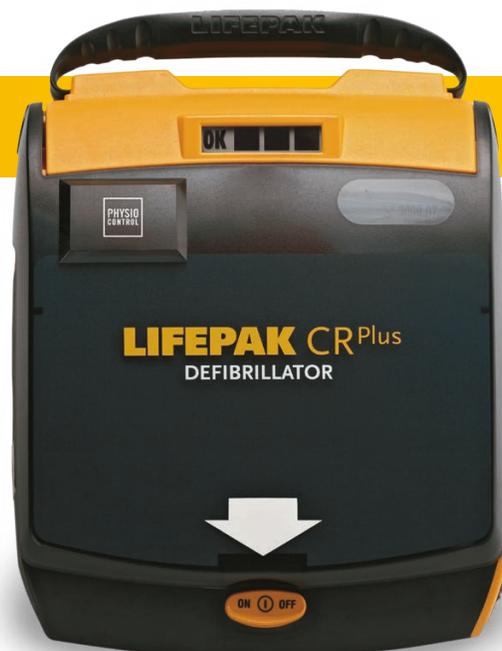


LIFEPAK CR[®] Plus Defibrillator

Data sheet

Make lifesaving simple

From a company with over 60 years of innovation, a steadfast commitment to quality and a position as the global leader in defibrillation, the LIFEPAK CR Plus automated external defibrillator (AED) is designed specifically for the first person to respond to a victim of sudden cardiac arrest and incorporates the same trusted technology used by more EMS and hospital units around the world than any other brand.



Simple to use

- Simple to turn on
- Simple to find, remove and place electrodes correctly
- Simple to deliver therapy—no shock button to push
- Simple to increase the chance for survival by automatically escalating energy up to 360 joules if needed¹

Simple to own

- The LIFEPAK CR Plus comes ready to use: Your purchase includes carry case, extra electrodes, CHARGE-PAK™ battery charger and Ambu® Res-Cue Mask® Kit
- Low total cost of ownership
- Simple transition to EMS teams who also use LIFEPAK® products

Simple to maintain

- One of the longest warranties in the industry at 8 years
- Synchronized CHARGE-PAK battery charger and electrode replacement cycle

Simply put...

Stryker's LIFEPAK CR Plus AED is the effective, safe and affordable choice.

Specifications*

Defibrillator

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

Output energy sequence: Multiple levels, configurable from 150 joules to 360 joules (200 joules min for Japan). Factory default settings of 200J, 300J, 360J.

Output energy accuracy: ±10% into 50 ohms, ±15% into 25 to 200 ohms.

Shock advisory system: An ECG analysis system that advises whether a shock is appropriate; meets rhythm recognition criteria specified in DF39.

The device charges for shock only when the Shock Advisory System advises defibrillation.

Device capacity:

Typical: Thirty (30) full discharges or 210 minutes of “on time” with a fully charged device.

Minimum: Twenty (20) full discharges or 140 minutes of “on time” with a fully charged device.

Shock charge time: Charge times with a fully charged device: 200 joules in less than 9 seconds, 360 joules in less than 15 seconds.

System recharge times: Recharge times with a fully discharged device: Able to deliver 6 shocks or provide 42 minutes of operating time after 24 hours of recharge time and 20 shocks or 140 minutes of operating time after 72 hours of recharge time with a new CHARGE-PAK at temperatures above 15° C (59° F).

Controls

Lid release/ON-OFF: Controls device power.

Shock button, semi-automatic: Delivers defibrillation energy. After electrodes are attached to a patient, the fully automatic version of the device delivers a shock, if appropriate, not requiring operator intervention.

Electrical protection : Input protected against high voltage defibrillator pulses per IEC60601-1/EN60601-1.

Safety classification: Internally powered equipment. IEC60601-1/EN60601-1.

Physical characteristics

Height: 10.7 cm (4.2 in).

Width: 20.3 cm (8.0 in).

Depth: 24.1 cm (9.5 in), excluding handle.

Weight: 2.0 kg (4.5 lb) with CHARGE-PAK and electrodes

User interface

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

Readiness display: The readiness display shows the device status.

OK indicator: Shows “OK” when the last self-test was completed successfully. When the “OK” indicator is visible, all other indicators are not visible. The “OK” indicator is not displayed during device operation.

CHARGE-PAK indicator: When displayed, replace the CHARGE-PAK battery charger.

Attention indicator: When first displayed, at least six (6) discharges or 42 minutes of operating time remain.

Service indicator: Service required when displayed.

Environmental

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

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

Long-term storage temperature: +15° to +35°C (59° to 95°F)

Short-term storage temperature: -40° to +70°C (-40° to 158°F) for a maximum of one week.

Atmospheric pressure: 760 mmHg to 429 mmHg, 0 to 15,000 feet above sea level.

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

Water resistance: IEC60529/EN60529 IPX4 “Splash proof” with electrodes connected, CHARGE-PAK installed.

Default settings

Energy sequence: Energy sequence is set to 200J, 300J, 360J.

Motion detection: The motion detection system is set to on during analysis.

Energy protocol: The energy protocol is set to increase energy only after a lower energy shock was unsuccessful.

Stack shocks: Stack shocks option is set to off.

Turn-On prompt: The turn-on prompt is set to provide voice prompts upon power on.

CPR time: The CPR Time is set to 120 seconds.

Voice prompt volume: The voice prompt volume is set to medium.

Accessories

CHARGE-PAK battery charger:

Type: Li/SO₂Cl₂ Lithium Sulfuryl Chloride, 12V, 1.5 amp-hours.

Replacement: Replace the CHARGE-PAK battery charger and QUIK-PAK™ electrodes packet after using the defibrillator, if the CHARGE-PAK symbol appears in the readiness display or when the Use By date is reached (typically 2 years).

Weight: 80.5 grams (0.18 lb).

QUIK-PAK electrode pads:

Pads: ECG is received from disposable defibrillation electrodes, standard placement (anterior-lateral).

Pads packaging: User intuitive, rapid release QUIK-PAK electrodes allow the electrode pads to be preconnected to the device and protected under a top cover.

Pads replacement: Replace every two (2) years.

Infant/child reduced energy defibrillation

Electrodes: For use on infants and children less than 8 years of age or less than 55 lbs (25kg).

Data storage

Memory type: Internal digital memory.

ECG storage: Dual patient data storage. Minimum 20 minutes of ECG stored for the current patient, summarized data stored for the previous patient.

Report types:

- Continuous ECG – A continuous patient ECG report.
- Continuous Summary report – A summary of critical resuscitation events and ECG waveform segments associated with these events.
- Event Log report – A report of time stamped markers, which reflect operator and device activity.
- Test Log report – A device self-test activity report.

Capacity: Minimum 200 time-stamped event log markers.

Communications: Wireless transfer to a personal computer.

Data review: Physio-Control provides an array of tools to meet customer needs for data viewing and analysis.

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

**The specifications apply from 25 to 200 ohms. Voltage compensation is limited to the voltage that would result in delivery of 360 joules into 50 ohms.

LIFEPAK CR Plus and LIFEPAK EXPRESS® Automated External Defibrillators (AEDs)

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE:

LIFEPAK CR® Plus and LIFEPAK EXPRESS® AEDs are indicated for use on patients in cardiac 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). LIFEPAK AEDs are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The AEDs may be used with QUIK-PAK™ defibrillation pads only on adults and children who are 8 years old or more, or who weigh more than 55 lbs (25 kg). The AEDs may be used on children who are less than 8 years old or weigh less than 55 lbs (25 kg) with Physio-Control Infant/Child Reduced Energy Defibrillation Electrodes. The AEDs may be used with the CHARGE-PAK™ battery charger.

CONTRAINDICATIONS:

Do not use LIFEPAK AEDs when the victim is conscious and responsive.

WARNINGS

AED:

- LIFEPAK AEDs deliver up to 360 joules of electrical energy. Unless properly used, this electrical energy may cause serious injury or death. Do not attempt to operate AED unless thoroughly familiar with the function of all controls, indicators, connectors, and accessories.
- When instructed “Do not touch patient,” “Stand by,” or “Everyone clear,” remain still, do not touch AED, patient, defibrillation pads or any material in contact with patient. Make sure no one is touching patient when AED shocks the patient.
- Performing CPR or otherwise handling or transporting the patient while AED is evaluating the heart rhythm can cause an incorrect or delayed diagnosis. Keep patient as still as possible.
- Do not immerse AED in water or other fluids. Avoid spilling any fluids on AED or its accessories.
- Do not use in presence of flammable gases or anesthetics. Use care when operating close to oxygen sources. Turn off gas source or move source away from patient during defibrillation.
- Contact authorized service personnel for repair.
- 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.
- Always keep a CHARGE-PAK battery charger in AED. Routinely check that AED is ready for use. Replace CHARGE-PAK battery charger and QUIK-PAK defibrillation pads after each use of AED. Insert only CHARGE-PAK battery charger into well of AED.

- Use only parts and accessories specified by Physio-Control or Stryker. Using other manufacturers' accessories may cause AED to perform improperly and will invalidate safety agency certification.
- Using damaged or expired accessories may cause AED to perform improperly and may injure the patient or user.

Defibrillation pads:

- Place defibrillation pads so they adhere to skin completely.
- Do not allow defibrillation pads to touch each other or any other material on patient's chest.
- Do not use damaged, expired, or dried-out defibrillation pads. If you cannot determine a child's age or weight, or if infant/child electrodes are not available, proceed with QUIK-PAK defibrillation pads.

CAUTIONS:

- If AED has been damaged, remove from use and contact qualified technician.
- Do not open device lid unnecessarily as this will reduce the internal battery power.

POTENTIAL ADVERSE EFFECTS

(for example, complications):

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), 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 the defibrillation pad placement area
- Allergic dermatitis due to sensitivity to materials used in defibrillation pad construction
- Minor skin rash
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- EMI from the 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 the Operating Instructions at www.strykeremergencycare.com or call 800.442.1142 for the complete list of indications, contraindications, warnings, cautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

Reference

1 Stiell IG, et al. *Circulation* 2007;115:1511-1517.

All claims valid as of January 2019.

For further information, please contact Stryker at 800.442.1142 (U.S.), 800.668.8323 (Canada) or visit our website at www.strykeremergencycare.com

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