



EN-US

# HeartSine samaritan PAD

## 350P

User  
handbook

### Important:

Please watch online training videos  
and read this User Handbook



[heartsine.com/videos](https://www.heartsine.com/videos)





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# HeartSine samaritan PAD 350P

(SAM 350P)

HeartSine samaritan PAD 350P (HeartSine SAM 350P) Automated External Defibrillator (AED) is designed to automatically assess a patient's heart rhythm and to quickly provide a defibrillation shock to victims of sudden cardiac arrest (SCA). The AED provides instructions that you can hear and see to guide you through the entire resuscitation process, including CPR.

HeartSine SAM 350P is a semi-automatic defibrillator, which means that you will need to push the shock button if the AED tells you that a shock is required.

## Recommended training


SAM 350P is intended for use in the public access and home environments. Anyone who might use HeartSine SAM 350P should:

- Watch the training videos at [heartsine.com/videos](https://www.heartsine.com/videos)
- Carefully read this User Handbook and quick start guides
- Review these materials periodically

Training on CPR and in the use of an AED is strongly recommended. You should attend a basic life support course, which will teach you to perform CPR and use an AED. The company or store where you bought your HeartSine AED may provide CPR/AED training, or you can search online to find CPR/AED training near you.

The following symbols are used in this User Handbook:

 **WARNING:** Warning statements describe conditions or actions that can result in death or serious injury

 **CAUTION:** Caution statements describe conditions or actions that can result in minor injury or damage to the AED

**Note:** Notes contain important additional information about using the AED

## When should I use the AED?

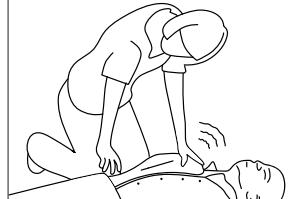
You should use your HeartSine SAM 350P on a person suffering cardiac arrest who is:

- Unconscious
- Not breathing normally

You can tell this by doing the following:

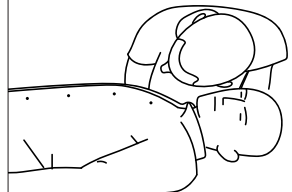
### Shake the person

- Gently shake the person to see if they respond
- If the person is conscious, **do not use** the HeartSine SAM 350P



### Listen to breath

- Put your ear next to the person's mouth to hear if they are breathing normally
- If the person is breathing normally, **do not use** the HeartSine SAM 350P



### Look for breath

- Look at person's chest to see if they are breathing normally
- If the person is breathing normally, **do not use** the HeartSine SAM 350P



## What is sudden cardiac arrest?

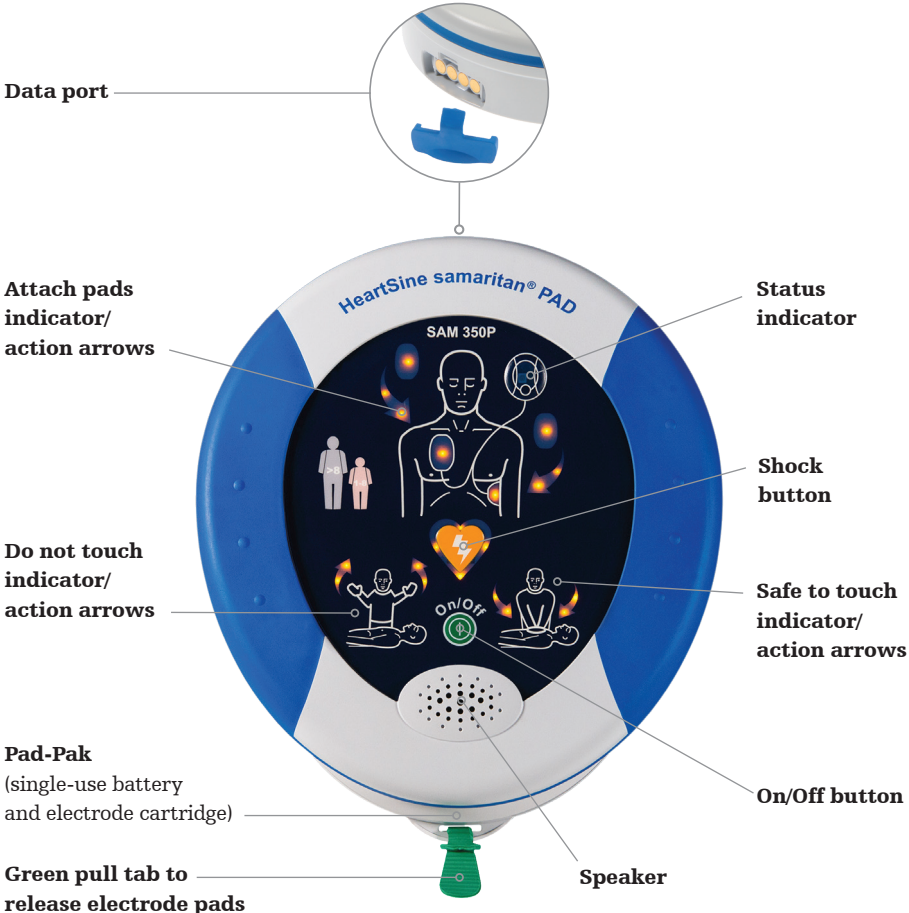
This AED is for use on someone who has suffered a sudden cardiac arrest:

- Heart has suddenly stopped beating (no pulse)
- Unconscious
- Not breathing normally

**A sudden cardiac arrest is not the same as a heart attack**, where a person is awake and may have chest pain or pressure, shortness of breath, or tightness in the chest or somewhere else in the body.

Use of this AED on someone whose heart has stopped beating can help save their life and give them a chance for emergency services to get them to the hospital.

**Getting to know your HeartSine SAM 350P AED**



# Set up

your AED

## 1. Watch the training video

- Scan the QR code with your smartphone camera to link to training videos page
- Watch Set up Your AED at [heartsine.com/videos](https://heartsine.com/videos)



## 2. Unpack your AED and Pad-Pak

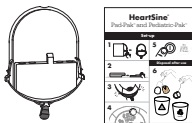
### Unpack your AED, removing these items from the box:

HeartSine SAM 350P AED in carry case with attached quick use guide hangtag



### Unpack your Pad-Pak:

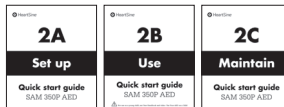
Pad-Pak (Battery and electrode cartridge), Set-up insert (Pad-Pak is provided in a separate box. It must be inserted into the AED at Set Up.)



### Important notice plus Warranty Registration Card



### Quick start guides




### User Handbook





### 3. Remove AED from carry case and place AED and Pad-Pak on a table


- Remove AED from carry case
- Place your HeartSine SAM 350P AED and Pad-Pak face up on a table

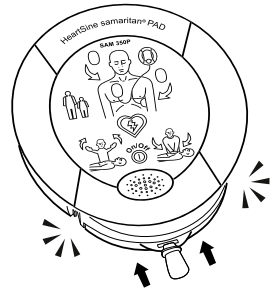
 **CAUTION:** If the expiration date has passed, immediately replace the expired Pad-Pak. **Do not use** the expired Pad-Pak



### 4. Insert the Pad-Pak

- Slide the Pad-Pak into bottom of the AED as shown until you hear the “double click”

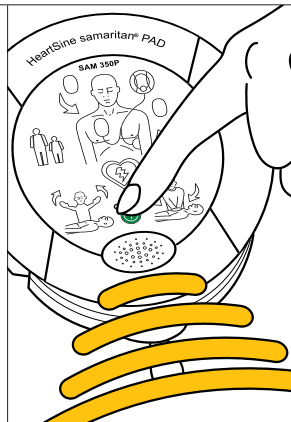
 **CAUTION:** **Do not** pull the green tab on the Pad-Pak at this time. If you have pulled the tab or opened the foil around the pads, you may need to replace your Pad-Pak. If you are not sure if you need to replace your Pad-Pak, contact us at [heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com)



## 5. Check the language on the AED

- Press the On/Off button to turn on the AED
- Listen for – **but do not follow** – the voice prompts to ensure that you hear English and do not hear a warning message
- If you do not hear your expected language, email Stryker at [heartlinesupport@stryker.com](mailto:heartlinesupport@stryker.com)
- Press the On/Off button again to turn off the AED

**Note:** Only turn on the AED once. If you turn it on and off over and over, you will drain the batteries before the expiration date and may need to replace the Pad-Pak



## 6. Check that the status indicator is flashing green


- Check that the status indicator on the AED is flashing green as this means your AED is ready for use

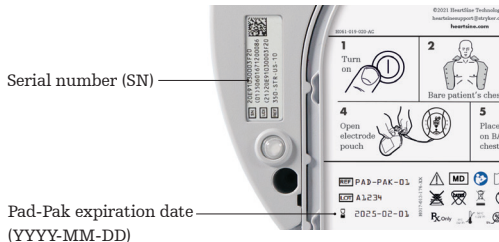
**Note:** Do not remove Pad-Pak from the AED as it must be stored with the Pad-Pak inserted




## 7. Write AED information on inside front cover of User Handbook

- Find the AED serial number on the rear of the AED and write it in the space provided
- Find the expiration date on the rear of the Pad-Pak (YYYY-MM-DD) and write it in the space provided
- Write the date you purchased your HeartSine AED and the name of the company or store where you bought your AED

<h1>About your AED</h1>	Put information about your AED here: 
	<b>Model</b> HeartSine SAM 350P
	<b>Serial number</b> <u>20E91030003F20</u>
	<b>Pad-Pak expiration date</b> <u>12/01/2026</u>
	<b>Date of purchase</b> <u>11/15/2022</u>
	<b>Purchased from</b> <u>ABC Retailer</u>
<b>Registration date</b> <u>11/16/2022</u>	



 **CAUTION:** If the expiration date has passed, immediately replace the expired Pad-Pak. **Do not use** the expired Pad-Pak

## 8. Register your AED

We are required to track the location of each HeartSine AED in the market. Therefore, it is very important that you register your AED. This will enable us to contact you with any important information about your AED.

- Please register your AED at [heartsine.com/register](https://heartsine.com/register)
- Or, complete the warranty registration card and return it to the HeartSine Technologies address on the card

**Note:** If you move the AED to another location or sell or give the AED to another person, please provide the updated information to us using the online registration page or email [heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com)

Scan the QR code with your smartphone camera to link to registration page:



[heartsine.com/register](https://heartsine.com/register)

## 9. Review training videos, quick start guides and User Handbook

So you and anyone who might use the AED will be ready to use the HeartSine samaritan PAD 350P:

- Watch the training videos at [heartsine.com/videos](https://heartsine.com/videos)
- Read the quick start guides
- Review this User Handbook which provides basic instructions on using the AED. For full instructions, including technical data, download the complete SAM 350P user manual at [heartsine.com](https://heartsine.com)

Scan the QR code with your smartphone camera to link to training videos:



[heartsine.com/videos](https://heartsine.com/videos)

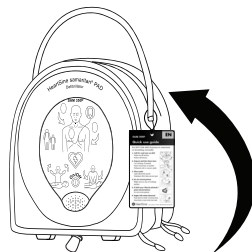
## 10. Place AED, instructions, scissors and razor in carry case

Place the following in the storage compartment on the back of the carry case:

- User Handbook
- Quick reference guides
- Scissors (Not included in AED package\*)
- Razor (Not included in AED package\*)
- If you ordered an extra Pad-Pak or a Pediatric-Pak, remove each from the box and place it in the storage compartment

**Note:** The hangtag tied to your carry case is a quick use guide that can help remind you how to use your AED in an emergency

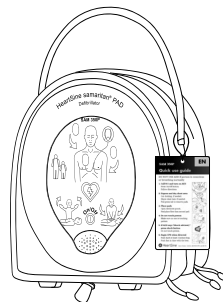
\* You may need scissors to cut a person's clothing and a razor to shave a chest with a lot of hair. You can use your own scissors or razor or you may be able to buy a kit with scissors and a razor from the AED store or company where you bought the AED.



## 11. Store your AED to complete the set up

- Store your AED in the carry case with the adult Pad-Pak inserted
- Store your AED where it can be seen and heard and quickly accessed
- Store AED in a clean and dry location where the temperature is between 32°F to 122°F

**Note:** Store your spare Pad-Pak and/or Pediatric-Pak in the carry case



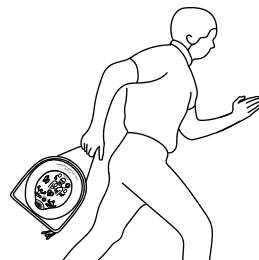
# Use your AED

on an adult

## 1. Call 911 for medical help

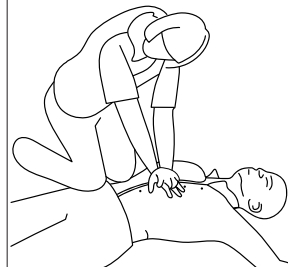


## 2. Get the AED



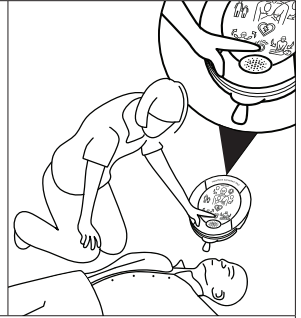
## 3. Begin CPR (until AED arrives)

- While waiting for the AED to arrive, begin CPR on the person
- Place overlapping hands in the middle of the person's chest
- With your arms straight, press down hard at least two inches deep and fast (100 to 120 compressions per minute)

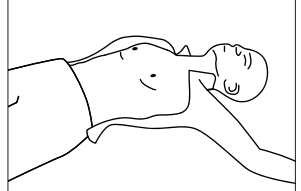


**4. Press the On/Off button and follow the voice directions**

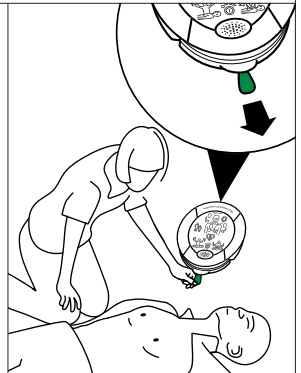
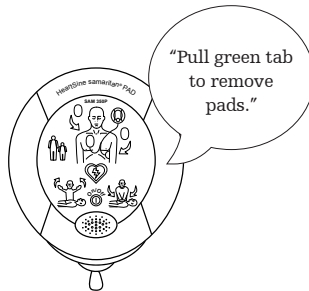
- Kneel next to the person
- Place the AED on the floor next to you
- Press the On/Off button to turn on AED
- Listen for the voice prompts and follow the directions

**5. Expose and dry chest area**

- Remove the clothing to expose the person's bare chest
- Cut the clothing with scissors, if needed
- If person's upper body is wet, dry the chest area
- If person has a lot of chest hair, use a razor to quickly shave the hair where the pads will be placed


**6. Pull green tab to remove pads**

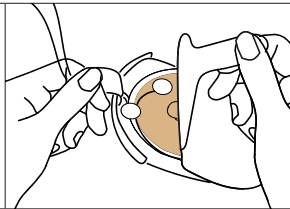
- Pull the green tab to remove the electrode pad pouch from the AED



## 7. Open the electrode pouch

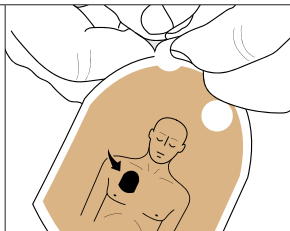
- With both thumbs on the foil tabs, open the foil to release the pads

 **WARNING: Do not use** the pads if pouch is opened or damaged; immediately replace the Pad-Pak



## 8. Peel first pad from liner

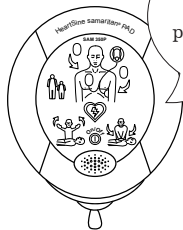
- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner



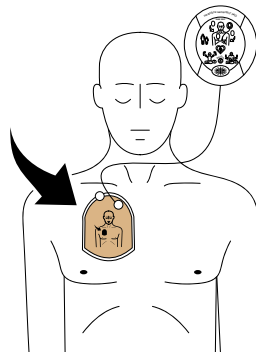
## 9. Place first pad

- Place the first pad as shown in picture

**Note:** If you are placing pads on a person with a pacemaker, do not place pads on top of the implant, which you will see as a lump in the skin or a scar. Make sure the pads are placed at least 3.1 inches (8 cm) away from the pacemaker



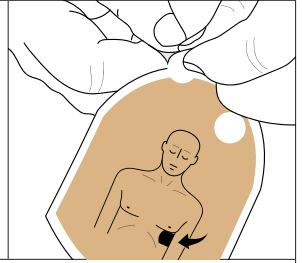
“Press pads firmly to patient’s bare chest.”





## 10. Peel second pad from liner

- With both thumbs on the white and clear round tabs, peel the second pad from the plastic liner



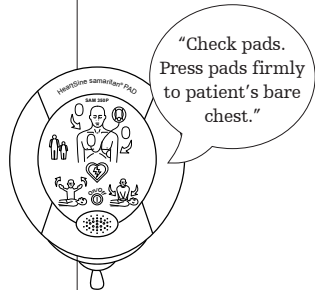
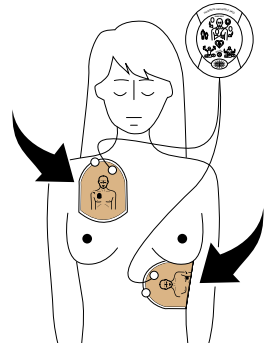
## 11. Place second pad

- Place the second pad as shown in picture

**⚠ WARNING:** Pads should be at least 1 inch apart and never touching one another

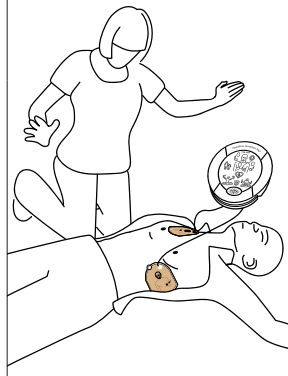
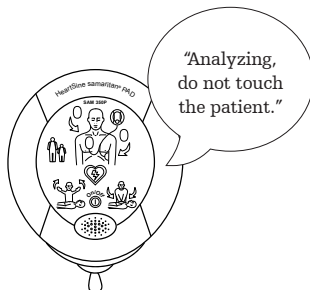
**Note:** On a large-breasted person, place the pad on the person's left to the side of or underneath the left breast, avoiding breast tissue

- After you have placed pads on the person's chest, if you continue to hear "Check pads. Press pads firmly to patient's bare chest," check that:
  - Pads are placed correctly as shown in the pictures
  - Pads are not touching and at least 1 inch apart
  - Entire surface of each pad is stuck to bare skin
  - If the chest is hairy, shave the chest
  - If the chest is wet, dry the chest



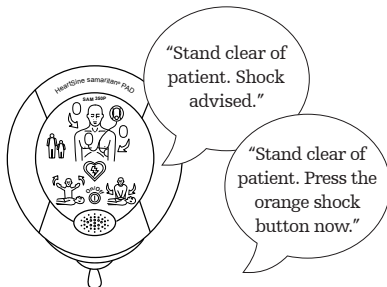
## 12. Do not touch the person

- When you hear “Analyzing, do not touch the person,” make sure no one is touching the person



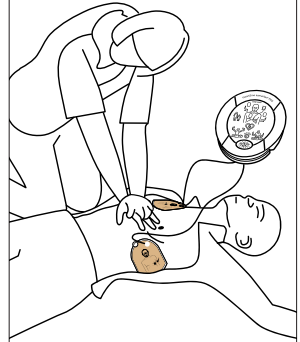
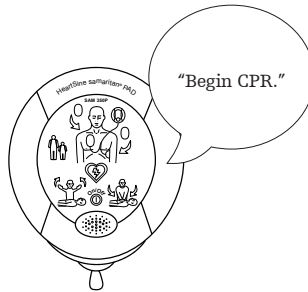
## 13. If a shock is needed, stand clear and press the shock button (as directed)

- When you hear “Stand clear of patient. Shock advised,” lean away from the person as directed
- When you hear “Stand clear of patient. Press the orange shock button now,” press the flashing shock button to deliver a shock



#### 14. Begin CPR when directed

- When you hear “Begin CPR,” begin CPR on the person
- Place overlapping hands in the middle of the person’s chest
- With your arms straight, press down hard at least 2 inches deep and fast in time with the beat
- Continue CPR until the AED tells you to stop



#### 15. Continue to follow the directions

Follow the directions, which may include providing additional CPR and shocks, until:

- Person begins breathing normally or is conscious or
- Medical help arrives

After emergency services has taken over care of the person:


- Press the On/Off button to turn off the AED
- Remove the pads and stick pads together, with the sticky sides stuck to one another
- For instructions on disposing of the used Pad-Pak and electrode pads, see page 26






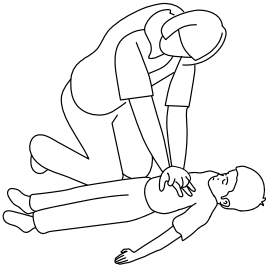
# Use your AED

## on a young child

If the person is a young child (from 1 to 8 years of age or weighing 55 lb or less), you should use a pink Pediatric-Pak in place of the gray Pad-Pak, if available. If you do not have a Pediatric-Pak, continue using the Pad-Pak.

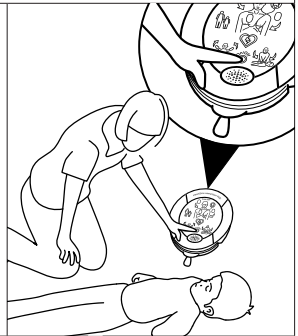
 **WARNING: Do not use** if the child is under one year old

 **WARNING: Do not** delay treatment trying to find out the child's exact age and weight

<b>1. Call 911 for medical help</b>	
	
<b>2. Get the AED</b>	
	
<b>3. Begin CPR (until AED arrives)</b>	
<ul style="list-style-type: none"><li>• While waiting for the AED to arrive, begin CPR on the child</li><li>• Place overlapping hands in the middle of the child's chest*</li><li>• With your arms straight, press down hard at least two inches deep and fast (100 to 120 compressions per minute)</li></ul> <p>*You may use either one hand or two hands to perform CPR on children!</p>	

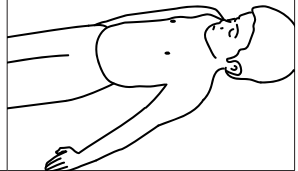
#### 4. Press the On/Off button and follow the directions

- Kneel next to the child
- Place the AED on the floor next to you
- If you have a pink Pediatric-Pak, remove the Pad-Pak and put in the Pediatric-Pak (as described in Set Up Your AED)
- If you don't have a Pediatric-Pak, continue to use the Pad-Pak
- Press the On/Off button to turn on AED
- Follow the directions



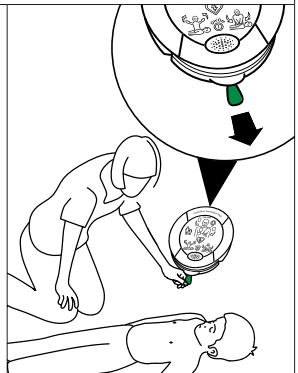
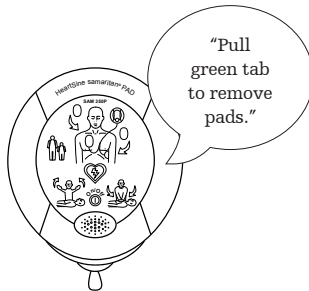
#### 5. Expose and dry chest area

- Remove all clothing from the child's upper body
- If the child's upper body is wet, dry the chest area



#### 6. Pull green tab to remove pads

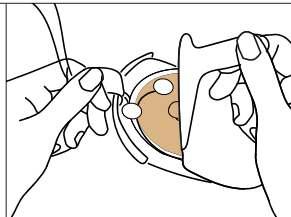
- Pull the green tab to remove the electrode pads from the AED



## 7. Open the electrode pouch

- With both thumbs on the foil tabs, open the foil to release the pads

**⚠ WARNING: Do not use** the pads if pouch is opened or damaged; immediately replace the Pad-Pak or Pediatric-Pak



## 8. Peel first pad from liner

- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner



## 9. Place first pad

Pads should be placed at least 1 inch apart and never touching one another

- If you cannot place the pads at least 1 inch apart, place the first pad on the center of the bare chest as shown in Figure A
- If you can place the pads at least 1 inch apart on the child's chest, place the first pad on the child's upper chest as show in Figure B

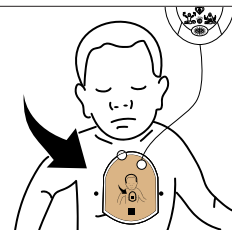
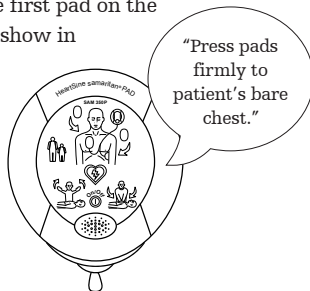


Figure A

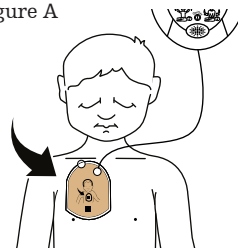
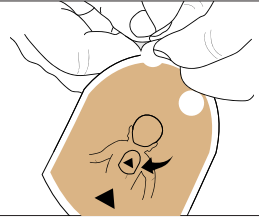


Figure B

## 10. Peel second pad from liner

- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner



## 11. Place second pad

- If you cannot place the pads 1 inch apart, place the second pad on the center of the bare back as shown in Figure C
- If you can place the pads 1 inch apart on the child's chest, place the second pad on the child's side of the chest as shown in Figure D
- After you have placed pads on the child, if you continue to hear "Check pads. Press pads firmly to patient's bare chest," check that:
  - Pads are not touching and are at least 1 inch apart
  - Pads are placed correctly as shown in pictures
  - Entire surface of each pad is stuck to bare skin
  - If wet, dry the chest or back

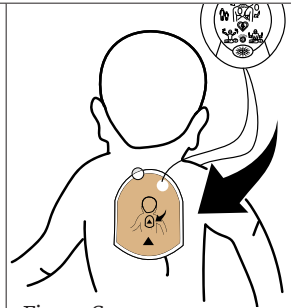
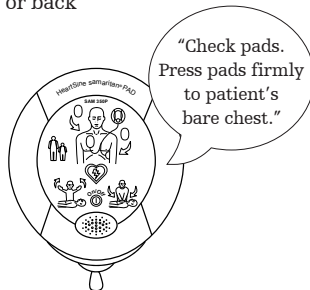


Figure C

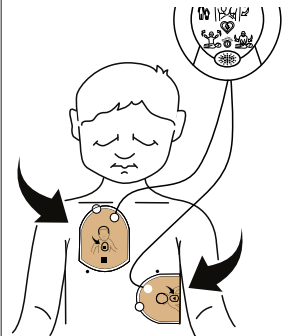
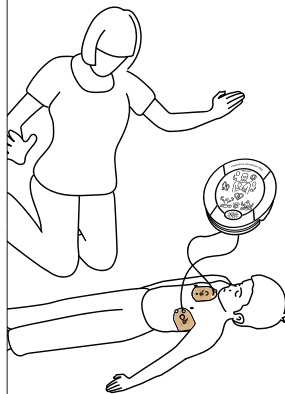
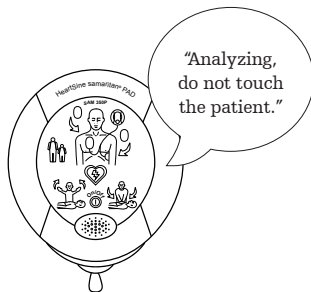


Figure D

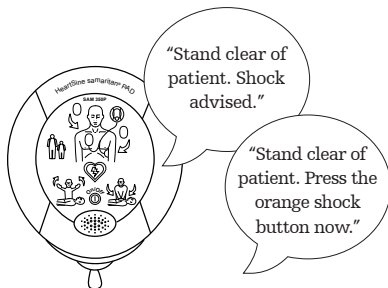
## 12. Do not touch the child

When you hear “Analyzing, do not touch the patient,” make sure no one is touching the child



## 13. If a shock is needed, stand clear and press the shock button (as directed)

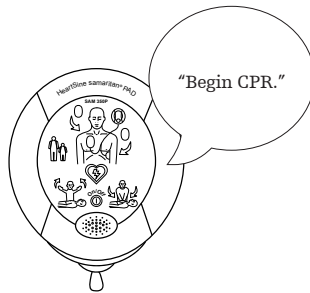
- When you hear “Stand clear of patient. Shock advised,” lean away from the child as directed
- When you hear “Stand clear of patient. Press the orange shock button now,” press the flashing shock button to deliver a shock





#### 14. Begin CPR when directed

- When you hear “Begin CPR,” begin CPR on the child
- Place overlapping hands in the middle of the child’s chest
- With your arms straight, press down hard and fast in time with the beat
- Continue CPR until the AED tells you to stop



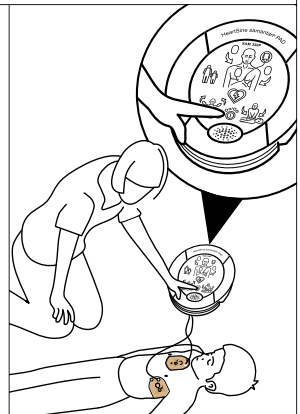
#### 15. Continue to follow the directions

Follow the directions, which may include providing additional CPR and shocks, until:

- Child begins breathing normally or is conscious or
- Medical help arrives

After emergency services has taken over care of the child:

- Press the On/Off button to turn off the AED
- Remove the pads and stick pads together, with the sticky sides stuck to one another
- For instructions on disposing of the used Pad-Pak and electrode pads, see page 26



# After you use

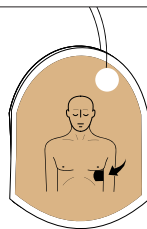
## your AED

Follow the steps in this section only after you have used the AED on a person. If you have not used the AED, follow the steps in the next section, Maintain your AED, to ensure that your AED is ready to use.

In the event you have used your HeartSine samaritan PAD, you must clean the AED and replace the Pad-Pak, which can be used only once.

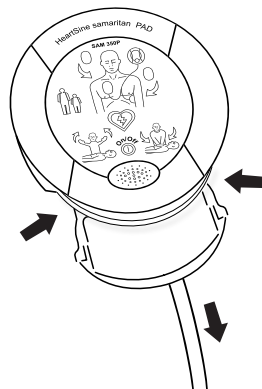
### 1. Remove the electrode pads

- Remove electrode pads from the person
- Stick pads together, with the sticky sides stuck to one another



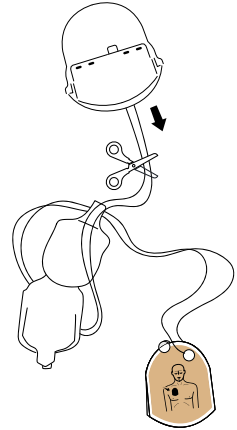
### 2. Remove the entire Pad-Pak or Pediatric-Pak from the AED

- Place HeartSine samaritan PAD face up on a table or other flat surface
- Squeeze the tab on each side of the Pad-Pak
- Pull to remove Pad-Pak from the AED; it will slide forward with the electrodes attached



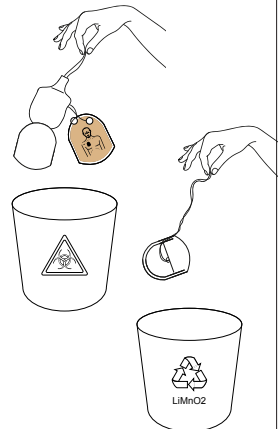
### 3. Separate electrode pads from battery

- Cut both cords to separate pads, tray and foil from the battery cartridge




### 4. Dispose of electrode pads and battery separately


- As the electrode pads may have contacted human bodily tissue, fluid or blood, they should be disposed of as infectious waste
- Alternatively, you can place the pads in a bag before putting them in your household trash
- Place the plastic tray and foil in your household trash
- Take the Pad-Pak battery cartridge to a place that accepts used batteries as this type of battery should not be put into your household trash

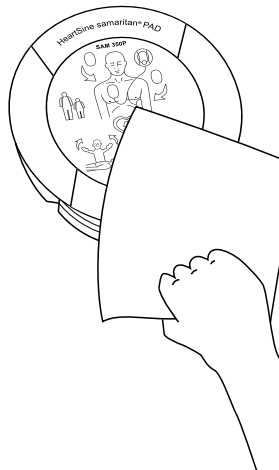


## 5. Clean the HeartSine samaritan PAD

- If necessary, use a damp cloth to clean the AED
- You may use 70% isopropyl alcohol to remove dirt that is hard to clean

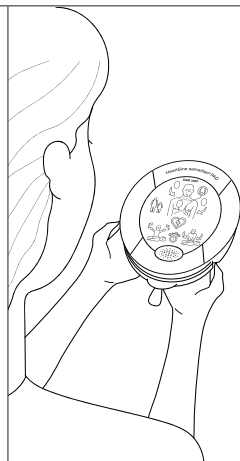
 **CAUTION: Do not** clean the HeartSine SAM 350P with cloths or cleaners that might damage the AED

 **CAUTION: Do not** place any part of the AED in water or any type of fluid as contact with liquids may damage the AED or cause a fire or shock risk



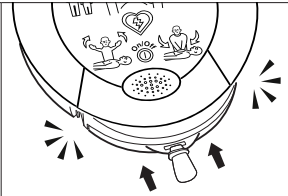
## 6. Check for damage

- Check the HeartSine SAM 350P for damage
- If the AED is damaged, replace it immediately and email us at [heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com)



## 7. Insert a new Pad-Pak and note new expiration date

- Before you insert the new Pad-Pak, note the expiration date on the inside front cover (see Set up your AED on page 9)



## 8. Check that the status indicator is flashing green

- Check that the status indicator to indicate your AED is ready for use
- Store your AED



## 9. Tell us when you use your AED!

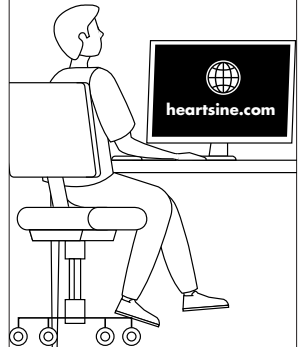
- As soon as your HeartSine SAM 350P AED has been used, please report the use of the AED to Stryker at [aedevent@stryker.com](mailto:aedevent@stryker.com) or to the AED store or company where you purchased your AED
- Data captured when you use your AED on a person is kept on the HeartSine SAM 350P until it is erased or overwritten. If you send us this data, you may be eligible to receive a free replacement Pad-Pak. See [heartsine.com/freepadpak](http://heartsine.com/freepadpak) for more information and instructions
- To download event data, see the instructions in the HeartSine samaritan PAD 350P user manual, available at [heartsine.com](http://heartsine.com). If you need help, please email us at [heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com)



[aedevent@stryker.com](mailto:aedevent@stryker.com)



[heartsine.com](http://heartsine.com)



# Maintain

## your AED

Your HeartSine SAM 350P AED runs a self-test each Sunday at 7 p.m. Eastern Time. If an issue is found during the self-test, the status indicator will change from flashing green to flashing red and you will hear an alert and voice instructions.

You should perform the following routine maintenance checks each week and each month:

### Each week

#### 1. Check that the status indicator is flashing green

- Check that the status indicator is flashing green every 5 to 10 seconds
- If the status indicator is not flashing green, a problem has been detected (See Troubleshooting in Appendix A)
- If the status indicator is flashing red, a problem has been detected (See Troubleshooting in Appendix A)
- If you hear a beep that does not stop, a problem has been detected (See Troubleshooting in Appendix A)
- After you have fixed the problem that caused the beep or flashing red status indicator, check that the status indicator is flashing green every 5 to 10 seconds

**Note:** During the self-test, the status indicator changes to flashing red. After the AED has passed the self-test, the status indicator returns to flashing green



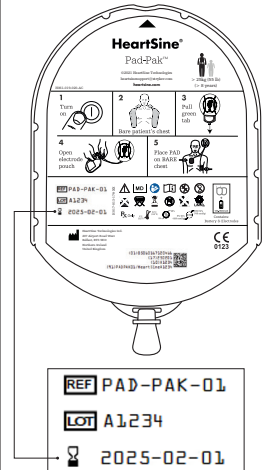
## Each month

### 2. Check the AED for damage

- Check for damage, including:
  - Cracks or marks on the face or plastic casing
  - Pad-Pak electrode drawer (green tab) is damaged or not closing properly
- If the AED is damaged, email [heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com)

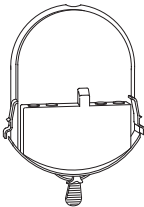
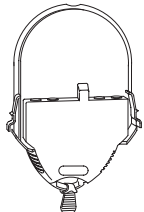
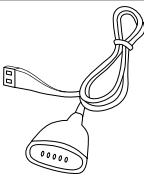
### 3. Look at the Pad-Pak expiration date

- If the Pad-Pak expiration date (YYYY-MM-DD) has passed or is close, immediately replace the Pad-Pak



# Order accessories

The following accessories are available for your HeartSine samaritan PAD:

<b>Pad-Pak</b>	
<p>PAD-PAK-01 PAD-PAK-07 (Aviation version: Required when AED is used on aircraft)</p> <p>This cartridge contains the battery and electrode pads and is for use on adults or children over 8 years of age or weighing more than 55 lb. Pad-Pak is a single-use cartridge, so you will need to discard and replace it after the AED is used or when the expiration date is reached.</p>	
<b>Pediatric-Pak</b>	
<p>PAD-PAK-02</p> <p>This cartridge contains the battery and electrode pads and is for use on children between 1 and 8 years of age or weighing up to 55 lb. If your AED might be used on a child, you should keep a Pediatric-Pak in the carry case, in addition to the Pad-Pak in the AED. Pediatric-Pak is a single-use cartridge so you will need to discard and replace it after the AED is used with the Pediatric-Pak or when the expiration date is reached.</p>	
<b>USB data cable (optional)</b>	
<p>PAD-ACC-02</p> <p>This USB cable allows you to get data from the HeartSine samaritan PAD after the AED has been used on a person. The cable is needed to get data from the HeartSine samaritan PAD.</p>	



# Appendices

## **Appendix A**

Troubleshooting

## **Appendix B**

Warnings and cautions

## **Appendix C**

Potential adverse effects

## **Appendix D**

Voice prompts


## **Appendix E**

Limited warranty statement


## Appendix A Troubleshooting

While device is off:	
Indication	Solution
<b>The Status indicator is flashing red or not lit, or you hear a continual beep</b>	<p>Check the expiration date on your Pad-Pak (see step 7 on page 11):</p> <ul style="list-style-type: none"><li>• If the expiration date has passed, immediately replace the Pad-Pak</li><li>• If the expiration date has not passed, press the On/Off button to turn on the AED and listen for the voice prompt “Call for medical assistance.”</li><li>• Press the On/Off button again to turn off the AED</li><li>• If either of these steps do not correct the problem, immediately email <a href="mailto:heartsinesupport@stryker.com">heartsinesupport@stryker.com</a></li></ul>
<b>You hear three fast beeps when the AED is turned off or after the self-test</b>	<p>Your AED has sensed it is being stored in a temperature that is outside the specified operating range.</p> <ul style="list-style-type: none"><li>• Return your AED to the specified operating temperature range of 32°F to 122°F, in which your AED, with its battery and pads, is designed to operate</li><li>• Check that you no longer hear the beeps</li></ul>

## While device is on:

Indication	Solution
<b>When the AED is on, the Status indicator is red and the AED beeps</b>	 <b>WARNING: THERE IS NOT ENOUGH BATTERY CAPACITY TO DELIVER A SHOCK. IMMEDIATELY REPLACE THE PAD-PAK OR FIND ANOTHER AED</b>
	<ul style="list-style-type: none"><li>• If you cannot find another Pad-Pak or AED, the AED will continue to analyze the person's heart rhythm and tell you when CPR is needed, but it will not be able to deliver a shock</li><li>• Continue CPR until emergency services arrive</li></ul>
<b>You hear "Check pads" when you use the device</b>	<ul style="list-style-type: none"><li>• Check that the pads are fully stuck to the person as shown on the picture and that the skin is free from hair, moisture and debris</li><li>• Adjust pads if necessary</li><li>• If message continues, remove the Pad-Pak and put it in again, and then press the On/Off button to turn on the AED</li><li>• If the message continues, seek an alternative AED and continue CPR</li></ul>

## Appendix A Troubleshooting

While device is on:	
Indication	Solution
<b>You hear “Warning, device service required” prompt</b>	 <b>WARNING: YOU CANNOT USE THIS AED. SEEK AN ALTERNATIVE DEFIBRILLATOR IMMEDIATELY. IF ONE IS NOT AVAILABLE, CONTINUE TO PROVIDE CPR UNTIL EMERGENCY SERVICES ARRIVE</b>
	<ul style="list-style-type: none"><li>• Do not attempt to service the AED as you will not be able to make it work</li><li>• After emergency services takes over care of the patient, contact HeartSine Technologies or email <a href="mailto:heartsinesupport@stryker.com">heartsinesupport@stryker.com</a> as soon as possible</li></ul>
<b>You hear “Memory full” prompt</b>	<p>The AED can still analyze and deliver a shock if required. However, the memory is full and can no longer record ECG data or events.</p> <ul style="list-style-type: none"><li>• Contact <a href="mailto:heartsinesupport@stryker.com">heartsinesupport@stryker.com</a> for assistance on clearing the memory</li></ul>

## While device is on:

Indication	Solution
<b>You hear “Warning low battery”</b>	<p>The first time you hear this message, the AED will continue to work properly. However, it may have less than 10 shocks left so make sure you have an extra Pad-Pak ready to use and be prepared to swap it quickly.</p> <ul style="list-style-type: none"><li>• Replace the Pad-Pak (which contains the battery) as soon as possible as the battery capacity is low</li></ul>
<b>You hear “Warning, off button pressed”</b>	<p>You have pressed the On/Off button while the AED is being used to treat a person.</p> <ul style="list-style-type: none"><li>• If you do not want to turn off the AED, continue following the prompts</li><li>• If you are sure you want to turn off the AED, quickly press On/Off again to turn off the AED</li></ul>
<b>You hear “Disarming”</b>	<p>This message does not indicate a fault; there is nothing wrong with the AED. It means that the AED has decided to not recommend a shock after it has initially decided to shock.</p> <ul style="list-style-type: none"><li>• Continue to follow the device prompts</li></ul>

## Appendix B Warnings and cautions

For a complete list of warning and cautions, download the complete SAM 350P user manual at [heartsine.com](http://heartsine.com).

### WARNINGS

#### **People on whom you can use the AED**

The HeartSine samaritan PAD has been designed to work on people who are not awake (unconscious) and not breathing normally. If the person is awake (conscious) or breathing normally, do not use the HeartSine samaritan PAD on the person.

This AED is for use on persons greater than 8 years old or weighing over 55 lb when used with the adult Pad-Pak (Pad-Pak-01), which is included with the AED.

It is also for use on children between 1 and 8 years of age or weighing up to 55 lb when used with the optional Pediatric-Pak (Pad-Pak-02). However, if you do not have a Pediatric-Pak, continue to use the Pad-Pak. **DO NOT WAIT TO USE THE AED ON THE PERSON IF YOU ARE NOT SURE OF THEIR EXACT AGE OR WEIGHT.**

#### **Risk of electric shock**

The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to anyone who uses the AED or is near the person. Be sure that no one touches the person when a shock is to be delivered.

#### **Do not use the AED near gas that may explode or easily catch fire**

The HeartSine samaritan PAD is safe to use with oxygen mask delivery systems. However, to make sure you don't risk an explosion, **do not** use the AED near explosive gases, such as concentrated oxygen, or medicines that may easily catch fire.

#### **Use with pacemakers**

You may use the AED on a person with a pacemaker. However, so that you do not damage the pacemaker, make sure the pads are placed at least 3.1 inches (8 cm) away from the pacemaker. A lump with a surgical scar in the person's chest will mark where the pacemaker is located.<sup>1</sup>

## CAUTIONS

### **Correct placement of electrode pads**

Proper placement of the HeartSine samaritan PAD electrode pads is very important. The AED may not work well if the pads are placed in the wrong location or if air, hair, surgical dressings or medicine patches are between the pads and the skin. It is normal for a person to have some red skin after receiving a shock.

### **Do not use electrode pads if pouch is not sealed**

The Pad-Pak and Pediatric-Pak are single-use so you must discard and replace them after each use or if the pouch that seals the electrode pads has been opened in any way. If you suspect that the Pad-Pak or Pediatric-Pak is damaged, replace it immediately.

### **Temperature range for operation**

The HeartSine samaritan PAD, with its battery and pads, is designed to operate in the temperature range of 32°F to 122°F. Use of the device outside of this range may cause the device to not work properly.

### **Make the battery last longer**

Do not turn on the AED unnecessarily as this may reduce the standby life of the AED. Standby storage outside the range of 32°F to 122°F may reduce the shelf-life of the Pad-Pak.

### **Compliance with local regulations**

Check with your local government health department for information about any requirements associated with owning and using your AED in your city or state.

## Appendix C Potential adverse effects

The potential adverse effects (complications) associated with the use of an automated external defibrillator include, but are not limited to, the following:

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury
- Inappropriate energy which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- Interaction with pacemakers
- Skin burns around the electrode placement area
- Allergic dermatitis due to sensitivity to materials used in electrode construction
- Minor skin rash

For the full safety and effectiveness information, download the complete SAM 350P User Manual at [heartstine.com](http://heartstine.com).



## Appendix D Voice Prompts

Following are the voice prompts used by the HeartSine SAM 350P. Read the voice prompts in advance of use to be familiar with the types of instructions given.

### PROMPT

#### Before and during analysis

"Adult patient" (heard when Pad-Pak installed)

"Child patient" (heard when Pediatric-Pak installed)

"Call for medical assistance"

"Remove clothing from patient's chest to expose bare skin"

"Pull green tab to remove pads"

"Peel pads from liner"

"Apply pads to patient's bare chest as shown in picture"

"Press pads firmly to patient's bare skin"

"Assessing heart rhythm; do not touch the patient"

"Analyzing; do not touch the patient"

"Check pads"

## PROMPT

### If a shock is not required

"No shock advised"

"Begin CPR"

"It is safe to touch the patient"

"Place overlapping hands in middle of chest"\*

"Press directly down on the chest in time with metronome"\*

"Remain calm"\*

### If a shock is required

"Stand clear of patient; shock advised"

"Stand clear of patient; press the orange shock button now"

"Shock delivered"

"Begin CPR"

"It is safe to touch the patient"

"Place overlapping hands in middle of chest"\*

"Press directly down on the chest in time with metronome"\*

"Remain calm"\*

\* Voice prompts not provided when Pediatric-Pak is installed.

## Appendix E Limited warranty statement

### **What is covered?**

Stryker provides to the original end user a limited warranty that all HeartSine products that are purchased in the United States from a distributor, sub-distributor, person or entity authorized by Stryker (“Authorized Agents”) are substantially free from defects in material and workmanship. This limited warranty applies only to the original end user and may not be assigned or transferred. An original end user is one who is able to provide proof of purchase from Stryker or an Authorized Agent. Persons who are not original end users take the products “as is” and with all faults. Please be prepared to provide proof of purchase demonstrating that you are the original end user and eligible to make a valid claim under this warranty. If you are not sure if the distributor, sub-distributor, person or entity from whom you purchased any HeartSine samaritan products is authorized by Stryker please contact Customer Support at 800 442 1142 or heartsinesupport@stryker.com.

### **For how long?**

HeartSine warrants, from the date of the sale to the original end user, the HeartSine samaritan PAD for the full eight (8) year service life. Products with a stated expiration date are warranted until such expiration date.

### **Limited warranty does not cover:**

This limited warranty does not cover defects or damages of any sort resulting from, but not limited to, accidents, damage while in transit to our service location, alterations, unauthorized service, unauthorized product case opening, failure to follow instructions, improper use, improper or inadequate maintenance, abuse, neglect, fire, flood, war or acts of God. We do not warrant your HeartSine products to be compatible with any other medical devices.

### **This limited warranty is void if:**

You purchased any HeartSine products from anyone other than an Authorized Agent; your HeartSine product is serviced or repaired by anyone other than Stryker; your HeartSine product is opened by unauthorized personnel or if a product is not used in accordance with the “Instructions for Use” and the “Indications for Use” provided with your product; your HeartSine product is used in conjunction with incompatible parts or accessories, including, but not limited to batteries. Parts and accessories are not compatible if they are not HeartSine products.

**What you should do:**

As the original end user you should return the completed postage-paid warranty registration card within 30 days of original purchase to HeartSine Technologies at the address provided on the card. If you wish to mail the warranty card in a stamped envelope, please use the following address:

HeartSine Technologies  
PO Box 1297  
Newtown, PA 18940-0874

Or register online using the Warranty Registration link on our website [heartsine.com](http://heartsine.com). To obtain warranty service for your HeartSine product, contact your local Stryker Authorized Agent or call Customer Support at 800 442 1142. Our technical representative will try to resolve your issue over the phone. If necessary, and at our sole discretion, we will arrange for service or a replacement of your HeartSine product. You must not send back any product without our authorization.

**What we will do:**

If your HeartSine product contains defects in material or workmanship and it is returned, at the direction of a technical service representative, within the warranty period, we, at our sole discretion, will repair your product or replace it with a new or reconditioned product of the same or similar design. The repaired or reconditioned product will be warranted subject to the terms and conditions of this limited warranty for either (a) 90 days or (b) the remainder of the original warranty period, whichever is longer, provided the warranty applies and the warranty period has not expired.

If our inspection does not detect any defects in material or workmanship of your HeartSine product, regular service charges will apply.

**Obligations and limitation of liability:**

THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT. Some states do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you.

NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF Stryker) IS AUTHORIZED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING HEARTSINE PRODUCTS, EXCEPT TO REFER TO THIS LIMITED WARRANTY.

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# Notes

## Notes

# heartsine.com

1. Panchal R, Bartos JA, Cabañas JG, et al. Part 3: Adult Basic and Advanced Life Support 2020 American Heart Association Guidelines for Cardiopulmonary *Resuscitation* and Emergency Cardiovascular Care. *Circulation*. 2020;142(suppl 2): S366–S468.

The complete user manual for HeartSine samaritan PAD 350P, which includes specifications, technical data and a symbol glossary, is available on our website. This User Handbook along with HeartSine samaritan PAD user manuals in all available languages can be found on our website at

**[heartsine.com/product-manuals](https://heartsine.com/product-manuals)**

To view information regarding environmental regulatory requirements, please refer to **[heartsine.com/environmental-regulations](https://heartsine.com/environmental-regulations)**

**For further information contact us at [heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com) or visit our web site at [heartsine.com](https://heartsine.com)**



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The absence of a product, feature, or service name, or logo from this list does not constitute a waiver of Stryker's trademark or other intellectual property rights concerning that name or logo.

Please report any serious incident that occurs with this device to HeartSine Technologies, Ltd. and to the U.S. Food and Drug Administration as per local regulations.

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HeartSine Technologies Ltd.  
207 Airport Road West  
Belfast

Northern Ireland  
BT3 9ED

United Kingdom

Tel +44 28 9093 9400

Fax +44 28 9093 9401

[heartsinesupport@stryker.com](mailto:heartsinesupport@stryker.com)  
[heartsine.com](https://heartsine.com)

## **Distributed in U.S. by:**

Stryker Emergency Care  
11811 Willows Road NE  
Redmond, WA, 98052 U.S.A.  
Toll free 800 442 1142  
[strykeremergencycare.com](https://strykeremergencycare.com)

**CE 0123** Pad-Pak; Pediatric-Pak



HeartSine samaritan PAD: UL Classified. See complete marking on product.