

Wireless 2000 **PAM™3000** **Bed Sensor Panel** **(BSP)**

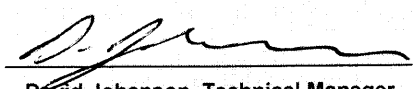
**CE Mark EMC Directive
Compliance Test Report**

per
**IEC60601-1-2: 3rd Ed.:2007 General Requirements for
Basic Safety and Essential Performances Standard for
Emissions & Immunity**

and
Report of Measurements
to
IC ICES-003 & FCC CFR47 Part 15/B
for
Emissions

Revision 1.0

August 01, 2008

Approval		
Checked by	 David Johanson, Technical Manager	<u>01 AUG 08</u> Date

Protocol Data Systems Inc, EMC Testing Lab, Abbotsford BC, Canada
SCC ISO/17025 (CAN-P-4E) Accredited Laboratory No. 612
FCC O.A.T.S. Registration Number 96437
Industry Canada O.A.T.S. Registration Number IC3384

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Section I: Report of Measurements Testing Information

Testing Details

TESTED BY: Emissions Testing: David Johanson/ Dan Petrulian
Immunity Testing: David Johanson

TEST CONDITIONS: Temperature and Humidity: July 1, 2008 26.0°C, 60%

TEST VOLTAGE: 120Vac, 60Hz, 230Vac, 50Hz

Testing Lab

Protocol Data Systems Inc. EMC Testing Lab
28945 McTavish Rd.
Abbotsford BC, Canada, V4X 2E7

SCC ISO/17025 (CAN-P-4E) Accredited Laboratory No. 612
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Industry Canada O.A.T.S. Registration Number IC3384

Test Equipment List

EMISSION:

Manufacturer	Model	Equipment Description	Serial No.	Next Cal
HP	85650A	CDN Quasi-Peak Adapter	2043A00240	18/09/09
HP	85662A	Spectrum Analyzer Display	2318A05184	18/09/09
HP	8566B	Spectrum Analyzer RF Section	2241A02102	18/09/09
HP	85685A	RF-Preselector	3107A01222	18/09/09
LaPlace Instruments	AC1000	Low Distortion Power Source	138041	01/11/08
Thurlby Thandar	HA1600	Power and Harmonics Analyzer	140108	01/11/08
Solar	8012-50-R-24	LISN	863092	28/09/08
EMCO	CPA-30	Ant Log Periodic 200-1000MHZ	563	05/12/08
EMCO	3110B	Ant Biconical 20-300MHz	9401-1850	05/12/08
Fischer	F-33-1	VHF-UHF Current Clamp	725	01/04/09
AH Systems	SAS-200/550-1	Active Monopole Antenna	631	08/05/09
EMCO	6502	Active Loop Antenna	9002-2489	28/02/09
Rhientech	Custom	Antenna Mast	N/A	N/A
Protocol EMC	Custom	Turntable	N/A	N/A

IMMUNITY:

Manufacturer	Model	Equipment Description	Serial No.	Next Cal
EIN	3100L	RF Amplifier	309	N/A
Amplifier Research	30W1000M7	RF Amplifier	22606	N/A
HD Communications	HD18876	RF Amplifier	1003	N/A
HP	8657A	Signal Generator	2913A00373	N/A
HP	8672A	Signal Generator (2-18GHz)	1930A00890	N/A
HP	11721A	Frequency Doubler (100-2600MHz)	1950A02276	N/A
Schaffner	NSG432	ESD Simulator:	1243	01/12/09
Keytek	EMC-Pro	CE Combination Tester *	0312235	22/01/09
Fischer CustomCommu.	F-140	Bulk Injection Clamp	337	N/A
EMCO	95236-1	Bulk Injection Clamp	50958	N/A
AmP Research	FP 4000	Isotropic Field Probe	71776	13/02/09

The CE-Master EMCPro will perform the Electrical Fast Transient test, the Surge Transient Test, the Power Frequency Magnetic Field Test, the pulsed Magnetic Field test and the Voltage Dips and Interruptions test all according to the specific standards.

Measurement Uncertainty

Parameter	Uncertainty
Radio Frequency	±1 x 10 ⁻⁵
Total RF power, conducted	±1,5 dB
RF power density, conducted	±3 dB
Spurious emissions, conducted	±3 dB
All emissions, radiated	±3 dB
Temperature	±1°C
Humidity	±5 %
DC and low frequency voltages	±3 %

Company Under Test

NAME: Wireless RF & UWB Technologies Ltd. 2000

ADDRESS: 2421 Alpha Avenue
Burnaby, BC V5C 5L2

CONTACT PERSON: Mr. Vlad Goldenberg

EMAIL: vgoldenberg@wireless2000.com

PHONE NUMBER: 604-298-8471

Equipment Under Test

THE TEST SYSTEM:

EUT 1: PAM™3000 Bed Sensor Panel (BSP)
Manufacturer: Wireless RF & UWB Technologies Ltd. 2000
Part Number:
Serial Number: ENG001

EUT 2: Power Supply
Manufacturer: Jerome Industries
Part Number: WSC150M
Serial Number: ENG001

CABLING:

Cable	Pins	Connector	Load/Termination	Shielded	Ferrites
AC Power	3	3 prong	No	No	No
DC power	2	8mm Batonet	No	No	No

Conclusion

The PAM™3000 Bed Sensor Panel (BSP) that was tested complies with the requirements of Medical Directive IEC60601-1-2: 3rd Ed.:2007 for Emission and Immunity plus IC ICES-003 and FCC Part 15 for Emissions. These test results are representative of the provided sample given to us for testing as documented above in the EUT section.

Section II: Report of Measurements for CE Mark Emissions

Summary of IEC60601-1-2: 3rd Ed.: 2007

Tests were conducted on a sample of the equipment for the purpose of demonstrating compliance with General requirements for basic safety and essential performance Collateral Standard and self-declaration of the CE Mark requirements under the EMC Directive.

Test Results

Radiated Emission tests were performed using measurement procedure IEC CISPR 11:2003 +Ed. 4.1:2004 Industrial, Scientific and Medical (ISM) Radio Frequency Equipment Standard. Radiated emissions were performed on an open area 3m-test site.

AC Power Line Conducted Emissions was performed using measurement procedure IEC CISPR 11:2003 +Ed. 4.1:2004 Industrial, Scientific and Medical (ISM) Radio Frequency Equipment Standard

Applicable Standard	Test Or Measurement	Required by CISPR 11:2003+Ed. 4.1:2004	Performance Criteria
Conducted Emissions IEC CISPR 11:2003 +Ed. 4.1:2004	Phase & Neutral Power Lines	0.15 - 30.0 MHz Class B Group 1	Complies
Radiated Emissions IEC CISPR 11:2003 +Ed. 4.1:2004	Horizontal And Vertical Polarization	30-1000 MHz Class B Group 1	Complies

Classification of Equipment Under Test

As per, Annex CCC Classification according to CISPR 11 Ed. 4.1:2004 (Sub clause 4.0 Division into classes): IEC60601-1-2: 3rd Ed.:2007. Classification of the (ISM), Industrial, Scientific, and Medical Equipment, shall be labelled by the manufacturer indicating the Class and Group of the equipment.

Separation into Groups

(4.1) Group 1 ISM equipment - contains all ISM equipment in which there is intentionally generated and/or used conductivity coupled radio frequency energy which is necessary for the internal functioning of the equipment itself.

(4.1) Group 2 ISM equipment - Group 2 contains all ISM equipment in which radio frequency energy is intentionally generated and/or used in the form of electromagnetic radiation for the treatment of material, and spark erosion equipment.

Division into Class

Class A -equipment suitable for uses in all establishments other than domestic and those directly connected to a low voltage power supply network, which supplies buildings used for domestic purposes. (Class A - equipment shall meet Class A limits)

Class B - equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network, which supplies buildings used for domestic purposes. (Class B equipment shall meet Class B limits)

EQUIPMENT and SYSTEMS that are intended to be connected (e.g. hospitals) to dedicated supply systems (normally fed by separation transformers) should meet the requirements for either CISPR 11 Class A or Class B.

Part 1 - Conducted Emission Testing

DATE: July 1, 2008

TEST STANDARD: IEC60601-1-2: 3rd Ed.: 2007

TEST METHOD: IEC55011: 2003 +A1: 2004

TEST VOLTAGE: 240Vac, 50Hz

REQUIRED STANDARD: Class B EN55011

Class B Equipment Limits dB(μV)		
Frequency (MHz)	Group 1 and 2	
	Quasi-Peak	Average
0.15 - 0.50	66	56
	Decreasing linearly with logarithm of frequency to	Decreasing linearly with logarithm of frequency to
	56	46
0.50 - 5.00	56	46
5.00 - 30.0	60	50
Note Care should be taken to comply with leakage current requirements		

METHOD OF MEASUREMENT: Measurements were made using a spectrum analyzer with 10kHz RBW, Peak detector. Any emissions that are close to the limit are measured using a test receiver with 10kHz bandwidth, CISPR Quasi-Peak detector. Bandwidths used on the test receiver are those specified in EN55011/22.

MEASUREMENT DATA: See Appendix B for Plots,

EMISSIONS DATA: See Tables 3 and 4 in Appendix B for corresponding frequencies.

PERFORMANCE: Complies

Part 2 - Radiated Emission Testing

DATE: October 22, 2007

TEST STANDARD: IEC 60601-1-2: 3rd Ed. 2007

TEST METHOD: CISPR 11:2003 +Ed. 4.1:2004

TEST VOLTAGE: 230Vac, 50Hz

TESTED TO: Group 1 Class B IEC CISPR 11:2003 +Ed. 4.1:2004

Frequency (MHz)	Measured on a test site			
	Group 1 Class A measurement distance dB μ V/m		Group 1 Class B measurement distance dB μ V/m	
	10 - m	3 -m	10- m	3 -m
0.15 – 30	Under Consideration		Under Consideration	
30 - 230	40	50	30	40
230 - 1000	47	57	37	47

TEST SETUP: The equipment was set up in a 10-meter open field test site; Tests were performed at 3 meters. Limit lines were modified to compensate as per procedures for short range, as below, using the manufacturer's specified normal cabling configuration, with all cables over 1 meter in length bundled at 1 meter and retained from the floor. A typical application was tested.

Emissions in both horizontal and vertical polarization's were measured while rotating the EUT on a turntable to maximize the emissions signal strength.

In cases where the presence of high ambient noise makes it impossible to measure an emission at the required distance, the measurement is performed at a closer distance and the limit is adjusted per EN61000-6-3:2006

20 Log (D1/D2)
Where D1 = New Distance D2 = Required Distance The result is added or subtracted to the required emission level to ensure compliance at the new distance.

METHOD OF MEASUREMENT: Emissions in both horizontal and vertical polarizations were measured while rotating the EUT on a turntable to maximize the emissions signal strength.

MODIFICATIONS: The EUT did not require any modifications.

EMISSIONS DATA: No Data

PERFORMANCE: Pass. All Frequencies are greater than 20dB below Class B Limit Lines

Section III: Report of Measurements per IC ICES-003

Testing was performed pursuant to Industry Canada ICES-003 issue 4

Test	Standard	Description	Result
Conducted Emissions subclause 8.3	ICES-003 Issue 4 Class B Limits	The Conducted Emissions are measured on the phase and Neutral Power lines in the 0.15 - 30.0MHz range.	Complies
Radiated Emissions subclause 8.2	ICES-003 Issue 4 Class B Limits	The radiated emissions are measured in the 30-1000MHz range	Complies

Part 1 - Conducted Emission Testing

DATE: July 1, 2008

TEST STANDARD: ICES-003 Issue 4

TEST VOLTAGE: 120Vac, 60Hz

MINIMUM STANDARD: Class B Limit:

Frequency (MHz)	Conducted Limit (dB μ V)	
	Quasi-Peak	Average
0.15 - 0.50	66 to 56	56 to 46
0.50 - 5	56	46
5 - 30	60	50
Note 1 The lower limit shall apply at the transition frequencies		
Note 2 The limit decreases linearly with the logarithm of the frequency in the range 0.15 MHz to 0.50 MHz		

TEST SETUP: The EUT was connected to the conducted emissions LISN apparatus. The equipment was operated and tested at 120Vac 60Hz while in transmit and receive modes of operation.

METHOD OF MEASUREMENT: Measurements were made using a spectrum analyzer with 9kHz RBW, Peak detector. Any emissions that are close to the limit are measured using a test receiver with 9kHz bandwidth, CISPR Quasi-Peak detector as well as an averaging meter.

DEVICE DESCRIPTIONS: As described in the Equipment under Test Section, above.

MEASUREMENT DATA: See Appendix B for Plots,

EMISSIONS DATA: See Table 1 and 2 in Appendix B for corresponding data.

PERFORMANCE: Complies.

Part 2 - Radiated Emission Testing

DATE: October 22, 2007

TEST STANDARD: ICES-003 Issue 4

TEST VOLTAGE: 120Vac, 60Hz

MINIMUM STANDARD: Class B Limit:

Frequency (MHz)	Maximum Field Strength dB μ V/m at 10 m
30 - 230	30.0
230 - 1000	37.0
Note 1. The lower limit shall apply at the transition frequency	
Note 2. Additional provisions may be required for cases where interference occurs	

METHOD OF MEASUREMENT: The equipment was set up in a 10-meter open field test site; Tests were performed at 3 meters. Limit lines were modified to compensate as per procedures for short range, as below, using the manufacturer's specified normal cabling configuration, with all cables over 1 meter in length bundled at 1 meter and retained from the floor. A typical application was tested.

Emissions in both horizontal and vertical polarization's were measured while rotating the EUT on a turntable to maximize the emissions signal strength. In cases where the presence of high ambient noise makes it impossible to measure an emission at the required distance, the measurement is performed at a closer distance and the limit is adjusted per CEI IEC 61000-6-3:2nd Ed.2006.

20 Log (D1/D2)
Where D1 = New Distance D2 = Required Distance The result is added or subtracted to the required emission level to ensure compliance at the new distance.

All frequencies 30-2000GHz were tested at 3m and all frequencies 2GHz and up were tested at 1meter in accordance with ANSI c63.4

EMISSIONS DATA: No Data

PERFORMANCE: Pass. All Frequencies are greater than 20dB below Class B Limit Lines

Section IV: Report of Measurements per FCC CFR47 Part 15/B

General

Tests were conducted on a sample of the equipment for the purpose of demonstrating compliance with FCC Part 15B- Unintentional Radiators, Class B.

Both the Radiated and Power Line Conducted Emission tests were performed using measurement procedure outlined in the above standard.

FCC Labelling and Marking Requirements:

Markings

According to FCC Section 15.19, and ICES 003, a statement similar to the following must be included on an identification label, which also uniquely identifies the Manufactured date, either explicitly or through a Serial number etc.:

"This equipment complies with FCC Rules, Part 15 and Industry Canada's ICES 003 for a Class B Digital Device. Operation is subject to two conditions:

- 1) This device may not cause harmful interference, and
- 2) This device must accept any interference that may cause any undesired operation"

Additionally, if the manufacturer markets product to Quebec, the following supplemental information should be added to the label:

"Cet Appareil numerique de la Classe B respecte toutes les exigences du Reglement sur le material
broilleur du Canada."

Labelling

According to FCC Section 15.105, and ICES 003, the following statement must be included in a prominent location your User's Manual:

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules and ICES 03. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- o Reorient or relocate the receiving antenna.
- o Increase the separation between the equipment and receiver.
- o Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- o Consult the dealer or an experienced radio/TV technician for help.

It is also required according to FCC Part B Section 15.21 that a caution is included such as:

Caution: Changes or modifications to this equipment, not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Part 1 - Conducted Emission Testing

DATE: July 1, 2008

TEST STANDARD: FCC CFR47, Part 15, Subpart B

TEST VOLTAGE: 120Vac, 60Hz

MINIMUM STANDARD: Class B Limit:

Frequency (MHz)	Maximum Level (dB μ V)	Maximum Level (dB μ V)
	Quasi-Peak	Average
0.15 - 0.50	66-56 (Log Delta)	56-46 (Log Delta)
0.50 - 5.00	56	46
5.00 - 30.0	60	50

TEST SETUP: The EUT was connected to the conducted emissions LISN apparatus.

METHOD OF MEASUREMENT: Measurements were made using a spectrum analyzer with 10kHz RBW, Peak detector. Any emissions that are close to the limit are measured using a test receiver with 10kHz bandwidth, CISPR Quasi-Peak detector.

DEVICE DESCRIPTIONS: As described in the Equipment Under Test Section, above.

CABLING DETAILS: The EUT was set up using the manufacturer's specified normal cabling configuration.

CABLE DESCRIPTIONS: Refer to the Equipment Under Test Section

MEASUREMENT DATA: See Appendix B for Plots

EMISSIONS DATA: See Table 1 and 2 in Appendix B for corresponding data.

PERFORMANCE: Complies.

Part 2 - Radiated Emission Testing

DATE: October 22, 2007

TEST STANDARD: FCC CFR47, Part 15, Subpart B

TEST VOLTAGE: 120Vac, 60Hz

MINIMUM STANDARD: Class B Limits:

Frequency (MHz)	Field Strength	
	uV/m @ 3-m	dBµV/m at 3m
30 - 88	100	40.0
88 - 216	150	43.5
216 - 960	200	46.0
960 - 1000	500	54.0

TEST SETUP: The equipment was set up in a 3-meter open field test site. Emissions in both horizontal and vertical polarization were measured while rotating the EUT on a turntable to maximize the emissions signal strength.

DEVICE DESCRIPTIONS: Refer to the Equipment Under Test Section, above, for EUT Descriptions.

CABLING DETAILS: The EUT was set up using the manufacturer's specified normal cabling configuration.

CABLE DESCRIPTIONS: Refer to the Equipment Under Test Section

EMISSIONS DATA: No Data

PERFORMANCE: Pass. All Frequencies are greater than 20dB below Class B Limit Lines

Section V: Report of Measurements to Immunity Testing

Test Set Up

All observations were within the manufacturer's criteria for specified normal operation.

Testing Summary

Testing was performed per the following standard, pursuant to IEC60601-1-2: 3rd Ed.: 2007 using the following standards below as to the method of measurements.

Applicable Standard	Description	Test or Measurement	Required by EN60601-1-2: 2007	Performance Criterion
Electrostatic Discharge EN 61000-4-2	Direct and Indirect Air Discharge ESD and Contact Discharge at several points with 10 + and 10 - 'hits' per location.	Air Discharge Contact Discharge	+/-2kV, +/-4kV, +/-8kV +/-2kV, +/-4kV, +/-6kV	Complies Complies
Radiated Immunity EN 61000-4-3	Subject to electromagnetic field from 80 MHz to 2.0GHz	Frequency Field Modulation (Non Life supporting Equipment) Frequency Field Modulation (Life supporting Equipment)	3V/m 10V/m	Complies N/A
Electrical Fast Transient/Burst EN 61000-4-4	EFT/Burst coupled to the all I/O and control signals respectively is injected on the Power Line.	AC Line (Direct injection) Signal Lines <3m (Cap. Clamp)	2.0kV 1.0kV	Complies Complies
Surge Transient Susceptibility EN 61000-4-5	5 hits each of Surge Transients at + and - polarization are injected on the Power Line. For AC - L1-L2, L1-PE, L2-PE, and at 0, 90 and 270 phase degree	AC Line to Earth AC Line to Line	2.0kV 1.0kV	Complies Complies
Conducted Immunity EN 61000-4-6	Radio energy is coupled through I/O and control signals at 0.15 to 80 MHz	Power, Signal lines Frequency field Modulation Outside the ISM bands Inside the ISM Bands	3 Vrms 10Vrms	Complies N/A
Voltage Dips EN61000-4-11	Voltage on the power line is reduced	Voltage Dip	60% for 5 cycles 30% for 25 cycles >95% for 0.5 cycles	Complies
Voltage Interruptions EN61000-4-11	Voltage on the power lines is interrupted	Voltage Interruption	>95% for 5 sec	Complies

6.2.1.10 Compliance Criteria

Under the test conditions specified in 6.2 the ME EQUIPMENT of ME SYSTEM Shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed

- Component failures
- Changes in programmable parameters:
- Reset to factory defaults (MANUFACTURER'S presets);
- Change of operating mode;
- False alarms;
- Cessation 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, treatment or monitoring;
- Noise on a wave form in which the noise would interfere with diagnosis, treatment or monitoring;
- Artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
- Failure of automatic diagnosis or treatment ME EQUIPMENT and ME SYSTEMS to diagnose or treat, even if accompanied by an alarm

Test Set Up

All observations were within the manufacturer's criteria for specified normal operation.

Testing Summary

Testing was performed per the following standard, pursuant to IEC60601-1-2:2007 3rd Ed. using the following standards below as to the method of measurements.

Testing was performed per the following standards, pursuant to IEC60601-1-2:2007 3rd Ed..

Applicable Standard	Direct and Indirect Air Discharge ESD and Contact Discharge at several points with 10 + and 10 - 'hits' per location.	Test or Measurement	Required by EN60601-1-2:2001	Performance Criterion
Electrostatic Discharge EN 61000-4-2	Subject to electromagnetic field from 80 MHz to 2.7GHz	Air Discharge Contact Discharge	+/-2kV, +/-4kV, +/-8kV +/-2kV, +/-4kV, +/-6kV	Complies Complies
Radiated Immunity EN 61000-4-3	EFT/Burst coupled to the all I/O and control signals respectively is injected on the Power Line.	Frequency Field Modulation (Non Life supporting Equipment) Frequency Field Modulation (Life supporting Equipment)	3V/m 10V/m	Complies N/A
Electrical Fast Transient/Burst EN 61000-4-4	5 hits each of Surge Transients at + and - polarization are injected on the Power Line. For AC - L1-L2, L1-PE, L2-PE, and at 0, 90 and 270 phase degree	AC Line (Direct injection) Signal Lines <3m (Cap. Clamp)	2.0kV 1.0kV	Complies Complies
Surge Transient Susceptibility EN 61000-4-5	Radio energy is coupled through I/O and control signals at 0.15 to 80 MHz	AC Line to Earth AC Line to Line	2.0kV 1.0kV	Complies Complies
Conducted Immunity EN 61000-4-6	Voltage on the power line is reduced	Power, Signal lines Frequency field Modulation Outside the ISM bands Inside the ISM Bands	3 Vrms 10Vrms	Complies N/A
Voltage Dips EN61000-4-11	Voltage on the power lines is interrupted	Voltage Dip	60% for 5 cycles 30% for 25 cycles >95% for 0.5 cycles	Complies
Voltage Interruptions EN61000-4-11	Direct and Indirect Air Discharge ESD and Contact Discharge at several points with 10 + and 10 - 'hits' per location.	Voltage Interruption	>95% for 5 sec	Complies

Note: Performance Criterion determines the Pass/Fail result of the test as per 36.202.1-(J) Compliance Criteria. The test conditions specified in 36.202, the EQUIPMENT or SYSTEM should be able to provide the ESSENTIAL PERFORMANCE and remain safe.

Criterion A - the equipment must continue to operate during and after the test.

Criterion B - the Equipment performance is allowed to degrade during the test, but must recover to the original state, and not lose any data.

Criterion C - temporary loss of function is permitted, but all functionality must be recoverable by the operation of external controls.

Part 1 - ESD Testing

DATE: January 31, 2008

TEST STANDARD: IEC60601-1-2:2007 3rd Ed.

TEST METHOD: EN 61000-4-2:1995+A2:2000-11

TEST CONDITIONS: The EUT shall be tested within its intended operating and climatic conditions

TEST VOLTAGE: 230Vac, 50Hz

MINIMUM STANDARD: ME Equipment and Me Systems shall comply with the requirements of 6.2.1.10

METHOD OF TEST: The test methods and equipment specified by IEC61000-4-2 apply, with the following modifications.

- * The test time between discharges is set to an initial value of 1s. Longer time between discharges may be required in order to be able to distinguish between a response caused by a single discharge and a response caused by a number of discharges.
- * Contact discharges are applied to conductive accessible parts of the ME EQUIPMENT of ME SYSTEM and coupling.
- * Air Discharges are applied to non-conductive accessible parts of the ME EQUIPMENT of ME SYSTEM and conductive non-accessible portions of ACCESSIBLE PARTS. If the ME EQUIPMENT of ME SYSTEM is labelled with the IEC 60417-5134(2003-04) symbol adjacent to a connector that connector is exempt from this testing
- * ME EQUIPMENT and ME SYSTEMS that are INTERNALLY POWERED, are of CLASS II or contain circuitry isolated from protective earth are tested in such a way as to ensure that there is no appreciable charge retention between individual test discharges. The potential on the ME EQUIPMENT or ME SYSTEM may be equalized with that of the ground plane, between individual test discharges, by temporarily grounding it through two 470kΩ resistors connected in series. The potential equalization connection shall be disconnected and moved away from the ME EQUIPMENT of ME SYSTEM during application of a test discharge.
- The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies

TEST VOLTAGE: Air Discharges: +/-2kV, +/-4kV, +/-8kV
Contact Discharges: +/-2kV, +/-4kV, +/-6kV

TEST DEFINITIONS: Pass Denotes successful discharge with no effect.
Fail Denotes failure to pass Required Standard.

MEASUREMENT DATA: See attached Test Data

PERFORMANCE: Complies with Required Standard.

INDIRECT ESD APPLICATION**Vertical and Horizontal Coupling Plane**

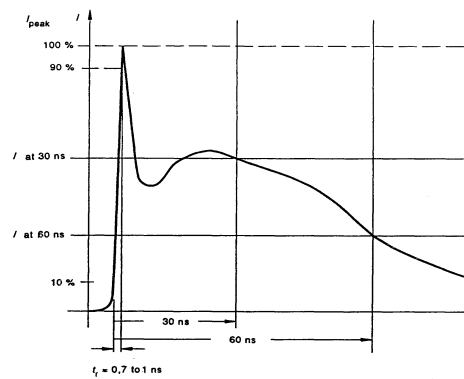
Four Faces Of EUT	Horizontal Plane		Vertical Plane	
Variables	+/-4kV	+/-6kV	+/-4kV	+/-6kV
Front of EUT	Pass	Pass	Pass	Pass
Left Side of EUT	Pass	Pass	Pass	Pass
Back of EUT	Pass	Pass	Pass	Pass
Right Side of EUT	Pass	Pass	Pass	Pass

Contact Discharge +/-2kV +/-4kV +/-6kV

	Hit 1	Hit 2	Hit 3	Hit 4	Hit 5	Hit 6	Hit 7	Hit 8	Hit 9	Hit 10
Point 1	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 2	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 3	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 4	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 5	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 6	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 7	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 8	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 9	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Air Discharge +/-2kV +/-4kV +/-8kV

	Hit 1	Hit 2	Hit 3	Hit 4	Hit 5	Hit 6	Hit 7	Hit 8	Hit 9	Hit 10
Point 1	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 2	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 3	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 4	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 5	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 6	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 7	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 8	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 9	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Point 10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass



Typical waveform of the output current of the ESD generator

EN61000-4-2 ESD Waveform

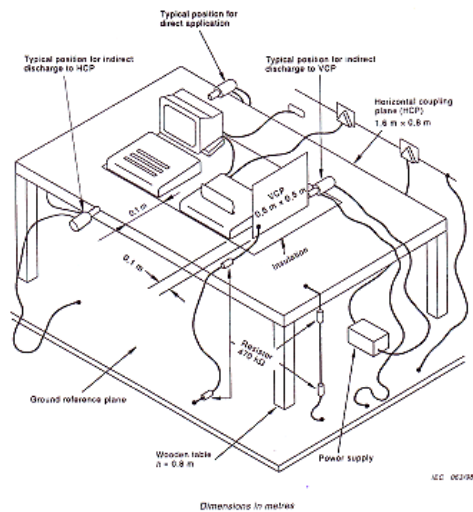


Figure 5 – Example of test set-up for table-top equipment – Laboratory tests

EN61000-4-2 ESD Test Setup

Part 2 - Radiated Immunity Testing (A.M.)

DATE: January 30, 2008

TEST STANDARD: IEC60601-1-2:3rd Ed.:2007

METHOD STANDARD: EN 61000-4-3:1995+A2:2001-11

TEST CONDITIONS: The EUT shall be tested within its intended operating and climatic conditions

TEST VOLTAGE: 230Vac, 50Hz

MINIMUM STANDARD: ME Equipment and Me Systems shall comply with the requirements of 6.2.1.10

METHOD OF TEST: The test methods and equipment specified by IEC 61000-4-3 apply with the following additions and modifications:

- The test frequency is swept or stepped from 80MHz to 2.5GHz
- The uniform field calibration steps are to be no greater than 1% of the fundamental frequency
- The test signal is set to 80% amplitude modulated at the modulation frequency specified in the table below, based upon the IUNTENDED USE of the ME EQUIPMENT of ME SYSTEM. Modulation Freq. Physiological Simulation Freq. & Operating Freq.
- The EUT is configured within a semi-Anechoic Chamber and subjected to an electromagnetic field of
- 3V/m across the frequency range 80MHZ.– 2.5GHz noted below:

Amplitude 3V/M

Frequency Range: 80MHz – 2.5GHz

Modulation: 80% AM (kHz tone)

Sweep Rate: Less than 1.5×10^{-3} decades/s

Step Size: 1% of previous Frequency (i.e. Previous Frequency X 1.01)

Dwell Time: 3000msec

TEST DATA:

#	Testing Frequency (GHz)	Field Strength	EUT	Pass/Fail
1	80MHz – 1.0 MHz	3V/M	4 Sides	Pass
2	1.0GHz – 2.5 GHz	3V/M	4 sides	Pass

PERFORMANCE: Complies with Required Standard.

Part 3 - EFT/Burst Testing (Fast Transient - AC Power Supply and I/O Lines)

DATE: February 1, 2008

TEST STANDARD: IEC60601-1-2:2007 3rd Ed.

TEST METHOD: IEC EN 61000-4-4:1995 +A1:2000 +A2:2001

TEST CONDITIONS: The EUT shall be tested within its intended operating and climatic conditions

TEST VOLTAGE: 230Vac, 50Hz

MINIMUM STANDARD: ME Equipment and Me Systems shall comply with the requirements of 6.2.1.10

REQUIREMENTS: Immunity Test Levels of +/-2kV for AC and DC power lines and +/-1kV for signal and interconnecting cables. Signal and interconnecting cables specified to be (i.e. restricted to) less than 3m in length by the MANUFACTURER of the ME EQUIPMENT of ME SYSTEM and all patient-coupled cables are not tested directly. However, the effects of any coupling between cables that are tested directly and cables that are not tested directly shall be taken into account. The test methods and equipment specified by IEC 61000-4-4 apply with the following modifications

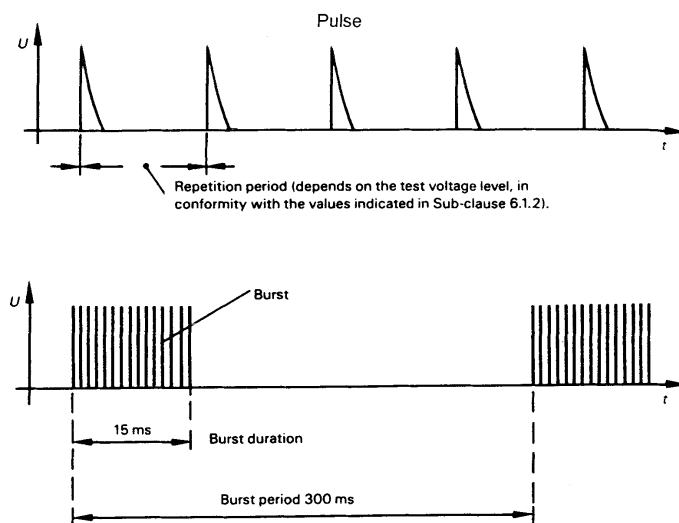
Direct Injection - AC Power Ports +/-2.0kV (5/50ns) @ 5kHz (frequency)

Capacitive Clamp - Signal & Communication Ports: +/-1kV (5/50ns) @ 5kHz (frequency)

TEST DATA: FAST TRANSIENTS / BURST CE Mater Class #

Cable	Test Type	Test Levels (kV)	Performance Criterion
AC Power	Direct Injection	+/-2.0	Complies

PERFORMANCE: Complies with Required Standard.



General graph of a fast transient/burst.

IEC 801-4, EN61000-4-4 EFT Waveforms

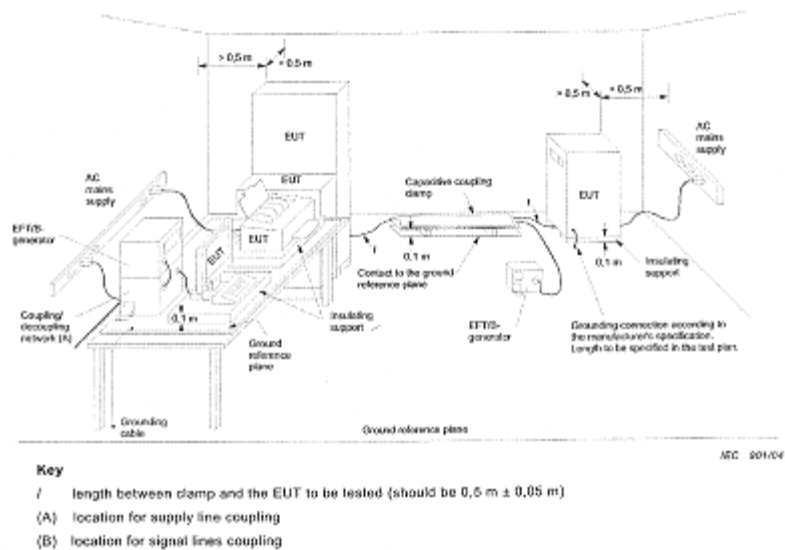


Figure 7 – General test set-up for laboratory type tests

IEC 801-4, EN61000-4-4 EFT Test Setup

Part 4 - Surge Transient Immunity

DATE: January 31, 2008

TEST STANDARD: IEC60601-1-2:2007 3rd Ed.

TEST METHOD: IEC EN61000-4-5:1995 +A1:2000

TEST CONDITIONS: The EUT shall be tested within its intended operating and climatic conditions

TEST VOLTAGE: 230Vac, 50Hz

MINIMUM STANDARD: ME Equipment and Me Systems shall comply with the requirements of 6.2.1.10

REQUIREMENTS: Immunity test levels of +/-0.5kV, +/-1kV and +/-2kV for AC power line(s) to earth and +/-0.5kV and +/-1kV for AC power line(s) to line(s). All other ME EQUIPMENT and ME SYSTEM cables are not tested directly. However the effects of any coupling between cables that are tested directly and cables that are not tested directly shall be taken into account.

METHOD OF TEST: Five positive and negative surges are applied across each leg of the power line to each other and with respect to protective earth. Each surge was applied after a one-minute recovery period. All test levels are conducted at 0°, 90° and 270° angles.

MODIFICATIONS: No modifications were required for the EUT to pass.

TEST DATA: FULL TEST

Surge Location	Surge Voltage (V)	Pass/Fail
L1/L2 to PE	+/- 500, 1000, 2000	Complies
L1 to L2	+/- 500, 1000, 2000	Complies

PERFORMANCE: Complies with Required Standard.

Part 5 - Conducted Immunity Testing (A.M.)

DATE: January 31, 2008

TEST STANDARD: IEC60601-1-2:3rd Ed.:2007

TEST METHOD: EN61000-4-6:1996 1st Ed

TEST CONDITIONS: The EUT shall be tested within its intended operating and climatic conditions

TEST VOLTAGE: 230Vac, 50Hz

REQUIREMENTS: General: ME EQUIPMENT and ME SYSTEMS that are not Life Supporting, except as specified in c), d) and e), shall comply with the above mentioned minimum standard at an Immunity test level of 3Vrms over the frequency range beginning at the start frequency determined as specified in f) and extending to 80MHz.

METHOD OF TEST: The EUT is tested with a test generator that will include all equipment and components for supplying ports with the disturbing signal at the required test level at the required point. With this unit a 3V amplitude RF signal was injected into the power and control lines using Bulk Current Injection Clamp, using the frequency range and parameters noted below.

Amplitude 3 Vrms

Frequency Range: 150 kHz - 80 MHz

Modulation: 80% AM (1kHz tone)

Sweep Rate: Less than 1.5×10^{-3} decades/s

Step Size: 1 % of previous Frequency (i.e. Previous Frequency X 1.01)

Dwell Time: 3000 msec

TEST CONFIGURATION:

Cable	Test Type	Test Levels (kV)	Met Criterion
AC Power	Bulk Injection Clamp	3Vrms	A
DC Power	Bulk Injection Clamp	3Vrms	A

PERFORMANCE: Complies with Required Standard

Part 6 - Dips and Interruptions Testing

DATE: February 1, 2008

TEST STANDARD: IEC60601-1-2:3rd Ed.:2007

TEST METHOD: EN61000-4-11:1995 +A1:2000

TEST CONDITIONS: The EUT shall be tested within its intended operating and climatic conditions

TEST VOLTAGE: 230Vac, 50Hz

REQUIRED STANDARD: Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j).

MINIMUM STANDARD: ME Equipment and Me Systems shall comply with the requirements of 6.2.1.10

METHOD OF TEST: This standard applies to electrical equipment having a rated input current not exceeding 16A per phase. It does not apply to electrical and electronic equipment for connection to DC networks or 400 Hz AC. networks. The object of this test is to establish a common reference for evaluating voltage dips, short interruptions, and voltage variation.

TEST DATA:

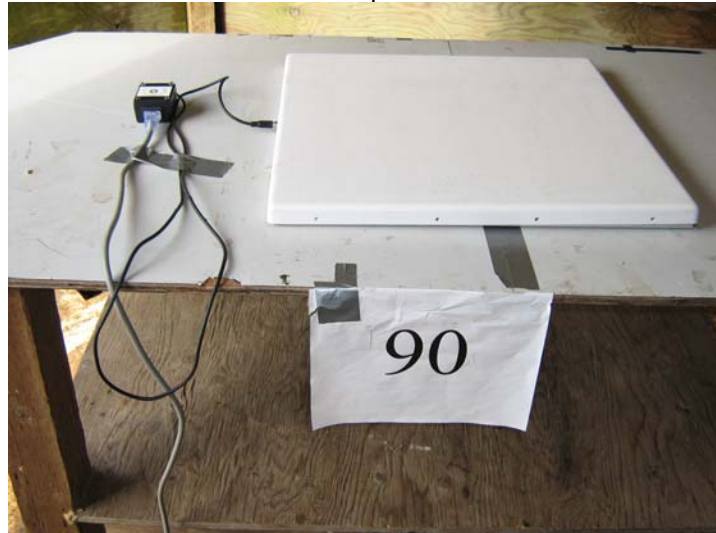
Test Performed	Test Specifications	Pass/Fail
Voltage Dips @50Hz	0% during 0.5 Cycle	Pass
	0% during 10/12 ^h 1Cycles	Pass
	40% for 5 cycles	Pass
	70% during 25/30 ^h Cycles	Pass
Voltage Interruptions	0% Open 5 sec	Pass

PERFORMANCE: Complies with Required Standard

Appendix A: Report of Measurements EUT Photos



Emissions Test Setup of EUT Side View



Emissions Test Setup of EUT Front View Close Up



Emissions Test Setup of LISN used for Testing

Appendix B: Report of Measurement Data and Plots

Conducted Emissions - Wireless 2000 – BSP Patient Monitor

Criteria: FCC/CE Class B 3 meters

Table 1: Line 1- 120Vac, 60Hz Peak

Frequency (MHz)	Limit (dB μ V)	DelLim-Pk (dB)
0.6999	47.7	+1.7
0.7263	46.4	-0.4
0.6816	46.3	+0.3
0.6638	43.0	-3.0
0.6329	42.5	-3.5
0.7497	42.5	-3.5
AVERAGE		
0.6999	39.6	-6.4
0.6003	31.8	-14.2
0.6329	30.4	-15.6
0.7577	29.0	-17.0

Table 2: Line 2- 120Vac, 60Hz Peak

Frequency (MHz)	Limit (dB μ V)	DelLim-Pk (dB)
0.6889	45.6	-0.4
0.7340	42.7	-3.3
0.6744	42.2	-3.8
0.6999	42.0	--4.0
0.7617	40.4	-5.6
0.6099	40.1	-5.9
AVERAGE		
0.6999	36.6	-9.4
0.7263	34.3	-11.7
0.7977	28.4	-17.6
0.6099	27.3	-18.7
0.6329	26.9	-19.1

Table 3: Line 1- 230Vac, 50Hz Peak

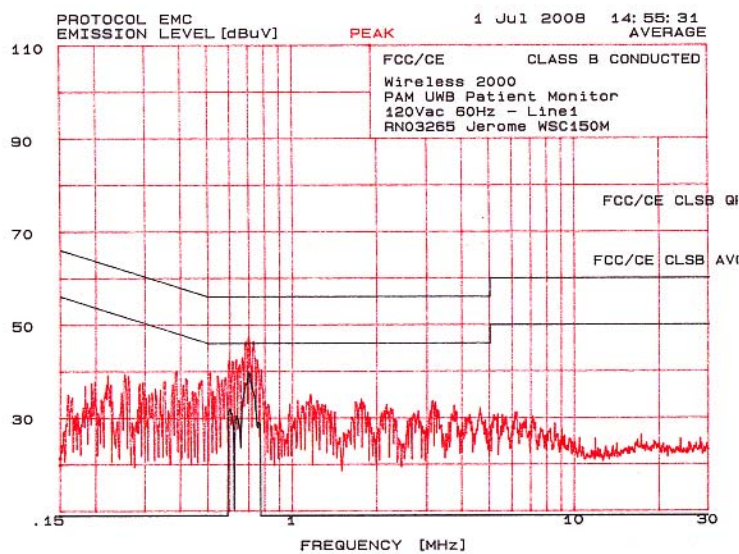
Frequency (MHz)	Limit (dB μ V)	DelLim-Pk (dB)
0.6889	47.1	+1.1
0.4370	45.7	-1.4
0.6533	44.3	-1.7
0.4079	45.8	-1.8
0.4607	44.6	-2.0
0.6744	43.9	-2.1
AVERAGE		
0.6962	36.3	-9.7
0.4346	34.4	-12.7
0.4079	34.7	-12.9
0.4806	32.8	-13.5
0.3828	34.5	-13.7
0.5121	30.4	-15.6

Table 4: Line 2- 230Vac, 50Hz Peak

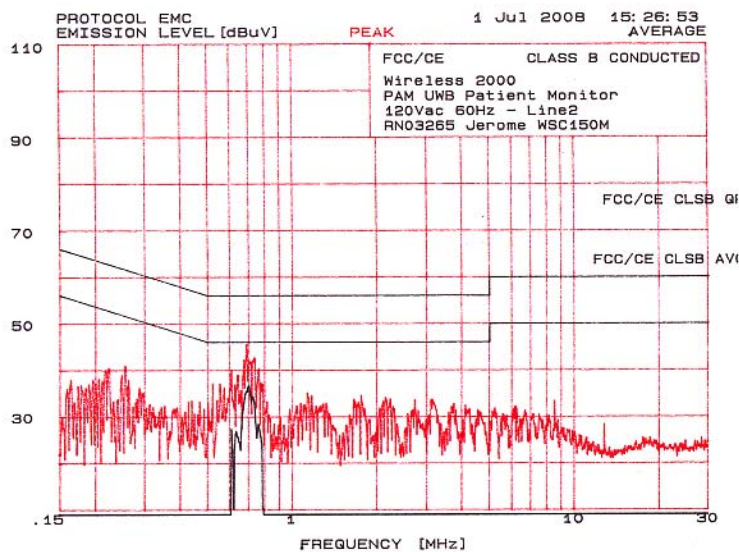
Frequency (MHz)	Limit (dB μ V)	DelLim-Pk (dB)
0.6816	42.4	-3.6
0.6999	40.7	-5.3
0.6397	40.2	-5.8
0.7073	39.4	-6.6
0.6638	38.9	-7.1
0.6229	38.4	-7.6

Radiated Emissions All Emissions are Greater than 20dB below Class B Limit Lines

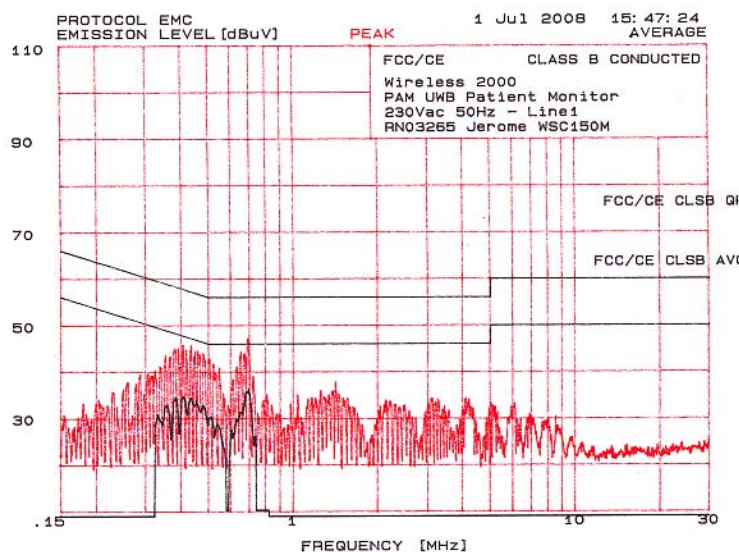
Conducted Emission Plots



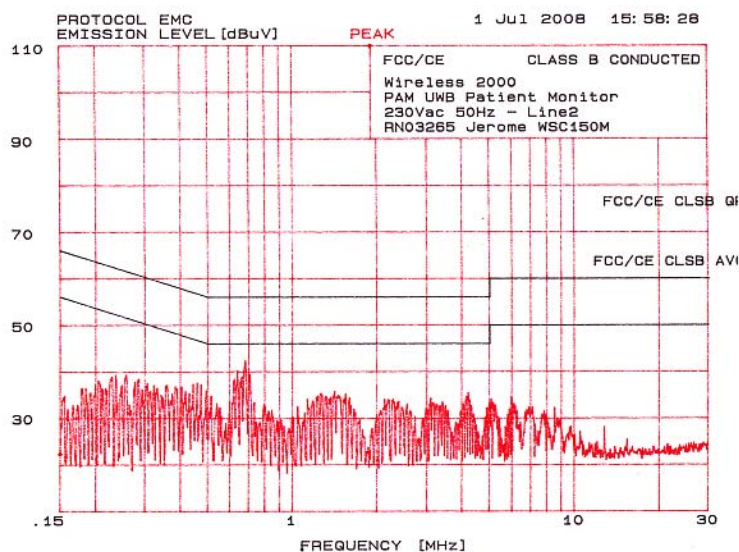
Conducted Emissions Line 1 – 120Vac, 60Hz



Conducted Emissions Line 2- 120Vac, 60Hz



Conducted Emissions Line 1 – 230Vac, 50Hz



Conducted Emissions Line 2- 230Vac, 50Hz