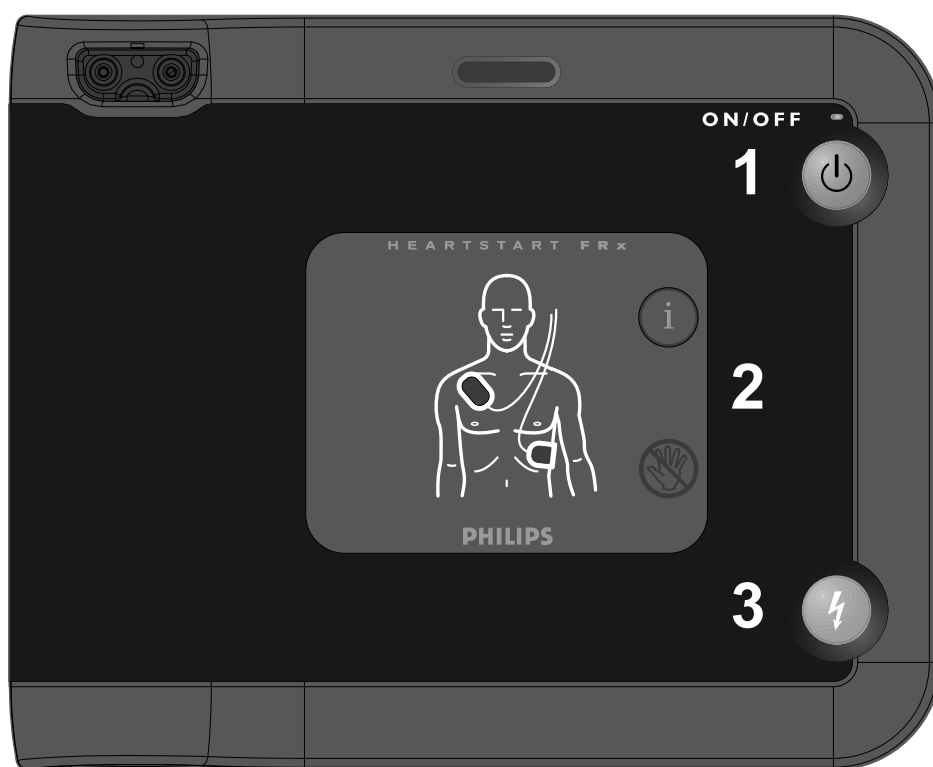


# PHILIPS

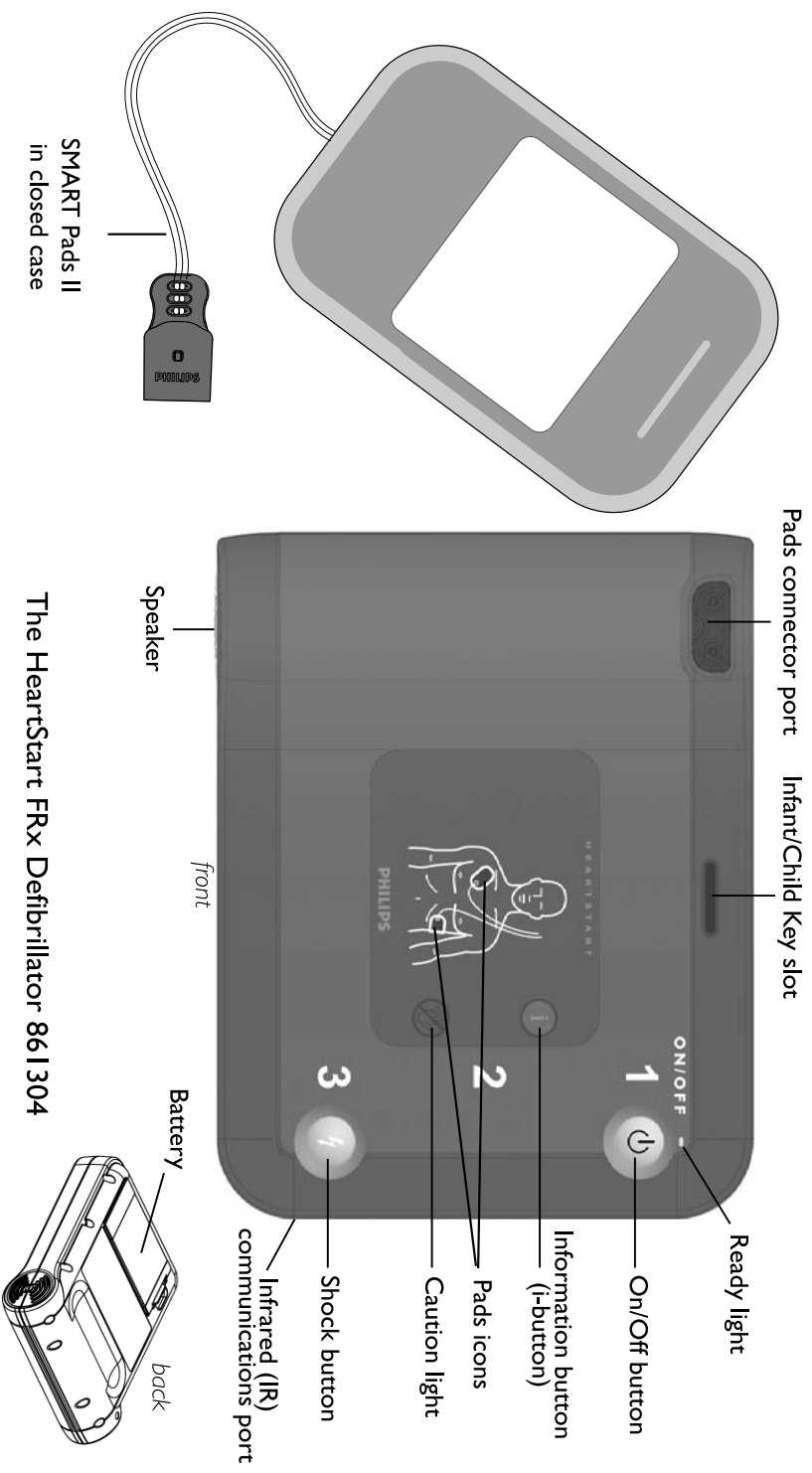


## HEARTSTART FRx DEFIBRILLATOR

OWNER'S MANUAL

861304  
Edition 8

**HEARTSTART**  
DEFIBRILLATORS



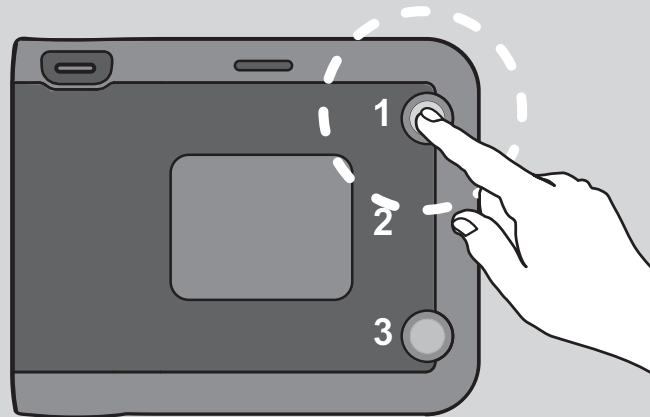
# HeartStart FRx Defibrillator

## QUICK REFERENCE

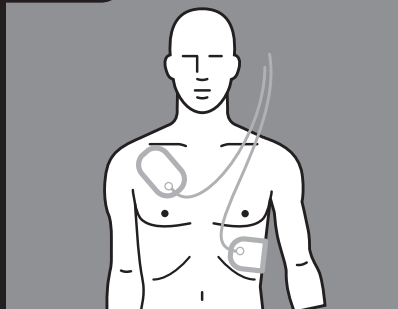
Check for signs of Sudden Cardiac Arrest:

☒ Unresponsive ☒ Not Breathing Normally

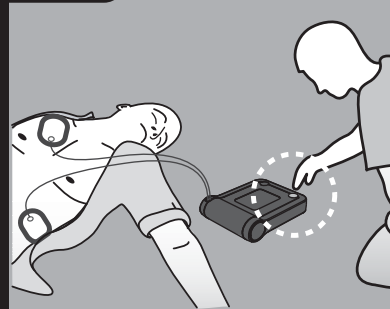
### 1 TURN ON



### 2 PLACE PADS



### 3 PRESS SHOCK



Intentionally blank.

# HeartStart FRx

## 861304

### Automated External Defibrillator

OWNER'S MANUAL

Edition 8

#### IMPORTANT NOTE:

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

Defibrillation cannot assure survival, no matter how rapid the treatment. In some patients, the underlying problem causing the cardiac arrest is simply not survivable despite any available care.

## About This Edition

The information in this guide applies to the HeartStart FRx Defibrillator 861304. This information is subject to change. Please contact Philips at [www.medical.philips.com/heartstart](http://www.medical.philips.com/heartstart) or your local distributor for information on revisions.

## Edition History

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## Authorized EU Representative

Philips Medizin Systeme Boeblingen GmbH  
Hewlett-Packard Strasse 2  
71034 Boeblingen, Germany  
(+49) 7031 463-2254

## CAUTION

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

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

## Device Tracking

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

## Device Manufacturer

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

## Patents

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

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## CONTENTS

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1	Introduction to the HeartStart FRx	
	Description .....	1
	Sudden Cardiac Arrest .....	1
	Indications for Use .....	2
	Training and practice .....	2
	State and local requirements .....	2
	For more information .....	3
2	Setting up the HeartStart FRx	
	Package contents .....	3
	Setting up the FRx .....	4
	Recommended accessories .....	6
3	Using the HeartStart FRx	
	Overview .....	7
	STEP 1: Press the green on/off button .....	8
	STEP 2: Follow the FRx's voice instructions .....	8
	STEP 3: Press the flashing orange Shock button if instructed .....	9
	Treating infants and children .....	10
	When emergency medical services arrive .....	12
4	After using the HeartStart FRx	
	After each use .....	14
	FRx data storage .....	15
5	Maintaining the HeartStart FRx	
	Routine maintenance .....	16
	Periodic checks .....	17
	Cleaning the FRx .....	17
	Disposing of the FRx .....	17
	Troubleshooting tips .....	18

## APPENDICES

A	Accessories .....	21
B	Glossary of terms .....	23
C	glossary of symbols/controls .....	27
D	Warnings and Precautions .....	31
E	Technical information .....	33
F	Configuration .....	41
G	Testing and troubleshooting .....	46
H	Additional technical data required for European conformity .....	50



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# I Introduction to the HeartStart FRx

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## Description

The Philips HeartStart FRx Defibrillator 861304 (“FRx”) is an automated external defibrillator (AED). Small, lightweight, rugged, and battery powered, it is designed for simple and reliable operation by minimally trained users. The FRx is highly configurable for local protocol considerations.\*

## Sudden Cardiac Arrest

The FRx is used to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA). SCA is a condition that occurs when the heart unexpectedly stops pumping. SCA can occur to anyone – young or old, male or female – anywhere, at any time. Many victims of SCA do not have warning signs or symptoms. Some people may have a higher risk for SCA than others. Causes vary and may be different for infants and children than for adults.

VF is a chaotic quivering of the heart muscle that prevents it from pumping blood. The only effective treatment for VF is defibrillation. The FRx treats VF by sending a shock across the heart, so it can start beating regularly again. Unless this is successful within the first few minutes after the heart stops beating, the victim is not likely to survive.

---

\* Configurability includes timing of the “Call Emergency Medical Services” reminder, CPR protocol variations, and other features. See Appendix F, “Configuration,” for details.

## Indications for Use

The FRx should be used to treat someone you think may be a victim of SCA. A person in SCA:

- does not respond when shaken, and
- is not breathing normally.

If in doubt, apply the pads. Follow the voice instructions for each step in using the defibrillator.

## Training and practice

The FRx is intended to be used under the oversight of a physician as part of a well-designed emergency response plan. Any emergency response plan should provide for training of FRx users in cardiopulmonary resuscitation (CPR) and defibrillator use. Philips recommends that you train on the device you will be using.

Several national and local organizations offer combined CPR/defibrillator training. Contact your Philips representative, or visit us on-line at [www.medical.philips.com/heartstart](http://www.medical.philips.com/heartstart), for information about training programs in your area.

**NOTE:** Training accessories are available from Philips for practicing use of the FRx. See Appendix A for information on ordering accessories.

## State and local requirements

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

## For more information

Contact your local Philips distributor for additional information about the FRx. We will be happy to answer any questions you may have and to provide you with copies of the clinical summaries of several key studies using Philips automated external defibrillators.\*

You can also find the clinical summaries online at [www.medical.philips.com/heartstart](http://www.medical.philips.com/heartstart). Technical information about all Philips HeartStart automated external defibrillators is also available online, in the *Technical Reference Manual* for HeartStart Defibrillators.

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## 2 Setting up the HeartStart FRx

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### Package contents

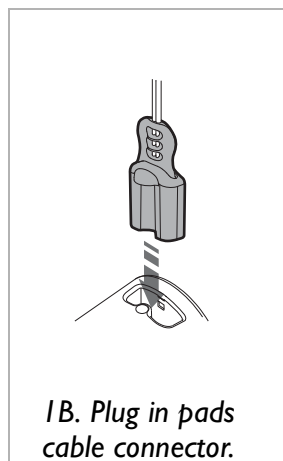
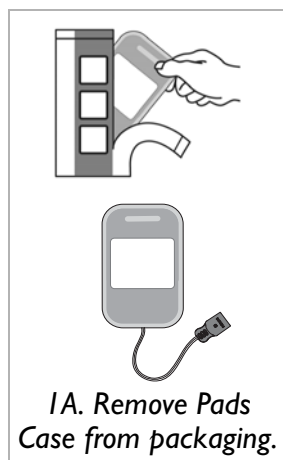
Check the contents of the FRx box to be sure it contains:

- 1 Philips HeartStart FRx Defibrillator 861304
- 1 four-year battery M5070A†
- 1 package of HeartStart SMART Pads II 989803139261, containing a pair of single-use adhesive defibrillation pads in a disposable plastic case
- 1 Owner's Manual
- 1 Quick Reference Guide

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

† The FRx sold for aviation applications includes a TSO-certified battery, REF: 989803139301, instead of the M5070A.

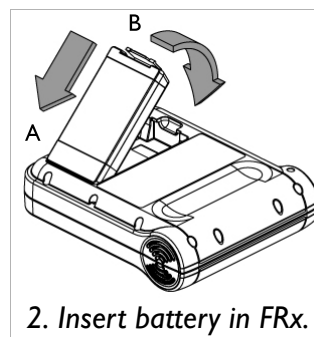


**IMPORTANT NOTE:** The FRx is designed to be used with a carry case. A number of carry cases are offered to meet the needs of your individual defibrillation program. These include a standard carry case and a hard-shell carry case. See Appendix A for information about these as well as a list of training materials and other accessories available from Philips.

## Setting up the FRx

Setting up the FRx is simple and quick.

1. Open the SMART Pads II\* package and take out the Pads Case (A). Do not open the pads case until you need to use the pads in an emergency. Plug the pads cable connector into the connector port on the FRx (B). Store the unopened Pads Case in the pocket provided in the defibrillator carry case.
2. Open the battery package and remove the battery. Place the bottom end (A) of the battery into the bottom of the compartment on the back of the FRx, then firmly press down the top (latch) end of the battery into the compartment, until it clicks into place (B).
3. Set the FRx and the Pads Case on a flat surface and let the FRx run its automatic battery insertion self-test. Testing the Shock button and the On/Off button is part of the self-test. The FRx will say “shock button test” and then instruct you to push the Shock button. It will then say “On/Off button test” and instruct you to push the On/Off button. Push the buttons when



\* Unless otherwise noted, references to pads in this document are to HeartStart SMART Pads II.

instructed. When the self-test is over, the FRx will report the results, then turn off and go to standby mode. The blinking green Ready light shows the defibrillator is ready for use.\*

4. Place the Quick Reference Guide, a brief illustrated guide for using the FRx to treat a victim of sudden cardiac arrest, in the defibrillator carry case.†

**NOTE:** Do not store anything in the defibrillator carry case that it is not designed to accommodate. Store all objects in their intended location in the case.

5. Store the FRx in accordance with your site's emergency response protocol. Typically, this will be in a high-traffic area that is easy to access, convenient for checking the Ready light periodically, and easy to hear the alarm chirp if the battery power gets low or the defibrillator needs attention. Ideally, the HeartStart should be stored near a telephone, so the Emergency Response Team or Emergency Medical Services can be alerted as fast as possible in the event of a possible SCA. Keep a spare SMART Pads II cartridge and other accessories with the defibrillator – in the carry case – for quick access when needed. Be sure to store the defibrillator according to its specifications. See Appendix E for details.

**NOTE:** Always store the FRx with a set of SMART Pads II connected and a battery installed, so it will be ready to use.

\* As long as a battery is installed and a set of SMART Pads II is connected, turning the FRx "off" puts it into standby mode, which means that it is ready for use.

† Any of the carry case options has room for storing the Quick Reference Guide.

## 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 FRx include:

- scissors — for cutting the victim's clothes if needed
- 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
- a towel or absorbent wipes — to dry the victim's skin for good pads contact

Philips has a Fast Response Kit with all these items. See Appendix A for details.



*If you may need to defibrillate an infant or a child under 55 pounds (25 kg) or 8 years old, it is recommended that you order the Infant/Child Key accessory, available separately. When the Infant/Child Key is inserted in the FRx, the FRx automatically reduces the defibrillation energy to 50 joules and, if optional CPR Coaching is selected, provides coaching appropriate for infants and children. Directions for using the Infant/Child Key are provided in Chapter 3, “Using the HeartStart FRx.”*

See Appendix A for a list of accessories and training products for the FRx available from Philips.

## 3 Using the HeartStart FRx

**IMPORTANT NOTE:** Be sure to read the Reminders section at the end of this chapter as well as the warnings and precautions in Appendix D.

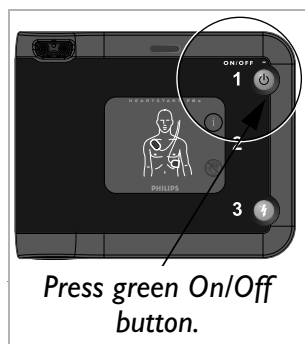
### Overview

If you think someone is in SCA, act quickly and calmly. *If someone else is available*, ask him or her to call for emergency medical assistance while you get the FRx. *If you are alone*, follow these steps:


- Call your emergency services provider.
- Quickly get the FRx and bring it to the victim's side. If there is any delay in getting the defibrillator, check the patient and perform cardiopulmonary resuscitation (CPR) if needed until the FRx is available.
- If the victim is an infant or child, see directions for treating infants and children starting on page 10.
- Check the immediate environment for flammable gases. Do not use the FRx in the presence of flammable gases, such as an oxygen tent. However, it is safe to use the FRx on someone wearing an oxygen mask.

There are three basic steps to using the defibrillator to treat someone who may be in sudden cardiac arrest:

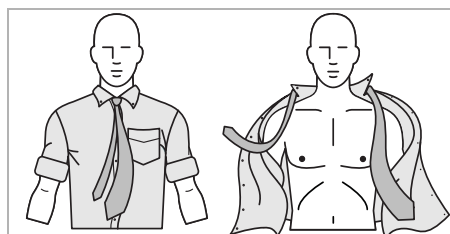
1. Press the green On/Off button.
2. Follow the FRx's voice instructions.
3. Press the flashing orange Shock button if instructed.



### STEP 1: Press the green on/off button

Press the On/Off button  to turn on the FRx.

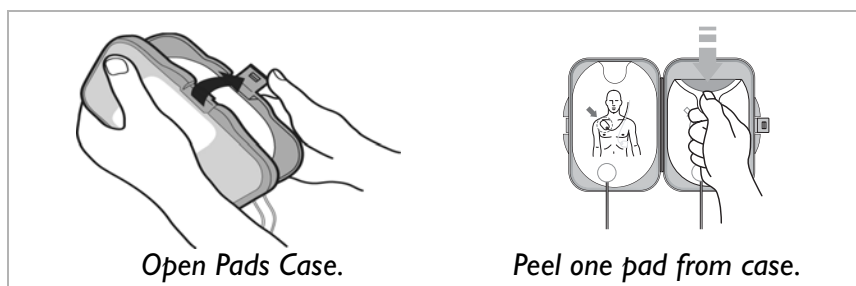
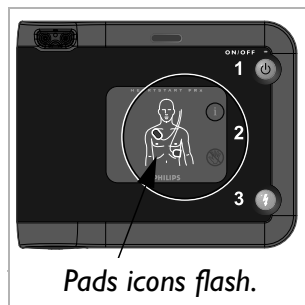
The FRx tells you to remove all clothes from the person's chest. If necessary, rip or cut off the clothing to bare the person's chest.



### STEP 2: Follow the FRx's voice instructions

Remove the SMART Pads II case from the carry case. Clean and dry the patient's skin, and, if necessary, clip or shave excessive chest hair to ensure good pads contact with the bare skin.

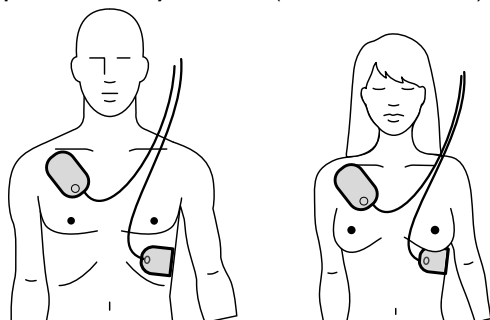
Open the pads case as shown below. Peel off one pad.



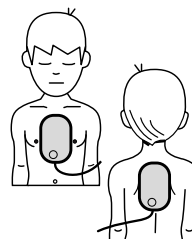
Pads placement is very important. The icons on the pads placement diagram on the FRx front panel will be flashing, to help guide you. Place the pad on the patient's bare skin *exactly as shown* in the following drawing. Press the adhesive portion of the pad down firmly. Then repeat this with the other pad.



Where to place pads on adults and children over 55 pounds or 8 years old (anterior-anterior).



Where to place pads on infants or children under 55 pounds or 8 years old (anterior-posterior).



### STEP 3: Press the flashing orange Shock button if instructed

As soon as the HeartStart FRx detects that the pads are attached to the patient, the pads icons turn off. The FRx begins analyzing the patient's heart rhythm. It tells you that no one should be touching the patient, and the Caution light begins flashing as a reminder.



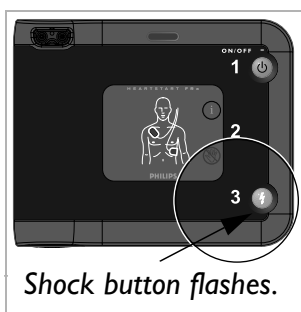
Caution  
light

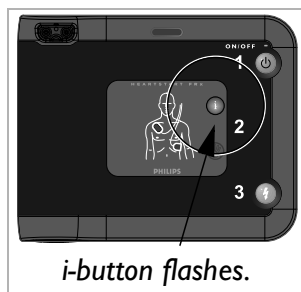
*If a shock is needed:*

The Caution light stops flashing and stays on, and the orange Shock button starts flashing. The FRx tells you to press the flashing orange button. You must press the Shock button for a shock to be delivered. Before you press the button, make sure no one is touching the patient. When you press the Shock button, the FRx tells you that the shock has been delivered. Then the defibrillator tells you it is safe to touch the patient, instructs you to begin CPR, and invites you to press the flashing blue i-button for CPR Coaching if desired.



Shock  
Button





### *If a shock is not needed:*

The blue i-button comes on solid, to show that it is safe to touch the patient. The FRx also tells you to perform CPR if needed. (If CPR is not needed – for example, if the patient is moving or regaining consciousness – follow your local protocol until emergency medical personnel arrive.) Then the FRx invites you to press the flashing blue i-button for CPR Coaching if desired.

### *For CPR Coaching:*

Press the flashing blue i-button during the first 30 seconds of the patient care pause to activate CPR Coaching.\* (If the Infant/Child Key is inserted, the CPR Coaching provided will be for infant/child CPR.) When the pause is over, the defibrillator tells you to stop CPR, so it can analyze the patient's heart rhythm. The motion caused by CPR can interfere with analysis, so be sure to stop all motion when instructed.



*i-button*

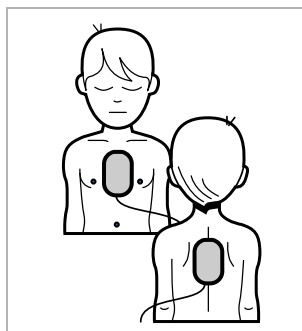
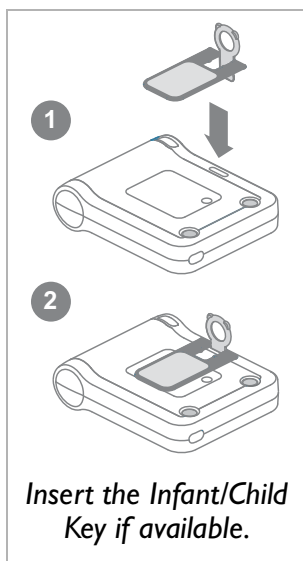
## Treating infants and children

**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 FRx.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the FRx.
- If you witnessed the child's collapse, call EMS *immediately* and *then* get the FRx.

Alternatively, follow your local protocol.

\* The default configuration for the FRx provides CPR Coaching when you press the i-button in this situation; however, the default setting can be revised by your Medical Director using Philips software available separately. See Appendix F for more information.



*If the victim is under 55 pounds or 8 years old, and you have an Infant/Child Key:*

- Insert the Infant/Child Key into the slot at the top center of the front panel of the FRx (see illustration at left). The pink portion of the Key pivots (1) and fits into the slot (2), with the front of the Key lying flat on the surface of the FRx so the infant/child pads placement diagram is visible. (The back of the Infant/Child Key also has a diagram showing how to insert it.)
- Turn on the FRx and follow instructions to remove all clothing from the torso, to bare both the chest and the back.
- Place the pads on the child's front and back, as illustrated. 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 FRx. However, the Key should be inserted before placing the pads on the patient.

With the Infant/Child Key inserted, the FRx will announce "Infant/Child Mode," automatically reduce the defibrillation energy from the adult dose of 150 Joules to 50 Joules,\* and provide optional infant/child CPR Coaching.

If the Infant/Child Key is removed during use, the FRx will announce "Adult Mode." Any shocks delivered will be at adult energy, and optional CPR Coaching will be for adult CPR.

\* This lower energy level may not be effective for treating an adult.

*If the victim is under 55 pounds or 8 years old, but you do NOT have an Infant/Child Key:*

- DO NOT DELAY TREATMENT.
- Turn on the FRx and follow instructions to remove all clothing from the torso, to bare both the chest and the back.
- Place the 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 pounds or 8 years old, or if you are not sure of the exact weight or age:*

- DO NOT DELAY TREATMENT.
- Turn on the FRx without inserting the Key and follow instructions to 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.

### When emergency medical services arrive

When Emergency Medical Services (EMS) personnel arrive to care for the patient, they may decide to apply another defibrillator to allow monitoring of the patient. Depending on their equipment, the EMS team may apply different pads. In that case, the SMART Pads II should be removed. EMS personnel may want a summary of the last-use data<sup>\*</sup> stored in the FRx. To hear the summary data, hold down the i-button until the FRx beeps.

**NOTE:** After the EMS team removes the SMART Pads II from the patient, remove the Infant/Child Key, if used, and install a new pads set before returning the FRx to service, to be sure it is ready for use.

<sup>\*</sup> See Chapter 4, “After Using the HeartStart FRx,” for details about data storage.

### Reminders

- Remove any medicine patches and residual adhesive from the patient's chest before applying the pads.
- Do not place the pads directly over an implanted pacemaker or defibrillator. A noticeable lump with a surgical scar should indicate the position of an implanted device.
- Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.
- If the pads do not stick well, check that the pads adhesive has not dried out. Each pad has a layer of adhesive gel. If the gel is not sticky to the touch, replace the pads with a new set. (For ease of handling, the pad is designed with a non-gel area around the connector cable.)
- Keep the patient still and keep any movement around the patient to a minimum during rhythm analysis. Do not touch the patient or the pads while the Caution light is on solid or flashing. If the FRx is unable to analyze due to electrical "noise" (artifact), it will tell you to stop all movement and remind you not to touch the patient. If the artifact continues for more than 30 seconds, the FRx will pause briefly to allow you to deal with the source of the noise, then resume analysis.
- The FRx will only deliver a shock if the flashing orange Shock button is pressed when the instruction is given. If the Shock button is not pressed within 30 seconds after the instruction, the FRx will disarm itself, and (for the first CPR interval) give a reminder to make sure emergency medical services have been called, then begin a CPR interval. This is designed to minimize interruption of CPR and help ensure ongoing patient support.
- While waiting for you to press the Shock button, the FRx will continue to analyze the heart rhythm. If the patient's rhythm changes before you press the Shock button, and a shock is no longer needed, the defibrillator will disarm and tell you a shock is not advised.
- If for any reason you want to turn off the defibrillator during a use, you can press the On/Off button – holding it down for at least one second – to return the device to standby mode.