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FCC TEST REPORT

FCC 47 CFR Part 95I

Medical Device Radiocommunication Service (MedRadio)

Industry Canada RSS-243

Medical Devices Operating in the 401 – 406 MHz Frequency Band

Report Reference No. ..... :	G0M-1611-6060-TFC95IMR-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 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 95I RSS-243, Issue 3, 2010-02
Test scope…….. ..... :	partial Radio compliance test (C2PC)
Equipment under test (EUT):	
Product description	Primus Nano Plus Pacemaker Family
Model No.	Edora 8 HF-T
Additional Model(s)	See family listing
Brand Name(s)	Biotronik
Hardware version	ASM-0474 (for master)
Firmware / Software version	7801RomRev_02.02 / 7801RamRev_02.03
	FCC-ID: QRIPNP IC: N/A
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 ..... : 2016-12-02

Date (s) of performance of tests ..... : 2016-12-02 – 1216-12-05

Compiled by ..... : Wilfried Treffke

Tested by (+ signature) ..... : Wilfried Treffke .....W. Treffke.....
(Responsible for Test)

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

Date of issue ..... : 2017-02-06

Total number of pages ..... : 81

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:

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 variants are available with DF-1 and DF-4
All of these differences are only relevant in terms of medical aspects. They do not interfere with the RF-performance.

Antenna pattern measurements were performed for worst case antenna selection and the Edora 8 HF-T was selected. The model Edora 8 HF-T, 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 Name / PMN	HVIN	Description of Differences
1	Edora 8 HF-T (Master)	407138	(Master configuration), 3 chamber, 3x IS-1 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 1) With Home Monitoring and MRI Software
2	Edora 8 HF-T QP	407137	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 1) With Home Monitoring and MRI Software
3	Evity 8 HF-T	407140	3 chamber, 3x IS-1 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
4	Evity 8 HF-T QP	407139	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
5	Enitra 8 HF-T	407142	3 chamber, 3x IS-1 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 3) With Home Monitoring and MRI Software
6	Enitra 8 HF-T QP	407141	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 3) With Home Monitoring and MRI Software
7	Enticos 8 HF-T	407144	3 chamber, 3x IS-1 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 4) With Home Monitoring
8	Enticos 8 HF-T QP	407143	3 chamber, 2x IS-1, 1x IS-4 Connector, BOM-0340, SCH-0185, ASM-0474 Premium-Tier Software Features (Brand 4) With Home Monitoring
9	Edora 8 DR-T	407145	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 1) With Home Monitoring and MRI Software
10	Edora 8 SR-T	407157	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 1)

			With Home Monitoring and MRI Software
11	Edora 8 DR	407152	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 1) **Without** Home Monitoring, With MRI Software
12	Edora 8 SR	407164	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 1) **Without** Home Monitoring, With MRI Software
13	Evity 8 DR-T	407146	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
14	Evity 8 SR-T	407158	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
15	Enitra 8 DR-T	407147	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 3) With Home Monitoring and MRI Software
16	Enitra 8 SR-T	407159	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 3) With Home Monitoring and MRI Software
17	Enticos 8 DR-T	407148	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 4) With Home Monitoring
18	Enticos 8 SR-T	407160	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 4) With Home Monitoring
19	Evity 6 DR-T	407149	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
20	Evity 6 SR-T	407161	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
21	Enitra 6 DR-T	407150	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 3) With Home Monitoring and MRI Software
22	Enitra 6 SR-T	407162	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 3) With Home Monitoring and MRI Software

23	Enitra 6 DR	407153	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 3) **Without** Home Monitoring, With MRI Software
24	Enitra 6 SR	407165	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 3) **Without** Home Monitoring, With MRI Software
25	Enticos 6 DR-T	407151	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 4) With Home Monitoring
26	Enticos 6 SR-T	407163	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 4) With Home Monitoring
27	Enticos 6 DR	407154	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 4) **Without** Home Monitoring
28	Enticos 6 SR	407166	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 4) **Without** Home Monitoring
29	Enticos 4 DR	407155	2 chamber, 2x IS-1 Connector, BOM-0297, SCH-0186, ASM-0476 **Low**-Tier Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**
30	Enticos 4 SR	407167	1 chamber, 1x IS-1 Connector, BOM-0297, SCH-0186, ASM-0476 **Low**-Tier Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**
31	Enticos 4 D	407156	2 chamber, 2x IS-1 Connector, BOM-0297, SCH-0186, ASM-0476 **Low**-Tier Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**
32	Enticos 4 S	407168	1 chamber, 1x IS-1 Connector, BOM-0297, SCH-0186, ASM-0476 **Low**-Tier Software Features (Brand 4) **No Radio Circuit or Antenna, Coil Only**

Version History

Version	Issue Date	Remarks	Revised by
01	2017-02-06	Initial Release	

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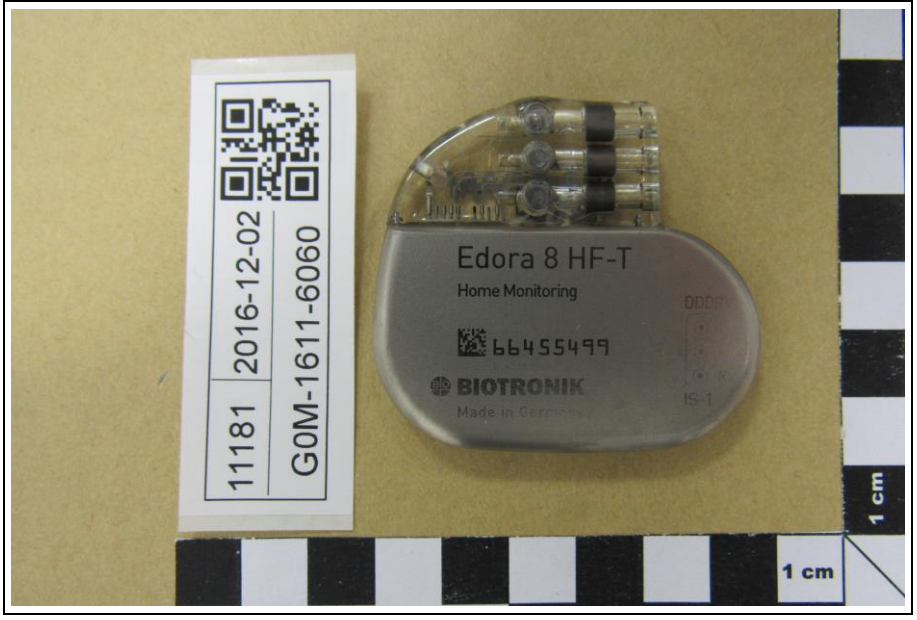
1 Equipment (Test item) Description

Description	Primus Nano Plus Pacemaker Family	
Model	Edora 8 HF-T	
Additional Model(s)	See family listing	
Brand Name(s)	Biotronik	
Serial number	66455499	
Hardware version	ASM-0474 (for master)	
Software / Firmware version	7801RomRev_02.02 / 7801RamRev_02.03	
PMN	N/A	
HVIN	N/A	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRIPNP	
IC	4708A-PNP	
Equipment type	End product	
Radio type	Transceiver	
Number of Radios	1	
Radio technology	MedRadio (MICS) active medical implant	
Operating frequency range	402 - 405 MHz	
Assigned frequency band	402 - 405 MHz	
Main test frequencies	F_{LOW}	402.45 MHz
	F_{MID}	403.65 MHz
	F_{HIGH}	404.85 MHz
Modulations	2FSK	
Emission designator	F1D	
Number of channels	9	
Channel spacing	300 kHz	
Spectrum access	LBT/AFA (channel access controlled by ULP-AMI-P device outside the human body)	
Number of antennas	1	
Antenna	Type	integrated
	Model	PNP Mini Rings
	Manufacturer	Biotronik SE & Co. KG
	Gain	-31.9 dBi (Determined by measurements)
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

Power supply	V_{NOM}	3.0 VDC
	V_{MIN}	2.0 VDC
	V_{MAX}	3.5 VDC
Temperature	T_{NOM}	37 °C
	T_{MIN}	25 °C
	T_{MAX}	45 °C
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

1.1 Photos - Equipment external

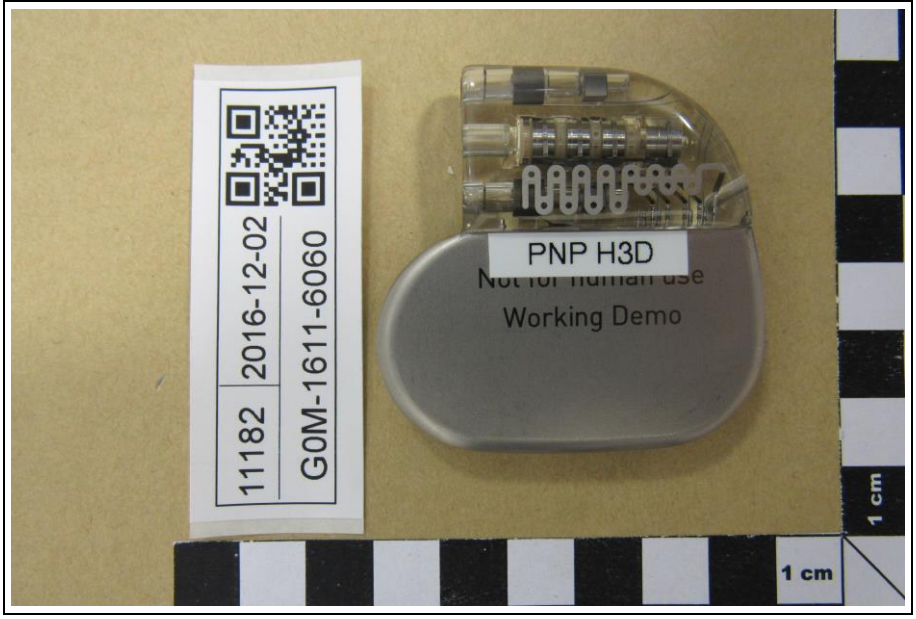
EDORA HF-T (Master) TOP



EDORA HF-T (Master) BOTTOM

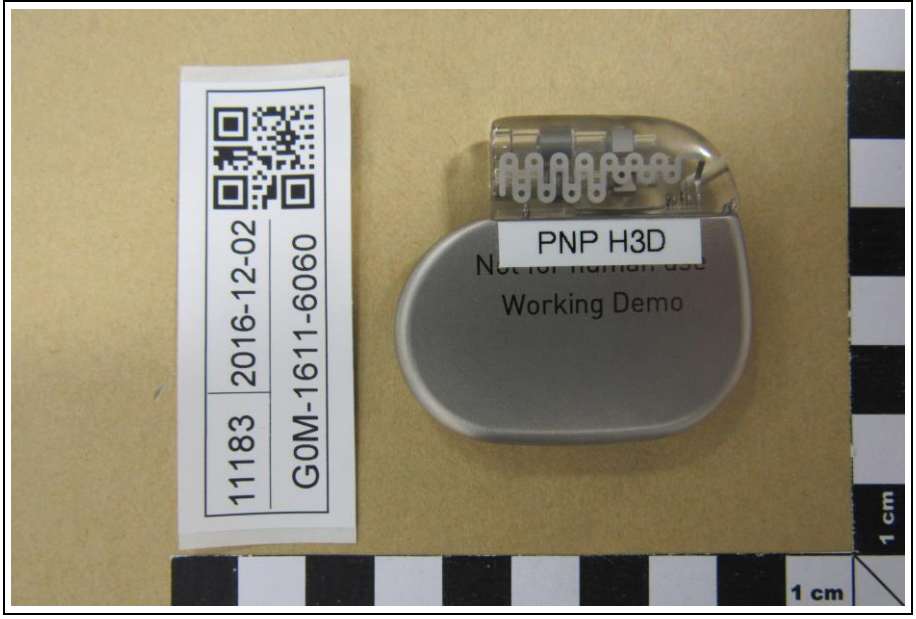
EDORA HF-T QP TOP

EDORA HF-T QP BOTTOM



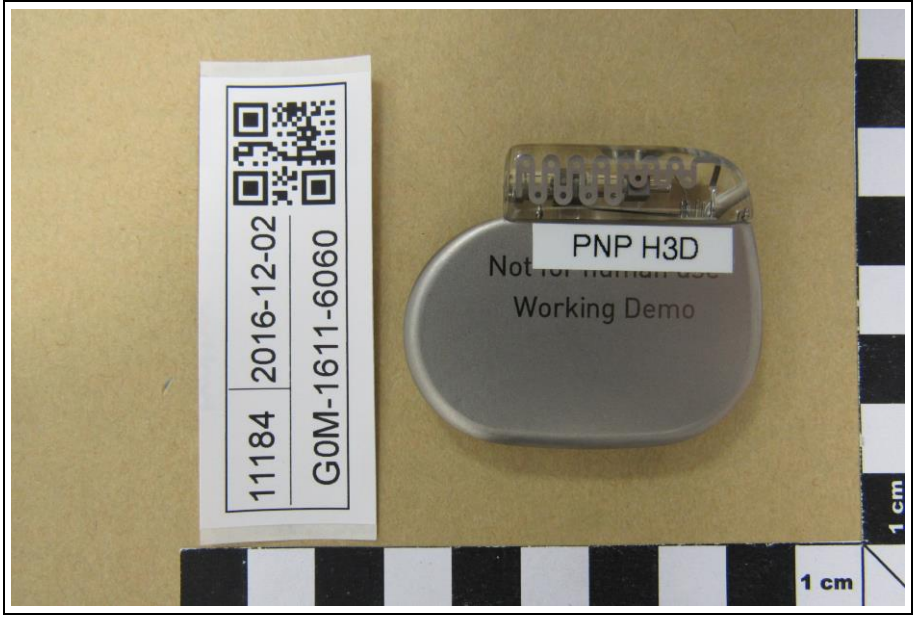
EDORA DR-T TOP

EDORA DR-T BOTTOM

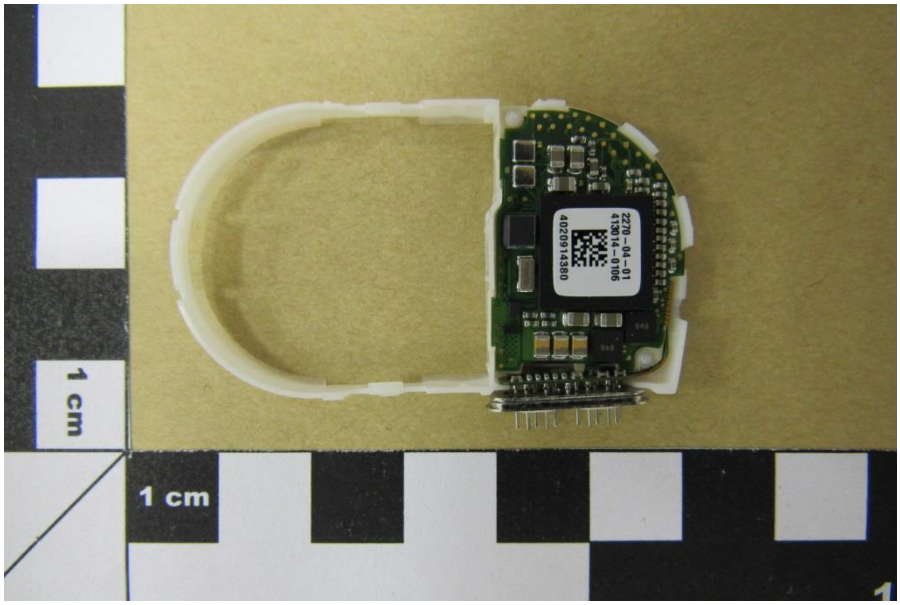


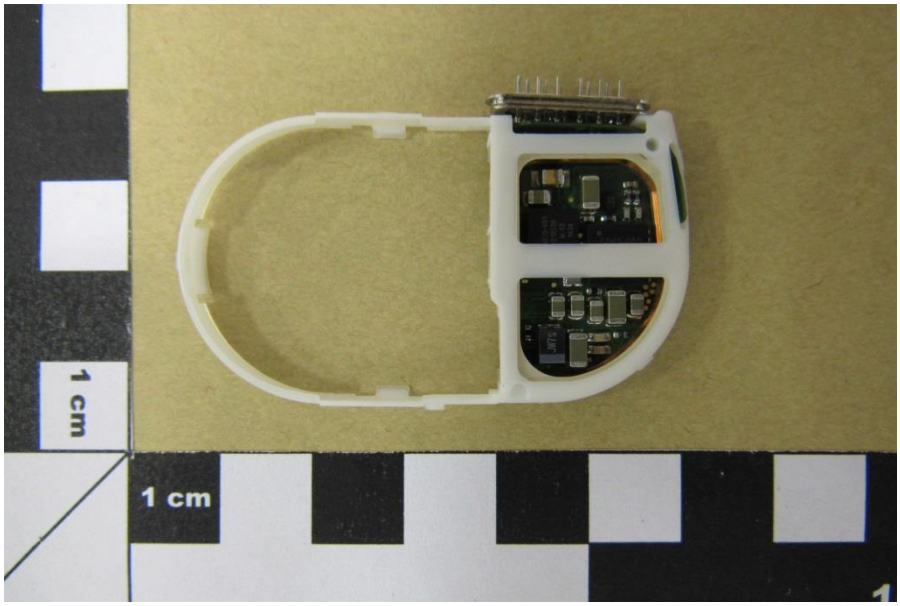
EDORA SR-T TOP

EDORA SR-T BOTTOM

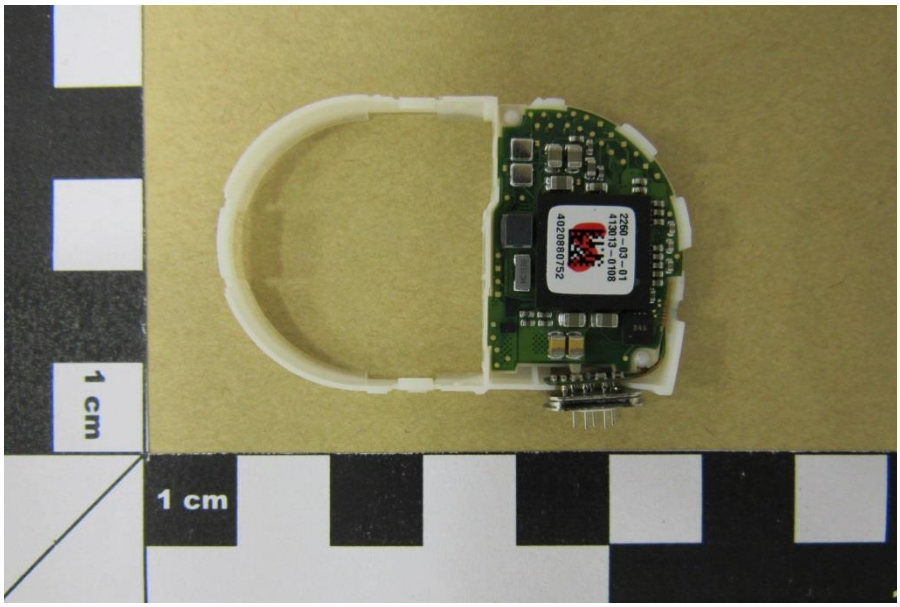


1.2 Photos - Equipment internal

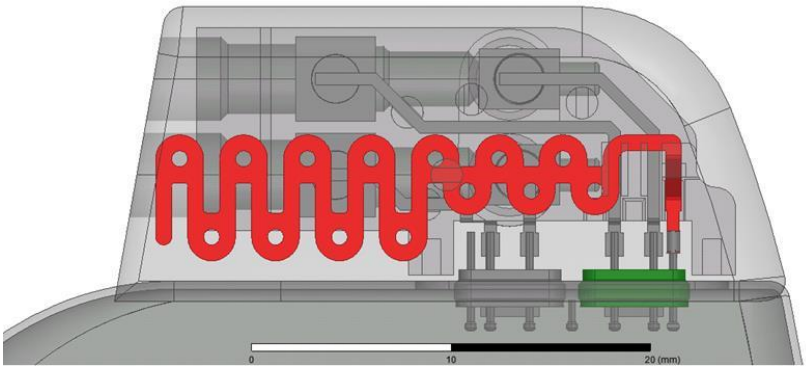
PCB, HF-T, TOP


PCB, HF-T, BOTTOM


PCB, DR-T / SR-T, TOP

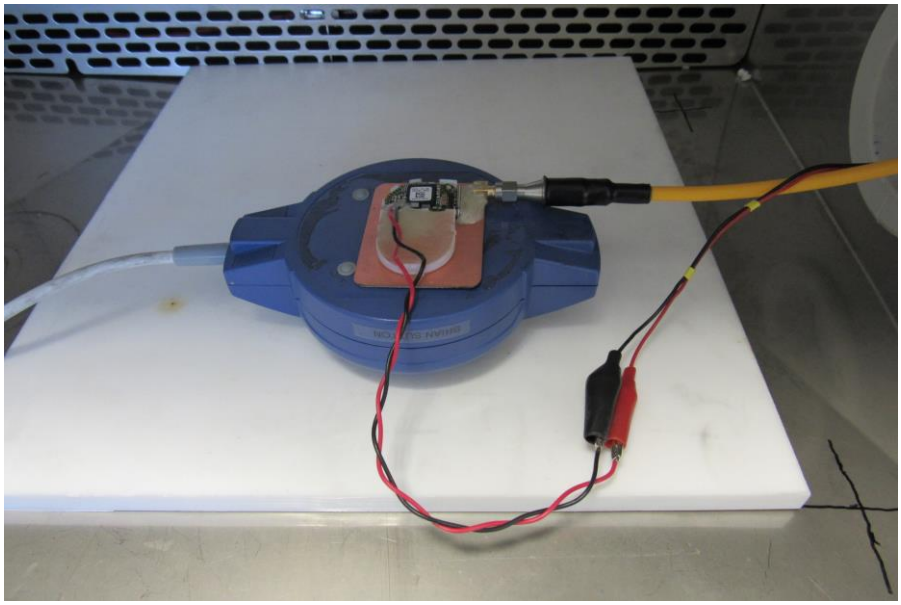


PCB, DR-T / SR-T, BOTTOM

ANTENNA


1.3 Photos – Test setup

Radiated emissions

Conducted Setup


1.4 Photos – Auxiliary/Associated Equipment

AE1: TEL BOX WITH WIRELESS WAND

1.5 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	TelBox	Biotronik	N/A	Programmer

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

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.6 Test Modes

Mode #	Description	
Unmodulated	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated 1	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = 2FSK Duty cycle = 100 % Power level = Maximum
Modulated 2	General conditions:	EUT powered by power supply
	Radio conditions:	Mode = standalone transmit Modulation = 2FSK Duty cycle = 100 % Power level = Maximum
Receive	General conditions:	EUT powered by fully charged battery
	Radio conditions:	Mode = standalone receive Modulation = FSK

1.7 Test Equipment Used During Testing

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2015.2.4

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04

Emission Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04

Frequency Stability					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF00197	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-01	2017-01
LPD Antenna	R&S	HL 223	EF00212	2016-04	2019-04

Radiated spurious emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF00197	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04
Biconical Antenna	R&S	HK 116	EF00012	2016-05	2019-05
LPD Antenna	R&S	HL 223	EF00187	2016-05	2019-05
LPD Antenna	R&S	HL 025	EF00327	2015-10	2018-10

1.8 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

1.9 Simulated human body

For radiated tests the implant was placed in a simulated human body.

Liquid components	
Component	percentage per weight
Deionized water	52.4
Bactericide	0.08
Hydroxy ethyl cellulose (HCE)	1.0
Sodium chloride	1.4
Sucrose	45.0

Measured tissue parameters:

Tissue parameters – 403.5MHz			
Component	Target	Measured	Tolerance [%]
Dielectric constant ε	62.5	63.08	0.93
Conductivity σ [ms/cm]	0.9	0.88	-2.22

2 Result Summary

FCC 47 CFR Part 95E, 95I, 15C, IC RSS-243, IC RSS-Gen				
Product Specific Standard Section	**Requirement – Test**	**Reference Method**	**Result**	**Remarks**
IC RSS-243 3.2 IC RSS-Gen 6.6	Occupied bandwidth	RSS-Gen 6.6	N/A	Informational only
FCC 95.628(d) FCC § 95.633(e)	Emission bandwidth	FCC § 95.628(a)(6)(i) FCC § 95.633(e)(3)	PASS	
FCC 95.628(e) IC RSS-243 3.3, 5.3 RSS-Gen 8.11	Frequency stability	EN 301 839-1 8.1	PASS	
FCC § 95.6369(f) IC RSS-243 § 5.4	Transmitter output power	EN 301 839-1 8.3	PASS	
FCC § 95.635(d) IC RSS-243 § 3.4, 5.5	Band edge compliance	FCC § 95.635(d) ANSI C63.4	PASS	
FCC § 95.635(d) IC RSS-243 § 3.4, 5.5 RSS-Gen 6.13	Transmitter unwanted emissions	FCC § 95.635(d) ANSI C63.4	PASS	
IC RSS-243 3.5, 5.6 IC RSS-Gen 7.1	Receiver spurious emissions	ANSI C63.4	PASS	
FCC § 15.207 IC RSS-Gen 8.8	AC power line conducted emissions	ANSI C63.4	N/A	EUT battery powered
FCC § 95.628(a)(3) IC RSS-243 3.6, 5.7.1	System threshold power levels	EN 301 839-1 10.1	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(1) IC RSS-243 3.6, 5.7.2	Monitoring system bandwidth	EN 301 839-1 10.2	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(2) IC RSS-243 3.6, 5.7.3	Scan cycle time	EN 301 839-1 10.3	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(2) IC RSS-243 3.6, 5.7.4	Minimum channel monitoring period	EN 301 839-1 10.3	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(4) IC RSS-243 3.6, 5.7.5	Channel Access	EN 301 839-1 10.4	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(4) IC RSS-243 3.6, 5.7.6	Discontinuation of MICS or MEDS session	EN 301 839-1 10.5	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(5) IC RSS-243 3.6, 5.7.7	Use of the pre-scanned alternate channel	EN 301 839-1 10.6	N/A	Not used
Remarks:				

3 Test Conditions and Results

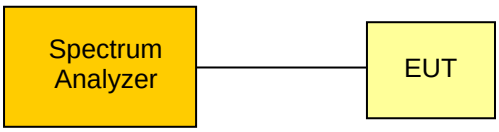
3.1 Test Conditions and Results – Occupied Bandwidth

Occupied Bandwidth acc. to IC RSS-243	**Verdict: PASS**
Test according to measurement reference	Reference Method
	RSS-Gen 6.6
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated 1

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

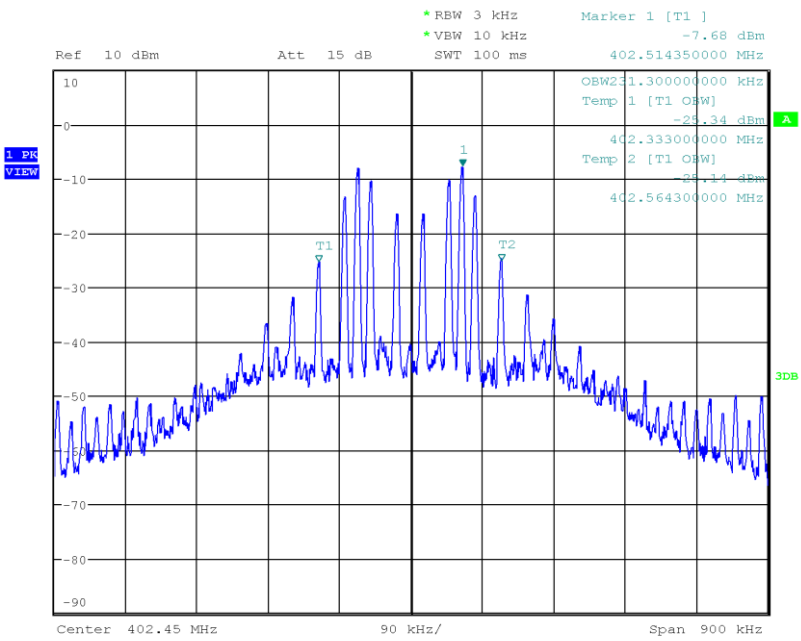
Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	16	402.45	231.300	≤ 300	PASS
F_{MID}	16	403.65	231.525	≤ 300	PASS
F_{HIGH}	16	404.85	231.075	≤ 300	PASS

Comments:

Occupied Bandwidth – F_{LOW} (16kBit)

Occupied Bandwidth RSS-243

Project Number:	G0M-1611-6060
Applicant	Biotronik SE & Co. KG
Model Description	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T
Test Sample ID:	4021314850
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 16 kbps, Channel: 8, 402.45 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2016-12-02
Occupied Bandwidth [kHz]:	231.300

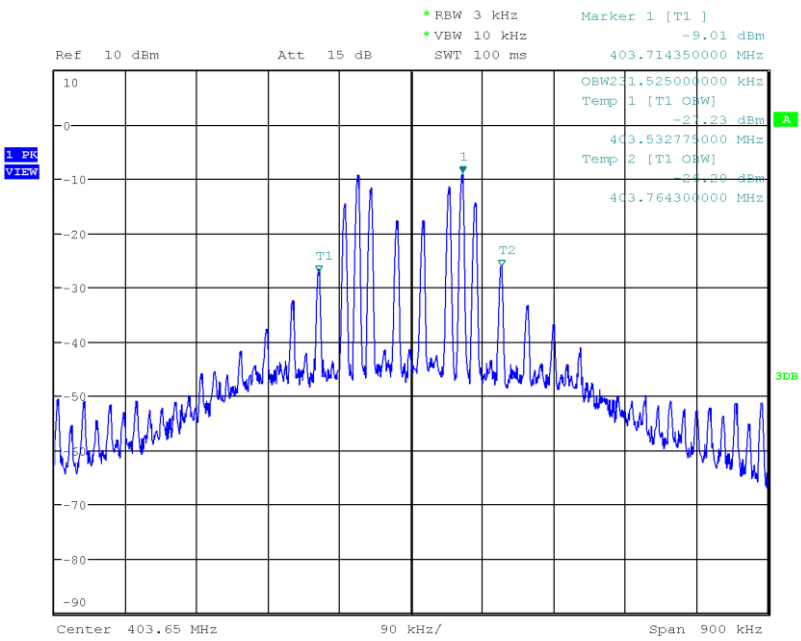


Date: 2.DEC.2016 08:33:29

Occupied Bandwidth - F_{MID} (16kBit)

Occupied Bandwidth RSS-243

Project Number:	G0M-1611-6060
Applicant	Biotronik SE & Co. KG
Model Description	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T
Test Sample ID:	4021314850
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 16 kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2016-12-02
Occupied Bandwidth [kHz]:	231.525

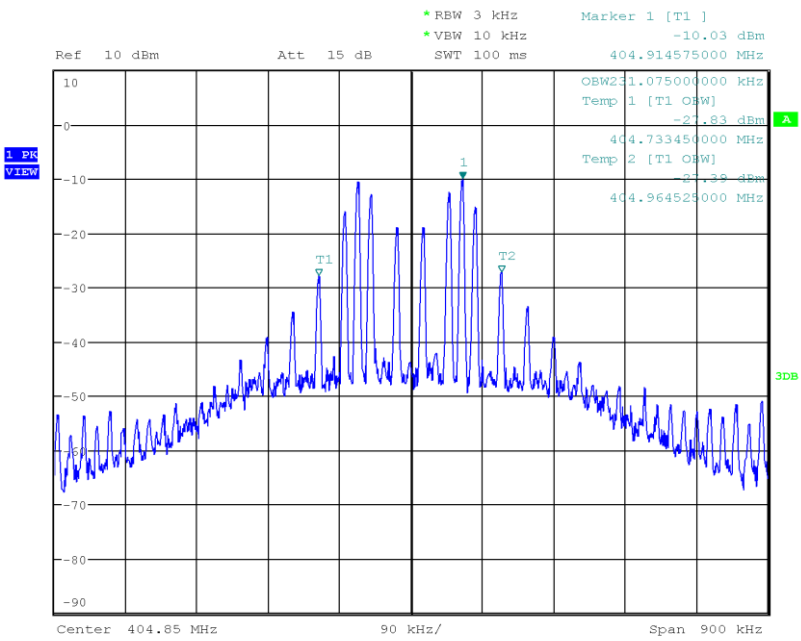


Date: 2.DEC.2016 08:32:30

Occupied Bandwidth – F_{HIGH} (16kBit)

Occupied Bandwidth RSS-243

Project Number:	G0M-1611-6060
Applicant	Biotronik SE & Co. KG
Model Description	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T
Test Sample ID:	4021314850
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 16 kbps, Channel: 7, 404.85 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2016-12-02
Occupied Bandwidth [kHz]:	231.075



Date: 2.DEC.2016 08:31:22

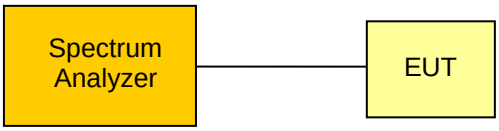
3.2 Test Conditions and Results – Emission Bandwidth

Emission Bandwidth acc. to FCC Part 95	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.628(d) / FCC 95.633(e)
Test according to measurement reference	Reference Method
	FCC 95.628(a)(6)(i) / FCC 95.633(e)(3)
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated

Limits

≤ 300 kHz

Test setup



Test procedure

1. EUT set to test mode
2. Span set to at least twice the emission spectrum
3. Detector set to peak and max hold
4. Envelope peak value of emission spectrum is selected
5. Marker on envelope of spectrum is set to level of -20 dB to the left of the peak
6. Marker on envelope of spectrum is set to level of -20 dB to the right of the peak
7. 20 dB Emission Bandwidth is determined by marker frequency separation

Test results

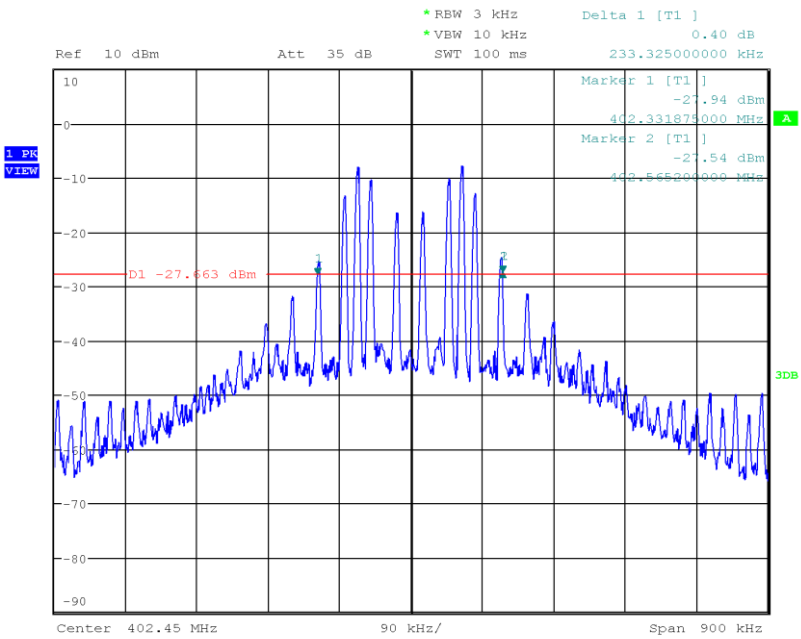
Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	16	402.45	233.325	≤ 300	PASS
F_{MID}	16	403.65	233.550	≤ 300	PASS
F_{HIGH}	16	404.85	233.325	≤ 300	PASS

Comments:

Emission Bandwidth – F_{LOW} (16kBit)

20 dB Bandwidth FCC

Project Number:	G0M-1611-6060
Applicant	Biotronik SE & Co. KG
Model Description	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T
Test Sample ID:	4021314850
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 16 kbps, Channel: 8, 402.45 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2016-12-02
Lower Frequency [MHz]:	402.332
Upper Frequency [MHz]:	402.565
20 dB Bandwidth [kHz]:	233.325

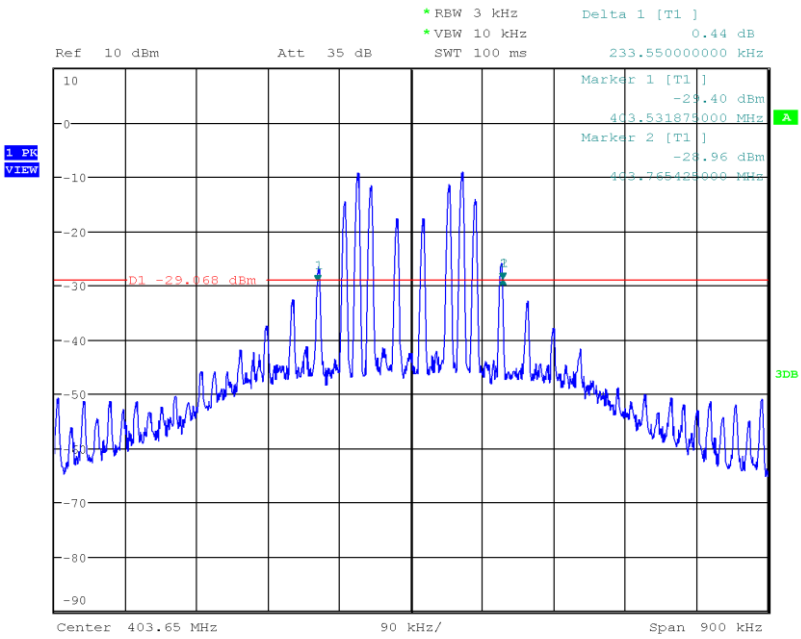


Date: 2.DEC.2016 08:50:28

Emission Bandwidth - F_{MID} (16kBit)

20 dB Bandwidth FCC

Project Number:	G0M-1611-6060
Applicant	Biotronik SE & Co. KG
Model Description	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T
Test Sample ID:	4021314850
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 16 kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2016-12-02
Lower Frequency [MHz]:	403.532
Upper Frequency [MHz]:	403.765
20 dB Bandwidth [kHz]:	233.550

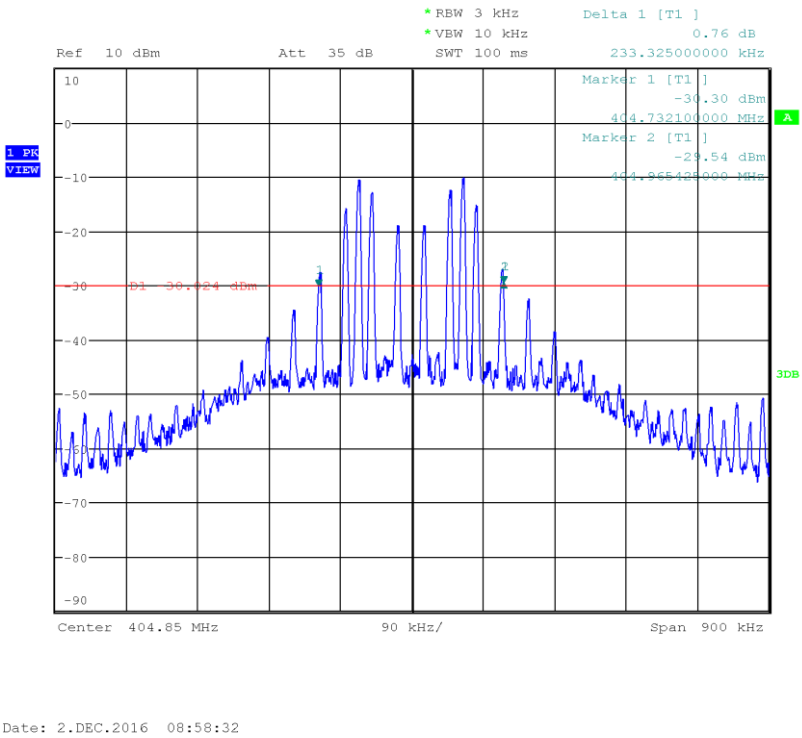


Date: 2.DEC.2016 08:51:36

Emission Bandwidth – F_{HIGH} (16kBit)

20 dB Bandwidth FCC

Project Number:	G0M-1611-6060
Applicant	Biotronik SE & Co. KG
Model Description	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T
Test Sample ID:	4021314850
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 16 kbps, Channel: 7, 404.85 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2016-12-02
Lower Frequency [MHz]:	404.732
Upper Frequency [MHz]:	404.965
20 dB Bandwidth [kHz]:	233.325



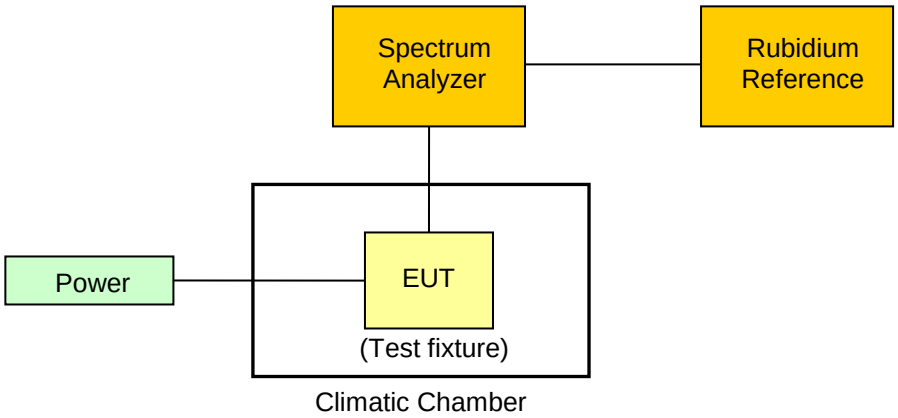
3.3 Test Conditions and Results – Frequency stability

Frequency stability acc. to FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.628(e) / IC RSS-243 3.3 5.3 / RSS-Gen 4.7
Test according to measurement reference	Reference Method
	EN 301 839-1 8.1
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Unmodulated

Limits

≤ ±100 ppm

Test setup



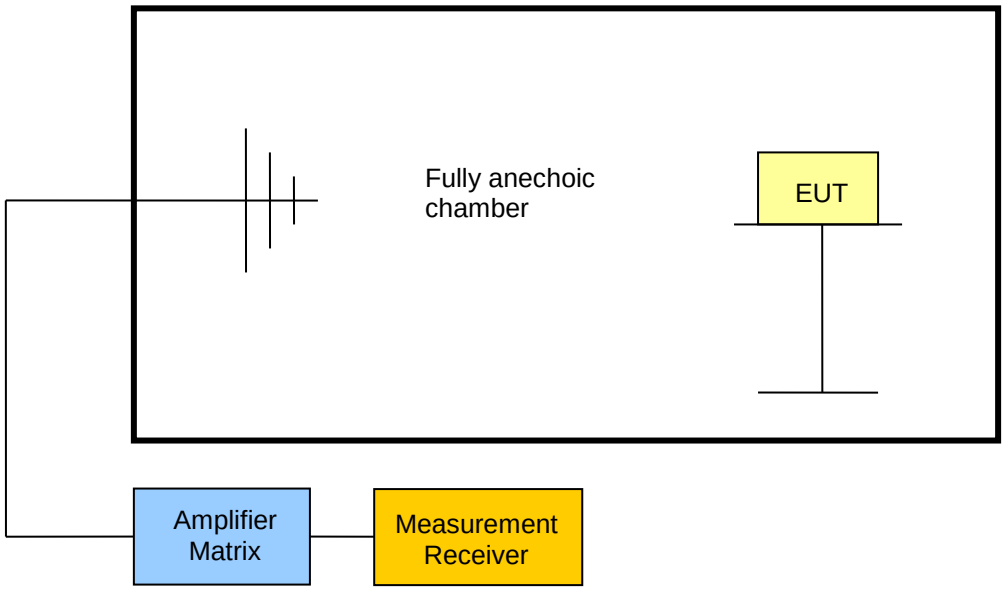
Test procedure

1. EUT set to test mode with supply voltage and temperature set to nominal conditions
2. EUT transmits without modulation
3. Detector set to peak and max hold
4. Peak of emission is measured using a frequency counter
5. The frequency error is determined as the deviation of the emission frequency from the nominal frequency stated by the customer.

Test results					
Channel	Nominal Frequency [MHz]	Temperature	Supply voltage	Frequency [MHz]	Drift [ppm]
F_{LOW}	402.45	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	402.448431	-03.90
F_{LOW}	402.45	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	402.449198	-01.99
F_{LOW}	402.45	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	402.448069	-04.80
F_{MID}	403.65	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	403.648509	-03.69
F_{MID}	403.65	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	403.649268	-01.81
F_{MID}	403.65	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	403.648147	-04.59
F_{HIGH}	404.85	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	404.848587	-03.49
F_{HIGH}	404.85	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	404.849358	-01.59
F_{HIGH}	404.85	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	404.848230	-04.37
Comments:					

3.4 Test Conditions and Results – Transmitter output power

Transmitter output power acc. to FCC Part 95 / IC RSS-243	Verdict: PASS
EUT requirement rule parts and clause	Reference
	FCC 95.639(f) / IC RSS-243 5.4
Test according to measurement reference	Reference Method
	EN 301 839-1 8.3
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Unmodulated
Limits	
≤ 25 µW (-16 dBm) e.i.r.p.	
Test setup	



Test procedure

1. EUT set to test frequency without modulation
2. Measurement polarization is set to vertical
3. Span it set according to measurement range and detector is set to peak and max hold
4. Resolution bandwidth is set two be at least twice the emission bandwidth
5. During the sweep the EUT is rotated to obtain maximum emission level
6. Measurement is repeated with horizontal measurement polarization

Test results					
Channel	Frequency [MHz]	Emission Level [dBm e.i.r.p.]	Detector	Limit [dBm e.i.r.p.]	Margin [dB]
F_{LOW}	402.45	-38.2	pk	-16	-22.20
F_{HIGH}	404.85	-38.2	pk	-16	-22.20
Comments:					

3.5 Test Conditions and Results – Band-edge and In-band Emissions

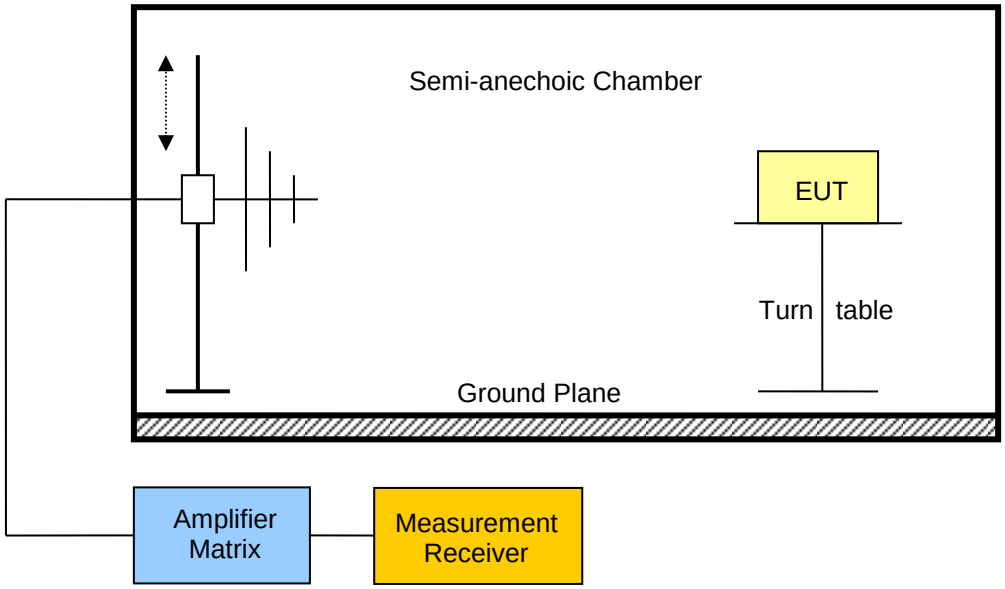
Band-edge and in-band emission compliance acc. to FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9
Test according to measurement reference	Reference Method
	FCC 95.635(d) / ANSI C 63.4
Test frequency range	Tested frequencies
	F_{LOW} / F_{HIGH}
EUT test mode	Modulated 1

Limits - FCC	
Frequency range	Limit
402 MHz – 250 kHz ≤ f ≤ 402 MHz	20 dB below maximum permitted output power
402 MHz < f < 150 kHz - f_C	20 dB below transmitter output power
150 kHz + f_C < f < 405 Mhz	20 dB below transmitter output power
405 MHz ≤ f ≤ 405 MHz + 250 kHz	20 dB below maximum permitted output power

Limits - IC	
Frequency range	Limit
402 MHz – 250 kHz < f < 150 kHz-f_C	20 dB below maximum permitted output power
150 kHz+f_C < f < 405 MHz + 250 kHz	20 dB below maximum permitted output power

Because the FCC limits are more stringent than the Industry Canada limits, the FCC limits are used to show compliance with the band-edge emission requirements.

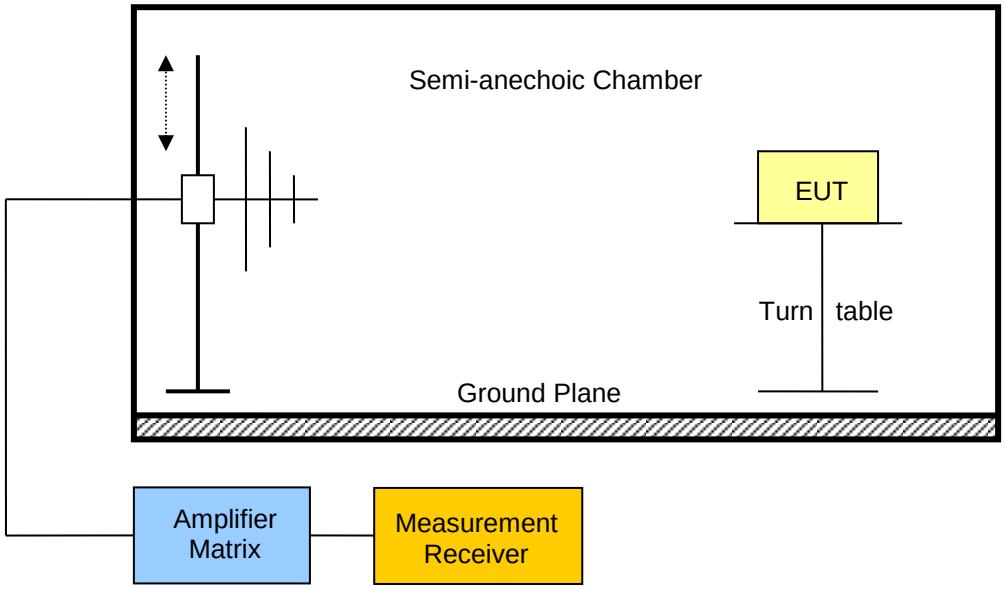
Test setup



Test procedure						
1. EUT set to test frequency with modulation 2. Measurement polarization is set to vertical 3. Span it set according to measurement range 4. Resolution bandwidth is set to 1% of the emission bandwidth and detector is set to peak 5. During the sweep the EUT is rotated to obtain maximum emission level 6. Measurement is repeated with horizontal measurement polarization						
Test results						
Channel	Frequency [MHz]	Emission [MHz]	Level [dBµV/m]	Pol.	Limit [dBµV/m]	Margin [dB]
F_{LOW}	402.45	401.985	04.77	hor	59.40	-54.63
F_{LOW}	402.45	401.986	01.10	ver	59.40	-58.30
F_{LOW}	402.45	402.299	22.13	hor	47.00	-24.87
F_{LOW}	402.45	402.299	17.84	ver	47.00	-29.16
F_{LOW}	402.45	402.629	16.49	hor	47.00	-30.51
F_{LOW}	402.45	403.238	31.04	hor	47.00	-15.96
F_{LOW}	402.45	403.238	26.66	ver	47.00	-20.34
F_{LOW}	402.45	403.963	18.45	hor	47.00	-28.55
F_{LOW}	402.45	404.093	18.75	hor	47.00	-28.25
F_{HIGH}	404.85	403.933	09.89	hor	47.00	-37.11
F_{HIGH}	404.85	404.192	09.33	hor	47.00	-37.67
F_{HIGH}	404.85	404.695	15.53	hor	47.00	-31.47
F_{HIGH}	404.85	404.695	19.34	ver	47.00	-27.66
F_{HIGH}	404.85	404.999	14.46	hor	47.00	-32.54
F_{HIGH}	404.85	404.999	09.75	ver	47.00	-37.25
F_{HIGH}	404.85	405.027	19.63	hor	59.40	-39.77
F_{HIGH}	404.85	405.027	14.14	ver	59.40	-45.26
Comments: see attached diagrams						

3.6 Test Conditions and Results – Transmitter unwanted emissions

Transmitter unwanted emissions acc. to FCC Part 95 / IC RSS-243				Verdict: PASS
Test according referenced standards		Reference Method		
		FCC 95.635(d) / IC RSS-243 3.4 5.5 / IC RSS-Gen 4.9		
Test according to measurement reference		Reference Method		
		FCC 95.635(d) / ANSI C 63.4		
Test frequency range		Tested frequencies		
		30 MHz – 10th Harmonic		
EUT test mode		Modulated 1		
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
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
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 peak emission levels within restricted bands

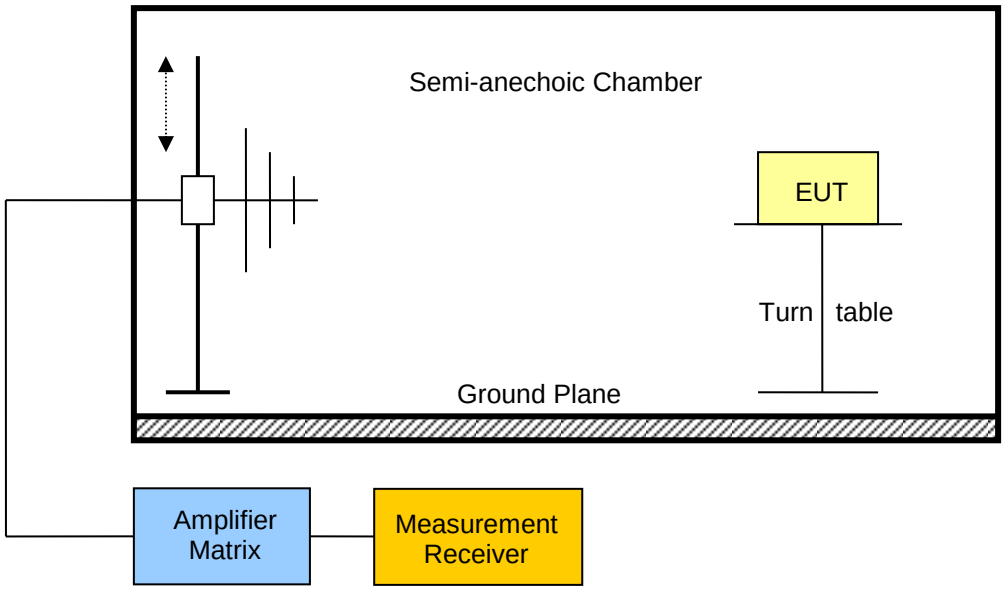
Test results

Channel	Frequency [MHz]	Mode	Emission [MHz]	Level [dbµV/m]	Det.	Pol.	Limit [dbµV/m]	Limit dist. [m]*	Margin [dB]
F_{LOW}	402.45	Modulated 1	401.347	16.28	pk	hor	46.00	3	-29.72
F_{LOW}	402.45	Modulated 1	407.629	17.68	pk	hor	46.00	3	-28.32
F_{LOW}	402.45	Modulated 1	407.629	14.00	pk	ver	46.00	3	-32.00
F_{LOW}	402.45	Modulated 1	3574	41.66	pk	hor	54.00	3	-12.34
F_{LOW}	402.45	Modulated 1	4007	41.24	pk	ver	54.00	3	-12.76
F_{HIGH}	404.85	Modulated 1	398.522	20.89	pk	hor	46.00	3	-25.11
F_{HIGH}	404.85	Modulated 1	398.522	17.08	pk	ver	46.00	3	-28.92
F_{HIGH}	404.85	Modulated 1	405.25	28.26	pk	hor	46.00	3	-17.74
F_{HIGH}	404.85	Modulated 1	405.25	24.09	pk	ver	46.00	3	-21.91

Comments: * Physical distance between EUT and measurement antenna.

3.7 Test Conditions and Results – Receiver spurious emissions

Receiver spurious emissions acc. to IC RSS-243				**Verdict: PASS**
Test according referenced standards	Reference Method			
	IC RSS-243 3.5 5.6 / IC RSS-Gen 4.10 6.1			
Test according to measurement reference	Reference Method			
	ANSI C 63.4			
Test frequency range	Tested frequencies			
	30 MHz – 5th Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
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
Test setup				



Test procedure
1. EUT set to receive mode (Communication tester is used if needed) 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 peak emission levels

Test results

Channel	Frequency [MHz]	Emission [MHz]	Emission Level [dBµV/m]	Det.	Pol.	Limit [dBµV/m]	Margin [dB]
F_{MID}	403.65	910.4	26.50	pk	ver	46.00	-19.50
F_{MID}	403.65	1690	34.03	pk	ver	53.98	-19.95
F_{MID}	403.65	3958	40.03	pk	hor	53.98	-13.95

Comments:

ANNEX A Transmitter radiated power

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2016-11-30
Note:	Tx power EIRP

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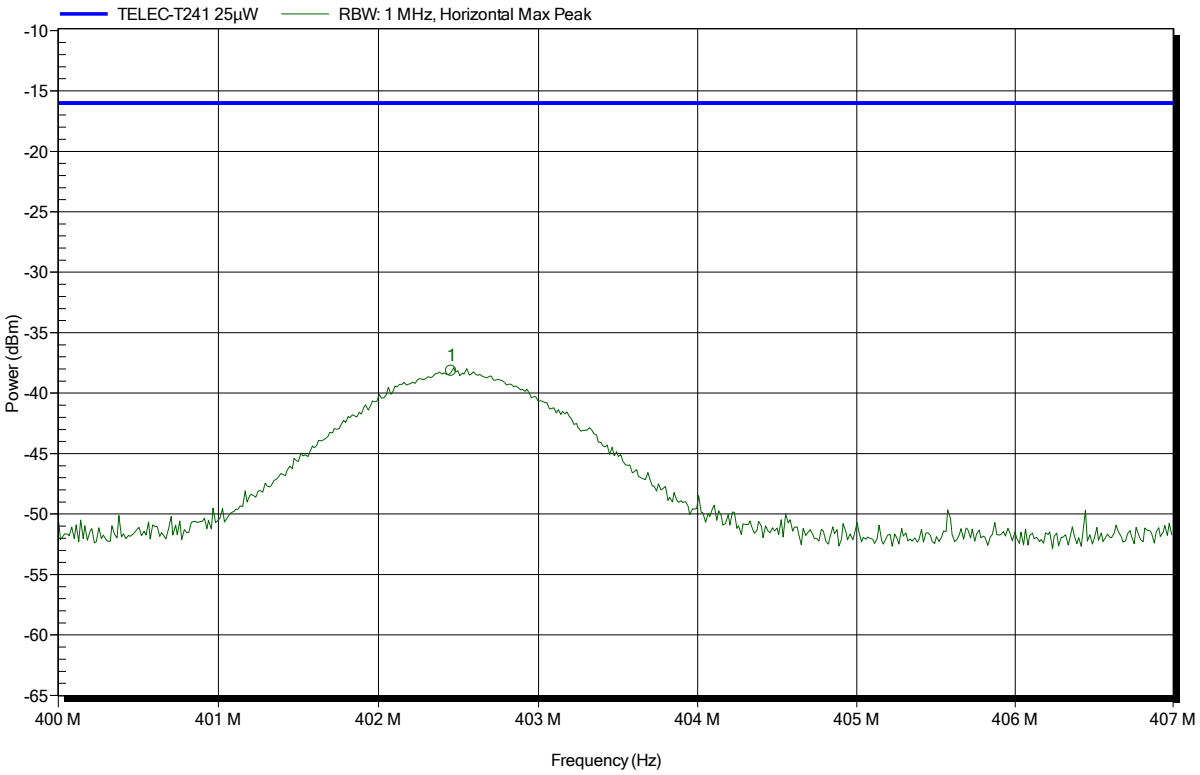

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.453 MHz	-38.2 dBm	-16 dBm	-22.16 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2016-11-30
Note:	Tx power EIRP

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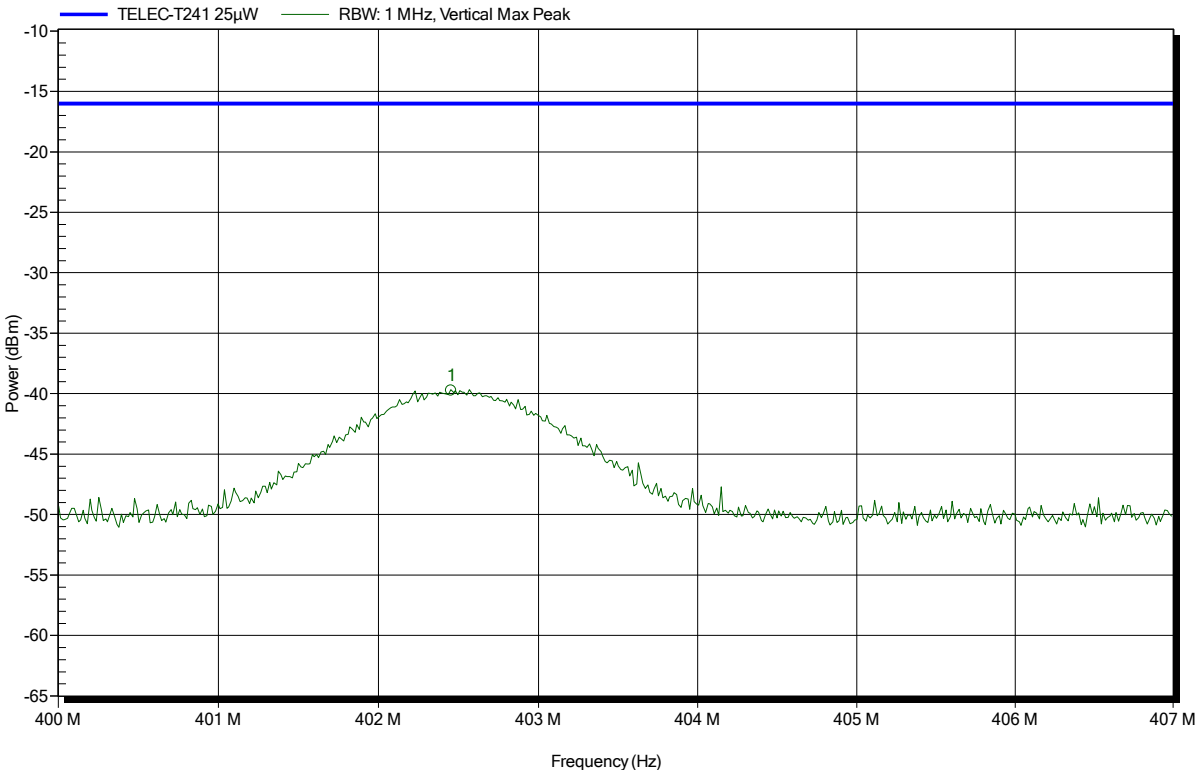

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.453 MHz	-39.8 dBm	-16 dBm	-23.75 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2016-11-30
Note:	Tx power EIRP

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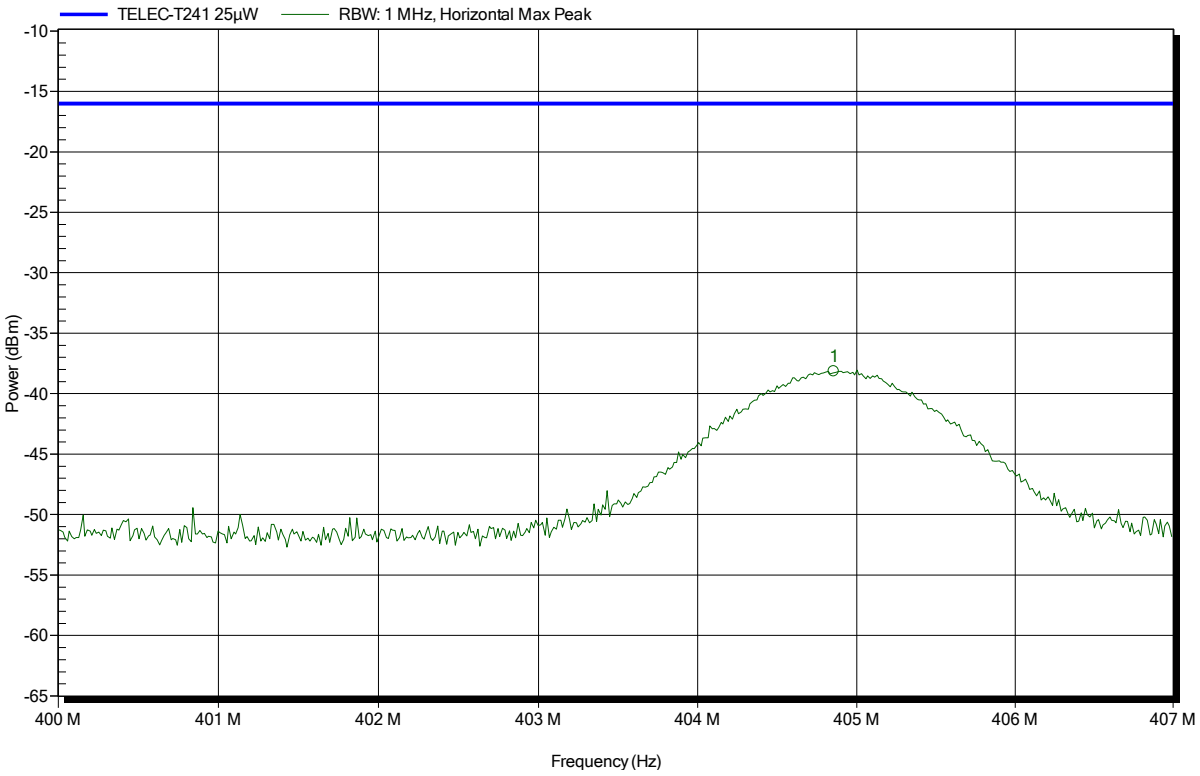

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.856 MHz	-38.2 dBm	-16 dBm	-22.16 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2016-11-30
Note:	Tx power EIRP

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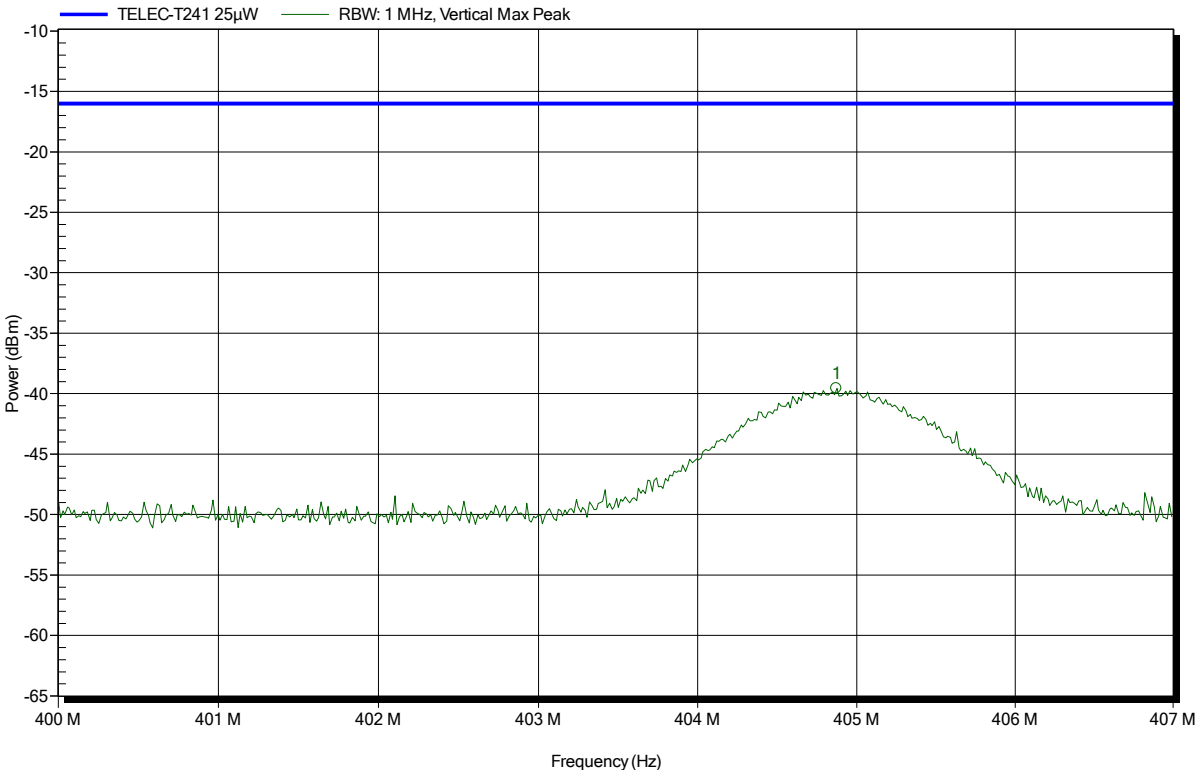

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.872 MHz	-39.6 dBm	-16 dBm	-23.56 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2016-12-01
Note:	Power dBµV/m ERP

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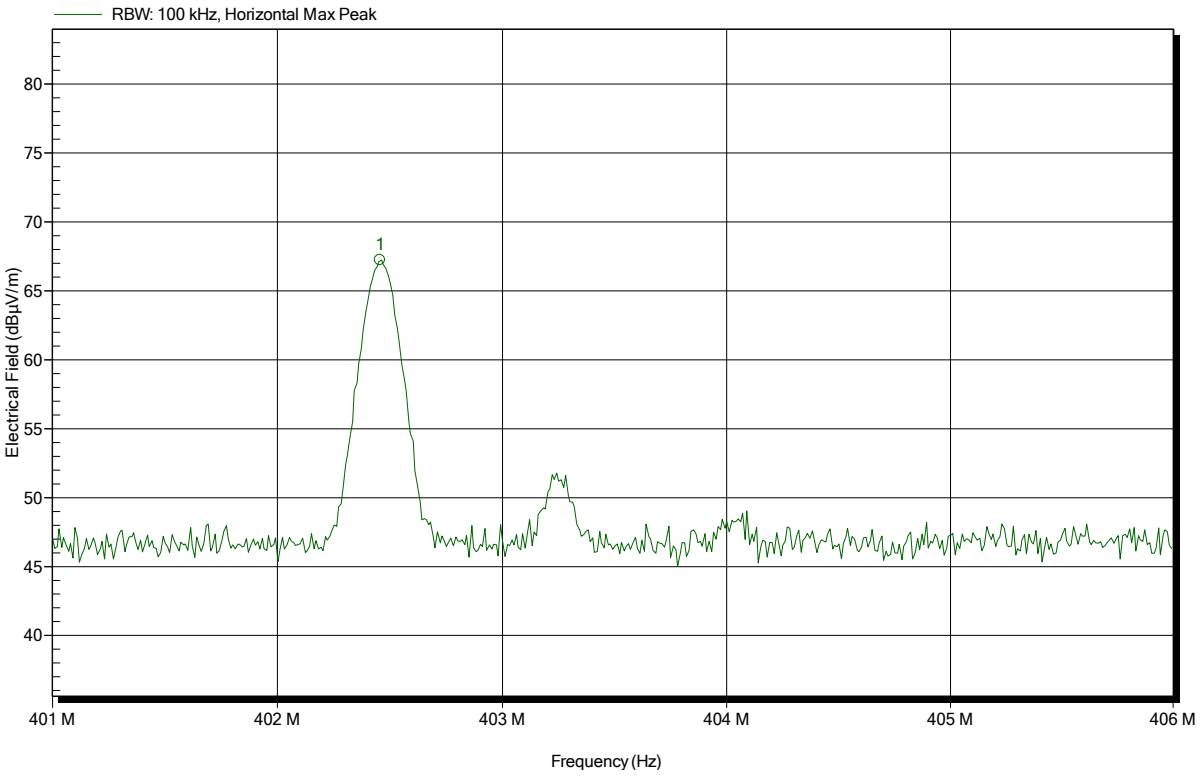


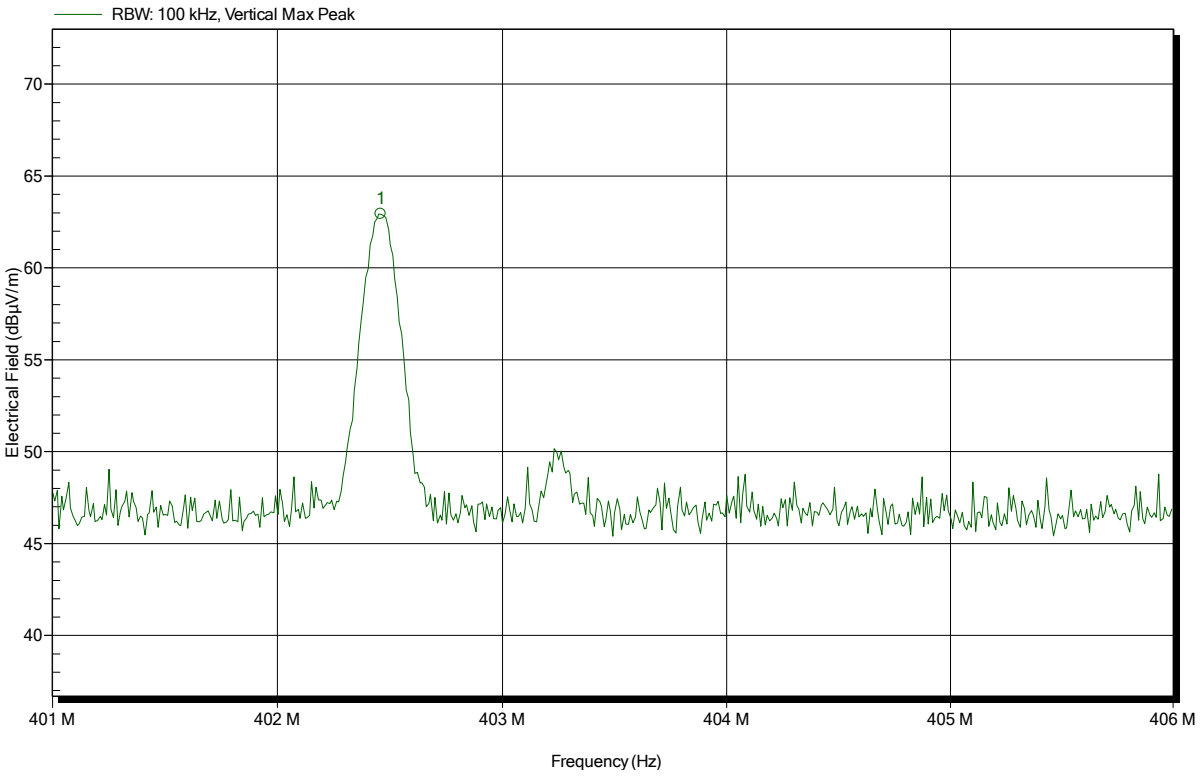
Frequency	Peak
402.456 MHz	67.23 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2016-12-01
Note:	Power dBµV/m ERP

Index 63



Frequency	Peak
402.458 MHz	62.94 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2016-12-01
Note:	Power dBµV/m ERP

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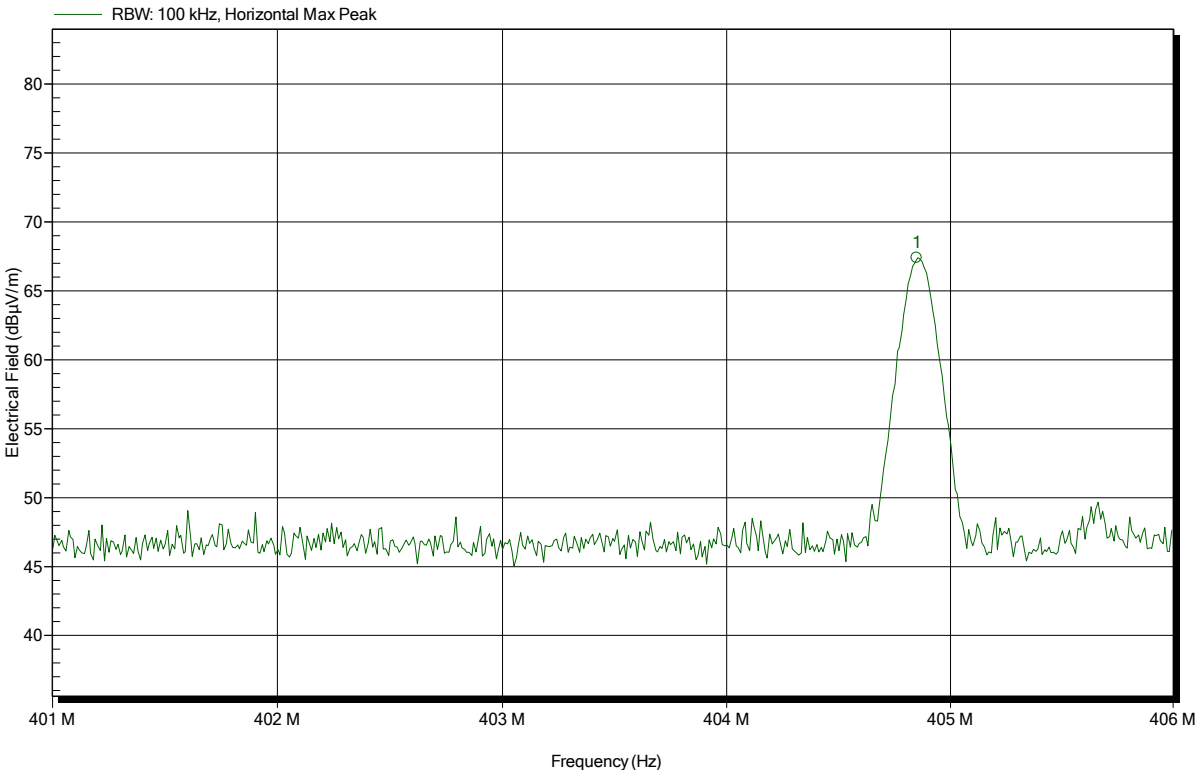

Frequency	Peak
404.85 MHz	67.39 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2016-12-01
Note:	Power dBµV/m ERP

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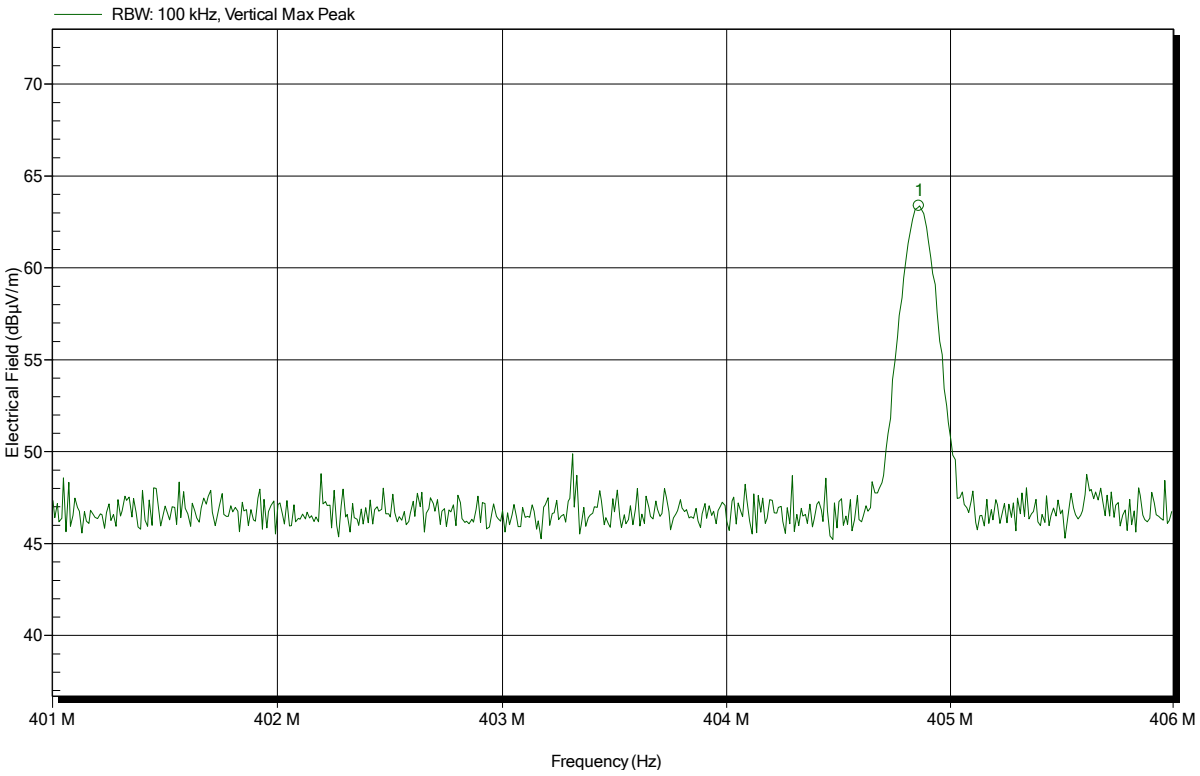

Frequency	Peak
404.86 MHz	63.38 dBµV/m

ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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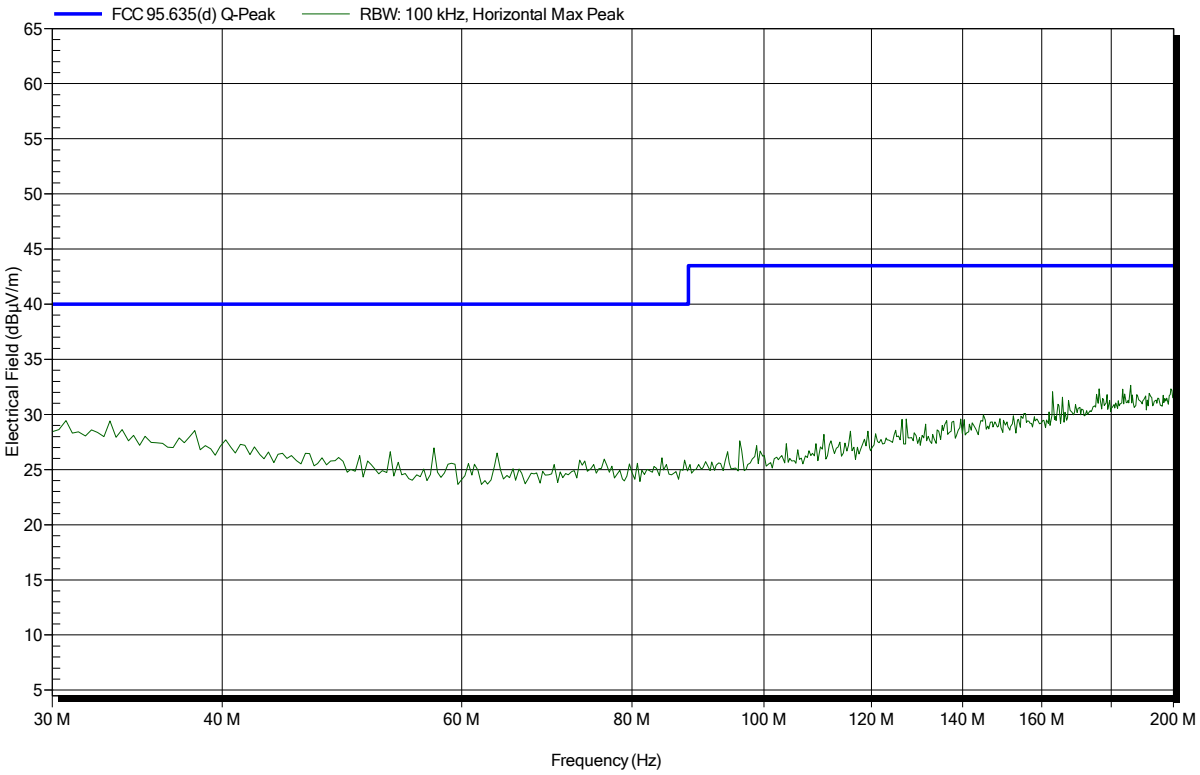

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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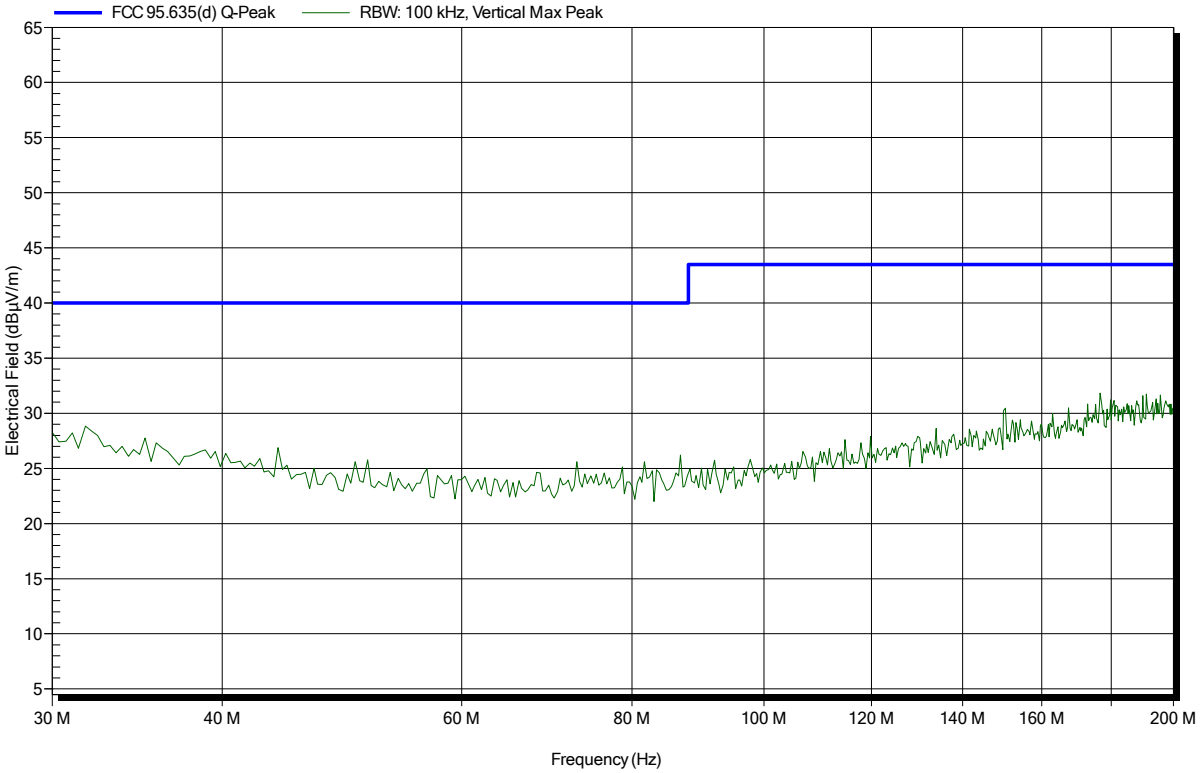

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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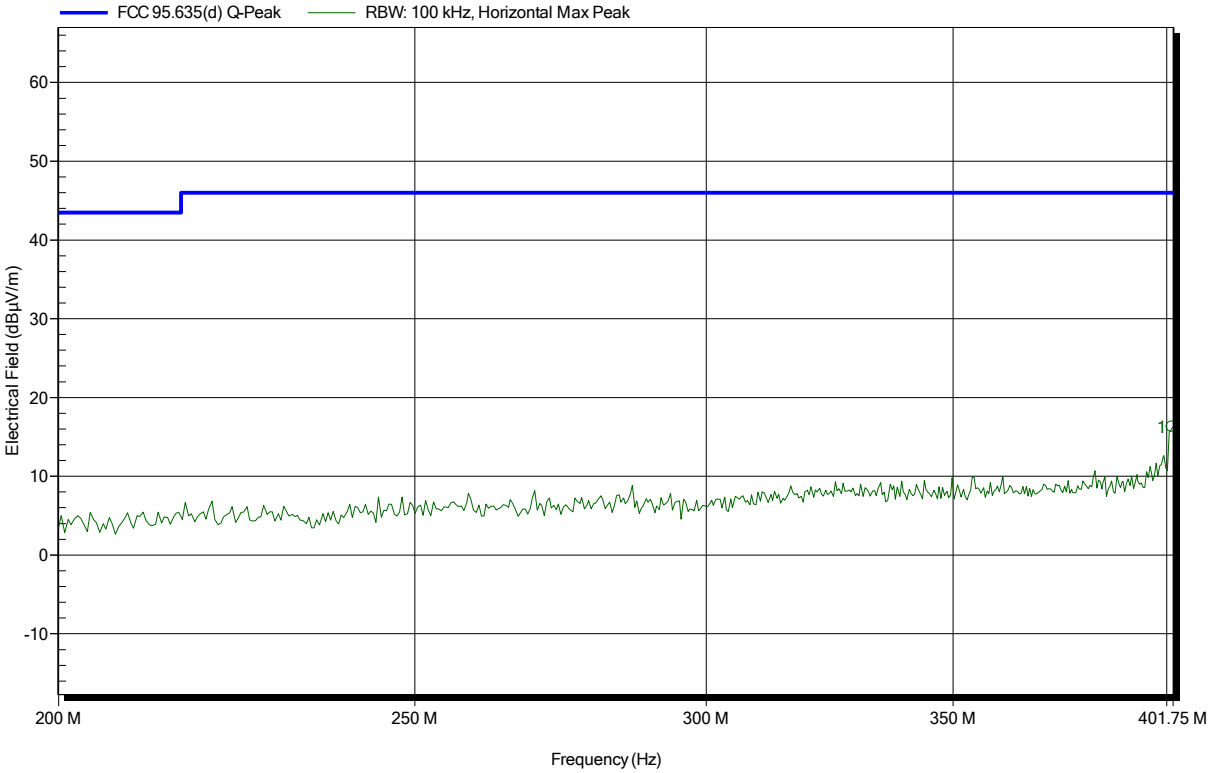

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.347 MHz	16.28 dBµV/m	46 dBµV/m	-29.72 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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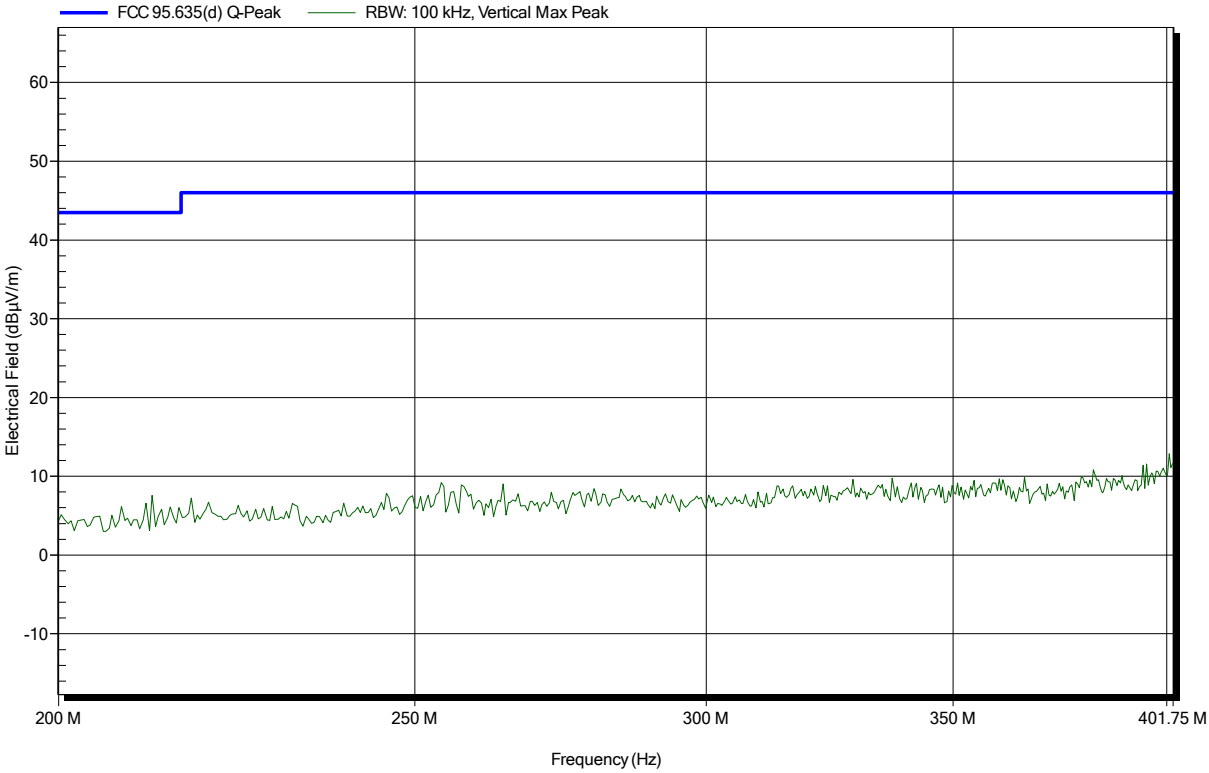

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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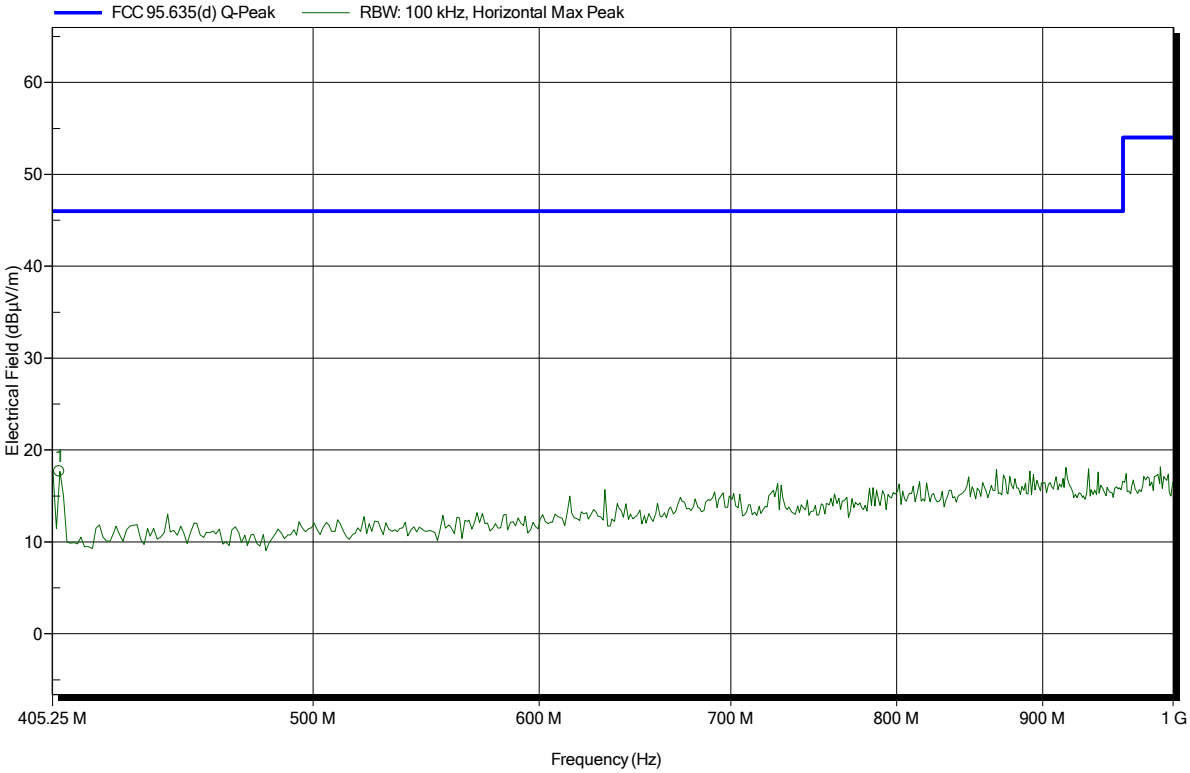

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
407.629 MHz	17.68 dBµV/m	46 dBµV/m	-28.32 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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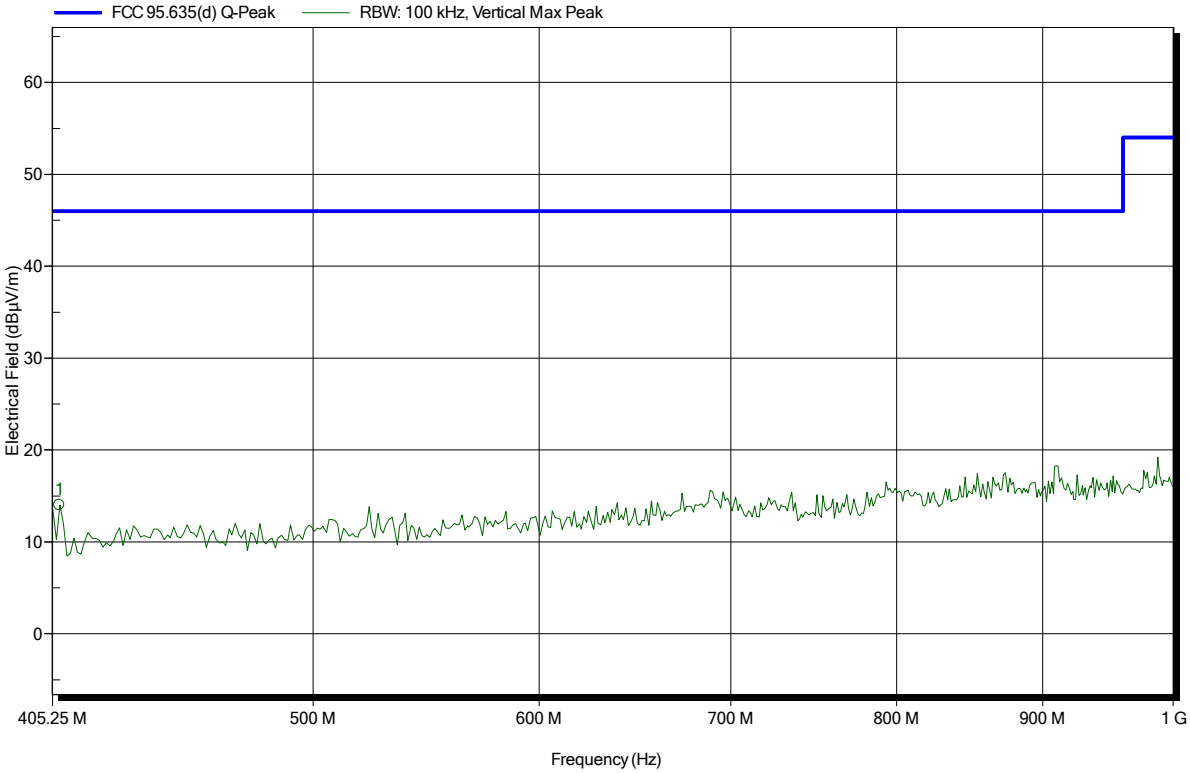

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
407.629 MHz	14 dBµV/m	46 dBµV/m	-32 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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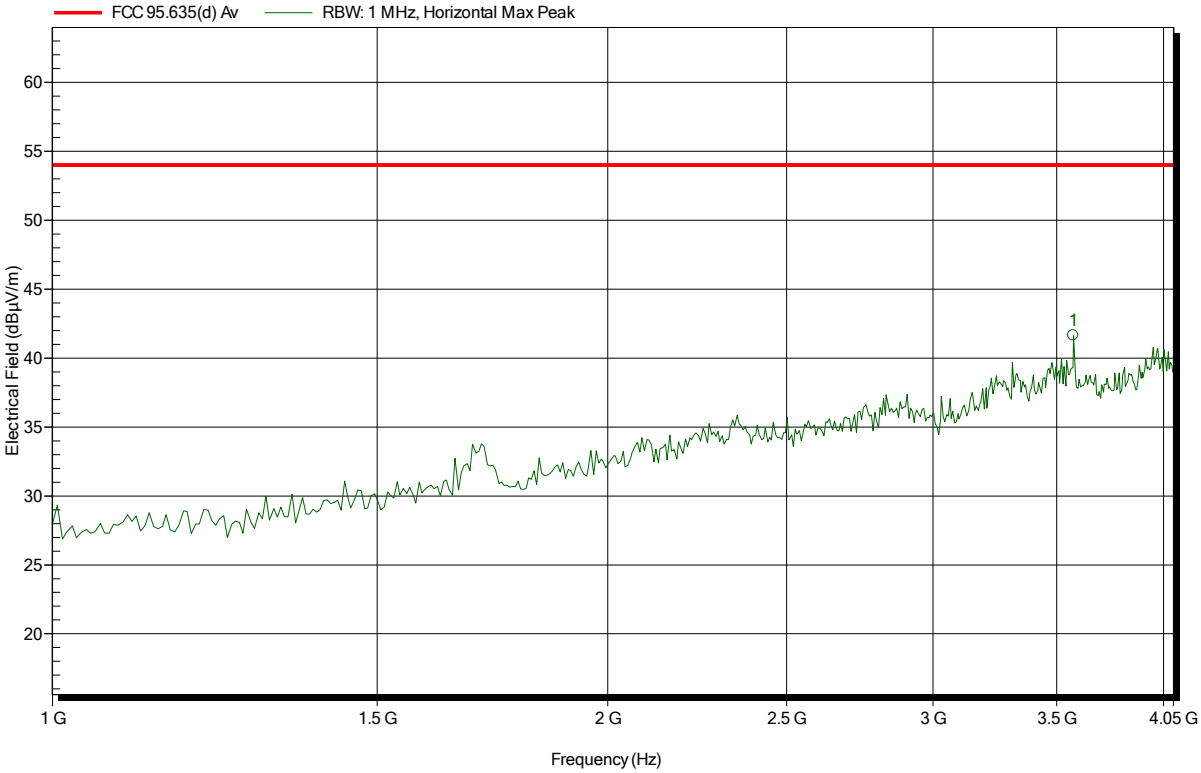

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
3.574 GHz	41.66 dBµV/m	54 dBµV/m	-12.34 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	

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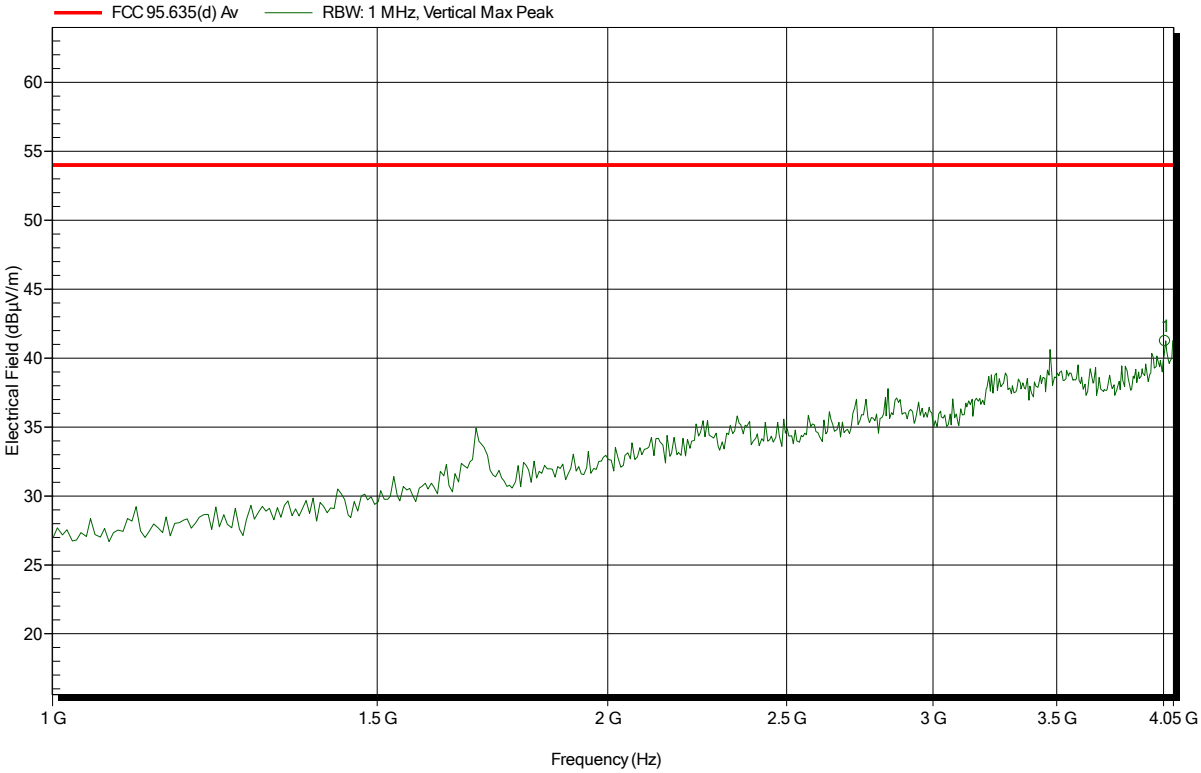

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
4.007 GHz	41.24 dBµV/m	54 dBµV/m	-12.76 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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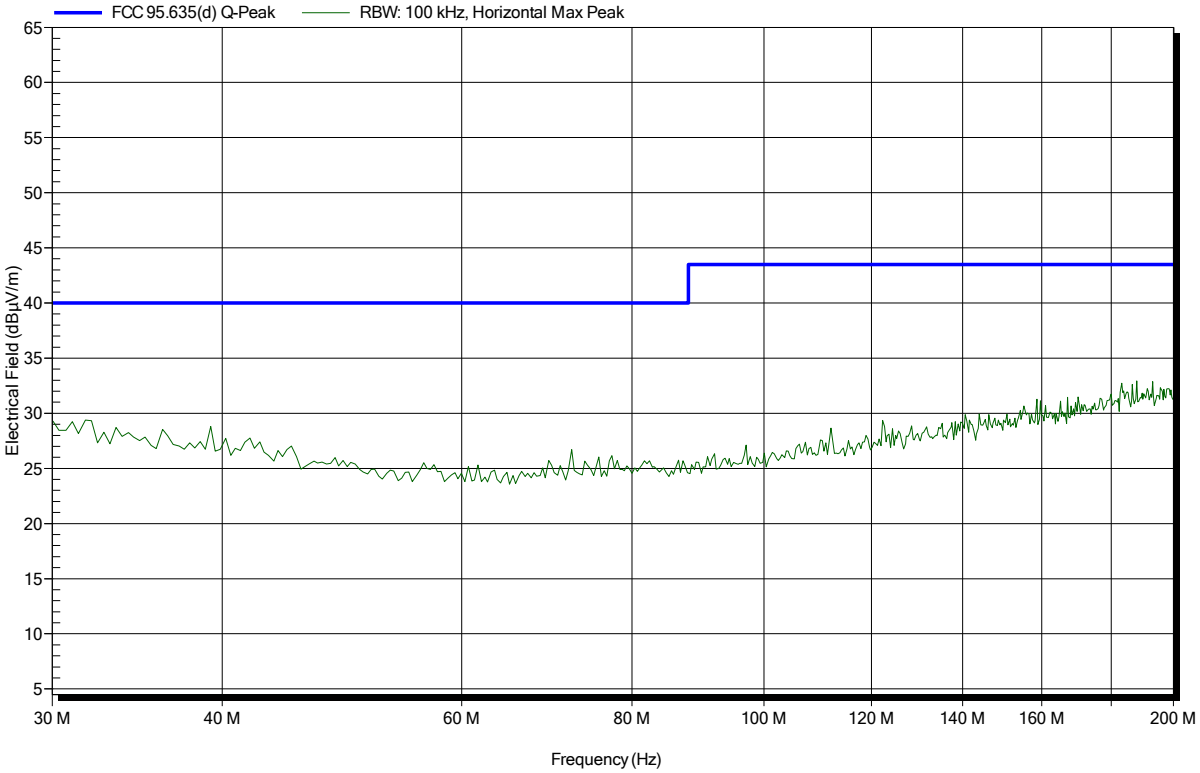

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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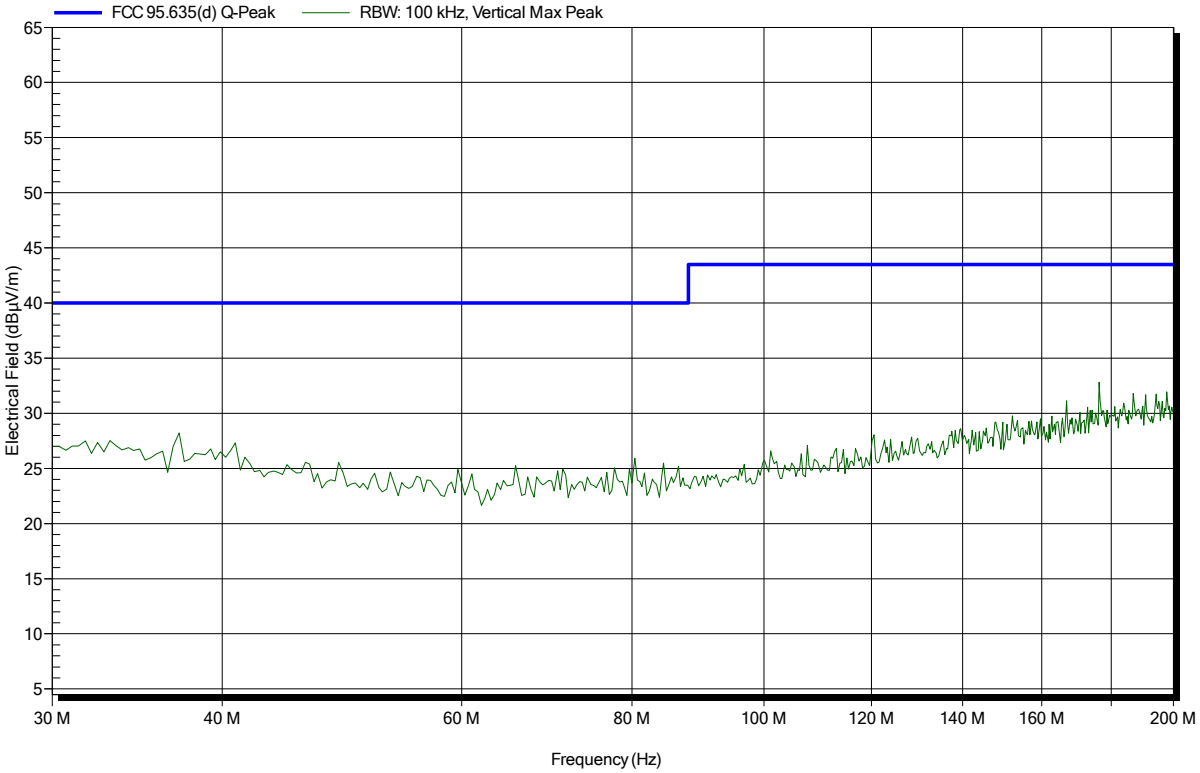

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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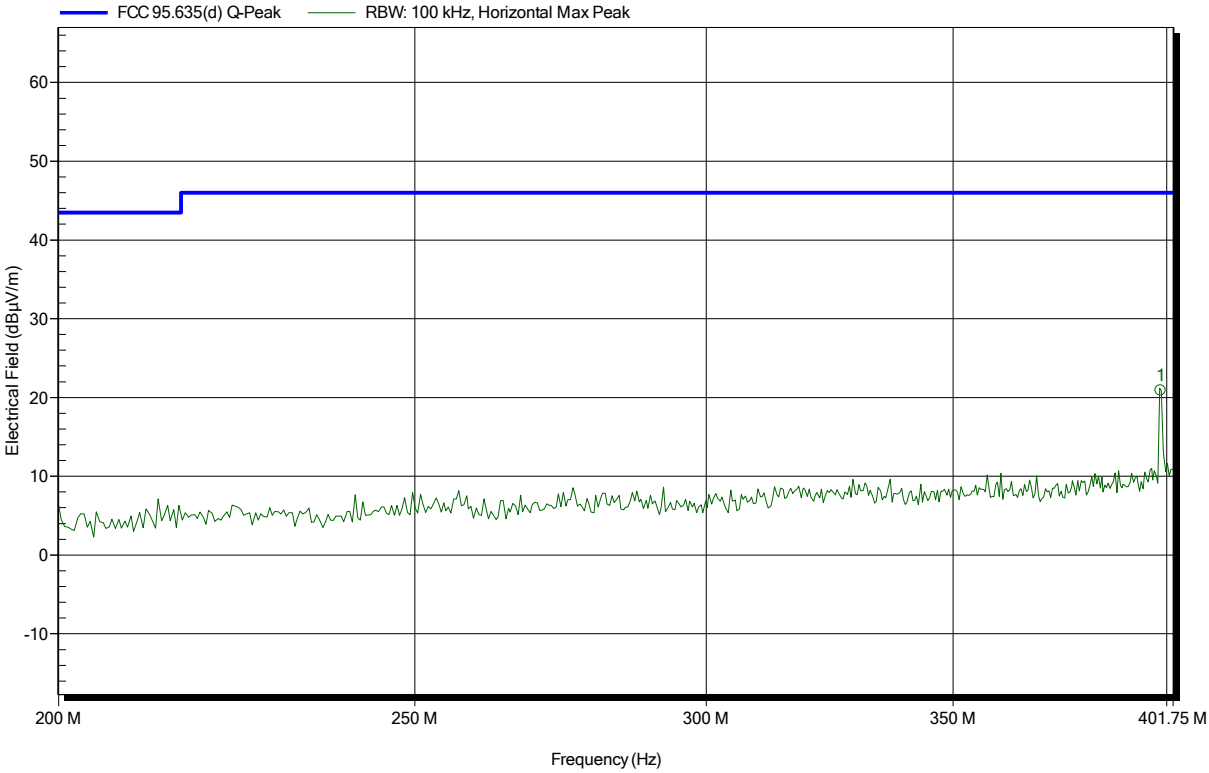

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
398.522 MHz	20.89 dBµV/m	46 dBµV/m	-25.11 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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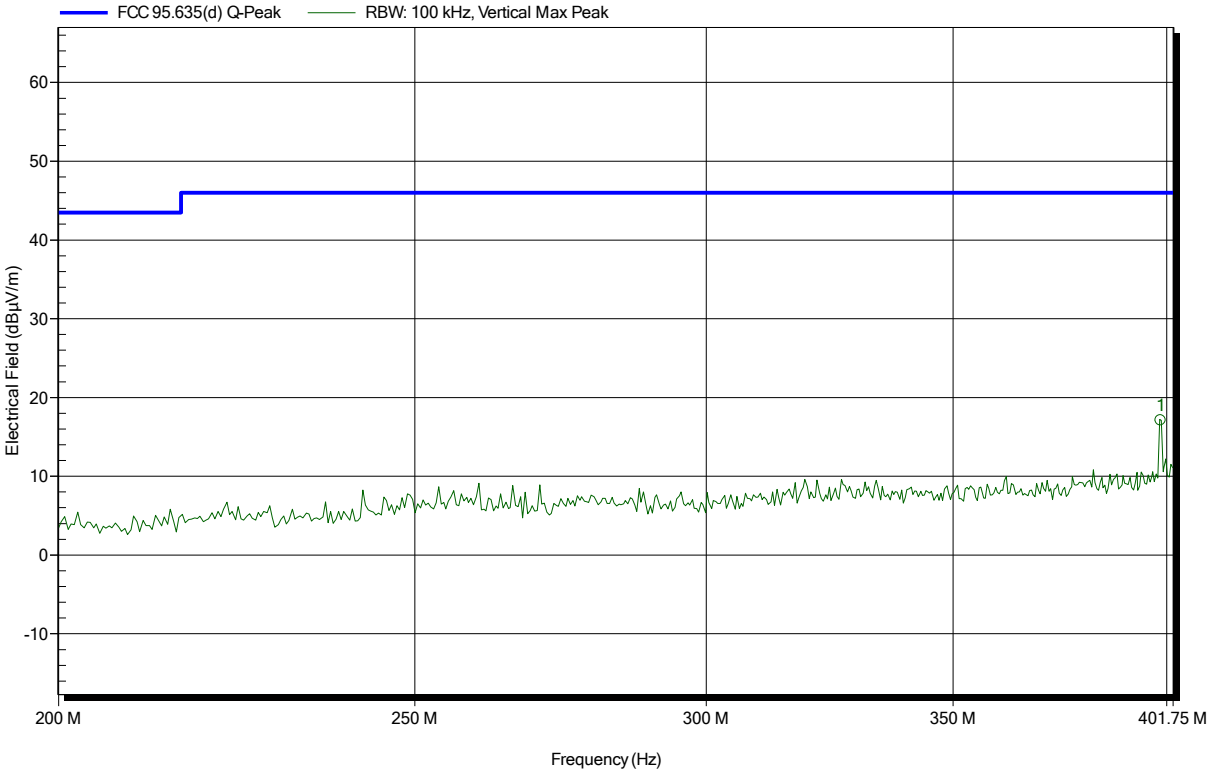

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
398.522 MHz	17.08 dBµV/m	46 dBµV/m	-28.92 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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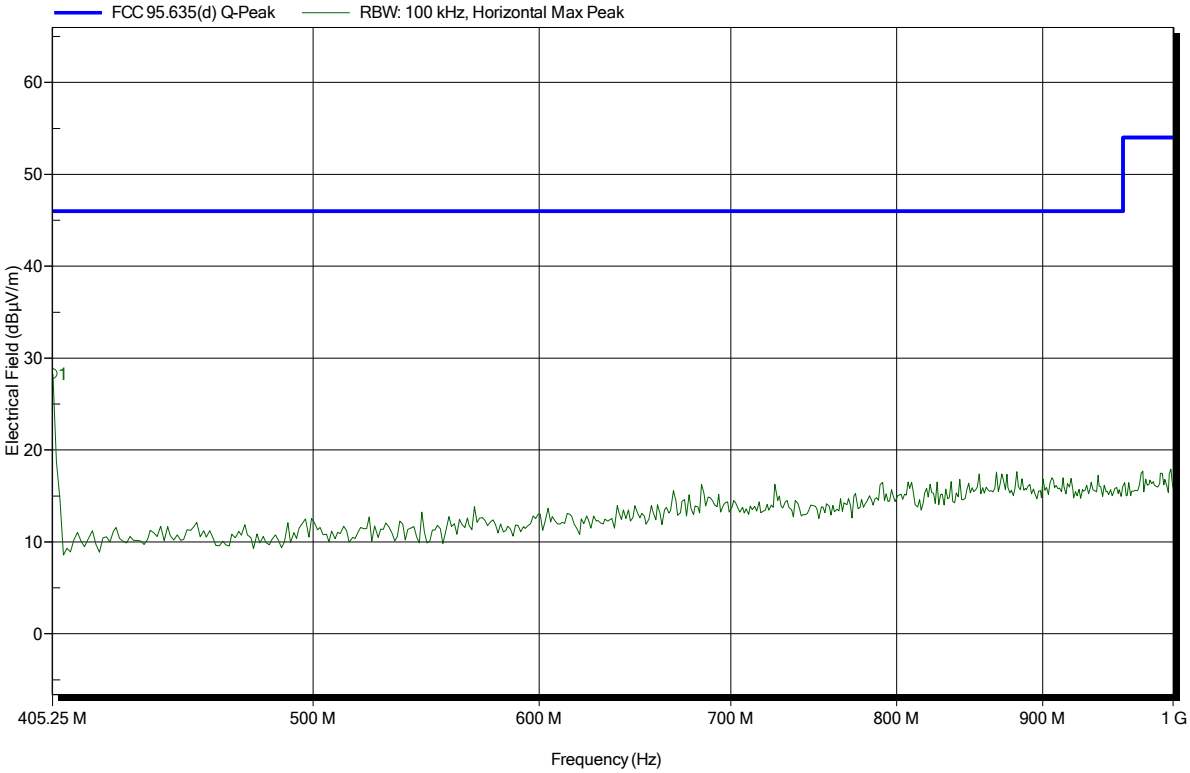

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	28.26 dBµV/m	46 dBµV/m	-17.74 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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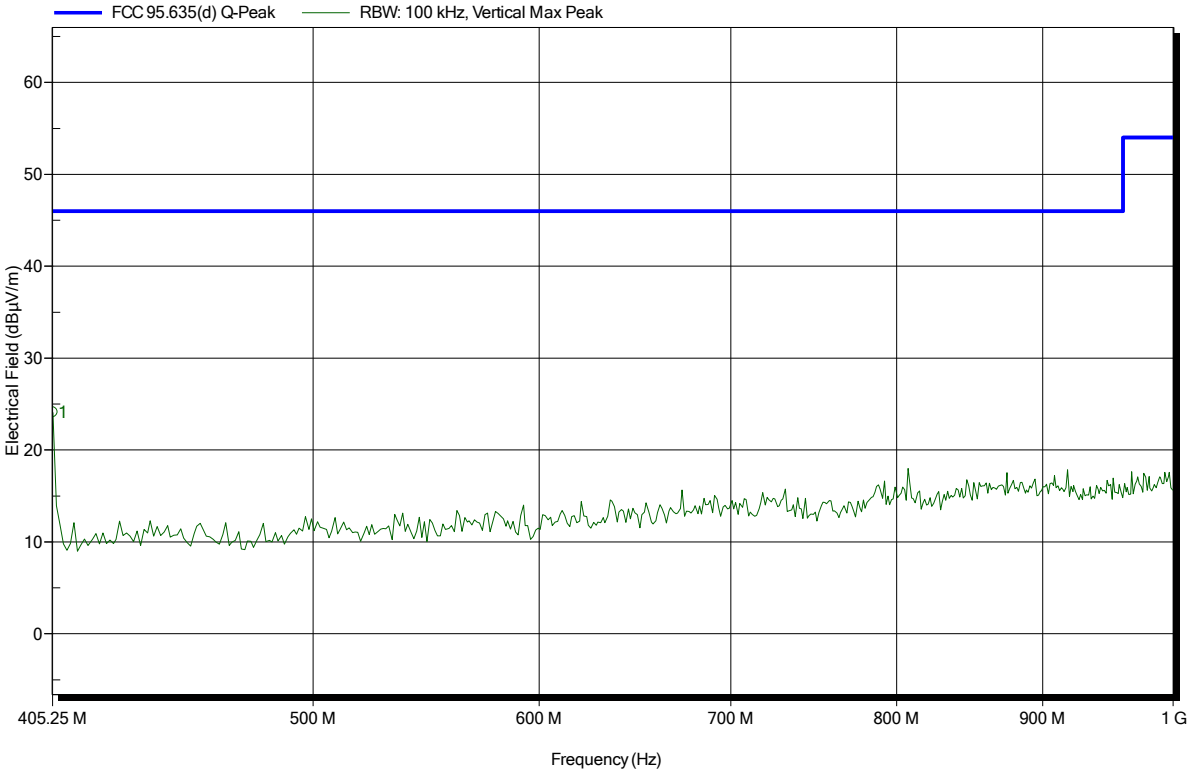

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	24.09 dBµV/m	46 dBµV/m	-21.91 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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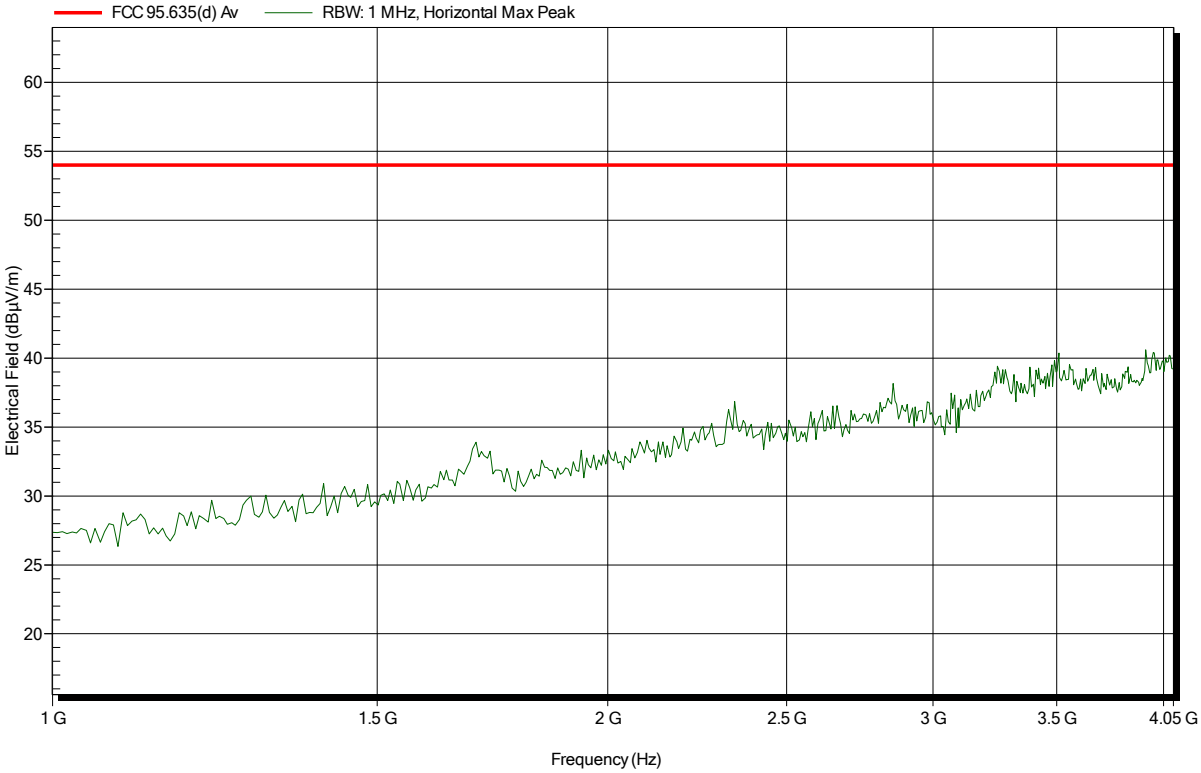

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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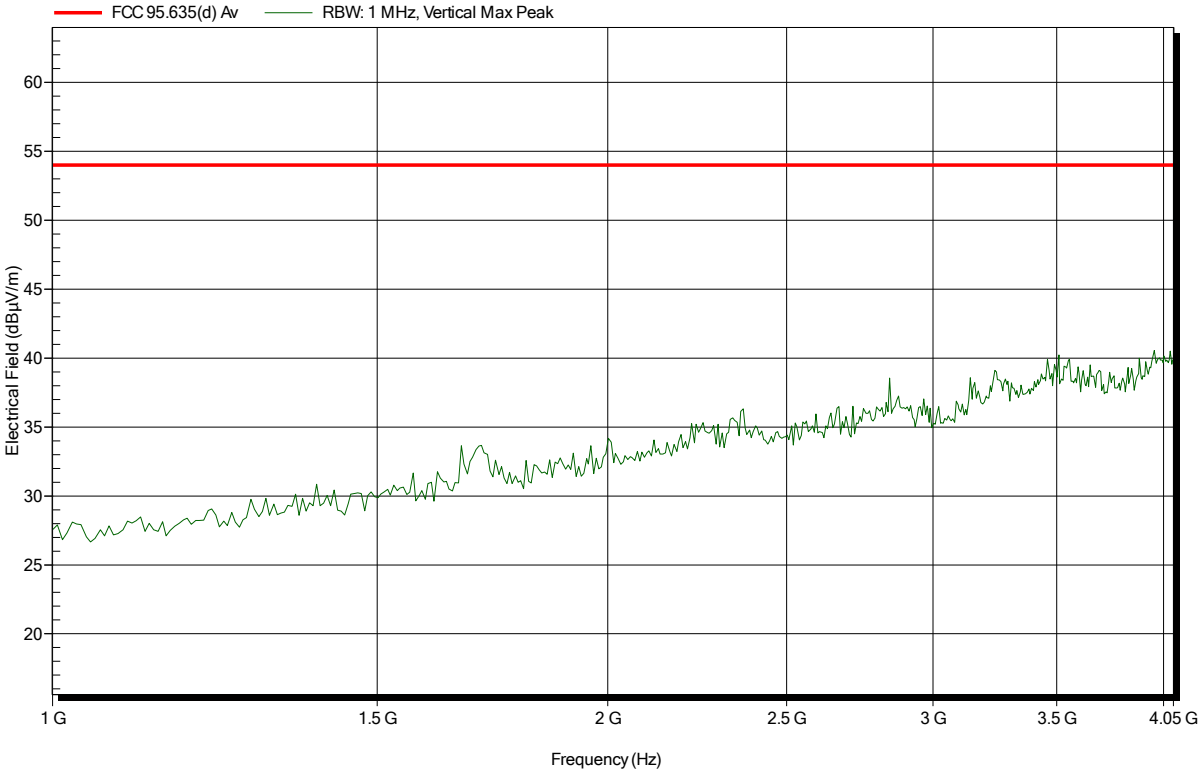

ANNEX C Transmitter In-band and Band-edge

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	Band-edge

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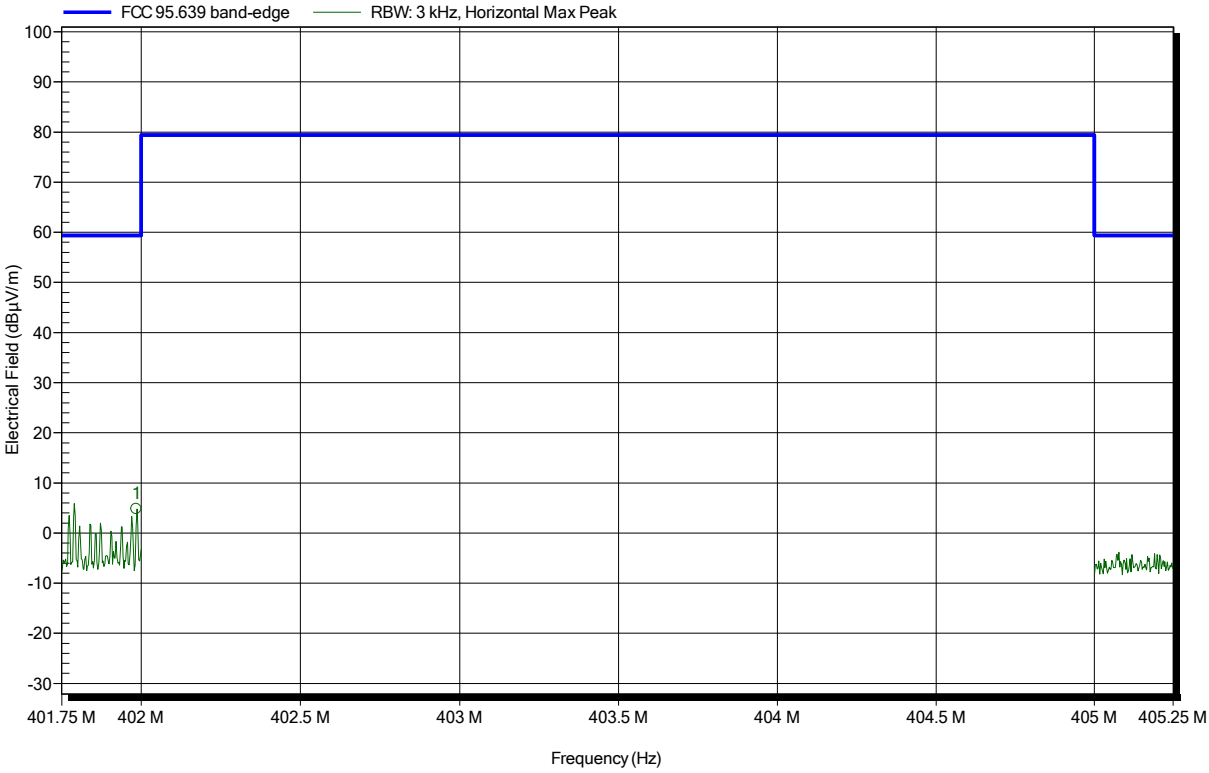

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.985 MHz	4.77 dBµV/m	59.4 dBµV/m	-54.63 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	Band-edge

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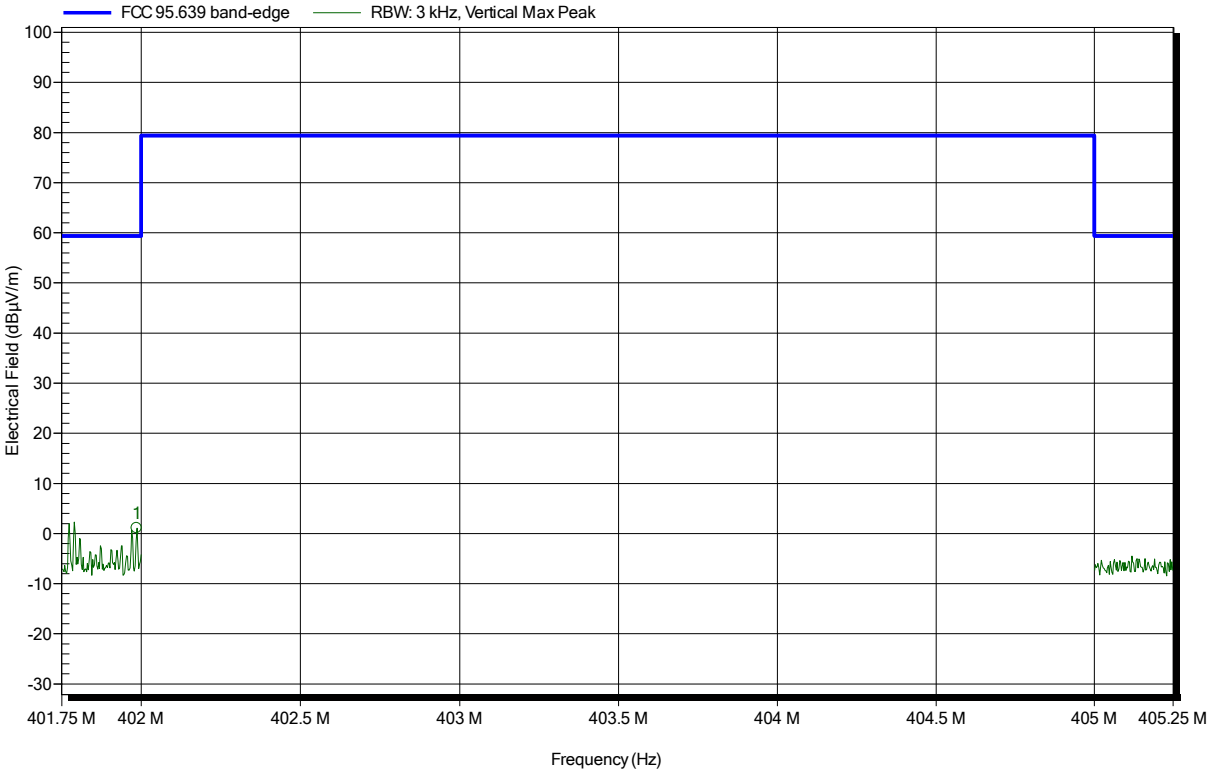

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.986 MHz	1.1 dBµV/m	59.4 dBµV/m	-58.3 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	In-band emissions

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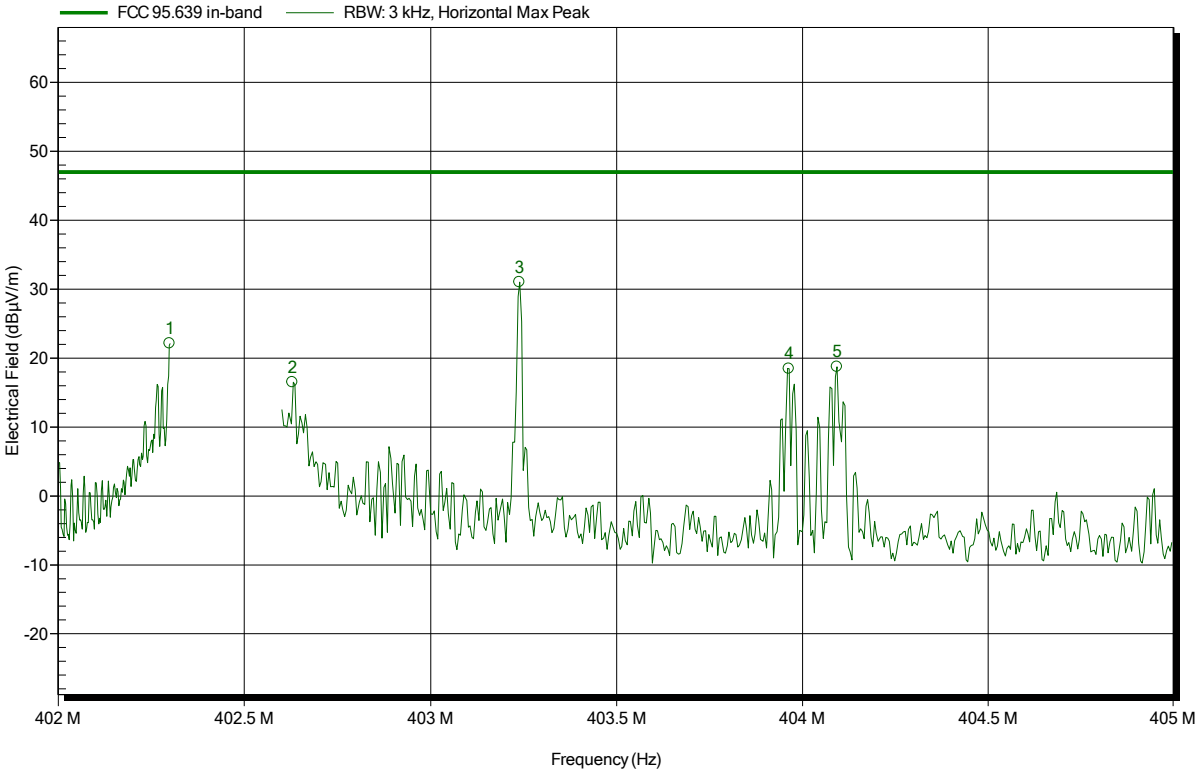

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.299 MHz	22.13 dBµV/m	47 dBµV/m	-24.87 dB	Pass
402.629 MHz	16.49 dBµV/m	47 dBµV/m	-30.51 dB	Pass
403.238 MHz	31.04 dBµV/m	47 dBµV/m	-15.96 dB	Pass
403.963 MHz	18.45 dBµV/m	47 dBµV/m	-28.55 dB	Pass
404.093 MHz	18.75 dBµV/m	47 dBµV/m	-28.25 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45 MHz
Test Date:	2016-12-01
Note:	In-band emissions

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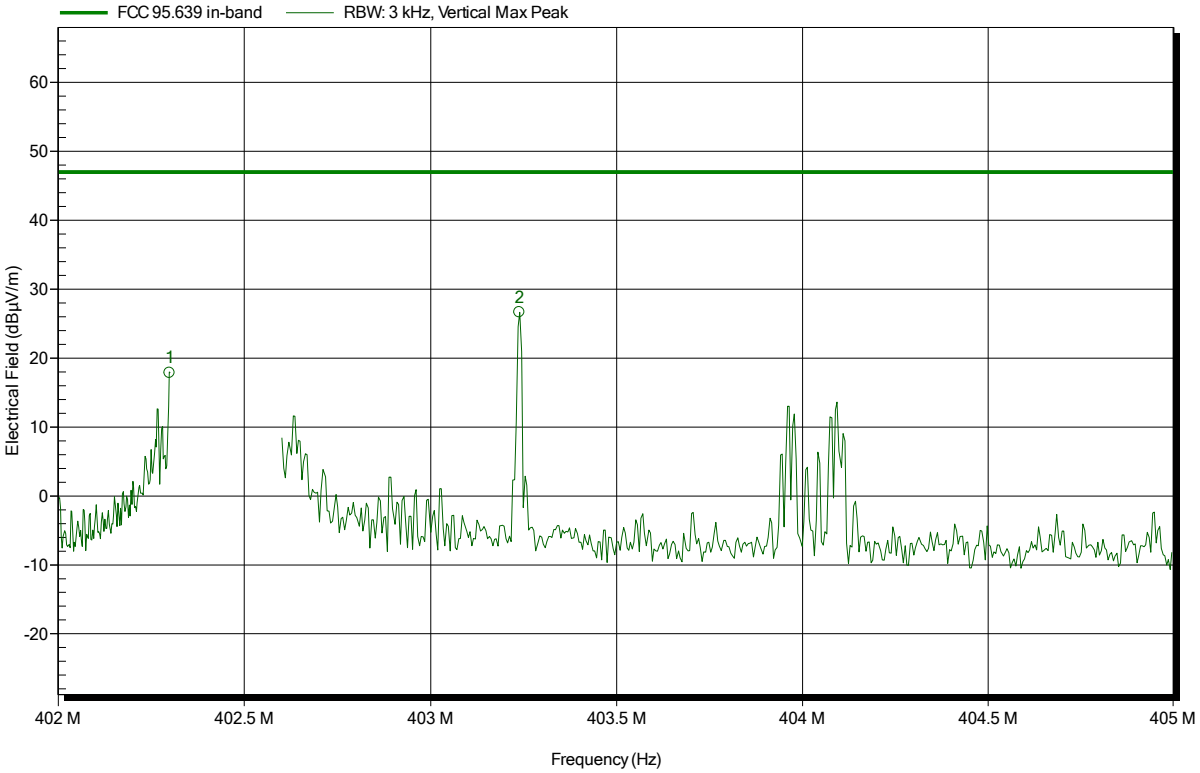

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.299 MHz	17.84 dBµV/m	47 dBµV/m	-29.16 dB	Pass
403.238 MHz	26.66 dBµV/m	47 dBµV/m	-20.34 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	Band-edge

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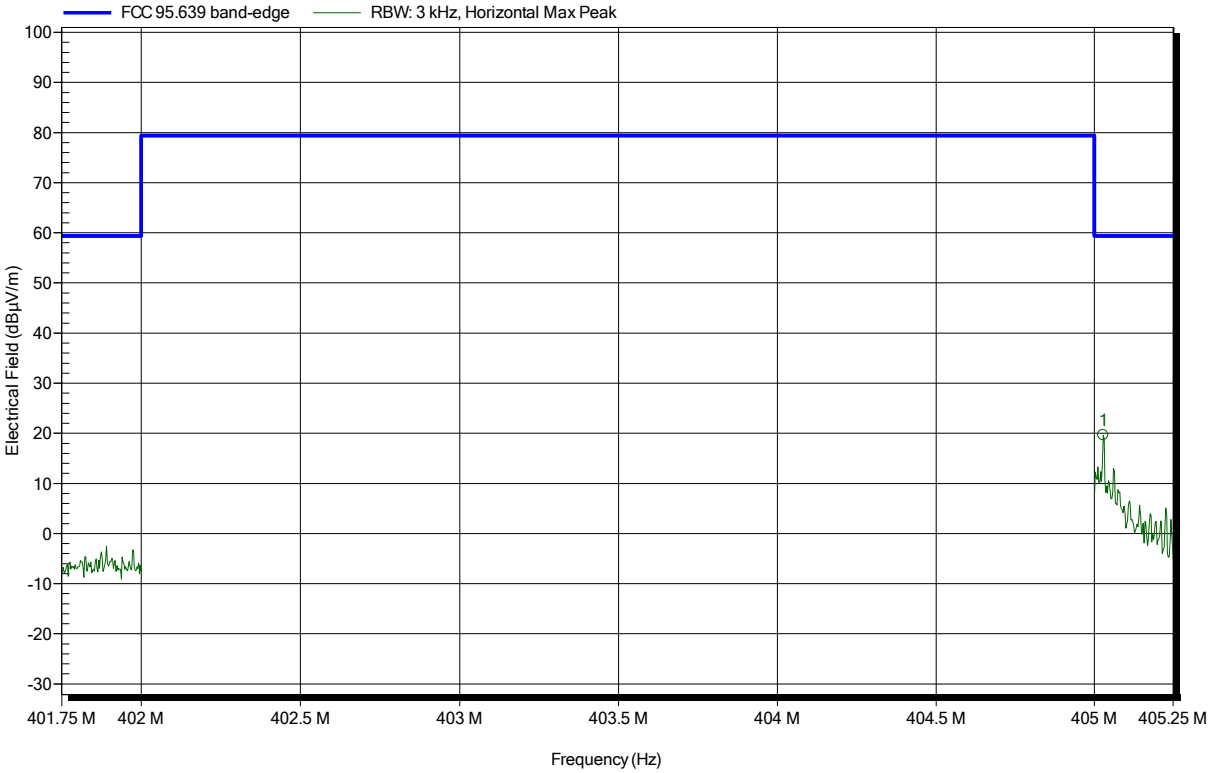

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.027 MHz	19.63 dBµV/m	59.4 dBµV/m	-39.77 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	Band-edge

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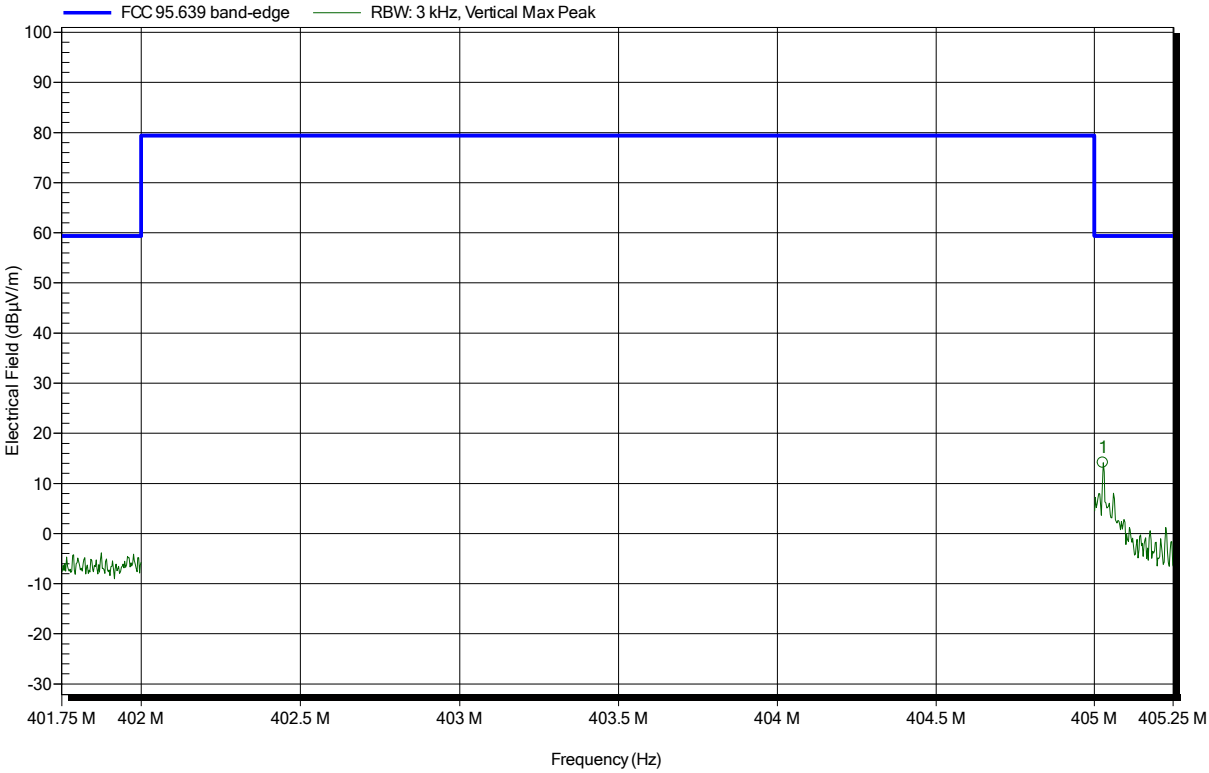

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.027 MHz	14.14 dBµV/m	59.4 dBµV/m	-45.26 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	In-band emissions

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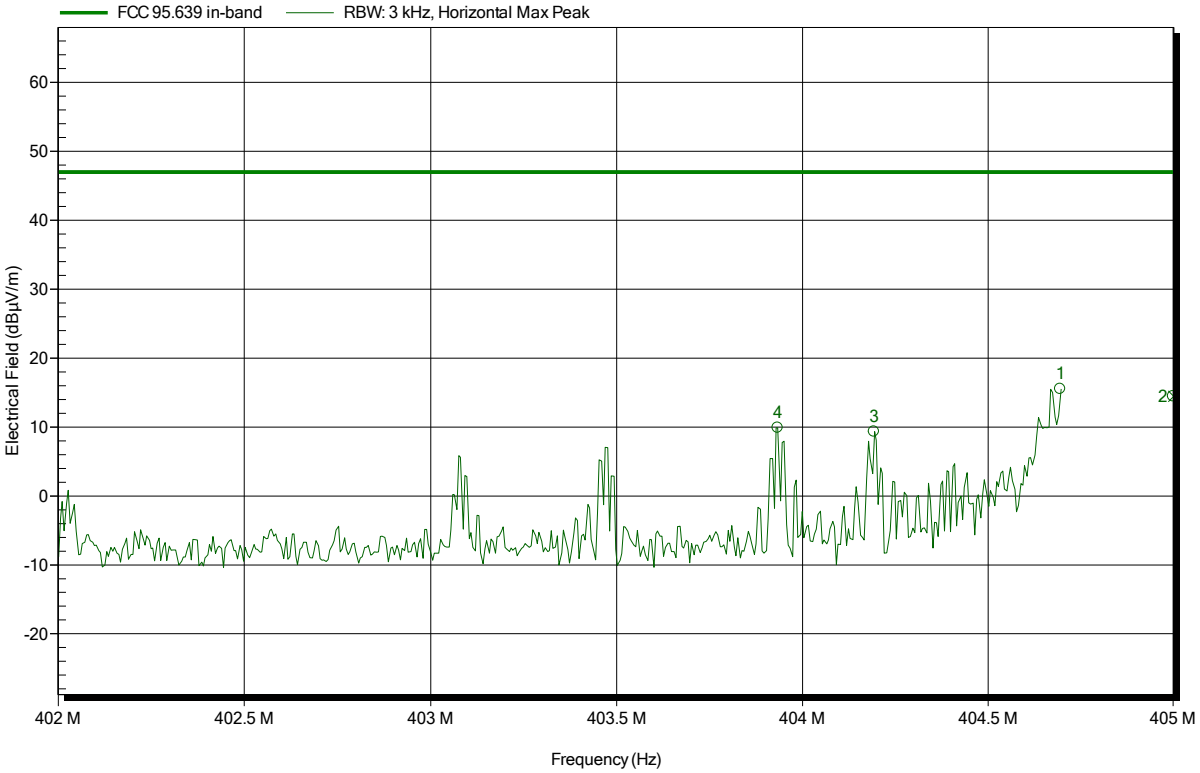

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403.933 MHz	9.89 dBµV/m	47 dBµV/m	-37.11 dB	Pass
404.192 MHz	9.33 dBµV/m	47 dBµV/m	-37.67 dB	Pass
404.695 MHz	15.53 dBµV/m	47 dBµV/m	-31.47 dB	Pass
404.999 MHz	14.46 dBµV/m	47 dBµV/m	-32.54 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	In-band emissions

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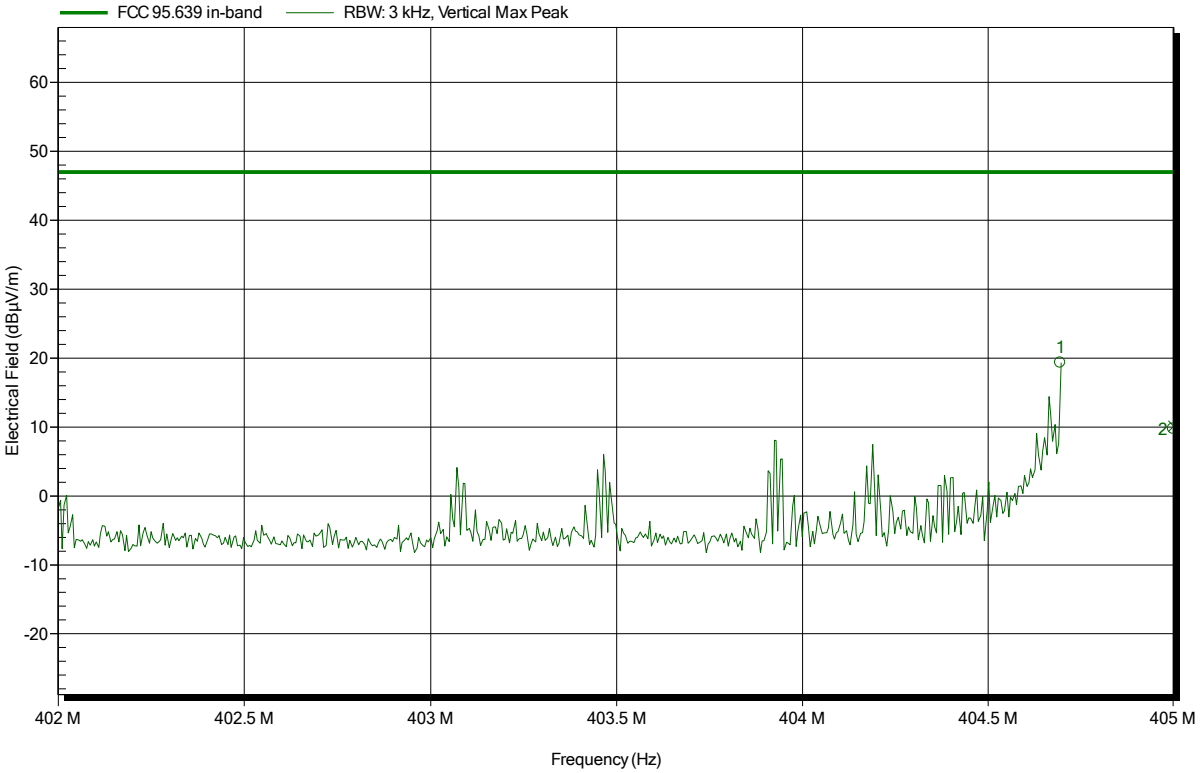

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.695 MHz	19.34 dBµV/m	47 dBµV/m	-27.66 dB	Pass
404.999 MHz	9.75 dBµV/m	47 dBµV/m	-37.25 dB	Pass

ANNEX D Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	RX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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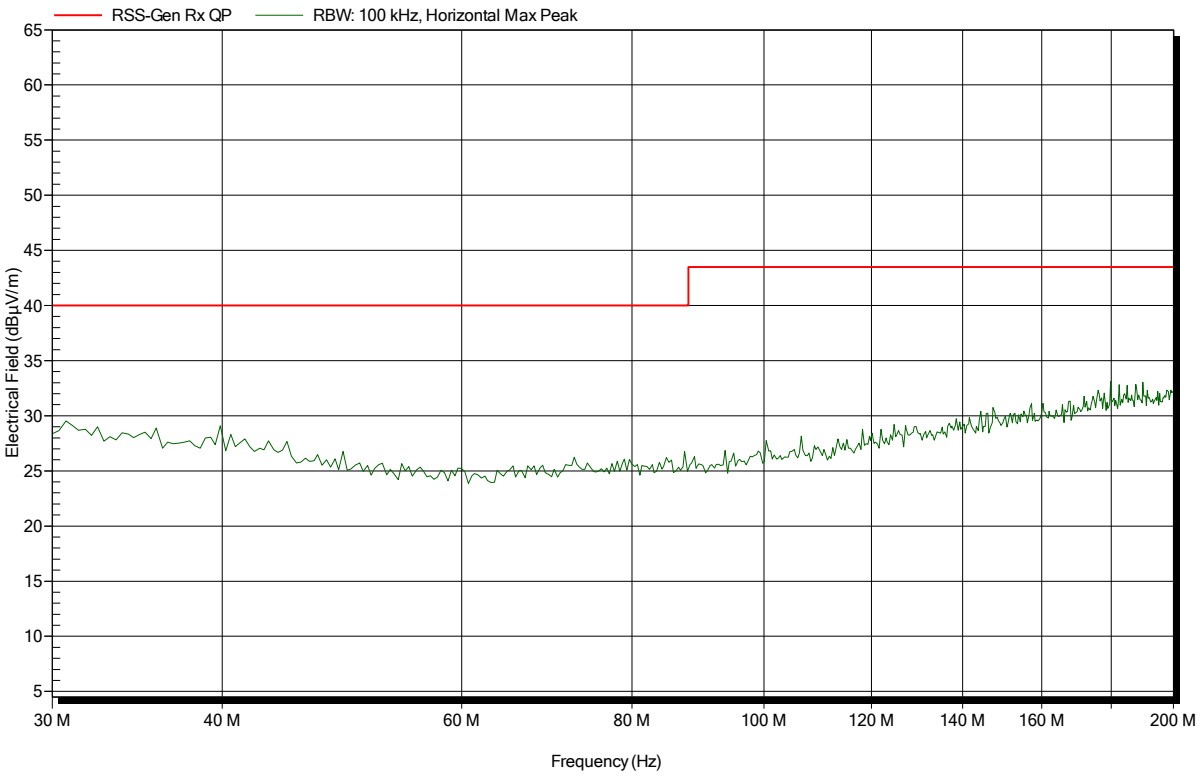

Spurious emissions according to RSS-Gen

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	RX; 2FSK; 404.85 MHz
Test Date:	2016-12-01
Note:	

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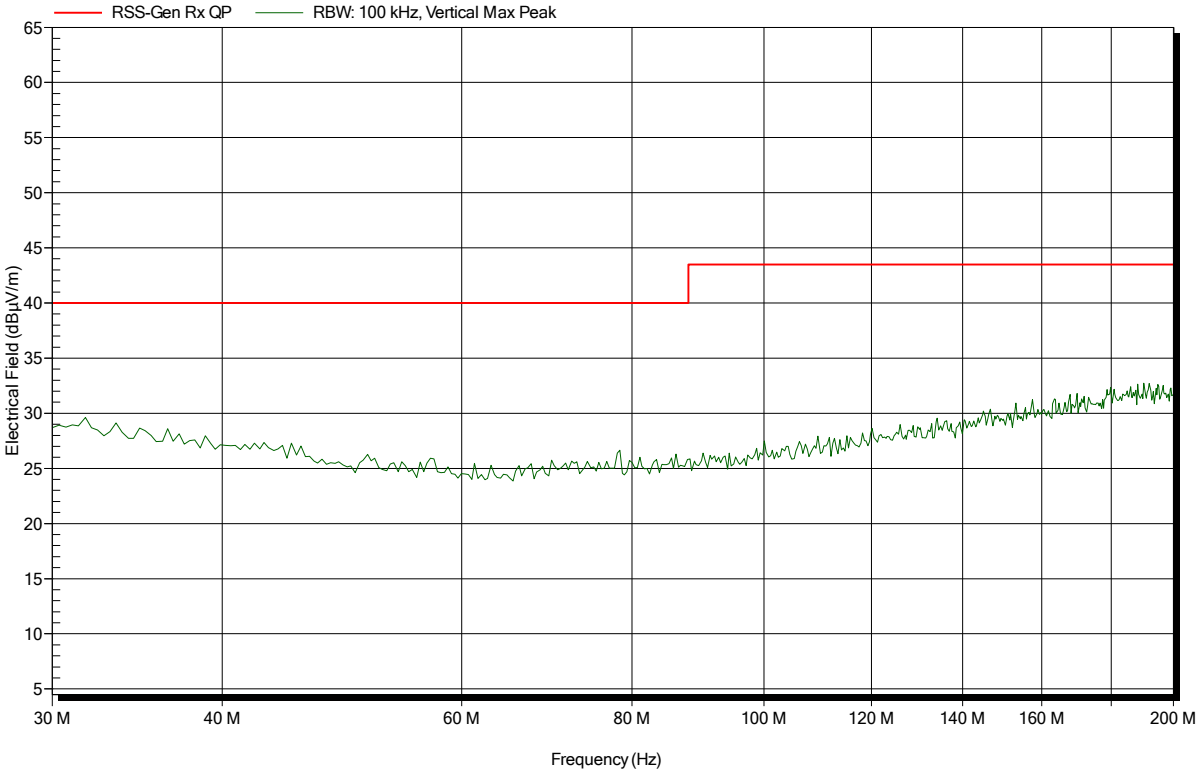

Spurious emissions according to RSS-Gen

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-12-01
Note:	

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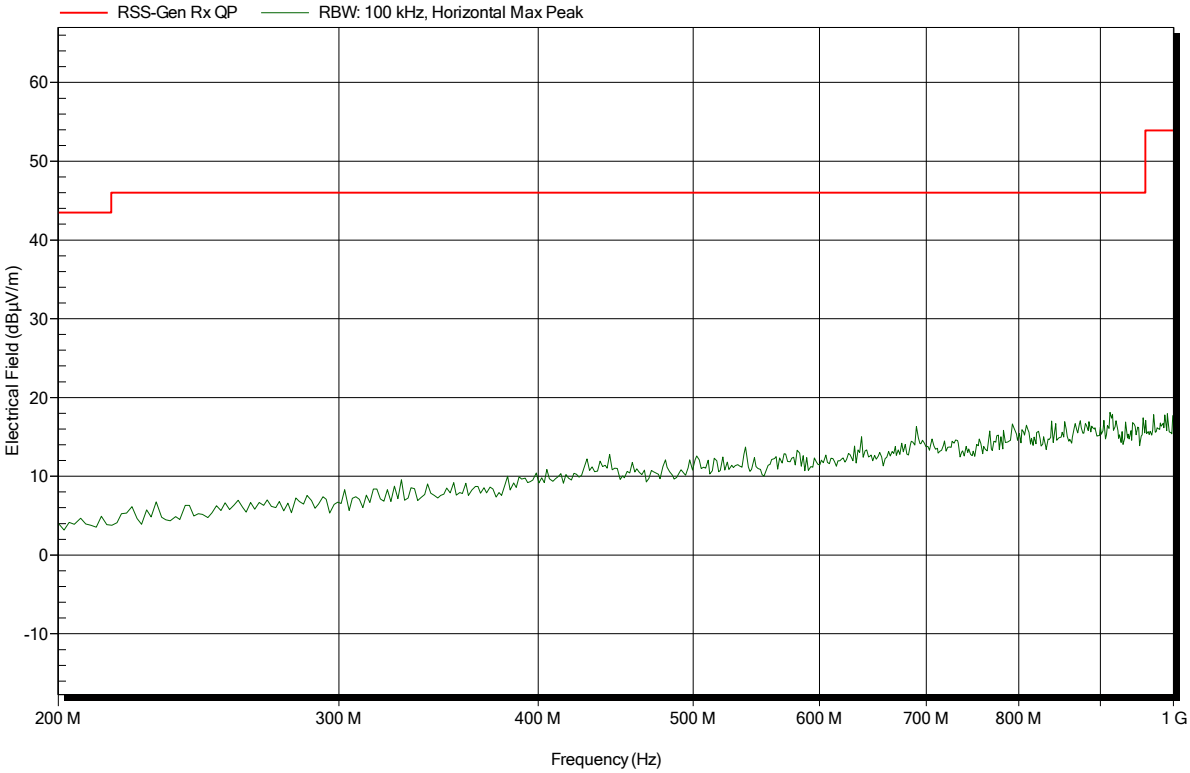

Spurious emissions according to RSS-Gen

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-12-01
Note:	

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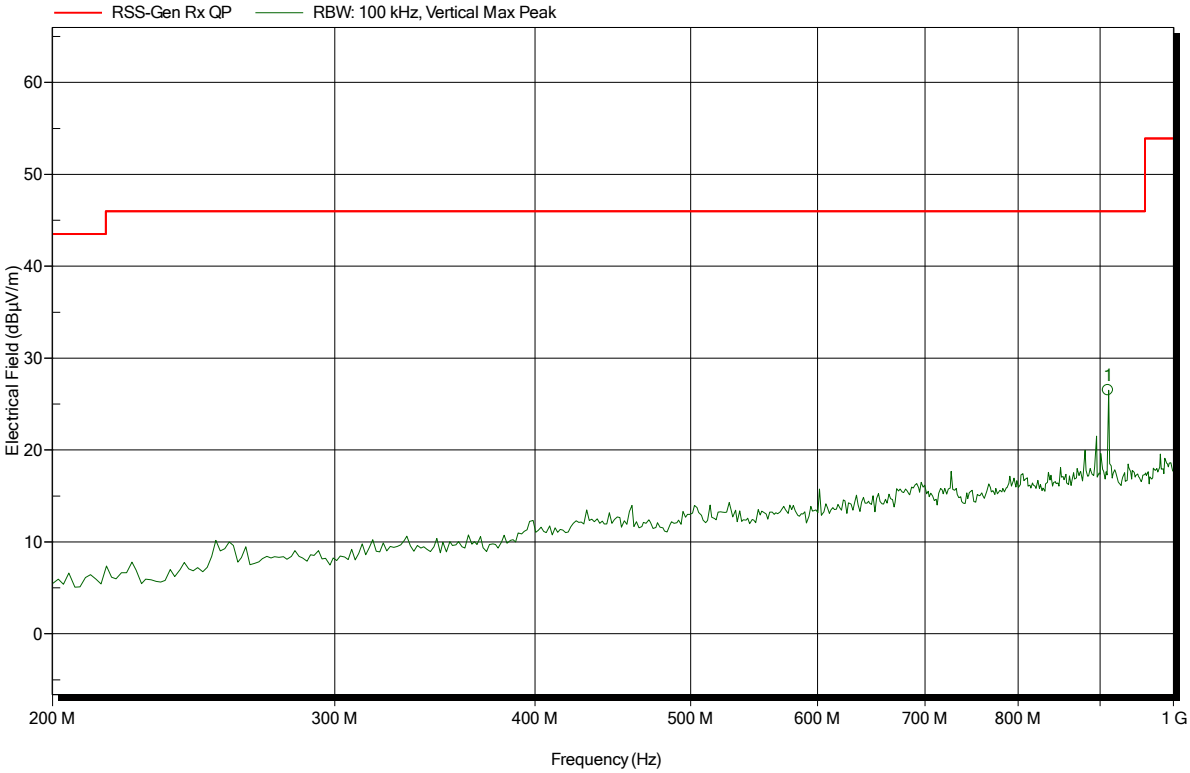

Frequency	Peak	Peak Limit	Peak Difference	Status
910.4 MHz	26.5 dBµV/m	46 dBµV/m	-19.5 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-12-01
Note:	

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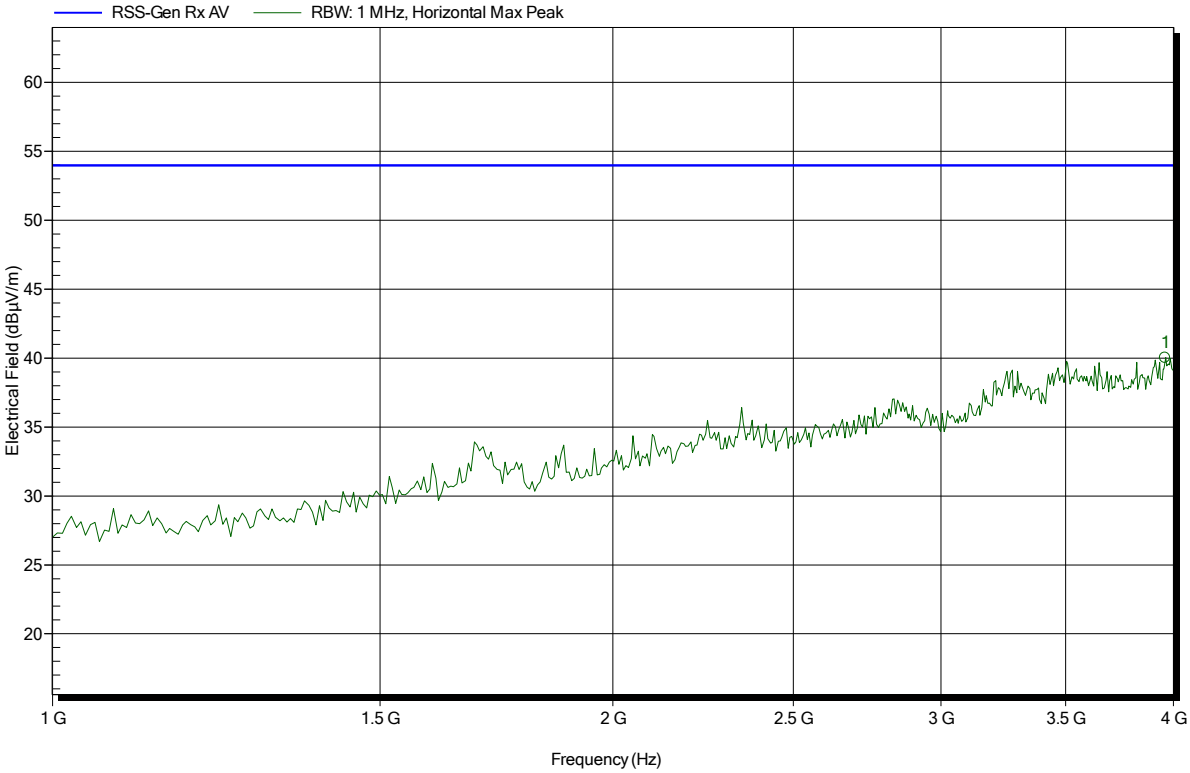

Frequency	Peak	Peak Limit	Peak Difference	Status
3.958 GHz	40.03 dBµV/m	53.98 dBµV/m	-13.95 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1611-6060

Applicant:	Biotronik SE & Co. KG
EUT Name:	Primus Nano Plus Pacemaker Family
Model:	Edora 8 HF-T SerNo: 66455499
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 100°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-12-01
Note:	

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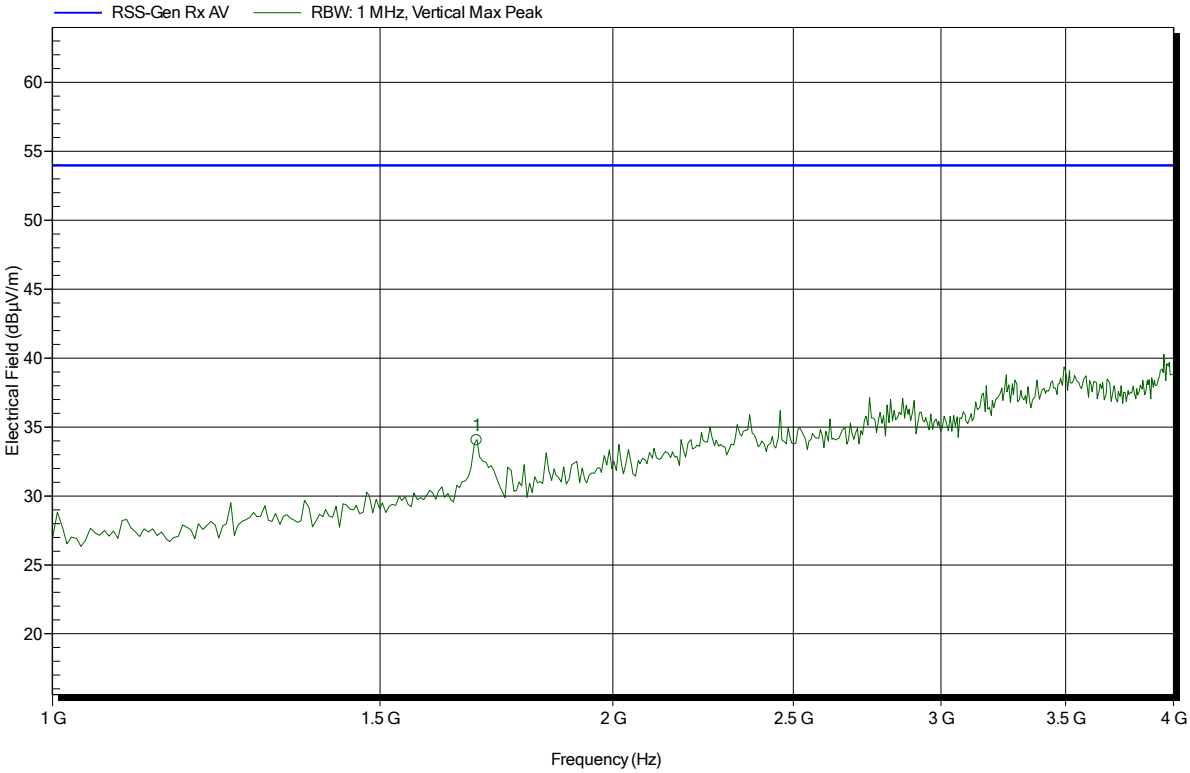

Frequency	Peak	Peak Limit	Peak Difference	Status
1.69 GHz	34.03 dBµV/m	53.98 dBµV/m	-19.95 dB	Pass