LIFEPAK® 1000 defibrillator

Data sheet

Durability

- LIFEPAK TOUGH™
- Rigorously drop-tested
- Protective case and bumpers
- Designed to survive in a high-vibration environment
- IP55

Usability

- Simple, easy to use
- Large graphical or ECG display screen
- ClearVoice technology prompts
- Easy customization of settings to meet protocol needs

Clinical Effectiveness

- 360J biphasic
- 3-lead ECG monitoring capability
- Manual override
- cprMAX technology

Continuum of Care

- Easy transition to ALS care teams
- Compatible electrodes and energy levels with ALS LIFEPAK monitor/defibrillators
- Strong LIFEPAK brand

Specifications

Defibrillator

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

Waveform: Biphasic truncated exponential with voltage and duration compensation for patient impedance*.

Energy sequence: User configurable, 150 joules–360 joules. Default energy output settings are 200, 300, 360 joules. 360 joules for every shock thereafter.

Charge time: With new, nonrechargeable battery pack; 200 joules in less than 9 seconds (360 joules in less than 15 seconds).

3-Wire (Lead II) monitoring capability: (If ECG display option purchased). Requires purchase of 3-wire (Lead II) monitoring cable and LIFE-PATCH® electrodes.

Device software: Field upgradeable.

Infant/Child reduced energy defibrillation electrodes: Reduces selected energy by a factor of 4. Intended for use only with children up to 8 years of age or 55 lbs (25 kg).

Safety classification: Internally powered equipment IEC 60601-1.

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

*Voltage compensation is limited to the voltage that would result in delivery of 360 joules into 50 ohms.

Device settings

Modes:

- **AED** – Provides operating capability for basic users.
- **Manual** – Provides operating capability for advanced users.
- **ECG** – Provides ECG display capability with 3-wire ECG cable.
- **Setup** – Allows user to configure the device.
- **Data transfer** – Allows user to transfer patient data.
- **Auto test** – Provides daily automatic tests of hardware and software.

Controls: On/Off, Shock, Menu, Two (2) configurable soft keys.

User defined options:

- **Device ID** – Assigns unique identifier to particular device.
- **Energy sequence** – User configurable from 150 to 360 joules.
- **Flexible energy** – Increases only after a lower energy was unsuccessful.
- **Auto analyze** – User can configure device to auto analyze, auto analyze after first shock, or prompt user to push analyze key before each analysis period.
- **CPR time** – (Post shock or after no shock advised) User configurable – 15, 30, 45, 60, 90, 120, 180 seconds.
- **Device date/time**
- **Voice prompt volume** – Allows user to change speaker volume.
- **ECG display** – (If option purchased) – Turns display on/off for AED mode.
- **Motion detection** – User defined On/Off (default On).
- **Service alert** – Audio alarm if the device needs servicing. Configurable on/off.
- **Manual access** – (If ECG display option purchased) – Devices configured with an ECG display may be set up to allow user to initiate a charge and shock without analysis.

cprMAX technology settings:

- **Initial CPR** – User defined time for CPR after first analysis regardless of analysis decision. Can be set to OFF, 15, 30, 45, 60, 90, 120 and 180 seconds.
- **Pre-shock CPR** – Allows for CPR while device is charging. Can be set to OFF, 15, or 30 seconds.
- **Stacked shocks** – (ON/OFF) When Off, allows for provision of CPR after each shock.
- **Pulse check** – (Always, After Every NSA, After Second NSA, Never) Allows device to prompt for a pulse check either after each shock, after every NSA pulse check, or never prompt for a pulse check (default Never).

Specifications cont.

Display

Backlit LCD displays number of shocks delivered, elapsed time, text and graphics of heart rhythm and optional ECG.

Size: 4.7 in (120mm) x 3.5 in (89 mm).

Frequency response: 0.55 Hz to 21 Hz (-3 dB), nominal

ECG option:

- **Waveform sweep speed** – 25 mm/sec for ECG, nominal.
- **Waveform viewing time** – Minimum 4 seconds.
- **Waveform amplitude** – 1 cm/mV, nominal.
- **Heart rate** – 20 to 300 BPM digital display, Display "---" if heart rate is less than 20 bpm. Heart symbol flashes for each QRS detection.

ECG information is received from the adult and Infant/Child electrodes in anterior-lateral or anterior-posterior positions. A 3-wire cable can be used for ECG monitoring (Lead II).

Environmental

One hour operating temperature (from room temperature to temperature extreme, one hour duration): -4 to +140°F (-20 to 60°C).

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 limited to 7 days).

Atmospheric pressure: 575 hPa to 1060 hPa (15,000 to -1253 feet; 4572 to -382 meters).

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

Dust/water resistance: IP55 with battery and REDI-PAK™ electrodes installed (IEC 60529/EN 60529).

Bump: 15 g, 1000 bumps (IEC 600-68-2-29).

Shock: 40 g peak, 15-23 ms, 45 Hz cross over frequency.

Drop: 1 meter drop on each corner, edge and surface (MIL-STD-810F, 516.5, Procedure IV).

Vibration: Random vibration test – MIL-STD-810F, Method 514.5, Category 20; Ground vehicle 3.15 g rms 1 hour per axis.

EMI:

- **Radiated** – IEC 60601-2-4, IEC60601-1-2, CISPR 11 Class B Group 1.
- **Immunity** – IEC 60601-2-4, IEC 60601-1-2; IEC 61000-4-2 (Level 4), IEC 61000-4-3, IEC 61000-4-6, IEC 61000-4-8.

Event documentation and communication

Memory capacity: Dual patient storage. Minimum 40 minutes ECG for current patient. Summarized data for previous patient.

Report types: Continuous ECG, summary (critical resuscitation events and associated waveforms), event log report (report of time stamped entries reflecting operator and device activity), test log report (self test activity report).

Capacity: Minimum 100 time stamped event log entries.

Data review: CODE-STAT™ 6.1 Medical Informatics System, DT Express™ 2.1 Information Management System or higher.

Communications: Infrared wireless transfer to personal computer.

Battery and readiness display

Note: See operating instructions for information on battery care.

Nonrechargeable battery:

- **Type** – Lithium manganese dioxide (Li/MnO_2), 12.0 V, 4.5 Ah
- **Capacity** – Typically will provide 440 200-joule discharges or 1030 minutes of operating time with a new battery (370 200-joule shocks or 900 minutes of operating time at 32°F (0°C)).
- **Weight** – 1.0 lb (0.45 kg)
- **Shelf life** – (prior to installation) After the battery is stored for 5 years at 68°F to 86°F (20° to 30°C), the device will provide 48 months of standby life.
- **Standby life** – A new battery provides device power for 5 years.
- **Low battery indicator** – At least 30 200-joule shocks or 75 minutes of operating time remain when low battery is first indicated.

Rechargeable battery:

- **Type** – Lithium-ion, 11.1 V, 4.8 Ah, 53 Wh
- **Capacity** – Typically will provide 261 200-joule discharges or 608 minutes of operating time with a new fully-charged battery (247 200-joule shocks or 576 minutes of operating time at 32°F (0°C)).
- **Battery charging time** – Within 4.5 hours
- **Weight** – 1.0 lb (0.45 kg), maximum
- **Standby Life** – A new fully-charged battery provides device power for 6 months.
- **Low battery indicator** – At least 30 200-joule shocks or 75 minutes of operating time remain when low battery is first indicated.

Battery charger:

- **Supported battery** – Lithium-ion rechargeable battery, 11.1 V, 4.8 Ah, 53 Wh
- **Electrical** – External power supply: 100-240VAC, 50/60Hz
- **Temperature** – Operating: 32°F to 104°F (0°C to 40°C); Storage: -22°F to 158°F (-30°C to 70°C)
- **Charge time** – Within 4.5 hours
- **Charge** – Constant current/constant voltage within temperature limits
- **Length** – 270 mm
- **Width** – 97 mm
- **Height** – 92 mm
- **Weight** – 0.5 kg

Physical characteristics

Height: 3.4 in (8.7 cm).

Width: 9.2 in (23.4 cm).

Depth: 10.9 in (27.7 cm).

Weight: 7.1 lbs (3.2 kg) with one set of REDI-PAK electrodes and one nonrechargeable battery.

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE:
DEFIBRILLATION is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. LIFEPAK 1000 is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation. LIFEPAK 1000 may be used with standard defibrillation pads only on adults and children who are 8 years old or more or who weigh more than 25 kg (55 lbs). LIFEPAK 1000 may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes. **ECG MONITORING** is for use on conscious and unconscious patients of all ages for the purpose of ECG rhythm recognition and heart rate monitoring.

CONTRAINDICATIONS: None.

OPERATOR CONSIDERATIONS:
LIFEPAK 1000 requires operator interaction to defibrillate patient. It is intended for use by personnel who are authorized by a physician or medical director and have, at a minimum, the following skills and training: CPR training, defibrillator training equivalent to that recommended by American Heart Association, and training in the use of the LIFEPAK 1000 defibrillator. LIFEPAK 1000 is intended for use in hospital and out-of-hospital environments. Manual mode is intended for use by personnel trained in ECG recognition who want to use defibrillator to deliver a shock independent of AED mode. Operator has control over charging and delivery of shocks. ECG mode provides a nondiagnostic ECG display and is intended for use by personnel trained in ECG recognition to allow for rhythm and heart rate monitoring using standard ECG electrodes. When in ECG mode, the defibrillator's shock capability is disabled; however, LIFEPAK 1000 continues to analyze patient's ECG for potentially shockable rhythm.

GENERAL/DEFIBRILLATION WARNINGS.
SHOCK HAZARDS:
- LIFEPAK 1000 delivers up to 360 joules of electrical energy. Unless properly used, this electrical energy may cause serious injury or death. Do not attempt to operate unless thoroughly familiar with operating instructions and function of all controls, indicators, connections, and accessories.
- Clear everyone away from contact with patient, bed, and other conductive material before discharging defibrillator.
- When discharging defibrillator, do not touch electrodes.
- Do not immerse defibrillator in water or other fluids. Avoid spilling fluids on device or accessories.
- Do not disassemble defibrillator or its batteries. Contact authorized service personnel for repair.

Possible skin burns and ineffective energy delivery:
- Dried out or damaged electrodes may cause electrical arcing and patient skin burns during defibrillation. Do not use electrodes that have been removed from foil package for >24 hours or expired electrodes. Check that electrode adhesive is intact and undamaged.

Possible misinterpretation of ECG data:
- Do not analyze in a moving vehicle or move the AED during analysis. Motion artifact may affect ECG signal resulting in inappropriate shock or no shock advised message. Motion detection may delay analysis. Stop vehicle.
- Do not touch the patient or the AED during analysis.

Excessive Energy Delivery (AED mode):
- Do not use Pediatric QUIK-COMBO® electrodes; these electrodes do not attenuate the energy delivery by LIFEPAK 1000.

Implanted electrical devices:
- Defibrillation may interfere with implanted devices and cause them to malfunction. Place therapy electrodes away from implanted devices if possible.

Possible defibrillator shutdown:
- Always have access to spare, fully-charged, properly maintained battery to avoid possible device shutdown without warning.
- Replace battery when LIFEPAK 1000 displays warning of REPLACE BATTERY.

Possible device failure:
- Do not modify LIFEPAK 1000 or its batteries.

Possible explosion, fire, noxious gas or burns:
- Do not use device 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.

Possible electrical interference or improper device performance:
- Use only parts and accessories specified by Physio-Control or Stryker. Using other manufacturers' accessories may affect performance of device or equipment in close proximity and may invalidate safety agency certification.
- Defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers which may affect performance of equipment operating in close proximity.
- Equipment operating in close proximity may emit strong EMI or radio frequency interference (RFI) which could affect performance of device.
- Recommended distances of equipment provided in Operating Instructions.
- Safety risk and possible equipment damage.
- Keep AED away from magnetic resonance imaging (MRI) equipment as it is unsafe.

ECG MONITORING (ECG MODE) WARNINGS.
Possible delay in therapy:
- Do not attempt to connect 3-wire ECG cable to QUIK-COMBO therapy cable or any other AED.
- ECG cable is functional only with LIFEPAK 1000.

Possible misinterpretation of ECG data:
- Frequency response of screen intended only for basic ECG rhythm identification; it does not provide resolution required for pacemaker pulse visibility, accurate measurements, such as QRS duration, and ST segment interpretation. For such purposes, use ECG monitors with appropriate frequency response.

GENERAL CAUTION:
Possible equipment damage:
- Before using LIFEPAK 1000 disconnect all equipment that is not defibrillator-protected from patient.

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

Please consult Operating Instructions at www.physio-control.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.

For further information, please contact Stryker at 800 442 1142 (U.S.), 800 668 8323 (Canada) or visit our website at strykeremergencycare.com

Emergency Care

This document is intended solely for the use of healthcare professionals. A healthcare professional must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that healthcare professionals be trained in the use of any particular product before using it.

The information presented is intended to demonstrate Stryker's product offerings. A healthcare professional must always 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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