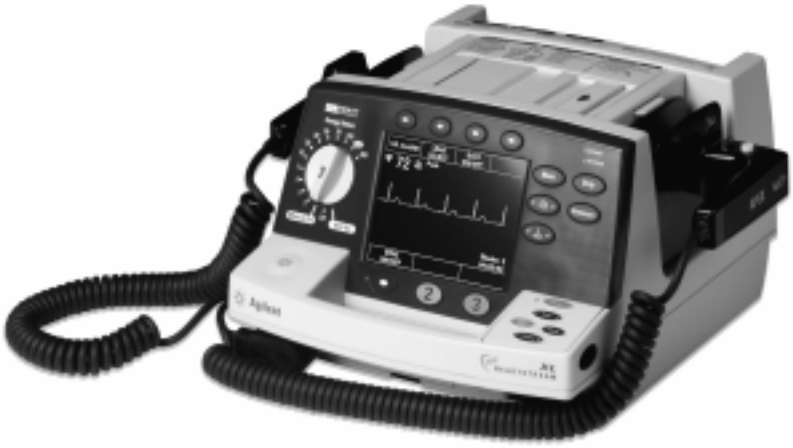


Agilent M4735A
Heartstream XL Defibrillator/Monitor

User's Guide

Agilent Technologies

Agilent Technologies

User’s Guide

M4735A Heartstream XL Defibrillator/Monitor

Notice

About This Edition

Edition 1
Printed in the USA
Publication number M4735-91900

The information in this guide applies to the M4735A Heartstream XL, release A.00. This information is subject to change without notice.

Agilent Technologies 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 1, September, 2000

Copyright

SMART Biphasic is a registered trademark of Agilent Technologies.

Use of supplies or accessories other than those recommended by Agilent Technologies 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 M4735A Heartstream XL Defibrillator/Monitor complies with the requirements of the Medical Device Directive 93/42/EEC and carries the

CE 0123 mark accordingly.

Authorized EU-representative:
Agilent Technologies
Deutschland GmbH
Herrenbergerstr.130
D 71034 Boeblingen, Germany
Fax: +49-7031-14-2346

Warning

Radio frequency (RF) interference from nearby transmitting devices may degrade the performance of the M4735A Heartstream XL Defibrillator/Monitor. Electromagnetic compatibility with surrounding devices should be assessed prior to using the defibrillator/monitor.

This guide uses 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.

TEXT	represents messages that appear on the display
Softkey	represents softkey labels that appear on the display above or below the button to which they correspond

Introduction

Getting Started

Defibrillating in AED Mode

Monitoring the ECG

Monitoring SpO2

Defibrillating in Manual Mode

Performing Synchronized Cardioversion

Pacing (Optional)

Storing, Retrieving & Printing

Setting Up and Configuring the Heartstream XL

Maintaining the Heartstream XL

Troubleshooting

Specifications & Safety

1 Introduction

The M4735A Heartstream XL Defibrillator/Monitor is designed to meet your resuscitation and monitoring needs. This guide provides instructions for safe and proper operation, set-up, configuration, and care of your M4735A Heartstream XL Defibrillator/Monitor.

In this chapter, you'll find general information that you should become familiar with before using the defibrillator/monitor.

Overview

The M4735A Heartstream XL Defibrillator/Monitor is a lightweight, portable, semi-automatic external defibrillator. It offers two modes of operation for defibrillation:

- Automated External Defibrillation (AED) Mode
- Manual Mode

Both modes incorporate a low energy SMART Biphasic waveform for defibrillation.

In AED Mode, the M4735A Heartstream XL Defibrillator/Monitor analyzes the patient's ECG and advises you whether or not to deliver a shock. Voice prompts guide you through the defibrillation process by providing instructions and patient information. Voice prompts are reinforced by messages that appear on the display.

In Manual Mode, the M4735A Heartstream XL Defibrillator/Monitor turns control of the defibrillation process over to you. You analyze the patient's ECG, and select the energy setting for defibrillation if necessary. Manual Mode also allows you to perform synchronized cardioversion and offers noninvasive pacing (optional).

Defibrillation is performed through attached paddles or multifunction defib electrode pads. Monitoring is available in AED and Manual Mode through pads, 3-lead ECG monitoring electrodes, or optional 5-lead ECG monitoring electrodes. Optional pulse oximetry (SpO_2) monitoring is also available in AED and Manual Modes. While monitoring ECG or SpO_2, you may set heart rate and/or SpO_2 alarms to alert you when these parameters are outside the defined limits.

The M4735A Heartstream XL Defibrillator/Monitor automatically stores critical events in its internal memory, such as shocks and alarm violations. Additional events of interest may also be marked for storage. These events can be printed as they occur or as part of an Event Summary. The M4735A Heartstream XL Defibrillator/Monitor also enables you to store data and events on an optional Data Card for downloading to CodeRunner Web Data Management Systems.

The versatile M4735A Heartstream XL Defibrillator/Monitor is highly configurable to better meet the needs of diverse users. The messages and softkeys vary, depending on how the M4735A Heartstream XL Defibrillator/Monitor is configured. Be sure to familiarize yourself with your configuration before using the M4735A Heartstream XL Defibrillator/Monitor (see “Configuring the Heartstream XL” on page 10-7).

The M4735A Heartstream XL Defibrillator/Monitor is powered by AC power and a rechargable sealed lead acid (SLA) battery which allows the defibrillator to charge to 200 joules in less than three seconds. Proper care of your batteries will ensure that they have the energy required to operate the M4735A Heartstream XL Defibrillator/Monitor and to deliver the appropriate therapy. (See “Battery Maintenance” on page 11-7.) Similarly, performing the specified operational checks will ensure that the M4735A Heartstream XL Defibrillator/Monitor is functioning properly and ready for use. (See “Operational Checks” on page 11-2.)

Intended Use

The M4735A Heartstream XL Defibrillator/Monitor is for use in the hospital 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. It must be used by or on the order of a physician.

When operating as a semi-automatic external defibrillator in AED Mode, the M4735A Heartstream XL Defibrillator/Monitor is suitable for use by medical personnel trained in basic life support that includes the use of an AED.

When operating as a defibrillator/monitor in Manual Mode, the M4735A Heartstream XL Defibrillator/Monitor is suitable for use by emergency medical personnel trained in advanced cardiac life support.

Defibrillation Therapy

Defibrillation therapy is the definitive method for termination of a variety of potentially fatal arrhythmias. The M4735A Heartstream XL Defibrillator/Monitor 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 defib 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 defibrillator/monitor 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.

Indications for 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

Contraindications for AED Therapy

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

- Responsiveness
- Spontaneous breathing
- Palpable pulse

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 M4735A Heartstream XL Defibrillator/Monitor may have reduced sensitivity and not detect all shockable rhythms.

NOTE

The AED algorithm 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. American Heart Association *Textbook of Advanced Cardiac Life Support*. Dallas, Texas.: AHA; 1997.

Indications for Manual Defibrillation Therapy

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia, in patients who are pulseless and unresponsive.

The SMART Biphasic waveform utilized in the M4735A Heartstream XL Defibrillator/Monitor has undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at the 150J

In manual mode operation, the M4735A Heartstream XL Defibrillator/Monitor incorporates some user selectable lower energy levels that were not used in the clinical trials.

There are currently no clinical studies related to the use of the SMART Biphasic waveform in pediatric applications or in direct defibrillation of the heart during open chest surgery.

Contraindications for Manual Defibrillation Therapy

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

- Responsiveness
- Spontaneous breathing
- Palpable pulse

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.

Noninvasive Pacing Therapy (Optional)

The M4735A Heartstream XL Defibrillator/Monitor 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 current and rate settings. The energy is delivered through multifunction defib electrode pads applied to the patient's bare chest.

Indications

Noninvasive pacing is one method of treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

Contraindications

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

SpO_2 Monitoring (Optional)

A pulse oximeter is a noninvasive device that indicates the oxygen saturation (SpO_2) 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 SpO_2 reading.

Indications

SpO_2 monitoring is indicated for use when it is beneficial to assess a patient's oxygen saturation level.

Contraindications

There are no known contraindications for SpO2.

NOTE

Readings should be carefully considered in the presence of certain circumstances. Inaccuracies may result from the use of pulse oximeters in the presence of certain circumstances, such as hemoglobin saturated with compounds other than oxygen, (such as carbon monoxide), hypothermia, hypovolemia, patient movement, nail polish and excessive ambient light.

Safety Considerations

General warnings and cautions that apply to use of the M4735A Heartstream XL Defibrillator/Monitor are provided in Chapter 13. Additional warnings and cautions specific to a particular feature are provided in the appropriate section of this guide.

Documentation and Training

Documentation for the M4735A Heartstream XL Defibrillator/Monitor includes:

- *M4735A Heartstream XL Defibrillator/Monitor User Guide*,
- *M4735A Heartstream XL Defibrillator/Monitor Quick Reference Card*, and
- *About Sealed Lead Acid Batteries*, an application note on battery maintenance.

Training tools available for use with the M4735A Heartstream XL include:

- *Using the M4735A Heartstream XL Defibrillator/Monitor*, a workbook
- *Heartstream XL User Training CD-ROM* (optional)

For additional online documentation and training, please visit our website:

www.agilent.com/healthcare/heart

Available online training materials include:

- AED Application Note
- SpO2 Concept Guide
- Pacing Application Note

Documentation and Training

2 Getting Started

Congratulations on purchasing your Heartstream XL!

This chapter will give you a quick tour of your new defibrillator/monitor's controls and display.

The Heartstream XL ships complete with paddles and the cables necessary for easy operation. This chapter will help you get your Heartstream XL up and running by following a few easy steps, including:

- Connecting to AC Power
- Inserting the battery
- Inserting the optional Data Card (if desired).

NOTE

To connect cables to the Heartstream XL, refer to "Setting Up and Configuring the Heartstream XL" in chapter 10.

Getting Acquainted

This section provides an overview of the Heartstream XL controls, connections, and display layout. A review of control functionality is also provided.

Basic Orientation

Review the figure for a general layout of the controls, where the patient cables connect, and where to insert the battery and Data Card.

Figure 2-1 Basic Orientation (Front)

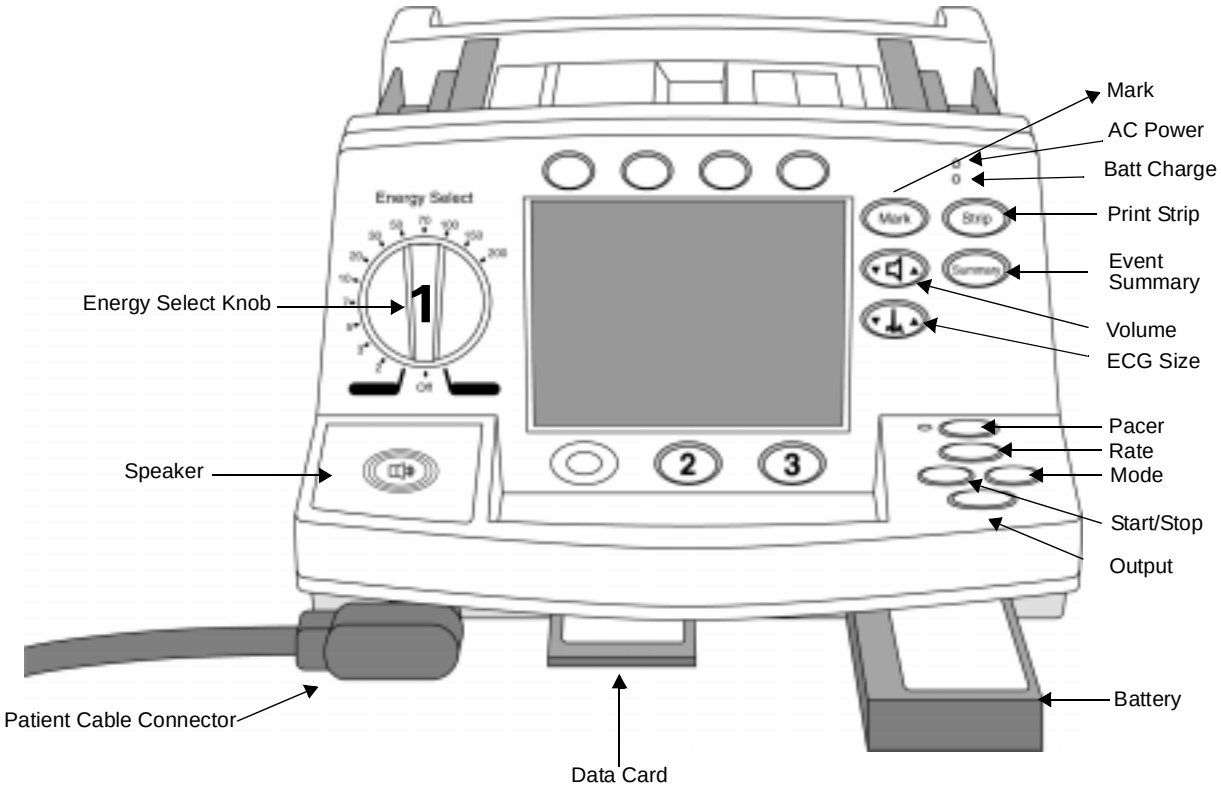
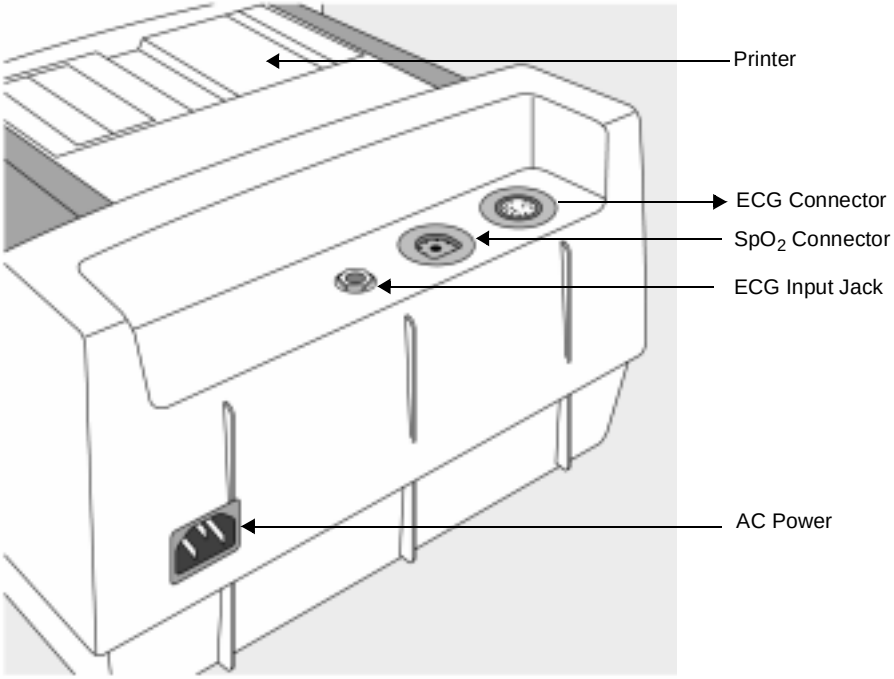


Figure 2-2 Heartstream XL (Back)



NOTE

If your Heartstream XL does not have the SpO_2 or Pacing option, disregard these controls and the related information described in this section.

Defibrillation Controls

Defibrillation controls consist of an energy select knob and a set of softkeys that perform the function displayed as a label above each button. These controls assist in both AED and Manual Mode defibrillation.

Audiovisual Controls

Adjusts the volume of voice prompts and the QRS beeper.

Adjusts the size of the ECG waveform displayed, printed, and stored. Pressing ▲ and ▼ simultaneously generates a 1 mV calibration pulse.

To completely turn the QRS beeper off, it must be changed from the configuration menu.

Monitoring Controls

Monitoring controls consist of a set of softkeys that perform monitoring functionality. These functions are displayed in the softkey label below each button. Monitoring softkeys also control heart rate and SpO_2 alarms, and selection of the ECG source to monitor.

Print Controls

Print controls perform the function shown above each button. The print controls from are:

Prints ECG data, defibrillation events, and marked events real-time or with a 6 second delay (as configured). Press to start printing; press again to stop printing.

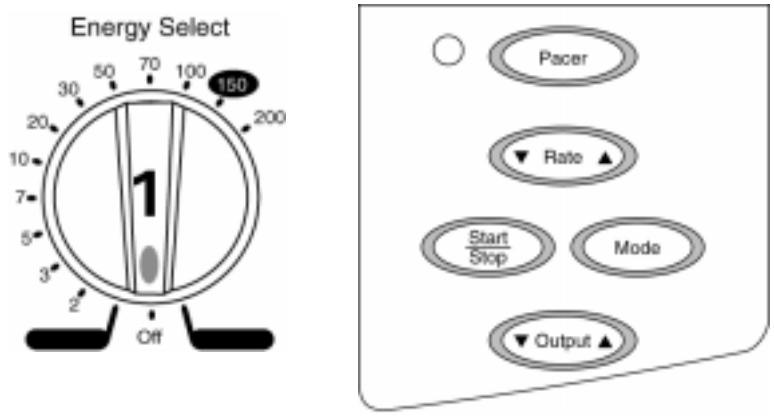
Prints the Event Summary. (See “Storing, Retrieving & Printing” for more information.) Printing may be stopped by pressing the **Summary** or **Strip** button.

Inserts a time-stamped annotation in the Event Summary. May be configured to print an annotated ECG strip when pressed.

Manual Mode Controls

Manual Mode controls provide access to manual defibrillation, and synchronized cardioversion and optional pacing functionality.

Figure 2-3 Manual Mode Controls: Energy Select Knob and Pacing Controls



Display Buttons

Energy Select Knob — Can enable both Manual Mode and AED Mode. The AED On position activates AED Mode. Manual On enables Manual Mode, synchronized cardioversion and pacing (optional).

Button below the display (far left) that enables synchronized cardioversion when first pressed in Manual Mode; disables synchronized cardioversion when pressed again.

Activates the pacing function buttons (as indicated by the green LED), allowing you to use the buttons below to define pacing rate, mode, and current output. Also turns off the Pacer function when pressed a second time.

Adjusts the pacing rate.

Starts pacing. Delivers pacer pulses when first pressed; stops pacing when pressed again.

Selects Demand or Fixed Mode for pacing.

Adjusts the current output for pacing.

NOTE

Synchronized cardioversion and pacing controls only function when Manual Mode is enabled.

Display Layout

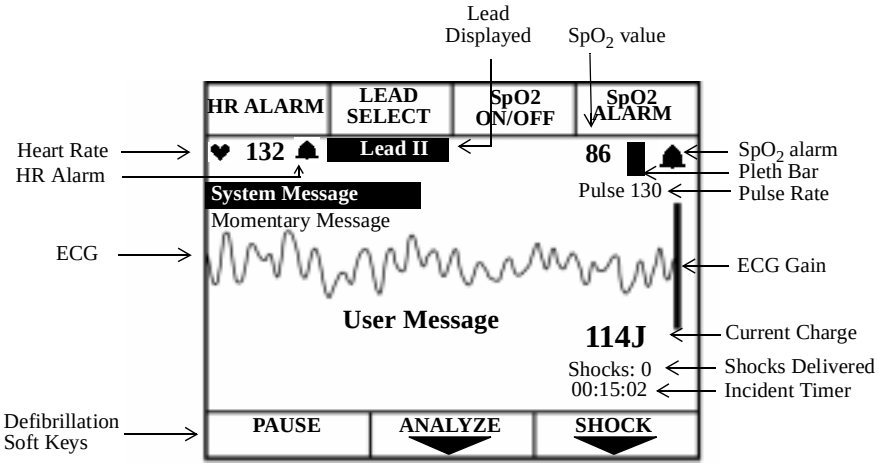
The following figures show the layout of the display in:

- AED Mode, with ECG and SpO2 monitoring capabilities enabled
- AED Mode, with ECG and SpO2 monitoring capabilities disabled
- Manual Mode

NOTE

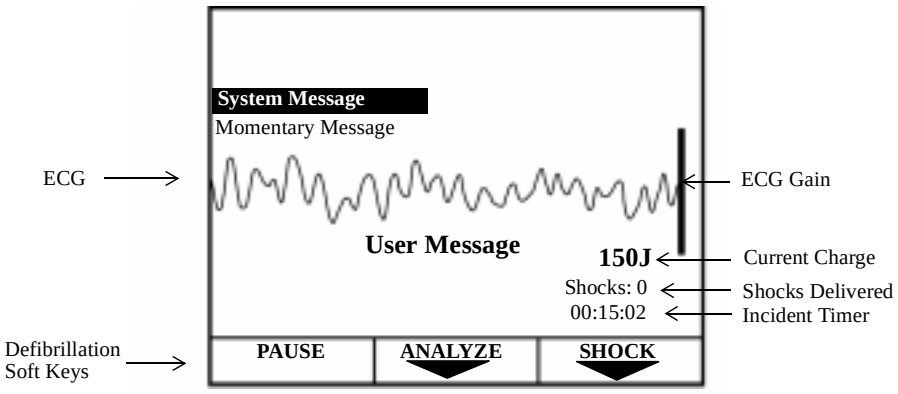
ECG and SpO2 monitoring capabilities for AED Mode may be enabled and disabled independently in the configuration.

Figure 2-4 AED Mode Display Layout (ECG and SpO_2 Enabled)



The Incident Timer shows the elapsed time since the Heartstream XL was turned on, provided patient contact was established. If the Heartstream XL is powered on after being off for less than two minutes, the Incident Timer resumes where it left off. If power is off for more than two minutes, the Incident Timer resets to zero (00:00:00). If an Event Summary is printed, the incident timer will be set to zero the next time the unit is turned on.

Figure 2-5 AED Mode Display Layout (ECG and SpO_2 disabled)



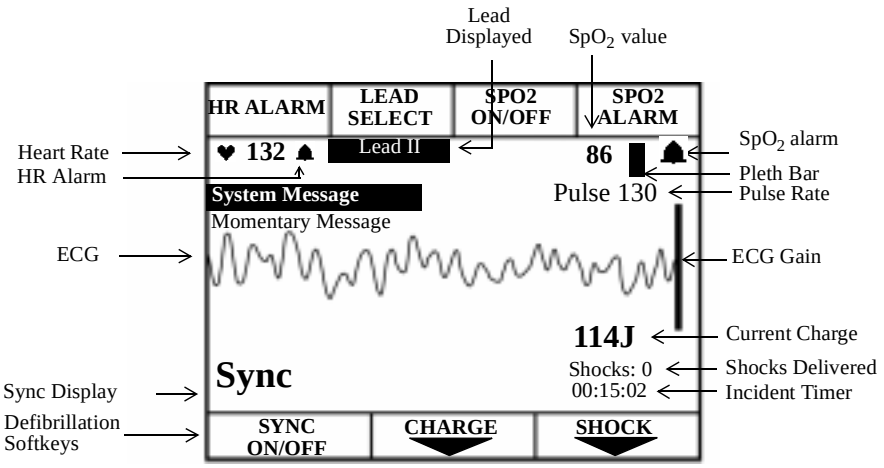
User messages accompany voice prompts to guide you through the defibrillation process.

System and Momentary Messages:

- alert you to conditions that require your attention,
- provide status information, or
- offer recommendations.

A System Message remains on the display until the condition that generated the message no longer exists. A Momentary Message is temporary and appears on the display for a minimum of 3 seconds. For a list of system and momentary messages, see Chapter 12.

Figure 2-6 Manual Mode Display Layout



Connecting to Power

The Heartstream XL is powered by AC Power and the M3516A battery. Prior to inserting the battery, make sure that the battery is charged and has been properly maintained (See “Battery Maintenance” on page 11-7). It is recommended that a second, charged battery be available at all times.

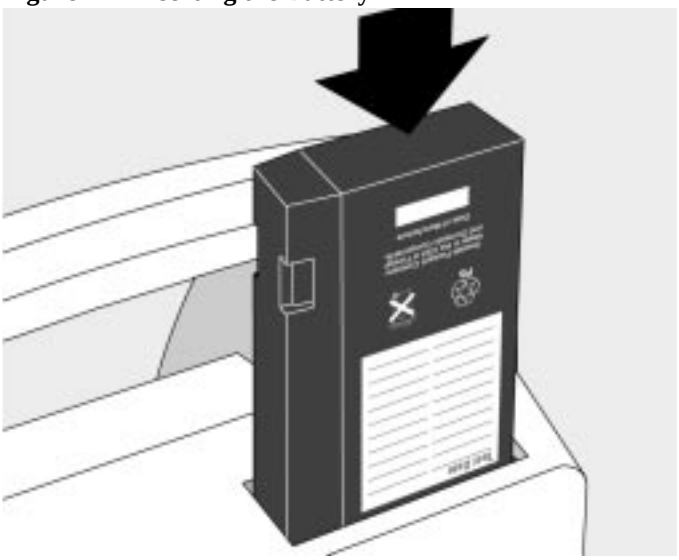
NOTE

The Heartstream XL will take longer to charge to the desired energy level when using only AC Power and without the battery.

Inserting the Battery

To insert the battery, slide it into the battery receptacle as shown in Figure 2-7. Then push the battery in until you hear an audible click.

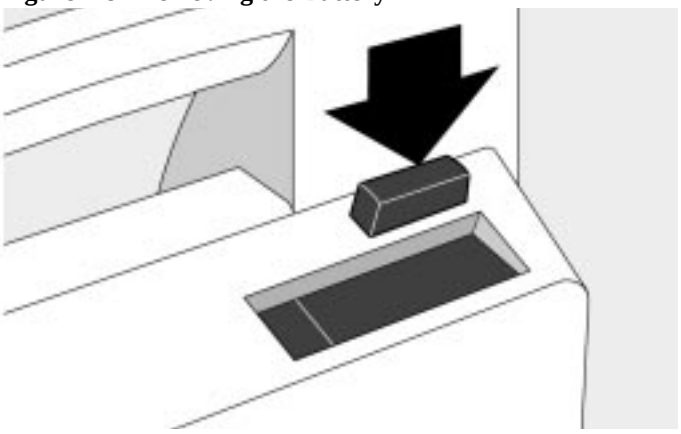
Figure 2-7 Inserting the Battery



Removing the Battery

To remove the battery from the Heartstream XL, press the black battery eject button and pull the battery out, as shown in Figure 2-8.

Figure 2-8 Removing the Battery



Low Battery Warning

The message Low Battery is displayed when the battery is low and needs recharging. This message indicates that the battery has sufficient remaining capacity to provide only about ten minutes of monitoring time and five shocks before the Heartstream XL shuts off. Replace the battery or get access to AC power as soon as possible.

If the power is off for less than 2 minutes, while you change the battery, the Heartstream XL assumes that you are continuing to treat the same patient, provided patient contact was established and the Event Summary was not printed prior to turning the power off. It continues to store data on the Data Card if being used and append events to the existing Event Summary. Alarms set prior to the power loss remain active.

If power remains off for more than 2 minutes, the Heartstream XL assumes you are treating a different patient and assigns a new incident number. A new Event Summary begins when patient contact is made.

Using a Data Card (Optional)

If you would like to collect patient information on a Data Card, the card must be inserted into the Heartstream XL before

- the device is turned on, and
- the incident has begun.

The recommended practice is to use one Data Card per patient. Once a Data Card fills, recording stops; a second Data Card may not be inserted for the current incident. Data cards hold up to two hours of patient information.

Multiple incidents can be recorded on a single Data Card. Each incident is assigned a unique incident number.

NOTE Patient data from a Data Card may be downloaded to a CodeRunner Web data management system. CodeRunner Web also allows you to erase patient data from a Data Card, allowing the card to be reused for another patient.

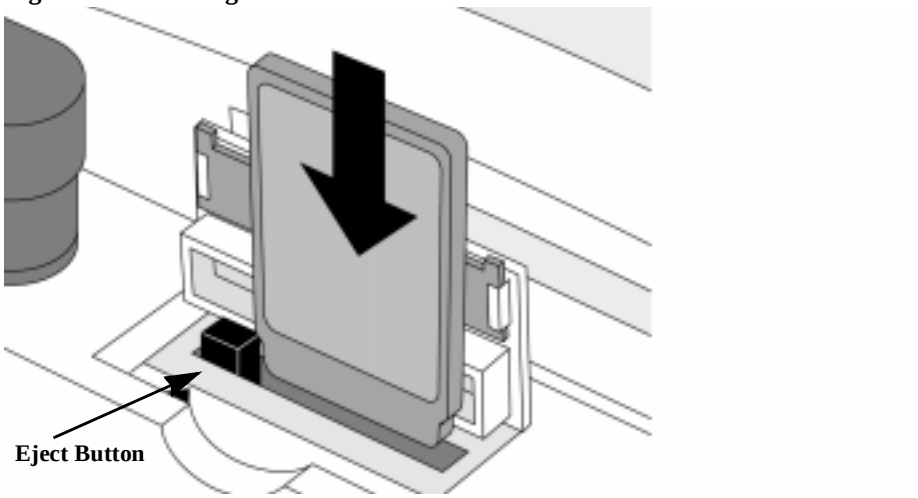
NOTE It’s recommended that you use a designated data card to configure one or more defibrillator/monitor.

Inserting a Data Card

To insert a Data Card:

1. Make sure the Heartstream XL is powered off.
2. Press up on the release latch to open the door to the Data Card compartment.
3. If a Data Card is already in the compartment, press the black button to the left of the card to eject the card (see Figure 2-9). Then pull the card out.
4. With the yellow label facing up and the ▲ pointing towards the Heartstream XL, slide the Data Card into the compartment. Be sure the card is seated securely within the compartment.
5. Close the Data Card compartment door. Make sure that you hear a click, indicating that the door is latched shut.

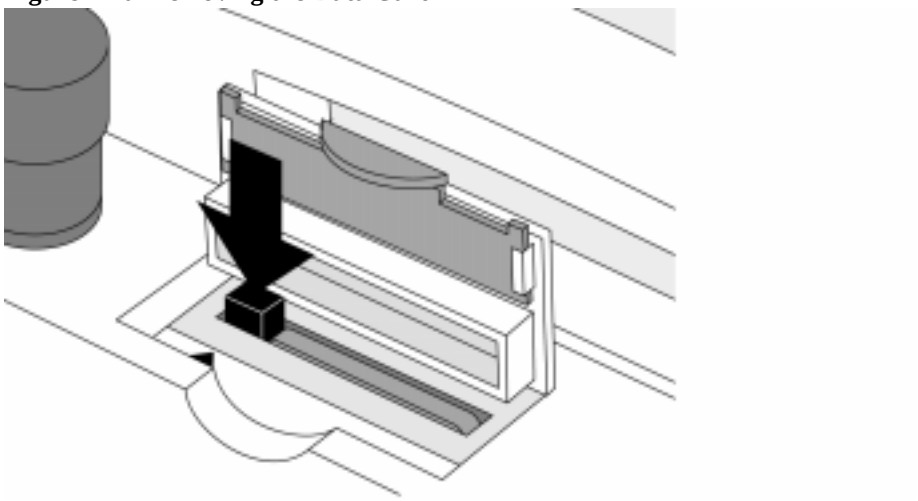
Figure 2-9 Inserting a Data Card



Removing a Data Card

To remove the Data Card, press the black eject button (see Figure 2-9) and pull the Data Card from the compartment.

Figure 2-10 Removing the Data Card



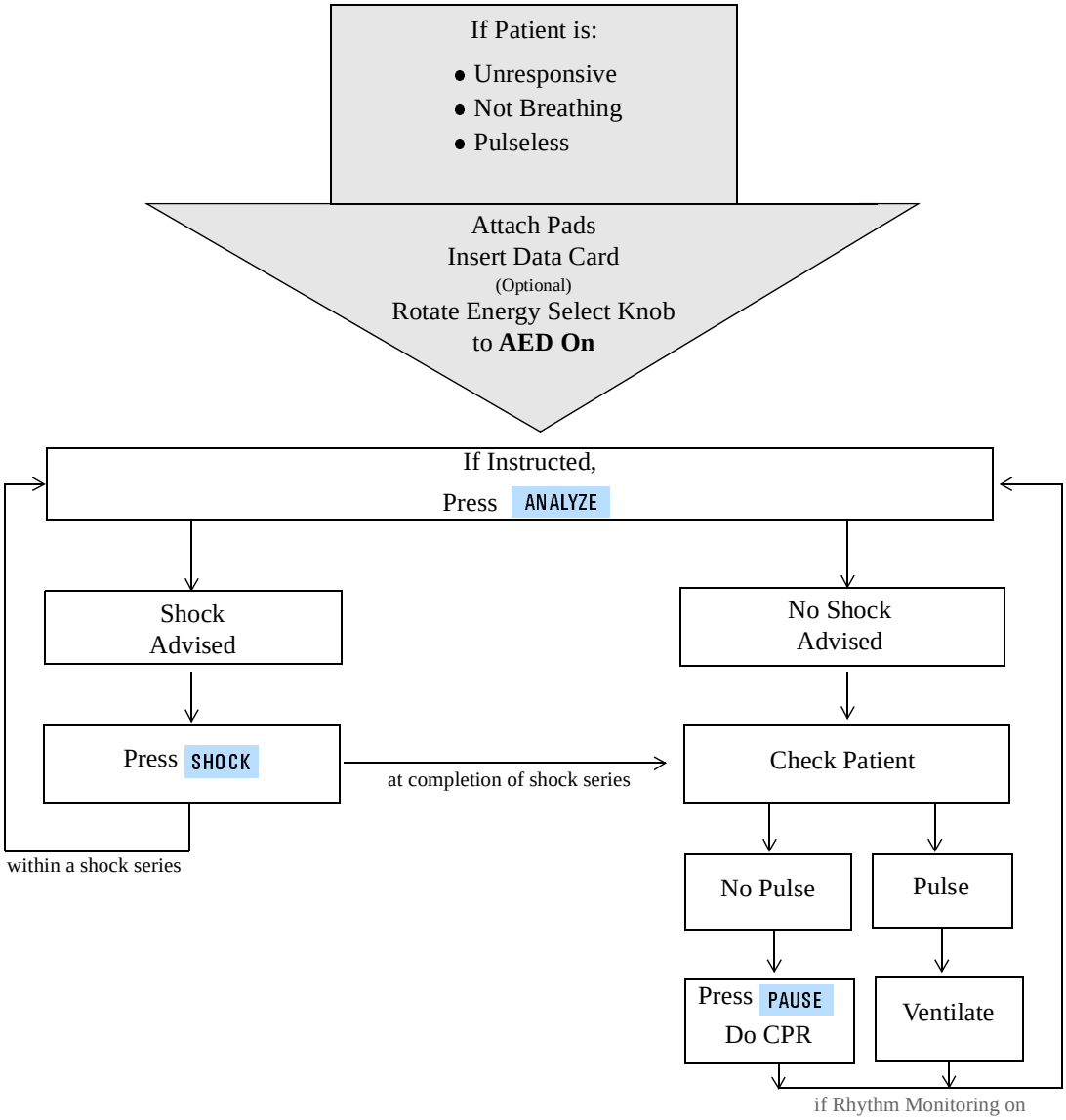
3 Defibrillating in AED Mode

The Heartstream XL's AED Mode is designed to guide you through standard treatment algorithms for cardiac arrest, including those provided by the American Heart Association and the European Resuscitation Council. Configuration choices allow you to customize AED Mode to better follow a specific treatment algorithm and to meet the unique needs of your life-saving team.

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

For information on storing, retrieving, and printing patient information acquired in AED Mode, see Chapter 9.

Figure 3-1 AED Mode Overview



Overview

An overview of the AED Mode defibrillation process is shown in Figure 3-1.

The process begins only after you have:

- assessed that the patient is unresponsive, not breathing, and pulseless,
- turned the Energy Select knob to AED On
- prepared for defibrillation by attaching pads and cables, and
- inserting a Data Card (if desired).

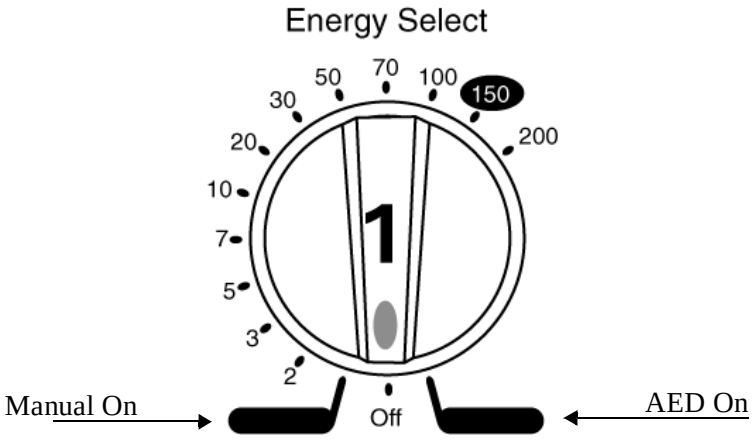
The defibrillation process is dependent upon the configuration of your Heartstream XL, as described in the following paragraphs.

Defibrillation (using the default configuration)

In its default configuration, the defibrillation process is:

Turn the Energy Select knob to AED On.

Figure 3-2 Energy Select Knob



The Heartstream XL checks to see if the pads patient cable and multifunction defib electrodes pads are properly connected. If either connection is compromised, you are prompted to fix the problem.

2 Analysis begins automatically - there is no need to press ANALYZE.

Once analysis is complete, the Heartstream XL tells you Shock Advised or No Shock Advised.

3 If a shock is advised, press SHOCK.

After the first shock is delivered, the Heartstream XL automatically begins analyzing the ECG and the process repeats until a shock series is complete or no shock is advised. At this point, you are prompted to check the patient.

Defibrillation (with a modified configuration)

Chapter 10 details the configurable parameters for AED Mode. Three parameters significantly impact the defibrillation process. They are:

Device Initiated Analysis - initiates ECG analysis when the Heartstream XL is first turned on. The default configuration setting is On. If you choose to set this parameter to Off, you need to press ANALYZE to initiate analysis in step 2 of the defibrillation process.

Automatic Re-analysis - initiates ECG analysis in between shocks within a shock series. The default configuration setting is On. If you choose to set this parameter to Off, you need to press ANALYZE to initiate analysis in between shocks within a shock series (i.e. after the first and second shock of a three shock series).

Rhythm Monitoring - monitors the ECG for potentially shockable rhythms when the Heartstream XL is not analyzing, defibrillating, or paused. The default setting is On. If you choose to set this parameter to Off, the Heartstream XL will not look for potentially shockable rhythms during these idle times. Idle times also include:

- power on, when Device Initiated Analysis is off.
- in between shocks within a shock series, when Auto Re-analysis is off.

If Rhythm Monitoring is off, you need to observe the patient during idle times and determine when to press ANALYZE.

The following sections describe the defibrillation process in detail. They also describe what happens at the completion of a shock series and if a shockable rhythm is not detected.

Preparation

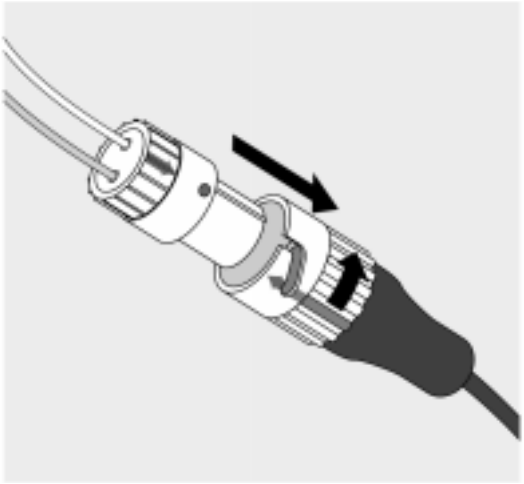
If the patient is:

- unresponsive
- not breathing
- pulseless

Then:

1. Apply multifunction defib electrode pads to the patient, as directed on the package. Use the anterior-apex electrode placement.
2. Connect the pads to the pads patient cable, as shown in Figure 3-3.
3. If needed, insert a Data Card (as described in “Using a Data Card (Optional)” on 2-13).

Figure 3-3 Connecting Pads to the Patient Cable



Defibrillating

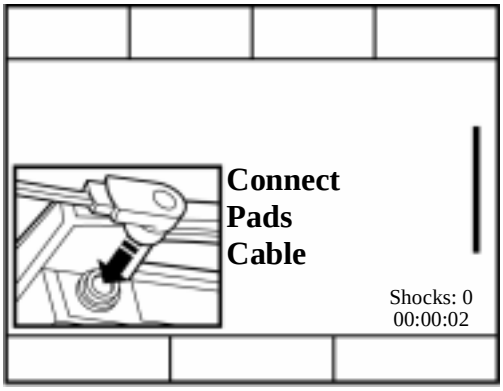
Follow the voice and screen prompts as they guide you through the following steps:

1. Turn the Energy Select knob to AED On.

In this first step of the defibrillation process, the Heartstream XL checks to see if the pads patient cable and the pads are connected. If they are, it proceeds to step 2.

If the pads patient cable is not properly attached, you are prompted to Connect Pads Cable.

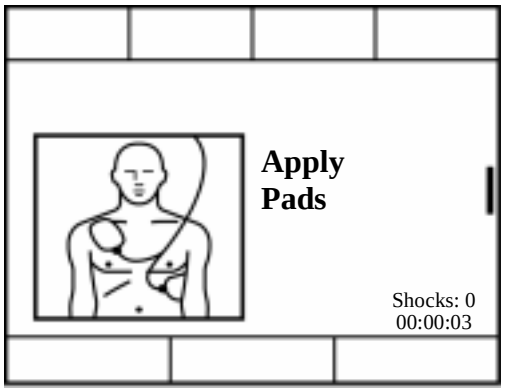
Figure 3-4 Connect Pads Cable Display



Once the cable is connected, the Heartstream XL will ensure the pads have adequate contact with the patient's skin. Contact quality is measured by monitoring the electrical impedance between the two pads.

If the pads have not been applied or are not making proper contact with the patient, you are prompted to Apply Pads and Check Connections.

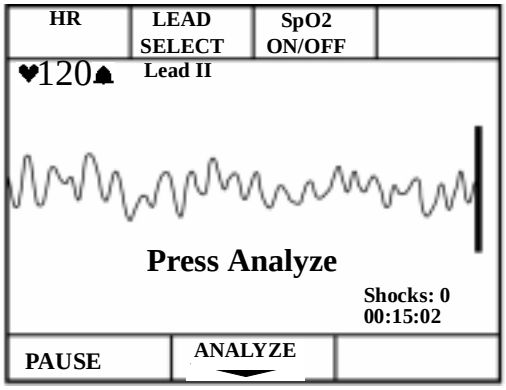
Figure 3-5 Apply Pads Display



2. If instructed, press ANALYZE.

If device-initiated analysis is **off**, the Heartstream XL monitors the rhythm provided Rhythm Monitoring is on. The Heartstream XL prompts you to press ANALYZE if a potentially shockable rhythm is detected.

Figure 3-6 Press ANALYZE Display

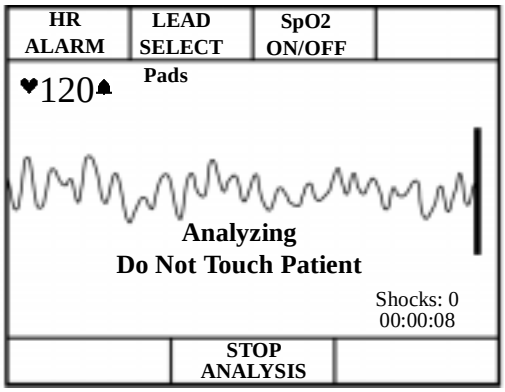


NOTE

ECG Analysis is always performed through multifunction defib electrode pads. Analysis can not be performed through monitoring electrodes.

If device-initiated analysis is **on**, you do not need to press ANALYZE; ECG analysis begins automatically.

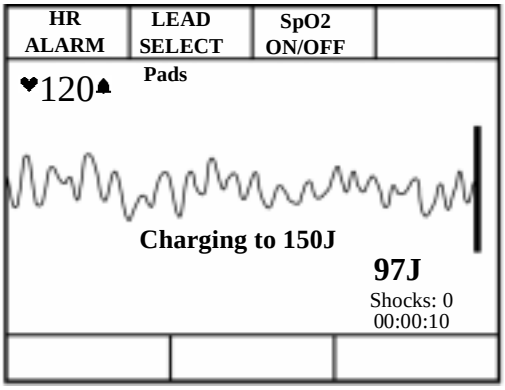
Figure 3-7 Analyzing Display



WARNING **Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis.**

If a shockable rhythm is detected, as indicated by the message Shock Advised, analysis stops and the Heartstream XL automatically charges to 150J. Charging is accompanied by an intermittent charge tone.

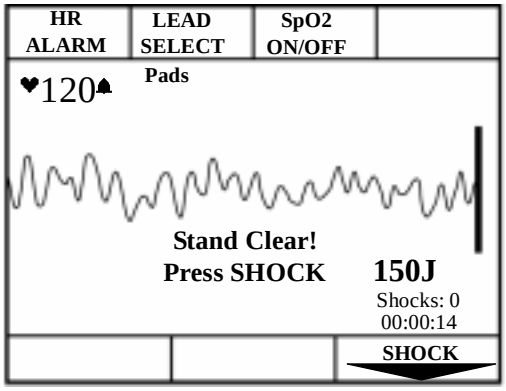
Figure 3-8 Charging Display



3. If shock advised, press SHOCK.

Once charging is complete, the charge tone becomes continuous. Make sure no one is touching the patient or anything connected to the patient. Call out clearly and loudly "Stand Clear." Then press SHOCK to deliver a shock to the patient.

Figure 3-9 Press SHOCK Display



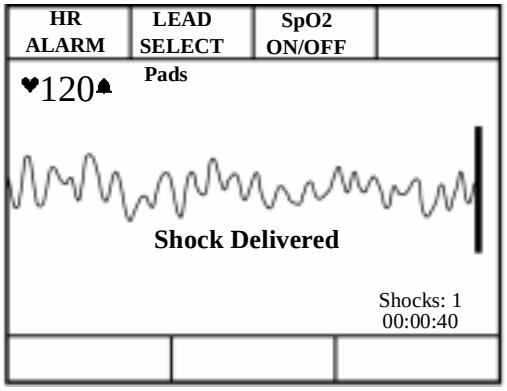
WARNING

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

The defibrillator automatically disarms within 30 seconds if you do not press SHOCK.

Delivery of the shock is confirmed by the message Shock Delivered and the shock counter is updated.

Figure 3-10 Shock Delivered Display



Automatic Re-analysis On

If Automatic Re-analysis is on, the Heartstream XL analyzes the ECG following delivery of the shock. You are prompted to press SHOCK, if an additional shock is advised. This cycle repeats until the rhythm converts or a shock series is complete. (A shock series may be configured to 2, 3, or 4 shocks.)

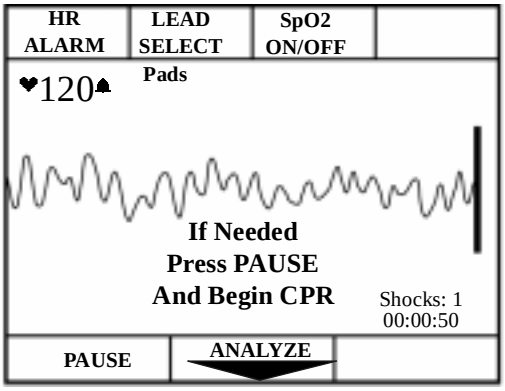
Automatic Re-analysis Off

If Automatic Re-analysis is off, the Heartstream XL monitors the ECG for potentially shockable rhythms provided Rhythm Monitoring is on and prompts you to press ANALYZE if one is detected. You can initiate analysis without being prompted by pressing ANALYZE.

Pausing for CPR

The Heartstream XL prompts you to Check Patient, Check Pulse at the completion of a shock series or when no shock is advised*. This default configuration will allow eight seconds to check the pulse, then prompts you as follows:

Figure 3-11 Press Pause Display

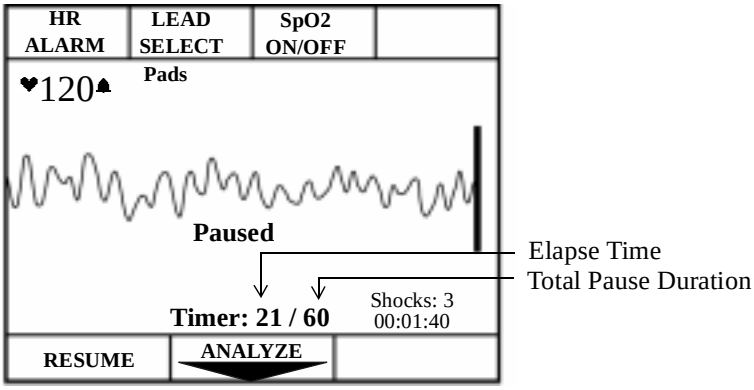


If CPR is needed, press PAUSE. While paused, the Pause Timer indicates the elapsed time and the total duration of the pause state, in seconds. The Pause Timer is configurable to meet your local CPR protocol needs. Rhythm, SpO_2 and heart rate monitoring alarms are suspended for the duration of the pause.

NOTE

* If your Heartstream XL is configured to support the European Resuscitation Council Guidelines for Resuscitation, refer to the “ERC Protocol” section on page 3-18 for details.

Figure 3-12 Pause Display



The pause state ends when the Pause Timer reaches the preconfigured pause state duration, or if you press RESUME or ANALYZE. At the completion of the pause state, the defibrillation process begins again. If instructed, press ANALYZE.

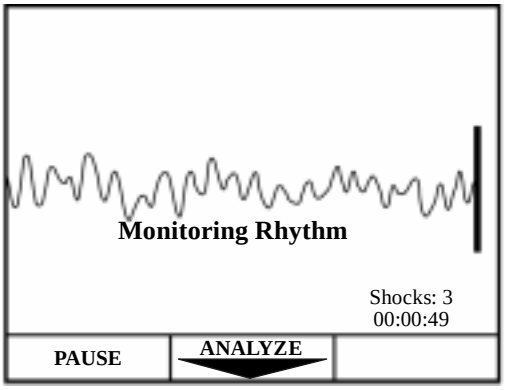
If you do not press PAUSE, the Heartstream XL begins monitoring the ECG rhythm provided Rhythm Monitoring is on.

You may initiate ECG analysis at any time by pressing ANALYZE.

Monitoring Rhythm

When the Heartstream XL is not analyzing, defibrillating, or paused, Rhythm Monitoring alerts you to potentially shockable rhythms (provided Rhythm Monitoring is set to the default configuration, On). The message Monitoring Rhythm appears on the display to let you know this feature is active and remains on the display for the duration of the monitoring.

Figure 3-13 Monitoring Rhythm Display

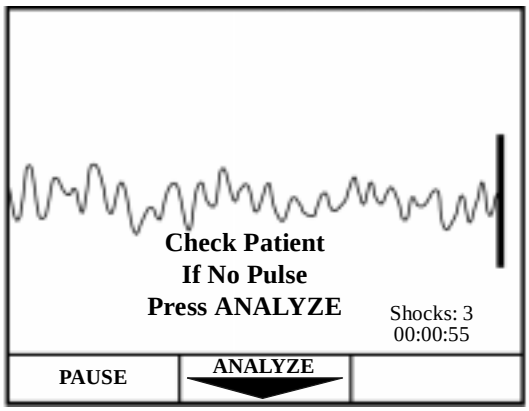


WARNING

The recommended configuration setting for Rhythm Monitoring is On. If Rhythm Monitoring is off, you are not alerted when a patient's rhythm changes from non-shockable to shockable (as in refibrillation or an initially nonshockable rhythm that converts to a shockable rhythm).

If Rhythm Monitoring detects a shockable rhythm, you are prompted as follows:

Figure 3-14 Shockable Rhythm



This prompt is repeated periodically, as configured, until ANALYZE or PAUSE is pressed. If you press ANALYZE, the defibrillation process starts again.

If you press PAUSE, rhythm monitoring is suspended for the duration of the pause. PAUSE is used when administering CPR, as noted earlier. It may also be useful when performing medical procedures or encountering artifact during patient transport. Active SpO2 and heart rate alarms are suspended during the pause duration, as well.

Press RESUME to restore rhythm monitoring. Active SpO_2 and heart rate alarms are also restored.

ERC Protocol

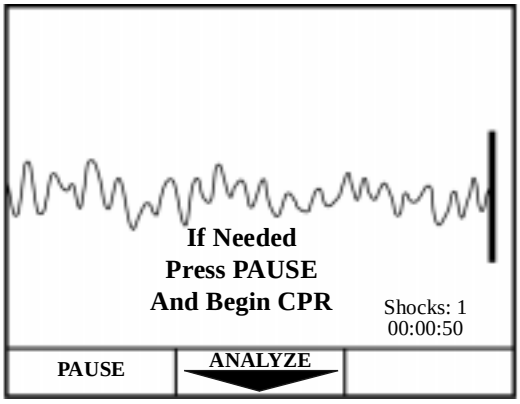
The Heartstream XL can be configured to support the European Resuscitation Council (ERC) Guidelines for Resuscitation. If European Protocol is configured to On, the defibrillation process described in this chapter is the same, with the exception of how the Pause state functions (see “Pausing for CPR” on 3-14).

As described, you can enter a Pause state:

- at the completion of a shock series, or
- when no shock is advised

In both cases, the ERC protocol prompts you to Check Patient. Then it prompts you as follows:

Figure 3-15 Check Patient Message

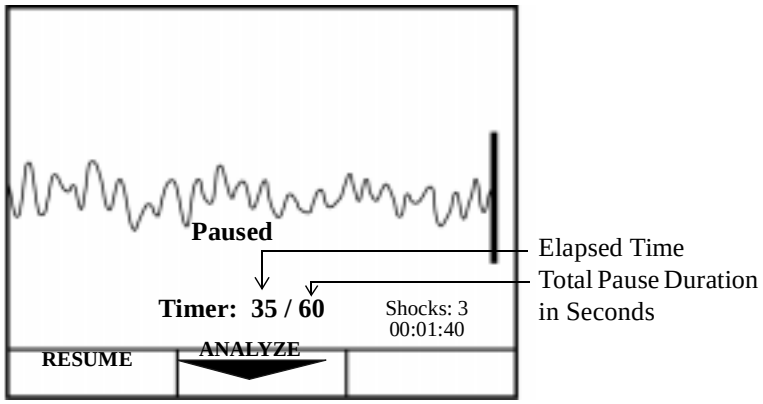


NOTE

Using the ERC protocol, you are not prompted (or given time) to check the patient’s pulse.

If CPR is needed, press PAUSE. While paused, a timer indicates the elapsed time and the total duration of the Pause state, as shown:

Figure 3-16 Display in Paused State



The total pause duration depends on the event preceding the Pause state. If you entered the Pause state:

- at the completion of a shock series or shortly after a shock is delivered, the duration is equal to the Post Shock CPR Timer configuration setting (the default setting is 60 seconds).
- when no shock was advised, the duration is equal to the "NSA" Timer configuration setting, where NSA is an acronym for No Shock Advised (the default setting is 180 seconds).

Troubleshooting

When the Heartstream XL detects a problem, it provides display and/or voice prompts to guide you to resolution. The table below lists the prompts you may encounter in AED Mode, the cause, and the suggested corrective action. Prompts related to the battery and Data Card are discussed in Chapter 12.

Table 3-1: Troubleshooting in AED Mode

Prompt	Possible Cause	Corrective Action
Pads Off (display) *or* Apply Pads (voice)	• The multifunction defib electrode pads are not properly applied to the patient.	• Check that the pads are applied to the patient's bare chest, as directed on the pads' package. Replace the pads if the prompt continues.
Pads Cable Off (display) *or* Apply Pads (voice)	• The pads cable is not connected to the defibrillator.	• Check that the defibrillation pads connector is locked in place.
Artifact Detected/ Do Not Touch Patient	• Patient motion interferes with analysis. • Electrical sources are causing interference.	• Attempt to eliminate patient motion. Avoid analyzing while transporting or performing CPR. • Move suspected devices away from the defibrillator, when possible.
Shock Canceled	• Shock key not pressed within 30 seconds.	• Press within 30 seconds of prompt.

Table 3-1: Troubleshooting in AED Mode

Prompt	Possible Cause	Corrective Action
No Shock Delivered	• Pads are not properly connected to the patient.	• Check pads connection.
Key Inactive	• The key pressed only functions in Manual Mode. • The key pressed does not function during analysis or charging. • The key pressed does not function while in a pause state.	• Turn the Energy Select knob to Manual on prior to pressing the key. • Wait for analysis or charging to complete prior to pressing the key. • Press RESUME prior to pressing the key.

Troubleshooting

4 Monitoring the ECG

This chapter will provide information about:

- applying monitoring electrodes,
- selecting the correct lead,
- setting and disabling the heart rate (HR) alarm, and
- adjusting the ECG size.

For information on how to apply multifunction defib electrode pads, follow the directions on the pads packaging.

NOTE For information on storing, and retrieving, and printing patient information acquired while monitoring, see Chapter 9.

Overview

The Heartstream XL can be used for short or long-term ECG monitoring. The ECG monitoring function allows you to monitor through:

- multi-function defib electrode pads, or
- 3- or 5-lead ECG monitoring electrodes, as configured.

When the Heartstream XL is turned on, the ECG acquired is shown on the display. ECG monitoring allows you to continue to monitor through the pads or to select a lead from an alternate ECG source. (3- or 5-lead). ECG monitoring also displays the heart rate (HR) and allows you to set HR alarms. ECG monitoring is always active in Manual Mode. In AED Mode, ECG monitoring is only active if Lead Select is configured to on (the default is on). Plug the 3 or 5-lead ECG patient cable into the connector marked ECG as shown in Figure 4-1.

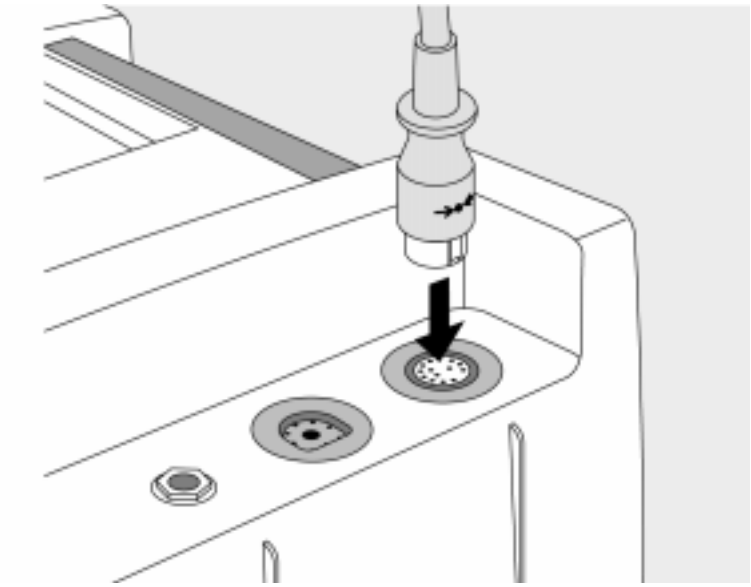
A new, fully-charged battery provides approximately 100 minutes of continuous monitoring.

Connecting the ECG Patient Cable

To connect a 3- or 5-lead ECG patient cable:

1. Align the keyed patient cable connector with the slot on the ECG receptacle, as shown in Figure 4-1.
2. Push the patient cable firmly into the ECG receptacle, until the white portion is no longer visible.

Figure 4-1 ECG Patient Cable Connector/Receptacle



To disconnect the ECG patient cable, gently pull the white patient cable connector out of the ECG receptacle.

Applying Monitoring Electrodes

Proper application and placement of electrodes is essential for reliable monitoring. Good contact between the electrode and the skin reduces the effects of motion artifact and signal interference.

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.

To apply electrodes:

1. Identify the appropriate electrode sites. (See Figure 4-2 and Figure 4-3.)
2. Shave the electrode sites, if necessary.
3. Clean and abrade the skin at the electrode sites.
4. Dry the skin at the electrode sites.
5. Open a new package of M2202A Radio-Translucent Monitoring Electrodes; verify that the "Use Before" date has not passed.
6. Apply the electrodes by peeling them, one at a time, from the protective backing and sticking them firmly to the patient’s skin. Press around the entire edge of each electrode to ensure that they are secure.
7. Snap the lead wires onto the electrodes. Make sure the lead wires do not pull on the electrodes.

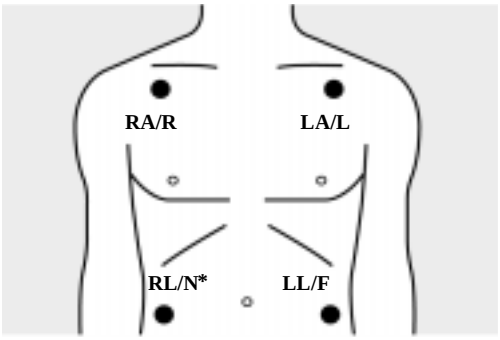
NOTE

If monitoring for long periods of time, new monitoring electrodes and multifunction defib electrode pads may need to be changed periodically. Refer to the manufacturer’s documentation for how often.

Electrode Placement

Figure 4-2 shows typical electrode placement for the limb leads of a 3- or 5-lead patient cable. The V/C lead of the 5-lead cable can be placed in any of the precordial lead positions (V1/C1 through V6/C6) shown in Figure 4-3.

Figure 4-2 Limb Lead Electrode Placement



AHA Labels	IEC Labels
RA Right Arm	**R** Right
LA Left Arm	**L** Left
RL Right Leg*	**N** Negative*
LL Left Leg	**F** Foot

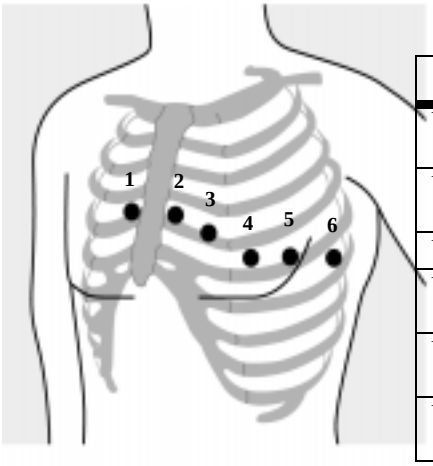
* Not used for 3-lead.

Table 4-2 3-Lead ECG Lead Formation

Lead	+	-	reference
I	LA	RA	LL
II	LL	RA	LA
III	LL	LA	RA

4

Figure 4-3 Precordial Lead Electrode Placement



Lead		Location
V1	C1	forth intercostal space, at right sternal margin
V2	C2	forth intercostal space, at left sternal margin
V3	C3	midway between V2/C2 and V4/C4
V4	C4	fifth intercostal space, at left midclavicular line
V5	C5	same level as V4/C4, on anterior axillary line
V6	C6	same level as V4/C4, at left mid axillary line

Table 4-3: 5-Lead ECG Lead Formation

Lead	Lead Formation
I	LA - RA
II	LL - RA
III	LL - LA
aVR	$RA - \frac{LA + LL}{2}$
aVF	$LL - \frac{RA + LA}{2}$
aVL	$LA - \frac{RA + LL}{2}$
V_x	$V/C - \frac{RA + LA + LL}{2}$

Selecting the Lead

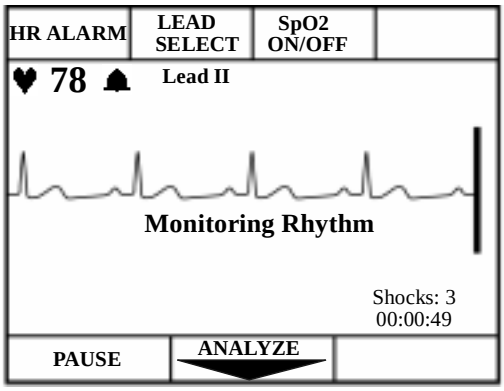
Available monitoring leads depend upon how your device is configured.

Table 4-4: Lead Select Choices

Lead Select Choices are:	If Configured for a:
Paddles, Pads, Lead I, Lead II, Lead III	3-lead ECG cable
Paddles, Pads, Lead I, Lead II, Lead III, aVR, aVL, aVF, V lead.	5-lead ECG cable

To select a lead to monitor, cycle through the choices by pressing LEAD SELECT until the desired lead is displayed.

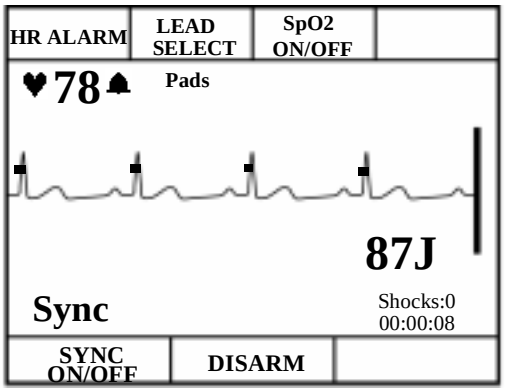
Figure 4-4 ECG Monitoring Display in AED Mode



NOTE

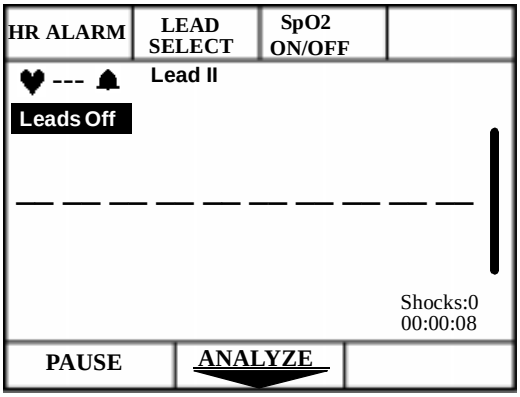
To change to a different V Lead, move the electrode rather than pressing the Lead Select softkey.

Figure 4-5 ECG Monitoring Display in Manual Mode



The message Leads Off is displayed in the System Message area accompanied by a beep when a lead is disconnected or the electrodes have poor patient contact. A dashed line on the display indicates that there is no ECG signal as shown in Figure 4-6.

Figure 4-6 Leads Off Display in AED Mode



Setting the Heart Rate Alarm

The computed heart rate (the number of detected QRS complexes per minute) is displayed below the HR ALARM softkey, next to the ♥. The heart rate represents the number of QRS complexes detected in a minute. If configured to on, a QRS beeper identifies each QRS complex detected.

WARNING

Heart rate alarms and meters function with internal and external pacemakers but they can be unreliable. Observe the patient closely if pacemakers are used.

The HR alarm may be configured to alert you when the heart rate is outside the specified limits. Limit choices are listed in Table 4-5: HR Alarm Limit Choices.

Table 4-5: HR Alarm Limit Choices

Alarm If Under:	Or Over:
30	100
60	140
90	160
120	200

To set a HR alarm, cycle through the limit choices by pressing HR ALARM until the desired limits are shown. The 🔔 then appears next to the heart rate value to indicated that the HR alarm is set.

WARNING

Heart rate alarms are temporarily suspended in AED Mode during ECG analysis or when PAUSE is pressed (for the duration of the paused period). Heart rate alarms are also suspended while charging for defibrillation and delivering a shock.

Disabling the HR Alarm

If the heart rate is outside the HR alarm limits, an alarm sounds. To disable the alarm, press HR ALARM. appears to indicate that the alarm is disabled.

Adjusting the ECG Size

To increase or decrease the size of the ECG, press ▲ or ▼ on the gain control,  . Preset ECG sizes are x.25, x.5, x1.0, x2.0, and x4.0. The default setting at power on is x1.0.

Adjusting the ECG Volume

To increase or decrease the volume of voice prompts and/or alarms, press ▲ or ▼ on the volume control,  .

NOTE

Note: When using the Heartstream XL during a new event, the ECG volume is set at the default volume level. However, if the unit is turned off and then back on within 2 minutes (continued use), the volume settings will remain where you left them when the unit was turned off.

Troubleshooting

Table 4-6 provides troubleshooting tips for ECG Monitoring.

Table 4-6 Troubleshooting when Monitoring the ECG

Situation	Cause	Solution
Leads Off message or dashed line (------)	• The monitoring electrodes are not applied or are not making proper contact with the patient. • The monitoring cable is not connected.	• Check that the monitoring electrodes are properly applied. • Check that the monitoring cable is properly connected.
Pads Off message	• The pads are not making proper contact with the patient.	• Check that the pads are properly applied.
Poor ECG signal quality	• The monitoring electrodes are not making proper contact with the patient. • The monitoring electrodes are outdated or dried-out. • Radio frequency interference (RFI) is causing artifact.	• Check that the monitoring electrodes are properly applied. If necessary, prepare the patient's skin and apply new electrodes. • Check the date code on the electrodes. Do not open the electrode package until immediately prior to use. • Relocate or turn off equipment that may be causing RFI.

Situation	Cause	Solution
QRS Volume	• No sound • Too low • Too loud	• Adjust the volume. • Check configurations.
QRS beeper inaudible or beeps do not occur with each QRS complex.	• The QRS beeper is configured to **Off**. • The amplitude of the QRS complex is too small to detect.	• Check that the QRS beeper is configured to **On**. • Adjust the volume. • Adjust the size of the ECG.

5 Monitoring SpO_2

This chapter will provide information about:

- how pulse oximetry works
- selecting and applying the correct sensor
- monitoring SpO_2
- discontinuing SpO_2

Introduction

Pulse oximetry is a noninvasive method of continuously measuring oxygen saturation (SpO_2) in arterial blood. The resultant SpO_2 reading indicates the percentage of hemoglobin molecules in the arterial blood which are saturated with oxygen. SpO_2 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 Heartstream XL to monitor SpO_2.

SpO_2 monitoring is always available both in AED and Manual Mode (if the option is purchased).

For information on printing, storing, and retrieving patient information acquired while monitoring, see Chapter 9.

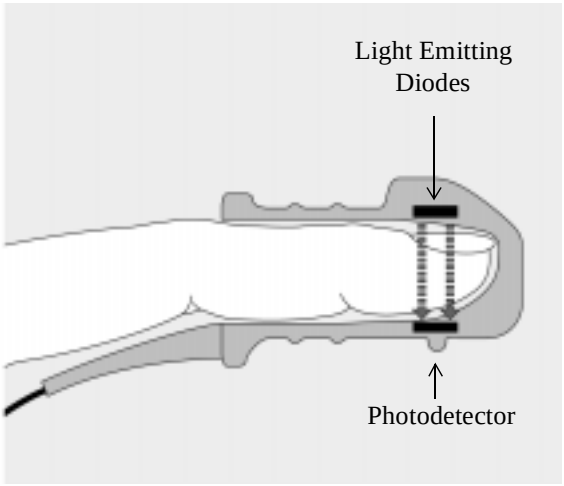
WARNING

Do not rely solely on SpO_2 readings; assess the patient at all times. SpO2 readings may be inaccurate in the presence of significant levels of carboxyhemoglobin or methomoglobin, in patients with restricted blood flow to the extremities (such as those in severe shock or hypothermia), or in the presence of excessive motion.

Understanding Pulse Oximetry

A pulse oximetry sensor sends light through patient tissue to a receiver on the other side of the sensor. As Figure 5-1 shows, light emitting diodes transmit red and infrared light through peripheral areas of the body, such as a finger.

Figure 5-1 Pulse Oximetry Sensor



A photodector 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 SpO_2 value is displayed.

For accurate SpO_2 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 5-1 shows the SpO_2 sensors that may be used with the Heartstream XL.

Table 5-1 Approved Sensors

Sensor	Type	Patient	Patient Size	Ideal Site
M1191A	Reusable	Adult	> 50 kg	Finger
M1192A	Reusable	Small adult Pediatric	15-50 kg	Finger
M1194A	Reusable	Pediatric Adult	> 40 kg	Fleshy part of ear
M1903A/B (Nellcor D-20)	Disposable	Pediatric	10-50 kg	Toe/Finger

NOTE

To use Nellcor sensors, you must connect the M1943A Nellcor Adaptor patient cable to the Heartstream XL. (See “Connecting the SpO2 Patient Cable” on page 10-5.)

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 within 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.
- Avoid application to sites with edematous tissue.

Reusable Sensors

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

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

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.
- Avoid excessive pressure at the sensor site; ensure that circulation is not obstructed.
- 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 any extremity with an arterial catheter, blood pressure cuff, or intravascular venous infusion line.

WARNING

Failure to apply the sensor properly may reduce the accuracy of the SpO_2 measurment.

WARNING

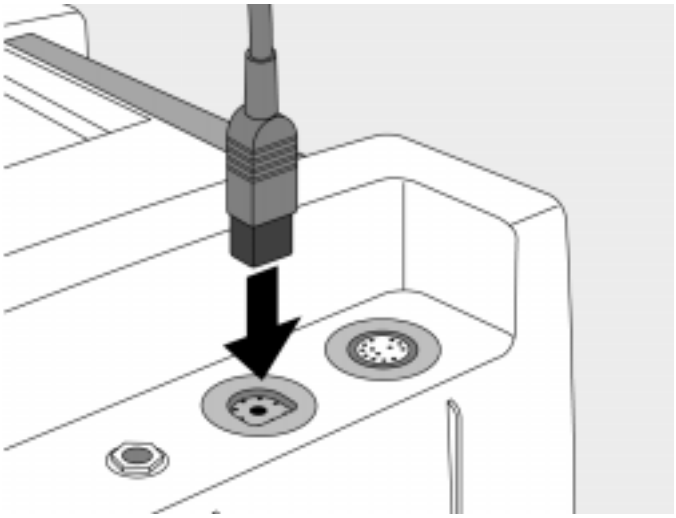
Inspect the sensor application site at least every two hours for changes in skin quality, correct optical alignment, and proper sensor application. If skin quality is compromised, change the sensor site. More frequent checking may be required due to an individual patient's condition.

Connecting the Sensor Cable

To connect a sensor cable:

1. Hold the connector with the flat side up so that the part number is visible.
2. Insert the connector into the receptacle and push until the blue portion of the connector is no longer visible.

Figure 5-2 Connecting the Sensor Cable



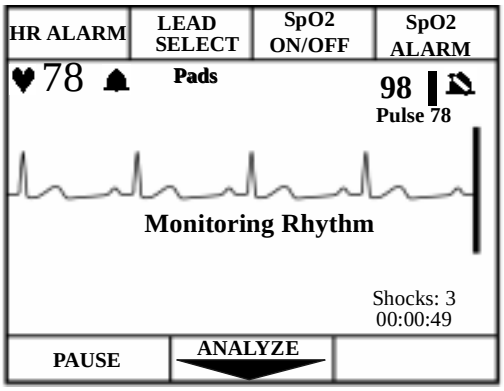
Monitoring

To monitor SpO_2:

1. If the Heartstream XL is not on, turn the Energy Select knob to AED On or Manual On.
2. Apply the appropriate sensor to the patient.
3. Make sure the sensor cable is connected to the Heartstream XL.
4. Press SpO_2 ON/OFF to turn on SpO_2 monitoring.

A dashed line (---) is displayed under SpO_2 ALARM, while the oxygen saturation is measured and an SpO_2 value is calculated. In a few seconds the SpO_2 value is displayed in place of the dashed line. As the patient's oxygen saturation changes, the SpO_2 value is updated continuously.

Figure 5-3 SpO_2 Monitoring Display in AED Mode



To the right of the SpO_2 value, a pleth bar and SpO_2 alarm indicator are displayed. The pleth bar should be observed for fluctuation. It is an indication of pulsation detected by the sensor. The pleth bar should not be used as the sole indicator of pulsation because it can be influenced by movement and artifact.

The symbol indicates no alarm is set.

Below the SpO_2 value is the pulse rate derived from the pulse oximetry.

Setting Alarms

An alarm may be set to alert you if the SpO_2 value falls below a specified lower limit. Lower limit alarm choices are (no alarm), 90, 85, or 80. The defaulted high limit is 100 and cannot be changed. Press SpO_2 ALARM repeatedly to cycle through the choices. Stop when the desired choice is displayed. A appears in three seconds, indicating that the selected alarm is active. To review the alarm limit, press SpO_2 ALARM.

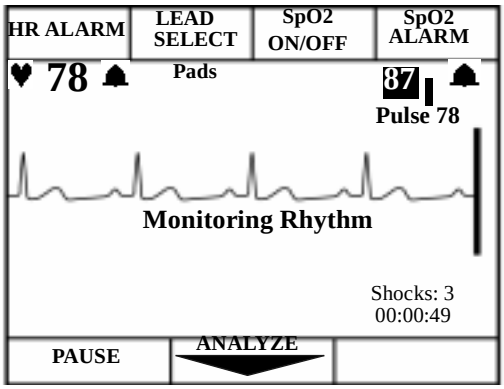
WARNING

SpO_2 alarms are temporarily suspended in AED Mode during ECG analysis or when PAUSE is pressed (for the duration of the paused period). SpO_2 alarms are also suspended while charging for defibrillation and delivering a shock.

Responding to an Alarm

When the SpO_2 value falls below the alarm limit, a continuous tone alerts you and the SpO_2 value is displayed in inverse video.

Figure 5-4 SpO_2 Alarm Triggered



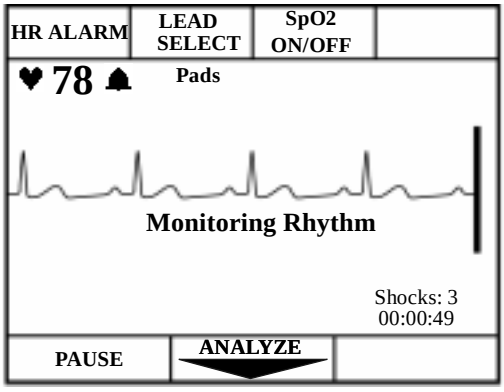
Press SpO_2 ALARM to turn off the alarm. Refer to “Setting Alarms” if subsequent alarms are desired.

5

Discontinuing SpO_2 Monitoring

To shut off SpO_2 monitoring, press SpO_2 ON/OFF once. Nothing should appear below the SpO_2 ALARM softkey.

Figure 5-5 SpO_2 Monitoring Off



Caring for Sensors

Refer to the manufacturers instructions for care and cleaning of sensors. To get the best results from your SpO_2 reusable 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

The table below lists system messages that you may encounter when monitoring SpO_2.

Table 5-2: Troubleshooting when Monitoring SpO_2

Problem or Message	Possible Cause	Corrective Action
Non Pulsatile	• Pulse absent or too weak to be detected.	• Check the sensor is applied properly. • Make sure the sensor site has a pulse. • Relocate the sensor to a site with improved circulation. • Try another sensor type. • Make sure nail polish is not present.
SpO_2 Low Signal	• SpO_2 signal is too low to give an accurate reading.	• Check the sensor is applied properly. • Try another sensor type.
SpO_2 Noisy Signal	• Excessive patient movement, electrical interference, RF interference, or optical interference.	• Minimize patient motion or apply sensor to site with less movement. • Secure the sensor cable loosely to the patient • Reduce sources of electrical, RFI, or optical interference.

Table 5-2: Troubleshooting when Monitoring SpO_2

Problem or Message	Possible Cause	Corrective Action
SpO_2 Light Interf	• The level of ambient light is so high that the sensor cannot obtain an SpO_2 reading. • Sensor or cable is damaged.	• Cover sensor with an opaque material. • Check sensor for damage; try another sensor.
SpO_2 Cable Off	• The SpO_2 cable is not connected to the device.	• Attach the cable to the Heartstream XL.
SpO_2 Sensor Fail	• The transducer is broken.	• Apply a new transducer.

6 Defibrillating in Manual Mode

In Manual Mode you analyze the ECG, decide if defibrillation is indicated, select the energy level, charge the device, and deliver the shock. The defibrillation process is under your control. There are no voice prompts. However, system and momentary messages provide relevant information throughout the process. It is important to be attentive to these messages.

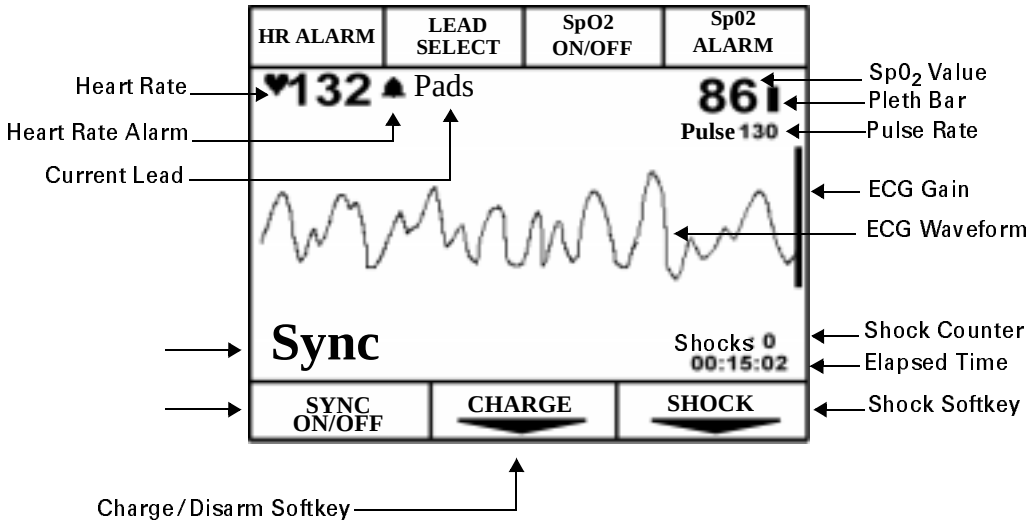
This chapter describes how to defibrillate using Manual Mode. For Manual Mode features such as synchronized cardioversion and pacing, see Chapter 7: Performing Synchronized Cardioversion and Chapter 8: Pacing (Optional).

For information on storing, retrieving, and printing patient information acquired in Manual Mode, see Chapter 9: Storing, Retrieving, and Printing.

Manual Mode Display

The following figure (Figure 6-1) identifies the major elements for the Manual Mode display. Unlike the AED Mode display, Manual Mode gives you access to synchronized cardioversion and self-selected energy levels.

Figure 6-1: Manual Mode Display



Enabling Manual Mode

To enable Manual Mode, turn the Energy Select knob to Manual On.

Defibrillating in Manual Mode

This section will explain how to prepare for and perform asynchronous defibrillation in Manual Mode using multifunction defib electrode pads, and paddles.

NOTE

In Manual Mode, defibrillation is always performed through paddles or pads. However, during defibrillation, you may choose to monitor leads acquired through an alternate ECG source (3- or 5-lead monitoring electrodes).

Using External Paddles

In preparation for defibrillation in Manual Mode using external paddles, perform the following steps:

1. If needed, insert a Data Card (as described in “Using a Data Card (Optional)” on 2-13).
2. Turn the Energy Select knob to Manual On.
3. Remove paddles by simultaneously pulling them up and out of the holders.

4. Apply conductive matter.

NOTE

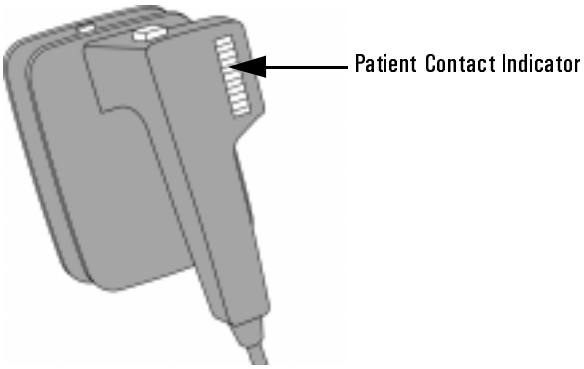
Do apply conductive matter by rubbing paddles together. Improper usage will result in a "Paddles On" event that will be registered in the Event Summary and may damage paddles.

5. Apply paddles to patient’s chest, using the anterior-apex placement.

NOTE

To optimize patient contact, adjust paddle pressure and placement. Once proper contact has been made, the patient contact indicator (PCI) located on the Sternum paddle will show a green LED. (See Figure 6-2).

Figure 6-2 Patient Contact Indicator on Sternum Paddle

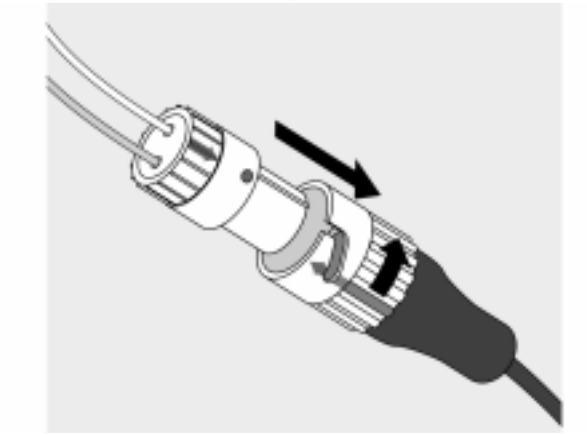


Using Multifunction Defib Electrode Pads

In preparation for defibrillation in Manual Mode using pads, perform the following steps:

1. If needed, insert a Data Card (as described in “Using a Data Card (Optional)” on 2-13).
2. Turn the Energy Select knob to Manual On.
3. If you are using multifunction electrode pads, apply as directed on the package. Use either the anterior-apex or anterior-posterior electrode placement, as appropriate.
4. Connect the pads to the pads patient cable, as shown in Figure 6-3.

Figure 6-3 Connecting Pads to the Patient Cable



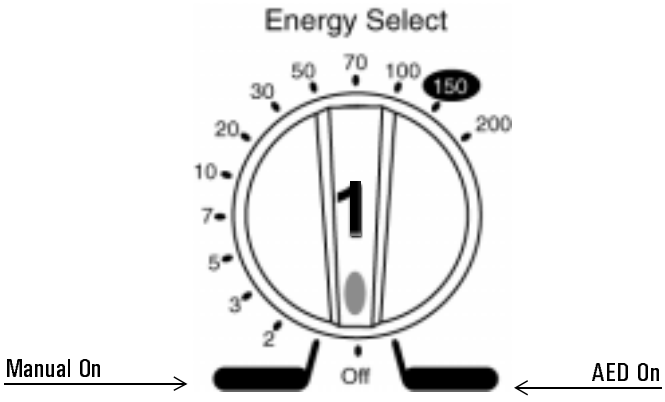
Defibrillation Procedure

Once you have prepared to defibrillate in Manual Mode, perform the following steps.

1. Select Energy

To select the energy setting, move the Energy Select knob to the desired energy level as shown in Figure 6-4. Energy choices range from 2 to 200 joules, with the suggested level for adults being 150 joules.

Figure 6-4 Energy Select Knob

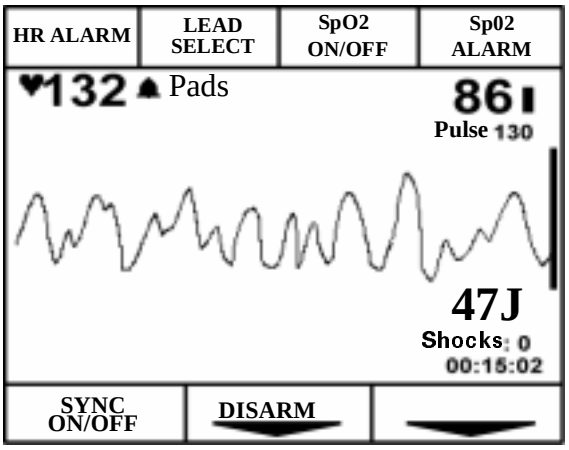


2. Charge

Press CHARGE or charge button on paddles.

As the defibrillator charges, the current charge is displayed above the shock counter (if configured on) as shown in Figure 6-5. A charging tone beeps until the desired energy level is reached, at which point you'll hear a continuous charge tone.

Figure 6-5 Charging Display



You may increase or decrease the selected energy level after pressing the CHARGE button. Simply move the Energy Select knob to desired energy level as before.

The defibrillator charges to the selected energy level automatically.

WARNING **Wait until the current charge reaches the selected energy level before readjusting the selected energy level.**

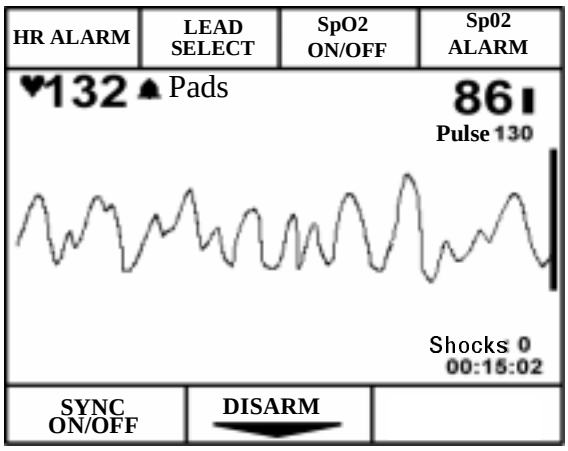
3. Shock

Confirm that a shock is still indicated. Make sure no one is touching the patient or anything connected to the patient. Call out loudly and clearly "Stand Clear!"

If using pads paddles, press SHOCK to deliver a shock to the patient.

If using external paddles, simultaneously press the shock buttons located on the paddle/s until the shock is delivered.

Figure 6-6 Manual Mode Shock Display.



To disarm the defibrillator, press DISARM. If SHOCK or the shock buttons are not pressed within 30 seconds, the defibrillator disarms automatically.

If additional shocks are indicated, repeat the defibrillation process.

WARNING

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

Entering AED Mode

To enter AED Mode from Manual Mode, simply turn the Energy Select knob from Manual On to AED On.

ECG and/or SpO2 monitoring are defaulted enabled in AED Mode. If these settings are still active, the alarms set in Manual Mode remain active when you switch to AED Mode.

Entering AED Mode

7 Performing Synchronized Cardioversion

Synchronized cardioversion is a Manual Mode function that allows you to synchronize the defibrillator shock with the R-wave of the ECG being monitored.

There are three ways to monitor ECG for synchronized cardioversion:

- multifunction defib electrode pads,
- 3- or 5-lead monitoring electrodes, or
- external paddles attached to the M4735A Heartstream XL

You may also use an external Agilent or Hewlett Packard ECG monitor while performing synchronized cardioversion.

When selecting a lead, choose the best lead that displays a large QRS complex. The synchronized shock is delivered through the mulifunction defib electrode pads, or external paddles regardless of the lead being monitored.

This chapter describes how to perform synchronized cardioversion with the Heartstream XL.

NOTE

See chapter 4, “Monitoring the ECG” for information on how to apply electrodes and select a lead.

Using Multifunction Defib Electrode Pads

To prepare for synchronized cardioversion using multifunction defib electrode pads, perform the following steps:

1. If needed, insert a Data Card (as described in “Using a Data Card (Optional)” on 2-13).
2. Apply monitoring electrodes, if desired. (See “Applying Monitoring Electrodes” on page 4-4.)
3. Turn Energy Select knob to Manual On.
4. Apply multifunction defib electrode pads to the patient as directed on the package. Use either the anterior-apex or anterior-posterior placement, as appropriate.
5. Connect the pads to the patient cable. (See Figure 6-3.)
6. Press the Sync On/Off button to turn synchronized cardioversion functionality on.
7. Use LEAD SELECT to select the best lead that displays a large QRS complex. (See “Selecting the Lead” on page 4-7.)

Using 3 or 5-wire ECG Leads

To prepare for synchronized cardioversion using 3 or 5-wire ECG leads, perform the following steps:

1. If needed, insert a Data Card (as described in “Using a Data Card (Optional)” on 2-13).
2. Apply monitoring electrodes, if desired. (See “Applying Monitoring Electrodes” on page 4-4.)
3. Turn Energy Select knob to Manual On.
4. Connect the ECG cable to the Heartstream XL. (See Figure 6-3.)
5. Press Sync On.
6. Use LEAD SELECT to select the best lead that displays a large QRS complex. (See “Selecting the Lead” on page 4-7.)

Using External Paddles

To prepare for synchronized cardioversion using external paddles, perform the following steps.

1. If needed, insert a Data Card (as described in “Using a Data Card (Optional)” on 2-13).
2. Apply monitoring electrodes, if desired. (See “Applying Monitoring Electrodes” on page 4-4.)
3. Turn the Energy Select knob to Manual On.
4. Remove paddles from pockets by simultaneously pulling out and up Apply conductive material.

NOTE

Do not apply conductive matter by rubbing paddles together. Improper usage will result in a "Paddles On" event that will be registered in the Event Summary and may cause paddle damage.

5. Apply paddles.
6. Press Sync On.
7. Use LEAD SELECT to select the best lead that displays a large QRS complex. (See “Selecting the Lead” on page 4-7.)

WARNING

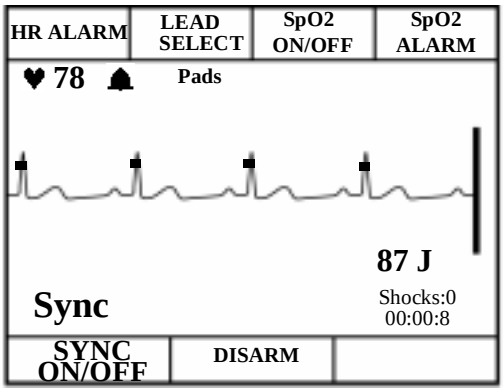
Artifact introduced by paddle movement may resemble an R-wave and trigger a defibrillation shock. When performing synchronized cardioversion, pads are suggested.

Delivering a Synchronized Shock

Once you are properly prepared to perform synchronized cardioversion, perform the following steps.

1. Press  located below the Sync On/Off display to enable Sync Mode. The message SYNC appears on the display.
2. Use the gain control,  , to adjust the ECG size so that the marker dot appears only with each R-wave.
3. Select the desired energy level.
4. Press CHARGE or the yellow charge button located on the Apex paddle. Wait until the current charge has reached the energy level selected and you hear a continuous charge done tone.

Figure 7-1: Charging in Sync Mode



If desired, you may increase or decrease the selected energy level after pressing CHARGE by moving the Energy Select knob until the desired energy level is displayed. 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 "Stand Clear!" Then press SHOCK.

If you are using external paddles, deliver the shock by pressing and simultaneously holding the orange keys on both external paddles.

NOTE

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

WARNING

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

Using External ECG Monitors

When the patient is already connected to the bedside monitoring equipment, there is an external monitoring cable which plugs into the ECG Output jack of the bedside monitor and connects to the M4735A Heartstream XL ECG Input for monitoring.

To use an external monitor with the Heartstream XL, perform the following steps:

1. Select Lead I or Lead II on the Heartstream XL.
2. Plug the cable into the external monitor ECG Output jack and plug the input end of the cable into the ECG Input plug on the Heartstream XL.

Delivering Additional Synchronized Shocks

If additional synchronized shocks are indicated, make sure Sync Mode is still enabled and repeat steps 2-5. In its default configuration, the Heartstream XL remains in Sync Mode after a shock is delivered, as indicated by the message Sync on the display.

The Heartstream XL can be configured to exit Sync Mode after each shock is delivered.

Disabling Sync Mode

To disable Sync Mode, press  located below the Sync display. The message Sync is no longer displayed. Sync Mode is also disabled when you exit Manual Mode.

Disabling Sync Mode

8 Pacing (Optional)

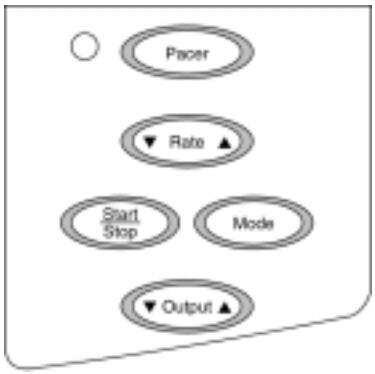
Noninvasive transcutaneous pacing is a Manual Mode function that is used to deliver paced pulses to the heart. Paced pulses are delivered through multi-function defib electrode pads that are applied to the patient's bare chest.

This chapter explains the pacing option available with the Heartstream XL and describes how to perform pacing.

Pacing Operational Controls

In Manual Mode, the following pacing operational controls are displayed on the handle of the Heartstream XL.

Figure 8-1 Pacing Controls (Manual Mode only)



Demand Mode Versus Fixed Mode

The Heartstream XL 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.

Monitoring During Pacing

Multifunction defib electrode pads cannot be used to monitor the ECG and deliver paced pulses simultaneously. When pacing in demand or fixed mode, you must monitor the patient through either 3- or 5-lead monitoring electrodes. The Heartstream XL uses the R-wave detection from this monitoring source to determine if a paced pulse should be delivered.

WARNING **Use demand mode pacing whenever possible. Use fixed mode pacing when motion artifact or other ECG noise makes R-wave detection unreliable.**

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

Preparing for Pacing

To prepare for pacing, perform the following steps.

1. Apply multifunction defib electrode pads as directed on the package. Use either the anterior-apex or anterior-posterior placement, as appropriate.
2. Connect the pads to the patient cable. (See Figure 6-3.)
3. If needed, insert a Data Card (as described in "Using a Data Card (Optional)" on 2-13).
4. Turn the Energy Select knob to Manual On.

In addition, for demand mode pacing:

1. Apply monitoring electrodes. (See “Applying Monitoring Electrodes” on page 4-4.)
2. Use LEAD SELECT to select the best lead with an easily detectable R-wave (See “Selecting the Lead” on page 4-7.) If you do not select a lead (i.e. pads is the selected ECG source), Lead I is automatically selected when the pacing function is turned on.

NOTE

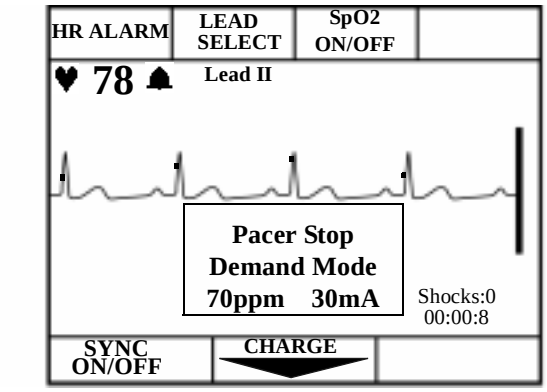
If pacing for long periods of time, new monitoring electrodes and multifunction defib electrode pads may need to be applied periodically. Refer to the manufacturer’s documentation for recommendations regarding frequency.

Performing Pacing

To use pacing, perform the following steps.

1. Press Pacer. The green LED next to Pacer lights up and a dialogue box appears on the display.

Figure 8-2: Pacing with ECG Monitoring Electrodes Display



The Pacer Stop message indicates that the pacing function is on but paced pulses are not being delivered. The pacer turns on in the mode last used.

2. Verify that the dot markers appears near the middle of the QRS complexes of the ECG.

   If the dot markers do not appear, or are in the wrong location, adjust the ECG size or select another lead. (See “Monitoring the ECG” in Chapter 4.)

3. Press Mode to change to fixed mode, if in demand mode or if R-wave detection is unreliable.

   The pacing dialogue box displays the current mode. To switch back to demand mode, press Mode again.

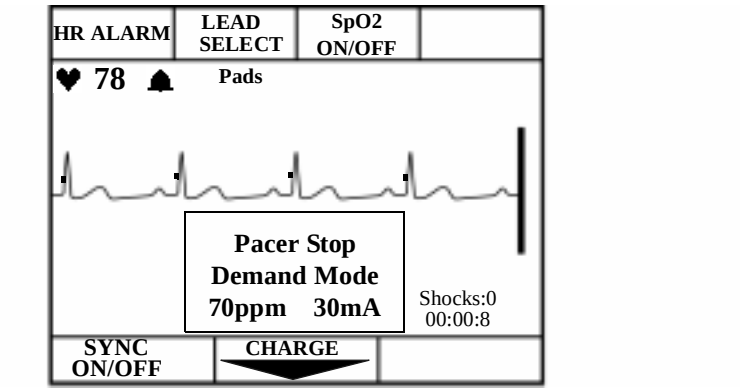
4. Adjust the rate to the desired number of paced pulses per minute (ppm).

   Press up (▲) or down (▼), on Rate to increase or decrease the number of paced pulses per minute.

5. To start pacing, press Start Stop.

   The message Pacing indicates that paced pulses are being delivered in the selected mode at the rate and output level displayed.

Figure 8-3: Pacing with Pads Display



6. Increase the output until cardiac capture occurs.

   Press ▲ on Output to increase the output in increments of 10 mA.

7. Decrease the output to the lowest level that still maintains capture.

   Press ▼ on Output to decrease the output in increments of 5 mA.

8. Press Start Stop to stop pacing.

9. Press Pacer to exit the pacing function. The green LED next to the button goes out, indicating pacing is no longer active.

NOTE If pacing using pads, pacing will not start if there is a problem with the multi-function defib electrode pads connections. If in demand mode, pacing will not start if there is a problem with the ECG monitoring electrodes connections. In either case, if a problem occurs a system message is displayed.

NOTE The pacing window remains on as long as the pacing function is enabled.

Changing Pacing Modes

If paced pulses are being delivered, you must stop pacing before changing the pacing mode. For example:

1. Press Start Stop to stop pacing.
2. Press Mode to change the Mode.
3. Adjust the rate, if needed.
4. Press Start Stop to resume pacing.
5. Adjust the output, as needed to obtain capture.

Defibrillating During Pacing

If the patient must be defibrillated during pacing, follow the procedure for defibrillating in Manual Mode on page 6-1.

Pacing is automatically turned off when you charge the defibrillator and the pacing dialogue box is removed from the display. After a shock, pacing remains off.

To resume pacing, refer to “Performing Pacing” on page 8-5. When you resume, settings selected prior to defibrillation (rate, mode, and output) remain the same.

Troubleshooting

The table below lists the pacing-related system and momentary messages that you may encounter when using the pacing function.

Table 8-1: Pacing System Messages

Message	Possible Cause	Corrective Action
Leads Off	• The selected monitoring lead is not making proper contact with the patient. • Pacing was attempted in demand mode without monitoring electrodes attached.	• Check that the monitoring electrodes are properly applied. • Check that the monitoring cable and electrodes are properly connected.
Pacer Failure	The pacing system is not functioning.	Remove the device from active use and call for service.
Pacer Output Low	High patient impedance is resulting in the delivering less current to the patient than specified in the output current setting.	Check that the pads are applied properly.
Stop Pacer	Mode is pressed while paced pulses are being delivered.	Stop pacing before changing the pacing mode.
Key Inactive	Pacer, or one of the other pacing function keys, is pressed when Manual Mode is not active.	Make sure Manual Mode is active before pressing Pacer or one of the other pacing function keys.

8

9 Storing, Retrieving & Printing

This chapter describes how the Heartstream XL creates an Event Summary, or patient record, for later retrieval and printing. Marking events for storage in the Event Summary and printing individual events as they occur are also discussed.

Overview

The Heartstream XL automatically creates an Event Summary for each patient. The Event Summary is stored in both internal memory and on a Data Card (if one is used).

The Heartstream XL's internal Event Summary stores:

- up to 300 events (pieces of critical information), and
- 50 ECG strips (at 11 seconds each).

Events include things such as charging, shocks, and alarm violations. You also trigger an event each time you press Mark or Strip.

Storage on a Data Card is limited only by available space on the card. In addition to storing all of the events that occur, a continuous copy of the displayed ECG and Patient Contact Impedance are stored.

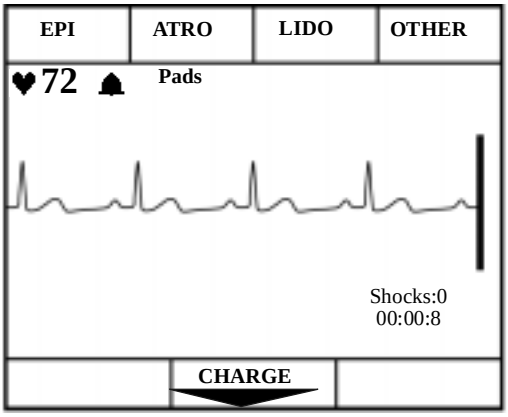
You can print the internal Event Summary at any time. You can also configure your Heartstream XL to print individual events automatically as they occur. Finally, you can activate printing of individual events and patient information at any time by pressing Strip.

To print an Event Summary stored on the Data Card, the information must first be downloaded to the Agilent Technologies CodeRunner Web data management system. Refer to the CodeRunner Web User's Guide for download instructions.

Marking Events

The Mark button allows you to annotate the ECG strip at the point in time the button is pressed. In AED Mode, when monitoring is disabled, the event is marked with a ▲. In Manual Mode, or when monitoring is enabled in AED Mode, you can use the softkeys to select the annotation from the choices displayed (See Figure 9-1)*. If no selection is made, the event is marked with just a ▲.

Figure 9-1 Annotations



NOTE

* In Australia and the U.K., EPI is replaced by ADRN (adrenaline).

The marked event is stored in the Event Summary. If the printer is configured to Print on Mark, an ECG strip prints when Mark is pressed. If the printer is configured to 6 second delay, the strip is 9 seconds and includes 6 seconds preceding the event and 3 seconds following the event. If No Delay is configured, a 3 second ECG strip prints in real time. To stop printing before the entire strip is printed, press Strip.

Events Recorded

The following events and related information are stored in the Event Summary:

Table 9-1: Event Information

Event Types	Related Information Stored
Power Change	Power on, Power off, Continued use, Battery low.
Pads Change	Pads on, Pads off.
AED Mode Analysis	Analyzing, Analysis Stopped, Artifact Detected, Cannot Analyze, Shock Advised, No Shock Advised.
Mode Change	AED Mode or Manual Mode.
Rhythm Monitoring	Check Patient, Pause, Resume.
Charging	ECG waveform, Energy charged to.
Shock	ECG waveform, Shock#, Delivered energy, Peak current, and Patient impedance.
Shock Failed	No Shock Delivered.
Disarm	ECG waveform.
ECG Monitoring	Leads on/off, Lead change, Gain change.
Heart Rate Alarm Violation	Lead, Heart Rate, and Heart Rate alarm limits.

Table 9-1: Event Information

Event Types	Related Information Stored
SpO_2 Violation	SpO2 value and SpO2 alarm limit.
Mark	ECG waveform with annotation (▲, Epi, Atro, Lido, or Other).
Print Strip	ECG waveform.
Sync	Sync on, Sync off, Sync pace marker.
Pacing	Pacer start, Pacer stop, Pacer settings.

Creating a Patient Record

The Heartstream XL creates an Event Summary patient record for each new patient. Each record is assigned a unique incident number. The Heartstream XL keeps the Event Summary in its internal memory until you begin caring for a new patient. It assumes the following:

Table 9-2: Power Status and Patient Records

If:	Then:
Power is off for more than 2 minutes and a new event is recorded	The Heartstream XL assumes you are caring for a new patient. The last internal Event Summary is deleted; a new Event Summary is started and a new incident record is created
Power is off less than 2 minutes	The Heartstream XL assumes you are continuing to care for the same patient. Additional events are appended to the Event Summary; the annotation "Continued Use" is printed on the Event Summary, provided it wasn't printed prior to turning the Heartstream XL off and/or patient contact was never made.

If the Heartstream XL is off for more than two minutes and turned on with no new event the data is saved.

The Continued Use feature allows you to change batteries or shut the Heartstream XL off briefly (for 2 minutes or less), while preserving the current patient record. Events recorded after the power interruption are appended to the patient record. Continued use also preserves alarm settings.

Printing the Internal Event Summary

To print the internal Event Summary, press Summary. To stop printing before the complete summary is printed, press Summary again or press Strip.

The Event Summary includes the following information, in the order listed:

- a header with a place for you to write in the patient's name and the operator's name.
- a directory list of events that occurred during the incident and the time of their occurrence.
- ECG strips of the events in the directory list, where relevant.

Figure 9-2 shows the beginning of an Event Summary.

Figure 9-2 Event Summary

Patient _____		Device On	12:41:00
		AED Mode	12:41:00
Operator _____		Pads On	12:41:01
		Leads On	12:41:03
Device On	03 Jan 00 12:41:00	Analyzing	12:41:03
		Shock Advised	12:41:11
Last Event	03 Jan 00 01:09:04	Shock #1	12:41:17
		Analyzing	12:41:24
Total Shocks 2		Shock Advised	12:41:31
Incident: 0000045		Shock #2	12:41:38
Serial Number 123456789		Manual Mode	12:41:42

The Event Summary also includes waveforms and the appropriate annotation for each of the following events:

Table 9-3: Event Summary Information

Event	Waveform Information Stored
Shock Advised	11 seconds of ECG just prior to the message Shock Advised.
No Shock Advised	11 seconds of ECG just prior to the message No Shock Advised.
Cannot Analyze	11 seconds of ECG just prior to the message Cannot Analyze.
Shock Delivered	11 seconds; 3 seconds prior to the shock, plus 8 seconds after the shock.
Strip pressed	11 seconds; 3 seconds prior to Strip being pressed, plus 8 seconds after Strip is pressed.
Mark pressed	11 seconds; 3 seconds prior to Mark being pressed, plus 8 seconds after Mark is pressed.
Heart Rate or SpO_2 Alarm	11 seconds; 3 seconds prior to the alarm, plus 8 seconds after the alarm.

Printing Events

The Heartstream XL can be configured to print automatically when certain events occur. The table below lists these events and the length of the strip printed, depending on whether the printer is configured to print real-time or with a 6-second delay.

Table 9-4: Configurations for Length of Printed Strips

Event	Real-Time Strip Length	Delayed Strip Length
Defibrillator charges	continuous	6 seconds just prior to charging, plus continuous printing throughout the charge duration.
Shock Delivered	12 seconds	6 seconds just prior to shock, plus 12 seconds after shock.
Shock Failed	6 seconds	6 seconds just prior to the message No Shock Delivered, plus 6 seconds after the message.
Defibrillator disarmed	6 seconds	6 seconds just prior to disarm, plus 6 seconds after disarm.
SpO2 or Heart Rate Alarm Violation	6 seconds	6 seconds just prior to alarm violation, plus 6 seconds after alarm violation.
Mark pressed	6 seconds	6 seconds just prior to marking, plus 6 seconds after button pressed.

Printing is configured independently for each of these events. You can stop the printing before it has printed the entire strip by pressing Strip.

To print additional events that you observe in the course of caring for your patient, press Strip.

NOTE

An ECG strip will print continuously until you press Strip a second time to stop printing. If the printer is configured to have a 6-second delay, the print-out contains an additional 6 seconds of the ECG that occurred just prior to pressing Strip.

10 Setting Up and Configuring the Heartstream XL

This chapter describes how to set-up and configure your Heartstream XL. Chapter 10 covers:

- Connecting Patient Cables
- Configuring the Heartstream XL

Connecting/Disconnecting Patient Cables

This section describes how to connect and disconnect the:

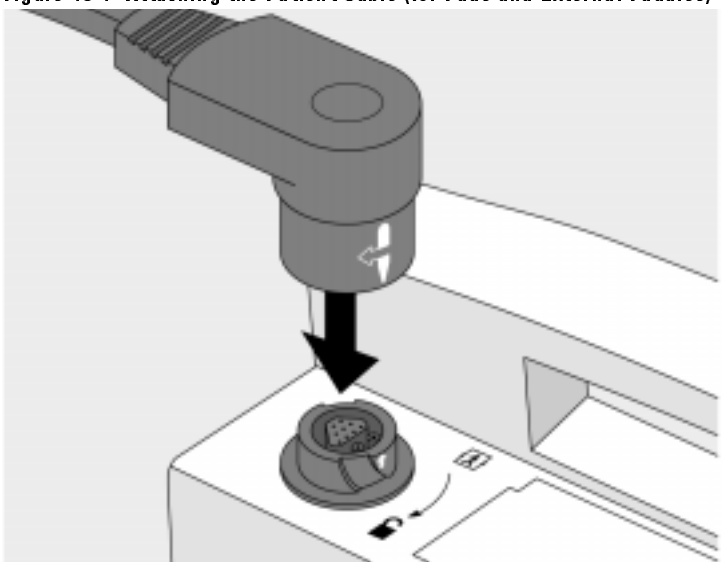
- Pads/Paddles Patient Cable
- ECG Patient Cable (3- or 5-lead)
- SpO2 Patient Cable

Pads/Paddles Patient Cable

To connect external paddles to the defibrillator:

1. Align the white arrow on the patient cable with the white arrow on the defibrillator's cable connector, as shown in Figure 10-1.
2. Insert the cable into the connector. Push until you hear it click in place.

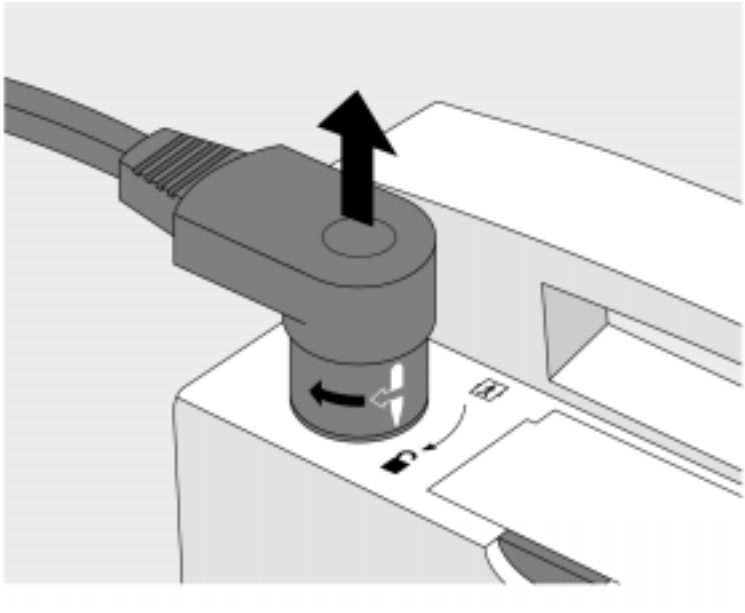
Figure 10-1 Attaching the Patient Cable (for Pads and External Paddles)



To disconnect the patient cable from the defibrillator:

1. Rotate the green locking mechanism on the cable in the direction of the green arrow (clockwise), until it stops (as shown in Figure 10-2).
2. Hold the locking mechanism in this position as you pull the cable out.

Figure 10-2 Disconnecting the Pads/Paddles Patient Cable

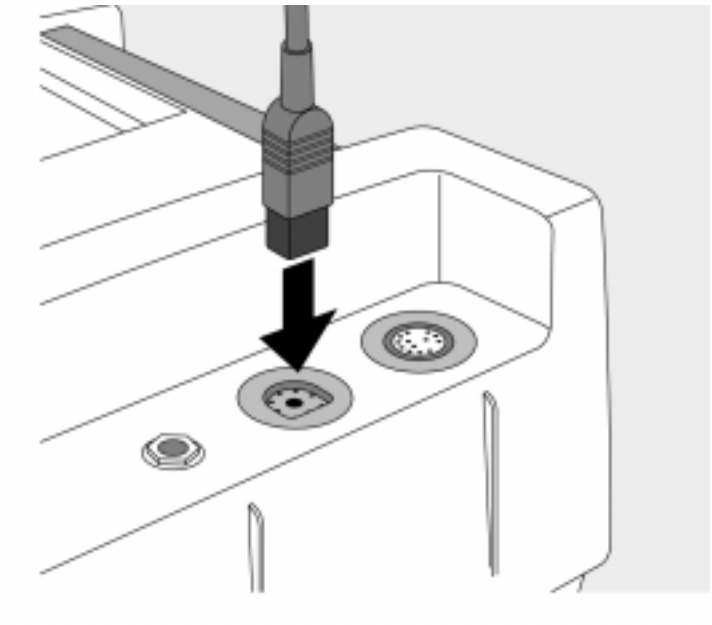


SpO_2 Patient Cable

To connect the SpO_2 patient cable:

1. Hold the connector with the flat side facing away from the Heartstream XL, as shown in Figure 10-3.
2. Insert the connector into the receptacle and push until the blue portion of the connector is no longer visible.

Figure 10-3 Connecting the SpO_2 Patient Cable



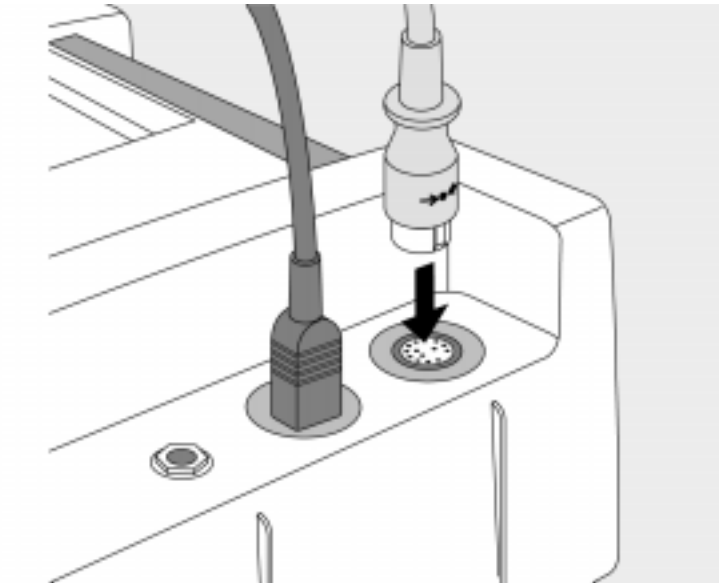
To disconnect the SpO_2 patient cable, gently pull the connector out of the SpO_2 receptacle.

ECG Patient Cable

To connect a 3- or 5-lead ECG patient cable:

1. Align the keyed patient cable connector with the slot on the ECG receptacle, as shown in Figure 10-4.
2. Push the patient cable firmly into the ECG receptacle, until the white portion is no longer visible.

Figure 10-4 ECG Patient Cable Connector/Receptacle



To disconnect the ECG patient cable, gently pull the white patient cable connector out of the ECG receptacle.

Configuring the Heartstream XL

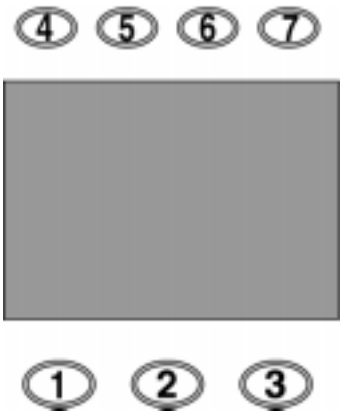
Configuration options allow you to customize the Heartstream XL to best meet your needs. This section describes:

- how to access the configuration menu
- configurable items and their setting options
- how to change the configuration
- how to save the configuration to a Data Card
- how to load the configuration from a Data Card
- how to print the configuration

Accessing the Configuration Menu

There is a special combination of softkeys that, when pressed simultaneously, turn the Heartstream XL on in Configuration Mode. For the purposes of executing this procedure, softkeys are assigned numbers as shown in Figure 10-5.

Figure 10-5 Softkey Numbers

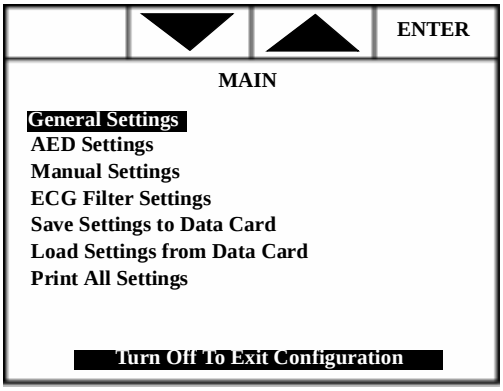


To turn the Heartstream XL on in Configuration Mode:

1. If the device is already on, turn the Energy Select knob to Off.
2. While holding down softkeys 4 & 5, turn the Energy Select knob to AED On.

The configuration menu appears as shown in Figure 10-6. The menu lists the categories of settings that may be configured.

Figure 10-6 Configuration Menu



Configurable Parameters

The following tables show the configurable parameters for each category of settings. A description of each parameter is provided, along with the possible choices. Default settings are in bold.

Table 10-1: General Settings

Parameter	Description	Setting Choices
Date (dd mmm yyyy)	Current date, where dd is the day, mmm is the month, and yyyy is the year.	any valid date
Time (hh:mm)	Current time, where hh is the hour and mm is the minutes. Time is based on a 24 hour clock.	any valid time
Print on Mark	Prints a 3 second strip when Mark is pressed.	**On** / Off
Print on Charge	Prints a continuous strip during charging. Printing continues until a shock is delivered, the device is disarmed, or Strip is pressed.	**On** / Off
Print on Shock	Prints a 12 second strip when a shock is delivered.	**On** / Off
Print on Alarm	Prints a 6 second strip during alarms.	**On** / Off
Printer Delay	Captures what you just saw. All printed strips, including those generated by an event (mark, charge, shock or alarm), include an additional 6 seconds of information - the 6 seconds of information that occurred just prior to printing being initiated.	**6 Sec Delay** / No Delay
Pace Pulse Markers	Shows pace pulse markers on the ECG displayed, if an internal pacemaker is detected.	**Leads & Pads** / Leads Only
ECG Lead Cable	Selects the monitoring electrodes source.	**3-lead** / 5-lead
QRS Beeper	Provides an audible beep with each QRS complex detected.	**On** / Off

Table 10-2: AED Settings

Parameter	Description	Setting Choices
AED Shock Series	Defines the maximum number of shocks to deliver before prompting Check Patient, Check Pulse, If Needed Begin CPR.	2, **3**, 4
Shock Series Timer	Defines the number of seconds that must pass before the next shock is considered the first shock of a new shock series, rather than the next shock of the current shock series.	30, **60**, 90, 120, 150, 180, 210, Off
Device Initiated Analysis	Initiates ECG analysis when the Heartstream XL is turned on in AED Mode for new use.	**On**, Off
Automatic Re-analysis	Initiates ECG analysis in between shocks within a shock series.	**On**, Off
Rhythm Monitoring	Monitors the ECG for potentially shockable rhythms when the Heartstream XL is not analyzing, defibrillating, or paused.	**On**, Off
Lead Select	Turns on ECG monitoring via ECG Leads.	**On**, Off
SpO2	Turns on SpO2 monitoring. Only listed as a configurable item if the SpO_2 option was purchased.	**On**, Off
Check Patient Timer	Defines how often (in seconds) the Check Patient prompt is repeated when Rhythm Monitoring detects a potentially shockable rhythm.	**30**, 45, 60, 90, Off

Table 10-2: AED Settings

Parameter	Description	Setting Choices
Pause Timer*	Defines the duration of the pause time (in seconds), when PAUSE is pressed (when European Protocol is set to Off). Appears only when European Protocol is configured off. Pause Timer is the default.	30, **60**, 120, 180
European Protocol	Modifies Pause state prompts and replaces the Pause Timer with either the Post Shock CPR Timer or the "NSA" Timer, depending on the event preceding the Pause state.	**Off**/On
Post Shock CPR Timer*	Appears only when European Protocol is on. Defines the duration of the Pause time (in seconds) when PAUSE is pressed and the time since the last shock is less than or equal to the Shock Series Timer setting - typically at the completion of a shock series.	30, **60**, 120, 180
"NSA" Timer*	Appears only when European Protocol is on. Defines the duration of the Pause time (in seconds) when PAUSE is pressed. Also defines the time since the last shock is greater than the Shock Series Timer setting when No Shock Advised.	30, 60, 120, **180**

* If European Protocol is set to Off, the Pause Timer is used during the Pause state and appears as a configurable parameter. If European Protocol is set to On, either the Post Shock CPR Timer or the "NSA" Timer are used during the Pause state and appear as configurable parameters in place of Pause Timer.

NOTE

If European Protocol is set to On, the setting for the Shock Series Timer must be ≤ Post Shock CPR Timer ≤ NSA Timer. Also, the Shock Series Timer can not be configured to either Off or 210.

Table 10-3: Manual Settings

Parameter	Description	Choices
Sync After Shock	Determines if the Sync function stays on after a synchronized shock is delivered.	**On**, Off
Display Shock Counter	Determines if the number of shocks delivered appears on the display during an event.	On, **Off**
Display Incident Timer	Determines if the elapsed time appears on the display during an event.	On, **Off**

Table 10-4: ECG Filter Settings

Item	Description	Setting Choices
AC Line Filter	Selects the setting used to filter out AC line noise.	**60** Hz, 50 Hz
Pads ECG for Display	Selects the display filter frequency for the therapy cable attached.	**Monitor (.15-40Hz)**, EMS (1-30 Hz)
Pads ECG for Printer	Selects the printer filter frequency for the therapy cable attached.	**Monitor (.15-40Hz)**, EMS (1-30 Hz)
Leads ECG for Display	Selects the display filter frequency for the monitoring electrodes ECG.	**Monitor (.15-40Hz)**, EMS (1-30 Hz)
Leads ECG for Printer	Selects the printer filter frequency for the monitoring electrodes ECG.	**Diag (.05 - 150 Hz)**, EMS (1 - 30 Hz, Monitor (.15 - 40 Hz)

Modifying the Configuration

To modify the configuration, from the main menu:

1. Use the softkeys (▲ and ▼) to highlight the desired category of settings.
2. Press ENTER.
3. Use the softkeys to highlight the item you want to change.
4. Press CHANGE.
5. Use the softkeys to select the desired setting.
6. Press SAVE to save the change. To exit without making the change, press CANCEL.
7. Press MAIN to return to the main menu.

To make additional changes, repeat steps 1-7.

Returning to the Default Configuration

Press ▲ and ▼ on simultaneously, while in the main configuration menu, to return all settings to their default settings. Although there is no visible change in the display, default settings are restored.

Saving Settings to a Data Card

Configuration settings may be saved to a Data Card and used to load the same configuration into other Heartstream XLs or to restore the configuration, if necessary.

To save the configuration:

1. Make sure a Data Card is in the Heartstream XL before you turn the defibrillator/monitor on.
2. Select Save Settings to Data Card from the main configuration menu.
3. Press SAVE in response to the question Save Settings to Data Card?

The Heartstream XL saves the configuration settings to the Data Card and returns to the main configuration menu.

NOTE

To avoid possible confusion, designate one Data Card as the "Configuration Card" and label it clearly. Keep this card physically separate from cards used for storing patient data.

Loading Settings from a Data Card

To load configuration settings:

1. Make sure a Data Card is in the Heartstream XL before you turn the defibrillator/monitor on.
2. Select Load Settings from Data Card from the main configuration menu.
3. Press LOAD in response to the question Load Settings from Data Card?.

The Heartstream XL loads the configuration settings from the Data Card and returns to the main configuration menu.

Printing Settings

To print the configuration settings, select Print All Settings from the main configuration menu.

11 Maintaining the Heartstream XL

This chapter describes how to care for your Heartstream XL Defibrillator/ Monitor and its accessories, including:

- operational checks
- battery maintenance procedures
- instructions on loading printer paper
- cleaning instructions
- a list of approved supplies and accessories, and
- instructions for disposal of the device

The operational checks described must be performed at the specified intervals in order to help prevent and detect electrical and mechanical problems. The battery maintenance procedures specified must be strictly adhered to in order to ensure that your batteries have the energy required to operate the defibrillator and deliver the appropriate therapy.

Operational Checks

The following operational checks are intended to quickly verify the viability of the Heartstream XL. Perform these checks regularly, at the intervals specified, along with visual inspection of the device and all cables, controls, accessories and supplies. Also regularly check expiration dates of all supplies, such as multifunction defib electrode pads and monitoring electrodes.

Every Shift

Perform a "Shift/System Check" every shift (see “Using External Paddles” on page 11-3) to verify that the Heartstream XL is functioning properly and to ensure that necessary supplies and accessories are present and ready for use.

Every Month

Check expiration dates on multifunction defib electrode pads and monitoring electrodes every month. Replace them if the expiration date has passed.

Every Three Months

Perform a "Battery Capacity Test" on each battery, every three months, to ensure that your batteries meet the specifications for safe and effective use.

Using External Paddles

To perform the Shift/System Check using external paddles:

1. Turn the Heartstream XL off.
2. If routinely used, insert a Data Card into the Heartstream XL.
3. Unplug the AC power cord.
4. Insert a charged battery.
5. While pressing Strip, turn the Energy Select knob to Manual On to start the test.

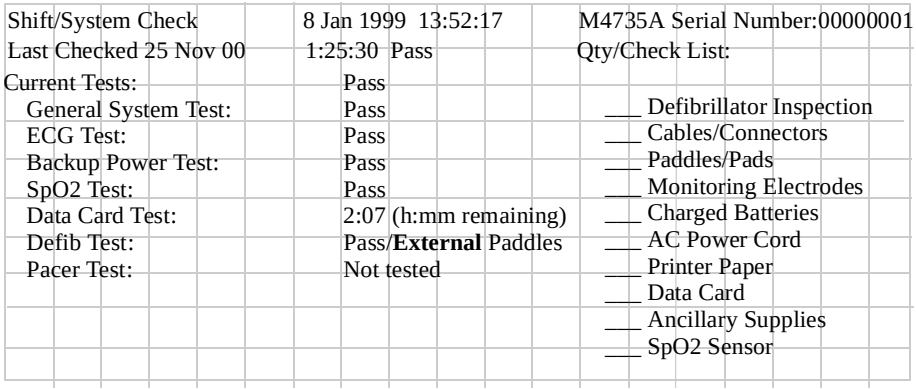
NOTE

If the paddles are in the holders and the message "Place Paddles in Pockets" appears, adjust the paddles to improve contact. Poor contact may be due to due to clinical use (e.g. oxidation or residue on either the connectors or paddles). If the message continues to appear, contact a certified technician.

6. Follow the prompts on the display to proceed with the test. If the message Service Unit appears, do not use the device, and call for service.

The test takes less than a minute to complete. When it is done, a report is printed, as shown in Figure 11-1.

Figure 11-1 Shift/System Check Report Using External Paddles



Shift/System Check	8 Jan 1999 13:52:17	M4735A Serial Number:00000001
Last Checked 25 Nov 00	1:25:30 Pass	Qty/Check List:
Current Tests:	Pass	
General System Test:	Pass	___ Defibrillator Inspection
ECG Test:	Pass	___ Cables/Connectors
Backup Power Test:	Pass	___ Paddles/Pads
SpO2 Test:	Pass	___ Monitoring Electrodes
Data Card Test:	2:07 (h:mm remaining)	___ Charged Batteries
Defib Test:	Pass/**External** Paddles	___ AC Power Cord
Pacer Test:	Not tested	___ Printer Paper
		___ Data Card
		___ Ancillary Supplies
		___ SpO2 Sensor

WARNING

Be sure to safely discharge external paddles.

Using Pads

To perform the Shift/System Check using multifunction defib electrode pads:

1. Turn the Heartstream XL off.
2. Connect the M1781A 50 ohm test load to the pads patient cable (instead of pads).
3. If a Data Card is routinely used, insert a Data Card into the Heartstream XL.
4. Unplug the AC power cord.
5. Insert a charged battery.
6. While pressing Strip, turn the Energy Select knob to AED On to start the test.
7. Follow the prompts on the display to proceed with the test. If the message Service Unit appears, do not use the device, and call for service.

The test takes less than a minute to complete. When it is done, a report is printed, as shown in Figure 11-2.

Figure 11-2 Shift/System Check Report Using Pads

Shift/System Check	8 Jan 1999 13:52:17	SN:00000001
Current Tests:	Pass	Qty/Check List:
General System Test	Pass	___ Defibrillator Inspection
ECG Test	Pass	___ Cables/Connectors
Backup Power Test	Pass	___ Defibrillation Pads/Paddles
Data Card Test	Pass	___ Monitoring Electrodes
Defib Test	Pass	___ Charged Batteries
Pacer Test	Pass	___ AC Power Cord
		___ Printer Paper
		___ Data Card
		___ Ancillary Supplies
		___ Pads

The Shift/System Check report lists the results of the test and additional checks that you should do. Perform each of these checks and record the results. The guidelines for completing the checks are as follows:

Defibrillator Inspection - make sure the Heartstream XL is clean, clear of objects on top and has no visible signs of damage.

Paddles/Cables/Connectors - make sure there are no cracks, broken wires, or other visible signs of damage. Make sure the connectors engage securely.

Battery - make sure:

- a charged battery is in the Heartstream XL
- another battery is charged or being charged
- the batteries have no visible signs of damage

AC Power

1. Make sure a battery is in the Heartstream XL.
2. Plug the power cord into a power outlet and connect it to the Heartstream XL.
3. Verify that the power and charging indicators on the front of the defibrillator/monitor are lit.
4. Remove the battery from the Heartstream XL and verify that the charging indicator on the front of the defibrillator/monitor is no longer lit. Replace the battery.

Printer - make sure the printer:

- has sufficient paper
- prints properly

Battery Capacity Test

To perform a Battery Capacity Test:

1. Turn the Heartstream XL off.
2. Label the Heartstream XL to indicate to others that testing is in progress and the battery may not be used.
3. Insert a charged battery.
4. If an AC power cord is connected, unplug it. While pressing Mark, turn the Energy Select knob to AED On to start the test.
5. Allow the test to proceed to completion. The test takes approximately three hours and is complete when test results print out and the device turns itself off.
6. Review the test results and take the appropriate action, as follows:

Table 11-1: Battery Capacity Test Results

If	Then...
Elapsed Time ≥ 85 minutes **and** Low Battery Time ≥ 10 minutes	1. The battery passed the test. 2. Record "pass CT" and the date on the bottom of the battery. 3. Recharge the battery before use.
Elapsed Time < 85 minutes **or** Low Battery Time < 10 minutes	1. The battery failed the test. 2. Record "fail CT" and the date on the bottom of the battery. 3. Discard the battery appropriately.

Battery Maintenance

The Heartstream XL uses the M3516A Battery Pack. It is a rechargeable sealed lead acid battery. Battery maintenance begins when you receive a new battery and continues throughout the life of the battery. Detailed information on battery care is provided in the application note *"About Sealed Lead Acid Batteries,"* that came with your Heartstream XL.

Table 11-2 lists battery maintenance activities and when they should be performed.

Table 11-2: Battery Maintenance Activities

Activity:	When to Perform:
Perform a visual inspection	Daily, as part of the Shift/System Check.
Charge the battery	After each use, or if the message Low Battery is displayed.
Perform a Battery Capacity Test	At the time of purchase and every three months thereafter.
Store the battery appropriately	When not in use.

Recharging Batteries

You may charge batteries while they are in either the Heartstream XL or the optional M4747A Battery Charger Kit.

If the battery is being charged while in the defibrillator/monitor (with the Heartstream XL powered off) a discharged battery will typically be 90% charged after 3 hours (at 25°C), as indicated by the Batt Charge LED on the front panel turning from amber to green. After the LED turns green, the battery will typically be fully recharged after an additional 12 hours at (25°C).

CAUTION

The battery should be fully charged whenever possible. Repeated charges to just the 90% level will degrade the battery, reducing its life and capacity.

Refer to the charging procedures provided in the operating instructions for the Battery Charger Kit.

Battery Capacity

A new, fully-charged M3516A battery, operating at room temperature (25°C), provides 100 minutes of monitoring or more than 50 200-joule charge-shock cycles.

Battery Life Expectancy

Life-expectancy of a battery depends on the frequency and duration of use. When properly maintained and stored, the life-expectancy of a battery is about 1.5 years. For more aggressive use models, life-expectancy may be less. The date of manufacture is located at the bottom of the battery's back label.

Storing Batteries

Batteries should be used regularly and rotated to distribute the use evenly. When storing batteries, make sure that the battery terminals do not come in contact with metallic objects.

Batteries should not be stored without charging for more than one month, if installed in the defibrillator, or more than three months, if not installed in the defibrillator. Storage at temperatures between 15°C (59°F) and 30°C (86°F) is recommended to maximize life expectancy.

CAUTION

Storing at temperatures above 40°C (104°F) for extended periods of time will significantly reduce a battery's life-expectancy.

Discarding Batteries

Batteries should be discarded if there are visual signs of damage or if they fail the Battery Capacity Test. Batteries should be discarded in an environmentally safe manner. Properly dispose of batteries according to local regulations.

WARNING

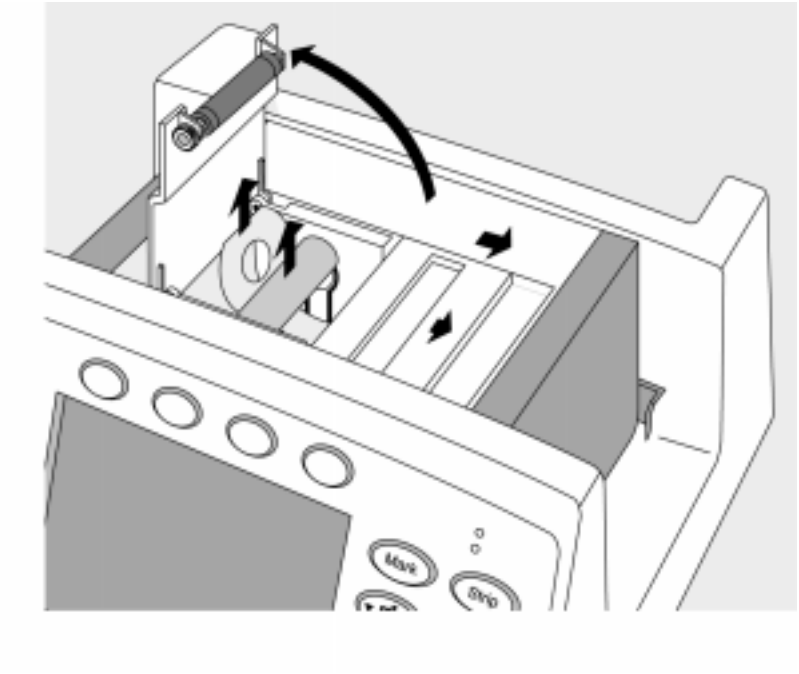
Do not disassemble, puncture, or incinerate batteries. Be careful not to short the battery terminals because this could result in a fire hazard.

Loading Printer Paper

To load printer paper:

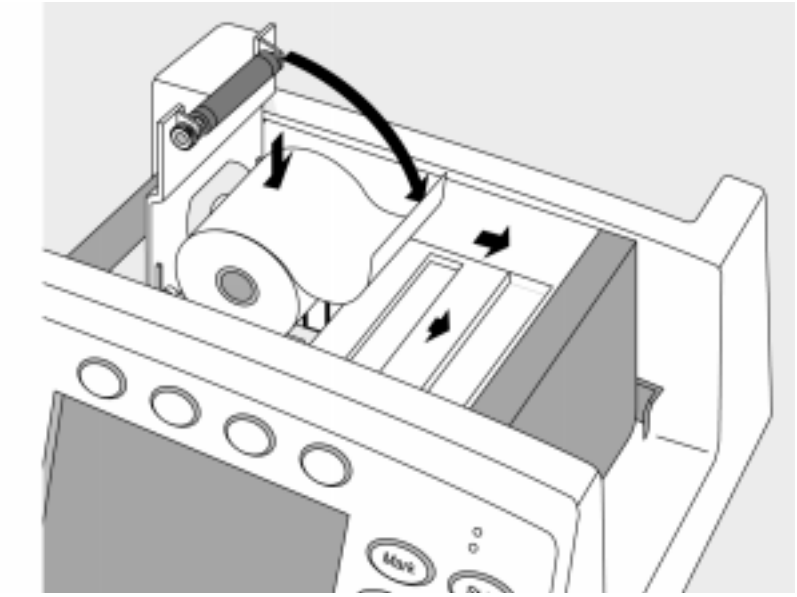
1. Slide the printer door to the right until the paper roller pops up.
2. If there is an empty or low paper roll in the printer, pull up on the plastic removal tab to remove the roll.

Figure 11-3 Opening the Printer



3. Place a new roll of printer paper (40457C/D) into the printer paper well, positioning the roll so that the end of the roll is on the top and the grid faces down. Be sure to push the roll down so that it is firmly seated in the paper well.
4. Pull the end of the paper past the paper roll.
5. Slide the printer door to the right and hold it open. Press the roller down over the paper and release the door.

Figure 11-4 Loading Paper



Cleaning Instructions

Cleaning the Heartstream XL

The following cleaning products may be used to clean the exterior surfaces of the Heartstream XL, as well as the battery and data card:

- Isopropyl alcohol (70% in water)
- Mild soap and water
- Chlorine bleach (3% in water)
- Quaternary ammonium compounds, such as Lysol (10% in water)

When cleaning, be sure to avoid pouring fluids on the device and do not allow fluids to penetrate the exterior surfaces of the device. Use of a soft cloth is recommended for cleaning the display, to prevent scratching.

CAUTION

The Heartstream XL may not be autoclaved, ultrasonically cleaned, or immersed. Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.

Cleaning the Printer Printhead

If the printout has light or varying density printing, clean the printhead to remove any buildup of paper residue.

To clean the printhead:

1. Slide the printer door to the right until the paper roller pops up.
2. Pull up on the plastic removal tab to remove the roll of paper.
3. Clean the printhead surface (above the brush) with a cotton swab dipped in rubbing alcohol.
4. Replace the roll of paper (see “Loading Printer Paper” on page 11-10).

Cleaning Paddles, Pads, Electrodes & Cables

Defibrillation pads and monitoring electrodes are single use and do not require cleaning.

The paddles, paddles cable, and pads patient cable may be cleaned with:

- Alcohol-free hand soap
- 2% gluteraldehyde solution (such as Cidex)
- Sodium hypochlorite (chlorine bleach) solution 10% in water
- Quaternary ammonium compounds (such as Lysol)
- Isopropyl alcohol

CAUTION The paddles and paddles cable may not be ultrasonically cleaned or immersed. Nor may they be autoclaved or steam sterilized.

The ECG cable may be cleaned by wiping it with any of the following:

- 2% gluteraldehyde solution (such as Cidex®)
- Alcohol-free hand soap
- Chlorine bleach (100ml/l)

CAUTION Do not ultrasonically clean, immerse, autoclave or steam sterilize the pads or ECG cable. Do not clean the ECG cable with alcohol. Alcohol can cause the plastic to become brittle and may cause the cable to fail prematurely.

To clean the SpO_2 sensor and cable, follow the manufacturer's instructions.

NOTE For information about paddle sterilization procedures, see the M4741-91000 Agilent Technologies Sterilizable Paddles Owner's Guide.

Supplies & Accessories

Approved supplies and accessories for the Heartstream XL are listed in l. To order:

- In the USA, call 1-800-225-0230.
- Outside the USA, contact your local Agilent Technologies Sales Office, your authorized Agilent Technologies Dealer or Distributor, or visit our Medical Supplies website at: www.healthcare.agilent.com/mpgsupplies/.

Table 11-3: Upgrades, Supplies, and Accessories

Part Number	Description
	Upgrades
M4738A	Pacing Upgrade
M4739A	SpO_2 Upgrade
	Defibrillation Pads/Electrodes
M3501A	Multi-function Defib Adult Electrodes, AAMI
M3502A	Multi-function Defib Adult Electrodes, IEC
M3503A	Multi-function Defib Pediatric Electrodes, IEC
M3504A	Multi-function Defib Pediatric Electrodes, AAMI
DP2	Heartstream Defibrillation Pads: 2-Pack
DP6	Heartstream Defibrillation Pads: 5-Pack
	Paper

Table 11-3: Upgrades, Supplies, and Accessories

Part Number	Description
40457C	50 mm Strip Chart Thermal Paper -1 box (10 rolls)
40457D	50 mm Strip Chart Thermal Paper -1 box (80 rolls)
	External Paddles (PCI/Sterilizable)
M4745A	Sterilizable External Paddles
M4746A	External Paddles with PCI
M17898	Adult Adapter (clips onto external paddle)
	Pads Cables
M3507A	Agilent Pad Connector Cable
M3508A	Heartstream Pad Connector Cable
05-10200	Heartstream Pads Adapter (DP2 & DP6), use with M3507A

Table 11-3: Upgrades, Supplies, and Accessories

Part Number	Description
	ECG Cables
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 (IEC)
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 Cable
M1783A	12-pin Sync Cable
	Monitoring Electrodes
M2202A	High-Tack Foam ECG Electrodes - 5 electrodes/pouch (300 electrodes/case)

Table 11-3: Upgrades, Supplies, and Accessories

Part Number	Description
	SpO_2 Cables/Sensors
M1191A	Adult Reusable SpO_2 Sensor
M1192A	Pediatric Reusable SpO_2 Sensor
M1194A	Adult/Pediatric Ear Clip, Reusable SpO_2 Sensor
M1943A	Nellcor SpO_2 Sensor Adapter Cable
	Data Card
M3510A	Data Card
	Battery
M3516A	Sealed Lead Acid Battery
M4747A	Battery Charger Kit
	Test Load
M1781A	50 ohm defibrillator test load
	User Training CD-ROM
M4735-91000	User Training CD-ROM Kit

Disposing of the Heartstream XL

Prior to disposing of the Heartstream XL, remove the battery. Then dispose of the device and its accessories in accordance with local regulations.

WARNING **Disposal of the device with the battery inserted presents a potential shock hazard.**

Disposing of the Heartstream XL

12 Troubleshooting

If the Heartstream XL detects an error or potential problem during use, it displays a system or momentary message. These messages are often accompanied by a voice prompt. This chapter describes the messages and what you should do in response. In addition, this chapter provides general troubleshooting tips and information on calling for service.

NOTE

For instructions for repair or for further technical information, refer to the M4735-90900 Heartstream XL Service Manual.

System Messages

System messages remain on the display until the specified action is taken or no longer relevant. Each new message displayed is accompanied by three beeps to alert you. Table 12-1 lists system messages.

Table 12-1 System Messages

Message	Description	Corrective Action
Configuration Lost	The configuration is reset to the default settings.	• Reconfigure the Heartstream XL. • Check to see if the battery is properly charged. • Replace the battery. • If the message persists, call for service.
Data Card Disabled	The Data Card is not in use because it is full, incompatible, absent, or inserted after the Heartstream XL was turned on.	If possible, turn the Heartstream XL off for more than 2 minutes, insert an empty, compatible Data Card, and turn the device on. You may also enter configuration mode and turn the machine off, then on again.
ECG Fault	The ECG data acquisition system failed and data is unavailable from the 3- or 5-wire monitoring electrodes.	Remove the device from active use and call for service.
Low Battery	The battery has sufficient capacity remaining to provide only about ten minutes of monitoring time and 5 shocks before the Heartstream XL shuts off.	• Replace the battery with a fully charged battery. • Plug in AC power.

Table 12-1 System Messages *(Continued)*

Message	Description	Corrective Action
Leads Off	• The monitoring electrodes are not applied. • The monitoring electrodes are not making proper contact with the patient. • The monitoring cable is not connected.	• Check the monitoring electrodes are properly applied. • Check the monitoring cable is properly connected.
No Pads	The multifunction defib electrode pads are not properly connected to the Heartstream XL.	Check the pads cable connection.
Pads Cable Off	The pads cable is not connected to the defibrillator.	Check pads connector is locked in place.
Pads Off	The pads are not making proper contact with the patient.	Make sure the pads are properly applied to the patient.
Pacer Failure	The pacing system is not functioning.	Remove the device from active use and call for service.
Pacer Output Low	High patient impedance is resulting in the pacer delivering less current to the patient than specified in the output current setting.	Check the pads are applied properly.
No Paddles Connected	The paddles are not properly connected to the Heartstream XL.	Check that external paddles are connected.

Table 12-1 System Messages *(Continued)*

Message	Description	Corrective Action
SpO2 Cable Off	The SpO_2 cable is not connected to the device.	Attach the SpO_2 cable to the Heartstream XL.
SpO2 Light Interf	The level of ambient light is so high that the sensor cannot obtain an SpO_2 reading or the sensor or cable is damaged.	• Cover the sensor with an opaque material. • Check the sensor for damage; try another sensor.
Non Pulsatile	The patient's pulse is absent or too weak to be detected.	• Check that the sensor is applied properly. • Make sure the sensor site has a pulse. • Relocate the sensor to a site with improved circulation. • Try another sensor.
SpO2 Low Signal	SpO_2 signal is too low to give an accurate reading.	• Check the sensor is applied properly. • Try another sensor type.
SpO2 Noisy Signal	Excessive patient movement, electrical interference, or optical interference is present.	• Minimize patient movement or apply the sensor to a site with less movement. • Secure the sensor cable loosely to the patient. • Reduce sources of electrical or optical interference.
SpO2 Sensor Fail	The SpO_2 transducer is broken.	Try another sensor.

Momentary Messages

Momentary messages are temporary and only appear on the display for a few seconds. Each message is accompanied by a three second beep to alert you. Table 12-2 lists momentary messages.

Table 12-2 Momentary Messages

Message	Possible Cause	Corrective Action
Attach Pads	The multifunction defib electrode pads are not making proper contact with the patient.	• Check the pads are applied to the patient, as directed on the pads' package. • Replace the pads if the prompt continues.
Defib Disarmed	• The pads connection is compromised. • The mode is changed from Manual to AED while the defibrillator is charged. • SHOCK or shock buttons are not pressed within 30 seconds of the defibrillator being charged. • DISARM is pressed.	• Check the pads are applied to the patient properly. • If a shock is indicated, deliver the shock before changing modes. • To deliver a shock, press SHOCK or shock buttons on paddles within 30 seconds of the defibrillator being charged.
No Shock Delivered	Patient impedance is too high.	• Make sure the pads are applied properly. • Replace the pads, if necessary
Check Printer	Printer paper is absent or jammed; the printer door is not closed properly.	• Reload printer paper. • Make sure the door is closed properly.

Table 12-2 *(Continued)* Momentary Messages

Message	Possible Cause	Corrective Action
Data Card Full	• The incident is more than 2 hours in duration, causing the Data Card to fill. • An empty Data Card was not inserted for the incident, causing the Data Card to fill sooner.	• None. A new Data Card can not be inserted during an incident. • Use one Data Card per incident/ patient to decrease the chance of the card filling.
Data Card Interrupted	The Data Card is removed during an incident.	• None. The Data Card can not be re-inserted during an incident. • Do not remove the Data Card during an incident.
Data Card Not In Service	The Data Card is inserted while the Heartstream XL is on.	None. A Data Card must be inserted prior to turning the Heartstream XL on for the current patient.
Incompatible Data Card	A Data Card other than the M3510A is inserted.	Use only M3510A Data Cards.
No Data Card Present	A Data Card is not in the Heartstream XL.	Turn the Heartstream XL off and insert a Data Card prior to the first event for the patient.
Key Inactive	The key pressed is currently inactive (i.e. Pacer is inactive in AED Mode).	Use the appropriate mode for the key.
Stop Pacer	Mode is pressed while pacing pulses are being delivered.	Stop pacing before changing the pacing mode.
Attach Cable	Patient cable is not properly attached to Heartstream XL.	Check cable connections.

Troubleshooting Tips

Table 12-3 lists some situations that you may encounter, their possible causes, and a few suggested solutions.

Table 12-3 Troubleshooting Tips

Situation	Cause	Possible Solution
The Heartstream XL does not turn on.	There is no power.	• Insert a fully charged battery. • Attach AC Power cord.
There is a dashed (----) line on the display instead of an ECG.	ECG data is not being acquired.	• Check the patient cable is connected. • Check the pads, paddles or electrodes are properly applied. • Check that the desired lead is selected.
The Heartstream XL does not appear to be functioning properly.	• The battery is low. • There is a system failure.	• Change the battery. • Take the device out of use and call for service.
The displayed time is incorrect.	The time was not correctly set in the configuration.	Set the time in the General Settings menu of the Configuration Mode.
The printed date is incorrect.	The date was not correctly set in the configuration.	Set the time in the General Settings menu of the Configuration Mode.
The Heartstream XL will not power on.	Corrupt data card may prevent the unit from powering on.	Take the Data Card out replace it with new Data Card, if possible. Then, attempt to turn the Heartstream XL on.

Calling for Service

For telephone assistance, call the Response Center nearest to you, or visit our website at: www.healthcare.agilent.com/mpgcsd/.

United States of America

Medical Response Center	Tel: (800) 548-8833

Canada

Eastern Region	**Central & Western Regions**
Tel: (800) 361-9790	Tel: (800) 268-1221

Other International Areas

Australia	**France**
Tel: 131147	Tel: 0803 35 34 33

Germany	**Italy**
Tel: 0130-4730	Tel: 0292 122999

Netherlands	**United Kingdom**
Tel: (0) 20-547-6333	Tel: 44-344-36633

Belgium
Tel: 32 2 778 35 31

13 Specifications & Safety

This section provides:

- Specifications for the Heartstream XL
- Symbol definitions for symbols appearing on the Heartstream XL
- Clinical Performance Summary data
- Safety related information
- Electromagnetic compatibility information

Specifications

Defibrillator

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

Shock Delivery: Via multi-function defib electrode pads or paddles.

Delivered Energy Accuracy:

Selected Energy (J)	Delivered Energy (J) Load Impedance (ohms)					Accuracy
	25	50	100	125	150	
5	4.7	5	5.2	5.4	5.2	±2 J
10	9.3	10	10.4	10.7	10.4	±2 J
25	23.4	25	26.2	26.9	26.2	±4 J
50	46.7	50	52.3	53.5	52.1	±15%
70	65.4	70	73.1	75.0	72.9	±15%
100	93.5	100	104.7	107.2	104.4	±15%
150	140.3	150	156.8	161.0	156.5	±15%
200	187	200	209.3	214.6	208.6	±15%

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

Patient Impedance Range:

- Minimum: 10-25 Ohm, depending upon energy level
- Maximum: 180 Ohm

Manual Mode

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

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

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

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

Energy Selection: Front panel rotary knob.

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

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

Synchronizer: SYNC message appears on the monitor and is annotated on the printer (if printing while in Sync mode) An audible beep sounds with each detected R-wave, while a tick mark on the monitor and printed strip indicate the discharge points. Synchronizer delay is less than 60 msec from peak R-wave to peak current of the defibrillation discharge.

AED Mode

AED Energy Profile: Fixed energy (150 Joules).

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

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

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

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

Indicators: EL display for ECG waveform and text prompts, Audio alerts, Voice Prompts, QRS Beeper, Charging Tone, Charge Done Tone, Printer, AC Power LED, Battery Charging LED.

Armed Indicators: Charge Done Tone, Available Energy indicated on display, Voice Message.

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

Shockable Rhythms: Ventricular Fibrillation with amplitude>100 uV and wide complex ventricular tachycardia with rates greater than 150 bpm.

Sensitivity and Specificity: Meets AAMI guidelines.

ECG Monitoring

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

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

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

Pad Fault: PADS OFF message and dashed line appear on the display if a pad becomes disconnected.

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

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

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

ECG Cable Length: 12 ft (3.7 m).

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

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

Frequency Response:

AC Line Filter:	60 Hz or 50 Hz.
Pads ECG for Display:	Monitor (.15-40 Hz) or EMS (1-30 Hz).
Pads ECG for Printer:	Monitor (.15-40 Hz) or EMS (1-30 Hz).
Leads ECG for Display:	Monitor (.15-40 Hz) or EMS (1-30 Hz).
Leads ECG for Printer:	Diagnostic (.05-150 Hz) or EMS (1-30 Hz) or Monitor (.15-40 Hz).

Patient Isolation (defibrillation proof):

ECG: Type CF

SpO2: Type CF

Defib: Type BF

ECG Analysis Performance

RHYTHM CLASS	ECG TEST SAMPLE[A] SIZE	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 requirement and AHA recommendation[b] (specificity >95%) for adult defibrillation
Non-Shockable Rhythm — All other non-shockable rhythms	600	Meets AAMI DF39 requirement and AHA recommendation[b] (specificity >95%) for adult defibrillation

a. From Agilent Technologies 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.

Display

Size: 115 mm x 86 mm

Type: EL - Electroluminescent

Resolution: 320 x 240 pixels

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

Viewing Time: 4 seconds.

Battery

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

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

Weight: 1.4 lb. (0.65 kg).

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

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

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

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

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

Thermal Array Printer

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

Header 1: Date, Time, Heart Rate, the SPO2 Value (if available), and the text "Delayed" if printing has been configured for Delayed Mode. Prints every 12 seconds.

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

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

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

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

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

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

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

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

Speed: 25 mm/s with an accuracy of ± 5%.

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

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

Noninvasive Pacing

Waveform: Monophasic Truncated Exponential.

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

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

Rate: 30 ppm to 180 ppm (10 ppm increments); accuracy ± 1.5%.

Modes: Demand or Fixed Rate.

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

SpO2 Pulse Oximetry

Accuracy with:

M1191A sensor - 1 standard deviation 70% to 100%, ± 2.5%.

M1192A sensor - 1 standard deviation 70% to 100%, ± 2.5%.

M1194A sensor - 1 standard deviation 70% to 100%, ± 4.0%.

NELLCOR sensors - 1 standard deviation 80% to 100%, ± 3.0%.

Resolution: 1%.

Sp02 Alarm Limits: Three preset low alarm limits: 90%, 85%, and 80%.

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

Event Storage

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

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

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

Data Card Event Summary: The Data Card stores continuous ECG waveforms and events on a Type II PCMCIA card, SanDisk SDP3B 8MB ATA FlashDisk. One 8MB card can store approximately 2 hours of continuous ECG waveforms and events.

General

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

Weight: Standard Configuration weighs 6.5 kg (14.3 lbs.) including battery, full roll of paper, and external paddles.

Environmental

Temperature: 0º C to 55ºC operating, -20º to 70ºC storage.

- Charging the battery at temperatures above 35ºC may degrade battery life
- Storing the battery for extended periods at temperatures above 40ºC will reduce battery capacity and degrade battery life.

Humidity: Up to 95% Relative Humidity

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

Altitude:

Operating: up to 15,000 ft.

Storage: up to 15,000 ft.

Shock: Agilent Technologies, Section 760 Class B1 Drop Test (200 G's, < 3 msec pulse).

Vibration: Agilent Technologies, Section 759 Class B1 Vibration.

Water Resistance: Meets IEC 601-2-4, IPX0.

EMC: Meets EN 60601-1-2.

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

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

Mode of Operation: Continuous.

AC Line Powered: 100-240 VAC, 50/60 Hz, 1.5 A (Class 1)

Battery Powered: 12 V Rechargeable, SLA

Symbol Definitions

The following table lists the meaning of each symbol shown on the Heartstream XL and the M3516A battery:

Table 13-1: Defibrillator and Battery Symbols

Symbol	Definition
	Defibrillation Shock.
	Attention - See operating instructions in user's guide.
	Input.
	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 and major arteries).
	Alarms are active.
	Alarms are inactive.
	Recyclable material.

Table 13-1: Defibrillator and Battery Symbols

Symbol	Definition
	Biphasic energy is being used.
	Must be recycled or disposed of properly.
	Unlock.
	Audio Speaker
	Protective earth ground.
	Alternating current.
	Dangerous voltage.

13

Table 13-2: Abbreviations and Acronyms

Abbreviation/ Acronym	Definition
AC	Alternating Current
AED	Automated External Defibrillator
ECG	Electrocardiogram
SpO_2	Pulse oximetry
Batt	Battery
ECG Out	Monitoring Signal from Defibrillator

The following table lists the symbols that appear on the Heartstream XL shipping carton:

Table 13-3: Shipping Carton Symbols

Symbol	Definition
	Atmospheric pressure range.
	Temperature range.
	Relative humidity range.
	Recyclable paper product.
	Fragile.
	Right side up.
	Do not get wet.

13

Table 13-3: Shipping Carton Symbols

Symbol	Definition
	Shelf life.
	Long-term storage conditions.
	Short-term transport storage.

Clinical Performance Summary

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 Clinical SummaryTable 13-4:

Table 13-4: Clinical Summary

	Biphasic Patients Number/(Percent)	Monophasic Patients Number/(Percent)	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%)	<0.001
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).

Safety Considerations

The following general warnings and cautions apply to use of the Heartstream XL. Additional warning and cautions specific to a particular feature are provided in the appropriate section.

WARNING **The Heartstream XL 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 **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 the multifunction defib electrode pads, battery, and accessories listed in "Outside the USA, contact your local Agilent Technologies Sales Office, your authorized Agilent Technologies Dealer or Distributor, or visit our Medical Supplies website at: www.healthcare.agilent.com/mpgsupplies/." on page 11-14. Substitutions may cause the Heartstream XL to function improperly.**

WARNING **Use multifunction defib 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.**

WARNING **In AED Mode, the multifunction defib electrode pads must be in the anterior-apex position as shown on the packaging. The Heartstream XL was not designed to assess data acquired from pads in an anterior-posterior position.**

WARNING **Use only 3-wire AC power cords with 3-pronged grounded plugs.**

WARNING **Keep hands and feet clear of paddle electrode edges. Use your thumbs to depress the shock buttons on the paddle handle.**

CAUTION	Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.
WARNING	**Do not allow multifunction defib 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 defib 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	**Never operate the Heartstream XL in standing water.**
	Do not immerse, or pour fluids on, any portion of the Heartstream XL.
WARNING	**Do not use the Heartstream XL 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 Heartstream XL.**
NOTE	The Heartstream XL can be operated with only AC line power, only 12v M3516A SLA Battery or AC power and M3516A SLA battery simultaneously.
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	**Operating the Heartstream XL or its accessories in conditions outside the environmental specifications can result in device or accessory malfunction.**
WARNING	**Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.**
WARNING	**Electric shock hazards exist internally. Do not remove assembly screws. Refer servicing to qualified personnel.**

CAUTION	This device has not been evaluated for use with electrosurgery equipment.
NOTE	This device and accessories are not intended for home use.
CAUTION	Do not discharge the defibrillator with the paddles shorted together.
WARNING	**Properly dispose of or recycle depleted batteries according to local regulations. Do not puncture, disassemble, or incinerate batteries.**
WARNING	**Where the integrity of the external protective earth conductor is in doubt, the device shall be operated from its internal power source.**
NOTE	For operation in the U.S., the attachment plug must be the proper NEMA type for connection to the alternative voltage.
CAUTION	Be aware of patient cables, including ECG monitoring equipment when used with high frequency surgical equipment.
WARNING	**To break connection with main power remove plug from wall outlet.**

Electromagnetic Compatibility

When using the M4735A Heartstream XL Defibrillator/Monitor, 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 M4735A Heartstream XL Defibrillator/Monitor. Electromagnetic compatibility with surrounding devices should be assessed prior to using the defibrillator.

Reducing Electromagnetic Interference

The M4735A Heartstream XL Defibrillator/Monitor and associated accessories are 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 SpO2 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?
- Does the SpO2 value change dramatically when the AC line cord is unplugged?

Once the source is located, attempt to attenuate the EMC coupling path by distancing the defibrillator from the source as much as possible. If assistance is needed, call your local service representative.

Restrictions for Use

Artifact on the ECG 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.

Immunity Level

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. It is recognized that the Heartstream XL defibrillator/monitor is designed to receive and amplify low level signals in the same bandwidth as the interference.

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.

NOTE

For additional information about compliance with the EMC standards, please see the Declaration of Conformity Statement available at: http://www.healthcare.agilent.com/mpg-reginfo/conformity.html.

Electromagnetic Compatibility

Index

C

D

T

U

V

W

Edition 1
M4735-91900

Printed in the U.S.A. September 2000