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Confidential Report

Client:	Test of:
HeartSine Technologies, Ltd. **Canberra House** **203 Airport Road West** **Belfast, BT3 9ED** **Northern Ireland** **Att: Mr Allister McIntyre**	**Samaritan PAD (Public Access Defibrillator)** **To:** **EN60601-1-2: 2002 &** **EN 55011: 1998 + A2: 2002 (Applicable Parts of)**

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REPORT REF: 07E2712-1 **TESTED BY: Paul Reilly**

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CONTENTS

Test of: Samaritan PAD (Public Access Defibrillator) to:

EN 60601-1-2: 2002 & EN 55011: 1998 + A2: 2002
(Applicable parts of)

1 Equipment Under Test (EUT)

1.1 Identification of EUT

Brand Name:	Heartsine
Description:	Samaritan PAD
Country of Manufacture:	Northern Ireland

1.2 Description of EUT

The EUT was a portable battery operated automated defibrillator.

1.3 Modifications

There were no modifications incorporated in the EUT

1.4 Support Equipment

Brand Name:	Heartsine
Description:	Patient Simulator
Model Number:	Samaritan AED Simulator
Country of Manufacture:	Northern Ireland

1.5 Date of Test

The tests were carried out on the 25th and 26th of June, 2007

2 Test Specification, Methods and Procedures

2.1 Emissions Test Specification

Radiated Emissions

EN 55011: 1999 + A2: 2001
Title:
Industrial, scientific and medical (ism) radio-frequency equipment - radio disturbance characteristics - limits and methods of measurement

2.2 Immunity Test Specification

Immunity was assessed to the following standard as requested by the manufacturer:

EN 60601-1-2: 2002
Title: Medical Electrical Equipment
Section 1.2: Collateral standard: Electromagnetic Compatibility – Requirements and tests.

EN 61000-4-2: 2001	Electromagnetic Compatibility (EMC) Part4: Testing and measurement techniques Section 2: ElectroStatic Discharge test
EN 61000-4-3: 2002	Electromagnetic Compatibility (EMC) Part4: Testing and measurement techniques Section 3: Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-8: 2001	Electromagnetic compatibility (EMC) Part 4. Testing and measurement techniques. Section 8: Power frequency magnetic field immunity test

2.3 Purpose of test

To determine compliance with the EU EMC Directive 2004/108/EC.

3 Deviations or Exclusions from the Test Specifications

3.1 Deviations

There were no deviations from the test specification.

3.2 Exclusions

There were no exclusions from the test specification.

4 Operation of EUT During Testing

4.1 Operating Environment

The following were the conditions at the time of immunity testing.

Temperature: 21˚C
Humidity: 44% RH

4.2 Operating Modes:

The EUT was tested by connecting it to the patient simulator in analysis mode.

5 Results

5.1 Radiated Emissions

Compliant measurements of radiated emissions were carried out on an open area test site from 30 MHz to 1 GHz. The equipment and cable orientation were investigated to ensure that maximum emissions were obtained at critical frequencies. The antenna height was also adjusted through the range of 1m - 4m.
The receiver bandwidth was set to 120 kHz for frequencies between 30 MHz and 1 GHz. See Table 1, Appendix 3 for results.

5.1.1 Measurement Uncertainty

The measurement uncertainty (with a 95% confidence level) for the radiated emissions test was ±5.3 dB (from 30 to 100 MHz), ±4.7 dB (from 100 to 300 MHz) and ±3.9 dB (from 300 to 1000 MHz).

5.2 Electrostatic Discharge Test

Port:	Enclosure
Basic Standard:	EN61000-4-2: 2001
Performance Criterion:	B
Limit:	2,4 & 6 kV contact discharges 2,4,6 & 8 kV air discharges

The ESD generator contained a discharge capacitor of 150pF and resistor of 330Ω in accordance with the requirements of EN61000-4-2: 2001. The tests were carried out using both positive and negative discharges.

Only conductive parts of the equipment that can be touched during normal operation were subjected to contact discharges.

Air Discharges of 2, 4, 6 & 8kV were applied to the EUT. No discharges took to the EUT. 10 contact discharges of each polarity were applied to the vertical coupling plane on all four sides of the EUT. 10 contact discharges of each polarity were also applied to the horizontal coupling plane.

The EUT maintained normal operation during the ESD testing and was subsequently found to be operating satisfactorily.

5.3 Immunity to Radiated, Radio Frequency Electromagnetic Fields

Measurements were performed according to EN61000-4-3: 2001 from 80 MHz to 2500 MHz.

Port:	Enclosure
Performance Criterion:	A
Limit:	10 V/m
Frequency range:	80-2500 MHz (Modulation: 80% AM 1kHz & 2Hz)
Dwell time:	3 seconds

The EUT was placed in the anechoic chamber.

The step sizes from 80-2500 MHz were in 1% steps. The dwell time at each frequency was 3 seconds. The test level was maintained at over 10 V/m at all frequencies in accordance with clause 36.202.3 a.) 2) of EN 60601-1-2: 2001.

The EUT was in normal running mode during the test.

A field sensor was placed in close proximity to the system. The distance of the antenna from the E.U.T. was 2.2 metres. The tests were carried out with the antenna oriented in horizontal and vertical polarisations.

During the tests the monitor was remotely observed with a CCTV camera to assess any errors in the operation of the EUT.

Frequency MHz	Polarisation (V/H)	Level (V/m)	Result
80-2500 MHz	V and H	10	Complied

Results of Radiated Immunity Tests

5.4 Power Frequency Magnetic Field Immunity Test

Basic Standard: IEC 61000-4-8: 2001
Performance Criterion: A
Level: 3 A/m

The unit was placed on a non-conductive table of 0.8 meter height from the ground plane.

The current level was set to 3 A/m and the unit was centred in the middle of the loop. The EUT was tested with the loop in both horizontal and vertical positions for one minute.

During the tests the E.U.T. was visually observed to assess any disturbance.

The E.U.T. was found to be operating satisfactorily during and subsequent to testing.

See Appendix 2 for the test configuration.

6 Analysis of Test Results, Conclusions

6.1 Measurement Uncertainties

The measurement uncertainties stated were calculated in accordance with the requirements of CISPR 16-4 with a confidence level of 95%.

6.2 Radiated Emissions

The E.U.T. complied with the Class A radiated emission specification by a margin of greater than 10 dB.

6.3 Immunity

The EUT complied with the immunity tests carried out to demonstrate compliance with EN 61000-6-1: 2001.

Appendix 1
Test Equipment Used:

Instrument	Mftr.	Model	Serial No.
Bilog Antenna	CEI	699	699
Horn Antenna	EMCO	3115	9905-5809
Signal Generator	Rohde & Schwarz	SME 03	DE24204
Power Amplifier	Milmega	ASM1000-75R	981440
Field Monitor System	Amplifier Research	FM2000	13142
Field Probe	Amplifier Research	FP2000	13130
OPHIR Power Amplifier	OPHIR	5141	713
Signal Generator	Rohde & Schwarz	SMH	883739 /044
Electrostatic Discharge Simulator	Schaffner	NSG432	00978
Positive Discharge Adapter	Schaffner	402 628	9318
Negative Discharge Adapter	Schaffner	402 645	9325
TWT Amplifier	Varian	VZS6950K1	5757
Signal Generator	Hewlett Packard	8672A	R4520S
Transient Simulator	Schaffner	Best Plus	199749A016SC
Magnetic Loop	CEI	-	-

Appendix 2
Test Configuration:

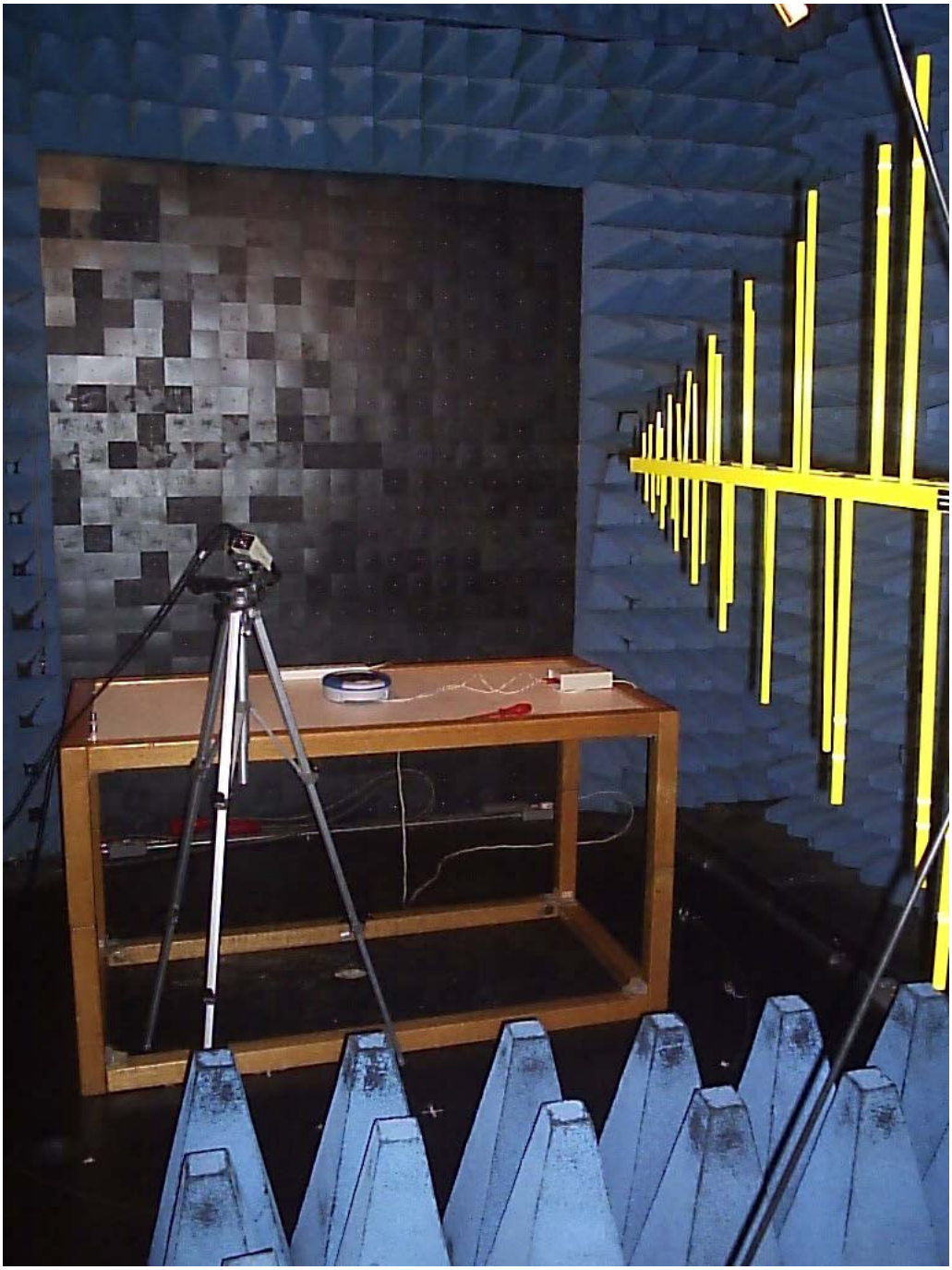

Figure 1: Radiated Immunity test

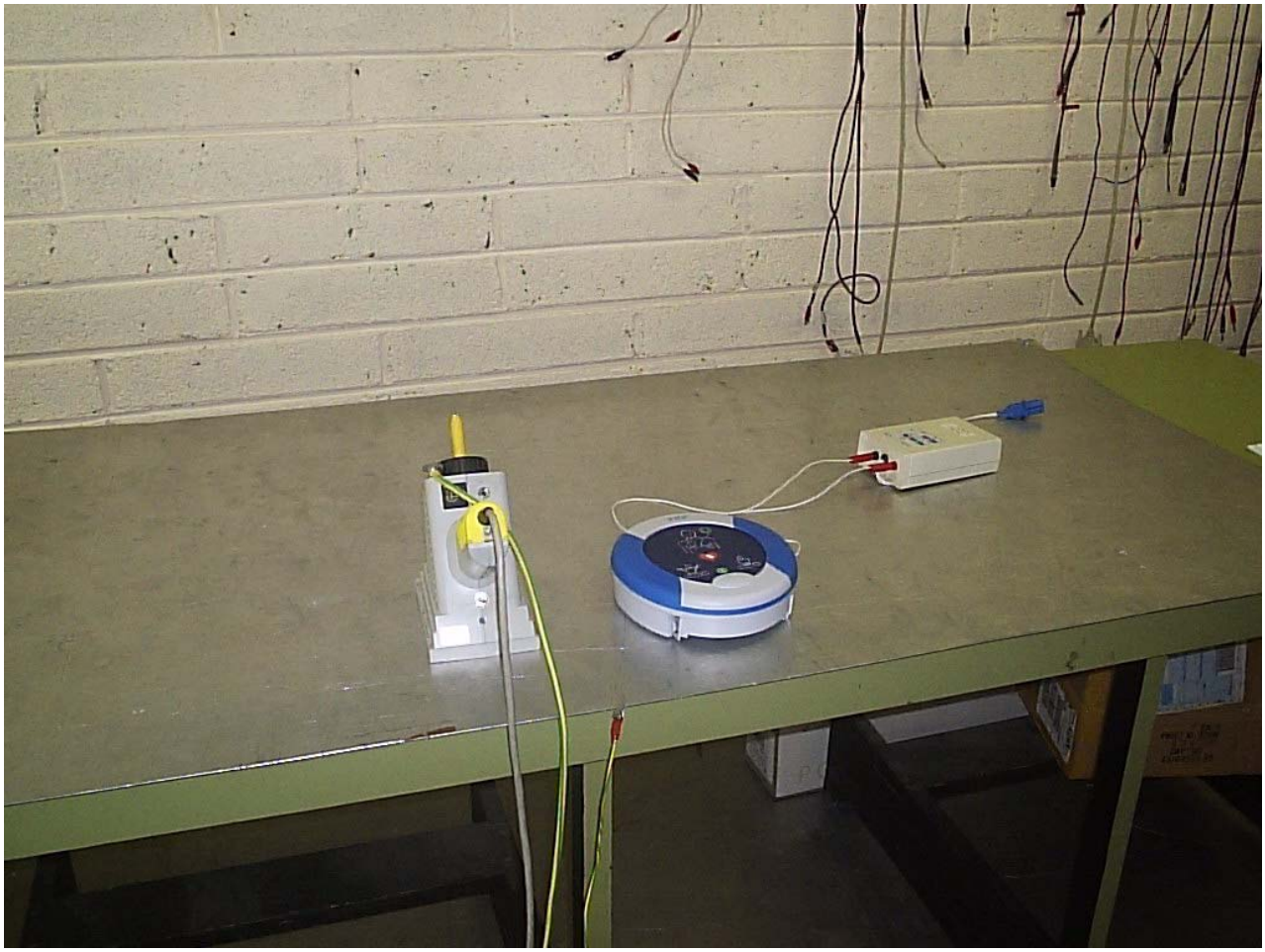

Figure 2: ESD Test

Figure 3: Power frequency magnetic field immunity test

Figure 4: Radiated Emissions test