

Certificate of Compliance

EMC Technologies Report No: T30507

Test Sample: Ultrasonic Cardiac Output Monitor
Model Number: USCOM1A
Serial Number: 0008
Part Number: None

Manufacturer: USCOM Pty Ltd



Tested for: USCOM Pty Ltd
Address: 4/199 Clarence Street
Sydney NSW 2000

Phone: (02) 9299 3370
Fax: (02) 9299 3929
Responsible Party: Mr Paul Butler

Test Standards: **IEC60601-1-2: 2001**
Medical electrical equipment, Part 1: General requirements for safety
Section 2. Collateral Standard: Electromagnetic compatibility -
Requirements and tests

Result of Test: The test sample complied with the above listed Test Standard. Refer to Report T30507 for full details.

Test Dates: 05/05/03, 08/05/03, 13/05/03, 14/05/03, 28/05/03 and 29/05/03

Test Officers: 
Bruce Holdsworth 
Gerald Gidah

Authorised Signature: 
Les Dickenson
Branch Manager
EMC Technologies Pty Ltd

Issued by EMC Technologies Pty Ltd, Unit 16/6 Gladstone Road, Castle Hill, NSW, 2154, Australia.
Phone: +61 2 9899 4599 Fax: +61 2 9899 4019



Part 1

**Summary of EMC Tests
on the Ultrasonic Cardiac Output Monitor,
Manufactured By USCOM Pty Ltd**

1. INTRODUCTION

This report details the results of the test performed on the Ultrasonic Cardiac Output Monitor, Model: USCOM1A.

2. SUMMARY of RESULTS**2.1 Emissions – CISPR 11**

Conducted EMI: Complies with a Group 1 Class A margin of greater than 10dB.

Radiated EMI: Complies with a Group 1 Class A margin of at least 1.9dB*.

* This result falls within the laboratory's measurement uncertainty.

2.2 Immunity

Electrostatic Discharge (ESD)	IEC 61000-4-2	Complies
Radiated RF Fields	IEC 61000-4-3	Complies
Electrical Fast Transient/Bursts	IEC 61000-4-4	Complies
Surges	IEC 61000-4-5	Complies
Conducted RF Disturbances	IEC 61000-4-6	Complies
Power frequency magnetic field	IEC 61000-4-8	Complies
Voltage Dips	IEC 61000-4-11	Complies
Voltage Interruptions	IEC 61000-4-11	Complies

2.3 IEC 61000-3-2

The Ultrasonic Cardiac Output Monitor was tested in accordance with the Class D requirements of IEC 61000-3-2.

Current Harmonics Test Complies

2.4 IEC 61000-3-3

The Ultrasonic Cardiac Output Monitor was tested in accordance with the requirements of IEC 61000-3-3.

Voltage Fluctuations and Flicker Complies



Part 2

**EMI Tests on the Ultrasonic Cardiac Output Monitor,
in accordance with IEC60601-1-2**

1. INTRODUCTION

This report is intended to document the conformance of the Ultrasonic Cardiac Output Monitor, Model No: USCOM1A, tested on behalf of USCOM Pty Ltd with the Electromagnetic Compatibility (EMC) requirements of IEC60601-1-2. The details of the Equipment Under Test (EUT) and the test results are provided.

2. SUMMARY of RESULTS – CISPR 11:2002

Conducted EMI: CISPR11 Complies with a Group 1 Class A margin of greater than 10dB

Radiated EMI: CISPR11 Complies with a Group 1 Class A margin of at least 1.9dB*

* This result falls within the laboratory's measurement uncertainty.

3. IEC60601-1-2 REQUIREMENTS

Clauses

Section 1	General	
Clause 1	Scope and object	Noted
Clause 2	Terminology and definitions	Noted
Clause 3	General requirements	Noted
Clause 6	Identification, marking and documents	Noted
Sections 2 – 4	Not Used	
Section 5	Protection against hazards from unwanted or excessive radiation	
Clause 36	Electromagnetic compatibility	
Clause 36.201	Emissions	Complies
Clause 36.202	Immunity	Complies, refer to Part 2
Sections 6 – 10	Not Used	

4. RESULTS – CISPR 11

4.1 Conducted EMI Results

Complied with the Group 1 Class A quasi peak and average limits by margins of greater than 10dB.

The measurement uncertainty for conducted EMI was ±1.8dB.

Refer to Appendix B, Graphs 1 and 2.



Part 3

**EMC Tests on the Ultrasonic Cardiac Output Monitor,
in accordance with IEC60601-1-2**

1. INTRODUCTION

This report is intended to document the conformance of the Ultrasonic Cardiac Output Monitor, Model: USCOM1A with the Electromagnetic Compatibility requirements of IEC60601-1-2.

2. SUMMARY of RESULTS

Electrostatic Discharge (ESD)	IEC 61000-4-2	Complies
Radiated RF Fields	IEC 61000-4-3	Complies
Electrical Fast Transient/Bursts	IEC 61000-4-4	Complies
Surges	IEC 61000-4-5	Complies
Conducted RF Disturbances	IEC 61000-4-6	Complies
Power frequency magnetic field	IEC 61000-4-8	Complies
Voltage Dips	IEC 61000-4-11	Complies
Voltage Interruptions	IEC 61000-4-11	Complies

3. REGULATIONS AND STANDARDS APPLIED**IEC60601-1-2: 2001**

*Medical Electrical Equipment, Part 1: General requirements for safety
Section 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests*

IEC 61000-4-2:1995, Including Amdt 1 & 2

Electromagnetic compatibility for industrial process measurement and control equipment. Part 2: Electrostatic discharge requirements.

IEC 61000-4-3:2002

Electromagnetic compatibility for industrial process measurement and control equipment. Part 3: Radiated electromagnetic field requirements.

IEC 61000-4-4:1995, Including Amdt 1 & 2

Electromagnetic compatibility for industrial process measurement and control equipment. Part 4: Electrical fast transient/burst requirements.

IEC 61000-4-5:1995, Including Amdt 1

Electromagnetic compatibility for industrial process measurement and control equipment. Part 5: High Voltage Surges requirements.

IEC61000-4-6:1996, Including Amdt 1

Electromagnetic Compatibility - Part 4: Testing and Measuring Techniques
Section 6: Conducted disturbances induced by radio-frequency fields, immunity test.

IEC61000-4-8:1993, Including Amdt 1

Electromagnetic Compatibility - Part 4: Testing and Measuring Techniques
Section 8: Power-frequency magnetic field immunity test.

IEC61000-4-11:1994, Including Amdt 1

Electromagnetic Compatibility - Part 4: Testing and Measuring Techniques
Section 11: Voltage dips, short interruptions and voltage variations immunity test.

