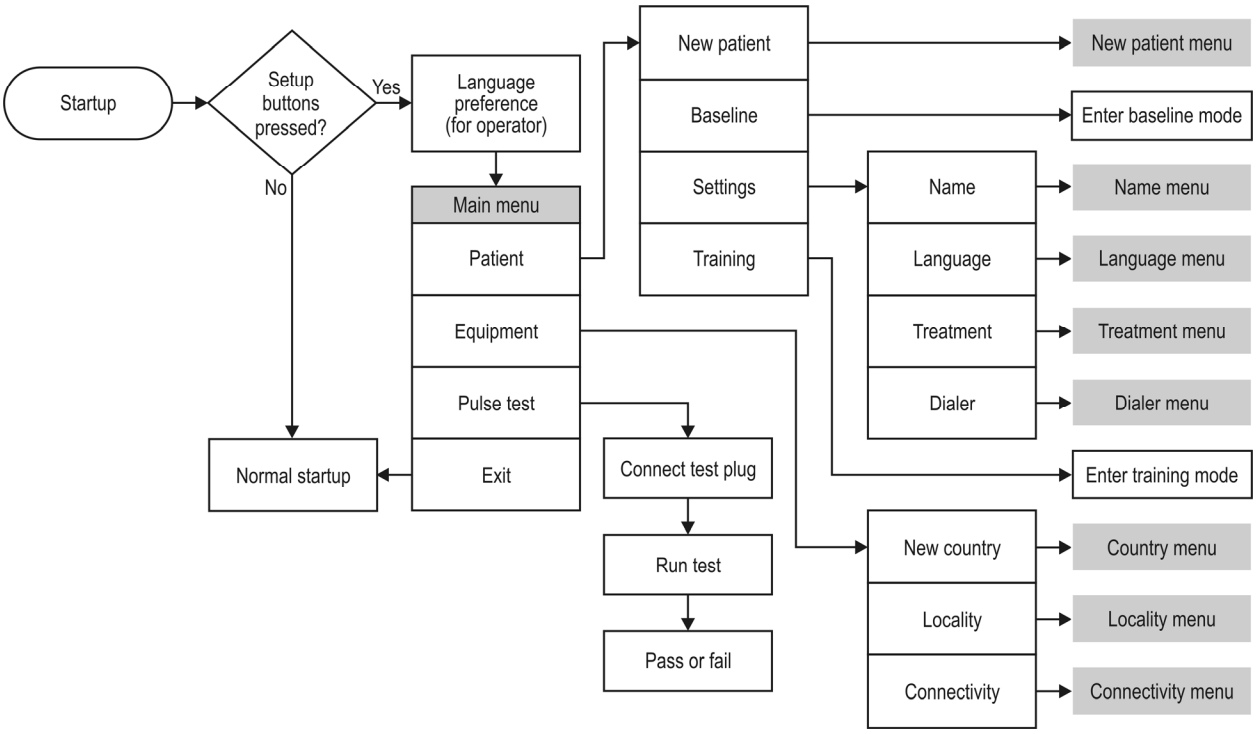
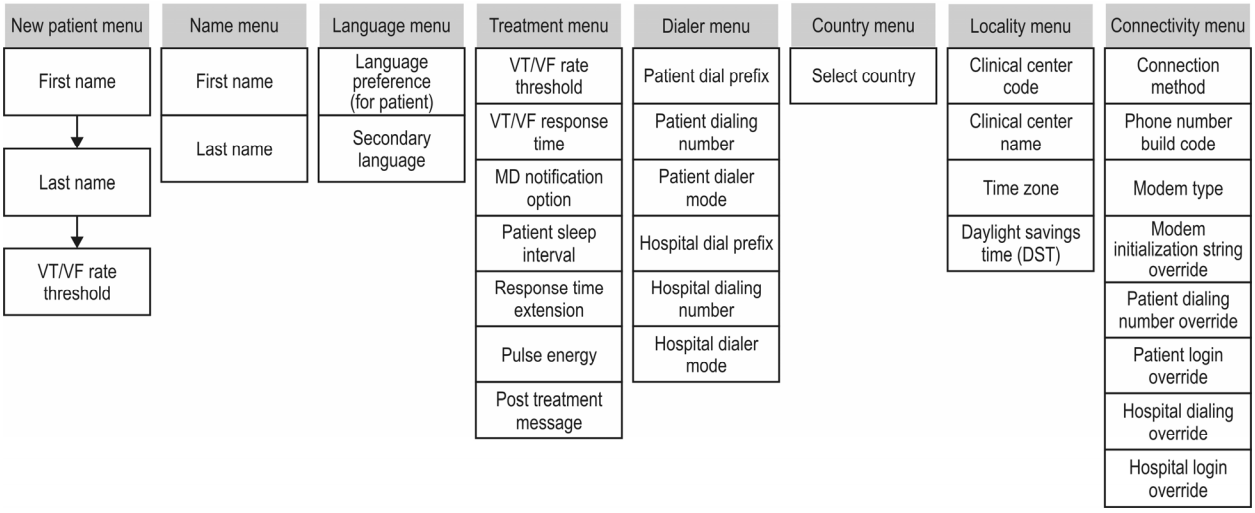
2: Monitor programming

About this section

- This section covers programming beyond the basic monitor setup.
- This section applies to software version 5.1 and up.
- For basic monitor setup for a new patient, see the Operator's Manual.

Menu structure





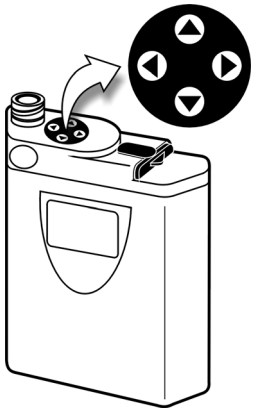
About the menus

Menu	What it lets you select or enter	When to use it
New patient menu	Patient's name and VT/VF rate threshold settings (in beats per minute).	To set up a new patient. See Operator's Manual.
Name menu	Patient's name for the displayed messages and voice prompts.	To change or correct a patient's name.
Language menu	Languages for the displayed messages and voice prompts. This language is for the patient, and does not affect the language displayed during setup	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.	May need to be programmed when setting up a new patient, or to change a patient's treatment settings.
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 out when sending patient data.	Enter the details about the phone system when installing the device. Update this menu if there are any changes to the phone system that require updates to the dialing mode or prefix.
Country menu	Country where device is being used.	Select the country when installing the device. 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.
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 device is being used.	When setting up the device for initial use, or if the device is moved 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.

Menu navigation

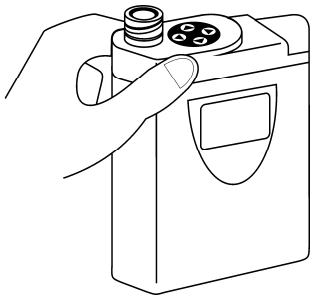
All of the setups described in this chapter can be performed by using the navigation buttons on the monitor.

Using the navigation buttons



View the navigation buttons from the top of the monitor with the display facing you.

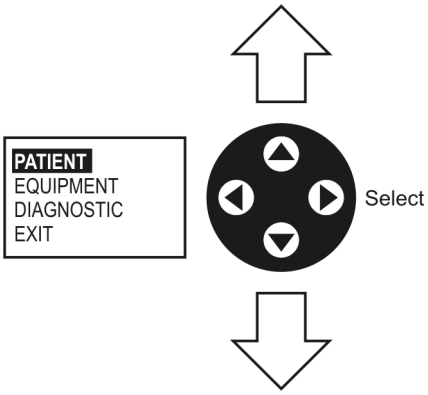
Press the arrow button that corresponds with the direction shown in the manual or on the display.



Once you have navigated to a menu with variables, press the response buttons to put the monitor into edit mode. Response buttons light when the monitor is in edit mode.

To save the displayed value, press the response buttons.

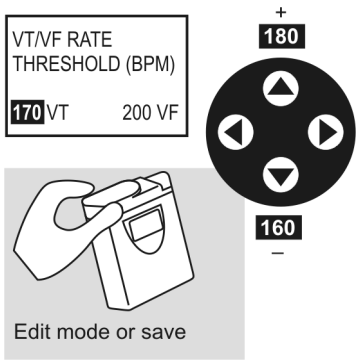
To select a menu option



Press ▲ or ▼ to highlight a menu option.

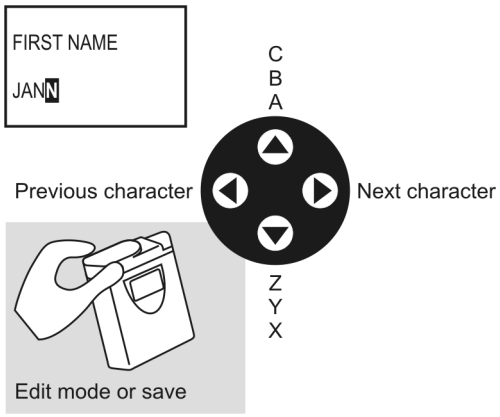
Press ► to select the highlighted option.

To change a value



- Have the menu displayed with the value you want to change.
- Press the response buttons so they light, putting the monitor in edit mode.
- If more than one value is displayed, press the response buttons to select the value to be changed.
- To change the value, press ▲ or ▼.
- To save the displayed value, press the response buttons.

To enter a text field

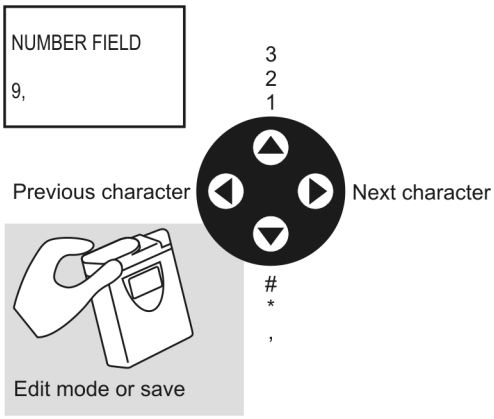


- Have the menu displayed with the value you want to change.
- Press the response buttons so they light, putting the monitor in edit mode.
- Use ▲ or ▼ to scroll through the alphabet.
- The display starts with the letter A. Each time you press ▲, you will scroll through the letters A through Z, then numbers 0 through 9.
- To accept a character and go on to the next character, press ►.
- To go back to a previous character, press ◄.
- To save the displayed value, press the response buttons.

Hints

- Press ▲ or ▼ to move through the alphabet in either direction.
- Hold down ▲ or ▼ to move through the letters quickly.

To enter a number field



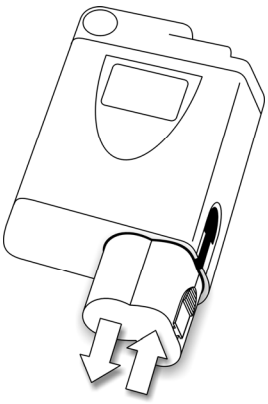
- Have the menu displayed with the value you want to change.
- Press the response buttons so they light, putting the monitor in edit mode.
- Use ▲ or ▼ to scroll through the numbers.
- Each time you press the up arrow, you will scroll through the numbers 0 through 9. If you continue pressing the up arrow, you will then see symbols and a comma.
- To accept a character and go on to the next character, press ►.
- To go back to a previous character, press ◄.
- To save the displayed value, press the response buttons.

Hints

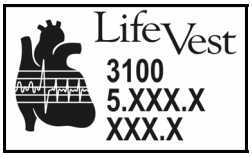
- Press ▲ or ▼ to move through the numbers in either direction.
- Hold down ▲ or ▼ to move through the numbers quickly.
- If you need to insert a pause for modem dialing, use the comma. Each comma inserts a 1-second pause. You can insert multiple commas if you need a longer pause.

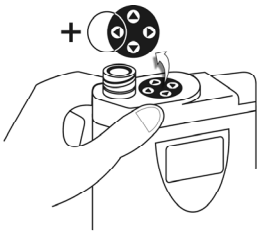
How to put the monitor in setup mode

Before doing any of the monitor setups described in this chapter, follow this procedure to put the monitor in setup mode.



1 Remove and reinsert the battery.



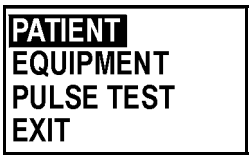


2 While the opening screen is displayed, hold the response buttons and hold ◄ at the same time. Continue holding these buttons until the screen changes.

This screen may be displayed for more than 10 seconds.

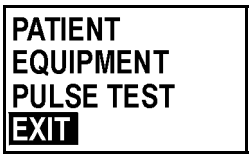
3 Press ▲ or ▼ to choose a language, then press ►.

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.

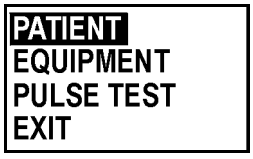


5 When you are finished programming the monitor, do one of the following:

- Navigate back to the main menu, select **EXIT**, then press ►.
- Wherever you are in any menu, remove and reinsert the battery.

How to change patient name

Follow this procedure to change the patient's first or last name.



1 With the monitor in setup mode (see page 2-6), press ▲ or ▼ to select **PATIENT**, then press ►.

2 Press ▲ or ▼ to select **SETTINGS**, then press ►.

3 Press ▲ or ▼ to select **NAME**, then press ►.

4 To change the first or last name, press ▲ or ▼ until you see the menu containing the setting you want to change. Then:

- Press the response buttons so they light.
- Press ▲ and ▼ to select characters.
- To advance to next character, press ►. To go back, press ◄.
- To save a name change, press the response buttons.

5 Press ► or ◄ to select **OK**, then press the response buttons.

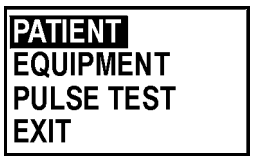
6 Press ◄ repeatedly to return to the opening menu.

Patient name menu and settings

Menu	Menu option	What it means	How to select
Name menu First name Last name	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 change language settings

Follow this procedure to set the patient's language for the displays and voice prompts. A secondary language can also be selected for bystanders.



1 With the monitor in setup mode (see page 2-6), press ▲ or ▼ to select **PATIENT**, then press ►.

2 Press ▲ or ▼ to select **SETTINGS**, then press ►.

3 Press ▲ or ▼ to select **LANGUAGE**, then press ►.

4 Select a language preference as follows:

- Press the response buttons so they light.
- Press ▲ or ▼ to select a language. This is the language for the displayed messages and voice prompts. Spanish has been approved for use in the USA.
- To save the change, press the response buttons.

5 Next you can select a secondary langauge if desired. The secondary language is for voice prompts only and will be used in addition to the primary lanagage.

To select a secondary language:

- Press ▲ or ▼ to display the secondary language.
- Press the response buttons so they light.
- Press ▲ or ▼ to select a language. In the USA, if you selected Spanish as the primary language (in step 4), select English as the secondary language.
- To save the change, press the response buttons.

To turn this option off, press the response buttons so they light, then press ▲ or ▼ to select **OFF**, then press the response buttons again.

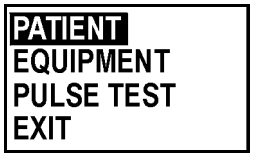
6 Press ◄ repeatedly to return to the opening menu.

Language menu and settings

Menu	Menu option	What it means	How to select
Language menu Language preference (for patient) Secondary language	Language preference	Language that monitor will use for display messages and voice prompts.	Select from list of languages.
	Secondary language	Second language that will be used for voice prompts to advise bystanders (in addition to the primary language).	Select from list of languages or select off. Any language can be selected except what has been chosen for Language Preference.

How to change treatment settings

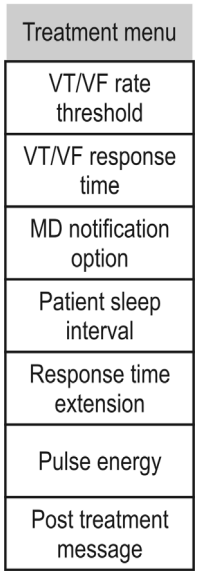
Follow this procedure to change rate thresholds (in beats per minute), response time (how many seconds until the device delivers the defibrillating shock), pulse energy (in joules), and other treatment options.



1 With the monitor in setup mode (see page 2-6), press ▲ or ▼ to select **PATIENT**, then press ►.

2 Press ▲ or ▼ to select **SETTINGS**, then press ►.

3 Press ▲ or ▼ to select **TREATMENT**, then press ►.



4 Press ▲ or ▼ until you see the setting you want to change. Then:

- Press the response buttons so they light.
- Press ▲ or ▼ to change the setting.
- If the setting contains more than one option (such as VT/VF rate threshold), press the response buttons to highlight the option you want to change, then press ▲ or ▼ to change the setting.
- To save the changes, press the response buttons.
- The chart on the next page lists treatment settings, what they mean, and how to select them.

5 Press ◄ repeatedly to return to the opening menu.

Treatment menu and settings

Menu	Menu option	What it means	How to select
Treatment menu VT/VF rate threshold VT/VF response time MD notification option Patient sleep interval Response time extension Pulse energy Post treatment message	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 option	Determines if patient receives “call doctor” message after receiving 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 goes to sleep and awakens.	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.	Range: 75-150 joules Default: 150 joules
	Post treatment message	Message displayed after a treatment shock.	Optional. Can be set to any alphanumeric message you want to display after the patient receives treatment. For example, can be set to display “CALL 911” or other phone number for the patient to call.

Dialer menu and settings

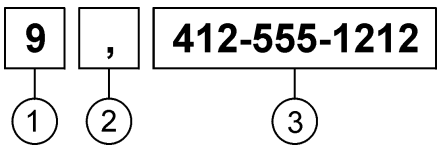
Menu	Menu option	What it means	How to select
Dialer menu Patient dial prefix Patient dialing number Patient dialer mode Hospital dial prefix Hospital dialing number Hospital dialer mode	Patient dial prefix	Prefix number that may be required to dial out from primary location (see example below). For example, 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 download data from monitor using the modem. This is a complete number with area code and phone number.	Determined by device provider and does not normally need to be changed. Contact ZOLL Lifecor for assistance before changing this setting.
	Patient dialer mode	Type of phone used to download data.	Tone or pulse.
	Hospital dial prefix	If using a secondary location, prefix number that may be required to dial out.	Select any number, based on what is required. If any pauses are required, each comma equals 1 second.
	Hospital dialing number	If using a secondary location, the phone number that will be called to transmit data from monitor using the modem.	Determined by device provider and does not normally need to be changed. Contact ZOLL Lifecor for assistance before changing this setting.
	Hospital dialer mode	Type of phone used to download data.	Tone or pulse.

About dialing modes

To transfer data from home, using the patient dialer settings, the patient simply connects the phone line to the modem, then connects the modem to the monitor.

To transfer data using the hospital dialer settings, hold ► when connecting the modem to the monitor. Hold the button until you see the CHECKING MODEM message. In this case the monitor uses the hospital dialer settings that have been programmed into it.

Phone number example



1 Dial prefix (precedes any phone numbers)

2 Pause (each comma equals 1 second)

3 Dialing number

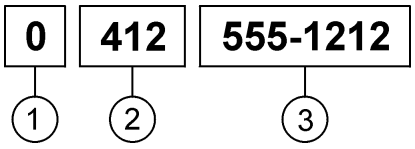
Locality menu and settings

Menu	Menu option	What it means	How to select
Locality menu Clinical center code Clinical center name Time zone Daylight savings time (DST)	Clinical center code	Code assigned to patient's clinical center.	Use the code number for the clinical center. Determined by device provider and does not normally need to be changed. Contact ZOLL Lifecor for assistance before changing this setting.
	Clinical center name	Name of patient's 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 ZOLL Lifecor for assistance before changing this setting.
	Time zone	Allows choosing local 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.

Connectivity menu and settings

Menu	Menu option	What it means	How to select
Connectivity menu Connection method Phone number build code Modem type Modem initialization string override Patient dialing number override Patient login override Hospital dialing override Hospital login override	Connection method	Determines how monitor accesses LifeVest Network, whether through server direct numbers or Internet service provider numbers.	Select the type of dialing method during installation. Defaults to the type of connection numbers most likely to be used in the selected country. Does not normally need to be changed. Contact ZOLL Lifecor for assistance before changing 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 ZOLL Lifecor for assistance before changing 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 ZOLL Lifecor for assistance before changing this setting.
	Modem initialization string override	These values allow you to enter manual dialing information.	These values are normally not used. For service purposes, ZOLL Lifecor 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

Default settings

All settings return to their default values when you set up a new patient.

Menu option	Default setting
VT rate threshold	150 beats per minute
VF rate threshold	200 beats per minute
Secondary language	Off
VT response time	60 seconds
VF response time	25 seconds
MD notification option	Off
Patient sleep interval	00:00 (midnight) and 06:00 (6:00 a.m.)
Response time extension	0 seconds
Pulse energy	150 joules for all 5 shocks
Post treatment message	Blank
Patient dial prefix	Determined by device provider
Patient dialing number	Determined by device provider
Patient dialer mode	Tone
Hospital dial prefix	Blank or determined by ZOLL Lifecor
Hospital dialing number	Blank or determined by ZOLL Lifecor
Hospital dialer mode	Tone
Clinical center code	Determined by ZOLL Lifecor
Clinical center name	Determined by ZOLL Lifecor
Time zone	Select from options determined by country
Daylight savings time (DST)	Default determined by country
Connection method	Connection method most likely used in country
Phone number build code	Defined by country
Modem type	Defined by country
Modem initialization string override	Blank, use only as directed by ZOLL Lifecor
Primary dialing number override	Blank, use only as directed by ZOLL Lifecor
Primary login override	Blank, use only as directed by ZOLL Lifecor
Secondary dialing override	Blank, use only as directed by ZOLL Lifecor
Secondary login override	Blank, use only as directed by ZOLL Lifecor

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3: Maintenance

Routine maintenance

We recommend that you do the following after each patient use:

- Inspect the system components as described below.
- Recondition the components as described on page 3-3.
- Test the monitor as described on page 3-6.

Inspection

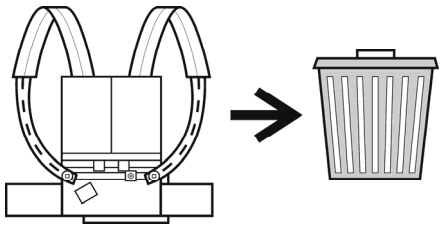
Inspect the system components as follows:

What to inspect	What to look for	Recommended action
Monitor	Dirt or other substances.	Clean as described on page 3-5.
	Evidence of being dropped, such as damage or cracks.	Contact ZOLL Lifecor to have device repaired or replaced.
Battery	Evidence of having been dropped, such as dents, cracked finish, cracked housing, or cracked latch.	Replace damaged battery.
Battery charger	Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.	Replace damaged battery charger.
	Evidence of tampering, such as contacts being distorted.	
Modem	Evidence of having been dropped, such as dents, cracked finish, or cracked housing parts.	Replace damaged modem.
	Evidence of tampering, such as screws exposed through a torn label.	

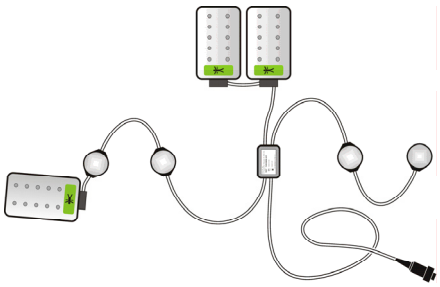
What to inspect	What to look for	Recommended action
Electrode belt and cable	Dirt or other substances.	Clean as described on page 3-3.
	Damaged, cracked, split, or extremely worn cable.	Replace damaged or worn-out cable.
	Damaged or cracked connector, or connector with bent pins.	
	Deterioration from use of bleach or other laundry additives.	
	Confirm that connectors engage securely.	
	Cables pulled out of normal position.	Replace damaged or worn-out electrode belt.
	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.	
	Defective vibration box.	

Reconditioning

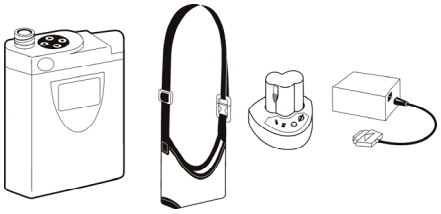
When reconditioning the system components (such as before issuing the system to another patient), follow the inspection instructions on page 3-1, then take the following actions:



- Discard the garment.



- Recondition the electrode belt as described on page 3-4.



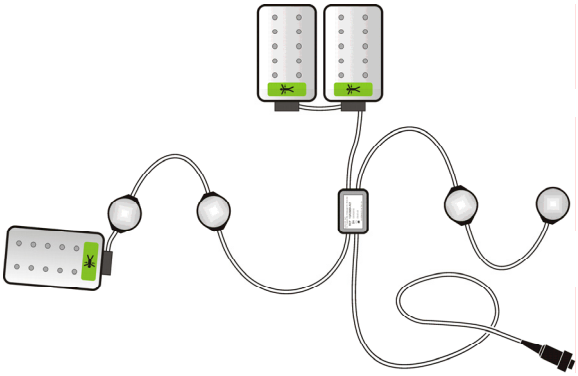
- Recondition the monitor and accessories as described on page 3-5.

Cleaning guidelines

- Remove the battery from the monitor before cleaning.
- Unplug and disconnect all accessories before cleaning.
- Use only recommended cleaning solution (see pages 3-4 and 3-5). Follow directions on cleaning solution.
- Do not soak the monitor, any accessory, or cable in any solution. (An exception is the holster, which can be laundered.)
- Allow to air dry before storing.

CAUTION: Possible equipment damage. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas sterilize the monitor or accessories.

Electrode belt reconditioning



Materials needed:

- Cleaning and disinfecting solution, such as Formula 409® Commercial Solution
- 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.

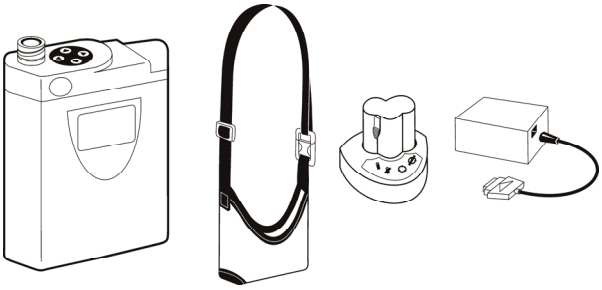
Step 2: Clean all components

- 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, such as Formula 409® Commercial Solution
- 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 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 the test plug to test the monitor. See page 3-6.

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.

Testing the monitor

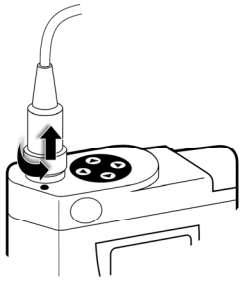
Follow this procedure to test the monitor's ability to generate and deliver a shock. To perform this test, you will need the test plug.

We suggest that you test the monitor every 6 months.

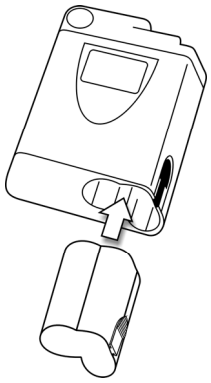
Be sure to transmit patient data before testing the monitor (see Patient Manual for details).

Before testing the monitor, make sure it is not in training mode.

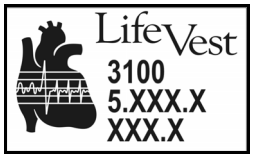
How to test the monitor

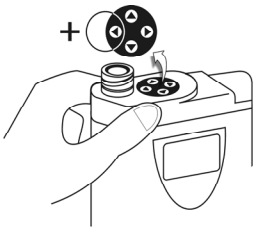


1 Disconnect the electrode belt from the monitor.



2 Insert a fully-charged battery into the monitor.





3 While the opening screen is displayed, hold the response buttons and hold ◄ at the same time. Continue holding these buttons until the display changes.

This screen may be displayed for more than 10 seconds.

LANGUAGE
PREFERENCE:

ENGLISH

4 Press ▲ or ▼ to choose a language, then press ►.

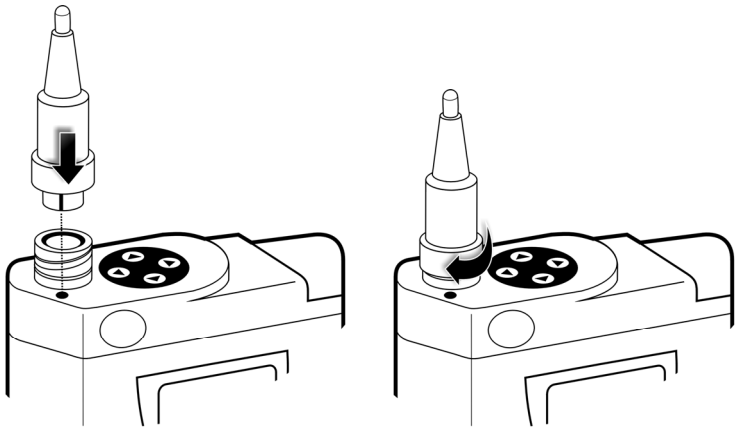
Note: The language you choose only affects the setup screens and will not affect the patient screens.

PATIENT
EQUIPMENT
PULSE TEST
EXIT

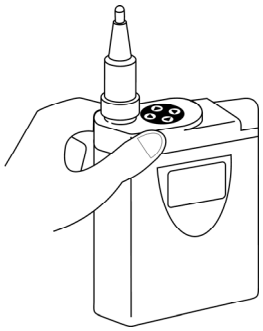
5 Press ▲ or ▼ to select **PULSE TEST**, then press ►.

CONNECT
TEST PLUG

6 Connect the test plug to the monitor.



Leave the test plug connected until the test is complete.



7 Press the response buttons to start the test.

TESTING...
TIME LEFT
MM:SS

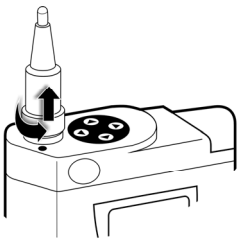
8 A message tells you the time remaining to finish the test.

- The monitor sounds a loud alarm near the end of the test.
- If you want to stop the test before completion, press both response buttons.
- If you get an error message during the test, see next page.

When the test is finished

1 When the test is finished, 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. The system becomes inoperable. Contact ZOLL Lifecor for a replacement.



2 Disconnect the test plug from the monitor, then remove the battery from the monitor

If you have a problem testing the system

If you have a problem testing the system, use this chart to determine how to correct the problem.

If you have any other problem testing the system, call ZOLL Lifecor.

Message	What it means	What to do
CODE XX 	System has a problem that requires servicing. The monitor is inoperable and cannot be used.	Send data via modem. Contact ZOLL Lifecor to report problem and arrange to have monitor replaced.
NOT ENOUGH RUNTIME TO COMPLETE TEST	Battery doesn't have enough reserve power to run test.	Remove battery and put a fully-charged battery into the monitor. Start the test again.
TESTING ABORTED	The test was stopped, probably by pressing the response buttons. The monitor may also be in training mode.	Remove the battery, put it back into the monitor, then start the test again. Don't press any buttons during the test. Make sure the monitor is not in training mode.

Battery maintenance

What you need to know

- Two batteries are provided with each monitor so the patient can use one while charging the other. The patient is to change and recharge the batteries every 24 hours.
- Recharging the battery usually takes less than 3.5 hours, but occasionally can take up to 16 hours if the battery runs a test cycle before charging. Details are in the Patient Manual.

WARNINGS:

- Recharge batteries before giving them to a patient.
- Recharge batteries in storage at least once every 3 months. If you don't recharge them while in storage, the batteries may not be usable.

Battery recycling

Batteries used with the LifeVest system are recyclable and should be returned to ZOLL Lifecor.

WARNINGS:

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

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4: Troubleshooting

This section guides you in solving simple problems with the LifeVest system. If you cannot solve a problem by following the guidelines in this section, call ZOLL Lifecor.

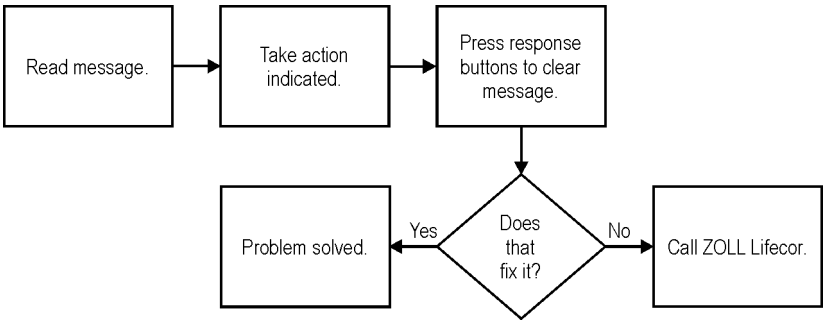
Initial considerations

When you are having trouble with the device, consider:

- When is the problem occurring, such as during startup or after the device has operated for a while?
- Is there a message indicating the problem? If so, follow the basic troubleshooting procedure below.
- For startup messages, see page 4-2.
- If you're having startup problems and there's no message, see page 4-3.

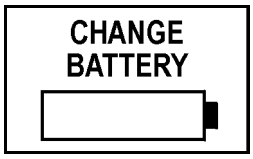
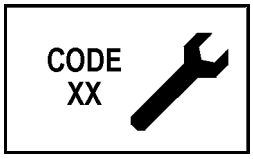
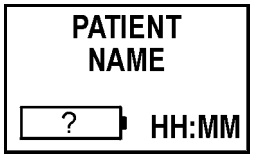
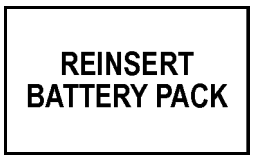
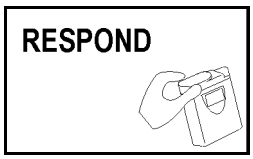
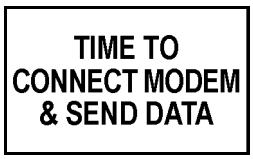
Basic troubleshooting procedure

Follow this procedure when you get any type of alarm and there is a message on the monitor:



Startup problem messages

If you see any of these messages on the monitor at startup (when you install the battery in the monitor), use this chart to determine what it means and how to fix the problem.

Message	What it means	What to do
	Battery has discharged and needs to be changed.	Change to a fully-charged battery and place discharged battery into the charger.
	System has a problem that requires servicing.	Write down code number and call ZOLL Lifecor.
	Battery condition cannot be determined, but battery may continue to function normally.	If battery holds a charge, continue to use and recharge battery as normal. Have battery replaced.
	Battery has not been inserted properly.	Remove battery, then put it back into the monitor, being sure to fully insert the battery.
	Patient is holding the response buttons instead of pressing and releasing them.	At startup, have the patient press the response buttons momentarily, then release them. If the patient is not holding the response buttons, device may be defective. Call ZOLL Lifecor.
	Patient is to press the response buttons to test their function every time the battery is installed.	At startup, have the patient press the response buttons as a reminder of what to do when an alarm sounds.
	Data should be sent because either a treatment shock was delivered or the monitor has data that should be viewed.	Connect the modem and send data at your convenience. This message will appear with each power-up until data is sent.

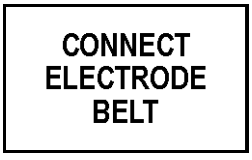
Startup problems with no message

If you have problems during startup and there's no message, use this chart to determine how to fix the problem.

Problem	Possible cause	What to do
Monitor will not turn on (no display, no sounds)	Depleted battery.	Exchange with fully charged battery. Then recharge depleted battery.
	Improperly inserted battery.	Remove battery, then put it back into the monitor, making sure to fully insert the battery.
	Defective battery.	Try another battery. Try recharging battery. If defective, replace battery.
	Defective monitor.	Replace monitor. Call ZOLL Lifecor.
Can't insert battery, or battery won't stay inserted	Bad battery or monitor connection.	Try another battery. Replace defective battery or monitor. Call ZOLL Lifecor.
Can't read display (shows random letters on screen or is otherwise unreadable)	Broken display or defective monitor circuitry.	Replace monitor. Call ZOLL Lifecor.

Electrode belt problems

Use this chart to help resolve problems associated with the electrode belt.

Message	What it means	What to do
	Noisy ECG signal is being received.	Adjust belt for snug fit. Make sure ECG electrodes contact skin. Clean electrodes and apply hand lotion.
	Noisy ECG signal has continued for some time, or has escalated in severity.	Remove battery from monitor, then remove garment from patient. Remove belt from garment, clean ECG electrodes, and reassemble. Put on garment and apply hand lotion to ECG electrodes. Adjust belt for snug fit. Make sure ECG electrodes contact skin. Try another garment. Make sure bleach or fabric softener is not used when laundering garment.
	Therapy pads are not getting good contact with patient's skin.	Make sure therapy pads are flat against patient's skin, not flipped sideways or reversed. If problem continues, remove battery from monitor, then remove garment from patient. Make sure therapy pads are installed correctly, with metal side towards metal mesh in garment, which must contact patient's skin. Try another garment. Make sure bleach or fabric softener is not used when laundering garment.
	Bad or intermittent connection.	Remove battery and check electrode belt connection to monitor. Reconnect electrode belt, then reinstall battery.

5: Technical information

Specifications

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, 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

Cardioverting/defibrillating shock criteria

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 25 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	Up to 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.

Asystole detection

Asystole detection	ECG amplitude of less than 100 microvolts for at least 16 continuous seconds.

Operating environment

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

Storage environment

Temperature range	0 to 55°C (32 to 131°F)
Humidity range	5% to 95% relative humidity, non-condensing
Altitude	To 10,000 feet

System life expectancy

Monitor	3 years of monitoring and defibrillating service
Battery	at least 1 year (about 200 charge/discharge cycles)
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
Modem	3 years
Test plug	3 years
Serial cable	3 years
Holster	6 months, cleaned and reused between patients

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.

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 2601-1:1994, 2nd Ed. Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2:2000 Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-4:2000 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 11:2004 Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics – Limits and methods of measurement
- EN55011:1998 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)
- EN61000-3-3:1995 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
- EN61000-4-3:1995 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

Environmental testing

Electromagnetic compatibility (EMC) testing results in accordance with:

- EN 55011 1998, Radiated and Conducted Emissions
- 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 applicable standards. Results are shown in the tables below and on the next page.

Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The WCD 3100 LifeVest defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the WCD 3100 LifeVest should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The WCD 3100 LifeVest 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 CISPR 11	Class B	The WCD 3100 LifeVest defibrillator is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions	N/A	

Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The WCD 3100 LifeVest defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the WCD 3100 LifeVest 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	±6 kV Contact ±8 kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz[1]	Complies	d = 1.20 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.30 $\sqrt{P}$ 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:  _____ Note 1: At 80 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[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 40.70MHz.

[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 WCD 3100 is used exceeds the applicable RF compliance level above, the WCD 3100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WCD 3100.

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

Guidance and manufacturer's declaration – electromagnetic immunity			
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	N/A	N/A
Electrical fast transient IEC 61000-4-4	±2kV power line ±1kV I/O lines	N/A	N/A
Surge IEC 61000-4-5	±1kV differential ±2kV common	N/A	
Power frequency magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	>95% dip, 0.5 cycle 60% dip, 5 cycles 70% dip, 25 cycles 95% dip 5 sec	N/A	N/A

Mechanical strength

IEC 60601-1, subclause 21a: The monitor was 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 was 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 was dropped from height of 1 meter onto a 50 mm thick hardwood board, once from three 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 was 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.

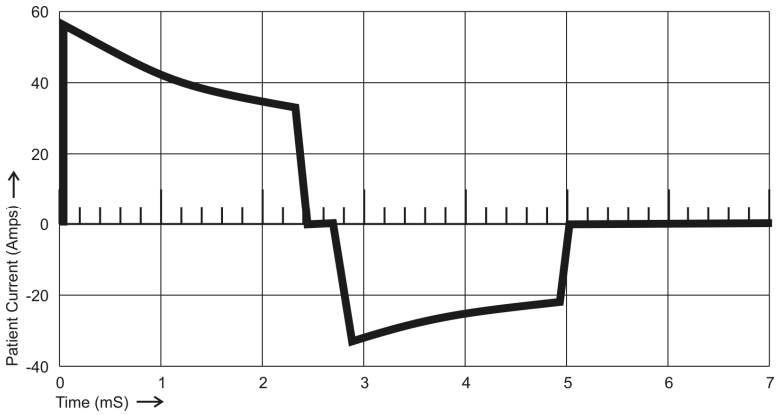
The monitor functioned normally, did not present a safety hazard, and met the dielectric strength tests required for defibrillators.

Defibrillating pulse waveforms

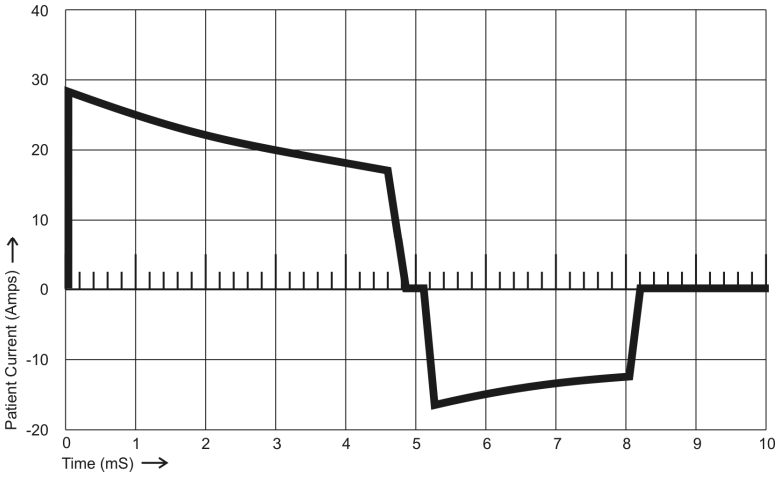
This section provides the technical details of the LifeVest therapy, as required by IEC 60601-2-4 clause 6.8.3.

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

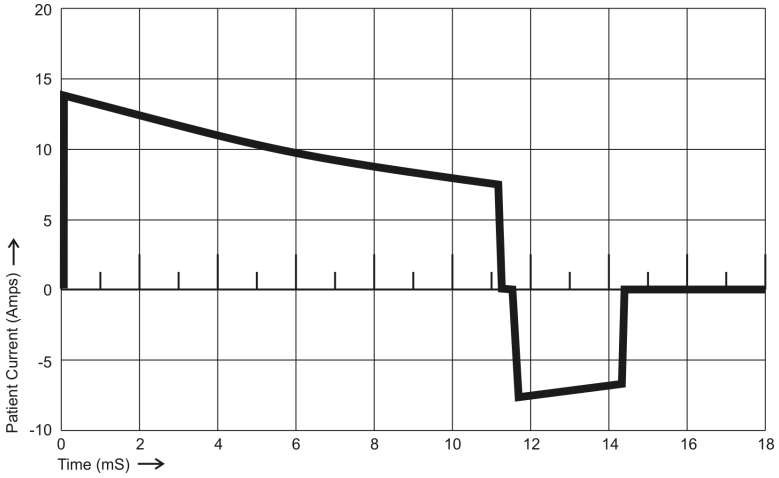
150 joules at 25 ohms



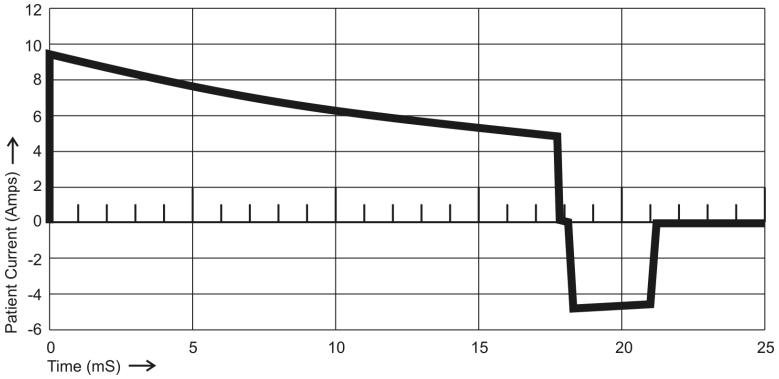
150 joules at 50 ohms



150 joules at 100 ohms



150 joules at 150 ohms



Pulse delivery synchronization

The LifeVest device attempts to deliver the therapy pulse within 60 milliseconds of the R-wave. If it cannot deliver a synchronized pulse within 3 seconds, it delivers an unsynchronized pulse.

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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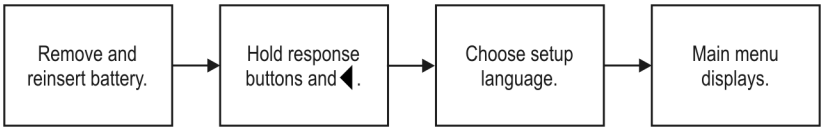
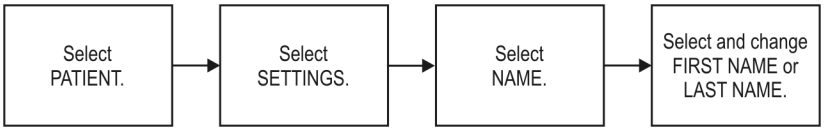
Appendix A: Quick charts

To enter setup mode

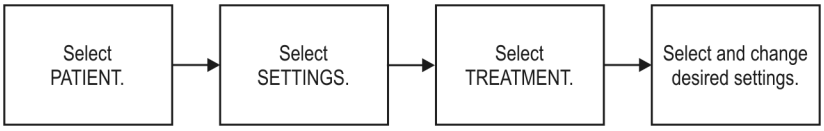


To change language or second language

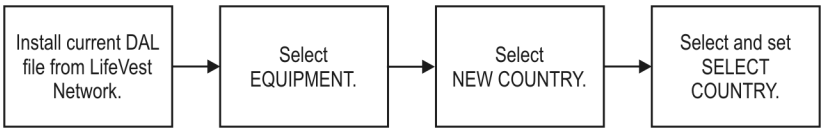
To change patient name (after initial setup)



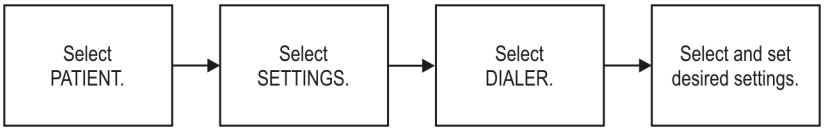
To change detection settings (rate threshold, pulse energy, response time, etc.)



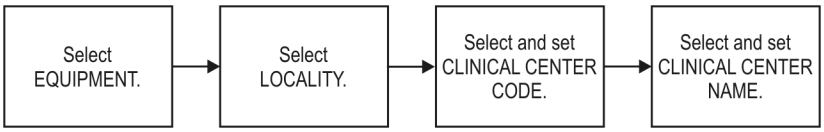
To change country



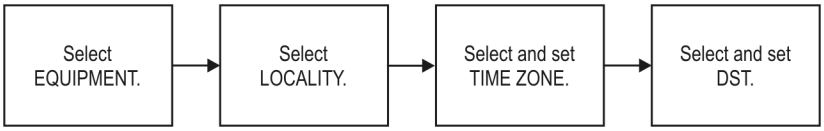
To change dialer settings



To enter or change clinical center

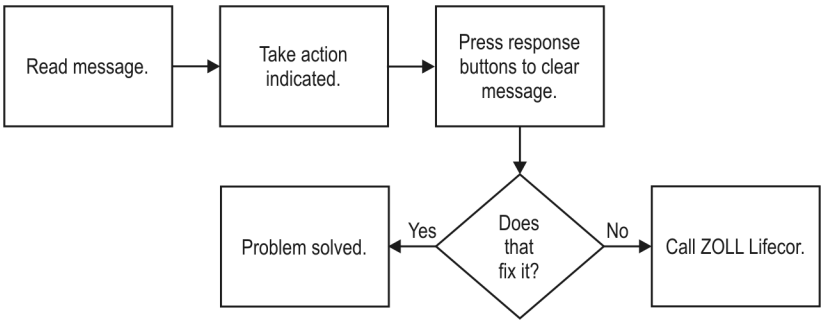


To enter or change time zone or DST

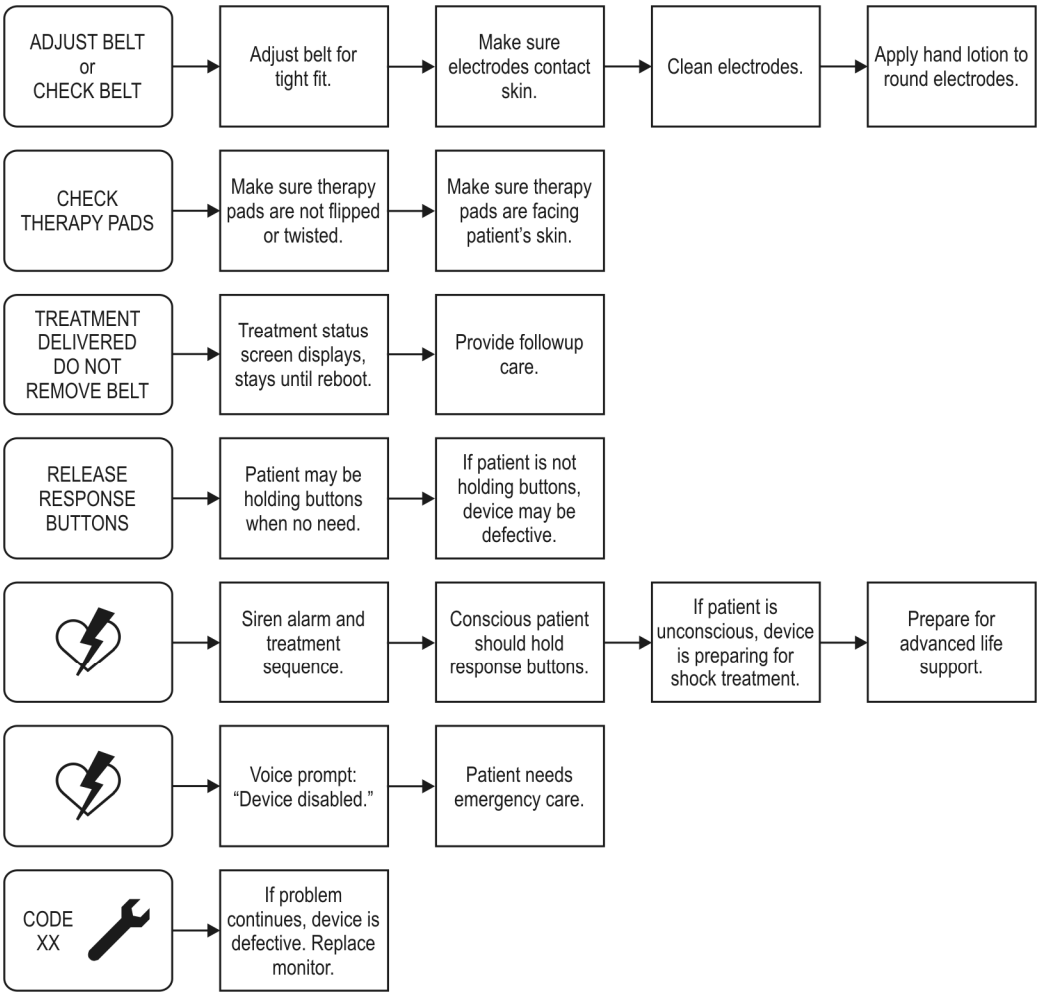


To change connectivity settings (connection method, modem type, etc.)

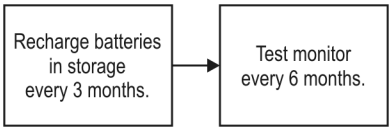
Basic troubleshooting procedure



Troubleshooting from messages



Maintenance while device is in storage



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Appendix B: Maintenance checklist

This is a suggested checklist for maintaining the LifeVest system. This form may be copied.

Unit serial no._____

Date							
Initials							

Instruction	Corrective action	Check below after completing:						
Inspect system components. Follow procedure in section 5: Maintenance.	If there is any damage, do not use on a patient. Contact ZOLL Lifecor for replacement components.	☐	☐	☐	☐	☐	☐	☐
Recondition system components. Follow procedure in section 5: Maintenance.		☐	☐	☐	☐	☐	☐	☐
Clean holster. Launder in hot, soapy water.		☐	☐	☐	☐	☐	☐	☐
Recharge batteries at least every 3 months during storage.	Replace batteries that fail to take a charge. Contact ZOLL Lifecor for replacements.	☐	☐	☐	☐	☐	☐	☐
Test monitor using test plug every 6 months	If monitor fails test, contact ZOLL Lifecor.	☐	☐	☐	☐	☐	☐	☐

Notes

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