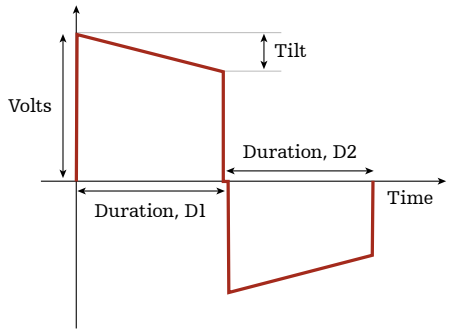
# SCOPE™ Biphasic escalating waveform

## History

Early external defibrillators 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 | Tilt |
|---|---|---|---|---|
| **HeartSine SCOPE** | Variable | Variable | Variable | Variable |
| **Cardiac Science STAR**[1] | Variable | Fixed | Variable | Variable |
| **LIFEPAK**[2] | Variable | Variable | Variable | Variable |
| **Philips SMART**[3] | Variable | Variable | Fixed | Variable |
| **ZOLL**[4] | Fixed | Fixed | Variable | n/a |

## SCOPE waveform

SCOPE (Self Compensating Output Pulse Envelope) is HeartSine's proprietary low-energy, 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 HeartSine samaritan PAD.

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**[1] | 25 Ohms | 180 Ohms |
| **LIFEPAK**[2] | 10 Ohms | 300 Ohms |
| **Philips SMART**[3] | 25 Ohms | 180 Ohms |
| **ZOLL**[4] | 0 Ohms | 300 Ohms* |

*Delivered energy reduces after 175 ohms.[5]

Please note, with HeartSine SCOPE technology, 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. *User's Guide, Cardiac Science Powerheart Automated External Defibrillator.* 70-01704-01 B.
2. *LIFEPAK CR2 Defibrillator with LIFELINKcentral AED Program Manager Operating Instructions*. 3322738-023.
3. *HeartStart Defibrillator OWNER'S MANUAL*. M5066A Edition 11.
4. *ZOLL AED Plus Administrator's Guide*. 9650-0301-01 Rev. V.
5. Kettea F, Locatelli A, Bozzolaa M, et al. Electrical features of eighteen automated external defibrillators: A systematic evaluation. *Resuscitation* 2013;84: 1596–1603.

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 lb (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 lb (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 lb (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.

**Please consult the user manual at heartsine.com for the complete list of indications, contraindications, warnings, precautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.**

**All claims valid as of June 2021.**

**For further information, please contact your Stryker representative or visit our website at strykeremergencycare.com**

# Emergency Care Public Access

Stryker's AEDs require a prescription in the U.S. Please consult your physician. AED users should be trained in CPR and in the use of the AED.

Although not everyone can be saved, studies show that early defibrillation can dramatically improve survival rates. AEDs are indicated for use on adults and children. AEDs may be used on children weighing less than 25 kg (55 lb) but some models require separate defibrillation electrodes.

The information presented is intended to demonstrate Stryker's product offerings. Refer to operating instructions for complete directions for use indications, contraindications, warnings, cautions, and potential adverse events, before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual m;arkets. Please contact your representative if you have questions about the availability of Stryker's products in your area. Specifications subject to change without notice.



UL Classified. See complete marking on product.

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