

Test Report #408.155.1

EMC tests on the devices/equipment:

OxyTrue FC
OxyTrue SC

Equipment under Test:

Description: Pulse Oximeter Monitor
Model: OxyTrue FC
OxyTrue SC

Manufacturer/Customer: bluepoint medical GmbH & Co. KG
An der Trave 15
D-23923 Selmsdorf, Germany

Test laboratory: CEcert GmbH.
Alter Holzhafen 19
D-23966 Wismar, Germany

Test specification:

Tests:	Standards:	Result:
Emission:		
Radiated emission (30 MHz - 1 GHz)	IEC 60601-1-2:2007 FDA Reviewer Guidance /93/	PASS
Magnetic fields (RE 101)	FDA Reviewer Guidance /93/	PASS
Interference immunity:		
Electrostatic discharge	IEC 60601-1-2:2007 FDA Reviewer Guidance /93/	PASS
Electromagnetic field	IEC 60601-1-2:2007 FDA Reviewer Guidance /93/	PASS
Magnetic field (power-frequency)	IEC 60601-1-2:2007	PASS
Magnetic field (low frequency)	FDA Reviewer Guidance /93/	PASS
Quasi-Static electric field	FDA Reviewer Guidance /93/	PASS

Explanation:

PASS – The EUT meets the test requirements. FAIL – The EUT does not meet the requirements N/A – Test is not applicable.

Evaluation :

The Equipment under Test (EuT) meets the EMC requirements for Group 1, Class B in accordance to IEC 60601-1-2 for not life-supporting equipment (including the additional requirements of FDA Reviewer Guidance) and the additional applicable requirements of ISO 9919 (not intended for use during patient transport outside the healthcare facility).

Period of test: 2008-06-06 - 2008-06-24

This test report with appendix consists of 25 pages.

1. General information on the test item(s)

Description: Pulse Oximeter Monitor
Model: OxyTrue FC
 OxyTrue SC
Serial no.: 2008052301 (OxyTrue FC)
 2008052302 (OxyTrue SC)
Manufacturer/Customer: bluepoint medical
Contact person: Mr. Heiner Busche

Brief description:

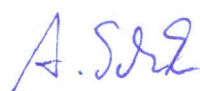
EMC conformity test of a Pulse Oximeter Monitor to record the pulse and the oxygen content of the patient blood. The sensor is integrated into the monitor (see chapter 3.4). The tests were performed on two versions of the monitor. Both versions are electrical identical. They differ only in the monitor casing (form and material).

Steps to EMC, suppressions:

- none

Participant in the tests: none

Responsible for the technical content of the test report:

	name	signature
Examiner	Matthias Becker Andreas Schenk	

Head of Test Laboratory	Bernd Schmidt
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Note:

The CEcert GmbH assures the applicant that the tests are carried out within the scope of the tests outlined under point 2 and in accordance with the test specifications outlined under point 3. Any exceptions or deviations will be clearly indicated.

The results contained in this test report are relevant exclusively to the item(s) submitted for testing. The CEcert GmbH: is not liable for any conclusions and generalizations which may be drawn from the test results and applied to further samples and examples of the type of device represented by the item submitted for testing.

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2. Test Specification

2.1. Emission

Applied standards:

IEC 60601-1-2:2007

Classification: **Group 1, Class B**

FDA Reviewer Guidance for Premarket Notification Submission /1993/

Tests performed:

Test method:	Basic Standard:	Chapter:
Radiated disturbance (ER)	CISPR 16-1/-2	4. 1.
Magnetic fields (RE 101)	MIL-STD-461E	4. 2.

Exceptions and explanations: none

2.2. Susceptibility

Applied standards:

IEC 60601-1-2:2007 with additional requirements of **ISO 9919:2005**

Classification: **Non life-supporting equipment; Not intended for use during patient transport outside the healthcare facility**

Tests performed:

Test method:	Basic Standard:	Chapter:
Electrostatic discharge – ESD (ID)	IEC 61000-4-2:2000	5. 1.
Electromagnetic field (IR)	IEC 61000-4-3:2006	5. 2.
Magnetic fields (power-frequency) (IM1)	IEC 61000-4-8:2000	5. 3.
Magnetic fields (low-frequency)	MIL-STD 461E RS101	5. 4.
Quasi-Static electric fields	FDA Reviewer Guidance	5. 5.

Exceptions and explanations: none

2.3. Low frequency phenomena, line feedback

none

2.4. Applied non-standard methods

none

3. Specification of the device/equipment

3.1. Configuration

Description:	Model:	Type No.:	Manufacturer:	Notes:
Product:				
Pulse Oximeter Monitor	OxyTrue FC	2008052301	bluepoint medical	
Pulse Oximeter Monitor	OxyTrue SC	2008052302	bluepoint medical	
Components:				
--				
Accessories/peripherals:				
--				
Simulators: Patient Simulator to generate Pulse and a SpO2 values Software: nn				

3.2. Cables and Lines

none

3.3. Particulars related to EMC

System frequencies: --
 Earth / Grounding: none
 Shielding: none

3.4. Notes and/or sketches

Fig. 1: Test set-up radiated disturbances

Dimension of EuT: 60 x 45 x 40 mm (OxyTrue FC)
 55 x 35 x 25 mm (OxyTrue SC)

Devices under test

3.5. Operating condition of the product

The status of the test object during the tests represented its normal area of deployment.

Measurement	The sensor part of the monitor was connected to the patient simulator. The monitor operating condition was measuring ON. The simulator generates the normal pulse and the oxygen content of patient blood. While testing, the values were observed.
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Power supply:	internal battery
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Climatic conditions during the tests:

Ambient temperature:	15 °C - 35 °C	(if not otherwise specified in this report)
Relatively air humidity:	25 % - 75 %	(if not otherwise specified in this report)
Air pressure:	86 kPa - 106 kPa	(860 mbar - 1060 mbar)

3.6. Simulation of operating conditions

Normal pulse (60 bpm) and the oxygen content (95 %) generated by the optical simulator, no conductive or capacitive contact to earth or other potentials.

3.7. Sampling particulars

The product was tested as a single device.

Measurements and Test Results

4. Emission

4.0.1 Particulars of measuring uncertainties and tolerance range

The calculated uncertainties and tolerance ranges of the Tests are in accordance with the requirements of IEC/CISPR 16-4.

4.0.2 Preliminary remarks and classification

Classification:

Group 1: ISM equipment with intentionally internal used conducted RF-energy

Group 2: ISM equipment in which the intentionally generated RF energy is used as radiation for treatment of materials.

Class A: Equipment to use in non-domestic properties and facilities with direct connection to the low-voltage supply system

Class B: Equipment for use in residential properties, light-industrial locations, business or commercial premises, outdoor locations

The device is classified as follows:

Group 1, Class B.

4.0.3 Pre information

The test object was tested with the configuration and operating conditions described in section 3.

Notes on measuring the radiated measurements:

The spectrographs have a logarithmic frequency division. Measurements with the Peak-detector were used to assess the product. If these measuring values are in the range of the Quasi-Peak or Average limits, the frequencies are measured using the Quasi-Peak or Average detector.

4.1. Radiated Emissions (ER)

Basic standard: IEC 60601-1-2:2007

Measuring set-up: CISPR 16-2 (see photo documentation)

Measuring process:

A prescan with in horizontal and vertical polarization was done at the beginning. The accessories/peripherals were placed inside the test set-up.

The radiated emissions were measured in the whole frequency range with the maximum level. The position of the equipment and the antenna height were changed during the measurements.

Measurement results:

Operating condition	Frequency range [MHz]	Polarization	Position of the EUT / Antenna height	Test results diagram/table	Compliance Pass/ Fail/ N/A
Measurement OxyTrue FC and OxyTrue SC	30 – 1000	horizontal, vertical	0 - 360° / 1 - 4 m	see annex	PASS

Measuring Distance: 10 m

During this EMC test several relevant interference emissions from the test object could be determined. Final test results (frequencies, max hold level) see appendix.

The measurement environment was the shielded, absorber-lined hall.

Measurement results:

According to the above test set-up the equipment under test specified in chapter 3 meets the radiated emission requirements in accordance with IEC 60601-1-2:2007 for group 1, class B and FDA Reviewer Guidance /1993/.

4.2. Magnetic Fields (MIL-STD-461E RE101)

Measuring set-up: MIL-STD-461E / Test coil and distance (7 cm) in accordance with MIL-STD-461E

Measuring process:

The radiated emissions are measured in the whole frequency range with each sensor. The maximum level was listed. The winding planes of the test coil were arranged parallel to the surface. On each side of the casing and sensor cable, for each measurable interference signal, the maximum flow densities are ascertained, the position characterised and the test values recorded.

Measurement results:

Operating condition	Frequency range [Hz]	Position	Detected Peaks [dBpT]	Compliance Pass/ Fail/ N/A
OxyTrue FC				
Measurement	30 - 1000	Monitor front, right, left, top, back	see Appendix	PASS
Measurement	1000 - 10000	Monitor front, right, left, top, back	see Appendix	PASS
Measurement	10000 - 100000	Monitor front, right, left, top, back	see Appendix	PASS
OxyTrue SC				
Measurement	30 - 1000	Monitor front, right, left, top, back	see Appendix	PASS
Measurement	1000 - 10000	Monitor front, right, left, top, back	see Appendix	PASS
Measurement	10000 - 100000	Monitor front, right, left, top, back	see Appendix	PASS

The measurement environment was a shielded, absorber-lined cabin.

During this EMC test several relevant interference emissions from the test object could be determined. Final test results (frequencies, max hold level) see appendix.

Measurement results:

The measured magnetic field emissions were caused by the Pulse oximeter monitor. The magnetic field strength does not depend on the sensor cable.

According to the above test set-up the equipment under test specified in part 3 meets the radiated magnetic emission requirements in the frequency range 30 Hz to 100 kHz in accordance with FDA Reviewer Guidance /93/.

5. Susceptibility

5.0 Performance criteria of failure at the immunity tests

Performance criteria of failure at the immunity tests

The Equipment or System shall be able to provide the Essential Performance and remain safe.

The following Degradations associated with Essential Performance and safety shall not be allowed:

- component failures;
- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of operating mode;
- false alarms;
- cessation or interruption of any intended operation, even if accompanied by an alarm;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals;
- artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- failure of automatic diagnosis or treatment Equipment and System to diagnose or treat, even if accompanied by an alarm.

For Equipment and Systems with multiple Functions, the criteria apply to each Function, parameter and channel.

The Equipment or System may exhibit Degradation of performance (e.g. deviation from manufacturer's specifications) that does not affect Essential Performance or safety.

Additional Essential performance requirements of ISO 9919:

For the purposes of IEC 60601-1-2:2001, 36.202.1 j) Compliance criteria, the pulse oximeter equipment shall operate within its specified SpO₂ accuracy limits and pulse rate accuracy limits during immunity testing.

In the event of disruption during transient tests as defined by IEC 61000-4-2, IEC 61000-4-4, IEC 61000-4-5 and IEC 61000-4-11, the pulse oximeter equipment shall recover from any disruption within 30 s.

Criteria of failure of FDA Reviewer Guidance:

The device must continue to operate as specified. No noticeable loss of function or performance is allowed below a performance level specified by the manufacturer.

An equipment alarm, temporary degradation or loss of function or performance which requires operator intervention or system reset, or loss or corruption of stored data is not allowed.

5.1. Electrostatic Discharge – ESD (ID)

Test set-up:

The test set-up was conforming to the standard IEC 61000-4-2 for desk-type equipment.

Test process:

At each test point there were for each polarity, at least 50 discharges. The product was monitored during this test. The test object and the measuring values were observed as to whether any deviation from normal performance occurred. The periphery was arranged beside the horizontal coupling plate for the indirect discharge.

Tests:

working condition:	point of discharge	test:	test level:	polarity	Compliance Pass/ Fail/ N/A
OxyTrue FC					
Measurement	enclosure, display, buttons	D,L	2 kV	pos./neg.	PASS
Measurement	enclosure, display, buttons	D,L	4 kV	pos./neg.	PASS
Measurement	enclosure, display, buttons	D,L	8 kV	pos./neg.	PASS
Measurement	coupling plate	I,H,V	2 kV	pos./neg.	PASS
Measurement	coupling plate	I,H,V	4 kV	pos./neg.	PASS
Measurement	coupling plate	I,H,V	6 kV	pos./neg.	PASS
Measurement	-- (no touchable metal parts)	D,K	2 kV	pos./neg.	N/A
Measurement	-- (no touchable metal parts)	D,K	4 kV	pos./neg.	N/A
Measurement	-- (no touchable metal parts)	D,K	6 kV	pos./neg.	N/A
OxyTrue SC					
Measurement	enclosure, display, buttons	D,L	2 kV	pos./neg.	PASS
Measurement	enclosure, display, buttons	D,L	4 kV	pos./neg.	PASS
Measurement	enclosure, display, buttons	D,L	8 kV	pos./neg.	PASS
Measurement	coupling plate	I,H,V	2 kV	pos./neg.	PASS
Measurement	coupling plate	I,H,V	4 kV	pos./neg.	PASS
Measurement	coupling plate	I,H,V	6 kV	pos./neg.	PASS
Measurement	-- (no touchable metal parts)	D,K	2 kV	pos./neg.	N/A
Measurement	-- (no touchable metal parts)	D,K	4 kV	pos./neg.	N/A
Measurement	-- (no touchable metal parts)	D,K	6 kV	pos./neg.	N/A

Note:

D	direct discharge onto the test object	L	air discharge
I	indirect discharge onto the test object	H	horizontal coupling plate under the EUT
K	contact discharge	V	vertical coupling plate

Environmental Conditions while test:

Humidity: 38,6 % rH

Temperature: 25,6 °C

Functional test after test procedure: PASS

Test results:

No relevant influencing functions of the equipment were detected during this EMC-Test. The performance criterion for the immunity was met. There was no function failure nor loss of data, neither was there any change in the working conditions.

According to the above test set-up the equipment under test specified in chapter 3 complies with the electrostatic discharge requirements, in accordance with IEC 60601-1-2:2007 and in accordance with the FDA Reviewer Guidance /93/.

5.2. High Frequency Electromagnetic Fields (IR)

Test set-up:

The test set-up was conforming to the standard IEC 61000-4-3 for desk-type equipment.

The equipment was built up 0,8 m over the ground plane. The field strength was calibrated in a distance of 3 m. There the Equipment under Test was placed.

- Antenna distance: 3 m
- Time per step, depends on the reaction time of the product: 10 sec.
- Test level: 3 V/m

Test procedure:

The output of the level in the frequency range was gradually changed in steps of 1% of the first frequency and then 1% of the frequency before.

Tests:

Operating conditions:	Frequency range: [MHz]	Modulation:	Polarization, Antenna direction	Comments/Test report	Compliance Pass/ Fail/ N/A
OxyTrue FC					
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, front	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, front	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, left	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, left	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, right	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, right	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, back	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, back	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, front	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, front	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, left	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, left	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, right	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, right	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, back	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, back	see annex	PASS
OxyTrue SC					
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, front	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, front	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, left	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, left	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, right	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, right	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	horizontal, back	see annex	PASS
Measurement	80 – 2500	80 % AM, 2Hz	vertical, back	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, front	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, front	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, left	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, left	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, right	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, right	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	horizontal, back	see annex	PASS
Measurement	26 – 1000	100 % PM, 0,5 Hz	vertical, back	see annex	PASS

Functional test after test procedure: PASS

Test results:

No relevant influencing functions of the equipment were detected during this EMC-Test. The performance criterion for the immunity was met. There was no function failure nor loss of data, neither was there any change in the working conditions.

According to the above test set-up the equipment under test specified in chapter 3 complies with the immunity requirements in respect of high frequency electromagnetic field, in accordance with IEC 60601-1-2:2007 for not life supporting equipment and in accordance with the FDA Reviewer Guidance /93/.

5.3. Magnetic Field with Power-frequency (IM)

Test set-up:

The tests were performed in accordance to IEC 61000-4-8.

The main parts of the configuration are a ground plane, a sufficient big inductance coil with a well known coil factor for producing a homogeny magnetic field and a test generator with sufficient current supply. A square inductance coil with 1 m x 1 m was used for generation of the magnetic field.

Tests:

working conditions:	equipment:	test level:	duration:	Compliance Pass/ Fail/ N/A
OxyTrue FC				
Measurement	whole configuration x-axis	3 A/m , 50Hz	5 min	PASS
Measurement	whole configuration y-axis	3 A/m , 50Hz	5 min	PASS
Measurement	whole configuration z-axis	3 A/m , 50Hz	5 min	PASS
Measurement	whole configuration x-axis	3 A/m , 60Hz	5 min	PASS
Measurement	whole configuration y-axis	3 A/m , 60Hz	5 min	PASS
Measurement	whole configuration z-axis	3 A/m , 60Hz	5 min	PASS
OxyTrue SC				
Measurement	whole configuration x-axis	3 A/m , 50Hz	5 min	PASS
Measurement	whole configuration y-axis	3 A/m , 50Hz	5 min	PASS
Measurement	whole configuration z-axis	3 A/m , 50Hz	5 min	PASS
Measurement	whole configuration x-axis	3 A/m , 60Hz	5 min	PASS
Measurement	whole configuration y-axis	3 A/m , 60Hz	5 min	PASS
Measurement	whole configuration z-axis	3 A/m , 60Hz	5 min	PASS

Functional test after test procedure: PASS

Test results:

No relevant influencing functions of the equipment were detected during this EMC-Test. The performance criterion for the immunity was met. There was no function failure nor loss of data, neither was there any change in the working conditions.

According to the above test set-up the equipment under test specified in part 3 complies with the magnetic field requirements with power-frequency, in accordance with IEC 60601-1-2:2007.

5.4. Magnetic field low frequency (RS 101)

Test set-up: The test set-up was conform with MIL-STD-461E RS 101.

The output of the level in the frequency range was gradually changed in steps of 1% of the first frequency and then 1% of the frequency before.

Time per step: **10 sec.**
 Frequency range: **30 Hz – 100 kHz**
 Modulation: **0.5 Hz PM**

Tests:

working conditions:	Direction:	test level:	Comment:	Compliance Pass / Fail / N/A
OxyTrue FC				
Measurement	Monitor (all parts)	RS 101	30 Hz – 1 kHz	PASS
Measurement	Monitor (all parts)	RS 101	1 kHz – 100 kHz	PASS
OxyTrue SC				
Measurement	Monitor (all parts)	RS 101	30 Hz – 1 kHz	PASS
Measurement	Monitor (all parts)	RS 101	1 kHz – 100 kHz	PASS

Functional test after test procedure: PASS

Test results:

No relevant influencing functions of the equipment may detect during this EMC-Test. The criterion for the immunity was met. There was no function failure nor loss of data, neither was there any change in the working conditions. The Essential performance requirements were met. The patient safety was not influenced.

According to the above test set-up the equipment under test specified in part 3 complies with the magnetic field requirements MIL-STD-461D RS 101 in accordance with the FDA Reviewer Guidance /93/.

5.5. Quasi-static Electric Field

Test set-up: The device (Monitor and Sensor) was tested between parallel horizontal planes. It is supported by insulating material so that it is positioned entirely between 1/3 and 2/3 the distance between the horizontal planes.
Distance between the planes: 50 cm

Tests:

working conditions:	Direction:	Frequency:	Test level:	test time: [s]	Compliance Pass/ Fail/ N/A
OxyTrue FC					
Measurement	X (left, right)	0.5 Hz	2000 V/m	60	PASS
Measurement	Y (top, bottom)	0.5 Hz	2000 V/m	60	PASS
Measurement	Z (front, back)	0.5 Hz	2000 V/m	60	PASS
OxyTrue FC					
Measurement	X (left, right)	0.5 Hz	2000 V/m	60	PASS
Measurement	Y (top, bottom)	0.5 Hz	2000 V/m	60	PASS
Measurement	Z (front, back)	0.5 Hz	2000 V/m	60	PASS

Functional test after test procedure: PASS

Test results:

No relevant influencing functions of the equipment may detect during this EMC-Test. The criterion for the immunity was met. There was no function failure nor loss of data, neither was there any change in the working conditions. The Essential performance requirements were met. The patient safety was not influenced.

According to the above test set-up the equipment under test specified in part 3 complies with the quasi-static electric field requirements, in accordance with the FDA Reviewer Guidance /93/.

6. Information about the measurement equipment

Description	Model/Type	Manufacturer	Serial-No.	Test method
EMI Receiver (20 MHz - 1000 MHz)	ESVS-10	R&S	843207/008	EC, EP, ER, E1-EUB
EMI Receiver (9 KHz - 30 MHz)	ESHS-10	R&S	842884/013	EC, EP, ER
EMI Receiver (20 Hz - 26,5 GHz)	ESIB 26	R&S	100135	EC, EP, ER
Two-line-V-artificial mains network 16 A	ESH3-Z5	R&S	843012/025	EC, ER
V- artificial mains network 5 µH/ 50 Ohm	ESH 3-Z6	R&S	837950/008	EC, E1-EUB
V- artificial mains network 5 µH/ 50 Ohm	ESH 3-Z6	R&S	843864/030	EC, E1-EUB
Two-line-V-artificial mains network 2 x 10 A	NNB 2/16	Rolf Heine	2/16-96017B	EC, EP, ER
Four-line-V-artificial mains network 4 x 25 A	ESH2-Z5	R&S	100099	EC, EP, ER
Dual directional coupler 0,8- 4,2 GHz	DC 7144	ar	--	IR
Dual directional coupler	DC 6180 M1	ar	--	IR
Active voltage probe	ESH2-Z2	R&S	843837/010	EC
Passive voltage probe	ESH2-Z3	R&S	100007	EC
Biconical antenna 20- 300 MHz	HK116	R&S	842938/005	ER, E1-EUB
Log.- per.antenna 300 MHz- 1 GHz	HL 223	R&S	843338/004	ER, E1-EUB
Loop Antenna 60 cm 1KHz-30 MHz	HFH2-Z2	R&S	880665/0012	ER
Ultalog antenna 30 MHz- 3 GHz	HL562	R&S	100065	ER
Magnetic field antenna 1x1 m 1A/m- 100 A/m	MF 1000	EMC	1000-35	IM
Chase antenna 30 MHz- 1 GHz	CBL 6111B	EMC	1925	IR, E1-EUB
Active rod Antenna 10 KHz- 80 MHz	HE 010	R&S	100139	ER
Log.- per. Antenna 80 MHz- 1GHz	AT 1080	ar	305184	IR
Magnetic field antenna for RE 101	MFA 01	CEcert	--	ER, IR
Broadband horn antenna 1- 18 GHz	BBHA 9120 D	Schwarzbr.	348	ER, IR
Horn antenna 0,8- 5 GHz	AT 4002 A	ar	304917	ER, IR, E1-EUB
Horn antenna 4- 18 GHz	AT 4218	ar	312265	ER, IR
Universal power analyzer	PM 3000 A	Voltech	5370	MC1, MC2
Power supply	6560	Chroma	0462	MC1, MC2, IM
Artificial mains network	NI 2415	ZES	A9703016	MC1, MC2
Variac for power variation	TRA1H03B	EMC	100-05	DIPS
Capacitive coupling clamp	ESD 101-66	EMC	--	ICI 1
Surge-coupling kit for signal lines	TRA1Z10B	EMC	--	ICI 2
100 Ohm direct coupler	DEK 100	CEcert	--	ICI
Adapter network 1:20	APW 20:1	CEcert	--	ICI, E1-EUB
ESD-discharge kit	ESD 30C	EM Test	V0521100389	ID
Generator for transients	TRA 2000	EMC	790	ID, ICI, IM, E1-EUB
ESD-discharge kit		EMC		ID
Load dump generator	LD 200 B	EM Test	0701- 08	ICI, E1-EUB
Micro Pulse Generator	MPG 200 B	EM Test	0104- 01	ICI, E1-EUB
Coupling clamp	ACC	EM Test		ICI, E1-EUB
Voltage Drop Generator	VDS200	EM Test	V0608101200	ICI, E1-EUB
1 - cannel power meter	LMG95	ZES	8060505	MC1, MC2
Signal generator 9KHz- 1040 MHz	SMY 01	R&S	842483/030	ICS, IR, E1-EUB
Signal generator 9KHz- 1,1 GHz	SML 01	R&S	101415	IR, ICS, E1-EUB
Signal generator 1GHz- 20 GHz	SMR 20	R&S	100547	IR, E1-EUB
Comparison Noise Emitter 9KHz- 2GHz	NE 3000	ar	305380	ER
Power amplifier < 250 MHz 75W	75A250	ar	18681	IR, ICS, E1-EUB
Power amplifier < 1000 MHz 100W	FLH 100	Frankonia	--	IR, E1-EUB
Broadband RF amplifier 0,8-4,2 GHz/ 25W	25S1G4A	ar	305439	IR, E1-EUB
Broadband RF amplifier 0,08-1 GHz 500W	500W1000A	ar	305559	IR, E1-EUB
Broadband RF amplifier 1-11 GHz 27 dB	LN1G11	ar	313109	IR
Broadband RF amplifier 10-125 MHz 58,7dB	KMA3020	ar	9975-1	IR
Power meter, single channel	NRVS	R&S	843209/009	ICS, IR, E1-EUB
Power meter, single channel	NRVS	R&S	843537/030	ICS, IR, E1-EUB
Power meter, dual channel	NRVD	R&S	100644	ICS, IR, E1-EUB
10-V-voltage probe (Insertion unit)	URV5-Z2	R&S	842558/075	ICS, IR
100-V-voltage probe (Insertion unit)	URV5-Z4	R&S	842619	ICS, IR
Thermal power sensor 50 Ohm	NRV- Z53	R&S	100084	ICS, IR
Thermal power sensor 50 Ohm	NRV- Z51	R&S	100608	IR, ICS, E1-EUB
EM- field analyzer system	EFA3	W&G	G-0093	MR
H- field sensor	2245/90.10	W&G	H-0033	MR
E- field sensor	2245/90.30	W&G	K-0048	MR
EM Radiation Monitor	EMR-30	W&G	2244/30	IR
E- field probe	Typ 8	W&G	2244/90.20	IR
E- field probe	RadiSense	Dare	01D00057SNO	IR
EM Coupling clamp	203i	FCC	168	ICS
CDN, M 1 Conductor, 16 A	KEN 801 M1	MEB	12059	ICS
CDN, C 1 line, coaxial	FCC-801-C1	FCC	73	ICS
CDN, M 3 Conductor, 16 A	FCC-801-M3-16AMP	FCC	175	ICS
CDN, M 2 Conductor, 16 A	FCC-801-M2-16AMP	FCC	86	ICS
CDN, M 3 Conductor, 16 A	FCC-801-M3-16AMP	FCC	2022	ICS
CDN, M 2 Conductor, 16 A	FCC-801-M2-16AMP	FCC	2013	ICS
CDN, AF 4 Conductor, unshielded signal lines	FCC-801-AF4	FCC	51	ICS

Test Report: 408155_1 BLUEPOINT OXYTRUE EMC

CDN, S 4 Conductor, shielded signal lines	FCC-801-S4	FCC	19	ICS
CDN, T 4 Conductor, symmetry signal lines	FCC-801-T4	FCC	74	ICS
Impedance stabilization network	ISN T200	Schaffn.	15553	ICS, EC
Impedance stabilization network	ISN T400	Schaffn.	15534	ICS, EC
100 Ohm direct coupler	Typ 100	CEcert	001	ICS
CDN, 9 Conductor, shielded signal lines	FCC-801-S9	FCC	01001	ICS
CDN, 25 Conductor, shielded signal lines	FCC-801-S25	FCC	01002	ICS
CDN, M 5 Conductor, 32 A	FCC-801-M5	FCC	04019	ICS
Impedance stabilization network	ISN T200	Schaffn.	15553	ICS, EC
Coaxial attenuator 6 dB 100W	R417706118	Radiall	LOT: 0117/1	ICS
Coaxial attenuator 6 dB 100W	R417706118	Radiall	LOT: 0117/2	ICS
Coaxial attenuator 20 dB 10W	ESH2Z11	R&S	9349.7518.52	
Coaxial attenuator 6 dB 100W	24-6-34	Weinschel	AT 3598	
Pulse limiter	ESH3-Z2	R&S	100199	EC
Fixed coaxial attenuator 2dB	1 R-2	Weinschel	LDC 9751	IR
Current probe	F-36-2	FCC	36	EC
RF current probe	F-55	FCC	34	EC
Bulk current injection probe (0,1 - 400 MHz)	95242-1	EMCO	50989	E1-EUB
Bulk current injection probe	95236-1	ETS	00032243	
Scopemeter	96B	FLUKE	DM6630620	
True RMS multi meter	189	FLUKE	81440003	SEB
Digital Oscilloscope	DL9140	Yokogawa	91F104187	E1-EUB
Climatic tester	testo 645	testo	365696/007	SEB
Climatic tester	THB4141	AIRFLOW	03900185	ID
Climatic tester	testo 110	testo	K104406	SEB
Climatic chamber	C-40/350	CTS	013085	SEB
Software Fluke Scopemeter	FlukeView	FLUKE		SEB
Software Pulsgeneratoren				
LD200/MPG200/VDS200	ISM ISO	EM Test		ICI, E1-EUB
Software supply voltage drop and transients	65XX Soft Panel	Chroma	--	MC1, MC2, IM
semi anechoic chamber	10- Meter	Frankonia	--	ER, EC, IR, ...
semi anechoic chamber immunity	3- Meter	Frankonia	--	ER, EC, IR, ...
semi anechoic chamber immunity	1- Meter	Frankonia	--	ER, EC, IR, ...
fully anechoic chamber	1- Meter	Frankonia	--	ER, EC, IR, ...
RF cabel long	BI - K9 (8m)	emv	--	ER, IR
RF cabel short	BI	emv	--	ER, IR
cable immunity	K8 (6m)	emv	--	IR
cable fully anechoic chamber	1 Meter	emv	--	E1-EUB
Tap offs (F-connector)	DM 21 A	WISI	3344	

Test method:

EC	conducted emission measurement	ID	ESD
ER	radiated emission measurement	IR	electromagnetic field immunity
EP	power line radiation	ICI1	electrical transient immunity
MC1	harmonics current	ICS	conducted disturbance immunity
MC2	flicker	IMS	magnetic fields immunity (power frequency, transient)
DIPS	voltage variation and dips	E1-EUB	electronic components used in vehicles

Annex List :

Test (description)	Page
Radiated emission (Peak-detector) Max-Hold-Graph	20
Magnetic Fields; MIL-STD-461 E RE 101; OxyTrue FC	21
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Radiated immunity (RF field), Calculated field, horizontal	23
Radiated immunity (RF field), Calculated field, vertical	24
Magnetic field low frequency MIL-STD-461E RS 101; Calculated field	25

CEcert GmbH

EUT:

Serial Number:

Manufacturer:

Operating Condition:

Test Engineer:

Comment:

Radiated Emissions

OxyTrue FC and OxyTrue SC

2008052301 and 2008052302

bluepoint medical

Measurement

Andreas Schenk

Scan Settings:

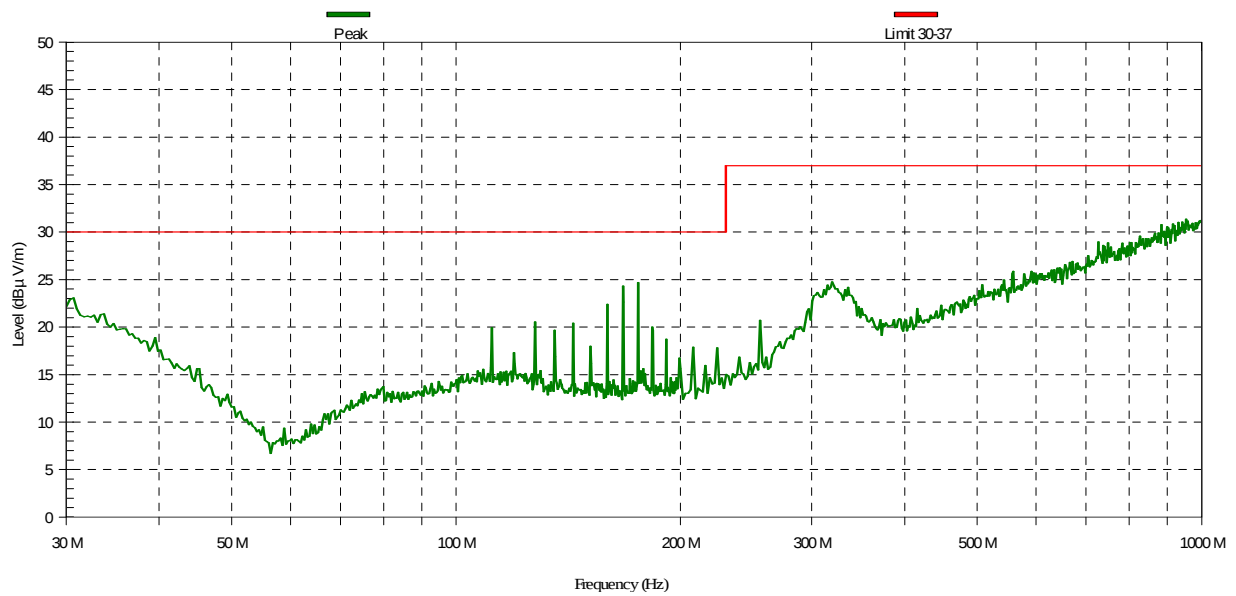
Frequency Range: 30 MHz – 1000 MHz

Receiver Bandwidth: 120 kHz

Measure Time: 15 ms (Prescan), 3 s (Final Measurement)

Measurement Distance: 10 m

Prescan (MAX Hold Graph):

**Detected Peaks:**

Frequency (MHz)	PK Value (dBµV/m)	QP Value (dBµV/m)	QP Limit (dBµV/m)	Angle (degrees)	Height (m)	Polarization	Result
167,977	24,9	23,2	30	160	4	H	Pass
175,988	25,3	23,6	30	180	4	H	Pass

Cecert GmbH
MIL-STD-461 E RE 101

EUT:
Serial Number:
Manufacturer:
Operating Condition:
Test Engineer:
Comment:

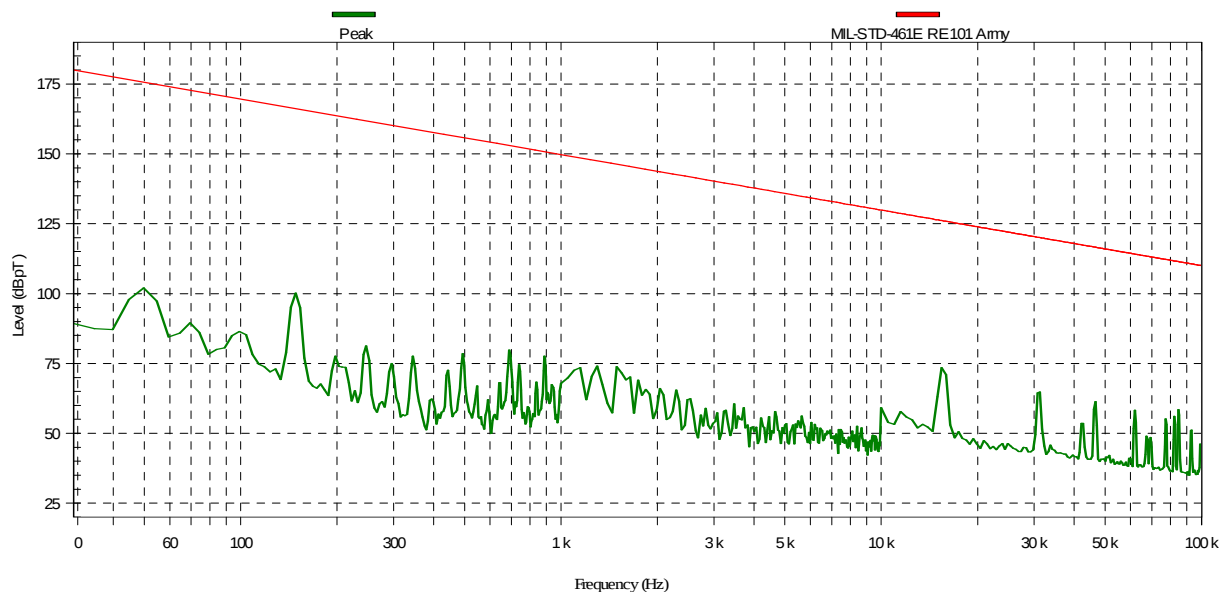
Radiated Emissions

OxyTrue FC
2008052301
bluepoint medical
Measurement
Andreas Schenk

Scan Settings:

Frequency Range: 30 Hz – 100 kHz
Measure Time: 15 ms (Prescan), 1 s (Final Measurement)
Measurement Distance: 7 cm

Prescan (MAX Hold Graph):



Detected Peaks:
none

CEcert GmbH
MIL-STD-461 E RE 101

EUT:
Serial Number:
Manufacturer:
Operating Condition:
Test Engineer:
Comment:

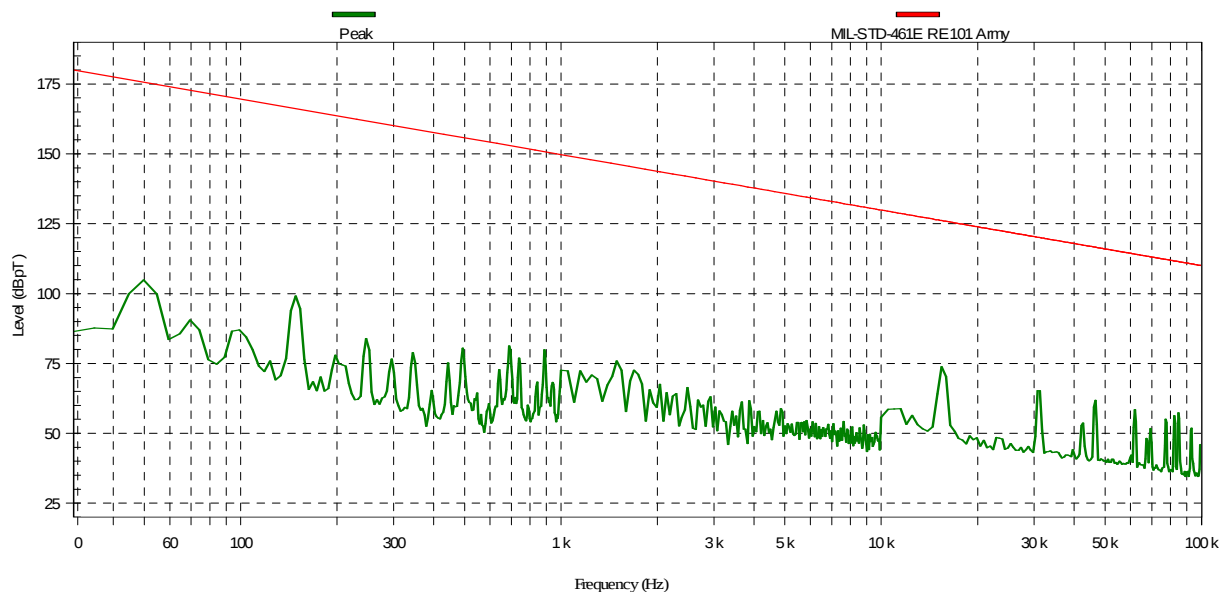
Radiated Emissions

OxyTrue SC
2008052302
bluepoint medical
Measurement
Andreas Schenk

Scan Settings:

Frequency Range: 30 Hz – 100 kHz
Measure Time: 15 ms (Prescan), 1 s (Final Measurement)
Measurement Distance: 7 cm

Prescan (MAX Hold Graph):



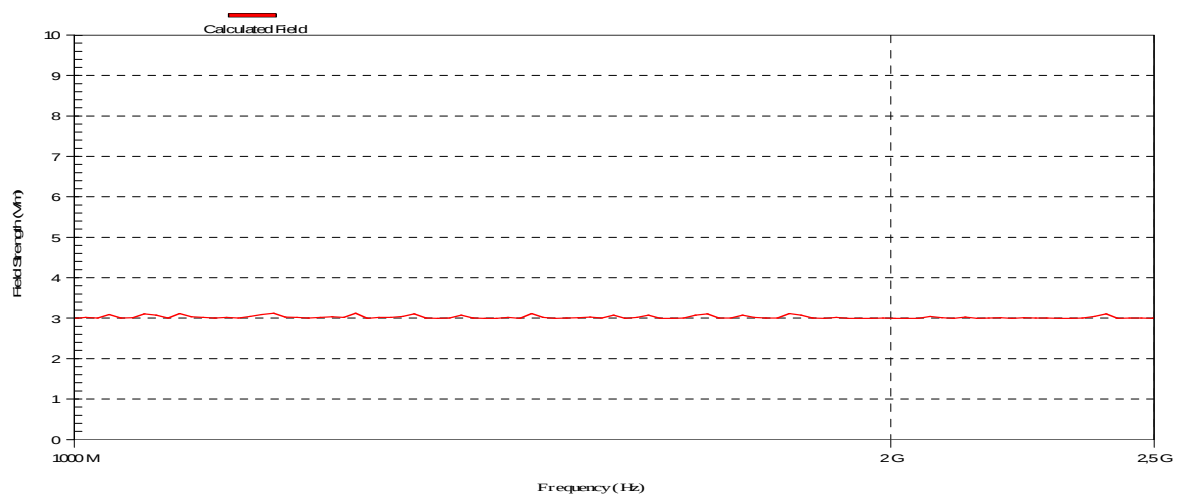
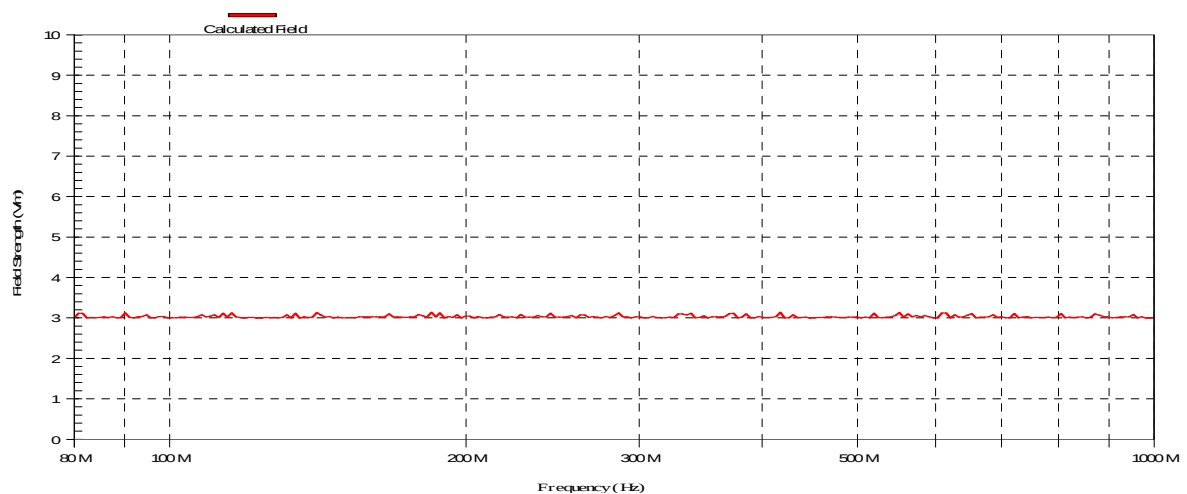
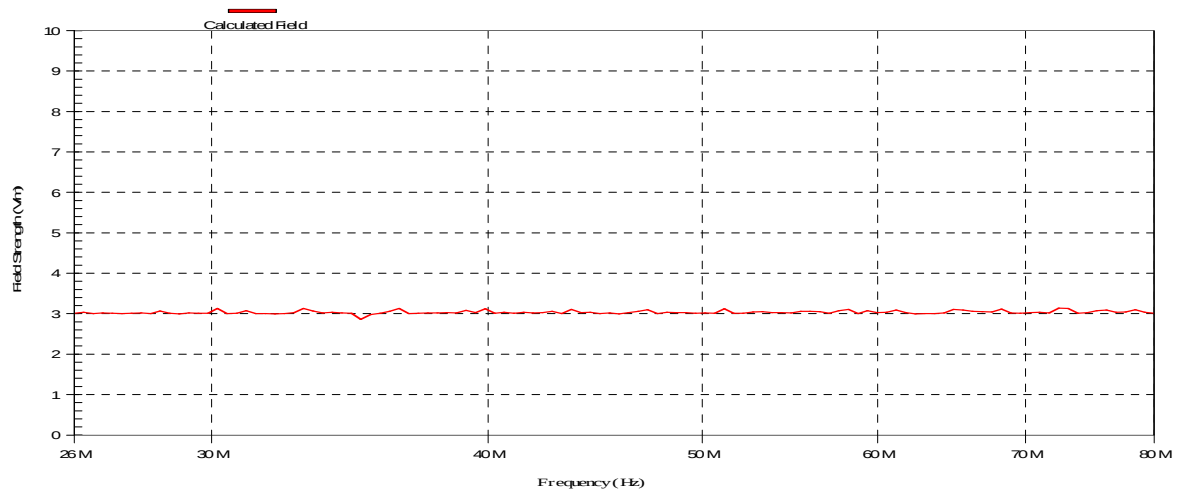
Detected Peaks:
none

CEcert GmbH
IEC 61000-4-3

EUT:
 Manufacturer:
 Operating Condition:
 Test Engineer:
 Antenna Polarisation:
 Comment:

Radiated Immunity

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 horizontal

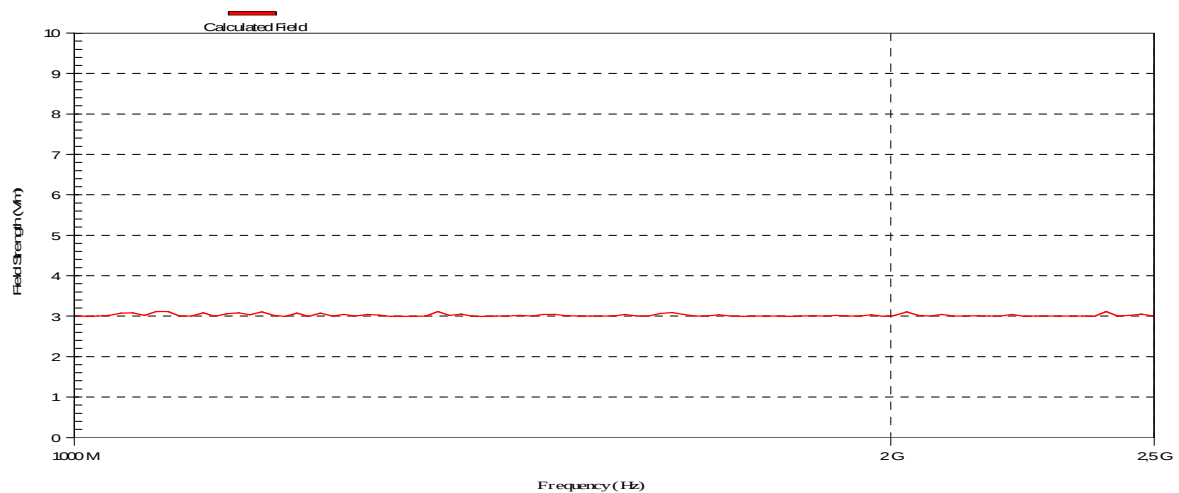
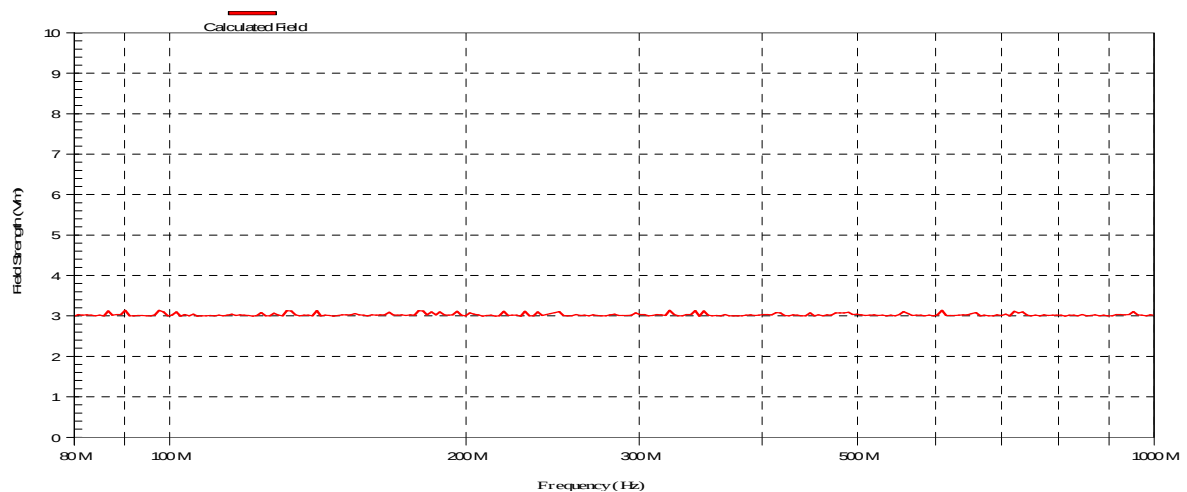
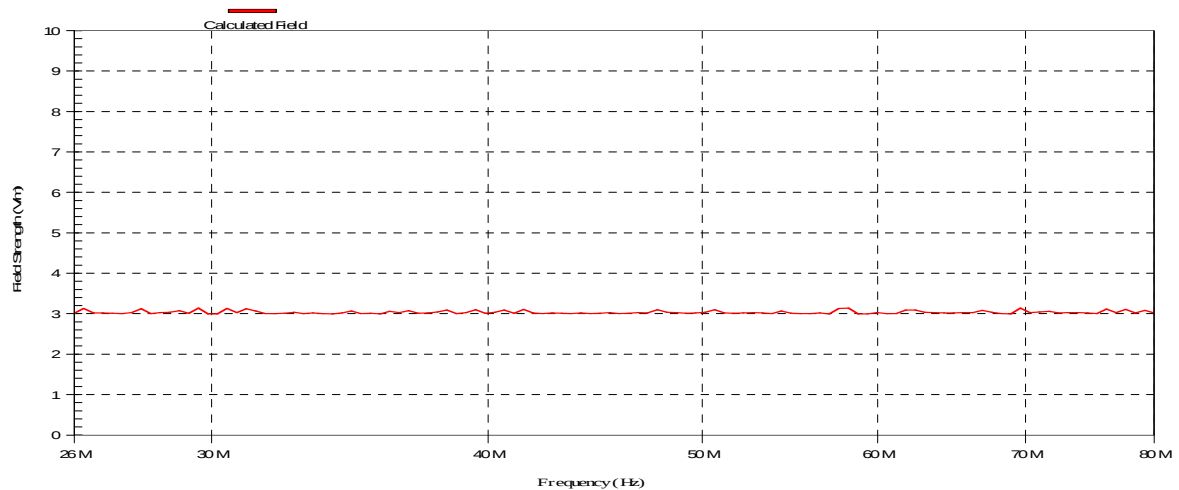
Field strength:


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IEC 61000-4-3

EUT:
 Manufacturer:
 Operating Condition:
 Test Engineer:
 Antenna Polarisation:
 Comment:

Radiated Immunity

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 vertical

Field strength:


CEcert GmbH
MIL-STD-461E RS101

EUT:
Serial Number:
Manufacturer:
Operating Condition:
Test Engineer:
Comment:

Radiated Immunity

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Test Level (dBpT):