LIFEPAK® CR2 AED

Helmsley First Responder Program - FAQs

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Design and use

Q: What is included in the first responder grantee LIFEPAK CR2 package?
A:

- LIFEPAK CR2 AED
- Carrying case with shoulder strap
- Four-year electrodes
- Four-year battery
- USB cable
- LIFELINKcentral AED program manager premium service package
- Operating Instructions (OI)
- Getting started guide
- Wireless set up guide
- Customer support contact list

Q: What is the device warranty period?
A: Eight years with Stryker's limited warranty.

Q: What is the expected product life (standard use)?
A: Eight years.

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Battery

Q: How long is the battery life? Does Wi-Fi® capability drain the battery?
A: If a new battery is installed in a defibrillator and the device is not used, the useful life of the battery lasts at least four years. This includes all self-tests and monthly connection to LIFELINKcentral AED program manager, when used as a connected or non-connected device. Wi-Fi capability does not drain the battery.

Q: Does opening and closing the lid drain the battery?
A: Battery power is reduced every time the lid is opened. Do not open the lid after completing initial inspection except for emergency response.

Q: Where can I store an extra battery and set of electrodes?
A: The LIFEPAK CR2 carrying case includes a storage compartment on the back for accessories.

Electrodes

Q: Can the adult electrode pads be used on a pediatric patient?
A: Yes, the QUIK-STEP™ pads are approved for use on both adult and pediatric patients. When the Child Mode button is pressed (even if pads are already applied) CPR coaching prompts and energy protocol will adjust for children.
Note: The cprINSIGHT® analysis technology algorithm for heart rhythm analysis during CPR also works in Child Mode.

Q: Can I recycle the electrodes?
A: The OI states: "Do not dispose of this product or its batteries in the unsorted municipal waste stream. Any batteries must be removed from the device and disposed of separately before disposing of the device. At all times, dispose of this product and its accessories, including batteries, according to local regulations."

In-use

Q: Can the LIFEPAK CR2 pads freeze?
A: The OI provides storage and operating temperatures for the device and pads:

- 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 one week

Status

Q: How does the LIFEPAK CR2 visually and audibly indicate its readiness status?

A: The readiness indicator is a bright green LED that flashes every six seconds to indicate the defibrillator is ready for use.

If the device detects an issue affecting readiness, the readiness indicator will stop flashing and a loud alert will sound every 15 minutes. A readiness alert could be an indication that the electrodes are nearing expiration date or an indication the device may not power on. Always follow up on alerts as soon as possible.

Absence of the flashing green LED, audible alert tone, and the LIFELINKcentral AED program manager email notification are all important warnings that a device may not be ready for use.

Find more information in the automatic email notification, LIFELINKcentral AED program manager or by opening the device's lid and pressing the Language and Child Mode buttons simultaneously.

Q: Is the self-test scheduled for a specific time?

A: The default time is at 3 a.m. EST. The day is determined when you first place the battery in the device, which triggers the first self-test.

For connected devices, logs are stored in LIFELINKcentral AED program manager for the date and time of check-ins. You may configure date of tests with the help of a Stryker LIFELINKcentral AED Program Administrator (APA).

Q: When and how does the LIFEPAK CR2 report an issue that requires attention?

A: The LIFEPAK CR2 performs automatic self-tests daily, weekly, monthly and each time it is powered on. If the automatic self-tests are successful, the device connects to LIFELINKcentral AED program manager monthly and reports that the device is 'ready.'

If an automatic self-test detects an issue that requires attention, the device connects to LIFELINKcentral AED program manager and changes the status shown for the AED, sending an email notification to the designated recipient(s). If an issue is detected, the readiness indicator will be a steady off (no green flashing LED) and an alert will sound every 15 minutes.

Q: Will the self-test check that the electrodes are present and functional?

A: Yes, device readiness status will update to "Not Ready (electrodes not connected)", "Not Ready (used electrodes) or "Not Ready (electrodes expired)" if the self-test determines an electrode issue is present.

Configurations/customization

Q: Does the LIFEPAK CR2 prompt to start hands-only CPR configuration?

A: LIFEPAK CR2 devices are shipped in a hands-only configuration, prompting for chest compressions at 104 compressions/minute for Adult Mode. If Child Mode is activated, the device switches to 30:2 (30 compressions to 2 rescue breaths). Once set to 30:2, the device will prompt to perform rescue breaths. You may change settings with the help of a LIFELINKcentral APA.

Accessories

Q: Do you offer a water-tight case for the LIFEPAK CR2?

A: We do not currently offer a water-tight case for this device. The included carrying case helps protect the AED from outside elements, offers an IP55 rating and passes a one-meter drop test.

Connectivity

Q. Where can I get information on how to connect the LIFEPAK CR2 to Wi-Fi?

A. Start here. This website is for Helmsley grantee reference only and includes:

- LIFEPAK CR2 wireless set-up guide (also included with device)
- LIFEPAK CR2 Operating Instructions
- LIFEPAK CR2 pre-implementation checklist (for Wi-Fi set-up)
- In-service videos

Q: Can the LIFEPAK CR2 be used without a Wi-Fi connection?

A: Yes, the device can be used as a non-connected AED without setting up Wi-Fi.

Q. What are the benefits of connecting my LIFEPAK CR2 to Wi-Fi?

A. Connecting your LIFEPAK CR2 will allow you to take advantage of the following features:

- Monitoring defibrillator readiness 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 to specified recipients 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, including heart rhythm, to emergency if they are set up to receive the data. Responders can send AED and patient data reports to medical personnel or the receiving hospital if they are also using Stryker's data products.

Q: **If my device is not connected to Wi-Fi, will I still receive readiness issues/alerts?**

A: The readiness indicator on the device will not flash and the alert tone may sound but you will not receive an email through LIFELINKcentral AED program manager. You will know your device is not ready because the readiness indicator will stop flashing and a loud alert tone will sound every 15 seconds until the device issue is addressed.

Q: **If a device is not connected to Wi-Fi, will it alert me?**

A: If the device was once connected to Wi-Fi and is no longer connected, it will show as "Outdated" in LIFELINKcentral. If the device has never been connected to Wi-Fi, it will show as "No data available" in LIFELINKcentral.

Q: **If the LIFEPAK CR2 is not connected to Wi-Fi, are the self-tests still performed?**

A: A non-connected device operates the same way as a connected device: self-tests will occur on a daily, weekly and monthly basis. However, the status will not be sent to LIFELINKcentral AED program manager and you will not receive an email notification.

Q: **If a device is connected to Wi-Fi when the lid is closed, what happens to the post-event data?**

A: The device will send the data wirelessly to LIFENET AED Event Viewer, which can be accessed by local EMS personnel if they have added AED Event Viewer to their system. It will move the file to a hidden location on the device, where it will remain until overwritten (after about 20 events are recorded). The hidden data can be extracted using DT EXPRESS™ software and a software key if necessary. Contact your LIFELINKcentral APA for more information.

Q: **If a device is <u>not</u> connected to Wi-Fi when the lid is closed, what happens to the post-event data?**

A: The device will try to connect several times and send the data in the first hour. If unsuccessful, it will continue to try and send the data each hour for a few hours. If it's still unsuccessful, it will try once a day for seven days. If unsuccessful after seven days, it goes back to its normal monthly check-in schedule, but the data remains in the device.

Q: **If a device is connected to Wi-Fi but is moved out of Wi-Fi range every day, will the device automatically reconnect when in range again?**

A: The device will conduct its regularly scheduled tests and report changes to readiness status once it has reconnected to Wi-Fi. Typically, the device will attempt to connect overnight to the same Wi-Fi that was initially used to set up the device. If that Wi-Fi location is not available, the device will connect to the next Wi-Fi system present in the configuration program.

LIFELINKcentral AED program manager/LIFENET AED Event Viewer

Q: In LIFELINKcentral AED program manager, is it possible to locate a connected LIFEPAK CR2 if it has been moved from its designated locations?

A: We do not track position data of devices via LIFELINKcentral AED program manager.

Q: How does EMS receive event/post-event data via AED Event Viewer?

A: When a Wi-Fi-enabled LIFEPAK CR2 is being used to respond to a cardiac event (and the device is within Wi-Fi range) the LIFEPAK CR2 will begin to send event data in near real-time as soon as the lid is open. The data is sent to AED Event Viewer software if the software has been set up to receive cases in an EMS service area. Any EMS agency with AED Event Viewer that has been configured to receive these cases in the service area will have access.

EMS agencies will receive a notification email confirming the case has been sent to AED Event Viewer (if the email is configured in the LIFENET account). Any EMS agency in the service area that receives the case may claim it. However, additional agencies in the area receiving the same case will not see if the case has been claimed by others.

Q. What happens after EMS receives a case via AED Event Viewer?

A. If the LIFEPAK CR2 is subscribed to a LIFELINKcentral AED program manager account, event data will also be sent to a state-owned CODE-STAT™ data review software system(s) if any have been pre-assigned in LIFENET to receive the case for post-event review. EMS systems may also manually push the event data to LIFENET Alert in a hospital if any are assigned in their service area.

Similarly, if the LIFEPAK CR2 is subscribed to a LIFENET account, the case will *automatically* be sent to any CODE-STAT system(s) that have been pre-assigned in LIFENET to receive the case for post-event review. The case also can be manually transferred to LIFENET Alert in a hospital that is assigned in their service area.

Q: Which versions of CODE-STAT can receive LIFEPAK CR2 cases?

A: CODE-STAT 10.1 or later.

Q: When AED Event Viewer detects a LIFEPAK CR2 in use, does it alert the user like LIFENET Alert?

A: No. However, AED Event Viewer users will receive an email notification if the user has set up an email in LIFENET.

Q: Is AED Event Viewer available for *all* LIFENET accounts to download?

A: Yes, please contact your Stryker APA for assistance with set up.

Q: Which operating system is required to run AED Event Viewer (e.g. Windows, iOS)?

A: Only Windows-based devices.

- Windows 7 (64 bit)
- Windows 10 (64 bit)
- No known issue with any Operating System newer than Windows XP
- LIFENET AED Event Viewer is not designed to support Microsoft Windows XP SP2 or earlier versions of the Windows operating system.

Q: How can I get AED Event Viewer if I don't have LIFENET?

A: AED Event Viewer is available free of charge to medical professionals with or without a LIFENET account. For agencies without a LIFENET account, Stryker can set up a LIFENET transmitting account that will enable the agency to download the AED Event Viewer app and access settings for account setup. However, it will not provide access to the full range of LIFENET features. The Stryker APA can assist in the implementation requirements for the agency needing AED Event Viewer, requesting Stryker's implementation team to set up the account and send access instructions.

Q: How can I transmit the ECG from AED Event Viewer into LIFENET Alert at a hospital?

A: The case is transferred from AED Event Viewer to LIFENET Alert with a 'forwarding button' and a drop-down menu of available hospitals (that have been set up in the agency's LIFENET account). The button is in the upper right corner of AED Event Viewer. This manual process is used for LIFEPAK CR2 devices subscribed to either LIFENET or LIFELINKcentral AED program manager. This feature is only available to medical professionals who can forward AED Event Viewer to the hospital.

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: LIFEPAK CR2 AED 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). cprCOACH™ Feedback Technology in *CR2* AED is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with AHA Guidelines for patients 1 year of age or older. AED 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 Electrodes and the LIFEPAK CR2 Lithium Battery.

CONTRAINDICATIONS: LIFEPAK CR2 AED is not indicated for patients who are conscious and responsive.

DANGER: Do not use LIFEPAK CR2 in presence of flammable gases or anesthetics.

WARNINGS: LIFEPAK CR2 AED delivers up to 360 joules of electrical energy. Unless used properly by following AED's visual and audio prompts, this electrical energy may cause serious injury or death. • When instructed EVERYONE CLEAR, do not touch AED, patient, electrode pads or any material/fluid in contact with patient. Make sure no one is touching patient when AED shocks patient. • Do not immerse AED in water or other fluids. Avoid spilling fluids on AED or its accessories. • Do not store in presence of flammable gases, anesthetics or in direct contact with flammable material. Use care when operating close to oxygen sources. Turn off gas source or move it away from patient during defibrillation. • Equipment operating in close proximity may emit strong electromagnetic interference (EMI) or radio frequency interference (RFI) which could affect performance of AED. • Keep AED away from magnetic resonance imaging (MRI) equipment as it is unsafe. • AED should not be used adjacent to or stacked with other equipment. • Do not touch patient and USB connector on back of AED simultaneously. • Replace battery immediately when AED indicates battery is low. • Use only accessories specified by Stryker. Using other manufacturers' accessories may cause AED to perform improperly and may invalidate safety agency certification. Contact authorized service personnel for repair. • QUIK-STEP electrode pads: Place pads so they adhere to skin completely. • Do not allow pads to touch each other or any material on patient's chest. • Do not use damaged, expired, or dried-out pads. Dried out or damaged pads may cause electrical arcing and skin burns during defibrillation. • Do not pull red handle to open electrodes until immediately before use. • QUIK-STEP electrodes provided with *CR2* are not compatible with LIFEPAK 500 device. Emergency medical personnel should not connect these electrodes to LIFEPAK 500 device.

CAUTIONS: Damaged batteries may leak and cause personal injury or equipment damage; handle with extreme care. • Do not open device lid unnecessarily as this will reduce internal battery power.

POTENTIAL ADVERSE EFFECTS (for example, complications): Failure to identify shockable arrhythmia • Failure to deliver a defibrillation shock in presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia, which may result in death or permanent injury • Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction • Myocardial damage • 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 electrode pad placement area • Allergic dermatitis due to sensitivity to materials used in electrode construction • Minor skin rash • Fire hazard in presence of high oxygen concentration or flammable anesthetic agents • EMI from AED impacting other devices especially during charge and energy transfers.

U.S. Federal law restricts this device to sale by or on the order of a physician.

Please consult Operating Instructions at strykeremergencycare.com or call 800.442.1142 for complete list of indications, contraindications, warnings, cautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

Stryker's AEDs require a prescription in the U.S. Please consult your physician. AED users should be trained in CPR and in the use of the AED.

Although not everyone can be saved, studies show that early defibrillation can dramatically improve survival rates. AEDs are indicated for use on adults and children. AEDs may be used on children weighing less than 25 kg (55 lbs) but some models require separate defibrillation electrodes.

The information presented is intended to demonstrate Stryker's product offerings. Refer to operating instructions for complete directions for use indications, contraindications, warnings, cautions, and potential adverse events, before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of Stryker's products in your area. Specifications subject to change without notice.

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