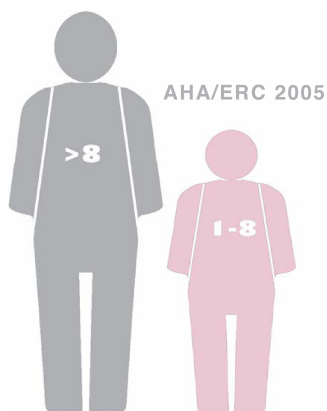




HeartSine®

Pediatric-Pak User Instructions (For Use with the samaritan® PAD Model SAM300P)



CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a licensed practitioner.

H023-001-009-10
English

INDICATIONS FOR USE:












The samaritan® Pediatric-Pak is indicated for use to treat patients in cardiopulmonary arrest who are unconscious, without a pulse and not breathing spontaneously. They should only be used by personnel who have been trained in its operation.

The samaritan® Pediatric-Pak is specially designed for use with the samaritan® PAD (Model SAM 300P) only. This product allows the samaritan® PAD to deliver lower-energy therapy to infants & children up to the age of 8 years or up to 55lbs (25kg). **DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.**

The samaritan® PAD (Automated External Defibrillator) is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program. Once attached and turned on, the defibrillator will analyze the patient's ECG rhythm. If a shockable rhythm is detected the device will charge automatically and advise the operator to deliver therapy.



Warnings

-  Only samaritan® Pads' with the label  are suitable for use with the Pediatric-Pak. If the samaritan® PAD you are using does not have this label - use the Adult Pad-Pak if no alternatives are available.
-  In the United States the samaritan® PAD and Pediatric-Pak are intended for use by or on the order of a physician or persons licensed by state law.
-  The use of the Pediatric-Pak will enable delivery of 50 Joule shocks to the pediatric patient.
-  Not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55lbs (25kg). **DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.**
-  The samaritan® PAD has the capability to deliver therapeutic electrical shocks. The electrical shock can cause serious harm to either operators or bystanders. Caution must be taken to ensure that neither the operators nor bystanders touch the patient when a shock is going to be delivered.
-  The samaritan® PAD is designed to work on patients who are unconscious, not breathing, and without circulation.
-  Touching or moving the patient during analysis of heart rhythm can interfere with the diagnostic process. Avoid physical contact with the patient until analysis and/or treatment has been completed unless the device instructs the operator to perform CPR.
-  Due to the danger of explosion it is strongly advised that the samaritan® PAD should not be used in the vicinity of explosive gases. This includes flammable anesthetics or concentrated oxygen.
-  Proper placement of the samaritan® PAD pads is critical. Strict observance of pad positioning instructions, as indicated on the labeling and in training, is essential. Care must be taken to ensure pads adhere to the patient's skin properly. Air pockets between the adhesive pad and skin must be eliminated. Failure in pad adhesion may hinder effectiveness of therapy or cause excessive skin burns to the patient if a therapeutic shock is applied. Reddening of the skin may appear after use, this is normal.
-  The samaritan® Pediatric-Pak is a single use item and must be replaced after the Pediatric Electrode pouch seal has been broken or compromised in any way. If damage is suspected the Pediatric-Pak must be replaced immediately.



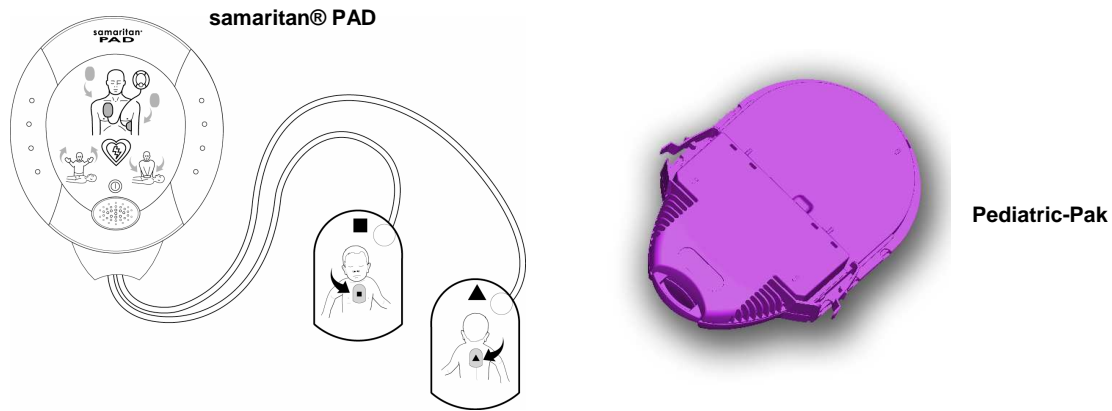
samaritan® Pediatric-Pak

User Instructions

- ⚠ This device is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support and use of AEDs', advanced life support, or a physician-authorized emergency medical response training program.

- ⚠ Your Pediatric-Pak contains a magnetic component (surface strength 4500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use.

samaritan® Pediatric-Pak



1. General Information You Should Know About the Pediatric-Pak:

Refer to the samaritan® PAD User Manual for comprehensive information on how to operate the defibrillator. **Note that the Pediatric-Pak gives the capability to use the samaritan® PAD (Model SAM300P) on children. When used this patient group is no longer contraindicated with the samaritan® PAD.**

The Pediatric-Pak should remain in the protective plastic pouch until use.

The Pediatric-Pak electrodes are sealed in a protective foil and should only be opened during use.

Each samaritan Pediatric-Pak combines a fresh battery and set of electrodes in a single cartridge. It is recommended that the samaritan PAD be stored with Adult electrodes installed and the Pediatric-Pak be stored in the carry case or nearby.

The Pediatric-Pak has a shelf life. Replace the Pediatric-Pak if used or if the “Use by” date has been exceeded.

CPR for children and infants follow slightly different protocols than adults. It is important to obtain training in Infant/Child CPR to be prepared in an emergency.

2. Instructions for Use:

Installing the Pediatric-Pak into the samaritan® PAD

Remove the Pediatric-Pak from the protective plastic.

Remove the Adult Pad-Pak from the samaritan® PAD.

Slide the Pediatric-Pak into the samaritan® PAD until you hear and feel a “click”.

When you switch on your samaritan® PAD you should hear the speech prompt “Child Patient”.

Using the Pediatric-Pak in an Emergency

It is recommended that if a child is unresponsive and not breathing the first step is to perform CPR FOR ONE MINUTE before using an AED. A bystander should call the emergency services.

If no bystander is available, call the emergency services after one minute of CPR.

Install the Pediatric-Pak in the samaritan® PAD (described above).

Turn on the samaritan® PAD and follow audible and visual instructions.

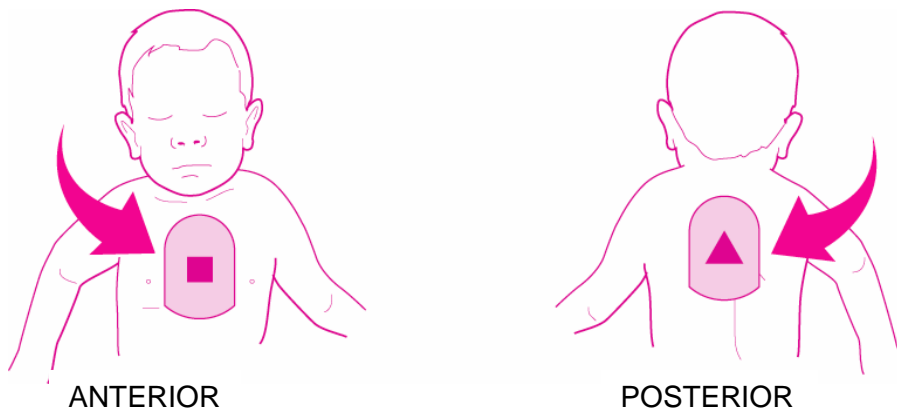


User Instructions

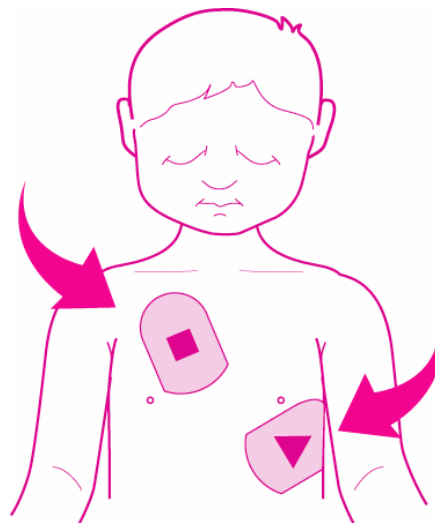
Electrode Placement:

1. Due to the smaller size of a pediatric victim, there are two options for electrode placement:
 - a. If a child's chest is small it may be necessary to place one pad on the child's BARE chest in the center, and the other pad on the child's BARE back in the center of the ribcage.
 - b. If a child's chest is large enough to permit a 1 inch (2.5cm) gap between the pads, pad placement can be used similar to adult placement. Place one pad on child's BARE upper right chest above nipple and one pad on child's BARE lower left ribcage below nipple.
2. The electrodes must be positioned as shown in the diagrams below for the two placement options described above:

a)



b)



Electrodes can be placed on the child's chest if their chest is large enough

OR

if trauma doesn't allow for the placement as shown in diagram a).



Warnings

Defibrillation electrodes must be at least 1 inch (approx 2.5 cm) apart and should never be touching one another.

Victim's chest should be bare and dry when applying electrodes.

Do not touch the child when the device is analyzing or shocking the patient.

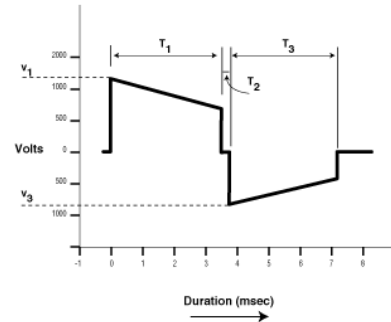
Specifications

Waveform: Biphasic Truncated Exponential

PAD impedance range: 0 – 176Ω

Energy Accuracy: 50J ±15%

Impedance, Ω	Energy, J
25	47.4
50	51.3
75	52.1
100	51.8
125	52.4



Samaritan PAD

Resistance (Ohms)	Waveform Voltages (Volts)		Waveform Duration (msec)	
	V1	Tilt %	T1	T3
25	514	55.6	7.8	5.4
50	671	50.4	8.8	6.0
75	751	47.1	10.0	6.6
100	813	44.3	10.8	6.8
125	858	41.4	11.5	7.3

Sample Nominal Energy Delivered to a 50Ω load

Age (Yrs)	50 TH Percentile Weight* (Kg)	Energy Dose In Joules Per Kg For Adult Energy Settings
Newborn	3.6	14.1
1	10.3	4.9
2	12.7	4.0
3	14.3	3.5
4	16.0	3.2
5	18.0	2.8
6	21.0	2.4
7	23.0	2.2
8	25.0	2.0

* Doses are based on CDC growth charts for the 50th percentile body weight of boys. National Center for Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).




samaritan® Pediatric-Pak

User Instructions



Warning



Only samaritan® Pads' with the label  are suitable for use with the Pediatric-Pak. In cases where there is no the Pediatric-Pak available the AHA and ERC recommend that an adult defibrillation pads are used. It is strongly recommended you use the adult Pad-Pak in cases where there are no other alternative.

Electrode Pads:

Conductive/Gel Surface Area: 100 cm² (200 cm² combined)
Overall Size: 100mm x 130mm
Standard Pad Placement: Anterior-Posterior or Anterior-Lateral

Environmental:

Operating Temperature: 0°C to 50°C (32°F to 122°F)
Stand by Temperature: 10°C to 50°C (50°F to 122°F)
Relative Humidity: 5% to 95% (non-condensing)
Atmospheric Pressure: 760 mmHg to 439 mmHg, 0 to 15,000 feet above sea level
Shipping Temperature Range: -10°C to 50°C (14°F to 122°F)

- Note:**
- 1 Store electrodes in a cool dry place. Continuous exposure to temperatures above 25°C (77°F) will reduce electrode shelf life.
 2. 'Shipping' temperatures are permitted for up 24 hours. (If device has been stored below -10°C (14°F) it should be returned to an ambient temperature of between 0 to 50°C (32 to 122°F) for at least 24 hours before use.)

Summary of Clinical Studies:

ECG Analysis Detection System (EADS)

The HeartSine samaritan® EADS has been tested using a database of a broad range pediatric and adult patients ECG exhibiting shockable and non-shockable rhythms. The results for pediatric analysis indicate that the samaritan EADS properly detects shockable and non-shockable rhythms with a sensitivity of 100.00 % and a Specificity of 100.00 %.

15,104 different ECG strips were analyzed from a total of 463 pediatric subjects giving a total of 13620.87 minutes of normal control and one strip from a pediatric patient in VF giving 25 minutes 58 seconds of positive shock advisable rhythm.

The results were 100% sensitive and specific with lower side 90% confidence levels being immeasurable (i.e. no measurable error).

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