



RF - TEST REPORT

- Human Exposure -

Model Name : OneTouch Verio Flex / HVIN: ZH

Product Description : Blood glucose meter with BLE 5.0

Applicant : Lifescan Scotland Ltd.

Address : Beechwood Park North

INVERNESS, IV2 3ED, SCOTLAND

Manufacturer : Lifescan Europe GmbH

Address : Gubelstrasse 34

6300 ZUG, SWITZERLAND

Licence holder : Lifescan Europe GmbH

Address : Gubelstrasse 34

6300 ZUG, SWITZERLAND

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

Test Report No. : 80125751-05 Rev_3	15. February 2023 Date of issue
---	------------------------------------



Deutsche
Akkreditierungsstelle
D-PL-12030-01-03
D-PL-12030-01-04

Contents

1	<u>TEST STANDARDS</u>	3
2	<u>EQUIPMENT UNDER TEST</u>	4
2.1	Information provided by the Client	4
2.2	Sampling	4
2.3	Photo documentation of the EUT – See ATTACHMENT A	4
2.4	Equipment type, category	4
2.5	Short description of the equipment under test (EUT)	4
2.6	Variants of the EUT	4
2.7	Operation frequency and channel plan	5
2.8	Transmit operating modes	5
2.9	Antennas	5
2.10	Power supply system utilised	5
3	<u>TEST RESULT SUMMARY</u>	6
3.1	Revision history of test report	6
3.2	Final assessment	6
4	<u>TEST ENVIRONMENT</u>	7
4.1	Address of the test laboratory	7
4.2	Environmental conditions	7
4.3	Statement of the measurement uncertainty	7
5	<u>HUMAN EXPOSURE</u>	8
5.1	Maximum permissible exposure (MPE)	8
5.2	Co-location and Co-transmission	9
5.3	SAR test exclusion considerations	10
5.4	Exemption limits for routine evaluation - SAR evaluation	11
6	<u>USED TEST EQUIPMENT AND ACCESSORIES</u>	13

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 2.1093	Radiofrequency radiation exposure evaluation: portable devices.
KDB 447498 D01	RF Exposure procedures and equipment authorisation policies for mobile and portable devices, April 20, 2021.
ANSI C95.1: 2005	IEEE Standard for Safety Levels with respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

RSS-102, Issue 5, February 2, 2021

Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)

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

2 EQUIPMENT UNDER TEST

2.1 Information provided by the Client

Please note, we do not take any responsibility for information provided by the client or his representative which may have an influence on the validity of the test results.

2.2 Sampling

The customer is responsible for the choice of sample. Sample configuration, start-up and operation is carried out by the customer or according to his/her instructions.

2.3 Photo documentation of the EUT – See ATTACHMENT A

2.4 Equipment type, category

BLE device, portable equipment.

2.5 Short description of the equipment under test (EUT)

The EUT is a blood glucose meter equipped with Bluetooth Low Energy. A single PCB antenna is used within the system. The EUT has only one integrated antenna, no temporary connector and no external antenna can be connected. The modulation used by the EUT is GFSK with a data rate of 1 Mbit/s.

Number of tested samples : 1
 Serial number : Z1QGJ07P
 Firmware number : DTM version 1.0.0
 Type : OneTouch Verio Flex

Items	Description
BT type	5.0 Low Energy
BT chipset type	Nordic Semiconductors nRF52805
Modulation	GFSK
Frequency range	2400 MHz to 2483.5 MHz
Channel numbers	40
Data rate (kbps)	1000
Power setting	-4
Antenna type	PCB

2.6 Variants of the EUT

The Element Verio Platform consists of two devices: OneTouch Verio Flex and OneTouch Ultra Plus Flex. According to the customer the only difference between the two devices is the colour of the housing and the different strip port connectors.

2.7 Operation frequency and channel plan

The operating frequency is 2400 MHz to 2483.5 MHz.

Channel plan:

Channel	Frequency (MHz)	Channel	Frequency (MHz)
37	2402	18	2442
0	2404	19	2444
1	2406	20	2446
2	2408	21	2448
3	2410	22	2450
4	2412	23	2452
5	2414	24	2454
6	2416	25	2456
7	2418	26	2458
8	2420	27	2460
9	2422	28	2462
10	2424	29	2464
38	2426	30	2466
11	2428	31	2468
12	2430	32	2470
13	2432	33	2472
14	2434	34	2474
15	2436	35	2476
16	2438	36	2478
17	2440	39	2480

Note: the marked frequencies are determined for final testing.

2.8 Transmit operating modes

The EUT uses GFSK modulation and may provide following data rates:

- 1000 kbps

(kbps = *kilobits per second*)

2.9 Antennas

A single integrated PCB antenna is used with the EUT, no other antenna can be used with the device.

All measurements were performed radiated, for additional photo documentation of the antenna please refer to Attachment A.

2.10 Power supply system utilised

Power supply voltage, V_{nom} : 3 VDC (battery)

3 TEST RESULT SUMMARY

BLE device using digital modulation and operates in the 2400 MHz – 2483.5 MHz band:

FCC Rule Part	RSS Rule Part	Description	Result
KDB 447498, 7.1	RSS 102, 2.5.2	MPE	not applicable
KDB 447498, 4.3.1	RSS 102, 2.5.1	SAR exclusion consideration	passed
KDB 447498, 7.2	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 + Amendment 1 (February 2021)

3.1 Revision history of test report

Test report No	Rev.	Issue Date	Changes
80125751-05	0	13 July 2022	Initial test report
80125751-05	1	27 January 2023	5.3 EIRP updated
80125751-05	2	08 February 2023	HVIN corrected
80125751-05	3	15 February 2023	5.3 + 5.4 EIRP updated

The test report with the highest revision number replaces the previous test reports.

3.2 Final assessment

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

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

Testing commenced on : 14 February 2023

Testing concluded on : 14 February 2023

Checked by:

Tested by:

Klaus Gegenfurtner
Teamleader Radio

Sabine Kugler
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 on basis of the ETSI Technical Report TR 100 028 Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics; Part 1 and Part 2. The results are documented in the quality system acc. to DIN EN ISO/IEC 17025. 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 Conformity Decision Rule

The applied conformity decision rule is based on ILAC G8:09/2019 clause 4.2.1 Binary Statement for Simple Acceptance Rule ($w = 0$).

Details can be found in the procedure CSA_B_V50_29.

5 HUMAN EXPOSURE

5.1 Maximum permissible exposure (MPE)

For test instruments and accessories used see section 6 Part **CPC 3**.

5.1.1 Description of the test location

Test location: NONE

5.1.2 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).

5.1.3 Description of Determination

The maximum rated output power conducted included the tune up tolerance is used to calculate the EIRP. 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)

Remarks: Not applicable, EUT is portable

5.2 Co-location and Co-transmission

Applicable standard:

OET Bulletin 65, Edition 97-01, Section 2: Multiple-transmitter sites and Complex Environments

The FCC's MPE limits vary with frequency. Therefore, in mixed or broadband RF fields where several sources and frequencies are involved, the fraction of the recommended limit (in terms of power density or square of the electric or magnetic field strength) incurred within each frequency interval should be determined, and the sum of all fractional contributions should not exceed 1.0, or 100 % in terms of percentage.

Remarks: Not applicable, EUT has only one transmitter

5.3 SAR test exclusion considerations

5.3.1 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.

5.3.2 Determination of the standalone SAR test exclusion threshold

b) For BLE device:

The minimum separation distance results from the application of the EUT which is handled by hand. This distance is assumed to ≤ 5 mm from antenna to the hand of the user.

The hand of the user is the nearest extremity of a human being therefore the threshold for 10-g is determined.

The formula under 4.3.1 1) for 100 MHz to 6 GHz for standalone equipment is used:

$$[(\text{max. power of channel, including tune-up tolerance, mW})/(\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}] \leq 7.5;$$

The max EIRP including tune-up tolerance is according to the equipment:

Channel frequency (MHz)	EIRP (dBm)	Tune-up tolerance (dB)	max. EIRP (mW)	Threshold level	Limit 10g	Margin 10g
2402	-1.9	2.0	1.0	0.32	7.5	-7.2
2440	-1.8	2.0	1.0	0.33	7.5	-7.2
2480	-2.7	2.0	0.9	0.27	7.5	-7.2

Conclusion: The Threshold level is higher than the limit, SAR measurement is necessary.

The requirements are **FULFILLED**.

Remarks: For EIRP measurement please refer to test report 80125751-06 Rev_0 issued by CSA Group
Bayern GmbH.

5.4 Exemption limits for routine evaluation - SAR evaluation

5.4.1 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

Frequency (MHz)	Exemption Limits (mW)				
	At separation distance of 30 mm	At separation distance of 35 mm	At separation distance of 40 mm	At separation distance of 45 mm	At separation distance of ≥50 mm
≤ 300	223 mW	254 mW	284 mW	315 mW	345 mW
450	141 mW	159 mW	88 mW	195 mW	213 mW
835	80 mW	92 mW	177 mW	117 mW	130 mW
1900	99 mW	153 mW	225 mW	316 mW	431 mW
2450	83 mW	123 mW	173 mW	235 mW	309 mW
3500	86 mW	124 mW	170 mW	225 mW	290 mW
5800	56 mW	71 mW	85 mW	97 mW	106 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.

5.4.2 Conclusion according RSS-102.

EIRP:	-1.8 dBm
Tune-up tolerance:	2.0 dBm
Maximum EIRP:	1.0 mW
Minimum distance r:	5.0 mm

Maximum output power (EIRP) at 2450 MHz, **1.0 mW** is < 4 mW;

For the EUT is SAR measurement is NOT necessary

The requirements are **FULFILLED**.

Remarks: For EIRP measurement please refer to test report 80125751-06 Rev_0 issued by CSA Group
Bayern GmbH.

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.
-	-	-	-	-	-	-

- End of test report -

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.