

EMI – TEST REPORT

- Human Exposure -

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. : **T38836-14-05GK**

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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ATTACHMENT A as separate supplement

1 TEST STANDARDS

The tests were performed according to following standards:

FCC Rules and Regulations Part 1, Subpart I - Procedures Implementing the National Environmental Policy Act of 1969

Part 1, Subpart I, Section 1.1310 Radiofrequency radiation exposure limits

Part 1, Subpart 2, Section 2.1091 Radiofrequency radiation exposure evaluation: **mobile devices**.

Part 1, Subpart 2, Section 2.1093 Radiofrequency radiation exposure evaluation: **portable devices**.

OET Bulletin 65, 65A, 65B Edition 97-01, August 1997 – Evaluating Compliance with FCC Guidelines for Human Exposure to Radio Frequency Electromagnetic Fields.

KDB 447498 D01 v06 Mobile and portable devices RF Exposure procedures and equipment authorisation policies, October 23, 2015.

KDB 865664 D01 v01r04 SAR Measurement Requirements for 100 MHz to 6 GHz, August 7, 2015.

ANSI C95.1: 2005 IEEE Standard for Safety Levels with respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

ETSI TR 100 028 V1.3.1: 2001-03, Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Uncertainties in the Measurement of Mobile Radio Equipment Characteristics—Part 1 and Part 2

2 EQUIPMENT UNDER TEST

2.1 Photo documentation of the EUT – See ATTACHMENT A

2.2 Equipment type, category

BLE device, 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. The EUT must be controlled via terminal program to select the modulation and data rate manually. A personal computer was used to control the settings of the EUT.

Number of tested samples: 2 (1 radiated and 1 conducted sample)
 Serial number (radiated sample): Z2KGMN5Z
 Serial number)conducted sample): Z2KGMN66
 Firmware version of system microcontroller: N/A
 Firmware version of BLE chip: DTM firmware : 99.11.69

EUT configuration:

(The CDF filled by the applicant can be viewed at the test laboratory.)

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

The operating frequency is 2400 MHz to 2483.5 MHz.

2.6 Antennas

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 Power supply system utilised

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

3 TEST RESULT SUMMARY

BLE device using digital modulation:

Operating in the 2400 MHz – 2483.5 MHz and 5725 MHz – 5850 MHz band:

FCC Rule Part	RSS Rule Part	Description	Result
15.247(i)	RSS 102, 2.5.2	MPE	passed
KDB 447498	RSS 102, 2.5.1	SAR exclusion consideration	passed
OET Bulletin 65	RSS102, 3.2	Co-location, Co-transmission	not applicable

The mentioned RSS Rule Parts in the above table are related to:
RSS 102, Issue 5, March 2015

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 : 29 May 2017

Testing concluded on : 29 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.

Measurement Type	Range	Confidence Level	Calculated Uncertainty
AC power line conducted emissions	0.15 MHz to 30 MHz	95%	± 3.29 dB
EBW and OBW	2400 MHz to 3000 MHz	95%	$\pm 2.5 \times 10^{-7}$
Maximum peak conducted output power	2400 MHz to 3000 MHz	95%	± 0.62 dB
Power spectral density	2400 MHz to 3000 MHz	95%	± 0.62 dB
Conducted Spurious Emissions	9 kHz to 10000 MHz	95%	± 2.15 dB
Conducted Spurious Emissions	10000 MHz to 40000 MHz	95%	± 3.47 dB
Radiated Spurious Emissions	9 kHz to 30 MHz	95%	± 3.53 dB
Radiated Spurious Emissions	30 MHz to 1000 MHz	95%	± 3.71 dB
Radiated Spurious Emissions	1000 MHz to 10000 MHz	95%	± 2.34 dB
Field strength of the fundamental	100 kHz to 100 MHz	95%	± 3.53 dB

4.4 Measurement protocol for FCC and ISED

4.4.1 General information

The Open Area test site is a listed Open Site under the Canadian Test-Sites File-No:

IC 3009A-1

The Anechoic chamber is a listed test site under the Canadian Test-Sites File-No:

IC 3009A-2

In compliance with RSS 247 testing for RSS compliance may be achieved by following the procedures set out in ANSI C63.10 and applying the CISPR 22 limits.

5 TEST CONDITIONS AND RESULTS

5.1 Maximum peak radiated output power

5.1.1 Test result

The output power of the device is taken from the power measurement in the test report according T38836-14-02GK of the test laboratory CSA Group Bayern GmbH.

Maximum peak conducted output power:

		Test results conducted		
		A [Pmax] (dBm)	Limit (dBm)	Margin (dB)
Lowest frequency: CH37				
T_{nom}	V_{nom}	-3.9	30.0	-33.9
Middle frequency: CH18				
T_{nom}	V_{nom}	-4.0	30.0	-34.0
Highest frequency: CH39				
T_{nom}	V_{nom}	-4.6	30.0	-34.6

Gain of the antenna: 0 dBi

Maximum peak radiated output power: $A + G = -3.9 \text{ dBm} + 0 \text{ dBi} = -3.9 \text{ dBm}$

Remarks:

6 HUMAN EXPOSURE

6.1 Maximum permissible exposure (MPE)

6.1.1 Description of the test location

Test location: NONE

6.1.2 Applicable standard

According to FCC Part 15, Section 15.247(i):

Systems operating under the provisions of this section shall be operated in a manner that the public is not exposed to radio frequency energy levels in excess of the Commission's guidelines.

The test methods used comply with ANSI/IEEE C95.1, "IEEE Standard for Safety Levels with respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz".

This test report shows the compliance with the limits for Maximum Permissible Exposure (MPE) specified in FCC Part 1, Section 1.1310 and the criteria to evaluate the environmental impact of human exposure to radio frequency (RF) radiation as specified in FCC Part 1, Section 1.1307(b).

6.1.3 Description of Measurement

The maximum total power input to the antenna has been measured conducted as described in clause 5.3 of this document. Through the Friis transmission formula, the known maximum gain of the antenna and the maximum power, can be calculated the MPE in a defined distance away from the product.

Friis transmission formula:

$$P_d = \frac{P_{out} * G}{4 * \pi * r^2}$$

Where:

P_d = power density (mW/cm²)

P_{out} = output power to antenna (mW)

G = gain of antenna (linear scale)

r = distance between antenna and observation point (cm)

According to FCC Rules 47CFR 2.1093(b) the EUT is not a portable device. The EUT is designed to be used that radiating structures are 20 cm outside of the body of the user. ($r = 20$ cm)

6.1.4 Test result

Channel frequency	P_{EIRP}	P	P	P_d	Limit P_d	Exposure ratio
(MHz)	(dBm)	(mW)	(W)	(mW/cm ²)	(mW/cm ²)	(%)
2402	-3.9	0.407	0.000407	0.000081	0.54	0.02
2442	-4.0	0.398	0.000398	0.000079	0.54	0.01
2480	-4.6	0.347	0.000347	0.000069	0.55	0.01

Limits for maximum permissible exposure (MPE):

Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm ²)	Averaging time (minutes)
(B) Limits for General Population / Uncontrolled Exposure				
0.3 – 3.0	614	1.63	100	30
3.0 – 30	824/ <i>f</i>	2.19/ <i>f</i>	180/ <i>f</i> ²	30
30 - 300	27.5	0.073	0.2	30
300-1500	---	---	<i>f</i> /1500	30
1500-100000	---	---	1.0	30

f = Frequency in MHz

Limits for maximum permissible exposure (MPE) according RSS102, table 4:

Frequency Range (MHz)	Electric Field (V/m rms)	Magnetic Field (A/m rms)	Power Density (W/m ²)	Reference Period (minutes)
300-6000	3.142 <i>f</i>^{0.3417}	0.008335 <i>f</i>^{0.3417}	0.02619 <i>f</i>^{0.6834}	6
6000-15000	61.4	0.163	10	6

Note: *f* is frequency in MHz. *Based on nerve stimulation (NS). ** Based on specific absorption rate (SAR).

f = Frequency in MHz

Determination of the limit per frequency:

Applied frequency (MHz)	RSS102 Power density limit (W/m ²)	RSS102 Power density limit (mW/cm ²)	FCC-limit (mW/cm ²)
2402	5.4	0.54	1
2442	5.4	0.54	1
2480	5.5	0.55	1

The requirements are **FULFILLED**.

Remarks:

6.2 Co-location and Co-transmission

Remarks:

Not applicable, the EUT has only one transmitter.

6.3 SAR test exclusion considerations

6.3.1 Applicable standard

According to RF exposure guidance:

Systems operating under the provisions of this section shall be operated in a manner that the public is not exposed to radio frequency energy levels in excess of the Commission's guidelines.

6.3.2 Determination of the standalone SAR test exclusion threshold

Limbs

Separation distance (mm)	Channel frequency (MHz)	EIRP (dBm)	EIRP (mW)	10-g SAR	Limit 10-g SAR	Percentage %
5	2402	-3.9	0.41	0.13	7.5	1.7

Head and trunk

Separation distance (mm)	Channel frequency (MHz)	EIRP (dBm)	EIRP (mW)	1-g SAR	Limit 1-g SAR	Percentage %
5	2402	-3.9	0.41	0.13	3.0	4.2

The EUT fulfills the limits for the limbs and additionally for head and trunk.

The requirements are **FULFILLED**.

Remarks: As worst case the power values are not averaged over time.

6.1 Exemption limits for routine evaluation - SAR evaluation

6.1.1 Applicable standard

According to RSS-102, item 2.5.1:

SAR evaluation is required if the separation distance between the user and/or bystander and the antenna and/or radiating element of the device is less than or equal to 20 cm, except when the device operates at or below the applicable output power level (adjusted for tune-up tolerance) for the specified separation distance defined in Table 1.

Table 1: SAR evaluation – Exemption limits for routine evaluation based on frequency and separation distance 4, 5

Frequency (MHz)	Exemption Limits (mW)				
	At separation distance of ≤5 mm	At separation distance of 10 mm	At separation distance of 15 mm	At separation distance of 20 mm	At separation distance of 25 mm
≤ 300	71 mW	101 mW	132 mW	162 mW	193 mW
450	52 mW	70 mW	88 mW	106 mW	123 mW
835	17 mW	30 mW	42 mW	55 mW	67 mW
1900	7 mW	10 mW	18 mW	34 mW	60 mW
2450	4 mW	7 mW	15 mW	30 mW	52 mW
3500	2 mW	6 mW	16 mW	32 mW	55 mW
5800	1 mW	6 mW	15 mW	27 mW	41 mW

4 The exemption limits in Table 1 are based on measurements and simulations of half-wave dipole antennas at separation distances of 5 mm to 25 mm from a flat phantom, providing a SAR value of approximately 0.4 W/kg for 1 g of tissue. For low frequencies (300 MHz to 835 MHz), the exemption limits are derived from a linear fit. For high frequencies (1900 MHz and above), the exemption limits are derived from a third order polynomial fit.

5 Transmitters operating between 0.003-10 MHz, meeting the exemption from routine SAR evaluation, shall demonstrate compliance to the instantaneous limits in Section 4.

6.1.2 Conclusion according RSS-102.

Limbs

Separation distance (mm)	Channel frequency (MHz)	EIRP (dBm)	EIRP (mW)	Limit 10-g SAR (mW)	Percentage %
5	2402	-3.9	0.41	10.0	4.1

Head and trunk

Separation distance (mm)	Channel frequency (MHz)	EIRP (dBm)	EIRP (mW)	Limit 1-g SAR (mW)	Percentage %
5	2402	-3.9	0.41	4.0	10.2

For the EUT SAR measurement is NOT necessary

The requirements are **FULFILLED**.

Remarks: As worst case the power values are not averaged over time.