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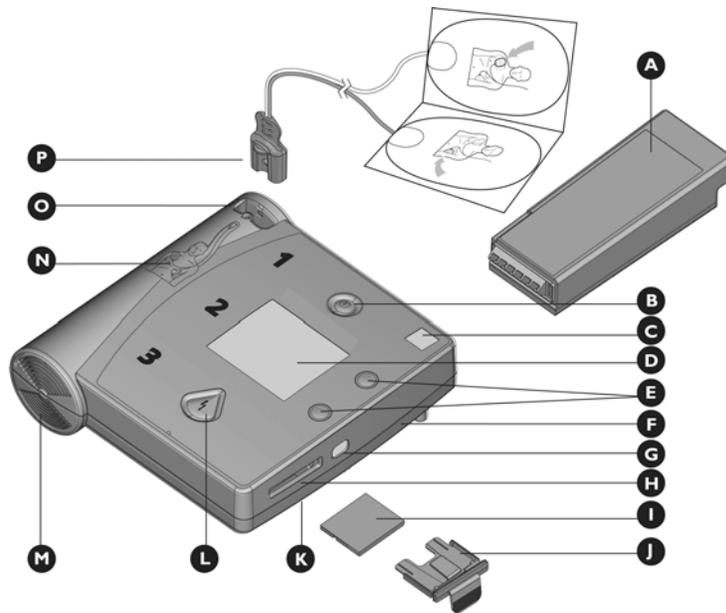
HeartStart FR2+ Defibrillator

INSTRUCTIONS FOR USE

M3860A, M3861A

Edition 14

HEARTSTART
DEFIBRILLATORS



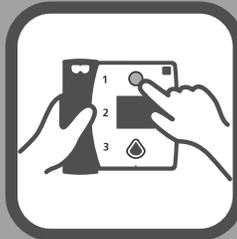
The HeartStart FR2+ Defibrillator

- A** Battery. Standard long-life or rechargeable battery used to power the FR2+.
- B** On/Off button. Turns on the FR2+ and starts voice and text prompts. Second press turns off the FR2+.
- C** Status Indicator. Shows you the readiness status of the FR2+.
- D** Display screen. Displays text prompts and incident data. The 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 an 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 HeartStart 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 adult pads. *Diagrams are also shown on the defibrillator pads.*
- O** Defibrillator pads connector socket. Receptacle for connector of the defibrillator pads cable. An adjacent LED light flashes to show socket location and is covered when connector is inserted.
- P** Defibrillator pads. Self-adhesive pads with attached cable and connector. (Adult pads shown.)

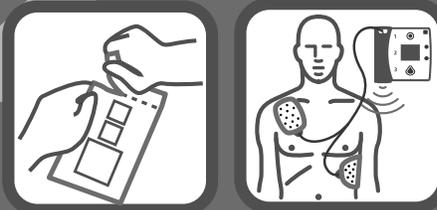
HeartStart FR2+ Defibrillator QUICK REFERENCE CARD

**IF PATIENT IS UNRESPONSIVE
AND NOT BREATHING NORMALLY:**

**1
TURN ON**



**2
FOLLOW
PROMPTS**



**3
PRESS SHOCK BUTTON
IF INSTRUCTED**



Intentionally blank.

PHILIPS

HeartStart FR2+ M3860A/M3861A Automated External Defibrillator

INSTRUCTIONS FOR USE

Edition 14

IMPORTANT NOTE:

It is important to understand that survival rates for sudden cardiac arrest are directly related to how soon victims receive treatment. For every minute of delay, the chance of survival declines by 7% to 10%.

Defibrillation cannot assure survival. In some patients, the underlying problem causing the cardiac arrest is simply not survivable despite any available care.

About this edition

The information in this guide applies to the model M3860A/M3861A HeartStart FR2+ Defibrillator. This information is subject to change. Please contact Philips at www.medical.philips.com/heartstart or your local Philips representative for information on revisions.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

The HeartStart FR2+ is designed to be used only with Philips-approved accessories. The HeartStart FR2+ may perform improperly if non-approved accessories are used.

Device Tracking

In the U.S.A., this device is subject to tracking requirements by the manufacturer and distributors. If the defibrillator has been sold, donated, lost, stolen, exported, or destroyed, notify Philips Medical Systems or your distributor.

Device Manufacturer

The HeartStart FR2+ Defibrillator is manufactured by Philips Medical Systems, Seattle, Washington, USA.

Patents

This product is manufactured and sold under one or more of the following United States patents: U.S. Pat. No US6047212, US6317635, US5892046, US5891049, US6356785, US5650750, US6553257, US5902249, US6287328, US6662056, US5617853, US5951598, US6272385, US6234816, US6346014, US6230054, US6299574, US5607454, US5803927, US5735879, US5749905, US5601612, US6441582, US5889388, US5773961, US6016059, US6075369, US5904707, US5868792, US5899926, US5879374, US5632280, US5800460, US6185458, US5611815, US6556864, and other patents pending.

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I Introduction to the HeartStart FR2+

Device description

The HeartStart FR2+ Defibrillator (“FR2+”) is a compact, lightweight, portable, and battery powered automated external defibrillator designed for use by a trained responder to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA).

The FR2+ has a Status Indicator that is always active, so you can tell at a glance if it has passed its last selftest. 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 FR2+ is available in two models, the M3860A and the M3861A. They share a set of basic features, detailed in Chapter 6. The principle differences between the two models are identified below:

Model M3860A	Model M3861A
Configurable ECG display on screen	Text prompt display on screen, no ECG display
Configurable manual charge in advanced mode (See Chapter 6)	No manual charge in advanced mode (See Chapter 6)

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

Indications for use

The HeartStart FR2+ is intended to be used with disposable defibrillator pads applied to victims of sudden cardiac arrest exhibiting the following symptoms:

- Unresponsiveness
- Absence of normal breathing

If in doubt, apply the pads.

To use the FR2+ on children under 8 years or 55 pounds (25 kg), apply FR2 Infant/child reduced-energy defibrillator pads, if available. Otherwise, apply the standard pads.

WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings has not been established in patients under 8 years or 55 lb. (25 kg). See Appendix E for more information.

The FR2+ is intended for use by responders who have been trained in its operation. The user should be qualified by training in Basic Life Support (BLS), in Advanced Life Support (ALS), or another physician-authorized emergency medical response program.

At the discretion of emergency care personnel, the FR2+ M3860A can also be used with the FR2+ ECG assessment module to provide non-diagnostic display and evaluation of the heart rhythm of a responsive or breathing patient, regardless of age, for attended patient monitoring. While connected to the FR2+ ECG assessment module, the FR2+ M3860A disables its shock capability.

Principles of operation

The HeartStart FR2+ Defibrillator is designed to provide external defibrillation therapy to someone experiencing sudden cardiac arrest caused by ventricular fibrillation (VF), the most common cause of SCA. The only effective treatment for VF is defibrillation. The FR2+ treats VF by sending a shock across the heart, so it can start beating regularly again.

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

2 Getting Started

Package contents

The HeartStart FR2+ Defibrillator is supplied with a standard long-life battery, two sets of adult defibrillator pads with integrated cable and connector, and a data card tray. Other accessories, including FR2 infant/child reduced-energy defibrillator pads, an FR2+ rechargeable battery, and (for M3860A only, with ECG display enabled) a three-wire FR2+ ECG assessment module, are available. See Appendix A for a list of accessories and other recommended supplies.

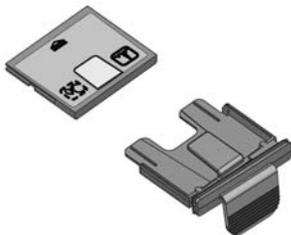
Setup overview

Setting up the HeartStart FR2+ for use is quick and simple.

- Install a data card. (optional)
- 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.

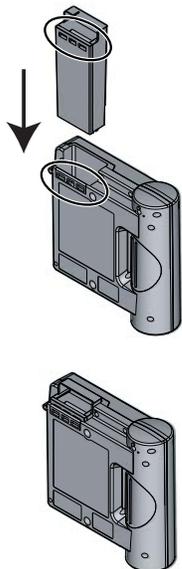
Installing the data card

The HeartStart FR2+ comes with a data card tray, which should be kept in the data card port even if no data card is used. If a data card is to be used, install it as follows:



1. Load the data card face up into the data card tray, with the tray's "tongue" fitting over the matching yellow area on the data card.
2. Press the On/Off button to turn off the HeartStart FR2+ if it is on.
3. Hold the loaded data card tray by its handle and gently insert the tray all the way into the defibrillator's data card port until only the tab remains outside the case.

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



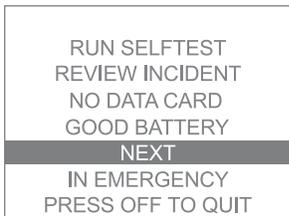
Installing the battery and setting the clock

The HeartStart FR2+ Defibrillator is shipped with an M3863A standard, long-life battery. The battery is enclosed in a gray plastic case with a yellow latch at one end, designed to hold the battery in place when it is correctly installed. (The optional M3848A FR2+ rechargeable battery case is blue, and it also has a yellow latch. Except where otherwise noted, the following information applies to both battery types.) To install the battery:

1. Hold the battery by the latch end and slide it into the battery compartment at the top of the HeartStart FR2+.
2. Slide the battery all the way into the opening, until the latch clicks into place.

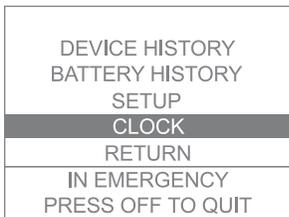
CAUTION: Follow all instructions supplied with the battery. Install the battery before the install-by date shown on the battery.

When the battery is installed, the FR2+ automatically turns on. The Status Indicator displays a flashing black hourglass. The Shock button light and the indicator light for the defibrillator pads connector socket turn on briefly. The display screen brings up the main menu.



It is recommended that you set the FR2+'s internal clock to the correct date and local time at this point.

1. Within 10 seconds of installing the battery, press the lower Option button to move the highlight bar on the displayed main menu to NEXT.
2. Press the upper Option button to select NEXT to bring up the second menu 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 menu.
5. To receive clock settings from another FR2+, see directions provided in Chapter 6. To manually set the time and date, follow the remaining steps.



6. Press the lower Option button to move the highlight bar to the date or time field to be changed.
7. Using the upper Option button, scroll through the available settings to the desired value.
8. Use the lower Option button to move to any other date or time field to be changed, and repeat step 6.
9. When all selections have been made, use the lower Option button to move the highlight bar to RETURN, then press the upper Option button to return to the second menu.
10. After ten seconds, the HeartStart FR2+ automatically starts the battery insertion selftest.*



If you choose not to set the clock at this point, the HeartStart FR2+ automatically starts the battery insertion selftest within ten seconds of battery insertion. You can remove and reinsert the battery at any time to review or adjust the clock settings.

Running the Battery Insertion Test

The battery insertion selftest has two parts, an automatic part, during which the screen displays a bar that fills in as the test continues, followed by an interactive part. Follow the defibrillator's prompts during the interactive part of the test. When the FR2+ has passed the battery insertion selftest, it turns off and goes to standby mode to be ready for use. Standby mode is indicated by the flashing black hourglass status indicator.

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

Placing and securing the HeartStart FR2+

Place the HeartStart FR2+ Defibrillator in an accessible area with the Status Indicator easily visible. The defibrillator can be secured in a carrying case suitable for use with a wallmount bracket or defibrillator cabinet. Useful accessories for

* See Chapter 4 for details about the battery insertion selftest.

storage with the HeartStart FR2+ include a spare battery, spare pads, spare data card (if used), and a Fast Response Kit containing a pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe. See Appendix A for a list of accessories.

NOTE: Be careful not to overpack the carrying case, to avoid placing inadvertent pressure on the control buttons. Do not store the FR2+ with the defibrillator 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 FR2+ performs detailed daily, weekly, and monthly selftests to check its readiness for use. These periodic selftests are described in Chapter 4.

While the FR2+ is in the standby mode, the Status Indicator shows the flashing black hourglass unless the periodic selftest detects 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 chirp to alert you. Chapter 4 contains instructions for troubleshooting.

* See Appendix B for environmental specifications.

3 Using the HeartStart FR2+

Overview

This chapter describes how to use the HeartStart FR2+ Defibrillator in an emergency. Some general things to remember are:

- Try to relax and stay calm. The HeartStart FR2+ automatically provides voice and text prompts to guide you through each step of its use.
- The defibrillator pads must have good contact with the patient's skin. The pads have a layer of sticky, conductive gel beneath the protective backing.
- It may be necessary to dry the patient's skin or to clip or shave excessive chest hair to provide good contact between the defibrillator pads and the patient's skin.

Be sure to read the Warnings and Cautions on the last page of this chapter.

Detailed directions for use based on default configuration are provided on the following pages.

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

Treating infants and children

WARNING: Most cardiac arrests in children are not caused by heart problems. When responding to cardiac arrest in an infant or child:

- Provide infant/child CPR while a bystander calls EMS and brings the FR2+.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the FR2+.
- If you witnessed the child's collapse, call EMS and get the FR2+.

Alternatively, follow your local protocol.

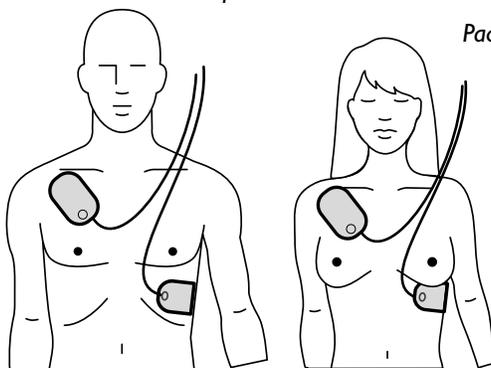
Step I: Preparation

Press the On/Off button to turn on the HeartStart FR2+ Defibrillator. Follow the instructions provided by the FR2+ voice and text prompts.

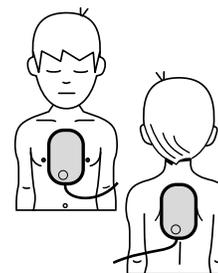


- Remove clothing from the patient's upper body. If needed, wipe moisture from the patient's skin and clip or shave excessive chest hair.
- If the patient appears to be under eight years of age or 55 lb. (25 Kg), use M3870A FR2 infant/child reduced-energy defibrillator pads, if available. If the infant/child pads are not available, or if the child appears older/larger, use adult defibrillator pads. **DO NOT DELAY TREATMENT TO DETERMINE THE CHILD'S EXACT AGE/WEIGHT.**
- Open the defibrillator pads package. Pull off the protective backing from the defibrillator pads.
- Place the sticky side of each pad on the patient's bare skin, exactly as shown on the drawing on each pad.

Pad placement for adults and children 8 years old or 55 pounds or more.



Pad placement for infants and children under 8 years old or 55 pounds.



- Insert the defibrillator pads connector firmly into the defibrillator's connector socket, indicated by a flashing light at the top left of the FR2+.

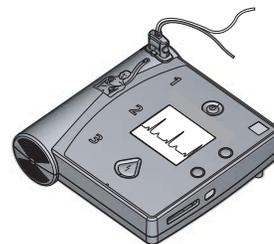


Step 2: ECG analysis and CPR interval

Follow the instructions provided by the FR2+ Defibrillator's voice and text prompts.

As soon as the FR2+ detects that the defibrillator pads are connected properly, it automatically begins analyzing the patient's heart rhythm. Do not touch the patient during rhythm analysis.

If no shock is advised, the HeartStart FR2+ provides voice and text prompts to tell you so and provides a CPR interval with a prompt to perform CPR, if needed. The duration of the CPR interval is determined by CPR Timer setting.



3

Following the CPR interval, the FR2+ reanalyzes the patient's heart rhythm. If no shock is again advised, the device goes into a patient care interval, during which you can perform CPR if needed or otherwise tend to the patient. The duration of the patient care interval is determined by the NSA Action setting.

NOTE: CPR may interfere with background heart rhythm monitoring by the FR2+ in monitoring mode. During CPR, periodically pause for 15 seconds to reassess the patient and allow the FR2+ to analyze the patient's heart rhythm without possible interference from CPR artifact.

If a shock is advised, the HeartStart FR2+ charges to prepare for shock delivery. It gives the voice and text prompts to tell you that a shock is advised.



Step 3: Shock delivery

First, make sure that no one is touching the patient or the pads. While the FR2+ is charging, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer appropriate, the FR2+ disarms. Voice and text prompts advise you what action to take.

There are four ways you can tell that the defibrillator 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 text prompt telling you to press the orange (Shock) button.

Press the Shock button to deliver the shock.

IMPORTANT: You must press the button for a shock to be delivered. The HeartStart FR2+ Defibrillator will not automatically deliver a shock. This safety feature allows you to verify that the patient is clear before a shock is delivered.



NOTE: If you do not press the Shock button within 30 seconds of being prompted, the HeartStart FR2+ will disarm itself and provide a pause. It will resume analyzing heart rhythm after 30 seconds or when the Resume Analyzing key is pressed.

After you press the Shock button, a voice prompt tells you the shock was delivered. Then the FR2+ pauses to allow you to perform CPR. The duration of this CPR interval is determined by the CPR Timer setting.

CPR Interval

After telling you that it has paused, the FR2+ gives no more voice prompts during the CPR interval, so that you can provide uninterrupted patient care. During the CPR interval, the FR2+ screen shows a bar that fills in as the CPR interval is used up. The HeartStart FR2+ M3860A also displays the ECG, if enabled, during this period.

NOTE: It is important to perform CPR for the entire duration of the CPR interval, until you hear the voice prompt telling you to stop CPR.

ECG display for ongoing observation

At the discretion of emergency care personnel, the HeartStart FR2+ M3860A with ECG display enabled can also be used with the M3873A/M3874A FR2+ ECG assessment module to provide a non-diagnostic ECG display of the patient's heart rhythm for attended patient monitoring. The system is intended for use on a conscious or breathing patient, regardless of age. While connected to the FR2+ ECG assessment module, the FR2+'s shock capability is disabled, but the FR2+ continues to evaluate the patient's ECG. There are no known contraindications to use of the FR2+ ECG assessment module.

The module is designed for connection to ECG electrodes per AAMI (M3873A) or IEC (M3874A) color convention. The module's colored leadwires are connected to ECG electrodes, which are then placed on the patient's bare chest, and the module's device connector is inserted in the FR2+'s connector socket.

NOTE: It is not necessary to turn the FR2+ Defibrillator off prior to connecting the ECG assessment module.

Once connected, the HeartStart FR2+ displays and evaluates the patient's ECG (Lead II). Follow all prompts from the defibrillator. If a data card is used when the ECG assessment module is connected, all recorded events can be viewed using one of the Event Review data management software products.

Check the patient if:

- indicated by the observed ECG display,
- the patient becomes unresponsive or stops breathing, or
- the FR2+ prompts IF NEEDED, ATTACH DEFIBRILLATION PADS.

If appropriate, unplug the ECG assessment module from the FR2+, attach the defibrillator pads to the patient, and connect the defibrillator pads to the FR2+. Verify that the defibrillator pads are at least one (1) inch (2.5 cm) away from the ECG electrodes.

WARNING: During defibrillation, air pockets between the skin and defibrillator pads can cause patient skin burns. To help prevent air pockets, make sure defibrillator pads completely adhere to the skin.

WARNING: Do not let the defibrillator 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: Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the FR2+ gives a SHOCK ADVISED prompt, keep the patient as still as possible for at least 15 seconds so the HeartStart FR2+ can reconfirm the rhythm analysis before a shock is delivered.

WARNING: CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the FR2+. Under certain circumstances, this may result in a prompt to stop all movement so that the device can confirm rhythm analysis.

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

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

CAUTION: Do not place the pads directly over an implanted pacemaker or defibrillator. A noticeable lump with a surgical scar should indicate its position.