

RF-EXPOSURE REPORT FCC 47 CFR Part 2.1091 ISED RSS-102 Maximum permissible exposure	
Report Reference No	G0M-1909-8467-TFC091MP-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	    DAkkS - Registration number : D-PL-12092-01-03 (ISED) ISED Testing Laboratory site: 3470A-2 DAkkS - Registration number : D-PL-12092-01-04 (FCC) FCC Filed Test Laboratory, Reg.-No.: 96970
Applicant	BIOTRONIK SE & Co. KG
Address	Woermannkehe 1 12359 Berlin GERMANY
Test Specification	According to FCC/ISED rules
Standard	FCC 47 CFR 2.1091 ISED RSS-102
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	Programming device
Model(s)	BIOWand
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware Version(s)	B
Software Version(s)	BFW_FW_1_0_x
FCC-ID	QRI-BIOWAND
IC	-/-
Test Result	PASSED

Possible test case verdicts:		
required by standard but not tested	N/T	
not required by standard	N/R	
test object does meet the requirement	P(PASS)	
test object does not meet the requirement	F(FAIL)	
Testing:		
Test Lab Temperature	15 - 35 °C	
Test Lab Humidity	30 – 50 %	
Date of receipt of test item	2019-09-16 (Test Sample ID 25528) 2019-09-26 (Test Sample ID 25529)	
Report:		
Compiled by	Abdullah Al Jamal	
Tested by (+ signature) (Responsible for Test)	Abdullah Al Jamal	
Approved by (+ signature) (Head of Lab)	Christian Weber	
Date of Issue	2020-01-25	
Total number of pages	14	
General Remarks:		
The test results presented in this report relate only to the object tested. The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.		
Additional Comments:		
None.		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2020-01-25	Initial Release	

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EIRP	Equivalent Isotropic Radiated Power
EUT	Equipment Under Test
MPE	Maximum Permissible Exposure

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1 Equipment (Test Item) Under Test

Description	Programming device
Model	BIOWand
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Serial Number(s)	80300002 (Test Sample ID 25528) 80300009 (Test Sample ID 25529)
Hardware Version(s)	B
Software Version(s)	BFW_FW_1_0_x
PMN	-/-
HVIN	-/-
FVIN	-/-
HMN	-/-
FCC-ID	QRI-BIOWAND
IC	-/-
Equipment type	End Product
Environment	General public

1.1 Reference Documents

Document Type	Document No.	Issued by	Date
Test Report (Radio) – FCC 47 CFR Part 15B + ISED RSS-247, Issue 2 (February 2017) – Bluetooth Low Energy	1-5687/17-01-07-A	CTC advanced GmbH	2018-03-26
Test Report (Radio) – FCC 47 CFR Part 15C + ISED RSS-247, Issue 2 (February 2017) – Bluetooth Low Energy	G0M-1909-8467- TFC247BL-V01	Eurofins Product Service	2019-10-02
Test Report (Radio) – FCC 47 CFR Part 15B + ISED RSS-210, Issue 9 (August 2016) – ULP-AMI	G0M-1909-8467- TFC209LP-V01	Eurofins Product Service	2019-11-27

1.2 Power density radiation sources

Mode	Operating Frequency [MHz]	Maximum conducted power [dBm]	Maximum radiated power [dBm EIRP]	Maximum duty cycle [%]	Maximum antenna gain [dBi]	Maximum antenna diameter [cm]
Bluetooth LE	2402	3.5	4.6	33	1.1	N/A
	2440	3.4	4.5	33	1.1	N/A
	2480	3.5	4.6	33	1.1	N/A
Comment: The source of G0M-1909-8467-TFC209LP-V01 was excluded due to its low power (-11.0 dBμV/m),						

1.3 Field strength radiation sources

None.

1.4 Concurrent Sources

No concurrent radiation sources.

2 Result Summary

FCC MPE Evaluation - Single radiation sources					
Product Standard Reference	Requirement	Reference Method	Mode	Distance [m]	Verdict
47 CFR 2.1091	Maximum permissible exposure	FCC KDB 447498	Bluetooth LE	0.20	PASS
Comment: None.					

ISED MPE Evaluation - Single radiation sources					
Product Standard Reference	Requirement	Reference Method	Mode	Distance [m]	Verdict
ISED RSS-102	Maximum permissible exposure	ISED RSS-102	Bluetooth LE	0.20	PASS
Comment: None.					

3 RF-Exposure classification

RF-Exposure Categories	
Fixed	A fixed device is defined as a device physically secured at one fixed location and cannot be easily re-located.
Mobile	A mobile device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that a separation distance of at least 20 centimeters is normally maintained between the transmitter's radiating structure(s) and the body of the user or nearby persons.
Portable	A portable device is defined as a transmitting device designed to be used so that the radiating structure(s) of the device is/are within 20 centimeters of the body of the user.

RF-Exposure Categories	
Occupational / Controlled	Limits apply in situations in which persons are exposed as a consequence of their employment provided those persons are fully aware of the potential for exposure and can exercise control over their exposure. Limits for occupational/controlled exposure also apply in situations when an individual is transient through a location where occupational/controlled limits apply provided he or she is made aware of the potential for exposure.
General population / Uncontrolled	Exposures apply in situations in which the general public may be exposed, or in which persons that are exposed as a consequence of their employment may not be fully aware of the potential for exposure or cannot exercise control over their exposure.

4 RF-Exposure limits

FCC Limits – General Population / Uncontrolled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.3 – 1.34	614	1.63	1000	30
1.34 – 30	824/f	2.19/f	1800/f ²	30
30 – 300	27.5	0.073	2	30
300 – 1500	-	-	f/150	30
1500 – 100000	-	-	10.0	30

FCC Limits – Occupational / Controlled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.3 – 3.0	614	1.63	1000	6
3.0 – 30	1842/f	4.89/f	9000/f ²	6
30 – 300	61.4	0.163	10.0	6
300 – 1500	-	-	f/30	6
1500 – 100000	-	-	50	6

ISED Limits – General Population / Uncontrolled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.003 – 10	83	90	-	Instantaneous
0.1 – 10	-	0.73/f	-	6
1.1 – 10	87/f ^{0.5}	-	-	6
10 – 20	27.46	0.0728	2	6
20 – 48	58.07/f ^{0.5}	0.1540/f ^{0.25}	8.944/f ^{0.5}	6
48 – 300	22.06	0.05852	1.291	6
300 – 6000	3.142 · f ^{-0.3417}	0.008335 · f ^{-0.3417}	0.02619 · f ^{-0.6834}	6
6000 – 15000	61.4	0.163	10	6
15000 – 150000	61.4	0.163	10	616000/f ^{1.2}
150000 – 300000	0.158 · f ^{0.5}	4.21 · 10 ⁻⁴ · f ^{0.5}	6.67 · 10 ⁻⁵ · f	616000/f ^{1.2}

ISED Limits – Occupational / Controlled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.003 – 10	170	180	-	Instantaneous
0.1 – 10	-	1.6/f	-	6
1.1 – 10	193/f ^{0.5}	-	-	6
10 – 20	61.4	0.163	10	6
20 – 48	129.8/f ^{0.5}	0.3444/f ^{0.25}	44.72/f ^{0.5}	6
48 – 300	49.33	0.1309	6.455	6
300 – 6000	15.60 · f ^{0.25}	0.04138 · f ^{0.25}	0.6455 · f ^{0.5}	6
6000 – 15000	137	0.364	50	6
15000 – 150000	137	0.364	50	616000/f ^{1.2}
150000 – 300000	0.354 · f ^{0.5}	9.40 · 10 ⁻⁴ · f ^{0.5}	3.33 · 10 ⁻⁴ · f	616000/f ^{1.2}

5 RF-Exposure Evaluation

Evaluation Relations
$\lambda[m] = \frac{c \left[\frac{m}{s} \right]}{f[Hz]} ; R_{FF}[m] \geq \frac{2 \cdot D[m]^2}{\lambda[m]}$ $S[W/m^2] = \frac{P_{E.I.R.P.}[W]}{4\pi R[m]^2} ; R[m] = \sqrt{\frac{P_{E.I.R.P.}[W]}{4\pi S[W/m^2]}}$ $DCC [dB] = 10 \cdot \text{Log}_{10} \left(\frac{DC[\%]}{100} \right)$ $\sum_{i=1}^N \frac{S_i \left[\frac{W}{m^2} \right]}{S_{Li} \left[\frac{W}{m^2} \right]} + \sum_{j=1}^M \left(\frac{E_j \left[\frac{V}{m} \right]}{E_{Lj} \left[\frac{V}{m} \right]} \right)^2 + \sum_{k=1}^O \left(\frac{H_k \left[\frac{A}{m} \right]}{H_{Lk} \left[\frac{A}{m} \right]} \right)^2 < 1$

Evaluation Procedure
<u>Standalone operation evaluation:</u> For each radio and frequency band the worst case transmission mode with the highest peak conducted or radiated power is evaluated at the frequency that results in the most restrictive rf-exposure limit. From the peak power values, antenna gains and duty cycles taken from the reference documents, the source average radiated power values are calculated. From the average radiated power the power densities at antenna far-field distance is calculated. The distance from the radiation source for compliance power density is calculated. If the separation distance is lower than the far-field distance, the far-field distance is given as compliance separation distance because the plane wave power density assessment is only valid in the far-field of the radiation source. For radiation sources for which the average electric and magnetic fields are measured using field probes, the measured field strength values are compared to the reference limits. For those sources no calculations are performed. Compliance with the reference values is determined with the near field measurements. <u>Concurrent operation evaluation:</u> First the evaluation distance is set to an appropriate value. For all radiation sources for which power densities are calculated, the power densities at the evaluation distance are calculated and for all other sources the electric or magnetic field strengths are measured using field probes. Finally the ratios of the power densities and/or field strength values and the corresponding limits are calculated and summed and the sum is compared to the maximum of 1.

6 Single Source Evaluation Results - FCC

Bluetooth LE			
Transmission Mode			
Transmission Frequency (f) [MHz]	2402	2440	2480
Antenna far-field distance			
Maximum antenna diameter (D) [m]	N/A	N/A	N/A
Transmission wavelength (λ) [m]	N/A	N/A	N/A
Antenna far-field distance (R_{FF}) [m]	N/A	N/A	N/A
Source average power			
Peak radiated power (PR) [dBm EIRP]	4.6	4.5	4.6
Maximum transmission duty cycle (DC)	0.33	0.33	0.33
Duty cycle correction (DCC) [dB]	-4.81	-4.81	-4.81
Average radiated power (PRAVG) [dBm EIRP]	-0.21	-0.31	-0.21
Power density			
Compliance power density limit [W/m^2]	10.000	10.000	10.000
Power density (S) @ Antenna far-field distance [W/m^2]	N/A	N/A	N/A
Power density (S) @ 0.20 m [W/m^2]	0.002	0.002	0.002
Power density ratio @ 0.20 m	0.00	0.00	0.00
Distance for compliance power density (S=SL) [m]	0.003	0.003	0.003
Compliance			
Verdict	PASS	PASS	PASS
Comment: None.			

7 Single Source Evaluation Results - ISED

Bluetooth LE			
Transmission Mode			
Transmission Frequency (f) [MHz]	2402	2440	2480
Antenna far-field distance			
Maximum antenna diameter (D) [m]	N/A	N/A	N/A
Transmission wavelength (λ) [m]	N/A	N/A	N/A
Antenna far-field distance (R_{FF}) [m]	N/A	N/A	N/A
Source average power			
Peak radiated power (PR) [dBm EIRP]	4.6	4.5	4.6
Maximum transmission duty cycle (DC)	0.33	0.33	0.33
Duty cycle correction (DCC) [dB]	-4.81	-4.81	-4.81
Average radiated power (PRAVG) [dBm EIRP]	-0.21	-0.31	-0.21
Power density			
Compliance power density limit [W/m^2]	5.351	5.409	5.469
Power density (S) @ Antenna far-field distance [W/m^2]	N/A	N/A	N/A
Power density (S) @ 0.20 m [W/m^2]	0.002	0.002	0.002
Power density ratio @ 0.20 m	0.00	0.00	0.00
Distance for compliance power density (S=SL) [m]	0.004	0.004	0.004
Compliance			
Verdict	PASS	PASS	PASS
Comment: None.			