

RF-EXPOSURE ASSESSMENT REPORT

FCC 47 CFR Part 2.1093
Industry Canada RSS-102

RF-Exposure evaluation of portable equipment

Report Reference No. : G0M-1602-5371-TFC093PE-V02

Testing Laboratory : Eurofins Product Service GmbH

Address : Storkower Str. 38c
15526 Reichenwalde
Germany

Accreditation :



A2LA Accredited Testing Laboratory, Certificate No.: 1983.01
FCC Filed Test Laboratory, Reg.-No.: 96970
IC OATS Filing assigned code: 3470A

Applicant's name : Emperra GmbH E-Health Technologies

Address : Friedrich-Ebert-Str. 33
14469 Potsdam
Germany

Test specification:

Standard..... : 47 CFR 2.1093
KDB 447498 D01 v06:2015-10-23
RSS-102, Issue 5:2015-03

Equipment under test (EUT):

Product description	Insulin Pen with BLE interface	
Model No.	ESYSTA BT Pen B	
Additional Model(s)	ESYSTA BT Pen w	
Brand Name(s)	None	
Hardware version	A	
Firmware / Software version	AA	
	FCC-ID: 2AHMS-BTPEN1	IC: None

Test result : **Passed**

Test Report No.: G0M-1602-5371-TFC093PE-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:

Date of receipt of test item : 2016-04-11

Date (s) of assessment : 2016-05-13

Compiled by : Matthias Handrik

Assessed by (+ signature) : Matthias Handrik
(Responsible for Assessment)



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



Date of issue : 2016-11-15

Total number of pages : 13

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.

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Additional comments:

Emperra GmbH® E-Health Technologies
Friedrich-Ebert-Straße 33 • D-14469 Potsdam • Germany

Emperra
Digital Diabetes Care

Declaration of Identical to Type

	Original APPLICANT / Approval Holder	Changed (new) Applicant / Approval Holder (if any)
Company Name	Emperra GmbH E-Health Technologies	
Address line 1		
Address line 2		
Address line 3		
ZIP		
City		
Contry		
Company Phone		
Contact Person		
Phone		
E-Mail		
	Original EQUIPMENT	OEM-EQUIPMENT
Type	Insulin Pen with BLE interface	Insulin Pen with BLE interface
Model Name / ID	ESYSTA BT Pen B	ESYSTA BT Pen W
Brand Name		
Hardware Version	A	A
Software Version	AA	AA

Hereby we (the Original Applicant) declare that the changed equipment is electrically identical (including its RF characteristics), to the original equipment, the only change is the colour of the four following outer plastic parts:

Pos	Description
1	Sleeve
2	Sleeve locking mechanism
3	Battery Cover
4	Cap

The original test results continue to be representative of and applicable to the changed equipment.
Reference to the test reports / tested standards

The approval of original equipment will remain in effect: Yes ☒ No ☐

Additional information: n.a.

Signature of original applicant

Authorized signature of changed (new applicant)



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Version History

Version	Issue Date	Remarks	Revised by
01	2016-05-13	Initial Release	
02	2016-11-14	References updated	C. Weber

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1 Equipment (Test item) Description

Description	Insulin Pen with BLE interface
Model	ESYSTA BT Pen B
Additional Model(s)	ESYSTA BT Pen w
Brand Name(s)	None
Serial number	None
Hardware version	A
Software / Firmware version	AA
FCC-ID	2AHMS-BTPEN1
IC	None
Equipment type	End product

1.1 Reference Documents

Document type	Document No.	Issued by	Date
FCC Radio Test report	G0M-1602-5371-TFC247BL-V02	Eurofins Product Service GmbH	2016-11-14

1.2 Radiation Sources

Mode #	Description	
Bluetooth Low Energy	Frequency range [MHz]	2402 – 2480
	Channels	40
	Modulations	GFSK
	Maximum conducted power [dBm]	-7.548
	Maximum transmission duty cycle [%]	100

2 Result Summary

FCC 47 CFR Part 2.1093, KDB447498, IC RSS-102			
Product Specific Standard Section	Requirement	Result	Remarks
47 CFR 2.1093 KDB447498	SAR evaluation exemption : Bluetooth Low Energy	PASS	
RSS-102 2.5.1	SAR evaluation exemption : Bluetooth Low Energy	N/A	
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 SAR Exemption Assessment –FCC KDB447498 / RSS-102

Low Power Exclusion acc. to FCC KDB447498 / IC RSS-102		Verdict: PASS
Assessment according to reference	Reference Method	
	KDB447498 & 2.1093 / RSS-102 & Safety Code 6	
Device type	portable	
Exposure category	General population	
FCC/IC SAR Limits		
Region	Occupational SAR values [W/kg]	General public SAR values [W/kg]
Whole-body SAR averaging mass = entire body	0.4	0.08
Partial-body SAR averaging mass = 1g	8.0	1.6
Hands, Wrists, Feet and Ankles SAR averaging mass = 10g	20	4
FCC SAR test exclusion		
<u>Excerpt from KDB 447498:</u>		
<p>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 Exclusion Threshold condition, listed below, is satisfied. These test exclusion conditions are based on source-based time-averaged maximum conducted output power of the RF channel requiring evaluation, adjusted for tune-up tolerance, and the minimum test separation distance required for the exposure conditions.</p> <p>The minimum test separation distance is determined by the smallest distance from the antenna and radiating structures or outer surface of the device, according to the host form factor, exposure conditions and platform requirements, to any part of the body or extremity of a user or bystander</p> <p>The 1-g and 10-g SAR test exclusion thresholds for 100 MHz to 6 GHz at <i>test separation distances</i> ≤ 50 mm are determined by:</p> $\frac{\text{max. power of channel [mW]}}{\text{min. test separation distance [mm]}} \cdot \sqrt{f[\text{GHz}]} \leq \begin{cases} 3.0 & 1g \text{ SAR} \\ 7.5 & 10g \text{ SAR} \end{cases}$ <ul style="list-style-type: none">▪ f [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 <p>The test exclusions are applicable only when the minimum test separation distance is ≤ 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.</p>		

IC SAR evaluation exemptions

Excerpt from RSS-102 Issue 5:

SAR evaluation is required if the separation distance between the user and the radiating element of the **device is less than or equal to 20 cm, except** when the device operates at a power level below the following threshold limits:

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

Assessment procedure

For the radiation source included into the device the output power is taken from a corresponding RF test report. If needed the output power is converted to source based, time-averaged output power. Finally the output power is compared to the FCC and IC low power SAR evaluation exemption level.

Assessment results Bluetooth Low Energy	
Transmission mode	
Operating mode frequency range [MHz]	2402 – 2480
Assessment frequency [MHz]	2480
Transmission duty cycle [%]	100
Peak conducted power [dBm]	-7.548
Minimum separation distance [mm]	5.0
Source-based, time averaged power	
Duty cycle correction [dB]	0.0
Averaged conducted power [dBm]	-7.548
Averaged conducted power [mW]	0.176
Averaged radiated power	
Antenna gain [dBi]	0.8
Averaged radiated power [dBm e.i.r.p.]	-6.748
Averaged radiated power [mW e.i.r.p.]	0.211
SAR evaluation exemption power levels	
FCC SAR test exclusion condition	$\frac{0.176[mW]}{5.0[mm]} \cdot \sqrt{2.480} = 1.7 \leq 3.0 \rightarrow \text{PASS}$
IC SAR test exclusion condition	N/A
Verdict	
The source-based, time-averaged output power of the EUT fulfills the SAR test exclusion requirements according to FCC KDB447498.	
Comments:	