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FCC TEST REPORT

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

Report Reference No. ..... :	G0M-1803-7311-TFC95IMR-V01
Testing Laboratory ..... :	Eurofins Product Service GmbH
Address ..... :	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation ..... :	 FCC Test Firm Designation Number: DE0008 IC Testing Laboratory site: 3470A-2
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…….. ..... :	complete Radio compliance test
Equipment under test (EUT):	
Product description	ICD-4200 / Implantable Cardioverter Defibrillator
Model No.	Acticor 7 HF-T
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware version	Rev.: 0A
Firmware / Software version	RAM: 5.0 / ROM: 5.0
	FCC-ID: QRI-ICD4200 IC: 4708A-ICD4200
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 ..... :	2018-04-03	
Date (s) of performance of tests ..... :	2018-04-03 - 2018-04-06	
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 ..... :	2018-04-12	
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.

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-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. The Acticor 7 HF-T Ser.60520233 was selected for the measurements.

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ICD-4200 Family Explanation

1. Family Letter

	Product Name	Type	no. of chambers	Connector RV	Connector LV	HVIN
1	Acticor 7 HF-T QP	CRT	3	DF-4	IS-4	429522
2	Acticor 7 HF-T	CRT	3	DF-4	IS-1	429523
3	Acticor 7 DR-T	DR	2	DF-4	-	429524
4	Acticor 7 VR-T DX	DX*	1	DF-4	-	429525
5	Acticor 7 VR-T	VR	1	DF-4	-	429526
6	Rivacor 7 HF-T QP	CRT	3	DF-4	IS-4	429532
7	Rivacor 7 HF-T	CRT	3	DF-4	IS-1	429533
8	Rivacor 7 DR-T	DR	2	DF-4	-	429534
9	Rivacor 7 VR-T DX	DX*	1	DF-4	-	429535
10	Rivacor 7 VR-T	VR	1	DF-4	-	429536
11	Rivacor 5 HF-T QP	CRT	3	DF-4	IS-4	429561
12	Rivacor 5 HF-T	CRT	3	DF-4	IS-1	429562
13	Rivacor 5 DR-T	DR	2	DF-4	-	429563
14	Rivacor 5 VR-T	DX*	1	DF-4	-	429564
15	Rivacor 5 VR-T	VR	1	DF-4	-	429565
16	Rivacor 3 HF-T QP	CRT	3	DF-4	IS-4	429571
17	Rivacor 3 HF-T	CRT	3	DF-4	IS-1	429572
18	Rivacor 3 DR-T	DR	3	DF-4	IS-4	429573
19	Rivacor 3 VR-T	VR	1	DF-4	-	429574

*: additional atrial detection (therapy function)

2. Family description

Header difference overview

Variant	*Family member's*
1	VR-T/DF4
2	DR-T/DF4, VR-T (DX)/DF4
3	HF-T/DF4
4	HF-T/QP (DF4 / IS4)

table 1: Header variants

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

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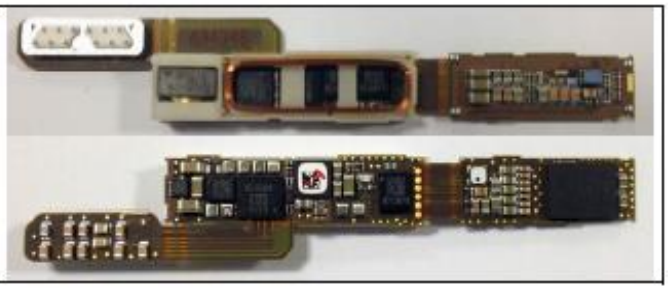
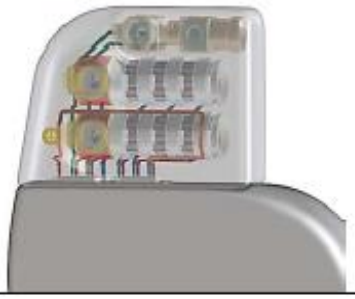
2.1 PC-Board

All family devices are using the same electronic.

PC Board #2 12pol feedtrough Schematic file SCH-0232_0A.pdf	

2.2 RF-Antenna

All family members are equipped with the same RF antenna.

DF4 header with antenna


Signature: ***Date:*** **4/13/2018**

Dirk König
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Version History

Version	Issue Date	Remarks	Revised by
01	2018-04-12	Initial Release	

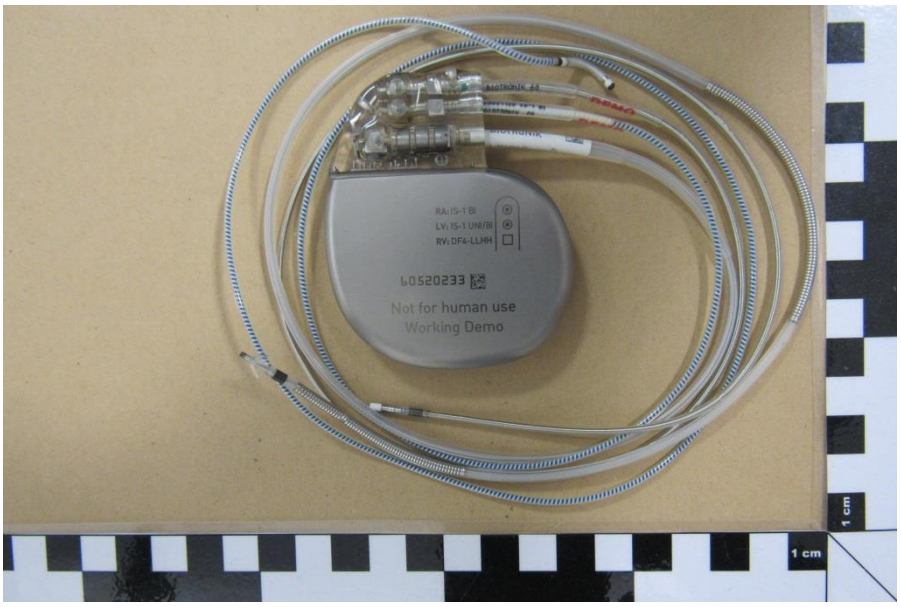
REPORT INDEX

1 Equipment (Test item) Description

Description	ICD-4200 / Implantable Cardioverter Defibrillator	
Model	Acticor 7 HF-T	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Serial number	60520233	
Hardware version	Rev.: 0A	
Software / Firmware version	RAM: 5.0 / ROM: 5.0	
PMN	Acticor 7 HF-T	
HVIN	429523	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRI-ICD4200	
IC	4708A-ICD4200	
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	2-FSK	
Emission designator	F1D	
Number of channels	9	
Channel spacing	300 kHz	
Spectrum access	LBT/AFA (channel access controlled by ULP-AMI-P device outside the human body)	
Number of antennas	1	
Antenna	Type	integrated
	Model	4200
	Manufacturer	Biotronik
	Gain	-22.4 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

1.1 Photos - Equipment external

EUT Acticor 7 HF-T (Master Device)


EUT Acticor 7 HF-T Top


EUT Acticor 7 HF-T Bottom


Acticor 7 VR-T Top


Acticor 7 VR-T Bottom


Acticor 7 VR-T DX Top


Acticor 7 VR-T DX Bottom

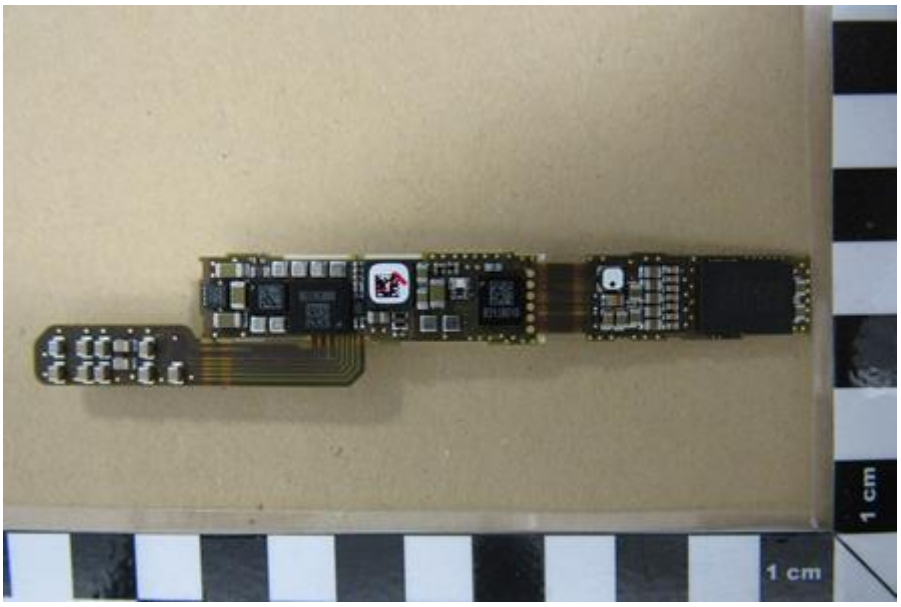

Acticor 7 DR-T Top

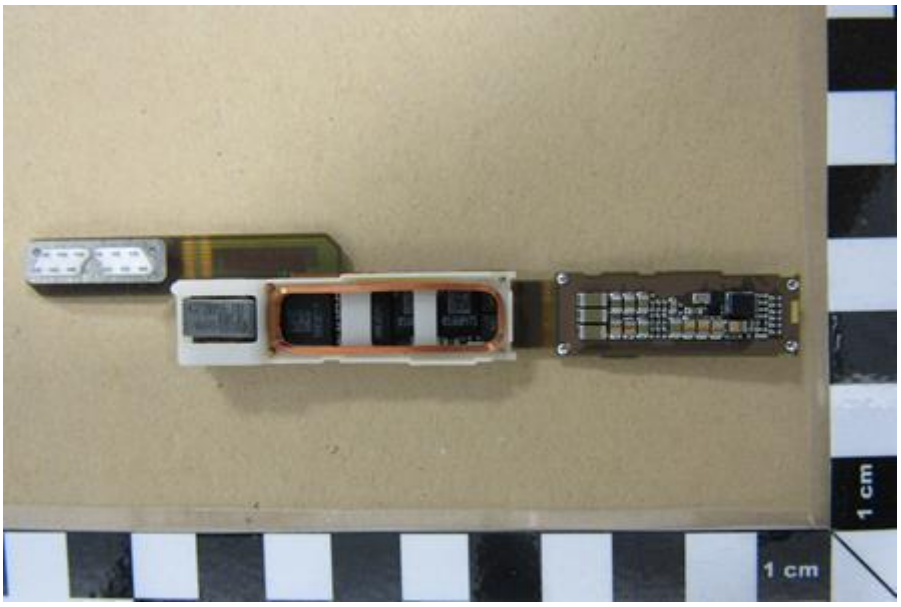

Acticor 7 DR-T Bottom


Activator 7 HF-T QP Top

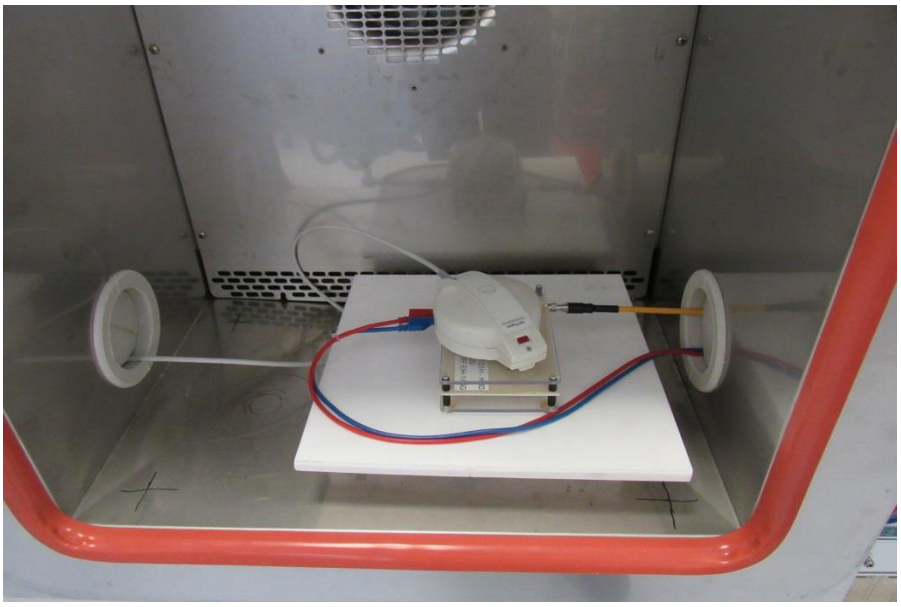

Acticor 7 HF-T QP Bottom

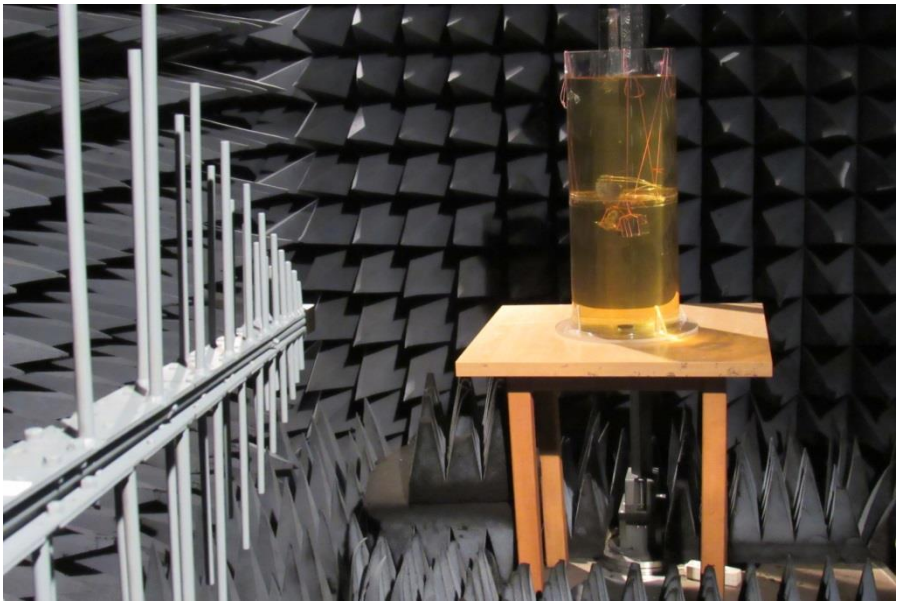

1.2 Photos - Equipment internal

PCB TOP


PCB Bottom


1.3 Photos – Test setup

Conducted Setup


Radiated Setup


1.4 Photos – Auxiliary/Associated Equipment

AE1: Cardio Messenger II


AE2: Programming Head PGH 3000


AE3: TelBox II


1.5 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Cardio Messenger	Biotronk	Cardio Messenger II	Companion device
AE2	Communication Adaptor	Biotronk	TelBox II	-
AE3	Programming Head	Biotronk	PGH 3000	-

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

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.6 Test Modes

Mode #	Description	
Unmodulated	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated 1	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = FSK Data rate 32.848 kBit/s Duty cycle = 100 % Power level = Maximum
Modulated 2	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = FSK Data rate 82.122 kBit/s Duty cycle = 100 % Power level = Maximum
Monitoring	General conditions:	EUT powered by battery. EUT adjusted to monitoring conditions by with companion device.
	Radio conditions:	Mode = standalone transmit Modulation = 2-FSK Duty cycle = normal
Receive	General conditions:	EUT powered on
	Radio conditions:	Mode = standalone receive Modulation = 2-FSK

1.7 Test Equipment Used During Testing

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

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2017-07	2018-07

Emission Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2017-07	2018-07

Frequency Stability					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2017-07	2018-07

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Fully-anechoic chamber	Frankonia	AC 4	EF00200	-	-
Spectrum Analyzer	R&S	FSU 26	EF01003	2017-07	2018-07
LPD Antenna	R&S	HL 223	EF00212	2016-04	2019-04

Radiated spurious emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF00062	-	-
Spectrum Analyzer	R&S	FSU 26	EF01003	2017-07	2018-07
Biconical Antenna	R&S	HK 116	EF00030	2016-04	2019-04
LPD Antenna	R&S	HL 223	EF00187	2016-05	2019-05
LPD Antenna	R&S	HL 025	EF00327	2015-10	2018-10

1.8 Sample emission level calculation

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

Reading:

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

A.F.:

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

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

Net:

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

Limit:

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

Limit (dBµV/m) = 20*log (µV/m)

Margin:

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

Example only:

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

1.9 Simulated human body

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

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

Measured tissue parameters:

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

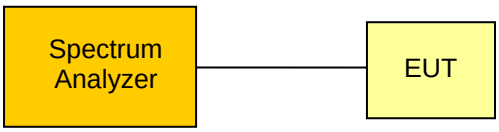
3.1 Test Conditions and Results – Occupied Bandwidth

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

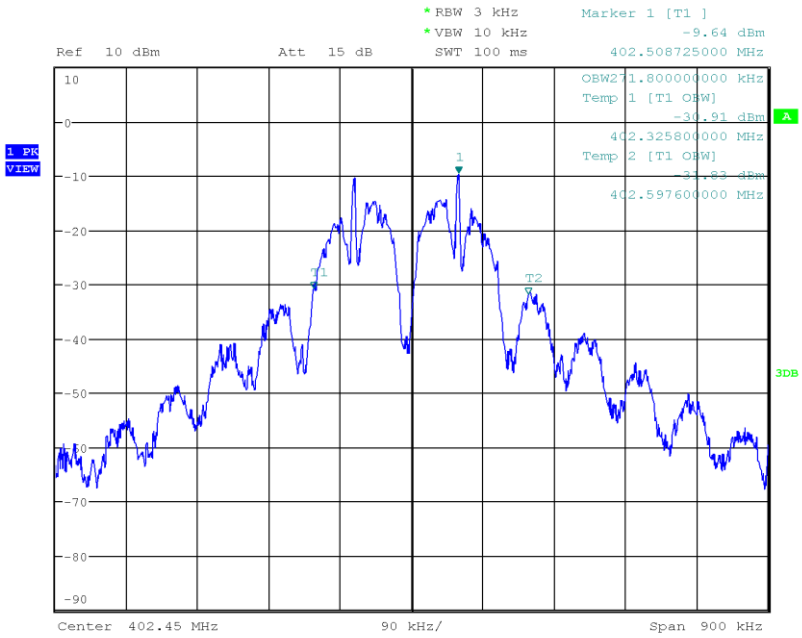
Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	32	402.45	271.800	≤ 300	PASS
F_{MID}	32	403.65	267.075	≤ 300	PASS
F_{HIGH}	32	404.85	292.950	≤ 300	PASS
F_{LOW}	82	402.45	201.150	≤ 300	PASS
F_{MID}	82	403.65	204.975	≤ 300	PASS
F_{HIGH}	82	404.85	208.800	≤ 300	PASS

Comments:

Occupied Bandwidth – F_{LOW} (32kBit)

Occupied Bandwidth RSS-243

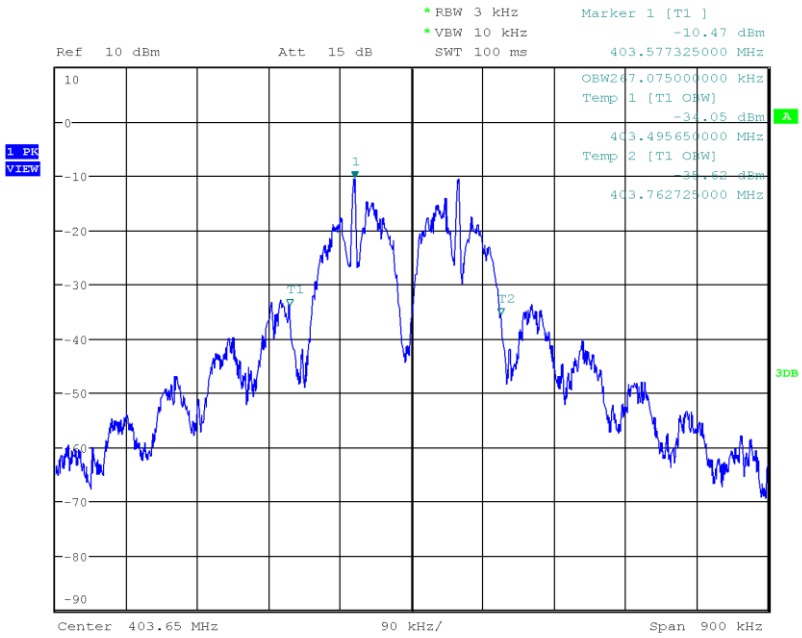
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 32 kbps, Channel: 8, 402.45 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Occupied Bandwidth [kHz]:	271.800



Occupied Bandwidth - F_{MID} (32kBit)

Occupied Bandwidth RSS-243

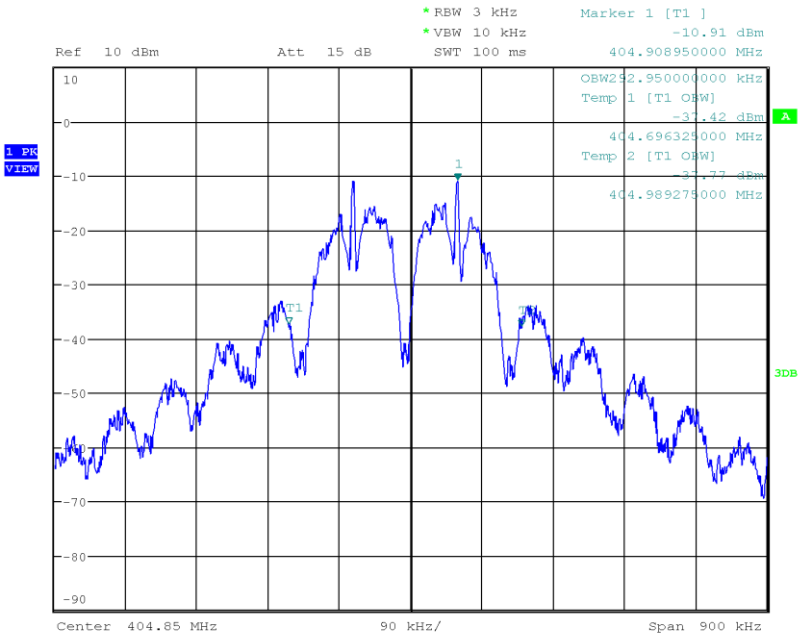
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 32 kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Occupied Bandwidth [kHz]:	267.075



Occupied Bandwidth – F_{HIGH} (32kBit)

Occupied Bandwidth RSS-243

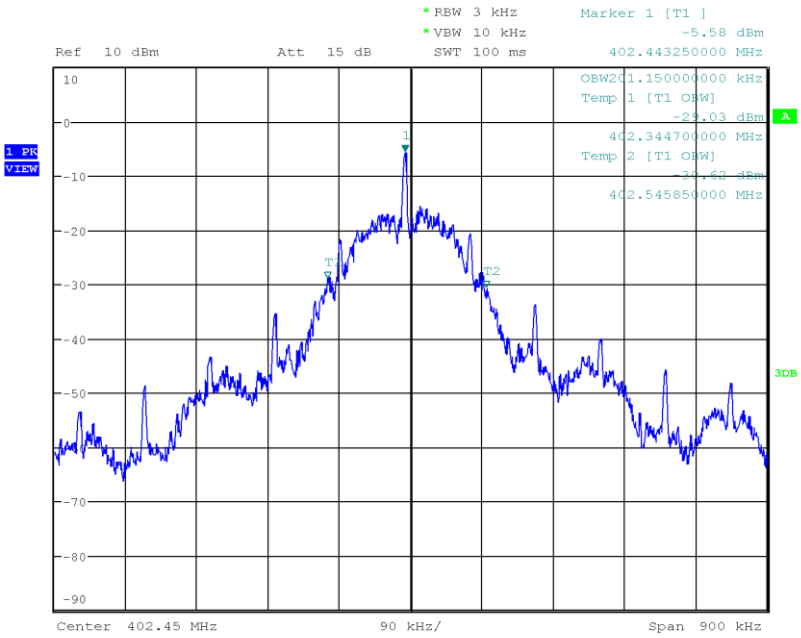
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 32 kbps, Channel: 7, 404.85 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Occupied Bandwidth [kHz]:	292.950



Occupied Bandwidth – F_{LOW} (82kBit)

Occupied Bandwidth RSS-243

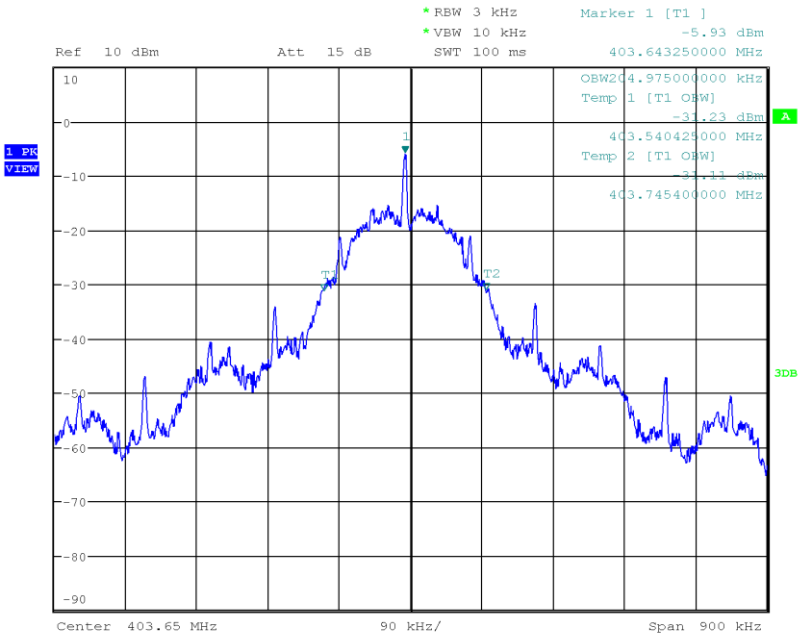
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 82kbps, Channel: 8, 402.45 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Occupied Bandwidth [kHz]:	201.150



Occupied Bandwidth – F_{MID} (82kBit)

Occupied Bandwidth RSS-243

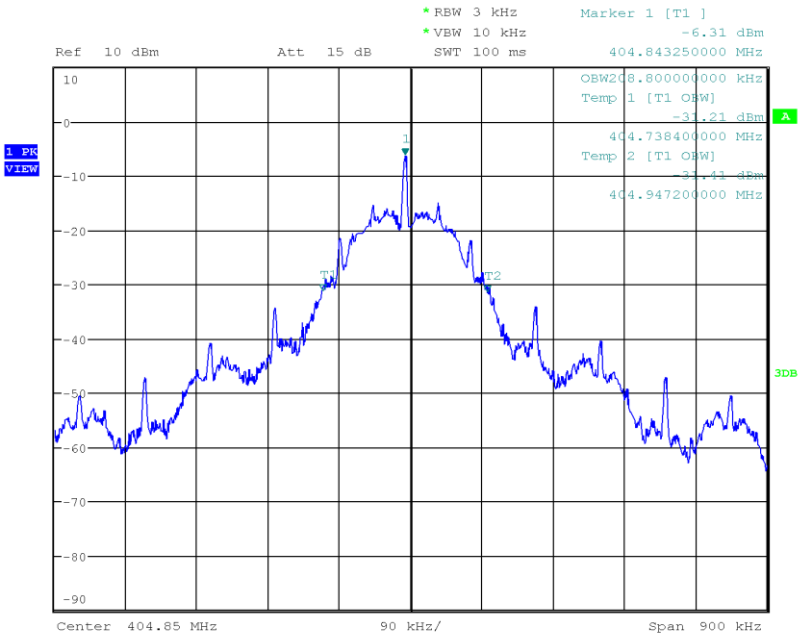
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 82kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Occupied Bandwidth [kHz]:	204.975



Occupied Bandwidth – F_{HIGH} (82kBit)

Occupied Bandwidth RSS-243

Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 82kbps, Channel: 7, 404.85 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Occupied Bandwidth [kHz]:	208.800



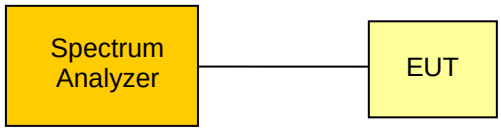
3.2 Test Conditions and Results – Emission Bandwidth

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

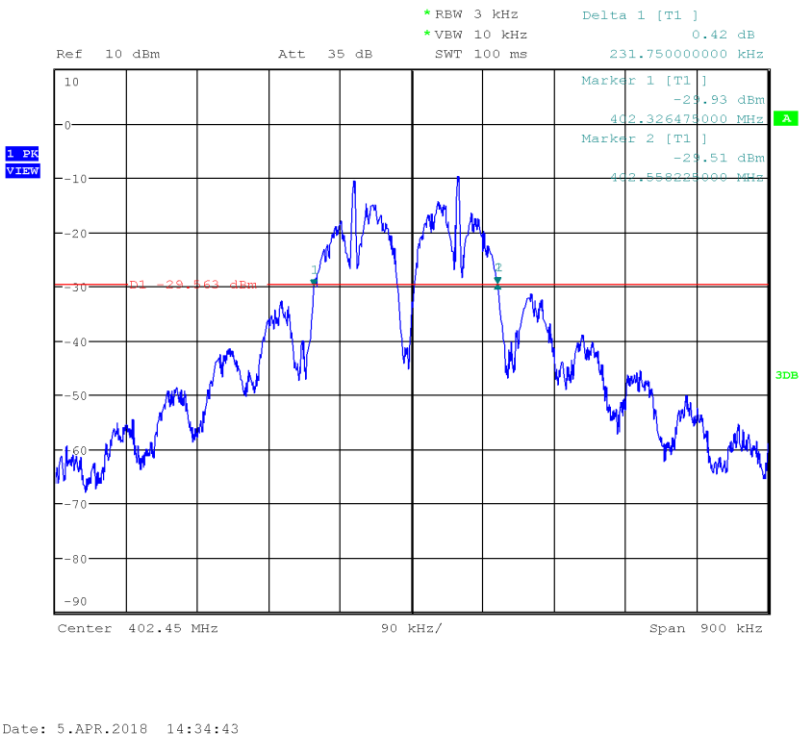
Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	32	402.45	231.750	≤ 300	PASS
F_{MID}	32	403.65	232.425	≤ 300	PASS
F_{HIGH}	32	404.85	233.325	≤ 300	PASS
F_{LOW}	82	402.45	169.425	≤ 300	PASS
F_{MID}	82	403.65	169.650	≤ 300	PASS
F_{HIGH}	82	404.85	169.650	≤ 300	PASS

Comments:

Emission Bandwidth – F_{LOW} (32kBit)

20 dB Bandwidth FCC

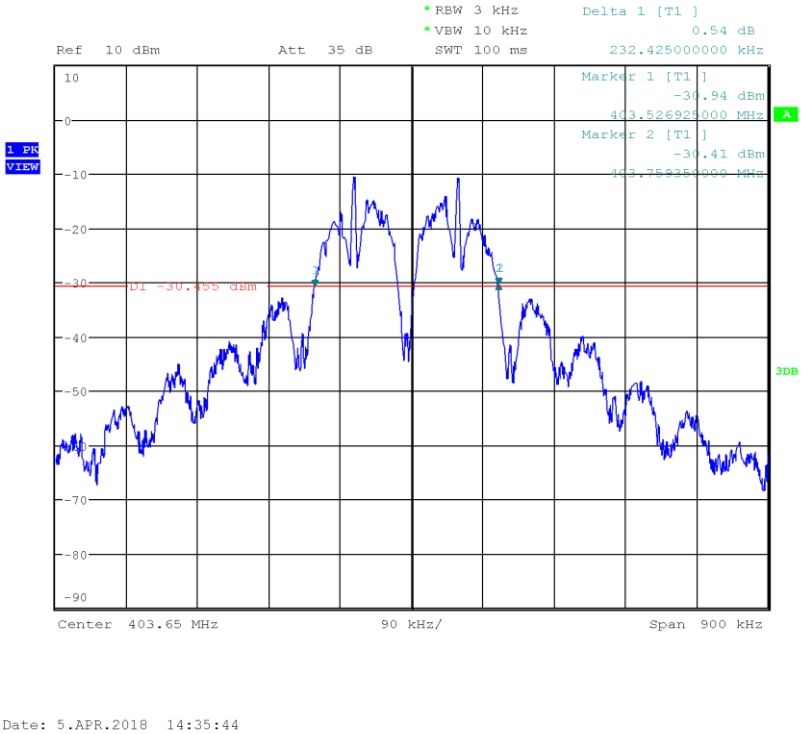
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 32 kbps, Channel: 8, 402.45 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Lower Frequency [MHz]:	402.326
Upper Frequency [MHz]:	402.558
20 dB Bandwidth [kHz]:	231.750



Emission Bandwidth - F_{MID} (32kBit)

20 dB Bandwidth FCC

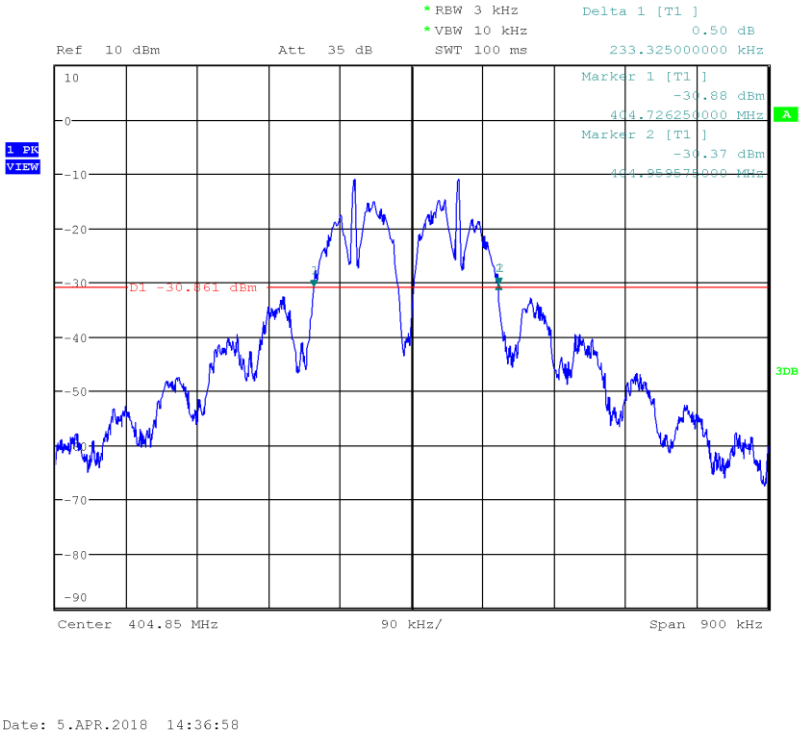
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 32 kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Lower Frequency [MHz]:	403.527
Upper Frequency [MHz]:	403.759
20 dB Bandwidth [kHz]:	232.425



Emission Bandwidth – F_{HIGH} (32kBit)

20 dB Bandwidth FCC

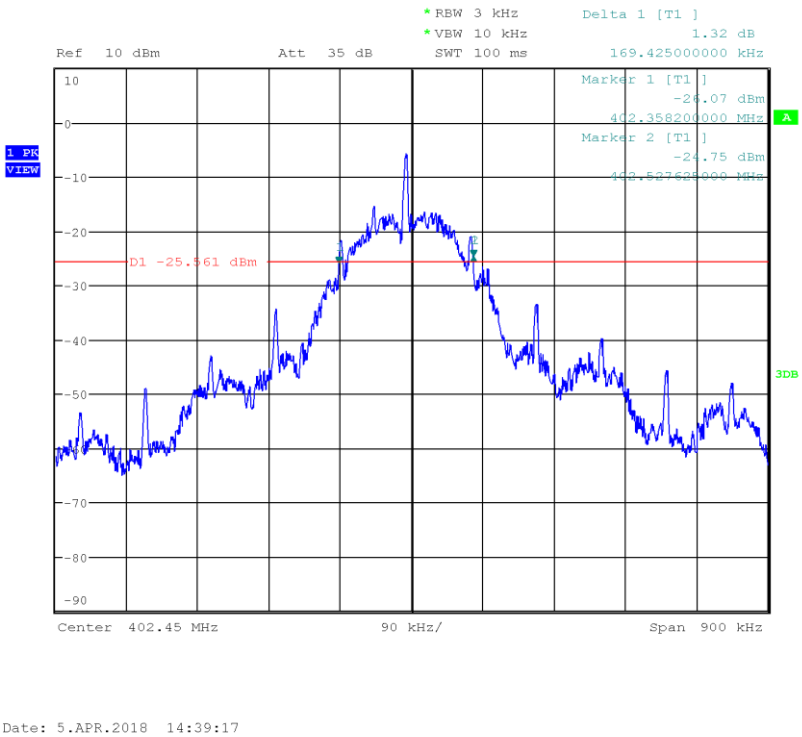
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 32 kbps, Channel: 7, 404.85 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Lower Frequency [MHz]:	404.726
Upper Frequency [MHz]:	404.960
20 dB Bandwidth [kHz]:	233.325



Emission Bandwidth – F_{LOW} (82kBit)

20 dB Bandwidth FCC

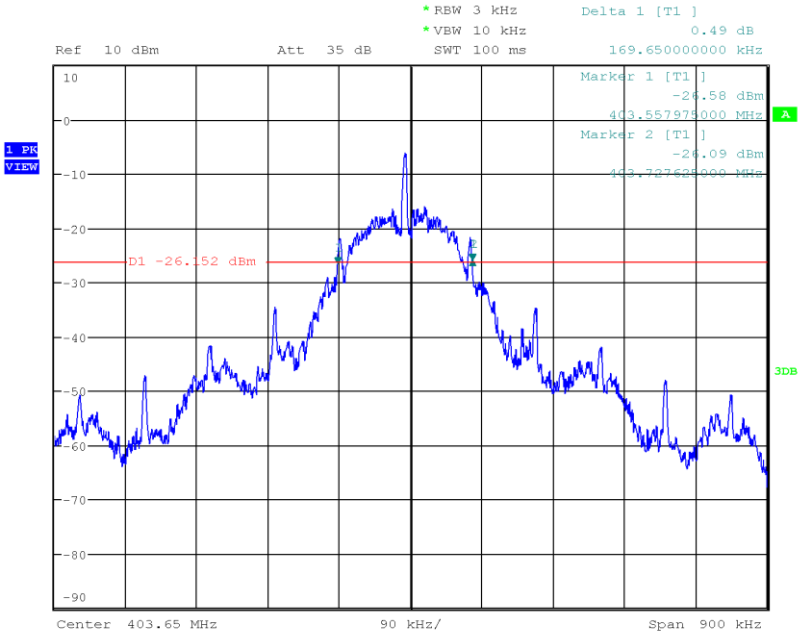
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 82kbps, Channel: 8, 402.45 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Lower Frequency [MHz]:	402.358
Upper Frequency [MHz]:	402.528
20 dB Bandwidth [kHz]:	169.425



Emission Bandwidth – F_{MID} (82kBit)

20 dB Bandwidth FCC

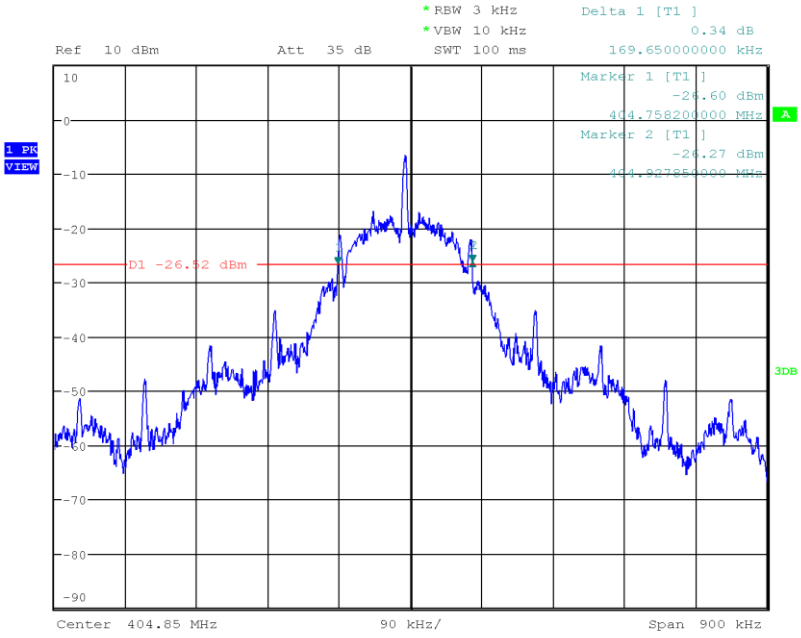
Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 82kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Lower Frequency [MHz]:	403.558
Upper Frequency [MHz]:	403.728
20 dB Bandwidth [kHz]:	169.650



Emission Bandwidth – F_{HIGH} (82kBit)

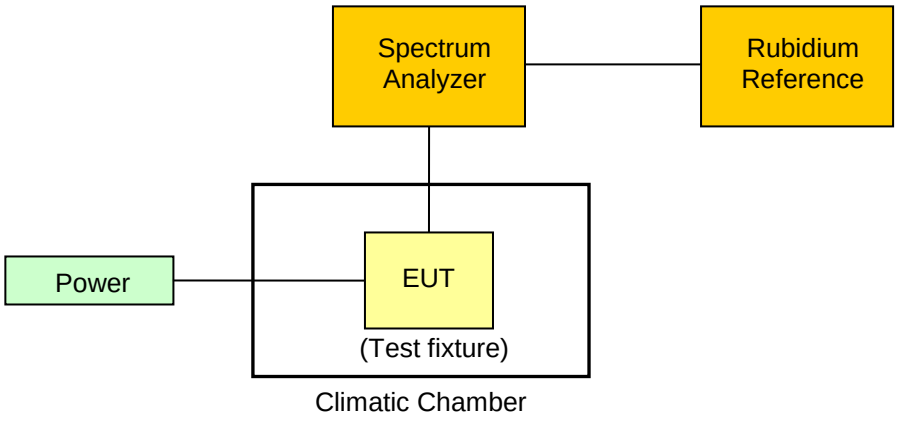
20 dB Bandwidth FCC

Project Number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
Model Description:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Sample ID:	18054
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 82kbps, Channel: 7, 404.85 MHz
Operating Conditions:	Tnom/Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2018-04-05
Lower Frequency [MHz]:	404.758
Upper Frequency [MHz]:	404.928
20 dB Bandwidth [kHz]:	169.650



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	



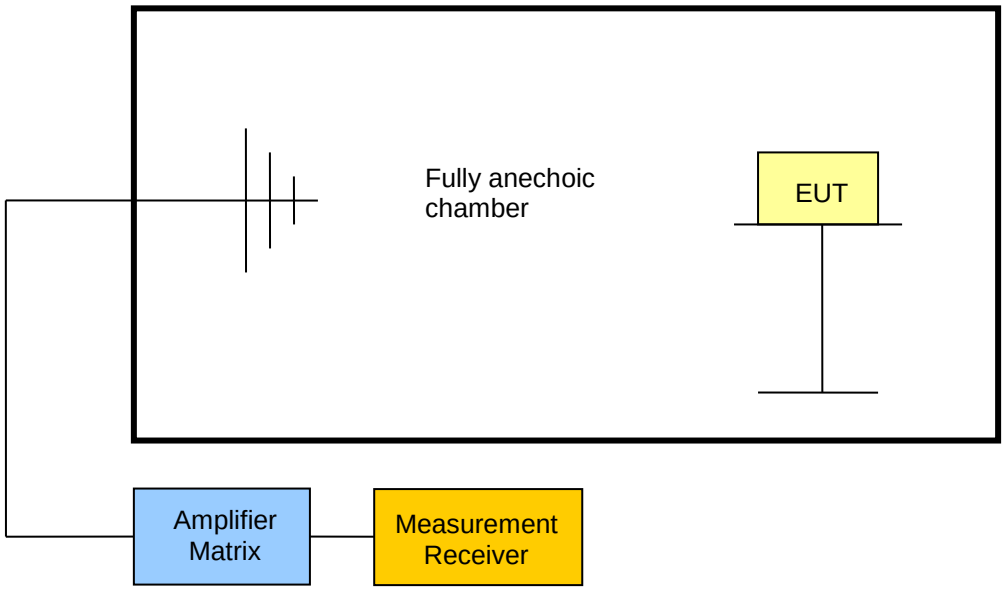
Test procedure

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	402.442835	-17.80
F_{LOW}	402.45	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	402.442766	-17.97
F_{LOW}	402.45	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	402.442987	-17.43
F_{MID}	403.65	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	403.642892	-17.61
F_{MID}	403.65	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	403.642809	-17.81
F_{MID}	403.65	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	403.643043	-17.24
F_{HIGH}	404.85	T_{NOM} = 37 °C	V_{NOM} = 3.0 VDC	404.842958	-17.39
F_{HIGH}	404.85	T_{MIN} = 25 °C	V_{NOM} = 3.0 VDC	404.842877	-17.59
F_{HIGH}	404.85	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	404.843111	-17.02
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	-27.5	pk	-16	-11.50
F_{HIGH}	404.85	-27.3	pk	-16	-11.30
Comments:					

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

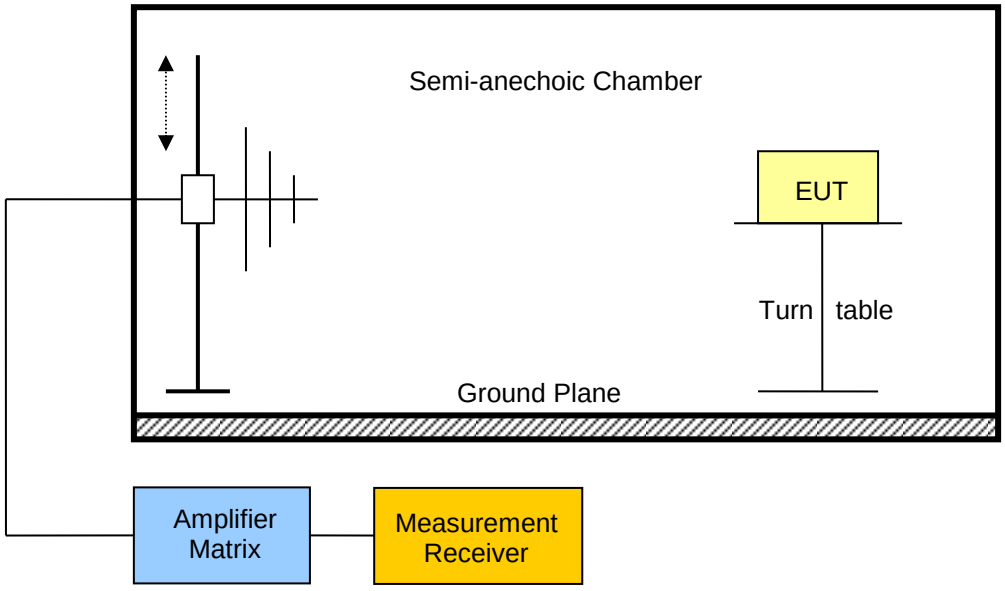
Band-edge and in-band emission compliance acc. to FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9
Test according to measurement reference	Reference Method
	FCC 95.635(d) / ANSI C 63.4
Test frequency range	Tested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

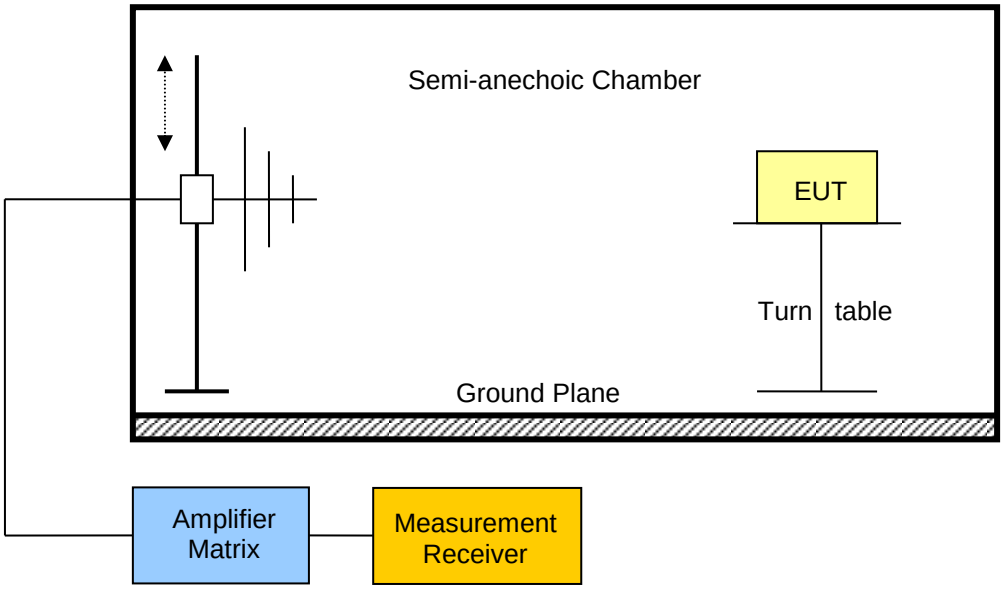
Test results

Channel	Frequency [MHz]	Emission [MHz]	Level [dBµV/m]	Pol.	Limit [dBµV/m]	Margin [dB]
F_{LOW}	402.45	401.788	23.33	hor	59.40	-36.07
F_{LOW}	402.45	401.788	21.16	ver	59.40	-38.24
F_{LOW}	402.45	402.287	30.67	ver	49.70	-19.03
F_{LOW}	402.45	402.288	34.06	hor	49.70	-15.64
F_{LOW}	402.45	402.6	30.53	ver	49.70	-19.17
F_{LOW}	402.45	402.615	34.12	hor	49.70	-15.58
F_{LOW}	402.45	403.235	29.61	hor	49.70	-20.09
F_{LOW}	402.45	403.235	26.24	ver	49.70	-23.46
F_{HIGH}	404.85	404.691	35.25	hor	49.70	-14.45
F_{HIGH}	404.85	404.691	30.94	ver	49.70	-18.76
F_{HIGH}	404.85	405.006	35.14	hor	59.40	-24.26
F_{HIGH}	404.85	405.016	31.69	ver	59.40	-27.71

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

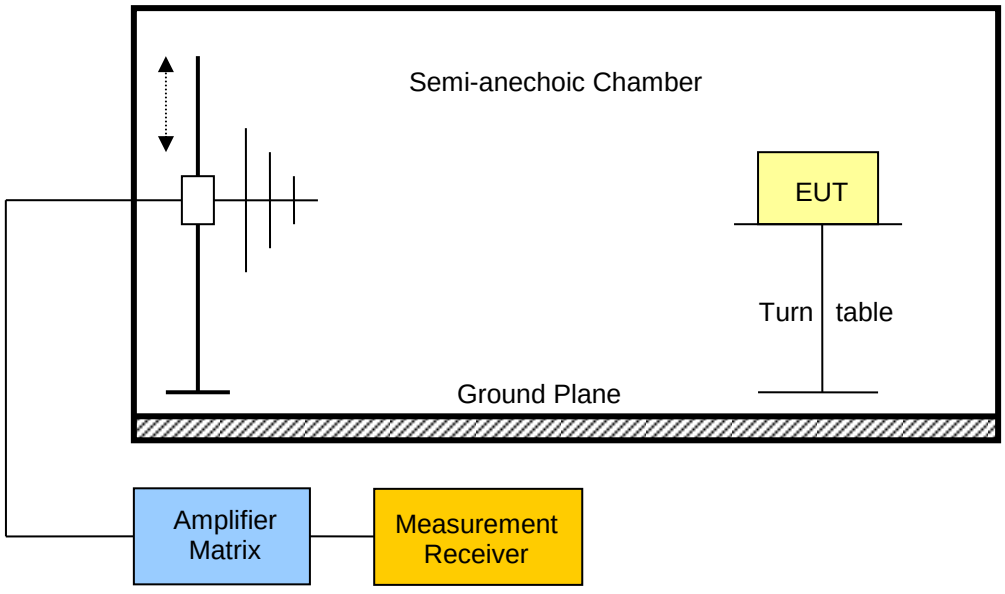
Test results

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	408.109	26.31	pk	ver	46.00	3	-19.69
F_{HIGH}	404.85	Modulated 1	398.84	28.26	pk	hor	46.00	3	-17.74
F_{HIGH}	404.85	Modulated 1	405.25	29.24	pk	hor	46.00	3	-16.76
F_{HIGH}	404.85	Modulated 1	405.25	24.51	pk	ver	46.00	3	-21.49

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	866.667	17.38	pk	hor	46.00	-28.62
F_{MID}	403.65	884.615	18.26	pk	ver	46.00	-27.74
F_{MID}	403.65	3976	39.29	pk	ver	53.98	-14.69

Comments:
* Physical distance between EUT and measurement antenna.
** Emission level corresponds to ambient noise floor

ANNEX A Transmitter radiated power

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2018-04-03
Note:	Tx Power EIRP

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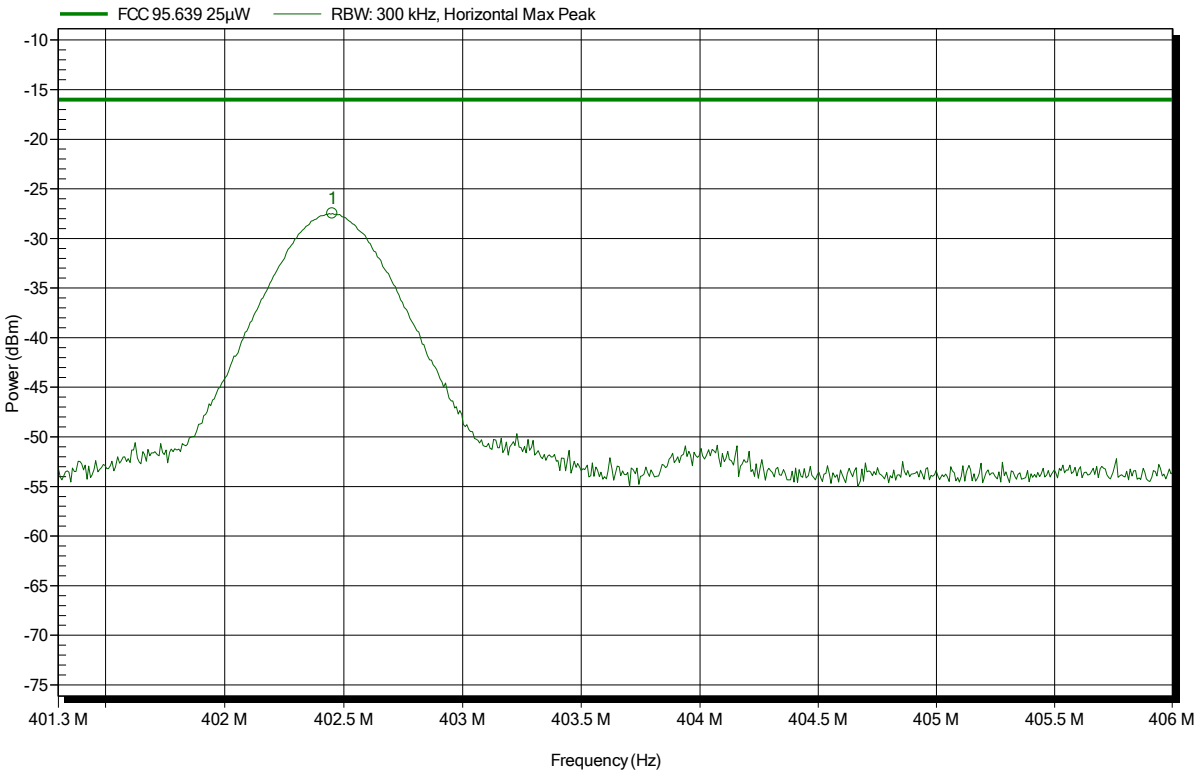

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.452 MHz	-27.5 dBm	-16 dBm	-11.49 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2018-04-03
Note:	Tx Power EIRP

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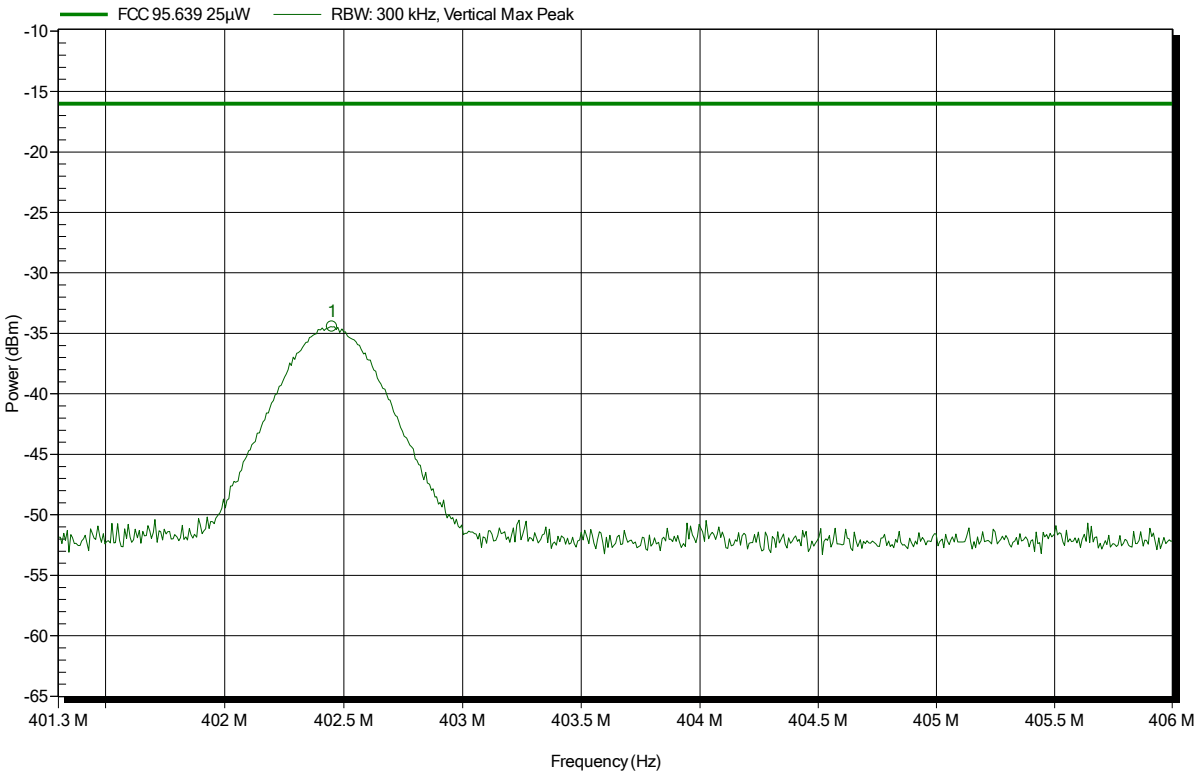

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.451 MHz	-34.4 dBm	-16 dBm	-18.43 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2018-04-03
Note:	Tx Power EIRP

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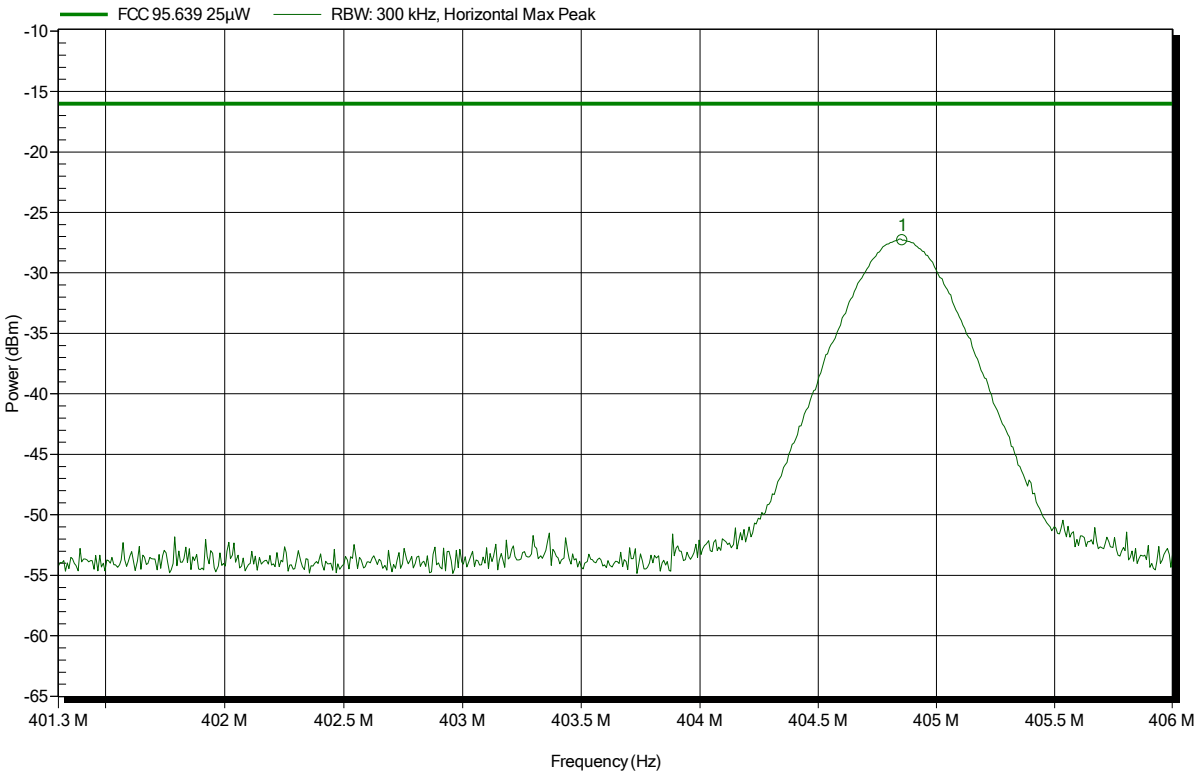

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.855 MHz	-27.3 dBm	-16 dBm	-11.3 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2018-04-03
Note:	Tx Power EIRP

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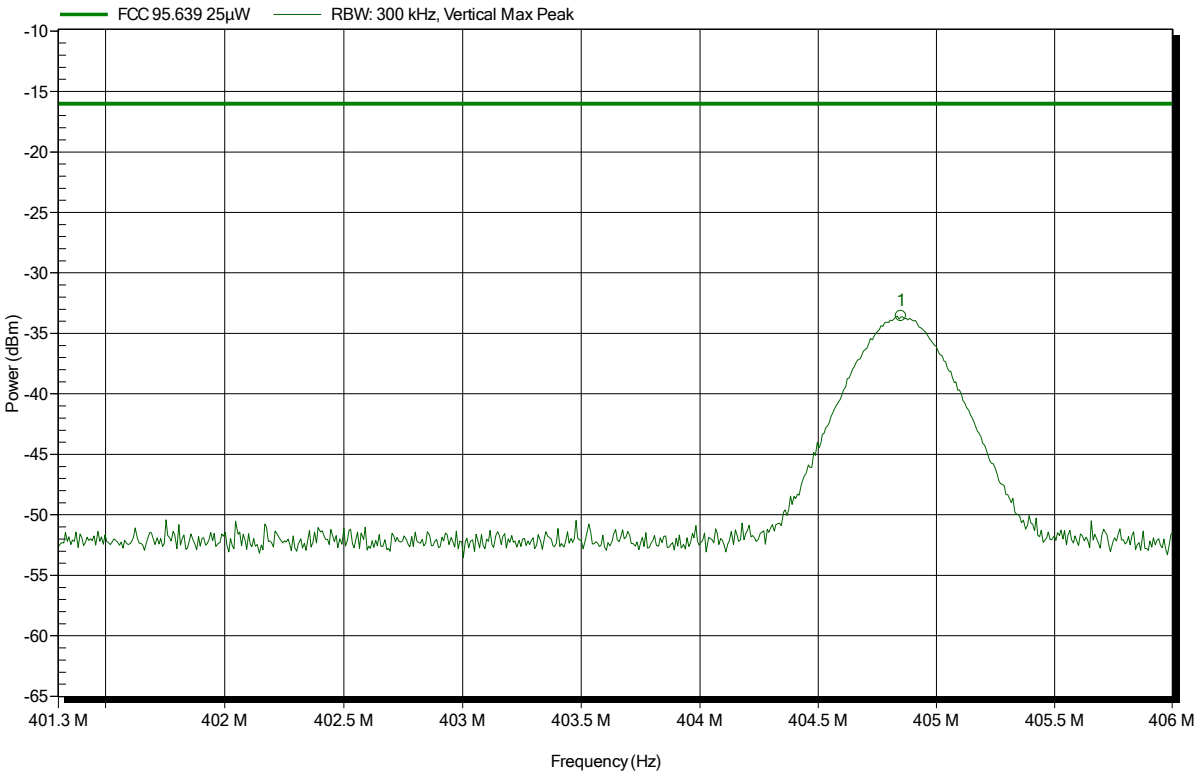

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.85 MHz	-33.6 dBm	-16 dBm	-17.56 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2018-04-03
Note:	Power dBµV/m ERP

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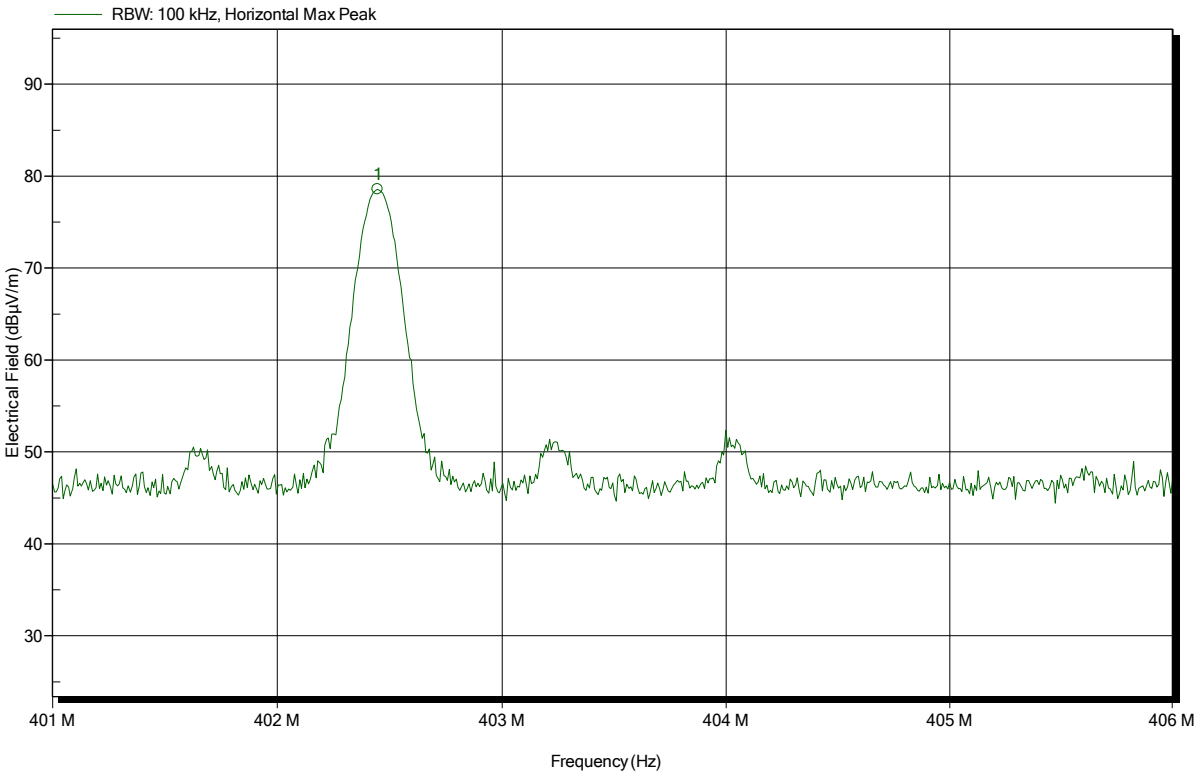

Frequency	Peak
402.446 MHz	78.57 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 402.45 MHz
Test Date:	2018-04-03
Note:	Power dBµV/m ERP

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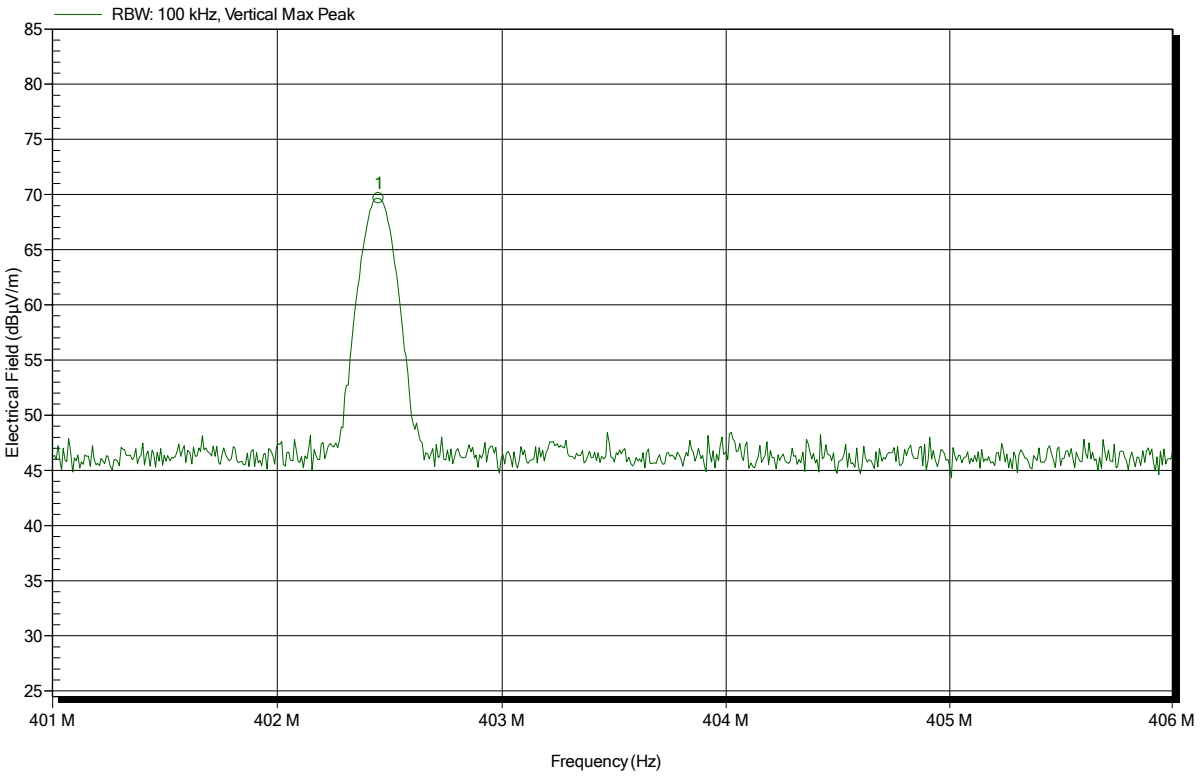

Frequency	Peak
402.45 MHz	69.67 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2018-04-03
Note:	Power dBµV/m ERP

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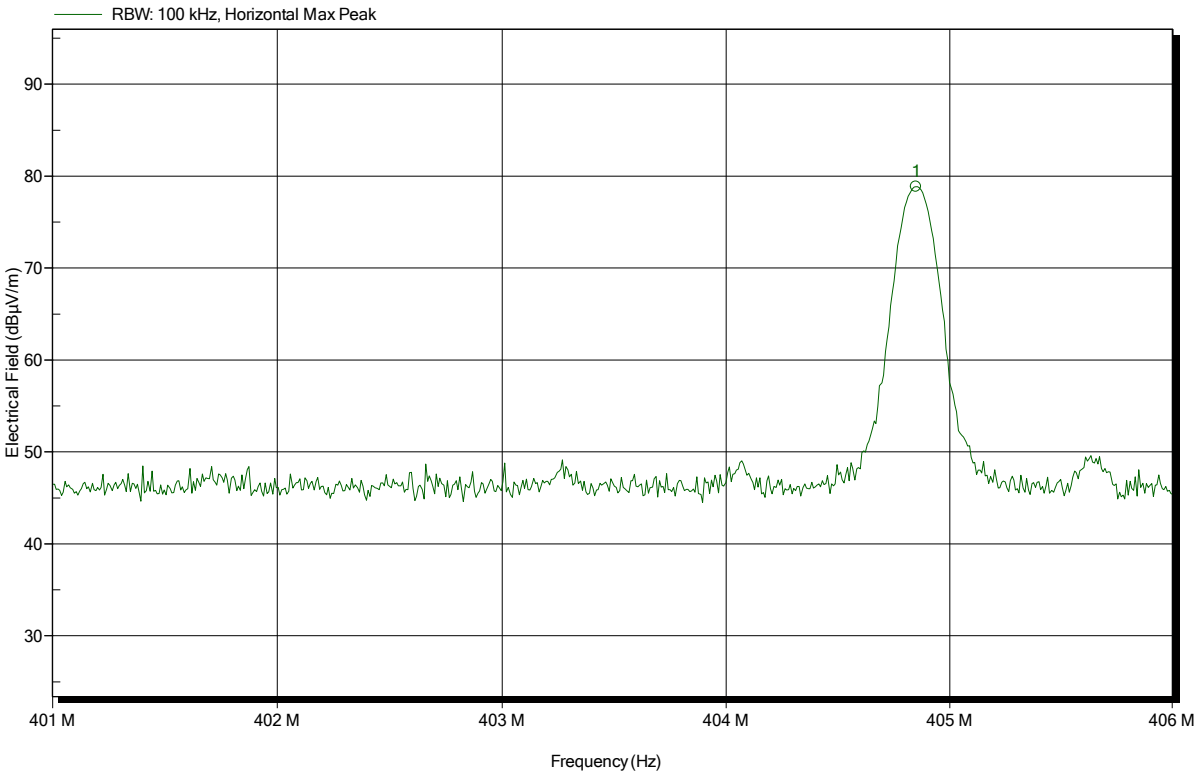

Frequency	Peak
404.85 MHz	78.85 dBµV/m

Radiated power according to FCC Part 95; Subpart I

Order number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; CW; 404.85 MHz
Test Date:	2018-04-03
Note:	Power dBµV/m ERP

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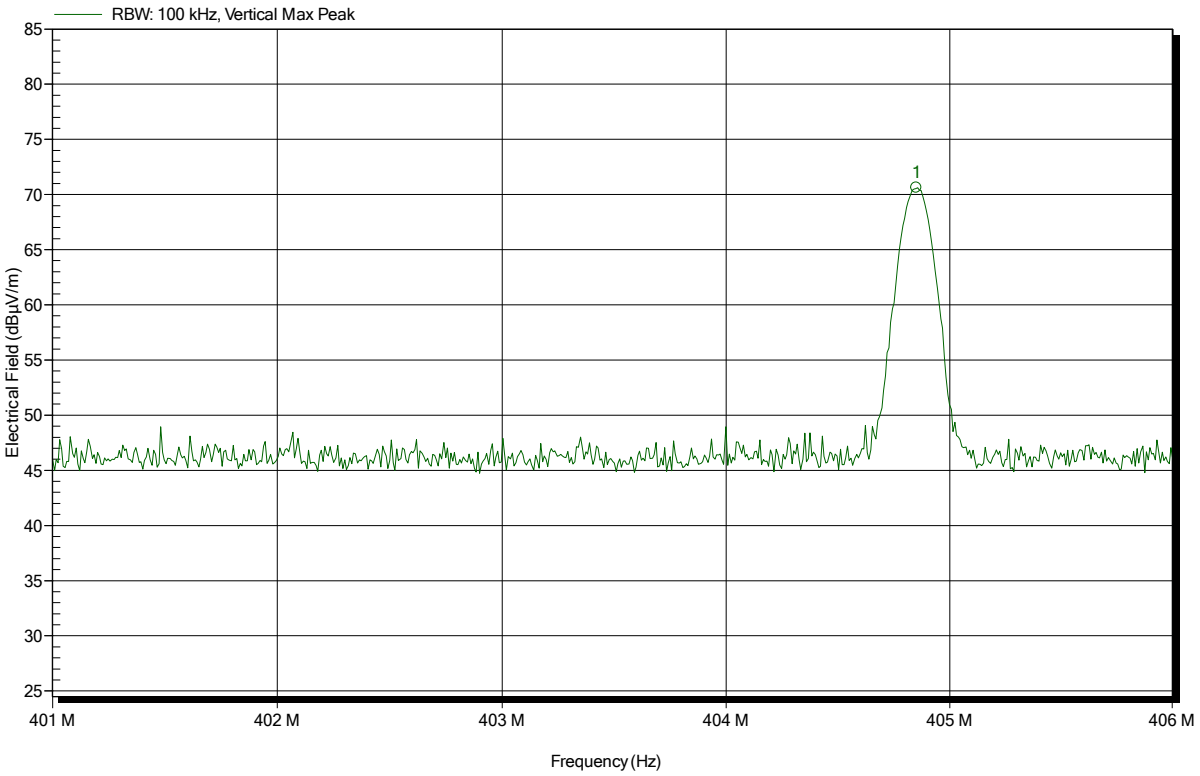

Frequency	Peak
404.851 MHz	70.62 dBµV/m

ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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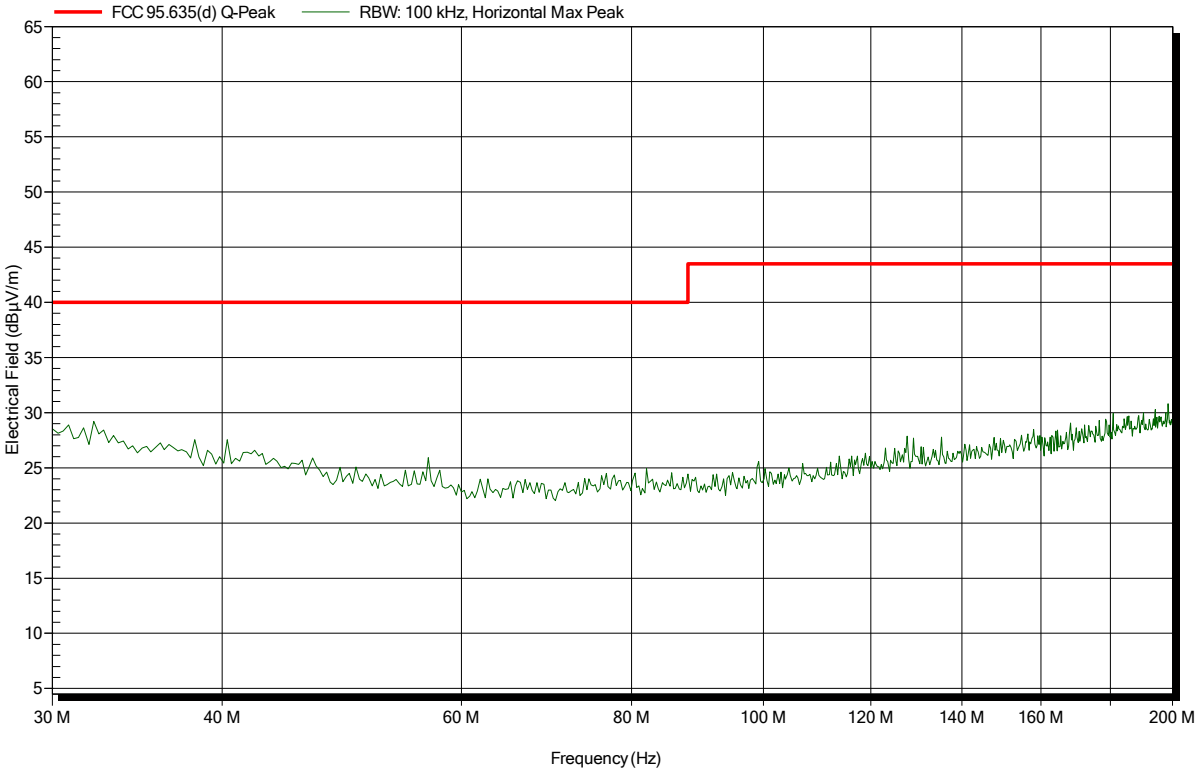

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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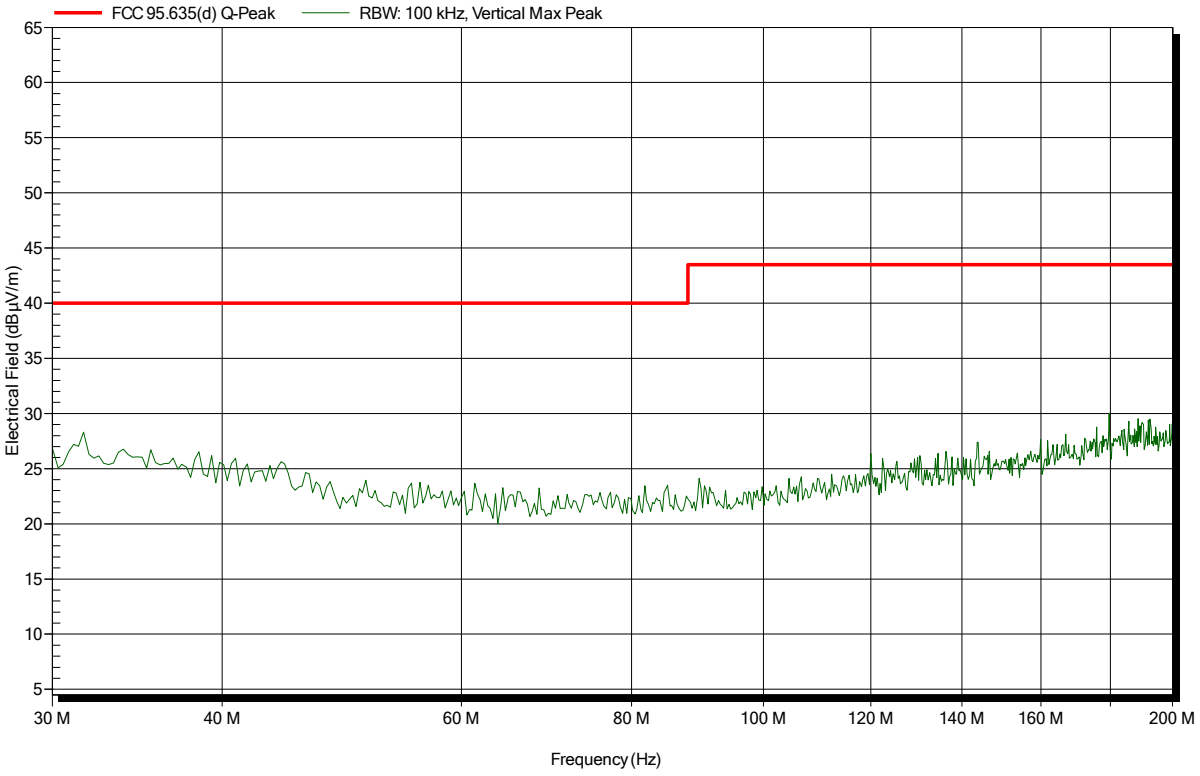

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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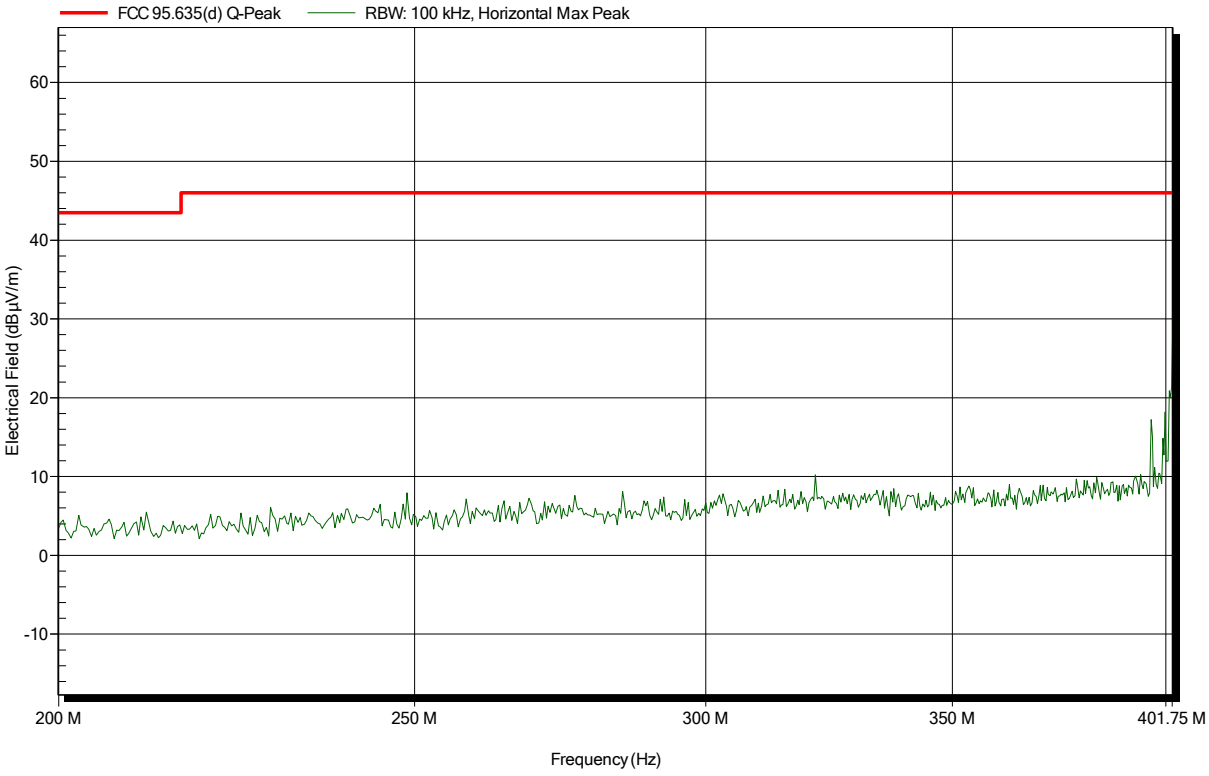

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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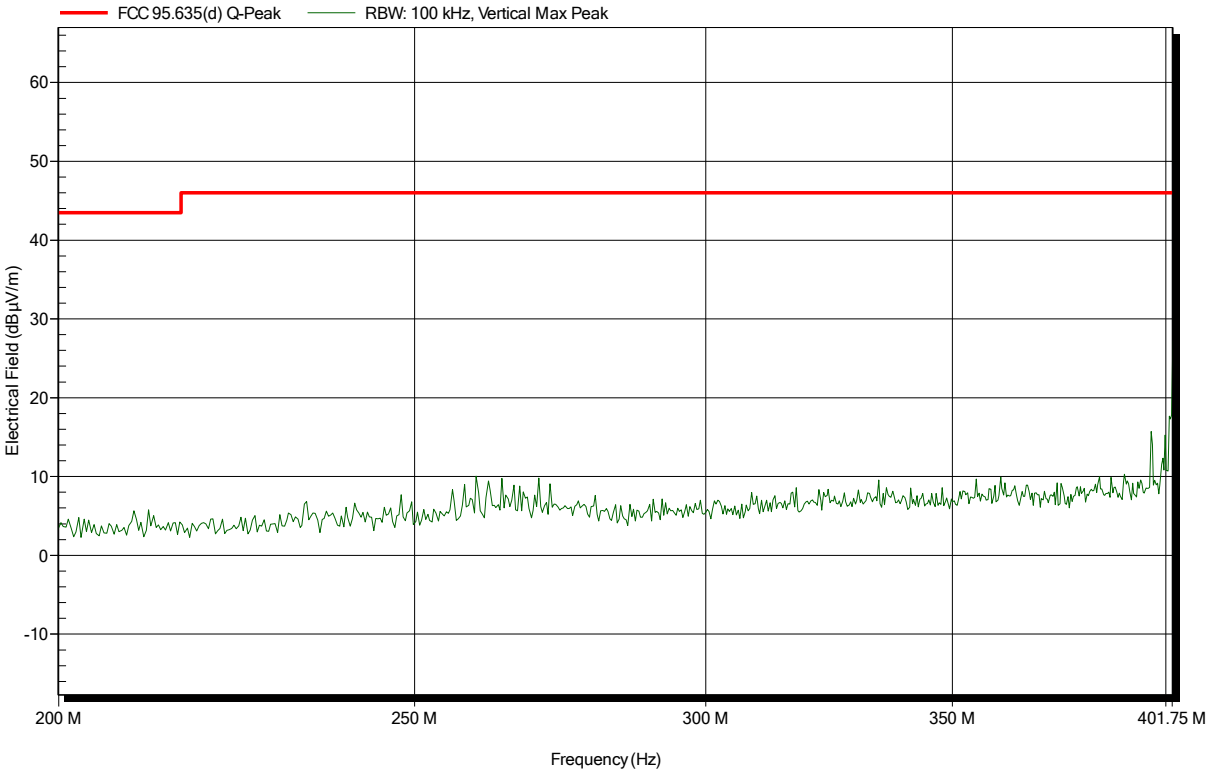

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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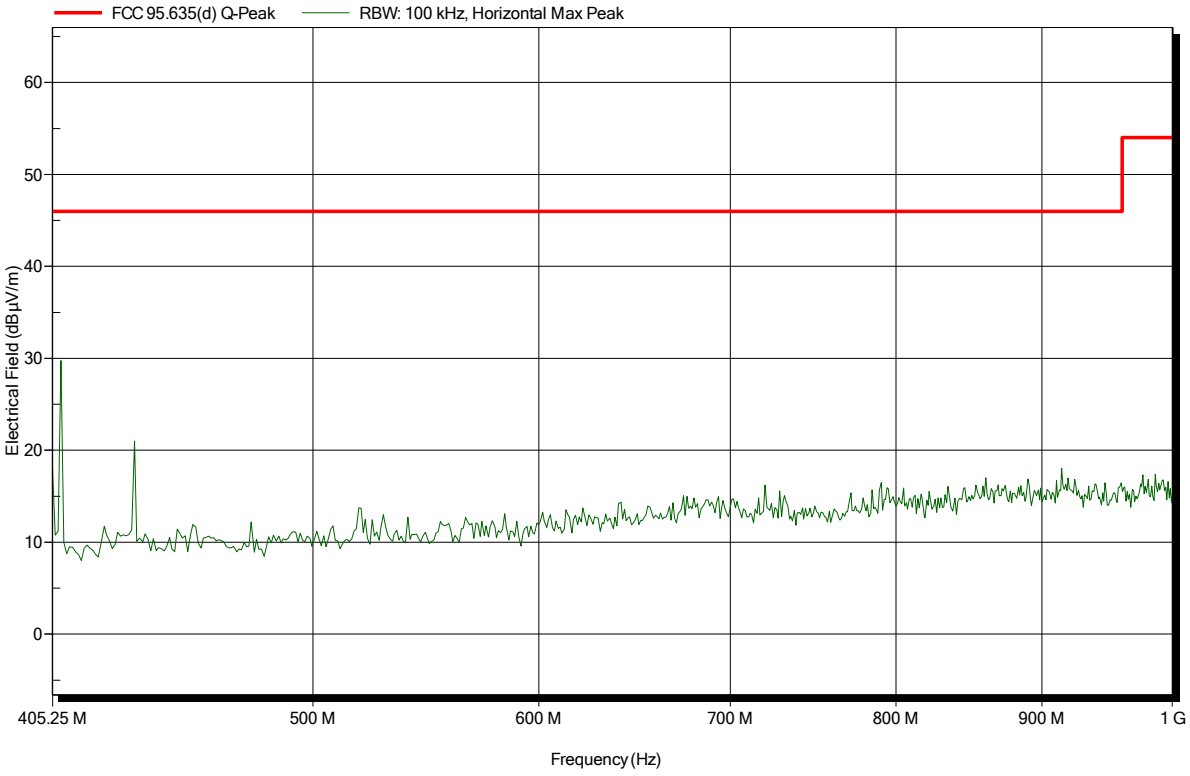

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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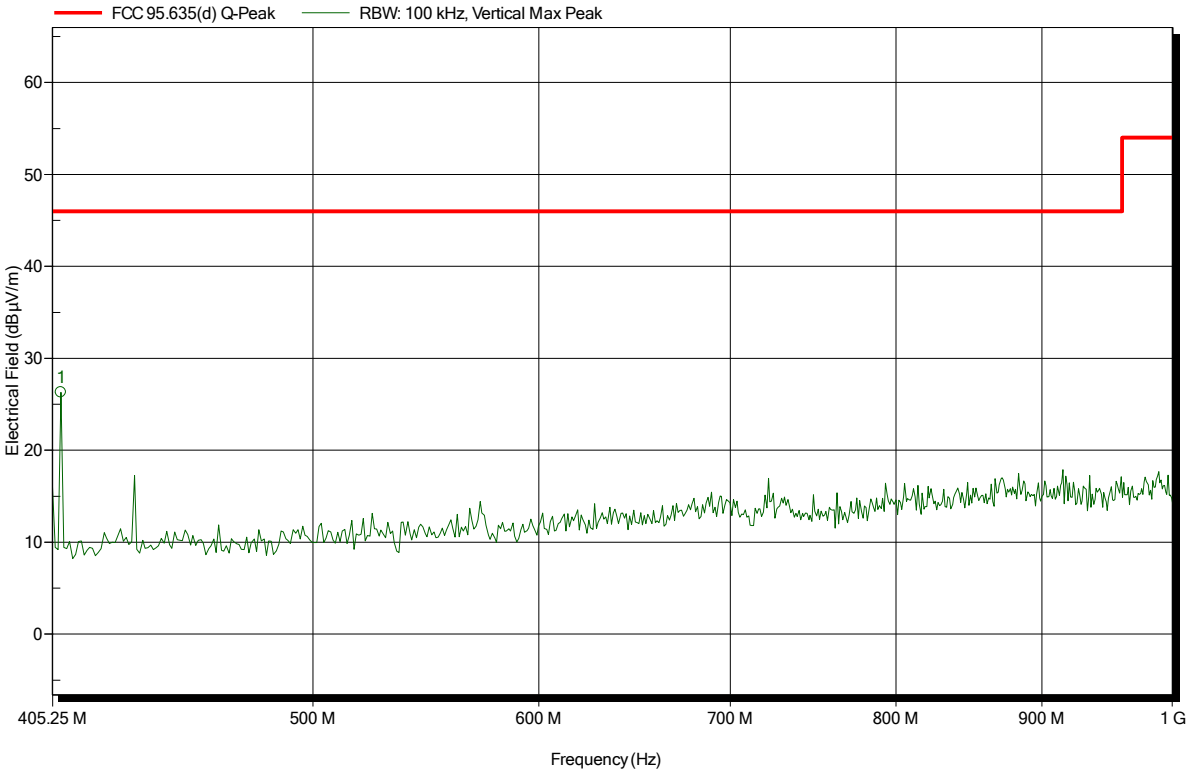

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
408.109 MHz	26.31 dBµV/m	46 dBµV/m	-19.69 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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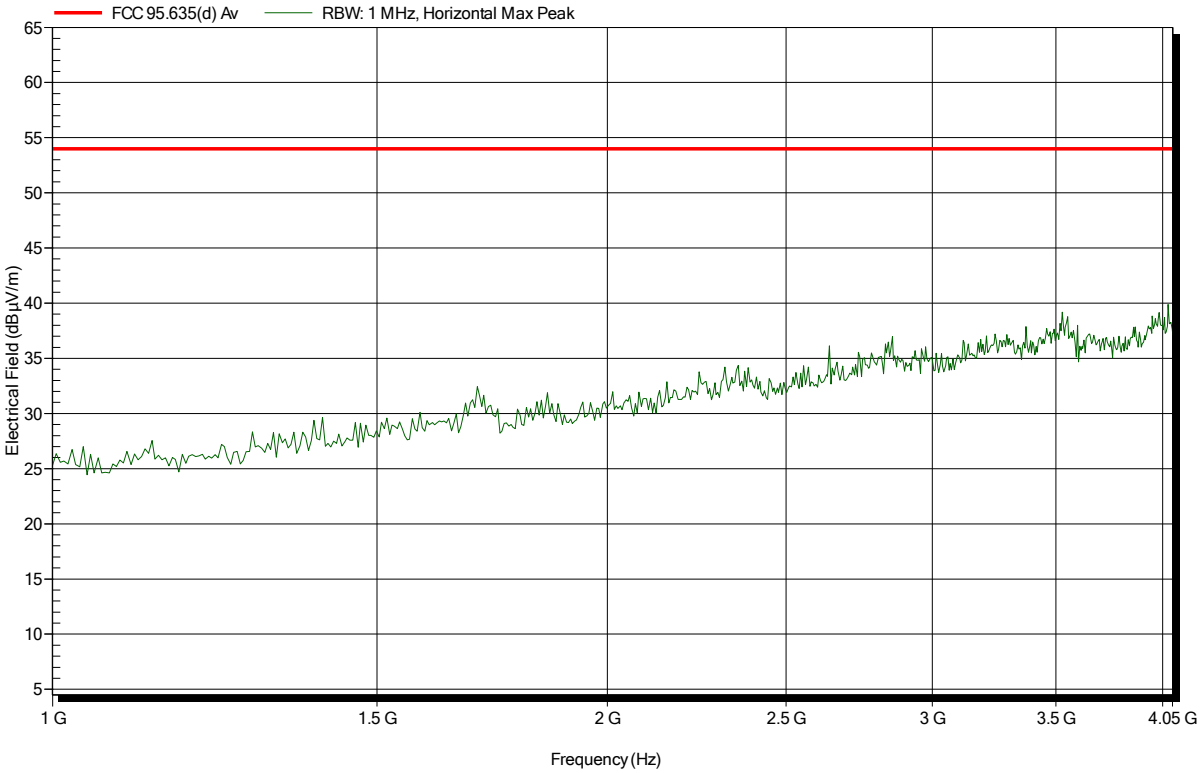

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	

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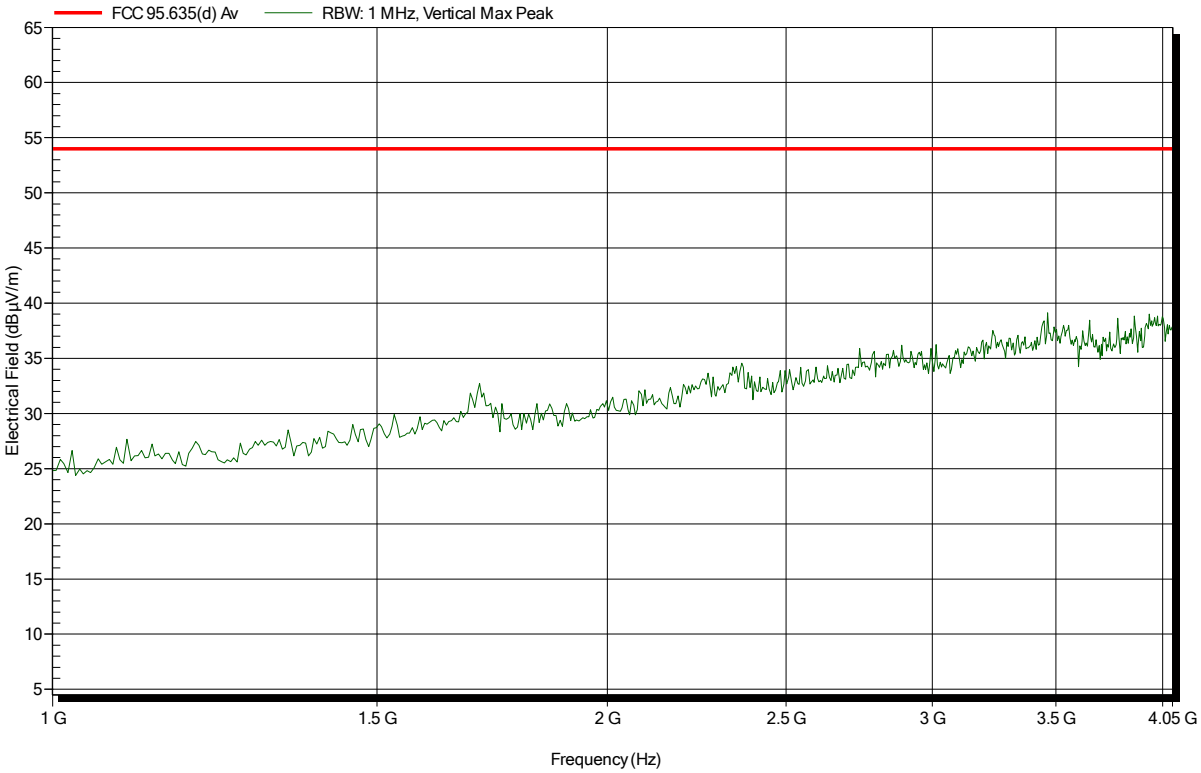

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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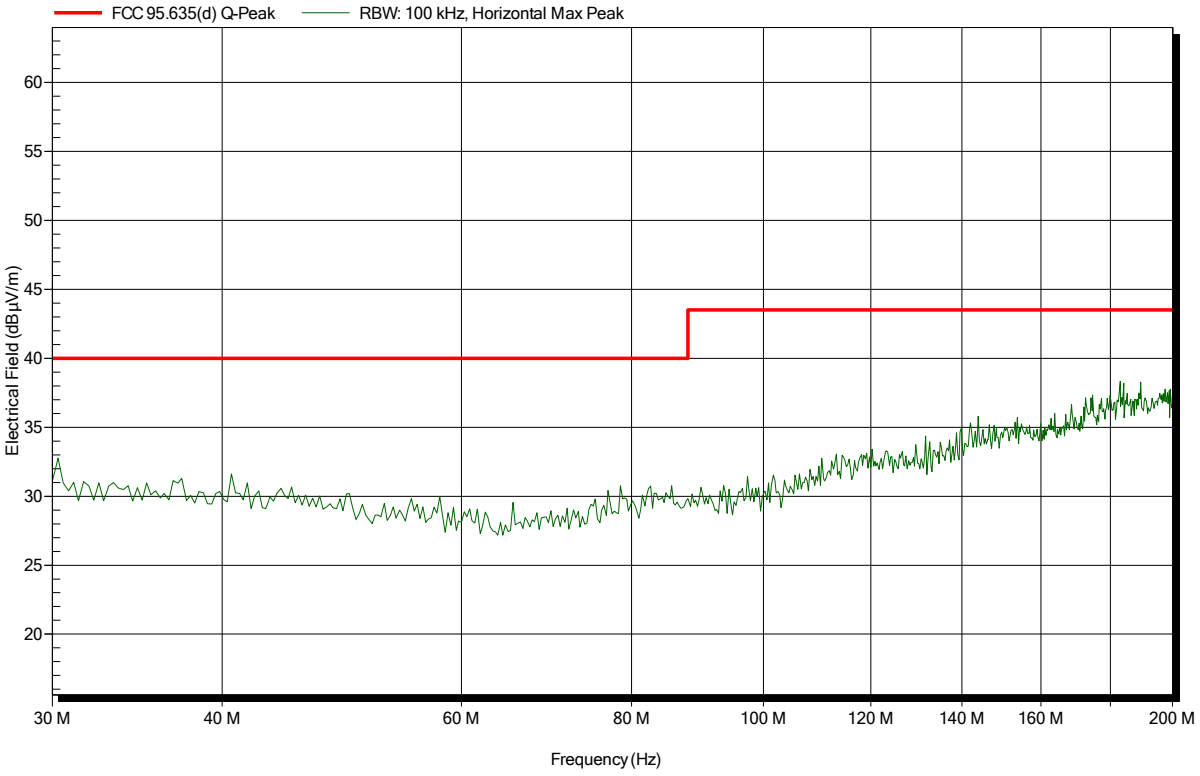

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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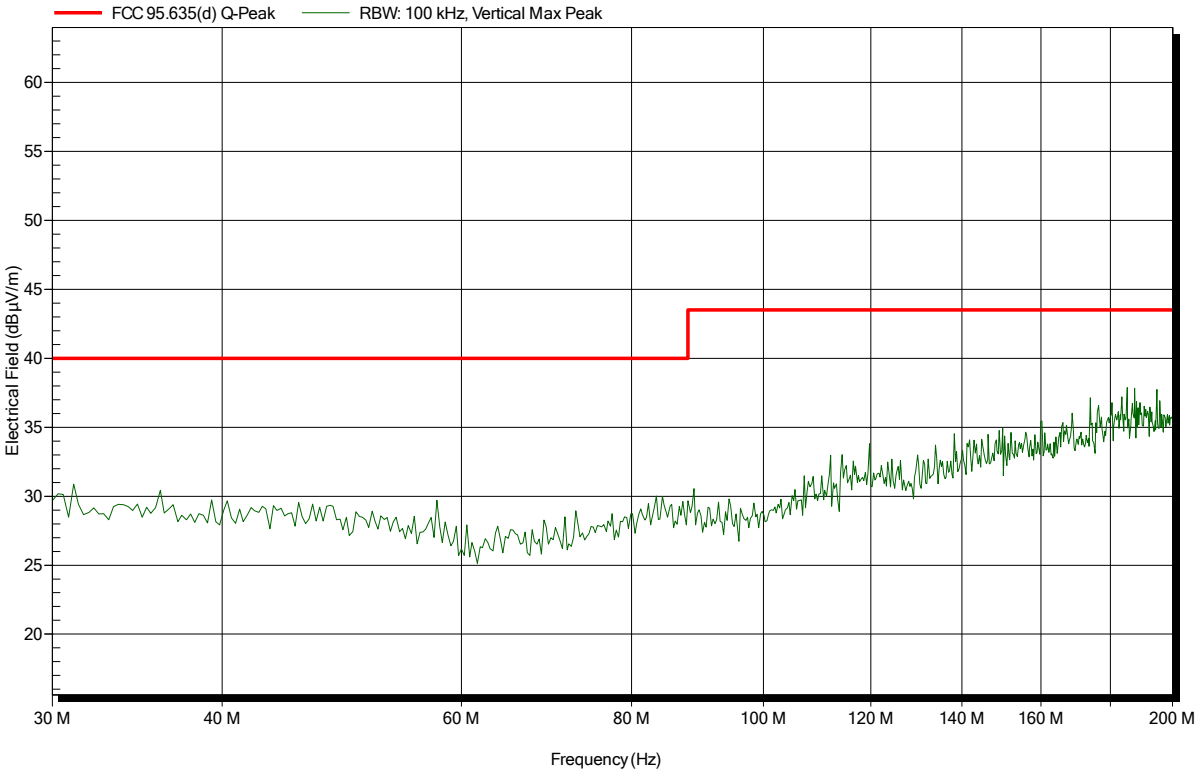

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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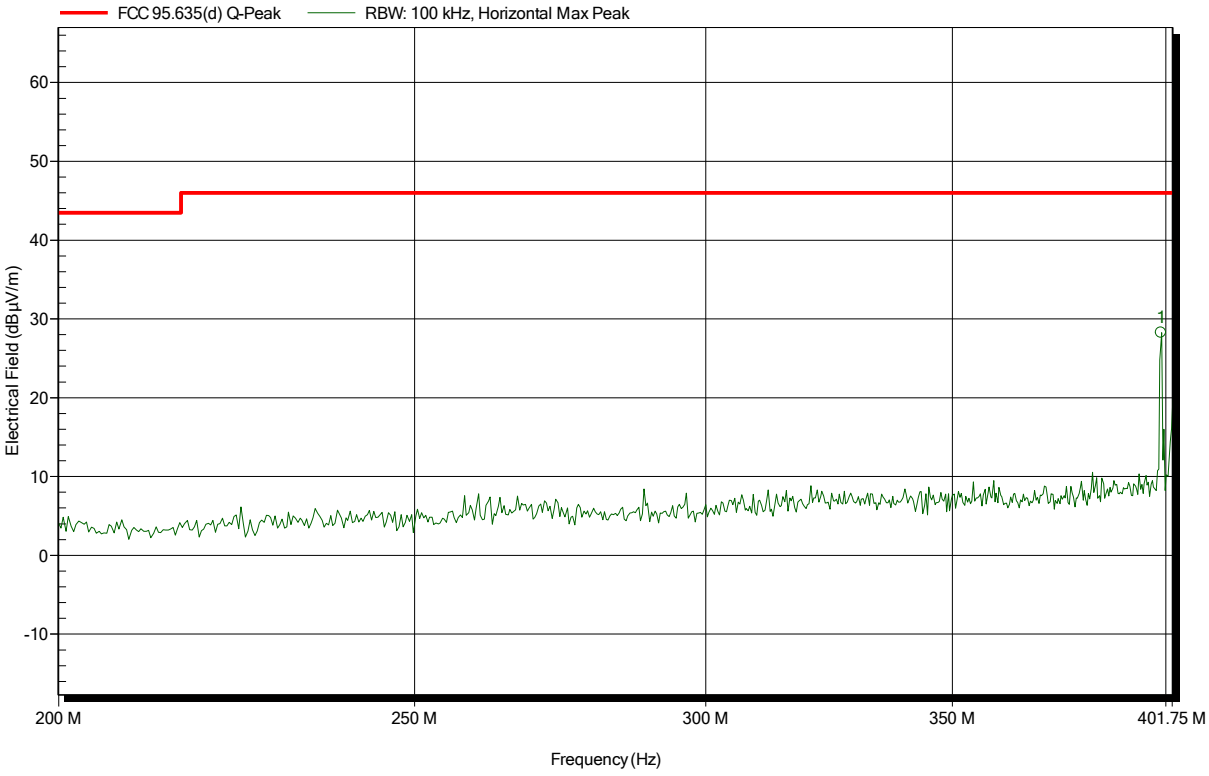

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
398.84 MHz	28.26 dBµV/m	46 dBµV/m	-17.74 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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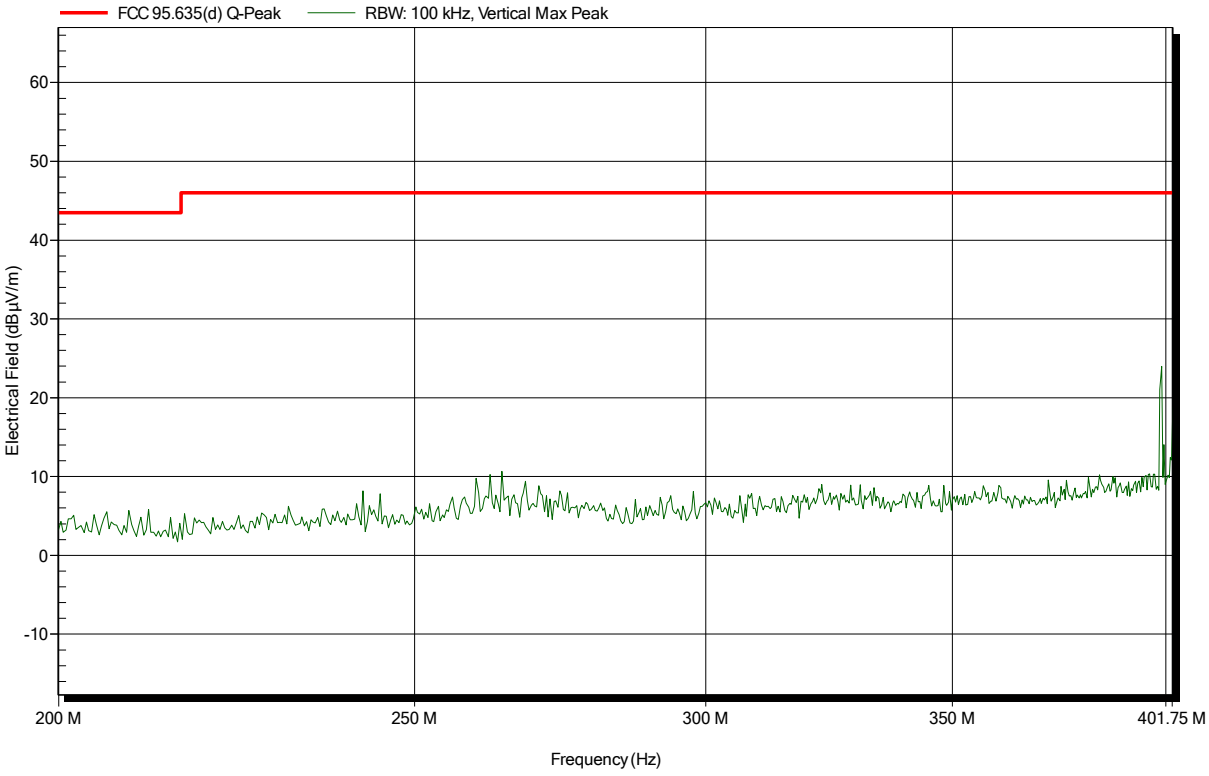

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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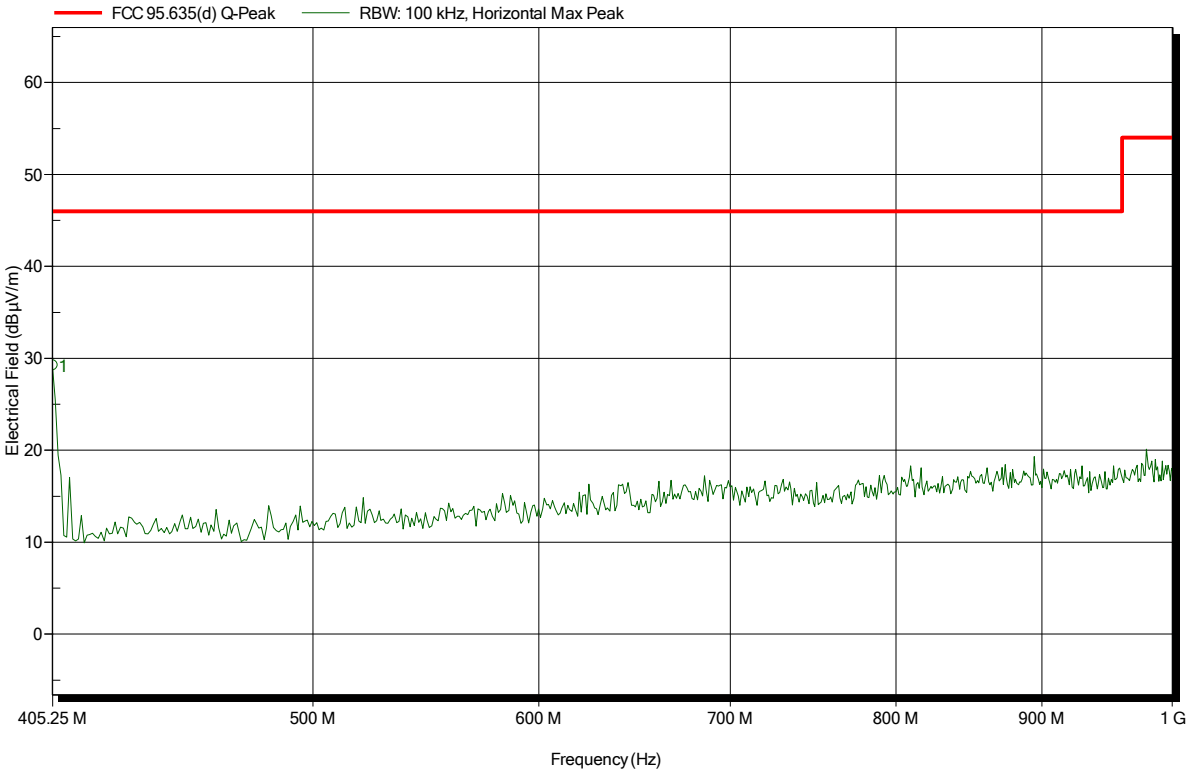

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	29.24 dBµV/m	46 dBµV/m	-16.76 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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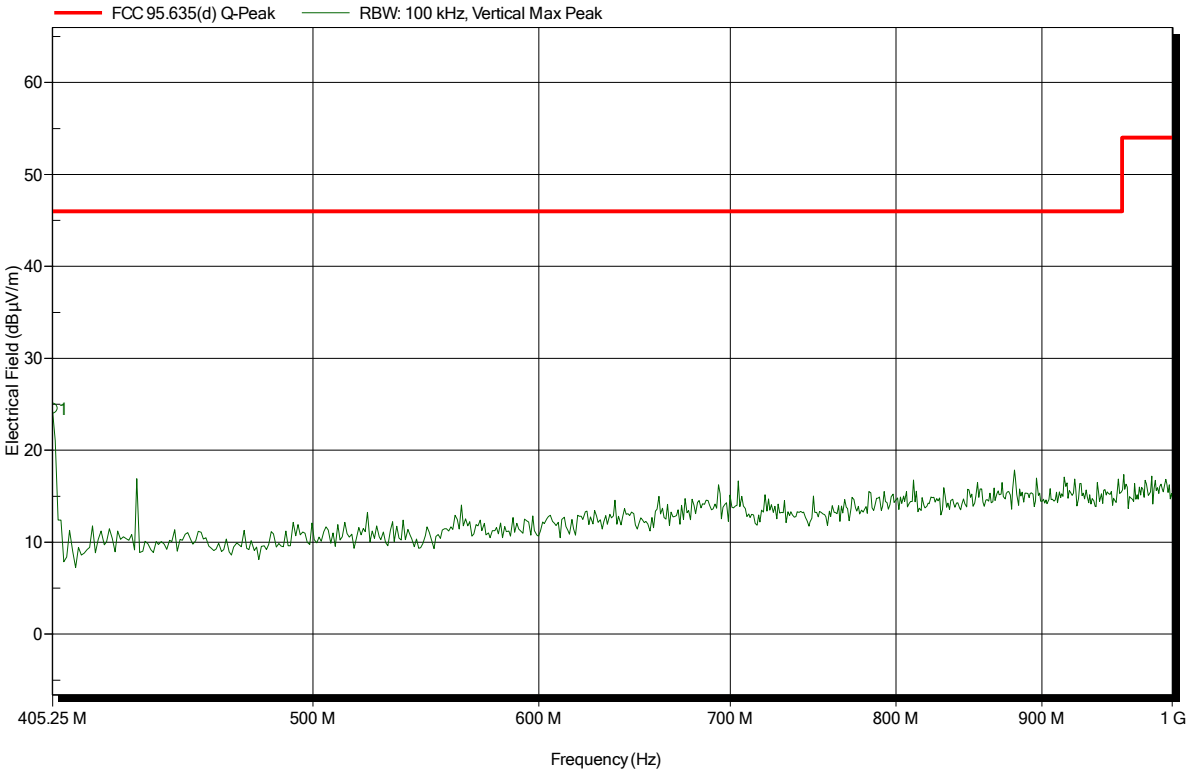

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.25 MHz	24.51 dBµV/m	46 dBµV/m	-21.49 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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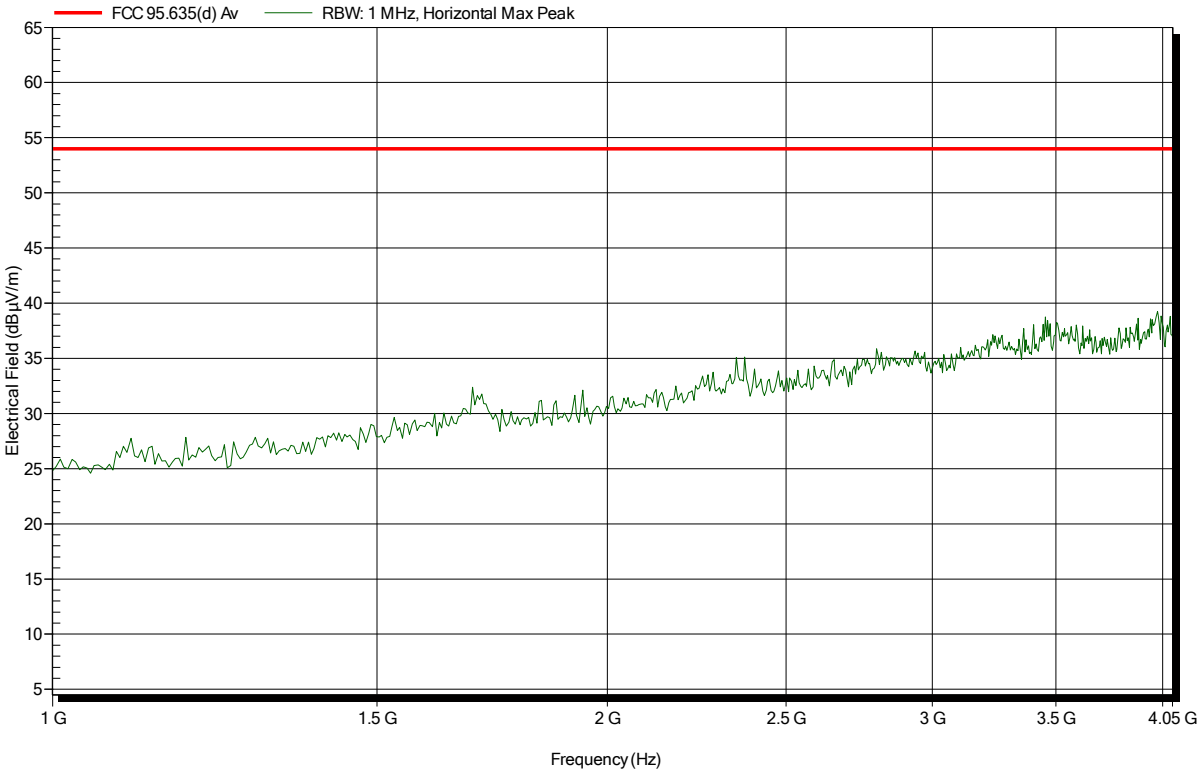

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	

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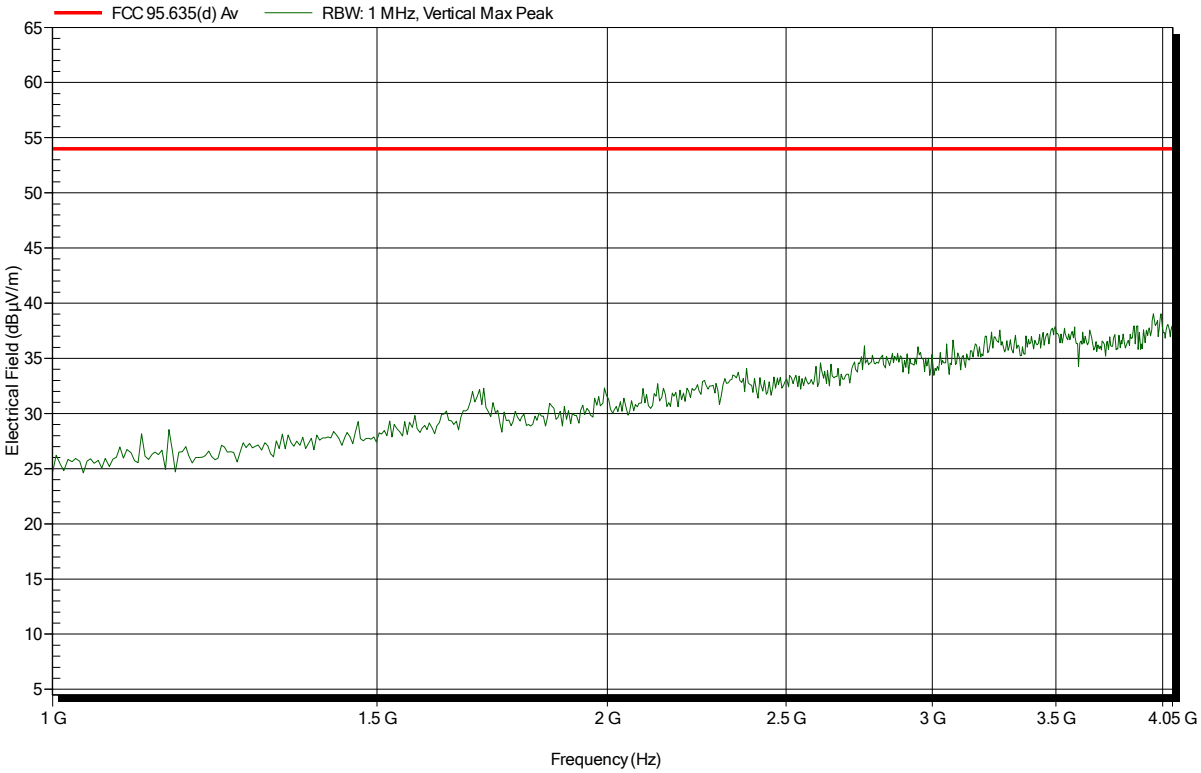

ANNEX C Transmitter In-band and Band-edge

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	Band-edge

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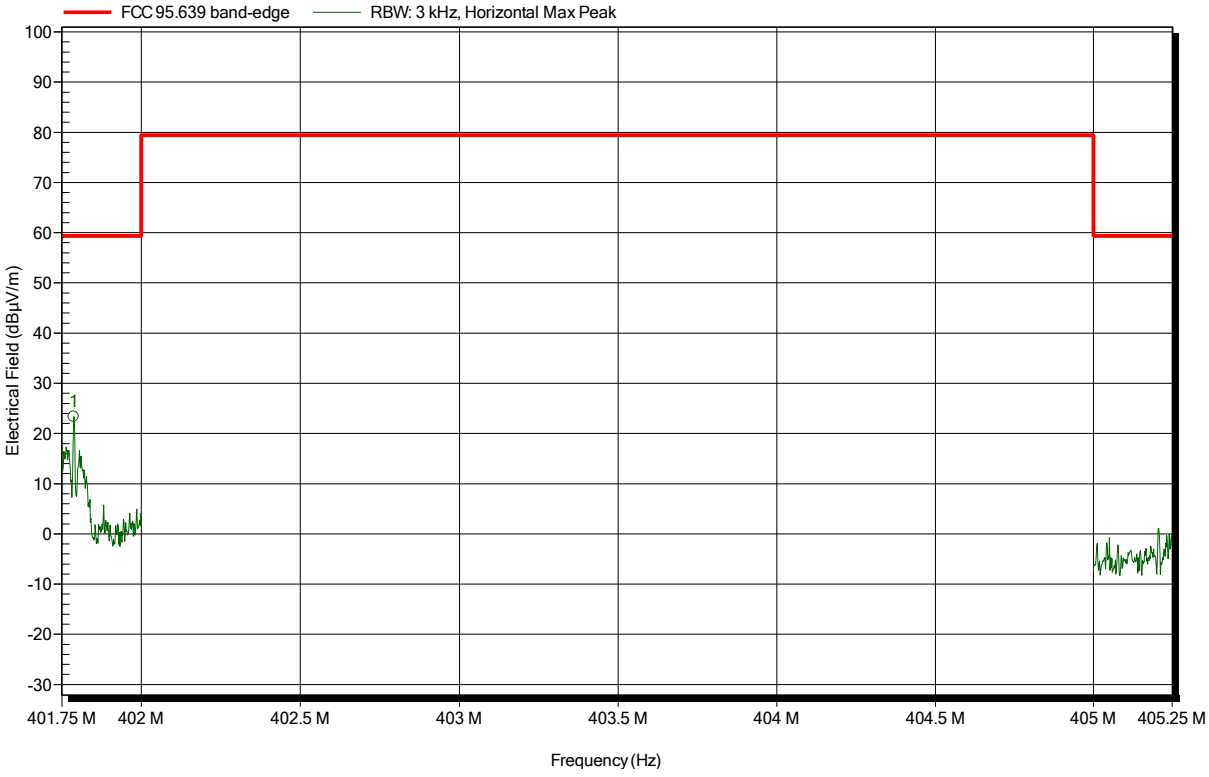

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.788 MHz	23.33 dBµV/m	59.4 dBµV/m	-36.07 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	Band-edge

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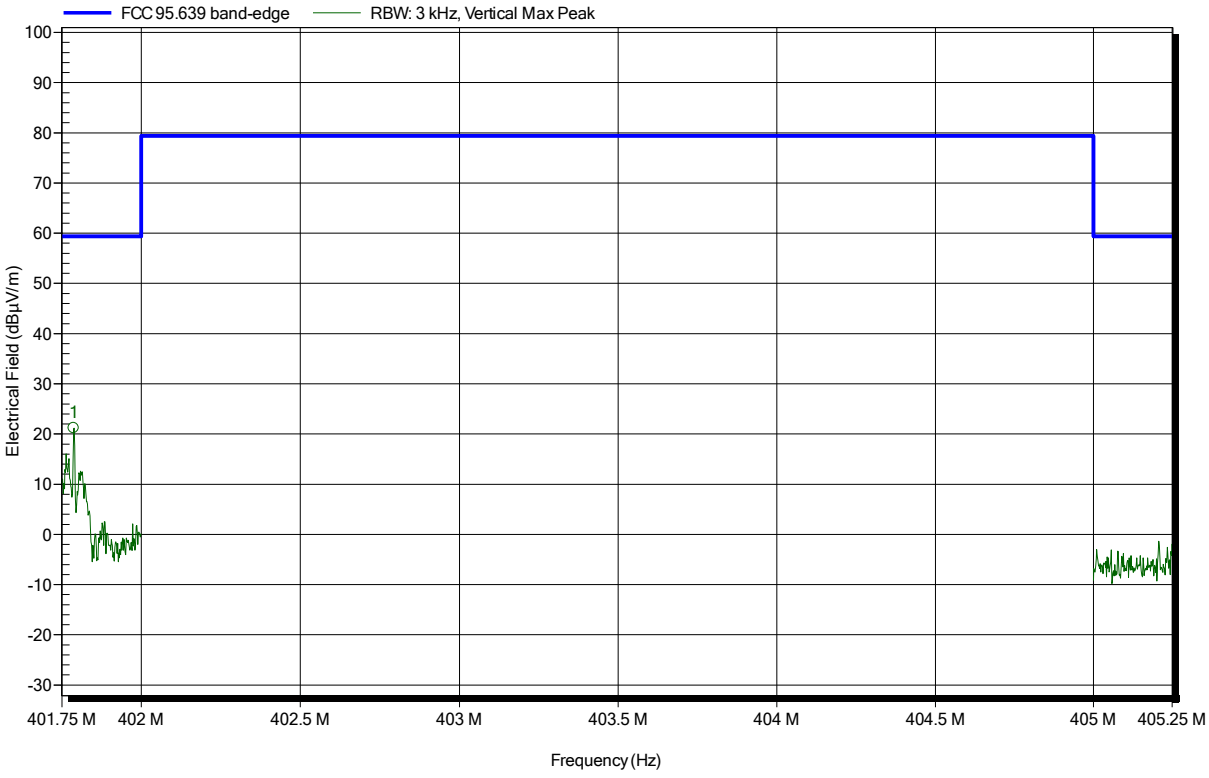

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.788 MHz	21.16 dBµV/m	59.4 dBµV/m	-38.24 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	In-band emissions

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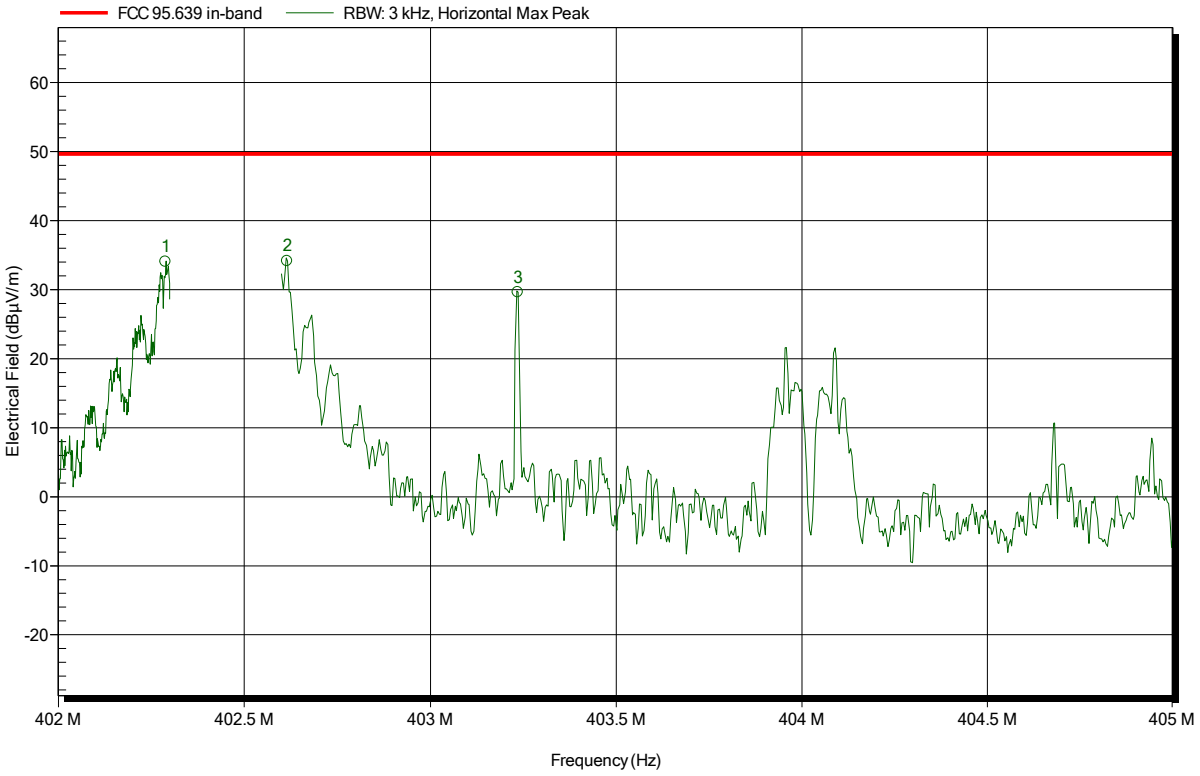

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.288 MHz	34.06 dBµV/m	49.7 dBµV/m	-15.64 dB	Pass
402.615 MHz	34.12 dBµV/m	49.7 dBµV/m	-15.58 dB	Pass
403.235 MHz	29.61 dBµV/m	49.7 dBµV/m	-20.09 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 402.45 MHz
Test Date:	2018-04-04
Note:	In-band emissions

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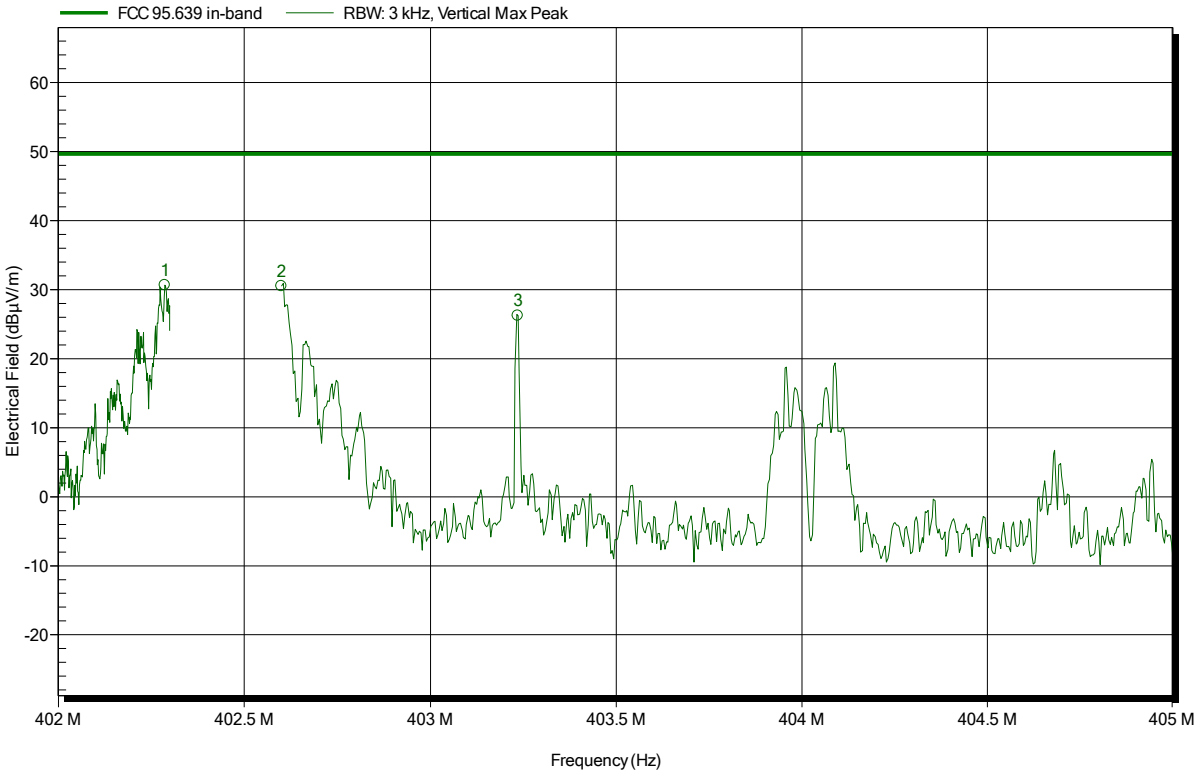

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.287 MHz	30.67 dBµV/m	49.7 dBµV/m	-19.03 dB	Pass
402.6 MHz	30.53 dBµV/m	49.7 dBµV/m	-19.17 dB	Pass
403.235 MHz	26.24 dBµV/m	49.7 dBµV/m	-23.46 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	Band-edge

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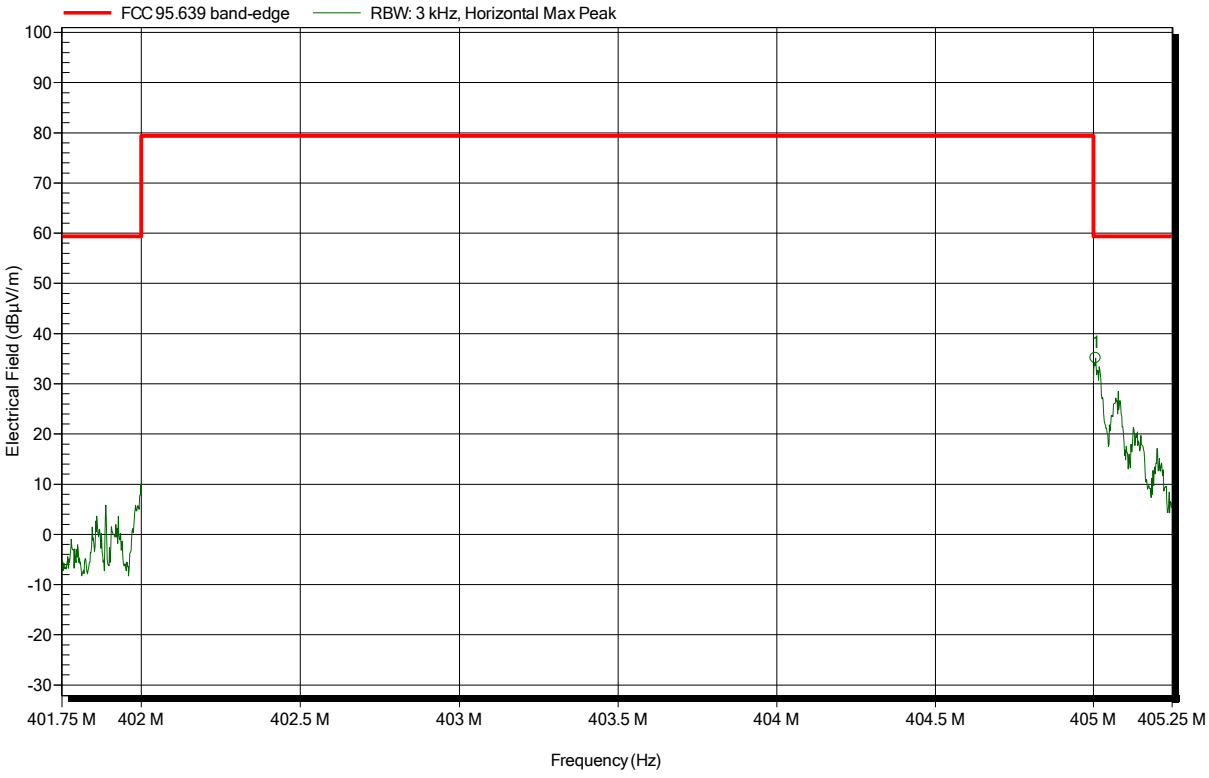

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.006 MHz	35.14 dBµV/m	59.4 dBµV/m	-24.26 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	Band-edge

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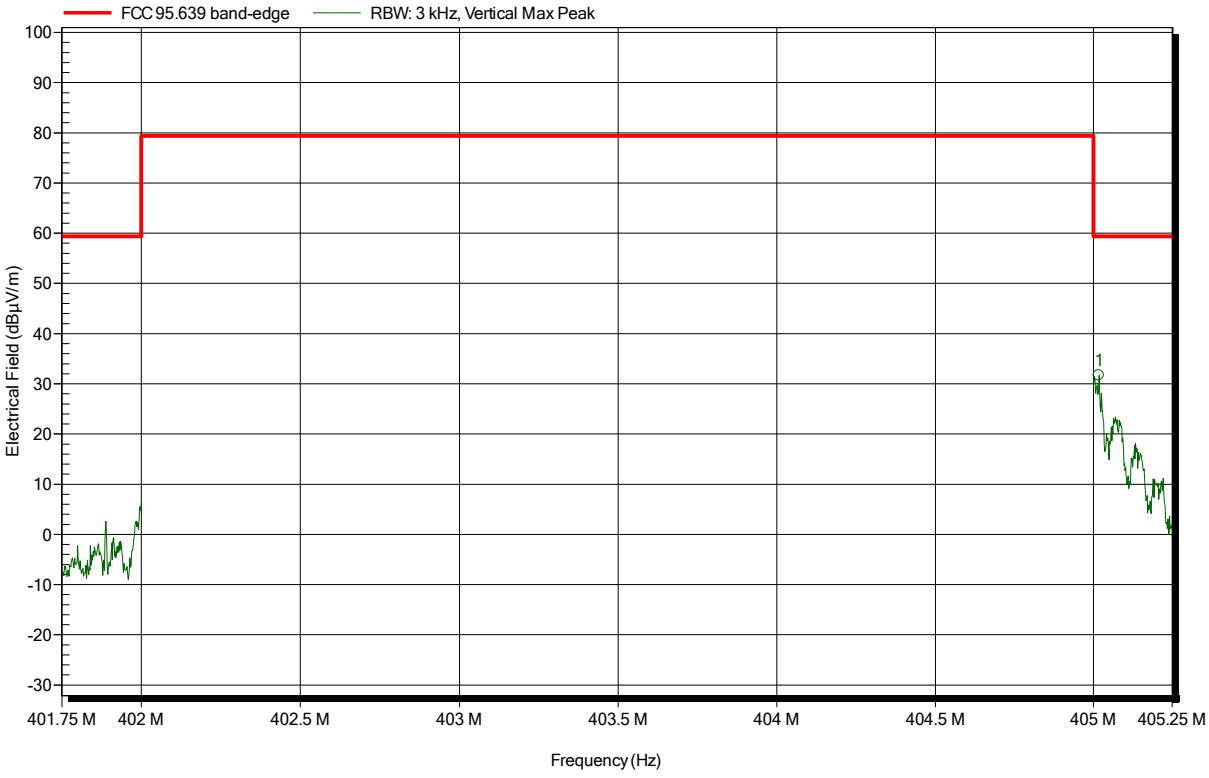

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.016 MHz	31.69 dBµV/m	59.4 dBµV/m	-27.71 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	In-band emissions

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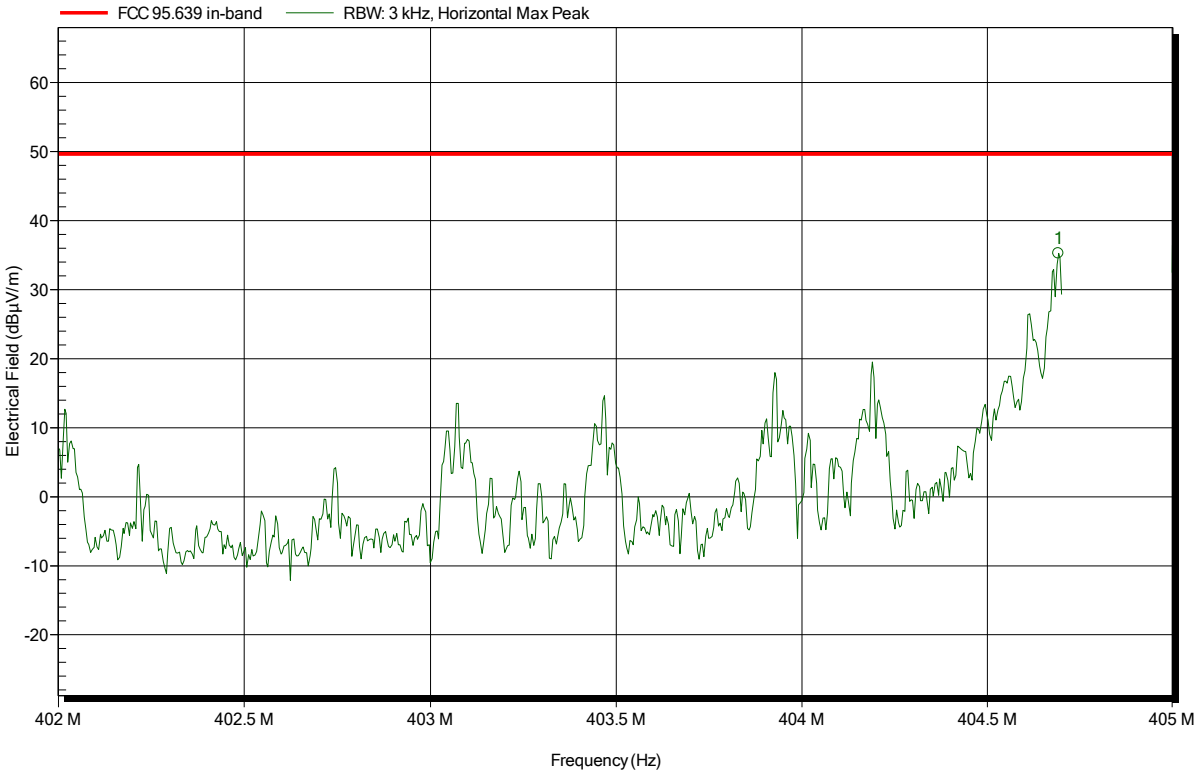

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.691 MHz	35.25 dBµV/m	49.7 dBµV/m	-14.45 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number:	G0M-1803-7311
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 23°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2-FSK; 404.85 MHz
Test Date:	2018-04-04
Note:	In-band emissions

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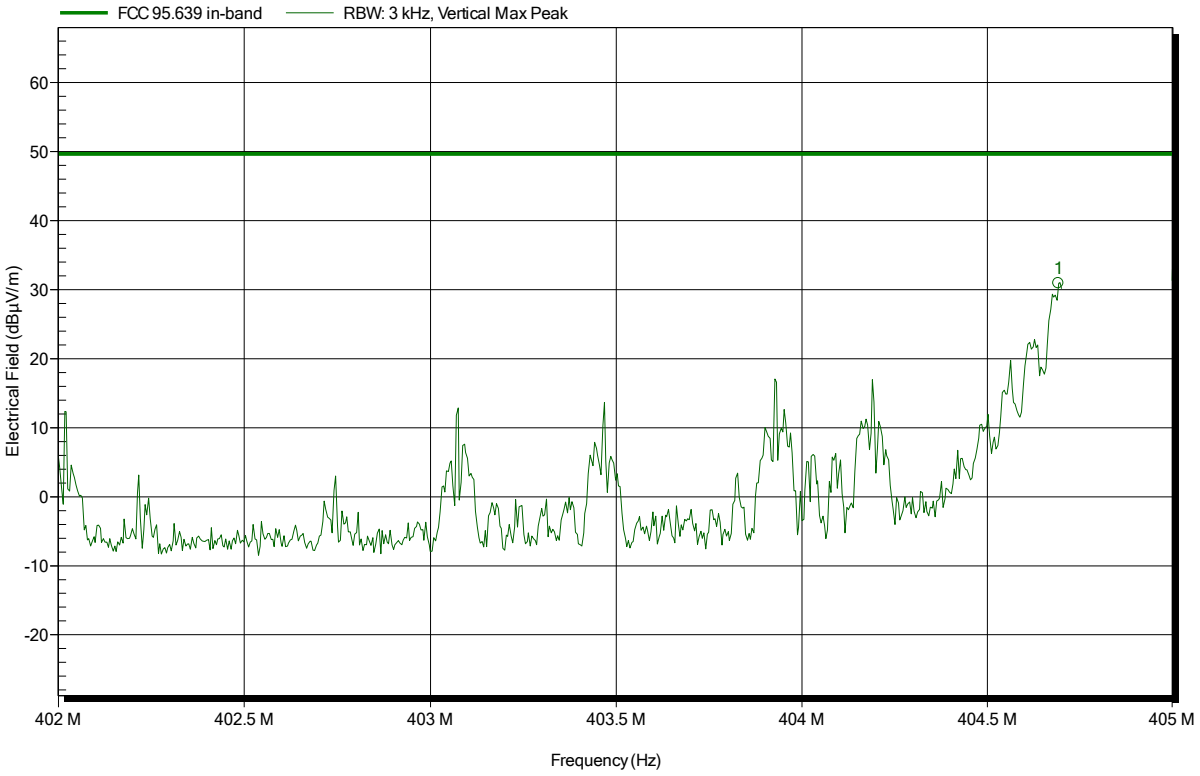

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.691 MHz	30.94 dBµV/m	49.7 dBµV/m	-18.76 dB	Pass

ANNEX D Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1803-7311

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 22°C, Vnom: 3.0 VDC (Battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2018-04-03
Note:	

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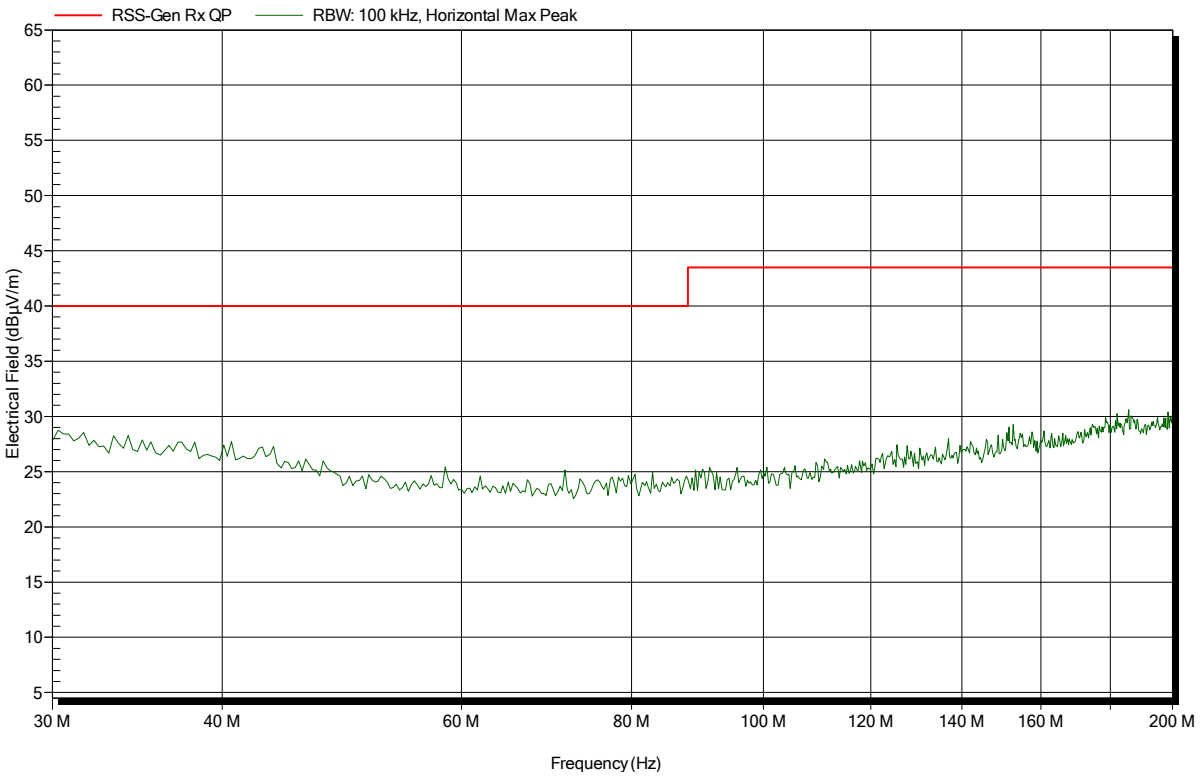

Spurious emissions according to RSS-Gen

Project number: G0M-1803-7311

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 22°C, Vnom: 3.0 VDC (Battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2018-04-03
Note:	

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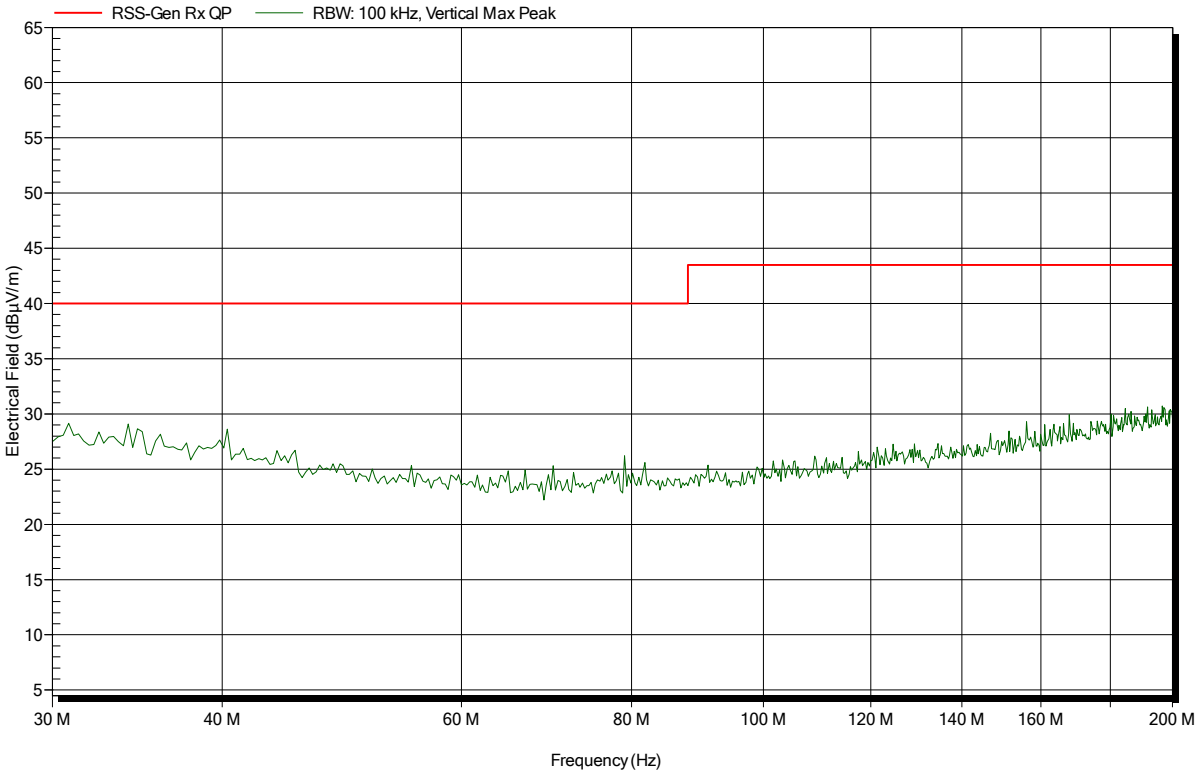

Spurious emissions according to RSS-Gen

Project number: G0M-1803-7311

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 22°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2018-04-03
Note:	

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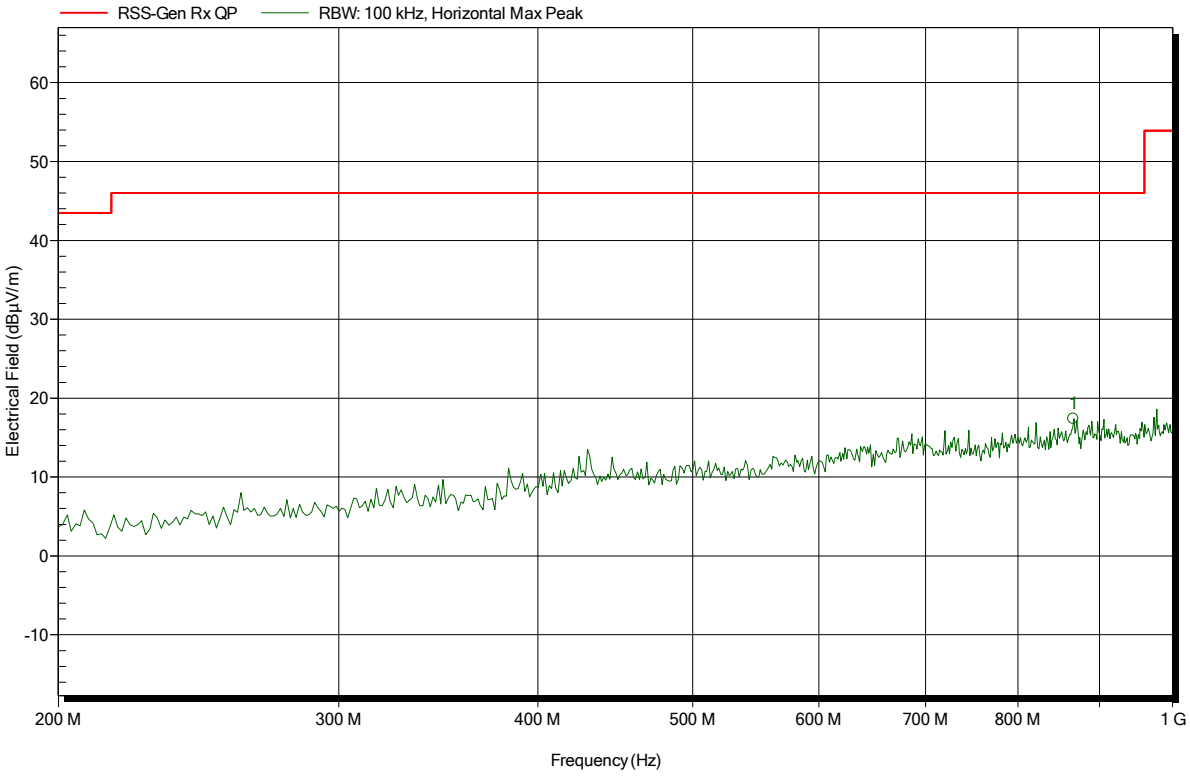

Frequency	Peak	Peak Limit	Peak Difference	Status
866.667 MHz	17.38 dBµV/m	46 dBµV/m	-28.62 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1803-7311

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 22°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2018-04-03
Note:	

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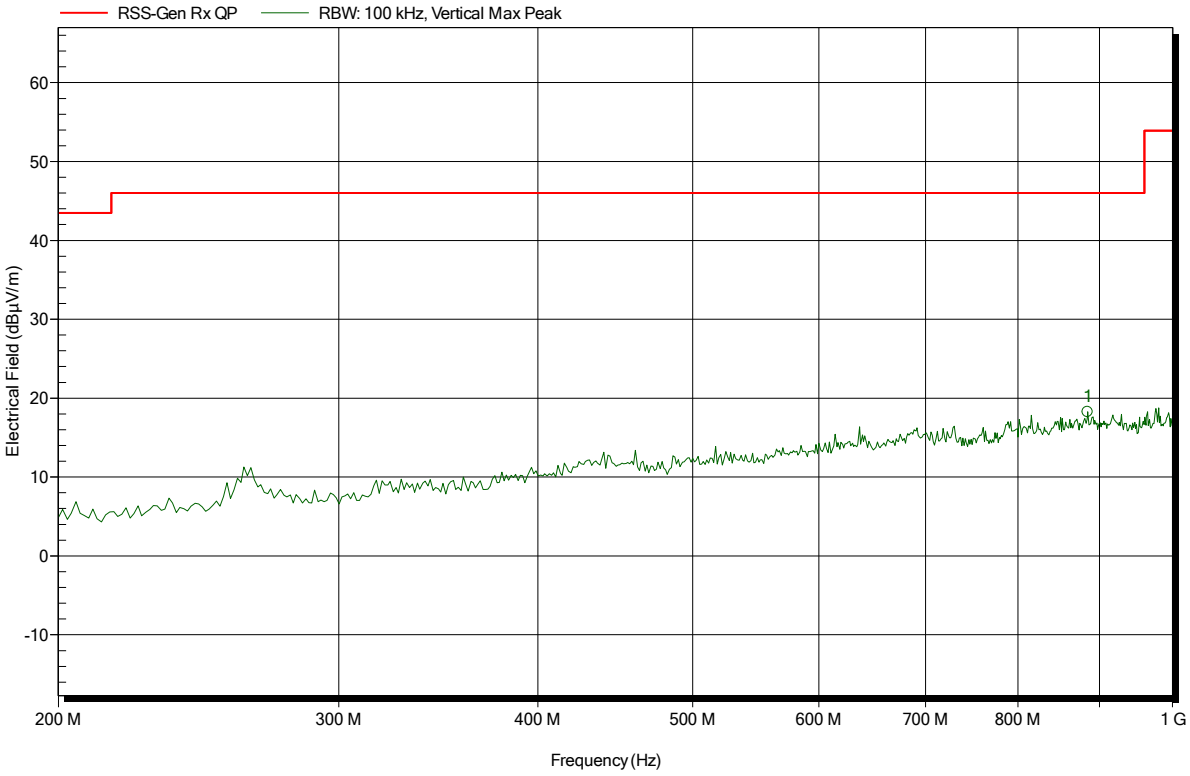

Frequency	Peak	Peak Limit	Peak Difference	Status
884.615 MHz	18.26 dBµV/m	46 dBµV/m	-27.74 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1803-7311

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 22°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2018-04-03
Note:	

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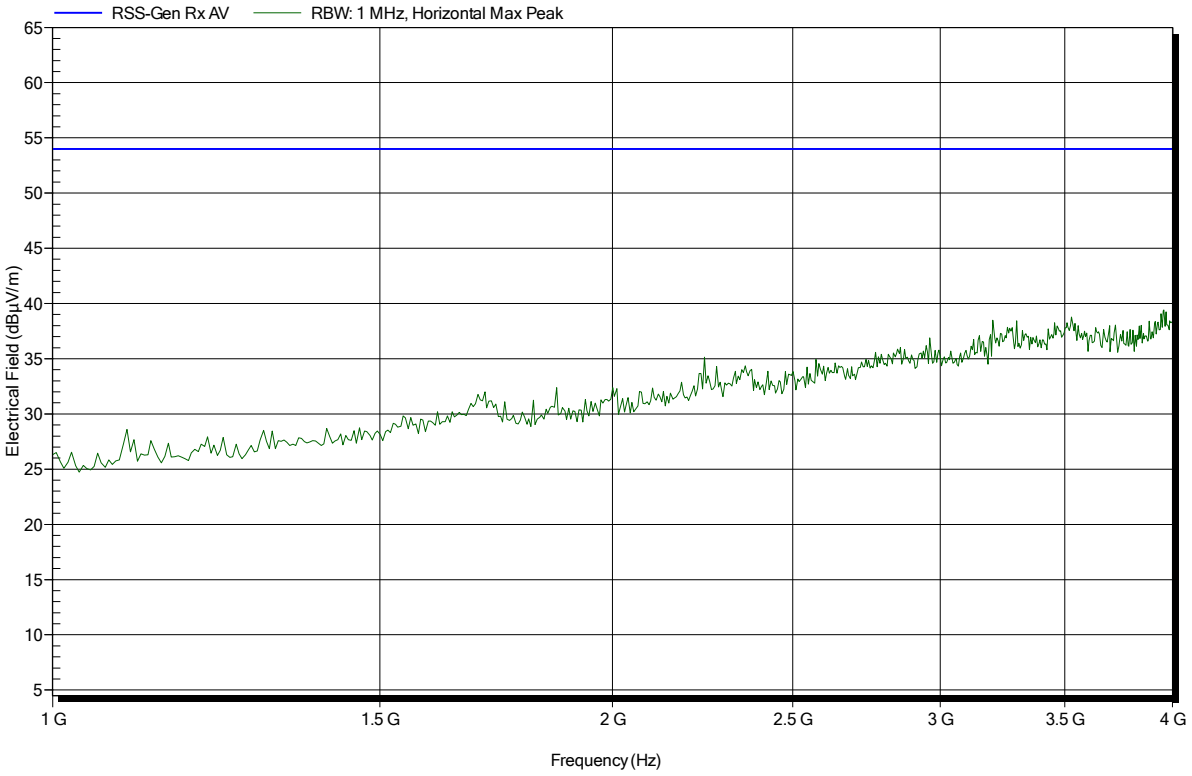

Spurious emissions according to RSS-Gen

Project number: G0M-1803-7311

Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD-4200 / Implantable Cardioverter Defibrillator
Model:	Acticor 7 HF-T
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom: 22°C, Vnom: 3.0 VDC (Battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2018-04-03
Note:	

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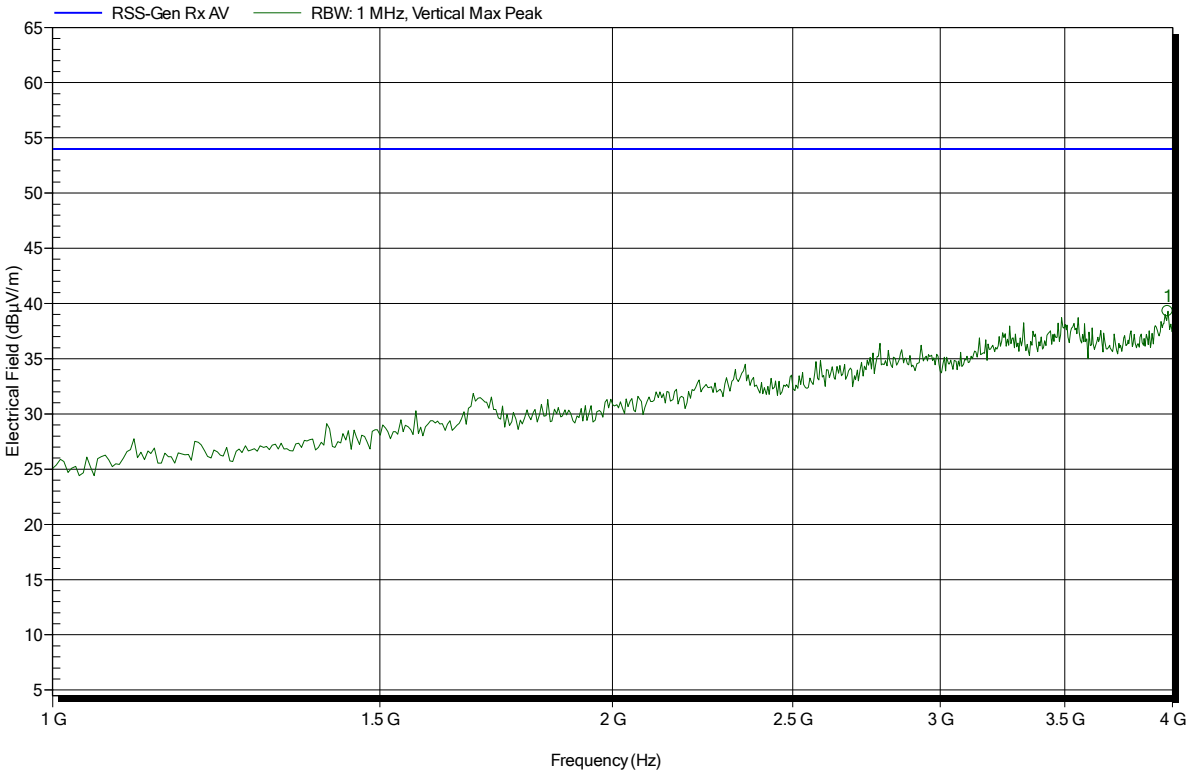

Frequency	Peak	Peak Limit	Peak Difference	Status
3.976 GHz	39.29 dBµV/m	53.98 dBµV/m	-14.69 dB	Pass