

Test Report #413.451.1 Rev.0**EMC tests on the devices/equipment:*****Digital Apgar Timer*****Equipment under Test:**

Description: Medical Timer Unit
Model: Digital Apgar Timer

Applicant/ Manufacturer: Viamed Ltd
15/17 Station Road, Cross Hills, Keighley
West Yorkshire BD20 7DT, United Kingdom

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

Summary of Test and Certification:

Tests:	Standards:	Result:
Emission:		
Radiated emission	EN 60601-1-2:2007	PASS
Interference immunity:		
Electrostatic discharge	EN 60601-1-2:2007	PASS
Electromagnetic field	EN 60601-1-2:2007	PASS
Magnetic field (power-frequency)	EN 60601-1-2:2007	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 of EN 60601-1-2 for not life supporting group 1, class B equipment.

Period of test: 2013-12-12 - 2013-12-13

This test report with appendix consists of **18** pages.

1. General information on the test item(s)

Description: Medical Timer Unit
Model: Digital Apgar Timer
Serial no.: 00676

Manufacturer/Customer: Viamed Ltd
Contact person: Mr. Bernd Lindner (bluepoint medical)

Brief description:

EMC conformity test of a Timer Unit for use in medical applications (here: Apgar score.) The EUT counts the time and gives an audible indication at 1, 5 and 10 minutes.

Steps to EMC, suppressions: none

Participant in the tests: none

Responsible for the technical content of the test report:

name

signature

Written by Dipl. Ing. (FH) Andreas Schenk

Approved by Dipl. Ing. (FH) Guido Mumerey

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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Report history Log:

Ref.	Date of issue	Comment	Approved by
413.451.1 Rev.0	2013-12-16	first certification	G. Mumerey

2. Test Specification

2.1. Emission

Applied standards:

EN 60601-1-2:2007

Classification:

Note:

group 1, class B (residential, commercial and light industry)

Due to device characteristic / classification, information according to chapter 5.2 of the EN 60601-1-2:2007 has to be included in the accompanying documents.

Tests performed:

Test method:

Radiated disturbance (ER)

Basic Standard:

IEC/CISPR 11: 2010

Chapter:

4.1.

Exceptions and explanations: none

2.2. Susceptibility

Applied standards:

EN 60601-1-2:2007

Classification:

Note:

Not life supporting equipment

Due to device characteristic / classification, information according to chapter 5.2 of the EN 60601-1-2:2007 has to be included in the accompanying documents.

Tests performed:

Test method:

Electrostatic discharge – ESD (ID)

Electromagnetic field (IR)

Magnetic fields (power-frequency) (IM1)

Basic Standard:

IEC 61000-4-2:2008

IEC 61000-4-3:2010

IEC 61000-4-8:2009

Chapter:

5.1.

5.2.

5.3.

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:				
Medical Timer Unit	Digital Apgar Timer	00676	Viamed Ltd	Part No.: 0310100
Components:				
--				
Accessories/peripherals:				
--				
Simulators: none Software: not defined				

3.2. Cables and Lines

none

3.3. Particulars related to EMC

System frequencies:

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Earth / Grounding:

none

Shielding:

none

3.4. Notes and/or sketches

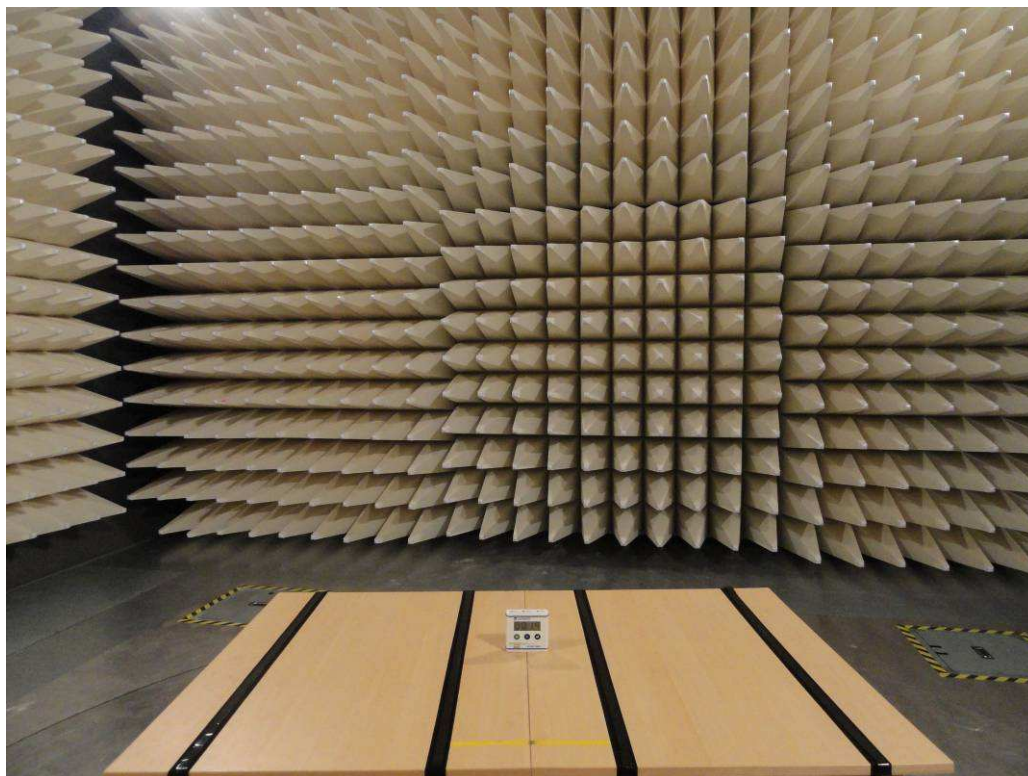


Fig. 1: Test set-up radiated disturbances



Fig. 2: Equipment under Test

Dimension of EuT: **14 cm x 13 cm x 4 cm**

3.5. Operating condition of the product

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

counting: The EUT counts the time and gives an audible indication at 1, 5 and 10 minutes. During the immunity tests the correct counting on the display was observed for the correct counting.

Power supply: internal battery

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. The observation time at the relevant frequencies will take at least 3 seconds.

4.1. Radiated Emissions

Basic standard: EN 60601-1-2:2007

Measuring set-up: CISPR 16-2-3 (see photo documentation)

Measuring Equipment:

Invent No.	Description	Model/Type	Manufacturer	Serial-No.	Calibration	Next Calibration
002/03	EMI Receiver (9kHz - 7GHz)	ESCI 7	R&S	100795	2013,04	2014,04
008/06	Chase antenna (30MHz - 1GHz)	CBL 6111B	EMC	1925	2013,05	2014,04
070/06	semi anechoic chamber	3- Meter	Frankonia	--	2013,04	2016,04
071/05	RF cable	Eco15P 14m	SSB		2013,10	2014,10

Measuring process:

A prescan with in horizontal and vertical polarization was done at the beginning. 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.

Tested by: Jens Vilöhr

Measurement results:

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

Measuring Distance: 3 m

During this EMC test no relevant interference emission 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 EN 60601-1-2:2007 for group 1, class B equipment.

5. Susceptibility

5.0 Performance criteria of failure at the immunity tests

Performance criteria of IEC 60601-1-2:

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.

Particular performance criteria determined by the manufacturer:

none

5.1. Electrostatic Discharge – ESD

Test set-up:

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

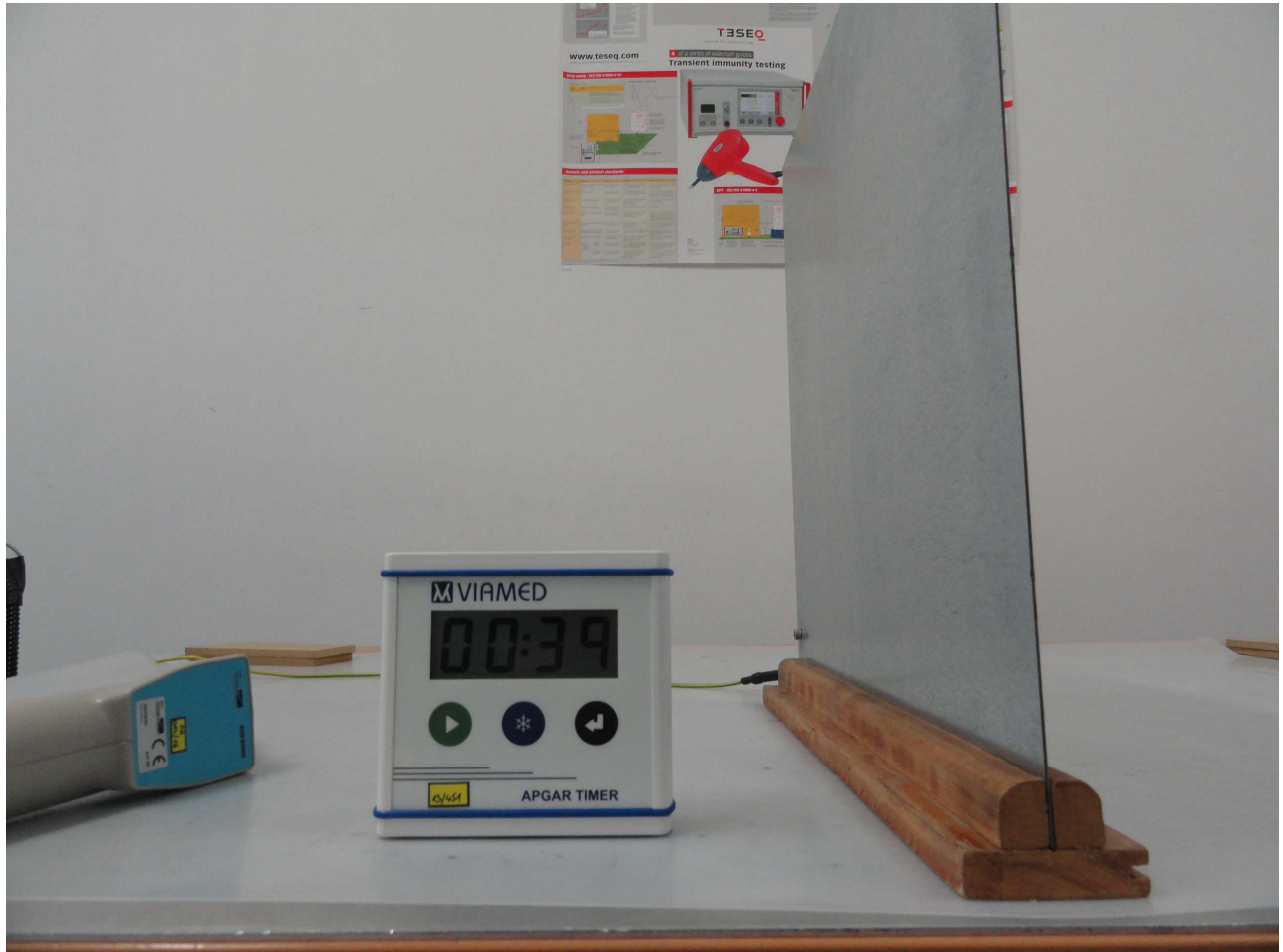


Fig. 3: Test set-up ESD

Test Equipment:

Invent No.	Description	Model/Type	Manufacturer	Serial-No.	Calibration	Next Calibration
014/10	Generator for transients	TRA 2000	EMC	790	2013,04	2014,04
014/11	ESD-discharge kit	ESD2000	EMC	169	2013,04	2014,04
065/09	Data logger temp./humid.	SP-2000-20R-117	Veriteq	11062233	2013,04	2014,04

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.

Tested by:

Jens Vilöhr

Tests:

working condition:	point of discharge	test:	test level:	polarity	Compliance Pass/ Fail/ N/A
counting	Display, keys, battery compartment cover	D,L	2 kV	pos./neg.	PASS
counting		D,L	4 kV	pos./neg.	PASS
counting		D,L	8 kV	pos./neg.	PASS
counting	Coupling plate	I,H,V	2 kV	pos./neg.	PASS
counting		I,H,V	4 kV	pos./neg.	PASS
counting		I,H,V	6 kV	pos./neg.	PASS
counting	Enclosure (all sides)	D,K	2 kV	pos./neg.	PASS
counting		D,K	4 kV	pos./neg.	PASS
counting		D,K	6 kV	pos./neg.	PASS

Note:

D direct discharge onto the test object
 I indirect discharge onto the test object
 K contact discharge

L air discharge
 H horizontal coupling plate under the EUT
 V vertical coupling plate

Environmental Conditions while test:Humidity: **37,8 % rH**Barometric pressure: **102,2 kPa**Temperature: **20,8 °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 EN 60601-1-2:2007.

5.2. High Frequency Electromagnetic Fields

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: 1 sec.
- Test level: 3 V/m

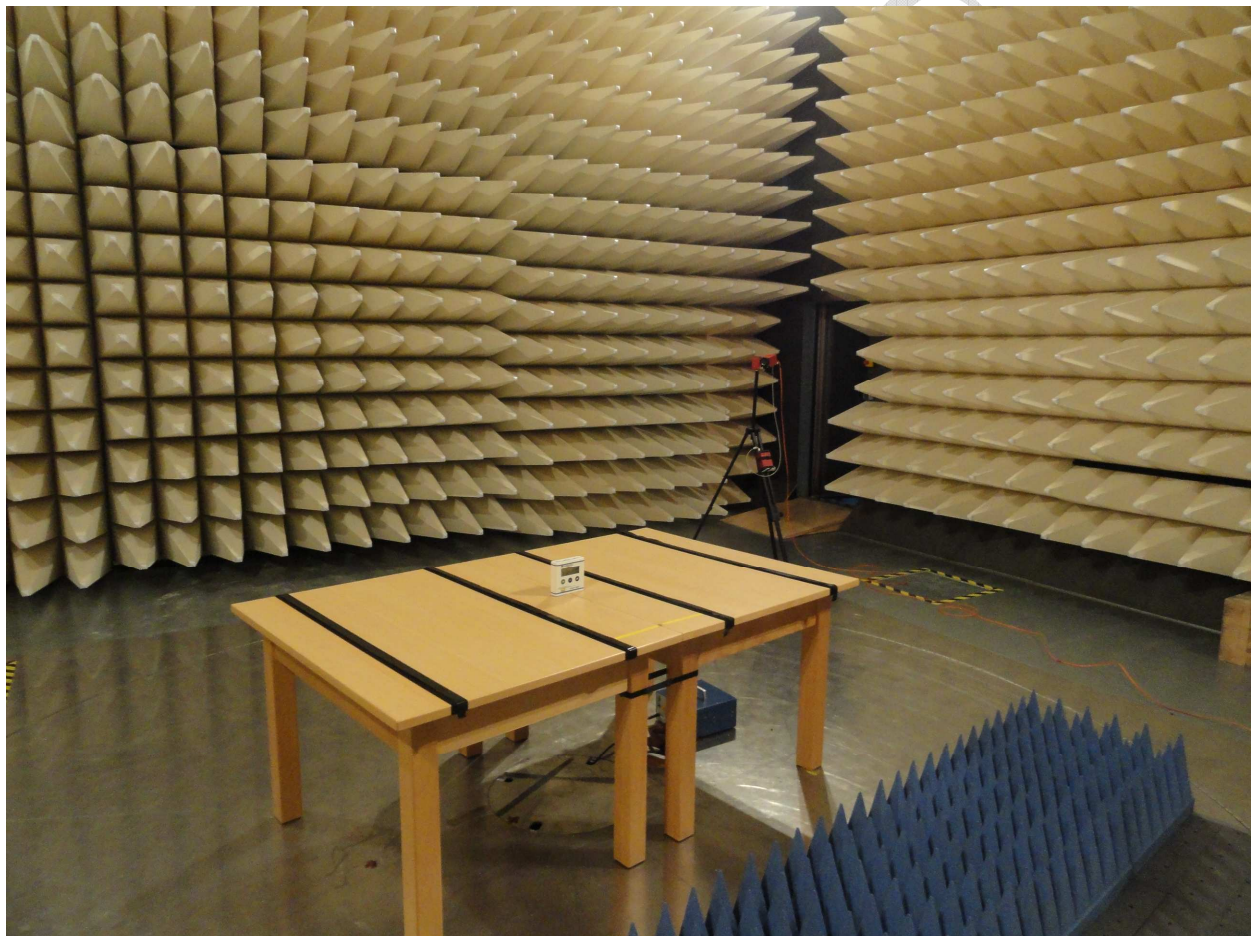


Fig. 4: Test set-up electromagnetic Fields

Test Equipment:

Invent No.	Description	Model/Type	Manufacturer	Serial-No.	Calibration	Next Calibration
004/03	directional coupler 80-1000MHz	DC6180A	ar	335212	2013,04	2014,04
004/04	directional coupler 0,8-4,2GHz	DC7144A	ar	334023	2013,04	2014,04
008/08	Log.- per. Antenna (80MHz - 1GHz)	AT 1080	ar	305184	2013,04	2014,04
008/20	Horn antenna (1 - 18GHz)	HAX-18	Frankonia	801	2013,04	2014,04
019/05	Signal generator (9kHz - 3,2GHz)	SMC100A	R&S	102135	2013,10	2014,10
020/03	Broadband microwave amplifier (0,8- 4,2GHz 25W)	25S1G4A	ar	305439	2013,03	2014,04
020/11	Broadband rf amplifier (80 - 1000 MHz)	250W1000A	ar	335036	2013,04	2014,04
025/03	E- field probe	RadiSense	Dare	01D00057SN O	2013,05	2016,04
065/09	Data logger temp./humid.	SP-2000-20R-117	Veriteq	11062233	2013,04	2014,04
070/07	semi anechoic chamber immunity	3- Meter	Frankonia	--	2013,04	2014,04

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.

Tested by:

Jens Vilöhr

Tests:

Operating conditions:	Frequency range: [MHz]	Modulation:	Polarization, Antenna direction	Comments/Test report	Compliance Pass/ Fail/ N/A
counting	80 – 2500	80 % AM, 1 kHz	horizontal, front	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	vertical, front	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	horizontal, left	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	vertical, left	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	horizontal, right	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	vertical, right	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	horizontal, back	see annex	PASS
counting	80 – 2500	80 % AM, 1 kHz	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 EN 60601-1-2:2007 for not life supporting equipment.

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 sufficient big inductance coil with a well known coil factor for producing a homogeny magnetic field and a programmable power supply with sufficient current supply. A square inductance coil with 1 m x 1 m was used for generation of the magnetic field.

Test Equipment:

Invent No.	Description	Model/Type	Manufacturer	Serial-No.	Calibration	Next Calibration
008/05	Magnetic field antenna 1x1m 1- 100A/m	MF 1000	EMC	1000-35	2013,04	2014,04
012/01	Power supply	6560	Chroma	462	2013,04	2014,04
013/00	Artificial mains network	NI 2415	ZES	A9703016	2013,10	2014,10
017/00	1 - channel power meter	LMG95	ZES	8060505	2013,08	2014,10

Tested by: Jens Vilöhr

Tests:

working conditions:	equipment:	test level:	duration:	Compliance Pass/ Fail/ N/A
counting	whole configuration x-axis	3 A/m, 50 Hz	5 min	PASS
counting	whole configuration y-axis	3 A/m, 50 Hz	5 min	PASS
counting	whole configuration z-axis	3 A/m, 50 Hz	5 min	PASS
counting	whole configuration x-axis	3 A/m, 60 Hz	5 min	PASS
counting	whole configuration y-axis	3 A/m, 60 Hz	5 min	PASS
counting	whole configuration z-axis	3 A/m, 60 Hz	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 EN 60601-1-2:2007.

Annex List :

Test (description)	Page
Radiated emission (Peak-detector) Max-Hold-Graph;	16
Radiated immunity (RF field), Calculated field, horizontal	17
Radiated immunity (RF field), Calculated field, vertical	18

DRAFT

CEcert GmbH

EUT:

Serial Number:

Manufacturer:

Operating Condition:

Comment:

Radiated Emissions

Digital Apgar Timer

00676

Viamed Ltd

counting

Scan Settings:

Frequency Range:

30 MHz – 1000 MHz

Receiver Bandwidth:

120 kHz

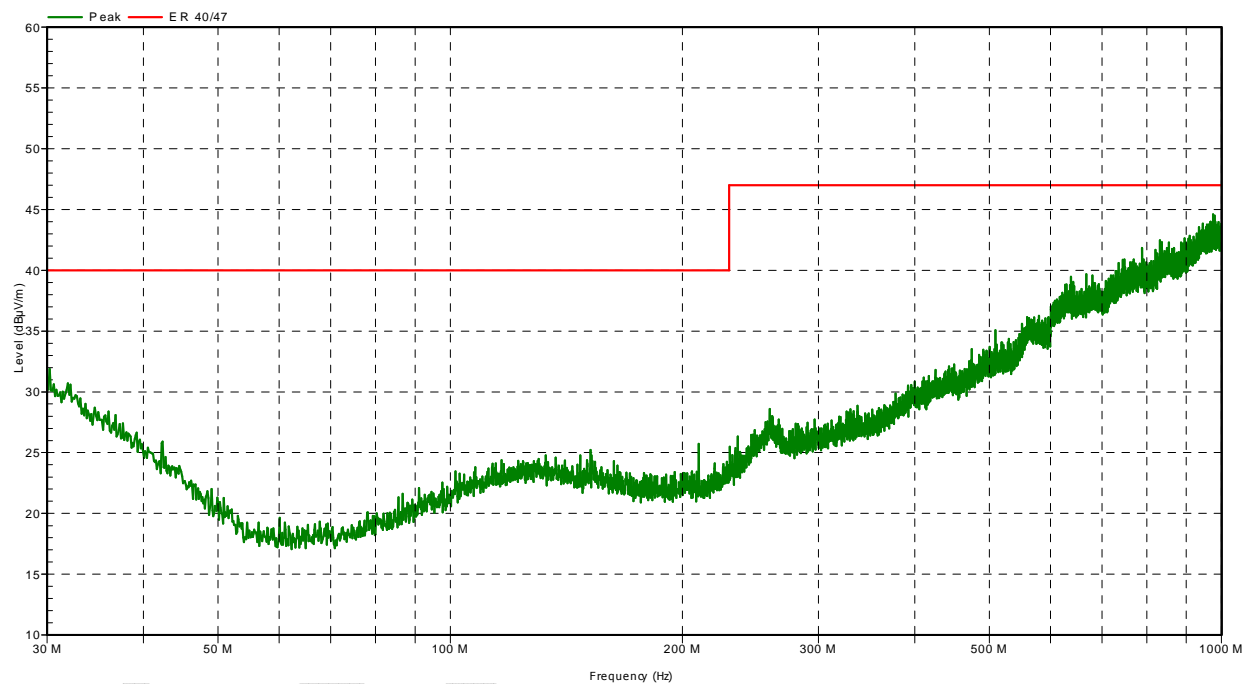
Measure Time:

15 ms (Prescan), 3 s (Final Measurement)

Measurement Distance:

3 m

Prescan (MAX Hold Graph):



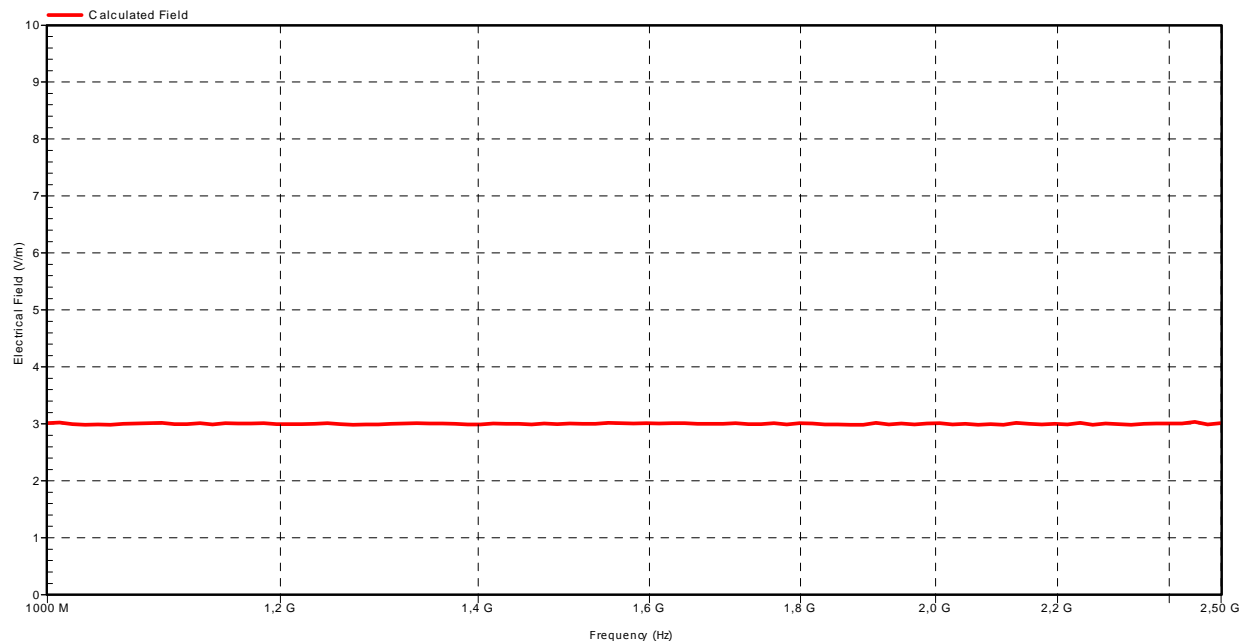
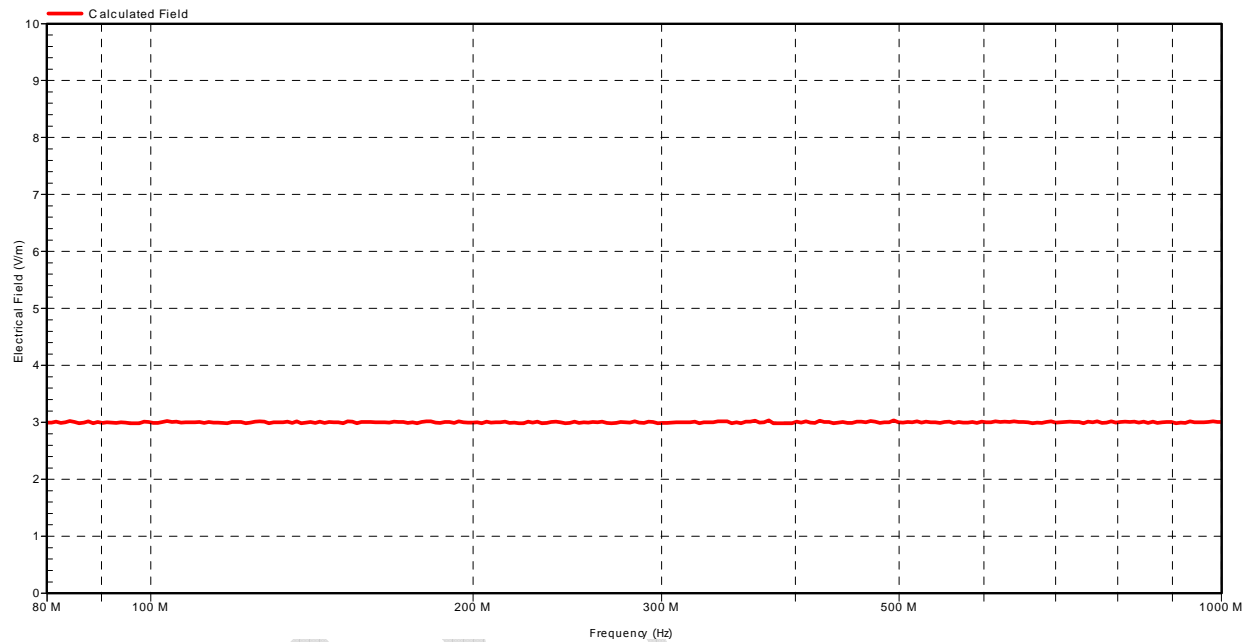
Detected Peaks:

none

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

EUT:
Serial Number:
Manufacturer:
Operating Condition:
Antenna Polarisation:
Comment:

Digital Apgar Timer
00676
Viamed Ltd
counting
horizontal

Field strength:

**Cecert GmbH
IEC 61000-4-3**

EUT:
Serial Number:
Manufacturer:
Operating Condition:
Antenna Polarisation:
Comment:

Radiated Immunity

Digital Apgar Timer
00676
Viamed Ltd
counting
vertical

Field strength: