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### EMC COMPLIANCE REPORT

In accordance with

IEC 60601-1-2: 2001

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MEGAPULSE PTY. LTD.

48V MEGAPULSE MKIII BATTERY CONDITIONER

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REPORT TL4719B

March 2005



# Certificate of Compliance

**RFI Industries Test Report: TL4719B**  
**Issue Date: March 2005**

**Test Sample(s):** 48V Megapulse MKIII Battery Conditioner  
**Model No:** Not Specified  
**Serial No:** 0449-0448

**Client Details:** Mr. Ross Naddei,  
Megapulse Pty Ltd,  
11 Fortuna Court,  
Eaton's Hill,  
Queensland, 4037

Phone: (07) 3325 4200  
Fax: (07) 3325 4199

**Test Specification:** IEC 60601-1-2: 2001  
Medical electrical equipment –  
Part 1-2: General requirements for safety –  
Collateral standard:  
Electromagnetic compatibility –  
Requirements and tests

**Summary:** **IEC 60601-1-2: 2001 (PARTIAL)**

Electrostatic Discharge	IEC 61000-4-2: 1995	<b>PASS</b>
Radiated RF Immunity	IEC 61000-4-3: 2002	<b>PASS</b>
Power Frequency Magnetic Immunity	IEC 61000-4-8: 1994	<b>PASS</b>

**Test Date(s):** 18<sup>th</sup> & 22<sup>nd</sup> of March 2005.

**Test House:  
(Issued by)** R.F.I. Industries Pty. Limited,  
EMI/EMC Laboratories,  
52 Holloway Drive,  
Bayswater, Victoria  
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The Megapulse, MKIII Battery Conditioner, complied with the requirements of IEC 60601-1-2: 2001, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.



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Steven Koljatic  
(Test Engineer)



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Andrew Burden  
(EMC Engineering Manager)

31/03/2005

.....  
Date

## **EMC COMPLIANCE REPORT FOR MEGAPULSE PTY LTD.**

### **1. INTRODUCTION**

Electromagnetic Compatibility (EMC) tests were performed on a 48V Megapulse MKIII Battery Conditioner in accordance with IEC 60601-1-2: 2001. Only a partial number of measurements are detailed in this report.

### **2. PRODUCT SAMPLE, MODIFICATIONS, TEST FACILITY AND EQUIPMENT**

#### **2.1 Product Sample**

The product, as supplied by the client, is described as follows:

48V Megapulse MKIII Battery Conditioner.  
Model No: Not specified  
Serial No: 0449-0448

This product shall be referred to as the EUT (Equipment under test).

#### **2.2 Modifications**

RFI Industries performed no modifications on the EUT.

#### **2.3 Test Facility**

Tests were performed at the EMI/EMC Laboratories of RFI Industries, located at 52 Holloway Drive, Bayswater, Victoria, Australia. All tests were carried out inside a semi anechoic chamber.

#### **2.4 Test Equipment**

Refer to Appendix A for the measurement instrument list.

### **3. REFERENCE STANDARDS**

#### **IEC 60601-1-2: 2001**

Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (Partial requirements only)

#### **IEC 61000-4-2: 1995**

Electromagnetic Compatibility – Part 4. Testing and measurement techniques  
Section 2. Electrostatic discharge immunity test.

#### **IEC 61000-4-3: 2002**

Electromagnetic Compatibility – Part 4. Testing and measurement techniques  
Section 3. Radiated, radio frequency, electromagnetic field immunity test.

#### **IEC 61000-4-8: 1994**

Electromagnetic Compatibility – Part 4. Testing and measurement techniques  
Section 8. Power frequency magnetic field immunity test.

#### 4. PERFORMANCE (PASS/FAIL) CRITERIA

The performance of the EUT was subject to the following performance criteria as specified in the referenced standard:

##### **Non-medical electrical equipment**

Non-medical electrical equipment that is supplied as part of a SYSTEM and the use of which in the SYSTEM can be reasonably expected not to affect the ESSENTIAL PERFORMANCE or safety of the SYSTEM if the non-medical electrical equipment exhibits DEGRADATION, is exempt from the IMMUNITY testing requirements of this standard, provided the non-medical electrical equipment complies with applicable international IMMUNITY standards. The determination of reasonable expectation not to affect the ESSENTIAL PERFORMANCE or safety of the SYSTEM shall be based upon a risk analysis. This risk analysis is not required if the non-medical electrical equipment supplied as part of a system is tested for IMMUNITY in accordance with 36.2002.

##### **Compliance Criteria**

The EQUIPMENT or SYSTEM shall be able to provide the ESSENTIAL PERFORMANCE and remain safe. The following DEGRADATIONS associated with ESSENTIAL PERFORMANCE and safety shall not be allowed:

- Component failures;
- Changes in programmable parameters;
- Reset to factory defaults (manufacturer's presets);
- Changes in operating mode;
- False alarms;
- Cessation or interruption of any intended operation, even if accompanied by an alarm;
- Initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- Error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- Noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals;
- Artifact of distortion in a image in which the artifact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of the physiologically-produced signals;
- Failure of automatic diagnosis or treatment EQUIPMENT and SYSTEMS to diagnose or treat, even if accompanied by an alarm.

For EQUIPMENT and SYSTEMS with multiple FUNCTIONS, the criteria apply to each FUNCTION, parameter and channel.

The EQUIPMENT or SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from manufacturer's specifications) that does not affect ESSENTIAL PERFORMANCE or safety.

## 5. Electrostatic Discharge Immunity – IEC 61000-4-2

### 5.1 Test Procedure

#### TABLE TOP EQUIPMENT

A horizontal coupling plane (HCP), 1.6 metre x 0.8 metre is placed on top of a wooden table 0.8 metres high, standing on the ground reference plane. The EUT and cables are isolated from the coupling plane by an insulating film 0.5mm thick.

#### FLOOR STANDING EQUIPMENT

The EUT and cables are isolated from the ground reference plane by an insulating support 100mm thick.

- Tabletop or floor standing equipment is placed in the center of a 1m<sup>2</sup>, reference plane, at a distance of 1 metre from the enclosure walls or any other metallic structure.
- Both contact and air discharge are applied (as applicable) to:
  - all faces and access points of the enclosure,
  - the vertical coupling plane (VCP),
  - the horizontal coupling plane (HCP).
- All coupling planes are connected to the ground reference point via a 470kΩ resistor located at each end.
- Contact discharge was made to all conductive surfaces and to the coupling planes. Air discharge was made only at the insulating surfaces.
- Discharges made to the HCP and VCP were applied on each side of the EUT. Discharges made to the VCP were applied to the center of one vertical edge of the coupling plane. The VCP (0.5 metre x 0.5 metre), was placed parallel to and positioned 0.1 metre from the EUT.
- The test voltage was increased from the minimum to the selected test level, in order to determine any threshold of failure.
- At least 10 single discharges were applied in both positive and negative polarities.

See photograph in Appendix B of a typical test configuration.

### 5.2 Discharge Point

Indirect contact discharges were made to the horizontal coupling plane (HCP) at the following positions:

- Front & Rear
- Right and Left hand sides

Indirect contact discharges were made to the vertical coupling plane (VCP) at the following positions:

- Front & Rear
- Right and Left hand side

Direct contact discharges were applied to the following points;

- All over the EUT enclosure

Direct air discharges were applied to the following points:

- Front of the EUT
- Rear of the EUT

### 5.3 Test Results

Contact Discharges	ESD Voltage	Observation	Result
Horizontal Coupling Plane	±6.0 kV	See comment	Pass
Vertical Coupling Plane	±6.0 kV	No effect	Pass
Direct	±6.0 kV	No effect	Pass

Level 1 = ±2 kV, Level 2 = ±4 kV, Level 3 = ±6 kV, Level 4 = ±8 kV

Air Discharges	ESD Voltage	Observation	Result
Insulating Surface	±8.0 kV	No effect	Pass

Level 1 = ±2 kV, Level 2 = ±4 kV, Level 3 = ±8 kV, Level 4 = ±15 kV

**Comments:** When +6kV (contact) was discharged on the Horizontal Coupling Plane it caused the EUT to glitch. This glitch is believed to be a reset of the EUT. After the test the EUT operated as expected.

**Conclusion:** The EUT complied.

Climatic Conditions	
Temperature:	20°C (15°C to 35°C)
Humidity:	45% (30% to 60%)

## 6. Radiated RF Immunity – IEC 61000-4-3: 2002

### 6.1 Test Procedure

Prior to testing, a CW electric field was calibrated at a distance of 3 metres for the frequency band 80MHz to 1GHz and 2.5 metres for the frequency band 1GHz to 2.5GHz, from the transmitting antenna using an orthogonal electric field probe. The drive level to the amplifier was recorded using immunity software and stored as a look up table.

For IEC 61000-4-3, the frequency range of 80MHz to 2500MHz was swept incrementally using 1% step sizes, whilst a leveled RF field of 3V/m (cw calibration) was maintained.

During actual testing, the orthogonal electric field probe was replaced by the EUT and the recorded electric fields stored as a lookup table were replayed back.

Once again the frequency range of 80MHz to 2500MHz was swept incrementally using 1% step sizes, however this time 80% AM @ 1kHz with a dwell time of 2 seconds was added to the calibrated RF field of 3V/m (cw calibration).

Both horizontal and vertical antenna polarizations were used to radiate the EUT in turn.

See photograph in Appendix B of a typical test configuration.

## 6.2 Test Results

Field Level	EUT Orientation & Operating Mode	Polarization	Result
3V/m	Front panel – Normal operating mode	Vertical	Pass
3V/m	Front panel – Normal operating mode	Horizontal	Pass

Frequency Band: 80 – 2500MHz with 80% AM @ 1kHz

**Comments:** No degradation or malfunction was observed

**Conclusion:** The EUT complied.

Climatic Conditions	
Temperature:	22°C
Humidity:	41%

## 7. Power Frequency Magnetic Immunity – IEC 61000-4-8: 1994

### 7.1 Test Procedure

The EUT was placed on a wooden table, 0.4 metres above the ground reference plane for table top equipment, or 0.1 metres above the ground reference plane for floor mounted equipment.

The EUT was subjected to a 50Hz, 3A/m, magnetic field using an induction coil of 1 metre x 1 metre. The induction coil was rotated by 90° in order to expose the EUT to the test field in different orthogonal orientations. All cables were also exposed to the magnetic field for 1 metre of their length.

### 7.2 Test Results

Axis	Magnetic Field Strength A/m	Observation	Result
X	3	No effect	Pass
Y	3	No effect	Pass
Z	3	No effect	Pass

**Comments:** No degradation or malfunction was observed.

**Conclusion:** The EUT complied.

Climatic Conditions	
Temperature:	18°C (15°C to 35°C)
Humidity:	51% (30% to 60%)

## APPENDIX A

### EMC LABORATORY TEST EQUIPMENT

(Immunity testing)

Inv.	Equipment	Make	Model No	Serial No	Calibration		Equip Used
					Date	Type	
467	1-1000MHz RF Amplifier	Amplifier Research	100W1000	20724	-	V	•
597	TWT RF Amplifier	HUGHES	1177H10F000	112	-	V	•
608	TWT RF Amplifier	HUGHES	1177H01F000	-	-	V	•
310	E-Field Probe	Holaday	HI-4422	89862	Aug-05	E	•
501	E-Field Probe	Holaday	HI-4450	96627	Mar-06	E	•
560	Mainframe Field Monitor	Amplifier Research	FM 5004	21422	-	V	•
269	Biconilog Antenna	EMCO	3143	1026	-	V	•
209	Double Ridged Horn Antenna	EMCO	3115	3945	Jul-06		•
507	Signal Generator	Rohde & Schwarz	SMY 02	847510/038	Oct-06	I	•
638	Synthesized Signal Generator	Hewlett Packard	8673B	2938A01504	-	V	•
471	Transient 1000 System	EMC Partner	TRA1H01B	TRA1000-215	-	V	•
475	Magnetic Test Coil	EMC Partner	TRA 1Z44B	MF1000-26	-	V	•
473	ESD Mouse	EMC Partner	TRA 1Z02A	ESD 101-195	-	V	•
409	Digital Oscilloscope	Tektronix	TDS 380	B012299	Aug-06	V	•

**V** = Verification of operation against an internal reference  
**I** = Internal calibration against a NATA traceable standard  
**E** = External calibration by a NATA endorsed facility

## APPENDIX B

### PHOTOGRAPHS

Photograph	Description
1	Radiated RF Immunity Setup – 80MHz to 1GHz
2	Radiated RF Immunity Setup – 1GHz to 2.5GHz
3	Verification check before and after RF Immunity
4	Radiated Magnetic Field Immunity – X axis
5	Radiated Magnetic Field Immunity – Y axis
6	Radiated Magnetic Field Immunity – Z axis
7	ESD Contact Discharge – Horizontal Coupling Plane
8	ESD Air Discharge
9	Verification check before and after ESD
10	Front view of the EUT
11	Rear view of the EUT
12	Label
13	Internal Circuit Board Layout – Component Side
14	Internal Circuit Board Layout – Foil Side



Photograph 1.



Photograph 2.



Photograph 3.



Photograph 4.



Photograph 5.



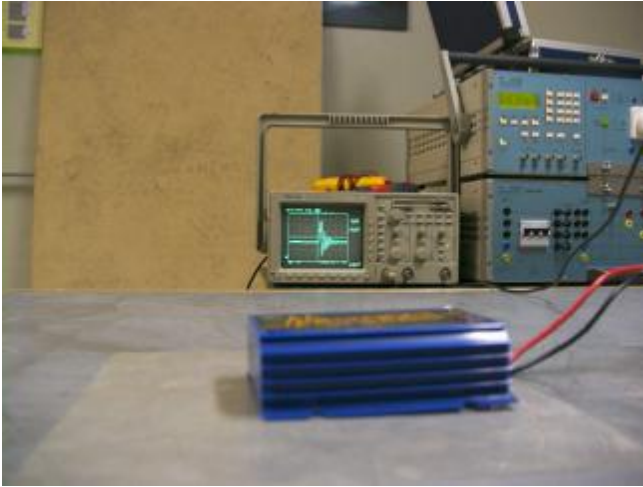
Photograph 6.



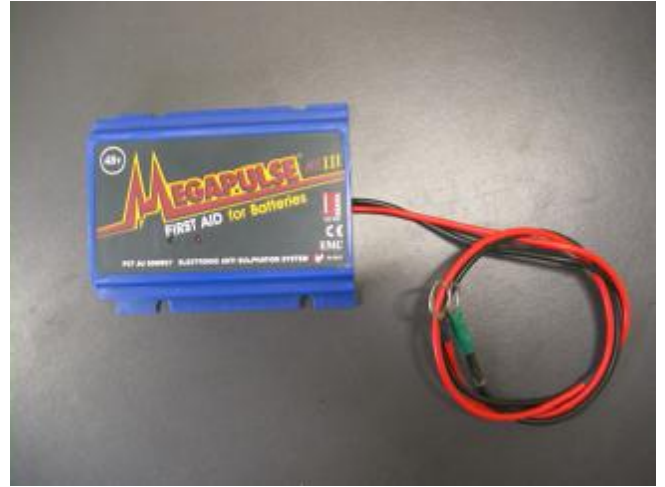
Photograph 7.



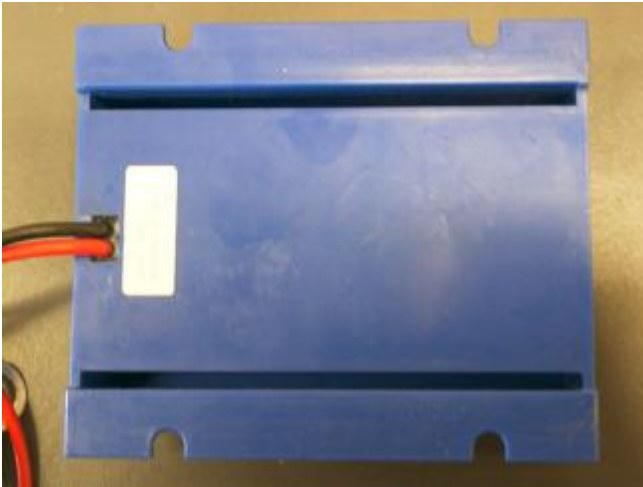
Photograph 8.



Photograph 9.



Photograph 10.



Photograph 11.



Photograph 12.

Photograph 13 (removed for patent protection purposes).

Photograph 14 (removed for patent protection purposes).