LIFEPAK® CR2 defibrillator with LIFELINKcentral™ AED program manager

Data sheet

Features

- Self-monitoring
- Wireless connectivity
- Fastest time to first shock[1]
- cprINSIGHT® analysis technology
- Layered, easy to follow design

Sudden cardiac arrest (SCA) can happen to anyone—anywhere. Immediate treatment is vital. A victim's chance of survival dramatically decreases for every minute without treatment.[2] That's why public access defibrillators are so important. They put lifesaving technology where it can do the most good. So when an emergency happens, you should have nothing less than the best.

- **Layered design**
  Layered design with easy-to-follow bold graphics. Both trained and untrained Automated External Defibrillator (AED) users clearly know how to begin.
- **QUIK-STEP® electrodes**
  Peel directly off the base for faster placement.
- **cprINSIGHT analysis technology**
  Enables the defibrillator to analyze the patient's heart rhythm while CPR is being performed.
- **Metronome and CPR coaching**
  Sets an effective pace and audibly guides users.
- **ClearVoice™ technology**
  Detects background noise and adjusts tones and voice prompts to ensure they can be heard clearly in noisy environments.
- **Fully automatic**
  Available in fully or semi-automatic models.
- **Highest available escalating energy**
  Up to 360J for more effective shocks as needed.
- **Bilingual**
  Toggle between two pre-set languages when using the device.
- **Child mode**
  Child mode delivers lower energy levels appropriate for young children without having to change electrodes.
- **LIFEPAK TOUGH™**
  IP55 rating for challenging environments.
- **8-year warranty**
  Backed by an 8-year warranty.
- **LIFELINKcentral AED program manager**
  Monitor AED programs by tracking AED status, sending patient data to emergency responders and hospitals, detecting AED locations and other tools.
- **Wireless Connectivity**
  Device can be purchased as a Wi-Fi only device, a 4G cellular device (that also has Wi-Fi) or as a USB version.

Specifications

Defibrillator

Waveform: Biphasic Truncated Exponential with voltage and duration compensation for patient impedance.

Patient impedance range: 10 – 300 ohms

Energy accuracy:
10% of the energy setting into 50 ohms 15% of the rated energy output into 25 – 175 ohms

Output energy sequence: Multiple levels, configurable from 150 joules to 360 joules.

Energy default: 200J, 300J, 360J (adult)
50J, 75J, 90J (pediatric)

Shock Advisory System™: An ECG analysis system that advises whether a shock is appropriate.

cprINSIGHT analysis technology: Enables the defibrillator to analyze the patient's heart rhythm while CPR is being performed.

CPR coaching: Instructions for adult and pediatric CPR, including feedback when no CPR is detected, rate and depth guidance, a metronome and instructions on hand placement.

Time to shock at 360J after CPR (with cprINSIGHT enabled):
- **Semi-automatic:** < 7 seconds
- **Fully automatic:** < 13 seconds

Charge time: 0 seconds for first 150J or 200J shock (as device is pre-charged). With cprINSIGHT enabled, subsequent shocks will be charged during CPR and ready to shock at the end of the CPR period.

Controls

Lid release/ON-OFF: Controls device power.

Shock button, semi-automatic: Delivers energy when button pressed by the user.

Shock button, fully automatic: Flashes prior to delivering shock without requiring user intervention.

Child Mode button: Allows operator to switch to Child Mode for reduced energy and CPR guidance appropriate for children.

Language button: Optional feature allows operator to switch between the primary and secondary languages for an optional multi-language configuration.

Electrical protection: Input protected against high voltage defibrillator pulses per IEC 60601-1/EN 60601-1.

Safety classification: Internally powered equipment. IEC 60601-1/EN 60601-1.

User interface

User interface: The user interface includes voice prompts and audible tones.

ClearVoice technology: Detects background noise and adjusts audio and voice prompts to ensure they can be heard clearly in noisy environments.

Device status indicators: Visual and audible indicators indicating system readiness (device, pads and battery).

Environmental

Note: All performance specifications defined assume the unit has been stored (two hours minimum) at operating temperature prior to operation.

Operating temperature: +32° to +122°F (0° to +50°C).

Storage temperature: -22° to +140°F (-30° to +60°C) with battery and electrodes, maximum exposure time limited to one week.

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

Altitude: -1,253 to 15,000 ft (-382 to 4,572 m).

Relative humidity: 5 to 95% (non-condensing).

Dust and water resistance: IEC 60529/EN 60529 IP55 with electrodes connected and battery installed.

Shock: IEC 60068-2-27, (40g, 11 ms pulse, ½ sine each axis).

Vibration: MIL-STD-810G, method 514.6, helicopter – category 14 and ground vehicle – category 20.

Physical characteristics

With handle, including electrodes and battery:
- **Height:** 3.8 in (9.7 cm)
- **Width:** 8.9 in (22.6 cm)
- **Depth:** 10.8 in (27.4 cm)
- **Weight:** 4.5 lb (2.0 kg)

Accessories

Primary battery:
- **Type:** Lithium manganese dioxide (Li/MnO_2), 12.0V, 4.7 amp-hours.
- **Capacity (at 20°C):** Will provide 166 200 joule shocks (with one minute of CPR between shocks) or 103 360 joules shocks (with one minute of CPR between shocks) or 800 minutes of operating time.
- **Standby life (assuming daily tests only):** A new battery provides device power for 4 years if installed in device that is not used.
- **Replace battery indication:** At least 6 shocks and 30 minutes of operating time remain when first indicated.
- **Weight:** 0.7 lb (0.3 kg)

Electrode pads:
- **Pads:** Can be used on both adult and pediatric patients.
- **Pads packaging:** User intuitive, rapid access electrodes.
- **Pads replacement:** Replace every 4 years or after each patient use.

Data storage

Memory type: Internal digital memory (flash RAM).

ECG storage: Minimum 60 minutes of ECG stored for two patient episodes.

Communications

Communications: USB, Wi-Fi 802.11b/g/n, 4G LTE cellular connectivity for data transfer to LIFELINKcentral AED program manager or LIFENET System.
- Wi-Fi Frequency Band: 2412-2472 MHz
- Wi-Fi Typical Power Output: 15dBm (ERP)
- Cellular Frequency Band: See IFU Cellular Specifications table
- Cellular Transmit Power Output: 25.59dBm (ERP)

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 Physio-Control or 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 **stryker.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.

If you purchased your LIFEPAK CR2 defibrillator from an authorized Stryker distributor or reseller, this distributor or reseller will have access to your LIFELINKcentral AED program manager account and may receive notifications prompted by the LIFEPAK CR2 defibrillator. Please note that this setting to notify your distributor or reseller can be disabled at ANY time: If you wish to disable this setting, please send a request to Stryker Customer Support to self-manage your site without notifications to your distributor or reseller.

For more information, visit **stryker.com** or call **800 323 2220** to learn more.

References: 1. Physio-Control Internal Semi-Automatic AED Comparison Usability Study, August 2016. **2.** Graham R, McCoy M, Schultz A. Strategies to Improve Cardiac Arrest Survival, A Time to Act. Institute of Medicine Report, 2015.

Physio-Control, Inc
Willows Road NE 11811
Redmond, WA, 98052 U.S.A
Toll free 800 442 1142

Stryker.com

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