

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-1509-5046-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	Woermannkehe 1 12359 Berlin GERMANY
Test specification:	
Standard	47 CFR Part 95E 47 CFR Part 95I 47 CFR Part 15C RSS-243, Issue 3, 2010-02 RSS-Gen, Issue 4, 2014-11 ANSI C63.4:2014 EN 301 839-1 V1.3.1:2009-10
Test scope	complete Radio compliance test (C2PC)
Equipment under test (EUT):	
Product description	Pacemaker family PRIMUS NXT
Model No.	Eluna 8 HF-T
Additional Model(s)	see page5: List of Models to be included in the family
Brand Name(s)	BIOTRONIK
Hardware version	ASM-0217_0B with BOM-0288_06_396062 (2230-04)
Firmware / Software version	7300RomRev_01.02/7474RamRev_04.02
	FCC-ID: QRIPRIMUSNXT IC: 4708A-PRIMUSNXT
Test result	Passed

Possible test case verdicts:

- neither assessed nor tested : N/N
- required by standard but not appl. to test object : N/A
- required by standard but not tested : N/T
- not required by standard for the test object : N/R
- test object does meet the requirement : P (Pass)
- test object does not meet the requirement : F (Fail)

Testing:

Test Lab Temperature : 20 – 23 °C

Test Lab Humidity : 32 – 38 %

Date of receipt of test item : 2015-10-02

Date (s) of performance of tests : 2015-10-05 – 2015-10-08

Compiled by : Wilfried Treffke

Tested by (+ signature) : Wilfried Treffke 

(Responsible for Test)

Approved by (+ signature) : Christian Weber 

(Head of Lab)

Date of issue : 2015-11-11

Total number of pages : 79

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:1

Family Explanation Primus NXT

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 Home Monitoring capabilities.

HF-T are triple-chamber devices. (Master for all tests)

DR-T are dual-chamber devices.

SR-T are single-chamber devices.

DR are dual-chamber without home monitoring.

SR are single-chamber without home capabilities.

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

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

BIOTRONIK SE & Co. KG · Postfach 470255 · 12311 Berlin

To whom it may concern

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www.biotronik.com

Berlin, October 20, 2015

Gentlemen,

Herewith we, BIOTRONIK SE & Co. KG, declare the following changes that were done to the already approved product family PRIMUS NXT (FCC-ID: QRIPRIMUSNXT)

The major change filed under application is:

- Change 1: The SAW filter was changed from the Vectron 403A to the Vectron 403B.
Change 2: Matching components for the SAW filter were changed
(L804 was 11nH and is now 36nH, L808 was 27nH and is now 30nH).
Change 3: The antenna design was modified to improve manufacturability. The electrical length remains the same.

According to our internal design validation no difference in conducted output power was observed as part of the design change.

If you have any questions regarding this application, please feel free to contact

Contact name Dirk König
Company name BIOTRONIK SE & CO. KG
Phone No.: +49 (0) 30 68905 1291

Sincerely,

Signature
Dirk König
Manager Regulatory Affairs
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HRA 6501 B, AG Berlin-Charlottenburg
Komplementärin: BIOTRONIK MT SE
HRS 118866 B, AG Berlin-Charlottenburg

PRIMUS NXT product family
Family Certification
List of the models to be included in the family

Applicant: BIOTRONIK SE & Co. KG

Certification Number: QRIPRIMUSNXT

Model	Description
Eluna 8 SR	One chamber , Coil telemetry and RF Transceiver
Eluna 8 SR-T	One chamber , Coil telemetry and RF Transceiver
Eluna 8 DR	Two chambers , Coil telemetry and RF Transceiver
Eluna 8 DR-T	Two chamber , Coil telemetry and RF Transceiver
Eluna 8 HF-T	Three chambers , Coil telemetry and RF Transceiver
Epyra 6 SR-T	One chamber , Coil telemetry and RF Transceiver
Epyra 6 DR-T	Two chambers , Coil telemetry and RF Transceiver
Epyra 8 SR-T	One chamber , Coil telemetry and RF Transceiver
Epyra 8 DR-T	Two chambers , Coil telemetry and RF Transceiver
Epyra 8 HF-T	Three chambers , Coil telemetry and RF Transceiver
Etrinsa 6 SR	One chamber , Coil telemetry and RF Transceiver
Etrinsa 6 SR-T	One chamber , Coil telemetry and RF Transceiver
Etrinsa 6 DR	Two chambers , Coil telemetry and RF Transceiver
Etrinsa 6 DR-T	Two chambers , Coil telemetry and RF Transceiver
Etrinsa 8 SR-T	One chamber , Coil telemetry and RF Transceiver
Etrinsa 8 DR-T	Two chambers , Coil telemetry and RF Transceiver
Etrinsa 8 HF-T	Three chambers , Coil telemetry and RF Transceiver

The BIOTRONIK PRIMUS NXT family of products includes the following models:

Eluna, Epyra and Etrinsa.

All models comprise identical internal electronic including a low frequency telemetry coil and packaged in titanium cases with a header where the leads connect.

All devices include additional an internal RF Transceiver and an antenna within the header.

The internal electronic of HF-T devices differs slightly from SR and DR devices to include the third channel electronic. Therefore the device under test is three chambers model **Eluna 8 HF-T**.

The PRIMUS NXT models contain a different therapeutic feature set. The features differ only by the number of connectable leads and software.

Version History

Version	Issue Date	Remarks	Revised by
01	2015-11-11	Initial Release	

REPORT INDEX

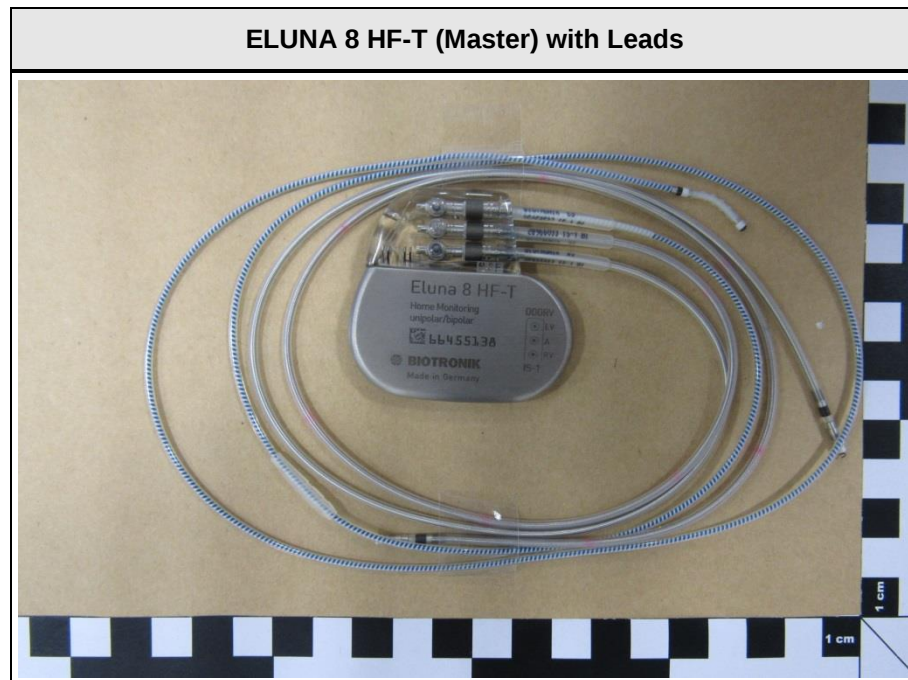
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1 Equipment (Test item) Description

Description	Pacemaker family PRIMUS NXT	
Model	Eluna 8 HF-T	
Additional Model(s)	see page5: List of Models to be included in the family	
Brand Name(s)	BIOTRONIK	
Serial number	66455138	
Hardware version	ASM-0217_0B with BOM-0288_06_396062 (2230-04)	
Software / Firmware version	7300RomRev_01.02/7474RamRev_04.02	
FCC-ID	QRIPRIMUSNXT	
IC	4708A-PRIMUSNXT	
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	loop antenna
	Manufacturer	Biotronik SE & Co. KG
	Gain	-31.32 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

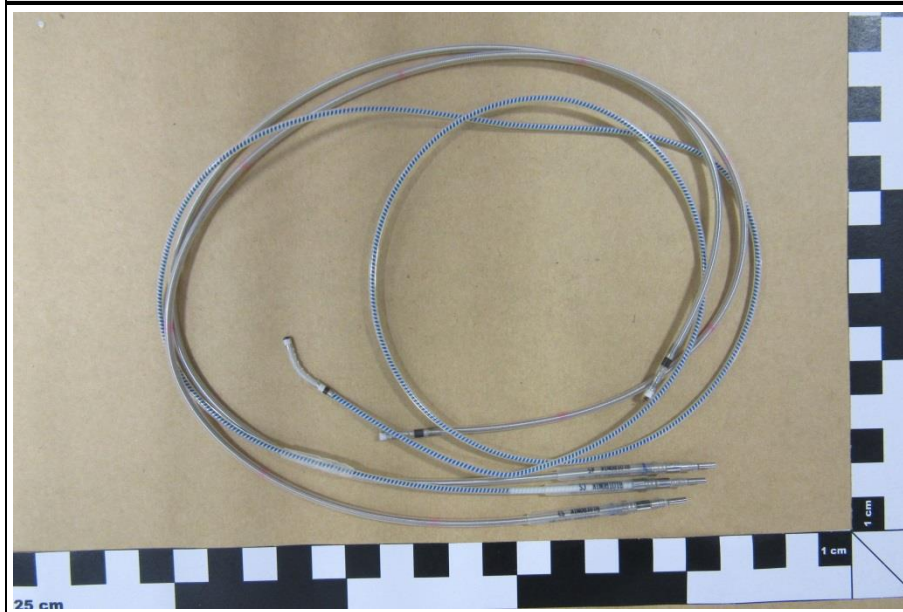
1.1 Photos - Equipment external



ELUNA 8 HF-T (Master) BOTTOM



LEADS

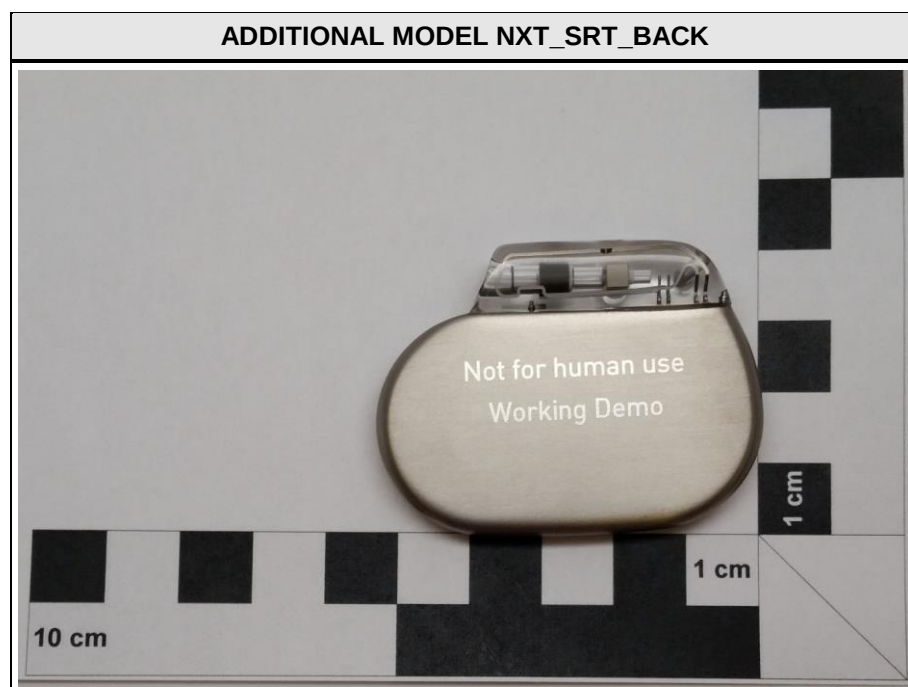
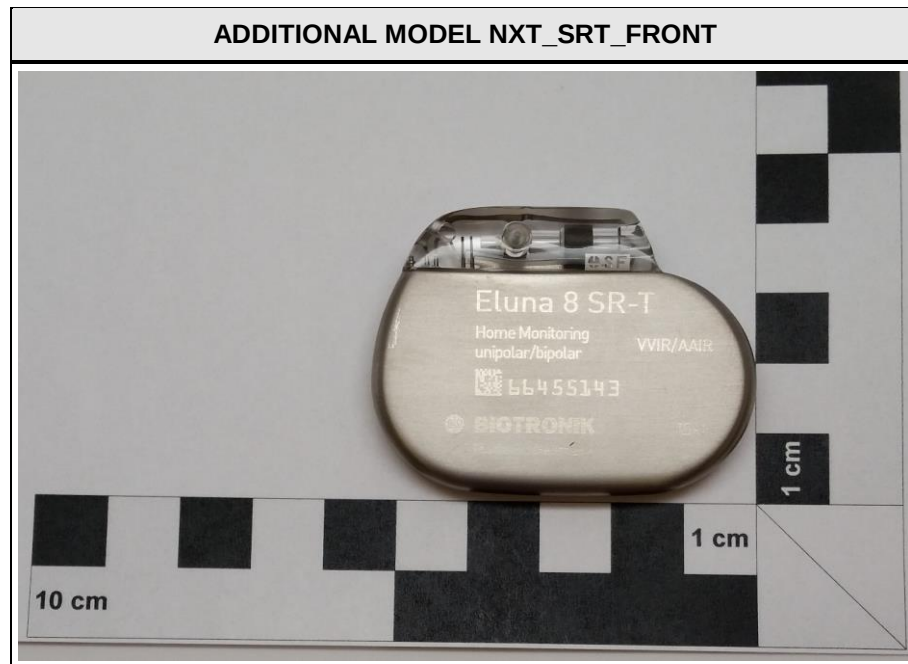


ADDITIONAL MODEL NXT_DRT_FRONT

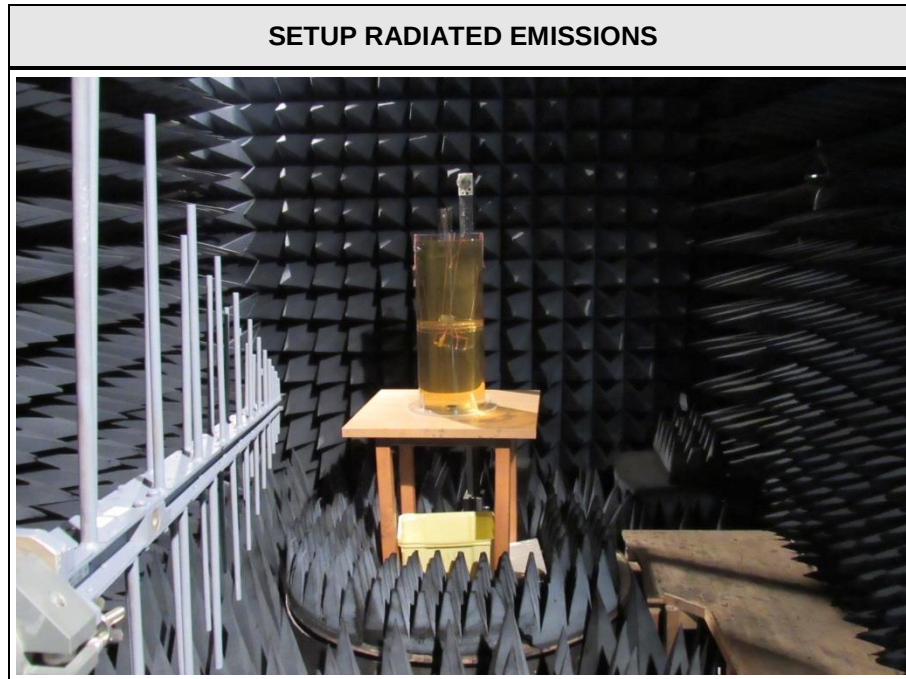


ADDITIONAL MODEL NXT_DRT_BACK





1.3 Photos – Test setup



1.4 Photos – Auxiliary/Associated Equipment



1.5 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Programmer	Biotronik	USB TelBox	64kHz system
AE2	Programmer	Biotronik	405 TELBOX II	400MHz system
*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 fully charged battery
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated	General conditions:	EUT powered by fully charged battery
	Radio conditions:	Mode = standalone transmit Modulation = FSK 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	2014.1.15

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2015-04	2016-04

Emission Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2015-04	2016-04

Frequency Stability					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2015-04	2016-04

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Fully-anechoic chamber	Frankonia	AC 4	EF00200	-	-
Spectrum Analyzer	R&S	FSEK30	EF00168	2015-01	2016-01
LPD Antenna	R&S	HL 223	EF00212	2013-02	2016-02

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

1.8 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 dB μ V. 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 dB μ V/m). The FCC limits are given in units of μ V/m. The following formula is used to convert the units of μ V/m to dB μ V/m:

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

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:

$$\begin{array}{rclclcl} \text{Reading} & + & \text{AF} & = & \text{Net Reading} & : & \text{Net reading - FCC limit} & = & \text{Margin} \\ 21.5 \text{ dB}\mu\text{V} & + & 26 \text{ dB} & = & 47.5 \text{ dB}\mu\text{V/m} & : & 47.5 \text{ dB}\mu\text{V/m} - 57.0 \text{ dB}\mu\text{V/m} & = & -9.5 \text{ dB} \end{array}$$

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]	9.0	8.8	-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	Information only
FCC 95.628(d) FCC § 95.633(e) IC RSS-243 3.6, 5.1	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	No powered (directly or indirectly) via AC-Mains
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: Test selection for Class II Permissive change according to permissive change letter.				

3 Test Conditions and Results

3.1 Test Conditions and Results – Occupied Bandwidth

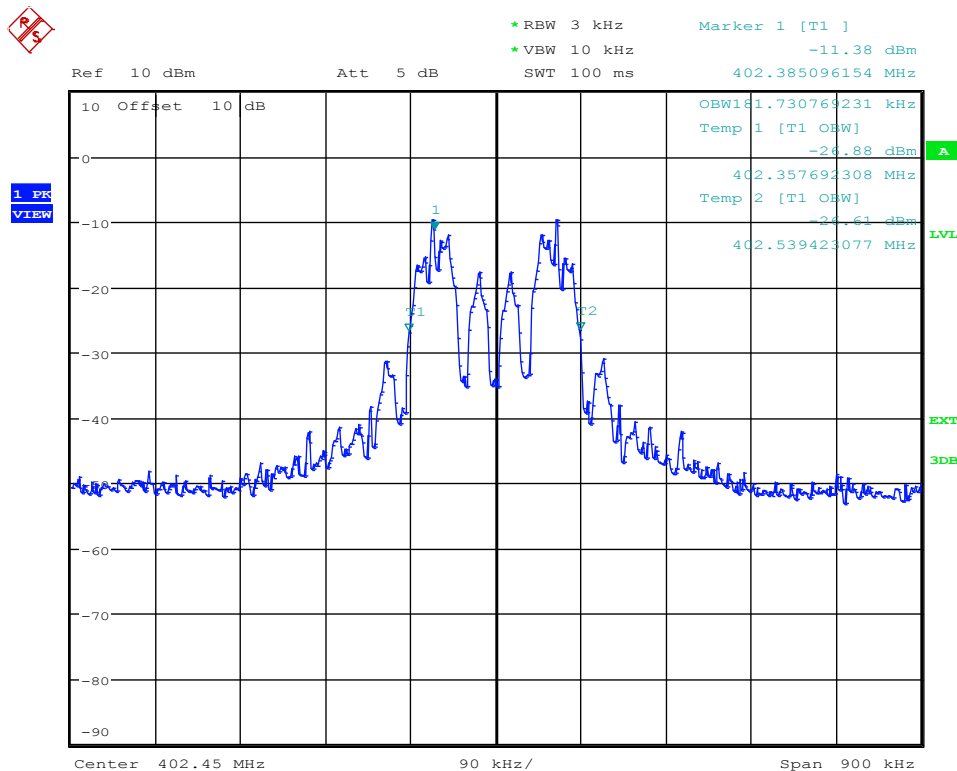
Occupied Bandwidth acc. to IC RSS-243			Verdict: PASS
Test according to measurement reference		Reference Method	
		RSS-Gen 6.6	
Test frequency range		Tested frequencies	
		F _{LOW} / F _{MID} / F _{HIGH}	
EUT test mode		Modulated	
Limits			
None (Informational only)			
Test setup			
Spectrum Analyzer EUT			
Test procedure			
1. EUT set to test mode (Communication tester is used if needed) 2. Span set to at least twice the emission spectrum 3. Resolution bandwidth set to 1 % of span 4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function			
Test results			
Channel	Frequency [MHz]	Occupied Bandwidth [kHz]	
F _{LOW}	402.45	181.7	
F _{MID}	403.65	183.2	
F _{HIGH}	404.85	180.3	
Comments:			

Occupied Bandwidth – F_{Low}

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
EUT Name: Pacemaker family PRIMUS NXT
Model: Eluna 8 HF-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: T_{nom} / V_{nom}
Mode: Tx 402.45 MHz, 2FSK
Test Date: 2015-10-22
Verdict: NONE (INFORMATION ONLY)
Note 1: A spectrum analyzer with an integrated 99% power bandwidth function is used



Date: 22.OCT.2015 13:32:08

Test Report No.: G0M-1509-5046-TFC95IMR-V01

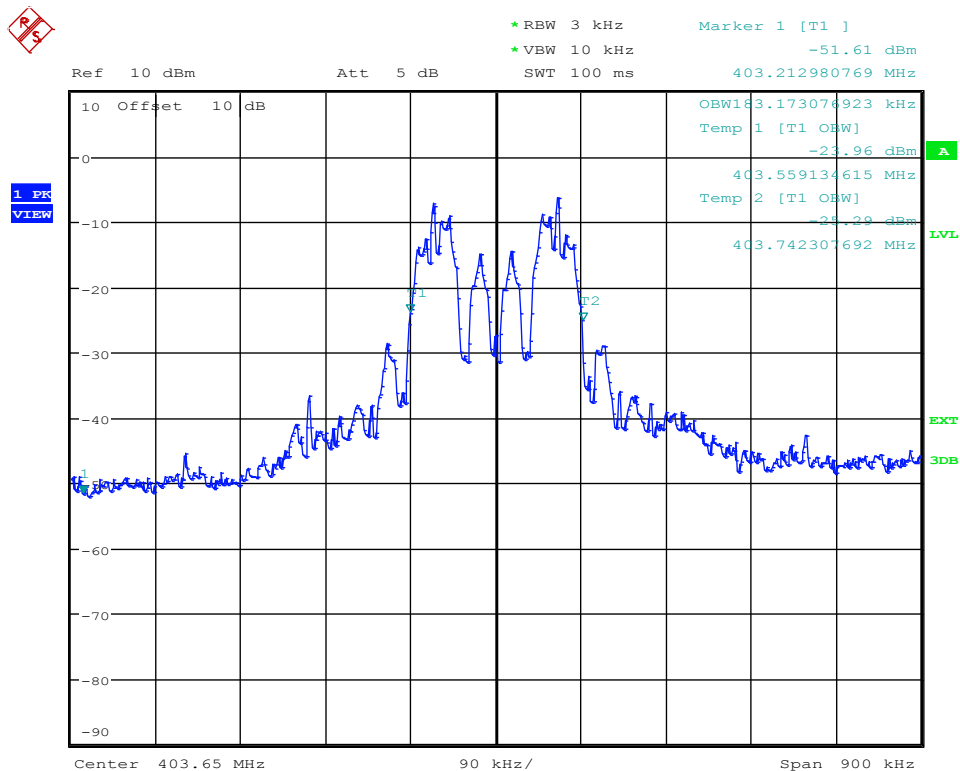
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Occupied Bandwidth - F_{MID}

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
EUT Name: Pacemaker family PRIMUS NXT
Model: Eluna 8 HF-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom / Vnom
Mode: Tx 403.65 MHz, 2FSK
Test Date: 2015-10-22
Verdict: NONE (INFORMATION ONLY)
Note 1: A spectrum analyzer with an integrated 99% power bandwidth function is used



Date: 22.OCT.2015 13:35:41

Test Report No.: G0M-1509-5046-TFC95IMR-V01

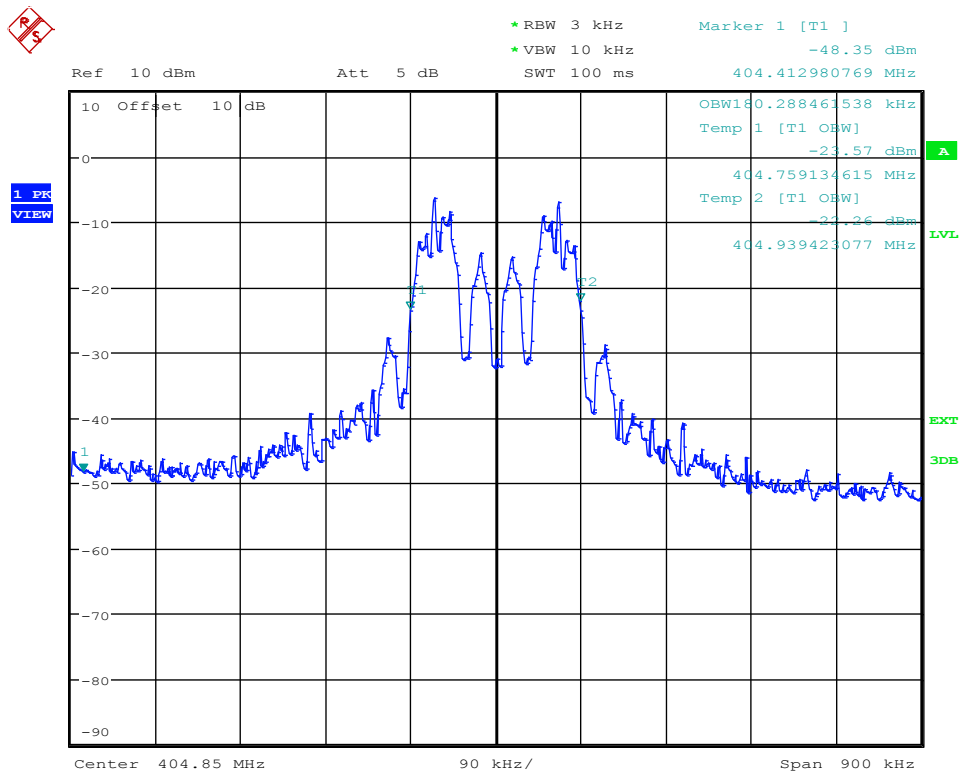
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Occupied Bandwidth - F_{HIGH}

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
EUT Name: Pacemaker family PRIMUS NXT
Model: Eluna 8 HF-T
Test Site: Eurofins Product Service GmbH
Operator: Wilfried Treffke
Test Conditions: Tnom / Vnom
Mode: Tx 404.85 MHz, 2FSK
Test Date: 2015-10-22
Verdict: NONE (INFORMATION ONLY)
Note 1: A spectrum analyzer with an integrated 99% power bandwidth function is used



Date: 22.OCT.2015 13:37:42

Test Report No.: G0M-1509-5046-TFC95IMR-V01

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

3.2 Test Conditions and Results – Emission Bandwidth

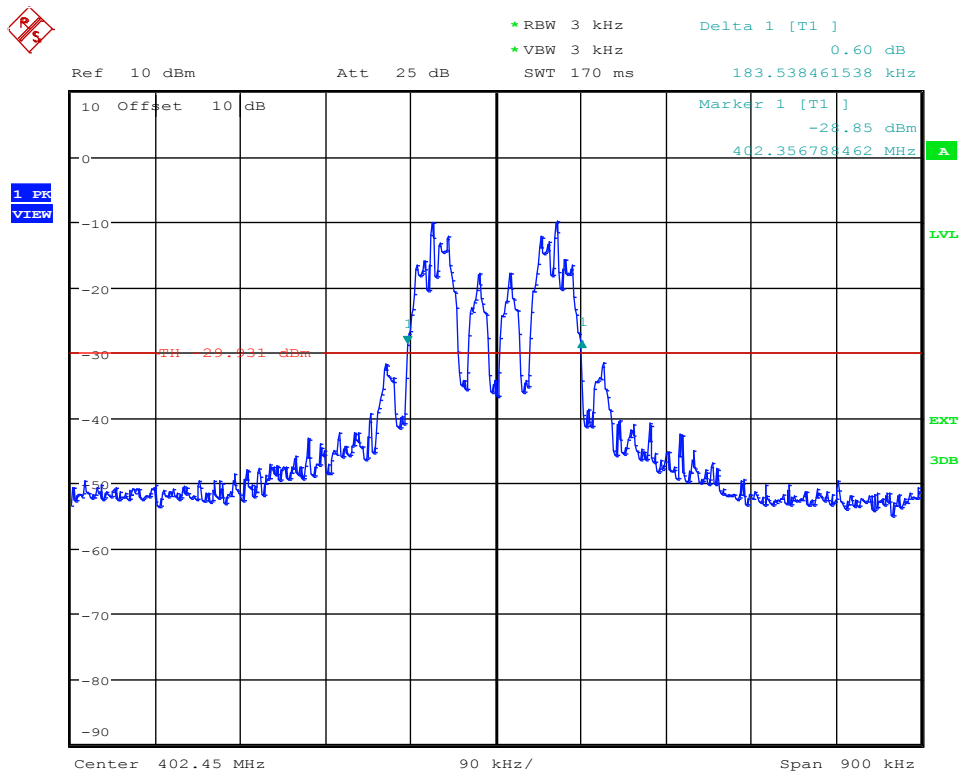
Emission Bandwidth acc. to FCC Part 95 / IC RSS-243				Verdict: PASS
EUT requirement rule parts and clause	Reference			
	FCC 95.628(d) / FCC 95.633(e) / IC RSS-243 3.3 5.1			
Test according to measurement reference	Reference Method			
	FCC 95.628(a)(6)(i) / FCC 95.633(e)(3)			
Test frequency range	Tested frequencies			
	F _{LOW} / F _{MID} / F _{HIGH}			
EUT test mode	Modulated			
Limits				
≤ 300 kHz				
Test setup				
Spectrum Analyzer EUT				
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	Frequency [MHz]	Emission Bandwidth [kHz]	Limit [kHz]	Result
F _{LOW}	402.45	183.5	≤ 300	PASS
F _{MID}	403.65	183.5	≤ 300	PASS
F _{HIGH}	404.85	183.5	≤ 300	PASS
Comments:				

Emission Bandwidth – F_{Low}

Emission Bandwidth acc. to FCC Part 95.633

Project Number: GOM-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: T_{nom} / V_{nom}
 Mode: Tx 402.45 MHz, 2FSK
 Test Date: 2015-10-22
 Verdict: PASS
 Note 1: 20 dB bandwidth



Date: 22.OCT.2015 13:16:32

Test Report No.: GOM-1509-5046-TFC95IMR-V01

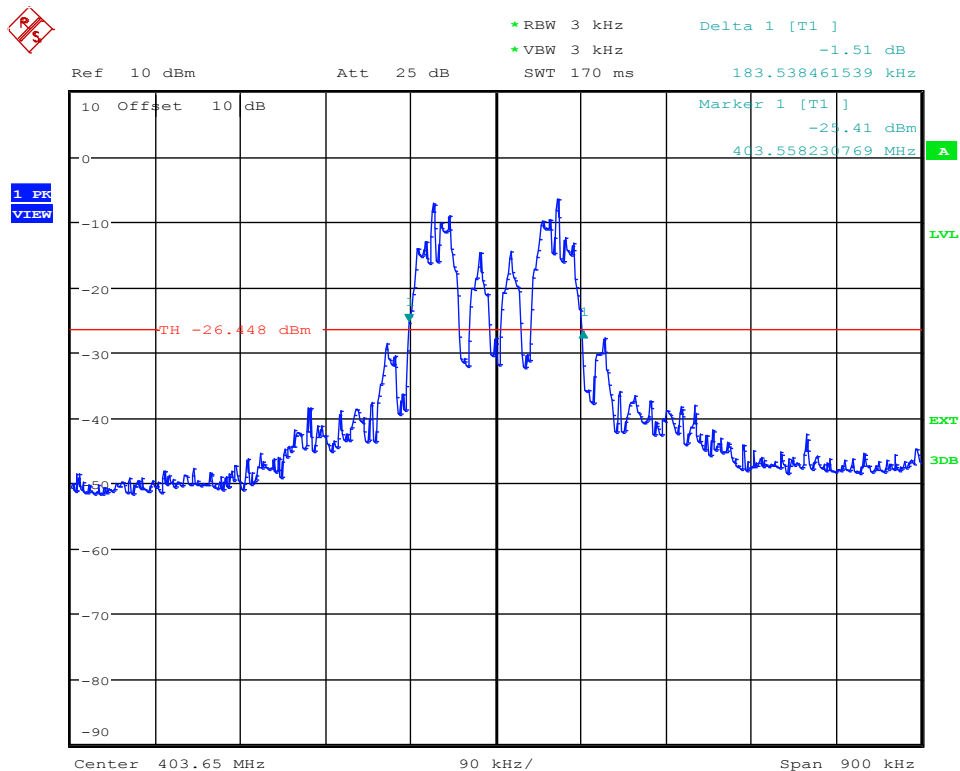
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Emission Bandwidth – F_{MID}

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: T_{nom} / V_{nom}
 Mode: Tx 403.65 MHz, 2FSK
 Test Date: 2015-10-22
 Verdict: PASS
 Note 1: 20 dB bandwidth



Date: 22.OCT.2015 13:21:11

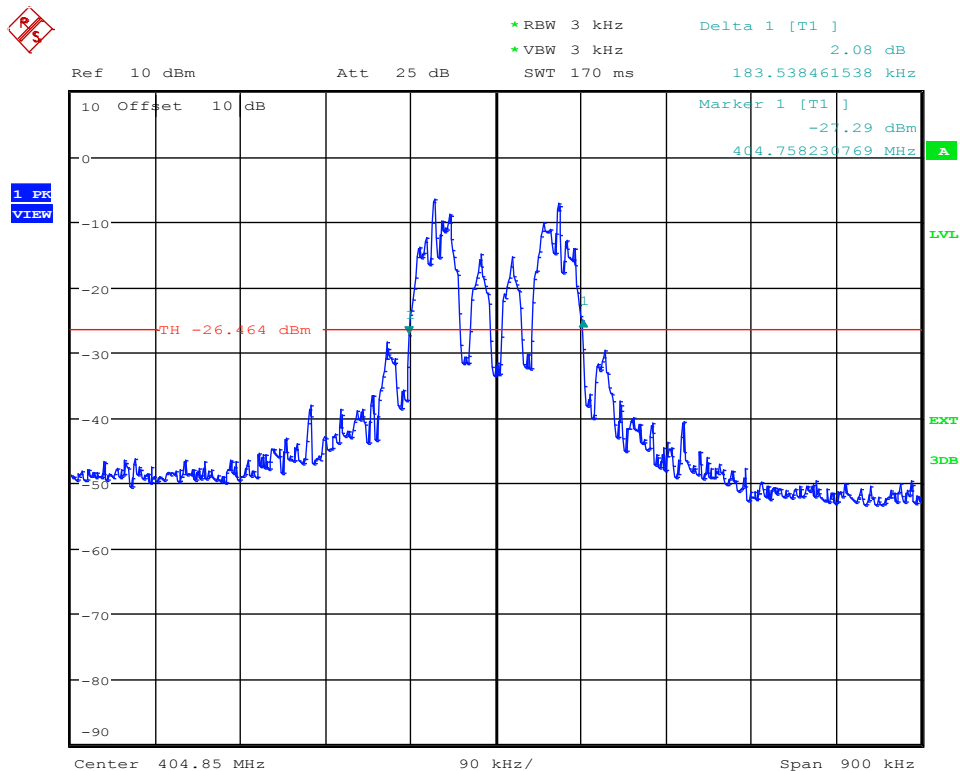
Test Report No.: G0M-1509-5046-TFC95IMR-V01

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

Emission Bandwidth – F_{HIGH}
Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Wilfried Treffke
 Test Conditions: Tnom / Vnom
 Mode: Tx 404.85 MHz, 2FSK
 Test Date: 2015-10-22
 Verdict: PASS
 Note 1: 20 dB bandwidth

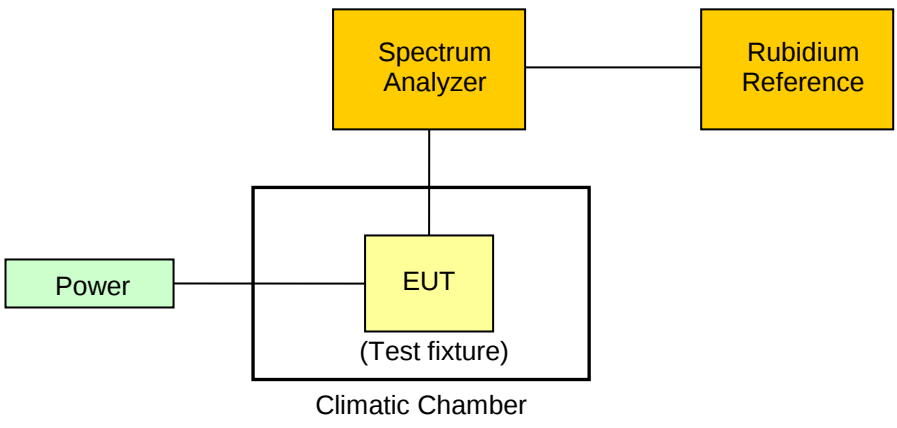


Date: 22.OCT.2015 13:26:22

Test Report No.: G0M-1509-5046-TFC95IMR-V01

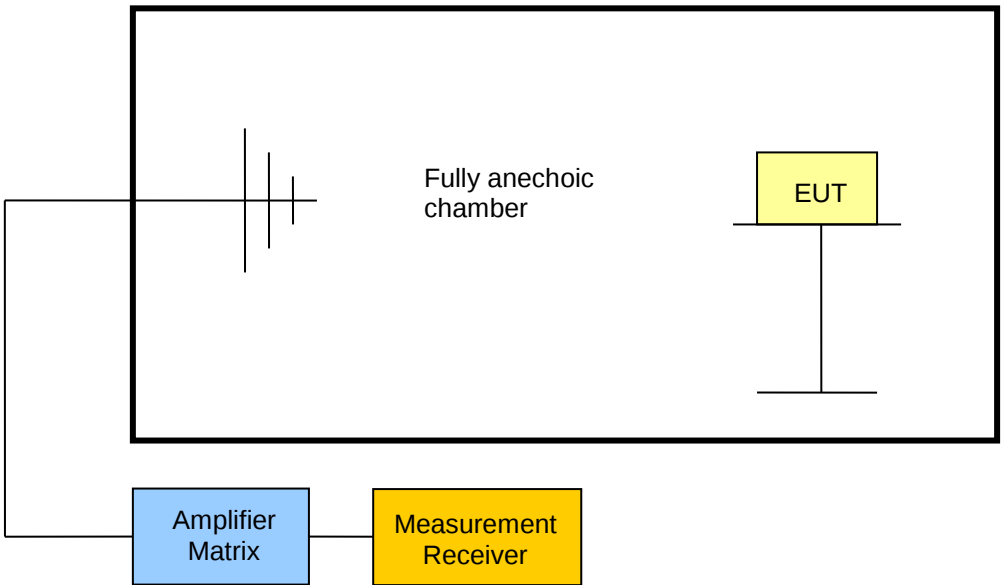
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

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	
	$F_{\text{LOW}} / F_{\text{MID}} / F_{\text{HIGH}}$	
EUT test mode	Unmodulated	
Limits		
$\leq \pm 100$ ppm		
Test setup		
 <pre> graph LR Power[Power] --- EUT[EUT (Test fixture)] subgraph Climatic Chamber EUT end EUT --- SA[Spectrum Analyzer] SA --- RR[Rubidium Reference] </pre>		
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.		

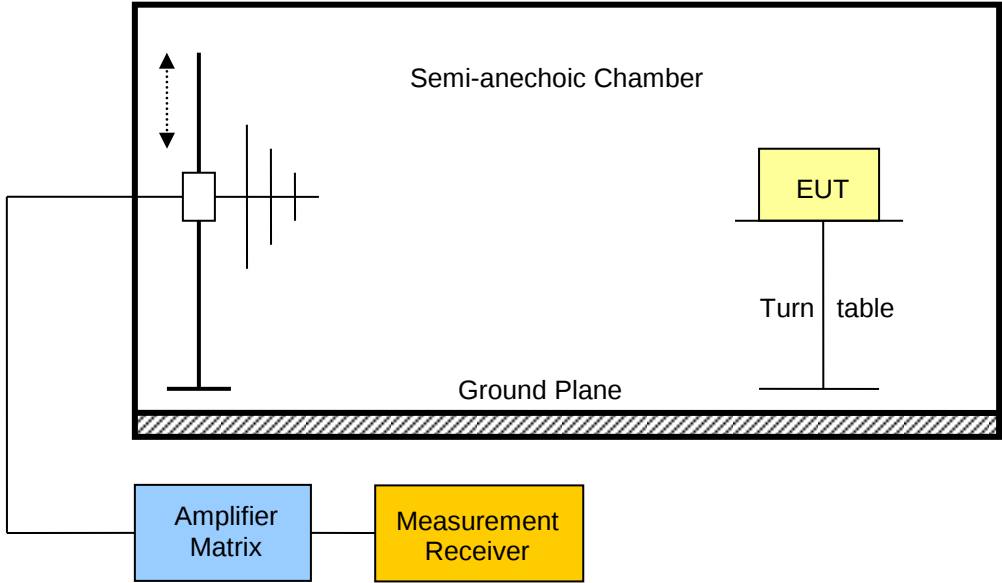
Test results					
Channel	Nominal Frequency [MHz]	Temperature	Supply voltage	Frequency [MHz]	Drift [ppm]
F _{LOW}	402.45	T _{NOM} = 37 °C	V _{NOM} = 3.0 VDC	402.448368	-04.06
F _{LOW}	402.45	T _{MIN} = 25 °C	V _{NOM} = 3.0 VDC	402.448517	-03.68
F _{LOW}	402.45	T _{MAX} = 45 °C	V _{NOM} = 3.0 VDC	402.448252	-04.34
F _{MID}	403.65	T _{NOM} = 37 °C	V _{NOM} = 3.0 VDC	403.649394	-01.50
F _{MID}	403.65	T _{MIN} = 25 °C	V _{NOM} = 3.0 VDC	403.649536	-01.15
F _{MID}	403.65	T _{MAX} = 45 °C	V _{NOM} = 3.0 VDC	403.649271	-01.81
F _{HIGH}	404.85	T _{NOM} = 37 °C	V _{NOM} = 3.0 VDC	404.850448	01.11
F _{HIGH}	404.85	T _{MIN} = 25 °C	V _{NOM} = 3.0 VDC	404.850610	01.51
F _{HIGH}	404.85	T _{MAX} = 45 °C	V _{NOM} = 3.0 VDC	404.850353	00.87
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	
	$F_{\text{LOW}} / F_{\text{MID}} / F_{\text{HIGH}}$	
EUT test mode	Unmodulated	
Limits		
$\leq 25 \mu\text{W}$ (-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 is set according to measurement range and detector is set to peak and max hold 4. Resolution bandwidth is set to 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	-32.6	pk	-16	-16.60
F _{HIGH}	404.85	-30.3	pk	-16	-14.30
Comments:					

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

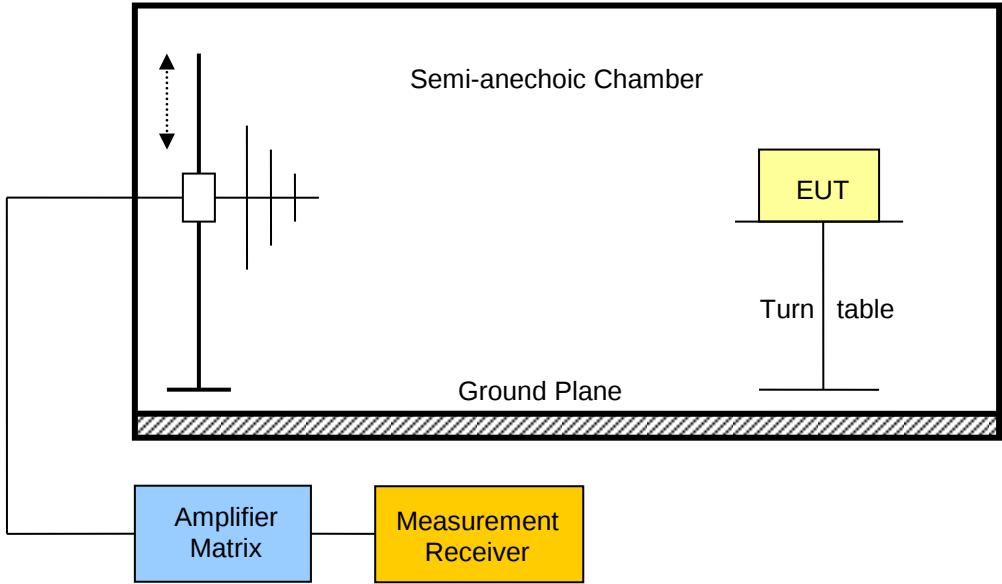
Band-edge compliance acc. to FCC Part 95 / IC RSS-243		Verdict: PASS
EUT requirement rule parts and clause	Reference	
	FCC 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9	
Test according to measurement reference	Reference Method	
	FCC 95.635(d) / ANSI C 63.4	
Test frequency range	Tested frequencies	
	F _{LOW} / F _{HIGH}	
EUT test mode	Modulated	
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 Report No.: G0M-1509-5046-TFC95IMR-V01

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

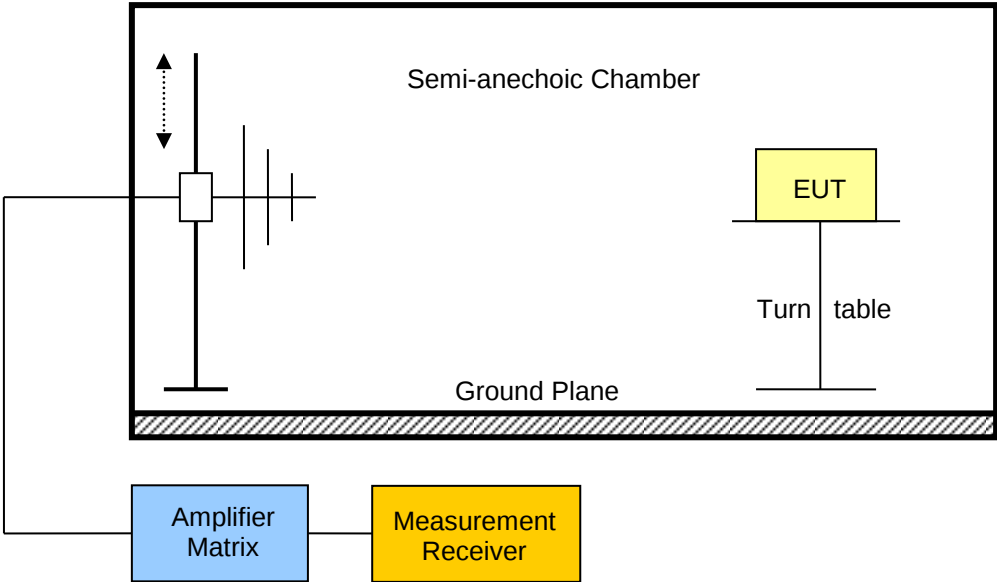
Test procedure					
1. EUT set to test frequency with modulation 2. Measurement polarization is set to vertical 3. Span it set according to measurement range 4. Resolution bandwidth is set to 1% of the emission bandwidth and detector is set to peak 5. During the sweep the EUT is rotated to obtain maximum emission level 6. Measurement is repeated with horizontal measurement polarization					
Test results					
Channel	Frequency [MHz]	Max. Emission Level [dBμV/m]	Max. Carrier Level [dBμV/m]	In-band Limit [dBμV/m]	Result
F _{LOW}	402.45	31.96	74.3	54.3	PASS
F _{LOW}	402.45	23.26	74.3	54.3	PASS
F _{LOW}	402.45	21.74	74.3	54.3	PASS
F _{HIGH}	404.85	33.43	76.3	56.3	PASS
F _{HIGH}	404.85	24.31	76.3	56.3	PASS
F _{HIGH}	404.85	18.21	76.3	56.3	PASS
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 – 10 th Harmonic				
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	400.943	33.66	pk	hor	46.00	3	-12.34
F _{LOW}	402.45	Modulated	401.347	23.86	pk	ver	46.00	3	-22.14
F _{LOW}	402.45	Modulated	401.96	05.95	pk	ver	59.40	3	-53.45
F _{LOW}	402.45	Modulated	401.993	14.42	pk	hor	59.40	3	-44.98
F _{LOW}	402.45	Modulated	405.076	05.29	pk	hor	59.40	3	-54.11
F _{LOW}	402.45	Modulated	405.095	-01.65	pk	ver	59.40	3	-61.05
F _{LOW}	402.45	Modulated	406.44	26.24	pk	hor	46.00	3	-19.76
F _{LOW}	402.45	Modulated	406.44	18.81	pk	ver	46.00	3	-27.19
F _{LOW}	402.45	Modulated	1689	33.40	pk	hor	54.00	3	-20.60
F _{LOW}	402.45	Modulated	1708	33.37	pk	ver	54.00	3	-20.63
F _{LOW}	402.45	Modulated	3263	40.42	pk	ver	54.00	3	-13.58
F _{HIGH}	404.85	Modulated	400.943	28.55	pk	hor	46.00	3	-17.45
F _{HIGH}	404.85	Modulated	400.943	19.73	pk	ver	46.00	3	-26.27
F _{HIGH}	404.85	Modulated	401.805	05.94	pk	hor	59.40	3	-53.46
F _{HIGH}	404.85	Modulated	405.015	23.75	pk	hor	59.40	3	-35.65
F _{HIGH}	404.85	Modulated	405.015	13.39	pk	ver	59.40	3	-46.01
F _{HIGH}	404.85	Modulated	405.25	30.15	pk	hor	46.00	3	-15.85
F _{HIGH}	404.85	Modulated	406.44	13.71	pk	ver	46.00	3	-32.29
F _{HIGH}	404.85	Modulated	1701	34.12	pk	hor	54.00	3	-19.88
F _{HIGH}	404.85	Modulated	3995	41.12	pk	ver	54.00	3	-12.88
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 – 5 th 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	34.08	29.18	pk	hor	40.00	-10.82
F _{MID}	403.65	167.02	32.66	pk	ver	43.50	-10.84
F _{MID}	403.65	668.8	16.61	pk	hor	46.00	-29.39
F _{MID}	403.65	878.4	19.33	pk	ver	46.00	-26.67
F _{MID}	403.65	3508	40.89	pk	hor	53.98	-13.09
F _{MID}	403.65	3940	41.91	pk	ver	53.98	-12.07
Comments:							

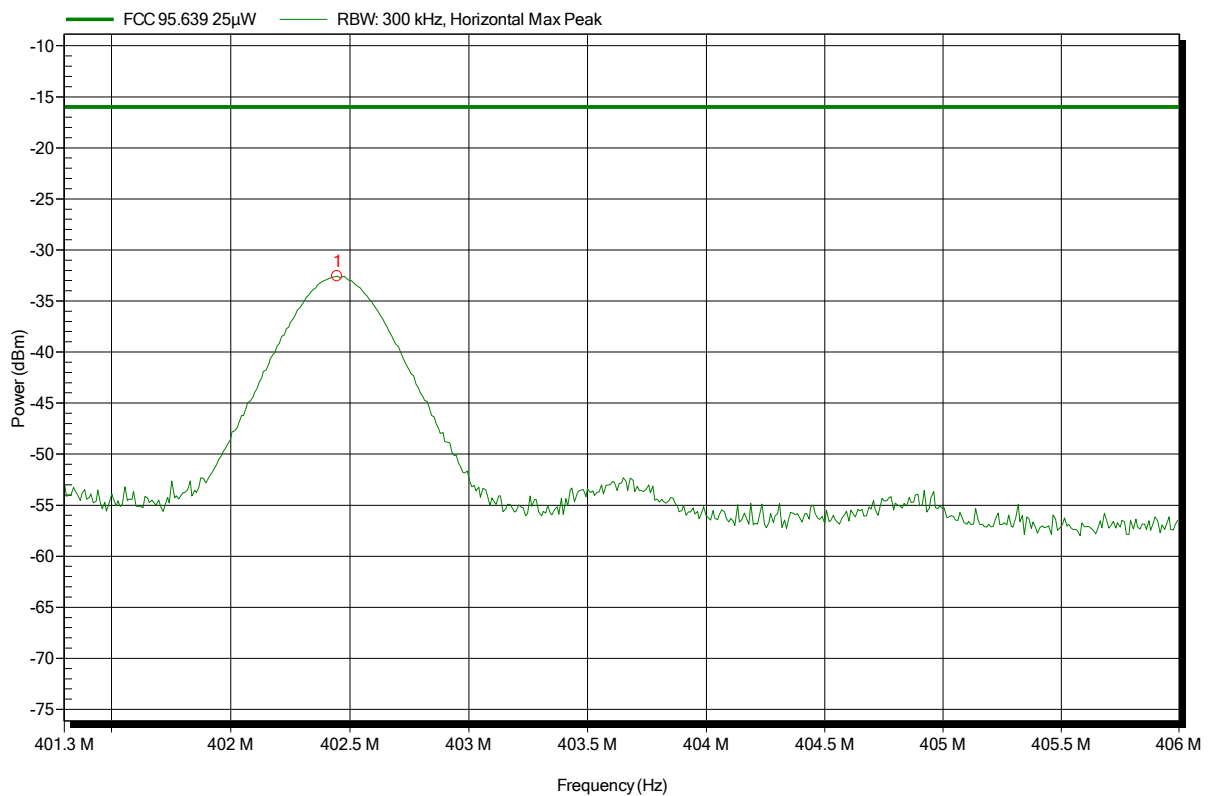
ANNEX A Transmitter radiated power

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-10-05
Note:	Tx Power EIRP

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.447 MHz	-32.6 dBm	-16 dBm	-16.6 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

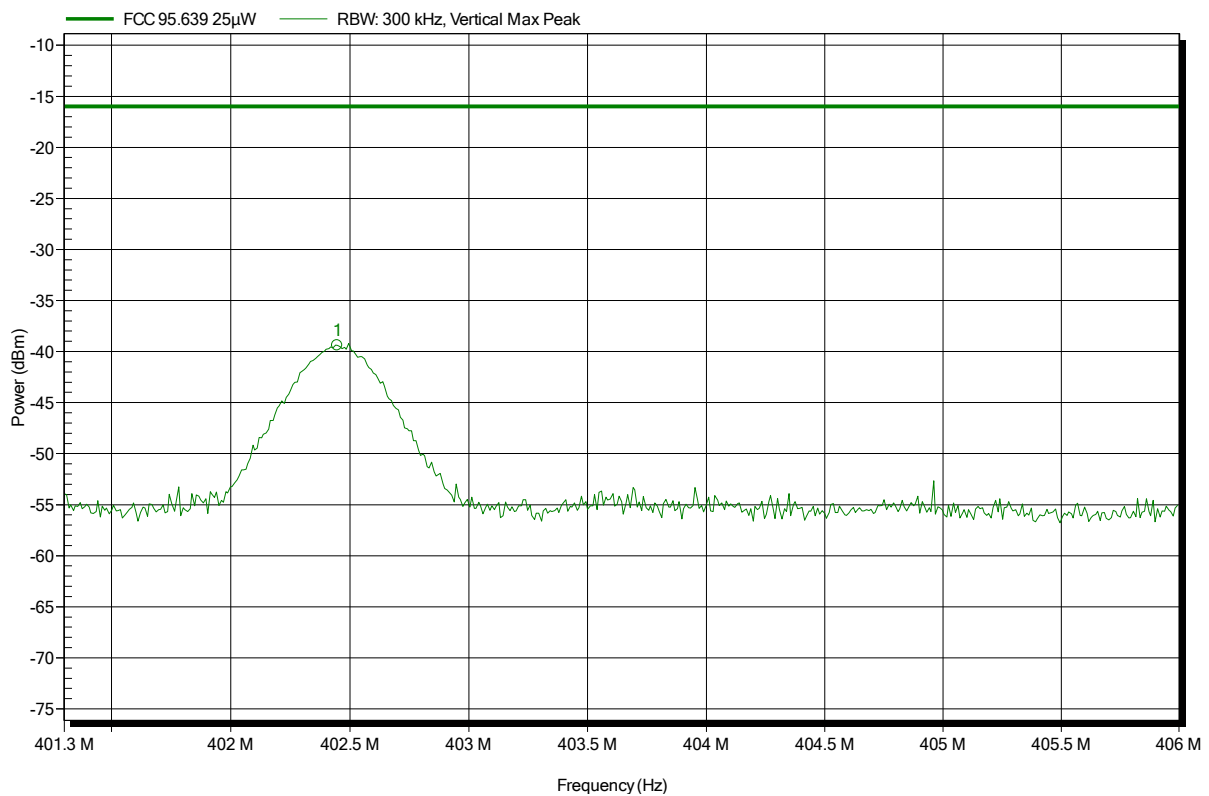
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: Tx; 402.45 MHz, CW
 Test Date: 2015-10-05
 Note: Tx Power EIRP

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.447 MHz	-39.4 dBm	-16 dBm	-23.39 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

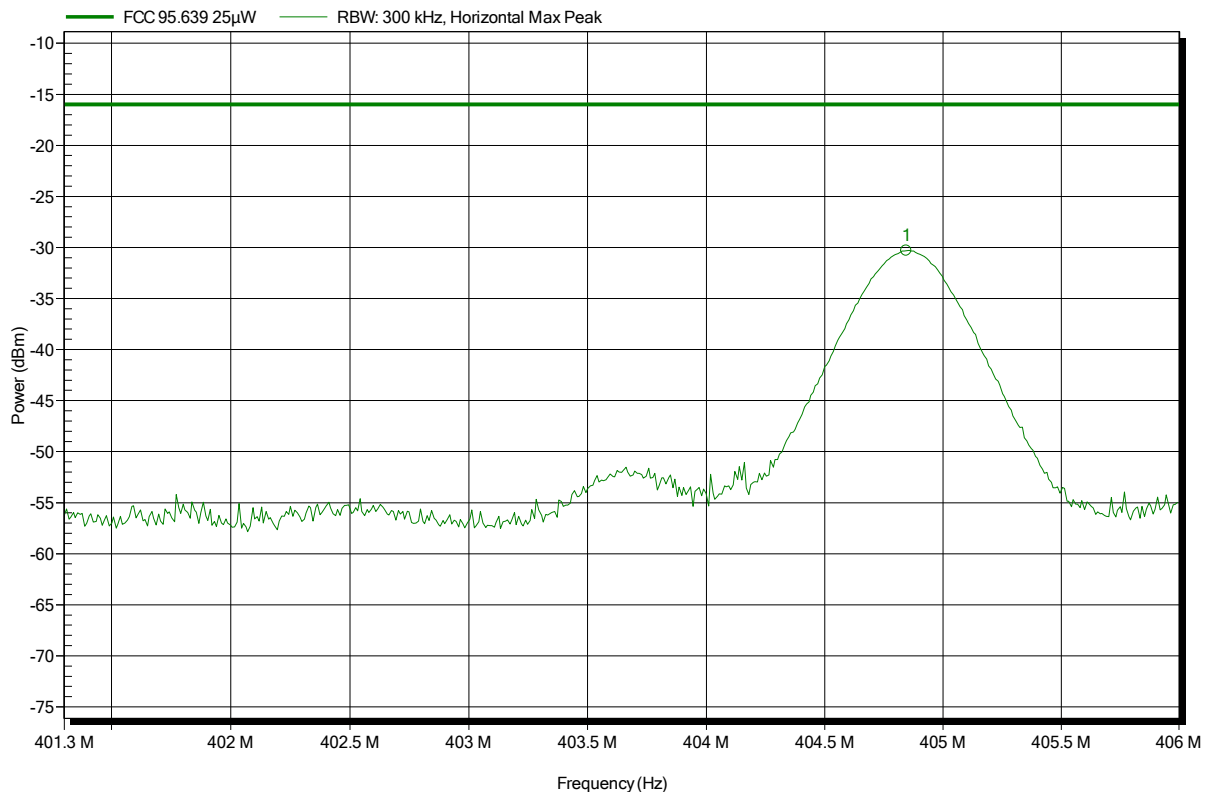
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: Tx; 404.85 MHz, CW
 Test Date: 2015-10-05
 Note: Tx Power EIRP

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.844 MHz	-30.3 dBm	-16 dBm	-14.32 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

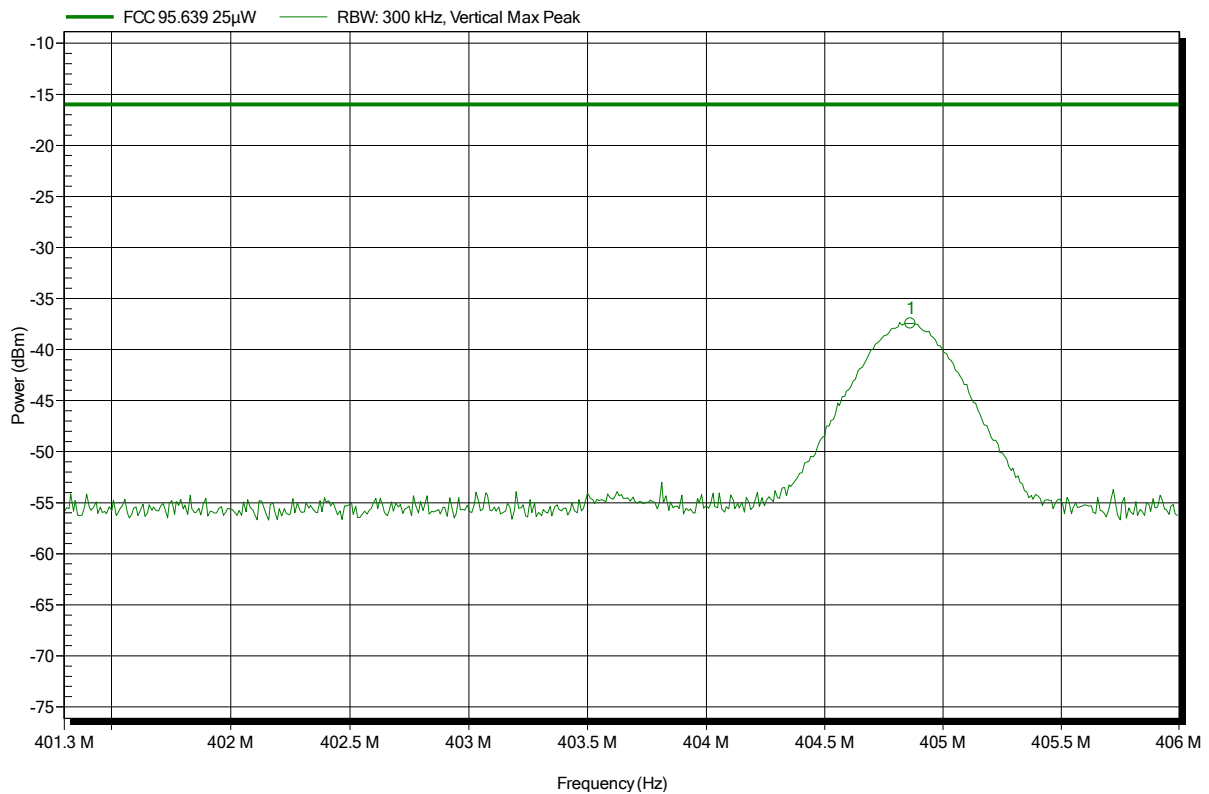
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: Tx; 404.85 MHz, CW
 Test Date: 2015-10-05
 Note: Tx Power EIRP

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.863 MHz	-37.5 dBm	-16 dBm	-21.45 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

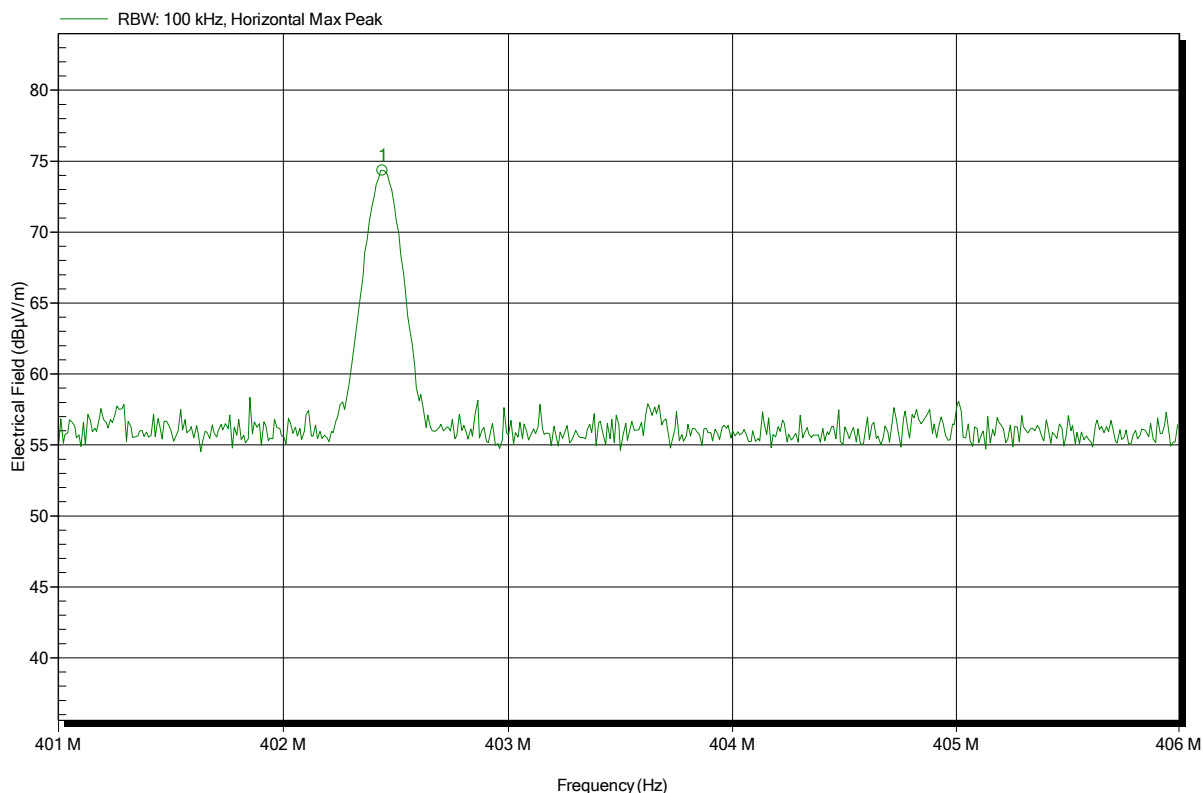
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-10-05
Note:	Power dB μ V/m ERP

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Frequency
402.44 MHz

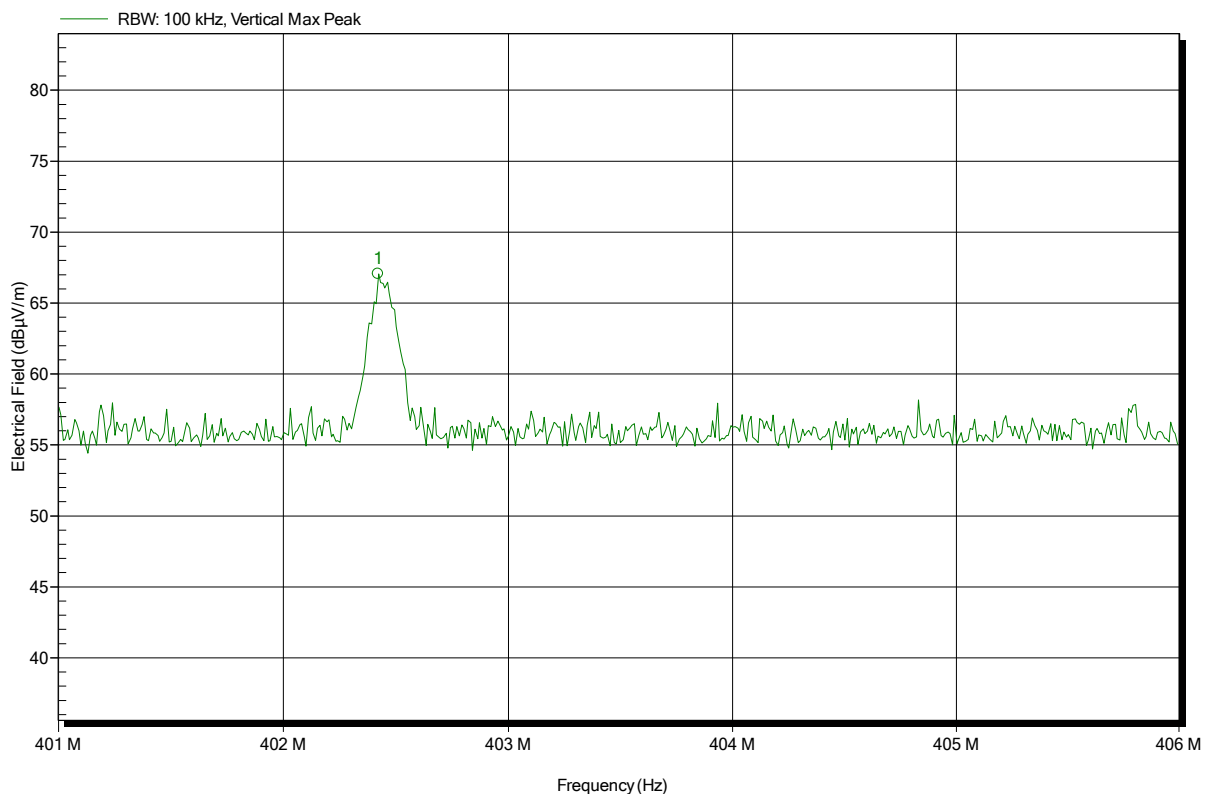
Peak
74.33 dB μ V/m

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-10-05
Note:	Power dB μ V/m ERP

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Frequency
402.42 MHz

Peak
67.05 dB μ V/m

Test Report No.: G0M-1509-5046-TFC95IMR-V01

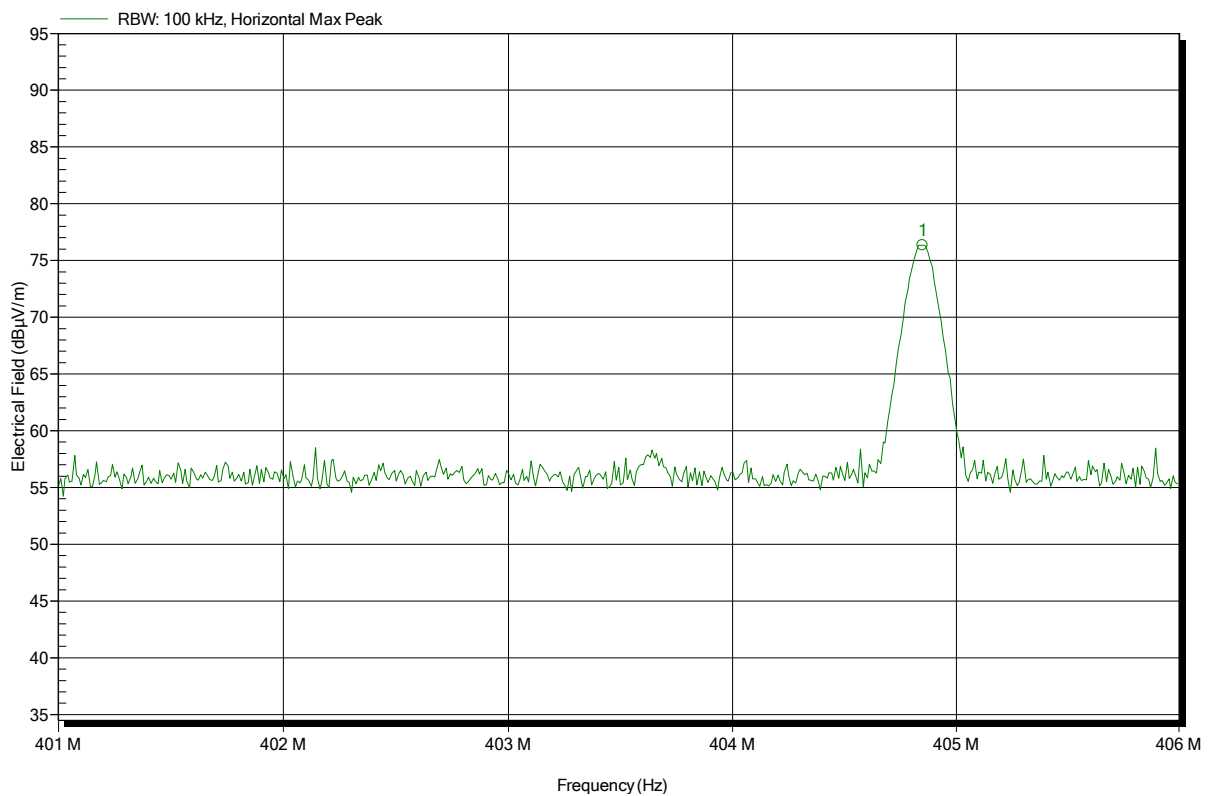
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz, CW
Test Date:	2015-10-05
Note:	Power dBμV/m ERP

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Frequency
404.85 MHz

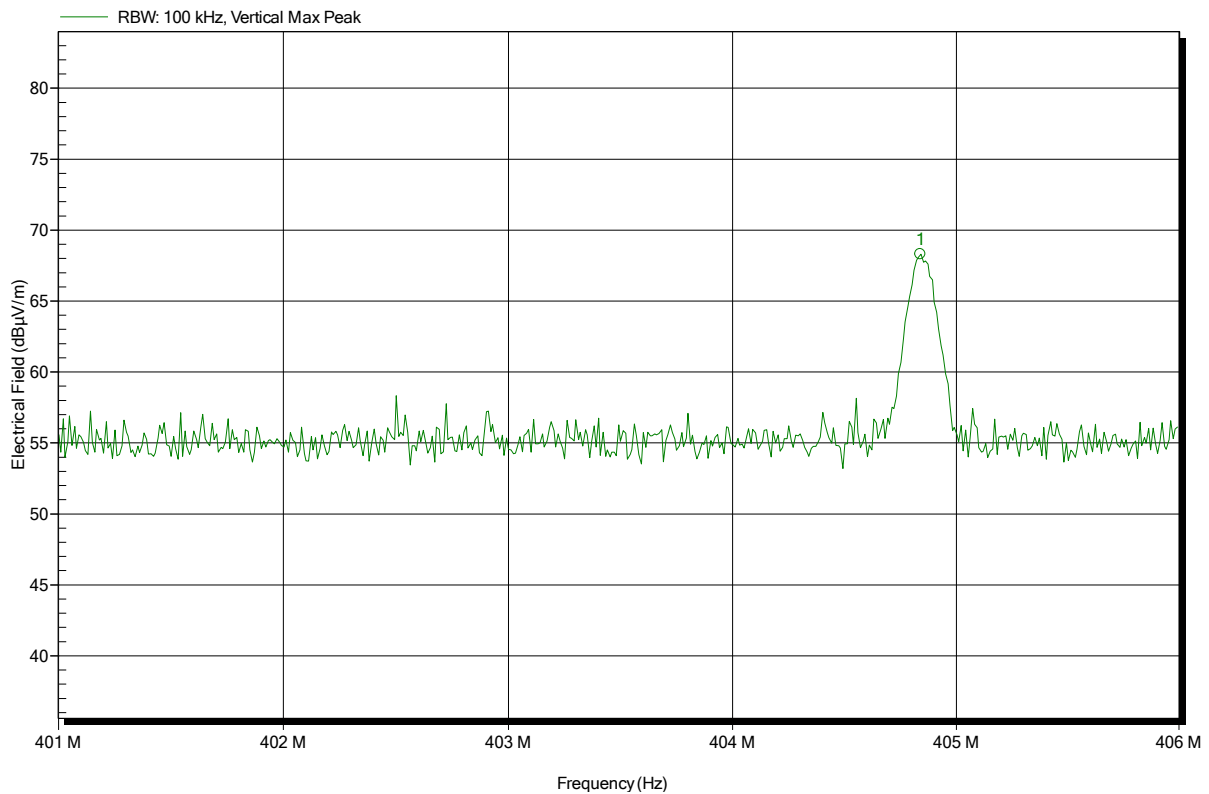
Peak
76.35 dBμV/m

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz, CW
Test Date:	2015-10-05
Note:	Power dB μ V/m ERP

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Frequency
404.84 MHz

Peak
68.3 dB μ V/m

Test Report No.: G0M-1509-5046-TFC95IMR-V01

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

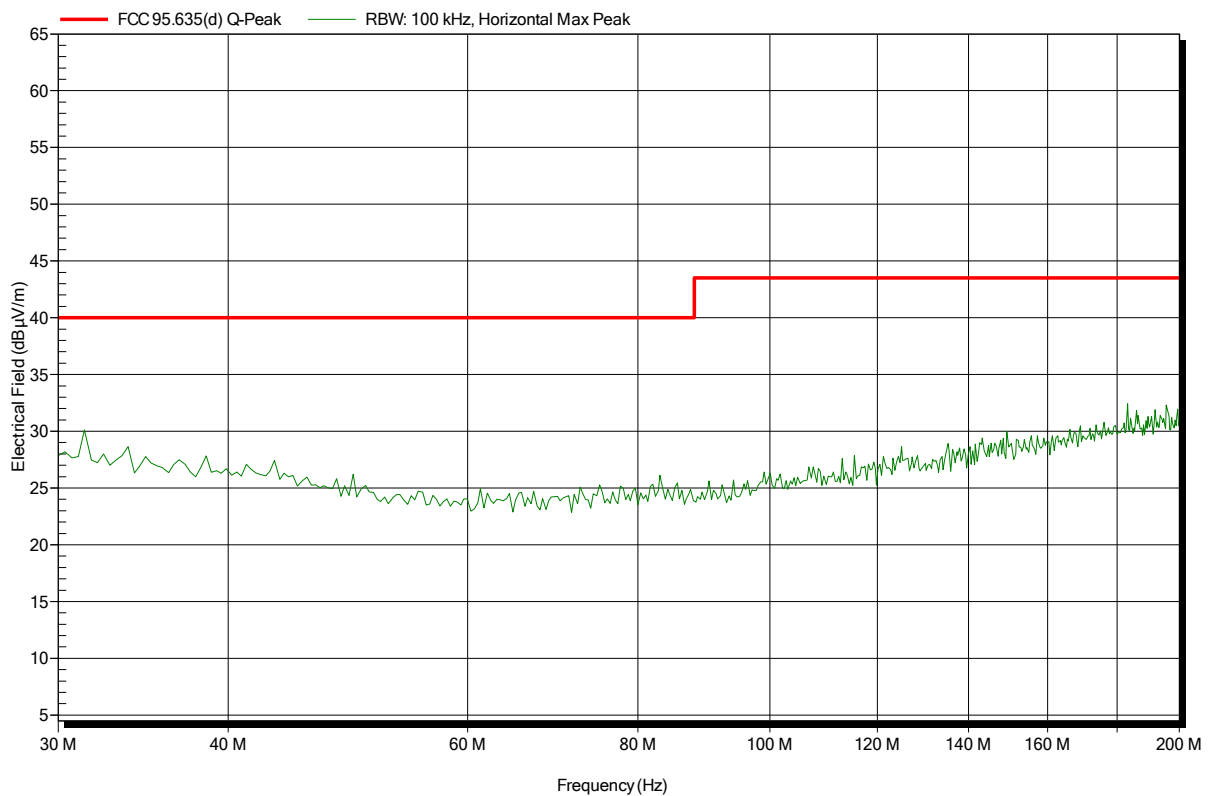
ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HK116, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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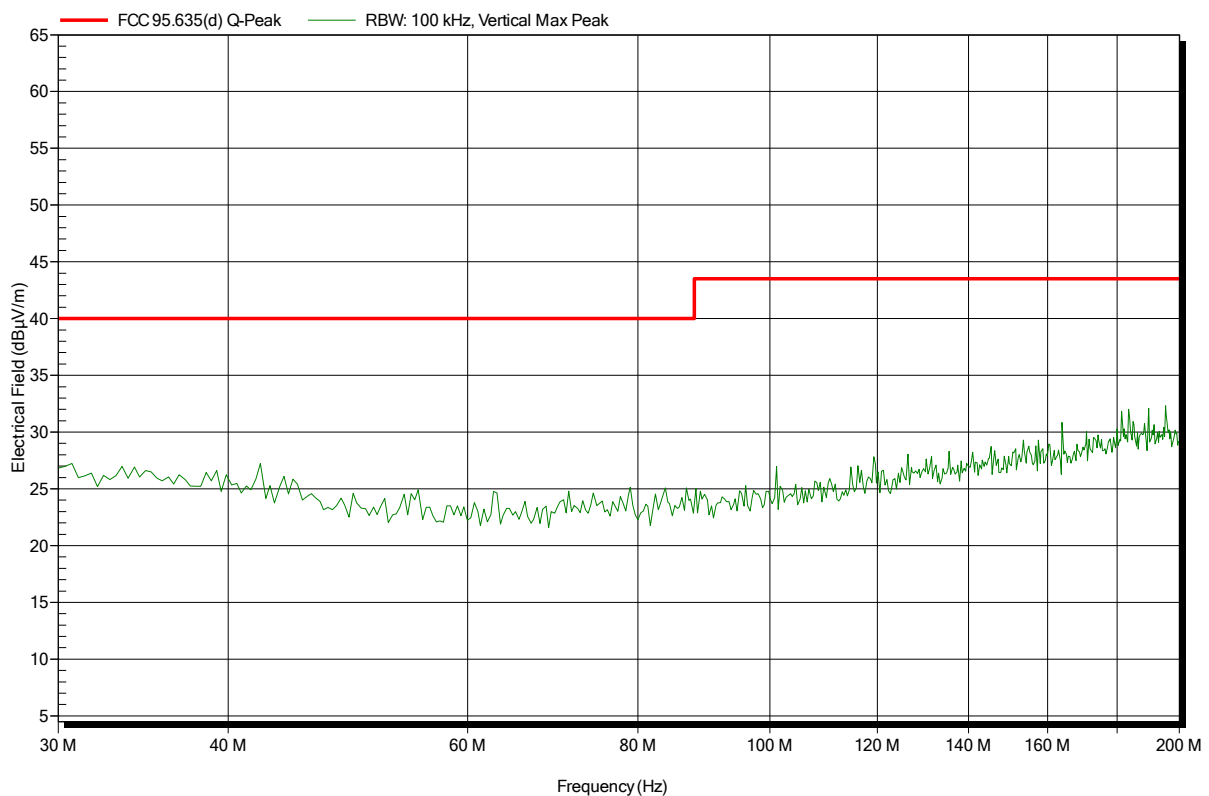


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-10-05
Note:	

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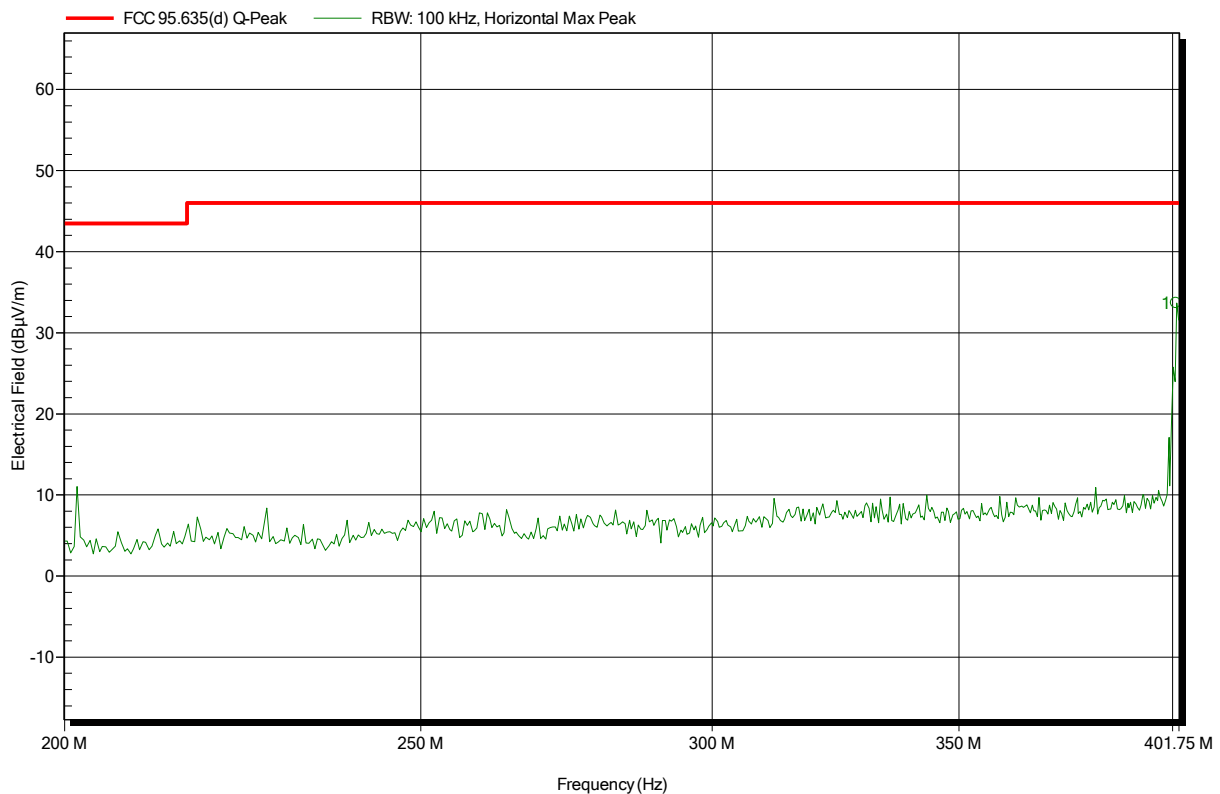


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
400.943 MHz	33.66 dBµV/m	46 dBµV/m	-12.34 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

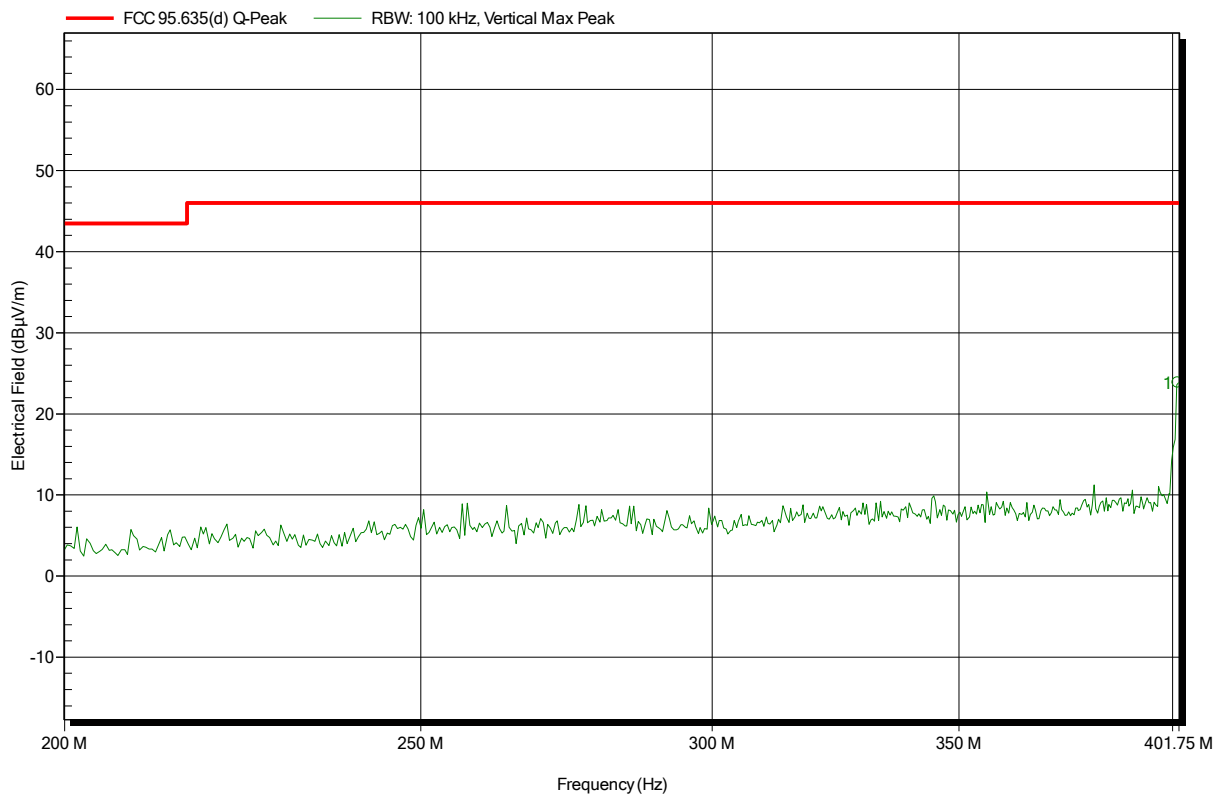
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.347 MHz	23.86 dBμV/m	46 dBμV/m	-22.14 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

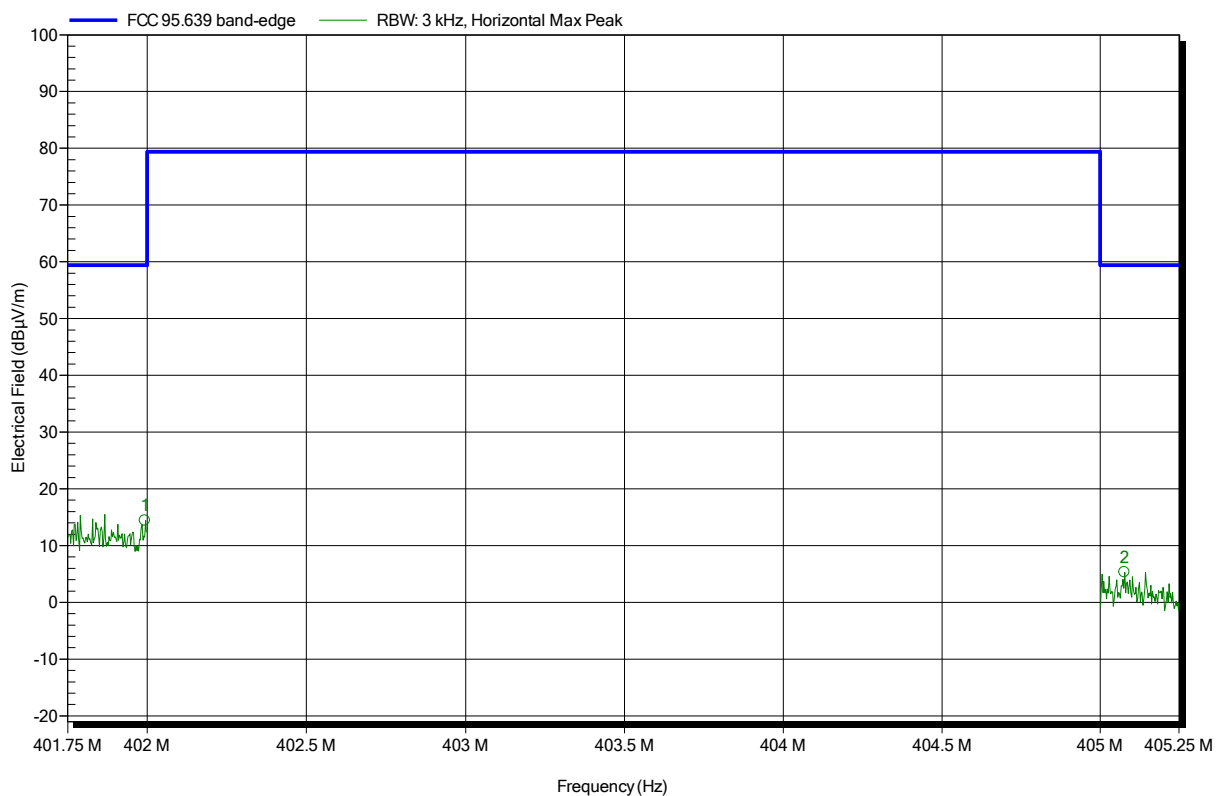
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note: Band-edge

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.993 MHz	14.42 dBµV/m	59.4 dBµV/m	-44.98 dB	Pass
405.076 MHz	5.29 dBµV/m	59.4 dBµV/m	-54.11 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

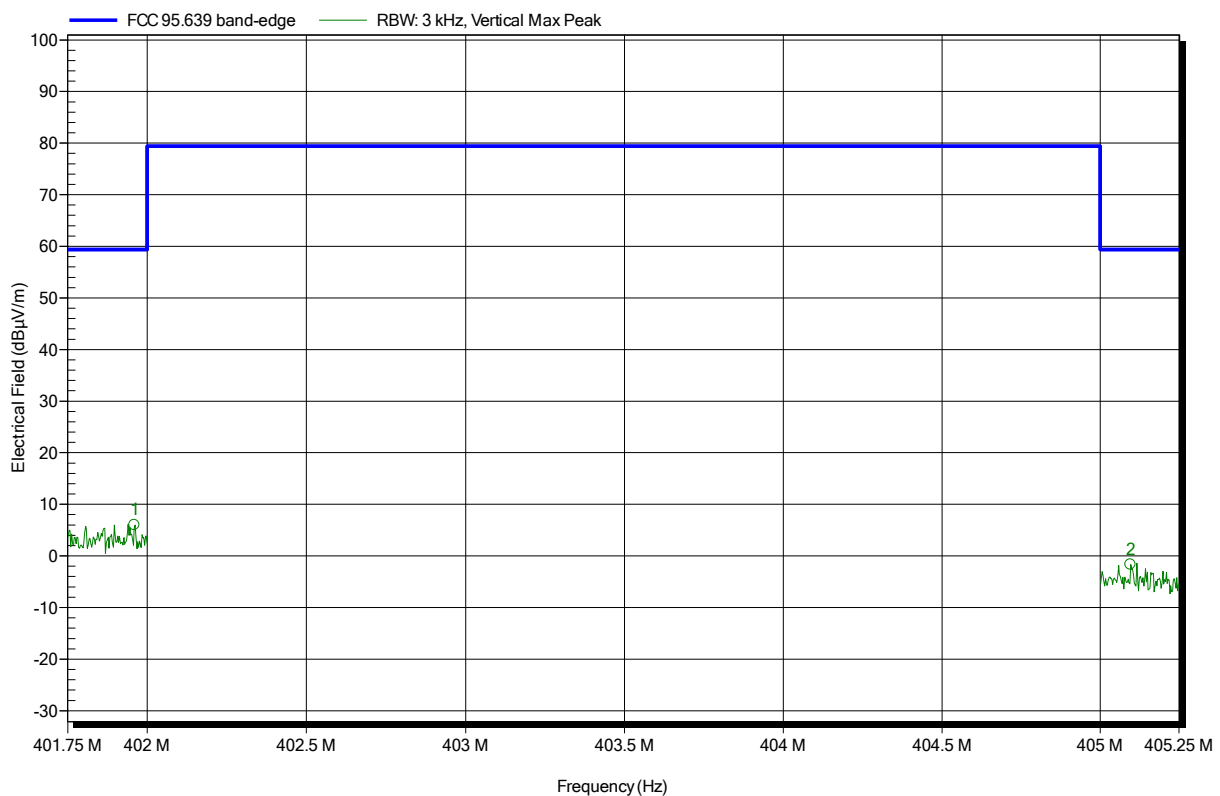
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note: Band-edge

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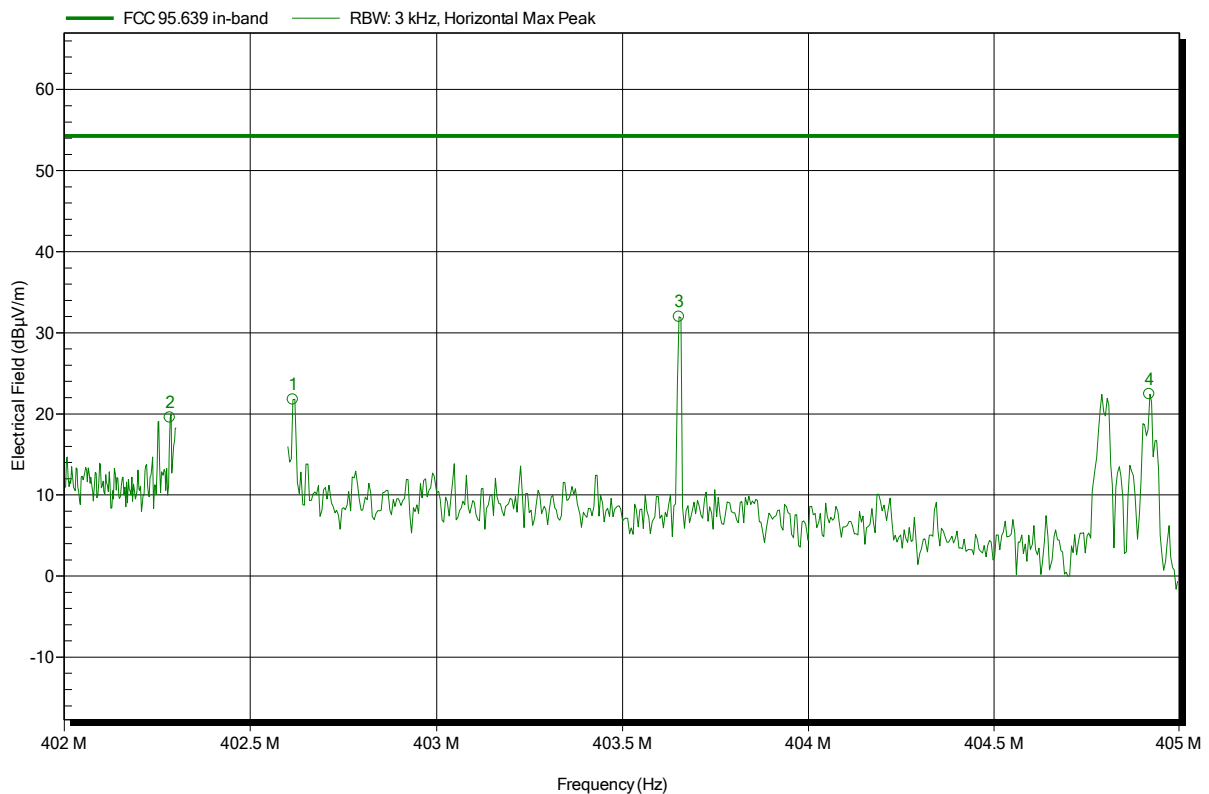
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.96 MHz	5.95 dBμV/m	59.4 dBμV/m	-53.45 dB	Pass
405.095 MHz	-1.65 dBμV/m	59.4 dBμV/m	-61.05 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note: In-band emissions

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.284 MHz	19.55 dBµV/m	54.3 dBµV/m	-34.75 dB	Pass
402.614 MHz	21.74 dBµV/m	54.3 dBµV/m	-32.56 dB	Pass
403.651 MHz	31.96 dBµV/m	54.3 dBµV/m	-22.34 dB	Pass
404.918 MHz	22.43 dBµV/m	54.3 dBµV/m	-31.87 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

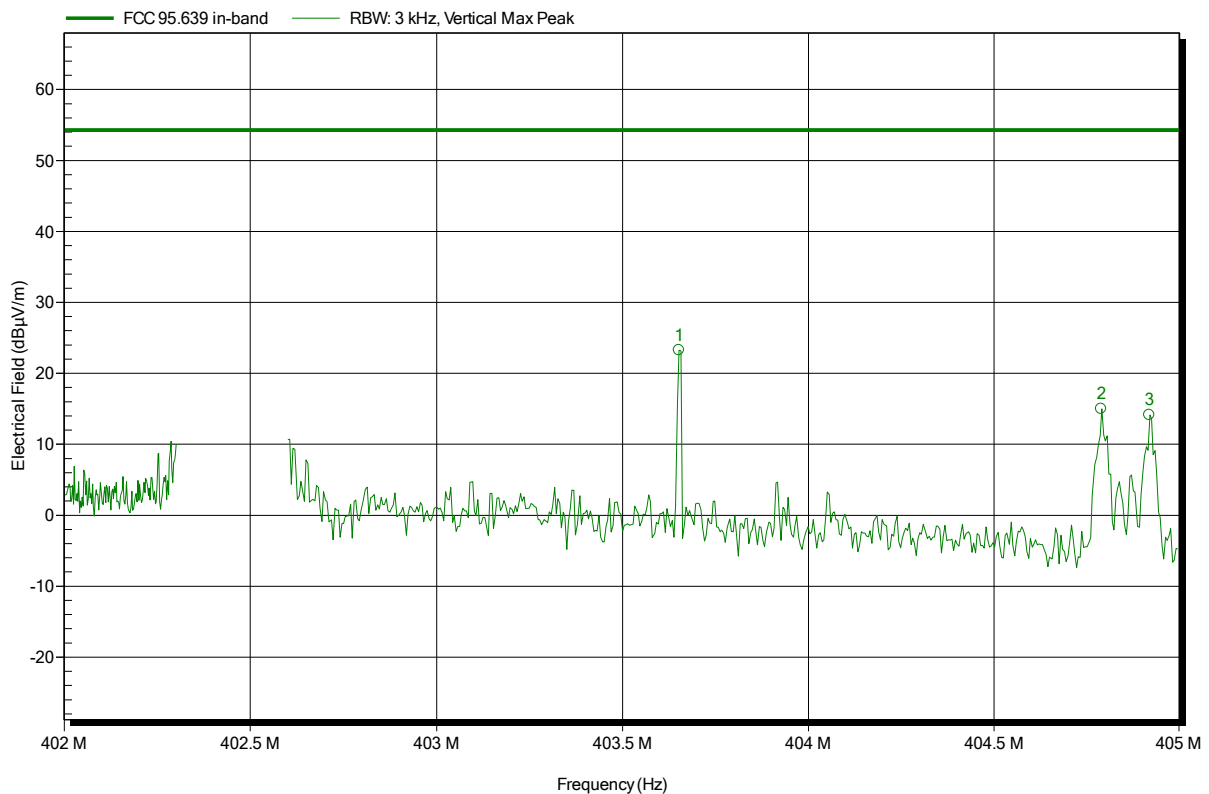
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note: In-band emissions

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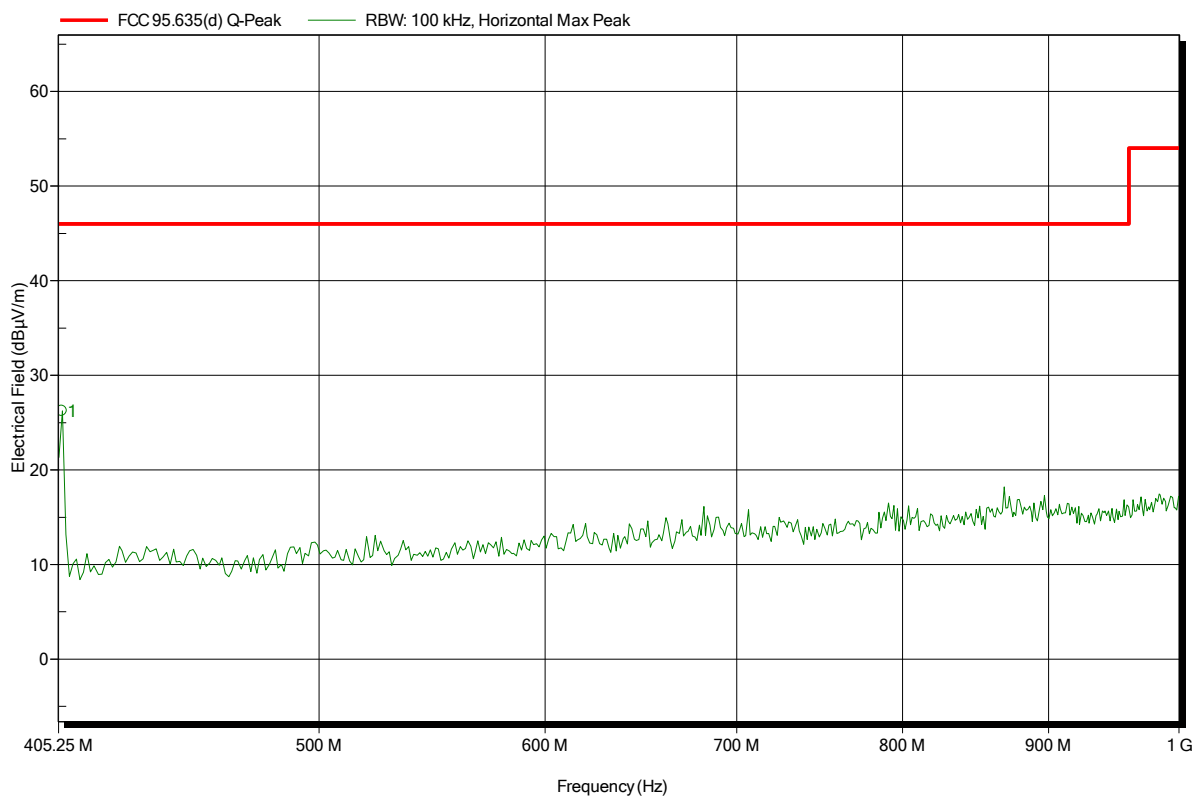
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403.651 MHz	23.26 dBµV/m	54.3 dBµV/m	-31.04 dB	Pass
404.789 MHz	14.97 dBµV/m	54.3 dBµV/m	-39.33 dB	Pass
404.918 MHz	14.12 dBµV/m	54.3 dBµV/m	-40.18 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	26.24 dBμV/m	46 dBμV/m	-19.76 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

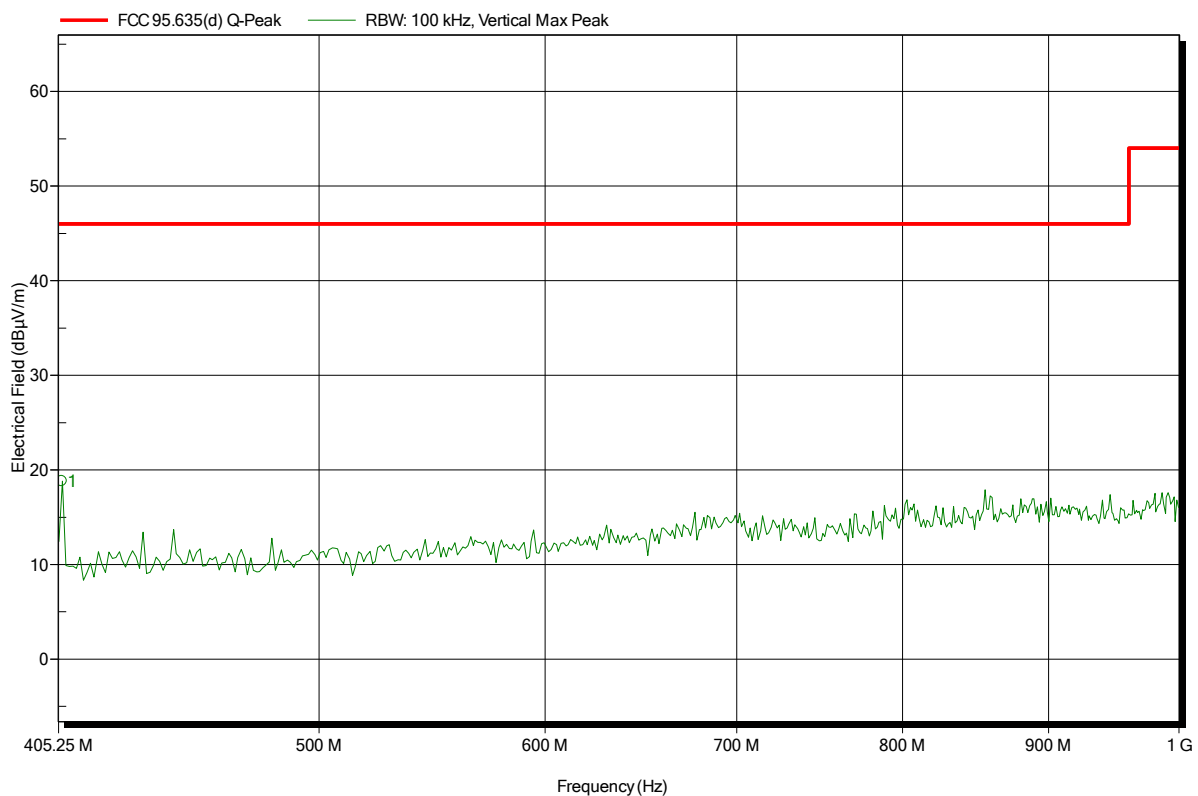
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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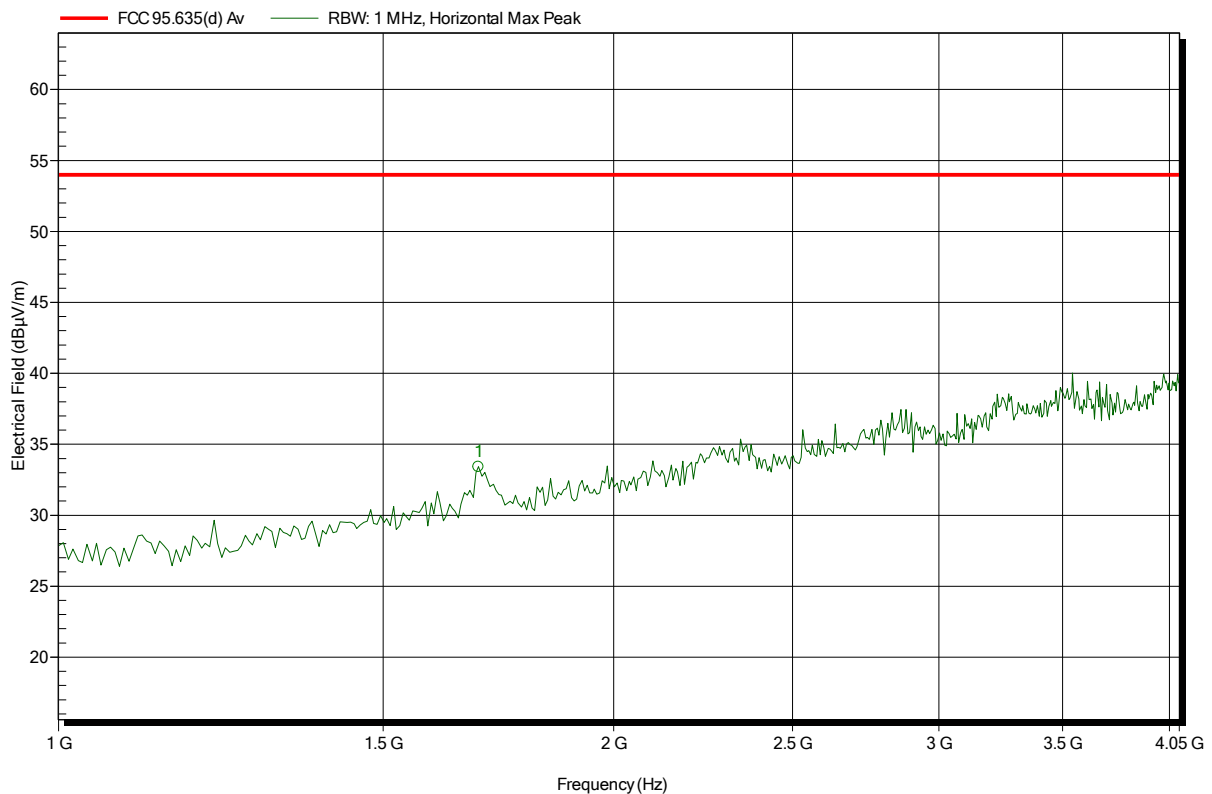
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	18.81 dBµV/m	46 dBµV/m	-27.19 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL025, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
1.689 GHz	33.4 dBμV/m	54 dBμV/m	-20.6 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

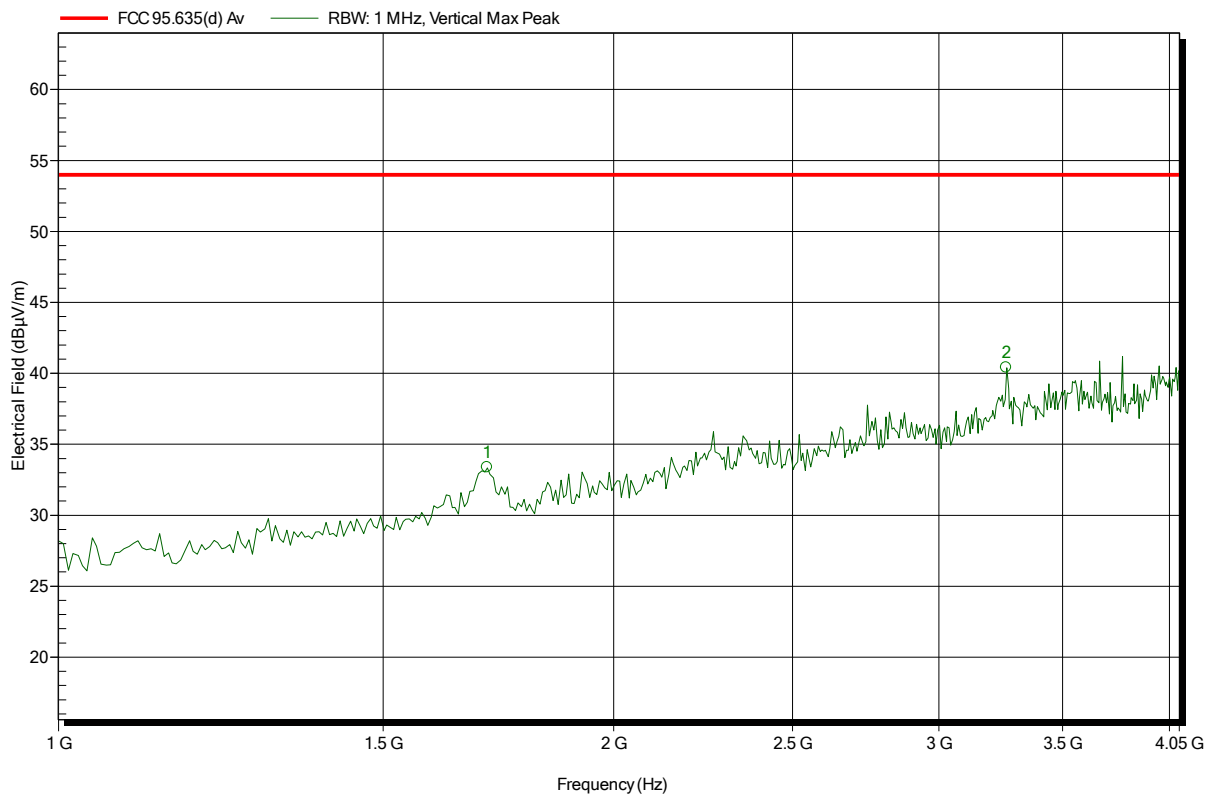
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL025, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
1.708 GHz	33.37 dBµV/m	54 dBµV/m	-20.63 dB	Pass
3.263 GHz	40.42 dBµV/m	54 dBµV/m	-13.58 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

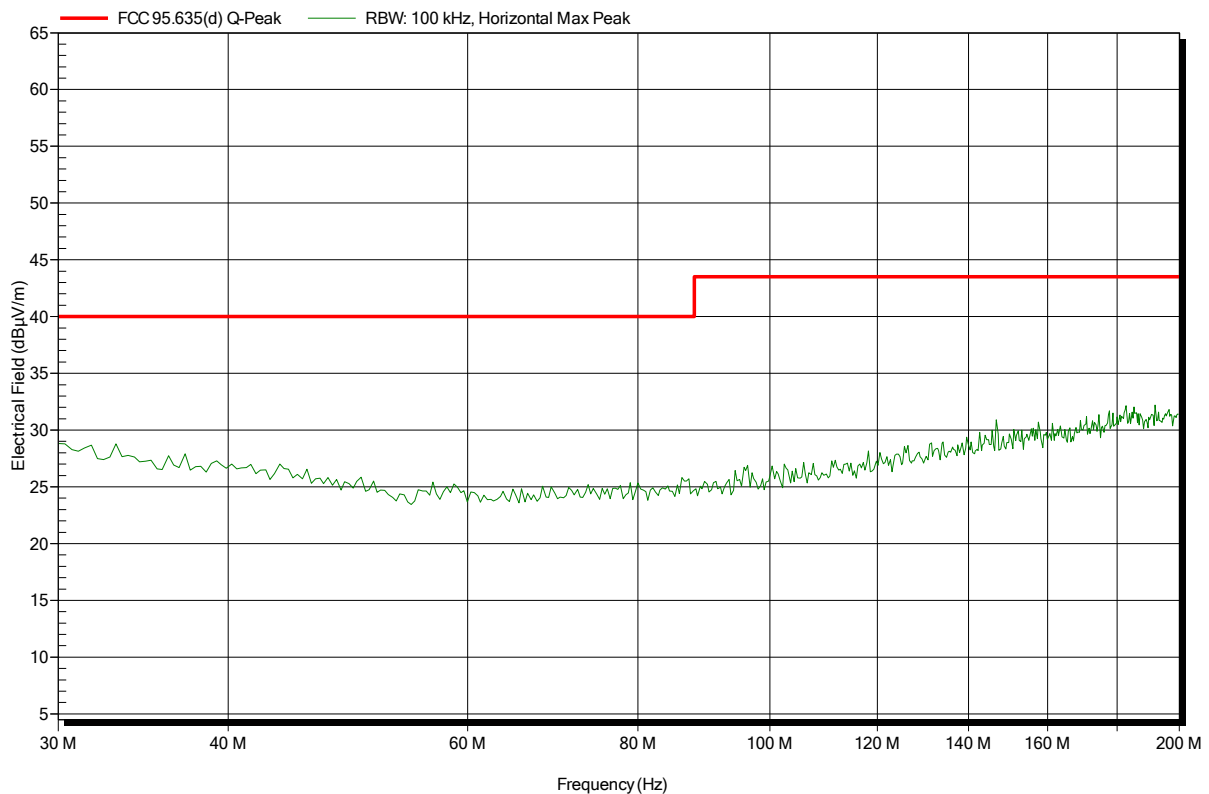
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HK116, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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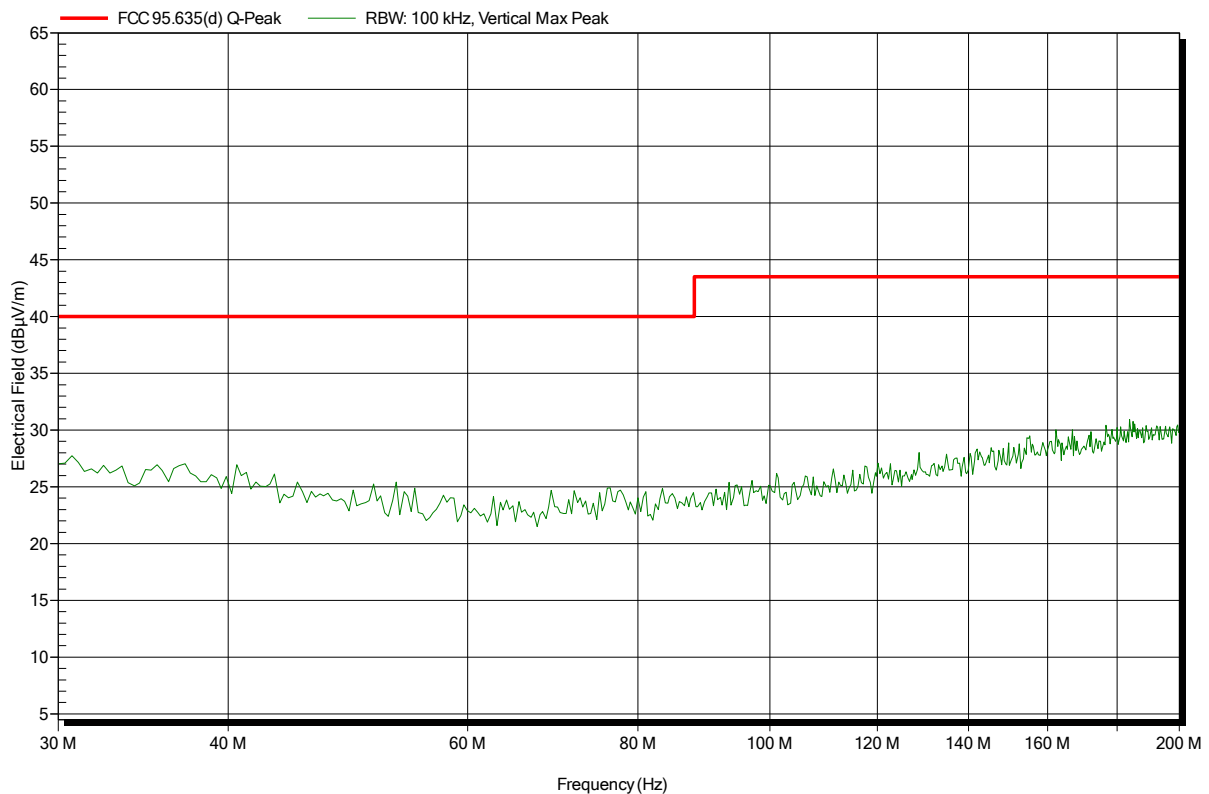


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant:	Biotronik SE & Co. KG
EUT Name:	Pacemaker family PRIMUS NXT
Model:	Eluna 8 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3 V DC battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-10-05
Note:	

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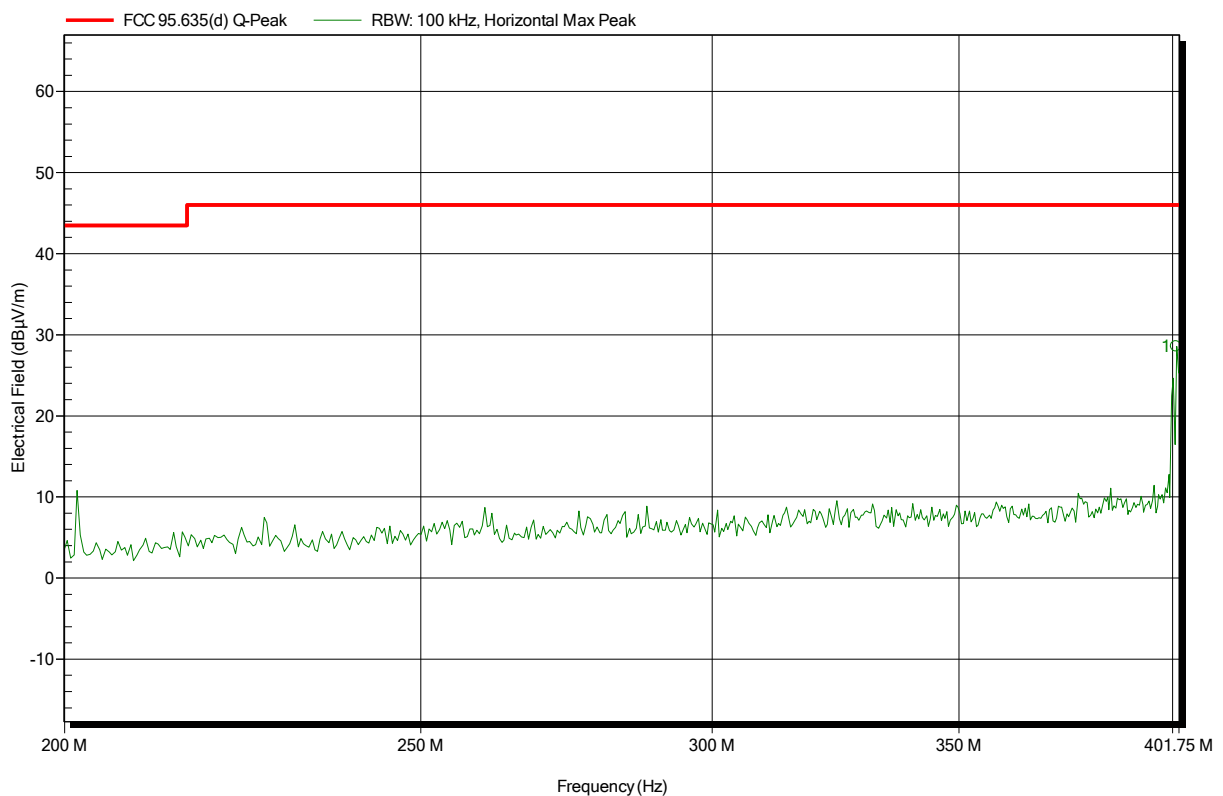


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
400.943 MHz	28.55 dBµV/m	46 dBµV/m	-17.45 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

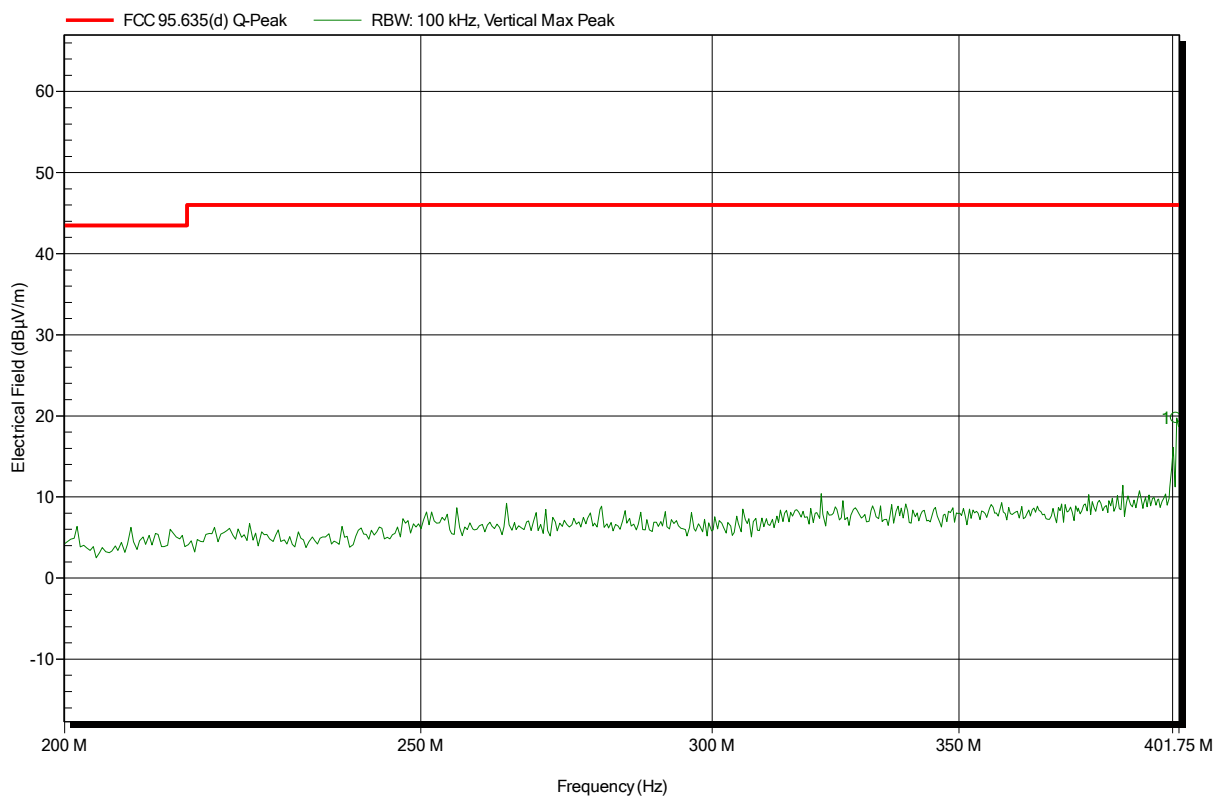
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-07
 Note:

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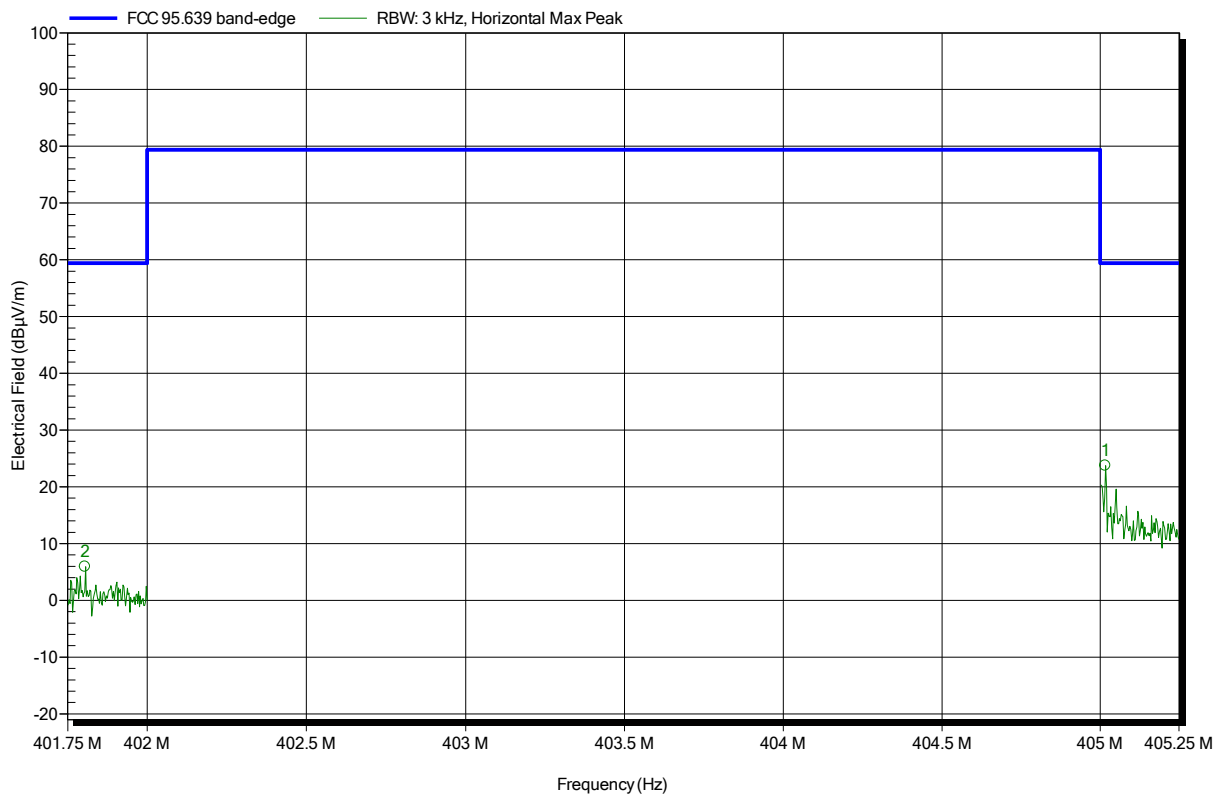
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
400.943 MHz	19.73 dBµV/m	46 dBµV/m	-26.27 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-05
 Note: Band-edge

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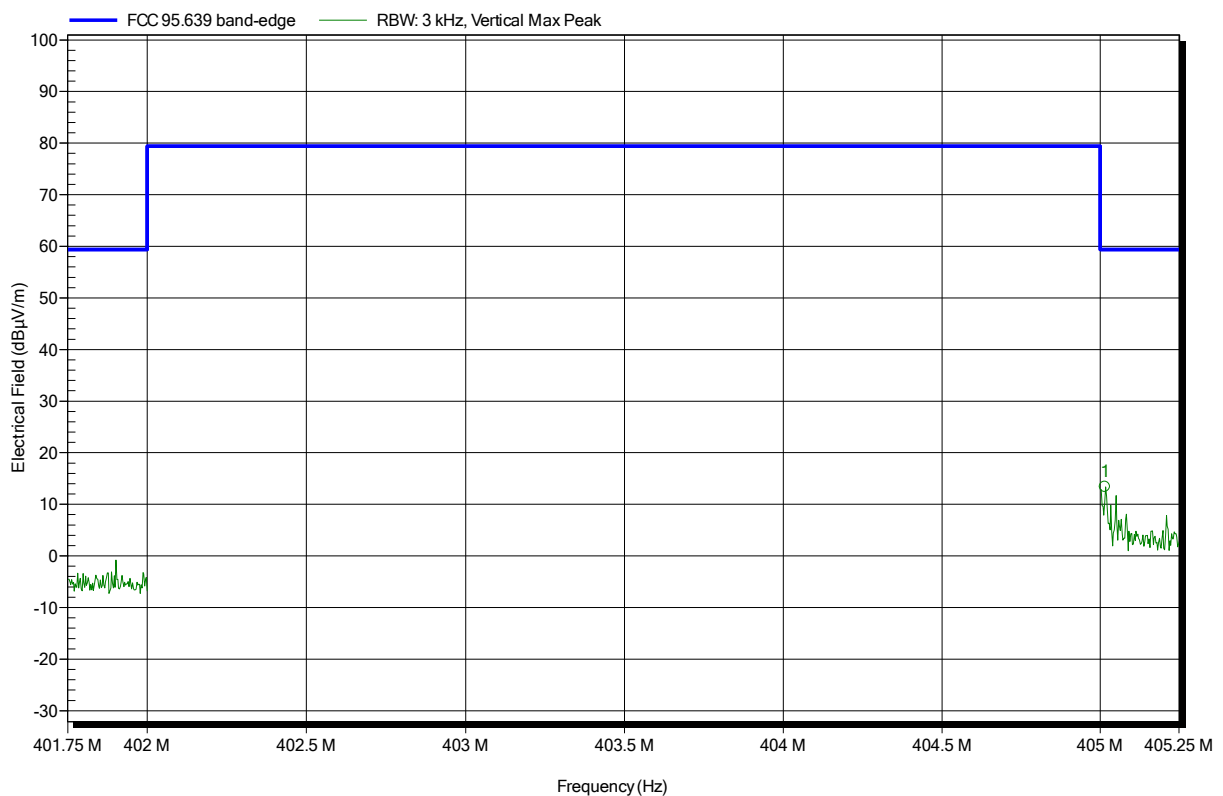
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.805 MHz	5.94 dBµV/m	59.4 dBµV/m	-53.46 dB	Pass
405.015 MHz	23.75 dBµV/m	59.4 dBµV/m	-35.65 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-07
 Note: Band-edge

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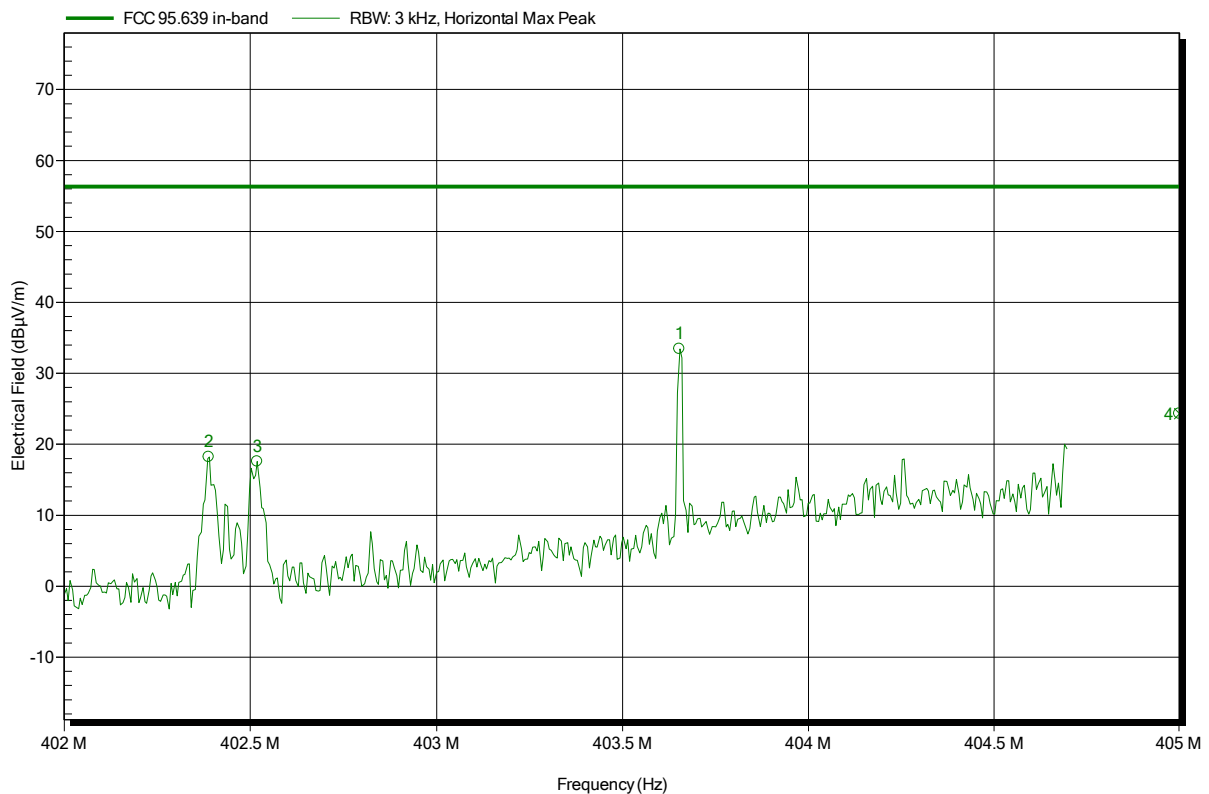
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.015 MHz	13.39 dBµV/m	59.4 dBµV/m	-46.01 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-05
 Note: In-band emissions

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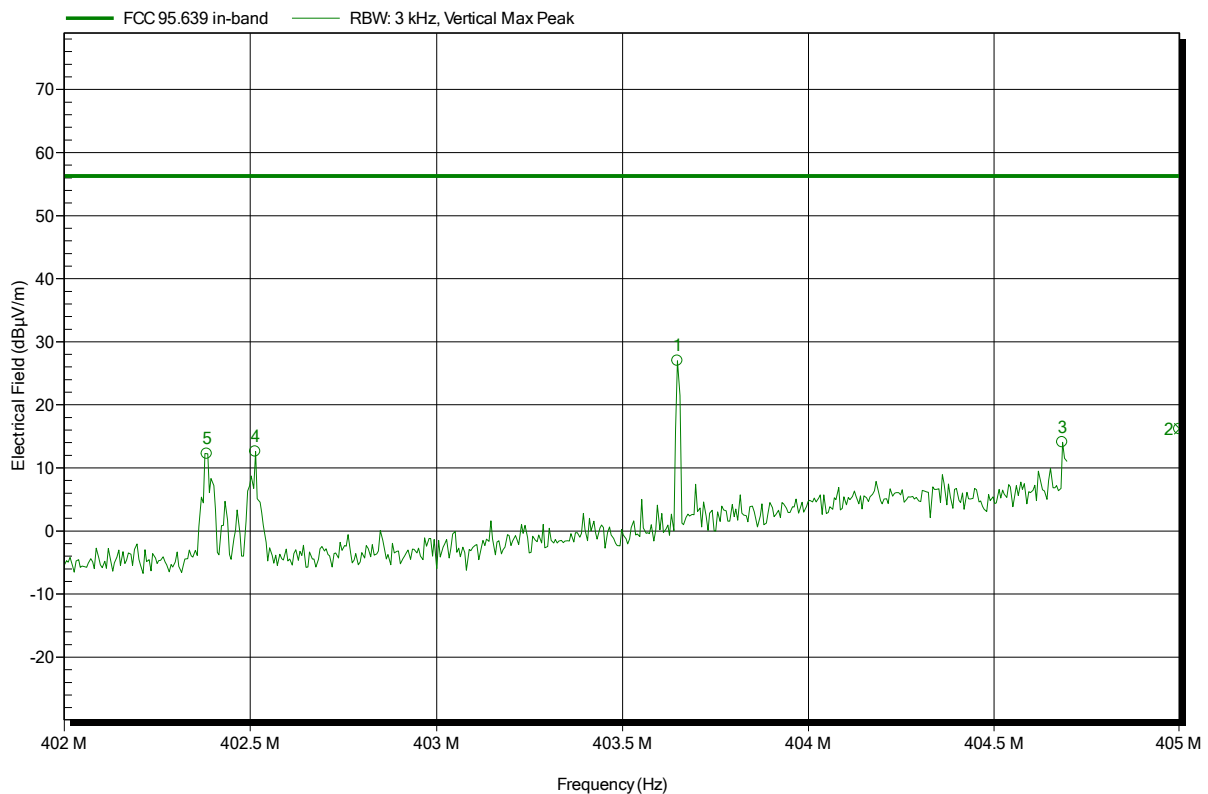
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.389 MHz	18.21 dBµV/m	56.3 dBµV/m	-38.09 dB	Pass
402.518 MHz	17.58 dBµV/m	56.3 dBµV/m	-38.72 dB	Pass
403.652 MHz	33.43 dBµV/m	56.3 dBµV/m	-22.87 dB	Pass
404.999 MHz	24.31 dBµV/m	56.3 dBµV/m	-31.99 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-07
 Note: In-band emissions

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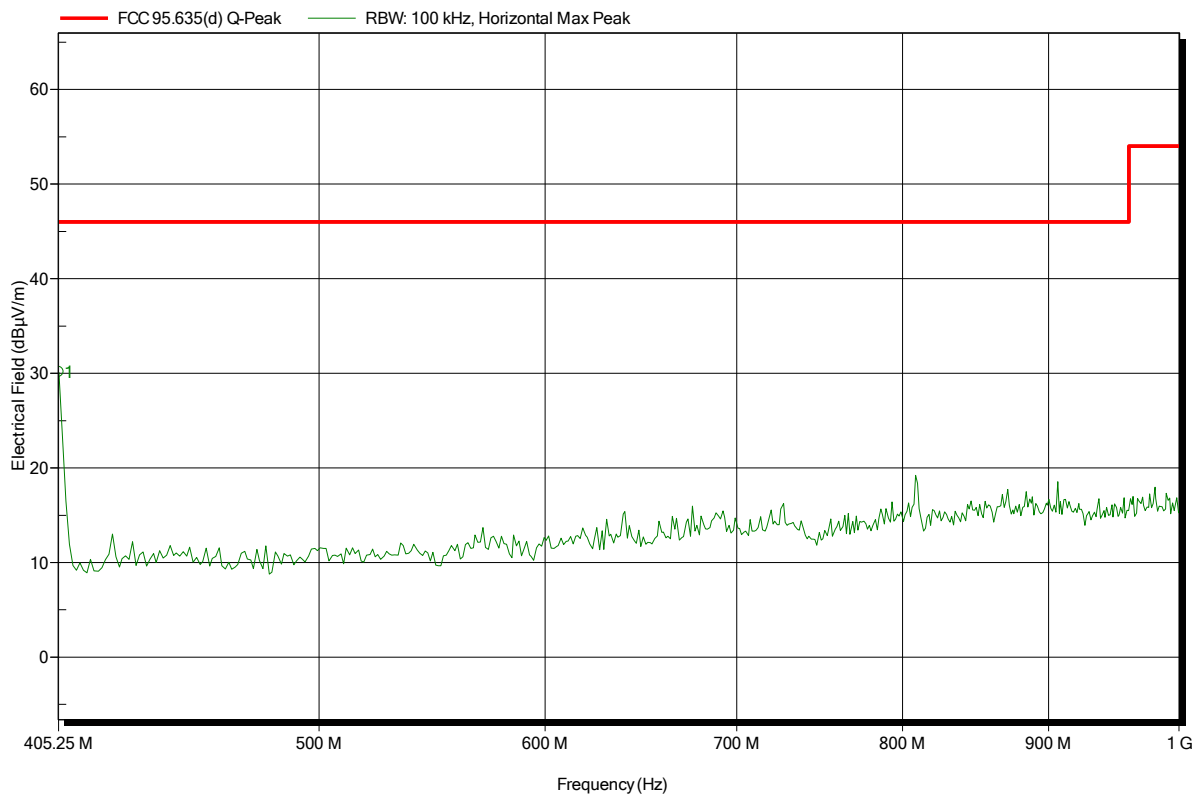
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.383 MHz	12.24 dBµV/m	56.3 dBµV/m	-44.06 dB	Pass
402.513 MHz	12.61 dBµV/m	56.3 dBµV/m	-43.69 dB	Pass
403.647 MHz	26.98 dBµV/m	56.3 dBµV/m	-29.32 dB	Pass
404.684 MHz	14.06 dBµV/m	56.3 dBµV/m	-42.24 dB	Pass
404.999 MHz	16.16 dBµV/m	56.3 dBµV/m	-40.14 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	30.15 dBµV/m	46 dBµV/m	-15.85 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

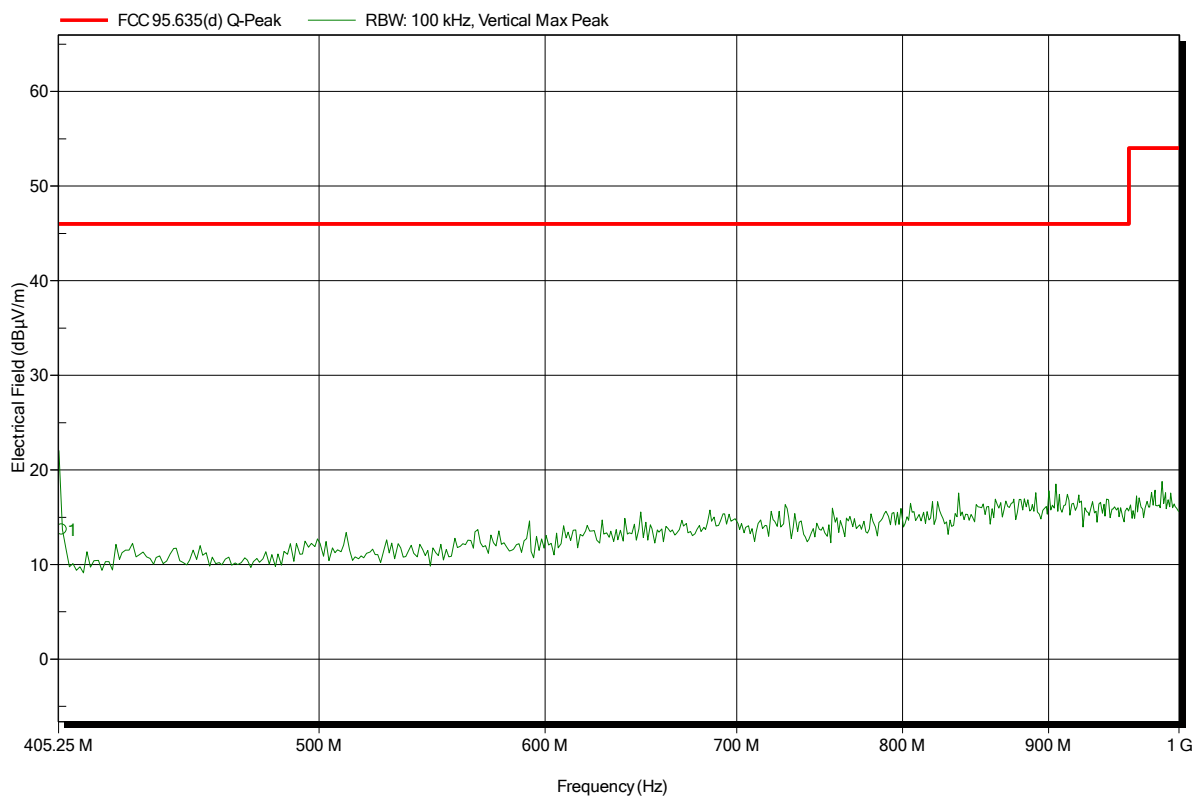
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-07
 Note:

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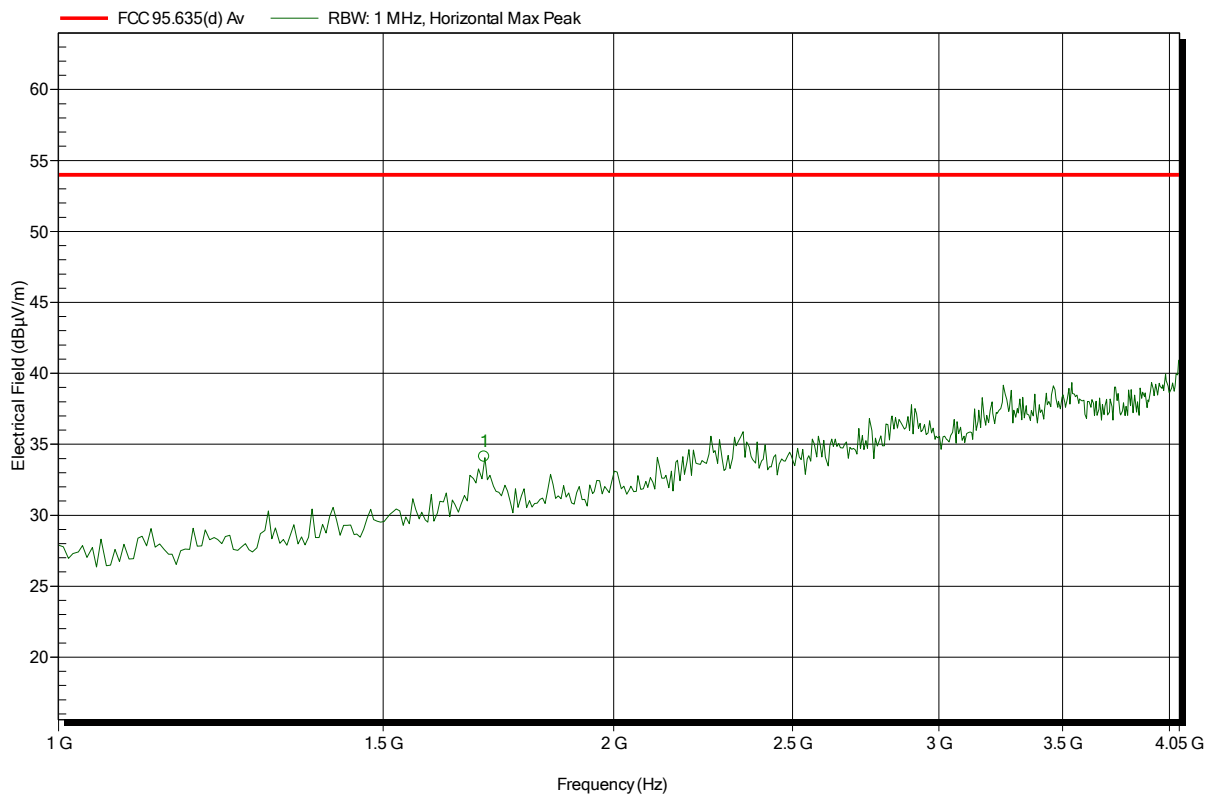
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	13.71 dBµV/m	46 dBµV/m	-32.29 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL025, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-05
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
1.701 GHz	34.12 dBµV/m	54 dBµV/m	-19.88 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

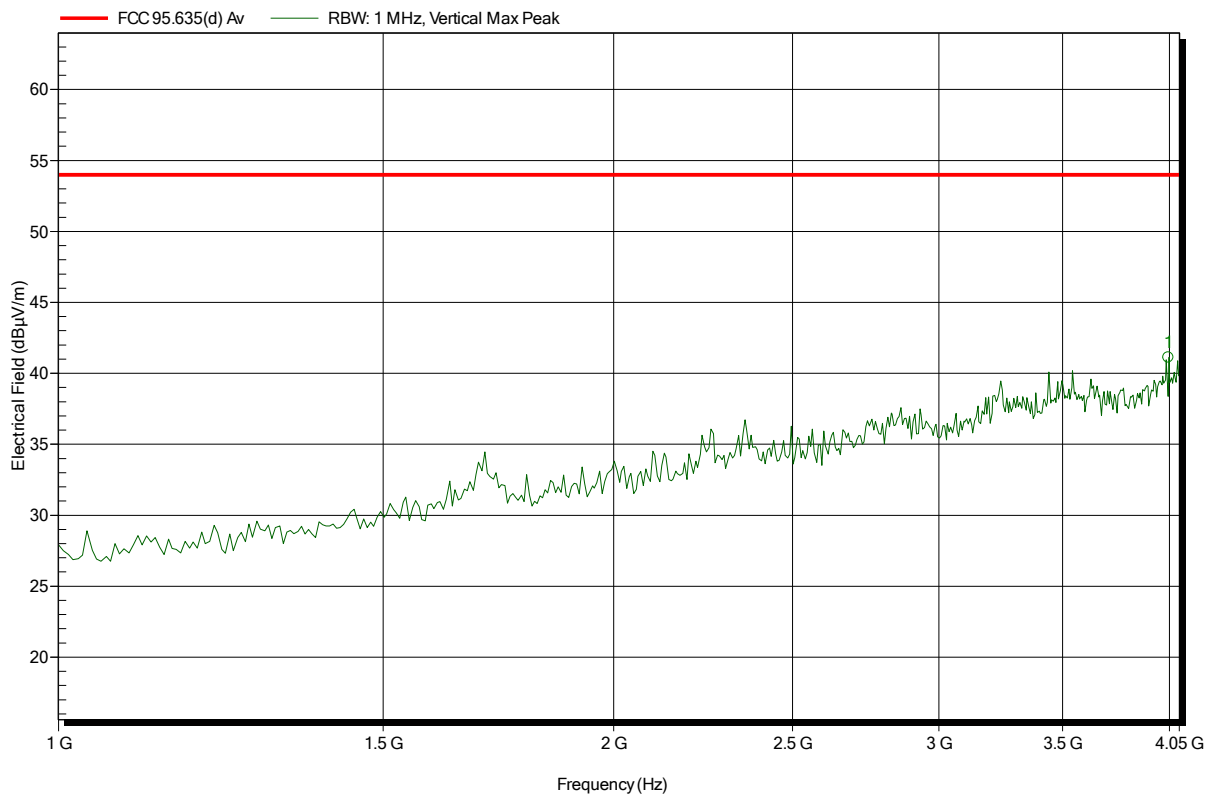
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL025, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz, 2FSK
 Test Date: 2015-10-07
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
3.995 GHz	41.12 dBµV/m	54 dBµV/m	-12.88 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

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

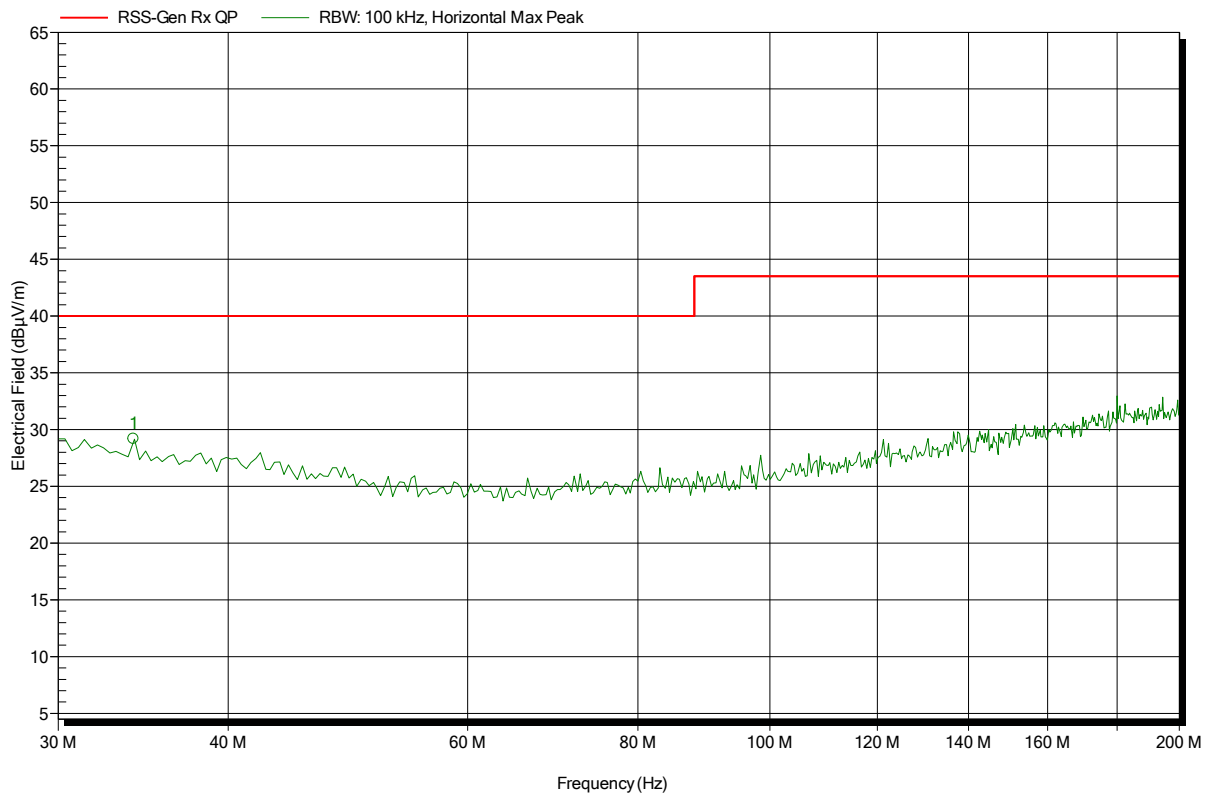
ANNEX C Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HK116, Horizontal
 Measurement distance: 3 m
 Mode: RX; 404.85 MHz
 Test Date: 2015-10-07
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
34.08 MHz	29.18 dBµV/m	40 dBµV/m	-10.82 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

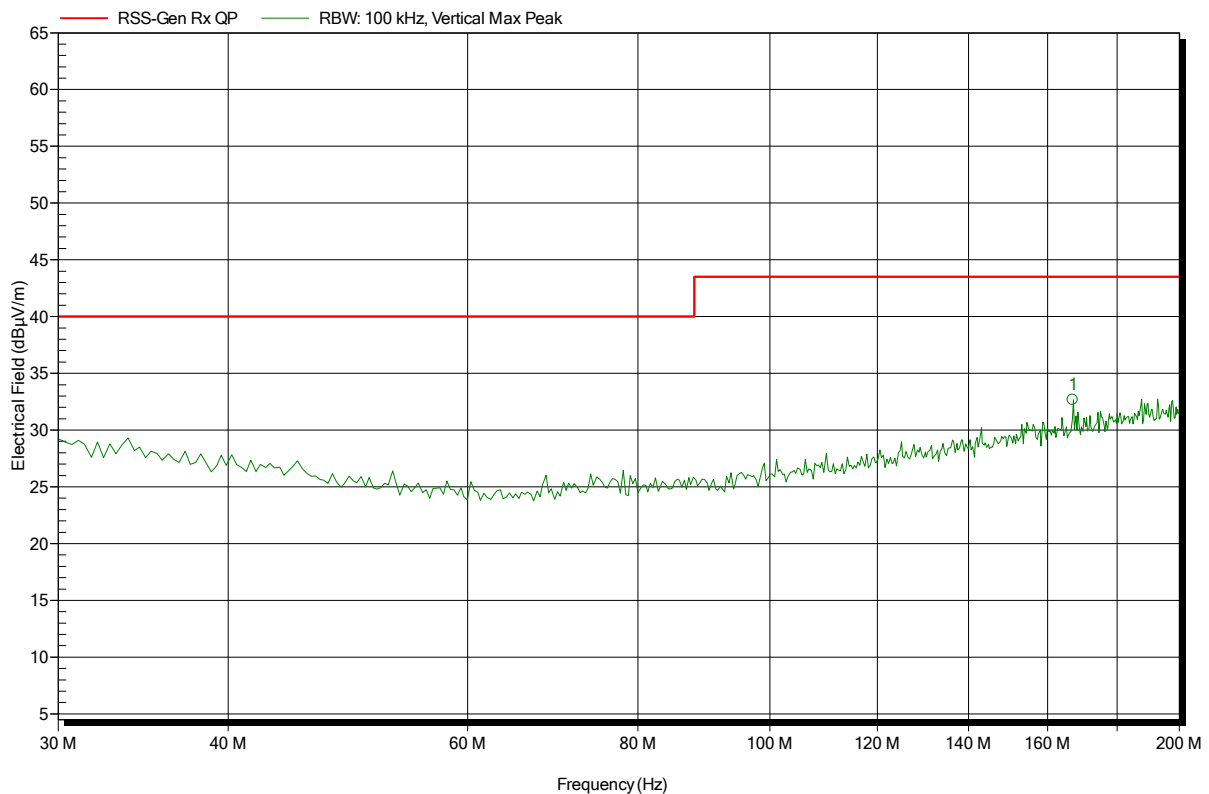
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HK116, Vertical
 Measurement distance: 3 m
 Mode: RX; 404.85 MHz
 Test Date: 2015-10-07
 Note:

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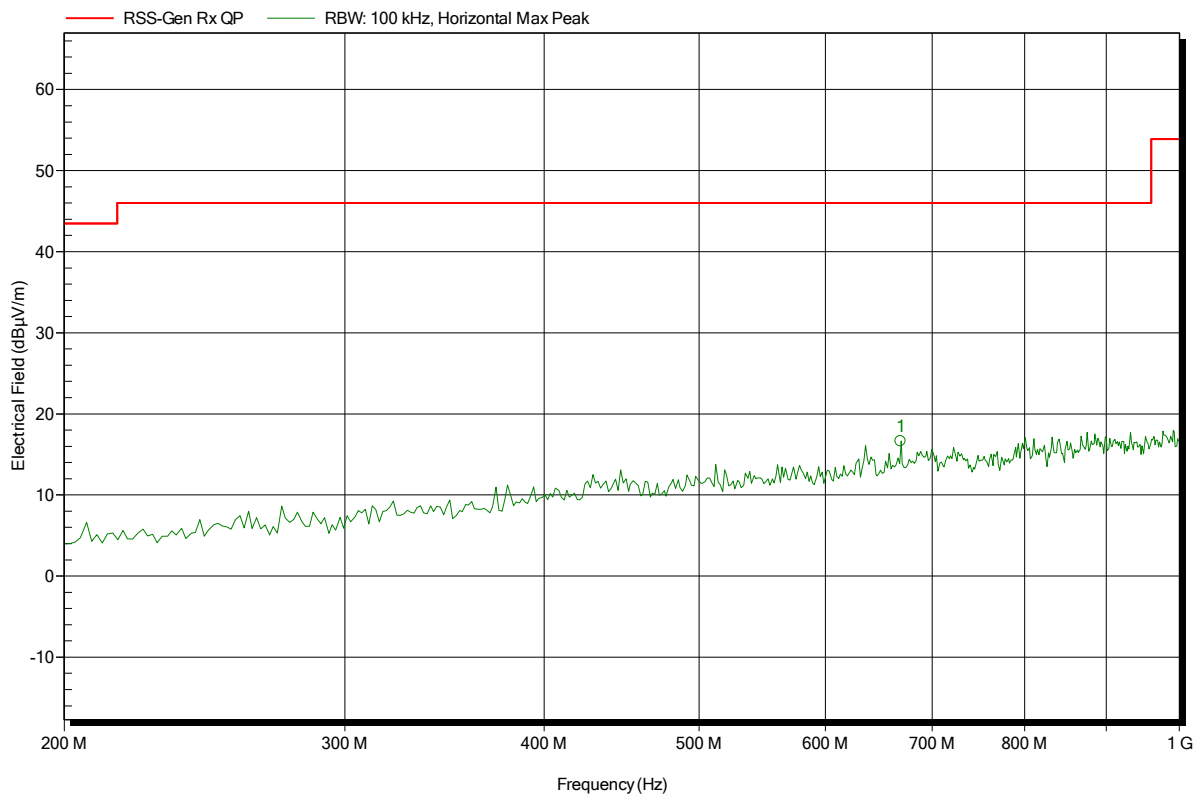
Frequency	Peak	Peak Limit	Peak Difference	Status
167.02 MHz	32.66 dBµV/m	43.5 dBµV/m	-10.84 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: RX; 404.85 MHz
 Test Date: 2015-10-07
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
668.8 MHz	16.61 dBµV/m	46 dBµV/m	-29.39 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

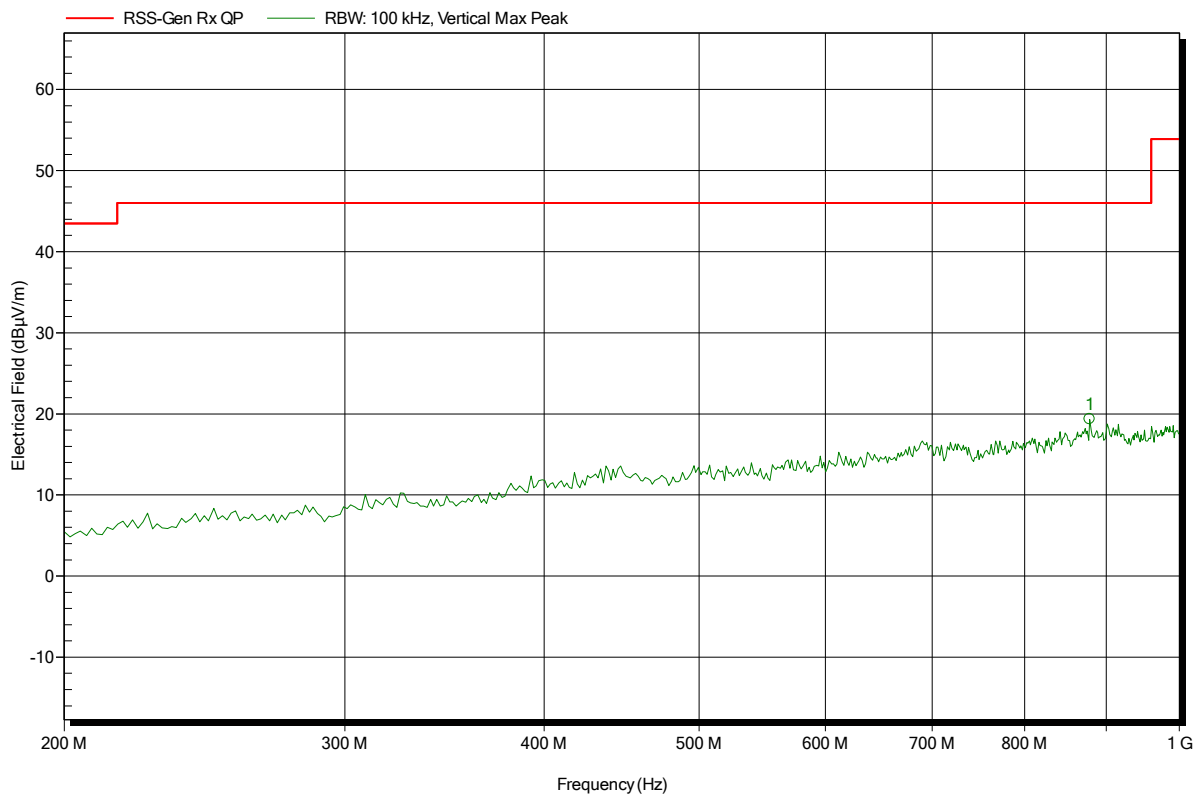
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: RX; 404.85 MHz
 Test Date: 2015-10-07
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
878.4 MHz	19.33 dBµV/m	46 dBµV/m	-26.67 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

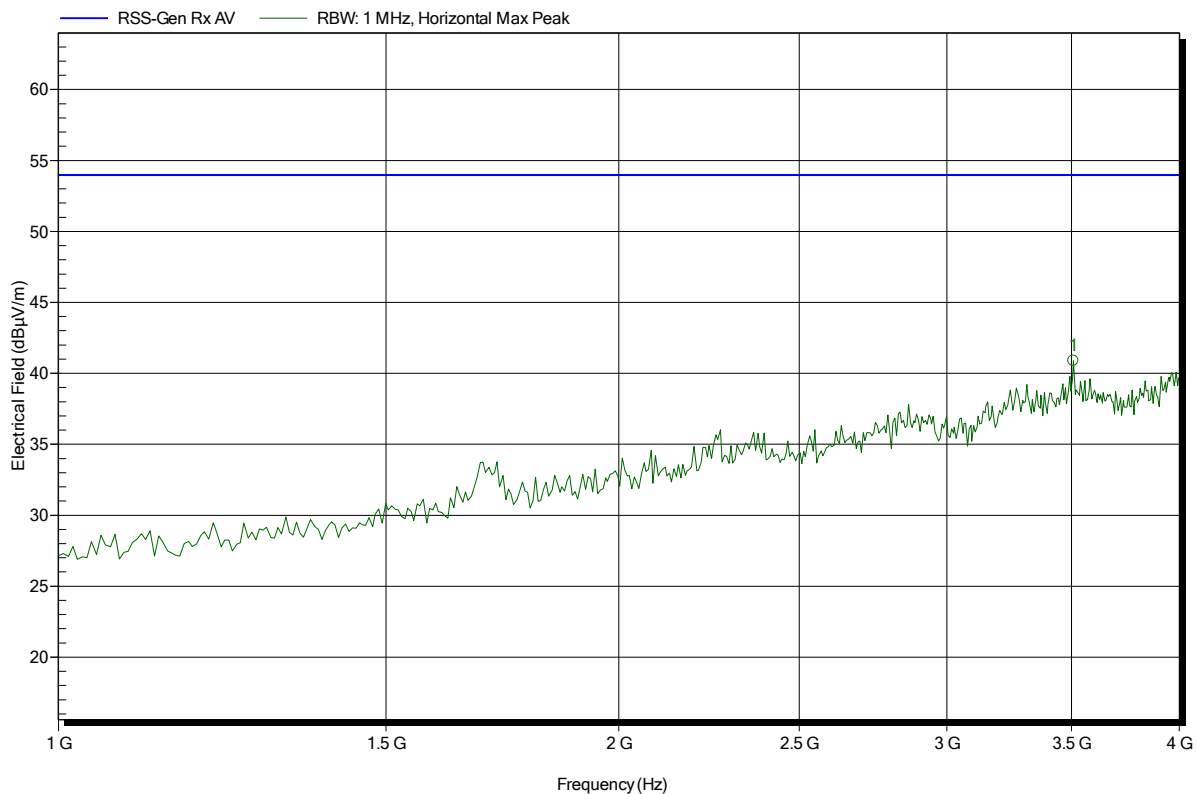
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL025, Horizontal
 Measurement distance: 3 m
 Mode: RX; 404.85 MHz
 Test Date: 2015-10-07
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
3.508 GHz	40.89 dBµV/m	53.98 dBµV/m	-13.09 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

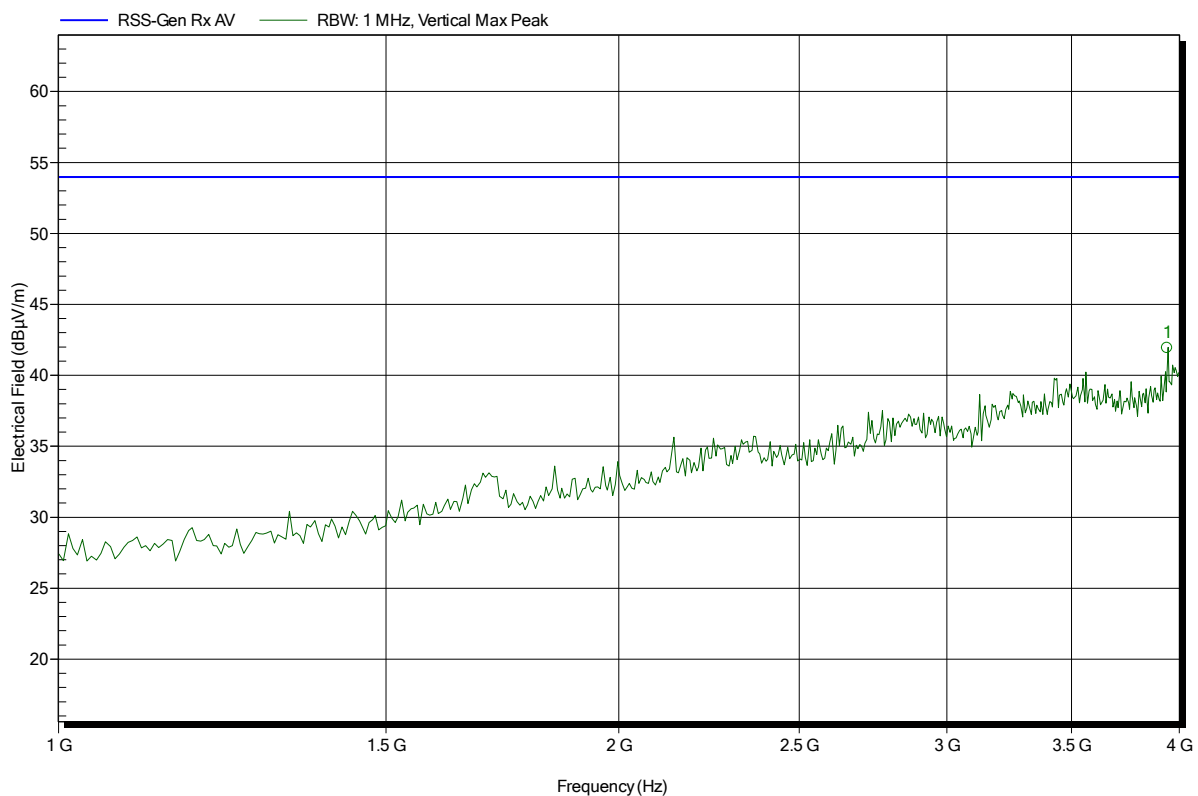
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG
 EUT Name: Pacemaker family PRIMUS NXT
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery
 Antenna: HL025, Vertical
 Measurement distance: 3 m
 Mode: RX; 404.85 MHz
 Test Date: 2015-10-07
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
3.94 GHz	41.91 dBµV/m	53.98 dBµV/m	-12.07 dB	Pass

Test Report No.: G0M-1509-5046-TFC95IMR-V01

Eurofins Product Service GmbH
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