LIFEPAK® 12 DEFIBRILLATOR/MONITOR

Works like you work.™

Everyday, you make a difference.

Your job demands more.

Use a tool that can tackle today's patient care needs and adapt to tomorrow's challenges.

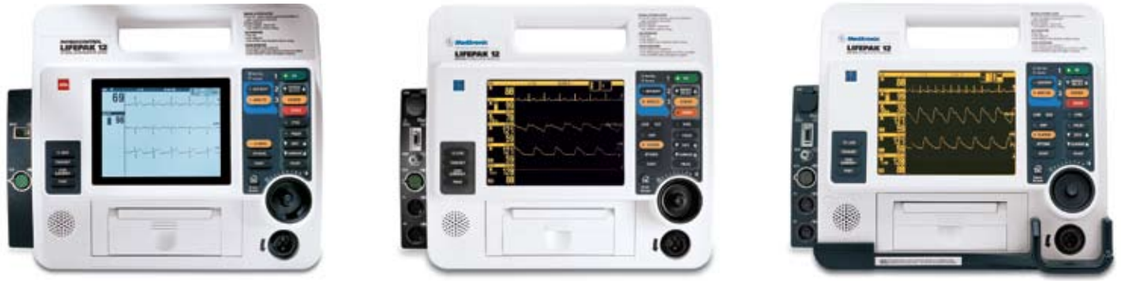
The gold standard for more than 30 years, LIFEPAK products are continually evolving to keep pace with the changing nature of patient care. The LIFEPAK 12 defibrillator/monitor packs multi-parameter therapeutic and diagnostic functions into a single, portable device.

Over 80,000 LIFEPAK 12 defibrillator/monitors are in use today—on rescue rigs and in hospitals worldwide. Feedback from this global community keeps us innovating—adding features to help you in your lifesaving work.

Trusted

EVOLUTION

Keeping pace as patient care evolves.



The LIFEPAK 12 defibrillator/monitor revolutionized acute cardiac care in 1998, with expanded diagnostic and monitoring capabilities. As your job grows, so does the *12*.

Here are highlights of advances since its first release:

1998

The LIFEPAK 12 defibrillator/monitor revolutionizes acute cardiac care, with expanded diagnostic and monitoring capabilities.

1999

LIFEPAK 12 defibrillator/monitor is enhanced with ADAPTIV™ biphasic technology up to 360J, NIBP and CO_2 monitoring capabilities.

2001

Among many features added to the *12* are ST Monitoring up to 8 hours and invasive pressure monitoring.

2004

Bluetooth® capabilities enable wireless transmission of 12-lead ECGs.

2007

cprMAX™ technology provides increased flexibility for protocols to maximize CPR.

STEMI Management technology enables secure and flexible flow of ECG data, linking EMS and hospitals for improved STEMI treatment.

Complemented by a rich range of services and options.

Technical Field Service

We offer one of the largest and best-trained networks of technical service representatives in the industry. On call 24 hours a day, 7 days a week (North America), our goal is to return your phone call within two hours, to work with you to quickly assess the problem and find the best solution. An integral part of your team, our field service reps have an average tenure of more than 12 years and log an average of 2,400 field hours each year. We work with you to design a customized service offering that meets your needs. Options include a comprehensive plan covering repair, preventative maintenance and inspection; or plans limited to repair-only or inspection-only.

Training

Whether you are taking delivery of your first LIFEPAK 12 defibrillator/monitor, or adding new options, your sales rep will provide inservice training to help you get the most from your Physio-Control products. Specialized training—ranging from self-paced CDs to live webcasts to on-site classes—is also available for features such as End-tidal CO_2 monitoring and 12-lead ECG. Continuing education credits are available for some offerings.

Grant Consultation

This complimentary program helps Physio-Control customers streamline the grant research and writing process. Free assistance is provided to communities, hospitals, law enforcement, fire and EMS agencies in applying for grants to upgrade equipment, implement new programs, and provide training. Customers receive guidance on identifying funding sources, timing grant applications, and crafting a grant proposal to improve the likelihood of success.

Accessories

We offer a full catalog of more than 150 accessories to suit your needs, including options for batteries, paddles, electrodes and cables.

Meeting the demands of your changing job.

Easy to use when every second counts

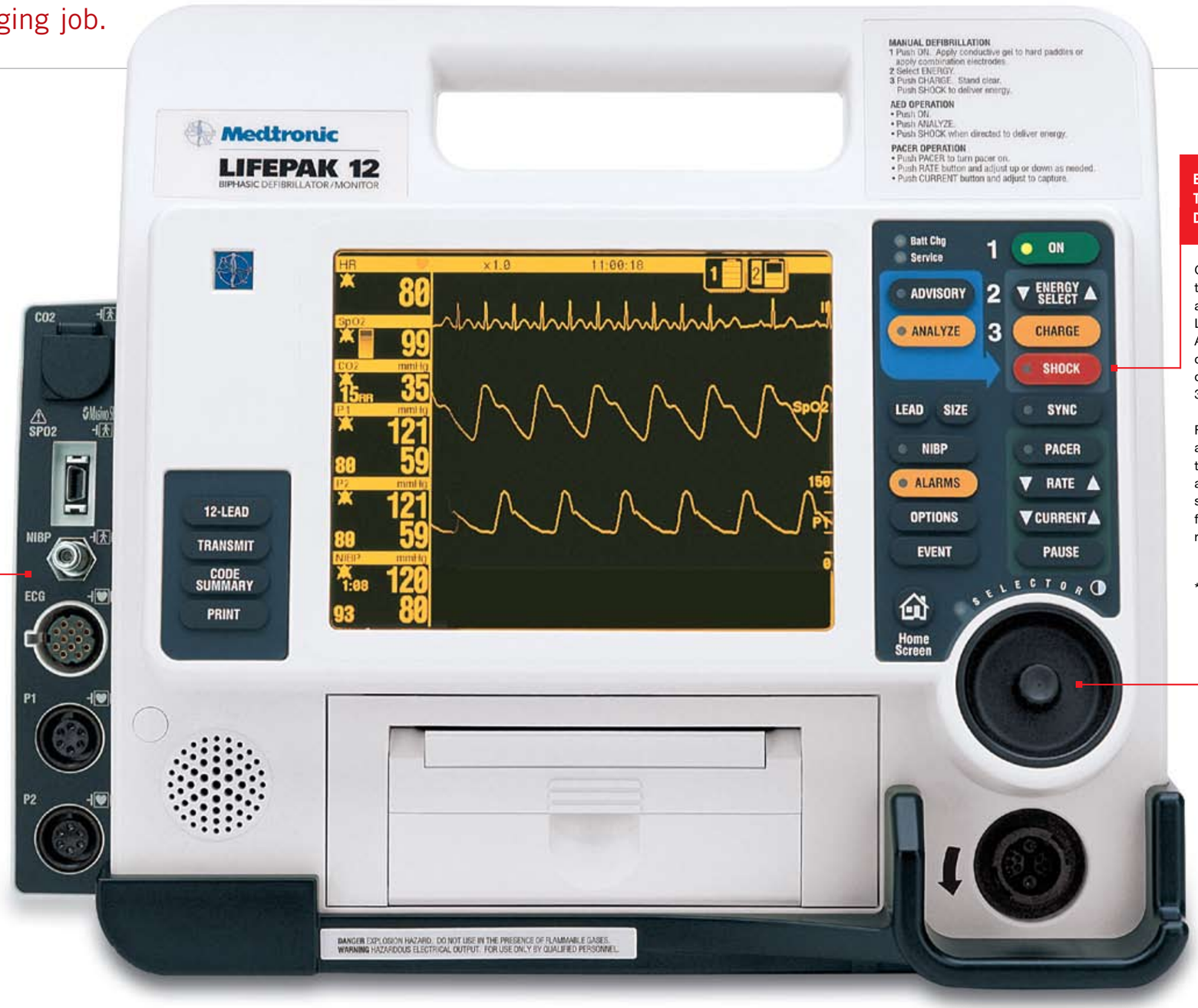
The *12* is designed to work like you work—in the most demanding conditions and environments.

- Generously sized screen lets you quickly scan clutter-free waveforms and monitoring data.
- Stands up to rugged use—drop test/impact test of 18 inches; IPX4 rating.

SETTING THE STANDARD ON MONITORING TO INFORM PATIENT CARE

The pioneer in prehospital 12-lead ECG acquisition and transmission, Physio-Control continues to advance the state of the art, with ST Monitoring to quickly identify changes in a patient's 12-lead ECG.

- The *12* is the only defibrillator/monitor on the market today* with an ST Monitoring feature. Because ECGs (and the diagnosis) can change so significantly so quickly, the device takes a series of ECGs at frequent intervals and alerts you to changes in a patient's ST measurement.
- The *12* helps track patient status breath by breath with patented Microstream® capnography technology and FilterLine® accessories that operate smoothly even in high humidity. EtC0$_2$ monitoring is effective for both intubated and nonintubated patients.
- Graphic display of vital signs allows for evaluation of changes in patient condition and patient response to therapy over time.
- MASIMO SET® pulse oximetry offers accurate and stable oxygen saturation monitoring.



ESCALATING DOSE TO 360J TO MAXIMIZE DEFIBRILLATION SUCCESS

Get the option to escalate to the highest energy available in a defibrillator/monitor today.* LIFEPAK defibrillators with ADAPTIV biphasic technology offer the maximum range of energy settings, up to 360 joules.

For patients who need additional shocks, increasing the dose of subsequent shocks above the first shock has shown to be a better strategy for terminating VF than simply repeating a failed dose.[1,2,3]

* As of October 2007.

SELECTOR KNOB MAKES IT SIMPLE TO SCROLL THROUGH AND QUICKLY SELECT FUNCTIONS.

Setting the standard. Raising the bar.

Improving treatment with secure flow of ECG data

Mortality for Acute Coronary Syndrome (ACS) has been shown to increase 40% if door-to-balloon time stretches from 90 minutes to 120 minutes.[4]

Transmitting 12-lead ECGs from the field so hospitals can confirm STEMI diagnosis and activate the cardiac cath lab before the patient arrives can help you meet the ACC/AHA 90-minute door-to-balloon guideline for STEMI patients.[5] The LIFENET STEMI Management Solution links EMS response with hospitals via the internet to improve treatment and management of patients with ACS. Using cutting edge technology, 12-lead ECG data is sent from the *12* to a network of receiving targets in the ED, cath lab, or anywhere the LIFENET Client software is installed, so patient data can be shared quickly. This technology enables hospitals to make patient care decisions such as referral to a PCI capable hospital, or cath lab activation, all while you are still en route.

Studies have reported a significant association between prehospital 12-lead ECGs and shorter door-to-balloon times. Two recent studies found the effect was strongest when the cath lab was activated while the patient was still en route to the hospital.[6,7]

Medical Informatics

LIFENET® STEMI Management Solution. Our cutting-edge technology facilitates a seamless, secure and flexible flow of ECG data between prehospital, emergency room, and PCI treatment centers, enabling you to improve door-to-balloon times and reduce false-positive cath lab activations. A virtual STEMI care network linking EMS response with hospitals is created using our web application and secure datacenter and your gateway devices like SmartPhone PDAs. While paramedics in the field focus on patient care, a gateway device sends diagnostic quality ECGs wirelessly from the LIFEPAK defibrillator to the proper destination, helping you meet the ACC/AHA 90-minute door-to-balloon guideline for STEMI patients. The system works on a variety of wireless carrier networks and requires no dedicated hardware. Application services—including a state-of-the-art datacenter that maximizes security and system availability—are provided on a subscription basis. Several levels of support are available to meet your needs.

CODE-STAT™ 7.0 Data Review Software with Advanced CPR Analytics. This post-event review tool annotates chest compressions onto the patient's continuous ECG report and calculates CPR statistics, helping you meet 2005 AHA Guidelines. The software simplifies data collection and reporting by consolidating all dispatch, treatment and outcome data into a single e-file. With this single tool, you can download, review, manage and analyze emergency medical data from multiple LIFEPAK defibrillators. The application also facilitates quality analysis and business decisions, allowing creation of benchmarking and trending reports to review your system's performance.

DT EXPRESS™ Data Transfer Software. The simple Windows-based software application manages data from LIFEPAK devices. The software makes it easy to download critical event and waveform data to your PC, add supplemental patient data, print out a hardcopy report, and store records on a disk. For storage and on-screen viewing of reports, export files to CODE-STAT 7.0 data review software.

Powerful

Specifications

GENERAL

The LIFEPAK 12 defibrillator/monitor series has five main operating modes:

Advisory Mode (SAS): Provides all features available except manual defibrillation, synchronous cardioversion and pacing

Manual Mode: Provides normal operating capability for ALS users

Setup Mode: Allows operator to customize the device

Service Mode: Allows operator to execute device diagnostic tests and calibrations

Inservice Mode: Provides simulated waveforms for demonstration purposes

POWER

Battery Only Configuration: Choice of NiCd (FASTPAK® battery, FASTPAK 2 battery, LIFEPAK NiCd battery) or SLA (LIFEPAK SLA battery)

Dual battery capability

Optional external AC Power Adapter

Batteries charge while device operates from Power Adapter

Operating Time: Two new fully charged batteries will provide the following prior to shutdown:

	TOTAL				AFTER LOW BATTERY			
	Typical		Min.		Typical		Min.	
	LCD	EL	LCD	EL	LCD	EL	LCD	EL
Monitoring (minutes)								
NiCd*	110	81	60	43	10	6	2	1
NiCd**	155	114	85	62	14	8	2	1
NiCd***	220	162	120	86	20	12	4	2
SLA	180	132	100	73	16	10	2	1
Defibrillation (360 joule discharges)								
NiCd*	80	72	45	40	7	7	3	3
NiCd**	110	99	60	54	10	10	3	3
NiCd***	160	144	90	80	14	14	6	6
SLA	145	131	85	76	12	12	3	3
Monitoring plus Pacing (minutes at 100ma, 60ppm)								
NiCd*	105	75	60	42	9	6	2	1
NiCd**	145	104	85	60	12	8	2	1
NiCd***	210	150	120	84	18	12	4	2
SLA	170	122	100	71	14	10	2	1

*FASTPAK, FASTPAK 2 (11141-000044, 11141-000025)
**LIFEPAK NiCd (11141-000027)
***LIFEPAK NiCd (11141-000026)

Low Battery Indication and Message: Low battery icon at top of display and low battery message in status area for each battery. When low battery is indicated, device autoswitches to second battery. When both batteries reach a low battery condition, there is a voice prompt to replace battery.

Warmstart: With inadvertent loss of power (<30 seconds) device retains settings

Service Indicator: When an error is detected

PHYSICAL CHARACTERISTICS

Weight: Basic defibrillator/monitor with QUIK-COMBO® cable: 6.6kg (14.5 lbs) (unit and QUIK-COMBO cable only, no batteries). Add 0.3 lbs when configured with front case guard.

FASTPAK and FASTPAK 2 Battery: .6kg (1.3 lbs)

LIFEPAK NiCd Battery: 0.8kg (1.7 lbs)

LIFEPAK SLA Battery: 1.3kg (2.8 lbs)

Standard Paddles (hard): 0.9kg (1.9 lbs)

Height: 31.7cm (12.5 in)

Width: 39.6cm (15.6 in)

Depth: 23.1cm (9.1 in)

DISPLAY

Size (active viewing area):
LCD: 140.8mm (5.5 in) wide x 105.6mm (4.2 in) high
EL: 165.1mm (6.5 in) wide x 123.8mm (4.9 in) high

Resolution:
640 x 480 black and white LCD
640 x 480 amber and black EL display

User selectable LCD contrast

Displays a minimum of 4 seconds of ECG and alphanumerics for values, device instructions or prompts

Option to display one or two additional waveforms

Waveform Display Sweep Speed: 25mm/sec for ECG and 12.5mm/sec of CO_2

DATA MANAGEMENT

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

The user can select and print reports and transfer the stored information via an internal modem through landline or mobile phones.

Report Types: Three format types of CODE SUMMARY™ critical event record (short, medium and long)

- Initial ECG (except short format)
- Automatic capture of vital signs measurements every 5 minutes
- 3-channel or 4-channel 12-lead ECG report
- Continuous waveform records (transfer only)
- Trend Summary – includes patient information, vital signs log and vital signs graphs
- Vital Signs – includes patient information, event and vital signs log
- Snapshot – includes patient information and 8 seconds of ECG captured at the time of transmission

Memory Capacity: Two full-capacity patient records that include:

CODE SUMMARY critical event record – up to 100 single waveform events

Continuous Waveform – 45-minute continuous ECG record

COMMUNICATIONS

The device is capable of transferring data records by internal modem, external EIA/TIA modem, cellular modem or serial connection

Bluetooth wireless data transfer to cell phone to LIFENET RS receiving station

Supports EIA/TIA-602 compatible modems using Xon/Xoff or RTS/CTS flow control at 9600 to 38400 bps

EIA/TIA-RS232E compatible at 9600, 19200, 38400 and 57600 bps

Group III, Class 2 or 2.0 fax

MONITOR

Voice Prompts: Used for selected warnings and alarms (configurable on/off)

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 monitoring

A 10-wire cable is used for 12-lead 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 or FAST-PATCH® disposable defibrillation/ECG electrodes are used for paddles lead monitoring

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, V1 (Labeled "C" on 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 to 300 bpm digital display

Out of Range Indication: Display symbol "—-"

Heart symbol flashes for each QRS detection

Continuous Patient Surveillance System (CPSS): In advisory mode while Shock Advisory System™ is not active, CPSS monitors the patient, via paddles or Lead II ECG, for potentially shockable rhythms

Analog ECG Output: 1V/mV x 1.0 gain

Common Mode Rejection: 90dB at 50/60Hz

SpO_2

MASIMO SET Sensors
Saturation Range: 1 to 100%

Saturation Accuracy: (70–100%) (0–69% unspecified)
Adults/Pediatrics:
+/- 2 digits (during no motion conditions)
+/- 3 digits (during motion conditions)

Neonates:
+/- 3 digits (during no motion conditions)
+/- 3 digits (during motion conditions)

Dynamic signal strength bar graph

Pulse tone at the onset of the pleth waveform

SpO_2 Update Averaging Rate: User selectable 4, 8, 12 or 16 seconds

SpO_2 Measurement: Functional SpO_2 values are displayed and stored

Pulse Rate Range: 25 to 240 pulses per minute

Pulse Rate Accuracy: (Adults/Pediatrics/Neonates)
+/- 3 digits (during no motion conditions)
+/- 5 digits (during motion conditions)

SpO_2 waveform with autogain control

NIBP

Oscillometric measurement

Systolic Pressure Range: 30 to 245mmHg

Diastolic Pressure Range: 12 to 210mmHg

Units: mmHg, kPa

Mean Arterial Pressure Range: 20 to 225mmHg

Blood Pressure Accuracy: maximum mean error of ± 5mmHg with a standard deviation no greater than ± 8mmHg

Pulse Rate Range: 30 to 200 pulses per minute

Pulse Rate Accuracy: ± 2 pulses per minute or ± 2% whichever is greater

Typical Measurement Time: 40 secs

$EtCO_2$

Microstream technology

Measurement range: 0 to 99mmHg

Display: CO_2 waveform and $EtCO_2$ numerics

Units: mmHg, kPa, %; user selectable

Automatic ambient pressure compensation

CO_2 Accuracy (>20 minutes): 0 to 38mmHg: ± 2mmHg39 to 99mmHg: ± 5% of reading + 0.08% for every 1mmHg

Warm Up Time: 30 seconds (typical), 180 seconds max

Response Time: 2.9 seconds (includes delay time and rise time)

Respiration Rate Range: 0 to 60 breaths per minute

Respiration Rate Accuracy: 0 to 40 bpm: ± 1 bpm, 41 to 60 bpm: ± 2 bpm

Invasive Pressure (2 channels)

Measurement Range: -30 to +300mmHg in six user selectable ranges

Display: IP waveform and numerics

Units: mmHg, kPa

User-selectable Labels: ART, PA, CVP, ICP, LAP

Transducer Type: Strain-gauge resistive bridge

Transducer Sensitivity: 5mV/V/mmHg

Bandwidth: 0 - 30 Hz (<-3dB)

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

Leakage Current: Meets ANSI/AAMI/IEC requirements

Trend

Display: Choice of HR, SpO_2(%), EtCO2, RR, NIBP, P1, P2, ST shown in channels 2 or 3

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

Duration: Up to 8 hours with -06 Memory PCB or later. Reduced storage capacity with earlier versions.

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

ALARMS

Quick Set: Activates alarms for all parameters

VF/VT Alarm: Activates continuous CPSS monitoring in Manual Mode

Apnea Alarm: Occurs when 30 seconds have elapsed since last detected respiration

INTERPRETIVE ALGORITHMS

12-Lead Interpretive Algorithm: GE Medical 12SL, Includes AMI statement

PRINTER

Prints continuous strip of the displayed patient information

Paper Size: 50mm (2.0 in) or optional 100mm (3.9 in)

Print Speed: 25mm/Sec +/- 5% (measured in accordance with AAMI EC-11, 4.2.5.2)

Delay: 8 seconds

Autoprint: Waveform events print automatically (user configurable)

Optional 50mm/sec timebase for 12-lead ECG reports

FREQUENCY RESPONSE

Diagnostic: 0.05 to 150Hz or 0.05 to 40Hz (user configurable)

Monitor: 0.67 to 40Hz or 1 to 30Hz (user configurable)

Paddles: 2.5 to 30Hz

Analog ECG Output: 0.67 to 32Hz (except 2.5 to 30Hz for Paddles ECG and 1.3 to 23Hz for 1 to 30Hz monitor frequency response)

DEFIBRILLATOR

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

Energy Accuracy: ±1 joule or 10% of setting, whichever is greater, into 50 ohms

±1 joule or ±5%, whichever is greater, of 50 ohm value into 25 to 200 ohms*

Paddle Options: QUIK-COMBO pacing/defibrillation/ECG electrodes (standard)

FAST-PATCH disposable defibrillation/ECG electrodes (optional)

Standard Paddles (optional)

Internal Handles with discharge control (optional)

External Sterilizable Paddles (optional)

Cable Length: 2.4m (8 ft) long QUIK-COMBO cable (not including electrode assembly)

Manual

Energy Select (Biphasic): 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 or user configurable sequence 100 to 360 joules

Energy Select (Internal): 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30 and 50 joules

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

Synchronous Cardioversion: Energy transfer begins within 60ms of the QRS peak

AED

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"

Output Energy (Biphasic): User configurable, sequence of three sequential shock levels ranging from 150-360 joules (200-360 joules, Japan)

* Note: ±5% accuracy applies when disposable therapy electrodes are attached. Energy output is limited to the available energy which results in delivery of 360 joules into 50 ohms.

cprMAX technology setup options (items marked with * are default settings):

- Stacked shocks: off*, on
- Initial CPR: off*, analyze first, CPR first
- Preshock CPR: off*, 15, 30 seconds
- Pulse check: never*, after second no shock advised, after every no shock advised, always
- CPR time 1 & 2: 15, 30, 45, 60, 90, 120*, 180 seconds, 30 minutes

PACER

Pacing Mode: Demand or non-demand rate and current defaults (user configurable)

Pacing Rate: 40 to 170ppm

Rate Accuracy: +/- 1.5% over entire range

Output Waveform: Monophasic, truncated exponential current pulse (20 + 1ms)

Output Current: 0 to 200mA

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

Refractory Period: 200 to 300ms +/-3% (function of rate)

ENVIRONMENTAL

Temperature, Operating: 0˚ to 50˚C (32˚ to 122˚F)
SpO2: 5˚ to 45˚C (41˚ to 113˚F)

Temperature, Non-operating: -20˚ to +60˚C (-4˚ to 140˚F) except therapy electrodes and batteries

Relative Humidity, Operating: 5 to 95%, non-condensing

Atmospheric Pressure, Operating: Ambient to 429mmHg (0 to 4572m) (0 to 15,000 ft)

Water Resistance, Operating: IPX4 (splash proof) per IEC 60529 (with batteries and cables installed)

EMC: IEC 60601-1-2: 2001/EN 60601-1-2:2001, Medical Equipment-General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility-Requirements
and Tests

IEC 60601-2-4:2002; Clause 36/EN 60601-2-4:2003; Clause 36, Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator monitors

Shock (drop): Five drops on each side from 18 in. onto a steel surface

Vibration: MIL-STD-810E Method 514.4, Propeller Aircraft – category 4, Helicopter – category 6 (3.75g), and Ground Mobile – category 8 (3.14g)

AC POWER ADAPTER

Function

Dimensions: 27.7 x 16.8cm (10.9 x 6.6 in)

Weight: < 2.3kg (<5 lbs) (including cables)

Charge Time (with fully depleted battery):

FASTPAK and FASTPAK 2: 1.5 hours

LIFEPAK NiCd: 2.1 hours

LIFEPAK NiCd: 3.0 hours

LIFEPAK SLA: 6 hours typical, 12 hours maximum

AC Input: Accepts line power from both: 90 to 264VAC, 47 to 63Hz (domestic/international)108 to 118VAC, 380 to 420Hz (military)

Fuses: Two 250V fuses (100 to 200V: T5A; 220 to 240V: T2.5A) in the power input module

Environmental

IPX4 per IEC 60529

Altitude, Operating: To 4545m (15,000 ft)

Altitude, Non-operating: To 5455m (18,000 ft)

Humidity: 5 to 95% non-condensing

Temperature, Operating: 0˚ to 50˚C (32˚to 122˚F)

Temperature, Storage: -20˚ to 65˚C (-4˚ to 150˚F) (followed by one hour temperature stabilization in operating temperature range)

Vibration, Operating and Non-operating: MIL-STD-810E, Method 514.4 Categories 4, 6, 8

All specifications are at 20˚C unless otherwise stated.

The most field-proven defibrillator/monitor in the world.

Experience the legendary quality that has made LIFEPAK products the clear favorite around the world—for every level of responder.

For more than 50 years, Physio-Control, maker of the renowned LIFEPAK defibrillators, has been developing technologies and designing devices that are legendary among first response professionals, clinical care providers and citizens everywhere.

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