HeartSine®

TechNote

Electrodes

Electrode Choice Is Important

Electrodes are not only the primary point of contact between the patient and the defibrillator, but in many ways they form the critical link between the AED and its ability to deliver lifesaving energy to the patient.

HeartSine Electrodes

HeartSine electrode technology provides an outstanding four-year shelf life without a significant increase in cost or compromise in specification.

This same technology provides good electrical performance, rapid recovery time and greatly reduced noise.

HeartSine electrodes are large and have very low impedance, both of which are critical to successful defibrillation.[1, 2, 3]

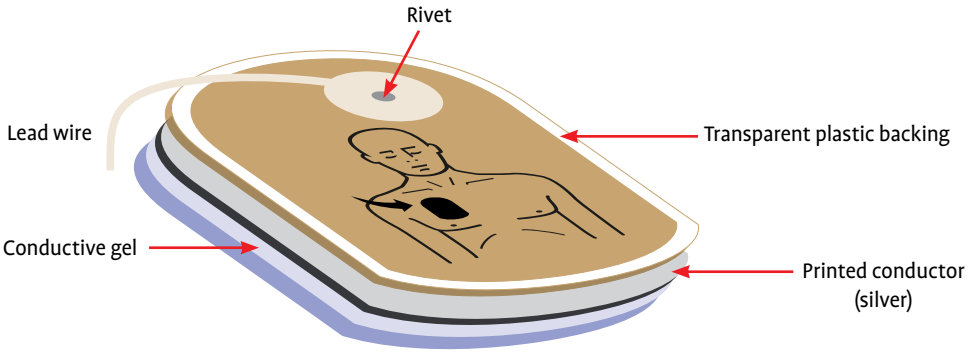
Due to both the high stability and low impedance of the electrodes it is possible to acquire additional Impedance Cardiography (ICG) information that can be utilized to provide detailed CPR feedback.

How It Works

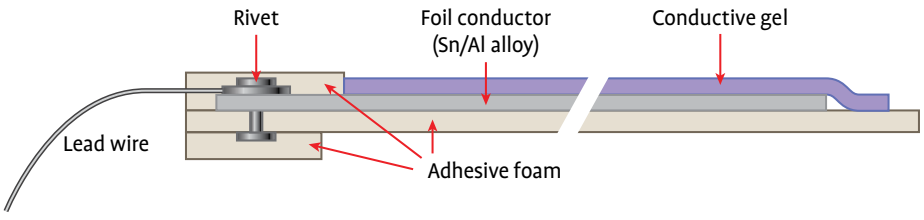
Traditional electrodes use a tin/aluminum alloy conductor with a hydrochloride gel layer. The aging mechanism involves a chemical reaction between the chloride and the aluminium, which usually limits the useful life of the electrode to up to 2.5 years.

HeartSine electrode technology is based on an entirely different structure. HeartSine electrodes are formed by printing a thick layer of silver onto a substrate. The addition of a hydrochloride gel layer initiates a chemical reaction with the silver during the manufacturing process. After approximately one week, this reaction has formed a thin layer of silver chloride, creating a stable and self-limiting layer.

This technology effectively creates a defibrillation electrode that will be stable for at least four years. In addition, the silver/chloride interface exhibits very low offset potentials and fast recovery characteristics, providing good noise and recovery performance.



HeartSine Electrode



Traditional Electrode

A History of Innovation

Innovation in technology drives HeartSine in the design, development and manufacture of Automated External Defibrillators (AED).

The company's pedigree dates back over 50 years to the development of the world's first out-of-hospital defibrillator in the 1960s. Since then, HeartSine technologists have been at the forefront of placing lifesaving technology in the hands of users of all skill levels.

At HeartSine our technology changes lives. And saves lives.

References

1. Dalzell G, Cunningham S, Anderson J, Adgey J. Electrode pad size, transthoracic impedance and success of external ventricular defibrillation. Regional Medical Cardiology Center, Royal Victoria Hospital, Belfast, Northern Ireland.
2. Dalzell G, Anderson J, Magee H, Adgey J. Predicted trans-thoracic impedance and ECG-defibrillator electrode pad size in patients with ventricular fibrillation and ventricular tachycardia. *Pacing and Clinical Electrophysiology.* 1987;10:874-878.
3. Anderson J, Dalzell G, Magee H, Adgey J. Transthoracic impedance in cardiac arrest. *European Heart Journal.* 1987;8:58-62:Supplement 2.

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications for Use: TIndications 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 samaritan PAD to provide treatment.

Warnings: The 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 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 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 samaritan PAD. • The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. • Do not use if the gel is dry.

Precautions: Proper placement of the 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 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 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 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. • Check expiration date.

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, 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.

H009-020-002-3

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

www.heartsine.com

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