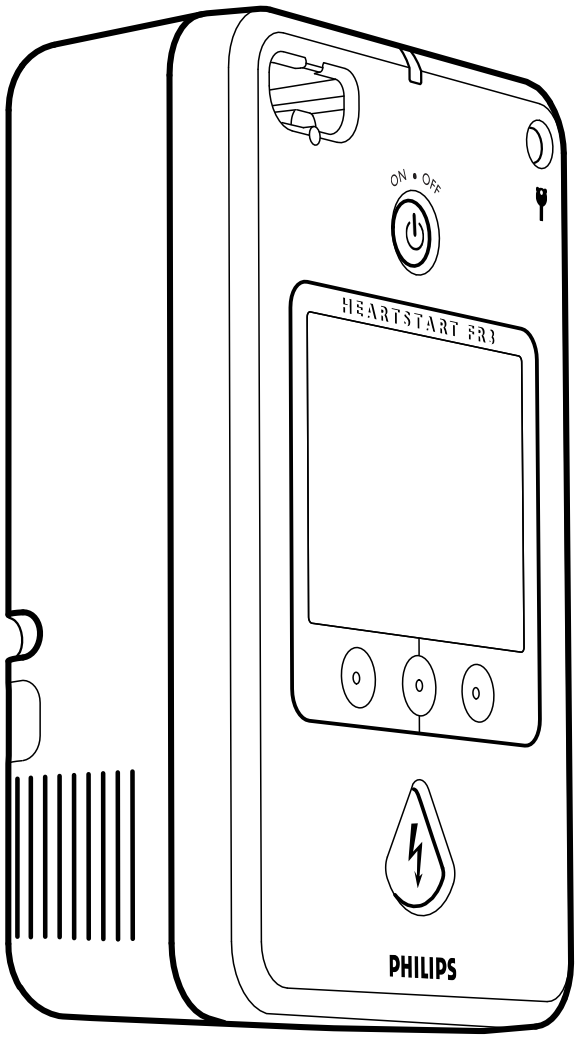
HeartStart FR3 Defibrillator

INSTRUCTIONS FOR ADMINISTRATORS



861388 and 861389
Edition 3

PHILIPS

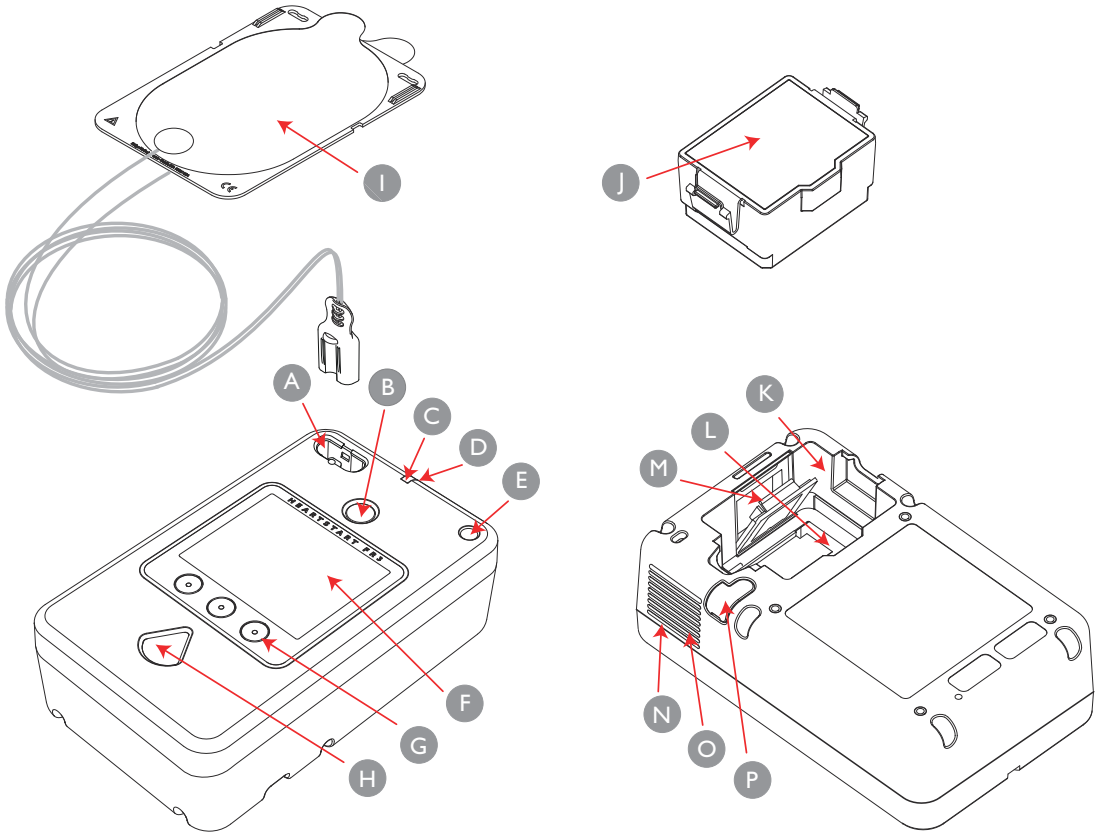


Diagram of the HeartStart FR3 Defibrillator

A **Defibrillator pads connector socket.** Receptacle for the defibrillator pads cable connector. A light on the socket flashes when the FR3 is turned on to show socket location.

B **Green On/Off button.** Turns on the FR3 and starts voice and text prompts. A second press brings up the status screen, and then turns off the FR3.

C **Green Ready light.** Shows the readiness status of the FR3.

D **Microphone.** Used optionally to record audio during an incident.

E **Infant/Child Key port.** Accommodates the optional FR3 Infant/Child Key accessory to enable pediatric treatment protocols for patients under 55 lbs (25 kg) or 8 years old.

F **Screen.** Displays text prompts, graphics, and incident data. The FR3 ECG model also displays the patient's ECG if enabled.

G **Option buttons (three).** When pressed, activates the function identified on the screen.

H **Orange Shock button.** Controls shock delivery. The button flashes when the FR3 is ready to deliver a shock.

I **SMART Pads III.** Self-adhesive pads supplied with attached cable and connector. If using the optional FR3 system case and/or the Pads Sentry, store pads in Pads Sentry and pre-connect pads to FR3 for automatic self-test.

J **Battery.** Long-life battery used to power the FR3.

K **Battery compartment.** Provides electrical connection for the installed battery and contains the data card slot and *Bluetooth*® wireless technology transceiver module compartment.

L **Data card slot.** Receptacle for the optional data card accessory. Located beneath the battery in the battery compartment.

M ***Bluetooth* wireless technology transceiver module compartment.** Accommodates the optional transceiver module accessory. Located behind a removable door in battery compartment.

N **Speaker.** Broadcasts FR3 voice prompts and alert tones when appropriate.

O **Beeper.** Broadcasts FR3 alert chirps when appropriate.

P **Accessory port.** Connection port for future use.

HeartStart FR3

ECG 861389 and Text 861388
Automated External Defibrillator

INSTRUCTIONS FOR ADMINISTRATORS

Edition 3

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%.

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

PHILIPS MEDICAL SYSTEMS

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About this Edition

The information in this guide applies to the HeartStart FR3 ECG model 861389 and FR3 Text model 861388 defibrillators. This information is subject to change. Please contact Philips at www.philips.com/productdocs 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.

Device Tracking

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

Philips Medical Systems, Seattle, WA 98121-1825, USA

Patents

This product is manufactured and sold under one or more of the following United States patents: US5591213, US5601612, US5607454, US5611815, US5617853, US5632280, US5650750, US5735879, US5749905, US5773961, US5776166, US5800460, US5803927, US5836993, US5868792, US5879374, US5889388, US5891046, US5891049, US5899926, US5902249, US5904707, US5951598, US5967817, US6016059, US6075369, US6185458, US6230054, US6234816, US6272385, US6287328, US6299574, US6317635, US6319031, US6350160, US6356785, US6405081, US6417649, US6441582, US6553257, US6556864, US6611708, US6871093, US7079894, and other patents pending.

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For Technical Support

If you need technical support, please contact your local Philips representative or go to www.philips.com/AEDsupport.

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1 INTRODUCTION

DEVICE DESCRIPTION

The HeartStart FR3 Defibrillator (FR3) is a compact, lightweight, battery-powered automated external defibrillator designed for use by trained responders to treat suspected victims of ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs).

The FR3 has a Ready light that flashes to indicate that the FR3 has passed its last self-test and is therefore ready to use. The front panel of the FR3 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, graphics, and incident information. Voice prompts are provided through a speaker located at the base of the FR3. See the diagram on the inside front cover of this manual for details.

The FR3 is available in the FR3 ECG model 861389 and the FR3 Text model 861388. They share a set of basic features, detailed in Chapter 6, "Configuration." The principle differences between the two are identified below:

FR3 ECG Model 861389	FR3 Text Model 861388
Text prompt and configurable ECG display on screen	Text prompt display on screen, no ECG display
Configurable manual charge in advanced mode	No manual charge in advanced mode

NOTE: The FR3 comes with a factory default setup that can be modified under medical direction. For a description of setup defaults and options, see Chapter 6, "Configuration."

INDICATIONS FOR USE

The FR3 is intended for use by trained responders to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). The FR3 is used with disposable defibrillator pads applied to potential victims of SCA with the following symptoms:

- Unresponsiveness
- Absence of normal breathing

If in doubt, apply the pads.

The FR3 is intended for adults and children over 55 lbs (25 kg) or 8 years old. The FR3 is also intended for children under 55 lbs (25 kg) or 8 years old when used with the optional FR3 Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child's age or weight, do not delay treatment. Apply the pads as illustrated for a child and use the defibrillator. For pads placement and details, see Chapter 3, "Application."

WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings for the CPR First feature has not been established in patients under 55 lbs (25 kg) or 8 years old. For more information, see Appendix D, "SMART CPR."

The FR3 is intended for use by responders who have been trained in its operation and in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized emergency medical response program.

For a list of accessories and training products for the FR3 available from Philips, see Appendix A, "Accessories."

PRINCIPLES OF OPERATION

The FR3 is designed to provide external defibrillation therapy to someone experiencing sudden cardiac arrest caused by ventricular fibrillation (VF), the most common cause of SCA, and certain ventricular tachycardias (VTs). The only effective treatment for these non-perfusing arrhythmias is defibrillation. The FR3 treats them by sending a shock across the heart, so it can start beating regularly again.

The FR3 is designed to be easy to use. In its default AED mode, when connected to defibrillator pads that are properly applied to the patient's bare chest, the FR3 prompts you to take specific actions; automatically analyzes the patient's heart rhythm and advises you whether or not the rhythm is shockable; and, if advised by its rhythm analysis algorithm, arms the Shock button and instructs you to press it to deliver a biphasic electric pulse designed to defibrillate the heart.

For detailed instructions for use, see Chapter 3, "Application."

TRAINING AND PRACTICE

The FR3 is intended for use with the oversight of a physician as part of a well-designed emergency response plan. Responders should be trained in operation of the FR3 and in Basic Life Support (BLS), in Advanced Life Support (ALS), or another physician-authorized emergency medical response program. Philips recommends that responders be trained on the device they will be using.

Several national and local organizations offer combined CPR/defibrillator training. Contact your Philips representative, or visit us online at www.philips.com/AEDServices for information, including certified training and web-based refresher training, currently offered in the U.S. only, through Philips HeartStart AED Services.

NOTE: Training accessories are available from Philips for practicing how to use the FR3. For a list of available accessories, see Appendix A, "Accessories."

STATE AND LOCAL REQUIREMENTS

Check with your local health department officials to see if there are any state or local requirements about owning and using a defibrillator.

FOR MORE INFORMATION

If, after reading this manual, you have additional questions about the FR3, contact your local Philips representative. We will be happy to answer any questions you may have.

Technical information about all Philips HeartStart automated external defibrillators, including clinical summaries of several key studies using Philips automated external defibrillators,* is also available online at www.philips.com/productdocs, in the *Technical Reference Manuals* for HeartStart Automated External Defibrillators.

* Clinical summaries also include defibrillators sold as ForeRunner and FR2.

2 SETUP

PACKAGE CONTENTS

Check the contents of the HeartStart FR3 Defibrillator (FR3) box to be sure it contains the following items:

- ✓ 1 HeartStart FR3 Defibrillator
- ✓ 1 FR3 battery
- ✓ 1 set of SMART Pads III
- ✓ 1 *Guide to Setup, Operation, and Maintenance*
- ✓ 1 *Administrator's Reference* CD-ROM

The *Guide to Set-Up, Operation, and Maintenance* provides directions for use of the FR3 with the factory-set default configuration and the FR3 language card. The FR3 language card is supplied with certain versions of the FR3 and is also available separately. Under supervision of the Medical Director, you can use the language card to change the primary language of the FR3. See "Changing the Primary Language Only" on page 6-16 for instructions.

Under supervision of the Medical Director, you can use the HeartStart Configure software, available separately from Philips, to modify the default configuration for FR3 device operation, self-test options, patient care, defibrillation, and advanced mode parameters. HeartStart Configure is also required to enable the FR3 bilingual option and select a secondary language. See Chapter 6, "Configuration."

If you purchased additional accessories, the shipping box will include the items and their indications for use and instructions for use, as appropriate.

NOTE: This chapter provides directions for setting up the FR3. In addition to the battery and pads, the instructions cover the following optional accessories:

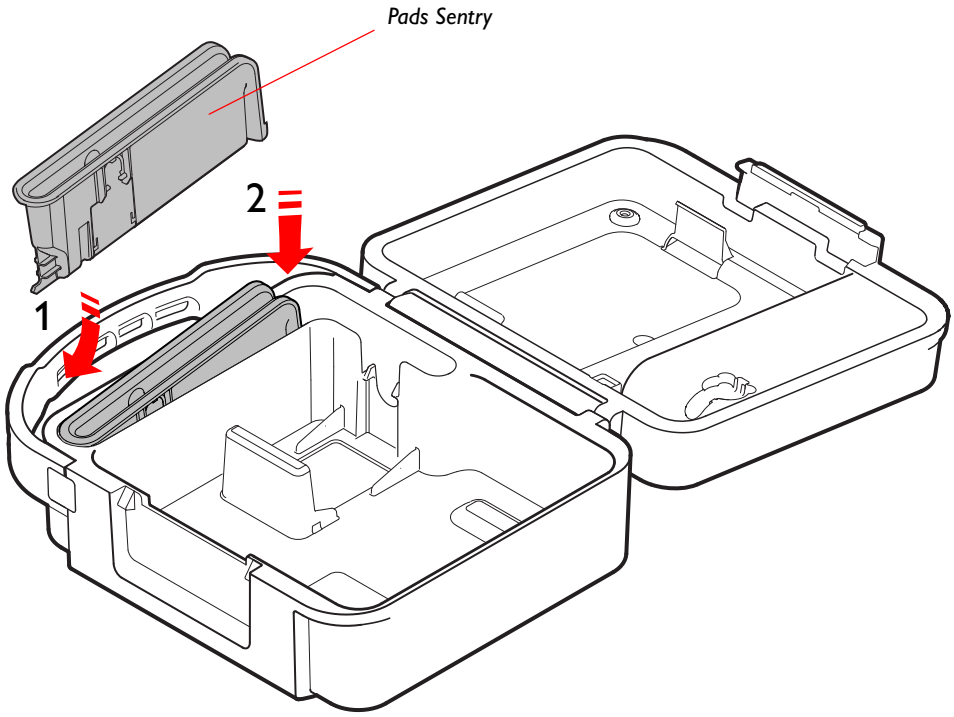
- FR3 rigid system case, including Pads Sentry
- FR3 data card
- *Bluetooth* wireless technology transceiver module
- FR3 Infant/Child Key
- FR3 Fast Response Kit
- Secure pull case seal

For information on ordering accessories, see Appendix A, "Accessories."

ASSEMBLING THE OPTIONAL FR3 RIGID SYSTEM CASE

The FR3 rigid system case* requires some minor assembly prior to use. To assemble the case, following these steps:

1. Remove the system case and its components from packaging and open the system case.
2. If you will be pre-connecting the HeartStart SMART Pads III to the FR3, install the **Pads Sentry** in the case. The Pads Sentry is required for testing the pre-connected pads during the FR3 periodic self-tests.
   - Fit the tab at the closed end of the Pads Sentry into the corresponding socket inside the front of the compartment (1).
   - Then press the open end of the Pads Sentry down into the back of the compartment until it clicks into place (2).

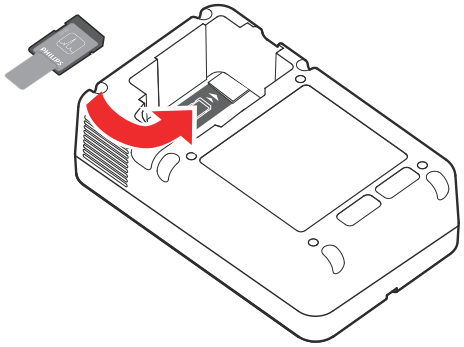


INSTALLING THE OPTIONAL FR3 DATA CARD

You can use the optional FR3 data card to record detailed information about the operation and use of the FR3. For details about how to manage incident data stored on the data card, see Chapter 7, "Data Management."

* Directions and illustrations in this chapter address use of the FR3 rigid system case. The FR3 soft system case and small soft case, described in Appendix A, "Accessories." are shipped with directions for setup and use.

To install the data card in the FR3, follow these steps:

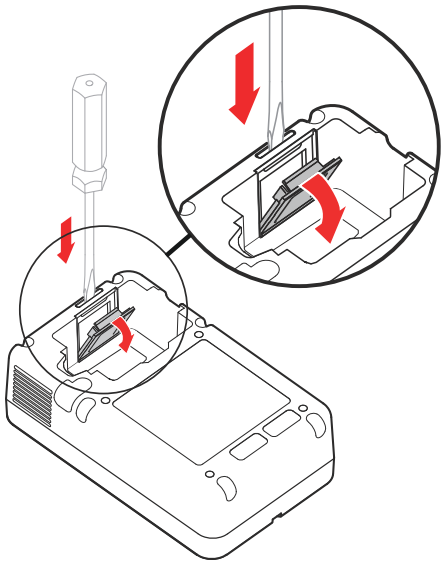


1. Locate the data card slot in the bottom of the battery compartment on the back of the FR3. A label in the battery compartment shows the location of the data card slot.
2. Slide the data card into the data card slot in the direction indicated on the label. A retention clip helps hold the card in the slot. The tail on the data card serves as a visual reminder that a card is installed and aids in card removal.

NOTE: To remove the data card, grasp the card by its tail, press the retention clip away from the card, and pull the card out. See illustration on page 6-17.

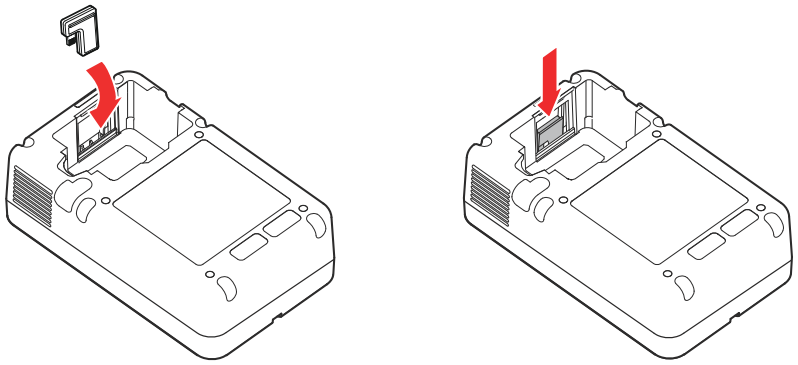
INSTALLING THE OPTIONAL *BLUETOOTH* WIRELESS TECHNOLOGY TRANSCEIVER MODULE

If you have the optional *Bluetooth* wireless technology transceiver module, follow these steps to install it in the FR3:

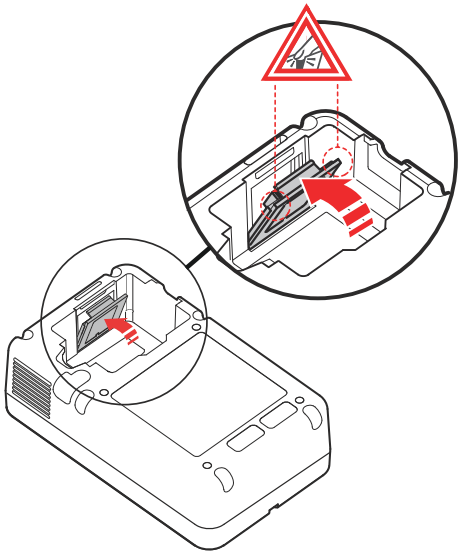


1. Locate the transceiver module compartment in the side of the battery compartment on the back of the FR3.
2. Insert the blade of a flat-head screwdriver or a similar tool (not included) into the slot on the surface of the FR3. Pry open the top of the module compartment cover, then lift out the cover and set it aside.

3. Place the transceiver module inside the compartment and fit it all the way down into the compartment.



4. Place the bottom edge of the module compartment cover in the track at the bottom of the compartment. *Be sure the small tab on the bottom of the cover fits into the track.* Then snap the top in place, being careful not to pinch your finger.



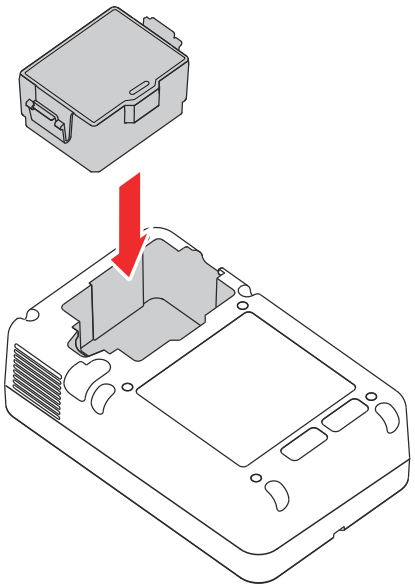
IMPORTANT NOTE: Be sure to reinstall the module compartment cover properly. The cover is part of the water protection seal of the FR3 and *must be flush with the compartment wall.*

INSTALLING THE BATTERY

The FR3 is shipped with an FR3 clinical use standard battery. The battery pack is gray with a latch at each end, designed to hold the battery in place when it is correctly installed in the FR3. To install the battery, follow these steps:

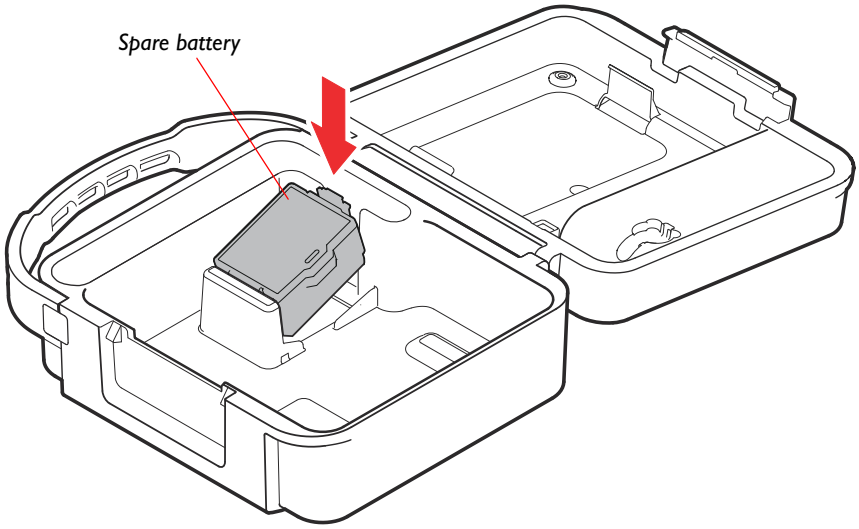
1. Check the battery label to be sure the battery is within its install-by date in order to get the full specified battery life.
2. Remove the battery from its packaging. Keep the battery insert for reference.

3. Insert the battery into the battery compartment on the back of the FR3. Be sure that both the battery's latches click into place.



The first time you set up the FR3, the FR3 automatically runs a detailed user-initiated test as soon as the battery is in place.* Press each button when directed, or the test will fail.

NOTE: Philips recommends that you have a spare battery. If you are using an FR3 system case, store the spare battery in the space provided in the bottom of the case, as illustrated below. Otherwise, keep the spare battery in its packaging.



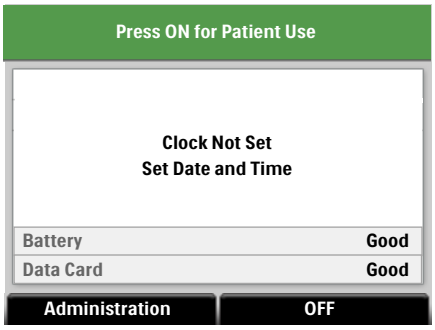
SETTING THE DATE AND TIME

The date format of the FR3 is the year in four digits, followed by the name of the month, then the day in two digits. For example: 2010 February 17. The time format uses a 24-hour clock and shows two digits each for the hour, minute, and second. For example: 18:05:54.

* For details, see "User-Initiated Test" on page 4-7

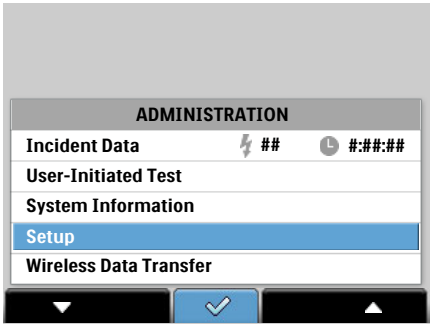
The first time you set up the FR3, it automatically runs a user-initiated test when the battery is inserted. When the test is complete, the FR3 displays a reminder that the clock is not set and a prompt to set the date and time. To check the clock and modify it, if needed, to match local date and time, follow these steps.

1. When the FR3 displays the CLOCK NOT SET message, press the ADMINISTRATION option button to go to the ADMINISTRATION screen.*

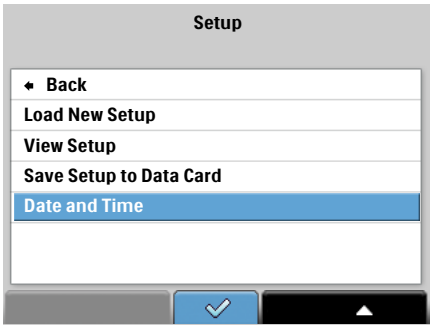


NOTE: If you do not press the option button within 20 seconds, the FR3 shuts down and goes into standby.

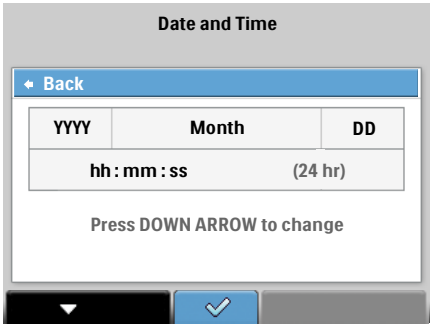
2. On the ADMINISTRATION screen, press the ▼ option button to scroll to SETUP, then press the ✓ option button to select it.



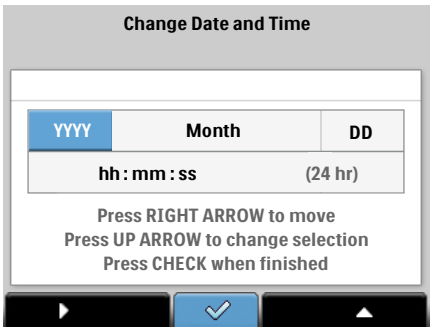
3. On the SETUP screen, press the ▼ option button to scroll to DATE AND TIME, then press the ✓ option button to select it.



4. On the DATE AND TIME screen, press the ▼ option button to stop the automatic time incrementing and display the CHANGE DATE AND TIME screen.



* If the FR3 is already in standby, press the green On/Off button to turn on the FR3. When voice prompts begin, press the button again to display the status screen.



5. The year element of the date is highlighted when you first activate the CHANGE DATE AND TIME screen. To modify the year, press the ▲ option button until the correct value is displayed.*
6. Press the ▶ option button to move the highlight bar to the next element in the date or time. Press the ▲ option button to display the next value for a highlighted element. *Do not press the ✓ option button until you have made all modifications needed, or the process will have to be repeated.*
7. When you see the correct entry for the highlighted element, press the ▶ option button to move to the next element of the date and time. Repeat steps 6 and 7 for each element of the date and time you want to modify.
8. When you have completed all the changes needed, press the ✓ option button to accept the new date and time settings. The FR3 then displays the revised DATE AND TIME screen, with BACK highlighted.
9. Press the ✓ option button to exit the screen, then press the On/Off button to display the status screen and let the FR3 go into standby. The green Ready should be flashing to show that the FR3 is ready for use.

NOTE: To set the date and time using HeartStart Configure and wireless technology, see "Using HeartStart Configure and Wireless Transmission" on page 6-12.

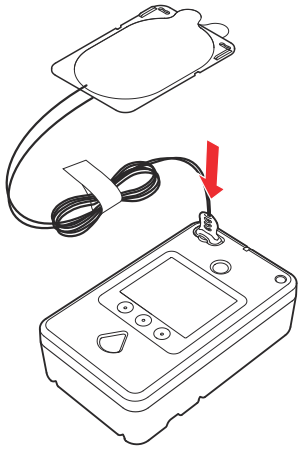
CONNECTING THE PADS

If you are NOT using an optional FR3 case with Pads Sentry, do not pre-connect the pads. Store the SMART Pads III in their unopened package with the FR3 defibrillator and ensure that the pads are protected from damage. *If you ARE using an FR3 case*, connect the SMART Pads III to the FR3 as follows:

1. Check the expiration date on the pads package.

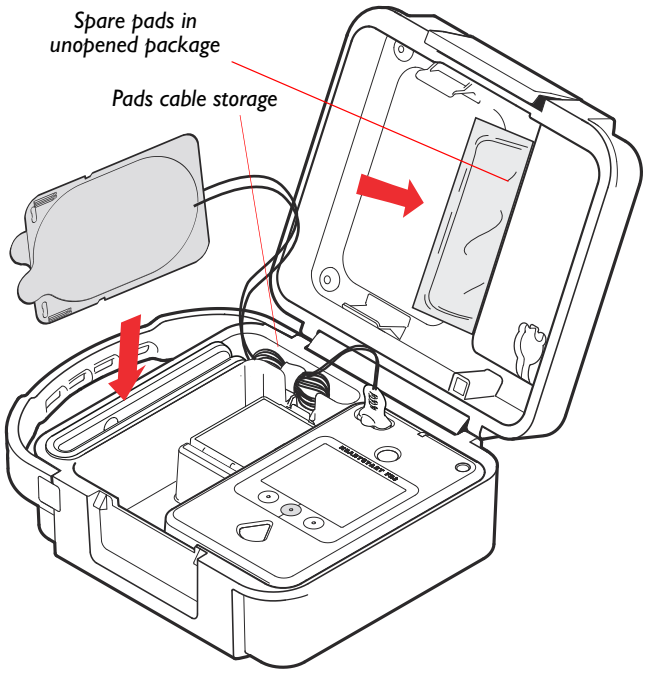
* If you pass the year you wish to select, continue to press the ▲ option button to scroll through the range of years (2000 through 2039) until the correct year is displayed again.

2. Open the SMART Pads III package and take out the pads, *leaving them on their liner*. Leave the paper wrap on the coiled cable; it will tear off when you extend the cable to use the pads.



WARNING: Do not peel the pads from the liner until they are needed for use in an emergency.*

3. Insert the pads connector plug firmly into the pads connector socket.
4. Check that the Pads Sentry has been installed in the FR3 system case. See page 2-2 for directions on installing the Pads Sentry in the case.
5. Keep the pads on their liner and insert them firmly in the Pads Sentry. The Pads Sentry shields the pads and provides a mechanism that allows the pads to be tested during each FR3 self-test. If pre-connected pads are not installed in the Pads Sentry, the FR3 will fail its self-test. Place the coiled pad cables into the compartment provided in the case.



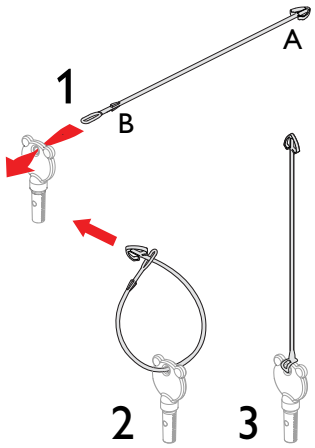
* Peeling any part of the pads from the liner breaks the protective seal and allows the pads adhesive to dry out. If this happens, the pads will fail the FR3 self-test.

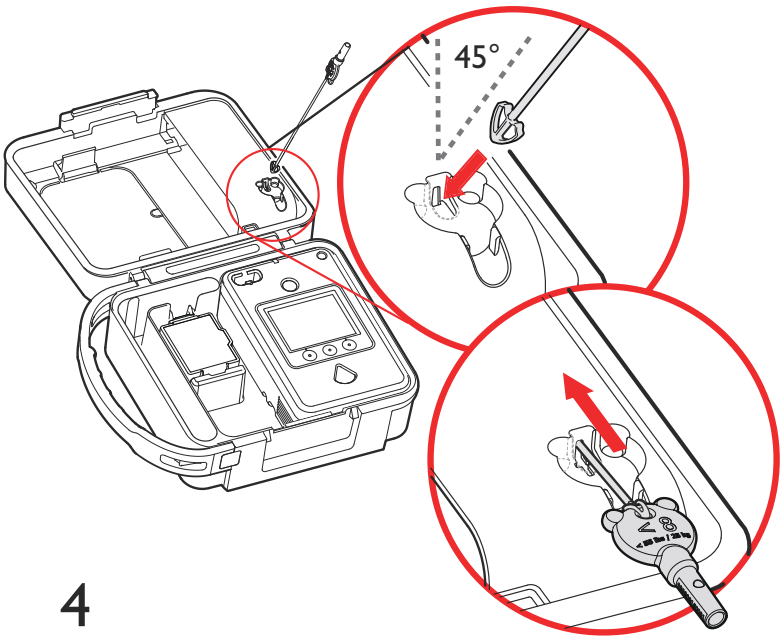
NOTE: Philips recommends that you have a spare set of pads. If you have a spare set of SMART Pads III — or are using other compatible pads that should not be pre-connected to the FR3 — do not open the pads package. Store the unopened package in the spare pads compartment in the upper lid of the FR3 system case. See "Other Compatible Defibrillator Pads" on page G-8 for a list of compatible pads.

STORING THE OPTIONAL INFANT/CHILD KEY

The optional FR3 Infant/Child Key is supplied with a tether cable designed to secure the Key to an FR3 system case, if used. *The tether is not required* for use of the Infant/Child Key. To use the tether, follow these steps:

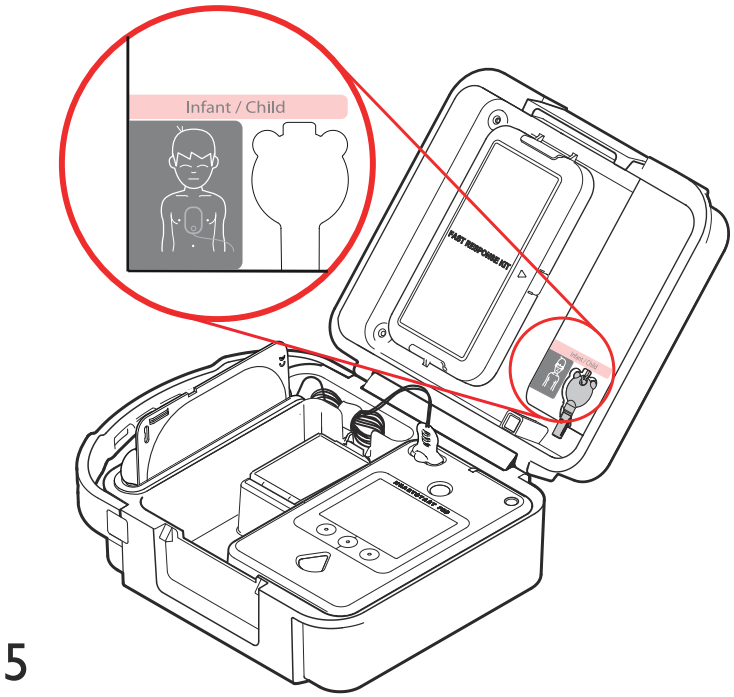
1. Insert the tether through the hole in the top of the Infant/Child Key.
2. Thread the "winged" end of the tether (A) through the single hole in its other end (B).
3. Straighten out the tether and tighten the loop around the Key.
4. Insert the "winged" end of the tether into the slot inside the Infant/Child Key compartment in the upper lid of the case at a 45° angle. Feed the tether into the slot, then snap the Key into the compartment.





NOTE: Do not install the FR3 Infant/Child Key in the FR3 defibrillator except when it is needed for use in an emergency. If the Key is left installed when the FR3 goes into standby, the next FR3 self-test will fail.

5. For increased visibility of the Infant/Child Key, Philips recommends that you label the Infant/Child Key compartment in the FR3 case, as illustrated below, with the appropriate language(s) from the set of decals provided with the Key. The decal is designed to permit labeling in two languages for situations in which the FR3 is configured for bilingual operation.



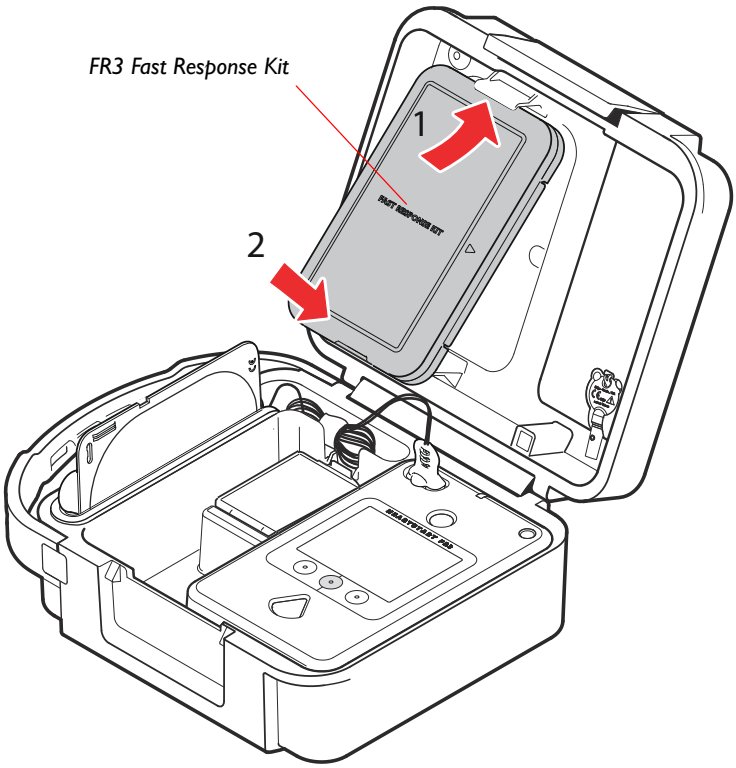
5

STORING THE OPTIONAL FAST RESPONSE KIT

The optional FR3 Fast Response Kit contains a pair of paramedics scissors, two pairs of gloves, a disposable razor, a pocket mask, and an absorbent wipe, housed in a hard plastic storage case. The FR3 rigid system case — but not the FR3 soft system case* — is designed to hold the Fast Response Kit. If you have the Fast Response Kit and are using the FR3 rigid system case, follow these steps:

1. Remove the FR3 Fast Response Kit from its packaging and check the contents.
2. Close the Fast Response Kit and slide it under the top clip in the upper case insert, then press it down into the lower clip, as illustrated below.

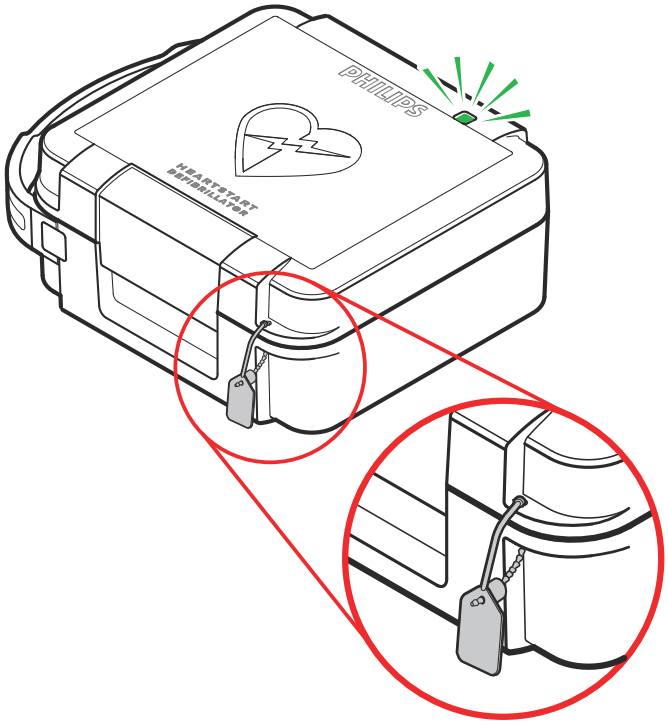
* The zippered pouch version of the Fast Response Kit can be attached to the outside of the soft system case.



PLACING AND SECURING THE FR3

IMPORTANT NOTE: To ensure that the FR3 is ready for use when needed, store it *with the battery installed and the SMART Pads III connected* and installed in the Pads Sentry. Store spare battery and pads, if available, in the case. Do not remove the battery unless the FR3 self-tests indicate that it should be replaced or to access an installed data card.

Place the FR3 in an accessible area where the green Ready light is easily visible and the FR3 alert chirps can be heard. Philips recommends that the defibrillator and pads be secured in a protective carry case, such as the FR3 system case.



If desired, thread an optional secure-pull case seal through the holes in the corner of the case and trim the lanyard if desired, as shown above, to help prevent tampering,

To facilitate visibility and rapid deployment, the FR3 system case is designed for use with a Philips wall-mount bracket or defibrillator cabinet. For information on available brackets and cabinets, see Appendix A, "Accessories."

With the battery installed and the FR3 stored under specified environmental conditions,* the FR3 performs detailed daily, weekly, and monthly self-tests to check its readiness for use. For descriptions of these periodic self-tests, see Chapter 4, "Maintenance, Testing, and Troubleshooting."

While the FR3 is in standby, the green Ready light flashes unless the periodic self-test detects a problem. If a problem is detected, the Ready light turns off and the FR3 gives alert chirps. For troubleshooting instructions, see Chapter 4, "Maintenance, Testing, and Troubleshooting."

* For environmental specifications, see Appendix G, "Environmental."

RECOMMENDED ACCESSORIES

It is always a good idea to have a spare battery and a spare pads set. Other things that are useful to keep with the FR3 include the following*:

- Scissors — to cut the victim's clothes if necessary
- Disposable gloves — to protect the user
- A disposable razor — to shave the chest if hair prevents good pads contact
- A pocket mask or face shield — to protect the user during CPR ventilations
- A towel or absorbent wipes — to dry the victim's skin for good pads contact

For a list of accessories and training products for the FR3 available from Philips, see Appendix A, "Accessories."

* All items listed are included in the FR3 Fast Response Kit.

3 APPLICATION

The instructions on the following pages are based on factory-set default configuration settings for the HeartStart FR3 Defibrillator (FR3). See Chapter 5, "Safety," for information on safety considerations in using the FR3.

NOTE: Except where otherwise noted, the information in the following pages applies to both the FR3 ECG model 861389 and the FR3 Text model 861388.

BASIC DIRECTIONS

When you need to use the FR3 in an emergency, deploy it as follows:

1. TURN ON THE FR3. Press the green On/Off button.

NOTE: If you store the defibrillator in a HeartStart FR3 rigid system case, the FR3 automatically turns on when you open the case lid. If for any reason the FR3 does not turn on automatically, or if you do not use an FR3 case, press the green On/Off button to turn on the FR3.



2. FOLLOW THE VOICE AND TEXT PROMPTS. The FR3 directs you in each step of using it to treat a suspected victim of SCA.
3. If prompted by the FR3, PRESS THE SHOCK BUTTON to deliver a shock.



DETAILED DIRECTIONS

1. TURN ON THE FR3

If you store the defibrillator in an FR3 system case, the FR3 automatically turns on when you open the lid. Otherwise, press the green On/Off button.

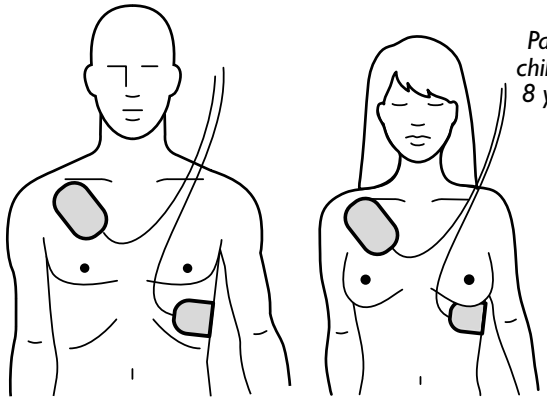
- If the victim is an infant or a child under 55 lbs (25 kg) or 8 years old, insert the optional FR3 Infant/Child Key in the Infant/Child Key port on the FR3. If the Infant/Child Key is not available or if you do not know the child's exact age or weight, do not delay treatment. Use the FR3 without the Infant/Child Key. For details, see "Treating Infants and Children" on page 3-4.
- If the pads are not preconnected, open the pads pouch, remove the pads, and plug the pads connector into the connector socket of the FR3.

2. FOLLOW THE VOICE AND TEXT PROMPTS

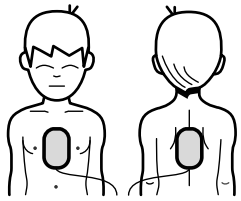
The FR3 directs you in each step of using it to treat a suspected victim of SCA.*

- Remove clothing from the patient's upper body. If needed, wipe moisture from the patient's skin and clip or shave excessive chest hair.
- Apply the pads to the patient's bare chest as shown below.

Pad placement for adults and children over 55 lbs (25 kg) or 8 years old (anterior-anterior).



Pad placement for infants and children under 55 lbs (25 kg) or 8 years old (anterior-posterior).



- As soon as the pads are attached to the patient, the FR3 begins analysis of the patient's heart rhythm. The FR3 instructs you to stay clear of the patient. Do not touch the patient.
- *If no shock is advised,* the FR3 gives No Shock Advised (NSA) voice and text prompts and provides an attend-to-patient period.
- *If a shock is advised,* the FR3 charges to prepare for shock delivery. It gives the voice and text prompts to tell you that a shock is advised.

* Users familiar with the FR3 need not wait for prompts to place pads. The FR3 senses pads contact and will automatically go to the next appropriate prompt.

3. IF PROMPTED BY THE FR3, PRESS THE SHOCK BUTTON TO DELIVER A SHOCK

- First, make sure that no one is touching the patient or the pads. While the FR3 is charging, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer appropriate, the FR3 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 now.
  - You see the orange Shock button flashing.
  - You see a text prompt telling you to press the orange (Shock) button.
  - You hear a steady tone from the FR3.
- As soon as you are prompted, check to be sure no one is touching the patient, and press the Shock button to deliver the shock.

  NOTE: If you do not press the Shock button within 30 seconds of being prompted, the FR3 disarms and provides an attend-to-patient period and an Analyze option button. It resumes analyzing heart rhythm after 30 seconds or when the Analyze option button is pressed.

  NOTE: You cannot turn off the FR3 while it is prompting you to deliver a shock.*
- After you press the Shock button, a voice prompt tells you the shock was delivered. Then the FR3 provides a configured CPR protocol.
- Perform CPR for the entire duration of the CPR protocol, until you hear the voice prompt telling you to stop CPR. Following the protocol, the FR3 conducts rhythm analysis. Do not touch the patient during rhythm analysis.

IMPORTANT NOTE: After completing use of the FR3, be sure to replace the pads. If you are using pre-connected pads, insert the pads connectors in the connector socket and install the pads in the Pads Sentry as described on page 2-11. Otherwise, if the FR3 is configured to test for the presence of pads, it will fail its next periodic self-test (see page 4-6).

* If you press the On/Off button when the FR3 has advised a shock and instructed you to press the flashing orange Shock button, a voice prompt tells you "Press the flashing orange button now or device will disarm."

TREATING INFANTS AND CHILDREN

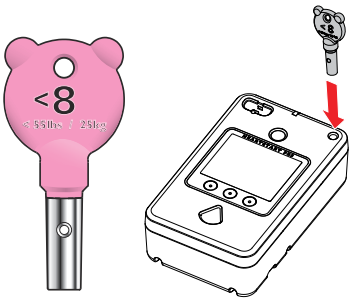
WARNING: Most cardiac arrests in children are not caused by heart problems. When responding to cardiac arrest in an infant or child:

- Provide infant/child CPR while a bystander calls EMS and brings the FR3.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the FR3.
- If you witnessed the child's collapse, call EMS *immediately* and *then* get the FR3.

Alternatively, follow your local protocol.

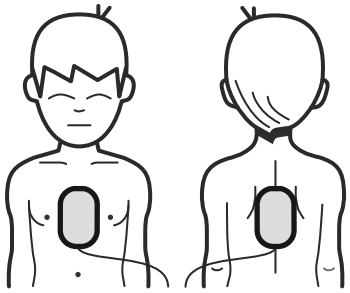
If the victim is under 55 lbs (25 kg) or 8 years old, and you have an FR3 Infant/Child Key:

- Insert the Infant/Child Key firmly into the port at the top right of the front panel of the FR3.



NOTE: If the Infant/Child Key tether pulls out of the system case during use, do not take time to reinstall it. The Key will work without it.

- Turn on the FR3 and follow instructions to remove all clothing from the torso, to bare both the chest and the back.
- Place one pad in the center of the chest between the nipples, and the other in the center of the back (anterior-posterior). It does not matter which pad is placed on the chest or the back.



NOTE: It does not matter whether you insert the Infant/Child Key before or immediately after turning on the FR3. Preferably, however, the Key should be inserted before placing the pads on the patient, for accurate pads placement directions.

When the Infant/Child Key is inserted, the FR3 announces "Infant/Child Mode" and provides directions on how to place the pads. The FR3 automatically reduces the defibrillation therapy to a level* more appropriate for infants and children.

* The Infant/Child Key should not be used when treating an adult because the lower therapy level may not be effective.

If the victim is under 55 lbs (25 kg) or 8 years old, but you do NOT have an Infant/Child Key:

- DO NOT DELAY TREATMENT.
- Turn on the FR3 and follow instructions. Remove all clothing from the torso, to bare both the chest and the back.
- Place one pad in the center of the chest between the nipples, and the other in the center of the back (anterior-posterior).

If the victim is over 55 lbs (25 kg) or 8 years old, or if you are not sure of the exact weight or age:

- DO NOT DELAY TREATMENT.
- Turn on the FR3 without inserting the Key and follow instructions. Remove all clothing from the chest.
- Place the pads as illustrated on each pad (anterior-anterior). Make sure the pads do not overlap or touch each other.

IMPORTANT NOTE: After completing use of the FR3, be sure to remove the infant/child key. If the Key is left installed in the FR3, it will fail its next periodic self-test (see page 2-9).

4 MAINTENANCE, TESTING, AND TROUBLESHOOTING

MAINTENANCE

Maintenance of the HeartStart FR3 Defibrillator (FR3) is very simple, but it is a very important factor in its dependability. When in standby (i.e., the battery is installed), the FR3 performs many maintenance activities itself. These include daily, weekly, and monthly self-tests of respectively increasing detail to verify readiness for use. In addition, each time the FR3 is turned on, it executes a power-on self-test. You can also run a detailed user-initiated test when desired. These tests are described beginning on page 4-6. The FR3 also checks its performance while it is in use.

The FR3 requires no calibration or external verification of defibrillation therapy delivery. The FR3 has no user-serviceable parts.

CAUTION: Improper maintenance may damage the FR3 or cause it to function improperly. Maintain the FR3 only as described in these *Instructions for Administrators* or as designated by your program's Medical Director.

CAUTION: Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the FR3, remove its covers, or attempt repair. There are no user-serviceable components in the FR3. The FR3 should be returned to Philips for repair.

ROUTINE MAINTENANCE

The following table presents a sample maintenance schedule for the FR3. Different frequency intervals may be appropriate, depending upon the environment in which the FR3 is used. The required maintenance frequency is at the discretion of the program's Medical Director.

NOTE: Philips recommends that you keep a log of device maintenance activities. The Operator's Checklist provides a convenient place to note results, remarks, and corrective actions. (See page 4-5.) If a trend is noted - for example, repeated instances of clearable self-test failures - please check your operating environment for elements that might exceed the AED specifications. Should the issue continue, contact Philips for support.

PHILIPS MEDICAL SYSTEMS

DAILY	MONTHLY	MAINTENANCE TASK/RESPONSE
✓		Check the Ready light. • If the green Ready light is flashing: The FR3 has passed its last self-test and is ready to use. No action required. • If the green Ready light is off and the FR3 is continuously chirping: The FR3 needs attention. If it is giving single chirps, press the On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen for information about the status of the FR3 and how to resolve the problem. • If the FR3 is giving triple chirps, press the On/Off button to start the FR3. The FR3 will display the status screen for the error message. Record the error, turn off the FR3, and remove it from service. Then contact Philips at www.philips.com/AEDSupport for technical support. • If the green Ready light is off but the FR3 is not chirping and the display screen is blank: There is no battery inserted, the battery is depleted, or the defibrillator needs repair. Insert/replace battery and let it run the power-on self-test. If the FR3 passes the self-test, it is ready for use.
	✓	• Check supplies, accessories, and spares for damage and expiration dating. Do not use damaged or expired accessories. Replace them immediately. • If the green Ready light is off and the FR3 is giving single chirps: Press the On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen. If a REPLACE BATTERY message is displayed: Replace the battery and run the self-test. If a REPLACE PADS message is displayed: Replace the pads and run the self-test. • If the FR3 is giving triple chirps, press the On/Off button to start the FR3. The FR3 will display the status screen for the error message. Record the error, turn off the FR3, and remove it from service. Then contact Philips at www.philips.com/AEDSupport for technical support.
	✓	• Check the outside of the FR3 and the connector socket for cracks or other signs of damage. • If you see signs of damage: Contact Philips at www.philips.com/AEDSupport for technical support.

AFTER EACH USE

After each use of the FR3, perform the following post-use checks before returning the FR3 to service:

- Remove the battery to check the FR3 data card if one is installed. Follow your local guidelines and medical protocol to download incident data from the FR3 data card if one is installed. See "Reviewing Data from an FR3 Data Card" on page 7-4 for directions.
- To ensure that data is not lost due to a full data card, Philips recommends that you replace a used FR3 data card with a blank FR3 data card after each use.
- Install a new set of pads. If using the Pads Sentry, pre-connect the new set of HeartStart SMART Pads III.* Install the pads, on their liner, in the Pads Sentry. Otherwise, store the unopened set of pads with the FR3.
- Check the outside of the FR3 and the connector socket for signs of dirt or contamination. If the FR3 is dirty or contaminated, clean it as directed. See "Cleaning," below.
- Run a user-initiated test. See "User-Initiated Test" on page 4-7, for directions. Note any messages on the status screen prior to shut down.

* See "Other Compatible Defibrillator Pads" on page G-8 for a list of other pads that are compatible with the FR3.

CLEANING

The outside of the FR3, including the pads connector socket, can be cleaned as described below.

- Make sure a battery is installed when cleaning the FR3, to keep fluids out of the device.
- Clean the FR3 and the connector socket with a soft cloth dampened with one of the cleaning agents listed below:
  - Isopropyl alcohol (70% solution in water)
  - Ammonia-based cleaners
  - Mild soap and water
  - Sodium hypochlorite (chlorine bleach 3% solution in water)
  - 70% ethanol

  Do not use abrasive materials, cleaners, strong solvents such as acetone or acetone-based cleaners, or enzymatic cleaners.

CAUTION: Do not immerse any portion of the FR3 in water or other fluids. Do not allow fluids to enter the FR3. Avoid spilling any fluids on the FR3 or accessories. Spilling fluids into the FR3 may damage it or present a fire or shock hazard. Do not sterilize the FR3 or accessories.

OPERATOR'S CHECKLIST

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

OPERATOR'S CHECKLIST

HeartStart FR3 Model No.: _____ Serial No.: _____

HeartStart FR3 Location or Vehicle ID: _____

DATE							
SCHEDULED FREQUENCY							
FR3 Clean, no dirt or contamination; no signs of damage							
SUPPLIES AVAILABLE • One set of defibrillator pads installed, undamaged, within expiration date • One spare set of defibrillator pads in packaging, within expiration date • Ancillary supplies (hand towel, scissors, razor, pocket mask, gloves) • Spare 989803150161 battery, within "Install Before" date • Data card 989803150061 installed, undamaged							
READY LIGHT flashing green; self-test passed.							
INSPECTED BY Signature or initials of operator completing the maintenance inspection							
REMARKS, PROBLEMS, CORRECTIVE ACTIONS							

TESTING

The FR3 has several ways of testing itself and alerting you if it finds a problem. A power-on self-test is performed each time the FR3 is turned on, and the FR3 runs a detailed user-initiated test under conditions described on page 4-7. In addition, the FR3 automatically monitors its performance during a use and automatically performs periodic self-tests while in standby mode. These include daily, weekly, and monthly self-tests of respectively increasing detail to verify readiness for use.

NOTE: The FR3 self-tests are designed to check that the FR3 is ready for use. However, in the event that the FR3 has been dropped or mishandled, Philips recommends that you run a user-initiated test. If the FR3 has visible signs of damage, contact Philips at www.philips.com/AEDSupport for technical support.

PERIODIC SELF-TESTS

When the FR3 is in standby (with a good battery installed), it automatically runs periodic self-tests at least once every 24 hours and two hours after being turned off or after a battery is installed. These self-tests are designed to detect and alert you to any error condition in the battery or operation of the FR3.

NOTE: While a self-test is running, the green Ready light is on steady, and the display is dark. If you press the On/Off button or open your FR3 system case with an installed FR3 during a self-test, the FR3 automatically aborts the self-test and turns on for use.

The FR3 self-test also includes testing of the following optional accessories, if they are attached to the device:

- Pre-connected HeartStart SMART Pads III in Pads Sentry
- Data card

If the FR3 is specifically configured to include any of these accessories as part of its periodic self-tests but that accessory is not attached at the time of self-test, the test will result in an error message. For self-test configuration, see Chapter 6, "Configuration."

If the FR3 detects that an Infant/Child Key is installed during a self-test, the test results in an error and the FR3 gives single alert chirps.

If the self-test determines that the FR3 is out of the specified temperature range, the FR3 aborts and reschedules the self-test. If three self-tests in a row are aborted because the FR3 is being stored in temperatures out of range, the device gives single alert chirps. See "Troubleshooting Guide," later in this chapter.

If the FR3 detects a problem during a periodic self-test and the battery is subsequently removed and reinstalled, the FR3 automatically prompts you to run a user-initiated test, as described below.

When the periodic self-test is complete, the FR3 updates the status in its internal memory and returns to standby. If the self-test has passed, the green Ready light resumes flashing and the FR3 is ready for use. If any part of the self-test fails, the FR3 chirps to alert you that it needs attention and the Ready light goes off (i.e., does not illuminate or flash). Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.

USER-INITIATED TEST

The first time you set up the FR3, the FR3 automatically runs a user-initiated self-test as soon as the battery is in place.* This detailed test will also run automatically anytime the battery is installed after having been out of the FR3 for a long enough that the clock time has been lost. This can range from 2 to 24 hours.

In addition, the FR3 automatically runs the user-initiated test if the FR3 has a failure condition when the battery is installed or when the last time it was turned on was to complete language and/or configuration loading.

Philips recommends you initiate the test after each use of the device. The FR3 prompts you to run the test if it detects a problem during routine self-testing.

NOTE: Do not connect or disconnect any accessories, such as the pads or Infant/Child Key, during the user-initiated test.

You can also run the test at any time. However, as long as the green Ready light is flashing and the FR3 is not chirping, it is NOT necessary to test the defibrillator by initiating a test. This uses battery power and drains the battery prematurely.

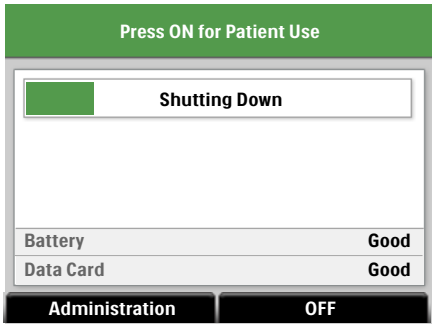
To run the user-initiated test, make sure that the battery is installed and, if an FR3 system case is used and the pads are pre-connected, that the pads are in the Pads Sentry. Make sure a data card is installed if you want to record the test results. Then follow these steps:

IMPORTANT NOTE: Do not remove the battery during the user-initiated test. To abort the test, press the On/Off button to turn off the device.

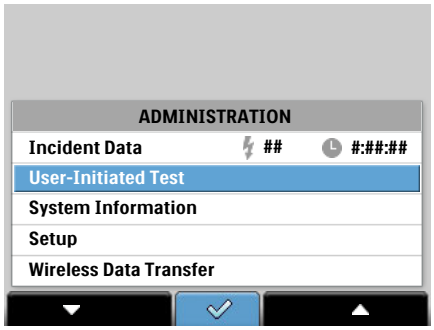
* This is the FR3 user-initiated equivalent of the automatic battery insertion test (BIT) used for HeartStart ForeRunner and FR2 defibrillators.

1. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.

2. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button.



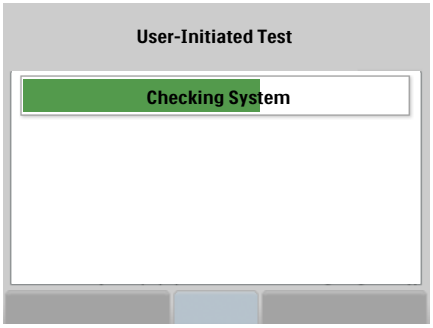
3. On the ADMINISTRATION screen, press the ▼ option button to scroll to USER-INITIATED TEST, then press the ✓ option button to select it. The FR3 gives a tone and begins the test.



4. Follow the instructions on the screen. The first part of the test is interactive. Follow the prompts to press each button when instructed, or the test will fail. Then listen for two audio tones. If you do not hear the tones, there is a problem with the speaker or the beeper. Contact Philips at www.philips.com/AEDSupport for technical support.

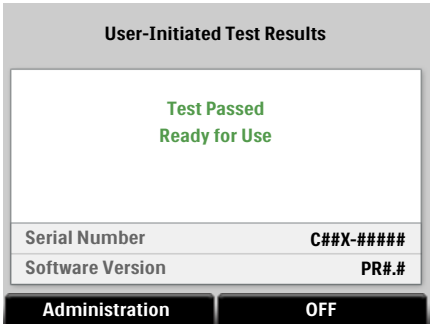


5. The second part of the test is automatic. During the automatic part of the test, the screen displays a progress bar indicating the test's progress.



* If you do not make a selection while the status screen is displayed, the FR3 does not complete the test and goes into standby to be ready for use.

6. When the test is complete, the FR3 displays the results of the test, the device serial number, and the software version, then displays the ADMINISTRATION screen again.



7. Press the On/Off button to display the status screen and put the defibrillator into standby.

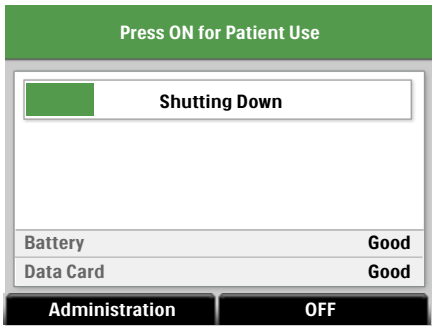
8. If the FR3 or any attached accessory fails the self-test for any reason, the screen displays information about the failure. See "Troubleshooting Guide" on page 4-14.

9. If the FR3 passes the test, the green Ready light flashes to show that the FR3 is ready for use.

DEVICE HISTORY

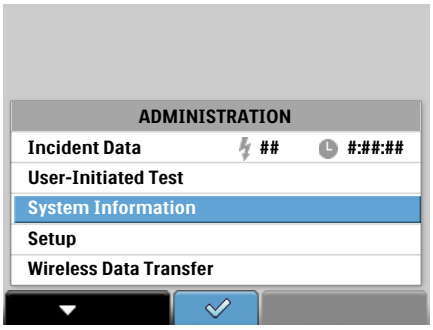
The FR3 stores key information about its history in internal memory. To review the history of your FR3, follow these steps:

1. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.



2. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

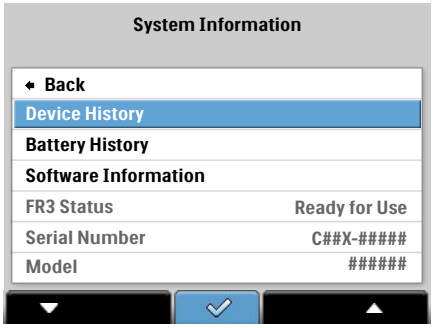
3. Press the ▼ option button to scroll to SYSTEM INFORMATION, then press the ✓ option button to select it.†



* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

† The Wireless Data Transfer option does not appear on the screen unless the optional *Bluetooth* wireless technology transceiver module is installed in the FR3.

4. The SYSTEM INFORMATION screen displays device model number, serial numbers, and device status (Ready for Use, Test Failed, or Service Required). It also provides access to the DEVICE HISTORY, BATTERY HISTORY, and SOFTWARE INFORMATION screens. Press the ▼ option button to scroll to DEVICE HISTORY, then press the ✓ option button to select it.

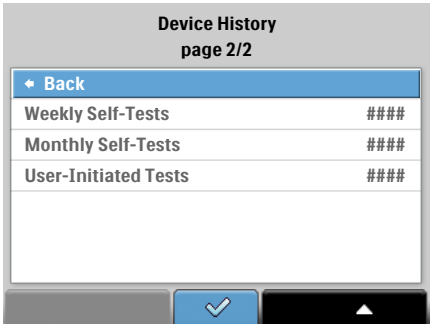


5. The DEVICE HISTORY screens display detailed information about the history of your FR3. The first screen displays the following information for review:



   - Therapy Uses — how many times the FR3 has been turned on and pads applied
   - Therapy Time — the total time in hours and minutes (hh:mm) the FR3 has been used with pads applied
   - Shocks Delivered — the total number of shocks the FR3 has delivered
   - Training Uses — the total number of times the FR3 training battery has been installed to activate training*
   - Training Time — the total time in hours and minutes (hh:mm) the FR3 has been used with a training battery
   - Daily Self-Tests — the total number of daily self-tests the FR3 has run

6. Press the ▼ option button to scroll to the second DEVICE HISTORY screen. This screen displays the following information for review:



   - Weekly Self-Tests — the total number of weekly self-tests the FR3 has run

* If the training battery is not removed after 30 minutes of inactivity, the FR3 will go into training standby mode and begin giving alert chirps. It will count the next device activation as well as any periodic self-tests that occur during training standby as Training Uses. This will inflate the number of Training Uses displayed on the DEVICE HISTORY screen.

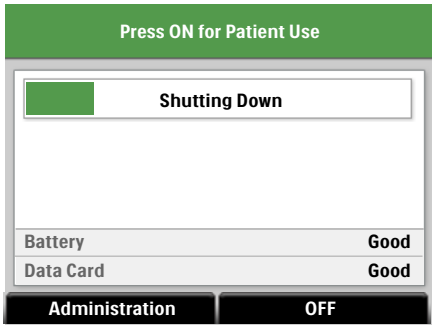
- Monthly Self-Tests — the number of monthly self-tests the FR3 has run
- User-Initiated Tests — the total number of user-initiated tests of the FR3 that have been run

7. If you have other administrative tasks to perform, press the ✓ option button to return to the first DEVICE HISTORY screen, then press the ✓ option button on that screen to return to the SYSTEM INFORMATION screen, then press the ✓ option button on that screen to return to the ADMINISTRATION screen.

BATTERY HISTORY

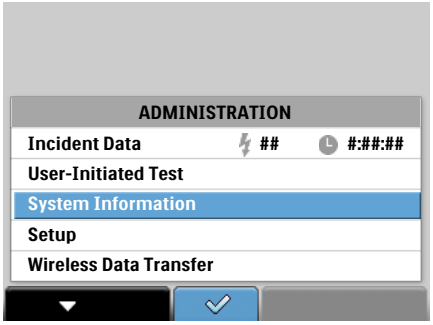
Information about use of the battery currently installed in your FR3 is also available. To review the history of the battery, follow these steps:

1. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.



2. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

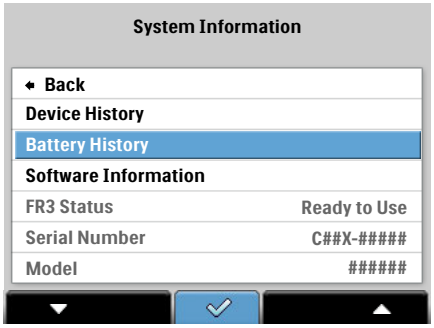
3. Press the ▼ option button to scroll to SYSTEM INFORMATION, then press the ✓ option button to select it.†



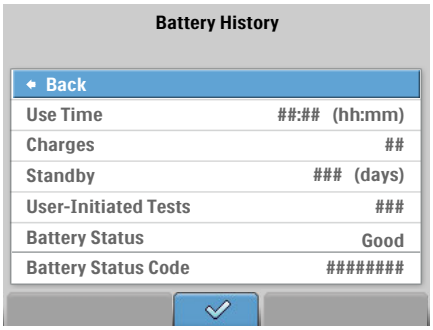
* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

† The Wireless Data Transfer option does not appear on the screen unless the optional *Bluetooth* wireless technology transceiver module is installed in the FR3.

4. The SYSTEM INFORMATION screen displays device serial number and status (Ready for Use, Test Failed, or Service Required) and provides access to the DEVICE HISTORY, BATTERY HISTORY, and SOFTWARE INFORMATION screens. Press the ▼ option button to scroll to BATTERY HISTORY, then press the ✓ option button to select it.



5. The BATTERY HISTORY screen displays the following information about the history of the battery currently installed in your FR3:



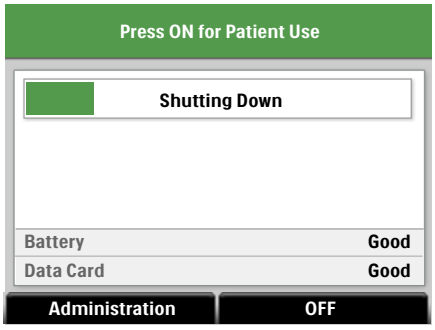
   - Use Time — the total operating time in hours and minutes (hh:mm), including self-test time, for this battery
   - Charges — the total number of full defibrillation charges that have been provided by this battery, including self-test and user-initiated test charges.
   - Standby Time — the total number of days the installed battery has been in standby
   - User-Initiated Tests — the total number of user-initiated tests that have been run using this battery
   - Battery Status — the status of the battery (Good, Replace, or Unrecognized)
   - Battery Status Code — for use by Philips technical support

6. If you have other administrative tasks to perform, press the ✓ option button to exit the screen and return to the SYSTEM INFORMATION screen, then press the ✓ option button on that screen to return to the ADMINISTRATION screen. Otherwise, press the On/Off button to display the status screen and put the FR3 into standby.

SOFTWARE INFORMATION

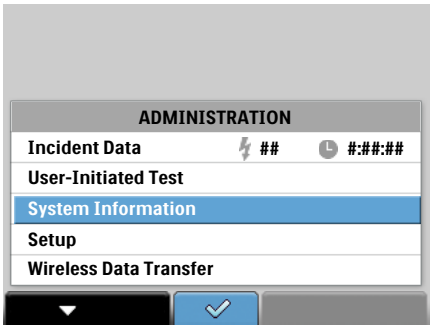
Information about the software currently installed in your FR3 is available in FR3 internal memory. You will only need to access this screen when requested by Philips technical support personnel. When requested, follow these steps:

1. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.

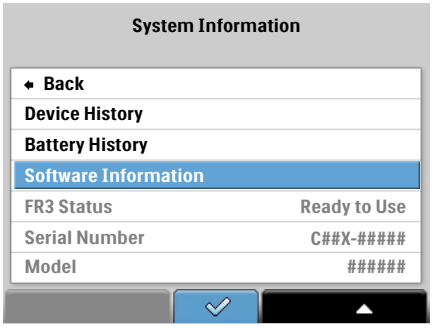


2. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

3. Press the ▼ option button to scroll to SYSTEM INFORMATION, then press the ✓ option button to select it.†



4. The SYSTEM INFORMATION screen displays device serial number and status (Ready for Use, Test Failed, or Service Required) and provides access to the DEVICE HISTORY, BATTERY HISTORY, and SOFTWARE INFORMATION screens. Press the ▼ option button to scroll to SOFTWARE INFORMATION, then press the ✓ option button to select it.



5. Upon request by Philips technical support, report the data displayed on the SOFTWARE INFORMATION screens to assist in troubleshooting your device.

6. If you have other administrative tasks to perform, press the ✓ option button to exit the screen and return to the SYSTEM INFORMATION screen, then press the ✓ option button on that screen to return to the ADMINISTRATION screen. Otherwise, press the On/Off button to display the status screen and put the FR3 into standby.

* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

† The Wireless Data Transfer option does not appear on the screen unless the optional *Bluetooth* wireless technology transceiver module is installed in the FR3.

TROUBLESHOOTING GUIDE

GENERAL TROUBLESHOOTING

The green Ready light on the FR3 is your primary guide to knowing if the defibrillator is ready for use. If the Ready light is flashing, the FR3 has passed its most recent self-test or user-initiated test and is therefore ready for use. If the Ready light is on steady, the FR3 is in use or is running a periodic self-test. The following table lists conditions where the Ready light is off, and recommended action.

INDICATOR	RECOMMENDED ACTION
Ready light is off and the FR3 is chirping	If the FR3 is giving single chirps, press the On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen for information about the status of the FR3 and how to resolve the problem. If the FR3 is giving triple chirps, press the On/Off button once. If an error message is displayed on the status screen, record the error, turn off the FR3, and remove it from service. Then contact Philips at www.philips.com/AEDSupport for technical support. (See "Informational and Error Messages" on page 4-18.)
Ready light is off, the FR3 is not chirping, and the display screen is blank	The battery is depleted or missing, or the FR3 needs repair. Insert or replace a battery. The FR3 automatically runs a power-on self-test. If the green Ready lights starts flashing, the FR3 has passed the self-test and is therefore ready for use. If not, contact Philips at www.philips.com/AEDSupport for technical support.

TROUBLESHOOTING DURING PATIENT USE

NOTE: The information in this section is provided for use by Administrators in training responders in operation of the FR3.

If the green Ready light is flashing, press on the On/Off button to turn on the FR3, then follow all voice and text prompts.

If the green Ready light is off and the FR3 is giving single chirps, the FR3 may still be able to be used to treat a victim of SCA. Press the On/Off button then follow all voice and text prompts.

In the unlikely event that the device becomes unresponsive during use, press the On/Off button once, wait one second, then press it again. If this does not clear

the problem, remove and reinstall the battery or replace it with a new FR3 battery, if available. If this still does not clear the problem, do not use the FR3.

If you are able to complete emergency use of the FR3, but cannot clear the problem as instructed on the status screen and the green Ready light is not flashing after the FR3 is put into standby, contact Philips at www.philips.com/AEDSupport for technical support

NOTE: Perform CPR, if needed, any time there is a delay before or an interruption in using the FR3.

If the FR3 detects a condition during use that requires immediate attention, it provides voice and/or screen prompts that identify the condition and, in most cases, directs the user how to correct it. The following table lists sample troubleshooting prompts the FR3 may give during patient use, the possible cause, and recommended action for each. See also "Restart Messages during Patient Use" on page 4-22.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Low battery	• The battery power is low or the FR3 does not recognize the battery.	• Install a new clinical battery as soon as possible. If a new battery is not available, attempt to complete use of the FR3.
Replace battery	• The battery is depleted or the FR3 does not recognize the battery and cannot use it.	• Install a new FR3 battery immediately. The FR3 will turn off unless a new battery is installed.
Training	• The training battery is installed.	• Install a clinical battery.
Remove training pads	• The training pads are connected to the FR3.	• Disconnect the training pads and connect a set of SMART Pads III.
Replace pads	• The FR3 does not detect pads application to the patient after extended prompting. • The pads are damaged.	• Be sure pads are applied properly. If prompt persists, replace the original pads with new ones. • Check for pads damage and replace if necessary.
Plug in pads connector	• The pads connector is unplugged or not fully inserted.	• Plug in the pads connector firmly.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Insert connector firmly	• The pads connector is not fully inserted. • The pads are not correctly applied to the patient. • Only one pad is applied to the patient.	• Plug in the pads connector firmly. • Replace the pads and apply to patient to continue treatment. • Remove the second pad from the liner and apply it to the patient.
Press pads firmly to patient's bare skin Be sure pads connector is completely inserted Pads must not be touching clothing or each other If needed, remove hair from patient's chest	• The pads are not properly applied to the patient. • The pads connector is not fully inserted. • The pads are on the patient's clothing or touching each other. • The pads are not making good contact with the patient's bare chest because of moisture or excessive hair.	• Make sure that the pads are sticking completely to the patient's skin. • Make sure the pads connector is fully inserted. • Make sure pads are not on their liner or the patient's clothing; reposition the pads. • If the pads are not sticking, dry the patient's chest and shave or clip any excessive chest hair.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Analyzing interrupted … Stop all motion … Cannot analyze	• The patient is being moved or jostled, interfering with heart rhythm analysis.	• Stop CPR; do not touch the patient. Minimize patient motion. If the patient is being transported, stop the vehicle.
	• The environment is dry; movement around the patient is causing static electricity to interfere with ECG analysis.	• Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity.
	• Radio or electrical sources are interfering with ECG analysis.	• Check for possible sources of radio and electrical interference and turn them off or remove them from the area.
	• Radio or electrical sources are interfering with ECG analysis or there is excessive patient motion.	• Check for possible sources of radio and electrical interference and turn them off or remove them from the area. Minimize patient motion. Then press the ANALYZE option button if available.
No shock delivered	• The pads are not making good contact with the patient's skin.	• Press the pads firmly to the patient's bare chest.
	• The pads are touching each other.	• Make sure the adhesive pads are correctly positioned on the patient. For example, the pads may be touching each other if adult pads placement is used on a very small patient.
	• The pads are damaged or the adhesive dried out.	• Replace the pads if necessary.
Shock button not pressed	• Shock has been advised but the shock button has not been pressed within 30 seconds.	• When next prompted, press the Shock button to deliver shock.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Attend to patient	• A shock has been advised but the Shock button was not pressed within 30 seconds.	• Provide CPR if needed. When next prompted, press the Shock button to deliver a shock.
	• The AED has been unable to analyze for more than 45 seconds.	• Provide CPR if needed or follow your local protocol.
Press Shock button or device will disarm	• The On/Off button has been pressed while the FR3 is armed.	• Press the Shock button to deliver shock.

INFORMATIONAL AND ERROR MESSAGES

The FR3 is designed to assist in troubleshooting any problems it detects in its operation and use. In addition to the Ready light and alert chirping indicators, the FR3 displays an informational or error text message to alert the user to situations requiring attention. The FR3 logs error messages in internal memory.

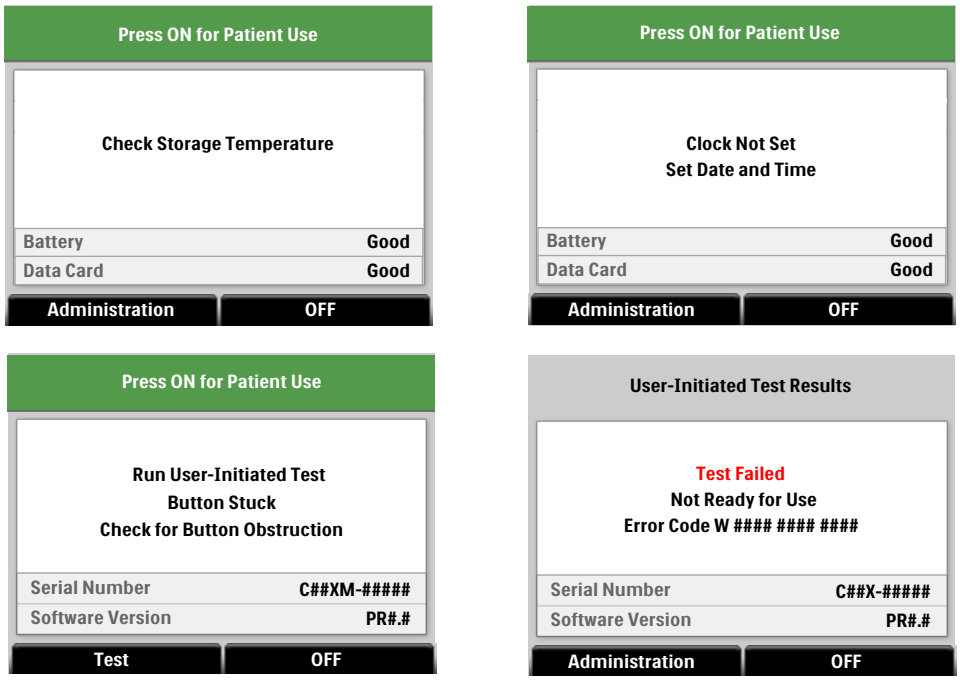
With the exception of service-required error messages, which are displayed for 60 seconds, informational and error messages are displayed for 15 seconds. If more than one message is appropriate, each screen is displayed for 15 seconds. Afterwards, the FR3 briefly displays the status screen before going to standby.

MESSAGES AT SHUTDOWN

The FR3 provides informational and error messages at shutdown to identify conditions detected by the FR3 that *do not affect use of the FR3*. These conditions should be corrected so that the FR3 can pass its next self-test. In most cases, the messages include directions for resolving the issue. Follow the directions on the screen.

If the FR3 is already giving single chirps because it has failed a self-test, correct the problem identified, then run a user-initiated test to ensure that the defibrillator is ready for use. If an error code is displayed, please record the code and contact Philips at www.philips.com/AEDSupport to report the error.

Sample message-at-shutdown error screens are shown below.



The following table lists sample information and error messages that the FR3 may give at shutdown, the probable cause, and recommended action for each.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Check Storage Temperature	The FR3 has been stored outside its specified temperature range. See page G-1.	Make sure the FR3 is stored in a location within the specified storage temperature range.
Clock Not Set … Set Date and Time	The FR3 internal clock is not set or has lost its setting because the battery was removed for more than 2 hours.	Press the Administration option button and select DATE AND TIME from the SETUP menu. Set the date and time in the FR3 before shutting it down. The date and time may also be set using wireless data transfer and the HeartStart Configure software. See Chapter 7, "Data Management."

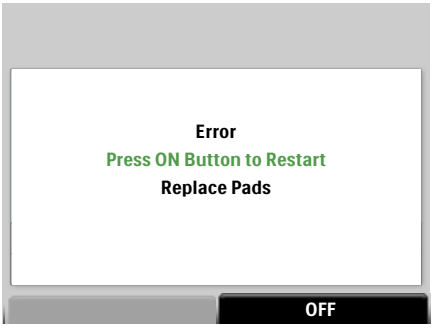
TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Replace Pads and Restart	The FR3 cannot detect pads attachment after five minutes of prompting.	Make sure pads are undamaged and are correctly applied to patient's bare chest. Clip or shave excess chest hair from pads placement areas. If necessary, connect a new set of pads.
Replace Pads Now	The pads are not ready for use.	Make sure pads are not damaged, expired, or dried out. If necessary, connect a new set of pads.
Button Stuck … Check for Button Obstruction	A button on the FR3 panel is stuck in the pressed position.	Ensure that all buttons are clear of obstruction when the carry case is closed.
Incomplete Self-Test	The FR3 has attempted to run an automatic periodic self-test three times and aborted each time due to a problem.	Run a user-initiated test to identify the problem.
Remove Infant/ Child Key	The Infant/Child Key has been left installed.	Remove the Infant/Child Key. The Infant/Child Key should be installed only during a pediatric use.
Data Card Full … Replace Data Card	The installed data card is full.	Remove the data card download the data for analysis, then erase and reinstall the data card, or install a new data card. After reinstalling the battery, press the On/Off button to turn the FR3 on and then off again to clear the error.
Invalid Data Card … Replace Data Card	The installed data card is invalid.	Remove the invalid data card and install an appropriate data card. After reinstalling the battery, press the On/Off button to turn the FR3 on and then off again to clear the error.
Remove Training Pads	Training pads are connected.	Remove the training pads and replace them with appropriate clinical pads.

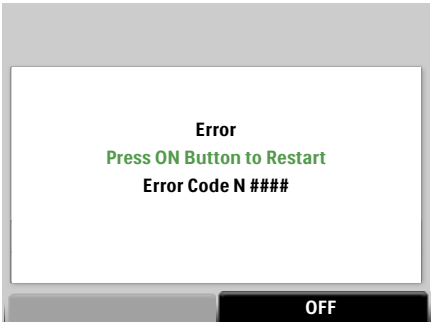
TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Plug in Pads Connector	The FR3 is configured to check pre-connected pads during self-test and does not detect the pads.	Make sure pads are pre-connected to the FR3.
No Data Card Detected … Install Data Card	The FR3 is configured to check the data card during self-test and does not detect a data card.	Install a data card in the FR3. After reinstalling the battery, press the On/Off button to turn the FR3 on and then off again to clear the error.
Button Test Incomplete	The user did not press the button(s) during the interactive portion of the user-initiated test.	Repeat the user-initiated test and be sure to press each button when instructed.
Replace Battery	The FR3 does not recognize the battery, or the battery power is low.	Remove the depleted or unrecognized battery and replace it with a new FR3 battery. *NOTE: If battery power is seriously depleted, the FR3 briefly displays a shutdown screen indicating the battery should be replaced, then goes to standby*
Setup Lost … Reload Setup	The setup file is corrupt or lost and the FR3 has reverted to the default configuration. (This is extremely unlikely.)	Reload desired custom configuration using HeartStart Configure and the administration mode. For directions, see Chapter 6, "Configuration." Contact Philips at www.philips.com/AEDSupport for technical support.
Test Failed … Run User-Initiated Test … Error Code W ##### ##### #####	The FR3 has encountered an error.	Record the error code number. Run the user-initiated test. Contact Philips at www.philips.com/AEDSupport for technical support.
User-Initiated Test Results …Test Failed … Not Ready for Use … Error Code W ##### ##### #####	The user-initiated test has failed.	Record the error code number. Contact Philips at www.philips.com/AEDSupport for technical support.

RESTART MESSAGES DURING PATIENT USE

In the unlikely event that the FR3 detects an error during patient use, the FR3 logs the error, records all data for the current use, and then displays the error message and shuts down. If the FR3 provides a pads problem message, replace the pads. If it provides an error code message, "reboot" the defibrillator by pressing the green On/Off button to turn it on and complete the use. After the use, contact Philips at www.philips.com/AEDSupport to report the error.

Sample restart message screens are shown below.





NOTE: Perform CPR, if needed, any time there is a delay before or an interruption in using the FR3.

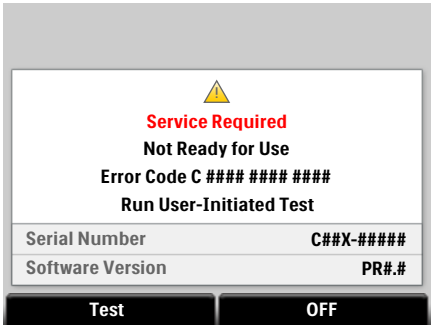
The following table presents sample restart error messages that the FR3 displays during use, probable cause, and recommended action.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Error … Press ON button to Restart … Replace Pads and Restart	After three attempts, the FR3 was not able to deliver a shock through the pads and is shutting down.	Turn off the FR3, replace the pads, and turn on the FR3.
Error … Press ON button to Restart … Error Code N #####	The FR3 has encountered an error.	Press the On/Off button to clear. After the use, contact Philips at www.philips.com/AEDSupport for technical support.

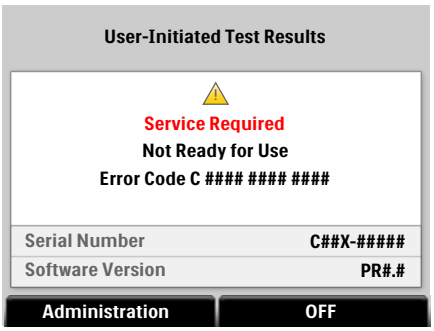
SERVICE-REQUIRED ERROR MESSAGES

When an FR3 self-test detects an error that renders the device not ready for use, it displays a service-required message with an error code for 60 seconds, then shuts down and gives triple chirps to alert you to the problem. *You cannot use the FR3 to deliver therapy until the error is cleared.*

To clear the error, first record the error code, software version, and device serial number. Then press the Test option button to run a user-initiated test. Follow the directions during the interactive portion of the user-initiated test.

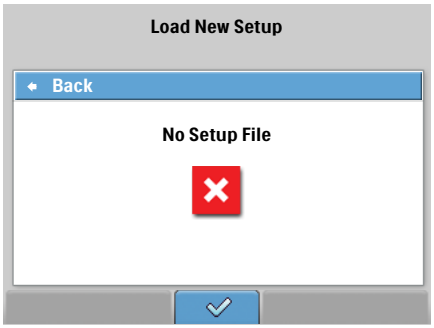


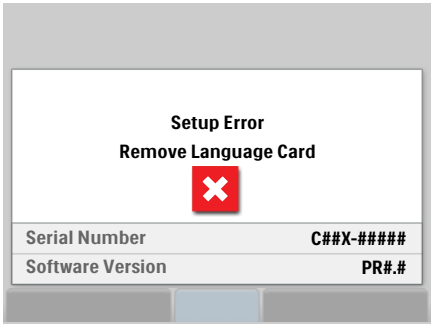
If the user-initiated test fails to clear the error, the FR3 displays a test results service-required error message. Record the error code, software version, and device serial number, and contact Philips at www.philips.com/AEDSupport for technical support.



ERROR MESSAGES DURING CONFIGURATION AND LANGUAGE LOADING

If the FR3 encounters an error during configuration or language loading, it displays an error message. Sample screens are shown below.





NOTE: If you encounter errors during wireless data transfer of a new device configuration file, see the HeartStart Configure software documentation.

The following table lists sample error messages that the FR3 may display during configuration and language loading, the probable cause, and recommended action for each.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
No Setup File	While attempting to load a new setup, the FR3 detects that the data card is missing or does not contain a device configuration file.	Check to make sure the data card is installed and has the setup file from HeartStart Configure on it. For information about changing the setup of the FR3, see Chapter 6, "Configuration."
Invalid Setup	While loading a new setup, the FR3 detects that the setup file on the data card is corrupt.	Copy the setup file to another FR3 data card and retry or create a new setup file using the HeartStart Configure software.
Setup Error … Remove Language Card	Installation of the device configuration or new primary language has not completed successfully; configuration reverts to default settings.	Retry installing the configuration or language, or copy the file to another FR3 data card for use.
Setup Not Saved … Check Data Card	While saving a setup to a data card, the FR3 detects that a file cannot be created on a data card or there is no data card installed.	Make sure a data card is installed and has sufficient room for the device configuration file.
Language Unchanged … See Instructions for Administrators	While loading a new setup from a data card, the FR3 detects that the configuration contains language files for a new primary or selected secondary language.	The FR3 language card is required to make any changes to language. Language files cannot be loaded using the Load New Setup command on the ADMINISTRATION screen or via wireless data transfer. See "Modifying FR3 Language" on page 6-15. *NOTE: Configuration changes other than language can be loaded using either an FR3 data card or, for convenience, the FR3 language card.*

5 SAFETY

You should be aware of the safety considerations listed here when you use the HeartStart FR3 Defibrillator (FR3). Read them carefully. You will also see some of these messages in other parts of this manual. The messages are classified as 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 FR3, or loss of data stored in the device.

These safety considerations are divided into four groups: safety concerns about the FR3 in general use, defibrillation, monitoring, and maintenance activities. Unless otherwise noted, the dangers, warnings, and cautions listed in the following tables apply to the FR3 ECG model 861389 and FR3 Text model 861388.

GENERAL DANGERS, WARNINGS, AND CAUTIONS

SAFETY LEVEL	POSSIBLE SHOCK OR FIRE HAZARD, OR EXPLOSION
DANGER	IF THE FR3 IS USED TO GIVE A SHOCK IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR CONCENTRATED OXYGEN, THERE IS A RISK OF EXPLOSION. MOVE SUPPLEMENTAL OXYGEN AND OXYGEN DELIVERY DEVICES AWAY FROM THE DEFIBRILLATION PADS. HOWEVER, IT IS SAFE TO USE THE FR3 ON SOMEONE WEARING AN OXYGEN MASK.
DANGER	THE FR3 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 FR3 IS NOT TO BE USED IN THE PRESENCE OF FLAMMABLE SUBSTANCE/AIR MIXTURES.
DANGER	THE 989803150161 CLINICAL USE BATTERY IS NOT RECHARGEABLE. DO NOT TRY TO RECHARGE, OPEN, CRUSH, OR BURN THE BATTERY, OR IT MAY EXPLODE OR CATCH FIRE.

SAFETY LEVEL	POSSIBLE SHOCK OR FIRE HAZARD, OR EXPLOSION
WARNING	Use the FR3 only as described in this manual. Improper use of the FR3 can cause death or injury. Do not press the Shock button if the defibrillator pads are touching each other or are open and exposed.
WARNING	If the battery leaks/vents, seek immediate medical attention for any physical contact/inhalation.
CAUTION	Hazardous electrical output. The FR3 is for use only by qualified personnel.
CAUTION	Do not immerse any portion of the FR3 in water or other fluids. Do not allow fluids to enter the FR3. Avoid spilling any fluids on the FR3 or its accessories. Spilling fluids into the FR3 may damage it or present a fire or shock hazard. Do not sterilize the FR3 or accessories.

SAFETY LEVEL	POSSIBLE IMPROPER DEVICE PERFORMANCE
WARNING	Prolonged or aggressive CPR to a patient with defibrillator pads attached can damage the pads. Replace the defibrillator pads if they are damaged during use or handling.
WARNING	Using damaged or expired equipment or accessories may cause the FR3 to perform improperly, and/or injure the patient or the user.
WARNING	CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the FR3. Under certain circumstances, this may result in a prompt to stop all movement so that the device can confirm rhythm analysis.
WARNING	Poor electrode pad-to-patient contact may result in a related defibrillator prompt or other indication. Check all electrical and patient connections.
CAUTION	The FR3 is designed to be used only with Philips-approved accessories. The FR3 may perform improperly if non-approved accessories are used.
CAUTION	Follow all instructions supplied with the HeartStart defibrillator pads. Use the defibrillator pads before the expiration date shown on the package. Do not reuse the defibrillator pads. Discard them after use.
CAUTION	Aggressive handling of the defibrillator pads in storage or prior to use can damage the pads. Discard the defibrillator pads if they become damaged.
CAUTION	Follow all instructions supplied with the FR3 batteries. For non-rechargeable FR3 batteries, install the battery before the “Install before” labeled date.

SAFETY LEVEL	POSSIBLE IMPROPER DEVICE PERFORMANCE
CAUTION	Follow all instructions supplied with the FR3 rechargeable training battery. Recharge using the 861394 charger only.
CAUTION	Do not use the 861394 battery charger on aircraft.
CAUTION	The FR3 was designed to be sturdy and reliable for many different field use conditions. However, excessively rough handling can result in damage to the FR3 or its accessories. Inspect the unit and accessories periodically according to instructions.
CAUTION	Alteration of the factory default setup of the FR3 can affect its performance and should be performed under the authorization of the Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.
CAUTION	Use only Philips-approved FR3 data cards. The FR3 may record improperly if a non-approved data card is used. Install a blank FR3 data card after each use to avoid loss of data.

SAFETY LEVEL	POSSIBLE ELECTRICAL INTERFERENCE WITH ECG MONITORING
WARNING	Radio-frequency (RF) interference from devices such as cellular phones, two-way radios, surgical equipment, electronic article surveillance equipment, and metal detectors can cause improper operation of the FR3. If the FR3 prompts that it cannot analyze, remove the FR3 from potential RF sources. Alternatively, move or turn off the RF source.

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 defibrillator pads to touch any metal surfaces. Disconnect the pads connector from the FR3 before using any other defibrillator.
WARNING	Before delivering a shock, it is important to disconnect the patient from other medical electrical equipment, such as blood-flow meters, that may not incorporate defibrillation protections. In addition, make sure the pads are not in contact with metal objects such as a bedframe or stretcher.

SAFETY LEVELS	POSSIBLE ECG MISINTERPRETATION
WARNING	For patient safety reasons, some very low-amplitude or low-frequency heart rhythms may not be interpreted by the FR3 as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.
WARNING	Performing CPR or otherwise handling or moving the patient while the FR3 is analyzing the heart rhythm can cause an incorrect or delayed analysis. Under certain circumstances, this may result in a prompt to stop all movement so that the device can confirm rhythm analysis.
WARNING	Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed analysis. If the FR3 gives a shock advised prompt, keep the patient as still as possible for at least 15 seconds so the FR3 can reconfirm the rhythm analysis before a shock is delivered.
CAUTION	Do not place the pads directly over an implanted pacemaker or defibrillator. A noticeable lump with a surgical scar should indicate its position.

SAFETY LEVELS	POSSIBLE BURNS AND INEFFECTIVE THERAPY
WARNING	Do not allow the defibrillator pads to touch each other or other ECG electrodes, lead wires, dressings, transdermal patches, or metal parts that are in contact with the patient such as a bedframe or stretcher. 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 defibrillator pads can cause patient skin burns. To help prevent air pockets, make sure defibrillator pads completely adhere to the skin. Do not use dried out pads.

SAFETY LEVEL	POSSIBLE PATIENT INJURY
CAUTION	The FR3 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 FR3 ECG model 861389 is intended only for basic ECG rhythm identification. The frequency response of the FR3 display 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 FR3, remove its covers, or attempt repair. There are no user-serviceable components in the FR3. The FR3 should be returned to Philips for repair.
CAUTION	Improper maintenance may damage the FR3 or cause it to function improperly. Maintain the FR3 only as described in these Instructions for Use or as designated by your program's Medical Director.

6 CONFIGURATION

The HeartStart FR3 Defibrillator (FR3) is shipped with a factory-default setup optimized for compliance with Guidelines 2010 to meet the needs of most users. However, the FR3 is extensively configurable. Any changes to default settings must be done under supervision of the Medical Director.

The configuration parameters and settings described in this chapter are for FR3 software revision 1.#. You can order upgrades to FR3 software, as they become available. New software versions will be supplied on an FR3 data card, along with instructions for installation.

For directions on how to modify FR3 setup from default factory settings, see "Modifying Setup" on page 6-10. The following table provides an overview of the modifications you can make using the FR3 administration mode, an FR3 language card, and/or the HeartStart Configuration software. For information on ordering HeartStart Configure and the FR3 language card, see Appendix A, "Accessories."

Modification	FR3 in Admin. Mode	FR3 Language Card*	HeartStart Configure	Wireless Transceiver Module
Change device operation *(except primary language and bilingual option)*: self-test options, patient care, defibrillation, and advanced mode parameters (page 6-10)	✓		✓	✓
Change primary language only (page 6-16)		✓		
Enable bilingual option and select secondary language (page 6-18)		✓	✓	
Set FR3 date and time (page 2-5 and page 6-12)	✓		✓	✓
Use computer date and time for FR3 (page 7-5)			✓	✓

* The FR3 language card is provided with certain versions of the FR3 and is also available separately. If parameter configuration changes other than language are desired, an FR3 data card can be used instead of the language card.

NON-PROTOCOL PARAMETERS

The following tables present the settings for configuration parameters that are not directly related to the patient care protocol. Default settings are indicated by an asterisk (*).

NOTE: For information on setting the date and time for your FR3, see "Setting the Date and Time" on page 2-5.

LANGUAGE SELECTION PARAMETERS

The FR3 can operate in any of several available languages. If you want to configure the FR3 to a non-default language, you must have the FR3 language card. If you want to enable bilingual operation, you need both the language card and the HeartStart Configure software.

PARAMETER	SETTINGS	DESCRIPTION
Primary Language	* U.S. English, U.K. English, or Japanese (depending on model) • any on language card	Sets the language used for FR3 text and voice prompts. See "Changing the Primary Language Only" on page 6-16.
Bilingual Option	* off • any on language card	Disables (OFF) or enables (ON) use of a secondary language for optional activation by a responder in an emergency. *NOTE: To select the bilingual option, the FR3 language card must be installed in a computer equipped with HeartStart Configure.* See *"Enabling the Bilingual Option or Changing Other Configuration Settings" on page 6-18.*

DEVICE OPERATION PARAMETERS

The device operation parameter settings determine the basic setup of the FR3, irrespective of individual protocols.

PARAMETER	SETTINGS	DESCRIPTION
Volume	* loud • medium • soft	Sets the FR3 speaker volume.

PARAMETER	SETTINGS	DESCRIPTION
ECG Display (FR3 model 861389 only)	* on • off	Enables (ON) or disables (OFF) display of the patient's ECG on the FR3 screen.*
Record Audio	• on * off	Enables (ON) or disables (OFF) audio recording on the data card during use. *NOTE: Metronome audio beats, if enabled, will mask ambient sounds during CPR in the Record Audio data.*
Wireless PIN	* 2071 • custom	Sets use of default *Bluetooth* wireless technology personal identification number (PIN) or a custom PIN created by Administrator using HeartStart Configure. Activation of a custom PIN requires turning the FR3 off and then on. *NOTE: Required for use with the optional wireless transceiver module.* *NOTE: For security reasons, the FR3 does not display the PIN. In the administration mode's VIEW SETUP, the PIN is shown as "Default" if never changed, or "****" if customized.*

* Even if ECG display is disabled in the FR3 model 861389, if the advanced use mode is selected, the FR3 screen displays the ECG.

SELF-TEST OPTIONS PARAMETERS

The FR3 can be configured to test for the presence of certain pre-connected accessories during its periodic self-tests (PST) and user-initiated test (UIT). The default setting is OFF; if the accessory is not detected, the self-test does not fail. However, if the self-test for an accessory is configured to ON and the FR3 does *not* detect the accessory, it provides alert chirps.

NOTE: The FR3 automatically tests the functional integrity of any detected accessory during the PST, even if the test for its *presence* is configured to OFF. This gives Administrators a tool that helps ensure the accessories they want used are in place and ready for use.

PARAMETER	SETTINGS	DESCRIPTION
Test Pads	• on * off	Enables (ON) or disables (OFF) testing for the presence of pre-connected pads during each self-test.
Test Data Card	• on * off	Enables (ON) or disables (OFF) testing for the presence of an installed data card during each self-test.

PATIENT CARE PARAMETERS

The FR3 is designed to follow a patient care protocol defined by the parameters in the following tables. The default settings are optimized for compliance with Guidelines 2010. Changes to the FR3 configuration should be done by or under the supervision of a Medical Director, using the HeartStart Configure software.

Because many of the patient care protocol parameters interact with each other, it is important to understand how each parameter affects the protocol. The description of each parameter identifies any interacting parameters, indicated by underlined text.

TYPES OF CPR PROTOCOLS

The FR3 provides three kinds of separately configurable CPR protocols. The kind of CPR protocol applied depends on its context in the patient care cycle.

- Basic CPR — *Upon completion of a shock series*[*], *or upon use of a configured CPR option button during rhythm analysis*, the FR3 provides a CPR protocol.
- CPR First — The FR3 provides a CPR protocol *before defibrillation therapy,* based on the selected SMART CPR algorithm or the User setting.
- NSA CPR — *After a no shock advised (NSA) decision,* the FR3 provides an attend-to-patient period with a CPR option button or, if NSA CPR is configured ON, an NSA CPR protocol.

Each of these three protocol types can also be configured separately for adult and infant/child applications, for a total of six distinct CPR protocols.

* FR3 default shock series is one shock.

CPR PROTOCOL PARAMETERS

The CPR protocol parameters for the FR3 are either "general" or "specific." General CPR parameters apply to all CPR protocols. Specific CPR parameters apply to each CPR protocol individually.

The following tables present the available settings, default setting, and a description of each general and specific CPR protocol parameter. Default settings are indicated by an asterisk (*).

GENERAL CPR PARAMETERS

Unless otherwise noted, these parameters pertain to *all* adult and infant/child CPR protocols (Basic CPR, CPR First, and NSA CPR) initiated by the FR3. If you change a general CPR parameter setting, it will be applied to every CPR protocol.

NOTE: CPR protocols are time-based, using the selected CPR duration setting.

PARAMETER	SETTINGS	DESCRIPTION
Metronome	• on * off	Enables (ON) and disables (OFF) audio beats for CPR compressions. *NOTE: Metronome audio beats, if enabled, will mask ambient sounds during CPR in the Record Audio data.*
CPR First	* off • SMART CPR auto1 • SMART CPR auto2 • user	Sets whether the FR3 provides an interval for CPR prior to defibrillation, in the first rhythm analysis in a use. For details on settings, selection criteria, and device operation for this parameter, see Appendix D, "SMART CPR." *NOTE: The **Analyze option button** is always available in any CPR First protocol. Press the button to initiate FR3 analysis of heart rhythm.*
CPR Option Button	• on * off	Enables (ON) or disables (OFF) ability to initiate a Basic CPR protocol, by pressing the designated option button, when active during rhythm analysis or a shock-related sequence, on the front panel of the FR3.
Analyze Option Button	• on * off	Enables (ON) or disables (OFF) ability to interrupt a CPR protocol, NSA monitoring, or attend-to-patient period and resume rhythm analysis, by pressing the designated option button on the front panel of the FR3.

PARAMETER	SETTINGS	DESCRIPTION
NSA Action	* NSA CPR • NSA monitor	Sets FR3 available behavior during the attend-to-patient period that follows any NSA (no shock advised) decision. During this period, the responder may perform CPR or otherwise attend to the patient, as needed. For details on settings, selection criteria, and device operation for this parameter, see Appendix E, "NSA Action." *NOTE: When configured to NSA CPR, the FR3 enables configuration of NSA CPR Coaching for use during the attend-to-patient period. NSA CPR Coaching settings are ALWAYS and USER.*
NSA CPR Coaching	• User * Always	When configured to NSA CPR, allows selection of NSA CPR Coaching following an NSA decision, either at user discretion (USER) or ALWAYS. For details on settings, selection criteria, and device operation for this parameter, see Appendix E, "NSA Action."
NSA Monitor Repeat (minutes)	* 1.0 • 2.0 • 3.0 • infinite	Sets the repeat rate for patient care prompts provided by the FR3 during monitoring, only when NSA action is set to MONITOR. *NOTE: Selection of INFINITE means that no repeat prompting will be provided during background monitoring.*

PROTOCOL-SPECIFIC CPR PARAMETER

The CPR Duration parameter can be configured separately for each adult and infant/child CPR protocol.

PARAMETER	SETTINGS	DESCRIPTION
Adult Basic CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for adult Basic CPR.
Adult CPR First Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for adult CPR First.

PARAMETER	SETTINGS	DESCRIPTION
Adult NSA CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the adult attend-to-patient period for the adult NSA CPR protocol.
Infant/Child Basic CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for infant/child Basic CPR.
Infant/Child CPR First Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for infant/child CPR First.
Infant/Child NSA CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the attend-to-patient period for the infant/child NSA CPR protocol.

DEFIBRILLATION PARAMETERS

These parameters govern the number of and time between defibrillation shocks in a shock series. The FR3 uses a biphasic shock waveform. The shock therapy level is not configurable. When you insert the optional Infant/Child Key in the FR3, the FR3 automatically reduces the therapy dose to a level more appropriate for infants and children.

PARAMETER	SETTINGS	DESCRIPTION
Shock Series (number of shocks per stack)	* 1 • 2 • 3 • 4	Sets the number of shocks in a series that must be delivered before the FR3 automatically activates a Basic CPR protocol. A new shock series begins when a shock is delivered: • after the FR3 is turned on • after a completion of any CPR protocol • if the time since the previous shock exceeds the shock series interval setting (when the shock series setting is more than one).

PARAMETER	SETTINGS	DESCRIPTION
Shock Series Interval (minutes)	* 1.0 • 2.0 • infinite	Sets the time interval used to determine if a delivered shock should be counted as part of the current shock series. This parameter applies only when the shock series setting is greater than 1. *NOTE: Selection of infinite means that the shock series interval will not time out until the configured number of shocks per stack (shock series) has been delivered.*

ADVANCED MODE PARAMETERS

The advanced mode is intended for use by authorized operators only. When configured to ON, advanced mode use allows manual override of certain FR3 functions and configuration of the prompt repeat rate. For instructions on using the advanced mode, see Appendix F, "Advanced Mode."

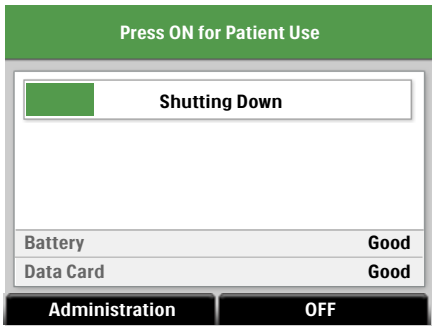
PARAMETER	SETTINGS	DESCRIPTION
Advanced Mode Use	• analyze • charge * off	Enables (ANALYZE and CHARGE) or disables (OFF) advanced mode. ANALYZE — The FR3 permits user-initiated rhythm analysis when the advanced mode is entered by pressing the ANALYZE option button. CHARGE — The FR3 permits user-initiated rhythm analysis, plus charge, shock delivery, and disarm when the advanced mode is entered, by pressing the CHARGE option button. *NOTE: The CHARGE setting is available for FR3 ECG model only.*
Advanced Use Prompt Repeat Rate (minutes)	* 0.5 • 1.0 • 2.0	Sets the repeat rate for patient care prompts provided by the FR3 when advanced mode use is configured to ANALYZE or CHARGE.

VIEWING SETUP

You can view the current setup of your FR3 at any time. If your FR3 is in standby, start with Step 1, below. If you have just completed loading a new setup, the FR3 automatically displays the SETUP screen; go to Step 4, below.

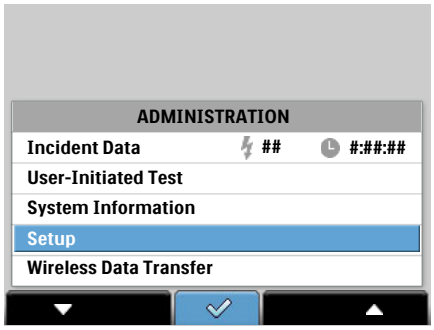
To view the FR3 setup, follow these steps:

1. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.

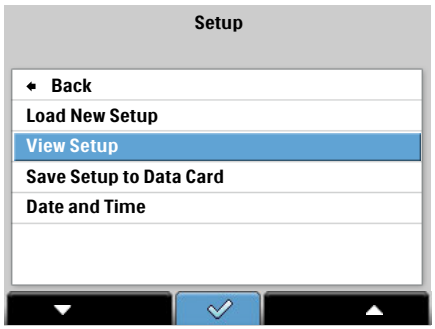


2. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.†

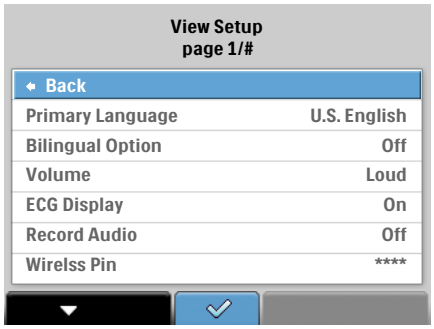
3. On the ADMINISTRATION screen, press the ▼ option button to scroll to SETUP, then press the ✓ option button to select it.



4. Press the ▼ option button on the SETUP screen to scroll to VIEW SETUP, then press the ✓ option button to select it.



5. The FR3 displays the entire current configuration across multiple screens. Press the ▼ option button to move to each succeeding screen. To return to a previous screen, press the ▲ option button. To exit, press the ✓ option button to select the highlighted BACK command on any screen.



NOTE: If a parameter is not active in the device configuration, it will be shown with "—" as its setting.

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* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

† The Wireless Data Transfer option does not appear on the screen unless the optional *Bluetooth* wireless technology transceiver module is installed in the FR3.

MODIFYING SETUP

CAUTION: Alteration of the factory default setup of the FR3 affects its performance and should be performed under the authorization of the Medical Director. Modifications to device behavior resulting from changes to the default settings should be specifically covered in user training.

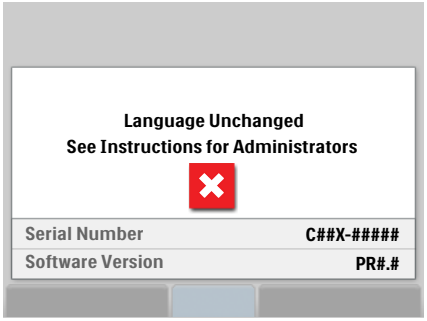
As shown in the table on page 6-1, you need the following items to modify the default setup of your FR3:

- HeartStart Configure, separately available software, installed on a computer, and a blank FR3 data card or FR3 language card installed in the computer or in the optional USB data card reader connected to the computer, *OR*
- HeartStart Configure, separately available software, installed on a computer equipped with *Bluetooth* serial port profile support, and a *Bluetooth* wireless technology transceiver module installed in the FR3.*

NOTE: If you plan to modify the FR3 language, Philips recommends that you change the language before modifying the setup. You cannot use the data card for language changes.

USING HEARTSTART CONFIGURE AND AN FR3 DATA CARD

NOTE: You cannot change the language or enable the bilingual option of the FR3 using an FR3 data card and the LOAD NEW SETUP option. You must use the FR3 language card for language changes. If the FR3 detects new language settings in the setup file on a data card, it ignores those files and displays a LANGUAGE UNCHANGED screen after loading new setup. See "Modifying FR3 Language" on page 6-15 for details.



To modify setup using a computer equipped with HeartStart Configure and an FR3 data card, follow these steps:

1. From the computer's Start menu, open HeartStart Configure.

* You cannot change the language of the FR3 using wireless transmission. The configuration download using a wireless transceiver does not support modifying language. See "Modifying FR3 Language" on page 6-15 for details on changing a language.

2. Insert a blank FR3 data card into the data card slot on the computer, or into the optional USB data card reader connected to the computer.

3. Follow the directions provided with HeartStart Configure to select the setup values desired. For detailed information, see the *HeartStart Configure User Guide* provided with the software.

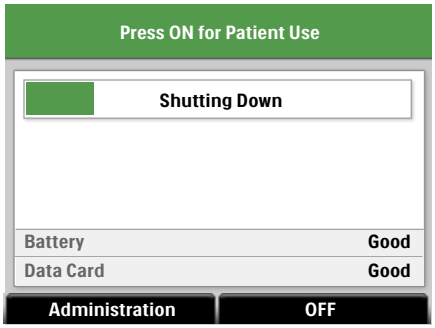
4. In HeartStart Configure, write the revised setup to the data card.

5. Remove the data card from the computer or from the USB data card reader.

6. Remove the battery from the FR3 and install the data card in the data card slot in the bottom of the battery compartment. See "Installing the Optional FR3 Data Card" on page 2-2 for directions.

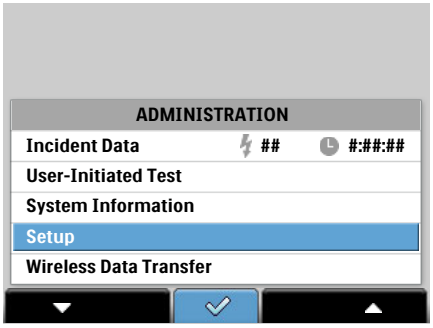
7. Re-install the battery.

8. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.



9. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

10. On the ADMINISTRATION screen, press the ▼ option button to scroll to SETUP, then press the ✓ option button to select it.†

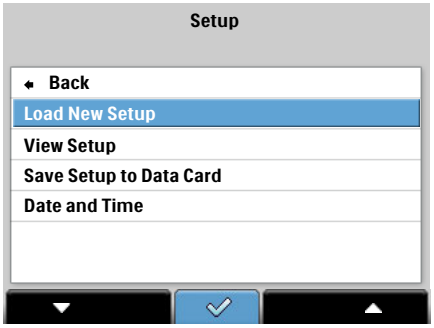


* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

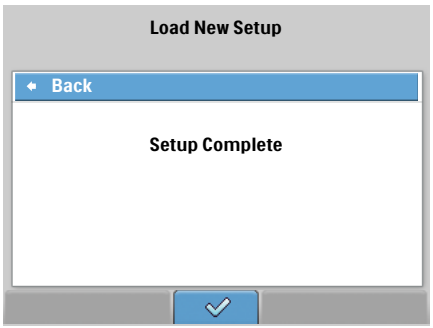
† The Wireless Data Transfer option does not appear on the screen unless the optional *Bluetooth* wireless technology transceiver module is installed in the FR3.

11. On the SETUP screen, press the ▼ option button to scroll to LOAD NEW SETUP, then press the ✓ option button to select it.

12. The FR3 automatically loads the configuration file from the installed data card.



13. When the new setup has been successfully loaded, the FR3 displays a SETUP COMPLETE message. After 10 seconds, the FR3 displays the SETUP screen.



If an error occurs during loading, the FR3 displays a SETUP ERROR message.

USING HEARTSTART CONFIGURE AND WIRELESS TRANSMISSION

NOTE: You cannot change the language of the FR3 using wireless transmission. The configuration download using a wireless transceiver does not support modifying the primary language or enabling/disabling the bilingual option and changing a configured secondary language. See "Modifying FR3 Language" on page 6-15 for details on changing a language.

To modify the FR3 setup using a computer equipped with HeartStart Configure and wireless transmission, follow these steps:

1. From the Start menu of a computer equipped with *Bluetooth* serial port profile support, open HeartStart Configure.

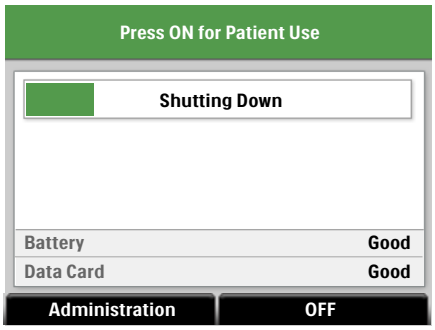
2. Follow the directions provided with HeartStart Configure to select the setup values desired. For detailed information, see the *HeartStart Configure User Guide* provided with the software.

NOTE: Using HeartStart Configure, you can set the Date and Time for the FR3 to match that computer clock.

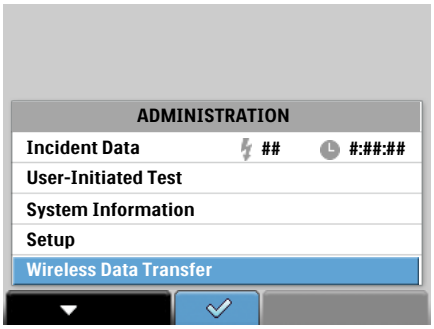
3. Check that a *Bluetooth* wireless technology transceiver module is installed in the FR3. See "Installing the Optional Bluetooth Wireless Technology Transceiver Module" on page 2-3 for installation directions.

4. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.

5. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

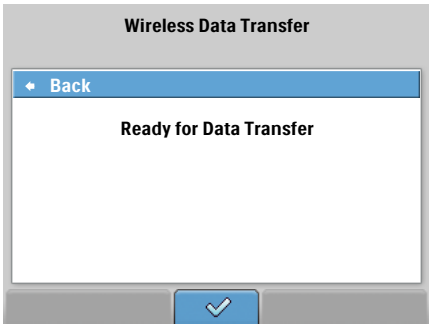


6. On the ADMINISTRATION screen, press the ▼ option button to scroll to WIRELESS DATA TRANSFER, then press the ✓ option button to select it.



NOTE: If you do not see the Wireless Data Transfer option on the screen, make sure the optional *Bluetooth* wireless technology transceiver module is installed in the FR3.

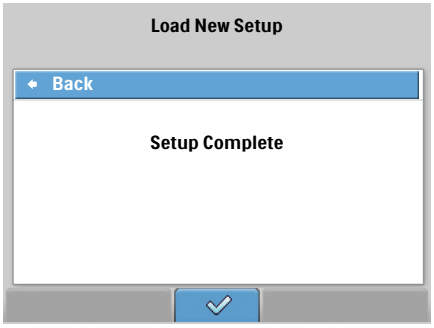
7. The WIRELESS DATA TRANSFER screen displays a READY FOR DATA TRANSFER message and a ✓ option button. This screen allows a computer with HeartStart Configure installed and *Bluetooth* serial port profile support to send a new setup to the FR3. To exit the screen, press the ✓ option button and return to the ADMINISTRATION screen.



8. Start HeartStart Configure and follow the instructions for sending the new setup to the FR3.

* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

9. When transfer is complete, the screen displays a SETUP COMPLETE message.



10. Press the ✓ option button to select the BACK command and exit WIRELESS DATA TRANSFER to the ADMINISTRATION screen.

11. If you have no additional tasks to perform in ADMINISTRATION, press the green On/Off button to display the status screen. The defibrillator turns off and goes into standby.

If an error occurs during transfer, Configure displays an error message.

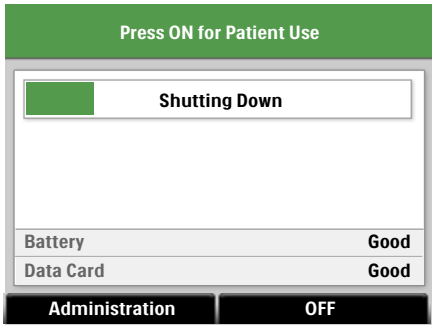
SAVING SETUP TO AN FR3 DATA CARD

To save the current FR3 setup to an FR3 data card, follow these steps:

1. If you do not already have an FR3 data card installed in the defibrillator, remove the battery from the battery compartment on the back of the FR3 and install the data card in the labeled data card slot. For directions for data card installation, see "Installing the Optional FR3 Data Card" on page 2-2. Re-install the battery.

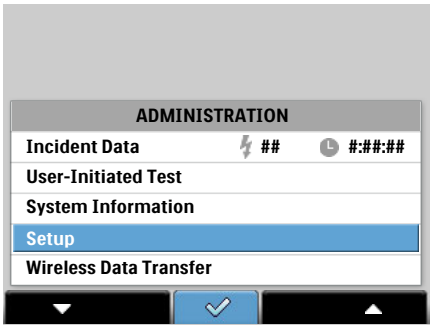
2. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen.

3. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

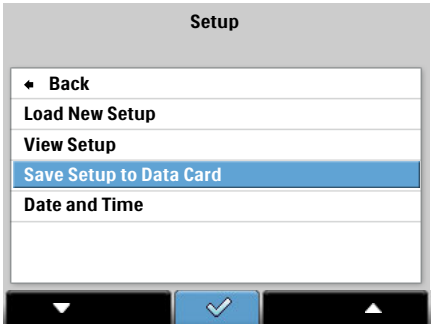


* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

4. On the ADMINISTRATION screen, press the ▼ option button to scroll to down to SETUP, then press the ✓ option button to select it.



5. On the SETUP screen, press the ▼ option button to scroll to SAVE SETUP TO DATA CARD, then press the ✓ option button to select it. The FR3 automatically saves the current configuration to the installed data card.



6. When the save process is complete, the FR3 display provides a SETUP COMPLETE message. After 10 seconds, the FR3 returns to the SETUP screen.

NOTE: The configuration file saved on the data card using this process cannot be used to configure another FR3 unit. However, HeartStart Configure can use this data to create a setup file on another FR3 data card, which can be used to configure multiple FR3 units.

MODIFYING FR3 LANGUAGE

The FR3 can be configured to operate in any language that is provided on the FR3 language card. In addition, if the bilingual option is enabled, the FR3 allows the user to choose a configured secondary language at the time of use.

As shown in the table on page 6-1, the FR3 language card can be used in two ways:

1. To change the FR3 default primary language only.
2. In conjunction with HeartStart Configure, to enable the bilingual option and select a secondary language.

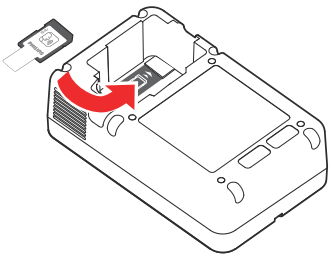
NOTE: Modifying the language does not affect other configured settings.

CHANGING THE PRIMARY LANGUAGE ONLY

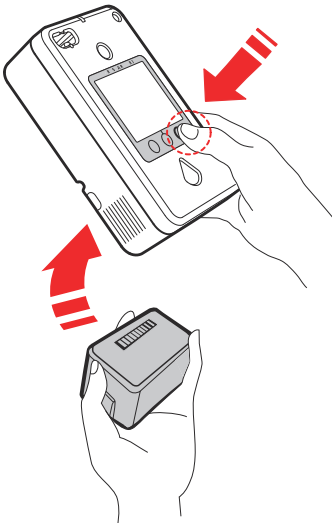
The primary language is the language the FR3 automatically uses for voice and text prompts. The FR3 uses the language card to identify available languages. To change the primary language, follow these steps:

INSTALLING THE LANGUAGE CARD

1. Remove the battery from the FR3 and remove the data card, if present. To remove the data card, grasp the card by its tail, press the retention clip away from the card, and pull the card out. See the illustration on page 6-17.



2. Insert the FR3 language card into the data card slot in the bottom of the FR3 battery compartment. A label on the floor of the compartment shows the correct orientation for inserting the card. A retention clip helps hold the card in the slot. The tail on the data card serves as a visual reminder that a card is installed and aids in card removal.



3. Reinstall the battery *while holding down the **right** option button*. Keep the button pressed until the language selection screen is displayed.

SELECTING A NEW PRIMARY LANGUAGE

1. The FR3 display screen automatically provides a list of languages. There may be more than one screen of languages.

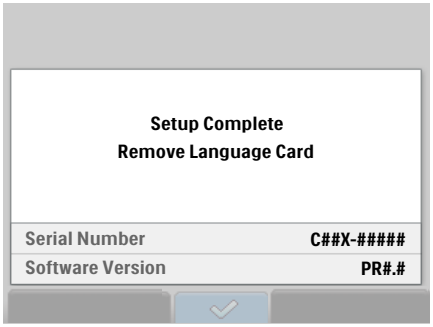


2. Press the ▼ option button to scroll to the language you want, then press the ✓ option button to select it. (If no selection is made within 60 seconds, the FR3 shuts down. To restart the process, remove and reinsert the battery while holding down the right option button.)

NOTE: If you select the wrong language by mistake, remove the battery. Reinstall the battery while holding down the right option button. Keep the button pressed until the language selection screen is displayed, then make a new language selection.

3. The new language file automatically loads. The FR3 displays the language name and a progress bar. During language installation, the FR3 cannot be turned off. (If the new language installation does not complete, the FR3 reverts to the default primary language and displays a setup error screen.)

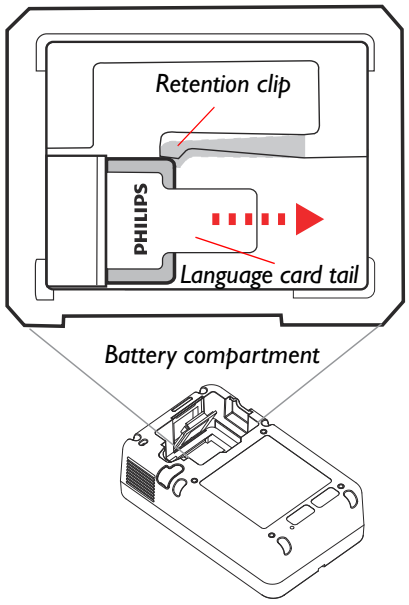
4. When the language load is complete, the FR3 operates in the new language. It displays a screen announcing that the setup is complete, and reminding you to remove the language card.



REMOVING THE LANGUAGE CARD

1. Now remove the battery and the FR3 language card. This will turn off the device. Store the language card in a safe place for future use or reference.

NOTE: To remove the language card, grasp the card by its tail, press the retention clip away from the card, and pull the card out.



2. Insert an FR3 data card, if desired, in the data card slot, and reinstall the battery. As soon as the battery is installed, the FR3 automatically runs a detailed user-initiated test. Press the buttons when directed, or the test will fail. See "User-Initiated Test" on page 4-7 for directions.

3. On completion of the test, the FR3 displays the results and then displays the main Administration menu. If the FR3 clock has not yet been set, the FR3 will provide a reminder message. See "Setting the Date and Time" on page 2-5 for directions. The device will automatically turn off after a few minutes.

NOTE: If you change the primary language or choose a secondary language for bilingual operation, Philips recommends that you relabel the green On/Off button on the FR3 with the appropriate language decal(s) from the set provided with the language card.

ENABLING THE BILINGUAL OPTION OR CHANGING OTHER CONFIGURATION SETTINGS

Under the supervision of the Medical Director, you can change the primary language, and also enable the bilingual option, select a secondary language for bilingual operation, or make other changes to the FR3 configuration. These changes require both the language card and HeartStart Configure, separately available software. HeartStart Configure uses the FR3 language card to identify available languages and provides directions to changing the configuration settings. To change configuration settings, follow these steps:

1. Install HeartStart Configure on a computer.
2. From the computer's Start menu, open HeartStart Configure.
3. Insert the FR3 language card into the data card slot on the computer, or into an optional USB data card reader, available separately from Philips, connected to the computer.
4. Follow the directions provided by HeartStart Configure for enabling the bilingual option, if desired, and selecting the secondary language, *OR* for making changes to configuration settings, if desired.
5. Follow the directions for saving the revised setup on the computer and writing the saved setup to the FR3 language card.
6. Remove the language card from the computer or the USB data card reader.

LOADING THE NEW SETUP CONFIGURATION USING THE LANGUAGE CARD

1. Install the language card in the FR3 as described on page 6-16. Reinstall the battery while holding down the right option button.
2. The new configuration changes automatically load to the FR3. During setup loading, the FR3 cannot be turned off.
3. When new setup has been successfully loaded, the FR3 displays a screen for five minutes, announcing that the setup is complete, and reminding you to remove the language card. (If an error occurs during loading, the FR3 displays a SETUP ERROR message in the default language.)

4. Follow the directions for removing the language card as described on page 6-17. Insert an optional FR3 data card, if desired, in the data card slot.

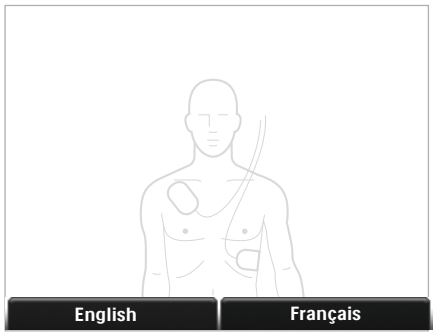
5. Reinstall the battery.

6. The FR3 automatically runs a user-initiated test. Press the buttons when directed, or the test will fail. Thereafter, any time you turn on the FR3, it will operate using the new configuration settings.

NOTE: If you change the primary language or choose a secondary language for bilingual operation, Philips recommends that you relabel the green On/Off button on the FR3 with the appropriate language decal(s) from the set provided with the language card. The decals allow for relabeling the primary language and identifying the secondary language.

DEVICE BEHAVIOR IN BILINGUAL OPERATION

When the FR3 is configured for bilingual operation, you can select between a primary and a secondary language after turning on the FR3 for use. The device immediately prompts you to select either the primary language or the secondary language by pressing one of the option buttons. The selection prompts are provided in each language.

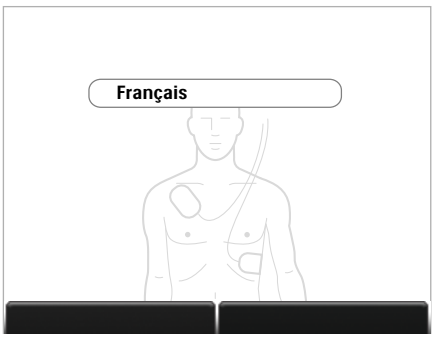


If you select the secondary language, the FR3 announces the language selection and uses that language for all operation until the FR3 returns to standby mode. If you do not select the secondary language within 10 seconds, the FR3 continues to operate in the primary language.

You must select either the primary or the secondary language each time you turn on the FR3 for use.

When you select the language, the FR3 displays a screen acknowledging the language selection.

NOTE: If you select the wrong language by mistake, you can press the On/Off button twice to restart the FR3 and select the correct language.



7 DATA MANAGEMENT

The HeartStart FR3 Defibrillator (FR3) is designed to make it easy to manage incident data. Last-use information is automatically stored in the internal memory of the FR3. You can review this data on the FR3 screen. Note that this data is overwritten the next time the FR3 is used.

You can store more detailed data on an FR3 data card* if desired. You can use optional HeartStart Event Review data management software on a computer to store and review the detailed recorded information from an FR3 data card. For information about ordering the appropriate program from the HeartStart Event Review data management software suite, go to www.philips.com/EventReview or see Appendix A, "Accessories."

RECORDED INCIDENT DATA

The FR3 has two ways of recording information about an emergency incident so that it can be reviewed after the incident: summary data of the last use in internal memory and detailed incident data on an optional FR3 data card.

NOTE: You must turn off the FR3 before removing the battery during a patient use, or some data from the current use may be lost. Data from previous uses will be retained on the data card.

LAST-USE DATA RECORDED IN INTERNAL MEMORY

The FR3 automatically records summary data for an incident in internal memory during use. This data includes the following:

- Incident duration — Elapsed time of the recorded incident from when the FR3 was turned on, in hours (if applicable), minutes, and seconds (h:mm:ss).
- Shocks delivered — The total number of shocks that were delivered during the recorded incident.
- First shock time — Elapsed time to first shock delivery from when the FR3 was turned on, in hours (if applicable), minutes, and seconds (h:mm:ss).
- Presenting ECG — Up to 15 seconds of the presenting ECG from the time the pads were applied to the patient.†

* Non-Philips data cards may not work properly with the FR3.
† The FR3 records use data every time it is turned on. If the FR3 is turned on but pads are not applied, the recorded data will not include an ECG recording.

DATA RECORDED ON AN FR3 DATA CARD

You can use an FR3 data card to store several hours of detailed incident data.

To remove or replace an FR3 data card after a use, remove the battery from the FR3 to access the data card slot in the bottom of the battery compartment. Remove the data card and give it to the appropriate person in your organization. Install a blank FR3 data card and re-install the battery so the FR3 will be ready for use in an emergency. Alternatively, without removing the data card, you can wirelessly transmit the data from and then erase the card using a computer equipped with the optional Event Review software product. See "Wireless DATA Transfer" on page 7-5 for requirements.

The information recorded on the data card includes the following:

- ECG.* The recorded patient ECG from the time the pads were applied to the patient until the FR3 was turned off.
- Comprehensive event timeline. Record of patient use events in the order of occurrence with the elapsed time of each event.
- Audio recording,* if the FR3 is so configured.

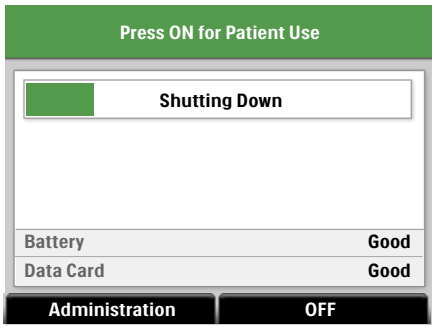
NOTE: The FR3 ignores the lock switch on the side of the data card. The FR3 writes to a data card until it is full. When the card is full, the FR3 displays a DATA CARD FULL, REPLACE DATA CARD message at shutdown. Install a blank FR3 data card after each use to avoid loss of data.

REVIEWING INCIDENT DATA

REVIEWING LAST-USE DATA IN INTERNAL MEMORY

To review summary information of the last incident stored in the internal memory on the FR3 screen, follow these steps:

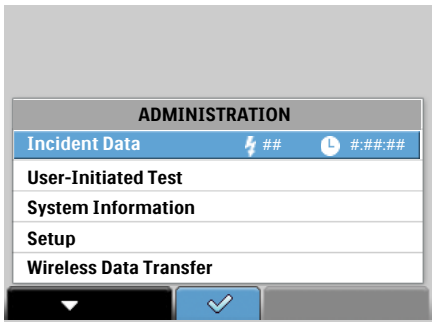
1. Press the green On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen



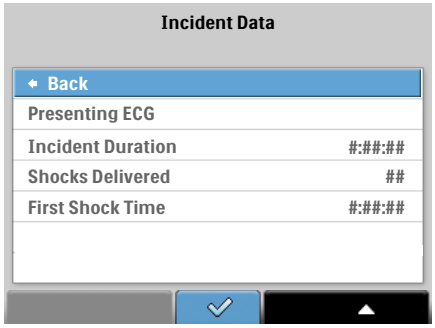
* ECG and Audio recording begin within seconds of the initial FR3 voice prompts. As a result, the first voice prompt may not be recorded. If pads have already been placed on the patient before the FR3 is activated, the first second of the presenting ECG may not be recorded.

2. Before the progress bar on the status screen is filled, press the ADMINISTRATION option button to go to the ADMINISTRATION screen.

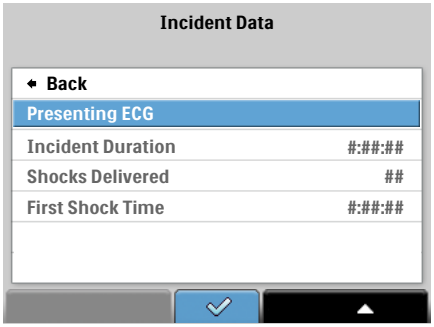
3. INCIDENT DATA is highlighted. Note that the shock count and total time for the last use are displayed. Press the ✓ option button to select the INCIDENT DATA screen.



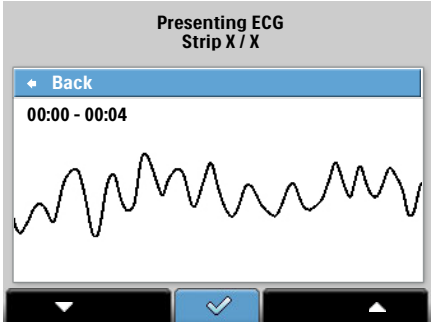
4. The INCIDENT DATA screen displays the incident duration in hours (if applicable), minutes, and seconds (h:mm:ss);* the total number of shocks delivered, and elapsed time from device on to first shock in hours (if applicable), minutes, and seconds (h:mm:ss); and provides access to the PRESENTING ECG screen.



5. To review the first 15 seconds of the presenting ECG, press the ▼ option button to scroll to PRESENTING ECG, then press the ✓ option button to select it.



6. The presenting ECG is displayed in 4-second segments on successive screens. To move to the next ECG screen, press the ▼ option button. To return to the previous ECG screen, press the ▲ option button. To exit any screen, press the ✓ option button and return to the INCIDENT DATA screen.



* If the battery has not been replaced when prompted and becomes depleted during a use, the incident duration is not updated and the data displayed will be from the previous use.

7. When you finish reviewing the data, press the ✓ option button to go back to the previous screen and so on until you return to the INCIDENT DATA screen.

8. Press the ▲ option button then press the ✓ option button to select BACK and return to the ADMINISTRATION screen. If you have no additional tasks to perform in ADMINISTRATION, press the On/Off button to display the status screen and put the defibrillator into standby.

The FR3 saves summary data for the most recent use in internal memory until the FR3 is used again.

REVIEWING DATA FROM AN FR3 DATA CARD

If an FR3 data card is installed when the FR3 is turned on, the FR3 automatically records detailed incident data on the card.

After the incident, you can access the information on the data card for review in either of the two ways described below.

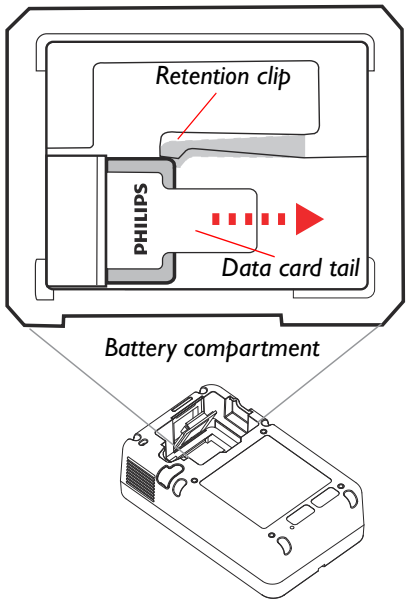
DATA CARD DOWNLOAD

To download detailed incident data directly from the FR3 data card to a computer with an appropriate HeartStart Event Review data management software product installed, follow these steps:

> NOTE: Unless the data card has been erased after each recorded use, it is possible that more than one incident will be recorded on the card. When the data card is full, the FR3 stops recording data to it

1. Remove the battery from the FR3 to access the FR3 data card.

2. Remove the data card from the data card slot in the bottom of the battery compartment.



NOTE: To remove the data card, grasp the card by its tail, press the retention clip away from the card, and pull the card out.

3. Install the data card in a computer with an appropriate Event Review software product installed or in a USB data card adapter connected to a computer with the software.

4. From the computer Start menu, open the Event Review software and follow the software's directions for downloading the recorded data.

5. If desired, use the Event Review program to erase the data card for reuse in the FR3. Philips recommends that you back up data then erase it from the data card after each incident in order to prevent loss or corruption of data.

6. Install a blank FR3 data card and re-install the battery so the FR3 will be ready for use in an emergency.

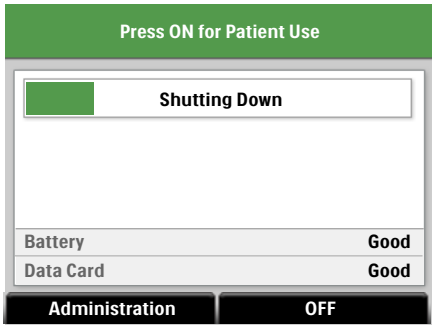
WIRELESS DATA TRANSFER

If you have an optional *Bluetooth* wireless technology transceiver module installed in your FR3, you do not need to remove the FR3 data card in order to transmit incident data. When installed in the FR3, the Philips *Bluetooth* wireless technology transceiver module can be used to facilitate data exchange between the defibrillator and a paired master device, such as a computer equipped with HeartStart Event Review or HeartStart Configure software. A *Bluetooth* wireless technology-enabled FR3 can:

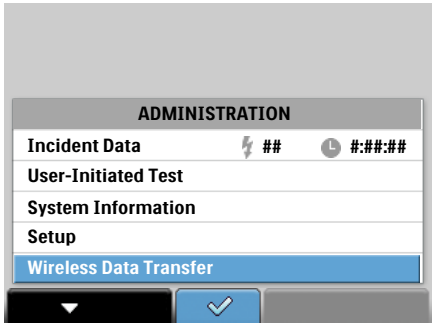
- Send event data.
- Send current configuration settings.
- Receive and update its device configuration settings (with the exception of language changes).
- Read and set the FR3 date and time clock to synchronize with the clock of the computer equipped with HeartStart Configure or a HeartStart Event Review software product.

When the FR3 is in administration mode, the files on the FR3 data card can be transmitted wirelessly via the transceiver to any nearby device with *Bluetooth* File Transfer Profile support. Certain versions of Event Review software products are required to view the data.

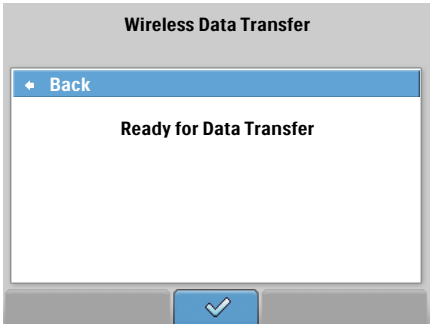
To transmit information from the data card via wireless transmission, follow these steps:



1. Press the green On/Off button to start the defibrillator. When voice prompts begin, press the button again to display the status screen.
2. Before the progress bar on the status screen is filled,* press the ADMINISTRATION option button to go to the ADMINISTRATION screen.
3. On the ADMINISTRATION screen, press the ▼ option button to scroll to WIRELESS DATA TRANSFER, then press the ✓ option button to select it.



4. The WIRELESS DATA TRANSFER screen displays a READY FOR DATA TRANSFER message and a ✓ option button. This screen enables the FR3 to communicate via *Bluetooth* wireless technology. To exit the screen, press the ✓ option button to return to the ADMINISTRATION screen.†



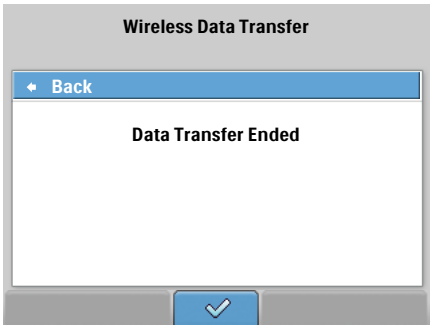
5. If you are using a computer equipped with one of the HeartStart Event Review software products, open the software and follow the instructions for wirelessly retrieving data from the FR3. Otherwise, use the software available on your *Bluetooth* wireless technology-enabled device to find and pair with the FR3 using your configured *Bluetooth* PIN. (See the Wireless PIN information under "Device

* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.

† If there is no Bluetooth activity for ten (10) minutes, the FR3 will return to the ADMINISTRATION screen. If you wish to resume activity, select WIRELESS DATA TRANSFER again.

Operation Parameters" on page 6-2.) Then use the *Bluetooth* File Transfer Profile capability on the device to transfer the file.

6. The FR3 screen displays a TRANSFERRING message during data transfer to Event Review.
7. When transfer is complete,* the screen displays a DATA TRANSFER ENDED message.
8. Press the ✓ option button to select the BACK command and exit to the READY FOR DATA TRANSFER screen.
9. If you have no additional tasks to perform in the WIRELESS DATA TRANSFER screen, press the ✓ option button to display the ADMINISTRATION screen. You can then press the On/Off button on the ADMINISTRATION screen and put the defibrillator into standby.



NOTE: These steps may be used to view and copy files on the FR3 data card using any device and software that has *Bluetooth* wireless technology File Transfer Profile capability. However, to prevent accidental erasure of patient data, wireless erasure of the data card event files can only be done using the appropriate Event Review software application. New incident data is recorded on the card until the card is full. To help ensure adequate recording space of an entire incident, use HeartStart Event Review data management software to transfer the data to a computer and erase the data card for re-use, or replace it with a new card as soon as possible after an incident.

* The transfer rate for patient data files that include audio recordings is about 14 seconds for each minute of audio recording.

A ACCESSORIES

LIST OF ACCESSORIES

The following accessories* for the HeartStart FR3 Defibrillator (FR3) are available separately from Philips:

- FR3 clinical use battery (spare recommended) [REF: 989803150161]
- Defibrillator Pads (spare recommended)
  - HeartStart SMART Pads III, 1 set [REF: 989803149981]
  - HeartStart SMART Pads III, 5 sets [REF: 989803149991]
  - HeartStart DP adult defibrillator pads, 1 set [REF: 989803158211]†
  - HeartStart DP adult defibrillator pads, 5 sets [REF: 989803158221]†
  - HeartStart SMART Pads II, 1 set [REF: 989803139261]
- FR3 Infant/Child Key with tether and decals [REF: 989803150031]
- Carry cases‡ and related items
  - FR3 rigid system case, with top and bottom case inserts, and Pads Sentry; accommodates spare pads, spare battery, Infant/Child Key, and Fast Response Kit [REF: 989803149971]
  - Bottom insert for FR3 rigid system case 989803149971 with Pads Sentry [REF: 989803150211]
  - FR3 soft system case, with Pads Sentry; accommodates spare pads, spare battery, and Infant/Child Key [REF: 989803150221]
  - FR3 small soft case, with Pads Sentry; accommodates spare pads and Infant/Child Key [REF: 989803173711]
  - Secure-pull case seal [REF: M3859A]
  - Replacement FR3 Pads Sentry for HeartStart SMART Pads III [REF: 989803150011]
- FR3 data card [REF: 989803150061]
- USB data card reader [REF: M3524A]
- FR3 language card and language decals [REF: 989803150101]
- *Bluetooth* wireless technology transceiver module [REF: 989803150081]
- Cabinets and mounts
  - Defibrillator wall-mount bracket [REF: 989803170891]
  - Defibrillator cabinet, semi-recessed [REF: PFE7023D]
  - Defibrillator cabinet, wall surface mount [REF: PFE7024D]
  - Defibrillator cabinet, basic [REF: 989803136531]

* Certain accessories require a prescription in the United States. Not all items are available worldwide; check with Philips for availability of optional accessories.

† These pads are indicated for external defibrillation, pacing, monitoring, and cardioversion and cannot be pre-connected to the FR3. The FR3 provides defibrillation only.

‡ Laerdal-branded rigid system case [REF: 989803157531], soft system case [REF: 989803162221] and small soft case [REF: 989803173721] are also available.

- Fast Response Kits
  - FR3 Fast Response Kit (hard case containing a pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe) [REF: 989803150111]
  - Fast Response Kit (zippered pouch containing a pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe) [REF: 68-PCHAT]
- Data Management and Configuration Software
  - HeartStart Event Review version 4.2* or higher, single PC license [REF: M3834A] or organization-wide license [REF: 989803141811]
  - HeartStart Event Review Pro version 4.2* or higher, single PC license [REF: 861431 option A01] or organization-wide license [REF: 861431 option A03]
  - HeartStart Event Review Pro upgrade for version 4.2* or higher,† single PC license [REF: 861436 option A01] or organization-wide license [REF: 861436 option A03]
  - HeartStart Configure version 3.0 or higher [REF: 861487]
  - HeartStart Data Messenger version 4.2* or higher, single PC license [REF: 989803143041 option A01] or organization-wide license [REF: 989803143041 option A03]
- Training
  - HeartStart FR3 Training Pack (rechargeable FR3 training battery, one pair of HeartStart Training Pads III, interconnect cable, and external manikin adapter) [REF: 989803150191]
  - Charger, for the FR3 989803150191rechargeable training battery; includes power cord [REF: 861394]
  - Replacement HeartStart Training Pads III [REF: 989803150181]
  - Spare HeartStart Training Pads III interconnect cable [REF: 989803150201]
  - AED Trainer 3 [REF: 861467]
  - FR2 Adult Training Pads‡ [REF: 07-10900]
  - Adult Pads Placement Guide [REF: M5090A]
  - Infant/Child Pads Placement Guide [REF: 989803139281]
  - External manikin adapter, 5 pack [REF: M5089A]

* Available to support FR3 in 2011.
† Upgrade for earlier HeartStart Event Review Pro software to support the FR3.
‡ Do not pre-connect these pads when training.

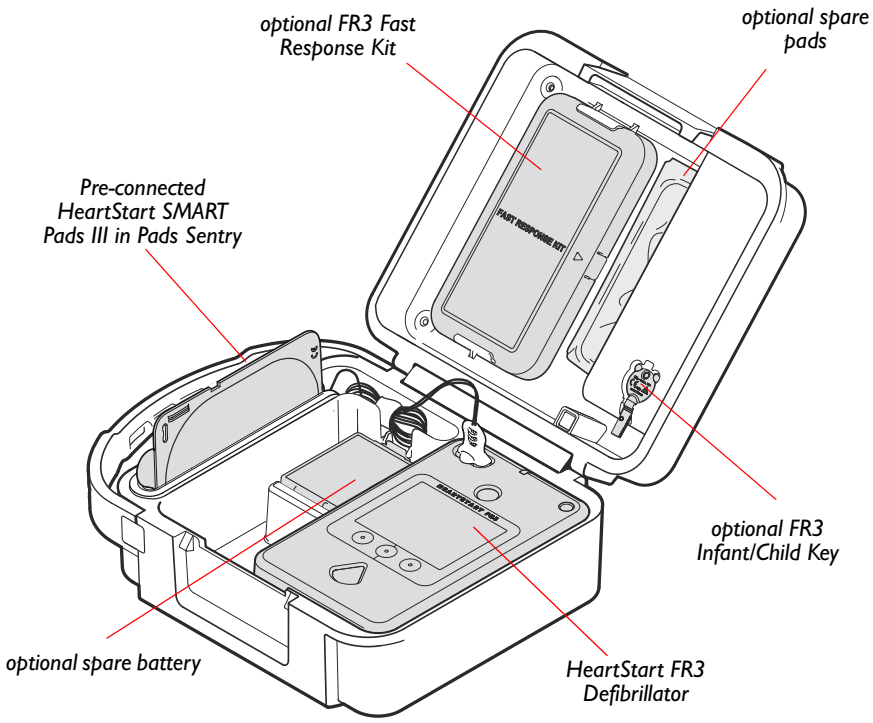
SELECTED OPTIONAL ACCESSORY DESCRIPTIONS

FR3 RIGID SYSTEM CASE

This rugged, rigid case provides a compact and convenient way to organize the FR3 and its major accessories. In addition, the case is designed so that opening the latch automatically turns on the FR3, saving time in an emergency. The FR3 does not have to be removed from the case for use.

The case bottom insert is also available separately to organize the FR3 and accessories in your own custom case. It provides a compartment for the defibrillator; a Pads Sentry that houses preconnected pads and allows for their testing as part of the periodic self-tests by the FR3; and storage for a spare battery.

The case top provides snap-in storage for optional accessories including a Fast Response Kit case, a spare pads pouch, and an Infant/Child Key. The Infant/Child Key can be tethered to the case to help ensure it is available when needed.



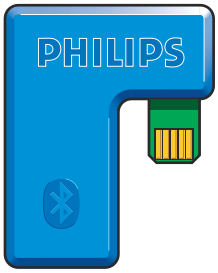
NOTE: Two other carry cases are also available: The FR3 soft system case with Pads Sentry accommodates spare pads, spare battery, and the Infant/Child Key; and the FR3 small soft case with Pads Sentry accommodates spare pads and the Infant/Child Key. See page A-1.



INFANT/CHILD KEY

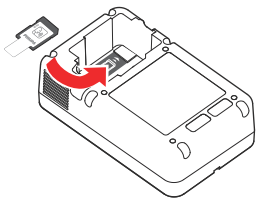
The FR3 Infant/Child Key has a distinctive pink, teddy-bear shaped head and a cylindrical post that is inserted into the FR3 to treat a sudden cardiac arrest victim who is under 55 lbs (25 kg) or 8 years old. The Infant/Child Key is supplied with a tether that can be threaded through the Key and then inserted through a slot in the top of the Infant/Child Key compartment in the upper portion of your FR3 system case, if desired. The tether is not required for using the Key.

With the Key in place, the FR3 automatically decreases the defibrillation therapy delivered from the adult dose to a level more appropriate for these patients and implements the configured infant/child CPR protocols.



BLUETOOTH WIRELESS TECHNOLOGY TRANSCEIVER MODULE

When installed in the FR3, the Philips *Bluetooth* wireless technology transceiver module can be used to facilitate data exchange between the defibrillator and a paired master device, such as a computer equipped with HeartStart Event Review Pro or HeartStart Configure or, with appropriate software, a third-party electronic patient care report (ePCR) or run reporting system. Over a serial link, the *Bluetooth* wireless technology-enabled FR3 can send event data, receive and update its device configuration settings, read and set the FR3 date and time clock to synchronize it with another clock, and send current configuration settings.

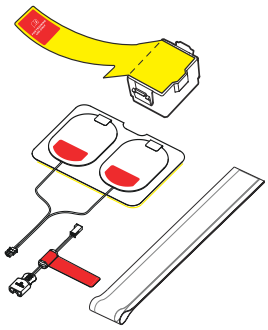


Installing the FR3 language card.

FR3 LANGUAGE CARD

The FR3 language card permits you to change the primary language of the FR3 from the default language. Directions for using the language card are provided with the card.

The FR3 language card and the HeartStart Configure software, available separately, are required to download a secondary language when the bilingual option is enabled in the FR3. The enabled bilingual option allows the responder to choose either the primary language or the configured secondary language immediately upon turning on the FR3. All voice and text prompts for that use of the FR3 will be in the selected language.



Training battery, training pads, and interconnect cable.

FR3 TRAINING PACK

The FR3 Training Pack includes the FR3 training battery, a set of HeartStart Training Pads III, a HeartStart Training Pads III interconnect cable, and an external manikin adapter. These reusable, optional accessories are designed for use with the FR3 for demonstration and training applications. The FR3 training battery is rechargeable using the 861394 battery charger only. Replacement training pads can be ordered separately. The interconnect cable is intended for indefinite reuse; a spare interconnect cable can be ordered separately. The training pack allows selection of three pre-set emergency scenarios designed to help responders become familiar with operating the FR3.

B GLOSSARY

The terms listed in this Glossary are defined in the context of the HeartStart FR3 Defibrillator (FR3) and its use.

TERM	MEANING
Advanced Mode	A programmable treatment mode that permits an authorized responder to control when the FR3 starts rhythm analysis and (model 861389 only) charging for shock delivery.
AED	Automated external defibrillator.
AED Mode	The standard FR3 treatment mode, with voice and text prompts guiding the responder through applying the defibrillator 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 FR3.
ALS	Advanced Life Support.
Alternative Language	See "Secondary Language."
Analysis	See "SMART Analysis."
Arrhythmia	An unhealthy, often irregular, beating of the heart.
Artifact	A signal from motion or other sources that is detected on the ECG.
Attend-to-Patient Period	A period following a no shock Advised (NSA) decision during which the responder may perform CPR, if needed, or otherwise attend to the patient.
Background Analysis/ Monitoring	Analysis for potentially shockable rhythms during NSA monitoring mode.
Bilingual Option	A feature of the FR3 that, when enabled, permits the user to choose between two configured languages when the device is turned on for use.
BLS	Basic Life Support.
Bluetooth File Transfer Profile and *Bluetooth* Serial Profile	The *Bluetooth* applications required on a computer with a *Bluetooth* transceiver and HeartStart Event Review Pro to wirelessly transfer data with an FR3 containing an installed *Bluetooth* transceiver module.

PHILIPS MEDICAL SYSTEMS

TERM	MEANING
Chirps	FR3 communication to user. Single chirps indicate the FR3 needs attention; press the On/Off button twice to access the status screen for information. Triple chirps indicate that the FR3 should be removed from service; contact Philips.
Clinical Use Battery	The 989803150161 battery. This battery is 12 VDC, 4.7 Ah, lithium manganese dioxide, disposable, long-life primary cells.
Configuration	The settings for all operating options of the FR3. The factory default configuration can be modified by authorized personnel using HeartStart Configure, separately available software. See "Setup."
CPR Duration	A programmable period provided by the FR3 during which the responder can administer CPR.
Defibrillation	Termination of cardiac fibrillation by applying electrical therapy across the heart.
Defibrillation Charge	Electrical energy stored in the capacitor of the FR3 as it arms for shock delivery.
Defibrillation Shock	See "SMART Biphasic Waveform."
Defibrillator Pads	The self-adhesive electrode pads applied to patient and used to detect the patient's heart rhythm and transfer the defibrillation shock.
ECG	Electrocardiogram, the electrical rhythm of the heart as detected through defibrillator pads.
ESD	Electrostatic discharge.
EMI	Electromagnetic interference.
Event	An action recognized or performed by the FR3 as a step in the sequence of using the device in an incident. Examples include: applying the pads to the patient, analyzing heart rhythm, delivering a shock, etc.
Fibrillation	See "Ventricular Fibrillation."
Heart Rhythm (ECG) Analysis	A system used by the FR3 to determine if the patient's heart rhythm is shockable — ventricular fibrillation (VF) or certain ventricular tachycardias (VTs). See "SMART Analysis."
HeartStart Configure	A software application, available separately, that allows the Medical Director to modify the factory default configuration of the FR3.
HeartStart Event Review	A suite of data management software for use by trained personnel to review and analyze FR3 use on a patient. Information is available from Philips on the internet at www.philips.com/EventReview.

TERM	MEANING
Impedance	Electrically, the total opposition offered by the body to the flow of the electrical shock waveform delivered by the FR3. The FR3 automatically monitors the electrical impedance between the defibrillator pads placed on the patient's bare skin, and adjusts the shock waveform appropriately.
Incident	The series of events involved in treating a patient with the FR3.
Liner	The surface on which HeartStart defibrillator and training pads are supplied. The pads should not be peeled from the liner until they are needed for use.
Manual Charge	A feature of the advanced mode that allows the user to arm the FR3 for shock delivery.
Manual Disarm	A feature of the advanced mode that allows the user to safely dissipate the FR3 stored shock energy internally.
Non-shockable Rhythm	A heart rhythm that the FR3 determines is not appropriate for shock delivery.
NSA	No Shock Advised decision, made by the FR3 based on analysis of the patient's heart rhythm.
NSA Monitoring Mode	A mode of background analysis available following a no shock advised (NSA) decision when NSA Action is configured to NSA Monitor. In NSA monitoring mode, the FR3 conducts background monitoring of patient rhythm and automatically goes into rhythm analysis if a shockable rhythm is detected.
Option Button	One of three buttons below the FR3 display screen. Any active option button is contextually labeled on the screen above it.
Pads	See "Defibrillator Pads."
Peak Current	The highest current level reached during the biphasic waveform. This happens at the beginning of the first phase.
Pediatric Defibrillation	Defibrillation of a child under 55 lbs (25 kg) or 8 years old. It is recommended that the FR3 Infant/Child Key accessory, available separately from Philips, be used for pediatric patients, if available.
Periodic Self-Tests	Daily, weekly, and monthly tests automatically conducted by the FR3 when it is in standby. The tests monitor many key functions and parameters of the FR3, including battery capacity and the state of its internal circuitry.

TERM	MEANING
Presenting ECG	The heart rhythm seen by the FR3 when it is first connected to the patient (via the defibrillator pads) and begins rhythm analysis. The first 15 seconds of the presenting ECG are recorded in FR3 internal memory.
Primary Battery	See "Clinical Use Battery."
Primary Language	The language the FR3 uses for voice and text prompts when the bilingual option is not enabled.
Prompts	The voice commands and screen text used to guide the responder through use of the FR3 to treat the patient.
Protocol	A sequence of operations performed by the FR3 to direct patient care in the AED mode.
Quick Shock	A feature of the FR3 that provides a time from the end of the "Stop CPR" prompt to armed state for shock delivery of less than 8 seconds.
Ready Light	The green LED at the top center of the front panel of the FR3 that flashes to indicate that the FR3 is in standby, and is on steady when the FR3 is in use.
Rechargeable Training Battery	The FR3 rechargeable training battery, available in the FR3 Training Pack 989803150191, used with the 861394 charger only.
Record Audio	A feature of the FR3 that, if enabled, allows sound recording to an FR3 data card during use of the FR3 in an incident.
Rhythm Analysis	See "SMART Analysis."
Secondary Language	The alternative language the FR3 uses for voice and text prompts when the bilingual option is enabled and the responder chooses it after turning on the FR3 for use.
Sensitivity	A measure of the ability of the FR3 to reliably detect and identify shockable heart rhythms.
Setup	See "Configuration."
Shock Series	Also called shock stack. A sequence of one or more shocks, each separated by no more than a preset interval. After completion of a shock series, the FR3 automatically provides a CPR protocol. See "Shock Series Interval."
Shock Series Interval	A programmable interval used by the FR3 to decide if the shocks are part of the same shock series.
Shockable Rhythm	Ventricular fibrillation and certain ventricular tachycardias associated with sudden cardiac arrest.

TERM	MEANING
Shock Waveform	See "SMART Biphasic Waveform."
SMART Analysis	The proprietary algorithm used by the FR3 to analyze the patient's heart rhythm and determine whether a shock is advised.
SMART Biphasic Waveform	The patented defibrillation shock waveform used by the FR3. It is an impedance-compensated truncated biphasic waveform. It delivers adult defibrillation therapy at a peak current of 32 amperes (150 Joules, nominal), into a 50 ohm load. Pediatric defibrillation with optional FR3 Infant/Child Key installed provides therapy at a peak current of 19 amperes (50 Joules, nominal), into a 50 ohm load.
SMART CPR	An algorithm that evaluates key characteristics of the presenting VF and determines the initial therapy: shock first, or CPR First quickly followed by shock.
Specificity	A measure of the ability of the FR3 to reliably detect and identify non-shockable heart rhythms.
Standby	The operating mode of the FR3 when a battery has been installed, and the unit is turned off. When the FR3 is standby and ready for use, the green Ready light flashes. When the FR3 is in standby but needs attention, it gives alert chirps.
Status Indicator	See "Ready Light."
Sudden Cardiac Arrest (SCA)	The sudden cessation of the heart's pumping rhythm.
Training Mode	Operation of the FR3 with an FR3 training battery and training pads. Use in training mode permits selection of predefined ECG input training scenarios without actual shock energy delivery.
User-Initiated Test	Detailed test of the FR3 including interactive and automatic testing.
Ventricular Fibrillation (VF)	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 the most common cause of sudden cardiac arrest.
Ventricular Tachycardia (VT)	An abnormal fast heart rhythm that originates in the ventricles of the heart. The FR3 detects certain types of VTs and advises a shock in response.
Waveform	See "SMART Biphasic Waveform."

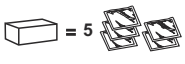
TERM	MEANING
Wireless Transmission	Use of an optional FR3 *Bluetooth* wireless technology transceiver module to transmit data from the FR3 to a *Bluetooth* wireless technology-enabled computer or from such a computer using HeartStart Configure or a HeartStart Event Review suite application to the FR3.

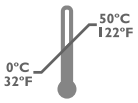
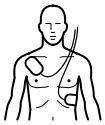
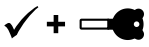
PHILIPS MEDICAL SYSTEMS

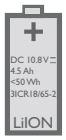
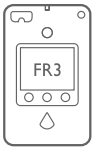
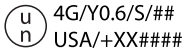
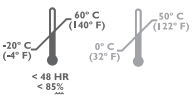
C SYMBOLS AND CONTROLS

The following table explains the symbols used on the HeartStart FR3 Defibrillator (FR3), its accessories, and their packaging.

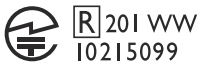
SYMBOL	DESCRIPTION
	REGULATORY MARKS AND GENERAL
CE 0123	Meets the requirements of the European medical device directives 93/42/EEC.
CE	Meets the requirements of the applicable European directive.
C SA US	This product has passed relevant U.S. and Canadian safety tests by CSA, a Nationally Recognized Test Lab.
N11695 V00341	This product has been certified by the Australian Communication Authority.
EC REP	Authorized representative in the European Community.
Rx ONLY	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Printed on recycled paper.
	Refer to operating instructions.
	Handle with care.
	Protect from moisture.
	Dispose of in accordance with your country's requirements.
	Manufacturer.
SN	Serial number.
REF	Reference order number.

SYMBOL	DESCRIPTION
LOT	Lot number.
	This product is disposable and is for single patient use only.
	FR3 DEFIBRILLATOR
	On/Off button (green). Turns the FR3 on or off; disarms the FR3, stops automatic self-test.
	Shock button (orange). Delivers shock to patient when the FR3 is charged.
	Option buttons (gray). When in administration mode, press the appropriate option button, identified by a label on the FR3 display screen, to move around in or to select an item from a menu on the FR3 display screen. When in AED or advanced mode, press the appropriate option button to enable device features relevant to the mode.
	Identifies the location of the FR3 Infant/Child Key port on the FR3.
	Install the FR3 data card or FR3 language card in the direction shown.
	Defibrillation protection. Defibrillation protected, type BF patient connection.
	Risk of electrical shock.
IP55	With battery installed, meets IEC 529 class IP55.
	This defibrillator uses the identified clinical battery.
	Do not use the FR3 in a magnetic resonance environment.
	DEFIBRILLATOR AND TRAINING PADS
	Box contents = 5 pads pouches.

SYMBOL	DESCRIPTION
	Pouch contents: one pair of pads.
	Store the pads at temperatures between 0° and 50° C (32° and 122° F).
	Non-sterile.
	This product does not contain natural rubber latex.
	Do not leave attached to patient for more than 24 hours.
	Use these pads before the expiration date shown. Date format is MM-YYYY.
	For use with Philips Heartstream/HeartStart and Laerdal Heartstart ForeRunner, FR, FR2/FR2+, and FR3 AEDs.
	Pads placement for adults.
	Pads placement for infants and children under 55 lbs (25 kg) or 8 years old.
	Do not use these pads with Laerdal Heartstart model 911, 1000, 2000, or 3000 AEDs.
	Do not use these pads with Philips HeartStart HS1 model M5066A, M5067A, and M5068A AEDs.
	These pads may be used with the FR3 on infants or children under 55 lbs (25 kg) or 8 years old in conjunction with the 989803150031 Infant/Child Key.
	These pads may be used with the HeartStart FRx on infants or children under 55 lbs (25 kg) or 8 years old in conjunction with the 989803139311 Infant/Child Key.

SYMBOL	DESCRIPTION
	BATTERIES
	Lithium manganese dioxide chemistry. 12 volts direct current output. 4.7 ampere hours. Contains < 7 grams lithium.
	Lithium ion battery chemistry. 10.8 volts direct current output. 4.5 ampere hours. < 50 Watt hours. (2 strings of 3 series-connected, cylindrically shaped, lithium ion-cobalt cells connected in parallel, each 18 mm maximum diameter and 65 mm maximum overall height.)
	Contains one battery.
	This battery is for use with the FR3.
	This packaging has been tested to United Nations standards and certified to be capable of protecting the lithium battery it contains.
	Class 9 miscellaneous dangerous goods. (Symbol required on outer packaging by freight carrier regulations to identify shipments containing lithium batteries.)
	Install battery before the date shown on this label. in order to get the full specified battery life. Date format is YYYY-MM.
	Do not crush.
	Do not expose to high heat or open flames. Do not incinerate.
	Do not mutilate or open.
	Transport and store the battery under the environmental conditions listed. Do not expose the battery to a relative humidity of more than 85% for more than 48 hours.

SYMBOL	DESCRIPTION
	Transportation requirements (refer to associated thermometer symbol).
	Storage requirements (refer to associated thermometer symbol).
	Dispose of the battery in accordance with your country's requirements.
BATTERY CHARGER	
	Electrical input.
	Electrical output.
	For indoor use only.
	Class II appliance with respect to protections against electric shock, per the requirements of IEC 60335-1.
	This product has passed relevant U.S. and Canadian safety tests by UL, Nationally Recognized Test Laboratory.
DATA CARD AND LANGUAGE CARD	
	FR3 data card.
	FR3 language card.
	“Lockable” switch symbol on FR3 data card or FR3 language card. (The FR3 ignores this switch.)
FR3 INFANT/CHILD KEY	
	Intended for use on patients under 8 years old or 55 lbs (25 kg).

SYMBOL	DESCRIPTION
	BLUETOOTH WIRELESS TECHNOLOGY MODULE
	*Bluetooth* wireless technology.
	Be careful not to pinch finger when replacing wireless technology module compartment cover.
	This device has passed the radio frequency emission requirement for FCC Rule Parts 15C.
	Interference could occur in the vicinity of equipment marked with this symbol.
	Complies with the Technical Regulations Conformity Certificate of Specified Radio equipment in Japan (ordinance of MPT No. 37, 1981)
	FR3 FAST RESPONSE KIT
	Pocket mask.
	Gloves.
	Disposable razor.
	Paramedics scissors.
	Absorbent wipe.

D SMART CPR

The HeartStart FR3 Defibrillator (FR3) has a CPR First parameter that provides a tool for Medical Directors to implement existing or emerging protocols. Currently, some emergency response protocols incorporate a CPR protocol prior to applying the AED. Although this provides for initial CPR treatment, since the device is not attached to the patient, it cannot collect data or provide the responder with prompts or an initial CPR protocol until the pads are applied.

Research has shown that some SCA patients – particularly those presenting with low-amplitude, low-frequency VF rhythms typical of longer downtimes – may not benefit from an initial shock, and for these patients a CPR protocol prior to defibrillation may improve outcome. [1-3]

Accordingly, some Medical Directors may wish to configure the FR3 to be able to provide an initial CPR protocol prior to defibrillation. Before making that decision, the Medical Director should consider the overall impact the selected setting would have on the SCA emergency response system, and train responders accordingly. Other factors to be considered include:

- Emergency system response times
- Responder skill level
- Prevailing protocols and time and cost for training
- Expected changes in response protocols

Based on a consideration of these factors, the Medical Director can configure the FR3 to any of four CPR First settings: OFF, SMART CPR AUTO1, SMART CPR AUTO2, and USER. These are defined in greater detail below.

1 Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad B, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: a random trial. *JAMA* March 19, 2003. 289:11:1389-1395.

2 Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. The influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation. *JAMA*, April 7, 1999, 281:13:1182-1188.

3 Weisfeldt ML, Becker LB. Resuscitation after cardiac arrest: a 3-phase time-sensitive model. *JAMA*, December 18, 2002. 288:23:3035-3038.

"OFF" SETTING

The OFF setting means the FR3 will not provide an initial CPR protocol prior to defibrillation of a shockable rhythm. Thus, once the FR3 is attached, it will advise an immediate shock for all SCA patients presenting with a shockable rhythm — even those who may benefit from CPR first — before it provides a CPR protocol. This setting represents the historical behavior of AEDs and is therefore the default setting for CPR First.

"SMART CPR AUTO1" AND "SMART CPR AUTO2" SETTINGS

It is often not possible for the responder to know whether an individual patient might benefit from CPR first or defibrillation first. When set to AUTO1 or AUTO2, the FR3 analyzes the patient's initial rhythm and automates the decision as to whether an individual patient should receive an initial shock or CPR first. Based on a database of ECG recordings of actual resuscitation attempts,* the SMART CPR algorithm evaluates the initial ECG amplitude and frequency characteristics — both known predictors of shock success — and calculates the likelihood of the return of spontaneous circulation (ROSC) following a defibrillation shock. If the likelihood is low, the FR3 will provide a CPR protocol prior to defibrillation. If high, the device will advise immediate defibrillation. In either case, the device adjusts its voice and text prompts appropriately.

WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings has not been established in patients under 55 lbs (25 kg) or 8 years old.

SMART CPR AUTO1. Provides immediate defibrillation for more than 90%† of shockable patients who are likely to achieve ROSC (less than 10% receive CPR first). Of those shockable patients who are unlikely to achieve ROSC, more than 50% will receive CPR first.

SMART CPR AUTO2. Provides immediate defibrillation for more than 80%† of shockable patients who are likely to achieve ROSC (less than 20% receive CPR first). Of those shockable patients who are unlikely to achieve ROSC, more than 60% will receive CPR first.

CAUTION: The SMART CPR algorithm may be affected by artifact in the ECG, including pacemaker artifact in patients with implanted pacemakers.

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* Data collected from multi-center, multi-national out-of-hospital and in-hospital adult sudden cardiac arrest rhythms. The SMART CPR algorithm was developed based on VF, polymorphic VT, and ventricular flutter rhythms.

† Based on observed performance. ROSC was determined by several parameters, including patient assessment, ECG analysis, and/or patient impedance cardiography.

"USER" SETTING

The USER setting provides the responder with a means to manually initiate a CPR protocol by pressing the CPR option button during the first rhythm analysis and shock cycle, based on either a patient assessment protocol or standing orders from the Medical Director. The FR3 can thus be applied immediately to the patient, enabling the device to collect data and provide reminder text prompts that the CPR option button is available. The responder presses the CPR option button to start a CPR protocol. The FR3 will continue with rhythm analysis unless the CPR option button is pressed.

With the FR3 CPR First setting set to USER, the FR3 provides an opportunity for the responder to initiate a CPR protocol for all patients. In addition, an Analyze option button is provided to allow the responder to exit a CPR protocol and restart analysis.

E NSA ACTION

The HeartStart FR3 Defibrillator (FR3) has an NSA Action parameter that provides a tool for Medical Directors to implement existing or emerging protocols regarding device behavior during the attend-to-patient period that follows any no shock advised (NSA) decision. During this period, the responder may perform CPR or otherwise attend to the patient, as needed.

The NSA Action setting selected should be based on the level of responder training, anticipated contextual use of the FR3, and the requirements of local protocol. Before making that decision, the Medical Director should consider the overall impact the selected setting would have on the SCA emergency response system, and train responders accordingly.

The NSA Action parameter can be configured for either NSA CPR or NSA Monitor.

NOTE: The ECG display provided by the FR3 is not intended to provide diagnostic or ST segment interpretation.

"NSA CPR" SETTING

This is the default setting for NSA Action. When set to NSA CPR, the FR3 provides an attend-to-patient period after each NSA decision.

- The duration of the attend-to-patient period is based on the configured Adult or Infant/Child NSA CPR Duration.

NOTE: The FR3 does not perform background monitoring during the attend-to-patient period. At the end of the period, the FR3 automatically returns to rhythm analysis unless the user has pressed a button, as described below.

If the FR3 is configured to NSA CPR, NSA CPR Coaching during the attend-to-patient period can be set to ALWAYS or USER, the default.

"NSA CPR COACHING — USER" SETTING

This setting is designed for use in systems where the responder is permitted to determine if CPR Coaching is appropriate during the attend-to-patient period.

- If the metronome is set to ON: The FR3 automatically provides a CPR option button* for the first 30 seconds of the attend-to-patient period.
- After announcing that no shock is advised, the FR3 prompts the user to press the button to begin CPR.
- If the responder presses the CPR option button while it is active, the FR3 initiates the configured NSA CPR protocol (based on the configured adult or infant/child NSA CPR duration) and provides an audio beat for each compression.

If the responder does *not* press the CPR option button while it is active, because he/she determines that CPR is not needed or prefers to provide CPR without the metronome, the audio beats are not provided. If the Analyze option button is configured to ON (non default):

- The Analyze button becomes automatically available for the full duration of the attend-to-patient period, unless NSA Action is set to NSA Monitor (see below).
- The Analyze button is available during NSA CPR or NSA monitoring, if the CPR or Monitor options were selected first.

"NSA CPR COACHING — ALWAYS" SETTING

This is the default CPR Coaching setting for NSA CPR. This setting is designed to accommodate local protocols that always require administration of CPR after any NSA decision. If configured for NSA CPR Coaching-Always:

After announcing the NSA decision, the FR3 immediately initiates the configured NSA CPR protocol with metronome, if configured. If the Analyze option button is configured to ON:

- The button is available for the full duration of the NSA CPR protocol.
- If the responder presses the Analyze option button, the FR3 ends the NSA CPR protocol and initiates heart rhythm analysis.

"NSA MONITOR" SETTING

This setting is designed for use in systems where, under medical direction, trained responders are permitted to use the FR3 ECG model to assess patients who may have an elevated risk for a life-threatening cardiac event. The NSA Monitor setting allows the responder, at his/her discretion, to initiate background monitoring by the FR3 after an NSA decision. This enables relatively long-term patient assessment during patient transport or air travel, for example.

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* The CPR option button parameter described on page 6-5 does not apply to NSA Action settings.

- When configured to NSA Monitor, upon making an NSA decision, the FR3 provides an attend-to-patient period and a Monitor option button for the duration of the attend-to-patient period. The duration of the attend-to-patient period is based on the configured Adult or Infant/Child NSA CPR Duration.

If the metronome setting is ON:

- The FR3 provides a CPR option button for the first 30 seconds of the attend-to-patient period.*
- After announcing that no shock is advised, the FR3 prompts the user to press the button to begin CPR.
- If the responder presses the CPR option button while it is active, the FR3 exits the attend-to-patient period and initiates the configured NSA CPR protocol and provides an audio beat for each compression.

If the responder does *not* press the CPR option button while it is active or prefers to provide CPR without the metronome, the audio beats are not provided. If the responder presses the Monitor option button at any time during the attend-to-patient period:

- The FR3 exits the attend-to-patient period and initiates continuous background monitoring with an active CPR option button for the duration of monitoring.

NOTE: The CPR option button becomes active as soon as the Monitor option button is pressed, and remains active for the duration of NSA monitoring mode.

- If the pads become detached or have poor contact, the FR3 exits NSA monitoring mode and provides prompts for pads attachment.
- If the FR3 detects a potentially shockable rhythm during NSA monitoring mode, it chirps once to alert the user, then automatically exits the NSA monitoring mode and begins rhythm analysis.
- If the FR3 detects 15 seconds of artifact, it prompts the responder to press the CPR button to begin CPR if needed.
- If it detects 60 seconds of artifact, it begins rhythm analysis.
- If the ECG display is enabled for the FR3 ECG model, the FR3 displays both the patient's ECG and heart rate during background monitoring.

* The separate CPR option button parameter setting does not apply to NSA Action settings.

- If the monitored heart rate drops below 30 bpm, the FR3 prompts the responder to check the patient and, if needed, to press the CPR button to begin CPR. If the responder presses the CPR option button, the FR3 exits NSA monitoring mode and initiates the configured NSA CPR protocol.

If the Analyze option button is configured to ON:

- The button is available for the full duration of the NSA monitoring mode.
- If the responder presses the Analyze option button, the FR3 exits the NSA monitoring mode and initiates heart rhythm analysis.

F ADVANCED MODE

The HeartStart FR3 Defibrillator (FR3) provides an advanced mode that allows responders who are appropriately trained to manually override the programmed FR3 protocol and take responsibility for certain aspects of the operating sequence used by the FR3 to treat the patient.

The FR3 can be configured to permit manual control of the analyze and, for the FR3 ECG model 861389 only, shock charge functions. As described in Chapter 6, "Configuration," the factory default configuration of the FR3 must be modified to provide access to advanced mode features.

CAUTION: Alteration of the factory default configuration of the FR3 can affect its performance and should be performed under the authorization of the Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

CAUTION: The FR3 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 manual shock delivery. See page 5-5, "Monitoring Cautions."

The advanced mode features are 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 FR3 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 and responsiveness; to deploy the defibrillator pads; and to follow the voice and text prompts provided by the FR3 in its automated (AED) mode. When an ALS-trained responder arrives, the BLS responder turns over 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 analysis and charge features of the FR3. In addition, when configured for advanced mode use, the repeat rate for patient care prompts can also be configured to any of three different settings.

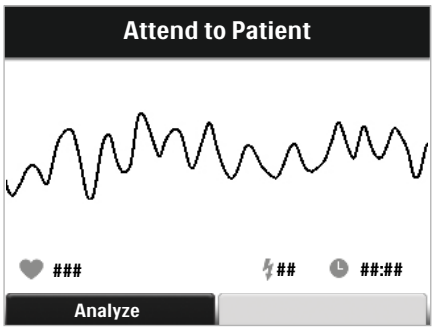
PHILIPS MEDICAL SYSTEMS

NOTE: When the secondary language in a bilingual option-enabled device is in use, the FR3 will continue to operate in the secondary language when the FR3 is put into advanced mode. To change to the primary language if desired, press the On/Off button twice to restart the FR3, select the language, and then select manual mode.

TO USE THE MANUAL ANALYZE FEATURE

The manual analyze feature is available in the FR3 Text model 861388, when the Advanced Mode Use parameter is set to ANALYZE, and in the FR3 ECG model 861389 when the Advanced Mode Use parameter is set to either ANALYZE or CHARGE.

To enter the advanced mode during use of an FR3 with the manual Analyze feature enabled, make sure pads are attached to the patient, then *press the left and right option buttons simultaneously.*



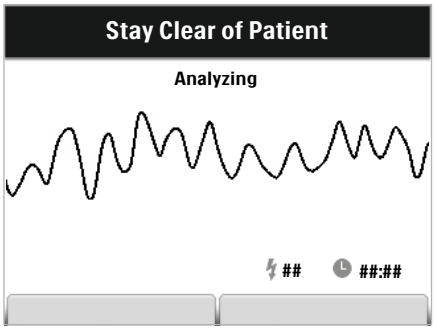
This brings up the main ADVANCED MODE screen, which displays the elapsed time of the use, the total number of shocks since the device was turned on, and (in the FR3 ECG model only) the current heart rate if available. The left option button is labeled ANALYZE. The screen on the FR3 ECG model 861389 also displays the patient's heart rate and ECG, even if the device is not configured for ECG display in the AED mode. The AED immediately begins background monitoring of the heart rhythm.

NOTE: If the FR3 detects a patient heart rate of less than 30 bpm, it provides a voice prompt to check the patient. The prompt is repeated at the configured advanced use prompt repeat rate as long as the low heart rate persists. If the FR3 detects a pacemaker, it provides a PACEMAKER DETECTED alert. Pacemaker artifact is displayed on the FR3 ECG model. In both the FR3 ECG and Text models, the FR3 rhythm analysis algorithm is designed to remove pacemaker artifact from the signal for analysis. However, due to differences between pacemaker therapy designs, artifact removal cannot always be achieved.

You can press the ANALYZE option button at any time to initiate rhythm analysis. If the FR3 detects a shockable rhythm during monitoring, it provides a voice prompt to press the ANALYZE button. The prompt is repeated at the configured advanced use prompt repeat rate as long as the shockable rhythm persists.

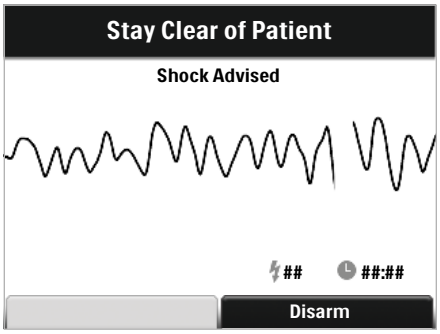
CAUTION: *If you do not press the ANALYZE option button when prompted,* the FR3 does *not* analyze and prompt if a shock is advised. It is important that you understand that entering the advanced mode entails taking responsibility for this function.

As soon as analysis begins, the FR3 prompts you to stay clear of the patient.



If rhythm analysis results in a No Shock Advised, the FR3 announces that no shock is advised, then returns to the main ADVANCED MODE screen and continues to monitor the patient's heart rhythm.

If the rhythm analysis results in a Shock Advised decision, the FR3 directs you to stay clear of the patient and provides Shock Advised prompts. When charging is complete, it gives a continuous tone and prompts you to press the flashing orange Shock button.*



If the FR3 determines while it is charging that the heart rhythm has changed to a non-shockable rhythm, it automatically aborts the shock and gives a voice prompt announcing that the shock was cancelled and that no shock is advised, then returns to the main ADVANCED MODE screen.

After shock delivery, the FR3 returns to the main ADVANCED MODE screen and continues to monitor the patient's heart rhythm.

To return to normal AED mode operation, turn the FR3 off and then on again, by pressing the On/Off button twice.

TO USE THE MANUAL CHARGE FEATURE (861389 ONLY)

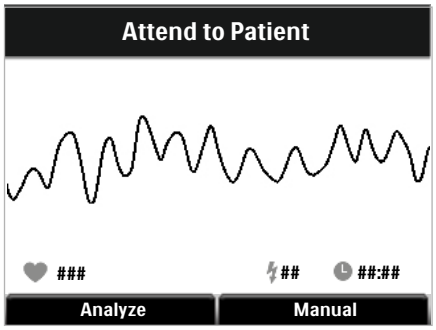
The manual charge feature is available only in the FR3 ECG model 861389, when the Advanced Mode Use parameter is set to CHARGE.

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* If you press the On/Off button when the FR3 has advised a shock and instructed you to press the flashing orange Shock button, a voice prompt tells you "Press the flashing orange button now or device will disarm." This prompt is repeated at intervals until 30 seconds have passed, when the FR3 announces "Shock button not pressed, attend to patient." At this point, you can turn off the FR3 if desired.

To enter the advanced mode during use of an appropriately configured FR3, make sure pads are attached to the patient, then press left and right option buttons simultaneously.

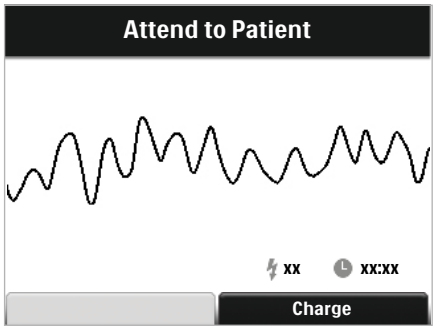
This brings up the main ADVANCED MODE screen, which displays the patient's ECG, the elapsed time of the use, the total number of shocks since the device was turned on, and the current heart rate if available. The ECG is displayed even if this parameter is set to OFF. The left and right option buttons are labeled ANALYZE and MANUAL, respectively.



You can press the ANALYZE option button to initiate rhythm analysis or, if the FR3 detects a shockable rhythm during monitoring, it provides a voice prompt to press the ANALYZE button. The prompt is repeated at the configured advanced use prompt repeat rate as long as the shockable rhythm persists.

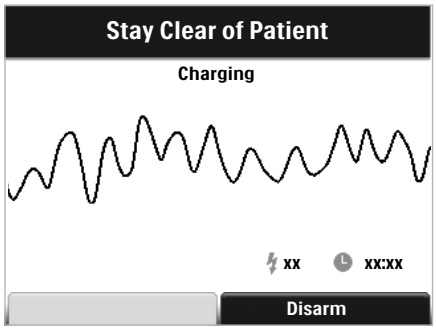
NOTE: If the FR3 detects a patient heart rate of less than 30 bpm, it provides a voice prompt to check the patient. The prompt is repeated at the configured advanced use prompt repeat rate as long as the low heart rate persists. If the FR3 detects a pacemaker, it provides a PACEMAKER DETECTED alert. Pacemaker artifact is displayed on the FR3 ECG model. In both the FR3 ECG and Text models, the FR3 rhythm analysis algorithm is designed to remove pacemaker artifact from the signal for analysis. However, due to differences between pacemaker therapy designs, artifact removal cannot always be achieved.

To enable manual initiation of charging for shock delivery, press the MANUAL option button. A voice prompt confirms the selection, and the screen provides a CHARGE option button.

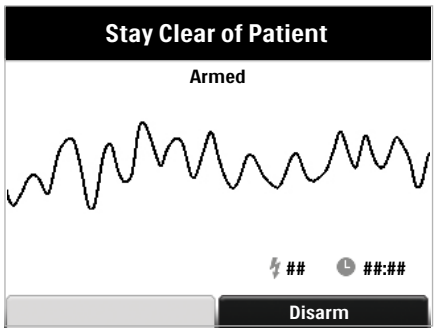


Observe the displayed ECG. If in your clinical judgment a shock is warranted, press the CHARGE option button. The FR3 will immediately charge for shock delivery.

As soon as charging begins, the FR3 provides CHARGING prompts and displays a message to stay clear of the patient. The FR3 gives intermittent tones while it is charging. If in your clinical judgment a shock is not warranted, you can press the DISARM option button to disarm the defibrillator and return to rhythm analysis.



When charging is complete, the FR3 gives a continuous tone. The screen message becomes ARMED and the Shock button light flashes. Press the Shock button to deliver a shock. However, if in your clinical judgment a shock is not warranted, you can press the DISARM option button to disarm the defibrillator and return to rhythm analysis.



CAUTION: *If you do not press the flashing Shock button within 30 seconds of being prompted,* the FR3 automatically disarms internally and does not deliver a shock. It provides a voice prompt that the shock button was not pressed, and the display returns to the main ADVANCED MODE screen.

NOTE: You cannot turn off the FR3 while it is prompting you to deliver a shock.*

After shock delivery, the FR3 returns to the main ADVANCED MODE screen. To return to normal AED mode operation, turn the FR3 off and then on again, by pressing the On/Off button twice.

* If you press the On/Off button when the FR3 has armed for delivering a shock and instructed you to press the flashing orange Shock button, a voice prompt tells you "Press the flashing orange button now or device will disarm." This prompt is repeated at intervals until either the Shock button is pressed or 30 seconds has passed, when the FR3 announces "Shock button not pressed, attend to patient." At this point, you can turn off the FR3 if desired.

G SPECIFICATIONS

The specifications for the HeartStart FR3 Defibrillator (FR3) provided in this chapter apply to both the FR3 ECG model 861389 and the FR3 Text model 861388, unless otherwise noted. Additional information can be found in the *Technical Reference Manual* for the FR3, located online at www.philips.com/productdocs.

FR3 SPECIFICATIONS

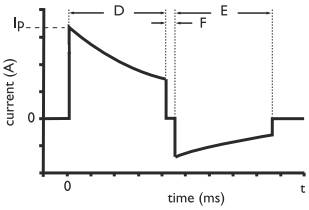
PHYSICAL

CATEGORY	NOMINAL SPECIFICATIONS
Size	2.7" high x 5.3" wide x 8.7" deep (6.9 cm x 13.5 cm x 22.1 cm).
Weight	3.5 lbs (1.6 kg) with FR3 standard clinical use battery installed.

ENVIRONMENTAL

CATEGORY	NOMINAL SPECIFICATIONS
Temperature and Relative Humidity	Operating (battery installed, pads connected): 32° to 122° F (0° to 50° C); 5% to 95% relative humidity (non-condensing). Standby/Storage (battery installed and defibrillator pads pre-connected): 32° to 122° F (0° to 50° C); 10% to 75% relative humidity (non-condensing). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.
Altitude	Meets IEC 60601-1:5.3 [1013 to 572 mbar (hPa), equivalent to air pressure from 0 to 15,000 feet; 0 to 4,572 meters].
Shock/Drop Abuse Tolerance	Meets MIL-810F 516.5, Procedure IV (after a 1 meter drop to any edge, corner, or surface, in standby mode).
Vibration	Meets MIL-810F 514.5C-17.
Sealing	Meets IEC 529 class IP55 with battery installed.
ESD/EMI	See Appendix H, "Additional Technical Data."
EMI – Aircraft	Meets RTCA/DO-160E:2004 Section 20 (Category D - Radiated Immunity; Category K - Conducted Immunity) and Section 21 (Category M - Charging). See Appendix H, "Additional Technical Data."

DEFIBRILLATOR

CATEGORY	NOMINAL SPECIFICATIONS
Charge Control	Controlled by SMART Analysis for automated operation. Can be programmed for manual initiation using advanced mode of the 861389.
Shock Cycle Timing	See page H-5, "Shock cycle timing."
"Charge Complete" Indicator	Orange Shock button flashes, the FR3 gives a continuous tone and prompts user to deliver shock.
Waveform Parameter	Biphasic truncated exponential. Waveform parameters are automatically adjusted as a function of patient defibrillation impedance. In the diagram at right, D is the duration of phase 1 and E is the duration of phase 2 of the waveform, F is the interphase delay (500 µs), and Ip is the peak current.  The FR3 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 below: Adult Defibrillation Load Resistance (Ω) / Phase 1 Duration (ms) / Phase 2 Duration (ms) / Peak Current (A) / Delivered Energy (J) 25 / 2.8 / 2.8 / 55.2 / 128 50 / 4.5 / 4.5 / 32.3 / 150 75 / 6.3 / 5.0 / 22.8 / 155 100 / 8.0 / 5.3 / 17.6 / 157 125 / 9.7 / 6.4 / 14.4 / 159 150 / 11.5 / 7.7 / 12.1 / 160 175 / 12.0 / 8.0 / 10.5 / 158 Pediatric Defibrillation (using 989803150031 FR3 Infant/Child Key) Load Resistance (Ω) / Phase 1 Duration (ms) / Phase 2 Duration (ms) / Peak Current (A) / Delivered Energy (J) 25 / 2.8 / 2.8 / 32.0 / 43.4 50 / 4.5 / 4.5 / 18.7 / 50.2 75 / 6.3 / 5.0 / 13.2 / 51.8 100 / 8.0 / 5.3 / 10.2 / 52.4 125 / 9.0 / 6.0 / 8.3 / 52.3 150 / 9.0 / 6.0 / 7.0 / 50.2 175 / 9.0 / 6.0 / 6.1 / 48.1 NOTE: The values given are nominal.

CATEGORY	NOMINAL SPECIFICATIONS
Disarm (AED Mode)	Once charged, the FR3 will disarm if: • patient's heart rhythm changes to non-shockable rhythm. • a shock is not delivered within 30 seconds after the FR3 is armed. • the CPR button (if enabled) is pressed. • the On/Off button is pressed to turn off the FR3. • rhythm analysis has continued for 45 seconds but extended artifact prevents shock determination. • the battery is depleted. • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FR3. • the Infant/Child Key is inserted.
Disarm (Advanced Mode)	Once charged, the FR3 will disarm if any of the AED disarm conditions (above) are met, or if: • the On/Off button is pressed to turn off the FR3 • a shock is not delivered within 30 seconds after charging. • the manual disarm button is pressed. • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FR3. • in advanced mode analysis, the patient's heart rhythm changes to a non-shockable rhythm.
Shock Delivery Vector	Via defibrillator pads placed in the anterior-anterior (Lead II) position or, for infants and children under 55 lbs (25 kg) or 8 years old, via defibrillator pads placed in the anterior-posterior position.

ECG ANALYSIS SYSTEM

CATEGORY	NOMINAL SPECIFICATIONS
Function	Evaluates impedance of defibrillator 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.
Shockable Rhythms	Ventricular fibrillation (VF) and certain ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia (VT). The FR3 uses multiple parameters to determine if a rhythm is shockable. NOTE: For patient 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. CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the FR3.
Asystole	On detection of asystole, provides CPR prompt at programmed interval.

CATEGORY	NOMINAL SPECIFICATIONS
Pacemaker Detection	Pacemaker artifact is displayed on the FR3 ECG model. In both the FR3 ECG and Text models, the FR3 rhythm analysis algorithm is designed to remove pacemaker artifact from the signal for analysis. However, due to differences between pacemaker therapy designs, artifact removal cannot always be achieved. In the advanced mode, upon detection of a pacemaker the FR3 provides screen display of PACEMAKER DETECTED alert.

ECG ANALYSIS PERFORMANCE

RHYTHM CLASS	ECG TEST SAMPLE* SIZE	MEETS AHA RECOMMENDATIONS† FOR ADULT DEFIBRILLATION	
		OBSERVED PERFORMANCE	90% ONE-SIDED LOWER CONFIDENCE LIMIT
Shockable Rhythm — Ventricular Fibrillation	300	sensitivity >90% (meets AAMI DF80 requirement)	(87%)
Shockable Rhythm — Ventricular Tachycardia	100	sensitivity >75% (meets AAMI DF80 requirement)	(67%)
Non-Shockable Rhythm — Normal Sinus Rhythm	300	specificity >99% (meets AAMI DF80 requirement)	(97%)
Non-shockable Rhythm — Asystole	100	specificity >95% (meets AAMI DF80 requirement)	(92%)
Non-Shockable Rhythm — All other non-shockable rhythms‡	450	specificity >95% (meets AAMI DF80 requirement)	(88%)

* From Philips Medical Systems ECG rhythm databases.

† 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. *Circulation* 1997;95:1677-1682.

‡ Supraventricular tachycardia (SVT) is specifically included in the non-shockable rhythm class, in accordance with AHA recommendations† and the AAMI standard DF80.

DISPLAY

CATEGORY	NOMINAL SPECIFICATIONS
Monitored ECG Lead	ECG information is received from defibrillator pads in anterior-anterior (Lead II) position or in anterior-posterior position. (Displayed on FR3 ECG model 861389 only.) NOTE: The ECG display provided by the FR3 is not intended to provide diagnostic or ST segment interpretation.
Screen Type and Resolution	High-resolution color liquid crystal display (LCD).
Screen Dimensions	2.8 in wide x 2.1in high (72 mm x 54 mm).
Sweep Speed (861389 only)	18 mm/sec, nominal.
ECG Display	4 second-segments displayed (861389 only).
Frequency Response (Bandwidth)	Non-diagnostic rhythm monitor 1 Hz to 30 Hz (-3 dB), nominal.
Sensitivity	9 mm/mV, nominal.

CONTROLS AND INDICATORS

CATEGORY	NOMINAL SPECIFICATIONS
Display Screen	High-resolution color LCD screen. Displays graphics, text prompts, status messages, and 4-second segments of ECG (861389 only).
Controls	On/Off button Shock button Option buttons
Sensors	Alert FR3 when: • the system case has been opened. • the Infant/Child Key has been installed. • the therapy pads or training pads connector has been connected.
LED Indicators	Ready light LED flashes to show device readiness for use. Connector socket LED flashes to indicate socket location. (LED is covered when defibrillator pad connector is properly inserted.) Shock button LED flashes when defibrillator is armed.
Speaker	Provides voice prompts and tones (volume is adjustable via setup screen).
Beeper	Chirps to alert user to a problem; e.g., when a self-test has failed.

ACCESSORIES SPECIFICATIONS

989803150161 CLINICAL USE BATTERY

CATEGORY	NOMINAL SPECIFICATIONS
Battery Type	Lithium manganese dioxide. Disposable, long-life primary cell.
Capacity	12 VDC, 4.7 AH, when new and stored at 77° F (25° C).
Battery Performance	Low Battery Indication • Configured for NSA monitoring: 12 hours operating time. • Configured for NSA CPR: 7.5 hours operating time. • Typical shock count: 300 shocks • Minimum remaining capacity after Low Battery warning: 9 shocks, 15 minutes of operating time.
Standby Life (after installation)	Minimum 3 years when stored under standby environmental conditions (battery installed, FR3 unused).
Status Indicators for Installed Battery	Battery status is displayed on FR3 status screen at shutdown. When appropriate, text and/or voice prompts during use.
Temperature and Relative Humidity	Operating: 32° to 122° F (0° to 50° C); 5% to 95% relative humidity (non-condensing). Standby/Storage: 32° to 122° F (0° to 50° C); 10% to 75% relative humidity (non-condensing). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.
Battery Limitations	Never charge, short circuit, puncture, deform, incinerate, heat above 60° C, or expose contents to water. Remove the battery when discharged.

989803150191 RECHARGEABLE TRAINING BATTERY

CATEGORY	NOMINAL SPECIFICATIONS
Battery Type	Lithium ion, rechargeable, using the 861394 charger only.
Capacity	10.8 VDC, 4.5 AH, typical. When fully charged, provides 4 hours of operating time at 77° F (25° C).
Time to Full Charge	3 hours.
Temperature and Relative Humidity	Operating: 32° to 104° F (0° to 40° C) Standby/Storage: 32° to 122° F (0° to 50° C). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.

861394 BATTERY CHARGER

CATEGORY	NOMINAL SPECIFICATIONS
Application	For use with FR3 rechargeable 989803150191 training battery only.
Power Requirements	100 to 240 VAC, 47 to 63 Hz, 35 W.
Status Indicators for Connected Battery	Flashing green LED: The battery is charging. Steady green LED: The battery is fully charged. Red LED: Charging has stopped due to failure during the charge process.
Temperature and Relative Humidity	Operating: 32° to 104° F (0° to 40° C) Standby/Storage: 32° to 122° F (0° to 50° C). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.
Conformance Testing	International: IEC 60601-1:1988+A1:1991+A2:1995 2nd Edition. North America: UL 60601-1, 1st Edition.

989803149981 AND 989803149991 HEARTSTART SMART PADS III

CATEGORY	NOMINAL SPECIFICATIONS
Application	Pads for defibrillation, pacing, monitoring, cardioversion. Pre-connectable to FR3; testable when preconnected and installed in Pads Sentry. Disposable, adhesive pads with a nominal active surface area of 80 cm^2 each, and an integrated 48 inch (122 cm), typical, cable. Set of two pads on liner are designed to fit into Pads Sentry for an FR3 system case. Provided as a single set (989803149981) or five sets (989803149991).
Pads Shelf Life	Pads package is labeled with an expiration date of at least 30 months from date of manufacture.
Storage/ Transport Temperature	32° to 122° F (0° to 50° C).

OTHER COMPATIBLE DEFIBRILLATOR PADS

CATEGORY	PRODUCT INFORMATION
Pre-connectable and Tested	HeartStart SMART Pads II 989803139261: Disposable, adhesive pads with a nominal active surface area of 80 cm^2 each, provided in a disposable plastic case, and an integrated 48 inch (122 cm), typical, cable. *Pre-connectable to FR3.* For adult and infant/child patient use with FR3.
Non-pre-connectable	HeartStart DP Series 989803158211 and 989803158221: Disposable, adhesive pads with a nominal active surface area of 85 cm^2 each, provided in a sealed package, and an integrated 48 inch (122 cm), typical, cable. *Not pre-connectable to FR3.* For adult and infant/child patient use with FR3.

989803149971 FR3 RIGID SYSTEM CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional accessories (Infant/Child Key, spare pads, and spare battery,). Includes top and bottom case inserts and Pads Sentry.
Dimensions	13.2 in x 10.3 in x 5.2 in (33.5 cm x 26.2 cm x 13.2 cm) including handle.
Weight	4.9 lbs (2.2 kg) including Pads Sentry.

989803150211 FR3 SYSTEM CASE BOTTOM INSERT

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional spare battery.
Dimensions	10.6 in x 9.1 in x 2.8 in (26.9 cm x 23.1 cm x 7.1 cm).
Weight	0.8 lb (0.4 kg).

989803150221 FR3 SOFT SYSTEM CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional accessories (Infant/Child Key, spare pads, and spare battery). Includes Pads Sentry and adjustable 59" (150 cm) shoulder strap.
Dimensions	4.8 in x 9.9 in x 11.0 in (12.1 cm x 25.1 cm x 27.9 cm).
Weight	1.8 lbs (0.8 kg).

989803173711 FR3 SMALL SOFT CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional accessories (Infant/Child Key and spare pads). Includes Pads Sentry and adjustable 59" (150 cm) shoulder strap.
Dimensions	4.8 in x 9.9 in x 7.7 in (12.2 cm x 25.1 cm x 19.5 cm).
Weight	1.3 lbs (0.6 kg)

989803150031 FR3 INFANT/CHILD KEY

CATEGORY	NOMINAL SPECIFICATIONS
Application	When installed in FR3, causes defibrillator to go into infant/child mode, deliver a lower therapy level more appropriate for infants and children.
Dimensions	2.09 in x 0.25 in (5.31 cm x 0.63 cm).
Weight	0.6 oz (17.0 g).

989803150061 FR3 DATA CARD

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores use data for download and subsequent review.
Minimum Capacity	8 hours of ECG, event and voice recording.

989803150101 FR3 LANGUAGE CARD

CATEGORY	NOMINAL SPECIFICATIONS
Application	Enables change of FR3 primary language or, in conjunction with the HeartStart Configure software, enables bilingual option.
Minimum Capacity	When used as an FR3 data card: 4 hours of audio, ECG, event and voice recording. NOTE: If used as a data card, the original language files on the language card will not be overwritten. As a result, the capacity for data recording on the language card is less than on a data card.

989803150081 *BLUETOOTH* WIRELESS TECHNOLOGY TRANSCEIVER MODULE

CATEGORY	NOMINAL SPECIFICATIONS
Compliance	V2.0 Core Specifications Bluetooth Class II.
Frequency	2.402 to 2.48 GHz.
Storage Temperature	-4° - 140° F (-20° - 60° C)
Supported Profiles	Serial Port Profile with compatible Philips software products. See Appendix A for a list of these products. File Transfer Profile for file retrieval.
Transmission Encryption	Pre-shared key, 128 bit.

989803150111 FR3 FAST RESPONSE KIT

CATEGORY	NOMINAL SPECIFICATIONS
Application	Designed to snap into 989803149971 FR3 rigid system case.
Contents	A pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe.
Dimensions	4.8 in x 7.75 in x 1.6 in (12.1 cm x 19.7 cm x 4.0 cm).
Case Material	High-density polyethylene.
Weight	0.5 lb (0.2 kg).

861467 AED TRAINER 3

CATEGORY	NOMINAL SPECIFICATIONS
Application	Training in use of FR3 AED.
Dimensions	8.6" x 5.2" x 2.2" (21.8 cm x 13.3 cm x 5.7 cm).
Weight (with batteries)	1.3 lb (600 g).
Battery type and quantity	4 AA size alkaline batteries (LR6).
Battery capacity	> 10 hours.
Temperature and Relative Humidity	Operating temperature: 50° - 95° F (10° - 35° C). Storage temperature: 32° - 104° F (0° - 40° C). Relative humidity: 0 - 90% non-condensing.

H ADDITIONAL TECHNICAL DATA

ENVIRONMENTAL CONSIDERATIONS

PRODUCT	INFORMATION
Defibrillator	The defibrillator contains electronic components. Dispose of it at an appropriate recycling facility in accordance with local regulations.
Battery	The battery cells contain chemicals. Recycle the battery at an appropriate recycling facility in accordance with local regulations.
Pads	The used pads may be contaminated with body tissue, fluid, or blood. Dispose of them as infectious waste.

IMPORTANT WARNINGS AND REMINDERS

- Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.
- Before delivering a shock, it is important to disconnect the patient from other medical electrical equipment, such as blood-flow meters, that may not incorporate defibrillation protections. In addition, make sure the pads are not in contact with metal objects such as a bedframe or stretcher.
- Check supplies, accessories, packaging, and spares for damage and expiration dating.

ELECTROMAGNETIC CONFORMITY

Guidance and manufacturer's declaration: The HeartStart FR3 Defibrillator (FR3) is intended for use in the electromagnetic environment specified in the tables below. The user of the FR3 should assure that it is used in such an environment.

Radio-frequency (RF) interference from nearby electronic equipment (e.g., high-frequency surgical equipment in active use, RFID readers, electronic article surveillance systems, or metal detectors) may affect performance of the FR3 in use.

The following tables present guidance for FR3 operation in certain electromagnetic environments. If the FR3 may be used in an RF environment that is not covered specifically by the data provided below, Philips recommends that you assess the impact of that environment on the performance of the FR3, as follows:

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- Set up the FR3 — connect pads and install battery — and place it in its carry case in the RF environment to be evaluated. Perform a user-initiated test (see Chapter 4, "User-Initiated Test") and verify that the FR3 passes the test.
- Connect the FR3 to a defibrillator/analyzer configured to output a ventricular fibrillation waveform. Verify that the FR3 can successfully analyze and deliver a shock. If the FR3 prompts that it cannot analyze or analyzing is interrupted, RF interference may exist.
- Connect the FR3 to a defibrillator/analyzer configured to output an asystolic waveform. Verify that the FR3 can successfully analyze and issue a no shock advised decision. If the FR3 prompts that it cannot analyze or analyzing is interrupted, RF interference may exist.

If you have any remaining questions, please contact Philips at www.philips.com/AEDSupport for technical support.

ELECTROMAGNETIC EMISSIONS

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF CISPR 11	Group 1 Class B	The FR3 uses RF energy only for its internal function, except when the optional *Bluetooth* module is installed. Even under these circumstances, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The FR3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

ELECTROMAGNETIC IMMUNITY

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 15 kV air	There are no special requirements with respect to electrostatic discharge.*

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/hospital environment. There are no special requirements for non-commercial/non-hospital environments.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the FR3, including cables, than is absolutely necessary.† The recommended separation distances for various transmitters and the AED are shown in the following table. Interference could occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-6	3 Vrms, except 10 Vrms in ISM Frequency Bands	10 Vrms 10 MHz to 80 MHz	Recommended separation distance: $d = 1.2\sqrt{P}$.

NOTE 1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Generally, AEDs are sometimes susceptible to interference generated by patient and/or responder motion in environments in which a high static electric field is present (e.g., low humidity, synthetic carpets, etc.). As a safety measure, Philips AEDs incorporate a patented method to sense possible corruption of the ECG signal by such interference and to respond by directing the user to stop all motion. In these cases, it is important to minimize movement in the vicinity of the patient during rhythm analysis in order to ensure that the signal being analyzed accurately reflects the patient's underlying heart rhythm.

† Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FR3 is used exceeds the applicable RF compliance level above, the FR3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FR3.

AIRCRAFT ENVIRONMENT

IMMUNITY TEST	RTCA DO-160E TEST LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Radiated RF	Category D	Representative of acceptable attenuation levels for all aircraft cabin environments
Conducted RF	Category K	Representative of acceptable attenuation levels for all aircraft cabin environments
EMISSIONS TEST	**RTCA DO-160E TEST LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Radiated RF	Category M - Charging	Meets the requirements for all aircraft cabin environments

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE HEARTSTART FR3 DEFIBRILLATOR

The FR3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FR3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FR3 as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M)		
	10 MHZ TO 80 MHZ $d = 1.2\sqrt{P}$	80 MHZ TO 1 GHZ $d = 0.6\sqrt{P}$	1 GHZ TO 18 GHZ $d = 0.46\sqrt{P}$
0.01	0.12	0.06	0.0
0.1	0.36	0.19	0.14
1	1.2	0.6	0.5
10	3.6	1.9	1.4
100	12.0	6.0	4.6

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 1 GHz, the separation distance for the higher frequency range applies.

NOTE 2. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 18 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 3. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 4. Transmitters/antenna of this power-level are most likely mounted on an emergency vehicle chassis. The distances cited here are for open field. For an external antenna, the separation distance is most likely shorter.

NOTE 5. Separation distances were calculated using the IEC formulas and the worst-case susceptibility test level of RTCA DO-160E and IEC 60601-1-2.

SHOCK CYCLE TIMING

The FR3 Quick Shock feature allows it to deliver a shock within eight seconds, typical, following the prompt ending a CPR protocol using a new battery. From shock to shock, the FR3 takes <20 seconds, typical, including analysis using a new battery. After 15 shocks using the same battery, the FR3 takes <30 seconds from analyzing to ready-to-shock. After 200 shocks using the same battery, the FR3 takes <40 seconds from initial power-on to ready-to-shock.

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