

PHILIPS

M3535A/M3536A
Instructions for Use



HeartStart MRx

HEARTSTART
DEFIBRILLATORS

Table of Contents

1 Introduction	3
Overview	3
Intended Use	5
Defibrillation Therapy	5
Synchronized Cardioversion Therapy	5
Noninvasive Pacing Therapy (Optional)	5
12-Lead ECG Analysis (Optional)	6
Noninvasive Blood Pressure (NBP) Monitoring (Optional)	6
CO ₂ Monitoring (Optional)	6
Pulse Oximetry (SpO ₂) Monitoring (Optional)	6
Indications for Use	7
Safety Considerations	8
Documentation and Training	8
2 Getting Acquainted	9
Basic Orientation	10
Front Panel	10
Side Panels	11
Top Panel	12
Back Panel	13
M3538A Lithium Ion Battery	14
Battery Capacity	14
Battery Life	14
Operating Modes	14
Password Security	15
Display Views	15
General Status	16
Wave Sectors	17
Parameter Blocks	18
Soft Key Labels	18
Display Menus	19
Message Windows	19
High Contrast Display	20
Controls	20
Therapy Knob	20
General Function Buttons	21
Defibrillation Controls	22
Soft Keys	22
Indicators	23

Responding to Alarms	24
Entering Patient Information	25
Continued Use	25
Return to Owner	26
3 Setting Up	27
<hr/>	
Attaching the Carrying Case and Accessory Pouches	27
Storing Accessories	29
Connecting the ECG Cable	31
Connecting the SpO ₂ Cable	32
Connecting the NBP Interconnect Tubing	33
Connecting the CO ₂ Nasal FilterLine [®]	34
Connecting the Therapy Cable	35
Installing Paper	36
50mm Printer	36
75mm Printer	37
Installing Batteries	38
Charging Batteries	38
Battery Safety	38
Installing the AC Power Module	39
Installing the Data Card	40
4 ECG and Arrhythmia Monitoring	41
<hr/>	
Overview	41
Monitoring View	42
Preparing to Monitor ECG	43
Electrode Placement	45
Lead Selection	47
Lead Choices	47
Selecting the Lead	48
Arrhythmia Monitoring	48
Aberrantly-Conducted Beats	49
Intermittent Bundle Branch Block	49
Heart Rate and Arrhythmia Alarms	50
Arrhythmia Alarm Latching	50
INOP Messages	51
Setting Alarms	52
Changing Heart Rate or Vtach Alarm Limits	52
Enabling/Disabling Heart Rate and Arrhythmia Alarms	52
Responding to HR and Arrhythmia Alarms	52
Displaying an Annotated ECG	53
Arrhythmia Learning/Relearning	54
Troubleshooting	54

5 Semi-Automated External Defibrillation	55
<hr/>	
AED View	56
Preparation	57
Using AED Mode	59
Step 1 - Turn the Therapy Knob to AED	59
Step 2 - Follow the Screen and Voice Prompts	60
Step 3 - Press the Orange Shock Button, if Prompted	62
Troubleshooting	63
6 Manual Defibrillation and Cardioversion	65
<hr/>	
Overview	65
Code View	66
Preparing for Defibrillation	67
Using Multifunction Electrode Pads	67
Using External Paddles	68
Using Pediatric Paddles	69
Using Internal Paddles	69
Defibrillating (asynchronously)	70
Performing Synchronized Cardioversion	72
Preparing for Synchronized Cardioversion	72
Delivering a Synchronized Shock	73
Delivering Additional Synchronized Shocks	74
Disabling the Sync Function	74
Troubleshooting	74
7 Noninvasive Pacing	75
<hr/>	
Overview	75
Alarms	76
Pacing View	77
Demand Mode Versus Fixed Mode	78
Preparing for Pacing	79
Demand Mode Pacing	80
Fixed Mode Pacing	81
Defibrillating During Pacing	82
Troubleshooting	82

8 Pulse Oximetry	83
Overview	83
Understanding Pulse Oximetry	84
Selecting a Sensor	85
Applying the Sensor	87
Monitoring SpO ₂	88
Pleth Wave	89
Setting SpO ₂ Alarms	90
Changing the SpO ₂ Alarm Limits	90
SpO ₂ Desat Alarm	90
Enabling/Disabling the SpO ₂ Alarms	90
Setting Pulse Rate Alarms	91
Enabling/Disabling the Pulse Rate Alarms	91
Changing the Pulse Rate Alarm Limits	91
Disabling the SpO ₂ Monitoring Function	92
Caring for Sensors	92
Troubleshooting	92
9 Noninvasive Blood Pressure	93
Overview	93
Preparing to Measure NBP	94
Measuring NBP	96
Changing the NBP Schedule	96
Alarms	97
Changing NBP Alarms	97
Enabling/Disabling NBP Alarms	97
Troubleshooting	97
10 Monitoring Carbon Dioxide	99
Overview	99
Preparing to Measure EtCO ₂	100
Selecting the Accessories	100
Setting Up Microstream EtCO ₂ Measurements	101
Using the Nasal FilterLine	101
Using the FilterLine and Airway Adapter	101
Measuring EtCO ₂	102
Setting Up the EtCO ₂ and AwRR Alarms	102
Changing the EtCO ₂ Alarm Limits	103
Enabling/Disabling the EtCO ₂ Alarms	103
Changing the AwRR Alarm Limits	103
Changing the Apnea Time Alarm Limit	104
Enabling/Disabling AwRR Alarms	104
Disabling the EtCO ₂ Monitoring Function	104
Troubleshooting	104

11 12-Lead ECG	105
<hr/>	
Overview	105
Preview Screen	106
Preparation	106
Acquiring the 12-Lead ECG	108
12-Lead Report	109
Accessing Stored Reports	109
Improving Signal Quality	111
Adjusting Wave Size	111
12-Lead Filters	112
Troubleshooting	112
12 12-Lead ECG Transmission	113
<hr/>	
Overview	113
Setting Up for Bluetooth Transmission	115
Adding a Bluetooth Device	115
Pairing a Bluetooth Device with the HeartStart MRx	115
Changing Bluetooth Profiles	116
Additional Bluetooth Device Information	116
Transmitting to a Configured Site using Bluetooth	117
Setting Up for RS 232 Transmission	118
Transmitting to a Configured Site Using RS 232	120
Transmitting to a Manually Entered Fax Number	121
Transmission Status	122
Transmitting Stored 12-Lead Reports	123
Cancelling Transmission	123
Troubleshooting	124
13 Configuration	125
<hr/>	
Overview	125
Accessing the Configuration Menu	125
Setting the Date and Time	126
Modifying Settings	126
Saving Configuration Settings to a Data Card	127
Loading Configuration Settings from a Data Card	127
Restoring the Default Settings	127
Printing Configuration Settings	127
Configurable Parameters	128

14 Data Management	141
Overview	141
Copying from Internal Memory	142
Viewing and Erasing the Data Card	142
Printing the Event Summary	143
Printing the 12-Lead ECG Report	143
Events Recorded	144
Marking Events	148
Printing Events	149
15 Maintenance	151
Overview	151
Automated Tests	152
Automated Test Summary	153
Ready For Use Indicator	155
Shift Checklist and Operational Check	156
Weekly Shock Test	156
Operational Check (Versions Prior to B.05)	157
Performing the Operational Check	157
Operational Check Report for Versions Prior to B.05	162
Operational Check Summary	165
Operational Check (Versions B.05 and Greater)	166
Performing the Operational Check	167
Operational Check Report for Versions B.05 or Greater	173
Operational Check Summary	177
Battery Maintenance	178
Battery Capacity	178
Battery Life	178
Charging Batteries	179
Battery Calibration	179
Storing Batteries	180
Discarding Batteries	181
Cleaning Instructions	182
Monitor/Defibrillator	182
Printer Printhead	182
Paddles, Therapy Cable	183
ECG Cable	183
Carrying Case	184
NBP Cuff	184
SpO ₂ Sensor and Cable	184
Disposing of the HeartStart MRx	185
Disposing of Empty Calibration Gas Cylinders	185
Supplies and Accessories	186

16 Troubleshooting	193
<hr/>	
Symptoms	194
Audio Tones and Alarm Indications	210
Calling for Service	211
17 Specifications and Safety	213
<hr/>	
Specifications	213
General	213
Defibrillator	213
ECG and Arrhythmia Monitoring	216
Display	218
Battery	218
Thermal Array Printer	219
Noninvasive Pacing	219
SpO2 Pulse Oximetry	220
NBP	221
EtCO2	221
AwRR	222
Calibration Gas for CO ₂ Measurement System	223
12-Lead ECG	223
Patient Data Storage	223
Environmental (M3535A)	223
Environmental (M3536A)	225
Symbol Definitions	227
Clinical Performance Summary - Defibrillation	230
Methods	230
Results	230
Conclusion	230
Clinical Performance Summary - Cardioversion	231
Methods	231
Results	231
Conclusion	232
Clinical Performance Summary - Internal Defibrillation	233
Overview	233
Methods	233
Results	233
Conclusion	233



Safety Considerations	234
General	234
Defibrillation	236
Battery	237
Supplies and Accessories	238
Electromagnetic Compatibility	238
Reducing Electromagnetic Interference	238
Restrictions for Use	239
Emissions and Immunity	239
Guidance and Manufacturer's Declaration	239

Index	247
--------------	-----

About This Edition

Edition 4

Printed in the USA

Publication number M3535-91900

To determine the product level version to which the Instructions for Use are applicable, refer to the version level appearing on the back cover of this book or on the label of the User Documentation CD-ROM that accompanied this device. This information is subject to change without notice.

Philips shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

Edition History

Edition	Print Date
1	December, 2003
2	June, 2004
3	October, 2004
4	October, 2005

Copyright

Copyright © 2005

Koninklijke Philips Electronics N.V.

All rights are reserved. Permission is granted to copy and distribute this document for your organization's internal educational use. Reproduction and/or distribution outside your organization in whole or in part is prohibited without the prior written consent of the copyright holder.

SMART Biphasic is a registered trademark of Philips.

Use of supplies or accessories other than those recommended by Philips may compromise product performance.

THIS PRODUCT IS NOT INTENDED FOR HOME USE.

IN THE U.S., FEDERAL LAW RESTRICTS THIS DEVICE TO SALE ON OR BY THE ORDER OF A PHYSICIAN.

Medical Device Directive

The HeartStart MRx complies with the requirements of the Medical Device Directive 93/42/EEC and carries the **CE**₀₁₂₃ mark accordingly.

Manufacturer

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

Authorized EU-representative

Philips Medizin Systeme Böblingen GmbH
Hewlett Packard Str. 2
71034 Böblingen
Germany

Canada EMC:ICES-001

For the Declaration of Conformity Statement, please see the Philips Medical web site at <http://incenter.medical.philips.com/PMSPublic>. Scroll over the Quality and Regulatory Tab located in the upper left corner of the window. Click to select Regulatory by Modality. Then click to select Defibrillators and select the entry for Declaration of Conformity (DoC).

Warning

Radio frequency (RF) interference from nearby transmitting devices may degrade the performance of the HeartStart MRx. Electromagnetic compatibility with surrounding devices should be assessed prior to using the monitor/defibrillator.

These Instructions for Use contain the following conventions:

WARNING Warning statements describe conditions or actions that can result in personal injury or loss of life.

CAUTION Caution statements describe conditions or actions that can result in damage to the equipment or loss of data.

NOTE Notes contain additional information on usage.

"Voice"	represents voice prompt messages
Text	represents messages that appear on the display
[Soft key]	represents soft key labels that appear on the display above the button to which they correspond.

Introduction

Thank you for choosing the HeartStart MRx monitor/defibrillator. Philips Medical Systems welcomes you to its family of resuscitation devices.

The HeartStart MRx is designed to meet your monitoring and resuscitation needs by providing advanced, multi-parameter monitoring functions and a full range of defibrillation therapies. This guide provides instructions for the safe and proper operation of the device, as well as set-up, configuration, and maintenance information.

Be sure to familiarize yourself with the features and operation of the HeartStart MRx prior to its use.

Overview

The HeartStart MRx is a lightweight, portable, monitor/defibrillator. It provides four modes of operation: Monitor, Manual Defib, AED, and Pacer (optional).

In Monitor Mode you can monitor up to four ECG waveforms, acquired through a 3-, 5-, or 10-lead ECG set. Optional monitoring of pulse oximetry (SpO₂), noninvasive blood Pressure (NBP), and carbon dioxide (EtCO₂) are also available. Measurements from these parameters are presented on the display and alarms are available to alert you to changes in the patient's condition.

Monitor Mode also provides an optional 12-Lead ECG function, enabling you to preview, acquire, store, and print 12-lead ECG reports, with or without analysis/interpretation.

Manual Defib Mode offers simple, 3-step defibrillation. You analyze the patient's ECG and, if appropriate: 1) select an energy setting, 2) charge, and 3) deliver the shock. Defibrillation may be performed using paddles or multifunction electrode pads. Manual Defib Mode also allows you to perform synchronized cardioversion and internal defibrillation. If desired, use of Manual Defib Mode may be password protected (for Version A.02 and later devices).

In AED Mode, the HeartStart MRx analyzes the patient's ECG and determines whether a shock is advised. Voice prompts guide you through the 3-step defibrillation process, providing easy-to-follow instructions and patient information. Voice prompts are reinforced by messages that appear on the display.

Both Manual Defib and AED Mode incorporate the Philips' low energy SMART Biphasic waveform for defibrillation. The Q-CPR™ option, available in both Manual Defib and AED Modes, offers real-time, measurement and corrective feedback on the rate, depth, and duration of CPR compressions, as well as the frequency and volume of ventilations. It also provides notification of lack of CPR activity. For more information about Q-CPR refer to the *Instructions for Use Addendum for Q-CPR*.

NOTE Q-CPR™ is a trademark of Laerdal Medical.

Optional Pacer Mode offers noninvasive transcutaneous pacing therapy. Pace pulses are delivered through multifunction electrode pads, using a monophasic waveform. If desired, use of Pacer Mode may be password protected (for Version A.02 and later devices).

The HeartStart MRx is powered by rechargeable lithium ion batteries. Available battery power is easily determined by viewing the convenient battery power indicators located on the device display or by checking the gauge on the battery itself. Additionally, an external AC or DC Power Module may be applied as a secondary power source and for continual battery charging.

The HeartStart MRx performs Automated Tests on a regular basis. The results of these tests are reported to the Ready For Use (RFU) indicator. Prominently displayed, the RFU indicator communicates the status of your device, letting you know it is operating correctly, needs attention, or is unable to deliver therapy. In addition, performing the specified Operational Check ensures that the HeartStart MRx is functioning properly.

The HeartStart MRx automatically stores critical event data in its internal memory, such as Event Summaries and 12-Lead Reports. The HeartStart MRx also enables you to store data and event information on an optional data card for downloading to Philips' data management solution, HeartStart Event Review Pro.

The HeartStart MRx is highly configurable to better meet the needs of diverse users. Be sure to familiarize yourself with your device's configuration before using the HeartStart MRx. See "Configuration" on page 125.

Intended Use

The HeartStart MRx is for use in hospital and pre-hospital settings by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac life support or defibrillation.

When operating as a semi-automatic external defibrillator in AED Mode, the HeartStart MRx is suitable for use by medical personnel trained in basic life support that includes the use of an AED.

When operating in Monitor, Manual Defib or Pacer Mode, the HeartStart MRx is suitable for use by healthcare professionals trained in advanced cardiac life support.

Defibrillation Therapy

Defibrillation therapy is the definitive method for termination of a variety of potentially fatal arrhythmias. The HeartStart MRx provides this therapy through the application of a brief biphasic pulse of electricity to the cardiac muscle. This electrical energy is transferred through attached paddles or disposable multifunction electrode pads applied to the patient's bare chest.

NOTE Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of monitor/defibrillator performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or device performance.

Precautions for Manual Defibrillation Therapy

Defibrillating asystole can inhibit the recovery of natural pacemakers in the heart and completely eliminate any chance of recovery. Asystole should not be routinely shocked.

Precautions for AED Therapy

The AED algorithm is not designed to handle erratic spiking problems caused by a properly or improperly functioning pacemaker. In patients with cardiac pacemakers, the HeartStart MRx may have reduced sensitivity and not detect all shockable rhythms.

NOTE The HeartStart MRx AED mode is not intended for children under 8 years of age. For children older than 8 years, the American Heart Association recommends that standard operating procedures for AEDs be followed. See the American Heart Association *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*. Dallas, Texas; AHA; 2000.

Synchronized Cardioversion Therapy

The HeartStart MRx provides synchronized cardioversion therapy by delivering a biphasic, electrical stimulus to the heart immediately following an R-wave detected in the ECG measurement. The SMART Biphasic waveform utilized in the HeartStart MRx has undergone clinical testing demonstrating its effectiveness for cardioversion of atrial fibrillation.

Noninvasive Pacing Therapy (Optional)

The HeartStart MRx provides noninvasive transcutaneous pacing by delivering a monophasic, electrical stimulus to the heart. This stimulus is intended to cause cardiac depolarization and myocardial contraction. The medical care provider selects the stimulus output and rate settings. The energy is delivered through multifunction electrode pads applied to the patient's bare chest.

12-Lead ECG Analysis (Optional)

The HeartStart MRx 12-lead ECG function uses the Philips 12-Lead Algorithm to analyze acquired 12-lead ECG signals from adult and pediatric patients. The algorithm provides an analysis of amplitudes, durations, and morphologies of the ECG waveforms and the associated rhythm, based on the age and sex of the patient. Measurements and interpretive statements are offered to the clinician on an advisory basis only. This information is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG waveforms, and other clinical findings.

Noninvasive Blood Pressure (NBP) Monitoring (Optional)

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff is deflated from above the systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. The pressure at which this occurs is very close to the systolic pressure. As the cuff pressure is decreased further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish rapidly. The index of diastolic pressure is taken where this rapid transition begins.

Studies have shown that, especially in critical cases (arrhythmia, vasoconstriction, hypertension, shock), oscillometric devices are more accurate and consistent than devices using other noninvasive measuring techniques.

The readings obtained from automatic oscillometric devices almost always deviate from those produced by the auscultatory technique. It is of particular importance to understand these deviations in environments such as Emergency and Recovery Departments where comparisons with intra-arterial measurements are seldom available.

CO₂ Monitoring (Optional)

Capnometry is the measurement and numerical display of end-tidal CO₂ (EtCO₂) or the maximum expired CO₂ concentration during a respiratory cycle. The capnograph is a graphical representation of the concentration or partial pressure of expired CO₂ during a respiratory cycle in a "waveform" format. The capnograph provides information not only regarding pulmonary function, but also indirect cardiac function, ventilator function and perfusion.

Pulse Oximetry (SpO₂) Monitoring (Optional)

A pulse oximeter is a noninvasive device that indicates the oxygen saturation (SpO₂) of arterial blood. This measurement is obtained through a probe that directs red and near infrared light through arterial beds. Hemoglobin absorbs these lights differently when it is bound with oxygen. Pulse oximetry measures this difference and translates the measurement into a saturation percentage that is displayed as an SpO₂ reading.

Indications for Use

The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation.

The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.

The SMART Biphasic waveform utilized in the HeartStart MRx has previously undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at 150J. There are currently no clinical studies related to the use of the SMART Biphasic waveform in pediatric applications.

Manual Defibrillation

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients who are pulseless and unresponsive. Synchronous defibrillation is indicated for termination of atrial fibrillation.

Asynchronous defibrillation therapy is contraindicated in patients that exhibit one or any combination of the following:

- Responsiveness
- Spontaneous breathing
- Palpable pulse

AED Therapy

An AED is to be used in the presence of a suspected cardiac arrest on patients of at least 8 years of age that are:

- Unresponsive
- Not breathing
- Pulseless

An AED is not to be used on patients that exhibit one or any combination of the following:

- Responsiveness
- Spontaneous breathing
- Palpable pulse

Noninvasive Pacing Therapy

The pacing option is intended for treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

Noninvasive pacing is contraindicated in the treatment of ventricular fibrillation. Noninvasive pacing in the presence of severe hypothermia may be contraindicated.

12-Lead ECG

The 12-Lead ECG function is to be used where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms.

Noninvasive Blood Pressure

The NBP option is intended for use to determine the noninvasive measurement of arterial blood pressure for adult and pediatric patients.

NBP monitoring is contraindicated in neonatal patients or infants whose upper arm circumference is less than 13 cm.

End-tidal CO₂

The EtCO₂ option is intended for noninvasive monitoring of exhaled carbon dioxide (EtCO₂) and to provide a respiration rate for adult, pediatric, and neonatal patients.

Pulse Oximetry

The SpO₂ option is intended for use when it is beneficial to assess oxygen saturation level for adult and pediatric patients.

Safety Considerations

General warnings and cautions that apply to use of the HeartStart MRx are provided in “Specifications and Safety” on page 213. Additional warnings and cautions specific to a particular feature are provided in the appropriate section of this guide.

WARNING Electric shock hazards exist internally. Do not attempt to open the device. Refer servicing to qualified personnel.

Documentation and Training

Available documentation and training for the HeartStart MRx includes:

- HeartStart MRx Instructions for Use
- HeartStart MRx Quick Reference Cards
- HeartStart MRx Battery Application Note
- HeartStart MRx Web-based User Training (Located at:
www.medical.philips.com/goto/mrxtraining. Enter training access password: meetMRx.)
- HeartStart MRx User Training Video

Other Application Notes can be found on the Philips website at:
www.medical.philips.com/goto/productdocumentation.

Getting Acquainted

The HeartStart MRx is designed with your needs in mind. Controls, indicators, and menus are carefully organized to facilitate ease of use, and display information is tailored to the current task.

This chapter will acquaint you with the HeartStart MRx operational modes, display views, controls, and indicators. It also provides general information on use of the device.

NOTE If your HeartStart MRx does not have optional SpO₂, CO₂, NBP, Pacing, 12-lead ECG acquisition, or 12-lead ECG transmission functionality, disregard these controls and the related information described in this chapter.

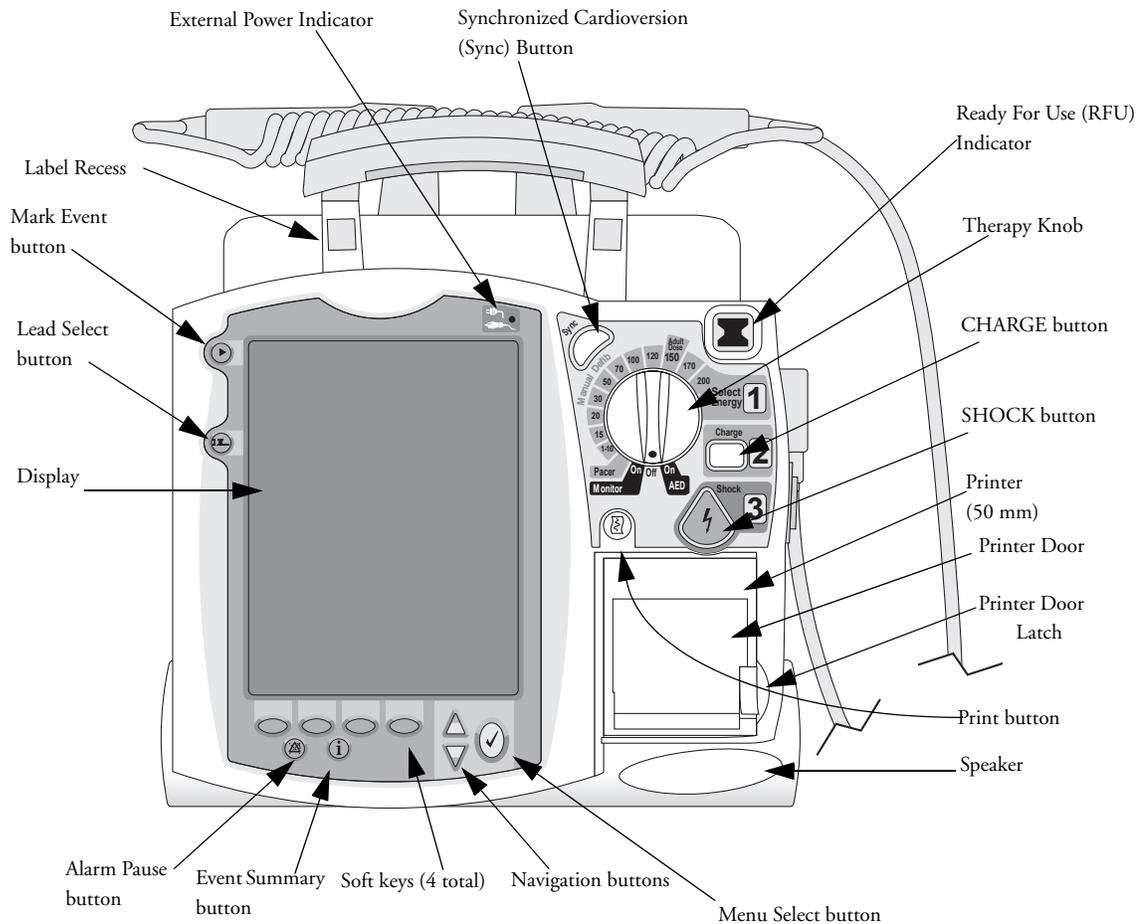
Basic Orientation

HeartStart MRx controls, indicators, and connections are carefully organized to facilitate ease of use.

Front Panel

The front panel contains operational controls and indicators, as shown below.

Figure 1 Basic Orientation (Front)



The front panel also contains the printer and speaker.

Additional controls and indicators are on the paddles (if used) and batteries.

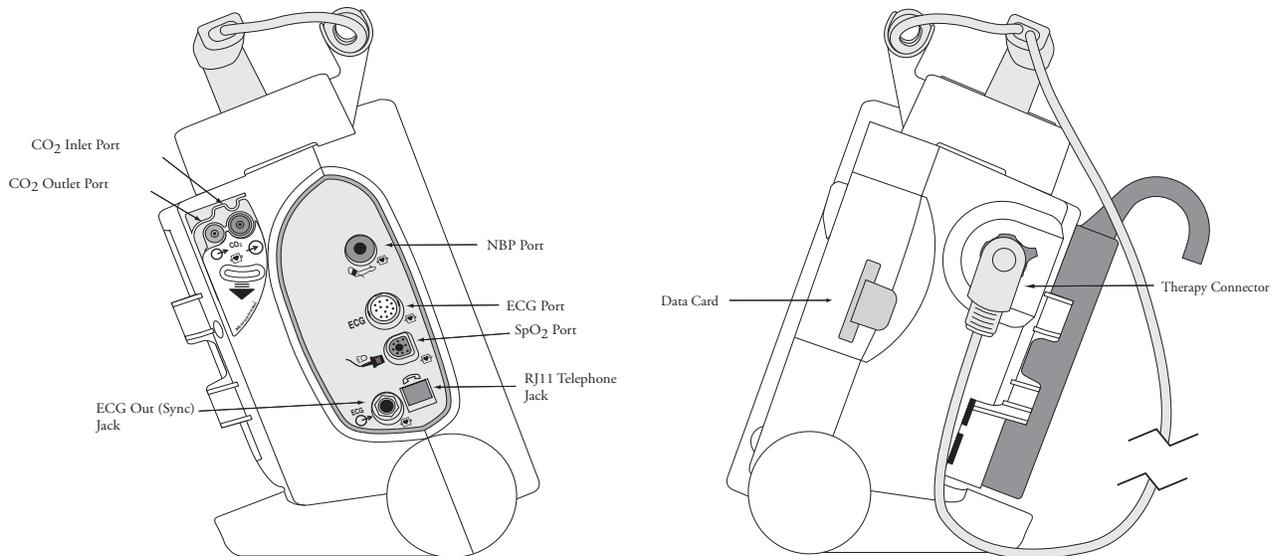
NOTE A palette of colored decals is included with your HeartStart MRx. These colored decals may be applied to the label recesses located on the device handle to aid in identification. Use an indelible marker to print identification information on the decal.

Side Panels

The left side of the HeartStart MRx has ports for monitoring cables, including ECG, pulse oximetry (SpO₂), noninvasive blood pressure (NBP), and carbon dioxide (CO₂). The ECG port may be used to connect a 3-, 5-, or 10-lead patient cable. The ECG Out jack may be used to connect to an external monitor. There is also a telephone jack (for future use).

The right side of the HeartStart MRx has a therapy port for paddles (external or internal) or multifunction electrode pads. It also has a slot for a data card to transfer patient information.

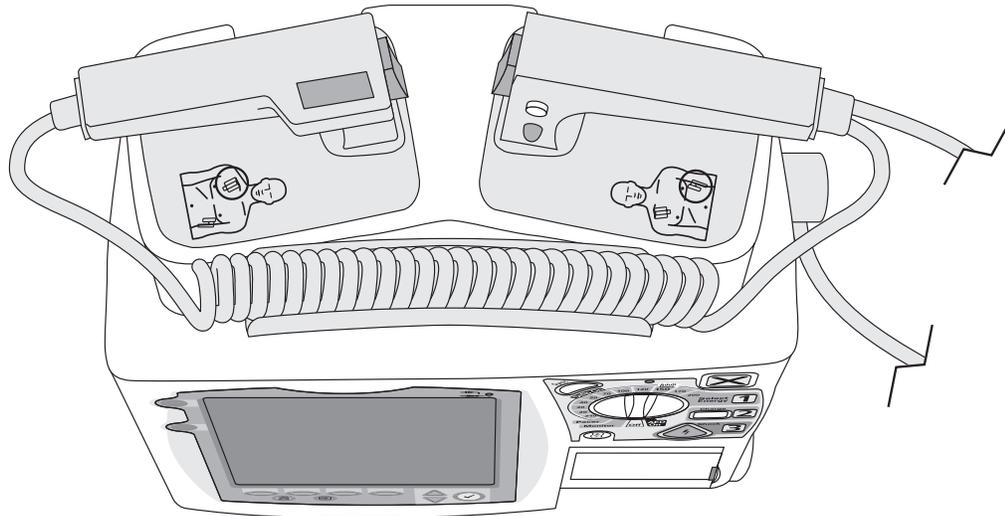
Figure 2 Basic Orientation (Right/Left Sides)



Top Panel

The top of the HeartStart MRx has a handle and basic operating instructions. If optional external paddles are present, they reside on the top panel as shown.

Figure 3 Basic Orientation (Top - with Optional Paddles)

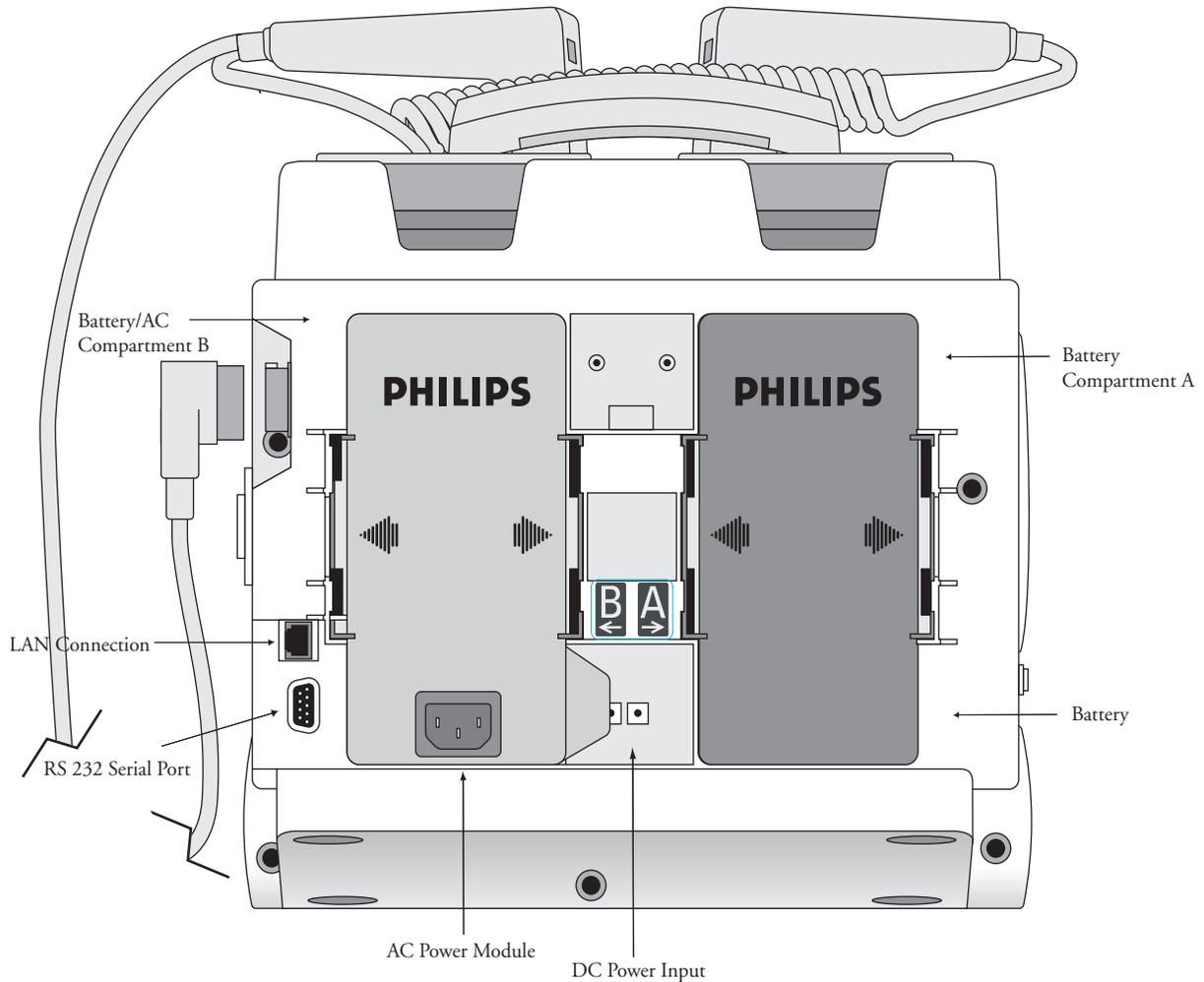


Back Panel

The back panel of the HeartStart MRx has two compartments for lithium ion batteries. Compartment B may instead be used to connect an AC power module. Between the battery compartments is a DC Power Input port.

The back panel also has an RS 232 serial port for 12-lead ECG transmission. The LAN port is for factory use only.

Figure 4 Basic Orientation (Back)



M3538A Lithium Ion Battery

The HeartStart MRx uses the M3538A Lithium Ion Battery. The battery has a fuel gauge with 5 LED indicators, each representing a charge of approximately 20% of capacity. Press the fuel gauge button to illuminate the fuel gauge.

NOTE A battery should be used as the primary power source, with AC/DC as a secondary source, if desired. If an AC/DC power module is used as the only power source, the HeartStart MRx will take longer to charge to the desired energy level.

Battery Capacity

A new, fully-charged M3538A battery, operating at room temperature 25°C(77°F), provides approximately 5 hours of monitoring, with ECG, SpO₂ and CO₂ monitored continuously and NBP measured every 15 minutes, or at least 50 full-energy discharges.

Battery Life

Battery life depends on the frequency and duration of use. When properly cared for, the M3538A Lithium Ion battery has a useful life of approximately 2 years. To optimize performance, a fully (or nearly fully) discharged battery should be charged as soon as possible.

Operating Modes

The HeartStart MRx has four clinical modes of operation, each with a customized display view. The modes are as follows:

Table 1 Operating Modes and Views

Mode of Operation	Display View	Description
Monitor Mode	Monitoring View, or 12-Lead View	Used to monitor ECG, take an optional 12-lead ECG, and monitor optional parameters such as SpO ₂ , EtCO ₂ and NBP.
AED Mode	AED View	Used to analyze ECG and if necessary, perform semi-automatic external defibrillation.
Manual Defib Mode	Code View	Used to perform asynchronous and synchronous defibrillation (cardioversion).
Pacer Mode	Pacing View	Used to perform demand or fixed mode pacing.

NOTE Upon returning to a clinical mode from a non-clinical mode such as Configuration or Data Management, all settings are re-set to the device's default values.

Password Security

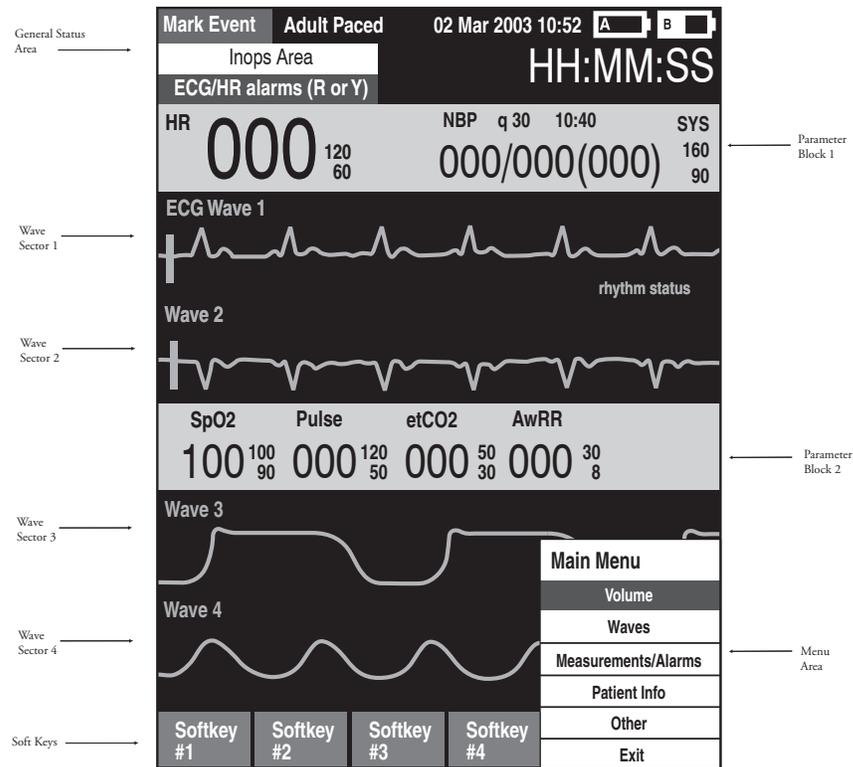
Access to Manual Defib Mode and Pacer Mode may be password protected (for Version A.02 and later devices) if enabled in Configuration. If enabled, you will be prompted to enter the password upon moving the Therapy Knob to either the Pacer position or an energy selection. The password is entered by using the Navigation buttons to select the password numbers and then selecting **Done** to complete the entry. The Charge  button and the **[Start Pacing]** soft key remain inactive until the password is entered.

WARNING Use of the Manual Therapy Security password requires the clinician to know and remember the password, as defined in Configuration. Failure to enter the correct password will prevent the delivery of manual defibrillation or pacing therapy. Prior to selecting this Configuration option, review this potential risk with your Risk Manager.

Display Views

The HeartStart MRx display layout is segmented as shown in Figure 5.

Figure 5 Display Layout



The content of these areas varies with the display view and the function being performed.

General Status

The general status area of the display contains:

- Mark Event button label
- Patient information

Some modes of operation allow for the entry of patient information via a menu choice. If no information is entered, the patient category is defaulted to **Adult**, unless configured otherwise, and the pacing status is set to **Non-Paced**, unless the Paced status is set to Paced for an internally paced patient, or the HeartStart MRx is pacing the patient. In Pacer Mode, Paced status is not displayed.

- Date and time
- Battery power indicators

Battery icons, labeled “A” and “B”, correspond with the battery compartments located at the back of the HeartStart MRx. Each battery icon displays the current available battery power, ranging from hollow (fully discharged) to full (fully charged), as shown in Figure 6. If the AC Power Module is inserted in Compartment B, the no battery icon is displayed.

Figure 6 Battery Charge Level Indicators



- Inop statements

Inop statements appear in the top left of the display if equipment problems are detected.

- ECG/HR alarm status

Alarm messages communicate arrhythmia alarms, as well as overall alarm status (alarms off, alarms paused).

- Event Timer

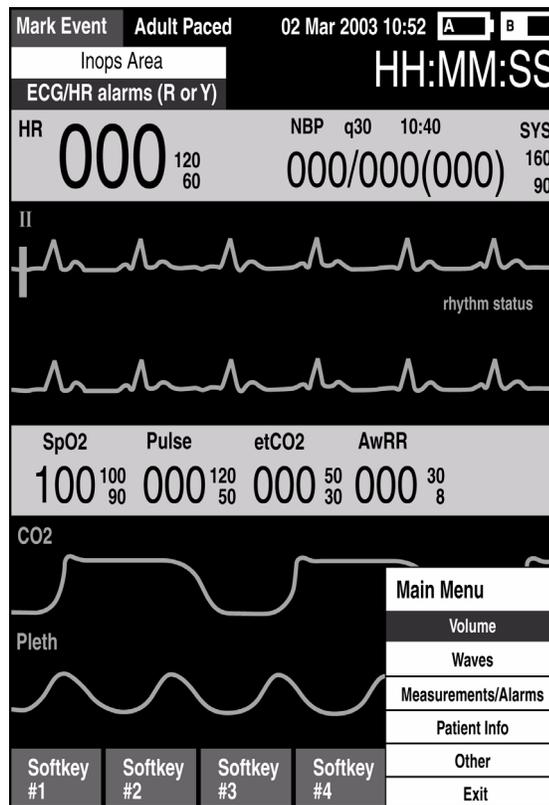
An Event Timer communicates the elapsed time since the device was turned on.

Wave Sectors

The HeartStart MRx is configured to populate each wave sector with a predetermined waveform, when powered on in Monitor, Manual Defib, or Pacer Mode. Figure 7 shows the default Waves configuration choices. See “Configuration” on page 125 for more information.

A dashed line in a wave sector or an empty wave sector indicates that the waveform source is not connected to the HeartStart MRx. Wave sectors may contain a variety of information, as appropriate to the parameter, view, and task. Additionally, ECG wave sectors contain a calibration bar.

Figure 7 Default Waves Configuration



Wave Sector 1

Wave Sector 1 will only contain an ECG waveform. This is the waveform used by the arrhythmia, heart rate derivation, and AED analysis algorithms. This waveform may be acquired through the therapy port for pads/paddles or the monitoring port for 3-, 5-, or 10-lead electrodes. If the configured source is not connected to the HeartStart MRx when turned on, the first valid ECG source is displayed in Wave Sector 1. Once the configured source is available, it automatically populates Wave Sector 1. Should the configured source then become invalid, a Leads Off condition is displayed. The HeartStart MRx *does not* revert to the initial source of ECG.

NOTE If Pads are configured as the primary ECG source for Wave Sector 1, the ECG patient cable must be connected to the MRx and to the monitoring electrodes on the patient in order to change the ECG source to a Leads selection.

NOTE When monitoring using a 3-lead ECG set, the MRx displays only 1 ECG lead at a time.

Wave Sectors 2-4

Wave Sectors 2 through 4 are automatically populated when parameter sources (cables/tubing) are connected to the HeartStart MRx. If the parameter source is the configured choice of a particular wave sector, it is displayed in that wave sector. If you connect a parameter source that is not configured to be displayed, it is displayed in the first empty wave sector. If you subsequently connect the configured parameter source, it does not replace the current parameter, instead it populates the first available empty wave sector.

Changing Displayed Waveforms

Wave Sector 1 has a dedicated Lead Select button to change the displayed lead/source. Waveforms displayed in other wave sectors may be changed for the current patient through the display menu. See “Display Menus” on page 19.

Parameter Blocks

Measurements for displayed waveforms and monitored parameters are provided in the parameter blocks. Parameter Block 1 always contains the heart rate and HR alarm settings. The NBP schedule, measurements, and alarm settings are also displayed in Parameter Block 1. Parameter Block 2 contains measurements and alarm settings for SpO₂, Pulse, EtCO₂ and Airway Respiration Rate (AwRR). Each measurement is labeled and displays the current value and the high and low alarm limit settings or the  (alarms off) icon. A “-?-” is displayed until a valid measurement can be obtained.

SpO₂ and EtCO₂ measurements are activated when the associated parameter cable/tubing is connected. When the SpO₂ and EtCO₂ cable/tubing is disconnected, a prompt message informs you and requests approval to turn off the measurement.

Parameter Alarm Messages are displayed in the space above each numeric value, replacing the parameter label.

Soft Key Labels

The four soft key labels correspond to the soft key buttons located immediately below. These labels change, as appropriate, according to the current display view and function. Soft key labels appearing as grey text indicate that the soft key is inactive.

Display Menus

Menus with controls and options specific to each function of the HeartStart MRx are easily accessible through the Menu Select and Navigation buttons located on the front panel. Menus are used to adjust volume, select waveforms for display, set alarms, schedule measurements, enter patient information, perform the Operational Check, generate reports, and a variety of other tasks. Menus and submenus are organized to allow you to conveniently make selections and enter information.

To display a menu, press the Menu Select  button. Then use the up  or down  Navigation buttons to scroll through the available choices until the desired selection is highlighted. To activate the selection, press the Menu Select button. Press **Exit** to close the menu without activating a selection.

Figure 8 Sample Menu

HR/Arrhythmia
Relearn Rhythm
Alarms Off
HR Limits
VTACH Limits
Exit

Message Windows

Periodically, message windows appear on the display to provide additional status information, alert you to an error or a potential problem, or direct you to take action. Remain alert to these messages. If a response is required, as shown in Figure 9, use the Navigation and Menu buttons to highlight and select the appropriate answer.

Figure 9 Sample Message Window

Configuration Not Saved - Exit Anyway?
Yes
No

High Contrast Display

To optimize visibility of the MRx display when used in bright sunlight, Version A.02 and later devices provide a High Contrast feature which may be enabled. In this view, the MRx display appears using a yellow background with all other screen elements appearing in black or shades of gray. High Contrast is enabled in Manual Defib, Pacer and Monitor Modes by pressing the Menu Select  button and selecting **High Contrast On** from the Main Menu.

NOTE The High Contrast feature does not display colors configured as red or blue, therefore, be sure your device is configured correctly with the appropriate parameter color settings. See Table 16 on page 132 in Configuration.

Controls

The Therapy Knob is used to turn the HeartStart MRx on in the desired mode of operation. Operating controls are organized by function, with general function buttons located along the left and bottom sides of the display, defibrillation controls to the right of the display, and soft keys immediately below the display. (See Figure 1.)

Therapy Knob

The Therapy Knob serves as the power switch for the HeartStart MRx. It can be set to:

- **Off**
- **AED** - to enable AED Mode for automated external defibrillation.
- **Monitor** - to enable Monitor Mode for 3- or 5-lead ECG monitoring, 12-lead ECG acquisition, or monitoring of optional parameters such as SpO₂, CO₂, and NBP.
- **Pacer** - to enable Pacer Mode (optional) for demand or fixed mode pacing.
- **Manual Defib** - to enable Manual Defib Mode for asynchronous or synchronous defibrillation (cardioversion) at the selected energy setting.

In Manual Defib Mode the defibrillation energy settings are labeled as 1-9, 10, 15, 20, 30, 50, 70, 100, 120, 150, 170, and 200 Joules. If your unit is equipped with the optional pacing function, the energy settings are labeled as 1-10, 15, 20, 30, 50, 70, 100, 120, 150, 170, and 200 Joules.

General Function Buttons

The general function buttons control monitoring or non-critical resuscitation activities. They include:

Mark Event button - allows you to insert a time-stamped annotation in the Event Summary Report to note events as they occur, including the administration of certain drugs. A Mark Event button label appears at the top left corner of the display.

Lead Select button - changes the ECG lead in Wave Sector 1. Pressing this button cycles through the available ECG waves, changing the displayed wave and label. The list of available ECG waves is based on the current lead set and device configuration, and includes pads or paddles, if the corresponding cable is connected to the device.

Alarm Pause button - The Alarm Pause button pauses all visual and audible physiological alarms and audible inops for the configured time interval. At the end of the pause interval, each alarm returns to its previous setting (On or Off). Pressing the Alarm Pause button during the pause interval also returns alarms to their previous settings.

Print button - The Print button initiates a continuous print-out of the primary ECG and the waveform displayed in Wave Sector 2, either real-time or with a 10-second delay, depending on your configuration.

Event Summary button - The Event Summary button prints the current or most recent Event Summary report.

Menu Select button - Pressing the Menu Select button either brings up the current menu or confirms a menu selection.

Navigation buttons - The Navigation buttons display the current menu just as the Menu Select button does. Additionally, within any menu or list, these buttons move to the next or previous item in the list. They also increase or decrease numbers or values in a sequence. They may be held down to accelerate through the available choices.

Defibrillation Controls

The defibrillation controls are shown in Figure 10. They include the:

Therapy Knob - Enables AED or selects an energy for Manual Defib Mode defibrillation or cardioversion.

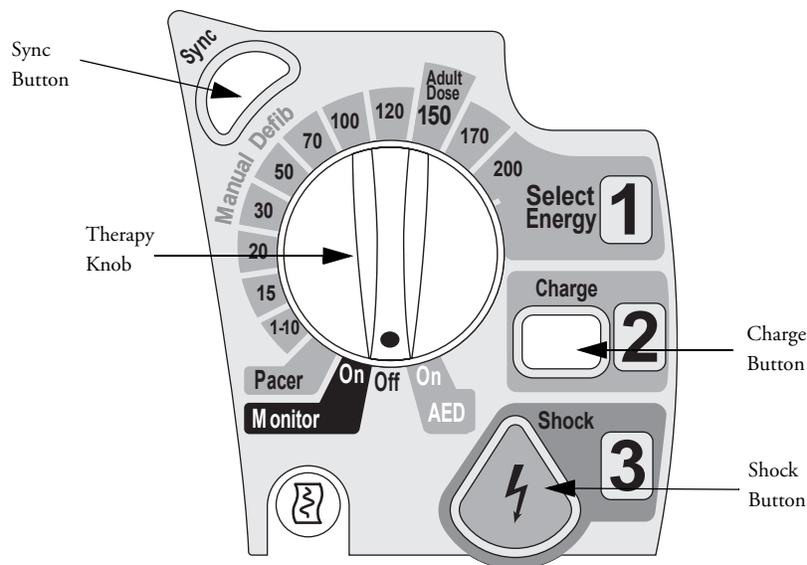
Charge Button - Charges the defibrillator to the selected Manual Defib energy setting. Used only in Manual Defib Mode. In AED Mode, the defibrillator charges automatically.

Shock Button - Delivers a shock through multifunction electrode pads or switchless internal paddles. In AED mode a 150J shock is delivered. In Manual Defib Mode, the shock is delivered at the selected Manual Defib energy setting.

NOTE When external paddles or switched internal paddles are used, once the HeartStart MRx is fully charged, the shock is delivered by pressing the Shock button(s) on the paddles.

Sync Button - Toggles between synchronized energy delivery used during cardioversion and asynchronous energy delivery used during defibrillation.

Figure 10 Defibrillation Controls



Soft Keys

The soft keys perform the function displayed as a label appearing immediately above on the display. The labels (and, therefore, the function) change appropriately for the various modes of operation and are described in the chapters which follow.

Indicators

The HeartStart MRx indicators provide a visual display of device status.

Ready For Use Indicator The Ready For Use (RFU) indicator is located on the upper, right corner of the device. It indicates the status of the therapy delivery functions of the monitor/defibrillator using the following definitions:

- A blinking black hourglass symbol  indicates the shock, pacing, and ECG functions of the device are ready for use. Sufficient battery power is available for device operation. Additionally, a blinking black hourglass, together with the presence of external power (AC or DC), indicates that installed battery(s) are being charged.
- A blinking red "X"  and a periodic audio chirp indicate no battery is present or a low battery condition. The device can be used, but its operation time is limited. If a battery is inserted and charging, the audio chirp is not present.
- A solid red "X"  and a periodic audio chirp indicate a failure has been detected that may prevent the delivery of defibrillation therapy, pacing, or ECG acquisition. When turned on, the device displays inop messages for the failures detected.
- A solid red "X"  without periodic audio chirps indicates either there is no power available, or the device cannot power on. If, after power is supplied, the indicator reverts to the blinking black hourglass symbol, the device is once again ready for use.

NOTE The RFU indicator may briefly display a solid red "X" when initially turning the device on, when switching between clinical and non-clinical operating modes, and at the start of any automated test.

External Power Indicator The external power indicator is located above the display. It is green if power is being provided by an external AC or DC power source. See Figure 11.

Figure 11 External Power Indicator



NOTE The external power indicator will momentarily go out when charging for defibrillation with a charged battery installed. This is normal operation, as the device is switching its power source to the battery for a faster charge time.

Responding to Alarms

When an alarm condition occurs and an alarm is indicated, visually and audibly, there are several ways to respond. Initially:

- 1 Attend to the patient.
- 2 Identify the alarm(s) indicated.
- 3 Silence the alarm(s). When an alarm is announced, the audio pause label (see Figure 12) is presented above the Navigation and Menu Select buttons. Pressing any of these buttons will silence the alarm audio while you are attending to the patient.

Figure 12 Audio Pause Label



For devices with serial numbers US001XXXXX

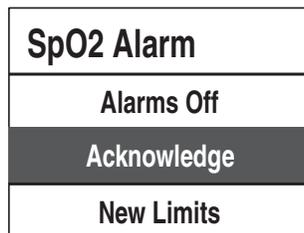


For devices with serial numbers US002XXXXX

Then:

- 4 Address the alarm condition on the HeartStart MRx. The menu shown in Figure 13 appears.

Figure 13 Sample Alarm Response Menu



Alarms Off Turns the monitoring parameter's alarms off. The alarm message is no longer displayed, and the  icon appears next to the parameter value.

Acknowledge The alarm message continues to display and, if after 2 minutes the alarm condition still exists, the alarm audio and response sequence occurs again.

New Limits Adjust the parameter limits accordingly.

WARNING Although the Alarm Pause button can be used when responding to alarms, the response procedures described above are recommended.

NOTE The information above does not pertain to Heart Rate or Arrhythmia Alarms. For information about responding to these alarms, see “Responding to HR and Arrhythmia Alarms” on page 52.

Entering Patient Information

Patient information may be entered for the following:

- Name
- ID
- Patient Category
- Age
- Sex
- Paced

Information is entered using the **Patient Info** menu. Patient Name is entered using 2 alphabetical lists, one to enter the last name, followed by another to enter the first name. When each name is complete, select **Done** or **Cancel** to close the patient name menu without saving.

Continued Use

Once a patient event is started, the Continued Use feature is activated. This feature facilitates continued treatment of the same patient by retaining the current settings and the patient record when the HeartStart MRx is turned off for less than 10 seconds, for instance when switching between AED and Manual Defib Modes or when the Therapy Knob is inadvertently moved to **Off**. When turned on within the 10 second time period, the HeartStart MRx retains the most recent settings, including:

- Alarm settings
- Wave Sector settings
- Event Timer
- QRS, alarm tone, and voice prompt volumes
- ECG gain
- Pacing settings
- Patient record in the Event Summary Report; new data is appended to the record.

The Sync feature remains active if the HeartStart MRx is turned off for less than 10 seconds. However, Sync is disabled when AED Mode is activated, and must be turned on upon returning to Manual Defib Mode.

NOTE The Continued Use feature will not function if all sources of power (battery and external AC/DC power modules) are removed from the device, even briefly.

Return to Owner

The Return to Owner feature is available in Version A.02 and later devices and allows the owner of the HeartStart MRx to enable a specified loan period, after which the borrower of the MRx will be reminded to return the device to its owner as identified on the display. The feature is password protected in Configuration and enabled through the **Other** Menu, where the owner can activate, deactivate, and specify the length of the loan period.

NOTE Monitoring and defibrillation functions are suspended while the Return to Owner set-up screen is displayed.

NOTE The appearance of the loan expiration message does not disable monitoring and defibrillation functionality.

To enable the Return to Owner feature:

- 1 Press the Menu Select  button.
- 2 Select **Other** from the menu and press the Menu Select button.
- 3 Select **Return To Owner** and press the Menu Select button.
- 4 Press the [**Activate**] soft key.
- 5 Enter the number of days in the loan period and press the Menu Select button.
- 6 Press the [**Exit Return-To**] soft key.

To disable the Return to Owner feature:

- 1 Press the Menu Select  button.
- 2 Select **Other** from the menu and press the Menu Select button.
- 3 Select **Return To Owner** and press the Menu Select button.
- 4 Press the [**Deactivate**] soft key.
- 5 Enter the password and press the Menu Select button.
- 6 Press the [**Exit Return-To**] soft key.

Setting Up

This chapter provides the basic set-up information you need to prepare your device for operation and to connect the optional monitoring accessories to your HeartStart MRx.

NOTE If your HeartStart MRx does not have optional SpO₂, CO₂, NBP, Pacing, or 12-lead ECG functionality, or optional accessory pouches, disregard these features and the related information described in this chapter.

Before using the HeartStart MRx, review the configuration settings of your device. Confirm and update the settings as appropriate.

Attaching the Carrying Case and Accessory Pouches

The HeartStart MRx accessory pouches are designed to hold your essential monitoring and defibrillation accessories. Follow the procedures below for assembly and recommended accessory placement.

- 1 Disconnect all external power and remove all batteries.
- 2 Lower the device into the sleeve of the carry case. The rear base of the device fits in the sleeve socket.

Paddle Tray

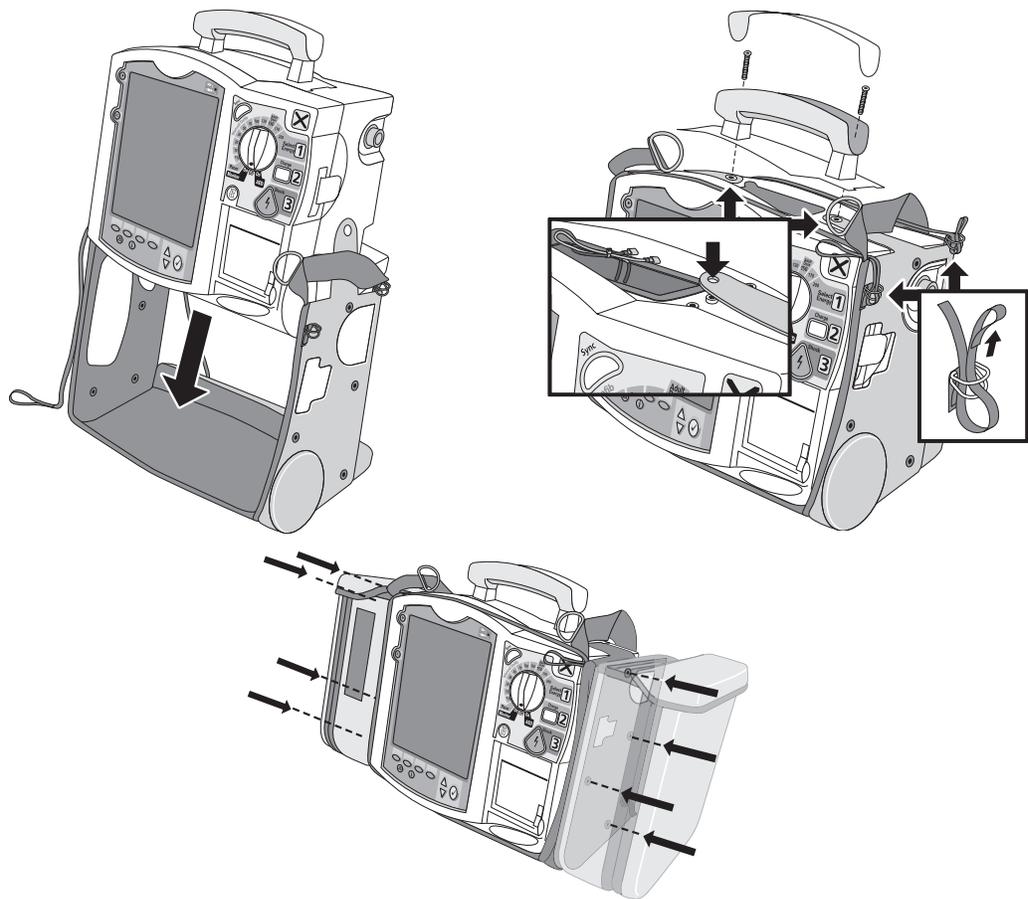
- a. If paddles are connected, disconnect them from the Therapy port and remove them from the paddle tray.
- b. Remove the 4 T-15 screws from the tray plates.
- c. Gently lift the paddle tray up, leaving all wires connected.

Handle Only

- a. Remove the handle cover by pushing in on either side of the handle cover and lifting up.
- b. Remove the 2 T-15 screws.
- c. Remove the handle.
- d. Gently lift the cap plate up.

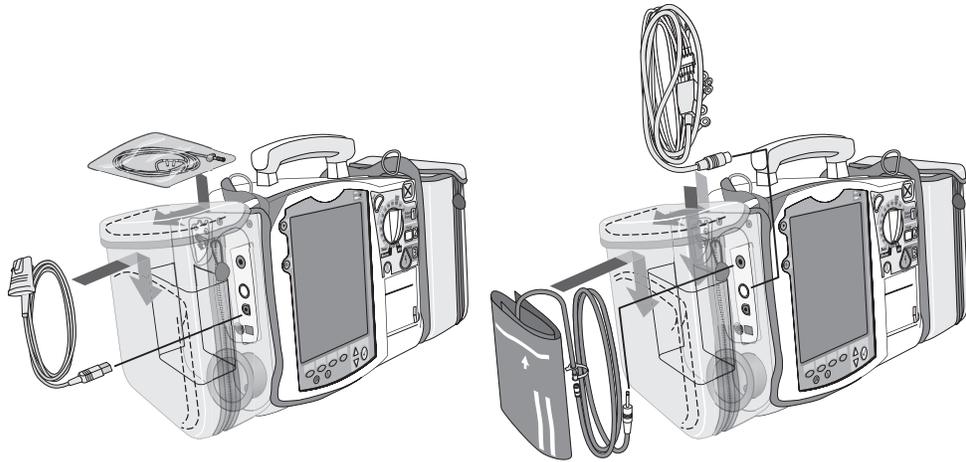
- 3 Fold the two sleeve flaps over the top of the device, positioning them so that the screw holes are exposed.
- 4 Replace the paddle tray or cap plate, as appropriate, so that the molded openings fit over the sleeve flaps.
- 5 Secure the front and rear cinch straps using the metal rings provided.
- 6 Perform an Operational Check as described in, “Maintenance” on page 151.
- 7 Attach the side pouches using the snaps located inside the pouch pockets.

Figure 14 Accessory Pouch Assembly and Accessory Placement



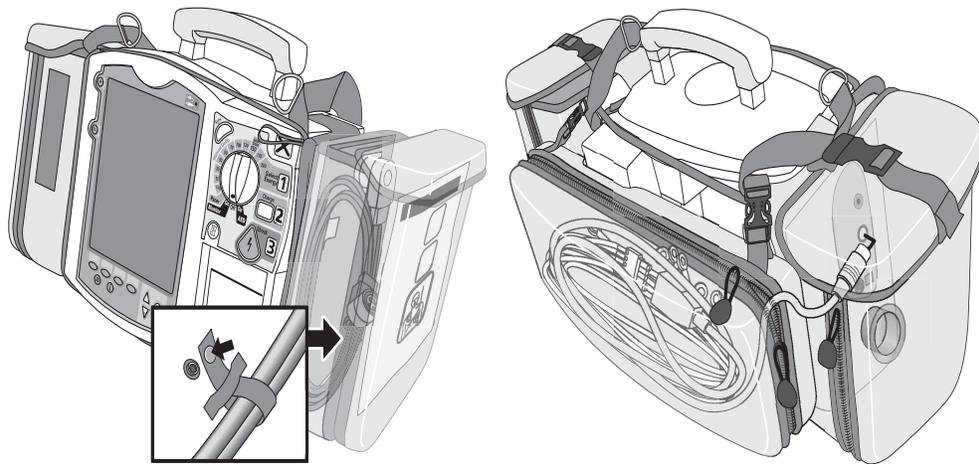
Storing Accessories

- 1 Store parameter cabling and accessories as shown below.
- 2 Route the ECG cabling underneath the paper storage cylinder.



- 3 Attach the Therapy cable and route it through cable fastener loop, securing the cable just below the strain relief.
- 4 Attach the rear pouch using the buckles provided.

NOTE Depressions are provided on the inside of the rear pouch should you wish to make a cut-out to accommodate external power.



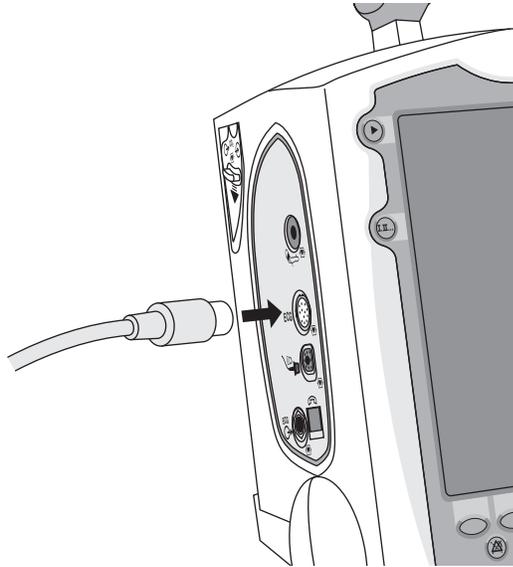
WARNING When using the carry bag to transport the HeartStart MRx, it is important to position it with the display facing away from the body. If not, the Therapy Knob may be bumped and inadvertently moved from its current position.

Connecting the ECG Cable

To connect a 3-, 5- or 10-lead cable:

- 1 Align the ECG cable with the white ECG port, as shown in Figure 15. The white key marker on the ECG cable faces the top of the device.
- 2 Push the ECG cable firmly into the ECG port, until the white portion of the cable connector is no longer visible.

Figure 15 Connecting the ECG Patient Cable

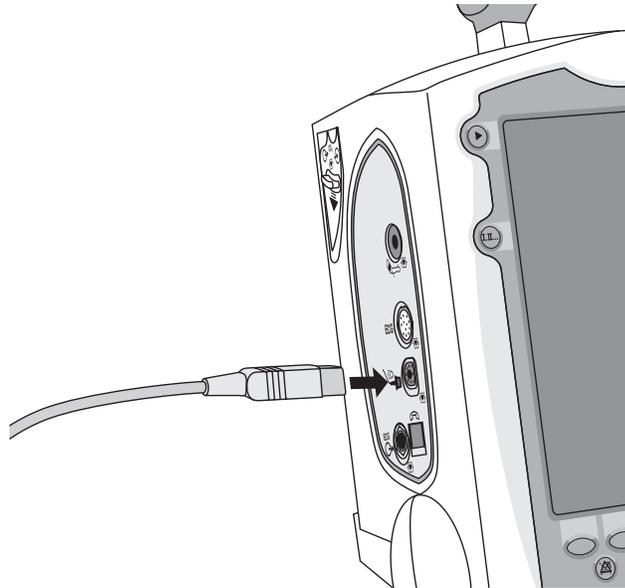


Connecting the SpO₂ Cable

To connect the SpO₂ cable:

- 1 Hold the cable connector with the flat side facing front, as shown in Figure 16.
- 2 Insert the cable into the blue SpO₂ port on the HeartStart MRx and push until the blue portion of the cable connector is no longer visible.

Figure 16 Connecting the SpO₂ Cable

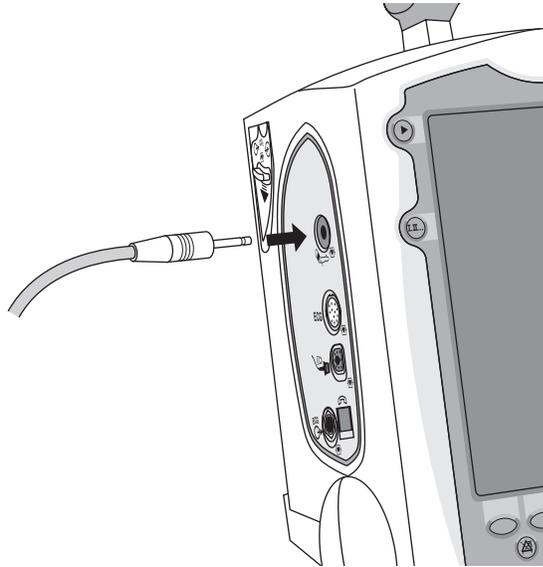


Connecting the NBP Interconnect Tubing

To connect the NBP Interconnect Tubing:

- 1 Insert the NBP Interconnect Tubing into the red NBP port as shown in Figure 17.
- 2 Attach the NBP Interconnect Tubing fitting to the NBP cuff.

Figure 17 Connecting NBP Interconnect Tubing / NBP Cuff

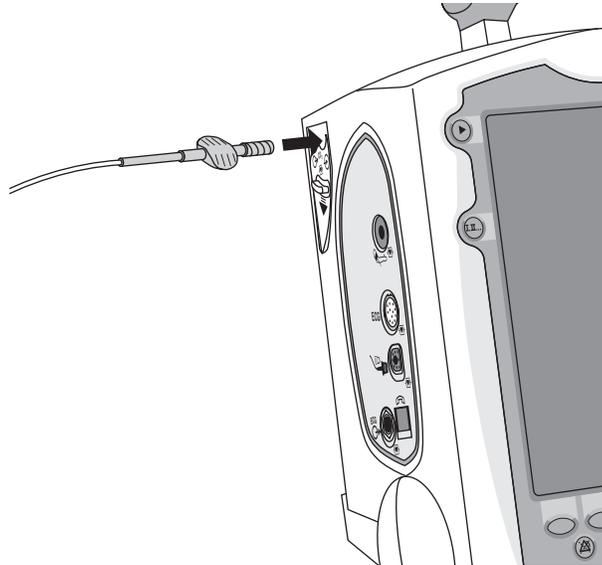


Connecting the CO₂ Nasal FilterLine[®]

To connect the CO₂ Nasal FilterLine[®]:

- 1 Using the end of the nasal FilterLine fitting, slide the CO₂ compartment door down.
- 2 Insert the fitting into the CO₂ Inlet port as shown in Figure 18.
- 3 Turn the fitting clockwise into place.

Figure 18 Connecting the CO₂ Nasal FilterLine[®]

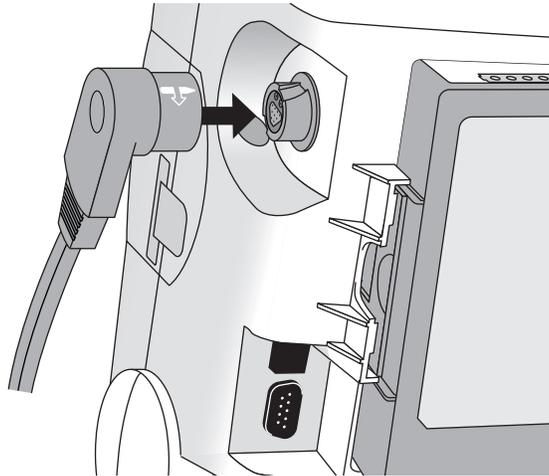


Connecting the Therapy Cable

To connect the Therapy cable:

- 1 Align the white pointer on the cable with the white arrow on the green Therapy port as shown in Figure 19.
- 2 Insert the cable into the green Therapy port. Push until you hear it click into place.

Figure 19 Connecting the Therapy Cable



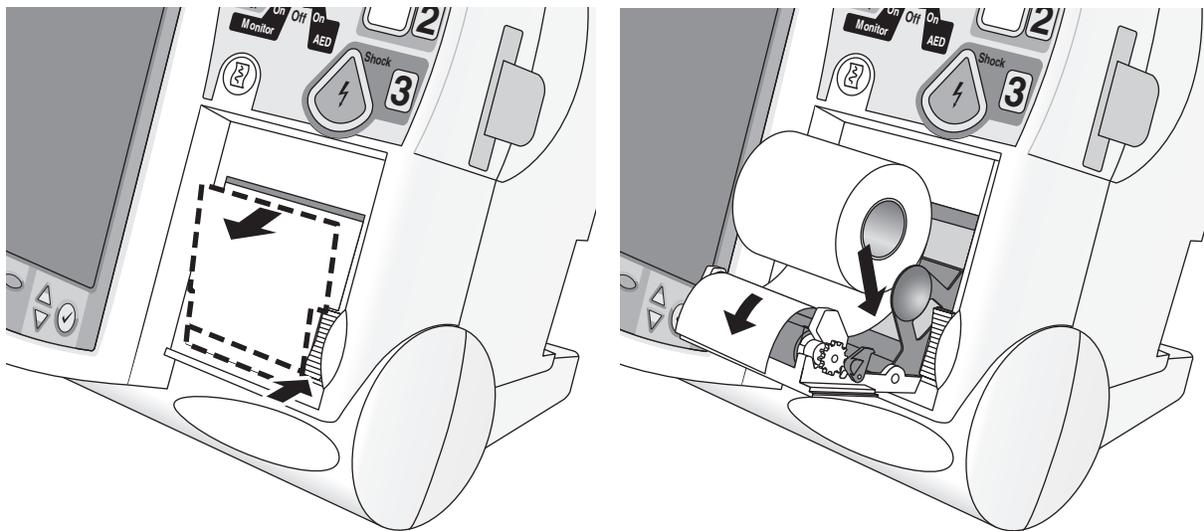
Installing Paper

50mm Printer

To install printer paper:

- 1 Open the printer door by pushing on the latch as shown in Figure 20.
- 2 If there is an empty or low paper roll in the printer, pull up on the roll to remove it.
- 3 Place a new roll of printer paper into the paper well, positioning the roll so that the end of the roll is on the bottom and the grid faces up.
- 4 Pull the end of the paper out past the paper roller.
- 5 Close the printer door.

Figure 20 Installing Paper(50mm)

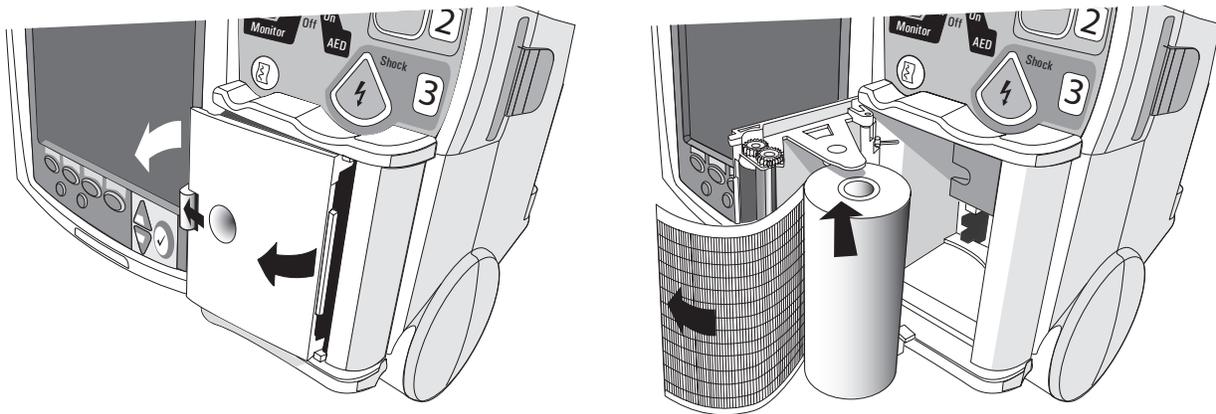


75mm Printer

To install printer paper:

- 1 Open the printer door by pushing on the latch as shown in Figure 21.
- 2 If there is an empty or low paper roll in the printer, pull up on the tab holding the paper roll to remove it.
- 3 Place a new roll of printer paper into the paper well, positioning the roll as shown in Figure 21.
- 4 Pull the end of the paper out past the paper roller.
- 5 Close the printer door.

Figure 21 Installing Paper (75mm)

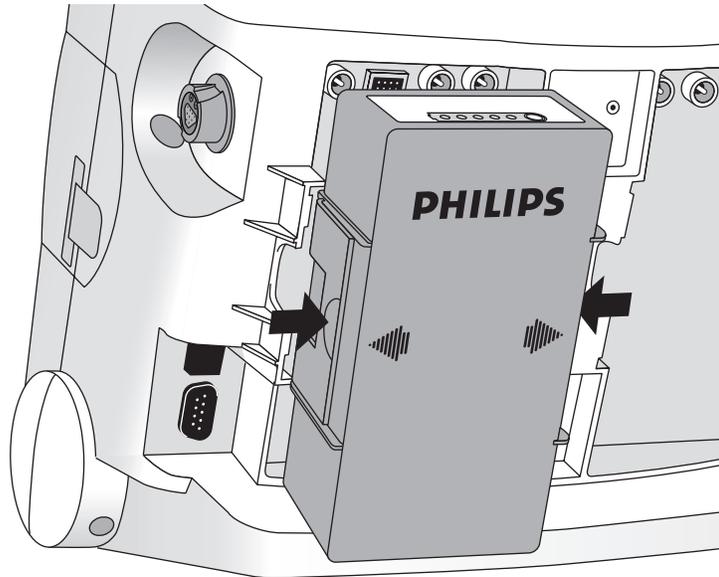


Installing Batteries

To install the batteries:

- 1 Align the M3538A Lithium Ion battery in a battery compartment.
- 2 Insert the battery, and press until you hear it click into place. Ensure that the latches located on both sides of the battery are engaged fully.

Figure 22 Installing batteries



Charging Batteries

Charge batteries fully upon receipt and prior to use. Be sure to familiarize yourself with the battery maintenance procedures discussed in “Maintenance” on page 151.

Battery Safety

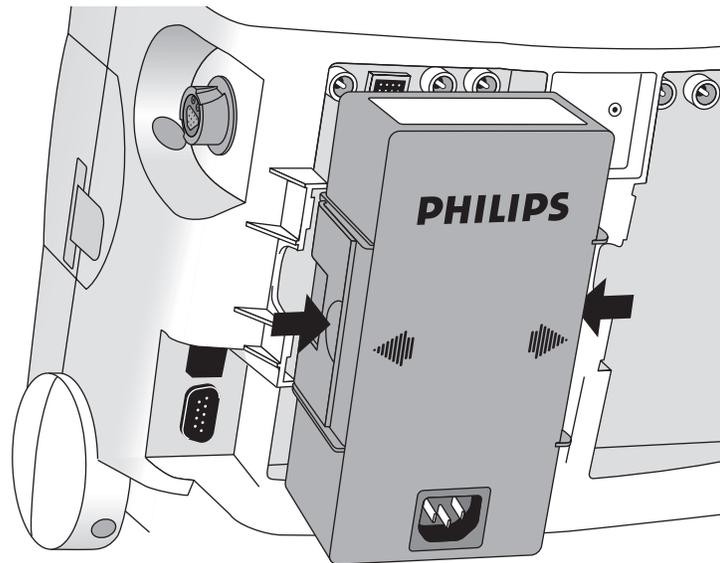
Review the Application Note, *M3538A Lithium Ion Battery - Characteristics and Care*, provided with your HeartStart MRx. Additionally, read the battery related warnings in “Specifications and Safety” on page 213, prior to using the M3538A Lithium Ion Battery.

Installing the AC Power Module

If not presently installed in your device, insert the M3539A AC power module as follows:

- 1 Align the M3539A AC power module in Compartment B.
- 2 Insert the AC power module, and press until you hear it click into place. Ensure that the latched located on both sides of the AC power module are engaged fully.
- 3 Insert the power cord into the AC power receptacle.
- 4 Plug into an AC power outlet.
- 5 Check that the External Power indicator on the front panel is illuminated.

Figure 23 Installing the AC Power Module

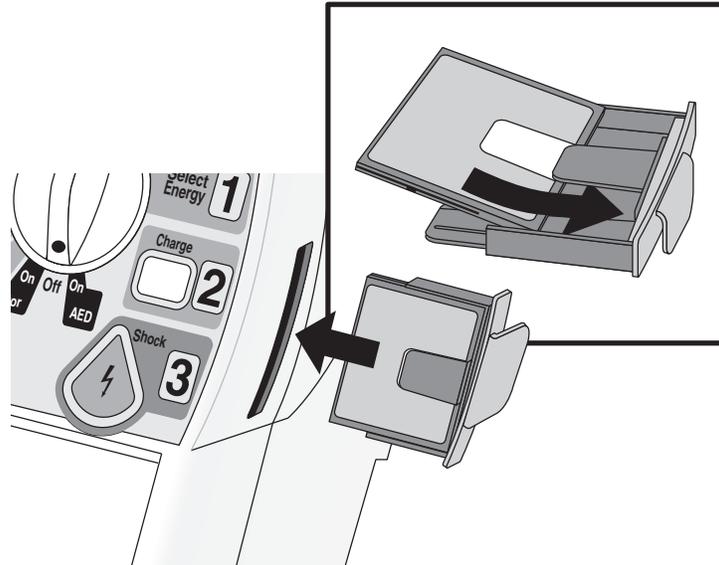


Installing the Data Card

If not presently installed in your device, install the data card as follows:

- 1 Insert the data card in the data card tray, sliding it under the tray clip.
- 2 With the front of the tray facing forward, insert the tray fully into the data card slot located on the right side of the HeartStart MRx.

Figure 24 Installing the Data Card/Tray



CAUTION Even if a data card is not used, the data card tray should always be installed to protect the device from the ingress of liquids or solids.

ECG and Arrhythmia Monitoring

This chapter describes the basic ECG and arrhythmia monitoring functions of the HeartStart MRx monitor/defibrillator. For specific information related to taking a 12-Lead ECG, refer to Chapter 11, “12-Lead ECG” on page 105.

Overview

The HeartStart MRx can be used for ECG and arrhythmia monitoring. The monitoring function allows you to monitor through:

- multifunction electrode pads, or
- 3-, 5-, or 10-lead ECG sets.

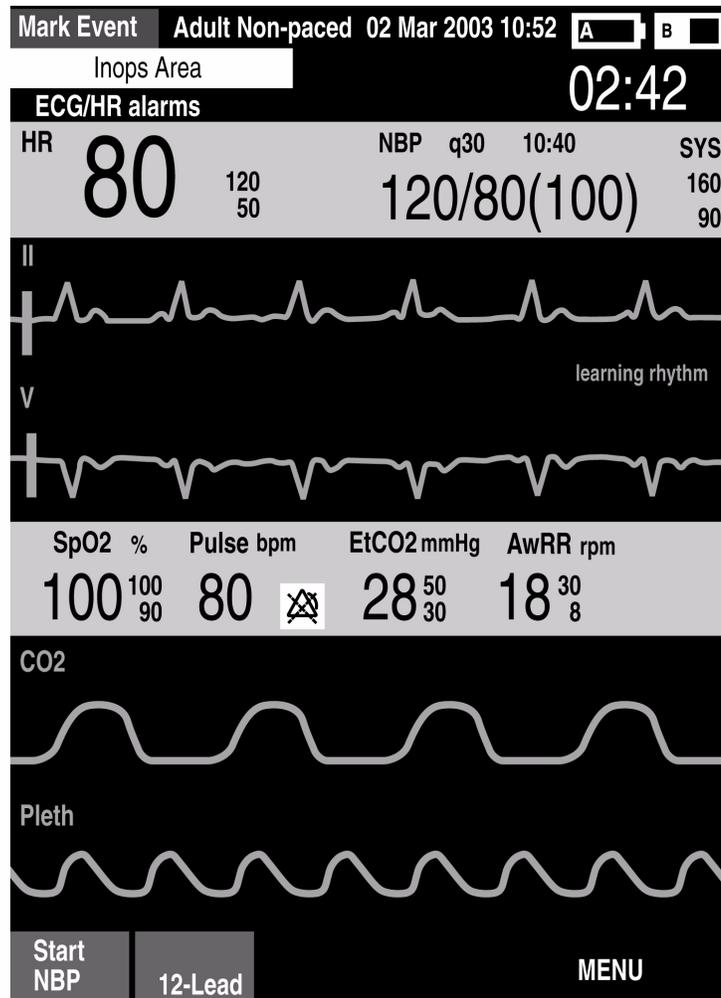
If both pads and monitoring electrodes are connected, monitoring allows you to select a lead from the 3-, 5- or 10-lead ECG source, or to monitor through the pads.

Configurable heart rate and arrhythmia alarms clearly communicate patient status, both audibly and visually.

Monitoring View

Monitoring View appears on the display when the Therapy Knob is in the **Monitor** position. Figure 25 shows the information displayed in Monitoring View.

Figure 25 Monitoring View



Monitoring View can display up to four ECG waves. Numeric values for heart rate and all other available parameters are displayed, as well as any active alarm settings.

There are two separate sources of ECG, the ECG leads connection and the Pads/Paddles connection. Leads/pads are displayed according to your device's configuration. Typically, Lead II is configured as the primary ECG lead source, displayed in Wave Sector 1. You may change this during use with the Lead Select button. You can also configure the HeartStart MRx to display up to 3 additional leads (or pads/paddles) when turned on (see Chapter 13, "Configuration" on page 125). The leads displayed may be changed during use through the **Waves** menu item.

Monitoring View displays the first valid source of ECG acquired in Wave Sector 1. For example, if your HeartStart MRx has Lead II configured to display in Wave Sector 1, but pads are attached to the patient and connected to the defibrillator before a valid ECG can be obtained from the monitoring electrodes, then Pads will be displayed in Wave Sector 1. However, Lead II will take its place as soon as it is acquired.

NOTE The ECG lead source appearing in Wave Sector 1 is used to determine heart rate and monitor arrhythmia.

Preparing to Monitor ECG

To prepare for monitoring ECG, perform the following steps.

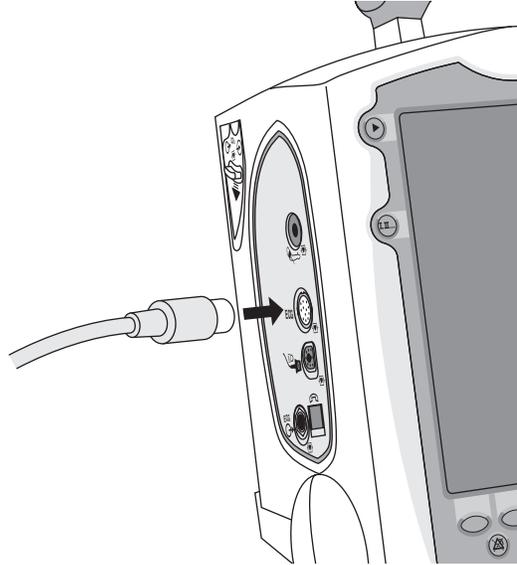
If monitoring via electrodes:

- 1 Prepare the patient's skin prior to applying monitoring electrodes. Skin is a poor conductor of electricity, so skin preparation is important in achieving good electrode-to-skin contact.
 - Identify the appropriate electrode sites (See Figures 27 and 28.)
 - If necessary, clip hair at the electrode sites (or shave sites if needed).
 - Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, as this increases skin resistance.)
 - Dry the electrode sites briskly to increase capillary blood flow in the tissues and to remove oil and skin cells.
- 2 Attach the snaps to the electrodes before placing them on the patient.
- 3 Apply the electrodes by peeling them, one at a time, from the protective backing and sticking them firmly to the patient's skin. Refer to Figures 27 and 28 for proper electrode placement. Press around the entire edge of each electrode to ensure they are secure. Make sure the lead wires do not pull on the electrodes.

WARNING Be sure that the electrodes do not come in contact with other conductive materials, especially when connecting or disconnecting the electrodes to/from the patient.

- 4 If not preconnected, connect the ECG patient cable.
 - Align the keyed patient cable connector with the ECG port on the Measurement module, as shown in Figure 26.
 - Push the patient cable firmly into the ECG port until the white portion is no longer visible.

Figure 26 ECG Cable Connection



If monitoring via multifunction electrode pads:

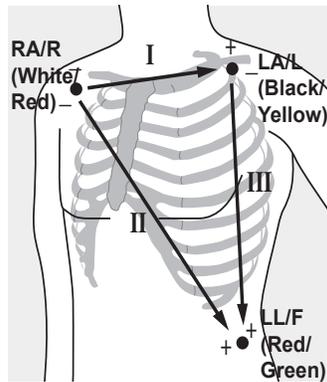
- 1 If not preconnected, connect the pads cable to the HeartStart MRx. See Figure 34 on page 57.
- 2 Connect the pads to the pads cable. See Figure 35 on page 58.
- 3 Apply the pads as directed on the package.

NOTE If monitoring for extended periods of time, monitoring electrodes and multifunction electrode pads may need to be changed periodically. Refer to the manufacturer's documentation for how often to replace the monitoring electrodes or pads.

Electrode Placement

Figure 27 shows the typical electrode placement for a 3-lead ECG set.

Figure 27 3-lead Placement



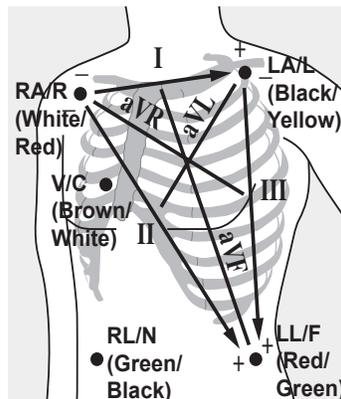
RA/R placement: directly below the clavicle and near the right shoulder

LA/L placement: directly below the clavicle and near the left shoulder

LL/F placement: on the left lower abdomen

Figure 28 shows the typical electrode placement for a 5-lead ECG set.

Figure 28 5-lead Placement



RA/R placement: directly below the clavicle and near the right shoulder

LA/L placement: directly below the clavicle and near the left shoulder

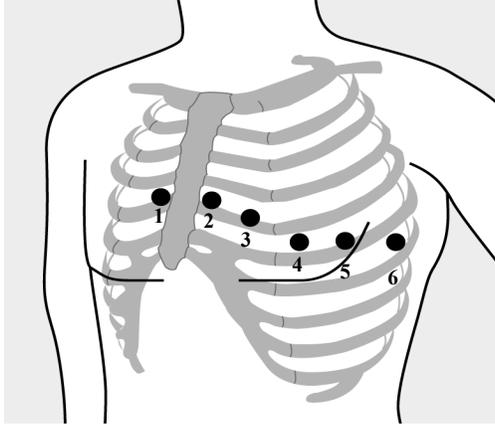
RL/N placement: on the right lower abdomen

LL/F placement: on the left lower abdomen

V/C placement: on the chest; the position depends on your required lead selection. See Figure 29.

The V/C lead may be placed in any of the precordial lead positions as shown in Figure 29 (V1/C1 through V6/C6).

Figure 29 V/C Electrode Placement



V1/C1 placement: fourth intercostal space at right sternal margin.

V2/C2 placement: fourth intercostal space at left sternal margin.

V3/C3 placement: midway between V2 and V4.

V4/C4 placement: fifth intercostal space at left midclavicular line.

V5/C5 placement: same level as V4 on anterior axillary line.

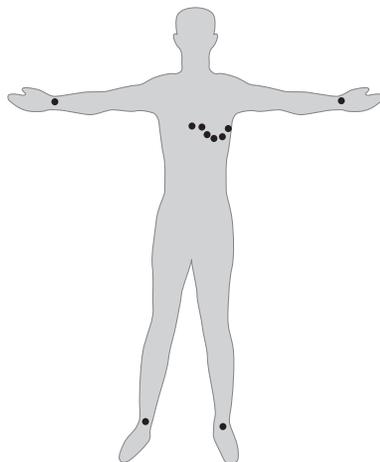
V6/C6 placement: same level as V4 at left midaxillary line.

For accurate V/C lead placement and measurement, it is important to locate the fourth intercostal space, as follows:

- 1 Locate the second intercostal space by first palpating the Angle of Lewis (the small bony protuberance where the body of the sternum joins the manubrium). This rise in the sternum is where the second rib is attached, and the space just below this is the second intercostal space.
- 2 Palpate and count down the chest until you locate the fourth intercostal space.

Figure 30 shows the typical electrode placement for a 10-lead ECG set.

Figure 30 10-lead Placement



Conventional 12-Lead ECG In conventional 12-Lead ECG using 10 electrodes, an electrode is placed on the right arm, left arm, right leg, and left leg. Six V/C electrodes are placed on the chest as shown in Figure 30. The right leg electrode is the reference electrode.

Lead Selection

It is important to select a suitable lead for monitoring so that a QRS complex can be accurately detected. The guidelines for lead selection are as follows:

For non-paced patients:

- QRS complex should be tall and narrow (recommended amplitude > 0.5mV).
- R-wave should be above or below the baseline (but not biphasic).
- P-wave should be smaller than 1/5 R-wave height.
- T-wave should be smaller than 1/3 R-wave height.

NOTE To prevent detection of P-waves or baselines noises as QRS complexes, the minimum detection level for QRS complexes is set at 0.15 mV, according to AAMI-EC 13 specifications. If the ECG signal is too weak, you may get false alarms for asystole.

For paced patients with internal/transvenous pacemakers, in addition to the above, the pace pulse should be:

- not wider than the normal QRS complex.
- large enough to be detected (half the height of the QRS complex), with no re-polarization artifact.

NOTE Adjusting the ECG wave size on the display does not affect the ECG signal which is used for arrhythmia analysis.

Lead Choices

Available monitoring leads vary depending upon what type of ECG cable is connected to your HeartStart MRx and its configuration. Table 2 shows the choice of leads available for 3-, 5-, and 10-lead ECG sets.

Table 2 Lead Choices

If you are using:	These leads are available:
a 3-lead ECG set	I, II, III
a 5-lead ECG set	I, II, III, aVR, aVL, aVF, V/C
a 10-lead ECG set	I, II, III, aVR, aVL, aVF, V1/C1, V2/C2, V3/C3, V4/C4, V5/C5, V6/C6

Selecting the Lead

The ECG lead for Wave Sector 1 is selected through the Lead Select  button or through the Waves menu. The ECG lead for Wave Sectors 2-4 is selected through the Waves menu, as follows:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the Waves menu and press the Menu Select button.
- 3 Select the Wave Sector and press the Menu Select button.
- 4 Select the desired lead and press the Menu Select button.
- 5 If needed, use the Navigation buttons to adjust the ECG wave size (gain) and press the Menu Select button.

Figure 31 Waves Menu

Main Menu	Waves	Wave 1	I Size
Volume	Wave 1	Paddles	x4
Waves	Wave 2	I	x2
Measurements/Alarms	Wave 3	II	x1
Patient Info	Wave 4	III	x1/2
Other	Exit	aVR	x1/4
Exit		aVL	Auto
		aVF	
		v	

Arrhythmia Monitoring

The HeartStart MRx uses the ST/AR Basic Arrhythmia Algorithm. Arrhythmia analysis provides information on your patient's condition, including heart rate and arrhythmia alarms. The HeartStart MRx uses the ECG lead appearing in Wave Sector 1 for single-lead arrhythmia analysis.

NOTE Because the ST/AR Basic Arrhythmia Algorithm is the HeartStart MRx's cardiotech source and is needed to generate heart rate and heart rate alarms, the algorithm can never be disabled. However, if desired, arrhythmia and heart rate alarms can be turned off.

During arrhythmia analysis, the monitoring function continuously:

- optimizes ECG signal quality to facilitate arrhythmia analysis. The ECG signal is continuously filtered to remove baseline wander, muscle artifact, and signal irregularities. Also, if the Patient Paced status is set to Yes, pace pulses are filtered out to avoid processing them as QRS beats.
- measures signal features such as R-wave height, width and timing.
- creates beat templates and classifies beats to aid in rhythm analysis and alarm detection.
- examines the ECG signal for ventricular fibrillation, asystole, and noise.

Aberrantly-Conducted Beats

As P-waves are not analyzed, it is difficult and sometimes impossible for the algorithm to distinguish between an aberrantly-conducted supraventricular beat and a ventricular beat. If the aberrant beat resembles a ventricular beat, it is classified as a ventricular beat. You should always select a lead where the aberrantly-conducted beats have an R-wave that is as narrow as possible to minimize incorrect classifications.

Intermittent Bundle Branch Block

Bundle branch and other fascicular blocks create a challenge for the arrhythmia algorithm. If the QRS complex changes considerably from the learned normal due to a bundle branch block, the blocked beat may be incorrectly identified as ventricular, and may cause false PVC alarms. You should always select a lead where the bundle branch block beats have an R-wave that is as narrow as possible to minimize incorrect classifications.

NOTE For more information on arrhythmia analysis, refer to the Application Note, “Arrhythmia Monitoring Algorithm” available on the web at www.medical.philips.com/goto/productdocumentation.

Heart Rate and Arrhythmia Alarms

The HeartStart MRx detects arrhythmia alarm conditions by comparing ECG data to a set of pre-defined criteria. An alarm can be triggered by a rate exceeding a threshold (for example HR > XX), an abnormal rhythm (for example, Ventricular Tachycardia), or an ectopic event (for example, PVC > limit).

HR/Arrhythmia Alarms can be generated for the conditions shown in Tables 3 and 4. Once generated, they appear as alarm messages in the alarm status area of the display located just above the HR numeric. The notification of an alarm is indicated by both an audible and visual alert signal.

The presence of multiple alarm conditions is quite possible. Announcing all of the detected alarms would cause confusion and a less serious condition might hide a more serious condition. For this reason, alarms are prioritized and categorized so that the most serious or highest priority alarm condition is the one announced.

Arrhythmia Alarm Latching

Arrhythmia Alarms are categorized as “latching” or “non-latching” alarms. Latching alarms are announced and remain present, regardless of whether the alarm condition still exists, until they are either acknowledged or a higher priority alarm condition occurs. Indications for non-latching alarms are automatically removed when their alarm condition no longer exists.

Latching and non-latching alarms are categorized in Tables 3 and 4.

Table 3 HR/Arrhythmia Red Alarms

Alarm Message	Condition	Indicator	Latching/ Non-Latching
Asystole	No detectable beats for four seconds in the absence of Vfib	Red alarm message, alarm tone	Latching
VFIB/VTACH	A fibrillatory wave detected for four seconds	Red alarm message, alarm tone	Latching
VTACH	Consecutive PVCs and HR exceed defined limits	Red alarm message, alarm tone	Latching
Extreme Brady	10 bpm below HR Low limit, capped at 30 bpm	Red alarm message, alarm tone	Latching
Extreme Tachy	20 bpm above HR High limit capped at 200 bpm (adult) or 240 bpm (pedi)	Red alarm message, alarm tone	Latching

Table 4 HR/Arrhythmia Yellow Alarms

Alarm Message	Condition	Indication	Latching/ Non-Latching
HR High	The HR exceeds the configured HR high limit	Yellow alarm message, alarm tone	Non-Latching
HR Low	The HR is below the configured HR low limit	Yellow alarm message, alarm tone	Non-Latching
PVC/min High (value > limit)	The number of detected PVCs in a minute exceeds the limit of 15(adult/pedi.)	Yellow alarm message, alarm tone	Non-Latching
Pacer Not Capture	No QRS following a pacer pulse	Yellow alarm message, alarm tone	Latching
Pacer Not Pacing	No QRS or pacer pulse detected	Yellow alarm message, alarm tone	Latching

NOTE Pacer Alarm Messages are associated with internal/transvenous pacemakers only

INOP Messages

INOP messages communicate conditions that prevent the device from monitoring or analyzing the ECG. INOP messages are displayed just above the HR/Arrhythmia alarm status area. If multiple INOP conditions exist, the associated INOP messages will cycle through, alternating every 2 seconds.

Table 5 ECG INOPS

Alarm Message	Condition	Indication
Cannot Analyze ECG	Cannot reliably monitor the ECG in Wave Sector 1.	INOP message, INOP tone
ECG Cable Failure	During the Operational Check, a short has been detected between a lead wire and ground	INOP message, INOP tone
Leads Off	An electrode used for Wave Sector 1 may be off or not attached securely.	INOP message, INOP tone
Pads /Paddles Off	The multifunction electrode pads used as the source for the Wave Sector 1 may be off or not attached securely.	INOP message, INOP tone
ECG Unplugged	The primary ECG is derived from leads and the ECG cable is not connected.	INOP message, INOP tone
ECG Equip Malfunction	A malfunction has occurred in the ECG hardware.	INOP message, INOP tone
Pads/Paddles Cable Failure	During the Operational Check, a failure was detected in the pads or paddles cable during the pads/paddles ECG test.	INOP message, INOP tone
Pads ECG Equip Malfunction	A device hardware failure was detected.	INOP message, INOP tone

Setting Alarms

Alarms are automatically enabled in Monitor and Pacer Modes. In Manual Defib mode alarms are automatically enabled if the Sync function is enabled. If the Sync function is not enabled, alarms are enabled in Manual Defib mode using the Alarm Pause button. Alarm settings for Heart Rate (HR) and VTACH are as configured but may be changed during operation for the current patient. The setting for PVC Rate Limit may only be changed in response to a PVC Rate alarm condition. Settings for other HR and arrhythmia alarms may not be changed.

Changing Heart Rate or Vtach Alarm Limits

To change the HR or Vtach Limits:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select **Measurements/Alarms** from the menu and press the Menu Select button.
- 3 Select **HR/Arrhythmia** and press the Menu Select button.
- 4 Select **HR or VTACH Limits** and press the Menu Select button.
- 5 Using the Navigation buttons, select the new values and press the Menu Select button.

Enabling/Disabling Heart Rate and Arrhythmia Alarms

To enable/disable the HR and Arrhythmia Alarms,

- 1 Press the Menu Select  button.
- 2 Select **Measurements/Alarms** from the menu and press the Menu Select button.
- 3 Select **HR/Arrhythmia** and press the Menu Select button.
- 4 Select **Alarms On/Off** and press the Menu Select button.

Responding to HR and Arrhythmia Alarms

When an alarm is announced, the audio pause label is presented above the Navigation and Menu Select buttons. Pressing any of these buttons silences the alarm audio while you are attending to the patient. See Figure 32.

Figure 32 Audio Pause



For devices with
serial numbers US001XXXXXX



For devices with
serial numbers US002XXXXXX

Then respond to the alarm condition on the HeartStart MRx. There are two ways to respond to an HR or Arrhythmia alarm:

- 1 **Acknowledge** the alarm condition.
- 2 Adjust the limits using the **New Limits** menu.

Displaying an Annotated ECG

You may choose to display an annotated ECG with arrhythmia beat labels in Wave Sector 2. The same ECG source appearing in the Wave Sector 1 is displayed with a six second delay along with white arrhythmia beat labels. See Table 6 below for additional information on beat classification.

Table 6 Arrhythmia Beat Labels

Label	Description	Displayed Location
N	Normal	Above QRS
V	Ventricular Ectopic	Above QRS
P	Paced	Above QRS
'	Pacer spike	Above the waveform where the pacer spike is detected. (If the patient is both atrially and ventricularly paced, the display will show two ' marks above the waveform aligned with the atrial and ventricular pacing.)
L	Learning Patient's ECG	Above QRS
A	Artifact (noisy episode)	Above the waveform where the noise is detected.
?	Insufficient information to classify beats	Above QRS
I	Inoperative condition (e.g. LEAD OFF)	Above the waveform at start of INOP, every second of INOP, and at end of INOP.
M	Pause, Missed Beat, No QRS	Above the waveform where the condition is detected.

To display an annotated ECG:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, Select **Waves** and press the Menu Select button.
- 3 Select **Wave 2** and press the Menu Select button.
- 4 Select **Annotated ECG** and press the Menu Select button.

Arrhythmia Learning/Relearning

When arrhythmia monitoring starts, a “learning” process is initiated. The goal is to learn the patient's normal complexes and/or paced complexes (if the patient with an internal/transvenous pacemaker is in paced rhythm). The learning process involves the first 15 valid (non-noisy) beats encountered during the learning phase.

The family selected to represent the “normal” complex includes the beat that is the most frequently seen, narrowest, on-time beat. For this reason, learning should not be initiated when the patient's rhythm is primarily ventricular.

Arrhythmia learning/relearning automatically occurs when the Therapy Knob is turned to **Monitor**, **Pacer** or **Manual Defib**, any time there is a change in the lead selection for Wave Sector 1, and after the correction of a “Leads or Pads Off” INOP condition that has been active longer than 60 seconds.

Manual relearning should be initiated if the beat detection is not occurring or if beat classification is incorrect and results in a false alarm. Remember, however, that if the same signal condition which caused the algorithm to perform poorly still persists, relearning will not be able to correct the problem. The problem can only be corrected by improving the quality of the signal (e.g., by selecting a different lead.)

To initiate relearning manually,

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select **Measurements/Alarms** from the menu and press the Menu Select button.
- 3 Select **HR/Arrhythmia** and press the Menu Select button.
- 4 Select **Relearn Rhythm** and press the Menu Select button.

The messages “Learning ECG” and “Learning Rhythm” appear in the rhythm status area of the display.

WARNING If arrhythmia relearning takes place during a ventricular rhythm or during a period of poor ECG signal quality, ectopic beats may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent events of V-tach and high PVC rates.

For this reason, you should:

- take care to initiate arrhythmia relearning only when the ECG signal is noise-free.
 - be aware that arrhythmia relearning can happen automatically.
 - respond to any INOP messages (for example, if you are prompted to reconnect electrodes).
 - always ensure that the arrhythmia algorithm is labeling beats correctly.
-

Troubleshooting

If your HeartStart MRx does not operate as expected during ECG monitoring, see “Troubleshooting” on page 193.

Semi-Automated External Defibrillation

The HeartStart MRx's Semi-automated External Defibrillation (AED) Mode is designed to guide you through standard treatment algorithms for cardiac arrest. Configuration choices allow you to customize AED Mode to better meet the unique needs of your organization or resuscitation team.

This chapter describes how to use AED Mode. It explains the prompts that guide you through the defibrillation process and describes how prompts vary depending upon the condition of the patient and the configuration of your device.

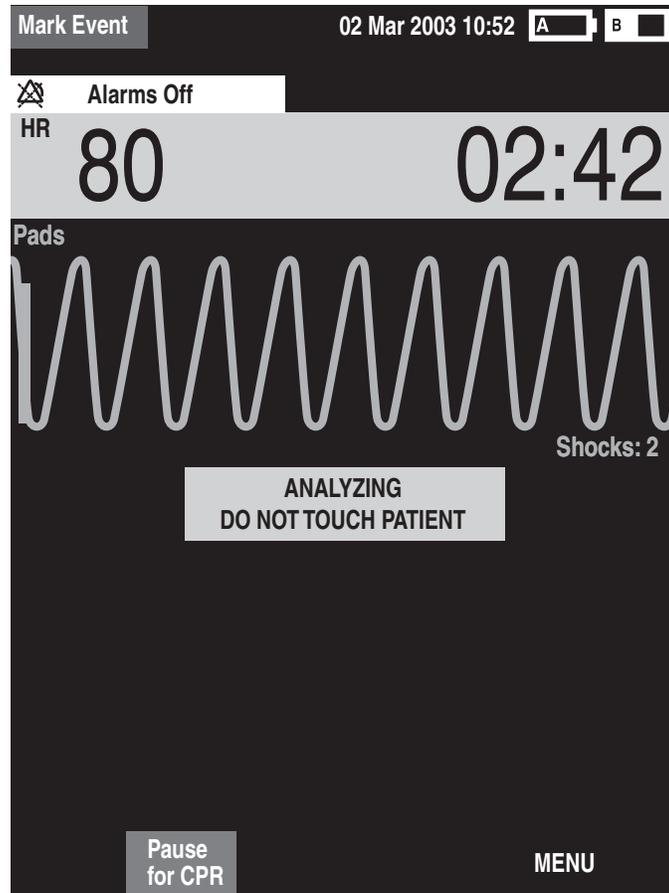
For information on annotating, storing, and printing event information acquired in AED Mode, see "Data Management" on page 141.

For information on setting configuration choices, see "Configuration" on page 125.

AED View

Once the Therapy Knob is moved to AED, AED View is displayed.

Figure 33 AED View Display



Wave Sectors 1 and 2 are combined so that a large ECG may be shown. The Event Timer is also large for easier viewing. A Shock Counter is displayed just below the ECG and shows the total number of shocks delivered to the patient in AED and Manual Defib Mode. Also below the ECG is a prominent text message window which accompanies the voice prompts annunciated in AED Mode.

NOTE Only the ECG acquired through multifunction electrode pads is displayed in AED Mode.

Preparation

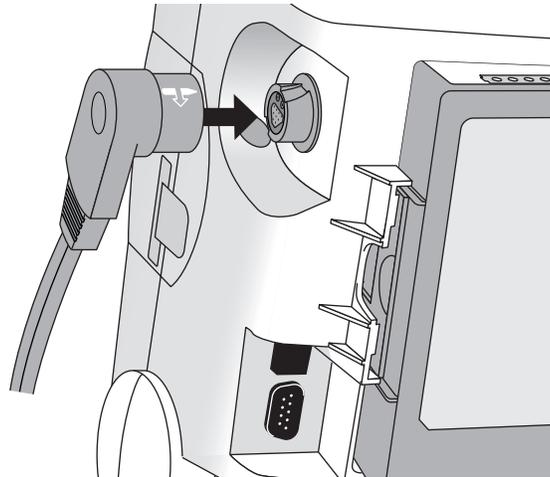
Confirm that the patient is:

- unresponsive
- not breathing
- pulseless

Then:

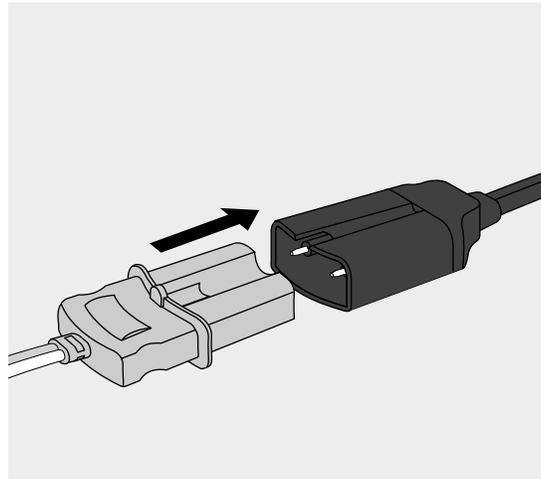
- 1 Remove clothing from the patient's chest. Wipe moisture from the patient's chest and, if necessary, clip or shave excessive chest hair.
- 2 Make sure the multifunction electrode pads packaging is intact and within the expiration date shown.
- 3 Apply multifunction electrode pads to the patient as directed on the pads package. Use the anterior-anterior electrode placement.
- 4 If not pre-connected, insert the pads cable into the green Therapy port located on the right side of the device. See Figure 34.

Figure 34 Pads Cable Connection



- 5 Connect the pads to the pads cable as shown in Figure 35.

Figure 35 Pads Connection



WARNING Do not use anterior-posterior pads placement (multifunction electrode pads placed on the patient's chest and back). The AED algorithm used by the HeartStart MRx has not been validated using this placement.

WARNING Do not let the multifunction electrode pads touch each other or other monitoring electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillation current away from the heart.

WARNING During defibrillation, air pockets between the skin and multifunction electrode pads can cause patient skin burns. To help prevent air pockets, make sure defibrillation pads completely adhere to the skin. Do not use dried-out multifunction electrode pads.

CAUTION Aggressive handling of multifunction electrode pads in storage or prior to use can damage the pads. Discard the pads if they become damaged.

NOTE Impedance is the resistance between the defibrillator's pads or paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin.

The low-energy SMART Biphasic waveform is an impedance-compensating waveform that is designed to be effective across a wide range of patients. However, if you receive a "No Shock Delivered" message, check that the patient's skin has been washed and dried and that any chest hair has been clipped. If the message persists, change the pads and/or the pads cable.

Using AED Mode

To operate the HeartStart MRx in AED Mode, follow these three basic steps:

- 1 Turn the Therapy Knob to AED.
- 2 Follow the voice and screen prompts.
- 3 Press the orange Shock button, if prompted.

These steps are described more fully in the sections that follow.

While operating in AED Mode, the capabilities of the device are limited to those essential to the performance of semi-automated external defibrillation. Only the ECG acquired through pads is displayed. Previously set alarms and scheduled measurements are indefinitely paused and entry of patient information is disabled. Additionally, the Sync, Lead Select, and Alarm Pause buttons are inactive.

Step 1 - Turn the Therapy Knob to AED

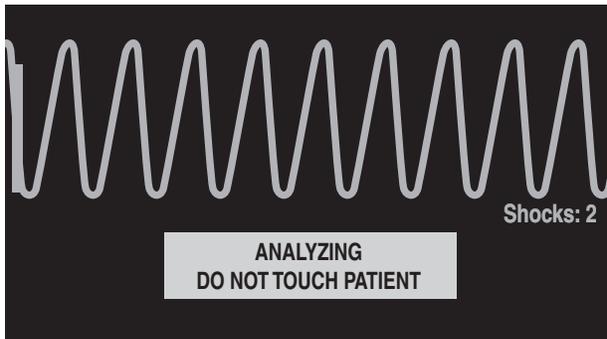
When the HeartStart MRx is turned on in AED Mode, it checks to see if the pads cable and multifunction electrode pads are properly connected. If the:

- pads cable is not properly attached, you are prompted to **"Connect Pads Cable"**.
- multifunction electrode pads are not connected to the pads cable, pads are not applied to the patient, or pads are not making proper contact with the patient's skin, you are prompted to **"Apply Pads"** and **"Plug in Connector"**.

Step 2 - Follow the Screen and Voice Prompts

Once an ECG is detected through the multifunction electrode pads, the HeartStart MRx automatically analyzes the patient's heart rhythm and warns you not to touch the patient as shown in Figure 36.

Figure 36 ECG Analysis Screen in AED Mode



WARNING Handling or transporting the patient during ECG rhythm analysis can cause an incorrect or delayed diagnosis. Under these circumstances, if the HeartStart MRx issues a **"Shock Advised"** prompt, keep the patient as still as possible for at least 10 seconds so the HeartStart MRx can reconfirm the rhythm analysis before you deliver a shock.

If artifact interferes with analysis, the message **"Analyzing Interrupted, Do Not Touch the Patient"** is announced while the HeartStart MRx attempts to continue analyzing. If the artifact persists, the message **"Cannot Analyze"** is announced and the message **Paused. Attend To Patient** is displayed. While paused, analysis is suspended. Check that the pads are making proper contact with the patient's skin and minimize movement. Analysis resumes automatically after 30 seconds or when you press **[Resume Analyzing]**.

Adjusting Voice Prompt Volume

You may adjust the volume of the voice prompts at any time by accessing the Voice Volume menu.

Press the Menu Select  button.

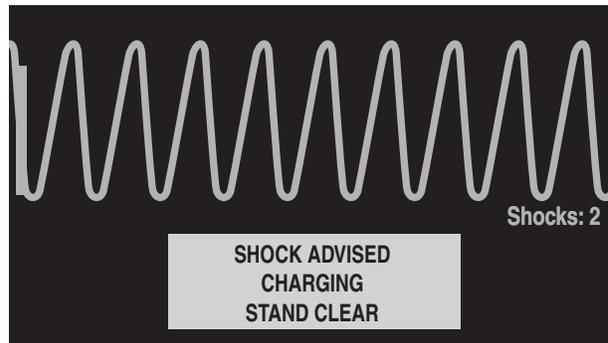
Select the desired volume level and press the Menu Select button.

Shock Advised

If a shockable rhythm is detected, the HeartStart MRx automatically charges to 150J. Charging is accompanied by voice and screen prompts as shown in Figure 37. A steady high-pitched tone is sounded, and the orange Shock button flashes when the device is fully charged.

Heart rhythm analysis continues while the HeartStart MRx charges. If a rhythm change is detected before the shock is delivered and a shock is no longer appropriate, the defibrillator is disarmed.

Figure 37 Shock Advised, Charging Display



NOTE When the HeartStart MRx is fully charged, you can disarm it any time by turning the Therapy Knob to the “Off” position or by pressing the [Pause for CPR] soft key. Resume monitoring the patient by turning the Therapy Knob back to AED.

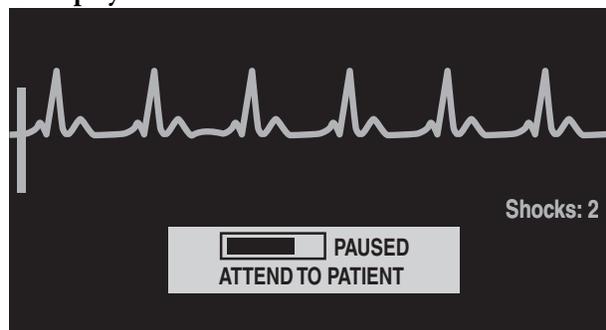
No Shock Advised (NSA)

If a shockable rhythm is not detected, the HeartStart MRx tells you, “**No shock advised**”. If the NSA Action Configuration Choice is set to:

Monitor - the HeartStart MRx monitors the ECG and automatically resumes analysis if a potentially shockable rhythm is detected. You are periodically prompted to “**Check airway, check breathing, check circulation. If needed, press Pause and begin CPR.**” The frequency of these prompts is defined in the Monitor Prompt Interval Configuration Choice. You may press [**Pause for CPR**] to suspend monitoring and administer CPR. The pause period is defined by the CPR Time Configuration Choice.

Pause Time- analysis is suspended for the specified period, during which time you may administer CPR and attend to the patient. A Pause status bar is displayed as shown in Figure 38. The pause period is defined by the NSA Time Configuration Choice. At the completion of the pause period, the HeartStart MRx resumes analyzing.

Figure 38 Paused Display



Step 3 - Press the Orange Shock Button, if Prompted

Once charging is complete, the HeartStart MRx prompts you to **"Deliver Shock Now; Press the Orange Button Now"**. Make sure no one is touching the patient or anything connected to the patient. Call out clearly and loudly, "Stay Clear." Then press the orange Shock button to deliver a shock to the patient.

WARNING Defibrillation can cause operator or bystander injury. Do not touch the patient or equipment connected to the patient during defibrillation.

WARNING The Shock button must be pressed to deliver a shock. The HeartStart MRx will not automatically deliver a shock.

Delivery of the shock is confirmed by the message **"Shock Delivered"** and the shock counter on the display is updated to reflect the number of shocks given. The defibrillator returns to analyzing the patient's heart rhythm to see if the shock was successful. Voice and text prompts continue to guide you through additional shocks, if appropriate.

Upon completing the number of shocks in a shock series (as defined in your Shock Series Configuration Choice), the HeartStart MRx pauses for the configured CPR Timer period and you are prompted to **"If Needed, Begin CPR"**. Prompts may be brief or detailed, as defined by the CPR Prompt Configuration Choice. Analysis begins again at the completion of the pause period or when you press **[Resume Analyzing]**.

If you press **[Pause for CPR]** after a shock is delivered in the current Shock Series, the length of the CPR Pause is defined by the CPR Timer Configuration Choice.

NOTE You may return to analyzing the patient's heart rhythm at any time by pressing the **[Resume Analyzing]** soft key.

NOTE Once prompted to **"Deliver Shock Now; Press the Orange Button Now"**, if you do not do so within the configured Auto Disarm time interval, the HeartStart MRx disarms itself and provides a pause for CPR. The device resumes analyzing at the end of the configurable pause period (with a default of 30 seconds) or when the **[Resume Analyzing]** soft key is pressed.

Troubleshooting

If your HeartStart MRx does not operate as expected during defibrillation, see “Troubleshooting” on page 193.

Manual Defibrillation and Cardioversion

This chapter explains how to prepare for and perform asynchronous and synchronous (cardioversion) defibrillation using multifunction electrode pads, external paddles, and internal paddles.

NOTE Defibrillation is always performed through paddles or pads. However, during defibrillation you may choose to monitor the ECG using an alternate ECG source (3-, 5-, or 10-lead monitoring electrodes). If an alternate ECG source is connected, any available lead may be displayed.

For information on monitoring optional SpO₂, EtCO₂, and NBP while in Manual Defib Mode, see the corresponding chapter in these Instructions for Use.

Overview

In Manual Defib Mode, you must assess the ECG, decide if defibrillation or cardioversion is indicated, select the appropriate energy setting, charge the monitor/defibrillator, and deliver the shock. The entire defibrillation process is under your control. Voice prompts are not present. However, text messages on the display provide relevant information throughout the process. It is important to be attentive to these messages when displayed.

The ECG strip and Event Summary are easily annotated with event information using the Mark Event function button. See “Marking Events” on page 148 for more information.

Monitoring alarms are available in Manual Defib Mode, however, they are indefinitely paused once an energy is selected for defibrillation. Alarms may be turned on in Manual Defib Mode by pressing the Alarm Pause  button. Alarms are also reactivated once the Therapy Knob is moved to **Monitor** or **Pacer**.

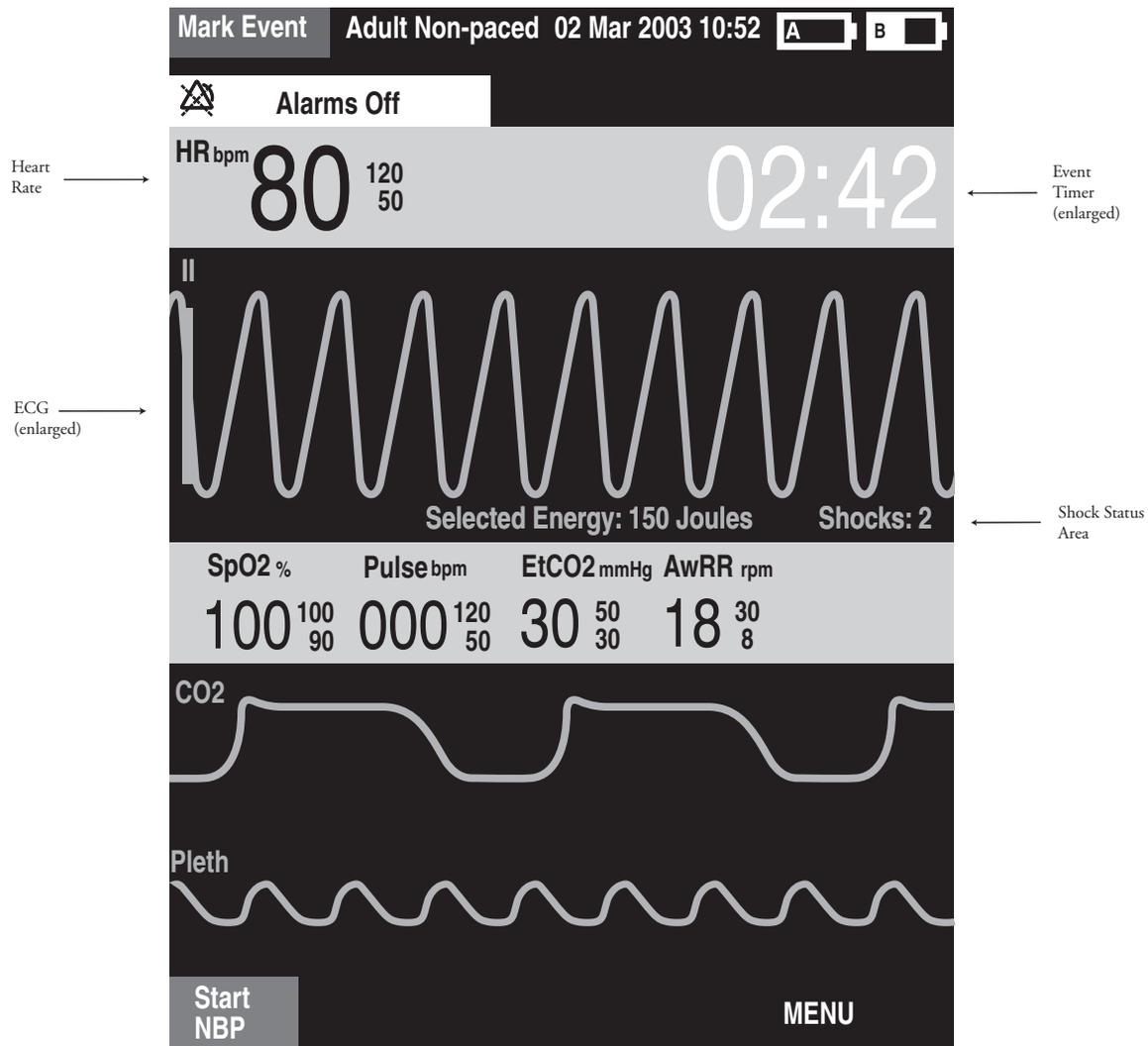
When an energy is selected, automatic NBP measurements are discontinued. If a manual NBP measurement is requested by pressing the **[Start NBP]** soft key, the NBP information, including the current schedule, is displayed in its normal position, and scheduled NBP measurements resume.

NOTE The use of Manual Defib Mode may be password protected in Version A.02 and later devices, as defined in Configuration. See “Password Security” on page 15.

Code View

In Manual Defib Mode, an energy is selected and the Code View is displayed. Code View is optimized to clearly communicate data associated with a resuscitation event. Notice the increased prominence of the Event Timer, as well as the enlarged ECG in Wave Sectors 1 and 2 as shown in Figure 39.

Figure 39 Code View Display



NOTE The Shock Counter displays the number of shocks delivered while in AED and Manual Defib Modes.

Preparing for Defibrillation

In preparation for defibrillation:

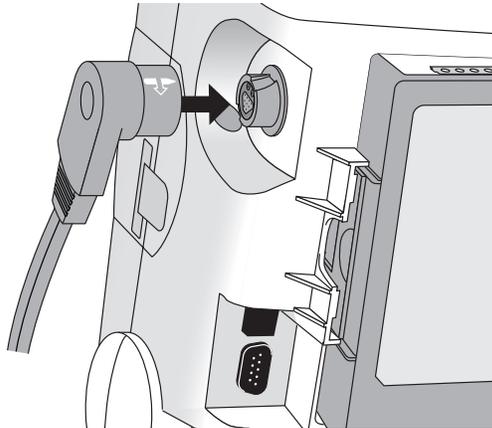
- 1 Connect the appropriate Therapy cable.
- 2 Apply the paddles or pads as described below.

Using Multifunction Electrode Pads

To prepare for defibrillation using multifunction electrode pads:

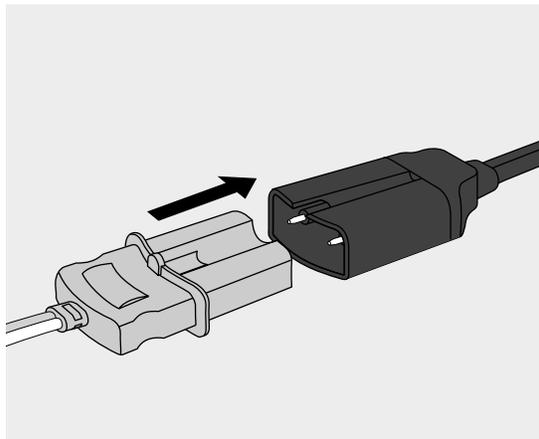
- 1 If not pre-connected, connect the pads cable to the HeartStart MRx by aligning the white pointer on the pads cable connector with the white arrow on the green Therapy port. Then push until you hear it click into place. See Figure 40.

Figure 40 Pads/Internal Paddles Cable Connection



- 2 Check the expiration date that appears on the pads package.
- 3 Inspect the packaging for any damage.
- 4 Connect the pads connector to the pads cable. See Figure 41.

Figure 41 Pads Connector



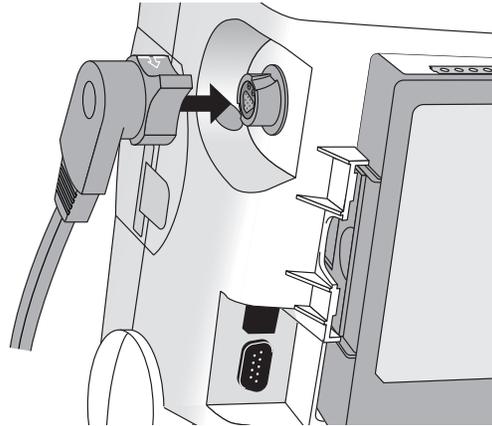
- 5 Apply the pads to the patient as directed on the pads packaging or according to your organization's protocol.

Using External Paddles

To defibrillate using external paddles:

- 1 If not pre-connected, connect the paddles cable to the HeartStart MRx by aligning the white pointer on the paddles cable connector with the white arrow on the green Therapy port. Then push until you hear it click into place. See Figure 42.

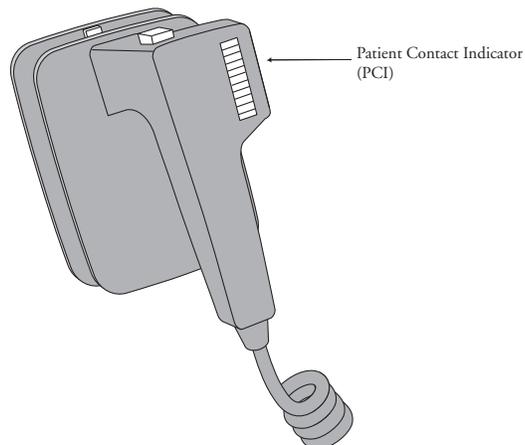
Figure 42 Paddles Cable Connection



- 2 Remove the Paddle Set from the Paddle Tray by pulling the paddles straight up and out of the paddle tray.
- 3 Apply conductive matter to the paddle electrodes.
Do not distribute conductive matter by rubbing the paddle electrodes together.
- 4 Apply paddles to the patient's bare chest, using the anterior-anterior placement (or in accordance with your organization's protocol).

The sternum paddle contains a patient contact indicator (PCI). See Figure 43. If necessary, as indicated by the appearance of either a red or orange LED on the PCI, adjust paddle pressure and placement to optimize patient contact. Once proper contact is made, the PCI shows a green LED.

Figure 43 Patient Contact Indicator



NOTE Reasonable effort should be made to obtain a reading of at least one green LED. Due to impedance, this may not be possible for some patients, and orange LEDs may be the best that can be achieved.

Using Pediatric Paddles

The HeartStart MRx's external paddle set comes with pediatric paddles included. To use the pediatric paddles set:

- 1 Depress the latch at the front of the external paddle set while pulling forward on the adult paddle electrode.
- 2 Store the adult paddle electrodes in the paddle tray pockets.
- 3 To defibrillate, see "Using External Paddles" on page 68.

NOTE Impedance is the resistance between the defibrillator's pads or paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin.

The low-energy SMART Biphasic waveform is an impedance-compensating waveform that is designed to be effective across a wide range of patients. However, if you receive a "No Shock Delivered" message, check that the patient's skin has been washed and dried and that any chest hair has been clipped. If the message persists, change the pads and/or the pads cable.

Using Internal Paddles

To defibrillate using internal paddles:

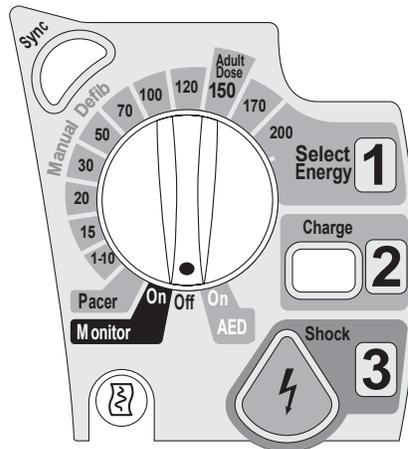
- 1 Select the appropriate paddle electrode size.
- 2 If using switchless internal paddles, connect the paddles to the M4740A Paddle Adapter Cable.
- 3 Connect the paddles cable (or the paddle adapter cable) to the HeartStart MRx by aligning the pointer on the paddles cable (or paddle adapter cable) with the white arrow on the green Therapy port. Then push until you hear it click into place. See Figure 40.

Defibrillating (asynchronously)

Once you have performed the necessary preparation for defibrillation, perform the following steps:

- 1 **Select Energy** - To select the energy setting, rotate the Therapy Knob to the desired energy level as shown in Figure 44. Energy choices range from 1 to 200, with 150J the recommended level for adult patients.

Figure 44 Energy Selection



Selecting the 1-10 (1-9) energy setting displays the Select Energy menu, with a default setting of 6J. The low energy setting can be changed using the Navigation buttons to increase or decrease the desired setting. Complete your selection by pressing the Menu Select  button. Your current energy selection is shown in the Shock Status area of the display as shown in Figure 39.

WARNING Clinicians must select an appropriate energy level for defibrillation of pediatric patients.

WARNING The HeartStart MRx has a built-in limitation of 50 Joules when using internal paddles.

- 2 **Charge** - Press the Charge  button on the front panel. If using external paddles, the charge button on the paddles may be used instead. As the defibrillator charges, the energy selection shown in the Shock Status area changes to show the current charge energy. A continuous, low-pitch charging tone sounds until the desired energy level is reached, at which point you will hear a continuous, high-pitch charge done tone.

You may increase or decrease the selected energy at any time during charging or after charging is complete. Simply move the Therapy Knob to the desired energy level as explained above. The defibrillator charges to the selected energy level automatically.

To disarm the defibrillator, press [**Disarm**]. If the Shock button has not been pressed within the time period specified in the Time to Auto Disarm Configuration setting, the defibrillator disarms automatically.

- 3 **Shock** - Confirm that a shock is still indicated and that the defibrillator has charged to the selected energy level. Make sure no one is touching the patient or anything connected to the patient. Call out loudly and clearly, “Stay Clear!”

If using:

- pads or switchless internal paddles, press the flashing Shock  button to deliver a shock to the patient.
- external paddles, simultaneously press the shock buttons located on the paddles to deliver a shock to the patient.
- switched internal paddles, press the Shock button located on the paddles to deliver a shock to the patient.

The number of shocks delivered is displayed in the Shock Status area of the display. This number includes any shocks administered while in AED Mode.

WARNING Defibrillation current can cause operator or bystander injury. Do not touch the patient, or equipment connected to the patient, during defibrillation.

CAUTION Alarms are turned off when an energy is selected for asynchronous defibrillation, and the “Alarms Off” message is displayed. Alarms remain paused until toggled on using the Alarm Pause button, the Sync function is enabled, or the Therapy Knob is moved to **Monitor** or **Pacer**.

Performing Synchronized Cardioversion

Synchronized Cardioversion allows you to synchronize delivery of the defibrillator shock with the R-wave of the ECG being monitored in Wave Sector 1. You may choose to perform synchronized cardioversion through either:

- multifunction electrode pads, or
- external paddles

When using paddles, you should monitor the ECG through monitoring electrodes connected to a 3-, 5- or 10-lead ECG cable or a Philips bedside monitor. You may choose to monitor through an alternate source when using pads, as well. Cardioversion is still delivered through either pads or paddles.

Preparing for Synchronized Cardioversion

In preparation for synchronized cardioversion:

- 1 Perform the tasks as described in “Preparing for Defibrillation” on page 67
- 2 If monitoring through a 3-, 5-, or 10-lead ECG cable, plug the ECG cable into the ECG port on the HeartStart MRx and apply monitoring electrodes to the patient. (See “ECG and Arrhythmia Monitoring” on page 41.)
- 3 Use the Lead Select  button to select pads, paddles or a lead from attached monitoring electrodes. The selected ECG source should have a clear signal and a large QRS complex. (See “Lead Selection” on page 47.)

NOTE When the patient is already connected to Philips bedside monitoring equipment, an external ‘Sync’ cable plugs into the ECG Output jack of the bedside monitor and connects to the ECG port of the HeartStart MRx. This connects the ECG signal from the monitor into the HeartStart MRx, where it is displayed and synchronization occurs.

The signal from the bedside monitor is displayed as Lead II on the HeartStart MRx, even though it is not necessarily Lead II coming from the bedside monitor.

-
- WARNING**
- If you use an external monitor as the ECG source, a biomedical technician **MUST** verify that the external monitor and the HeartStart MRx combination will deliver a synchronized shock within 60 ms of the peak of the R-wave. Use a 1 mV QRS complex with a QRS width of 40 ms. This performance cannot be guaranteed with all commercially available monitors.
 - When monitoring through paddles only, artifact introduced by paddle movement may resemble an R-wave and trigger a defibrillation shock.
-

Delivering a Synchronized Shock

To perform synchronized cardioversion:

- 1 With the Therapy Knob in the **Monitor** position, press the Sync  button located beside the Therapy Knob to activate the Sync function. A Sync message appears in the upper right corner of Wave Sector 1.
- 2 Confirm that the Sync marker appears with each R-wave.
- 3 Turn the Therapy Knob to the desired energy level setting.
- 4 Press the Charge  button on the HeartStart MRx or, if using paddles, the yellow charge button located on the handle of the Apex paddle. Wait until the charge has reached the energy level selected, and you hear a continuous charge done tone.

To disarm the defibrillator, press [**Disarm**]. If Shock has not been pressed within the time period specified in the Time to Auto Disarm Configuration Choice, the defibrillator disarms automatically.

If desired, you may increase or decrease the selected energy level after pressing the Charge button by moving the Therapy Knob to the desired setting. The defibrillator charges to the modified energy level automatically. Wait until the current charge reaches the selected energy level before proceeding.

- 5 Make sure no one is touching the patient or anything connected to the patient. Call out clearly and loudly, “Stay Clear!”.
- 6 Press **and hold** the Shock  button on the HeartStart MRx or, if you are using external paddles, press **and hold** the orange buttons on both paddles. The shock will be delivered when the next R-wave is detected.

NOTE It is important to continue to hold the Shock  button (or the paddle shock buttons) until the shock is delivered. The defibrillator shocks with the next detected R-wave.

NOTE Should a device INOP occur while performing synchronized cardioversion, the HeartStart MRx will not charge, or if charged, will disarm automatically.

WARNING Defibrillation current can cause operator or bystander injury. Do not touch the patient or equipment connected to the patient during defibrillation.

Delivering Additional Synchronized Shocks

If additional synchronized shocks are indicated, perform the following steps:

- 1 Make sure the Sync function is still enabled, as indicated by the presence of the Sync message in the upper right corner of the Wave Sector 1.
- 2 Repeat Steps 4-6 under “Delivering a Synchronized Shock”.

The Sync function of the HeartStart MRx can be configured to either be enabled or disabled after each shock is delivered. If configured to remain enabled and the Therapy Knob is moved to either **Monitor** or **Pacer**, the Sync function is still enabled. However, should the Therapy Knob be moved to either the **Off** or **AED** positions, the Sync function is disabled.

Disabling the Sync Function

To turn off the Sync function of the HeartStart MRx, press the Sync  button.

Troubleshooting

If your HeartStart MRx monitor/defibrillator does not operate as expected during defibrillation, see “Troubleshooting” on page 193.

Noninvasive Pacing

This chapter explains the noninvasive transcutaneous pacing option available with the HeartStart MRx and describes how to perform pacing.

Overview

Noninvasive transcutaneous pacing therapy is used to deliver pace pulses to the heart. Pace pulses are delivered through multifunction electrode pads that are applied to the patient's bare chest.

While in Pacer Mode, the ECG strip and Event Summary are easily annotated with event information using the Mark Event function button. See "Marking Events" on page 148 for more information.

- NOTE** For treatment of patients with implantable devices such as permanent pacemakers or cardioverter-defibrillators, consult a physician and the instructions for use provided by the device's manufacturer.
- NOTE** Waveforms, ECG monitoring, measurements, and most alarms remain active and retain their settings when you transition from Monitor or Manual Defib Mode to Pacer Mode. However, the waveform displayed in Wave Sector 4 is replaced by the pacing status bar.
- NOTE** The use of Pacer Mode may be password protected in Version A.02 and later devices, as defined in Configuration. See "Password Security" on page 15.

Alarms

Arrhythmia alarms for Pacer Not Pacing and Pacer Not Capture are associated with non-transcutaneous pacing, therefore, these alarms are off when the HeartStart MRx is in Pacer Mode. All other red and yellow alarms are active if enabled, and their limits may be changed while in Pacer Mode. Refer to the specific chapter for each measurement for information on changing alarm limits.

While pacing, should a Pads Off condition occur or the pads cable is disconnected, a latching, red alarm is generated and pacing is stopped. The message, **Pacing Stopped. [Pads Off] [Pads Cable Off]** is displayed in the top line of the pacing status bar. Once the condition is corrected, resume pacing by pressing the **[Resume Pacing]** soft key.

While pacing in demand mode, should the ECG source for Wave Sector 1 become invalid, e.g. a Leads Off condition or the ECG cable is disconnected, a latching, red alarm is generated and pacing is stopped. The message, **Pacing Stopped. Leads Off.** is displayed in the top line of the pacing status bar. Once the condition is corrected, resume pacing by pressing the **[Resume Pacing]** soft key.

When pacing in demand mode using a 3-lead ECG set, if the lead in Wave Sector 1 is changed, a latching, red alarm is generated. The message, **Pacing Stopped. Leads Off.** is displayed in the top line of the pacing status bar. Resume pacing by pressing the **[Resume Pacing]** soft key.

NOTE The Pacing Stopped red alarm cannot be disabled.

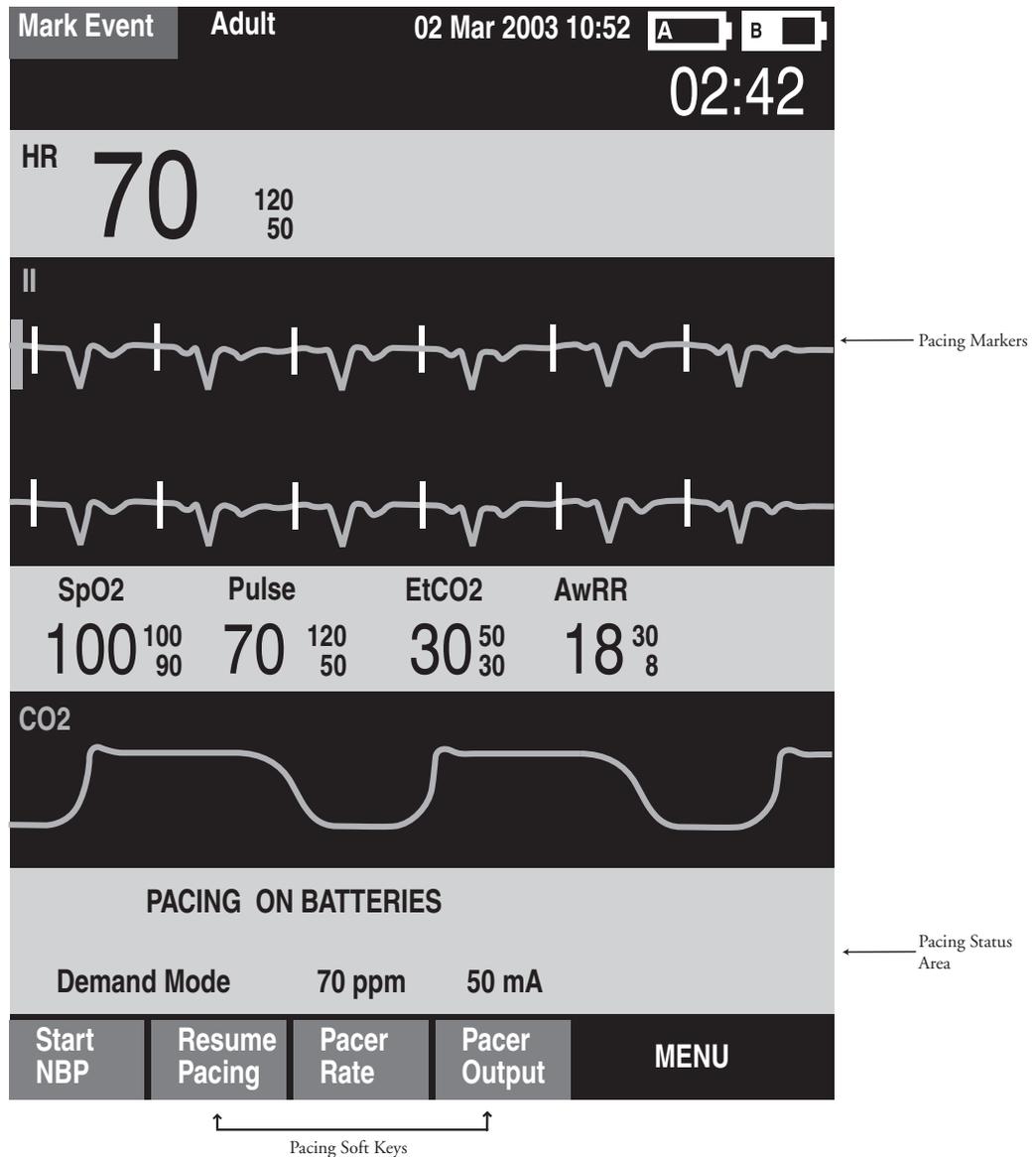
ECG INOPS, as described in “ECG INOPS” on page 51, are also annunciated while in Pacer Mode.

WARNING Heart rate displays and alarms function during pacing, but they can be unreliable. Observe the patient closely while pacing. Do not rely on the indicated heart rate or heart rate alarms as a measure of the patient’s perfusion status.

Pacing View

Pacing View appears when the Therapy Knob is set to the **Pacer** position. Figure 45 shows information displayed in Pacing View.

Figure 45



Pacing View includes a status block which appears in Wave Sector 4 of the display. The first line of the status block communicates whether pacing is active or paused. If pacing is powered by batteries, this is indicated here as well, if configured. The second line of the status block identifies the Pacer Mode (demand or fixed), pacing rate (ppm), and pacing output (mA).

Soft keys are available for setting pacing status ([**Start Pacing**], [**Pause Pacing**], [**Resume Pacing**]) and adjusting [**Pacer Rate**], [**Pacer Output**].

NOTE If pacing is interrupted for any reason, the [**Resume Pacing**] soft key must be pressed to continue pacing.

A white pacing marker appears on the ECG waveform in Wave Sector 1 each time a pacer pulse is delivered to the patient. If pacing in demand mode, white R-wave markers also appear on the ECG until capture occurs.

NOTE R-wave markers do not appear on paced beats.

Demand Mode Versus Fixed Mode

The HeartStart MRx can deliver paced pulses in either demand or fixed mode.

- In **demand mode**, the pacer only delivers paced pulses when the patient's heart rate is lower than the selected pacing rate.
- In **fixed mode**, the pacer delivers paced pulses at the selected rate.

WARNING Use demand mode pacing whenever possible. Use fixed mode pacing when motion artifact or other ECG noise makes R-wave detection unreliable or when monitoring electrodes are not available.

The HeartStart MRx requires a 3-, 5-, or 10-lead ECG cable and monitoring electrodes as the source of the ECG during demand pacing. Pace pulses are delivered through the multifunction electrode pads, however, the pads cannot be used to monitor the ECG and deliver pace pulses simultaneously.

NOTE The ECG derived from pads does not need to be displayed in a wave sector in order to deliver pacing therapy.

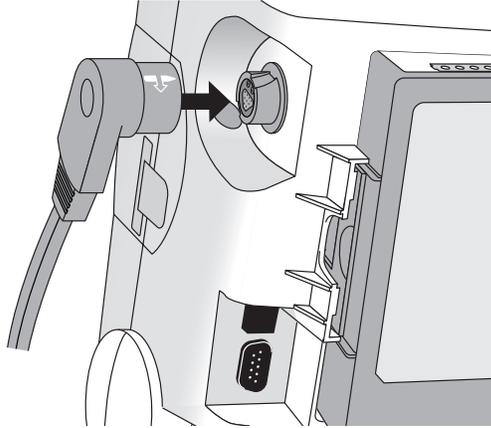
NOTE When using demand mode, pads are not an available choice for display in Wave Sector 1, through either the Lead Select button or the **Waves** menu.

Preparing for Pacing

To prepare for pacing:

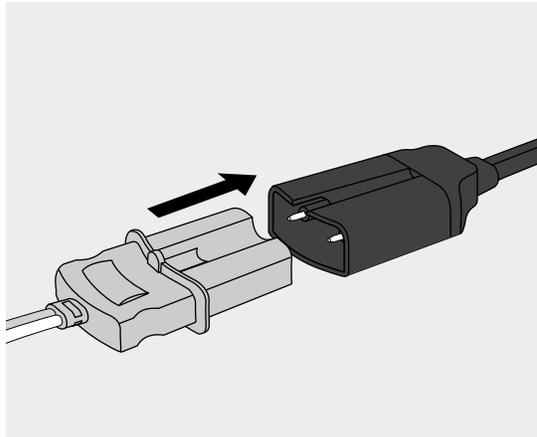
- 1 If not pre-connected, connect the pads cable to the HeartStart MRx by aligning the white pointer on the pads cable with the white arrow on the green Therapy port. Then push until you hear it click into place. See Figure 46.

Figure 46 Pads Cable Connection



- 2 Make sure the multifunction electrode pads packaging is intact and within the expiration date shown.
- 3 Connect the pads connector to the pads cable. See Figure 47.

Figure 47 Pads Connector



- 4 Apply the pads to the patient as directed on the pads packaging or according to your organization's protocol.
- 5 If pacing in demand mode, apply monitoring electrodes (see "Electrode Placement" on page 45), and connect the ECG cable to the HeartStart MRx (see "Connecting the ECG Cable" on page 31).

NOTE If pacing for long periods of time, new monitoring electrodes and multifunction electrode pads should be applied periodically. Refer to the manufacturer's documentation for replacement recommendations.

Demand Mode Pacing

To pace in demand mode:

- 1 Turn the Therapy Knob to the **Pacer** position.

The message, **Pacing Paused**, appears in the status block and indicates that the pacing function is enabled, however, pace pulses are not being delivered. Pacing is enabled in demand mode, with the configured lead displayed in Wave Sector 1. If the configured lead is set to Pads, Lead II or the first available monitoring lead is displayed.

- 2 Press the Lead Select  button to select the best lead with an easily detectable R-wave. (See “Lead Selection” on page 47).
- 3 Verify that white R-wave markers appear above or on the ECG waveform. A single marker should be associated with each R-wave. If the R-wave markers do not appear or do not coincide with the R-wave, select another lead.
- 4 Press [**Pacer Rate**] and use the Navigation and Menu Select buttons to select the desired number of pace pulses per minute. The initial rate is configurable.
- 5 If needed, adjust the initial pacer output. To do this, press [**Pacer Output**] and use the Navigation and Menu Select buttons to select the desired output. The initial output is configurable.
- 6 Press [**Start Pacing**]. The message, **Pacing**, appears.

WARNING Use care when handling the multifunction electrode pads on the patient to avoid shock hazard during pacing.

- 7 Verify that white pacing markers appear on the ECG waveform.
- 8 Press [**Pacer Output**]. Then use the Navigation and Menu Select buttons to:
 - a. increase the output until cardiac capture occurs. Capture is indicated by the appearance of a QRS complex after each pacing marker.
 - b. decrease the output to the lowest level that still maintains capture.
- 9 Verify the presence of a peripheral pulse.

NOTE Spontaneous beats may be present which are not associated with the delivery of pace pulses. Additionally, if the patient’s heart rate is above the pacer rate, pace pulses are not delivered and, therefore, pacing markers do not appear.

To stop delivery of pace pulses, press [**Pause Pacing**]. Once paused, press [**Resume Pacing**] to resume delivery of pace pulses.

You may also stop delivery of pace pulses by moving the Therapy Knob off the **Pacer** position.

WARNING When Pacing in demand mode, the ECG cable must be directly connected from the patient to the HeartStart MRx.

WARNING If you are using the pacing function with battery power and the Low Battery Alarm is annunciated, connect the device to external power or insert a fully charged battery.

NOTE Routinely assess the patient's cardiac output.

NOTE Pacing will not start if there is a problem with the multifunction electrode pads connection or patient contact. Pace pulses will not be delivered if there is a problem with the ECG monitoring electrodes connections. If either situation occurs, a system message is displayed to alert you that a lead is disconnected or that the pads have a poor connection.

Fixed Mode Pacing

To pace in fixed mode:

- 1 Turn the Therapy Knob to the **Pacer** position.

The message, **Pacing Paused**, appears and indicates that the pacing function is enabled, however, pace pulses are not being delivered. Pacing is enabled in demand mode, with the configured lead displayed in Wave Sector 1. If the configured lead is set to Pads, Lead II or the first available monitoring lead is displayed.

- 2 Change the pacer mode to fixed mode, using the menu selections shown below in Figure 48

Figure 48 Changing Pacer Modes

Main Menu	
Pacer Mode	
Volume	
Waves	
Measurements/Alarms	
Patient Info	
Other	
Exit	

Pacer Mode
Demand
Fixed

- 3 Use the Lead Select  button to select the desired lead for viewing.
- 4 Press [**Pacer Rate**] and use the Navigation and Menu Select buttons to select the desired number of paced pulses per minute. The initial rate is configurable.
- 5 If needed, adjust the initial pacer output. To do this, press [**Pacer Output**] and use the Navigation and Menu Select buttons to select the desired output. The initial output is configurable.
- 6 Press [**Start Pacing**]. The message, **Pacing**, appears.

WARNING Use care when handling the multifunction electrode pads on the patient to avoid shock hazard during pacing.

- 7 Verify that white pacing markers appear on the ECG waveform.

- 8 Press [**Pacer Output**]. Then use the Navigation and Menu Select buttons to:
 - a. increase the output until cardiac capture occurs. Capture is indicated by the appearance of a QRS complex after each pace pulse marker.
 - b. decrease the output to the lowest level that still maintains capture.
- 9 Verify the presence of a peripheral pulse.
- 10 To pause or stop pacing:
 - Press [**Pause Pacing**] to stop the delivery of paced pulses to the patient, or
 - Move the Therapy Knob off the **Pacer** position.

Defibrillating During Pacing

Should it be necessary to defibrillate the patient during pacing, refer to the procedure for defibrillating in Manual Defib Mode in Chapter 6, or AED Mode in Chapter 5. Once the Therapy Knob is moved from the **Pacer** position to a Manual Defib Mode energy setting or **AED**, pacing is stopped.

To resume pacing after defibrillation, repeat the pacing procedure, as described in “Demand Mode Pacing” on page 80 or “Fixed Mode Pacing” on page 81. When pacing is resumed, pacing settings selected prior to defibrillation (mode, rate, and output) are retained. Be sure to confirm that cardiac capture has been maintained.

CAUTION Pacing must be turned off before defibrillating with a second defibrillator. The HeartStart MRx can be damaged as a result.

Troubleshooting

If your HeartStart MRx does not operate as expected during pacing, see Chapter 15, “Troubleshooting” on page 193.

Pulse Oximetry

Pulse Oximetry (SpO₂) monitoring is one of the tools available to assist in assessing a patient's cardiac and respiratory systems. This chapter explains how pulse oximetry works and describes how to use the HeartStart MRx to monitor SpO₂.

Overview

Pulse oximetry is a noninvasive method of continuously measuring oxygen saturation (SpO₂) in arterial blood. The resultant SpO₂ reading indicates the percentage of hemoglobin molecules in the arterial blood which are saturated with oxygen.

-
- WARNING** Do not rely solely on SpO₂ readings; assess the patient at all times. Inaccurate measurements can be caused by:
- Incorrect sensor application or use.
 - Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin).
 - Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin or carboxyhemoglobin.
 - Exposure to excessive illumination such as surgical lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
-

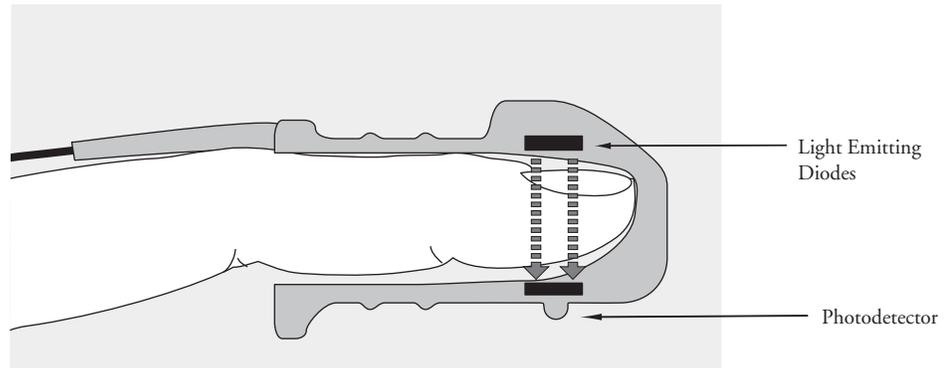
The HeartStart MRx allows you to monitor SpO₂ while in Monitor, Manual Defib, and Pacer Modes.

NOTE For more information on SpO₂, refer to the Application Note, *Philips Pulse Oximetry*.

Understanding Pulse Oximetry

A pulse oximetry sensor sends light through patient tissue to a receiver on the other side of the sensor. As Figure 49 shows, light emitting diodes transmit red and infrared light through peripheral areas of the body, such as a finger.

Figure 49 Pulse Oximetry Sensor



A photodetector positioned opposite the light emitting diodes compares light absorption before and after pulsation. The amount of light getting through reflects the blood flow in the arterioles. This measurement of light absorption during pulsation is translated into an oxygen saturation percentage and an SpO₂ value is displayed.

For accurate SpO₂ measurements, the following conditions must apply:

- The patient must have perfusion in that extremity.
- The light emitter and the photodetector must be directly opposite each other.
- All of the light from the emitter must pass through the patient's tissue.
- The sensor site should be free of vibration and excessive motion.
- Power cables should be kept away from the sensor cable and connector.

Selecting a Sensor

Table 7 shows the SpO₂ sensors that may be used with the HeartStart MRx.

Table 7 SpO₂ Sensors

Sensor	Type	Patient Type	Patient Size	Sensor Site
M1191A	Reusable	Adult	>50 kg	Finger
M1192A	Reusable	Pediatric Small Adult	15-50 kg	Finger
M1193A	Reusable	Adult	>50 kg	Thumb
M1194A	Reusable	Adult Pediatric	>40 kg	Ear
M1195A	Reusable	Pediatric	4-15 kg	Finger
M1131A	Disposable	Adult/ Pediatric	> 20 kg	Finger
M1903B	Disposable	Pediatric	10-50 kg	Finger
M1904B	Disposable	Adult	> 30 kg	Finger

NOTE M1903B and M1904B sensors are available outside the US only.

-
- CAUTION**
- Do not use disposable sensors in high humidity environments or in the presence of fluids which may contaminate sensor and electrical connections, causing unreliable or intermittent measurements.
 - Do not use disposable sensors on patients who have allergic reactions to the adhesive.
 - Do not use the ear transducer on patients with small ear lobes, as incorrect measurements may result.
-

NOTE To use Nellcor sensors (M1903B, M1904B), you must connect the M1943B Nellcor adapter cable to the HeartStart MRx.

The most important factor when selecting a sensor is the position of the light emitting diodes in relation to the photodetector. When a sensor is applied, the diodes and the photodetector must be opposite each other. Sensors are designed for patients with a specific weight range and for specific sites. Be sure to:

- Select a sensor appropriate for the patient's weight.
- Select a sensor site with adequate perfusion. Improve perfusion at the site by rubbing or warming the site.
- Avoid application to sites with edematous tissue.

Reusable Sensors may be reused on different patients after they have been cleaned and disinfected (see the manufacturer's instructions supplied with the sensor).

Disposable Sensors should be used only once and then discarded. They may be relocated to another sensor site on the patient if the first location does not give the desired results. Disposable sensors must not be reused on different patients.

NOTE A 2-meter SpO₂ extension cable (M1941A) is available for use with the HeartStart MRx.

Applying the Sensor

Follow the manufacturer's directions for applying and using the sensor, making sure to observe any warnings or cautions. For the best results:

- Make sure the sensor is dry.
- If the patient is moving, secure the sensor cable loosely to the patient.
- Make sure the transducer is not too tight. Too much pressure can cause venous pulsation or can impede the blood flow, resulting in low readings.
- Keep power cables away from the sensor cable and connection.
- Avoid placing the sensor in an environment with bright lights. If necessary, cover the sensor with opaque material.
- Avoid placing the sensor on an extremity with an arterial catheter, blood pressure cuff, or intravenous infusion line.

-
- WARNING**
- Failure to apply the sensor properly may reduce the accuracy of the SpO₂ measurement.
 - Inspect the sensor application site at least every two hours for changes in skin quality, correct optical alignment, and proper sensor application. If skin quality is compromised, change the sensor site. Change the application site at least every four hours. More frequent checking may be required due to an individual patient's condition.
 - Using an SpO₂ sensor during MR imaging can cause severe burns. Minimize this risk by positioning the cable so that no inductive loops are formed. If the sensor does not appear to be operating properly, remove it immediately from the patient.
-

-
- CAUTION** Do not use more than one extension cable (M1941A).
Position the sensor cable and connector away from power cables to avoid electrical interference.
-

Monitoring SpO₂

To monitor SpO₂:

- 1 Connect the appropriate sensor cable to the to the HeartStart MRx as described in “Connecting the SpO₂ Cable” on page 32.
- 2 Apply the sensor to the patient.
- 3 If the HeartStart MRx is not turned on, turn the Therapy Knob to **Monitor**.
- 4 The default patient category is set to adult. If necessary, use the **Patient Info** menu to access **Patient Category** and select the correct patient category setting (adult/pediatric). This is used to optimize the calculation of the SpO₂ and pulse values.

A **·?·** is displayed in Parameter Block 2 while the oxygen saturation is initially measured and a value is calculated. In a few seconds a value appears, replacing the **·?·**. As the patient’s oxygen saturation changes, the SpO₂ value is updated continuously. See Figure 50.

If SpO₂ alarms are turned on, alarm limits are displayed to the right of the SpO₂ value. If alarms are turned off, the  symbol is displayed instead of the alarm limits. SpO₂ alarms are on by default. See “Setting SpO₂ Alarms” on page 90.

The patient’s pulse rate as derived from pulse oximetry, is also displayed in Parameter Block 2. If pulse rate alarms are turned on, alarm limits are displayed to the right of the pulse rate value. If alarms are turned off, the  symbol is displayed instead of the alarm limits. Pulse alarms are off by default. See “Setting Pulse Rate Alarms” on page 91.

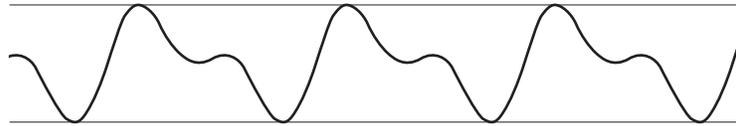
Figure 50 SpO₂ and Pulse / Parameter Block 2

SpO ₂ %	Pulse bpm	EtCO ₂ mmHg	AwRR rpm
100 ¹⁰⁰ / ₉₀	110 ¹²⁰ / ₅₀	34 ⁵⁰ / ₃₀	18 ³⁰ / ₈

Pleth Wave

The pleth wave is displayed in the configured Wave Sector (with a default of Wave Sector 4), if available. If the configured Wave Sector is already populated, the pleth wave is displayed in the first available empty Wave Sector. It is drawn at an approximate speed of 25 mm/second. Grid lines are displayed to indicate signal quality. When signal quality is good, the pleth wave is auto scaled to the grid lines. When signal quality is poor, the size of the pleth wave is proportionately decreased.

Figure 51 Pleth Wave Size



When the Therapy Knob is moved to an energy setting, the SpO₂ and Pulse values, as well as the pleth wave, continue to be displayed. When the Therapy Knob is moved to **Pacer**, the pacing status bar appears in Wave Sector 4, replacing the waveform in that sector. However, the SpO₂ and Pulse values and alarm settings are retained even if the pleth wave is no longer displayed. If the Therapy Knob is moved to **AED**, SpO₂ and pulse related information is no longer monitored.

Setting SpO₂ Alarms

Alarms are annunciated if measurements fall outside the configured limits for high or low SpO₂, or if the measurement falls below the configured SpO₂ Desat Limit.

Alarms are on unless you turn them off during use. Once disabled, alarms remain off until they are turned on.

WARNING Turning off alarms prevents all alarms associated with the SpO₂ measurement from being annunciated. If an alarm condition occurs, NO alarm indication will be given.

Changing the SpO₂ Alarm Limits

To change the SpO₂ Alarm Limits, perform the following steps:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **SpO₂** and press the Menu Select button.
- 4 Select **SpO₂ Limits** and press the Menu Select button.
- 5 Using the Navigation buttons, select the new high limit value and press the Menu Select button.
- 6 Select the new low limit value and press the Menu Select button.

SpO₂ Desat Alarm

The HeartStart MRx also provides an alarm for SpO₂ Desat Limit. The SpO₂ Desat alarm provides an additional limit setting below the low limit setting to notify you of potentially life threatening decreases in oxygen saturation. This additional limit setting is preset through the **Configuration** menu.

NOTE If the SpO₂ Low Limit alarm value is set below the configured SpO₂ Desat Limit, the SpO₂ Desat Limit value is automatically adjusted to the SpO₂ Low Limit alarm value. Should the SpO₂ reading fall below this limit, the SpO₂ Desat Limit alarm is annunciated.

Enabling/Disabling the SpO₂ Alarms

To enable the SpO₂ Alarms, perform the following steps:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **SpO₂** and press the Menu Select button.
- 4 Select **Alarms On/Off** and press the Menu Select button.

NOTE While an NBP measurement is in progress, SpO₂ INOP messages are suppressed for up to 60 seconds.

Setting Pulse Rate Alarms

Pulse Rate alarms are annunciated if measurements fall outside the configured limits for high and low pulse rate. Pulse Rate alarms are off unless you enable them during use. The configured alarm limits may be changed during use.

Enabling/Disabling the Pulse Rate Alarms

To enable the Pulse Rate Alarms, perform the following steps:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **Pulse** and press the Menu Select button.
- 4 Select **Alarms On/Off** and press the Menu Select button.

Changing the Pulse Rate Alarm Limits

To change the Pulse Rate Alarm Limits, perform the following steps:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **Pulse** and press the Menu Select button.
- 4 Select **Pulse Limits** and press the Menu Select button.
- 5 Using the Navigation buttons, select the new high limit value and press the Menu Select button.
- 6 Select the new low limit value and press the Menu Select button.

Disabling the SpO₂ Monitoring Function

To disable the SpO₂ monitoring function, disconnect the sensor cable from the SpO₂ port. The message **SpO2 Unplugged. Turn off SpO2?** appears. Select **Yes** and press the Menu Select button.

Should the sensor cable be disconnected accidentally, the message **SpO2 Unplugged. Turn off SpO2?** appears to notify you of the disconnection. Select **No** and press the Menu Select button. Secure the connection. The SpO₂ monitoring function is once again enabled.

Caring for Sensors

Refer to the manufacturer's instructions for care and cleaning of sensors. To get the best results from your reusable SpO₂ sensors, always handle the sensor and cable with care and protect them from sharp objects. The sensor sleeve houses a sensitive electronic device that can be damaged. Harsh treatment of sensors will drastically reduce their lifetime.

WARNING Do not use a damaged sensor or one with exposed electrical circuits.

Troubleshooting

If your HeartStart MRx does not operate as expected during SpO₂ Monitoring, see Chapter 15, "Troubleshooting" on page 193.

Noninvasive Blood Pressure

This chapter describes how to monitor noninvasive blood pressure (NBP) with the HeartStart MRx.

Overview

Your HeartStart MRx measures blood pressure for both adult and pediatric patients using the oscillometric method. Systolic, diastolic, and mean measurements are provided, and alarms are available to alert you to changes in the patient's condition. NBP measurements may be taken while in Monitor, Pacer, or Manual Defib Modes. NBP measurements can be taken automatically on a schedule or manually on demand.

While an NBP measurement is in progress, the current cuff pressure is displayed in Parameter Block 1. Once the measurement is complete, the values for systolic, diastolic, and mean pressure are displayed, along with the measurement schedule (manual or automatic intervals) and a time stamp (see Figure 52). If NBP alarms are enabled, alarm limits appear next to the NBP value and the alarm source (systolic, diastolic, or mean) is displayed above the NBP alarm limits. If alarms are off, the alarms off symbol  replaces the limits.

Figure 52 NBP / Parameter Block 1

HR	82	NBP q 30 10:40	SYS
	120 60	120/80 (100)	160 90

For more information on monitoring NBP, refer to the Application Note, *About Noninvasive Blood Pressure*.

The first time an NBP measurement is taken, the cuff's initial inflation pressure is 160 mmHg (adult) or 120 mmHg (pediatric). If the measurement is successful, the next inflation pressure is 35-40 mmHg above the systolic measurement, with a minimum inflation pressure of 120 mmHg. If the patient's systolic pressure measurement is higher than the inflation pressure, the cuff inflation pressure is automatically increased by 35-40 mmHg and another measurement is attempted. The maximum cuff inflation pressure is 280 mmHg, while the maximum systolic value is 260 mmHg.

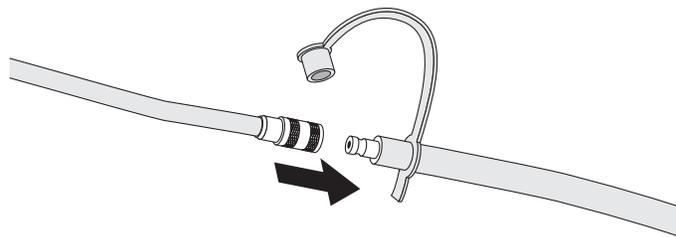
WARNING Initial cuff inflation pressure is based on the configured patient type, adult or pediatric. If necessary, select the correct patient type during use by changing the Patient Category selection through the Patient Info menu.

Preparing to Measure NBP

To prepare for NBP measurement:

- 1 Select the appropriately sized cuff for the patient. The cuff width should be either 40% of the limb circumference or $2/3$ of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50%-80% of the limb. The wrong cuff size may give false and misleading results. If you do not have the correct cuff size, use a larger one to minimize error.
- 2 Attach the cuff to the NBP tubing, making sure that air can pass through the tubing and that the tubing is not squeezed or kinked (see Figure 53).

Figure 53 Connecting the NBP Cuff/Tubing



- 3 Insert the NBP tubing into the NBP port as described in “Connecting the NBP Interconnect Tubing” on page 33.

- 4 Apply the blood pressure cuff to the patient's arm or leg as follows:
 - a. Ensure that the cuff is completely deflated.
 - b. The cuff should not be placed on the same extremity as an SpO₂ sensor. Wrap the cuff around the arm, making sure that the artery marker is aligned over the brachial artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities. Also ensure that the NBP tubing from the defibrillator to the cuff is not compressed, crimped, or damaged.
 - c. Check that the edge of the cuff falls within the range identified by the <---> markings. If it does not, use a larger or smaller cuff that fits better.
- 5 Place the limb used for taking the measurement at the same level as the patient's heart.

-
- WARNING**
- Do not perform noninvasive blood pressure measurements on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
 - Use clinical judgement to decide whether or not to perform automatic blood pressure measurements on patients with severe blood clotting disorders, because of the risk of hematoma in the limb wearing the cuff.
 - Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
 - Use only approved cuffs and tubing in order to prevent inaccurate data, injury, or damage. All specified cuffs are protected against the effects of the discharge of a defibrillator.
 - Prolonged series of noninvasive blood pressure measurements in automatic mode may be associated with purpura, ischemia, and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth, and sensitivity. If any abnormality is observed, stop the blood pressure measurements immediately.
 - Blood pressure readings may be affected by the position of the subject, his/her physiologic condition, and other factors.
 - To obtain accurate blood pressure readings, the cuff must be the correct size and also be correctly fitted to the patient. Incorrect size or incorrect fitting may result in incorrect readings.
-

-
- CAUTION**
- Do not compress or restrict pressure tubes during an NBP measurement.
 - If a spill occurs and liquid appears to be inside the tubing, contact your service personnel.
-

NOTE When using the HeartStart MRx aboard aircraft, NBP measurements should only be taken while on the ground or once cruising altitude is reached. Measurements taken during ascent or descent may not be accurate.

Measuring NBP

To measure NBP, press the **[Start NBP]** soft key. The cuff pressure is displayed as the cuff inflates and deflates. When the measurement is complete, the NBP values are displayed. Additional measurements are taken according to the configured NBP schedule. If the schedule is configured to:

Manual - There is no schedule for additional measurements. One measurement is taken each time you press **[Start NBP]**. Take additional measurements by pressing **[Start NBP]**.

Automatic - The measurement is repeated at the configured interval of 1, 2.5, 5, 10, 15, 30, 60, or 120 minutes from the time you press the **[Start NBP]** soft key. Additional manual measurements may be taken without affecting the automatic measurement schedule, by pressing **[Start NBP]**.

The configured NBP schedule may be changed during use through the **Measurements/Alarms** menu. If the automatic measurement schedule is changed, the new time interval is applied to the start time of the last measurement. If the new time interval is less than or the same as the time since the last measurement, a measurement begins immediately.

NOTE You may perform a manual NBP measurement at any time, even when an automatic schedule is set. Simply press the **[Start NBP]** soft key. To stop an NBP reading in progress, press the **[Stop NBP]** soft key.

Changing the NBP Schedule

To change the NBP schedule and/or the interval of automatic measurements for the current patient:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **NBP** and press the Menu Select button.
- 4 Select **NBP Schedule** and press the Menu Select button.
- 5 Using the Navigation buttons, select the desired interval and press the Menu Select button.

NOTE Interval choices are presented in the format “qx”, indicating measurements will be taken every “x” minutes from the time you first press **[Start NBP]**.

Alarms

An NBP alarm is annunciated when a measurement for the configured source (systolic, diastolic, or mean) falls outside the configured high or low limits. Both the source of the alarm and the limits may be changed during use, for the current patient. NBP alarms are on unless you disable them. Once disabled, alarms remain off until enabled.

WARNING Turning off alarms prevents all alarms associated with the NBP measurement from being annunciated. If an alarm condition occurs, NO alarm indication will be given.

Changing NBP Alarms

To change the NBP alarm source and/or limits for the current patient:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **NBP** and press the Menu Select button.
- 4 Select **NBP Limits** and press the Menu Select button.
- 5 Select the desired source for the alarm, **Systolic**, **Diastolic**, or **Mean**, and press the Menu Select button.
- 6 Using the Navigation buttons, increase or decrease the high limit value and press the Menu Select button.
- 7 Set the new low limit value and press the Menu Select button.

Enabling/Disabling NBP Alarms

To enable/disable NBP Alarms:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **NBP** and press the Menu Select button.
- 4 Select **Alarms On/Off** and press the Menu Select button.

Troubleshooting

If your HeartStart MRx does not operate as expected during NBP Monitoring, see Chapter 15, “Troubleshooting” on page 193.

Monitoring Carbon Dioxide

This chapter describes how to monitor carbon dioxide (CO₂) and measure end-tidal carbon dioxide (EtCO₂) and Airway Respiration Rate (AwRR) with the HeartStart MRx using the Microstream (sidestream) method. CO₂ Monitoring is available in Monitor, Pacer, and Manual Defib Modes.

NOTE Microstream® and FilterLine® are trademarks of Oridion Medical Ltd.

Overview

The carbon dioxide monitoring function of the HeartStart MRx, together with the appropriate FilterLine and, if necessary, airway adapter, measures the partial pressure of carbon dioxide in a sample of the patient's exhaled breath aspirated from the breathing circuit. The HeartStart MRx may be used to monitor carbon dioxide in both intubated and non-intubated patients.

The partial pressure of carbon dioxide is derived by multiplying the measured carbon dioxide concentration with the ambient pressure. From the partial pressure measurement, the end-tidal carbon dioxide (EtCO₂) is derived. EtCO₂ is the peak CO₂ value measured during expiration. It is used to monitor the patient's respiratory status. The EtCO₂ measurement uses a technique based on the absorption of infrared radiation by some gases. It indicates the change in:

- The elimination of CO₂.
- The delivery of O₂ to the lungs.

The CO₂ monitoring function of the HeartStart MRx provides an EtCO₂ value, a CO₂ waveform, and an airway respiration rate (AwRR).

WARNING The EtCO₂ readings do not always correlate closely with blood gas values, especially in patients with pulmonary disease, pulmonary embolism or inappropriate ventilation.

Do not measure CO₂ in the presence of pharmaceuticals in aerosols.

NOTE For more information on capnography and EtCO₂, refer to the Application Note, *Uses of Capnography and Benefits of the Microstream® Method*.

Preparing to Measure EtCO₂

Selecting the Accessories

There are four factors to consider when selecting accessories:

- the type of patient, adult, pediatric, or neonate.
- airway status of the patient, ventilated or not ventilated.
- if a ventilated patient, whether humidified or non-humidified ventilation is used.

WARNING Do not re-use, clean, or sterilize Microstream CO₂ accessories as they are intended for single-patient, one-time use.

Table 8 shows CO₂ accessories with their corresponding application areas.

Table 8 Microstream CO₂ Accessories

Part Number	Circuit	Description
M1920A	Intubated	FilterLine Set - Adult/Pediatric 25 sets/case
M1921A	Intubated	FilterLine H Set - Adult/Pediatric 25 sets/case
M1923A	Intubated	FilterLine H Set - Infant/Neonatal yellow, 25 sets/case
M2520A	Non-Intubated Dual Purpose	Smart CapnoLine - Pediatric
M2522A	Non-Intubated Dual Purpose	Smart CapnoLine - Adult
M2524A	Non-Intubated Single Purpose	Smart CapnoLine - Pediatric
M2526A	Non-Intubated Single Purpose	Smart CapnoLine - Adult

WARNING Use only Microstream accessories (as listed above) to ensure correct functioning of the CO₂ sidestream measurement.

Setting Up Microstream EtCO₂ Measurements

-
- WARNING**
- Danger - explosion hazard - sidestream measurement should not be used in the presence of flammable anesthetics such as:
 - flammable anesthetic mixture with air
 - flammable anesthetic mixture with oxygen or nitrous oxide
 - CO₂ should not be measured in the presence of aerosolized pharmaceuticals.
 - When using the nasal FilterLine, if one or both nostrils are partially or completely blocked, or the patient is breathing through the mouth, the displayed EtCO₂ values may be significantly low.
-

Using the Nasal FilterLine

To set up EtCO₂ measurements using the nasal FilterLine, perform the following steps:

- 1 Attach the FilterLine tubing to the CO₂ Inlet port as described in “Connecting the CO₂ Nasal FilterLine[®]” on page 34.
- 2 Check that both nostrils are clear.
- 3 Position the nasal FilterLine on the face by inserting the FilterLine tips into the nostrils.
- 4 Pass the FilterLine tubing over the ears, then slide the sleeve up the tubing towards the neck to a comfortable fit under the chin.
- 5 If using dual purpose FilterLine tubing, connect the green tubing to the oxygen source.
- 6 Check the positioning of the FilterLine regularly to ensure proper monitoring function.
- 7 Change the nasal FilterLine every 24 hours, if the **CO₂ Occlusion** INOP message appears, or if measurement readings become erratic.

Using the FilterLine and Airway Adapter

To set up EtCO₂ measurements using the FilterLine and airway adapter:

- 1 Attach the FilterLine tubing to the CO₂ Inlet port as described in “Connecting the CO₂ Nasal FilterLine[®]” on page 34.
- 2 Connect the wide end of the airway adapter to the endotracheal tube.
- 3 Connect the narrow end of the airway adapter to the ventilator tubing or manual resuscitator.

Disconnect the FilterLine during suctioning and nebulizing therapies.

For best results for non-humidified use, change the FilterLine after 24 hours of continuous use. For humidified use, change the FilterLine H after 72 hours of continuous use.

-
- WARNING** When using the Microstream EtCO₂ measurement on patients who are receiving or have recently received anesthetics, connect exhaust tubing from the CO₂ Outlet port to a scavenging system or to the anesthesia machine/ventilator to prevent exposing medical staff to anesthetics.
-

NOTE Should the FilterLine or exhaust tubing be blocked when the HeartStart MRx is turned on, the CO₂ Check Exhaust INOP message is displayed. Should the blockage occur during CO₂ monitoring, the CO₂ waveform appears as a flat line, and if alarms are on, an apnea alarm is annunciated.

Measuring EtCO₂

The EtCO₂ measurement is turned on automatically when you connect the FilterLine to the CO₂ Inlet port. The CO₂ waveform is displayed in the configured Wave Sector (with a default of Wave Sector 3), if available. If the configured Wave Sector is already populated, the CO₂ waveform is displayed in the first available empty Wave Sector. The measurement values for EtCO₂ and AwRR are displayed in Parameter Block 2 (see Figure 54).

Figure 54 EtCO₂ and AwRR / Parameter Block 2

SpO ₂ %	Pulse bpm	EtCO ₂ mmHg	AwRR rpm
100 ¹⁰⁰ / ₉₀	110 ¹²⁰ / ₅₀	34 ⁵⁰ / ₃₀	18 ³⁰ / ₈

Setting Up the EtCO₂ and AwRR Alarms

Alarms are annunciated if measurements fall outside the set limits for:

- high and low EtCO₂.
- high and low Airway Respiration Rate (AwRR).
- Apnea Time.

NOTE If the Apnea Time measurement falls outside the configured limits, a red alarm is indicated.

Alarms are on unless you turn them off during use. Once turned off, alarms remain off until they are turned on.

WARNING Turning off alarms prevents all alarms associated with the EtCO₂ or AwRR measurements from being annunciated. If an alarm condition occurs, NO alarm indication will be given.

Changing the EtCO₂ Alarm Limits

To change the EtCO₂ Alarm Limits:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **EtCO₂** and press the Menu Select button.
- 4 Select **EtCO₂ Limits** and press the Menu Select button.
- 5 Using the Navigation buttons, increase or decrease the high limit value and press the Menu Select button.
- 6 Set the new low limit value and press the Menu Select button.

Enabling/Disabling the EtCO₂ Alarms

To enable or disable the EtCO₂ Alarms:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **EtCO₂** and press the Menu Select button.
- 4 Select **Alarms On/Off** and press the Menu Select button.

Changing the AwRR Alarm Limits

To change the AwRR Alarm Limits:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **AwRR** and press the Menu Select button.
- 4 Select **AwRR Limits** and press the Menu Select button.
- 5 Using the Navigation Buttons, increase or decrease the high limit value and press the Menu Select button.
- 6 Set the new low limit value and press the Menu Select button.

Changing the Apnea Time Alarm Limit

To change the Apnea Time Alarm Limit:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **AwRR** and press the Menu Select button.
- 4 Select **Apnea Time** and press the Menu Select button.
- 5 Using the Navigation buttons, increase or decrease the limit and press the Menu Select button.

Enabling/Disabling AwRR Alarms

To enable the AwRR Alarms:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select the **Measurements/Alarms** menu and press the Menu Select button.
- 3 Select **AwRR** and press the Menu Select button.
- 4 Select **Alarms On/Off** and press the Menu Select button.

-
- WARNING**
- The safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of infancy, has not been established.
 - The selected apnea alarm delay may be prolonged by up to 17 seconds, if apnea occurs during the automatic zero process.
-

Disabling the EtCO₂ Monitoring Function

To disable the EtCO₂ monitoring function, disconnect the FilterLine from the CO₂ inlet port. The message **CO2 Unplugged. Turn off EtCO2?** appears. Select **Yes** and press the Menu Select button.

Should the FilterLine be disconnected accidentally, the message **CO2 Unplugged. Turn off EtCO2?** appears to notify you of the disconnection. Select **No** and press the Menu Select button. Secure the connection. The CO₂ monitoring function is once again enabled.

Troubleshooting

If your HeartStart MRx does not operate as expected during CO₂ Monitoring, see Chapter 15, “Troubleshooting” on page 193.

12-Lead ECG

This chapter describes how to use the diagnostic 12-lead ECG function of the HeartStart MRx.

Overview

The optional 12-lead ECG function of the HeartStart MRx is available in Monitor Mode and allows you to preview, acquire, print, copy, and store a 12-lead ECG. In addition, the 12-lead function provides computerized ECG analysis, using the Philips 12-Lead Algorithm. A report with measurements and interpretive statements from the analysis is displayed, stored and printed, as configured.

The Philips 12-Lead Algorithm provides an analysis of the amplitudes, durations, and morphologies of the ECG waveforms and the associated rhythm. The algorithm is highly age and gender specific and very dependent on the patient's paced status. Patient age and gender are used to define normal limits for heart rate, axis deviation, time intervals, and voltage values, for interpretation accuracy in tachycardia, bradycardia, prolongation or shortening of PR and QT intervals, hypertrophy, early repolarization, and myocardial infarction. Adult criteria apply if the patient age is 16 years old or older. Pediatric criteria apply if the patient age is less than 16.

WARNING Computerized ECG interpretation is not intended to be a substitute for interpretation by a qualified physician.

NOTE For information on the Philips 12-Lead Algorithm, see *The Philips 12-Lead Algorithm Physician's Guide*, available at <http://www.medical.philips.com/main/products/resuscitation>, under "Documentation and Downloads." The HeartStart MRx offers only the "Non-paced" and "Paced" Pacing Detection Settings, with Non-paced the default setting.

Preview Screen

The 12-lead function's Preview Screen allows you to see real-time 12-lead ECG data and verify signal quality before acquiring the ECG. As shown in Figure 55, it displays patient information and approximately 2.5 seconds of each of the 12 leads acquired. Waveforms are presented at a rate of 25mm/sec and the configured wave size. A dashed line is displayed if a lead cannot be derived. The message **(Lead-Wire) Lead Off** is displayed if an electrode is not making adequate contact with the patient.

The Preview Screen's patient information includes ID, age, and sex. The Event ID is displayed until you enter the patient's ID. Age and sex are displayed once entered (see "Entering Patient Information" on page 25).

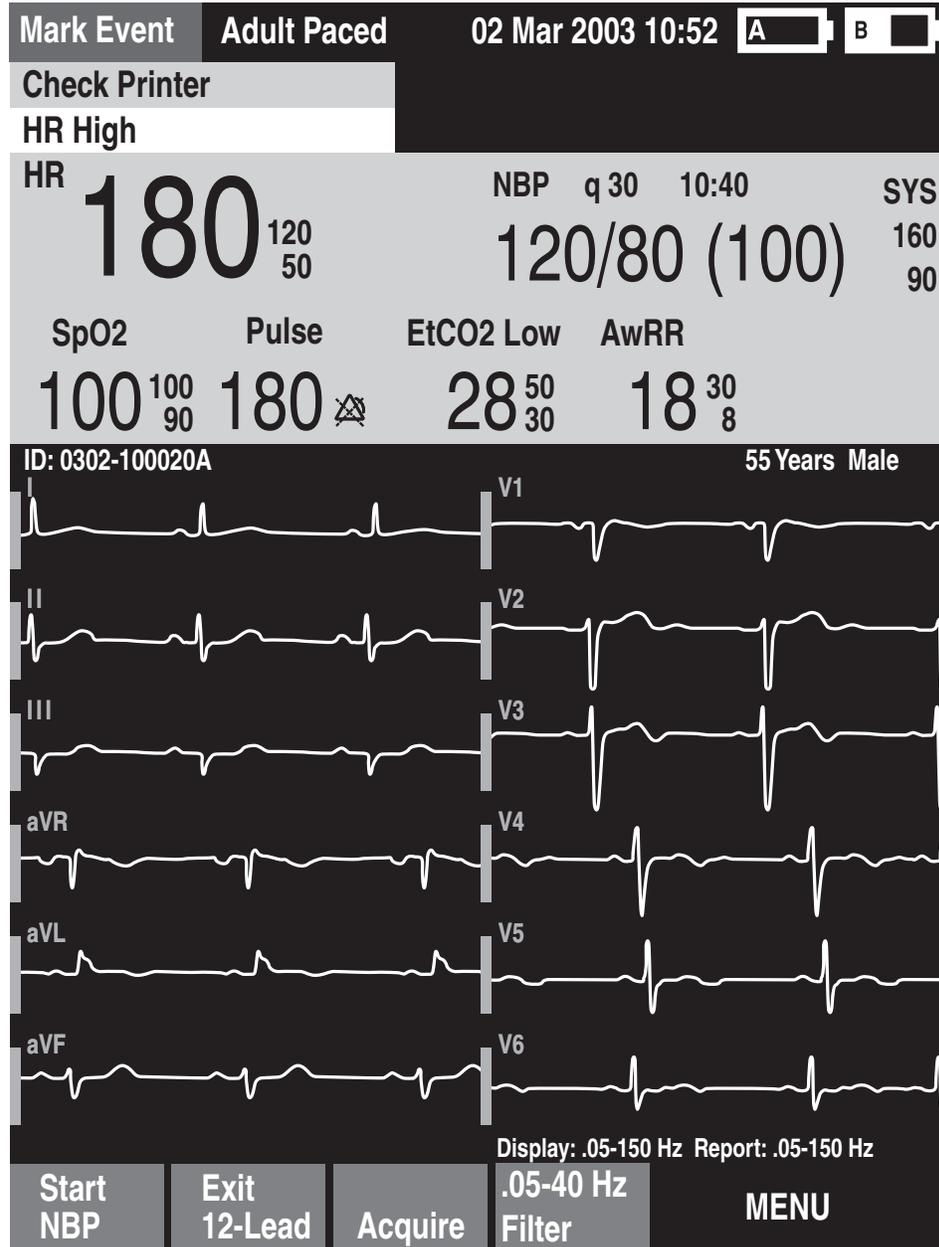
Although waveforms for monitored parameters such as ECG, SpO2 and CO2 are not visible on the Preview Screen, related alarms, measurements and inop messages remain active and are reported in Parameter Blocks 1 and 2 and the general status area.

Preparation

Proper patient preparation and electrode placement are the most important elements in producing a high quality 12-lead ECG. The patient should be supine and relaxed when an ECG is acquired. In preparation for acquiring the ECG:

- 1 Connect the 10-lead cable to the HeartStart MRx, as described in "Connecting the ECG Cable" on page 31.
- 2 Prepare the patient and apply electrodes, as described in "Preparing to Monitor ECG" on page 43.
- 3 Turn the Therapy Knob to **Monitor**.
- 4 Enter the patient's ID, name, age and sex as described in "Entering Patient Information" on page 25.
- 5 Confirm the patient's pacing status is correct.

Figure 55 12-Lead ECG Preview Screen



NOTE The Filter soft key is available only in Version A.02 and later devices.

Acquiring the 12-Lead ECG

Once preparation is complete, to acquire a 12-lead ECG in Monitor Mode:

- 1 Press the [**12-Lead**] soft key.
The Preview Screen is displayed, as shown in Figure 55.
- 2 Check the signal quality on each lead and, if necessary, make adjustments as described in “Improving Signal Quality” on page 111.
- 3 Press the [**Start Acquire**] soft key. The message **Acquiring 12-Lead** is then displayed while the HeartStart MRx acquires ten seconds of ECG data.
- 4 If patient age and sex were not previously entered, you are prompted to enter the information.
 - a. For age, use the Navigation buttons to increase or decrease the displayed value of the patient’s age. Then press the Menu Select button .
 - b. For sex, use the Navigation buttons to select the patient’s sex and press the Menu Select button.
- 5 Keep the patient still while the message **Acquiring 12-Lead** is displayed.

Once ECG acquisition is complete, ECG analysis begins automatically and is accompanied by the message **Analyzing 12-Lead**. The patient does not need to be still during this time.

Following analysis, the 12-Lead Report is displayed, printed, and stored internally.

To acquire another 12-Lead ECG, press [**New 12-Lead**]. To exit the 12-lead function, press [**Exit 12-Lead**].

WARNING Failure to enter correct patient age, sex and pacing status can result in erroneous diagnosis.

NOTE The Lead Select  button is disabled when the 12-lead function is active.

12-Lead Report

The 12-Lead Report View is in a format similar to Monitor View, so that you may monitor the patient while viewing the report. In this view, the 12-Lead Report replaces Monitoring View's Wave Sectors 3 and 4, as shown in Figure 56, and includes the following information, if configured:

Measurements - The measurements component of the algorithm generates standard interval and duration measurements, in milliseconds, limb lead axis measurements, in degrees, and heart rate, in beats per minute.

Interpretive statements - Measurements and patient information (age, gender, paced status) are used by the Philips 12-Lead Algorithm to generate statements describing the patient's cardiac rhythm and waveform morphology. Statements regarding signal quality problems encountered during ECG acquisition are also included in this section.

ECG severity - Each interpretive statement on the report has an associated severity. The severities of all selected interpretive statements are assessed to determine an overall severity for the ECG. The categories of severity are "No Severity," "Normal ECG," "Otherwise Normal ECG," "Borderline ECG," "Abnormal ECG," and "Defective ECG."

Stored and printed 12-Lead Reports can be configured to include all 12 leads, measurements, and interpretive analysis statements.

One or two copies of the 12-Lead Report are printed at the completion of acquisition and/or analysis, as configured. Press the **[Print]** soft key to print another copy. In addition to the information on the displayed 12-Lead Report, the printed report includes up to three rhythm strips, with the configured leads.

WARNING

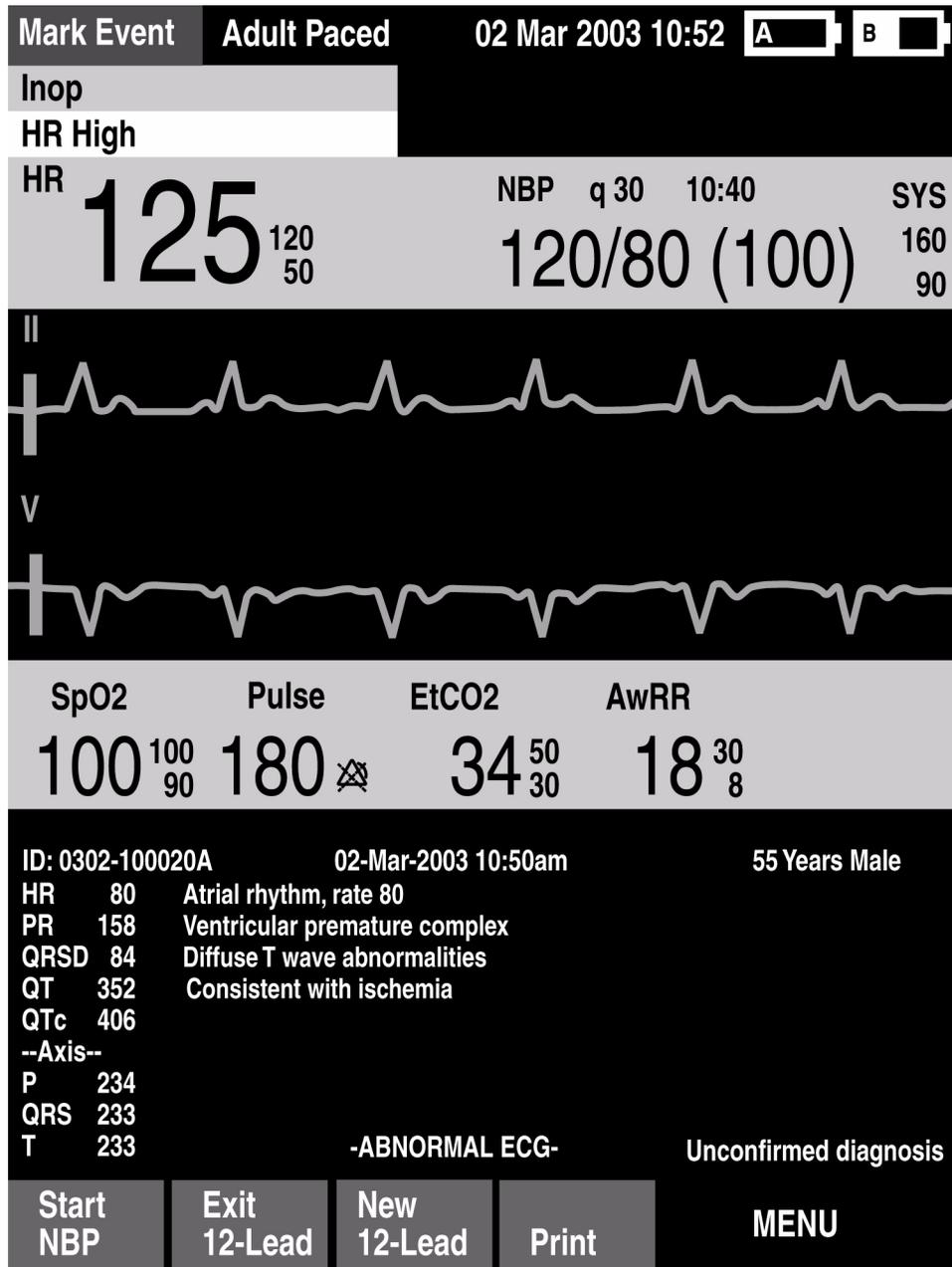
- Should an alarm condition occur while a 12-Lead Report is printing, an alarm strip is not printed, however, the corresponding ECG waveform is stored and available in the Event Summary.
 - Do not pull on the paper while a report is being printed. This can cause distortion of the waveform and lead to potential misdiagnosis.
-

Accessing Stored Reports

You may access stored reports to print additional copies or delete the report from internal storage. For Version A.02 and later devices, you may also copy the report to a data card. The list of stored reports for the current patient event may be accessed while a report is displayed or from either the 12-Lead Acquire Screen or the 12-Lead Preview Screen. To do this:

- 1 Press the Menu Select  button.
- 2 Use the Navigation buttons to select **Reports**.
Reports for the current patient event are listed by date, time and sequence number.
- 3 Use the Navigation buttons to select a report and press the Menu Select button.
- 4 Select **Print**, **Copy**, or **Delete** and press the Menu Select button.
- 5 To select another report repeat steps 1 through 3, or press **Exit** to close the menu.

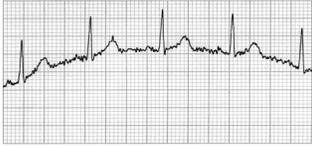
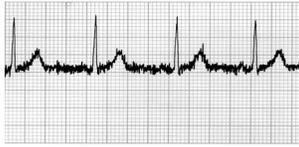
Figure 56 Displayed Report



Improving Signal Quality

Signal quality can impact ECG analysis. Refer to Table 9 for possible solutions to common ECG quality problems.

Table 9 ECG Signal Problems

Problem	Possible Causes	Possible Solutions
Tremor or muscle artifact 	<ul style="list-style-type: none"> Poor electrode placement. A cold patient. Tense, uncomfortable patient. Patient tremors. 	<ul style="list-style-type: none"> Clean the site and reapply electrodes. Be sure the electrodes are placed on flat, non-muscular areas of the body. Warm the patient. Reassure and relax the patient. Attach electrodes high on the extremities, near the trunk.
Baseline wander 	<ul style="list-style-type: none"> Patient movement Electrode movement. Poor electrode contact and skin preparation. Respiratory interference. 	<ul style="list-style-type: none"> Reassure and relax the patient. Be sure lead wires are not pulling on the electrodes. Move electrodes away from areas with the greatest respiratory motion, if possible.
Power line AC Interference 	<ul style="list-style-type: none"> Poor electrode contact. Dry or dirty electrodes. Interference from poorly grounded instrument near patient. 	<ul style="list-style-type: none"> Reapply electrodes. Route electrode wires along the limbs and away from other electrical equipment.
Intermittent or jittery waveform 	<ul style="list-style-type: none"> Poor electrode contact. Dry electrodes. Faulty lead wires 	<ul style="list-style-type: none"> Clean the site and reapply electrodes. Apply new electrodes. Repair or replace faulty leads.

Adjusting Wave Size

Adjusting ECG wave size may improve signal viewability. To do this:

- 1 Press the Menu Select  button.
- 2 Using the Navigation buttons, select **ECG Size** and press the Menu Select button.
- 3 Using the Navigation buttons, select the desired size value and press the Menu Select button.

The lead size is retained when you exit and then return to 12-lead functionality, without turning off power for more than 10 seconds.

NOTE Selecting ECG wave size of either **10mm/mV ½ V** or **20 mm/mV ½ V** displays V/C leads at half of the selection, 5 mm/mV and 10 mm/mV, respectively.

12-Lead Filters

For Version A.02 and later devices, ECG bandwidth filters of 0.15 - 40 Hz, 0.05 - 40 Hz, or 0.05 - 150 Hz may be selected in Configuration to apply to 12-lead ECG waveforms shown on the display. Additionally, the 12-Lead Report may be configured to apply either the same filter choice used for the display, or a 0.05 - 150 Hz filter. The filter setting for the 12-Lead Report is applied to both printed and stored 12-Lead Reports.

NOTE Although, the 0.05 -150 Hz, or "Diagnostic" bandwidth filter may be selected for the display filter, LCD display limitations prevent the ECG from appearing in true diagnostic quality.

A filter soft key is available to switch between filter settings during use. When changing the filter during use, the filter setting is applied to both the display and the 12-Lead Report. The display and 12-Lead Report filter settings are returned to their configured settings whenever the [**New 12-Lead**] soft key is pressed or when the Therapy Knob is moved from the **Monitor** position.

Troubleshooting

If your HeartStart MRx does not operate as expected during 12-Lead ECG operation, see Chapter 15, "Troubleshooting" on page 193.

12-Lead ECG Transmission

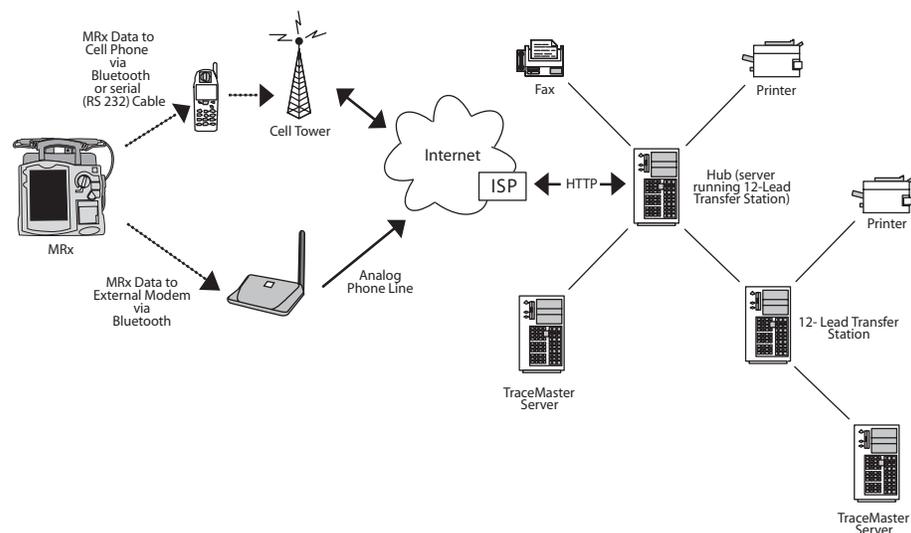
This chapter provides instructions for the transmission of 12-Lead Reports from the HeartStart MRx using wireless Bluetooth technology or its RS 232 Serial Port.

NOTE The HeartStart MRx contains an Ezurio PC Card with Bluetooth® wireless technology. The Bluetooth wordmark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by Ezurio is under license. Other trademarks and trade names are those of their respective owners.

Overview

12-Lead reports may be transmitted to a printer, a fax machine, another server running Philips 12-Lead Transfer Station software, or Philips TraceMaster ECG Management System. Reports are sent from the MRx to the hub (a web server running Philips 12-Lead Transfer Station software). Using Bluetooth transmission, they are transmitted to the hub using configured wireless devices such as cell phones and handheld devices. Using RS 232 Transmission, they are transmitted via a cell phone with internet capability connected to the MRx's RS 232 Serial Port. The 12-Lead Transfer Station then forwards the report to the selected destination site. Additionally, reports can be sent to a wireless modem connected to an analog line for areas where cell transmission is unavailable. See Figure 57 for an overview of the transmission process.

Figure 57 12-Lead Report Transmission Process



Waveforms for monitored parameters such as ECG, SpO₂ and CO₂ can be viewed during the 12-Lead Report transmission process, however, the waveform appearing in Wave Sector 4 is partially obscured when the transmission status bar is displayed. Related alarms, measurements and inop messages remain active and are reported in Parameter Blocks 1 and 2 and the general status area.

CAUTION Data transmission via cell phone can sometimes be unreliable. A strong signal and stationary transmission will improve the transmittal success rate. Follow the directions provided with your cell phone.

CAUTION Many institutions prohibit the use of cell phones on their premises. Please abide by local rules and regulations.

NOTE Patient Name and ID must be entered prior to 12-Lead acquisition in order for it to appear on the 12-Lead Report.

NOTE The .05 - 40 Hz 12-Lead filter setting is not supported by the TraceMaster ECG Management System.

Setting Up for Bluetooth Transmission

12-Lead ECG Transmission using Bluetooth requires the configuration and set up of wireless devices that will send the 12-Lead Report to the hub.

NOTE For further information concerning the setup and configuration of transmission devices and the HeartStart MRx, refer to the *12-Lead Transmission Implementation Guide*. For further information concerning the 12-Lead Transfer Station, refer to the *12-Lead Transfer Station Instructions for Use*.

Adding a Bluetooth Device

Up to 20 Bluetooth devices may be configured for use. Adding a twenty-first device replaces the device used least recently.

NOTE Bluetooth devices may not be added or modified during 12-Lead transmission. Conversely, 12-Lead transmission is not allowed during Bluetooth device configuration.

To add a Bluetooth device to the list of Transmission Devices:

- 1 Press the Menu Select  button.
- 2 From the 12-Lead Main Menu, select **Bluetooth Devices** and press the Menu Select button. A list of discovered Bluetooth devices is displayed.
- 3 Select **Add Device** and press the Menu Select button. The message **Searching for Bluetooth Devices** is displayed.
- 4 From the Add Device menu, select the desired device and press the Menu Select button.

The selected device must now go through the “Pairing” process described below.

NOTE All Bluetooth devices within the specified range are discovered by the HeartStart MRx and are displayed on the Add Device menu, even if you have already paired with the device.

Pairing a Bluetooth Device with the HeartStart MRx

Once a Bluetooth device is selected from the Add Devices menu, a passkey sequence must be performed in order to communicate or “pair” the wireless device with the HeartStart MRx. The passkey is user-defined character sequence, such as 000, or 1234, etc.

Some Bluetooth devices only allow pairing for 30 seconds, so be ready to enter the passkey.

- 1 Use the Navigation buttons to enter the passkey on the MRx and select **Done**.
The Bluetooth device prompts you for a passkey.
- 2 Enter the same passkey on your Bluetooth device. See the documentation that came with your Bluetooth device for instructions.
- 3 Select the designated profile from the Phone/Modem Profiles menu.

NOTE The profile contains specific information about the Bluetooth device that enables it to communicate with the 12-Lead Transfer Station. Your administrator sets up the profiles and can tell you which one to choose.

Once the Bluetooth device is paired with the MRx and the profile selected, the MRx performs a transmission test. After successfully connecting to the device and network, the message **Transmission Test Passed** is displayed. Press the Menu Select button to acknowledge the message. Should the transmission test fail, the message **Transmission Test Failed** is displayed, along with additional information about where the failure occurred. See Table 45 in "Troubleshooting".

NOTE There may be exceptions to the pairing process, particularly for devices that do not have a user interface. Please refer to the documentation for your Bluetooth device. Additionally, pairing may sometimes be referred to by other names, such as "bonding".

NOTE Pairing information is not retained when importing a configuration file from the data card. The devices must be paired again using the process above.

Changing Bluetooth Profiles

Once you have added and paired a Bluetooth device, you can change its profile using the following steps:

- 1 Press the Menu Select  button.
- 2 From the 12-Lead Main Menu, select **Bluetooth Devices** and press the Menu Select button. A list of paired Bluetooth devices is displayed.
- 3 Use the Navigation buttons to select a device and press the Menu Select button.
- 4 To change a profile, select Change Profile and press the Menu Select button. A menu of configured profiles for that device is displayed, with the currently associated profile highlighted.
- 5 Select the profile you want to associate with the device.

The MRx tests the profile to determine if the Bluetooth device can communicate with the 12-Lead Transfer Station. Progress messages are displayed during the test. If the test is successful, the message **Transmission Test Passed** is displayed. Press the Menu Select button to acknowledge the message. Should the transmission test fail, the message **Transmission Test Failed** is displayed, along with additional information about where the failure occurred. See Table 45 in "Troubleshooting".

Additional Bluetooth Device Information

Keep the following points in mind when working with Bluetooth devices:

- Many Bluetooth devices are not discoverable by default. Check your device's documentation to see if you need to enable discovery.
- As a general security practice, you should not leave your Bluetooth device in discoverable mode.
- Some devices require that you turn on the Bluetooth functionality.
- Some devices may prompt you to authenticate each time. Check your device's documentation to see if you can configure it to always communicate with the MRx.
- Give your Bluetooth device an easily recognizable name as this is the name that appears on the MRx menus. The name should be no more than 15 characters in order for it to display properly on the MRx.
- Bluetooth modems and fax machines use analog lines to transmit data. If you are transmitting using a Bluetooth modem, plug it into the analog line used by the fax machine.

Transmitting to a Configured Site using Bluetooth

Upon acquisition of the 12-Lead ECG, the 12-Lead Report View is displayed.

To transmit the displayed 12-Lead Report to a previously configured destination:

- 1 Press the Menu Select  button.
- 2 Using the Navigation   buttons if necessary, select **Send** from the 12-Lead Main Menu and press the Menu Select button.
- 3 Use the Navigation buttons to select the destination site from the configured list. See Figure 60.
- 4 Press the Menu Select button to complete the selection.
- 5 Select the transmission device from the configured list.
- 6 Press the Menu Select button to complete the selection.

NOTE If the profile associated with the Bluetooth device is configured as a landline, use the numeric menu to edit the configured dial prefix if necessary. To confirm the prefix, select Done from the menu and press the Menu Select button.

Setting Up for RS 232 Transmission

12-Lead ECG Transmission using RS 232 requires a serial cable connected to the RS 232 Serial Port located on the back panel of the HeartStart MRx. See Figure 58. The cell phone is connected to the serial cable as shown in Figure 59.

NOTE For further information concerning the setup and configuration of transmission devices and the HeartStart MRx, refer to the *12-Lead Transmission Implementation Guide*. For further information concerning the 12-Lead Transfer Station, refer to the *12-Lead Transfer Station Instructions for Use*.

Figure 58 RS 232 Serial Port Connection

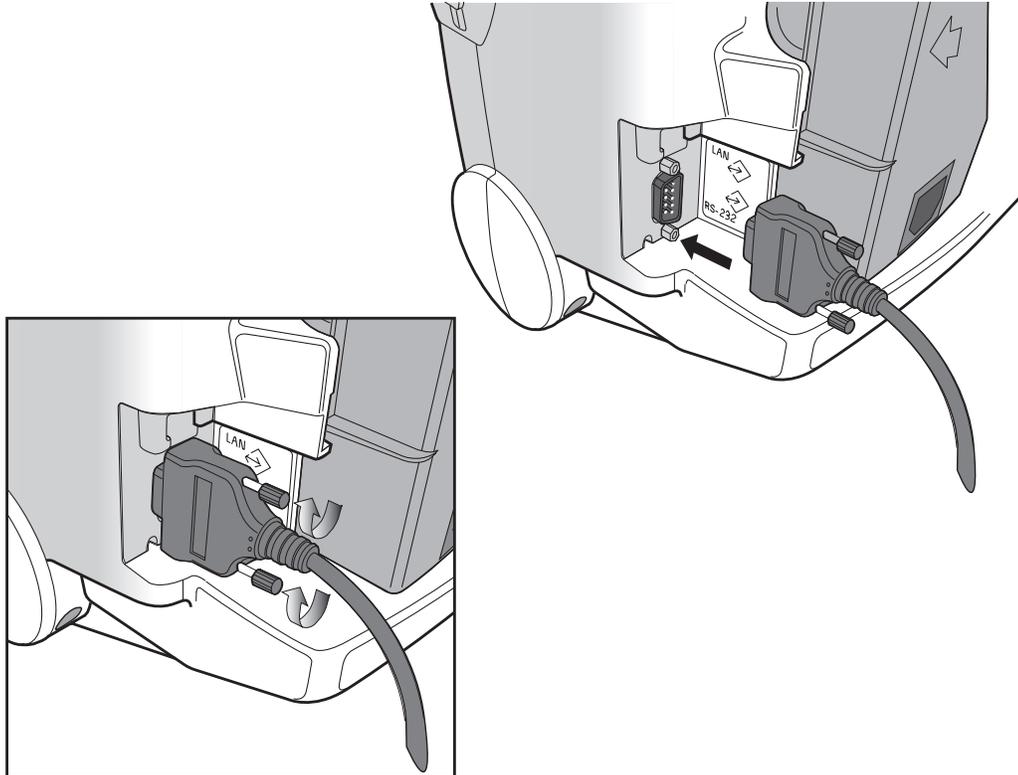
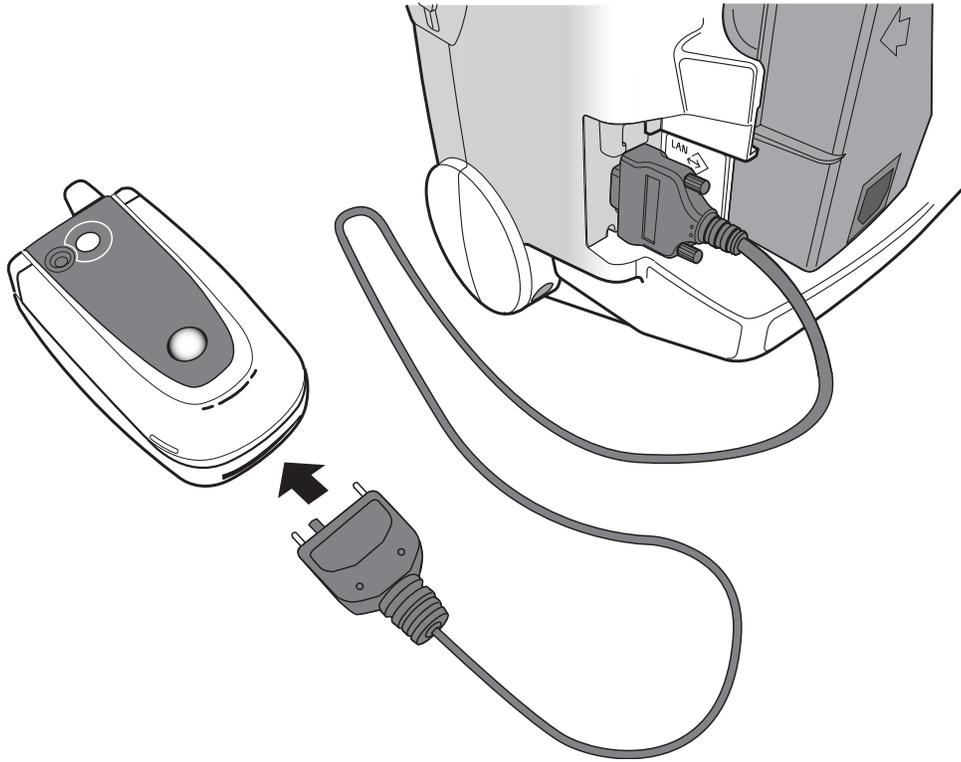


Figure 59 RS 232 Serial Cable Connection



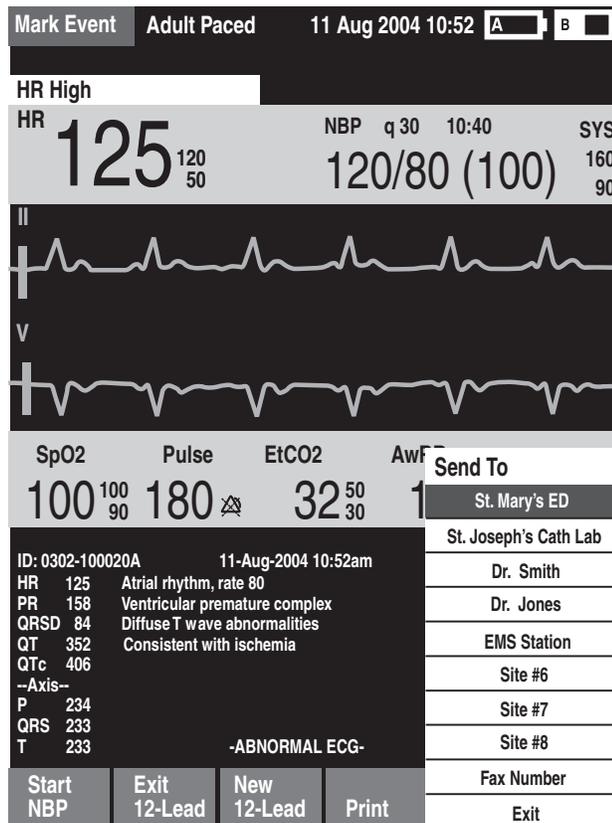
Transmitting to a Configured Site Using RS 232

Upon acquisition of the 12-Lead ECG, the 12-Lead Report View is displayed.

To transmit the displayed 12-Lead Report to a previously configured destination:

- 1 Press the Menu Select  button.
- 2 Using the Navigation   buttons if necessary, select **Send** from the 12-Lead Main Menu and press the Menu Select button.
- 3 Use the Navigation buttons to select the destination site from the configured list. See Figure 60.
- 4 Press the Menu Select button to complete the selection.

Figure 60 12-Lead Send To Menu



Transmitting to a Manually Entered Fax Number

Upon acquisition of the 12-Lead ECG, the 12-Lead Report View is displayed.

To manually enter a fax number destination:

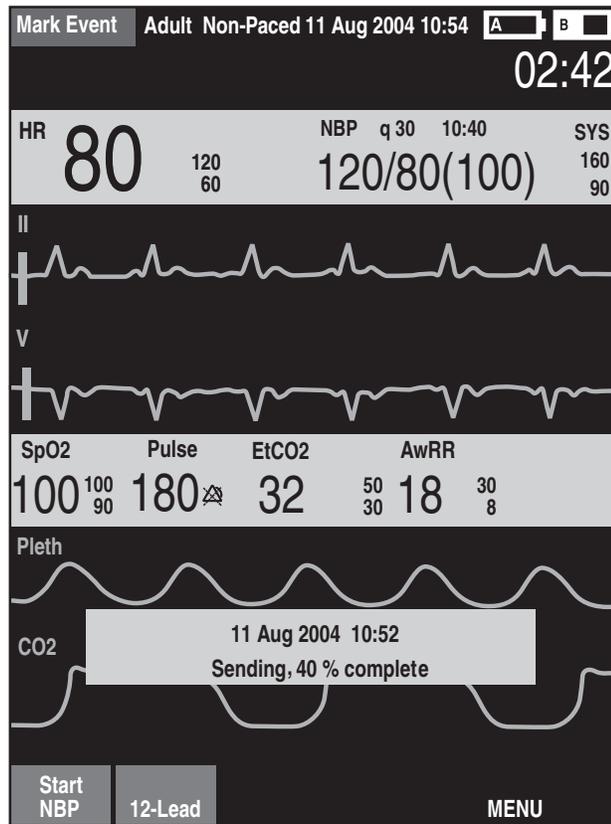
- 1 Press the Menu Select  button.
- 2 Using the Navigation   buttons if necessary, select **Send** from the 12-Lead Main Menu and press the Menu Select button.
- 3 Use the Navigation buttons to select **Fax Number** from the Send To Menu.
- 4 Enter the fax number from the numeric list using the Navigation buttons. Include any extra digits necessary, such as 9 for an outside line or 1 plus the area code for long distance.
- 5 Select **Done** and press the Menu Select button.

NOTE If you are transmitting to a manually entered fax number using a Bluetooth device, the device and landline prefix, if applicable, must be entered.

Transmission Status

During 12-Lead Report transmittal, a status bar is displayed to show the progress of the connection and report transmission. Once the connection is made, the status bar contains the date and time stamp of the 12-Lead Report being sent. See Figure 61.

Figure 61 12-Lead Transmission Status Bar



The status bar continues to display in any clinical mode of operation.

NOTE 12-Lead Reports successfully transmitted to the hub are logged to the Event Summary and appear using the format, "12-Lead (12:25:33) Transmitted to *site name*".

Transmitting Stored 12-Lead Reports

12-Lead Reports for the current patient that are stored in internal memory may also be transmitted. To transmit a stored 12-Lead Report:

- 1 From the 12-Lead Preview or Report View, press the Menu Select  button.
- 2 Use the Navigation   buttons to select **Reports** from the 12-Lead Main Menu.
- 3 Use the Navigation buttons to scroll through the list of stored reports and highlight the desired report. Reports are identified by date/time stamp and sequence number.
- 4 Press the Menu Select button to complete your selection.
- 5 Select **Send** from the 12-Lead Report Menu and press the Menu Select button.
- 6 Use the Navigation buttons to select the destination site or to manually enter a fax number.
- 7 Press the Menu Select button to complete the selection. For manual fax number entry, enter the fax number from the numeric list, select **Done** and press the Menu Select button.

Subsequent 12-Lead Reports can be placed in queue for transmittal while transmission is in progress, or the originally selected 12-Lead Report can be chosen for transmission to multiple sites.

NOTE If stored 12-Lead Reports are transmitted using a Bluetooth device, the Bluetooth device must be selected.

Cancelling Transmission

To cancel a transmission once a connection has been initiated, perform the following steps:

- 1 From the 12-Lead Preview or Report View, press the Menu Select  button.
- 2 Select **Cancel Transmission** from the 12-Lead Main Menu and press the Menu Select button.
- 3 Confirm the cancellation by pressing the Menu Select button.

The transmission of any pending 12-Lead Reports is also canceled.

Troubleshooting

If your HeartStart MRx does not operate as expected during 12-lead transmission, see "Troubleshooting" on page 193

Configuration

This chapter describes the configurable parameters of the HeartStart MRx and the procedures for modifying configuration.

Overview

Configuration settings allow you to customize the HeartStart MRx to best meet your needs. Configuration is performed through the Configuration menu of the device and may be saved to a data card for replication on multiple devices. At any time, configuration settings may be viewed and exported to a data card, and the date and time may be changed. However, a password is required to change the configuration of the device.

Accessing the Configuration Menu

To access the Configuration Main menu:

- 1 Turn the Therapy Knob to **Monitor**.
- 2 Press the Menu Select  button.
- 3 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 4 Using the Navigation buttons, select **Configuration** and press the Menu Select button.

To return to normal operating mode, press the [**Exit Config**] soft key.

The Configuration Main menu is displayed, listing sub-menus for each category of configurable parameters. You may use this menu to view or print your device's configuration, as well as to modify the date and time settings. To modify any other settings, you must enter the configuration password printed on the front of the *HeartStart MRx User Documentation* CD-ROM.

WARNING The HeartStart MRx should never be connected to a patient while performing configuration activities.

Setting the Date and Time

To modify the date and time setting from the Configuration menu:

- 1 Press the Menu Select  button.
- 1 Use the Navigation buttons to select **Date and Time**. Then press the Menu Select button.
- 2 Use the Navigation buttons to adjust the value for the year. Then press the Menu Select button.
- 3 Select the appropriate month. Then press the Menu Select button.
- 4 Adjust the value for the day. Then press the Menu Select button.
- 5 Adjust the value for the hour. Then press the Menu Select button.
If the device is configured to use a 12-hour clock format, **am** or **pm** is displayed next to the hour.
For a 24-hour format only the hour is shown, with choices from 0 to 23.
- 6 Press the **[Exit Config]** soft key if finished with configuration.

Date and time should be changed to correspond with local clock changes for Daylight Savings Time and Summer Time.

Modifying Settings

When modifying configuration settings, the device should be connected to external power and have a battery with at least 20% capacity installed. To modify configuration settings, from the Configuration Main menu:

- 1 Press the **[Change Config]** soft key.
- 2 When prompted, enter the configuration password.
- 3 Press the Menu Select  button. Use the Navigation buttons to select the sub-menu for the category of parameters to be changed. Then press the Menu Select button.
- 4 Use the **[Prev Item]** and **[Next Item]** soft keys to select a parameter.
- 5 Use the Navigation buttons to highlight the desired choices. Press the Menu Select button to select the highlighted choice.
- 6 Repeat steps 3, 4 and 5 to select another sub-menu and modify additional settings.
- 7 Once the desired setting changes have been made, from the Configuration Main screen, press the **[Save Changes]** soft key.
You may press the **[Cancel Changes]** soft key to return to the previous settings.
- 8 Press the **[Exit Config]** soft key to return to normal operating mode.
If you press **[Exit Config]** before saving the changes, you are prompted with the message **Configuration Not Saved - Exit Anyway?** Select **No** and press the Menu Select button. Then press the **[Save Changes]** soft key.

Saving Configuration Settings to a Data Card

To save configuration settings to a data card:

- 1 Make sure a data card is in the HeartStart MRx.
- 2 Press the [**Export**] soft key.

The HeartStart MRx copies the configuration settings to the data card.

Loading Configuration Settings from a Data Card

To load configuration settings from a data card:

- 1 Insert the data card with the saved configuration in the HeartStart MRx.
- 2 Press the Change Config soft key and enter the configuration password.
- 3 Press the Import soft key.
- 4 Make any device specific configuration changes, such as 12-Lead location code.
- 5 Press the Save Changes soft key.

Restoring the Default Settings

To return to using the configuration settings initially entered during manufacture:

- 1 Press the [**Change Config**] soft key.
- 2 Enter the Configuration password.
- 3 Press the [**Factory Defaults**] soft key.
- 4 Press the [**Save Changes**] soft key.

Printing Configuration Settings

To print the configuration settings, select **Print Configuration** from the Configuration Main menu and press the Menu Select button. The configuration report is printed on the printer.

NOTE Upon exiting Configuration and returning to a clinical mode (Monitor, Pacer, Manual Defib or AED), all settings will be reset to the device's configured values.

Configurable Parameters

The following tables list configurable parameters for each of the sub-menus on the Configuration Main menu. A description of each parameter is provided, along with the possible choices for settings. Default settings are in **bold** type.

Table 10 General Settings

Parameter	Description	Setting Choices
IP Address	For future use.	
Voice Volume	Voice prompt volume level.	Very Soft, Soft, Medium , Loud, Very Loud
Alarm Volume	Audible alarm volume level.	Very Soft, Soft, Medium , Loud, Very Loud
Minimum Alarm Volume	Minimum audible alarm level available during use.	Very Soft, Soft , Medium, Loud, Very Loud
QRS Volume	Volume of audible beep with each QRS complex detected.	Off, Very Soft, Soft, Medium , Loud, Very Loud
Time Format	Selects time format to display.	12-hour, 24-hour
Pacing on Batteries Warning	Displays the warning message Pacing on Batteries if pacing using only battery power.	Yes, No
Unit Display	Defines if parameter values are displayed with or without corresponding measurement units.	On , Off
Patient Category	Selects the default patient category.	Adult , Pedi
Device Owner (Version A.02 and later devices)	Identification for Return to Owner feature.	20 characters, Owner
Return to Owner Password (Version A.02 and later devices)	Password required in order to deactivate the loan period setting.	4 characters

NOTE The Return to Owner Password should be documented in a secure manner. Should it need to be reset, all configuration settings must be reset to factory default values, and the device must then be re-configured.

Table 11 Heart Rate and ECG Settings

Parameter	Description	Setting Choices
Auto Gain	Determines whether ECG size is automatically adjusted to the standard maximum wave size without clipping the wave sector. If auto-gain is off, the gain is set to 1 (10mm/mV).	On, Off
AC Line Filter	Selects the setting used to filter out AC line noise	60 Hz, 50 Hz
ECG Bandwidth for Display	Selects the display filter frequency for the attached therapy cable or 3-/5-lead ECG cable. (This setting does not affect 12-Lead View.)	.15-40 Hz Monitor, 1-30 Hz EMS
ECG Bandwidth for Printer	Selects the printer filter frequency for the attached therapy cable or 3-/5-lead ECG cable. (This setting does not affect 12-Lead Reports.) If Diagnostic is selected, pads ECG is set to Monitor.	0.05-150 Hz Diagnostic, .15-40Hz Monitor, 1-30Hz EMS
ECG Electrode Labels	Selects electrode and V/C lead label format. AAMI: RA, LA, LL, RL, V. IEC: R, L, F, N, C.	AAMI, IEC
HR/Pulse High Limit	Selects the default High Alarm Limit for the HR derived from the ECG and the pulse derived from SpO ₂ .	Adult: 35-200, 120 , (bpm) Pediatric: 35-240, 160 adjusted in increments of 5
HR/Pulse Low Limit	Selects default Low Alarm Limit for the HR derived from the ECG and the pulse derived from SpO ₂ .	Adult: 30-High Alarm Limit, 50 (bpm) Pediatric: 30- High Alarm Limit, 80 adjusted in increments of 5
VTach	Detection of ventricular tachycardia based on heart rate limit and PVC run limit.	Heart Rate Limit: Adult: 95-150, 100 (bpm) Pediatric: 95-150, 120 adjusted in increments of 5 PVC run limit Adult: 3-20, 5 Pediatric: 3-20, 5 adjusted in increments of 1

Table 12 Noninvasive Blood Pressure Settings

Parameter	Description	Setting Choices
NBP Schedule	Selects the schedule for NBP measurements, manual, or automatic at the selected frequency.	Manual , q1, q2.5, q5, q10, q15, q30, q60, q120
NBP Alarm Source	Selects the alarm source.	Systolic , Diastolic, Mean
Unit	Selects the measurement units.	mmHg , kPa
Systolic High Limit	Selects the high limit alarm value used when systolic is the selected alarm source.	Adult: 35-270, 160 (mmHg) Pediatric: 35-180, 120 adjusted in increments of 5 mmHg or 1 kPa
Systolic Low Limit	Selects the low limit alarm value when systolic is the selected alarm source.	Adult: 30-265, 90 (mmHg) Pediatric: 30-175, 70 adjusted in increments of 5 mmHg or 1 kPa
Diastolic High Limit	Selects the high limit alarm value when diastolic is the selected alarm source.	Adult: 15-245, 90 (mmHg) Pediatric: 15-150, 70 adjusted in increments of 5 mmHg or 1 kPa
Diastolic Low Limit	Selects the low limit alarm value when diastolic is the selected alarm source.	Adult: 10-240, 50 (mmHg) Pediatric: 10-145, 40 adjusted in increments of 5 mmHg or 1 kPa
Mean High Limit	Selects the high limit alarm value when mean is the selected alarm source.	Adult: 25-255, 110 (mmHg) Pediatric: 25-160, 90 adjusted in increments of 5 mmHg or 1 kPa
Mean Low Limit	Selects the low limit alarm value when mean is the selected alarm source.	Adult: 20-250, 60 (mmHg) Pediatric: 20-155, 50 adjusted in increments of 5 mmHg or 1 kPa

Table 13 End-Tidal Carbon Dioxide Settings

Parameter	Description	Setting Choices
Unit	Selects the unit of measure	mmHg, kPa
EtCO ₂ High Limit	Selects the high limit alarm value.	Adult: 20-95, 50 (mmHg) Pediatric: 20-95, 50 adjusted in increments of 1mmHg or .1 kPa
EtCO ₂ Low Limit	Selects the low limit alarm value.	Adult: 10-94, 30 (mmHg) Pediatric: 10-94, 30 adjusted in increments of 1mmHg or .1 kPa
AwRR High Limit	Selects the high limit alarm value.	Adult: 10-100, 30 (rpm) Pediatric: 10-100, 60 adjusted in increments of 1
AwRR Low Limit	Selects the low limit alarm value.	Adult: 0-99, 8 (rpm) Pediatric: 0-99, 12 adjusted in increments of 1
Apnea Time	Length of time without respiration required to trigger an apnea alarm.	Adult: 10-40, 20 (seconds) Pediatric: 10-40, 20 adjusted in increments of 5

Table 14 SpO₂ Settings

Parameter	Description	Setting Choices
SpO ₂ High Limit	Selects high limit alarm value.	Adult: 51-100, 100 (%) Pediatric: 51-100, 100 adjusted in increments of 1
SpO ₂ Low Limit	Selects low limit alarm value.	Adult: 50-99, 90 (%) Pediatric: 50-99, 90 adjusted in increments of 1
SpO ₂ Desat Limit	Selects extreme low limit alarm value.	Adult: 50-low limit, 80 (%) Pediatric: 30-low limit, 80 adjusted in increments of 1

Table 15 Wave Sector Settings

Parameter	Description	Setting Choices
Wave 1	Selects the waveform displayed in Wave Sector 1.	Pads, I, II, III, aVR, aVL, aVF, V/C
Wave 2	Selects the waveform displayed in Wave Sector 2.	Pads, I, II, III, aVR, aVL, aVF, V/C, CO ₂ , Pleth, Cascade , Annotated ECG, None
Wave 3	Selects the waveform displayed in Wave Sector 3.	Pads, I, II, III, aVR, aVL, aVF, V/C, CO ₂ , Pleth, None
Wave 4	Selects the waveform displayed in Wave Sector 4.	Pads, I, II, III, aVR, aVL, aVF, V/C, CO ₂ , Pleth , Cascade, None

Table 16 Parameter Color Settings

Parameter	Description	Setting Choices
ECG	Selects the color of ECG waveforms and HR value.	Red, Yellow, Blue, Green , Cyan, Magenta, White
SpO ₂	Selects the color of the pleth waveform and SpO ₂ and Pulse values.	Red, Yellow, Blue, Green, Cyan , Magenta, White
CO ₂	Selects the color of the CO ₂ waveform and EtCO ₂ and AwRR values.	Red, Yellow , Blue, Green, Cyan, Magenta, White
NBP	Selects the color of the NBP values.	Red, Yellow, Blue, Green, Cyan, Magenta, White
Comp	Selects the color of the compression waveform and values for compression rate and no flow time.	Red, Yellow, Blue, Green, Cyan , Magenta, White

NOTE The High Contrast feature does not display the colors red or blue, therefore, be sure your device is configured correctly with the appropriate parameter color settings.

Table 17 Alarm Settings

Parameter	Description	Setting Choices
Alarm Tone	Selects either traditional Philips or IEC Standard alarm tones.	Philips , IEC
Alarm Pause Time	Selects the interval of time during which alarms are paused, after the Alarm Pause button is pressed.	3, 5, 10, indefinite (minutes)

Table 18 12-Lead Settings

Parameter	Description	Setting Choices
Institution Name	Enters your organization's name for printing on the 12-Lead ECG Report.	32 characters, blank
Location Code	Enters an institution number and a department number for printing on the 12-Lead Report.	3 digits, blank (institution number) 2 digits, blank (department number)
Device ID	Enters a device identification number.	4 digits, blank
Analysis	Defines the analysis information included on the 12-Lead Report. None prints waveforms, Event/patient ID, date and time. Measurements Only adds HR, interval and axis measurements. Standard adds severity, interpretive statements and reasons.	None, Measurements Only, Standard
ECG Bandwidth for 12-Lead Display (Version A.02 and later devices)	Defines the default ECG bandwidth for the 12-Lead preview display.	.15-40 Hz, .05-40 Hz , .05-150 Hz
ECG Bandwidth for 12-Lead Report (Version A.02 and later devices)	Defines the default ECG bandwidth for printed and stored 12-Lead Reports.	Same as Display , .05-150 Hz
Number of Automatic Printouts	Selects the number of 12-Lead ECG Reports printed at the completion of analysis.	0, 1, 2
Printer Format	Selects the number of rhythm strips to be printed with the 12-Lead Report, 0, 1, or 3.	3x4, 3x4 1R , 3x4 3R
Rhythm Strip #1	Selects the first rhythm strip printed in the 3x4 1R or 3x4 3R format.	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Rhythm Strip #2	Selects the second rhythm strip printed for reports in the 3x4 3R format.	I, II, III, aVR, aVL, aVF , V1, V2, V3, V4, V5, V6
Rhythm Strip #3	Selects the third rhythm strip printed for reports in the 3x4 3R format.	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 , V6

NOTE If the same configuration file is used to configure multiple devices, be sure to assign a unique number to each device.

NOTE The 3x4 3R Printer Format Setting is not for use with the 12-Lead Transmission option.

Table 19 12-Lead Transmission Settings (Bluetooth and Modem Profile)

Parameter	Description	Setting Choices
Profile Name	Name of the profile.	20 characters, blank
Configuration String	Available from your cell phone service provider.	45 characters, blank
Landline	Set to Yes if you are using a modem.	Yes, No
Dial Prefix	Only configurable if Landline is set to Yes. The dial prefix is the number or numbers you dial before the phone number. For example, you may need to dial a 9 for an outside line or an area code in addition to the number.	10 characters, blank
Dial String	Available from your cell phone service provider.	40 characters, blank
Wait for Dial Tone	Available from your cell phone service provider.	Yes, No
PPP User Name	Typically not needed but may be required by some cell phone service providers.	30 characters, blank
User Name / Password Config	Available from your cell phone service provider. Per profile - allows you to associate a user name and password with this profile. Per device - allows you to associate a different user name and password for every device that uses this profile.	Per Profile , Per device
PPP Password	Typically not needed but may be required by some cell phone service providers.	40 characters, blank
Static IP Address	Typically not needed but may be required by some cell phone service providers.	15 characters (nnn.nnn.nnn.nnn), blank
Primary DNS	Typically not needed but may be required by some cell phone service providers.	nnn.nnn.nnn.nnn, blank
Secondary DNS	Typically not needed but may be required by some cell phone service providers.	nnn.nnn.nnn.nnn, blank
http Proxy Address	Typically not needed but may be required by some cell phone service providers.	15 characters, blank
http Proxy Port	Typically not needed but may be required by some cell phone service providers.	15 characters, blank

Table 20 12-Lead Transmission Settings (Serial Phone Profile)

Parameter	Description	Setting Choices
Profile Name	Name of the profile. For RS232 connections, this name is fixed at "Serial Phone Profile".	12-20 characters (must fit in the menu), blank
Configuration String	Available from your cell phone service provider.	45 characters, blank
Dial String	Available from your cell phone service provider.	40 characters, blank
Wait for Dial Tone	Available from your cell phone service provider.	Yes, No
PPP User Name	Typically not needed but may be required by some cell phone service providers.	30 characters, blank
PPP Password	Typically not needed but may be required by some cell phone service providers.	40 characters, blank
Static IP Address	Typically not needed but may be required by some cell phone service providers.	15 characters (nnn.nnn.nnn.nnn), blank
Primary DNS	Typically not needed but may be required by some cell phone service providers.	nnn.nnn.nnn.nnn, blank
Secondary DNS	Typically not needed but may be required by some cell phone service providers.	nnn.nnn.nnn.nnn, blank
http Proxy Address	Typically not needed but may be required by some cell phone service providers.	15 characters, blank
http Proxy Port	Typically not needed but may be required by some cell phone service providers.	15 characters, blank
Baud Rate	Available from your cell phone documentation. If your phone transmits "high speed" data, set to 115200.	9600, 19200, 38400, 57600, 115200
Flow Control	Available from your cell phone documentation.	None, Hardware

Table 21 12-Lead Transmission Settings (Hub)

Parameter	Description	Setting Choices
Server URL	Hub server address. Available from your ISP.	40 characters, blank
User Name	http user name. Use your web server documentation to create user accounts on the hub.	30 characters, blank
Password	http password. Use your web server documentation to create user accounts on the hub.	40 characters, blank

Table 22 12-Lead Transmission Settings (Site)

Parameter	Description	Setting Choices
Site Name	This label appears in the Send To menu when initiating a 12-Lead Report transmission. The label should be an easy to recognize name.	12-20 characters, blank
Site Type	Indicates the type of device receiving the 12-Lead Report.	Fax, Printer, 12LTS, TraceMaster, Hub
Phone number	Phone number for fax site type, otherwise N/A. Note: It is important that the you know the dialing rules for the 12-Lead Transfer Station. For example, does the 12-Lead Transfer Station need to dial a 1 or an area code in addition to the number? If it does, the number sent by the MRx must include these digits.	20 characters
URL	URL for PC site type (i.e., TraceMaster or another 12-Lead Transfer Station), otherwise N/A	40 characters, blank
Use Hub's Routing	Reserved for future use.	
Default Site	If yes, this will be the highlighted site when the Send to menu is displayed. When set to yes, this field will automatically be set to no for all other sites.	Yes, No

Table 23 Manual Therapy Settings

Parameter	Description	Setting Choices
Remain In Sync Mode After Shock	Defines whether the device remains in Sync Mode after a synchronized shock is delivered.	Yes, No
Time To Auto Disarm	Determines the amount of time the device will remain charged if a shock has not been delivered. Applies to both Manual Defib and AED Modes.	30, 60, 90 (seconds)
Pacing Rate	Upon entering the selected Pacer Mode (Demand or Fixed), defines the default rate of delivery of paced pulses.	30-180, 70 (ppm) adjusted in increments of 10
Pacing Output	Upon entering the selected Pacer Mode (Demand or Fixed), defines the default current setting at which paced pulses are delivered.	10-175, 30 (mA) adjusted in increments of 5
Manual Therapy Security (Version A.02 and later devices)	Defines whether Manual Defib and Pacer Modes are password protected. A password entry screen is displayed when the setting is changed to On . Using the Menu, enter a 4-character password. Selecting Cancel during password entry resets the setting to Off . Once the password is set, changing the setting to Off clears the password from the device memory.	Off , On (See Warning below.)

WARNING Use of the Manual Therapy Security password requires the clinician to know and remember the password, as defined in Configuration. Failure to enter the correct password will prevent the delivery of manual defibrillation or pacing therapy. Prior to selecting this Configuration option, review this potential risk with your Risk Manager.

Table 24 AED Settings

Parameter	Description	Setting Choices
Shock Series	<p>Sets the number of shocks that must be delivered to activate an automatic CPR Pause. The length of the CPR pause is determined by the CPR Timer Setting. A new Shock Series begins when a shock is delivered:</p> <ul style="list-style-type: none"> • after the device is turned on, • after the automatic CPR pause, • after the [Pause for CPR] soft key has been pressed, or • if the time since the previous shock exceeds the Protocol Timeout setting. 	1, 2, 3, 4
Protocol Timeout	Sets the time interval used to determine if a delivered shock should be counted as part of the shock series (see Shock Series above.)	30, 60 , 90, 120, 150, 180, 210, Off (seconds)
CPR Timer	<p>Sets the length of the pause interval that automatically starts when:</p> <ul style="list-style-type: none"> • a Shock Series is completed, • The [Pause for CPR] soft key is pressed, • A No Shock Advised (NSA) decision is made, the NSA CPR pause is enabled, and the conditions for using the CPR Timer setting for the NSA CPR pause interval are met (see below), • The Shock button is not pressed for the configured “Time to Auto Disarm” setting after the device is armed in AED mode, or • Continuous artifact is detected during rhythm analysis. 	30, 60 , 90, 120, 150, 180 (seconds)
No Shock Advised (NSA) Action	<p>Defines how the device behaves following a No Shock Advised (NSA) decision:</p> <ul style="list-style-type: none"> • Monitor - directs the device to monitor the patient’s ECG following an NSA decision and prompts the user to periodically perform CPR. The CPR prompt interval is defined by the Monitor Prompt interval. • Time Setting - directs the device to provide a CPR Pause interval following a NSA decision. If a shock has been delivered in the current Shock Series, the length of the CPR Pause interval is defined by the CPR Timer setting. Otherwise, the length of the CPR Pause interval is defined by the NSA Action time setting. 	Monitor , 30, 60, 90, 120, 150, 180 (seconds)
CPR Prompt	<p>Defines the level of detail provided in the CPR reminder voice prompts provided at the completion of a Shock Series.</p> <ul style="list-style-type: none"> • Long - provides detailed instruction to check airway, breathing and pulse/circulation before beginning CPR. • Short - provides instruction to begin CPR, if needed, only. 	Long , Short
Monitor Prompt Interval	Sets the interval for patient care prompts provided during AED monitoring of the patient’s ECG following an NSA decision. Off means there are no prompts during AED monitoring.	30, 60 , 90, 120, 150, 180, Off (seconds)

Table 25 Print Settings

Parameter	Description	Setting Choices
Print on Alarm	Prints a 15 second strip (10 seconds of pre-alarm data and 5 seconds of post alarm data) when selected alarm type occurs.	Red/Yellow, Red
Print on Charge	Prints a continuous strip during charging. Printing continues until a shock is delivered, the device is disarmed, or the Print button is pressed.	Yes, No
Print on Shock	Prints a 12 second strip when a shock is delivered or when a shock is attempted but unable to be delivered.	Yes, No
Print on Mark	Prints a 6 second strip when the Mark Event button is pressed.	Yes, No
Printer Delay	Defines whether printed strips, including those requested manually and those generated by an event (mark, charge, or shock), include an additional 10 seconds of information - the 10 seconds occurring just prior to printing being initiated.	No Delay, 10 sec.
Event Summary Report	Selects the Event Summary Report format. Short includes a log of events and vitals. Medium adds waveforms. Long adds 12-Lead Reports.	Short, Medium , Long
Strip Print Speed	Selects the ECG strip print speed.	25, 50 (mm/sec)
12-Lead Print Speed	Selects the 12-Lead ECG Report print speed.	25, 50 (mm/sec)

Table 26 Mark Event Settings

Parameter	Description	Setting Choices
(Menu Option) 1	Defines menu choice #1 on the Mark Events menu.	20 characters, ET Access
(Menu Option) 2	Defines menu choice #2 on the Mark Events menu.	20 characters, IV Access
(Menu Option) 3	Defines menu choice #3 on the Mark Events menu.	20 characters, Adrenaline (for Europe), Epinephrine (for the rest of the world)
(Menu Option) 4	Defines menu choice #4 on the Mark Events menu.	20 characters, Lidocaine
(Menu Option) 5	Defines menu choice #5 on the Mark Events menu.	20 characters, Atropine
(Menu Option) 6	Defines menu choice #6 on the Mark Events menu.	20 characters, Morphine
(Menu Option) 7	Defines menu choice #7 on the Mark Events menu.	20 characters, Nitroglycerin
(Menu Option) 8	Defines menu choice #8 on the Mark Events menu.	20 characters, Aspirin

Data Management

This chapter describes the data management features of the HeartStart MRx.

Overview

The HeartStart MRx automatically creates an Event Summary for each patient case. Each Event Summary is assigned a unique event identification number and is date/time stamped. Measurements are recorded in the Event Summary every 5 minutes, with the exception of NBP measurements which are recorded every time a measurement is taken. Event Summaries, including any associated 12-Lead Reports, are automatically stored in internal memory. When internal memory reaches capacity, with each addition of an Event Summary to internal memory, the oldest Event Summary is subsequently deleted. The current or most recent Event Summary Report may be printed by pressing the  button. For Version A.02 and later devices, Event Summaries stored in internal memory may be individually selected and printed. Event Summaries may be selected and copied to a data card using the **Data Management** menu.

New Event Summaries are initiated each time one of the following activities occurs:

- The arrival of a valid ECG signal.
- The arrival of valid SpO₂ data.
- The arrival of valid CO₂ data.
- An NBP measurement is requested.
- The Charge  button is pressed.
- The Mark Event  button is pressed.
- A 12-Lead Report is successfully transmitted from the HeartStart MRx.

Both internal memory and the data card allow for storage of up to 8 hours of continuous ECG waveforms and events per Event Summary, with a maximum capacity of 60 Event Summaries or 62 megabytes of patient data, whichever comes first. In addition, configuration data may be stored to a data card to replicate configuration settings on multiple devices.

NOTE Monitoring and defibrillation functions are disabled while using the data management features of the HeartStart MRx. An active patient event will be closed upon entering Data Management.

Copying from Internal Memory

To copy Event Summaries and 12-Lead ECG Reports stored in internal memory to a data card:

- 1 Insert a data card, see “Installing the Data Card” on page 40.
- 2 Turn the Therapy Knob to either **Monitor**, **Pacer** or **Manual Defib**.
- 3 Press the Menu Select  button.
- 4 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 5 Select **Data Management** and press the Menu Select button.
- 6 Press the Menu Select button to acknowledge the message, **Leaving Normal Operational Mode**.
- 7 Use the [**Prev Item**] and [**Next Item**] soft keys to select an Event Summary.
- 8 Press the Menu Select button to display the Data Management menu.
- 9 Select **Copy** and press the Menu Select button. The message, **Copying Patient Data**, is displayed while the Event Summary and any 12-Lead Reports are copied to the data card.

Viewing and Erasing the Data Card

The contents and status of your data card are conveniently available for viewing. To display data card information:

- 1 Turn the Therapy Knob to either **Monitor**, **Pacer** or **Manual Defib**.
- 2 Press the Menu Select  button.
- 3 Using the Navigation buttons, select the **Other** menu and press the Menu Select button.
- 4 Select **Data Management** and press the Menu Select button.
- 5 Press the Menu Select button to acknowledge the message, **Leaving Normal Operational Mode**.
- 6 Press the Menu Select button to display the Data Management menu.
- 7 Select **View Data Card** and press the Menu Select button.

[**Prev Page**] and [**Next Page**] soft keys appear to navigate to additional display pages.

Use the **Erase Card** menu entry to delete the contents of the data card.

Printing the Event Summary

You can print the current Event Summary at any time during the event by pressing the Event Summary  button. If an event is not in progress, pressing the Event Summary  button prints the most recent Event Summary. The printed format of the Event Summary is defined in Configuration.

To select and print an Event Summary after an event:

- 1 Turn the Therapy Knob to either **Monitor**, **Pacer** or **Manual Defib**.
- 2 Press the Menu Select  button.
- 3 Using the Navigation buttons, select the **Other** menu and press the Menu Select button.
- 4 Select **Data Management** and press the Menu Select button.
- 5 Press the Menu Select button to acknowledge the message, **Leaving Normal Operational Mode**.
- 6 Press the Menu Select button to display the Data Management menu.
- 7 Select **Print** and press the Menu Select button. The Event Summary is printed using the configured format.

WARNING Should an alarm condition occur while an Event Summary is printing, an alarm strip is not printed, however, the corresponding ECG waveform is stored and available in the Event Summary.

To print an Event Summary stored on the removable data card, the information must first be downloaded to the HeartStart Event Review Pro data management system. Refer to the *HeartStart Event Review Pro Instructions for Use* for download instructions.

Printing the 12-Lead ECG Report

You can print individual 12-Lead ECG Reports for the current or most recent patient event through the 12-Lead Report View menu. See “12-Lead Report” on page 109.

Events Recorded

The following events and related information are stored in the Event Summary (short format). *Italicized* text in logged events is replaced by an appropriate value or selected option.

Table 27 Event Information

Logged Event	Frequency
Power On/Off	
Device On	First event logged for incident.
Device Off	Logged when Therapy Knob is turned to Off position.
Continued Use	Logged when device is turned on after being turned off for less than 10 seconds.
Mode	
AED Mode	Logged at start of incident and when mode or selected energy changes.
Monitor Mode	
Pacer Mode	
Selected Energy <i>xx</i> J	
Patient Info	
Adult/Pedi	Logged at start of incident and when changed.
Paced/Non-Paced	Logged at start of incident and when changed.
Age <i>xx unit</i>	Logged when set.
Male/Female	Logged when set.
Battery Status	
Battery Low	Logged when batteries are low and external power is not available.
***Batteries Low	Logged when batteries are low and device is pacing.
Shutting Down in 1 Minute	Logged when warning issued.
Shutting Down Now	
Pads/Paddles/Leads	
Pads On	Logged when pads are applied to patient.
Pads Off	Logged after a Pads On event if adult/pediatric multifunction electrode pads are removed from the patient or the pads cable is disconnected.
External Paddles On	Logged when external paddles make contact with the patient.
External Paddles Off	Logged after an External Paddles On event if paddles lose contact with the patient.
Internal Paddles On	Logged when internal paddles make contact with the patient.
Internal Paddles Off	Logged after an Internal Paddles On event if paddles lose contact with the patient.
Leads On	Logged when monitoring electrodes for primary ECG are attached to the patient.
Primary ECG <i>label</i>	Logged for initial or change in primary ECG source.

Table 27 Event Information

Logged Event	Frequency
Measurements	
HR Limits <i>low high</i>	Logged when device is turned on if ECG alarms are on, when settings are changed, or when ECG alarms are turned on.
PVC/min Limit	
VTACH Limits HR <i>value Run value</i>	
ECG Alarms Off	Logged when ECG alarms are turned off.
HR <i>value</i>	Logged every 5 minutes.
Learning Rhythm	Logged when ST/AR algorithm learns ECG rhythm.
SpO ₂ On/Off EtCO ₂ On/Off	Logged when device is turned on if measurement is connected and subsequently when measurement is disconnected/connected.
SpO ₂ Limits <i>low high</i> EtCO ₂ Limits <i>low high</i>	Logged with measurement on event if measurement alarms are on, when settings are changed, or when measurement alarms are turned on.
SpO ₂ Alarms Off EtCO ₂ Alarms Off	Logged when measurement alarms are turned off.
SpO ₂ <i>value</i> EtCO ₂ <i>value</i>	Logged every 5 minutes.
Apnea Time <i>limit sec.</i>	Logged when device is turned on if EtCO ₂ is connected, when connected if device is on, and when settings are changed.
AwRR Limits <i>low high</i>	Logged with measurement on event if measurement alarms are on, when settings are changed, or when measurement alarms are turned on.
AwRR Alarms Off	Logged when AwRR alarms are turned off.
AwRR <i>value</i>	Logged every 5 minutes.
Pulse Limits <i>low high</i>	Logged when device is turned on if SpO ₂ is connected, when connected if device is on, and when settings are changed.
Pulse Alarms Off	Logged when Pulse alarms are turned off.
Pulse <i>value</i>	Logged every 5 minutes.
NBP Schedule [<i>Manual, q1, ...</i>]	Logged when schedule is changed.
NBP Limits <i>source low high</i>	Logged when Start NBP soft key pressed and when settings are changed.
NBP Alarms Off	Logged when NBP alarms are turned off.
NBP <i>value</i>	For A.00/A.01 - Logged whenever manually taken, automatically taken if schedule > q5, every 5 minutes if schedule is ≤ q5. For A.02 and later - Logged for every NBP measurement
Alarms	
yellow or *red alarm	Logged when alarm condition occurs.
Alarms Paused	Logged when action occurs.
Alarms Resumed	Logged when action occurs.
Alarms Off	Logged when action occurs.
Audio Paused	Logged when action occurs.
Audio Resumed	Logged when action occurs.

Table 27 Event Information

Logged Event	Frequency
INOPS	See Chapter 15 for information regarding INOP statements.
Defibrillation	
Charging to <i>xx</i> J	Logged when device starts charging to selected energy setting.
Disarm [<i>Manual, Auto</i>]	Logged when device disarmed by user or automatically after time-out period.
Shock # <i>x</i>	Logged when discharge to patient (energy delivered, impedance and peak current are stored with the waveform).
No Shock Delivered	Logged when discharge to patient fails.
Sync On	Logged when Sync function turned on by user.
Sync Off	Logged when Sync function turned off by user.
AED Mode	
Pause/Resume	Logged when the [Pause for CPR] or [Resume Analyzing] soft keys are pressed.
Analyzing	Logged when advisory algorithm begins analysis.
Artifact Detected	Logged when advisory algorithm detects noise or motion artifact.
Cannot Analyze ECG	Logged when advisory algorithm cannot complete analysis sequence.
No Shock Advised	Logged when a non-shockable rhythm is detected.
Shock Advised	Logged when a shockable rhythm is detected.
Pacer	
Pacer Mode [<i>Demand, Fixed</i>]	Logged when pacing is started and when mode is changed.
Pacer [<i>Start or Resume</i>] <i>xx ppm xx mA</i>	Logged when pacing is started and when pacing is resumed.
Pacer Rate <i>xx ppm</i>	Logged when rate or output is changed and maintained for 2 seconds while pacing. The logged time will be the time the setting took effect. If this event is logged out of order, a * will be appended to the time stamp.
Pacer Output <i>xx mA</i>	
Pacer Pause/Stop	Logged when the Therapy Knob is moved off the Pacer position while pacing.
12-Lead	
12-Lead Acquired	Logged when action occurs.
12-Lead Printed <i>date/time</i>	Logged when action occurs.
12-Lead Deleted <i>date/time</i>	Logged when action occurs.
12-Lead Transmitted <i>date/time</i>	Logged when 12-Lead Report is successfully transmitted from the MRx.
Mark Event	
Mark Event	Logged when Mark Event button is pressed.
Mark <i>event/drug</i>	Logged when user selects an entry from the Mark Event menu.
Print	
Print Strip	Logged when Print button is pressed

If selected in Configuration, the medium format of the Event Summary includes all events listed above, as well as any associated ECG waveforms. The long format includes these elements, as well as 12-Lead Reports.

Marking Events

The Mark Event  button allows you to annotate the Event Summary and the ECG strip at the point in time the button is pressed. If configured, pressing the Mark Event button prints a 6-second ECG strip. Depending on configuration, the ECG strip is either printed real time, or prepended with the previous 10 seconds of data leading up to the marked event.

Once pressed, the Mark Event label in the upper left corner of the display changes to Select Event and the Mark Events menu is displayed (see Figure 62).

Figure 62 Mark Events Menu

Mark Events
ET Access
IV Access
Epinephrine
Lidocaine
Atropine
Morphine
Nitroglycerin
Aspirin
Other

Use the Navigation buttons to select the desired event and press the Menu Select  button.

The ECG strip is annotated with the mark event  symbol and the selected annotation. If an annotation item is not selected within five seconds after the Mark Event button is pressed, only the generic mark event  symbol will appear on the ECG strip.

The marked event is stored in the Event Summary.

NOTE Entries on the Mark Events menu are as configured. Changes are made using the Configuration menu.

Printing Events

The HeartStart MRx can be configured to print automatically when certain events occur. Table 28 lists these events and the length of the strip printed, depending on whether the printer is configured to print real-time or with a 10-second delay.

Table 28 Printed Strip Lengths

Event	Real-Time Strip Length	Delayed Strip Length
HeartStart MRx charges to deliver a shock.	Continuous	10 seconds just prior to charging, plus continuous printing through the charge duration.
Shock delivered	12 seconds	10 seconds just prior to shock, plus 12 seconds after shock.
Shock failed	12 seconds	10 seconds just prior to the message No Shock Delivered , plus 12 seconds after the message.
Alarm condition	15 seconds (10 seconds of pre-alarm data and 5 seconds of post alarm data when specified alarm type occurs.	N/A
Mark Event ► button pressed	6 seconds	10 seconds just prior to marking, plus 6 seconds after the button is pressed.

Maintenance

This chapter describes how to care for your HeartStart MRx and its accessories.

Overview

Proper maintenance of the HeartStart MRx is very simple, yet it is an important factor in its dependability. It involves:

- Running Automated Tests
- Observing the Ready For Use (RFU) indicator
- Performing the Operational Check
- Caring for batteries
- Cleaning the device and accessories
- Ordering replacement supplies and accessories

WARNING Electric shock hazards exist internally. Do not remove assembly screws. HeartStart MRx service should only be performed by qualified service personnel, in accordance with the *HeartStart MRx Service Manual*.

NOTE Calibration of the optional end-tidal CO₂ and noninvasive blood pressure modules of the HeartStart MRx needs to be performed yearly by a qualified service provider, as described in the *HeartStart MRx Service Manual*.

Automated Tests

The HeartStart MRx performs many maintenance activities independently, including three tests that run automatically at regularly scheduled intervals while the device is off to assess operational performance and alert you if a problem exists. Results of tests associated with critical functionality of the device are reported through the Ready For Use indicator and the Automated Test Summary report. Results are also reported through inop statements on the display when the HeartStart MRx is turned on. Table 29 provides a brief explanation of the tests and lists the frequency with which each is performed.

Table 29 Automated Tests

Test Name	Description	Frequency
Hourly	Tests batteries, internal power supplies, and internal memory.	Hourly
Daily	Tests batteries, internal power supplies, internal memory, internal clock battery, defibrillation, pacing, ECG, SpO ₂ , EtCO ₂ , NBI, and printer. The defibrillation test includes low energy internal discharges. If a 3-, 5-, or 10-lead ECG cable is attached, the cable is tested as well.	Daily, between 11 pm and 1 am
Weekly	Performs the Daily Test described above, plus delivers a high energy internal discharge to further exercise the defibrillation circuitry.	Weekly, on Sunday, between 11 pm and 1 am

NOTE Automated tests do not test therapy cables, paddles, buttons, audio, or the display. An ECG cable is tested, if connected at the time of the test.

Automated Test Summary

An Automated Test Summary (ATS), showing the results of recent tests, may be printed as evidence that the HeartStart MRx is tested regularly. To display the ATS and print its results:

- 1 Turn the Therapy knob to **Monitor**.
- 2 Press the Menu Select  button.
- 3 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 4 Select **Operational Check** and press the Menu Select button.
- 5 Using the Navigation buttons, select **Automated Test Summary** and press the Menu Select button. The Automated Test Summary is displayed.

The message, **Leaving Normal Operating Mode**, appears to let you know that you are exiting from clinical functionality of the monitor/defibrillator.

- 6 Press the [Print] soft key to print the report.

The report shows the results of the most recent Hourly Test, the Daily Tests that have run since the last Weekly Test, and the last 53 Weekly Tests. Test results are reported, as described in Table 30.

Table 30 Automated Test Summary Results (Versions Prior to B.05)

Result	Definition	Required Action
Pass	All tests passed	None
Fail/C	A critical failure was detected. Critical failures impact life-saving functionality, including defibrillation, pacing, and ECG acquisition. The RFU indicator displays a solid red "X," accompanied by a chirp.	Respond to the RFU indicator as described in Table 32.
Fail/NC	A non-critical failure was detected. Non-critical failures do not impact life-saving functionality.	Turn the HeartStart MRx Therapy Knob to Monitor . An inop statement indicating the failure is displayed. Refer to Chapter 16, Troubleshooting, for the action to take. The message will continue to display in all clinical modes until the problem is corrected.
Fail/BF	The total battery capacity (combination of both batteries) is less than 20%.	Replace the battery or apply external power to charge the battery.

Table 31 Automated Test Summary Results (Versions B.05 and Greater)

Result	Definition	Required Action
Pass	All tests passed	None
Fail/DX	A problem has been detected that may prevent the delivery of a shock, pacing, or ECG acquisition.	Turn the Therapy Knob to Monitor. An inop indicating a problem has occurred is displayed. Refer to Chapter 16, Troubleshooting, for the action to take.
Fail/BF	The total battery capacity (combination of both batteries) is less than 20%.	Charge the battery as soon as possible and/or replace the battery with a charged battery. Charging may be done in the HeartStart MRx or by connecting to AC/DC power, or in a Philips-approved battery support system.
Fail/D	A problem has been detected with a component that does not affect therapy delivery.	Turn the Therapy Knob to Monitor. An inop indicating the failed component is displayed. Refer to Chapter 16, Troubleshooting, for the action to take.

Ready For Use Indicator

The results from Automated Tests are reported through the Ready For Use (RFU) indicator. Be sure to observe the RFU indicator periodically and take the appropriate action, as described in Table 32.

Table 32 RFU Indicator Status

RFU Status	Meaning	Required Action
Blinking black hourglass	Shock, pacing, and ECG functions are ready for use and sufficient battery power is available.	None
Blinking red "X" with or without a periodic chirp	Low battery. The device can be used but run time is limited. Chirping indicates the battery is not being charged. No chirping indicates the battery is being charged.	Charge the battery as soon as possible and/or replace the battery with a charged battery. Charging may be done in the HeartStart MRx by connecting to AC/DC power, or in a Philips-approved battery support system
Solid red "X" and a periodic chirp	A failure has been detected that may prevent the delivery of a shock, pacing, or ECG acquisition.	Turn the Therapy Knob to Monitor . An inop message describing the failure is displayed. See Chapter 16, Troubleshooting, for the corrective action. If needed, run an Operational Check for further information. If the condition persists, take the device out of use and call for service.
Solid red "X" without a periodic chirp	No power, or device failure (cannot turn on).	Insert a charged battery or connect to AC/DC power. If the condition persists, take the device out of use and call for service.

NOTE The RFU indicator may briefly display a solid red "X" when initially turning on the device, switching between clinical and non-clinical operating modes, and at the start of any Automated test.

Shift Checklist and Operational Check

In order to help ensure that defibrillators are ready when needed, the American Heart Association (AHA) recommends that users complete a check list, often referred to as a shift check, at the beginning of each change in personnel. The activities on this check list include verifying that the appropriate supplies and accessories are present, the device is plugged in and has sufficient battery power, and the device can discharge energy. Philips Medical Systems supports the AHA check list recommendations and has provided a Shift Checklist document with the MRx.

Weekly Shock Test

In addition to the shift check, you must verify the ability to deliver defibrillation therapy once a week by performing one of the following:

- Operational Check (See “Operational Check (Versions Prior to B.05)” on page 157 or “Operational Check (Versions B.05 and Greater)” on page 166.)
- Weekly Shock Test (See following instructions.)

NOTE Test reusable sterilizable paddles (internal or external) prior to each use. See the *Sterilizable Defibrillator Paddles Instructions for Use* for more information.

To perform the Weekly Shock test:

- 1 If you are using paddles, make sure the paddles are secure in their pockets and that the Patient Contact Indicator (PCI) LEDs located on the sternum paddle are not lit. If the LEDs light, adjust the paddles in their pockets. If the LEDs continue to light, clean both the adult and pediatric paddle electrode surfaces.

or

If you are using multifunction electrode pads, attach a test load to the end of the patient Therapy cable.

- 2 Turn the Therapy knob to 150J.
- 3 Press the Charge button.

NOTE If it becomes necessary to disarm the defibrillator, press **[Disarm]**.

- 4 The strip prints if configured to do so. If the strip does not print immediately, press the Print button.
- 5 If using:
 - Pads, press the Shock button on the MRx to deliver a shock into the test load.
 - External paddles, simultaneously press the shock buttons located on the paddles to deliver a shock into the pockets.
- 6 Confirm on the printed strip that the energy delivered to the test load is $150\text{J} \pm 23\text{J}$ (127J to 173J). If not, take the device out of use and begin troubleshooting.

Operational Check (Versions Prior to B.05)

Modifications were made to the Operational Check with software version B.05. If your device is running software prior to B.05, refer to this section for an explanation of the Operational Check procedure. If your device is running software version B.05 or greater, refer to “Operational Check (Versions B.05 and Greater)” on page 166.

NOTE To determine the device’s software version, select **Other>Print Device Info** from the Main menu.

Operational Checks should be performed at regular intervals to supplement the hourly, daily, and weekly Automated Tests executed by the MRx. Automated Tests provide adequate assurance that the device is in a functional state of readiness. Operational Checks supplement the Automated Tests by verifying therapy cables, the ECG cable, paddles, audio, and display functionality, along with replicating the Weekly test. Operational Checks also notify you if the battery, NBP module, or CO2 module need calibration. The printout at the end of the Operational Check lists the items you should check. The "User Checks" on page 174 provide guidelines for conducting this check.

The Operational Check is run with a battery installed to reflect optimal operating conditions for defibrillation. The device automatically disconnects AC/DC power. Each type of patient therapy cable used (multifunction electrode pads or paddles) should be tested during the defibrillator portion of the check.

Prior to performing the Operational Check, ensure that the paddles (if tested) are secure in their pockets and that the PCI LEDs are not lit. Should the LEDs light, adjust the paddles in their pockets. If the LEDs continue to light, clean both the adult and pediatric paddle electrode surfaces.

NOTE If the MRx is equipped with multifunction defib pads only and does not have a paddle tray, you cannot test paddles during an Operational Check. To test the paddles you **must** have a test load. Run the Weekly Shock Test, delivering the shock into the test load. See “Weekly Shock Test” on page 156.

Performing the Operational Check

To perform the Operational Check:

- 1 Insert a charged battery (capacity of 20% or greater).
- 2 Connect a pads or paddles therapy cable.
- 3 Connect an ECG cable.
- 4 Turn the Therapy Knob to **Monitor**.
- 5 Press the Menu Select  button
- 6 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 7 Select **Operational Check** and press the Menu Select button.
- 8 Select **Run Operational Check** and press the Menu Select button.

The message window, **Leaving Normal Operating Mode**, appears to let you know that you are exiting from clinical functionality and entering a test mode of the monitor/defibrillator. Press the Menu Select button to acknowledge the message.

As each test is run, the name of the test appears on the display with the message **In Progress**, as shown in Figure 63.

- 9 Carefully read and respond to the Operational Check prompts for each test. In Version A.02 and later devices, screen prompts are accompanied by an audio prompt to provide indication of a message that should be acknowledged before proceeding with the rest of the Operational Check. Table 33 shows the tests, in the order in which they are performed, explains the prompts that may appear, and describes the actions you should take (if any).
The test result (pass or fail) is displayed at the completion of each test. If you cancel the Operational Check before it completes, there is no record of it in the Operational Check Summary.

WARNING Be sure to safely discharge external paddles tested during the Operational Check, as described in Table 33.

Figure 63 Operational Check

02 Mar 2006 10:52 **A** **B**

Operational Check

Model Number:	M3535A
Serial Number:	US00108360
Last Operational Check:	01 Mar 2006 9:35 Pass
Display Test:	Pass
General System Test:	Pass
Audio Test:	Pass
Leads ECG Test:	Pass/ECG Cable
Pads/Paddles ECG Test:	Pass/Pads
Pacer Test:	Pass
Defib Test:	Pass/External Paddles
	Pass/Pads
Battery Compartment A Test:	Pass/Cal Recommended
Battery Compartment B Test:	Pass
SpO2 Test:	In Progress
NBP Test:	
CO2 Test:	In Progress
Printer Test:	

Exit
Op Check

Table 33 Operational Check Tests

Test	Description	Prompts	Action
Display	A test pattern is displayed; the display is filled with black, then white, then red from top to bottom, then green from left to right.	Did you see the test pattern correctly?	Use the navigation buttons to respond Yes or No . Then press the Menu Select button.
General System	Tests internal clock battery, power supply, and internal memory.	None.	None.
Audio	The voice prompt, No Shock Delivered is announced.	Did You Hear, "No Shock Delivered?"	Use the navigation buttons to respond Yes or No . Then press the Menu Select button.
Leads ECG Test	Tests leads ECG acquisition and, if attached, the ECG cable. The recommended practice is to run the test with the ECG cable attached.	<ul style="list-style-type: none"> • Connect ECG Cable, Cable Connected or Test Without Cable, if the cable is not connected. • Detach Leads, if the ECG cable is connected to a patient or the leads are shorted together. • Disconnect ECG Cable, if the test fails with the cable connected. 	<ul style="list-style-type: none"> • Connect an ECG cable and respond Yes or use the navigation buttons to respond No. Then press the Menu Select button. • Make sure the leads are not attached to a patient or touching each other. • Disconnect the ECG cable from the device.
Pads/Paddles ECG	Checks ECG acquisition through pad/paddles.	Remove Paddles from Holders Place Paddles in Holders Connect Pads/Paddles Cable, Connect Therapy Cable	Remove the paddles from the holders. Place the paddles in the holders. Attach the pads or paddles cable typically used.
Pacer (only runs if the option is present)	Tests pacing functionality and delivers a pace pulse into a 50 ohm test load.	<ul style="list-style-type: none"> • Connect Pads Cable, if the pads cable is not detected. • Attach Test Load, if a test load is not detected. 	<ul style="list-style-type: none"> • Connect the pads cable to the HeartStart MRx. • Connect the test load to the pads cable.

Table 33 Operational Check Tests (Continued)

Test	Description	Prompts	Action
Defib	<p>Tests defibrillation circuitry and delivers a shock through:</p> <ul style="list-style-type: none"> • pads, into a test load, and/or • external paddles, into the HeartStart MRx. 	<p>Depending on the cable connected, as follows:</p> <ul style="list-style-type: none"> • If the pads cable is attached, you are prompted to, Verify Test Load is Attached and Press the Charge Button. • If external paddles are attached, you are prompted to, Verify Paddles are in Holders and Press the Charge Button. • If no cable is attached, you are prompted to, Connect Therapy Cable. <p>Once charged the Shock button lights and you are prompted to, Press Shock.</p> <p>After the test completes using one therapy cable, you are prompted to, Run defib test again with a different therapy cable?</p>	<p>Respond to the prompt, as follows:</p> <ul style="list-style-type: none"> • Check the test load is attached and press the Charge button. • Make sure the paddles are seated in their pockets and press the Charge button. • Connect a therapy cable. <p>Press the Shock button.</p> <p>Use the Navigation and Menu Select buttons to respond. Connect a different cable and select Yes to repeat the test for another cable. You should repeat the test for each cable used. Select No, once all cables have been tested.</p>
Battery Compartment A Battery Compartment B	Checks the total battery capacity (combination of both batteries) and calibration status of the batteries in Compartments A and B.	Cal Recommended , if battery calibration is required.	If prompted, calibrate the battery.
SpO ₂	Checks the SpO ₂ module. The SpO ₂ cable is not tested.	None.	None.
NBP	Checks the NBP module; determines if it is due for calibration.	None.	None.
CO ₂	Checks the CO ₂ module; determines if it is due for calibration.	None.	None.
Printer	Runs a printer self test.	None.	None.

As each test is completed the test result is displayed. At completion of the Operational Check, the message, **Operational Check Passed**, is displayed if all of the tests have passed successfully. If any test fails, either the message, **Non-Critical Failure**, **Critical Failure**, or **Battery Failure** is displayed depending upon the severity of the failed functionality. Refer to Table 34 for an explanation of test results and actions to take.

Operational Check Report for Versions Prior to B.05

The Operational Check takes only a short time to complete. When it is done, a report is printed, as shown in Figure 64. The first part of the report lists test results. The second part lists checks to be performed by the user.

Figure 64 Operational Check Report

Operational Check Report Model Number: M3535A Serial Number: USD0123456 Ver.: A.00.00	Current Test Results: Display Test: Pass General System Test: Pass Audio Test: Pass Leads ECG Test: Pass/ECG Cable Pads/Paddles ECG Test: Pass/Pads Pacer Test: Pass Defib Test: Pass/Pads Pass/External Paddles	NBP Test: Pass CO2 Test: Pass Printer Test: Pass
Current Operational Check: DD Mon YYYY HH:MM:SS	Battery Compartment A Test: Pass/Cal Recommended Battery Compartment B Test: Pass/Cal Recommended SpO2 Test: Pass	
Last Operational Check: DD Mon YYYY HH:MM:SS Pass		

Qty/Check List:	___ CO2 FilterLine	Comments:
___ Defibrillator Inspection		<div style="border: 1px solid black; height: 80px; width: 100%;"></div>
___ Cables/Connectors		
___ Paddles/Pads		
___ Monitoring Electrodes		
___ Charged Batteries		
___ AC/DC Power & Cord		
___ Printer Paper		
___ Data Card		
___ SpO2 Sensor		
___ NBP Cuffs & Tubing		
	Inspected by: _____	

Press the [**Print**] soft key when the Operational Check is complete to print an additional copy of the report.

User Checks

The guidelines for completing user checks are as follows:

Defibrillator Inspection Make sure the HeartStart MRx is clean, clear of objects, and has no visible signs of damage.

Cables/Connectors/Paddles/Pads/Monitoring Electrodes Make sure there are no cracks, broken wires, or other visible signs of damage. Make sure the connections are secure. Check expiration date and quantity of pads and monitoring electrodes

Batteries Make sure a charged battery is in the HeartStart MRx. Another charged battery should be available or should be charging. Ensure the batteries have no visible signs of damage.

AC/DC Power Check the AC/DC power source:

- 1 Connect the AC/DC power module to the HeartStart MRx and plug it into a power outlet.
- 2 Verify that the external power indicator on the front panel is lit.

Printer Paper Make sure the printer has sufficient paper and is printing properly.

Data Card If applicable, make sure a data card is inserted and has sufficient space available.

SpO₂ Sensor Inspect the sensor and cable for visible signs of damage

NBP Cuffs and Tubing Inspect the pressure cuffs and tubing for visible signs of damage.

CO₂ FilterLine Confirm that at least one un-opened, sterile package is available.

Table 34 Operational Check Test Results (Versions Prior to B.05)

Test	Results	Action if Test Does Not Pass
Display	<ul style="list-style-type: none"> Pass - You responded Yes to the prompt, Did you see the test pattern correctly. Fail - You responded No to the prompt, Did you see the test pattern correctly. 	Take the device out of use and call for service.
General System	<ul style="list-style-type: none"> Pass - The clock battery, power supplies, and internal memory are functioning. Fail - The clock battery, power supplies, and/or internal memory are not functioning. The remaining tests are aborted and reported as Not Tested. 	If the test fails with the AC/DC power module present, remove the module and repeat the test. If the test continues to fail, call for service. If the test passes, replace the power module.
Audio	<ul style="list-style-type: none"> Pass - You responded Yes, that you were able to hear the test voice prompt. Fail - You responded No, to hearing the voice prompt. 	Take the device out of use and call for service.
Leads ECG	<ul style="list-style-type: none"> Pass/ECG Cable - leads ECG acquisition and the ECG cable connected are both functioning. Pass/No Cable - leads ECG acquisition is functioning. Fail/ECG Cable- leads ECG acquisition and/or the ECG cable connected are not functioning. Fail/No Cable - leads ECG acquisition is not functioning. 	If the test fails without an ECG cable connected, take the device out of use and call for service. If the test fails with a cable, repeat the test without an ECG cable attached. A passing result without a cable attached indicates the cable is defective and should be replaced. If the test continues to fail, take the device out of use and call for service.
Pads/Paddles	Pass/cable type - ECG acquisition and the cable are both functioning. Pass/No cable - ECG acquisition is functioning; a cable was not tested. Fail/cable type- ECG acquisition and/or the cable specified are not functioning.	If the test fails with a cable connected, remove the cable and repeat the test. If the test passes without the cable, replace the cable. If the test continues to fail, take the device out of use and call for service.
Pacer	<ul style="list-style-type: none"> Pass - Pacing is functioning. Fail - Pacing is not functioning. 	If the pacer fails, attach a different pads cable and test load and repeat the test. If the pacer fails again, take the device out of use and call for service.

Table 34 Operational Check Test Results (Versions Prior to B.05) (Continued)

Test	Results	Action if Test Does Not Pass
Defib	<ul style="list-style-type: none"> Pass/cable type - The defib test passed with the specified cable type (pads, external paddles, internal paddles) attached. Fail/cable type - The test failed with the specified cable type connected. 	If the test fails, repeat it using a different therapy cable. A passing result with a different cable indicates the previous cable is defective and should be replaced. If the test continues to fail, take the device out of use and call for service.
Battery Compartment A Battery Compartment B	<ul style="list-style-type: none"> None - There is no battery in the slot. Pass - The battery has 20% or greater capacity. Fail - The battery has 20% or less capacity. Cal Recommended - The battery requires calibration. 	Charge the battery. Calibrate the battery.
SpO ₂	<ul style="list-style-type: none"> Pass - SpO₂ passed its self-test. Fail - SpO₂ is not functioning. 	If the test fails, call for service to repair the SpO ₂ module. If SpO ₂ monitoring is essential to patient care, take the device out of use.
NBP	<ul style="list-style-type: none"> Pass - NBP passed its self-test. Fail - NBP is not functioning. Cal Due - NBP passed its self-test and is due to be calibrated. Cal Overdue - NBP passed its self-test and is overdue for calibration. Measurements may be inaccurate. Replacement Recommended - NBP passed its self-test but has exceeded 50,000 cycles. 	If the test fails, call for service to repair the NBP module. If NBP monitoring is essential to patient care, take the device out of use. If calibration is due or overdue, arrange for a qualified service provider to perform the calibration. If replacement is recommended, call for service.
CO ₂	<ul style="list-style-type: none"> Pass - CO₂ passed its self-test. Fail - CO₂ is not functioning. Cal Due - CO₂ is passed its self-test and is due for calibration. Cal Overdue - CO₂ passed its self-test and is overdue for calibration. Measurements may be inaccurate. Replacement Recommended - CO₂ passed its self-test but has exceeded 15,000 operating hours. 	If the test fails, call for service to repair the CO ₂ module. If CO ₂ monitoring is essential to patient care, take the device out of use. If calibration is due or overdue, arrange for a qualified service provider to perform the calibration. If replacement is recommended, call for service.
Printer	<ul style="list-style-type: none"> Pass - The printer passed its self-test. Fail - The printer needs repair. 	If the test fails, call for service.

Operational Check Summary

The Operational Check Summary lists the results from the last 60 Operational Checks. Test results are reported as described in Table 37.

To view the Operational Check Summary:

- 1 Turn the Therapy Knob to **Monitor**.
- 2 Press the Menu Select  button.
- 3 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 4 Select **Operational Check** and press the Menu Select button.
- 5 Using the Navigation buttons, select **Op Check Summary** and press the Menu Select button.
- 6 Press the Menu Select button to acknowledge the message, **Leaving Normal Operational Mode**.

The Operational Check Summary screen is displayed.

Table 35 Operational Check Summary Results

Result	RFU Indicator	Definition	Required Action
Pass	Hourglass	All tests passed	None
Fail/C	Solid Red “X” accompanied by a chirp	A critical failure was detected. Critical failures impact life-saving functionality, including defibrillation, pacing, and ECG acquisition.	Turn the Therapy Knob to Monitor. An inop indicating the problem is displayed. See Chapter 16, Troubleshooting.
Fail/NC	Hourglass	A non-critical failure was detected. Non-critical failures do not impact life-saving functionality.	Turn the Therapy Knob to Monitor. An inop indicating the problem is displayed. See Chapter 16, Troubleshooting.
Fail/BF	N/A ¹	A battery failure was detected.	Replace the battery.

1. The Automated Tests continually check for a low battery condition and set the RFU Indicator appropriately.

Operational Check (Versions B.05 and Greater)

Modifications were made to the Operational Check with software version B.05. If your device is running software prior to B.05, refer to “Operational Check (Versions Prior to B.05)” on page 157. If your device is running software version B.05 or greater, refer to this section for an explanation of the Operational Check procedure.

NOTE To determine the device’s software version, select **Other>Print Device Info** from the Main menu.

Operational Checks should be performed at regular intervals to supplement the hourly, daily, and weekly Automated Tests executed by the MRx. Automated Tests provide adequate assurance that the device is in a functional state of readiness. Operational Checks supplement the Automated Tests by verifying therapy cables, the ECG cable, paddles, audio, the Charge and Shock buttons, Therapy Knob, and Compression Sensor, along with replicating the Weekly test. Operational Checks also notify you if the battery, NBP module, or CO₂ module need calibration.

NOTE It is important to establish a schedule for conducting Operational Checks, as well as for checking supplies and accessories associated with the MRx. This will ensure that the device is ready to monitor and deliver therapy. The Operational Check is run with a battery installed to reflect optimal operating conditions for defibrillation. The device automatically disconnects AC/DC power. Each type of patient therapy cable used (multifunction electrode pads or paddles) should be tested during the defibrillator portion of the check.

Prior to performing the Operational Check, ensure that the paddles (if tested) are secure in their pockets and that the PCI LEDs are not lit. Should the LEDs light, adjust the paddles in their pockets. If the LEDs continue to light, clean both the adult and pediatric paddle electrode surfaces.

At completion of the Operational Check, the message “Operational Check Passed” is displayed if all of the tests pass.

If any test fails the message “Operational Check failed” is displayed along with one (or more) of the following messages, depending upon the severity of the failed functionality:

- Service device.
- Replace battery.
- Replace Compression Sensor.
- Replace Pads cable.
- Replace Paddles cable.
- Replace Therapy cable.
- Replace ECG cable

You must fix the problem and successfully run the Operational Check to clear the failure.

NOTE If the MRx has Software Version B.05 or greater with the Pacing option, test external paddles using the Weekly Shock test. You must run Operational Check with a pads cable in order to pass the Pacer test.

NOTE If the MRx is equipped with multifunction defib pads only and does not have a paddle tray, you cannot test paddles during an Operational Check. To test paddles, you **must** have a test load. Run the Weekly Shock Test, delivering the shock into the test load. See “Weekly Shock Test” on page 156.

Performing the Operational Check

To perform the Operational Check:

- 1 Insert a charged battery (capacity of 20% or greater).
- 2 Turn the Therapy Knob to **Monitor**.
- 3 Press the Menu Select  button
- 4 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 5 Select **Operational Check** and press the Menu Select button.
- 6 Select **Run Operational Check** and press the Menu Select button.

The message window, **Leaving Normal Operating Mode**, appears to let you know that you are exiting from clinical functionality and entering a test mode of the monitor/defibrillator.
- 7 Press the Menu Select button to acknowledge the message.
- 8 When a response is required, use the Navigation buttons to select your answer and the Menu Select button to confirm your choice. Table 36 shows the tests, in the order in which they are performed, explains the prompts that may appear, and describes the actions you should take (if any).

As each test is run, the name of the test appears on the display with the message **In Progress**, as shown in Figure 63.

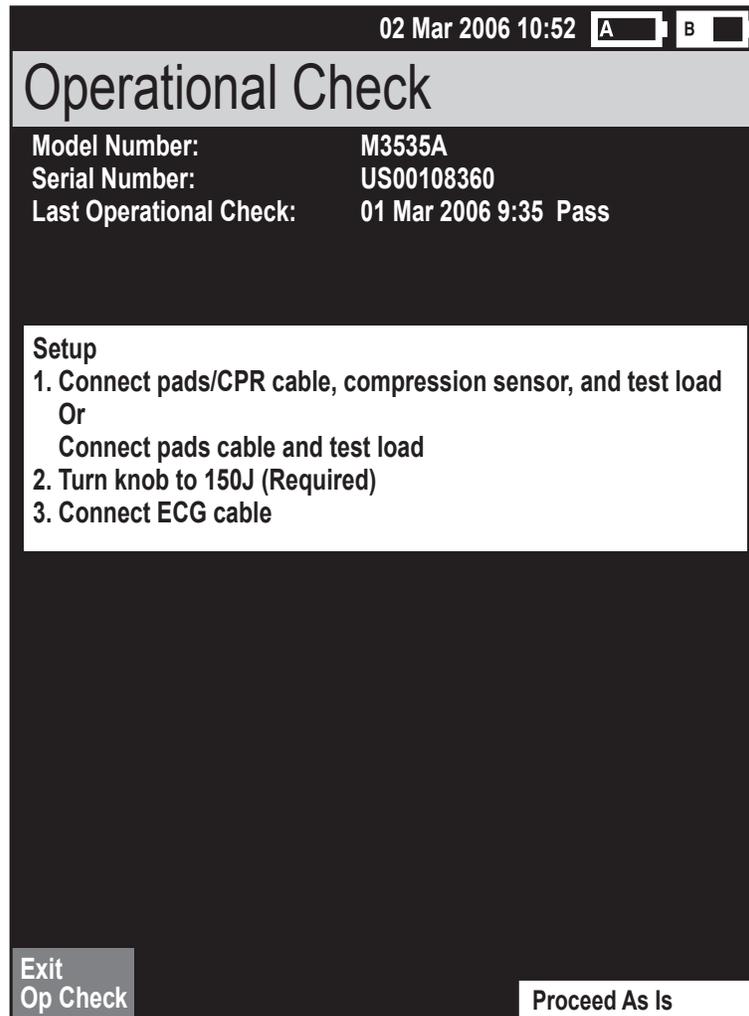
Operational Check Setup

Carefully read the setup instructions on the screen. Once the MRx is set up properly, you can proceed with the Operational Check. If the device has the Q-CPR option, you should run the Operational Check with the Pads/CPR cable and the Compression Sensor, keeping the Compression Sensor still during the test. If the MRx has the Pacing option, you must run the Operational Check with a Pads cable.

WARNING Be sure to safely discharge internal and external paddles tested during the Operational Check, as described in Table 36.

NOTE If you choose to proceed without setting up properly, the Operational Check may fail. Once you have answered the last prompt (Audio test), you can leave the MRx unattended and the Operational Check will complete. If you cancel the Operational Check before it completes, there is no record of it in the Operational Check Summary.

Figure 65 Operational Check Setup Screen



02 Mar 2006 10:52 **A** **B**

Operational Check

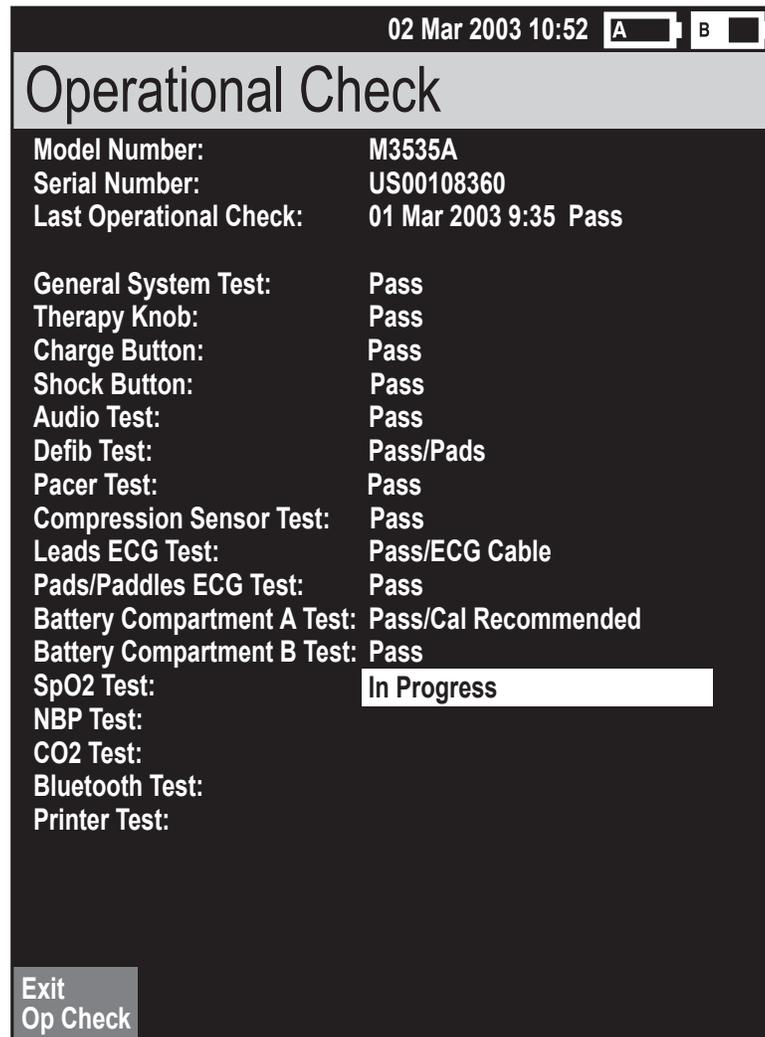
Model Number: M3535A
Serial Number: US00108360
Last Operational Check: 01 Mar 2006 9:35 Pass

Setup

1. Connect pads/CPR cable, compression sensor, and test load
Or
Connect pads cable and test load
2. Turn knob to 150J (Required)
3. Connect ECG cable

Exit Op Check **Proceed As Is**

Figure 66 Operational Check Screen



The image shows a handheld device screen displaying an 'Operational Check' menu. At the top right, the date and time are '02 Mar 2003 10:52', with two battery level indicators labeled 'A' and 'B'. The title 'Operational Check' is centered at the top. Below it, a list of system components and their test results is shown. The 'SpO2 Test' is currently 'In Progress', highlighted with a white background. At the bottom left, there is a button labeled 'Exit Op Check'.

02 Mar 2003 10:52	
Operational Check	
Model Number:	M3535A
Serial Number:	US00108360
Last Operational Check:	01 Mar 2003 9:35 Pass
General System Test:	Pass
Therapy Knob:	Pass
Charge Button:	Pass
Shock Button:	Pass
Audio Test:	Pass
Defib Test:	Pass/Pads
Pacer Test:	Pass
Compression Sensor Test:	Pass
Leads ECG Test:	Pass/ECG Cable
Pads/Paddles ECG Test:	Pass
Battery Compartment A Test:	Pass/Cal Recommended
Battery Compartment B Test:	Pass
SpO2 Test:	In Progress
NBP Test:	
CO2 Test:	
Bluetooth Test:	
Printer Test:	
Exit Op Check	

Table 36 Operational Check Tests

Test	Description	Prompts	Action
General System	Tests internal clock battery, power supply, and internal memory card.	None.	None.
Therapy Knob	Tests if the Therapy Knob is set to 150J.	None.	None.
Charge Button	Tests the Charge button.	<p>Depending on the cable connected, as follows:</p> <ul style="list-style-type: none"> If the Pads cable is attached, you are prompted to, Verify Test Load is Attached and Press the Charge Button. If external paddles are attached, you are prompted to, Verify Paddles are in Holders and Press the Charge Button. If no cable is attached, the test is marked Not Tested. <p>If the MRx does not detect a press of the Charge button within 10 seconds the message If the Charge button does not work, select Charge from the menu below is displayed.</p>	<p>Respond to the prompt, as follows:</p> <ul style="list-style-type: none"> Check the test load is attached and press the Charge button. Make sure the paddles are seated in their pockets and press the Charge button. <p>If the Charge button is not working, press Charge from the No Button Response menu. The Charge button test is marked Fail and the Operational Check fails.</p>
Shock Button	Tests the Shock button.	<ul style="list-style-type: none"> Once charged the Shock button lights and you are prompted to, Press Shock or Press Shock buttons on paddles. If the MRx does not detect a press of the Shock button within 10 seconds the message If the Shock button does not work, select Shock from the menu below is displayed. <p>Note: The device automatically disarms after the time specified in the configuration is reached.</p> <ul style="list-style-type: none"> The message Defib Disarmed is displayed. 	<ul style="list-style-type: none"> Press the Shock button. If the Shock button is not working, press Shock from the No Button Response menu. The Shock button test is marked Fail. Select Shock from the menu to continue the Operational Check or press Exit Op Check. The Shock button test is marked Fail.

Table 36 Operational Check Tests (Continued)

Test	Description	Prompts	Action
Audio	<p>If a shock was delivered during the Shock test, the voice prompt, Shock Delivered is announced.</p> <p>If no shock was delivered during the Shock test, the voice prompt No Shock Delivered is announced.</p>	Did you hear No Shock Delivered?	Use the navigation buttons to respond Yes or No . Then press the Menu Select button.
Defib	<p>Tests defibrillation circuitry and delivers a shock through:</p> <ul style="list-style-type: none"> • pads, into a test load, <p>and/or</p> <ul style="list-style-type: none"> • external paddles, into the MRx <p>Note: The Defib test has two components: a high energy internal discharge and a low energy (5J) external discharge. The results of the device's ability to charge and shock are reported in the Defib test.</p>	None.	None.
Pacer	Tests pacing functionality and delivers a paced pulse into a 50 ohm test load.	None.	None.
Compression Sensor	Checks the basic communication circuitry of the sensor.	None.	None.
Leads ECG	Tests leads ECG acquisition and the ECG cable.	None, if test passes. If test fails the following prompt is displayed at the end of all remaining tests: Leads ECG Test failed with cable. Disconnect ECG cable to rerun test without cable.	<p>If the ECG test fails with the cable and passes without the cable, the ECG cable is bad. Replace the ECG cable and rerun Operational Check.</p> <p>If the ECG test fails with and without the cable, see "Troubleshooting" on page 193.</p>

Table 36 Operational Check Tests (Continued)

Test	Description	Prompts	Action
Pads/Paddles ECG	Checks ECG acquisition through pad/paddles.	None, if test passes. If test fails the following prompt is displayed at the end of all remaining tests: Pads/Paddles ECG Test failed with cable. Disconnect therapy cable to rerun test without cable.	If the Pads/Paddles test fails with the cable and passes without the cable, the cable is bad. Replace the Therapy cable and rerun Operational Check. If the Pads/Paddles test fails with and without the cable, see “Troubleshooting” on page 193.
Battery A Battery B	Checks the total battery capacity (combination of both batteries) and calibration status of the batteries in Compartments A and B.	None.	None.
SpO ₂	Checks the internal SpO ₂ PCA. The SpO ₂ cable is not tested.	None.	None.
NBP	Checks to see if the NBP module is functioning; determines if it is due for calibration.	None.	None.
CO ₂	Checks to see if the CO ₂ module is functioning; determines if it is due for calibration.	None.	None.
Bluetooth	Checks for the presence of the Bluetooth card and database integrity.	None.	None.
Printer	Runs a printer self test.	None.	None.

Operational Check Report for Versions B.05 or Greater

The Operational Check takes only a short time to complete. When it is done, a report is printed, as shown in Figure 64. The first part of the report lists test results. The second part lists checks to be performed by the user.

Figure 67 Operational Check Report

Operational Check Report	Current Test Results:	
Model Number: M3535A	General System Test: Pass	Battery Compartment A Test: Pass
Serial Number: USD0123456	Therapy Knob: Pass	Battery Compartment B Test: Pass
Ver.: B.05.00	Charge Button: Pass	SpO2 Test: Pass
	Shock Button: Pass	NBP Test: Pass
Current Operational Check:	Audio Test: Pass	CO2 Test: Pass
DD Mon YYYY HH:MM:SS Pass	Defib Test: Pass/Pads	Bluetooth Test: Pass
	Pacer: Pass	Printer Test: Pass
Last Operational Check:	Compression Sensor: Pass	
DD Mon YYYY HH:MM:SS Pass	Leads ECG Test: Pass/ECG Cable	
	Pads/Paddles ECG Test: Pass/Pads	

Qty/Check List:	Comments:
<input type="checkbox"/> Defibrillator Inspection	<div style="border: 1px solid black; height: 80px; width: 100%;"></div>
<input type="checkbox"/> Cables/Connectors	
<input type="checkbox"/> Paddles/Pads	
<input type="checkbox"/> Compression Sensor Inspection	
<input type="checkbox"/> Compression Sensor Pads	
<input type="checkbox"/> Monitoring Electrodes	
<input type="checkbox"/> Charged Batteries	
<input type="checkbox"/> AC/DC Power & Cord	
<input type="checkbox"/> Printer Paper	
<input type="checkbox"/> Data Card	
<input type="checkbox"/> SpO2 Sensor	
<input type="checkbox"/> NBP Cuffs & Tubing	
<input type="checkbox"/> CO2 FilterLine	
Inspected by: _____	

Press the [**Print**] soft key when the Operational Check is complete to print an additional copy of the report.

User Checks

The guidelines for completing user checks are as follows:

Defibrillator Inspection Make sure the HeartStart MRx is clean, clear of objects, and has no visible signs of damage.

Cables/Connectors/Paddles/Pads/Monitoring Electrodes Make sure there are no cracks, broken wires, or other visible signs of damage. Make sure the connections are secure. Check expiration date and quantity of pads and monitoring electrodes

Batteries Make sure a charged battery is in the HeartStart MRx. Another charged battery should be available or should be charging. Ensure the batteries have no visible signs of damage.

AC/DC Power Check the AC/DC power source:

- 1 Connect the AC/DC power module to the HeartStart MRx and plug it into a power outlet.
- 2 Verify that the external power indicator on the front panel is lit.

Printer Paper Make sure the printer has sufficient paper and is printing properly.

Data Card If applicable, make sure a data card is inserted and has sufficient space available.

SpO₂ Sensor Inspect the sensor and cable for visible signs of damage

NBP Cuffs and Tubing Inspect the pressure cuffs and tubing for visible signs of damage.

CO₂ FilterLine Confirm that at least one un-opened, sterile package is available.

Compression Sensor Inspect the Compression Sensor and cable for visible signs of damage. If damaged, remove from use.

Compression Sensor Adhesive Pads Make sure there is a Compression Sensor Adhesive Pad applied to the Compression Sensor and there is an adequate supply available.

NOTE Upon completing the Operational Check and returning to a clinical mode (Monitor, Pacer, Manual Defib or AED), all settings will be reset to the device's configured values.

Table 37 Operational Check Test Results (Versions B.05 and Greater)

Test	Results	Action if Test Does Not Pass
General System	<ul style="list-style-type: none"> Pass - The clock battery, power supplies, and internal memory are functioning. Fail - The clock battery, power supplies, and/or internal memory are not functioning. The remaining tests are aborted and reported as Not Tested. 	If the test fails with the AC/DC power module present, remove the module and repeat the test. If the test continues to fail, call for service. If the test passes, replace the power module.
Therapy Knob	<ul style="list-style-type: none"> Pass - The Therapy Knob is set to 150J. Fail - The Therapy Knob is not set to 150J. Fail - The Therapy Knob is not functioning. 	If the test fails, confirm that the Therapy Knob is set to 150J and repeat the test. If the test continues to fail, call for service.
Charge Button	<ul style="list-style-type: none"> Pass - The Charge Button passed its self-test. Fail - Proceed was selected from the No Button Response Menu. Fail - The Charge Button is not functioning. 	Repeat the test. If the test continues to fail because there is no response from the Charge Button, call for service.
Shock Button	<ul style="list-style-type: none"> Pass - The Shock Button passed its self-test. Fail - Proceed was selected from the No Button Response Menu. Fail - The Shock Button was not pressed before the configured Auto Disarm time period ended. 	Repeat the test being sure to press the Shock Button before reaching the Auto Disarm time. If the test continues to fail, call for service.
Audio	<ul style="list-style-type: none"> Pass - You responded Yes, that you were able to hear the test voice prompt. Fail - You responded No, to hearing the voice prompt. 	Take the device out of use and call for service.
Defib	<ul style="list-style-type: none"> Pass/cable type - The defib test passed with the specified cable type (pads, external paddles) attached. Fail/cable type - The test failed with the specified cable type connected. 	If the test fails, repeat it using a different therapy cable. A passing result with a different cable indicates the previous cable is defective and should be replaced. If the test continues to fail, take the device out of use and call for service.
Pacer	<ul style="list-style-type: none"> Pass - Pacing is functioning. Fail - Pacing is not functioning. 	If the pacer fails, attach a different pads cable and test load and repeat the test. If the pacer fails again, take the device out of use and call for service.
Compression Sensor	<ul style="list-style-type: none"> Pass - The Compression Sensor passed its self test. Fail - The Compression Sensor failed its self test. 	If the test fails, call for service to test the Compression Sensor. If Q-CPR is essential to patient care, take the device out of use.
Leads ECG	<ul style="list-style-type: none"> Pass/ECG Cable - leads ECG acquisition and the ECG cable connected are both functioning. Pass/No Cable - leads ECG acquisition is functioning. Fail/ECG Cable- leads ECG acquisition and/or the ECG cable connected are not functioning. Fail/No Cable - leads ECG acquisition is not functioning. 	If the test fails without an ECG cable connected, take the device out of use and call for service. If the test fails with a cable, repeat the test without an ECG cable attached. A passing result without a cable attached indicates the cable is defective and should be replaced. If the test continues to fail, take the device out of use and call for service.

Table 37 Operational Check Test Results (Versions B.05 and Greater) (Continued)

Test	Results	Action if Test Does Not Pass
Pads/Paddles ECG	<p>Pass/cable type - ECG acquisition and the cable are both functioning.</p> <p>Pass/No cable - ECG acquisition is functioning; a cable was not tested.</p> <p>Fail/cable type- ECG acquisition and/or the cable specified are not functioning.</p>	If the test fails with a cable connected, remove the cable and repeat the test. If the test passes without the cable, replace the cable. If the test continues to fail, take the device out of use and call for service.
Battery A Battery B	<ul style="list-style-type: none"> • None - There is no battery in the slot. • Pass - The battery has 20% or greater capacity. • Fail - The battery has 20% or less capacity. • Cal Recommended - The battery requires calibration. 	<p>Charge the battery.</p> <p>Calibrate the battery.</p>
SpO ₂	<ul style="list-style-type: none"> • Pass - SpO₂ passed its self-test. • Fail - SpO₂ is not functioning. 	If the test fails, call for service to repair the SpO ₂ module. If SpO ₂ monitoring is essential to patient care, take the device out of use.
NBP	<ul style="list-style-type: none"> • Pass - NBP passed its self-test. • Fail - NBP is not functioning. • Pass (Cal Due) - NBP passed its self-test and is due to be calibrated. • Fail (Cal Overdue) - NBP passed its self-test but is overdue for calibration. Measurements may be inaccurate. • Fail (Replacement Recommended) - NBP passed its self-test but has exceeded 50,000 cycles. 	<p>If the test fails, call for service to repair the NBP module. If NBP monitoring is essential to patient care, take the device out of use.</p> <p>If calibration is due or overdue, arrange for a qualified service provider to perform the calibration.</p> <p>If replacement is recommended, call for service.</p>
CO ₂	<ul style="list-style-type: none"> • Pass - CO₂ passed its self-test. • Fail - CO₂ is not functioning. • Pass (Cal Due) - CO₂ is passed its self-test and is due for calibration. • Fail (Cal Overdue) - CO₂ passed its self-test and is overdue for calibration. Measurements may be inaccurate. • Fail (Replacement Recommended) - CO₂ passed its self-test but has exceeded 15,000 operating hours. 	<p>If the test fails, call for service to repair the CO₂ module. If CO₂ monitoring is essential to patient care, take the device out of use.</p> <p>If calibration is due or overdue, arrange for a qualified service provider to perform the calibration.</p> <p>If replacement is recommended, call for service.</p>
Bluetooth	<ul style="list-style-type: none"> • Pass - A Bluetooth card is detected and communicating. • Fail - A Bluetooth card is not installed or is not functioning. 	If the test fails, call for service.
Printer	<ul style="list-style-type: none"> • Pass - The printer passed its self-test. • Fail - The printer needs repair. 	If the test fails, call for service.

Operational Check Summary

The Operational Check Summary lists the results from the last 60 Operational Checks. Test results are reported as described in Table 37.

To view the Operational Check Summary:

- 1 Turn the Therapy Knob to **Monitor**.
- 2 Press the Menu Select  button.
- 3 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 4 Select **Operational Check** and press the Menu Select button.
- 5 Using the Navigation buttons, select **Op Check Summary** and press the Menu Select button.
- 6 Press the Menu Select button to acknowledge the message, **Leaving Normal Operational Mode**. The Operational Check Summary screen is displayed.
- 7 Press the [**Print**] soft key to print the report.

Table 38 Operational Check Summary Results

Result	RFU Indicator	Definition	Required Action
Pass	Hourglass	All tests passed	None
Fail/DX	Solid red X, chirp	A problem has been detected that may prevent the delivery of a shock, pacing, or ECG acquisition.	Turn the Therapy Knob to Monitor. An inop indicating the problem is displayed. See Chapter 16, Troubleshooting, for the corrective action.
Fail/CX	Solid red X, chirp.	A problem has been detected with a cable.	Turn the Therapy Knob to Monitor. An inop indicating the failed cable is displayed. Replace the failed cable.
Fail/BF	N/A ¹	A battery failure was detected.	Replace the battery.
Fail/D	Hourglass	A problem has been detected with a component that does not affect therapy delivery.	Turn the Therapy Knob to Monitor. An inop indicating the failed component is displayed. See Chapter 16, Troubleshooting, for the corrective action.
Fail/S	Hourglass	Compression Sensor failure.	Check the Compression Sensor and cable connections. If necessary, replace the Compression Sensor.

1. The Automated Tests continually check for a low battery condition and set the RFU Indicator appropriately.

Battery Maintenance

Battery maintenance is essential to ensure that the battery's state of charge is accurately reported, there is sufficient charge and capacity to operate your HeartStart MRx, and battery life is optimized.

Battery maintenance begins upon receipt of a new battery, and continues throughout the life of the battery. Detailed information on battery care is available in the Application Note, "*M3538A Lithium Ion Battery Characteristics and Care*", which was provided with your HeartStart MRx.

Table 39 lists battery maintenance activities and when they should be performed.

Table 39 Battery Maintenance Procedures

Activity:	When to Perform:
Perform a visual inspection.	As part of the Operational Check.
Charge the battery.	Upon receipt, after use, or if the message Batteries Low is displayed.
Perform a calibration.	When the Operational Check test results state Calibration Recommended , or every 6 months, whichever comes first.
Store batteries in a state of charge in the range of 20% - 40%	When not in use for an extended period of time.
Discard the battery.	When there are visual signs of damage or calibration reports less than 80% capacity.

Battery Capacity

A new, fully-charged M3538A battery, operating at room temperature 25°C(77°F), provides approximately 5 hours of monitoring, with ECG, SpO₂ and CO₂ monitored continuously and NBP measured every 15 minutes, or at least 50 full-energy discharges.

Battery Life

Battery life depends on the frequency and duration of use. When properly cared for, the M3538A Lithium Ion battery has a useful life of approximately 2 years. To optimize performance, a fully (or nearly fully) discharged battery should be charged as soon as possible.

Charging Batteries

The M3538A Lithium Ion Battery should be charged in either the HeartStart MRx or in a Philips-approved battery support system. The two methods of charging in the HeartStart MRx are as follows:

Using AC power - Insert the battery to be charged into Battery Compartment A. Insert the AC Power Module into Battery Compartment B and connect to an AC power source.

Using DC power - Insert a battery to be charged into Battery Compartment A. If a second battery is in need of charging, insert it in Battery Compartment B. Connect the DC Power Module to the HeartStart MRx and the DC power source.

Once AC or DC power is applied, the External Power Indicator turns green and batteries in the HeartStart MRx charge. Batteries are charged one at a time. With the HeartStart MRx turned off and at a temperature of 25°C (77°F), a fully discharged battery typically charges to 80% of its capacity in 2 hours, and to 100% of its capacity in 3 hours. Batteries charge at a slower rate with the device turned on.

Batteries should be charged at temperatures between 0°C (32°F) and 45°C(113°F).

Charge Status

You can check the battery's state of charge by:

- periodically pushing the fuel gauge button on the battery to illuminate the fuel gauge. Each LED represents a charge of approximately 20% of capacity.
- turning the Therapy Knob to any mode of operation and observing the battery power indicators displayed in the General Status area (see "General Status" on page 16).

Battery Calibration

Battery capacity diminishes with use and age. Battery calibration checks to see if the battery is nearing the end of its useful life and should be discarded. Battery calibration also ensures that the fuel gauge provides accurate estimates of the battery's state of charge, based on the total available capacity.

Calibrate a battery when the **Cal Recommended** message appears during an Operational Check, or every 6 months, whichever comes first. Battery calibration may be performed in the HeartStart MRx or in a Philips-approved battery support system. To calibrate a battery in the HeartStart MRx:

- 1 Connect the HeartStart MRx to AC or DC power.
- 2 Insert the battery to be calibrated into Battery Compartment A or B.
- 3 Turn the Therapy Knob to **Monitor**.
- 4 Press the Menu Select  button.
- 5 Using the Navigation buttons, select **Other** and press the Menu Select button.
- 6 Select **Battery Calibration** and press the Menu Select button.
- 7 Press the Menu Select button to acknowledge the message, **Leaving Normal Operational Mode**. The Calibration view is displayed. If external power is not detected, you are prompted to **Apply External Power**. If there is no battery in either battery compartment, you are prompted to **Insert Battery**. If there are batteries in both battery compartments, you are prompted to select which battery to calibrate.

- 8 Press the [Start] soft key to begin calibrating.

The calibration procedure charges the battery to full capacity, drains the battery in preparation for calibration, calibrates the battery, and then charges it again following calibration. Once you see the message, **Calibration Complete. The battery charges faster when the device is turned off**, you may turn the Therapy Knob to **Off** to allow the battery to charge more quickly.

Calibration takes approximately 11 hours to complete in the HeartStart MRx. Progress is shown on the display. It takes significantly less time to calibrate in a Philips-approved battery support system. Monitoring/therapy functions are not available during battery calibration in the MRx. If it is necessary to terminate calibration to resume clinical use, press the [Cancel] soft key.

WARNING Battery calibration is terminated if external power or the battery being calibrated is removed before the calibration process is completed. If calibration is terminated, the battery will not be calibrated and its capacity may be very low.

Calibration Results

At the completion of battery calibration, a **Pass** or **Fail** is reported to indicate whether calibration completed successfully. In addition, an estimate of battery capacity is provided so that you can determine if the battery is fit for use. If the capacity is:

- $\geq 80\%$ continue to use the battery
- $< 80\%$ discard the battery

Storing Batteries

Batteries should be rotated regularly to ensure even usage. When storing batteries, make sure that the battery terminals do not come in contact with metallic objects.

If batteries are stored for an extended period of time, they should be stored in a cool place, with a partial charge of 20% (1 LED illuminated) to 40% (2 LED's illuminated) capacity. Storing batteries in a cool place slows the aging process. The ideal storage temperature is 15°C (60°F). Batteries should not be stored at temperatures outside the range of -20°C (-4°F) to 60°C (140°F).

-
- CAUTION**
- Do not store batteries in the HeartStart MRx if it is out of service for an extended period of time.
 - Storing batteries at temperatures above 38°C (100°F) for extended periods of time significantly reduces a battery's life expectancy.
-

Stored batteries should be charged every 2 months to 20% - 40% of their full capacity. They should be charged to full capacity prior to use.

Discarding Batteries

Batteries should be discarded if there are visual signs of damage or if they fail calibration. Batteries should be discarded in an environmentally safe manner. Properly dispose of batteries according to local regulations.

WARNING Do not disassemble, puncture, or incinerate batteries. Be careful not to short the battery terminals because this could result in a fire hazard.

CAUTION Use caution when handling, using, and testing the batteries. Do not short circuit, crush, drop, mutilate, puncture, apply reverse polarity, expose to high temperatures, or disassemble. Misuse or abuse could cause physical injury.

Cleaning Instructions

Listed below are recommendations for cleaning the HeartStart MRx and its associated accessories.

-
- CAUTION**
- The HeartStart MRx, along with its accessories and supplies, may not be autoclaved, steam sterilized, ultrasonically cleaned, or immersed unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.
 - Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
 - Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
 - Do not clean electrical contacts or connectors with bleach.
 - Disinfect the device as determined by your institution's policy to avoid long-term damage to the device.
-

Monitor/Defibrillator

The following cleaning products may be used to clean the exterior surfaces of the monitor/defibrillator, as well as the batteries and data card:

- Isopropyl alcohol (70% solution in water).
- Mild soap and water.
- Sodium hypochlorite (chlorine bleach) (3% solution in water).
- Quaternary ammonium compounds (21% quaternary ammonium content) (such as Steris Coverage Plus NPD) (.5 oz. per gallon water - one part Coverage Plus NPD to 255 parts water).

Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.

When cleaning, do not immerse. Wring any excess moisture from the cloth before cleaning. Be sure to avoid pouring fluids on the device, and do not allow fluids to penetrate the exterior surfaces of the device. To prevent scratching the display, the use of a soft cloth is recommended.

Printer Printhead

If the printout has light or varying print density, clean the printhead to remove any buildup of paper residue.

To clean the printhead:

- 1 Push the printer door latch to open the door.
- 2 Remove the roll of paper.
- 3 Clean the printhead surface (above the brush) with a cotton swab dipped in isopropyl alcohol.
- 4 Replace the roll of paper (See Figures 20 and 21 on pages 36 and 37).

Paddles, Therapy Cable

External non-sterilizable paddles and the Therapy cables may be cleaned with a soft cloth moistened with:

- Mild soap and water.
- Gluteraldehyde solution (such as Cidex) (3.4% gluteraldehyde content).
- Sodium hypochlorite (chlorine bleach) (3% solution in water).
- Quaternary ammonium compounds (21% quaternary ammonium content) (such as Steris Coverage Plus NPD) (.5 oz. per gallon water - one part Coverage Plus NPD to 255 parts water).
- Isopropyl alcohol (70% solution in water).

CAUTION The paddles and Therapy cables may not be ultrasonically cleaned or immersed. Nor may they be autoclaved or ETO sterilized.

NOTE For information about cleaning and sterilizing internal and external sterilizable paddles, see the *Sterilizable Defibrillator Paddles Instructions for Use*, Part Number M4741-91000.

Philips' disposable sterile internal defibrillation paddles, multifunction electrode pads and monitoring electrodes are single use items and do not require cleaning.

ECG Cable

The ECG cable may be cleaned by wiping it with any of the following:

- Gluteraldehyde solution (such as Cidex) (2% solution in water).
- Alcohol-free hand soap.
- Sodium hypochlorite (chlorine bleach) (3% solution in water). This solution may discolor the cable.

CAUTION Do not ultrasonically clean, immerse, autoclave, or steam sterilize the ECG cable. Do not clean the ECG cable with alcohol. Do not clean electrical contacts or connectors with chlorine bleach. Alcohol can cause the plastic to become brittle and may cause the cable to fail prematurely.

Carrying Case

The carrying case may be cleaned by hand with mild soap and water. Fabric stain removers may be used to remove stubborn stains. Air dry the carrying case. Do not wash or dry by machine.

NBP Cuff

The cuff can be disinfected by immersion in a decontamination solution of 70-85% isopropyl alcohol, but remember to remove the rubber bag if you use this method. The cuff should not be dry cleaned.

The cuff can also be machine-washed or hand-washed as recommended by the manufacturer; the latter method will prolong the service life of the cuff. Before washing, remove the latex rubber bag and, for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, then reinsert the rubber bag.

SpO₂ Sensor and Cable

To clean the SpO₂ sensor and cable, follow the instructions provided with the accessory.

Disposing of the HeartStart MRx

Prior to disposal, remove the batteries. Then dispose of the device in accordance with your country's regulations for equipment containing electronic parts.

WARNING Disposal of the device with the battery inserted presents a potential shock hazard.

To avoid contaminating or infecting personnel, the environment, or other equipment, make sure you disinfect and decontaminate the monitor/defibrillator appropriately prior to disposal.

Disposing of Empty Calibration Gas Cylinders

To dispose of empty calibration gas cylinders:

- 1 Empty the cylinder completely by pushing the pin of the regulator valve or by pulling out the pin of the fill valve using a tire valve stem wrench or a pair of needle nose pliers.
- 2 When the cylinder is empty, either remove the valve stem from the fill (or regulator) hole, or drill a hole in the cylinder.
- 3 Write "Empty" on the cylinder and dispose of it appropriately for scrap metal.

WARNING Ensure that the cylinder is completely empty before trying to remove the valve stem or drill the tank.

Supplies and Accessories

Approved supplies and accessories for your HeartStart MRx are listed in the following tables. To order: In the USA, call 1-800-225-0230 (pads, electrodes, cables, paper, etc.).

Outside the USA, contact your local Philips Medical Systems Sales Office, your authorized Philips Medical Systems Dealer or Distributor, or visit our website at: <http://shop.medical.philips.com> and follow the Supplies link.

Table 40 Supplies and Accessories

External Paddles	
M3542A	Standard External Paddles
M3543A	Water Resistant External Paddles
M4745A	Sterilizable External Paddles

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
989803127121	Large Disposable Switched
989803127131	Medium Disposable Switched
989803127141	Small Disposable Switched
989803127151	Large Disposable Switchless
989803127161	Medium Disposable Switchless
989803127171	Small Disposable Switchless
M4740A	Internal Paddles Adapter Cable

Multifunction Electrode Pads	
M3713A	Adult Plus
M3716A	Adult Radiolucent
M3717A	Pediatric Plus
M3718A	Adult Radiotransparent/Reduced Skin
M3719A	Pediatric Radiotransparent/Reduced Skin
M3501A	Defib Adult, AAMI
M3502A	Defib Adult, IEC
M3503A	Defib Pediatric, IEC
M3504A	Defib Pediatric, AAMI

Pads Cables	
M3507A	Defib Hands-free Pads Cable, barrel style
M3508A	Hands-free Pads Cable, plug style
05-10200	Pads Adapter (use with M3507A)

ECG Monitoring Electrodes	
M2202A	High-Tack Foam ECG Electrodes, 5 electrodes/pack (60 packs/case)

12-Lead ECG Cable Set	
M3525A	10-lead ECG Trunk Cable, 12-pin Connector (for 3-Lead and 12-Lead use)
M3526A	3-wire Lead Set with Snap (AAMI)
M3527A	Add 7-wire Lead Set for 12-Lead use (AAMI)
M3528A	3-wire Lead Set with Snap (IEC)
M3529A	Add 7-wire Lead Set for 12-Lead use (IEC)
M5530A	Combiner Plug for 3-wire Lead Set for use with M3526A/M3528A
M1949A	10-lead ECG Patient Trunk Cable, 12-pin ECG Input Connector (for 5-Lead and 12-Lead use)
M1968A	10-electrode Cable Set, Extremities, Grabber (use with M1976A) (AAMI)
M1976A	10-electrode Cable Set, Chest, Grabber (use with M1968A) (AAMI)
M1971A	10-electrode Cable Set, Extremities, Grabber (use with M1978A) (IEC)
M1978A	10-electrode Cable Set, Chest, Grabber (use with M1971A) (IEC)

3-Lead ECG Cable Set	
M1500A	3-lead ECG Trunk Cable (AAMI)
M1605A	3-lead ECG Lead Set with Snaps (AAMI)
M1510A	3-lead ECG Trunk Cable (IEC)
M1615A	3-lead ECG Lead Set with Snaps (IEC)

5-Lead ECG Cable Set	
M1520A	5-lead ECG Trunk Cable (AAMI)
M1625A	5-lead ECG Lead Set with Snaps (AAMI)
M1530A	5-lead ECG Trunk Cable (IEC)
M1635A	5-lead ECG Lead Set with Snaps (IEC)

Sync Cables	
M1783A	Sync Cable (8 ft.)
M5526A	Sync Cable (25 ft.)

SpO₂ Sensors and Cables	
M1191A	Reusable SpO ₂ Sensor - Adult Finger
M1192A	Reusable SpO ₂ Sensor - Pediatric/Small Adult Finger
M1193A	Reusable SpO ₂ Sensor - Adult Thumb
M1194A	Reusable SpO ₂ Sensor - Adult/Pediatric Ear Clip
M1195A	Reusable SpO ₂ Sensor - Infant
M1941A	SpO ₂ Extension Cable, 2 m
M1943A	Nellcor SpO ₂ Sensor Adapter Cable, 1 m (use with M1903/4B)
M1131A	Disposable SpO ₂ Sensor - Pediatric/Adult Finger
M1903B	Disposable SpO ₂ Sensor - Pediatric Finger (Available outside the US only)
M1904B	Disposable SpO ₂ Sensor - Adult Finger (Available outside the US only)

NBP	
	Interconnect Tubing
M1598B	Adult Pressure Interconnect Cable (1.5 m)
M1599B	Adult Pressure Interconnect Cable (3 m)
	Reusable Blood Pressure Cuffs
40400A	Reusable NBP Cuff Kit, 3 sizes (pediatric, adult, large adult)
40400B	Reusable NBP Cuff Kit, 5 sizes (infant, pediatric, adult, large adult, thigh)
40401A	Traditional Reusable NBP Cuff - Infant
40401B	Traditional Reusable NBP Cuff - Pediatric
40401C	Traditional Reusable NBP Cuff - Adult
40401D	Traditional Reusable NBP Cuff - Large Adult
40401E	Traditional Reusable NBP Cuff - Thigh
M4552A	Antimicrobial Reusable NBP Cuff - Infant
M4553A	Antimicrobial Reusable NBP Cuff - Pediatric
M4554A	Antimicrobial Reusable NBP Cuff - Small Adult
M4555A	Antimicrobial Reusable NBP Cuff - Adult
M4557A	Antimicrobial Reusable NBP Cuff - Large Adult
M4559A	Antimicrobial Reusable NBP Cuff - Thigh
M1572A	Multi-Patient Comfort Cuffs - Pediatric
M1573A	Multi-Patient Comfort Cuffs - Small Adult
M1574A	Multi-Patient Comfort Cuffs - Adult
M1575A	Multi-Patient Comfort Cuffs - Large Adult
	Disposable Blood Pressure Cuffs
M4572A	Soft Single-Patient Disposable Cuff - Infant
M4573A	Soft Single-Patient Disposable Cuff - Pediatric
M4574A	Soft Single-Patient Disposable Cuff - Small Adult
M4575A	Soft Single-Patient Disposable Cuff - Adult
M4576A	Soft Single-Patient Disposable Cuff - Adult X-Long
M4577A	Soft Single-Patient Disposable Cuff - Large Adult
M4578A	Soft Single-Patient Disposable Cuff - Large Adult X-Long
M4579A	Soft Single-Patient Disposable Cuff - Thigh

EtCO₂	
	Intubated Circuits
M1920A	Filter Line Set - Adult/Pediatric (25 sets/case)
M1921A	Filter H Set - Adult/Pediatric (25 sets/case)
M1923A	Filter H Set - Infant/Neonatal (yellow, 25 sets/case)
	Non-Intubated Dual Purpose Circuits (CO₂ + O₂)
M2520A	Smart CapnoLine - Pediatric
M2522A	Smart CapnoLine - Adult
	Non-Intubated Single Purpose Circuits (CO₂)
M2524A	Smart CapnoLine - Pediatric
M2526A	Smart CapnoLine - Adult

Power	
M3538A	Lithium Ion Battery
M3539A	AC Power Module
M5529A	DC Power Module
M5528A	DC Power Module Mounting Bracket
989803135301	2-Bay Battery Support System for Lithium Ion Batteries
989803135331	4-Bay Battery Support System for Lithium Ion Batteries
989803135341	4-Bay Battery Support System for Sealed Lead Acid and Lithium Ion Batteries

Paper	
40457C	50 mm Chemical Thermal Paper, Gray Grid (10 rolls)
40457D	50 mm Chemical Thermal Paper, Gray Grid (80 rolls)
989803138171	75 mm Chemical Thermal Paper, Gray Grid (10 rolls)
989803138181	75 mm Chemical Thermal Paper, Gray Grid (80 rolls)

Color Handle	
M5521A	Green
M5522A	Blue
M5523A	Yellow
M5524A	Rose
M5525A	Gray

Miscellaneous	
M1781A	Test Load for use with M3507A Pad Cable
M3725A	Test Load for use with M3508A Pad Cable
M3541A	Carrying Case
M3545A	Data Card and Tray

Troubleshooting

If the HeartStart MRx detects an error or potential problem during use, it displays an inop statement or a message window with text to guide you. Inop statements and messages are often accompanied by a voice prompt or an audible beeping tone. This chapter describes the inop statements and messages that you may see, along with other symptoms, and provides suggestions for what to do. In addition, this chapter provides an explanation of audible tones and information on contacting your service representative.

If you are unable to resolve a problem using the suggestions in this chapter:

- Run an Operational Check to determine if there is a malfunction requiring service.
- If a malfunction is identified, call for service.
- Take the HeartStart MRx out of use if there is a malfunction affecting ECG monitoring, defibrillation, or pacing. For malfunctions related to SpO₂, NBP, or CO₂ monitoring, or 12-Lead functionality, take the device out of service if the function is essential to patient care in your organization.

Results of Automated Tests associated with critical functionality of the device are reported through the Ready For Use indicator and the Automated Test Summary report. For information on responding to these results, see “Ready For Use Indicator” on page 155. To respond to errors reported through Operational Check see “Operational Check Test Results (Versions B.05 and Greater)” on page 175.

For further technical and repair information, refer to the HeartStart MRx Service Manual, Part Number M3535-90900.

WARNING Product servicing and repair should only be performed by qualified service personnel.

Symptoms

The following tables list symptoms, inop statements, and messages that you may encounter, along with possible causes of the problem, and potential solutions. Symptoms are characterized by functionality.

Table 41 General Problems

Symptom	Possible Cause	Possible Solution
The HeartStart MRx does not turn on.	There is no power.	<ul style="list-style-type: none"> • Insert a fully charged battery. • Connect to AC/DC power.
Audio is too low or absent.	The QRS , Voice , or Alarm volume is configured to a Very Soft or Off setting.	Use the Volume menu to adjust the volume of the QRS beeper, voice prompts, and/or alarms.
Low battery life (appears to deplete quickly).	The battery may be nearing its end of life.	Replace the battery.
Battery charge indicators inaccurate.	The battery may need calibration.	Calibrate the battery.
All Settings Have Been Reset To Default Values message.	A power failure or critical software error has occurred.	Reset alarms, waveforms, volumes, and other settings previously defined for the current patient.
All Settings Have Been Set To Factory Default Values message, accompanied by a Power Interrupted or Device Restarted message.	Corrupt or incomplete configuration file.	Reload device configuration file.
Batteries Low message.	The batteries may not have enough remaining charge to provide 10 minutes of monitoring time or six 200J shocks.	<ul style="list-style-type: none"> • Insert a fully charged battery. • Connect to AC/DC power.
Battery A Low - Switching to Battery B (or vice-versa) message.	The specified battery needs charging.	Charge the low battery.
Critical Failure Detected. Service Unit. message. or Device Error. Service Required. message	Failure detected during start-up.	Take the device out of use and call for service.
External Power Interrupted message.	AC/DC power was removed; now operating from battery power.	Connect to AC/DC power, if appropriate.
Fan Failure message.	The internal fan should be running but it is not.	Call for service.
Internal Memory Failure message. INOP message appears every time the device is turned on.	<p>The internal memory card has been reformatted after failing an automated test.</p> <p>Patient data cannot be stored in internal memory because the internal memory card is not recognized.</p>	<p>Although all previous data stored on the card has been erased, it is now ready once again to record data.</p> <p>Call for service.</p>

Table 41 General Problems (Continued)

Symptom	Possible Cause	Possible Solution
Internal Memory Full message.	Event Summary data for the current patient case exceeds the storage capacity of internal memory.	<ul style="list-style-type: none"> • Begin a new patient case. • Print the Event Summary Report. Begin a new patient case.
Power Supply Failure inop.	There is a problem with the internal power supply.	Remove the device from use and call for service.
Replace Clock Battery message.	The battery on the internal clock needs to be replaced.	Call for service.
Shock Equip Malfunction inop.	A shock can not be delivered due to a hardware failure.	Remove the device from use and call for service.
Shutting Down in 1 Minute message.	Very low battery and the device is not connected to AC/DC power.	Insert a charged battery and/or connect to AC/DC power.
Shutting Down Now message.	Battery charge is depleted and the device is not connected to AC/DC power.	Insert a charged battery and/or connect to AC/DC power. Settings for the current patient may need to be reset.

Table 42 ECG Monitoring Problems

Symptom	Possible Cause	Possible Solution
QRS beeper inaudible or beeps do not occur with each QRS complex.	<p>The QRS volume is configured to Off or the setting is too low.</p> <p>The QRS volume was turned Off or set too low through the Volume menu.</p> <p>The amplitude of the QRS complex is too small to detect.</p>	<p>Configure the QRS beeper volume.</p> <p>Adjust the volume through the Volume menu.</p> <p>Select a different lead.</p>
Poor ECG signal quality (noisy trace, wandering baseline, etc.) from signal acquired through monitoring electrodes.	<p>The monitoring electrodes are not making proper contact with the patient.</p> <p>The monitoring electrodes are outdated or dried-out.</p> <p>Radio frequency interference (RFI) is causing artifact.</p> <p>The ECG cable may be faulty.</p>	<p>Check that the monitoring electrodes are properly applied. If necessary, prepare the patient's skin and apply new electrodes.</p> <p>Check the date code on the electrodes. Do not open the electrode package until immediately prior to use.</p> <p>Relocate or turn off equipment that may be causing RFI. Try repositioning cables/leads.</p> <p>Run the Operational Check with the ECG cable. If the test fails, run it without the ECG cable. If the test passes, replace the cable. If not, remove the device from use and call for service.</p>
Poor ECG signal quality (noisy trace, wandering baseline, etc.) from signal acquired through paddles/pads.	<p>The paddles/pads are not making proper contact with the patient.</p> <p>The pads are outdated or dried-out.</p> <p>Radio frequency interference (RFI) is causing artifact.</p> <p>The paddles/pads cable may be faulty.</p>	<p>Ensure proper skin preparation and correction application. If necessary, apply new pads.</p> <p>Check the date code on the pads. Do not open the pads package until immediately prior to use.</p> <p>Relocate or turn off equipment that may be causing RFI. Try repositioning the pads cable.</p> <p>Run the Operational Check with the pads cable. If the test fails, run it without the pads cable. If the test passes, replace the cable. If not, remove the device from use and call for service.</p>
ECG Unplugged inop.	No ECG cable is connected and the configured/selected ECG in Wave Sector 1 is from leads	Check that the ECG cable is firmly connected. Connect an ECG cable or a pads therapy cable.
Leads Off inop.	<p>Electrode(s) for the configured/selected ECG in Wave Sector 1 may be off or insecurely attached.</p> <p>Lead(s) are not making proper contact with the patient.</p>	<p>Apply electrodes/pads to the patient.</p> <p>Check that monitoring electrodes are properly applied. If necessary, prepare the patient's skin and apply new electrodes.</p>
Solid flat line - no waveform, no Leads Off inop.	Short in patient cable or leads.	Run the Operational Check with the ECG cable. If the test fails, run it without the ECG cable. If the test passes, replace the cable. If not, remove the device from use and call for service.

Table 42 ECG Monitoring Problems (Continued)

Symptom	Possible Cause	Possible Solution
Pads/Paddles Off inop	Pads/Paddles for Wave Sector 1 are off or insecurely attached.	<ul style="list-style-type: none"> • Check that pads/paddles are properly applied. If necessary, replace the pads. • Change the ECG in Wave Sector 1 to a lead derived from monitoring electrodes.
There is a dashed line (----) on the display instead of an ECG.	ECG data is not being acquired.	<ul style="list-style-type: none"> • Check the pads, paddles or ECG cable is connected. • Check the pads, paddles, or monitoring electrodes are properly applied. • Check that the desired lead is selected.
"Lead-wire" Off message displayed in wave sector.	The specified monitoring electrode is off or not making proper contact with the patient.	Check that the monitoring electrode is properly applied.
Check Limb Leads message displayed in wave sector.	2 or more limb lead electrodes are off or not making proper contact with the patient.	Check that the limb lead electrodes are properly applied.
Pads Off message displayed in a wave sector.	Pads are not making proper contact with the patient.	Make sure the pads therapy cable is connected and pads are properly applied. If necessary, prepare the patient's skin and apply new pads.
Cannot Analyze ECG inop.	The arrhythmia algorithm cannot reliably analyze the ECG data.	Check ECG signal quality. If necessary, improve lead position or reduce patient motion.
Pads ECG Cable Failure inop.	A short was detected between a lead wire and ground.	Replace the pads cable and perform an Operational Check.
ECG Cable Failure inop.	A short has been detected between a lead wire and ground.	Replace the ECG cable.
Pads ECG Equip Malfunction inop.	A device hardware failure was detected.	Perform an Operational Check. If the Pads/Paddles ECG Test fails with Therapy cable, disconnect the Therapy cable from the device when prompted in order for the Pads/Paddles ECG Test to run without the cabled connected. If the Pads/Paddles ECG test passes without the cable connected, replace the Therapy cable.

Table 42 ECG Monitoring Problems (Continued)

Symptom	Possible Cause	Possible Solution
ECG Equip Malfunction inop.	A device hardware failure was detected.	Disconnect the ECG cable and perform an Operational Check. If the Leads ECG Test fails, remove the device from use and call for service. If the Leads ECG Test passes, replace the ECG cable and perform an Operational Check.
Lead Select button does not respond.	The 12-lead function is active. Device is in AED Mode.	Exit the 12-lead function. None.
Lead Select button does not display a pads choice.	The pads therapy cable is not connected. Demand mode pacing is active.	Connect the pads therapy cable. Exit pacing or choose fixed mode pacing.
One or more controls do not respond (e.g., select lead or soft keys).	Faulty control or connection.	Remove the device from use and call for service.

Table 43 NBP Monitoring Problems

Symptom	Possible Cause	Possible Solution
NBP Cuff Not Deflated inop. The NBP numeric value is replaced with a -?-.	The NBP cuff pressure has been greater than 5mmHg (0.67kPa) for more than 3 minutes.	<ul style="list-style-type: none"> Release pressure in the cuff (disconnect cuff from tubing). Replace the cuff. If the problem persists, call for service.
NBP Cuff Overpressure inop. The NBP numeric value is replaced with a -?-.	The NBP cuff pressure has exceeded the overpressure safety limit of 260 mmHg.	No action is required, the cuff should deflate automatically. If not, disconnect the cuff and deflate it.
NBP Interrupted inop. The NBP numeric value is replaced with a -?/-?-(?-).	The measurement needed longer than the maximum time provided for inflation, deflation, or the total measurement.	<ul style="list-style-type: none"> Check that the cuff size is appropriate. Check cuff placement.
NBP Measurement Failed inop. The NBP numeric value is replaced with a -?/-?-(?-).	A measurement value could not be obtained.	Check cuff size and placement.
NBP Calibration Overdue inop.	NBP module needs calibration. Calibration should be performed once a year or every 10,000 cycles, whichever comes first.	Call for service of the NBP module. Do not use the NBP monitoring capabilities until the calibration has been performed. If NBP monitoring is essential to patient care, take the device out of use.
NBP Equip Malfunction inop.	NBP hardware failure.	Call for service of the NBP module. Do not use the NBP monitoring capabilities. If NBP monitoring is essential to patient care, take the device out of use.

Table 43 NBP Monitoring Problems

Symptom	Possible Cause	Possible Solution
NBP Service Required inop.	The NBP module has reached its end of life, defined as 50,000 cycles.	Call for service of the NBP module. Do not use the NBP monitoring capabilities. If NBP monitoring is essential to patient care, take the device out of use.
Measurement cycle doesn't automatically start.	NBP is not configured for automatic measurements. Automatic measurements are not scheduled for the current patient. The [Start NBP] soft key has not been pressed.	Check/modify the configuration as needed. Use the Measurements/Alarms menu to define an automatic schedule of measurements for the current patient. Press the [Start NBP] soft key.
The pump operates, but the cuff does not inflate or fails to inflate fully.	Defective cuff. Poor connection between the cuff and the HeartStart MRx.	Replace the cuff. Check connections and replace tubing, if needed.
NBP measurements appear high/low.	The cuff size is too small/large for the patient.	Use the correct cuff size.

Table 44 SpO₂ Monitoring Problems

Symptom	Possible Cause	Possible Solution
The SpO ₂ waveform is not displayed.	The sensor is not properly connected or the sensor cable is damaged. The SpO ₂ waveform is not configured to be displayed and there is not an unused wave sector.	<ul style="list-style-type: none"> Check the sensor connection and cable. Try another sensor. Use the Waves menu to select a wave sector for display of the SpO ₂ waveform.
SpO ₂ Non Pulsatile inop.	The patient's pulse is absent or too weak to be detected. The sensor has come off.	<ul style="list-style-type: none"> Check perfusion at the measurement site. Check that the sensor is applied properly. Make sure the sensor site has a pulse. Relocate the sensor to another site with improved circulation. If the message occurs due to NBP measurement on the same limb, wait until the NBP measurement is finished. Try another sensor.
SpO ₂ Erratic inop. The SpO ₂ numeric value is replaced with a -?-.	SpO ₂ measurement readings are erratic.	<ul style="list-style-type: none"> Check that the sensor is applied properly. Make sure the sensor site has a pulse. Relocate the sensor to another site with improved circulation. Try another sensor.
SpO ₂ Noisy Signal inop.	Excessive patient movement or electrical interference.	<ul style="list-style-type: none"> Minimize patient movement. Make sure the sensor cable is not positioned too close to power cables.
SpO ₂ Interference inop. The SpO ₂ numeric value is replaced with a -?-.	Ambient light is too high. There is too much interference. The sensor is damaged.	Cover the sensor with an opaque material to minimize ambient light. Make sure the sensor cable is not positioned too close to power cables. Make sure that the sensor cable is not damaged.
SpO ₂ Unplugged inop.	The SpO ₂ sensor is not connected.	Check the SpO ₂ connection.
SpO ₂ Unplugged. Turn off SpO₂? message appears when the device is turned on and the SpO ₂ sensor is not connected.	The SpO ₂ sensor is not connected. The software was not upgraded after an SpO ₂ repair or upgrade was performed.	<ul style="list-style-type: none"> Check that the sensor connection is secure. Try another sensor. Call for service.

Table 44 SpO₂ Monitoring Problems (Continued)

Symptom	Possible Cause	Possible Solution
SpO₂ Sensor Malfunction inop. The SpO ₂ numeric value is replaced with a -?-.	The SpO ₂ sensor or cable is faulty.	<ul style="list-style-type: none"> Try another sensor. If the problem persists, call for service of the SpO₂ module. If SpO₂ monitoring is essential to patient care, take the device out of use.
SpO₂ Equip Malfunction message.	Faulty SpO ₂ hardware.	<ul style="list-style-type: none"> Call for service of the SpO₂ module. If SpO₂ monitoring is essential to patient care, take the device out of use.
SpO₂ Extended Update inop. The SpO ₂ numeric value is replaced with a -?-.	An NBP measurement or an excessively noisy signal is delaying display/update of the SpO ₂ measurement for more than 30 seconds (60 seconds if an NBP measurement is in progress).	<ul style="list-style-type: none"> Wait until the NBP measurement is complete. Try another sensor site. Move sensor to a different limb from the NBP cuff.
SpO₂ Low Perfusion inop. The SpO ₂ numeric value is replaced with a -?-.	The SpO ₂ signal is too low to give an accurate reading.	<ul style="list-style-type: none"> Check the sensor is applied properly. Try another sensor type.

Table 45 12-Lead Transmission Problems (Bluetooth)

Symptom	Possible Cause	Possible Solution
Bluetooth Malfunction inop.	<ul style="list-style-type: none"> The MRx does not have a Bluetooth card. The Bluetooth card is incompatible. The Bluetooth card is corrupt. 	<ul style="list-style-type: none"> Call for service. Call for service. Call for service.
No Bluetooth Devices Detected message.	<ul style="list-style-type: none"> The MRx could not discover the Bluetooth device. The Bluetooth device is not turned on. The Bluetooth device is not authorized to pair with the MRx. The Bluetooth device is not within range. The Bluetooth card is corrupt. 	<ul style="list-style-type: none"> Try searching again for Bluetooth devices. Make sure the Bluetooth device is turned on. See the Bluetooth device's documentation to set authorization. Move the Bluetooth device closer to the MRx, within the transmitting range. (See the <i>12-Lead Transmission Implementation Guide</i> for information on transmission ranges.) Call for service.
No Bluetooth Profiles Configured message.	<ul style="list-style-type: none"> There are no profiles configured for the Bluetooth device. 	<ul style="list-style-type: none"> Create a profile for the Bluetooth device. See the <i>12-Lead Transmission Implementation Guide</i> for more information.
Transmission Settings Have Not Been Configured message.	<ul style="list-style-type: none"> The Hub information settings are not correct. 	<ul style="list-style-type: none"> Modify the Hub Configuration settings on the MRx as needed.
Bluetooth Connection Lost message.	<ul style="list-style-type: none"> The Bluetooth device is not within range. 	<ul style="list-style-type: none"> Move the Bluetooth device closer to the MRx, within the transmitting range. (See the <i>12-Lead Transmission Implementation Guide</i> for information on transmission ranges.)
Bluetooth device pairing failed message.	<ul style="list-style-type: none"> The wrong pass code was entered on the Bluetooth device The pairing process timed out. The Bluetooth card is corrupt. 	<ul style="list-style-type: none"> Check the pass code. Select the device from the MRx Add Devices list and pair again. Try pairing again. Call for service.
No Bluetooth Devices Configured message.	<ul style="list-style-type: none"> The Bluetooth device has not been paired with the MRx. 	<ul style="list-style-type: none"> Pair the Bluetooth device with the MRx.

Table 45 12-Lead Transmission Problems (Bluetooth) (Continued)

Symptom	Possible Cause	Possible Solution
No transmission devices detected message.	<ul style="list-style-type: none"> The Bluetooth device is not turned on. The Bluetooth device is not within range. The Bluetooth pairing information has been lost. The Bluetooth card is corrupt. 	<ul style="list-style-type: none"> Make sure the Bluetooth device is turned on. Move the Bluetooth device closer to the MRx, within the transmitting range. See the <i>12-Lead Transmission Implementation Guide</i> for more information. Pair the Bluetooth device with the MRx. Replace the Bluetooth card.
Transmission Failed. No Dial Tone. message.	<ul style="list-style-type: none"> Cell phone service is unavailable. The Bluetooth modem connection is not secure. The connection you are using does not provide dial tones. 	<ul style="list-style-type: none"> Check that the cellular signal strength is sufficient. Check that the connection between the Bluetooth modem and the analog line is secure. Set the “Wait for Dial Tone” configuration parameter to No. See the <i>12-Lead Transmission Implementation Guide</i> for more information.
Transmission Failed. Error configuring transmission device. message.	<ul style="list-style-type: none"> The wrong Bluetooth Profile was selected. The Configuration String under the Bluetooth Profile settings is not correct. 	<ul style="list-style-type: none"> Check the profile to ensure it is the correct one for that Bluetooth device. Work with your cell phone provider to ensure that the Configuration String is correct.
Transmission Failed. Connection Interrupted. message.	<ul style="list-style-type: none"> The network is down. The Bluetooth device is not within range. 	<ul style="list-style-type: none"> Check that the cellular signal strength is sufficient. Move the Bluetooth device closer to the MRx, within the transmitting range. See the <i>12-Lead Transmission Implementation Guide</i> for more information.
Transmission Failed. Cannot reach server. message.	<ul style="list-style-type: none"> No server or the connection has been lost. 	<ul style="list-style-type: none"> Resend the 12-Lead Report.
Transmission Failed. Server Unknown. message.	<ul style="list-style-type: none"> The DNS has timed out or there has been a failure in the DNS. 	<ul style="list-style-type: none"> Work with your ISP to ensure the Bluetooth Profile and Hub settings are correct.

Table 45 12-Lead Transmission Problems (Bluetooth) (Continued)

Symptom	Possible Cause	Possible Solution
Transmission Failed. Settings Configured Incorrectly. message.	<ul style="list-style-type: none"> There is a problem with the Server URL, Proxy user name, Proxy password 	<ul style="list-style-type: none"> Work with your ISP to ensure the Bluetooth Profile and Hub settings are correct.
Transmission Failed. Connection Failed. message.	<ul style="list-style-type: none"> The wrong Bluetooth Profile was selected. The Dial String under the Phone Profile settings is incorrect. Data transfer service is unavailable on the phone. Wrong number. 	<ul style="list-style-type: none"> Check the profile to ensure it is the correct one for that Bluetooth device. Work with your cell phone provider to ensure that the Dial string is correct. Work with your cell phone provider to ensure that your cell phone plan has data transfer capability. Check the number and re-send.
Invalid Password message.	<ul style="list-style-type: none"> The wrong Bluetooth Profile was selected. The PPP User Name or PPP Password under the Profile Phone settings is incorrect. The server User Name or Password is incorrect. 	<ul style="list-style-type: none"> Check the profile to ensure it is the correct one for that Bluetooth device. Modify the Bluetooth Profile setting as needed. Modify the Hub settings as needed.
Transmission Failed message.	<ul style="list-style-type: none"> The network is down. The server connection has timed out. TCP/IP Failure The web server has rejected the data. 	<ul style="list-style-type: none"> Check with your ISP to see if your service is down. Re-send the 12-lead report. Re-send the 12-lead report. If still unsuccessful, check the MRx configuration settings. Check the MRx and the 12-Lead Transfer Station to ensure that the correct product versions are installed.

Table 46 12-Lead Transmission Problems (RS 232)

First, attempt to solve the problem by disconnecting the serial cable from the cell phone, reconnecting it, and resending the 12-Lead Report.

Symptom	Possible Cause	Possible Solution
Transmission Settings Have Not Been Configured message.	Hub information has not been entered or is entered incorrectly in Configuration.	Modify the Hub configuration settings as needed.
No Transmission Devices Detected message.	The cell phone is not an approved model for 12-Lead Transmission. The cell phone's RS 232 port has not been configured. The cell phone is not connected properly. The serial cable is defective or incompatible.	Use an approved cell phone model. See the requirements listed in the <i>12-Lead Transmission Implementation Guide</i> . Check the cell phone configuration settings. Check that the cell phone is turned on and the connection is secure. Disconnect and reconnect the serial cable. Work with your cell phone provider to obtain a serial cable that connects to your phone with a 9-pin D serial cable connection.
No Dial Tone message.	There is no dial tone. Cell phone service is unavailable.	Check that the connections are secure. Check that the cellular signal strength is sufficient.
Transmission Failed message, accompanied by an Error Configuring Transmission Device message	The phone configuration settings are invalid/incorrect. Wrong number.	Modify the Serial Phone Profile configuration settings as needed. For more information refer to the <i>12-Lead Transmission Implementation Guide</i> . Check the number and re-send.
Invalid Password message.	The Internet Service Provider (ISP) or Hub user name or password is incorrect.	Modify the Serial Phone Profile or Hub configuration settings as needed. For more information refer to the <i>12-Lead Transmission Implementation Guide</i> .
Transmission Failed message, accompanied by a Connection Failed message.	The connection with the ISP cannot be made.	Modify the Serial Phone Profile configuration settings as needed. For more information refer to the <i>12-Lead Transmission Implementation Guide</i> .
Transmission Failed message, accompanied by a Cannot Reach Server message.	The network server is unavailable.	Contact the network administrator.

Table 46 12-Lead Transmission Problems (RS 232) (Continued)

First, attempt to solve the problem by disconnecting the serial cable from the cell phone, reconnecting it, and resending the 12-Lead Report.

Symptom	Possible Cause	Possible Solution
Transmission Failed message, accompanied by a Server Unknown message	Server Name or address is not recognized.	Modify the Server configuration settings as needed. For more information refer to the <i>12-Lead Transmission Implementation Guide</i> .
Transmission Failed message, accompanied by a Connection Interrupted message.	The connection with the network server has terminated.	Choose the destination site again and re-connect.
Transmission Failed message, accompanied by a Settings Configured Incorrectly message	The URL or Proxy configuration settings are incorrect.	Modify the Serial Phone Profile, Hub or Site configuration settings as needed. For more information refer to the <i>12-Lead Transmission Implementation Guide</i> .
Transmission Failed message.	The 12-Lead Report did not transmit correctly.	Choose the destination site again and re-connect. Check the cell phone connection to the HeartStart MRx.
	The network is down.	Check with your internet provider to see if your service is unavailable.

Table 47 CO₂ Monitoring Problems

Symptom	Possible Cause	Possible Solution
The CO ₂ waveform does not appear on the display.	The FilterLine is not properly connected. The CO ₂ waveform is not configured to be displayed and there is not an unused wave sector.	<ul style="list-style-type: none"> • Check the FilterLine connection. • Check tubing for knots, kinks or pinches. Use the Waves menu to select a wave sector for display of the CO ₂ waveform.
CO ₂ Unplugged inop.	The FilterLine is disconnected.	<ul style="list-style-type: none"> • Check the FilterLine connection and tubing. • Check the tubing for knots, kinks, or pinches.
CO ₂ Purging inop.	A blockage in the FilterLine or airway adapter has been detected. If it is not successful, a CO ₂ Occlusion condition will occur.	The HeartStart MRx automatically attempts to purge the blockage.
CO ₂ Occlusion inop.	Attempts to purge the FilterLine and exhaust tube were unsuccessful. A sample cannot be taken because of the blockage.	Make sure the FilterLine and exhaust tubing (if connected) are not kinked and are free of blockages. Then disconnect and reconnect the FilterLine to retry. If necessary, replace the FilterLine and/or exhaust tubing.
CO ₂ Overrange inop.	The CO ₂ value is higher than the measurement range.	If you suspect a false high value, do not use the CO ₂ monitoring capabilities and call for service of the CO ₂ module. If CO ₂ monitoring is essential to patient care, take the device out of use.
CO ₂ Auto Zero inop.	The automatic zero process is running. It takes from 10 to 30 seconds and CO ₂ values may not be accurate during this time.	No action required. The module automatically resets itself.

Table 47 CO₂ Monitoring Problems (Continued)

Symptom	Possible Cause	Possible Solution
CO ₂ Calibration Overdue inop.	The CO ₂ module should be calibrated once a year or after 4,000 operating hours.	Do not use the CO ₂ monitoring capabilities and call for service to calibrate the CO ₂ module. If CO ₂ monitoring is essential to patient care, take the device out of use.
CO ₂ Check Exhaust inop.	When CO ₂ is turned on, the exhaust tube is blocked to the extent that a measurement sample cannot be taken.	Make sure the exhaust tubing is not kinked and is free of blockages. If necessary, replace the tubing.
CO ₂ Equip Malfunction inop.	CO ₂ hardware failure.	Do not use the CO ₂ monitoring capabilities and call for service of the CO ₂ module. If CO ₂ monitoring is essential to patient care, take the device out of use.
CO ₂ Service Required inop.	The CO ₂ module has reached its end of life, defined as 15,000 operating hours.	Do not use the CO ₂ monitoring capabilities and call for service of the CO ₂ module. If CO ₂ monitoring is essential to patient care, take the device out of use.

Table 48 Defibrillation and Pacing Problems

Symptom	Possible Cause	Possible Solution
Analyzing Stopped , or Cannot Analyze ECG message in AED Mode.	Excessive patient movement. Radio or electrical sources are interfering with ECG analysis.	Minimize patient movement. If the patient is being transported, stop if necessary. Remove possible sources of interference from the area.
Charge Button Failure inop.	During an Operational Check, when the Charge button was pressed, there was no response.	Remove the device from use and call for service.
Defib Disarmed message.	The Shock button was not pressed within the time period specified in the Time to Auto Disarm Configuration setting. Therapy cable not attached. Pads/paddles connection compromised.	No action required. If desired, charge the device and press the Shock button. Make sure the therapy cable is connected and the pads/paddles are making proper contact with the patient.
Maximum Energy 50J message.	Attempted delivery of greater than 50J using internal paddles.	Only energies up to 50J are available for internal defibrillation. Select a lower energy.
No Shock Delivered, Replace Pads Now message.	Faulty pads or poor pads application to patient. (Low impedance.)	Make sure pads are applied properly. If the problem persists, replace the pads.
No Shock Delivered, Press Pads Firmly message.	Poor pads contact with the patient. (High impedance.)	Make sure pads are applied properly. Firmly press pads on the patient's chest.
No Shock Delivered, Low/High Impedance message.	Poor paddles contact with patient skin. Paddles failure.	Make sure paddles are making adequate contact with the patient's skin. If the problem persists, replace the paddles.
Pacer Equip Malfunction inop.	Pacing hardware failure.	Call for service. If pacing functionality is essential to patient care, take the device out of use.

Table 48 Defibrillation and Pacing Problems (Continued)

Symptom	Possible Cause	Possible Solution
Press Charge Before Shock message.	The device is not charged to the selected energy.	Make sure the desired energy is selected. Then press the Charge button.
Press Shock Buttons on Paddles message.	The Shock button on the device is disabled because external paddles or switched internal paddles are connected.	Press the Shock button(s) on the paddles to deliver a shock.
R-Wave Not Detected message.	During synchronized cardioversion, the r-wave was not detectable.	Choose a lead with a clearly define QRS complex.
Pacing Stopped. [Leads Off] message.	Pacing has stopped because the ECG source for Wave Sector 1 has become invalid because of a Leads Off condition or an ECG cable disconnection.	Check that the monitoring electrodes are applied properly to the patient. Check cable connections. Press the [Resume Pacing] soft key to continue pacing.
Pacing Stopped. [Pads Off] [Pads Cable Off] message.	Pacing has stopped because of poor pads/patient contact or a pads cable disconnection.	Check that the pads are applied correctly to the patient. Check cable connections. Press the [Resume Pacing] soft key to continue pacing.
Shock Button Failure inop	During an Operational Check, when the Shock button was pressed, there was no response.	Remove the device from use and call for service.
Therapy Knob Failure inop	During an Operational Check, the Therapy Knob test failed.	Remove the device from use and call for service.
Time to charge to selected energy is slow.	The device is being operated with only AC/DC power (no battery) or the battery power is low.	Install a fully charged battery.
No shock delivered when Shock button on external or switched internal paddles is pressed.	Faulty paddles.	If a shock can be delivered using the Shock button on the HeartStart MRx using pads, replace the paddles.

Table 49 Printer Problems

Symptom	Possible Cause	Possible Solution
Paper won't move.	Paper improperly loaded or jammed, or paper is wet.	Reload paper or clear jam. If paper is wet, replace with fresh, dry roll.
Paper moves then stops.	<ul style="list-style-type: none"> Door improperly latched. Paper improperly loaded or jammed. 	<ul style="list-style-type: none"> Check door latch. Reload paper or clear jam.
Paper moves but printing is faint or absent.	<ul style="list-style-type: none"> Paper roll improperly installed. Incorrect paper type. Printhead temperature approaching maximum recommended operating temperature. 	<ul style="list-style-type: none"> Check that the paper is installed correctly. Use only recommended paper type. Wait until the printer cools down and restart printing.
Paper moves but print quality poor or some dots missing.	Dirty printhead.	Clean the printhead.
Loud buzzing or grinding noise.	Door improperly latched.	Check door latch.
White line running along paper.	Dirt on printhead.	Clean the printhead.
Incompatible Printer message.	The installed printer does not support the fonts required. Asian fonts require the 75 mm printer.	<ul style="list-style-type: none"> Install the 75 mm printer.
Check Printer message.	The printer is out of paper or the door is open.	<ul style="list-style-type: none"> Load/reload the printer paper. Make sure the printer door is closed.
Printer Malfunction message.	The printer is faulty or there is a problem communicating with the printer.	Turn the HeartStart MRx off for 15 seconds and then turn it on again. If the problem persists, call for service. If printing is essential to patient care, take the device out of use.
Printer Temperature High message.	The temperature of the print head exceeds the recommended operating temperature.	Wait until the printer cools down and restart printing.

Table 50 Data Card Problems

Symptom	Possible Cause	Possible Solution
Incompatible Data Card message.	Data card is not compatible with the HeartStart MRx.	Use only Philips M3545A Data Cards.
Data Card Full message.	The data card has reached capacity.	Insert new data card or erase data from card.
No Data Card Present message.	<p>A data card is not inserted in the device.</p> <p>Sufficient time not allowed for data card recognition.</p>	Insert data card. Once inserted, wait 5 seconds before trying to access the data card.

Audio Tones and Alarm Indications

The following table describes the audio tones and alarm indications, when they occur, and their meaning.

NOTE Alarm tone volume levels exceed 60 dB.

Table 51 Audio Tones

Tone/Indication	Definition
Single beep.	Message tone. Accompanies a new message on the display. Informational such as switching to the other battery.
Continuous tone, lower pitch than charged tone.	Charging tone. Generated when the Charge button is pressed and continues until the device is fully charged.
Continuous tone.	Charged tone. Generated when the selected defibrillation energy is reached and continues until the Shock button is pressed, the [Disarm] soft key is pressed, or the device disarmed automatically after the configured time had elapsed since pressing the Charge button.
Periodic chirp.	Low battery or RFU failure. Repeated periodically while the condition exists.
Continuous tone, alternating pitch.	Device will shut down in one minute.
Tone repeated once a second. Red alarm indicator message for applicable HR/arrhythmia, apnea, and extreme desat alarms.	Philips' Red Alarm Tone: Generated while at least one red alarm is occurring.
High pitched tone repeated five times followed by a pause. Red alarm indicator message for applicable HR/arrhythmia, apnea, and extreme desat alarms.	IEC Red Alarm Tone: Generated while at least one red alarm is occurring.
Tone repeated every two seconds, lower pitch than red alarm tone. Yellow alarm indicator message for applicable HR/arrhythmia, SpO ₂ , NBP, and EtCO ₂ alarms.	Philips' Yellow Alarm Tone: Generated while at least one yellow alarm is occurring.
Lower pitched tone is repeated three times, followed by a pause. Yellow alarm indicator message for applicable HR/arrhythmia, SpO ₂ , NBP, and EtCO ₂ alarms.	IEC Yellow Alarm Tone: Generated while at least one yellow alarm is occurring
Tone repeated every two seconds, lower pitch than yellow alarm tone. Cyan indicator message.	Philips' Inop Tone: Generated while at least one inop condition is occurring.
Lower pitched tone is repeated twice, followed by a pause. Cyan indicator message.	IEC Inop Tone: Generated while at least one inop condition is occurring.
Tone occurring synchronously with each heart beat.	QRS tone.

Calling for Service

For telephone assistance, call the Response Center nearest to you, or visit our website at: www.medical.philips.com/cms and follow the links for “CMS Response Center.”

Table 52 Response Center Phone Numbers

North America	
Canada	800-323-2280
United States of America	800-722-9377
Europe	
European International Sales	41 22 354 6464
Austria	01 25125 333
Belgium	02 778 3531
Finland	010 855 2455
France	0803 35 34 33
Germany	0180 5 47 50 00
Italy	800 825087
Netherlands	040 278 7630
Sweden	08 5064 8830
Switzerland	0800 80 10 23
United Kingdom	07002 43258472
Asia/Asia Pacific	
Australia	1800 251 400
China (Beijing)	800 810 0038
Hong Kong Macau	852 2876 7578 0800 923
India New Delhi Mumbai Calcutta Chennai Bangalore Hyderabad	011 6295 9734 022 5691 2463/2431 033 485 3718 044 823 2461 080 5091 911 040 5578 7974
Indonesia	021 794 7542
Japan	0120 381 557
Korea	080 372 7777 02 3445 9010
Malaysia	1800 886 188
New Zealand	0800 251 400
Philippines	02 845 7875
Singapore	1800 PHILIPS
Thailand	02 614 3569
Taiwan	0800 005 616

Specifications and Safety

This chapter describes the specifications and safety features of the HeartStart MRx monitor/defibrillator.

Specifications

General

Dimensions with pads 31.5 cm (W) x 21.0 cm (D) x 29.5 cm (H); (12.4 in. x 8.3 in. x 11.7 in.)

Dimensions with paddles 34.0 cm (W) x 21.0 cm (D) x 34.5 cm (H); (13.4 in. x 8.3 in. x 13.6 in.)

Weight Less than 13.2 lbs. including pads, pads cable, battery, and full roll of paper. Incremental weight of external standard paddles and paddle tray is less than 2.5 lbs. Additional battery weighs less than 1.6 lbs.

Defibrillator

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

Shock Delivery Via multifunction electrode pads or paddles.

Delivered Energy Accuracy

Selected Energy	Nominal Delivered Energy vs. Patient Impedance							Accuracy
	Load Impedance (ohms)							
	25	50	75	100	125	150	175	
1J	1.2	1.3	1.2	1.1	1.0	0.9	0.8	±2J
2J	1.8	2.0	2.0	1.9	1.7	1.6	1.5	±2J
3J	2.8	3.0	3.0	3.1	3.0	2.9	2.7	±2J
4J	3.7	4.0	4.0	4.1	4.2	4.2	4.0	±2J
5J	4.6	5.0	5.1	5.1	5.2	5.2	5.0	±2J
6J	5.5	6.0	6.1	6.2	6.3	6.3	6.1	±2J
7J	6.4	7.0	7.1	7.2	7.3	7.3	7.1	±2J
8J	7.4	8.0	8.1	8.2	8.4	8.3	8.1	±2J
9J	8.3	9.0	9.1	9.3	9.4	9.4	9.1	±2J
10J	9.2	10	10	10	10	10	10	±2J
15J	14	15	15	15	16	16	15	±15%
20J	18	20	20	21	21	21	20	±15%
30J	28	30	30	31	31	31	30	±15%
50J	46	50	51	51	52	52	50	±15%
70J	64	70	71	72	73	73	71	±15%
100J	92	100	101	103	104	104	101	±15%
120J	110	120	121	123	125	125	121	±15%
150J	138	150	152	154	157	156	151	±15%
170J	156	170	172	175	177	177	172	±15%
200J	184	200	202	206	209	209	202	±15%

Charge Time:

- Less than 5 seconds to 200 Joules with a new, fully charged Lithium Ion battery pack at 25°C.
- Less than 15 seconds when operating without a battery, using the M3539A AC power module alone at 90-100% rated mains voltage.
- Less than 15 seconds with a new, fully charged Lithium Ion battery pack at 25°C, depleted by up to 15 200 Joule discharges.
- Less than 25 seconds from initial power on, with a new, fully charged Lithium Ion battery pack at 25°C, depleted by up to 15 200 Joule discharges.
- Less than 25 seconds from initial power on when operating without a battery, using the M3539A AC power module alone at 90-100% rated mains voltage.
- Less than 30 seconds from initiation of rhythm analysis (AED Mode) with a new, fully charged Lithium Ion battery pack at 25°C, depleted by up to 15 200 Joule discharges.
- Less than 30 seconds from initiation of rhythm analysis (AED Mode) when operating without a battery, using the M3539A AC power module alone at 90-100% rated mains voltage.

- Less than 40 seconds from initial power on (AED Mode) with a new, fully charged Lithium Ion battery pack at 25°C, depleted by up to 15 200 Joule discharges.
- Less than 40 seconds from initial power on (AED Mode) when operating without a battery, using the 3539A AC power module alone at 90-100% rated mains voltage.

Patient Impedance Range:

- Minimum: 25 Ohm (external defibrillation); 15 Ohm (internal defibrillation)
- Maximum: 180 Ohm

Note: Actual functional range may exceed the above values.

Manual Defib Mode

Manual Output Energy (Selected): 1-10, 15, 20, 30, 50, 70, 100, 120, 150, 170, 200 Joules; maximum energy limited to 50J with internal paddles

Controls: On/Off Therapy Knob, Charge, Shock, Sync, Print, Mark Event, ECG Lead Select, Alarm Pause, Event Review, Disarm

Energy Selection: Front panel Therapy Knob

Charge Control: Front panel button, button on external paddles

Shock Control: Front panel button, buttons on external or switched internal paddles

Synchronized Control: Front panel SYNC button

Indicators: Text Prompts, Audio Alerts, QRS Beeper, Battery Status, Ready For Use, External Power, Sync Mode

Armed Indicators: Charging tone, charge done tone, flashing shock button, and energy level indicated on display

AED Mode

AED Energy Profile: 150 Joules nominal into a 50 ohm test load

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

AED Controls: On/off, Shock

Indicators: Monitor display messages and prompts, voice prompts, battery status, Ready For Use, external power

Armed Indicators: Charging tone, charged tone, flashing shock button, and energy level indicated on display

ECG Analysis: 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 and certain ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia

Shock Advisory Algorithm Sensitivity and Specificity: Meets AAMI DF-39

Table 53 AED ECG Analysis Performance

Rhythm Class	ECG Test Sample Size ^a	Nominal Specifications
Shockable Rhythm Ventricular Fibrillation	600	Meets AAMI DF39 requirement and AHA recommendation ^b (sensitivity > 90%) for adult defibrillation
Shockable Rhythm Ventricular Tachycardia	300	Meets AAMI DF39 requirement and AHA recommendation ^b (sensitivity > 75%) for adult defibrillation
Non-shockable Rhythm Normal Sinus Rhythm	250	Meets AAMI DF39 requirement (specificity > 95%) and AHA recommendation ^b (specificity > 99%) for adult defibrillation
Non-shockable Rhythm Asystole	500	Meets AAMI DF39 requirements and AHA recommendation ^b (specificity > 95%) for adult defibrillation
Non-shockable Rhythm All other non-shockable rhythms	600	Meets AAMI DF39 requirements and AHA recommendation ^b (specificity > 95%) for adult defibrillation

a. From Philips Medical Systems ECG rhythm databases.

b. American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Efficacy. Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation of New Waveforms, and Enhancing Safety. American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Efficacy. *Circulation* 1997;95:1677-1682.

ECG and Arrhythmia Monitoring

Inputs: Up to four (4) ECG waves may be viewed on display and up to two (2) waves printed simultaneously. Lead I, II, or III is obtained through the 3-wire ECG cable and separate monitoring electrodes. With a 5-lead ECG cable, leads aVR, aVL, aVF, and V can also be obtained. Pads ECG is obtained through 2 multifunction electrode pads.

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

Pad Fault: Dashed line appears on the display if a pad becomes disconnected.

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

Heart Rate/Arrhythmia Alarms: HR, Asystole, VFIB/VTACH, VTACH, Extreme Tachy, Extreme Brady, PVC rate, Pacer Not Capture, Pacer Not Pacing

Hands Free Defibrillation Patient Cable Length:

- M3508A - 2.2 m (7 ft.)
- M3507A - 2.2 m (7 ft.)

ECG Cable Length: 2.7 m (9 ft.)

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, autogain

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 Monitor (.15-40 Hz) or EMS (1-30 Hz)

Patient Isolation (defibrillation proof):

- ECG: Type CF
- SpO₂: Type CF
- EtCO₂: Type CF
- NBP: Type CF
- External Defib: Type BF
- Internal Defib: Type CF

Other Considerations: The HeartStart MRx is suitable for use in the presence of electrosurgery. Burn hazard protection is provided via a 1K current limiting resistor contained in each ECG lead wire.

Display

Size: 128 mm x 171 mm

Type: TFT Color LCD

Resolution: 640 x 480 pixels (VGA)

Sweep Speed: 25mm/s nominal (stationary trace; sweeping erase bar) for ECG and SpO₂; 6.25 mm/sec for CO₂

Wave Viewing Time: 5 seconds (ECG)

Battery

Type: 6.0 Ah, 14.8 V, rechargeable, Lithium Ion

Dimensions: 165 mm (H) x 95 mm (W) x 42 mm (D); (6.5 in. x 3.8 in. x 1.6 in)

Weight: Less than 1.6 lb. (0.73 kg)

Charge Time with instrument off: Approximately 3 hours to 100%. Approximately 2 hours to 80%, indicated by indicator. Charging the battery at temperatures above 45°C may degrade battery life.

Capacity: At least 5 hours of monitoring with ECG, SpO₂, and CO₂ monitored continuously and NBP measured every 15 minutes, or at least 50 full-energy discharges (with a new, fully charged battery, operating at room temperature, 25°C).

Battery Indicators: Battery gauge on battery, capacity indicator on display; flashing RFU indicator, chirp, and LOW BATTERY message appears on display for low battery condition*

*When LOW BATTERY message first appears, there is still enough energy remaining for at least 10 minutes of monitoring time and six maximum energy discharges (with a new battery at room temperature, 25°C).

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

Thermal Array Printer

Continuous ECG Strip: The Print key starts and stops the strip. The printer can be configured to run real time or with a 10-second delay. The strip prints the primary ECG lead with event annotations and measurements.

Auto Printing: The printer can be configured to automatically print on Mark Events, Charge, Shock, and Alarm. When an alarm condition occurs, the unit prints the Primary ECG wave and the alarming wave, if configured.

Reports: The following can be printed:

- Event Summary (short, medium, and long)
- 12-Lead
- Operational Check
- Configuration
- Status Log
- Device Information

Speed: 25 or 50 mm/s with an accuracy of $\pm 5\%$

Amplitude Accuracy: $\pm 5\%$ or ± 40 uV, whichever is greater

Paper Size:

- 50 mm (W) x 30 m (100 ft.) (L)
- 75 mm (W) x 30 m (100 ft.) (L)

Noninvasive Pacing

Waveform: Monophasic Truncated Exponential

Current Pulse Amplitude: 10 mA to 175 mA (5 mA resolution); accuracy 10% or 5 mA, whichever is greater

Pulse Width: 40 ms with $\pm 10\%$ accuracy

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

Range:

- SpO₂: 0-100%
- Pulse Rate: 30 to 300 bpm

Resolution: 1%

Display Update Period: 1 sec typical numeric update rate

SpO₂ Accuracy with:

- M1191A sensor - 1 standard deviation 70% to 100%, ± 2.5%
- M1192A sensor - 1 standard deviation 70% to 100%, ± 2.5%
- M1193A sensor - 1 standard deviation 70% to 100%, ± 2.5%
- M1194A sensor - 1 standard deviation 70% to 100%, ± 4.0%
- M1195A sensor - 1 standard deviation 70% to 100%, ± 4.0%
- M1131A sensor - 1 standard deviation 70% to 100%, ± 3.0%
- M1903B sensor - 1 standard deviation 70% to 100%, ± 3.0%
- M1904B sensor - 1 standard deviation 70% to 100%, ± 3.0%

NOTE The above referenced sensors were validated for use with the HeartStart MRx using the Philips picoSAT II SpO₂ module with Fourier Artifact Suppression Technology (FAST). This module is not available as a stand-alone device.

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

Alarm Range:

- Low Limit: 50 to 99% (Adult/Pediatric)
- High Limit: 51 to 100% (Adult/Pediatric)

Alarm Delay: 10 seconds

NBP

Pressure Range:

- Systolic: 40-260 mmHg
- Diastolic: 20-200 mmHg

Initial Pressure: 160 mmHg Adult; 120 mmHg Pediatric**Maximum Pressure:** 280 mmHg**Overpressure Safety Limits:** Maximum of 300 mmHg**Cuff Inflation Time:** 75 second maximum (pediatric or adult)**Accuracy:** ± 3 mmHg**Alarm Range:**

- Systolic high limit: 35-270 (Adult), 35-180 (Pediatric)
- Systolic low limit: 30-265 (Adult), 30-175 (Pediatric)
- Diastolic high limit: 15-245 (Adult), 15-150 (Pediatric)
- Diastolic low limit: 10-240 (Adult), 10-145 (Pediatric)
- Mean high limit: 25-255 (Adult), 25-160 (Pediatric)
- Mean low limit: 20-250 (Adult), 20-155 (Pediatric)

Rated Life: 50,000 measurement cycles (36/day for 2.3 years)**Auto Mode Repetition Time:** 1, 2.5, 5, 10, 15, 30, 60, or 120 minutes**Measurement Time:** Auto/manual mode: 30 seconds (average) @ HR>60 bpm, 170 seconds maximum)**Interconnect Tube Length:**

- M1598B Connect tubing 1.5 m
- M1599B Connect tubing 3.0 m

EtCO₂

Range: 0 to 99 mmHg**Resolution:** 1 mmHg (0.1kPa)**Accuracy:** For values between 0 and 38 mmHg: ± 2 mmHg. For values between 39 and 99 mmHg: $\pm 5\%$ of reading + 0.08% for every 1 mmHg (above 40 mmHg). Values read at sea level after ≥ 20 min warm up.

The accuracy specification is maintained to within 4% for the following gas mixtures (all values are in Vol. %).

CO ₂	N ₂	O ₂	N ₂ O	H ₂ O	Anesthetic Agents
0 to 13	0 to 97.5	0 to 100	0 to 80	dry to saturated	According to EN864

Rise Time: 190 ms maximum @ 10ml/min

Delay Time: 2.7 seconds typical

System Response Time: 2.9 seconds typical

Sample Flow Rate: Nominally 50 ml/min, ± 7.5 ml/min

Microstream CO₂ Humidity Correction Factor:

BTPS (Body Temperature and Pressure, Saturated - 37°C, 750mmHg, 100% humidity or 47mmHg) is the humidity correction factor for the Microstream CO₂ readings. The formula for the correction calculation is:

$$P_{BTPS} = F_{CO_2} \times (P_b - 47) \\ \sim F_{CO_2} \times 0.94$$

Where FCO₂ = fractional concentration of CO₂ in dry gas.

$$F_{CO_2} = \%CO_2 / 100$$

P_b = ambient pressure

Alarm Range:

- Low Limit: 10 to 94 mmHg (Adult/Pediatric)
- High Limit: 20 to 95 mmHg (Adult/Pediatric)

AwRR

Range: 0 to 150 rpm

Resolution: 1 rpm

Accuracy:

- 0 to 40 rpm ± 1 rpm
- 41 to 70 rpm ± 2 rpm
- 71 to 100 rpm ± 3 rpm
- 101 to 150 rpm ± 5 rpm

Alarm Range:

- Low Limit: 0 to 95 rpm (Adult/Pediatric)
- High Limit: 10 to 100 rpm (Adult/Pediatric)

Apnea Alarm: 10-40 seconds, in increments of 5

Calibration Gas for CO₂ Measurement System

Ingredients: 5% Carbon Dioxide, 21% Oxygen, 74% Nitrogen

Cylinder Size: BD

Method of Preparation: Gravimetric

Blend Tolerance: 0.03%

Accuracy: 0.03% absolute

Moisture: 10 PPM Maximum

Expiration Period: 2 years

Pressure: 144 PSIG, Volume: 10L

12-Lead ECG

Inputs: With a 10-lead cable, leads I, II, III, aVR, aVL, aVF, V/C1-V/C6 can be obtained. All 12-Lead ECG waves can be viewed on the display simultaneously. All 12 leads can be printed on the strip chart printer in 3x4 format.

Patient Data Storage

Internal Event Summary: The internal Event Summary stores up to 8 hours of continuous ECG waveforms and events per Event Summary, with a maximum capacity of 60 Event Summaries or 62 megabytes of patient data, whichever comes first.

Data Card Event Summary: The Data Card stores up to 8 hours of continuous ECG waveforms and events per Event Summary, with a maximum capacity of 60 Event Summaries or 62 megabytes of patient data, whichever comes first.

Environmental (M3535A)

Temperature: 0°C to 45°C operating, -20° to 70°C storage

- Charging the battery at temperatures above 45°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: 0 to 15,000 ft (0 to 4,500 m)
- Storage: 0 to 15,000 ft (0 to 4,500 m)

Shock:

- Operating: Half-sine waveform, duration < 3 ms, acceleration > 145 g, 1 time on all six faces
- Storage: Trapezoidal waveform, acceleration ≥ 30 g, velocity change=742 cm/s $\pm 10\%$ on all six faces

Vibration:

- Operating: Random vibration, 0.30 Grms, 5-500 Hz for ≥ 10 minutes/axis PSD=0.0002 g²/Hz from 5 to 350 Hz, -6 dB/octave slope from 350 to 500 Hz
- Storage:
Random vibration, 2.41 Grms, 5-500 Hz for ≥ 10 minutes/axis PSD=0.02 g²/Hz from 5 to 100 Hz, -6 dB/octave slope from 100 to 137 Hz, 0 dB/octave slope from 137 to 350 Hz, -6 dB/octave slope from 350 to 500 Hz.
Swept sine vibration, (0.75 g [0 to peak] 5 to 500 Hz) resonant search, 1 octave/minute sweep rate, 5 minute resonant dwell at 4 resonances per axis.

Water/Solids Resistance:

- Water Resistance: Meets EN60601-2-4. Water testing performed with cables connected to the device.
- Solids Resistance: IP2X.

EMC: Complies with the requirements of standard EN 60601-1-2:2001.

Safety: Complies with the requirements of applicable safety standards.

Other Considerations:

- The HeartStart MRx is not suitable for use in the presence of concentrated oxygen or a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Hazards arising from software errors were minimized by the product's compliance with the software requirements contained in EN 60601-1-4:1996.

Mode of Operation: Continuous

AC Line Powered: 100 - 240 VAC, 50 - 60 Hz, 1 - 0.46 A (Class 1)

Battery Powered: 14.8 V Rechargeable, Lithium Ion

DC Powered:

- Input: 11-32 VDC, 11 A
- Output: 18 V, 5 A, 90 W

Environmental (M3536A)

Temperature: 0°C to 45°C operating, -20° to 70°C storage

- Charging the battery at temperatures above 45°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: 0 to 15,000 ft (0 to 4,500 m)
- Storage: 0 to 15,000 ft (0 to 4,500 m)

Shock:

- Operating Impact: Half-sine waveform, duration < 3 ms, velocity change > 111 in/s ±5% 3 times on all six faces
- Non-operating Shipping: Trapezoidal waveform, acceleration ≥ 30 g, velocity change=742 cm/s ±10% on all six faces
- Bump: EN60068-2-29 Bump (Half-sine, 40 g peak, 6 msec duration, 1,000 bumps x 3 axes)
- Free Fall: IEC 68-2-32 Free Fall. Drops on all faces onto a steel surface (excluding bed rail hook)
 - 30 in. (76.2 cm) with carrying case
 - 16 in. (40.6 cm) without carrying case

Vibration:

- Operating: MIL STD 810E 514.4 Category 6 Helicopter, General Storage, UH60
- Non-Operating:
 - IEC 68-2-6 Vibration (sinusoidal) (10-57 Hz± 0.15mm; 58-150 Hz, 2g; 20 sweeps x 3 axes)
 - IEC 68-2-64 Vibration, broad-band random (10-20 Hz, 0.05 g²/Hz; 20-150 Hz, -3 dB/octave; 150 Hz, 0.0065 g²/Hz; 1.5 hours x 3 axes)

Solids/Water Resistance: IP24. Water testing performed with cables connected to the device.

EMC: Complies with the requirements of standard EN 60601-1-2:2001.

Safety: Complies with the requirements of applicable safety standards.

Other Considerations:

- The HeartStart MRx is not suitable for use in the presence of concentrated oxygen or a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Hazards arising from software errors were minimized by the product's compliance with the software requirements contained in EN 60601-1-4:1996.

Mode of Operation: Continuous

AC Line Powered: 100 - 240 VAC, 50 - 60 Hz, 1 - 0.46 A (Class 1)

Battery Powered: 14.8 V Rechargeable, Lithium Ion

DC Powered:

- Input: 11-32 VDC, 11 A
- Output: 18 V, 5 A, 90 W

Symbol Definitions

Table 54 lists the meaning of each symbol shown on the HeartStart MRx and the M3538A battery.

Table 54 Monitor/Defibrillator and Battery Symbols

Symbol	Definition
	Defibrillation Shock.
	Attention - See operating instructions in Instructions for Use.
	Input.
	Output.
	Meets IEC type BF leakage current requirements and is defibrillator protected. (Patient Applied Part is isolated and defib-proof suitable for direct patient contact except the heart or major arteries.)
	Meets IEC type CF leakage current requirements and is defibrillator protected. (Patient Applied Part is isolated and defib-proof suitable for direct patient contact including the heart or major arteries.)
	Alarms are active.
	Alarms are paused.
	Alarms are disabled.

Table 54 Monitor/Defibrillator and Battery Symbols (Continued)

Symbol	Definition
	Recyclable material.
	Dispose of in accordance to your country's requirements.
IP24	Protected against ingress of solid foreign objects >12.5mm in diameter. Protected against access to hazardous parts with a finger. Protected against splashing water.
IP2X	Protected against ingress of solid foreign objects >12.5mm in diameter. Protected against access to hazardous parts with a finger.

Table 55 lists the meaning of the symbols appearing on the shipping carton.

Table 55 HeartStart MRx Shipping Carton Symbols

	Atmospheric pressure range.
	Temperature range
	Relative humidity range.
	Recyclable paper product.
	Fragile.
	Right side up.
	Do not get wet.

Clinical Performance Summary - Defibrillation

An international, multicenter, prospective, randomized, clinical study was conducted to assess the effectiveness of the SMART Biphasic waveform in out-of-hospital sudden cardiac arrests (SCAs), as compared to monophasic waveforms. The primary objective of the study was to compare the percent of patients with ventricular fibrillation (VF) as the initial monitored rhythm that were defibrillated in the first series of three shocks or less.

This section summarizes the methods and results of this study.

Methods

Victims of out-of-hospital SCA were prospectively enrolled in four emergency medical service (EMS) systems. Responders used either 150J SMART Biphasic AEDs or 200-360J monophasic waveform AEDs. A sequence of up to three defibrillation shocks were delivered. For the biphasic AEDs, there was a single energy output of 150J for all shocks. For monophasic AEDs, the shock sequence was 200, 200, 360J. Defibrillation was defined as termination of VF for at least five seconds, without regard to hemodynamic factors.

Results

Randomization to the use of monophasic or SMART Biphasic automatic external defibrillators (AEDs) was done in 338 SCAs from four emergency medical service systems. VF was observed as the first monitored rhythm in 115 patients. The biphasic and monophasic groups for these 115 patients were similar in terms of age, sex, weight, primary structural heart disease, cause or location of arrest, and bystanders witnessing the arrest or performing CPR.

The 150J SMART Biphasic waveform defibrillated 98% of VF patients in the first series of three shocks or less, compared with 69% of patients treated with monophasic waveform shocks. Outcomes are summarized in Table 56.

Table 56 Clinical Summary - Defibrillation

	Biphasic Patients Number (%)	Monophasic Patients Number (%)	P Value (chi-square)
Defibrillation Efficacy			
- Single shock only	52/54 (96%)	36/61 (59%)	<0.0001
- ≤2 shocks	52/54 (96%)	39/61 (64%)	<0.0001
- ≤3 shocks	53/54 (98%)	42/61 (69%)	<0.0001
Patients Defibrillated	54/54 (100%)	49/58 (84%)	0.003
Return of Spontaneous Circulation	41/54 (76%)	33/61 (54%)	0.01
Survival to Hospital Admission	33/54 (61%)	31/61 (51%)	0.27
Survival to Hospital Discharge	15/54 (28%)	19/61 (31%)	0.69
CPC = 1 (Good)	13/15 (87%)	10/19 (53%)	0.04

Conclusion

The 150J SMART Biphasic waveform defibrillated at higher rates than 200-360J monophasic waveforms, resulting in more patients achieving return of spontaneous circulation (ROSC) (p=0.01). EMS system outcomes of survival discharge were not significantly different statistically. However, patients resuscitated with the lower energy SMART Biphasic waveform were more likely to have good cerebral performance (CPC, cerebral performance category) (p=0.04).

Clinical Performance Summary - Cardioversion

An international, multicenter, prospective, double-blinded, randomized, clinical trial was conducted to assess the effectiveness of the SMART Biphasic waveform in treatment of atrial fibrillation (AF), as compared to monophasic waveforms. The primary objective of the study was to determine the required energy for cardioversion of AF using the SMART Biphasic waveform, as compared with a monophasic damped sine waveform.

This section summarizes the methods and results of this study.

Methods

Patients enrolled for this study were adults scheduled for elective cardioversion of AF at one of 11 clinical sites. Clinicians used both a defibrillator delivering the SMART Biphasic waveform, and one delivering a monophasic waveform. A sequence of up to five shocks was administered: four with the initial defibrillator, and a fifth cross-over shock was delivered with the other defibrillator if necessary. The sequence of energy settings was 100J, 150J, 200J through the first three shocks on either type of defibrillator. A fourth shock, if necessary, was delivered at 200J if the initial defibrillator was biphasic, and at 360J if the initial defibrillator was monophasic. The cross-over shock was 360J monophasic if the initial defibrillator was biphasic, and 200J biphasic if the initial defibrillator was monophasic. Successful cardioversion was defined as the occurrence of two P waves uninterrupted by atrial fibrillation within 30 seconds of the shock.

Results

Randomization to the use of monophasic or SMART Biphasic defibrillators was done in 212 elective cardioversions involving 210 patients at eleven clinical sites in the United States and Europe. Of these, 203 results met the protocol criteria for inclusion in this analysis. The biphasic and monophasic groups were similar in terms of age, sex, weight, current medical history, cause of heart disease, and estimated ejection fraction.

The 150J SMART Biphasic waveform successfully converted far more patients with an initial 100J shock (60% compared with 22% for the monophasic waveform), and successfully converted patients at least as well with a maximum energy of 200J as the monophasic did with its maximum energy of 360J (91% compared to 85% for the monophasic waveform). Overall, the biphasic waveform required fewer shocks (1.7, compared to 2.8 for the monophasic waveform) and lower delivered energy (217J, compared to 548J for the monophasic waveform). Outcomes are summarized in Table 57.

Table 57 Clinical Summary - Cardioversion

	Biphasic Patients Number (%)	Monophasic Patients Number (%)	P Value
Cumulative Cardioversion Efficacy			
- Single shock only	58/96 (60%)	24/107 (22%)	<0.0001
- ≤2 shocks	74/96 (77%)	47/107 (44%)	<0.0001
- ≤3 shocks	86/96 (90%)	56/107 (53%)	<0.0001
- ≤4 shocks	87/96 (91%)	91/107 (85%)	0.29
Skin "burn"			
None	25/90 (28%)	15/105 (14%)	0.0001
Mild	50/90 (56%)	47/105 (45%)	
Moderate	15/90 (17%)	41/105 (39%)	
Severe	0/90 (0%)	2/105 (2%)	
Number of shocks	1.7 ± 1.0	2.8 ± 1.2	<0.0001
Cumulative delivered energy	217 ± 176J	548 ± 331J	<0.0001
Skin reaction definitions: (evaluated 24 - 48 hours after procedure)			
Mild - erythema, no tenderness			
Moderate - erythema, tenderness			
Severe - blistering or necrosis, tenderness			

Conclusion

The SMART Biphasic waveform cardioverted at higher rates than the monophasic damped sine waveform at each step of the protocol, although the cumulative biphasic rate after 4 shocks was not significantly different from the monophasic rate. Tissue damage was more pronounced in the monophasic population.

Clinical Performance Summary - Internal Defibrillation

Overview

A study was conducted during the first half of 2002 to assess the effectiveness of the HeartStart MRx (biphasic) for use in intra-thoracic application, as compared to a control biphasic waveform. This appendix summarizes the methods and results of the study.

Methods

Twelve swine, each weighing approximately 30 kg, were anesthetized and intubated. A sternotomy was performed to expose the heart. VF was induced electrically by 60 Hz current via a pacemaker catheter in the right ventricle. After 15 seconds of VF, a defibrillating shock was applied, using hand-held (2-inch diameter) "surgical" electrode paddles applied directly to the epicardium. Shock energies of 2, 5, 10, 20, and 30 J were used in random order. At least 4 shocks at each energy level were administered for 4 separate VF episodes to derive a "% success" data point at that energy. Success was defined as conversion of fibrillating rhythm to non-fibrillating rhythm five seconds after the shock.

Results

The results showed that the average impedance was about 40 ohms in this study, which is similar to the human impedance data encountered in direct heart defibrillation. The efficacy results of the HeartStart MRx are shown in Table 58, along with historical efficacy results of a standard monophasic damped sine (MDS) waveform.¹

Table 58 Clinical Performance Summary - Internal Defibrillation

	Energy				
	2J	5J	10J	20J	30J
HeartStart MRx (biphasic) Mean Success	4%	47%	77%	86%	88%
Sample Size	48	53	53	51	41
Control Biphasic Mean Success	10%	60%	93%	92%	92%
Sample Size	49	48	54	49	40
p-value Fisher's Exact (p<0.050)	0.436	0.232	0.032	0.526	0.712
Historical MDS Mean Success	3%	25%	34%	57%	76%

Conclusion

Overall, the intra-thoracic defibrillation success rate for the HeartStart MRx (Biphasic) versus a control biphasic waveform had no significant difference (p<0.05) except at 10J.

1. Zhang, Y., Davies R., Coddington W., Jones J., Kerber RE., Open Chest Defibrillation: Biphasic versus Monophasic Waveform Shocks, JACC 2001;37;320A.

Safety Considerations

The following general warnings and cautions apply to use of the HeartStart MRx. Additional warning and cautions specific to a particular feature are provided in the appropriate section.

General

WARNING The HeartStart MRx is not intended to be deployed in settings or situations that promote use by untrained personnel. Operation by untrained personnel can result in injury or death.

WARNING HeartStart MRx service should only be performed by qualified service personnel, in accordance with the *HeartStart MRx Service Manual*.

WARNING Use of the HeartStart MRx is restricted to a single patient at a time.

WARNING When transporting the HeartStart MRx, it is important to position it with the display facing away from the body. If not, the Therapy Knob may be bumped and inadvertently moved from its current position.

WARNING Remain attentive to the patient during the delivery of therapy. Delay in delivering a shock may result in a rhythm that was analyzed as shockable converting spontaneously to non-shockable and could result in inappropriate delivery of a shock.

WARNING Use only 3-wire AC power cords with 3-pronged grounded plugs.

WARNING Never operate the HeartStart MRx in standing water. Do not immerse, or pour fluids on, any portion of the HeartStart MRx.

WARNING Do not use the HeartStart MRx in a flammable or oxygen-rich atmosphere. This can cause an explosion hazard.

WARNING Avoid connecting the patient to several devices at once. Leakage current limits may be exceeded. Do not use a second defibrillator on the patient while pacing with the HeartStart MRx.

WARNING Electric shock hazards exist internally. Do not remove assembly screws except as described in the carry bag assembly procedure. Refer servicing to qualified personnel.

WARNING Operating the HeartStart MRx or its accessories in conditions outside the environmental specifications can result in device or accessory malfunction. The HeartStart MRx should be allowed to stabilize within the operating temperature range for 30 minutes prior to operation.

CAUTION Do not discharge the defibrillator with the paddles shorted together.

CAUTION Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.

CAUTION Following electrosurgery interference, the equipment returns to the previous operating mode within 10 seconds without loss of stored data. Measurement accuracy may be temporarily decreased while performing electrosurgery or defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to x-ray or strong magnetic fields (MRI).

CAUTION Be aware of patient cables, including ECG monitoring equipment when used with high frequency surgical equipment.

NOTE This device and its accessories are not intended for home use.

NOTE The HeartStart MRx can be operated with only AC/DC power, only 14V M3538A Lithium Ion Battery, or AC/DC power and M3538A battery simultaneously.

NOTE For operation in the U.S., the AC power cord must have the proper NEMA type plug.

NOTE The HeartStart MRx does not require the practice of any special ElectroStatic Discharge (ESD) precautionary procedures.

Defibrillation

WARNING Keep hands and feet clear of paddle electrode edges. Use your thumbs to depress the shock buttons on the paddle handle.

WARNING Do not allow multifunction electrode pads to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.

WARNING During defibrillation, air pockets between the skin and multifunction electrode pads may cause patient skin burns. To help prevent air pockets, make sure the pads completely adhere to the skin. Do not use dried out pads; do not open pads package until just prior to use.

WARNING Never touch the patient or any equipment connected to the patient (including the bed or gurney) during defibrillation.

WARNING Avoid contact between the patient and conductive fluids and/or metal objects, such as the gurney. Contact with metal objects could cause unintentional current pathways.

WARNING Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.

WARNING In AED Mode, the multifunction electrode pads must be in the anterior-anterior position as shown on the packaging. The HeartStart MRx was not designed to assess data acquired from pads in an anterior-posterior position.

Battery

WARNING Properly dispose of or recycle depleted batteries according to local regulations. Do not puncture, disassemble, or incinerate batteries.

WARNING Built in safety circuits can not protect against handling abuse. Adhere to all warnings and cautions in handling and using lithium ion batteries.

WARNING Do not expose batteries to temperatures greater than 60°C (140°F). Excess temperatures may result in battery damage.

WARNING Keep batteries away from flame and other heat sources.

WARNING Do not short circuit the battery. Avoid placing batteries around metal objects that may short circuit the battery.

WARNING Avoid getting batteries wet or using batteries in high humidity environments.

WARNING Do not crush, dent or allow any deformation of the batteries.

WARNING Do not disassemble or open batteries. Do no attempt to alter or bypass the safety circuit.

WARNING Avoid extreme shock and vibration to the battery.

WARNING Do not use or connect the battery to batteries of other chemistries.

Supplies and Accessories

WARNING Use only the multifunction electrode pads, battery, and accessories as listed in this guide. Substitutions may cause the HeartStart MRx to function improperly.

WARNING Use multifunction electrode pads prior to their expiration date. Discard pads after use. Do not reuse pads. Do not use for more than 8 hours of continuous pacing.

Electromagnetic Compatibility

When using the HeartStart MRx, electromagnetic compatibility with surrounding devices should be assessed.

A medical device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility EMC with and without the appropriate accessories has been performed according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The EMC standards describe tests for both emitted and received interference. Emission tests deal with interference generated by the device being tested.

WARNING Radio frequency (RF) interference from nearby transmitting devices may degrade performance of the HeartStart MRx. Electromagnetic compatibility with surrounding devices should be assessed prior to using the defibrillator.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See Table 63 for the minimum recommended separation distance between RF communications equipment and the HeartStart MRx.

Reducing Electromagnetic Interference

The HeartStart MRx and associated accessories may be susceptible to interference from other RF energy sources and continuous, repetitive, power line bursts. Examples of other sources of RF interference are medical devices, cellular products, information technology equipment and radio/television transmission. Should interference be encountered, as demonstrated by artifact on the ECG or dramatic variations in parameter measurement values, attempt to locate the source. Assess:

- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical devices?
- Do parameter measurement values change dramatically when the AC line cord is unplugged?

Once the source is located, attempt to attenuate the EMC coupling path by distancing the monitor/defibrillator from the source as much as possible. If assistance is needed, call your local service representative.

Restrictions for Use

Artifact on the ECG and parameter waveforms caused by electromagnetic interference should be evaluated by a physician or physician authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

Emissions and Immunity

The HeartStart MRx is designed and tested to comply with the radiated and conducted emissions requirement of international and national standards IEC 60601-1-2:2001 and EN 60601-1-2:2002. See Tables 59 through 63 for detailed information regarding declaration and guidance.

WARNING The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the HeartStart MRx.

The list of cables, transducers, and other accessories with which Philips claims compliance with the emissions and immunity requirements of IEC standard 60601-1-2 are listed in the Supplies and Accessories section of “Maintenance” on page 151.

The local area network (LAN) connector of the HeartStart MRx is marked with the  label. The pins of connectors marked with this warning symbol should not be touched or connections made to until the following precaution is taken:

Discharge yourself to a conductive metal surface which is connected to earth ground before making connections or touching the marked connector.

All staff using the HeartStart MRx should be instructed on these precautionary measures in order to avoid damage to this sensitive medical equipment.

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. See Tables 59 through 62 for this detailed immunity information. See Table 63 for recommended minimum separation distances between portable and mobile communications equipment and the HeartStart MRx.

Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of an electromagnetic disturbance. Degradation in ECG quality is a qualitative assessment which can be subjective.

Caution should, therefore, be taken in comparing immunity levels of different devices. The criteria used for degradation is not specified by the standard and may vary with the manufacturer.

Guidance and Manufacturer’s Declaration

The HeartStart MRx is intended for use in the electromagnetic environment specified in the tables below. The customer or the user of the HeartStart MRx should assure that it is used in such an environment.

Table 59 Electromagnetic Emissions

For devices with serial numbers US001XXXXX

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The HeartStart MRx uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The HeartStart MRx is suitable for use in all establishments, other than domestic establishments or those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. It may be used in domestic establishments if it is under the supervision of healthcare professional. ¹
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
¹ International standard IEC 60601-1-2 (dated April 1993) allows for equipment to be operated in domestic locations if it is under the supervision of a healthcare professional. Note that national authorities may apply whatever measures they consider necessary to protect radio communications. This allowance will no longer apply to medical equipment being sold or put into service after 1 November 2004.		

For devices with serial numbers US002XXXXX

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The HeartStart MRx uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The HeartStart MRx is suitable for use in all establishments, including domestic establishments or those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 60 Electromagnetic Immunity - General

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0,5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0,5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
U_T is the AC mains voltage prior to application of the test level.			

Table 61 Electromagnetic Immunity - Life Supporting Functions

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartStart MRx, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	<p style="text-align: center;">Recommended Separation Distance</p> $d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	<p style="text-align: center;">Recommended Separation Distance</p> $d = 1.2\sqrt{P}$

Table 61 Electromagnetic Immunity - Life Supporting Functions (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 2.3\sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter's specified output power and d is the recommended separation distance in meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.^d</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
At 80 MHz and 800 MHz, the higher frequency range applies.			
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz and 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.			
^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.			
^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartStart MRx is used exceeds the applicable RF compliance level above, the HeartStart MRx should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartStart MRx.			
^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 62 Electromagnetic Immunity - Nonlife Supporting Functions

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartStart MRx, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p style="text-align: center;">Recommended Separation Distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter's specified output power and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
At 80 MHz and 800 MHz, the higher frequency range applies.			
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartStart MRx is used exceeds the applicable RF compliance level above, the HeartStart MRx should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartStart MRx.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances

The HeartStart MRx is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HeartStart MRx can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartStart MRx as recommended below, according to the maximum output power of the communications equipment.

Table 63 Recommended Separation Distances

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)	
	150 kHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4 m	7 m
100	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter's manufacturer.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Index

#

- 12-Lead
 - preparation 106
 - preview screen 106, 107
- 12-Lead ECG 105
 - acquiring 108
 - algorithm 105
 - filters 112
 - report 109
- 12-Lead ECG Transmission 113
 - Bluetooth setup 115
 - Bluetooth transmission 117
 - overview 113
 - RS 232 setup 118
 - RS 232 transmission 120

A

- AC Power Module
 - installing 39
- Accessories 186
- Accessory Pouches
 - connecting 27
- Alarms 24
 - responding 24
- Annotated ECG 53
- Apnea Time Alarm 104
- Arrhythmia 47
 - alarm latching 50
 - alarms 50
 - learning/relearning 54
 - setting alarms 52
- Automated External Defibrillation (AED) 55
 - AED mode 55
 - AED therapy
 - precautions 5
 - AED view 56
 - preparation 57
 - process 56
- Automated Tests 152
- Automated tests
 - CX 177
 - D 154, 177
 - DX 154, 177
 - Fail/BF 154, 165, 177
 - Fail/CF 165
 - Fail/NC 165
 - S 177

- AwRR Alarms 102
 - changing 103
 - enabling/disabling 104

B

- Batteries
 - calibration 179
 - capacity 14, 178
 - charge level indicators 16
 - charging 179
 - discarding 181
 - installing 38
 - life expectancy 14, 178
 - M3538A Lithium Ion Battery 14
 - maintenance 178
 - storing 180
- Beat Labels 53

C

- Cleaning 182
 - carrying case 184
 - ECG cable 183
 - monitor/defibrillator 182
 - paddles 183
 - printer printhead 182
 - therapy cable 183
- CO₂ Monitoring 99
 - measuring etCO₂ 102
 - selecting accessories 100
 - setting up 101
- CO₂ Nasal FilterLine
 - connecting 34
- Code View 66
- Continued Use 25
- Controls 20
 - alarm pause button 21
 - charge button 22
 - event summary button 21
 - lead select button 21
 - mark event button 21
 - menu select button 21
 - navigation buttons 21
 - print button 21
 - shock button 22
 - therapy knob 20
- CX 177

D

- D 154, 177
- Data Card
 - installing 40
 - internal 141
 - removable 142
- Data Management 142
 - data card 142
 - internal memory 142
- Data Storage 141
- Defibrillating 82
- Defibrillation Controls 22
- Display
 - high contrast 20
 - menus 19
 - views 15
- DX 154, 177

E

- ECG and Arrhythmia Monitoring 41–54
 - ECG wave size 48
 - electrode placement 45
 - monitoring arrhythmia 52
 - monitoring view 42
 - overview 41
 - preparation 43
 - selecting the lead 52
- ECG Cable
 - cleaning 183
 - connecting 31
- Electrode Placement 45
 - 10-lead 46
 - 3-lead 45
 - 5-lead 45
 - V/C 46
- EtCO₂ Alarms 102
 - changing 103
 - enabling/disabling 103
- Event Summary 141, 143
- External Power Indicator 23

F

- Fail/BF 154, 165, 177
- Fail/CF 165
- Fail/NC 165

H

- Heart Rate Alarms 52
 - changing 52
 - enabling/disabling 52
- HeartStart MRx
 - intended use 5

I

- INOP Messages 51

L

- Lead Selection 47

M

- Manual Defibrillation 65
 - code view 66
 - defibrillating 70
 - indications 7
 - Manual Defib Mode 66
 - overview 65
 - precautions 5
 - preparation 67
- Marking Events 148
- Monitoring View 42

N

- NBP Interconnect Tubing
 - connecting 33
- NBP Monitoring
 - indications 8
- Noninvasive Pacing 75
 - alarms 76
 - defibrillating 82
 - demand mode 78
 - fixed mode 78
 - overview 75
 - pacing 80
 - pacing view 77
 - preparation 79
- Noninvasive Pacing Therapy
 - indications 7

O

- Operational Check 157
 - performing 157, 167
 - report 162, 173
 - summary 165, 177
 - test results 174
 - tests 160, 170

P

- Pacing
 - see Noninvasive Pacing 75
- Paddles
 - using external 68
- Pads, multifunction electrode 67
- Parameter Blocks 18
- Password Security 15
- Pleth Wave 89
- Printer
 - installing paper 36

Q

QRS beeper 196

R

Ready For Use (RFU) Indicator 4, 23

Return to Owner 26

S

S 177

SpO2 Alarms 90

 changing 90

 enabling/disabling 90

SpO2 Cable

 connecting 32

SpO2 Monitoring 83, 88

 applying the sensor 85, 87

 selecting a sensor 85

Supplies 186

Synchronized Cardioversion 72

 delivering 73

 disabling 74

 preparing 72

 shock delivery 73

 using an external monitor 72

T

Therapy Cable

 connecting 35

U

User Checks 174

W

Wave Sectors 17



M3535-91900
Edition 4
Philips Medical Systems
Printed in the U.S.A. October 2005

