HeartSine™

HeartSine PDU 400

PERSONAL DEFIBRILLATION UNIT

ENGLISH

www.heartsine.com

The HeartSine PDU 400 is a semi-automatic external defibrillator designed for fast delivery of defibrillation electric shock treatment on victims of sudden cardiac arrest (SCA).

The PDU 400 is designed to operate in accordance with the joint European Resuscitation Council (ERC) and American Heart Association (AHA) 2005 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 for an SCA victim depends on immediate cardio-pulmonary resuscitation (CPR).
The use of an external defibrillator within the first few minutes of collapse can greatly improve the patients' chances of survival. Heart attack and SCA are not the same, though sometimes a heart attack can lead to a SCA. If you are experiencing symptoms of a heart attack (pain, pressure, shortness of breath, squeezing feeling in 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.

Training

SCA is a condition requiring immediate emergency medical intervention. Due to the nature of the condition this intervention can be performed prior to seeking the advice of a physician.
In order to properly diagnose this condition HeartSine recommends that all potential users of the PDU 400 are fully trained in cardiopulmonary resuscitation (CPR), basic life support (BLS) and in particular the use of an Automated External Defibrillator. It is also recommended that this training be kept up to date by means of regular refresher courses as and when recommended by your training provider.
If potential users of the PDU 400 are not trained in these techniques contact your HeartSine dealer or HeartSine directly either of whom can arrange for training to be provided. Alternatively contact your local government health department for information on certified training organisations in your region.

ABOUT THIS MANUAL

It is important that you read this manual before using the HeartSine PDU 400. This manual is presented in support of any training you may have received. Please read carefully. If you have any questions, contact HeartSine Technologies or your authorised distributor for advice or explanation.

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Explanation of the symbols

This symbol refers to the user manual.

This symbol warns that the PDU 400 must be used only ONCE.

This symbol warns to dispose of the device through controlled waste or send it back to your distributor.

This symbol warns that the device needs to be recycled.

LiMnO2 Lithium-Manganese Dioxide Battery. Do not open or destroy. Send device back to your distributor.

0°C (32F) 50°C (122F) This symbol shows the operating Temperature Range (0°C - 50°C). Standby temperature :10°C - 50C°.

03/2010 This symbol shows the expiry date of the PDU 400 - the date after which the device should not be used.

>25Kgs (55lbs) The HeartSine PDU 400 is intended to be used only on patients over 25 kilograms (55 pounds) in weight or equivalent to a child of aproximately eight years old or over.

Explanation of icons

Note

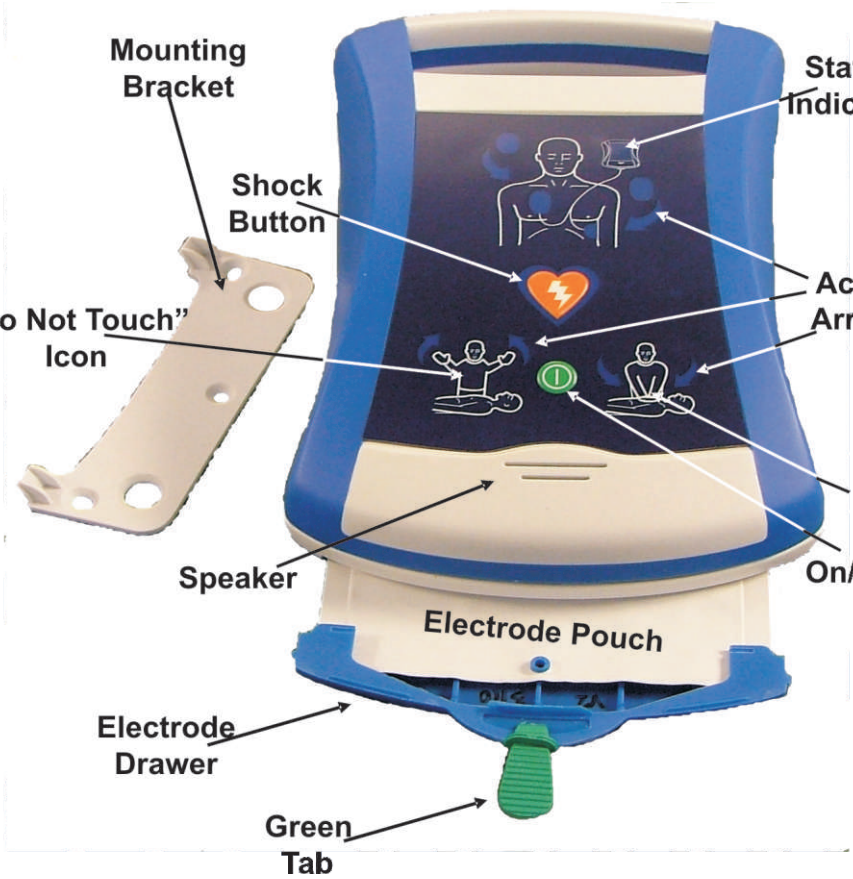
Warning/Important

Voice prompt

Action

Caution

Check with 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.


Mounting Bracket
Status Indicator
Shock Button
Action Arrows
"Do Not Touch" Icon
CPR Icon
Speaker
On/Off
Electrode Pouch
Electrode Drawer
Green Tab

YOUR PDU 400!

On/Off button

Press this button to turn the device on and off.

Shock button

Press this button to deliver a therapeutc shock.

Status indicator

When the indicator is flashing green the PDU 400 is ready for use.

Attach pads indicator

The action arrows around this icon will flash to intruct the user that the PDU 400 pads should be attached to the patient as indicated.

Safe to touch icon

It is safe to touch the patient when the action arrows around this icon are flashing. You may perform CPR or check the patient.

Do not touch icon

Do not touch the patient when the action arrows around this icon are flashing. The PDU 400 may be analysiing the patients heart rhythm or about to upload to deliver a shock.

ATTENTION

INDICATIONS FOR USE

The HeartSine PDU 400 is indicated for use on victims of Sudden Cardiac Arrest who are exhibiting the following signs:

Unconscious
Not breathing
No life signs

The HeartSine PDU 400 is indicated for patients over 25 kilograms (55pounds) in weight or equivalent to a child of approximately eight years or over.

WHEN YOU RECEIVE YOUR HEARTSINE PDU 400

Check contents include user manual, guarantee card and wall bracket.

Check that the green light is blinking!
If so your PDU is ready for use.

Turn the PDU 400 on and verify that it is operating in the correct manner. Listen for the appropriate voice prompts. Ensure no warning messages are played. Turn the PDU 400 off. Check the status indicator is flashing GREEN. If there have been no warning messages and the status indicator is flashing GREEN the device is ready for use. The flashing GREEN LED indicates the availability of the device for immediate use.

03/2010

Check the expiry date.

Mount bracket on wall using suitable screws or place in suitable storage box.

Place in an unobstructed and secure location. Store the PDU 400 in a clean and dry environment.

Complete the guarantee card and return to Heartsine or your authorised distributor.

WHAT DO I DO IF I NEED TO USE IT?

1 REMOVE DANGER

Remove the source of danger or move the victim away from danger. Ensure your own safety!

2 CHECK FOR RESPONSE AND LIFE SIGNS

Shake the victim by the shoulders.
Speak loudly to the victim.
Check for breathing - open airway if necessary.

3 CALL EMERGENCY SERVICES

Get other people to help you!
- to get the PDU 400.
- to stay with the patient while you call emergency services.
- to help with Cardio Pulmonary Resuscitation (CPR).

4 PERFORM CPR

Perform CPR until emergency services arrive, or the PDU 400 is made available.

Open the airway with a head tilt-chin lift. Give 2 breaths. Push hard and fast at a rate of 100 beats per minute, 3-5cm deep on patients chest; 30 compressions: 2 breaths (30:2) or 2 breaths : 30 compressions.

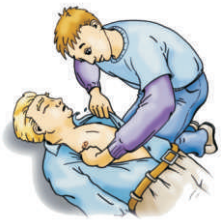
HOW DO I DEFIBRILLATE?

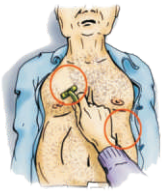
5 SWITCH ON

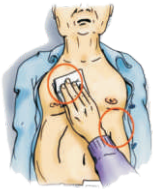
when the PDU 400 becomes available, switch ON and follow the

Voice Prompts

6 REMOVE ALL CLOTHES AND PREPARE CHEST AREA







If necessary shave part of chest where electrodes are to be put - Dry wet skin

7 OPEN THE ELECTRODE POUCH AND PLACE PADS ON PATIENT

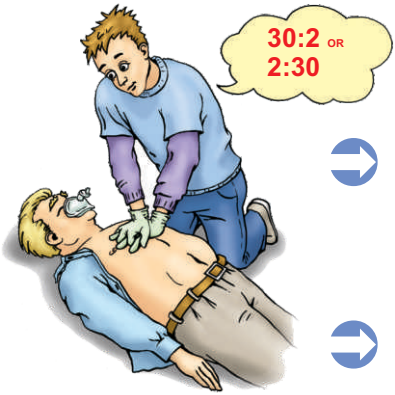
Pull out pad drawer

Tear open pad pouch

Place pads on patient's chest as shown

8 FOLLOW THE VOICE PROMPTS

MAKE SURE NO-ONE TOUCHES THE PATIENT WHILE DEVICE IS ANALYSING OR DELIVERING A SHOCK



- Keep giving CPR for 2 minutes (the PDU 400 will tell you when to stop) and repeat until the emergency services arrive.
- If possible alternate with another person.

- The PDU 400 will only administer a shock if it is needed. A voice prompt will tell you when to press the shock button to administer defibrillation therapy.

- The PDU 400 should not be used on someone who is responsive when shaken or breathing normally.

WARNINGS AND PRECAUTIONS

It is advised that the PDU 400 is used by a person trained in Cardio Pulmonary Resuscitation – Defibrillation (CPR-D).

The HeartSine PDU 400 has the capability to deliver therapeutic electrical shocks. The electrical shock can cause serious harm to either operators or bystanders. Caution must be taken to ensure that neither the operators nor bystanders touch the patient when a shock is to be delivered.

To safeguard against interference you must operate the PDU 400 2 meters (6 feet) away from all Radio Frequency devices and other susceptible equipment. Alternatively switch off equipment affected by or causing electromagnetic interference.

The PDU 400 has been designed to work on unconscious, non-responding patients. If the patient is responsive or conscious do not use the PDU 400 to provide treatment.

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.

It has been determined that the PDU 400 is safe to use in conjunction with oxygen mask delivery systems. However, to avoid the risk of an explosion, it is strongly advised that the PDU 400 should not be used in the vicinity of explosive gases. This includes flammable anaesthetics or concentrated oxygen.

The HeartSine PDU 400 must only be used on patients over 25 kilograms (55 pounds) in weight or equivalent to a child of approximately eight years old or over.

Proper placement of the PDU 400's pads is critical. Strict observance of pad positioning instructions, as indicated in the section 'HOW DO I DEFIBRILLATE' and on the device, is essential. Care must be taken to ensure pads are adhered to the patient's skin properly. Wrong placement or air between pads and skin could burn skin. Slightly red skin after shock therapy is normal.

Periodic checks of this device must be undertaken to ensure amongst other things that the HeartSine PDU 400 has not become damaged in any way. **Check: the green LED is flashing every 5 seconds, the red light is not flashing, the device is within expiry date and free from any physical damage.**

The PDU 400 is a single use item and must be replaced after each use or if the pouch that seals defibrillation electrodes has been broken or compromised in any way.

The PDU 400, with its battery, pads and electrodes, is designed to operate in the temperature range of 0^{0}C to 50^{0}C. Use of device outside this range may cause malfunction.

Standby storage outside the range or 10 - 50^{0}C may decrease the shelf-life of the device.

The PDU 400 has no serviceable parts. Under no circumstances should the device be opened or repaired as there could be danger of electric shock. If damage is suspected the PDU 400 must be replaced immediately.

For disposal in accordance with the European WEEE Directive, contact your HeartSine Distributor.

Do not switch device on unneccessarily as this may reduce the standby life of the unit.

The PDU 400 is a self contained device. Do not use any unauthorized accessories with the PDU. The PDU 400 may not function properly if non-approved accessories are used.

AFTER USE

1

Switch Off the PDU 400.

Remove pads from the patient and stick together ‘face to face’.

2

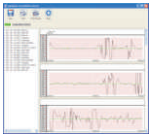
Do NOT dispose of the PDU 400 or any of its parts in normal waste. Return it to your distributor for disposal or replacement.

DATA MANAGEMENT

Contact HeartSine or your distributor about the After-Use Data Management Service.

Distributor information

Withdraw the memory card from PDU 400. Insert the memory card into your card reader connected to a PC.



Launch the HeartSine Saver™EVO utility and print or save the file as an Adobe PDF.

Do NOT attempt to read the memory card with any program other than Saver™ EVO. Do NOT ‘FORMAT’ the card.

SERVICE AND MAINTENANCE

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

1. Check the status indicator. If the green status indicator is not flashing approximately every 5 seconds a problem has been detected. Refer to TROUBLESHOOTING.

2. Check the expiration date of the PDU 400. If the date has expired, replace with a new device or contact your local HeartSine distributor for replacement.

3. If a warning message is heard when the PDU 400 is turned on or if for any reason, you have suspicions that your PDU 400 is not working correctly, contact your authorised HeartSine dealer or HeartSine directly for support (support@heartsine.com).

4. The PDU 400 performs a self-test routine at midnight GMT on Sunday. During this self test period the status light will blink RED. The status light shall return to GREEN on successful completion of the self test routine.
The self test will take no more than 10 seconds to complete.

TRACKING REQUIREMENTS

Under the Medical Devices Regulations we are required to track the location of all medical devices sold.

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

Your participation will allow us to contact you about important notifications about the PDU 400 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, change of address, change in ownership of your PDU 400 etc please contact us with the updated information.

TROUBLESHOOTING

1. If the status indicator is flashing Red and/or device emitting a “Beep”, check the expiry date on your PDU 400 has not expired. If the device is within the expiry date, switch on the PDU 400 and listen for the voice prompt “call for emergency services”. Then switch off. This may correct the problem. If not, contact HeartSine or your distributor.

2. The first time the device plays the message “warning low battery” during an event, it will be possible to deliver at least 10 shocks. If this happens the device will still function properly. This warning can be played even when the PDU 400 is new and can occur if the storage or operating temperature is, or has been, very low. This does not indicate a fault.

3. If the device plays the message “warning memory full”, then no further ECG data or events can be recorded to the memory. However, the device will still be able to analyse and deliver a shock if required. Contact HeartSine Technologies technical support.

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

5. Physical damage
If the device shows any signs of physical damage, contact HeartSine or your distributor.

6. 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 analyze the patient's heart rhythm and advise CPR.

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

HeartSine or its authorized distributors are not obliged to replace or repair under warranty if:

1. The device has been opened.
2. Unauthorized modifications have been made.
3. It has not been used in accordance with the Indications for Use and instructions provided in this Manual.
4. The serial number has been removed, defaced, altered or, by any other means, made unreadable.
5. The device is used or stored outside its indicated temperature range.

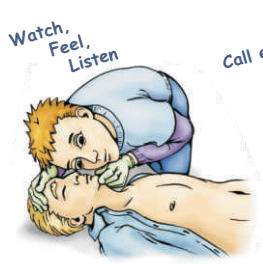
KEEP CALM - LIFE SAVING IS SO SIMPLE!!

Available as a pocket folder - Quick Reference.

1 GENERAL

Remove patient from a risk area! Ensure your own safety!

2 PERSON NOT RESPONSIVE? NO SIGNS OF LIFE? Check breathing, open the airway.



Engage other people to help you get PDU 400

3 Perform CPR until a PDU 400 is available.

4 Switch on PDU 400 and follow instructions.

5 Remove clothes.

6 Open PDU 400, remove electrodes, peel electrodes from liner. Apply pads of electrodes to bare chest as shown in the picture.

If necessary shave part of chest where electrodes are to be put - Dry wet skin.

7 Follow the instructions.

Either press SHOCK button or ...

... perform CPR for 2 minutes or 5 cycles.

Alternate with second person after one cycle until emergency services arrive.

Technical Data

Physical.

Size:	24.5 x 16 x 7.5cm.
Weight:	1.1kg (2.4 lbs).

Environmental operating limits.

Operating temperature:	0 to 50˚C (32 to 122˚F).
Standby temperature:	10 to 50˚C (50 to 122˚F).
Relative humidity:	5 to 95% (non-condensing).
Enclosure:	IEC 60529/EN 60529 IP44.
Altitude:	0 to 15,000 feet (0 - 4,575 meters).
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.

Patient analysis system.

Method:	Evaluates patient's ECG, ICG and patient impedance.
Sensitivity:	Meets ISO 60601-2-4 and AAMI DF80:2003.
Specificity:	Meets ISO 60601-2-4 and AAMI DF80:2003.

User Interface.

Visual Prompts:	Illuminating icons.
Audible prompts:	Extensive audible prompts.
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.

From switch on	Less than 20 seconds.
From "Shock Advised"	Less than 12 seconds.
Following CPR	Typically 9 seconds.

Battery.

Battery type:	Single use self contained battery. Non rechargeable. Lithium Manganese Dioxide (LiMnO2) 12V, 1.4 AH.
Battery capacity:	>30 shocks or 6 hours of continuous monitoring.
Standby life:	Typically 5.5 years from Date of Manufacture (DoM).

Electrodes.

Type:	Single use pre-attached. Combined ECG sensor/ICG sensor/Defibrillation pad.
Placement:	Anterior-lateral .
Active area:	120 cm^2.
Cable length:	3.5 ft (1m).
Shelf life:	Typically 5.5 years from DoM.

Therapeutic shock.

Waveform:	Low tilt biphasic waveform.
Energy:	120 Joules non escalating.

Event recording.

Type:	Removable SD memory card.
Memory:	100hrs+ of ECG and event/incident recording.
Review:	SD memory card connected to PC via card slot or reader. Saver™EVO windows-based data review software.

Electro-magnetic compatibility.

EMC:	EN 60601-1-2, 2nd Edition: 2001.
Radiated emissions:	CISPR11:1997+1A:1999+A2:2001 Group1 Class B.
Electrostatic discharge:	EN61000-4-2:1995 (8KV) Immunity:+A1:1998+A2:2000.
RF immunity:	EN61000-4-3:1996, 80MHz-2.5GHz, (10V/m). +A1:1998+A2:2000.
Magnetic field immunity:	EN61000-4-8:1993 (3 A/m) +A1:2000.
Aircraft:	RTCA/DO-160D:1997, Section 21 (Category M).

Low Tilt waveform specification

The PDU 400 delivers a Low Tilt biphasic waveform. The waveform is automatically tailored for a wide range of patient impedances, from 20 ohms to 230 ohms, and delivers an optimized, impedance-compensated waveform at a fixed energy of 120 Joules.

Delivered Energy:	120 Joules ± 10%
Peak Voltage:	1190 Volts ± 8%
1st phase duration:	3 - 12.5 mSecs
2nd phase duration:	Equal to 1st phase duration
Inter-phase duration:	0.4 mSecs

It is known that the lower the energy required for conversion from Ventricular Fibrillation to Normal Sinus Rhythm, the less the damage to the tissue of the heart and the less likely the patient is to suffer repeat attacks which formerly might have ensued from defibrillation. However, there is a threshold below which the energy might not be effective.

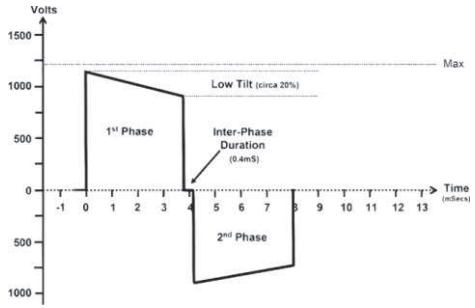
HeartSine has conducted extensive research in an attempt to both increase efficacy and decrease delivered energy. In clinical trials, it has been shown that using a 'low-tilt' waveform increases the efficacy of the therapeutic shock and allows a reduction of delivered energy from over 150 Joules to 120 Joules.

A 'Low-Tilt' waveform is one in which the difference in voltage between the start and end of both phases is of the order of 20% (compared to the previous differences of some 50% or greater).

The results of the clinical trials have shown that with a low-tilt (circa 20%) waveform and a 120 Joule energy, the efficacy of conversion is currently shown to be equivalent to the standard tilt (circa 50%) waveform delivering 150 Joules.

This pioneering research was conducted by HeartSine Technologies Ltd, in association with the Royal Victoria Hospital, Belfast.

The low tilt waveform characteristics for a 120J pulse are shown below:



Resistance (Ohms)	Waveform Voltages (Volts)		Waveform Duration (msec)	
	V_1	Tilt %	T_1	T_3
25	1090	38.1	3	3
50	1240	21.3	3	3
75	1270	21.3	4.5	4.5
100	1280	19.7	5.5	5.5
125	1290	20	7	7
150	1290	19.2	8	8
175	1280	20.4	10	10
200	1280	19.7	11	11
225	1280	19.9	12.5	12.5

Arrythmia detection algorithm

The HeartSine PDU 400 incorporates an innovative new algorithm for the detection of shockable heart rhythms. This new algorithm uses two sensor technologies to determine if a therapeutic shock is required. Electro cardiogram (ECG) detection is coupled with impedance cardiogram (ICG) to determine if a suspected victim of Sudden Cardiac Arrest (SCA) requires a therapeutic shock.

Detection system description
During the periods of patient analysis the PDU 400 analysis detection system continuously analyzes both the ECG and ICG signals. If the presence of a shockable rhythm is confirmed (typically 6 to 8 seconds of analysis) then the PDU 400 shall provide a “Shock advised” audible and visual prompt. A “No shock advised” is provided otherwise.
The PDU 400 analysis detection system has been designed to provide a “no-shock” advised decision for ECG arrythmias consisting of but not limited to

Normal sinus rhythm
Ventricular Tachycardia (which is not HRVT i.e. not high rate or broad complex)
Bradycardia
Pulseless electrical activity (PEA)
Asystole or fine ventricular fibrillation (the peak to amplitude <200µV)

The PDU 400 analysis detection system has been designed to provide a shock advised decision for the following ECG arrhythmias whenever the peak to peak amplitude of the ECG signal is higher than 200µV

Ventricular fibrillation
Shockable High Rate Ventricular Tachycardia (SHRVT)

Rhythm Class	ECG Test Sample Size	Performance Specifications	Performance Results (%)	90% One-Sided Lower Confidence Limit
Shockable Rhythm: Ventricular Fibrillation (VF)	5699	Sensitivity > 90%	97.68	96.71
Shockable Rhythm: High Rate broad complex Ventricular Tachycardia (HRVT) (without corresponding ICG data)	510	Sensitivity > 75%	100	100
Non-Shockable Rhythm: Asystole	562	Specificity > 95%	100	100
Non-Shockable Rhythm: All other Rhythms	188167	Specificity > 95%	99.99	99.98

The ECG Algorithm Performance:

The PDU 400 ECG Arrhythmia Analysis Algorithm has been extensively evaluated by using the American Heart Association's (AHA) database and the Massachusetts Institute of Technology MIT – NST database1. The algorithm sensitivity and specificity meets the AAMI DF80:2003 requirements and AHA recommendations.

The PDU 400 ECG analysis fulfils the Arrhythmi Association for the Advancement of Medical Instrumentation. DF80:2003 Standard for Medical electrical equipment, Part 2-4, with particular requirements for the safety of cardiac defibrillators (including automated external defibrillators).

Whenever the heart rate is higher than 180BPM, a broad complex is present and no cardiac disturbance is detected. This cardiac disturbance is determined by analyzing the impedance electrocardiogram.

Even after a “Shock advised” decision has been made, the PDU 400 analysis detection system continuously assesses the patient's ECG. If the patient's heart rhythm spontaneously returns to a non-shockable rhythm, the PDU 400 will automatically disarm and advise the operator.

Rhythm Class	ECG Test Sample Size	Performance Specifications	Performance Results (%)	90% One-Sided Lower Confidence Limit
High Rate broad complex Ventricular Tachycardia (HRVT) without cardiac output	16	Sensitivity > 75%	100	100
High Rate broad complex Ventricular Tachycardia (HRVT) with cardiac output	112	Specificity > 95%	100	100

Guidance and manufacturer's declaration – electromagnetic emissions

The HeartSine PDU 400 is intended for use in the electromagnetic environment specified below. The customer or user of the HeartSine PDU 400 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The HeartSine PDU 400 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	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The HeartSine PDU 400 is intended for use in the electromagnetic environment specified below. The customer or user of the HeartSine PDU 400 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	±6kV contact ± 8kv air	Complies Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	
Surge IEC 61000-4-5	+ 1 kV line(s) to line(s) + 2kV line(s) to earth	Not applicable Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Not applicable Not applicable Not applicable Not applicable	
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.

Note U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The HeartSine PDU 400 is intended for use in the electromagnetic environment specified below. The customer or user of the HeartSine PDU 400 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the HeartSine PDU 400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not applicable	$d = \frac{12}{E_1}\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d = \frac{23}{E_1}\sqrt{P}$ 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). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 KHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] 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/potable 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.

[c] Field strengths form 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 asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured filed strength in the location in which the HeartSine PDU 400 is used exceeds the applicable RF compliance level above, the HeartSine PDU 400 should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the HeartISine PDU 400.

[d] Over the frequency range 150 kHz to 80 MHz, filed strength should be less than [V_1] V/m

GLOSSARY OF TERMS

HeartSine® PDU 400
The PDU is a semi-Automatic External Defibrillator (AED).

AED
(semi) Automatic External defibrillators are medical devices designed to deliver therapeutics electric shocks intended to correct erratic electrical impulses in the heart.

Arrhythmia
An Arrhythmia is any irregularity in the rhythm or shape of the heart's electrical activity.

Biphasic Shock
A biphasic shock is an electrical current that is passed through the heart, firstly in one direction and then in another.

Cardio-, Cardiac
Any physical or electrical activity associated with the heart.

Defibrillation Electrodes
The Defibrillation electrodes (pads) are the part of the device that are connected to the patient's chest in order to administer therapy.

Impedance Measurement
Impedance measurement is a check that is performed to check the integrity of PDU 400 patient contact and to determine the resistance of the patient to the passage of electricity.

Radio Frequency Interference
Radio Frequency Interference (RFI) is radio interference that may cause erroneous operation of electronic equipment.

Saver™ EVO Software
Saver™ EVO is software that can be used in conjunction with the data card of the PDU 400 and a suitable card reading device. Saver™ EVO can be used to retrieve and view information about therapy delivered using the PDU.

Sinus Rhythm
Sinus Rhythm is the normal electrical rhythm which causes the heart muscle to contract to create blood flow around the body.

Self-Test
A self-test is an automatic test that is used to check that the PDU 400 is working correctly.

Ventricular Fibrillation
Is a life-threatening heart rhythm that is treatable with an electrical shock using the PDU 400.

HeartSine

HeartSine PDU 400 UNIT

- 5.5 Years guarantee.
- 5.5 Years shelf time of battery and electrodes.
- Wall bracket.
- User Manual.

DATA MANAGEMENT & ACCESSORIES

- Saver™ EVO Software (Saver™ Software CD ROM & License).

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