

Assessment report No:

**NIE: 55960RAN.001**

## Assessment report RF EXPOSURE REPORT ACCORDING TO FCC 47 CFR Part 2.1093 ISED RSS -102 Issue 5:2015

Identification of item tested.....:	Blood Glucose meter with Bluetooth Low Energy
Trademark .....	OneTouch
Model and /or type reference .....	Ultra Plus Reflect
Other identification of the product .....	FCC ID: 2ACT5-K IC ID: 12202A-K
Final HW version .....	DV1
Final SW version .....	Main Firmware 1.3.0, Bluetooth Firmware 1.3.3
Features .....	Bluetooth LE
Manufacturer .....	LIFESCAN EUROPE, DIVISION OF CILAG GMBH INTERNATIONAL Gubelstrasse 34, 6300 ZUG. Switzerland.
Test method requested, standard.....:	FCC 47 CFR Part 2.1093. (10-1-15 Edition) Radiofrequency radiation exposure evaluation: portable devices. ISED RSS-102 Issue 5 (2015-03) – Radio Frequency Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)
Summary .....	IN COMPLIANCE
Approved by (name / position & signature) .....	Miguel Lacave Antennas Lab Manager
Date of issue .....	2018-05-03
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# Index

Competences and guarantees.....	3
General conditions.....	3
Identification of the client .....	3
General description of the device under evaluation .....	4
Remarks and comments.....	5
Assessment summary .....	6
Appendix A – FCC RF Exposure.....	7
FCC Exposure evaluation portable or mobile devices.....	8
FCC SAR test exclusion considerations .....	8
FCC Evaluation Results.....	10
Appendix B – ISED RF Exposure.....	11
ISED SAR test exclusion considerations.....	12
ISED Evaluation Results .....	13

## Competences and guarantees

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## Identification of the client

LIFESCAN SCOTLAND LTD.

Beechwood Park North.

ZIP: IV2 3ED. Inverness. Highland. Scotland.

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## General description of the device under evaluation

The device under evaluation consists of a blood glucose meter for measuring the levels of Glucose in a patient's blood. Bluetooth is used to transfer the patient's result(s) to their smart device.

The Blood Glucose meter "OneTouch" can be commercialized under different models: OneTouch Verio Reflect and OneTouch Ultra Plus Reflect. Both models are electrically and mechanically identical. The differences between models are the housing colour and one connector that has reversed polarity (see applicant's declaration letter in point "Remarks and Comments").


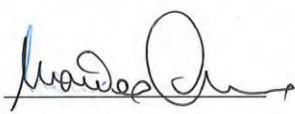
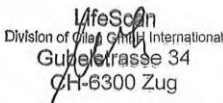
The equipment specifications declared by the manufacturer for the Bluetooth LE mode are:

Mode	Frequency (MHz)	Maximum output power (dBm)	Antenna Gain (dBi)
Bluetooth LE	2402	-8.0	-0.09
	2440	-8.0	-0.09
	2480	-8.0	-0.09

**Table 1:** Maximum output power and antenna gain value

## Remarks and comments

Applicant's declaration letter:

 <p>LifeScan Europe Division of Cilag GmbH International Gubelstrasse 34, CH-6300 Zug, Switzerland</p>	<p>LIFESCAN EUROPE, DIVISION OF CILAG GMBH INTERNATIONAL Gubelstrasse 34, 6300 ZUG, Switzerland</p>
<p>Date: 06/03/18</p>	
<p>Ref: Declaration of Identity</p>	
<p>To whom it may concern</p>	
<p>We, LIFESCAN EUROPE, DIVISION OF CILAG GMBH INTERNATIONAL, declare that both devices OneTouch Verio Reflect and OneTouch Ultra Plus Reflect share the same electronics, including Bluetooth IC and FW, with only the housing colour changed, one connector (strip port connector) has a reversed polarity between the two devices.</p>	
<p>We attest that the above differences are not relevant for any behavior subject to regulatory items.</p>	
	
<p>By: Mariano Chiusano Title: Director Regulatory Affairs EMEA Company: LifeScan Europe Telephone: +41 58 231 58 15 Email: mchiusano@its.jnj.com</p>	
	
<p>Page 1 of 1</p>	

## Assessment summary

Radiofrequency radiation exposure limits			
FCC 47 CFR § 2.1093 & ISSED RSS-102 Issue 5 (2015-03)			
Band (MHz)	Technology	Band	VERDICT (Pass/Fail)
2450	Bluetooth LE	ISM	Pass

**Table 2:** Assessment summary

## Appendix A – FCC RF Exposure

## FCC Exposure evaluation portable or mobile devices

Human exposure to RF emissions from portable devices (47 CFR §2.1093), as defined by the FCC, must be evaluated with respect to the FCC-adopted limits for SAR. Evaluation of mobile devices, as defined by the FCC, may also be performed with respect to SAR limits, but in such cases it is usually simpler and more cost-effective to evaluate compliance with respect to field strength or power density limits. For certain devices that are designed to be used in both mobile and portable configurations similar to those described in 47 CFR §2.1091(d)(4), such as certain desktop phones and wireless modem modules, compliance for mobile configurations is also satisfied when the same device is evaluated for SAR compliance in portable configurations.

## FCC SAR test exclusion considerations

According to FCC OET KDB 447498 D01 General RF Exposure Guidance:

Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Threshold condition is satisfied.

### - For distances $\leq 50$ mm

The 1-g and 10-g SAR test exclusion thresholds for 100 MHz to 6 GHz at test separation distances  $\leq 50$  mm are determined by:

$$[(\text{max. power of channel, including tune-up tolerance, mW})/(\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}] \leq 3.0 \text{ for 1-g SAR and } \leq 7.5 \text{ for 10-g extremity SAR}$$

Where

- $f(\text{GHz})$  is the RF channel transmit frequency in GHz
- Power and distance are rounded to the nearest mW and mm before calculation
- The result is rounded to one decimal place for comparison

The test exclusions are applicable only when the minimum test separation distance is  $\leq 50$  mm and for transmission frequencies between 100 MHz and 6 GHz. When the minimum test separation distance is  $< 5$  mm, a distance of 5 mm is applied to determine SAR test exclusion.

Approximate SAR Test Exclusion Power Thresholds at Selected Frequencies and Test Separation Distances are illustrated in the following Table:

MHz	5	10	15	20	25	30	35	40	45	50	mm
150	39	77	116	155	194	232	271	310	349	387	SAR Test Exclusion Threshold (mW)
300	27	55	82	110	137	164	192	219	246	274	
450	22	45	67	89	112	134	157	179	201	224	
835	16	33	49	66	82	98	115	131	148	164	
900	16	32	47	63	79	95	111	126	142	158	
1500	12	24	37	49	61	73	86	98	110	122	
1900	11	22	33	44	54	65	76	87	98	109	
2450	10	19	29	38	48	57	67	77	86	96	
3600	8	16	24	32	40	47	55	63	71	79	
5200	7	13	20	26	33	39	46	53	59	66	
5400	6	13	19	26	32	39	45	52	58	65	
5800	6	12	19	25	31	37	44	50	56	62	

**Table 3:** SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and  $\leq 50$  mm



### - For distances > 50 mm

For 100 MHz to 6 GHz frequencies and for test separation distances > 50 mm, the SAR test exclusion threshold is determined according to the following:

1) [Power allowed at numeric threshold for 50 mm in table 1) + (test separation distance - 50 mm)·(f(MHz)/150)] mW, at 100 MHz to 1500 MHz

2) [Power allowed at numeric threshold for 50 mm in table 1) + (test separation distance - 50 mm)·10] mW, at > 1500 MHz and ≤ 6 GHz

Approximate SAR test exclusion power thresholds at selected frequencies and test separation distances are illustrated in the following table

MHz	50	60	70	80	90	100	110	120	130	140	150	160	170	180	190	mm
100	474	481	487	494	501	507	514	521	527	534	541	547	554	561	567	SAR Test Exclusion Threshold (mW)
150	387	397	407	417	427	437	447	457	467	477	487	497	507	517	527	
300	274	294	314	334	354	374	394	414	434	454	474	494	514	534	554	
450	224	254	284	314	344	374	404	434	464	494	524	554	584	614	644	
835	164	220	275	331	387	442	498	554	609	665	721	776	832	888	943	
900	158	218	278	338	398	458	518	578	638	698	758	818	878	938	998	
1500	122	222	322	422	522	622	722	822	922	1022	1122	1222	1322	1422	1522	
1900	109	209	309	409	509	609	709	809	909	1009	1109	1209	1309	1409	1509	
2450	96	196	296	396	496	596	696	796	896	996	1096	1196	1296	1396	1496	
3600	79	179	279	379	479	579	679	779	879	979	1079	1179	1279	1379	1479	
5200	66	166	266	366	466	566	666	766	866	966	1066	1166	1266	1366	1466	
5400	65	165	265	365	465	565	665	765	865	965	1065	1165	1265	1365	1465	
5800	62	162	262	362	462	562	662	762	862	962	1062	1162	1262	1362	1462	

**Table 4:** SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and > 50 mm

### - For frequencies below 100 MHz

The following may be considered for SAR test exclusion:

1) For test separation distances > 50 mm and < 200 mm, the power threshold at the corresponding test separation distance at 100 MHz in step b) is multiplied by  $[1 + \log(100/f(\text{MHz}))]$

2) For test separation distances ≤ 50 mm, the power threshold determined by the equation in c) 1) for 50 mm and 100 MHz is multiplied by  $\frac{1}{2}$

Approximate SAR test exclusion power thresholds at selected frequencies and test separation distances are illustrated in the following table

MHz	< 50	50	60	70	80	90	100	110	120	130	140	150	160	170	180	190	mm
100	237	474	481	487	494	501	507	514	521	527	534	541	547	554	561	567	mW
50	308	617	625	634	643	651	660	669	677	686	695	703	712	721	729	738	
10	474	948	961	975	988	1001	1015	1028	1041	1055	1068	1081	1095	1108	1121	1135	
1	711	1422	1442	1462	1482	1502	1522	1542	1562	1582	1602	1622	1642	1662	1682	1702	
0.1	948	1896	1923	1949	1976	2003	2029	2056	2083	2109	2136	2163	2189	2216	2243	2269	
0.05	1019	2039	2067	2096	2125	2153	2182	2211	2239	2268	2297	2325	2354	2383	2411	2440	
0.01	1185	2370	2403	2437	2470	2503	2537	2570	2603	2637	2670	2703	2737	2770	2803	2837	

**Table 5:** SAR Test Exclusion Thresholds for frequencies < 100 MHz

## FCC Evaluation Results

The maximum output power of the device is -8.0 dBm for the Bluetooth LE technology, which corresponds to 0.158 mW.

The evaluation according to an intended use distance of 5 mm will be as follow:

Technology	Max. Declared Output Power (dBm)		Min. Test Distance (mm)	Freq. (GHz)	Result	Test Exclusion
	(dBm)	(mW)				
BT	-8.0	0.158	5	2.48	0.05	PASS

**Table 6:** Evaluation Result

The computed 0.13 value is < 3.0, so according to KDB 447498 D01 – General RF Exposure Guidance, this mode qualifies for Standalone SAR test exclusion for 1-g SAR and 10-g SAR.

## Appendix B – ISED RF Exposure

## ISED SAR test exclusion considerations

According to “RSS-102 Issue 5 (2015-03) – Radio Frequency Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)”, paragraph “2.5.1 Exemption Limits for Routine Evaluation – SAR Evaluation”, the device operates 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<sup>4,5</sup>**

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	177 mW	195 mW	213 mW
835	80 mW	92 mW	105 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

Output Power level shall be the higher of the maximum conducted or equivalent isotropically radiated power (e.i.r.p.) source-based time-averaged output power. If the operating frequency of the device is between two frequencies located in Table 1, linear interpolation shall be applied for the applicable separation distance. For test separation distance less than 5 mm, the exemption limits for a separation distance of 5 mm can be applied to determine if a routine evaluation is required

## ISED Evaluation Results

According to paragraph “2.5.1 Exemption Limits for Routine Evaluation – SAR Evaluation”, the exemption limits for the applicable separation distance have been calculated by linear interpolation for the following operating frequencies:

Frequency (MHz)	Distance (mm)	Exemption Limits (mW)
2402	5	4.26
2440	5	4.05
2480	5	3.95

**Table 7:** Exemption Limits

The maximum output power of the device is -8.0 dBm for the Bluetooth Low Energy technology, which corresponds to 0.158 mW. As the transmitting antenna of the device has a negative gain, the maximum output power has been used for the evaluation as a worst case condition:

The evaluation for the applicable output power levels and exemption limits for each operating frequency and technology will be as follow:

Technology	Frequency (MHz)	Max. Output Power (dBm)	Max. Output Power (mW)	ISED Exemption Limits (mW)	Verdict
Bluetooth LE	2402	-8.0	0.158	4.26	Pass
	2440	-8.0	0.158	4.05	Pass
	2480	-8.0	0.158	3.95	Pass

**Table 8:** Evaluation Result

As all operating frequencies comply with SAR Test Exclusion Thresholds, according to the standard “ISED RSS-102 Issue 5 (2015-03)”, SAR testing is not required.