Wismar, 14. July 2008

# Test Report #408.123.1

## EMC tests on the devices/equipment:

## *OxyTrue A II*

**Equipment under Test:**

**Description:** Pulse Oximeter Monitor
**Model:** OxyTrue A II

**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

**Applied Standards:** IEC 60601-1-2:2001 +A1:2004 (EN 60601-1-2:2001) and FDA Reviewer Guidance for Premarket Notification Submission /1993/ with applicable additional requirements of ISO 9919:2005

**Test specification:**

| Tests: | Standards: | Result: |
|---|---|---|
| Emission: | | |
| Radiated emission | IEC 60601-1-2:2007<br>FDA Reviewer Guidance /93/ | **PASS** |
| Magnetic fields (RE 101) | FDA Reviewer Guidance /93/ | **PASS** |
| Interference immunity: | | |
| Electrostatic discharge | IEC 60601-1-2:2007<br>FDA Reviewer Guidance /93/ | **PASS** |
| Electromagnetic field | IEC 60601-1-2:2007<br>FDA Reviewer Guidance /93/ | **PASS** |
| Conducted disturbances, induced by RF-fields | IEC 60601-1-2:2007<br>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 (for use during patient transport outside the healthcare facility) as listed in the above specification.***

**Period of test:** 2008-04-25 - 2008-05-10

This test report with appendix consists of **27** pages.

# 1. General information on the test item(s)

**Description:** Pulse Oximeter Monitor
**Model:** OxyTrue A II
**Serial no.:** 2008041601

**Manufacturer/Customer:** Bluepoint MEDICAL GmbH & Co. KG
**Contact person:** Mr. Heiner Busche

**Brief description:**
The monitor is tested with the intended sensor (see chapter 3) to certify their conformity regarding EMC. All EMC related requirements of the pulse oximeter product standard ISO 9919 are adopted in accordance to the classification in chapter 2.

**Steps to EMC, suppressions:**
- Ferrite WE 742 700 33 on internal USB cable

**Participant in the tests:** none

**Responsible for the technical content of the test report:**

| | **name** | **signature** |
|---|---|---|
| Examiner | Matthias Becker<br>Andreas Schenk | |
| Head of Test Laboratory | Bernd Schmidt | |

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; for use during patient transport outside the healthcare facility**

**FDA Reviewer Guidance for Premarket Notification Submission /1993/**

**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.** |
| Conducted disturbances, induced by RF fields (ICS) | IEC 61000-4-6:2000<br>MIL-STD 461E CS114#3 | **5. 3.** |
| Magnetic fields (power-frequency) (IM1) | IEC 61000-4-8:2000 | **5. 4.** |
| Magnetic fields (low-frequency) | MIL-STD 461E RS101 | **5. 5.** |
| Quasi-Static electric fields | FDA Reviewer Guidance | **5. 6.** |

**Exceptions and explanations:** none

## 2.3. 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 A II | 2008041601 | Bluepoint MEDICAL GmbH & Co. KG | Prototyp |
| **Components:** | | | | |
| Mainboard | V3.2 | | Bluepoint Medical | |
| USB-Isolationboard | V1.1 | | Bluepoint Medical | |
| Firmware | C1.86BC1.2 | | Bluepoint Medical | |
| **Accessories/peripherals:** | | | | |
| Sensor | Softcap SC6500 | EWA01439 | Bluepoint Medical | |
| **Simulators:** none<br>**Software:** nn | | | | |

## 3.2. Cables and Lines

| Interface: | Type/model/plug: | Length: | Shielding: | Comments: |
|---|---|---|---|---|
| Sensorcable | Minimed_plug 6-pin | 1,15 m | no | |
| USB | Typ A toTyp Mini 5-pin | 1,20 m | yes | |

## 3.3. Particulars related to EMC

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

## 3.4. Notes and/or sketches

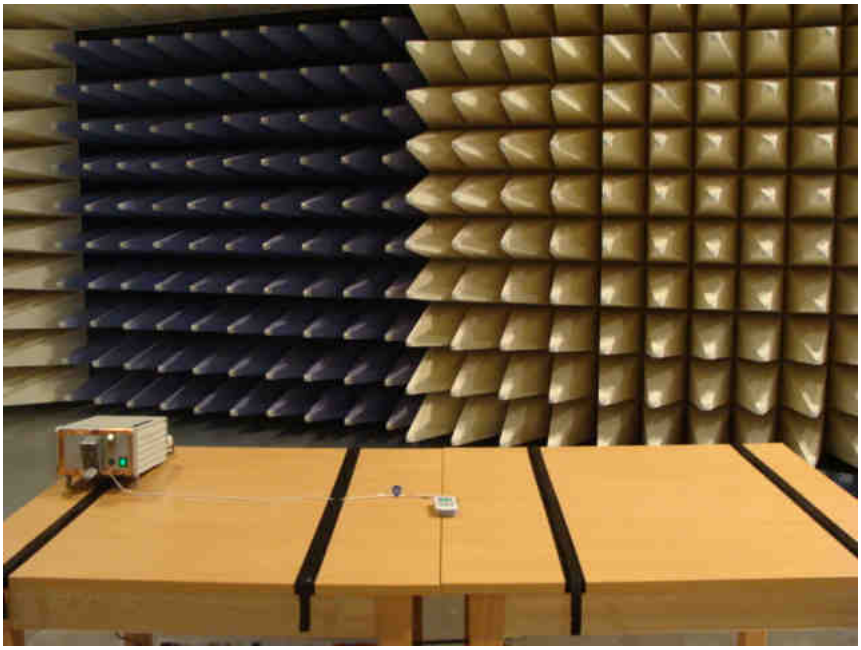


Fig. 1: Test set-up radiated disturbances

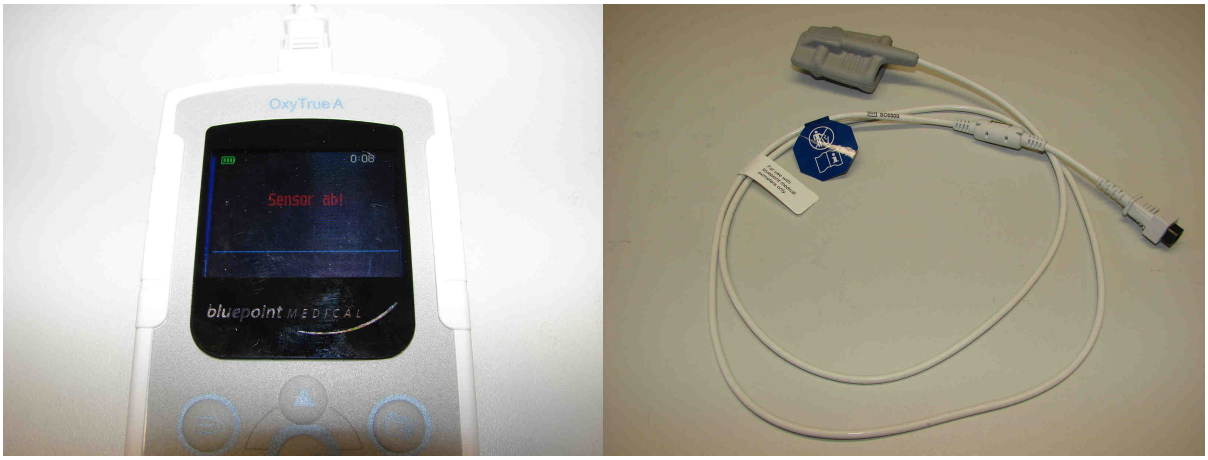



Fig. 2: EUT

Dimension of EuT: **12 x 6 x 3 cm**

## 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 was connected to the pulse oximeter monitor. The monitor operating condition was measuring ON with a pulse rate of 60 beats per minute and a saturation level of 95 %SpO2. The signal was generated by a optical simulator with proofed EMC. While testing, the values were observed. |

**Power supply:** battery powered

**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

None

## 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:** CISPR 11

**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 | 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 |
|---|---|---|---|---|
| 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** |
| Measurement | 30 - 1000 | Sensor cable front, right, left, top, back | see Appendix | **PASS** |
| Measurement | 1000 - 10000 | Sensor cable front, right, left, top, back | see Appendix | **PASS** |
| Measurement | 10000 - 100000 | Sensor cable front, right, left, top, back | see Appendix | **PASS** |
| Measurement | 30 - 1000 | Sensor head front, right, left, top, back | see Appendix | **PASS** |
| Measurement | 1000 - 10000 | Sensor head 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 conform with 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 |
|---|---|---|---|---|---|
| Measurement | Enclosure (all sides), Display, cable and connector case, buttons | D,L | **2 kV** | pos./neg. | **PASS** |
| Measurement | Enclosure (all sides), Display, cable and connector case, buttons | D,L | **4 kV** | pos./neg. | **PASS** |
| Measurement | Enclosure (all sides), Display, cable and connector case, 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: **58,4 % rH** Temperature: **24,1 °C**

**Functional test after test procedure: PASS**

**Test results:**
No relevant influencing function of the equipment was 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 FDA Reviewer Guidance /1993/.***

## 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 |
|---|---|---|---|---|---|
| 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. Conducted disturbances, induced by radio-frequency fields (ICS)

**Test set-up:** **a)** performed in accordance to IEC 61000-4-6.
**b)** performed in accordance to MIL-STD 461E CS114

**Information about the test:**
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.

a) Time per step: **3 sec.**
Frequency range: **150 kHz - 80 MHz**
Modulation: **2 Hz, 80% AM**

b) Time per step: **10 sec.**
Frequency range: **10 kHz - 100 MHz**
Modulation: **0.5 Hz, 100 % PM; 1 kHz, 80% AM**

**Tests:**

| working conditions: | wire / line: | test level: | coupling- and decoupling network | Compliance Pass/ Fail/ N/A |
|---|---|---|---|---|
| Measurement | Sensor cable | **3 V** | BCI clamp | **PASS** |
| Measurement | USB cable | **3 V** | BCI clamp | **PASS** |
| Measurement | Sensor cable | **CS114** | BCI clamp | **PASS** |
| Measurement | USB cable | **CS114** | BCI clamp | **PASS** |

Note: actual test level see appendix

**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 requirements of conducted disturbances, induced by radio-frequency fields, in accordance with IEC 60601-1-2:2007 for not life supporting equipment and in accordance with the FDA Reviewer Guidance /93/.***

## 5.4. Magnetic Field with Power-frequency (IM)

**Test set-up:**
The tests where 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 |
|---|---|---|---|---|
| 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 function of the equipment was 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.***

## 5.5. 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 |
|---|---|---|---|---|
| Measurement | Sensor cable | RS 101 | 30 Hz – 1 kHz | **PASS** |
| Measurement | Sensor | RS 101 | 30 Hz – 1 kHz | **PASS** |
| Measurement | Monitor | RS 101 | 30 Hz – 1 kHz | **PASS** |
| Measurement | Sensor cable | RS 101 | 1 kHz – 100 kHz | **PASS** |
| Measurement | Sensor | RS 101 | 1 kHz – 100 kHz | **PASS** |
| Measurement | Monitor | 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/.***

## 5.6. 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 |
|---|---|---|---|---|---|
| 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 | Schwarzb. | 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 |
| Comparision 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 |
| 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 :

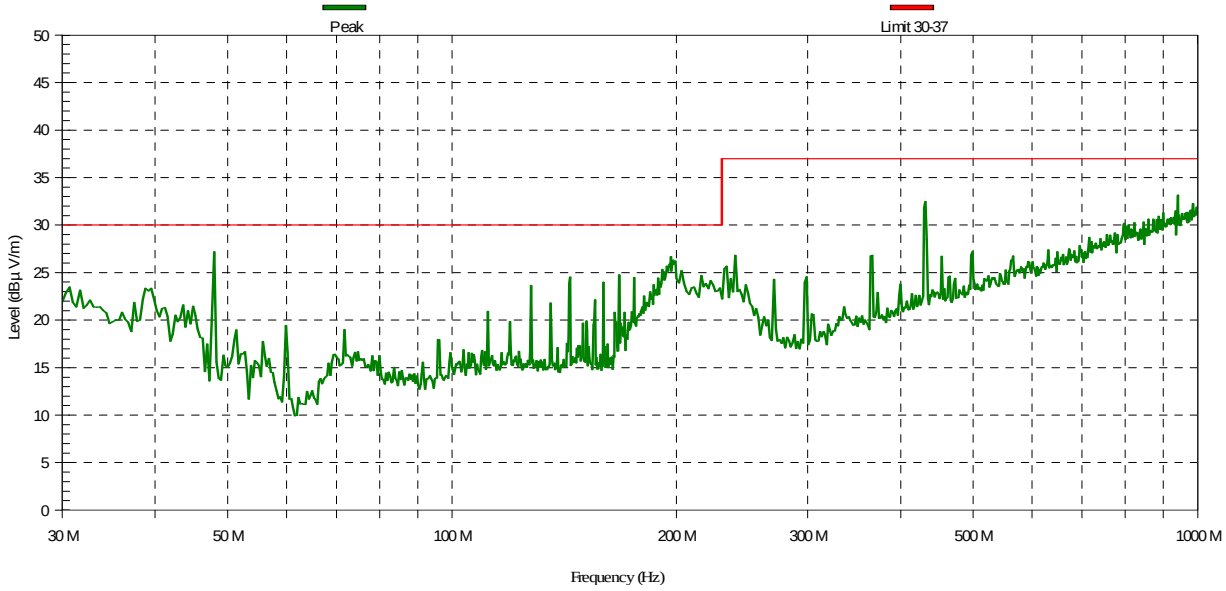
**CEcert GmbH** **Radiated Emissions**

EUT: OxyTrue A II
Serial Number: 2008041601
Manufacturer: Bluepoint MEDICAL GmbH & Co. KG
Operating Condition: Measurement
Test Engineer: Andreas Schenk
Comment:

**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 |
|---|---|---|---|---|---|---|---|
| 48,085 | 29,7 | 27,2 | 30 | 340 | 4 | H | Pass |
| 191,981 | 26,1 | 22,1 | 30 | 0 | 1 | V | Pass |
| 194,919 | 26,6 | 23,2 | 30 | 0 | 1 | V | Pass |
| 195,603 | 26 | 22,2 | 30 | 0 | 1 | V | Pass |
| 199,205 | 27 | 23,8 | 30 | 0 | 1 | V | Pass |
| 199,748 | 27,6 | 24 | 30 | 0 | 1 | V | Pass |
| 203,088 | 26 | 21,7 | 30 | 0 | 1 | V | Pass |
| 215,983 | 26,8 | 23,2 | 30 | 20 | 1 | V | Pass |
| 433,054 | 31,9 | 29,1 | 37 | 180 | 2,5 | H | Pass |

## CEcert GmbH — Radiated Emissions

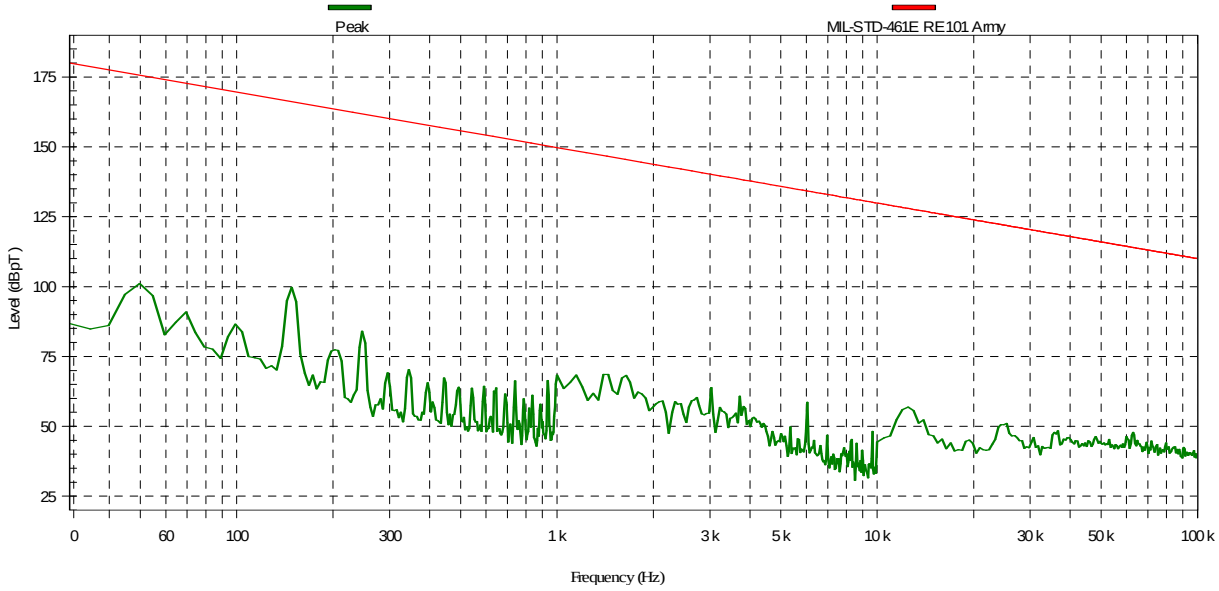
**MIL-STD-461 E RE 101**

| | |
|---|---|
| EUT: | OxyTrue A II |
| Serial Number: | 2008041601 |
| Manufacturer: | Bluepoint MEDICAL GmbH & Co. KG |
| Operating Condition: | Measurement |
| Test Engineer: | Andreas Schenk |
| Comment: | |

**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):

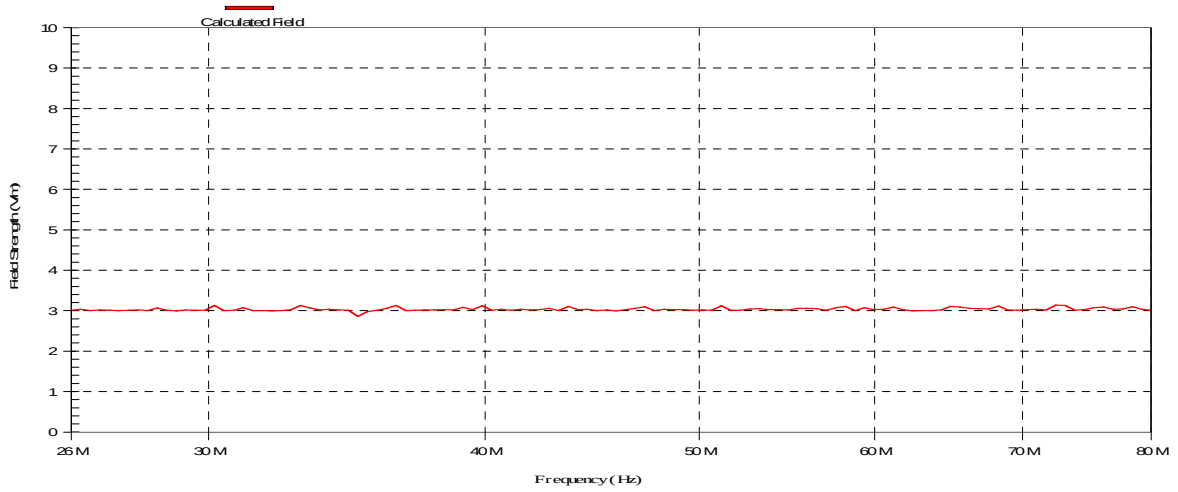


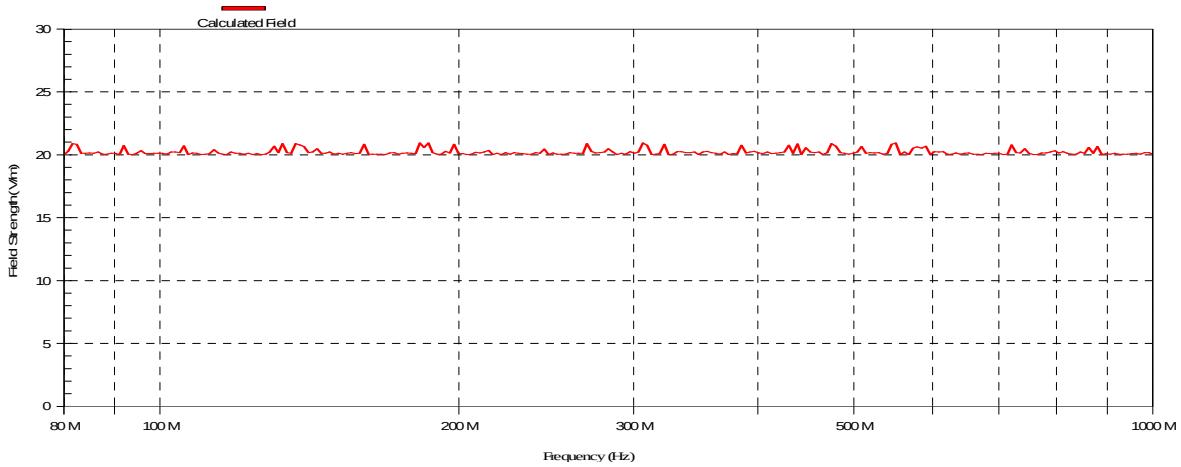

Detected Peaks:
none

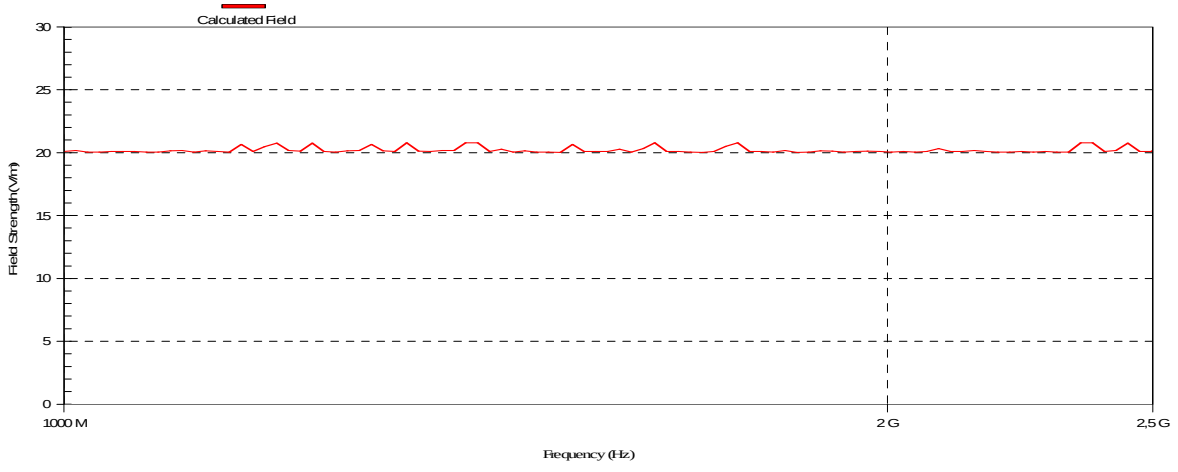
**CEcert GmbH** **Radiated Immunity**
**IEC 61000-4-3**

| | |
|---|---|
| EUT: | OxyTrue A II |
| Manufacturer: | Bluepoint MEDICAL GmbH & Co. KG |
| Operating Condition: | Measurement |
| Test Engineer: | Andreas Schenk |
| Antenna Polarisation: | horizontal |
| Comment: | |

## Field strength:



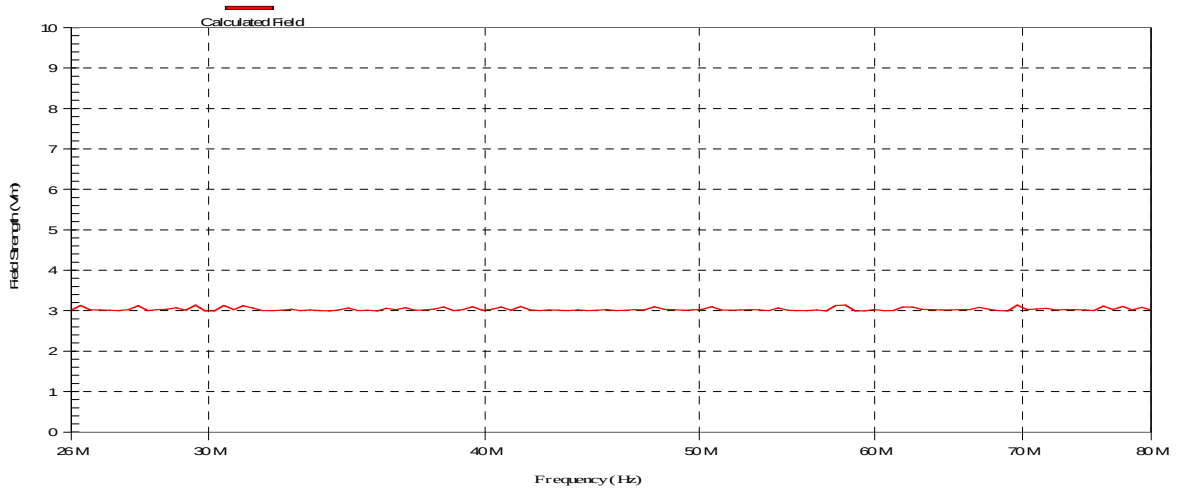



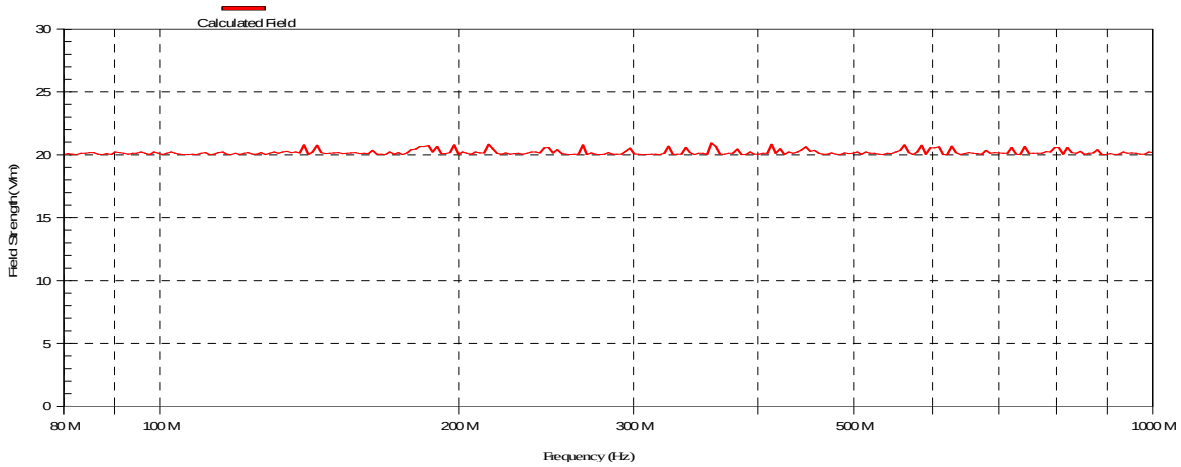



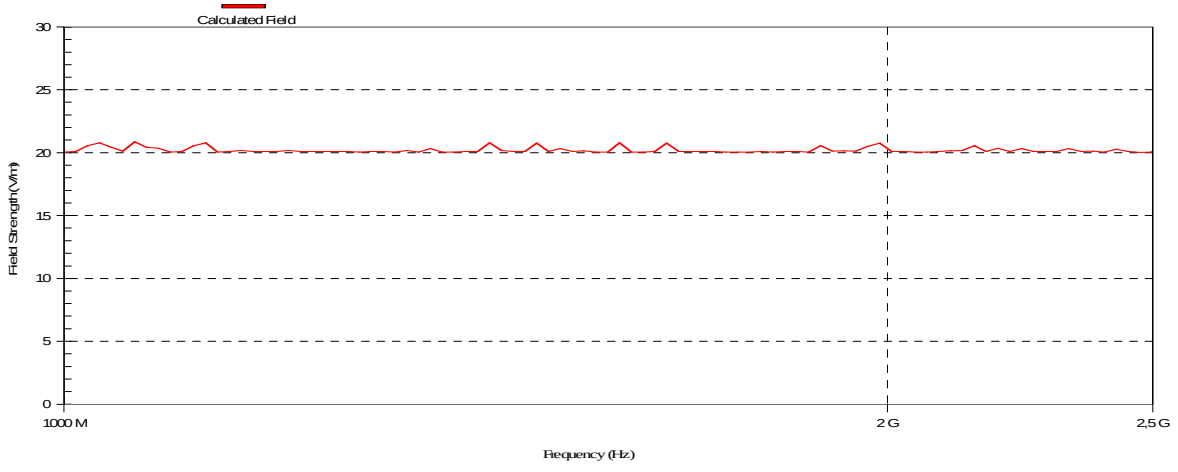
**CEcert GmbH** **Radiated Immunity**
**IEC 61000-4-3**

EUT: OxyTrue A II
Manufacturer: Bluepoint MEDICAL GmbH & Co. KG
Operating Condition: Measurement
Test Engineer: Andreas Schenk
Antenna Polarisation: vertical
Comment:

## Field strength:



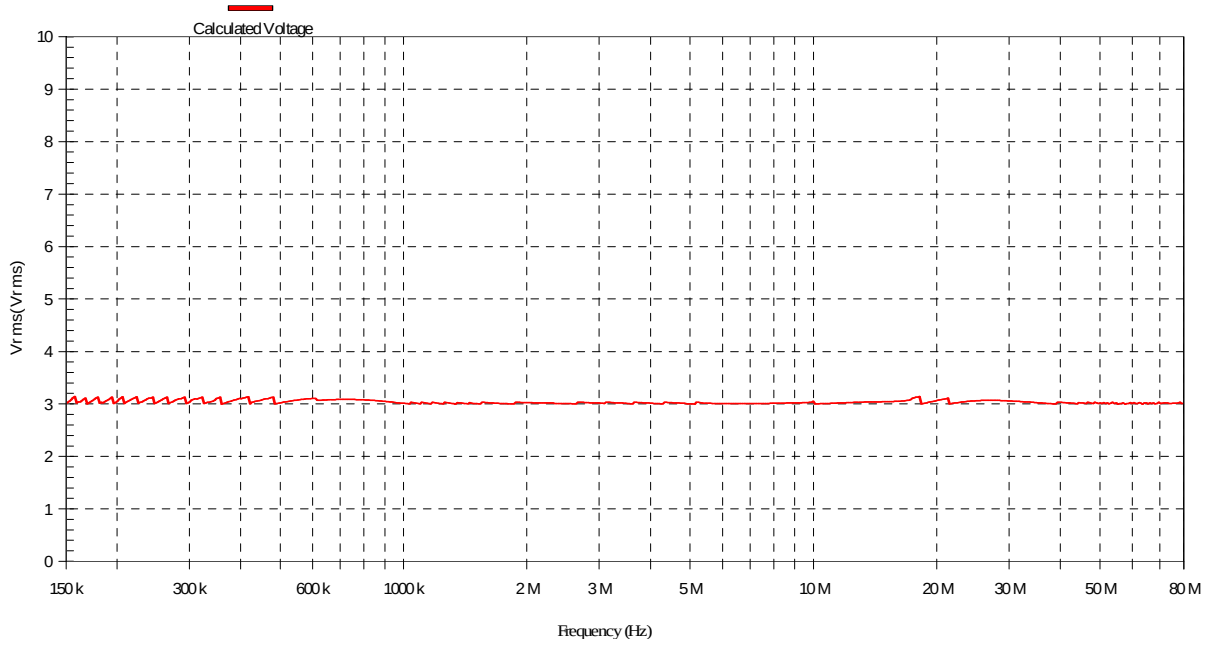



**CEcert GmbH** **Conducted Immunity**
**IEC 61000-4-6**

| | |
|---|---|
| EUT: | OxyTrue A II |
| Serial Number: | 2008041601 |
| Manufacturer: | Bluepoint MEDICAL GmbH & Co. KG |
| Operating Condition: | Measurement |
| Test Engineer: | Andreas Schenk |
| Comment: | sensor cable |

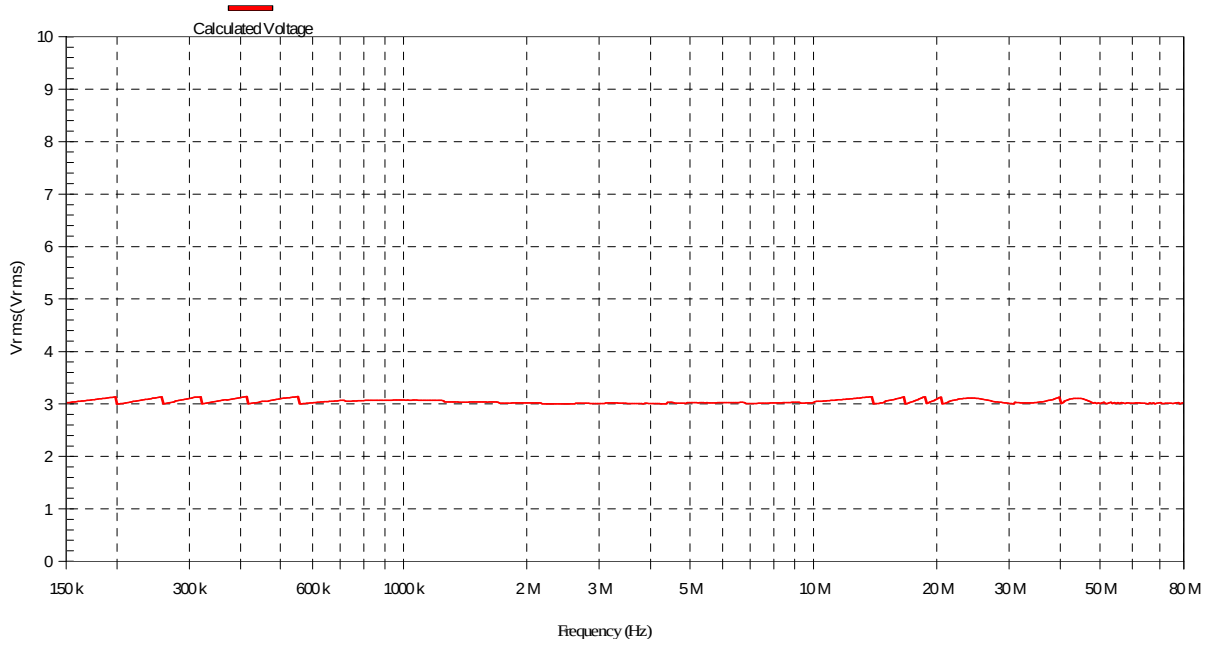
**Test Level:**



**CEcert GmbH** **Conducted Immunity**
**IEC 61000-4-6**

| | |
|---|---|
| EUT: | OxyTrue A II |
| Serial Number: | 2008041601 |
| Manufacturer: | Bluepoint MEDICAL GmbH & Co. KG |
| Operating Condition: | Measurement |
| Test Engineer: | Andreas Schenk |
| Comment: | USB cable |

**Test Level:**

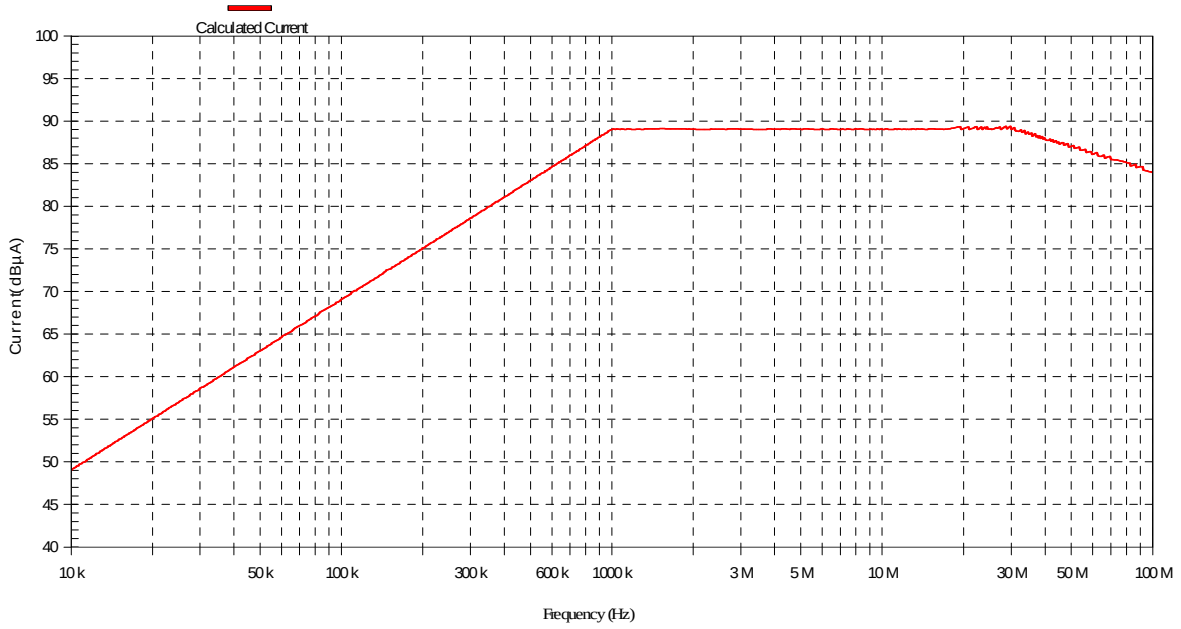


## CEcert GmbH — Conducted Immunity

**MIL-STD 461E CS114**

| | |
|---|---|
| EUT: | OxyTrue A II |
| Serial Number: | 2008041601 |
| Manufacturer: | Bluepoint MEDICAL GmbH & Co. KG |
| Operating Condition: | Measurement |
| Test Engineer: | Andreas Schenk |
| Comment: | all lines |

**Test Level:**



## CEcert GmbH — Radiated Immunity

**MIL-STD-461E RS101**

| | |
|---|---|
| EUT: | OxyTrue A II |
| Serial Number: | 2008041601 |
| Manufacturer: | Bluepoint MEDICAL GmbH & Co. KG |
| Operating Condition: | Measurement |
| Test Engineer: | Andreas Schenk |
| Comment: | |

### Test Level (dBpT):