RF-EXPOSURE REPORT

FCC 47 CFR Part 2.1091
ISED RSS-102

RF-Exposure evaluation of mobile equipment

Report Reference No.....:	G0M-1603-5489-TFC091ME-V01
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 ISED OATS Filing assigned code: 3470A
Applicant's name.....:	Biotronik SE & Co. KG
Address.....:	Woermannkehre 1 12359 Berlin GERMANY
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	Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
Model No.	Qubic Force
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware version	HWS.A
Firmware / Software version	FU_MR1.x
	FCC-ID: QRIQFORCE IC: 4708A-QFORCE
Test result	**Passed**

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 ..... :	2016-03-28	
Date (s) of assessment ..... :	2016-05-02	
Compiled by ..... :	Christian Weber	
Assessed by (+ signature) ..... : (Responsible for Assessment)	Burkhard Pudell	B. Pudell .....
Approved by (+ signature) ..... : (Head of Lab)	Christian Weber	C. Weber .....
Date of issue ..... :	2016-05-27	
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:

Version History

Version	Issue Date	Remarks	Revised by
01	2016-05-27	Initial Release	

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1 Equipment (Test item) Description

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Hardware version	HWS.A
Software / Firmware version	FU_MR1.x
FCC-ID	QRIQFORCE
IC	4708A-QFORCE
Equipment type	End product

1.1 Standalone Radiation Sources

Mode #	Description	
RFID	Frequency range [MHz]	13.56
	Channel spacing	N/A
	Modulations	ASK / OOK
	Maximum electric field [V/m @ 20cm]	25.1
	Maximum magnetic field [A/m @ 20cm]	0.05

1.2 Multi-transmitter Modes

None

1.3 Test Equipment Used

Field Strength Measurement					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF00198	-	-
Isotropic E-Field Probe	EMCO Elektronik GmbH	EP-601	EF00747	2015-11	2017-11

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	Maximum permissible exposure @ 20cm below limit	PASS	
Remarks:			

3 Radiated Field Measurement

3.1 Test Conditions and Results – Electric and magnetic field strength

ELECTRIC AND MAGNETIC FIELD STRENGTH	
Test frequency range	Tested frequencies
	F_{MID}
EUT test mode	RFID
Measurement methode	radiated only

Test procedure

1. EUT transmitter is activated in test mode under normal conditions
2. The perimeter of the EUT is scanned with an electric and magnetic field probe at a fixed distance
3. The electric and magnetic field strength is measured
4. The maximum field strength values are recorded

Test results

Channel	Frequency [MHz]	Mode	Distance [m]	Max. electric field strength [V/m]	Max. magnetic field strength [V/m]
F_{MID}	13.56	RFID	0.2	21.1	0.05

Comments:

4 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.

5 Evaluation

5.1 MPE Evaluation Conditions – 47 CFR 2.1091 / RSS-102

MPE EVALUATION ACC. TO 47 CFR 2.1091 / IC RSS-102				VERDICT: PASS
Assessment according to reference	Reference Method			
	KDB 447498 D01 / RSS-102 & Safety Code 6			
Device type	mobile			
Exposure category	General public			
IC 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**
1.29-10	193 / $f^{0.5}$	-	-	6**
10-20	61.4	0.163	-10	6
20-48	129.8 / $f^{0.25}$	0.3444 / $f^{0.25}$	44.72 / $f^{0.5}$	6
48-100	49.33	0.1309	6.455	6
100-6000	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 x 10^{-4} $f^{0.5}$	3.33 x 10^{-4} f	616000 / $f^{1.2}$
IC 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 / $f^{0.25}$	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 x 10^{-4} $f^{0.5}$	6.67 x 10^{-5} f	616000 /$f^{1.2}$
* = 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 procedure

The evaluation is performed at a separation distance of 20 cm. The reference levels are taken from 47 CRF 1.1310 for FCC and RSS-102 for ISED according to the exposure category declared by customer.

For each radio and frequency band the worst case transmission mode with the highest output power is activated and the surrounding area around the EUT is scanned using an electric and a magnetic field probe at the distance given in the test report. The maximum electric and magnetic field strength values measured are compared to the corresponding reference levels. If both measured field strength values are below the reference levels the EUT has passed the RF-Exposure requirements.

5.2 Single-Transmitter Evaluation – 47 CFR 2.1091 / RSS-102

Assessment results – RFID		
Transmission mode		
Operating mode frequency range [MHz]	13.56	
Assessment frequency (f) [MHz]	13.56	
Compliance separation distance to EUT [m]	0.2	
Electric Field		
Measured max. electric field strength [V/m]	21.1	
Reference level [V/m]	FCC = 62.09	ISED = 27.46
Verdict	PASS	
Magnetic Field		
Measured max. magnetic field strength [A/m]	0.05	
Reference level [A/m]	FCC = 0.16	ISED = 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:		