eurofins | Product Service

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-1509-5054-TFC95IMR-V02
Testing Laboratory ..... :	Eurofins Product Service GmbH
Address ..... :	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation ..... :	A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Filed Test Laboratory, Reg.-No.: 96970 IC OATS Filing assigned code: 3470A
Applicant's name ..... :	Biotronik SE & Co. KG
Address ..... :	Woermannkehre 1 12359 Berlin GERMANY
Test specification:	
Standard..... :	47 CFR Part 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
Equipment under test (EUT):	
Product description	ICD / Implantable Cardioverter Defibrillator
Model No.	TachNT2
Additional Model(s)	Additional Models according to Family Letter
Brand Name(s)	BIOTRONIK
Hardware version	Rev.: 0A
Firmware / Software version	ROM: 5.0 / RAM: 4.0
	FCC-ID: QRITACHNT2 IC: 4708A-TACHNT2
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 ..... :	2015-11-02	
Date (s) of performance of tests ..... :	2015-11-02 – 2015-11-06	
Compiled by ..... :	Wilfried Treffke	
Tested by (+ signature) ..... : (Responsible for Test)	Wilfried Treffke	W. Treff
Approved by (+ signature) ..... : (Head of Lab)	Christian Weber	C. Weber
Date of issue ..... :	2015-11-26	
Total number of pages ..... :	97	

General remarks:

The test results presented in this report relate only to the object tested.

The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

Additional comments:

All devices feature the two RF-Telemetry functions Home Monitoring and wireless Wand.
RF-Telemetry functions are using the MICS-Band (402MHz – 405MHz).
A „-T“ inside the name of the device represents a device containing RF-Telemetry.
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.60829779 was selected. Besides the model Intica 7 HF-T QP Ser.60829779, as the most complex model, was selected for the measurements.

BIOTRONIK
excellence for life

TachNT2 Family Explanation (G0M-1509-5054)

1. Family Letter

	Product Name	Type	no. of chambers	Connector	max.stored energy	SN
1	Ilivia 7 HF-T	CRT	3	DF-1	40J	60829935
2	Ilivia 7 HF-T	CRT	3	DF-4	40J	60829836
3	Ilivia 7 HF-T QP	CRT	3	DF-1 + IS-4	40J	
4	Ilivia 7 HF-T QP	CRT	3	DF-4 + IS-4	40J	
5	Ilivia 7 DR-T	DR	2	DF-1	40J	60829801
6	Ilivia 7 DR-T	DR	2	DF-4	40J	60829791
7	Ilivia 7 VR-T DX	DX*	1	DF-1	40J	60829804
8	Ilivia 7 VR-T	VR	1	DF-1	40J	60829925
9	Ilivia 7 VR-T	VR	1	DF-4	40J	60829828
10	Intica 7 HF-T	CRT	3	DF-1	40J	
11	Intica 7 HF-T	CRT	3	DF-4	40J	
12	Intica 7 HF-T QP	CRT	3	DF-1 + IS-4	40J	60829771
13	Intica 7 HF-T QP	CRT	3	DF-4 + IS-4	40J	60829779
14	Intica 7 DR-T	DR	2	DF-1	40J	
15	Intica 7 DR-T	DR	2	DF-4	40J	
16	Intica 7 VR-T DX	DX*	1	DF-1	40J	
17	Intica 7 VR-T	VR	1	DF-1	40J	
18	Intica 7 VR-T	VR	1	DF-4	40J	
19	Inlexa 7 HF-T	CRT	3	DF-1	40J	
20	Inlexa 7 HF-T	CRT	3	DF-4	40J	
21	Inlexa 7 HF-T QP	CRT	3	DF-1 + IS-4	40J	
22	Inlexa 7 HF-T QP	CRT	3	DF-4 + IS-4	40J	
23	Inlexa 7 DR-T	DR	2	DF-1	40J	
24	Inlexa 7 DR-T	DR	2	DF-4	40J	
25	Inlexa 7 VR-T DX	DX*	1	DF-1	40J	
26	Inlexa 7 VR-T	VR	1	DF-1	40J	
27	Inlexa 7 VR-T	VR	1	DF-4	40J	
28	Intica 5 HF-T	CRT	3	DF-1	40J	
29	Intica 5 HF-T	CRT	3	DF-4	40J	
30	Intica 5 HF-T QP	CRT	3	DF-1 + IS-4	40J	
31	Intica 5 HF-T QP	CRT	3	DF-4 + IS-4	40J	
32	Intica 5 DR-T	DR	2	DF-1	40J	
33	Intica 5 DR-T	DR	2	DF-4	40J	
34	Intica 5 VR-T DX	DX*	1	DF-1	40J	
35	Intica 5 VR-T	VR	1	DF-1	40J	
36	Intica 5 VR-T	VR	1	DF-4	40J	
37	Inlexa 3 HF-T	CRT	3	DF-1	40J	
38	Inlexa 3 HF-T	CRT	3	DF-4	40J	
39	Inlexa 3 HF-T QP	CRT	3	DF-1 + IS-4	40J	
40	Inlexa 3 HF-T QP	CRT	3	DF-4 + IS-4	40J	
41	Inlexa 3 DR-T	DR	2	DF-1	40J	
42	Inlexa 3 DR-T	DR	2	DF-4	40J	
43	Inlexa 3 VR-T	VR	1	DF-1	40J	
44	Inlexa 3 VR-T	VR	1	DF-4	40J	

*: additional atrial detection (therapy function)

All rights pertaining to this document are exclusively held by BIOTRONIK SE & Co. KG.
Any non-authorized copying, reproduction or distribution is not permitted.
Confidentiality: This document and/or its contents are only for internal use.

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

BIOTRONIK
excellence for life

2. Family description

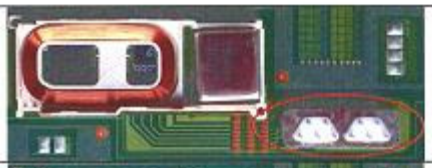
Header difference overview

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

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	

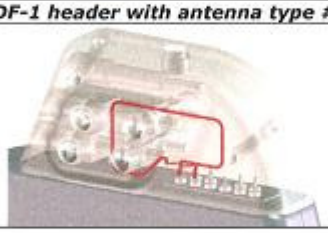
All rights pertaining to this document are exclusively held by BIOTRONIK SE & Co. KG.
Any non-authorized copying, reproduction or distribution is not permitted.
Confidentiality: This document and/or its contents are only for internal use.

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

BIOTRONIK
excellence for life

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 DF-4 header based devices are using also the same antenna, but type #2.

DF-1 header with antenna type #1	DF-4 header with antenna type #2
	

Signature: **Date:** 11/10/2015

Mark Briesemeister
Manager Regulatory Affairs
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin
Germany

All rights pertaining to this document are exclusively held by BIOTRONIK SE & Co. KG.
Any non-authorized copying, reproduction or distribution is not permitted.
Confidentiality: This document and/or its contents are only for internal use.

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

Version History

Version	Issue Date	Remarks	Revised by
01	2015-11-17	Initial Release	
02	2015-11-26	The Brand Name was corrected.	C. Weber

REPORT INDEX

1	**EQUIPMENT (TEST ITEM) DESCRIPTION**	**9**
1.1	Photos - Equipment external	11
1.2	Photos - Equipment internal	21
1.3	Photos – Test setup	26
1.4	Photos – Auxiliary/Associated Equipment	27
1.6	Supporting Equipment Used During Testing	28
1.7	Test Modes	29
1.8	Test Equipment Used During Testing	30
1.9	Sample emission level calculation	31
1.10	Simulated human body	32
2	**RESULT SUMMARY**	**33**
3	**TEST CONDITIONS AND RESULTS**	**34**
3.1	Test Conditions and Results – Occupied Bandwidth	34
3.2	Test Conditions and Results – Emission Bandwidth	41
3.3	Test Conditions and Results – Frequency stability	48
3.4	Test Conditions and Results – Transmitter output power	50
3.5	Test Conditions and Results – Band-edge and In-band Emissions	52
3.6	Test Conditions and Results – Transmitter unwanted emissions	54
3.7	Test Conditions and Results – Receiver spurious emissions	56
ANNEX A	Transmitter radiated power	58
ANNEX B	Transmitter radiated spurious emissions	68
ANNEX C	Receiver radiated spurious emissions	92

1 Equipment (Test item) Description

Description	ICD / Implantable Cardioverter Defibrillator	
Model	TachNT2	
Additional Model(s)	Additional Models according to Family Letter	
Brand Name(s)	BIOTRONIK	
Serial number	None	
Hardware version	Rev.: 0A	
Software / Firmware version	ROM: 5.0 / RAM: 4.0	
FCC-ID	QRITACHNT2	
IC	4708A-TACHNT2	
Equipment type	End product	
Radio type	Transceiver	
Number of Radios	1	
Radio technology	MedRadio (MICS) active medical implant	
Operating frequency range	402.45 - 404.85 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	-28.15 dBi (Determined by measurements)
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

1.6 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Engineering communication box	BIOTRONIK	USB Telex	for test mode

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

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.7 Test Modes

Mode #	Description	
Unmodulated	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated 1	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = 2FSK Data rate = 32 kBit Duty cycle = 100 % Power level = Maximum
Modulated 2	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = 2FSK Data rate = 82 kBit Duty cycle = 100 % Power level = Maximum
Receive	General conditions:	EUT powered on
	Radio conditions:	Mode = standalone receive Modulation = FSK

1.8 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
Anechoic chamber	Frankonia GmbH	AC 2	EF00196	-	-
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
Anechoic chamber	Frankonia GmbH	AC 2	EF00196	-	-
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	2015-10	2018-10

1.9 Sample emission level calculation

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

Reading:

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

A.F.:

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

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

1.10 Simulated human body

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

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

Measured tissue parameters:

Tissue parameters – 403.5MHz			
Component	Target	Measured	Tolerance [%]
Dielectric constant ε	62.5	63.08	0.93
Conductivity σ [ms/cm]	9.0	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

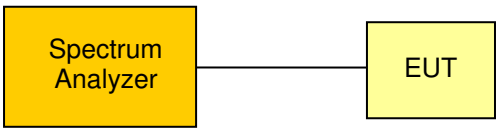
3.1 Test Conditions and Results – Occupied Bandwidth

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 1 / 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}	32	402.45	229.3	≤ 300	PASS
F_{MID}	32	403.65	229.3	≤ 300	PASS
F_{HIGH}	32	404.85	227.9	≤ 300	PASS
F_{LOW}	82	402.45	168.8	≤ 300	PASS
F_{MID}	82	403.65	168.8	≤ 300	PASS
F_{HIGH}	82	404.85	168.8	≤ 300	PASS

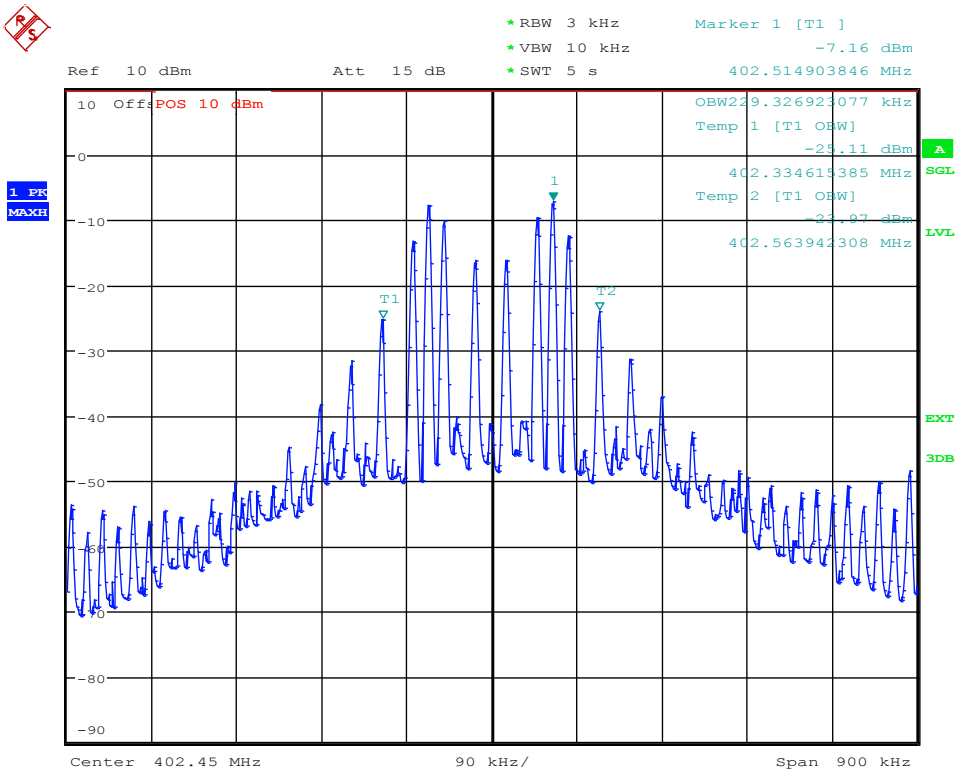
Comments:

Occupied Bandwidth – F_{LOW} (32kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 32 kBit/s
Test Date:	2015-11-05
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



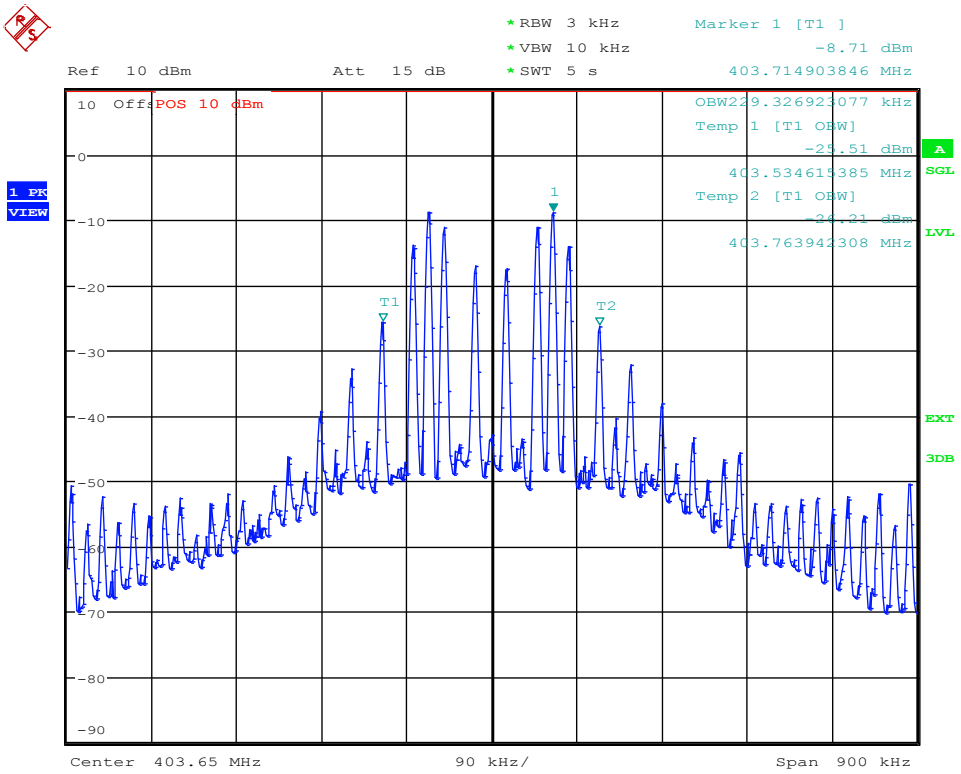
Date: 5.NOV.2015 13:35:13

Occupied Bandwidth - F_{MID} (32kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 32 kBit/s
Test Date:	2015-11-05
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



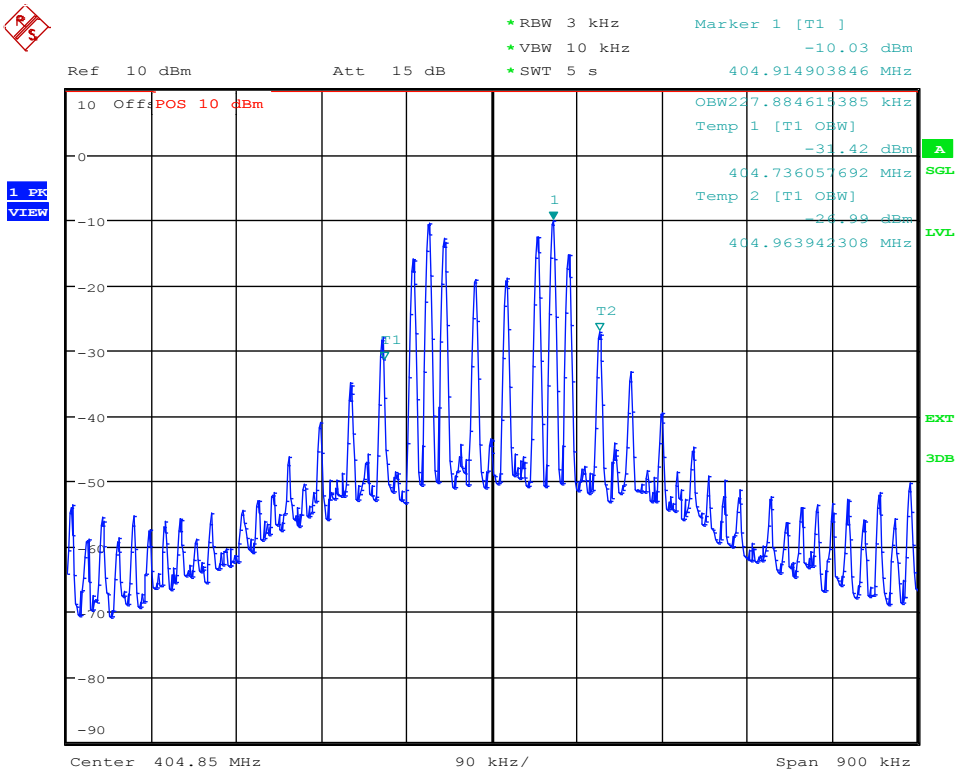
Date: 5.NOV.2015 13:27:17

Occupied Bandwidth – F_{HIGH} (32kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 32 kBit/s
Test Date:	2015-11-05
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



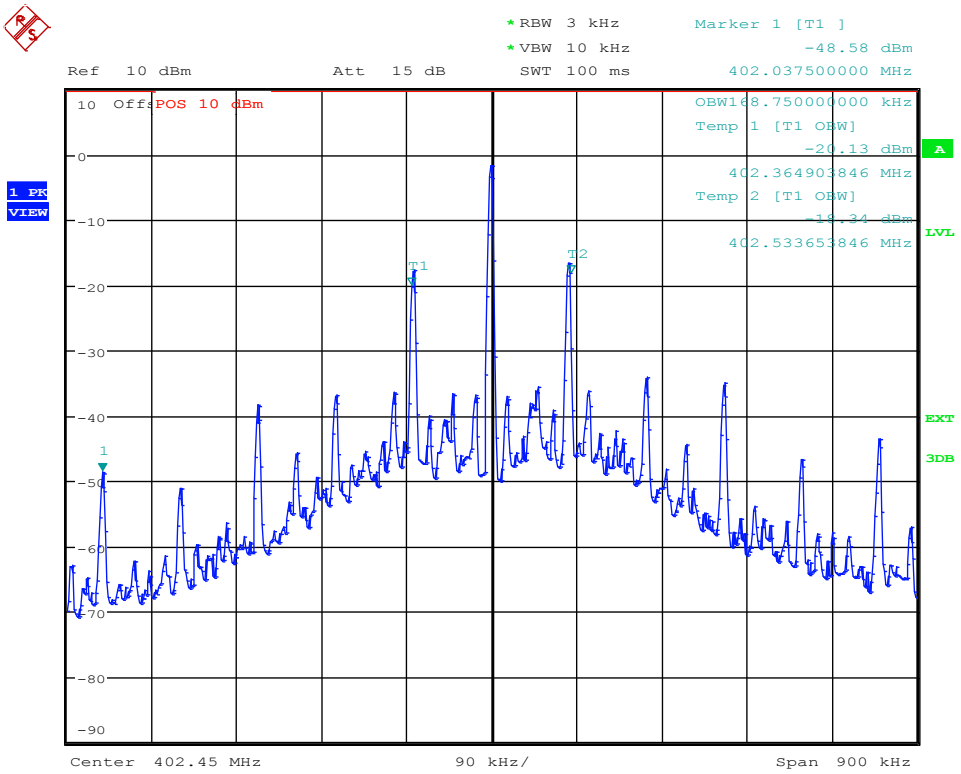
Date: 5.NOV.2015 13:38:01

Occupied Bandwidth – F_{LOW} (82kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 82 kBit/s
Test Date:	2015-11-06
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



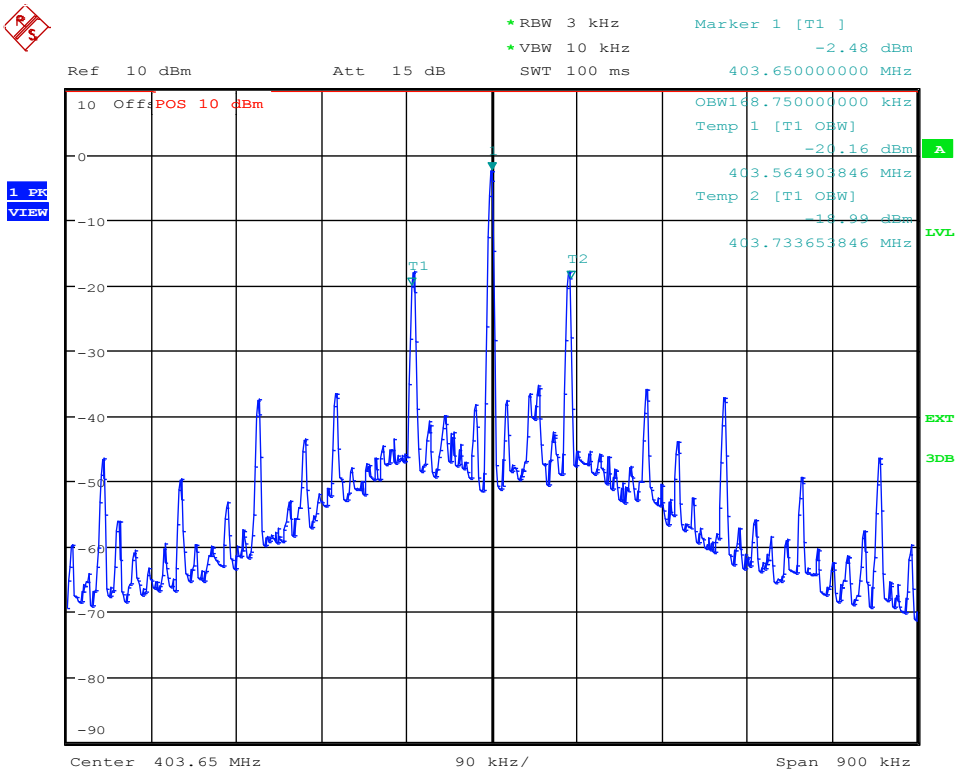
Date: 6.NOV.2015 08:44:47

Occupied Bandwidth – F_{MID} (82kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 82 kBit/s
Test Date:	2015-11-06
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



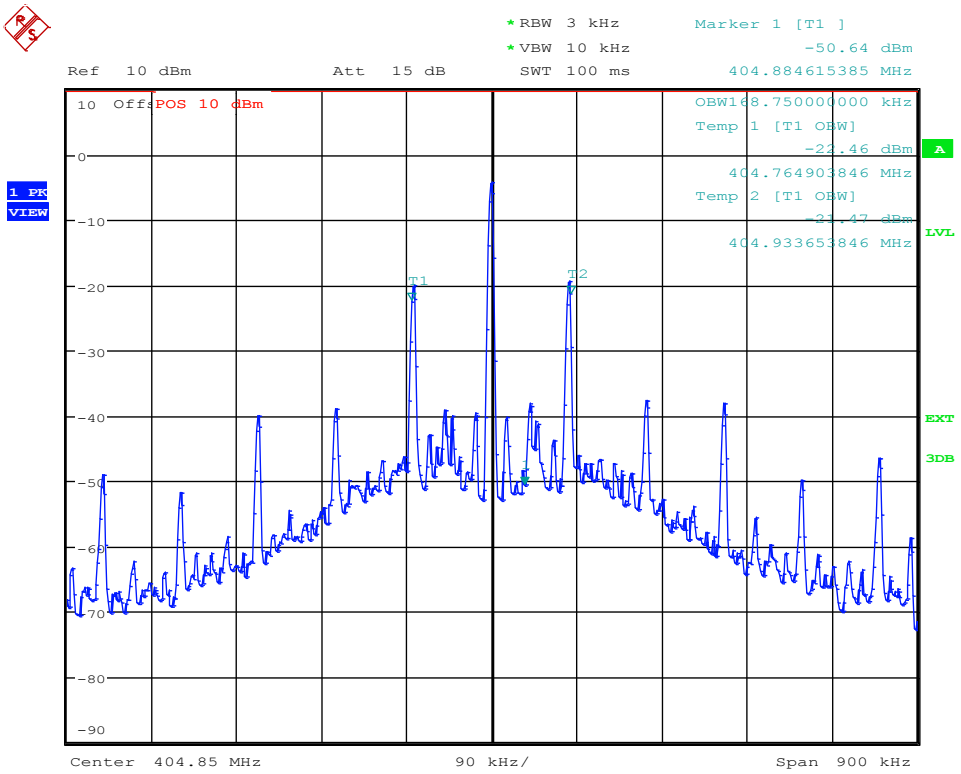
Date: 6.NOV.2015 08:39:19

Occupied Bandwidth – F_{HIGH} (82kBit)

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 82 kBit/s
Test Date:	2015-11-06
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used



Date: 6.NOV.2015 08:52:58

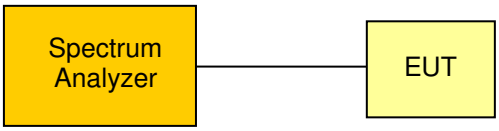
3.2 Test Conditions and Results – Emission Bandwidth

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}	32	402.45	234.4	≤ 300	PASS
F_{MID}	32	403.65	234.4	≤ 300	PASS
F_{HIGH}	32	404.85	235.0	≤ 300	PASS
F_{LOW}	82	402.45	168.3	≤ 300	PASS
F_{MID}	82	403.65	169.5	≤ 300	PASS
F_{HIGH}	82	404.85	169.5	≤ 300	PASS

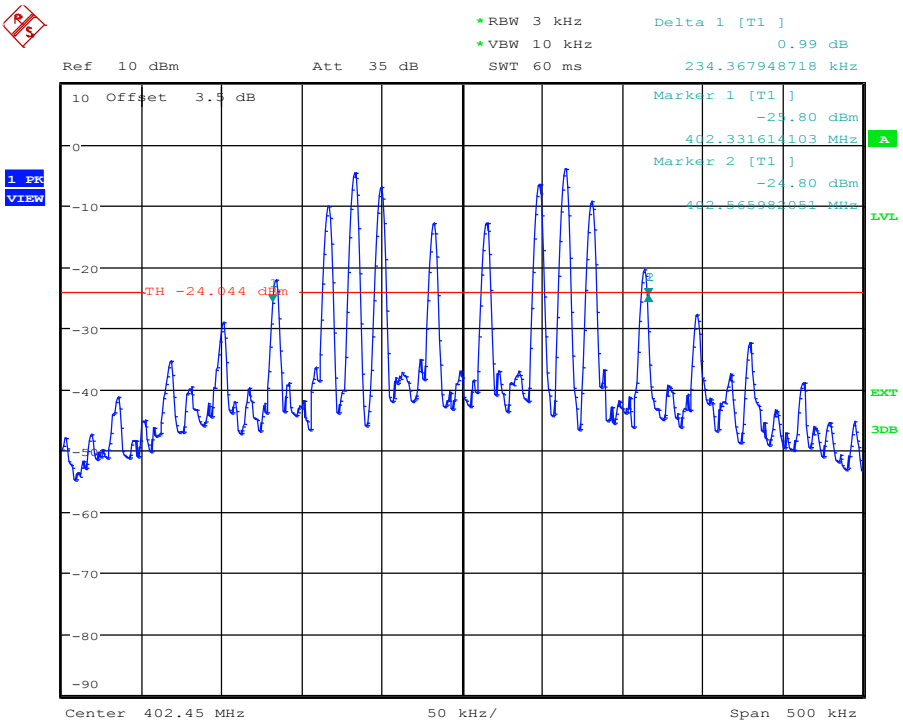
Comments:

Emission Bandwidth – F_{LOW} (32kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 32 kBit/s
Test Date:	2015-11-05
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 234.4 KHz

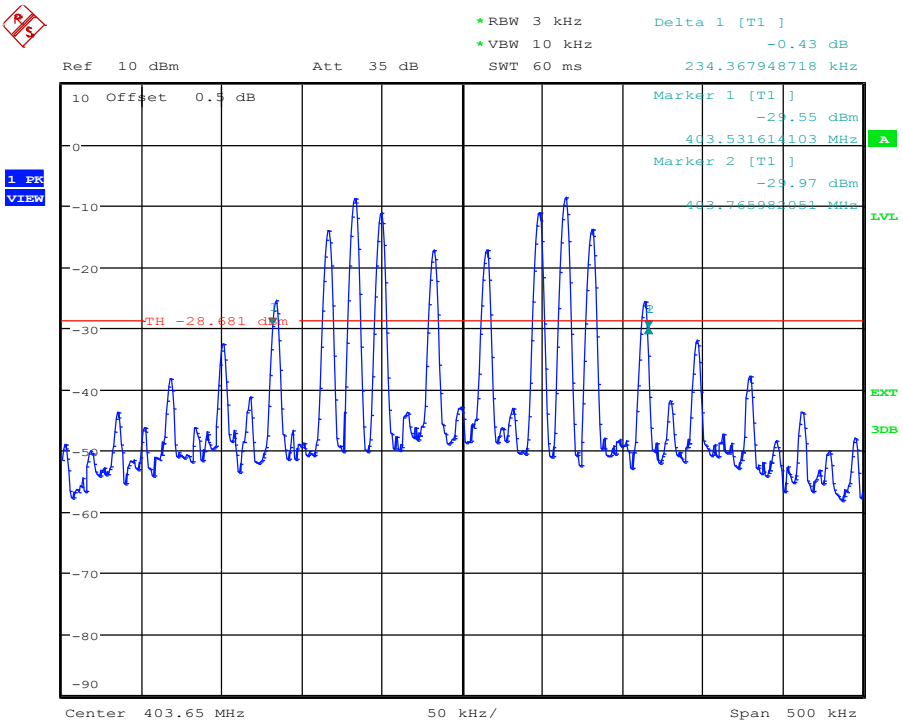
Date: 5.NOV.2015 14:29:24

Emission Bandwidth - F_{MID} (32kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 32 kBit/s
Test Date:	2015-11-05
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 234.4 KHz

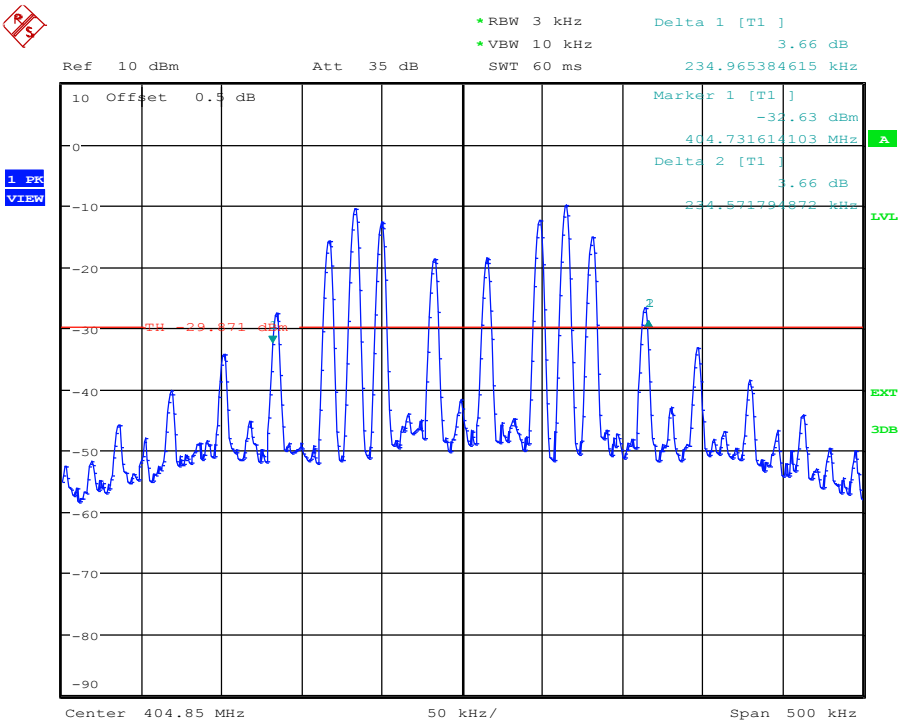
Date: 5.NOV.2015 14:15:01

Emission Bandwidth – F_{HIGH} (32kBit)

Emission Bandwidth acc. to EN 301 839

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 32 kBit/s
Test Date:	2015-11-05
Verdict:	PASS
Note 1:	20 dB bandwidth



20 dB bandwidth: 235 KHz

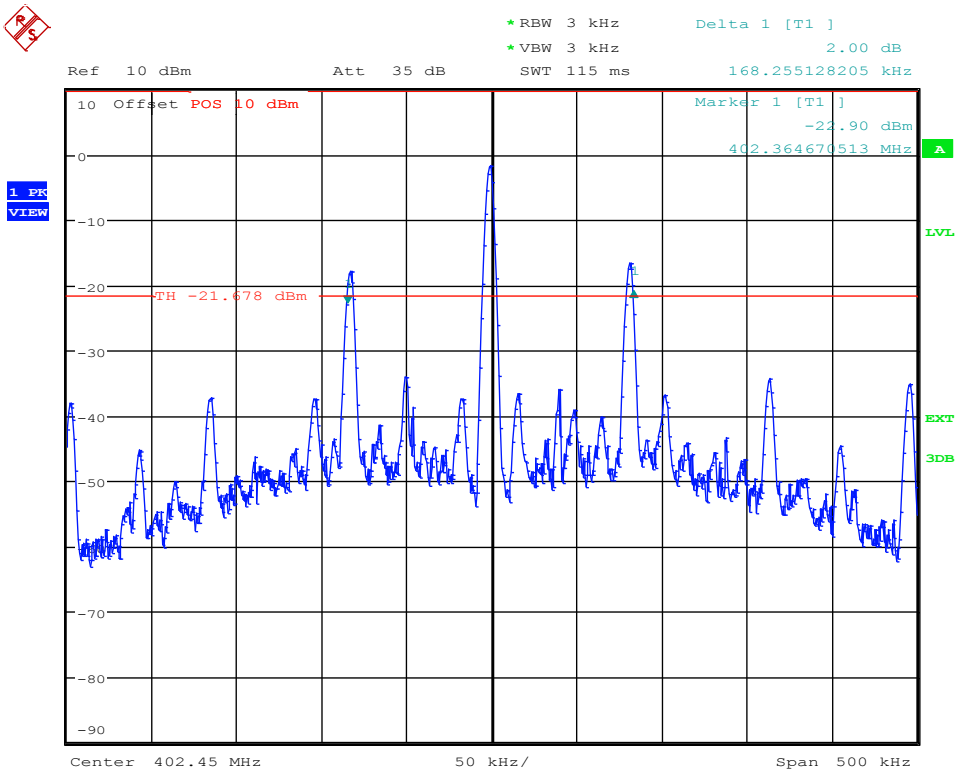
Date: 5.NOV.2015 14:06:40

Emission Bandwidth – F_{LOW} (82kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 402.45 MHz, 2FSK, 82 kBit/s
Test Date:	2015-11-06
Verdict:	PASS
Note 1:	20 dB bandwidth



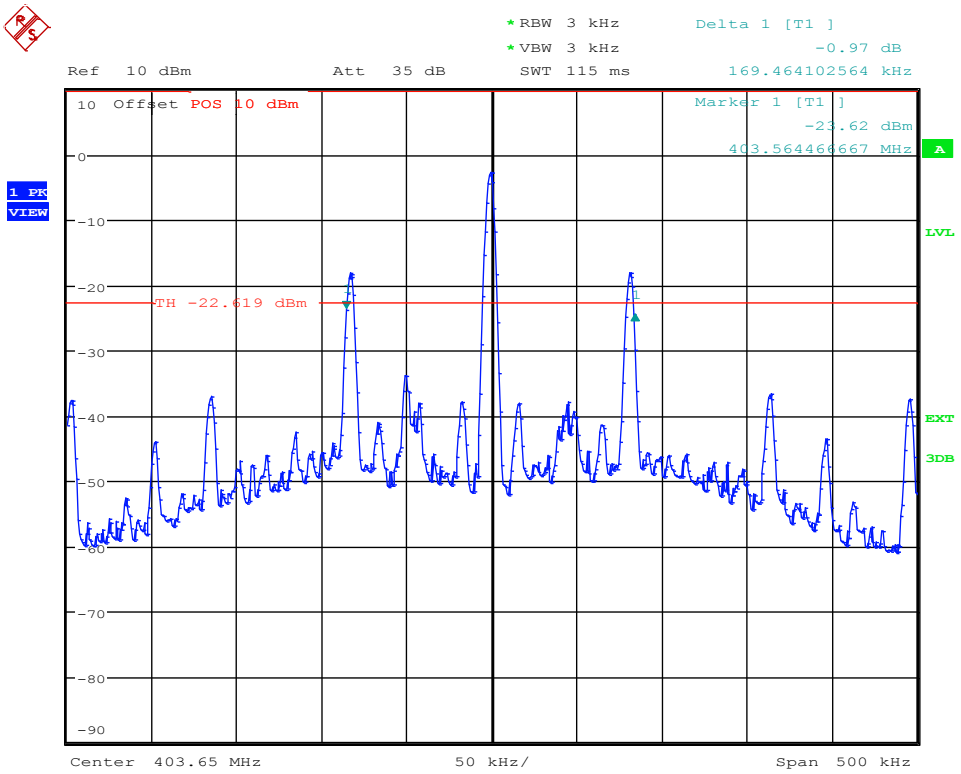
Date: 6.NOV.2015 09:12:50

Emission Bandwidth – F_{MID} (82kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 403.65 MHz, 2FSK, 82 kBit/s
Test Date:	2015-11-06
Verdict:	PASS
Note 1:	20 dB bandwidth



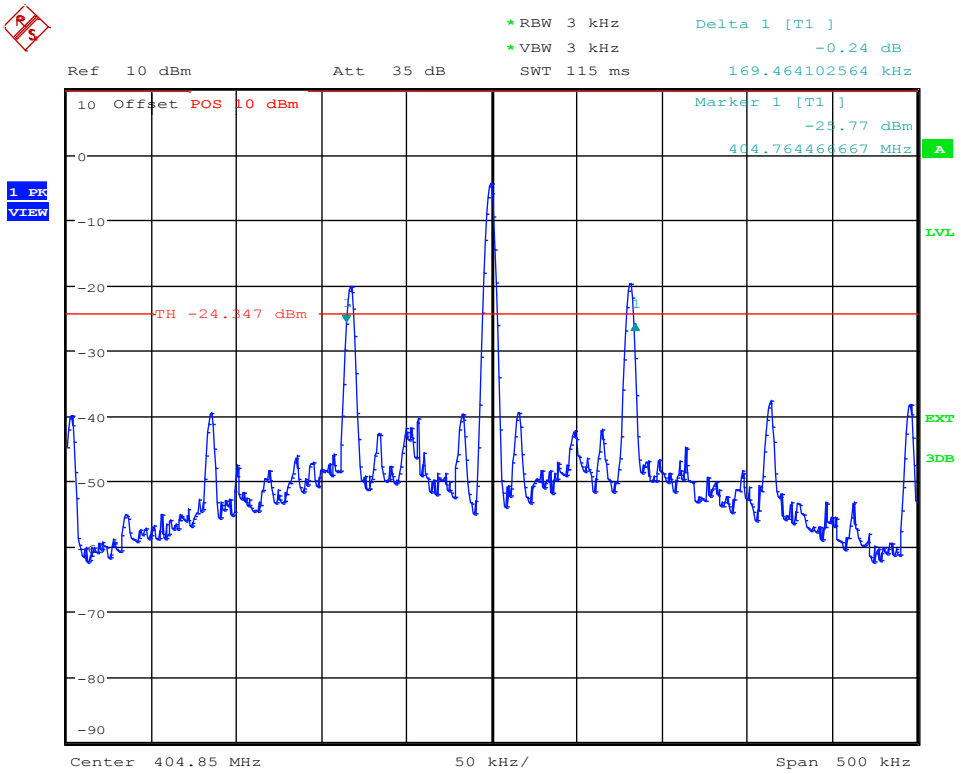
Date: 6.NOV.2015 09:17:10

Emission Bandwidth – F_{HIGH} (82kBit)

Emission Bandwidth acc. to FCC Part 95.633

Project Number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Ilivia 7
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 404.85 MHz, 2FSK, 82 kBit/s
Test Date:	2015-11-06
Verdict:	PASS
Note 1:	20 dB bandwidth



Date: 6.NOV.2015 09:20:42

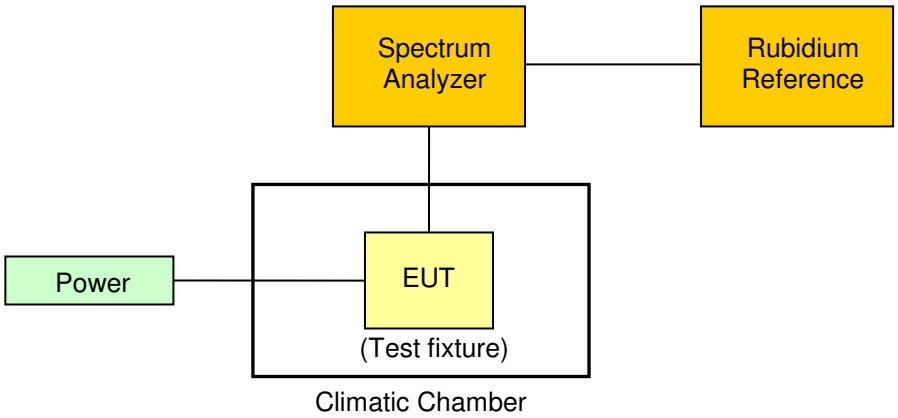
3.3 Test Conditions and Results – Frequency stability

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

Limits

≤ ±100 ppm

Test setup



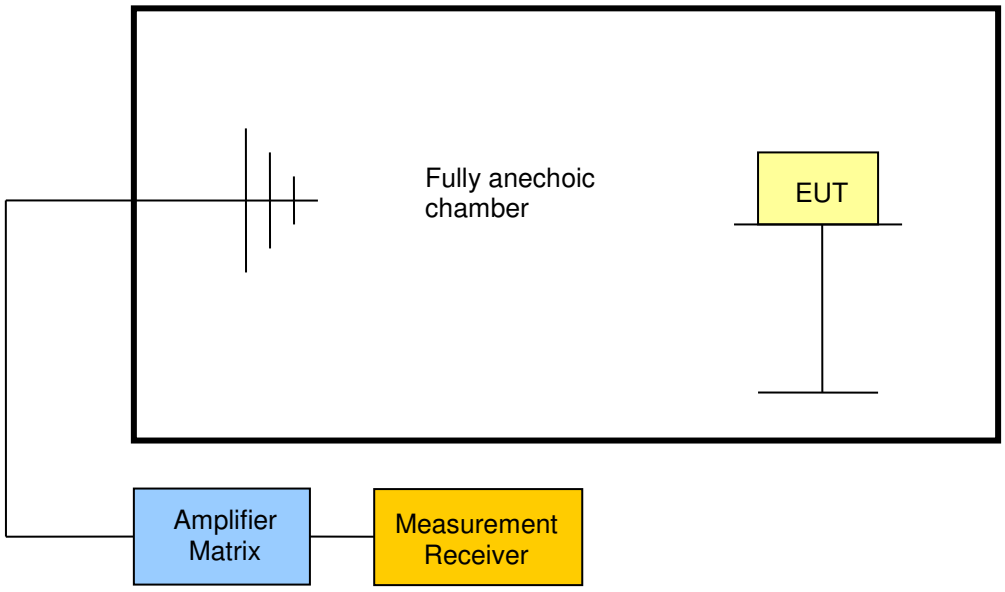
Test procedure

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

Test results					
Channel	Nominal Frequency [MHz]	Temperature	Supply voltage	Frequency [MHz]	Drift [ppm]
F_{LOW}	402.45	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	402.448523	-03.67
F_{LOW}	402.45	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	402.448738	-03.14
F_{LOW}	402.45	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	402.448406	-03.96
F_{MID}	403.65	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	403.648604	-03.46
F_{MID}	403.65	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	403.648855	-02.84
F_{MID}	403.65	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	403.648490	-03.74
F_{HIGH}	404.85	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	404.848685	-03.25
F_{HIGH}	404.85	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	404.848926	-02.65
F_{HIGH}	404.85	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	404.848566	-03.54
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_{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	-28.7	pk	-16	-12.70
F_{HIGH}	404.85	-28.4	pk	-16	-12.40
Comments:					

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

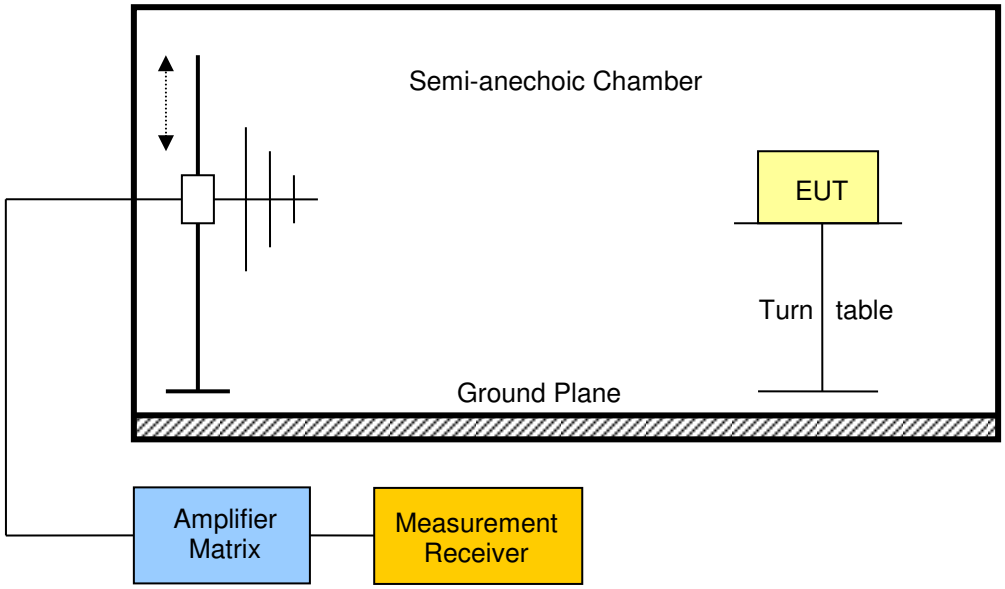
Band-edge and in-band emission compliance acc. to FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9
Test according to measurement reference	Reference Method
	FCC 95.635(d) / ANSI C 63.4
Test frequency range	Tested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

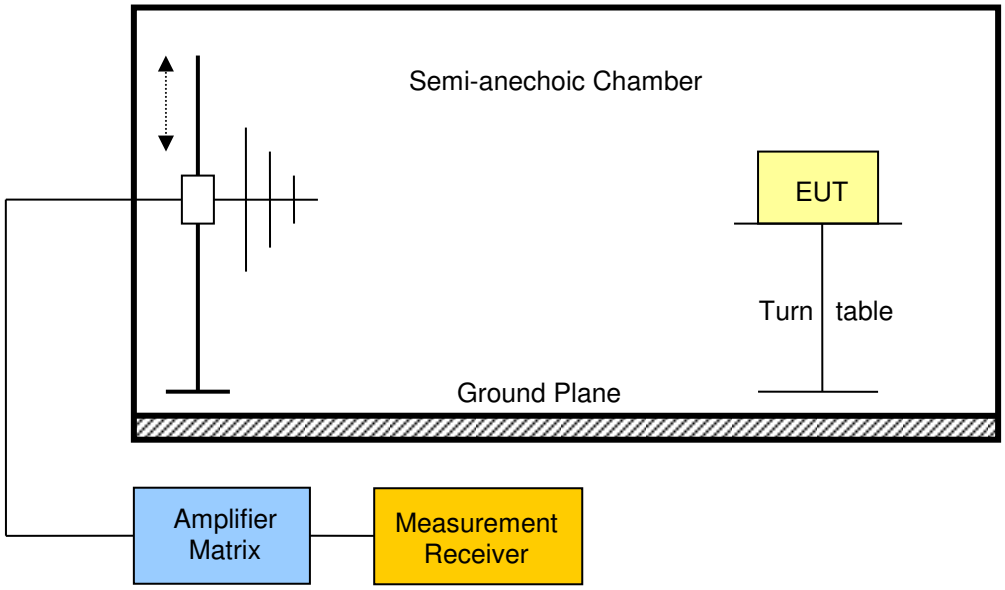
Test setup



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	402.287	29.13	hor	56.60	-27.47
F_{LOW}	402.45	402.299	33.42	ver	47.10	-13.68
F_{LOW}	402.45	402.61	30.30	hor	56.60	-26.30
F_{LOW}	402.45	402.61	33.66	ver	47.10	-13.44
F_{LOW}	402.45	403.238	19.54	ver	47.10	-27.56
F_{LOW}	402.45	403.958	19.26	hor	56.60	-37.34
F_{LOW}	402.45	403.958	22.82	ver	47.10	-24.28
F_{LOW}	402.45	404.093	19.11	hor	56.60	-37.49
F_{LOW}	402.45	404.093	22.02	ver	47.10	-25.08
F_{HIGH}	404.85	401.347	25.08	hor	46.00	-20.92
F_{HIGH}	404.85	401.347	27.38	ver	46.00	-18.62
F_{HIGH}	404.85	402.022	20.85	ver	56.60	-35.75
F_{HIGH}	404.85	402.027	20.29	hor	40.50	-20.21
F_{HIGH}	404.85	403.075	12.96	hor	40.50	-27.54
F_{HIGH}	404.85	403.469	14.21	hor	40.50	-26.29
F_{HIGH}	404.85	404.689	32.67	hor	40.50	-07.83
F_{HIGH}	404.85	404.695	32.46	ver	56.60	-24.14
F_{HIGH}	404.85	405.01	35.11	ver	59.40	-24.29
F_{HIGH}	404.85	405.011	33.48	hor	59.40	-25.92
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		
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

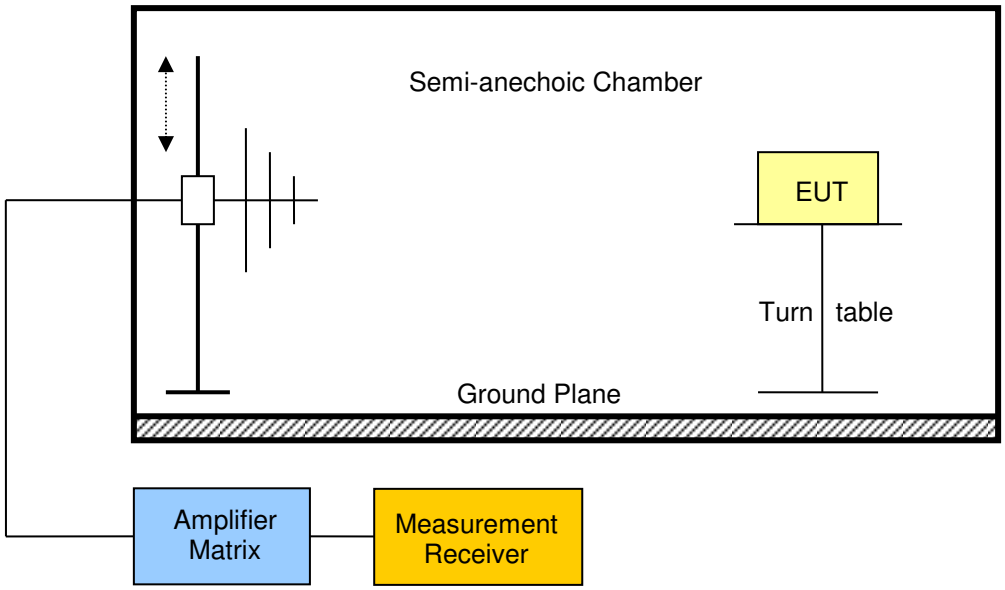
Test results

Channel	Frequency [MHz]	Mode	Emission [MHz]	Level [dbµV/m]	Det.	Pol.	Limit [dbµV/m]	Limit dist. [m]*	Margin [dB]
F_{LOW}	402.45	Modulated1	399.329	24.88	pk	hor	46.00	3	-21.12
F_{LOW}	402.45	Modulated1	399.329	28.69	pk	ver	46.00	3	-17.31
F_{LOW}	402.45	Modulated1	405.25	30.28	pk	hor	46.00	3	-15.72
F_{LOW}	402.45	Modulated1	405.25	31.41	pk	ver	46.00	3	-14.59
F_{HIGH}	404.85	Modulated1	406.44	22.36	pk	hor	46.00	3	-23.64
F_{HIGH}	404.85	Modulated1	406.44	22.49	pk	ver	46.00	3	-23.51

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	35.78	29.33	pk	hor	40.00	-10.67
F_{MID}	403.65	881.6	18.92	pk	ver	46.00	-27.08
F_{MID}	403.65	912	18.71	pk	hor	46.00	-27.29
F_{MID}	403.65	1714	34.61	pk	hor	53.98	-19.37
F_{MID}	403.65	3448	40.40	pk	ver	53.98	-13.58
F_{MID}	403.65	3976	40.45	pk	hor	53.98	-13.53
Comments:							

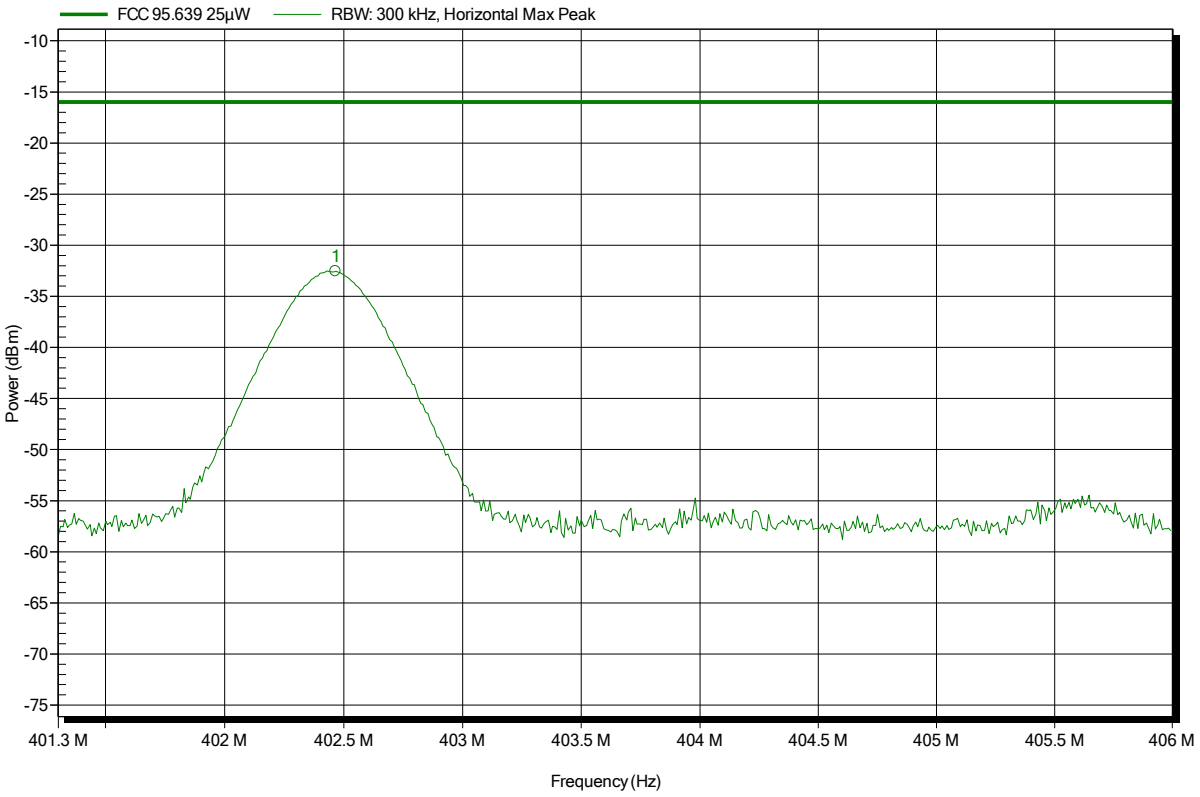
ANNEX A Transmitter radiated power

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-11-02
Note:	Tx Power EIRP

Index 27



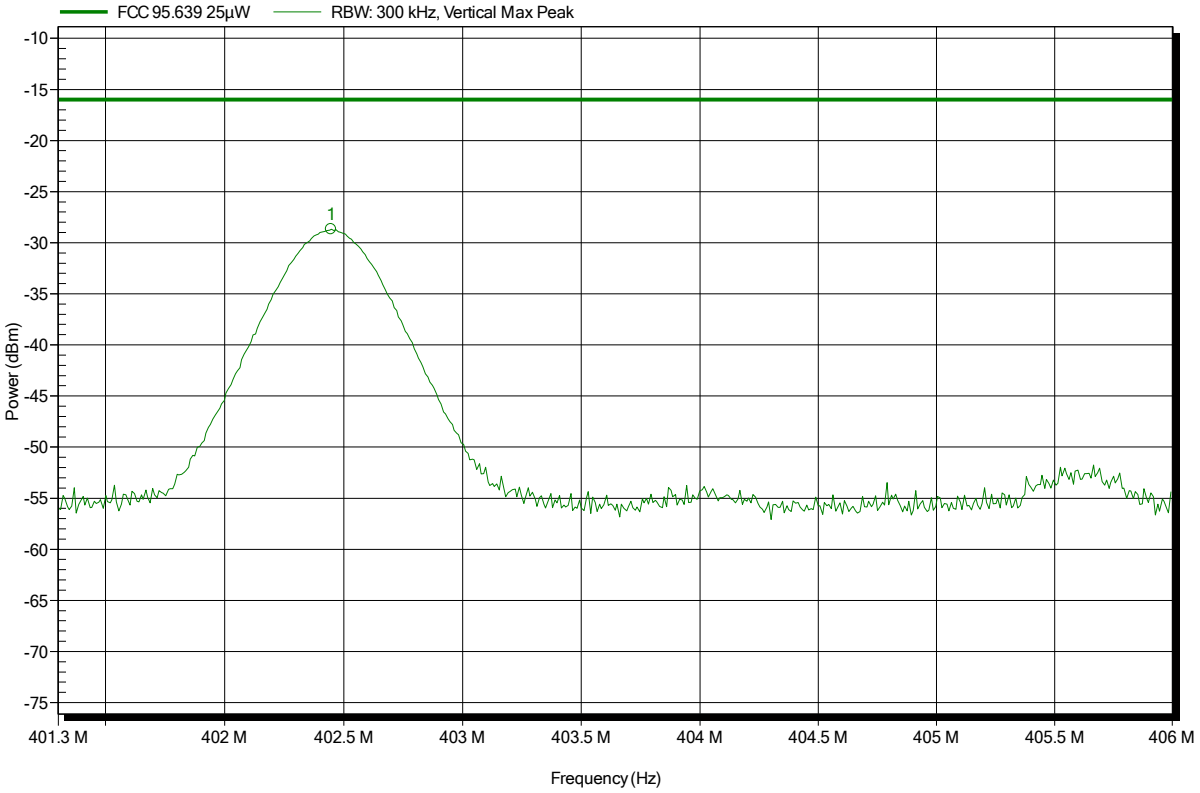
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.466 MHz	-32.6 dBm	-16 dBm	-16.56 dB	Pass

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-11-02
Note:	Tx Power EIRP

Index 29



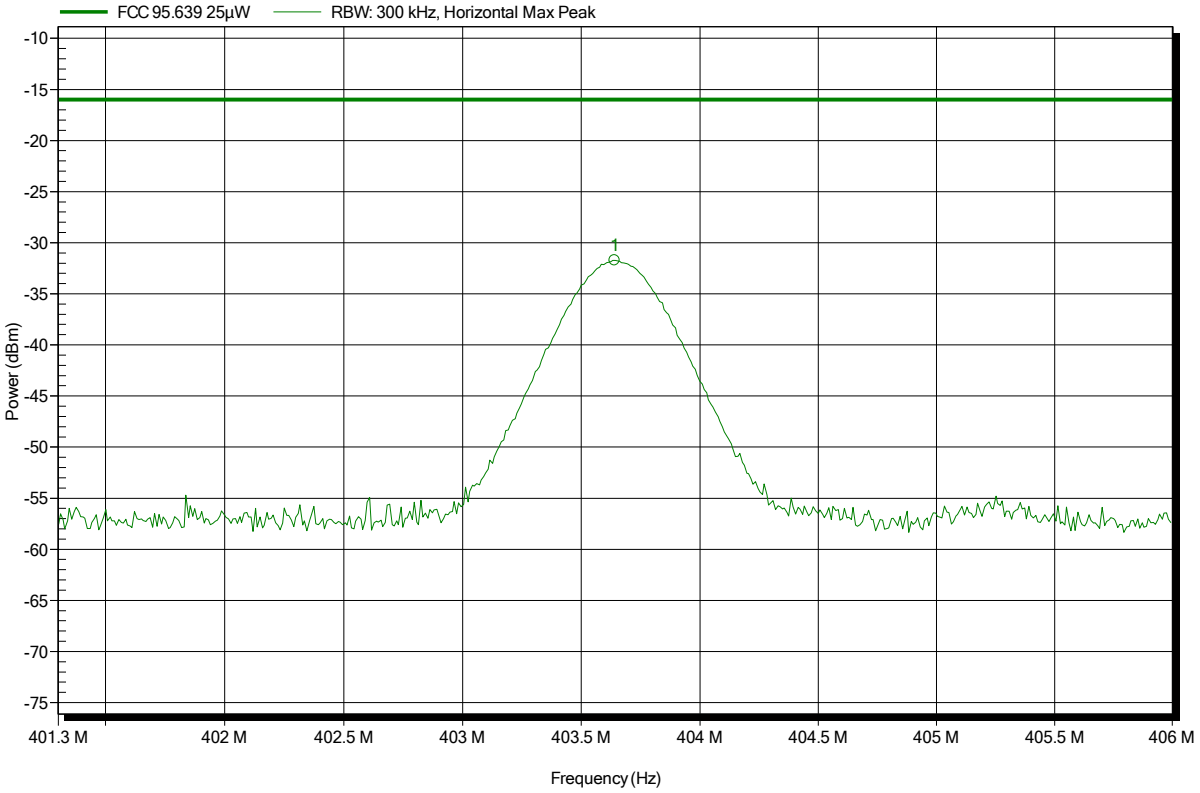
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.447 MHz	-28.7 dBm	-16 dBm	-12.68 dB	Pass

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 403.65 MHz, CW
Test Date:	2015-11-02
Note:	Tx Power EIRP

Index 31



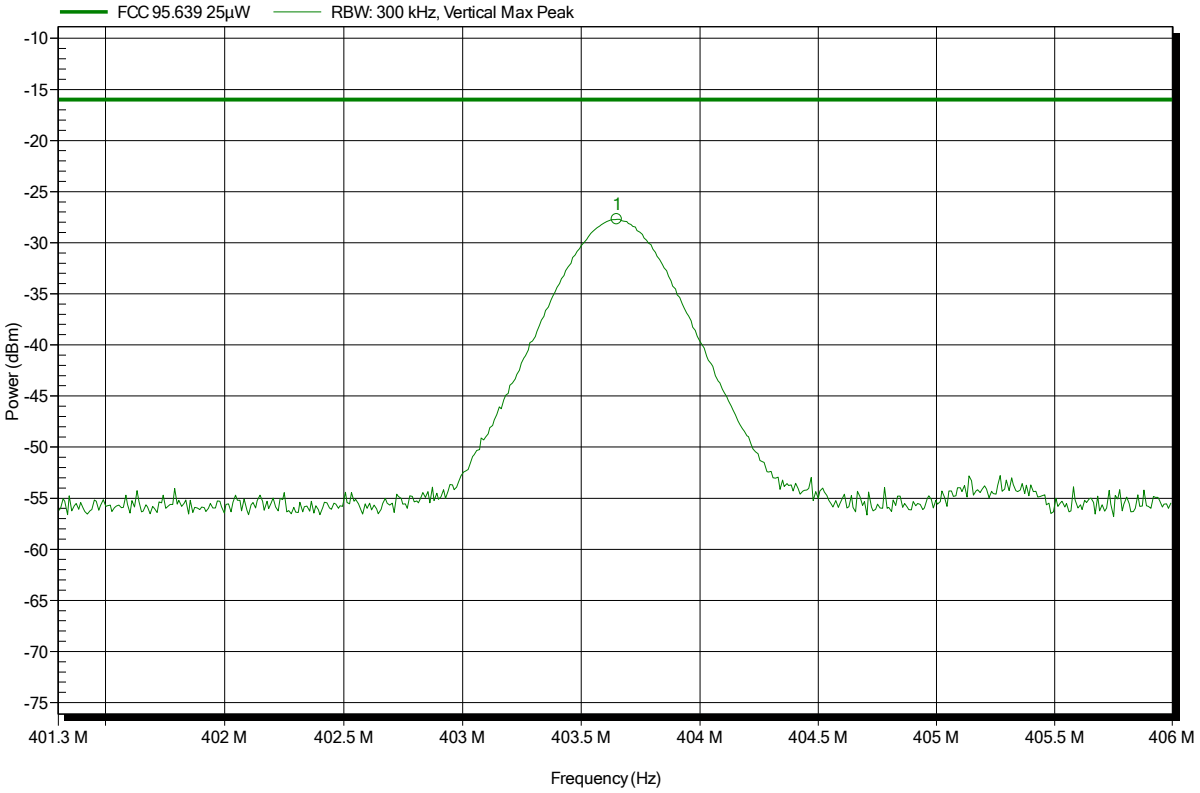
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403.641 MHz	-31.7 dBm	-16 dBm	-15.74 dB	Pass

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 403.65 MHz, CW
Test Date:	2015-11-02
Note:	Tx Power EIRP

Index 32



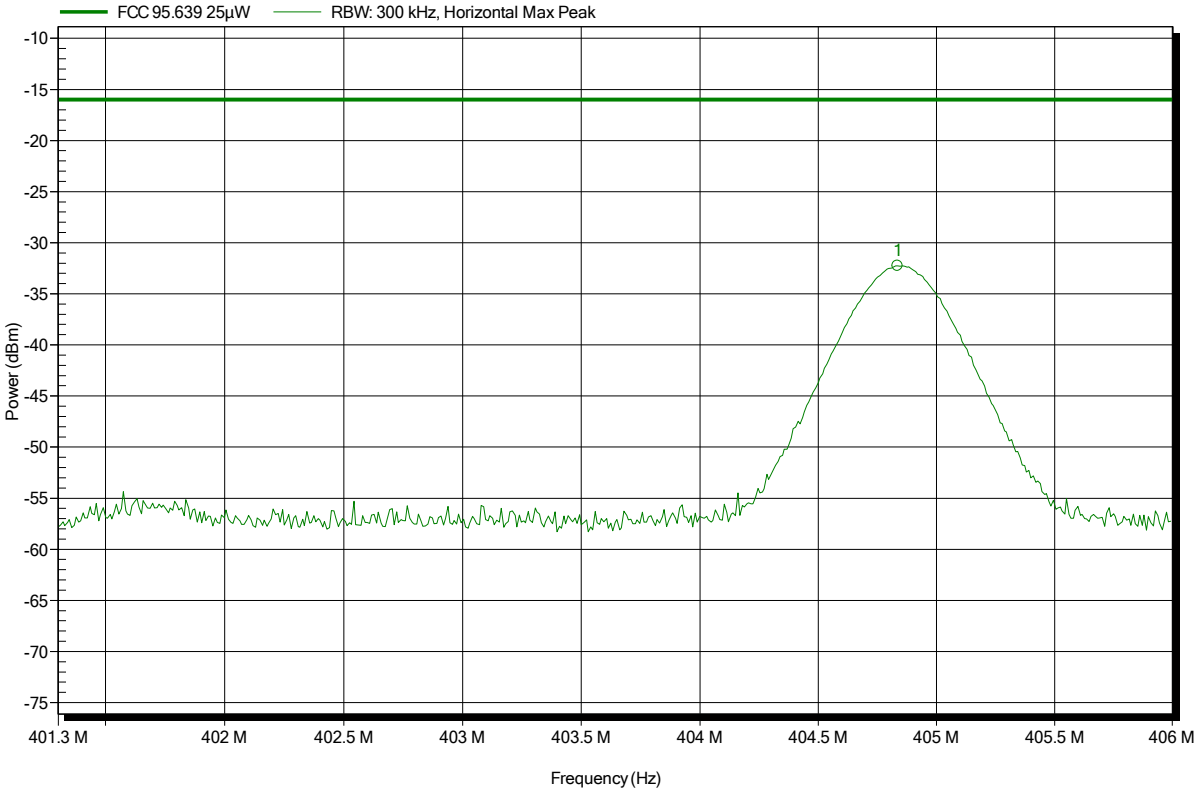
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403.65 MHz	-27.7 dBm	-16 dBm	-11.72 dB	Pass

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz, CW
Test Date:	2015-11-02
Note:	Tx Power EIRP

Index 33



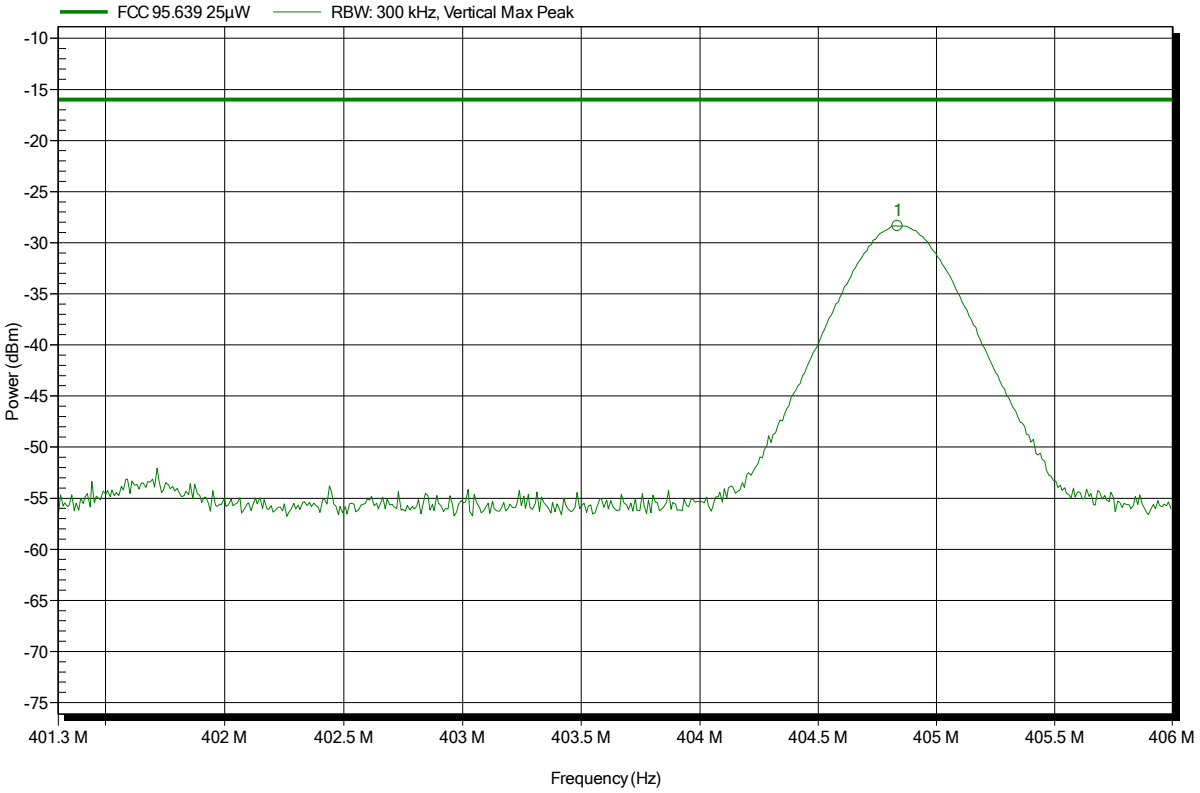
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.834 MHz	-32.3 dBm	-16 dBm	-16.28 dB	Pass

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz, CW
Test Date:	2015-11-02
Note:	Tx Power EIRP

Index 35



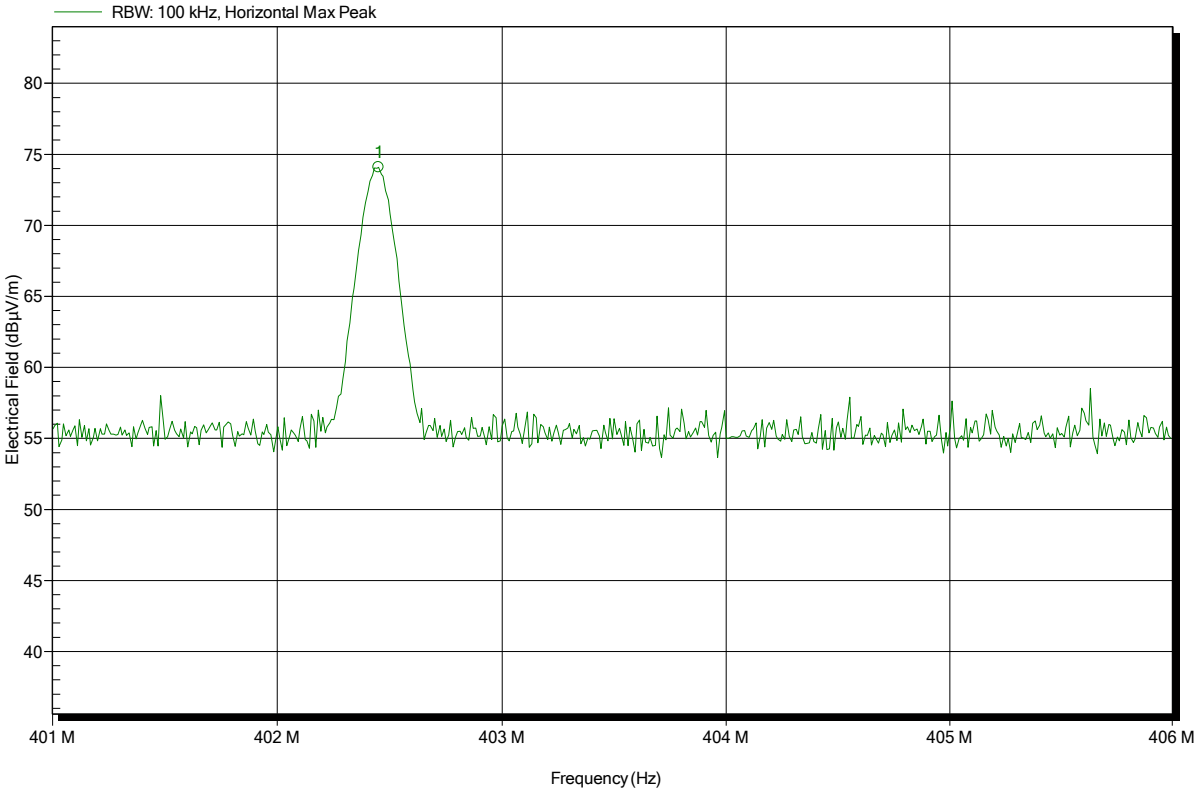
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.834 MHz	-28.4 dBm	-16 dBm	-12.36 dB	Pass

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-11-02
Note:	Power dBµV/m ERP

Index 28



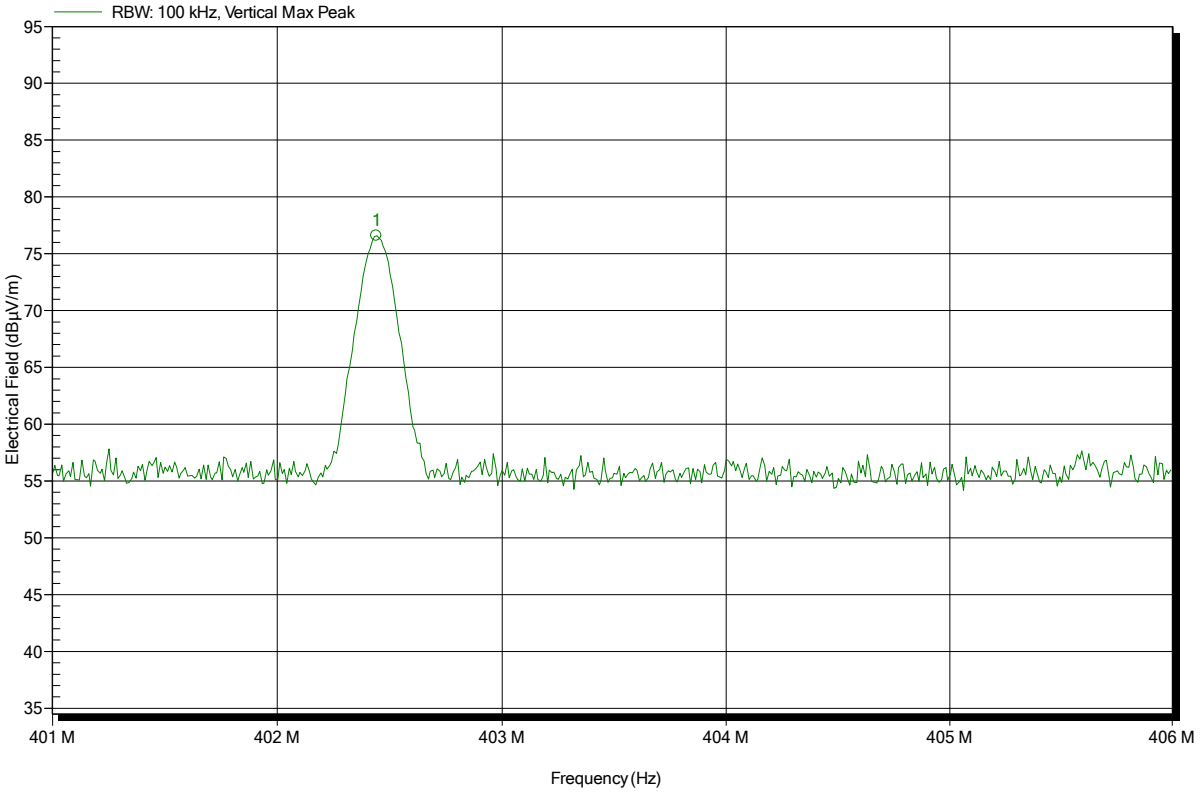
Frequency	Peak
402.45 MHz	74.08 dBµV/m

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz, CW
Test Date:	2015-11-02
Note:	Power dBµV/m ERP

Index 30



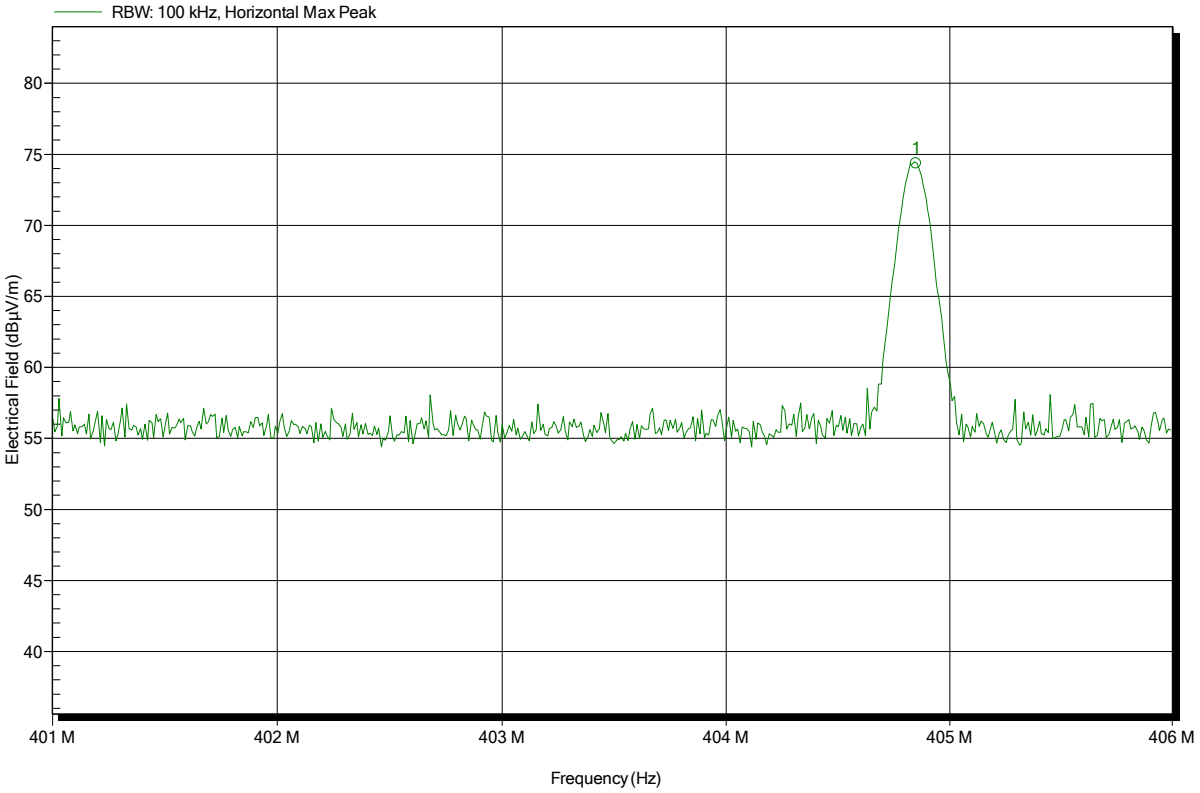
Frequency	Peak
402.44 MHz	76.58 dBµV/m

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz, CW
Test Date:	2015-11-02
Note:	Power dBµV/m ERP

Index 34



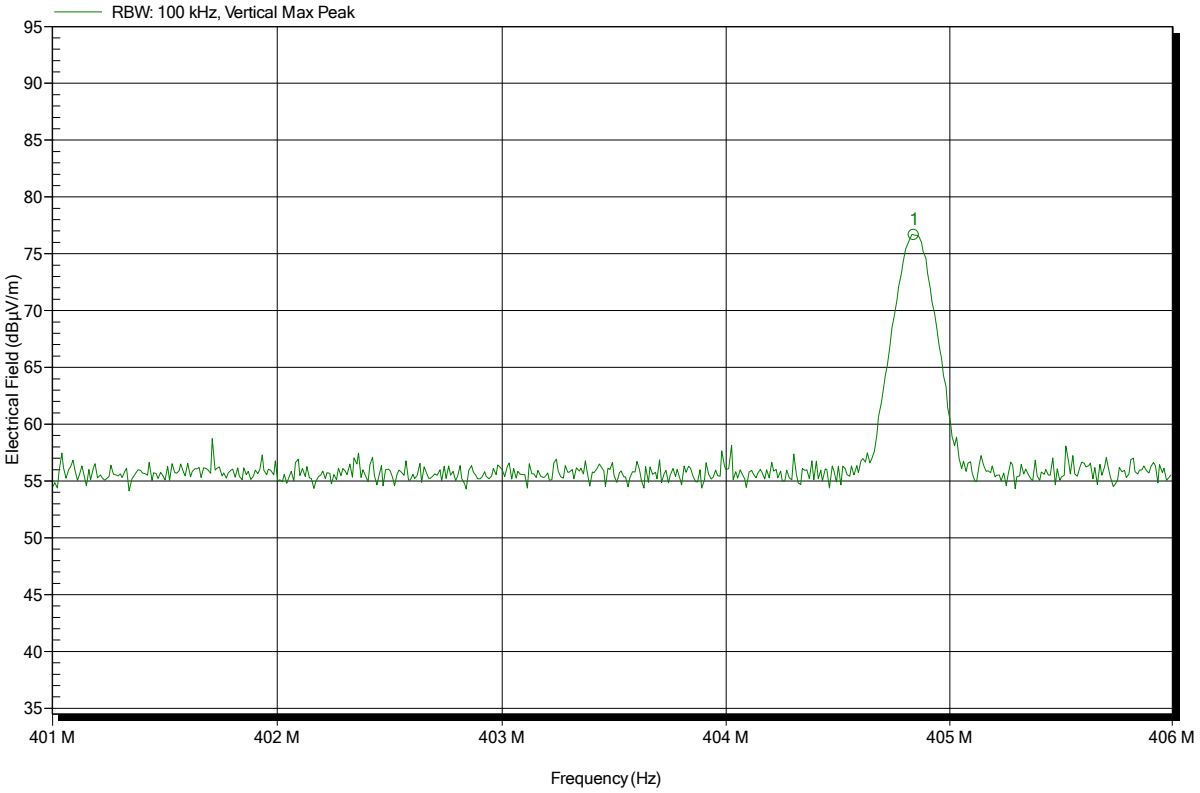
Frequency	Peak
404.85 MHz	74.37 dBµV/m

Radiated power according to FCC Part 95; Subpart E

Order number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz, CW
Test Date:	2015-11-02
Note:	Power dBµV/m ERP

Index 36



Frequency	Peak
404.84 MHz	76.64 dBµV/m

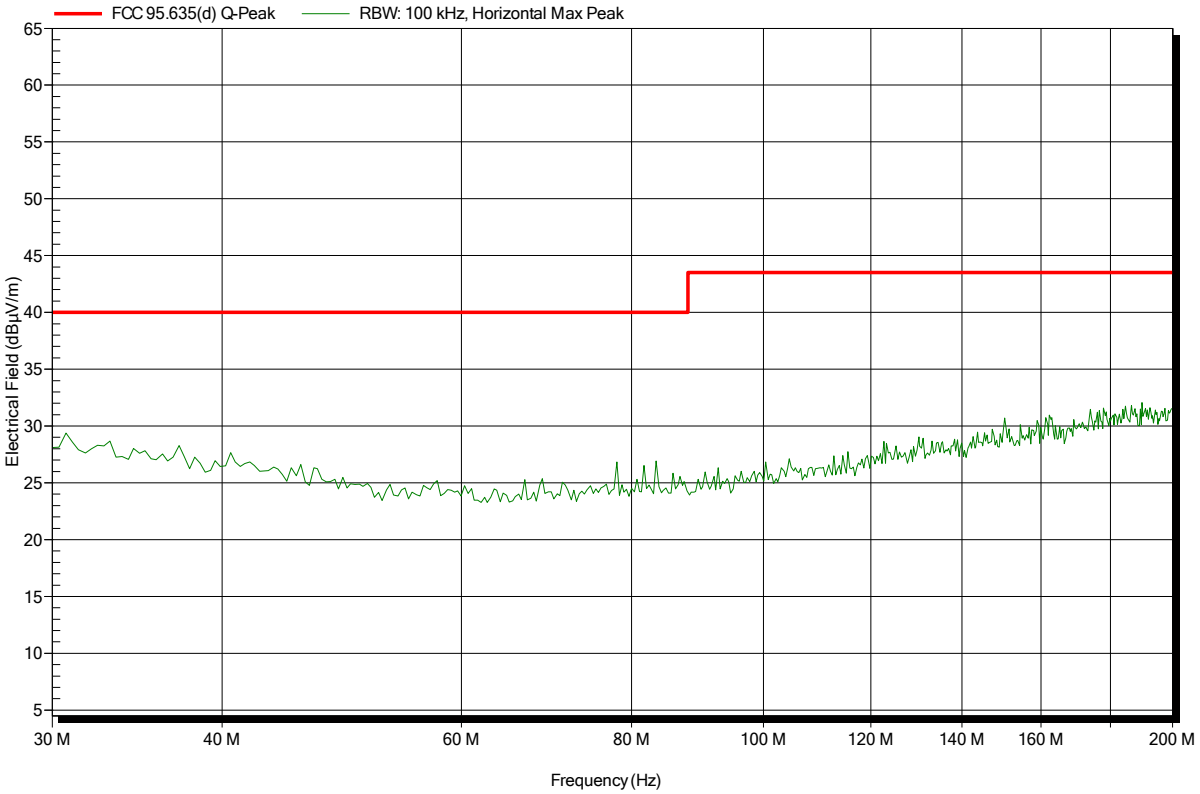
ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 37

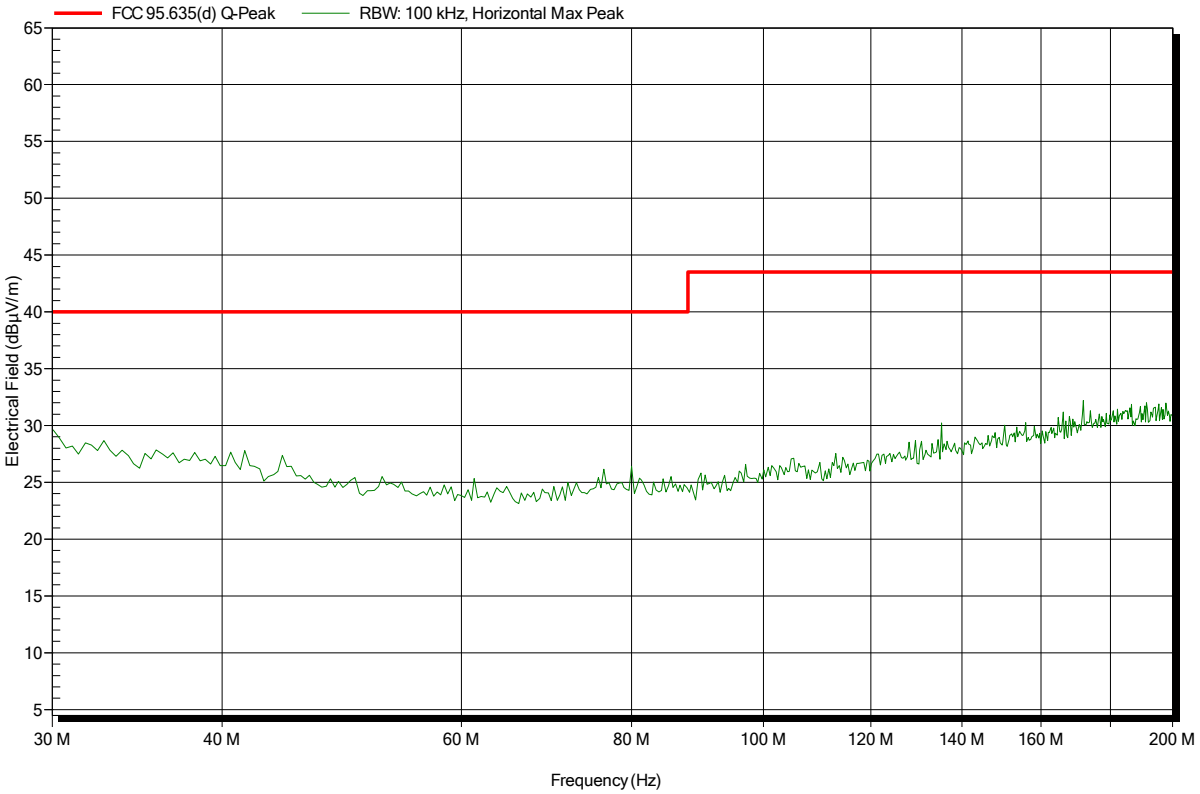


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

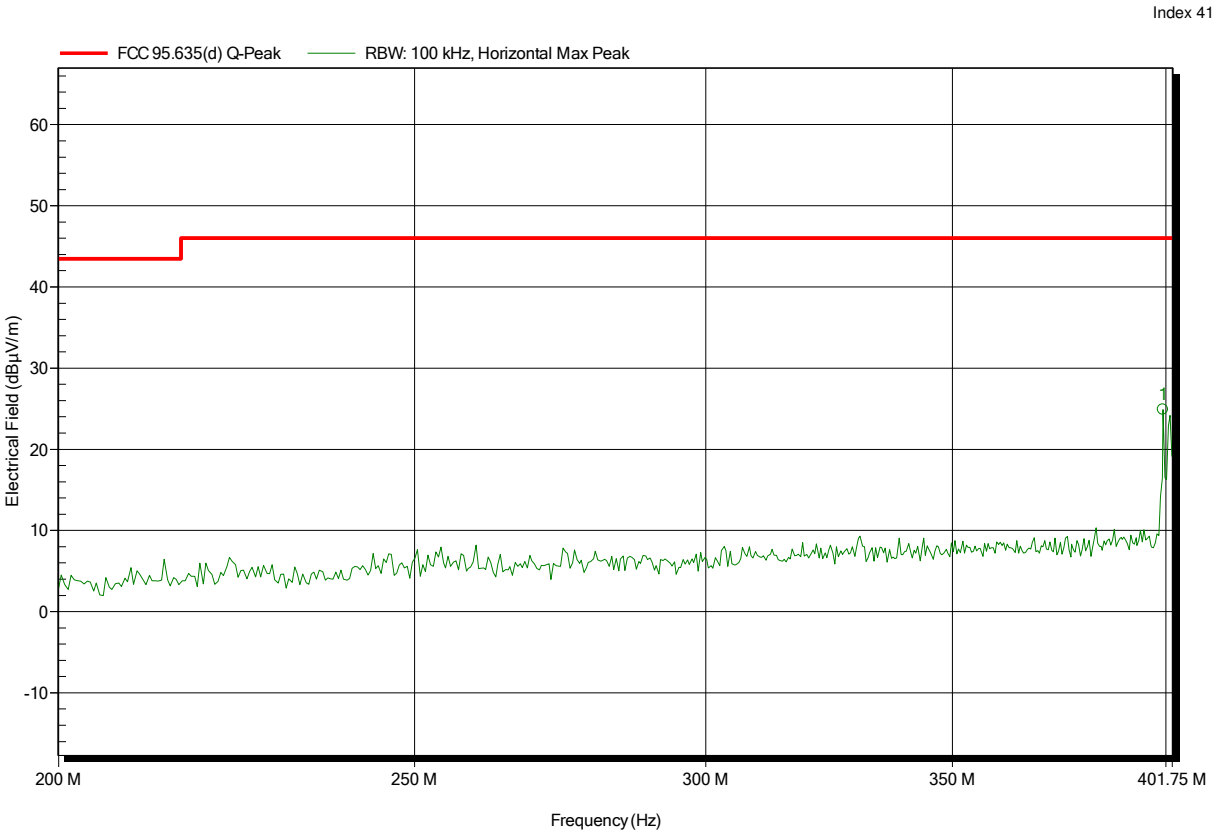
Index 38



Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	



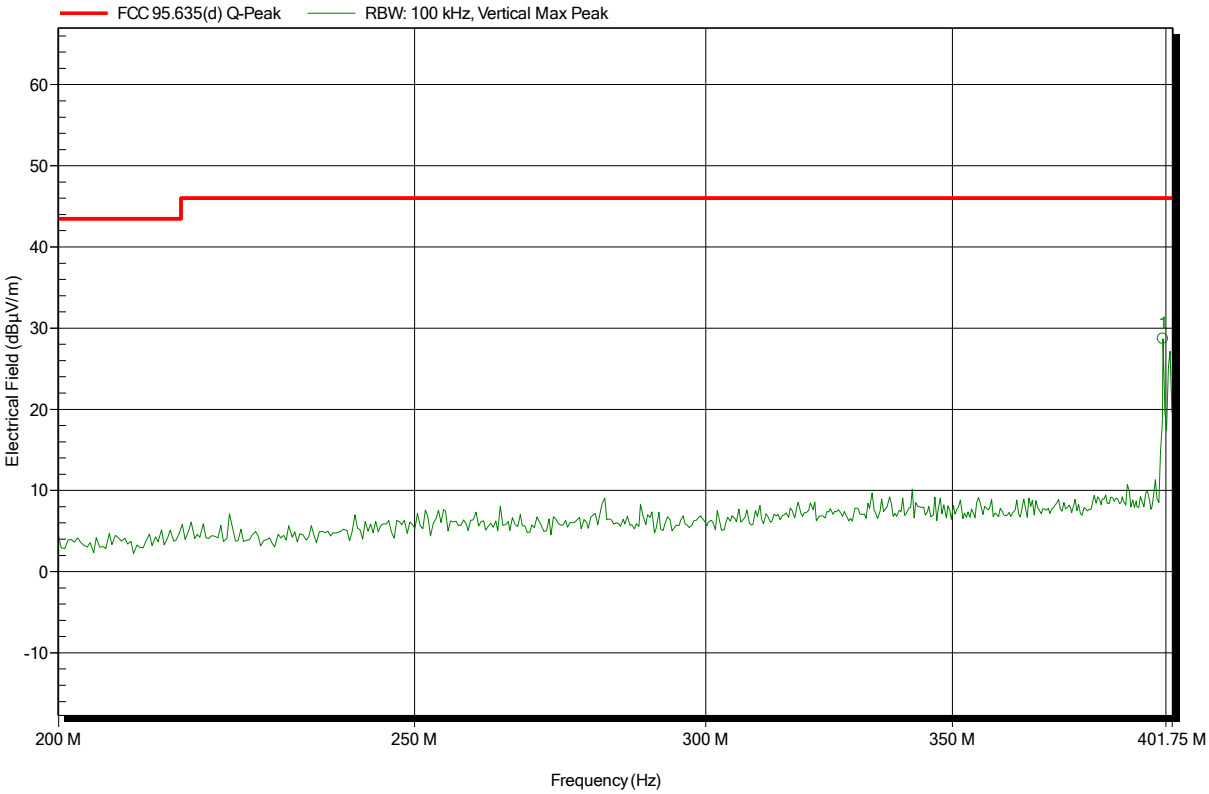
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
399.329 MHz	24.88 dBµV/m	46 dBµV/m	-21.12 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 42



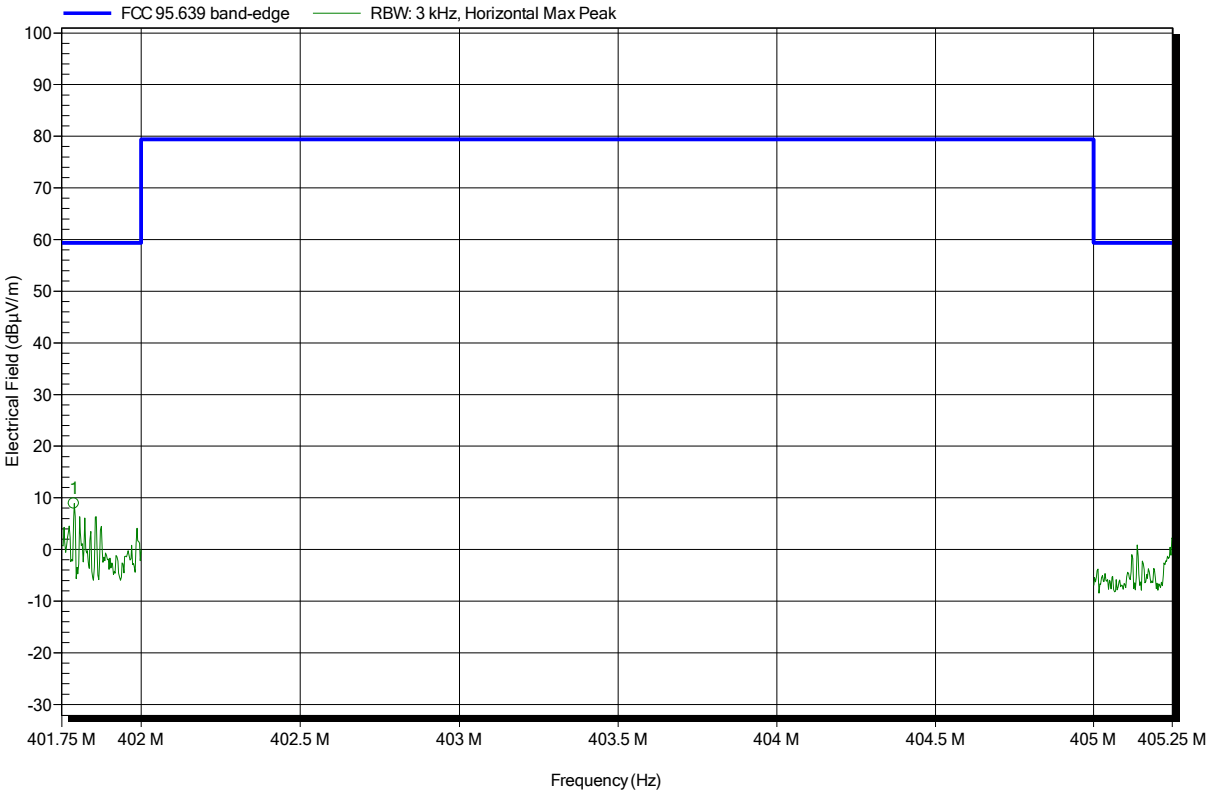
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
399.329 MHz	28.69 dBµV/m	46 dBµV/m	-17.31 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	Band-edge

Index 44



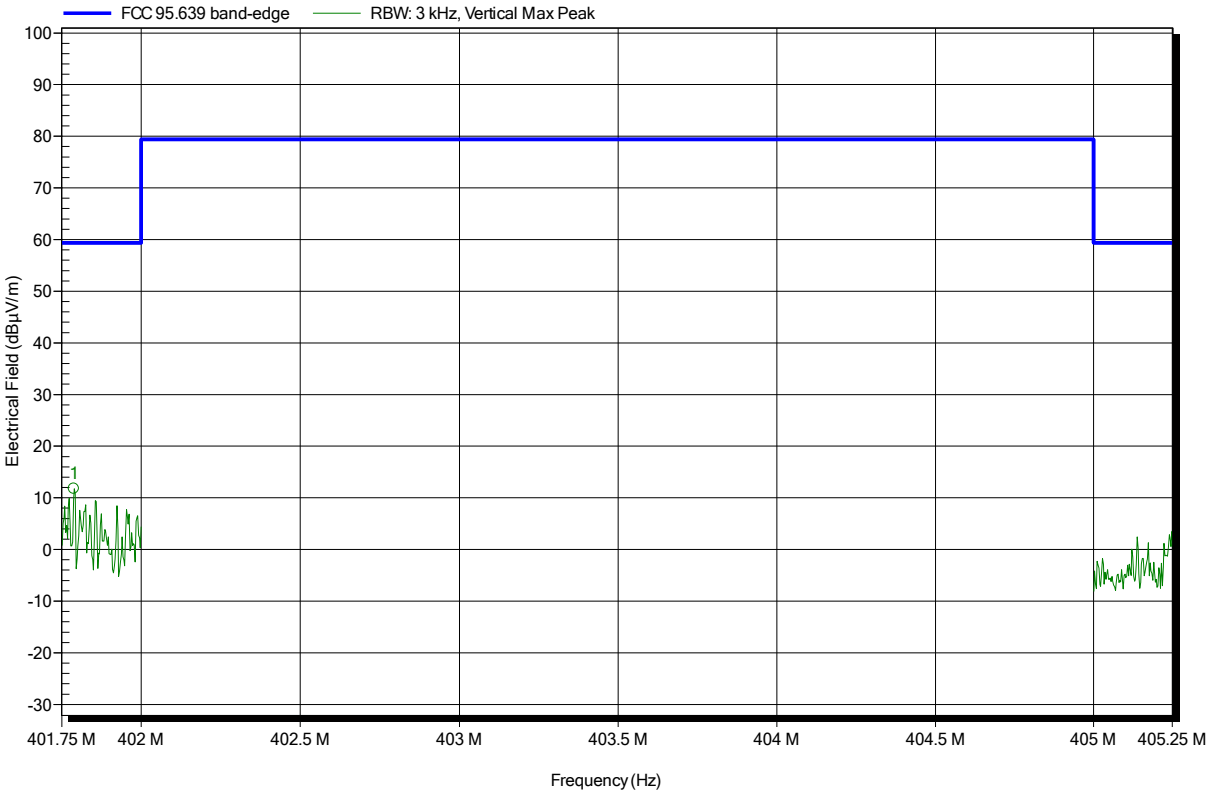
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.789 MHz	8.91 dBµV/m	59.4 dBµV/m	-50.49 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	Band-edge

Index 43



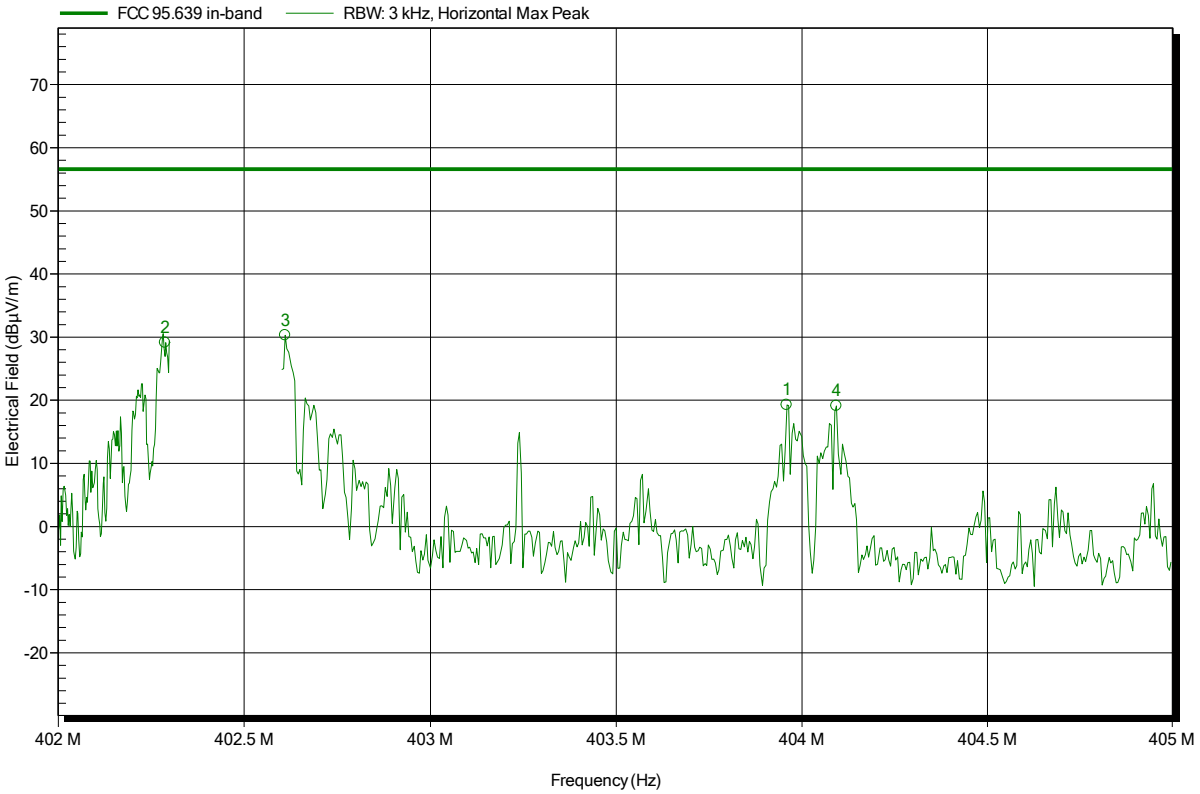
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.789 MHz	11.74 dBµV/m	59.4 dBµV/m	-47.66 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	In-band emissions

Index 45



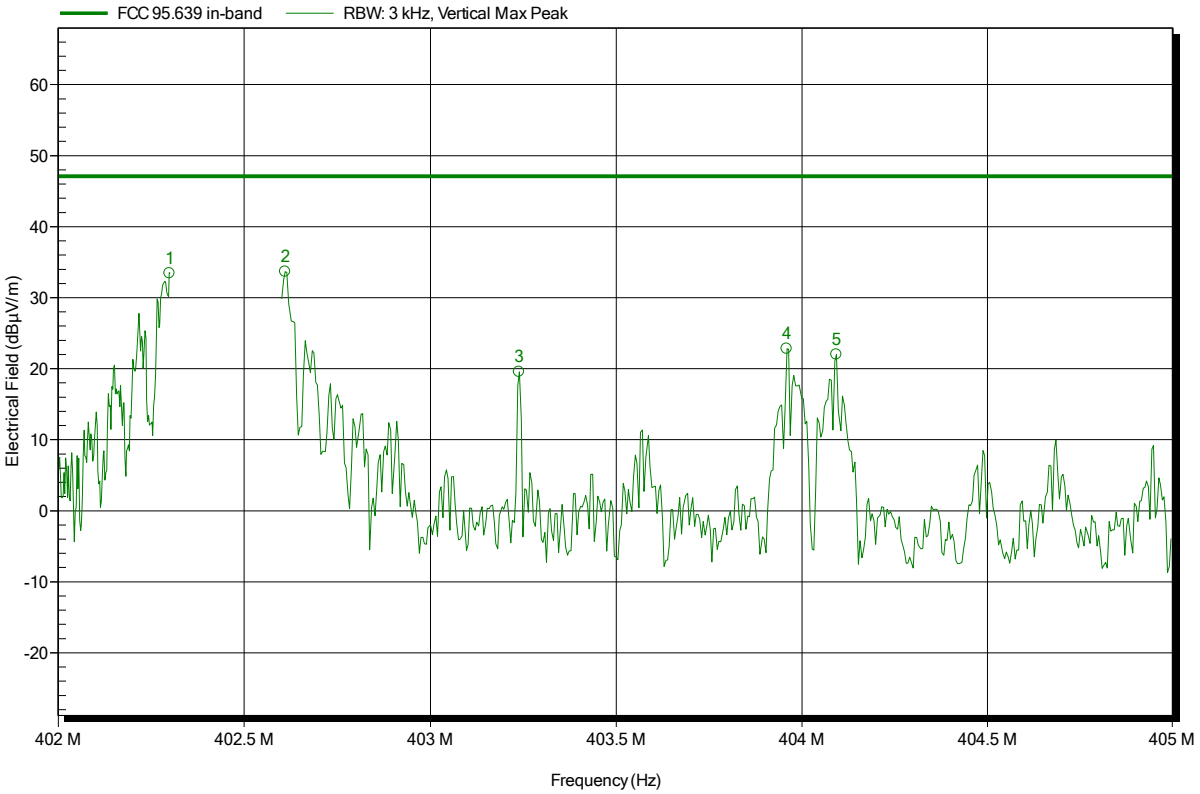
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.287 MHz	29.13 dBµV/m	56.6 dBµV/m	-27.47 dB	Pass
402.61 MHz	30.3 dBµV/m	56.6 dBµV/m	-26.3 dB	Pass
403.958 MHz	19.26 dBµV/m	56.6 dBµV/m	-37.34 dB	Pass
404.093 MHz	19.11 dBµV/m	56.6 dBµV/m	-37.49 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	In-band emissions

Index 46



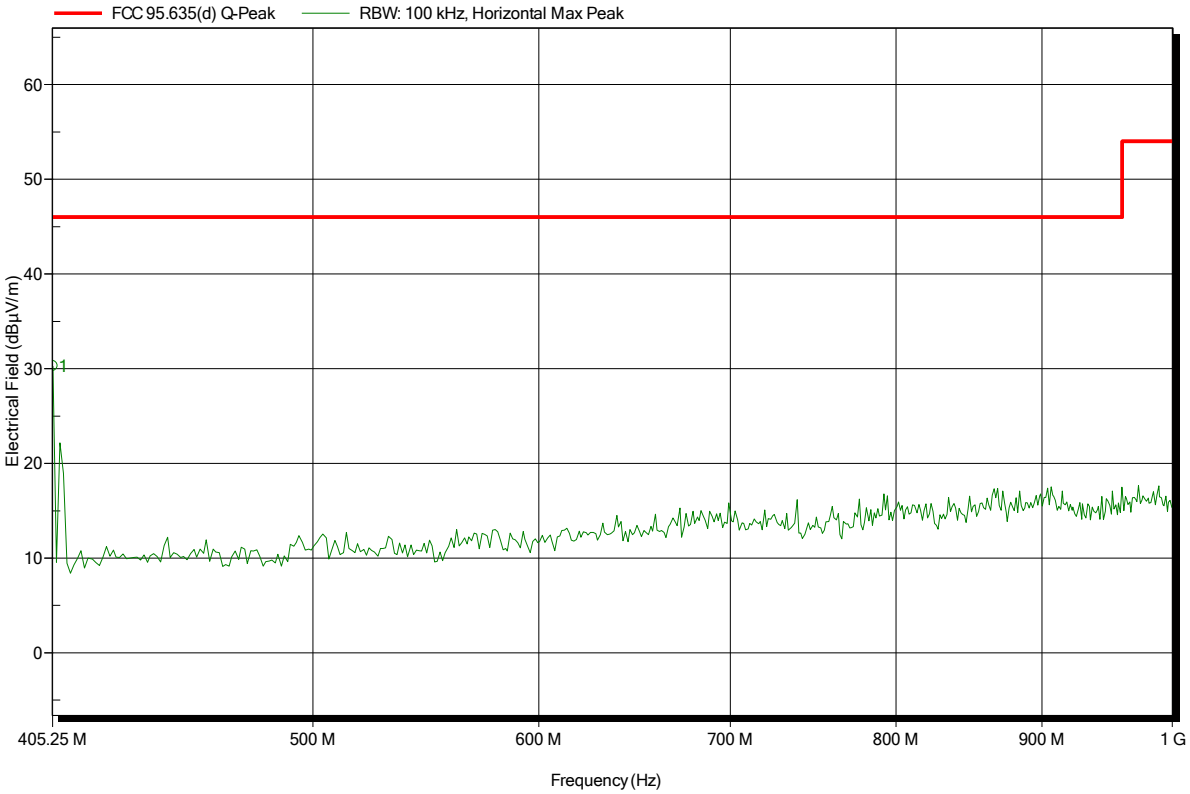
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.299 MHz	33.42 dBµV/m	47.1 dBµV/m	-13.68 dB	Pass
402.61 MHz	33.66 dBµV/m	47.1 dBµV/m	-13.44 dB	Pass
403.238 MHz	19.54 dBµV/m	47.1 dBµV/m	-27.56 dB	Pass
403.958 MHz	22.82 dBµV/m	47.1 dBµV/m	-24.28 dB	Pass
404.093 MHz	22.02 dBµV/m	47.1 dBµV/m	-25.08 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 49



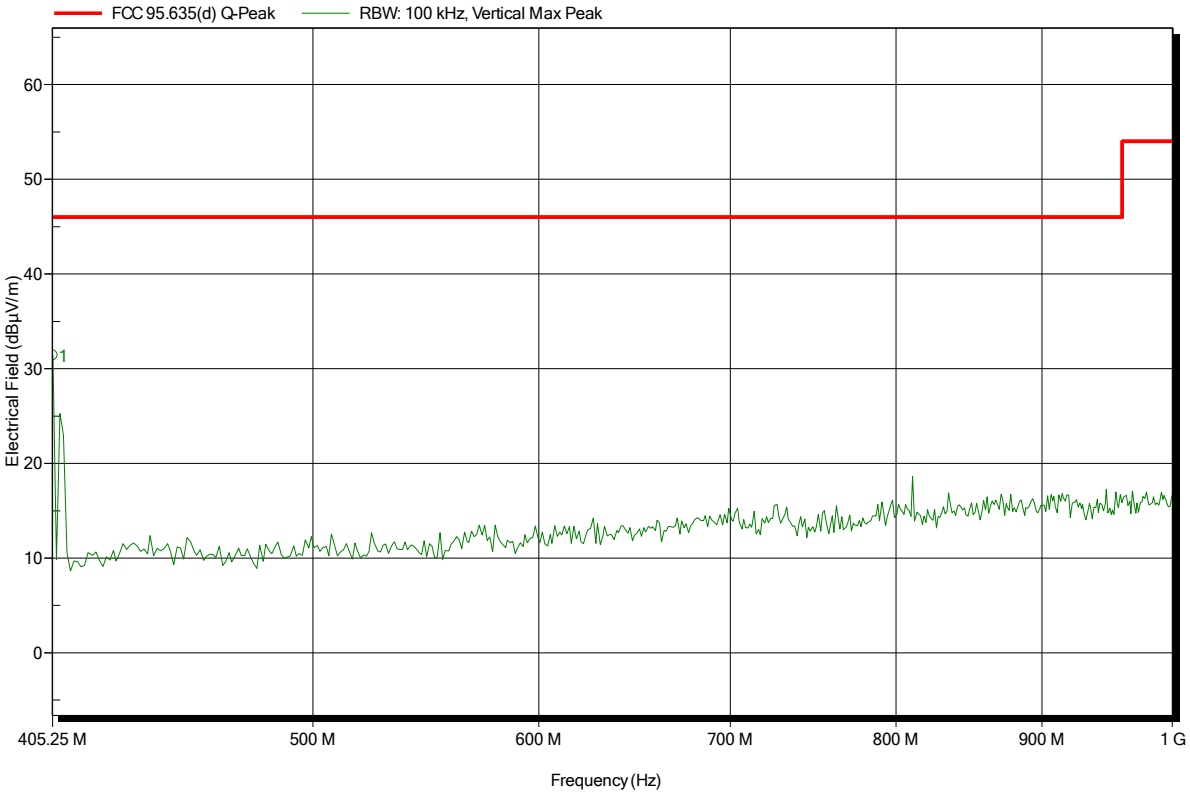
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	30.28 dBµV/m	46 dBµV/m	-15.72 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 48



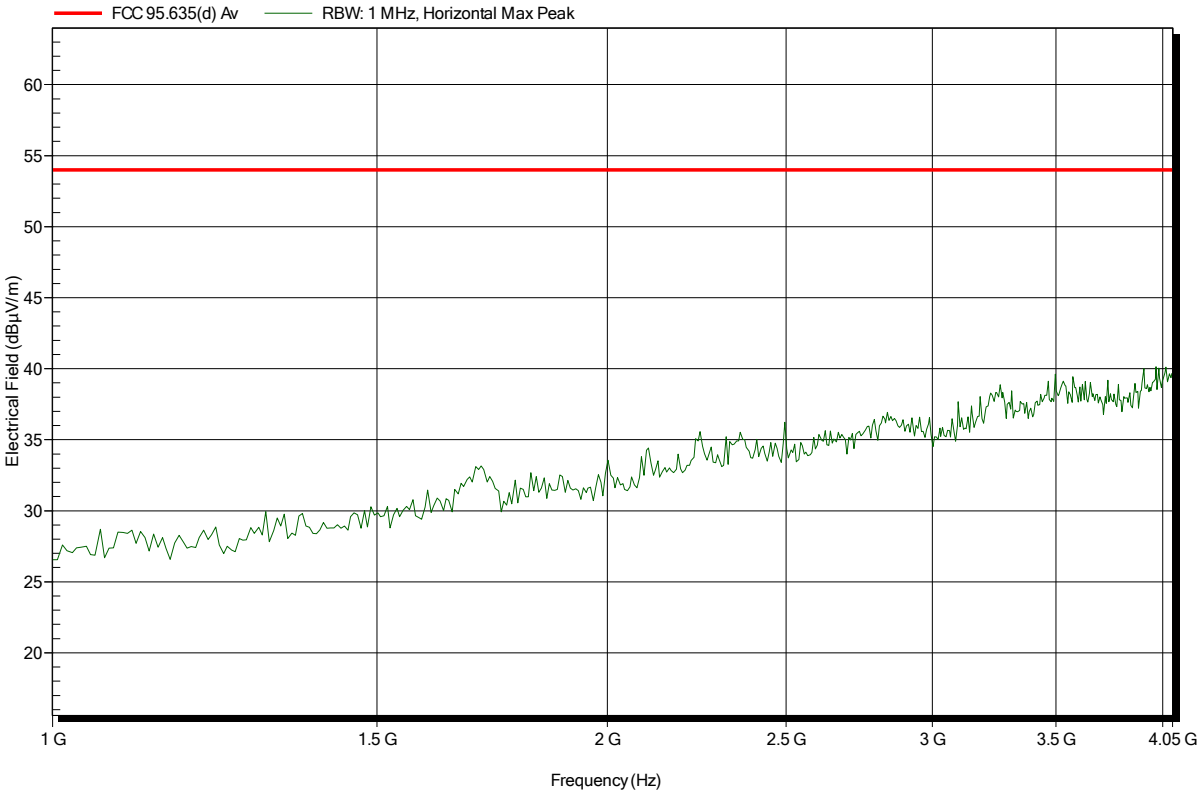
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	31.41 dBµV/m	46 dBµV/m	-14.59 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 50

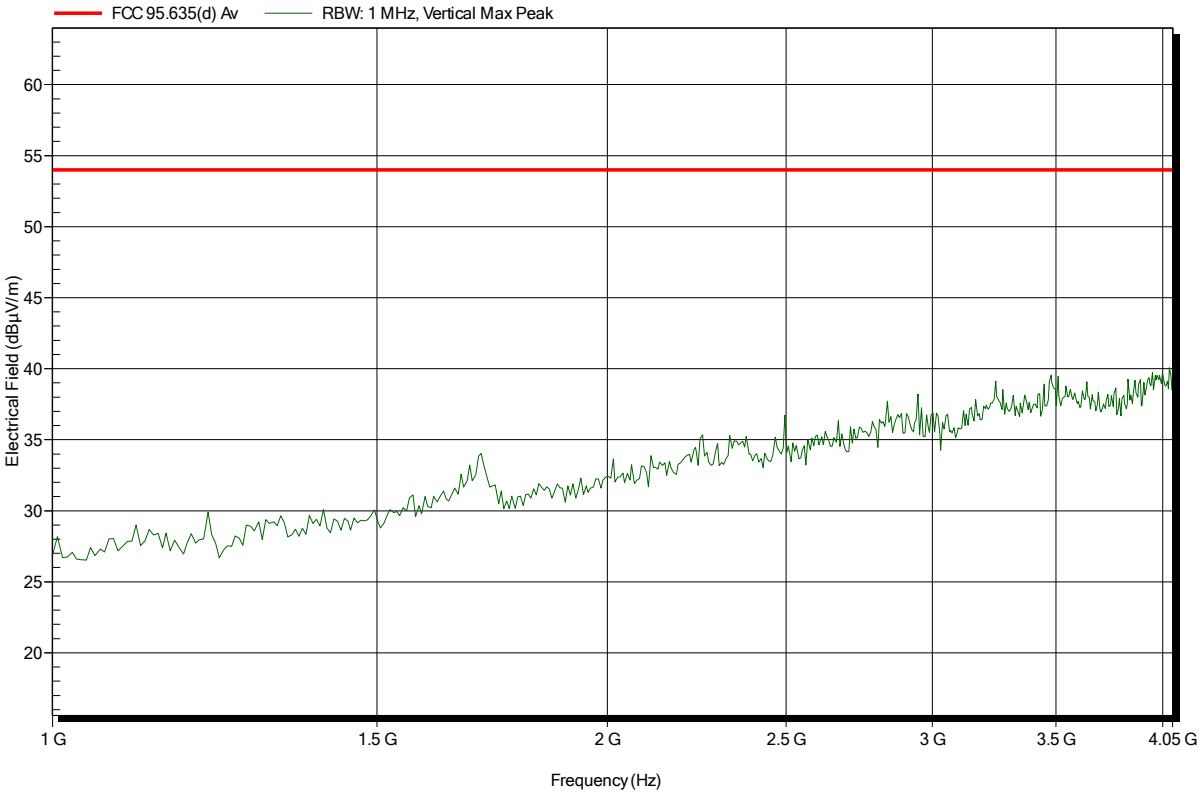


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 51

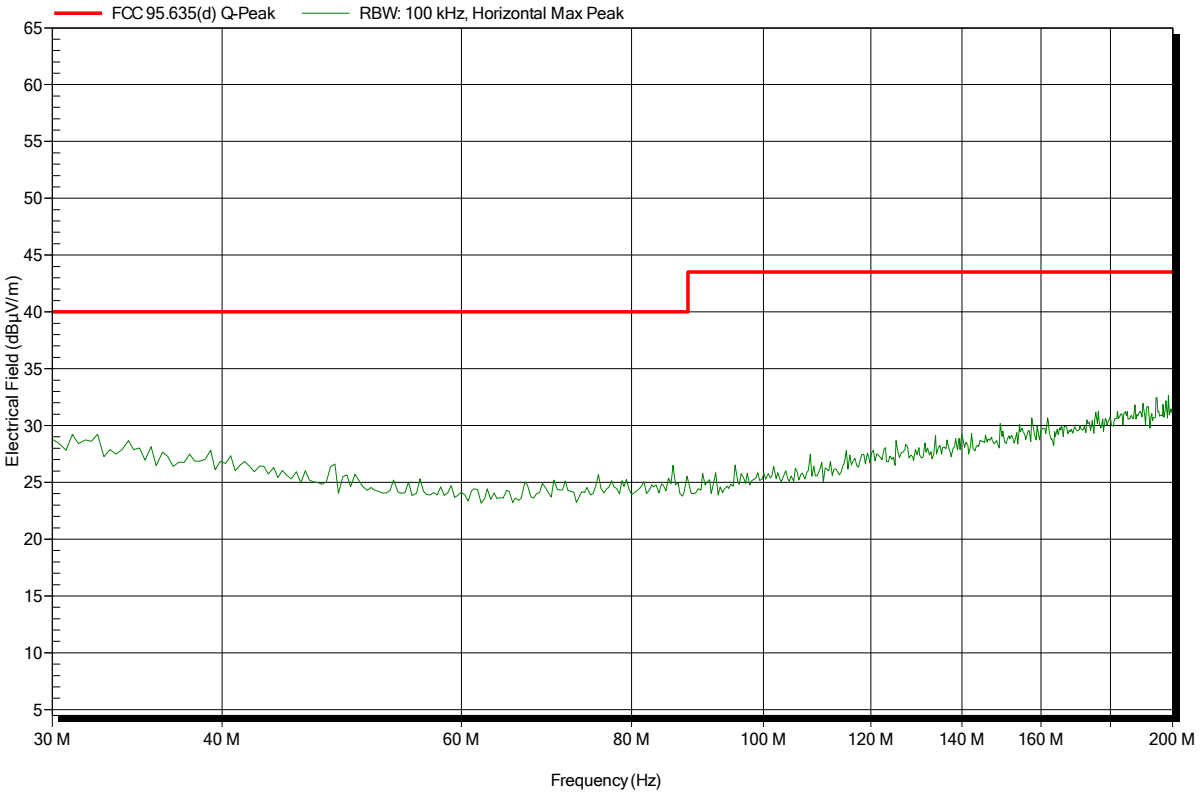


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 62

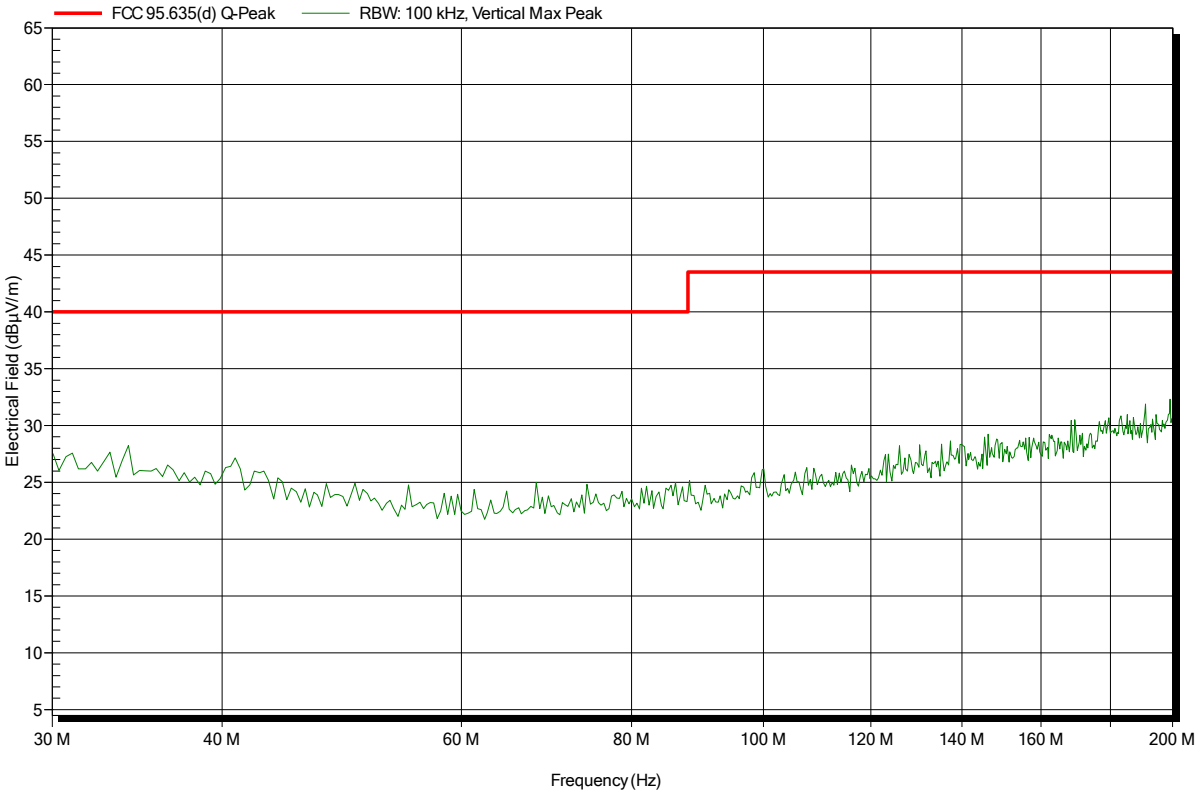


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

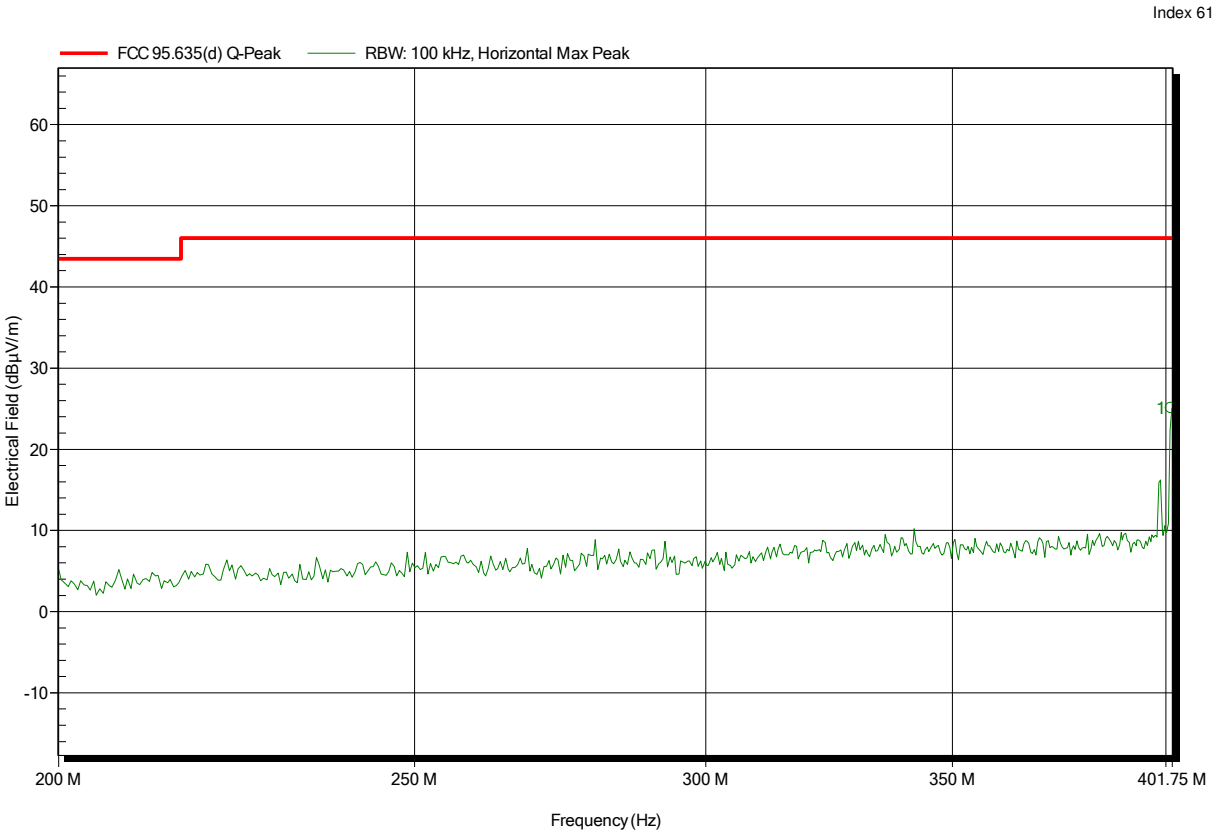
Index 63



Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	



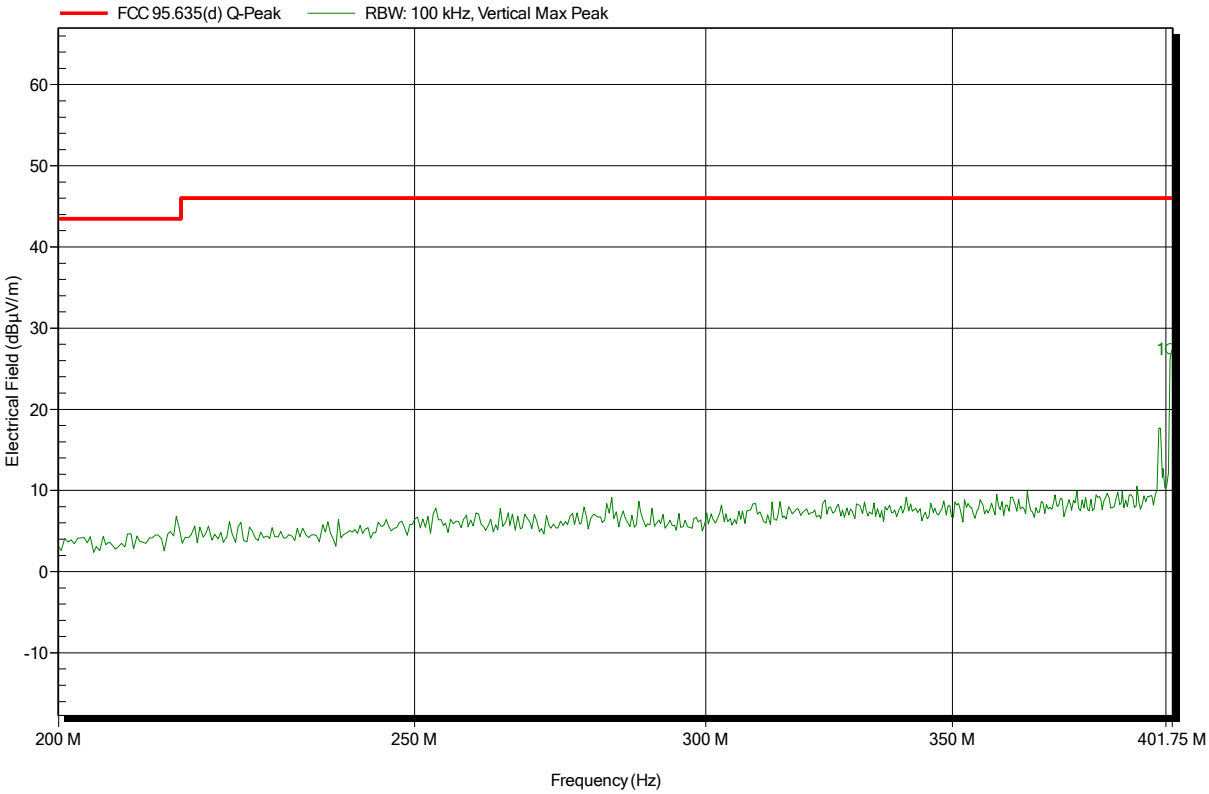
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.347 MHz	25.08 dBµV/m	46 dBµV/m	-20.92 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 60



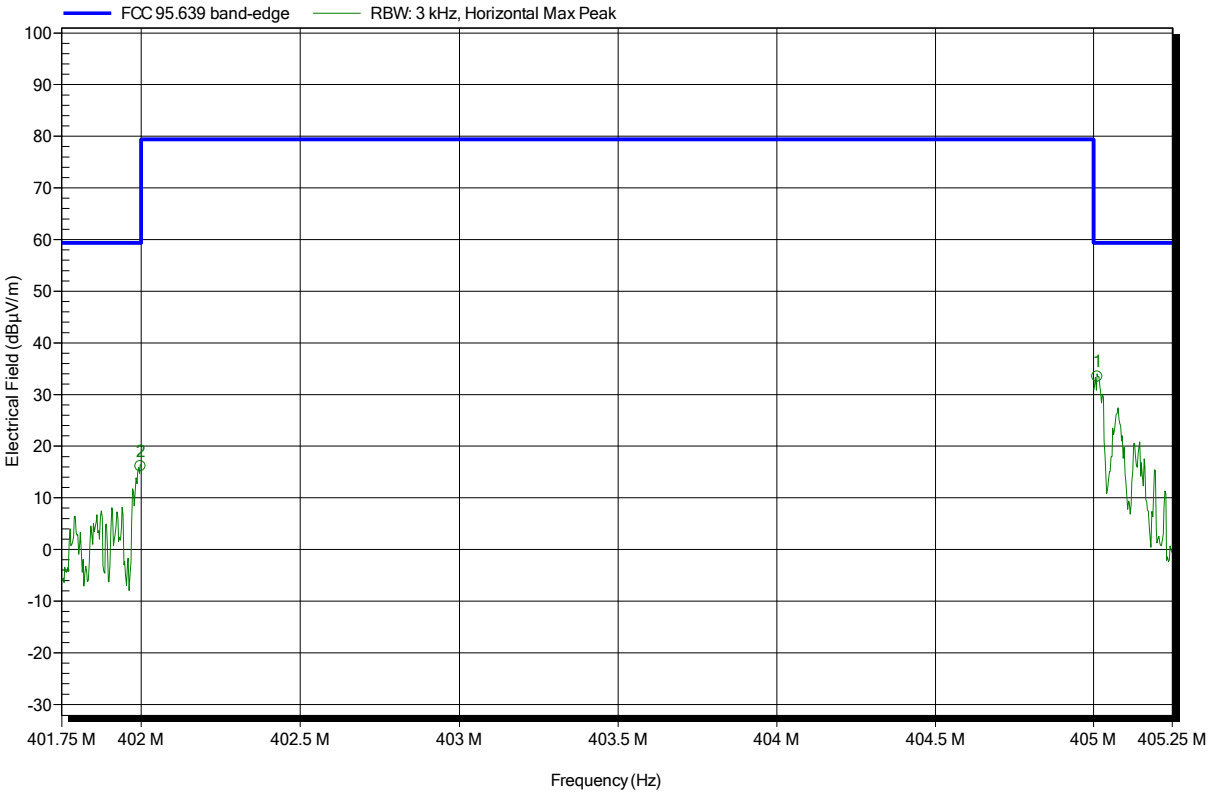
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.347 MHz	27.38 dBµV/m	46 dBµV/m	-18.62 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	Band-edge

Index 58



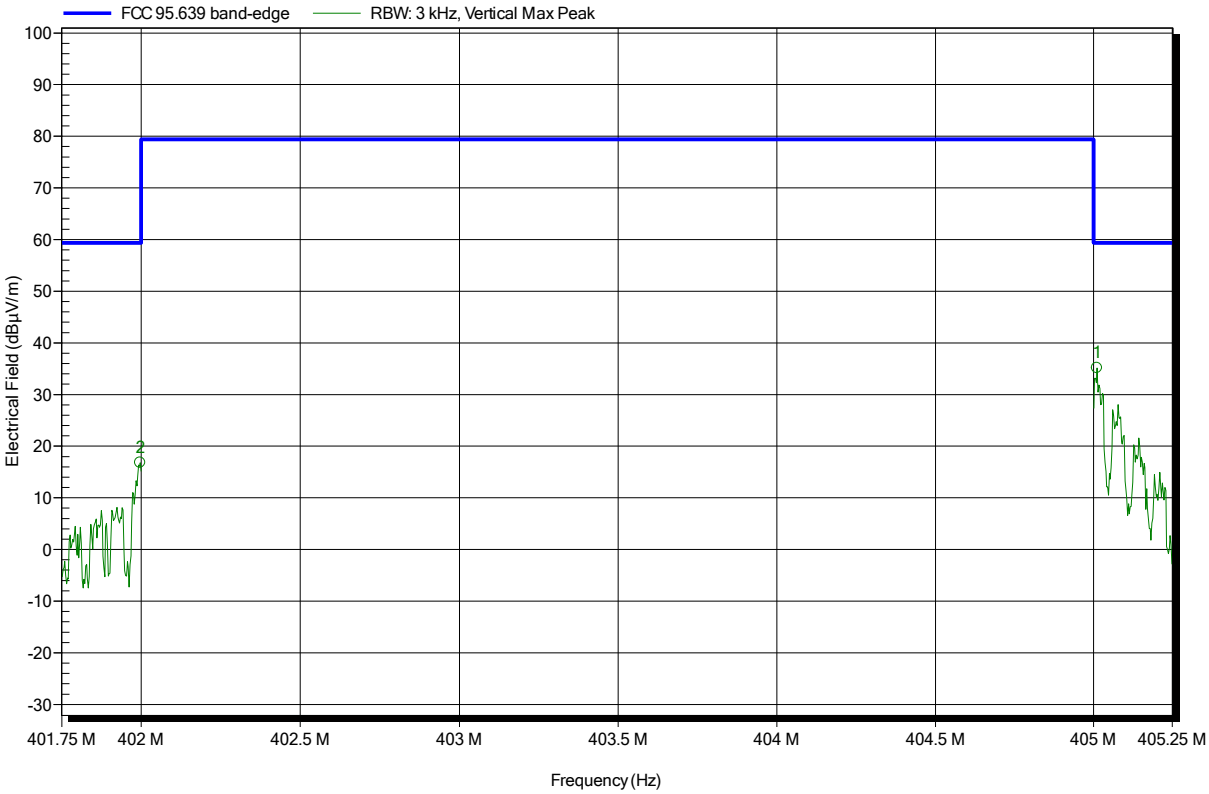
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.998 MHz	16.13 dBµV/m	59.4 dBµV/m	-43.27 dB	Pass
405.011 MHz	33.48 dBµV/m	59.4 dBµV/m	-25.92 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	Band-edge

Index 59



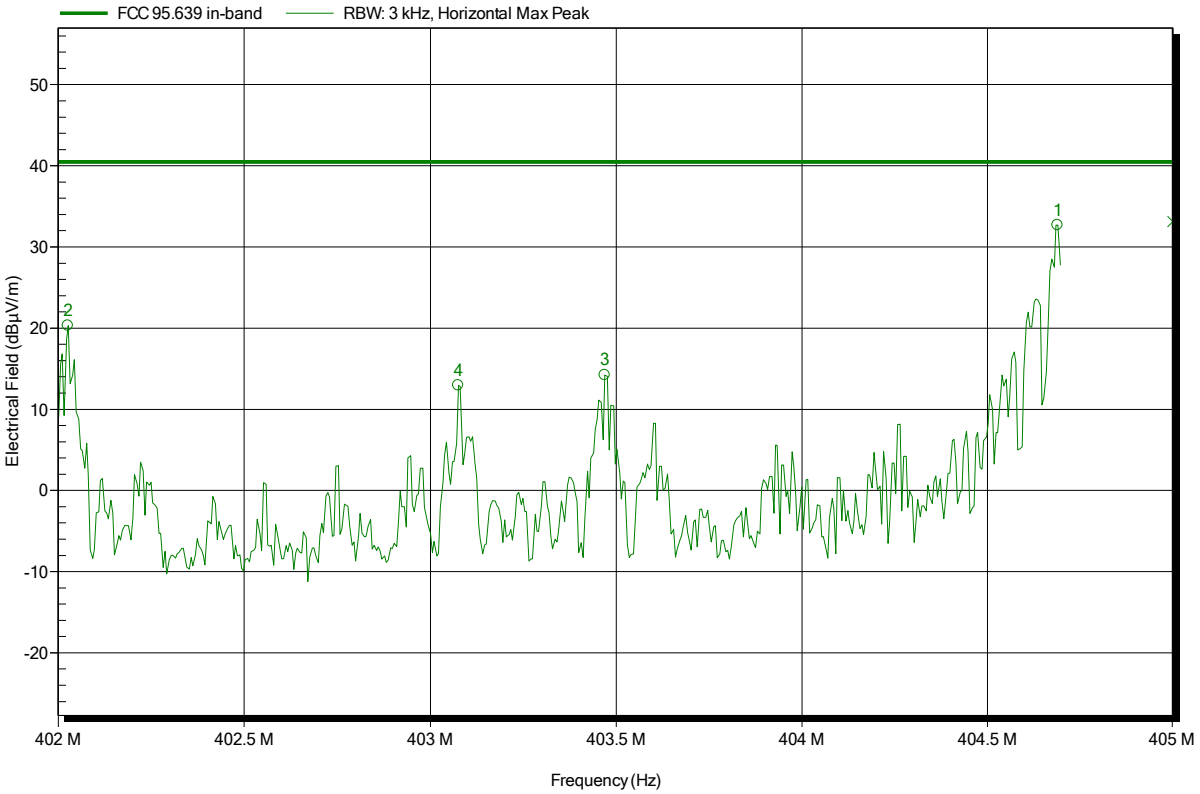
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.997 MHz	16.79 dBµV/m	59.4 dBµV/m	-42.61 dB	Pass
405.01 MHz	35.11 dBµV/m	59.4 dBµV/m	-24.29 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	In-band emissions

Index 57



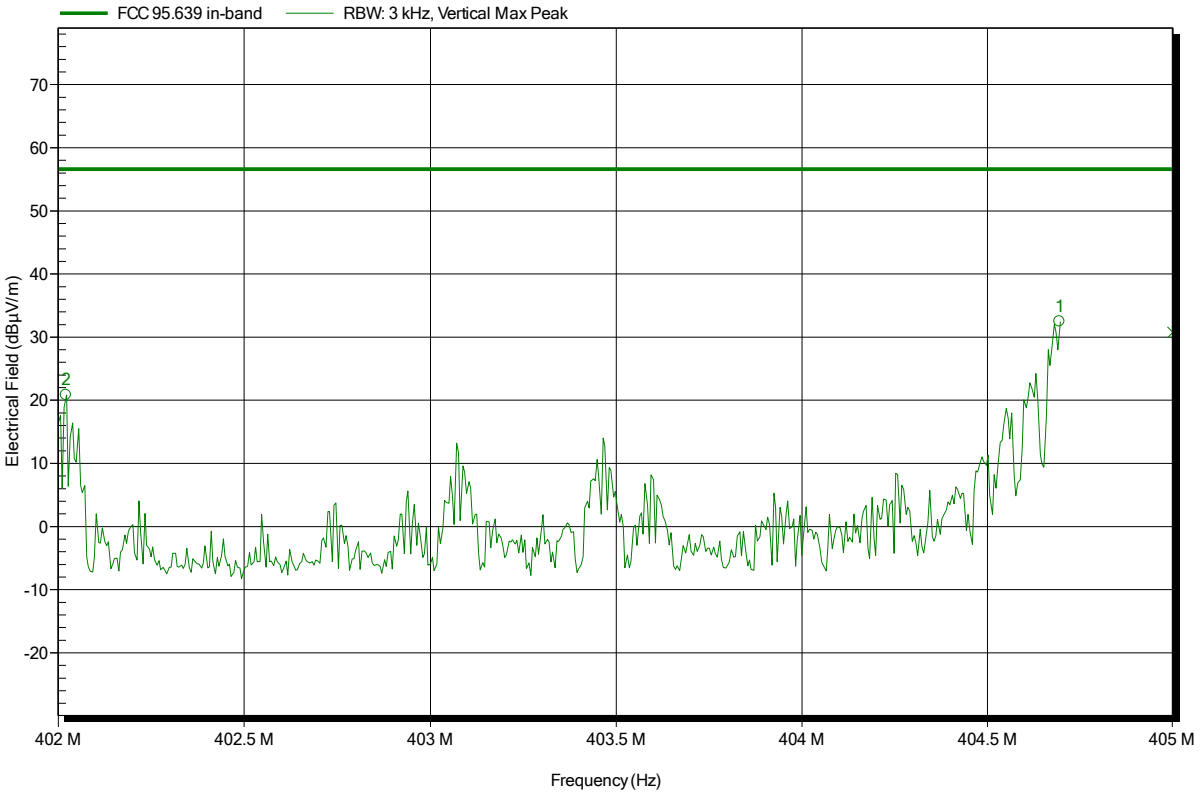
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.027 MHz	20.29 dBµV/m	40.5 dBµV/m	-20.21 dB	Pass
403.075 MHz	12.96 dBµV/m	40.5 dBµV/m	-27.54 dB	Pass
403.469 MHz	14.21 dBµV/m	40.5 dBµV/m	-26.29 dB	Pass
404.689 MHz	32.67 dBµV/m	40.5 dBµV/m	-7.83 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	In-band emissions

Index 56



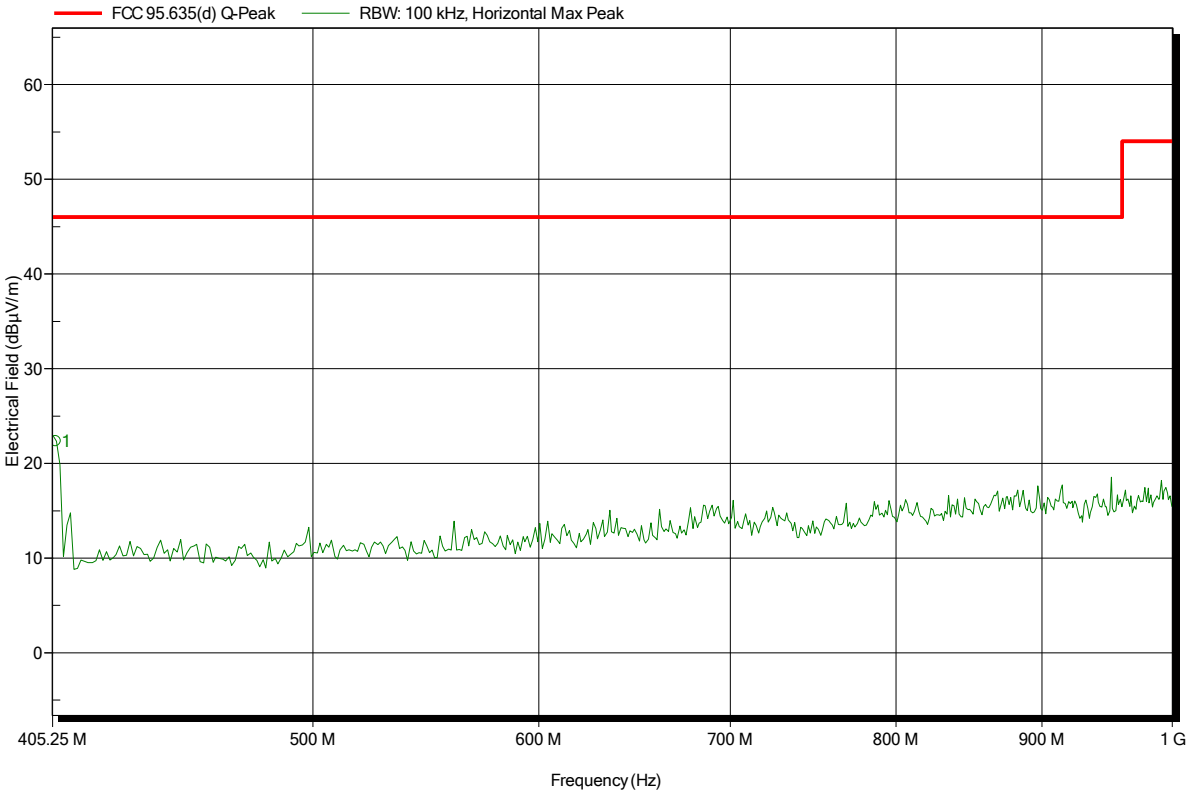
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.022 MHz	20.85 dBµV/m	56.6 dBµV/m	-35.75 dB	Pass
404.695 MHz	32.46 dBµV/m	56.6 dBµV/m	-24.14 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 54



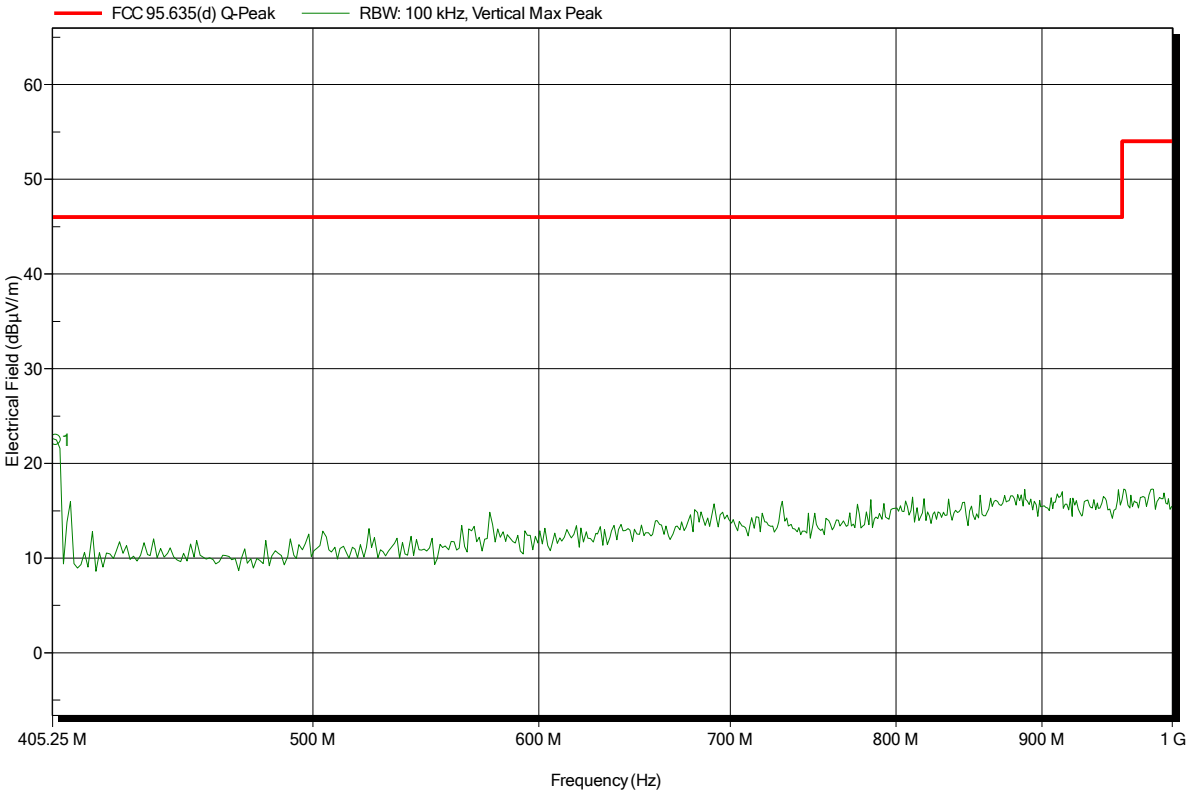
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	22.36 dBµV/m	46 dBµV/m	-23.64 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 55



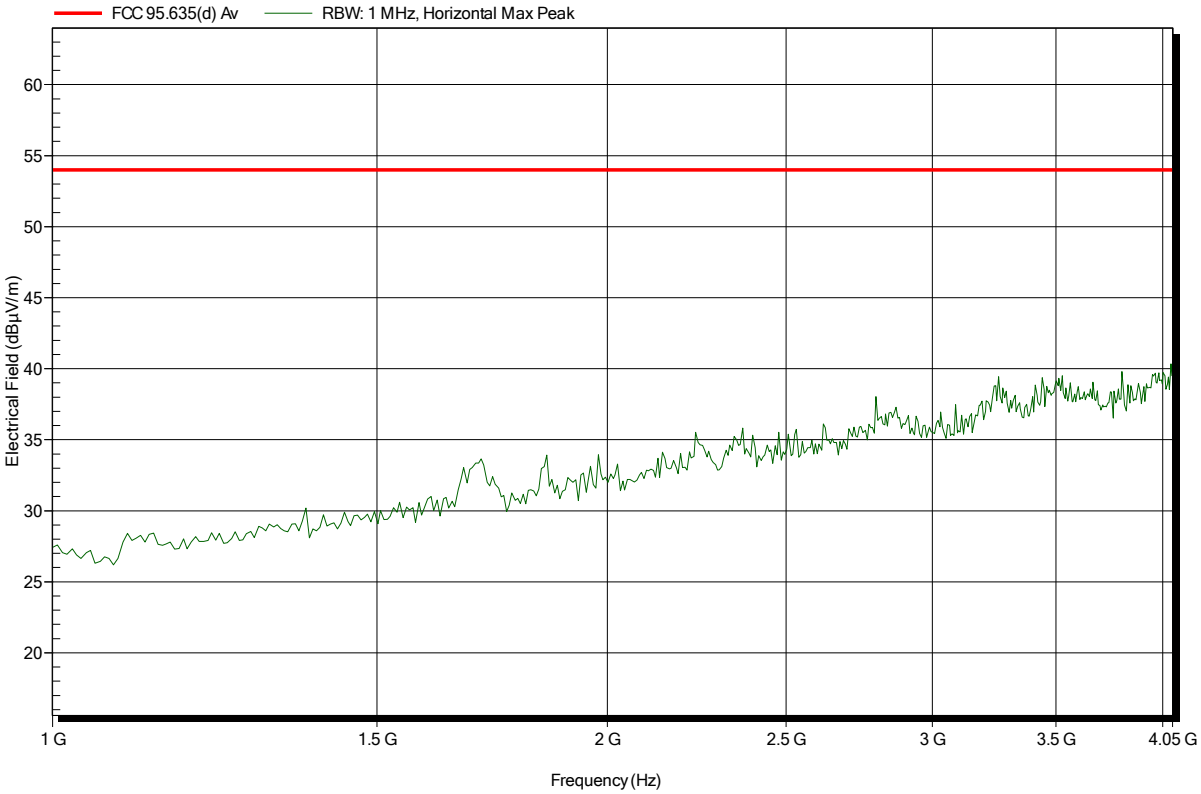
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406.44 MHz	22.49 dBµV/m	46 dBµV/m	-23.51 dB	Pass

Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 53

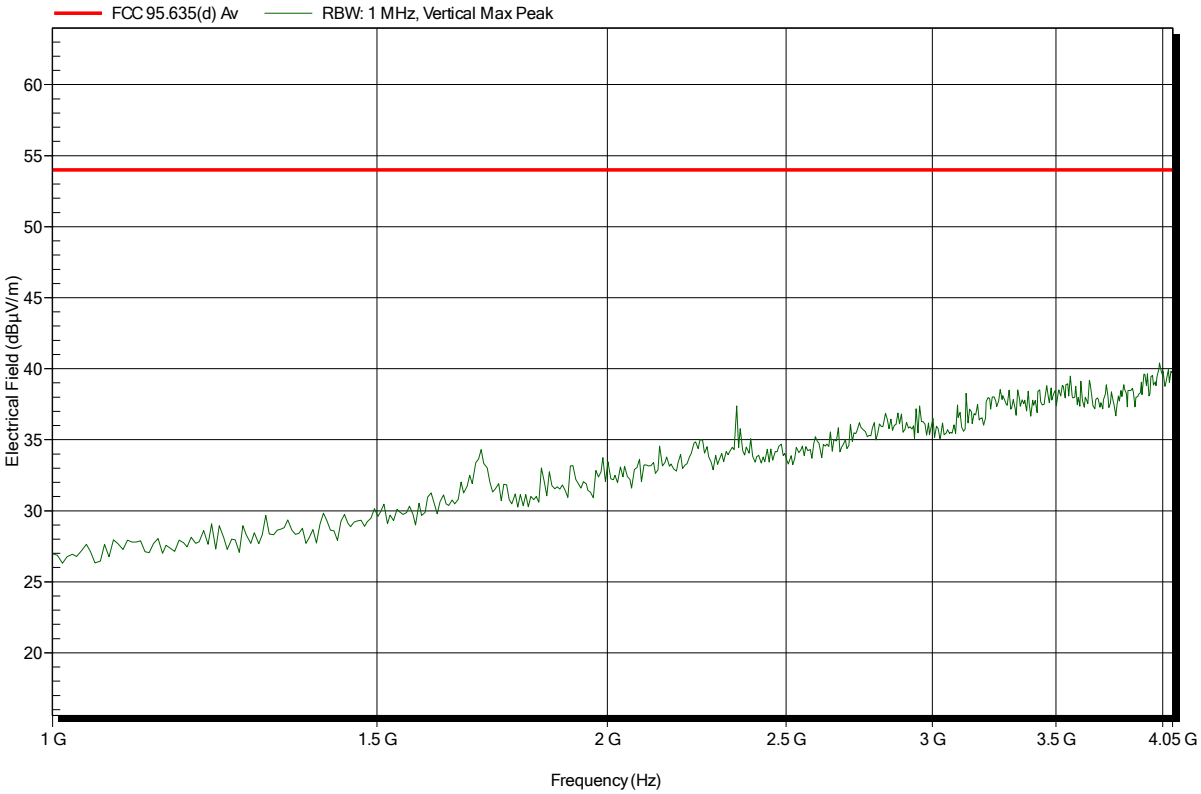


Spurious emissions according to FCC Part 95; Subpart E

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz, 2FSK
Test Date:	2015-11-02
Note:	

Index 52



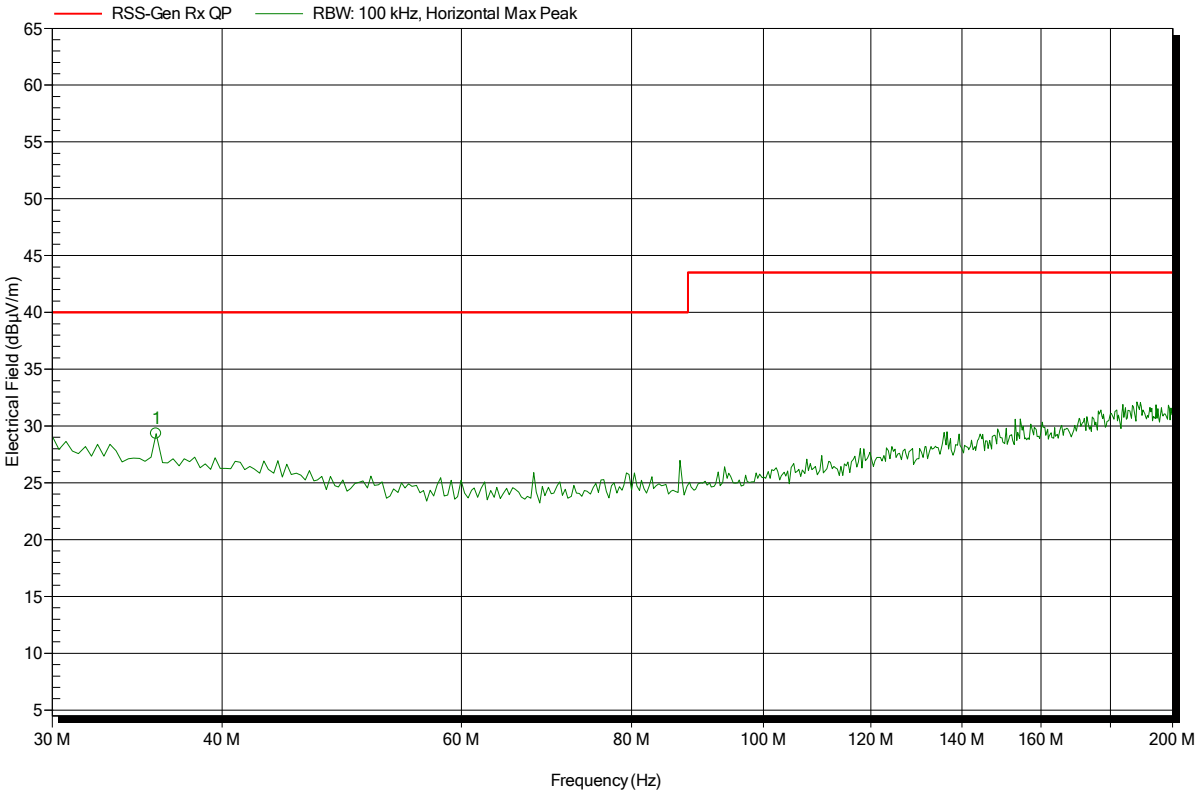
ANNEX C Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2015-11-04
Note:	

Index 27



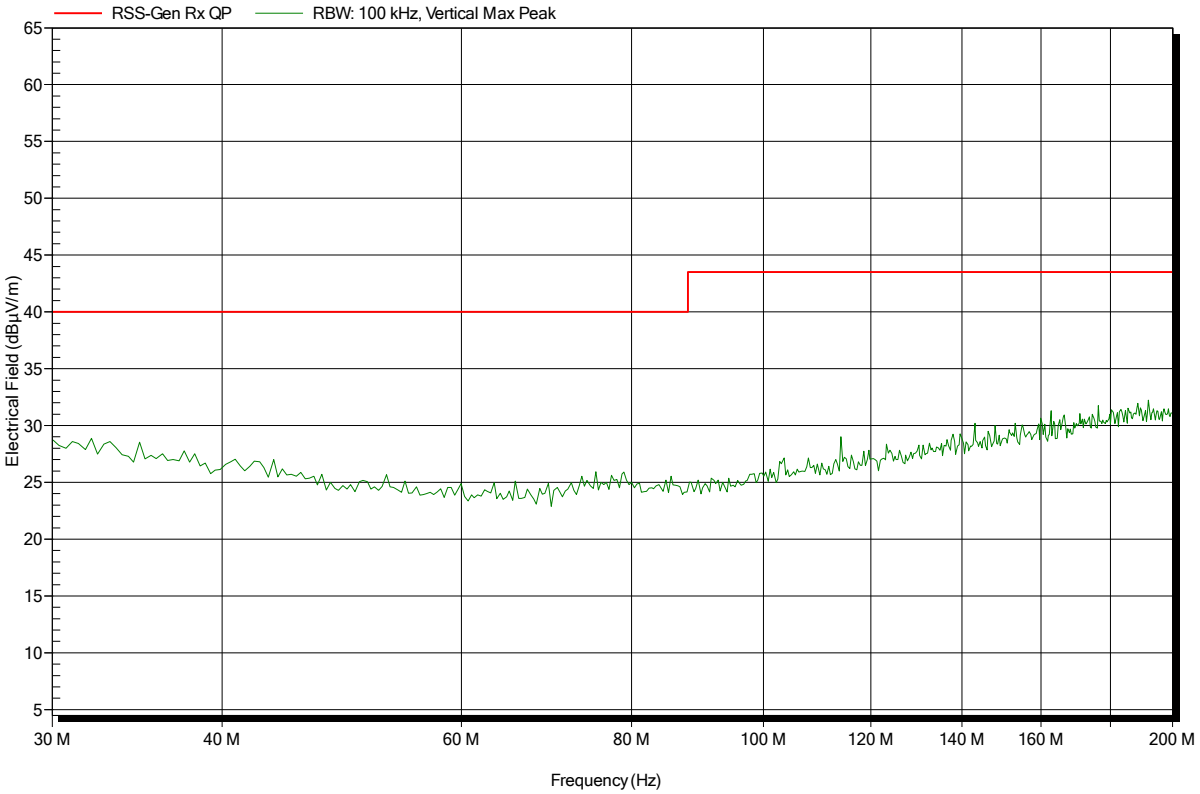
Frequency	Peak	Peak Limit	Peak Difference	Status
35.78 MHz	29.33 dBµV/m	40 dBµV/m	-10.67 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2015-11-04
Note:	

Index 28

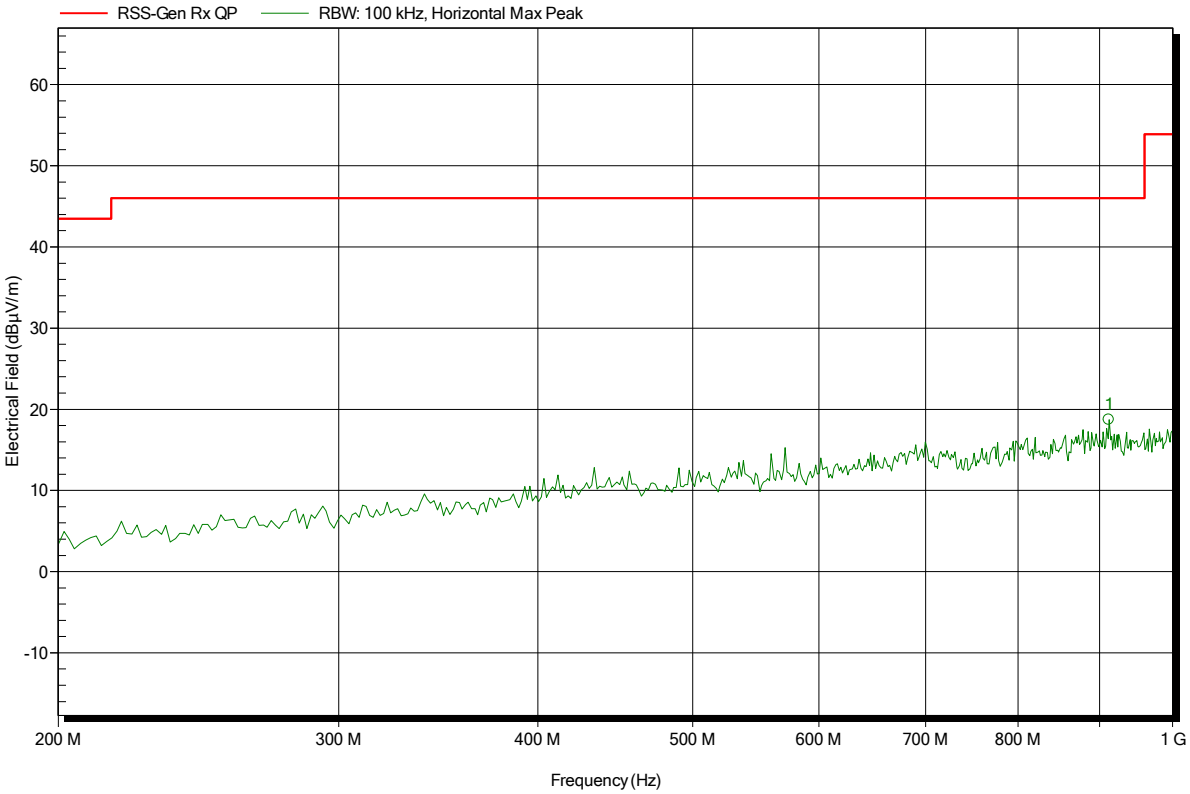


Spurious emissions according to RSS-Gen

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2015-11-04
Note:	

Index 30



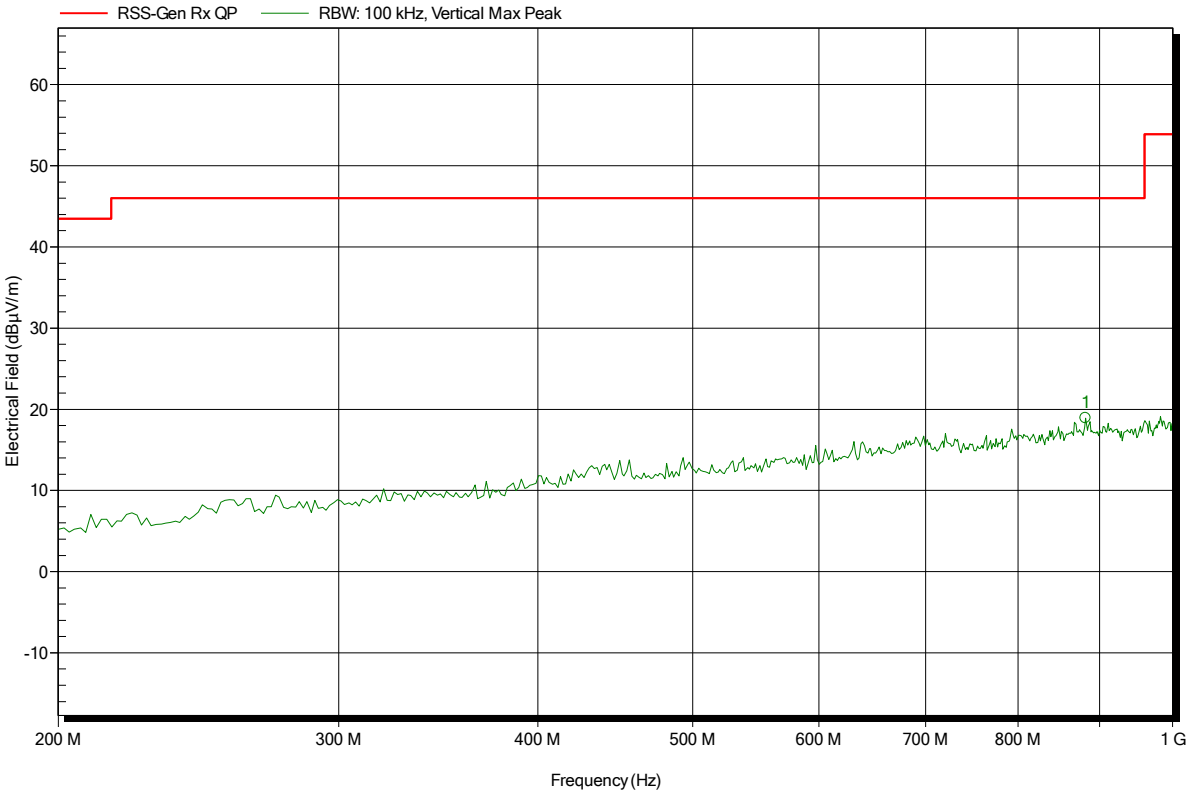
Frequency	Peak	Peak Limit	Peak Difference	Status
912 MHz	18.71 dBµV/m	46 dBµV/m	-27.29 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2015-11-04
Note:	

Index 29



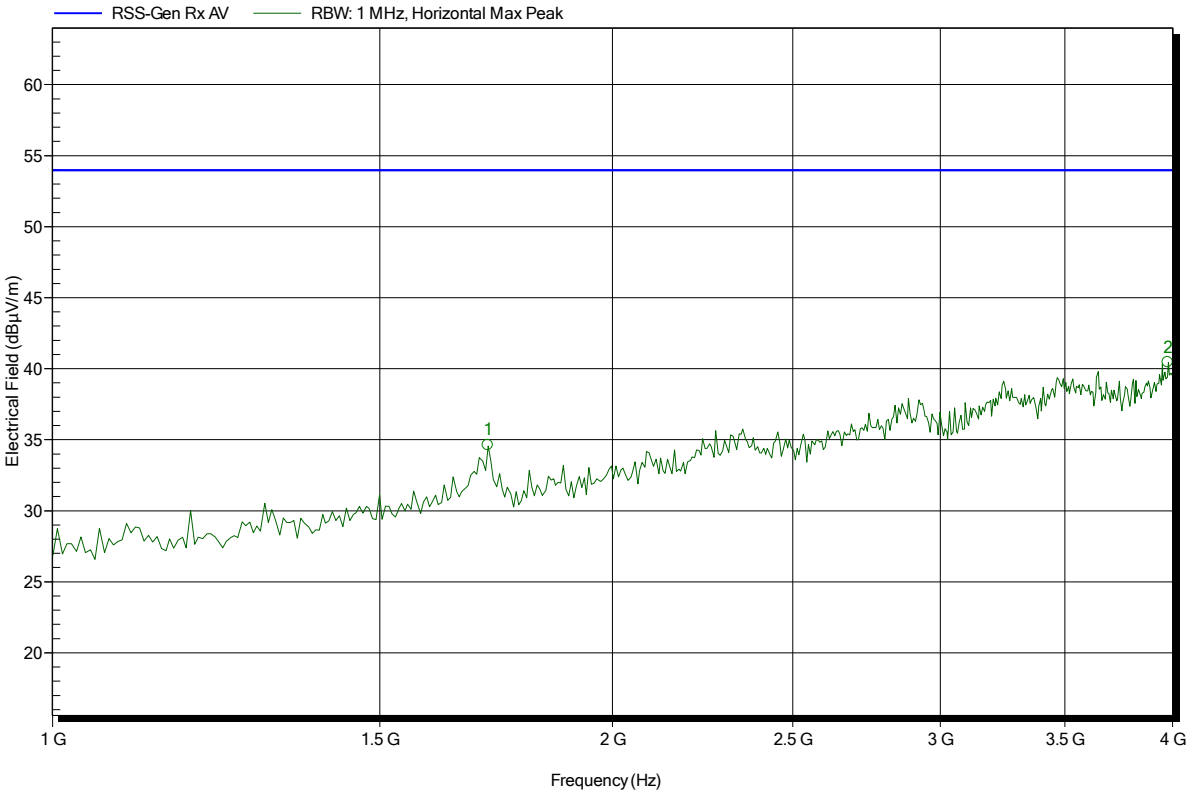
Frequency	Peak	Peak Limit	Peak Difference	Status
881.6 MHz	18.92 dBµV/m	46 dBµV/m	-27.08 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2015-11-04
Note:	

Index 31



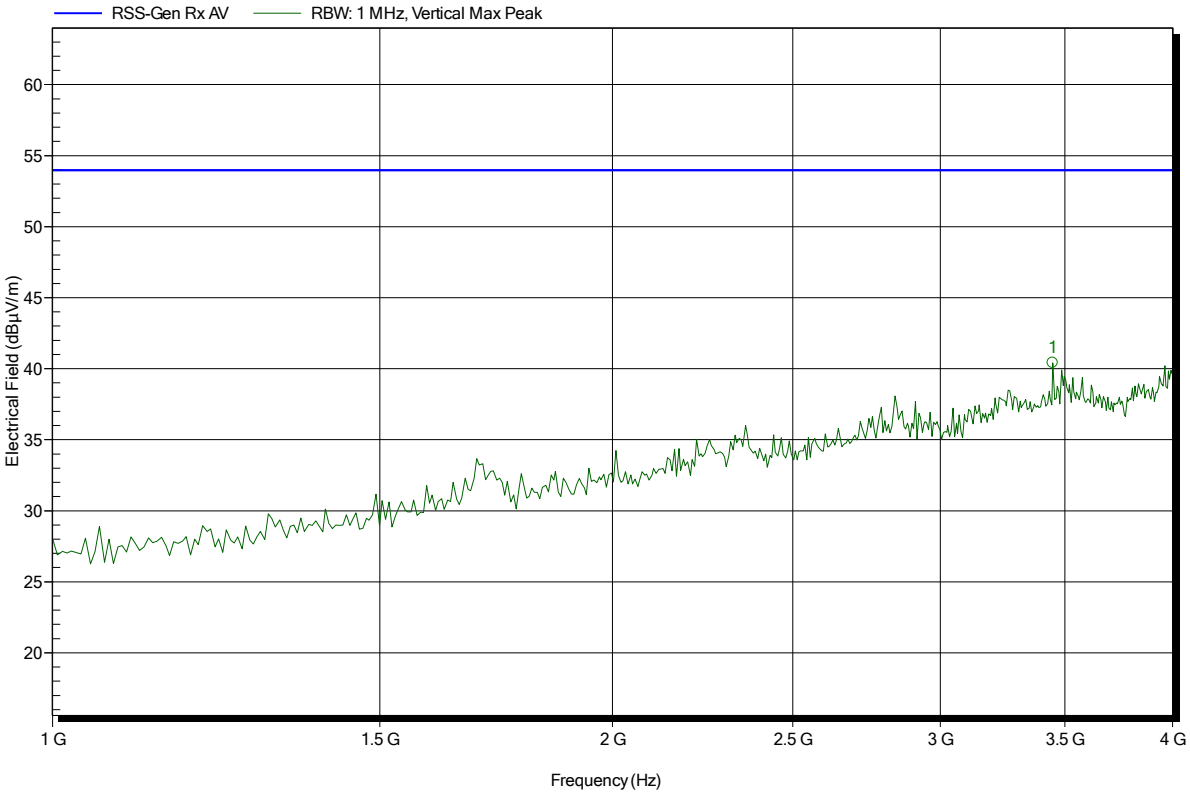
Frequency	Peak	Peak Limit	Peak Difference	Status
1.714 GHz	34.61 dBµV/m	53.98 dBµV/m	-19.37 dB	Pass
3.976 GHz	40.45 dBµV/m	53.98 dBµV/m	-13.53 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1509-5054

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2015-11-04
Note:	

Index 32



Frequency	Peak	Peak Limit	Peak Difference	Status
3.448 GHz	40.4 dBµV/m	53.98 dBµV/m	-13.58 dB	Pass