

TEST REPORT FROM RFI GLOBAL SERVICES LTD

Test of: Codman NeuroSciences Sarl.
MedStream™ Infusion Control Unit (Transceiver)

To: FCC Part 15.225

Test Report Serial No:
RFI/MPTE2/RP48039JD05A
Supersedes Test Report Serial No:
RFI/MPTE1/RP48039JD05A

This Test Report Is Issued Under The Authority Of Andrew Brown, Operations Manager: 	
Tested By: Raul Recio  pp	Checked By: Steven Wong 
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1. Client Information

Company Name:	Codman NeuroSciences Sarl.
Address:	Rue Girardet 29 Case Postale 128 Le Locle Switzerland CH-2400
Contact Name:	Mr A. Ginggen

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2. Equipment Under Test (EUT)

The following information (with the exception of the Date of Receipt) has been supplied by the client:

2.1. Identification of Equipment Under Test (EUT)

Brand Name:	Codman NeuroSciences Sarl (MedStream Control Unit (CU))
Model Name or Number:	91-4205
Serial Number:	05M01043 (used for all idle mode testing)
Hardware Revision:	PDL (MR-1000093, Rev 15 see <i>Appendices 4 & 5 for full information</i>)
Software Revision:	PS-100014
Software Version Number:	Rev. 1
FCC ID:	T9I-914205
Country of Manufacture:	Switzerland
Date of Receipt:	21 February 2006

Brand Name:	Codman NeuroSciences Sarl (MedStream Control Unit (CU))
Model Name or Number:	91-4205
Serial Number:	05M01027 (used for all transmitter tests except AC conducted emissions)
Hardware Revision:	PDL (MR-1000093, Rev 15 see <i>Appendices 4 & 5 for full information</i>)
Software Revision:	PS-100467
Software Version Number:	Rev. 15
FCC ID:	T9I-914205
Country of Manufacture:	Switzerland
Date of Receipt:	21 February 2006

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Identification of Equipment Under Test (EUT) (Continued)

Brand Name:	Codman NeuroSciences Sarl (MedStream Control Unit (CU))
Model Name or Number:	91-4205
Serial Number:	*05M01035 (used for transmitter AC mains conducted emissions only)
Hardware Revision:	PDL (MR-1000093, Rev 15 see <i>Appendices 4 & 5 for full information</i>)
Software Revision:	PS-100467
Software Version Number:	Rev. 15
FCC ID:	T9I-914205
Country of Manufacture:	Switzerland
Date of Receipt:	21 February 2006

**EUT was fitted with a 50 ohm termination instead of an antenna to facilitate testing of AC mains conducted emissions.*

Brand Name:	Mascott (MedStream CU Charger)
Model Name or Number:	2241
Country of Manufacture:	Norway
Date of Receipt:	21 February 2006

Brand Name:	ARP DATACON (MedStream CU USB Cable)
Model Name or Number:	204286-001
Country of Manufacture:	Taiwan
Date of Receipt:	21 February 2006

Note: The charger and the USB cable are included in the carrying case for the CU and form an integral part of the EUT.

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2.2. Description of EUT

The equipment under test is an external portable medical device that functions to interrogate / program the implantable infusion pump non-invasively. The MedStream™ Infusion Control Unit communicates with the pump through radio frequency telemetry and can be connected to a printer for documentation purpose.

2.3. Modifications Incorporated in the EUT

During the course of testing the EUT was not modified except for the performance of the AC mains conducted emissions test in transmit mode where the antenna was disconnected and terminated with a 50 ohms load. This is allowed by the FCC for this measurement to ensure pick up of the 13.56 MHz fundamental from the EUTs onto the power cord is minimised to ensure accuracy of measurement.

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2.4. Additional Information Related to Testing

Power Supply Requirement:	Nominal 110 V 60 Hz AC mains supply Internal battery supply of nominal 10.8 V		
Intended Operating Environment:	Medical		
Equipment Category:	IT Equipment		
Type of Unit:	Portable (Standalone battery powered device)		
Interface Ports:	Enclosure Printer Interface PC Interface (Service Port, not user accessible, used only to set EUT into continuous transmit mode) AC Mains		
Transmit Frequency Range:	13.56 MHz		
Transmit Channels Tested:	Channel ID	Channel Number	Channel Frequency (MHz)
	Single Frequency	1	13.56
Highest Unintentionally Generated Frequency:	13.56 MHz		
Receive Frequency Range:	13.56 MHz		
Receive Channels Tested:	Channel ID	Channel Number	Channel Frequency (MHz)
	Single Frequency	1	13.56
Highest Unintentionally Generated Frequency:	13.56 MHz		
Highest Fundamental Frequency:	13.56 MHz		
Occupied Bandwidth:	3.75 kHz		

2.5. Support Equipment

No support equipment was used to exercise the EUT during testing.

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3. Test Specification, Methods and Procedures

3.1. Test Specifications

Reference:	FCC Part 15 Subpart B: 2004 (Sections 15.225).
Title:	Code of Federal Regulations, Part 15 (47CFR215) Radio Frequency Devices.

3.2. Methods and Procedures

The methods and procedures used were as detailed in:

ANSI/TIA-603-B-2003

Land Mobile Communications Equipment, Measurements and performance Standards

ANSI C63.2 (1987)

Title: American National Standard for Instrumentation - Electromagnetic noise and field strength.

ANSI C63.4 (2001)

Title: American National Standard Methods of Measurement of Electromagnetic Emissions from Low Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.

ANSI C63.5 (1988)

Title: American National Standard for the Calibration of antennas used for Radiated Emission measurements in Electromagnetic Interference (EMI) control.

ANSI C63.7 (1988)

Title: American National Standard Guide for Construction of Open Area Test Sites for performing Radiated Emission Measurements.

CISPR 16-1: (1999)

Title: Specification For Radio Disturbance and Immunity Measuring Apparatus and Methods. Part 1: Radio Disturbance and Immunity Measuring Apparatus.

DA00-705 (2000)

Title: Filing and Frequency Measurement Guidelines for Frequency Hopping Spread Spectrum Systems.

3.3. Definition of Measurement Equipment

The measurement equipment used complied with the requirements of the standards referenced in the Methods & Procedures section above. Appendix 1 contains a list of the test equipment used.

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4. Deviations from the Test Specification

None.

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5. Operation of the EUT During Testing

5.1. Operating Modes

The EUT was tested in the following operating modes, unless otherwise stated.

For all transmitter tests, the EUT was set to transmit continuously at the highest output power.

For all Idle Mode tests, the EUT was set to Idle Mode only.

5.2. Configuration and Peripherals

The EUT was tested in the following configuration:

All EUTs were configured with two USB cables connected (with one of the cable being terminated by a USB dummy load) and powered by an external 110 V AC mains supply via the AC charger.

For all transmit tests (Except AC Mains Conducted Emissions), all testing were performed with the EUT serial number 05M01027.

The transmitting AC mains conducted emissions test was performed with the EUT, serial number 05M01035. The antenna was disconnected and terminated with a 50 ohms load.

All receiver / Standby mode tests were performed with EUT, serial number 05M01043.

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6. Summary of Test Results

Range of Measurements	Specification Reference	Port Type	Serial Number of Control Unit Tested	Compliance Status
Receiver AC Mains Conducted Emissions (150 kHz to 30 MHz)	C.F.R. 47 FCC Part 15: 2004 Section 15.107	AC Mains	05M01043	Complied
Receiver Radiated Spurious Emissions	C.F.R. 47 FCC Part 15: 2004 Section 15.109	Enclosure	05M01043	Complied
Transmitter AC Mains Conducted Emissions (150 kHz to 30 MHz)	C.F.R. 47 FCC Part 15: 2004 Section 15.207	AC Mains	05M01035	Complied
Transmitter Fundamental Fieldstrength	C.F.R. 47 FCC Part 15: 2004 Section 15.225(a)	Antenna	05M01027	Complied
Transmitter Radiated Spurious Emissions	C.F.R. 47 FCC Part 15: 2004 Sections 15.225 & 15.209	Enclosure	05M01027	Complied
Transmitter Band Edge Radiated Emissions	C.F.R. 47 FCC Part 15: 2004 Section 15.225(b)	Antenna	05M01027	Complied
Transmitter 20 dB Bandwidth	C.F.R. 47 FCC Part 2: 2004 Section 2.1049	Antenna	05M01027	Complied
Transmitter Frequency Stability (Temperature & Voltage Variation)	C.F.R. 47 FCC Part 15: 2004 Section 15.225(e)	Antenna	05M01027	Complied

6.1. Location of Tests

All the measurements described in this report were performed at the premises of RFI Global Services Ltd, Ewhurst Park, Ramsdell, Basingstoke, Hampshire, RG26 5RQ.
RFI Global Services Ltd, Ashwood Park, Ashwood Way, Basingstoke, Hampshire, RG23 8BG.

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7. Measurements, Examinations and Derived Results

7.1. General Comments

7.1.1. This section contains test results only.

7.1.2. Measurement uncertainties are evaluated in accordance with current best practice. Our reported expanded uncertainties are based on standard uncertainties, which are multiplied by an appropriate coverage factor to provide a statistical confidence level of approximately 95%. Please refer to Section 8 for details of measurement uncertainties.

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7.2. Receiver AC Mains Conducted Emissions: Section 15.107

7.2.1. The EUT was configured for AC conducted emissions measurements as described in Section 9 of this report.

7.2.2. Tests were performed to identify the maximum emission levels on the AC mains line of the EUT.

Results:

Quasi-Peak Detector Measurements on Live and Neutral Lines

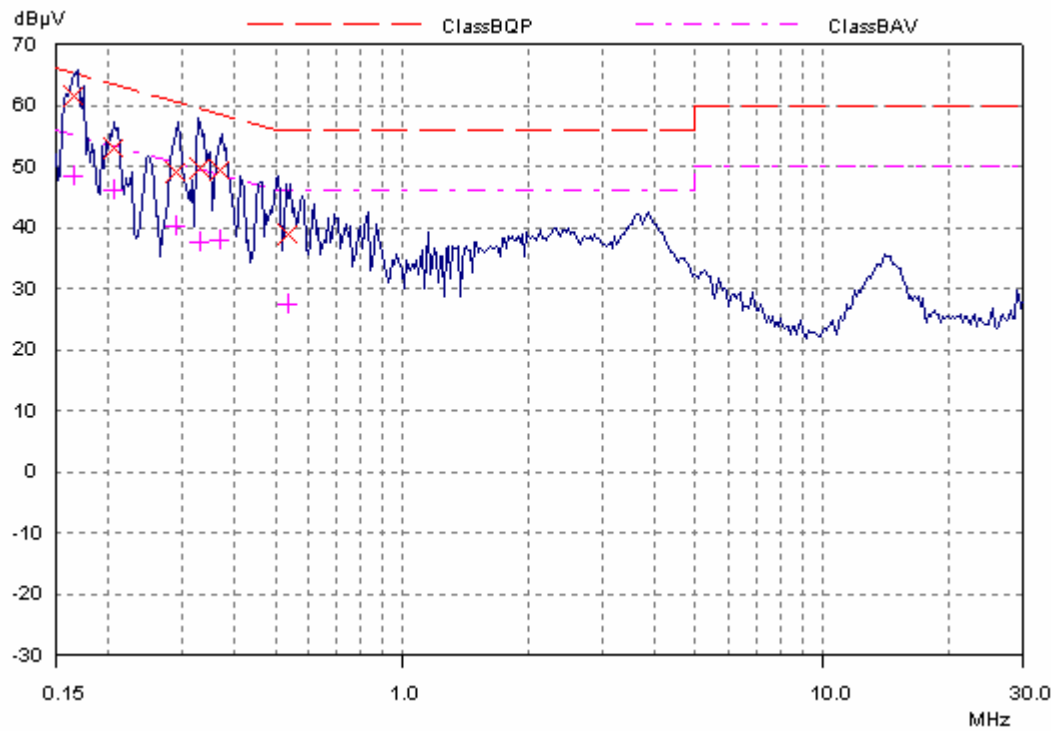
Frequency (MHz)	Line	Level (dBμV)	Limit (dBμV)	Margin (dB)	Result
0.16475	Neutral	61.63	65.22	3.59	Complied
0.20677	Live	52.84	63.33	10.49	Complied
0.29057	Neutral	49.11	60.51	11.40	Complied
0.32953	Neutral	49.56	59.46	9.90	Complied
0.37137	Neutral	49.21	58.47	9.26	Complied
0.53771	Neutral	38.90	56.00	17.10	Complied

Average Detector Measurements on Live and Neutral Lines

Frequency (MHz)	Line	Level (dBμV)	Limit (dBμV)	Margin (dB)	Result
0.16475	Neutral	48.24	55.22	6.98	Complied
0.20677	Live	46.21	53.33	7.12	Complied
0.29057	Neutral	40.22	50.51	10.29	Complied
0.32953	Neutral	37.53	49.46	11.93	Complied
0.37137	Neutral	37.86	48.47	10.61	Complied
0.53771	Neutral	27.47	46.00	18.53	Complied

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Receiver AC Mains Conducted Emissions: Section 15.107 (Continued)



Note: This plot is a pre-scan and for indication purposes only. For final measurements, see accompanying tables.

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7.3. Receiver Radiated Spurious Emissions: Section 15.109

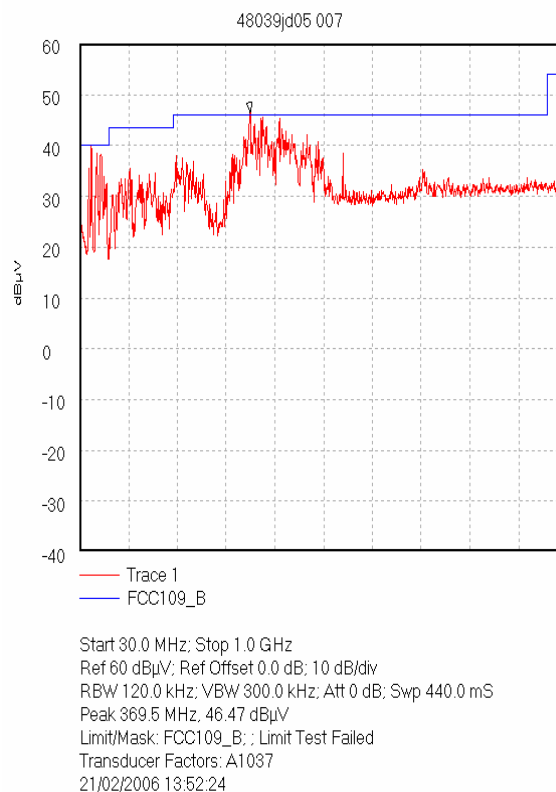
7.3.1. Electric Field Strength Measurements (Frequency Range: 30 to 1000 MHz)

7.3.1.1. The EUT was configured for radiated emissions testing as described in Section 9 of this report.

7.3.1.2. Tests were performed to identify the maximum receiver or standby radiated emission levels.

Results:

Frequency (MHz)	Antenna Polarity	Q-P Level (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)	Result
52.727	Vert.	18.9	40.0	21.1	Complied
62.750	Vert.	21.2	40.0	18.8	Complied
220.280	Vert.	38.6	46.0	7.4	Complied
367.820	Vert.	28.4	46.0	17.6	Complied
430.610	Vert.	30.5	46.0	15.5	Complied



Note: This plot is a pre-scan and for indication purposes only. For final measurements, see accompanying tables.

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7.4. Transmitter AC Mains Conducted Emissions: Section 15.207

7.4.1. The EUT was configured for AC conducted emissions measurements as described in Section 9 of this report.

7.4.2. Tests were performed to identify the maximum emission levels on the AC mains line of the EUT.

Results:

Quasi-Peak Detector Measurements on Live and Neutral Lines

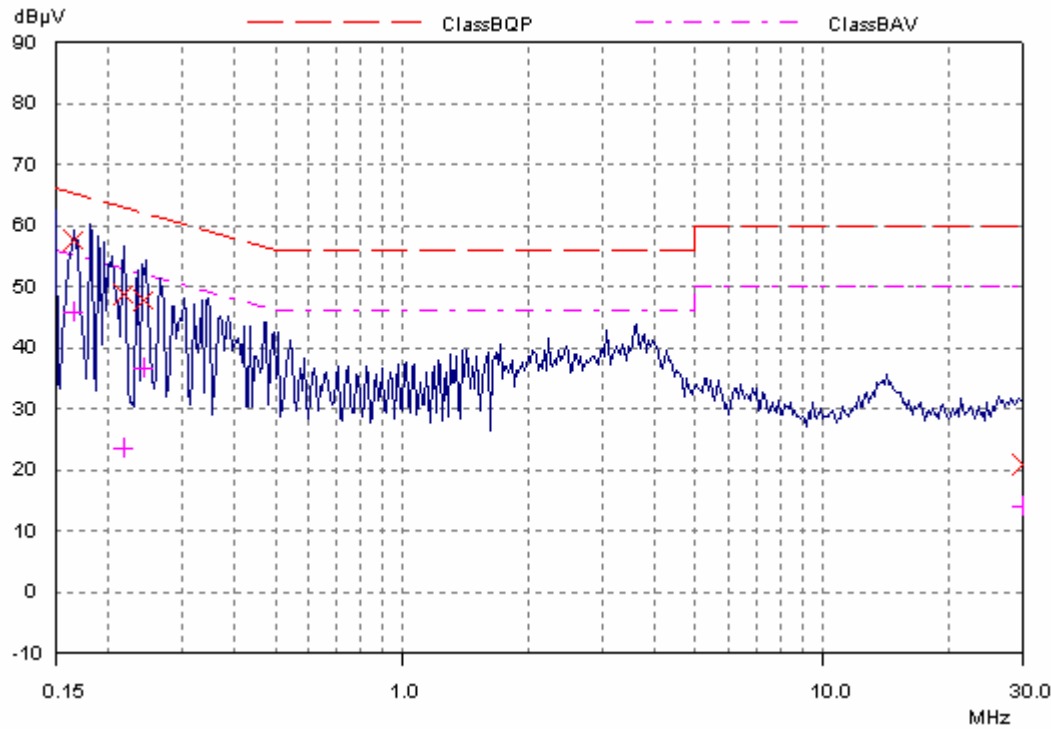
Frequency (MHz)	Line	Level (dBμV)	Limit (dBμV)	Margin (dB)	Result
0.16558	Live	57.64	65.18	7.54	Complied
0.21719	Neutral	48.55	62.93	14.38	Complied
0.24302	Live	47.71	61.99	14.28	Complied
29.93957	Live	20.82	60.00	39.18	Complied

Average Detector Measurements on Live and Neutral Lines

Frequency (MHz)	Line	Level (dBμV)	Limit (dBμV)	Margin (dB)	Result
0.16558	Live	45.86	55.18	9.32	Complied
0.21719	Neutral	23.48	52.93	29.45	Complied
0.24302	Neutral	36.66	51.99	15.33	Complied
29.93957	Live	13.81	50.00	36.19	Complied

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Transmitter AC Mains Conducted Emissions: Section 15.207 (Continued)



Note: This plot is a pre-scan and for indication purposes only. For final measurements, see accompanying tables.

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7.5. Transmitter Fundamental Fieldstrength: Section 15.225 (a)

7.5.1. The EUT was configured for transmitter radiated emissions testing as described in Section 9 of this report.

7.5.2. Tests were performed to identify the maximum fieldstrength of the fundamental frequency.

7.5.3. The limit is specified at a test distance of 30 metres. However as specified by section 15.31 (f(2)), measurements may be performed at a closer distance, and the measured level corrected to the specified measurement distance by using the square of an inverse linear distance extrapolation factor (40 dB/decade). *In this case the measurement was obtained using a peak detector during the pre-scan at a distance of 3 metres during which the antenna was orientated for maximum. A known correlation factor between the pre-scan environment and the OATS was used to extrapolate the result to a 10 metres distance and thereafter the inverse linear distance extrapolation factor was applied to 30 metres.*

Results:

Battery Powered

Frequency (MHz)	Antenna Polarity	Q-P Level (dBµV/m)	Limit at 30 metres (dBµV/m)	Margin (dB)	Result
13.56	Vert.	71.3	84.0	12.7	Complied

AC Powered

Frequency (MHz)	Antenna Polarity	Input Voltage (AC)	Q-P Level (dBµV/m)	Limit at 30 metres (dBµV/m)	Margin (dB)	Result
13.56	Vert.	110.0	71.3	84.0	12.7	Complied
13.56	Vert.	93.5	75.6	84.0	8.4	Complied
13.56	Vert.	126.5	73.9	84.0	10.1	Complied

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7.6. Transmitter Radiated Spurious Emissions: Sections 15.225 & 15.209

7.6.1. Electric Field Strength Measurements (Frequency Range: 9 kHz to 1000 MHz)

7.6.1.1. The EUT was configured for radiated emissions testing as described in Section 9 of this report.

7.6.1.2. Tests were performed to identify the maximum radiated spurious emission levels.

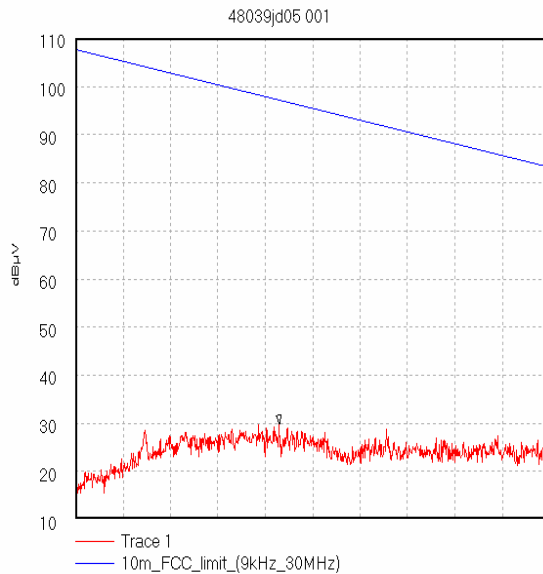
7.6.1.3. Limits below 30 MHz are specified at test distance of 30 metres, whilst below 0.49 MHz they are specified at a test distance of 300 metres. However as specified by section 15.31 (f)(2), measurements may be performed at a closer distance, and the measured level corrected to the specified measurement distance by using the square of an inverse linear distance extrapolation factor (40 dB/decade).

Results:

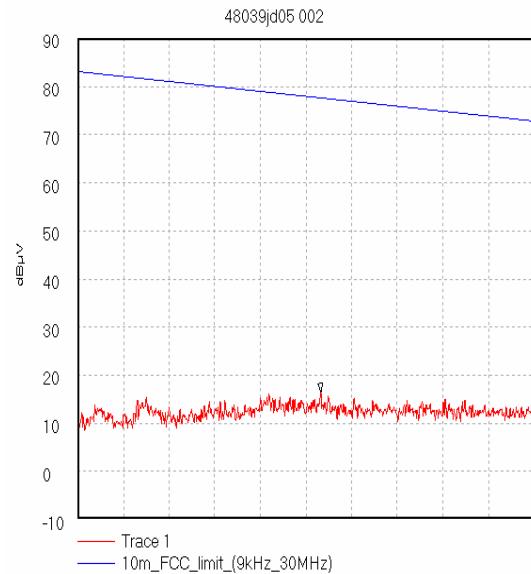
Frequency (MHz)	Antenna Polarity	Q-P Level (dBµV/m)	Limit (dBµV/m)	Measurement Distance (m)	Margin (dB)	Result
70.906	Vert.	27.8	40.0	3	12.2	Complied
125.293	Vert.	23.2	43.5	3	20.3	Complied
298.333	Horiz.	42.7	46.0	3	3.3	Complied
371.591	Vert.	28.7	46.0	3	17.3	Complied
528.857	Horiz.	34.3	46.0	3	11.7	Complied
840.710	Horiz.	40.4	46.0	3	5.6	Complied

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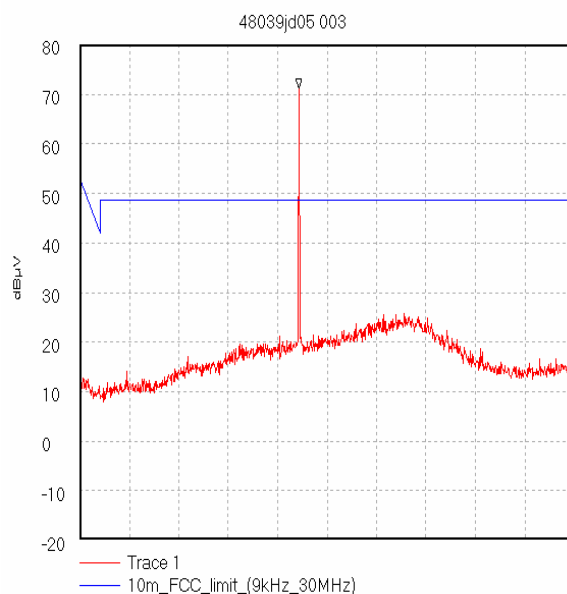
Transmitter Radiated Spurious Emissions: Sections 15.225 & 15.209 (Continued)



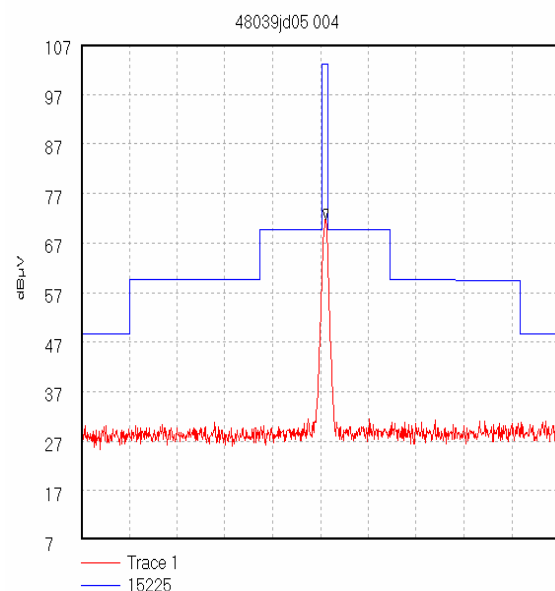
Start 9.0 kHz; Stop 150.0 kHz
Ref 110 dBµV; Ref Offset 0.0 dB; 10 dB/div
RBW 1000.0 Hz; VBW 10.0 kHz; Att 40 dB; Swp 900.0 mS
Peak 69.63 kHz, 29.84 dBµV
Limit/Mask: 10m_FCC_limit_(9kHz_30MHz); ; Limit Test Passed
Transducer Factors: 3mto10m_9k_490k
21/02/2006 09:48:25



Start 150.0 kHz; Stop 490.0 kHz
Ref 90 dBµV; Ref Offset 0.0 dB; 10 dB/div
RBW 9.0 kHz; VBW 10.0 kHz; Att 10 dB; Swp 40.0 mS
Peak 331.33333 kHz, 16.47 dBµV
Limit/Mask: 10m_FCC_limit_(9kHz_30MHz); ; Limit Test Passed
Transducer Factors: 3mto10m_9k_490k
21/02/2006 09:51:34



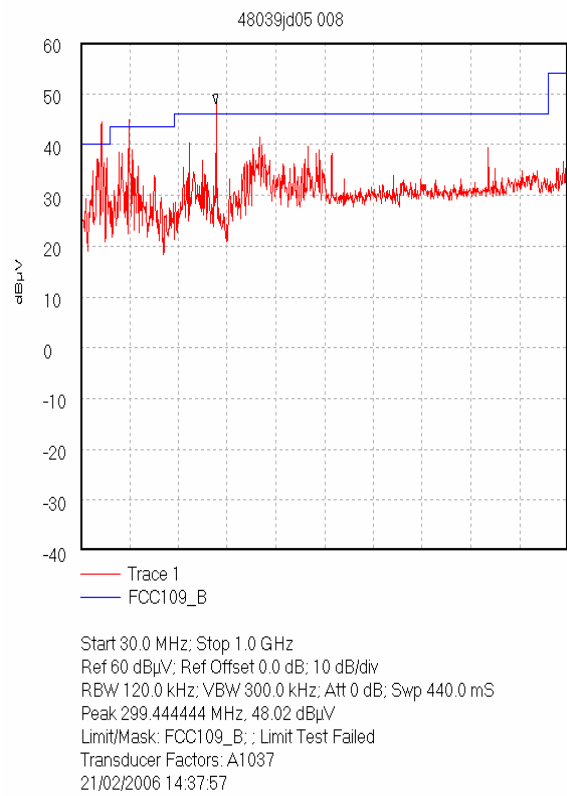
Start 490.0 kHz; Stop 30.0 MHz
Ref 80 dBµV; Ref Offset 0.0 dB; 10 dB/div
RBW 9.0 kHz; VBW 10.0 kHz; Att 5 dB; Swp 2.4 S
Peak 13.572767 MHz, 71.17 dBµV
Limit/Mask: 10m_FCC_limit_(9kHz_30MHz); ; Limit Test Failed
Transducer Factors: 3mto10m_490k_30M
21/02/2006 09:55:05



Start 13.0 MHz; Stop 14.1 MHz
Ref 107 dBµV; Ref Offset 0.0 dB; 10 dB/div
RBW 9.0 kHz; VBW 10.0 kHz; Att 10 dB; Swp 100.0 mS
Peak 13.562222 MHz, 71.78 dBµV
Limit/Mask: 15225; ; Limit Test Passed
Transducer Factors: 3mto10m_490k_30M
21/02/2006 10:18:09

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Transmitter Radiated Spurious Emissions: Sections 15.225 & 15.209 (Continued)



Note: These plots are pre-scans and for indication purposes only. For final measurements, see accompanying tables.

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7.7. Transmitter Radiated Emissions at Band Edges: Section 15.225 (b)

7.7.1. The EUT was configured for transmitter radiated emissions testing described in Section 9 of this report.

7.7.2. Tests were performed to identify the maximum emissions level at the band edges of the frequency band that the EUT will operate over.

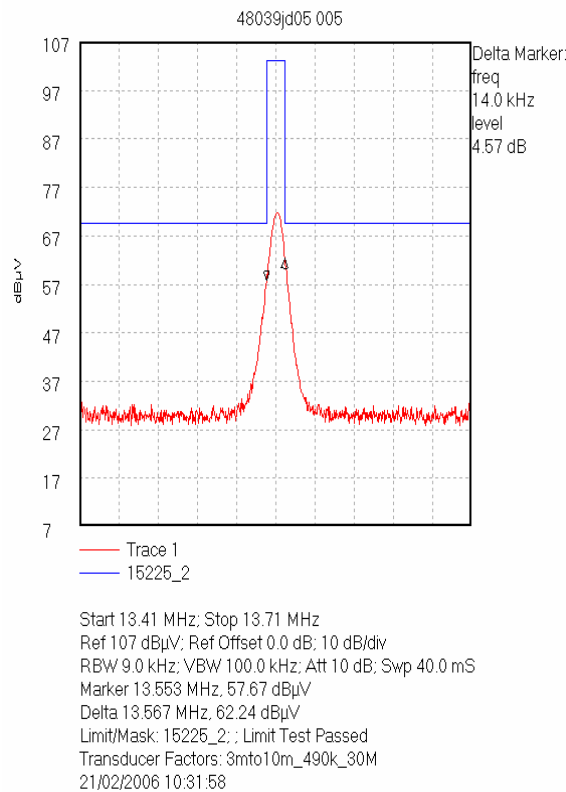
Results:

Bottom Band Edge

Frequency (MHz)	Q-P Level (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)	Result
13.553	38.6	50.5	11.9	Complied

Top Band Edge

Frequency (MHz)	Q-P Level (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)	Result
13.567	43.1	50.5	7.4	Complied



Note: This plot is a pre-scan and for indication purposes only. For final measurements, see accompanying tables.

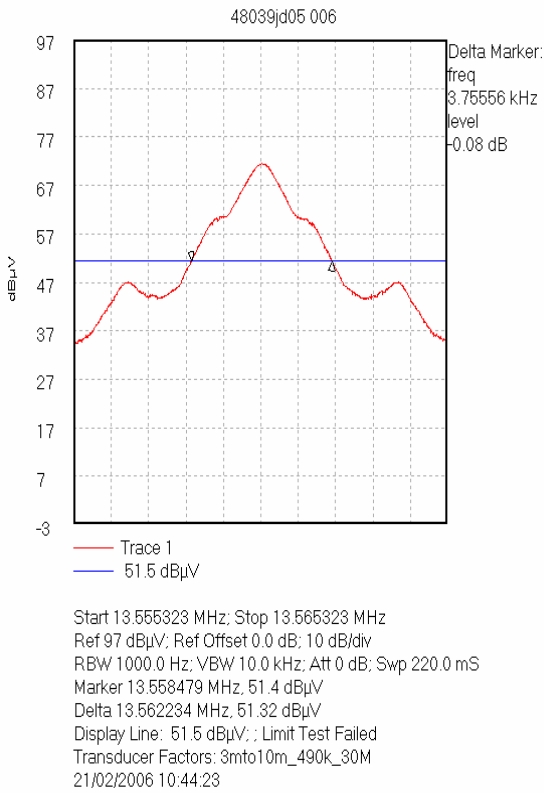
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7.8.Transmitter 20 dB Bandwidth: Section 2.1049

7.8.1. The EUT was configured for 20 dB bandwidth measurements as described in Section 9 of this report.

7.8.2. Tests were performed to identify the 20 dB bandwidth.

Transmitter 20 dB Bandwidth (kHz)
3.75



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7.9. Transmitter Frequency Stability (Temperature & Voltage Variation): **Section 15.225 (e)**

7.9.1. The EUT was configured for frequency stability measurements as described in Section 9 of this report.

7.9.2. Tests were performed to identify the maximum frequency error of the EUT with variations in ambient temperature.

7.9.3. Tests were performed to identify the maximum frequency error of the EUT with variations in nominal operating voltage at an ambient temperature of 20°C.

Results:

Temp (°C)	Nominal Frequency	Measured Frequency	Frequency Error (Hz)	Frequency Error (%)	Limit (%)	Margin (%)	Result
-20	13.56	13.560300	300	0.0022	0.01	0.0078	Complied
-10	13.56	13.560285	285	0.0021	0.01	0.0078	Complied
0	13.56	13.560264	264	0.0019	0.01	0.0081	Complied
10	13.56	13.560278	278	0.0020	0.01	0.0080	Complied
20	13.56	13.560291	291	0.0021	0.01	0.0079	Complied
30	13.56	13.560257	257	0.0019	0.01	0.0081	Complied
40	13.56	13.560264	264	0.0019	0.01	0.0081	Complied
50	13.56	13.560264	264	0.0019	0.01	0.0081	Complied

Supply Voltage (V)	Nominal Frequency	Measured Frequency	Frequency Error (Hz)	Frequency Error (%)	Limit (%)	Margin (%)	Result
93.5	13.56	13.560317	317	0.0023	0.01	0.0077	Complied
110.0	13.56	13.560291	291	0.0021	0.01	0.0079	Complied
126.5	13.56	13.560317	317	0.0023	0.01	0.0077	Complied

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8. Measurement Uncertainty

8.1. No measurement or test can ever be perfect and the imperfections give rise to error of measurement in the results. Consequently, the result of a measurement is only an approximation to the value of the measurand (the specific quantity subject to measurement) and is only complete when accompanied by a statement of the uncertainty of the approximation.

8.2. The expression of uncertainty of a measurement result allows realistic comparison of results with reference values and limits given in specifications and standards.

8.3. The uncertainty of the result may need to be taken into account when interpreting the measurement results.

8.4. The reported expanded uncertainties below are based on a standard uncertainty multiplied by an appropriate coverage factor, such that a confidence level of approximately 95% is maintained. For the purposes of this document “approximately” is interpreted as meaning “effectively” or “for most practical purposes”.

Measurement Type	Range	Confidence Level (%)	Calculated Uncertainty
AC Conducted Spurious Emissions	0.15 MHz to 30 MHz	95%	+/- 3.25 dB
Radiated Spurious Emissions	30 MHz to 1000 MHz	95%	+/- 5.26 dB
Radiated Spurious Emissions	1 GHz to 18 GHz	95%	+/- 4.18 dB

8.5. The methods used to calculate the above uncertainties are in line with those recommended within the various measurement specifications. Where measurement specifications do not include guidelines for the evaluation of measurement uncertainty, the published guidance of the appropriate accreditation body is followed.

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9. Measurement Methods

9.1. AC Mains Conducted Emissions

AC mains conducted emissions measurements were performed in accordance with the standard, against appropriate limits for each detector function.

The test was performed in a shielded enclosure with the equipment arranged as detailed in the standard on a wooden bench using the floor of the screened enclosure as the ground reference plane. The EUT was powered with 110V 60 Hz AC mains supplied via a Line Impedance Stabilisation Network (LISN).

Initial measurements in the form of swept scans covering the entire measurement band were performed in order to identify frequencies on which the EUT was generating interference. In order to minimise the time taken for these swept measurements, a Peak detector was used in conjunction with the appropriate detector IF measuring bandwidths (see table below). Repetitive scans were performed to allow for emissions with low repetition rates, and the duty cycle of the EUT. The test configuration was the same for the initial scans as for the final measurements.

Following the initial scans, a graph was produced giving an overview of the emissions from the EUT plotted against the appropriate specification limit. A tolerance line was set 6 dB below the specification limit and levels above the tolerance line were re-tested (at individual frequencies) using the appropriate detector function.

The test equipment settings for conducted emissions measurements were as follows:

Receiver Function	Initial Scan	Final Measurements
Detector Type:	Peak	Quasi-Peak (CISPR)/Average
Mode:	Max Hold	Not applicable
Bandwidth:	10 kHz	9 kHz
Amplitude Range:	60 dB	20 dB
Measurement Time:	Not applicable	> 1 s
Observation Time:	Not applicable	> 15 s
Step Size:	Continuous sweep	Not applicable
Sweep Time:	Coupled	Not applicable

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9.2. Receiver Radiated Emissions

Radiated emissions measurements were performed in accordance with the standard, against appropriate limits for each detector function.

Initial pre-scans covering the entire measurement band from the lowest generated frequency declared up to the upper frequency detailed in Section 15.33 were performed within a screened chamber in order to identify frequencies on which the EUT was generating interference. This determined the frequencies on which the EUT should be re-measured in full on the open area test site. In order to minimise the time taken for the swept measurements, a Peak detector was used in conjunction with the appropriate detector IF measuring bandwidth (see table below). Repetitive scans were performed to allow for emissions with low repetition rates, and for the duty cycle of the EUT. The test configuration was the same for the initial scans as for the final measurements.

The initial scans were performed using an antenna height of 1.5 m and a measurement distance of 3 m. Following the initial scans, graphs were produced giving an overview of the emissions from the EUT plotted against the appropriate specification limit. A tolerance line was set 6 dB below the specification limit and levels above the tolerance line were re-tested on the open area test site, at the appropriate distance, using a measuring receivers with a Quasi-Peak (or Average) detector (below 1000 MHz), where applicable, for measurements above 1000 MHz average and peak detectors were used.

For the main (final) measurements the EUT was arranged on a non-conducting table on an open area test site, as detailed in the specification.

All measurements on the open area test site were performed using broadband antennas.

On the open area test site, at each frequency where a signal was found, the levels were maximised by initially rotating the turntable through 360° and then varying the antenna height between 1 m and 4 m. At this point, any signals found to be between the limit and a level 6 dB below it were further maximised by changing the configuration of the EUT, e.g. re-routing cables to peripherals and moving peripherals with respect to the EUT.

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Radiated Emissions (Continued)

The test equipment settings for radiated emissions measurements were as follows:

Receiver Function	Initial Scan (Below 30 MHz)	Final Measurements (Below 30 MHz)
Detector Type:	Peak	Quasi-Peak (CISPR) or Average
Mode:	Max Hold	Not applicable
Bandwidth:	9 kHz	9 kHz
Amplitude Range:	60 dB	20 dB
Measurement Time:	Not applicable	> 1 s
Observation Time:	Not applicable	> 15 s
Step Size:	Continuous sweep	Not applicable
Sweep Time:	Coupled	Not applicable

Receiver Function	Initial Scan (30 to 1000 MHz)	Final Measurements (30 to 1000 MHz)
Detector Type:	Peak	Quasi-Peak (CISPR)
Mode:	Max Hold	Not applicable
Bandwidth:	100 kHz	120 kHz
Amplitude Range:	60 dB	20 dB
Measurement Time:	Not applicable	> 1 s
Observation Time:	Not applicable	> 15 s
Step Size:	Continuous sweep	Not applicable
Sweep Time:	Coupled	Not applicable

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Transmitter 20 dB Bandwidth

The EUT and spectrum analyser was configured for transmitter radiated emissions measurements.

To determine the occupied bandwidth, a resolution bandwidth of 1000 Hz was used, which is greater than 1% of the 20 dB bandwidth. A video bandwidth of at least the same value was used. The analyser was set for a maximum hold scan to capture the profile of the signal. The peak level was then determined, and a reference line was drawn 20 dB below the peak level. The bandwidth was determined at the points where the 20 dB reference crossed the profile of the emission.

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FCC Part 2.1055: Frequency Stability

The EUT was situated within an environmental test chamber and monitored on the test equipment via an antenna test fixture.

Measurements were performed with the EUT operating under extremes of temperature in 10 degree increments within the range -20°C to 50°C.

Measurements were also performed at voltage extremes between the declared nominal supply voltage and at the declared endpoint voltage (for hand carried battery operated equipment) or by varying the primary supply voltage from 85% to 115% of the nominal value for all other equipment types.

The requirement was to determine the frequency stability of the device under specified environmental operating conditions.

The EUT was switched off for a minimum of 30 minutes between each stage of testing while the environmental chamber stabilised at the next temperature within the stated temperature range.

The frequency error measured was converted to an error in % using the following formula as defined by TIA-603-B :-

$$\text{ppm error} = \left(\frac{MCF_{\text{MHz}}}{ACF_{\text{MHz}}} - 1 \right) * 10^6$$

*where MCF_{MHz} is the measured carrier frequency in MHz
 ACF_{MHz} is the assigned carrier frequency in MHz*

The measured % had to be less than the relevant limits in order to comply.

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Appendix 1. Test Equipment Used

RFI No.	Instrument	Manufacturer	Type No.	Serial No.
A007	Loop Antenna	Rohde & Schwarz	HFH2-Z2	880 458/020
A067	LISN	Rohde & Schwarz	ESH3-Z5	890603/002
A1037	Bilog Antenna	Chase EMC Ltd	CBL6112B	2413
A1360	Pulse Limiter	Rohde & Schwarz	ESH3-Z2	A1360-20112003
A259	Bilog Antenna	Chase	CBL6111	1513
C1024	Cable	Rosenberger	FA210A-1-020m	FA00B 7565
C387	Cable	Rosenberger	UFB 293B-1-0720-50x51 FSCM 64639	97B1011
C453	Cable	Rosenberger	RG142XX-001-RFIB	C453-10081998
C574	Cable	Rosenberger	UFA210A-1-788-50x50	97E0937
L0802	Environmental Chamber	Gallenkamp Industrial	FE300.T.R75	6974
M069	Spectrum Analyser / Receiver	Rohde & Schwarz	ESMI	829 808/007 (DU) / 827 063/008 (RU)
M088	Receiver / Spectrum Analyser System	Rohde & Schwarz	ESBI	DU:835862/018 RU:835387/006
M1243	Spectrum Analyser	Advantest	U3661	83140299
M1269	True RMS Multimeter	Fluke	179	90250210
S201	Site 1	RFI	1	
S212	Site 12	RFI	12	

NB In accordance with UKAS requirements, all the measurement equipment is on a calibration schedule.

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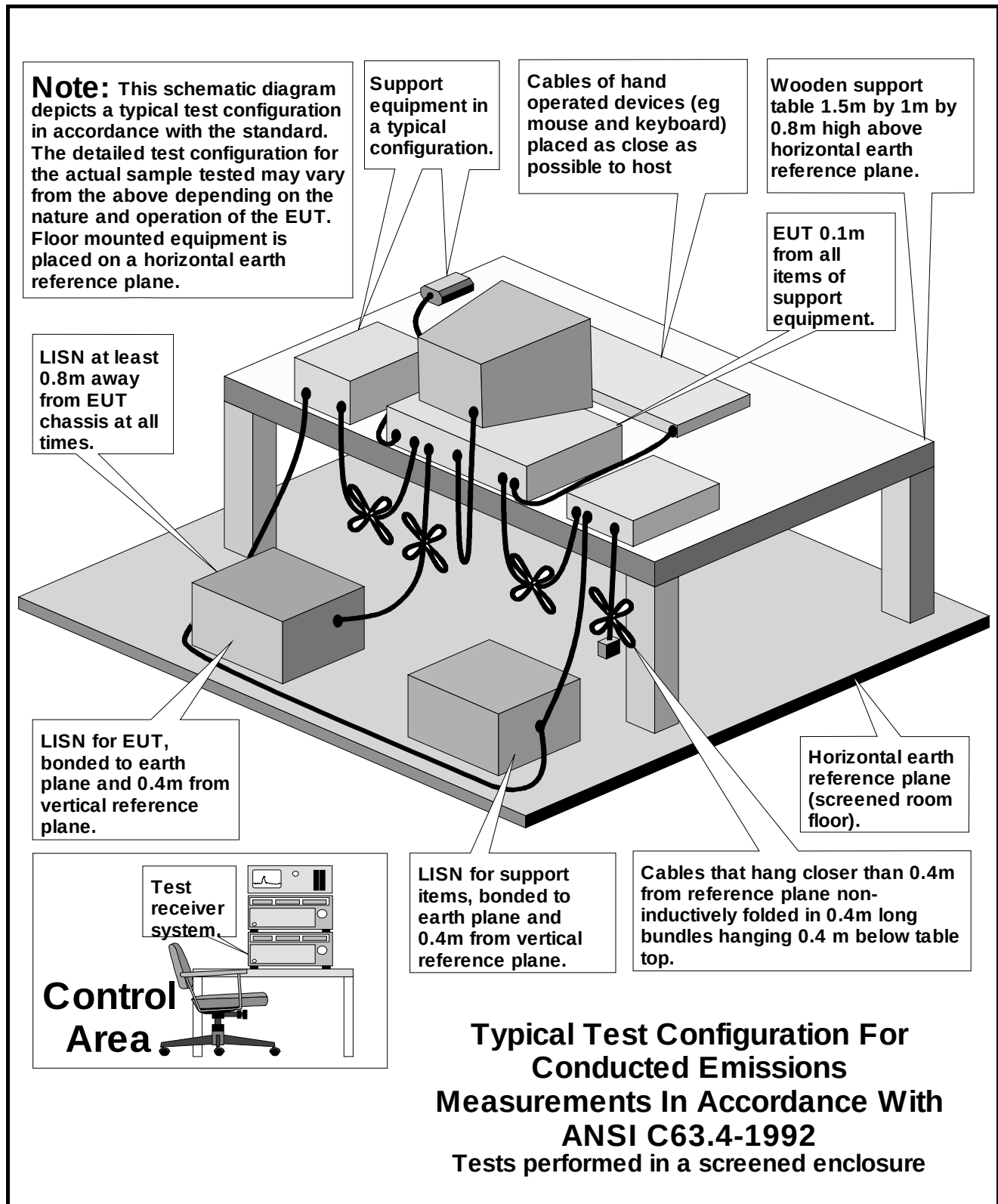
Appendix 2. Test Configuration Drawings

This appendix contains the following drawings:

Drawing Reference Number	Title
DRG\48039JD05\EMICON	Test configuration for measurement of conducted emissions.
DRG\48039JD05\EMIRAD	Test configuration for measurement of radiated emissions.

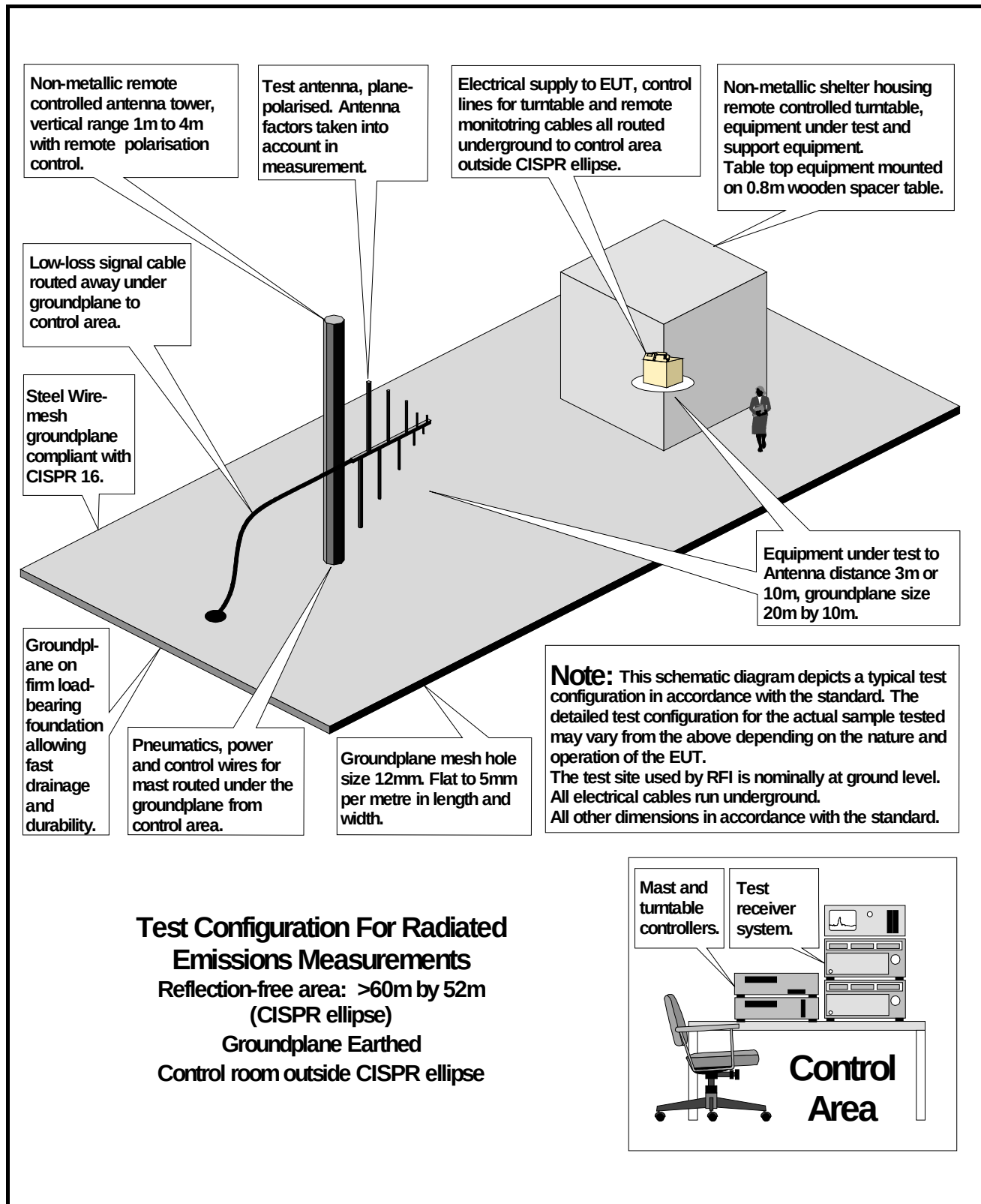
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DRG\48039JD05\EMICON



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DRG\48039JD05\EMIRAD



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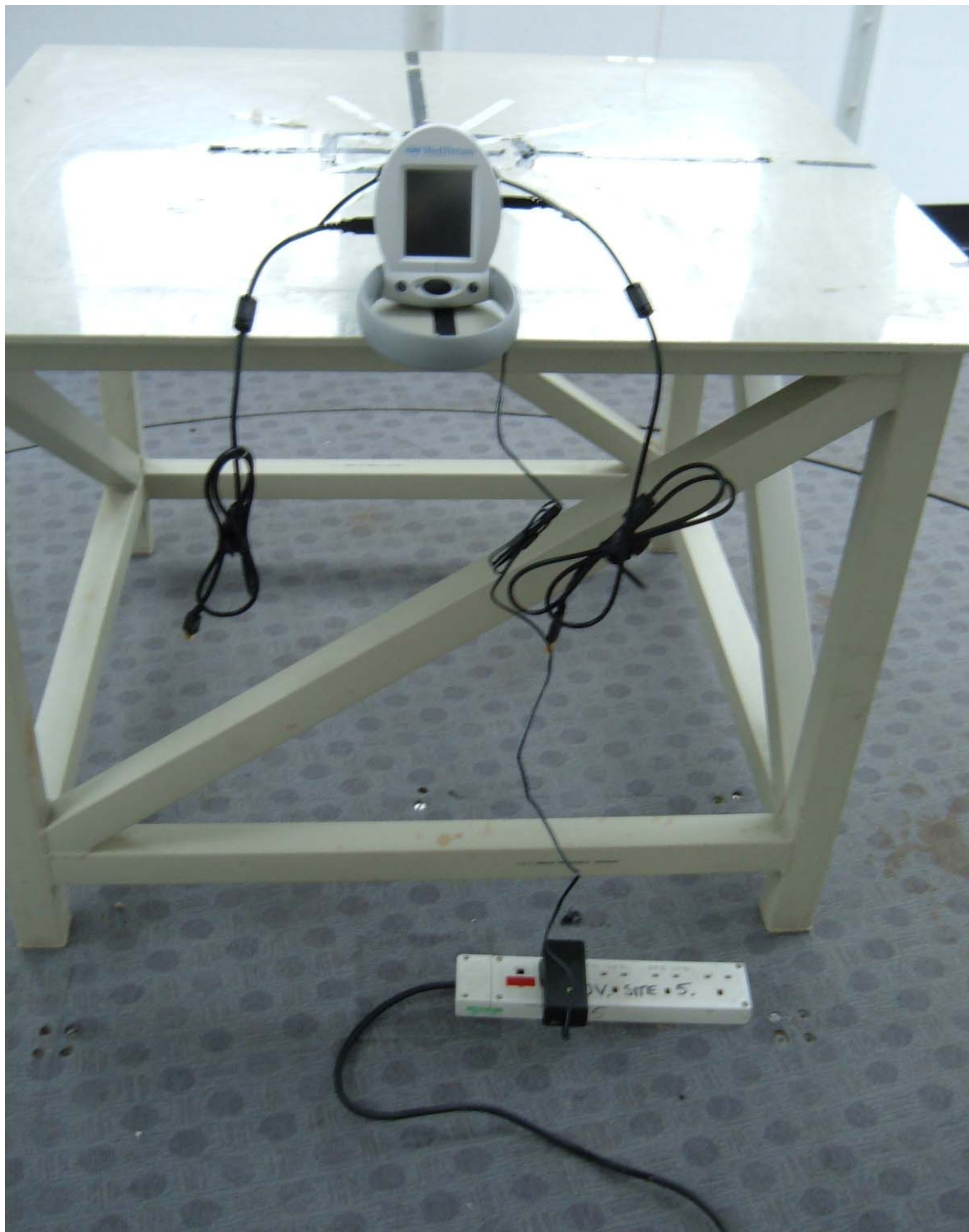
Appendix 3. Photographs of EUT

This appendix contains the following photographs:

Photo Reference Number	Title
PHT/48039/001	Radiated Spurious Emissions
PHT/48039/002	Receiver AC Conducted Emissions Left View
PHT/48039/003	Receiver AC Conducted Emissions Right View
PHT/48039/004	Transmitter AC Conducted Emissions

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PHT/48039/001: Radiated Spurious Emissions



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PHT/48039/002: Receiver AC Conducted Emissions Left View



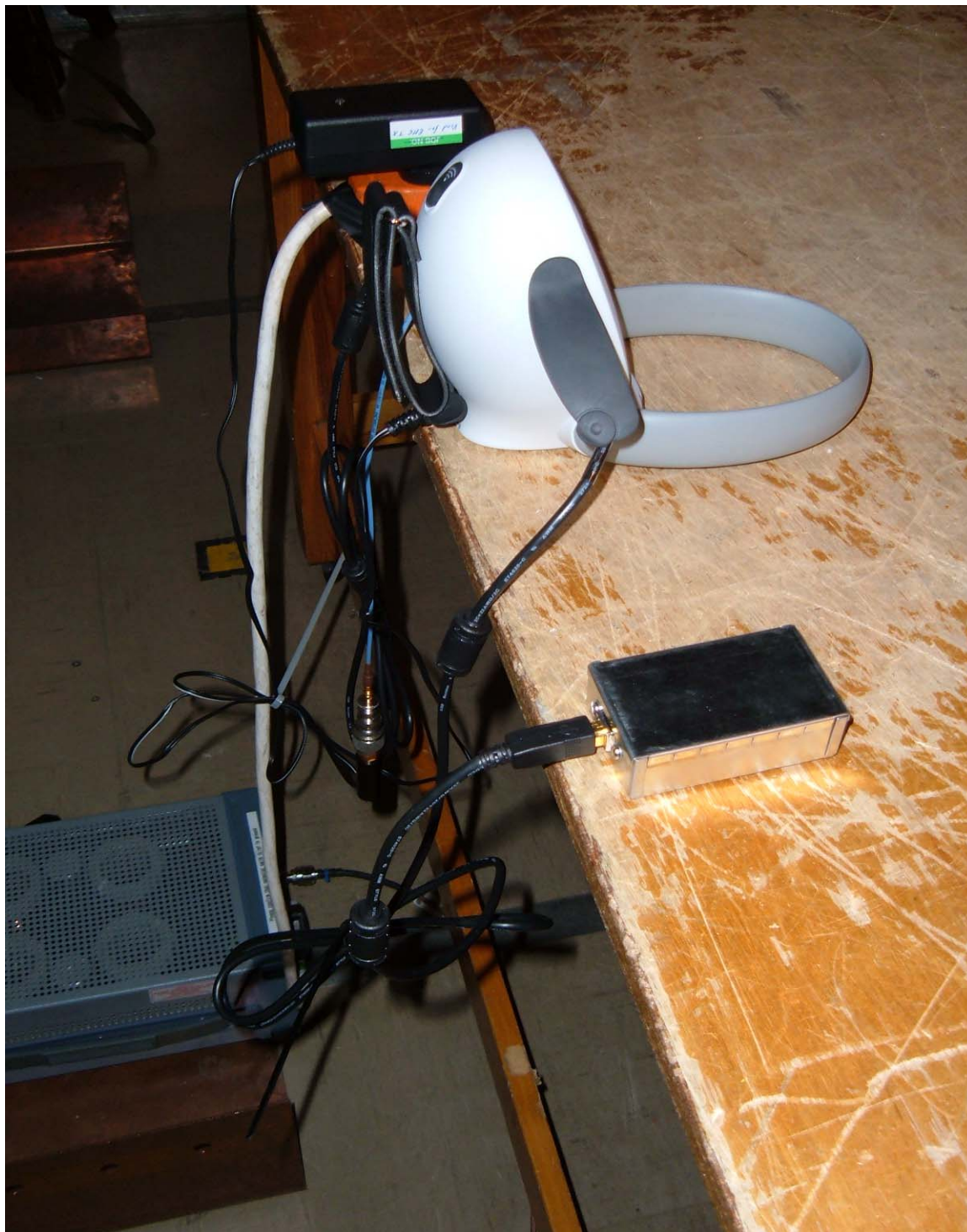
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PHT/48039/003: Receiver AC Conducted Emissions Right View



Test of: Codman NeuroSciences Sarl.
MedStream™ Infusion Control Unit (Transceiver)
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PHT/48039/004: Transmitter AC Conducted Emissions



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Appendix 4. Document 'Appendix to Configuration Item Listing Record and Certificate of Conformity – Product Code 91-4205, dated 9th February 2006'

This appendix contains the 'Appendix to Configuration Item Listing Record and Certificate of Conformity – Product Code 91-4205, dated 9th February 2006' document supplied by Codman which are not included in the total number of pages for this report.

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Appendix 5. Document 'Appendix to Configuration Item Listing Record and Certificate of Conformity – Product Code 91-4205, dated 13th February 2006'

This appendix contains the 'Appendix to Configuration Item Listing Record and Certificate of Conformity – Product Code 91-4205, dated 13th February 2006' document supplied by Codman which are not included in the total number of pages for this report.

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Appendix 6. MedStream Bugs List SSTP2

Seapine ID	Description	Items involved and version
13	The Control Unit antenna position is checked only before activating the RF transmission, not during the communication. Consequence: the user could fold the antenna during the communication with the pump with the RF still ON.	CU Application v2.02
21	Few messages are too long in the transaction log printout. These message are printed in the following configurations: 1) In case the temperature of the pump exits [36°C - 42°C] range, then the pump interrogated then the transaction log printed 2) A refill process is cancelled and the most recent "Cancel Refill" transaction log printed 3) A refill process is completed and the most recent "End Refill" transaction log printed	CU Application v2.02
22	Some printers are not recognized by the Control Unit.	CU Application v2.02
23	The icon that indicates the current time in the program graph has not the correct background color in color scheme 1.	CU Application v2.02
24	When at least 2 Control Unit Applications are present in the CU memory and the current application shall jump to another Control Unit application (compatible with the pump it is communicated with), the Control Unit goes into an infinite loop.	CU Application v2.02
25	The Pump application trigs randomly a "PRC communication error" into the pump	PU Application v2.07
33	When the Pump time is different by more than 10 minutes with Control Unit time, a warning screen is displayed to inform the user. The format used to display the pump time is not correct (always with US format whatever is the CU time format set)	CU Application v2.02
34	The MMC-PRC "Read Memory" command is not working fine	PU Application v2.07
35	The priming bolus duration is not displayed correctly in the transaction log and not printed correctly	CU Application v2.02
37	The single bolus infusion can not be activated ("SINGLE BOLUS" menu item).	PU Application v2.07
38	Complex program can be programmed into the pump but cannot be read back by the CU. Only constant program can be read back.	CU Application v2.02
39	The pump reports a battery check error during sterilization process.	PU Application v2.07

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MedStream Bugs List SSTP2 (Continued)

Seapine ID	Description	Items involved and version
41	When one of the catheter parameters is changed on the Control Unit, it is not displayed with the correct color in the summary screen displayed before communication with the pump	CU Application v2.02
42	In technician mode, the pump command "Read drug calibration table" accessible through the menu "PUMP INFORMATION -> ADVANCED PU INFO -> PUMP READ COMMANDS" is not working properly.	CU Application v2.02
43	The hardware is not managed as specified into SRS during control unit sleep mode	CU Application v2.02
44	Control Unit Screen - Zone 2 (top right area) is not managed correctly during pump initialization when drug name is modified.	CU Application v2.02
45	Control Unit Screen - Zone 2 (top right area) is not managed correctly when a pump critical error is reported. It should displays daily dose but should display "Pump stopped".	CU Application v2.02
46	When Pump is new and battery check error is simulated before writing new pump parameters, On writing, pump should return status as "Unsuccessful with Pump Error" and CU should display PU warning screen with text "Pump Hardware failure[1]". Instead of warning screen, CU displays "Pump status has changed. Perform pump interrogation again."	CU Application v2.02
47	The bridge bolus duration is not calculated correctly.	CU Application v2.02
48	When the Pump is stopped and a transaction log is created, the "number of days until pump empty" parameter should be set to "-" and not to the value calculated with current program daily dosage.	CU Application v2.02
49	In case of low Control Unit battery, the "Low battery warning" is triggered and displayed with few seconds delay when the Control Unit is powered on.	CU Application v2.02
53	The Control Unit goes randomly into infinite loop during RF communication	CU Application v2.02
55	The valve on time is not managed correctly during the transition between bolus and program.	PU Application v2.07
60	When a pump is refilled entirely and CU interrogates the PU, a "Transmission error [3]" could be reported by the CU. This is due to the fact that the pump measures and sends back a drug volume higher than the pump size. This value is rejected by the CU and CU displays "Transmission error [3]" warning.	CU Application v2.02
64	The user can enter too many characters for drug name	CU Application v2.02
68	The CU battery full charge detection is not implemented correctly	CU Application v2.02