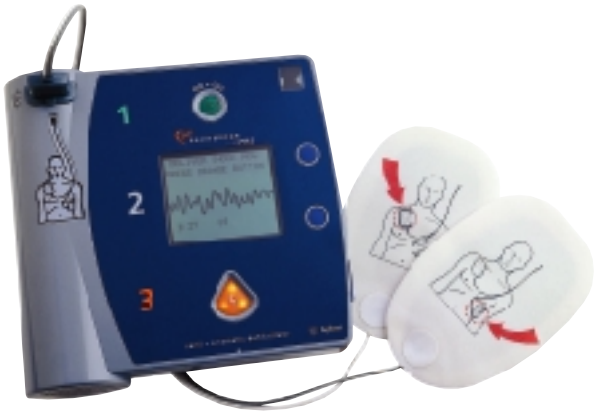


Agilent Heartstream FR2

M3860A, M3861A

Agilent Technologies

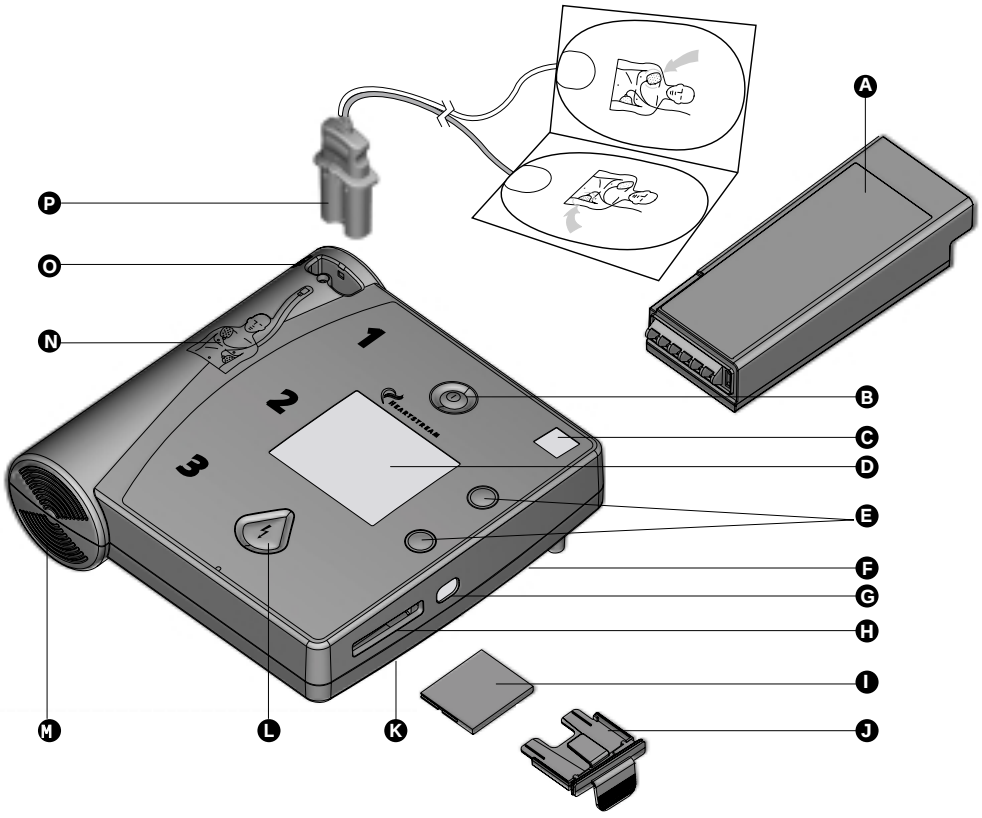
Agilent Technologies

User's Guide

Agilent M3860A, M3861A
Heartstream FR2
Semi-Automatic External Defibrillator (AED)

The HEARTSTREAM FR2 AED

Clockwise from top right.



A Battery. Disposable battery pack used to power the HEARTSTREAM FR2. (Check local regulations for disposal and recycling requirements.)

B On/Off button. Turns on the FR2 and starts voice and screen prompts. Second press turns off the FR2.

C Status Indicator. Shows you the readiness status of the HEARTSTREAM FR2.

D Display screen. Displays text prompts and incident data. The HEARTSTREAM FR2 M3860A screen also displays the patient's ECG.

E Option buttons. Adjust the contrast of the screen display and control special functions.

F Beeper port. Broadcasts alert beeps when required. It is located under the right edge of the FR2.

G Infrared (IR) communications port. A special lens, or "eye," used to transfer data directly to or from another device.

H Data card port. Receptacle for data card tray.

I Data card (optional). Used to store and review information about the incident, including ECG and optional voice recording.

J Data card tray. Special sleeve that holds the data card and fits into the data card port to help seal the FR2 against fluids. *The tray should be kept installed in the FR2 even if no data card is used.*

K Microphone. Used optionally to record surrounding audio during an incident. It is located under the right edge of the FR2.

L Shock button. Controls shock delivery. The button flashes when the HEARTSTREAM FR2 is ready to deliver a shock.

M Speaker. Amplifies voice prompts during use of the FR2.

N Pads placement diagram. Illustrates correct placement of pads. *Diagrams are also shown on the back of the defibrillation pads.*

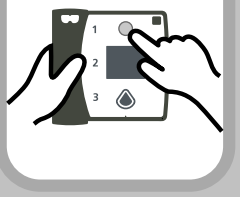
O Defibrillator pads connector port. Receptacle for connector of the defibrillation pads cable. An adjacent LED light flashes to show socket location and is covered when connector is inserted.

P Defibrillator pads assembly. Self-adhesive pads with attached cable and connector.

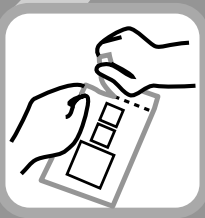
HEARTSTREAM FR2 AED
QUICK REFERENCE GUIDE

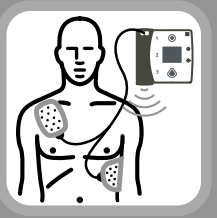
**PATIENT IS UNRESPONSIVE,
NOT BREATHING, WITHOUT A PULSE**

1 **TURN ON**

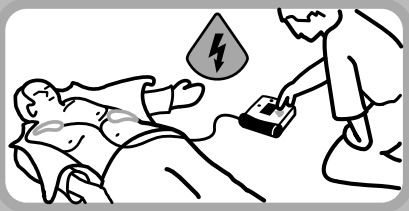


2 **FOLLOW PROMPTS**





3 **PRESS SHOCK BUTTON IF INSTRUCTED**



Notice

About This Edition

The information in this guide applies to the Agilent Technologies models M3860A and M3861A HEARTSTREAM FR2 semi-automatic external defibrillator. 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.

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CAUTION

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

The HEARTSTREAM FR2 is designed to be used only with Agilent Technologies-approved accessories. The HEARTSTREAM FR2 will perform improperly if non-approved accessories are used.

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www.agilent.com/healthcare/heart

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5 Clinical and Safety Considerations

6 Setup and Advanced Mode Features

7 Data Management and Review

Notes

1 Introduction to the HEARTSTREAM FR2

What is the HEARTSTREAM FR2?

The HEARTSTREAM FR2 defibrillator ("FR2") is a semi-automatic external defibrillator (AED). It is compact, lightweight, portable, and battery powered. It is designed for simple and reliable operation by a trained responder.

The HEARTSTREAM FR2 has a Status Indicator that is always active, so you can tell at a glance if it is ready for use. The front panel of the FR2 has an On/Off button at the top and a Shock button at the bottom. A display screen in the center of the panel provides text prompts and incident information. Voice prompts are provided through a speaker located at the base of the FR2. (See the diagram on the inside front cover for details.)

The HEARTSTREAM FR2 is available in two models, the M3860A and the M3861A. They share a set of basic features. In addition, the M3860A provides optional screen display of the patient's electrocardiogram (ECG) and can be programmed to permit the advanced mode's manual charge feature.

NOTE: The FR2 comes with a factory default setup that can be modified. (See Chapter 6, Setup and Advanced Mode Features, for a description of setup defaults and options.)

When Is the HEARTSTREAM FR2 Used?

The HEARTSTREAM FR2 is used with disposable HEARTSTREAM defibrillation pads applied to a person who is experiencing the symptoms of sudden cardiac arrest (SCA): lack of responsiveness, lack of breathing, and lack of detectable pulse. *Defibrillation should not be performed on anyone who is responsive, is breathing, or has a detectable pulse.*

The HEARTSTREAM FR2 is intended for use by emergency care personnel who have been specifically trained in the operation of the HEARTSTREAM FR2 or who are qualified by training in Basic Life Support (BLS), in Advanced Life Support (ALS), or in other physician-authorized emergency medical response.

The HEARTSTREAM FR2 is not intended for administration of energy at pediatric energy settings. In accordance with the recommendations of the American Heart Association,* the HEARTSTREAM FR2 should not be used to treat infant cardiac arrest, but standard operating procedures should be followed in treating children over eight years of age.

How Does the HEARTSTREAM FR2 Work?

The HEARTSTREAM FR2 is designed to provide external defibrillation therapy to someone in cardiac arrest. Defibrillation therapy is the best available way to treat a variety of potentially fatal heart arrhythmias.

The FR2 is extremely easy to use. When connected to defibrillation pads that are properly applied to the patient's bare chest, the HEARTSTREAM FR2:

1. prompts you to take specific actions,
2. automatically analyzes the patient's heart rhythm and advises you whether or not the rhythm is shockable, and
3. arms the Shock button, if appropriate, and instructs you to press it to deliver a biphasic electric pulse designed to defibrillate the heart.

Detailed instructions for use are provided in Chapter 3.

How Is the HEARTSTREAM FR2 Supplied?

The HEARTSTREAM FR2 is supplied with a battery pack, defibrillation pads with integrated cable and connector, and a data card tray. Other accessories are available. See Appendix A for a list of accessories and other recommended supplies.

* ***Textbook of Advanced Cardiac Life Support*. Dallas: AHA, 1997-99.**

2 Preparing Your HEARTSTREAM FR2 for Use

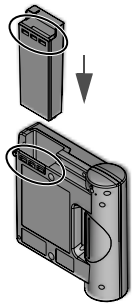
Overview

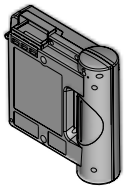
There are a few basic steps to preparing your HEARTSTREAM FR2 for use:

- Install a battery.
- Set the clock in the FR2 (optional).
- Run the battery insertion selftest.
- Place the FR2 with recommended accessories in a convenient location.

The instructions presented here briefly describe the normal sequence of preparation. *It assumes that you are using a fresh battery, that the selftest passes, and that the factory default settings will not be changed.* Exceptions to this sequence are provided elsewhere in this User's Guide.

Installing the Battery





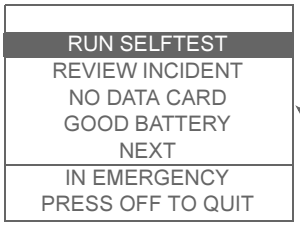
The HEARTSTREAM FR2 is shipped with a M3863A battery pack. The battery is enclosed in a gray plastic case. There is a yellow latch at one end that holds the battery pack in place when it is correctly installed in the FR2.

Before installing the battery, make sure the defibrillation pads are not connected to the FR2. To install the battery:

1. Hold the battery pack by the latch end and slide it into the battery compartment at the top of the HEARTSTREAM FR2.
2. Slide the battery all the way into the opening, until the latch clicks into place. The latch will click into place only when the battery is inserted correctly.

CAUTION: Follow all instructions supplied with the HEARTSTREAM M3863A battery pack. Install the battery before the expiration date shown on the battery.

When the battery is installed, the HEARTSTREAM FR2 automatically turns on. The Status Indicator displays a flashing black hourglass. The Shock button light and the indicator light for the defibrillation pads connector port turn on briefly.

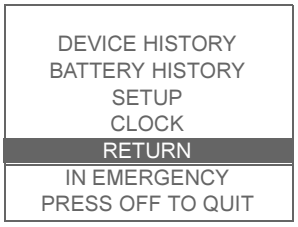


The display screen brings up the main menu. From this menu, you can start the FR2 battery insertion selftest, review information from the last time the FR2 was used, or go to the next screen for other options. Information about the optional data card and the battery status is also provided. (See Chapter 7, Data Management and Review, for details about reviewing an incident and using a data card.)

NOTE: This screen will *not* be displayed if the FR2 is connected to defibrillation pads (that are applied to the patient) when the battery is inserted, and you will not be able to access the menu items. In addition, the battery insertion selftest and periodic automatic selftests cannot run while the defibrillation pads are connected. **Be sure to unplug the pads connector from the FR2 after each use. Do not store the FR2 with the pads connected.**

NOTE: **To move around the menus displayed, use the Option buttons as follows:**

- Press the LOWER Option button to move the highlight bar from one item to another on the menu.
- Press the UPPER Option button to select the highlighted item or to scroll through the settings for that item.



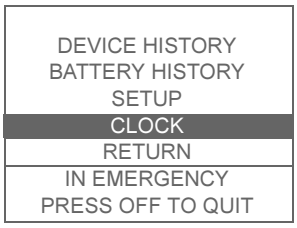
If you select NEXT, the menu displayed lets you review the history of the FR2, review the history of the battery being used, access setup data, set the clock, or return to the first menu. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2, for details about the review options and Chapter 6, Setup and Advanced Mode Features, for information on the setup option.)

NOTE: ***If you make no selection for 10 seconds, the selftest will automatically run.*** If you want to select something different from either of these menus, you must do so before the selftest begins, or remove and reinstall the battery to bring up the main menu. You can press the On/Off button at any time to turn off the FR2 and return it to standby (ready for use) mode. To use the FR2 when it is in standby mode, press the On/Off button to turn it on.

Setting the Clock

It is recommended that the first time you prepare your HEARTSTREAM FR2 for use, you check the FR2's internal clock to be sure it is set to the correct date and local time. You can reset it if necessary.

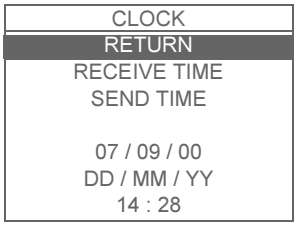
To see the clock settings, select NEXT from the first menu, within 10 seconds of installing the battery, and then select CLOCK. To do this:



1. Press the lower Option button to move the highlight bar to NEXT.
2. Press the upper Option button to bring up the NEXT screen.
3. Press the lower Option button to move the highlight bar to CLOCK.
4. Press the upper Option button to bring up the CLOCK screen.

The CLOCK screen displays the date and time currently set in the internal clock of the HEARTSTREAM FR2.

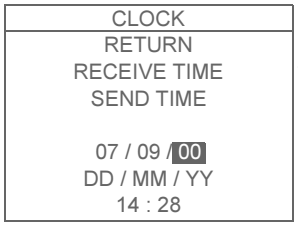
NOTE: The date is displayed as day (DD), month (MM), and year (YY), as shown on the screen. The time is displayed using the 24-hour international clock.



If no changes to the clock settings are needed, select RETURN and go back to the first menu. If the date and time are not correct, there are two ways to set them:

- Receive the clock settings from another HEARTSTREAM FR2 or from a computer using CODERUNNER® software, using the RECEIVE TIME option. This may be used to synchronize the clocks of several FR2s. You can also send the clock settings from one FR2 to another one, using the SEND TIME option. See Chapter 6, Setup and Advanced Mode Features, for instructions.
- Manually set the date and the time.

To manually set the clock:



1. Use the lower Option button to move the highlight bar to the part of the clock setting you want to change.
2. Press the upper Option button repeatedly to scroll through the settings until you reach the one you want. If you go past it, keep scrolling until it comes up again.
3. Use the lower Option button to select the next part you want to change, and repeat the process, until all parts of the date and time have been set.
4. When you have made all the changes, move the highlight bar to RETURN and press the upper Option button to go back to the main menu screen.

NOTE: New clock settings are used by the FR2 as soon as you set them. The clock time display is updated each minute this screen is displayed. The clock seconds, although not displayed, are set to 00 when you move the highlight bar out of the time settings.

NOTE: If the battery is removed from the FR2 for more than two hours, the clock settings will be lost and must be reset.

Running the Battery Insertion Selftest

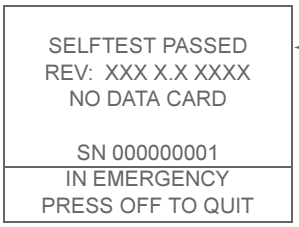
Except in an emergency, it is recommended that you run this selftest every time you change the battery. Make sure the defibrillation pads are not connected to the FR2 before running the battery insertion selftest.

The selftest has two parts. The first part tests the FR2 circuitry and memory. The second part is interactive and requires you to respond to prompts in order to make sure the display, buttons, lights, speaker, and beeper of the HEARTSTREAM FR2 are working properly. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2, for details about this selftest.)

To run the selftest:

1. Make sure the FR2 has not been in use for at least 5 minutes, and that the defibrillation pads are not connected to the device.
2. Insert the battery into the battery port. The first screen displayed has RUN SELFTEST highlighted.
3. Press the upper Option button to activate the test, OR
4. Make no selection for 10 seconds, and the selftest will start automatically.

NOTE: If you connect defibrillation pads (that are applied to the patient) to the FR2 during a battery insertion selftest, the selftest will stop so that the FR2 is in standby (ready for use) mode.



When the automatic part of the selftest is successfully completed, the screen displays a message that the test has passed, and then automatically starts the interactive part of the selftest. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2, for details about the interactive part of the test.)

When the selftest is complete, the HEARTSTREAM FR2 automatically turns off and returns to standby mode. In the standby mode, the FR2 is ready for use at any time, simply by pressing the On/Off button to turn it on.

Placing and Securing the HEARTSTREAM FR2

Place the HEARTSTREAM FR2 in an accessible area with the Status Indicator easily visible. Useful accessories for placing and securing the FR2 include a carrying case, which is suitable for use with a wall mount bracket. (See Appendix A for a list of accessories.)

NOTE: Do not store the FR2 with the defibrillation pads attached. Do not open the pads package until ready for use.

With the battery installed and the FR2 stored in appropriate environmental conditions, the HEARTSTREAM FR2 performs detailed periodic selftests, to make sure that it remains ready for use. (See Appendix B for the environmental storage specifications.)

While the FR2 is in the standby mode, the Status Indicator shows the flashing black hourglass unless the periodic selftests detect a problem. If a problem is detected, the Status Indicator will show a flashing red **X** or a solid red **X** and the FR2 will beep ("chirp") to alert you to the need for troubleshooting. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2, for instructions.)

Notes

3 Using Your HEARTSTREAM FR2

Overview

This chapter describes how to use the HEARTSTREAM FR2 in an emergency incident. Some general things to remember are:

- Try to relax and stay calm. The HEARTSTREAM FR2 automatically provides appropriate voice and display prompts to guide you.
- The defibrillation pads must have good contact with the patient's skin. The pads have a layer of sticky, conductive gel beneath the protective backing. To work effectively, the gel must not be dried out.
- It may be necessary to dry the patient's chest or to clip or shave excessive chest hair to provide good contact between the defibrillation pads and the patient's skin.

The following pages provide step-by-step instructions for normal use of the HEARTSTREAM FR2 in an emergency. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2, for troubleshooting tips.) Be sure to read the Warnings and Cautions on the last page of this chapter.

NOTE: These directions apply to both the model M3860A and the model M3861A HEARTSTREAM FR2, except where otherwise noted.

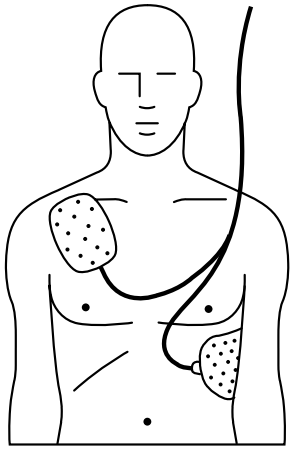
Step 1: Preparation

Press the On/Off button to turn on the HEARTSTREAM FR2. Follow the instructions provided by the FR2 voice and screen prompts in the order indicated.

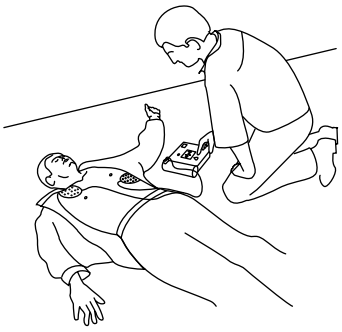
Remove clothing from the patient's chest. Wipe moisture from the patient's chest and clip or shave excessive chest hair, if necessary.

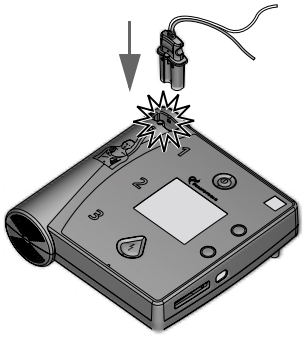
Open the defibrillation pads package. Check to see that the pads and attached cable and connector are undamaged. Pull off the protective backing from the defibrillation pads and check that the gel has not dried out. If the pads are damaged or the gel has dried out, use a new set of pads.

Place each pad on the patient. The pads must be placed with the sticky side on the patient's skin. IMPORTANT: Refer to the drawing on the back of each pad for correct positioning. One pad goes just below the patient's right collarbone, and the other one goes over the patient's ribs in line with the armpit and below the left breast.



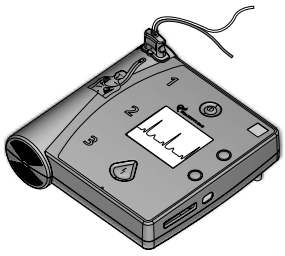
Connect the pads to the HEARTSTREAM FR2. Insert the defibrillation pads connector firmly in the connector socket. A flashing light shows you where the socket is located, at the top left of the HEARTSTREAM FR2.





Step 2: ECG Analysis and Monitoring

Follow the instructions provided by the HEARTSTREAM FR2 voice and screen prompts in the order indicated.



As soon as the FR2 detects that the defibrillation pads are connected properly, it automatically begins analyzing the patient's heart rhythm. The HEARTSTREAM FR2 model M3860A can display the patient's ECG on the screen. When the ECG display is enabled, the patient's heart rate is also displayed during background monitoring.ECG and patient heart rate are always displayed when the advanced mode is entered.

If no shock is advised, the HEARTSTREAM FR2 provides voice and screen prompts to tell you so. The FR2 instructs you to perform CPR if needed, and performs background monitoring of the patient's ECG while you give appropriate care to the patient. These instructions are repeated at the programmed Monitor Prompt interval (the default interval is one minute) while the FR2 is monitoring the patient.

NOTE: CPR may interfere with background monitoring. During CPR, periodically pause for 15 seconds to check the patient and allow the FR2 to analyze the patient's heart rhythm without CPR artifact.

Monitoring continues until and unless the HEARTSTREAM FR2 detects a change in the patient's heart rhythm that may be a shockable rhythm, detects interference with rhythm analysis, or is turned off.

If the HEARTSTREAM FR2 detects a potentially shockable heart rhythm, it automatically goes back to analyzing the rhythm to see if a shock is advised.

If a shock is advised, the HEARTSTREAM FR2 charges to prepare for shock delivery. It gives the voice warnings and screen prompts to tell you that a shock is advised. Make sure that no one is touching the patient. While the HEARTSTREAM FR2 is charging, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer appropriate, the HEARTSTREAM FR2 disarms and dumps the charge. Voice and display prompts advise you what action to take.

NOTE: When the HEARTSTREAM FR2 is fully charged, you can disarm it at any time by pressing the On/Off button to turn off the FR2 and return it to standby mode. (See the Defibrillator discussion in Appendix B, Technical Specifications, for details on disarming the FR2.)

Step 3: Shock Delivery

Press the Shock button to deliver the shock.

IMPORTANT: You must press the button for a shock to be delivered. *The HEARTSTREAM FR2 will not automatically deliver a shock.*

There are four ways you can tell that the HEARTSTREAM FR2 is ready to deliver a shock:

- you hear a voice prompt telling you to deliver a shock,
- you see the Shock button flashing,
- you hear a steady tone, and/or
- you see a screen prompt telling you to press the orange (Shock) button.

After you press the Shock button, a voice prompt tells you the shock was delivered. Then HEARTSTREAM FR2 goes back to analyzing the patient's heart rhythm to see if the shock was successful. The HEARTSTREAM FR2 continues to provide voice and text prompts to guide you through additional shocks, if appropriate.

NOTE: If you do not press the Shock button within 30 seconds of being prompted, the FR2 will disarm itself and provide a pause for CPR. The device will resume analyzing at the end of the pause period or when the Resume Analyzing key is pressed.

Pause for CPR. After the programmed number of shocks in a shock series are delivered, the HEARTSTREAM FR2 automatically pauses for a programmed amount of time to allow you to perform CPR. After the voice and screen prompts tell you that the FR2 has paused, there are no further voice prompts during the rest of the pause, so that you can provide uninterrupted patient care.

During the pause, the FR2 screen shows a bar that fills in as the pause time is used up. The screen also shows how much time has gone by since the FR2 was turned on, and how many shocks have been delivered. The HEARTSTREAM model M3860A displays the ECG, if enabled, during this period.

WARNING: Do not place the defibrillation pads on the patient's chest and back (anterior-posterior). The algorithm used by the HEARTSTREAM FR2 has not been validated with anterior-posterior pads placement.

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

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

WARNING: Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the HEARTSTREAM FR2 gives a SHOCK ADVISED prompt, keep the patient as still as possible for at least 15 seconds so the HEARTSTREAM FR2 can reconfirm the rhythm analysis before a shock is delivered.

WARNING: CPR rates significantly above the American Heart Association guidelines of 100 compressions per minute can cause incorrect or delayed analysis by the HEARTSTREAM FR2.

WARNING: Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Do not allow the defibrillation pads to touch any metal surfaces. Disconnect the pads connector from the HEARTSTREAM FR2 before using any other defibrillator.

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

Notes

4 Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2

Overview

This chapter provides information on HEARTSTREAM FR2 maintenance, detailed descriptions of the selftests, and a guide to troubleshooting.

Maintenance

Maintenance Schedule

Maintenance of the HEARTSTREAM FR2 is very simple, but it is a very important factor in its dependability. The HEARTSTREAM FR2 performs many maintenance activities itself. These include daily and weekly selftests to verify readiness for use and more detailed monthly selftests that also verify the shock waveform delivery system. In addition, a detailed selftest is run whenever a battery is installed in the FR2.

The HEARTSTREAM FR2 requires no calibration or verification of energy delivery. The HEARTSTREAM FR2 has no user-serviceable parts.

CAUTION: Improper maintenance may damage the HEARTSTREAM FR2 or cause it to function improperly. Maintain the HEARTSTREAM FR2 only as described in this User's Guide or as designated by your program's Medical Director.

CAUTION: Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the HEARTSTREAM FR2, remove its covers, or attempt repair. There are no user-serviceable components in the HEARTSTREAM FR2. The HEARTSTREAM FR2 should be returned to an authorized service center for repair.

The following table presents a schedule of suggested maintenance for the HEARTSTREAM FR2.

Daily	Monthly	After Each Use	MAINTENANCE TASK/RESPONSE
✓		✓	Check the Status Indicator. If you see the flashing black hourglass: • The HEARTSTREAM FR2 is ready to use. No action required. If you see anything other than a flashing black hourglass, remove and reinstall the battery to run the selftest. • If the selftest passes and the Status Indicator shows the flashing black hourglass, the HEARTSTREAM FR2 is ready to use. • If the selftest fails, install a new battery and run the selftest. If the selftest passes, the HEARTSTREAM FR2 is ready to use. If the selftest fails, contact Agilent Technologies for technical support.
	✓	✓	Check supplies, accessories, and spares for damage and expiration dating. If a LOW BATTERY or REPLACE BATTERY message is displayed: • Replace the battery and run the selftests. DO NOT ATTEMPT TO CHARGE THE M3863A BATTERY. It is not rechargeable. If supplies, accessories, or spares are damaged or have expired: • Do not use damaged or expired accessories. Replace them immediately.
		✓	Check the operation of the FR2 by removing and reinstalling the battery and running the battery insertion selftest. *Note: Perform also when replacing expired pads.*
	✓	✓	Check the outside of the HEARTSTREAM FR2 and the connector socket for cracks or other signs of damage. If you see signs of damage: • Contact Agilent Technologies for technical support.
		✓	Check the data card if one has been used. If the data card has been used to record incident data: • Remove and replace it with a blank data card. • Deliver the recorded data card to appropriate personnel according to your local guidelines and medical protocol.
		✓	Check the outside of the HEARTSTREAM FR2 and the connector socket for signs of dirt or contamination. If the HEARTSTREAM FR2 is dirty or contaminated: • Clean it according to the guidelines provided in this User's Guide.

Daily	Monthly	After Each Use	MAINTENANCE TASK/RESPONSE
		✓	Check the connector socket to make sure that defibrillation pads are disconnected from the HEARTSTREAM FR2 when it is not in use.
		✓	Check to make sure the data card tray is installed, even if a data card is not being used.

Cleaning the HEARTSTREAM FR2

The outside of the HEARTSTREAM FR2, including the defibrillator pads connector port, can be cleaned with a soft cloth dampened in one of several appropriate cleaning agents (see list below). The following guidelines include some important reminders:

- Do not immerse the HEARTSTREAM FR2 in fluids.
- Make sure a battery (or the Training & Administration Pack) and a data card tray are installed when cleaning the HEARTSTREAM FR2, to keep fluids out of the device.
- Do not use abrasive materials, cleaners, strong solvents such as acetone or acetone-based cleaners, or enzymatic cleaners.
- Clean the HEARTSTREAM FR2 and the connector socket with a soft cloth dampened with one of the cleaning agents listed below.
  - Isopropyl alcohol (70% solution)
  - Soapy water
  - Chlorine bleach (30 ml/l water)
  - Ammonia-based cleaners
  - Glutaraldehyde-based cleaners
  - Hydrogen peroxide

CAUTION: Do not immerse any portion of the HEARTSTREAM FR2 in water or other fluids. Do not allow fluids to enter the HEARTSTREAM FR2. Avoid spilling any fluids on the HEARTSTREAM FR2 or accessories. Spilling fluids into the HEARTSTREAM FR2 may damage it or present a fire or shock hazard. Do not sterilize the HEARTSTREAM FR2 or accessories.

Operator's Checklist

The checklist on the following page is for your reference. You may want to photocopy it or use it as the basis for creating your own checklist.

Inspect the HEARTSTREAM FR2 as suggested in the maintenance schedule above, or as specified by your Medical Director. When you use the Checklist, fill in the scheduled frequency intervals you will be using for your maintenance inspections.

Check off each requirement as you complete it, make a note of any problems you found or corrective action you took, and sign the form.

OPERATOR'S CHECKLIST

HEARTSTREAM FR2 Model No.: _____Serial No.:_____

HEARTSTREAM FR2 Location or Vehicle ID: _____

DATE							
SCHEDULED FREQUENCY							
HEARTSTREAM FR2 Clean, no dirt or contamination; no signs of damage							
Supplies Available • Two sets defibrillation pads, sealed, undamaged, within expiration date • Ancillary supplies (hand towel, scissors, razor) • Spare battery, within "Install Before" date • Data cards, undamaged, and spare data card tray							
Status Indicator Shows alternating hourglass/square; selftest passed.							
Inspected by Signature or initials of operator completing the maintenance inspection							
Remarks, Problems, Corrective Actions							

Testing

The HEARTSTREAM FR2 has several ways of testing itself and alerting you if it finds a problem. In addition to the selftest performed each time a battery is installed, the HEARTSTREAM FR2 also automatically performs periodic selftests daily.

NOTE: The FR2 selftests are designed to check that the HEARTSTREAM FR2 is ready for use. However, in the event that the FR2 has been dropped or mishandled, it is recommended that the battery be removed and reinstalled to initiate a selftest. If the FR2 has visible signs of damage, contact Agilent Technologies for technical support.

Battery Insertion Selftest

As described in Chapter 2, Preparing Your HEARTSTREAM FR2 for Use, when you insert the battery in the FR2, be sure that the defibrillation pads are not connected to the device. When you insert the battery, a menu is displayed and a two-part selftest will run unless you make another selection from the menu within 10 seconds. The selftest includes an automatic part and an interactive part.

NOTE: Under certain circumstances, the behavior of your FR2 will be different. For example, the menu screen will *not* appear when a battery is inserted if:

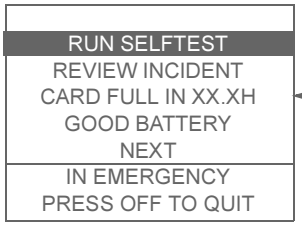
- the defibrillation pads are attached to a patient, indicating that the HEARTSTREAM FR2 is in continued use, or
- the battery is completely depleted.

The menu screen *will* be displayed, but after 10 seconds the FR2 will go to standby mode if you make no selection and:

- less than five minutes have passed since the FR2 was last used, indicating that the FR2 is still in use.

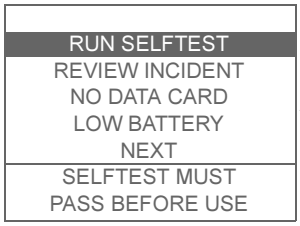
It is recommended that the full selftest (including the interactive portion) be run under the following circumstances:

- When the FR2 is first put into service and following each use.
- Whenever the battery is replaced.
- Whenever expired pads are replaced during periodic maintenance.
- Whenever the AED may have sustained physical damage.



When you install the battery, the screen tells you whether or not a data card is installed. If so, a screen message displays how much recording time is left until the data card is full. (See Chapter 7, Data Management and Review, for how to review the incident information from the internal memory of the HEARTSTREAM FR2 or from a data card, if one is used.)

NOTE: The data card is typically capable of storing a number of incidents. However, it is recommended that it be replaced after every use. In the unlikely event that the card fills up during an incident, no further data can be recorded, so it is important for you to monitor the CARD FULL IN... information on this screen.



Screen contrast can be adjusted during the battery insertion selftest by using the Option buttons.

If battery power is low, replace the battery. If a previous selftest has failed, the screen displays a message that the HEARTSTREAM FR2 must pass a selftest before being used.

It is recommended that you always have a spare battery available. However, if a screen display prompts you to replace the battery or the Status Indicator shows a flashing red **X**, but you do not have a spare battery, you can continue to use the HEARTSTREAM FR2 until the battery is completely depleted. This may be necessary in an emergency.

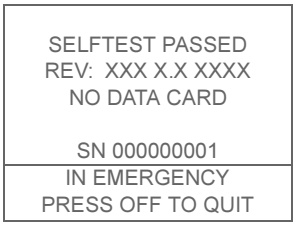
NOTE: If you connect defibrillation pads (that are applied to the patient) to the FR2 during a battery insertion selftest, the selftest will stop so that the FR2 is ready for use.

During the automatic part of the selftest, the screen displays a bar that fills in as the test continues. When that part of the test is finished, the HEARTSTREAM FR2 beeps. The results of the selftest are automatically recorded on the data card while the tests are running, if a data card was inserted in the FR2 prior to installing the battery.

If the automatic part of the selftest fails:

- The screen displays a message that the selftest has failed. After a short time, an error code is displayed. Write down the error code and contact Agilent Technologies for technical support.
- The Status Indicator shows a flashing or solid red **X**.

Replace the battery with a new battery and repeat the test. If the second selftest fails, contact Agilent Technologies for technical support.

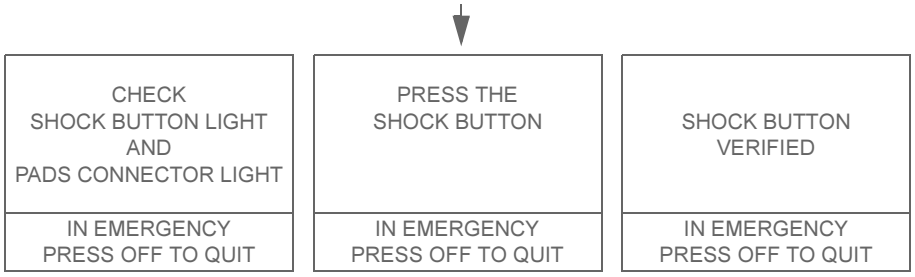


If the automatic part of the selftest passes:

- The screen displays a message that the selftest passed, then begins the interactive part of the test.

The interactive part of the selftest requires you to respond to prompts in order to make sure the display, buttons, lights, and speaker on the HEARTSTREAM FR2 are working properly.

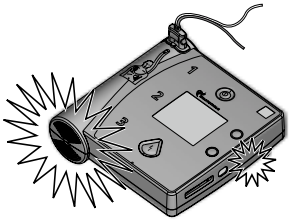
Screen prompts guide you through a series of steps in the interactive part of the selftest. Some ask you to observe that a feature of the HEARTSTREAM FR2 works properly. Others ask you to take certain actions – for example, to press a button. The screen then displays a message showing that the button's operation has been verified. If you do not press the button, or if you do but the button is not working, the screen displays a message that the button's function is not verified.

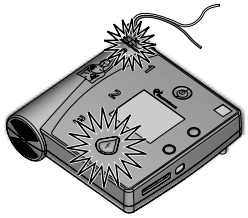
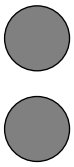
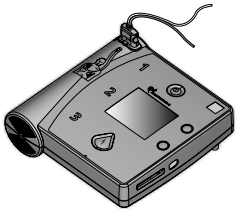


It is important for you to verify correct operation of each item tested. If something does not work correctly – for example, if lights do not come on or you do not hear beeps when expected – make a note of the problem and contact Agilent Technologies.

NOTE: Do not use the HEARTSTREAM FR2 until *all* parts of the interactive selftest verify correct performance. Be sure to note and report any problems you find.

The following table describes the parts of the HEARTSTREAM FR2 tested in the interactive part of the selftest and any action you are asked to take.

FEATURE	TEST DESCRIPTION
Speaker/Beeper 	Screen prompt: CHECK SPEAKER SOUND (2 beeps) Listen for the two beeps, one from the beeper and then one from the speaker.

FEATURE	TEST DESCRIPTION
Lights 	Screen prompt: CHECK SHOCK BUTTON LIGHT AND PADS CONNECTOR LIGHT Check that the lights come on.
Option Buttons 	Screen prompt: PRESS THE OPTION BUTTONS Press the upper and lower Option buttons and listen for a beep to confirm each press. Look at the screen to be sure the button presses have been verified.
Display Screen 	Screen prompt: CHECK DISPLAY. ADJUST CONTRAST IF NEEDED Check the test pattern displayed on the screen. Adjust the contrast if desired using the Option buttons. *NOTE: Screen contrast can be adjusted at any time during the interactive selftest by repeatedly pressing the appropriate Option button until desired contrast is achieved.*
Shock Button 	Screen prompt: PRESS THE SHOCK BUTTON Press the Shock button and listen for a beep to confirm the press. *No shock will be delivered when you press the Shock button during the test.* Look at the screen to be sure the button press has been verified.
On/Off Button 	Screen prompt: PRESS THE ON/OFF BUTTON Press the On/Off button and listen for a beep to confirm press. Look at the screen to be sure the button press has been verified. The screen then displays a message that the test is complete.

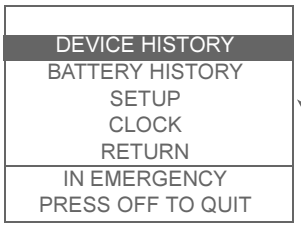
When the interactive part of the battery insertion selftest is complete, the HEARTSTREAM FR2 turns off and goes to standby mode to be ready for use.

If proper operation of all features has not been verified in the interactive selftest, you may want to rerun the battery insertion selftest. If a feature of operation cannot be verified, contact Agilent for technical support.

Periodic Selftests

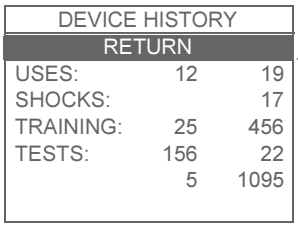
In addition to the battery insertion selftest, the FR2 automatically performs periodic selftests (PSTs). These daily, weekly, and extensive monthly selftests check many important functions of the FR2, including battery capacity and internal circuitry.

If it detects a problem during one of these periodic selftests, the FR2 beeps and displays a flashing red **X** or a solid red **X** on the Status Indicator.



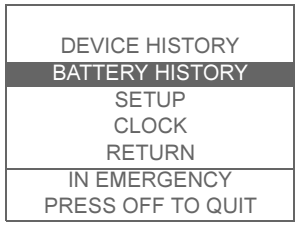
Device History

The HEARTSTREAM FR2 stores key information about its history in internal memory. To review the history of your FR2, select NEXT from the menu screen displayed when you insert the battery, then select DEVICE HISTORY from the next menu displayed.



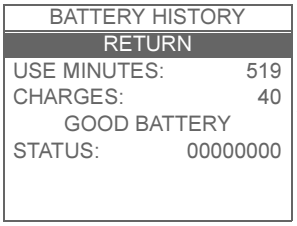
The device history information is automatically stored in the internal memory of the HEARTSTREAM FR2. It includes:

- USES – how many times the HEARTSTREAM FR2 has been used (shown in the left column of numbers) and the total time in minutes it has been used (shown in the right column of numbers);
- SHOCKS – the total number of shocks it has delivered;
- TRAINING – how many times it has been used with the Training & Administration Pack for training (left column) and the total time in minutes it has been used for training (right column); and
- TESTS – how many tests have been run. Four figures are shown: daily (upper left), weekly (upper right), and monthly (lower left) periodic selftests, and battery insertion selftests (lower right).



Battery History

Information about use of the battery currently installed in your HEARTSTREAM FR2 is also available. To review the history of the battery, select NEXT from the menu screen displayed when you insert the battery, then select BATTERY HISTORY from the next menu displayed.



The battery history information is automatically stored in the internal memory of the battery. It includes:

- USE MINUTES – the total operating time (in minutes), including selftest time, for this battery;

- CHARGES – the total number of full defibrillation charges that have been provided by this battery, including selftest charges;
- BATTERY – a GOOD BATTERY, LOW BATTERY or REPLACE BATTERY message, as appropriate, and
- STATUS – the current status of this battery, displayed in a binary code. Make a note of this code if technical support is needed.

Troubleshooting Guide

The HEARTSTREAM FR2 has several ways of communicating with you if it detects a problem during periodic selftesting or use. Depending on the nature of the problem, the FR2 will use audible beeps ("chirps"), voice prompts, screen prompts, and/or its Status Indicator.

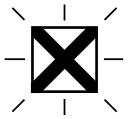
The following tables describe FR2 responses to problems that may occur during use, and provide recommendations for how to resolve them. Although there is some overlap in the information presented, for ease of reference the tables separately address the following types of issues:

- Status Indicator Summary – a basic overview of FR2 usability based on the states shown by the Status Indicator
- Status Indicator Details – possible causes of various Status Indicator and other signals, and recommended actions
- Battery and Training & Administration Pack – possible power-related problems and recommended actions
- Defibrillation Pads – possible defibrillation pads problems and recommended actions
- Analysis and Defibrillation – possible problems with rhythm analysis and defibrillation and recommended actions

It is important to read this information carefully, so you can act quickly in an emergency.

NOTE: Perform CPR (if needed) any time there is a delay before the HEARTSTREAM FR2 can be used.

Status Indicator Summary

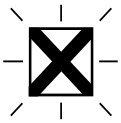
STATUS INDICATOR	RECOMMENDED ACTION DURING EMERGENCY
Flashing black hourglass 	**USE THE FR2**. Follow the voice and screen prompts. The FR2 passed the battery insertion selftest or the last periodic selftest and is ready for use.
Flashing red X 	**USE THE FR2**. Follow the voice and screen prompts. 1. Turn on the FR2 by pressing the On/Off button. 2. Follow the voice and screen prompts. If an error message is displayed: 1. Remove pads, if connected, and remove and reinstall the battery. 2. Run the battery insertion selftest. If the selftest passes and the flashing black hourglass appears, turn off the device by pressing the On/Off button. If the selftest fails, repeat with a spare battery, if available. 3. Turn on the device by pressing the On/Off button. 4. Follow the voice prompts. In some instances — for example, if the battery power is low and you do not have a spare battery available — it may not be possible to clear the flashing red **X**. However, the FR2 is designed to continue working in this condition. Therefore, **in an emergency** incident when there is no other defibrillator available, **it is recommended that you continue to use the FR2** when the Status Indicator shows a flashing red **X**.
Solid red X 	The FR2 may not be usable. 1. Remove pads, if connected, and remove and reinstall the battery. 2. Run the battery insertion selftest. If the selftest passes and the flashing black hourglass appears, turn off the device by pressing the On/Off button. If the selftest fails, repeat with a spare battery, if available. 3. Turn on the device by pressing the On/Off button. 4. Follow the voice prompts. If the solid red **X** is not cleared by running the entire battery insertion selftest, **DO NOT USE THE FR2**.

STATUS INDICATOR	RECOMMENDED ACTION DURING EMERGENCY
None of the above	The FR2 may not be usable. 1. Remove pads, if connected, and remove and reinstall the battery. 2. Run the battery insertion selftest. If the selftest passes and the flashing black hourglass appears and/or SELFTEST PASSED is displayed, turn off the device by pressing the On/Off button. If the selftest fails, repeat with a spare battery, if available. 3. Turn on the device by pressing the On/Off button. 4. Follow the voice prompts. In this condition, the FR2 may not perform to its specifications. However, if voice and screen prompts are present, it is likely that the device is usable despite the lack of a Status Indicator. Therefore, **in an emergency incident** when there is no other defibrillator available, **it is recommended that you continue to use the FR2**.

NOTE: After completing emergency use of the FR2, if you are unable to clear the problem as described in this Troubleshooting section, and the Status Indicator does not show the flashing black hourglass, contact Agilent for technical support.

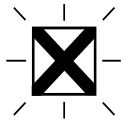
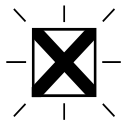
Status Indicator Details

STATUS INDICATOR	OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Flashing black hourglass 	Audio signal: **chirping**	The Training & Administration Pack is being used in the TRAINING function and more than 30 minutes have passed without a button press.	• To continue using the Training & Administration Pack, press any button. • To return the FR2 to standby mode, remove the Pack and install a battery.

STATUS INDICATOR	OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Flashing red X 	Audio signal: **chirping**	• Battery power is low. • The FR2 has been stored outside the recommended temperature range. • An error has been detected as part of the selftest. • The FR2 has been unable to perform its daily selftests.	• Remove and reinstall the battery and run a battery insertion selftest. A screen prompt will tell you if the FR2 has been stored outside the recommended temperature range. See Appendix B for recommended range. • Remove and reinstall the battery and perform the battery insertion selftest. If it fails, install a new battery and repeat the test. If it fails again, contact Agilent Technologies for technical support. • Make sure defibrillation pads are not attached to the FR2.
Solid red X 	**None**	• The Training & Administration Pack is being used in the administration function; solid red **X** is normal. • The battery is missing or completely depleted.	• Remove the Training & Administration Pack and install the battery. • Remove and reinstall the battery and perform the battery insertion selftest. If it fails, install a *new* battery and repeat the test. If it fails again, contact Agilent Technologies for technical support.

STATUS INDICATOR	OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Solid red X 	Audio signal: **chirping**	• A test revealed a failure or error. (The FR2 performs selftests every time you turn it on or insert a battery, and periodically while it is in standby mode.)	• Unplug the pads connector from the FR2, if connected. • Remove and reinstall the battery and check the results of the battery insertion selftest. If it fails, install a *new* battery and repeat the test. If it fails again, contact Agilent Technologies for technical support. An error code will be displayed for 10 seconds on completion of a selftest that fails. The code can be redisplayed by pressing the On/Off button. *NOTE: You can stop the battery insertion selftest to use the FR2 as soon as you see the Status Indicator change to the flashing black hourglass. Simply press the On/Off button to stop the selftest and put the FR2 into standby mode. To use the FR2, press the On/Off button again.*
		• The Training & Administration Pack is being used in the ADMINISTRATION function and more than 10 minutes have passed without a button press.	• To continue using the Training & Administration Pack, press any button. • To return the FR2 to standby mode, remove the Pack and install a battery.
None of the above	Audio signal: **chirping** or: **None**	The FR2 has been physically damaged.	• Check for visible damage. Do not use the FR2 if it appears to be damaged. • Remove and reinstall the battery to perform the battery insertion selftest. If it fails, install a *new* battery and repeat the test. If it fails again, contact Agilent Technologies for technical support.

Battery and Training & Administration Pack

STATUS INDICATOR	OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Flashing red X 	Screen and voice prompts: **LOW BATTERY**	• The power remaining in the FR2 battery or Training and Administration Pack is low. • The Training & Administration Pack is being used to run a scenario that includes a low-battery condition.	• Replace the battery with a new battery or the Training & Administration Pack with a fully charged Pack as soon as possible. • No action required.
Flashing red X 	Screen and voice prompts: **REPLACE BATTERY NOW**	No power remains to continue using the FR2. If you do not replace the battery or Training & Administration Pack, the FR2 turns off.	Replace the battery with a new battery or the Training & Administration Pack with a fully charged Pack immediately.

Defibrillation Pads

OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Screen and voice prompts: **APPLY PADS** and **PRESS PADS FIRMLY** or **PLUG IN CONNECTOR** Or voice prompt: **INSERT CONNECTOR FIRMLY**	The defibrillation pads: • are not properly applied to the patient, or • are touching each other, or • are no longer usable. The defibrillation pads connector: • is not firmly inserted in the connector port.	• Make sure that the defibrillation pads are sticking completely to the patient's skin. • If the pads are not sticking because of moisture or excessive hair, dry the patient's chest and shave or clip any excessive chest hair. • Make sure the defibrillation pads connector is completely inserted in the connector socket. • If the prompt continues after you do these things, replace the defibrillation pads.

OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Voice prompts: **PRESS PADS FIRMLY TO PATIENT'S BARE CHEST** or **POOR PADS CONTACT**	The defibrillation pads are not making good contact with the patient's bare chest.	• Make sure that the defibrillation pads are sticking completely to the patient's skin. • If the pads are not sticking because of moisture or excessive hair, dry the patient's chest and shave or clip off any excessive chest hair. • If the prompt continues after you do these things, replace the defibrillation pads.
Voice and screen prompts: **REPLACE PADS**	• The defibrillation pads, cable, or connector may be damaged. • The FR2 has detected a possible defect in the defibrillation pads or cable.	Replace the defibrillation pads with new HEARTSTREAM defibrillation pads.

Rhythm Analysis and Defibrillation

OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Voice prompts: **ANALYZING INTERRUPTED** or **CANNOT ANALYZE** or **STOP ALL MOTION**	• The patient is being moved or jostled. • Radio or electrical sources are interfering with ECG analysis. • The environment is dry and movement around the patient is causing static electricity to interfere with ECG analysis.	• Stop CPR; do not touch the patient. Try to minimize patient motion. • If the patient is being transported, stop the vehicle if needed. • Check for possible causes of radio and electrical interference and remove them from the area. • Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity.

OTHER SIGNAL	POSSIBLE CAUSE	RECOMMENDED ACTION
Voice and screen prompts: **NO SHOCK DELIVERED**	The patient impedance is not appropriate for the FR2 to deliver a biphasic shock.	• Make sure the defibrillation pads are correctly positioned on the patient. • Make sure the defibrillation pads connector is completely inserted in the connector socket. • Press the defibrillation pads firmly to the patient's chest. • Replace the defibrillation pads if necessary.
Voice prompt: **SHOCK BUTTON NOT PRESSED**	A shock has been advised but not delivered within 30 seconds. (The FR2 has been disarmed.)	When next prompted, press the Shock button to deliver a shock.

Notes

5 Clinical and Safety Considerations

Clinical Considerations

Indications

The HEARTSTREAM FR2 is indicated for use on victims of sudden cardiac arrest exhibiting all of the following signs:

- Unresponsiveness
- Absence of breathing
- Absence of detectable pulse

The HEARTSTREAM FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, advanced life support, or other physician-authorized emergency medical response.

The HEARTSTREAM FR2 is not intended for administration of energy at pediatric energy settings. In accordance with the recommendations of the American Heart Association, the HEARTSTREAM FR2 should not be used to treat infant cardiac arrest, but standard operating procedures should be followed in treating children over eight years of age.

Contraindications

The HEARTSTREAM FR2 is contraindicated for use (should *not* be used) on patients who show any of the following signs:

- Responsiveness
- Presence of breathing
- Presence of detectable pulse

Safety Considerations

You should be aware of the safety concerns listed here when you use the HEARTSTREAM FR2. Read them carefully. You will also see some of these messages in other parts of this User's Guide. The messages are labeled Danger, Warning, or Caution.

- DANGER — immediate hazards that will result in personal injury or death.
- WARNING — conditions, hazards, or unsafe practices that can result in serious personal injury or death.
- CAUTION — conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the HEARTSTREAM FR2, or loss of data stored in the device.

These safety considerations are divided into four groups: safety concerns about the HEARTSTREAM FR2 in general use, defibrillation, monitoring, and maintenance activities.

The dangers, warnings, and cautions listed in the following tables apply to both the model M3860A and the model M3861A HEARTSTREAM FR2, unless otherwise noted.

General Dangers, Warnings, and Cautions

SAFETY LEVEL	POSSIBLE SHOCK OR FIRE HAZARD, OR EXPLOSION
DANGER	**THERE IS A POSSIBILITY OF EXPLOSION IF THE HEARTSTREAM FR2 IS USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR CONCENTRATED OXYGEN.**
DANGER	**THE HEARTSTREAM FR2 HAS NOT BEEN EVALUATED OR APPROVED FOR USE IN HAZARDOUS LOCATIONS AS DEFINED IN THE NATIONAL ELECTRICAL CODE (ARTICLES 500-503). IN ACCORDANCE WITH THE IEC CLASSIFICATIONS (SECTION 5.5.), THE HEARTSTREAM FR2 IS NOT TO BE USED IN THE PRESENCE OF FLAMMABLE SUBSTANCE/AIR MIXTURES.**
DANGER	**DO NOT RECHARGE THE M3863A BATTERY.**
WARNING	**Use the HEARTSTREAM FR2 only as described in this User's Guide. Improper use of the HEARTSTREAM FR2 can cause death or injury. Do not press the Shock button if the defibrillation pads are touching each other or are open and exposed.**
CAUTION	Hazardous electrical output. The HEARTSTREAM FR2 is for use only by qualified personnel.
CAUTION	Do not immerse any portion of the HEARTSTREAM FR2 in water or other fluids. Do not allow fluids to enter the HEARTSTREAM FR2. Avoid spilling any fluids on the HEARTSTREAM FR2 or accessories. Spilling fluids into the HEARTSTREAM FR2 may damage it or present a fire or shock hazard. Do not sterilize the HEARTSTREAM FR2 or accessories.

SAFETY LEVEL	POSSIBLE IMPROPER DEVICE PERFORMANCE
WARNING	**The HEARTSTREAM FR2 runs a selftest whenever a new battery is installed and automatically runs periodic selftests. These tests are designed to check that the HEARTSTREAM FR2 is ready to use. However, the testing cannot assure proper performance if the HEARTSTREAM FR2 was abused or damaged after the last selftest.**
WARNING	**Prolonged or aggressive CPR to a patient with defibrillation pads attached can damage the pads. Replace the defibrillation pads if they are damaged during use or handling.**
WARNING	**Using damaged or expired equipment or accessories may cause the HEARTSTREAM FR2 to perform improperly, and/or injure the patient or the user.**
WARNING	**CPR rates significantly above the American Heart Association guidelines of 100 compressions per minute can cause incorrect or delayed analysis by the HEARTSTREAM FR2.**
CAUTION	The HEARTSTREAM FR2 is designed to be used only with Agilent Technologies-approved accessories. The HEARTSTREAM FR2 will perform improperly if non-approved accessories are used.
CAUTION	Follow all instructions supplied with the HEARTSTREAM defibrillation pads. Use the defibrillation pads before the expiration date shown on the package. Do not reuse the defibrillation pads. Discard them after use.
CAUTION	Aggressive handling of the pads in storage or prior to use can damage the pads. Discard the defibrillation pads if they become damaged.
CAUTION	Follow all instructions supplied with the HEARTSTREAM M3863A battery pack. Install the battery before the expiration date shown on the battery.
CAUTION	The HEARTSTREAM FR2 was designed to be sturdy and reliable for many different field use conditions. However, excessively rough handling can result in damage to the HEARTSTREAM FR2 or its accessories. Inspect the unit and accessories periodically according to instructions.
CAUTION	Alteration of the factory default setup of the FR2 can affect its performance and should be performed under the authorization of your Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.
CAUTION	Use only Agilent Technologies-approved data cards. The HEARTSTREAM FR2 will perform improperly if non-approved accessories are used.

SAFETY LEVEL	POSSIBLE ELECTRICAL INTERFERENCE WITH ECG MONITORING
WARNING	**Radio-frequency (RF) interference from devices such as cellular phones and two-way radios can cause improper HEARTSTREAM FR2 operation. The HEARTSTREAM FR2 should be used at least 6 feet (2 meters) away from RF devices, as stated in accordance with EN 61000-4-3:1996.**

Defibrillation Warnings and Cautions

SAFETY LEVEL	POSSIBLE SHOCK HAZARD
WARNING	**Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Do not allow the defibrillation pads to touch any metal surfaces. Disconnect the pads connector from the HEARTSTREAM FR2 before using any other defibrillator.**

SAFETY LEVELS	POSSIBLE ECG MISINTERPRETATION
WARNING	**Do not place the defibrillation pads on the patient's chest and back (anterior-posterior). This pad placement can interfere with correct rhythm analysis and shock/no shock decision. For correct operation, the HEARTSTREAM FR2 requires that the defibrillation pads be placed on the chest (anterior-anterior), as shown on the pads.**
WARNING	**For safety reasons, some very low-amplitude or low-frequency heart rhythms may not be interpreted by the HEARTSTREAM FR2 as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.**
WARNING	**Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the HEARTSTREAM FR2 gives a SHOCK ADVISED prompt, keep the patient as still as possible for at least 15 seconds so the HEARTSTREAM FR2 can reconfirm the rhythm analysis before a shock is delivered.**

SAFETY LEVELS	POSSIBLE BURNS AND INEFFECTIVE ENERGY
WARNING	**Do not allow the defibrillation pads to touch each other or other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may also divert the defibrillation current away from the heart.**
WARNING	**During defibrillation, air pockets between the skin and defibrillation pads can cause patient skin burns. To help prevent air pockets, make sure defibrillation pads completely adhere to the skin. Do not use dried out defibrillation pads.**

SAFETY LEVEL	POSSIBLE PATIENT INJURY
CAUTION	The HEARTSTREAM FR2 advanced mode's MANUAL CHARGE feature is intended for use only by authorized operators who have been specifically trained in cardiac rhythm recognition and in defibrillation therapy using manual charge and shock delivery.

Monitoring Cautions

SAFETY LEVEL	POSSIBLE MISINTERPRETATION OF ECG RECORDINGS
CAUTION	The LCD screen on the HEARTSTREAM FR2 model M3860A is intended only for basic ECG rhythm identification. The frequency response of the monitor screen is not intended to provide the resolution needed for diagnostic and ST segment interpretation.

Maintenance Cautions

SAFETY LEVEL	POSSIBLE FIRE OR SHOCK HAZARD
CAUTION	Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the HEARTSTREAM FR2, remove its covers, or attempt repair. There are no user-serviceable components in the HEARTSTREAM FR2. The HEARTSTREAM FR2 should be returned to an authorized service center for repair.
CAUTION	Improper maintenance may damage the HEARTSTREAM FR2 or cause it to function improperly. Maintain the HEARTSTREAM FR2 only as described in this User's Guide or as designated by your program's Medical Director.

Notes

6 Setup and Advanced Mode Features

Setup Overview

The "setup" of the HEARTSTREAM FR2 AED is made up of several programmable aspects, or parameters, of FR2 operation. Some setup parameters govern specific features that are not related to the patient care protocol, some are used to define the automatic patient care protocol used by the FR2, and some provide options for manual override of the protocol during use.

The FR2 comes with a factory default setup designed to meet the needs of most users. If desired, your Medical Director can revise the setup. Even if no changes are made, however, it is a good idea to understand the setup of your FR2 and how the different parameter settings affect the way the device works.

Non-Protocol Parameters

The parameters listed in the following table enable features of FR2 operation that are not related to the patient treatment protocol. The table describes each of these non-protocol parameters, lists the settings available for it, and identifies the default setting.

PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
SPEAKER VOLUME	1, 2, 3, 4, 5, 6, 7, 8	8	Sets volume of the FR2's speaker. 1 is lowest; 8 highest. The speaker is used for voice prompts and the charge-done tone.
RECORD VOICE	YES, NO	NO	Enables or disables the audio recording during incident. Voice recording requires use of a data card.
ECG DISPLAY (M3860A only)	ON, OFF	ON	Enables (ON) or disables (OFF) ECG display on the screen. FR2 rhythm analysis does not require ECG display to be on. **(ECG display cannot be changed from default OFF for M3861A.)**

PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
AUTOSEND PST	ON, OFF	OFF	Enables (ON) or disables (OFF) transmission of the results of the FR2's periodic selftests (PST) from its infrared communications port.
ECG OUT	ON, OFF	OFF	Enables (ON) or disables (OFF) ECG data transmission from the infrared communications port of the FR2. ECG data can be sent even if ECG display is unavailable or disabled.

Automatic Protocol Parameters

The HEARTSTREAM FR2 is designed to follow an automatic protocol that guides you through patient treatment with the AED. The default settings for programmable parameters used in the automatic protocol can be altered by your Medical Director if desired.

The setup parameters in the following table are used to define the automatic patient care protocol used by the FR2. Many of these parameters interact with each other, so it is very important to understand how each parameter affects the protocol. The description of each parameter identifies any interacting parameters in **boldface type**.

PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
SHOCK SERIES	1, 2, 3, 4	3	Sets the number of shocks that must be delivered to activate an automatic CPR pause. The length of the CPR pause after completion of a Shock Series is defined by the **CPR Timer** setting. A new Shock Series begins when a shock is delivered: • after the FR2 is turned on • after the automatic CPR pause, or • after the **Pause Key** (if enabled) has been pressed, or • if the time since the previous shock exceeds the **Protocol Timeout** setting.
PROTOCOL TIMEOUT (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, ∞ (infinite)	1.0	Sets the time interval used to determine if a delivered shock should be counted as part of the current **Shock Series**.

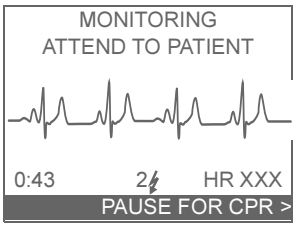
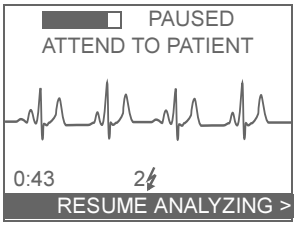
PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
CPR TIMER (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	1.0	Sets the length of the CPR pause period* that automatically starts when: • a **Shock Series** is completed; or • the **Pause Key** (if enabled) is pressed; or • a No Shock Advised (NSA) decision is made, the NSA CPR pause is enabled, and the conditions for using the CPR Timer setting for the NSA CPR pause period are met (see **NSA Action**); or • the Shock button is not pressed for 30 seconds after the FR2 is armed in the AED mode, or • continuous artifact is encountered during rhythm analysis. After the CPR pause, the FR2 returns to automatic rhythm analysis. ** The CPR pause period starts after the voice prompt completes.*
NSA ACTION (minutes)	MONITOR, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0	MONITOR	Sets how the FR2 behaves following a NO SHOCK ADVISED (NSA) decision: MONITOR – directs the FR2 to monitor the patient's ECG following an NSA decision and to prompt the user periodically to provide CPR. The interval for CPR prompting is set by the **Monitor Prompt Interval**. TIME SETTING – directs the FR2 to provide a CPR pause period following an NSA decision (NSA CPR Pause). • If no shocks have been delivered in the current **Shock Series** (e.g., the patient's initial monitored rhythm is non-shockable), the length of the CPR pause is defined by the **NSA Action** time setting. • If shocks have been delivered in the current **Shock Series** (e.g., the NSA decision follows a shock), the length of the CPR pause is instead defined by the **CPR Timer** setting.
CPR PROMPT	LONG, SHORT	LONG	Sets the level of detail provided in the CPR reminder voice prompts provided at the completion of a **Shock Series**. LONG – provides detailed coaching to check airway, breathing, and pulse before beginning CPR. SHORT – simply directs user to begin CPR if needed.

PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
MONITOR PROMPT INTERVAL (minutes)	1.0, 1.5, 2.0, 2.5, 3.0, ∞ (infinite)	1.0	Sets the interval for patient care prompts provided during FR2 monitoring of the patient's ECG following an NSA decision. Selection of ∞ (infinite) means that no repeat prompting will be provided during ECG monitoring.

Manual Override Parameters

The HEARTSTREAM FR2 provides several ways of overriding the automatic protocol. The parameters in the following table are used to enable different kinds of manual override. The description of each parameter identifies any interacting parameters in **boldface type.**

PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
ADVANCED	OFF, ANALYZE, CHARGE	OFF	Enables or disables advanced mode entry for ALS or tiered-response systems. OFF – disables advanced mode features. ANALYZE – enables user-initiated rhythm analysis and disarm, and (M3860A only) automatically turns on ECG display when advance mode is entered. CHARGE (M3860A only) – in addition to enabling the analyze feature, enables user-initiated charging and disarming.

PARAMETER	SETTINGS	DEFAULT	DESCRIPTION
PAUSE KEY	OFF, MONITOR, ALWAYS	OFF	Enables or disables user-initiated CPR pause in the automatic protocol. The length of the pause is defined by the **CPR Timer** setting. When an **Advanced** mode feature (ANALYZE or CHARGE) is enabled and accessed, the Pause key is disabled. OFF – disables availability of user-initiated pause. MONITOR – enables user-initiated pause only during FR2 monitoring of patient rhythm. ALWAYS – enables user-initiated pause any time except when the device is already paused. If enabled, the Pause Key is accessed by pressing the lower Option button indicated by an arrow on the FR2 display, as shown in the sample screen: 
RESUME KEY	ON, OFF	OFF	Enables (ON) or disables (OFF) user-initiated interruption of the CPR pause and return to analyzing. If either the **CPR Timer** or the **NSA Action** setting is programmed to 1.5 minutes or longer, the Resume Key setting is automatically enabled (ON). If enabled, the Resume Key is accessed by pressing the lower Option button indicated by an arrow on the FR2 display, as shown in the sample screen: 
ADVANCED USE PROMPT INTERVALS (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	0.5	Sets the interval for “Press to Analyze” prompts provided during **ADVANCED** mode operation.

Using Setup Features

NOTE: To move around the menus displayed, use the Option buttons as follows:

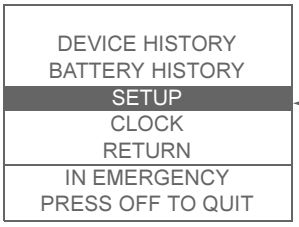
- Press the LOWER Option button to move the highlight bar from one item to another on the menu.
- Press the UPPER Option button to select the highlighted item or to scroll through the settings for that item.

The HEARTSTREAM FR2 comes with a factory default setup designed to meet the needs of most users. The setup feature of the FR2 lets you review the current setup of your HEARTSTREAM FR2 or install a revised setup if appropriate. To go to the SETUP menu:

1. Remove and reinstall the battery to bring up the first menu on the screen.

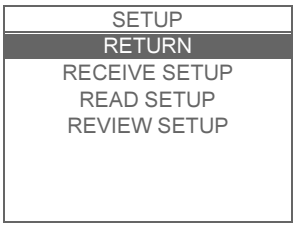
NOTE: This screen will *not* be displayed if the FR2 is connected to defibrillation pads (that are applied to the patient) when the battery is inserted, and you will not be able to access the menu items. In addition, the battery insertion selftest and periodic automatic selftests cannot run while the defibrillation pads are connected. **Be sure to unplug the pads connector from the FR2 after each use. Do not store the FR2 with the pads connected.**

2. Within 10 seconds of installing the battery, press the lower Option button to move the highlight bar to NEXT.
3. Press the upper Option button to select NEXT.



4. Press the lower Option button to move the highlight bar to SETUP.
5. Press the upper Option button to bring up the SETUP menu

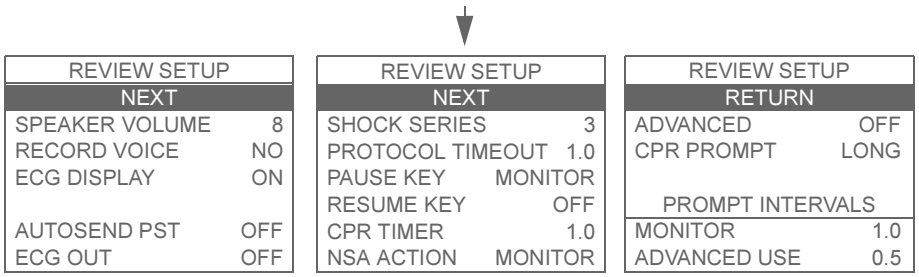
The SETUP menu allows you to receive setup directly from another HEARTSTREAM FR2 or a computer running CODERUNNER software, read setup from a data card, or review current setup.



Reviewing Current Setup

A good way to understand the setup of your FR2 is to review the setup it currently uses.

1. Select REVIEW SETUP from the SETUP menu. The first of a series of REVIEW SETUP screens is displayed.
2. After reviewing the screen contents, press the upper Option button to select NEXT and move to the next screen.
3. The last screen allows you to select RETURN and go back to the SETUP menu.



Revising Setup

There are several ways to change the setup of your HEARTSTREAM FR2. All of them require use of products or accessories available separately from Agilent Technologies.

- Use the M3864A Training & Administration Pack to enable software within the FR2 to modify its setup. (Instructions are provided with the Pack.)
- Read a revised setup from a data card containing the setup. (Instructions are provided later in this chapter.)
- Use the infrared communications feature of the FR2 to receive the revised setup from another FR2. (Instructions are provided later in this chapter.)
- Use the infrared communications feature of the FR2 to receive the revised setup from a computer running CODERUNNER software. (Instructions are provided with the CODERUNNER software.)

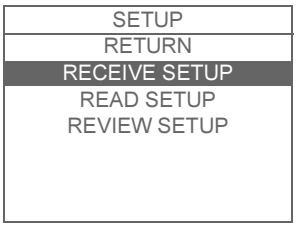
CAUTION: Alteration of the factory default setup of the FR2 can affect its performance and should be performed under the authorization of your Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

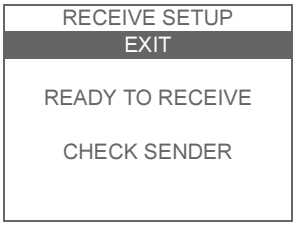
See the tables describing the various setup parameters at the beginning of this chapter. See Appendix E, Glossary of Terms, for definitions of setup items.

Receiving Setup

This method uses the infrared communication feature of the HEARTSTREAM FR2 to receive setup directly from another HEARTSTREAM FR2 (which must have the Training & Administration Pack installed in it) or from a computer running CODERUNNER software. (See instructions provided with CODERUNNER.) To receive setup from another FR2, follow these steps:

1. Locate the infrared communication port on each HEARTSTREAM FR2 and line them up with one another, so that the infrared “eye” in each one has an uninterrupted view of the “eye” in the other. (See the diagram on the inside front cover.) The two devices should be no more than 1 meter apart.





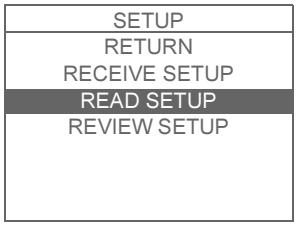
2. Make sure the "sending" HEARTSTREAM FR2 has the Training & Administration Pack installed and is ready to send. (See the M3864A HEARTSTREAM FR2 Training & Administration Pack Reference Guide for instructions.)
3. Select RECEIVE SETUP from the setup menu:
4. A new screen comes up. Until the two HEARTSTREAM FR2 devices are properly positioned, the screen displays READY TO RECEIVE and prompts you to check the sending FR2.
5. Setup data are automatically transferred as soon as the infrared ports are correctly aligned.
6. If you select EXIT before the transfer is complete, the revised setup will *not* be received. When the transfer is complete, the screen on the "receiving" FR2 displays a SETUP COMPLETE message. Your HEARTSTREAM FR2 immediately uses the new setup.

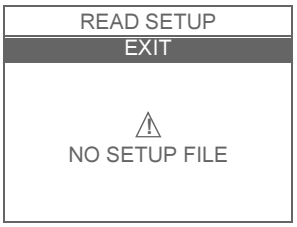
Receiving setup from a computer running CODERUNNER software is discussed in the directions for use provided with CODERUNNER software.

Reading Setup

This method copies setup data from a data card to your HEARTSTREAM FR2. To read the setup, follow these steps:

1. Insert the data card in the data card tray and install the loaded tray into the data card slot in the HEARTSTREAM FR2.
2. Remove and reinstall the battery pack to bring up the first menu on the screen.
3. Select NEXT to go to the second menu screen
4. Select SETUP to go to the setup menu screen.
5. Select READ SETUP from the setup menu.
6. A new screen comes up. If the HEARTSTREAM FR2 cannot read the data card or cannot find a valid setup on the data card, the screen displays a NO SETUP FILE error message. Otherwise, the HEARTSTREAM FR2 begins reading the setup information from the data card immediately.
7. If you select EXIT before the transfer is complete, the revised setup will *not* be copied. When the transfer is finished, the screen displays a SETUP COMPLETE message. Your HEARTSTREAM FR2 immediately uses the revised setup.





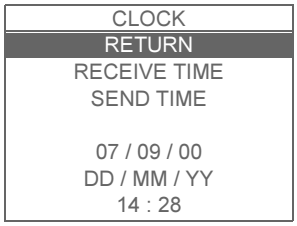
Sending and Receiving Clock Settings

To synchronize the clock settings of your HEARTSTREAM FR2 with the clock of another FR2 or a computer running CODERUNNER software, you can use the infrared communication feature.

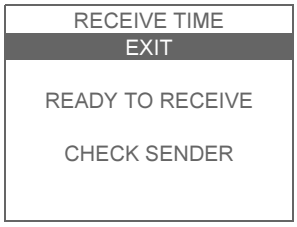
Instructions for synchronizing clock settings using a computer running CODERUNNER are provided with the CODERUNNER software.

To transfer clock settings from one FR2 to another:

1. Remove and reinstall the battery of both FR2 devices to bring up the first menu screen.
2. Select NEXT to go to the second menu screen.
3. Select CLOCK from the second menu screen. The CLOCK screen then comes up.



4. Locate the infrared communication port on each HEARTSTREAM FR2 and line them up with one another, so that the infrared "eye" in each one has an uninterrupted view of the "eye" in the other. (See the diagram on the back of the first page of this manual.) The two devices should be no more than 1 meter apart.
5. Select SEND TIME from the CLOCK screen on the "sending" HEARTSTREAM FR2.
6. Select RECEIVE TIME from the CLOCK screen of the "receiving" FR2.



7. A new screen comes up. Until the two HEARTSTREAM FR2 devices are properly positioned, the screen on the receiving FR2 displays READY TO RECEIVE and prompts you to check the sending FR2. The screen on the sending FR2 displays READY TO SEND and prompts you to check the receiving FR2.
8. Clock settings are automatically transferred as soon as the infrared ports are correctly aligned.

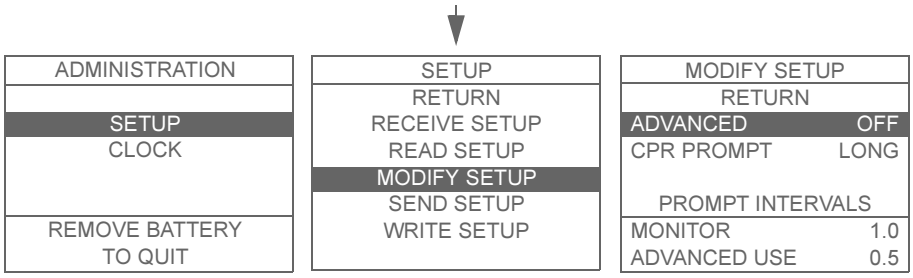
Using Advanced Mode Features

The HEARTSTREAM FR2 provides an advanced mode that allows responders who are appropriately trained to override the programmed FR2 protocol and take responsibility for certain aspects of the operating sequence used by the FR2 to treat the patient.

As described earlier in this chapter, the factory default setup of the FR2 must be modified to provide access to advanced mode features. This requires use of the administration function of the M3864A Training & Administration Pack.

If you are an expert user authorized by your Medical Director to modify setup, hold down both the Option buttons while installing the Training & Administration Pack

in the FR2, then select SETUP. Then select MODIFY SETUP from the SETUP menu. Select ADVANCED from the third menu of the MODIFY SETUP menu.



Using the upper Option button, scroll through the available settings for ADVANCED. The advanced mode options available are based on the FR2 model used. For the M3860A, the user can select ANALYZE or CHARGE. For the M3861A the user can select only ANALYZE. (Detailed directions for use are supplied with the Pack.)

CAUTION: Alteration of the factory default setup of the FR2 can affect its performance and should be performed under the authorization of your Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

CAUTION: The HEARTSTREAM FR2 advanced mode's MANUAL CHARGE feature is intended for use only by authorized operators who have been specifically trained in cardiac rhythm recognition and in defibrillation therapy using manual charge and shock delivery.

This feature is particularly useful for organizations that include responders who have Basic Life Support (BLS) training as well as more highly trained responders who may be certified in Advanced Life Support (ALS). In such situations, the Medical Director may set up a "tiered-response" system. The HEARTSTREAM FR2 is specifically designed to provide different product features appropriate to each tier of responder.

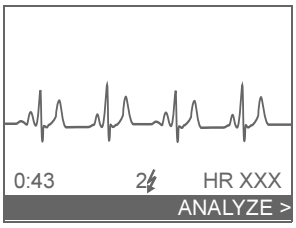
In a scenario where a BLS responder is the first on the scene of an incident, he or she is trained to treat the patient immediately – for example, to check for breathing, responsiveness, and pulse; to apply the defibrillation pads and connect them to the HEARTSTREAM FR2; and to follow the voice and text prompts provided by the HEARTSTREAM FR2 in its AED mode. When an ALS-trained responder arrives, the BLS responder "hands off" the patient's care to the more highly trained responder.

Because these second-tier responders have advanced training and developed clinical skills, they may be authorized to access the advanced mode features of the HEARTSTREAM FR2. These include user-initiated analysis and manual charge and disarm control.

Using the Manual Analyze Feature

The Manual Analyze feature is available in both the M3860A and the M3861A models, when enabled in setup.

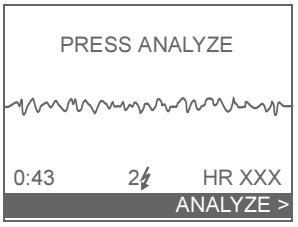
To enter the advanced mode during use of an FR2 that has this feature enabled, press both Option buttons simultaneously. This brings up a screen that includes a highlighted line at the bottom, labeled ANALYZE, with an arrowhead pointing to the lower Option button.



In the M3861A HEARTSTREAM FR2, the patient's ECG is not displayed; in the M3860A, the display includes the patient's ECG and heart rate.

Press the lower Option button (ANALYZE) to initiate rhythm analysis by the FR2. If a shock is advised, the FR2 automatically charges, and prompts you to press the Shock button.

After shock delivery, the HEARTSTREAM FR2 returns to the advanced mode display and monitors the patient's heart rhythm. If a potentially shockable rhythm is detected, the screen advises you to PRESS ANALYZE.



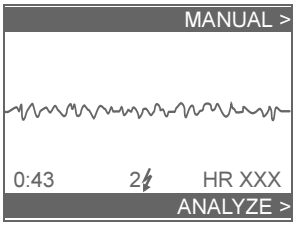
NOTE: If you do *not* press the lower Option button (labeled ANALYZE) to initiate rhythm analysis when prompted, the HEARTSTREAM FR2 does *not* analyze and prompt if a shock is advised. It is important that you understand that entering the advanced mode entails taking responsibility for these functions.

If the rhythm analysis results in a Shock Advised decision, the FR2 begins charging, prompts you to press the Shock button, and displays a MANUAL DISARM option at the top of the screen. If for any reason you want to cancel the shock, press the upper Option button to disarm the FR2.

To return to non-manual, AED mode operation, turn the FR2 off by pressing the On/Off button. Then turn the FR2 on by pressing the On/Off button again.

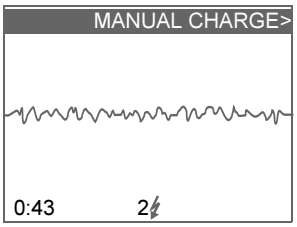
Using the Manual Charge Feature (M3860A only)

The manual charge feature is available only in the M3860A, when enabled in setup.



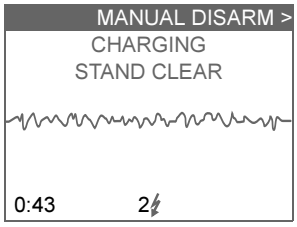
To enter the advanced mode during use of an FR2 that has this feature enabled, press both Option buttons simultaneously. This brings up a screen that includes a highlighted line at the top, labeled MANUAL, with an arrowhead pointing to the upper Option button, and another at the bottom, labeled ANALYZE, with an arrowhead pointing to the lower Option button.

When the advanced mode is entered, display of the patient's ECG and heart rate is automatically initiated.



Pressing the lower Option button (ANALYZE) provides user-initiated rhythm analysis as described above. Pressing the upper Option button (MANUAL) brings up a new screen. The highlighted top line is labeled MANUAL CHARGE, with an arrowhead pointing to the upper Option button.

If the ECG display shows that, in your expert clinical judgment, the patient has a shockable rhythm, press the upper Option button (MANUAL CHARGE). The HEARTSTREAM FR2 will immediately charge for shock delivery.



As soon as charging begins, the screen message changes to CHARGING, STAND CLEAR, and the label for the arrowhead pointing to the upper Option button changes to MANUAL DISARM.

The FR2 beeps while it is charging. When the beeping changes to a continuous tone and the Shock button light flashes, press the Shock button to deliver a shock. However, if the ECG display shows that the patient's rhythm has changed to a non-shockable rhythm, press the upper Option button to disarm the HEARTSTREAM FR2.

After shock delivery, the HEARTSTREAM FR2 returns to the initial advanced mode screen. To return to non-manual, AED mode operation, turn the FR2 off by pressing the On/Off button. Then turn the FR2 on by pressing the On/Off button again.

7 Data Management and Review

Overview

The HEARTSTREAM FR2 is designed to make it easy to manage incident data. Some information is automatically stored in the internal memory of the HEARTSTREAM FR2. More detailed data can be stored on a data card if desired. The incident information stored in the HEARTSTREAM FR2's internal memory, or a summary of the information recorded on the data card, can then be displayed on the HEARTSTREAM FR2 screen for review. In addition, CODERUNNER software can be used on a personal computer to store and review the detailed recorded information from a data card.

Recording Incident Data

The HEARTSTREAM FR2 has two ways of recording information about an emergency incident, so it can be reviewed after the incident: in internal memory and on a data card.

Recording Data in Internal Memory

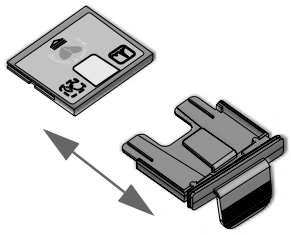
Summary data for an incident is automatically recorded in internal memory by the HEARTSTREAM FR2 while you are using it.

Recording Data on a Data Card

M3854A data cards can be used to store several hours of detailed incident data, including events and ECG.

IMPORTANT NOTE: To record incident data on a data card, the data card must be installed *before* you turn on the HEARTSTREAM FR2.

CAUTION: The HEARTSTREAM FR2 is designed to be used only with Agilent Technologies-approved accessories. The HEARTSTREAM FR2 may perform improperly if non-approved accessories are used.



To install a data card:

1. Make sure the data card is clean and dry.
2. Load the data card into its plastic tray, with the tray's "tongue" fitting over the matching yellow area on the data card. The label on the card should face up. The label has an arrow indicating which side to insert into the data card port.
3. Make sure the FR2 is off (in standby mode), or that the battery has been removed.
4. Hold the loaded tray by its handle and gently insert the tray into the data card port on the right side of the HEARTSTREAM FR2. Push the tray all the way into the port. Do not force the tray into the port. If the tray is hard to insert, remove it and make sure that the arrow label is face up and pointing toward the data card port.

The data card will automatically record incident data the next time the HEARTSTREAM FR2 is turned on.

To avoid running out of data card space during an incident, it is recommended that each data card be used to record the information for only one incident and that it be replaced after each use of the HEARTSTREAM FR2.

If you record information from more than one incident on a data card, it is important to review how much time is left on the used data card before recording a new incident. To do this, load the data card into the data card tray, insert the tray in the FR2, then remove and reinstall the battery. The first screen displayed shows how much recording time remains on the card.

NOTE: During an incident, if for any reason you replace the battery or turn off the HEARTSTREAM FR2 *for less than five minutes*, the FR2 considers this to be a "continued use" situation, and:

- the information stored about the incident is saved,
- any additional events recorded after the battery is reinstalled will be treated as part of the same incident, and
- the selftest will *not* automatically run when the battery is reinstalled.

To replace a data card:

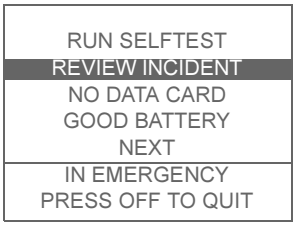
IMPORTANT: You must turn the FR2 off (return it to standby mode) *before* you remove the data card, to ensure that no incident data are lost.

1. Press the On/Off button to turn off the FR2. Never replace the data card unless the FR2 is turned off.
2. Remove the loaded data card tray by grasping its handle and pulling it out of the port.
3. Remove the data card from the tray.

4. Give the data card to the appropriate person in your organization.
5. Because it helps seal the FR2 against moisture, *the data card tray should always be reinserted into the port of the HEARTSTREAM FR2.* Either load a new data card into the tray and insert it, or insert the empty data card tray into the port.

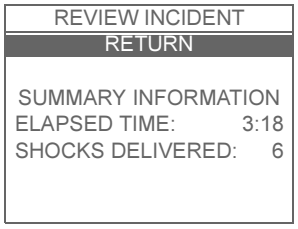
Reviewing Incident Data

Reviewing Data from Internal Memory



Summary information from the last incident that is stored in the internal memory of the HEARTSTREAM FR2 can be displayed on its screen for review. To review this information:

1. Remove the data card if one is installed and unplug the pads connector.
2. Remove and reinstall the battery. (Make sure you are using the regular gray battery, not the yellow Training & Administration Pack.)
3. Select REVIEW INCIDENT from the menu. A new screen comes up.



4. Observe and record, if desired, the summary information displayed on the screen:
   - how long the incident recorded by the FR2 lasted, and
   - how many shocks were delivered during the incident.

This information stays in the HEARTSTREAM FR2's memory and can be displayed for review until the next time the HEARTSTREAM FR2 is used. After that time, the data from the new incident will be displayed.

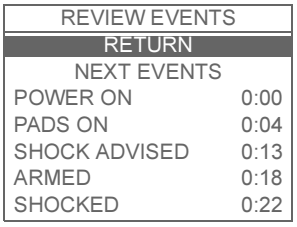
Reviewing Data from a Data Card

If a data card is installed when the HEARTSTREAM FR2 is turned on for use during an incident, the HEARTSTREAM FR2 automatically records detailed information on the data card. To review this information on the HEARTSTREAM FR2 screen:

1. Make sure the Training & Administration Pack is *not* installed.
2. Make sure the data card is installed. Unplug the pads connector.
3. Remove and reinstall the battery.
4. Select REVIEW INCIDENT from the menu. A new screen comes up. This screen displays:
   - ELAPSED TIME – how long the incident recorded by the FR2 lasted,
   - SHOCKS DELIVERED – how many shocks were delivered during the incident, and

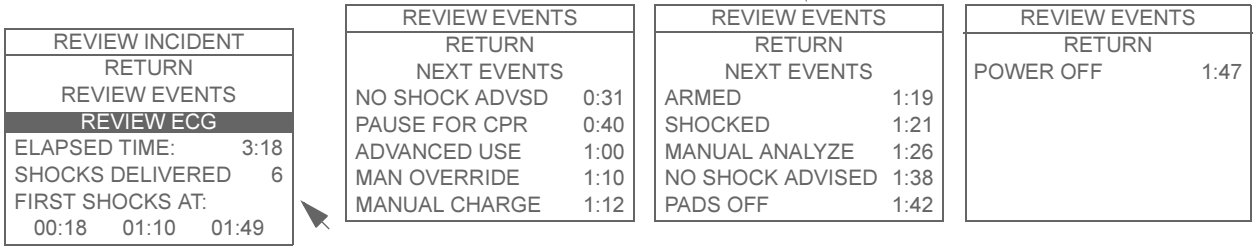
- FIRST SHOCKS AT – the times at which the first three shocks were delivered.

NOTE: If the data card does not contain an events file, only the summary information from FR2 internal memory will be displayed when REVIEW INCIDENT is selected.



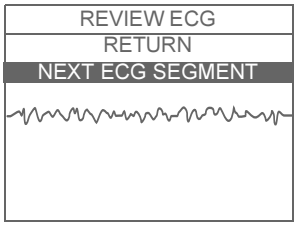
5. To review the events that occurred during the incident, select REVIEW EVENTS. A new screen comes up. This and following screens, accessed by selecting NEXT EVENTS, display elapsed time information for critical activities in using the HEARTSTREAM FR2. These include:
   - POWER ON – when the HEARTSTREAM FR2 was turned on,
   - PADS ON – when the defibrillation pads were connected,
   - SHOCK ADVISED – when a shock was advised,
   - ARMED – when the FR2 charged for shock delivery,
   - SHOCKED – when a shock was delivered,
   - SHOCK ABORTED – when a shock was aborted,
   - PAUSE FOR CPR – when a pause occurred
   - POWER OFF – when the FR2 was turned off

Additional information may be displayed if your HEARTSTREAM FR2 is using a revised setup allowing advanced mode operation.



6. To review the first six seconds of the recorded presenting ECG for the incident, select REVIEW ECG. A new screen comes up. This screen displays a three-second segment of the presenting ECG from the incident.

NOTE: If the data card does not contain a presenting ECG file, REVIEW ECG will not be available.



7. Select NEXT ECG SEGMENT to review the second three-second segment of the presenting ECG.

Data cards can be reused if desired. Using a personal computer running CODERUNNER software, you can copy the information from a data card, then erase the card and reuse it in the HEARTSTREAM FR2.

A Accessories for the HEARTSTREAM FR2

HEARTSTREAM Accessories

Accessories for the HEARTSTREAM FR2 available separately from Agilent Technologies or Laerdal-Agilent Alliance include the following:

- Spare M3863A Battery Pack (recommended)
- Spare Defibrillation Pads (recommended)
- Spare M3853A Data Card Tray
- M3854A Data Card, with Data Card Tray
- M3868A Carrying Case
- M3857A Wall Mount Bracket
- M3864A Training & Administration Pack
- M3855A Battery Charger, with power cord, for use with M3864A Training & Administration Pack only
- 68-PCHAT Fast Response Kit (pouch containing a pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe)

Suggested Additional Items

It may be useful to keep some additional items with your HEARTSTREAM FR2 for use if needed when an incident occurs. Some suggested supplies include:

- a pair of paramedic's shears or scissors*
- a disposable razor designed for removing chest hair*
- a pocket mask or face shield*
- disposable gloves*
- a towel or antiseptic wipes*

Your medical director may have other requirements for supplies.

* Contained in the Fast Response Kit available from Agilent Technologies.

Notes

B Technical Specifications

The specifications for the HEARTSTREAM FR2 provided in this chapter apply to both the M3860A and M3861A, unless otherwise noted.

HEARTSTREAM FR2 AED Specifications

Physical

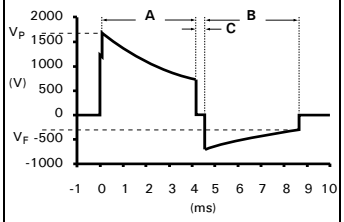
CATEGORY	NOMINAL SPECIFICATIONS
Size	2.6" high x 8.6" wide x 8.6" deep (6.6 cm x 21.8 cm x 21.8 cm).
Weight	Approximately 4.7 lbs (2 kg) with battery installed.

Environmental

CATEGORY	NOMINAL SPECIFICATIONS
Operating Temperature and Humidity	32° to 122° F (0° to 50° C). 0% to 95% relative humidity (non-condensing).
Standby Temperature and Humidity	32° to 109° F (0° to 43° C). 0% to 75% relative humidity (non-condensing). Applies to HEARTSTREAM FR2 with battery installed and stored with defibrillation pads.
Altitude	Meets MIL-810E 500.3, Procedure II (-500 feet to 15,000 feet).
Shock/Drop Abuse Tolerance	Meets MIL-STD-810E 516.4, Procedure IV (after a 1 meter drop to any edge, corner, or surface, in standby mode).
Vibration	Meets MIL-STD-810E 514.4-17.
Sealing	With data card tray and battery installed, meets IEC 529 class IP54.

CATEGORY	NOMINAL SPECIFICATIONS
ESD	Meets EN 61000-4-2:1998 Severity Level 4.
EMI (Radiated)	Meets EN 60601-1-2 limits (1993), method EN 55011:1998 Group 1 Level B.
EMI (Immunity)	Meets EN 60601-1-2 limits (1993), method EN 61000-4-3:1998 Level 2.
Aircraft: Method	Meets RTCA/DO-160D:1997 Section 21 (Category M - Charging).

Defibrillator

<table>
<tr><th>CATEGORY</th><th>NOMINAL SPECIFICATIONS</th></tr>
<tr><td>Waveform
 
</td><td>Biphasic truncated exponential.
Waveform parameters are automatically adjusted as a function of patient defibrillation impedance.
In the diagram at left, A is the duration of phase 1 and B is the duration of phase 2 of the waveform, C is the interphase delay, V_p is the peak voltage, and V_f the final voltage.
The HEARTSTREAM FR2 delivers shocks to load impedances from 25 to 180 ohms. The duration of each phase of the waveform is dynamically adjusted based on delivered charge, in order to compensate for patient impedance variations, as shown in the following examples:
<table>
<tr><th>Load Resistance (ohms)</th><th>Phase 1 Duration (ms)</th><th>Phase 2 Duration (ms)</th><th>Delivered Energy (J)</th></tr>
<tr><td>25</td><td>2.8</td><td>2.8</td><td>140</td></tr>
<tr><td>50</td><td>4.09</td><td>4.09</td><td>150</td></tr>
<tr><td>100</td><td>9.0</td><td>6.0</td><td>157</td></tr>
<tr><td>125</td><td>12.0</td><td>8.0</td><td>161</td></tr>
<tr><td>150</td><td>12.0</td><td>8.0</td><td>157</td></tr>
</table></td></tr>
<tr><td>Energy</td><td>150 J nominal into a 50 ohm load.</td></tr>
<tr><td>Charge Control</td><td>Controlled by Patient Analysis System for semi-automatic operation. Can be programmed for manual initiation using advanced mode of the M3860A.</td></tr>
<tr><td>Charge Time from “Shock Advised”</td><td>< 10 s typical, including confirming analysis. Charge time increases near end of battery service life.</td></tr>
<tr><td>Shock-to-Shock Cycle Time</td><td>< 20 s typical, including analysis, in AED mode.</td></tr>
</table>

CATEGORY	NOMINAL SPECIFICATIONS
"Charge Complete" Indicator	Shock button flashes, audio tone sounds.
Disarm (AED mode)	Once charged, the HEARTSTREAM FR2 will dump the charge if: • if patient's heart rhythm changes to non-shockable rhythm, *OR* • a shock is not delivered within 30 s after the FR2 is armed, *OR* • the PAUSE button (if enabled) is pressed, *OR* • the On/Off button is pressed to turn off the FR2, *OR* • the defibrillation pads are removed from the patient or the pads connector is disconnected from the FR2.
Disarm (advanced mode)	Once charged, the HEARTSTREAM FR2 will dump the charge if: **in advanced mode ANALYZE** • the MANUAL DISARM button is pressed, *OR* • if patient's heart rhythm changes to non-shockable rhythm, *OR* • a shock is not delivered within 30 s after the FR2 is armed, *OR* • the On/Off button is pressed to turn off the FR2, *OR* • the defibrillation pads are removed from the patient or the pads connector is disconnected from the FR2. **in advanced mode CHARGE (M3860A only)** • the MANUAL DISARM button is pressed, *OR* • a shock is not delivered within 30 s after charging , *OR* • the On/Off button is pressed to turn off the FR2, *OR* • the defibrillation pads are removed from the patient or the pads connector is disconnected from the FR2.
Shock Delivery Vector	Via defibrillation pads placed in the anterior-anterior (Lead II) position.

ECG Analysis System

CATEGORY	NOMINAL SPECIFICATIONS
Function	Evaluates impedance of defibrillation pads for proper contact with patient skin, and evaluates the ECG rhythm and signal quality to determine if a shock is appropriate.
Protocols	Follows pre-programmed settings to match local EMS guidelines or medical protocols. The settings can be modified using the setup options.

CATEGORY	NOMINAL SPECIFICATIONS
Shockable Rhythms	Ventricular fibrillation (VF) and certain ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia (VT). The HEARTSTREAM FR2 uses multiple parameters to determine if a rhythm is shockable. *NOTE: For safety reasons, some very low-amplitude or low-frequency rhythms may not be interpreted as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.*
Asystole	On detection of asystole, provides CPR prompt at programmed interval.
Pacemaker Detection	On detection of a pacemaker (in advanced mode only), provides screen display of PACEMAKER DETECTED alert, and M3860A includes pacemaker artifact in ECG display. In both models, pacemaker artifact is removed from the signal for rhythm analysis.

ECG Analysis Performance

RHYTHM CLASS	ECG TEST SAMPLE[a] SIZE	NOMINAL SPECIFICATIONS
Shockable Rhythm — ventricular fibrillation	300	Meets AAMI DF39 requirement and AHA recommendation[b] (sensitivity >90%) for adult defibrillation
Shockable Rhythm — ventricular tachycardia	100	Meets AAMI DF39 requirement and AHA recommendation[b] (sensitivity >75%) for adult defibrillation
Non-Shockable Rhythm — Normal Sinus Rhythm	300	Meets AAMI DF39 requirement (specificity > 95%) and AHA recommendation[b] (specificity >99%) for adult defibrillation
Non-Shockable Rhythm — Asystole	100	Meets AAMI DF39 requirement and AHA recommendation[b] (specificity >95%) for adult defibrillation
Non-Shockable Rhythm — All other non-shockable rhythms	450	Meets AAMI DF39 requirement and AHA recommendation[b] (specificity >95%) for adult defibrillation

a. From Agilent Technologies Heartstream Operation 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

CATEGORY	NOMINAL SPECIFICATIONS
Monitored ECG Lead	ECG information is received from defibrillation pads in anterior-anterior (Lead II) position. (Displayed on M3860A only.)
Display Range (M3860A only)	Differential: +/-2 mV full scale, nominal.
Screen Type	High-resolution liquid crystal display (LCD) with backlight.
Screen Dimensions	2.8" wide x 2.3" high (70 mm x 58 mm).
Sweep Speed (M3860A only)	23 mm/s nominal.
ECG Display	3 second-segments displayed (M3860A only).
Frequency Response (Bandwidth)	Nondiagnostic rhythm monitor 1 Hz to 20 Hz (-3 dB), nominal.
Sensitivity	1.16 cm/mV, nominal.
Heart Rate Displayed (Normal Sinus Rhythm)	30 to 300 bpm, updated each analysis period. Displayed (M3860A only) during monitoring and advanced modes.

Controls and Indicators

CATEGORY	NOMINAL SPECIFICATIONS
LCD Screen	High-resolution, backlighted LCD screen, displays text messages and, for model M3860A only, ECG.
Controls	On/Off button Shock button Option buttons
LED indicators	Connector socket LED, flashes to indicate socket location. LED is covered when defibrillation pad connector is properly inserted. Shock button LED flashes when defibrillator is armed.
Audio Speaker	Provides voice prompts (volume is adjustable via Setup screen).
Beeper	Chirps when a self-test has failed. Provides various warning beeps during normal use.

CATEGORY	NOMINAL SPECIFICATIONS
Status Indicator	Status indicator LCD displays device readiness for use.
Low Battery Detection	Automatic during daily periodic self-testing.
Low Battery Indicator	Solid or flashing red **X** Status Indicator on front panel; screen display LOW BATTERY or REPLACE BATTERY warning, as appropriate.

Accessories Specifications

M3863A Battery Pack Specifications

CATEGORY	NOMINAL SPECIFICATIONS
Battery Type	12 VDC, 4.2 Ah, lithium manganese dioxide. Disposable, recyclable, long-life primary cell.
Capacity	When new, a minimum of 300 shocks or 12 hours' operating time at 77° F (25° C).
Shelf Life prior to Installation	Typically, 5 years from date of manufacture when stored under standby environmental conditions in original packaging.
Standby Life after Installation	Typically, 5 years. >4 years when stored under standby environmental conditions (battery installed, FR2 unused).

HEARTSTREAM Defibrillation Pads Specifications

CATEGORY	NOMINAL SPECIFICATIONS
Pads, Cable, and Connector	Disposable and self-adhesive. Defibrillation pads have a nominal active surface area of 100 cm^2 each and are provided in a sealed package with an integrated 122 cm (48 inch), typical, cable and connector.
Defibrillation Pad Requirements	Use only HEARTSTREAM defibrillation pads with the HEARTSTREAM FR2. Place the pads on the patient as illustrated on the back of each pad.

(Optional) M3854A Data Card Specifications

CATEGORY	NOMINAL SPECIFICATIONS
Capacity	4 hours of event and ECG data, or 30 minutes with voice recording.

C Differences between the FORERUNNER and the HEARTSTREAM FR2 AEDs

Overview

If your organization is currently using the FORERUNNER AED and has recently purchased new HEARTSTREAM FR2 AEDs, you will find that the two devices are very similar, but the FR2 provides additional functionality.

Some of the improvements in the FR2 will be immediately obvious. In comparison to the original FORERUNNER, the FR2 has:

- a brighter and higher-contrast display screen,
- an increased battery capacity and service life, and
- an optional Training & Administration pack with an integrated rechargeable battery, and separate charger.

Other improved features in the FR2 are more subtle, such as:

- facilitation of patient hand-off in tiered-response system, including ability to review presenting ECG;
- more detailed voice and text prompts;
- more data management options, including infrared communications capability for data transfer; and
- manual (advanced) mode operation remains in effect after entry until the unit is turned off.

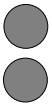
Some of the specific differences between the two devices are described in the following table.

NOTE: In the following table, where the name of a feature has been changed from the name used in the FORERUNNER literature, the new FR2 name is shown in quotation marks.

FORERUNNER		HEARTSTREAM FR2	
THREE MODELS		**TWO MODELS**	
EM	ECG display with optional manual mode (manual charge and discharge).	**M3860A**	ECG display, programmable advanced mode options (analysis on demand, or both analysis and charge/disarm on demand).
E	ECG display, no manual mode.	**M3861A**	No ECG display, programmable advanced mode option (analysis on demand only).
S	No ECG display, no manual mode.		
BATTERY		**BATTERY**	
Capacity	Typically 100 shocks or 5 hours of' operating time.	**Capacity**	Typically 300 shocks or 12 hours of operating time.
Standby Life	Typically 1 year.	**Standby Life**	Typically 5 years.
TRAINING & ADMINISTRATION		**TRAINING & ADMINISTRATION**	
Training	Requires Training Card; uses standard battery; provides 8 training scripts.	**Training**	Requires Training & Administration Pack; uses integrated rechargeable battery;* provides 10 training scripts
Administration	Requires Setup Card; uses standard battery.	**Administration**	Requires Training & Administration Pack; uses integrated rechargeable battery.* ** Battery Charger available separately*
Setup transfer	No transfer of setup data.	**Setup transfer**	Infrared transfer of setup data.
PANEL LAYOUT AND CONTROLS		**PANEL LAYOUT AND CONTROLS**	
Display	LCD display with backlighting.	**Display**	Brighter, higher-contrast LCD display.
Contrast buttons	Small, close together.	**"Option" buttons**	Larger, spaced further apart.
Manual Mode entry	Separate Manual Override button on front panel (EM only); returns to AED mode after shock delivery or manual timeout.	**"Advanced" Mode entry**	Uses Option buttons for fast patient hand-off to ALS responders; remains in advanced mode until turned off.
DATA REVIEW AND MANAGEMENT		**DATA REVIEW AND MANAGEMENT**	
PC cards	Three cards of limited capacity (ER1, typically 15 minutes; EC1, typically 30 minutes; VC1, typically 26 minutes), using clock on card. No setup data transfer capability.	**"Data" card**	One cost-effective card, with significantly increased capacity (approximately 4 hours of event and ECG data, or 30 minutes with voice, using FR2's internal clock.) Setup data transfer capability.
Data display	No on-screen review of presenting ECG.	**Data display**	On-screen review of presenting ECG.

D Glossary of Symbols and Controls

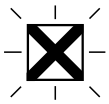
HEARTSTREAM FR2 Symbols and Controls

SYMBOL	DESCRIPTION
	**On/Off button.** Turns the HEARTSTREAM FR2 on or off; disarms HEARTSTREAM FR2, stops automatic self-test. When the optional Training & Administration Pack is being used in the Training function, this button is used to select and exit training scripts.
	**Shock button.** Delivers shock to patient when the HEARTSTREAM FR2 is charged.
	**Upper and lower Option buttons.** Allow you to move around in and select an item from a display menu; provide adjustment of display screen contrast.
	**Defibrillation protection.** Defibrillation protected, type BF patient connection.
	**High voltage.**
	**Refer to operating instructions.**

HEARTSTREAM FR2 Display Screen Symbols

SYMBOL	DESCRIPTION
HR XXX	**Heart rate.**
XX ϟ	**Number of shocks delivered.**
XX:XX	**Time.** How much time (minutes:seconds) has passed since the HEARTSTREAM FR2 was turned on.
⚠ **TEMPERATURE**	**Temperature.** Recommended storage temperature range has been exceeded since the last automatic self-test.
⚠ **SETUP**	**Setup.** Setup has been lost from memory; factory default setup is being used. Contact Medical Director for revised setup.
REV: XXXXXXXXX	**Software.** The version of software and hardware used in your HEARTSTREAM FR2.

Status Indicator Symbols

SYMBOL	DESCRIPTION
	**Flashing black hourglass.** Ready for use.
	**Solid red X**. Not ready for use. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2.)
	**Flashing red X**. Troubleshooting required. (See Chapter 4, Maintaining, Testing, and Troubleshooting Your HEARTSTREAM FR2.)

M3863A Battery Pack Symbols

SYMBOL	DESCRIPTION
	Do not crush the battery.
	Do not expose the battery to high heat or open flames. Do not incinerate the battery.
	Do not mutilate the battery or open the battery case.
	Install the battery in the HEARTSTREAM FR2 before the date shown on this label.

D

Notes

E Glossary of Terms

The terms listed in this Glossary are defined in the context of the HEARTSTREAM FR2 and its use.

Advanced Mode ..... A programmable treatment mode that permits an authorized user to control when the FR2 starts rhythm analysis and (model M3860A only) when to begin defibrillator charging for shock delivery.

AED ..... Semi-automatic external defibrillator.

AED Mode ..... The standard FR2 treatment mode, with voice and screen prompts guiding the responder through connecting the defibrillation pads, waiting for rhythm analysis, and delivering a shock if needed. In this mode, heart rhythm analysis and monitoring, and shock decision and charging for shock delivery are automatically performed by the FR2.

ALS ..... Advanced Life Support.

Analysis ..... See SMART Analysis.

Arrhythmia ..... An unhealthy, often irregular, beating of the heart.

Battery ..... The sealed lithium manganese dioxide battery used to power the FR2. It is provided in a gray pack that fits into a compartment at the top of the FR2.

BLS ..... Basic Life Support.

CODERUNNER ..... A dedicated data management software system from Agilent Technologies for use with the HEARTSTREAM FR2.

Continued Use ..... A condition in which use of the HEARTSTREAM FR2 is interrupted for less than five minutes (e.g., for battery replacement). When the battery is reinserted or the unit is turned on again, the information stored about the interrupted incident is saved, any additional events recorded after the battery is reinstalled are treated as part of the same incident, and the selftest does *not* automatically run when the battery is reinstalled.

CPR Timer ..... A programmable period provided by the HEARTSTREAM FR2 during which the responder can administer CPR.

Defibrillation	Termination of cardiac fibrillation by applying electrical energy
Defibrillation Charge	Electrical energy stored in the capacitor of the HEARTSTREAM FR2 as it arms for shock delivery.
Defibrillation Pads	The self-adhesive electrode pads applied to the patient's bare chest and used to detect the patient's heart rhythm and transfer the defibrillation shock. Only HEARTSTREAM defibrillation pads can be used with the FR2.
Defibrillation Shock	See SMART Biphasic Waveform.
ECG	Electrocardiogram, a display or printout of the electrical rhythm of the heart as detected through defibrillation electrode pads.
Event	An action recognized or performed by the HEARTSTREAM FR2 as a step in the sequence of using the device in an incident. Examples include: applying the pads and connecting them to the HEARTSTREAM FR2, analyzing heart rhythm, delivering a shock, etc.
Fibrillation	A disturbance of the normal heart rhythm that results in chaotic, disorganized activity that cannot effectively pump blood. Ventricular fibrillation (fibrillation in the lower chambers of the heart) is associated with sudden cardiac arrest.
Heart Rhythm (ECG) Analysis	A system used by the FR2 to determine if the patient's heart rhythm is shockable — ventricular fibrillation (VF) or certain ventricular tachycardias (VTs). See SMART Analysis.
Impedance	Electrically, this is the total opposition offered by the body to the flow of the electrical shock waveform delivered by the HEARTSTREAM FR2. The FR2 automatically monitors the electrical impedance between the defibrillation pads placed on the patient's bare chest, and adjusts the shock waveform appropriately.
Incident	The series of events involved in treating a patient with the HEARTSTREAM FR2.
Infrared Communications	A method of sending information using a special part of the light spectrum. It is used to transmit information to and from the HEARTSTREAM FR2 and another FR2 or a computer running CODERUNNER software.
Manual Charge	A feature of the advanced mode used by an authorized ALS-certified responder that allows the user to arm the HEARTSTREAM FR2 for shock delivery.
Manual Disarm	A feature of the advanced mode used by an authorized ALS-certified responder that allows the user to dump the HEARTSTREAM FR2 charge internally.
Monitoring	A mode of background analysis to determine if patient rhythm has changed to a shockable rhythm.

Non-Shockable Rhythm ..... A heart rhythm that the HEARTSTREAM FR2 determines is not appropriate for shock delivery.

NSA ..... No Shock Advised decision, made by the HEARTSTREAM FR2 based on analysis of the patient's heart rhythm.

Pacemaker ..... External or implanted cardiac pulse generator that stimulates the heart electronically.

Pads ..... See Defibrillation Pads.

Pause ..... A defined period during which the HEARTSTREAM FR2 does not perform rhythm analysis.

Periodic Selftests ..... Daily, weekly, and monthly tests automatically conducted by the FR2 when it is in the standby mode. The tests monitor many key functions and parameters of the FR2, including battery capacity and the state of its internal circuitry.

Presenting ECG ..... The heart rhythm seen by the HEARTSTREAM FR2 when it is first connected to the patient (via the defibrillation pads) and begins rhythm analysis.

Prompts ..... The voice commands and screen text used to guide the responder through use of the HEARTSTREAM FR2 to treat the patient.

Protocol ..... A sequence of operations performed by the HEARTSTREAM FR2 to direct patient care in the AED mode.

Protocol Timeout ..... A programmable interval between shocks, used by the HEARTSTREAM FR2 to decide if the shocks are part of the same shock series.

Read (Data) ..... A feature of the HEARTSTREAM FR2 that allows it to read setup data from a HEARTSTREAM M3854A data card.

Receive (Data) ..... A feature of the HEARTSTREAM FR2 that allows use of its infrared (IR) communications port to receive revised setup and clock settings directly from another device.

Record Voice ..... An optional feature of the HEARTSTREAM FR2 that allows sound recording to a data card during use of the device in an incident. Activation of this feature requires revision of the HEARTSTREAM FR2's default settings.

Rhythm Analysis ..... See SMART Analysis.

Send (Data) ..... A feature of the HEARTSTREAM FR2 that allows use of its infrared (IR) communications port to send data directly to another FR2 or a computer running CODERUNNER WEB software.

Sensitivity ..... A measure of the ability of the HEARTSTREAM FR2 to reliably detect and identify shockable heart rhythms.

Setup ..... The settings of all programmable operating parameters of the HEARTSTREAM FR2. The factory default setup can be modified using the HEARTSTREAM M3864A Training & Administration Pack.

Shock Series ..... One or more shocks, each separated by no more than a preset time (programmed Protocol Timeout). After completion of a shock series, the HEARTSTREAM FR2 automatically pauses for CPR.

Shockable Rhythm ..... Ventricular fibrillation and certain ventricular tachycardias associated with sudden cardiac arrest.

Shock Waveform ..... See SMART Biphasic Waveform.

SMART Analysis ..... The proprietary algorithm used by the FR2 to analyze the patient's heart rhythm and determine whether a shock is advised.

SMART Biphasic Waveform..... The patented, low-energy defibrillation shock waveform used by the FR2. It is an impedance-compensated biphasic waveform with 150 Joules, nominal, delivered to a 50 ohm load.

Specificity ..... A measure of the ability of the HEARTSTREAM FR2 to reliably detect and identify non-shockable heart rhythms.

Standby Mode ..... The operating mode of the HEARTSTREAM FR2 when a battery has been installed, and the unit is turned off and ready for use when needed. Shown by flashing black hourglass on the Status Indicator.

Status Indicator ..... This is a special window in the upper right-hand corner of the front panel of the HEARTSTREAM FR2 that lets you know the status of the device.

Sudden Cardiac Arrest ..... The sudden cessation of the heart's pumping rhythm, accompanied by loss of consciousness, absence of breathing, and lack of a pulse.

Training & Administration Pack ..... An optional accessory for the FR2 that enables training and administrative functions.

Waveform ..... See SMART Biphasic Waveform

Write (Data)..... A feature of the HEARTSTREAM FR2 that allows it to record setup information on a data card.

F Clinical Summary

Introduction

The HEARTSTREAM FR2 utilizes the patented SMART Biphasic waveform. This waveform has been extensively tested in pre-clinical and both electrophysiology laboratory and out-of-hospital clinical studies. The following information summarizes the results of a large study comparing the use of SMART Biphasic AEDs to conventional monophasic in out-of-hospital emergency resuscitation situations.

Background

Agilent Technologies conducted an international, multicenter, prospective, randomized clinical study 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 fewer.

Methods

Victims of out-of-hospital SCA were prospectively enrolled in four emergency medical service (EMS) systems. Responders used either 150 J SMART Biphasic AEDs or 200-360 J monophasic waveform AEDs. A sequence of up to three defibrillation shocks was delivered. For the biphasic AEDs there was a single energy output of 150 J for all shocks. For monophasic AEDs, the shock sequence was 200-200-360 J. 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 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 and location of arrest, and bystanders witnessing the arrest or performing CPR.

The 150 J SMART Biphasic waveform defibrillated 98% of VF patients in the first series of three shocks or fewer compared with 69% of patients treated with monophasic waveform shocks. Outcomes are summarized as follows:

	SMART Biphasic Patients Number (%)	Monophasic Patients Number (%)	P Value (chi square)
Defibrillation Efficacy			
Single shock only	52/54 (96%)	36/61 (59%)	<0.0001
</= 2 shocks	52/54 (96%)	39/61 (64%)	<0.0001
</= 3 shocks	53/54 (98%)	42/61 (69%)	<0.001
Patients Defibrillated	54/54 (100%)	49/58 (84%)	0.003
ROSC	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

Conclusions

The 150 J SMART Biphasic waveform defibrillated at higher rates than the 200-360 J 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).

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