HeartSine®

TechNote

CPR Rate Advisor™ Revolutionary ICG-Based Technology

Overview

CPR Rate Advisor for the HeartSine samaritan® PAD 450P (SAM 450P) automated external defibrillator provides real-time visual and audible feedback to the rescuer on the rate of chest compressions and helps improve CPR fraction during sudden cardiac arrest (SCA) resuscitation.

Because Cardiopulmonary Resuscitation, commonly known as CPR, is crucial to deliver oxygenated blood to the body's vital organs, CPR Rate Advisor helps the rescuer perform CPR at the rate recommended by the AHA/ERC guidelines.

To measure the rate of compressions, other AEDs require a third sensor (or puck) to be placed on the patient's chest. With its revolutionary technology, HeartSine's proprietary CPR Rate Advisor detects the rate of applied CPR via the defibrillator electrodes, without the addition of accelerometers (or pucks) commonly used in other AED solutions.

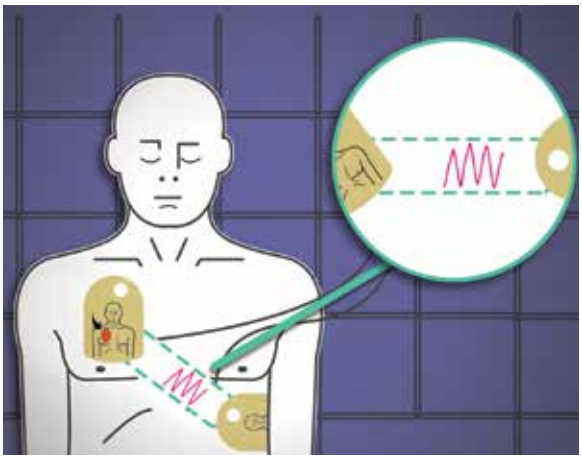

Figure 1. HeartSine's defibrillator detects changes in patient impedance.

How CPR Rate Advisor Works

When a patient collapses and a rescuer performs CPR, the compressions applied by the rescuer cause the patient's chest to change shape and result in a change to the patient's ICG (impedance cardiogram) waveform. CPR Rate Advisor captures the change in the ICG waveform which it uses to count the number of compressions a rescuer administers. By counting deflections in the ICG waveform, CPR Rate Advisor determines the compression rate and advises the rescuer to "Push faster" if the compression per minute (CPM) rate is below that recommended by the AHA/ERC guidelines.

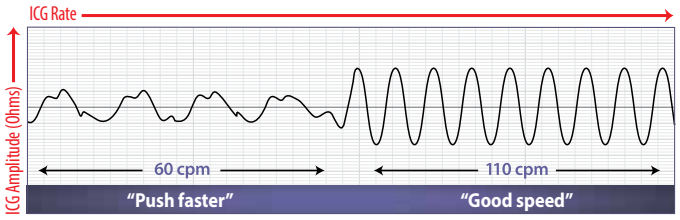

Figure 2. Rescuer's CPR compression rate is too slow, as determined by the low number of deflections detected by the ICG waveform. The SAM 450P will issue the audible prompt "Push faster" until the correct compression rate is achieved.

Likewise, if the rescuer's CPM rate is greater than that recommended by the AHA/ERC guidelines, CPR Rate Advisor will tell the rescuer to "Push slower".

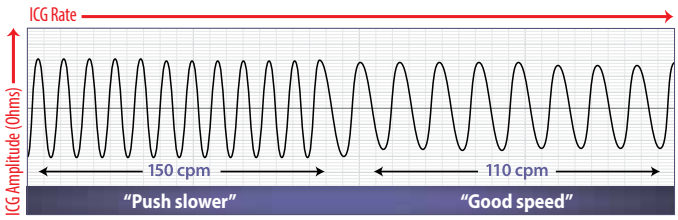

Figure 3. Rescuer's CPR compression rate is too fast, as determined from the high number of deflections detected by the ICG waveform. The SAM 450P issues the audible prompt "Push slower" until the correct compression rate is achieved.

The AHA and ERC also recognizes the need to keep interruptions to a minimum during CPR. The SAM 450P uses the signals detected through the electrode pads to determine if CPR is being performed when it should be and, if not, will prompt the rescuer to "Begin CPR." The SAM 450P also will detect when compressions have stalled between shock decision cycles and give feedback to the rescuer to ensure that CPR interruptions are minimized thus maximizing hands-on time.

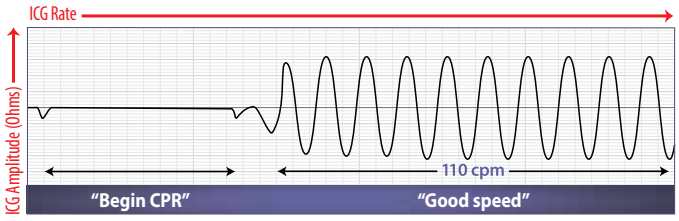

Figure 4. No movement detected in the ICG waveform. In an effort to maximize CPR compression time by the rescuer, the SAM 450P will issue the audible prompt "Begin CPR" repeatedly until CPR is started.

This real-time feedback is important as even though most trained rescuers understand the need to push hard and push fast, rescuer fatigue may set in after as little as one minute, resulting in slower compression rates.[1] The SAM 450P provides compression rate feedback to the rescuer via both visual indicators on the SAM 450P user interface and audible voice prompts.

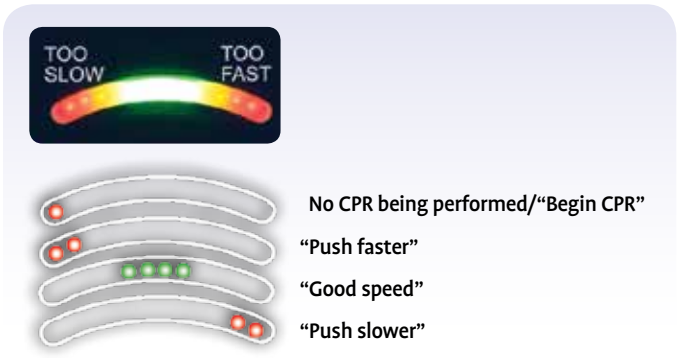

Figure 5. Visual indicators and audible feedback tell the rescuer if the rate of CPR is in line with the AHA/ERC guidelines.

CPR Rate Advisor

TechNote

Improved CPR Rate Efficacy

Usability study results showed that, without compromising compression depth, the percentage of users achieving good compression speed was higher with CPR Rate Advisor when compared to a device without CPR feedback.[2]

Studies have shown that effectiveness of CPR is most likely limited by poor performance in any of its components and that inadequate rate, even in the presence of sufficient depth and technique, likely reduces the effectiveness of CPR compressions[3]. Evidence suggests that even healthcare professionals do not always achieve the correct CPR compression rates according to AHA/ERC guidelines[3,4], and that chest compression rate is associated with the return of spontaneous circulation (ROSC)[5].

Effective CPR, provided alone or in conjunction with a lifesaving shock, can dramatically increase the chance of survival.[6] CPR Rate Advisor, in conjunction with the metronome, is intended to help rescuers perform CPR at the rate recommended by the AHA/ERC guidelines by monitoring their real-time CPR performance and helping to guide them toward the correct rate of compressions.

Integrated CPR Rate Advisor helps improve compliance with CPR rate and CPR fraction guidelines. And because CPR Rate Advisor is integrated within the innovative HeartSine SAM 450P defibrillator, it also can deliver a shock if needed.

By coaching the rescuer right through the rescue process, helping to ensure CPR is continuously performed at an effective rate and delivering a shock when necessary, the samaritan PAD 450P with integrated CPR Rate Advisor may help improve CPR efficacy.

References

1. Ochoa FJ, Ramalle-Gómara E, Lisa V, Saralegui I. The effect of rescuer fatigue on the quality of chest compressions. *Resuscitation.* 1998;37:149-152.
2. Torney H et al. A Usability Study of a Critical Man–Machine Interface: Can Layperson Responders Perform Optimal Compression Rates When Using a Public Access Defibrillator with Automated Real-Time Feedback During Cardiopulmonary Resuscitation. *IEEE Transactions on Human-Machine Systems.* 2016;vol.PP:no.99:1-6.
3. Abella B et al. Chest Compression Rates During Cardiopulmonary Resuscitation are Suboptimal. *Circulation.* 2005;111:428-434.
4. Milander MM, Hiscok PS, Sanders AB, et al. Chest compression and ventilation rates during cardiopulmonary resuscitation: the effects of audible tone guidance. *Acad Emerg Med.* 1995;2:708-713.
5. Idris A et al. Relationship Between Chest Compression Rates and Outcomes from Cardiac Arrest. *Circulation.* 2012;125:3004-3012.
6. Meaney PA, Bobrow BJ, Mancini ME, et al. Written on behalf of the CPR Quality Summit Investigators, the American Heart Association Emergency Cardiovascular Care Committee, and the Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation. CPR quality: improving cardiac resuscitation outcomes both inside and outside the hospital: a consensus statement from the American Heart Association. *Circulation.* 2013;128:1-19.

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.

Please consult the User Manual at www.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.

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CE 0120 The HeartSine products described in this brochure meet the European Medical Directive requirement.

UL Classified. See complete marking on product.

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