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FCC TEST REPORT

FCC 47 CFR Part 95I
Medical Device Radiocommunication Service (MedRadio)
Industry Canada RSS-243
Medical Devices Operating in the 401 – 406 MHz Frequency Band

Report Reference No. ..... :	G0D-1611-6014-TFC95IMR-V01
Testing Laboratory ..... :	Eurofins Product Service GmbH
Address ..... :	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation ..... :	A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Filed Test Laboratory, Reg.-No.: 96970 IC OATS Filing assigned code: 3470A
Applicant's name ..... :	Biotronik SE & Co. KG
Address ..... :	Woermannkehre 1 12359 Berlin GERMANY
Test specification:	
Standard..... :	47 CFR Part 95I RSS-243, Issue 3, 2010-02
Test scope…….. ..... :	partial Radio compliance test (C2PC)
Equipment under test (EUT):	
Product description	ICD / Implantable Cardioverter Defibrillator TachNT2
Model No.	Intica 7 HF-T QP
Additional Model(s)	Additional Models according to Family Letter
Brand Name(s)	BIOTRONIK
Hardware version	Rev.: 0A
Firmware / Software version	ROM: 5.0 / RAM: 4.1.0
	FCC-ID: QRITACHNT2 IC: N/A
Test result	**Passed**

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

Testing:		
Test Lab Temperature ..... :	20 – 23 °C	
Test Lab Humidity ..... :	32 – 38 %	
Date of receipt of test item ..... :	2016-11-21	
Date (s) of performance of tests ..... :	2016-11-21 - 2016-11-23	
Compiled by ..... :	Wilfried Treffke	
Tested by (+ signature) ..... : (Responsible for Test)	Wilfried Treffke	W. Treffke .....
Approved by (+ signature) ..... : (Head of Lab)	Christian Weber	C. Weber .....
Date of issue ..... :	2017-01-17	
Total number of pages ..... :	87	

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.

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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.
HF-T are triple-chamber devices.
DR-T are dual-chamber devices.
VR-T are single chamber devices without additional atrial detection.
All variants are available with DF-1 and DF-4.
All of these differences are only relevant in terms of medical aspects. They do not interfere the RF Performance.

Antenna pattern measurements were performed for worst case antenna selection and the Intica 7 HF-T QP Ser. 60509208 (HVIN 404630) was selected. Besides the model Intica 7 HF-T QP Ser. 60509208 (HVIN 404630), as the most complex model, was selected for the measurements.

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TachNT2 Family Explanation (G0D-1611-6014)

1. Family Letter

	Product Name	Type	no. of chambers	Connector	Battery	HVIN
1	Ilivia 7 HF-T	CRT	3	DF-1	GB	404601
2	Ilivia 7 HF-T	CRT	3	DF-1	LiS	406035
3	Ilivia 7 HF-T	CRT	3	DF-4	GB	404602
4	Ilivia 7 HF-T	CRT	3	DF-4	LiS	406036
5	Ilivia 7 HF-T QP	CRT	3	DF-1 + IS-4	GB	404620
6	Ilivia 7 HF-T QP	CRT	3	DF-4 + IS-4	GB	404621
7	Ilivia 7 HF-T QP	CRT	3	DF-4 + IS-4	LiS	406038
8	Ilivia 7 DR-T	DR	2	DF-1	GB / LiS	404622
9	Ilivia 7 DR-T	DR	2	DF-4	GB / LiS	404623
10	Ilivia 7 VR-T DX	DX*	1	DF-1	GB / LiS	404624
11	Ilivia 7 VR-T	VR	1	DF-1	GB / LiS	404625
12	Ilivia 7 VR-T	VR	1	DF-4	GB / LiS	404626
13	Intica 7 HF-T	CRT	3	DF-1	GB	404627
14	Intica 7 HF-T	CRT	3	DF-1	LiS	406039
15	Intica 7 HF-T	CRT	3	DF-4	GB	404628
16	Intica 7 HF-T	CRT	3	DF-4	LiS	406040
17	Intica 7 HF-T QP	CRT	3	DF-1 + IS-4	GB	404629
18	Intica 7 HF-T QP	CRT	3	DF-4 + IS-4	GB	404630
19	Intica 7 HF-T QP	CRT	3	DF-4 + IS-4	LiS	406042
20	Intica 7 DR-T	DR	2	DF-1	GB / LiS	404631
21	Intica 7 DR-T	DR	2	DF-4	GB / LiS	404632
22	Intica 7 VR-T DX	DX*	1	DF-1	GB / LiS	404633
23	Intica 7 VR-T	VR	1	DF-1	GB / LiS	404634
24	Intica 7 VR-T	VR	1	DF-4	GB / LiS	404635
25	Inlexa 7 HF-T	CRT	3	DF-1	GB	404636
26	Inlexa 7 HF-T	CRT	3	DF-1	LiS	406043
27	Inlexa 7 HF-T	CRT	3	DF-4	GB	404637
28	Inlexa 7 HF-T	CRT	3	DF-4	LiS	406044
29	Inlexa 7 HF-T QP	CRT	3	DF-1 + IS-4	GB	404638
30	Inlexa 7 HF-T QP	CRT	3	DF-4 + IS-4	GB	404639
31	Inlexa 7 HF-T QP	CRT	3	DF-4 + IS-4	LiS	406046
32	Inlexa 7 DR-T	DR	2	DF-1	GB / LiS	404640
33	Inlexa 7 DR-T	DR	2	DF-4	GB / LiS	404641
34	Inlexa 7 VR-T DX	DX*	1	DF-1	GB / LiS	404642
35	Inlexa 7 VR-T	VR	1	DF-1	GB / LiS	404643
36	Inlexa 7 VR-T	VR	1	DF-4	GB / LiS	404644
37	Intica 5 HF-T	CRT	3	DF-1	GB / LiS	404683
38	Intica 5 HF-T	CRT	3	DF-4	GB / LiS	404684
39	Intica 5 HF-T QP	CRT	3	DF-1 + IS-4	GB / LiS	406932

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BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804

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40	Intica 5 HF-T QP	CRT	3	DF-4 + IS-4	GB / LiS	404685
41	Intica 5 DR-T	DR	2	DF-1	GB / LiS	404686
42	Intica 5 DR-T	DR	2	DF-4	GB / LiS	404678
43	Intica 5 VR-T DX	DX*	1	DF-1	GB / LiS	404688
44	Intica 5 VR-T	VR	1	DF-1	GB / LiS	404689
45	Intica 5 VR-T	VR	1	DF-4	GB / LiS	404690
46	Inlexa 3 HF-T	CRT	3	DF-1	GB / LiS	404699
47	Inlexa 3 HF-T	CRT	3	DF-4	GB / LiS	404700
48	Inlexa 3 HF-T QP	CRT	3	DF-1 + IS-4	GB / LiS	416037
49	Inlexa 3 HF-T QP	CRT	3	DF-4 + IS-4	GB / LiS	416038
50	Inlexa 3 DR-T	DR	2	DF-1	GB / LiS	404701
51	Inlexa 3 DR-T	DR	2	DF-4	GB / LiS	404702
52	Inlexa 3 VR-T	VR	1	DF-1	GB / LiS	404703
53	Inlexa 3 VR-T	VR	1	DF-4	GB / LiS	404704

*: additional atrial detection (therapy function)

2. Family description

Header difference overview

Variant	*Family member's*	*PC Board*	*RF-Antenna*
1	VR-T/DF-1 (DX)	#1	#1
2	VR-T/DF-4	#1	#2
3	DR-T/DF-1	#1	#1
4	DR-T/DF-4	#1	#2
5	HF-T/DF-1	#1	#1
6	HF-T/DF-4	#1	#2
7	HF-T/QP (DF-1 / IS-4)	#2	#2
8	HF-T/QP (DF-4 / IS-4)	#2	#2

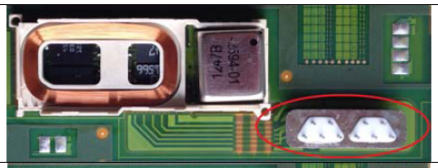
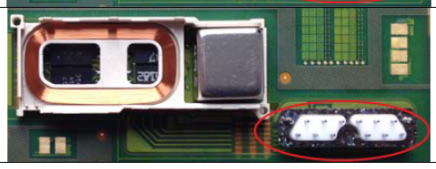
table 1: PC Board and RF Antenna

Battery vendor

Due to marketing reasons it was necessary to have different hardware identification numbers for the battery suppliers within the Ilivia 7 / Intica 7 / Inlexa 7 families for CRT models. The different battery vendors do not affect the RF and EMC performance.

2.1 PC-Board

All family devices are using the same electronic. This means all active and all passive electrical components are the same. The variant #7 and #8 HF-T QP header device are providing two additional electrical connections to the header. Therefore the variant #7 and #8 are using a different printed circuit board. The difference are the two wires MID3 and PROXIMAL4 (please refer schematic's) and a different feedtrough with 12 pols instead of 10 pols. QP means a quadruple left ventricular lead.

PC Board #1 10pol feedtrough Schematic file SCH-0143_0A.pdf	
PC Board #2 12pol feedtrough Schematic file SCH-0142_0A.pdf	

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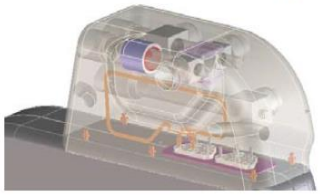
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804

2.2 RF-Antenna

The family members are equipped with two different RF antennas. All DF-1 header based devices are using the same antenna type #1. All DF4 header based devices are using also the same antenna, but type #2.

DF-1 header with antenna type #1	*DF4 header with antenna type #2*
	

Version History

Version	Issue Date	Remarks	Revised by
01	2016-01-17	Initial Release	

REPORT INDEX

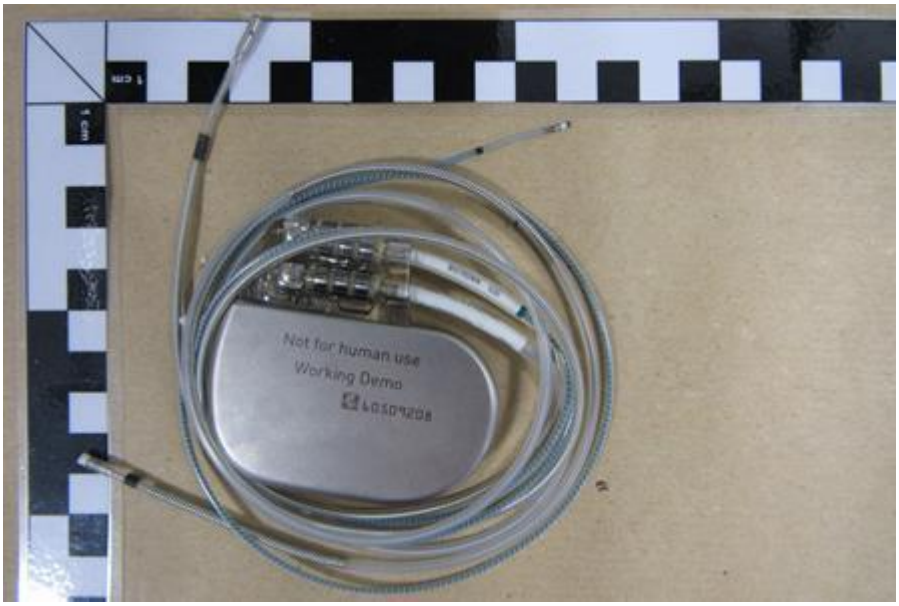
1 Equipment (Test item) Description

Description	ICD / Implantable Cardioverter Defibrillator TachNT2	
Model	Intica 7 HF-T QP	
Additional Model(s)	Additional Models according to Family Letter	
Brand Name(s)	BIOTRONIK	
Serial number	60509208 (HVIN 404630)	
Hardware version	Rev.: 0A	
Software / Firmware version	ROM: 5.0 / RAM: 4.1.0	
PMN	N/A	
HVIN	N/A	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRITACHNT2	
IC	N/A	
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	Ilivia 7
	Manufacturer	Biotronik SE & Co. KG
	Gain	-29.82 dBi (Determined by measurement)
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

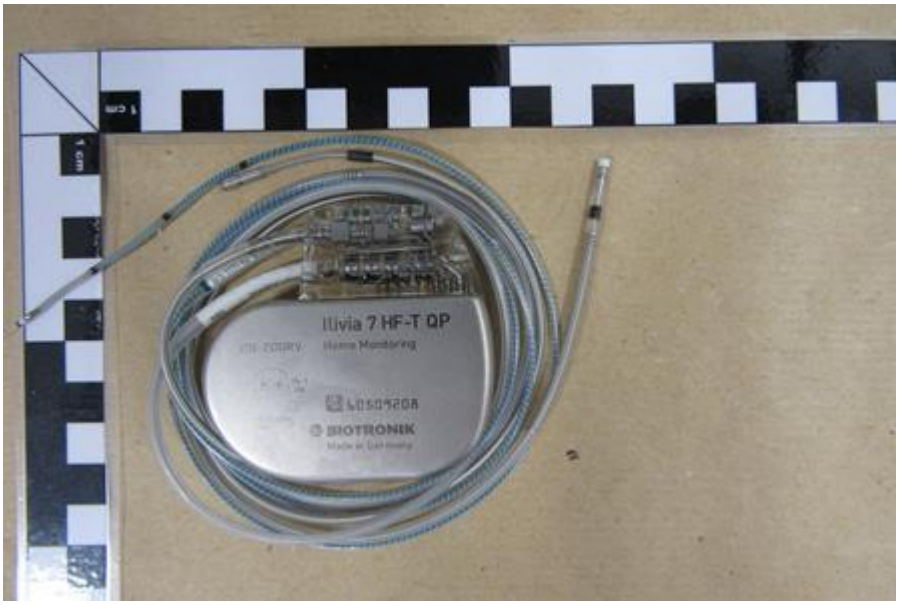
Power supply	V_{NOM}	3.0 VDC
	V_{MIN}	2.5 VDC
	V_{MAX}	3.2 VDC
Temperature	T_{NOM}	37 °C
	T_{MIN}	25 °C
	T_{MAX}	45 °C
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

1.1 Photos - Equipment external

Intica 7 HF-T QP DF-4 + IS-4 (Master) with Leads



Intica 7 HF-T QP DF-4 + IS-4 (Master) TOP



Ilivia 7 VR-T DF-4

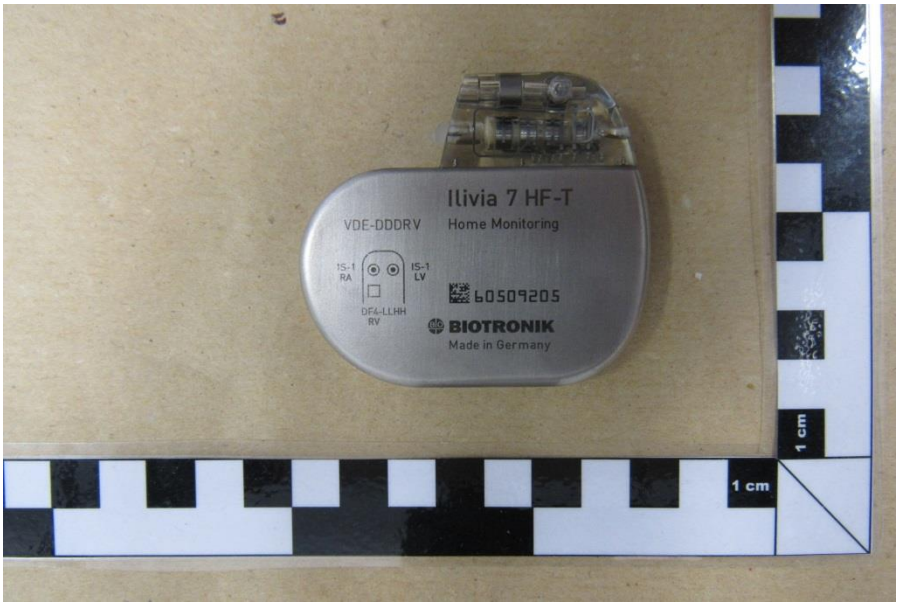

Ilivia 7 VR-T DF-1


Ilivia 7 VR-T DX DF-1

Ilivia 7 DR-T DF-1

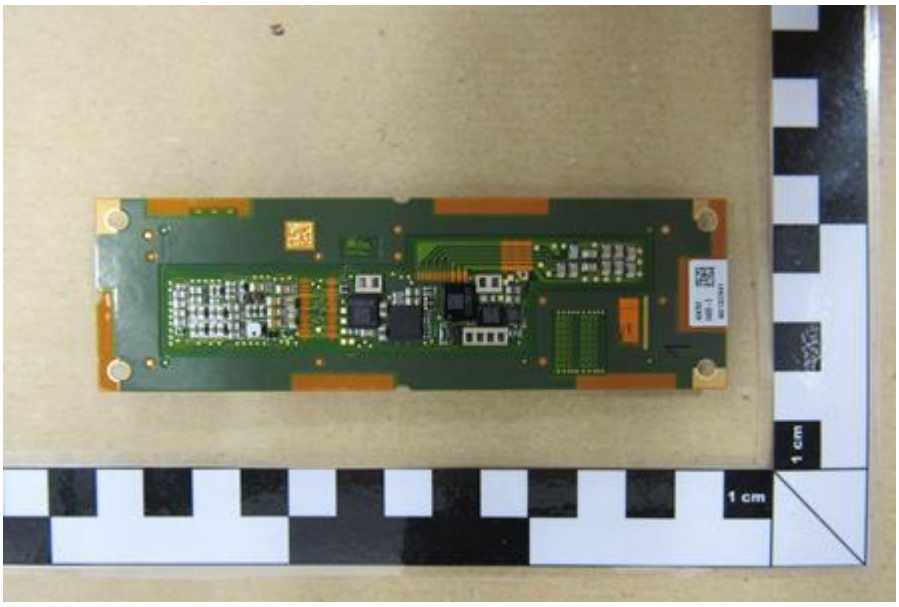
Ilivia 7 DR-T DF-4

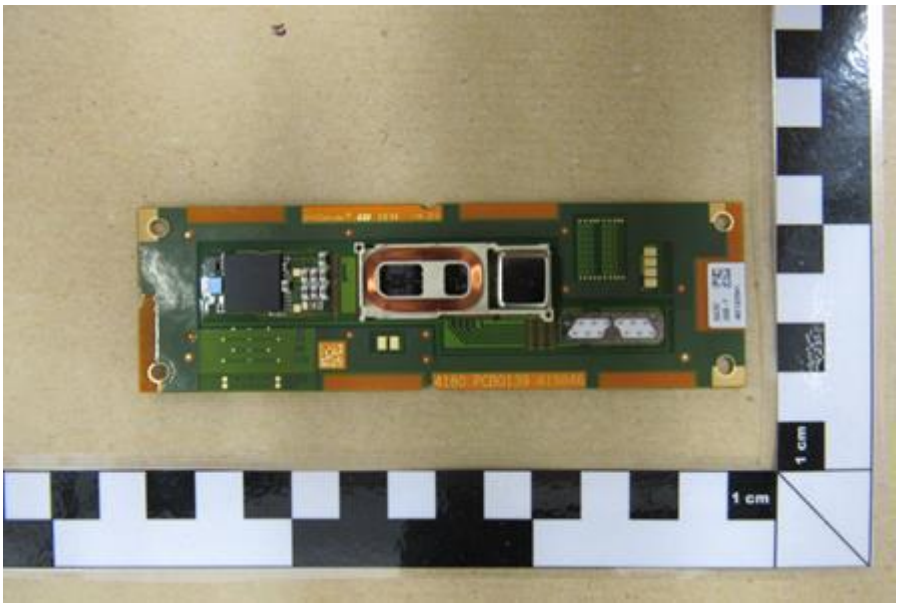

Ilivia 7 HF-T DF-1


Ilivia 7 HF-T DF-4


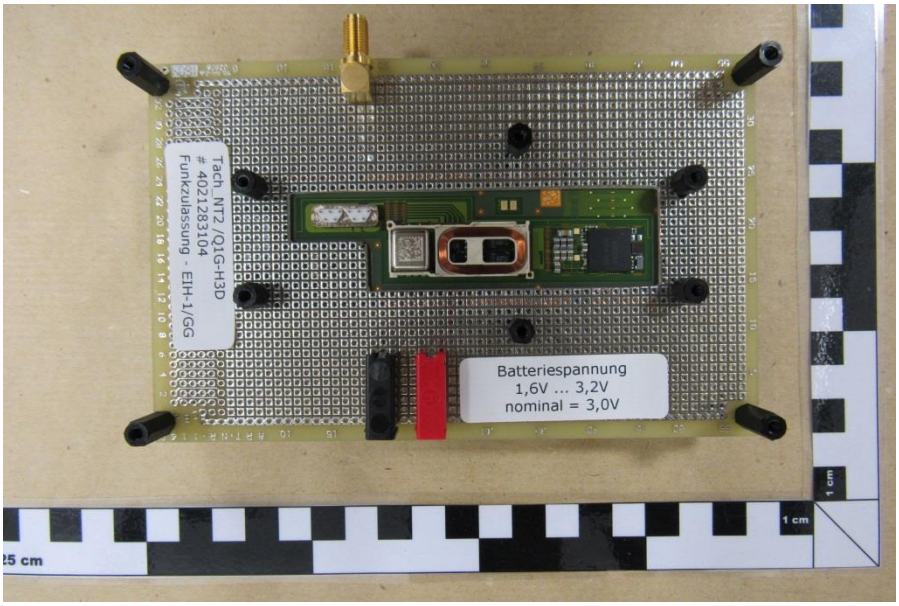
Intica 7 HF-T QP DF-1


1.2 Photos - Equipment internal

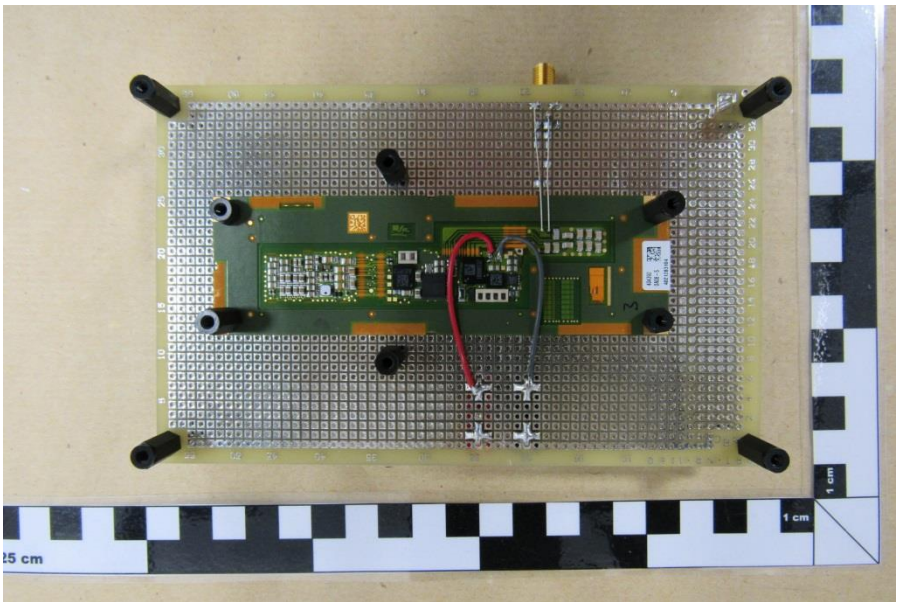
PCB TOP


PCB BOTTOM


CONDUCTED TEST SAMPLE TOP

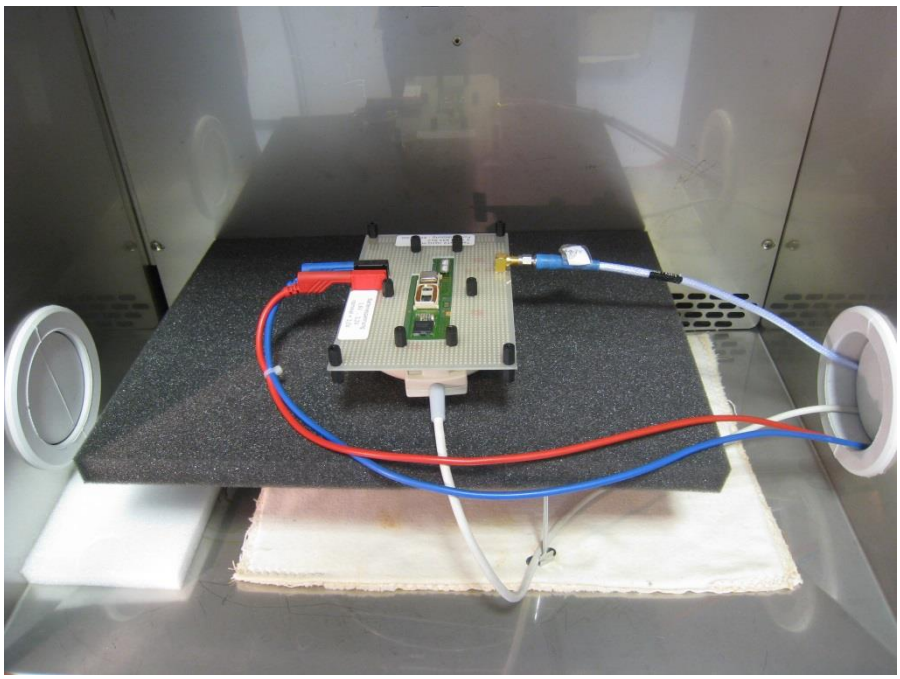


CONDUCTED TEST SAMPLE BOTTOM



1.3 Photos – Test setup

SETUP RADIATED EMISSIONS


SETUP CONDUCTED EMISSION


1.4 Photos – Auxiliary/Associated Equipment

AE1: USB Tel Box


1.5 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Programmer	Biotronik	USB TelBox	for test mode

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

1.7 Test Equipment Used During Testing

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

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

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

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

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Fully-anechoic chamber	Frankonia	AC 4	EF00200	-	-
Spectrum Analyzer	R&S	FSEK30	EF00168	2016-01	2017-01
LPD Antenna	R&S	HL 223	EF00212	2016-04	2019-04

Radiated spurious emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 1	EF00062	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04
Biconical Antenna	R&S	HK 116	EF00012	2016-05	2019-05
LPD Antenna	R&S	HL 223	EF00187	2016-05	2019-05
LPD Antenna	R&S	HL 025	EF00327	2015-10	2018-10

Discontinuation of MICS session					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04
Signal Generator	R&S	SMP 02	EF00165	2015-05	2017-05

1.8 Sample emission level calculation

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

Reading:

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

A.F.:

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

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

Net:

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

Limit:

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

Limit (dBµV/m) = 20*log (µV/m)

Margin:

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

Example only:

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

1.9 Simulated human body

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

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

Measured tissue parameters:

Tissue parameters – 403.5 MHz			
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	Informational 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	EUT battery powered
FCC § 95.628(a)(3) IC RSS-243 3.6, 5.7.1	System threshold power levels	EN 301 839-1 10.1	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(1) IC RSS-243 3.6, 5.7.2	Monitoring system bandwidth	EN 301 839-1 10.2	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(2) IC RSS-243 3.6, 5.7.3	Scan cycle time	EN 301 839-1 10.3	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(2) IC RSS-243 3.6, 5.7.4	Minimum channel monitoring period	EN 301 839-1 10.3	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(4) IC RSS-243 3.6, 5.7.5	Channel Access	EN 301 839-1 10.4	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(4) IC RSS-243 3.6, 5.7.6	Discontinuation of MICS or MEDS session	EN 301 839-1 10.5	N/A	Applies only to equipment by which LBT is performed
FCC § 95.628(a)(5) IC RSS-243 3.6, 5.7.7	Use of the pre-scanned alternate channel	EN 301 839-1 10.6	N/A	Not used
Remarks:				

3 Test Conditions and Results

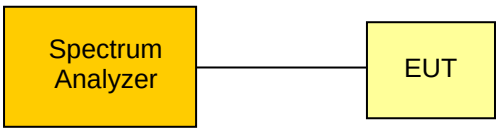
3.1 Test Conditions and Results – Occupied Bandwidth

Occupied Bandwidth acc. to IC RSS-243	**Verdict: PASS**
Test according to measurement reference	Reference Method
	RSS-Gen 6.6
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated 2

Limits

None (Informational only)

Test setup



Test procedure

1. EUT set to test mode (Communication tester is used if needed)
2. Span set to at least twice the emission spectrum
3. Resolution bandwidth set to 1 % of span
4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function

Test results

Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	16	402.45	225.000	≤ 300	PASS
F_{MID}	16	403.65	227.885	≤ 300	PASS
F_{HIGH}	16	404.85	225.000	≤ 300	PASS
F_{LOW}	82	402.45	199.038	≤ 300	PASS
F_{MID}	82	403.65	200.481	≤ 300	PASS
F_{HIGH}	82	404.85	200.481	≤ 300	PASS

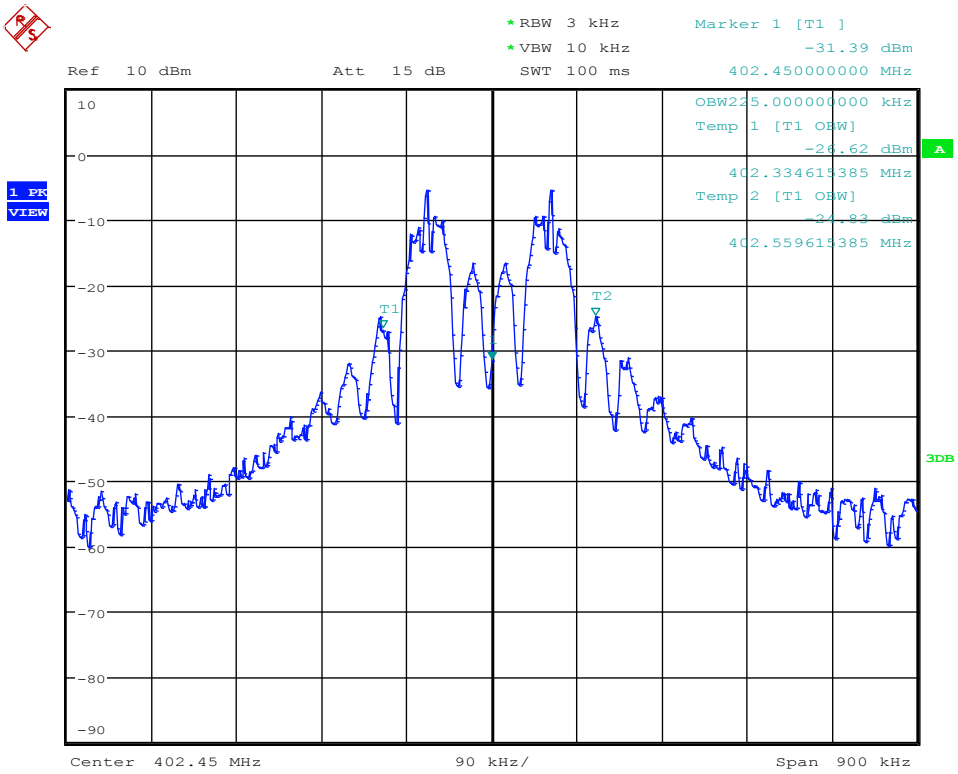
Comments:

Occupied Bandwidth – F_{LOW} (16kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK; 16 kBit/s
Test Date:	2016-11-23
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



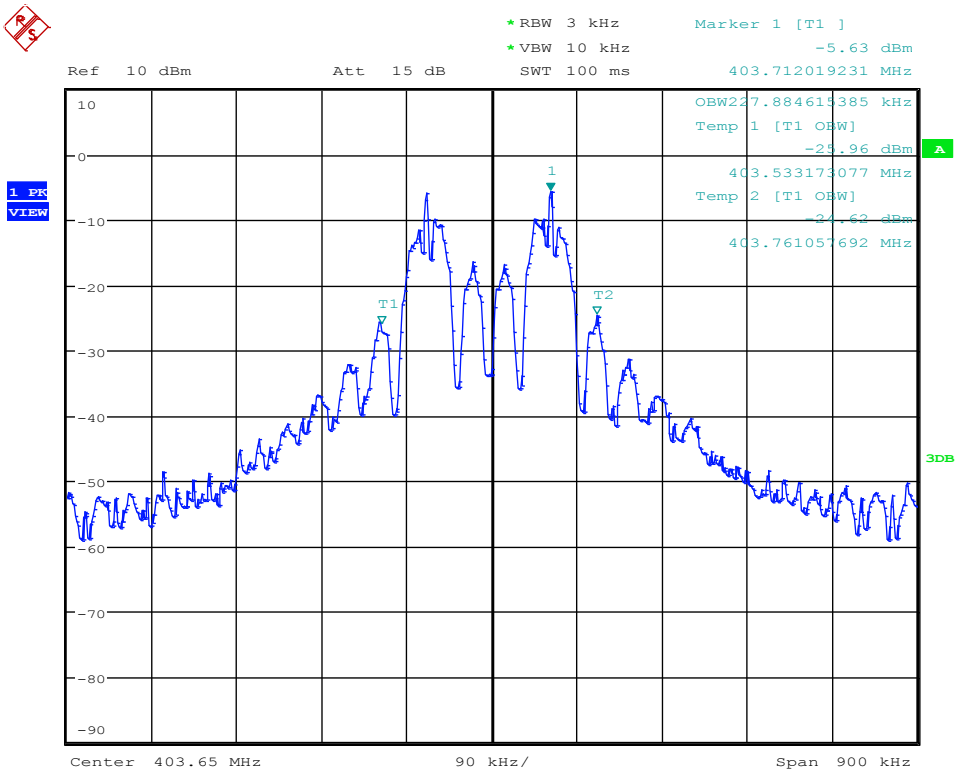
Date: 23.NOV.2016 10:23:22

Occupied Bandwidth - F_{MID} (16kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 16 kBit/s
Test Date:	2016-11-23
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used

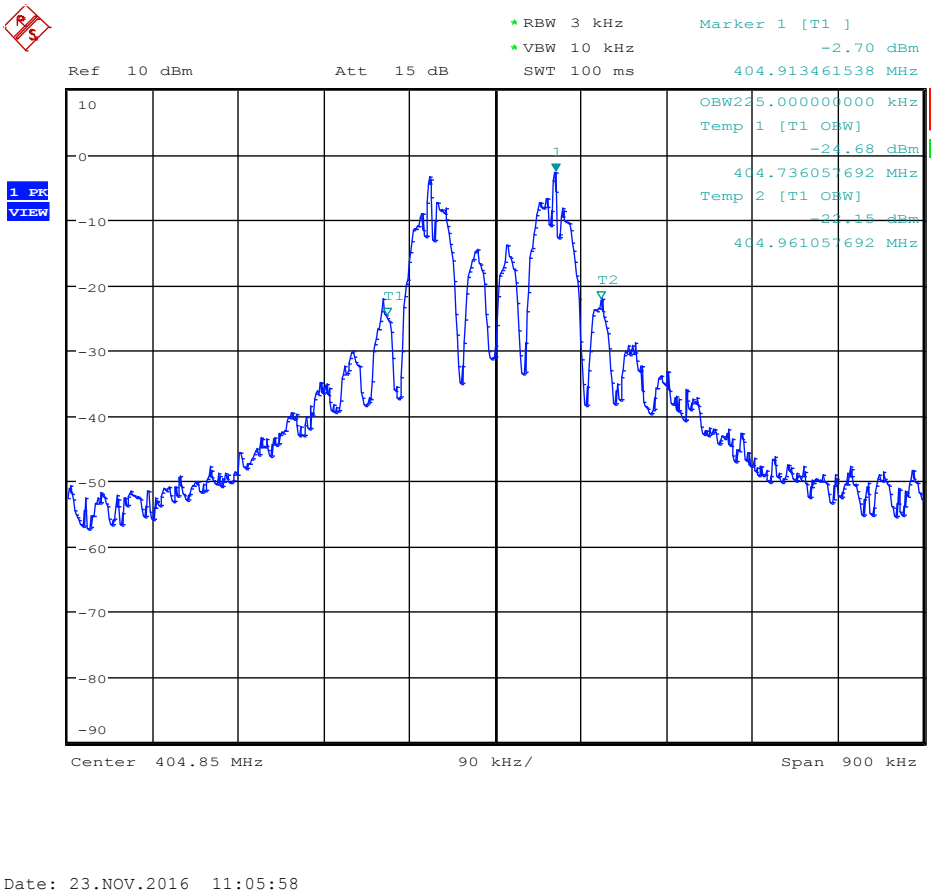


Occupied Bandwidth – F_{HIGH} (16kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 16 kBit/s
Test Date:	2016-11-23
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used

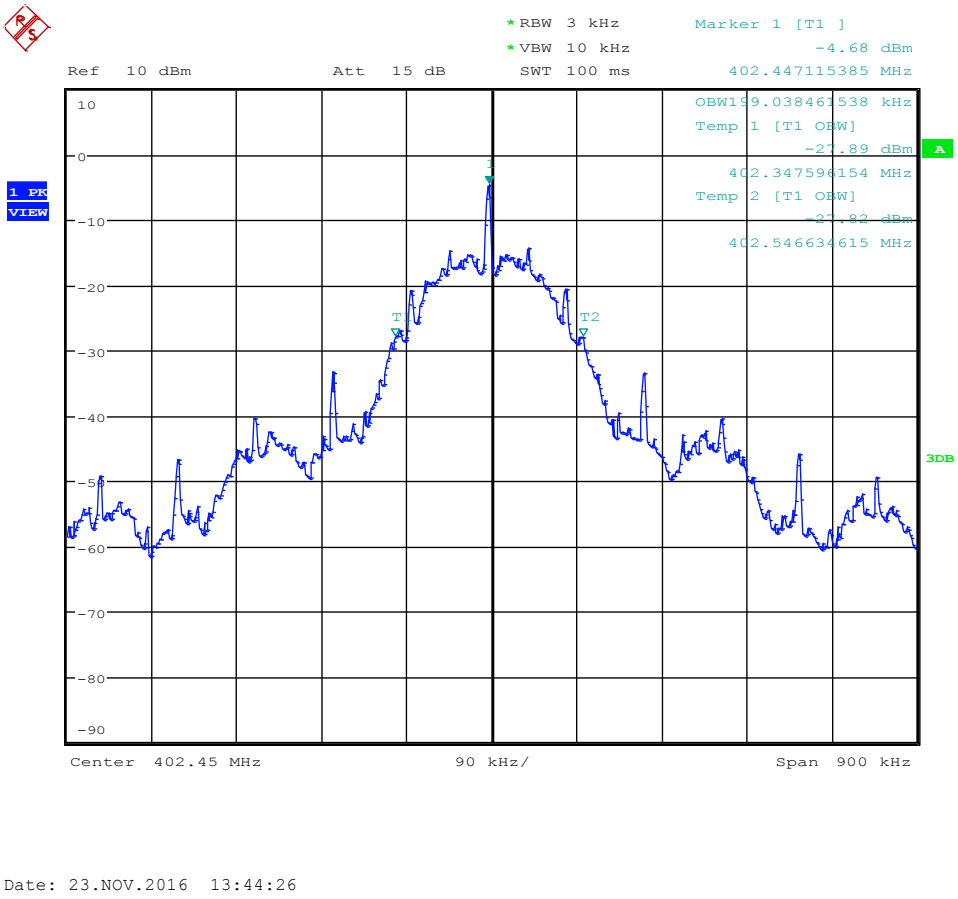


Occupied Bandwidth – F_{LOW} (82kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 82 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used

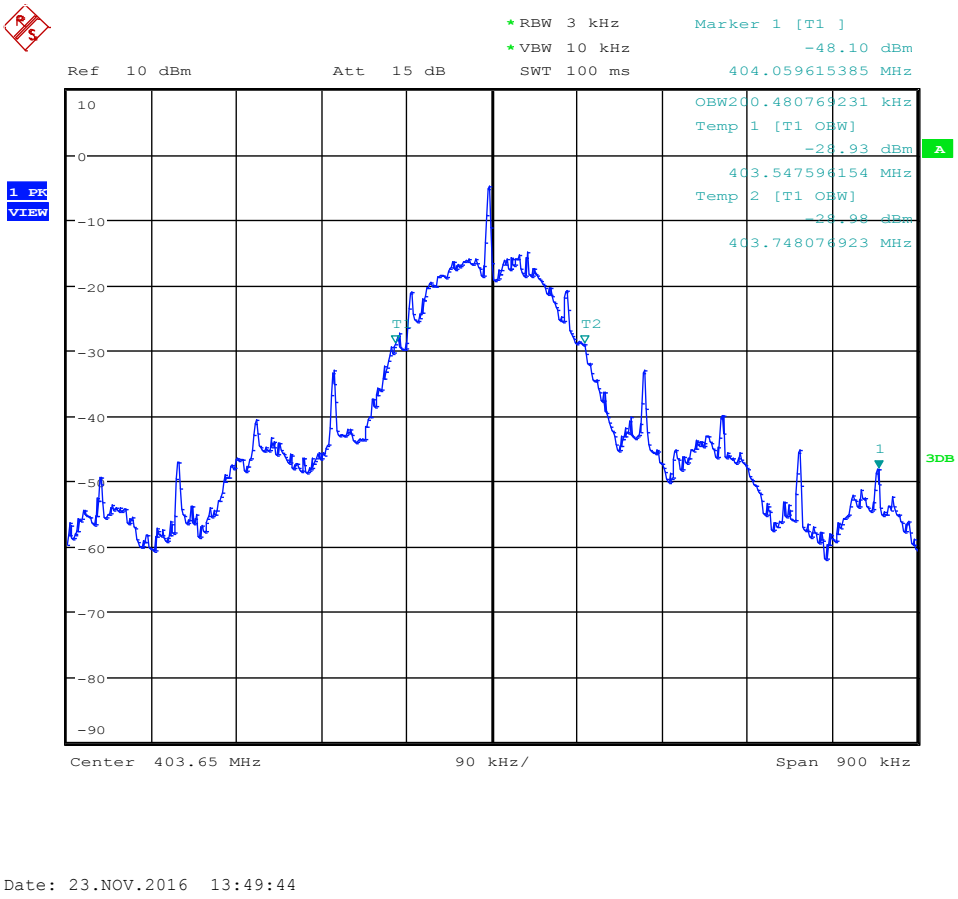


Occupied Bandwidth – F_{MID} (82kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 82 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used

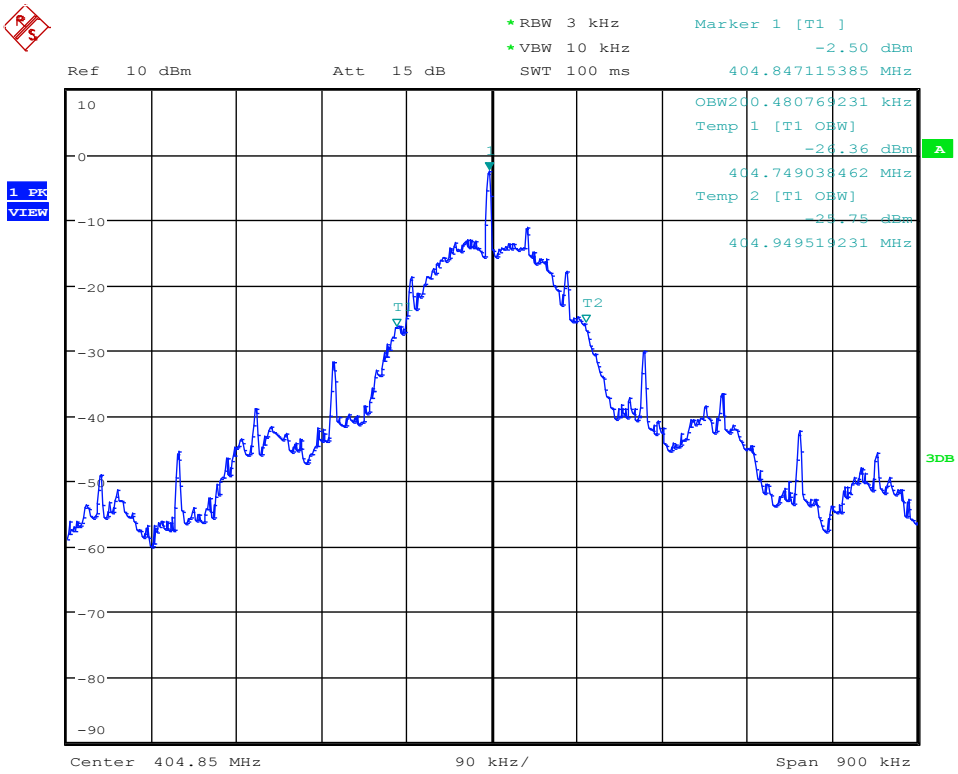


Occupied Bandwidth – F_{HIGH} (82kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 82 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



Date: 23.NOV.2016 13:51:58

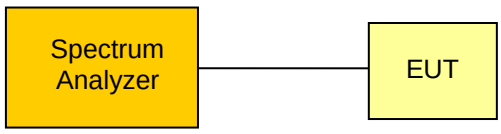
3.2 Test Conditions and Results – Emission Bandwidth

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 1 / Modulated 2

Limits

≤ 300 kHz

Test setup



Test procedure

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

Test results

Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	16	402.45	235.169	≤ 300	PASS
F_{MID}	16	403.65	234.368	≤ 300	PASS
F_{HIGH}	16	404.85	210.316	≤ 300	PASS
F_{LOW}	82	402.45	173.063	≤ 300	PASS
F_{MID}	82	403.65	173.864	≤ 300	PASS
F_{HIGH}	82	404.85	172.465	≤ 300	PASS

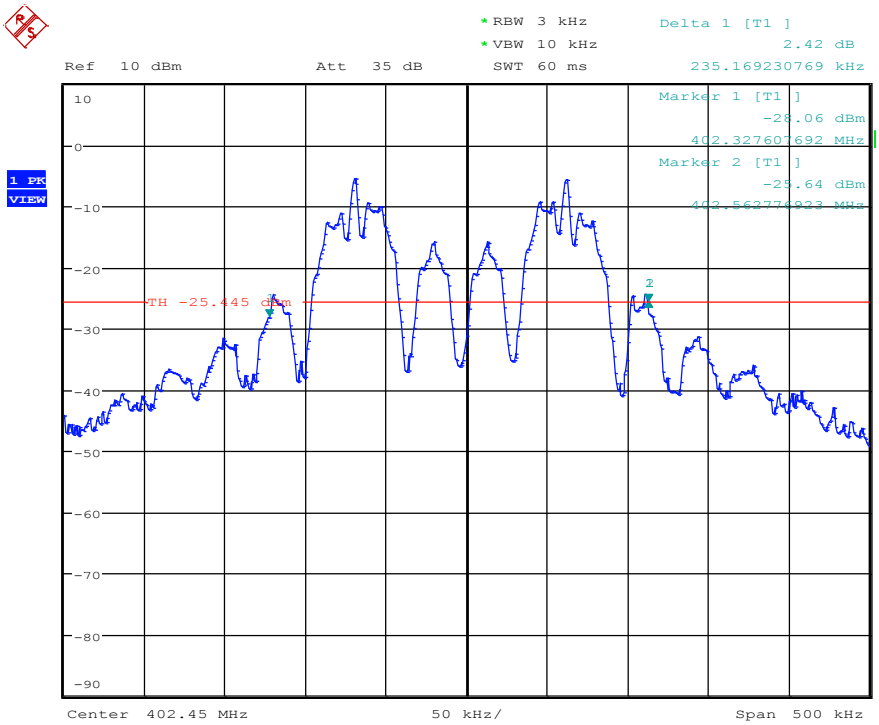
Comments:

Emission Bandwidth – F_{LOW} (16kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 16 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 235.2 KHz

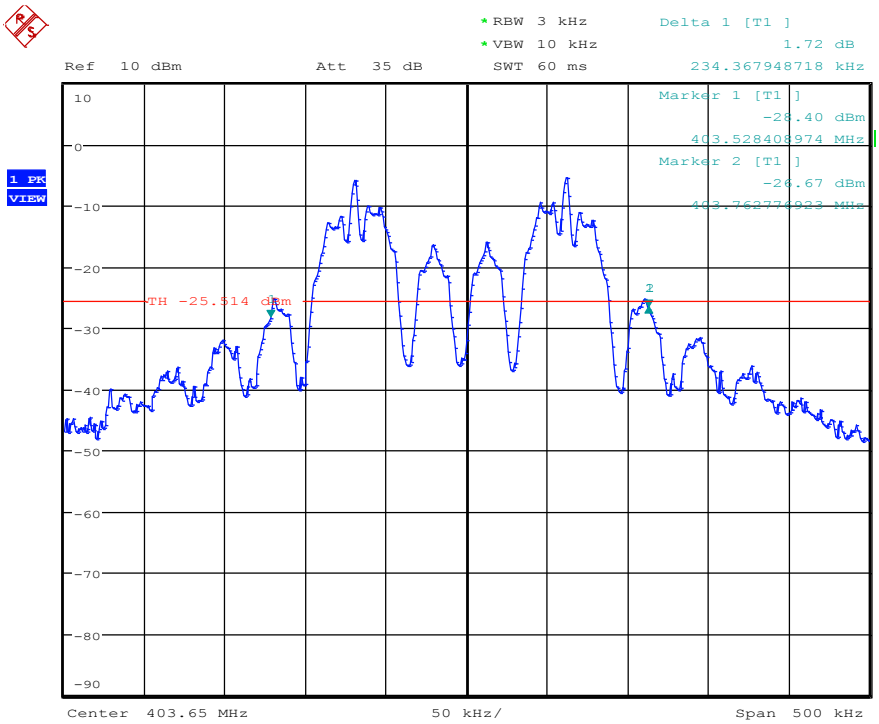
Date: 23.NOV.2016 11:52:55

Emission Bandwidth - F_{MID} (16kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 16 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 234.4 KHz

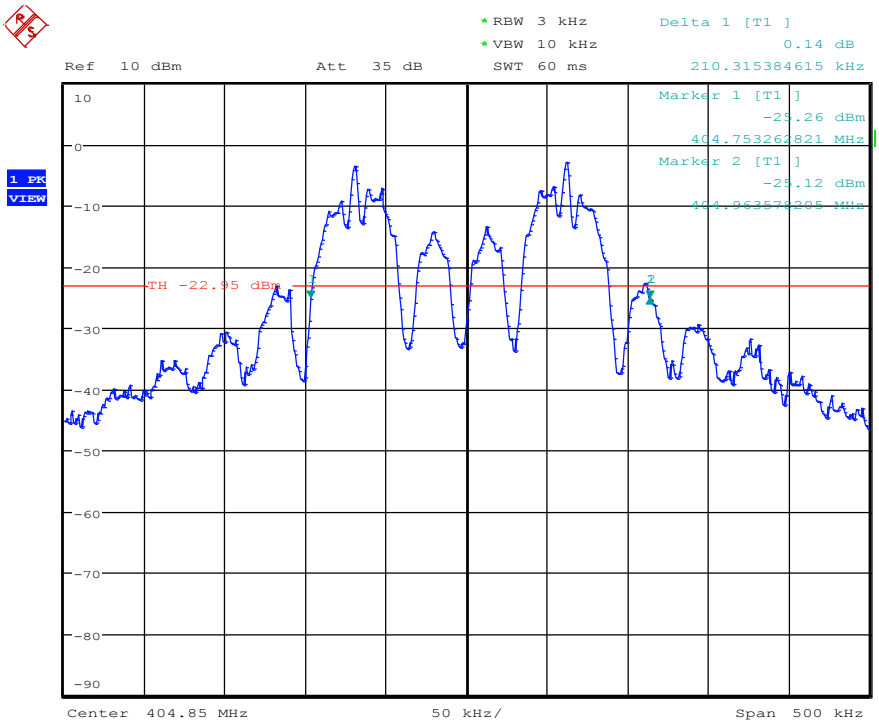
Date: 23.NOV.2016 12:20:56

Emission Bandwidth – F_{HIGH} (16kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 16 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 210.3 KHz

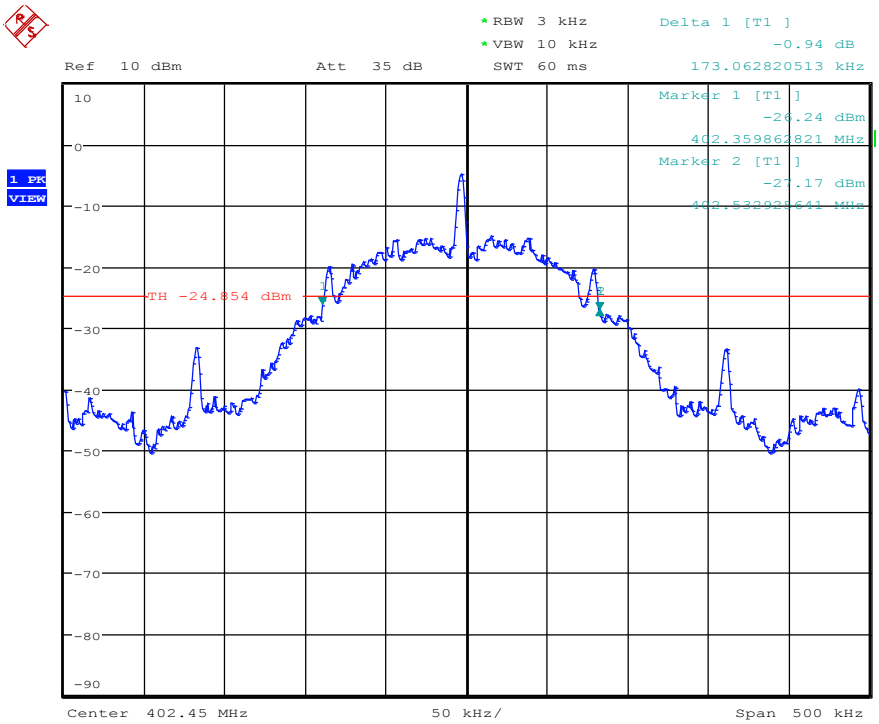
Date: 23.NOV.2016 12:22:57

Emission Bandwidth – F_{LOW} (82kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 82 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 173.1 KHz

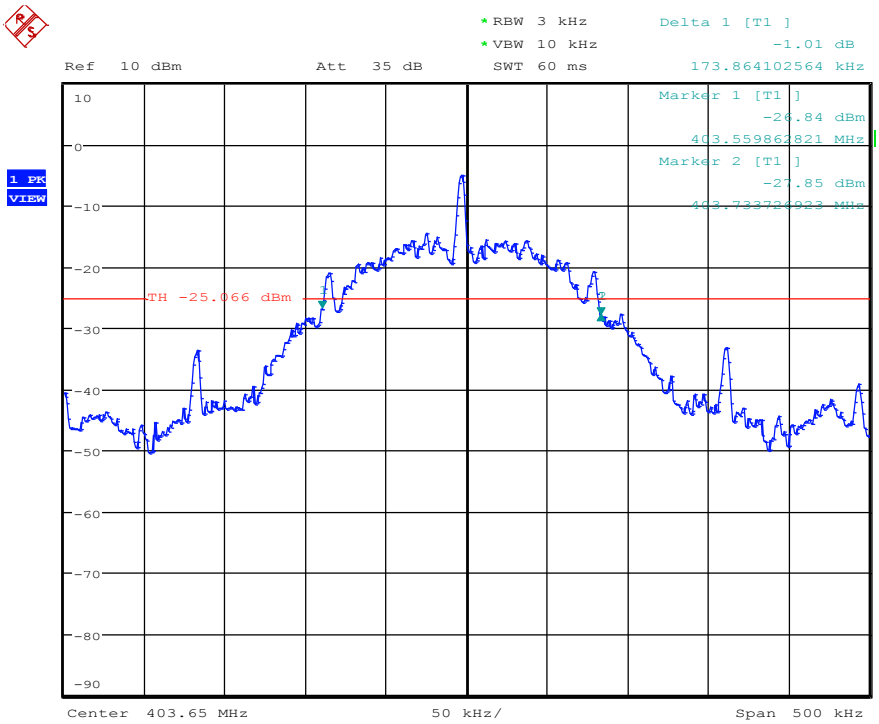
Date: 23.NOV.2016 14:04:45

Emission Bandwidth – F_{MID} (82kBit)

Emission Bandwidth acc. to EN 301 839

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 82 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 173.9 KHz

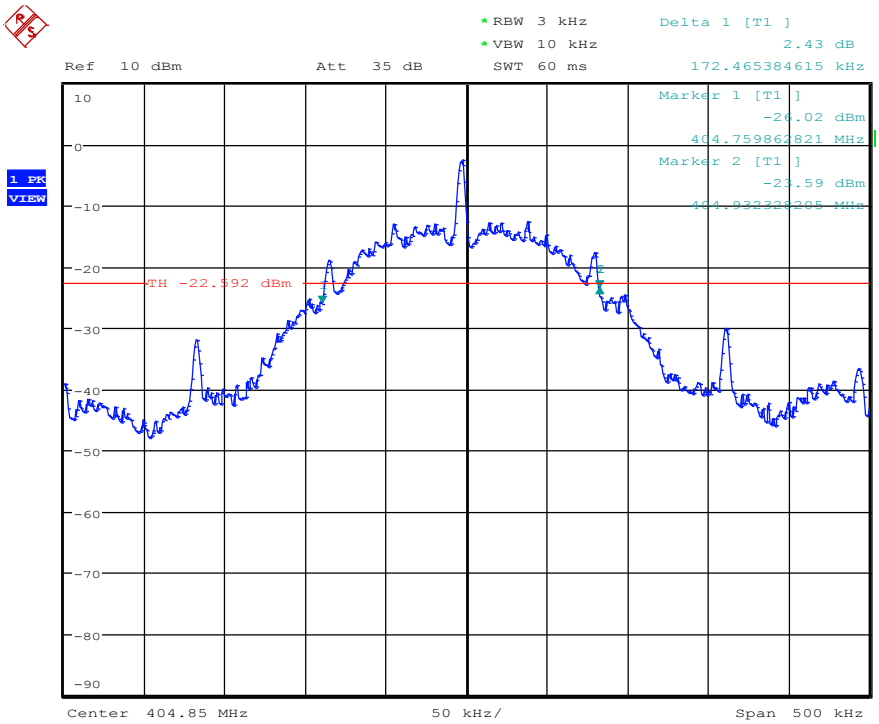
Date: 23.NOV.2016 14:08:52

Emission Bandwidth – F_{HIGH} (82kBit)

Emission Bandwidth acc. to EN 301 839

Project Number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 82 kBit/s
Test Date:	2016-11-23
Verdict:	PASS
Note 1:	20 dB bandwidth

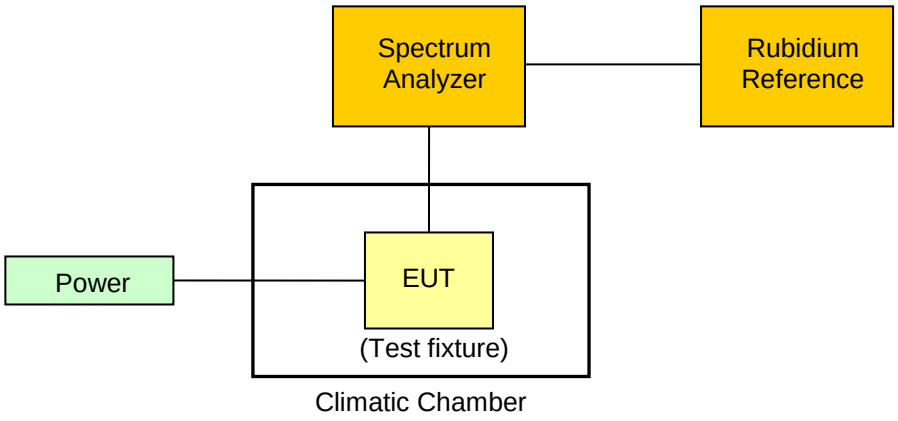


20 dB bandwidth: 172.5 KHz

Date: 23.NOV.2016 14:11:47

3.3 Test Conditions and Results – Frequency stability

Frequency stability acc. to FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.628(e) / IC RSS-243 3.3 5.3 / RSS-Gen 4.7
Test according to measurement reference	Reference Method
	EN 301 839-1 8.1
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Unmodulated 2
Limits	
≤ ±100 ppm	
Test setup	



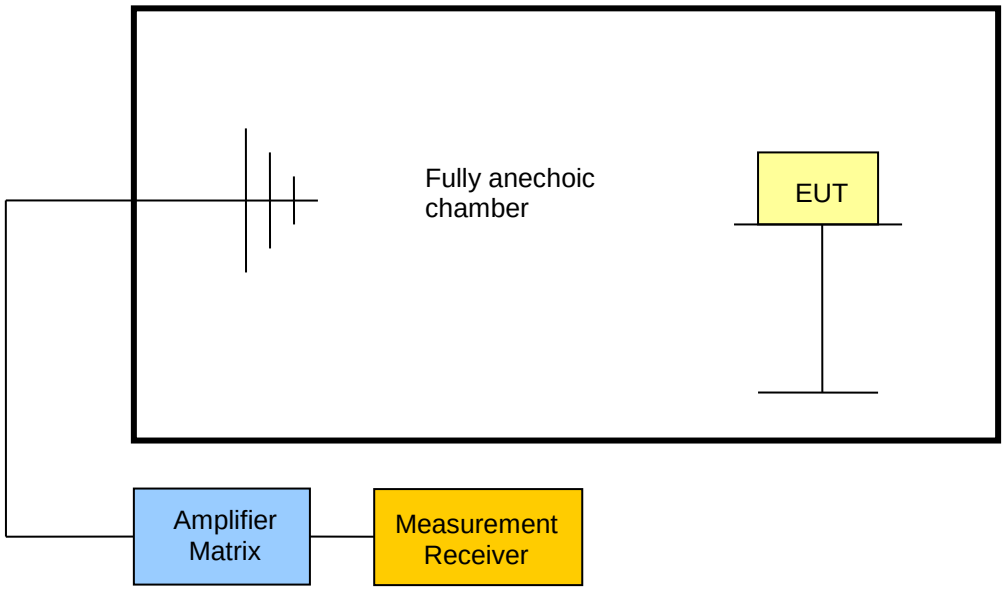
Test procedure

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

Test results					
Channel	Nominal Frequency [MHz]	Temperature	Supply voltage	Frequency [MHz]	Drift [ppm]
F_{LOW}	402.45	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	402.446120	-09.64
F_{LOW}	402.45	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	402.446860	-07.80
F_{LOW}	402.45	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	402.445737	-10.59
F_{MID}	403.65	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	403.646185	-09.45
F_{MID}	403.65	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	403.646945	-07.57
F_{MID}	403.65	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	403.645796	-10.41
F_{HIGH}	404.85	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	404.846256	-09.25
F_{HIGH}	404.85	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	404.846999	-07.41
F_{HIGH}	404.85	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	404.845883	-10.17
Comments:					

3.4 Test Conditions and Results – Transmitter output power

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



Test procedure

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

Test results					
Channel	Frequency [MHz]	Emission Level [dBm e.i.r.p.]	Detector	Limit [dBm e.i.r.p.]	Margin [dB]
F_{LOW}	402.45	-33.9	pk	-16	-17.90
F_{HIGH}	404.85	-30.7	pk	-16	-14.70
Comments:					

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

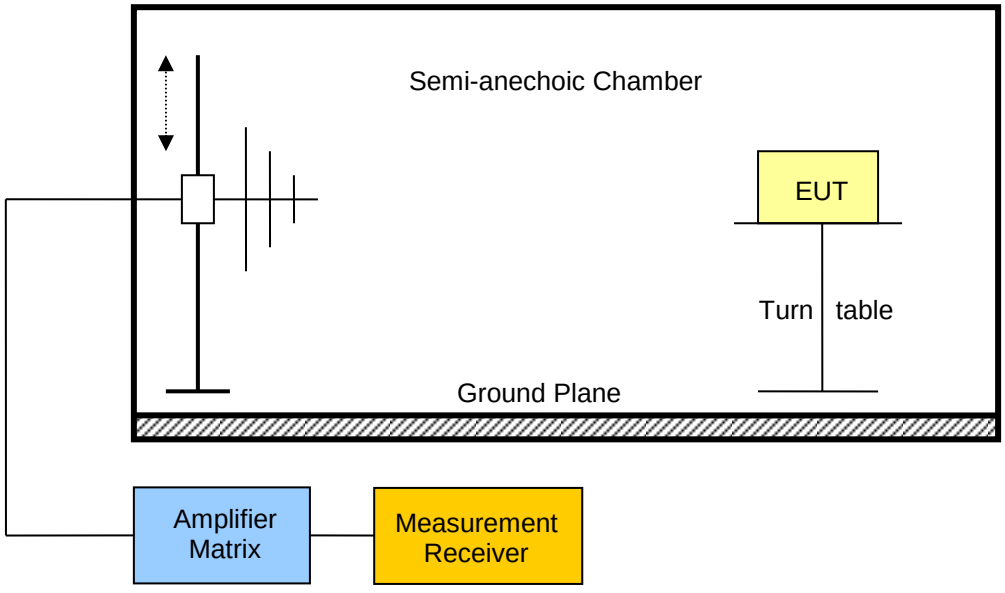
Band-edge and in-band emission compliance acc. to FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9
Test according to measurement reference	Reference Method
	FCC 95.635(d) / ANSI C 63.4
Test frequency range	Tested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

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

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

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

Test setup



Test procedure
1. EUT set to test frequency with modulation 2. Measurement polarization is set to vertical 3. Span it set according to measurement range 4. Resolution bandwidth is set to 1% of the emission bandwidth and detector is set to peak 5. During the sweep the EUT is rotated to obtain maximum emission level 6. Measurement is repeated with horizontal measurement polarization

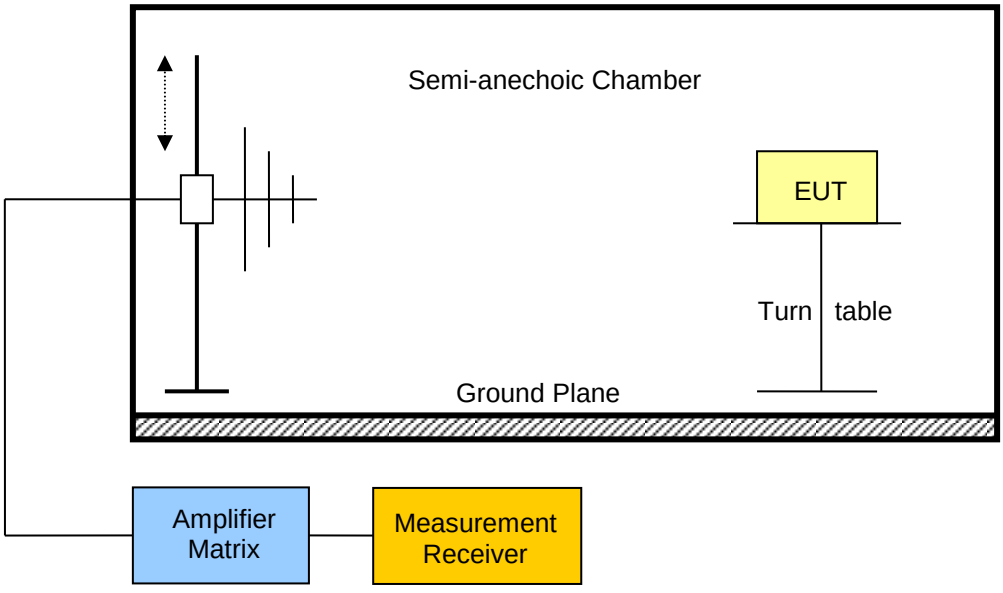
Test results

Channel	Frequency [MHz]	Emission [MHz]	Level [dBµV/m]	Pol.	Limit [dBµV/m]	Margin [dB]
F_{LOW}	402.45	401.793	13.85	hor	59.40	-45.55
F_{LOW}	402.45	401.793	14.01	ver	59.40	-45.39
F_{LOW}	402.45	402.292	29.71	hor	53.00	-23.29
F_{LOW}	402.45	402.295	29.76	ver	53.00	-23.24
F_{LOW}	402.45	402.614	27.91	ver	53.00	-25.09
F_{LOW}	402.45	402.619	28.52	hor	53.00	-24.48
F_{LOW}	402.45	403.243	17.57	hor	53.00	-35.43
F_{LOW}	402.45	403.243	18.40	ver	53.00	-34.60
F_{LOW}	402.45	403.963	17.30	hor	53.00	-35.70
F_{LOW}	402.45	403.963	18.18	ver	53.00	-34.82
F_{LOW}	402.45	404.093	16.64	hor	53.00	-36.36
F_{LOW}	402.45	404.096	17.49	ver	53.00	-35.51
F_{HIGH}	404.85	404.695	28.68	hor	53.00	-24.32
F_{HIGH}	404.85	404.695	30.98	ver	53.00	-22.02
F_{HIGH}	404.85	404.999	29.63	hor	53.00	-23.37
F_{HIGH}	404.85	404.999	31.11	ver	53.00	-21.89
F_{HIGH}	404.85	405.004	30.09	hor	59.40	-29.31
F_{HIGH}	404.85	405.009	31.01	ver	59.40	-28.39

Comments: see attached diagrams

3.6 Test Conditions and Results – Transmitter unwanted emissions

Transmitter unwanted emissions acc. to FCC Part 95 / IC RSS-243				**Verdict: PASS**
Test according referenced standards		Reference Method		
		FCC 95.635(d) / IC RSS-243 3.4 5.5 / IC RSS-Gen 4.9		
Test according to measurement reference		Reference Method		
		FCC 95.635(d) / ANSI C 63.4		
Test frequency range		Tested frequencies		
		30 MHz – 10th Harmonic		
EUT test mode		Modulated 1		
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
30 – 88	Quasi-Peak	100	40	3
88 – 216	Quasi-Peak	150	43.5	3
216 – 960	Quasi-Peak	200	46	3
960 – 1000	Quasi-Peak	500	54	3
> 1000	Average	500	54	3
Test setup				



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

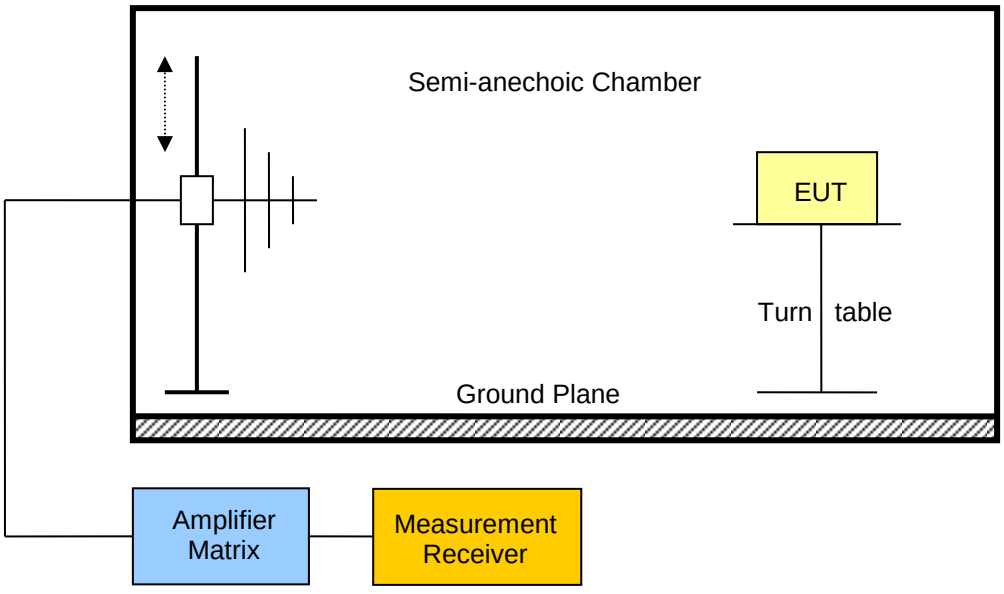
Test results

Channel	Frequency [MHz]	Mode	Emission [MHz]	Level [dbµV/m]	Det.	Pol.	Limit [dbµV/m]	Limit dist. [m]*	Margin [dB]
F_{LOW}	402.45	Modulated 1	401.347	20.92	pk	hor	46.00	3	-25.08
F_{LOW}	402.45	Modulated 1	401.347	21.52	pk	ver	46.00	3	-24.48
F_{LOW}	402.45	Modulated 1	407.629	21.09	pk	hor	46.00	3	-24.91
F_{LOW}	402.45	Modulated 1	407.629	22.17	pk	ver	46.00	3	-23.83
F_{HIGH}	404.85	Modulated 1	406.44	20.63	pk	hor	46.00	3	-25.37
F_{HIGH}	404.85	Modulated 1	406.44	22.55	pk	ver	46.00	3	-23.45

Comments: * Physical distance between EUT and measurement antenna.

3.7 Test Conditions and Results – Receiver spurious emissions

Receiver spurious emissions acc. to IC RSS-243				**Verdict: PASS**
Test according referenced standards	Reference Method			
	IC RSS-243 3.5 5.6 / IC RSS-Gen 4.10 6.1			
Test according to measurement reference	Reference Method			
	ANSI C 63.4			
Test frequency range	Tested frequencies			
	30 MHz – 5th Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
30 – 88	Quasi-Peak	100	40	3
88 – 216	Quasi-Peak	150	43.5	3
216 – 960	Quasi-Peak	200	46	3
960 – 1000	Quasi-Peak	500	54	3
> 1000	Average	500	54	3
Test setup				



Test procedure
1. EUT set to receive mode (Communication tester is used if needed) 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to peak emission levels

Test results

Channel	Frequency [MHz]	Emission [MHz]	Emission Level [dBµV/m]	Det.	Pol.	Limit [dBµV/m]	Margin [dB]
F_{MID}	403.65	3652	40.85	pk	ver	53.98	-13.13
F_{MID}	403.65	3964	40.44	pk	hor	53.98	-13.54

Comments:

ANNEX A Transmitter radiated power

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2016-11-22
Note:	Tx Power EIRP

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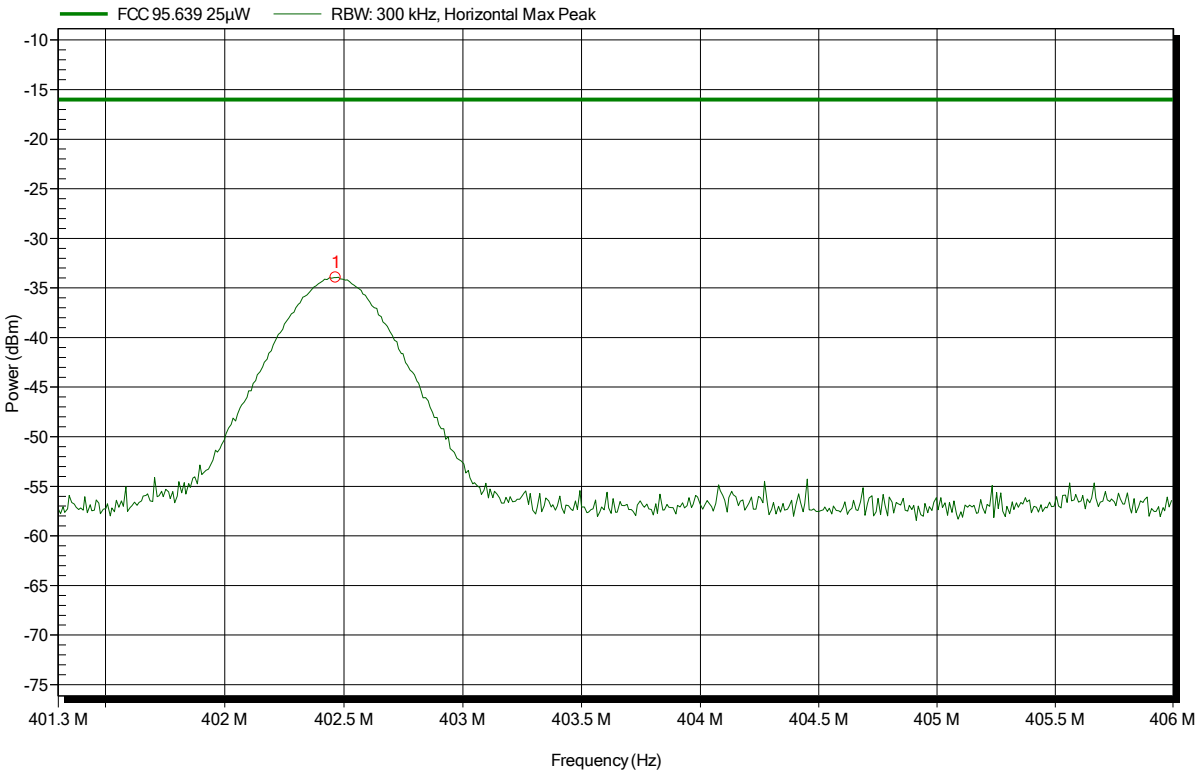

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.466 MHz	-33.9 dBm	-16 dBm	-17.95 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2016-11-22
Note:	Tx Power EIRP

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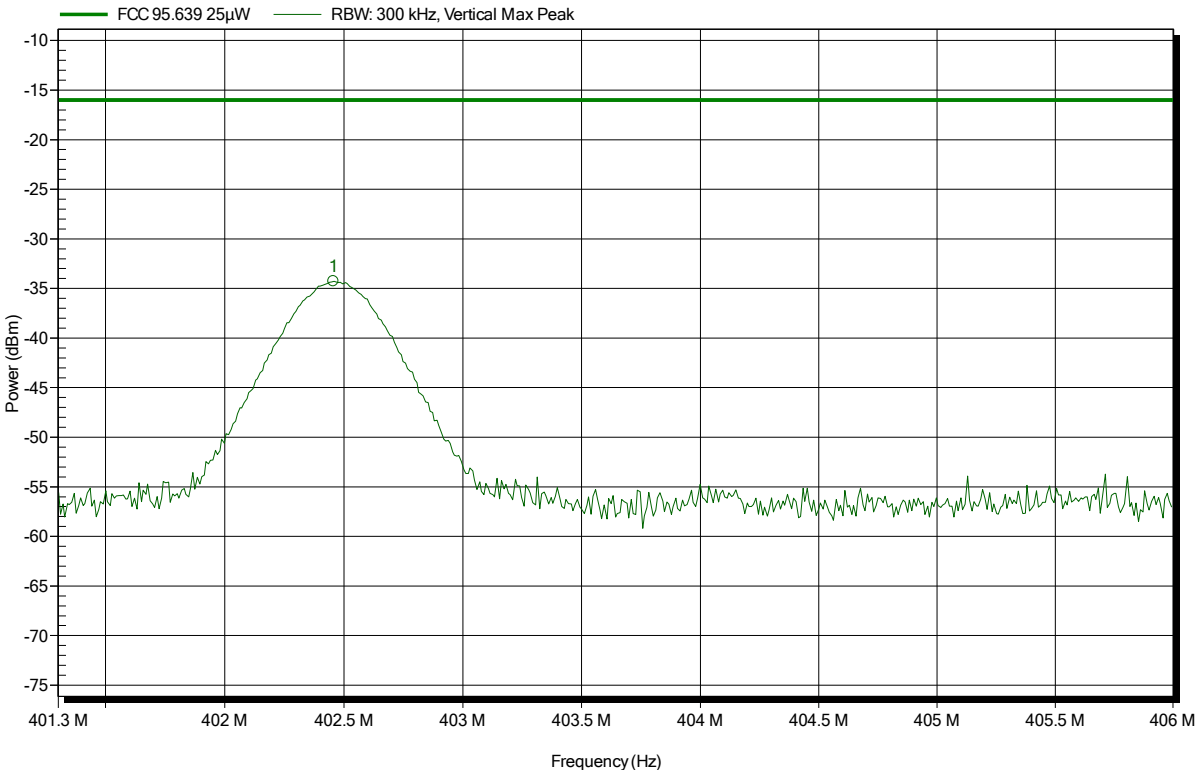

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.456 MHz	-34.3 dBm	-16 dBm	-18.29 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2016-11-22
Note:	Tx Power EIRP

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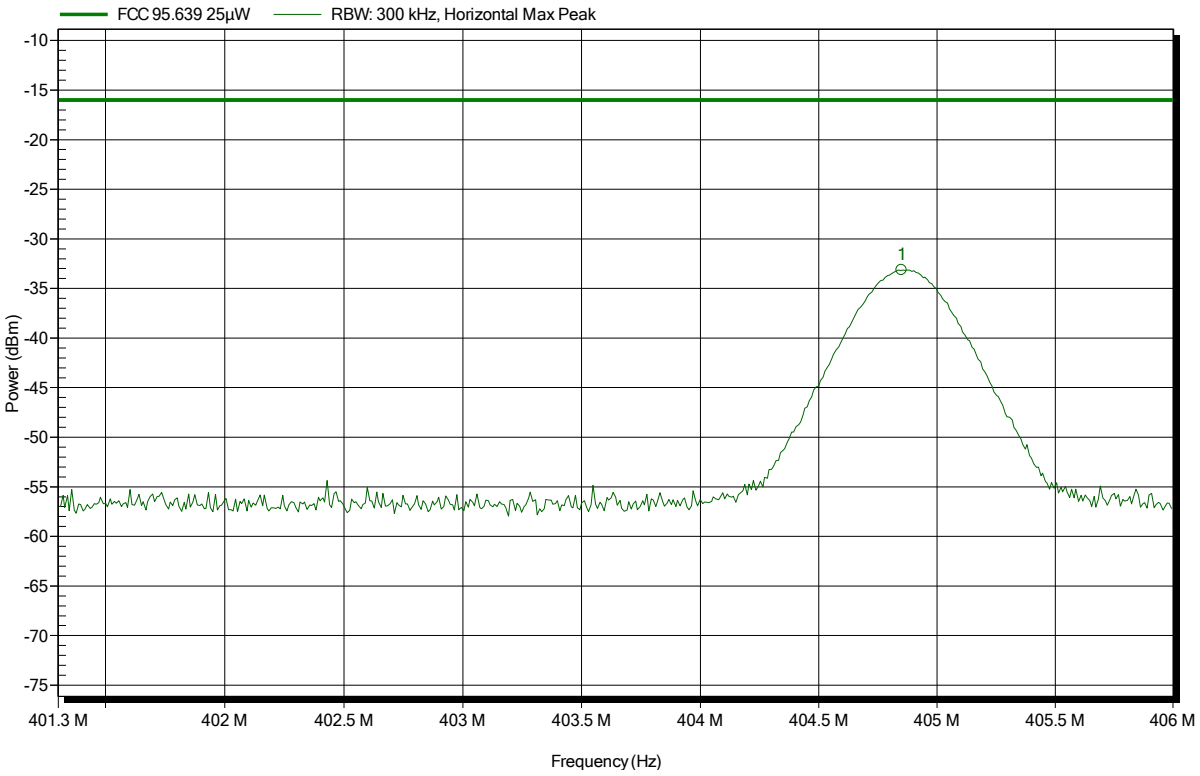

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.85 MHz	-33.1 dBm	-16 dBm	-17.14 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2016-11-22
Note:	Tx Power EIRP

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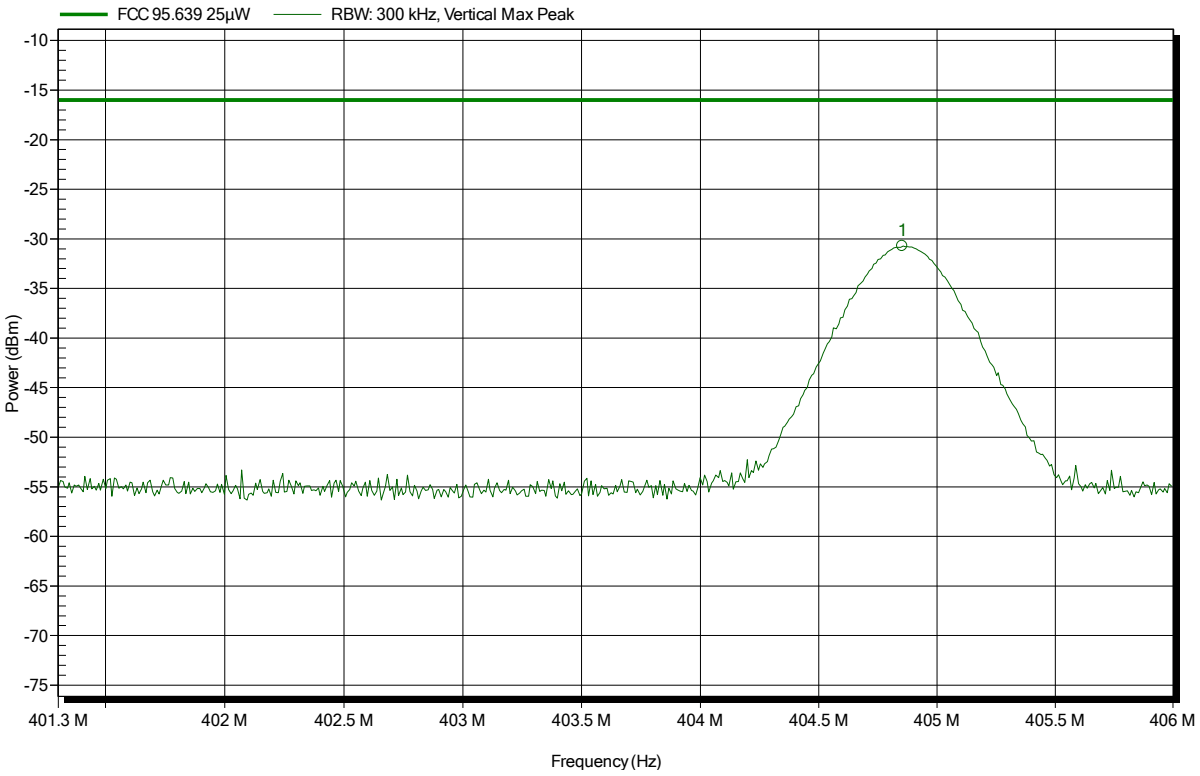

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.853 MHz	-30.7 dBm	-16 dBm	-14.73 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2016-11-22
Note:	Power dBµV/m ERP

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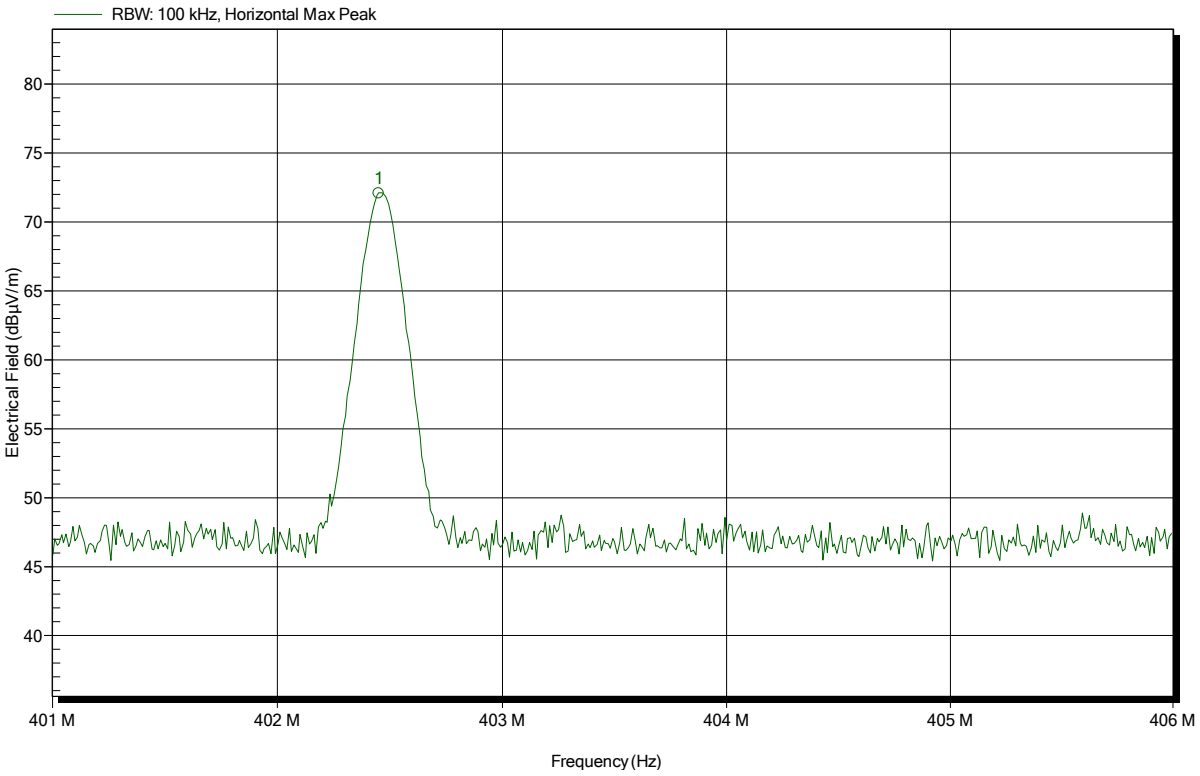

Frequency	Peak
402.45 MHz	72.07 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2016-11-22
Note:	Power dBµV/m ERP

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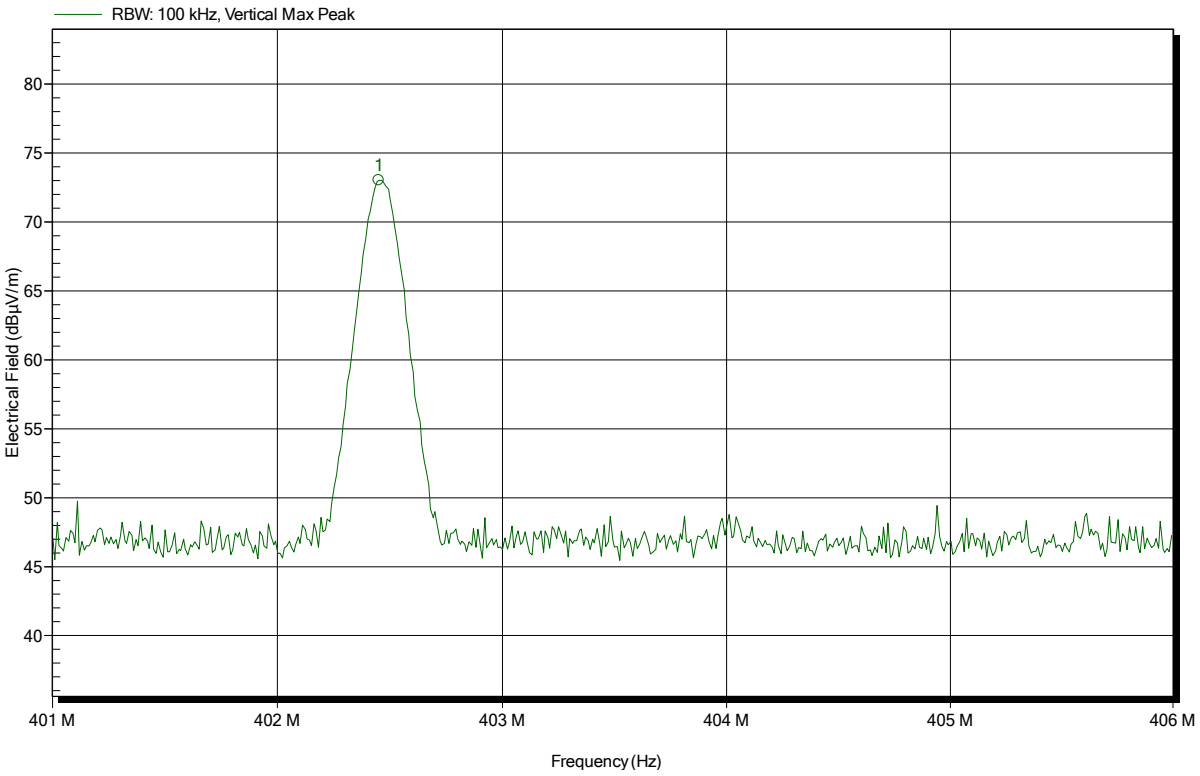

Frequency	Peak
402.45 MHz	73.03 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2016-11-22
Note:	Power dBµV/m ERP

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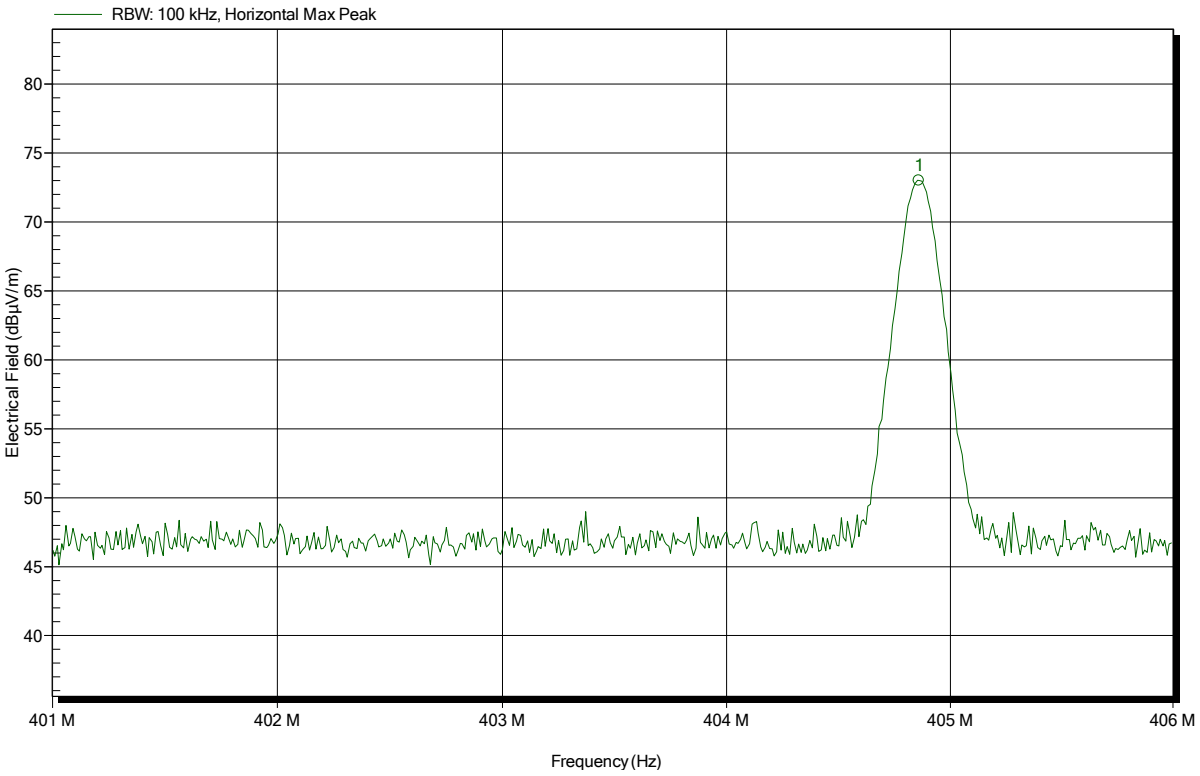

Frequency	Peak
404.86 MHz	73 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2016-11-22
Note:	Power dBµV/m ERP

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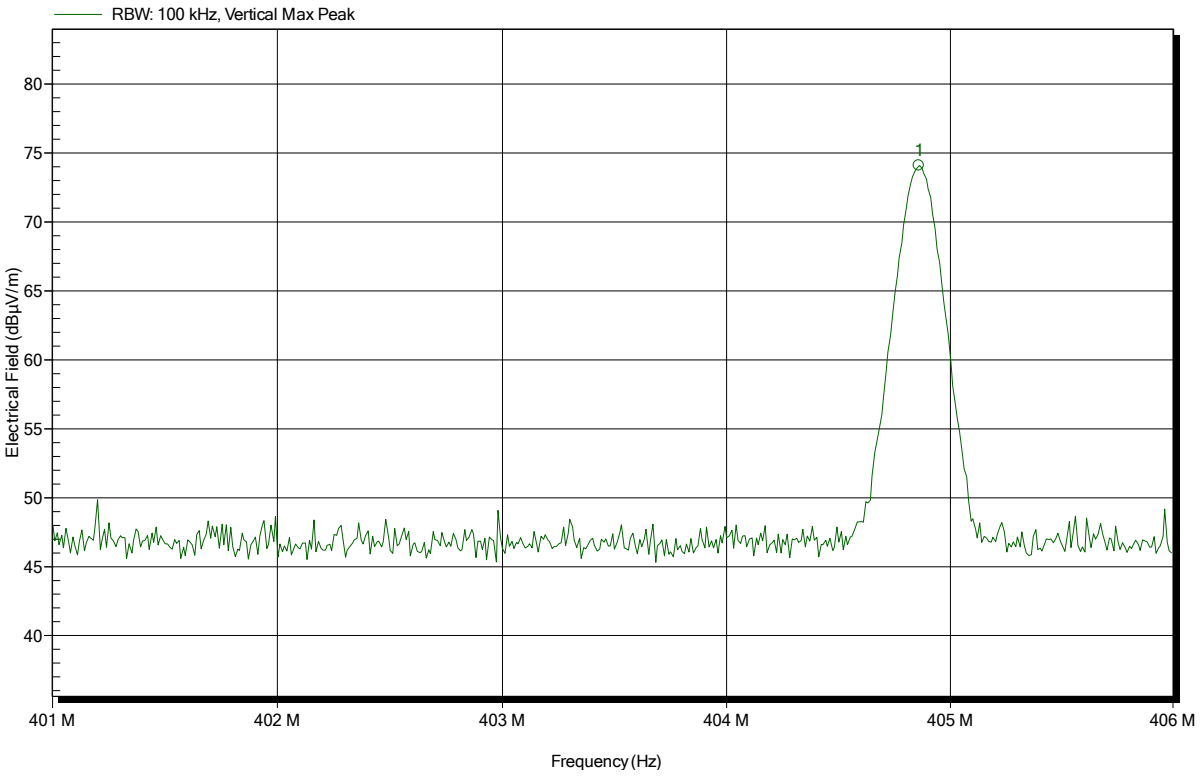

Frequency	Peak
404.86 MHz	74.11 dBµV/m

ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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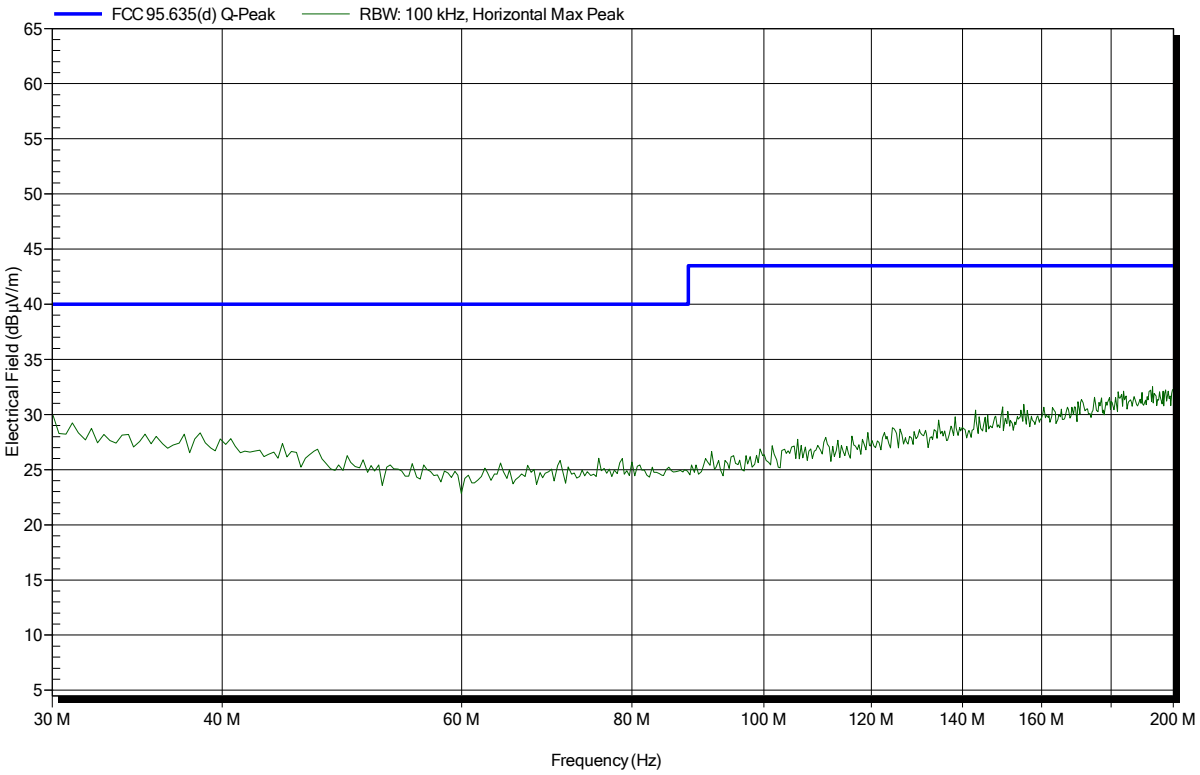

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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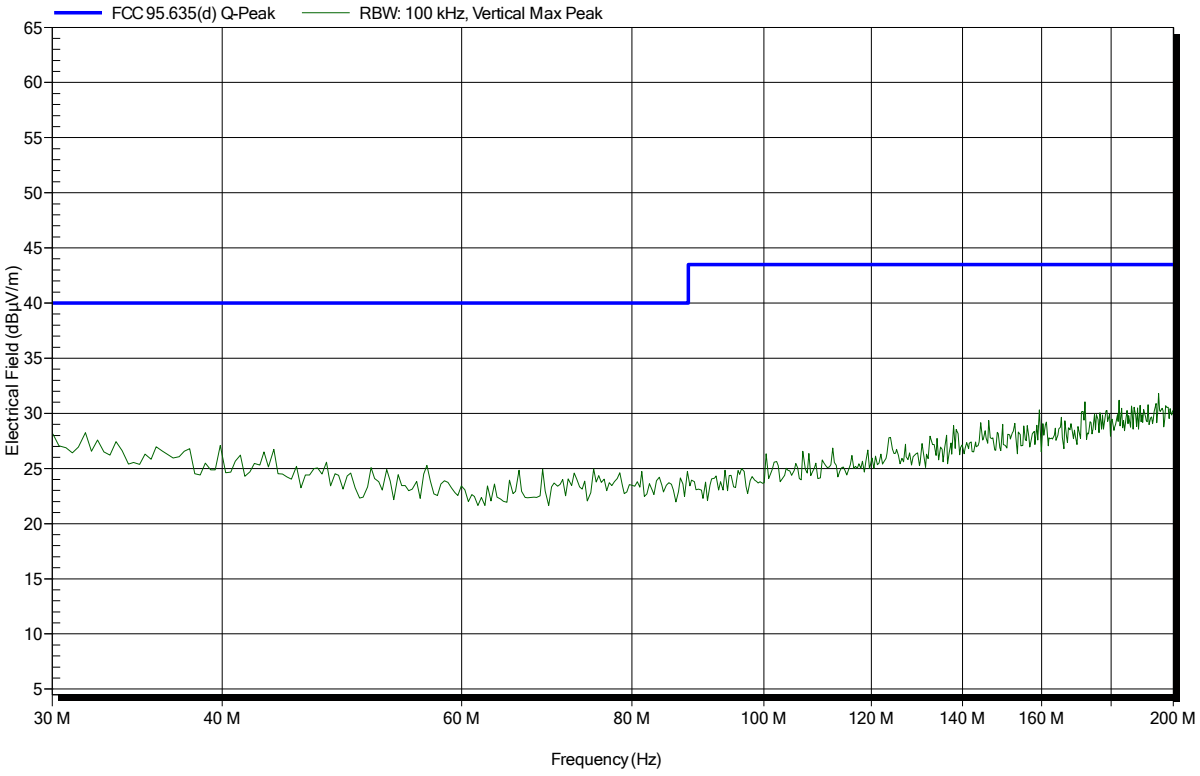

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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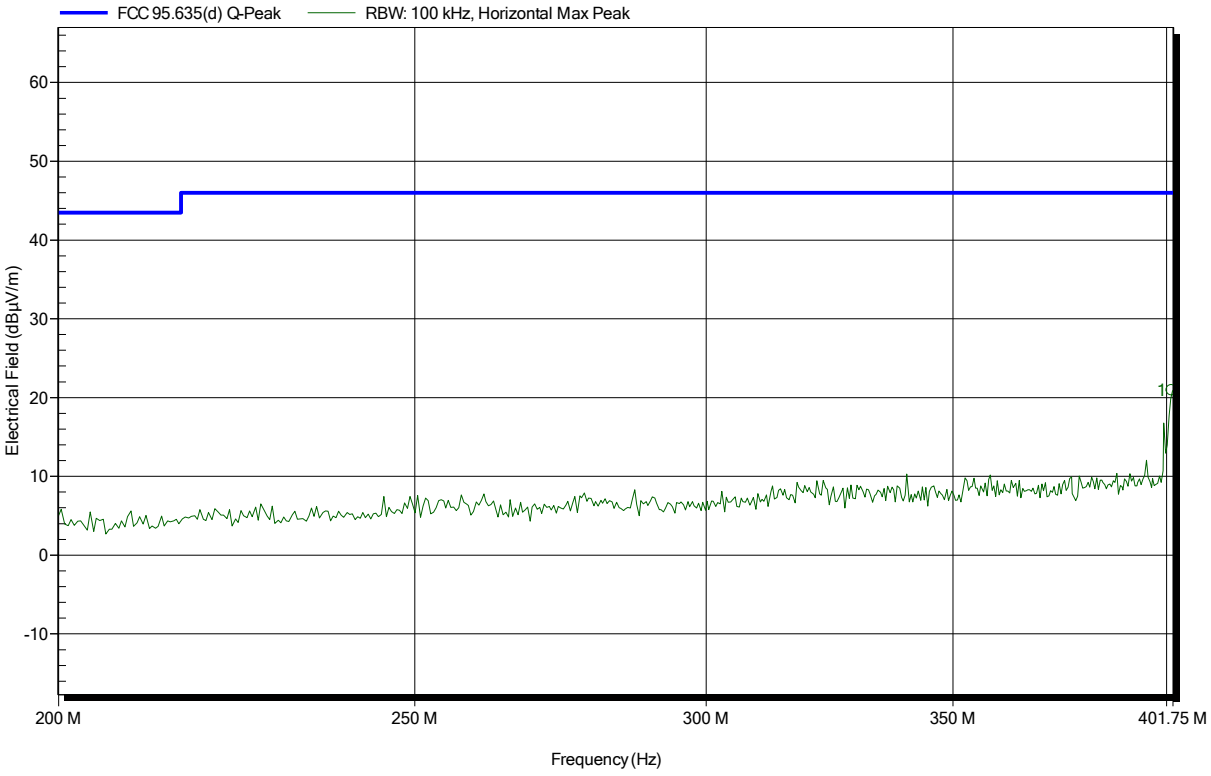

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.347 MHz	20.92 dBµV/m	46 dBµV/m	-25.08 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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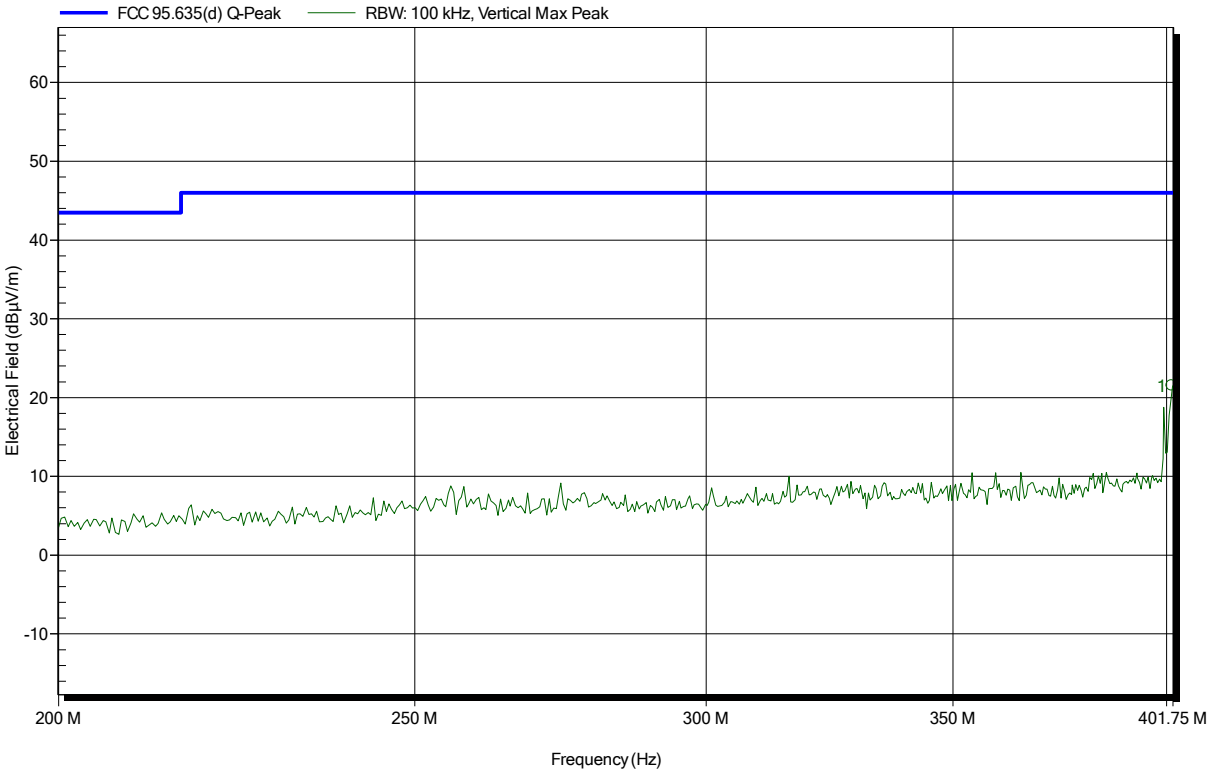

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.347 MHz	21.52 dBµV/m	46 dBµV/m	-24.48 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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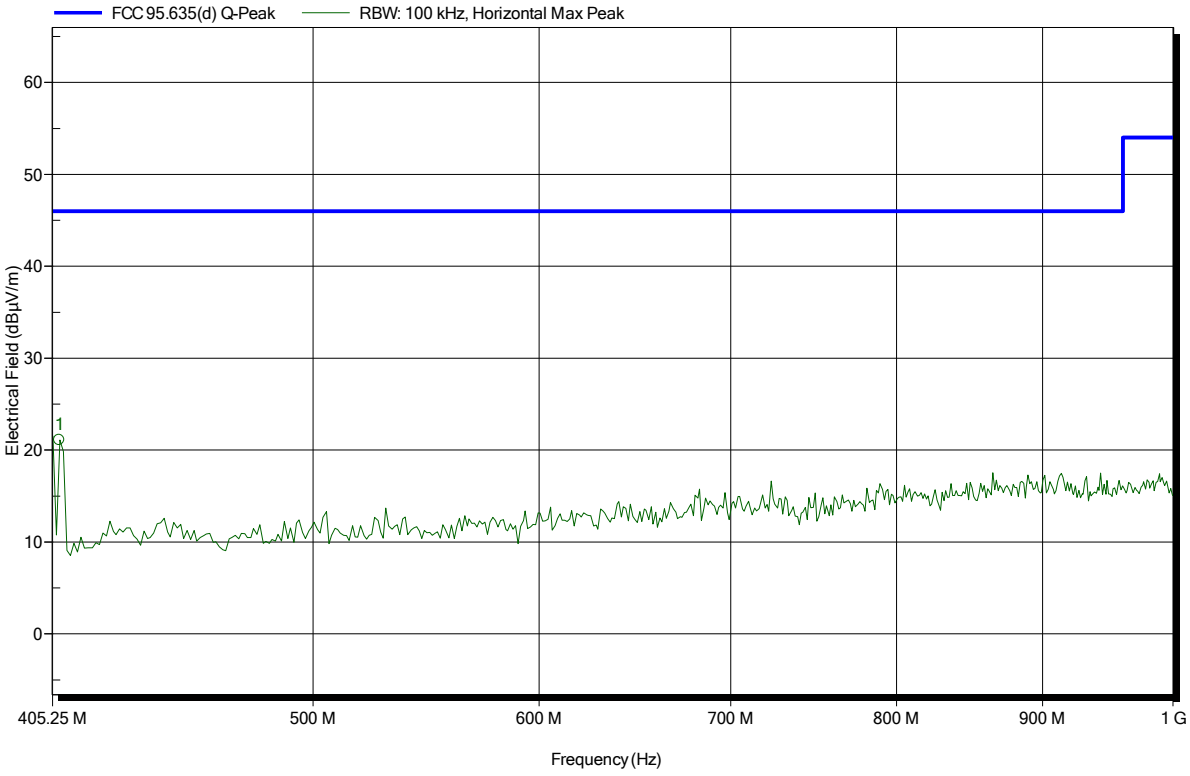

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
407.629 MHz	21.09 dBµV/m	46 dBµV/m	-24.91 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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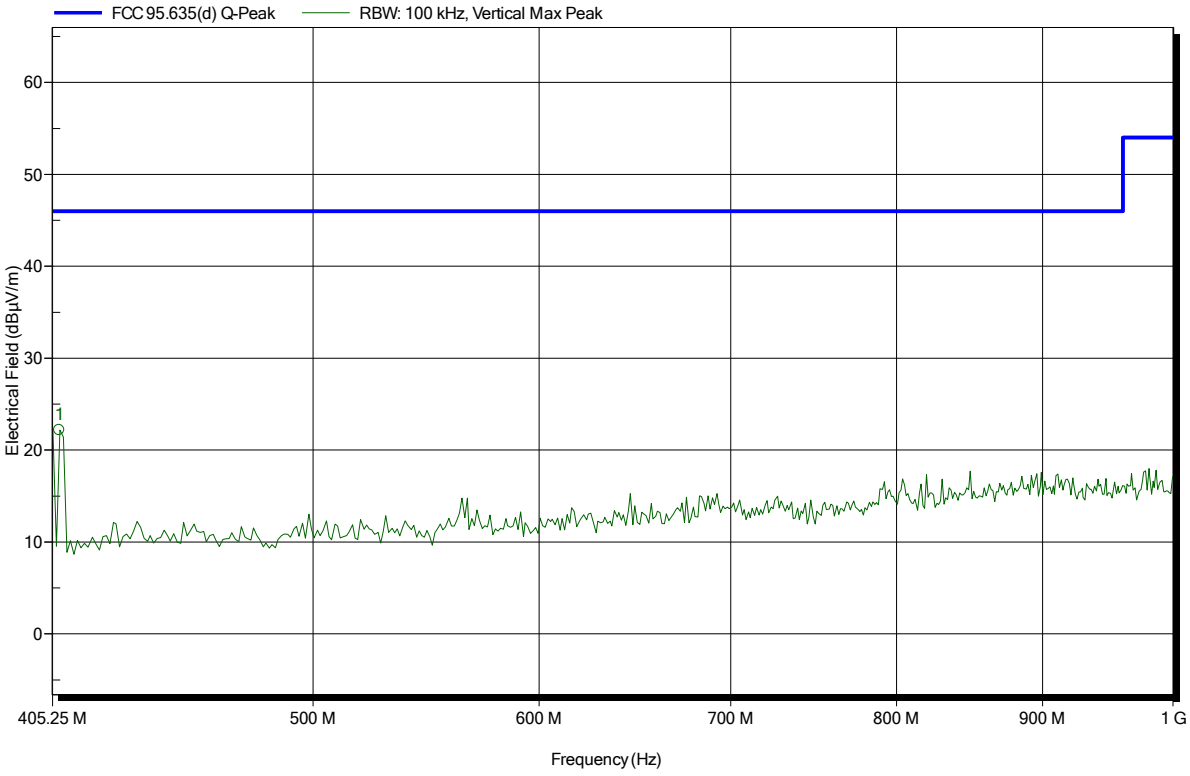

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
407.629 MHz	22.17 dBµV/m	46 dBµV/m	-23.83 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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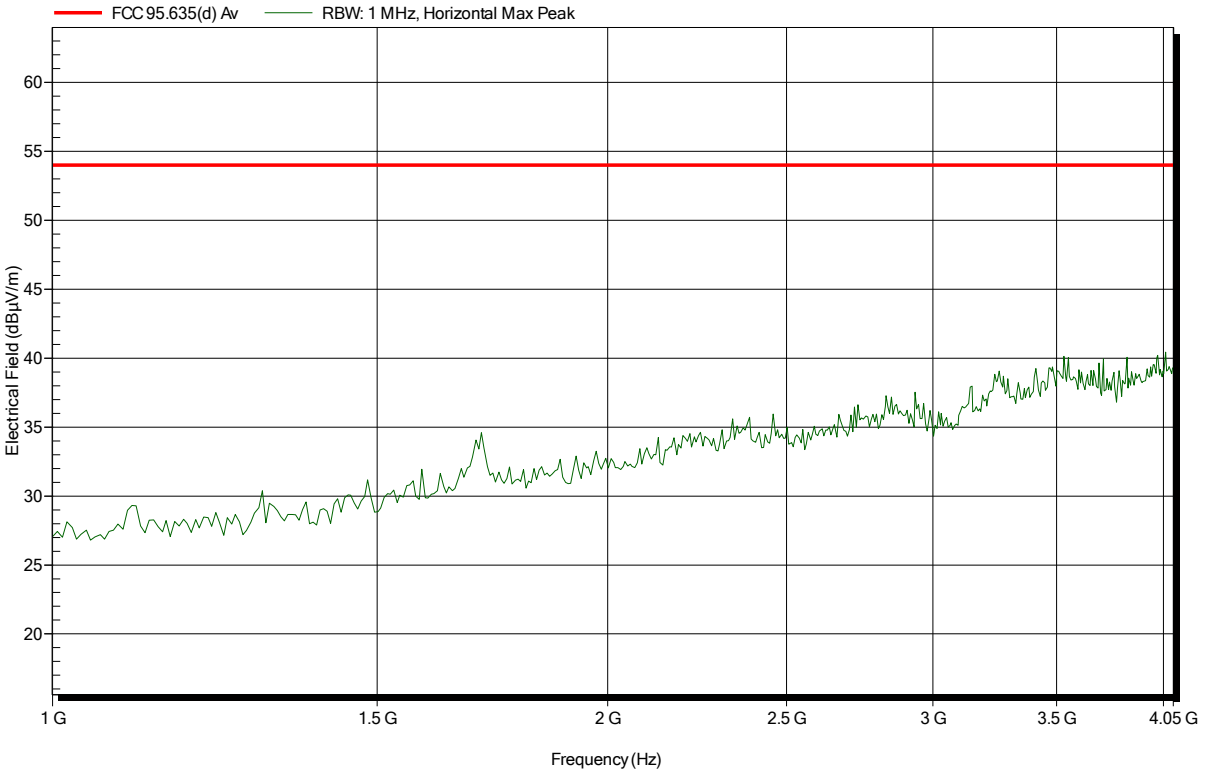

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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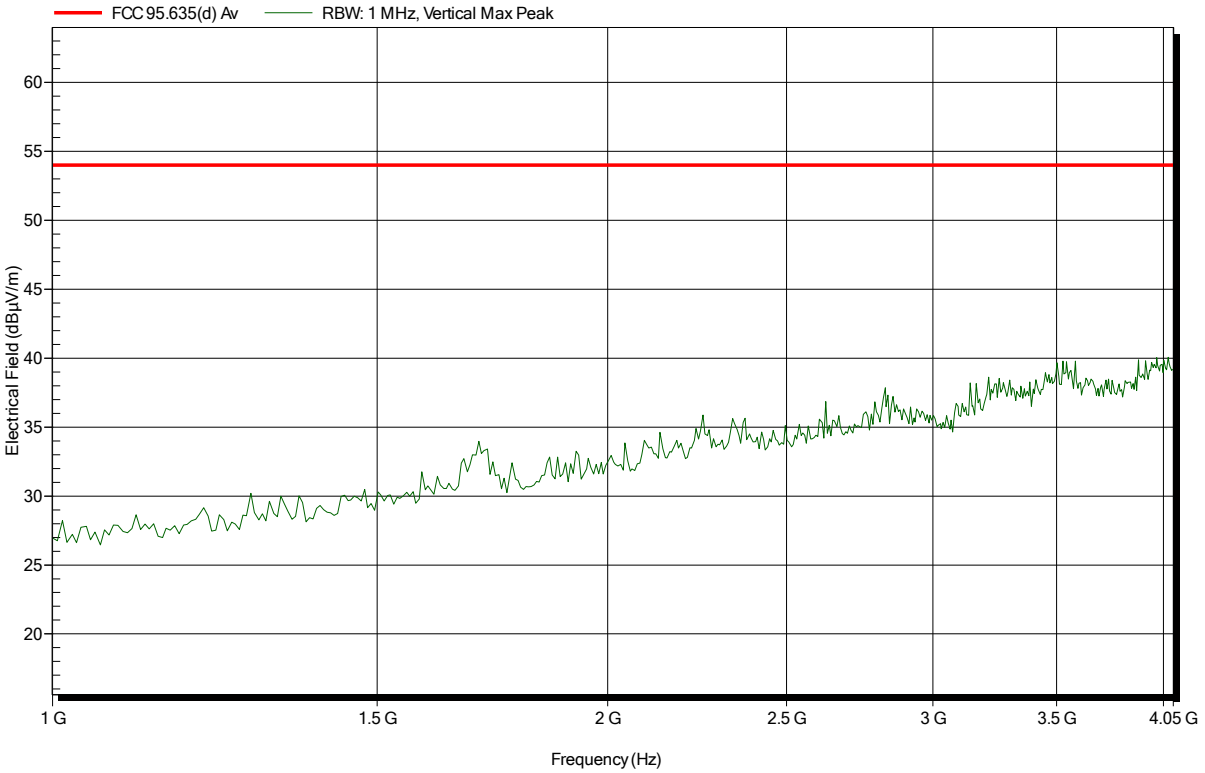

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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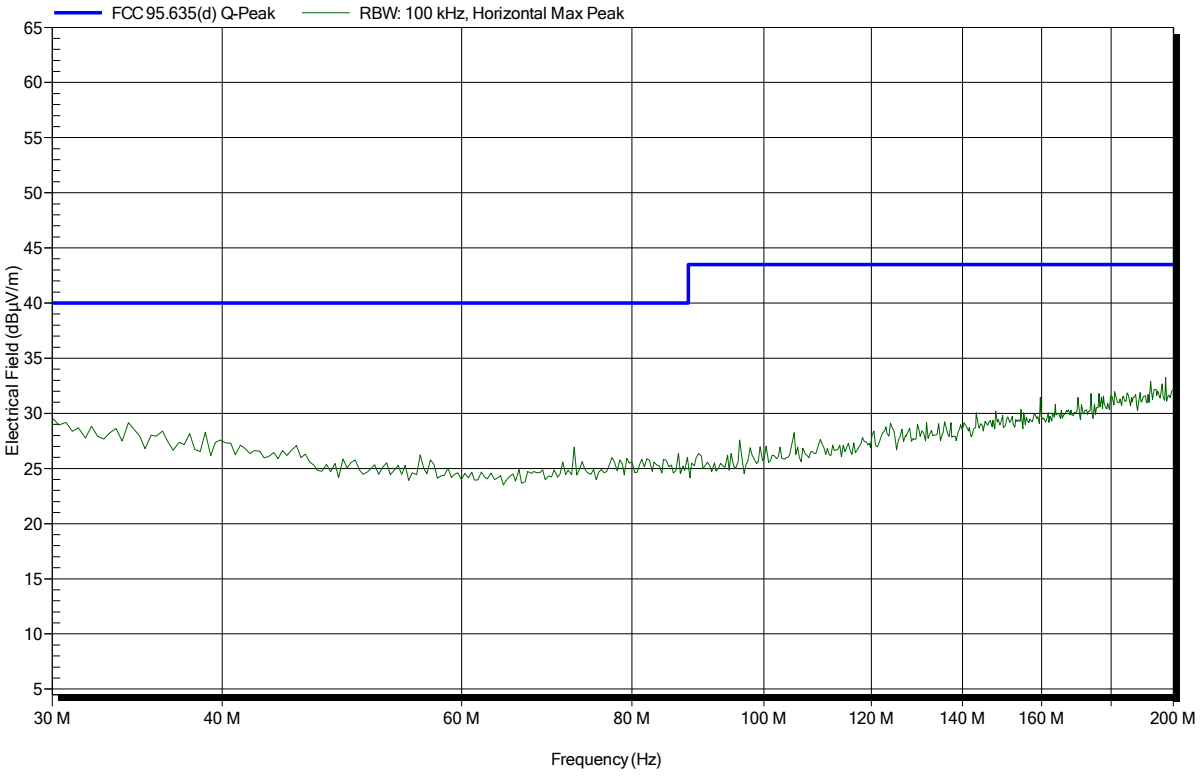

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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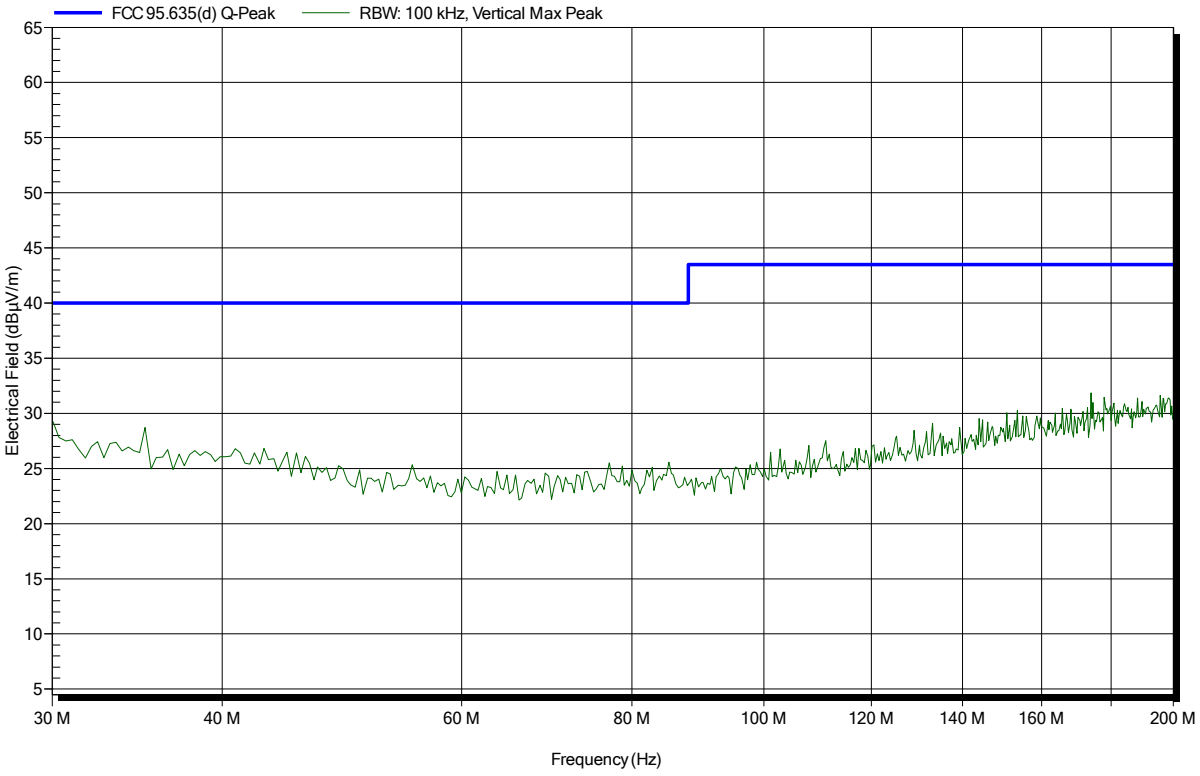

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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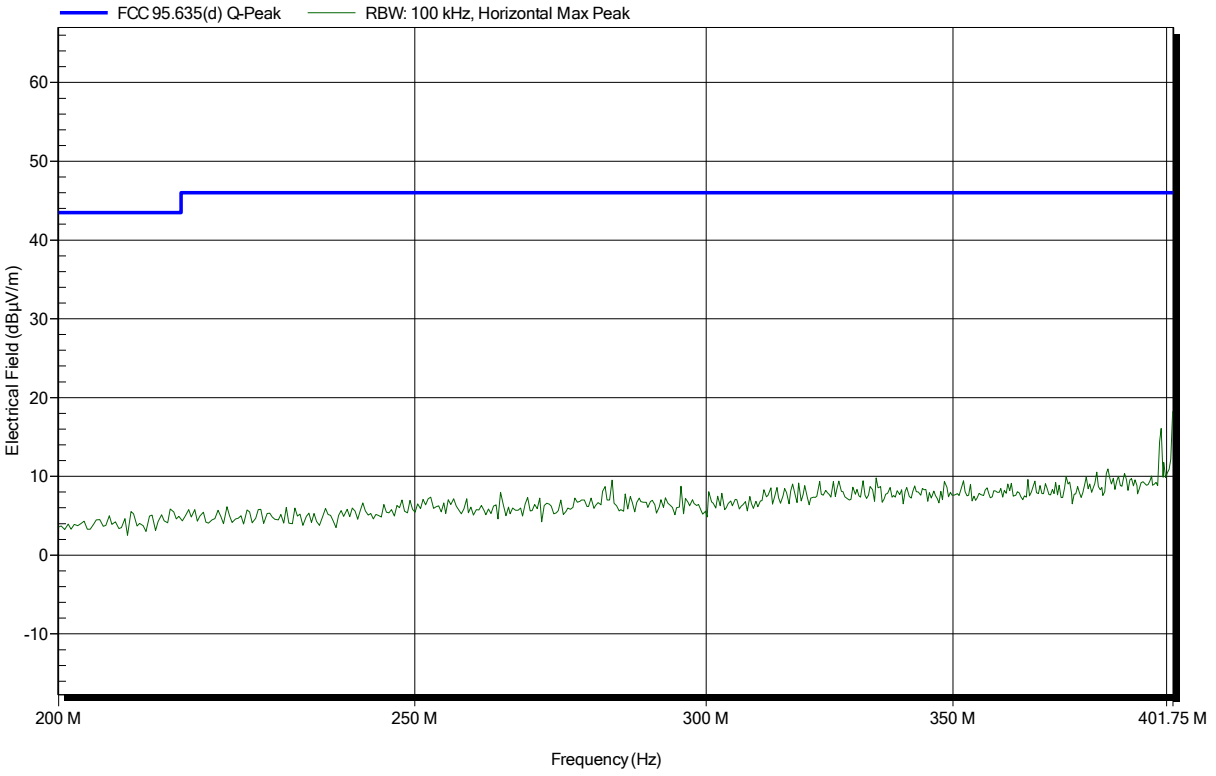

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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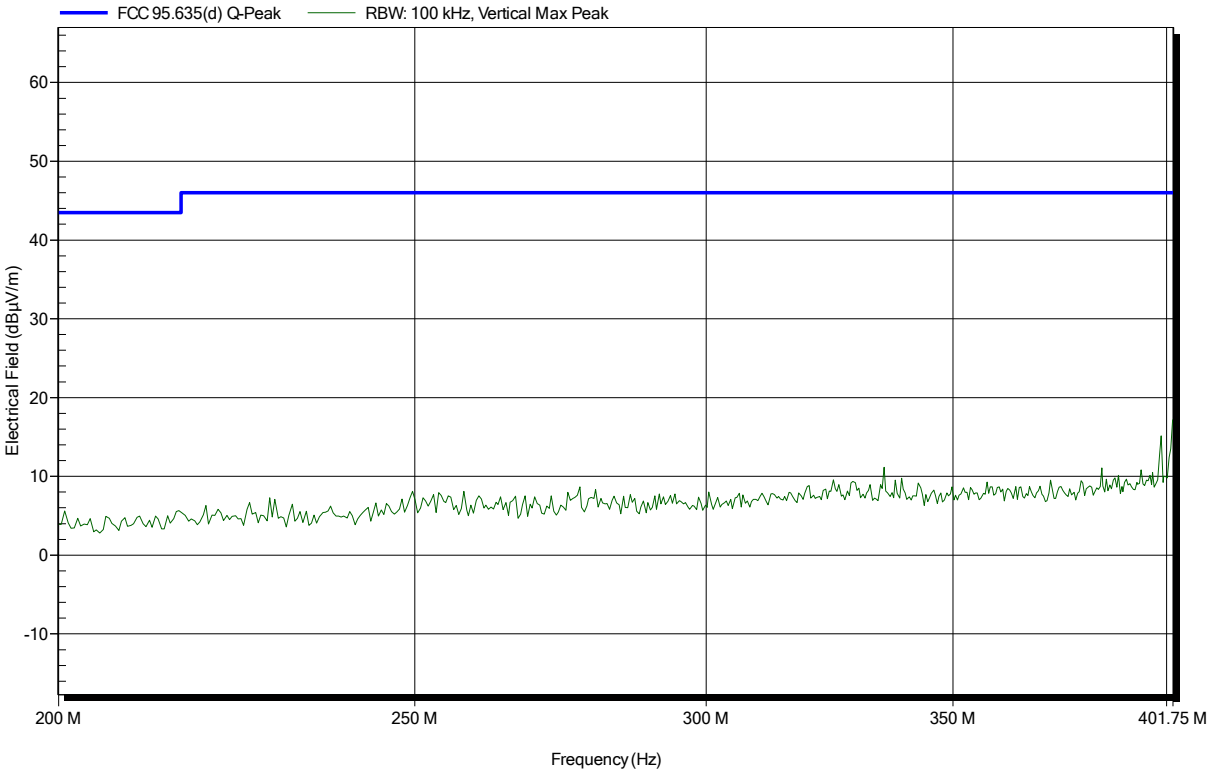

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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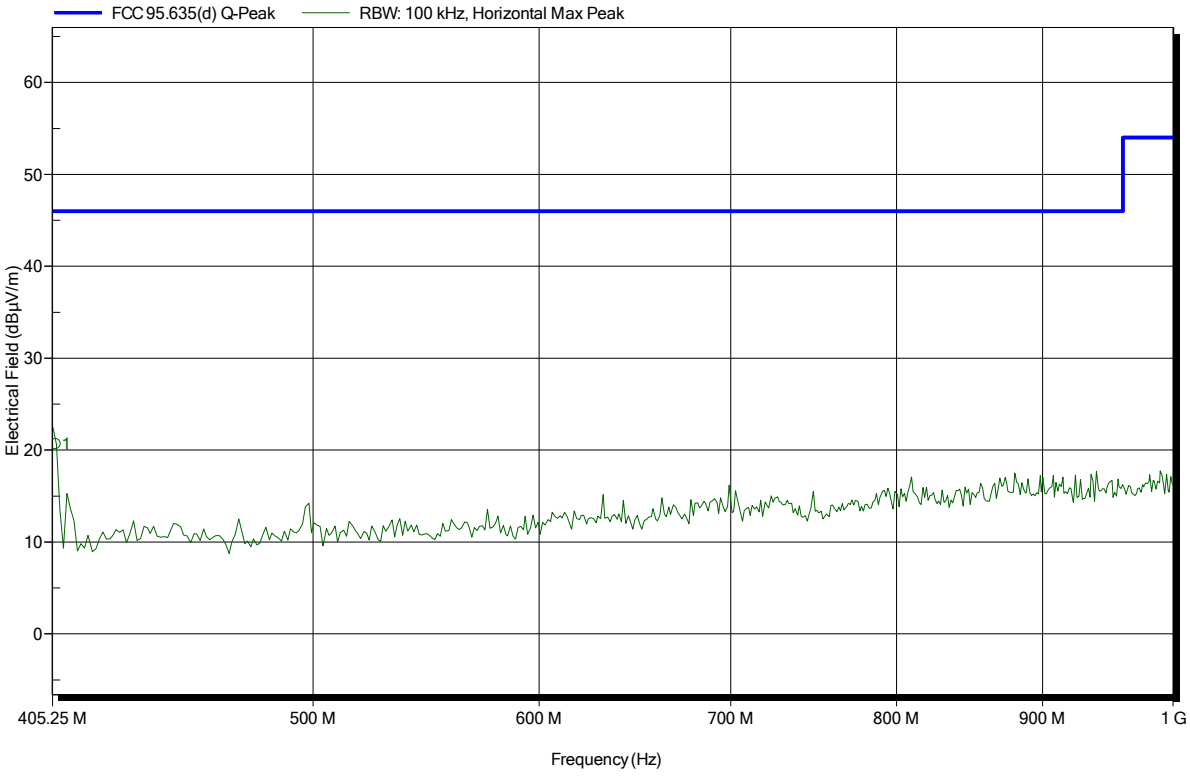

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	20.63 dBµV/m	46 dBµV/m	-25.37 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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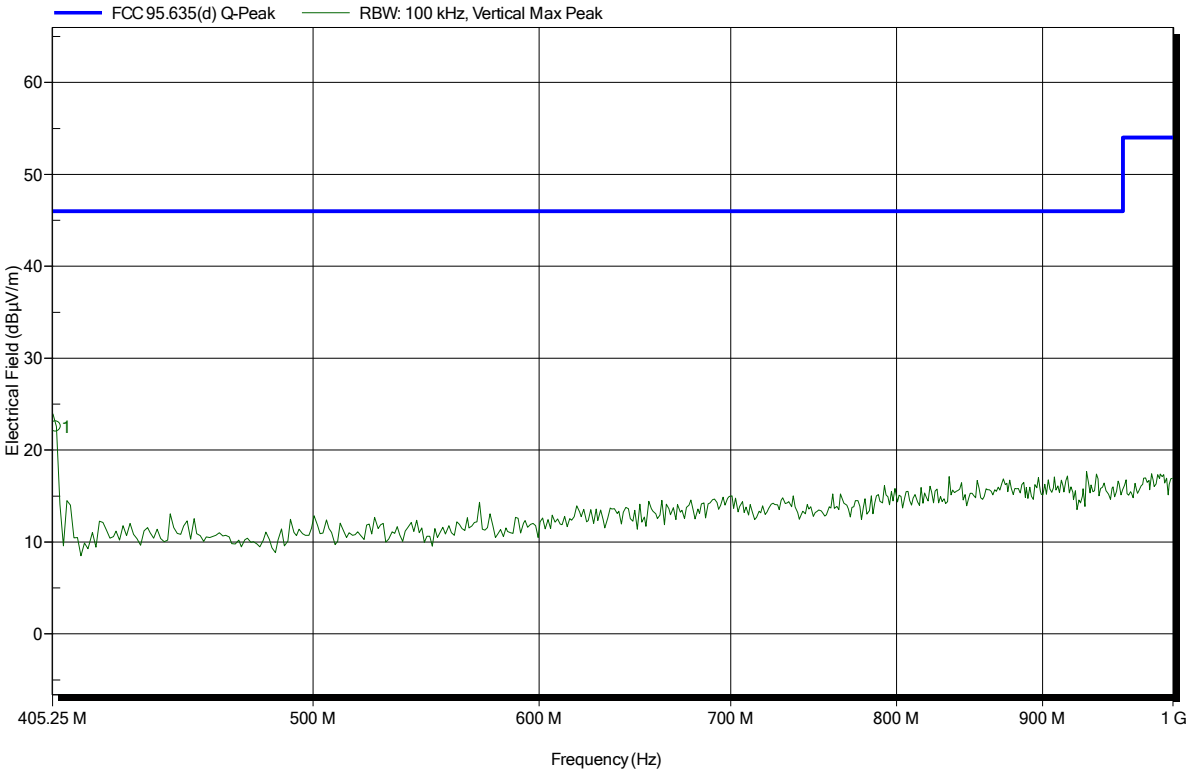

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	22.55 dBµV/m	46 dBµV/m	-23.45 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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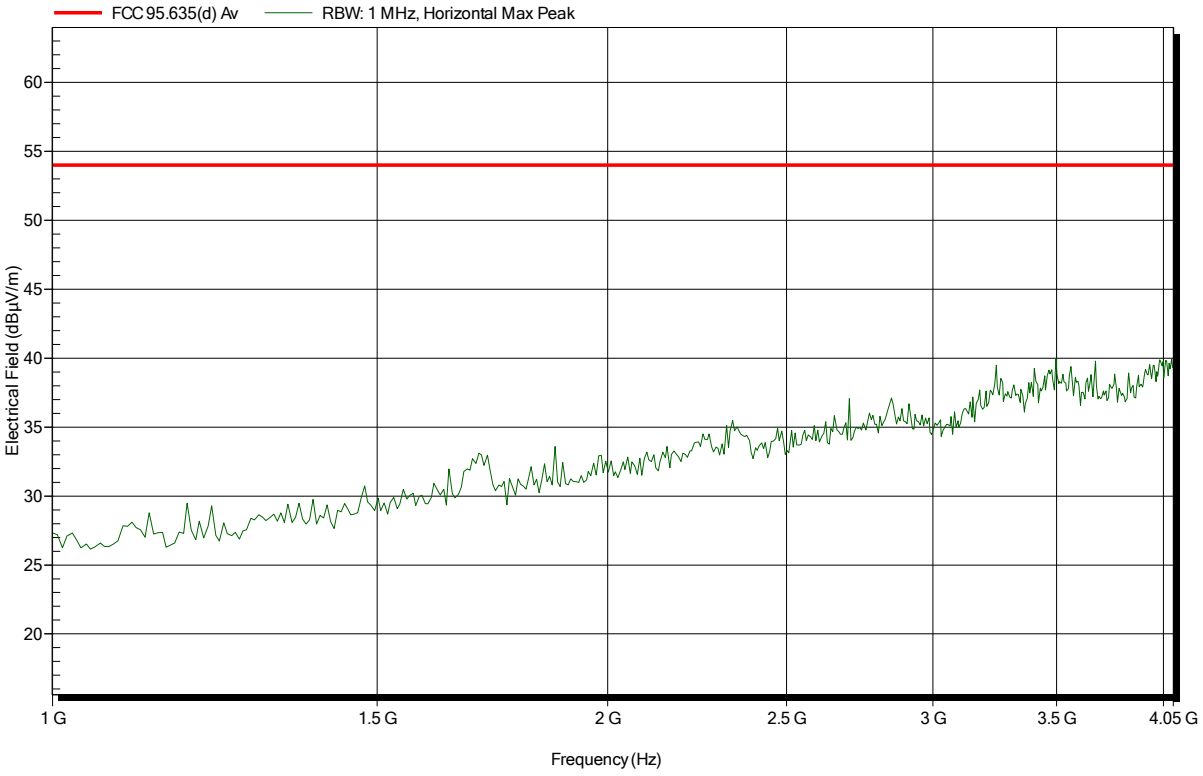

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	

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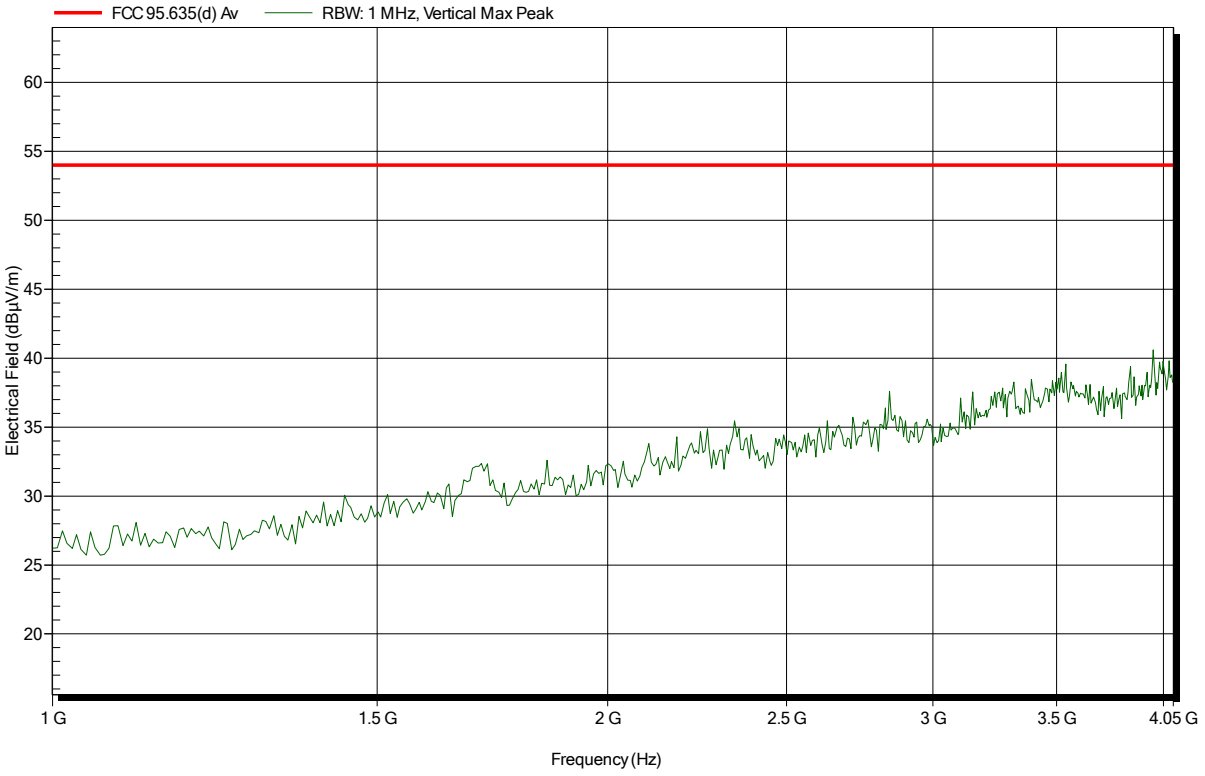

ANNEX C Transmitter in-band and band-edge

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	Band-edge

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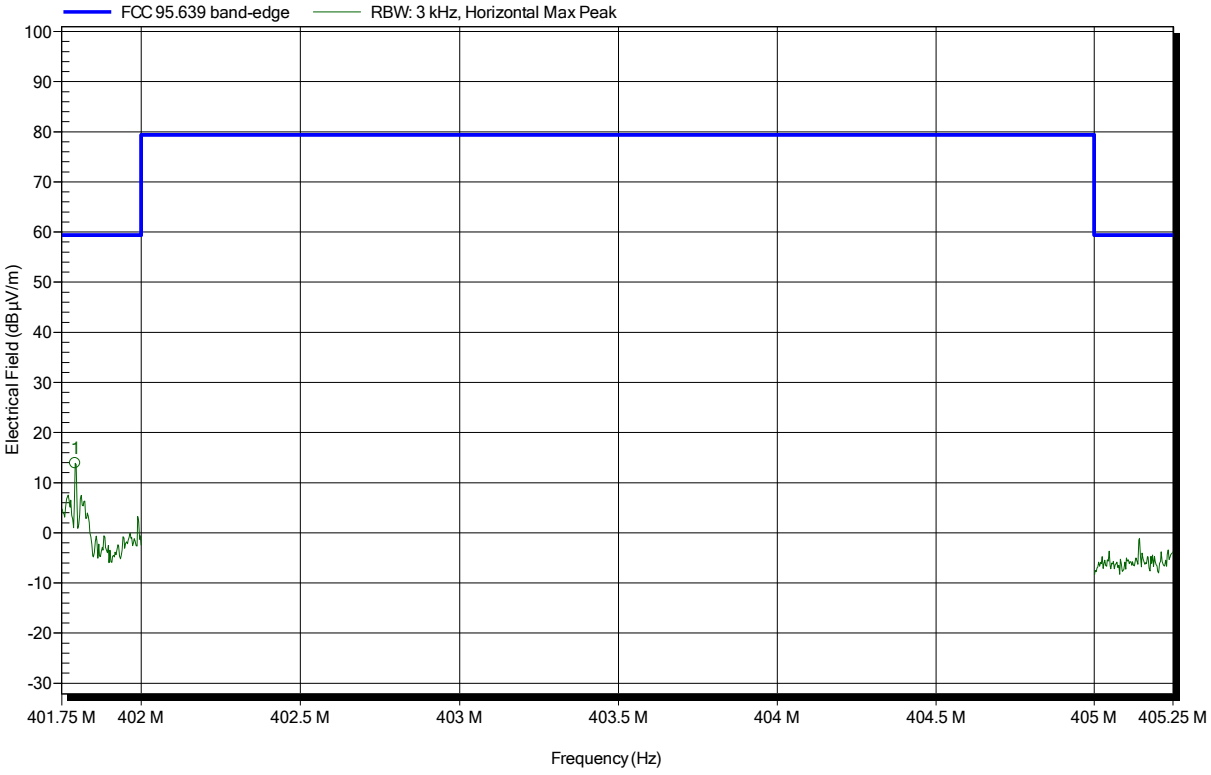

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.793 MHz	13.85 dBµV/m	59.4 dBµV/m	-45.55 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	Band-edge

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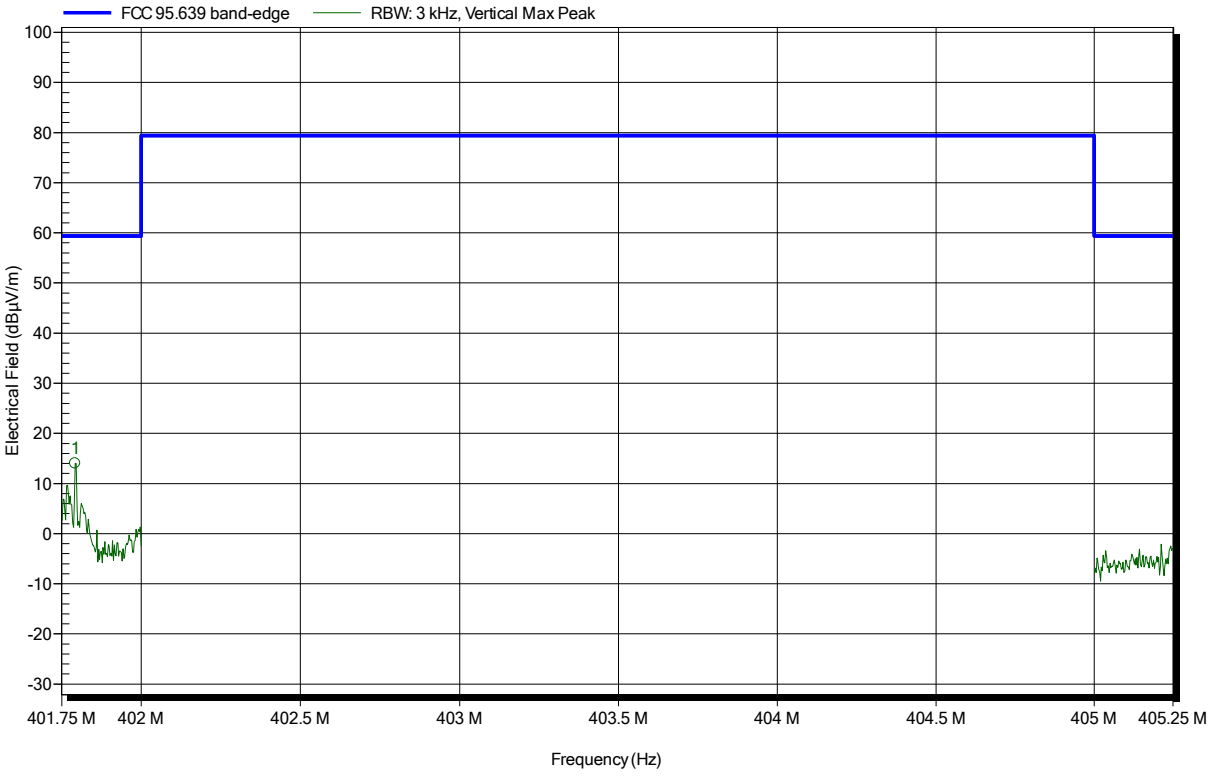

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.793 MHz	14.01 dBµV/m	59.4 dBµV/m	-45.39 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	Band-edge

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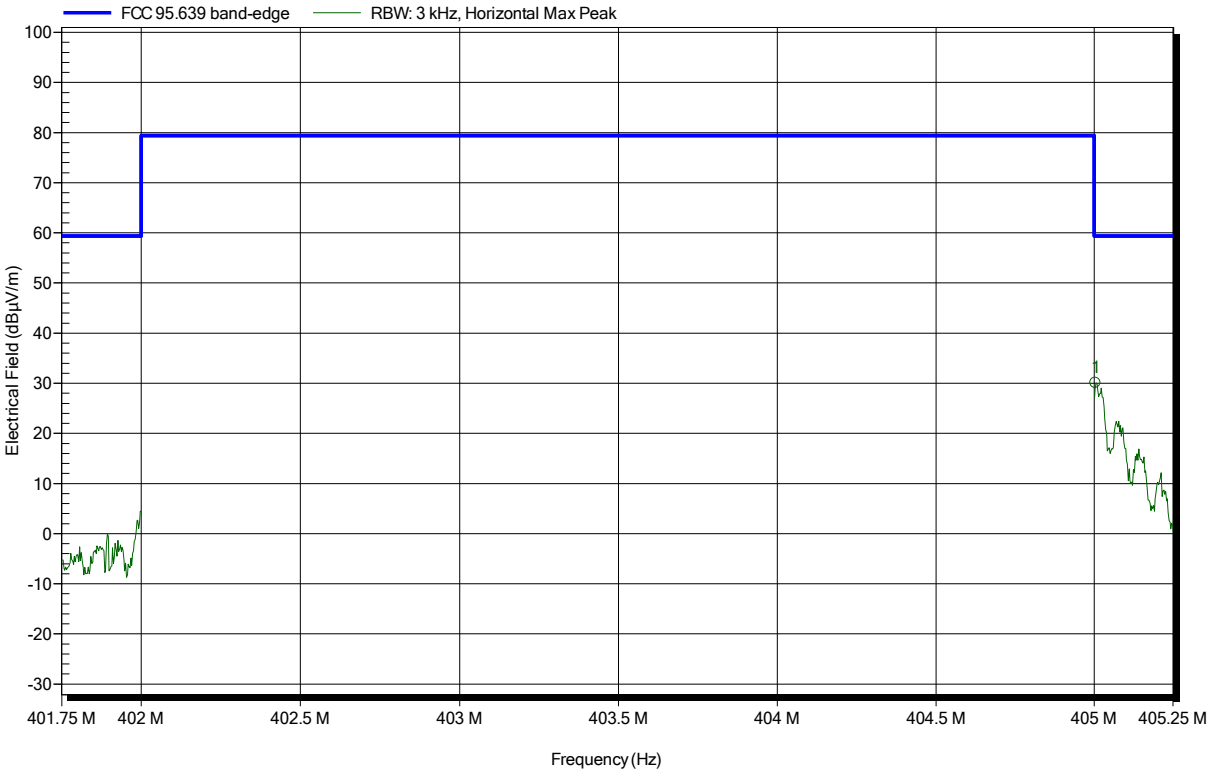

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.004 MHz	30.09 dBµV/m	59.4 dBµV/m	-29.31 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	Band-edge

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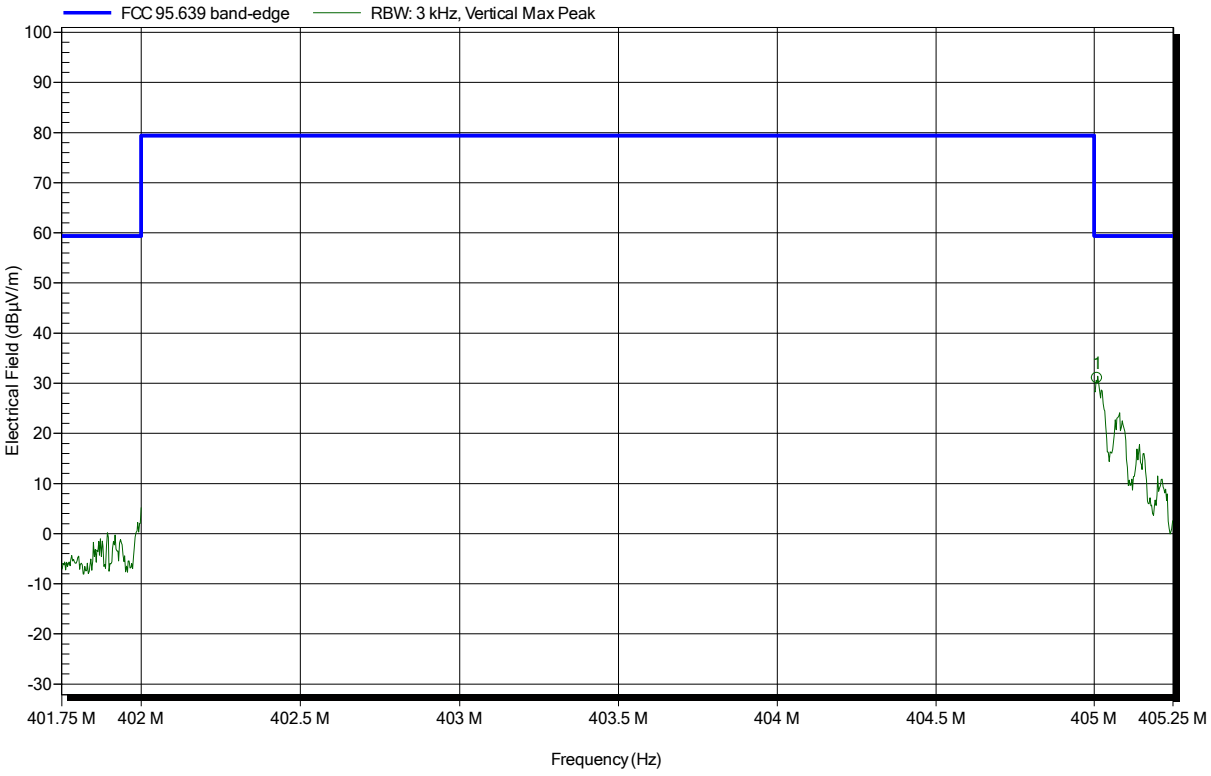

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.009 MHz	31.01 dBµV/m	59.4 dBµV/m	-28.39 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	In-band emissions

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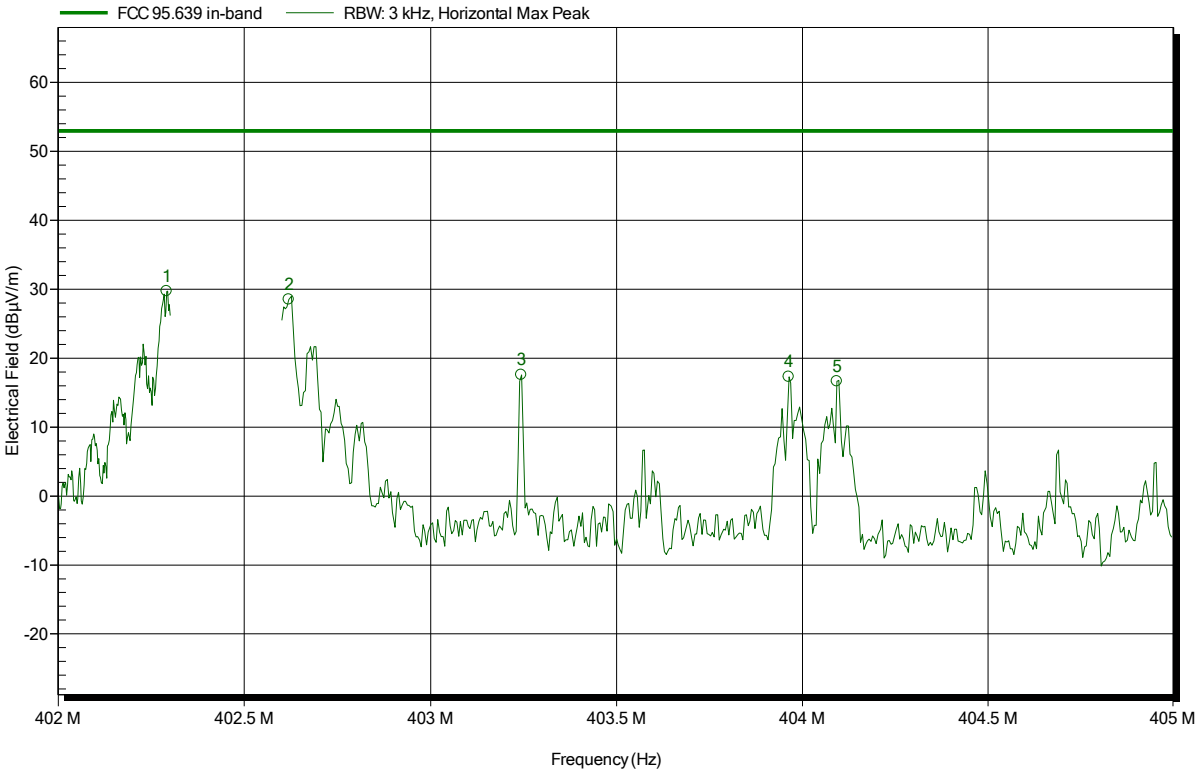

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.292 MHz	29.71 dBµV/m	53 dBµV/m	-23.29 dB	Pass
402.619 MHz	28.52 dBµV/m	53 dBµV/m	-24.48 dB	Pass
403.243 MHz	17.57 dBµV/m	53 dBµV/m	-35.43 dB	Pass
403.963 MHz	17.3 dBµV/m	53 dBµV/m	-35.7 dB	Pass
404.093 MHz	16.64 dBµV/m	53 dBµV/m	-36.36 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2016-11-22
Note:	In-band emissions

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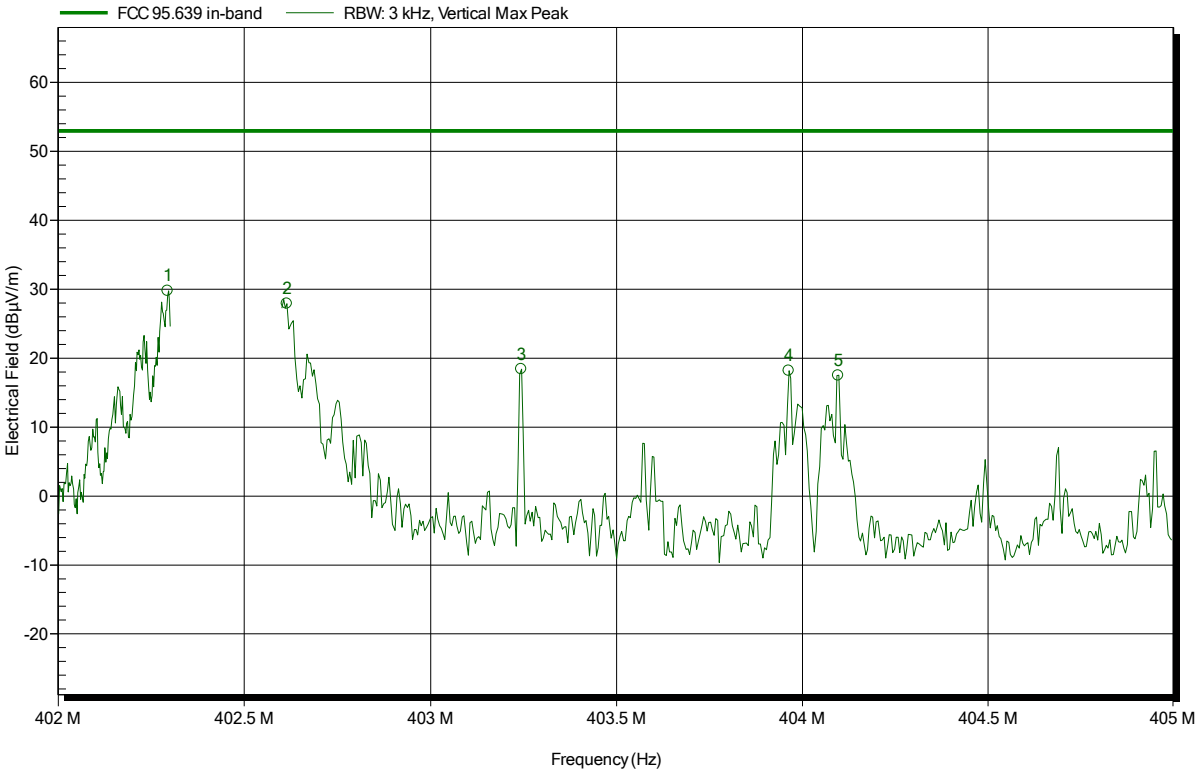

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.295 MHz	29.76 dBµV/m	53 dBµV/m	-23.24 dB	Pass
402.614 MHz	27.91 dBµV/m	53 dBµV/m	-25.09 dB	Pass
403.243 MHz	18.4 dBµV/m	53 dBµV/m	-34.6 dB	Pass
403.963 MHz	18.18 dBµV/m	53 dBµV/m	-34.82 dB	Pass
404.096 MHz	17.49 dBµV/m	53 dBµV/m	-35.51 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	In-band emissions

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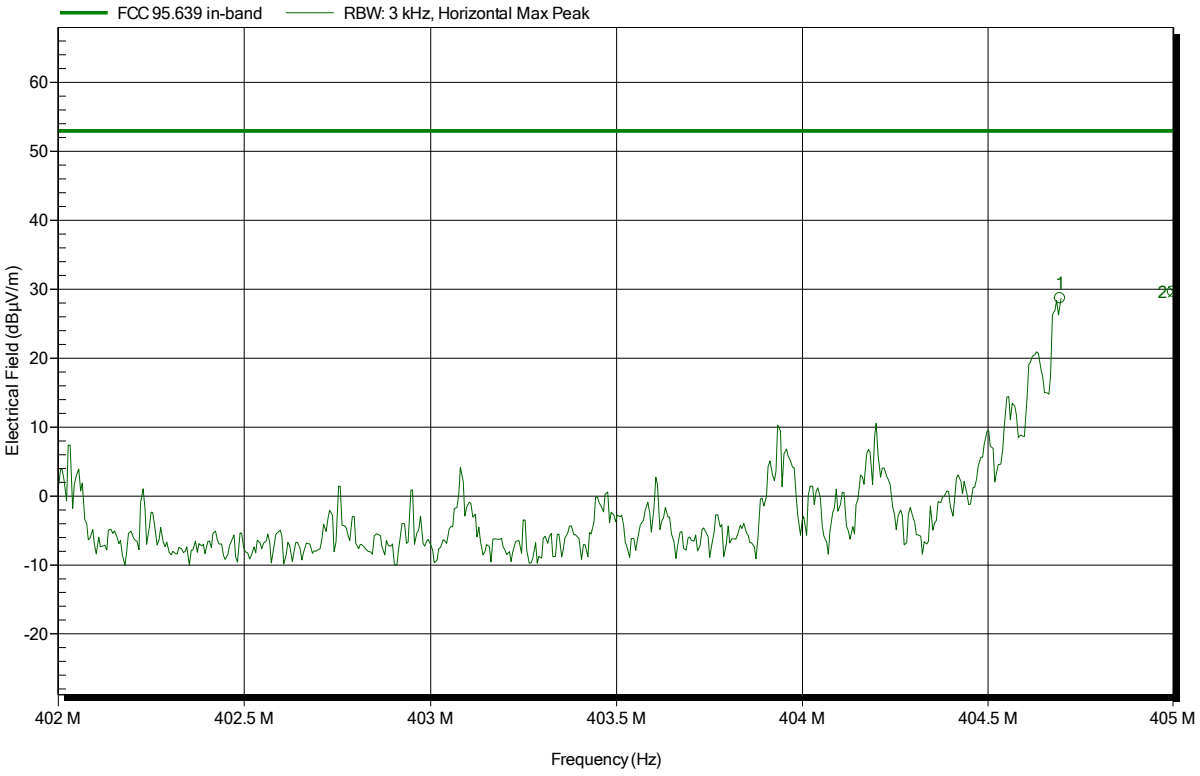

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.695 MHz	28.68 dBµV/m	53 dBµV/m	-24.32 dB	Pass
404.999 MHz	29.63 dBµV/m	53 dBµV/m	-23.37 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2016-11-22
Note:	In-band emissions

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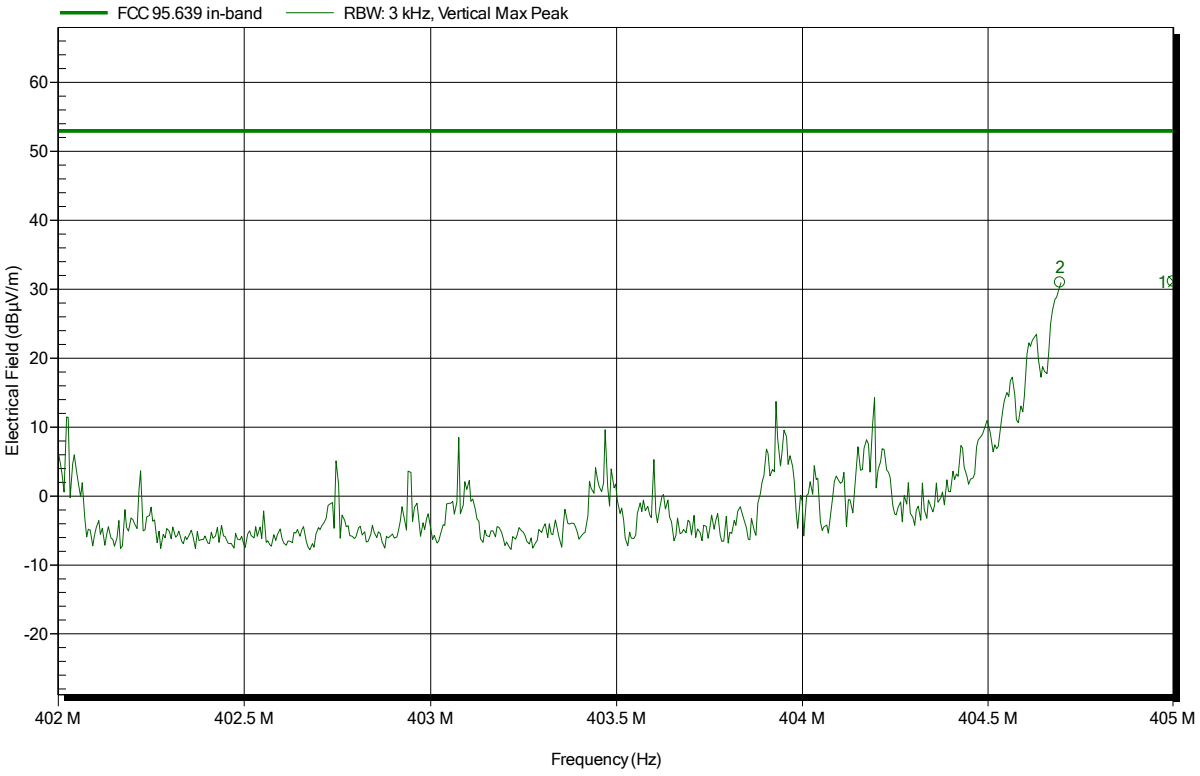

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.695 MHz	30.98 dBµV/m	53 dBµV/m	-22.02 dB	Pass
404.999 MHz	31.11 dBµV/m	53 dBµV/m	-21.89 dB	Pass

ANNEX D Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-11-22
Note:	

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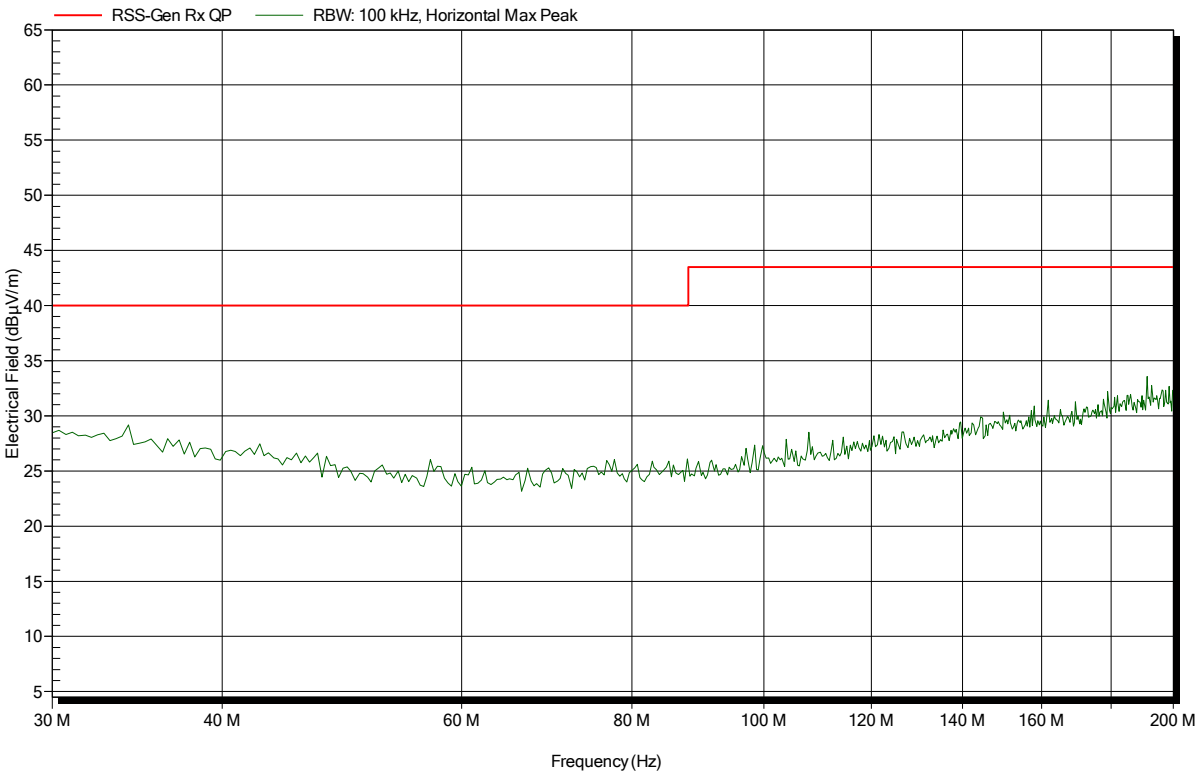

Spurious emissions according to RSS-Gen

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-11-22
Note:	

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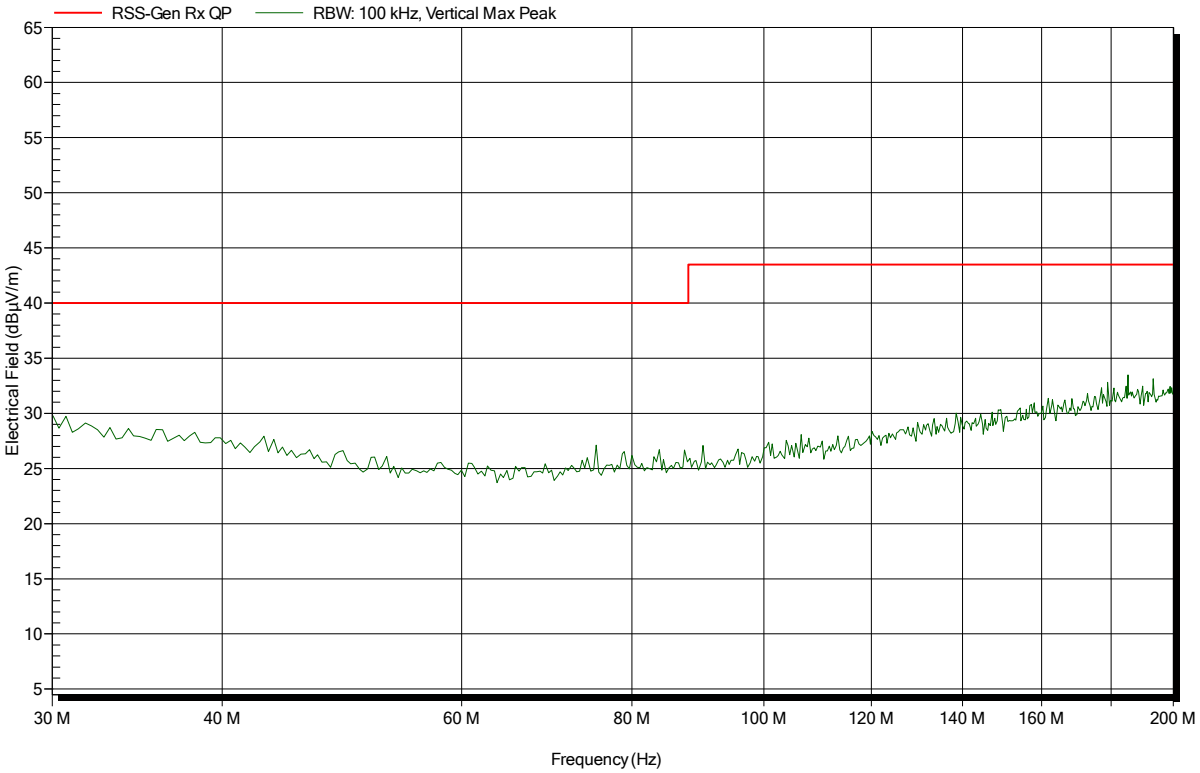

Spurious emissions according to RSS-Gen

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-11-22
Note:	

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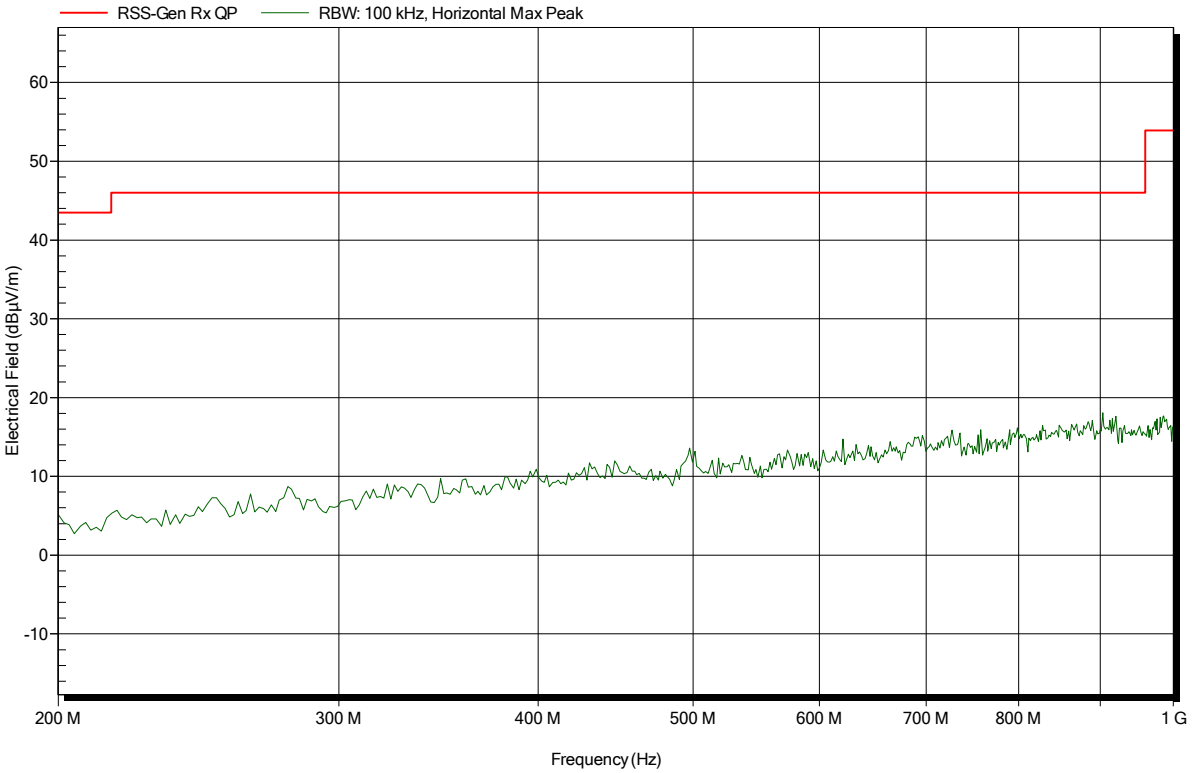

Spurious emissions according to RSS-Gen

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-11-22
Note:	

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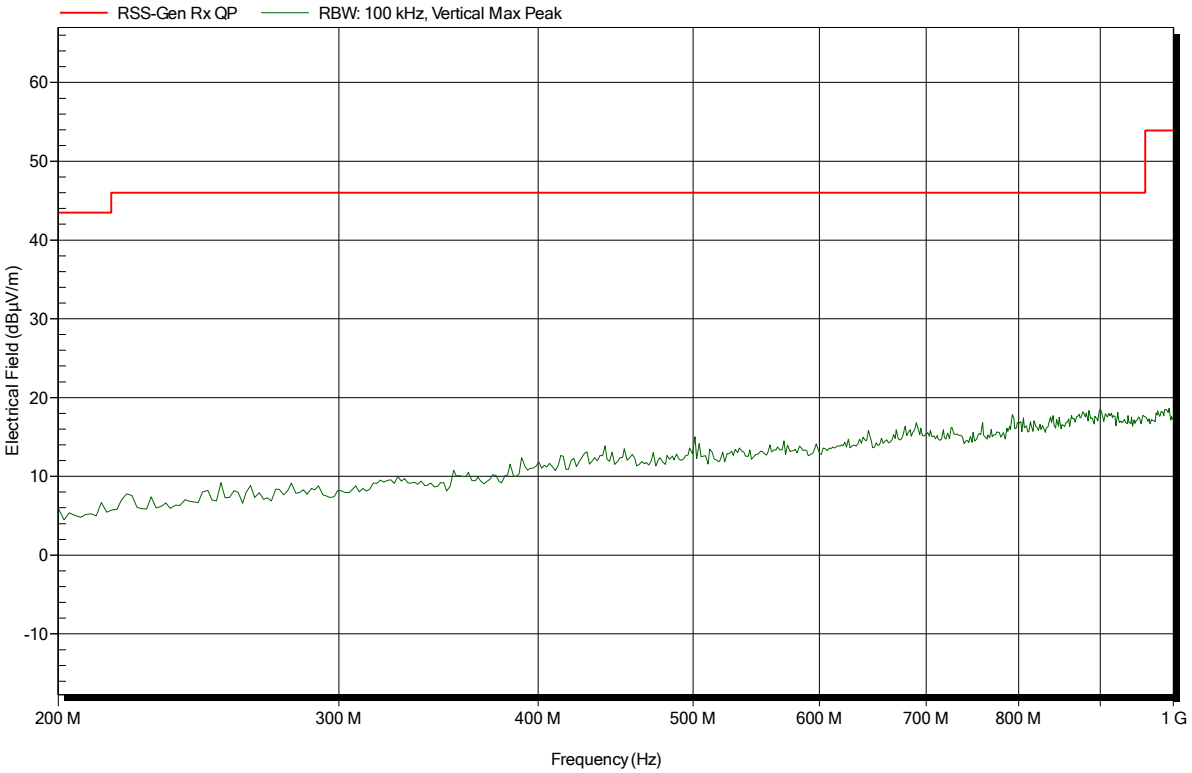

Spurious emissions according to RSS-Gen

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-11-22
Note:	

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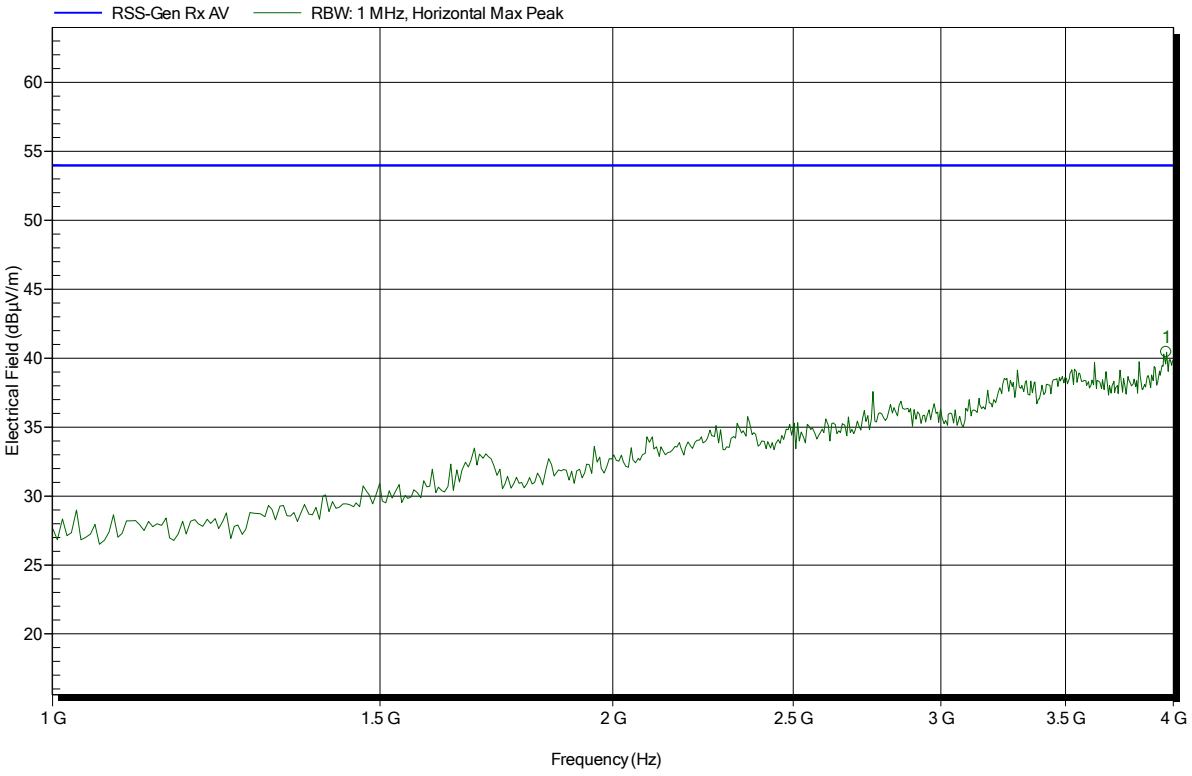

Frequency	Peak	Peak Limit	Peak Difference	Status
3.964 GHz	40.44 dBµV/m	53.98 dBµV/m	-13.54 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0D-1611-6014

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0V battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2016-11-22
Note:	

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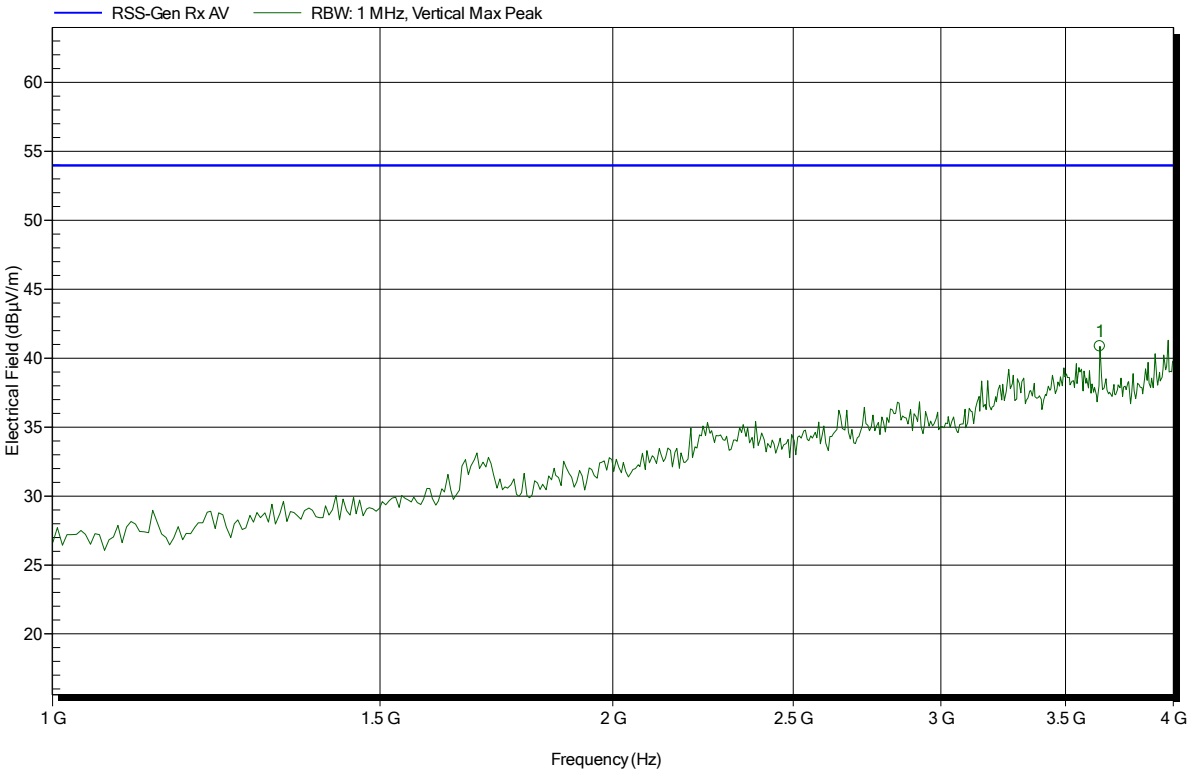

Frequency	Peak	Peak Limit	Peak Difference	Status
3.652 GHz	40.85 dBµV/m	53.98 dBµV/m	-13.13 dB	Pass