

RADIO REPORT FCC 47 CFR Part 95I Medical Device Radiocommunication Service (MedRadio) ISED RSS 243 Medical Devices Operating in the 401 – 406 MHz Frequency Band	
Report Reference No	G0M-1807-7555-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 Test Firm Designation Number: DE0008 IC Testing Laboratory site: 3470A-2
Applicant	Biotronik SE & Co. KG
Address	Woermannkehe 1 12359 Berlin GERMANY
Test Specification	According to FCC/ISED rules
Standard	47 CFR Part 95I RSS-243, Issue 3, 2010-02
Non-Standard Test Method	None
Test Scope	Partial Radio compliance test
Equipment under Test (EUT):	
Product Description	Primus Nano Plus IPG / Implantable Pulse Generator
Model(s)	Edora 8 DR-T
Additional Model(s)	None
Additional Variant(s) not tested	See attached model matrix
Brand Name(s)	BIOTRONIK
Hardware Version(s)	BOM-0339, SCH-0186, ASM-0476
Software Version(s)	7801RomRev_02.02 / 7801RamRev_02.03
FCC-ID	QRIPNP
IC	4708A-PNP
Test Result	PASSED

Test Report No.: G0M-1807-7555-TFC95IMR-V01

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

Possible test case verdicts:		
required by standard but not tested	N/T	
not required by standard	N/R	
not applicable to EUT	N/A	
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	2018-08-14	
Report:		
Compiled by	Wilfried Treffke	
Tested by (+ signature) (Responsible for Test)	Wilfried Treffke	
Approved by (+ signature) (Head of Lab)	Christian Weber	
Date of Issue	2018-09-12	
Total number of pages	60	
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:

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.

DR-T are dual-chamber devices.

SR-T are single-chamber devices with additional atrial detection.

SR are single-chamber without home monitoring software. All variants are available with DF-4.

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

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

Family Certification

List of Models to be included in the family

(1) Applicant:	<u>BIOTRONIK SE & CO. KG</u>
(2) Certification Number:	_____

No.	Model Name / PMN	HVIN	Description of Differences
1	Edora 8 DR-T (Master)	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
2	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
3	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
4	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
5	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
6	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
7	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
8	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
9	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
10	Enticos 8 SR-T	407160	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Premium-Tier Software Features (Brand 4)

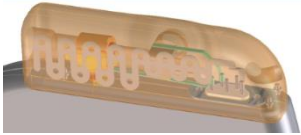
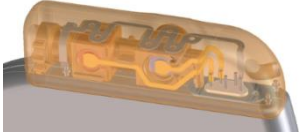
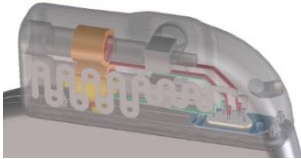
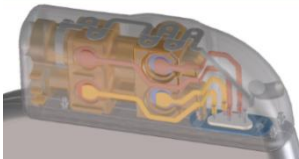
			With Home Monitoring
11	Evity 6 DR-T	407149	2 chamber, 2x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
12	Evity 6 SR-T	407161	1 chamber, 1x IS-1 Connector, BOM-0339, SCH-0186, ASM-0476 Mid-Tier Software Features (Brand 2) With Home Monitoring and MRI Software
13	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
14	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
15	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
16	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

Minor hardware changes to Primus Nano Plus pacemaker family

Herewith we like to inform about a hardware change of Primus Nano Plus pacemaker family. Due to cost optimization and optimization of manufacturability the following changes were made:

- Adjustments to RF antenna shape (single chamber and dual chamber devices only)
- Change from vertical to horizontal alignment of RF antenna inside the epoxy header of the devices (single chamber and dual chamber devices only)
- No changes to schematics, assembly and PCB were done

Please see below a summary of the applied changes and assignment to the relevant hardware versions:

HW version	Object	Old (drawing no.)	New (drawing no.)
PNP SR (-T)	Antenna shape and alignment	397493 	430006 
PNP DR (-T)	Antenna shape and alignment	397493 	430326 

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2018-09-12	Initial Release	

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
RBW	Resolution bandwidth
RMS	Root mean square
VBW	Video bandwidth
V _{NOM}	Nominal supply voltage

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1 Equipment (Test Item) Under Test

Description	Primus Nano Plus IPG / Implantable Pulse Generator	
Model	Edora 8 DR-T	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Serial Number(s)	69195717	
Hardware Version(s)	BOM-0339, SCH-0186, ASM-0476	
Software Version(s)	7801RomRev_02.02 / 7801RamRev_02.03	
PMN	Edora 8 DR-T	
HVIN	407145	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRIPNP	
IC	4708A-PNP	
Equipment type	End Product	
Radio type	Transceiver	
Assigned frequency bands	402 - 405 MHz	
Radio technology	MedRadio (MICS) active medical implant	
Modulation	FSK	
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 antenna ports	1	
Antenna	Type	integrated
	Model	PNP Mini Rings
	Manufacturer	Biotronik SE & Co. KG
	Gain	-29.65 dBi (Determined by measurements)
Supply Voltage	V _{NOM}	3.0 VDC
Operating Temperature	T _{NOM}	25 °C
AC/DC-Adaptor	Model	None
	Vendor	None
	Input	None
	Output	None
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

1.5 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE1	Communication Adaptor	Biotronik	Tell Box II	-
AE2	Programmerkopf	Biotronik	Renamic PGH 3000	-
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
Comment:				

1.6 Test mode duty cycle

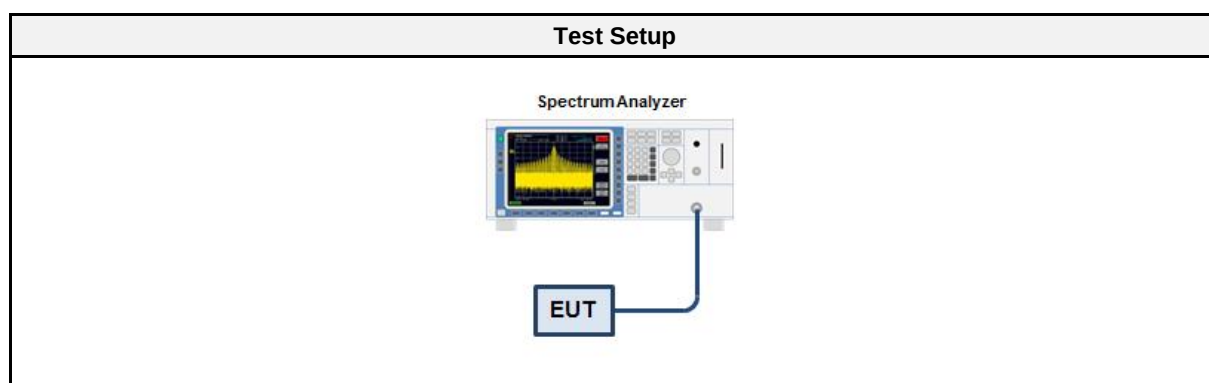
1.6.1 Information

Test Information	
Measurement Method	ANSI C63.10 11.6

1.6.2 Requirements

Requirements	
Duty cycle	Duty cycle correction
$\geq 98 \%$	No correction required
$< 98 \%$	Correction required ($10 \times \log_{10}(1/DC)$)

1.6.3 Setup



1.6.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 3	EF00241	2017-07	2019-07

1.6.5 Procedure

Test Procedure
1. EUT set to test mode 2. Span is set to zero span 3. Detector set to peak 4. Sweep time is set long enough to capture at least 5 bursts 5. Envelope peak value of emission spectrum is selected 6. The maximum burst duration T_{ON} is measured using two markers set to the start and the end of the longest burst 7. The minimum idle duration T_{OFF} is measured using two markers set to the start and the end of the shortest idle period 8. The duty cycle is calculated by $DC = T_{ON} / (T_{ON} + T_{OFF})$ 9. The duty cycle correction is calculated by $DC = 10 \times \log_{10}(T_{ON} / (T_{ON} + T_{OFF}))$

1.6.6 Results

Duty Cycle Results		
Mode	Duty Cycle	Correction Factor [dB]
Modulated	100 %	0

1.7 Test Modes

Mode	Description
Unmodulated	Mode = Transmit Modulation = None
Modulated	Mode = Transmit Modulation = FSK Power level = maximum
Receive	Mode = Receive Modulation = FSK
Comment:	

1.8 Test Frequencies

Designator	Mode	Channel	Frequency [MHz]
F1	Tx / Rx	8	402.45
F2	Tx / Rx	0	403.65
F3	Tx / Rx	7	404.85

1.9 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:

$$\text{Reading on Analyzer (dB}\mu\text{V)} + \text{A.F. (dB)} = \text{Net field strength (dB}\mu\text{V/m)}$$

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:

$$\text{Limit (dB}\mu\text{V/m)} = 20 \cdot \log (\mu\text{V/m})$$

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

1.10 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]	9.08	8.8	-2.22

2 Result Summary

FCC 47 CFR Part 95E, 95I, 15C, ISED RSS-243, ISED RSS-Gen				
Product Standard Reference	Requirement	Reference Method	Result	Remarks
ISED RSS-243 Issue 3 ISED RSS-Gen 6.6 Issue 5	Occupied Bandwidth	RSS-Gen 6.6 Issue 5	N/R	Informational only
FCC 95.628(d) FCC § 95.633(e)	Emission Bandwidth	FCC 95.628(a)(6)(i) FCC § 95.633(e)(3)	N/T	
FCC 95.628(e) ISED RSS-243 3.3, 5.3 Issue 3, RSS-Gen 8.11 Issue 5	Frequency stability	EN 301 839-1 8.1	N/T	
FCC § 95.6369(f) ISED RSS-243 § 5.4 Issue 3	Transmitter output power	EN 301 839-1 8.3	N/T	
FCC § 95.635(d) ISED RSS-243 § 3.4, 5.5 Issue 3	Band edge compliance	FCC § 95.635(d) ANSI C63.4-2014	PASS	
FCC § 95.635(d) ISED RSS-243 § 3.4, 5.5 Issue 3 RSS-Gen 6.13 Issue 5	Transmitter unwanted emissions	FCC § 95.635(d) ANSI C63.4-2014	PASS	
ISED RSS-243 3.5, 5.6 Issue 3 ISED RSS-Gen 7.1 Issue 5	Receiver spurious emissions	ANSI C63.4-2014	PASS	
FCC § 15.207 ISED RSS-Gen 8.8 Issue 5	AC power line conducted emissions	ANSI C63.4-2014	N/A	EUT battery powered
FCC § 95.628(a)(3) ISED RSS-243 3.6, 5.7.1 Issue 3	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) ISED RSS-243 3.6, 5.7.2 Issue 3	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) ISED RSS-243 3.6, 5.7.3 Issue 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) ISED RSS-243 3.6, 5.7.4 Issue 3	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) ISED RSS-243 3.6, 5.7.5 Issue 3	Channel Access	EN 301 839-1 10.4	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(4) ISED RSS-243 3.6, 5.7.6 Issue 3	Discontinuation of MICS of MEDS session	EN 301 839-1 10.5	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(5) ISED RSS-243 3.6, 5.7.7 Issue 3	Use of the pre-scanned alternate channel	EN 301 839-1 10.6	N/A	Applies only to equipment by which LBT is performed
Comment:				

Possible Test Case Verdicts	
PASS	Test object does meet the requirements
FAIL	Test object does not meet the requirements
N/T	Required by standard but not tested
N/R	Not required by standard for the test object

3 Test Conditions and Results

3.1 Test Conditions and Results - Band-edge and In-band Emissions

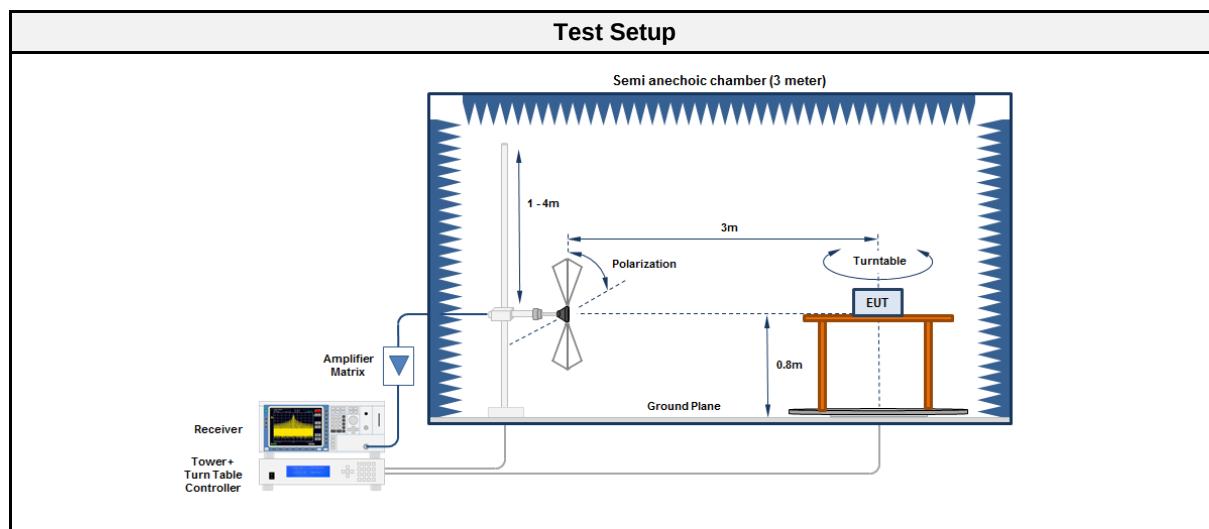
3.1.1 Information

Test Information	
Reference	FCC 95.635(d) / ISED RSS-243 3.5 5.5 / RSS-Gen 4.9
Measurement Method	FCC 95.635(d) / ANSI C 63.4
Operator	Wilfried Treffke
Date	2018-08-14

3.1.2 Limits

Limits FCC	
Frequency range	Limit
402 MHz – 250 kHz $\leq f \leq$ 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 $\leq f \leq$ 405 MHz + 250 kHz	20 dB below maximum permitted output power
Limits ISED	
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
The FCC limits are more stringent than the ISED limits, that is why the FCC limits are used to fulfil the band-edge emission requirements	

3.1.3 Setup



3.1.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2017-02	2020-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2017-08	2018-08
Antenna	R&S	HL 223	EF00187	2016-05	2019-05

Test Report No.: G0M-1807-7555-TFC95IMR-V01

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

3.1.5 Procedure

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

3.1.6 Results

Test Results					
Channel [MHz]	Emission [MHz]	Level [dBμV/m]	Pol.	Limit [dBμV/m]	Margin [dB]
402.45	402.283	30.31	ver	48.80	-18.49
402.45	402.284	26.36	hor	48.80	-22.44
402.45	402.612	24.95	hor	48.80	-23.85
402.45	402.612	28.07	ver	48.80	-20.73
402.45	403.235	12.69	hor	48.80	-36.11
402.45	403.235	15.32	ver	48.80	-33.48
404.85	404.684	18.55	hor	44.10	-25.55
404.85	404.684	26.01	ver	44.10	-18.09
404.85	405.012	22.63	hor	59.40	-36.77

3.2 Test Conditions and Results - Transmitter unwanted emissions

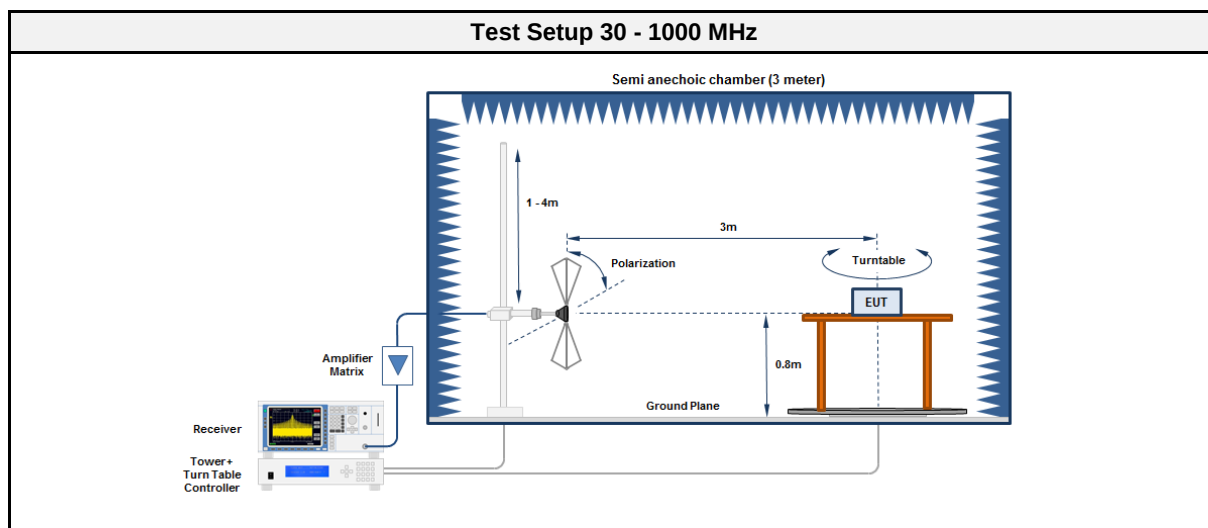
3.2.1 Information

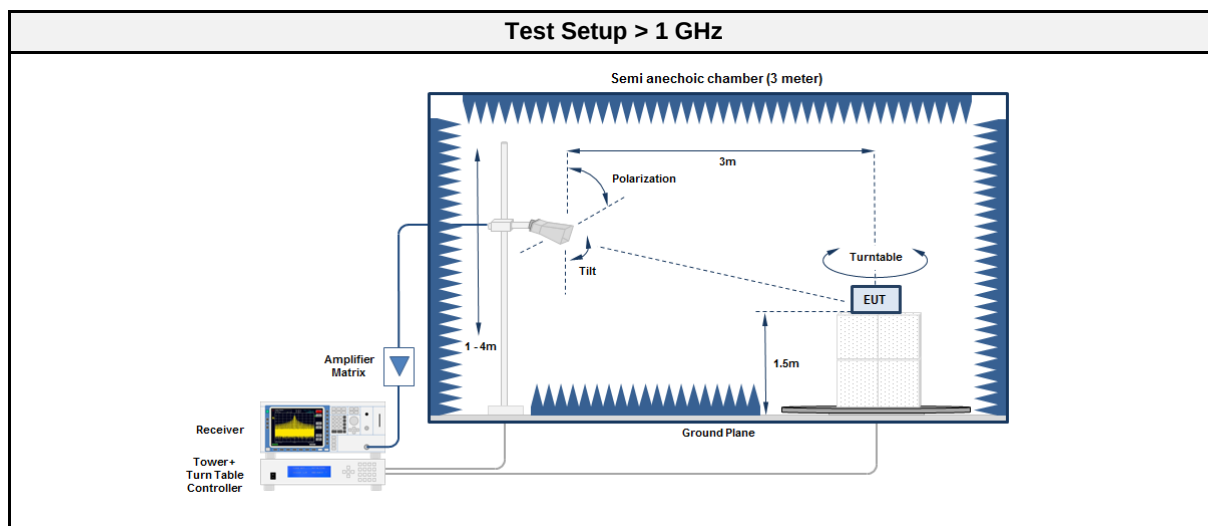
Test Information	
Reference	FCC 95.635(d) / ISED RSS-243 3.4 5.5 / ISED RSS-Gen 4.9
Measurement Method	FCC 95.635(d) / ANSI C63.4
Operator	Wilfried Treffke
Date	2018-08-14

3.2.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V/m}$]	Limit [$\text{dB}\mu\text{V/m}$]	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

3.2.3 Setup





3.2.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2017-02	2020-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2017-08	2018-08
Antenna	R&S	HK 116	EF00030	2016-04	2019-04
Antenna	R&S	HL 223	EF00187	2016-05	2019-05

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2017-02	2020-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2017-08	2018-08
Antenna	R&S	BBHA 9120D	EF00018	2016-09	2019-09

3.2.5 Procedure

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	

3.2.6 Results

Test Results							
Channel [MHz]	Emission [MHz]	Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Limit dist. [m]	Margin [dB]
404.85	3736	41.79	pk	ver	54.00	3	-12.21

3.3 Test Conditions and Results - Receiver spurious emissions

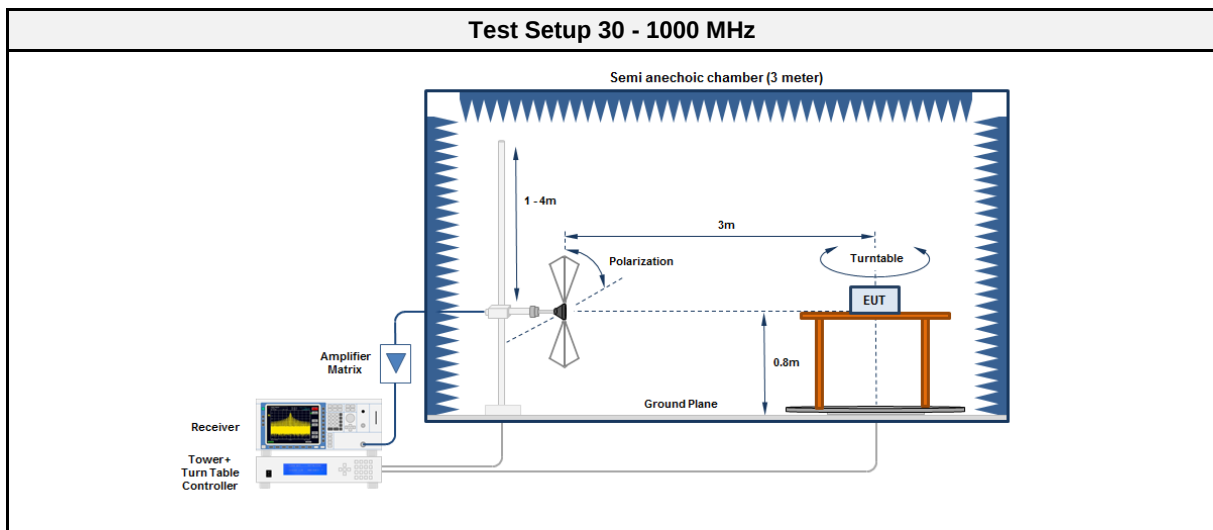
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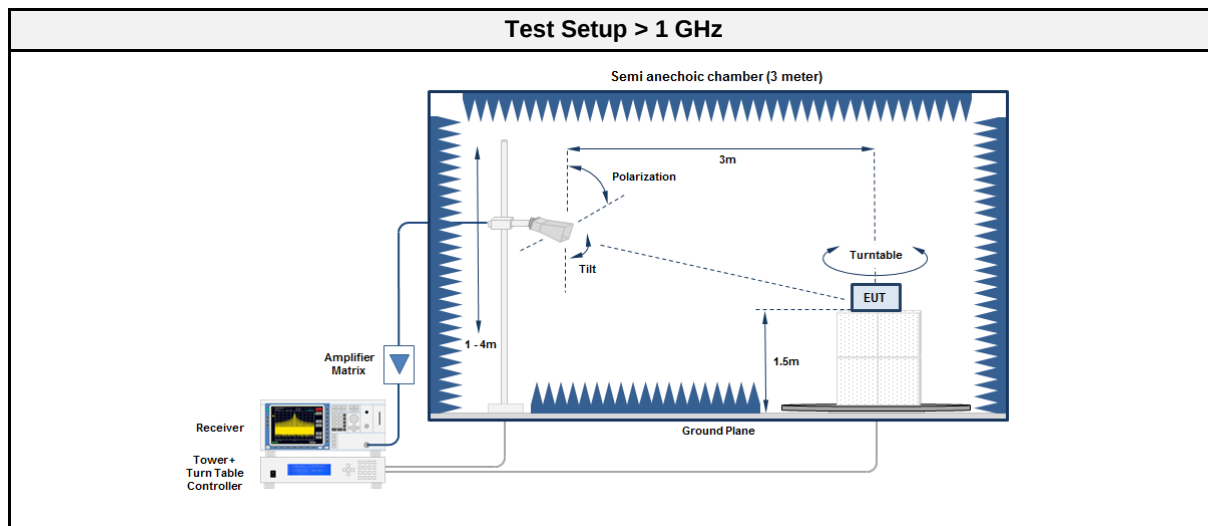
Test Information	
Reference	ISED RSS-243 3.5 5.6 / ISED RSS-Gen 4.10 6.1
Measurement Method	ANSI C 63.4
Operator	Wilfried Treffke
Date	2018-08-14

3.3.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V/m}$]	Limit [$\text{dB}\mu\text{V/m}$]	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

3.3.3 Setup





3.3.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2017-02	2020-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2017-08	2018-08
Antenna	R&S	HK 116	EF00030	2016-04	2019-04
Antenna	R&S	HL 223	EF00187	2016-05	2019-05

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2017-02	2020-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2017-08	2018-08
Antenna	R&S	BBHA 9120D	EF00018	2016-09	2019-09

3.3.5 Procedure

Test Procedure	
1. EUT set to receive 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	

3.3.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Emission Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Margin [dB]
403.65	196.094	31.60	pk	ver	43.50	-11.90
403.65	263.936	13.11	pk	ver	46.00	-32.89
403.65	1695	35.34	pk	ver	53.98	-18.64
403.65	3982	42.05	pk	ver	53.98	-11.93

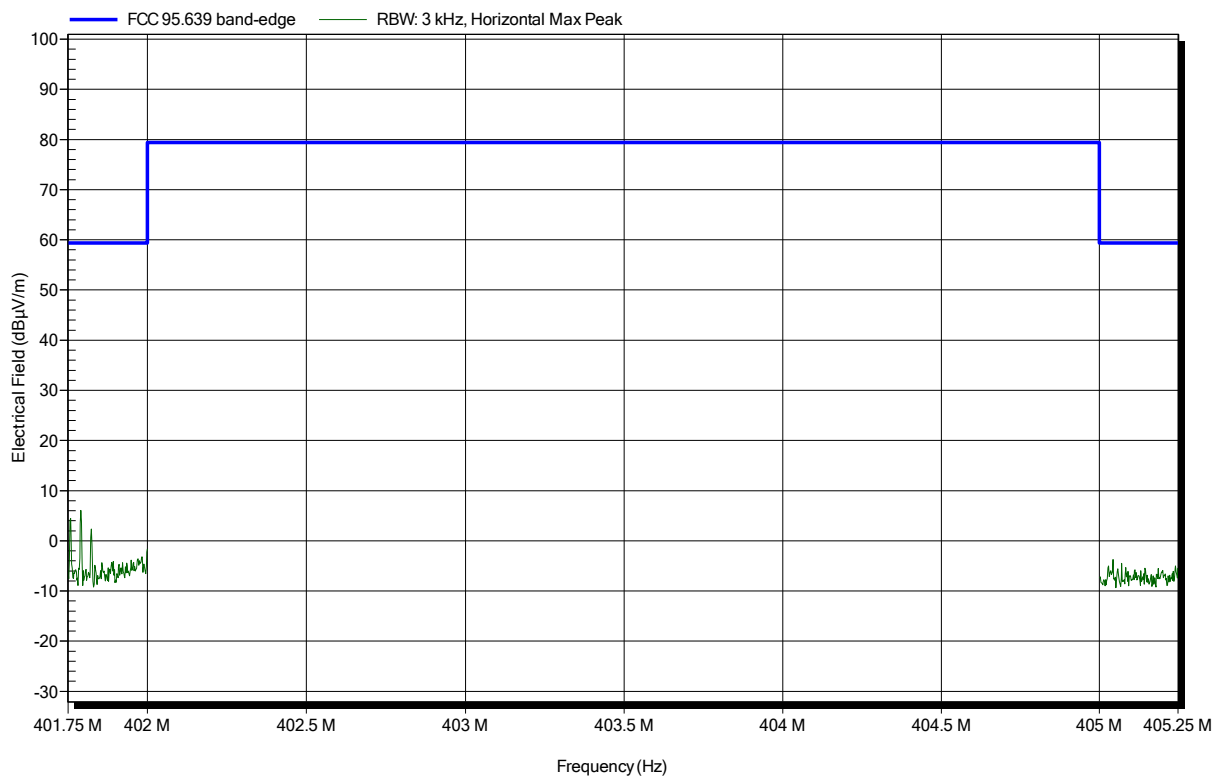
ANNEX A Band-edge and In-band Emissions

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Horizontal
Measurement distance: 3 m
Mode: TX; 2-FSK; 402.45 MHz
Test Date: 2018-08-14
Note: Band-edge

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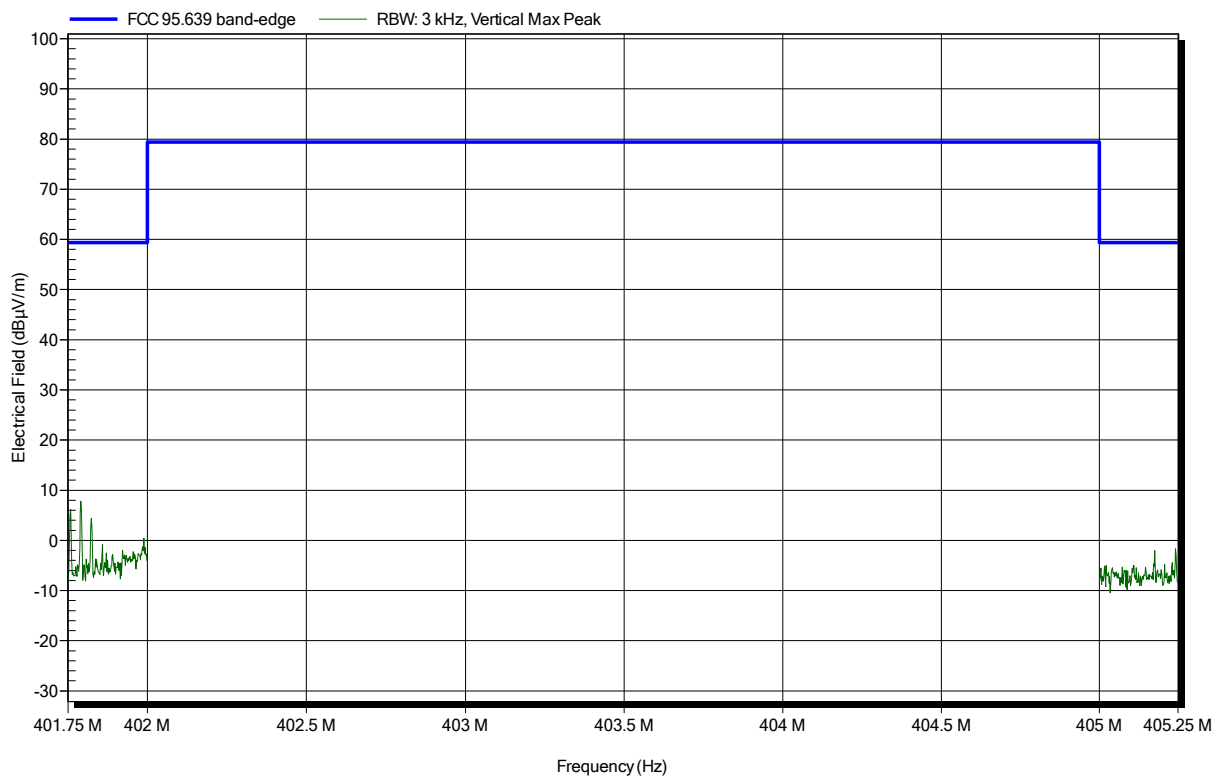


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 402.45 MHz
 Test Date: 2018-08-14
 Note: Band-edge

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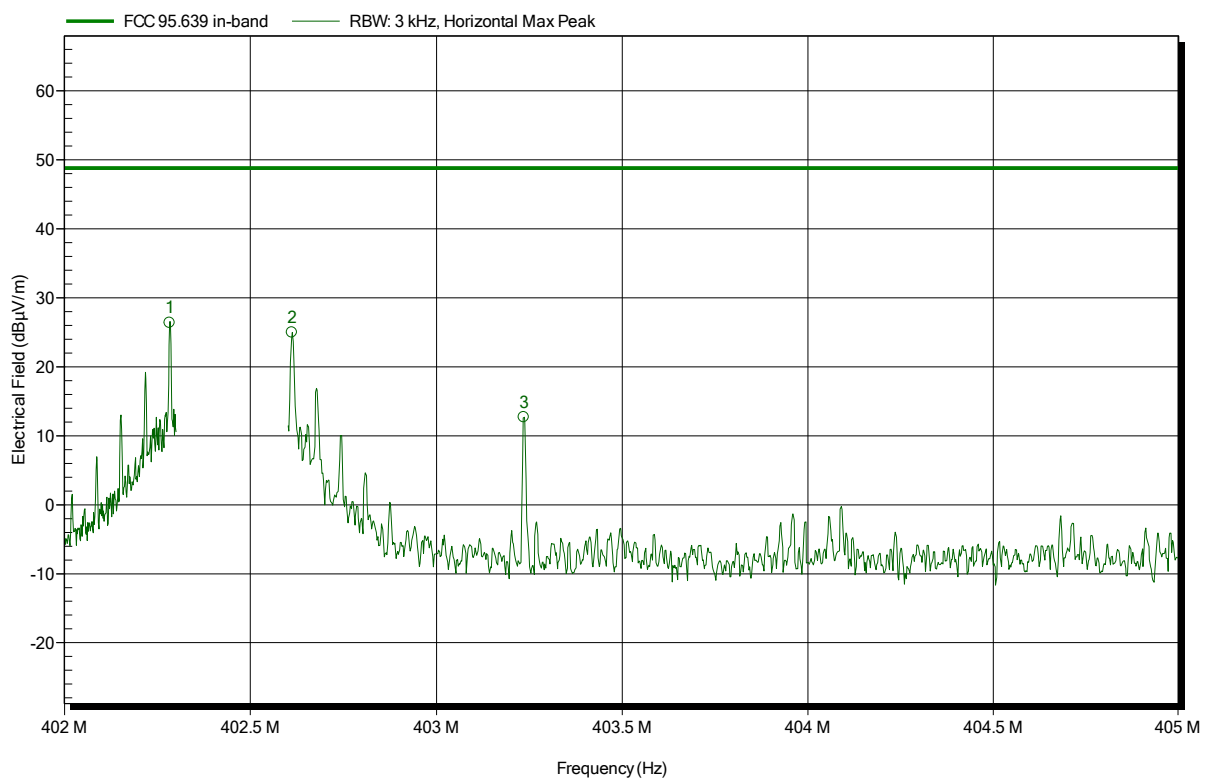


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Horizontal
Measurement distance: 3 m
Mode: TX; 2-FSK; 402.45 MHz
Test Date: 2018-08-14
Note: In-band emissions

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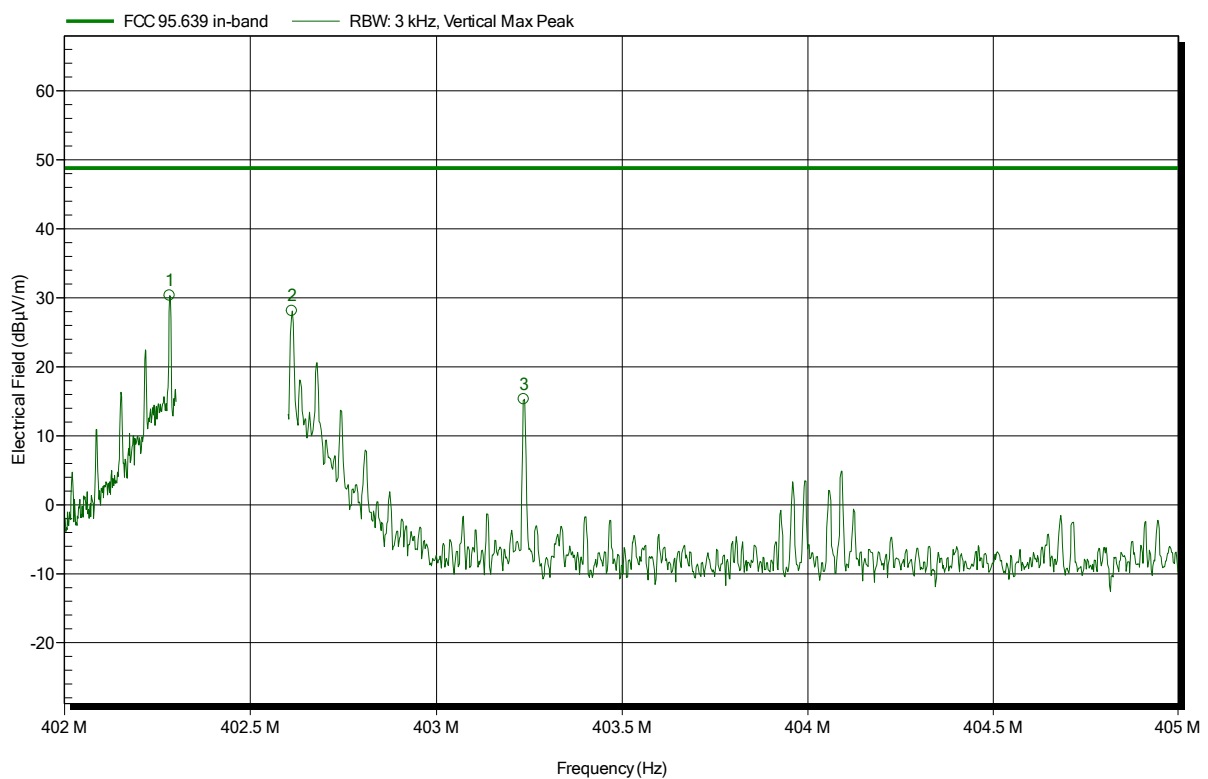
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.284 MHz	26.36 dBµV/m	48.8 dBµV/m	-22.44 dB	Pass
402.612 MHz	24.95 dBµV/m	48.8 dBµV/m	-23.85 dB	Pass
403.235 MHz	12.69 dBµV/m	48.8 dBµV/m	-36.11 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Vertical
Measurement distance: 3 m
Mode: TX; 2-FSK; 402.45 MHz
Test Date: 2018-08-14
Note: In-band emissions

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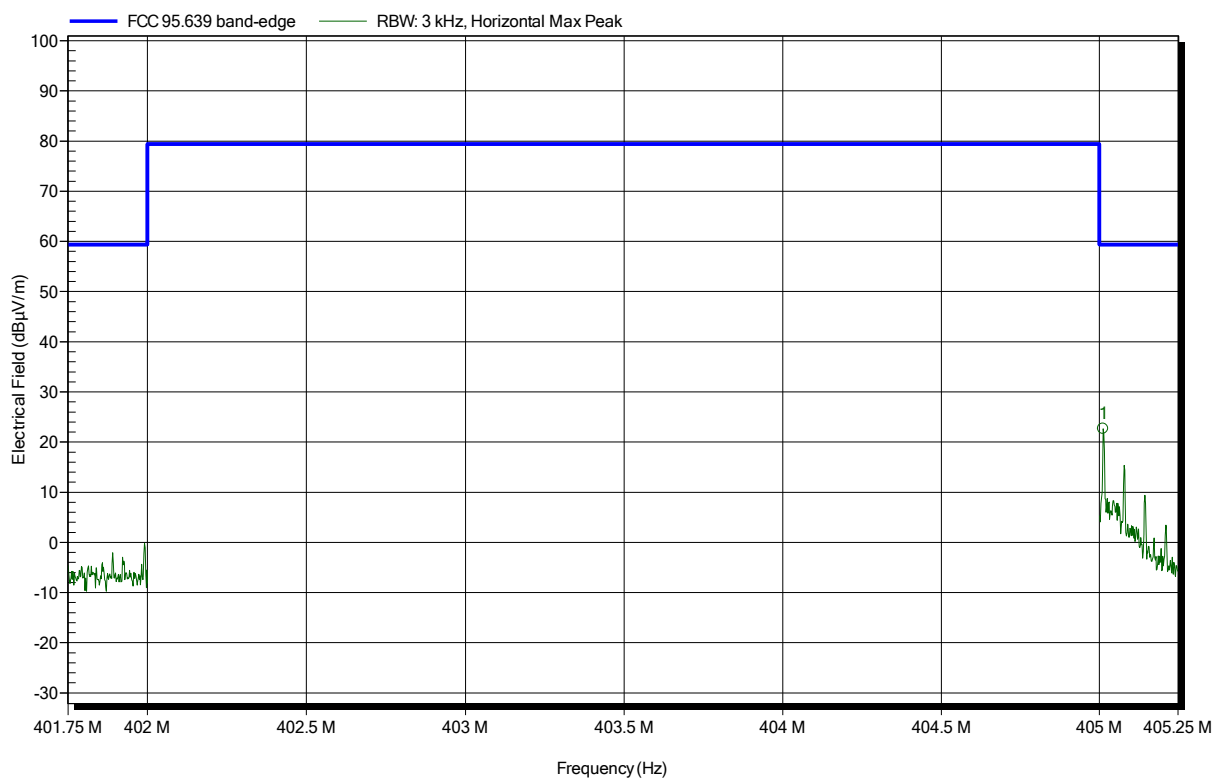
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.283 MHz	30.31 dBµV/m	48.8 dBµV/m	-18.49 dB	Pass
402.612 MHz	28.07 dBµV/m	48.8 dBµV/m	-20.73 dB	Pass
403.235 MHz	15.32 dBµV/m	48.8 dBµV/m	-33.48 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Horizontal
Measurement distance: 3 m
Mode: TX; 2-FSK; 404.85 MHz
Test Date: 2018-08-14
Note: Band-edge

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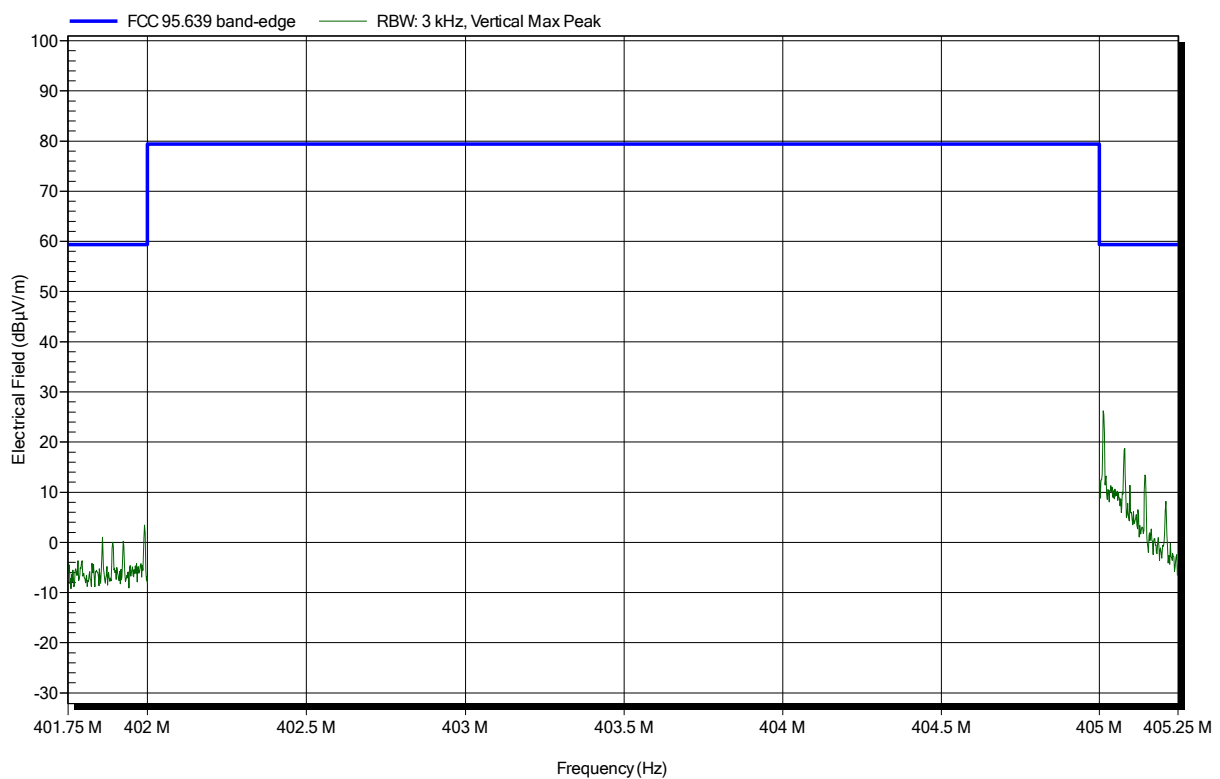
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.012 MHz	22.63 dBµV/m	59.4 dBµV/m	-36.77 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note: Band-edge

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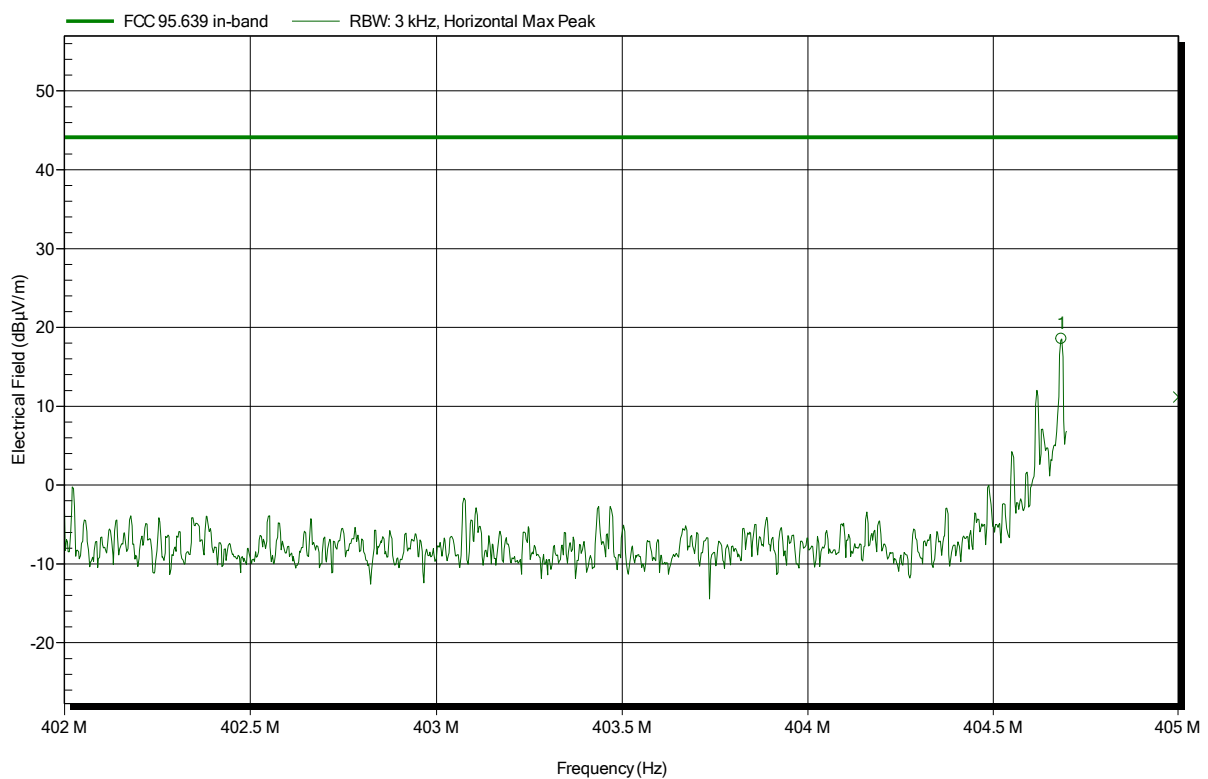


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Horizontal
Measurement distance: 3 m
Mode: TX; 2-FSK; 404.85 MHz
Test Date: 2018-08-14
Note: In-band emissions

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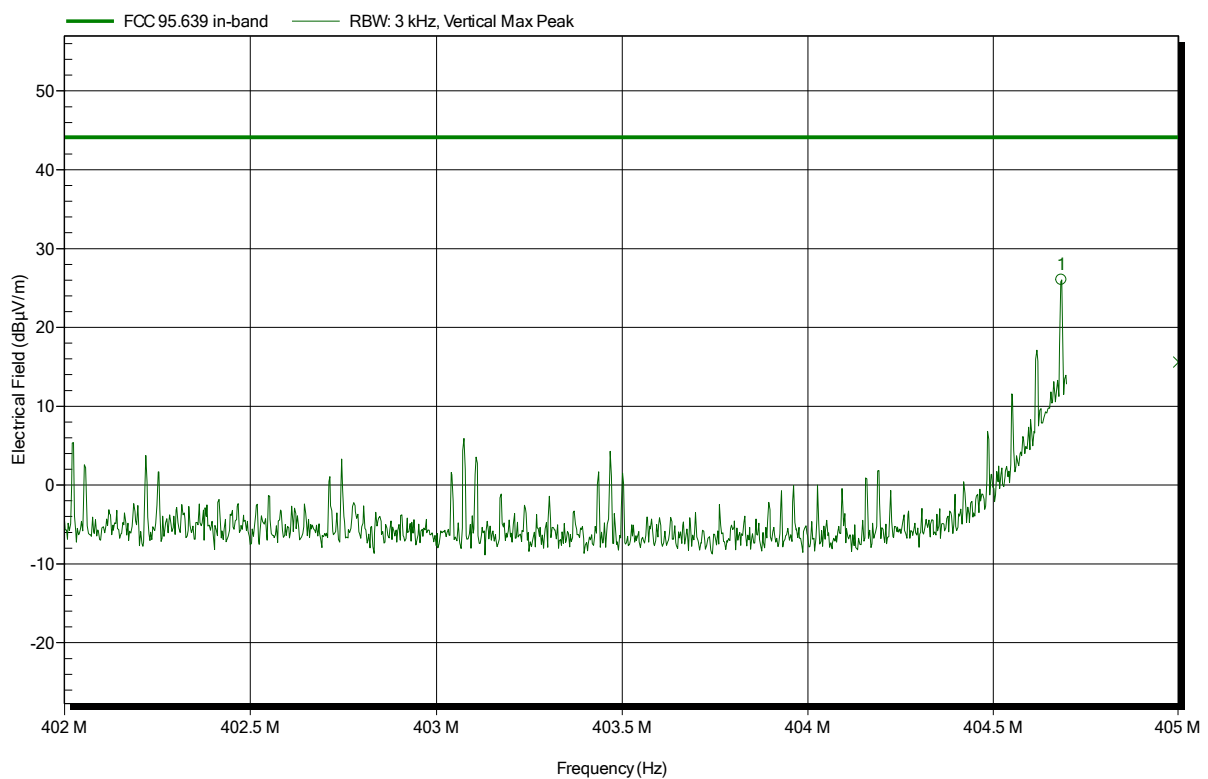
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.684 MHz	18.55 dBµV/m	44.1 dBµV/m	-25.55 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Vertical
Measurement distance: 3 m
Mode: TX; 2-FSK; 404.85 MHz
Test Date: 2018-08-14
Note: In-band emissions

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.684 MHz	26.01 dBµV/m	44.1 dBµV/m	-18.09 dB	Pass

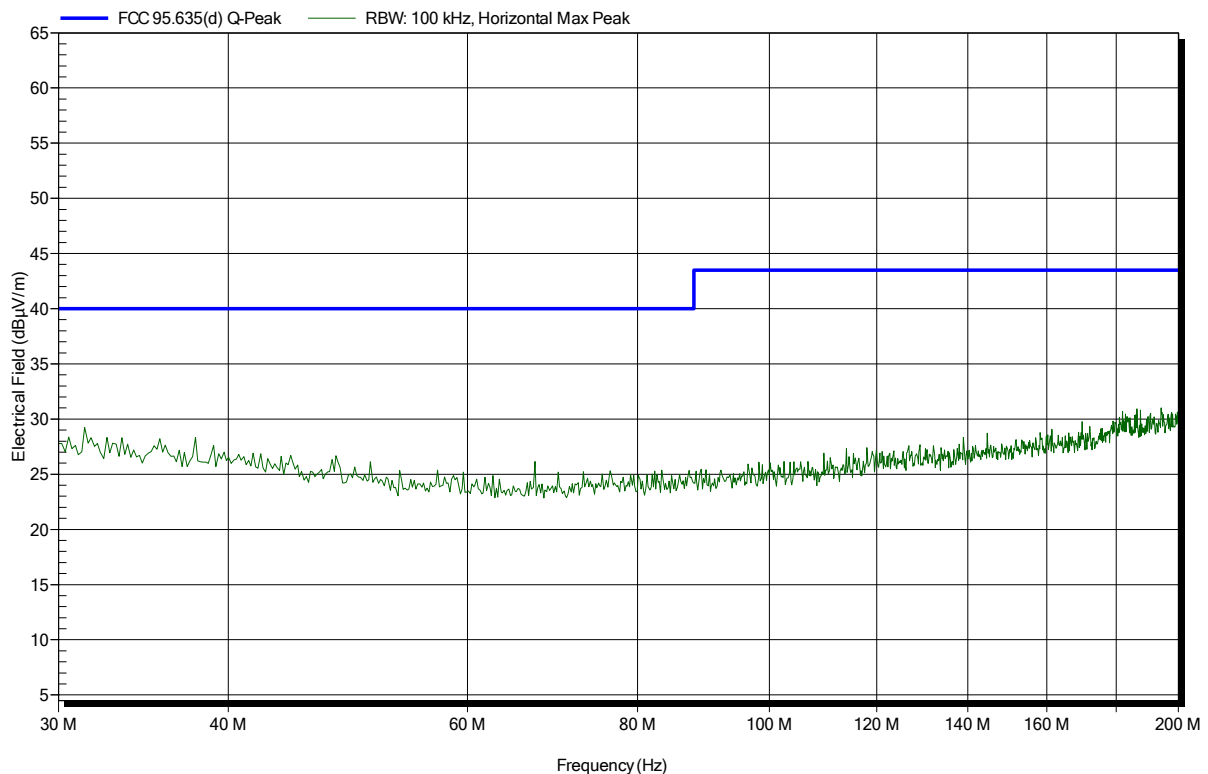
ANNEX B Transmitter spurious emissions

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HK116, Horizontal
Measurement distance: 3 m
Mode: TX; 2-FSK; 402.45 MHz
Test Date: 2018-08-14
Note:

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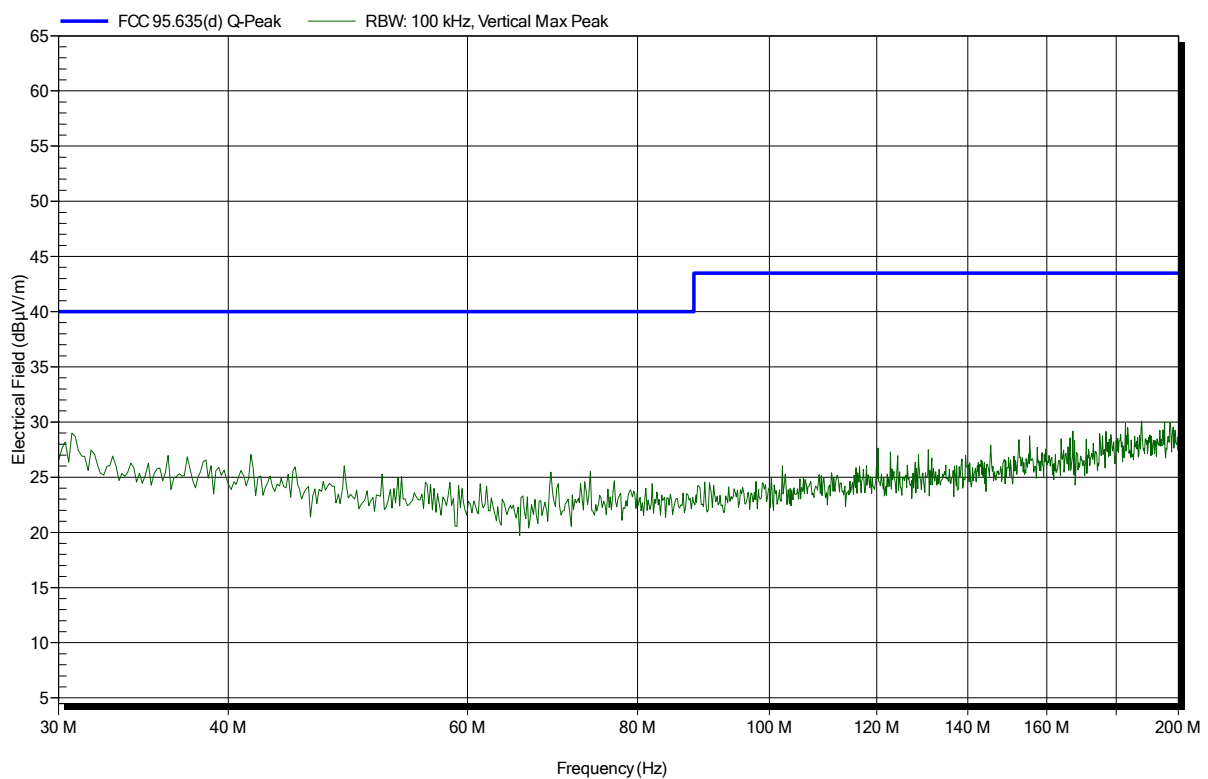


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HK116, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 402.45 MHz
 Test Date: 2018-08-14
 Note:

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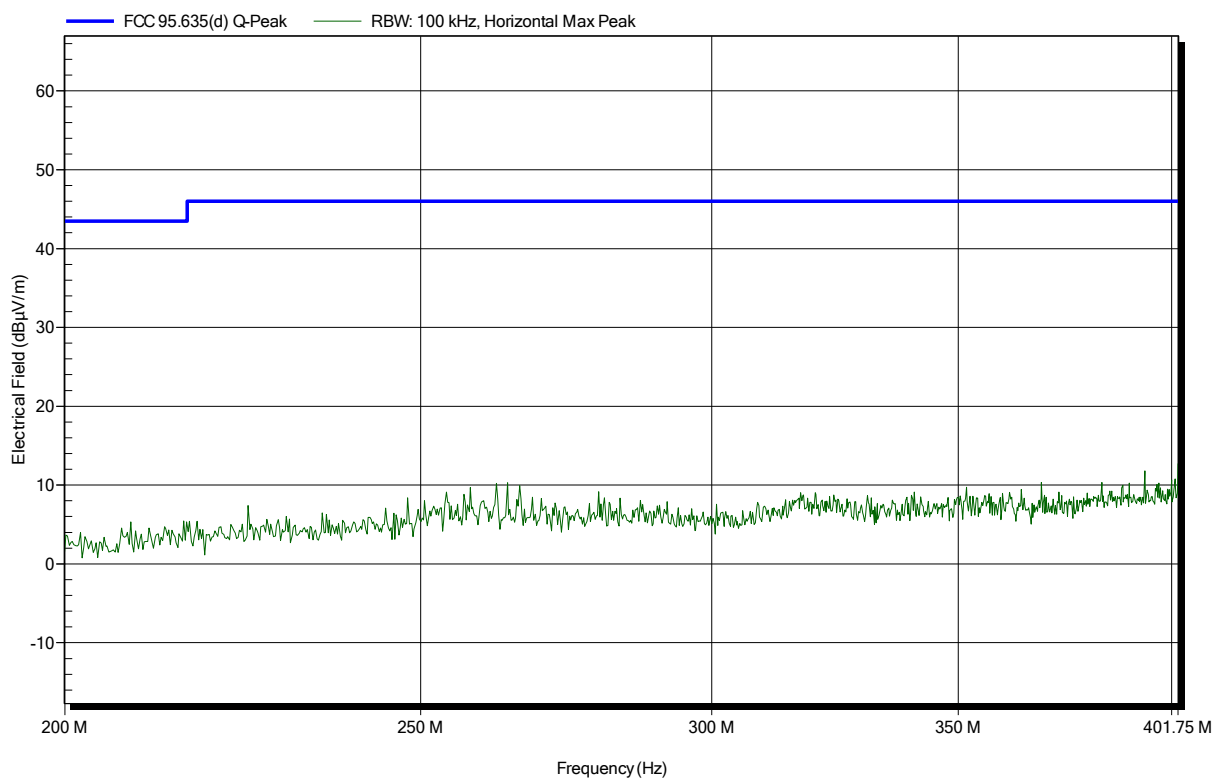


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 402.45 MHz
 Test Date: 2018-08-14
 Note:

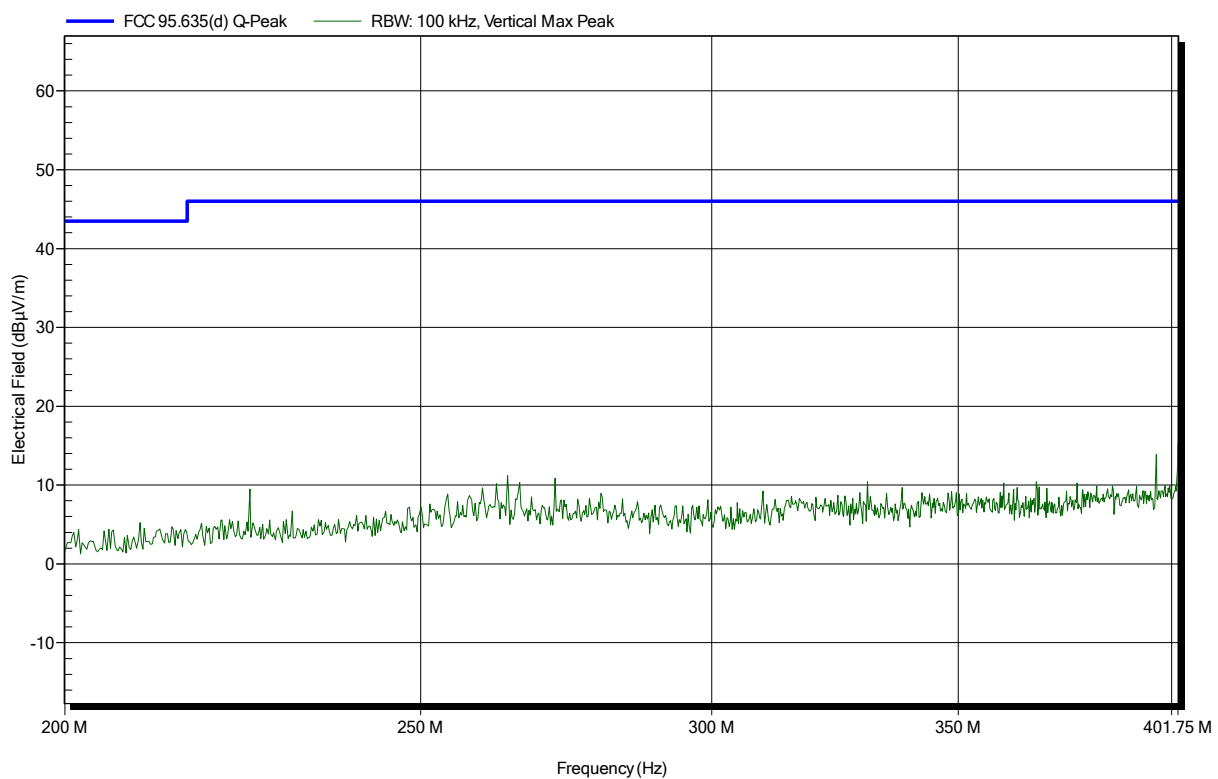
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Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555
 Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 402.45 MHz
 Test Date: 2018-08-14
 Note:

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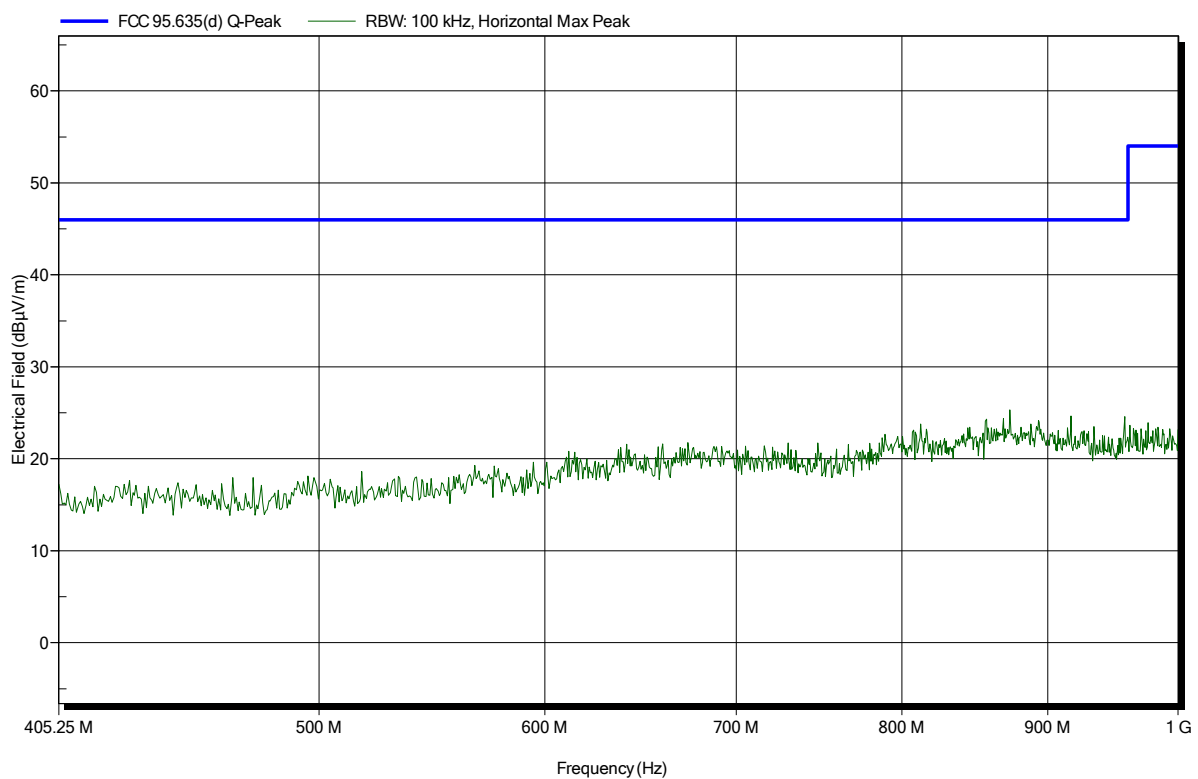


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 402.45 MHz
 Test Date: 2018-08-14
 Note:

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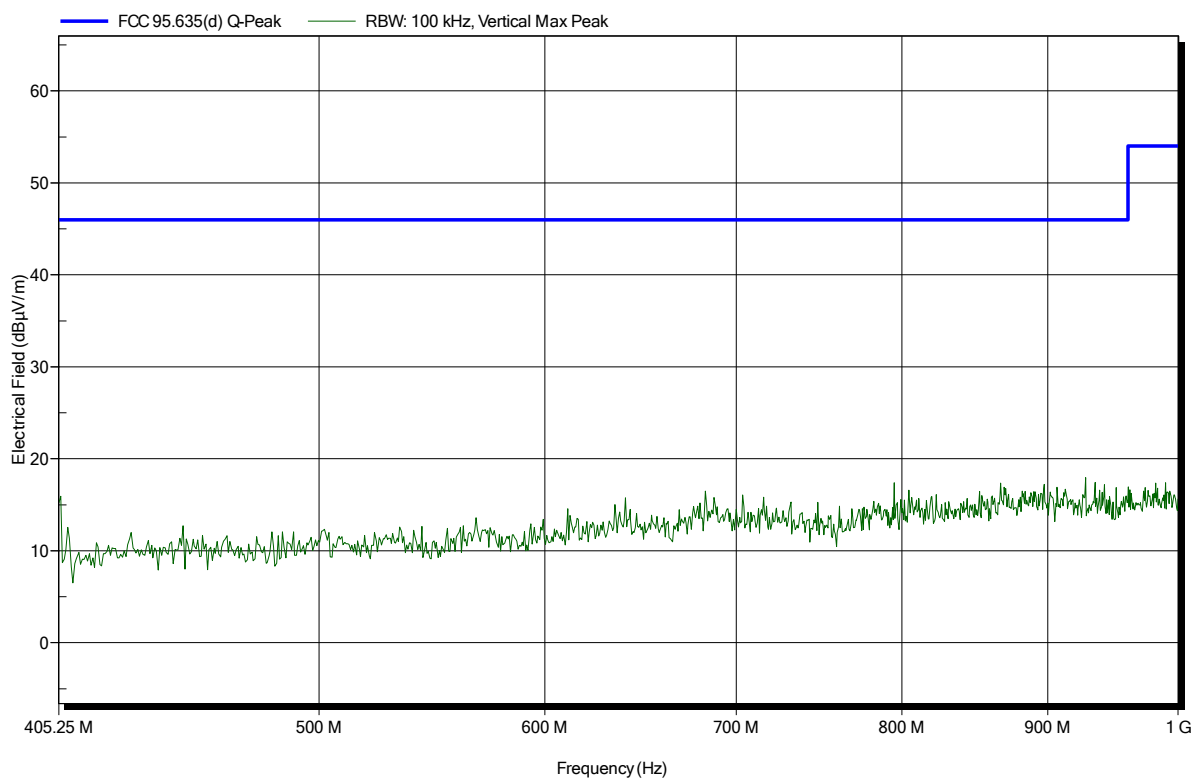


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Vertical
Measurement distance: 3 m
Mode: TX; 2-FSK; 402.45 MHz
Test Date: 2018-08-14
Note:

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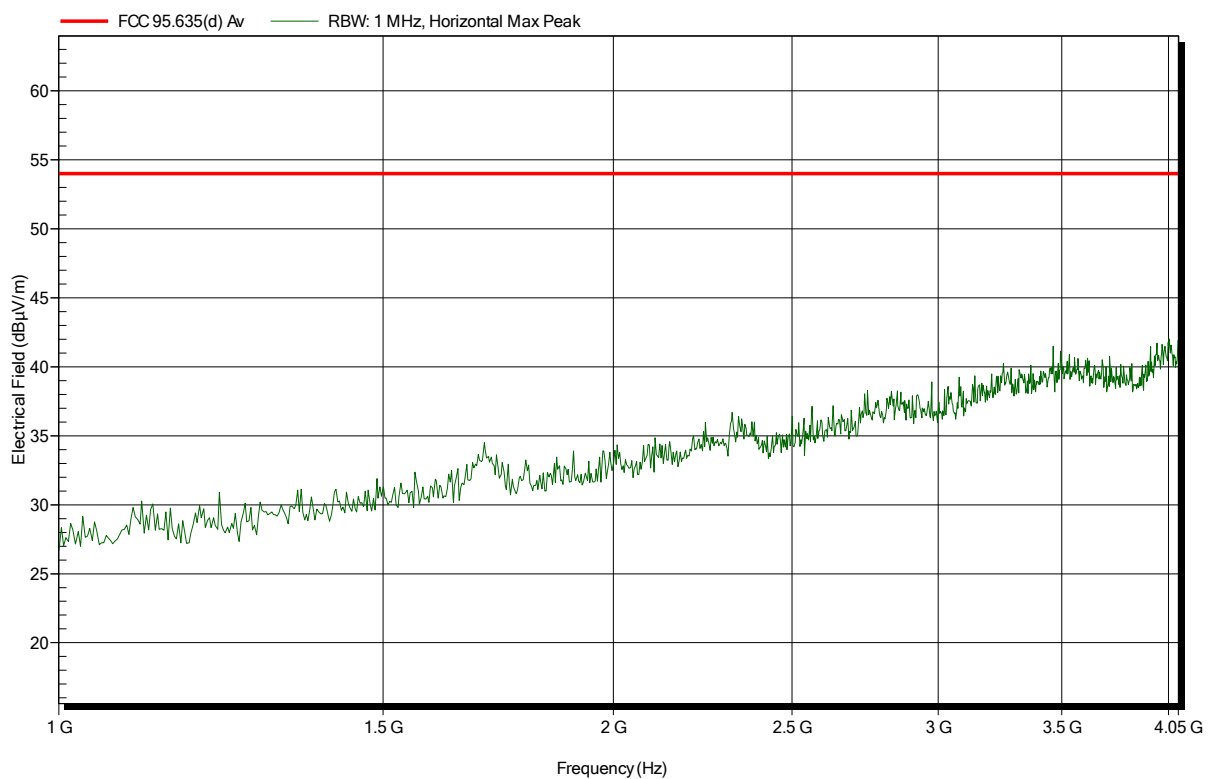


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL025, Horizontal
Measurement distance: 3 m
Mode: TX; 2-FSK; 402.45 MHz
Test Date: 2018-08-14
Note:

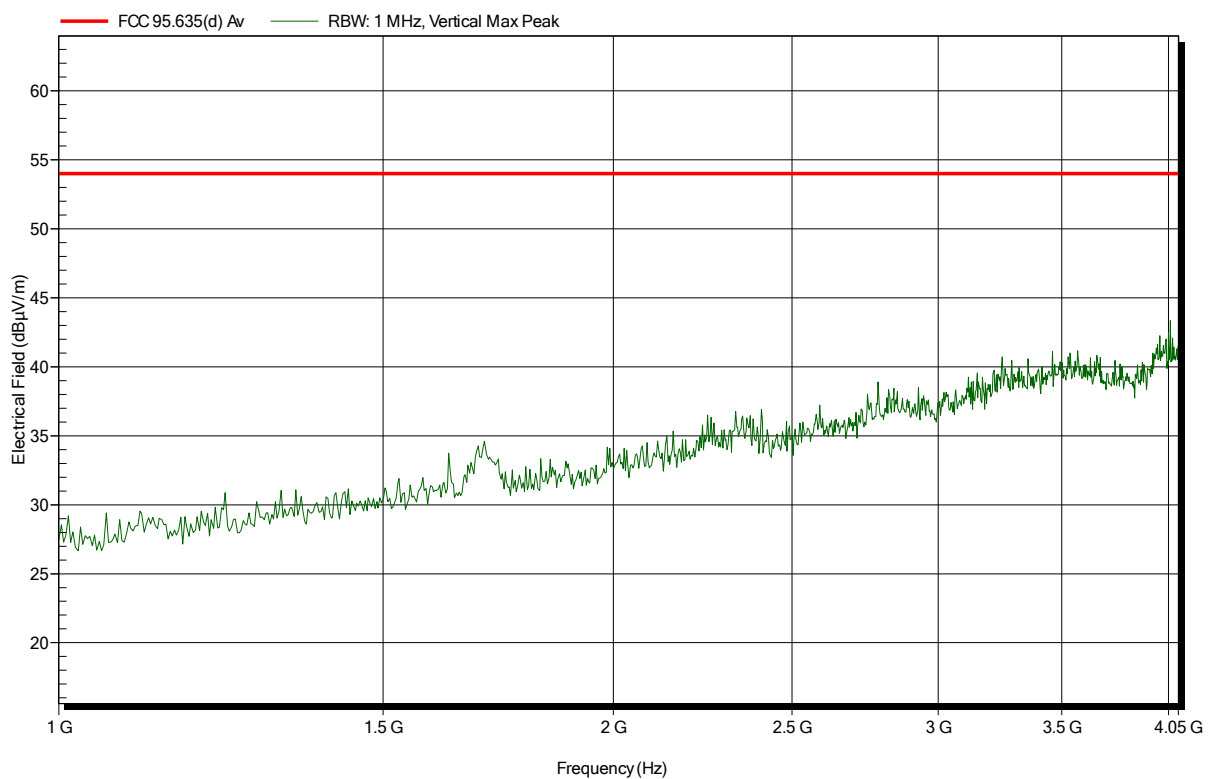
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Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555
 Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL025, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 402.45 MHz
 Test Date: 2018-08-14
 Note:

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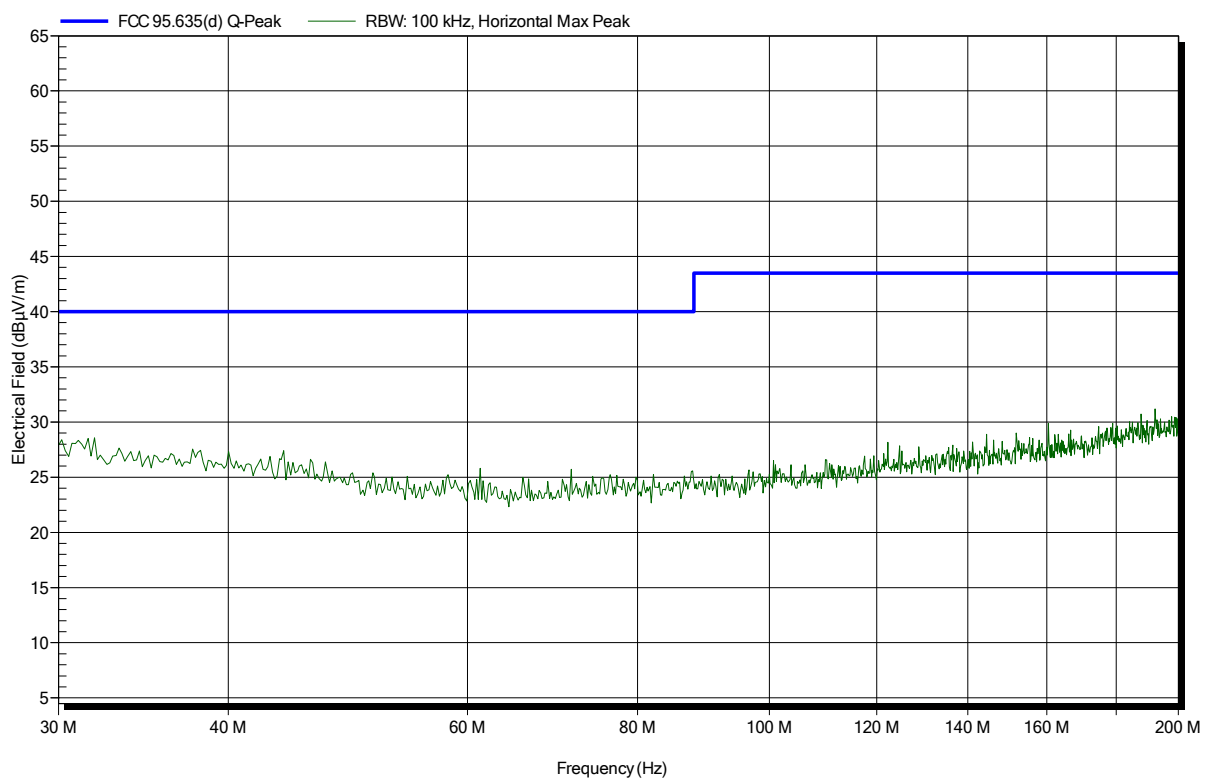


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HK116, Horizontal
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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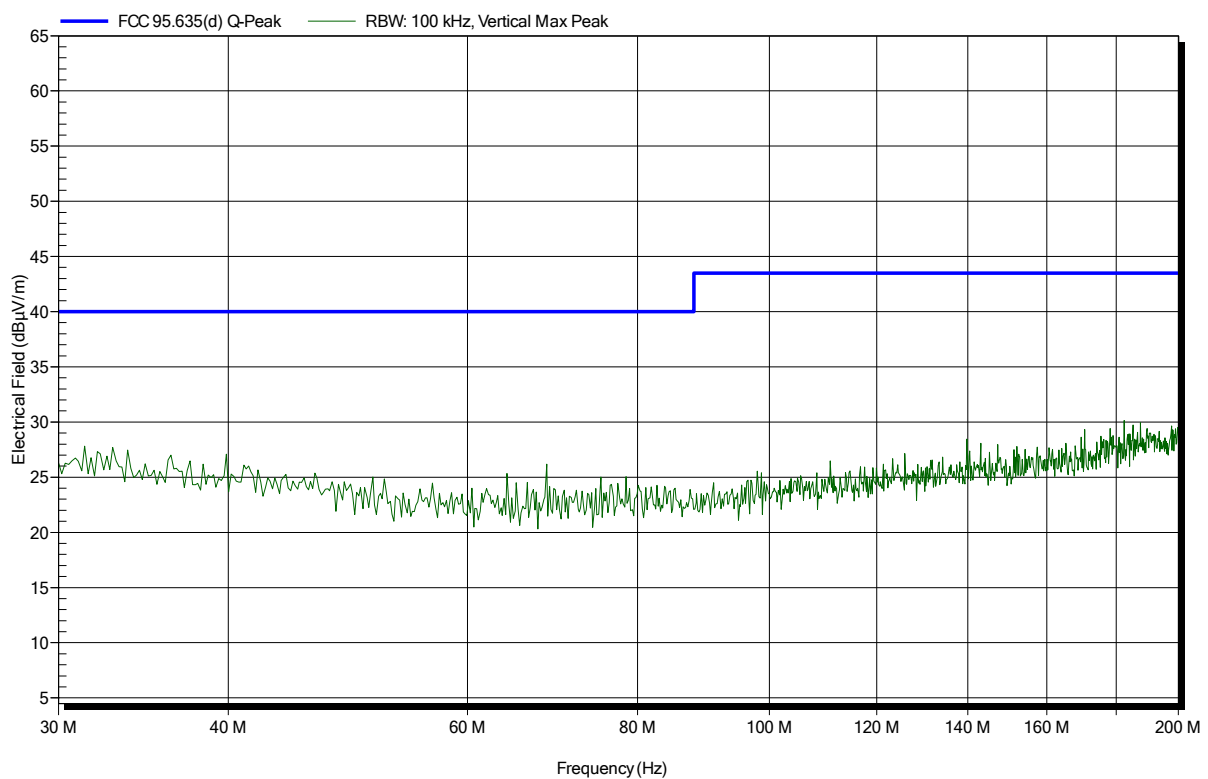


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HK116, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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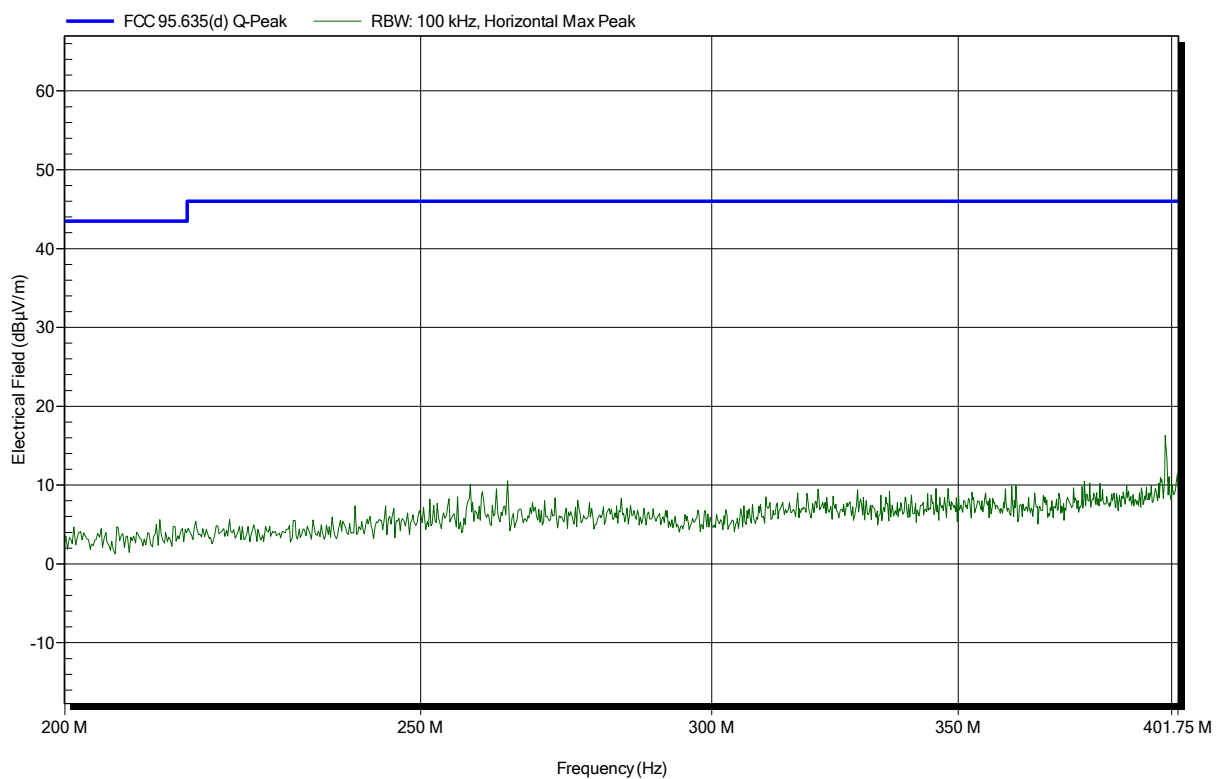


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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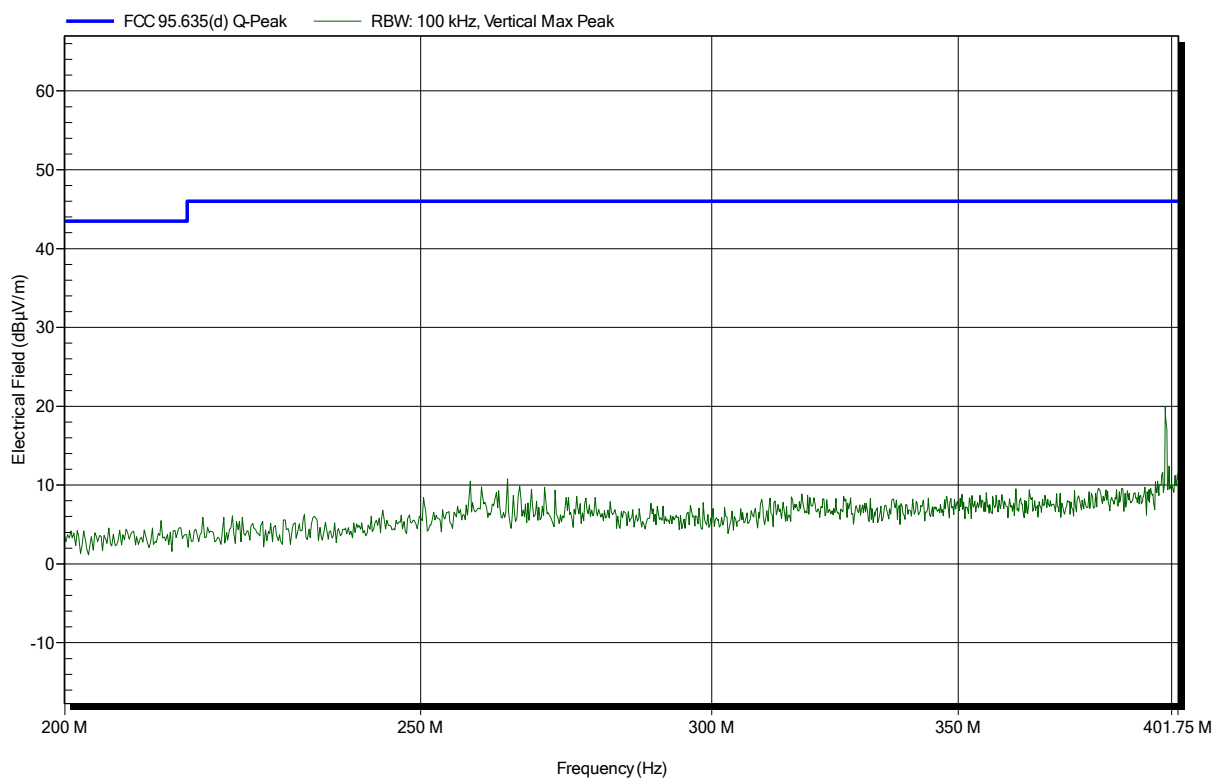


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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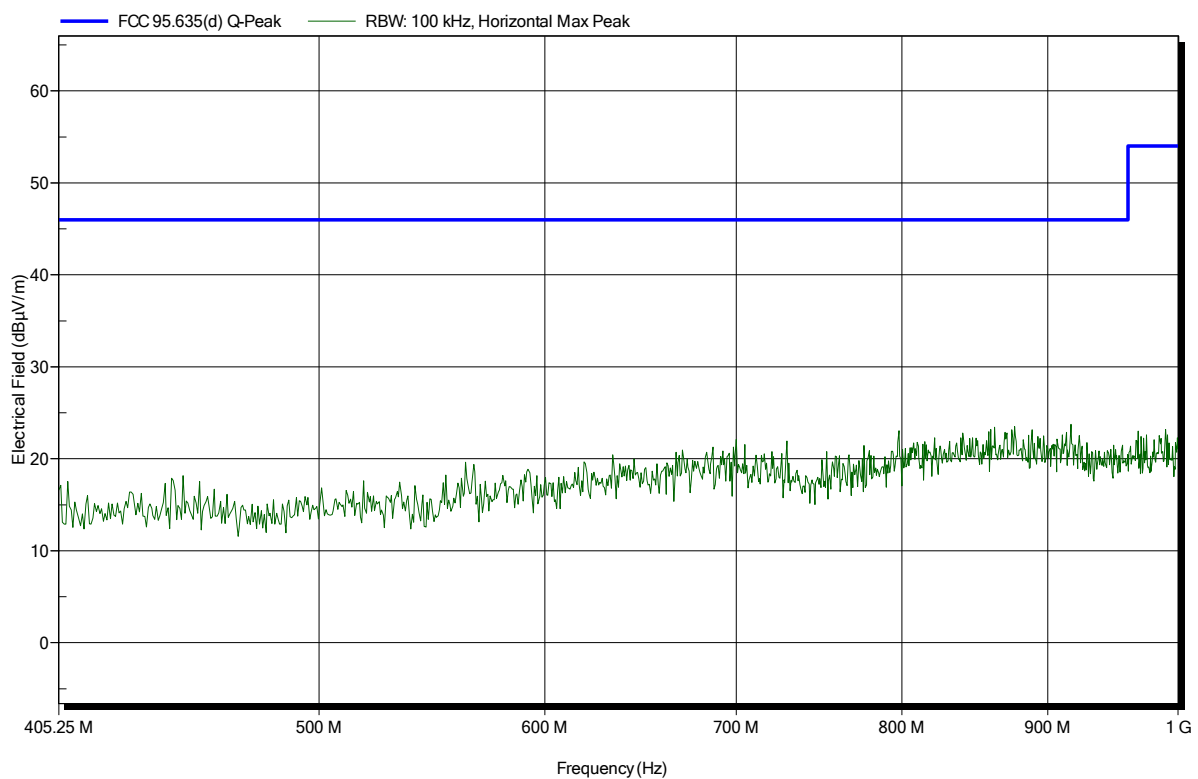


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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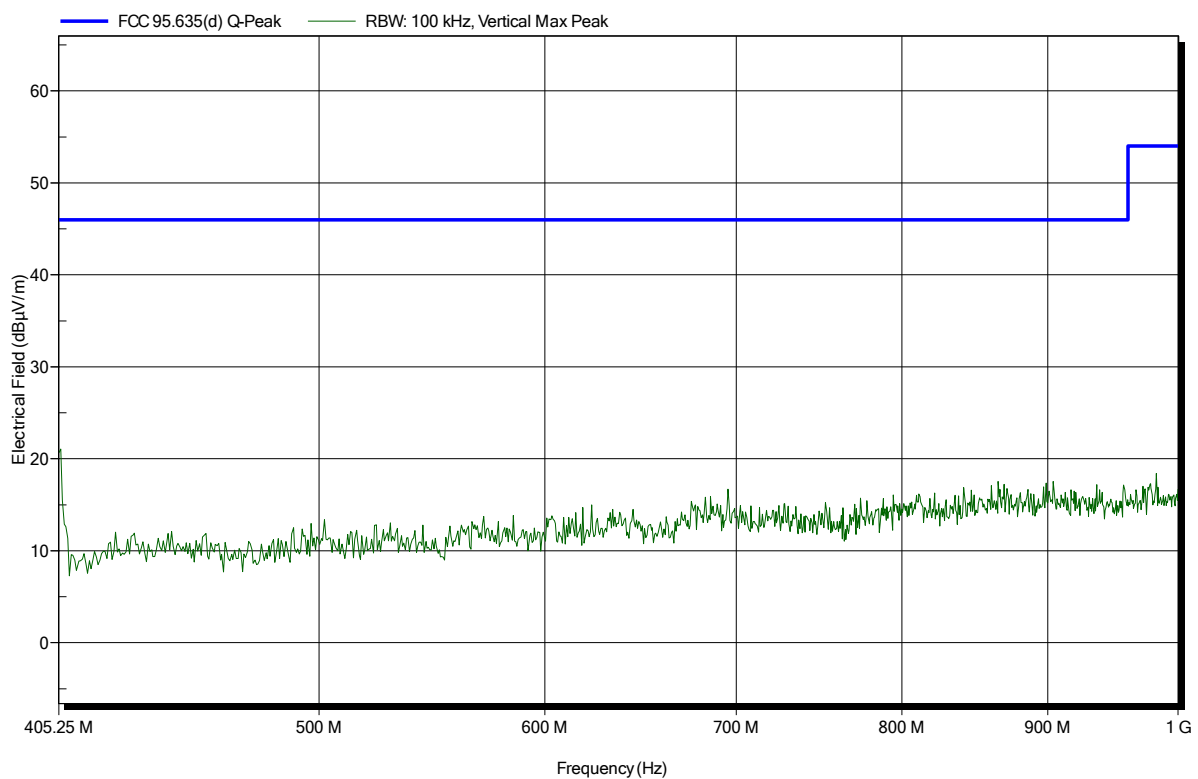


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

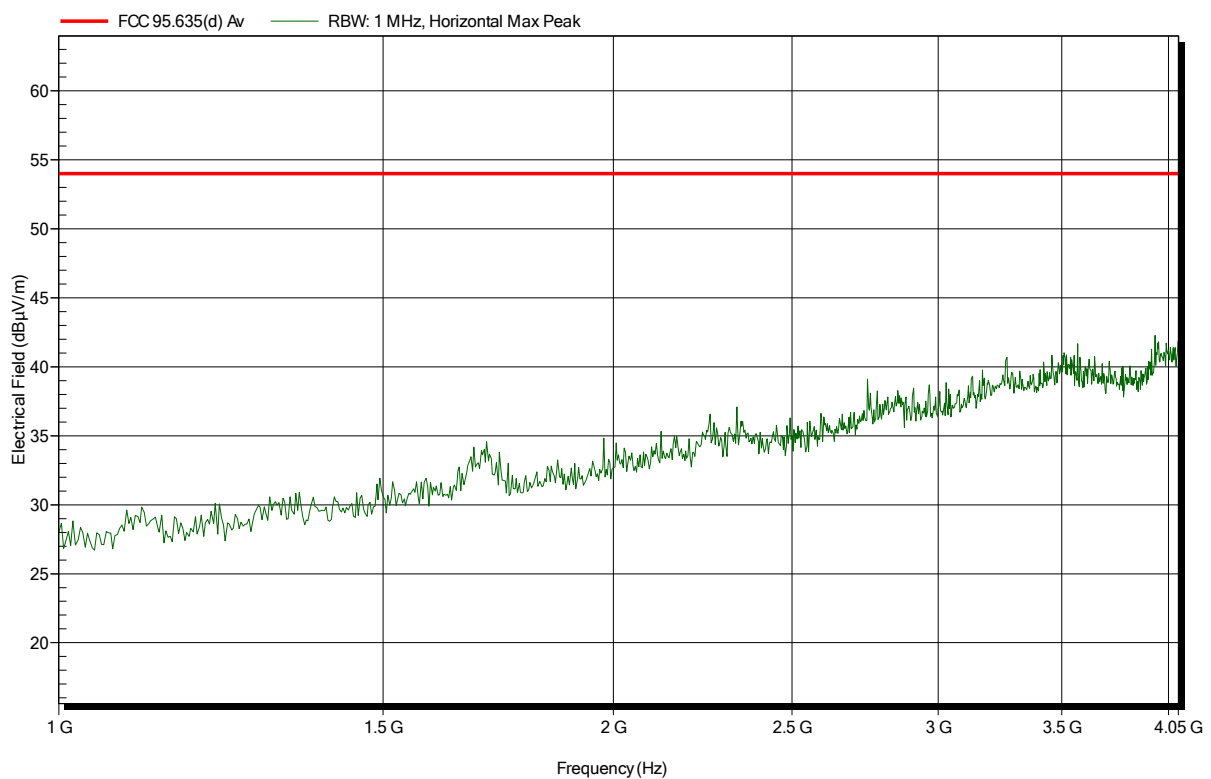
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Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555
 Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL025, Horizontal
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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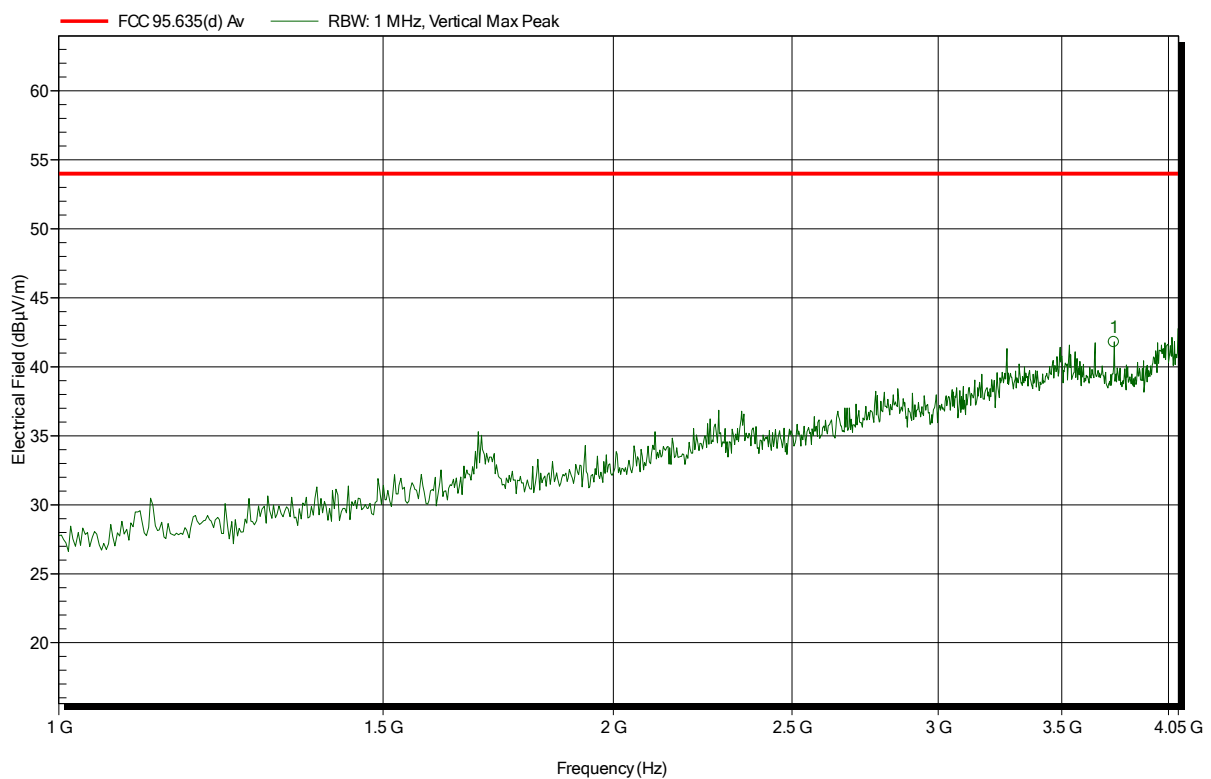


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL025, Vertical
 Measurement distance: 3 m
 Mode: TX; 2-FSK; 404.85 MHz
 Test Date: 2018-08-14
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
3.736 GHz	41.79 dBµV/m	54 dBµV/m	-12.21 dB	Pass

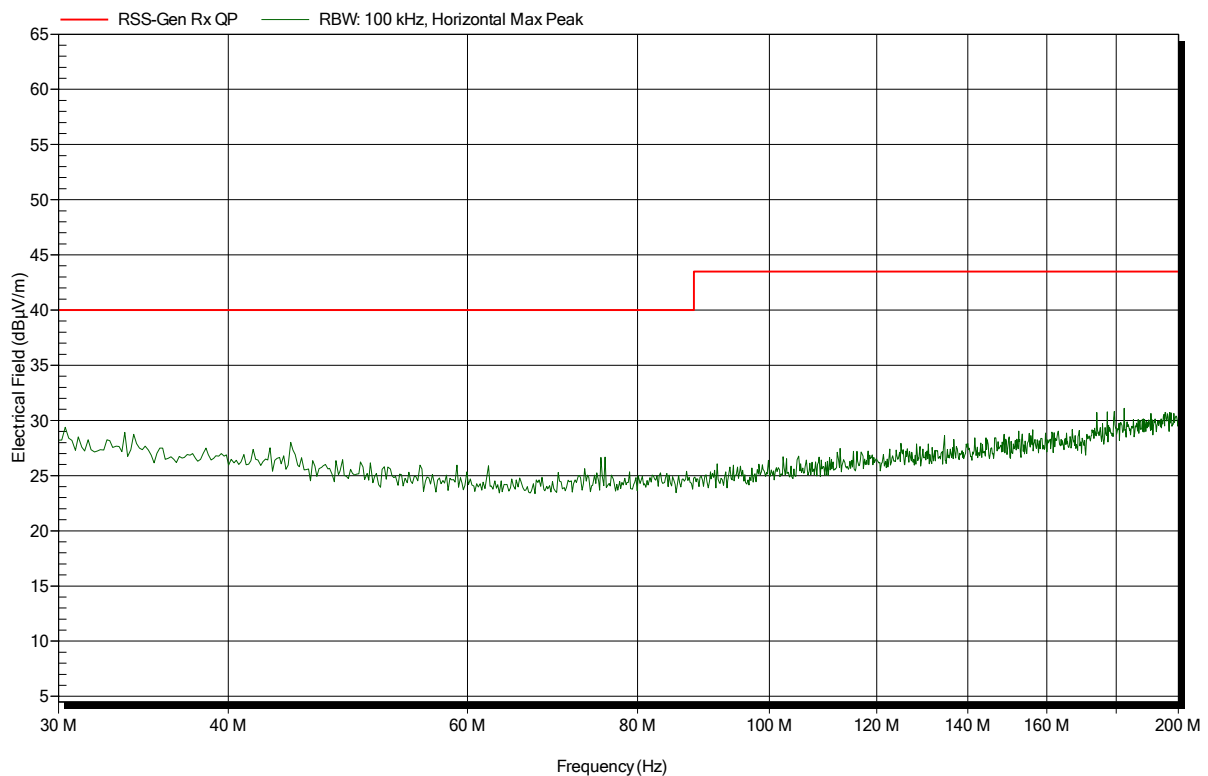
ANNEX C Receiver spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HK116, Horizontal
 Measurement distance: 3 m
 Mode: RX; 2-FSK; 403.65 MHz
 Test Date: 2018-08-14
 Note:

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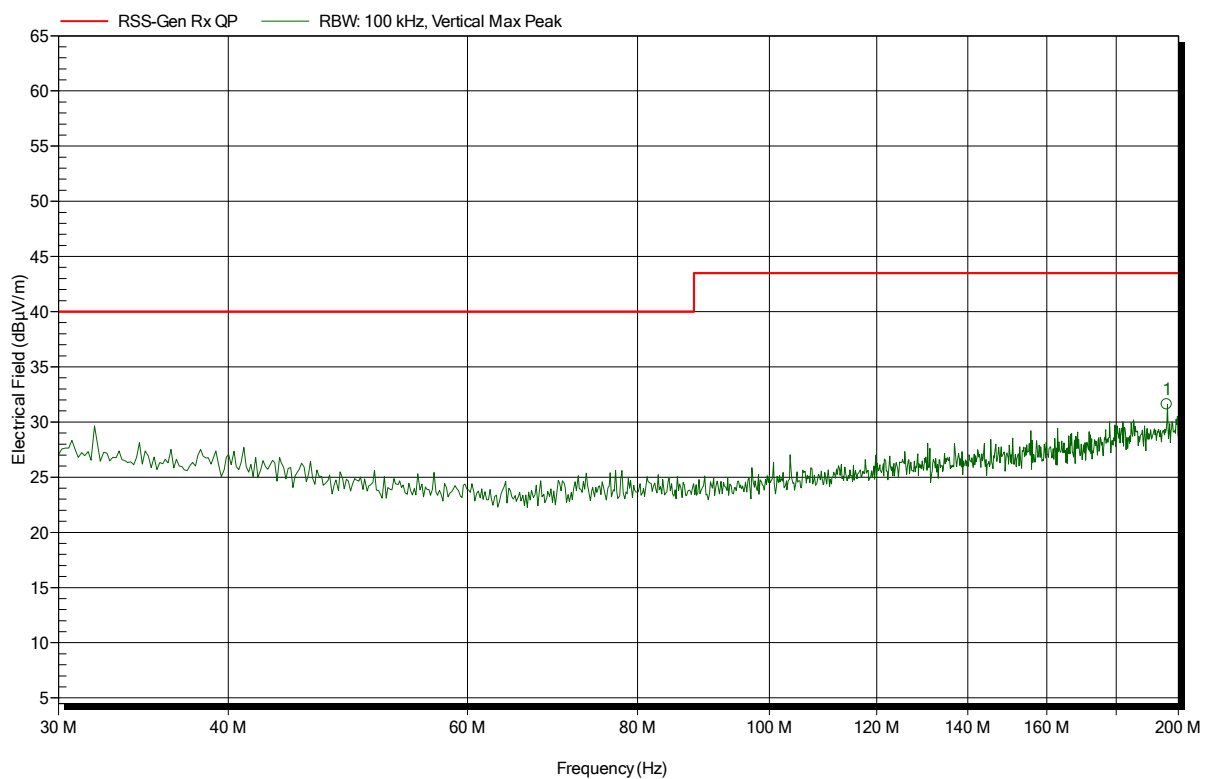


Spurious emissions according to RSS-Gen

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HK116, Vertical
 Measurement distance: 3 m
 Mode: RX; 2-FSK; 403.65 MHz
 Test Date: 2018-08-14
 Note:

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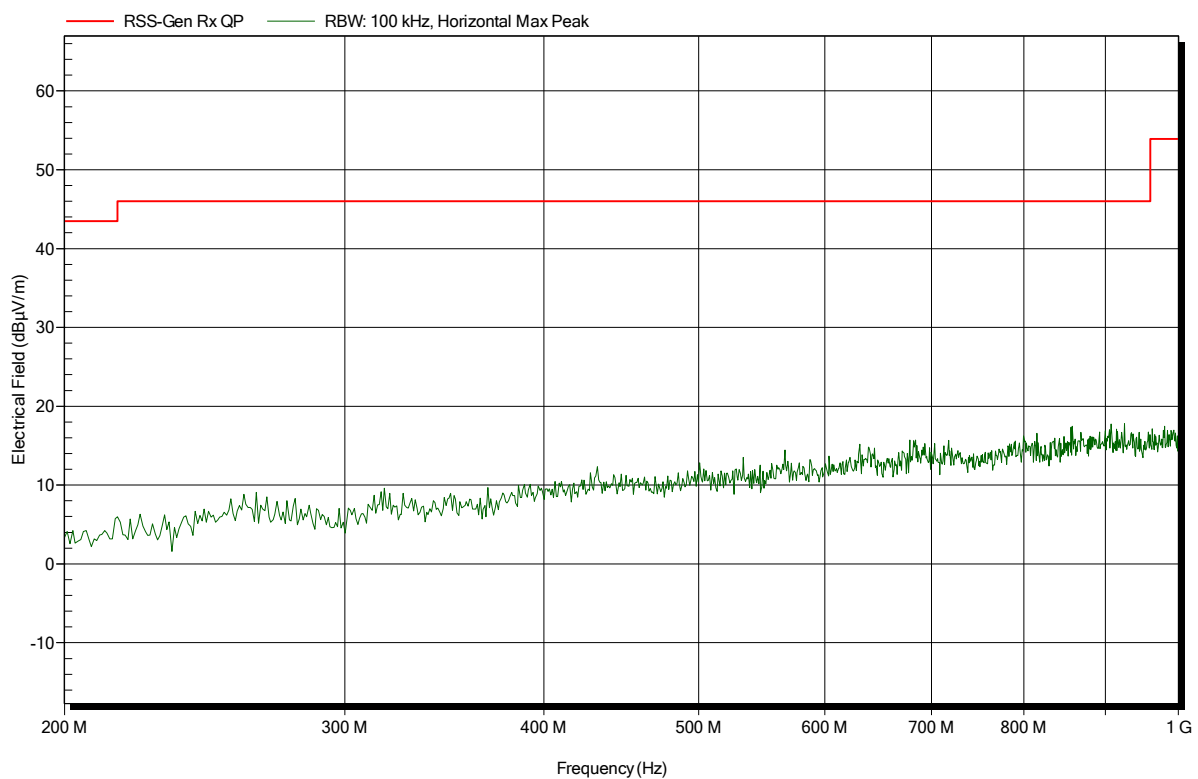
Frequency	Peak	Peak Limit	Peak Difference	Status
196.094 MHz	31.6 dBµV/m	43.5 dBµV/m	-11.9 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
 EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
 Model: Edora 8 DR-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: RX; 2-FSK; 403.65 MHz
 Test Date: 2018-08-14
 Note:

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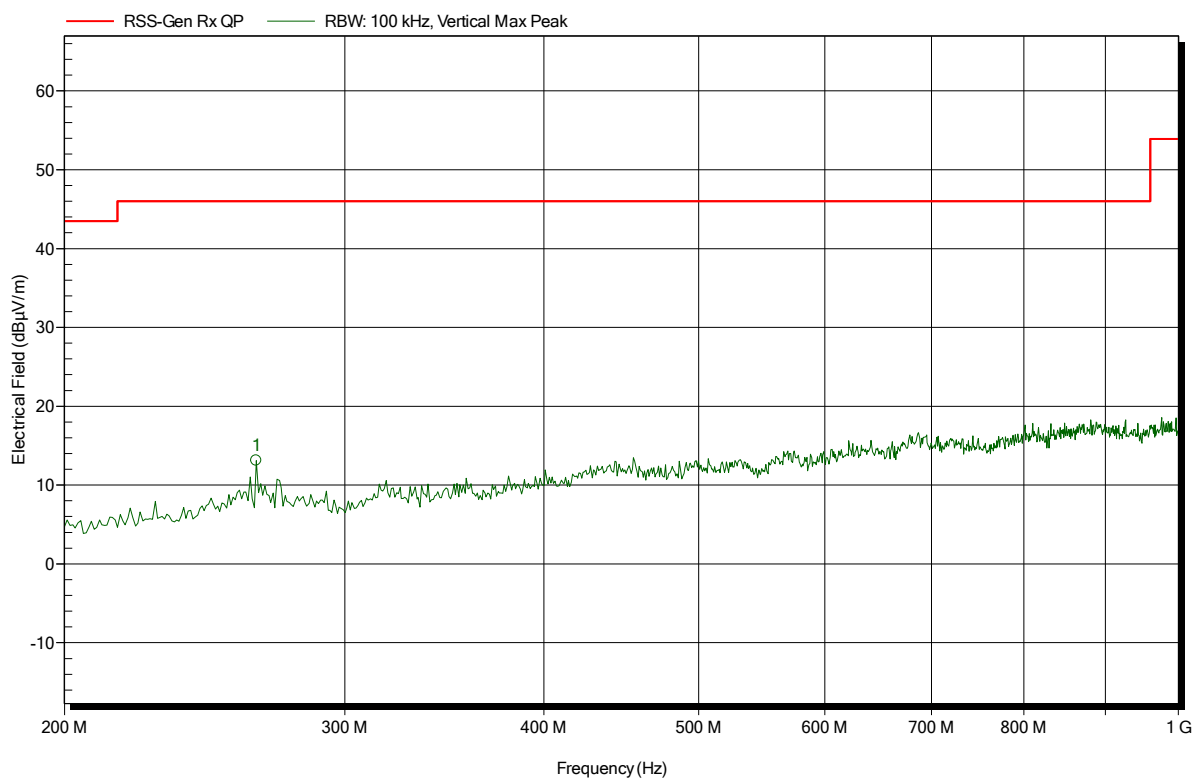


Spurious emissions according to RSS-Gen

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL223, Vertical
Measurement distance: 3 m
Mode: RX; 2-FSK; 403.65 MHz
Test Date: 2018-08-14
Note:

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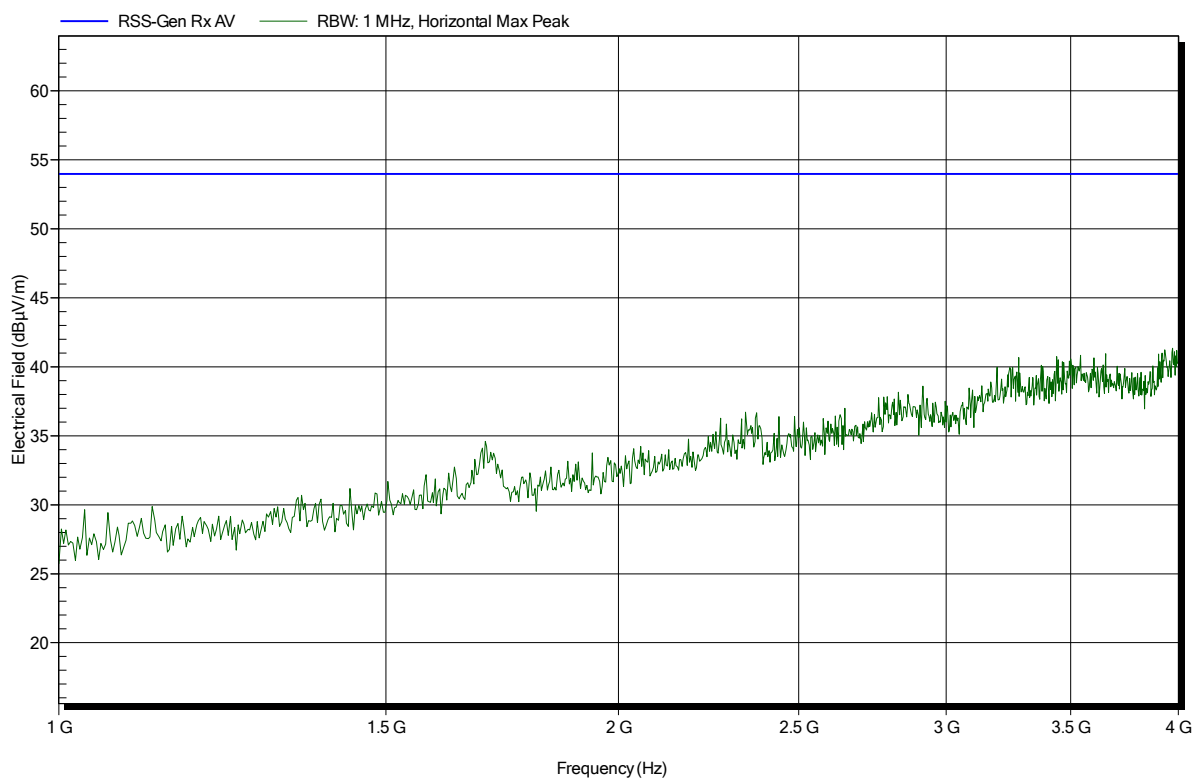
Frequency	Peak	Peak Limit	Peak Difference	Status
263.936 MHz	13.11 dBµV/m	46 dBµV/m	-32.89 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL025, Horizontal
Measurement distance: 3 m
Mode: RX; 2-FSK; 403.65 MHz
Test Date: 2018-08-14
Note:

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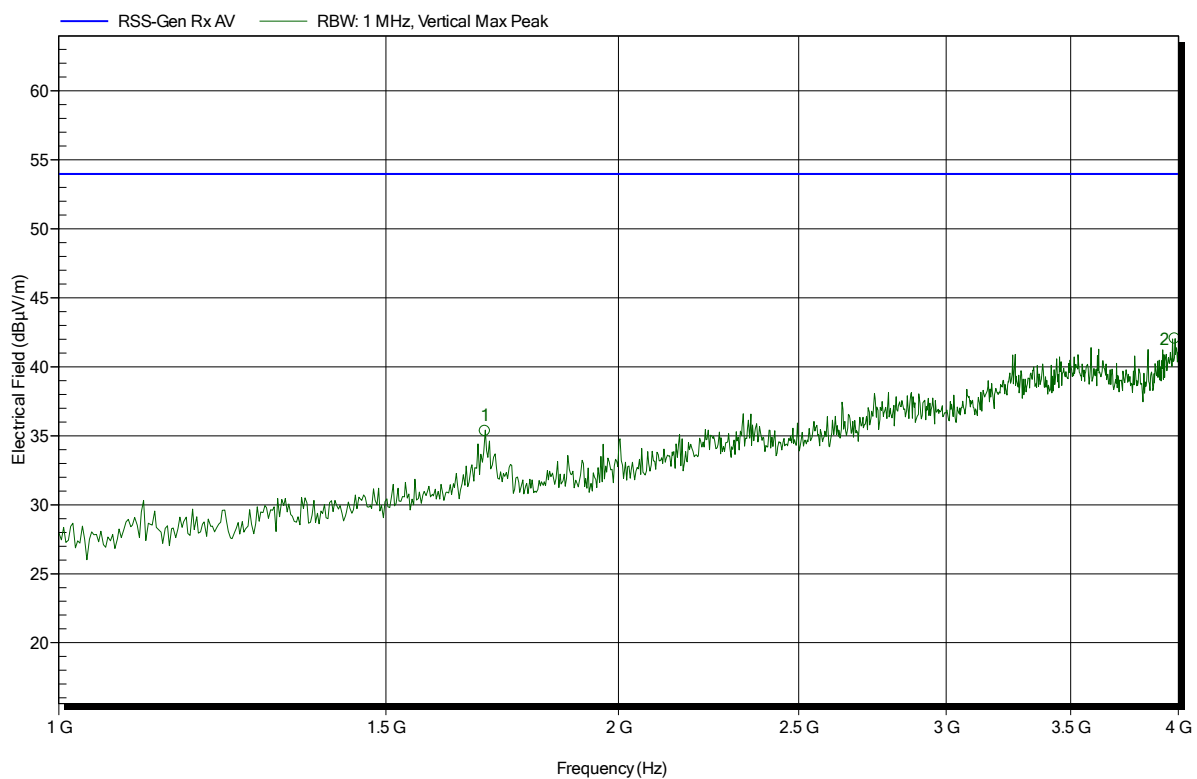


Spurious emissions according to RSS-Gen

Project number: G0M-1807-7555

Applicant: Biotronik SE & Co. KG
EUT Name: Primus Nano Plus IPG / Implantable Pulse Generator
Model: Edora 8 DR-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom: 25°C, Vnom: 3.0 VDC (battery)
Antenna: HL025, Vertical
Measurement distance: 3 m
Mode: RX; 2-FSK; 403.65 MHz
Test Date: 2018-08-14
Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
1.695 GHz	35.34 dBµV/m	53.98 dBµV/m	-18.64 dB	Pass
3.982 GHz	42.05 dBµV/m	53.98 dBµV/m	-11.93 dB	Pass