LIFEPAK® 15 monitor/defibrillator

Data sheet

Ease of use

- More than 20 clearly labeled, dedicated buttons
- Front-facing cables, connectors, and 100mm printer

Clinical effectiveness

- 360J biphasic
- ST-segment trending
- University of Glasgow 12-Lead ECG Analysis Program

Durability

- LIFEPAK TOUGH™
- Dual-layer screen protector
- Large, shock absorbing handle

Reliability

- Upgradeable platform
- Daily, 3AM diagnostic self-test

Specifications

General

The LIFEPAK 15 monitor/defibrillator has six main operating modes:

AED mode: for automated ECG analysis and a prompted treatment protocol for patients in cardiac arrest.

Manual mode: for performing manual defibrillation, synchronized cardioversion, noninvasive pacing, and ECG and vital sign monitoring.

Archive mode: for accessing stored patient information.

Setup mode: for changing default settings of the operating functions.

Service mode: for authorized personnel to perform diagnostic tests and calibrations.

Demo mode: for simulated waveforms and trend graphs for demonstration purposes.

Physical characteristics

Weight:

- Basic monitor/defibrillator with new roll paper and two batteries installed: 17.5 lb (7.9 kg)
- Fully featured monitor/defibrillator with new roll paper and two batteries installed: 18.5 lb (8.4 kg)

Lithium-ion battery: ≤1.3 lb (0.6 kg)

Accessory bags and shoulder strap: 3.9 lb (1.77 kg)

Standard (hard) paddles: 2.1 lb (0.95 kg)

Height: 12.5 in (31.7 cm)

Width: 15.8 in (40.1 cm)

Depth: 9.1 in (23.1 cm)

Display

Size (active viewing area): 8.4 in (212 mm) diagonal; 6.7 in (171 mm) wide x 5.0 in (128 mm) high

Resolution: display type 640 dot x 480 dot color backlit LCD

User selectable display mode: full color or SunVue™ display high contrast

Display: a minimum of 5 seconds of ECG and alpha-numerics for values, device instructions, or prompts

Display: up to three waveforms

Waveform display sweep speed: 25 mm/sec for ECG, SpO_2, IP, and 12.5 mm/sec for CO_2

Data management

The device captures and stores patient data, events (including waveforms and annotations), and continuous waveform and patient impedance records in internal memory.

The user can select and print reports, and transfer the stored information via supported communication methods.

Report types:

- Three format types of CODE SUMMARY™ critical event record: short, medium, and long
- 12-lead ECG with STEMI statements
- Continuous Waveform (transfer only)
- Trend Summary
- Vital Sign Summary
- Snapshot

Memory capacity: Total capacity is 360 minutes of continuous ECG, 90 minutes of continuous data from all channels, or 400 single waveform events.

Maximum memory capacity for a single patient includes up to 200 single waveform reports and 90 minutes of continuous ECG.

Communications

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.

- Serial Port RS232 communication + 12V available
- Limited to devices drawing maximum 0.5 A current
- Bluetooth® technology provides short-range wireless communication with other Bluetooth-enabled devices

Monitor

ECG

ECG is monitored via several cable arrangements:

A 3-wire cable is used for 3-lead ECG monitoring.

A 5-wire cable is used for 7-lead ECG monitoring.

A 10-wire cable is used for 12-lead ECG acquisition. When the chest electrodes are removed, the 10-wire cable functions as a 4-wire cable.

Standard paddles or QUIK-COMBO pacing/defibrillation/ECG electrodes are used for paddles lead monitoring.

Frequency response:

- Monitor: 0.5 to 40 Hz or 1 to 30 Hz
- Paddles: 2.5 to 30 Hz
- 12-lead ECG diagnostic: 0.05 to 150 Hz

Lead selection:

- Leads I, II, III, (3-wire ECG cable)
- Leads I, II, III, AVR, AVL, and AVF acquired simultaneously (4-wire ECG cable)
- Leads I, II, III, AVR, AVL, AVF, and C lead acquired simultaneously (5-wire ECG cable)
- Leads I, II, III, AVR, AVL, AVF, V1,V2,V3,V4,V5, and V6 acquired simultaneously (10-wire ECG cable)

ECG size: 4, 3, 2.5, 2, 1.5, 1, 0.5, 0.25 cm/mV (fixed at 1 cm/mV for 12-lead)

Specifications cont.

Heart rate display:
- 20–300 bpm digital display
- Accuracy: ±4% or ±3 bpm, whichever is greater
- QRS Detection Range Duration: 40 to 120 msec
- Amplitude: 0.5 to 5.0 m

Common mode rejection (CMRR): ECG Leads: 90 dB at 50/60 Hz

$Sp0_2$/SpC0/SpMet

Sensors:
- MASIMO® sensors including RAINBOW® sensors
- NELLCOR® sensors when used with the MASIMO RED™ MNC adapter

$Sp0_2$

Displayed saturation range: "<50" for levels below 50%; 50 to 100%

Saturation accuracy: 70–100% (0–69% unspecified)

Adults/pediatrics:
±2 digits (during no motion conditions)
±3 digits (during motion conditions)

Dynamic signal strength bar graph

Pulse tone as $Sp0_2$ pulsations are detected

$Sp0_2$ update averaging rate user selectable: 4, 8, 12 or 16 seconds

$Sp0_2$ sensitivity user selectable: Normal, High

$Sp0_2$ measurement: Functional $Sp0_2$ values are displayed and stored

Pulse rate range: 25 to 240 bpm

Pulse rate accuracy (adults/pediatrics):
±3 digits (during no motion conditions)
±5 digits (during motion conditions)

Optional $Sp0_2$ waveform display with autogain control

SpC0®

SpC0 concentration display range: 0 to 40%

SpC0 accuracy: ±3 digits

SpMET®

SpMet saturation range: 0 to 15.0%

SpMet display resolution: 0.1% up to 10%

SpMet accuracy: ±1 digit

NIBP

Blood pressure systolic pressure range: 30 to 255 mmHg

Diastolic pressure range: 15 to 220 mmHg

Mean arterial pressure range: 20 to 235 mmHg

Units: mmHg

Blood pressure accuracy: ±5 mmHg

Blood pressure measurement time: 20 seconds, typical (excluding cuff inflation time)

Pulse rate range: 30 to 240 pulses per minute

Pulse rate accuracy: ±2 pulses per minute or ±2%, whichever is greater

Operation features initial cuff pressure: User selectable, 80 to 180 mmHg

Automatic measurement time interval: User selectable, from 2 min to 60 min

Automatic cuff deflation excessive pressure: If cuff pressure exceeds 290 mmHg

Excessive time: If measurement time exceeds 120 seconds

CO_2

CO_2 range: 0 to 99 mmHg (0 to 13.2 kPa)

Units: mmHg, %, or kPa

Respiration rate accuracy:
- 0 to 70 bpm: ±1 bpm
- 71 to 99 bpm: ±2 bpm

Respiration rate range: 0 to 99 breaths/minute

Rise time: 190 msec

Response time: 4.3 seconds (includes delay time and rise time)

Initialization time: 30 seconds (typical), 10-180 seconds

Ambient pressure: automatically compensated internally

Optional display: CO_2 pressure waveform
- Scale factors: Autoscale, 0–20 mmHg (0–4 Vol%), 0–50 mmHg (0–7 Vol%), 0–100 mmHg (0–14 Vol%)

Invasive pressure

Transducer type: Strain-gauge resistive bridge

Transducer Sensitivity: 5μV/V/mmHg

Excitation voltage: 5 Vdc

Connector: Electro Shield: CXS 3102A 14S-6S

Bandwidth: Digital filtered, DC to 30 Hz (< -3db)

Zero drift: 1 mmHg/hr without transducer drift

Zero adjustment: ±150 mmHg including transducer offset

Numeric accuracy: ±1 mmHg or 2% of reading, whichever is greater, plus transducer error

Pressure range: -30 to 300 mmHg, in six user selectable ranges

Invasive pressure display

Display: IP waveform and numerics

Units: mmHg

Labels: P1 or P2, ART, PA, CVP, ICP, LAP (user selectable)

Temperature

Range: 76.6° to 113.4°F (24.8° to 45.2°C)

Resolution: 0.1°C

Accuracy: ±0.2°C including sensor

Reusable temperature cable: 5 foot or 10 foot

Disposable sensor types: Surface–Skin; Esophageal/Rectal

Trend

Time scale: Auto, 30 minutes, 1, 2, 4, or 8 hours

Duration: Up to 8 hours

ST segment: After initial 12-lead ECG analysis, automatically selects and trends ECG lead with the greatest ST displacement

Display choice of: HR, PR (SpO_2), PR (NIBP), SpO_2 (%), SpCO (%), SpMet (%), CO_2 ($EtCO_2$/$FiCO_2$), RR (CO_2), NIBP, IP1, IP2, ST

Alarms

Quick set: Activates alarms for all active vital signs

VF/VT alarm: Activates continuous (CPSS) monitoring in Manual mode

No breath alarm: Occurs when 30 seconds has elapsed since last detected respiration

Heart rate alarm limit range: Upper, 100–250 bpm; lower, 30–150 bpm

Interpretive algorithm

12-Lead interpretive algorithm: University of Glasgow 12-Lead ECG Analysis Program, includes AMI and STEMI statements

Printer

Prints continuous strip of the displayed patient information and reports

Paper size: 3.9 in (100 mm)

Print speed: 25 mm/sec or 12.5 mm/sec
- Optional: 50 mm/sec time base for 12-lead ECG reports

Delay: 8 seconds

Autoprint: Waveform events print automatically

Frequency response:
- Diagnostic: 0.05 to 150 Hz or 0.05 to 40 Hz
- Monitor: 0.67 to 40 Hz or 1 to 30 Hz

Defibrillator

Biphasic waveform: Biphasic Truncated Exponential

The following specifications apply from 25 to 200 ohms, unless otherwise specified:

Energy accuracy: ±1 joule or 10% of setting, whichever is greater, into 50 ohms, ±2 joules or 15% of setting, whichever is greater, into 25-175 ohms.

Voltage compensation: Active when disposable therapy electrodes are attached. Energy output within ±5% or ±1 joule, whichever is greater, of 50 ohms value, limited to the available energy which results in the delivery of 360 joules into 50 ohms.

Paddle options: QUIK-COMBO® pacing/defibrillation/ECG electrodes (standard). Cable Length 8 foot long (2.4 m) QUIK-COMBO cable (not including electrode assembly).

Standard paddles (optional)

Manual mode

Energy select: 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, and 360 joules

Charge time: Charge time to 360 joules in less than 10 seconds, typical

Synchronous cardioversion: Energy transfer begins within 60 msec of the QRS peak

Paddles leads off sensing: When using QUIK-COMBO electrodes, the device indicates Paddles Leads Off if the resistive part of the patient impedance is greater than 300 ±15% ohms, or if the magnitude of the patient impedance is greater than 440 ±15% ohms.

AED Mode

Shock Advisory System™ (SAS): an ECG analysis system that advises the operator if the algorithm detects a shockable or non-shockable ECG rhythm. SAS acquires ECG via therapy electrodes only.

Shock ready time: Using a fully charged battery at normal room temperature, the device is ready to shock within 20 seconds if the initial rhythm finding is "SHOCK ADVISED"

Biphasic output: Energy Shock levels ranging from 150–360 joules with same or greater energy level for each successive shock

cprMAX™ Technology: In AED mode, cprMAX™ technology provides a method of maximizing the CPR time that a patient receives, with the overall goal of improving the rate of survival of patients treated with AEDs.

Setup options:
- Auto Analyze: Allows for auto analysis. Options are OFF, AFTER 1ST SHOCK
- Initial CPR: Allows the user to be prompted for CPR for a period of time prior to other activity. Options are OFF, ANALYZE FIRST, CPR FIRST
- Initial CPR Time: Time interval for Initial CPR. Options are 15, 30, 45, 60, 90, 120, and 180 seconds.
- Pre-Shock CPR: Allows the user to be prompted for CPR while the device is charging. Options are OFF, 15, 30 seconds.
- Pulse Check: Allows the user to be prompted for a pulse check at various times. Options are ALWAYS, AFTER EVERY SECOND NSA, AFTER EVERY NSA, NEVER

- Stacked Shocks: Allows for CPR after 3 consecutive shocks or after a single shock. Options are OFF, ON
- CPR Time: 1 or 2 User selectable times for CPR. Options are 15, 30, 45, 60, 90, 120, 180 seconds and 30 minutes.

Pacer

Pacing mode: Demand or non-demand rate and current defaults

Pacing rate: 40 to 170 PPM

Rate accuracy: ±1.5% over entire range

Output waveform: Monophasic, truncated exponential current pulse (20 ± 1 ms)

Output current: 0 to 200 mA

Pause: Pacing pulse frequency reduced by a factor of 4 when activated

Refractory period: 180 to 270 msec (function of rate)

Environmental

Unit meets functional requirements during exposure to the following environments unless otherwise stated.

Operating temperature: 32° to 113°F (0° to 45°C); -4°F (-20°C) for 1 hour after storage at room temperature; 140°F (60°C) for 1 hour after storage at room temperature

Storage temperature: -4° to 149°F (-20° to 65°C) except therapy electrodes and batteries

Relative humidity, operating: 5 to 95%, non-condensing. NIBP: 15 to 95%, non-condensing

Relative humidity, storage: 10 to 95%, non-condensing

Atmospheric pressure, operating: -1,253 to 15,000 ft (-382 to 4,572 m). NIBP: -500 to 10,000 ft (-152 to 3,048 m)

Water resistance, operating: IP44 (dust and splash resistance) per IEC 529 and EN 1789 (without accessories except for 12-lead ECG cable, hard paddles, and battery pack)

Vibration: MIL-STD-810E Method 514.4, Propeller Aircraft - category 4 (figure 514.4-7 spectrum a), Helicopter - category 6 (3.75 Grms), Ground Mobile - category 8 (3.14 Grms), EN 1789: Sinusoidal Sweep, 1 octave/min, 10-150 Hz, ±0.15 mm/2 g

Shock (drop): 5 drops on each side from 18 inches onto a steel surface EN 1789: 30-inch drop onto each of 6 surfaces

Shock (functional): Meets IEC 60068-2-27 and MIL-STD-810E shock requirements 3 shocks per face at 40 g, 6 ms half-sine pulses

Bump: 1000 bumps at 15 g with pulse duration of 6 msec

Impact, non-operating: EN 60601-1 0.5 + 0.05 joule impact UL 60601-1 6.78 Nm impact with 2-inch diameter steel ball. Meets IEC62262 protection level IK 04.

EMC: EN 60601-1-2:2006 Medical Equipment -General Requirements for Safety - Collateral **Standard:** Electromagnetic Compatibility - Requirements and Tests EN 60601-2-4:2003: (Clause 36) Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator-Monitors

Cleaning: Cleaning 20 times with the following: Quaternary ammonium, isopropyl alcohol, hydrogen peroxide

Chemical resistance: 60 hour exposure to specified chemicals: Betadine (10% Povidone-Iodine solution), Coffee, Cola, Dextrose (5% Glucose solution), Electrode Gel/Paste (98% water, 2% Carbopol 940), HCL (0.5% solution, pH=1), Isopropyl Alcohol, NaCl solution (0.9% solution), Cosmetic discoloration of the paddle well shorting bar shall be allowed following exposure to HCL (0.5% solution).

Power

Power adapters: AC or DC

Power Adapters provide operation and battery charging from external AC or DC power

- Full functionality with or without batteries when connected to external AC/DC
- Typical battery charge time while installed in LIFEPAK 15 device is 190 minutes
- Indicators: external power indicator, battery charging indicator

Dual battery: Capability with automatic switching

Low battery indication and message: Low battery fuel gauge indication and low battery message in status area for each battery

Replace battery indication and message: Replace battery fuel gauge indication, audio tones and replace battery message in the status area for each battery. When replace battery is indicated, device auto-switches to second battery. When both batteries reach replace battery condition, a voice prompt instructs user to replace battery.

Battery capacity

For two, new fully-charged batteries, 68°F (20°C)

Operating mode		Monitoring (minutes)	Pacing (minutes)	Defibrillation (360J discharges)
Total capacity to shutdown	Typical	360	340	420
	Minimum	340	320	400
Capacity after low battery	Typical	21	20	30
	Minimum	12	10	6

Battery

Battery specifications

Battery type: Lithium-ion

Weight: ≤1.3 lb (0.6 kg)

Charge time (with fully depleted battery): < 190 minutes (typical)

Battery indicators: Each battery has a fuel gauge that indicates its approximate charge. A fuel gauge that shows two or fewer LEDs after a charge cycle indicates that the battery should be replaced.

Charging temperature range: 41° to 113°F (5° to 45°C)

Operating temperature range: 32° to 113°F (0° to 45°C)

Short term (<1 week) storage temperature range: -4° to 140°F (-20° to 60°C)

Long term (>1 week) storage temperature range: 68° to 77°F (20° to 25°C)

Operating and storage humidity range: 5 to 95% relative humidity, non-condensing

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

LIFEPAK 15 is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols.

INTENDED USE: LIFEPAK 15 intended for use by trained medical personnel out-of-doors, in indoor emergency care settings, and is designed to be used for ground transportation. Monitoring and therapy functions may only be used on one patient at a time. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients. Automated external defibrillation (AED) mode intended for use on patients ≥ 8 years of age.

INDICATIONS FOR USE – MANUAL DEFIBRILLATION: Indicated for termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of energy in synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia and, in relatively stable patients, ventricular tachycardia.

CONTRAINDICATIONS - MANUAL DEFIBRILLATION: Contraindicated in treatment of PEA and asystole. AED MODE: To be used only on patients in cardiopulmonary arrest. Patient must be unconscious, pulseless, and not breathing normally before using defibrillator to analyze patient's ECG rhythm. In AED mode, the LIFEPAK 15 is intended for use on pediatric patients ≥ 8 years of age.

CONTRAINDICATIONS - AED MODE: None known.

INDICATIONS FOR USE – MONITORING. AQUIRING 12-LEAD ECG: 12-lead electrocardiogram used to identify, diagnose, and treat patients with cardiac disorders and is useful in early detection and prompt treatment of patients with STEMI.

MONITORING SPO2, SPCO, AND SPMET: Pulse oximetry indicated for use in any patient who is at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglobinemia. SpO2 monitoring may be used during no motion and motion conditions, and in patients who are well or poorly perfused. SpCO and SpMet accuracies have not been validated under motion or low perfusion conditions.

MONITORING NONINVASIVE BLOOD PRESSURE: Intended for detection of hypertension or hypotension and monitoring blood pressure trends in patient conditions. NIBP monitoring not indicated for neonatal patients <1-month-old.

MONITORING ETCO2: Used to detect trends in level of expired CO2, used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care

MONITORING INVASIVE PRESSURE: Indicated for use in patients who require continuous monitoring of physiological pressures to rapidly assess changes in patient's condition or response to therapy. May also be used to aid diagnosis

MONITORING CONTINUOUS TEMPERATURE: Indicated for use in patients who require continuous monitoring of body temperature.

MONITORING CONTRAINDICATIONS: None known

Operating Instructions provide important information to help you operate LIFEPAK 15. Become familiar with all terms and warnings. GENERAL DANGER: Explosion hazard

GENERAL/THERAPY/MANUAL DEFIBRILLATION WARNINGS and CAUTION: Shock or fire hazards • Possible patient skin burns and ineffective energy delivery • Possible device failure, damage, inability to deliver therapy, shutdown, loss of power during patient care, improper device performance • Possible electrical interference with device performance or with other equipment • Safety risk • Failure to detect change in ECG rhythm • Possible failure to detect out of range condition • Possible interference with implanted electrical device • Possible paddle damage • Possible incorrect energy delivery

CPR METRONOME WARNING: CPR delivered when not needed

SYNCHRONIZED CARDIOVERSION WARNING: Possible lethal arrhythmia

NONINVASIVE PACING WARNING: Possible inability to pace, interruption of therapy, ineffective pacing, and patient skin burns

PEDIATRIC ECG MONITORING AND MANUAL MODE THERAPY: Possible patient skin burns

AED WARNINGS: Possible misinterpretation of data or ECG misinterpretation • Pediatric patient safety risk

ECG MONITORING WARNING: Possible misinterpretation of ECG data

12-LEAD ECG WARNINGS: Possible inability to obtain diagnostic quality 12-lead ECG or inaccurate diagnosis • Possible incorrect treatment with reperfusion therapy

SPO2, SPCO, AND SPMET WARNINGS AND CAUTION: Shock or burn hazard • Inaccurate pulse oximeter readings • Possible skin injury • Possible strangulation • Inaccurate SPO2, SPCO and/or SPMET readings • Possible equipment damage

NIBP MONITORING WARNINGS AND CAUTION: Possible loss of IV access and inaccurate infusion rate, circulation impairment or inaccurate blood pressure or oxygen saturation readings • Possible patient harm • Equipment damage

ETCO2 MONITORING WARNINGS AND CAUTION: Fire hazard • Possible inaccurate patient assessment or inaccurate CO2 readings • Possible strangulation • Infection hazard • Possible equipment damage

IP MONITORING WARNINGS: Possible inaccurate pressure readings, air embolism, blood loss or loss of sterility • Possible patient injury or equipment damage • Possible lethal arrhythmia • Increased intracranial pressure

TEMPERATURE MONITORING WARNINGS: Possible inaccurate temperature readings • Infection hazard • Possible strangulation

VITAL SIGN/ST SEGMENT TRENDS WARNING: Inaccurate interpretation of patient status

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

Please consult Operating Instructions at www.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.

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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