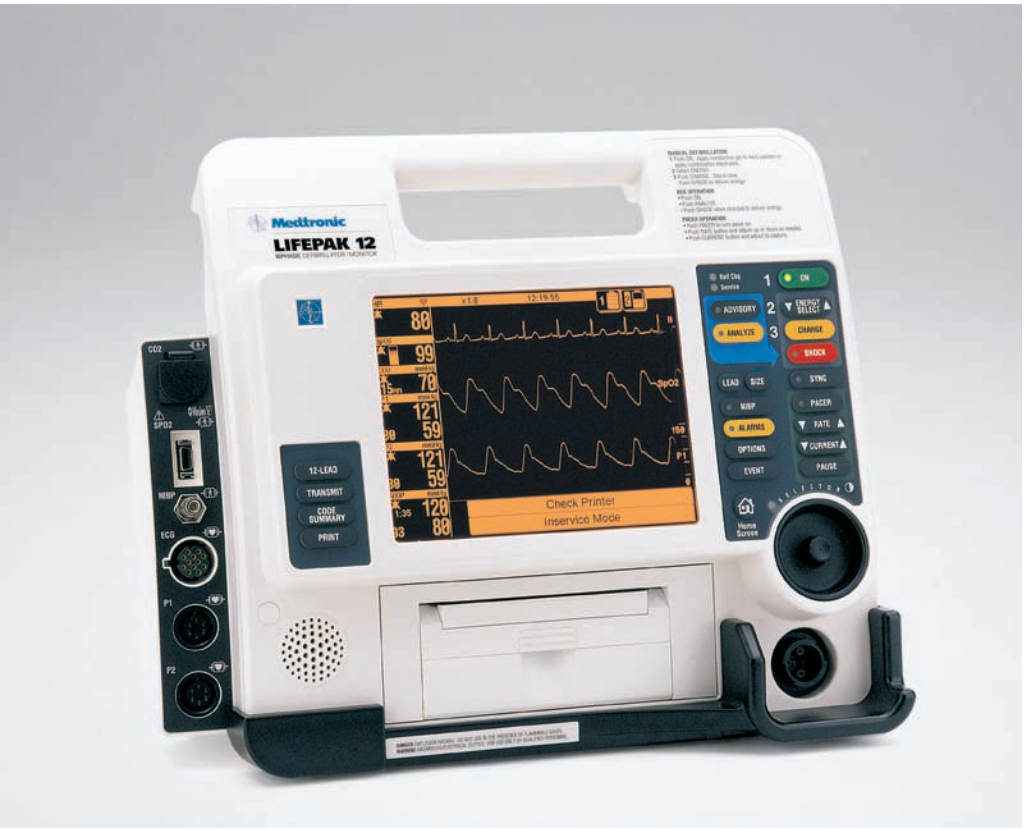
LIFEPAK® 12

Defibrillator / Monitor Series



Small, lightweight, rugged unit provides therapy and multi-parameter monitoring

Simple operation, dedicated therapy controls and one-touch operation

ADAPTIV™ Biphasic technology

Configurable options and convenient field upgrades

Automated External Defibrillator (AED) capability with Shock Advisory System™

Extensive data storage, transmission and retrieval capabilities

LIFENET® system compatible

OPTIONS:

EL or LCD display

Noninvasive pacing

Noninvasive blood pressure

GE Medical 12SL® ECG analysis program

Masimo SET® pulse oximetry (SpO_2)

Microstream® Capnography ($EtCO_2$)

Invasive Pressures (2)

Vital signs trending and ST segment monitoring

AC Power Adapter

NiCd or SLA batteries

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

Medtronic offers leading edge solutions for the problems you face today and configurable capabilities for the solutions you will need tomorrow. The LIFEPAK 12 defibrillator/monitor series provides therapeutic and diagnostic functions in a single, small device designed for both out-of-hospital and hospital users. The innovative platform design provides full-featured defibrillation and industry-standard monitoring all loaded into a single portable device.

The *12* utilizes ADAPTIV biphasic technology, with the capability to deliver shocks at energy levels consistent with International Resuscitation Guidelines.

Configurable options, including AED and manual defibrillation modes, allow standardization across user groups and ease of patient transfer.

Dedicated defibrillation and pacing therapy buttons provide fast and effective therapy for both beginning and advanced users. The selector knob and home screen button make it simple to switch between menus.

In AED mode, the LIFEPAK 12 defibrillator/monitor series utilizes the same Medtronic field proven Shock Advisory System used in thousands of LIFEPAK AEDs since 1986. Clear voice and visual prompts advise the operator when it detects a shockable rhythm.

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 SpO2 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(%), $EtCO_2$, 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 statements

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 200, 100 to 300, 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

Advisory

Shock Advisory System (SAS) is 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 200, 200 to 300, and 200 to 360 joules

* 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.

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) SpO_2: 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.

In manual mode, the LIFEPAK 12 defibrillator/ monitor series features simple 1-2-3 operation.

The large display allows 1, 2 or 3 ECG channels to be viewed simultaneously, with up to eight seconds of cascading ECG. Heart rate, oxygen saturation and other vital information is clearly visible.

GE Medical's 12SL ECG analysis program offers interpretive 12-lead ECG analysis. The 12SL ECG analysis program provides accuracy with simultaneous acquisition, analysis and interpretation of all 12-leads. 12-lead transmission capabilities give you a head start in diagnosis and treatment of AMI and other conditions. Patient data, including 12-lead ECG reports, can be integrated into the GE Medical MUSE® CV cardiovascular information system.

Pulse oximetry is available with Masimo SET technology, providing low perfusion accuracy and stability in the presence of motion and protection against bright, ambient light.

Capnography ($EtCO_2$) monitoring is available for use on intubated and nonintubated patients. Superior moisture handling eliminates the need for water traps or additional moisture filters. Innovative Microstream® technology and FilterLine® accessories reduces maintenance costs associated with mainstream sensor and cable damage.

Oscillometric noninvasive blood pressure (NIBP) monitoring with proven performance in most ambient noise and motion environments is also available. Automatic measurement modes provide vital signs assessment at intervals appropriate for patient condition.

The AC Power Adapter provides line power as well as battery charging capability. A full line of batteries are available to meet varied usage requirements, with fuel gauge indicators providing visual indication of remaining capacity.

Medtronic Emergency Response Systems
11811 Willows Road NE
P. O. Box 97006
Redmond, WA 98073-9706 USA
Tel: 425.867.4000
Fax: 425.867.4121
www.medtronic-ers.com

Europe
Tolochenaz, Switzerland
Tel: 41.21.802.7000
Fax: 41.21.802.7900

Switzerland
Tolochenaz, Switzerland
Tel: 41.21.803.8000
Fax: 41.21.803.8099

Canada
Mississauga, Ontario
Tel: 905.826.6020
Fax: 905.826.6620

United Kingdom, Ireland
Watford, Great Britain
Tel: 44.1923.212.213
Fax: 44.1923.241.004

France
Boulogne-Billancourt, France
Tel: 33.1.55.38.1700
Fax: 33.1.55.38.1800

Germany
Dusseldorf, Germany
Tel: 49.211.529.30
Fax: 49.211.529.31.00

Austria
Vienna, Austria
Tel: 43.1.240.44.160
Fax: 43.1.240.44.600

Italy
Milan, Italy
Tel: 39.02.24137.1
Fax: 39.02.24138.1

Netherlands
Heerlen, The Netherlands
Tel: 31.45.566.8000
Fax: 31.45.566.8668

Spain
Madrid, Spain
Tel: 34.91.625.04.00
Fax: 34.91.650.74.10

Scandinavia
Järfälla, Sweden
Tel: 46.8.52.22.00.00
Fax: 46.8.52.22.00.50

Asia Pacific
Hong Kong, S.A.R., PRC
Tel: 852.2891.4456
Fax: 852.2891.6830

Latin America
Miami, Florida USA
Tel: 954.500.9328
Fax: 786.709.4244

Middle East
Beirut, Lebanon
Tel: 961.1.370.670
Fax: 961.1.364.164

Hungary
Budapest, Hungary
Tel: 36.1.214.2228
Fax: 36.1.214.2230

Poland
Warsaw, Poland
Tel: 48.22.465.69.00
Fax: 48.22.465.69.17

Czech Republic
Prague, Czech Republic
Tel: 420.2.2017.2277
Fax: 420.2.2056.1617

People's Republic of China
Shanghai, China
Tel: 86.21.50800998
Fax: 86.21.50800978

South Africa
Bedfordview, South Africa
Tel: 27.11.677.4800
Fax: 27.11.616.1104

Japan
Kawasaki, Kanagawa, Japan
Tel: 81.44.540.6502
Fax: 81.44.540.6170

Australia
Sydney, Australia
Tel: 61.2.9879.5999
Fax: 61.2.9879.5100

Israel
Even-Yehuda, Israel
Tel: 972.9.891.2223
Fax: 972.9.891.9330

MIN 3011157-008 / CAT. 26500-000186

Medtronic
Alleviating Pain · Restoring Health · Extending Life