

# HeartSine® samaritan® PAD 350P/360P AEDs

Semi-Automatic/Fully Automatic  
Public Access Defibrillators

## Data sheet

### Compact, easy-to-use, lifesaving technology for public access

Sudden cardiac arrest strikes 7 million people a year worldwide with no warning and no pattern. There's little time to react and even less time to think. This means an Automated External Defibrillator (AED) must be close at hand, easy to use and ready to shock.

The semi-automatic HeartSine samaritan PAD 350P (SAM 350P) and fully automatic HeartSine samaritan PAD 360P (SAM 360P) offer industry-leading value and environmental protection, all in an easy-to-operate system in the smallest and lightest package available.

The fully automatic SAM 360P detects motion or other significant interference to reduce the likelihood that the user is touching the patient prior to shock delivery.



## Ready to shock

- **Portable and lightweight**

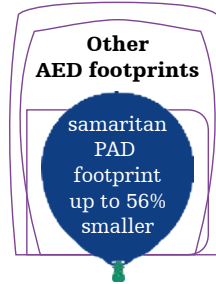
Most portable AED with its light weight (2.4 lb) and compact footprint.

- **Highest level of protection against dust and water**

Offers unmatched ruggedness with its high IP56 rating.

- **Clinically validated technology<sup>1</sup>**

Proprietary electrode technology and SCOPE™ biphasic technology, a low energy escalating waveform, that automatically adjusts for differences in patient impedance.



## Easy-to-follow visual and verbal guides

- **User-friendly**

Easy-to-understand visual and voice prompts guide the rescuer through the entire resuscitation process, including CPR—a key link in the chain of survival.

- **One- or two-button operation**

With just an ON/OFF button (and the SHOCK button on the SAM 350P), offers a simple, straightforward operation.

- **Automatic shock delivery**

After analyzing heart rhythm, automatically deliver a shock (if needed), eliminating the need for the rescuer to push a shock button (SAM 360P\*).

- **Always ready**

A System Status Ready Indicator flashes to show that the complete system is operational and ready for use. The device automatically runs a self-check each week.



“Apply pads to patient’s bare chest as shown in picture”



“Stand clear of the patient”



“Safe to touch the patient”

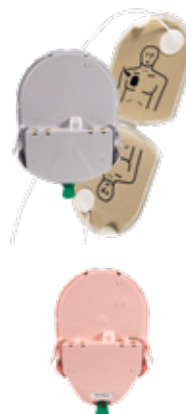
## Simple to own

- **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**

With a shelf life of four years, 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).

\* Warning: The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.

## 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<sub>2</sub>) 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<sup>2</sup>

(100 cm<sup>2</sup>)

**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



## 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.

##### References

1. 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.

#### 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® samaritan® PAD 350P/360P

## Connected AEDs

**Semi-Automatic/Fully Automatic Public Access Defibrillators  
with Integrated Wi-Fi® Connectivity**

## Data sheet

### A Ready AED. So simple.

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, easy to use and ready to shock. Designed for simplicity, HeartSine samaritan PAD 350P and 360P Connected AEDs offer 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

- **Real-time CPR coaching**  
Easy to understand visual and voice prompts guide the rescuer through the entire resuscitation process, including CPR—a key link in the chain of survival.
- **One- or two-button operation**  
With just an ON/OFF button (and the SHOCK button on the SAM 350P), offers a simple, straightforward operation.
- **Automatic shock delivery / Motion detection**  
After analyzing heart rhythm, automatically delivers a shock (if needed), eliminating the need for the rescuer to push a shock button (SAM 360P).
- **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

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

### Patient analysis system

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**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

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#### 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

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#### 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

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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

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#### 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<sub>2</sub>) 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<sup>2</sup> (100 cm<sup>2</sup>)

**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<sup>3</sup> (7 ccm)

### Data storage

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**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

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#### Defibrillator housing / HeartSine

**Gateway:** ABS, Santoprene

**Electrodes:** Hydrogel, Silver, Aluminium and Polyester

### Warranty

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**AED:** 8-year limited warranty

**HeartSine Gateway:** 2-year limited warranty

### Communications

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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 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

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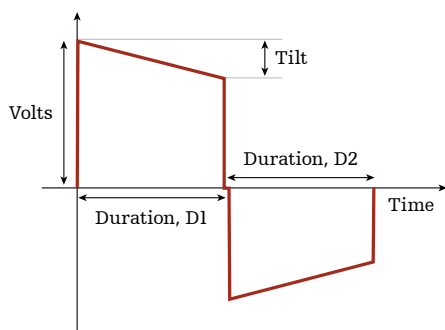
## SCOPE™ Biphasic escalating waveform

### 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<sup>1</sup>

Protected against solid objects		Protected against liquids	
First number	Definition	Second number	Definition
0	Not protected	0	Not protected
1	Protected against solid objects of over 50 mm in size (for instance, hands)	1	Protected against vertically falling drops of water
2	Protected against solid objects of over 12 mm in size (for instance, fingers)	2	Protected against direct sprays of water when tilted at any angle up to 15° on either side
3	Protected against solid objects of over 2.5 mm in size (for instance, tools and wires)	3	Protected against water sprayed at an angle of 60° on either side
4	Protected against solid objects of over 1 mm in size (for instance, small tools and wires)	4	Protected against water splashed from any direction
5	Protected against limited ingress of dust that will not penetrate in a quantity to interfere with satisfactory operation	5	Protected against low pressure jets of water from all directions
6	Protected against any dust ingress	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


<sup>1</sup> 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.

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

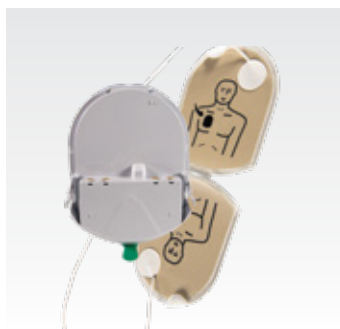
**HeartSine**<sup>®</sup>  
samaritan<sup>®</sup> PAD  
Family

Accessories

**stryker**

## Pad-Pak™

## Data Download



**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**



**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)



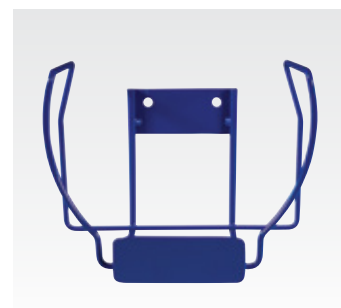
**Rotaid Solid Plus Wall  
Cabinet with Alarm**  
For indoor or outdoor use.

**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

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.