

# LIFEPAK<sup>®</sup> 15

## monitor/defibrillator



**For emergency medical services**



When you respond to emergencies, you need the most advanced monitor/defibrillator that sets the standard in innovation, operations and toughness.





## The LIFEPAK 15 monitor/defibrillator delivers

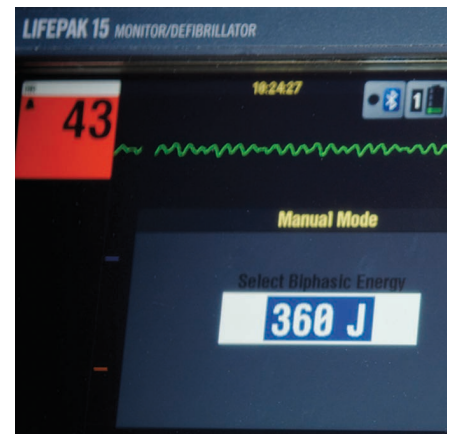
Physio-Control defibrillators have set the standard for six decades, and the latest version of the LIFEPAK 15 monitor/defibrillator raises the bar. As our most advanced emergency response monitor/defibrillator, the LIFEPAK 15 device balances sophisticated clinical technologies and supreme ease of use in a device that's tough enough to stand up to your most challenging environments. Evolving from its original platform, the LIFEPAK 15 features temperature monitoring and external power to complement 360J of energy and 12-lead ECG transmission capability. And that means your team can be even more effective.

A LIFEPAK device never stands on its own—and the LIFEPAK 15 monitor is no different. Physio-Control is committed to providing innovative solutions for emergency response care, from first responders to throughout the hospital.

**Our products have helped save tens of thousands of lives. We're proud to continue this work with the features in the LIFEPAK 15 monitor/defibrillator.**

# The standard in clinical innovation

The pioneer in portable defibrillation and monitoring technology, Physio-Control is committed to creating technologies and devices that change the way you provide emergency care. You can see the results in the latest version of the LIFEPAK 15 monitor/defibrillator, which sets the standard in innovation—yet again.



## Advanced monitoring parameters

With more monitoring capabilities than any other monitor/defibrillator, the LIFEPAK 15 gives you EtCO<sub>2</sub> with continuous waveform capture. Masimo® Rainbow® technology helps you detect hard-to-diagnose conditions



and improve patient care with noninvasive monitoring of carbon monoxide, SpO<sub>2</sub> and methemoglobin. In addition, the LIFEPAK 15 offers temperature monitoring—and like other data, you can transmit it to other systems, trend it, or display for post-event review in CODE-STAT™ data review software.

## Advanced support for treating cardiac patients

The LIFEPAK 15 continuously monitors all 12 leads in the background and alerts you to changes using the ST-Segment trend monitoring feature, after acquiring the initial 12-lead. Additionally, STJ values are included on the 12-lead printout to help you identify changes. The LIFEPAK 15 also works seamlessly with the web-based LIFENET System 5.0, so you can automatically share critical patient data with multiple patient care teams.

## Full energy up to 360 joules, for every patient who needs it

The LIFEPAK 15 monitor/defibrillator features 360J biphasic technology, which gives you the option of escalating your energy dose up to 360J for difficult-to-defibrillate patients. Why is this necessary? Recent studies have shown that refrillation is common among VF cardiac arrest patients and that defibrillation of recurring episodes of VF is increasingly difficult. A randomized controlled clinical trial shows the rate of VF termination was higher with an escalating higher energy regimen of 200J and over.<sup>1</sup>

## Proven CPR guidance and post event review

The CPR Metronome in the LIFEPAK 15 monitor uses audible prompts to guide you without distracting vocal critique. A metronome has been a feature that has been demonstrated to help professionals perform compressions and ventilations within the recommended range of the 2015 AHA Guidelines. Post-event review of CPR data and delivering feedback to the team has been shown to be effective in improving CPR quality in both hospital and out-of-hospital.<sup>2,3,4</sup> And by transmitting code data directly to CODE-STAT Data Review software, EMS personnel can review CPR statistics and provide training and feedback where it is most needed.



**Post-event review of CPR data and delivering feedback to the team has been shown to be effective in improving CPR quality in both hospital and out-of-hospital.<sup>2,3,4</sup>**

# The standard in operational effectiveness

Flexible, connected and easy to use, the LIFEPAK 15 monitor/defibrillator was designed based on the feedback and needs specific to working in the field.

## **Dual-mode LCD screen with SunVue™ display**

Switch from full-color to high-contrast SunVue mode with a single touch for the best full-glare view in the industry. A large screen (8.4 inches diagonally) and full-color display provide maximum viewability from all angles.

## **Flexible power options**

Choose between external worldwide AC or DC power, or use the latest Lithium-ion dual battery technology for up to six hours of power. The LIFEPAK 15 monitor's two-battery system requires no maintenance or conditioning, and allows you to charge batteries in the device. In addition, you can track the status and service life of your batteries using LIFENET® Asset, part of the LIFENET System data network.

## **Data connectivity**

The LIFEPAK 15 collects code summaries and equipment status data along with critical clinical information as you treat patients. Using LIFENET Connect, part of the LIFENET System data network, the code summaries can be sent directly to your quality improvement team for review with CODE-STAT Data Review Software. Your equipment manager can also view equipment status on the LIFENET System 5.0 using LIFENET Asset and alert you to any potential issues.

## **Upgradable platform**

The LIFEPAK 15 platform is flexible enough to adapt to evolving protocols and new guidelines, and can be upgraded as you're ready to deliver new capabilities. With more processing power and speed, the LIFEPAK 15 is designed to grow as your needs change, helping you avoid costly premature replacements.

## **Attention to detail**

The LIFEPAK 15 monitor is designed based on field feedback to make it a more effective tool. The LIFEPAK 15 has a larger handle for easier handoffs, an easy to clean keypad, and a common interface to the LIFEPAK 12 defibrillator/monitor that helps reduce training.

**Code summaries can be sent directly to your quality improvement team for review with CODE-STAT Data Review Software.**





LIFEPAK 15 MONITOR/DEFIBRILLATOR

PHYSIO CONTROL



- ON
- ENERGY SELECT
- CHARGE
- PACER
- RATE
- CURRENT
- MODE

12-LEAD

TRANSMIT

PRINT

in the presence of flammable gases. For use only by qualified personnel.

# The standard in toughness

We believe LIFEPAK equipment should live up to the highest expectations of those working in the harshest settings. The LIFEPAK 15 is LIFEPAK TOUGH™, with improved ruggedness and durability you can rely on.

## Works when dropped, kicked, soaked or dirty

The LIFEPAK 15 monitor/defibrillator passes 30-inch drop tests, which is equal to falling off a cot or dropping it in transit. And with an IP44 rating, it doesn't matter how wet or dirty it gets, so you can keep working in steady wind, rain and other harsh environments.

## Toughened inside and out

We heard from emergency response teams that they wanted a tougher device—so we added a shock-absorbing handle, a double-layer screen that can take a beating from doorknobs and cot handles, and redesigned cable connections for confident monitoring and therapy delivery.

## Unmatched field service

The unit's self-checking feature alerts our service team if the device needs attention. Our on site maintenance and repair, access to original manufacturer parts, and highly trained, experienced service representatives give you the peace of mind that your LIFEPAK 15 monitor will be ready when you need it.\*



Data connectivity



LIFEPAK TOUGH™



Dual-mode LCD screen with SunVue display

\*A variety of customized service options are available.





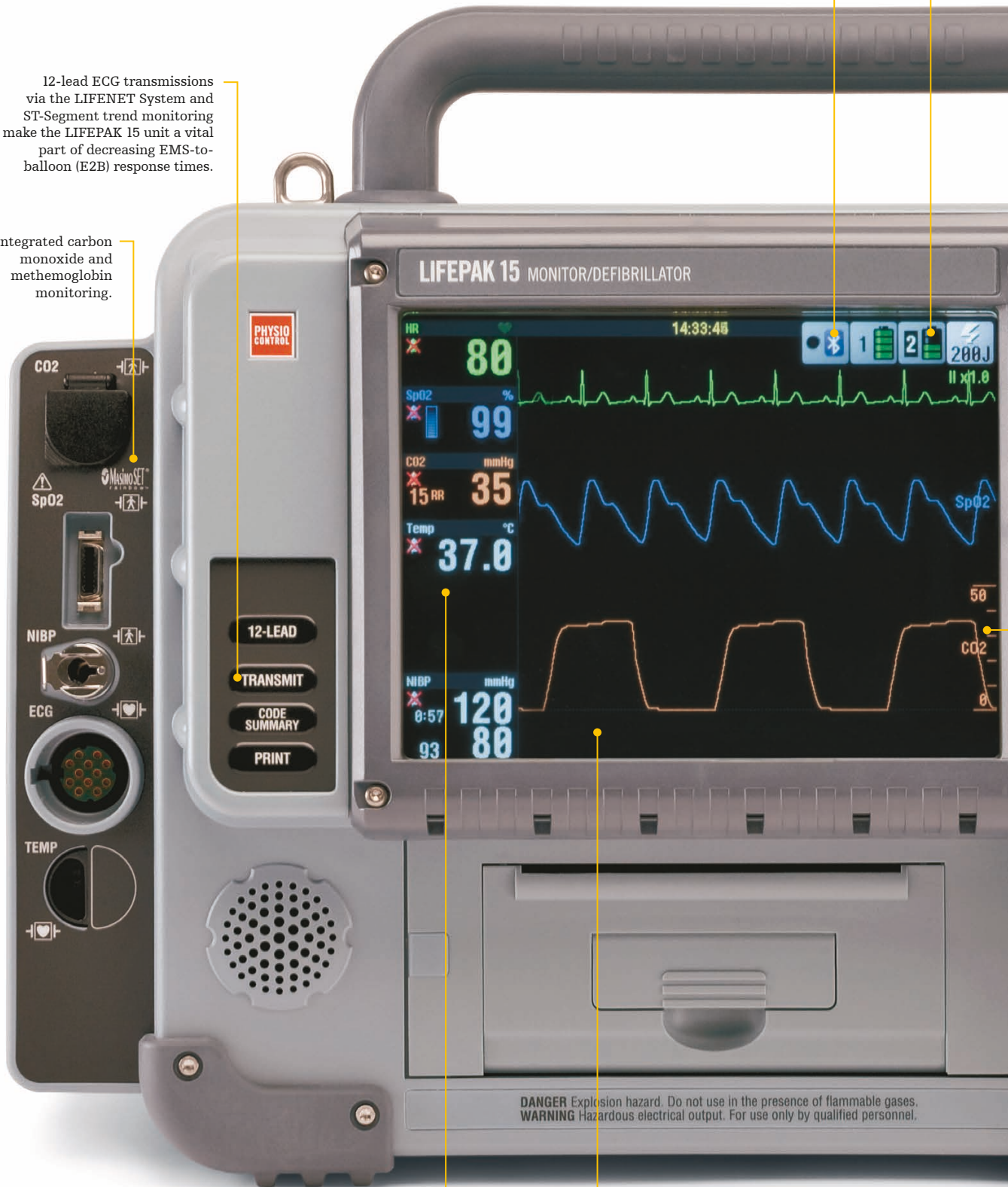
# LIFEPAK 15 monitor/defibrillator

The latest lithium-ion battery technology and dual battery system allows for nearly six hour run time, automatic switching between external power and batteries and an approximate two-year replacement cycle.

Easy one-touch Bluetooth® data transmission.

12-lead ECG transmissions via the LIFENET System and ST-Segment trend monitoring make the LIFEPAK 15 unit a vital part of decreasing EMS-to-balloon (E2B) response times.

Integrated carbon monoxide and methemoglobin monitoring.

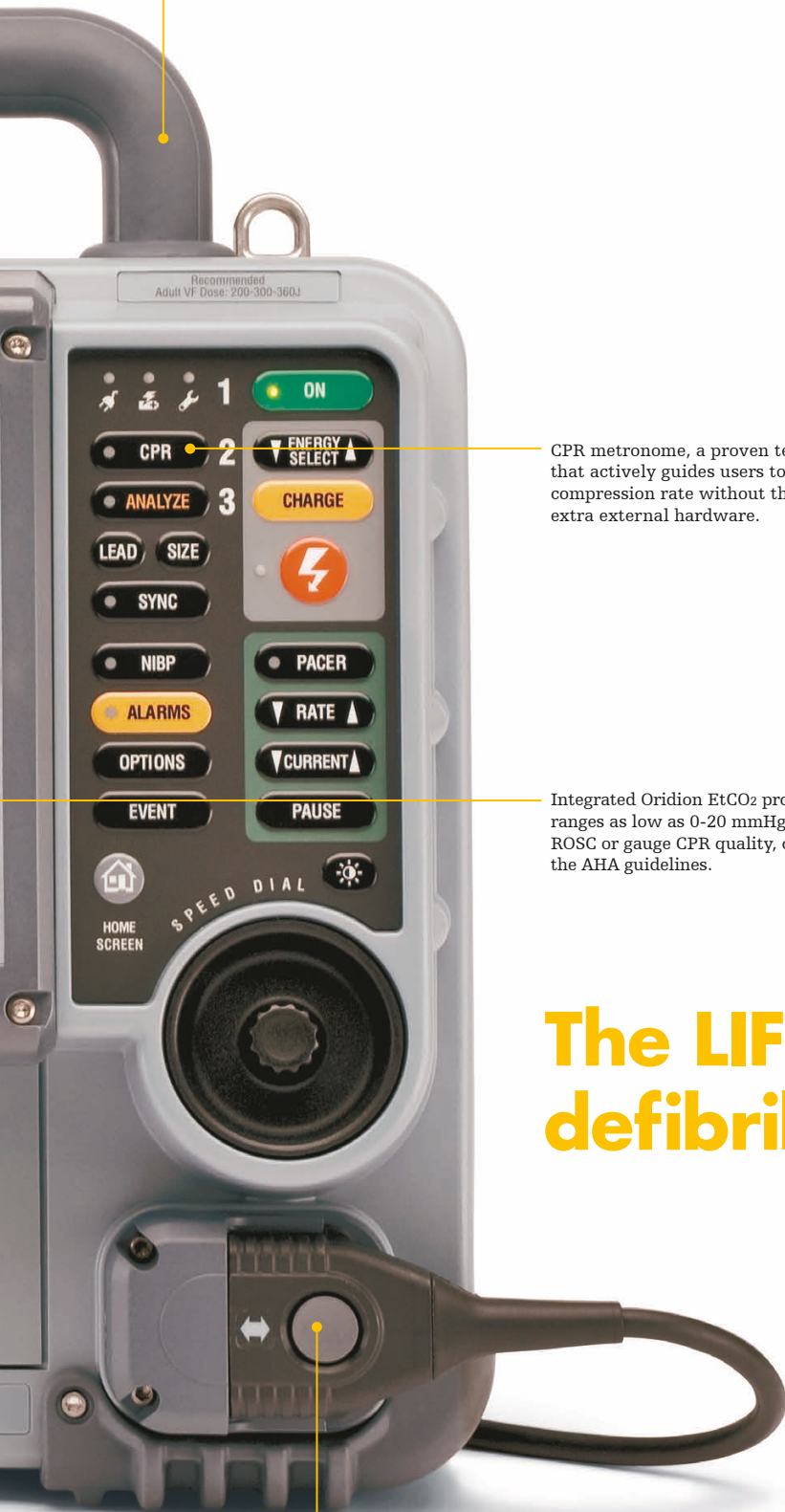


On-screen temperature display in either Celsius or Fahrenheit.

Large screen for better visibility and easy monitoring and one touch to switch from LCD color view to SunVue™ mode for best viewing in sunlight.



Ergonomically designed handle has built-in shock absorbers for cushion and fits two gloved hands for easy pass off.



CPR metronome, a proven technology that actively guides users to a consistent compression rate without the need for extra external hardware.

Integrated Oridion EtCO<sub>2</sub> provides waveform ranges as low as 0-20 mmHg to help identify ROSC or gauge CPR quality, consistent with the AHA guidelines.

## The LIFEPAK 15 monitor/ defibrillator at a glance

Redesigned cable connector for confidence in secure therapy delivery.





For six decades, Physio-Control has been developing technologies and designing devices that are legendary among first response professionals, clinical care providers, and the community.







## A legacy of trust

Since we were founded in 1955, Physio-Control has been giving medical professionals around the world legendary quality and constant innovation. Our LIFEPAK devices have been carried to the top of Mount Everest. They've been launched into orbit on the International Space Station. And you'll find more than half a million units in use today on fire rescue rigs, ambulances, and hospital crash carts worldwide.

We are inspired and informed by the rescuers who choose our products to save lives. The knowledge gained from working with some of the world's largest EMS organizations helps us constantly improve clinical standards and durability.

Today, we continue our legacy of innovation with leading technologies that improve patient care. Our 360J biphasic technology gives patients the best chance at survival. Our secure, web-based flow of ECG data helps improve STEMI patient outcomes. And our carbon monoxide monitoring helps catch the number one cause of poisoning deaths.

From the streets to the emergency room to the administrative office, we offer a powerful suite of solutions that range from code response to quality control analysis. And even as we bring ground-breaking products to the market, some things don't change. As always, when you choose our products, you don't just get a device. You also get the most comprehensive warranty in the business, industry-leading technical service, and a partner with six decades of experience in emergency care.

**For more information about the LIFEPAK 15 monitor/defibrillator—and how it can help you do what you do best—please contact your local Physio-Control representative or visit [www.physio-control.com](http://www.physio-control.com).**

## 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-numeric values, device instructions, or prompts

**Display:** up to three waveforms

**Waveform display sweep speed:** 25 mm/sec for ECG, SpO<sub>2</sub>, IP, and 12.5 mm/sec for CO<sub>2</sub>

### 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)

#### 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

#### SpO<sub>2</sub>/SpCO/SpMet

##### Sensors:

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

#### SpO<sub>2</sub>

**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 SpO<sub>2</sub> pulsations are detected

**SpO<sub>2</sub> update averaging rate user selectable:**

4, 8, 12 or 16 seconds

**SpO<sub>2</sub> sensitivity user selectable:** Normal, High

**SpO<sub>2</sub> measurement:** Functional SpO<sub>2</sub> 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 SpO<sub>2</sub> waveform display with autogain control

#### SpCO®

**SpCO concentration display range:** 0 to 40%

**SpCO accuracy:** ±3 digits

#### SpME™

**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<sub>2</sub>

**CO<sub>2</sub> 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:** 3.3 seconds (includes delay time and rise time)

**Initialization time:** 30 seconds (typical), 10–180 seconds

**Ambient pressure:** automatically compensated internally

**Optional display:** CO<sub>2</sub> 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<sub>2</sub>), PR (NIBP), SpO<sub>2</sub> (%), SpCO (%), SpMet (%), CO<sub>2</sub> (EtCO<sub>2</sub>/FiCO<sub>2</sub>), RR (CO<sub>2</sub>), 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:**  $\pm 1$  joule or 10% of setting, whichever is greater, into 50 ohms,  $\pm 2$  joules or 15% of setting, whichever is greater, into 25-175 ohms.

**Voltage compensation:** Active when disposable therapy electrodes are attached. Energy output within  $\pm 5\%$  or  $\pm 1$  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<sup>®</sup> 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  $300 \pm 15\%$  ohms, or if the magnitude of the patient impedance is greater than  $440 \pm 15\%$  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:**  $\pm 1.5\%$  over entire range

**Output waveform:** Monophasic, truncated exponential current pulse (20  $\pm$  1 ms)

**Output current:** 0 to 200 mA

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

**Refractory period:** 180 to 280 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,  $\pm 0.15$  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 60668-2-27 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 LIFEPACK 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)	
			Typical	Minimum
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:**  $\leq 1.3$  lb (0.6 kg)

**Charge time (with fully depleted battery):** 4 hours and 15 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

## References

1. Stiell I, Walker R, Nesbitt L, et al. Biphasic Trial: A randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest. *Circulation*. 2007;115:1511-1517.
2. Edelson D, Litzinger B, Arora V, et al. Improving in-hospital cardiac arrest process and outcomes with performance debriefing. *Arch Intern Med*. 2008;168:1063-1069.
3. Olasveengen T, Wik L, Kramer-Johansen J, et al. Is CPR quality improving? A retrospective study of out-of-hospital cardiac arrest. *Resuscitation*. 2007;75:260-266.
4. Fletcher D, Galloway R, Chamberlain D, et al. Basics in advanced life support: A role for download audit and metronome. *Resuscitation*. 2008;78:127-134.

**All claims valid as of August 2018.**

**Physio-Control is now part of Stryker.**

**For further information, please contact Physio-Control at 800.442.1142 (U.S.), 800.668.8323 (Canada) or visit our website at [www.physio-control.com](http://www.physio-control.com)**

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