HeartSine® samaritan® PAD 450P AED

Automated External Def ibrillator with Integrated CPR Rate Advisor™

Data sheet

Key link in the chain of survival

Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillators (AEDs) are key links in the chain of survival of sudden cardiac arrest (SCA). Some cardiac events are treatable with effective CPR alone. Others require a combination of effective CPR and the delivery a lifesaving shock by an AED. Either way, every minute counts.

Typically, only about five percent of SCA victims survive. However, survival rates can increase up to 74%[1] if CPR and a shock from an AED are provided within three minutes of collapse. Reducing response time by even one or two minutes from collapse to shock can mean the difference between death and survival.[2]

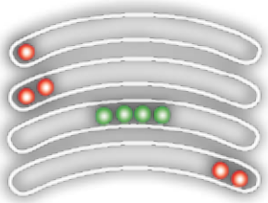
More than a simple AED, the HeartSine samaritan PAD 450P (SAM 450P) Automated External Defibrillator (AED) with integrated CPR Rate Advisor meets the needs of two key links in the chain of survival. Not only can the semi-automatic SAM 450P deliver a lifesaving shock, it provides real-time visual and verbal feedback to the rescuer on the rate of CPR compressions during an SCA resuscitation — effectively assisting the rescuer to perform CPR.

Real-time CPR Rate feedback

- **Integrated real-time CPR Rate feedback**
  Provides real-time visual and verbal feedback to the rescuer on the rate of CPR compressions during an SCA resuscitation, without the use of an accelerometer.

  Visual indicators and verbal feedback tell the rescuer if the rate of CPR is in line.

- **Improved CPR fraction**
  To improve hands-on time for CPR delivery, the HeartSine samaritan PAD 450P continues to remind the rescuer to perform CPR when no CPR is detected.



No CPR being performed/"Begin CPR"

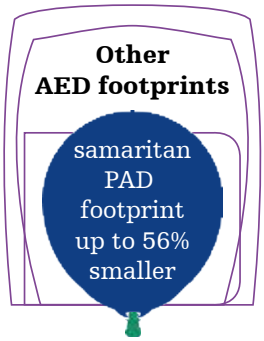
"Push faster"

"Good speed"

"Push slower"

Ready to shock

- **Highest level of protection against dust and water**
  Offers unmatched ruggedness with its high IP56 rating.
- **Clinically validated technology[3]**
  Proprietary electrode technology and SCOPE™ biphasic technology, a low energy escalating waveform, that automatically adjusts for differences in patient impedance.
- **Portable and lightweight**
  Most portable AED with its light weight (2.4 lb) and compact footprint.



Simple to own

- **Two parts, one expiration date**
  The innovative Pad-Pak,™ an integrated battery and electrode single-use cartridge with one expiration date, offers one simple maintenance change every four years.
- **Low cost of ownership**
  Shelf life of four years means that the Pad-Pak offers significant savings over other defibrillators that require separate battery and electrode replacements.

Pad-Pak and Pediatric-Pak™ with pre-attached electrodes
The HeartSine samaritan PAD's built-in intelligence and unique Pediatric-Pak ensure the appropriate energy level (50 J) is delivered for children, between 1 and 8 years of age or up to 55 lb (25 kg).

CPR Rate Advisor is deactivated when the Pediatric-Pak is in use.

Specifications

Defibrillator

Waveform: Self-Compensating Output Pulse Envelope (SCOPE) optimized biphasic escalating waveform compensates energy, slope and duration for patient impedance

Patient analysis system

Method: Evaluates patient's ECG, electrode contact integrity and patient impedance to determine if defibrillation is required

Sensitivity/Specificity: Meets IEC/EN 60601-2-4

Impedance range: 20-230 ohms

Energy selection

Pad-Pak
Shock 1: 150J
Shock 2: 150J
Shock 3: 200J

Pediatric-Pak:
Shock 1: 50J
Shock 2: 50J
Shock 3: 50J

Charge time (typical):
150J in < 8 seconds,
200J in < 12 seconds

Environmental

Operating/Standby temperature:
32°F to 122°F (0°C to 50°C)

Transportation temperature:
14°F to 122°F (-10°C to 50°C) for up to two days. If the device has been stored below 32°F (0°C), it should be returned to an ambient temperature of between 32°F to 122°F (0°C to 50°C) for at least 24 hours before use.

Relative humidity: 5% to 95% non-condensing

Enclosure: IEC/EN 60529 IP56

Altitude: 0 to 15,000 feet (0 to 4,575 meters)

Shock: MIL STD 810F Method 516.5, Procedure 1 (40 G's)

Vibration: MIL STD 810F Method 514.5, Procedure 1
Category 4 Truck Transportation – US Highways

Category 7 Aircraft – Jet 737 & General Aviation

EMC: IEC/EN 60601-1-2

Radiated emissions: IEC/EN 55011

Electrostatic discharge:
IEC/EN 61000-4-2 (8 kV)

RF immunity:
IEC/EN 61000-4-3 80MHz-2.5 GHz, (10 V/m)

Magnetic field immunity:
IEC/EN 61000-4-8 (3 A/m)

Aircraft: RTCA/DO-160G, Section 21 (Category M)

RTCA/DO-227 (TSO/ETSO-C142a)

Falling height: 3.3 feet (1 meter)

Physical characteristics

With Pad-Pak inserted:

Size:
8.0 in x 7.25 in x 1.9 in
(20 cm x 18.4 cm x 4.8 cm)

Weight: 2.4 lb (1.1 kg)

Accessories

Pad-Pak Electrode and Battery Cartridge

Shelf life/Standby life: See the expiration date on the Pad-Pak/Pediatric-Pak (4 years from manufacture date)

Weight: 0.44 lb (0.2 kg)

Size:
3.93 in x 5.24 in x 0.94 in
(10 cm x 13.3 cm x 2.4 cm)

Battery type: Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide ($LiMnO_2$) 18V)

Battery capacity (new):
> 60 shocks at 200J or
6 hours of continuous monitoring

Electrodes: Disposable defibrillation pads are supplied as standard with each device

Electrode placement: Anterior - lateral (Adult)

Anterior - posterior or Anterior - lateral (Pediatric)

Electrode active area: 15 in^2 (100 cm^2)

Electrode cable length: 3.3 feet (1 meter)

Aircraft safety test (TSO/ETSO-certified Pad-Pak): RTCA/DO-227 (TSO/ETSO-C142a)

Data storage

Memory type: Internal memory

Memory storage: 90 minutes of ECG (full disclosure) and event/incident recording

Review: Custom USB data cable (optional) directly connected to PC with Saver EVO™ Windows®-based data review software

Materials used

Defibrillator housing: ABS, Santoprene

Electrodes: Hydrogel, Silver, Aluminium and Polyester

Warranty

AED: 8-year limited warranty

Brief summary of indications and important safety information on back.

HeartSine® samaritan® PAD
Automated External Defibrillators (AEDs)

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE

The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) are indicated for use on victims of cardiac arrest who are exhibiting the following signs: unconscious, not breathing, without circulation (without a pulse). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/ AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the Pediatric-Pak™ (Pad-Pak-02).

CONTRAINDICATION

If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS

AEDs:

- The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered.
- Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.
- Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.
- The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.
- The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR.
- Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen.
- Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD.

Pad-Paks:

- Do not use if the gel is dry.
- The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.
- Only HeartSine samaritan PADs with the  label are suitable for use with the Pediatric-Pak. If the HeartSine samaritan PAD you are using does not have this label, use the adult Pad-Pak if no alternatives are available.
- The use of the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient.
- The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use.
- Never charge, short circuit, puncture, deform, incinerate, heat above 85ºC or expose contents of TSO (Aviation) Pad-Pak to water. Remove when discharged.

PRECAUTIONS

AEDs:

- Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another.
- Do not use electrode pads if pouch is not sealed.
- Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual.
- Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference.
- Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak.
- Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid.
- Do not turn on the device unnecessarily as this may reduce the standby life of the device.
- Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used.
- Dispose of the device in accordance with national or local regulations.
- Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used.

Pad-Paks:

- Check expiration date.

Saver EVO™ Software:

- Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS

The potential adverse effects (e.g., 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.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

References

1. Valenzuela TD, et al. 2000. Outcomes of Rapid Defibrillation by Security Officers After Cardiac Arrest in Casinos. New England Journal of Medicine. 343:1206-09.
2. Mosesso Jr VN, et al. 2002. Proceedings of the National Center for Early Defibrillation Police AED Issues Forum. Prehospital Emergency Care. 6(3):273–82.
3. Walsh SJ, McClelland A, Owens CG, Allen J, McC Anderson J, Turner C, Adgey J. Efficacy of distinct energy delivery protocols comparing two biphasic defibrillators for cardiac arrest. Am J Cardiol. 2004;94:378–380.

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HeartSine® samaritan® PAD 450P

Connected AED

Semi-Automatic Public Access Defibrillator with Integrated Wi-Fi® Connectivity

Data sheet

A Ready AED and High Quality CPR

Important links in the chain of survival

Sudden cardiac arrest strikes with little time to react and even less time to think. This means an Automated External Defibrillator (AED) must be close at hand, promote quality CPR and be ready to shock. Featuring CPR Rate Advisor™, HeartSine® samaritan® PAD 450P Connected AED offers real-time feedback on CPR rate as well as offering key features that help ensure readiness:

- Simplified readiness monitoring
- Integrated Wi-Fi® connectivity
- AED program management
- Low cost of ownership

Readiness made easy

- **LIFELINKcentral AED Program Manager**
  Monitors AED programs by tracking AED readiness status, Pad-Pak™ expirations, CPR/AED training certificates and more.
- **Integrated connectivity**
  Communicates via Wi-Fi with LIFELINKcentral™ AED Program Manager to enable AEDs to be managed across a single or multiple locations.

Made for you

- **Integrated real-time CPR feedback**
  Provides real-time visual and verbal feedback to the rescuer on the rate of CPR compressions during an SCA resuscitation, without the use of an accelerometer.
- **Portable and lightweight**
  Most portable AED with its light weight (2.83 lb) and compact footprint.
- **Clinically validated technology**
  Proprietary electrode technology and SCOPE™ biphasic technology, a low energy escalating waveform, that automatically adjusts for differences in patient impedance.
- **Highest level of protection against dust and water**
  Offers unmatched ruggedness with its high IP56 rating.

Simple to own

- **Two parts, one expiration date**
  The innovative Pad-Pak, an integrated battery and electrode single-use cartridge with one expiration date, offers one simple maintenance change every four years.
- **Low cost of ownership**
  Shelf life of four years means that the Pad-Pak offers significant savings over other defibrillators that require separate battery and electrode replacements.
- **8-year Warranty**
  AED is backed by an 8-year warranty.

Specifications

Defibrillator

Waveform: Self-Compensating Output Pulse Envelope (SCOPE) optimized biphasic escalating waveform compensates energy, slope and duration for patient impedance

Patient analysis system

Method: Evaluates patient's ECG, electrode contact integrity and patient impedance to determine if defibrillation is required

Sensitivity/Specificity: Meets IEC/EN 60601-2-4

Impedance range: 20-230 ohms

Energy selection

Pad-Pak shock:
Shock 1: 150J
Shock 2: 150J
Shock 3: 200J

Pediatric-Pak™:
Shock 1: 50J
Shock 2: 50J
Shock 3: 50J

Charge time (typical):
150J in < 8 seconds,
200J in < 12 seconds

Environmental

Operating/Standby temperature:
32°F to 122°F (0°C to 50°C)

Transportation temperature:
14°F to 122°F (-10°C to 50°C) for up to two days. If the device has been stored below 32°F (0°C), it should be returned to an ambient temperature of between 32°F to 122°F (0°C to 50°C) for at least 24 hours before use.

Relative humidity: 5% to 95% non-condensing

Water resistance:
IEC 60529/ EN60529 IPX6 with electrodes connected and battery installed

Dust resistance: IEC 60529/ EN60529 IP5X with electrodes connected and battery installed

Enclosure: IEC/EN 60529 IP56

Altitude: 0 to 15,000 feet (0 to 4,575 meters)

Shock: MIL STD 810F Method 516.5, Procedure 1 (40 G's)

Vibration: MIL STD 810F Method 514.5, Procedure 1

Category 4 Truck Transportation – US Highways

Category 7 Aircraft – Jet 737 & General Aviation

EMC: IEC/EN 60601-1-2

Radiated emissions: IEC/EN 55011

Electrostatic discharge:
IEC/EN 61000-4-2 (8 kV)

RF immunity:
IEC/EN 61000-4-3 80MHz-2.5 GHz, (10 V/m)

Magnetic field immunity:
IEC/EN 61000-4-8 (3 A/m)

Aircraft: RTCA/DO-160G, Section 21 (Category M)

RTCA/DO-227 (TSO/ETSO-C142a)

Falling height: 3.3 feet (1 meter)

Physical characteristics

With Pad-Pak inserted and HeartSine Gateway™, with batteries, attached:

Size:
9.21 in x 7.25 in x 1.9 in
(23.4 cm x 18.4 cm x 4.8 cm)

Weight: 2.83 lb (1.285 kg)

Accessories

Pad-Pak Electrode and Battery Cartridge

Shelf life/Standby life: See the expiration date on the Pad-Pak/ Pediatric-Pak (4 years from manufacture date)

Weight: 0.44 lb (0.2 kg)

Size:
3.93 in x 5.24 in x 0.94 in
(10 cm x 13.3 cm x 2.4 cm)

Battery type: Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide (LiMnO2) 18V)

Battery capacity (new):
> 60 shocks at 200J or
6 hours of continuous monitoring

Electrodes: Disposable defibrillation pads are supplied as standard with each device

Electrode placement: Anterior - lateral (Adult)

Anterior - posterior or Anterior - lateral (Pediatric)

Electrode active area: 15 in^2 (100 cm^2)

Electrode cable length: 3.3 feet (1 meter)

Aircraft safety test (TSO/ETSO-certified Pad-Pak): RTCA/DO-227 (TSO/ETSO-C142a)

HeartSine Gateway Battery

Type: CR123A 3V, Non-rechargeable

Type number: 6205

Designation IEC: CR 17345

Weight (per battery): 17g

Quantity: Four

System: Lithium Manganese Dioxide / Organic Electrolyte

UL recognition: MH 13654 (N)

Nominal voltage (per battery): 3V

Typical capacity load:
100 Ohm, at 68°F (20°C), 1550 mAh down to 2V

Volume: 0.43 in^3 (7 ccm)

Data storage

Memory type: Internal memory

Memory storage: 90 minutes of ECG (full disclosure) and event/incident recording

Review: Custom USB data cable (optional) directly connected to PC with Saver EVO™ Windows®-based data review software

Materials used

Defibrillator housing / HeartSine Gateway: ABS, Santoprene

Electrodes: Hydrogel, Silver, Aluminium and Polyester

Warranty

AED: 8-year limited warranty

HeartSine Gateway: 2-year limited warranty

Communications

Wireless 802.11 b/g/n data transfer to LIFELINKcentral AED Program Manager or LIFENET System. USB connection to Saver EVO software through Micro USB port

HeartSine® samaritan® PAD
Automated External Defibrillators (AEDs)

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE

The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) are indicated for use on victims of cardiac arrest who are exhibiting the following signs: unconscious, not breathing, without circulation (without a pulse). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/ AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the Pediatric-Pak™ (Pad-Pak-02).

CONTRAINDICATION

If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS

AEDs:

- The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered.
- Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.
- Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.
- The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.
- The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR.
- Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen.
- Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD.

Pad-Paks:

- Do not use if the gel is dry.
- The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.
- Only HeartSine samaritan PADs with the  label are suitable for use with the Pediatric-Pak. If the HeartSine samaritan PAD you are using does not have this label, use the adult Pad-Pak if no alternatives are available.
- The use of the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient.
- The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use.
- Never charge, short circuit, puncture, deform, incinerate, heat above 85ºC or expose contents of TSO (Aviation) Pad-Pak to water. Remove when discharged.

PRECAUTIONS

AEDs:

- Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another.
- Do not use electrode pads if pouch is not sealed.
- Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual.
- Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference.
- Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak.
- Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid.
- Do not turn on the device unnecessarily as this may reduce the standby life of the device.
- Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used.
- Dispose of the device in accordance with national or local regulations.
- Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used.

Pad-Paks:

- Check expiration date.

Saver EVO™ Software:

- Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS

The potential adverse effects (e.g., 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.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

HeartSine TechNote

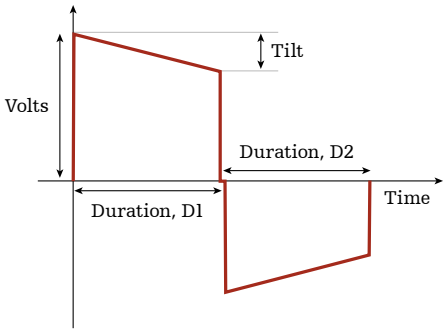
SCOPE™ Biphasic escalating waveform

History

Early external defibrillators used monophasic waveforms and were not designed to compensate for patient impedance. Instead, the devices used selectable energy levels that were set by the attending physician. The physician not only needed to estimate impedance based on a specific patient, but also needed to increase the energy level if defibrillation was not initially successful. In addition, the monophasic waveforms used energy levels up to 360 Joules to defibrillate effectively.

Biphasic waveforms

Biphasic waveforms, which were initially developed for use in implantable defibrillators, have become the standard in public access defibrillators. Importantly, many studies have shown that biphasic waveforms defibrillate successfully at lower energies because biphasic waveform technology allows the waveform to be adapted for different patient impedances. For any particular energy level there are three primary variables for the wave shape: voltage, tilt, and the duration of each phase.



Manufacturers of public access defibrillators have adopted different strategies for biphasic waveforms, adjusting one or more of the main variables to compensate for patient impedance. The various approaches are shown in the following table.

Waveform	D1	D2	Voltage	Slope
HeartSine SCOPE	Variable	Variable	Variable	Variable
Cardiac Science STAR	Variable	Fixed	Variable	Variable
Philips SMART	Variable	Variable	Fixed	Variable
Physio-Control	Variable	Variable	Fixed	Variable
Zoll RBW	Fixed	Fixed	Variable	n/a

SCOPE waveform

SCOPE™ (Self Compensating Output Pulse Envelope) is HeartSine's proprietary biphasic waveform. Unlike the technology used by other manufacturers, the HeartSine® SCOPE waveform adjusts all three variables for all impedances in the operating range and uses an escalating energy protocol to optimize the efficacy of the samaritan® PAD. The HeartSine SCOPE waveform also is a low energy waveform.

Because biphasic waveforms are adapted for varying patient impedance, the range of patient impedance over which the device operates is significant. As shown in the table below, the SCOPE waveform can deliver a shock over a wide impedance range (20-230 ohms) without a significant loss of energy—another advantage of the HeartSine SCOPE technology.

Waveform	Min Impedance	Max Impedance
HeartSine SCOPE	20 Ohms	230 Ohms
Cardiac Science STAR	25 Ohms	180 Ohms
Philips SMART	25 Ohms	180 Ohms
Physio-Control	25 Ohms	200 Ohms
Zoll RBW	25 Ohms	300 Ohms*

* Delivered energy reduces after 175 ohms.

Please note that if the patient impedance is below 20 ohms or in excess of the maximum 230 ohms, the device will NOT deliver a shock.

References

1. Walsh S, McClelland J, Owens CG, Allen J, McCanderson J, Turner C, Adgey J. Efficacy of distinct energy delivery protocols comparing two biphasic defibrillators for cardiac arrest. Am J Cardiol. 2004;94:378–380.

HeartSine® samaritan® PAD Automated External Defibrillators (AEDs)

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INDICATIONS FOR USE: The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) are indicated for use on victims of cardiac arrest who are exhibiting the following signs: unconscious, not breathing, without circulation (without a pulse). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the Pediatric-Pak™ (Pad-Pak-02).

CONTRAINDICATION: If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS: AEDs: • The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered. • Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient. • Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak. • The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention. • The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR. • Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen. • Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD. **Pad-Paks:** • Do not use if the gel is dry. • The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT. • Only HeartSine samaritan PADs with the label are suitable for use with the Pediatric-Pak. If the HeartSine samaritan PAD you are using does not have this label, use the adult Pad-Pak if no alternatives are available. • The use of the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient. • The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use. • Never charge, short circuit, puncture, deform, incinerate, heat above 85°C or expose contents of TSO (Aviation) Pad-Pak to water. Remove when discharged.

PRECAUTIONS: AEDs: • Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another. • Do not use electrode pads if pouch is not sealed. • Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual. • Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference. • Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak. • Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid. • Do not turn on the device unnecessarily as this may reduce the standby life of the device. • Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used. • Dispose of the device in accordance with national or local regulations. • Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used. **Pad-Paks:** • Check expiration date. **Saver EVO™ Software:** • Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS: The potential adverse effects (e.g., 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.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

IP Ratings Dust and water resistance chart[1]

Protected against solid objects	
First number	**Definition**
0	Not protected
1	Protected against solid objects of over 50 mm in size (for instance, hands)
2	Protected against solid objects of over 12 mm in size (for instance, fingers)
3	Protected against solid objects of over 2.5 mm in size (for instance, tools and wires)
4	Protected against solid objects of over 1 mm in size (for instance, small tools and wires)
5	Protected against limited ingress of dust that will not penetrate in a quantity to interfere with satisfactory operation
6	Protected against any dust ingress

Protected against liquids	
Second number	**Definition**
0	Not protected
1	Protected against vertically falling drops of water
2	Protected against direct sprays of water when tilted at any angle up to 15° on either side
3	Protected against water sprayed at an angle of 60° on either side
4	Protected against water splashed from any direction
5	Protected against low pressure jets of water from all directions
6	Protected against powerful jets of water from any direction
7	Protected against the effects of temporary immersion in water under standardized conditions and pressure
8	Protected against long periods of submersion in water more severe than 7
9	Protected against water projected at high pressure and temperatures from any direction

HeartSine® samaritan® PAD

IP56 Rating: Highest among leading AEDs for protection against dust and water ingress

References

[1] International Standard IEC 60529 - Degrees of protection provided by enclosures (IP Code)

HeartSine® samaritan® PAD Automated External Defibrillators (AEDs)

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) are indicated for use on victims of cardiac arrest who are exhibiting the following signs: unconscious, not breathing, without circulation (without a pulse). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the Pediatric-Pak™ (Pad-Pak-02).

CONTRAINDICATION: If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS: AEDs: • The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered. • Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient. • Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak. • The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention. • The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR. • Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen. • Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD. **Pad-Paks:** • Do not use if the gel is dry. • The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT. • Only HeartSine samaritan PADs with the label are suitable for use with the Pediatric-Pak. If the HeartSine samaritan PAD you are using does not have this label, use the adult Pad-Pak if no alternatives are available. • The use of the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient. • The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use. • Never charge, short circuit, puncture, deform, incinerate, heat above 85°C or expose contents of TSO (Aviation) Pad-Pak to water. Remove when discharged.

PRECAUTIONS: AEDs: • Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another. • Do not use electrode pads if pouch is not sealed. • Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual. • Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference. • Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak. • Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid. • Do not turn on the device unnecessarily as this may reduce the standby life of the device. • Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used. • Dispose of the device in accordance with national or local regulations. • Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used. **Pad-Paks:** • Check expiration date. **Saver EVO™ Software:** • Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS: The potential adverse effects (e.g., 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.

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HeartSine®

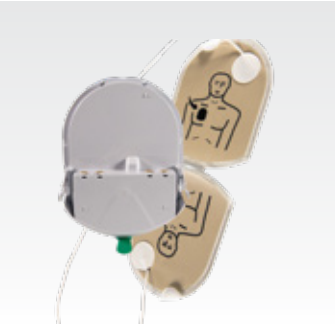
samaritan® PAD Family

Accessories

stryker

Not all accessories are available for sale in all countries.

Pad-Pak™



Adult Pad-Pak
For patients > 8 years or 55 lb (25 kg).
Pad-Pak-01
11516-000003

Pediatric-Pak™
For patients 1 to 8 years or up to 55 lb (25 kg).
Pad-Pak-02
11516-000004

Adult Pad-Pak
With TSO-C142a certification for use on aircraft.
Pad-Pak-07
11516-000027

Data Download

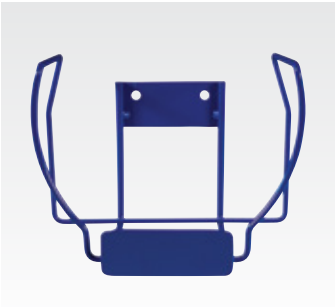
USB Data Cable
For use with the Saver EVO™ data management software to download event data and to perform software upgrades to the HeartSine samaritan PAD non-connected devices.
PAD-ACC-02
11516-000018

Cabinets and Mounting Options

Rotaid Plus Wall Cabinet with Alarm
For indoor use.
11996-000441 (White)
11996-000443 (Red)

Rotaid Solid Plus Wall Cabinet with Alarm
For indoor or outdoor use.
11996-000445 (White)
11996-000447 (Red)

Rotaid Solid Plus Heat Wall Cabinet with Heat and Alarm
For outdoor use.
11996-000449 (White)
11996-000451 (Red)



AED Wall Bracket
(Metal)
Dimensions:
6.14 H x 6.88 W x 4.48 D in
(15.6 H x 17.5 W x 11.4 D cm)
PAD-CAB-02
11516-000023

Training Tools

HeartSine samaritan PAD Trainer SAM 350P
TRN-350-US 11516-000059
TRN-350-AS 11516-000029

HeartSine samaritan PAD Trainer SAM 360P
TRN-360-US 11516-000091
TRN-360-AS 11516-000061

HeartSine samaritan PAD Trainer SAM 450P
TRN-450-US 11516-000092
TRN-450-AS 11516-000093

Trainer-Pak
(Replacement Electrode Cartridge)
TRN-PAK-04
11516-000017

HeartSine Gateway™

HeartSine Gateway
Includes removal tool, batteries and HeartSine Connected AED carrying case.
ACC-GTW-US-01

HeartSine Gateway Removal Tool
ACC-REM-GW

HeartSine Gateway Batteries
ACC-BAT-GW

Storage Options

Wall Cabinet with Alarm, Custom Made
Dimensions:
12 H x 11 W x 5 D in
(30.48 H x 27.94 W x 12.7 D cm)
Weight: 5 lb (2.27 kg)
PAD-CAB-04
11516-000024

HeartSine AED Carrying Case
PAD-BAG-01
11516-000022

Mobile AED Rescue Backpack
PAD-BAG-02
11516-000114

Replacement electrodes
(for use with Trainer-Pak)
TRN-ACC-02 (10/pak)
11516-000009
TRN-ACC-03 (25/pak)
11516-000011

HeartSine samaritan PAD Trainer Remote
TRN-ACC-16 (SAM 350P)
11516-000014
TRN-ACC-18 (SAM 360P)
11516-000016

TRN-ACC-19 (SAM 450P)
11516-000001

Battery Charger
(Replacement)
TRN-ACC-14
11516-000012

HeartSine® samaritan® PAD
Automated External Defibrillators (AEDs)

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE

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CONTRAINDICATION

If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS

AEDs:

- The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered.
- Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.
- Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.
- The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.
- The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR.
- Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen.
- Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD.

Pad-Paks:

- Do not use if the gel is dry.
- The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.
- Only HeartSine samaritan PADs with the  label are suitable for use with the Pediatric-Pak. If the HeartSine samaritan PAD you are using does not have this label, use the adult Pad-Pak if no alternatives are available.
- The use of the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient.
- The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use.
- Never charge, short circuit, puncture, deform, incinerate, heat above 85ºC or expose contents of TSO (Aviation) Pad-Pak to water. Remove when discharged.

PRECAUTIONS

AEDs:

- Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another.
- Do not use electrode pads if pouch is not sealed.
- Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual.
- Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference.
- Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak.
- Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid.
- Do not turn on the device unnecessarily as this may reduce the standby life of the device.
- Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used.
- Dispose of the device in accordance with national or local regulations.
- Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used.

Pad-Paks:

- Check expiration date.

Saver EVO™ Software:

- Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS

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

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- 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.
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