


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-1612-6102-TFC95IMR-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	 <p>A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Filed Test Laboratory, Reg.-No.: 96970 IC OATS Filing assigned code: 3470A</p>
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 (C2PC)
Equipment under test (EUT):	
Product description	Implantable Cardiac Monitor
Model No.	BioMonitor 2-AF
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware version	BOM-0346_11, ASM-0206_B, SCH-0043_B
Firmware / Software version	RAM: 7447_30_0306 / UpROM:7300_20_0102
	FCC-ID: QRIBM2 IC: N/A
Test result	Passed

Possible test case verdicts:

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

Testing:


Test Lab Temperature : 20 – 23 °C


Test Lab Humidity : 32 – 38 %

Date of receipt of test item : 2017-01-09

Date (s) of performance of tests : 2017-01-09 – 2017-01-11

Compiled by : Wilfried Treffke

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

Approved by (+ signature) : Christian Weber 
 (Head of Lab)

Date of issue : 2017-02-06

Total number of pages : 74

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 manufacturer has declared that the following models are technical identical (with respect to its RF circuit) to the tested model.

Variants:

- BioMonitor 2-AF (EUT)
- BioMonitor 2-S

Version History

Version	Issue Date	Remarks	Revised by
01	2017-02-06	Initial Release	

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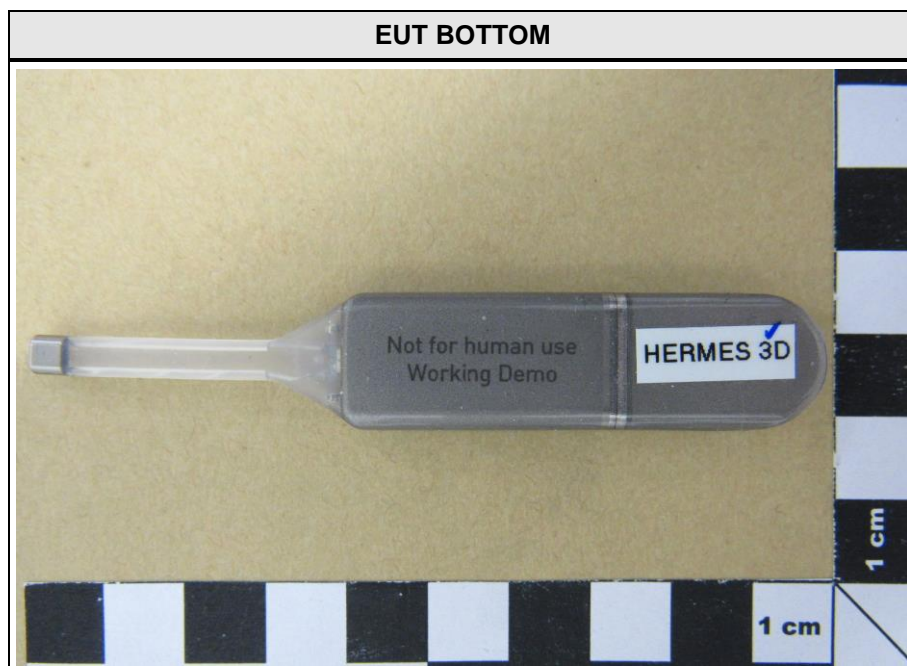
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1 Equipment (Test item) Description

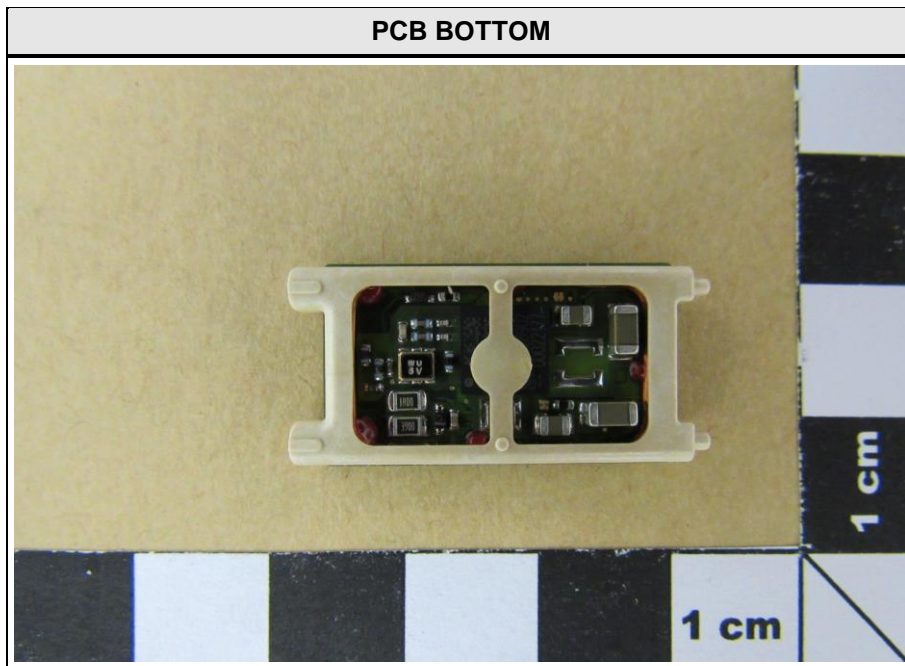
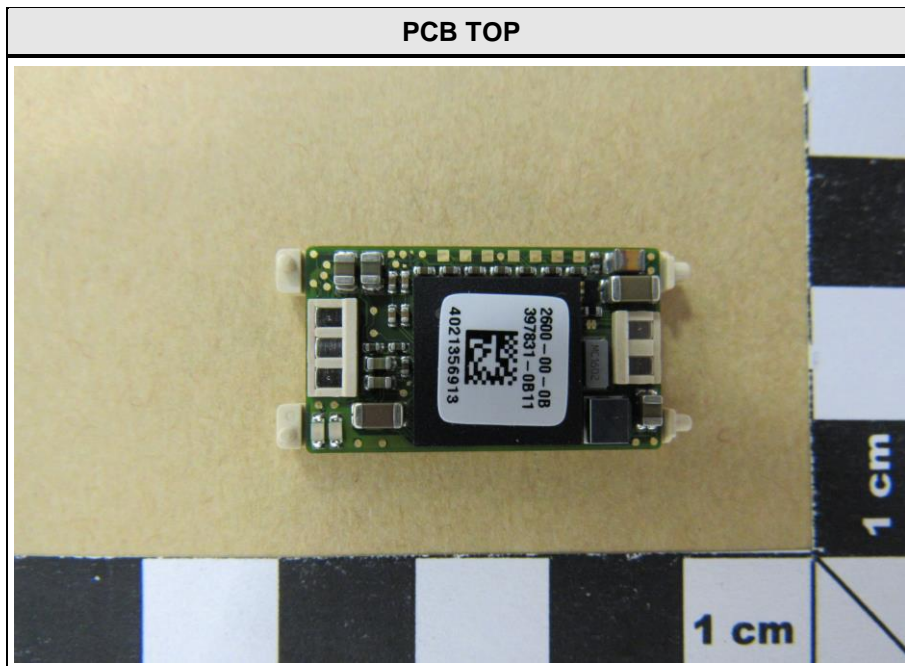
Description	Implantable Cardiac Monitor	
Model	BioMonitor 2-AF	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Serial number	91616138	
Hardware version	BOM-0346_11, ASM-0206_B, SCH-0043_B	
Software / Firmware version	RAM: 7447_30_0306 / UpROM:7300_20_0102	
PMN	N/A	
HVIN	N/A	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRIBM2	
IC	N/A	
Equipment type	End product	
Radio type	Transceiver	
Number of Radios	1	
Radio technology	MedRadio (MICS) active medical implant	
Operating frequency range	402 - 405 MHz	
Assigned frequency band	402 - 405 MHz	
Main test frequencies	F _{LOW}	402.45 MHz
	F _{MID}	403.65 MHz
	F _{HIGH}	404.85 MHz
Modulations	2-FSK	
Emission designator	F7D	
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	BioMonitor 2 Whip
	Manufacturer	Biotronik SE & Co. KG
	Gain	-25.46 dBi (Determined by measurements)
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

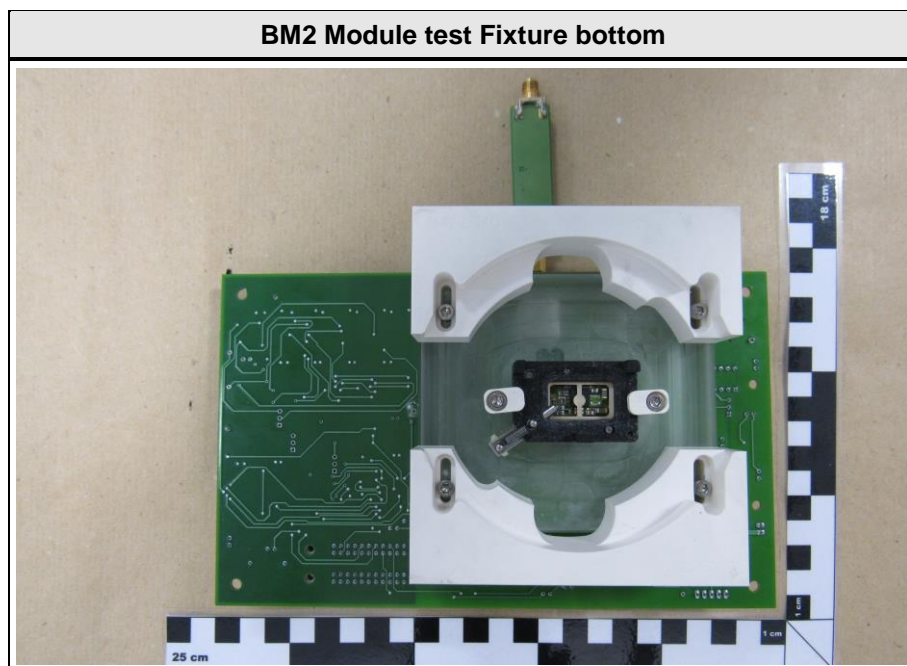
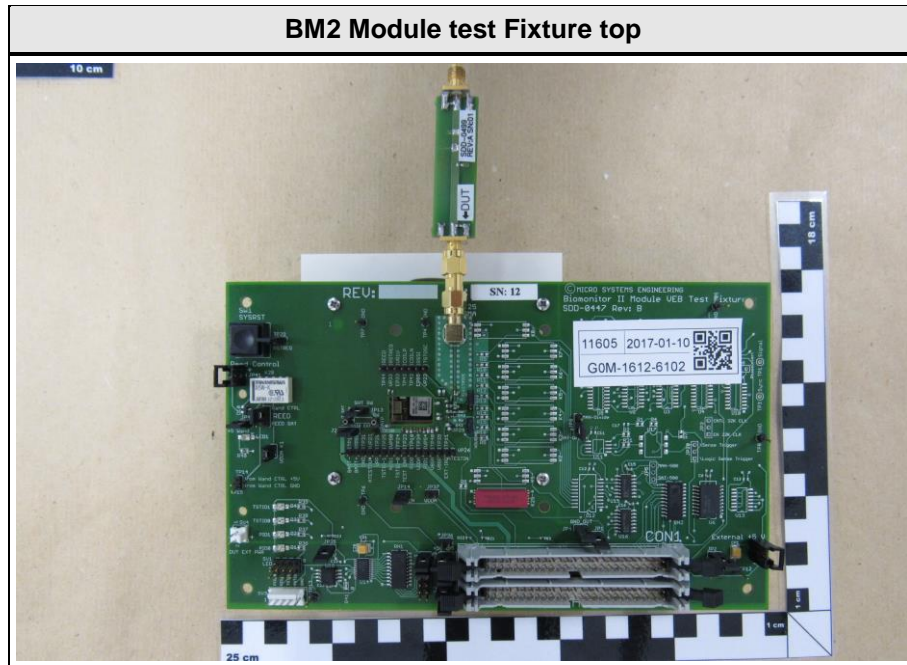
Power supply	V _{NOM}	3.0 VDC
	V _{MIN}	2.0 VDC
	V _{MAX}	3.5 VDC
Temperature	T _{NOM}	37 °C
	T _{MIN}	25 °C
	T _{MAX}	45 °C
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

1.1 Photos - Equipment external

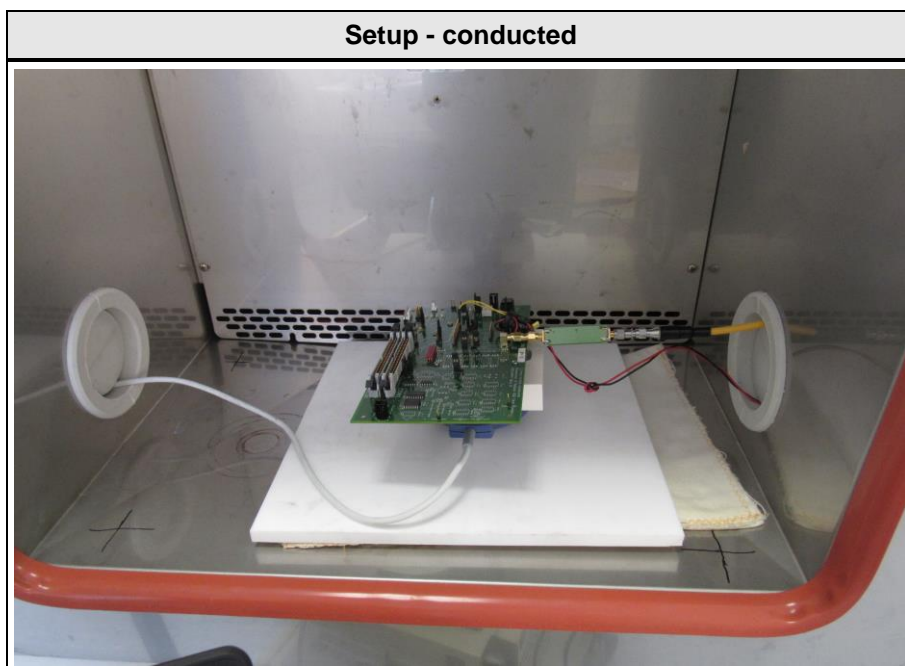
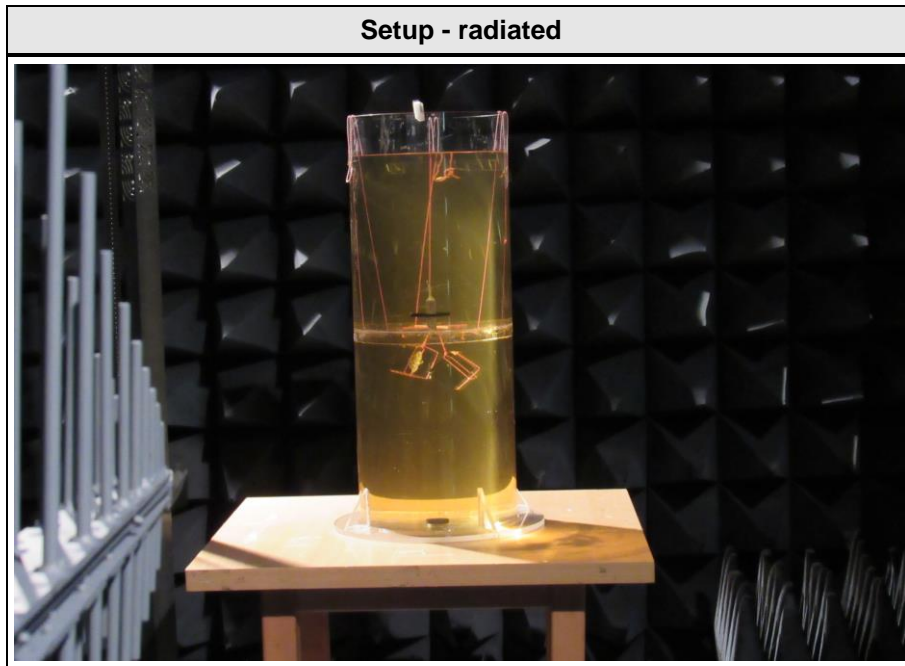


1.2 Photos - Equipment internal





1.3 Photos – Test setup



1.4 Photos – Auxiliary/Associated Equipment

AE 1: Biotronik Telbox 2 UBS - front



AE1: Biotronik Telbox 2 UBS - rear



AE2: PGH 3000 programming head top



AE2: PGH 3000 programming head bottom



1.5 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Programmer	Biotronik	Biotronik Telbox 2 UBS	
AE2	Programming head	Biotronik	PGH 3000 programming head	
<p>*Note: Use the following abbreviations:</p> <p>AE : Auxiliary/Associated Equipment, or</p> <p>SIM : Simulator (Not Subjected to Test)</p> <p>CABL : Connecting cables</p>				

1.6 Test Modes

Mode #	Description	
Unmodulated 1	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Unmodulated 2	General conditions:	EUT powered by power supply
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated 1	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = 2FSK Data rate 16 kBit/s Duty cycle = 100 % Power level = Maximum
Modulated 2	General conditions:	EUT powered by power supply
	Radio conditions:	Mode = standalone transmit Modulation = 2FSK Data rate 16 kBit/s Duty cycle = 100 % Power level = Maximum
Receive	General conditions:	EUT powered on
	Radio conditions:	Mode = standalone receive

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	2016-03	2017-03

Emission Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum analyzer	R&S	FSU 26	EF01003	2016-03	2017-03

Frequency Stability					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum analyzer	R&S	FSU 26	EF01003	2016-03	2017-03

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Fully-anechoic chamber	Frankonia	AC 2	EF00196	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04
LPD Antenna	R&S	HL 223	EF00212	2016-04	2019-04

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

1.8 Sample emission level calculation

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

Reading:

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

A.F.:

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

$$\text{Reading on Analyzer (dB}\mu\text{V)} + \text{A.F. (dB)} = \text{Net field strength (dB}\mu\text{V/m)}$$

Net:

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

Limit:

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

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

Margin:

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

Example only:

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

1.9 Simulated human body

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

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

Measured tissue parameters:


Tissue parameters – 403.5MHz			
Component	Target	Measured	Tolerance [%]
Dielectric constant ϵ	62.5	63.08	0.93
Conductivity σ [ms/cm]	0.9	0.88	-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:				

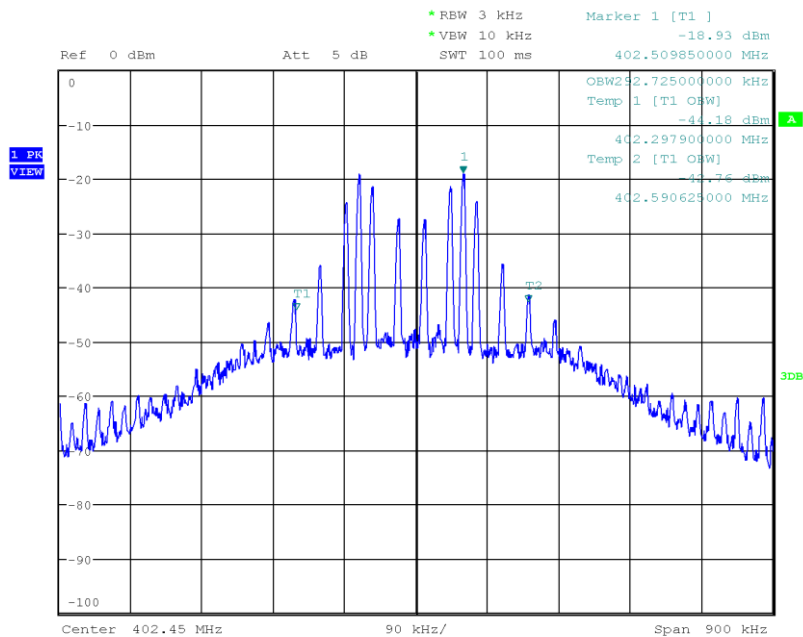
3 Test Conditions and Results

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 2				
Limits						
None (Informational only)						
Test setup						
 <pre> graph LR SA[Spectrum Analyzer] --- EUT[EUT] </pre>						
Test procedure						
<ol style="list-style-type: none"> 1. EUT set to test mode (Communication tester is used if needed) 2. Span set to at least twice the emission spectrum 3. Resolution bandwidth set to 1 % of span 4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function 						
Test results						
Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result	
F_{LOW}	16	402.45	292.725	≤ 300	PASS	
F_{MID}	16	403.65	295.650	≤ 300	PASS	
F_{HIGH}	16	404.85	295.425	≤ 300	PASS	
Comments:						

Occupied Bandwidth – F_{LOW} (16kBit)
Occupied Bandwidth RSS-243

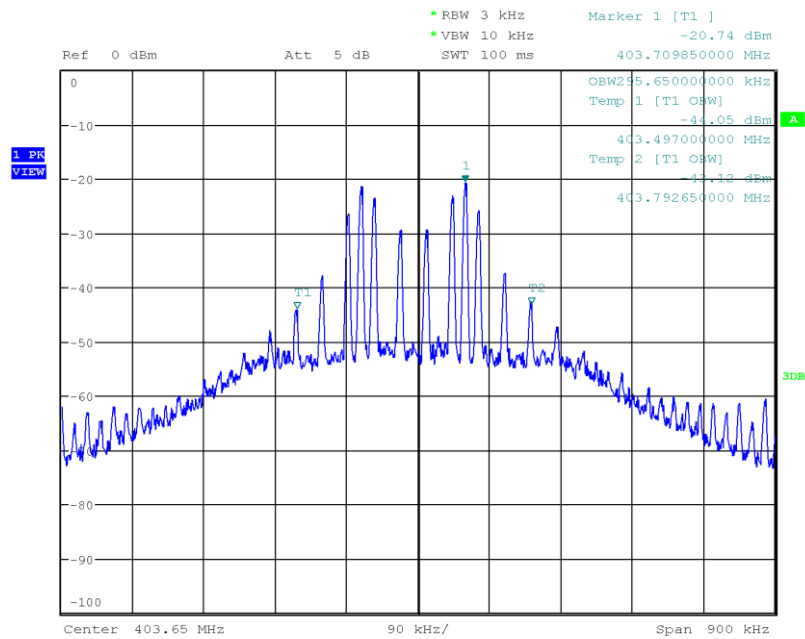
Project Number: G0M-1612-6102
 Applicant: Biotronik SE & Co. KG
 Model Description: BioMonitor 2-AF Parylene Coated
 Model: BioMonitor 2-AF
 Test Sample ID: 11605
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: W. Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2017-01-10
 Occupied Bandwidth [kHz]: 292.725



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Occupied Bandwidth - F_{MID} (16kBit)
Occupied Bandwidth RSS-243

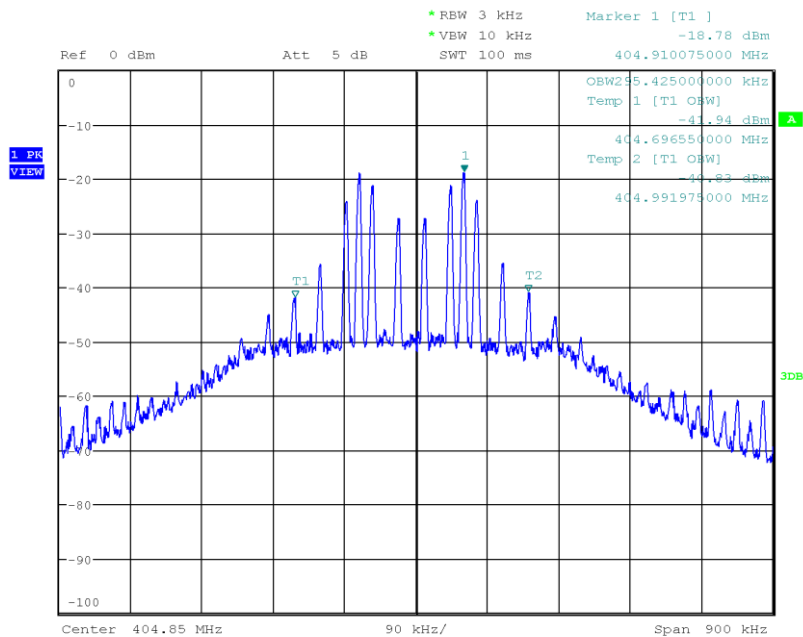
Project Number:	G0M-1612-6102
Applicant	Biotronik SE & Co. KG
Model Description	BioMonitor 2-AF Parylene Coated
Model:	BioMonitor 2-AF
Test Sample ID:	11605
Reference Method:	RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
Operational Mode:	2FSK, 16 kbps, Channel: 0, 403.65 MHz
Operating Conditions:	Tnom / Vnom
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2017-01-10
Occupied Bandwidth [kHz]:	295.650



Date: 10.JAN.2017 15:33:25


Occupied Bandwidth – F_{HIGH} (16kBit)
Occupied Bandwidth RSS-243

Project Number: G0M-1612-6102
 Applicant: Biotronik SE & Co. KG
 Model Description: BioMonitor 2-AF Parylene Coated
 Model: BioMonitor 2-AF
 Test Sample ID: 11605
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: W. Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2017-01-10
 Occupied Bandwidth [kHz]: 295.425



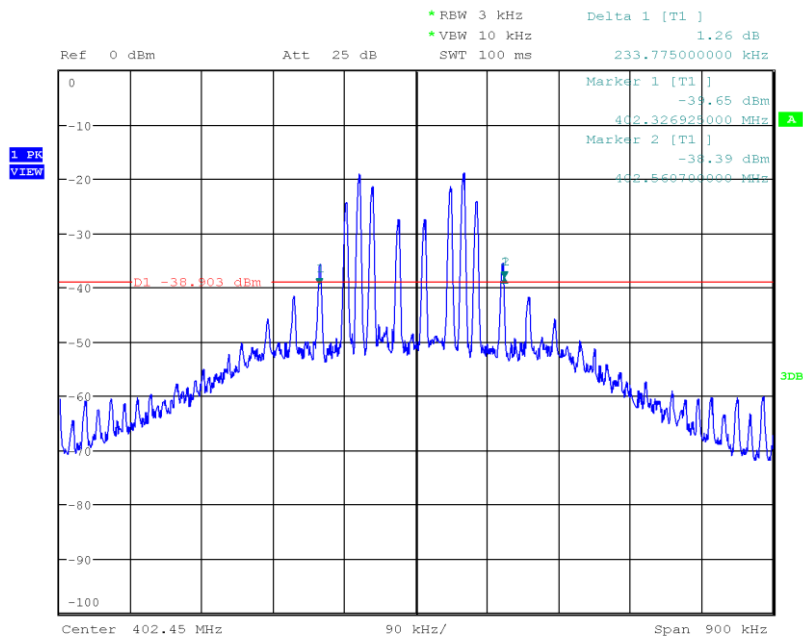
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3.2 Test Conditions and Results – Emission Bandwidth

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				
	$F_{\text{LOW}} / F_{\text{MID}} / F_{\text{HIGH}}$				
EUT test mode	Modulated 2				
Limits					
≤ 300 kHz					
Test setup					
 <pre> graph LR SA[Spectrum Analyzer] --- EUT[EUT] </pre>					
Test procedure					
<ol style="list-style-type: none"> 1. EUT set to test mode 2. Span set to at least twice the emission spectrum 3. Detector set to peak and max hold 4. Envelope peak value of emission spectrum is selected 5. Marker on envelope of spectrum is set to level of -20 dB to the left of the peak 6. Marker on envelope of spectrum is set to level of -20 dB to the right of the peak 7. 20 dB Emission Bandwidth is determined by marker frequency separation 					
Test results					
Channel	Data Rate [kBit]	Frequency [MHz]	Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	16	402.45	233.775	≤ 300	PASS
F_{MID}	16	403.65	233.775	≤ 300	PASS
F_{HIGH}	16	404.85	233.775	≤ 300	PASS
Comments:					

Emission Bandwidth – F_{LOW} (16kBit)
20 dB Bandwidth FCC

Project Number:	G0M-1612-6102
Applicant	Biotronik SE & Co. KG
Model Description	BioMonitor 2-AF Parylene Coated
Model:	BioMonitor 2-AF
Test Sample ID:	11605
Reference Standards:	FCC 95.627
Reference Method:	47 CFR § 95.627(a)(6)(i)
Operational Mode:	2FSK, 16 kbps, Channel: 8, 402.45 MHz
Operating Conditions:	T _{nom} /V _{nom}
Operator:	W. Treffke
Test Site:	Eurofins Product Service GmbH
Test Date:	2017-01-10
Lower Frequency [MHz]:	402.327
Upper Frequency [MHz]:	402.561
20 dB Bandwidth [kHz]:	233.775



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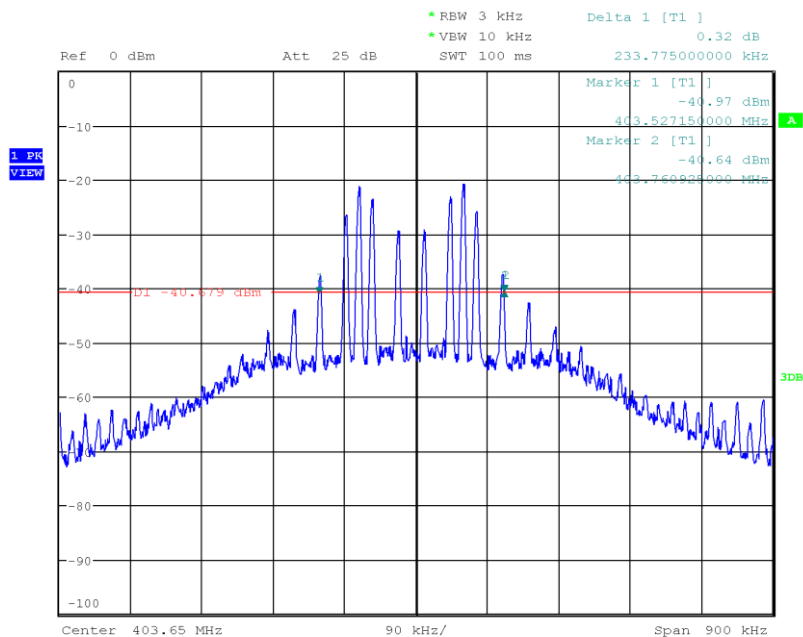
Test Report No.: G0M-1612-6102-TFC95IMR-V01

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

Emission Bandwidth - F_{MID} (16kBit)

20 dB Bandwidth FCC

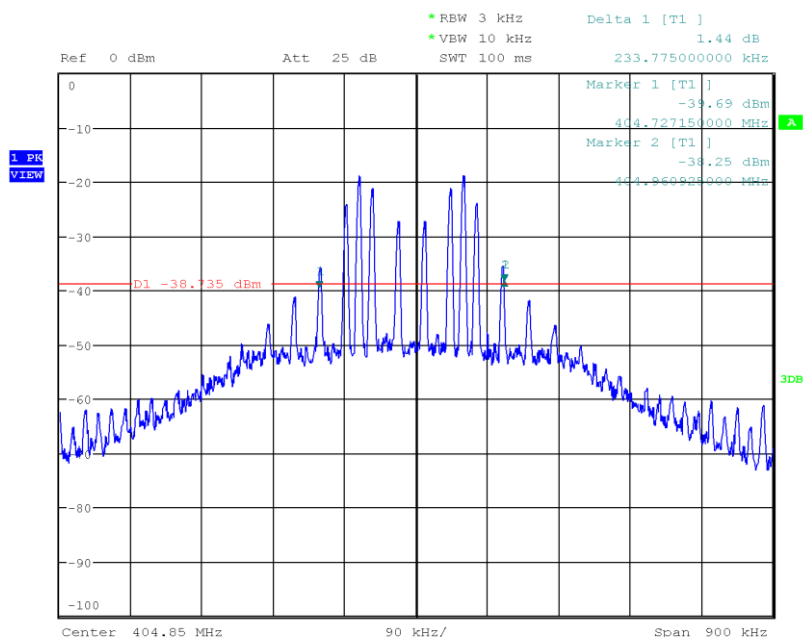
Project Number: G0M-1612-6102
 Applicant: Biotronik SE & Co. KG
 Model Description: BioMonitor 2-AF Parylene Coated
 Model: BioMonitor 2-AF
 Test Sample ID: 11605
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 16 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom/Vnom
 Operator: W. Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2017-01-10
 Lower Frequency [MHz]: 403.527
 Upper Frequency [MHz]: 403.761
 20 dB Bandwidth [kHz]: 233.775



Date: 10.JAN.2017 16:08:16

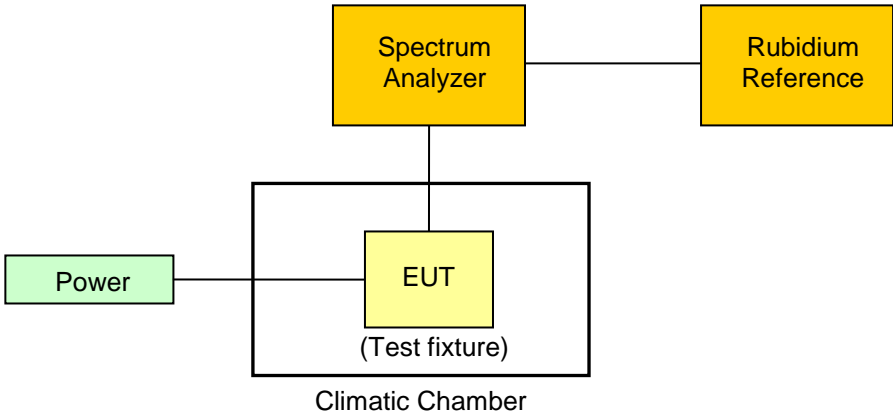
Emission Bandwidth – F_{HIGH} (16kBit)
20 dB Bandwidth FCC

Project Number: G0M-1612-6102
 Applicant: Biotronik SE & Co. KG
 Model Description: BioMonitor 2-AF Parylene Coated
 Model: BioMonitor 2-AF
 Test Sample ID: 11605
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 16 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom/Vnom
 Operator: W. Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2017-01-10
 Lower Frequency [MHz]: 404.727
 Upper Frequency [MHz]: 404.961
 20 dB Bandwidth [kHz]: 233.775



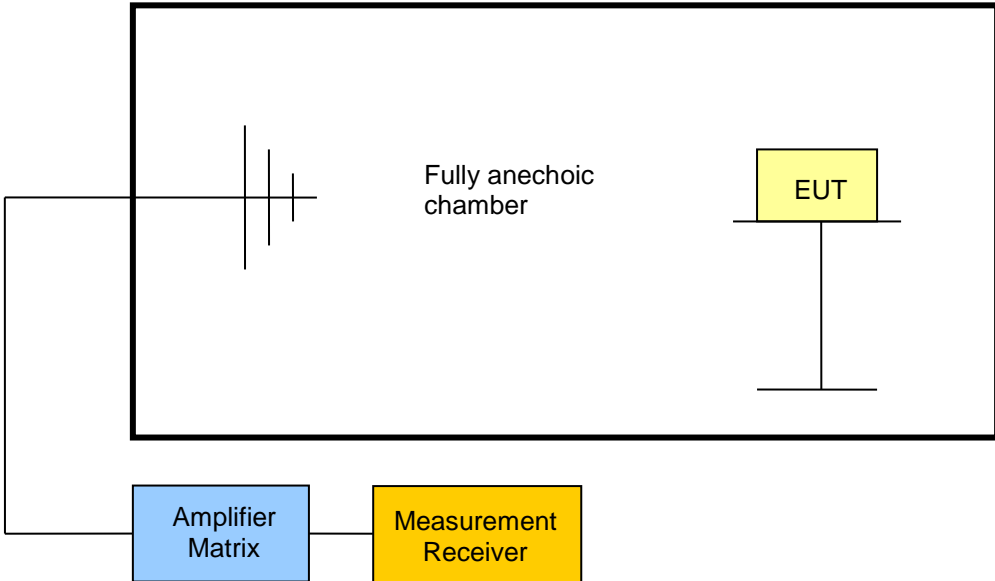
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3.3 Test Conditions and Results – Frequency stability

Frequency stability acc. to FCC Part 95 / IC RSS-243		Verdict: PASS
EUT requirement rule parts and clause	Reference	
	FCC 95.628(e) / IC RSS-243 3.3 5.3 / RSS-Gen 4.7	
Test according to measurement reference	Reference Method	
	EN 301 839-1 8.1	
Test frequency range	Tested frequencies	
	F _{LOW} / F _{MID} / F _{HIGH}	
EUT test mode	Unmodulated 2	
Limits		
≤ ±100 ppm		
Test setup		
		
Test procedure		
<ol style="list-style-type: none"> 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. 		

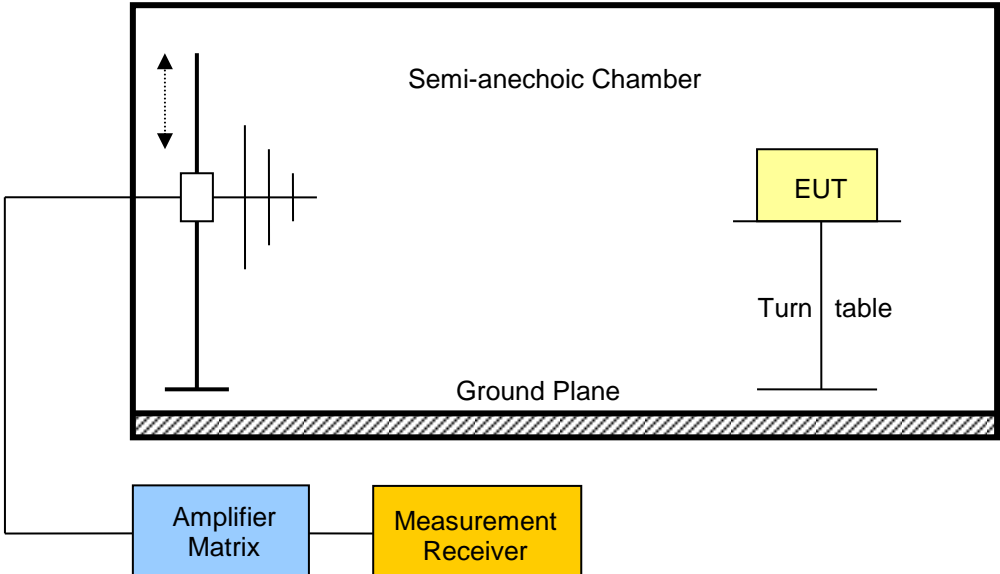
Test results					
Channel	Nominal Frequency [MHz]	Temperature	Supply voltage	Frequency [MHz]	Drift [ppm]
F _{LOW}	402.45	T _{NOM} = 37 °C	V _{NOM} = 3.0 VDC	402.443498	-16.16
F _{LOW}	402.45	T _{MIN} = 25 °C	V _{NOM} = 3.0 VDC	402.443924	-15.10
F _{LOW}	402.45	T _{MAX} = 45 °C	V _{NOM} = 3.0 VDC	402.443230	-16.82
F _{MID}	403.65	T _{NOM} = 37 °C	V _{NOM} = 3.0 VDC	403.643556	-15.96
F _{MID}	403.65	T _{MIN} = 25 °C	V _{NOM} = 3.0 VDC	403.644040	-14.77
F _{MID}	403.65	T _{MAX} = 45 °C	V _{NOM} = 3.0 VDC	403.643286	-16.63
F _{HIGH}	404.85	T _{NOM} = 37 °C	V _{NOM} = 3.0 VDC	404.843627	-15.74
F _{HIGH}	404.85	T _{MIN} = 25 °C	V _{NOM} = 3.0 VDC	404.843989	-14.85
F _{HIGH}	404.85	T _{MAX} = 45 °C	V _{NOM} = 3.0 VDC	404.843337	-16.46
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 1	
Limits		
$\leq 25 \mu W (-16 \text{ dBm}) \text{ e.i.r.p.}$		
Test setup		
 <p>The diagram illustrates the test setup. An Amplifier Matrix (blue box) is connected to a Fully anechoic chamber (large rectangle). Inside the chamber, an EUT (yellow box) is mounted on a stand. The chamber is connected to a Measurement Receiver (yellow box) outside. The chamber contains a symbol representing an anechoic chamber (a square with four vertical lines of varying lengths).</p>		
Test procedure		
<ol style="list-style-type: none"> 1. EUT set to test frequency without modulation 2. Measurement polarization is set to vertical 3. Span is set according to measurement range and detector is set to peak and max hold 4. Resolution bandwidth is set to be at least twice the emission bandwidth 5. During the sweep the EUT is rotated to obtain maximum emission level 6. Measurement is repeated with horizontal measurement polarization 		

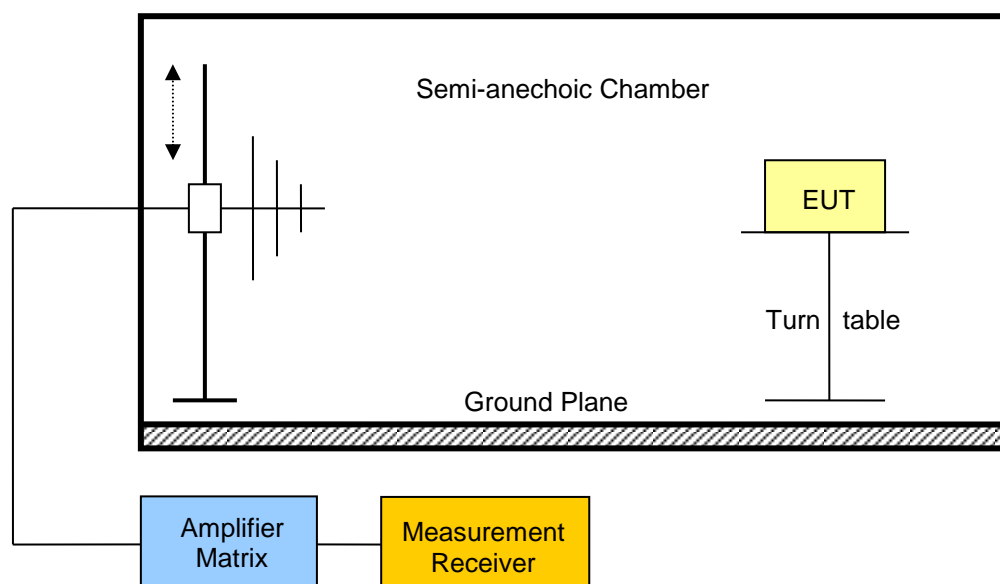
Test results					
Channel	Frequency [MHz]	Emission Level [dBm e.i.r.p.]	Detector	Limit [dBm e.i.r.p.]	Margin [dB]
F _{LOW}	402.45	-39.0	pk	-16	-23.00
F _{HIGH}	404.85	-38.9	pk	-16	-22.90
Comments:					

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	
$402\text{ MHz} - 250\text{ kHz} \leq f \leq 402\text{ MHz}$	20 dB below maximum permitted output power	
$402\text{ MHz} < f < 150\text{ kHz} - f_C$	20 dB below transmitter output power	
$150\text{ kHz} + f_C < f < 405\text{ MHz}$	20 dB below transmitter output power	
$405\text{ MHz} \leq f \leq 405\text{ MHz} + 250\text{ kHz}$	20 dB below maximum permitted output power	
Limits - IC		
Frequency range	Limit	
$402\text{ MHz} - 250\text{ kHz} < f < 150\text{ kHz} - f_C$	20 dB below maximum permitted output power	
$150\text{ kHz} + f_C < f < 405\text{ MHz} + 250\text{ kHz}$	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		
 <p>The diagram illustrates the test setup. A Semi-anechoic Chamber is shown with a Ground Plane at the bottom. Inside the chamber, an Amplifier Matrix is connected to a Measurement Receiver. The EUT (Equipment Under Test) is placed on a Turn table. The chamber is designed to minimize reflections, ensuring accurate measurement of the EUT's emissions.</p>		

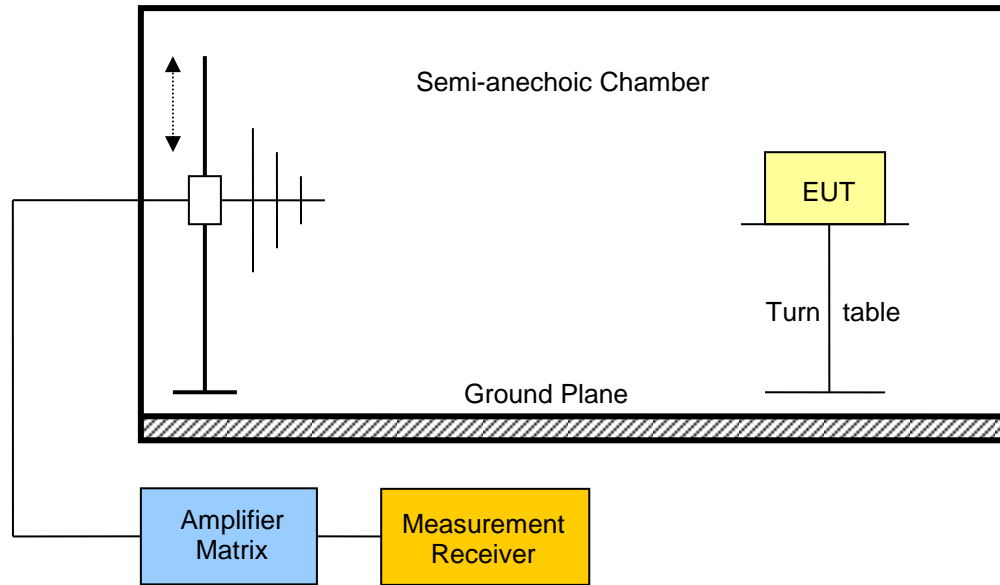
Test procedure						
<ol style="list-style-type: none"> 1. EUT set to test frequency with modulation 2. Measurement polarization is set to vertical 3. Span it set according to measurement range 4. Resolution bandwidth is set to 1% of the emission bandwidth and detector is set to peak 5. During the sweep 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 [dB μ V/m]	Pol.	Limit [dB μ V/m]	Margin [dB]
F _{LOW}	402.45	401.787	05.36	ver	59.40	-54.04
F _{LOW}	402.45	402.296	10.86	hor	45.50	-34.64
F _{LOW}	402.45	402.296	21.33	ver	45.50	-24.17
F _{LOW}	402.45	403.234	08.60	hor	45.50	-36.90
F _{LOW}	402.45	403.236	18.54	ver	45.50	-26.96
F _{HIGH}	404.85	404.695	05.14	hor	45.50	-40.36
F _{HIGH}	404.85	404.695	20.91	ver	45.50	-24.59
F _{HIGH}	404.85	405.000	16.52	ver	45.50	-28.98
F _{HIGH}	404.85	405.025	06.00	hor	59.40	-53.40
F _{HIGH}	404.85	405.025	17.03	ver	59.40	-42.37
Comments: see attached diagrams						

3.6 Test Conditions and Results – Transmitter unwanted emissions

Transmitter unwanted emissions acc. to FCC Part 95 / IC RSS-243				Verdict: PASS
Test according referenced standards		Reference Method		
		FCC 95.635(d) / IC RSS-243 3.4 5.5 / IC RSS-Gen 4.9		
Test according to measurement reference		Reference Method		
		FCC 95.635(d) / ANSI C 63.4		
Test frequency range		Tested frequencies		
		30 MHz – 10 th Harmonic		
EUT test mode		Modulated 1		
Limits				
Frequency range [MHz]	Detector	Limit [μ V/m]	Limit [dB μ V/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				
 <p>The diagram illustrates the test setup within a Semi-anechoic Chamber. A Ground Plane is located at the bottom. The Equipment Under Test (EUT) is placed on a Turn table. A probe is positioned to measure emissions from the EUT. The chamber is connected to an Amplifier Matrix and a Measurement Receiver.</p>				

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 [db μ V/m]	Det.	Pol.	Limit [db μ V/m]	Limit dist. [m]*	Margin [dB]
F _{LOW}	402.45	Modulated 1	No significant spurious emissions						
F _{HIGH}	404.85	Modulated 1	No significant spurious emissions						
Comments:									

3.7 Test Conditions and Results – Receiver spurious emissions

Receiver spurious emissions acc. to IC RSS-243				Verdict: PASS
Test according referenced standards	Reference Method			
	IC RSS-243 3.5 5.6 / IC RSS-Gen 4.10 6.1			
Test according to measurement reference	Reference Method			
	ANSI C 63.4			
Test frequency range	Tested frequencies			
	30 MHz – 5 th Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [μ V/m]	Limit [dB μ V/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 [dB μ V/m]	Det.	Pol.	Limit [dB μ V/m]	Margin [dB]
F _{MID}	403.65	3970	41.38	pk	hor	53.98	-12.60
Comments:							

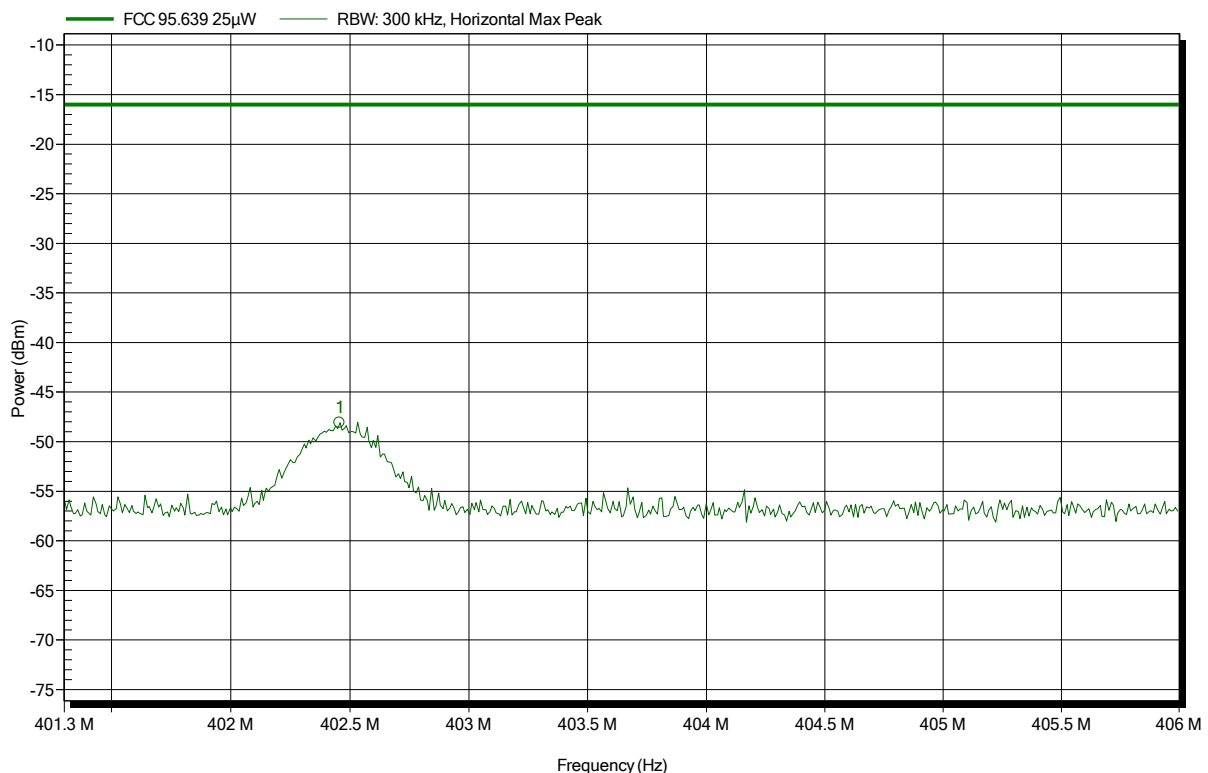
ANNEX A Transmitter radiated power

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2017-01-10
Note:	Tx Power EIRP

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.456 MHz	-48.1 dBm	-16 dBm	-32.1 dB	Pass

Test Report No.: G0M-1612-6102-TFC95IMR-V01

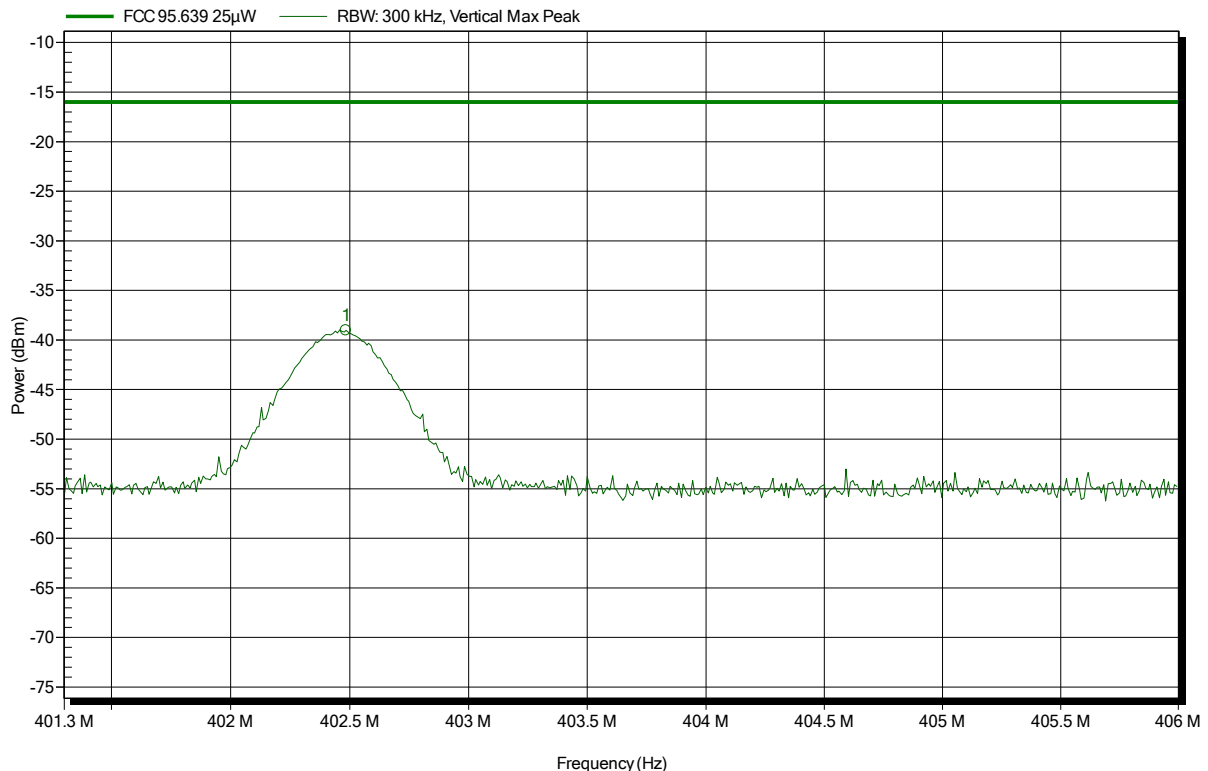
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2017-01-10
Note:	Tx Power EIRP

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.484 MHz	-39 dBm	-16 dBm	-23.04 dB	Pass

Test Report No.: G0M-1612-6102-TFC95IMR-V01

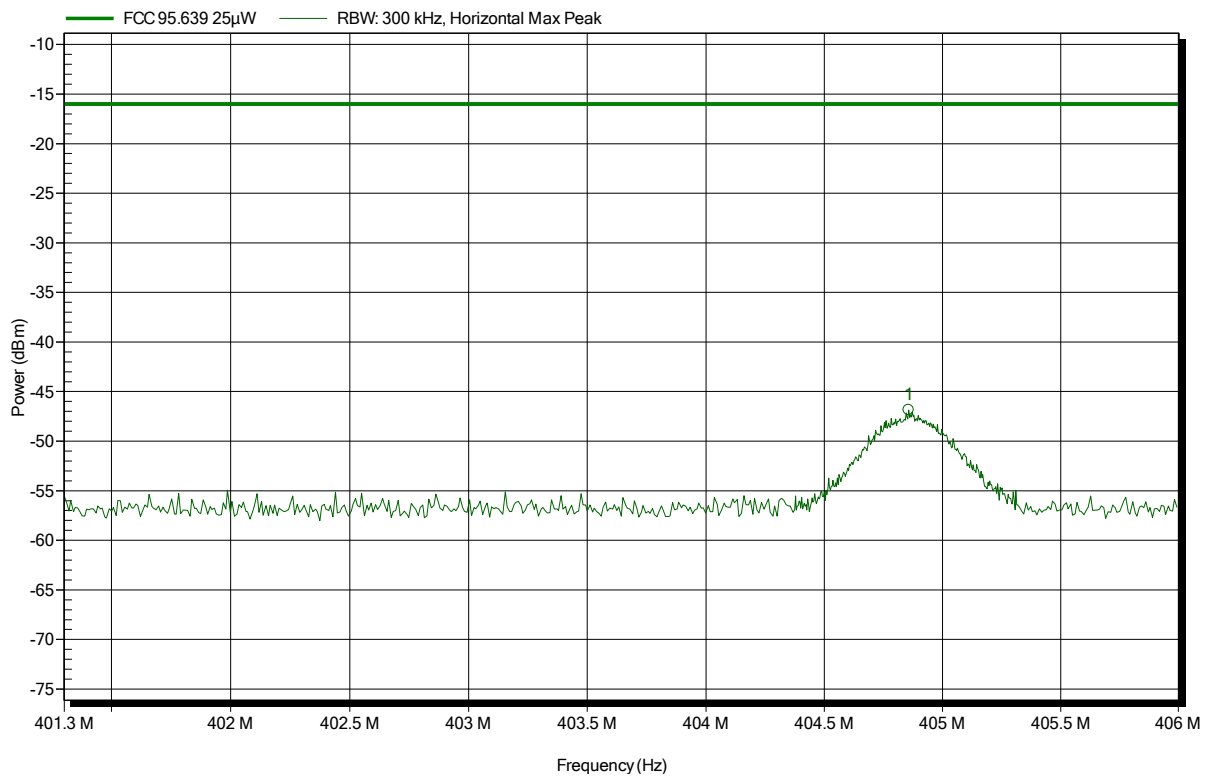
 Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2017-01-10
Note:	Tx Power EIRP

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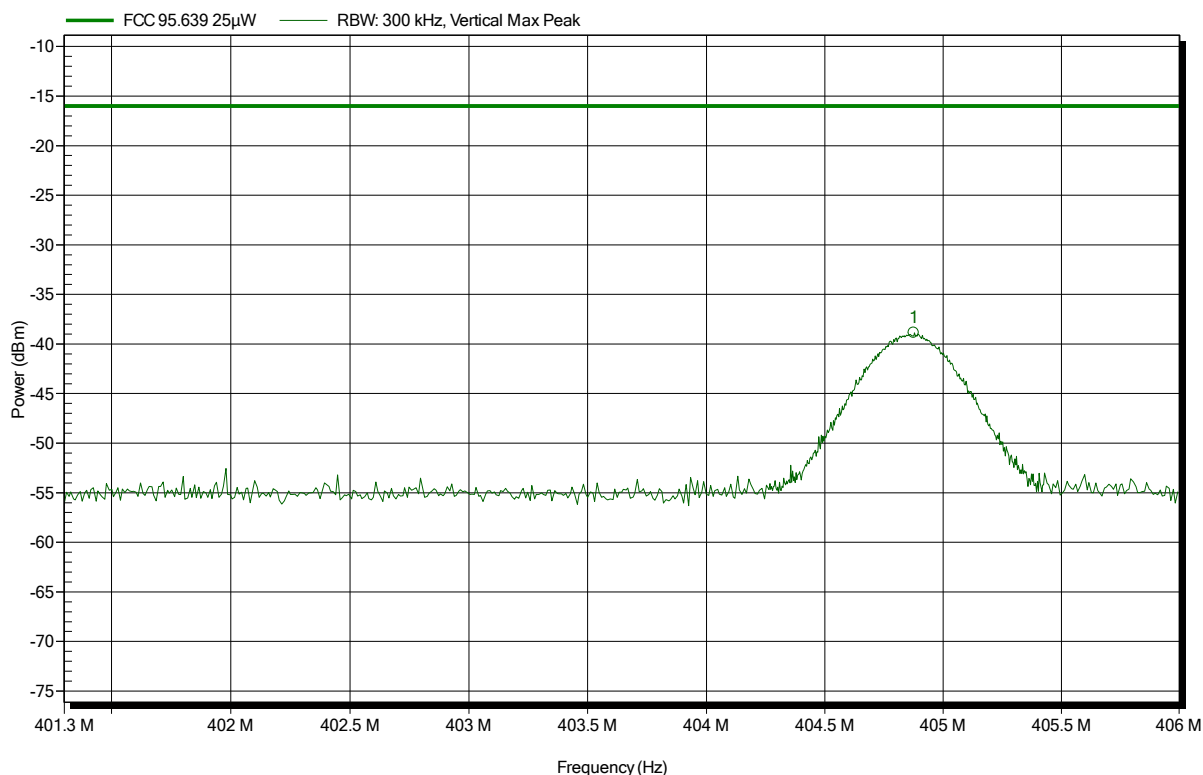
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.856 MHz	-46.9 dBm	-16 dBm	-30.85 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2017-01-10
Note:	Tx Power EIRP

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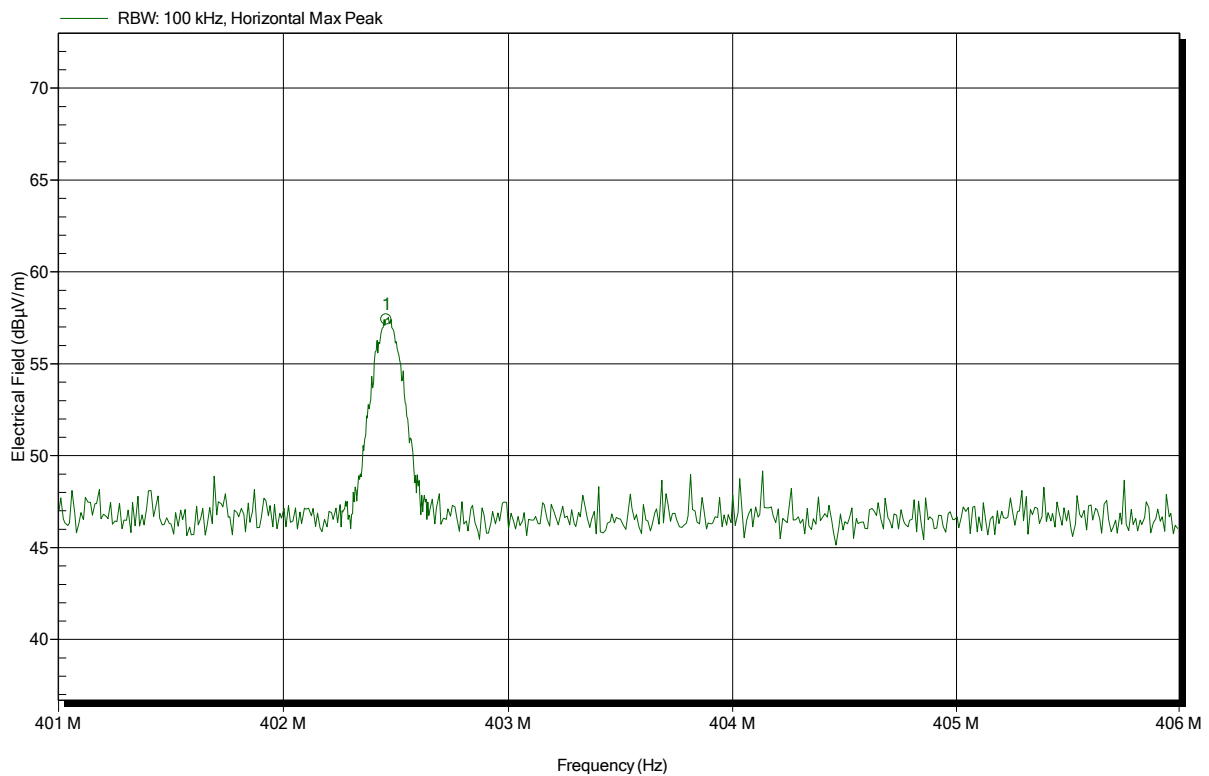
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.876 MHz	-38.9 dBm	-16 dBm	-22.88 dB	Pass

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2017-01-10
Note:	Power dB μ V/m ERP

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 Frequency
402.457 MHz

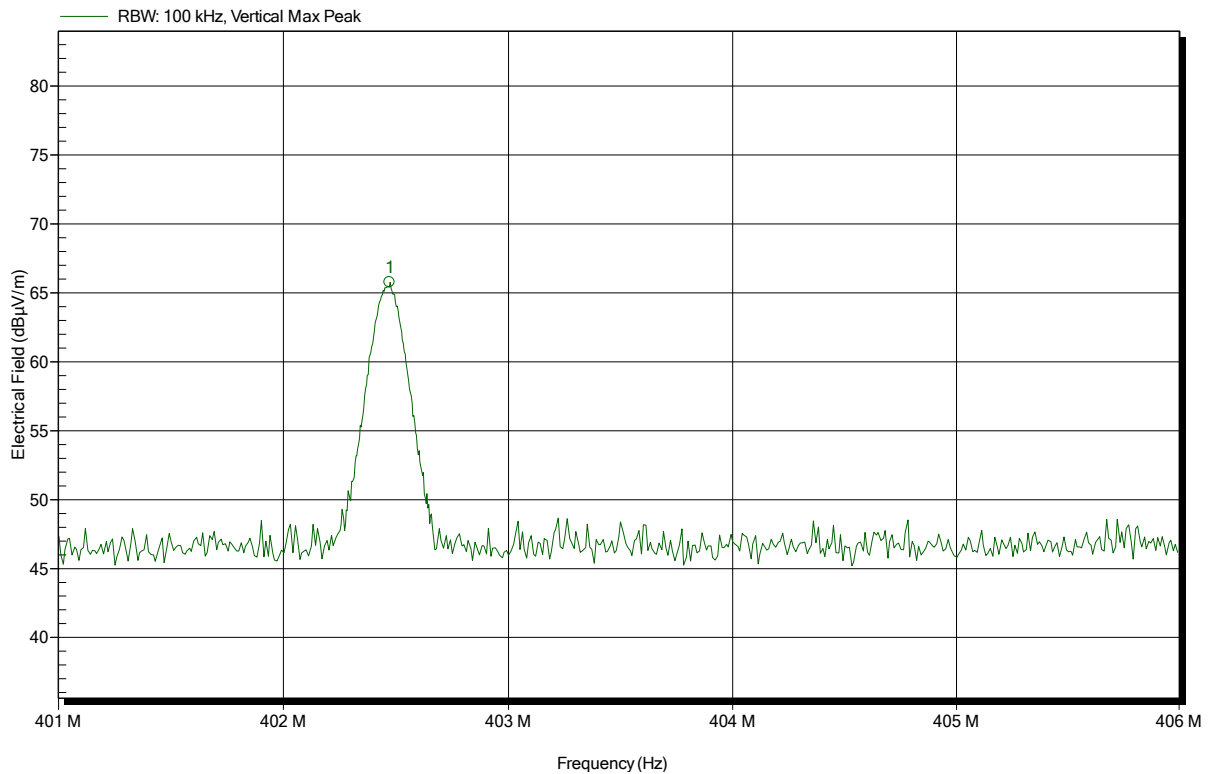
 Peak
57.4 dB μ V/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 402.45 MHz; CW
Test Date:	2017-01-10
Note:	Power dB μ V/m ERP

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 Frequency
402.471 MHz

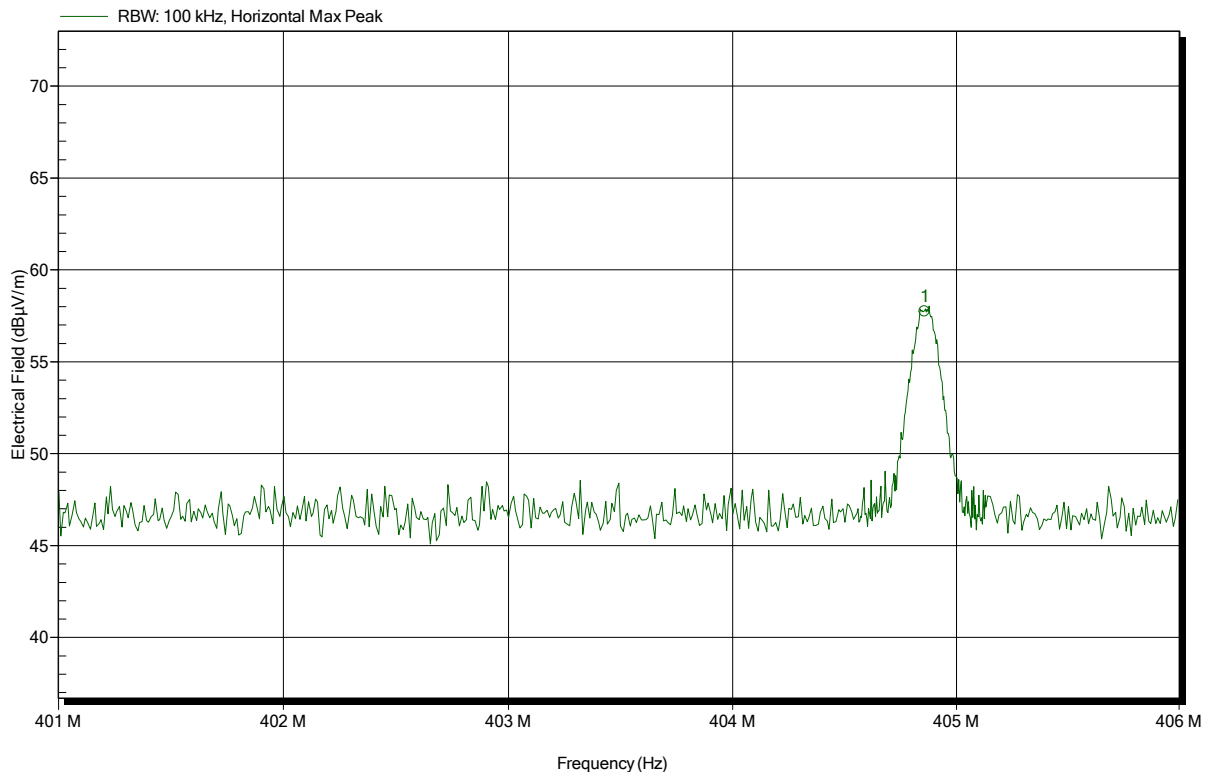
 Peak
65.78 dB μ V/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2017-01-10
Note:	Power dB μ V/m ERP

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 Frequency
404.858 MHz

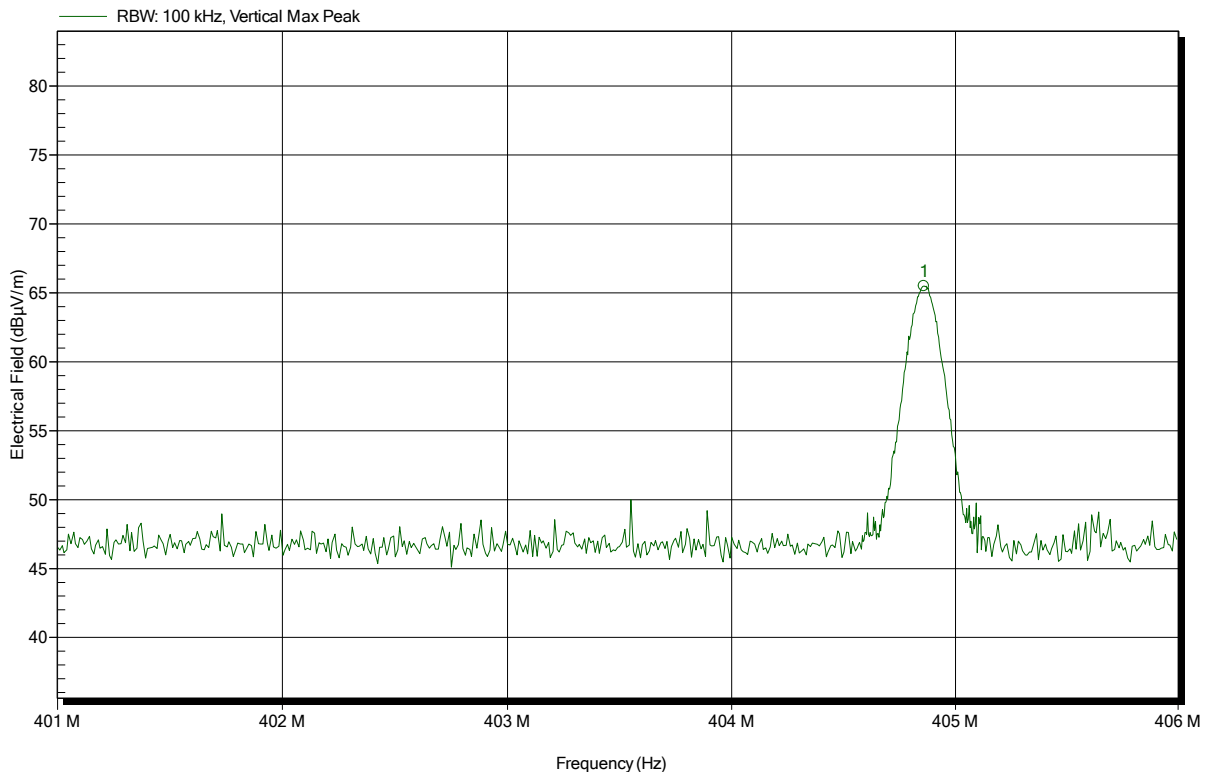
 Peak
57.74 dB μ V/m

Radiated power according to FCC Part 95; Subpart I

Order number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	Tx; 404.85 MHz; CW
Test Date:	2017-01-10
Note:	Power dB μ V/m ERP

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 Frequency
404.86 MHz

 Peak
65.49 dB μ V/m

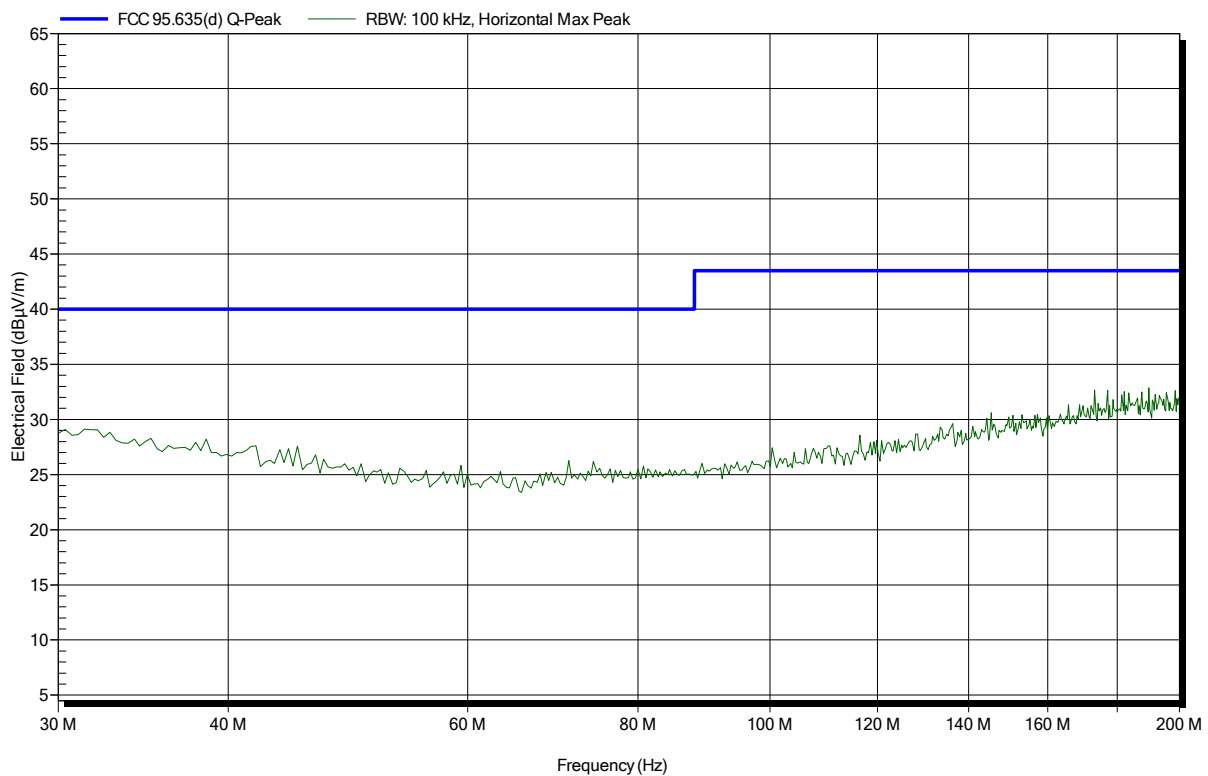
ANNEX B Transmitter radiated spurious emissions

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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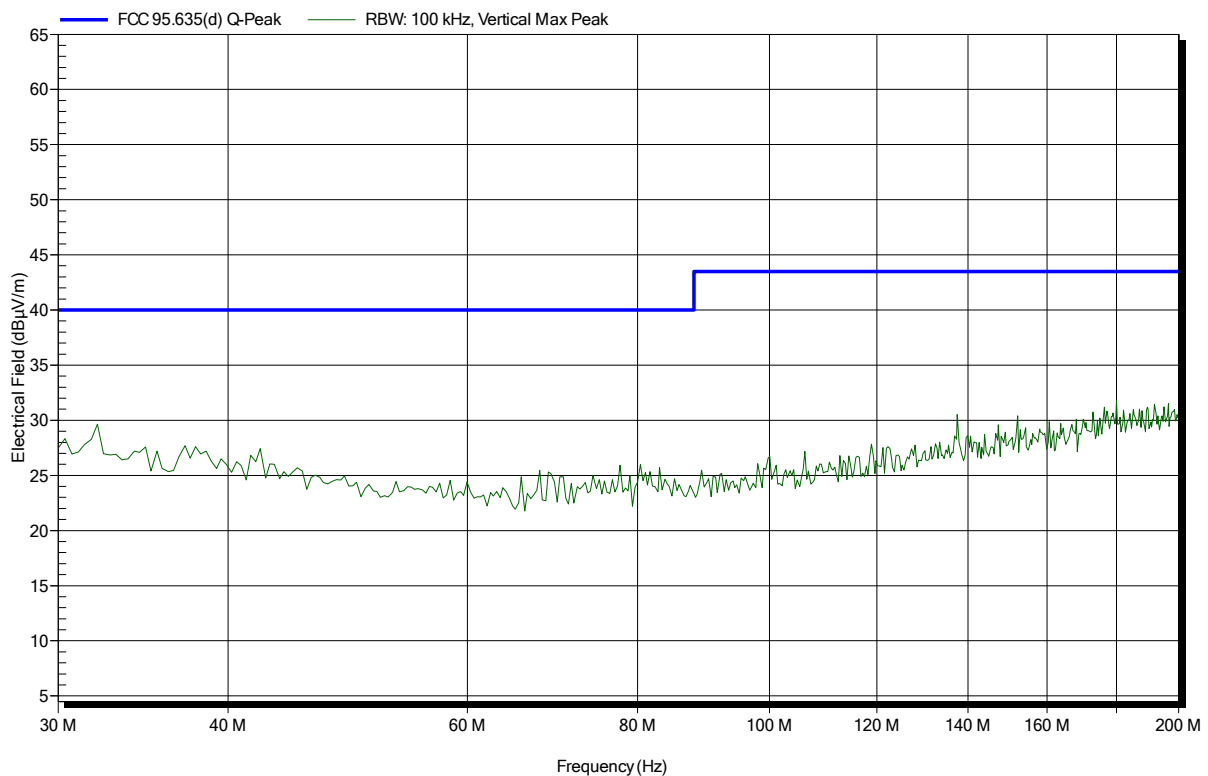


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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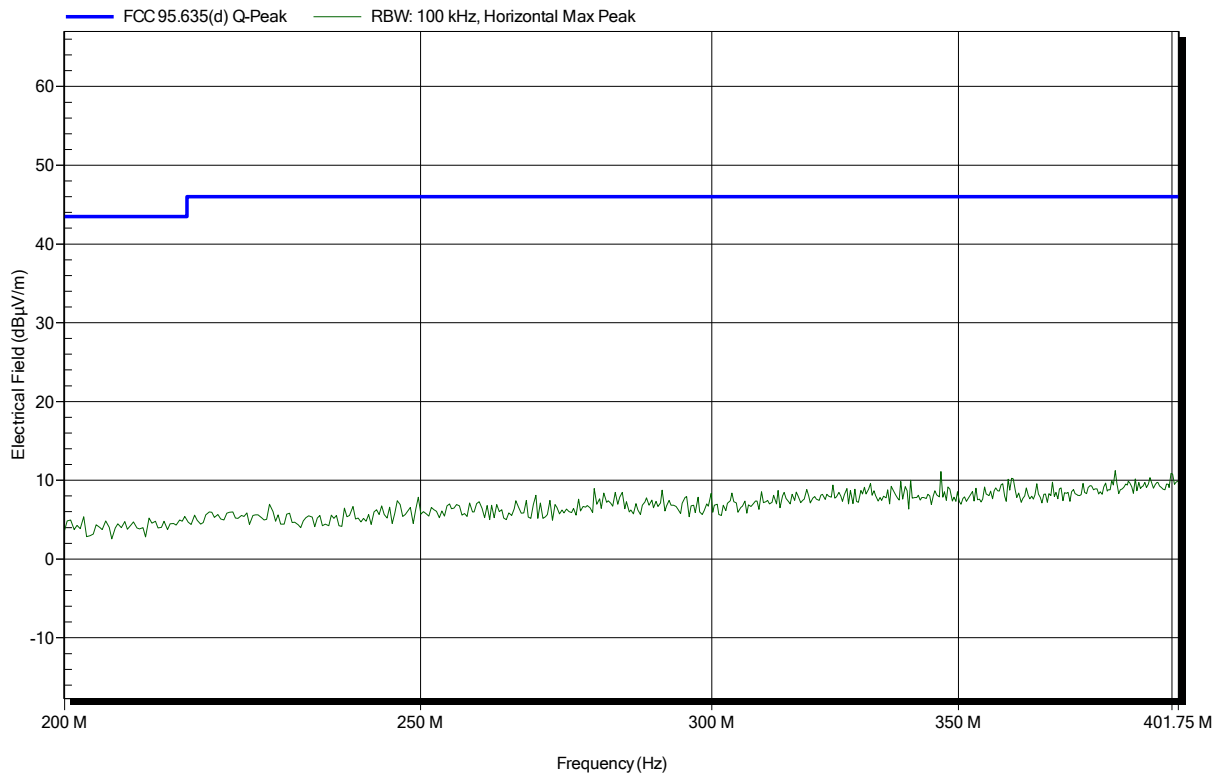


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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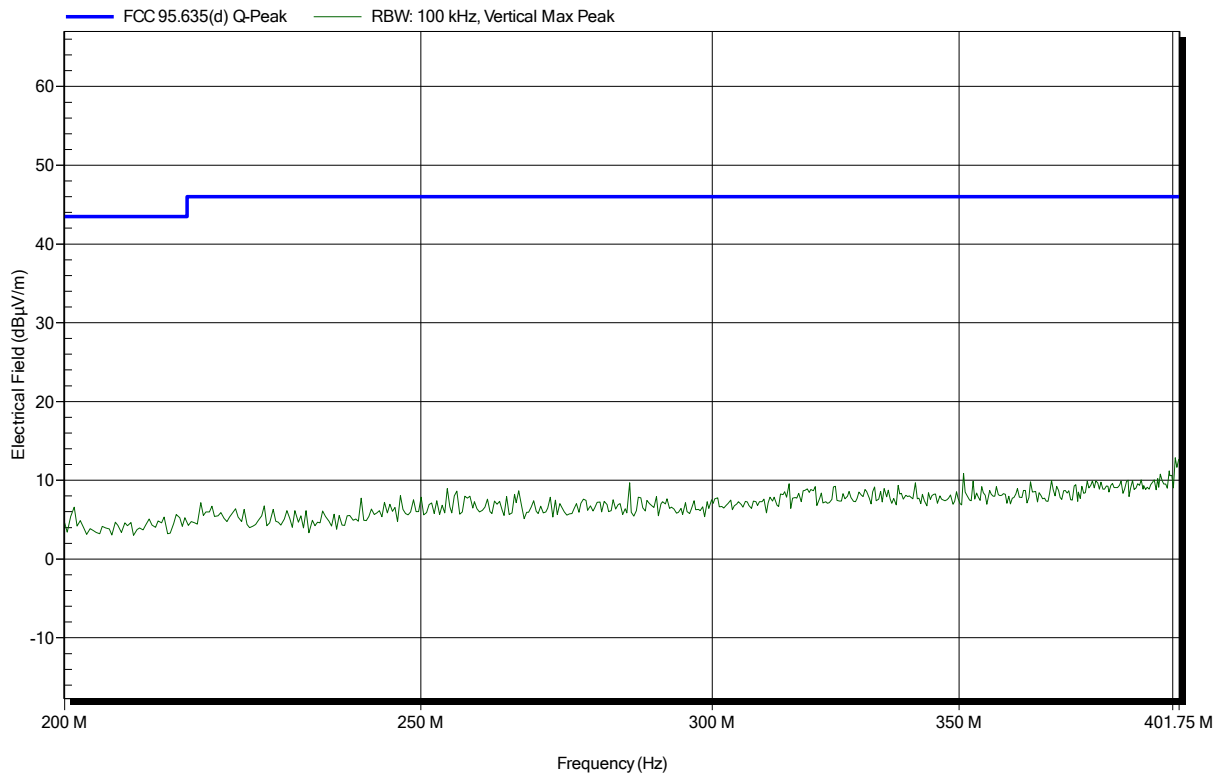


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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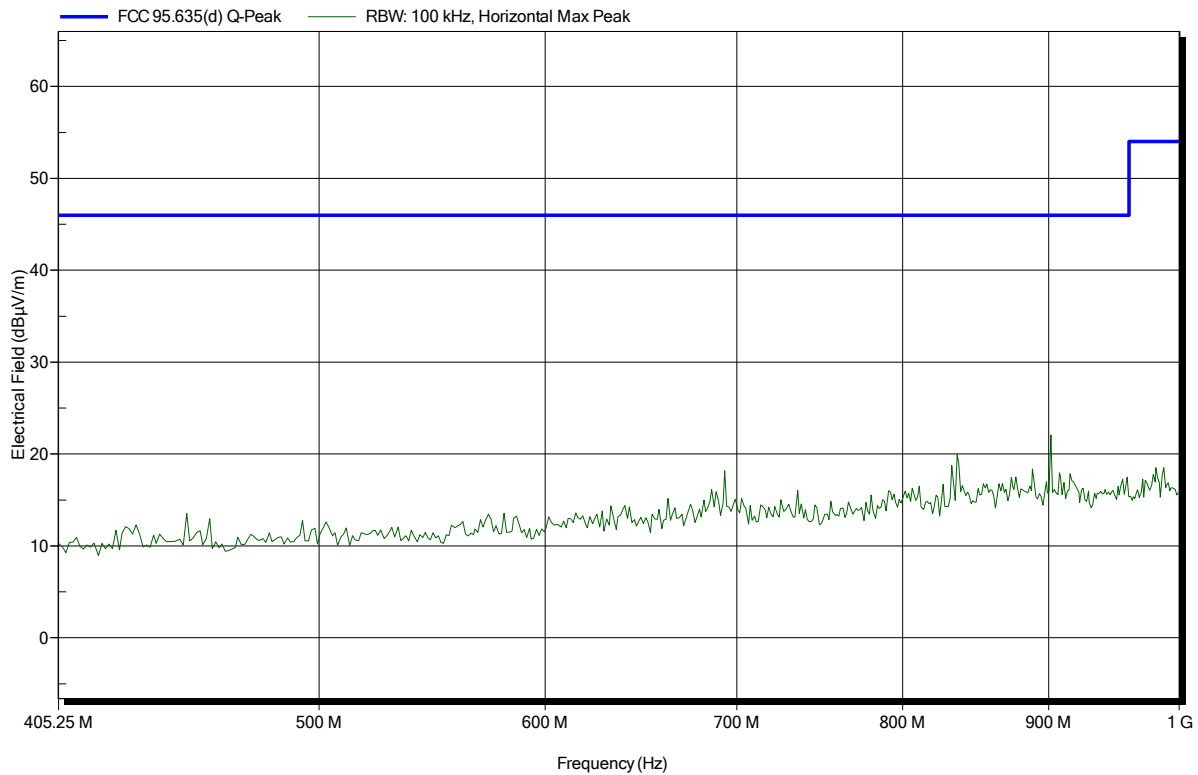


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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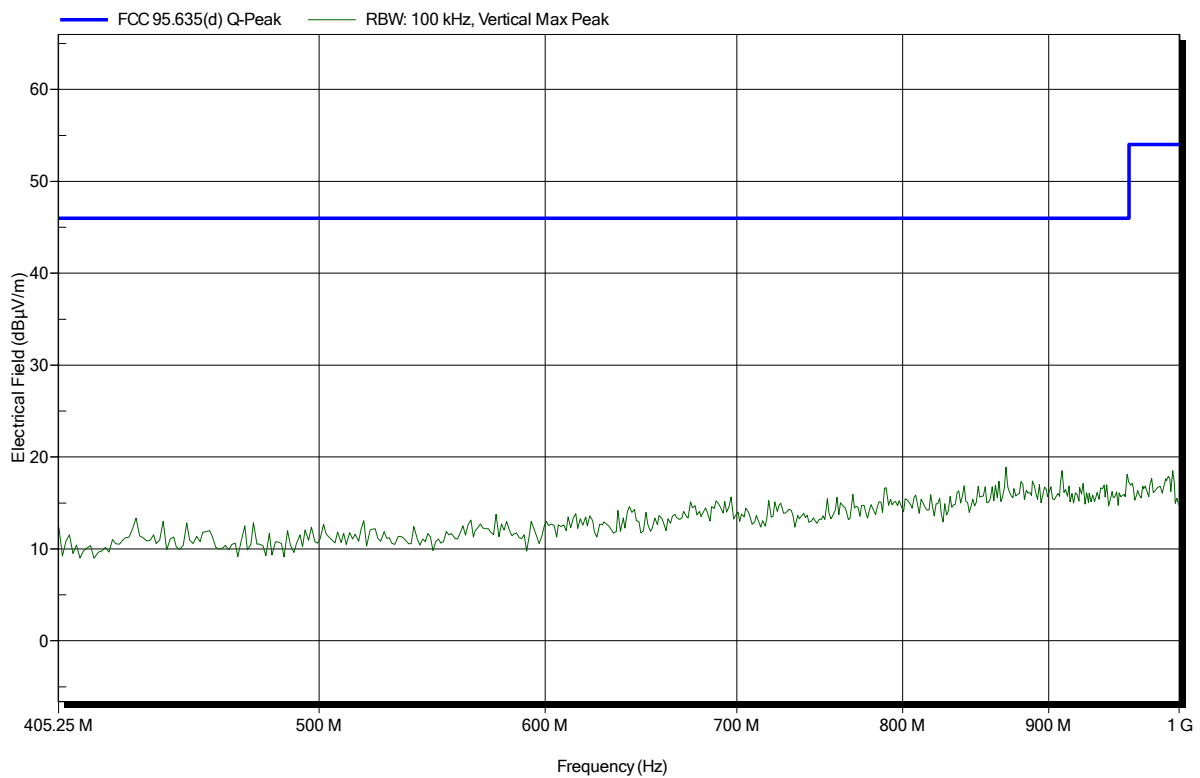


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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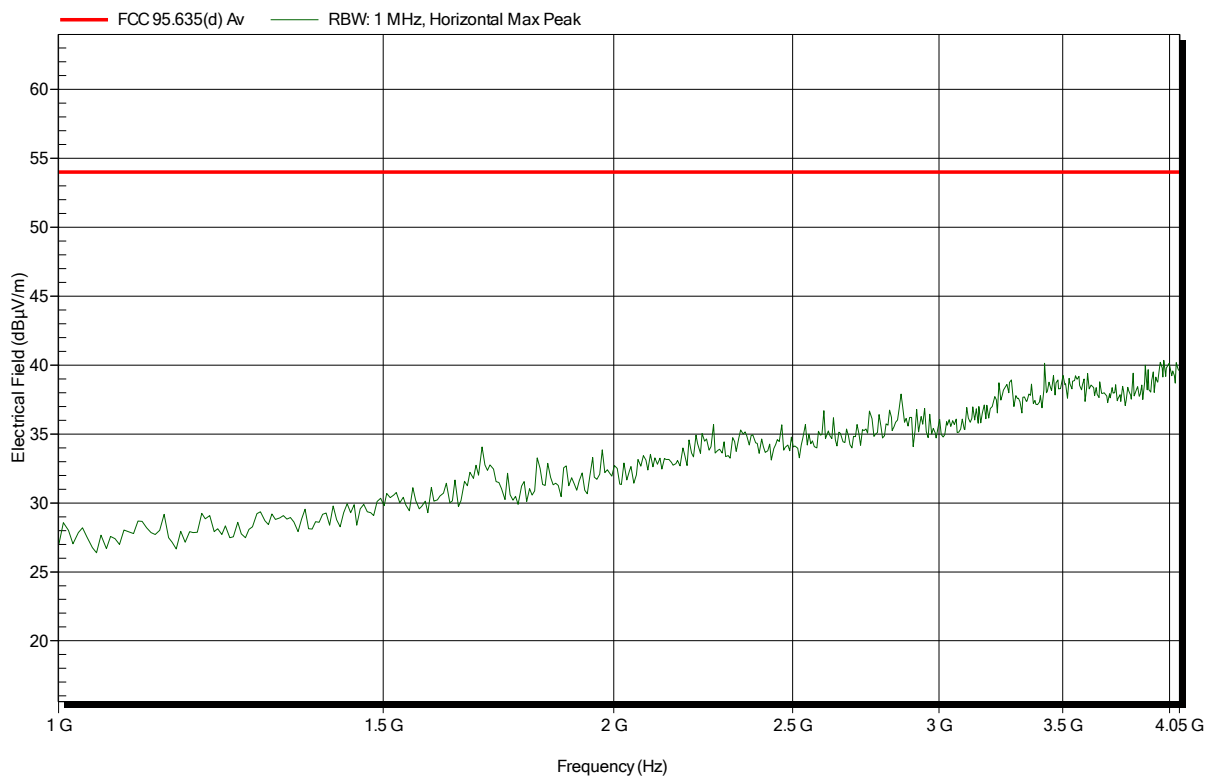


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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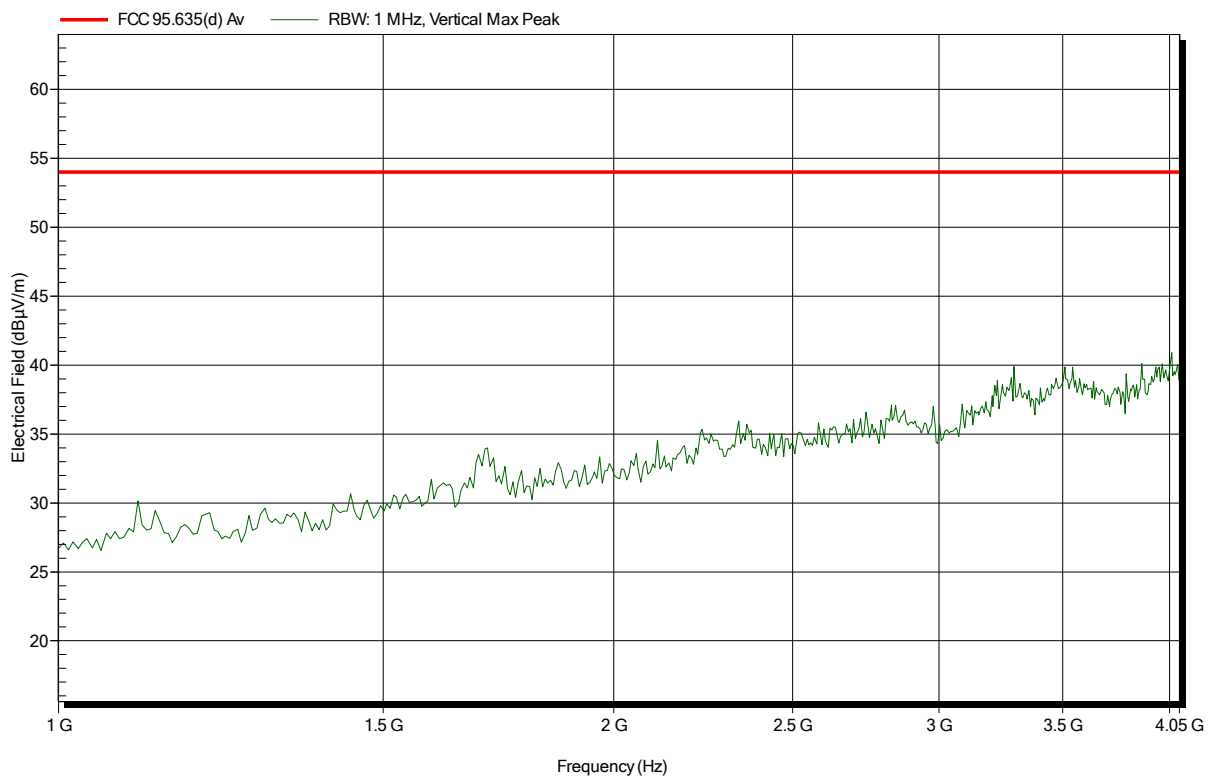


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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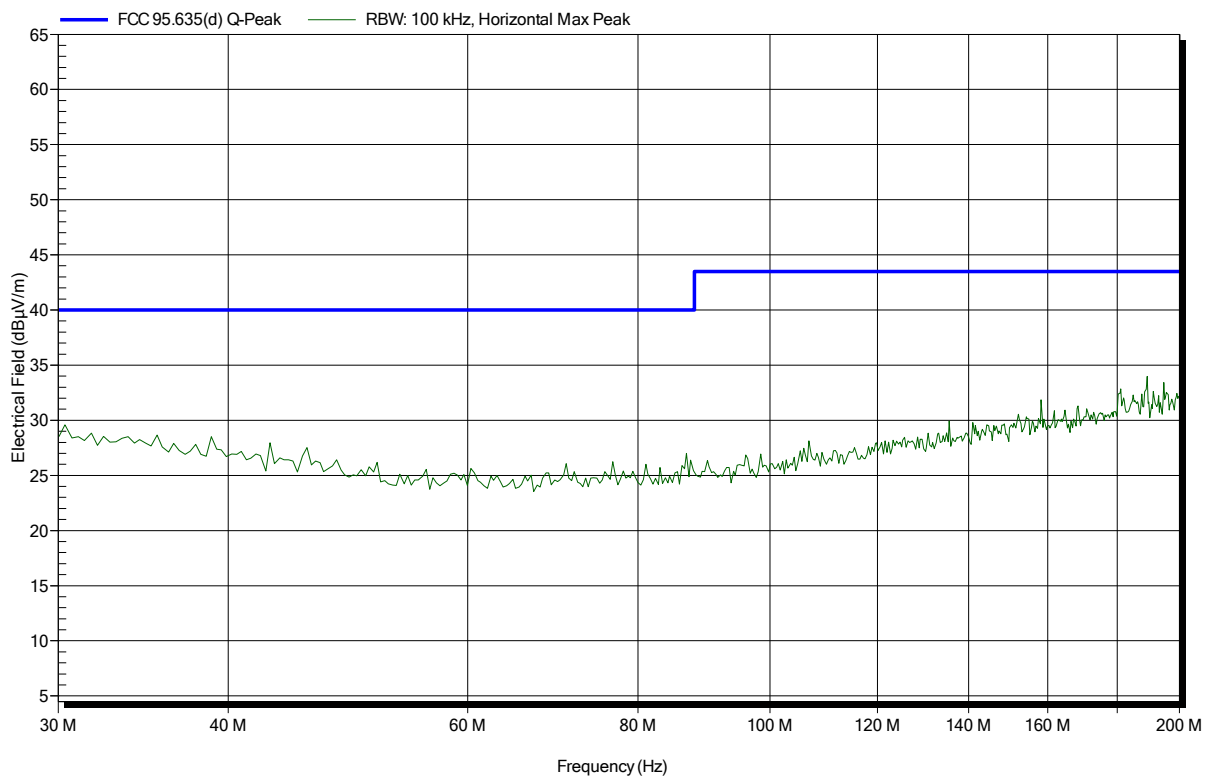


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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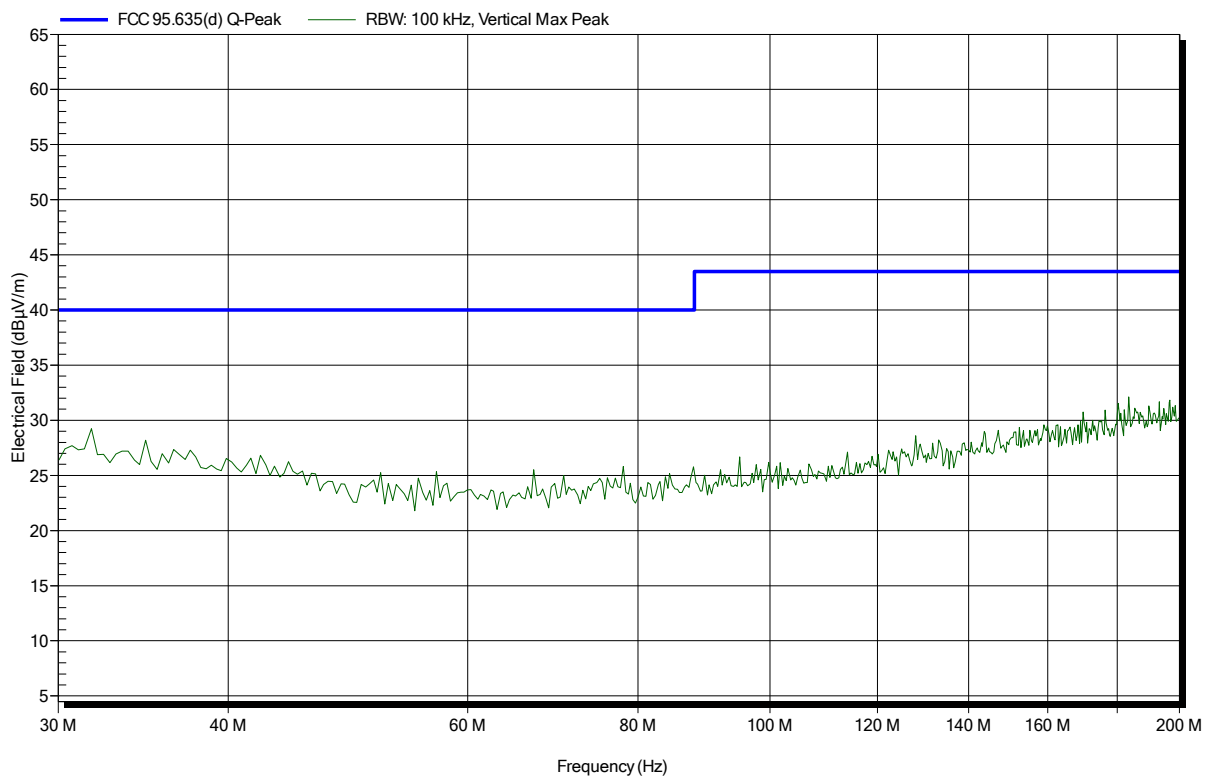


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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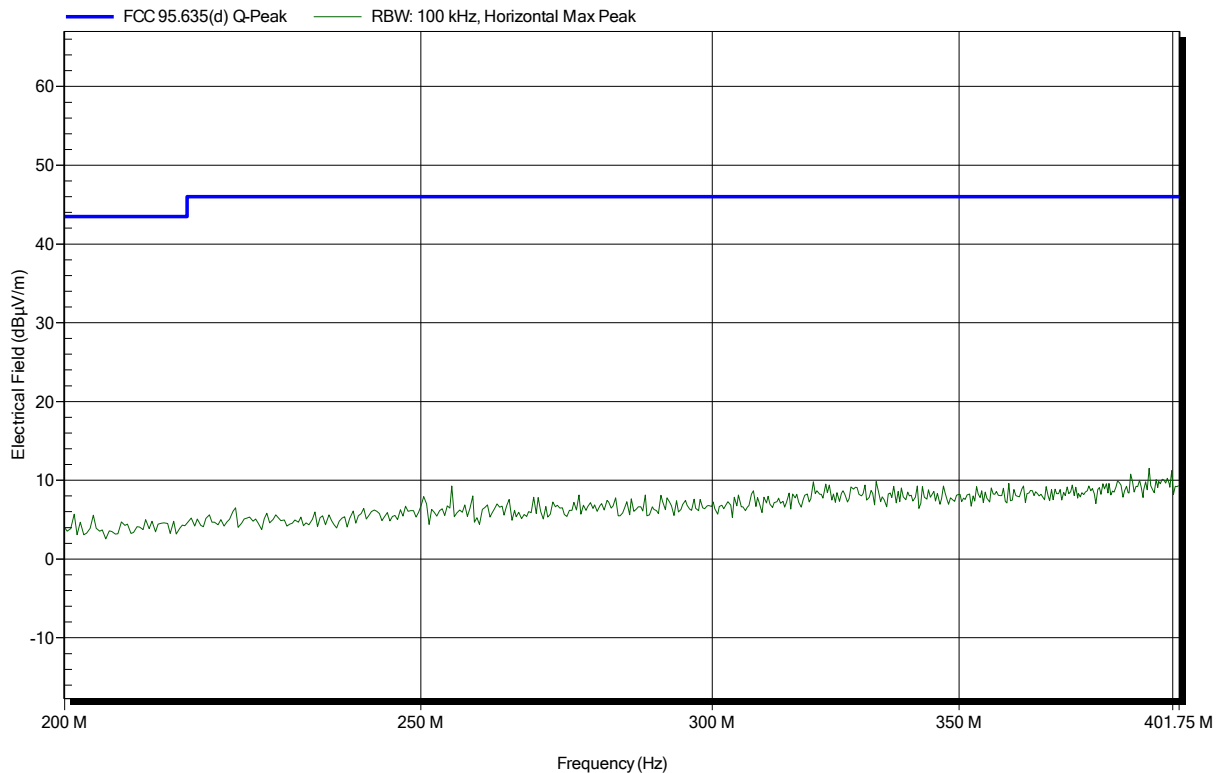


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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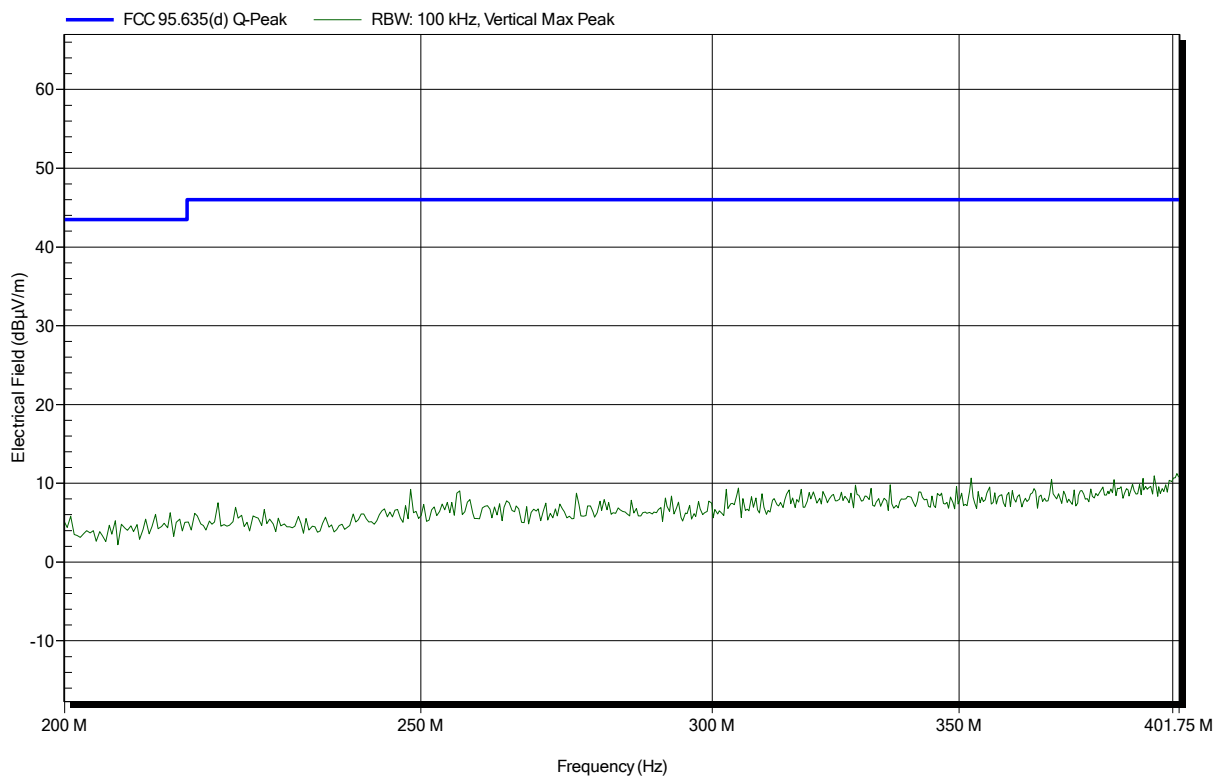


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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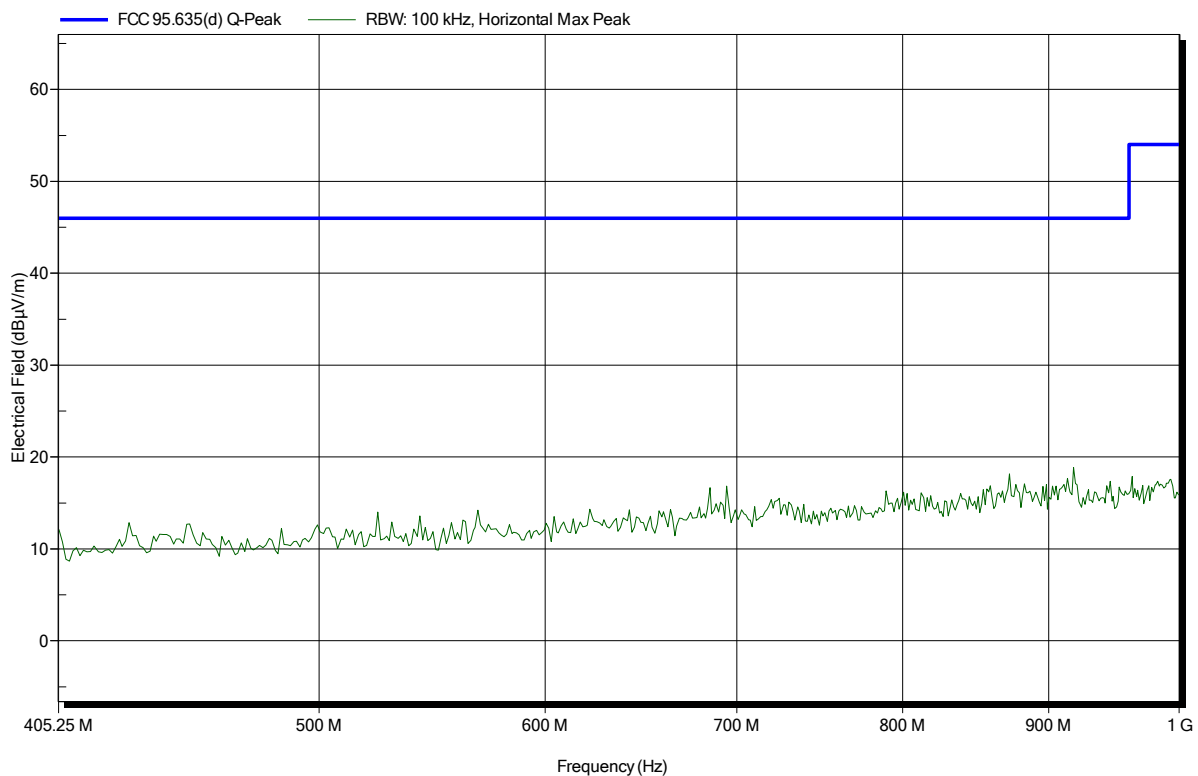


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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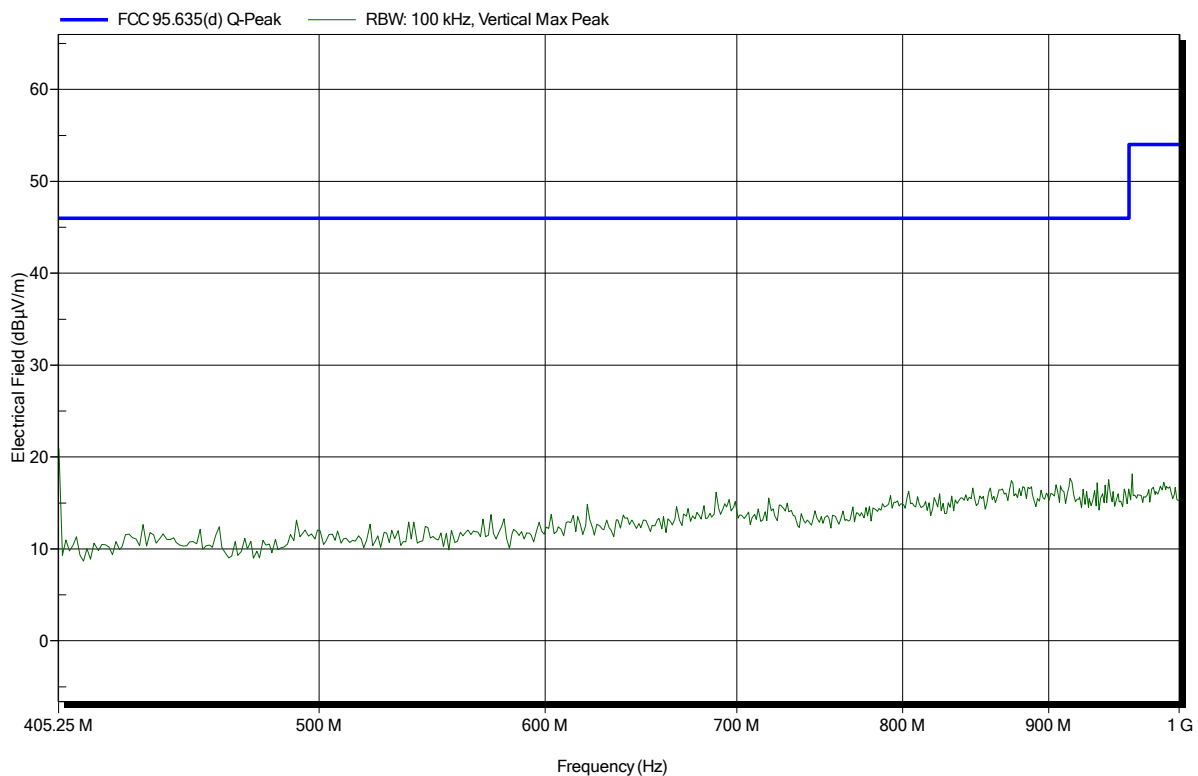


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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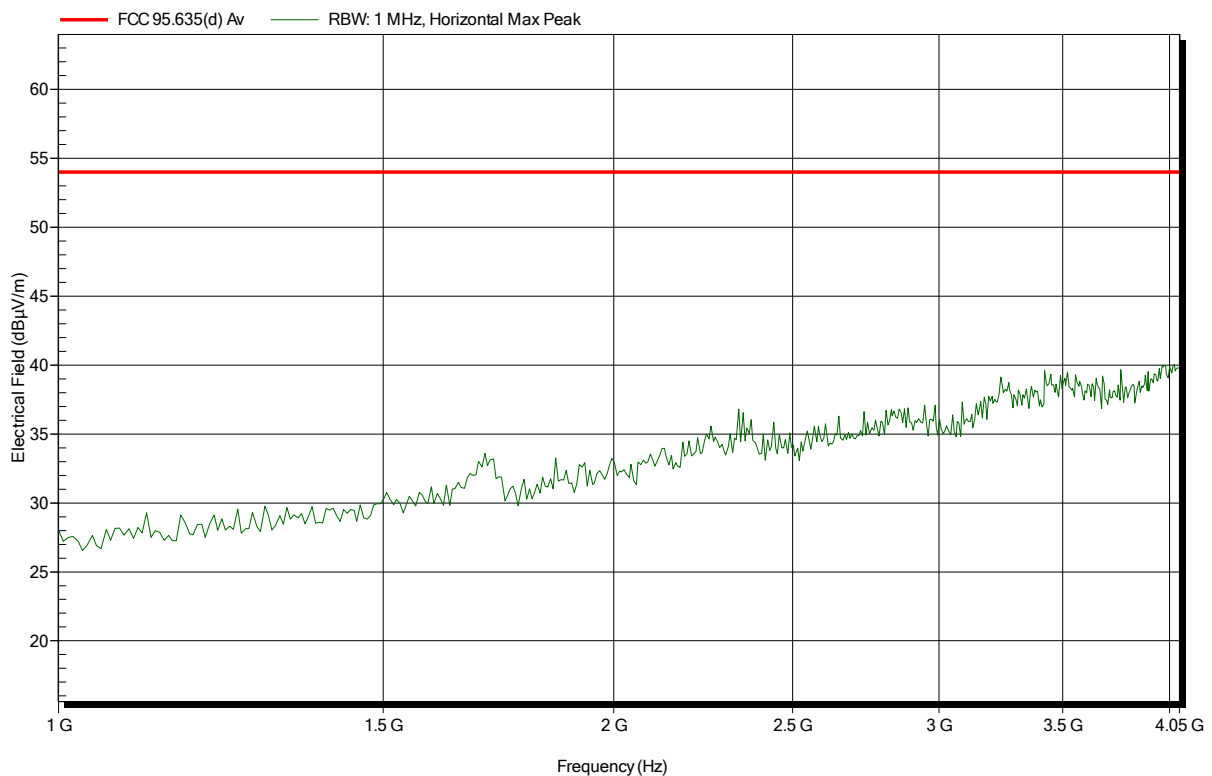


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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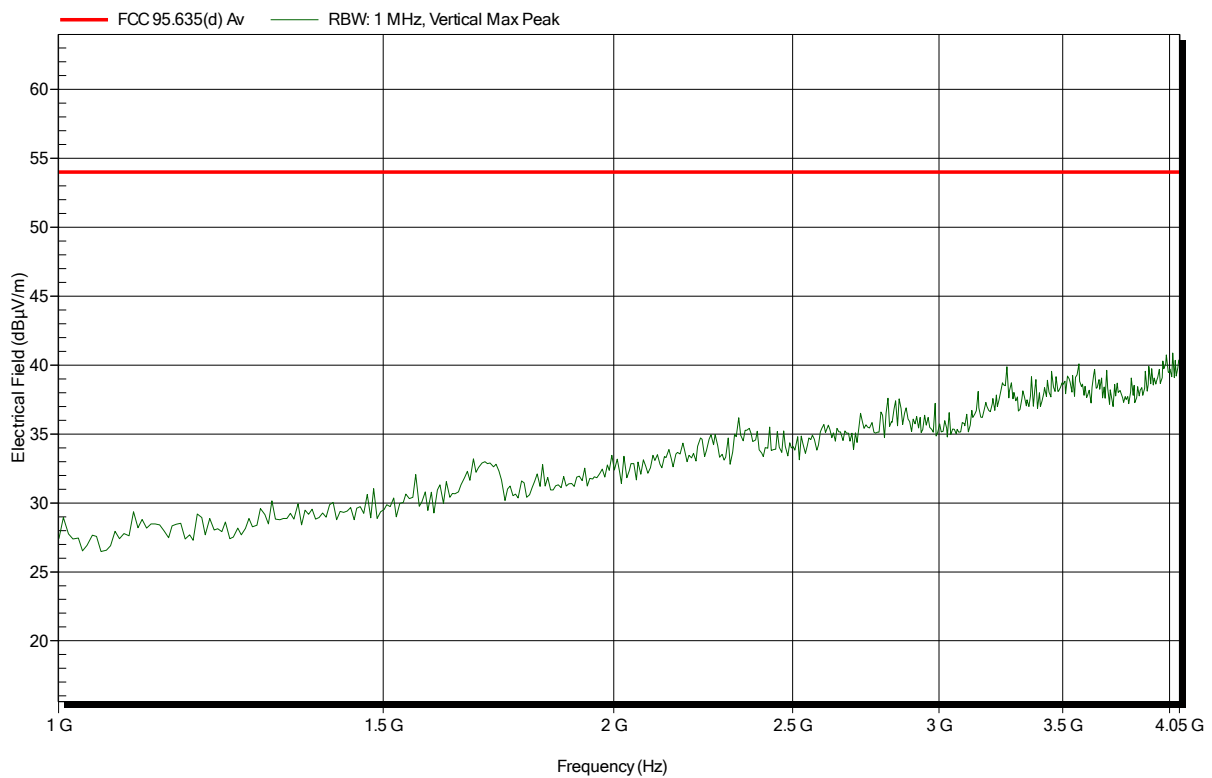


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	

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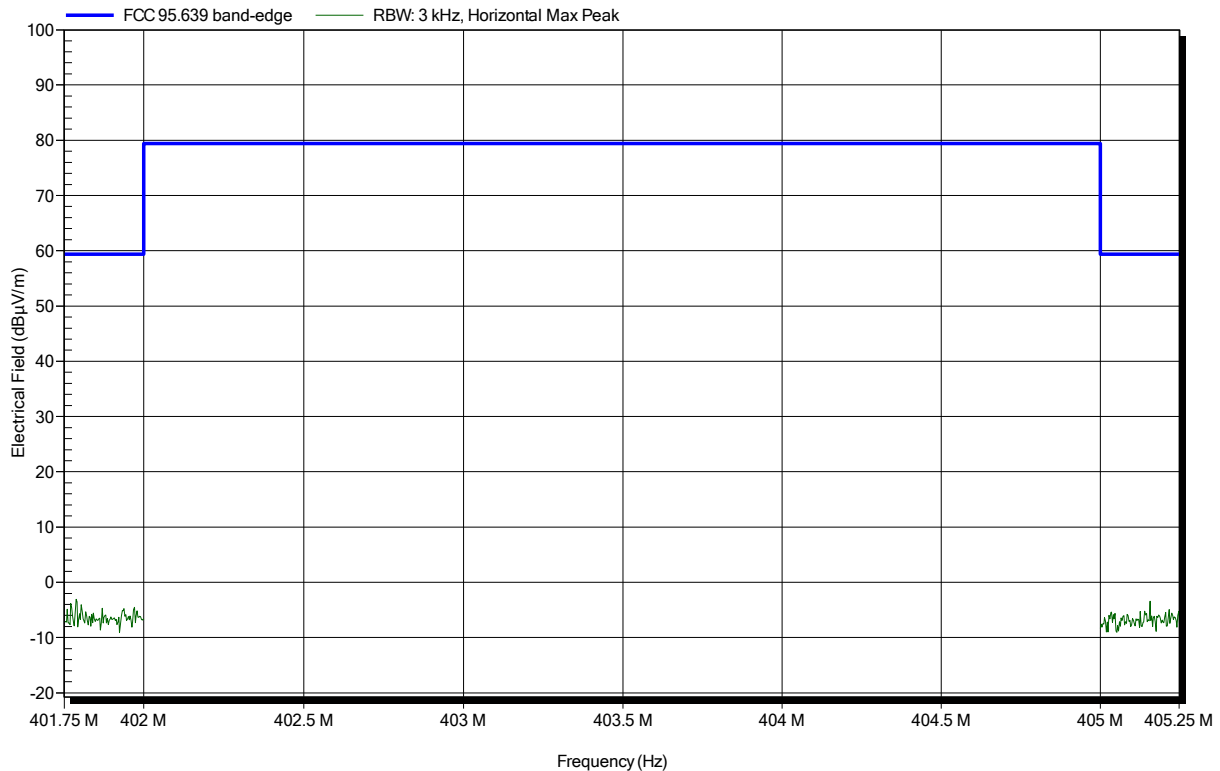
ANNEX C Transmitter In-band and Band-edge

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 402.45 MHz; 2FSK
Test Date:	2017-01-10
Note:	Band-edge

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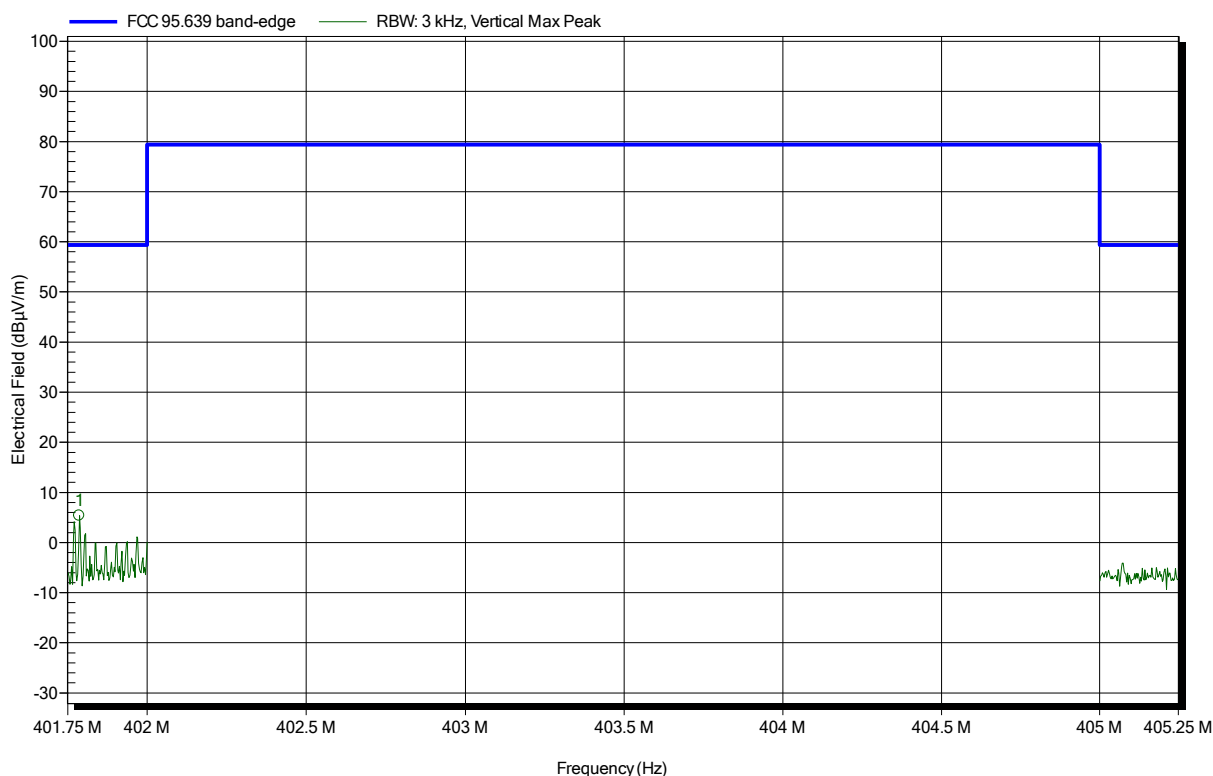


Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz; 2FSK
 Test Date: 2017-01-10
 Note: Band-edge

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
401.787 MHz	5.36 dBµV/m	59.4 dBµV/m	-54.04 dB	Pass

 Test Report No.: G0M-1612-6102-TFC95IMR-V01

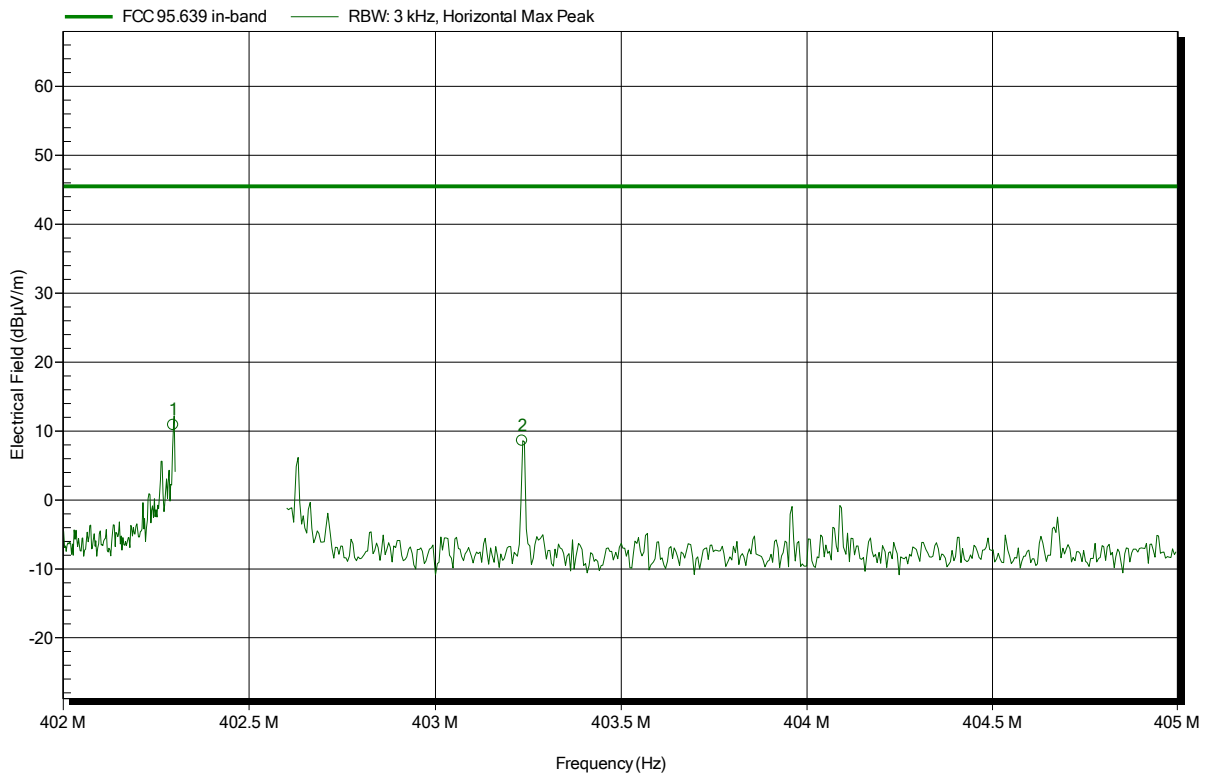
 Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz; 2FSK
 Test Date: 2017-01-10
 Note: In-band emissions

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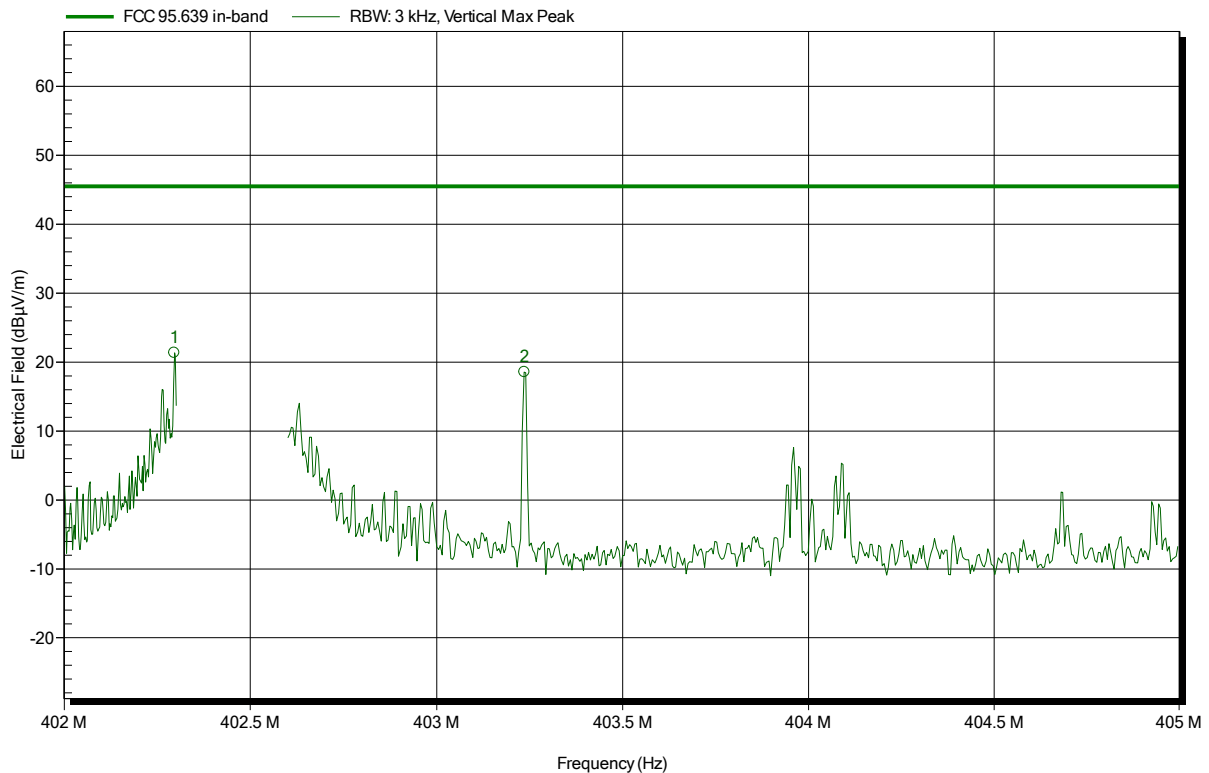
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.296 MHz	10.86 dBµV/m	45.5 dBµV/m	-34.64 dB	Pass
403.234 MHz	8.6 dBµV/m	45.5 dBµV/m	-36.9 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 402.45 MHz; 2FSK
 Test Date: 2017-01-10
 Note: In-band emissions

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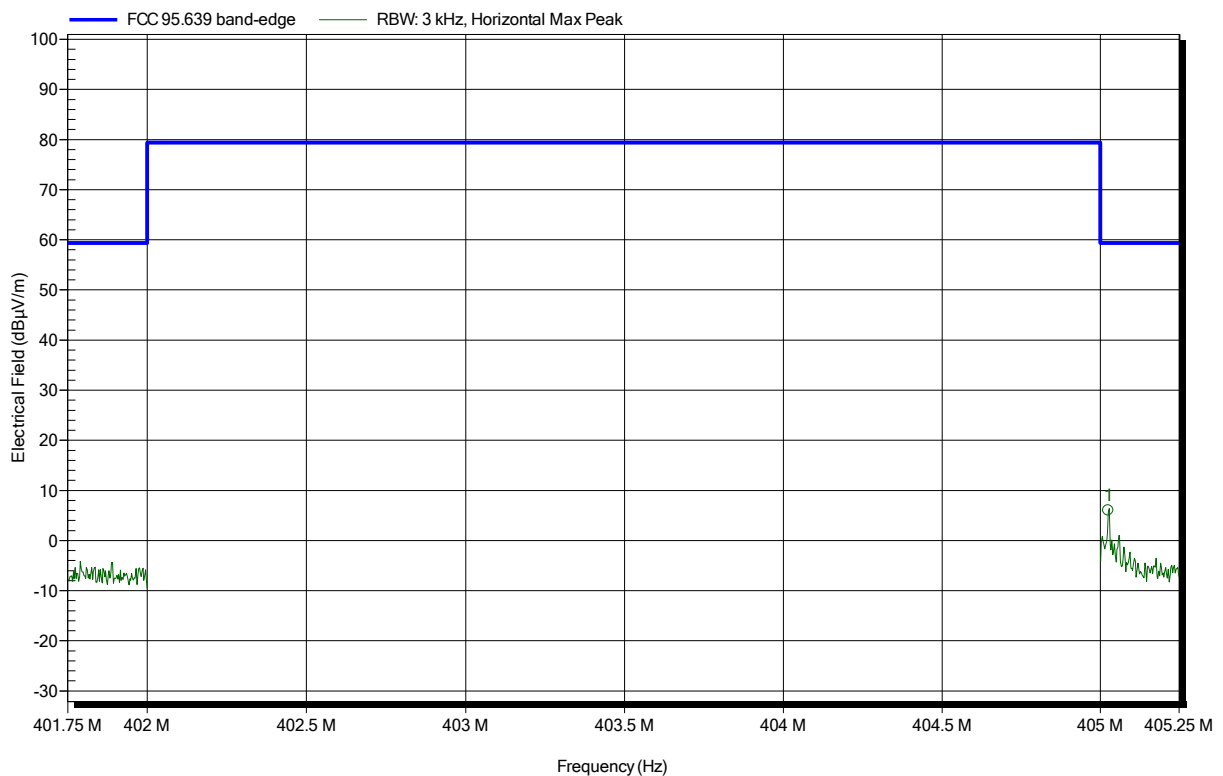
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.296 MHz	21.33 dBµV/m	45.5 dBµV/m	-24.17 dB	Pass
403.236 MHz	18.54 dBµV/m	45.5 dBµV/m	-26.96 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	TX; 404.85 MHz; 2FSK
Test Date:	2017-01-10
Note:	Band-edge

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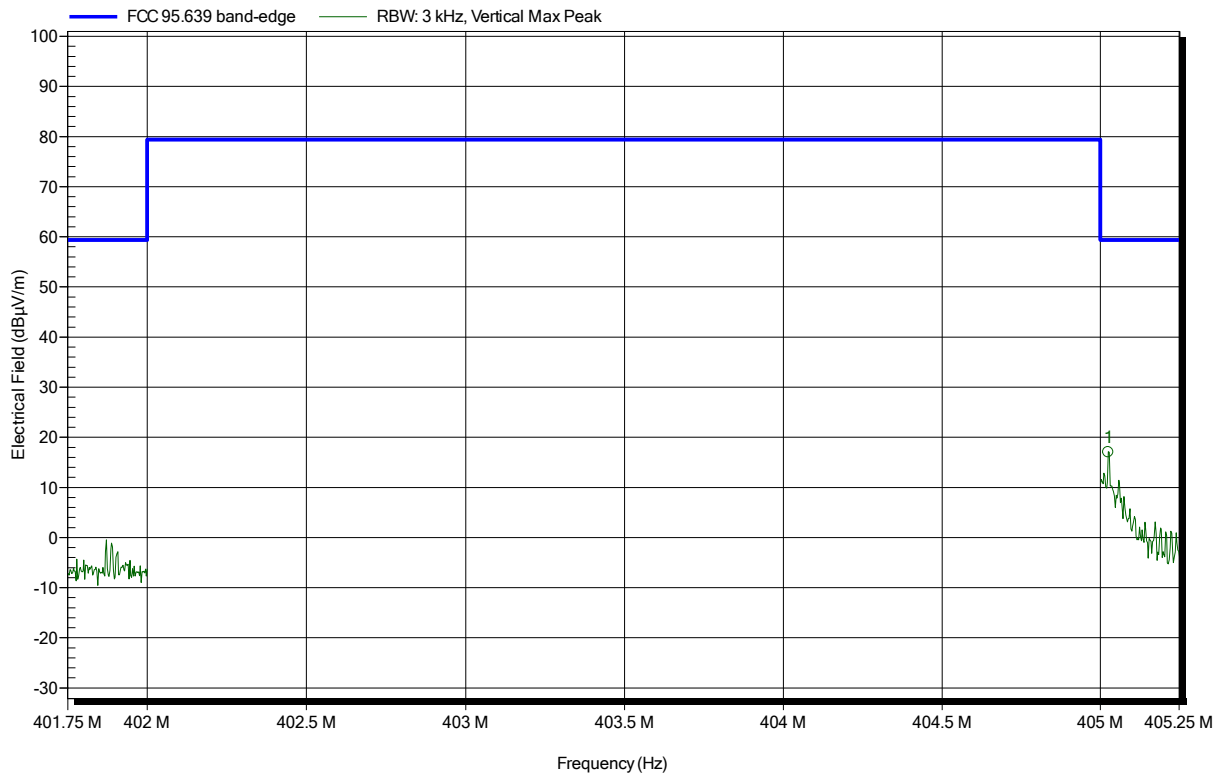
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.025 MHz	6 dBµV/m	59.4 dBµV/m	-53.4 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz; 2FSK
 Test Date: 2017-01-10
 Note: Band-edge

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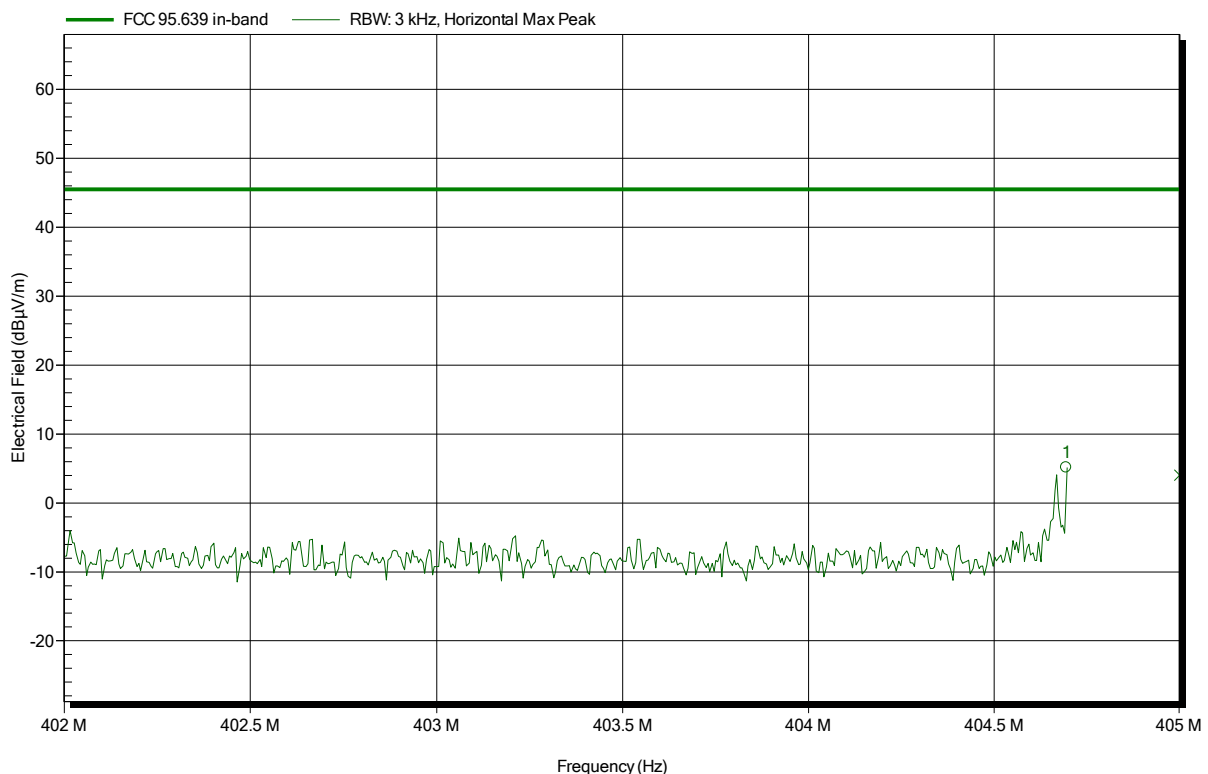
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
405.025 MHz	17.03 dBµV/m	59.4 dBµV/m	-42.37 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL223, Horizontal
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz; 2FSK
 Test Date: 2017-01-10
 Note: In-band emissions

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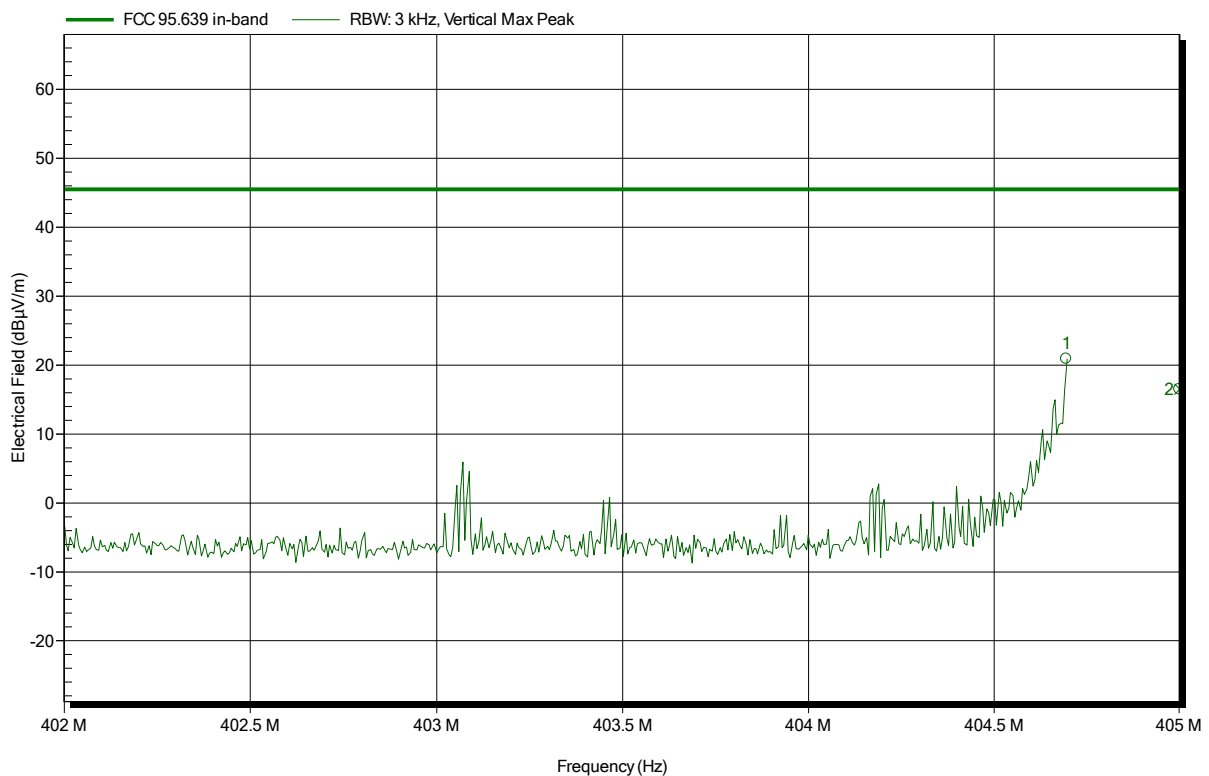
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.695 MHz	5.14 dBµV/m	45.5 dBµV/m	-40.36 dB	Pass

Spurious emissions according to FCC Part 95; Subpart I

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL223, Vertical
 Measurement distance: 3 m
 Mode: TX; 404.85 MHz; 2FSK
 Test Date: 2017-01-10
 Note: In-band emissions

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.695 MHz	20.91 dBµV/m	45.5 dBµV/m	-24.59 dB	Pass
405 MHz	16.52 dBµV/m	45.5 dBµV/m	-28.98 dB	Pass

Test Report No.: G0M-1612-6102-TFC95IMR-V01

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

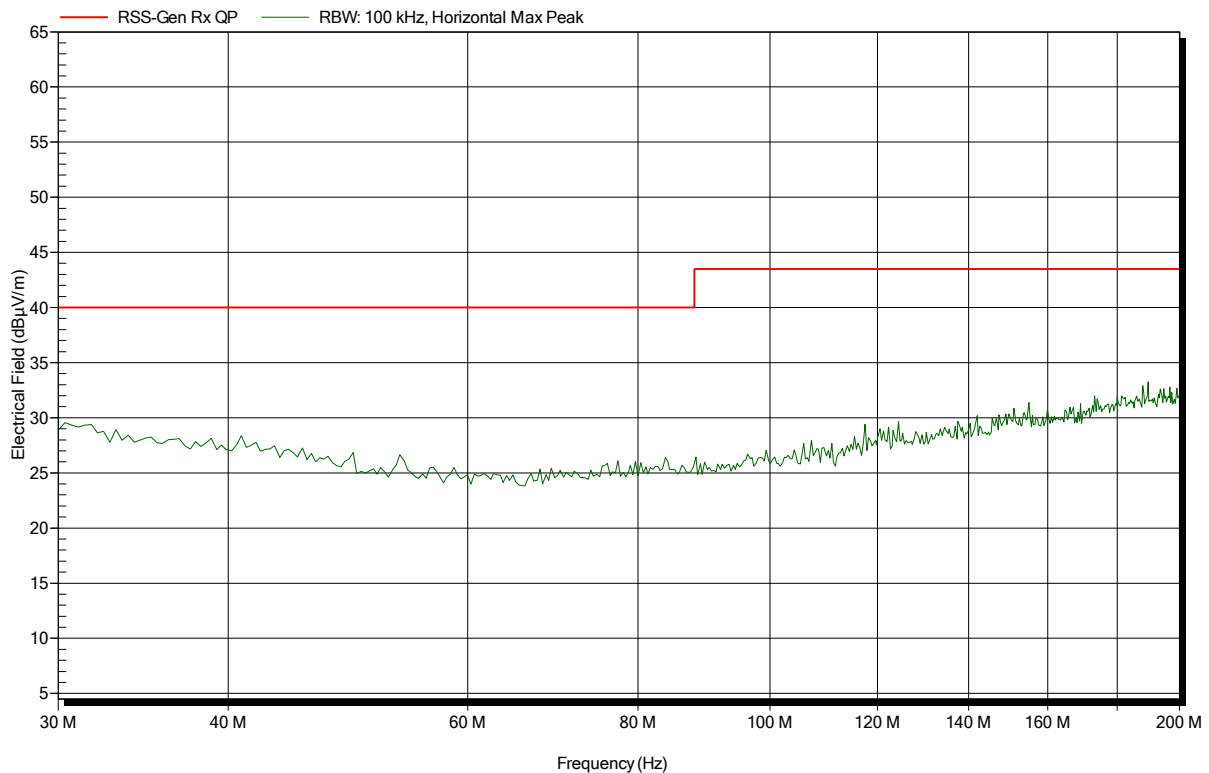
ANNEX D Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2017-01-09
Note:	

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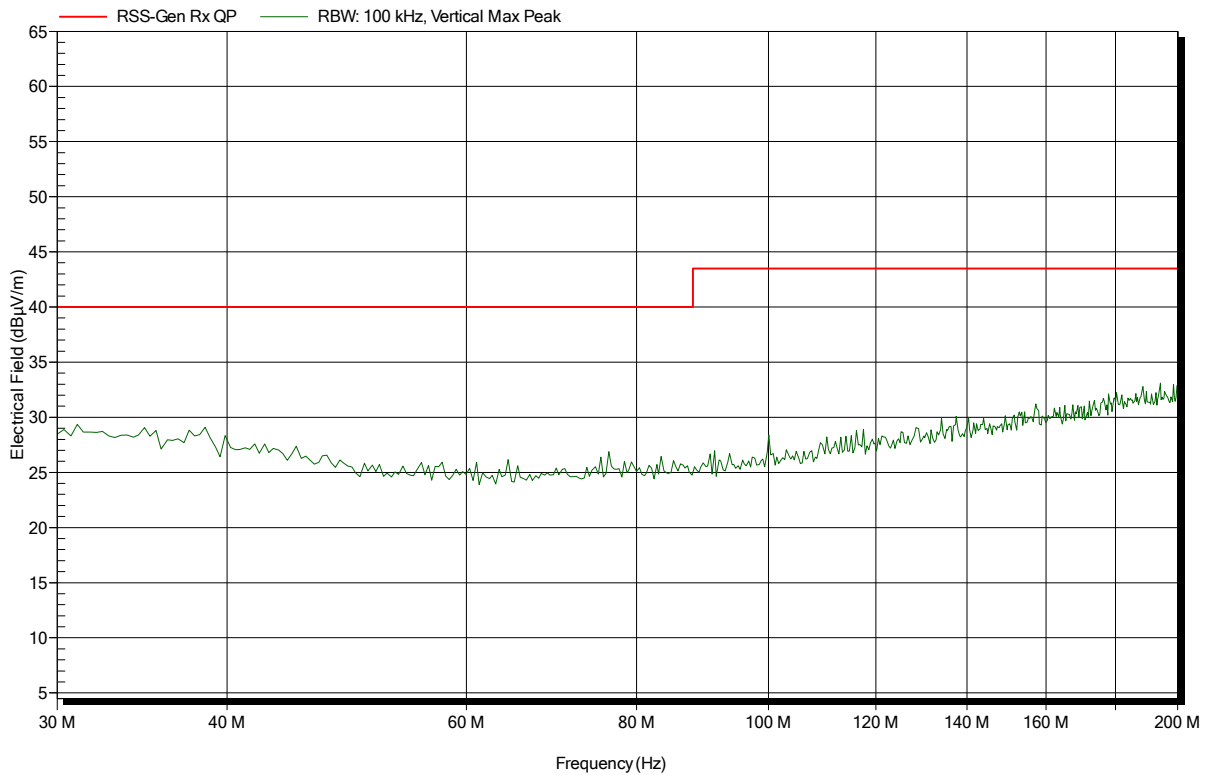


Spurious emissions according to RSS-Gen

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HK116, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2017-01-09
Note:	

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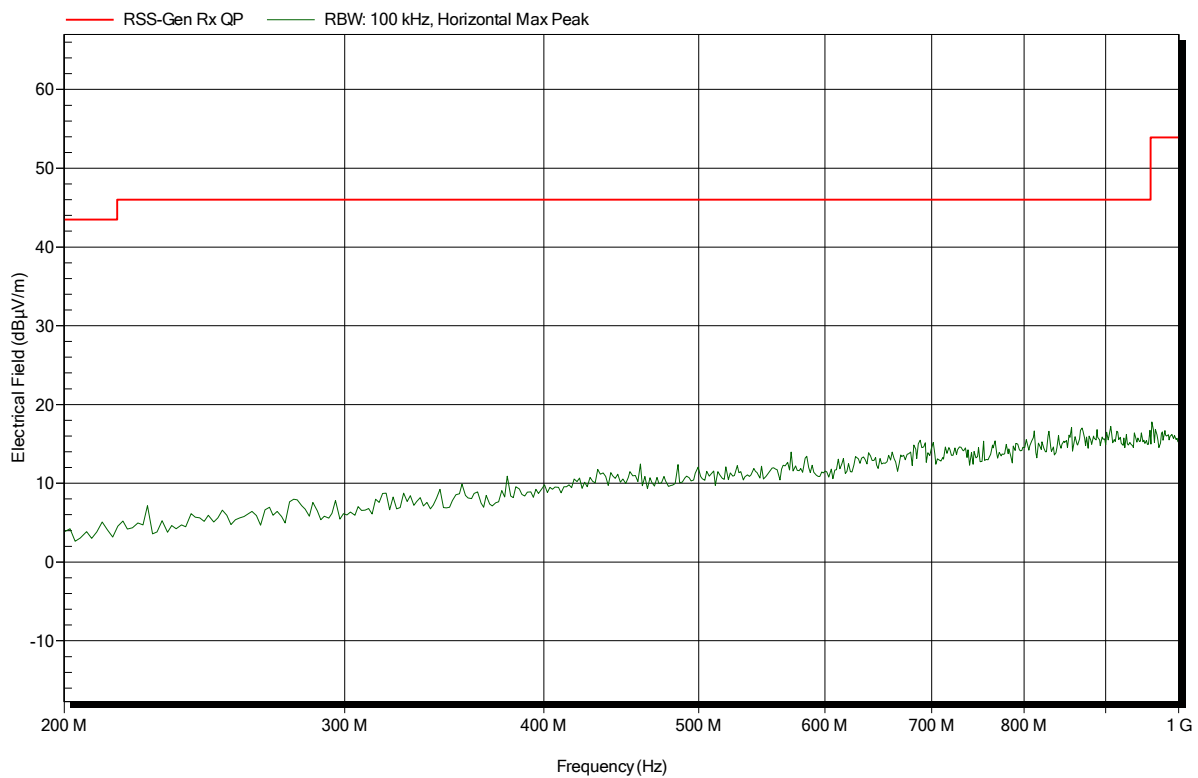


Spurious emissions according to RSS-Gen

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Horizontal
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2017-01-09
Note:	

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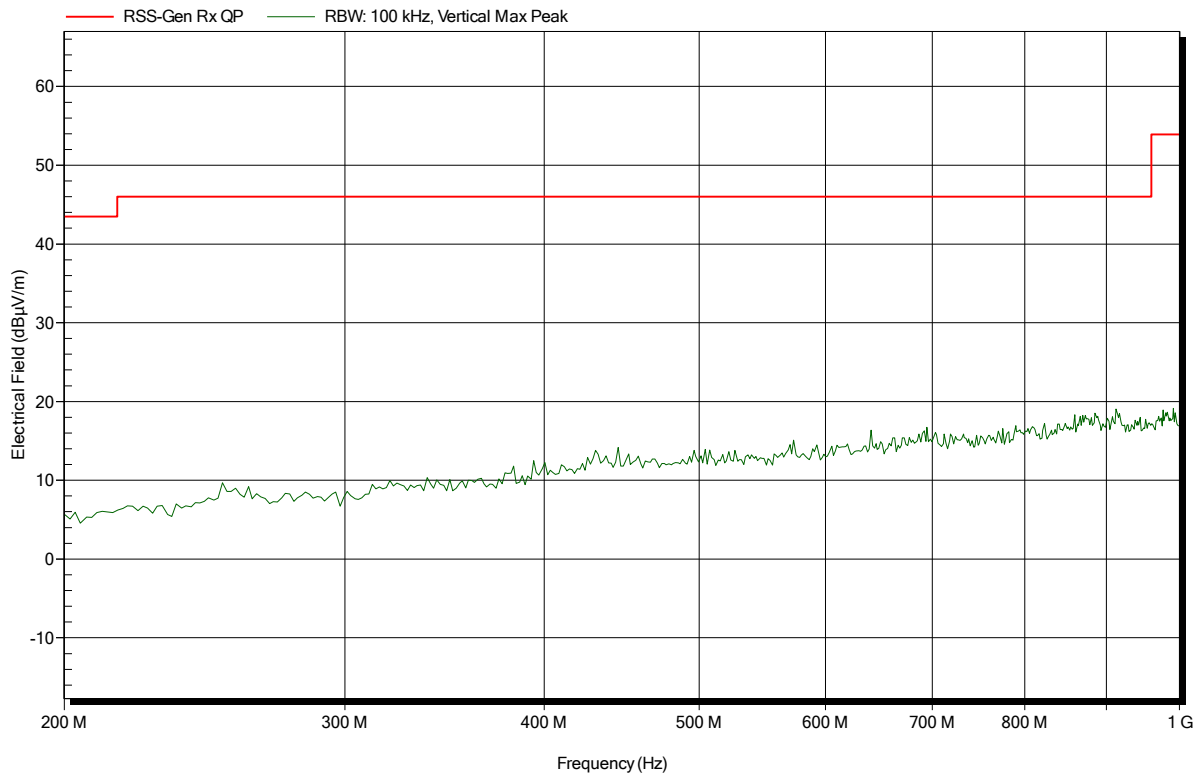


Spurious emissions according to RSS-Gen

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL223, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2017-01-09
Note:	

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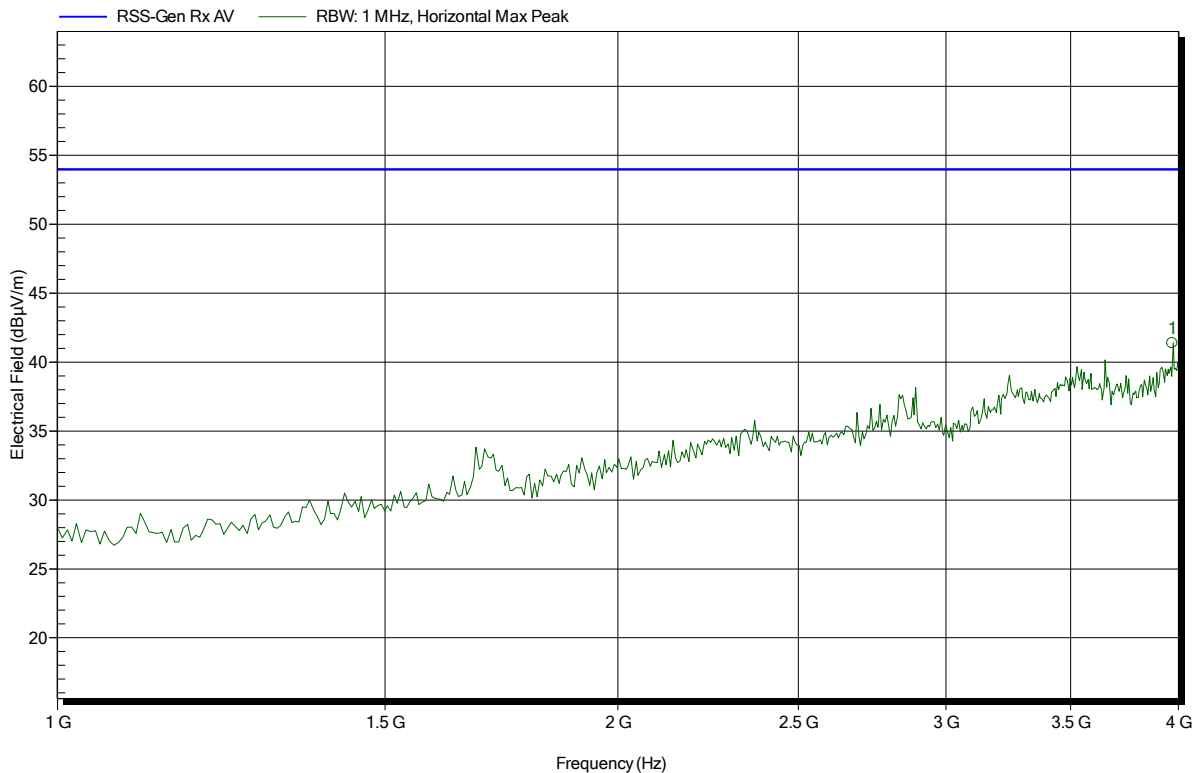


Spurious emissions according to RSS-Gen

Project number: G0M-1612-6102

Applicant: Biotronik SE & Co. KG
 EUT Name: Implantable Cardiac Monitor
 Model: BioMonitor 2-AF
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Test Conditions: Tnom: 24°C, Vnom: 3.0 V DC (battery)
 Antenna: HL025, Horizontal
 Measurement distance: 3 m
 Mode: RX; 403.65 MHz
 Test Date: 2017-01-09
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Status
3.97 GHz	41.38 dBµV/m	53.98 dBµV/m	-12.6 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1612-6102

Applicant:	Biotronik SE & Co. KG
EUT Name:	Implantable Cardiac Monitor
Model:	BioMonitor 2-AF
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Conditions:	Tnom: 24°C, Vnom: 3.0 V DC (battery)
Antenna:	HL025, Vertical
Measurement distance:	3 m
Mode:	RX; 403.65 MHz
Test Date:	2017-01-09
Note:	

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