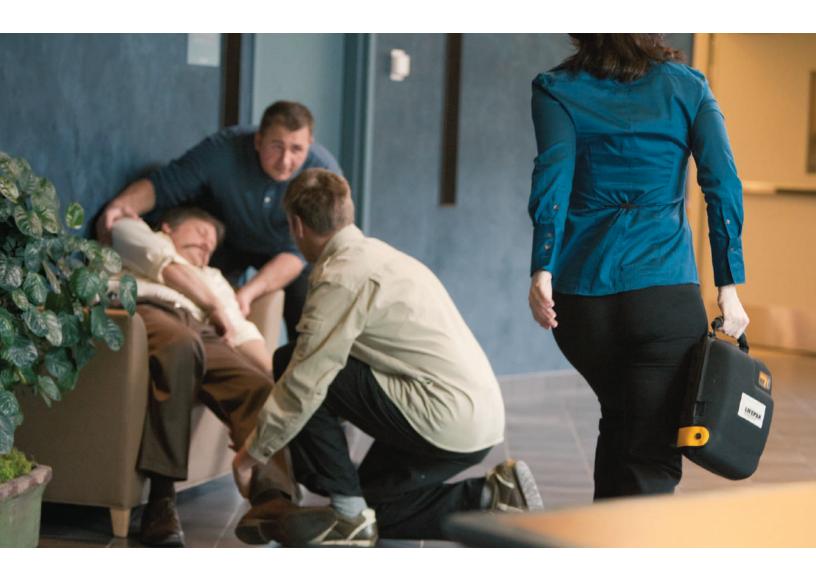


# LIFEPAK® and HeartSine® AEDs



# Which AED is right for you?

Physio-Control has a solution for every need.

# Choose the AED solution you can rely on.

## Be ready for Sudden Cardiac Arrest.

Sudden cardiac arrest (SCA) can strike anyone, anywhere. It's a leading cause of death among adults over the age of 40 in the United States and other countries.¹ Effective treatment is available, it just needs to be delivered fast—often before emergency responders can arrive. Automated external defibrillators (AEDs) work. SCA survival rates are more than four times higher when bystanders use CPR and an AED shock over CPR alone.² So when an SCA emergency happens, you want to be ready.

For more than 60 years, Physio-Control has manufactured the lifesaving equipment of choice for more emergency responders and hospital teams than anyone else. We've now merged with HeartSine, a global leader in public access defibrillator (PAD) technology, to offer the broadest range of automated external defibrillators (AEDs) with clinically proven technology.

## Clinical focus. Proven technology.

Physio-Control and HeartSine have a combined history of pioneering technologies and clinical effectiveness. Data shows that escalating energy is one of the keys to successful defibrillation outcomes.<sup>3</sup> That's why all of our AEDs allow subsequent shocks to be delivered at higher energy if the prior shocks were unsuccessful.

It's one example of our strong clinical focus, which also drives our commitment to continually improve our products. We conduct extensive usability testing with customers, review data from thousands of cases, and use that evidence to drive product updates and new releases. You should expect nothing less than a durable, effective AED system that's simple to use and maintain, and backed by support you can trust. You know to expect that quality and reliability from Physio-Control, and we deliver.

## Solutions that work.

With a Heart Safe Solutionsm program, you get a comprehensive AED implementation and management program custom-designed for the way your company works. We provide the guidance you need at every step, from implementation, training and regulations, to maintenance, support and review. You get peace of mind knowing that your workplace is ready.



Kelly Kettler, RN-BSN, Claims Manager, Cabela's Heart Safe Solution customer since 2010.

### HeartSine AFDs

Designed specifically for the lay responder, HeartSine samaritan AEDs offer industry-leading value and environmental protection, all in an easy-to-operate system in the smallest and lightest package available.

#### HeartSine AEDs offer:

- Clinically validated technology. Escalating, low-energy waveform technology automatically adjusts for differences in patient impedance to optimize energy delivery if necessary.
- **Simple to own.** Each HeartSine defibrillator uses the innovative Pad-Pak™, an integrated battery and electrode cartridge which offers one maintenance change every four years.
- Fully integrated CPR solutions. All HeartSine AEDs include advanced CPR coaching that
  reassures the user and optimizes hands on time. CPR Rate Advisor™ on the SAM 450 provides
  real-time verbal and visual feedback to increase effectiveness, without the need for cumbersome
  AED CPR accessories that can delay defibrillation.



# samaritan® PAD 350P samaritan® PAD 360P

Designed to be durable, affordable and highly portable, the HeartSine samaritan PAD 350P (semi-automatic) and 360P (fully automatic) are simple to use and simple to own AEDs which are well suited for the lay responder.



#### samaritan® PAD 450P

More than just an AED, the HeartSine samaritan PAD 450P adds integrated CPR Rate Advisor that uses only the defibrillator electrodes to monitor and uniquely provide visual and verbal feedback on the rate of applied CPR. This exclusive technology effectively assists the rescuer to perform CPR—a key link in the chain of survival.

### LIFEPAK AEDs

LIFEPAK AEDs combine full-energy dosing ranges and exceptional ease of use to set the standard in emergency care for professionals and public access customers.

#### LIFEPAK defibrillators offer:

- Powerful escalating energy. Every LIFEPAK defibrillator is capable of delivering up to 360 joules
  of energy for difficult-to-defibrillate patients—the most powerful AEDs in the industry. LIFEPAK device
  shock performance has been studied in nearly twice as many cardiac arrest victims than all other
  manufacturers combined.\*
- Trusted technology. Biphasic high-energy waveform technology in LIFEPAK devices is used by more emergency
  medical professionals than any other brand and is the most clinically studied and proven AED technology available.\*
- Connectivity and continuity. With electrodes that transfer to defibrillator/monitors used by most
  professional emergency responders, as well as connectivity to CODE-STAT™ data review software for post-event
  reviews, LIFEPAK AEDs offer strong continuity of care.



# LIFEPAK CR® Plus defibrillator

Featuring the same advanced technology trusted by emergency medical professionals—yet simple to use—the fully automatic LIFEPAK CR Plus AED combines easy two-step operation with just the right level of guidance. The ClearVoice™ audio prompt technology enhances sound quality for better clarity in loud and chaotic environments.



# LIFEPAK® 1000 defibrillator

The rugged LIFEPAK 1000 defibrillator is an easy-to-use AED designed for responders with more advanced training. A large, intuitive screen displays graphics and ECG readings that are clear and easy to read. The 1000 also features cprMAX™ technology which minimizes CPR interruptions by allowing compressions to continue during AED charging.

# An AED for every need. Every LIFEPAK and HeartSine AED is backed by the service and support

of Physio-Control, the industry leader.





samaritan® PAD 350P samaritan® PAD 360P

samaritan® PAD 450P

Therapy features		
Defibrillation	Biphasic waveform with impedance compensating escalating energy 150/150/200J	Biphasic waveform with impedance compensating escalating energy 150/150/200J
Shock	Semi-automatic (samaritan PAD 350P) Fully automatic (samaritan PAD 360P)	Semi-automatic

Device features		
CPR prompting	CPR coaching with metronome	CPR coaching with metronome plus real-time verbal and visual CPR-rate feedback
Readiness display	Flashing status indicator and audible alerts	Flashing status indicator and audible alerts
Electrode options	Pad-Pak, Pediatric-Pak™ (four-year shelf life) and TSO-Certified Pad-Pak integrated battery and electrodes	Pad-Pak, Pediatric-Pak (four-year shelf life) and TSO-Certified Pad-Pak integrated battery and electrodes
Post-event review	Saver EVO™ Windows®-based data review software	Saver EVO Windows-based data review software
Power	Pad-Pak—integrated electrode and battery cartridge, >60 shocks at 200J or 6 hours of continuous monitoring	Pad-Pak—electrode and battery cartridge, >60 shocks at 200J or 6 hours of continuous monitoring
Included accessories	Pad-Pak, carrying case	Pad-Pak, carrying case



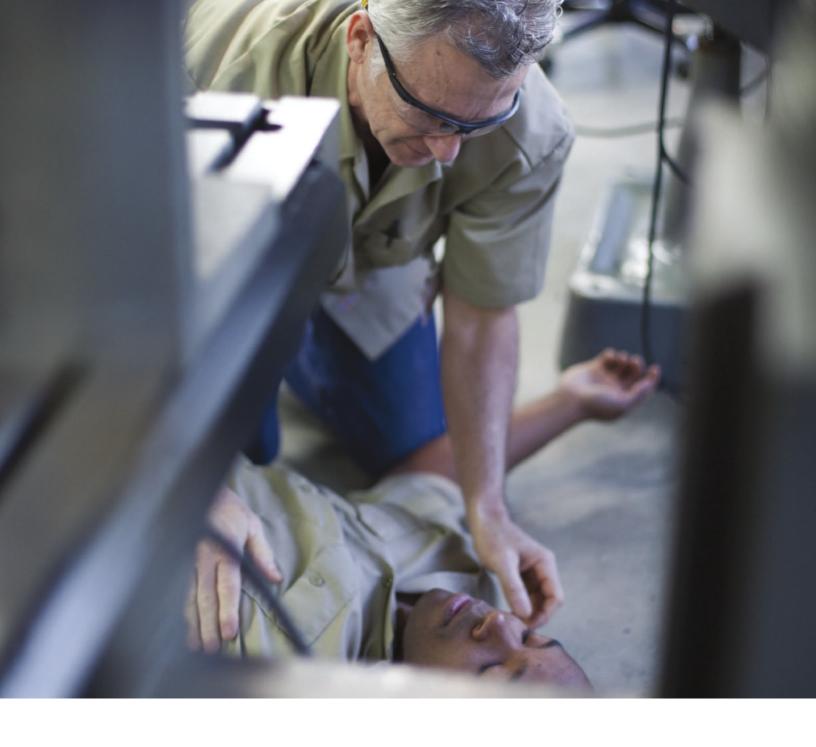
LIFEPAK CR® Plus defibrillator



LIFEPAK® 1000 defibrillator

Biphasic waveform with impedance compensation and highest-available escalating energy 200/300/360J	Biphasic waveform with impedance compensation and highest-available escalating energy 200/300/360J
Semi- and Fully automatic	Semi-automatic, with manual override capability option

Prompts to start CPR	Prompts to start CPR, CPR countdown timer, cprMAX technology
Information display with text and status icon alerts	Information display with text and status icon alerts
Preconnected QUIK-PAK™ electrodes compatible with LIFEPAK EMS devices	EDGE System™ electrodes with REDI-PAK® preconnect system, Infant/Child Reduced Energy Defibrillation electrodes
CODE-STAT™ data review software with emergency responder compatibility or DT EXPRESS™ data transfer software for importing and exporting data	CODE-STAT data review software with emergency responder compatibility or DT EXPRESS data transfer software for importing and exporting data
SafeGuard™ power system—internal battery with replaceable battery charger, 210 minutes or 30 shocks	Non-Rechargeable Battery—17 hours monitoring or 440 shocks (rechargeable battery option available)
Carrying case, two sets of electrodes, CHARGE-PAK™ battery charger, Ambu® Res-Cue Mask® Kit	Carrying case, shoulder strap, two sets of electrodes, one battery



Industry-leading technology.
Real-world solutions.

Whether you have a school, retail storefront, large corporation or industrial facility, we have an AED solution that can be tailored to your specific needs. Our knowledgeable consultants are ready to work with you to create and support an AED program from the broadest range of products on the market, so you can get exactly what you need for the health and safety of your students, staff and the public.

### 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<sup>™</sup> (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<sup>™</sup> (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 halabel 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**

#### AFDS:

- 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.
- nappropriate 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.
- $\bullet\,$  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 <a href="https://www.heartsine.com">www.heartsine.com</a> for the complete list of indications, contraindications, warnings, precautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

# You can trust the industry leader.

When SCA strikes, you want to provide the best chance of survival for your employees, customers, students and visitors. That's why Physio-Control provides the widest range of AEDs, all with clinically proven effectiveness and escalating energy, so you can choose the right fit for your needs and environment.

#### REFERENCES

- 1. http://www.sca-aware.org/about-sca
- 2. Weisfeldt M, Sitlani C, Ornato J, et al. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. *J Am Coll Cardiol*. 2010;55(16):1713–1720.
- 3. Stiell I, Walker R, Nesbitt L, Chapman F, et al. The BIPHASIC Trial: A randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest. Circulation. 2007;115:1511-1517.
- \* Based on published clinical data of cardiac arrest patients treated with biphasic shocks as of December 2015.

AED users should be trained in CPR and in the use of the AED. AEDs are intended for adults and children of all ages. AEDs may be used on children less than 25 kg (55 lbs) with pediatric defibrillation electrodes (available separately). LIFEPAK and samaritan PAD AEDs require a prescription in the U.S. Please consult your physician.

Although not everyone can be saved, studies show that early defibrillation can dramatically improve survival rates.

All information including comparative statements is valid as of April 2017.

#### Physio-Control is now part of Stryker.

For further information, please contact Physio-Control at 800.442.1142 (U.S.), or visit our website at www.physio-control.com

Physio-Control Headquarters 11811 Willows Road NE Redmond, WA 98052 www.physio-control.com Customer Support

P. O. Box 97006 Redmond, WA 98073 Toll free 800 442 1142



LIFEPAK devices: Physio-Control, Inc., 11811 Willows Road NE, Redmond, WA 98052 USA HeartSine devices: HeartSine Technologies, Ltd. 203 Airport Road West, Belfast, Northern Ireland, BT3 9ED