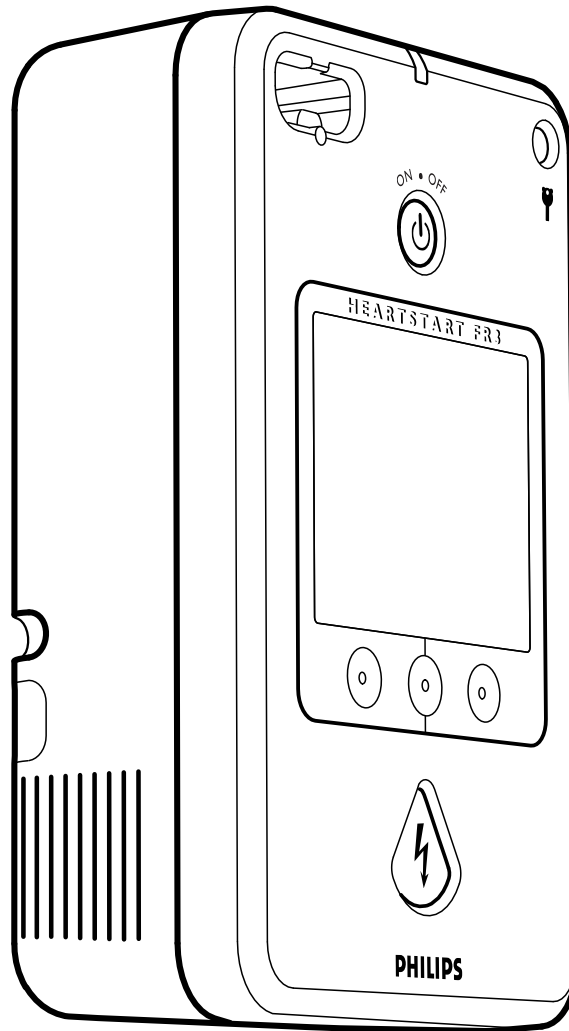this document brought to you by

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Philips

HeartStart FR3

AED Manual

Get an original copy of the Philips HeartStart FR3 AED Manual
for manufacturer information about service, available
accessories and how to use and maintain your device.

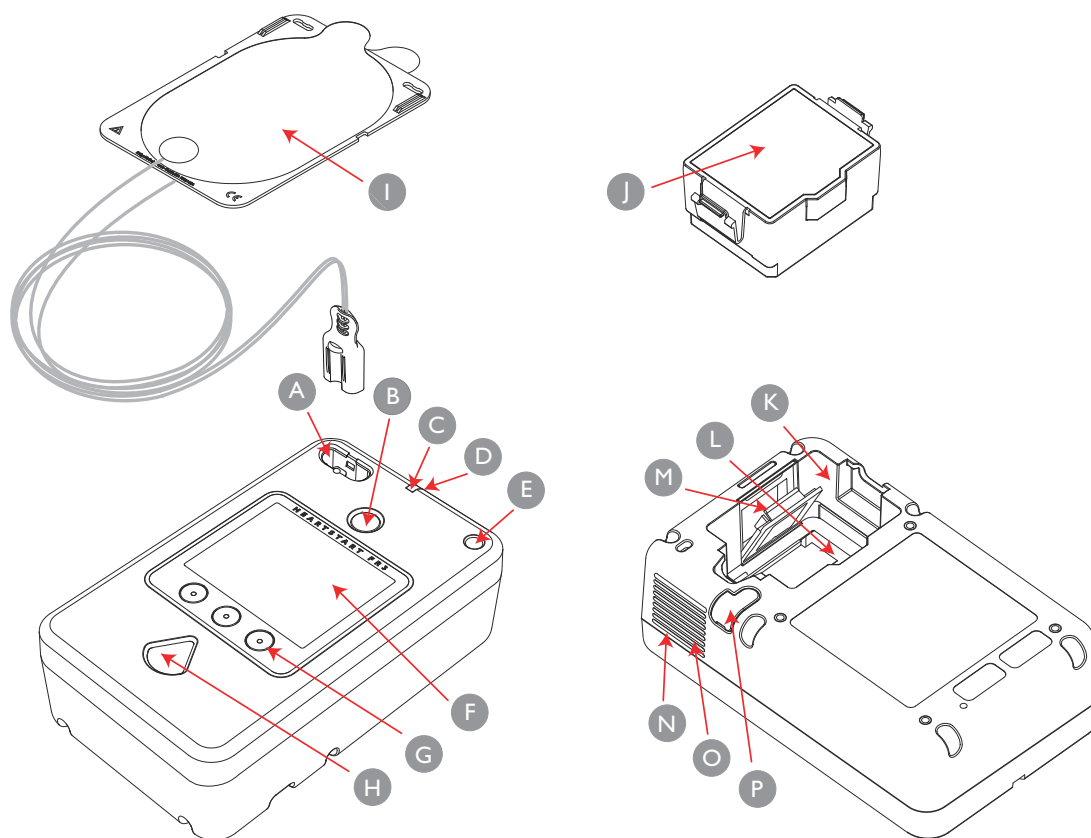861388 and 861389
Edition 3

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. This receptacle is also used to connect the optional FR3 3-Lead ECG Cable.

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 lb (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 CPR meter accessory.

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

Notices

Authorized EU Representative

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

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.

For Technical Support

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

CONTENTS

7   DATA MANAGEMENT

APPENDICES

PHILIPS MEDICAL SYSTEMS

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 principal 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 lb (25 kg) or 8 years old. The FR3 is also intended for children under 55 lb (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."

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. The FR3 can be configured under the guidance of a Medical Director to enable Advanced Use mode (see Appendix F, "Advanced Mode") and alternative cardiopulmonary resuscitation (CPR) protocols, such as CPR while Armed, CPR First—User, and CPR First—Always (see Appendix D, "CPR First").

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

The FR3 can be used with the optional CPR meter with Q-CPR® technology by Laerdal. The system is designed for application by a responder trained in its use. It serves as a guide in administering CPR to a suspected sudden cardiac arrest (SCA) victim at least 8 years old or 55 lb (25 kg). If the age or weight of the patient is in doubt, do not delay treatment. Perform CPR without using the CPR meter.

> WARNING: The CPR meter is not intended for use on SCA victims under 8 years old or 55 lb (25 kg). If the Infant/Child Key is installed in the FR3, the CPR meter is disabled.

When attached to the bare chest of a suspected victim of SCA and connected to an FR3 used with compatible pads[*] properly placed, the CPR meter provides real-time feedback on CPR in accordance with current CPR guidelines. It displays CPR feedback indicators for depth, release, and rate of chest compressions. It also provides notification for lack of expected CPR activity and a stay-clear icon display during FR3 rhythm analysis and shock delivery. In addition, the FR3 alerts the responder when it detects hyperventilation (more than 12 ventilations per minute) of the patient during CPR.

At the discretion of a responder trained in its use, the optional FR3 3-Lead ECG Cable can be connected to the FR3 ECG model to provide a non-diagnostic ECG display of the heart rhythm of a patient who is responsive and breathing normally but at risk of cardiac distress. The system is intended for use on a conscious or

[*] HeartStart SMART Pads III, HeartStart DP series adult defibrillator pads, or HeartStart SMART Pads II.

breathing patient, regardless of age, for attended patient monitoring. The responder can select display of lead vectors I, II, or III. While connected to the 3-Lead Cable, the defibrillator's shock capability is disabled, but the FR3 continues to evaluate the patient's ECG. In addition, the FR3 alerts the responder to check the patient if the heart rate is less than 30 BPM or if the heart rhythm may benefit from a defibrillation shock. If the patient's rhythm or status changes, the responder can attend to the patient, as appropriate.

> CAUTION: Do not use the 3-Lead Cable with other defibrillators or adapters, as this may damage the cable. If the 3-Lead Cable is subjected to a defibrillation shock, test the cable as described in the "Troubleshooting" section of the *Instructions for Use* provided with the 3-Lead Cable.

The FR3 is shipped with the FR3 primary (non-rechargeable) clinical use battery but can be also used with the optional FR3 rechargeable battery. The FR3 rechargeable battery is intended for use by organizations, such as EMS or fire departments, that use the FR3 frequently and want to decrease cost-per-use and reduce environmental waste. The rechargeable battery should only be used by organizations committed to providing the resources required to operate a battery maintenance program. Due to changes in the performance characteristics of rechargeable batteries over time, it is important for the battery maintenance program to monitor how many battery charge/discharge cycles the battery experiences, in order to determine when to retire it from service. The FR3 rechargeable battery is not recommended for infrequent-use environments such as office buildings, airlines, or public access defibrillation (PAD) programs. It should not be used as the spare or backup battery; instead, the standard primary battery should be used due to its long shelf-life.

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, with specific instructions in the combined behavior of FR3 system accessories such as the CPR meter and Infant/Child Key, included in the response protocol. In addition, responders should be trained 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 training 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.

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

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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 primary 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. 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 6-17 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
> - CPR meter with Q-CPR® technology by Laerdal[*]
> - FR3 3-Lead ECG Cable[*]
> - FR3 Infant/Child Key
> - FR3 Fast Response Kit
> - Secure pull case seal
>
> For information on ordering accessories, see Appendix A, "Accessories."

---

[*] Requires FR3 running software version PR2.0 or higher. Contact your local Philips representative if you require a software upgrade.

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 preconnected 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).

Pads Sentry
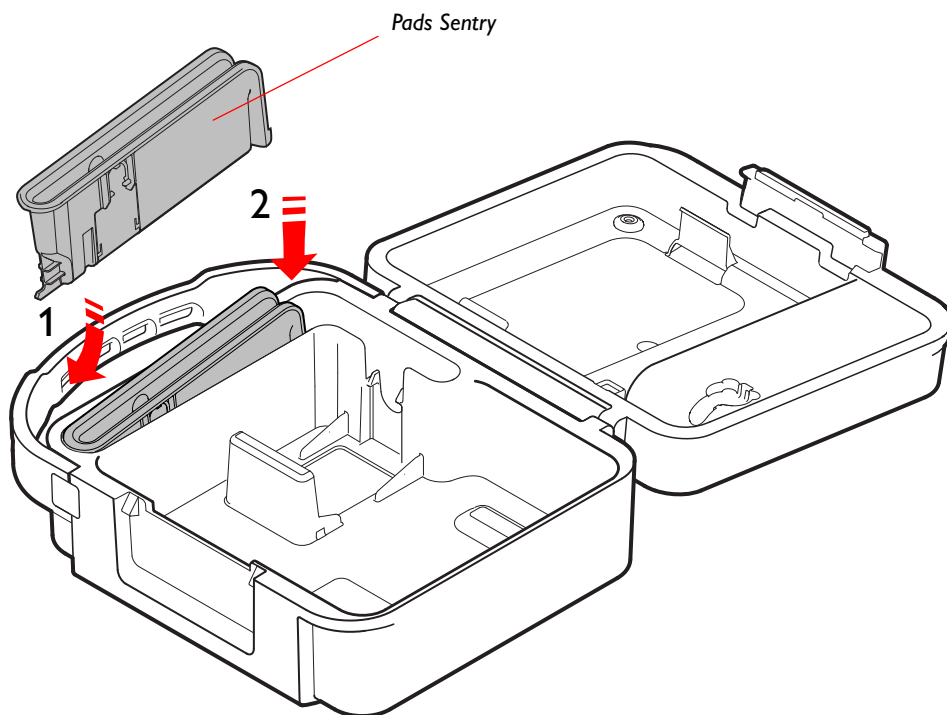
3. If you have the **optional CPR meter**, install the CPR meter cradle[†] provided with the CPR meter. Press the cradle very firmly over the support in the bottom of the case, as shown in the following illustration, until the cradle snaps into place. Complete the case assembly before installing the CPR meter.

---

*   Directions and illustrations in this chapter address use of the FR3 rigid system case. Other FR3 carry cases are available and are shipped with directions for setup and use. See Appendix A, "Accessories."

†   The CPR meter cradle is designed for use only in the FR3 rigid system case.

CPR meter cradle
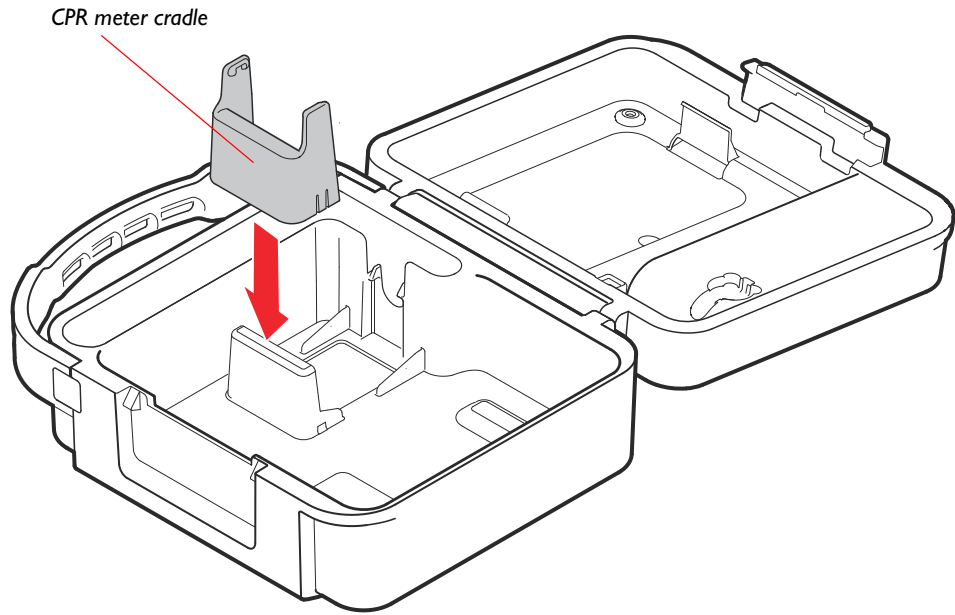
INSTALLING THE OPTIONAL FR3 DATA CARD

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."

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.
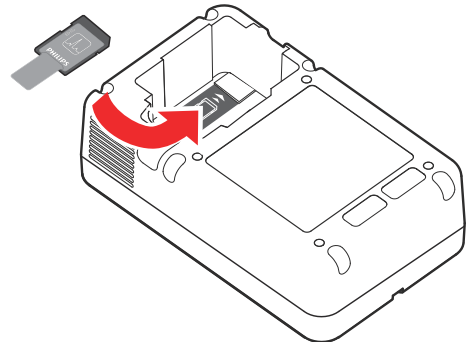
> NOTE: To remove the data card, grasp the card by its tail, press the retention clip away from the card, and pull the card out. See illustration on page 7-5.

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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.
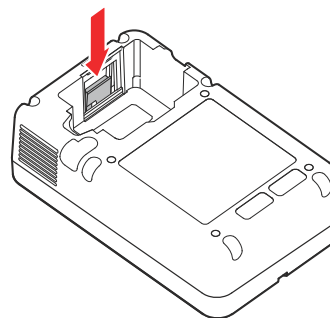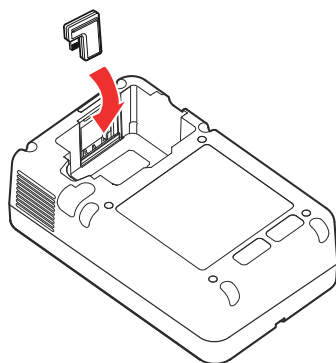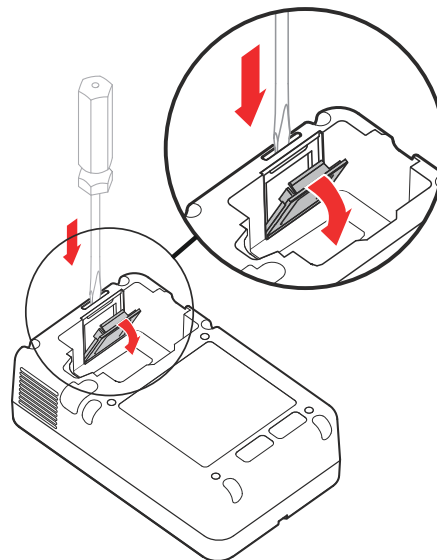
4. Place the bottom edge of the module compartment cover in the track at the bottom of the compartment. *Be sure the small tab on the bottom of the cover fits into the track.* Then snap the top in place, being careful not to pinch your finger.
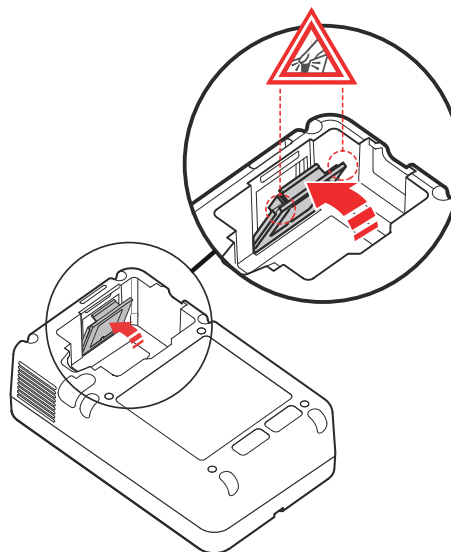
> IMPORTANT NOTE: Be sure to reinstall the module compartment cover properly. The cover is part of the water protection seal of the FR3 and *must be flush with the compartment wall*.

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INSTALLING THE BATTERY

The FR3 is shipped with an FR3 clinical use primary 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 information 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 primary 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.

Spare battery

---
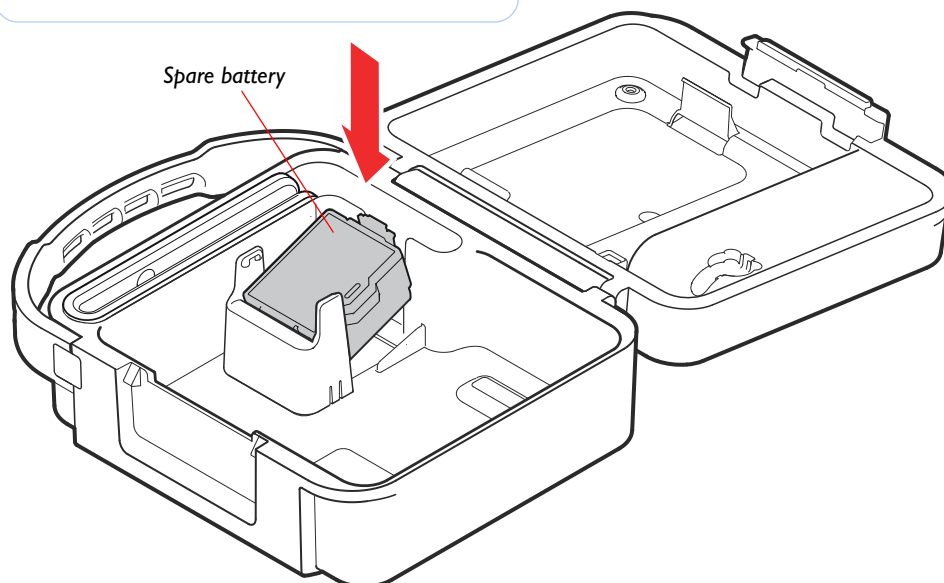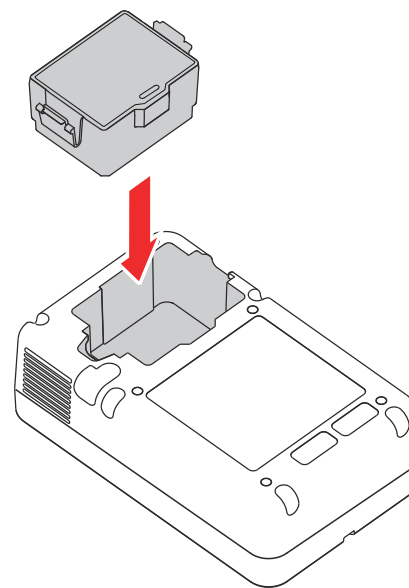
* An FAA compliant clinical use battery and a rechargeable clinical use battery are also available. See Appendix A, "Accessories."
† For details, see "User-Initiated Test" on page 4-7

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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.

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.

   > **Press ON for Patient Use**
   >
   > **Clock Not Set**
   > **Set Date and Time**
   >
   > ▉ Battery   Good
   > ▉ Data Card   Good
   >
   > | Administration | OFF |

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

   > **ADMINISTRATION**
   > **Wireless Data Transfer**
   > **Incident Data**   ⚡ ##   🕐 #:##:##
   > **User-Initiated Test**
   > **System Information**
   > **Setup**
   >
   > | ▼ | ✓ | ▲ |

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

   > **Setup**
   >
   > ◂ **Back**
   > **Load New Setup**
   > **View Setup**
   > **Save Setup to Data Card**
   > **Date and Time**
   >
   > | ✓ | ▲ |

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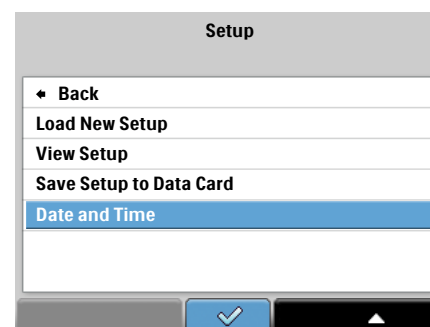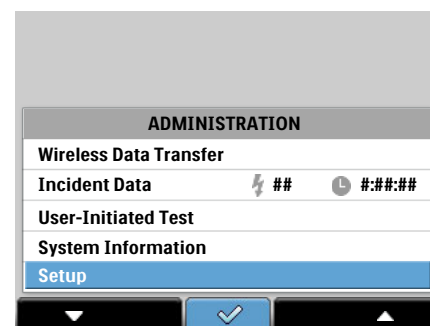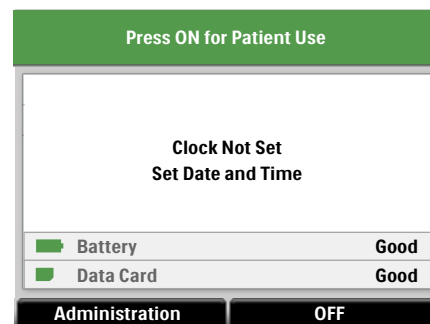
[*] If the FR3 is already in standby, press the green On/Off button to turn on the FR3. When voice prompts begin, press the button again to display the status screen.

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.

Date and Time

◆ Back

YYYY	Month	DD

hh : mm : ss   (24 hr)

Press DOWN ARROW to change

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.*

Change Date and Time

YYYY	Month	DD

hh : mm : ss   (24 hr)

Press RIGHT ARROW to move
Press UP ARROW to change selection
Press CHECK when finished

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 6-13.

---

* 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.

CONNECTING THE OPTIONAL CPR METER

If you have the optional CPR meter, follow these steps to connect it to the FR3:

1. The FR3 is supplied with a plastic plug in the accessories connector port on the bottom of the FR3. Pry out the plug and remove it.
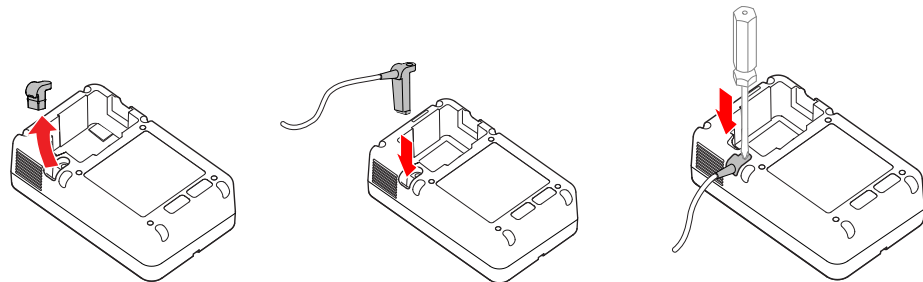
2. The CPR meter is supplied with an FR3 CPR meter cable link. Insert the cable link connector into the accessories connector port and secure it in place with the screw provided, using a Phillips screwdriver (not supplied).

3. Align the arrow marker on the CPR meter's attached cable with the arrow marker on the receptacle end of the FR3 CPR meter cable link as shown. Push until it clicks into place.

4. Check the label on the outside of the CPR meter patient adhesives to be sure that they are within their expiration date. Open the package of CPR meter patient adhesives and peel one off the **white liner** to expose the adhesive surface on its underside.

Integrated cable   *Installed cable link*
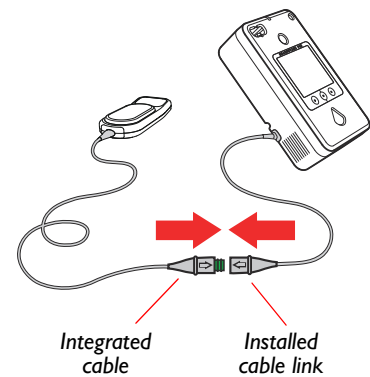
5. Align the bottom of the patient adhesive with the yellow patient-adhesive mount area on the rear cover of the CPR meter. Make sure the channel on the adhesive (indicated by a dotted line on the green liner) is directly over the visible groove in the plastic. Press the Patient Adhesive into place.

NOTE: To prevent the adhesive from drying out, do not peel off the **green liner** from the front of the attached adhesive until you are ready to apply the CPR meter to a patient during an emergency.

Vent channel

6. Return the remaining patient adhesives to their resealable pouch.
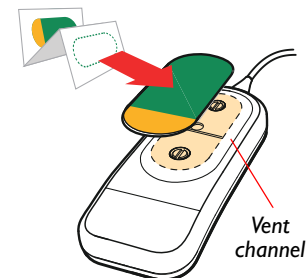
The FR3 rigid system case is designed with a cradle to accommodate the connected CPR meter. If you are using a rigid system

case, check that the CPR meter cradle has been installed. See page 2-2 for instructions for installing the cradle in the FR3 system case.

1. Place the FR3 with the connected CPR meter into the FR3 system case, with the display screen of the CPR meter facing up.

Display screen

FR3
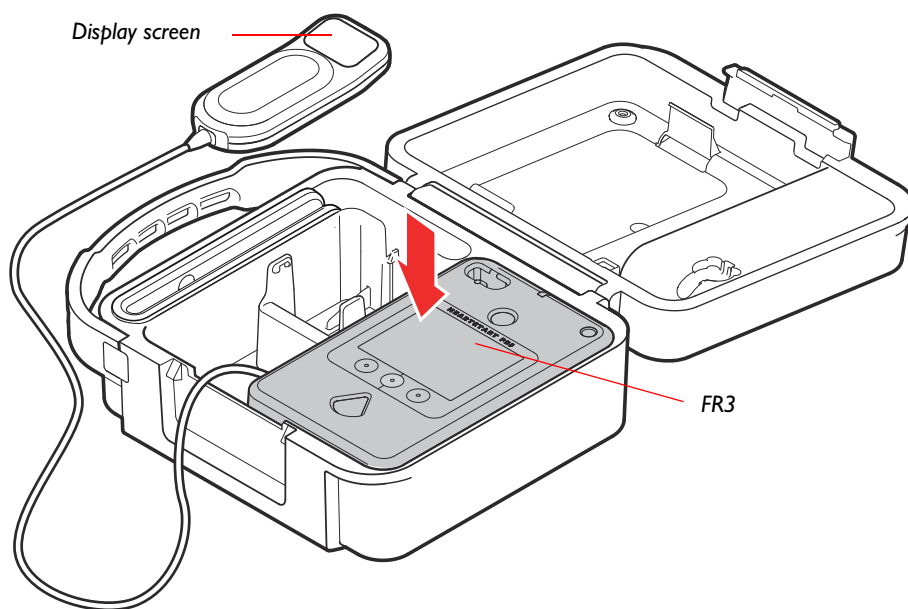
2. Snap the CPR meter into the cradle, making sure that the display end of the CPR meter is all the way back against the pads cable storage area.

Pads cable storage

CPR meter

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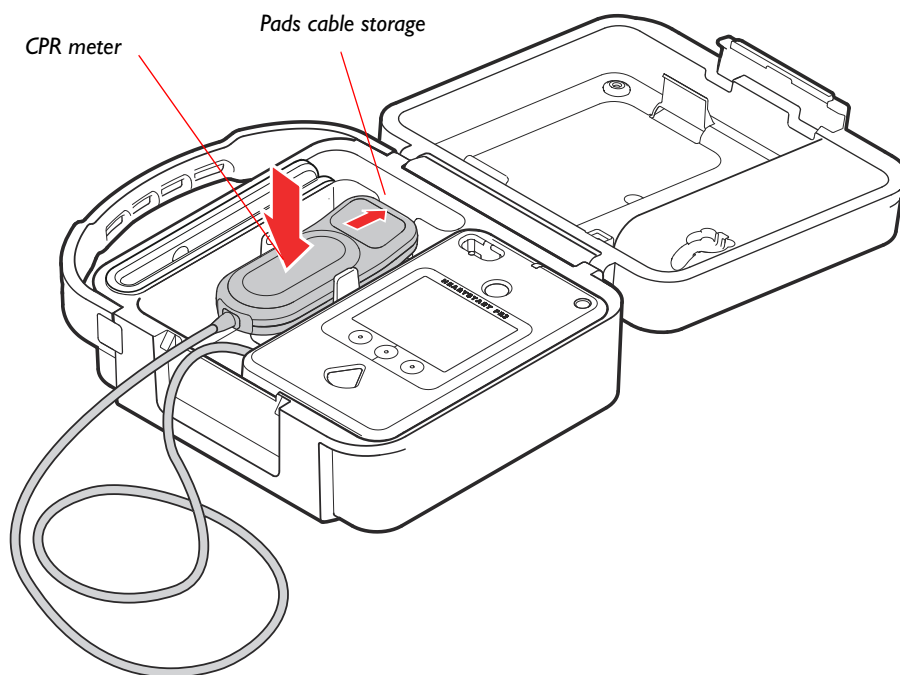
3. With the CPR meter installed in the cradle, extend the cable and coil it around your hand in a neat bundle.
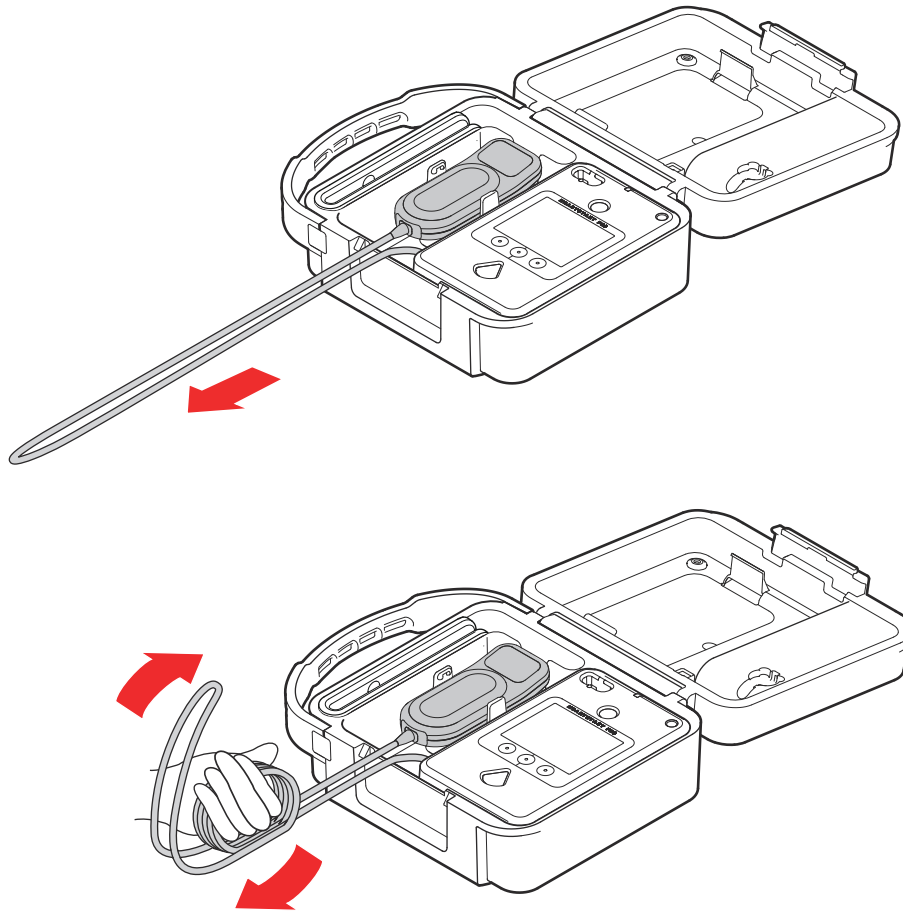
4. Tuck the coiled bundle into the compartment in the bottom of the case beneath the connector end of the CPR meter. This method minimizes cable fatigue and facilitates deployment of the CPR meter.

Space for spare patient adhesives
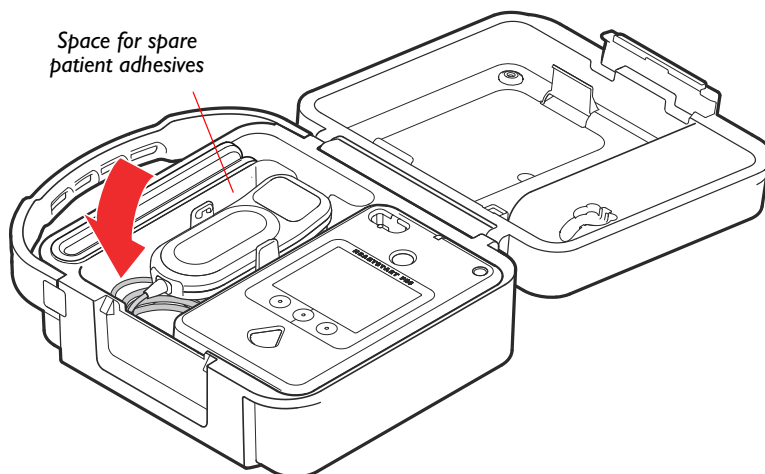
5. Place the remaining CPR meter patient adhesives in their packaging into the area to the left of the CPR meter cradle, as shown above.

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.

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 preconnected 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.

Spare pads in unopened package

Pads cable storage

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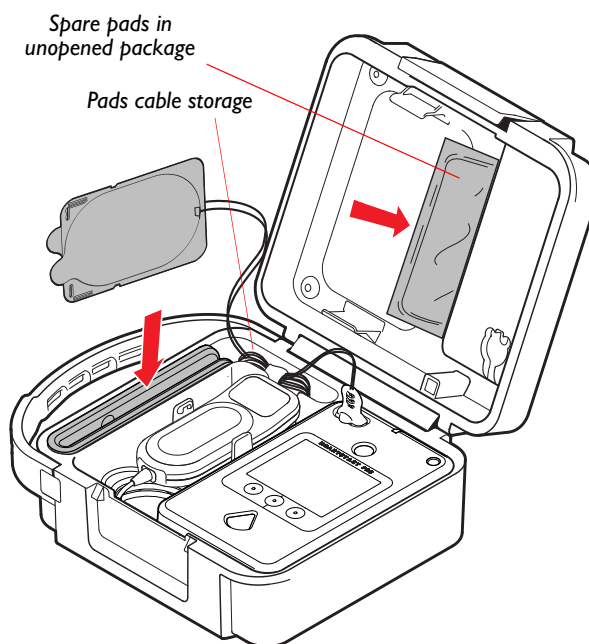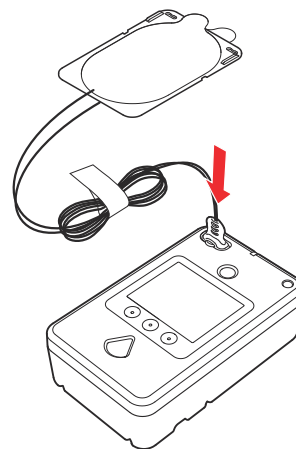
* Peeling any part of the pads from the liner breaks the protective seal and allows the pads adhesive to dry out. If this happens, the pads will fail the FR3 self-test.

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 preconnected 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-9 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.

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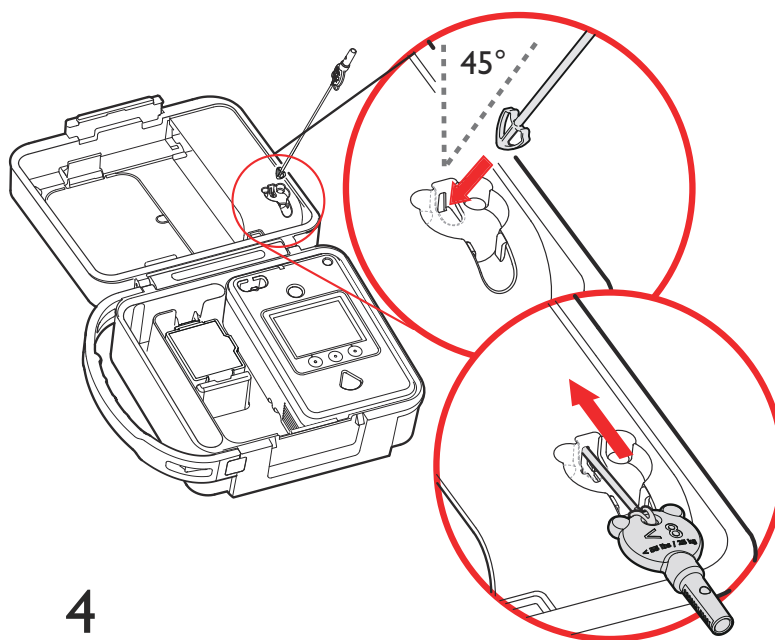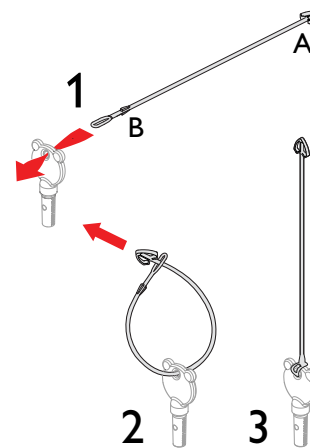
> NOTE: Do not install the FR3 Infant/Child Key in the FR3 defibrillator except when it is needed for use in an emergency. If the Key is left installed when the FR3 goes into standby, the next FR3 self-test will fail.

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.

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.

FR3 Fast Response Kit

1

2
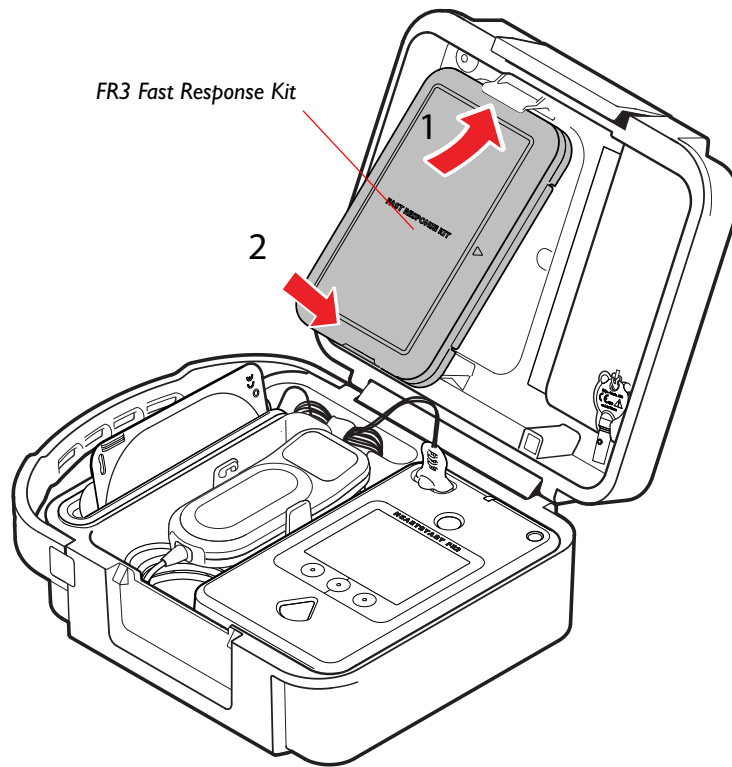
STORING THE OPTIONAL FR3 3-LEAD ECG CABLE

The optional FR3 3-Lead ECG cable is intended for use with the Philips HeartStart FR3 model 861389 only. It is provided with a storage pouch. The pouch accommodates the 3-Lead Cable and a package of ECG electrodes (not supplied). The pouch incorporates a clip for securing it to the handle of any FR3 carry 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, pads, and CPR meter patient adhesives, if available, in the case. Attach the 3-Lead Cable pouch, if available, to the handle of the case. Do not remove the battery from the FR3 unless an FR3 self-test indicates 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.
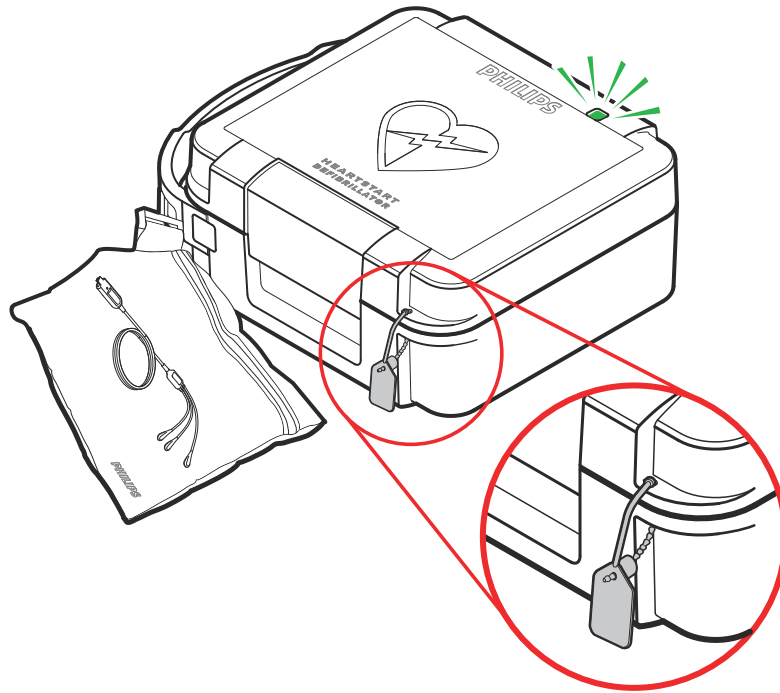
You can thread an optional secure-pull case seal through the holes in the corner of the case to help prevent tampering. If desired, trim the lanyard. The illustration above shows a trimmed lanyard.

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 lb (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.

    • If you have a CPR meter, see "CPR Meter for Optimized CPR" on page 3-5 for instructions.

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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 lb (25 kg) or 8 years old (anterior-anterior).
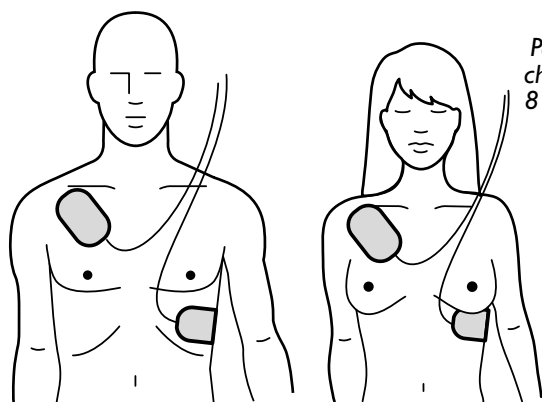
Pad placement for infants and children under 55 lb (25 kg) or 8 years old (anterior-posterior).
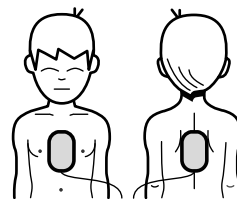
- As soon as the pads are attached to the patient, the FR3 begins analysis of the patient's heart rhythm. The FR3 instructs you to stay clear of the patient. Do not touch the patient.

- *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 preconnected 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."

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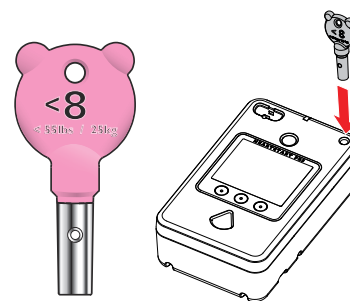
> NOTE: If the Infant/Child Key tether pulls out of the system case during use, do not take time to reinstall it. The Key will work without it.

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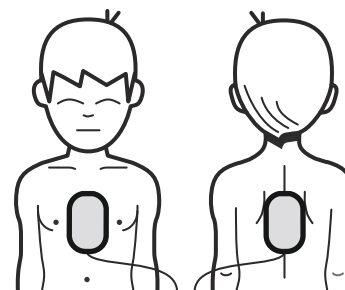
> NOTE: It does not matter whether you insert the Infant/Child Key before or immediately after turning on the FR3. Preferably, however, the Key should be inserted before placing the pads on the patient, for accurate pads placement directions.

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 and provides an infant/child CPR protocol.

---

* 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 lb (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 lb (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 2-12).

> WARNING: Do not use the CPR meter when treating an infant or child under 55 lb (25 kg) or 8 years old.

CPR METER FOR OPTIMIZED CPR

The CPR meter with Q-CPR technology by Laerdal is a small, lightweight device with an integrated cable, intended for use with the FR3.[*] The CPR meter is provided with a cradle for storage in the FR3 rigid system case, ten patient adhesives, and an FR3 CPR meter cable link for connection to the FR3. The FR3 powers the CPR meter and, if a data card is installed, records CPR performance data.

The system is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 55 lb (25 kg) or 8 years old. When attached to the bare chest of a suspected victim of SCA and connected to an FR3, the CPR meter provides real-time visual feedback on CPR in accordance with current CPR guidelines.

---

* The CPR meter can also be used with the HeartStart MRx monitor/defibrillator.

> WARNING: The CPR meter is not intended for use on SCA victims under 55 lb (25 kg) or 8 years old. If the Infant/Child Key is installed in the FR3, the CPR meter is disabled. If in doubt about the age or weight of the victim, perform CPR without using the CPR meter.

The CPR meter displays CPR feedback indicators for depth, release, and rate of chest compressions. It also provides notification of lack of expected CPR activity and a stay-clear icon display during FR3 rhythm analysis and shock delivery. In addition, the FR3 prompts the responder when it detects hyperventilation of the patient.

If a data card is installed, the FR3 records patient data during use of the CPR meter. The data recorded includes compression waveforms and events and ventilation waveforms and events.

Directions for using the CPR meter with the FR3 are provided with the CPR meter.

FR3 3-LEAD ECG CABLE FOR NON-DIAGNOSTIC ECG DISPLAY

At the discretion of a responder trained in its use, the FR3 3-Lead ECG Cable ("3-Lead Cable") can be connected to the model 861389 FR3 to provide a non-diagnostic ECG display of the patient's heart rhythm. The cable uses single-use ECG electrodes compliant with ANSI/AAMI EC12:2000/(R)2010 and indicated for application in ECG monitoring and/or stress testing. It is available in two models, one using AAMI label and color conventions, the other using IEC label and color conventions.

The system is intended for use on a conscious or breathing patient, regardless of age, for attended patient monitoring. Even if the model 861389 FR3 is configured for displaying only text in AED mode, the ECG mode is automatically enabled when the 3-Lead Cable is connected.

The responder can select to display lead vectors I, II, or III via ECG electrodes that snap onto the lead wires. The displayed ECG data is automatically recorded on an FR3 data card, if installed in the FR3. The responder can mark specific events during recording, for subsequent review and analysis.

The 3-Lead Cable is connected to the FR3 via the FR3 pads connector port. The defibrillator's shock capability is disabled during use of the ECG cable, but the FR3 continues to evaluate the patient's ECG. If the FR3 detects a potentially shockable rhythm, it provides a voice prompt to attach defibrillation pads if needed.

Directions for using the 3-Lead Cable with the FR3 are provided with the cable.

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 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) 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.

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.

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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.

CLEANING

The outside of the FR3 and all FR3 accessories except the CPR meter (see following) can be cleaned as described below.

> NOTE: Make sure a battery is installed when cleaning the FR3, to keep fluids out of the device.

- Clean the FR3, including the connector socket, and FR3 accessories 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

> 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.

* See "Other Compatible Defibrillator Pads" on page G-9 for a list of other pads that are compatible with the FR3.

The CPR meter can be cleaned as described below.

- Examine the vent membrane in the center of the yellow rear cover. If needed, use a soft cloth or toothbrush to gently clean the vent membrane. If damaged or still soiled after cleaning, replace the rear cover as described in the *Instructions for Use* provided with the CPR meter. Keep sharp objects away from the vent membrane.

- Wipe the CPR meter cables using an alcohol wipe (70% ethanol solution).

- Clean and scrub the exterior of the CPR meter using a mild detergent and either a soft cloth or toothbrush until the surfaces are visually clean.

- Wipe the exterior with a soft cloth or cotton ball dampened in lukewarm tap water.

- Clean the exterior using a 3% solution of RelyOn™ or Virkon® (3% solution in water). Spray the solution on to cover all exterior surfaces, and wait for at least five minutes. An alternative agent is isopropyl alcohol (70% solution).

- Wipe the exterior with a clean soft cloth dipped in distilled water. Allow to dry completely.

Do not use abrasive materials, cleaners, strong solvents such as acetone or acetone-based cleaners, or enzymatic cleaners on the FR3 or the CPR meter.

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 AND ACCESSORIES 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 primary battery, within "Install Before" date • FR3 data card installed, undamaged • Patient adhesives within expiration date, if CPR meter is used • ECG electrodes within expiration date, if 3-Lead Cable is used							
READY LIGHT flashing green; self-test passed.							
INSPECTED BY Signature or initials of operator completing the maintenance inspection							
REMARKS, PROBLEMS, CORRECTIVE ACTIONS							

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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 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:

- preconnected HeartStart SMART Pads III in Pads Sentry
- Data card
- CPR meter

The FR3 can be configured to include testing for the presence of pads and/or data card as part of its periodic self-tests. If either of these accessories 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

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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 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 preconnected, 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:

---

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

> 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.

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

Press ON for Patient Use
Shutting Down
Battery — Good
Data Card — Good
Administration — OFF

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.

ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		
▼	✓	▲

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.

Press ON for Patient Use
Press Shock Button to Run User-Initiated Test

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.

User-Initiated Test
Checking System

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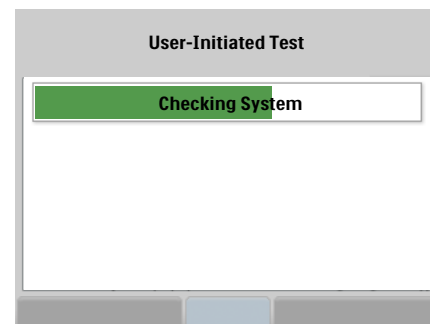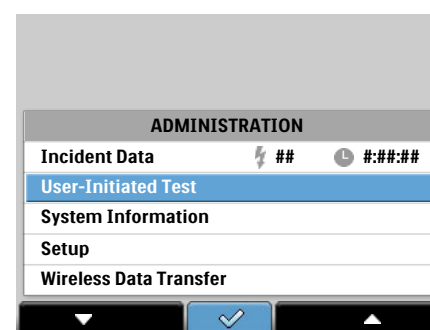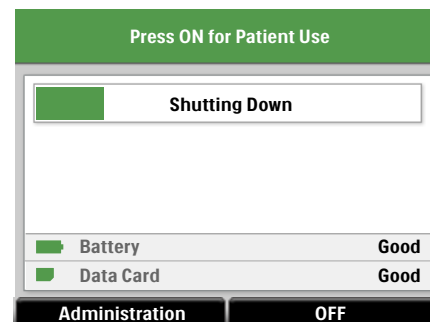
* If you do not make a selection while the status screen is displayed, the FR3 does not complete the test and goes into standby to be ready for use.
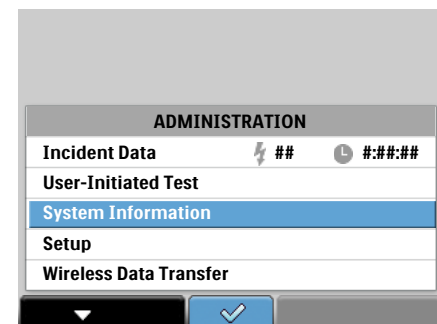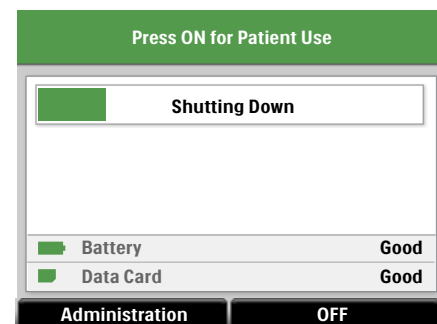
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6. When the test is complete, the FR3 displays the results of the test, the device serial number, and the software version, then displays the ADMINISTRATION screen again.

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

User-Initiated Test Results

Test Passed
Ready for Use

| Serial Number | C##X-##### |
| Software Version | PR#.# |

| Administration | OFF |

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.
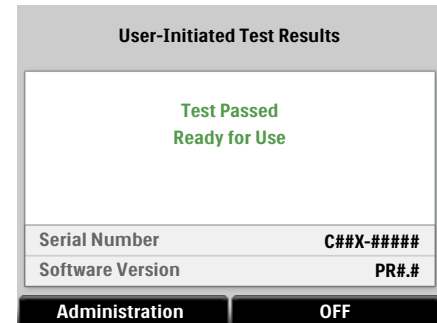
DEVICE HISTORY

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.

Press ON for Patient Use

Shutting Down

| Battery | Good |
| Data Card | Good |

| Administration | OFF |

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

ADMINISTRATION

Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		

| ▼ | ✓ | |

---

* 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.

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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.

| System Information	
← Back	
Device History	
Battery History	
Software Information	
FR3 Status	Ready for Use
Serial Number	C##X-#####
Model	######
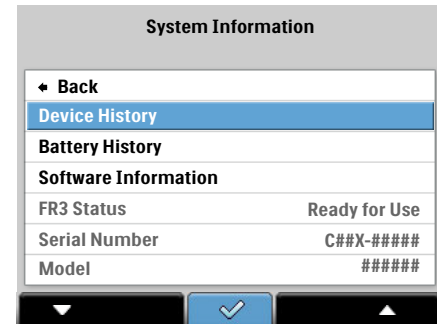
5. The DEVICE HISTORY screens display detailed information about the history of your FR3. The first screen displays the following information for review:

   • Therapy Uses — how many times the FR3 has been turned on and pads applied

Device History page 1/2	
← Back	
Therapy Uses	####
Therapy Time	##:## (hh:mm)
Shocks Delivered	####
Training Uses	####
Training Time	##:## (hh:mm)
Daily Self-Tests	####

   • 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

Device History page 2/2	
← Back	
Weekly Self-Tests	####
Monthly Self-Tests	####
User-Initiated Tests	####
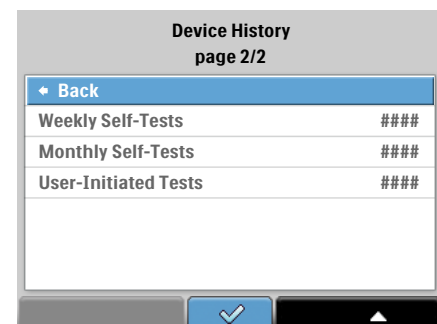
* If the training battery is not removed after 30 minutes of inactivity, the FR3 will go into training standby mode and begin giving alert chirps. It will count the next device activation as well as any periodic self-tests that occur during training standby as Training Uses. This will inflate the number of Training Uses displayed on the DEVICE HISTORY screen.
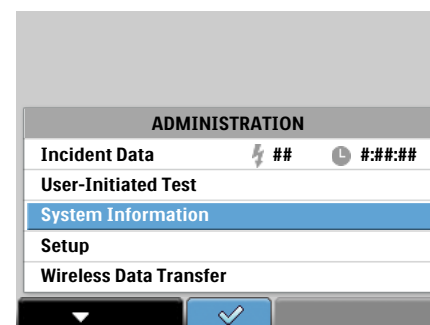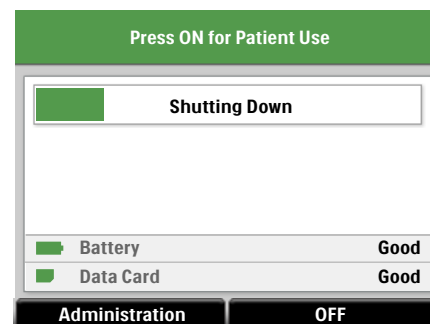
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- Monthly Self-Tests — the number of monthly self-tests the FR3 has run
- User-Initiated Tests — the total number of user-initiated tests of the FR3 that have been run

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.

Press ON for Patient Use	
Shutting Down	
Battery	Good
Data Card	Good
Administration	OFF

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

ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		

---

* 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.

PHILIPS MEDICAL SYSTEMS

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.

System Information

← Back	
Device History	
Battery History	
Software Information	
FR3 Status	Ready to Use
Serial Number	C##X-#####
Model	######
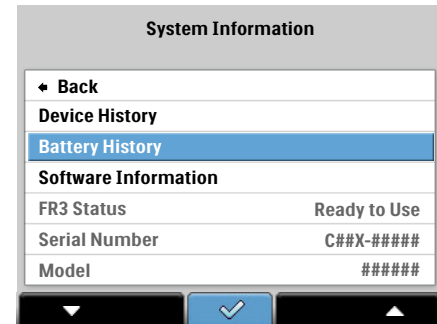
5. The BATTERY HISTORY screen displays the following information about the history of the battery currently installed in your FR3:

    - Use Time — the total operating time in hours and minutes (hh:mm), including self-test time, for this battery

Battery History

← Back	
Use Time	##:## (hh:mm)
Charges	##
Standby	### (days)
User-Initiated Tests	###
Battery Status	Good
Battery Status Code	########

    - 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)

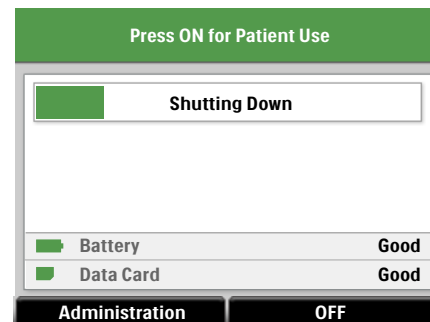   - Battery Status Code — for use by Philips technical support
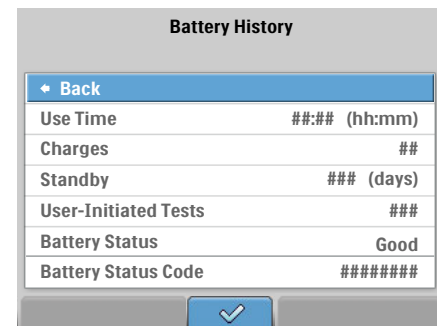
6. If you have other administrative tasks to perform, press the ✓ option button to exit the screen and return to the SYSTEM INFORMATION screen, then press the ✓ option button on that screen to return to the ADMINISTRATION screen. Otherwise, press the On/Off button to display the status screen and put the FR3 into standby.
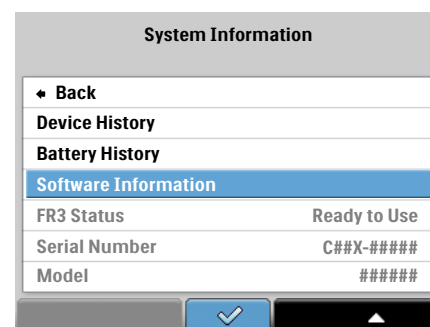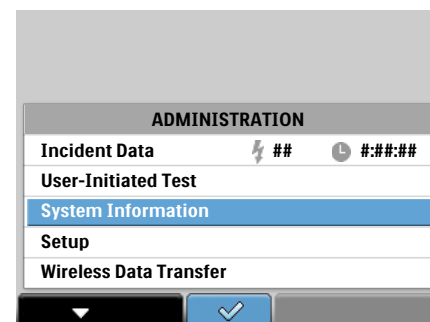
SOFTWARE INFORMATION

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.

Press ON for Patient Use	
Shutting Down	
Battery	Good
Data Card	Good
Administration	OFF

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

ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		
▼	✓	

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.

System Information	
◆ Back	
Device History	
Battery History	
Software Information	
FR3 Status	Ready to Use
Serial Number	C##X-#####
Model	######
✓	▲

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.

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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.

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 giving triple chirps	Contact Philips at www.philips.com/AEDSupport for technical support. (See "Informational and Error Messages" on page 4-18.)
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 for information about the status of the FR3 and how to resolve the problem. If you cannot resolve the problem, or if it recurs, contact Philips at www.philips.com/AEDSupport for technical support.
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 light 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, direct 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

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.

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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.
Do not use CPR meter	• The Infant/Child Key has been installed in the FR3 while the CPR meter is connected.	• The CPR meter is disabled when the Infant/Child Key is installed. Do not use the CPR meter on a patient under 8 years old or 55 lb (25 kg).

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 emissions 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 emissions 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.

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FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Attend to patient	• A shock has been advised but the Shock button was not pressed within 30 seconds. • The AED has been unable to analyze for more than 45 seconds.	• Provide CPR if needed. When next prompted, press the Shock button to deliver a shock. • Provide CPR if needed or follow your local protocol.
Press the flashing orange button now 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.
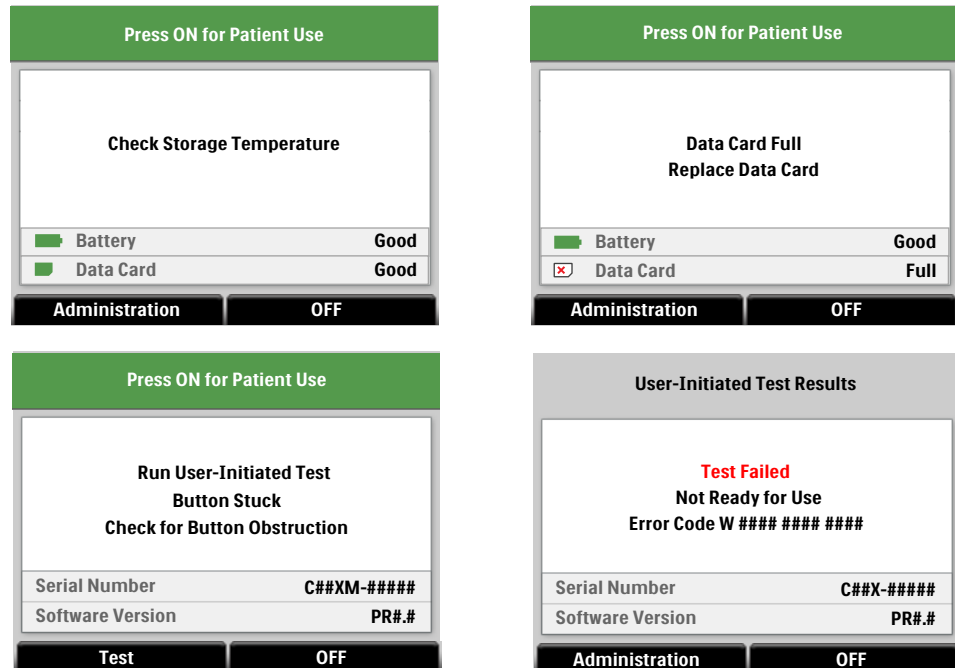
MESSAGES AT SHUTDOWN

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.

Press ON for Patient Use	
Check Storage Temperature	
▬ Battery	Good
▭ Data Card	Good
Administration	OFF

Press ON for Patient Use	
Data Card Full Replace Data Card	
▬ Battery	Good
☒ Data Card	Full
Administration	OFF

Press ON for Patient Use	
Run User-Initiated Test Button Stuck Check for Button Obstruction	
Serial Number	C##XM-#####
Software Version	PR#.#
Test	OFF

User-Initiated Test Results	
Test Failed Not Ready for Use Error Code W #### #### ####	
Serial Number	C##X-#####
Software Version	PR#.#
Administration	OFF

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."

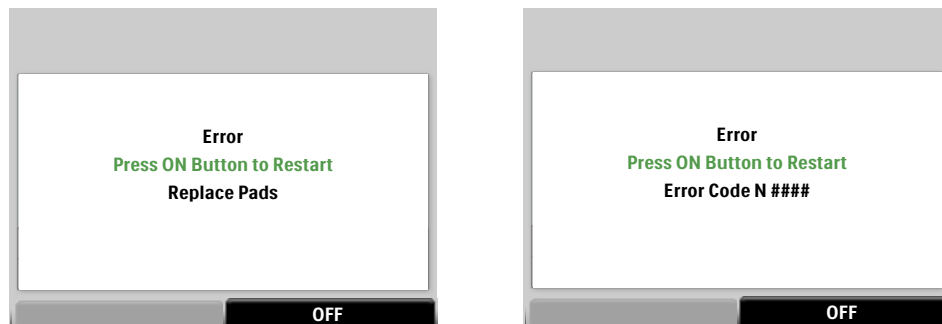| TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Replace Pads and Restart	The FR3 cannot detect pads attachment after five minutes of prompting.	Make sure pads are undamaged and are correctly applied to patient's bare chest. Clip or shave excess chest hair from pads placement areas. If necessary, connect 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. *NOTE: Although the FR3 may indicate that a data card is invalid, patient use data recorded on the card may still be accessible. Do not discard the card without attempting to retrieve the patient data.*

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TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Remove Training Pads	Training pads are connected.	Remove the training pads and replace them with appropriate clinical pads.
Unplug 3-Lead Connector	3-lead ECG cable is connected, causing the FR3 to fail its self-test.	Remove the 3-lead cable connector and replace it with appropriate clinical pads.
Plug in Pads Connector	The FR3 is configured to check preconnected pads during self-test and does not detect the pads.	Make sure pads are preconnected 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.

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TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
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.

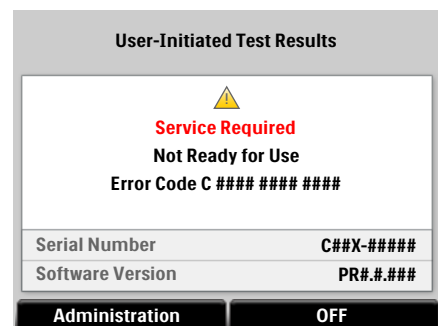| TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Error … Press ON button to Restart … Error Code N ####	The FR3 has encountered an error.	Press the On/Off button to clear. After the use, contact Philips at www.philips.com/ AEDSupport for technical support.

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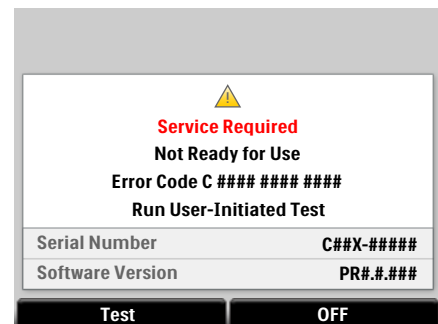
If the user-initiated test fails to clear the error, the FR3 displays a test results service-required error message. Record the error code, software version, and device serial number, and contact Philips at www.philips.com/AEDSupport for technical support.

⚠️

Service Required
Not Ready for Use
Error Code C #### #### ####
Run User-Initiated Test

Serial Number	C##X-#####
Software Version	PR#.#.###

Test	OFF

User-Initiated Test Results

⚠️

Service Required
Not Ready for Use
Error Code C #### #### ####

Serial Number	C##X-#####
Software Version	PR#.#.###

Administration	OFF

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.

Load New Setup

← Back

No Setup File

❌

✓

Setup Error
Remove Language Card

❌

Serial Number	C##X-#####
Software Version	PR#.#
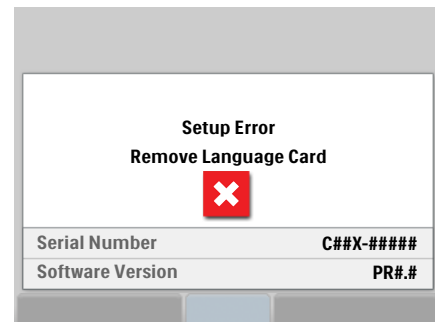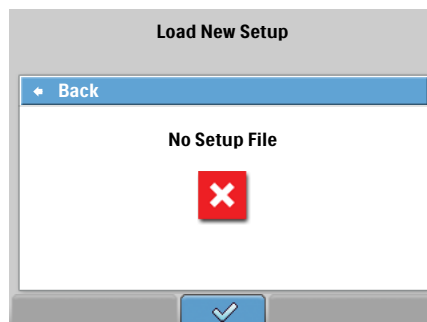
NOTE: If you encounter errors during wireless data transfer of a new device configuration file, see the HeartStart Configure software documentation.

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.

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TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
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.	Either the FR3 language card, or HeartStart Configure software with a data 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 6-16. *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	DO NOT OPEN, CRUSH, BURN, FORCE DISCHARGE, ENCAPSULATE, AND/OR MODIFY THE FR3 BATTERIES. DO NOT TRY TO RECHARGE FR3 NON-RECHARGEABLE BATTERIES. THESE ACTIONS MAY CAUSE THE BATTERY TO 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.

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SAFETY LEVEL	POSSIBLE IMPROPER DEVICE PERFORMANCE
CAUTION	Follow all instructions supplied with the FR3 rechargeable batteries. 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) emissions 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.
CAUTION	The CPR while Armed feature is intended for use by operators who have been specifically trained in its use according to local protocols established by the Medical Director.

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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.

CPR METER CAUTIONS

SAFETY LEVEL	POSSIBLE PATIENT INJURY OR MISINTERPRETATION OF Q-CPR METER FEEDBACK
WARNING	The CPR meter is not intended for use on SCA victims under 55 lb (25 kg) or 8 years old. If the Infant/Child Key is installed in the FR3, the CPR meter is disabled. If in doubt about the age or weight of the victim, perform CPR without using the CPR meter.
WARNING	Do not use the CPR meter in conjunction with any mechanical or automated compression device.
WARNING	The algorithm used by the CPR meter for calculating ventilation feedback has not been validated for use with anterior-posterior placement of defibrillation pads. Do not use the CPR meter for ventilation feedback with this pads placement.
WARNING	Ventilation feedback accuracy is decreased during patient handling or movement and when the CPR meter is used on patients with trauma, seizures, reduced lung volume, or high cardiac ejection fractions.

SAFETY LEVEL	POSSIBLE PATIENT INJURY OR MISINTERPRETATION OF Q-CPR METER FEEDBACK
WARNING	If motion artifact interferes with ventilation activity measurement, the system cannot determine frequency and provide a warning if ventilations are too frequent. Perform ventilations according to your protocol.
WARNING	CPR is best performed when the patient is lying on a firm surface. If the patient is on a surface that yields, such as a mattress, compression depth feedback from the CPR meter is inaccurate. Either move the patient to a rigid surface, or slide a backboard under the patient and compensate for mattress compliance by ensuring that each compression exceeds the compression depth target shown on the CPR meter.
WARNING	The CPR meter is not intended for use in a moving environment, such as an ambulance. If used during patient transport, the CPR meter may provide inaccurate feedback. If CPR is indicated in a moving environment, do not rely on the CPR meter depth feedback during such conditions. It is not necessary to remove the device from the patient.
WARNING	Do not practice by using the CPR meter on a person. The CPR meter may be used with a training manikin for practice.
WARNING	Properly performed CPR may result in fracturing of the patient's ribs. If rib integrity has been compromised, continue to provide CPR in accordance with your local protocol.
WARNING	Do not rely on CPR meter feedback during aircraft ascent and descent, as its accuracy is reduced in such conditions.
CAUTION	Proper anterior-anterior placement of defibrillation pads is required for accurate operation of the ventilation algorithm.
CAUTION	Do not immerse the CPR meter or cables in water, hold them under running water, or allow moisture to penetrate them. Do not sterilize the CPR meter or cables.
CAUTION	Do not install a battery in the CPR meter's internal battery compartment. The CPR meter is powered by the FR3 and will not work if a battery is installed.
CAUTION	The CPR meter is designed to be used only with Philips-approved accessories. The CPR meter may perform improperly if non-approved accessories are used. Do not attempt to modify the CPR meter in any way.
CAUTION	Do not apply the CPR meter to an open wound or recent incision site.

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FR3 3-LEAD ECG CABLE CAUTION

SAFETY LEVEL	POSSIBLE DAMAGE TO CABLE
CAUTION	Do not use the 3-Lead Cable with other defibrillators or adapters, as this may damage the cable. If the 3-Lead Cable is subjected to a defibrillation shock, test the cable as described in the "Troubleshooting" section of the *Instructions for Use* provided with the 3-Lead Cable.

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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 PR2.0. 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 and a data card. For information on ordering HeartStart Configure, 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 6-17)		✓	✓ with data card	
Enable bilingual option and select secondary language (page 6-19)		✓	✓ with data card	
Set FR3 date and time (page 2-6 and page 6-13)	✓		✓	✓
Use computer date and time for FR3 (page 7-5)			✓	✓

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

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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 a checkmark (✓).

> NOTE: For information on setting the date and time for your FR3, see "Setting the Date and Time" on page 2-6.

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 or HeartStart Configure software and a data 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 6-17.
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 6-19.*

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.
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.*
Auto-On	✓ yes • no	Enables (YES) or disables (NO) the automatic activation of the FR3 when the rigid FR3 carry case is opened. *NOTE: When Auto-On is configured to NO, the user must press the green On/Off button to activate the FR3. (The On/Off button can always be used to turn on the FR3.)* *NOTE: If Auto-On is configured to YES and activates the FR3 five consecutive times without a patient use, the feature is automatically disabled until the FR3 is activated by pressing the On/Off button or reinserting a battery.*

* 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 preconnected 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 for Pads	• on ✓ off	Enables (ON) or disables (OFF) testing for the presence of preconnected pads during each self-test. *NOTE: If configured to ON and the pads are not present, the FR3 will fail its next self-test.*
Test for Data Card	• on ✓ off	Enables (ON) or disables (OFF) testing for the presence of an installed data card during each self-test. *NOTE: If configured to ON and the data card is not present, the FR3 will fail its next 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. (If configured to <u>CPR First - Always</u> the FR3 provides a CPR protocol when turned on, independent of pads attachment.)

- 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.

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 a checkmark (✓).

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 <u>CPR duration</u> 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.*

---

* FR3 default shock series is one shock.

PARAMETER	SETTINGS	DESCRIPTION
CPR First	✓ off • SMART CPR auto1 • SMART CPR auto2 • user[*] • always	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, "CPR First." *NOTE: The Analyze option button is available during 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.
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.*

* Anytime the FR3 displays the CPR option button, the configured CPR protocol can also be initiated by use of the CPR meter, except during patient analysis.

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.
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 <u>shock series interval</u> setting (when the shock series setting is more than one).
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 <u>shock series</u> 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.*

PARAMETER	SETTINGS	DESCRIPTION
Advanced Use Repeat (minutes)	✓ 0.5 • 1.0 • 2.0	Sets the repeat rate for patient care prompts provided by the FR3 when <u>advanced mode use</u> is configured to ANALYZE or CHARGE.
CPR while Armed	✓ no • yes	Disables (NO) or enables (YES) CPR to be performed for up to 30 seconds after the FR3 has advised a shock and is armed. If configured to YES, the FR3 does not analyze patient rhythm during this period. An orange progress bar is provided on the FR3 screen. After 20 seconds, a voice prompt reminds the user to deliver a shock or the device will disarm. The user has until the end of the 30 seconds to press the Shock button. This allows shock delivery immediately following CPR. If configured to NO, CPR should not be done during this period, because the FR3 continues patient analysis after advising a shock. Compression artifact from CPR performed during analysis may cause the device to disarm. *CAUTION: The CPR while Armed feature is intended for use by operators who have been specifically trained in its use according to local protocols established by the Medical Director.*

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.[†]

Press ON for Patient Use
Shutting Down
Battery　　　　　　　　　**Good**
Data Card　　　　　　　　**Good**
Administration　　　**OFF**

---

* 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.

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

ADMINISTRATION		
Wireless Data Transfer		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		

▼　✓　▲

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

Setup

- ◆ Back
- Load New Setup
- View Setup
- Save Setup to Data Card
- Date and Time

▼　✓　▲

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.

View Setup
page 1/#

◆ Back	
Primary Language	U.S. English
Bilingual Option	Off
Volume	Loud
ECG Display	On
Record Audio	Off
Wirelss Pin	****

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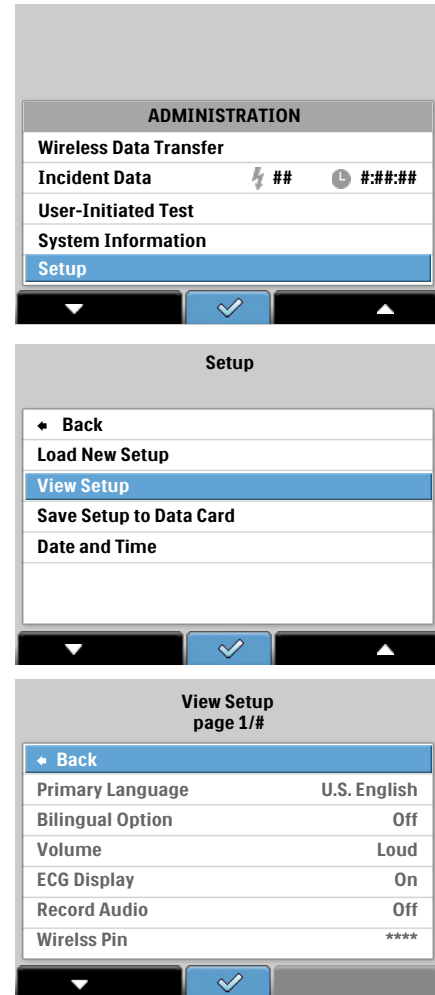
NOTE: If a parameter is not active in the device configuration, it will be shown with "—" as its setting.

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.

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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 the optional *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, or HeartStart Configure software and a data 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 6-16 for details.

Language Unchanged
See Instructions for Administrators

| Serial Number | C##X-##### |
| Software Version | PR#.#.### |
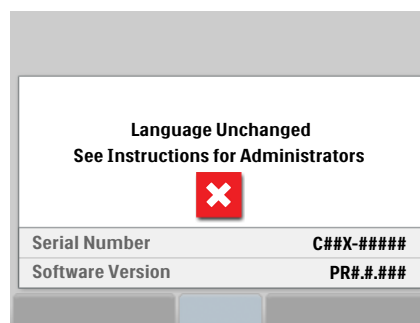
To modify setup using a computer equipped with HeartStart Configure and an FR3 data card, follow these steps:

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

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.

---

[*] 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 6-16 for details on changing a language.

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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 2-3 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.

Press ON for Patient Use
Shutting Down
Battery — Good
Data Card — Good
Administration / OFF

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

ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		

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.
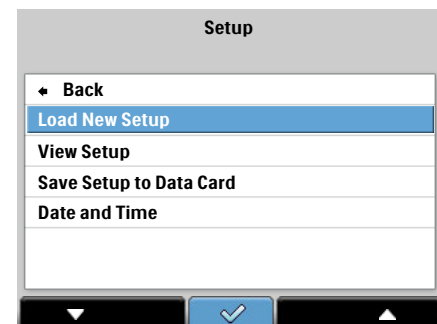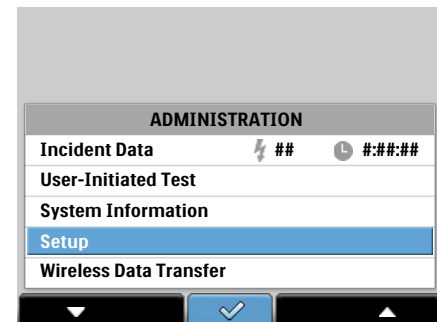
Setup
◂ Back
Load New Setup
View Setup
Save Setup to Data Card
Date and Time

---

* 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.

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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.
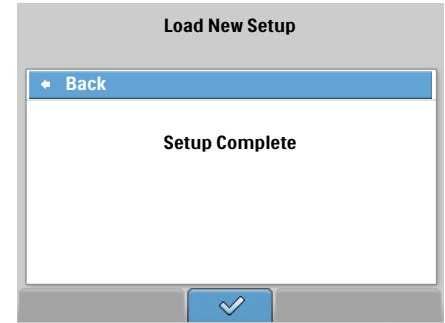
14. After loading a new setup, select the BACK command to return to the SETUP screen. Press the ▼ option button to scroll to VIEW SETUP, then press the ✓ option button to select it. Review the VIEW SETUP screens to confirm that your configuration changes have been made.

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 6-16 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 2-4 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.

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

Press ON for Patient Use	
Shutting Down	
■ Battery	Good
■ Data Card	Good
Administration	**OFF**

6. On the ADMINISTRATION screen, press the ▼ option button to scroll to WIRELESS DATA TRANSFER. Press the ✓ option button to select it.
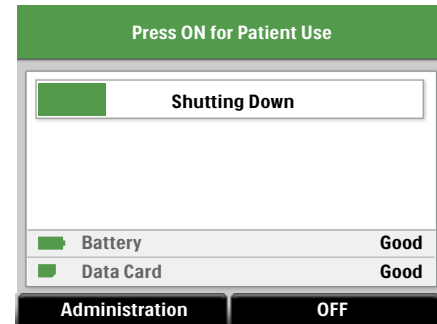
ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		
▼	✓	
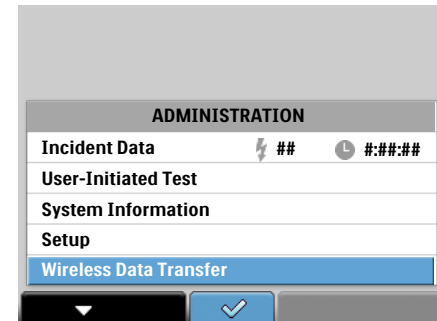
> NOTE: Make sure the optional *Bluetooth* wireless technology transceiver module is installed in the FR3. If a *Bluetooth* transceiver module is installed, the Administration screen remains active for 10 minutes to allow time to achieve connection.

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.

Wireless Data Transfer
◆ **Back**
Ready for Data Transfer
✓
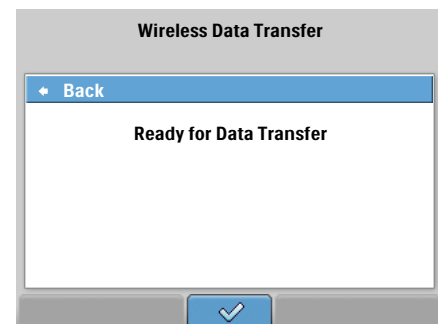
8. Start HeartStart Configure and follow the instructions for sending the new setup to the FR3.

---

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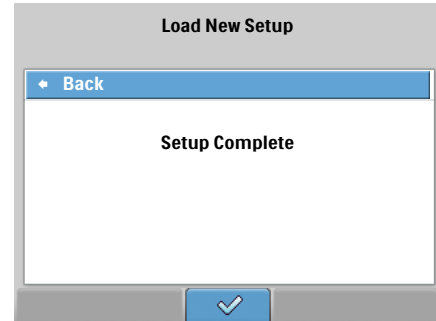
If an error occurs during transfer, Configure displays an error message.

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 2-3. 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.

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

ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		

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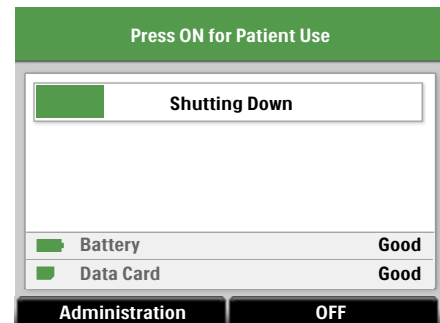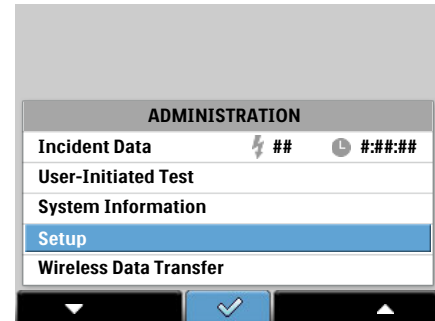
5. On the SETUP screen, press the ▼ option button to scroll to SAVE SETUP TO DATA CARD, then press the ✓ option button to select it. The FR3 automatically saves the current configuration to the installed data card.

Setup
← Back
Load New Setup
View Setup
Save Setup to Data Card
Date and Time

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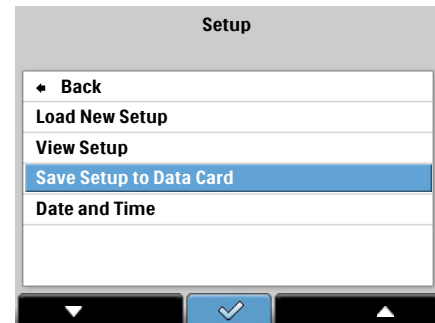
6. When the save process is complete, the FR3 display provides a SETUP COMPLETE message. After 10 seconds, the FR3 returns to the SETUP screen.

> 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 , 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 can operate in any language that is provided on the FR3 language card. If you do not have a language card and want to modify the default language of the FR3, or to enable the bilingual option and select a second language, use HeartStart Configure software, version 3.1 or higher and a data card. See page 6-19. To change the primary language using the language card, 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 6-18.
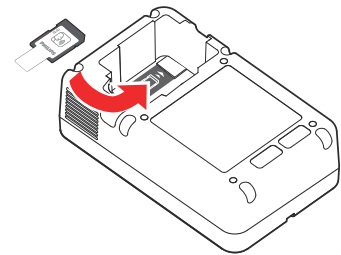
2. Insert the FR3 language card into the data card slot in the bottom of the FR3 battery compartment. A label on the floor of the compartment shows the correct orientation for inserting the card. A retention clip helps hold the card in the slot. The tail on the data card serves as a visual reminder that a card is installed and aids in card removal.
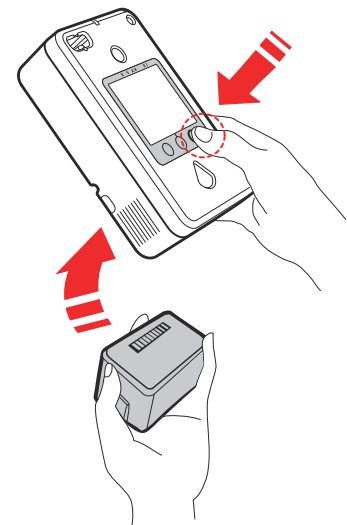
3. Reinstall the battery *while holding down the* **right** *option button*. Keep the button pressed until the language selection screen is displayed.

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 displays an error message and shuts down after approximately 5 minutes. To restart the language selection 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.

Setup Complete
Remove Language Card

Serial Number	C##X-#####
Software Version	PR#.#.##

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.

Retention clip

Language card tail

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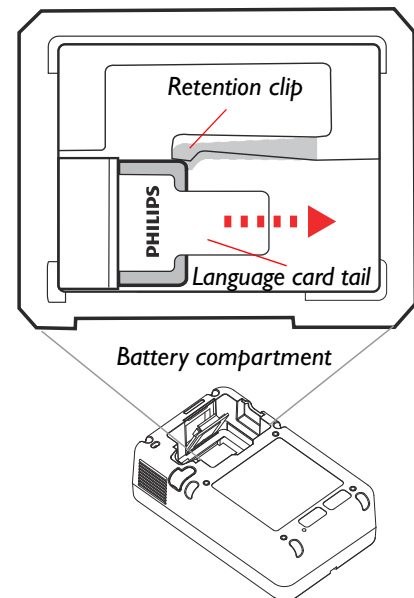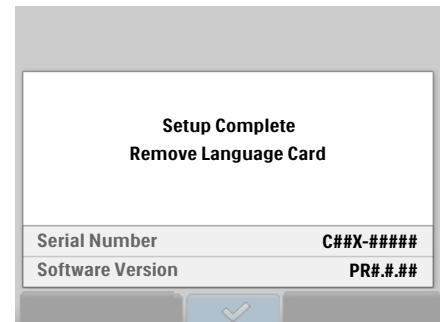
2. Insert an FR3 data card, if desired, in the data card slot, and reinstall the battery. As soon as the battery is installed, the FR3 automatically runs a detailed user-initiated test. Press the buttons when directed, or the test will fail. See "User-Initiated Test" on page 4-7 for directions.

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 2-6 for directions. The device will automatically turn off after a few minutes.

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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 (or a data card) and HeartStart Configure, separately available software. HeartStart Configure uses the FR3 language card to identify available languages and provides directions for 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 or a data 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 6-17. 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.)

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4. Follow the directions for removing the language card as described on page 6-18. 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.
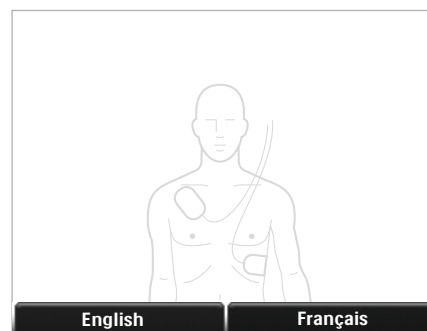
If you select the secondary language, the FR3 announces the language selection and uses that language for all operation until the FR3 returns to standby mode. If you do not select the secondary language within 10 seconds, the FR3 continues to operate in the primary language.

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.

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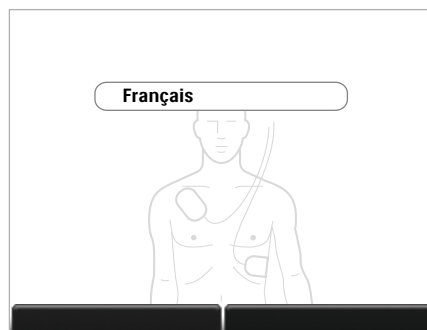
7   DATA MANAGEMENT

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.[†]

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*   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 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

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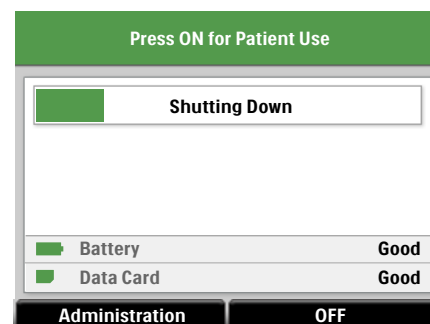
[*] ECG and Audio recording begin within seconds of the initial FR3 voice prompts. As a result, the first voice prompt may not be recorded. If pads have already been placed on the patient before the FR3 is activated, the first second of the presenting ECG may not be recorded.

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

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

ADMINISTRATION		
Incident Data	⚡ ##	🕐 #:##:##
User-Initiated Test		
System Information		
Setup		
Wireless Data Transfer		
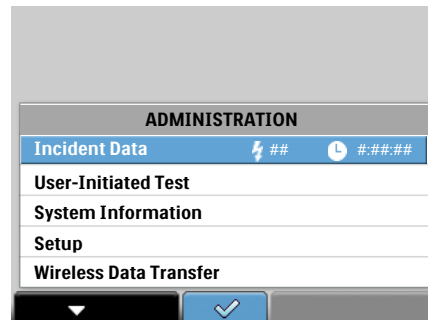
4. The INCIDENT DATA screen displays the incident duration in hours (if applicable), minutes, and seconds (h:mm:ss);[†] the total number of shocks delivered, and elapsed time from device on to first shock in hours (if applicable), minutes, and seconds (h:mm:ss); and provides access to the PRESENTING ECG screen.

Incident Data	
◄ **Back**	
Presenting ECG	
Incident Duration	#:##:##
Shocks Delivered	##
First Shock Time	#:##:##
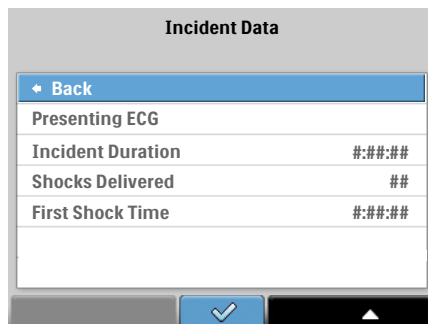
5. To review the first 15 seconds of the presenting ECG, press the ▼ option button to scroll to PRESENTING ECG, then press the ✓ option button to select it.

Incident Data	
◄ Back	
Presenting ECG	
Incident Duration	#:##:##
Shocks Delivered	##
First Shock Time	#:##:##
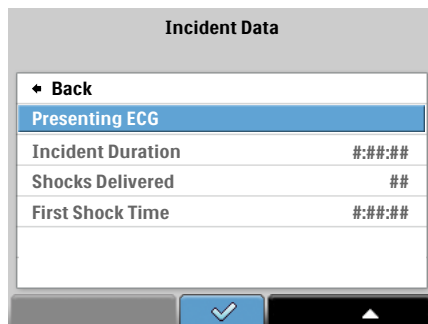
6. The presenting ECG is displayed in 4-second segments on successive screens. To move to the next ECG screen, press the ▼ option button. To return to the previous ECG screen, press the ▲ option button. To exit any screen, press the ✓ option button and return to the INCIDENT DATA screen.
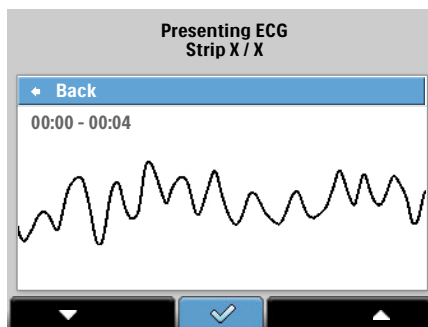
**Presenting ECG**
Strip X / X

◄ **Back**

00:00 – 00:04

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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.

† 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.

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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.

Retention clip

Data card tail

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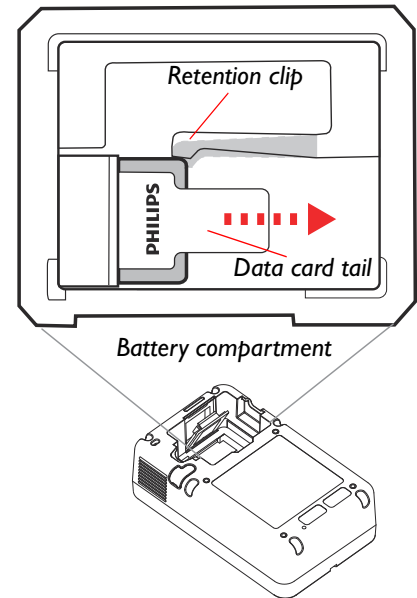
3. Install the data card in a computer with an appropriate Event Review software product installed or in a USB data card adapter connected to a computer with the software.

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.

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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. 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
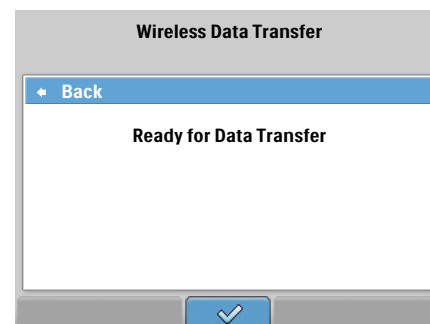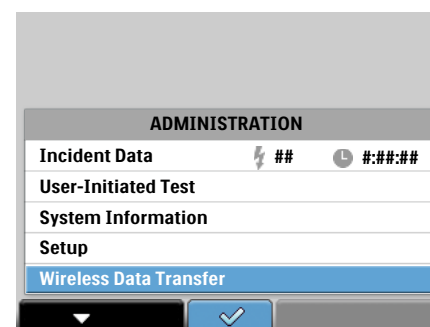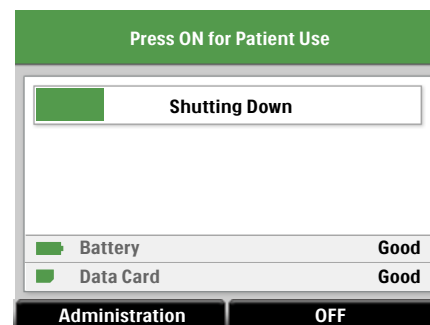
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* If you do not make a selection while the status screen is displayed, the FR3 turns off and goes into standby to be ready for use.
† If there is no Bluetooth activity for ten (10) minutes, the FR3 will return to the ADMINISTRATION screen. If you wish to resume activity, select WIRELESS DATA TRANSFER again.

Operation Parameters" on page 6-3.) 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.

<div align="center">

Wireless Data Transfer

← **Back**

Transferring

⇄

</div>
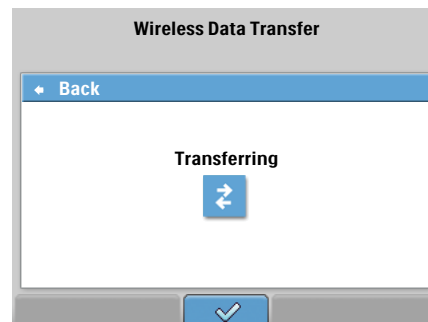
7. When transfer is complete,[*] the screen displays a DATA TRANSFER ENDED message.

8. Press the ✓ option button to select the BACK command and exit to the READY FOR DATA TRANSFER screen.

<div align="center">

Wireless Data Transfer

← **Back**

Data Transfer Ended

</div>

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.
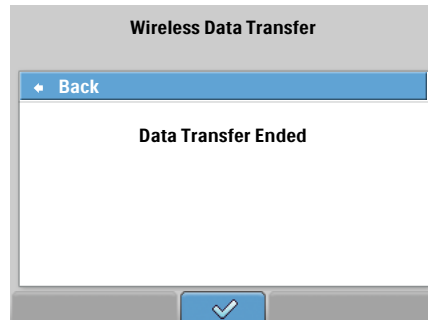
> NOTE: These steps may be used to view and copy files on the FR3 data card using any device and software that has *Bluetooth* wireless technology File Transfer Profile capability. However, to prevent accidental erasure of patient data, wireless erasure of the data card event files can only be done using 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.

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

PHILIPS MEDICAL SYSTEMS

A ACCESSORIES

LIST OF ACCESSORIES

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

- FR3 clinical use batteries
  — FR3 primary clinical use battery (spare recommended) [REF: 989803150161]
  — FR3 primary clinical use battery, FAA compliant [REF: 989803150171]
  — FR3 rechargeable clinical use battery [REF: 989803150241]
  NOTE: It is recommended that a primary battery be used as a spare battery.

- Charger for the FR3 989803150241 rechargeable clinical use battery and the FR3 rechargeable training battery included in the 989803150191 FR3 Training Pack; includes power cord [REF: 861394]

- 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 bottom case insert and Pads Sentry; accommodates spare pads, spare battery, Infant/Child Key, Fast Response Kit, and CPR meter and cradle; supports Auto-On [REF: 989803149971]
  — Bottom insert for FR3 rigid system case 989803149971 [REF: 989803150211]
  — FR3 soft system case, with Pads Sentry; accommodates spare pads, spare battery, Infant/Child Key, and CPR meter [REF: 989803179161]
  — FR3 small soft case, with Pads Sentry; accommodates spare pads and Infant/Child Key [REF: 989803179181]
  — Secure-pull case seal [REF: M3859A]
  — Replacement FR3 Pads Sentry for HeartStart SMART Pads III [REF: 989803150011]
  — Replacement CPR meter cradle [REF: 989803162231]

- FR3 data card [REF: 989803150061]

- USB data card reader [REF: M3524A]

- *Bluetooth* wireless technology items
  — Transceiver module [REF: 989803150081]
  — USB *Bluetooth* Dongle [REF: 861488]

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* 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 preconnected to the FR3. The FR3 provides defibrillation only.

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- FR3 3-Lead ECG Cables and related items
  — FR3 3-Lead ECG Cable (AAMI) with storage pouch
    [REF: 989803150041]
  — FR3 3-Lead ECG Cable (IEC) with storage pouch [REF: 989803150051]
  — Philips ECG monitoring electrodes, box of 20 packs of 3 electrodes
    [REF: 989803137771]
- 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]
- 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]
- CPR meter and related items
  — CPR meter for FR3 [REF: 989803149941]
  — CPR meter patient adhesives, set of 10 [REF: 989803163291]
  — Replacement FR3 CPR meter cable link [REF: 989803149951]
  — Replacement CPR meter rear cover (spare recommended)
    [REF: 453564147571]
  — Replacement CPR meter cradle for FR3 rigid system case
    [REF: 989803162231]
  — Replacement CPR meter [REF: 989803162401]
- Data Management and Configuration Software
  — HeartStart Event Review version 4.3 or higher.
      single PC license [REF: 861489 option A01]
      organization-wide license [REF: 861489 option A02]
  — HeartStart Event Review upgrade from version 3.5 to version 4.3 or
    higher
      single PC license [REF: 861489 option A03]
      organization-wide license [REF: 861489 option A04]
  — HeartStart Event Review Pro version 4.3 or higher
      single PC license [REF: 861431 option A01]
      organization-wide license [REF: 861431 option A03]
  — HeartStart Event Review Pro upgrade from version 3.5 to version 4.3 or
    higher
      single PC license [REF: 861436 option A01]
      organization-wide license [REF: 861436 option A03]
  — HeartStart Data Messenger version 4.3 or higher
      single PC license [REF: 861451 option A01]
      organization-wide license [REF: 861451 option A03]
  — HeartStart Configure version 3.1 or higher [REF: 861487]

- 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 989803150241 rechargeable clinical use and FR3 989803150191 rechargeable 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]

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* 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 (not supplied) that houses preconnected pads and allows for their testing as part of the periodic self-tests by the FR3; a cradle (not supplied) for an optional preconnected CPR meter; 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.

optional FR3 Fast Response Kit

optional spare pads

preconnected HeartStart SMART Pads III in Pads Sentry

optional CPR meter

optional FR3 Infant/Child Key

optional spare battery (beneath CPR meter)

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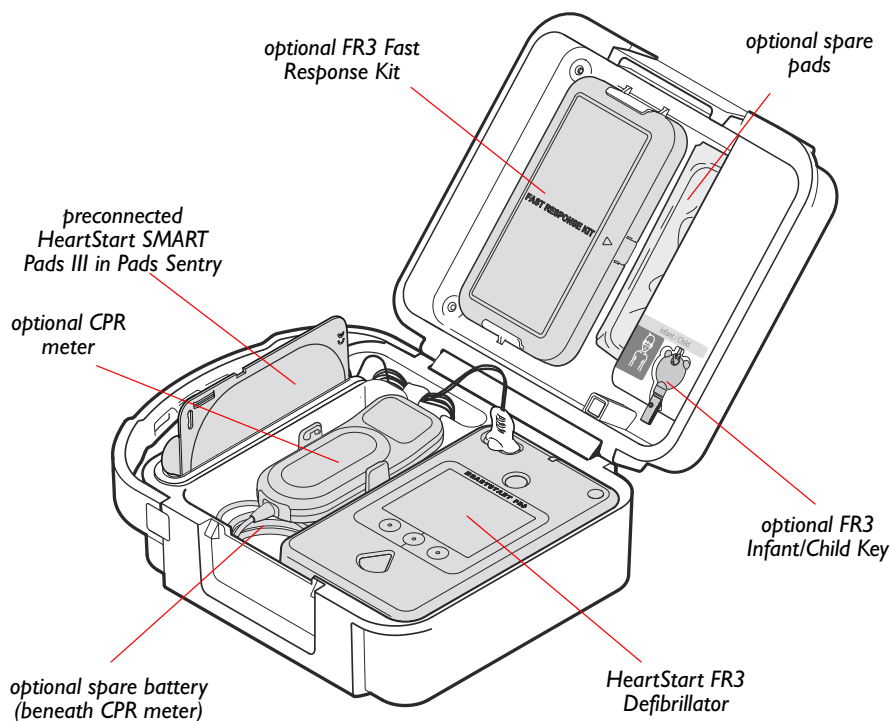
NOTE: Two other carry cases are also available: The FR3 soft system case with Pads Sentry accommodates spare pads, spare battery, Infant/Child Key, and CPR meter; and the FR3 small soft case with Pads Sentry accommodates spare pads and the Infant/Child Key. See page A-1.

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 lb (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.

CPR METER

The CPR meter with Q-CPR technology by Laerdal is a small, lightweight device with an attached cable, that is connected to a Philips FR3 using an FR3 CPR meter cable link. The system is used as a guide in administering cardiopulmonary resuscitation (CPR) to a suspected sudden cardiac arrest (SCA) victim at least 55 lb (25 kg) or 8 years old. The meter is disabled when the FR3 Infant/Child Key is installed.

The CPR meter is placed on the victim's chest using a CPR meter patient adhesive. The CPR meter's display screen provides real-time visual feedback on CPR performance in accordance with current CPR guidelines. Q-CPR data is recorded on the FR3 data card, if one is installed.

Compression Release Target — Compression Rate Target
Compression Depth Indicator — Compression Rate Indicator
Compression Depth Target — 104 — Compression Counter
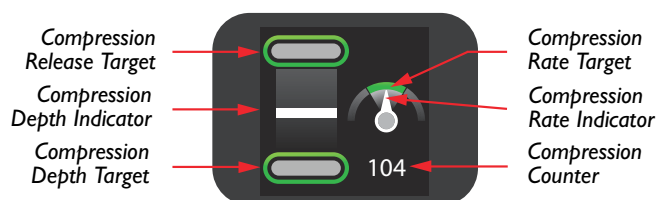
BLUETOOTH WIRELESS TECHNOLOGY TRANSCEIVER MODULE

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.

Training battery, training pads, and interconnect cable.
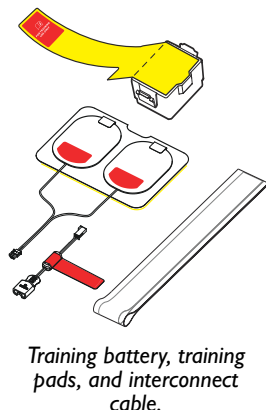
FR3 TRAINING PACK

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.
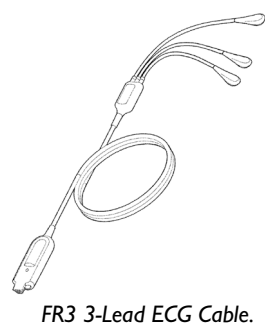
FR3 3-LEAD ECG CABLE

FR3 3-Lead ECG Cable.

The FR3 3-Lead ECG Cable can be connected to the model 861389 FR3 to provide a non-diagnostic ECG display of the patient's heart rhythm. The cable uses standard ECG monitoring electrodes. It is available in two models, one using AAMI label and color conventions, the other using IEC label and color conventions. The system is intended for use on a conscious or breathing patient, regardless of age, for attended patient monitoring. The responder can select to display lead vectors I, II, or III via standard ECG electrodes that snap onto the lead wires. The displayed ECG data is automatically recorded on an FR3 data card, if one is installed in the FR3. The responder can mark specific events during recording, for subsequent review and analysis.
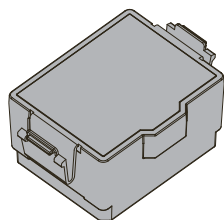
RECHARGEABLE CLINICAL USE BATTERY

The FR3 rechargeable battery is intended for use by organizations, such as EMS or fire departments, that use the FR3 frequently and want to decrease cost-per-use and reduce environmental waste. The rechargeable battery should only be used by organizations committed to providing the resources required to operate a battery maintenance program. Due to changes in the performance characteristics of rechargeable batteries over time, it is important for the battery maintenance program to monitor how many battery charge/discharge cycles the battery experiences, in order to determine when to retire it from service.

The FR3 rechargeable battery is not recommended for infrequent-use environments such as office buildings, airlines, or public access defibrillation (PAD) programs. It should not be used as the spare or backup battery; instead, the standard primary battery should be used due to its long shelf-life.

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B GLOSSARY

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

TERM	MEANING
3-Lead ECG Cable	An optional accessory for use with the FR3 at the discretion of a responder trained in its use. The ECG Cable provides a non-diagnostic display on the FR3 screen. During use, the responder can elect to display lead vector I, II, or III.
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.

TERM	MEANING
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.
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.
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.
CPR Duration	A programmable period provided by the FR3 during which the responder can administer CPR.
CPR Meter	An optional accessory that, when connected to the FR3, provides real-time feedback on CPR in accordance with current CPR guidelines.
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.
EMI	Electromagnetic interference.
ESD	Electrostatic discharge.
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.

TERM	MEANING
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.
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. The Q-CPR feature also uses the FR3 impedance channel in measuring CPR-related parameters.
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."
Patient Adhesive	An adhesive patch applied to the back of CPR meter. The exposed side is covered with a liner that is removed to attach the CPR meter to the bare chest of a patient.
Peak Current	The highest current level reached during the biphasic waveform. This happens at the beginning of the first phase.

TERM	MEANING
Pediatric Defibrillation	Defibrillation of a child under 55 lb (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.
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	These batteries are 12 VDC, 4.7 Ah, lithium manganese dioxide, disposable, long-life primary cells.
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.
Q-CPR Data	Data gathered by the FR3 from a connected CPR meter using Q-CPR Technology by Laerdal. Data includes compression waveforms and events and ventilation waveforms and events.
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 Battery	These batteries are 10.8 VDC, 4.5 AH, lithium ion rechargeable cells, for use 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.
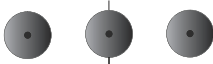
TERM	MEANING
Sensitivity	A measure of the ability of the FR3 to reliably detect and identify shockable heart rhythms.
Shock Series	Also called shock stack. A sequence of one or more shocks, each separated by no more than a preset interval. After completion of a shock series, the FR3 automatically provides 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.
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.

TERM	MEANING
Ventricular Fibrillation (VF)	A disturbance of the normal heart rhythm that results in chaotic, disorganized activity that cannot effectively pump blood. Ventricular 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."
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.

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C SYMBOLS AND CONTROLS
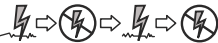
The following table explains the symbols used on the HeartStart FR3 Defibrillator (FR3), its accessories, and their packaging.
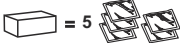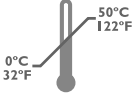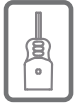
SYMBOL	DESCRIPTION
	REGULATORY MARKS AND GENERAL
$C\epsilon_{0123}$	Meets the requirements of the European medical device directives 93/42/EEC.
$C\epsilon$	Meets the requirements of the applicable European directive.
CSA	This product has passed relevant U.S. and Canadian safety tests by CSA, a Nationally Recognized Test Lab.
C 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.
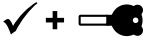
SYMBOL	DESCRIPTION
LOT	Lot number.
	This product is disposable and is for single patient use only.

FR3 DEFIBRILLATOR

SYMBOL	DESCRIPTION
	On/Off button (green). Turns the FR3 on or off, 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.
PHILIPS 013206 REV III	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, the FR3 meets IEC 529 class IP55.
REF 989803150161	This defibrillator uses the identified clinical battery.
MR	Do not use the FR3 in a magnetic resonance environment.
	On-screen icon indicating that the primary battery status is good.

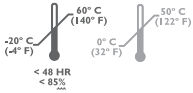| SYMBOL	DESCRIPTION
	On-screen icon indicating that the installed rechargeable clinical use battery status is good.
	On-screen icon indicating that the installed rechargeable clinical use battery is approximately one-quarter depleted.
	On-screen icon indicating that the installed rechargeable clinical use battery is approximately one-half depleted.
	On-screen icon indicating that the installed rechargeable clinical use battery is approximately three-quarters depleted.
	On-screen icon indicating that the installed battery is depleted or invalid.
	On-screen icon indicating that the data card is present and usable.
	On-screen icon indicating that the data card is full, invalid, or absent.
	On-screen icon indicating that the Infant/Child Key is inserted.
	On-screen icon indicating that the FR3 3-Lead ECG Cable is connected.
RA	On-screen icon indicating the proper placement of the RA electrode using the AAMI-configured FR3 3-Lead ECG Cable.
LA	On-screen icon indicating the proper placement of the LA electrode using the AAMI-configured FR3 3-Lead ECG Cable.
LL	On-screen icon indicating the proper placement of the LL electrode using the AAMI-configured FR3 3-Lead ECG Cable.
R	On-screen icon indicating the proper placement of the R electrode using the IEC-configured FR3 3-Lead ECG Cable.
L	On-screen icon indicating the proper placement of the L electrode using the IEC-configured FR3 3-Lead ECG Cable.

SYMBOL	DESCRIPTION
F	On-screen icon indicating the proper placement of the F electrode using the IEC-configured FR3 3-Lead ECG Cable.
I II III	On-screen icon when the device is connected to attached 3-Lead ECG Cable, indicating which ECG lead vector (I, II, or III) has been selected.
	On-screen icon indicating that the connected CPR meter has detected possible hyperventilation of the patient.
	On-screen icon indicating a user-marked event on the ECG tracing using the FR3 3-Lead ECG Cable.
	On-screen icon indicating that the number following represents detected patient heart rate.
	On-screen icon indicating wireless data transfer in progress.
	On-screen icon indicating that the number following represents shocks delivered during the current use.
	On-screen icon indicating that the number following represents time elapsed during the current use.
	On-screen icon indicating that the device language can be selected from the list displayed.
	On-screen icon indicating that the device requires service.
	On-screen icon indicating that a setup error has occurred.
	On-screen icon indicating that selection of training scenario 1 presents a simulated shockable rhythm with one shock required for conversion.
	On-screen icon indicating that selection of training scenario 2 presents a simulated shockable rhythm, conversion, return to shockable rhythm, and conversion.
	On-screen icon indicating that selection of training scenario 3 presents a non-shockable rhythm.

SYMBOL	DESCRIPTION
⎯ᴧᴧ⎯	On-screen icon indicating that selection of training scenario 4 presents a simulated ECG rhythm generated by a connected ECG simulator or a specially equipped manikin.

SYMBOL	DESCRIPTION
= 5	Box contents = 5 pads pouches.
	Pouch contents: one pair of pads.
50°C 122°F / 0°C 32°F	Store the pads at temperatures between 0° and 50° C (32° and 122° F).
NON-STERILE	Non-sterile.
LATEX	This product does not contain natural rubber latex.
> 24h	Do not leave attached to patient for more than 24 hours.
EXPIRATION DATE MM-YYYY	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 lb (25 kg) or 8 years old.
LAERDAL HEARTSTART 911 • 1000 2000 • 3000	Do not use these pads with Laerdal Heartstart model 911, 1000, 2000, or 3000 AEDs.

SYMBOL	DESCRIPTION
	Do not use these pads with Philips HeartStart HS1 model M5066A, M5067A, and M5068A AEDs.
✓ + 🔑	These pads may be used with the HeartStart FR3 on infants or children under 55 lb (25 kg) or 8 years old in conjunction with the FR3 Infant/Child Key.
✓ + 🔑	These pads may be used with the HeartStart FRx on infants or children under 55 lb (25 kg) or 8 years old in conjunction with the FRx Infant/Child Key.

<div align="center">

BATTERIES

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DC 12V⎓ 4.7 Ah <7g Li LiMnO₂	Lithium manganese dioxide chemistry. 12 volts direct current output. 4.7 ampere hours. Contains < 7 grams lithium.
DC 10.8V⎓ 4.5 Ah <50 Wh 3ICR18/65-2 LiIION	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.)
QTY (1)	Contains one battery.
FR3	This battery is for use with the FR3.
u n 4G/Y0.6/S/## USA/+XX####	This packaging has been tested to United Nations standards and certified to be capable of protecting the lithium battery it contains.
9	Class 9 miscellaneous dangerous goods. (Symbol required on outer packaging by freight carrier regulations to identify shipments containing lithium batteries.)
INSTALL BEFORE	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.

SYMBOL	DESCRIPTION
	Do not expose to high heat or open flames. Do not incinerate.
	Do not mutilate or open.
60° C (140° F) -20° C (-4° F) < 48 HR < 85% 50° C (122° F) 0° C (32° F)	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.
	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.
c UL US	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.)
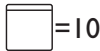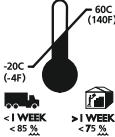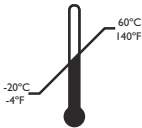
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SYMBOL	DESCRIPTION

UPGRADE CARD

	FR3 upgrade card.

FR3 INFANT/CHILD KEY

	Intended for use on patients under 8 years old or 55 lb (25 kg).

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.
R 201 WW 10215099	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.
LATEX	Gloves.
	Disposable razor.
	Paramedics scissors.
	Absorbent wipe.

SYMBOL	DESCRIPTION
CPR METER WITH Q-CPR TECHNOLOGY BY LAERDAL	
	Not for use on children under 8 years old.
IP 55	The CPR meter meets IEC 529 class IP55.
	The CPR meter is powered by direct current voltage.
=10	This package contains ten (10) patient adhesives for the CPR meter.
LATEX	The patient adhesives do not contain natural rubber latex.
	Transport and store the CPR meter under the environmental conditions listed. Do not expose the CPR meter to a relative humidity of more than 75% for more than 1 week.
	Store the patient adhesives for the CPR meter between -4° F (-20° C) and 140° F (60° C).
YYYY-MM	Use these patient adhesives for the CPR meter before the expiration date shown. Date format is YYYY-MM.
	Lift here to peel off the patient adhesive liner and apply to patient's bare chest.
	The patient adhesives are disposable and for single patient use only.
3-LEAD ECG CABLE	
	Meets IEC type CF leakage current requirements and is defibrillator protected.
LATEX	This product does not contain natural rubber latex.
RA	Identifies the RA lead of the AAMI-configured FR3 3-Lead ECG Cable.

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SYMBOL	DESCRIPTION
LA	Identifies the LA lead of the AAMI-configured FR3 3-Lead ECG Cable.
LL	Identifies the LL lead of the AAMI-configured FR3 3-Lead ECG Cable.
R	Identifies the R lead of the IEC-configured FR3 3-Lead ECG Cable.
L	Identifies the L lead of the IEC-configured FR3 3-Lead ECG Cable.
F	Identifies the F lead of the IEC-configured FR3 3-Lead ECG Cable.

D CPR FIRST

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 five CPR First settings: OFF, SMART CPR AUTO1, SMART CPR AUTO2, USER, and ALWAYS. These are defined in greater detail below.

PHILIPS MEDICAL SYSTEMS

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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 lb (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. When it is turned on, the FR3 displays a CPR option button. This allows the user to decide whether or not to provide the configured CPR First protocol before applying the pads, based on either a patient assessment protocol or standing orders from the Medical Director.

If the user does *not* press the CPR option button, the FR3 initiates rhythm analysis when the pads are applied to the patient.

If the user presses the CPR option button,[*] the FR3 screen displays a progress bar for the duration of the configured CPR protocol. When pads are applied during the protocol, the screen displays the patient ECG. For the last 18 seconds of the protocol, the green progress bar changes to orange to alert the user that the FR3 will begin rhythm analysis at the end of the period. This allows the user to initiate an immediate CPR protocol,

"ALWAYS" SETTING

The ALWAYS setting is designed to allow responders to provide immediate CPR prior to pads placement and rhythm analysis. The FR3 provides a CPR protocol when turned on, independent of pads attachment.

This setting is designed for situations in which multiple responders are available. One responder begins CPR while another applies the defibrillation pads to the patient. The pads should be placed prior to completion of the CPR protocol so that the FR3 can begin rhythm analysis immediately after CPR and quickly provide a shock if appropriate.

If the CPR First ALWAYS setting is configured for the FR3, the FR3 screen does not display a CPR option button. The configured CPR protocol is initiated as soon as the FR3 is turned on. The screen provides a progress bar as described above. When pads are applied during the protocol, the screen displays the patient ECG. For the last 18 seconds of the protocol, the green progress bar changes to orange to alert the user that the FR3 will begin rhythm analysis at the end of the period. If the FR3 Infant/Child Key is inserted during the protocol, it is reset to ensure the correct CPR protocol duration is provided. As soon as pads are applied during the protocol, the FR3 displays an ANALYZE option button. When the protocol is complete, as indicated by the progress bar, the FR3 will automatically begin analysis.

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* Anytime the FR3 displays the CPR option button, the configured CPR protocol can also be initiated by use of the CPR meter, except during patient 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 optional CPR meter is connected:

- The FR3 prompts the responder to begin CPR if needed.

If the optional CPR meter is connected and the metronome is set to ON:

- If the responder begins CPR using the CPR meter within 30 seconds of the start of the attend-to-patient period, the FR3 provides NSA CPR Coaching audio beats for the configured NSA CPR protocol.

 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.

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

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"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.

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 provide compressions using the CPR meter, because he/she determines that CPR is not needed, the audio beats are not provided.

If the optional CPR meter is connected:

- The FR3 prompts the responder to begin CPR if needed.
- If the responder begins CPR using the CPR meter within 30 seconds of the start of the attend-to-patient period, the FR3 prompts the responder to continue with compressions and begins the configured CPR protocol.

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.

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

- 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.

- 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.

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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.

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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.
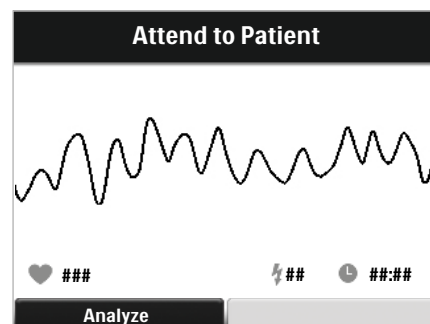
NOTE: If the FR3 detects a patient heart rate of less than 30 bpm, it provides a voice prompt to check the patient. The prompt is repeated at the configured advanced use prompt repeat rate as long as the low heart rate persists. If the FR3 detects a pacemaker, it provides a PACEMAKER DETECTED alert. 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.

Stay Clear of Patient

Analyzing

⚡ ##　🕐 ##:##

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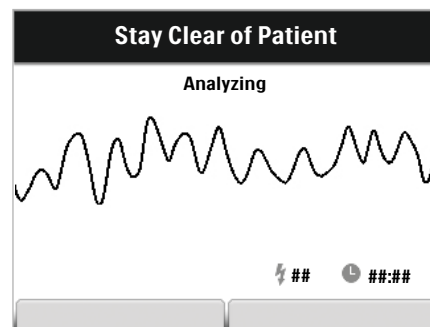
If the rhythm analysis results in a Shock Advised decision, the FR3 directs you to stay clear of the patient and provides Shock Advised prompts. When charging is complete, it gives a continuous tone and prompts you to press the flashing orange Shock button.*

Stay Clear of Patient

Shock Advised

⚡ ##　🕐 ##:##

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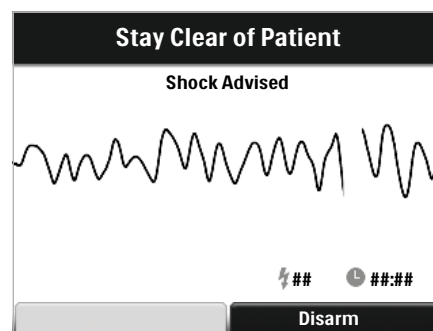
If the FR3 determines while it is charging that the heart rhythm has changed to a non-shockable rhythm, it automatically aborts the shock and gives a voice prompt announcing that the shock was cancelled and that no shock is advised, then returns to the main ADVANCED MODE screen.

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.

---

* 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.

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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.

Attend to Patient

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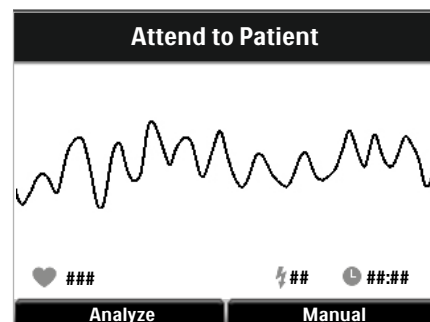
You can press the ANALYZE option button to initiate rhythm analysis or, if the FR3 detects a shockable rhythm during monitoring, it provides a voice prompt to press the ANALYZE button. The prompt is repeated at the configured advanced use prompt repeat rate as long as the shockable rhythm persists.

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.

Attend to Patient

⚡ xx 🕐 xx:xx
Charge

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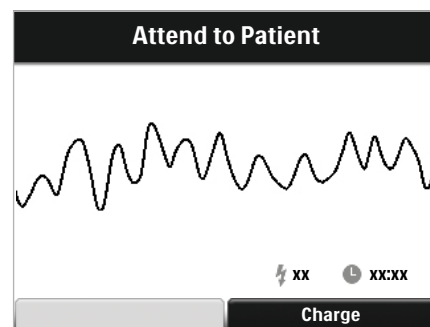
As soon as charging begins, the FR3 provides CHARGING prompts and displays a message to stay clear of the patient. The FR3 gives intermittent tones while it is charging. If in your clinical judgment a shock is not warranted, you can press the DISARM option button to disarm the defibrillator and return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

Stay Clear of Patient

Charging

⚡ xx   🕐 xx:xx

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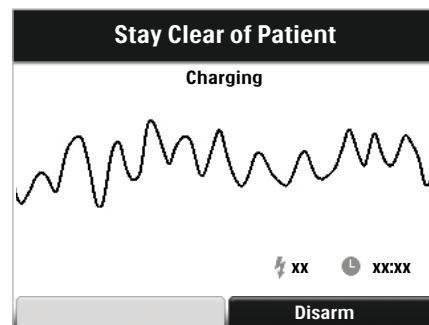
When charging is complete, the FR3 gives a continuous tone. The screen message becomes ARMED and the Shock button light flashes. Press the Shock button to deliver a shock. However, if in your clinical judgment a shock is not warranted, you can press the DISARM option button to disarm the defibrillator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

Stay Clear of Patient

Armed

⚡ ##   🕐 ##:##
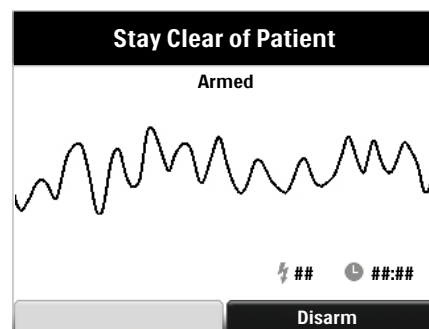
Disarm

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.

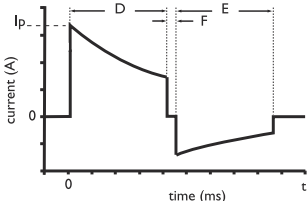## FR3 SPECIFICATIONS

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 lb (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 preconnected): 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.
Crush	Complies with all performance requirements following application of a 1,100 lb (499 kg) load distributed across 10 ± 1 square inches (65 ± 6.5 square cm) to any location on its top surface.
ESD/EMI	See Appendix H, "Additional Technical Data."
EMI – Aircraft	Using primary batteries, meets RTCA/DO-160G:2004 Section 20 (Category D - Radiated Immunity; Category K - Conducted Immunity) and Section 21 (Category M - Charging). See Appendix H, "Additional Technical Data."

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CATEGORY	NOMINAL SPECIFICATIONS
Certification	U.S. Army AWR certified (Airworthiness Release).

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.

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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. • rhythm analysis has continued for 30 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: • 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 lb (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.

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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 PRIMARY BATTERY
989803150171 PRIMARY BATTERY. FAA COMPLIANT

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	With a new battery: • Configured for NSA monitoring: 12 hours operating time or 10 hours of operating time with the CPR meter connected. • Configured for NSA CPR: 7.5 hours operating time or 6 hours of operating time with the CPR meter connected. • 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.
Environmental Qualification	Meets the applicable requirements of RTCA/DO-227, Section 2.3.
Application	Power source for use in the HeartStart FR3 AED.
Maintenance and Calibration Requirements for Continued Airworthiness (989803150171)	There are no periodic maintenance or calibration requirements that are necessary for continued airworthiness of the 989803150171 battery. For battery maintenance with respect to performance within the AED, please see the FR3 Instructions for Use. There are no user-serviceable parts in the 989803150171 battery.
Aviation Standard Compliance (989803150171)	The conditions and tests required for TSO approval of this battery are minimum performance standards. Those installing this article, on or in a specific type or class of aircraft, must determine that the aircraft installation conditions are within the TSO standards. TSO articles must have separate approval for installation in an aircraft. The article may be installed only according to 14 CFR part 43 or the applicable airworthiness requirements. Lithium cell and battery safety concerns include the possibility of fire and venting of toxic gases.

989803150241 RECHARGEABLE CLINICAL USE BATTERY

CATEGORY	NOMINAL SPECIFICATIONS
Battery Type	Lithium ion, rechargeable, using the 861394 charger only. See the 861394 charger *Instructions for Use* for directions.
Capacity	10.8 VDC, 4.5 Ah, typical, when new and stored at 77° F (25° C).
Time to Full Battery Charge	3 hours.
Expected Cycle Life	300 charge/discharge cycles.
Battery Performance	With a fully charged new battery: • Configured for NSA monitoring: 8 hours operating time or 6 hours of operating time with the CPR meter connected. • Configured for NSA CPR: 3.5 hours operating time or 3 hours of operating time with the CPR meter connected. • Typical shock count: 100 shocks. • Minimum remaining capacity after Low Battery warning: 9 shocks, 15 minutes of operating time.
Standby Life (after installation)	4 months when installed fully charged.
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. Recharging: 50° to 104° F (10° to 40° C).
Application	Power source for use in the HeartStart FR3 AED running software version PR2.0 or higher.

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 Battery Charge	3 hours.

CATEGORY	NOMINAL SPECIFICATIONS
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. Recharging: 55° to 104° F (13° to 40° C).
Application	Power source for use in the HeartStart FR3 AED in training mode.

861394 BATTERY CHARGER

CATEGORY	NOMINAL SPECIFICATIONS
Application	Only for use with the 989803150241 clinical use battery and the FR3 rechargeable training battery included in the 989803150191 FR3 Training Pack.
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).

PHILIPS MEDICAL SYSTEMS

OTHER COMPATIBLE DEFIBRILLATOR PADS

CATEGORY	PRODUCT INFORMATION
Preconnectable and Testable	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. *Can be preconnected to FR3, but not designed for storage in FR3 carry cases.* For adult and infant/child patient use with FR3.
Non-preconnectable	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. *Cannot be preconnected 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 preconnected SMART Pads III and optional accessories (Infant/Child Key, spare pads, and spare battery, CPR meter cradle, and CPR meter). Includes top and bottom case inserts and Pads Sentry. Supports configurable Auto-On feature.
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 lb (2.2 kg) including Pads Sentry.

989803150211 FR3 SYSTEM CASE BOTTOM INSERT

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with preconnected SMART Pads III and optional accessories (spare battery and CPR meter).
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).

989803179161 FR3 SOFT SYSTEM CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with preconnected SMART Pads III and optional accessories (Infant/Child Key, spare pads, spare battery, CPR meter cradle, and CPR meter). 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 lb (0.8 kg).

989803179181 FR3 SMALL SOFT CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with preconnected 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 lb (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, and to provide configured infant/child CPR protocol and infant/child prompts.
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 data, Q-CPR data, and voice recording.

FR3 LANGUAGE CARD

CATEGORY	NOMINAL SPECIFICATIONS
Application	Supplied with certain versions of the FR3, 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 data, Q-CPR data, 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.

989803150041/989803150051 FR3 3-LEAD ECG CABLES

CATEGORY	NOMINAL SPECIFICATIONS	
Application	For use with the FR3 ECG Model 861389 AED running software version PR2.0 or higher.	
Length	Device connector to bend relief of patient lead wire: 96 ± 4 inches (244 ± 10 cm). Patient lead wire: 24 ± 2 inches (61 ± 5 cm).	
Weight	4.8 oz (0.14 kg)	

Patient Lead Wire Designation	989803150041 (AAMI)
	    RA (right arm) — white
	    LA (left arm) — black
	    LL (left leg) — red
		989803150051 (IEC)
		    R (right arm) — red
		    L (left arm) — yellow
		    F (left leg) — green

CATEGORY	NOMINAL SPECIFICATIONS
Storage/ Transport Temperature	-4° - 140° F (-20° - 60° C).
Standards Compliance	989803150041: ANSI/AAMI EC53:1995/®2008. 989803150051: IEC 601-1-1:2000, IEC 60601-2-27: 2ed 2005.
Electrode Compatibility	Single-use ECG electrodes compliant with ANSI/AAMI EC12:2000/(R)2010 and indicated for application in ECG monitoring and/or stress testing. ECG electrodes indicated for use only in cardiography or resting-ECG are not suitable due to their potential to generate noise in the measured ECG.
Display Bandwidth	0.75 Hz to 30.0 Hz +/- 10%.
Service Life	Typically, 1,000 uses.
Performance with FR3 Defibrillator	Meets environmental specifications cited for FR3 defibrillator (see page G-1). Input Dynamic Range: Meets ANSI/AAMI EC13:2002/®2007. Common Mode Rejection: Meets ANSI/AAMI EC13:2002/® 2007. Display Bandwidth: 0.75 Hz to 30.0 Hz +/- 10%.

989803149941 CPR METER

CATEGORY	SPECIFICATION
Performance Requirements	The CPR meter meets the performance requirements of IEC 60601-1.
Dimensions	6" x 2.5" x 1" (154 mm x 64 mm x 28 mm) with a 36" (0.9 m) integrated cable.
Weight	8.3 oz (235 g).
Defibrillator Compatibility	Philips HeartStart FR3 automated external defibrillator running software version PR2.0 or higher, and Philips HeartStart MRx Monitor/Defibrillator running software version F.01 or higher.
Input Voltage	3.9 to 10 VDC, max 170 mA. The CPR meter is electrically and galvanically isolated from the defibrillator power and communication sources.
Temperature and Relative Humidity	Storage temperature: -4° to 140° F (-20° to 60° C). Relative humidity 10% to 75%. Operating temperature: 32° to 122° F (0° to 50° C). Relative humidity 5% to 95%.
Sealing	Meets ISO/IEC 60529 class IP55.
Electro-magnetic Conformity Compliance	Meets IEC 60601-1-2 and RTCA/DO-160G.

989803149951 FR3 CPR METER CABLE LINK

CATEGORY	SPECIFICATION
Length	10" (25 cm) long reusable cable used to connect the FR3 to the CPR meter.
Temperature and Relative Humidity	Storage temperature: -4° to 140° F (-20° to 60° C). Relative humidity 10% to 75%. Operating temperature: 32° to 122° F (0° to 50° C). Relative humidity 5% to 95%.

989803163291 CPR METER PATIENT ADHESIVES

CATEGORY	SPECIFICATION
Dimensions	1.5" x 3.5" (39 mm x 90 mm).
Temperature and Relative Humidity	Storage temperature: -4° to 140° F (-20° to 60° C). Relative humidity 10% to 75%. Operating temperature: 32° to 122° F (0° to 50° C). Relative humidity 5% to 95%.
Material	Foam pad with biocompatible adhesive on each side.
Shelf Life	2 years when applied to the CPR meter or 4 years in unopened package. Do not use after the expiration date on the packaging.

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

FR3 DEFIBRILLATOR

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 COMPATIBILITY GUIDANCE

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) emissions 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.

> NOTE: If using the FR3 with an accessory device, ensure that the use environment is within the range of specifications for both devices.

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:

• 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 might be occurring.

• 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 might be occurring.

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	± 8 kV contact ± 15 kV air	There are no special requirements with respect to electrostatic discharge.[*]
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 caused 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	Using primary batteries, meets the requirements for all aircraft cabin environments
Conducted RF	Category K	Using primary batteries, meets the requirements for all aircraft cabin environments
EMISSIONS TEST	RTCA DO-160E TEST LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Radiated RF	Category M - Charging	Using primary batteries, 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.

CPR METER

ELECTROMAGNETIC CONFORMITY

Guidance and manufacturer's declaration: The CPR meter is intended for use in the electromagnetic environment specified in the tables below. The responder should assure that it is used in such an environment.

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. Therefore, 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	± 8 kV contact ± 15 kV air	There are no special requirements with respect to electrostatic discharge.[*]
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/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	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 may occur in the vicinity of equipment marked with the following symbol:

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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[*] Generally, AEDs are sometimes susceptible to interference caused 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.

[†] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,660 MHz to 40,700 MHz.

[‡] 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.

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