



KTL EMC Test Report : 2G6141GUS1

Applicant : St Jude Medical CRMD

Apparatus : Housecall Plus Transmitter 3180-T

Authorised by : 
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Section 1:

Introduction

1.1 General

This report contains an assessment of an apparatus against Electromagnetic Compatibility Standards based upon tests carried out on samples submitted to the Laboratory.

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1.2 Tests Requested By

This testing in this report was requested by:

St Jude Medical CRMD
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1.3 Manufacturer

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1.4 Apparatus Assessed

The following apparatus was assessed between 09/07/03 and 05/08/03.

Housecall Plus Transmitter 3180-T

The above equipment was a unit used to monitor pacemaker performance and skin ECG within a patients home. The unit contained a v.34 modem for transmitting data back to a central monitoring centre.

1.5 Test Result Summary

Full details of test results are contained within Appendix A. The following table summarises the results of the assessment.

Test Type	Regulation	Measurement standard	Result
REFE	Title 47 of the CFR :2002, Part 15 Subpart (c)	ANSI C63.4:1992	PASS
PLCE	Title 47 of the CFR :2002, Part 15 Subpart (c)	ANSI C63.4:1992	PASS

Abbreviations used in the above table:

Mod	: Modification	ANSI	: American National Standards Institution
CFR	: Code of Federal Regulations	PLCE	: Power Line Conducted Emissions
REFE	: Radiated Electric Field Emissions		

1.6 Notes Relating To The Assessment

With regard to this assessment, the following points should be noted:

- a) The results contained in this report relate only to the items tested and were obtained in the period between the date of initial receipt of samples and the date of issue of the report.
- b) The apparatus was set up and exercised using the configurations, modes of operation and arrangements defined in this report only.
- c) Where relevant, the apparatus was only assessed using the monitoring methods and susceptibility criteria defined in this report.
- d) All testing with the exception of testing at the Open Area Test Site was performed under the following environmental conditions:

Temperature : 17 to 23 °C
Humidity : 45 to 75 %
Barometric Pressure : 86 to 106 kPa
- e) All dates used in this report are in the format dd/mm/yy.
- f) This assessment has been performed in accordance with the requirements of ISO/IEC 17025.
- g) KTL Hull is a listed electromagnetic compatibility Conformance Assessment Body (CAB) for EC access to the US market. (Decision No 3/2000 of the Joint Committee established under the Agreement on Mutual Recognition between the European Community and the United States of America. This decision was effective from 16th January 2001).

1.7 Deviations from Test Standards

There were no deviations from the standards tested to.

1.8 Summary of Compliance

The apparatus detailed above is compliant with the standards specified in Section 1.4 as tested.

Section 2:

Measurement Uncertainty

2.1 Introduction

The standard ISO/IEC 17025 used for laboratory accreditation requires laboratories to estimate measurement uncertainty using accepted methods of analysis.

Where required, the reported expanded uncertainty is based on a standard uncertainty providing a confidence level of approximately 95%.

Measurement uncertainty is calculated using the methods defined in the NAMAS document NIS81: May 1994.

KTL measurement uncertainty is recorded in the KTL document UNC/RFG/001 Issue 16.

2.2 Application of Measurement Uncertainty

The following procedure is used when determining the result of a measurement :

- (i) If specification limits are not exceeded by the measured result, extended by the positive component of the expanded uncertainty interval at a confidence level of 95%, then a pass result is recorded.
- (ii) Where a specification limit is exceeded by the result even when the result is decreased by the negative component of the expanded uncertainty interval, a fail result is recorded.
- (iii) Where measured result is below a limit, but by a margin less than the positive measurement uncertainty component, it is not possible to record a pass based on a 95% confidence level. However, the result indicates that a pass result is more probable than a fail result.
- (iv) Where a measured result is above a limit, but by a margin less than the negative measurement uncertainty component, it is not possible to record a fail based on a 95% confidence level. However the result indicates that a fail is more probable than a pass.

2.3 Measurement Uncertainty Values

All results were recorded in accordance with Section 2.2(i).

Section 3:

Modifications

3.1 Modifications Performed During Assessment

No modifications were performed during the assessment

Appendix A:

Formal Emission Test Results

Abbreviations used in the tables in this appendix:

Spec : Specification
Mod : Modification

EUT : Equipment Under Test
SE : Support Equipment

L : Live Power Line
N : Neutral Power Line
E : Earth Power Line

Pk : Peak Detector
QP : Quasi-Peak Detector
Av : Average Detector

ALSR : Absorber Lined Screened Room
OATS : Open Area Test Site
ATS : Alternative Test Site

Ref : Reference
Freq : Frequency

MD : Measurement Distance
SD : Spec Distance

Pol : Polarisation
H : Horizontal Polarisation
V : Vertical Polarisation

CDN : Coupling & decoupling network

A1 Radiated Electric Field Emissions

Preliminary radiated electric field emissions testing was performed using a peak detector in an absorber lined screened room.

The following test site was used for final measurements as specified by the standard tested to :

10m open area test site :



3m alternative test site :



The effect of the EUT set-up on the measurements is summarised in note (c) below.

Test Details	
Regulation	Title 47 of the CFR :2002, Part 15 Subpart (c)
Measurement standard	ANSI C63.4:1992
Class	B – refer to specification limit table below.
Frequency range	9KHz to 1GHz
EUT sample number	S10 and S11
Modification state	0
SE in test environment	None
SE isolated from EUT	S07, S08 and S09
EUT set up	Refer to Appendix C
Photographs (Appendix E)	Photographs 1 and 2

The worst case radiated emission measurements are listed below:

Ref No.	Freq (MHz)	Det.	Ang. Deg.	Height (cm)	Pol.	MD (m)	Result at MD (dB μ V/m)	SD (m)	Result at SD (dB μ V/m)	Spec. Limit (dB μ V/m)	Margin (dB)	Result Summary
1	0.0650	QP	0	100	90	10	43.7	300	-15.4	31.3	-46.7	Pass
2	0.1235	QP	0	100	90	10	34.7	300	-24.4	25.8	-50.2	Pass
3	8.51	QP	0	100	90	10	44.0	30	24.9	29.5	-4.6	Pass
4	44.356	QP	350	100	V	3	35.6	3	35.6	40.0	-4.4	Pass
5	314.620	QP	272	100	H	3	37.9	3	37.9	46.0	-8.1	Pass
6	393.276	QP	287	100	H	3	39.1	3	39.1	46.0	-6.9	Pass
7	423.441	QP	377	100	H	3	32.5	3	32.5	46.0	-13.5	Pass
8	550.584	QP	70	120	V	3	37.5	3	37.5	46.0	-8.5	Pass
9	705.731	QP	251	100	V	3	38.1	3	38.1	46.0	-7.9	Pass

Note : The Transmitter communicates with the implanted Device via a telemetry 'wand' over a short range (6 inches) inductive link, operating at 64kHz transmit/ 8kHz receive.

The upper frequency of the measurement range was decided according to 47 CFR 15:1999 Clause 15.33.

Radiated emission limits (47 CFR 15:1999 Clause 15.209):

Frequency of emission (MHz)	Field strength $\mu\text{V}/\text{m}$	Field strength $\text{dB}\mu\text{V}/\text{m}$
0.009-0.49	2400/F(kHz)	-
0.49-1.705	24000/F(kHz)	-
1.705-30	30	29.5
30-88	100	40.0
88-216	150	43.5
216-960	200	46.0
Above 960	500	54.0

Notes:

- (a) Where results have been measured at one distance, and a signal level displayed at another, the results have been extrapolated using the following formula:

$$\text{Extrapolation (dB)} = 20 \log_{10} \left(\frac{\text{measurement distance}}{\text{specification distance}} \right)$$

The results displayed take into account applicable antenna factors and cable losses.

- (b) The levels may have been rounded for display purposes.
- (c) The following table summarises the effect of the EUT operating mode, internal configuration and arrangement of cables / samples on the measured emission levels :

	See (i)	See (ii)	See (iii)	See (iv)
Effect of EUT operating mode on emission levels		✓		
Effect of EUT internal configuration on emission levels		✓		
Effect of Position of EUT cables & samples on emission levels		✓		
(i) Parameter defined by standard and / or single possible, refer to Appendix D (ii) Parameter defined by client and / or single possible, refer to Appendix D (iii) Parameter had a negligible effect on emission levels, refer to Appendix D (iv) Worst case determined by initial measurement, refer to Appendix D				

A2 Power Line Conducted Emissions

Preview power line conducted emission measurements were performed with a peak detector in a screened room.

The effect of the EUT set-up on the measurements is summarised in note (b) below.

Where applicable formal measurements of the emissions were performed with a peak, average and/or quasi peak detector. The formal measurements are detailed below:

Test Details	
Regulation	Title 47 of the CFR :2002, Part 15 Subpart (c)
Measurement standard	ANSI C63.4:1992
Class	B – refer to specification limit table below.
Frequency range	150kHz to 30MHz
EUT sample number	S12 and S13
Modification state	0
SE in test environment	S07, S08 and S09
SE isolated from EUT	None
EUT set up	Refer to Appendix C
Photographs (Appendix E)	Photograph 3

The worst case power line conducted emission measurements are listed below:

Ref No.	Freq (MHz)	Conductor	Detector Used	Result (dBuV)	Spec Limit (dBuV) AV	Result Summary
1	1	L	QP	19.4	46	Pass
2	2	L	QP	19.6	46	Pass
3	5	L	QP	20.3	46	Pass
4	10	N	QP	19.6	50	Pass
5	15	L	QP	20	50	Pass
6	20	L	QP	20.4	50	Pass

Conducted emission limits (47 CFR 15:1999 Clause 15.207):

Frequency range MHz	Limits dB μ V	
	Quasi-peak	Average
0.15 to 0.5	66 to 56	56 to 46
0.5 to 5	56	46
5 to 30	60	50

Notes:

1. The lower limit shall apply at the transition frequency.
2. The limit decreases linearly with the logarithm of the frequency in the range 0.15MHz to 0.5MHz.

Notes :

- (a) The levels may have been rounded for display purposes.
- (b) The following table summarises the effect of the EUT operating mode and internal configuration on the measured emission levels :

	See (i)	See (ii)	See (iii)	See (iv)
Effect of EUT operating mode on emission levels		✓		
Effect of EUT internal configuration on emission levels		✓		

(i) Parameter defined by standard and / or single possible, refer to Appendix D
(ii) Parameter defined by client and / or single possible, refer to Appendix D
(iii) Parameter had a negligible effect on emission levels, refer to Appendix D
(iv) Worst case determined by initial measurement, refer to Appendix D

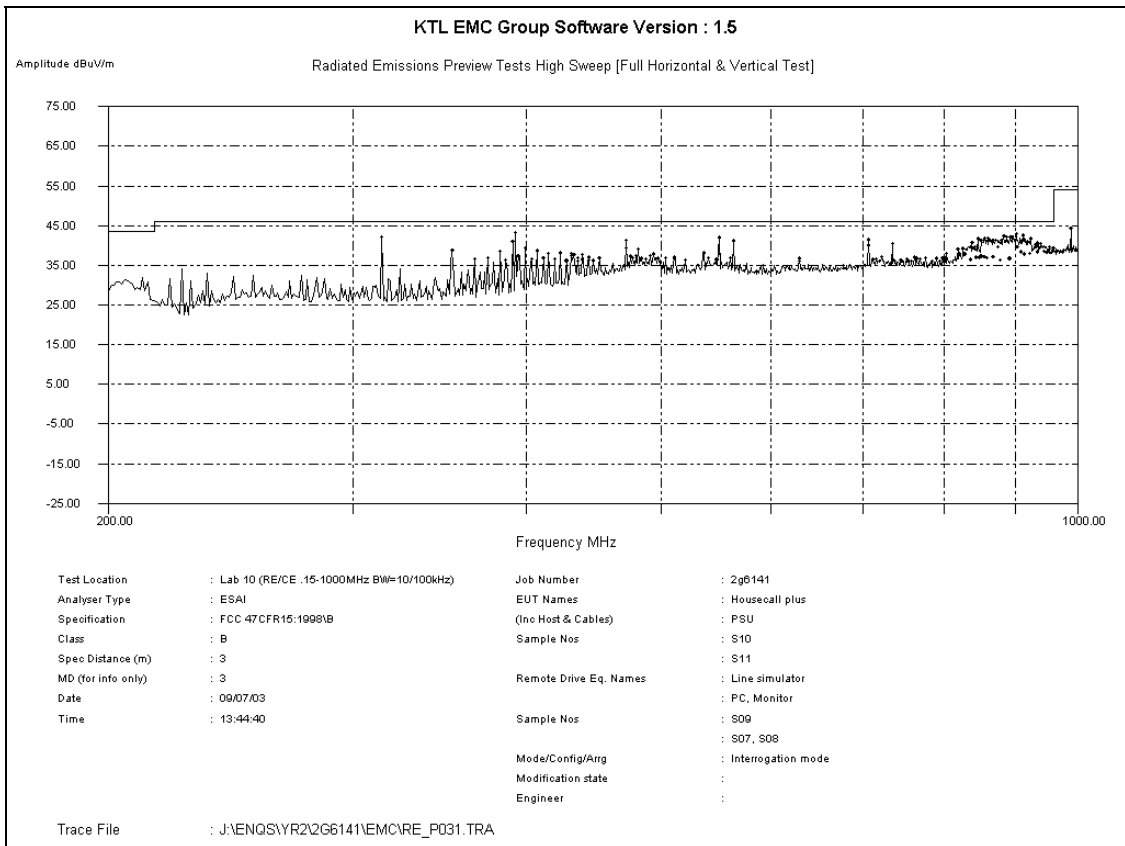
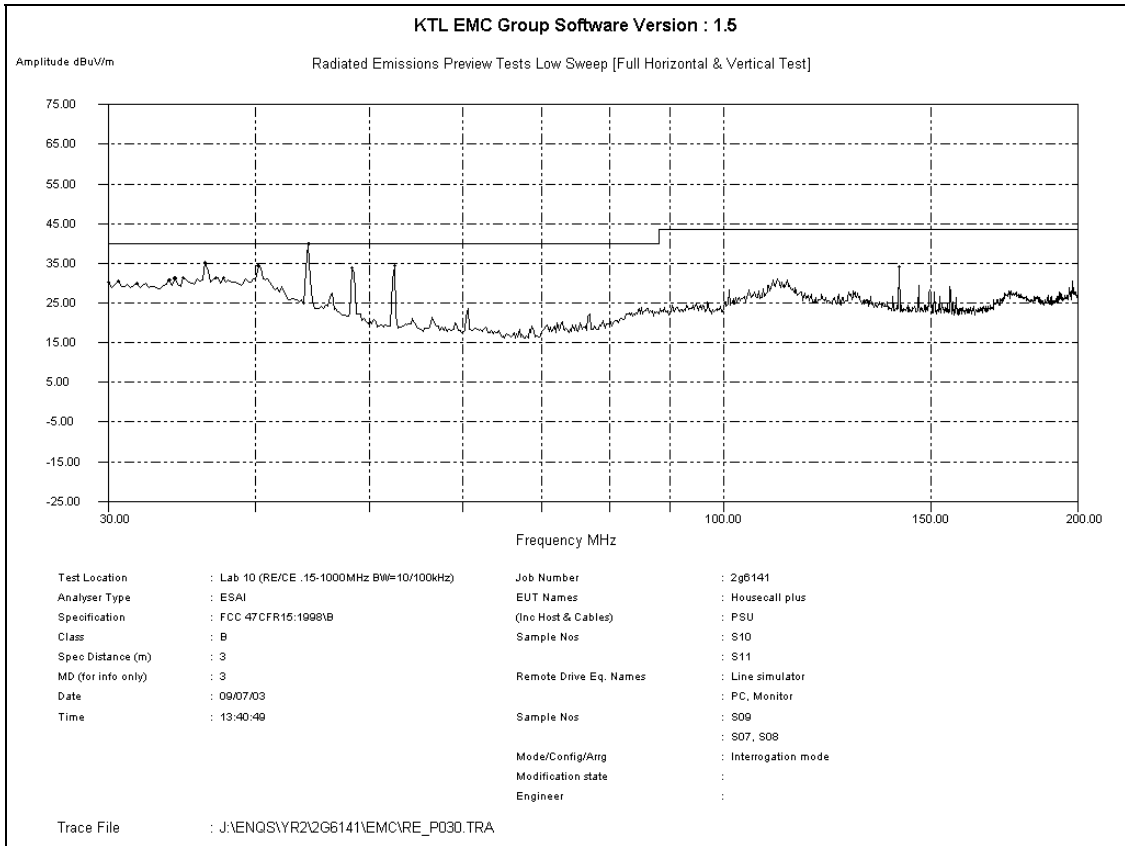
Appendix B:

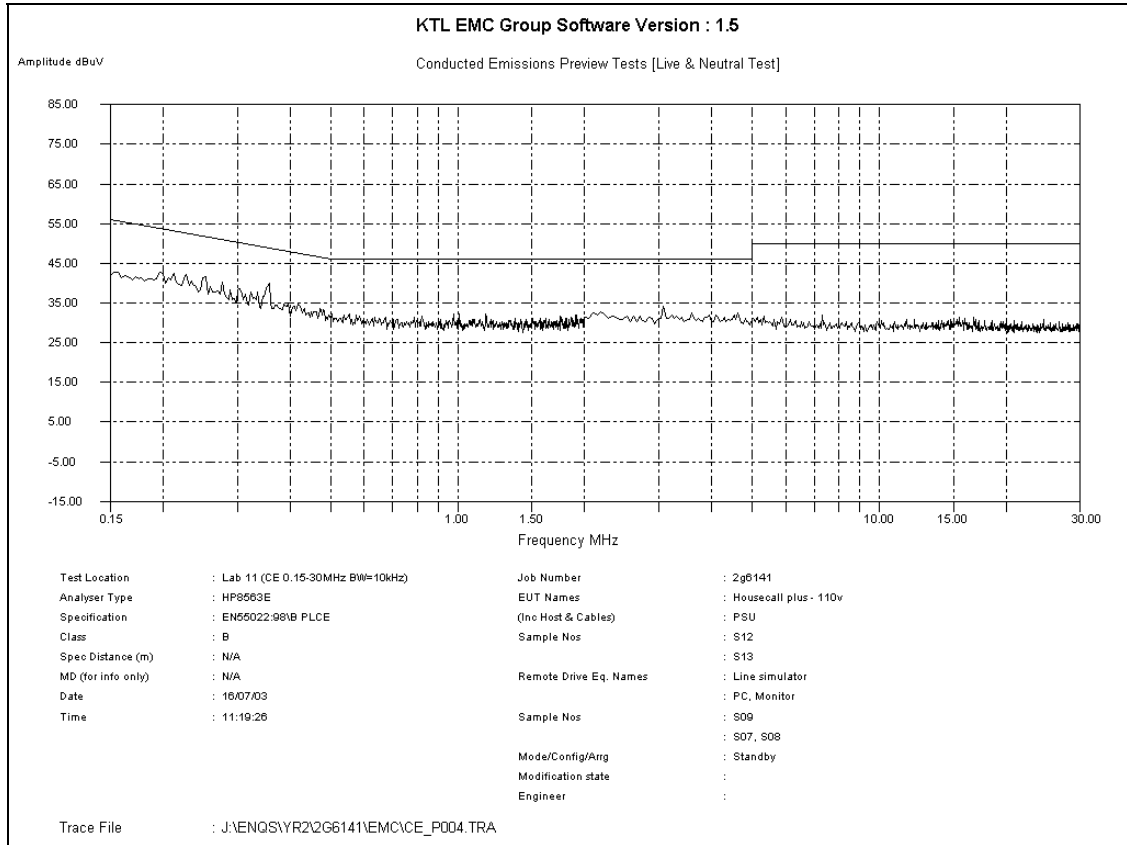
Supporting Graphical Data

This appendix contains graphical data obtained during testing.

Notes:

- (a) The radiated electric field emissions and conducted emissions graphical data in this appendix is preview data. For details of formal results, refer to Appendix A and Appendix B.
- (b) The time and date on the plots do not necessarily equate to the time of the test.
- (c) Where relevant, on power line conducted emission plots, the limit displayed is the average limit which is stricter than the quasi peak limit.
- (d) Appendix C details the numbering system used to identify the sample and its modification state.
- (e) The plots presented in this appendix may not be a complete record of the measurements performed, but are a representative sample, relative to the final assessment.
- (f) The limit line on the conducted emissions plots is the EN55022:1998 Class B limit. This is identical to the 47 CFR Part 15(b) limit.





Appendix C:**Additional Test and Sample Details**

This appendix contains details of:

1. The Samples submitted for testing.
2. Details of EUT operating mode(s)
3. Details of EUT configuration(s) (see below).
4. EUT arrangement (see below).

Throughout testing, the following numbering system is used to identify the sample and it's modification state:

Sample No: Sxx Mod w

where:

xx	= sample number	eg. S01
w	= modification number	eg. Mod 2

The following terminology is used throughout the test report:

Support Equipment (SE) is any additional equipment required to exercise the EUT in the applicable operating mode. Where relevant SE is divided into two categories:

SE in test environment: The SE is positioned in the test environment and is not isolated from the EUT (e.g. on the table top during REFE testing).

SE isolated from the EUT: The SE is isolated via filtering from the EUT. (e.g. equipment placed externally to the ALSR during REFE testing).

EUT configuration refers to the internal set-up of the EUT. It may include for example:

- Positioning of cards in a chassis.
- Setting of any internal switches.
- Circuit board jumper settings.
- Alternative internal power supplies.

Where no change in EUT configuration is **possible**, the configuration is described as "single possible configuration".

EUT arrangement refers to the termination of EUT ports / connection of support equipment, and where relevant, the relative positioning of samples (EUT and SE) in the test environment.

For further details of the test procedures and general test set ups used during testing please refer to the related document "EMC Test Methods - An Overview", which can be supplied by KTL upon request.

C1) Test Samples

The following samples of the apparatus were submitted for testing:

Sample No.	Description	Identification
S10	Housecall Plus Transmitter 3180-T	Client reference number 15
S11	Friwo plug top PSU	Client reference number 15
S12	Housecall Plus Transmitter 3180-T	Client reference number 14
S13	Friwo plug top PSU	Client reference number 14

The following samples of apparatus were submitted (or supplied by KTL) as host, support or drive equipment (auxiliary equipment):

Sample No.	Description	Identification
S07	Casper PC	ED16202
S08	LCD Monitor	NEC
S09	KCE Exchange	FX-207
2A6080S05	Toshiba laptop	110CS

C2) EUT Operating Mode During Testing.

During testing, the EUT was exercised as described in the following tables :

Test	Description of Operating Mode
All tests detailed in this report	Interrogation Mode (Method 1 : firmware version 1.10)
	EUT is connected to the mains and PSTN. ECG cables are extended and shorted together; Device telemetry cable is extended, with the inductive 'wand' placed near a sample implant. A modem connection is established to the Receiver PC. The implanted Device is interrogated, and real time skin ECG, and Device waveforms are displayed on the PC screen. These displayed waveforms should be 'flat line'.

C3) EUT Configuration Information.

The EUT was submitted for testing in one single possible configuration.

C4) Termination of EUT Ports.

The tables below describes the termination of EUT ports:

Sample : S10
Tests : REFE

Port	Description of Cable Attached	Cable length	Equipment Connected (sample no.)
DC I/P	2-way unshielded	2m	S11
PSTN	6-way unshielded	10m	S09
EXTN	None	N/A	None

Sample : S11
Tests : REFE

Port	Description of Cable Attached	Cable length	Equipment Connected (sample no.)
DC O/P	2-way unshielded	2m	S10
AC I/P	None	N/A	AC mains

The table below describes the termination of EUT ports:

Sample : S12
Tests : PLCE

Port	Description of Cable Attached	Cable length	Equipment Connected (sample no.)
DC I/P	2-way unshielded	2m	S13
PSTN	6-way unshielded	10m	S09
EXTN	None	N/A	None

Sample : S13
Tests : PLCE

Port	Description of Cable Attached	Cable length	Equipment Connected (sample no.)
DC O/P	2-way unshielded	2m	S12
AC I/P	None	N/A	AC mains

C5) Details of test equipment used

For power line conducted emissions

RFG No	Type	Description	Manufacturer	Date Calibrated.
n/a	Lab 11	Small Screened Chamber	KTL	-
030	ESH3-Z5	2-phase LISN	R & S	17/01/03
190	ESH3-Z2	Pulse Limiter	R & S	24/04/03
127	HP8563E	Spectrum Analyser	HP	07/04/03
012	ESH3	Test Receiver (LF)	R & S	10/04/03
296	BNC	RF coaxial cable	-	05/11/02
297	BNC	RF coaxial cable	-	05/11/02

For Radiated Electric Field Emissions 9KHz to 30MHz:

RFG No	Type	Description	Manufacturer	Date Calibrated.
062	OATS	10m range	KTL	07/01/03
023	HFHS-Z2	Magnetic loop antenna	R & S	03/04/02
125	ESHS10	Test Receiver (LF)	R & S	07/10/03
126	ESVS20	Test Receiver (LF)	R & S	22/07/03
247	N-type	RF coaxial cable	-	16/06/03
353	N-type	RF coaxial cable	-	10/01/03
222	N-type	RF coaxial cable	-	16/06/03

For Radiated Electric Field Emissions 30MHz to 1GHz:

RFG No	Type	Description	Manufacturer	Date Calibrated.
274	ATS	Ferrite Lined Chamber	KTL	16/09/02
231	CBL6111	Blue BILOG Antenna (0.03 - 1GHz)	Chase	20/03/03
214	ESAI	Spec Analyser/Test Receiver (LF/HF)	R & S	20/06/03
249	N-type	RF coaxial cable	-	05/11/02
255	N-type	RF coaxial cable	-	05/11/02
270	N-type	RF coaxial cable	-	05/11/02

Appendix D:

Additional Information

No additional information is included.

Appendix E:

Photographs and Figures

The following photographs were taken of the test samples:

1. Radiated electric field emissions using a loop antenna
2. Radiated electric field emissions using a loop antenna – EUT arrangement
3. Radiated electric field emissions arrangement: front view.
4. Radiated electric field emissions arrangement: back view.
5. Mains port conducted emissions arrangement.



Photograph 1



Photograph 2



Photograph 3



Photograph 4



Photograph 5