PHYSIO CONTROL

LIFEPAK® CR2 Defibrillator

with LIFELINKcentral™ AED Program Manager

Operating Instructions

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Important Information

!USA Rx Only

!USA Device Tracking

The U.S. Food and Drug Administration requires defibrillator manufacturers and distributors to track the location of their defibrillators. If the device is located somewhere other than the shipping address or the device has been sold, donated, lost, stolen, exported, destroyed, permanently retired from use, or if the device was not obtained directly from Stryker, please do one of the following: register the device at stryker.com/ec-device-registration, call the device registration phone line at 1 800 426 4448, or use one of the postage-paid address change cards located in the back of this manual to update this vital tracking information.

Text Conventions

Throughout these operating instructions, special text characters (for example, **CAPITAL LETTERS** such as **LANGUAGE** button and **EVERYONE CLEAR**) are used to indicate labels and voice prompts.

Manufacturer Information

If you have any questions about this product or its operation, please contact your local Stryker representative or the manufacturer, Physio-Control. This device is manufactured by Physio-Control, Inc. and distributed worldwide by Stryker.

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Redmond, WA 98052 USA

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Fax 425 867 4121

Applicable Products

These operating instructions are for use with the following product catalog numbers.

REF

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Chapter 1

Introduction

This chapter provides a brief introduction to the LIFEPAK CR2 defibrillator and its features.

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About Automated External Defibrillators

The LIFEPAK CR2 defibrillator is an automated external defibrillator (AED). For many years, defibrillators have been used by medical professionals to treat patients in sudden cardiac arrest. Today, the ability of defibrillators to save lives is so widely recognized that AEDs are being made available in public spaces worldwide. People who have been trained only in cardiopulmonary resuscitation (CPR) can also use AEDs to treat sudden cardiac arrest.

After electrode pads are applied to the patient's chest, the defibrillator analyzes the patient's heart rhythm. If a shockable rhythm is detected, the defibrillator will either deliver an intense pulse of electricity (shock) to the heart muscle (fully automatic model), or direct the responder to deliver the shock (semi-automatic model). The defibrillator delivers shocks through the electrode pads on the patient's chest.

When the pulse of electricity is delivered, it is called defibrillation. Defibrillation is recognized for treating life-threatening heart beat irregularities, such as ventricular fibrillation, that cause cardiac arrest.

Indications for Use

The LIFEPAK CR2 defibrillator is indicated for use on patients 1 year of age or older in cardiopulmonary arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement).

The cprCOACH Feedback Technology in the LIFEPAK CR2 defibrillator is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with the American Heart Association (AHA) Guidelines for patients 1 year of age or older.

The LIFEPAK CR2 defibrillator is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program.

The LIFEPAK CR2 defibrillator is indicated to be used with the QUIK-STEP pacing/ECG/defibrillation pads and the LIFEPAK CR2 lithium battery.

Contraindications

The LIFEPAK CR2 defibrillator is not indicated for patients who are conscious and responsive.

For information regarding the LIFEPAK CR2 defibrillator Clinical Summaries and Potential Adverse Effects, see Defibrillation Clinical Summaries.

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Terminology

The following terms appear in this manual.

Adult Mode	Operational mode to use if the patient is 8 years or older and weighs more than 25 kg (55 lb).
AED	Automated External Defibrillator. A device that evaluates the patient's heart rhythm and delivers an electrical shock to the heart if a shockable rhythm is detected.
Cardiac arrest	The termination of the heart's pumping action resulting in the lack of a heartbeat or pulse and breathing.
Child Mode	Operational mode to use if the patient is a child 1 year of age or older and less than 8 years old.
CPR	Cardiopulmonary resuscitation. This involves delivering chest compressions to a person in cardiac arrest. The chest compressions pump blood to the rest of the body. Rescue breaths may also be provided.
Defibrillation	Delivery of an electrical shock to the heart for the purpose of reversing ventricular fibrillation.
ECG	Electrocardiogram. A composite picture of what is occurring electrically in the heart.
Fibrillation	Chaotic activity of the heart's electrical system. This condition can occur in the atria or the ventricles. When it occurs in the ventricles, they quiver in a rapid, chaotic manner, preventing them from pumping blood to the body.
Heart attack	A nonspecific term referring to the death of heart muscle resulting from interruption of blood supply, often confused with cardiac arrest.
Impedance	Resistance to the flow of electrical current through the body.
Joule	The basic unit of energy delivered by a defibrillator.
Nonshockable rhythm	A heart rhythm that is detected by the defibrillator that does not need a shock, but may need CPR.
Patient	In this manual, the person suffering from cardiac arrest.
Responder	In this manual, the person giving aid to a patient in cardiac arrest. Used interchangeably with 'user'.
Shockable rhythm	A heart rhythm that is detected by the defibrillator as requiring a shock; for example, ventricular fibrillation.
User	In this manual, the person giving aid to a patient in cardiac arrest. Used interchangeably with 'responder'.
Ventricular fibrillation	A life-threatening chaotic heart rhythm.
Ventricular tachycardia	Rapid heart rhythm originating in the ventricle.

About the LIFEPAK CR2 Defibrillator

The LIFEPAK CR2 defibrillator is designed for indoor and outdoor use in a stationary environment. Fully automatic and semi-automatic models are available. After the electrode pads are applied, the fully automatic model evaluates the heart rhythm and, if a shockable rhythm is detected, delivers a shock without any responder assistance. The semi-automatic model evaluates the heart rhythm but requires the responder to press the shock button if a shockable rhythm is detected. Both models have voice instructions that guide the responder through the event.

The LIFEPAK CR2 defibrillator is also able to connect to your LIFELINKcentral AED Program Manager or LIFENET System account using an internet connection. The device uses either Wi-Fi, cellular, or USB to connect.

Note: LIFELINKcentral AED Program Manager and LIFENET System are not available in all countries.

All LIFEPAK CR2 defibrillators have USB capability. To determine whether the device also has Wi-Fi or cellular capability, check the serial number label located in the battery compartment on the back of the device.

Note: The micro-USB port is to be used by authorized users only. The micro-USB port does not provide power and should not be connected to other devices, such as mobile phones or other USB connected products.

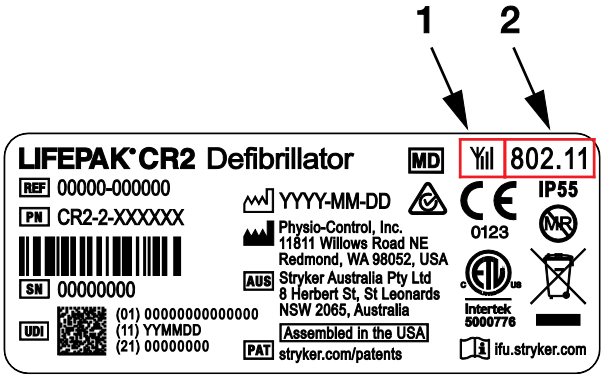

FIGURE LEGEND

1 If this symbol is present, the device has cellular capability and the SIM card is activated.

2 If this number is present, the device has Wi-Fi capability.

Check the option below that corresponds to your defibrillator for future reference.

- ☐ USB only
- ☐ Wi-Fi and USB
- ☐ Wi-Fi, Cellular, and USB

Notes:

- Throughout these instructions, "wireless" is used as a general term that includes both Wi-Fi and cellular.

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- cprINSIGHT Analysis Technology is only available in LIFEPAK CR2 defibrillators with Wi-Fi or cellular capability.

Capabilities and Features

The following paragraphs introduce specific features found in the defibrillator.

Readiness Indicator

The Readiness indicator flashes every 6 seconds to indicate the defibrillator is ready for use. If the defibrillator needs attention, the Readiness indicator does not flash and an alert tone sounds every 15 minutes. The alert tone option can be turned off. See Setup Options (on page 107) for more information.

QUIK-STEP Defibrillation Electrodes

QUIK-STEP Pacing/ECG/Defibrillation electrodes are designed to be quick and easy to open, reducing the amount of time that passes before a defibrillation shock can be provided.

When applied to the patient, QUIK-STEP defibrillation electrodes (pads) work with the defibrillator to analyze the heart rhythm and deliver a shock, if needed. The electrode pads can be used on both adults and children. If patient care is transferred to emergency medical personnel, these electrode pads can be disconnected from the defibrillator and reconnected to other LIFEPAK defibrillators, except the LIFEPAK 500 AED.

cprCOACH Feedback Technology

The defibrillator provides CPR coaching at appropriate times during the cardiac arrest response. A metronome provides tones at the correct rate for chest compressions to guide the responder. The defibrillator also detects whether chest compressions are being performed and adjusts the voice prompts, if needed, to help the responder provide the best possible care.

ClearVoice Technology

ClearVoice technology with adaptive volume control was created specifically for portable medical devices. This technology incorporates how the human ear interprets audio prompts and instructions within real world cardiac arrest response scenes such as shopping malls, highways, and emergency rooms. Adaptive volume control automatically adjusts the volume of audio instructions depending on surrounding noise levels. ClearVoice technology minimizes distortion and enhances speech intelligibility so the user can clearly understand audio instructions in a chaotic and stressful environment.

cprINSIGHT Analysis Technology

The cprINSIGHT Analysis Technology enables the defibrillator to analyze the patient's heart rhythm while CPR is being performed. This reduces pauses in chest compressions, which helps maintain circulation of the blood.

Note: cprINSIGHT Analysis Technology is only available in LIFEPAK CR2 defibrillators with Wi-Fi or cellular capability. To determine whether the device has Wi-Fi or cellular capability, check the serial number label located in the battery compartment on the back of the device. See About the LIFEPAK CR2 Defibrillator for details.

Child Mode

Child mode can be accessed by pressing the **CHILD MODE** button before applying the QUIK-STEP electrodes. When the defibrillator is in child mode, it delivers lower energy levels that are appropriate for young children without having to change electrodes. Child mode also adjusts CPR coaching to be appropriate for young children.

Note: Once the QUIK-STEP electrodes have been applied to the patient, the user will be unable to switch from Adult mode to Child mode.

Dual Language Capability

The defibrillator can be ordered with two languages. Dual-language devices begin operation in the primary language. A voice prompt and **LANGUAGE** button make it easy for the user to switch to the secondary language, if desired.

Additional Features for Connected Devices

Devices that are connected to LIFELINKcentral AED Program Manager or LIFENET System may have the following additional features.

Readiness Notifications

Email notifications are sent if a battery or electrode expiration date is approaching, if an expiration date has passed, or if the defibrillator has failed a self-test. A notification is also sent if a defibrillator with wireless capability has failed to check in.

AED In Use Notifications

An email notification is sent if the defibrillator is being used on a patient. If desired, a notification can also be sent whenever the defibrillator is turned on.

Software Updates

An email notification is sent when a software update is available. Software updates can be installed directly from LIFELINKcentral AED Program Manager or LIFENET System.

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Configurable Setup Options

The defibrillator has several operating settings that can be customized according to your local protocols and preferences. Settings that can be customized include defibrillation energy levels, CPR time, CPR protocols, and language. See Setup Options (on page 107) for more information.

AED Event Transmissions

If a LIFEPAK CR2 defibrillator has a Wi-Fi connection to LIFELINKcentral AED Program Manager or LIFENET System, information such as heart rhythm and shocks delivered can be transmitted to emergency responders during the cardiac arrest event. This information can help emergency responders prepare for arrival.

Note: Cellular transmission does not occur during patient use. Cellular transmissions occur following a patient use, after device self-tests, or when transmission is manually initiated.

AED Locator

If a LIFEPAK CR2 defibrillator is moved from its established location and has a cellular connection to LIFELINKcentral AED Program Manager or LIFENET System, an email notification is sent. If desired, the defibrillator can be instructed to beep and report its approximate location.

Chapter 2

Safety Information

This chapter provides important information to help you operate the LIFEPAK CR2 defibrillator. Familiarize yourself with all of these terms and warnings.

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General Dangers and Warnings 19
Symbols 21

Terms

The following terms are used either in these operating instructions or on the device:

Danger: Immediate hazards that will result in serious personal injury or death.

Warning: Hazards or unsafe practices that may result in serious personal injury or death.

Caution: Hazards or unsafe practices that may result in minor personal injury, product damage, or property damage.

General Dangers and Warnings

The following are general danger and warning statements. Other specific warnings and cautions are provided as needed in other sections of these operating instructions.

General Dangers and Warnings

Danger

Explosion Hazard. Do not use this device in the presence of flammable gases or anesthetics.

Warnings

- Possible Fire. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.
- Shock Hazard. The defibrillator delivers up to 360 joules of electrical energy. Unless properly by following the defibrillator's visual and audio prompts, this electrical energy may cause serious injury or death.
- Shock or Fire Hazard. Do not immerse any portion of this defibrillator in water or other fluids. Avoid spilling any fluids on defibrillator or accessories. Spilled liquids may cause the defibrillator and accessories to perform inaccurately or fail. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this defibrillator or accessories unless otherwise specified.
- Possible Device Failure. Do not modify the device or its accessories.
- Possible Electrical Interference. This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. Verify the effects of defibrillator discharge on other equipment prior to using the defibrillator in an emergency situation, if possible.
- Possible Electrical Interference With Device Performance. Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. RFI may result in failure to detect a shockable rhythm. If use of equipment in close proximity is necessary, observe the device to verify normal operation in the configuration in which the device will be used. Avoid operating the device near cauterizers, diathermy equipment, security systems, or medical devices, such as X-rays. Do not rapidly key EMS radios on and off. Contact Stryker Technical Support if assistance is required.

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Warnings

- Possible Electrical Interference with Device Performance. Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the LIFEPAK CR2 defibrillator, including cables specified by Stryker. Shorter distances may result in compromised performance.
- Possible Electrical Interference. This defibrillator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the defibrillator should be observed to verify normal operation in the configuration in which it will be used.
- Possible Electrical Interference. Using cables, electrodes, or accessories not specified for use with this defibrillator may result in increased emissions or decreased immunity from electromagnetic or radio frequency interference (RFI) which could affect the performance of this defibrillator or of equipment in close proximity. Use only parts and accessories specified in the operating instructions.
- Possible Improper Device Performance. Using other manufacturers' cables, electrodes, power adapters, or batteries may cause the device to perform improperly and may invalidate the safety agency certifications. Use only the accessories that are specified in the operating instructions.
- Possible Improper Device Performance. The QUIK-STEP electrodes provided with this device are not compatible with the LIFEPAK 500 AED. Emergency medical personnel should not connect these electrodes to a LIFEPAK 500 device.
- Safety Risk and Possible Equipment Damage. The device is MR Unsafe. Keep it outside the magnetic resonance imaging (MRI) scanner room.

Latex Information

This device is not made with natural rubber latex.

Symbols

The symbols in the following table may be found on the defibrillator, its accessories, or packaging. Visit ifu.stryker.com for additional information about symbols that are defined in standards developed by Standards Development Organizations (SDOs).

SYMBOL	DESCRIPTION
	ON/OFF button
	LANGUAGE button
	CHILD MODE button
	SHOCK button (on semi-automatic devices) **SHOCK** indicator (on fully automatic devices)
	Visit ifu.stryker.com for additional information
	Warning, high voltage
	Warning, intentional radiated power from device. See Wireless Specifications (on page 128) and local jurisdiction requirements.
	Do not reuse
LATEX	Not made with natural rubber latex
MR	The device is MR Unsafe.
	Use By date shown: YYYY-MM-DD (on electrodes) Expiration date: YYYY-MM-DD (on battery)
Li/MnO$_2$	Lithium manganese dioxide battery

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SYMBOL	DESCRIPTION
	Fire or Burn Hazard - Do not charge
	Fire or Burn Hazard - Do not open or dismantle
	Fire or Burn Hazard - Do not deform or damage
	Explosion Hazard - Do not dispose of in fire or heat above 100°C (212°F)
	Do not tamper
	Defibrillation-proof type BF applied part
25°C (77°F) 15°C (59°F)	Recommended storage temperature range 15° to 25°C (59° to 77°F)
60°C (140°F) -30°C (-22°F)	Recommended transport temperature range -30° to 60°C (-22° to 140°F) for up to 1 week
	Keep dry
	Keep away from sunlight
	Caution
50	Symbol for China RoHS indicating the Environmentally Friendly Use Period (EFUP) denoting the number of years before any substance is likely to leak out into the environment.

SYMBOL	DESCRIPTION
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. Visit stryker.com/ec-recycling for instructions on disposing of this product.
IP55	Protected against dust and jets of water
	Direct current voltage
	Peripheral devices port
	Cellular device
802.11	Wireless device
	Complies with applicable Australian telecommunications regulations
Certified for use in Hong Kong 經驗證可在香港使用 Certificate No. 證書號碼 ZZZZZYYXXXXX 通訊事務管理局 COMMUNICATIONS AUTHORITY	Complies with applicable Hong Kong telecommunications regulations
	Indicates device is certified to applicable Japanese wireless requirements
ICASA	Complies with applicable South African telecommunications regulations
TRA	Complies with UAE telecommunications regulations
Intertek	Intertek certification for Canada and the United States
c US	Underwriters Laboratories recognized component mark for Canada and the United States
CE or 0123	Mark of conformity to applicable European regulations and/or directives

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SYMBOL	DESCRIPTION
	This end up
	Fragile
	Manufacturer
	Date of manufacture shown: YYYY-MM-DD
EC REP	Authorized representative in the European Community
AUS	Australian sponsor address
!USA	For USA audiences only
Rx Only	By prescription only
PAT	Visit stryker.com/patents for patent information
QTY	Quantity
REF	Catalog number
LOT	Lot number (batch code)
SN	Serial number
PN	Part number
MD	Medical device
UDI	Unique device identifier
Assembled in the USA	Assembled in the USA

Chapter 3

Getting Started

This chapter provides an orientation to the LIFEPAK CR2 defibrillator and describes how to prepare the defibrillator for use. The defibrillator must be set up in accordance with these instructions.

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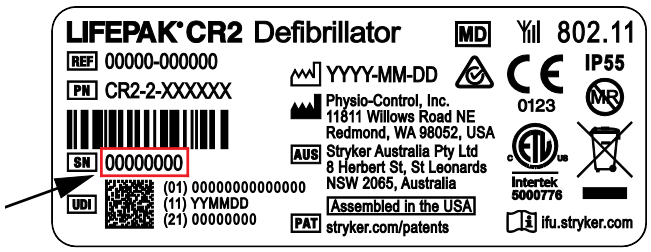
Unpacking and Inspecting Your LIFEPAK CR2 Defibrillator

To help ensure the integrity of your defibrillator and to verify that it is ready for use, perform the initial inspection as follows:

1. Remove your defibrillator and examine the outside for signs of damage that may have occurred during shipping.
2. Check the remaining contents in the shipping box against the sales order.
3. Locate the customer support contact list with region-specific phone numbers for Stryker Customer Support. Keep this information in a safe place for future reference.
4. Check the serial number label in the battery compartment to confirm whether the defibrillator has wireless (Wi-Fi or cellular) capability. See About the LIFEPAK CR2 Defibrillator for details.
5. Find the defibrillator's serial number as shown below and record it here.

   Serial Number _____



6. Check the date of manufacture on the battery label, printed in YYYY-MM-DD format. The battery must be installed within 1 year of this date to attain a 4-year service life. For detailed information about battery service life and maintenance, see Maintaining the Battery (on page 81).

7. Insert the battery into the battery compartment located on the back of the defibrillator. The defibrillator can be ordered either with a handle or with a carrying case. If your defibrillator has a carrying case, open the back of the carrying case to access the battery compartment.

The defibrillator will automatically begin a self-test. Wait until 3 audible tones sound before proceeding to the next step.

Notes:

- The self-test may take up to 2 minutes. Do not open the lid until you hear the 3 tones. Doing so will prevent the self-test from completing.
- If the same battery has been previously inserted, the 3 tones will not sound.

8. Verify that the green Readiness indicator is flashing. The Readiness indicator will flash every 6 seconds through a small hole located on top of the lid. A flashing Readiness indicator means the LIFEPAK CR2 defibrillator is ready for use.

9. Check the speaker. Open the lid and confirm that the voice prompts are audible. Do not respond to the voice prompts at this time.

   IMPORTANT! DO NOT pull the red handle at this time; only pull in an emergency. If the red handle is pulled, the electrode seal will be broken and the electrodes will dry out. If the seal is broken, replace the electrode tray immediately and dispose of the opened electrode tray as described in Recycling Information.

10. Close the lid to turn off the device. Do not reopen the lid unless necessary. Doing so will reduce battery power.
11. If the device has wireless capability, see one of the following to connect the device to your account:
    - LIFELINKcentral AED Program Manager (on page 43), or
    - LIFENET System (on page 59) for health care organizations that already have a LIFENET System account.

Caution

Possible Reduced Battery Life. After completing an initial inspection, do not open the lid unless necessary. Each time you open the lid, the defibrillator turns on and battery power is reduced.

Warning

Premature Battery Depletion. If the lid or lid magnet is missing, the LIFEPAK CR2 battery can become prematurely depleted.

Where to Locate Your LIFEPAK CR2 Defibrillator

The defibrillator should be placed in a high-visibility, frequently-traveled area. This could include a location near existing emergency equipment, such as fire extinguishers and first-aid kits.

In the workplace, employees should be informed as to the defibrillator location. Placing the defibrillator in a central location will help everyone get used to seeing it so they know where to find it in an emergency.

You can place your defibrillator on a stable surface, or in an AED cabinet (if purchased). If the defibrillator is placed in a surface-mounted cabinet, ensure sufficient space to avoid protruding into the path of travel for anyone walking or in a wheelchair.

When considering location, avoid areas that expose the defibrillator to moisture, dust, or extreme temperatures. The recommended storage temperature range for the defibrillator is 15° to 35°C (59° to 95°F); however, long-term storage at the higher temperatures in this range may reduce the life of the electrodes.

The defibrillator and electrodes are designed to withstand environmental temperature fluctuations between -30° to 60°C (-22° to 140°F), but storage at these extreme temperatures is limited to one week. If storage at these temperatures exceeds one week, the electrode shelf-life will be reduced. Storage at high temperatures will also reduce the life of the battery.

If the defibrillator has wireless capability, it should be placed in a location that has adequate signal strength.

Warning

Possible Fire or Explosion. Do not store this defibrillator in the presence of flammable gases or in direct contact with flammable material.

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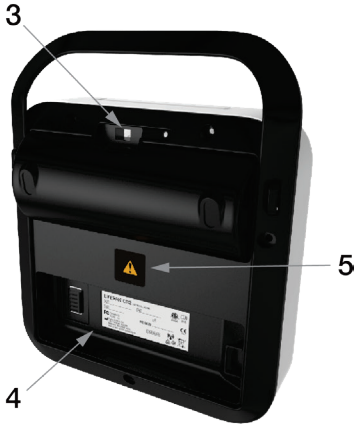
Controls, Indicators, and Labels

This section describes the controls, indicators, and labels on the device.

Outside Controls, Indicators, and Labels

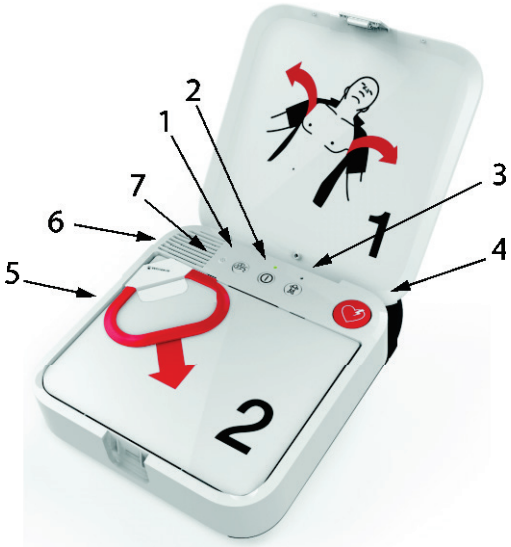
Controls, indicators, and labels on the outside of the defibrillator are shown below.



ITEM	FEATURE	DESCRIPTION
1	Readiness indicator	The green LED flashes every 6 seconds if the defibrillator is ready for use. The indicator is steady on if the defibrillator is turned on, and steady off if the defibrillator needs attention. If the Readiness indicator is off, immediately follow the instructions in Maintaining a State of Readiness (on page 77) to determine what is wrong. If the problem is a low battery, install a new battery as soon as possible to avoid loss of power during patient care. **Note:** When the Readiness indicator is off, an alert tone sounds every 15 minutes. The alert tone option can be turned off. See Setup Options (on page 107) for more information.
2	Latch	To open the defibrillator, insert your finger in the recessed area and pull up.
3	USB port	The USB connection is used to connect the defibrillator to a computer, to establish communication with LIFELINKcentral AED Program Manager or LIFENET System. The USB connection is also needed to specify Wi-Fi settings so the defibrillator can access your Wi-Fi network. See LIFELINKcentral AED Program Manager (on page 43) or LIFENET System (on page 59) for more information.
4	Battery compartment	Insert the LIFEPAK CR2 lithium battery into the battery compartment until it clicks into place. The serial number label is located in the battery compartment. To view the serial number, remove the battery.
5	Warning symbol	See General Dangers and Warnings (on page 19) for important information.

Inside Controls and Features

Controls and features on the inside of the defibrillator are shown below.



ITEM	FEATURE	DESCRIPTION
1	**LANGUAGE** button	If the defibrillator has two languages installed, press the **LANGUAGE** button to switch between languages. **Note:** To switch to Data mode and access certain maintenance functions, press the **LANGUAGE** and **CHILD MODE** buttons simultaneously for at least 2 seconds. For more information, see Maintaining a State of Readiness (on page 77).
2	**ON/OFF** button	The defibrillator turns on automatically when the lid is opened. Press and hold the **ON/OFF** button for 3 seconds to turn the defibrillator off. Press again to turn the defibrillator back on. The green LED is illuminated when the defibrillator is on. **Note:** The **ON/OFF** button is disabled when the electrode pads are applied to a patient.
3	**CHILD MODE** button	Press the **CHILD MODE** button to switch between Adult mode and Child mode. When Child mode is selected, the green LED above the **CHILD MODE** button is illuminated and a voice prompt announces "Child mode." **Note:** The user will be unable to switch from Adult mode to Child mode when the electrode pads are applied to the patient.
4	**SHOCK** button/indicator	On fully automatic defibrillators, the **SHOCK** indicator flashes when the defibrillator is preparing to deliver a shock. On semi-automatic defibrillators, press the flashing **SHOCK** button to deliver a shock to the patient.
5	Red handle	During a cardiac arrest event, the red handle is pulled to reveal the electrodes. **IMPORTANT!** Only pull the red handle in an emergency. If the red handle is pulled, the electrode seal will be broken and the electrodes will dry out. If the seal is broken, replace the electrode tray immediately and dispose of the opened electrode tray as described in Recycling Information.

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ITEM	FEATURE	DESCRIPTION
6	Speaker	Provides audio voice prompts and tones.
7	Noise sensor	The noise sensor monitors the noise level of the surrounding area while the defibrillator is in use. The defibrillator then automatically adjusts the volume of the voice prompts so they can be clearly heard.

Chapter 4

Using the Defibrillator

This chapter provides information and instructions for using the defibrillator on a patient in cardiac arrest.

Warnings and Cautions 35
Responding to a Sudden Cardiac Arrest Emergency 35
Troubleshooting Tips 41

Warnings and Cautions

To help ensure safe use of the defibrillator, familiarize yourself with the following warnings and cautions.

Warnings

- Shock Hazard. When instructed **EVERYONE CLEAR**, do not touch the defibrillator, patient, electrode pads, or any material or fluids in contact with the patient. Make sure no one is touching the patient when the defibrillator shocks the patient.
- Possible Fire, Burns, and Ineffective Energy Delivery. During defibrillation, material in contact with the electrode pads can cause electrical sparks, skin burns, and divert important defibrillating energy away from the heart. Place electrode pads so that they adhere to the skin completely. Do not allow the electrode pads to touch each other, medication patches, dressings, metal objects, other electrodes, or any other material on the patient's chest.
- Shock hazard. Do not touch the patient and the USB connector on the back of the device simultaneously.
- Possible Skin Burns. During defibrillation, air pockets between the skin and electrode pads can cause skin burns. To help prevent air pockets, make sure electrode pads completely adhere to the skin. Do not use damaged, expired, or dried-out electrode pads.
- Possible Skin Burns and Ineffective Energy Delivery. Electrode pads that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not pull the red handle to open the electrodes until immediately before use. Do not reuse electrodes.

Caution

Possible Equipment Damage. Before using this defibrillator, disconnect from the patient all equipment that is not defibrillator-protected.

Responding to a Sudden Cardiac Arrest Emergency

If not treated, sudden cardiac arrest will cause death. It is important to remember to immediately call for help and activate your emergency response system.

When you open the defibrillator, voice instructions (prompts) provide clear, step-by-step instructions for responding to a patient in cardiac arrest. For a complete list of voice instructions, see Voice Prompts.

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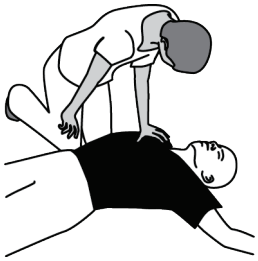
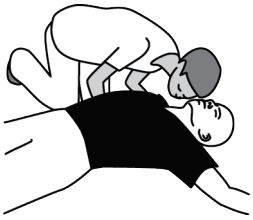
Basic Steps for Using the LIFEPAK CR2 Defibrillator

Responding to a cardiac emergency using the defibrillator involves these basic steps.



1 Tap the patient's shoulder and shout. A person in cardiac arrest will not respond.

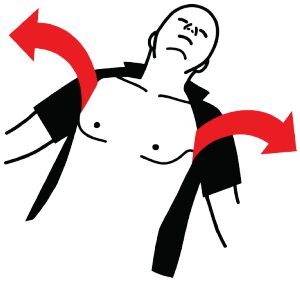


2 Check for breathing by listening next to the patient's mouth and looking for chest movement.

Use the defibrillator only if the patient is not responding, and not breathing or only gasping. If in doubt, use the defibrillator.

3 Place the defibrillator near the patient and on the side next to you. Open the lid to turn on the defibrillator. The defibrillator will guide you through the appropriate steps.

Note: If the defibrillator does not turn on or the lid is missing, press the **ON/OFF** button.



4 Remove all clothing, including undergarments, from the patient's chest. If the chest is excessively hairy and a razor is readily available, quickly shave the hair in the area where you will place the electrode pads. If the chest is dirty or wet, wipe the chest clean and dry. If there are medicine patches on the patient's chest, remove them.

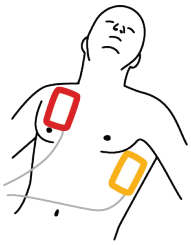
5 If the defibrillator is a dual-language model, a voice prompt occurs at this time in the secondary language. This voice prompt instructs you to press the **LANGUAGE** button to switch to the secondary language (if desired).

6 If the patient is a child less than 8 years old or who weighs less than 25 kg (55 lb), press the **CHILD MODE** button to enter Child mode before applying the QUIK-STEP electrodes. When Child mode is selected the green LED above the **CHILD MODE** button is illuminated and a voice prompt announces "Child mode." To switch back to Adult mode, press the **CHILD MODE** button again.

Note: The user will be unable to switch from Adult mode to Child mode when the electrode pads are applied to the patient.

7 Pull the red handle to reveal the electrode pads.

8 Pull the loops on the electrode pads to peel the pads from the tray.



9 Apply the pads to the patient's bare chest exactly as shown in the pictures on the pads. If possible, avoid placing the pads over broken skin. Be sure to press firmly so that the pads completely adhere to the patient's chest.

Notes:

- Be sure you do not place the electrode pads over an implanted device such as implanted pacemaker or ICD. An indication of an implant is a protrusion in the chest skin and a scar. If you are in doubt, apply the pads as shown in the pictures.
- Ensure the pads are at least 2.5 cm (1 in) apart. If the patient's chest is too small, place the pads on the chest and back as shown in the child pictures on the pads.

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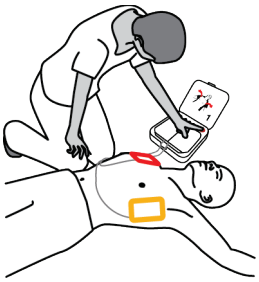
10 Listen to the voice prompts and do not touch the patient unless instructed to do so.

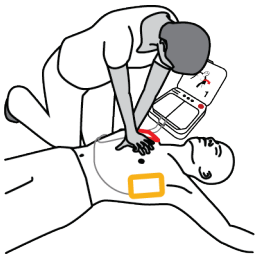


11 If the defibrillator heart rhythm analysis determines that a shock is needed you will hear **EVERYONE CLEAR,** followed by one of these two options.

- If you have a semi-automatic model, you will hear **PRESS FLASHING BUTTON**. Press the flashing **SHOCK** button to deliver a shock.
- If you have a fully automatic model, you will hear **DO NOT TOUCH PATIENT** followed by **DELIVERING SHOCK**. The defibrillator will automatically deliver a shock without requiring further action.

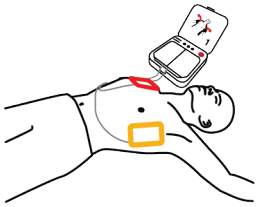
12 Do not touch the patient while a shock is being delivered.

Regardless of which model you have, continue to follow the voice prompts.



13 The defibrillator will instruct you to begin chest compressions. The defibrillator will provide instructions for hand placement during chest compressions, and 'tocks' at the correct compression rate. You may also be instructed to provide rescue breaths, depending on the settings for the defibrillator.

Note: Do not remove the electrode pads from the patient's chest during chest compressions.



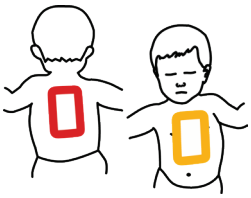
14 Continue to follow the voice prompts and provide chest compressions when instructed until one of the following occurs:

- The patient begins breathing regularly or moving
- Emergency medical personnel arrive and tell you to stop.

Do not remove the pads or disconnect them from the defibrillator unless emergency medical personnel instruct you to do so.

Special Instructions for Use on Young Children

If the patient is a young child, place the electrode pads on the chest and back, as shown below. The pads must be placed so they are not touching each other. Illustrations showing this placement are also provided on the pads for quick reference during use.



What to Do After Emergency Medical Personnel Arrive

When emergency medical personnel arrive, continue performing CPR until they tell you to stop. Tell them what actions you have taken, how long the patient has been unconscious, if you delivered shocks, and the number of shocks delivered.

Do not worry if you cannot recall precisely what happened. Your defibrillator records heart rhythms, shocks, and other data that can be transferred to medical professionals during the event or at a later time. Contact your local Stryker representative or local authorized distributor for assistance with data transfer.

Emergency medical personnel may be able to disconnect the electrode pads from the defibrillator and reconnect them to another defibrillator that has a compatible cable. To disconnect the electrode pads, pull the electrode cable straight out from the defibrillator and close the lid to turn off the defibrillator.

What to Do After Using Your Defibrillator

After you use your defibrillator to respond to a cardiac arrest, complete the following tasks.

1. If the defibrillator is turned on, press and hold the **ON/OFF** button for approximately 3 seconds to turn it off.
2. Clean the defibrillator and its accessories according to the instructions provided in Cleaning the Defibrillator (on page 82). Use only the cleaning agents listed.
3. The QUIK-STEP electrode tray must be replaced after it is opened, even if the electrodes were not used. If you do not have a spare electrode tray, contact your Stryker representative or local authorized distributor to order a new electrode tray.
4. When the new electrode tray arrives, install it according to the instructions provided in Replacing the Electrodes (on page 79).
5. Close the lid and verify that the Readiness indicator flashes every 6 seconds.

   Note: If the Readiness indicator does not flash, open the lid. When the voice prompts start, press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously for at least 2 seconds, until you hear **DEVICE READY** or **DEVICE NOT READY**. The defibrillator will provide voice prompts to help you determine what is wrong. See Caring for the Defibrillator (on page 75) for more information.
6. Dispose of the used electrode tray according to the instructions provided in Recycling Information.

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Additional Training Resources

Stryker recommends that all identified defibrillator users attend formal CPR and AED training provided by a recognized training organization. Training should be repeated every 2 years.

Training videos for the LIFEPAK CR2 defibrillator are available on the Stryker website at stryker.com/emergencycare. These short videos provide information about using and maintaining the defibrillator.

Stryker offers a training device to assist with training simulations. The LIFEPAK CR2 trainer simulates the LIFEPAK CR2 defibrillator, but does not deliver shocks. The trainer is recommended so users can practice using the LIFEPAK CR2 defibrillator in simulated cardiac arrest situations.

IMPORTANT! Do not use the LIFEPAK CR2 defibrillator for training. Doing so will reduce available battery charge, and could damage the electrodes.

To order the LIFEPAK CR2 trainer, contact your local Stryker representative or local authorized distributor. See the customer support contact list provided with the device for region-specific phone numbers.

Troubleshooting Tips

This section explains problem conditions that you may encounter while using the defibrillator.

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
CHECK PADS FOR GOOD CONTACT TO BARE SKIN or **CHECK ELECTRODE TRAY CONNECTION** voice prompts are heard	Electrode pads are not properly adhered to the patient's bare skin	• Clean, shave, and dry the patient's skin before placing pads on skin. • Firmly press the pads on the patient's skin.
	Inadequate connection to the defibrillator	• Be sure that the electrode tray is completely inserted in the defibrillator.
Defibrillator cannot deliver the required shock	Low battery power	• Administer CPR.
Voice prompts sound faint or distorted	Low battery power	• Follow voice prompts if possible. • Administer CPR.
	Speaker system failure	• Contact qualified service personnel.
MOTION DETECTED; STOP MOTION voice prompt is heard	Patient is being touched	• Do not touch patient.
	Patient movement because of breathing	• Check patient for normal breathing.
	Electrical/radio frequency interference	• Move communication or other suspected devices away from the defibrillator when possible.
Defibrillator does not provide voice prompts or beeping tones after you open the lid (turn it on).	Lid magnet is missing	• Use the ON/OFF button to turn the defibrillator on if required for emergency use. • Contact qualified service personnel.
	Depleted battery	• Replace the battery immediately. If a replacement is not available, order a new battery immediately.
	Speaker system failure	• Contact qualified service personnel.
Readiness indicator is not flashing	Low battery power or expired electrodes	• Open the lid. When the voice prompts start, press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously for at least 2 seconds. The defibrillator will provide voice prompts to help you determine what is wrong.

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OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
	Depleted battery	• Replace the battery immediately. If a replacement is not available, order a new battery immediately.
	Electrode tray not connected	• Be sure that the electrode tray is completely inserted in the defibrillator.
	Operating temperature is too low or too high	• Operate the defibrillator within 0° to 50°C (32° to 122°F).
	Defibrillator self-test failed	• Contact qualified service personnel.
Voice prompts continue after lid is closed.	Lid magnet is missing	• Use the ON/OFF button to turn the defibrillator off. • Contact qualified service personnel.

Chapter 5

LIFELINKcentral AED Program Manager

This chapter provides information about using LIFELINKcentral AED Program Manager to monitor device readiness, update setup options, and update software.

Overview 45
Features 45
Logging in to Your Account 46
Setting Up Wi-Fi 47
Initiating Wireless Connection 49
Connecting with Wi-Fi 50
Connecting with Cellular 50
Connecting with USB 51
Confirming AED Status Online 53
Updating Setup Options and Software 53
Troubleshooting Tips 57

Overview

You should have an online account on one of the following two websites:

- LIFELINKcentral AED Program Manager, or
- LIFENET System

Many health care organizations have existing LIFENET System accounts to manage their devices. If your organization has a LIFENET System account, refer to LIFENET System (on page 59) for instructions about using LIFENET System to manage your LIFEPAK CR2 AED (Automated External Defibrillator).

If your organization does not have a LIFENET System account, a LIFELINKcentral AED Program Manager account was set up for you when you ordered your LIFEPAK CR2 AED. Use the instructions in this chapter to manage your AED using LIFELINKcentral AED Program Manager.

Note: LIFELINKcentral AED Program Manager is not available in all countries. If LIFELINKcentral AED Program Manager is not available in your country and you want to change setup options or install a software update, please contact your local Stryker representative or local authorized distributor for assistance.

Features

LIFELINKcentral AED Program Manager features may include the following, depending on your subscription type and service area.

- Monitoring defibrillator status.
- Sending email notifications when the battery or electrodes need to be replaced, including advance notifications 30 and 60 days before the expiration date.
- Sending email notifications when the defibrillator is turned on or when the electrode pads are applied to a patient. These notifications can also be sent to your organization's Emergency Response Team.
- Configuring setup options for the defibrillator.
- Installing software updates.
- Sending AED and patient data, such as heart rhythm, to emergency responders before they arrive at the scene.
- Sending AED and patient data reports to medical personnel or the receiving hospital.
- Instructing a lost defibrillator to send its approximate location and beep frequently. (This feature is only available on devices with cellular capability.)

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Notes:

- If your LIFEPAK CR2 defibrillator has a Wi-Fi connection to LIFELINKcentral AED Program Manager, incident information such as heart rhythm and shocks delivered may be transmitted to emergency responders during the cardiac arrest event. This information can help emergency responders prepare for arrival.
- If your LIFEPAK CR2 defibrillator has a Wi-Fi or cellular connection to LIFELINKcentral AED Program Manager, Stryker may collect system diagnostic information from your device. This information will be used to optimize device quality.

The LIFEPAK CR2 defibrillator can connect to LIFELINKcentral AED Program Manager using a Wi-Fi, cellular, or USB connection to the internet.

Note: The micro-USB port is to be used by authorized users only. The micro-USB port does not provide power and should not be connected to other devices, such as mobile phones or other USB connected products.

To determine whether your defibrillator has Wi-Fi or cellular capability, see About the LIFEPAK CR2 Defibrillator.

Logging in to Your Account

Before you attempt to connect your defibrillator to LIFELINKcentral AED Program Manager for the first time, you should confirm your account is active.

Log in to your account using the logon name and password from your "Welcome to LIFELINKcentral" email. If you did not receive this email, it may have been sent to another person in your organization. If you are unable to find the email, look up the appropriate web

address for your country in the customer support contact list included with the device. Go to the website to create your account.

Setting Up Wi-Fi

The LIFEPAK CR2 defibrillator can be ordered with Wi-Fi capability, or both Wi-Fi and cellular capability. Stryker recommends that all LIFEPAK CR2 defibrillators with Wi-Fi capability be set up with a Wi-Fi network, even if the defibrillator also has cellular capability.

Your Wi-Fi network settings must be loaded into the defibrillator so it can connect to the Wi-Fi network. You will need the following:

- PC computer with Windows 7 or above operating system and an internet connection
- Administrator rights on the computer
- USB cable (provided with the AED). The USB cable must be USB type 2.0 A Male to Micro-B.

A typical Wi-Fi setup takes 10-20 minutes. To set up a Wi-Fi connection, follow these instructions.

1. Confirm that the intended location for the AED has a good connection to the Wi-Fi network. Test the signal strength of the Wi-Fi network at the intended AED location using a different Wi-Fi device such as a smartphone.
2. Identify the Wi-Fi network information you will need to connect the AED to the network. Most networks require a network name and security key. If you do not have this information, ask your IT department for assistance.
3. Log in to your LIFELINKcentral AED Program Manager account as described in Logging in to Your Account (on page 46).
4. Download and install the Wi-Fi Configuration Tool to your computer.
   a. Select **RESOURCE CENTER**.
   b. Select **WI-FI CONFIGURATION TOOL**.
   c. Click the download icon in the upper right corner of the screen to download the Wi-Fi Configuration Tool.
   d. After the Wi-Fi Configuration Tool has downloaded, double-click the **WCT.xxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

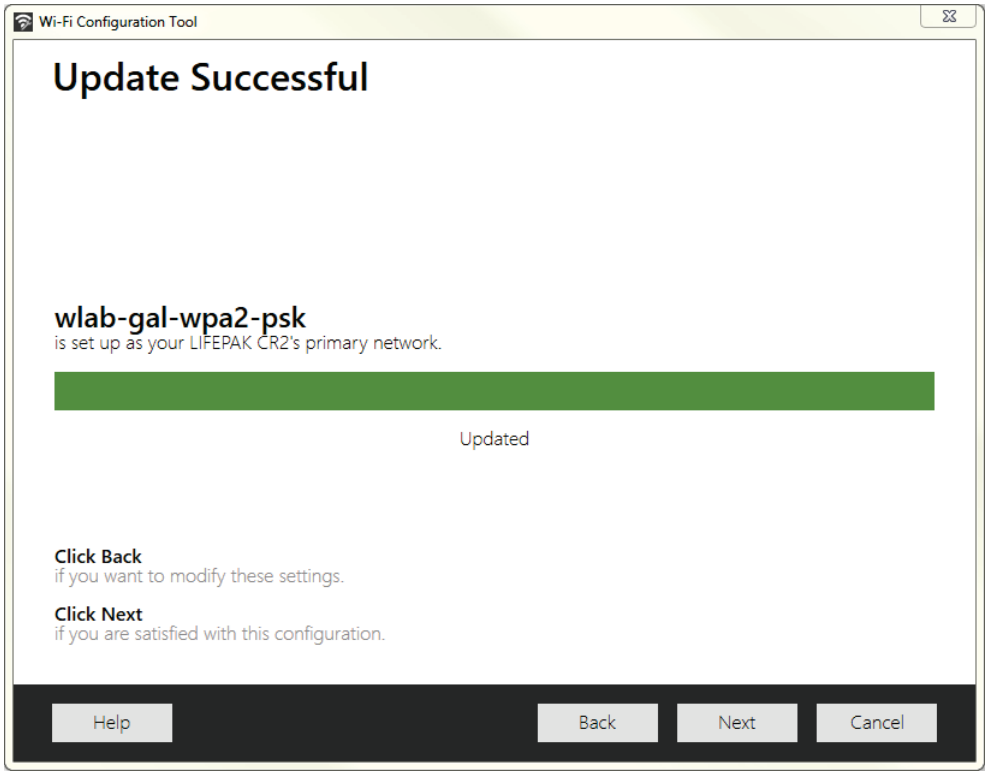
      Note: If any security warnings appear, select the option to allow the file.
   e. When the **INSTALLSHIELD WIZARD** appears, select your language and click **NEXT**.
   f. When you see the **INSTALLSHIELD WIZARD COMPLETED** screen, make sure the **LAUNCH WI-FI CONFIGURATION TOOL** checkbox is selected, and then click **FINISH**.

      Notes:

      - Your computer may reboot during the installation process. If this happens, the installation should continue automatically.

- The Wi-Fi Configuration Tool should launch automatically after installation. If you need to start the Wi-Fi Configuration Tool manually, open the **START** menu on your computer, open the **PHYSIO-CONTROL** folder, and click **WI-FI CONFIGURATION TOOL**.

5. Follow the onscreen instructions in the Wi-Fi Configuration Tool. When you are prompted to connect the AED to your computer, use the USB cable provided with the AED or an appropriate equivalent (type 2.0 A Male to Micro-B).
6. Continue to follow all instructions and click **NEXT**.
7. When the Wi-Fi setup is complete, you will see the **UPDATE SUCCESSFUL** screen. Click **NEXT**.



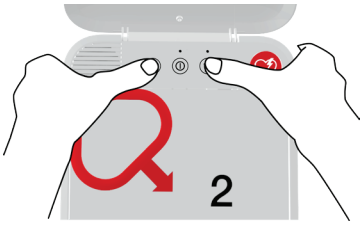
8. When you see **DISCONNECT LIFEPAK CR2**, disconnect the USB cable.
9. If you have another AED to set up, click **CONFIGURE ANOTHER LIFEPAK CR2**. Otherwise, click **CLOSE**.
10. Initiate a wireless connection to test the Wi-Fi settings and connection, as described in Initiating Wireless Connection (on page 49).

Initiating Wireless Connection

1. Take the AED to its intended location.

2. Open the lid and ***wait*** until the voice prompts start.

3. ***Immediately*** press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously until you hear **DEVICE READY**.



4 Immediately:

- Close the lid
- Place the AED in its permanent storage location (for example, cabinet or vehicle)
- Close the door of the cabinet or vehicle

The AED will attempt a Wi-Fi connection immediately after the **DEVICE READY** voice prompt, and it must be in its permanent location during this test.

5. If you hear **WI-FI CONNECTION INITIATED**, go to Connecting with Wi-Fi (on page 50).

   If you hear **MOBILE CONNECTION INITIATED**, go to Connecting with Cellular (on page 50).

Notes:

- The **DEVICE READY** voice prompt indicates whether the AED is ready for a cardiac emergency. It does **not** indicate whether wireless is ready.

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- If you hear **DEVICE NOT READY**, this means the AED is not ready for a cardiac emergency. Continue with the rest of the wireless setup. When you are finished, contact Stryker Customer Support for assistance.
- If you pressed both buttons but did not hear the **DEVICE READY** or **DEVICE NOT READY** voice prompts, you may need to try again. When you open the lid, you must ***wait*** until the voice prompts start before pressing the two buttons. After the voice prompts start, you must press the two buttons ***within 10 seconds***. If you miss these time limits, the AED proceeds as it would during a cardiac arrest. To try again, close and reopen the lid.

Connecting with Wi-Fi

1. Initiate the connection as described in Initiating Wireless Connection (on page 49).
2. Listen for the following voice prompts:
   - **WI-FI CONNECTION INITIATED**, followed by **CONNECTION IN PROGRESS**. There will be a pause while the AED connects.
   - **CONNECTION ESTABLISHED**. Once a Wi-Fi connection is established, the AED will update your online account with its current status. The AED beeps every few seconds during the update process.

3. When all updates are complete, you will hear **COMMUNICATION COMPLETE**.
   - If the AED does not have cellular capability, you will hear **POWERING OFF**. Go to Confirming AED Status Online (on page 53) to verify your LIFELINKcentral account was successfully updated.
   - If the AED has cellular capability, it will immediately attempt a cellular connection. Go to Connecting with Cellular (on page 50).

Note: If you hear **UNABLE TO ESTABLISH WI-FI NETWORK CONNECTION,** this may mean that the signal strength at your location is not strong enough to connect the AED to the Wi-Fi network. After you hear **POWERING OFF**, move the AED installation closer to your Wi-Fi access point and try again. If you need assistance, contact Stryker Customer Support. See the customer support contact list included with the device for region-specific phone numbers.

Connecting with Cellular

If your AED has cellular capability, it will attempt a cellular connection immediately after the Wi-Fi connection attempt. This occurs whether or not the Wi-Fi connection was successful.

Note: If you have not set up a Wi-Fi configuration, the AED will proceed directly to the cellular connection when you initiate the connection process. If a wireless connection is not already in progress, go to Initiating Wireless Connection (on page 49) for instructions.

The AED should be in its permanent location (for example, cabinet or vehicle) during this test.

1. Listen for the following voice prompts:

   - **MOBILE CONNECTION INITIATED**, followed by **CONNECTION IN PROGRESS**. There will be a pause while the AED connects.
   - **CONNECTION ESTABLISHED**. Once a cellular connection is established, the AED will update your online account with its current status. The AED beeps every few seconds during the update process.

   Note: If your account was already updated during the Wi-Fi connection, the updates are not repeated.

2. When all updates are complete, you will hear **COMMUNICATION COMPLETE**, followed by **POWERING OFF**. Go to Confirming AED Status Online (on page 53) to verify your LIFELINKcentral account was successfully updated.

Note: If you hear **UNABLE TO ESTABLISH MOBILE NETWORK CONNECTION,** this may mean that the signal strength at your location is not strong enough to connect the AED to the cellular network. If possible, move the AED installation and try again. If you need assistance, contact Stryker Customer Support. See the customer support contact list included with the device for region-specific phone numbers.

Connecting with USB

If you need to connect to your LIFELINKcentral AED Program Manager account without using Wi-Fi or cellular, you can use the USB connector. The USB cable must be USB type 2.0 A Male to Micro-B. An appropriate USB cable is provided with the defibrillator.

Note: For LIFEPAK CR2 defibrillators with Wi-Fi capability, the USB connection is also used to load your Wi-Fi network settings into the AED. See Setting Up Wi-Fi (on page 47) for more information.

To connect to LIFELINKcentral AED Program Manager using the USB connection, you must have a PC computer that has an internet connection. You will need to install a program called LIFENET Device Agent on your computer. You will use LIFENET Device Agent to transfer information between the AED and your LIFELINKcentral account.

To install LIFENET Device Agent on your computer, follow these instructions.

1. Log in to your LIFELINKcentral account using the logon name and password from your "Welcome to LIFELINKcentral" email. If you did not receive this email, it may have been sent to another person in your organization. If you are unable to find the email, look up the appropriate web address for your country in the customer support contact list included with the device. Go to the website to create your account.

   Note: If you have already logged in to your account and changed your logon name and password, use those logon credentials instead.

2. Select **RESOURCE CENTER**.
3. Select **LIFENET DEVICE AGENT**.
4. Click the download icon in the upper right corner of the screen to download LIFENET Device Agent.
5. After LIFENET Device Agent has downloaded, double-click the **LDA.xxxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

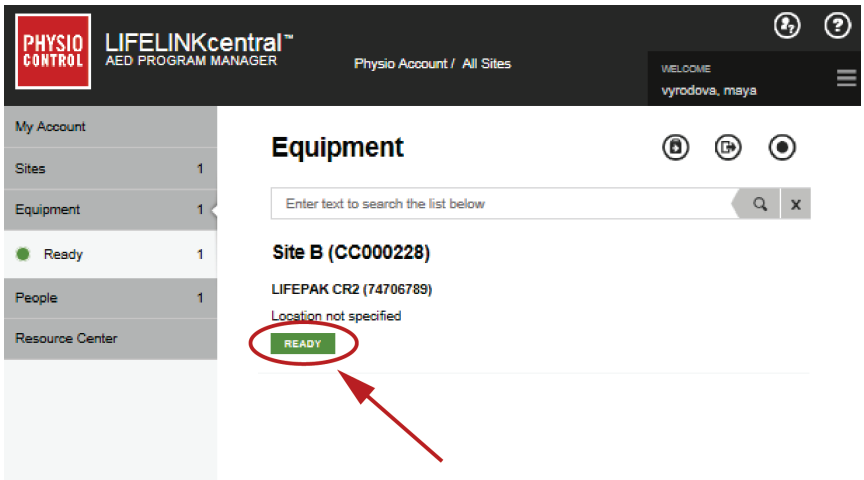
   Note: If any security warnings appear, select the option to allow the file.

6. When the **INSTALLSHIELD WIZARD** appears, select your language and click **OK**.
7. When you see **INSTALLSHIELD WIZARD COMPLETED**, make sure the **START LIFENET DEVICE AGENT** checkbox is selected, and then click **FINISH**.
8. When LIFENET Device Agent opens, you will be prompted to enter your "LIFENET System" credentials. Enter the same logon name and password you use to log in to your LIFELINKcentral account.
9. After LIFENET Device Agent is installed and running, you will be instructed to connect the LIFEPAK CR2 defibrillator to the computer using the USB cable that was provided with the AED, or an appropriate equivalent.
10. Once the connection is established, the AED will update your LIFELINKcentral AED Program Manager account with information about current device status. The AED will also download any updates you have specified in your account.
11. When you are finished, disconnect the USB cable from the AED and close LIFENET Device Agent.
12. Continue with Confirming AED Status Online to verify your LIFELINKcentral account was successfully updated.

Confirming AED Status Online

To confirm that the AED successfully updated its status in your LIFELINKcentral AED Program Manager account, check the AED status as described below. If the status is not **READY**, contact your local Stryker representative or local authorized distributor for assistance.

1. Log in to your LIFELINKcentral account.
2. Go to the **EQUIPMENT** page and verify that the status of your device says **READY** in green.



Updating Setup Options and Software

Descriptions of available setup options are provided in Setup Options (on page 107).

To update setup options or software using a wireless connection, follow the instructions below.

To update setup options or software using a USB connection, see Updating Setup Options or Software with USB Connection (on page 55).

Updating Setup Options or Software with Wireless Connection

Note: Any updates you specify will be applied to all LIFEPAK CR2 devices at your site.

1. Specify Updates

1. Log in to your LIFELINKcentral account using your logon credentials.
2. On the main menu, click **SITES**.
3. Click a site.
4. Select the **SOFTWARE AND SETUP OPTIONS** icon ⚙. This opens the Software and Setup Options view.
5. If a software profile shows a status of **UPDATE AVAILABLE:**

a. Click the profile.

b. Click the **AUTHORIZE SOFTWARE UPDATE** button to schedule your devices for the update

c. Click the **AUTHORIZE CONFIRMATION** button on the pop-up menu.

6. To edit setup options:

   a. Select a profile from the Software and Setup Options view.

   b. Select the **EDIT SETUP OPTIONS** icon ⊘.

   c. Change setup options as desired.

   Note: For additional information, click the Help icon ⓘ in the upper right corner of the screen.

7. Log out of your account.

2. Apply Updates to the AED

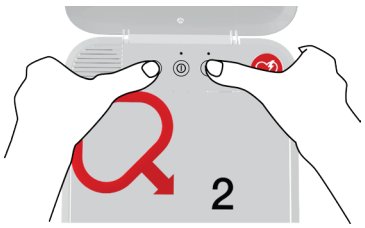
The updates you specified will be applied the next time the AED checks in to LIFELINKcentral AED Program Manager. The AED checks in automatically once each month.

If you want to apply the updates immediately, follow these steps.

1. Go to the AED.

2. Open the lid and ***wait*** until the voice prompts start.

3. ***Immediately*** press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously until you hear **DEVICE READY**.



4. You will hear either **WI-FI CONNECTION INITIATED** or **MOBILE CONNECTION INITIATED**, followed by **CONNECTION IN PROGRESS**.

   When you hear **CONNECTION ESTABLISHED**, the AED will update your LIFELINKcentral account with its current status and download the updates you specified.

   Note: Software updates may take up to 30 minutes. Do not turn off the AED during this time, unless it is needed for an emergency.

5. When the updates have finished downloading, the AED will reboot and then reconnect to your LIFELINKcentral account to complete the updates. You will hear **REBOOTING**, and the AED will reboot. The AED will be silent for 1-2 minutes while it performs a self-test. Then you will hear **WI-FI CONNECTION INITIATED** or **MOBILE CONNECTION INITIATED**.

   Note: The Readiness indicator will not flash until the updates are complete.

6. After the updates are complete, you will hear **POWERING OFF** and the Readiness indicator should begin flashing. If the Readiness indicator does not flash, contact Stryker Customer Support for assistance.

   Note: If the AED used a Wi-Fi connection to download the updates and also has cellular capability, it will test the cellular connection before it turns off.

7. Close the lid.

3. Verify Updates

You can verify whether updates were successful by checking your LIFELINKcentral account.

1. Log in to your account and go to **SITES**.
2. Click a site.
3. Select the **SOFTWARE AND SETUP OPTIONS** icon. If the status is **CURRENT**, the update was successful for all devices on this site. For additional information, click the Help icon in the upper right corner of the screen.

Updating Setup Options or Software with USB Connection

You will need a USB type 2.0 A Male to Micro-B. An appropriate USB cable is provided with the AED.

1. Specify Updates

Notes:

- This method can also be used on devices with wireless capability, if desired.
- Any updates you specify will be applied to all LIFEPAK CR2 devices at your site.

1. Log in to your LIFELINKcentral account using your logon credentials.
2. On the main menu, click **SITES**.
3. Click a site.
4. Select the **SOFTWARE AND SETUP OPTIONS** icon. This opens the Software and Setup Options view.
5. If a software profile shows a status of **UPDATE AVAILABLE:**
   a. Click the profile.
   b. Click the **AUTHORIZE SOFTWARE UPDATE** button to schedule your devices for the update

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c. Click the **AUTHORIZE CONFIRMATION** button on the pop-up menu.

6. To edit setup options:
   a. Select a profile from the Software and Setup Options view.
   b. Select the **EDIT SETUP OPTIONS** icon .
   c. Change setup options as desired.

   Note: For additional information, click the Help icon in the upper right corner of the screen.
7. Log out of your account.

2. Apply Updates to the AED

The updates you have specified must be loaded into the AED. To do this, you must use a computer with a program called LIFENET Device Agent installed. LIFENET Device Agent uses a USB connection between the AED and your computer to transfer information between the AED and your LIFELINKcentral account.

If you already have LIFENET Device Agent installed on your computer, open LIFENET Device Agent and skip to step 8 below. Otherwise, begin with step 1.

1. Log in to your account using the logon name and password from your "Welcome to LIFELINKcentral" email. If you did not receive this email, it may have been sent to another person in your organization. If you are unable to find the email, look up the appropriate web address for your country in the customer support contact list included with the device. Go to the website to create your account.

   Note: If you have already logged in to your account and changed your logon name and password, use those logon credentials instead.
2. Select **RESOURCE CENTER**.
3. Select **LIFENET Device Agent**.
4. Click the download icon in the upper right corner of the screen to download LIFENET Device Agent.
5. After LIFENET Device Agent has downloaded, double-click the **LDA.xxxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

   Note: If any security warnings appear, select the option to allow the file.
6. When the **INSTALLSHIELD WIZARD** appears, select your language and click **OK**.
7. When you see **INSTALLSHIELD WIZARD COMPLETED**, make sure the **START LIFENET DEVICE AGENT** checkbox is selected, and then click **FINISH**.
8. When LIFENET Device Agent opens, you will be prompted to enter your "LIFENET System" credentials. Enter the same logon name and password you use to log in to your LIFELINKcentral account.
9. After LIFENET Device Agent is installed and running, you will be instructed to connect the LIFEPAK CR2 defibrillator to the computer using the USB cable that was provided with the AED, or an appropriate equivalent.

10. Once the connection is established, the AED will download any updates you have specified in your LIFELINKcentral account. The AED will also update your account with information about current device status.
11. Continue to follow the instructions in LIFENET Device Agent until the updates are complete.
12. When you are finished, disconnect the USB cable from the AED and close LIFENET Device Agent.

3. Verify Updates

You can verify whether updates were successful by checking your LIFELINKcentral account.

1. Log in to your account and go to **SITES**.
2. Click a site.
3. Select the **SOFTWARE AND SETUP OPTIONS** icon. If the status is **CURRENT**, the updates were successful for all devices on this site. For additional information, click the Help icon in the upper right corner of the screen.

Troubleshooting Tips

This section explains problem conditions you may encounter with your LIFELINKcentral AED Program Manager connection.

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to establish USB connection to a computer with LIFENET Device Agent installed.	Incorrect cable type	• Use only a USB 2.0 A Male to Micro-B cable.
	USB cable not properly connected	• Ensure the USB cable is firmly inserted into the USB port on the device.
LIFELINKcentral AED Program Manager reports that the device has not checked in.	Wi-Fi network has changed (for example, the network password has changed)	• Use the Wi-Fi Configuration Tool to update the network settings in the device (see Connecting with Wi-Fi (on page 50)).
	Device has been moved to a location that does not have adequate Wi-Fi or cellular signal strength	• Verify the device is located in an area with good signal strength.

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
	Device has failed to initiate check-in	• Check the Readiness indicator. If it is not flashing, follow the instructions in Maintaining a State of Readiness (on page 77). • If you need assistance, contact Stryker Customer Support or your local authorized distributor. See the customer support contact list provided with the device for region-specific phone numbers, or visit stryker.com/emergencycare.

Chapter 6

LIFENET System

This chapter provides information about using LIFENET System to monitor device readiness, update setup options, and update software.

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Overview

You should have an online account on one of the following two websites:

- LIFELINKcentral AED Program Manager, or
- LIFENET System

Many health care organizations have existing LIFENET System accounts to manage their devices. If your organization has a LIFENET System account, follow the instructions in this chapter to manage your LIFEPAK CR2 AED (Automated External Defibrillator).

If your organization does not have a LIFENET System account, a LIFELINKcentral AED Program Manager account was set up for you when you ordered your LIFEPAK CR2 AED. Use the instructions in the preceding chapter to manage your AED using LIFELINKcentral AED Program Manager.

Note: LIFENET System is not available in all countries. If LIFENET System is not available in your country and you want to change setup options or install a software update, please contact your local Stryker representative or local authorized distributor for assistance.

Features

LIFENET System features may include the following, depending on your subscription type and service area.

- Monitoring defibrillator status.
- Sending email notifications when the battery or electrodes need to be replaced, including advance notifications 30 and 60 days before the expiration date.
- Sending email notifications when the defibrillator is turned on or when the electrode pads are applied to a patient. These notifications can also be sent to your organization's Emergency Response Team.
- Configuring setup options for the defibrillator.
- Installing software updates.
- Sending AED and patient data, such as heart rhythm, to emergency responders before they arrive at the scene.
- Sending AED and patient data reports to medical personnel or the receiving hospital.
- Instructing a lost defibrillator to send its approximate location and beep frequently. (This feature is only available on devices with cellular capability.)

Notes:

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- If your LIFEPAK CR2 defibrillator has a Wi-Fi connection to LIFENET System, incident information such as heart rhythm and shocks delivered may be transmitted to emergency responders during the cardiac arrest event. This information can help emergency responders prepare for arrival.
- If your LIFEPAK CR2 defibrillator has a Wi-Fi or cellular connection to LIFENET System, Stryker may collect system diagnostic information from your device. This information will be used to optimize device quality.

The LIFEPAK CR2 defibrillator can connect to LIFENET System using a Wi-Fi, cellular, or USB connection to the internet.

Note: The micro-USB port is to be used by authorized users only. The micro-USB port does not provide power and should not be connected to other devices, such as mobile phones or other USB connected products.

To determine whether your defibrillator has Wi-Fi or cellular capability, see About the LIFEPAK CR2 Defibrillator.

Logging in to Your Account

Before you attempt to connect your defibrillator to LIFENET System for the first time, you should confirm your account is active. Contact the LIFENET System account administrator at your facility for logon credentials, and log in to your LIFENET System account.

Setting Up Wi-Fi

The LIFEPAK CR2 defibrillator can be ordered with Wi-Fi capability, or both Wi-Fi and cellular capability. Stryker recommends that all LIFEPAK CR2 defibrillators with Wi-Fi capability be set up with a Wi-Fi network, even if the defibrillator also has cellular capability.

Your Wi-Fi network settings must be loaded into the defibrillator so it can connect to the Wi-Fi network. You will need the following:

- PC computer with Windows 7 or above operating system and an internet connection
- Administrator rights on the computer
- USB cable (provided with the AED). The USB cable must be USB type 2.0 A Male to Micro-B.

A typical Wi-Fi setup takes 10-20 minutes. To set up a Wi-Fi connection, follow these instructions.

1. Confirm that the intended location for the AED has a good connection to the Wi-Fi network. Test the signal strength of the Wi-Fi network at the intended AED location using a different Wi-Fi device such as a smartphone.
2. Identify the Wi-Fi network information you will need to connect the AED to the network. Most networks require a network name and security key. If you do not have this information, ask your IT department for assistance.
3. Log in to your LIFENET System account.
4. Download and install the Wi-Fi Configuration Tool to your computer.
   a. Pull down the **ASSETS** menu.
   b. Select **WI-FI CONFIGURATION TOOL APPLICATIONS**.
   c. Click **WI-FI CONFIGURATION TOOL (32 OR 64-BIT)** to download the Wi-Fi Configuration Tool.
   d. After the Wi-Fi Configuration Tool has downloaded, double-click the **WCT.xxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

      Note: If any security warnings appear, select the option to allow the file.
   e. When the **INSTALLSHIELD WIZARD** appears, select your language and click **NEXT**.
   f. When you see the **INSTALLSHIELD WIZARD COMPLETED** screen, make sure the **LAUNCH WI-FI CONFIGURATION TOOL** checkbox is selected, and then click **FINISH**.

      Notes:

      - Your computer may reboot during the installation process. If this happens, the installation should continue automatically.
      - The Wi-Fi Configuration Tool should launch automatically after installation. If you need to start the Wi-Fi Configuration Tool manually, open the **START** menu on your computer, open the **PHYSIO-CONTROL** folder, and click **WI-FI CONFIGURATION TOOL**.

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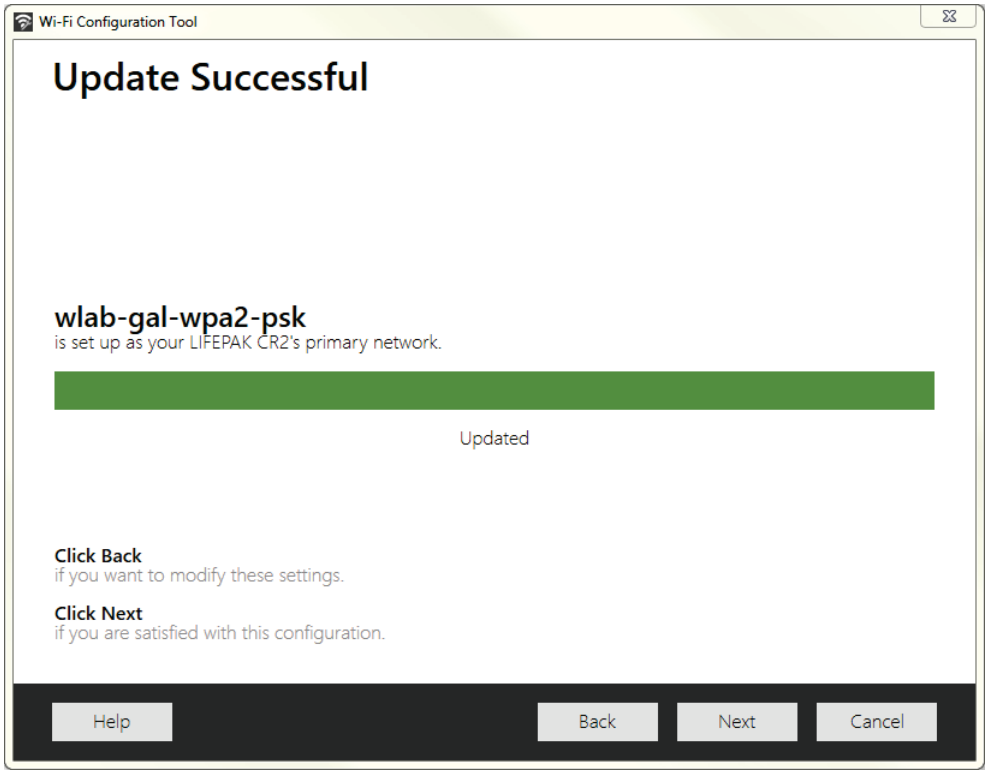
5. Follow the onscreen instructions in the Wi-Fi Configuration Tool. When you are prompted to connect the AED to your computer, use the USB cable provided with the AED or an appropriate equivalent (type 2.0 A Male to Micro-B).
6. Continue to follow all instructions and click **NEXT**.
7. When the Wi-Fi setup is complete, you will see the **UPDATE SUCCESSFUL** screen. Click **NEXT**.



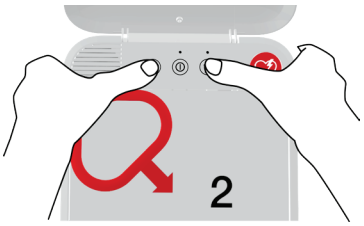
8. When you see **DISCONNECT LIFEPAK CR2**, disconnect the USB cable.
9. If you have another AED to set up, click **CONFIGURE ANOTHER LIFEPAK CR2**. Otherwise, click **CLOSE**.
10. Initiate a wireless connection to test the Wi-Fi settings and connection, as described in Initiating Wireless Connection (on page 65).

Initiating Wireless Connection

1. Take the AED to its intended location.

2. Open the lid and ***wait*** until the voice prompts start.

3. ***Immediately*** press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously until you hear **DEVICE READY**.



4. Immediately:
   - Close the lid
   - Place the AED in its permanent storage location (for example, cabinet or vehicle)
   - Close the door of the cabinet or vehicle

   The AED will attempt a Wi-Fi connection immediately after the **DEVICE READY** voice prompt, and it must be in its permanent location during this test.

5. If you hear **WI-FI CONNECTION INITIATED**, go to Connecting with Wi-Fi (on page 66).

   If you hear **MOBILE CONNECTION INITIATED**, go to Connecting with Cellular (on page 67).

Notes:

- The **DEVICE READY** voice prompt indicates whether the AED is ready for a cardiac emergency. It does **not** indicate whether wireless is ready.

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- If you hear **DEVICE NOT READY**, this means the AED is not ready for a cardiac emergency. Continue with the rest of the wireless setup. When you are finished, contact Stryker Customer Support for assistance.
- If you pressed both buttons but did not hear the **DEVICE READY** or **DEVICE NOT READY** voice prompts, you may need to try again. When you open the lid, you must ***wait*** until the voice prompts start before pressing the two buttons. After the voice prompts start, you must press the two buttons ***within 10 seconds***. If you miss these time limits, the AED proceeds as it would during a cardiac arrest. To try again, close and reopen the lid.

Connecting with Wi-Fi

1. Initiate the connection as described in Initiating Wireless Connection (on page 65).
2. Listen for the following voice prompts:
   - **WI-FI CONNECTION INITIATED**, followed by **CONNECTION IN PROGRESS**. There will be a pause while the AED connects.
   - **CONNECTION ESTABLISHED**. Once a Wi-Fi connection is established, the AED will update your online account with its current status. The AED beeps every few seconds during the update process.

3. When all updates are complete, you will hear **COMMUNICATION COMPLETE**.
   - If the AED does not have cellular capability, you will hear **POWERING OFF**. Go to Confirming AED Status Online (on page 69) to verify your LIFENET System account was successfully updated.
   - If the AED has cellular capability, it will immediately attempt a cellular connection. Go to Connecting with Cellular (on page 67).

Note: If you hear **UNABLE TO ESTABLISH WI-FI NETWORK CONNECTION,** this may mean that the signal strength at your location is not strong enough to connect the AED to the Wi-Fi network. After you hear **POWERING OFF**, move the AED installation closer to your Wi-Fi access point and try again. If you need assistance, contact Stryker Customer Support. See the customer support contact list included with the device for region-specific phone numbers.

Connecting with Cellular

If your AED has cellular capability, it will attempt a cellular connection immediately after the Wi-Fi connection attempt. This occurs whether or not the Wi-Fi connection was successful.

Note: If you have not set up a Wi-Fi configuration, the AED will proceed directly to the cellular connection when you initiate the connection process. If a wireless connection is not already in progress, go to Initiating Wireless Connection (on page 65) for instructions.

The AED should be in its permanent location (for example, cabinet or vehicle) during this test.

1. Listen for the following voice prompts:

   - **MOBILE CONNECTION INITIATED**, followed by **CONNECTION IN PROGRESS**. There will be a pause while the AED connects.

   - **CONNECTION ESTABLISHED**. Once a cellular connection is established, the AED will update your online account with its current status. The AED beeps every few seconds during the update process.

     Note: If your account was already updated during the Wi-Fi connection, the updates are not repeated.

2. When all updates are complete, you will hear **COMMUNICATION COMPLETE**, followed by **POWERING OFF**. Go to Confirming AED Status Online (on page 69) to verify your LIFENET System account was successfully updated.

Note: If you hear **UNABLE TO ESTABLISH MOBILE NETWORK CONNECTION,** this may mean that the signal strength at your location is not strong enough to connect the AED to the cellular network. If possible, move the AED installation and try again. If you need assistance, contact Stryker Customer Support. See the customer support contact list included with the device for region-specific phone numbers.

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Connecting with USB

If you need to connect to your LIFENET System account without using Wi-Fi or cellular, you can use the USB connector. The USB cable must be USB type 2.0 A Male to Micro-B. An appropriate USB cable is provided with the defibrillator.

Note: For LIFEPAK CR2 defibrillators with Wi-Fi capability, the USB connection is also used to load your Wi-Fi network settings into the AED. See Setting Up Wi-Fi (on page 63) for more information.

To connect to LIFENET System using the USB connection, you must have a PC computer that has an internet connection. You will need to install a program called LIFENET Device Agent on your computer. You will use LIFENET Device Agent to transfer information between the AED and your LIFENET System account.

To install LIFENET Device Agent on your computer, follow these instructions.

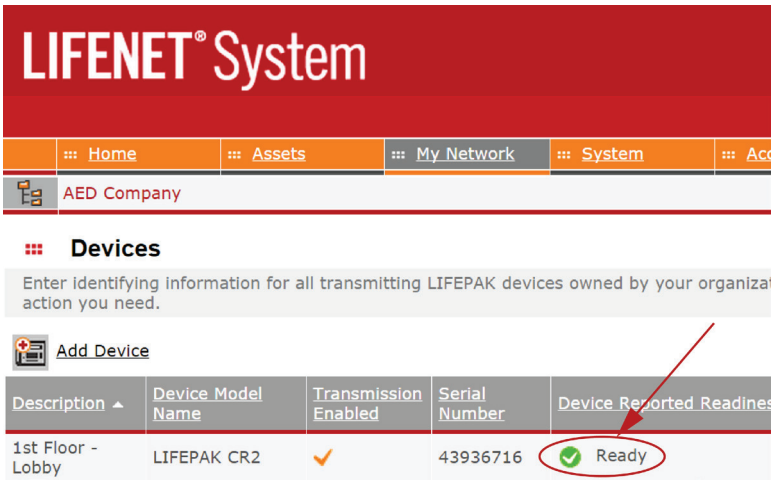
1. Log in to your LIFENET System account using your logon credentials.
2. Pull down the **ASSETS** menu.
3. Select **DEVICE AGENT APPLICATIONS**.
4. Select **ADD OR UPDATE DEVICE AGENT**.
5. Click the link to download LIFENET Device Agent to your computer.
6. After LIFENET Device Agent has downloaded, double-click the **LDA.xxxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

   Note: If any security warnings appear, select the option to allow the file.
7. When the **INSTALLSHIELD WIZARD** appears, select your language and click **OK**.
8. When you see **INSTALLSHIELD WIZARD COMPLETED**, make sure the **START LIFENET DEVICE AGENT** checkbox is selected, and then click **FINISH**.
9. When LIFENET Device Agent opens, you will be prompted to enter your LIFENET System credentials. Enter the same logon name and password you use to log in to your LIFENET System account.
10. Once the connection is established, the AED will update your LIFENET System account with information about current device status. The AED will also download any updates you have specified in your account.
11. When you are finished, disconnect the USB cable from the AED and close LIFENET Device Agent.
12. Continue with Confirming AED Status Online to verify your LIFENET System account was successfully updated.

Confirming AED Status Online

To confirm that the AED successfully updated its status in your LIFENET System account, log in to your account and check the AED status as described below. If the status is not **READY**, contact your local Stryker representative or local authorized distributor for assistance.

1. Log in to your LIFENET System account.
2. Pull down the **MY NETWORK** tab.
3. Go to the **DEVICES** page and verify that the status of your device says **READY**.



Updating Setup Options and Software

Descriptions of available setup options are provided in Setup Options (on page 107).

To update setup options or software using a wireless connection, follow the instructions below.

To update setup options or software using a USB connection, see Updating Setup Options or Software with USB Connection (on page 71).

Updating Setup Options or Software with Wireless Connection

1. Specify Updates

1. Log in to your LIFENET System account using your logon credentials.
2. Pull down the **ASSETS** menu.
3. Select **DEVICE SOFTWARE AND SETUP OPTIONS**.

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4. Select **CREATE SETUP OPTIONS**.
   a. In the **SETUP OPTIONS PROFILE NAME** field, enter a descriptive name for the profile you are creating.
   b. In the **DEVICE MODEL** field, select **LIFEPAK CR2**.
   c. In the **SOFTWARE VERSION** field, select the latest release.
   d. Select the set of setup options you want to start with:
      - Import from the settings in a current LIFEPAK CR2 device
      - Import from an existing profile in LIFENET System
      - Use default settings
   e. Click **CREATE**.
   f. Review the setup options and edit as desired.
   g. When you are finished, click **SAVE**.
5. On the **DEVICE SOFTWARE AND SETUP OPTIONS** page, locate your newly created profile within the list of setup options profiles and select the **ASSIGN SETUP OPTIONS TO YOUR DEVICES** button.
6. On the **ASSIGN SETUP OPTIONS TO DEVICES** page, select the checkbox next to each device you want to update with your newly created profile.
7. When you are finished, click **SAVE**.
8. Go to the **ASSETS** dropdown menu and select **ASSETS**.
9. Set the **VIEW ASSETS BY** dropdown list to **DEVICE SOFTWARE CONFIGURATION**. The synchronization state will show which devices need to be updated.
10. Log out of your account.

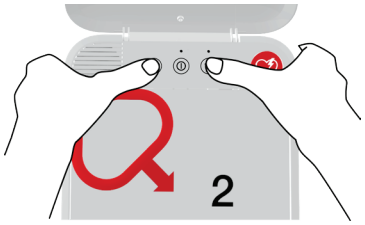
2. Apply Updates to the AED

The updates you specified will be applied the next time the AED checks in to LIFENET System. The AED checks in automatically once each month.

If you want to apply the updates immediately, follow these steps.

1. Go to the AED.
2. Open the lid and ***wait*** until the voice prompts start.

3. ***Immediately*** press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously until you hear **DEVICE READY**.



4. You will hear either **WI-FI CONNECTION INITIATED** or **MOBILE CONNECTION INITIATED**, followed by **CONNECTION IN PROGRESS**.

   When you hear **CONNECTION ESTABLISHED**, the AED will update your LIFENET System account with its current status and download the updates you specified.

   Note: Software updates may take up to 30 minutes. Do not turn off the AED during this time, unless it is needed for an emergency.

5. When the updates have finished downloading, the AED will reboot and then reconnect to your LIFENET System account to complete the updates. You will hear **REBOOTING**, and the AED will reboot. The AED will be silent for 1-2 minutes while it performs a self-test. Then you will hear **WI-FI CONNECTION INITIATED** or **MOBILE CONNECTION INITIATED**.

   Note: The Readiness indicator will not flash until the updates are complete.

6. After the updates are complete, you will hear **POWERING OFF** and the Readiness indicator should begin flashing. If the Readiness indicator does not flash, contact Stryker Customer Support for assistance.

   Note: If the AED used a Wi-Fi connection to download the updates and also has cellular capability, it will test the cellular connection before it turns off.

7. Close the lid.

3. Verify Updates

You can verify whether updates were successful by checking your LIFENET System account.

1. Log in to your account.
2. Go to the **ASSETS** page.
3. Set the view to **DEVICE SOFTWARE CONFIGURATION**. If the state is **SYNCHRONIZED**, the update was successful.

Updating Setup Options or Software with USB Connection

You will need a USB type 2.0 A Male to Micro-B. An appropriate USB cable is provided with the AED.

1. Specify Updates

Note: This method can also be used on devices with wireless capability, if desired.

1. Log in to your LIFENET System account using your logon credentials.

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2. Pull down the **ASSETS** menu.
3. Select **DEVICE SOFTWARE AND SETUP OPTIONS**.
4. Select **CREATE SETUP OPTIONS**.
   a. In the **SETUP OPTIONS PROFILE NAME** field, enter a descriptive name for the profile you are creating.
   b. In the **DEVICE MODEL** field, select **LIFEPAK CR2**.
   c. In the **SOFTWARE VERSION** field, select the latest release.
   d. Select the set of setup options you want to start with:
      - Import from the settings in a current LIFEPAK CR2 device
      - Import from an existing profile in LIFENET System
      - Use default settings
   e. Click **CREATE**.
   f. Review the setup options and edit as desired.
   g. When you are finished, click **SAVE**.
5. On the **DEVICE SOFTWARE AND SETUP OPTIONS** page, locate your newly created profile within the list of setup options profiles and select the **ASSIGN SETUP OPTIONS TO YOUR DEVICES** button.
6. On the **ASSIGN SETUP OPTIONS TO DEVICES** page, select the checkbox next to each device you want to update with your newly created profile.
7. When you are finished, click **SAVE**.
8. Go to the **ASSETS** dropdown menu and select **ASSETS**.
9. Set the **VIEW ASSETS BY** dropdown list to **DEVICE SOFTWARE CONFIGURATION**. The synchronization state will show which devices need to be updated.
10. Log out of your account.

2. Apply Updates to the AED

The updates you have specified must be loaded into the AED. To do this, you must use a computer with a program called LIFENET Device Agent installed. LIFENET Device Agent uses a USB connection between the AED and your computer to transfer information between the AED and your LIFENET System account.

If you already have LIFENET Device Agent installed on your computer, open LIFENET Device Agent and skip to step 9 below. Otherwise, begin with step 1.

1. Log in to your LIFENET System account using your logon credentials.
2. Pull down the **ASSETS** menu.
3. Select **DEVICE AGENT APPLICATIONS**.
4. Select **ADD OR UPDATE DEVICE AGENT**.
5. Click the link to download LIFENET Device Agent to your computer.

6. After LIFENET Device Agent has downloaded, double-click the **LDA.xxxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

   Note: If any security warnings appear, select the option to allow the file.

7. When the **INSTALLSHIELD WIZARD** appears, select your language and click **OK**.
8. When you see **INSTALLSHIELD WIZARD COMPLETED**, make sure the **START LIFENET DEVICE AGENT** checkbox is selected, and then click **FINISH**.
9. When LIFENET Device Agent opens, you will be prompted to enter your LIFENET System credentials. Enter the same logon name and password you use to log in to your LIFENET System account.
10. After LIFENET Device Agent is installed and running, you will be instructed to connect the LIFEPAK CR2 defibrillator to the computer using the USB cable that was provided with the AED, or an appropriate equivalent.
11. Once the connection is established, the AED will download any updates you have specified in your account. The AED will also update your account with information about current device status.
12. Continue to follow the instructions in LIFENET Device Agent until the updates are complete.
13. When you are finished, disconnect the USB cable from the AED and close LIFENET Device Agent.

3. Verify Updates

You can verify whether updates were successful by checking your LIFENET System account.

1. Log in to your account.
2. Go to the **ASSETS** page.
3. Set the view to **DEVICE SOFTWARE CONFIGURATION**. If the state is **SYNCHRONIZED**, the update was successful.

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Troubleshooting Tips

This section explains problem conditions you may encounter with your LIFENET System connection.

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to establish USB connection to a computer with LIFENET Device Agent installed.	Incorrect cable type	• Use only a USB 2.0 A Male to Micro-B cable.
	USB cable not properly connected	• Ensure the USB cable is firmly inserted into the USB port on the device.
LIFENET System reports that the device has not checked in.	Wi-Fi network has changed (for example, the network password has changed)	• Use the Wi-Fi Configuration Tool to update the network settings in the device (see Connecting with Wi-Fi (on page 66)).
	Device has been moved to a location that does not have adequate Wi-Fi or cellular signal strength	• Verify the device is located in an area with good signal strength.
	Device has failed to initiate check-in	• Check the Readiness indicator. If it is not flashing, follow the instructions in Maintaining a State of Readiness (on page 77). • If you need assistance, contact Stryker Customer Support or your local authorized distributor. See the customer support contact list provided with the device for region-specific phone numbers, or visit stryker.com/emergencycare.

Chapter 7

Caring for the Defibrillator

This chapter explains how to keep your defibrillator in good working condition. Cared for properly, your defibrillator is built to give you many years of service.

Maintaining a State of Readiness 77
Replacing the Electrodes 79
Maintaining the Battery 81
Storing the Defibrillator 82
Cleaning the Defibrillator 82
Obtaining Authorized Service 83
Service Life 83
Recycling Information 83
Accessories, Supplies, and Training Tools 84
Warranty Information 84

Maintaining a State of Readiness

Device readiness should be verified at least once each month. If your device has wireless access to LIFELINKcentral AED Program Manager or LIFENET System, you can verify the device status remotely. If your device does not have wireless access, you must check the Readiness indicator on the device.

Note for Germany and Austria: LIFEPAK CR2 defibrillator, Exclusion of periodic safety checks (§6 MPBetreibV).

The implementation of recurring safety inspections (STK) on medical devices in Germany and Austria is governed in paragraph 6 of the medical devices operator ordinance (MPBetreibV). **Stryker does not recommend the STK for the LIFEPAK CR2 defibrillator (§6 MPBetreibV – part 1).**

Verifying Readiness for Devices with Wireless Access

The device performs automatic self-tests daily, weekly, monthly, and every time you turn it on. If the automatic self-tests are successful, the device checks in to LIFELINKcentral AED Program Manager or LIFENET System once each month and reports that it is **READY**.

Note: If your device is wirelessly connected to a LIFELINKcentral AED Program Manager or LIFENET System account and the device fails to check in at least once each month, an email notification is sent to your organization's account administrator.

If an automatic self-test detects a condition that requires attention, the device immediately reports the issue to LIFELINKcentral AED Program Manager or LIFENET System and an email notification is sent to your organization's designated person. The email describes which of the following actions you need to perform:

- Replace electrode tray
- Replace battery
- Contact qualified service personnel

Warning

Possible Loss of Power During Patient Care. Replace the battery immediately when the defibrillator indicates the battery is low.

Verifying Readiness for Devices without Wireless Access

If the device does not have wireless capability or is unable to automatically connect to LIFELINKcentral AED Program Manager or LIFENET System (for example, if no internet connection is available where the device is located), you should check the Readiness indicator on the device at least once each month. If the device is not ready, the Readiness indicator does not flash and an alert tone sounds every 15 minutes.

Note: The alert tone option can be turned off. See Setup Options (on page 107) for more information.

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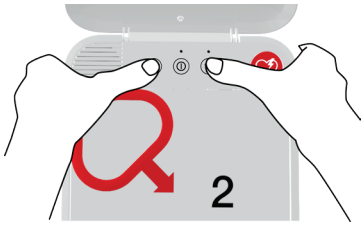
If the device is not ready, perform one of the following two actions.

- If possible, use the USB cable, Wi-Fi, or cellular to connect to LIFELINKcentral AED Program Manager or LIFENET System. Follow the onscreen instructions to diagnose the problem. For information about connecting, see LIFELINKcentral AED Program Manager (on page 43) or LIFENET System (on page 59).
- If you are unable to connect the defibrillator to LIFELINKcentral AED Program Manager or LIFENET System, use the following steps to determine why the Readiness indicator is not flashing.

1. Open the lid and ***wait*** until the voice prompts start.

2. ***Immediately*** press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously until you hear either **DEVICE READY** or **DEVICE NOT READY**.



3. The defibrillator will then provide voice instructions that tell you which of the following actions you need to perform:
    - Replace electrode tray
    - Replace battery
    - Contact qualified service personnel

Note: If you pressed both buttons but did not hear the **DEVICE READY** or **DEVICE NOT READY** voice prompts, you may need to try again. When you open the lid, you must ***wait*** until the voice prompts start before pressing the two buttons. After the voice prompts start, you must press the two buttons ***within 10 seconds***. If you miss these time limits, the AED proceeds as it would during a cardiac arrest. To try again, close and reopen the lid.

Warning

Possible Loss of Power During Patient Care. Replace the battery immediately when the defibrillator indicates the battery is low.

Replacing the Electrodes

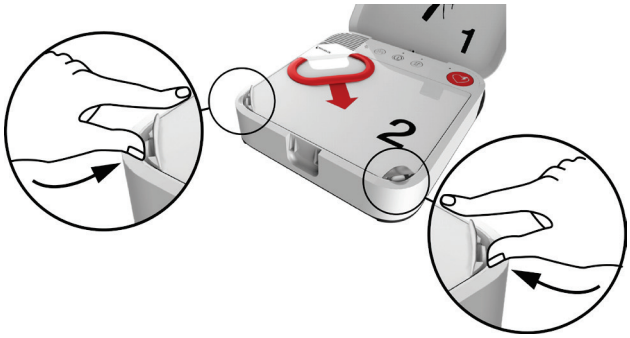
The QUIK-STEP pacing/ECG/defibrillation electrodes are packaged in a convenient tray that snaps in and out of the defibrillator.

The electrode tray must be replaced if any of the following occur:

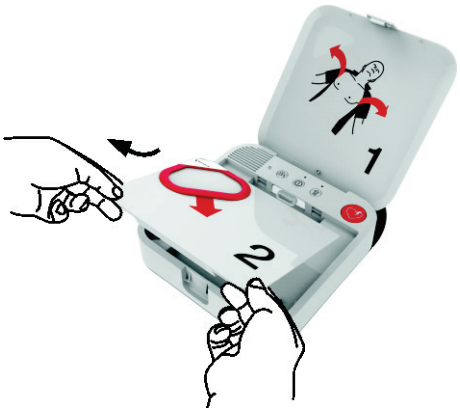
- The seal on the tray is broken
- The electrodes are used
- The Use By date (shown next to the hourglass symbol) has passed

Follow these steps to replace the electrode tray.

REMOVE OLD ELECTRODE TRAY:

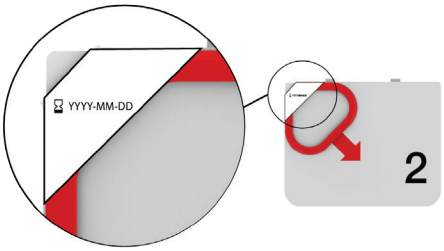


1 Press the clips on the front corners of the electrode tray and lift up.



2 Pull the electrode tray up and out of the defibrillator.

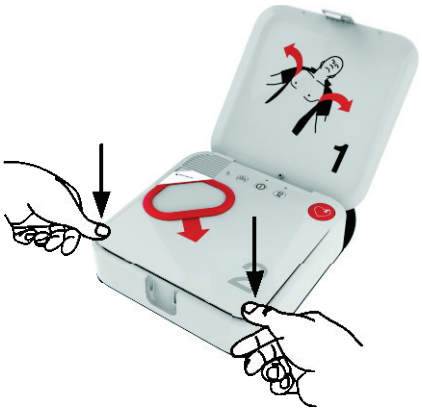
INSPECT NEW ELECTRODE TRAY:



3 Inspect the new electrode tray to ensure the seal is not broken and the Use By date has not passed.

INSTALL NEW ELECTRODE TRAY:

4 Insert the new electrode tray into the defibrillator as shown.



5 Press down on the front corners of the electrode tray until it clicks into place.

IMPORTANT! When you insert the new tray, be careful to press only on the corners of the tray where the foil is supported. Pressing on the center of the tray may damage the seal and cause the electrodes to dry out.

6 Dispose of the old electrode tray as described in Recycling Information.

Warning

Possible Skin Burns and Ineffective Energy Delivery. Electrode pads that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not pull the red handle to open the electrodes until immediately before use. Do not reuse electrodes.

Maintaining the Battery

The LIFEPAK CR2 defibrillator is powered by the LIFEPAK CR2 nonrechargeable lithium manganese dioxide battery.

Follow the guidelines described in this section to help maximize battery life and performance. Use only LIFEPAK CR2 batteries designed for use with the LIFEPAK CR2 defibrillator. Do not use any other batteries.

If the Readiness indicator is not flashing, the battery may be low. For information about determining whether the battery is low, see Maintaining a State of Readiness (on page 77).

Warnings

- Possible Loss of Power During Patient Care. Replace the battery immediately when the defibrillator indicates the battery is low.
- Safety Risk and Possible Equipment Damage. Damaged batteries may leak and cause personal injury or equipment damage. Handle damaged or leaking batteries with extreme care. Do not carry a battery where metal objects (such as car keys or paper clips) could short-circuit the battery terminals. The resulting excessive current flow can cause extremely high temperatures and may result in damage to the battery, or cause fire or burns.

The LIFEPAK CR2 lithium battery never requires recharging. A new battery can provide approximately 800 minutes of "ON" time **or** 166 discharges at 200 joules.

Battery capacity decreases while the battery is in the defibrillator because of the battery's normal self-discharge rate and the energy used by the defibrillator auto tests. If a new battery is installed in the defibrillator and the defibrillator is not used, the useful life of the battery is 4 years.

The date of manufacture is printed on the battery label in YYYY-MM-DD format. The battery must be installed within 1 year of this date to attain a 4-year service life. The maximum service life for the battery is the expiration date shown on the label (5 years after the date of manufacture) or 4 years after the date installed in the defibrillator, whichever occurs first.

To properly maintain nonrechargeable batteries:

- Do not attempt to recharge.
- Do not allow electrical connection between the battery contacts.
- Use and store batteries at temperatures specified in Appendix A.

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Warning

Possible Explosion, Fire, or Noxious Gas. Attempting to recharge a nonrechargeable battery can cause an explosion, fire, or release of noxious gas. Dispose of expired or depleted nonrechargeable batteries as described in Recycling Information.

Storing the Defibrillator

Always store the defibrillator within the recommended temperature range of 15° to 35°C (59° to 95°F).

Note: Long-term storage at the higher temperatures in this range will shorten the life of the battery and electrodes.

Warning

Possible Fire or Explosion. Do not store this defibrillator in the presence of flammable gases or in direct contact with flammable material.

Cleaning the Defibrillator

Clean the defibrillator after use and as needed with a damp sponge or cloth. Use only the cleaning agents listed below:

- Nonabrasive soap and water
- Quaternary ammonium compounds
- Rubbing (isopropyl) alcohol
- Peracetic (peroxide) acid solutions

Caution

Possible Equipment Damage. Do not clean any part of this device or its accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this device or any accessories unless otherwise specified in accessory operating instructions.

Clean the carrying case with a damp cloth or sponge. A scrub brush may be useful for heavily soiled spots. Mild soap or degreasing cleansers may helpful for tough stains.

Obtaining Authorized Service

If the defibrillator requires service, contact Stryker Customer Support or your local authorized distributor. See the customer support contact list provided with the defibrillator for region-specific phone numbers. Be prepared to identify the model and serial number when you call. To find the serial number, remove the battery. The serial number label is in the battery compartment.

Note: If you receive a readiness notification from LIFELINKcentral AED Program Manager or LIFENET System, follow the instructions provided.

Warning

Shock Hazard. Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

Service Life

The expected service life of the LIFEPAK CR2 defibrillator is 8 years.

Recycling Information

Recycle the device and accessories at the end of their useful life according to national and local regulations. Do not dispose of this product in the unsorted municipal waste stream. For more information on the disposal and recycling of the device and accessories contact your local Stryker representative or refer to stryker.com/ec-recycling.

For information regarding EU REACH Substances of Very High Concern (SVHC) and China RoHS hazardous substances in the device and accessories, see stryker.com/ec-recycling.

Preparation

The device should be clean and contaminant-free prior to being recycled.

Recycling of Disposable Electrodes

After using disposable electrodes, follow your local clinical procedures for recycling.

Packaging

Packaging should be recycled according to national and local regulations.

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Accessories, Supplies, and Training Tools

The following table lists accessories, supplies, and training tools that are available for the device. To order, contact your Stryker representative or your local authorized distributor.

DESCRIPTION	CATALOG NUMBER
QUIK-STEP pacing/ECG/defibrillation electrodes	11101-000021
LIFEPAK CR2 lithium battery	11141-000165
Emergency Response kit	11996-000454
LIFEPAK CR2 carry case	11260-000047
LIFEPAK CR2 device handle	11512-000002
USB cable	21300-008143
LIFEPAK CR2 Trainer	11250-000162
LIFEPAK CR2 Trainer carry case	11260-000048

Warranty Information

To obtain a detailed warranty statement, contact your local Stryker representative or visit stryker.com/emergencycare.

Note: If the tamper-proof label shown below is broken or missing, the warranty may be void.

Appendix A

Specifications

This appendix contains the specifications and performance characteristics for the LIFEPAK CR2 defibrillator and batteries.

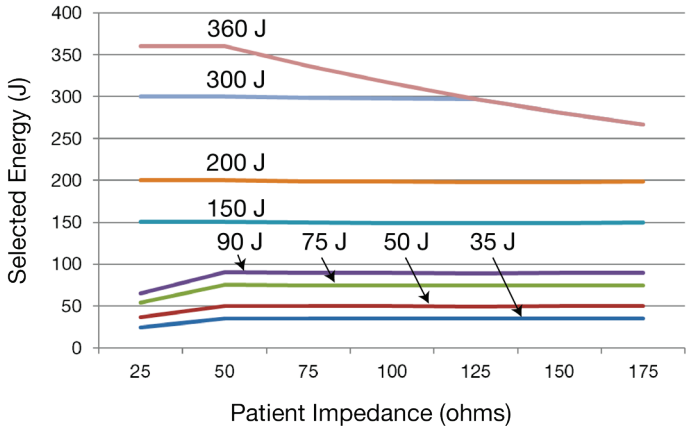
Specifications

All specifications are at 20°C (68°F) unless otherwise stated.

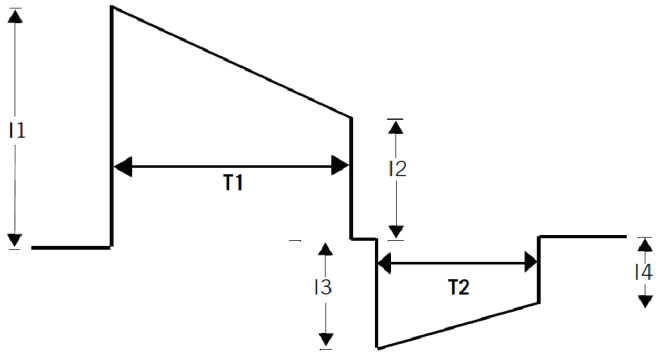
CHARACTERISTIC	DESCRIPTION
General	
Classification	Internally powered equipment per IEC 60601-1.
Electrical Protection	Applied parts - Electrodes are defibrillation-protected, type BF patient connection per IEC 60601-1.
Self-test	When powered on, the device performs a self-test to check internal electrical components and circuitry. The Readiness indicator stops flashing if an error is detected. The device also performs automatic self-tests daily, weekly, and monthly.
Defibrillator	
Waveform	Biphasic Truncated Exponential with voltage and duration compensation for patient impedance.
Patient Impedance Range	10 to 300 ohms. If the detected impedance is outside this range, the user is prompted to check the electrode pads and connector. The device will not deliver a shock if impedance is outside this range.
Output Energy	Configurable energy levels for Shock 1, Shock 2, and Shock 3 or greater. Adult mode: 150, 200, 300, or 360 joules. Child mode: 35, 50, 75, or 90 joules.
Output Energy Accuracy	10% of the energy setting into 50 ohms. 15% of the rated energy output into 25–175 ohms.

Rated Energy Output

Rated energy output is the nominal delivered energy based on the energy setting and patient impedance, as defined in the following chart.



Waveform Shape and Measured Parameters



Biphasic waveform at 200 joules, nominal

PATIENT IMPEDANCE (Ω)	I1 (A)	I2 (A)	I3 (A)	I4 (A)	T1 (MS)	T2 (MS)
25	58.1	21.0	20.9	10.6	5.0	3.3
50	30.0	14.8	14.8	9.2	6.9	4.6
75	20.7	11.8	11.8	8.1	8.3	5.5
100	16.0	9.9	9.9	7.3	9.3	6.2
125	13.2	8.7	8.7	6.6	10.1	6.7
150	11.3	7.8	7.8	6.1	10.8	7.2
175	9.9	7.1	7.1	5.7	11.4	7.6

Biphasic waveform at 90 joules, nominal

PATIENT IMPEDANCE (Ω)	I1 (A)	I2 (A)	I3 (A)	I4 (A)	T1 (MS)	T2 (MS)
25	33.1	12.0	11.9	6.1	5.0	3.3
50	20.1	9.9	9.9	6.2	6.9	4.6
75	13.9	7.9	7.9	5.4	8.3	5.5
100	10.7	6.7	6.7	4.9	9.3	6.2
125	8.8	5.8	5.8	4.4	10.1	6.7
150	7.6	5.2	5.2	4.1	10.8	7.2
175	6.7	4.8	4.8	3.8	11.4	7.6

Shock Advisory System	ECG analysis system used by this device. The Shock Advisory System determines whether a shock is appropriate. **Note:** The fully automatic device cannot cancel delivery of a shock after the Shock Advisory System determines a shock is advised. The semi-automatic device cancels the shock if the **SHOCK** button is not pressed within 15 seconds.

cprINSIGHT Analysis Technology	Additional ECG analysis system that is designed to analyze the ECG rhythm while CPR is being performed. The cprINSIGHT Analysis Technology can be set to be **ON** or **OFF**. When this feature is turned on, the voice prompts change so the user is instructed to continue CPR during analysis. **Note:** cprINSIGHT Analysis Technology is only available in LIFEPAK CR2 defibrillators with Wi-Fi or cellular capability. To determine whether the device has Wi-Fi or cellular capability, check the serial number label located in the battery compartment on the back of the device. See About the LIFEPAK CR2 Defibrillator for details.
Device Capacity	With new battery: Provides 166 200-joule shocks (with 1 minute of CPR between shocks), 103 360-joule shocks (with 1 minute of CPR between shocks), or 800 minutes of operating time. When device has just reached a low battery state (Readiness indicator has stopped flashing): Provides 6 360-joule shocks and 30 minutes of operating time.
Shock Ready Time	**Note:** These times apply for a device that has just reached a low battery state (Readiness indicator has stopped flashing). Fully automatic device: The time to charge to 360 joules after electrode pads are applied is 35 seconds or less. The time to charge to 360 joules after power is turned on is 45 seconds or less, if electrode pads are on the patient when device is turned on. Semi-automatic device: The time to charge to 360 joules after electrode pads are applied is 35 seconds or less. The time to charge to 360 joules after power is turned on is 45 seconds or less, if electrode pads are on the patient when device is turned on.
cprCOACH Feedback Technology	
Metronome rate	104 beats per minute
Setup options	Two options are available for CPR coaching: • Hands-Only (no rescue breaths) • 30:2 compression to breath ratio
Communications	USB, Wireless 802.11 b/g/n, or Cellular data transfer to LIFELINKcentral AED Program Manager or LIFENET System. USB cable type 2.0 A Male to Micro-B is required for USB communications.

Environmental	**Note:** All performance specifications defined assume that the device has been stored (two hours minimum) at the operating temperature prior to operation.
Operating Temperature	0° to 50°C (32° to 122°F)
Long-term Storage Temperature (except battery and electrodes)	15° to 35°C (59° to 95°F)
Short-term Storage Temperature	-30° to 60°C (-22° to 140°F) for a maximum of 1 week
Altitude	-382 to 4572 meters (-1253 to 15,000 feet) above sea level
Relative Humidity	5 to 95% (non-condensing)
Liquid and Solid Ingress	IP55 per IEC 60529
Physical (with handle)	
Height	9.7 cm (3.8 in)
Width	22.6 cm (8.9 in)
Depth	27.4 cm (10.8 in)
Weight	2.0 kg (4.5 lb) including electrodes and battery
Battery	
Type	Lithium Manganese Dioxide (Li/MnO_2), 12.0 V, 4.7 Ah, 55.8 Wh
Service Life	4 years if installed in device that is not used
Weight	0.3 kg (0.7 lb)
Operating Temperature	0° to 50°C (32° to 122°F)
Long-term Storage Temperature	0° to 25°C (32° to 77°F)
Short-term Storage Temperature	-30° to 60°C (-22° to 140°F) for up to 1 week
Relative Humidity	5 to 95% non-condensing
QUIK-STEP Electrodes	
Pads	Pacing/ECG/defibrillation electrodes
Packaging	Pre-connected tray with rapid-release cover
Service Life	4 years[1]
Electrode Shape	Oval-rectangular
Electrode Size	13.34 x 8.89 cm (5.25 x 3.50 in)
Lead Wire	1.1 m (42 in)
Conductive Gel Contact Area	80 cm^2 (12.4 in^2)
Maximum Adhesion Time	4 hours
Maximum ECG Monitoring Time	4 hours
Maximum Number of Defibrillation Shocks	20 at 360 joules

QUIK-STEP Electrodes	
Maximum Pacing Duration	1 hour
Operating Temperature	0° to 50°C (32° to 122°F)
Long-Term Storage Temperature	15° to 25°C (59° to 77°F)
Short-Term Storage Temperature	-30° to 60°C (-22° to 140°F) for up to 1 week
Altitude	-382 to 4572 meters (-1253 to 15,000 feet) above sea level

[1] The maximum shelf life for the electrode is 5 years after the date of manufacture. The electrode must be installed within 1 year of this date to attain a 4-year service life. The date of manufacturer is printed on the electrode label in YYYY-MM-DD format.

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Appendix B

Defibrillation Clinical Summaries

This appendix contains the defibrillation clinical summaries and potential adverse effects.

Clinical Summary: Monophasic vs. Biphasic Waveforms: In-Hospital Trial

Background

This prospective, double-blinded, randomized clinical trial[1] compared the first shock efficacies of Physio-Control ADAPTIV 200 J biphasic truncated exponential (BTE) waveform, 130 J BTE and 200 J monophasic damped sine shocks (MDS) in the electrophysiology lab, delivered from modified LIFEPAK 7 defibrillators (an early defibrillator cleared under 510(k) K810154, but modified to have the same BTE waveform as the LIFEPAK CR2 defibrillator.

Methods

VF was induced in 154 patients. After 19±10 seconds of VF, a randomized transthoracic shock was administered. Mean first shock success rate for the three (3) groups were compared.

Results

First shock VF termination rates were 61/68 (90%) for the 200 J monophasic, 39/39 (100%) for the 200 J biphasic, and 39/47 (83%) for the 130 J biphasic shocks.

Conclusion

The 200 J biphasic shocks were superior in first-shock efficacy to both 200 J MDS shocks and 130 J BTE shocks. There were no significant differences in hemodynamic parameters between the three (3) groups after successful shocks. The 200 J biphasic shocks were more effective than monophasic and the 130 J BTE shocks and may allow earlier termination of VF in cardiac arrest patients.

1 Higgins SL, Herre JM, Epstein AE, Greer, SG, Freidman PL, Gleva ML, Porterfield JG, Chapman FW, Finkel ES, Schmitt PW, Nova RC, Greene HL. A Comparison of Biphasic and Monophasic Shocks for External Defibrillation. Prehospital Emergency Care 2000;4(4):305-313

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Clinical Summary: Monophasic vs. Biphasic Waveforms: Out-of-Hospital Trial

Background

In a publication by Van Alem et al., the authors noted "Evidence suggests that biphasic waveforms are more effective than monophasic waveforms for defibrillation in out-of-hospital cardiac arrest (OHCA), yet their performance has only been compared in un-blinded studies."[1] The authors subsequently conducted and reported on a randomized clinical trial comparing the effectiveness of the LIFEPAK 500 defibrillation waveform (monophasic versus biphasic). Specifically, the success of biphasic truncated exponential (BTE) and monophasic damped sine wave (MDS) shocks for defibrillation were compared in a prospective, randomized, double-blinded clinical trial of out-of-hospital (OOH) cardiac arrest patients.

Note: The identical ECG analysis Shock Advisory System and BTE (ADAPTIV biphasic waveform) used in the LIFEPAK 500 AED is also used in the LIFEPAK CR2 defibrillator.

1 Van Alem AP, Chapman FW, Lank P, Hart AAM, Koster RW. A prospective, randomised and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest. Resuscitation 2003;58(1):17-24.

Methods

First responders were equipped with either a Physio-Control LIFEPAK 500 MDS or BTE (ADAPTIV biphasic waveform) AED in a random fashion. Patients in VF received BTE or MDS first shocks of 200 J. The ECG was recorded for subsequent analysis continuously. The success of the first shock as a primary endpoint was removal of VF and required a return of an organized rhythm for at least two (2) QRS complexes, with an interval of <5 seconds, within 1 minute after the first shock. The secondary endpoint was termination of VF at 5 seconds.

Results

VF was the initial recorded rhythm in 120 patients in OHCA, 51 patients received BTE and 69 received MDS shocks. The median time from collapse to first shock was 9 minutes for the monophasic shock and 11 minutes for the BTE. The success rate of 200 J first shocks was significantly higher for BTE than for MDS shocks, 35/51 (69%) and 31/69 (45%), p=0.01. Termination of VF at 5 seconds after the first shock was 91% for the monophasic shock and 98% for BTE waveform. Return of spontaneous circulation was 61% for the Physio-Control defibrillation shock.

In a logistic regression model, the odds ratio of success for a BTE shock was 4.01 (95% CI 1.01-10.0), adjusted for baseline cardiopulmonary resuscitation, VF-amplitude and time between collapse and first shock. No difference was found with respect to the secondary endpoint, termination of VF at 5 seconds (RR 1.07 95% CI: 0.99-1.11) and with respect to survival to hospital discharge (RR 0.73 95% CI:0.31-1.70).

Conclusion

The authors concluded that BTE-waveform AEDs provide significantly higher rates of successful defibrillation with return of an organized rhythm in OHCA than MDS waveform AEDs. This supports the safety and effectiveness of the LIFEPAK CR2 defibrillator.

Clinical Summary: Pediatric Defibrillation - Animal Study

Background

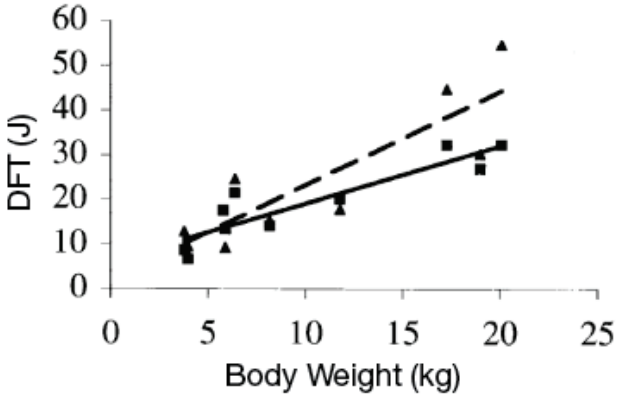
An experimental study by C. Killingsworth titled, “Defibrillation threshold and cardiac responses using an external biphasic defibrillator with pediatric and adult adhesive patches in pediatric-sized piglets”[3] provides evidence on safety and effectiveness of the therapy used in child mode.

Methods

The LIFEPAK CR2 defibrillator delivers the same waveform when treating adults and children, although the amplitude of the pulses reflects the lower energy settings. The Killingsworth article describes testing with shocks generated by the LIFEPAK 12 defibrillator/monitor which delivers shocks with a waveform like the shocks generated by the LIFEPAK CR2 defibrillator.

Results

In the study, defibrillation thresholds were measured in 10 pigs weighing from 3.8 to 20.1 kg as shown in the following chart. For adult-sized electrode pads, the defibrillation threshold was 2.1 ± 0.65 J/kg; for pediatric-sized electrode pads, it was 2.4 ± 0.81 J/kg; the difference was not statistically significant.



The above chart is from Killingsworth’s paper showing defibrillation threshold expressed in energy (Joules) vs. body weight with pediatric-size electrodes (▲) and adult-size electrodes (■). Also shown are regression lines for pediatric (dashed line) and adult (solid line) patches.

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The same study also investigated the effect of much larger shocks, with the same waveform, on heart function. Delivering shocks all the way up to the maximum adult dose of 360 J (without using an attenuator) to these small pigs produced only brief-duration, transient ST-segment, rhythm, and hemodynamic changes.

Conclusion

The authors concluded, “Despite the delivery of very large cumulative doses and multiple large individual shocks during the course of each experiment, myocardial function in these small animals was remarkably resilient.” This study demonstrates that, with the biphasic waveform employed by the LIFEPAK 12 defibrillator/monitor and the LIFEPAK CR2 defibrillator, there is a large safety factor between the dose needed to defibrillate, and the dose that would cause harm.

3 Killingsworth CR, Melnick SB, Chapman FW, Walker RG, Smith WM, Ideker RE, Walcott GP. Defibrillation threshold and cardiac responses using an external biphasic defibrillator with pediatric and adult adhesive patches in pediatric-sized piglets. Resuscitation 2002; 55:177-185.

Potential Adverse Effects

Below is a list of potential adverse effects (for example, complications) associated with the use of the device.

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- Electromagnetic interference (EMI) from the defibrillator impacting other devices especially during charge and energy transfers
- Incorrectly shocking a pulse sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- Interaction with pacemakers
- Skin burns around the electrode placement area
- Allergic dermatitis due to sensitivity to materials used in electrode construction
- Minor skin rash

Appendix C

Voice Prompts

This appendix contains a list of voice prompts that are used by the LIFEPAK CR2 defibrillator.

Voice Prompts

The voice prompts are listed approximately in the order in which they are used during a cardiac arrest event.

VOICE PROMPT	DESCRIPTION
CARDIAC EVENT PROMPTS	The following voice prompts may be heard during a cardiac arrest event.
Remove all clothing from patient's chest	First prompt when device is turned on.
For <Language Name>, press the **LANGUAGE** button on the left	Allows user to change the voice prompts to a different language. This prompt is only used on dual-language devices.
<Language Name>	Announces the new language after the **LANGUAGE** button is pressed.
Adult mode	The **CHILD MODE** button has been pressed again, and the device is now in Adult mode. Defibrillation shocks will be delivered at adult energy levels.
Child mode	The **CHILD MODE** button has been pressed, and the device is now in Child mode. Defibrillation shocks will be delivered at reduced energy levels, and CPR coaching prompts will change.
Pull red handle to reveal pads	Instructs user to open the electrode tray so electrode pads can be applied to patient.
Look at pictures on pads	Instructs user to observe the pictures on the pads that show correct pad placement.
Apply pads to bare skin exactly as shown in the pictures	Instructs user how to apply the pads.
Press pads firmly	Instructs user to press the pads onto the patient.
Do not touch patient	Instructs user not to touch the patient during heart rhythm analysis.
Analyzing heart rhythm	The device is analyzing the patient's heart rhythm to determine whether a defibrillation shock is needed.
Preparing to shock	The device is charging for defibrillation.
Everyone clear	Instructs user and bystanders to stay clear of the patient during defibrillation.
Delivering shock	The device is delivering the defibrillation shock (fully automatic model only).
Press flashing button	Instructs user to press the **SHOCK** button to deliver the defibrillation shock (semi-automatic model only).
Shock delivered	The device has successfully delivered a defibrillation shock.
Shock not delivered	An error has occurred, and the defibrillation shock was not delivered.
Motion detected; stop motion	Patient motion is interfering with heart rhythm analysis. Instructs user to stop the motion.

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VOICE PROMPT	DESCRIPTION
No shock advised	The device has determined that the patient's heart is not in a shockable rhythm.
Provide chest compressions to the beat	Instructs user to begin CPR, using the 'tocks' to help provide chest compressions at the correct rate.
The heel of one hand should be in center of chest; the other hand should be on top of first hand	Instructs user regarding correct hand placement.
Lean over the patient	Instructs user regarding correct body position. (Adult Mode only)
Keep elbows straight	Instructs user regarding correct CPR technique. (Adult Mode only)
Use body weight to push	Instructs user regarding correct CPR technique. (Adult Mode only)
Push down hard at least five centimeters	Instructs user regarding correct chest compression depth. (Adult Mode only) **Note:** This is two inches in the U.S.
Remember to push hard	Instructs user regarding correct CPR technique. (Adult Mode only)
Remember to push deep	Instructs user regarding correct CPR technique. (Child Mode only)
Push down deep	Instructs user regarding correct CPR technique. (Child Mode only)
You have one minute to go	Informs user that one minute of CPR time remains.
Provide two breaths	Instructs user to provide rescue breaths at the correct time during CPR. This prompt only occurs if **CPR METRONOME** is set to 30:2. See Setup Options (on page 107) for more information.
One	Instructs user to provide first rescue breath.
Two	Instructs user to provide second rescue breath.
Check for breathing	Instructs user to check whether the patient is breathing. This prompt only occurs if **CHECK PATIENT PROMPT** is set to **CHECK BREATHING**. See Setup Options (on page 107) for more information. **Note:** On Norwegian devices, this prompt is **CHECK FOR SIGNS OF LIFE**.
If not breathing . . .	Provides appropriate instructions for user if patient is not breathing. **Note:** On Norwegian devices, this prompt is **IF NO SIGNS OF LIFE**.
Stop chest compressions	Instructs user to stop chest compressions so the device can analyze the patient's heart rhythm.
Resume chest compressions	Instructs user to resume chest compressions.
Check pads for good contact to bare skin	The device has detected that the electrode pads do not have an adequate electrical connection with the patient.
Check electrode tray connection	The device is unable to detect that electrodes are connected.

VOICE PROMPT	DESCRIPTION
Replace battery	The battery is low and should be replaced as soon as possible.
Recharging	The device has discharged the defibrillation energy and is recharging.
MAINTENANCE PROMPTS	The following voice prompts may be heard in Data mode. To enter Data mode, press and hold the **LANGUAGE** and **CHILD MODE** buttons simultaneously for at least 2 seconds.
Device ready	The device is ready for use.
Device not ready	The device is not ready for use.
Replace battery	The battery is low and should be replaced as soon as possible.
Replace electrode tray	The electrodes have been used or expired and should be replaced as soon as possible.
Call service	The device has detected an issue that requires assistance from authorized service personnel. Contact your local Stryker representative or local authorized distributor for assistance.
Wi-Fi not configured	Wi-Fi settings in the device have not been configured. See Connecting with Wi-Fi (on page 50) for more information.
Wi-Fi connection initiated	The device is connecting to a Wi-Fi network.
Unable to establish Wi-Fi network connection	The device is unable to connect to a Wi-Fi network.
Mobile connection initiated	The device is connecting to a cellular network.
Unable to establish mobile network connection	The device is unable to connect to a cellular network.
LIFENET connection error	An error has occurred while attempting to connect to LIFELINKcentral AED Program Manager or LIFENET System.
Communication complete	The device has finished communicating with LIFELINKcentral AED Program Manager or LIFENET System.
Connection established	The device has established a connection with LIFELINKcentral AED Program Manager or LIFENET System.
Connection in progress	The device is establishing a connection with LIFELINKcentral AED Program Manager or LIFENET System.
Connection lost	The device has lost its connection to LIFELINKcentral AED Program Manager or LIFENET System.
Connection failed	The connection to LIFELINKcentral AED Program Manager or LIFENET System has failed.
Update in progress	A software update is being downloaded and installed to the device.
This may take several minutes	Informs user to allow several minutes for updates to complete.
Rebooting	Informs user that the software update is complete and the device is rebooting.
Powering off	Informs user that the device is turning off.

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Appendix D

Defibrillator Setup Options

This appendix describes the operating settings that are adjustable on the LIFEPAK CR2 defibrillator.

Setup Options

The LIFEPAK CR2 defibrillator has several operating settings (setup options). The setup options include defibrillation energy sequences, CPR protocols, and language settings. These setup options are described in this appendix.

For instructions about changing setup options using **LIFELINKcentral AED Program Manager**, see Updating Setup Options and Software (on page 53).

For instructions about changing setup options using **LIFENET System**, see Updating Setup Options and Software (on page 69).

Note: You must have a LIFELINKcentral AED Program Manager or LIFENET System account to change setup options. However, some regions do not have access to LIFELINKcentral or LIFENET System. If your defibrillator is located in one of these regions, contact your local Stryker representative or local authorized distributor for assistance with changing setup options.

The following table describes the operating settings and lists the factory default for each setting.

OPERATING SETTING	DESCRIPTION	DEFAULT SETTING
General Settings		
Primary Language	Sets the primary voice prompt language. This is the language the device will use when it starts providing voice instructions. This setting may be changed to another language that is authorized for your country.	Determined when device is ordered.
Secondary Language	Sets the secondary voice prompt language. This setting is only available for dual-language devices. Although this setting may be changed to any available language, it should only be set to a language used within your area.	Determined when device is ordered.
Readiness Alert Tones	Provides audible tones if device is not ready. The choices are **ON** or **OFF**.	On
Rhythm Analysis Settings		
Motion Detection	Provides an alert if device detects motion during heart rhythm analysis. The choices are **ON** or **OFF**.	On

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OPERATING SETTING	DESCRIPTION	DEFAULT SETTING
cprINSIGHT Analysis Technology	Enables device to analyze heart rhythm during CPR. This feature is not available in all countries. The choices are **ON** or **OFF**. **Note:** cprINSIGHT Analysis Technology is only available in LIFEPAK CR2 defibrillators with Wi-Fi or cellular capability. To determine whether the device has Wi-Fi or cellular capability, check the serial number label located in the battery compartment on the back of the device. See About the LIFEPAK CR2 Defibrillator for details.	On
Defibrillation Energy Settings	Sets the sequence of defibrillation energy levels for the first, second, and subsequent shocks.	
Adult Energy 1	150, 200, 300, or 360 joules	200 joules
Adult Energy 2	Same choices; must be ≥ Energy 1	300 joules
Adult Energy 3	Same choices; must be ≥ Energy 2	360 joules
Child Energy 1	35, 50, 75, or 90 joules	50 joules
Child Energy 2	Same choices; must be ≥ Energy 1	75 joules
Child Energy 3	Same choices; must be ≥ Energy 2	90 joules
Flexible Energy Protocol	Prevents defibrillator from escalating shock energy level if the previous shock resulted in a **NO SHOCK ADVISED** heart rhythm analysis. For example, if the defibrillator energy sequence is set to 200, 300, 360 and Flexible Energy is turned on, the first shock delivered will be 200 joules. If the next analysis results in a **NO SHOCK ADVISED** decision, and the following analysis results in a **SHOCK ADVISED** decision, the previous energy level of 200 joules is repeated. When there are consecutive **SHOCK ADVISED** decisions, the energy levels escalate as specified in Defibrillation Energy Settings. If Flexible Energy is turned off, the energy levels escalate as specified in Defibrillation Energy Settings, regardless of the heart rhythm analysis decision between defibrillation shocks. The choices are **ON** or **OFF**.	On

OPERATING SETTING	DESCRIPTION	DEFAULT SETTING
CPR Settings	Sets the options for CPR coaching	
CPR Time	Duration of CPR interval between heart rhythm analyses. The choices are **60**, **120**, and **180** seconds.	120 seconds[1]
Check Patient Prompt	Instructs user to check for breathing before resuming CPR after a **NO SHOCK ADVISED** decision. The choices are **NONE** and **CHECK BREATHING**.	None[2]
Adult CPR Metronome	For Adult mode, sets the chest compression to breath ratio to one of two options: • Hands-Only (This option provides continuous 'tocks' at the correct compression rate. The user is not instructed to provide breaths.) • 30:2 Compressions:Breaths (This option provides 'tocks' at the correct compression rate and instructs the user to provide 2 breaths after every 30 'tocks'.)	Hands-Only[3]
Child CPR Metronome	For Child mode, sets the chest compression to breath ratio to one of two options: • Hands-Only (This option provides continuous 'tocks' at the correct compression rate. The user is not instructed to provide breaths.) • 30:2 Compressions:Breaths (This option provides 'tocks' at the correct compression rate and instructs the user to provide 2 breaths after every 30 'tocks'.)	30:2 Compressions:Breaths

[1] The default setting for Norway is 180 seconds.
[2] The default setting for Finland is Check Breathing.
The choices for Norway are None and Check for Signs of Life. The default setting is Check for Signs of Life.
[3] The default setting for Belgium, Denmark, Finland, Iceland, Luxembourg, Netherlands, Norway, and Sweden is 30:2 Compressions:Breaths.

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Appendix E

Shock Advisory System and cprINSIGHT Analysis Technology

This appendix describes the basic function of the Shock Advisory System and cprINSIGHT Analysis Technology.

Overview

The Shock Advisory System (SAS) is an ECG analysis system in the LIFEPAK CR2 defibrillator that recommends whether or not a patient should be given a defibrillation shock. This system makes it possible for individuals who are not trained to interpret ECG rhythms to provide potentially life-saving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia. The Shock Advisory System is used to analyze the ECG rhythm during the first rhythm analysis after the electrode pads have been placed on the patient when CPR is not being performed. It is also used during subsequent rhythm analyses when the user has been instructed to stop CPR.

The cprINSIGHT Analysis Technology is designed to analyze the ECG rhythm while CPR is being performed. Performing analysis during CPR periods reduces pauses in chest compressions. When the rhythm is determined to be nonshockable, the pause for analysis can be eliminated altogether, allowing for continuous CPR. When the ECG rhythm is determined to be shockable, the necessary pause time is shortened to the time needed for the rescuer to stand clear and deliver the shock. Reducing CPR pause time helps maintain circulation of the blood. The cprINSIGHT Analysis Technology can be set to be **ON** or **OFF**. This setting must be selected in advance; it cannot be changed during a cardiac arrest event. See Setup Options (on page 107) for more information.

Note: cprINSIGHT Analysis Technology is only available in LIFEPAK CR2 defibrillators with Wi-Fi or cellular capability. To determine whether the device has Wi-Fi or cellular capability, check the serial number label located in the battery compartment on the back of the device. See About the LIFEPAK CR2 Defibrillator for details.

Automated Interpretation of the ECG

The LIFEPAK CR2 defibrillator recommends a shock if either of the following rhythms is detected:

- Ventricular fibrillation
- Rapid ventricular tachycardia (see below for definition)

The LIFEPAK CR2 defibrillator recommends no shock for nonshockable ECG rhythms as indicated in the Shock Advisory System Performance Report and cprINSIGHT Analysis Technology Performance Report in this appendix.

The LIFEPAK CR2 defibrillator is designed to detect and remove pacemaker pulses from the ECG so that an accurate decision can be reached while a pacemaker is functioning. Some pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm. If this occurs, the rescuer is advised to continue chest compressions.

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Shock Advisory System

The Shock Advisory System (SAS) in the LIFEPAK CR2 defibrillator was verified by inputting specific ECG waveform segments from Physio-Control databases through the electrode connector and recording the SAS decision of 'shock' or 'no shock.' The 'shock' or 'no shock' decision made by the SAS for each ECG waveform segment was compared to the treatment recommendation by clinical experts when they classified these individual ECG segments into rhythm groups and made a treatment recommendation of 'shock' or 'no shock.'

The main ECG database used to verify the performance of the LIFEPAK CR2 defibrillator for SAS is named the *Physio-Control Test Set.* In addition, the ECG database named *SAS Test Set* was used to provide samples of shockable rapid ventricular tachycardia from pulseless patients for verification purposes. The following information about the test sets and the Summary Performance Report is provided in accordance with AHA recommendations[1] and IEC requirements[2] for reporting performance data for a rhythm recognition detector.

Acquisition and Annotation Methodology

This section includes recording methods, rhythm source, rhythm selection criteria, annotation methods, and annotation criteria for the Shock Advisory System test sets.

Physio-Control Test Set

The Physio-Control Test Set includes ECG segments gathered from a variety of sources. The test set includes both adult and pediatric ECG segments, ECGs from the standard anterior-lateral (AL, AA) defibrillation electrode placement, ECGs from anterior-posterior (AP) defibrillation electrode placement, and ECGs from patients who have a pacemaker. Each ECG segment is 10 seconds in duration. Sources for the ECGs include:

- AHA Ventricular Arrhythmia Database (Holter recordings)
- MIT-BIH Arrhythmia Database (Holter)
- MIT-BIH Malignant Ventricular Arrhythmia Database (Holter)
- Creighton University Ventricular Tachyarrhythmia Database (hospital monitor)
- A series of consecutive LIFEPAK 500 automated external defibrillator recordings collected by Physio-Control
- DiMarco AA-AP ECG Database (simultaneous AA and AP defibrillation leads, recorded in the electrophysiology laboratory)
- Vanderbilt Pediatric ECG Database (AA and/or AP defibrillation leads, recorded in the pediatric intensive care unit, the pediatric electrophysiology laboratory, and the pediatric operating room during open heart surgery)
- A series of 12-lead recordings from consecutive chest pain patients, recorded in the pre-hospital setting with the LIFEPAK 11 monitor/defibrillator.

SAS Test Set

The SAS Test Set includes 65 ECG samples of shockable rapid ventricular tachycardia from pulseless patients recorded during pre-hospital use of LIFEPAK 5 defibrillators by paramedics. Selected ECG segments were sampled and the ECG rhythm was classified by clinical experts. Each ECG segment is 5 seconds in duration.

ECG Rhythm Types

The ECG rhythms were placed into the following categories by the clinical experts.

Shockable

- Coarse ventricular fibrillation (VF) (≥0.20 mV peak-to-peak amplitude)
- Rapid ventricular tachycardia, pulseless (VT) (HR ≥120 bpm, QRS duration ≥160 ms, no apparent P waves, patient reported to be pulseless by paramedics)

Nonshockable

- Normal sinus rhythm (NSR) (sinus rhythm, heart rate 60-100 bpm)
- Asystole (<0.08 mV peak-to-peak amplitude)
- Other QRS rhythms including atrial fibrillation/flutter, atrioventricular block, idioventricular rhythms, sinus bradycardia, supraventricular tachycardia, and premature ventricular contractions

Intermediate

- Fine VF (<0.20 and ≥0.08 mV peak-to-peak amplitude)
- Other VT (ventricular tachycardia that does not meet criteria for VT in the shockable rhythms category)

Also included are coarse VF with pacemaker pulses and nonshockable rhythms with pacemaker pulses.

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Summary Shock Advisory System Performance Report

The results of tests with the SAS and Physio-Control test sets in the LIFEPAK CR2 defibrillator are shown below in the context of requirements from IEC 60601-2-4 and the recommendations from the American Heart Association.

Table 1 IEC 60601-2-4 Requirements and SAS Performance

RHYTHM CATEGORY	REQUIREMENT	TEST RESULT
Shockable (Sensitivity)		
Coarse VF	>90%	Met
Rapid VT, pulseless	>75%	Met
Nonshockable (Specificity)	>95%	Met
Positive Predictive Value	Report Only	>90%
False Positive Rate	Report Only	<5%

Table 2 AHA Recommendations and SAS Performance

RHYTHM CATEGORY	PERFORMANCE GOAL	MINIMUM SAMPLE SIZE	SAMPLE SIZE TESTED	TEST RESULT (GOAL AND SAMPLE SIZE)
Shockable (Sensitivity)				
Coarse VF	>90%	200	269	Met
Rapid VT, pulseless	>75%	50	65	Met
Nonshockable (Specificity)	>95%	300		Met
Normal Sinus Rhythm	>99%	100	578	Met
Other QRS	>95%	30	1256	Met
Asystole	>95%	100	184	Met
Intermediate				
Fine VF	Report Only	25	33	>40% shocked
Other VT	Report Only	25	27	>20% shocked

Table 3 SAS Performance for Adult Patients

RHYTHM CATEGORY	PERFORMANCE GOAL	SAMPLE SIZE TESTED	TEST RESULT (GOAL)
Shockable (Sensitivity)			
Coarse VF	>90%	206	Met
Rapid VT, pulseless	>75%	65	Met
Nonshockable (Specificity)	>95%		Met
Normal Sinus Rhythm	>99%	509	Met
Other QRS	>95%	749	Met
Asystole	>95%	124	Met
Intermediate			
Fine VF	Report Only	32	>40% shocked
Other VT	Report Only	27	>20% shocked

The Shock Advisory System was also tested using ECGs acquired from hospitalized pediatric patients ranging in age from <1 day old to 17 years old. The results are summarized in the following table.

Table 4 SAS Performance for Pediatric Patients

RHYTHM CATEGORY	PERFORMANCE GOAL	SAMPLE SIZE TESTED	TEST RESULT (GOAL)
Shockable (Sensitivity)			
Coarse VF	>90%	63	Met
Nonshockable (Specificity)	>95%		Met
Normal Sinus Rhythm	>99%	69	Met
Other QRS	>95%	507	Met
Asystole	>95%	60	Met
Intermediate			
Fine VF	Report Only	1	>20% shocked

The Shock Advisory System was also tested using paced rhythms recorded at high-fidelity from patients with implanted pacemakers. The high-fidelity pacemaker spikes were also added to samples of ventricular fibrillation to test the defibrillator's ability to reach a shock decision in the case of ventricular fibrillation with an implanted, active pacemaker. The results are summarized in the following table.

Table 5 Shock Advisory System Performance with Active Pacemakers

RHYTHM CATEGORY	PERFORMANCE GOAL	SAMPLE SIZE TESTED	TEST RESULT
Shockable (Sensitivity)			
Coarse VF	>90%	35	Met
Nonshockable (Specificity)	>95%	35	Met

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Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. **MOTION DETECTION** can be set up to be **ON** or **OFF**. For more information, see Setup Options (on page 107).

A number of activities can create motion, including CPR, rescuer movement, patient movement, and vehicle movement. If variations in the transthoracic impedance signal exceed a maximum limit, the Shock Advisory System determines that patient motion of some kind is present. If motion is detected, the ECG analysis is inhibited. The operator is advised by a voice prompt. After 10 seconds, if motion is still present, the motion alert stops and the analysis always proceeds to completion. This limits the delay in therapy in situations where it may not be possible to stop the motion. However, the rescuer should remove the source of motion whenever possible to minimize the chance of artifact in the ECG.

There are two reasons why ECG analysis is inhibited when the motion alert occurs, and why the rescuer should remove the source of the motion whenever possible:

- Such motion may cause artifact in the ECG signal. This artifact may occasionally cause the Shock Advisory System to reach an incorrect decision.
- The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

cprINSIGHT Analysis Technology Performance

The cprINSIGHT Analysis Technology in the LIFEPAK CR2 defibrillator was verified by inputting specific ECG waveform segments through the electrode connector, and recording the decision of 'shock' or 'no shock.' The 'shock' or 'no shock' decision made by the cprINSIGHT Analysis Technology algorithm for each ECG waveform segment was compared to the decision made by three clinical experts when they classified these individual ECG segments into rhythm groups, thus making a treatment recommendation of 'shock' or 'no shock.'

The following information about the test sets and the Summary Performance Report is provided in accordance with AHA recommendations[1] and IEC requirements[2] for reporting performance data for a rhythm recognition detector.

Acquisition and Annotation Methodology

This section includes recording methods, rhythm source, rhythm selection criteria, annotation methods, and annotation criteria for the cprINSIGHT Analysis Technology test sets.

cprINSIGHT Test Sets

The cprINSIGHT Test Set used for verifying the algorithm consists of 2781 ECG and impedance segments gathered from ten emergency medical services with locations in North

America and Europe. A separate cprINSIGHT Pediatric Test Set with 700 segments of known pediatric patients gathered from two emergency medical services was also evaluated. Included were patients that were treated with a LIFEPAK 1000 automated external defibrillator or a LIFEPAK 12 defibrillator/monitor/noninvasive pacemaker with CPR performed some time during the case. Cases were included in which the CPR was administered manually or with the LUCAS chest compression system. The data was transferred digitally from the LIFEPAK devices used to treat the patients and provided to Physio-Control. Clinical experts determined the patient's rhythm by interpreting pauses in CPR if there was excessive artifact that prevented interpretation during the CPR period.

ECG Rhythm Types

The ECG rhythms were placed into the following categories by the clinical experts.

Shockable

- Coarse ventricular fibrillation (VF) (≥0.20 mV peak-to-peak amplitude)
- Rapid ventricular tachycardia, pulseless (VT) (HR ≥150 bpm, QRS duration ≥160 ms, no apparent P waves, no clear evidence of perfusion)

Nonshockable

- Normal sinus rhythm (NSR) (sinus rhythm, heart rate 60-100 bpm)
- Asystole (<0.08 mV peak-to-peak amplitude)
- Other QRS rhythms including atrial fibrillation/flutter, atrioventricular block, idioventricular rhythms, sinus bradycardia, supraventricular tachycardia, and premature ventricular contractions

Intermediate

- Fine VF (<0.20 and ≥0.08 mV peak-to-peak amplitude)
- Other VT (ventricular tachycardia that does not meet criteria for VT in the shockable rhythms category)

Summary cprINSIGHT Analysis Technology Performance Report

The results of tests with the cprINSIGHT Analysis Technology test sets in the LIFEPAK CR2 defibrillator are shown below in the context of requirements from IEC 60601-2-4 and the recommendations from the American Heart Association. The recommendations from the American Heart Association and the IEC 60601-2-4 reporting requirements are based on "artifact-free" ECG data. These results are provided for information only.

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Table 6 IEC 60601-2-4 Requirements and cprINSIGHT Analysis Technology Performance for the cprINSIGHT Data Set

RHYTHM CATEGORY	REQUIREMENT	TEST RESULT
Shockable (Sensitivity)		
Coarse VF	>90%	Met
Nonshockable (Specificity)	>95%	Met
Positive Predictive Value	Report Only	>90%
False Positive Rate	Report Only	<5%

Table 7 cprINSIGHT Analysis Technology Performance for the cprINSIGHT Test Set

RHYTHM CATEGORY	PERFORMANCE GOAL	SAMPLE SIZE TESTED	TEST RESULT (GOAL AND SAMPLE SIZE)
Shockable (Sensitivity)	>90%	612	Met
Nonshockable (Specificity)	>95%	1564	Met
Intermediate			
Fine VF	Report Only	19	63% Shocked
Other VT	Report Only	28	68% Not Shocked

The results of testing for the cprINSIGHT Analysis Technology with the cprINSIGHT Pediatric Test Set are summarized below.

Table 8 IEC 60601-2-4 Requirements and cprINSIGHT Analysis Technology Performance, cprINSIGHT Pediatric Test Set

RHYTHM CATEGORY	REQUIREMENT	TEST RESULT
Shockable (Sensitivity)	>90%	Met
Coarse VF	Report Only	>90%
Nonshockable (Specificity)	>95%	Met
Positive Predictive Value	Report Only	>80%
False Positive Rate	Report Only	<5%

Table 9 cprINSIGHT Analysis Technology Performance, cprINSIGHT Pediatric Test Set

RHYTHM CATEGORY	PERFORMANCE GOAL	SAMPLE SIZE TESTED	TEST RESULT (GOAL)
Shockable (Sensitivity)	>90%	30	Met
Nonshockable (Specificity)	>95%	496	Met

A true positive (A) is a correct classification of a shockable rhythm. A true negative (D) is a correct classifications of all rhythms for which a shock is not indicated. A false positive (B) is an organized or perfusing rhythm or asystole that has been incorrectly classified as a shockable

rhythm. A false negative (C) is a VF or VT associated with cardiac arrest that has been incorrectly classified as non-shockable.

The sensitivity of the device for shockable rhythms is A/(A+C). The true predictive value is expressed as A/(A+B). The specificity of the device for non-shockable rhythms is D/(B+D). The false positive rate is expressed as B/(B+D).[3]

[1] Kerber RE, et al, "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety: A Statement for Health Professionals from the American Heart Association Task Force on Automatic External Defibrillation", Subcommittee on AED Safety and Efficacy. *Circulation*, 1997: Vol. 95: 1677-1682.

[2] Clause 201.7.9.3.103, "Essential Performance data of the Rhythm Recognition Detector," International Electrotechnical Commission, *IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators: 2010*

[3] Quoted from clause 201.107, "Requirements for Rhythm Recognition Detector," International Electrotechnical Commission, *IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators: 2010.*

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Appendix F

Electromagnetic Compatibility Guidance

This appendix provides guidance and manufacturer's declaration of electromagnetic compatibility.

Electromagnetic Emissions

Table 10 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The LIFEPAK CR2 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK CR2 defibrillator should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The LIFEPAK CR2 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 LIFEPAK CR2 defibrillator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Federal Communications Commission (FCC) Declaration

The device is capable of transferring data records by wired or wireless connection. This device complies with Part 15 of the FCC rules, and its 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.

Caution

Changes or modifications not expressly approved by Stryker could void the user's authority to operate the equipment.

Radio Equipment Directive

Hereby, Stryker declares that the radio equipment type LIFEPAK CR2 defibrillator is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: stryker.com/ec-red-doc.

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Electromagnetic Immunity

Essential Performance

The LIFEPAK CR2 defibrillator's essential performance (energy delivery, Shock Advisory System, cprINSIGHT Analysis Technology, voice prompts, CPR metronome, **CHILD MODE** button, and **LANGUAGE** button) is both clinically acceptable and meets basic safety when operated in the electromagnetic environment specified in the following tables.

Table 11 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The LIFEPAK CR2 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK CR2 defibrillator should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T during 1/2 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 70% U_T during 25/30 cycles Single phase at 0°	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC Mains voltage prior to application of the test level.

Table 12 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The LIFEPAK CR2 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK CR2 defibrillator should ensure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1] 6 Vrms 150 kHz to 80 MHz in ISM and amateur bands[1]	3 Vrms 10 Vrms ISM 6 Vrms amateur
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz

[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. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7.0 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14.0 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Separation Distances

The LIFEPAK CR2 defibrillator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LIFEPAK CR2 defibrillator can help prevent electromagnetic interference by maintaining a minimum distance of 30 cm (12 in) between portable and mobile RF communications equipment (transmitters) and the defibrillator.

RF Exposure Information

The LIFEPAK CR2 defibrillator is designed and manufactured to not exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communication Commission (FCC) of the U.S. Government, the Industry Canada (IC) and the Council of the European Union (CE). The exposure standards for wireless devices employ a unit of measurement known as the Specific Absorption Rate (SAR). The SAR limits are shown in the table below.

	FCC/IC (1g)	**EU (10g)**
Limit	1.6 W/kg	2.0 W/kg
The Highest Reported Body Value (3 cm gap)	< 1.0 W/kg	< 0.8 W/kg

The maximum SAR level of this device is below the limits. Nevertheless, this device should be used in such a manner that the potential for human contact during wireless data transmission is minimized.

Note: When carrying the product or using it while worn on your body, maintain a distance of 3 cm (1.18 inch) to ensure compliance with RF exposure requirements.

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Wireless Specifications

The LIFEPAK CR2 defibrillator uses two wireless modules and the specifications for both modules are listed in the tables below. Refer to the LIFEPAK CR2 Defibrillator Configuration Guide shipped with your device to determine the specific module your devices uses.

Table 13 Wireless Specifications

The LIFEPAK CR2 defibrillator meets the following specifications for wireless transmission and reception, in accordance with IEC 60601-1-2.

IEEE Protocol 802.11	Center Frequency (MHz)	Modulation Type	Bandwidth (MHz)	Effective Radiated Power (mW)	Effective Radiated Power (dBm)
802.11b	2412–2472	DSSS[1]	20	32	15
802.11g	2412–2472	OFDM[2]	20	25	14
802.11n	2412–2472	OFDM	20	25	14

[1] Direct-Sequence Spread Spectrum
[2] Orthogonal Frequency-Division Multiplexing

Table 14 Wi-Fi Communications

Quality of Service (QoS)	• Wi-Fi module QoS is based on IEEE 802.11e (Wi-Fi Multi Media including Wi-Fi Multi Media Power Save)
	• The minimum recommended QoS required by the customer facility is as follows:
	  • WLAN access points are recommended to have minimum transmit power of 20 dBm
	  • Receive sensitivity of -93 dBm at 802.11b at 1 Mbps and -87 dBm at 802.11g at 6 Mbps and 802.11n at MCS0

Module	• Gainspan GS2011M • Protocol: 802.11b/g/n
Operating Distance	30 m indoor office environment
Encryption	• WPA • WPA2
Authentication Protocol	• OPEN • PSK • PEAPv0/EAP-MSCHAPv2 • EAP-TLS

Stryker recommends using WPA2 encryption protocol when setting up the Wi-Fi network.

Table 15 Wireless Specifications

The LIFEPAK CR2 defibrillator meets the following specifications for wireless transmission and reception, in accordance with IEC 60601-1-2.

IEEE Protocol 802.11	Center Frequency (MHz)	Modulation Type	Bandwidth (MHz)	Effective Radiated Power (mW)	Effective Radiated Power (dBm)
802.11b	2412–2472	DSSS[1]	20	36	15
802.11g	2412–2472	OFDM[2]	20	36	14
802.11n	2412–2472	OFDM	20	29	14
802.11n	2412-2472	OFDM	40	18	13

[1] Direct-Sequence Spread Spectrum
[2] Orthogonal Frequency-Division Multiplexing

Table 16 Wi-Fi Communications

Quality of Service (QoS)	• Wi-Fi module QoS is based on IEEE 802.11e (Wi-Fi Multi Media including Wi-Fi Multi Media Power Save)
	• The minimum recommended QoS required by the customer facility is as follows:
	  • WLAN access points are recommended to have minimum transmit power of 20 dBm
	  • Receive sensitivity of -97 dBm at 802.11b at 1 Mbps and -92 dBm at 802.11g at 6 Mbps and 802.11n at MCS0

Module	• Telit WE310F5 • Protocol: 802.11b/g/n • Supports 2.4 GHz band
Operating Distance	30 m indoor office environment
Encryption	• TLS-1.2 (server and client) • TKIP/AES (Wi-Fi)
Security Protocols	• Open • WPA/WPA2-PSK (personal) • WPA/WPA2-EAP (enterprise)
Authentication Protocol	• PSK • EAP-TLS • EAP-TTLS* • PEAPv0/EAP-MSCHAPv2

*Only on device software version 1.13 or higher.

Stryker recommends using WPA2-Enterprise security protocol (EAP-TLS/TTLS/PEAP) to afford the highest level of security while setting up the Wi-Fi network.

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Cellular Specifications

Table 17 Cellular Specifications

The LIFEPAK CR2 defibrillator meets the following specifications for cellular transmission and reception.

Wireless Protocol	Band	Frequency (MHz)	Modulation Type	Bandwidth (MHz)	Effective Radiated Power (mW)	Effective Radiated Power (dBm)
LTE	1	1920-1980	OFDM[1]	5, 10, 15, 20	234.4	23.7
LTE	2	1850-1910	OFMD	1.4, 3, 5, 10, 15, 20	234.4	23.7
LTE	3	1710-1785	OFMD	1.4, 3, 5, 10, 15, 20	234.4	23.7
LTE	4	1710-1755	OFMD	1.4, 3, 5, 10, 20	234.4	23.7
LTE	5	824-849	OFMD	1.4, 3, 5, 10	362.2	25.59
LTE	7	2500-2570	OFMD	5, 10, 15, 20	313.3	24.96
LTE	8	880-915	OFMD	1.4, 3, 5, 10	362.2	25.59
LTE	12	699-716	OFMD	1.4, 3, 5, 10	362.2	25.59
LTE	13	777-787	OFMD	5, 10	362.2	25.59
LTE	18	815-830	OFMD	5, 10, 15	362.2	25.59
LTE	19	830-845	OFMD	5, 10, 15	362.2	25.59
LTE	20	832-862	OFMD	5, 10, 15, 20	362.2	25.59
LTE	25	1850-1915	OFMD	1.4, 3, 5, 10, 15, 20	234.4	23.7
LTE	26	814-849	OFMD	1.4, 3, 5, 10, 15	362.2	25.59
LTE	28	703-748	OFMD	3, 5, 10, 15, 20	362.2	25.59
LTE	38	2570-2620	OFMD (TDD)[2]	5, 10, 15, 20	313.3	24.96
LTE	39	1880-1920	OFMD (TDD)	5, 10, 15, 20	234.4	23.7
LTE	40	2300-2400	OFMD (TDD)	5, 10, 15, 20	313.3	24.96
LTE	41	2496-2690	OFMD (TDD)	5, 10, 15, 20	313.3	24.96
UMTS	1	1920-1980	DS-CDMA[3]	5	234.4	23.7
UMTS	2	1850-1910	DS-CDMA	5	234.4	23.7
UMTS	4	1710-1755	DS-CDMA	5	234.4	23.7
UMTS	5	824-849	DS-CDMA	5	362.2	25.59
UMTS	8	880-915	DS-CDMA	5	362.2	25.59
UMTS	19	830-845	DS-CDMA	5	362.2	25.59

[1] Orthogonal Frequency-Division Multiplexing
[2] Time-Division Duplexing
[3] Direct-Sequence Spread Spectrum Code Division Multiple Access

Table 18 Cellular Communications

Quality of Service (QoS) - Based on the network provider	• Cellular functionality is used to transmit device readiness indication when the defibrillator is not being used to treat a patient. Cellular functionality is not used to transmit during patient use. • Cellular transmissions only occur following a patient use, after device self-tests or when transmission is manually initiated, by pressing the language and pediatric button at the same time. • LIFEPAK CR2 defibrillator uses the default QoS set by the cellular network provider
Module	Quectel EG21-G Mini PCIe
Operating Distance	Per 3GPP Specifications Release 9 or later for cellular standard.
Security	TCP/HTTP
Network	4G LTE

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