

EMI - TEST REPORT

- FCC Part 15B -

Type / Model Name : Element Verio CIP Platform

Product Description : Blood glucose meter with Bluetooth 4.0 Low Energy

Applicant : Lifescan Scotland Ltd.

Address : Beechwood Park North

INVERNESS, IV2 3ED, SCOTLAND

Manufacturer : Lifescan, Division of Cilag GmbH International

Address : Gubelstrasse 34

6300 ZUG, SWITZERLAND

Licence holder : Lifescan, Division of Cilag GmbH International

Address : Gubelstrasse 34

6300 ZUG, SWITZERLAND

Test Result according to the standards
listed in clause 1 test standards:

POSITIVE

Test Report No. : **T38836-14-01GK**

05. July 2017

Date of issue



Deutsche
Akkreditierungsstelle
D-PL-12030-01-01
D-PL-12030-01-02

The test report merely corresponds to the test sample.
It is not permitted to copy extracts of these test results
without the written permission of the test laboratory.

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1 TEST STANDARDS

The tests were performed according to following standards:

FCC Rules and Regulations Part 15 Subpart A - General (September, 2016)

Part 15, Subpart A, Section 15.31	Measurement standards
Part 15, Subpart A, Section 15.33	Frequency range of radiated measurements
Part 15, Subpart A, Section 15.35	Measurement detector functions and bandwidths

FCC Rules and Regulations Part 15 Subpart B - Unintentional Radiators (September, 2016)

Part 15, Subpart B, Section 15.107	AC Line conducted emission <input type="checkbox"/> Class A device <input checked="" type="checkbox"/> Class B device
Part 15, Subpart B, Section 15.109	Radiated emission, general requirements
Part 15, Subpart B, Section 15.111	Antenna power conduction

ANSI C63.4: 2014	Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.
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CISPR 16-4-2: 2011 EN 55016-4-2: 2011	Uncertainty in EMC measurement
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CISPR 22: 2008 EN 55022: 2010	Information technology equipment
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2 EQUIPMENT UNDER TEST

2.1 Photo documentation of the EUT – Detailed photos see ATTACHMENT A

2.2 Equipment category

Portable equipment

2.3 Short description of the equipment under test (EUT)

The EUT is a Bluetooth 4.0 Low Energy system integrated in a blood glucose meter. The EUT is compatible with the standard 802.15.1. It supports the 2.4 GHz frequency band. A single PCB antenna is used within the system.

Number of tested samples: 1
Serial number: Z2KGMN39

2.4 Variants of the EUT

The Element Verio Platform consists of 2 devices: One Touch Verio Flex and One Touch UltraPlus Flex
The difference between the two devices is the colour of the cabinet and the different strip port connectors.

2.5 Operation frequency and channel plan

2400 MHz to 2483.5 MHz

2.6 Antenna

The following antennas shall be used with the EUT:

Number	Characteristic	Certification name	Plug	Frequency range (GHz)	Gain (dBi)
1	Omni	PCB antenna	none	2.4 - 2.4835	0

2.7 Transmit operating modes

The equipment under test was operated during the measurement under the following conditions:

- USB connection with laptop, radio off

Note: When the USB connection is active, the integrated BLE technology is automatically switched off.

2.8 Power supply system utilised

Power supply voltage, V_{nom} : 3 V DC (battery powered)

2.9 Peripheral devices and interface cables

The following peripheral devices and interface cables are connected during the measurements:

- Laptop _____ Model : Fujitsu Lifebook E780 _____
- _____ Model : _____
- _____ Model : _____

2.10 Determination of worst case conditions for final measurement

2.10.1 Test Jig

No test jig is used.

2.10.2 Test software

3 TEST RESULT SUMMARY

3.1 Final assessment

The equipment under test fulfills the EMI requirements cited in clause 1 test standards.

Date of receipt of test sample : acc. to storage records

Testing commenced on : 02 May 2017

Testing concluded on : 03 May 2017

Checked by:

Tested by:

Klaus Gegenfurtner
Teamleader Radio

Konrad Graßl
Radio Team

4 TEST ENVIRONMENT

4.1 Address of the test laboratory

**CSA Group Bayern GmbH
Ohmstrasse 1-4
94342 STRASSKIRCHEN
GERMANY**

4.2 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

Temperature: 15-35 °C

Humidity: 30-60 %

Atmospheric pressure: 86-106 kPa

4.3 Statement of the measurement uncertainty

The data and results referenced in this document are true and accurate. It is noted that the expanded measurement uncertainty corresponds to the measurement results from the standard measurement uncertainty multiplied by the coverage factor $k = 2$. The true value is located in the corresponding interval with a probability of 95 %. The measurement uncertainty was calculated for all measurements listed in this test report acc. to CISPR 16-4-2 / 11.2003 „Uncertainties, statistics and limit modelling – Uncertainty in EMC measurements“ and is documented in the quality system acc. to DIN EN ISO/IEC 17025. For all measurements shown in this report, the measurement uncertainty of the test laboratory, CSA Group Bayern GmbH, is below the measurement uncertainty as defined by CISPR. Therefore, no special measures must be taken into consideration with regard to the limits according to CISPR. Furthermore, component and process variability of devices similar to that tested may result in additional deviation. The manufacturer has the sole responsibility of continued compliance of the device.

4.4 Measurement protocol for FCC

4.4.1 General information

4.4.1.1 Test methodology

Conducted and radiated disturbance testing is performed according to the procedures set out by the International Special Committee on Radio Interference (CISPR) Publication 22, European Standard EN 55022 as shown under section 1 of this report.

4.4.1.2 Justification

The equipment under test (EUT) is configured in a typical user arrangement in accordance with the manufacturer's instructions. A cable is connected to each available port and either terminated with a peripheral using the appropriate impedance characteristic or left unterminated. Where appropriate, cables are manually manipulated with respect to each other thus obtaining maximum disturbances from the unit.

4.4.2 Details of test procedures

4.4.2.1 General standard information

The test methods used comply with CISPR Publication 22, EN 55022 - "Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement" and with ANSI C63.4 - "Methods of Measurement of Radio-Noise Emission from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz". In compliance with 47 CFR Part 15 Subpart A, Section 15.38 testing for FCC compliance may be achieved by following the procedures set out in ANSI C63.4 and applying the CISPR 22 limits.

4.4.3 Conducted emission

4.4.3.1 Description of measurement

The final level, expressed in dB μ V, is arrived at by taking the reading directly from the EMI receiver. This level is compared directly to the FCC limit or to the CISPR limit.

To convert between dB μ V and μ V, the following conversions apply:

$$\begin{aligned} \text{dB}\mu\text{V} &= 20 \cdot \log(\mu\text{V}) \\ \mu\text{V} &= 10^{(\text{dB}\mu\text{V}/20)} \end{aligned}$$

Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT are measured in the frequency range of 150 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth and quasi-peak detection and a Line Impedance Stabilization Network (LISN) with 50 Ω / 50 μ H (CISPR 16) characteristics. Table top equipment is placed on a non-conducting table 80 centimetres above the floor and is positioned 40 centimetres from the vertical ground plane (wall) of the screen room. If the minimum limit margin appears to be less than 20 dB with a peak mode measurement, the emissions are re-measured using a tuned receiver with quasi-peak and average detection and recorded on the data sheets.

4.4.4 Radiated emission (electrical field 30 MHz - 1 GHz)

4.4.4.1 Description of measurement

Spurious emission from the EUT is measured in the frequency range of 30 MHz to 1000 MHz using a tuned receiver and appropriate broadband linearly polarised antennas. Measurements between 30 MHz and 1000 MHz are made with 120 kHz/6 dB bandwidth and quasi-peak detection. Table top equipment is placed on a 1.0 X 1.5 m non-conducting table 80 centimetres above the ground plane. Floor standing equipment is placed directly on the turntable/ground plane. The setup of the equipment under test is established in accordance with ANSI C63.4. The interface cables that are closer than 40 centimetres to the ground plane are bundled in the centre in a serpentine fashion so that they are at least 40 centimetres from the ground plane. Cables to simulators/testers (if used in this test) are routed through the centre of the table and to a screened room located outside the test area. The antenna is positioned in horizontal polarisation and is repeated vertically. To locate maximum emission from the test sample the antenna is varied in height from 1 to 4 metres and the EUT is rotated 360 degrees.

The final level in dB μ V/m is calculated by add the antenna correction factor and cable loss factor (dB) on the reading from the EMI receiver (dB μ V). The FCC or CISPR limit is subtracted from this result in order to provide the delta to limit listed in the measurement protocol.

Example:

Frequency (MHz)	Reading level (dB μ V)	+	Correction Factor (dB/m)	=	Level (dB μ V/m)	-	CISPR Limit (dB μ V/m)	=	Delta (dB)
719.0	75.0	+	32.6	=	107.6	-	110.0	=	-2.4

4.4.5 Radiated emission (electrical field 1 GHz - 40 GHz)

4.4.5.1 Description of measurement

Radiated emission from the EUT are measured in the frequency range 1 GHz up to the maximum frequency as specified in 47 CFR Part 15, Subpart A, Section 15.33, using a spectrum analyser and appropriate linearly polarized antennas. Table top equipment is placed on a 1.0 X 1.5 metre non-conducting table 80 centimetres above the ground plane. Floor standing equipment is placed directly on the turntable/ground plane. The setup of the equipment under test is following set out in ANSI C63.4. The interface cables that are closer than 40 centimetres to the ground plane are bundled in the centre in a serpentine fashion so they are at least 40 centimetres from the ground plane. Cables to simulators/testers (if used in this test) are routed through the centre of the table and to a screened room located outside the test area. Measurements are made in both the horizontal and vertical polarization planes in a fully anechoic room using a spectrum analyser set to max peak detector function and a resolution 1 MHz and video bandwidth 3 MHz for peak and 10 Hz for average measurement. The conditions determined as worst case will then be used for the final measurements. When the EUT is larger than the beam width of the measuring antenna it will be moved over the surface for the four sides of the equipment. Where appropriate, the test distance may be reduced in order to detect emission under better uncertainty and is calculated to the specified test distance.

5 TEST CONDITIONS AND RESULTS

5.1 Conducted emission

For test instruments and accessories used see section 6 Part A 4.

5.1.1 Description of the test location

Test location: Shielded Room S2

5.1.2 Photo documentation of the test set-up

Please see Attachment B

5.1.3 Applicable standard

According to FCC Part 15, Section 15.107(a):

Except for Class A devices, for equipment that is designed to be connected to the public utility (AC) power line, the radio frequency voltage that is conducted back onto the AC power line on any frequency or frequencies within the band 150 kHz to 30 MHz shall not exceed the given limits.

5.1.4 Description of Measurement

The measurements are performed following the procedures set out in ANSI C63.4. If the minimum limit margin appears to be less than 20 dB with a peak mode measurement, the emission are re-measured using a tuned receiver with quasi-peak and average detection and recorded on the data sheets.

5.1.5 Test result

Frequency range: 0.15 MHz - 30 MHz

Min. limit margin 20.7 dB at 0.1545 MHz

Limit according to FCC Part 15, Section 15.107(a):

Frequency of emission (MHz)	Conducted limit (dB μ V)	
	Quasi-peak	Average
0.15-0.5	66 to 56 *	56 to 46 *
0.5-5	56	46
5-30	60	50

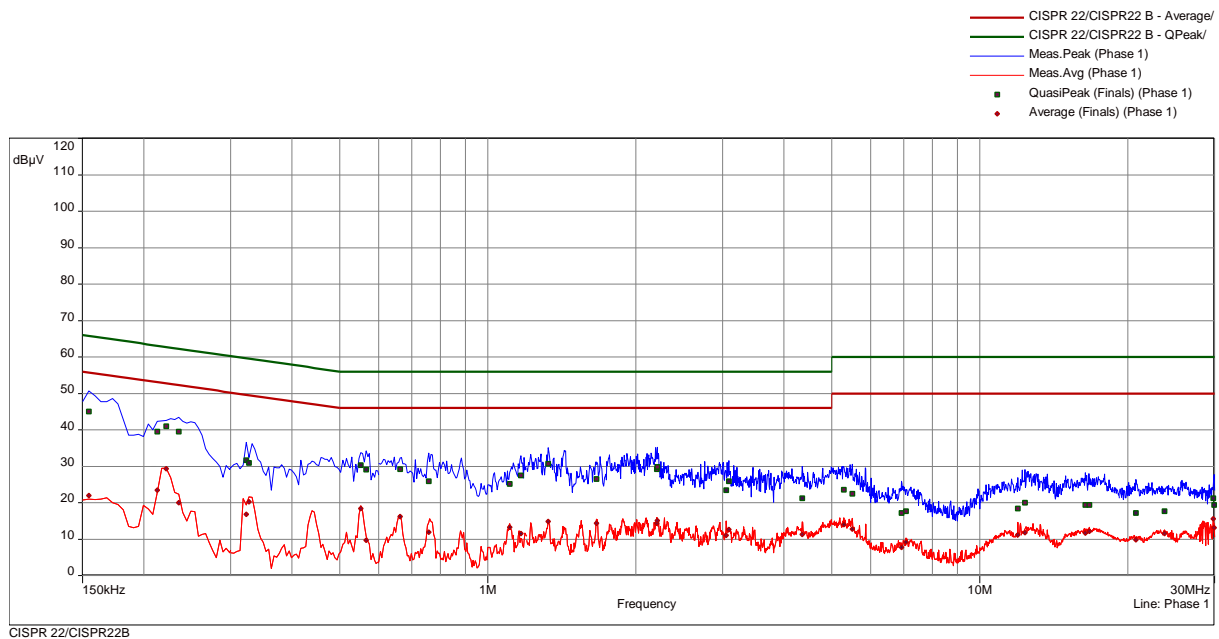
* Decreases with the logarithm of the frequency

The requirements are **FULFILLED**.

Remarks: For detailed test result please refer to following test protocols

5.1.6 Test protocol

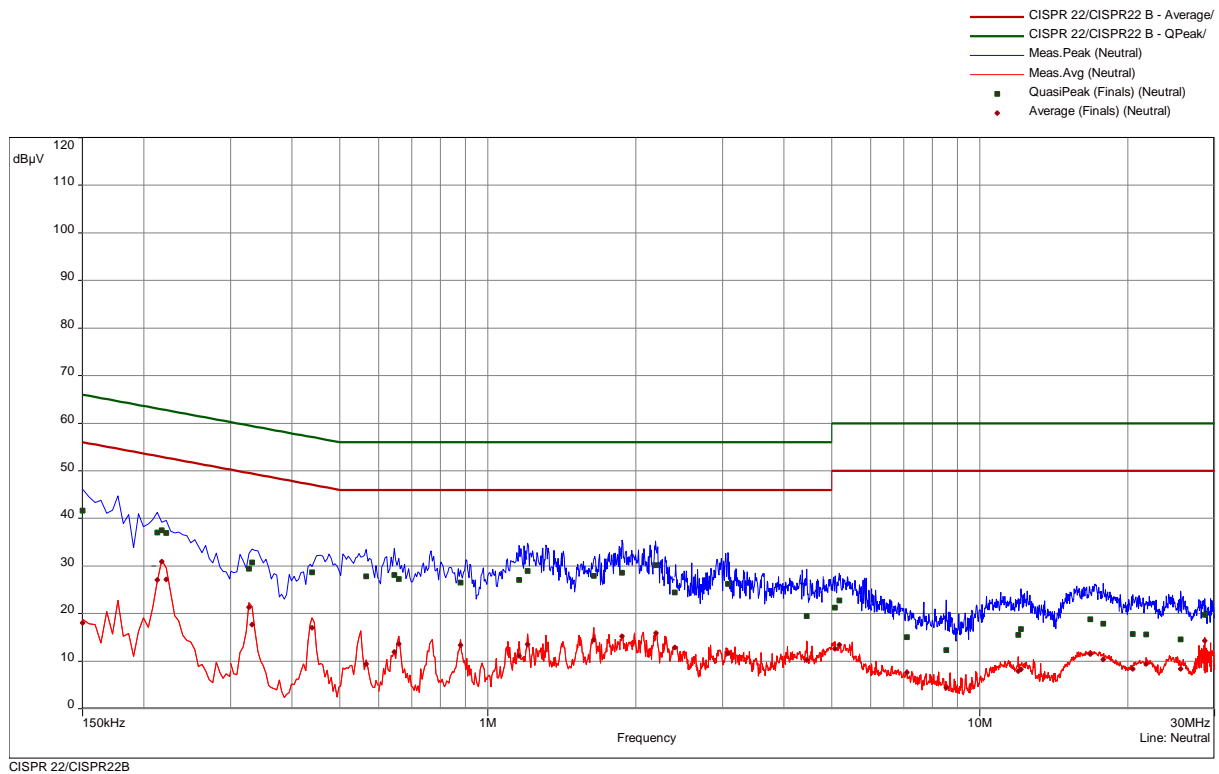
Test point L1
Operation mode: USB connection with laptop, radio off



freq MHz	SR	QP dB(μV)	margin dB	limit dB	AV dB(μV)	margin dB	limit dB	line
0.1545	1	45.05	20.70	65.75	22.02	33.74	55.75	Phase 1
0.213	1	39.46	23.63	63.09	23.49	29.60	53.09	Phase 1
0.222	1	40.93	21.81	62.74	29.33	23.41	52.74	Phase 1
0.2355	1	39.49	22.77	62.25	20.05	32.20	52.25	Phase 1
0.3225	2	31.64	28.00	59.64	16.85	32.79	49.64	Phase 1
0.327	2	30.98	28.54	59.53	20.20	29.33	49.53	Phase 1
0.552	2	30.29	25.71	56.00	18.44	27.56	46.00	Phase 1
0.5655	2	29.10	26.90	56.00	9.66	36.34	46.00	Phase 1
0.663	3	29.16	26.84	56.00	16.22	29.78	46.00	Phase 1
0.7575	3	25.86	30.14	56.00	11.88	34.12	46.00	Phase 1
1.1085	3	25.12	30.88	56.00	13.30	32.70	46.00	Phase 1
1.167	3	27.50	28.50	56.00	11.57	34.43	46.00	Phase 1
1.326	4	30.74	25.26	56.00	14.80	31.20	46.00	Phase 1
1.6635	4	26.56	29.44	56.00	14.39	31.61	46.00	Phase 1
2.2035	4	29.24	26.76	56.00	14.35	31.65	46.00	Phase 1
2.208	4	29.86	26.14	56.00	15.04	30.96	46.00	Phase 1
3.0525	5	23.48	32.52	56.00	11.10	34.90	46.00	Phase 1
3.0885	5	25.86	30.14	56.00	12.62	33.38	46.00	Phase 1
4.3575	5	21.23	34.77	56.00	11.25	34.75	46.00	Phase 1
5.286	6	23.56	36.44	60.00	14.02	35.98	50.00	Phase 1
5.502	6	22.44	37.56	60.00	12.83	37.17	50.00	Phase 1
6.924	6	17.24	42.76	60.00	7.75	42.25	50.00	Phase 1
7.0725	6	17.67	42.33	60.00	9.25	40.75	50.00	Phase 1
11.9445	7	18.46	41.54	60.00	11.23	38.77	50.00	Phase 1
12.363	7	20.05	39.95	60.00	11.74	38.26	50.00	Phase 1
16.368	7	19.34	40.66	60.00	11.72	38.28	50.00	Phase 1
16.6875	7	19.41	40.59	60.00	12.21	37.79	50.00	Phase 1
20.739	8	17.20	42.80	60.00	9.81	40.19	50.00	Phase 1

23.745	8	17.66	42.34	60.00	11.50	38.50	50.00	Phase 1
29.8425	8	21.24	38.76	60.00	15.59	34.41	50.00	Phase 1
29.955	8	19.39	40.61	60.00	13.12	36.88	50.00	Phase 1

Test point N
Operation mode: USB connection with laptop, radio off



freq	SR	QP	margin	limit	AV	margin	limit	line
MHz		dB(μV)	dB	dB	dB(μV)	dB	dB	
0.15	9	41.61	24.39	66.00	18.06	37.94	56.00	Neutral
0.213	9	37.03	26.06	63.09	27.11	25.98	53.09	Neutral
0.2175	9	37.55	25.37	62.91	30.88	22.03	52.91	Neutral
0.222	9	36.92	25.83	62.74	27.17	25.58	52.74	Neutral
0.327	10	29.41	30.11	59.53	21.31	28.22	49.53	Neutral
0.3315	10	30.72	28.69	59.41	17.67	31.75	49.41	Neutral
0.4395	10	28.63	28.44	57.07	16.97	30.10	47.07	Neutral
0.5655	10	27.78	28.22	56.00	9.37	36.63	46.00	Neutral
0.645	11	28.10	27.90	56.00	11.93	34.07	46.00	Neutral
0.6585	11	27.25	28.75	56.00	13.62	32.38	46.00	Neutral
0.879	11	26.54	29.46	56.00	13.34	32.66	46.00	Neutral
1.158	11	27.11	28.89	56.00	11.11	34.89	46.00	Neutral
1.2045	12	28.91	27.09	56.00	13.54	32.46	46.00	Neutral
1.641	12	27.89	28.11	56.00	14.52	31.48	46.00	Neutral
1.875	12	28.59	27.41	56.00	15.26	30.74	46.00	Neutral
2.1945	12	30.15	25.85	56.00	15.87	30.13	46.00	Neutral
2.4	13	24.43	31.57	56.00	12.84	33.16	46.00	Neutral
3.075	13	26.20	29.80	56.00	11.70	34.30	46.00	Neutral
4.4475	13	19.47	36.53	56.00	10.29	35.71	46.00	Neutral
5.07	14	21.25	38.75	60.00	12.56	37.44	50.00	Neutral

5.1825	14	22.72	37.28	60.00	13.44	36.56	50.00	Neutral
7.104	14	15.06	44.94	60.00	7.62	42.38	50.00	Neutral
8.5395	14	12.29	47.71	60.00	4.42	45.58	50.00	Neutral
11.967	15	15.54	44.46	60.00	7.88	42.12	50.00	Neutral
12.1245	15	16.75	43.25	60.00	8.24	41.76	50.00	Neutral
16.782	15	18.76	41.24	60.00	11.43	38.57	50.00	Neutral
17.8305	15	17.90	42.10	60.00	10.36	39.64	50.00	Neutral
20.4375	16	15.70	44.30	60.00	8.41	41.59	50.00	Neutral
21.7785	16	15.63	44.37	60.00	9.36	40.64	50.00	Neutral
25.6125	16	14.56	45.44	60.00	8.35	41.65	50.00	Neutral
28.668	16	19.76	40.24	60.00	14.25	35.75	50.00	Neutral

5.2 Radiated emission

For test instruments and accessories used see section 6 Part **SER 2**.

5.2.1 Description of the test location

Test location: OATS 1

Test distance: 3 m

5.2.2 Photo documentation of the test setup

Please see Attachment B

5.2.3 Applicable standard

According to FCC Part 15B, Section 15.109 (a):

Except for Class A digital devices, the field strength of radiated emission from unintentional radiators at a distance of 3 m shall not exceed the given limit.

5.2.4 Description of Measurement

The radiated emissions from the EUT are measured in the frequency range of 30 MHz to 1000 MHz using a tuned receiver and appropriate broadband linearly polarized antennas. The setup of the EUT and the measurement procedure is in accordance to ANSI C63.4, Item 8 and 12. In the frequency range above 1 GHz a spectrum analyser is used. If the emission level in peak mode complies with the average limit, testing is stopped and peak values will be reported, otherwise, the emission is measured in average mode again and both are reported. The EUT is measured in RX continuous mode under normal conditions.

Spectrum analyser settings:

30 MHz – 1000 MHz: RBW: 120 kHz

1000 MHz – 25 GHz: RBW: 1 MHz, VBW: 3 MHz, Sweep: Auto, Detector function: Peak

5.2.5 Test result

$f < 1 \text{ GHz}$

Frequency (MHz)	Reading Vert. (dB μ V)	Reading Hor. (dB μ V)	Correct. Vert. (dB)	Correct. Hor. (dB)	Level Vert. (dB μ V/m)	Level Hor. (dB μ V/m)	Limit (dB μ V/m)	Dlimit (dB)
39.57	5.8	-6.0	14.6	13.4	20.4	7.4	40.0	-19.6
40.03	-0.7	-3.7	14.7	13.4	14.0	9.7	40.0	-26.0
43.51	5.7	-6.5	15.1	13.9	20.8	7.4	40.0	-19.2
60.02	6.5	2.5	14.7	13.8	21.2	16.3	40.0	-18.8

Limit according to FCC Part 15B, Section 15.109(a):

Frequency (MHz)	Limit (μ V/m)	Limit (dB μ V/m)
30 - 88	100	40.0
88 - 216	150	43.5
216 - 960	200	46.0
Above 960	500	54.0

The requirements are **FULFILLED**.

Remarks: According to the manufacturer the highest internal frequency of the EUT is 20 MHz (excepted the BLE technology), therefore the measurement was performed up to 1 GHz.

6 USED TEST EQUIPMENT AND ACCESSORIES

All test instruments used are calibrated and verified regularly. The calibration history is available on request.

Test ID	Model Type	Equipment No.	Next Calib.	Last Calib.	Next Verif.	Last Verif.
A 4	ESCI	02-02/03-15-001	23/05/2017	23/05/2016		
	ESH 2 - Z 5	02-02/20-05-004	26/10/2017	26/10/2015	24/05/2017	24/11/2016
	N-4000-BNC	02-02/50-05-138				
	N-1500-N	02-02/50-05-140				
	ESH 3 - Z 2 6430	02-02/50-05-155 02-02/50-13-014	18/11/2019	18/11/2016	21/10/2017	21/04/2017
SER 2	ESR 7	02-02/03-13-001	15/06/2017	15/06/2016		
	VULB 9168	02-02/24-05-005	12/04/2018	12/04/2017	12/10/2017	12/04/2017
	NW-2000-NB	02-02/50-05-113				
	KK-EF393/U-16N-21N20 m	02-02/50-12-018				
	KK-SD_7/8-2X21N-33,0M	02-02/50-15-028				