HeartSine®

Inventor. Innovator. Lifesaver.

HeartSine samaritan PAD

SAM 300P

User Manual

Contents

Symbols used in this manual

Warning: Risk of death or serious injury

Caution: Risk of injury

Notice: Risk of damage to data or material

Further information

Symbols used on this device

On/Off

IP56 Ingress protection classified as IP56 according to EN 60529

Consult operating instructions

Follow instructions for use

Single use item. Do not re-use

Defibrillation protected, Type BF connection

Do not expose to high heat or open flame. Do not incinerate

Does not contain natural rubber latex

Non-sterile

Recyclable

Non- rechargeable battery

Do not short circuit battery

Do not crush battery

Temperature limitation as indicated

Use by yyyy/mm

Dispose of in accordance with country requirements

Automated External Defibrillator

With respect to electrical shock, fire and mechanical hazards only in accordance with

- ANSI/AAMI ES60601-1:2005
- CSA C22.2 NO. 60601-1:2008
- IEC60601-2-4:2010
- UL60601-1:2006
- CSA C22.2 No.601.1 M90
- IEC60601-2-4:2002

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Warnings and Cautions

Warning

Patients suitable for treatment

The SAM 300P has been designed to work on unconscious, nonresponsive patients. If the patient is responsive or conscious, do not use the SAM 300P to provide treatment.

The SAM 300P uses an interchangeable battery and electrode pack called Pad-Pak. The SAM 300P in combination with an adult Pad-Pak is suitable for use on patients of over 25 kilograms (55 pounds) in weight or equivalent to a child of approximately eight years old or over.

For use on children, remove the adult Pad-Pak and install a paediatric Pad-Pak. If a paediatric Pad-Pak or an alternative suitable defibrillator is not available, you may use an adult system.

Do not delay treatment trying to find out the patient's exact age and weight.

Risk of electric shock

The SAM 300P delivers therapeutic electrical shocks that can cause serious harm to either operators or bystanders. Take care to ensure that nobody touches the patient when a shock is to be delivered.

Avoid opening or repairing

The SAM 300P has no serviceable parts. Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, replace the SAM 300P immediately.

Avoid explosive or flammable gases

It has been determined that the SAM 300P is safe to use with oxygen mask delivery systems. However, to avoid the risk of an explosion, it is strongly advised that you do NOT use the SAM 300P in the vicinity of explosive gases, including flammable anaesthetics or concentrated oxygen.

Caution

Correct placement of the electrode pads

Proper placement of the SAM 300P's electrode pads is critical. You must strictly observe the instructions shown in the Quick Start Guide and on the device. Wrong placement, or the presence of air, hair, surgical dressings or medicine patches between the pads and the skin, could cause skin burns. Slightly red skin after shock therapy is normal.

Do not touch the patient during analysis

Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while analysis is being carried out. The device will instruct you when it is safe to touch the patient.

Warnings and Cautions

Do not use if the pouch containing the electrodes is not sealed

The Pad-Pak is a single-use item and you must replace it after each use or if pouch that seals defibrillation pads has been broken or compromised in any way. If you suspect that the Pad-Pak is damaged, you must replace it immediately.

Notice

Susceptibility to electromagnetic interference

To safeguard against interference, you must operate the SAM 300P at least 2 m (6 feet) away from all radio frequency devices and other susceptible equipment. Alternatively, switch off the equipment affected by or causing electromagnetic interference.

Temperature range for operation

The SAM 300P, with its battery, pads and electrodes, is designed to operate in the temperature range of 0 ºC to 50 ºC. Use of the device outside this range may cause malfunction.

Environmental protection

The IP56 rating does not cover the immersion of any part of the SAM 300P in water or any type of fluid. Contact with fluids may seriously damage the device or cause fire or a shock hazard.

Prolonging standby life

Do not turn the device on unnecessarily as this may reduce the standby life of the device.

Standby storage outside the range of 0 ºC to 50 ºC may decrease the shelf-life of the device.

Do not test on simulators and manikins

Our devices cannot be tested using industry-standard simulators and manikins.

Standard simulators have a constant r-r spacing and do not produce the variability displayed in the normal human heart. Our algorithm uses heart rate variability as one of its criteria for measuring ventricular fibrillation (VF). Consequently we do not recommend the use of normal simulators to test our device.

Further Information

Use of this manual

It is important that you read this manual carefully before using the HeartSine Samaritan PAD SAM 300P. This manual is presented in support of any training you may have received. If you have any questions, contact your authorised distributor or HeartSine Technologies directly for advice or explanation.

The information in this manual is subject to change without notice and does not represent a commitment on behalf of HeartSine Technologies. No part of this manual may be reproduced or transmitted in any form or by any means, electrical or mechanical, including photocopying and recording, for any purpose without the express written permission of HeartSine Technologies.

Warnings and Cautions

Operator training

HeartSine recommends that the SAM 300P is used by people trained in cardiopulmonary resuscitation – defibrillation (CPR-D).

Use of accessories

The SAM 300P is a self-contained device. Do not use any unauthorised accessories with it. The SAM 300P may malfunction if non-approved accessories are used.

Regular maintenance

Check the device periodically. See ‘Service and Maintenance’ on page 18.

Correct disposal of the device

Dispose of the device in accordance with the European WEEE Directive, or contact your HeartSine distributor. Please follow the ‘After use’ on page 16.

Compliance with 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.

Introduction

The HeartSine Samaritan PAD SAM 300P

The HeartSine Samaritan PAD SAM 300P is a semi-automatic external defibrillator designed to quickly deliver a defibrillation shock to victims of Sudden Cardiac Arrest (SCA).

The SAM 300P is designed to operate in accordance with the joint European Resuscitation Council (ERC) and American Heart Association (AHA) 2010 guidelines on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC).

Sudden Cardiac Arrest (SCA)

Sudden cardiac arrest is a condition in which the heart suddenly stops pumping effectively due to a malfunction of the heart's electrical system. Often victims of SCA have no prior warning signs or symptoms. SCA can also occur in people with previously diagnosed heart conditions. Survival from SCA depends on immediate cardiopulmonary resuscitation (CPR).

The use of an external defibrillator within the first few minutes of collapse can greatly improve patient's chances of survival. Heart attack and SCA are not the same, though sometimes a heart attack can lead to an SCA. If you are experiencing symptoms of a heart attack (chest pain, pressure, shortness of breath, tight feeling in the chest or elsewhere in the body), seek emergency medical attention immediately.

Ventricular fibrillation

The normal electrical rhythm by which the heart muscle contracts to create blood flow around the body is known as normal sinus rhythm (NSR). Ventricular fibrillation (VF), caused by chaotic electrical signals in the heart, is often the cause of SCA. In victims of SCA it is possible to re-establish normal sinus rhythm by means of an electric shock across the heart. This treatment is called defibrillation.

Introduction

Recommended training

SCA is a condition requiring immediate emergency medical intervention. Due to the nature of the condition, this intervention can be performed before seeking the advice of a physician.

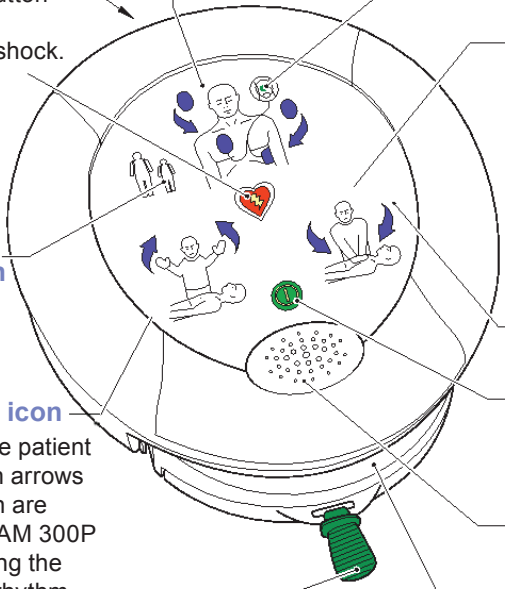
To properly diagnose this condition, HeartSine recommends that all potential users of the SAM 300P are fully trained in cardiopulmonary resuscitation (CPR), basic life support (BLS) and, in particular, the use of an automated external defibrillator. HeartSine also recommends that this training be kept up to date by regular refresher courses as and when recommended by your training provider.

If potential users of the SAM 300P are not trained in these techniques, contact your authorised distributor or HeartSine Technologies directly. Either can arrange for training to be provided. Alternatively contact your local government health department for information on certified training organisations in your region.

CPR metronome

The SAM 300P will play an audible click and flash the Safe To Touch indicator at a rate compliant with current AHA/ERC guidelines. This feature is referred to as the CPR metronome. Responders should use this as a guide to the rate for performing compressions.

SAM 300P Overview



Data port

Attach pads icon
The action arrows around this icon will flash to instruct you to attach the electrode pads to the patient as indicated.

Status indicator
When the indicator is flashing green the SAM 300P is ready for use.

Shock button
Press this button to deliver a therapeutic shock.

Safe to touch icon
It is safe to touch the patient when the action arrows around this icon are flashing.

Paediatric ready icon

Action arrows

Do not touch icon
Do not touch the patient when the action arrows around this icon are flashing. The SAM 300P may be analysing the patient's heart rhythm or about to charge, preparing to deliver a shock.

On/Off button
Press this button to turn the device on or off.

Speaker

Green tab

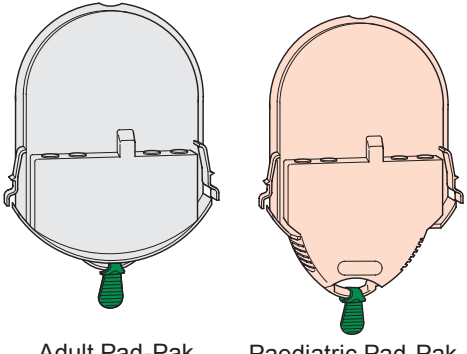
Electrode drawer

Preparation

Unpacking

Check that the contents include the User Manual, soft case, Pad-Pak, guarantee card and Quick Start Guide.

A Pad-Pak is a single-use removable battery and electrode pack in one unit. It is available in two versions: a pink coloured Pad-Pak for use with children and a grey coloured Pad-Pak for use with adults (see the illustration below).

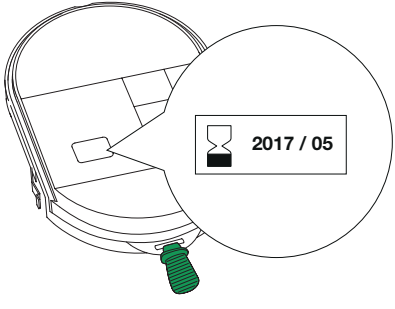


Adult Pad-Pak

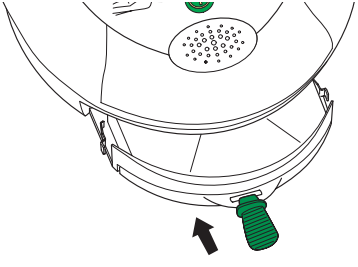
Paediatric Pad-Pak

Checks before putting into service

Check the expiry date (year/month) on the rear of the Pad-Pak (see the illustration below). If the expiry date has passed, you must replace the Pad-Pak.



Unpack the Pad-Pak. Retain the packaging in case you need to return the Pad-Pak to HeartSine. Insert the Pad-Pak into the SAM 300P (see the illustration below). Listen for the “click” sound and ensure both tabs are fully engaged.



The SAM 300P will run a self-test routine. The action arrows will flash during this process. On successful completion of the self-test routine, the green status indicator (see ‘SAM 300P Overview’ on page 11) will blink. If so, your SAM 300P is ready for use.

Notice: Do NOT pull the green tab on the Pad-Pak. If you have opened the electrode drawer, you must replace your Pad-Pak.

Turn on the SAM 300P by pressing on the front panel. To check that the device is operating correctly, listen for appropriate voice prompts and make sure that no warning messages are played.

Notice: Only turn the SAM 300P on ONCE. If you turn it on and off repeatedly, you will exhaust the batteries prematurely and you will need to replace the Pad-Pak.

Turn off the SAM 300P by pressing on the front panel. Check the status indicator (see ‘SAM 300P Overview’ on page 11) is flashing green. If you have heard no warning messages and the status indicator is flashing green, the device is ready for use.

Preparation

Guidelines for storage

Place the SAM 300P in its supplied soft carry case. Store the SAM 300P in an unobstructed, secure location in a clean, dry environment. Be sure to store according to specifications (see ‘Technical Data’ on page 23).

Notice: HeartSine recommends that you keep a spare Pad-Pak with your SAM 300P. You can store it in the rear section of the soft carry case.

Register your SAM 300P

Complete the guarantee card and return it to your authorised distributor or HeartSine Technologies directly (see ‘Tracking Requirements’ on page 19).

Using the SAM 300P

When to use

The HeartSine Samaritan PAD SAM 300P is indicated for use on victims of sudden cardiac arrest who are exhibiting the following signs:

Unconscious

Not breathing

No life signs

The SAM 300P has been designed to work on unconscious, nonresponsive patients. If the patient is responsive or conscious, do not use the SAM 300P to provide treatment.

The SAM 300P is suitable for use on patients of over 25 kg (55 lbs) in weight or equivalent to a child of approximately eight years old or over.

For use on younger children, remove the adult Pad-Pak and install a paediatric Pad-Pak. If a paediatric Pak-Pad or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.

Using the SAM 300P

Refer to the separate Quick Start Guide. During use the SAM 300P will give extensive voice prompts to guide the user. For full list of voice prompts see ‘Appendix A’ on page 34.

Notice: PAD aborts a ready to shock condition once a non-shockable rhythm is detected.

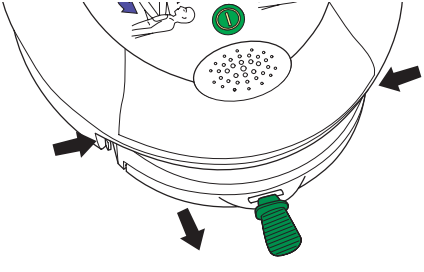
Using the SAM 300P

After use

Turn off the SAM 300P by pressing ⏻ on the front panel.

Remove the electrode pads from the patient and stick them together ‘face to face’. The electrodes may be contaminated with human bodily tissue, fluid or blood. Dispose of the electrodes separately as an infectious waste material.

The Pad-Pak is a single-use item and must be replaced after each use. Remove the Pad-Pak by pressing the two tabs on either side of the Pad-Pak. The Pad-Pak will slide forward (see the illustration below).



Do not dispose of the SAM 300P or Pad-Pak in the normal waste. Dispose of it at an appropriate recycling facility according to local requirements. Alternatively return it to your distributor for disposal or replacement.

Check the SAM 300P for dirt or contamination. If necessary, clean it using a soft cloth dampened by one of the following:

Soapy water.

Isopropyl alcohol (70% solution).

Caution: Do not immerse any part of the SAM 300P in water or any type of fluid. Contact with fluids may seriously damage the device or cause a fire or a shock hazard.

Notice: Do not clean the SAM 300P with abrasive materials, cleaners or solvents.

Check the SAM 300P for damage. If the SAM 300P is damaged, replace it immediately.

Install a new Pad-Pak. Before installing, check the Pad-Pak expiry date (see ‘Preparation’ on page 12). After installation check the status indicator is blinking green.

Service and Maintenance

HeartSine recommends users perform regular maintenance checks. A suggested maintenance check would be:

Weekly

1. Check the status indicator. If the green status indicator is not flashing approximately every 5 seconds, a problem has been detected. See 'Troubleshooting' on page 21. The SAM 300P performs a self-test routine at midnight GMT on Sunday. During this self-test period the status light blinks red but returns to green on successful completion of the self-test routine. The self-test takes no more than 10 seconds to complete. If the status indicator continues to flash red the SAM 300P has a fault (see 'Troubleshooting' on page 21).

Monthly

2. If the device shows any signs of physical damage, contact your authorised distributor or HeartSine Technologies directly.
3. Check the expiry date of the SAM 300P Pad-Pak (see 'Preparation' on page 12 for the location of the date). If the date has expired, replace with a new Pad-Pak or contact your local HeartSine distributor for a replacement.
4. If you hear a warning message when you turn on your SAM 300P or if, for any reason, you have suspicions that your SAM 300P is not working correctly, contact your authorised distributor or HeartSine Technologies directly (support@HeartSine.com).

Tracking Requirements

The Medical Devices Regulations require us to track the location of all medical devices sold.

It is important that you complete the warranty card with your details and return it to your authorised distributor or HeartSine Technologies directly.

Alternativley please send an email to support@heartsine.com containing the following information:

Name

Address

Device serial number

or use our on-line registration tool at https://secure.heartsine.com/UserRegistration.html

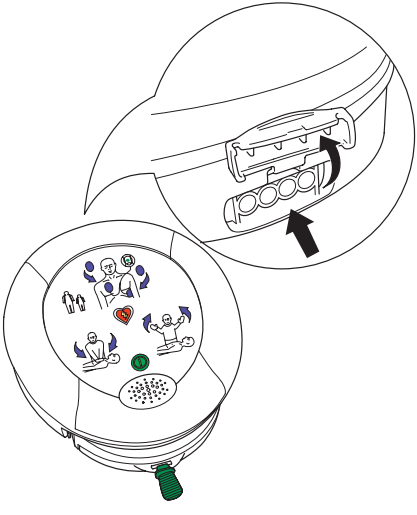
Your participation will allow us to contact you with any important notifications about the SAM 300P, such as any future software updates or field safety corrective actions.

If there is a change in the information you have provided to us, such as a change of address or a change in ownership of your SAM 300P, please contact us with the updated information.

Data Management

The HeartSine Saver™ EVO software is an optional accessory. Contact your authorised distributor or HeartSine Technologies directly about the After-Use Data Management Service.

1. Connect the supplied USB cable to the SAM 300P (see illustration below).



2. Connect the USB cable to a PC.
3. Launch the HeartSine Saver™ EVO utility.

Notice. The SAM 300P should only be connected to an IEC60950 PC.

Caution. You cannot defibrillate while the SAM 300P is connected to a PC.

For further information on this optional accessory, contact your authorised distributor or HeartSine Technologies directly.

Troubleshooting

Status indicator flashing red

If the status indicator is flashing red or if the device is emitting a ‘beep’, check the expiry date on your Pad-Pak (see ‘Preparation’ on page 12). If the expiry date has not been passed, turn on the SAM 300P by pressing on the front panel and listen for the voice prompt ‘call for medical assistance’. Then turn off by pressing on the front panel. If this action does not correct the problem, contact your authorised distributor or HeartSine Technologies immediately.

Low battery warning

This message does not indicate a fault.

The first time the device plays the message ‘warning low battery’, it will still continue to function properly. However, it may have fewer than 10 shocks left. If you hear this message during use, continue to use the SAM 300P until the emergency services arrive. If available, prepare the spare Pad-Pak for use and be prepared to swap it quickly. Order a new Pad-Pak as soon as possible.

Memory full warning

If the device plays the message ‘warning memory full’, then the memory can record no further ECG data or events. However, the device can still analyse and deliver a shock if required. If you hear this message, contact HeartSine Technologies technical support.

Audible warnings

If the device emits 3 beeps rapidly when turned off, it has sensed that the ambient temperature is outside of the specified operating range. This beeping could also occur during the weekly self-test.

During use, if the status indicator changes from green to red and the device starts to ‘beep’, there is insufficient battery capacity to deliver a shock. The device will continue to analyse the patient’s heart rhythm and advise when CPR is needed.

Troubleshooting

Device service required

If the device plays the message ‘device service required’, then it has detected a fault. Contact your authorised distributor or HeartSine directly for further instruction.

Warning. If you hear this message during use, seek an alternative defibrillator immediately.

Sources of support

If you have completed the troubleshooting steps above and you find the device is still not working correctly, contact your authorised distributor or HeartSine Technologies Technical Support at support@HeartSine.com.

Warning. No modification of this equipment is allowed

Warranty exclusion

HeartSine or its authorised distributors are not obliged to replace or repair under warranty if one or more of the following conditions apply:

The device has been opened.

Unauthorised modifications have been made.

The device has not been used in accordance with the instructions provided in this manual.

The serial number has been removed, defaced, altered or, by any other means, made unreadable.

The device has been used or stored outside its indicated temperature range.

The Pad-Pak packaging is not returned.

The device has been tested using unapproved methods or inappropriate equipment, (see ‘Warnings and Cautions’ on page 4).

Technical Data

Physical parameters (with Pad-Pak installed)

Size:	20 x 18.4 x 4.8 cm (8.0 x 7.25 x 1.9 in)
Weight:	1.1 kg (2.4 lbs)

Environmental

Operating temperature:	0 to 50 °C (32 to 122 °F)
Standby temperature:	0 to 50 °C (50 to 122 °F)
Transport temperature:	-10 to 50 °C (14 to 122 °F) for up to two days. If the device has been stored below 0 °C (32 °F), it should be returned to an ambient temperature of between 0 to 50 °C (32 to 122 °F) for at least 24 hours before use.
Relative humidity:	5 to 95% (non-condensing)
Enclosure:	IEC 60529/EN 60529 IP56
Altitude:	0 to 15 000 feet (0 to 4575 metres)
Shock:	MIL STD 810F Method 516.5, Procedure I (40G's)
Vibration:	MIL STD 810F Method 514.5 Procedure 1 Category 4 MIL STD 810F Method 514.5 Procedure 1 Category 7

Pad-Pak and Pediatric Pad-Pak

Shelf Life:	Check expiration date
Weight:	0.2 kg (0.44 lbs)
Battery type:	Meets ISO 60601-2-4 and AAMI DF80:2003

Technical Data

Patient analysis system

Method:	Evaluates patient's ECG, signal quality, electrode contact integrity and patient impedance to determine if defibrillation is required
Sensitivity/Specificity:	Meets ISO 60601-2-4 and AAMI DF80:2003

User Interface

Visual prompts:	Attach Pads, Stand Clear, Perform CPR, Shock now, Self Test Pass - Ready State
Audible prompts:	Extensive voice prompts guide the user through the operation sequence
Languages:	Contact your HeartSine authorised distributor
Controls:	Two buttons: 'On/Off' and 'Shock'

Defibrillator performance

Times to shock delivery (fresh battery) or after 6 shocks

Charging time:	Typically 150 J in < 8 sec, 200 J in < 12 sec
Following CPR:	Typically 8 seconds
Impedance range:	25 Ω to 230 Ω

Battery

Battery type:	Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide (LiMnO2) 18V)
Battery capacity:	>60 shocks at 200 J or 6 hours of continuous monitoring
Standby life:	See the expiry date on the product

Electrodes

Type:	Single-use pre-attached combined ECG sensor/ defibrillation pad
Placement:	Adult: anterior-lateral Paediatric: electrodes anterior-posterior or anterior-lateral
Active area:	100 cm^2
Cable length:	3.5 ft (1 m)
Shelf life:	See the expiry date on the product

Therapeutic shock

Waveform:	SCOPE (Self Compensating Output Pulse Envelope) biphasic escalating waveform. Optimised biphasic waveform compensates energy, slope and envelope for patient impedance
Energy:	Pre-configured factory settings for escalating energy are Version AHA/ERC 2010 Adult: 1. Shock 150 J 2. Shock 150 J 3. Shock 200 J Paediatric: 1. Shock 50 J 2. Shock 50 J 3. Shock 50 J

Event recording

Type:	Internal memory
Memory:	90 minutes of ECG (full disclosure) and event/ incident recording
Review:	Custom USB cable directly connected to a PC and Saver™ EVO Windows-based data review software

Technical Data

Electromagnetic compatibility

EMC:	EN 60601-1-2
Radiated Emissions:	EN55011:1999 +A2
Electrostatic Discharge:	EN61000-4-2 (8 kV)
RF Immunity:	EN61000-4-3 80 MHz – 2.5 GHz, (10 V/m)
Magnetic Field Immunity:	EN61000-4-8 (3 A/m)
Aircraft:	RTCA/DO-160D, Section 21 (Category M)
	RTCA DO-227 (TSO-C142a)

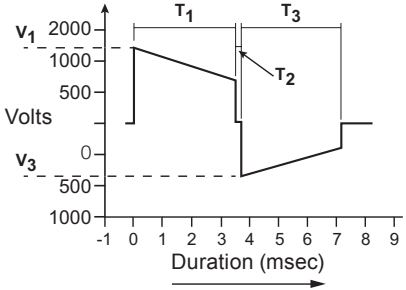
HeartSine Quality Management System

ISO 9001	GB02/54194
ISO 13485	GB02/54195
EEC 92/43	GB02/54193

SCOPE™ Biphasic Waveform

The SAM 300P delivers a Self Compensating Output Pulse Envelope (SCOPE) biphasic waveform. This waveform automatically optimises the waveform pulse envelope (amplitude, slope and duration) for a wide range of patient impedances, from 20 ohms to 230 ohms. The delivered waveform to the patient is an optimised, impedance-compensated, biphasic, truncated exponential waveform that incorporates an escalating energy protocol of 150 joules, 150 joules, and 200 joules. The duration of each phase is automatically adjusted to compensate for varying patient impedances. The first phase (T1) duration is always equivalent to the second phase (T3) duration. The interphase pause is always a constant 0.4 ms for all patient impedances.

The specific SCOPE waveform characteristics for a 150 joules pulse are listed opposite.



Resistance (ohms)	Waveform Voltages (volts)		Waveform Duration (ms)	
	V_1	Tilt %	T_1	T_3
25	1630	63.1	3	3
50	1640	52.7	4.5	4.5
75	1650	51.4	6.5	6.5
100	1660	48.7	8	8
125	1660	50.4	10.5	10.5
150	1660	48.7	12	12
175	1660	48.7	14	14
200	1660	47.6	15.5	15.5
225	1670	46.7	17	17

Adult Pad-Pak waveform specification

Technical Data

Resistance (ohms)	Energy (joules)	Waveform Voltages (volts)		Waveform Duration (ms)	
		V_1	Tilt %	T_1	T_3
25	47.5	514	55.6	7.8	5.4
50	51.3	671	50.4	8.8	6
75	52.1	751	47.1	10	6.6
100	51.8	813	44.3	10.8	6.8
125	52.4	858	41.4	11.5	7.3

Paediatric Pad-Pak waveform specification

Arrhythmia analysis algorithm

The SAM 300P uses the HeartSine samaritan® ECG arrhythmia analysis algorithm. This algorithm will evaluate the patient's ECG to ascertain if a therapeutic shock is appropriate. If a shock is required, the SAM 300P will charge and advise the user to press the shock button. If no shock is advised, the device will pause to allow the user to deliver CPR.

The SAM 300P ECG arrhythmia analysis algorithm performance has been extensively evaluated by using several databases of real-life ECG traces. Included in this are the American Heart Association's (AHA) database and the Massachusetts Institute of Technology MIT – NST database. The SAM 300P ECG arrhythmia analysis algorithm's sensitivity an specificity meet the AAMI DF80a 2003 requirements and AHA recommendations.

The SAM 300P ECG arrhythmia analysis algorithm performance is summarised in the table below:

Rhythm Class	ECG Test Sample Size	Performance Specifications	Performance Results (%)	90% One-Sided Lower Confidence Limit
Shockable rhythm: Ventricular fibrillation (VF) and ventricular tachycardia (VT)	2453	Sensitivity > 90%	93.48	90.58
Non-shockable rhythm: Asystole	1902	Specificity > 95%	100	100 *
Non-shockable rhythm: All other rhythms	46711	Specificity > 95%	99.11	95.04

* No error to measure

Technical Data

Guidance and manufacturer's declaration – electromagnetic emissions

The HeartSine Samaritan PAD SAM 300P is intended for use in the electromagnetic environment specified below. The customer or user of the HeartSine Samaritan PAD SAM 300P should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The HeartSine Samaritan PAD SAM 300P uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The HeartSine Samaritan PAD SAM 300P is intended for use in the electromagnetic environment specified below. The customer or user of the HeartSine Samaritan PAD SAM 300P should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	± 8 kV air	Complies	
Power-frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1 kV line(s) to line(s)	Not applicable	
	+ 2 kV line(s) to earth	Not applicable	

Technical Data

Guidance and manufacturer's declaration – electromagnetic immunity

The HeartSine Samaritan PAD SAM 300P is intended for use in the electromagnetic environment specified below. The customer or user of the HeartSine Samaritan PAD SAM 300P should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	d = 1.2 √P 800 Mhz to 800 Mhz d = 2.3 √P 800 Mhz to 2.5 Ghz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) [a]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [b], should be less than the compliance level in each frequency range [c]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

See footnotes on next page.

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a	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
b	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the HeartSine Samaritan PAD SAM 300P is used exceeds the applicable RF compliance level (see above), the HeartSine Samaritan PAD SAM 300P should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the HeartSine Samaritan PAD SAM 300P.
c	Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V1] V/m.

Appendix A

Voice prompts

Adult Patient/Child Patient

- “Call for Medical Assistance”
- “Remove Clothing from Patient’s Chest to Expose Bare Skin”
- “Pull ‘Green Tab’ to Remove Pads”
- “Peel Pads from Liner”
- “Apply Pads to Patient’s Bare Chest as Shown in Picture”
- “Press Pads Firmly to Patient’s Bare Skin”
- “Assessing Heart Rhythm – Do Not Touch the Patient”

If a shock is not required…

- “No shock advised”
- “Begin CPR”
- “It Is Safe to Touch the Patient”
- “Place overlapping hands on centre of chest”
- “Press down in time with the metronome”
- “Remain calm”

If a shock is required…

"Stand Clear of Patient – Shock Advised"

"Stand Clear of Patient – Press the Orange Shock Button Now"

"Shock Delivered

"Begin CPR"

"It Is Safe to Touch the Patient"

"Place overlapping hands on centre of chest"

"Press down in time with the metronome"

"Remain calm"

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