

RF-EXPOSURE ASSESSMENT REPORT

**FCC 47 CFR Part 2.1091
Industry Canada RSS-102**

RF-Exposure evaluation of mobile equipment

Report Reference No......: G0M-1708-6775-TFC091ME-V02

Testing Laboratory: Eurofins Product Service GmbH

Address.....: Storkower Str. 38c
15526 Reichenwalde
Germany

Accreditation:



FCC Test Firm Designation Number: DE0008
IC Testing Laboratory site: 3470A-2

Applicant's name: Phillips-Medisize A/S

Address.....: Gimsinglundvej 20
7600 Struer
DENMARK

Test specification:

Standard: 47 CFR 2.1091
KDB 447498 D01 v06:2015-10-23
RSS-102, Issue 5:2015-03

Equipment under test (EUT):

Product description: SynfuGo, an automated personalized infusion pump

Model No.: SynfuGo

Additional Model(s): None

Brand Name(s): SynfuGo

Hardware version: HDR ver 3.00

Firmware / Software version: 01.05.00

FCC-ID: 2AAGY-SYNFUGO IC: N/A

Test result: **Passed**

Test Report No.: G0M-1708-6775-TFC091ME-V02

Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Possible test case verdicts:

- neither assessed nor tested: N/N
- required by standard but not appl. to test object.....: N/A
- required by standard but not tested.....: N/T
- not required by standard for the test object: N/R
- test object does meet the requirement.....: P (Pass)
- test object does not meet the requirement.....: F (Fail)

Testing:

Test Lab Temperature: 20 – 23 °C

Test Lab Humidity: 32 – 38 %

Date of receipt of test item: 2017-08-23

Date of assessment: 2017-11-09

Compiled by: Toralf Jahn

Assessed by (+ signature): Toralf Jahn
(Responsible for Assessment)



Approved by (+ signature): Christian Weber
(Deputy Head of Lab)



Date of issue: 2019-02-27

Total number of pages: 15

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:

Version History

Version	Issue Date	Remarks	Revised by
01	2018-09-06	Initial Release	
02	2019-02-26	Applicant and manufacturer corrected.	T. Jahn

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1 Equipment (Test item) Description

Description	SynfuGo, an automated personalized infusion pump
Model	SynfuGo
Additional Model(s)	None
Brand Name(s)	SynfuGo
Serial number	None
Hardware version	HDR ver 3.00
Software / Firmware version	01.05.00
PMN	-/-
HVIN	-/-
FVIN	-/-
HMN	-/-
FCC-ID	2AAGY-SYNFUGO
IC	N/A
Equipment type	End product

1.1 Reference Documents

Document type	Document No.	Issued by	Date
External radio report	10053433 001	TÜV Rheinland	2015-09-18
FCC 15.247 Test Report	G0M-1708-6775-TFC247BL-V02	Eurofins Product Service GmbH	2019-02-26
FCC 15.225 Test Report	G0M-1708-6775-TFC225RI-V02	Eurofins Product Service GmbH	2018-02-26

1.2 Standalone Radiation Sources

Mode #	Description	
Bluetooth LE	Frequency range [MHz]	2400 – 2483.5
	Transmission modes	GFSK
	Maximum conducted power [dBm]	-9.3
	Maximum radiated power [dBm]	-9.7
	Maximum transmission duty cycle [%]	100
	Antenna gain [dBi]	-0.5
	Antenna diameter [cm]	0.032
	Assessment Frequency [MHz]	2402
RFID	Frequency range [MHz]	13.553 – 13.567
	Transmission modes	ASK
	Maximum electric field [V/m @ 20cm]	1.52
	Maximum magnetic field [A/m @ 20cm]	0.02611
	Maximum transmission duty cycle [%]	100
	Assessment Frequency [MHz]	13.56

1.3 Multi-transmitter Modes

	Bluetooth LE	RFID
Bluetooth LE	N/A	Yes
RFID	Yes	N/A

2 Result Summary

FCC 47 CFR Part 2.1091, IC RSS-102			
Product Specific Standard Section	Requirement	Result	Remarks
47 CFR 2.1091	Maximum permissible exposure @ 20cm below limit	PASS	
RSS-102 2.5.2	Maximum permissible exposure @ 20cm below limit	PASS	
Remarks:			

3 RF-Exposure Classifications

Device Types	
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. (47 CFR 2.1091)
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. (47 CFR 2.1093)
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 Assessment

4.1 MPE Assessment Conditions – 47 CFR 2.1091 / RSS-102

MPE ASSESSMENT ACC. TO 47 CFR 2.1091 / ISED RSS-102				VERDICT: PASS
Assessment according to reference		Reference Method		
		FCC OET Bulletin 65 / RSS-102 & Safety Code 6		
Device type		mobile		
Exposure category		General public		
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 / <i>f</i>	-	6**
1.29-10	193 / <i>f</i> ^{0.5}	-	-	6**
10-20	61.4	0.163	-10	6
20-48	129.8 / <i>f</i> ^{0.25}	0.3444 / <i>f</i> ^{0.25}	44.72 / <i>f</i> ^{0.5}	6
48-100	49.33	0.1309	6.455	6
100-6000	15.60 <i>f</i> ^{0.25}	0.04138 <i>f</i> ^{0.25}	0.6455 <i>f</i> ^{0.5}	6
6000-15000	137	0.364	50	6
15000-150000	137	0.364	50	616000 / <i>f</i> ^{1.2}
150000-300000	0.354 <i>f</i> ^{0.5}	9.40 x 10 ⁻⁴ <i>f</i> ^{0.5}	3.33 x 10 ⁻⁴ <i>f</i>	616000 / <i>f</i> ^{1.2}
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 / <i>f</i>	-	6**
1.1-10	87 / <i>f</i> ^{0.5}	-	-	6**
10-20	27.46	0.0728	2	6
20-48	58.07 / <i>f</i> ^{0.25}	0.1540 / <i>f</i> ^{0.25}	8.944 / <i>f</i> ^{0.5}	6
48-300	22.06	0.05852	1.291	6
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
15000-150000	61.4	0.163	10	616000 / <i>f</i> ^{1.2}
150000-300000	0.158 <i>f</i> ^{0.5}	4.21 x 10 ⁻⁴ <i>f</i> ^{0.5}	6.67 x 10 ⁻⁵ <i>f</i>	616000 / <i>f</i> ^{1.2}
* = Based on nerve stimulation				
** = Bases on specific absorption rate				

FCC Limits – Occupational / Controlled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [mW/cm ²]	Averaging time [min]
0.3 – 3.0	614	1.63	(100)*	6
3.0 - 30	1842 / f	4.89 / f	(900 / f ²)*	6
30 - 300	61.4	0.163	1.0	6
300 - 1500	N/A	N/A	f / 300	6
1500 - 100000	N/A	N/A	5.0	6
FCC Limits – General Population / Uncontrolled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [mW/cm ²]	Averaging time [min]
0.3 – 1.34	614	1.63	(100)*	30
1.34 - 30	842 / f	2.19 / f	(180 / f ²)*	30
30 - 300	27.5	0.073	0.2	30
300 - 1500	N/A	N/A	f / 1500	30
1500 - 100000	N/A	N/A	1.0	30
* = Plane wave equivalent power density; f in MHz				
Assessment Relations				
$\lambda[m] = \frac{c \left[\frac{m}{s} \right]}{f[Hz]} ; R_{FF}[m] \geq \frac{2 \cdot D[m]^2}{\lambda[m]}$ $S[mW/cm^2] = \frac{P_{E.I.R.P.}[mW]}{4\pi R[cm]^2} ; R[cm] = \sqrt{\frac{P_{E.I.R.P.}[mW]}{4\pi S[mW/cm^2]}}$ $P_R[mW] = P_C[mW] \cdot G ; P_R[dBm] = P_C[dBm] + G[dBi]$ $DCC [dB] = 10 \cdot \log_{10} \left(\frac{DC[\%]}{100} \right)$				
Assessment procedure				
<p>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, at 20cm separation distance from the radiation source is calculated. Compliance with the RF-Exposure limit is determined at 20cm separation distance.</p>				

4.2 Single-Transmitter Assessment – 47 CFR 2.1091 / RSS-102

Assessment result - Bluetooth LE		
Transmission mode		
Operating mode frequency range [MHz]	2400 – 2483.5	
Assessment frequency (f) [MHz]	2402	
Transmission duty cycle (DC) [%]	100	
Peak conducted power (P _C) [dBm]	-9.3	
Peak radiated power (P _R) [dBm e.i.r.p.]	-9.7	
Peak Antenna gain (G) [dBi]	-0.5	
Maximum Antenna Diameter D [cm]	0.032	
Antenna far-field distance		
Transmission frequency wavelength (λ)	0.125 m	12.49 cm
Antenna far-field distance (R _{FF})	0.000 m	0.00 cm
Power evaluation		
Peak conducted power (P _C)	0.12 mW	-9.30 dBm
Peak Antenna Gain (G)	0.89	-0.50 dBi
Calculated peak radiated power (P _{R-Calcd})	0.10 mW	-9.80 dBm
Measured peak radiated power (P _R)	0.11 mW	-9.70 dBm
Source average Power		
Maximum transmission duty cycle (DC)	100.0 %	
Duty cycle correction (DCC)	1.00	0.00 dB
Measured peak radiated power (P _R)	0.11 mW	-9.70 dBm
Averaged peak radiated power (P _{RAVG})	0.11 mW	-9.70 dBm
Power density		
Compliance power density limit FCC	1.000 mW/cm ²	10.00 W/m ²
Compliance power density limit IC	0.535 mW/cm ²	5.35 W/m ²
Power density @ Antenna far-field distance	317122.265 mW/cm ²	317122.650 W/m ²
Power density @ 20cm	0.000 mW/cm ²	0.000 W/m ²
Distance for compliance power density FCC	0.001 m	0.09 cm
Distance for compliance power density IC	0.001 m	0.13 cm
Verdict		
The power density of the EUT at 20cm is below the FCC MPE limit!		
The power density of the EUT at 20cm is below the IC MPE limit!		
Comments:		

Assessment results – RFID	
Transmission mode	
Operating mode frequency range [MHz]	13.553 – 13.567
Assessment frequency (f) [MHz]	13.56
Compliance separation distance to EUT [m]	0.2
Electric Field	
Measured max. electric field strength [V/m]	1.52
Reference level [V/m]	27.46*
Verdict	PASS
Magnetic Field	
Measured max. magnetic field strength [A/m]	0.02611
Reference level [A/m]	0.0728*
Verdict	PASS
Verdict	
The field strength level of the EUT are below the RF-Exposure reference level at the given compliance separation distance!	
Comments: ISED limits used as worst case	

4.3 Multi-Transmitter Assessment – 47 CFR 2.1091 / RSS-102

Assessment result – Bluetooth LE + RFID		
Concurrent Operating Modes		
Number of concurrent operating modes	2	
Compliance Distance		
Distance to EUT used for compliance evaluation [cm]	20	
Bluetooth LE		
FCC limit ($S_{FCCLimit}$)	1.000 mW/cm ²	10.00 W/m ²
ISED limit ($S_{ICLimit}$)	0.535 mW/cm ²	5.35 W/m ²
Power density @ compliance distance (S_{CD})	0.000 mW/cm ²	0.000 W/m ²
MPE Ratio (S_{CD} / $S_{FCCLimit}$) FCC	0.000 W/m ² / 10.00 W/m ² = 0.000	
MPE Ratio (S_{CD} / $S_{ICLimit}$) ISED	0.000 W/m ² / 5.35 W/m ² = 0.000	
RFID		
FCC limit ($S_{FCCLimit}$)	0.1615 A/m	
ISED limit ($S_{ICLimit}$)	0.0728 A/m	
Field strength @ compliance distance (H_{CD})	0.02611 A/m	
MPE Ratio (S_{CD} / $S_{FCCLimit}$) FCC	0.03	
MPE Ratio (S_{CD} / $S_{ICLimit}$) ISED	0.13	
Sum of MPE Ratios		
$\sum S_{CD}$ / $S_{FCCLimit}$ FCC	0.000 + 0.03 = 0.03	
$\sum S_{CD}$ / $S_{ICLimit}$ ISED	0.000 + 0.13 = 0.13	
Verdict		
The sum of MPE ratios is lower than 1 so that the co-location operational mode complies with the rf-exposure restrictions according to FCC rules		
The sum of MPE ratios is lower than 1 so that the co-location operational mode complies with the rf-exposure restrictions according to ISED rules		
Comments:		