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FCC TEST REPORT

FCC 47 CFR Part 15C
Industry Canada RSS-310

License exempt radio equipment

Report Reference No. ..... :	G0M-1507-4972-TFC209LP2-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 ..... :	Biotronik SE & Co. KG
Address ..... :	Woermannkehre 1 12359 Berlin GERMANY
Test specification:	
Standard..... :	47 CFR Part 15C RSS-310, Issue 4, 2015-07 RSS-Gen, Issue 4, 2014-11 ANSI C63.4:2014
Equipment under test (EUT):	
Product description	Primus Nano Plus Pacemaker Family
Model No.	Edora 8 HF-T ProMRI
Additional Model(s)	see page4: List of Models to be included in the family
Brand Name(s)	Biotronik
Hardware version	ASM-0474_0A (See model matrix on page 4 to 6)
Firmware / Software version	7801RomRev_02.02 / 7801RamRev_02.03
	FCC-ID: QRIPNP IC: 4708A-PNP
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 ..... :	2015-09-28	
Date (s) of performance of tests ..... :	2015-09-28 – 2015-09-29	
Compiled by ..... :	Christian Weber	
Tested by (+ signature) ..... : (Responsible for Test)	Matthias Handrik	.....
Approved by (+ signature) ..... : (Head of Lab)	Christian Weber	.....
Date of issue ..... :	2016-04-06	
Total number of pages ..... :	27	

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.

Additional comments:

Family Explanation

All devices feature the two RF-Telemetry functions Home Monitoring and wireless Wand.
RF-Telemetry functions are using the MICS-Band (402MHz – 405MHz).
A „-T“ inside the name of the device represents a device containing RF-Telemetry.
HF-T are triple-chamber devices. (Master for all tests)
HF-T QP are triple chamber quadro polar
DR-T are dual-chamber devices.
SR-T are single-chamber devices with additional atrial detection.
DR are dual-chamber without home monitoring software.
SR are single-chamber without home monitoring software.
D are dual-chamber with no radio, only coil communication.
S are single-chamber with no radio, only coil communication.

All of these differences are only relevant in terms of medical aspects. They do not interfere with the RF-performance.

Evaluation measurements were performed for worst case antenna selection and the Edora 8 HF-T ProMRI was selected. The model Edora 8 HF-T ProMRI, as the most complex model, was selected for the measurements.

Family Certification

List of Models to be included in the family

(1) Applicant: BIOTRONIK SE & CO. KG

(2) Certification Number: _____

No.	Model Number	Description of Differences
1	Edora 8 HF-T ProMRI **(Master)**	**(Master configuration),** 3 chamber, 3x IS-1 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 1) With Home Monitoring and MRI Software
2	Edora 8 HF-T QP ProMRI	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 1) With Home Monitoring and MRI Software
3	Evity 8 HF-T ProMRI	3 chamber, 3x IS-1 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 2) With Home Monitoring and MRI Software
4	Evity 8 HF-T QP ProMRI	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 2) With Home Monitoring and MRI Software
5	Enitra 8 HF-T ProMRI	3 chamber, 3x IS-1 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 3) With Home Monitoring and MRI Software
6	Enitra 8 HF-T QP ProMRI	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 3) With Home Monitoring and MRI Software
7	Enticos 8 HF-T	3 chamber, 3x IS-1 Connector, BOM-0296, SCH-0185, ASM-0474 Software Features (Brand 4) With Home Monitoring
8	Enticos 8 HF-T QP	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0296, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 4) With Home Monitoring
9	Edora 8 DR-T ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 1) With Home Monitoring and MRI Software
10	Edora 8 SR-T ProMRI	1 chamber, 1x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 1) With Home Monitoring and MRI Software

11	Edora 8 DR ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 1) **Without** Home Monitoring, With MRI Software
12	Edora 8 SR ProMRI	1 chamber, 1x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 1) **Without** Home Monitoring, With MRI Software
13	Evity 8 DR-T ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 2) With Home Monitoring and MRI Software
14	Evity 8 SR-T ProMRI	1 chamber, 1x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 2) With Home Monitoring and MRI Software
15	Enitra 8 DR-T ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 3) With Home Monitoring and MRI Software
16	Enitra 8 SR-T ProMRI	1 chamber, 1x IS-1 Connector, , BOM-0294, BOM-0295_0B, SCH-0186, ASM-0476 Software Features (Brand 3) With Home Monitoring and MRI Software
17	Enticos 8 DR-T	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 4) With Home Monitoring
18	Enticos 8 SR-T	1 chamber, 1x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 4) With Home Monitoring
19	Evity 6 DR-T ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294_0A, BOM-0295_0B, SCH-0186_0B, ASM-0476_0B Mid-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
20	Evity 6 SR-T ProMRI	1 chamber, 1x IS-1 Connector BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 2) With Home Monitoring and MRI Software
21	Enitra 6 DR-T ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 3) With Home Monitoring and MRI Software
22	Enitra 6 SR-T ProMRI	1 chamber, 1x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 3) With Home Monitoring and MRI Software
23	Enitra 6 DR ProMRI	2 chamber, 2x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 3) **Without** Home Monitoring, With MRI Software

24	Enitra 6 SR ProMRI	1 chamber, 1x IS-1 Connector, BOM-0294, BOM-0295, SCH-0186, ASM-0476 Software Features (Brand 3) **Without** Home Monitoring, With MRI Software
25	Enticos 4 DR	2 chamber, 2x IS-1 Connector, BOM-0297, BOM-0298, SCH-0186, ASM-0476 Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**
26	Enticos 4 SR	1 chamber, 1x IS-1 Connector, BOM-0297, BOM-0298, SCH-0186, ASM-0476 Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**
27	Enticos 4 D	2 chamber, 2x IS-1 Connector, BOM-0297, BOM-0298, SCH-0186, ASM-0476 Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**
28	Enticos 4 S	1 chamber, 1x IS-1 Connector, BOM-0297, BOM-0298, SCH-0186, ASM-0476 Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**

Version History

Version	Issue Date	Remarks	Revised by
01	2016-03-16	Initial Release	
02	2016-04-06	Result data adjusted	C. Weber

REPORT INDEX

1 Equipment (Test item) Description

Description	Primus Nano Plus Pacemaker Family	
Model	Edora 8 HF-T ProMRI	
Additional Model(s)	see page4: List of Models to be included in the family	
Brand Name(s)	Biotronik	
Serial number	66454950 (for master) additional see model matrix on page 4 to 6	
Hardware version	ASM-0474_0A (for master) additional see model matrix on page 4 to 6	
Software / Firmware version	7801RomRev_02.02 / 7801RamRev_02.03	
FCC-ID	QRIPNP	
IC	4708A-PNP	
Equipment type	End product	
Radio type	Transceiver	
Radio technology	custom	
Operating frequency range	64 kHz	
Frequency range	F_{MID}	64 kHz
Modulations	OOK	
Number of channels	1	
Channel spacing	None	
Number of antennas	1	
Antenna	Type	integrated
	Model	loop antenna
	Manufacturer	Biotronik SE & Co. KG
	Gain	unspecified
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
Power supply	V_{NOM}	3.0 VDC (MNO2 Included in hermetically sealed EUT)
	V_{MIN}	N/A
	V_{MIN}	N/A
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
None				

***Note:** Use the following abbreviations:

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.5 Test Modes

Mode #	Description	
Single	General conditions:	EUT powered by fully charged battery
	Radio conditions:	Mode = standalone transmit Modulation = OOK Power level = Maximum
Receive	General conditions:	EUT powered by fully charged battery
	Radio conditions:	Mode = standalone receive Modulation = OOK

1.6 Test Equipment Used During Testing

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2014.1.15

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSP 30	EF00312	2015-02	2016-02

Field strength emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 1	EF00062	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2015-04	2016-04
Biconical Antenna	R&S	HK 116	EF00012	2013-02	2016-02
LPD Antenna	R&S	HL 223	EF00187	2014-03	2017-03
LPD Antenna	R&S	HL 025	EF00327	2013-02	2016-02

1.7 Sample emission level calculation

The following is a description of terms and a sample calculation, as appears in the radiated emissions data table. The numbers used in the calculation are for example only. There is no direct correlation to the specific data taken for the product described in this document:

Reading:

This is the reading obtained on the spectrum analyzer in dBµV. Any external preamplifiers used are taken into account through internal analyzer settings.

A.F.:

This is the antenna factor for the receiving antenna. It is a conversion factor, which converts electric fields strengths to voltages, which can be measured directly on the spectrum analyzer. It is treated as a loss in dB. Cable losses have been included with the A.F. to simplify the calculations. The antenna factor is used in calculations as follows:

Reading on Analyzer (dBµV) + A.F. (dB) = Net field strength (dBµV/m)

Net:

This is the net field strength measurement (as shown above).

Limit:

This is the FCC Class B radiated emission limit (in units of dBµV/m). The FCC limits are given in units of µV/m. The following formula is used to convert the units of µV/m to dBµV/m:

Limit (dBµV/m) = 20*log (µV/m)

Margin:

This is the margin of compliance below the FCC limit. The units are given in dB. A negative margin indicates the emission was below the limit. A positive margin indicates that the emission exceeds the limit.

Example only:

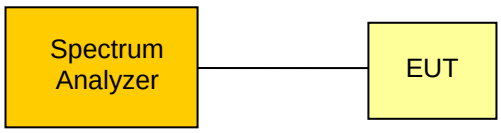
Reading	+	AF	=	Net Reading	:	Net reading - FCC limit	= Margin
21.5 dBµV	+	26 dB	=	47.5 dBµV/m	:	47.5 dBµV/m - 57.0 dBµV/m	= -9.5 dB

2 Result Summary

FCC 47 CFR Part 15C, IC RSS-310				
Product Specific Standard Section	**Requirement – Test**	**Reference Method**	**Result**	**Remarks**
RSS-Gen 6.6	Occupied Bandwidth	RSS-Gen 6.6	N/R	Informational only
FCC 15.201(a), FCC 15.209 IC RSS-310 3.7	Field strength emissions	ANSI C63.4	PASS	
IC RSS-310 2.3 IC RSS-Gen 7.1	Receiver radiated spurious emissions	ANSI C63.4	N/R	
Remarks:				

3 Test Conditions and Results

3.1 Test Conditions and Results – Occupied Bandwidth

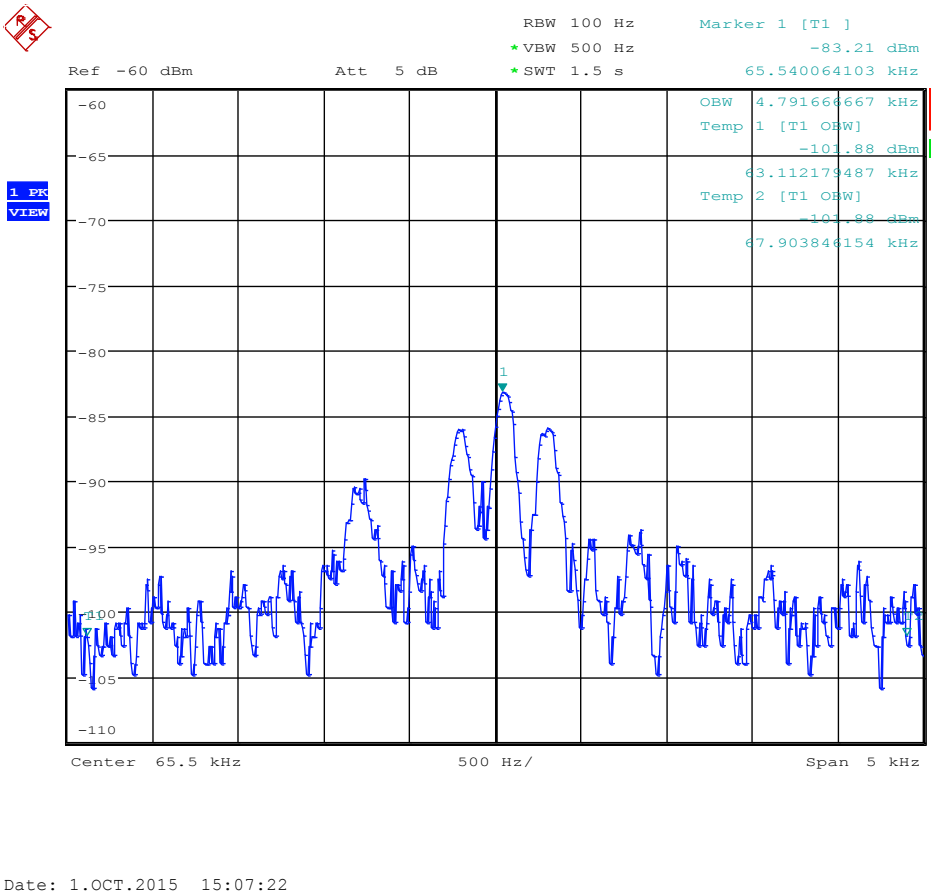
Occupied Bandwidth acc. to IC RSS-Gen		**Verdict: PASS**
Test according to measurement reference	Reference Method	
	RSS-Gen 6.6	
Test frequency range	Tested frequencies	
	F_{MID}	
EUT test mode	Single	
Limits		
None (Informational only)		
Test setup		
		
Test procedure		
1. EUT set to test mode (Communication tester is used if needed) 2. Span set to at least twice the emission spectrum 3. Resolution bandwidth set to 1 % of span 4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function		
Test results		
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]
F_{MID}	64	4.79
Comments: Measurement is applicable to all variants		

Occupied Bandwidth - F_{MID}

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1507-4972

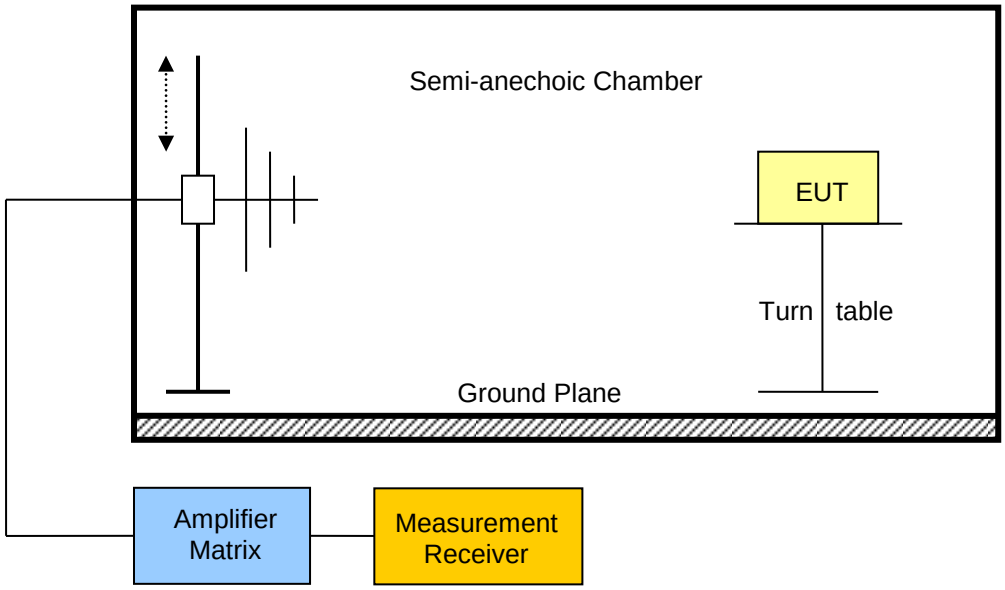
Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T ProMRI
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 64 kHz
Test Date:	2015-10-01
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used
Note 2:	Near-field measurement test fixture / 64 kHz system



3.2 Test Conditions and Results – Fundamental field strength emissions

Field strength emissions acc. to FCC 47 CFR 15.201 / IC RSS-310				**Verdict: PASS**
Test according referenced standards			Reference Method	
			FCC 15.201(a) + 15.209 / IC RSS-310 3.7	
Test according to measurement reference			Reference Method	
			ANSI C63.4	
Test frequency range			Tested frequencies	
			9 kHz – 10th Harmonic	
EUT test mode			Single	
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
0.009 – 0.490	Quasi-Peak	2400/F[kHz]	48.5 – 13.8	300
0.490 – 1.705	Quasi-Peak	2400/F[kHz]	13.8 – 1.4	30
1.705 – 30	Quasi-Peak	30	29.5	30
30 – 88	Quasi-Peak	100	40	3
88 – 216	Quasi-Peak	150	43.5	3
216 – 960	Quasi-Peak	200	46	3
960 – 1000	Quasi-Peak	500	54	3
> 1000	Average	500	54	3
The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector.				

Test setup



Test procedure

1. EUT set to test mode
2. Span it set according to measurement range
3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz
4. Markers are set to maximum emission levels

Test results

Channel	Frequency [kHz]	Emission [kHz]	Level [dbµV/m]	Detector	Pol.	Limit [dbµV/m]	Limit distance [m]*	Margin [dB]
F_{MID}	64	64	-68.40	avg	N/A	31.40	3	-99.85

Comments: * Physical distance between EUT and measurement antenna.