

HEARTSTART XL DEFIBRILLATOR/MONITOR

Model: M4735A

PRODUCT DESCRIPTION



Philips Medical Systems' M4735A HeartStart XL offers advanced and basic life-support clinicians a compact, lightweight, easy-to-use defibrillator/monitor with both Manual and AED capabilities. HeartStart XL features Philips' patented SMART Biphasic waveform, ECG monitoring, synchronized cardioversion, and optional non-invasive pacing and SpO₂.

A biphasic waveform is energy delivered in two phases. During the first phase, the electrical current passes through the heart muscle, reverses direction, and then passes through the heart a second time. This efficient transmission of energy requires less current than that delivered by a monophasic waveform.

Manual Mode operation is as easy as 1-2-3:

- 1 - Select an energy level from 2 to 200 Joules.
- 2 - Charge the unit.
- 3 - Deliver the shock.

The HeartStart XL charges to its highest energy level in less than 3 seconds. ALS providers can also perform synchronized cardioversion and deliver non-invasive pacing therapy.

In AED Mode, the HeartStart XL meets the needs of BLS users by offering a range of functions from basic AED to AED with monitoring. BLS clinicians will find these intuitive AED features supported by straightforward voice prompts and displayed text messages.

The HeartStart XL records a patient summary in either mode of operation. Patient data such as continuous ECG, shocks and alarm violations are stored in the unit's internal memory. Downloading and reporting data is available by using a data card. The Event Review Pro data management system allows authorized users to edit, store, and print reports.

The HeartStart XL is designed to meet a wide variety of resuscitation and monitoring needs in one lightweight, easy-to-use device.

Features

Standard Features

- ▶ SMART Biphasic waveform for defibrillation therapy
- ▶ ECG monitoring through pads and separate monitoring electrodes
- ▶ Alarms on HR limits and shockable rhythms
- ▶ Synchronized cardioversion
- ▶ Manual and AED operation
- ▶ Built-in 50 mm strip chart printer
- ▶ Bright Liquid Crystal Display (LCD) display for viewing waveforms and messages
- ▶ Internally stored event summary which may be printed
- ▶ Voice prompts in AED mode
- ▶ Adjustable ECG size
- ▶ Adjustable volume
- ▶ Setup mode, automatic self-tests and error handling
- ▶ Integrated AC power

Optional Features

- ▶ SpO₂/Pulse Oximetry with alarms
- ▶ Non-invasive pacing (using a monophasic truncated exponential current waveform)
- ▶ 5-lead ECG monitoring cable, AAMI or IEC labeling

Standard Accessories

- ▶ Sealed Lead Acid Battery
- ▶ Hands-Free Multifunction Defib Electrode Cable
- ▶ ECG Patient Cable (3 lead)
- ▶ Disposable Monitoring Electrodes (5)
- ▶ Rolls of printer paper (2)
- ▶ Instructions for Use
- ▶ Quick Reference Card
- ▶ User Training Workbook
- ▶ Test Load
- ▶ AC Power Cord

Ordering Option Information

0B3	Service Manual
OBP	User Training Video
C01	SpO ₂ Monitoring with adult reusable transducer
C02	Non-invasive Pacing
C03	12-pin, 5 lead ECG Cable
C05	User Training CD-ROM
C07	Hands-free cable M3507A (barrel connector) and Text Load (M1781A - barrel connector)
C08	Hands-free cable (M3508A - flat connector) and Test Load (M3725A - flat connector) - Default option
C10	Data Card
C13	External paddles with Paddle Contact Indicator
C24	External Sterilizable Paddles
J03	12-pin Sync Cable
W18	Extends 1-year CE On-site to 2-Year CE On-site Warranty
W19	Extends 1-year CE On-site to 3-Year CE On-site Warranty
W20	Extends 1-year CE On-Site to 5-Year CE On-site Warranty
WA0	Provides a 5-year unit exchange warranty (U.S./ Canada only)
WA1	Converts standard warranty to a 5-year BioMed Warranty (U.S. only)

Upgrades/Supplies/Accessories

Upgrades

M4738A	Pacing Upgrade
M4739A	SpO ₂ Upgrade

External Paddles

M4745A	Sterilizable External Paddles
M4746A	External Paddles with PCI

Internal Paddles

M1741A	7.5 cm Switchless
M1742A	6.0 cm Switchless
M1743A	4.5 cm Switchless
M1744A	2.8 cm Switchless
M4741A	7.5 cm Switched
M4742A	6.0 cm Switched
M4743A	4.5 cm Switched
M4744A	2.8 cm Switched
M4740A	Internal Paddles Adapter Cable

Pads/Electrodes

M3713A	HeartStart Multifunction Adult Plus
M3716A	HeartStart Multifunction Adult Radiolucent
M3717A	HeartStart Multifunction Pediatric Plus
M3718A	HeartStart Multifunction Adult Radiotransparent/ Reduced Skin Irritation
M3719A	HeartStart Multifunction Pediatric Radiotransparent/Reduced Skin Irritation
M3501A	Multifunction Defib Adult Electrode, AAMI
M3502A	Multifunction Defib Adult Electrode, IEC
M3503A	Multifunction Defib Pediatric Electrode, IEC
M3504A	Multifunction Defib Pediatric Electrode, AAMI
DP2	HeartStart AED Defibrillation Pads (2 pack)
DP6	HeartStart AED Defibrillation Pads (6 pack)

Pads/Paddle Cables

M3507A	Multifunction Defib Pads Connector Cable
M3508A	HeartStart Pads Connector Cable
05-10200	Pads Adapter (use with M3507A)
M4748A	Adapter Extension Cable

ECG Monitoring Electrodes

M2202A	High Tack Foam ECG Electrode 5 electrodes/ pouch (300 electrodes/case)
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ECG Cables

M1500A	3-Lead ECG Trunk Cable (AAMI)
M1663A	10-Lead Trunk Cable
M1668A	5-Lead Trunk Cable
M1669A	3-Lead Trunk Cable
M1949A	10-Lead Trunk Cable
M1605A	3-Lead ECG Patient Cable with Snaps (AAMI)
M1671A	3-Lead ICU Grabber (AAMI)
M1672A	3-Lead ICU Grabber (IEC)
M1673A	3-Lead ICU Snap (AAMI)
M1674A	3-Lead ICU Snap (IEC)
M1675A	3-Lead OR Grabber (AAMI)
M1678A	3-Lead OR Grabber (IEC)
M1510A	3-Lead ECG Trunk Cable (IEC)
M1615A	3-Lead ECG Patient Cable with Snaps (IEC)
M1520A	5-Lead ECG Trunk Cable (AAMI)
M1625A	5-Lead ECG Patient Cable with Snaps (AAMI)
M1530A	5-Lead ECG Trunk Cable (IEC)
M1635A	5-Lead ECG Patient Cable with Snaps (IEC)
M1968A	5-Lead ICU Grabber (AAMI)
M1644A	5-Lead ICU Snap (AAMI)
M1973A	5-Lead OR Grabber (AAMI)
M1971A	5-Lead ICU Grabber (IEC)
M1645A	5-Lead ICU Snap (IEC)
M1974A	5-Lead OR Grabber (IEC)

Sync Cables

M1783A	12-pin Sync Cable
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SpO₂ Sensors/Cables

M1191A	Adult Reusable SpO ₂ Sensor
M1192A	Pediatric Reusable SpO ₂ Sensor
M1194A	Adult/Pediatric Ear Clip, Reusable SpO ₂ Sensor
M1941A	2-meter extension cable
M1943A	Nellcor SpO ₂ Sensor Adapter Cable
M1131A	Disposable SpO ₂ Sensor - Adult/Pediatric
M1903B	Disposable SpO ₂ Sensor - Pediatric Finger (Available outside the U.S. only)
M1904B	Disposable SpO ₂ Sensor - Adult Finger (Available outside the U.S. only)

Miscellaneous

M4751A	Accessory Pouch
M1781A	Test Load for use with M3507A
M3725A	Test Load for use with M3508A
989803147711	Data Card
M3516A	HeartStart Sealed Lead Acid Battery
453564045111	User Training CD-ROM
M4747A	Battery Charger Kit
40457C	1 box 50 mm Strip Chart Thermal Paper (10 rolls/box)
40457D	1 box 50 mm Strip Chart Thermal Paper (80 rolls/box)
989803135291	Cadex C7200 Battery Charger (holds 2 XL batteries)
989803135321	Cadex C7400 Battery Charger (holds 4 XL batteries)
989803135341	Cadex C7400 Battery Charger (holds 2 XL and 2 MRx batteries)

Specifications

General

Dimensions: 19.0 cm (H) x 37.6 cm (W) x 34.6 cm (L)
(7.5 in. x 14.8 in. x 13.7 in.)

Weight: 6.0 kg (13.3 lbs.) including battery and full roll of paper.

Defibrillator

Waveform: Biphasic Truncated Exponential. Waveform parameters adjusted as a function of patient impedance.

Shock Delivery: Via multifunction defib electrode pads or paddles.

Delivered Energy Accuracy:

Selected Energy	Delivered Energy (J)					Accuracy
	Load Impedance (Ohms)					
	25	50	100	125	150	
5J	4.7	5.0	5.2	5.4	5.2	±2J
10J	9.3	10	10.4	10.7	10.4	±2J
20J	18.6	20	20.8	21.4	20.8	±4J
30J	27.9	30	31.2	32.1	31.2	±4J
50J	46.7	50	52.3	53.5	52.1	±15%
70J	65.4	70	73.1	75.0	72.9	±15%
100J	93.5	100	104.7	107.2	104.4	±15%
150J	140.3	150	156.8	161.0	156.5	±15%
200J	187	200	209.3	214.6	208.6	±15%

Charge Time: Less than 3 seconds to 200 Joules with a new, fully charged M3516A SLA battery pack at 25°C. Less than 15 seconds to 200 Joules when powered by AC with no battery installed.

Patient Impedance Range:

Minimum: 10-25 Ohm, depending upon energy level

Maximum: 180 Ohm

Manual Mode

Manual Output Energy (Delivered): 2, 3, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200 Joules. Energy limited to 50 Joules for internal defibrillation.

Controls: Manual/AED On/Energy Select knob, Charge/Disarm, Shock, ECG Lead Select, SpO₂ On/Off, SpO₂ Alarm, HR Alarm, Sync On/Off, Pacer, Pacer Start/Stop, Pacer Rate, Pacer Current, Pacer Mode, ECG Gain, Volume, Strip, Summary Mark.

Indicators: LCD display for ECG waveforms and text prompts, Audio alerts, QRS Beeper, Charging tones (for sync and asynchronous modes), AC Power LED, Battery Charging LED, Sync LED, Pacer LED.

Armed Indicators: Charge Done tone and available energy indicated on display.

Energy Selection: Front panel rotary knob.

Charge Control: Front panel "2" key or buttons on paddles.

Shock Control: Front panel "3" key or buttons on paddles.

Synchronizer: SYNC message appears on the monitor and is annotated on the printer (if printing while in Sync mode). An audible beep sounds with each detected R-wave while a tick mark on the monitor and printed strip indicate the discharge points.

Synchronizer delay is less than 60 msec from peak R-wave to peak current of the defibrillation discharge.

AED Mode

AED Energy Profile: Fixed energy (150 Joules).

AED Shock Series: 1, 2, 3, 4 shocks per series.

Shock Series Timer: off, 30, 60, 90, 120, 150, 180, or 210 seconds.

Text and Voice Prompts: Extensive text/audible messages guide user through protocol.

AED Controls: On, Off, Pause/Resume, Analyze/Stop Analysis, Shock, Lead Select, SpO₂ On/Off, SpO₂ Alarms, HR Alarms, ECG Gain, Volume, Strip, Summary Mark.

Indicators: LCD display for ECG waveforms and text prompts, Audio alerts, voice prompts, QRS Beeper, Charging tones, Charge Done Tone, Printer, AC Power LED, Battery Charging LED.

Armed Indicators: Charge Done tone, available energy indicated on display; Voice Message.

Patient Analysis: Per protocol, evaluates patient ECG and signal quality to determine if a shock is appropriate and evaluates connection impedance for proper defibrillation pad contact.

Shockable Rhythms: Ventricular fibrillation with amplitude greater than 100 μ V and wide complex ventricular tachycardia with rates greater than 150 bpm.

Sensitivity and Specificity: Meets AAMI guidelines.

ECG Monitoring

Inputs: Single channel ECG may be viewed on display and printed. Pads ECG is obtained through 2 multifunction defibrillation electrode pads. Lead I, II, or III is obtained through the 3-lead ECG cable and separate monitoring electrodes. With a 5-lead cable, lead aVR, aVL, aVF, and any one of the V (I-6) leads can also be obtained.

Lead Fault: LEADS OFF message and dashed line appear on the display if an electrode or lead wire becomes disconnected.

Paddle Fault: NO PADDLES CONNECTED message and dashed line appear on the display if paddles become disconnected.

Pad Fault: PADS OFF message and dashed line appear on the display if the pads become disconnected.

Heart Rate Display: Digital readout on display from 15 to 300 bpm, with an accuracy of \pm 10%.

Heart Rate Alarms: Configurable pairs of low and high heart rate alarm limits: 30 to 100, 60 to 140, 90 to 160 and 120 to 200 bpm.

Hands Free Defibrillation Cable Length: 7 ft. (2.13 m).

ECG Cable Length: 12 ft. (3.7 m).

Common Mode Rejection: Greater than 90 dB measured per AAMI standard for cardiac monitors (EC 13).

ECG Size: 2.5, 5, 10, 20, 40 mm/mV.

Frequency Response:

AC Line Filter: 60 Hz or 50 Hz.

Pads ECG for Display: Monitor (.15-40 Hz) or EMS (1-30 Hz).

Pads ECG for Printer: Monitor (.15-40 Hz) or EMS (1-30 Hz).

Leads ECG for Display: Monitor (.15-40 Hz) or EMS (1-30 Hz).

Leads ECG for Printer: Diagnostic (.05-150 Hz) or EMS (1-30 Hz) or Monitor (.15-40 Hz).

Patient Isolation (defibrillation proof):

ECG: Type CF

SpO₂: Type CF

Defib: Type BF

Display

Type: LCD - TFT Color Liquid Crystal Display.

Size: 111.4 mm x 83.5 mm.

Resolution: 320 x 240 pixels.

Sweep Speed: 29 mm/s nominal (stationary trace; sweeping erase bar).

Viewing Time: 4 seconds.

Battery

Type: 2 Ah, 12V, rechargeable, Sealed Lead Acid.

Dimensions: 2.4 in. (H) x 0.94 in. (W) x 7.2 in. (D) (61.7 mm x 23.9 mm x 182 mm).

Weight: 1.4 lbs. (0.65 kg)

Charge Time: Approximately 14.5 hours to 100%. Approximately 3 hours to 90%, indicated by LED on front panel.

Capacity: 100 minutes ECG monitoring or 50 full-energy discharges or 75 minutes ECG monitoring while pacing (with a new, fully charged battery at room temperature, 25° C).

Battery Indicators: LOW BATTERY message appears on display when at least 10 minutes of monitoring time and 5 maximum energy discharges remain (with a new battery at room temperature, 25° C).

Battery Storage: Should not be stored above 40°C for extended periods of time.

Charger Output: Unit can be operated using only AC Power; with no battery installed.

Thermal Array Printer

Continuous Real-Time Strip: User starts and stops the strip. The strip prints the selected ECG lead with the following data:

Header 1: Date, Time, Heart Rate, the SpO₂ Value (if available) and the text "Delayed" if printing has been configured for Delayed Mode. Prints every 12 seconds.

Header 2: Current mode (AED/Manual), Lead, Gain, filter setting, the text "Sync" (if Sync has been enabled), and Pacer Settings (consisting of the Pacer Mode, Rate and Current, if presently pacing the patient). Prints every 12 seconds with Header 1.

Header 3: Changes in Mode, Gain, Lead, Sync, and Pacer Settings.

Footer: Drug Annotations, HR/SpO₂ limits on a Limit Alarm, the Results of Analysis in AED Mode (No Shock Advised, Shock Advised or Cannot Analyze), Charging to xxx J, Shock Delivered, No Shock Delivered, Disarm, Battery Low.

Symbols: Mark Triangle (for presses of the Mark key), an Alarm Bell (Alarm Limits Violations), Lightning Bolt (Shock Delivered; followed by "b" for biphasic), Vertical Strip Boundaries/Pacer/Sync Tick marks.

Event printing: Mark key automatically documents ECG and events during defibrillation episodes. The Mark key can annotate the event with one of the following labels: Epinephrine (Adrenaline in U.K. and Australia), Atropine, Lidocaine and Other.

Auto Printing: The printer can be configured to automatically print on Mark, Charge, Shock and Alarm.

Delayed Printing: The printer can be configured to run real time or with a 6 second delay.

Reports: The following can be printed: Event Summary, Configuration, Extended Self Test, System Log, Battery Capacity Test, Shift/System Check.

Speed: 25 mm/s with an accuracy of $\pm 5\%$.

Amplitude Accuracy: $\pm 10\%$ or ± 50 uV, whichever is greater.

Paper Size: 50 mm by 30 m (100 ft).

Noninvasive Pacing

Waveform: Monophasic Truncated Exponential

Current Pulse Amplitude: 10 mA to 200 mA (5 mA resolution); accuracy 10 mA to 50 mA ± 5 mA, 50 mA to 200 mA $\pm 10\%$.

Pulse Width: 20 ms with accuracy +0, -5 ms.

Rate: 30 ppm to 180 ppm (10 ppm increments); accuracy $\pm 1.5\%$.

Modes: Demand or Fixed Rate

Refractory Period: 340 msec (30 to 80 ppm); 240 msec (90 to 180 ppm).

SpO₂ Pulse Oximetry

Accuracy with:

M1191A sensor - 1 standard deviation 70% to 100%, $\pm 2.5\%$

M1192A sensor - 1 standard deviation 70% to 100%, $\pm 2.5\%$

M1194A sensor - 1 standard deviation 70% to 100%, $\pm 4.0\%$

M1131A sensor - 1 standard deviation 70% to 100%, $\pm 3.0\%$

M1903B sensor - 1 standard deviation 70% to 100%, $\pm 3.0\%$

M1904B sensor - 1 standard deviation 70% to 100%, $\pm 3.0\%$

Pulse Rate Accuracy: 2% or 1 bpm (whichever is greater).

Wavelength Range: 500 to 1000 nm.

Emitted Light Energy: Less than or equal to 15 mW.

Display Update Interval: Less than or equal to 60 seconds.

Resolution: 1%.

SpO₂ Alarm Limits: Three preset low alarm limits: 90%, 85% and 80%.

INOP Alerts: Triggered by disconnected sensor; noisy signal, light interference or low signal (non-pulsatile).

Event Storage

Internal Event Summary: The Internal Event Summary stores up to 300 events and up to 50 waveforms.

Events can be marked with a Mark symbol and, if configured for drug annotation, the following labels can be added: Epinephrine (Adrenaline in U.K. and Australia), Atropine, Lidocaine or Other.

The Summary key on the front panel is used to print the internal Event Summary.

Data Card Event Summary: The Data Card stores continuous ECG waveforms and events on a Type II PCMCIA card.

Environmental

Temperature: 0° C to 55°C operating; -20° to 70°C storage.

Charging the battery at temperatures above 35°C may degrade battery life.

Storing the battery for extended periods at temperatures above 40°C will reduce battery capacity and degrade battery life.

Humidity: Up to 95% Relative Humidity

Printer paper may jam if paper is wet.

Thermal Printer may be damaged if wet paper is allowed to dry while in contact with printer elements.

Altitude:

Operating: up to 15,000 ft.

Storage: up to 15,000 ft.

Shock: Philips Medical Systems, Section 760 Class BI Drop Test (200 G's <3 msec pulse).

Vibration: Philips Medical Systems, Section 759 Class BI Vibration.

Water Resistance: Meets IEC 60601-2-4, IPX 0.

EMC: Meets EN 60601-1-2

Safety: Meets IEC 60601-1 (EN 60601-1), UL 2601-1, CAN/CSA C22.2 No. 601-1.

Other Considerations: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Mode of Operation: Continuous.

AC Line Powered: 100-240 VAC, 50/60 Hz, 1.5A (Class I)

Battery Powered: 12 V rechargeable, SLA



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