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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-1402-3601-TFC95IMR-V01
Testing Laboratory.....:	Eurofins Product Service GmbH
Address.....:	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation.....:	A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Filed Test Laboratory, Reg.-No.: 96970 IC OATS Filing assigned code: 3470A
Applicant's name.....:	Biotronik SE & Co. KG
Address.....:	Woermannkehre 1 12359 Berlin GERMANY
Test specification:	
Standard.....:	47 CFR Part 95E 47 CFR Part 95I 47 CFR Part 15C RSS-243, Issue 3, 2010-02 RSS-Gen, Issue 3, 2010-12 ANSI C63.4:2009 EN 301 839-1 V1.3.1:2009-10
Equipment under test (EUT):	
Product description	ICD / Implantable Cardioverter Defibrillator
Model No.	Inventra 7 HF-T QP / SN: 60508645 (additional models according to family letter)
Additional Model(s)	None
Brand Name(s)	Iperia; Itrevia; Inventra
Hardware version	Rev.: 0A
Firmware / Software version	ROM: 2.3 / RAM: 3.0
	FCC-ID: QRITACH70 IC: 4708A-TACH70
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 .....: 2014-02-10

Date (s) of performance of tests .....: 2014-02-10 - 2014-02-14

Compiled by ..... : Wilfried Treffke

Tested by (+ signature)..... : Wilfried Treffke .....W. Treffke.....
(Responsible for Test)

Approved by (+ signature) ..... : Christian Weber .....C. Weber.....

Date of issue ..... : 2014-03-27

Total number of pages ..... : 81

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:

The report applies to all model stated in the "TACH_70 Family Listing" issued by the Manufacturer 2014-02-10.

	Product Name	Type	no. of chambers	Connector	max.stored energy	SN
1	Inventra 7 HF-T	CRT	3	DF-1	45J	
2	Inventra 7 HF-T	CRT	3	DF-4	45J	
3	Inventra 7 HF-T QP	CRT	3	DF-4 + IS-4	45J	60508645 (Master)
4	Inventra 7 DR-T	DR	2	DF-1	45J	
5	Inventra 7 DR-T	DR	2	DF-4	45J	
6	Inventra 7 VR-T DX	DX	1	DF-1	45J	
7	Inventra 7 VR-T	VR	1	DF-1	45J	
8	Inventra 7 VR-T	VR	1	DF-1	45J	
9	Iperia 7 HF-T	CRT	3	DF-1	40J	60732362
10	Iperia 7 HF-T	CRT	3	DF-4	40J	60732030
11	Iperia 7 HF-T QP	CRT	3	DF-4 + IS-4	40J	
12	Iperia 7 DR-T	DR	2	DF-1	40J	60736887
13	Iperia 7 DR-T	DR	2	DF-4	40J	60732055
14	Iperia 7 VR-T DX	DX	1	DF-1	40J	
15	Iperia 7 VR-T	VR	1	DF-1	40J	60737145
16	Iperia 7 VR-T	VR	1	DF-4	40J	60732364
17	Itrevia 7 HF-T	CRT	3	DF-1	40J	
18	Itrevia 7 HF-T	CRT	3	DF-4	40J	
19	Itrevia 7 HF-T QP	CRT	3	DF-4 + IS-4	40J	
20	Itrevia 7 DR-T	DR	2	DF-1	40J	
21	Itrevia 7 DR-T	DR	2	DF-4	40J	
22	Itrevia 7 VR-T DX	DX	1	DF-1	40J	
23	Itrevia 7 VR-T	VR	1	DF-1	40J	
24	Itrevia 7 VR-T	VR	1	DF-4	40J	
25	Iperia 5 HF-T	CRT	3	DF-1	40J	
26	Iperia 5 HF-T	CRT	3	DF-4	40J	
27	Iperia 5 HF-T QP	CRT	3	DF-4 + IS-4	40J	
28	Iperia 5 DR-T	DR	2	DF-1	40J	
29	Iperia 5 DR-T	DR	2	DF-4	40J	
30	Iperia 5 VR-T DX	DX	1	DF-1	40J	
31	Iperia 5 VR-T	VR	1	DF-1	40J	
32	Iperia 5 VR-T	VR	1	DF-4	40J	
33	Itrevia 5 HF-T	CRT	3	DF-1	40J	
34	Itrevia 5 HF-T	CRT	3	DF-4	40J	
35	Itrevia 5 HF-T QP	CRT	3	DF-4 + IS-4	40J	
36	Itrevia 5 DR-T	DR	2	DF-1	40J	
37	Itrevia 5 DR-T	DR	2	DF-4	40J	
38	Itrevia 5 VR-T DX	DX	1	DF-1	40J	
39	Itrevia 5 VR-T	VR	1	DF-1	40J	
40	Itrevia 5 VR-T	VR	1	DF-4	40J	

The ulp-ami antenna is built into the headers (DF-1 / DF-4 or IS-4). The antenna of header model DF-1 / DF-4 is slightly different from the antenna built into header DF-4. Evaluation measurements were performed for worst case antenna selection and header DF-4 + IS-4 was selected. Besides the DF-4 + IS-4 header, model Inventra 7 HF-T QP, as the most complex model, was selected for the measurements. Hence, the measurements were performed with the following model: "Inventra 7 HF-T QP with connector DF-4 + IS-4".

2. TACH 70 Family Explanation

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 DX are single chamber devices with additional atrial detection.
VR-T are single chamber devices without additional atrial detection.
All variants are available either with DF-1 or with DF-4 connector except for the VR-T DX models that are only available with DF-1 connector. All VR-T DX devices do have the same header.
Iperia and Itrevia are the high energy devices with 40 J max. stored energy.
Inventra represents the ultra high energy device with 45 J max. stored energy.
All of these differences are only relevant in terms of medical aspects. They do not interfere the RF performance.
The different max. stored energies needed for the medical therapy are solely a medical feature that does not affect the RF performance of the devices.

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TACH_70 Header Configuration:

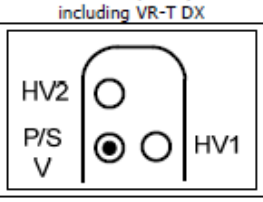
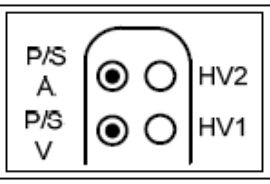
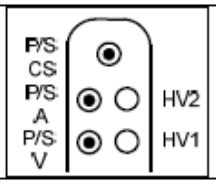
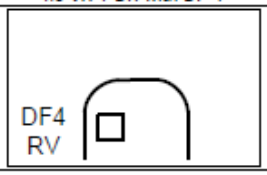
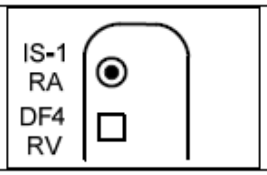
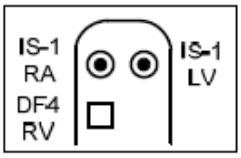
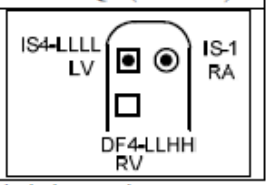
Abbreviations:
ICD Implantable Cardioverter Defibrillator

1. **Header configuration**

The ICD header configuration depends on how many chambers of the heart should be part of the therapy. The main configurations are:

- VR single chamber (ventricle) device
- DR dual chamber (atria, ventricle) device
- HF three chamber (atria, ventricle, coronary artery) device

All these cambers are related to the pacemaker part of the ICD. Therefore the used voltages are low (below10V). The ICD related connectors are the same for all three device configurations. The case, HV1 and HV2 are delivering the high voltage (800V) to the leads to deliver a shock to the patient.
The "-T" declares a device with RF Telemetry. This means the BIOTRONIK Home Monitoring function.
DX is a special VR-T device with a higher sensitivity for the ventricular sense signals.

	single chamber header	dual chamber header	three chamber header
	VR-T (DF1) including VR-T DX	DR-T (DF1)	HF-T (DF1)
DF1			
	VR-T (DF4) no VR-T DX with DF-4	DR-T (DF4)	HF-T (DF4)
DF4			
			HF-T QP (IS4/DF4)
QP			

The IS4 and DF-4 symbol shows are rectangular signs. In the reality the hole is round.

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2. Connector system overview

Connector explanation:

Connector	Explanation
IS-1	- pacemaker lead connector standard Each lead will be connected via one hole with two electrical contacts. The connected electrical signals are low voltage signals, pace and sense. The standard was used within the last 30 years.
IS-4	- new pacemaker lead connector standard All lead's will be connected via one hole with several electrical contacts. The connected electrical signals are low voltage signals, pace and sense.
DF-1	- ICD lead connector standard Each lead will be connected via one hole with two electrical contacts. The connected electrical signals are high voltage signals (800V), HV1 and HV2. The standard was used within the last 30 years.
DF-4	- new ICD HV lead connector standard All lead's will be connected via one hole with several electrical contacts. The connected electrical signals are high voltage signals (800V), HV1 and HV2.

Advantage of IS-4 /DF-4 versus IS-1/DF-1 is that the connection is smaller (one hole instead of 2), reduced number of screw's, a smaller header design, a improved handling and improved reliability of the leads.

DF-4 connector system (VR-T)	
DF-1 versus DF-4 leads	

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Version History

Version	Issue Date	Remarks	Revised by
01	2013-03-27	Initial Release	

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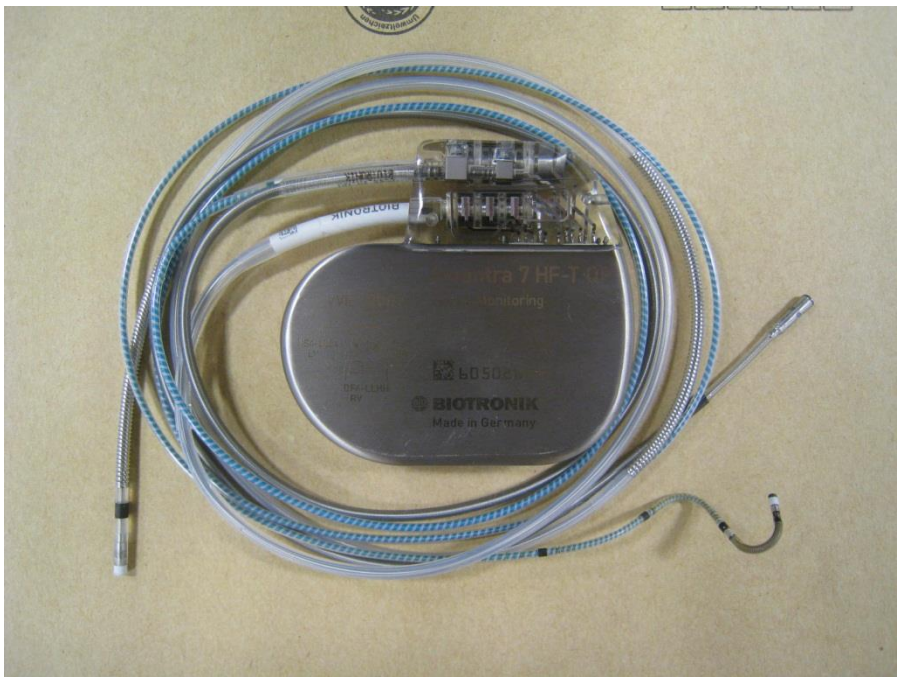
1 Equipment (Test item) Description

Description	ICD / Implantable Cardioverter Defibrillator	
Model	Inventra 7 HF-T QP / SN: 60508645 (additional models according to family letter)	
Additional Model(s)	None	
Brand Name(s)	Iperia; Itrevia; Inventra	
Serial number	None	
Hardware version	Rev.: 0A	
Software / Firmware version	ROM: 2.3 / RAM: 3.0	
FCC-ID	QRITACH70	
IC	4708A-TACH70	
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	Listen before transmit	
Number of antennas	2	
Antenna 1	Type	integrated
	Model	loop antenna
	Manufacturer	see Manufacturer
	Gain	-31.5 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}	25 °C
	T_{MIN}	10 °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

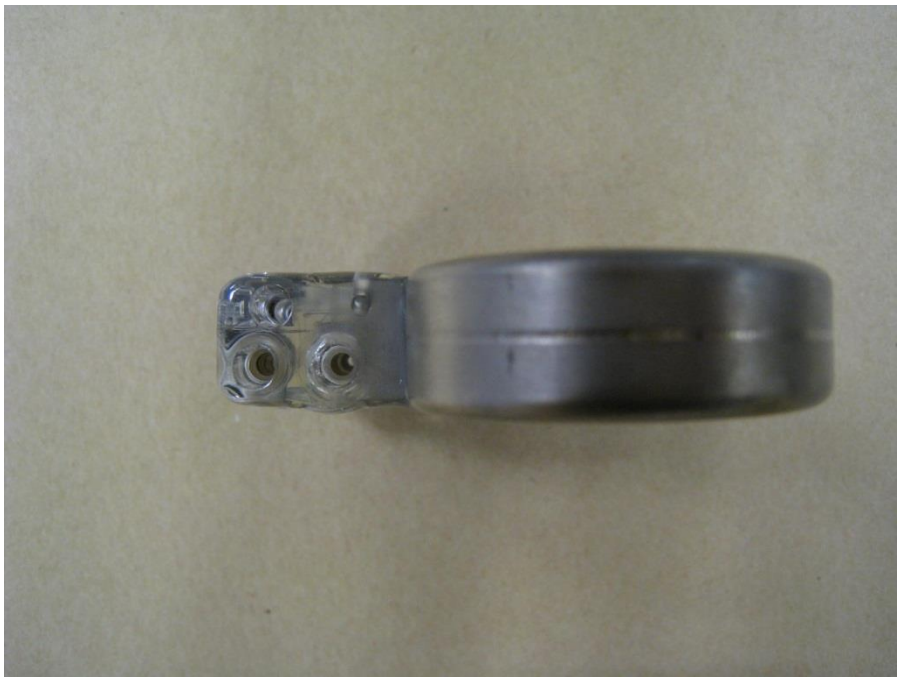
MASTER EUT OVERVIEW



MASTER EUT TOP

MASTER EUT BOTTOM

MASTER EUT HEADER

MASTER EUT CONNECTOR


Iperia 7 HF-T DF4 TOP

Iperia 7 HF-T DF4 BOTTOM

Iperia 7 HF-T DF4 HEADER

Iperia 7 HF-T DF4 CONNECTOR

Iperia 7 VR-T DF4 TOP

Iperia 7 VR-T DF4 BOTTOM

Iperia 7 VR-T DF4 HEADER	Iperia 7 VR-T DF4 CONNECTOR

Iperia 7 DR-T DF4 TOP	Iperia 7 DR-T DF4 BOTTOM

Iperia 7 DR-T DF4 HEADER	Iperia 7 DR-T DF4 CONNECTOR

Iperia 7 VR-T DF1 TOP

Iperia 7 VR-T DF1 BOTTOM

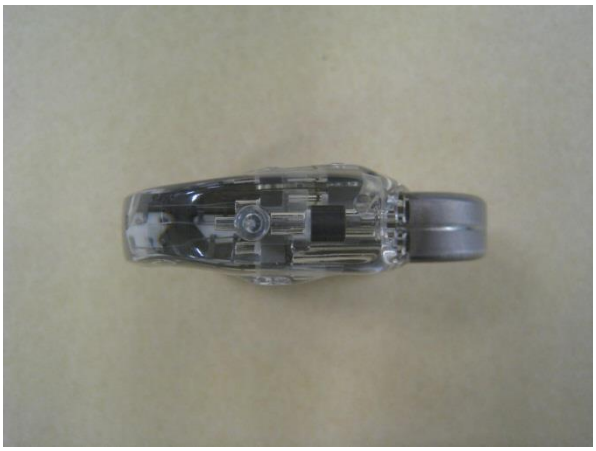
Iperia 7 VR-T DF1 HEADER

Iperia 7 VR-T DF1 CONNECTOR

Iperia 7 HF-T DF1 TOP

Iperia 7 HF-T DF1 BOTTOM

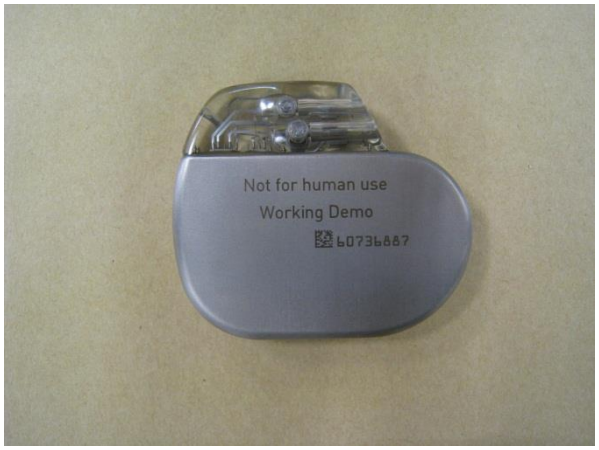
Iperia 7 HF-T DF1 HEADER



Iperia 7 HF-T DF1 CONNECTOR

Iperia 7 DR-T DF1 TOP

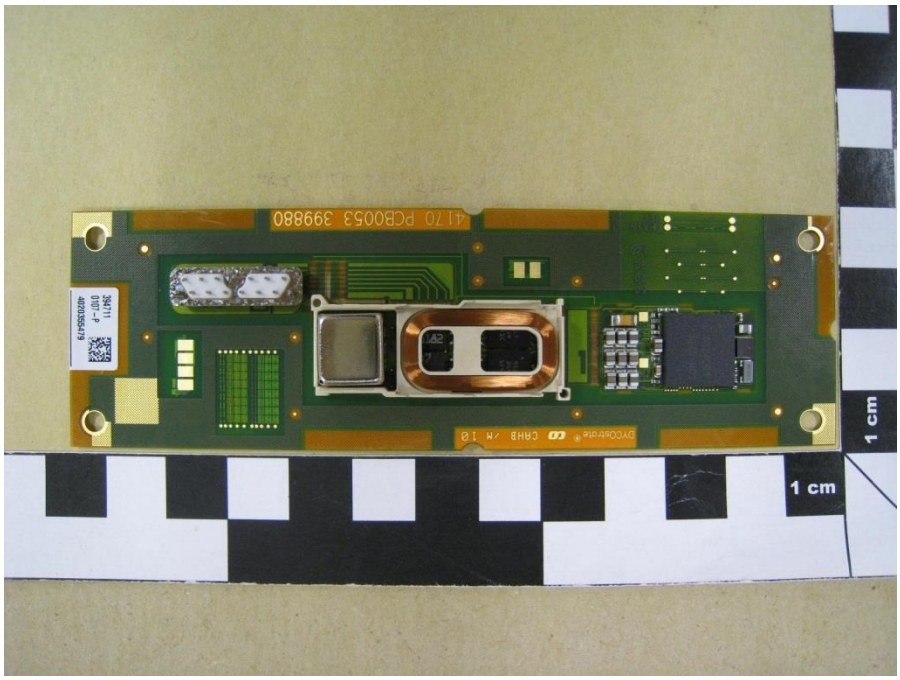
Iperia 7 DR-T DF1 BOTTOM

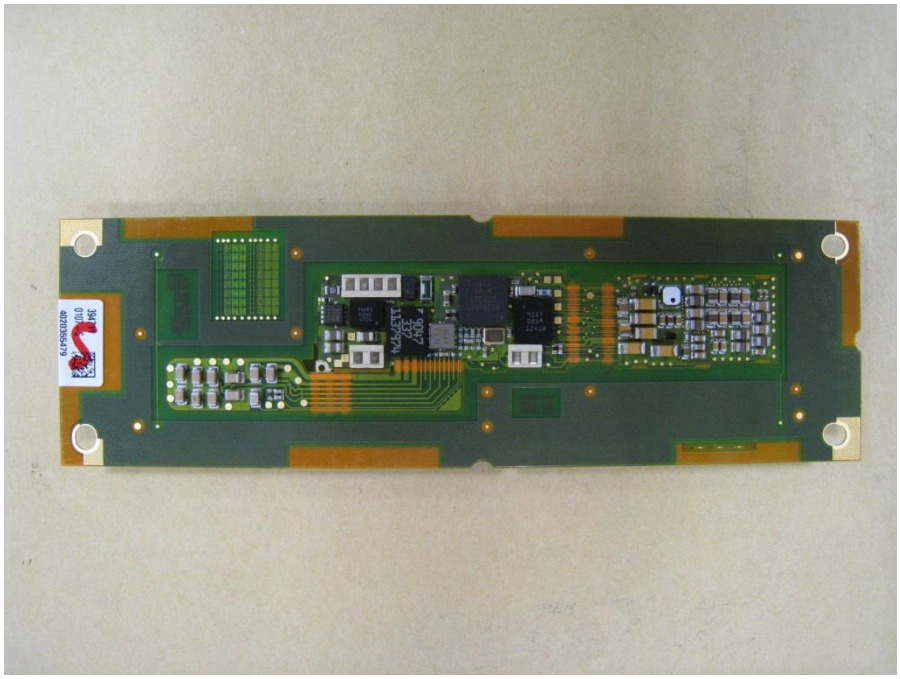


Iperia 7 DR-T DF1 HEADER

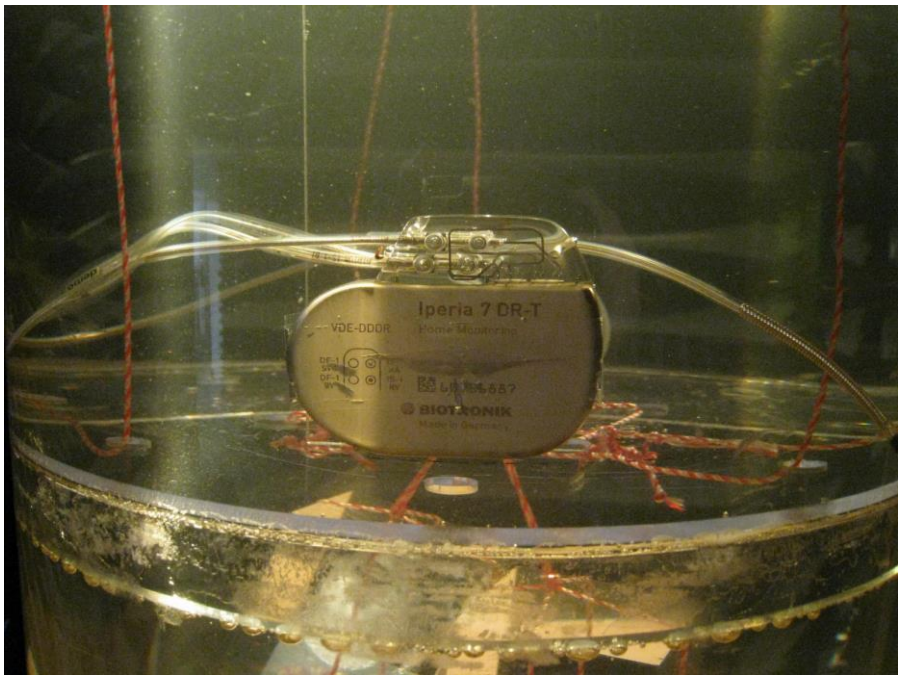
Iperia 7 DR-T DF1 CONNECTOR

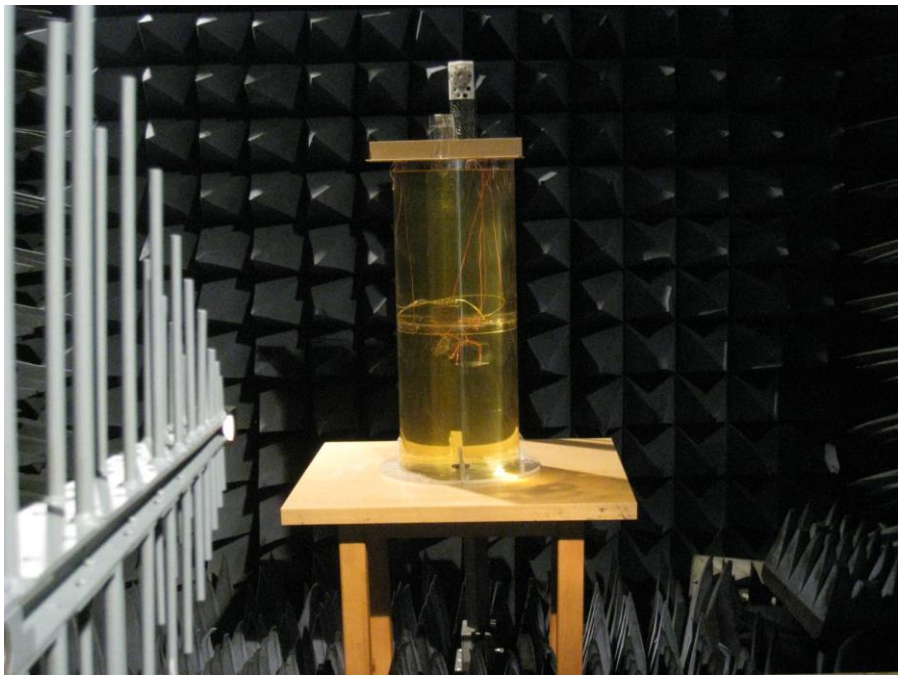
1.2 Photos - Equipment internal

PCB TOP


PCB BOTTOM


1.3 Photos – Test setup

Test setup – Radiated emissions EUT


Test setup – Radiated emissions


1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE	Enginnering communication box	BIOTRONIK	TelBoxII	for test mode
AE	Cardio Messenger	BIOTRONIK	TelexIII	Companion device

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

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.5 Test Modes

Mode #	Description	
Unmodulated	General conditions:	EUT powered by laboratory power supply.
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated	General conditions:	EUT powered by laboratory power supply.
	Radio conditions:	Mode = standalone transmit Modulation = FSK Duty cycle = 100 % Power level = Maximum
Receive	General conditions:	EUT powered by laboratory power supply.
	Radio conditions:	Mode = standalone receive Modulation = FSK

1.6 Test Equipment Used During Testing

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	5.8.37

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2013-06	2014-06

Emission Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2013-06	2014-06

Frequency Stability					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2013-06	2014-06

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Fully-anechoic chamber	Frankonia	AC 4	EF00200	-	-
Spectrum Analyzer	R&S	FSEK30	EF00168	2014-01	2015-01
LPD Antenna	R&S	HL 223	EF00212	2013-02	2016-02

Radiated spurious emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 5	EF00395	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2013-06	2014-06
Biconical Antenna	R&S	HK 116	EF00012	2013-02	2016-02
LPD Antenna	R&S	HL 223	EF00212	2013-02	2016-02
LPD Antenna	R&S	HL 025	EF00327	2013-02	2016-02

Discontinuation of MICS session					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00242	2013-06	2014-06
Signal Generator	R&S	SMP 02	EF00165	2012-06	2014-06

1.7 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

1.8 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	63.01	0.82
Conductivity σ [ms/cm]	9.0	8.9	-1.11

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 4.6	Occupied bandwidth	RSS-Gen 4.6.1	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 4.7	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 4.9	Transmitter unwanted emissions	FCC § 95.635(d) ANSI C63.4	PASS	
IC RSS-243 3.5, 5.6 IC RSS-Gen 4.10 6.1	Receiver spurious emissions	ANSI C63.4	PASS	
FCC § 15.207 IC RSS-Gen 7.2.4	AC power line conducted emissions	ANSI C63.4	N/R	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/R	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/R	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/R	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/R	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/R	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/R	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/R	Not used
Remarks:				

3 Test Conditions and Results

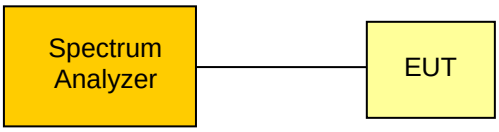
3.1 Test Conditions and Results – Occupied Bandwidth

Occupied Bandwidth acc. IC RSS-243	**Verdict: PASS**
Test according to measurement reference	Reference Method
	RSS-Gen 4.6.1
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated

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

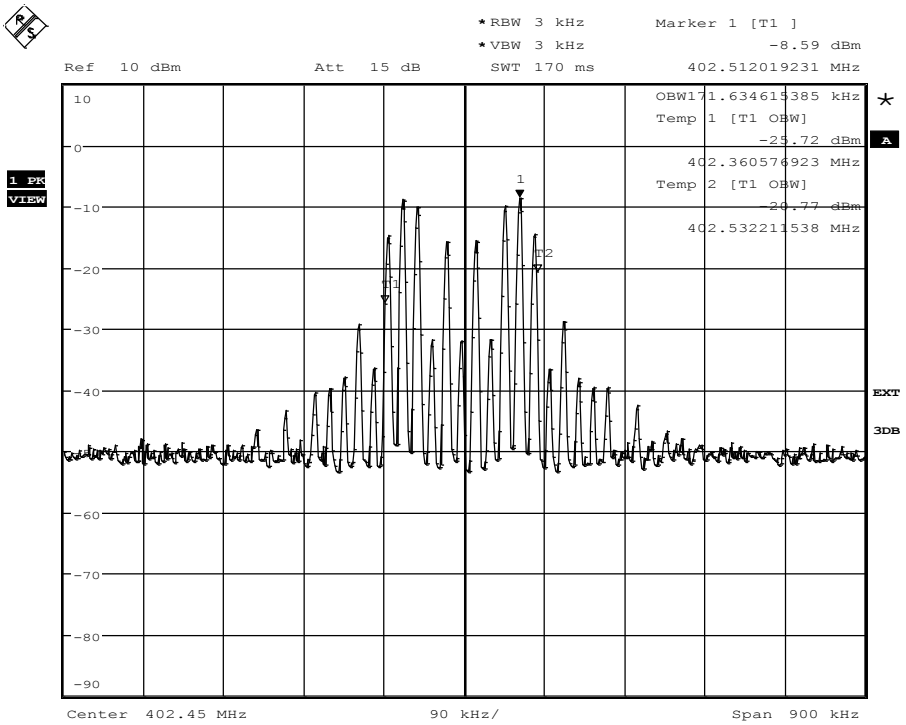
Channel	Frequency [MHz]	Occupied Bandwidth [kHz]
F_{LOW}	402.45	171.6
F_{MID}	403.65	173.1
F_{HIGH}	404.85	170.2

Comments:

Occupied Bandwidth – F_{LOW}

RSS-Gen
Occupied frequency bandwidth

EUT	IPG / Implantable Cardioverter Defibrillator
Model	Tach_70 / G0M-1402-3601
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	37°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 402.45 MHz
Comment 3	OBW: 171.63 kHz



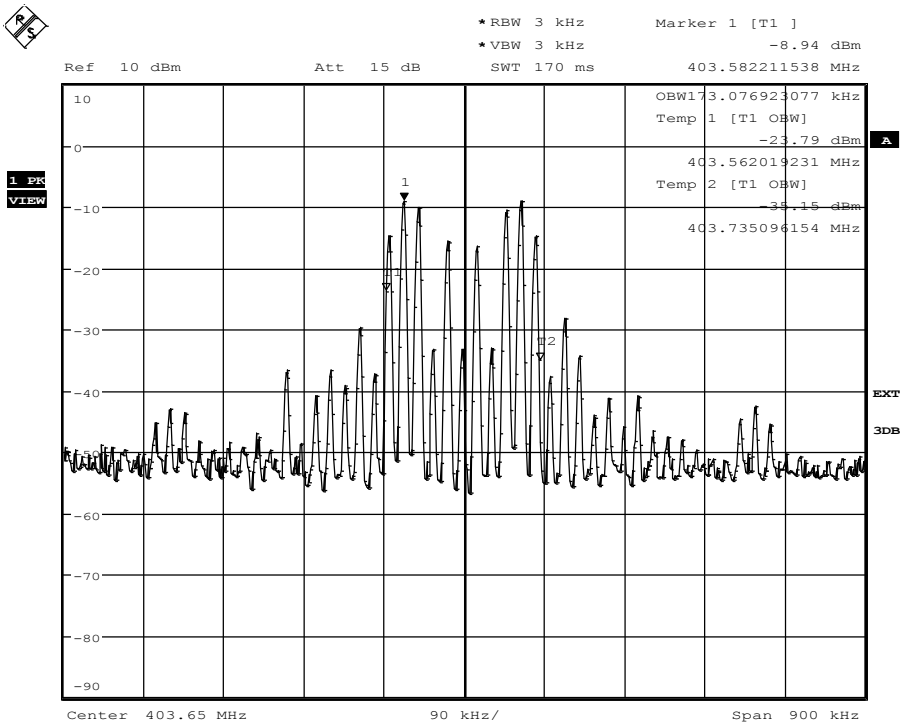
Occupied bandwidth: 171.6 KHz

Date: 13.FEB.2014 10:27:21

Occupied Bandwidth - F_{MID}

RSS-Gen
Occupied frequency bandwidth

EUT	IPG / Implantable Cardioverter Defibrillator
Model	Tach_70 / G0M-1402-3601
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	37°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 403.65 MHz
Comment 3	OBW: 173.08 kHz



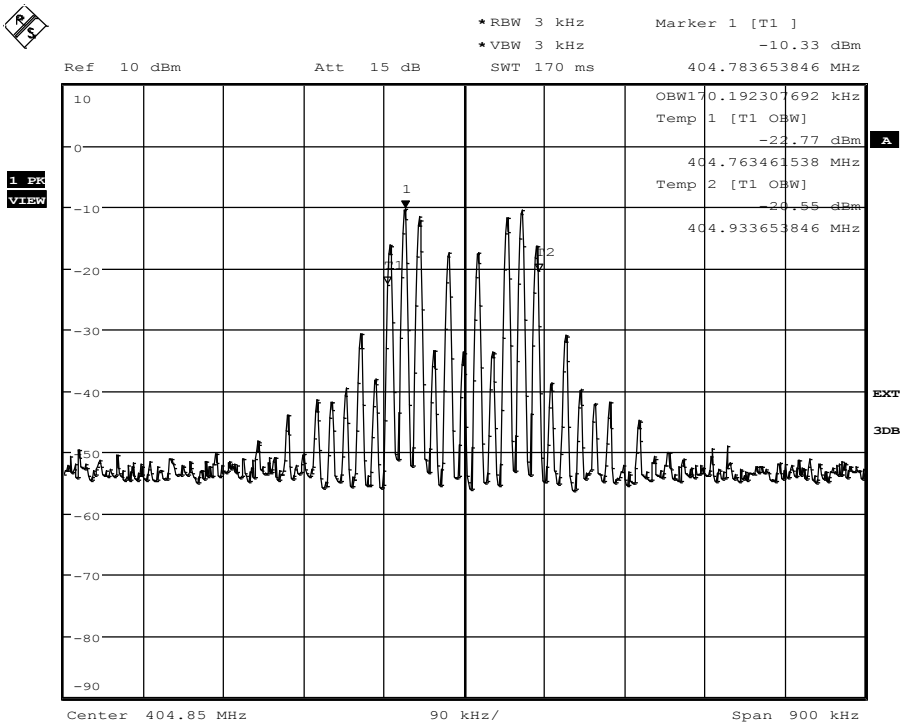
Occupied bandwidth: 199 KHz

Date: 13.FEB.2014 10:48:58

Occupied Bandwidth - F_{HIGH}

RSS-Gen
Occupied frequency bandwidth

EUT	IPG / Implantable Cardioverter Defibrillator
Model	Tach_70 / G0M-1402-3601
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	37°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 404.85 MHz
Comment 3	OBW: 170.19 kHz



Occupied bandwidth: 170.2 KHz

Date: 13.FEB.2014 10:54:55

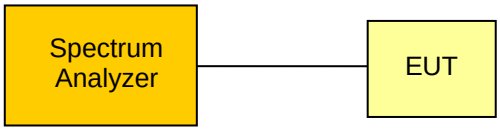
3.2 Test Conditions and Results – Emission Bandwidth

Emission Bandwidth acc. FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.628(d) / FCC 95.633(e) / IC RSS-243 3.3 5.1
Test according to measurement reference	Reference Method
	FCC 95.628(a)(6)(i) / FCC 95.633(e)(3)
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated

Limits

≤ 300 kHz

Test setup



Test procedure

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

Test results

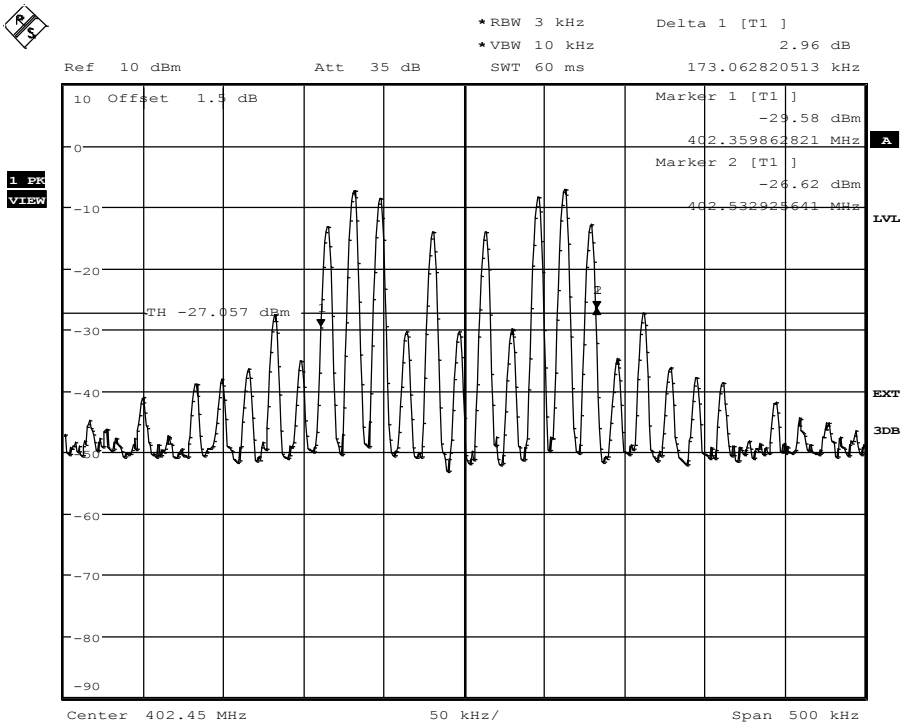
Channel	Frequency [MHz]	Emission Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	402.45	173.1	≤ 300	PASS
F_{MID}	403.65	204.5	≤ 300	PASS
F_{HIGH}	404.85	173.1	≤ 300	PASS

Comments:

Emission Bandwidth – F_{LOW}

FCC Part 95.633
Emission bandwidth

EUT	IPG / Implantable Cardioverter Defibrillator
Model	Tach_70 / G0M-1402-3601
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	37°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.633
Comment 1	20 dB Emission bandwidth
Comment 2	Channel: 402.45 MHz
Comment 3	Pass



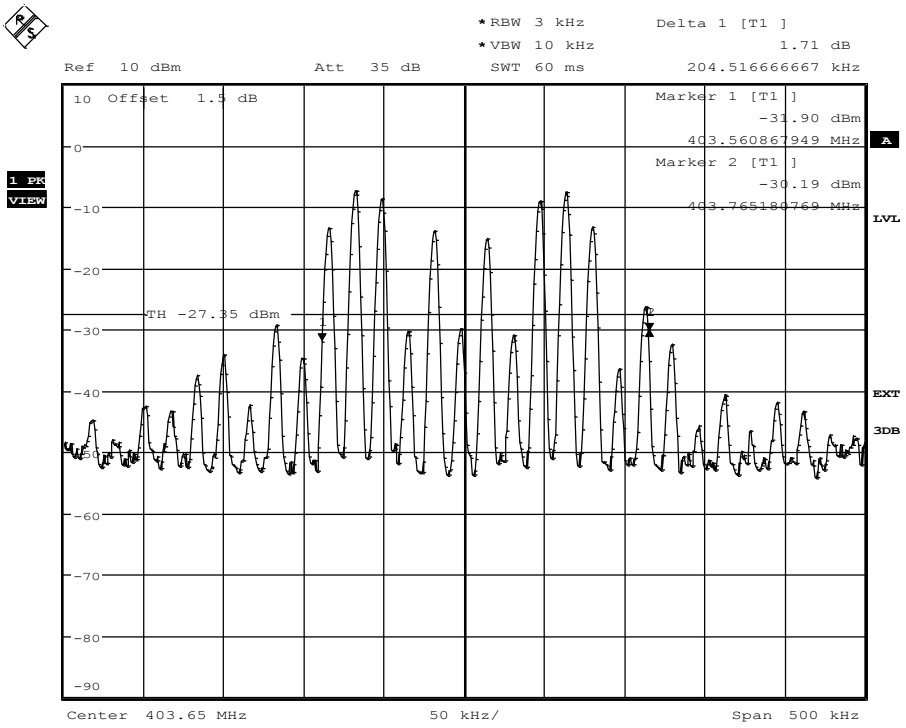
20 dB bandwidth: 173.1 KHz

Date: 13.FEB.2014 11:17:52

Emission Bandwidth – F_{MID}

FCC Part 95.633
Emission bandwidth

EUT	IPG / Implantable Cardioverter Defibrillator
Model	Tach_70 / G0M-1402-3601
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	37°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.633
Comment 1	20 dB Emission bandwidth
Comment 2	Channel: 403.65 MHz
Comment 3	Pass



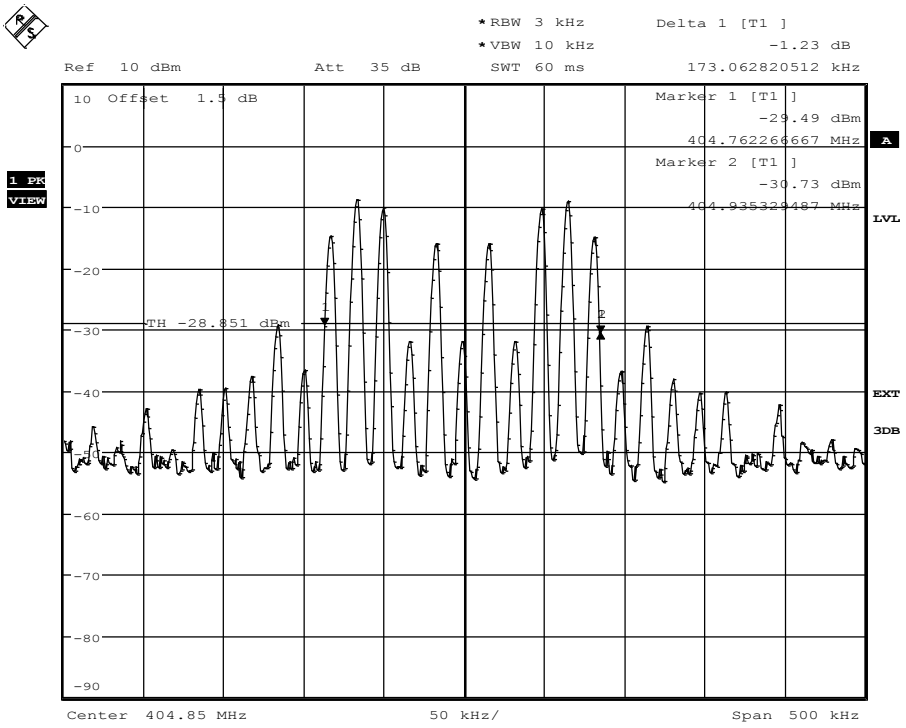
20 dB bandwidth: 204.5 KHz

Date: 13.FEB.2014 11:10:44

Emission Bandwidth – F_{HIGH}

FCC Part 95.633
Emission bandwidth

EUT	IPG / Implantable Cardioverter Defibrillator
Model	Tach_70 / G0M-1402-3601
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	37°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.633
Comment 1	20 dB Emission bandwidth
Comment 2	Channel: 404.85 MHz
Comment 3	Pass



20 dB bandwidth: 173.1 KHz

Date: 13.FEB.2014 11:03:19

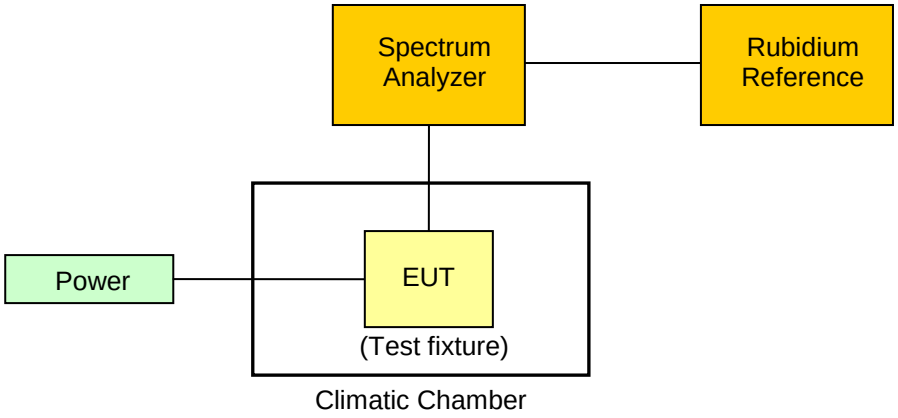
3.3 Test Conditions and Results – Frequency stability

Frequency stability acc. 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} = 25 °C	V_{NOM} = 3.0 VDC	402.446857	-7.81
F_{LOW}	402.45	T_{MIN} = 10 °C	V_{NOM} = 3.0 VDC	402.447152	-7.08
F_{LOW}	402.45	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	402.446892	-7.72
F_{MID}	403.65	T_{NOM} = 25 °C	V_{NOM} = 3.0 VDC	403.64789	-5.23
F_{MID}	403.65	T_{MIN} = 10 °C	V_{NOM} = 3.0 VDC	403.64821	-4.43
F_{MID}	403.65	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	403.647938	-5.11
F_{HIGH}	404.85	T_{NOM} = 25 °C	V_{NOM} = 3.0 VDC	404.848939	-2.62
F_{HIGH}	404.85	T_{MIN} = 10 °C	V_{NOM} = 3.0 VDC	404.849248	-1.86
F_{HIGH}	404.85	T_{MAX} = 45 °C	V_{NOM} = 3.0 VDC	404.848983	-2.51
Comments:					

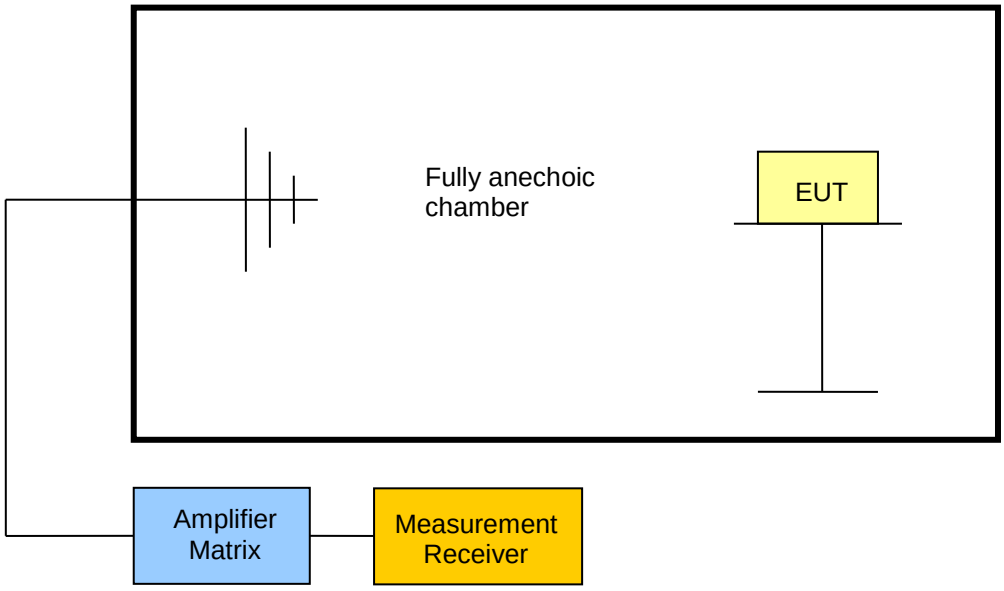
3.4 Test Conditions and Results – Transmitter output power

Transmitter output power acc. 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	Modulated

Limits

≤ 25 µW (-16 dBm) e.i.r.p.

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 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	-34.7	pk	-16	-18.70
F_{HIGH}	404.85	-34.5	pk	-16	-18.50
Comments:					

3.5 Test Conditions and Results – Band-edge compliance

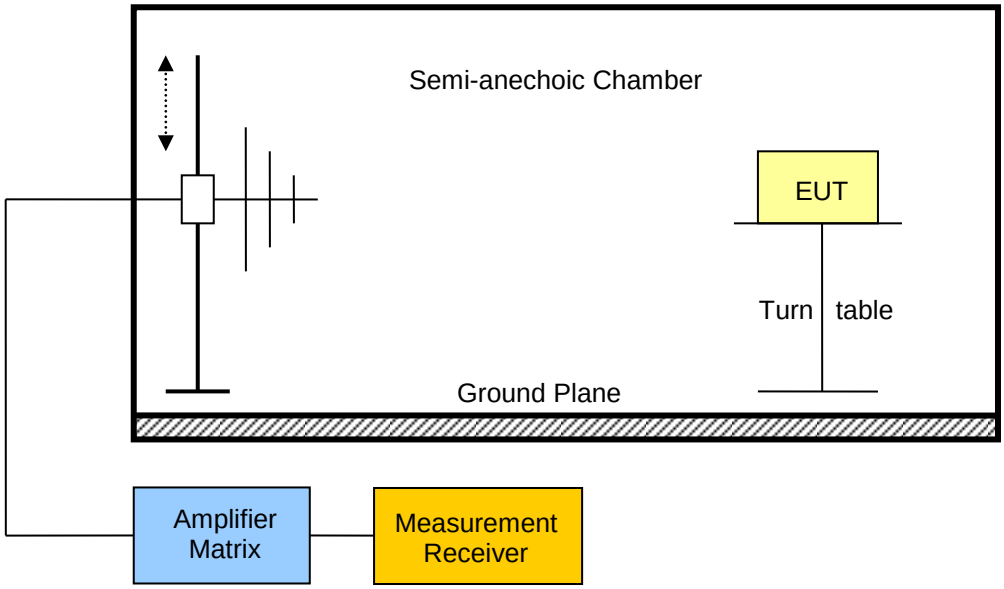
Band-edge compliance acc. FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9
Test according to measurement reference	Reference Method
	FCC 95.635(d) / ANSI C 63.4
Test frequency range	Tested frequencies
	F_{LOW}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

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

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

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

Test setup



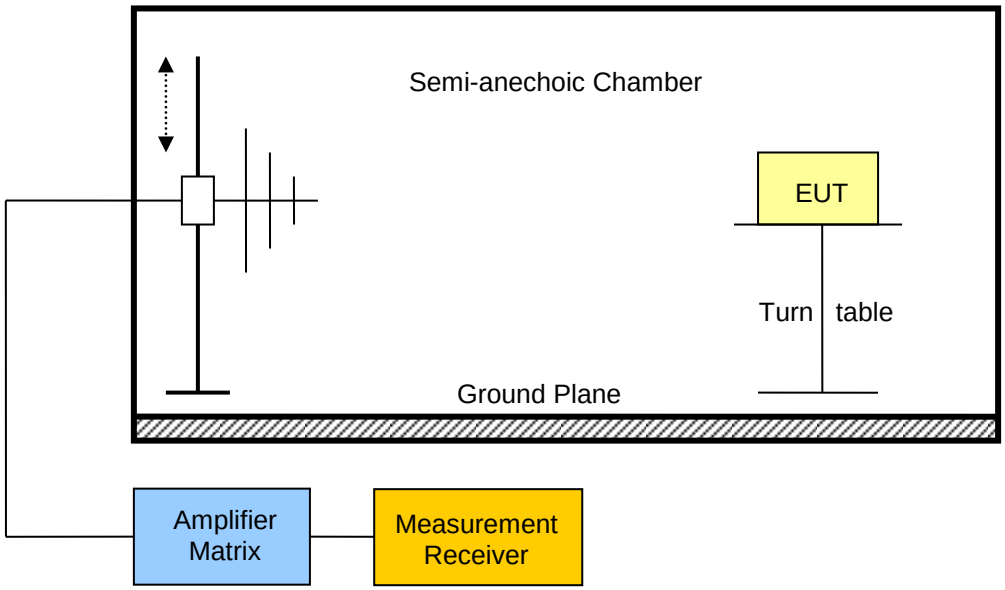
Test procedure
1. EUT set to test frequency with modulation 2. Measurement polarization is set to vertical 3. Span it set according to measurement range 4. Resolution bandwidth is set to 1% of the emission bandwidth and detector is set to peak 5. During the sweep the EUT is rotated to obtain maximum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

Test results

Channel	Frequency [MHz]	Max. Emission Level [dBµV/m]	Max. Carrier Level [dBµV/m]	In-band Limit [dBµV/m]	Result
F_{LOW}	402.45	30.04	59.3	39.3	PASS
F_{HIGH}	404.85	24.47	59.3	39.3	PASS
Comments: see attached diagrams					

3.6 Test Conditions and Results – Transmitter unwanted emissions

Transmitter unwanted emissions acc. 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

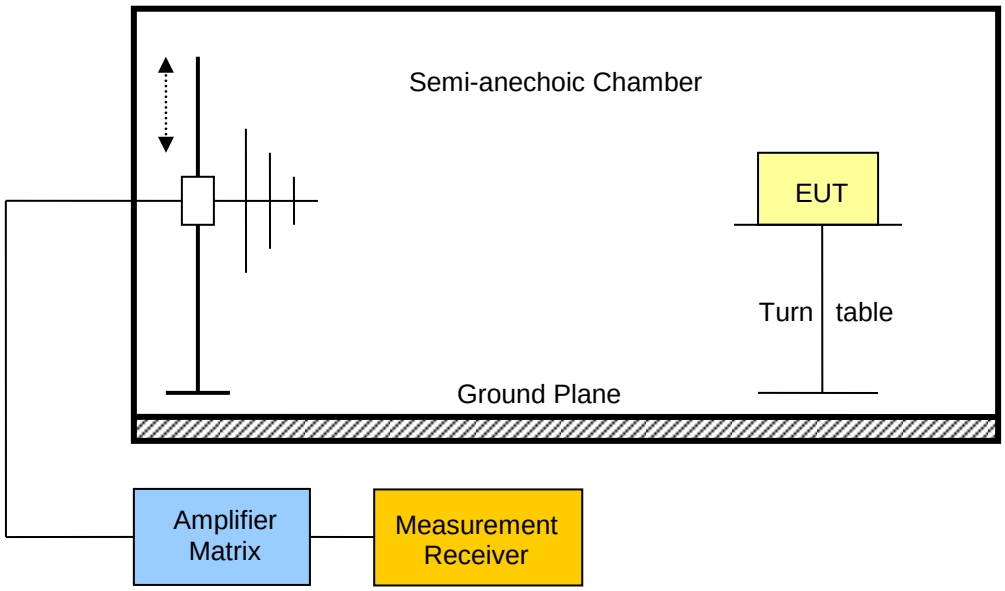
Test results

Channel	Frequency [MHz]	Mode	Emission [MHz]	Level [dbµV/m]	Det.	Pol.	Limit [dbµV/m]	Limit dist. [m]*	Margin [dB]
F_{LOW}	402.45	Modulated	406.44	21.86	pk	hor	46.00	3	-24.14
F_{LOW}	402.45	Modulated	406.44	21.19	pk	ver	46.00	3	-24.81
F_{HIGH}	404.85	Modulated	400.136	24.04	pk	hor	46.00	3	-21.96
F_{HIGH}	404.85	Modulated	400.136	22.81	pk	ver	46.00	3	-23.19
F_{HIGH}	404.85	Modulated	404.999	22.90	pk	hor	40.50	3	-17.60
F_{HIGH}	404.85	Modulated	405.014	18.13	pk	ver	59.40	3	-41.27
F_{HIGH}	404.85	Modulated	405.25	27.04	pk	hor	46.00	3	-18.96

Comments: * Physical distance between EUT and measurement antenna.

3.7 Test Conditions and Results – Receiver spurious emissions

Receiver spurious emissions acc. 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 – 3th 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]	Emission Level [µV/m]	Det.	Pol.	Limit [µV/m]	Margin [µV/m]
F_{MID}	403.65	3928	42.2	128.8	pk	ver	500	-371.2

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-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 2FSK; 402.45MHz
Test Date:	2014-02-11
Note:	Tx Power EIRP

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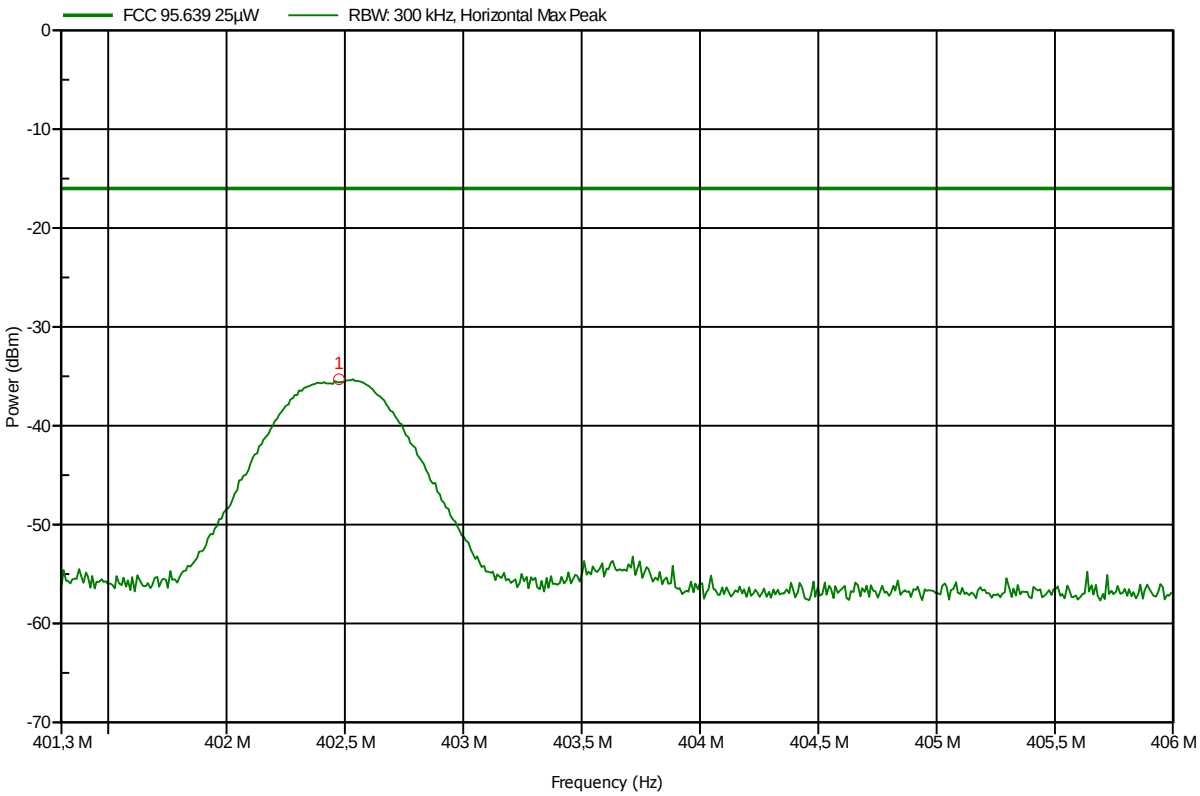

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402,475 MHz	-35,3 dBm	-16 dBm	-19,3 dB	Pass

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	Tx Power EIRP

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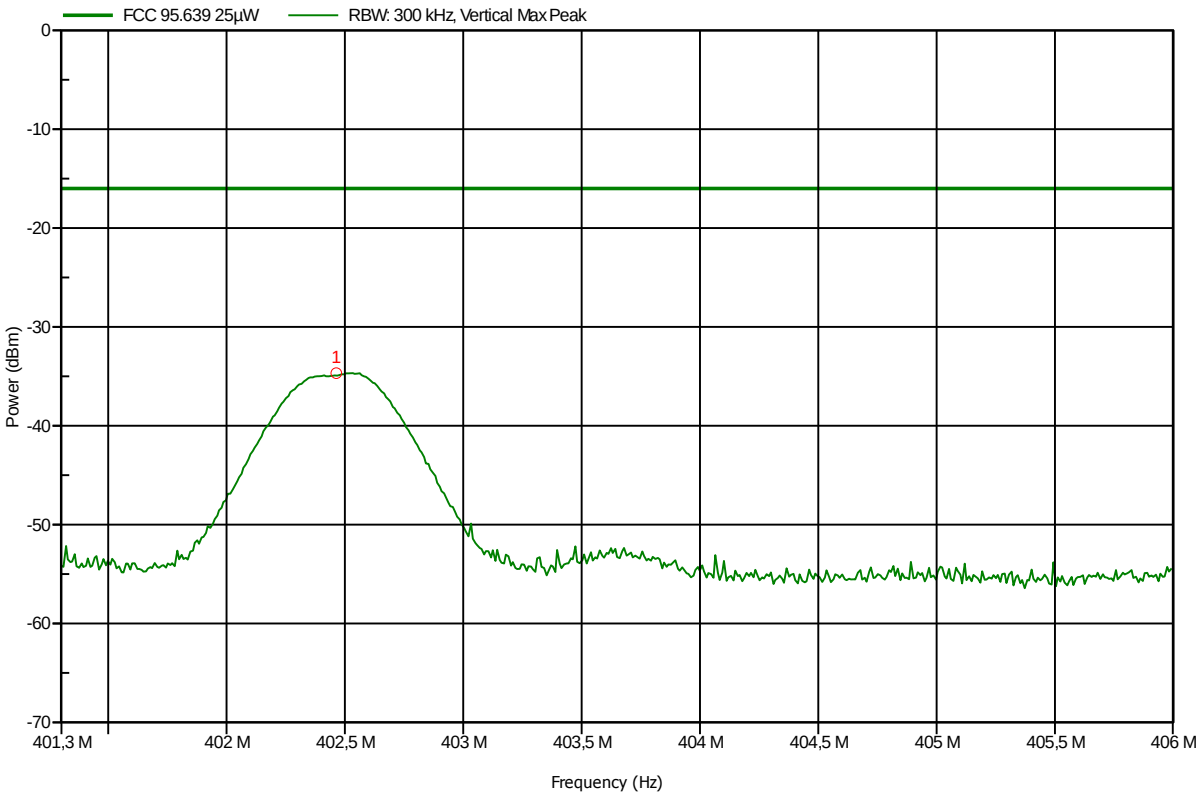

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402,464 MHz	-34,7 dBm	-16 dBm	-18,68 dB	Pass

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	Tx Power EIRP

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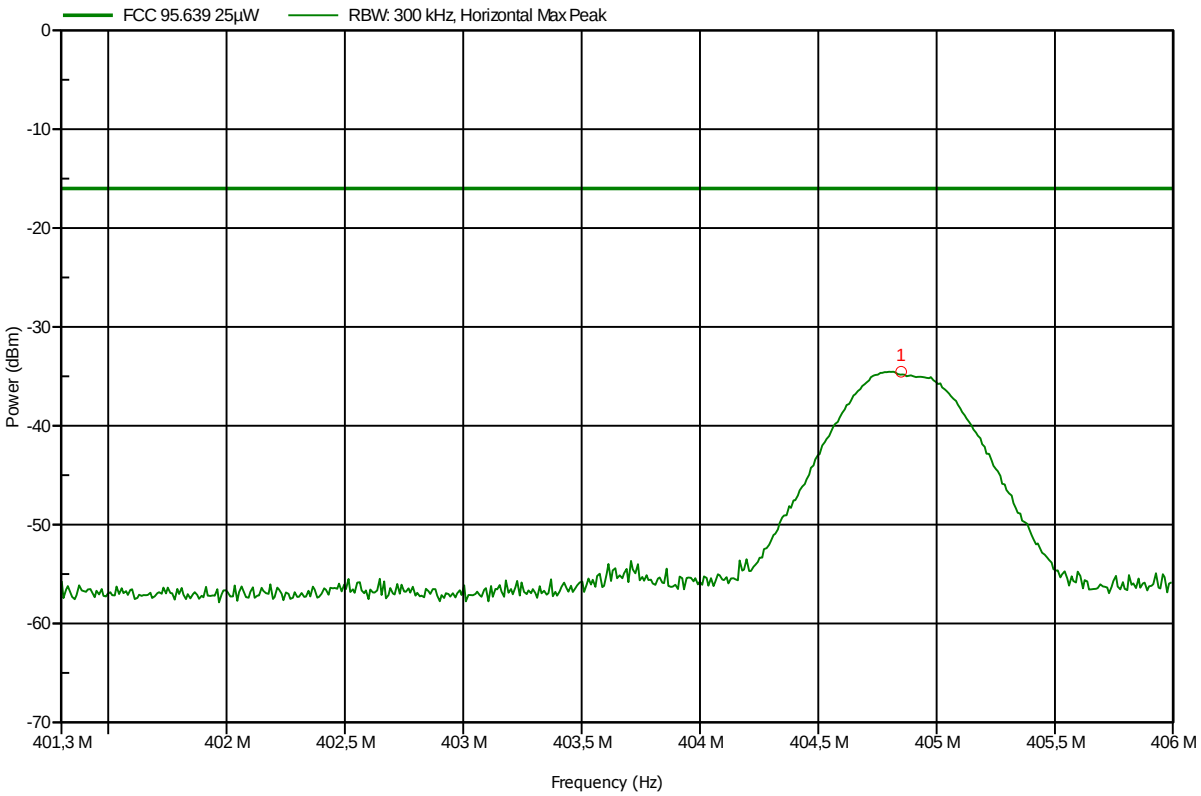
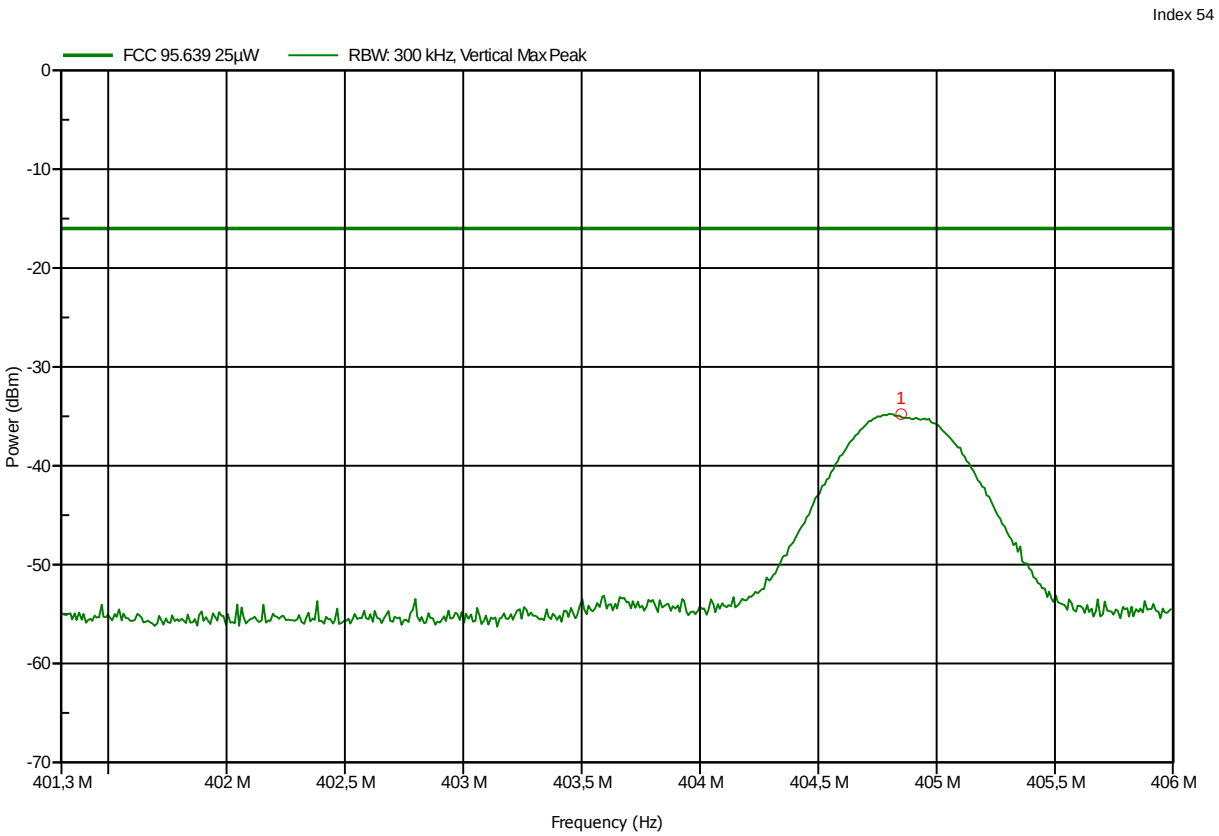


Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404,85 MHz	-34,5 dBm	-16 dBm	-18,54 dB	Pass

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	Tx Power EIRP



Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404,85 MHz	-34,8 dBm	-16 dBm	-18,78 dB	Pass

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	Power dBµV/m ERP

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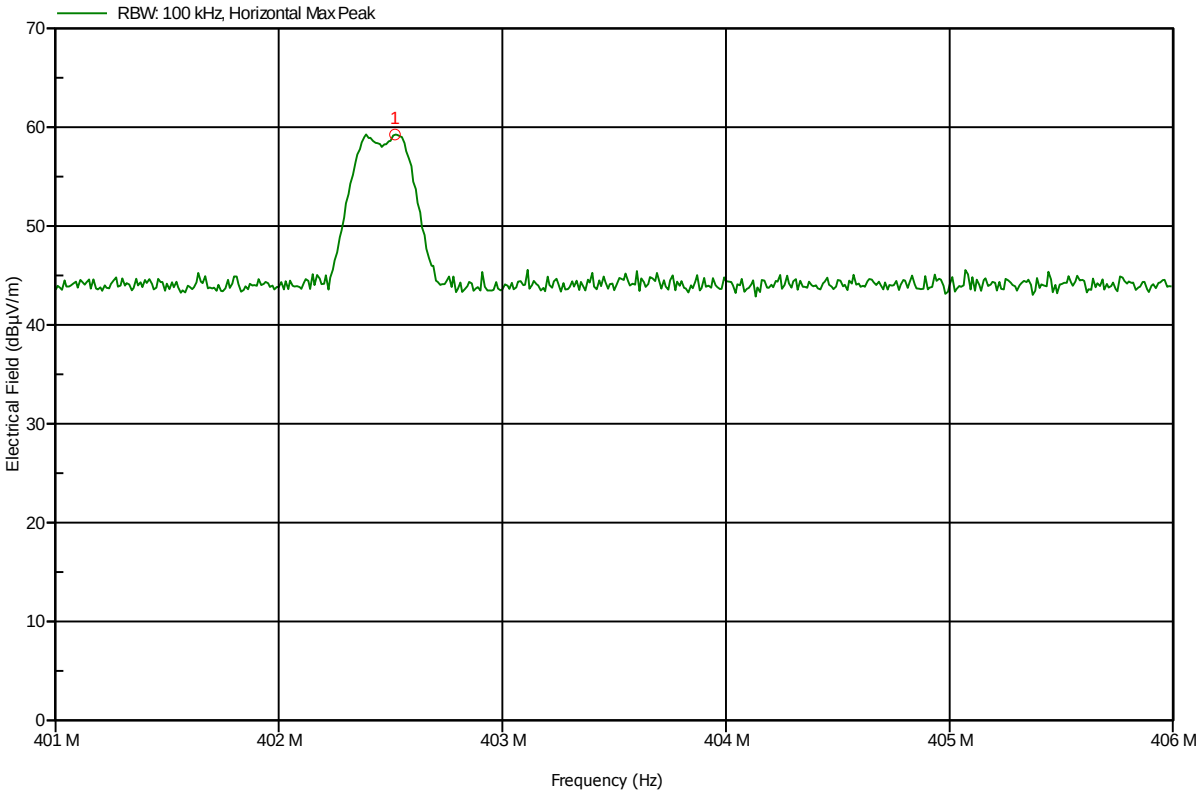

Frequency	Peak
402,52 MHz	59,26 dBµV/m

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	Power dBµV/m ERP

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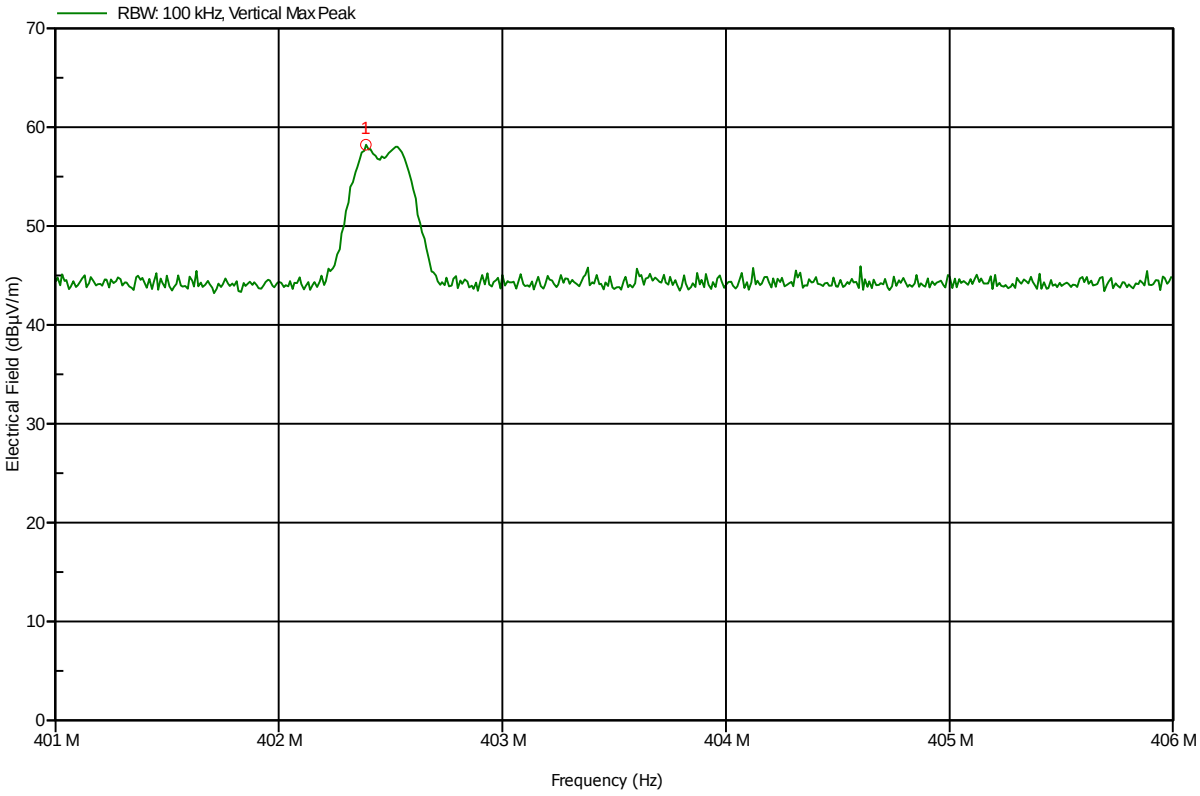
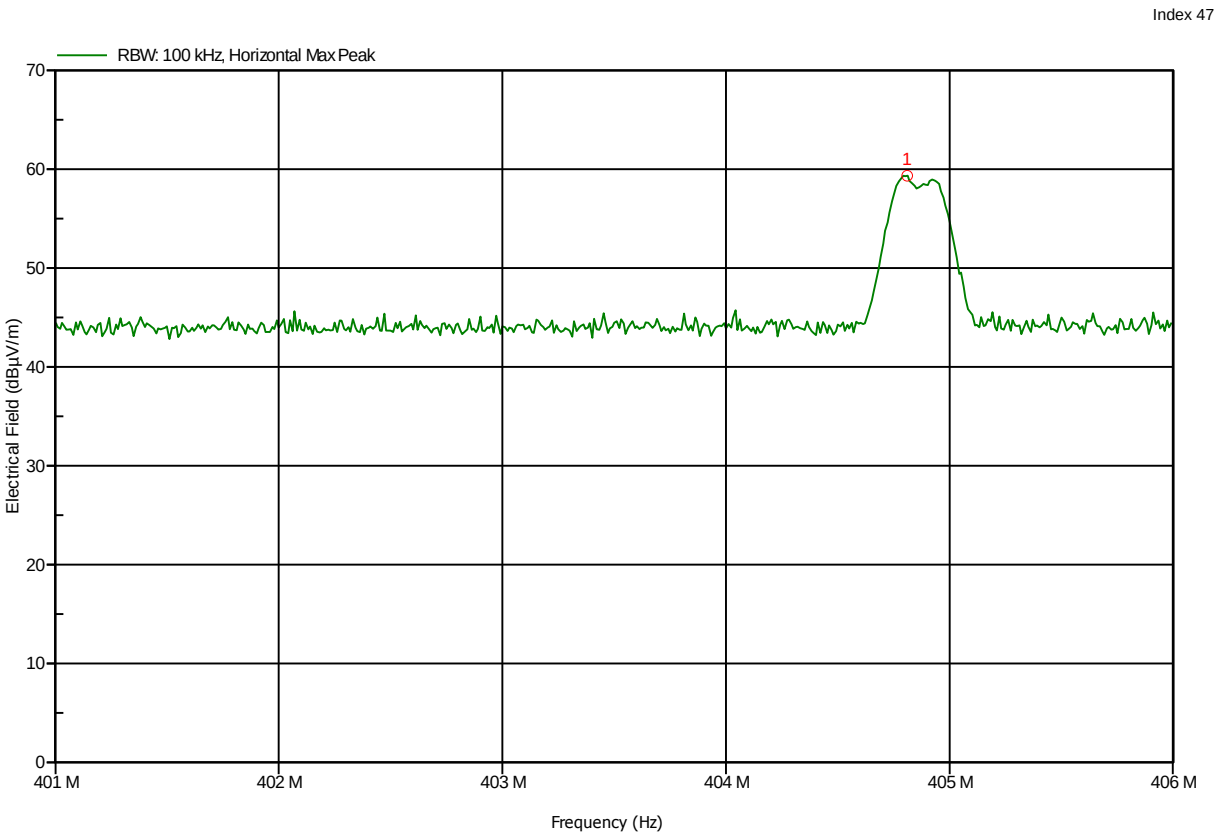


Frequency	Peak
402,39 MHz	58,23 dBµV/m

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	Power dBµV/m ERP

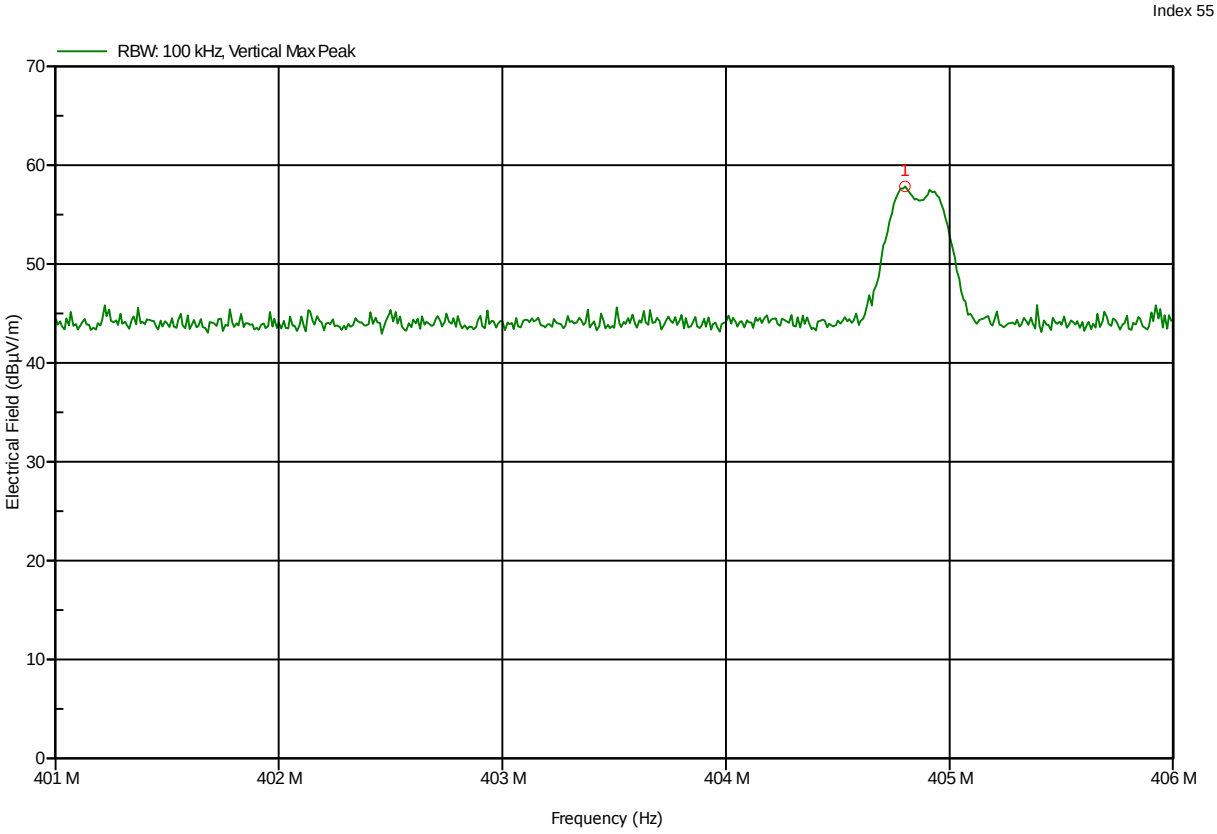


Frequency	Peak
404,81 MHz	59,34 dBµV/m

Radiated power according to FCC Part 95 Subpart I

Order number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	Power dBµV/m ERP



Frequency	Peak
404,8 MHz	57,84 dBµV/m

ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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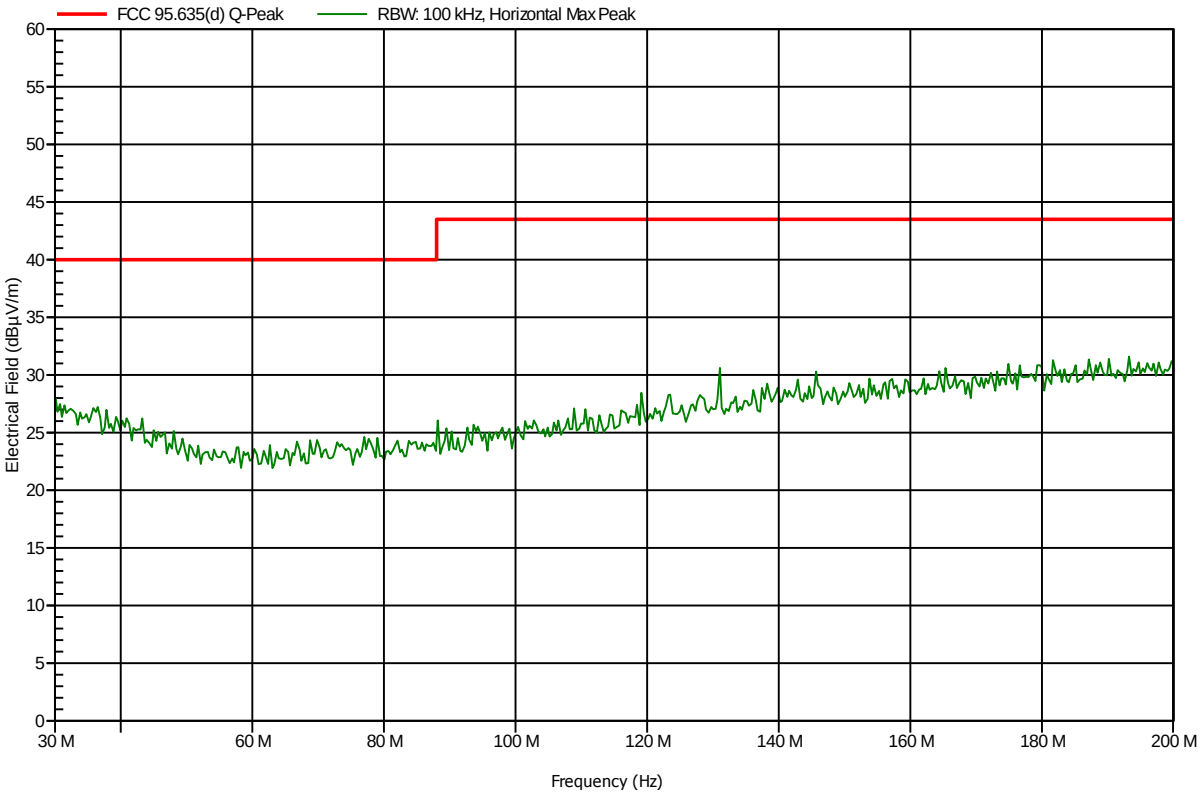

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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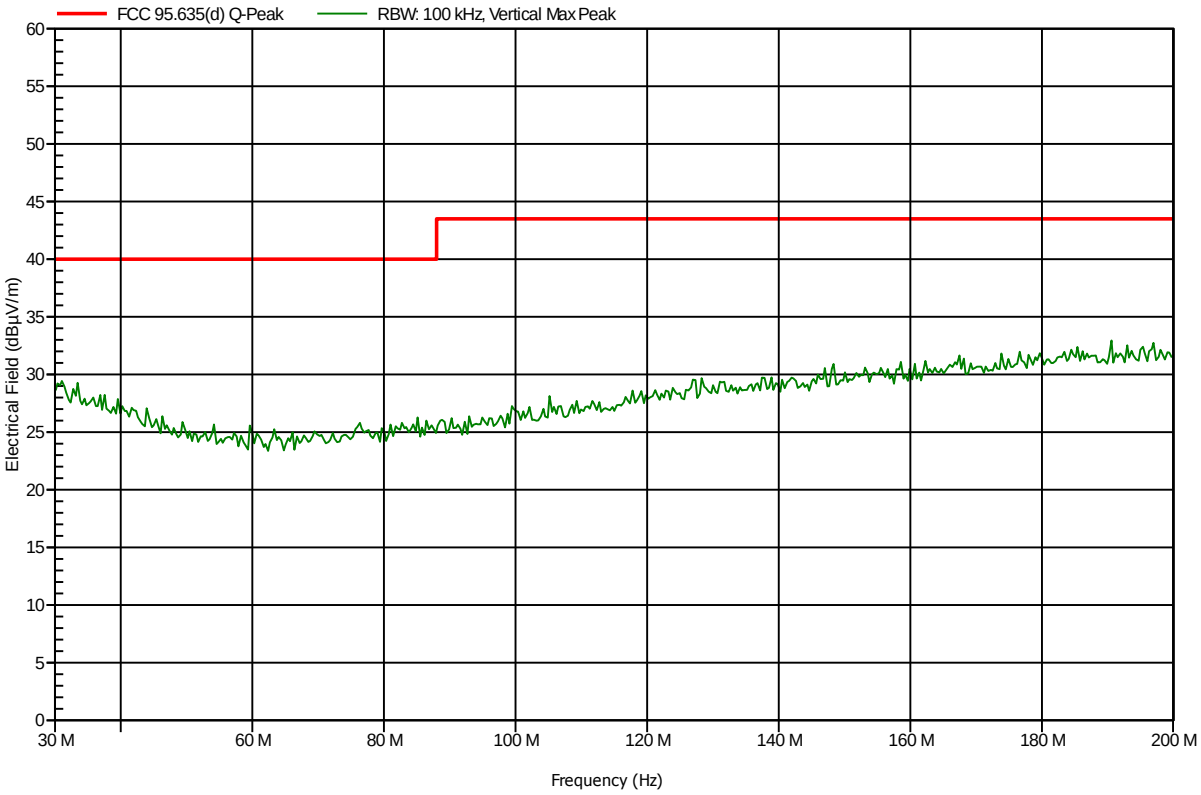

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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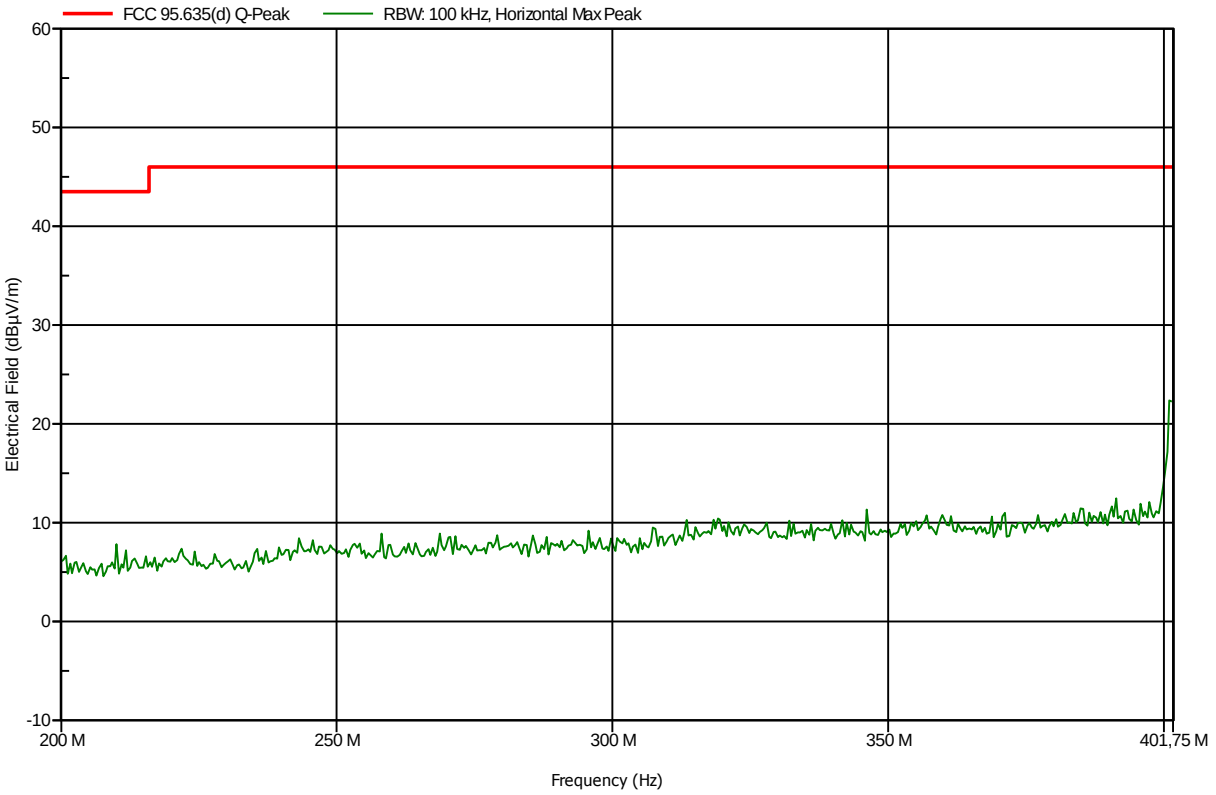

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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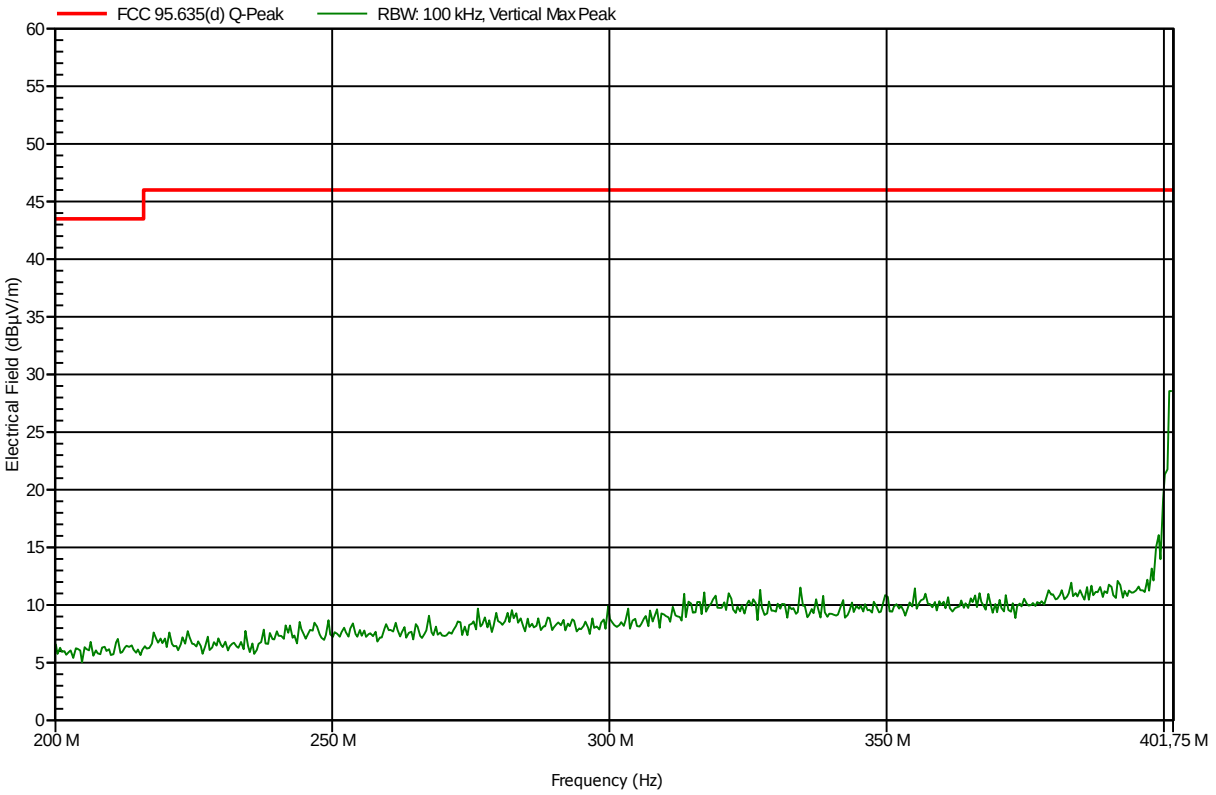

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	Band-edge

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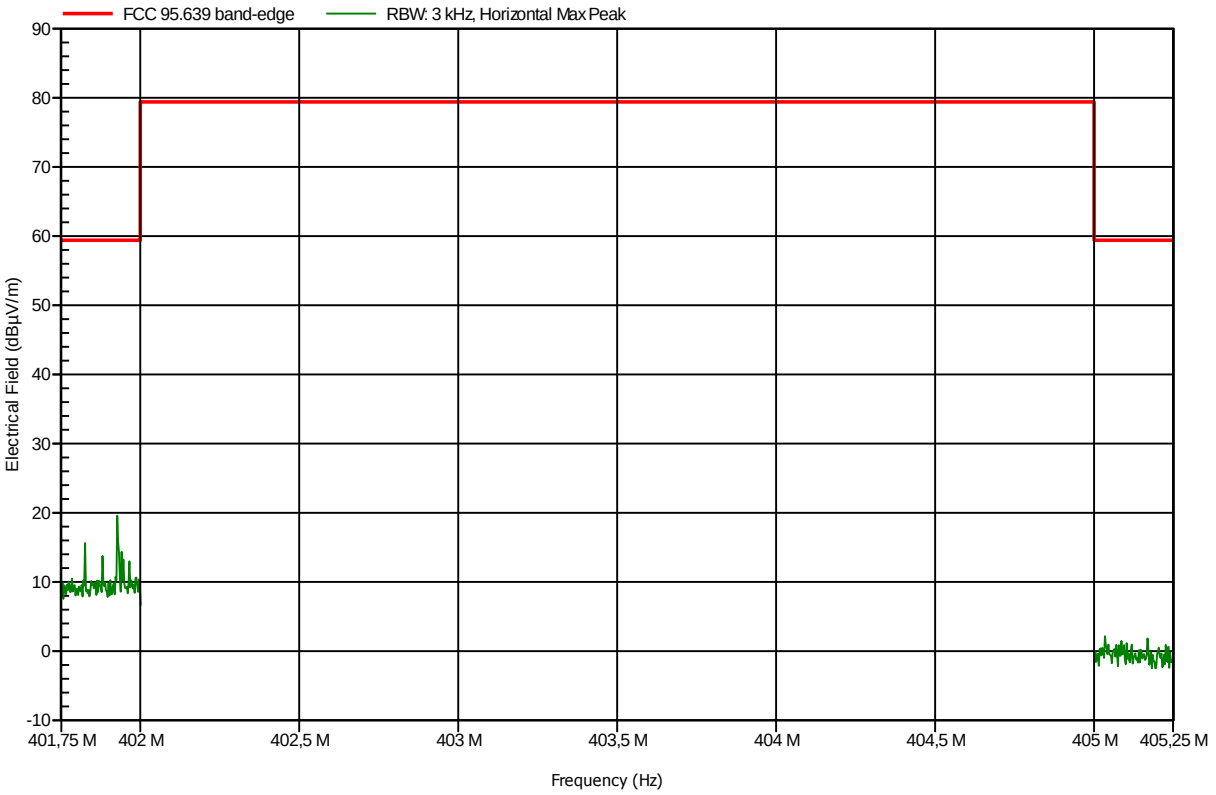

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	Band-edge

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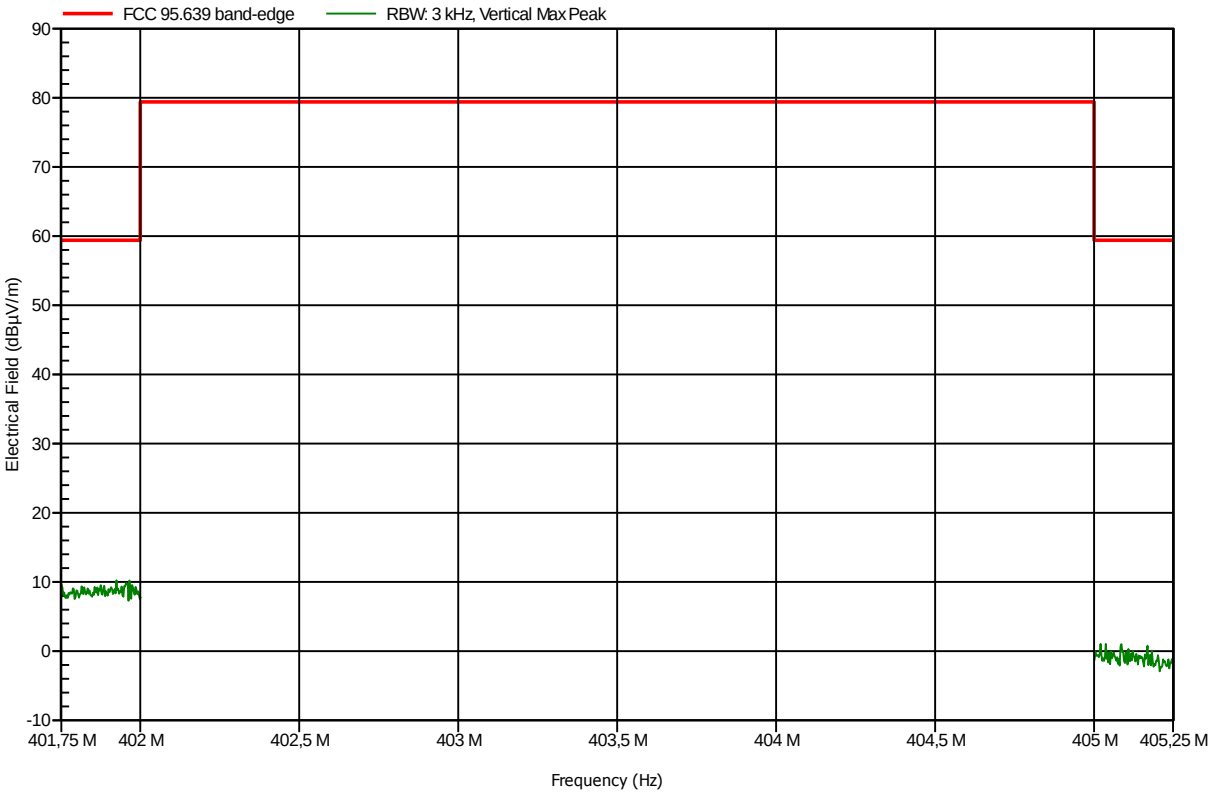

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	In-band emissions

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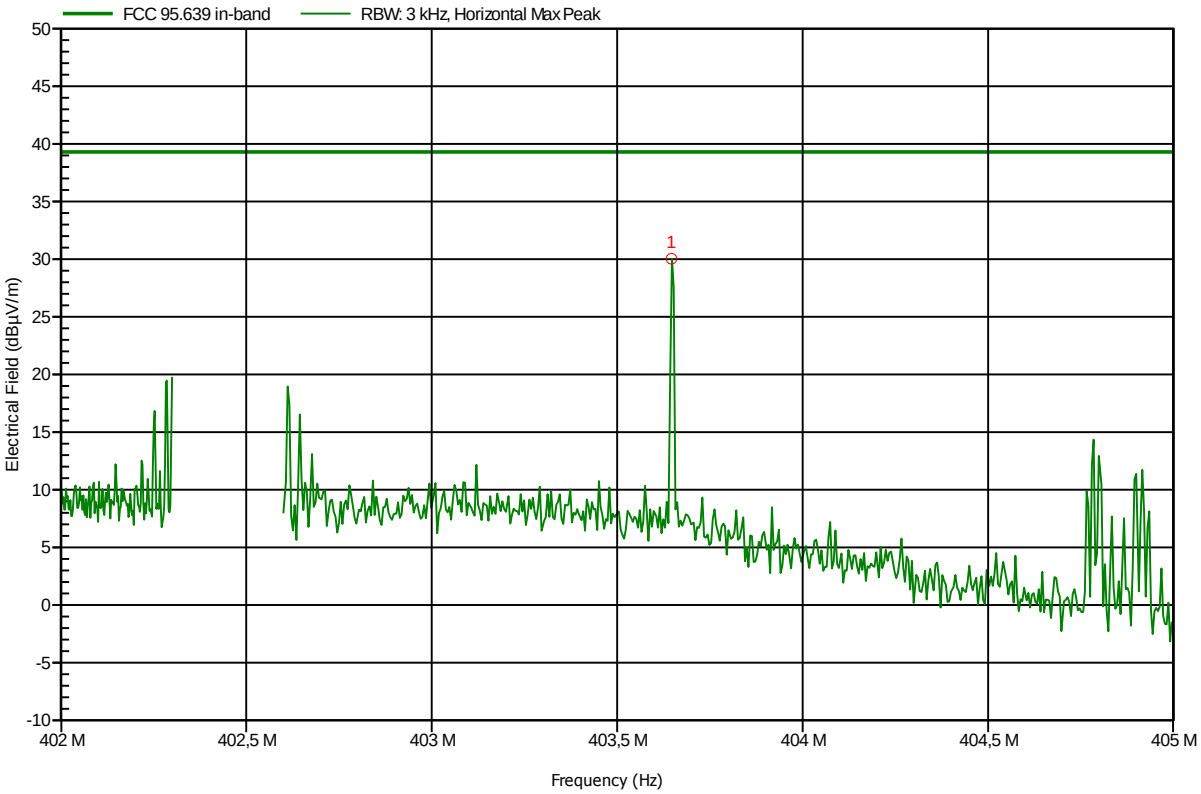

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403,646 MHz	30,04 dBµV/m	39,3 dBµV/m	-9,26 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	In-band emissions

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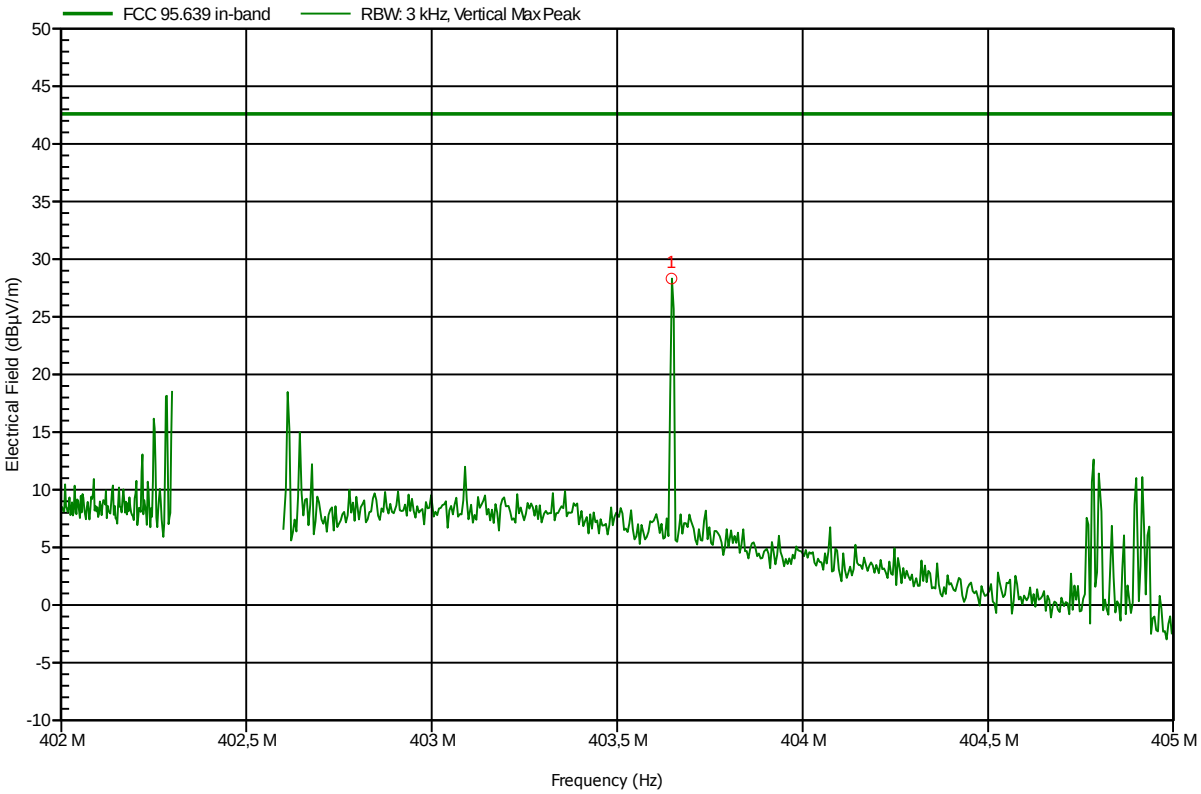

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403,646 MHz	28,32 dBµV/m	38.2 dBµV/m	-9.9 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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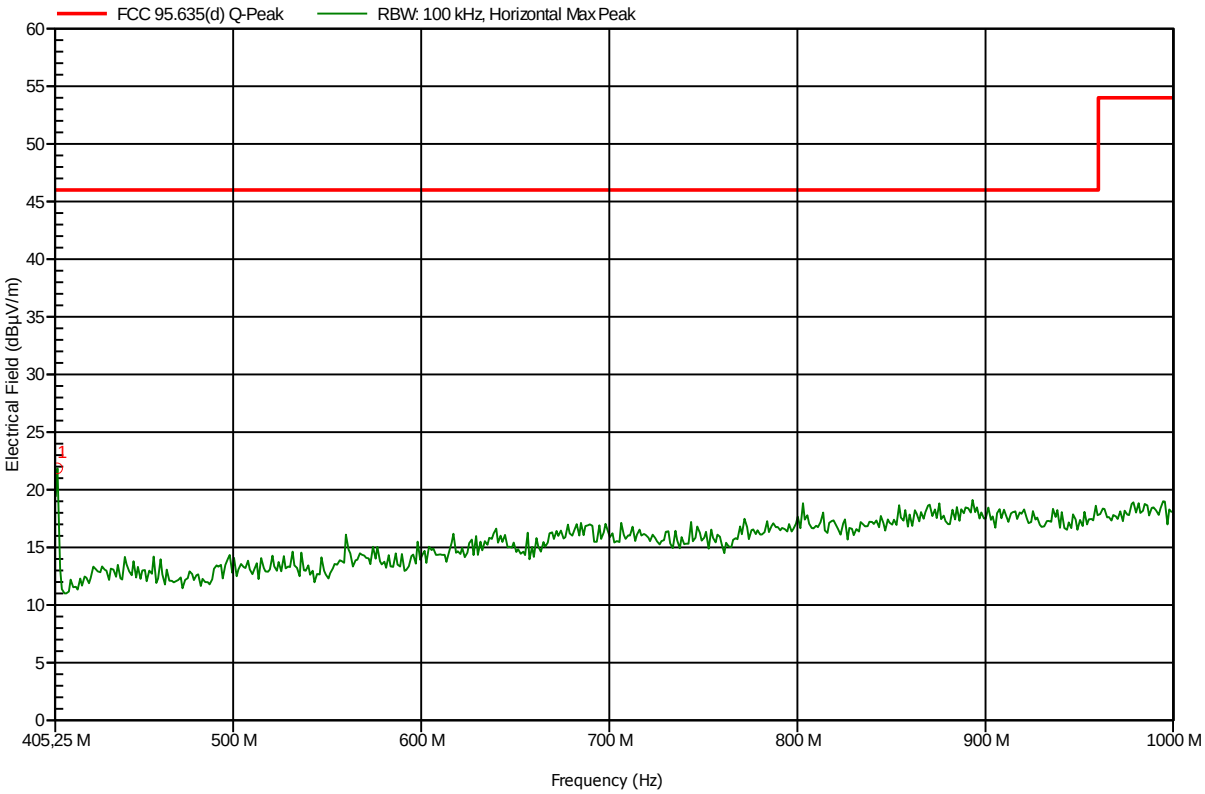

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406,44 MHz	21,86 dBµV/m	46 dBµV/m	-24,14 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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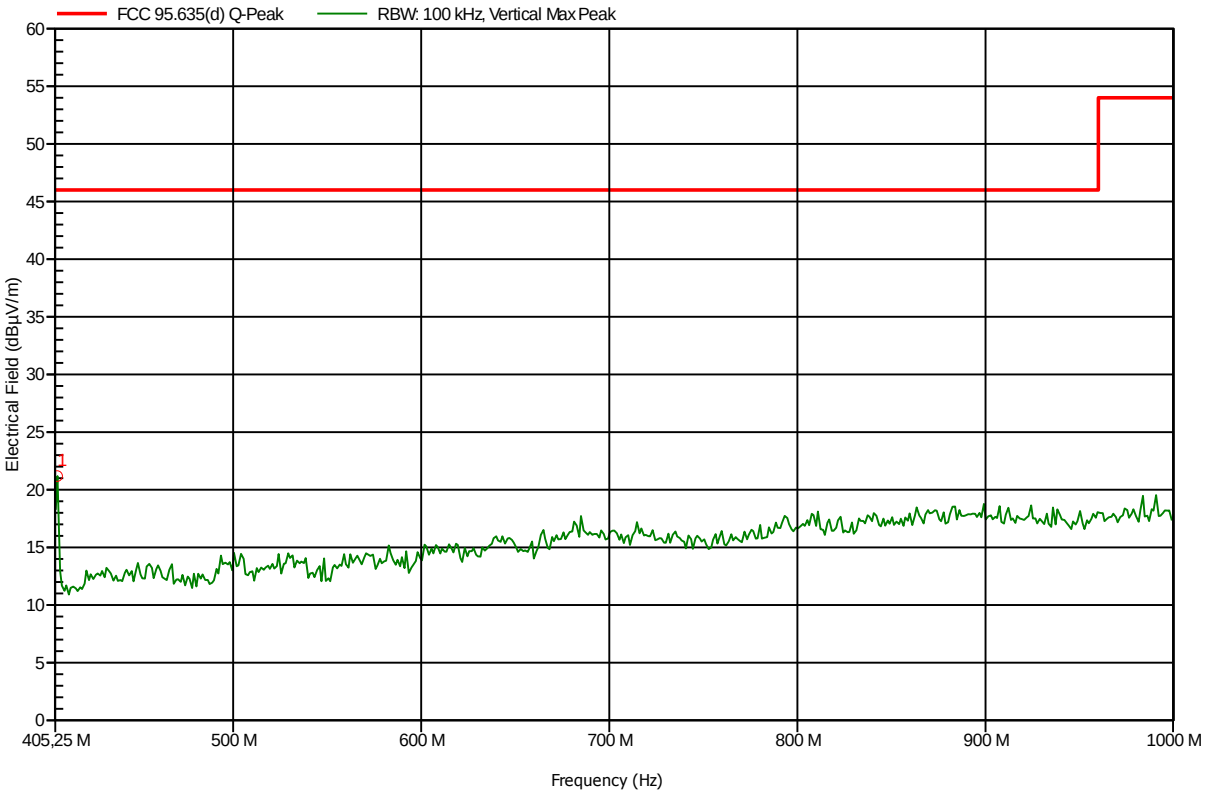

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
406,44 MHz	21,19 dBµV/m	46 dBµV/m	-24,81 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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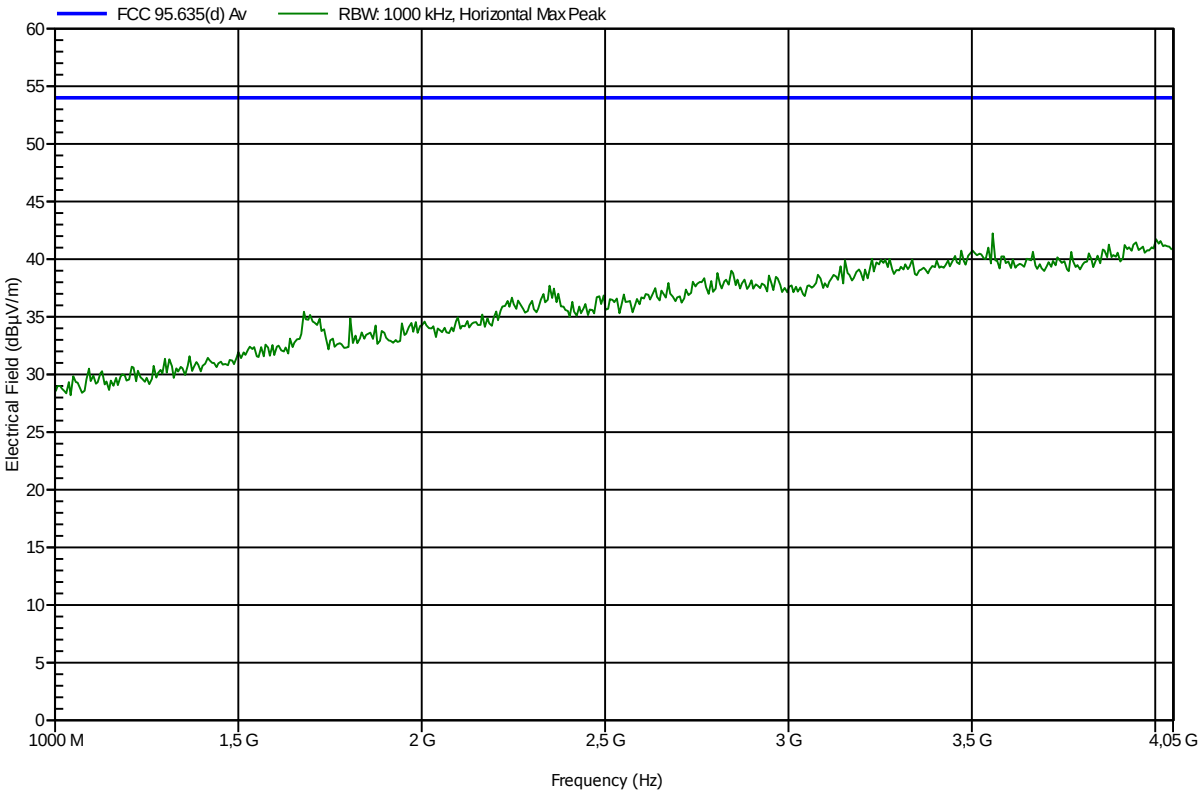

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 402.45MHz
Test Date:	2014-02-12
Note:	

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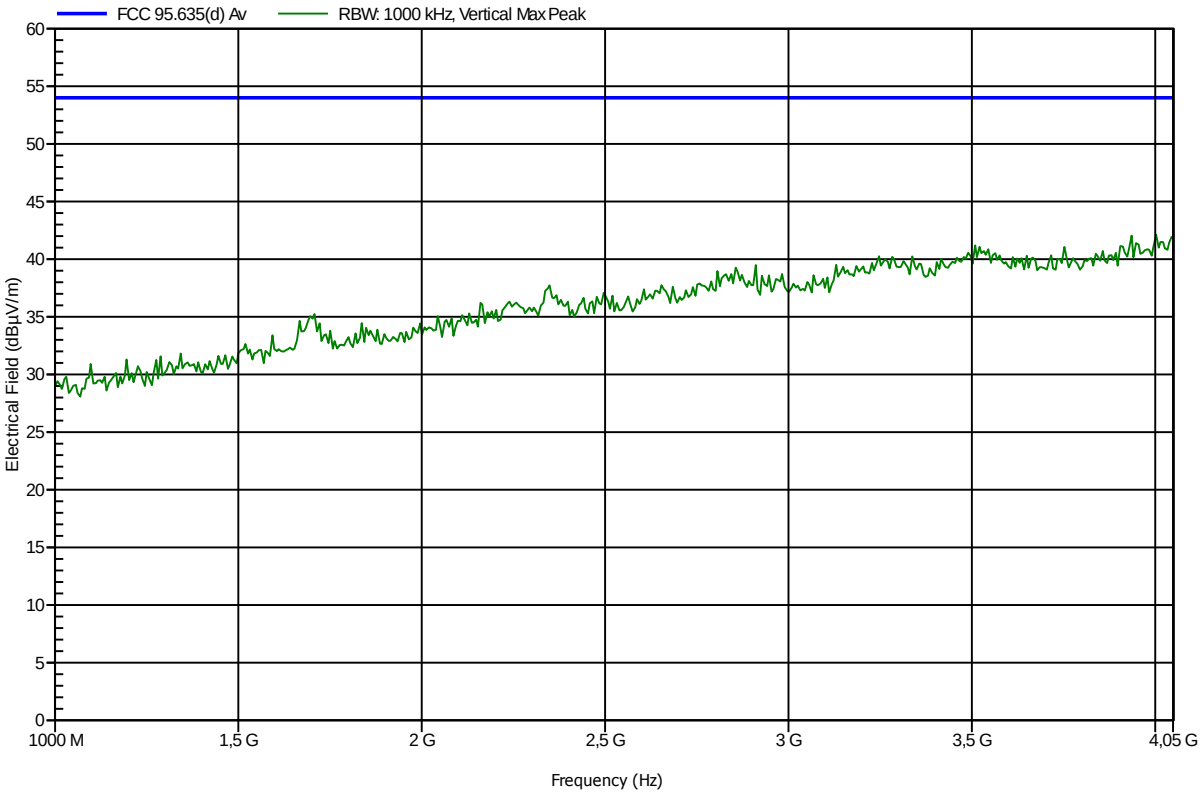

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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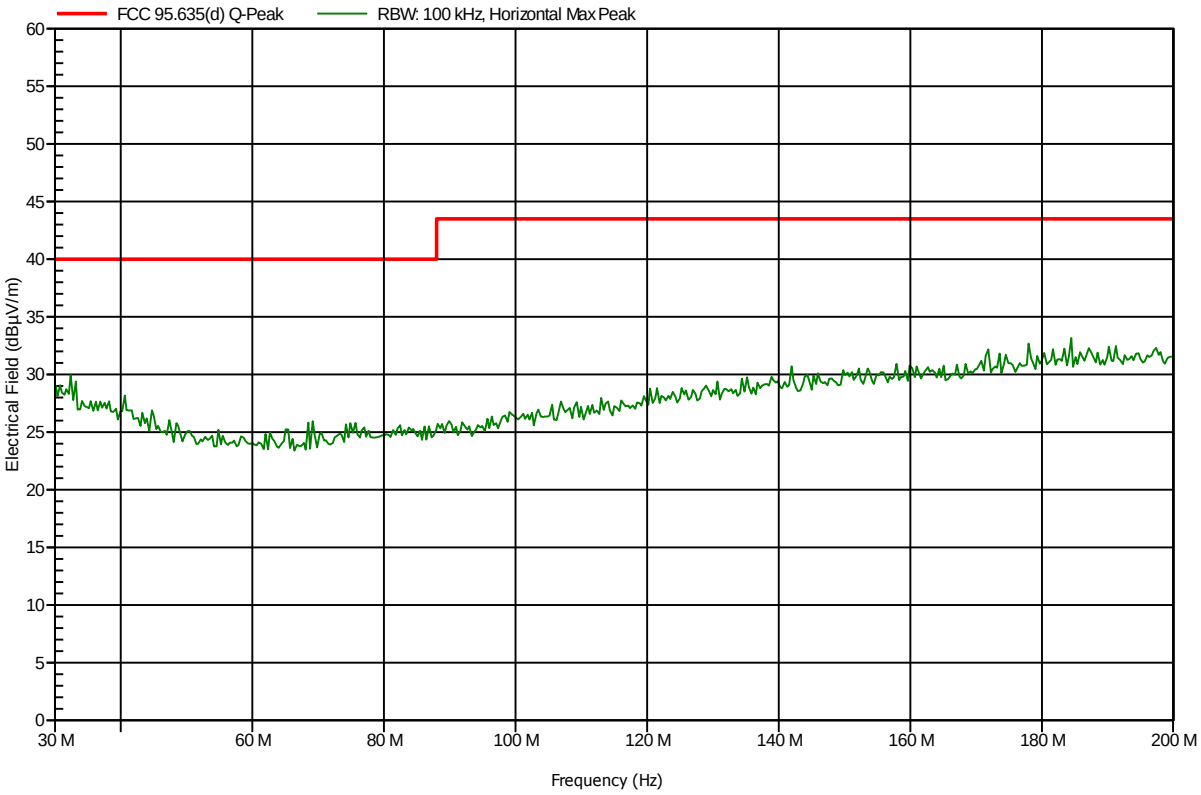

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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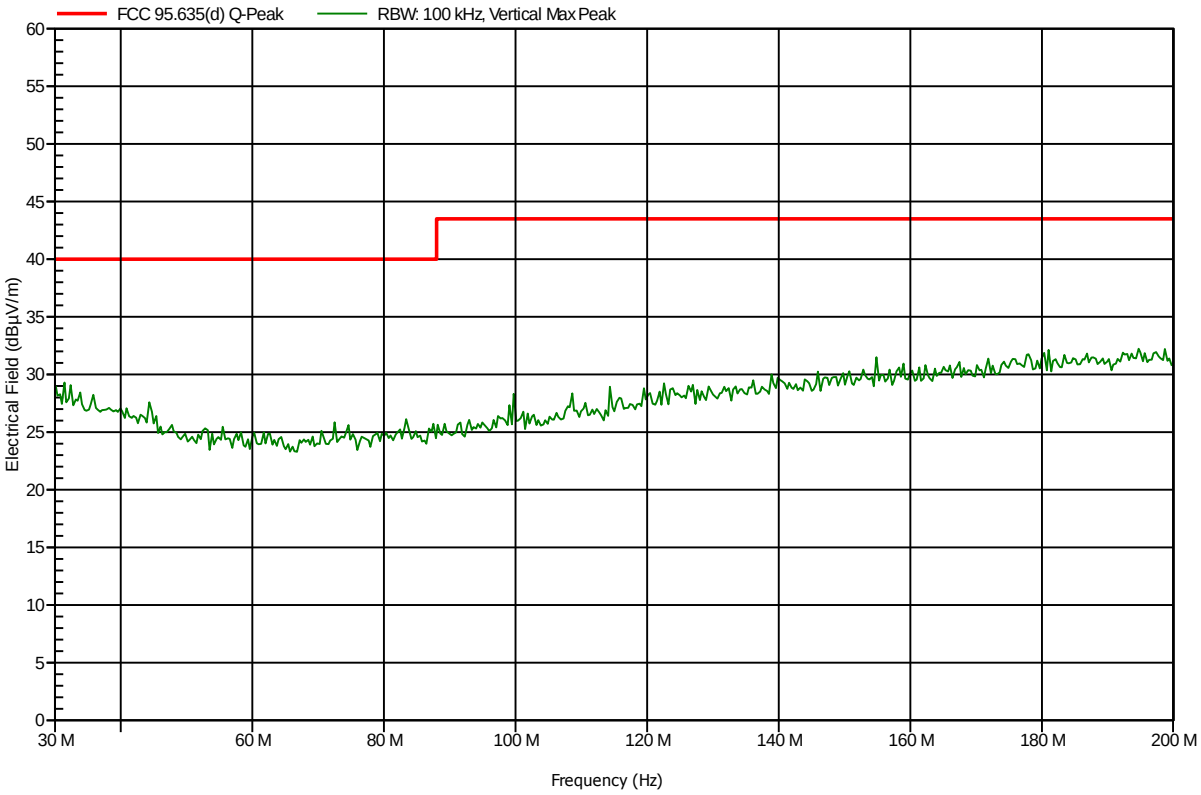

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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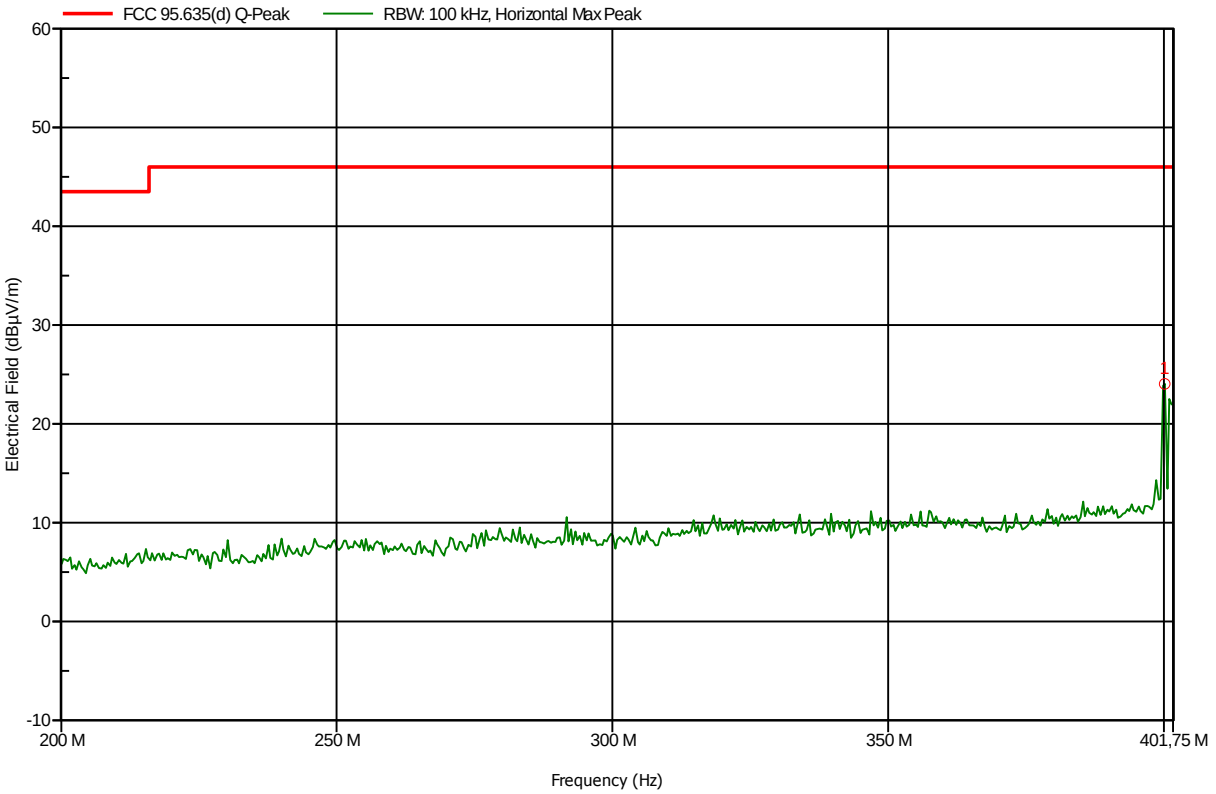

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
400,136 MHz	24,04 dBµV/m	46 dBµV/m	-21,96 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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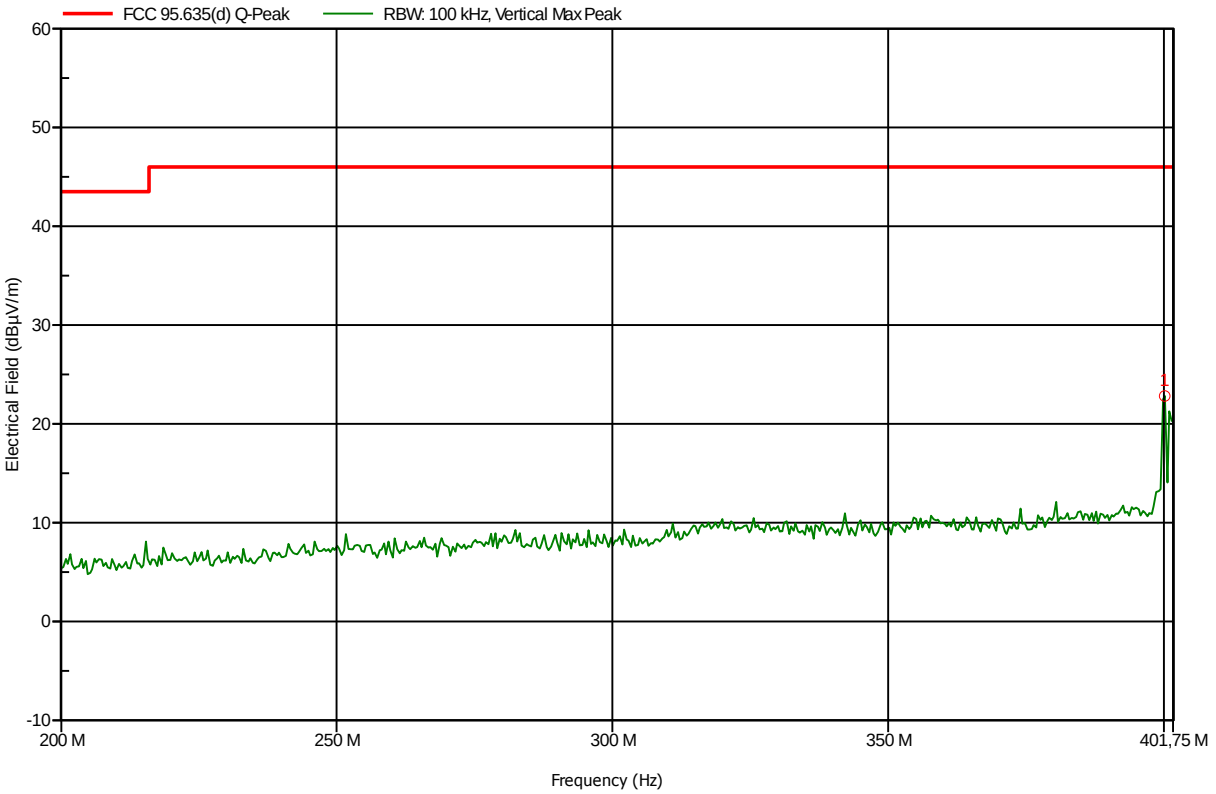

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
400,136 MHz	22,81 dBµV/m	46 dBµV/m	-23,19 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	Band-edge

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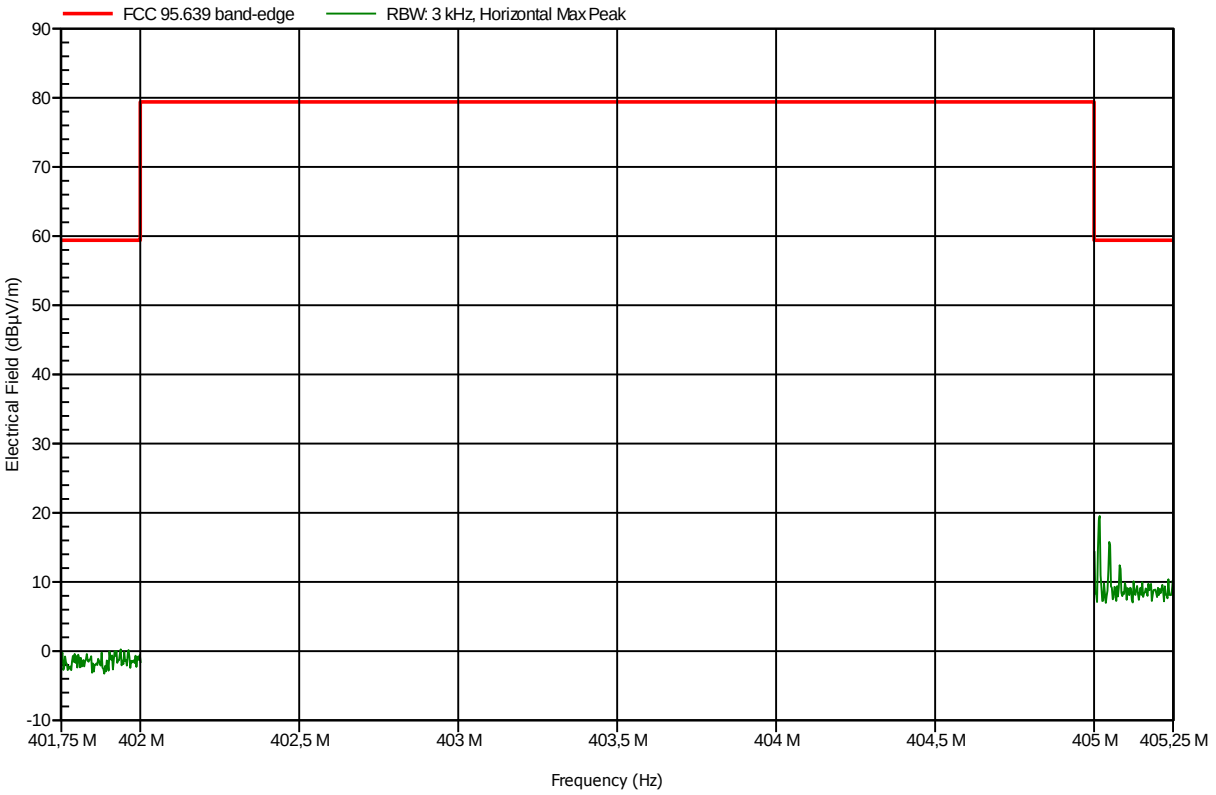

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	Band-edge

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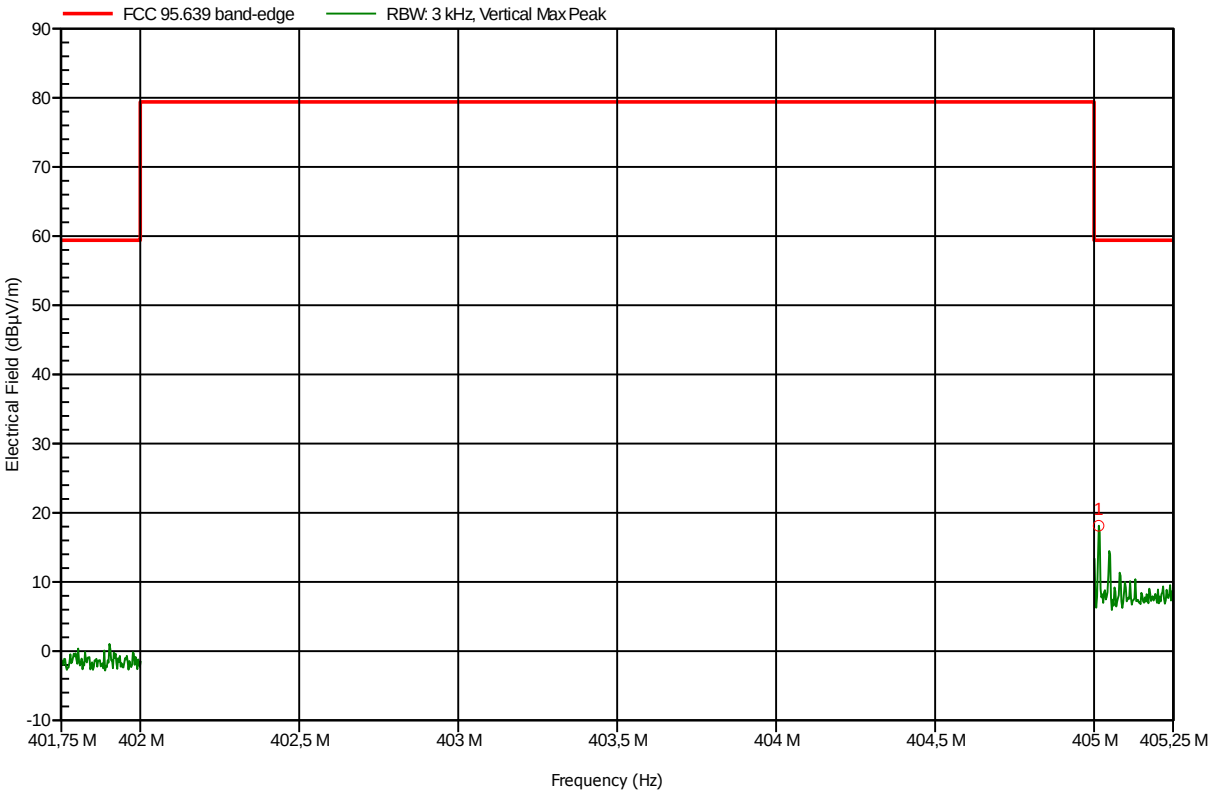

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405,014 MHz	18,13 dBµV/m	59,4 dBµV/m	-41,27 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	In-band emissions

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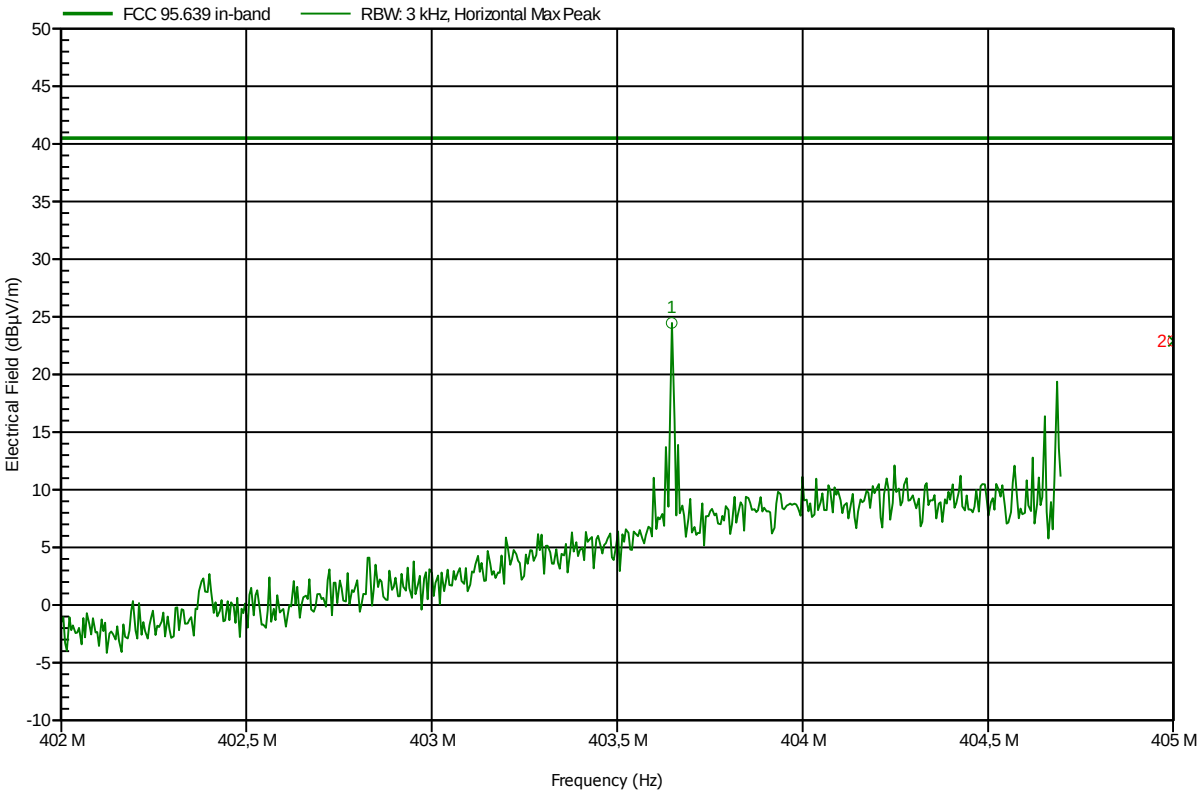

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403,647 MHz	24,47 dBµV/m	39.3 dBµV/m	-14.8 dB	Pass
404,999 MHz	22,9 dBµV/m	39.3 dBµV/m	-16.4 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	In-band emissions

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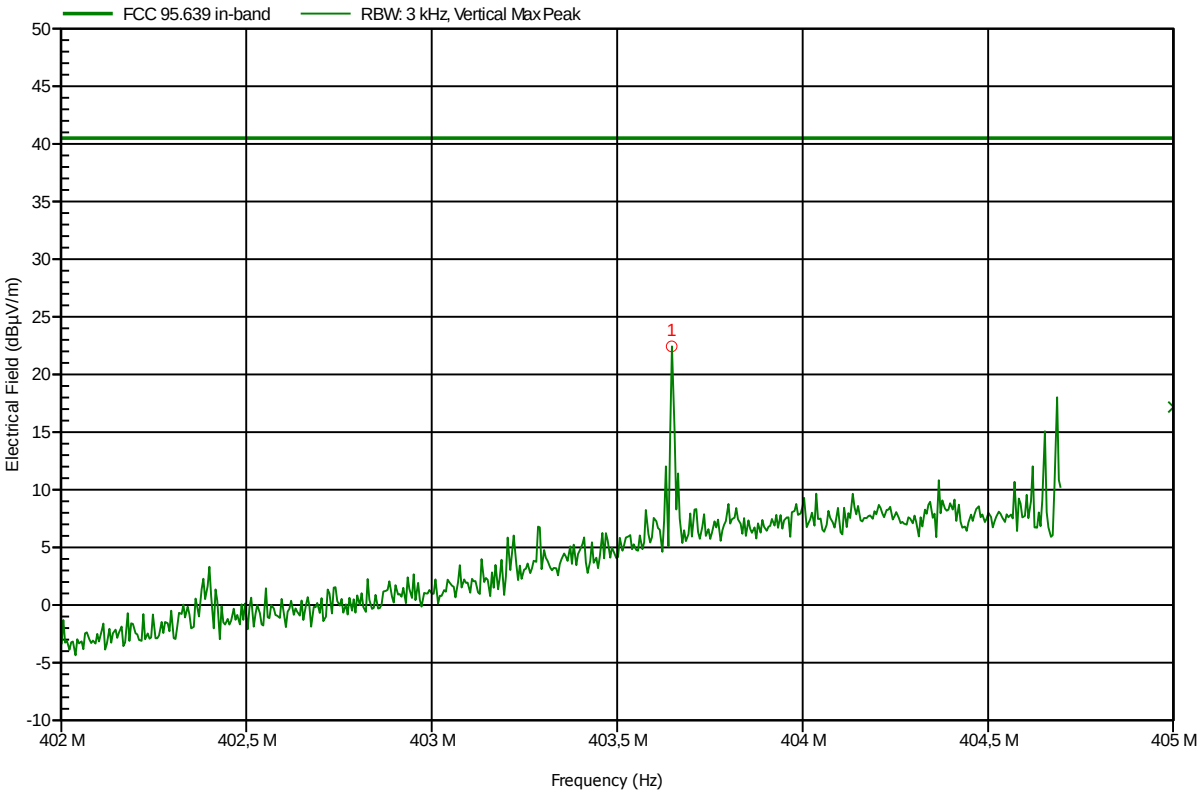

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
403,647 MHz	22,44 dBµV/m	40,5 dBµV/m	-18,06 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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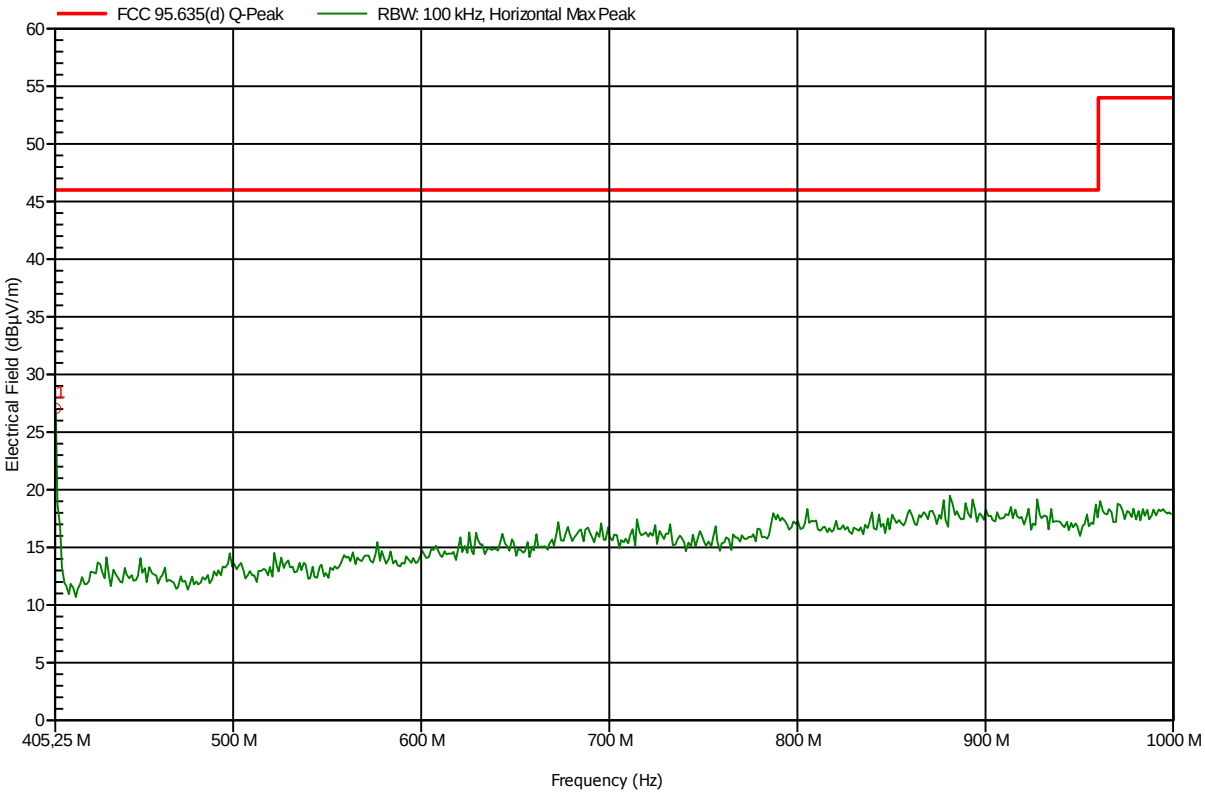

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405,25 MHz	27,04 dBµV/m	46 dBµV/m	-18,96 dB	Pass

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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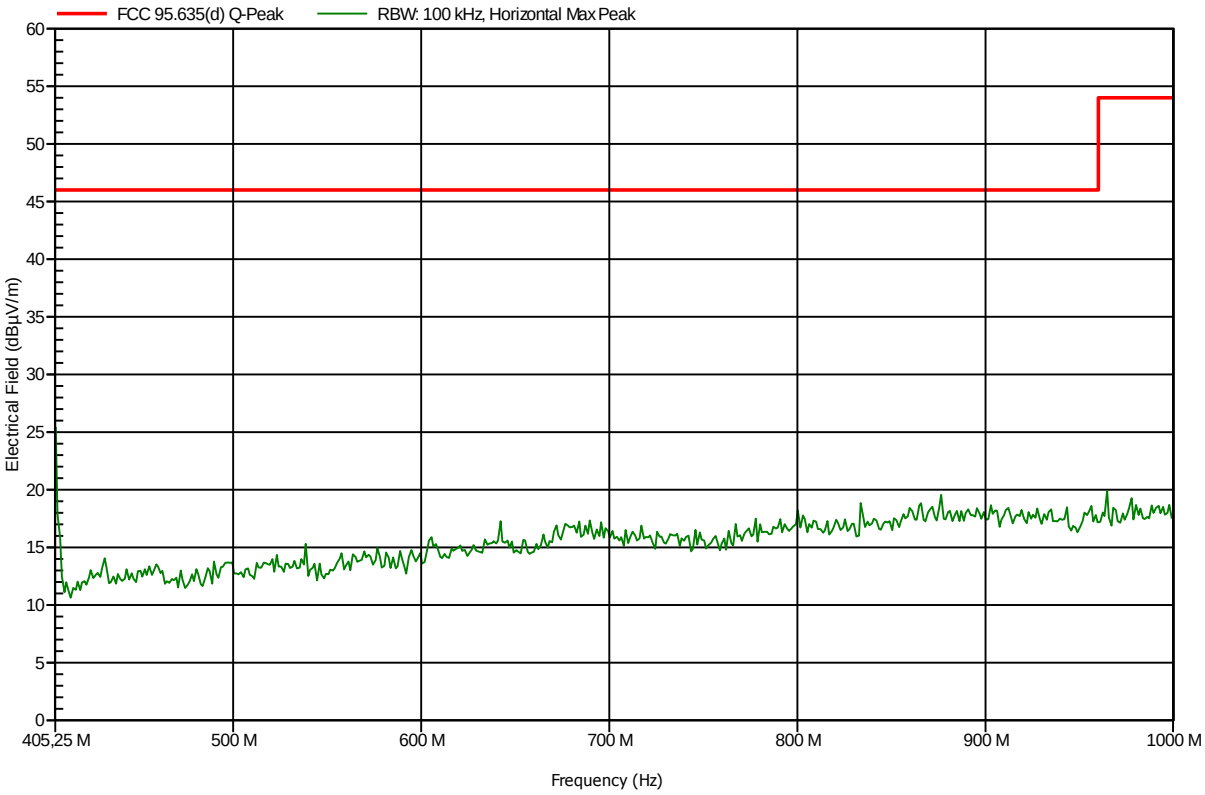

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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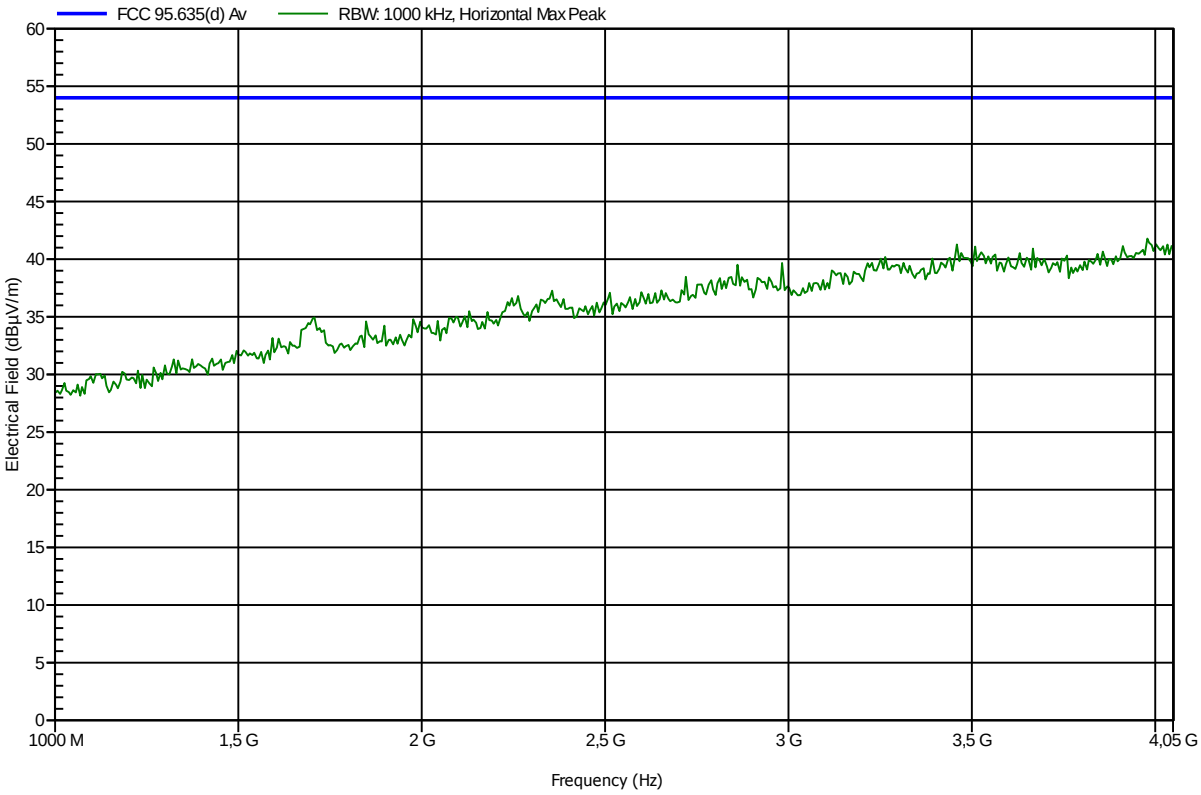

Spurious emissions according to FCC Part 95 Subpart I

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 2FSK; 404.85MHz
Test Date:	2014-02-12
Note:	

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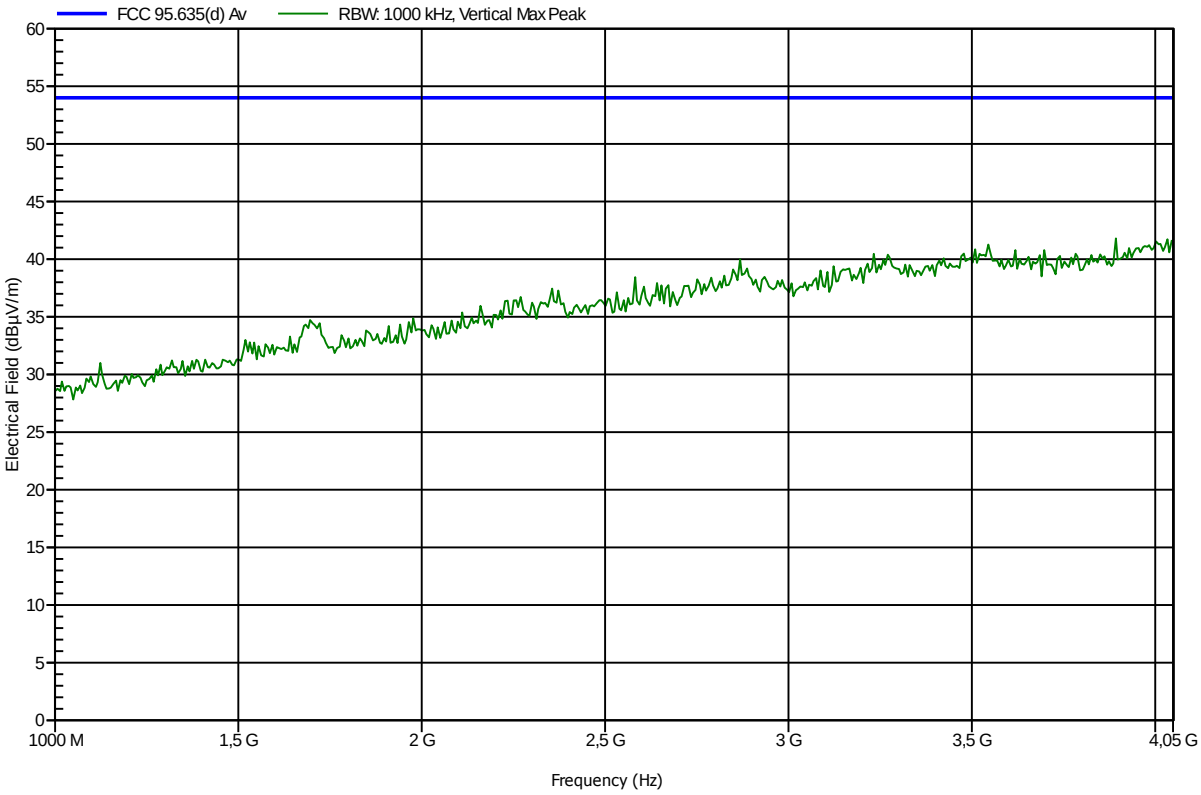

ANNEX C Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2014-02-10
Note:	

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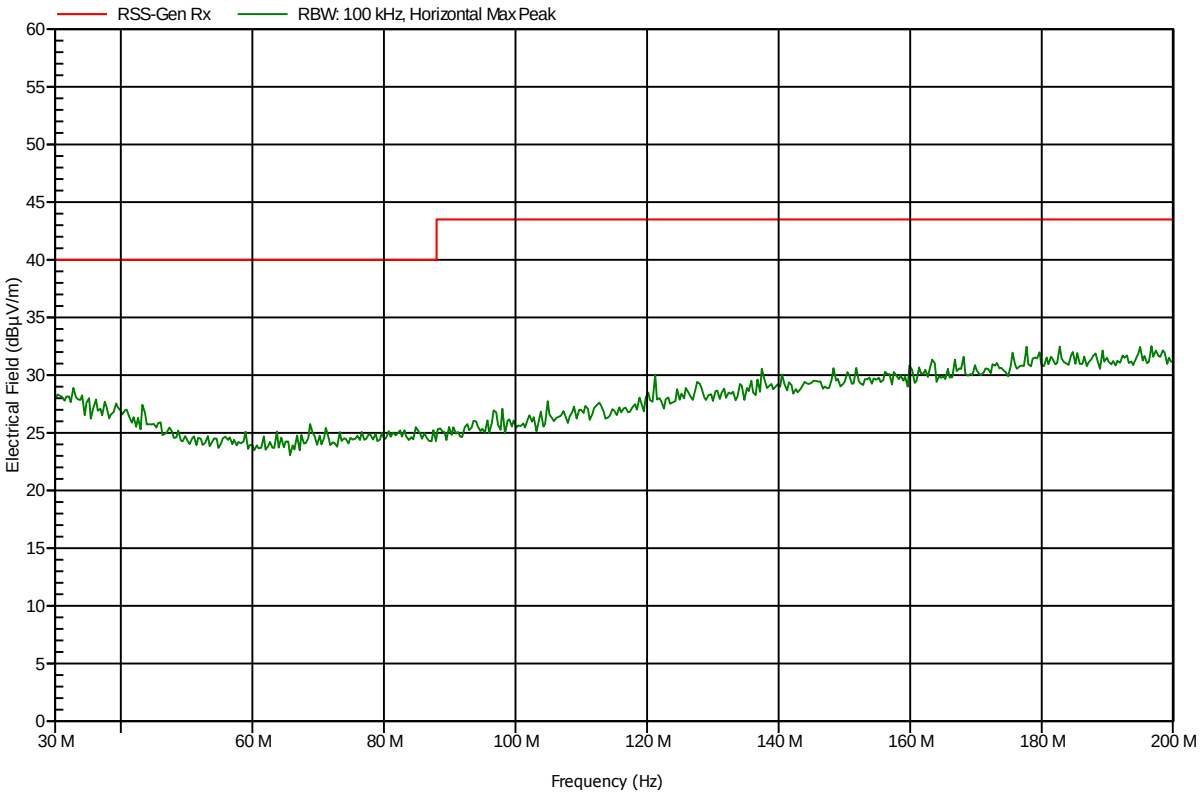

Spurious emissions according to RSS-Gen

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2014-02-10
Note:	

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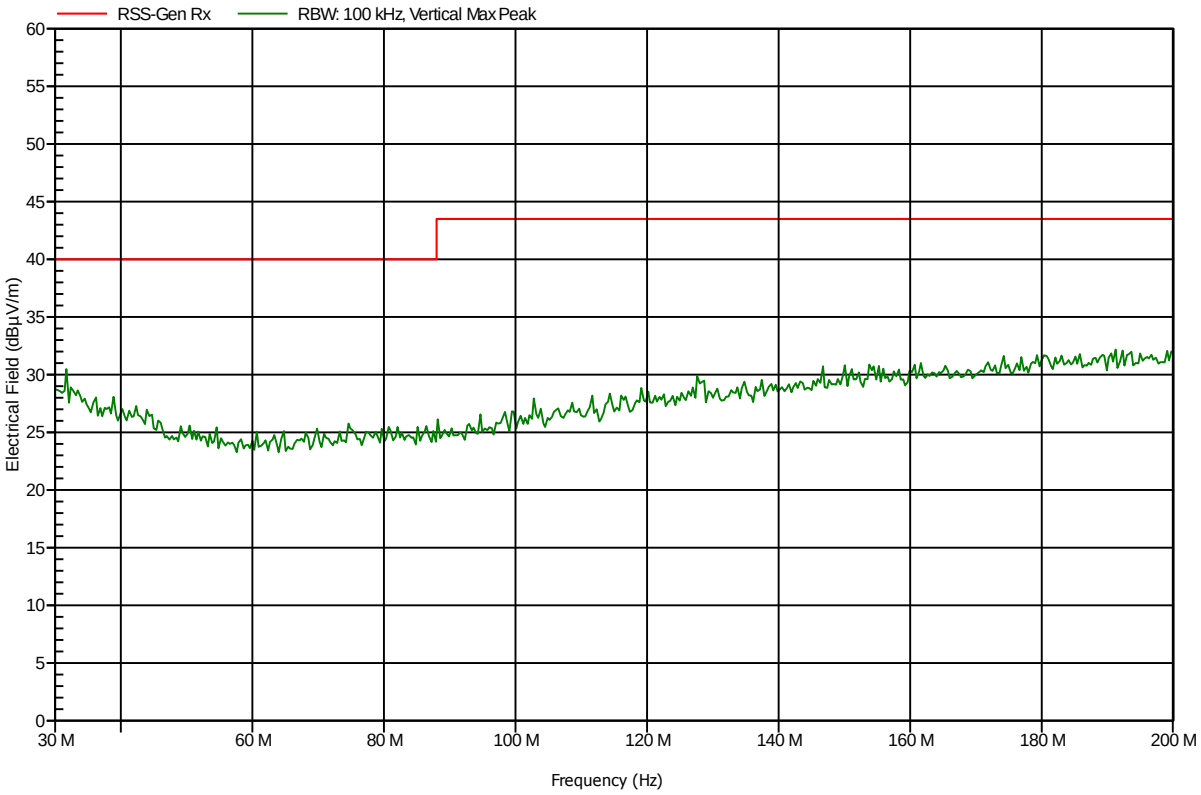

Spurious emissions according to RSS-Gen

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2014-02-10
Note:	

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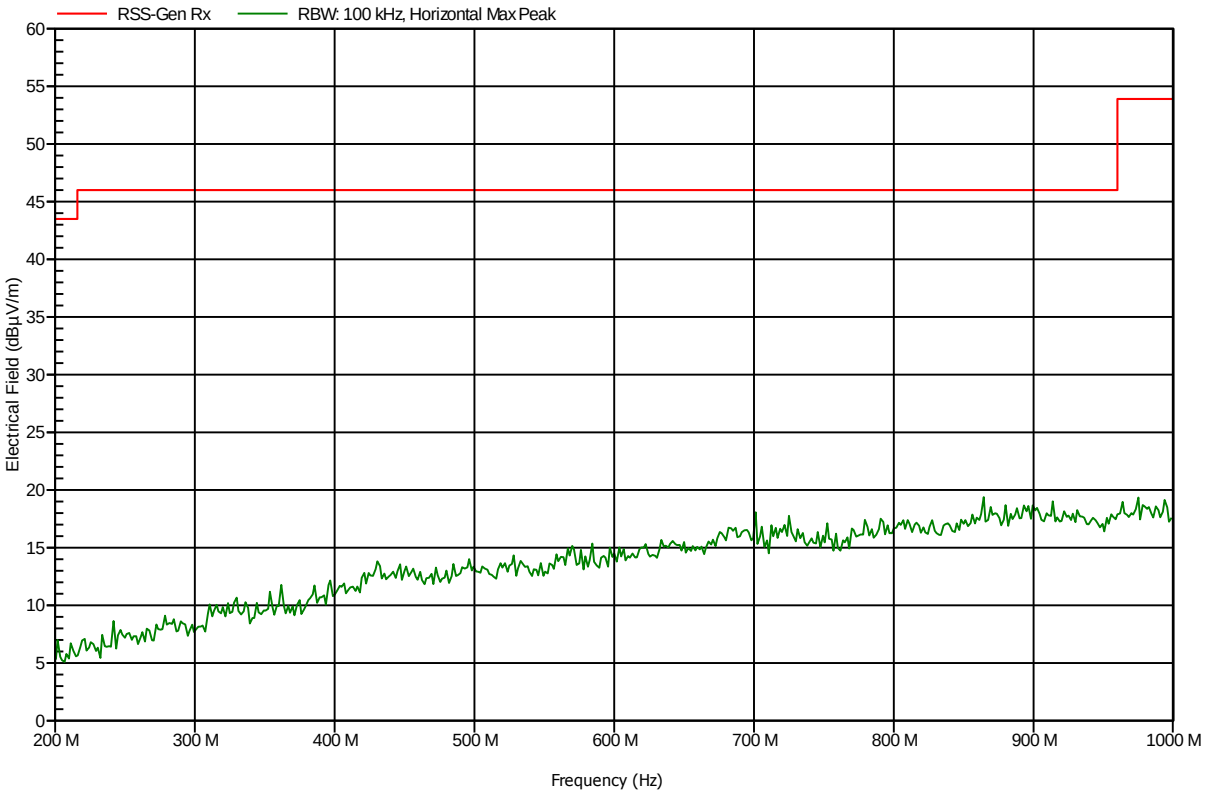

Spurious emissions according to RSS-Gen

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2014-02-10
Note:	

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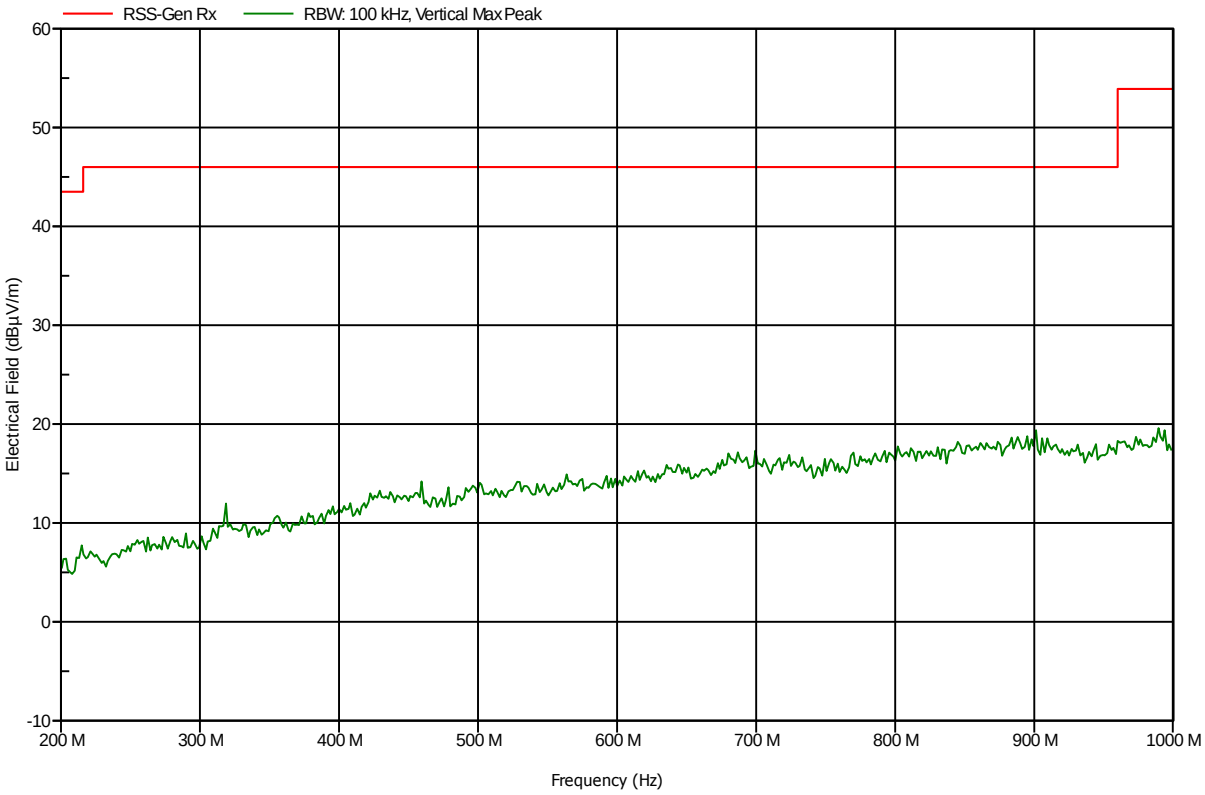

Spurious emissions according to RSS-Gen

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2014-02-10
Note:	

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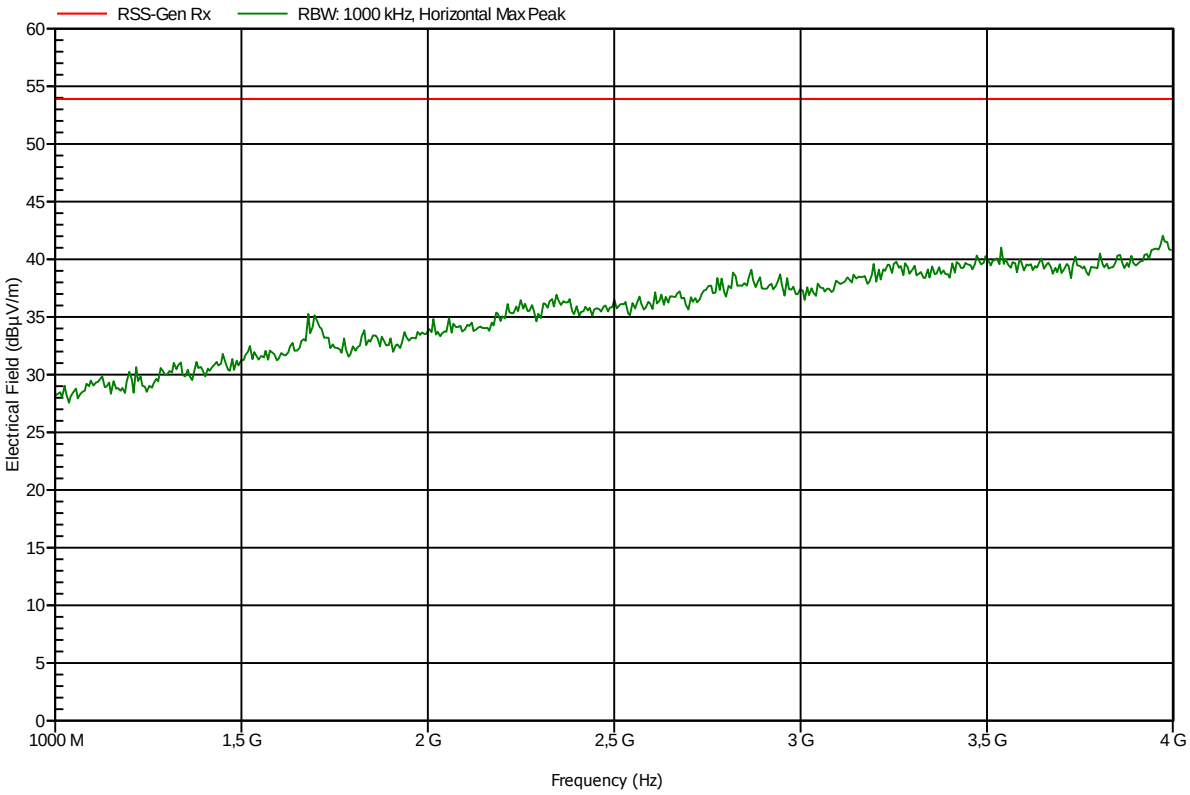
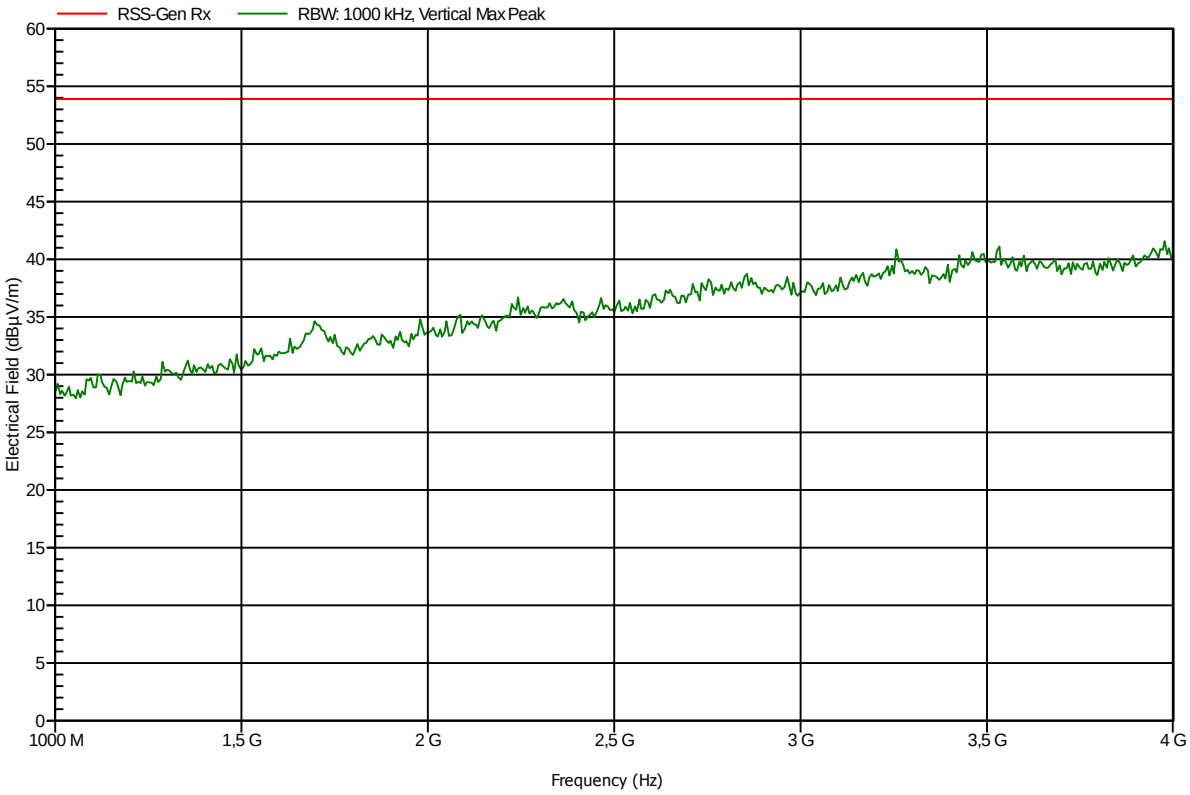


Spurious emissions according to RSS-Gen

Project number: G0M-1402-3601

Manufacturer:	Biotronik SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TACH_70
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 V DC lithium battery
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2014-02-10
Note:	

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