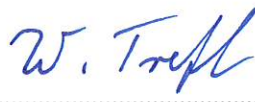


RADIO REPORT FCC 47 CFR Part 95I Medical Device Radiocommunication Service (MedRadio) ISED RSS-243 Medical Devices Operating in the 401 – 406 MHz Frequency Band	
Report Reference No	G0M-2210-1712-TFC95IMR-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	    DAkks - Registration number : D-PL-12092-01-03 (ISED) ISED Testing Laboratory site: 3470A DAkks - Registration number : D-PL-12092-01-04 (FCC) FCC Filed Test Laboratory, Reg.-No.: 96970
Applicant	BIOTRONIK SE & Co. KG
Address	Woermannkehre 1 12359 Berlin DE
Test Specification	47 CFR Part 95I ISED RSS-243, Issue 3, 2010-02 ISED RSS-Gen, Issue 5, Amendment 2, 2021-02
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	Implantable Cardiac Monitor
Model(s)	BIOMONITOR IV
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware Version(s)	BOM-0578_01_474897 (2610-30), SCH-0295_0B, ASM-0929_0C
Software Version(s)	ROM: 7748ROMRev_1.03 / RAM: 7341RamRev_3.01
FCC ID	QRI-BM2610P2
IC	4708A-BM2610P2
Test Result	PASSED

Possible test case verdicts:		
Required by standard but not tested	N/T	
Not required by standard	N/R	
Not applicable to EUT	N/A	
Test object does meet the requirement	P(PASS)	
Test object does not meet the requirement	F(FAIL)	
Testing:		
Test Lab Temperature	20 °C - 30 °C	
Test Lab Humidity	25 % - 55 %	
Date of receipt of test item	2022-12-14	
Report:		
Compiled by	Wilfried Treffke	
Tested by (+ signature) (Responsible for Test)	Wilfried Treffke	
Approved by (+ signature) (Test Lab Engineer)	Radwan Jaafar	
Date of Issue	2023-02-16	
Total number of pages	59	
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:		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2023-02-16	Initial Release	

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
RBW	Resolution bandwidth
RMS	Root mean square
VBW	Video bandwidth
V _{NOM}	Nominal supply voltage

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1 Equipment (Test Item) Under Test

Description	Implantable Cardiac Monitor	
Model	BIOMONITOR IV	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Serial Number(s)	95043357(radiated test sample) Proto type (conducted test sample)	
Test Sample Id(s)	42363 (radiated test sample) 42486 (conducted test sample)	
Hardware Version(s)	BOM-0578_01_474897 (2610-30), SCH-0295_0B, ASM-0929_0C	
Software Version(s)	ROM: 7748ROMRev_1.03 / RAM: 7341RamRev_3.01	
PMN	BIOMONITOR IV	
HVIN	471155	
FVIN	n/a	
HMN	n/a	
FCC ID	QRI-BM2610P2	
IC	4708A-BM2610P2	
Equipment type	End Product	
Radio type	Transceiver	
Assigned frequency bands	402 - 405 MHz	
Radio technology	MedRadio (MICS) active medical implant	
Modulation	FSK	
Emission designator	F1D	
Number of channels	9	
Channel spacing	300 kHz	
Spectrum access	LBT/AFA (channel access controlled by ULP-AMI-P device outside the human body)	
Number of antenna ports	1	
Antenna	Type	Integrated
	Model	Biomonitor IV Lead
	Manufacturer	BIOTRONIK SE & Co. KG
	Gain	-27.9 dBi (by antenna pattern measurement)
Supply Voltage	V _{NOM}	2.7 VDC (battery)
	V _{MIN}	2.0 VDC
	V _{MAX}	3.3 VDC
Operating Temperature	T _{NOM}	37 °C
	T _{MIN}	25 °C
	T _{MAX}	42 °C
AC/DC-Adaptor	Model	None
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin DE	

Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE1	USB Telbox	Biotronik	Telbox II (087)	to set the test mode
AE2	Programming Wand	Biotronik	Renamic PGH	to set the test mode
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment:				

1.5 Test mode duty cycle

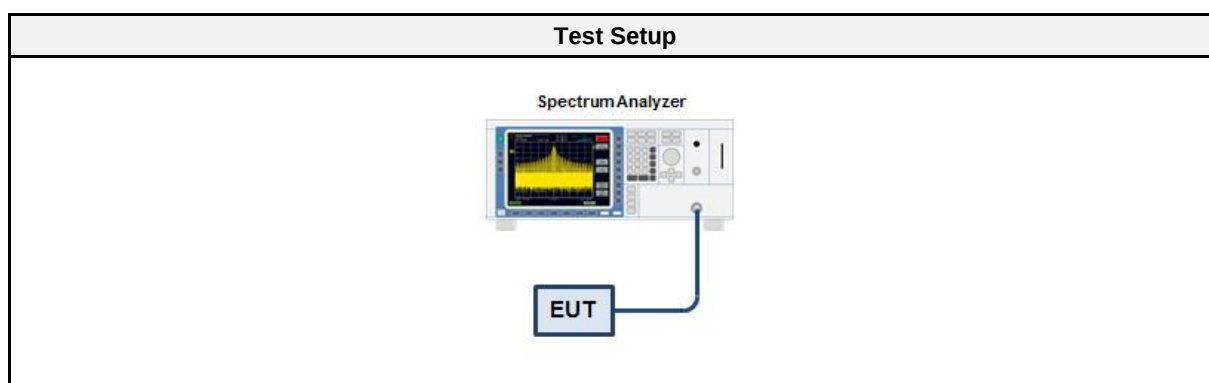
1.5.1 Information

Test Information	
Measurement Method	ANSI C63.10 11.6

1.5.2 Requirements

Requirements	
Duty cycle	Duty cycle correction
$\geq 98 \%$	No correction required
$< 98 \%$	Correction required ($10 \times \log_{10}(1/DC)$)

1.5.3 Setup



1.5.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2022-07	2023-07

1.5.5 Procedure

Test Procedure
1. EUT set to test mode 2. Span is set to zero span 3. Detector set to peak 4. Sweep time is set long enough to capture at least 5 bursts 5. Envelope peak value of emission spectrum is selected 6. The maximum burst duration T_{ON} is measured using two markers set to the start and the end of the longest burst 7. The minimum idle duration T_{OFF} is measured using two markers set to the start and the end of the shortest idle period 8. The duty cycle is calculated by $DC = T_{ON} / (T_{ON} + T_{OFF})$ 9. The duty cycle correction is calculated by $DC = 10 \times \log_{10}(T_{ON} / (T_{ON} + T_{OFF}))$

1.5.6 Results

Duty Cycle Results		
Mode	Duty Cycle	Correction Factor [dB]
Modulated	100 %	0

1.6 Test Modes

Mode	Description
Unmodulated	Mode = Transmit Modulation = None
Modulated	Mode = Transmit Modulation = 2-FSK Power level = maximum
Receive	Mode = Receive Modulation = 2-FSK
Comment:	

1.7 Test Frequencies

Designator	Mode	Channel	Frequency [MHz]
F1	Tx / Rx	8	402.45
F2	Tx / Rx	0	403.65
F3	Tx / Rx	7	404.85

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:

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

Net:

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

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.

Field strength 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:

$$\text{Field strength limit (dB}\mu\text{V/m)} = 20 \cdot \log (\mu\text{V/m})$$

Example only for radiated field strength:

Reading + AF	= Net Reading	:	Net reading	- Field strength limit	= Margin
+21.5 dB μ V	+ 26 dB/m	:	47.5 dB μ V/m	- 57.0 dB μ V/m	= -9.5

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	
Tissue parameters – 403.5MHz Measured tissue parameters:			
Component	Target	Measured	Tolerance [%]
Dielectric constant ϵ	57.2	59.2	03.50
Conductivity σ [ms/cm]	0.93	0.91	-02.15

2 Result Summary

FCC 47 CFR Part 95I, 15C, ISED RSS-243, ISED RSS-Gen				
Product Standard Reference	Requirement	Reference Method	Result	Remarks
ISED RSS-243 3.2 ISED RSS-Gen 6.7	Occupied Bandwidth	ANSI C63.10 6.9.3	N/R	Informational only
FCC 95.2573(a) ISED RSS-243 3.6	Emission Bandwidth	ANSI C63.10 6.9.2 ETSI EN 301 839 5.3.2	PASS	
FCC 95.2565 ISED RSS-243 3.3, 5.3	Frequency stability	ETSI EN 301 839 5.3.1	PASS	
FCC 95.2567(a), 95.2569 ISED RSS-243 5.4	Transmitter output power	ETSI EN 301 839 5.3.3	PASS	
FCC 95.2579 ISED RSS-243 3.4, 5.5	Band edge compliance	ANSI C63.10 6.10	PASS	
FCC 95.2579 ISED RSS-243 3.4, 5.5	Transmitter unwanted emissions	ANSI C63.10 6.10	PASS	
ISED RSS-243 3.5, 5.6 ISED RSS-Gen 7.3	Receiver spurious emissions	ANSI C63.10 6.10	PASS	
FCC 15.207 ISED RSS-Gen 7.2, 8.8	AC power line conducted emissions	ANSI C63.10 6.2	N/A	EUT battery powered
FCC 95.2559(a)(3),(a)(4) ISED RSS-243 3.6, 5.7.1	System threshold power levels	ETSI EN 301 839 5.3.7.1.3	N/A	Applies only to equipment by which LBT is performed
FCC 95.2559(a)(1) ISED RSS-243 3.6, 5.7.2	Monitoring system bandwidth	ETSI EN 301 839 5.3.7.1.4	N/A	Applies only to equipment by which LBT is performed
FCC 95.2559(a)(2) ISED RSS-243 3.6, 5.7.3	Scan cycle time	ETSI EN 301 839 5.3.7.1.5	N/A	Applies only to equipment by which LBT is performed
FCC 95.2559(a)(2) ISED RSS-243 3.6, 5.7.4	Minimum channel monitoring period	ETSI EN 301 839 5.3.7.1.5	N/A	Applies only to equipment by which LBT is performed
FCC 95.2559(a)(5) ISED RSS-243 3.6, 5.7.5	Channel Access	ETSI EN 301 839 5.3.7.1.6	N/A	Applies only to equipment by which LBT is performed
FCC 95.2559(a)(5) ISED RSS-243 3.6, 5.7.6	Discontinuation of MICS of MEDS session	ETSI EN 301 839 5.3.7.1.7	N/A	Applies only to equipment by which LBT is performed
FCC 95.2559(a)(6) ISED RSS-243 3.6, 5.7.7	Use of the pre-scanned alternate channel	ETSI EN 301 839 5.3.7.1.8	N/A	Applies only to equipment by which LBT is performed
Comment: The Decision Rule is applied on the basis of ETSI TR 102 273 and ETSI TR 100 028. These standards provide guidance on how to calculate and apply measurement uncertainty whilst providing maximum uncertainties allowance. In all cases due consideration will be given to ILAC-G8:09/2019. Where a result is considered conditional in respect of its proximity to the limit line, the customer would be made aware of situation so that they can make an informed decision on how to proceed.				

Possible Test Case Verdicts	
PASS	Test object does meet the requirements
FAIL	Test object does not meet the requirements
N/T	Required by standard but not tested
N/R	Not required by standard for the test object

Test Report No.: G0M-2210-1712-TFC95IMR-V01

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

3 Test Conditions and Results

3.1 Test Conditions and Results - Occupied bandwidth

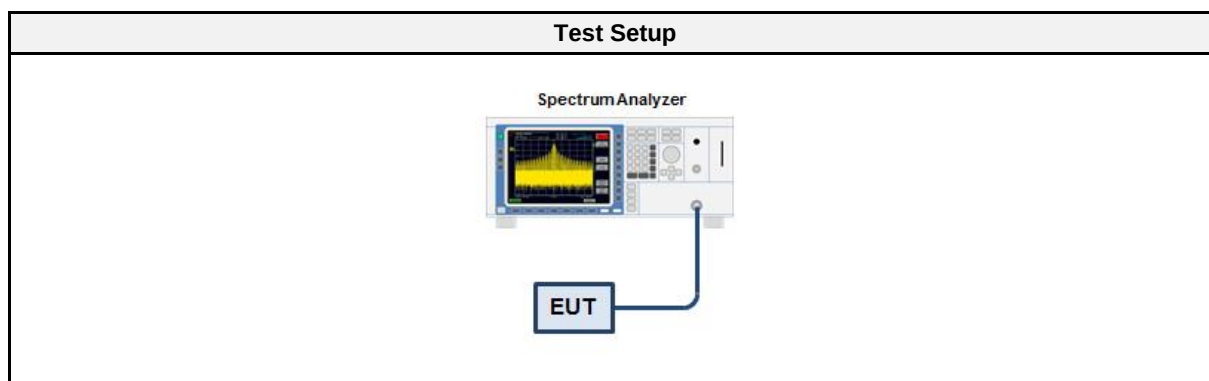
3.1.1 Information

Test Information	
Reference	ISED RSS-243 3.2, RSS-Gen 6.6
Measurement Method	ANSI C63.10 6.9.3
Measurement Uncertainty	$\pm 1.26 \%$
Operator	Wilfried Treffke
Date	2023-01-11

3.1.2 Limits

Limits
None (Informational only)

3.1.3 Setup



3.1.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2022-07	2023-07
Cable	Gigalane	SMS111B	EF00779 CAAZ	2022-02	2023-02

3.1.5 Procedure

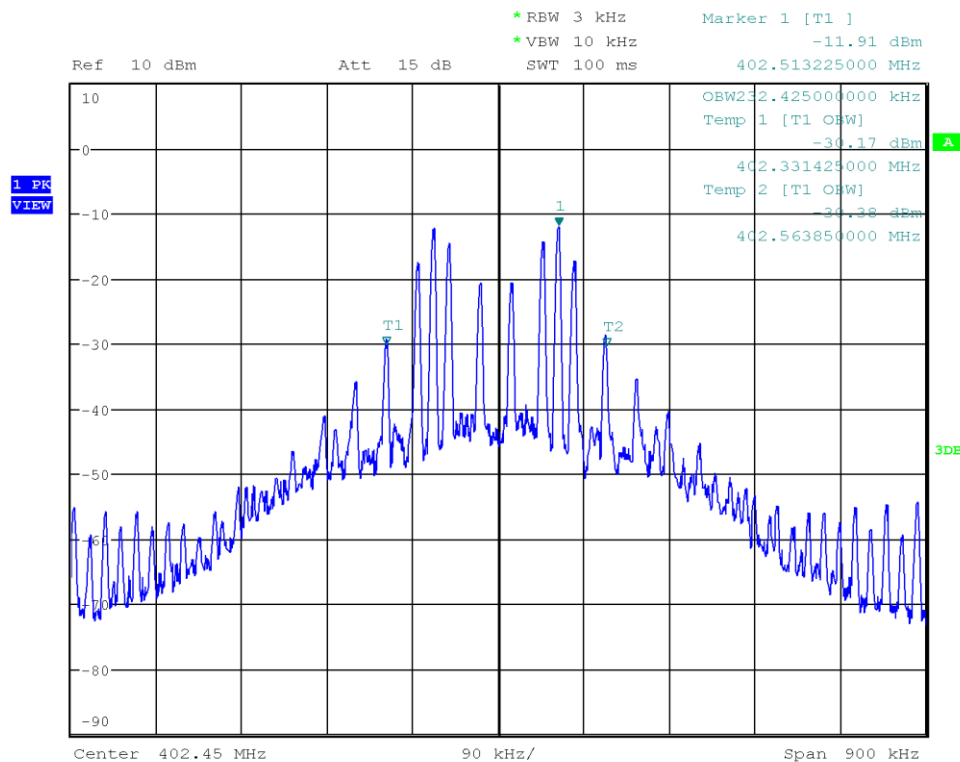
Test Procedure
1. EUT transmitter is activated in test mode under normal conditions 2. The spectrum analyzer is set to peak detection and maximum hold with a span twice the emission spectrum 3. The resolution bandwidth is set 1 % to 5 % of the bandwidth 4. The occupied bandwidth (99%) is measured with the build-in analyzer function

3.1.6 Results

Test Results		
Mode	Channel [MHz]	Bandwidth [MHz]
Modulated	402.45	232.425
Modulated	403.65	231.300
Modulated	404.85	232.650

Occupied Bandwidth RSS-243

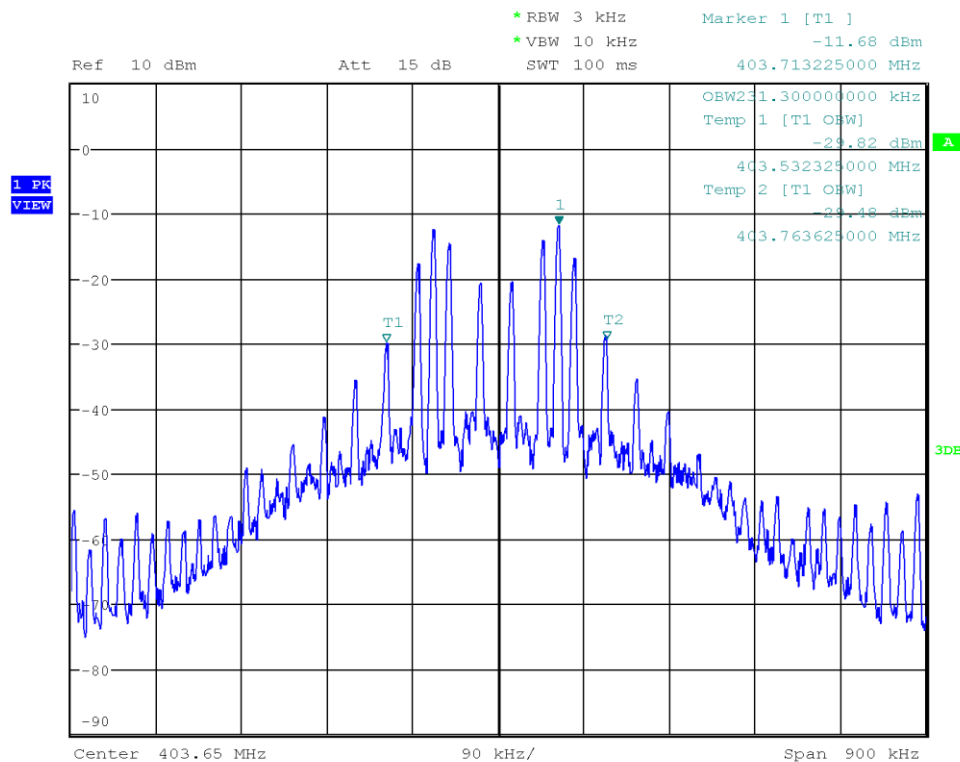
Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2023-01-11
 Occupied Bandwidth [kHz]: 232.425



Date: 11.JAN.2023 13:55:20

Occupied Bandwidth RSS-243

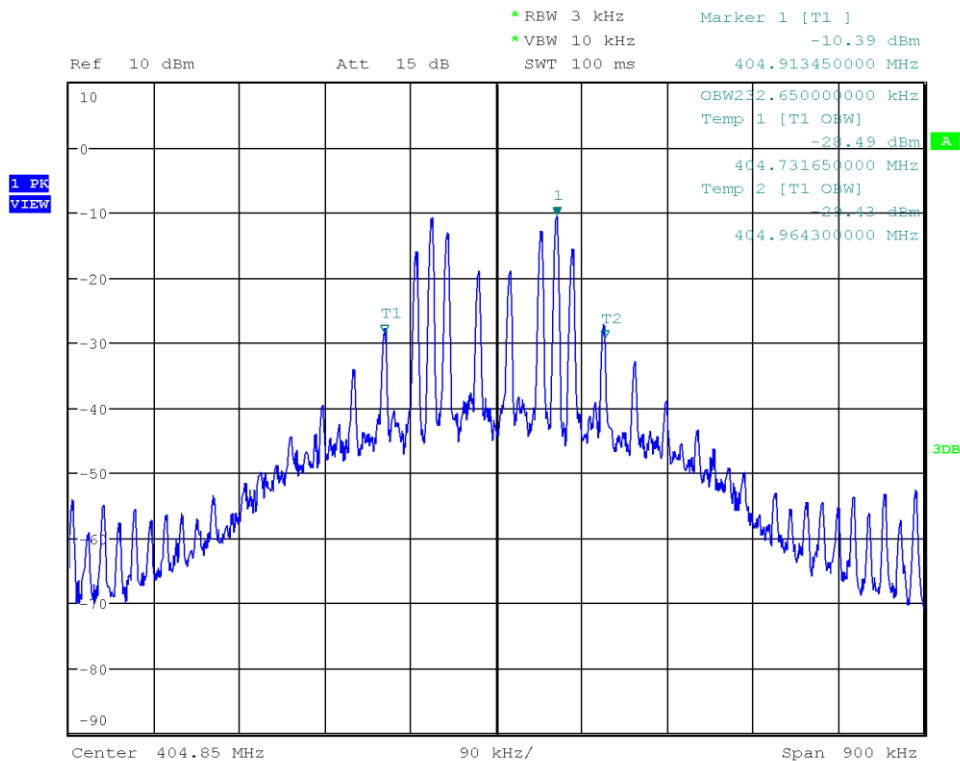
Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2023-01-11
 Occupied Bandwidth [kHz]: 231.300



Date: 11.JAN.2023 13:56:19

Occupied Bandwidth RSS-243

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 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: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2023-01-11
 Occupied Bandwidth [kHz]: 232.650



Date: 11.JAN.2023 13:57:48

3.2 Test Conditions and Results - Emission bandwidth

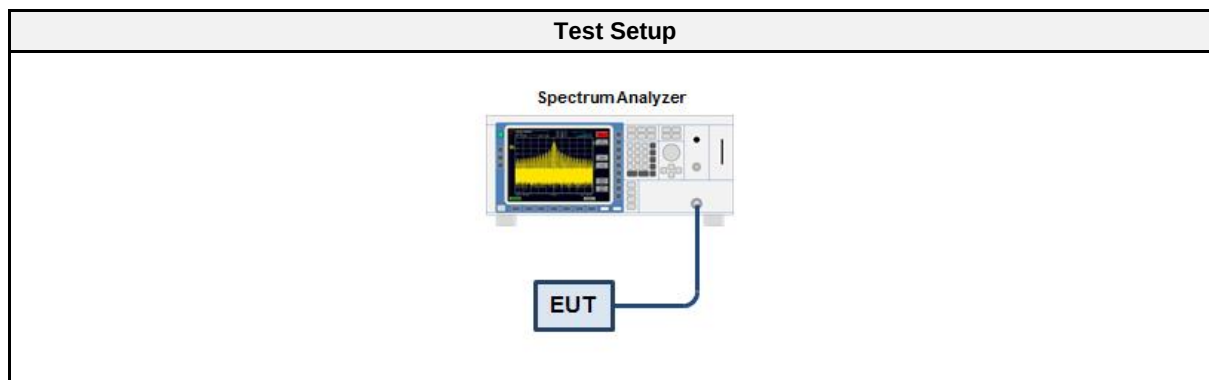
3.2.1 Information

Test Information	
Reference	FCC 95.2573(a) ISED RSS-243 3.6
Measurement Method	ANSI C63.10 6.9.2 ETSI EN 301 839 5.3.2
Measurement Uncertainty	$\pm 1.26 \%$
Operator	Wilfried Treffke
Date	2023-01-11

3.2.2 Limits

Limits
$\leq 300 \text{ kHz}$

3.2.3 Setup



3.2.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2022-07	2023-07
Cable	Gigalane	SMS111B	EF00779 CAAZ	2022-02	2023-02

3.2.5 Procedure

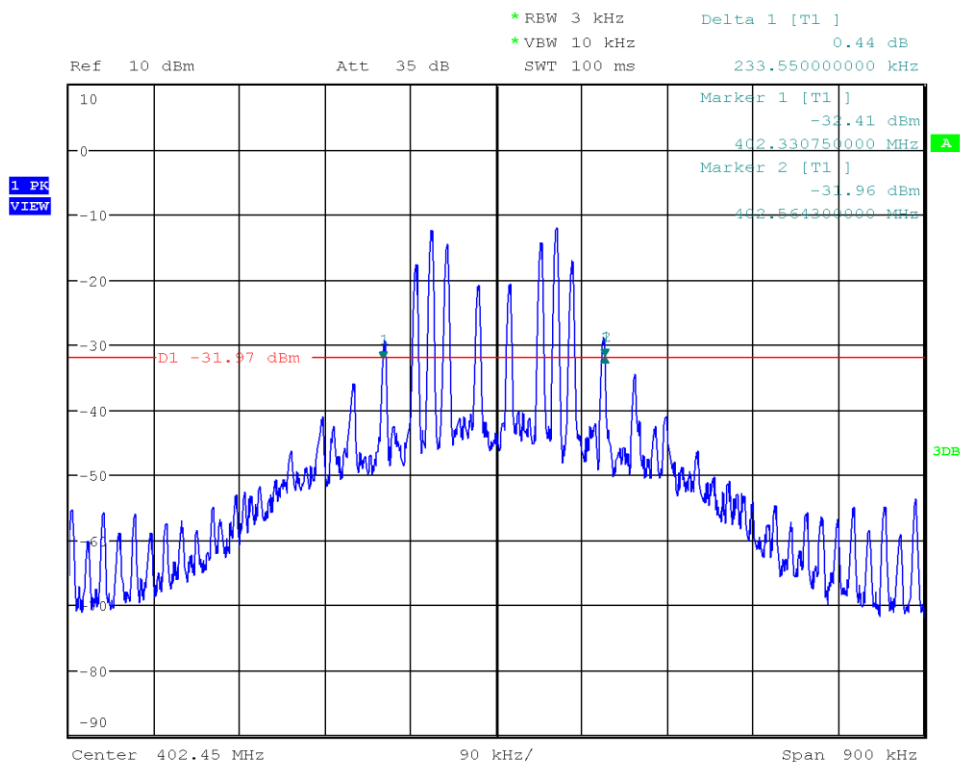
Test Procedure
1. EUT set to test mode 2. Span set to at least twice the emission spectrum 3. Detector set to peak and max hold 4. Envelope peak value of emission spectrum is selected 5. Marker on envelope of spectrum is set to level of -20 dB to the left of the peak 6. Marker on envelope of spectrum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

3.2.6 Results

Test Results		
Mode	Channel [MHz]	Bandwidth [MHz]
Modulated	402.45	233.550
Modulated	403.65	233.325
Modulated	404.85	233.775

20 dB Bandwidth

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 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: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2023-01-11
 Lower Frequency [MHz]: 402.331
 Upper Frequency [MHz]: 402.564
 20 dB Bandwidth [kHz]: 233.550



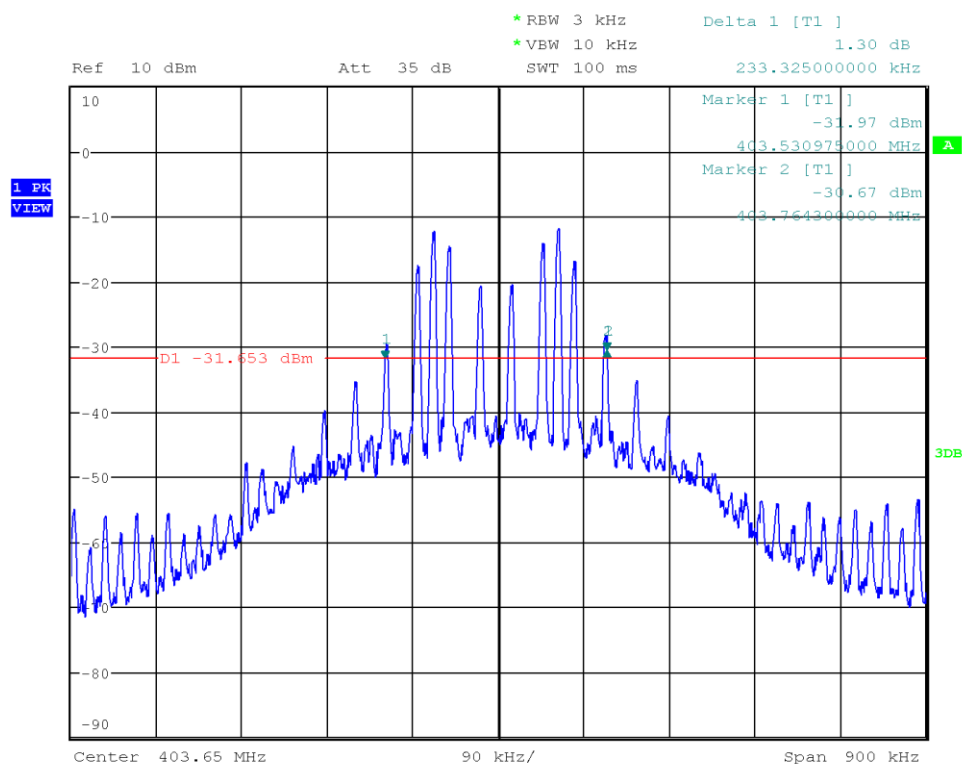
Date: 11.JAN.2023 14:02:08

Test Report No.: G0M-2210-1712-TFC95IMR-V01

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

20 dB Bandwidth

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 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: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2023-01-11
 Lower Frequency [MHz]: 403.531
 Upper Frequency [MHz]: 403.764
 20 dB Bandwidth [kHz]: 233.325



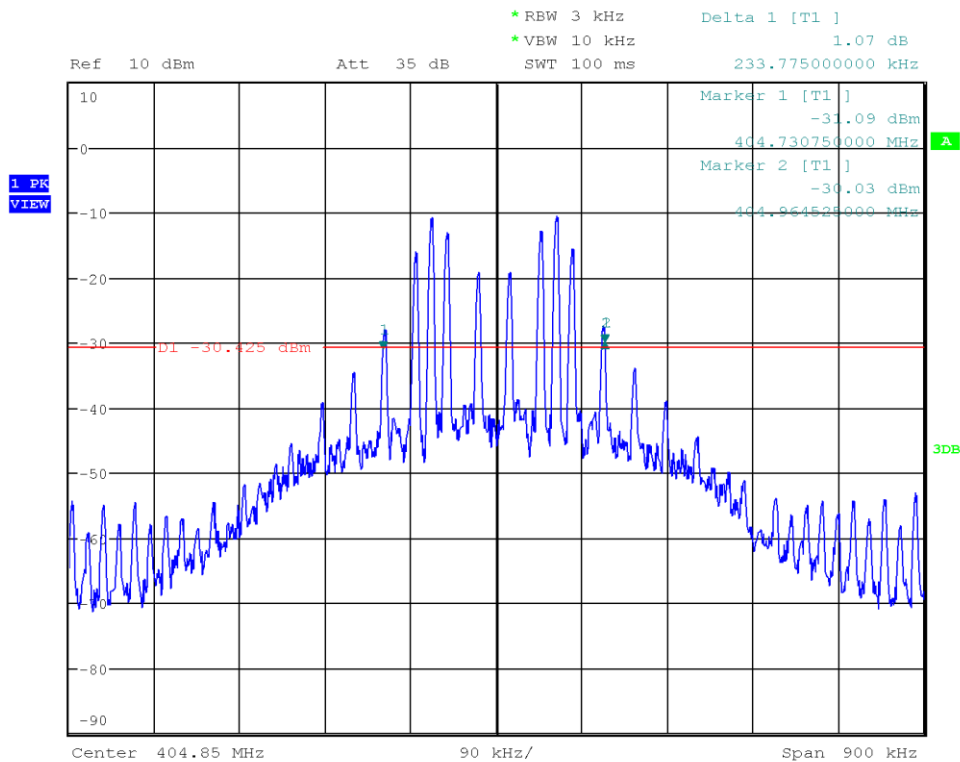
Date: 11.JAN.2023 14:03:31

Test Report No.: G0M-2210-1712-TFC95IMR-V01

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

20 dB Bandwidth

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 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: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2023-01-11
 Lower Frequency [MHz]: 404.731
 Upper Frequency [MHz]: 404.965
 20 dB Bandwidth [kHz]: 233.775



Date: 11.JAN.2023 14:04:29

Test Report No.: G0M-2210-1712-TFC95IMR-V01

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

3.3 Test Conditions and Results - Frequency stability

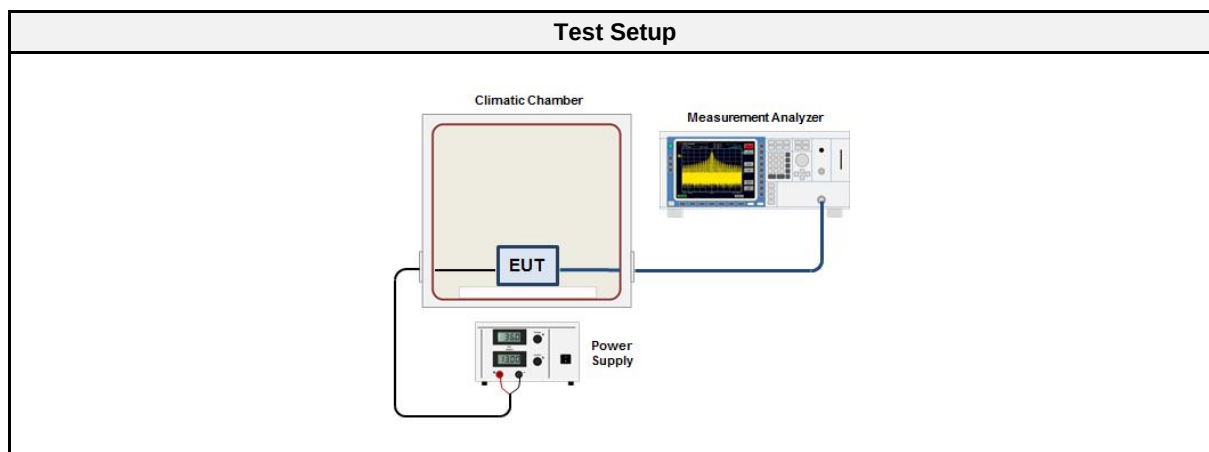
3.3.1 Information

Test Information	
Reference	FCC 95.2565 ISED RSS-243 3.3, 5.3
Measurement Method	ETSI EN 301 839 5.3.1
Measurement Uncertainty	± 0.06 PPM
Operator	Wilfried Treffke
Date	2023-01-11

3.3.2 Limits

Limits
$\leq \pm 100$ ppm

3.3.3 Setup



3.3.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01003	2022-07	2023-07
Cable	Gigalane	SMS111B	EF00779 CAAZ	2022-02	2023-02

3.3.5 Procedure

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.

3.3.6 Results

Test Results				
Channel [MHz]	Temperature [°C]	Supply voltage [VDC]	Frequency [MHz]	Drift [ppm]
402.45	37	2.7	402.447396	06.47
402.45	25	2.7	402.448223	04.42
402.45	42	2.7	402.446989	07.48
403.65	37	2.7	403.647463	06.29
403.65	25	2.7	403.648301	04.21
403.65	42	2.7	403.647058	07.29
404.85	37	2.7	404.847543	06.07
404.85	25	2.7	404.848370	04.03
404.85	42	2.7	404.847139	07.07

3.4 Test Conditions and Results - Transmitter output power

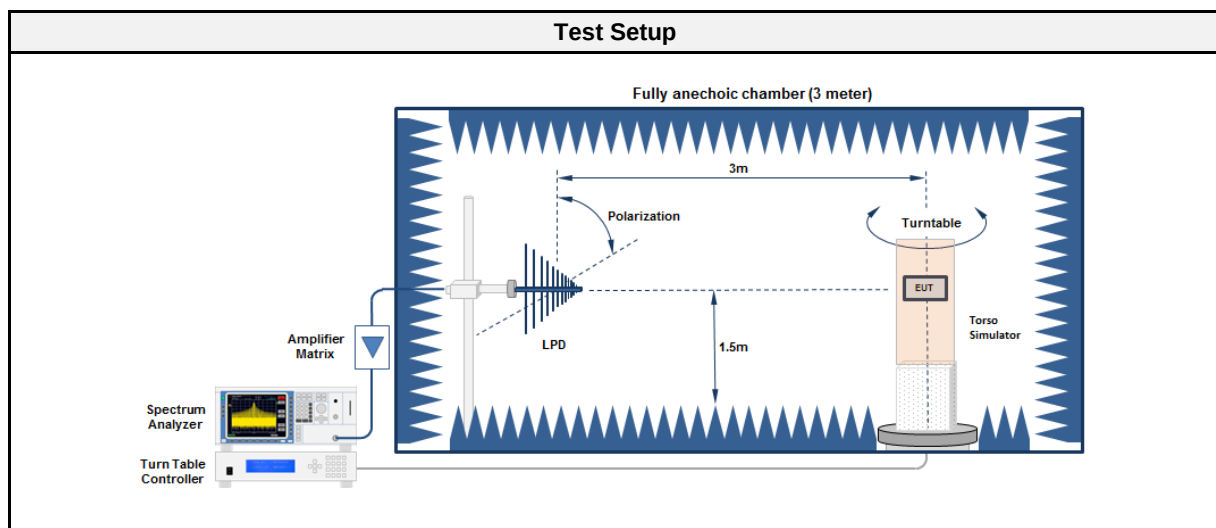
3.4.1 Information

Test Information	
Reference	FCC 95.2567(a), 95.2569 ISED RSS-243 5.4
Measurement Method	EN 301 839 5.3.3
Measurement Uncertainty	± 4.22 dB
Operator	Wilfried Treffke
Date	2022-12-15

3.4.2 Limits

Limits
$\leq 25 \mu\text{W}$ (-16 dBm) e.i.r.p.

3.4.3 Setup



3.4.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC2	EF01616	2022-10	2023-10
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08
Antenna	R&S	HL 223	EF01565	2020-03	2023-03

3.4.5 Procedure

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

3.4.6 Results

Test Results				
Channel [MHz]	Emission Level [dBm e.i.r.p.]	Detector	Limit [dBm e.i.r.p.]	Margin [dB]
402.45	-33.8	pk	-16	-17.80
404.85	-33.5	pk	-16	-17.50

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

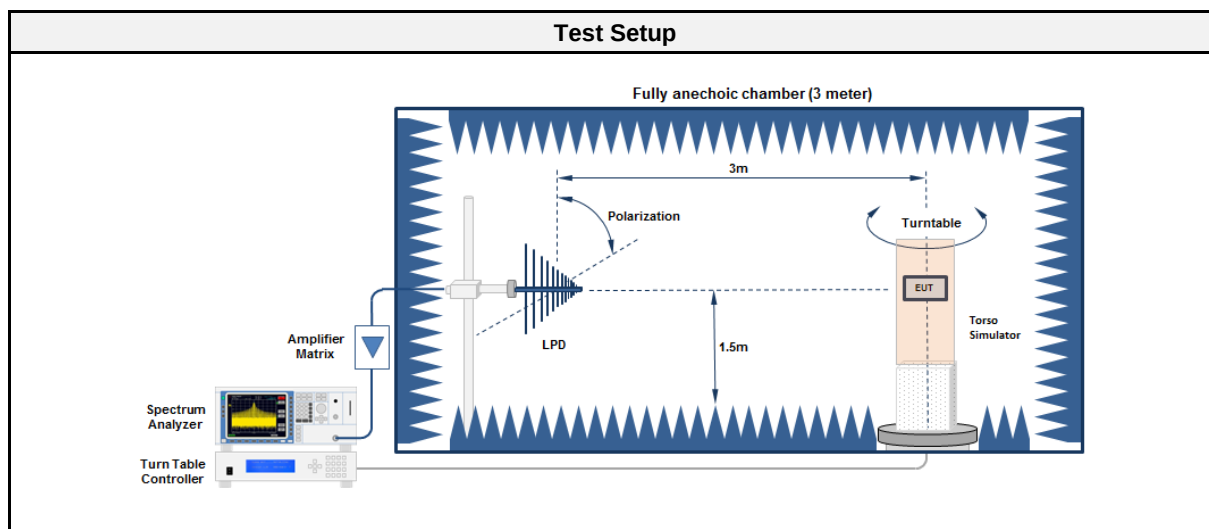
3.5.1 Information

Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.10 6.10
Measurement Uncertainty	± 1.80 dB
Operator	Wilfried Treffke
Date	2022-12-15

3.5.2 Limits

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 ISED	
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
The FCC limits are more stringent than the ISED limits, that is why the FCC limits are used to fulfil the band-edge emission requirements	

3.5.3 Setup



3.5.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC2	EF01616	2022-10	2023-10
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08
Antenna	R&S	HL 223	EF01565	2020-03	2023-03

3.5.5 Procedure

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	

3.5.6 Results

Test Results					
Channel [MHz]	Emission [MHz]	Level [dBμV/m]	Pol.	Limit [dBμV/m]	Margin [dB]
402.45	402.3	29.74	ver	54.10	-24.36
402.45	402.629	26.44	ver	54.10	-27.66
402.45	403.236	29.21	ver	54.10	-24.89
402.45	403.959	21.66	ver	54.10	-32.44
404.85	404.7	32.43	ver	44.10	-11.67
404.85	404.999	29.99	ver	44.10	-14.11
404.85	405.028	29.45	ver	59.40	-29.95

3.6 Test Conditions and Results - Transmitter unwanted emissions

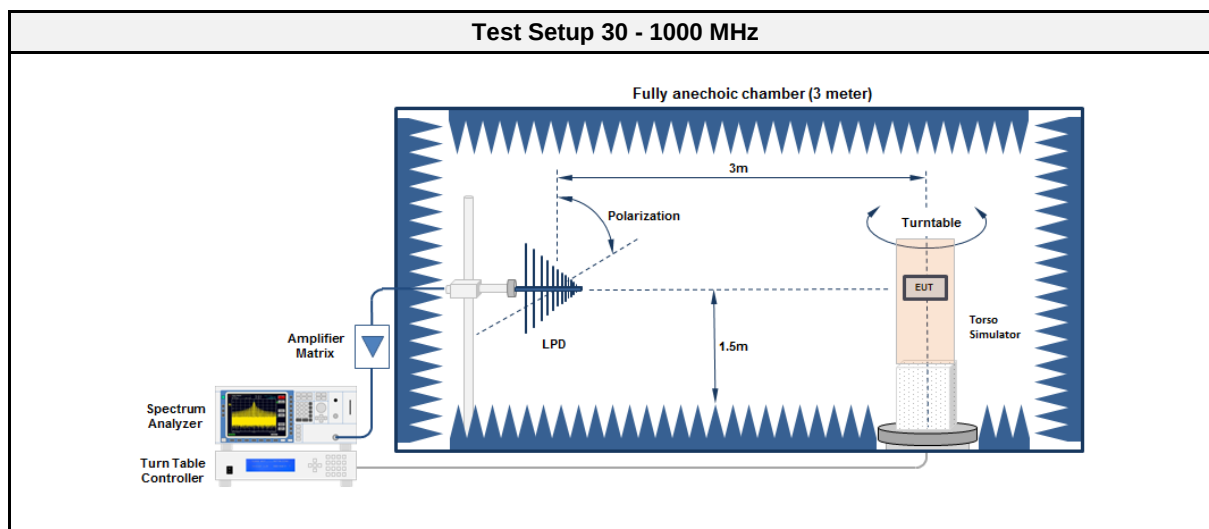
3.6.1 Information

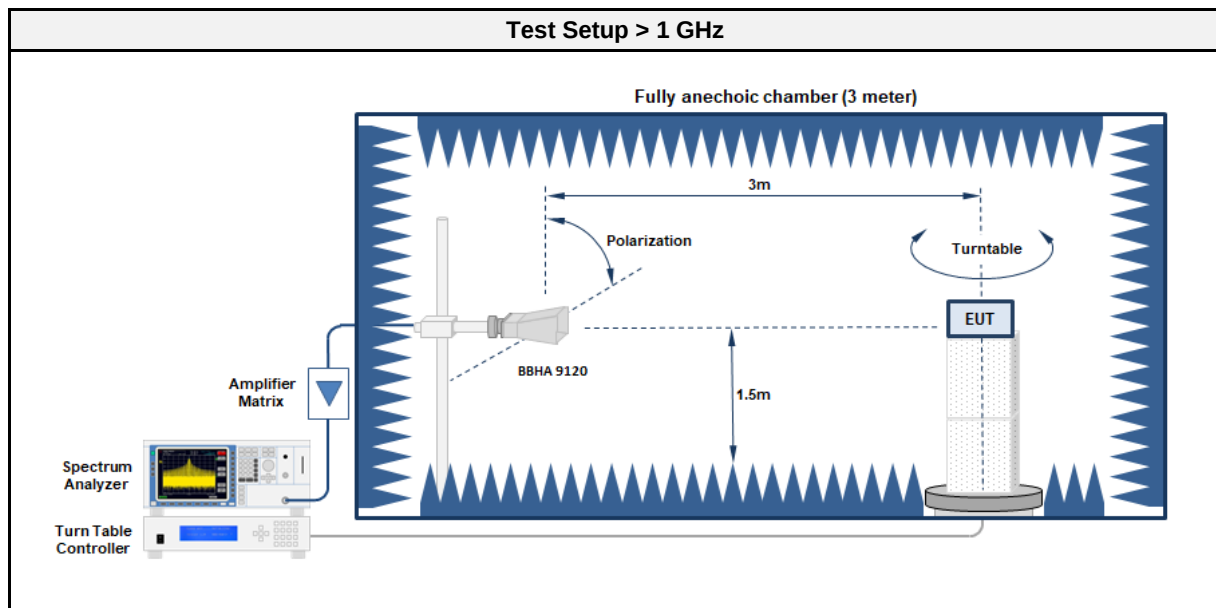
Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.10 6.10
Measurement Uncertainty	± 5.95 dB
Operator	Wilfried Treffke
Date	2022-12-15

3.6.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V}/\text{m}$]	Limit [$\text{dB}\mu\text{V}/\text{m}$]	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

3.6.3 Setup





3.6.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC2	EF01616	2022-10	2023-10
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08
Antenna	R&S	HK 116	EF01564	2020-03	2023-03
Antenna	R&S	HL 223	EF01565	2020-03	2023-03
Antenna	R&S	BBHA 9120B	EF00187	2022-06	2025-06

3.6.5 Procedure

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	

3.6.6 Results

Test Results							
Channel [MHz]	Emission [MHz]	Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Limit dist. [m]	Margin [dB]
402.45	405.409	24.24	pk	ver	46.00	3	-21.76
402.45	408.7	25.29	pk	ver	46.00	3	-20.71
402.45	399.632	20.48	pk	ver	46.00	3	-25.52
404.85	405.627	30.13	pk	ver	46.00	3	-15.87
404.85	398.455	27.65	pk	ver	46.00	3	-18.35

3.7 Test Conditions and Results - Receiver spurious emissions

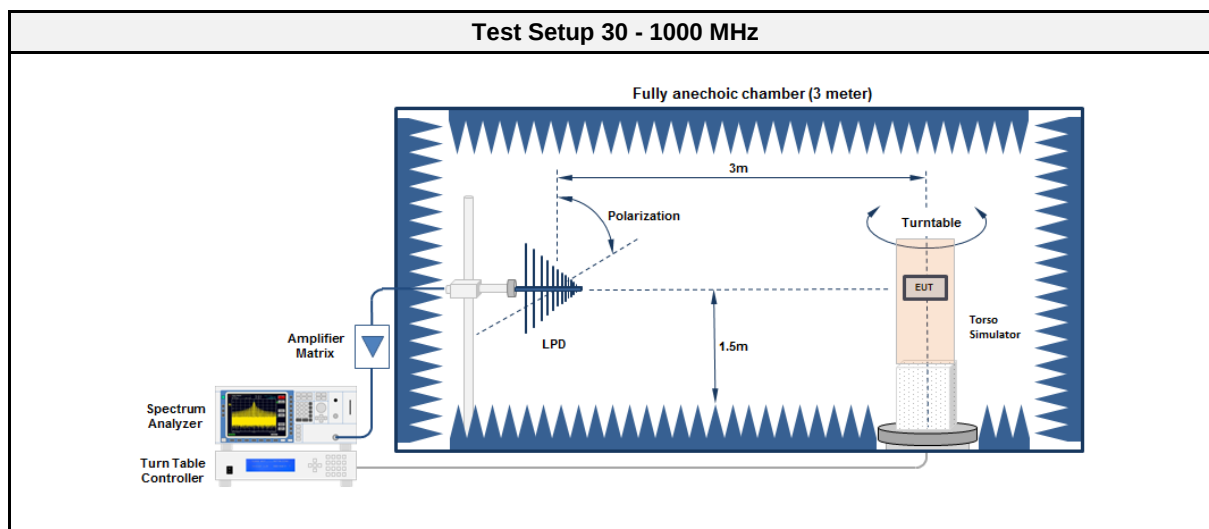
3.7.1 Information

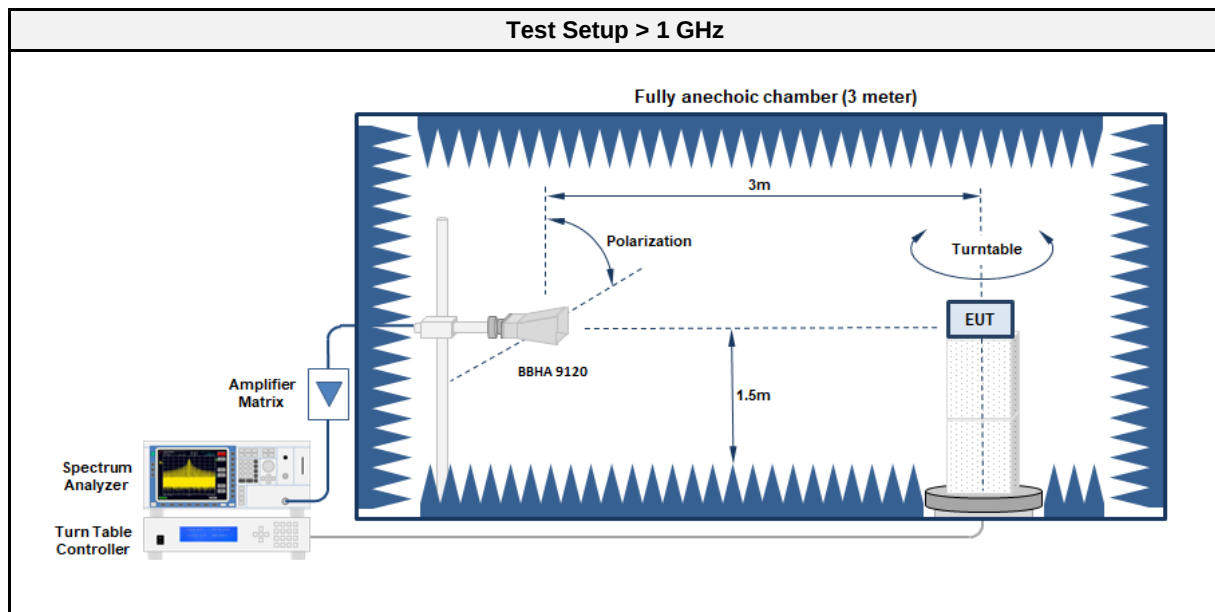
Test Information	
Reference	ISED RSS-243 3.5, 5.6 ISED RSS-Gen 7.3
Measurement Method	ANSI C63.10 6.10
Measurement Uncertainty	± 5.95 dB
Operator	Wilfried Treffke
Date	2023-01-11

3.7.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V}/\text{m}$]	Limit [$\text{dB}\mu\text{V}/\text{m}$]	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

3.7.3 Setup





3.7.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC2	EF01616	2022-10	2023-10
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08
Antenna	R&S	HK 116	EF01564	2020-03	2023-03
Antenna	R&S	HL 223	EF01565	2020-03	2023-03
Antenna	R&S	BBHA 9120B	EF00187	2022-06	2025-06

3.7.5 Procedure

Test Procedure	
1. EUT set to receive 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	

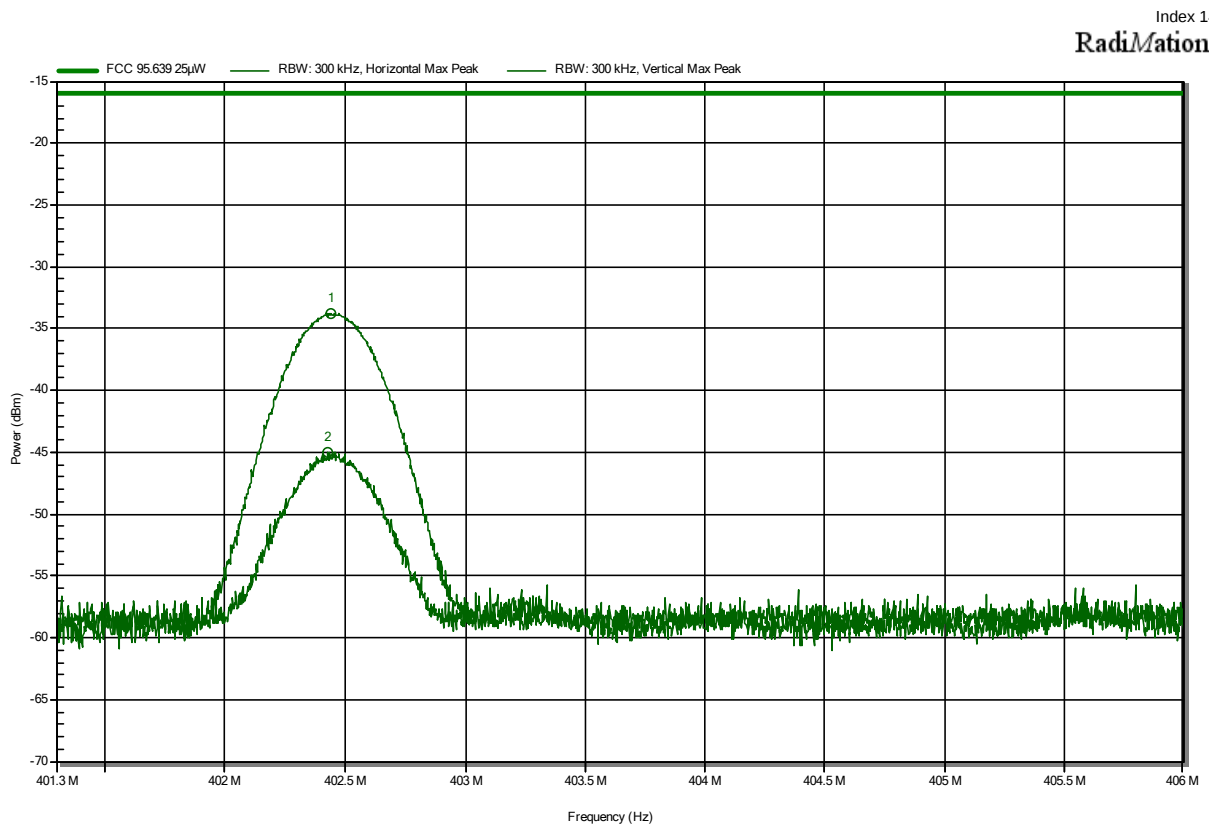
3.7.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Emission Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Margin [dB]
403.65	Comments: Emission level corresponds to ambient noise floor					

ANNEX A Transmitter output power

Radiated carrier according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223, Horizontal
 Measurement distance: 3 m
 Mode: Tx; CW; 402.45 MHz
 Test Date: 2022-12-14
 Note: Tx Power EIRP



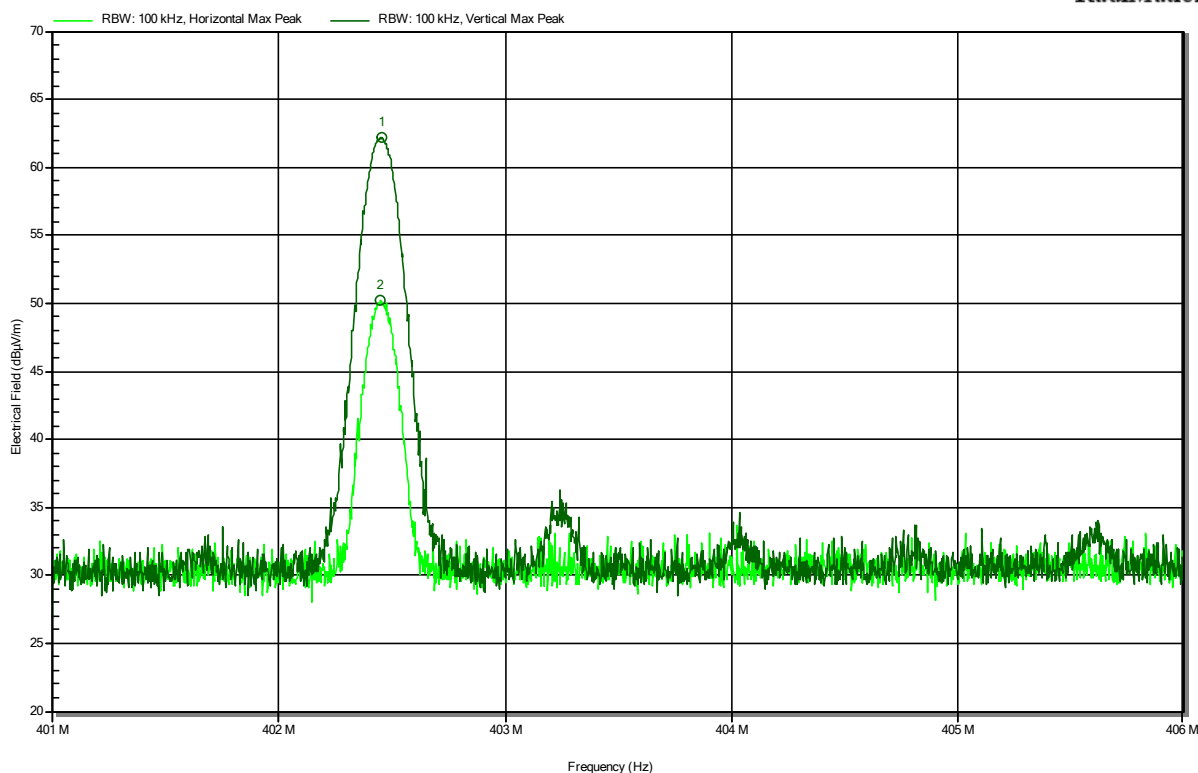
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.425 MHz	-45.1 dBm	-16 dBm	-29.06 dB	Pass
402.439 MHz	-33.8 dBm	-16 dBm	-17.81 dB	Pass

Radiated carrier according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 402.45 MHz
 Test Date: 2022-12-14
 Note: Power dB μ V/m ERP

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RadiMation



Frequency
 402.447 MHz
 402.455 MHz

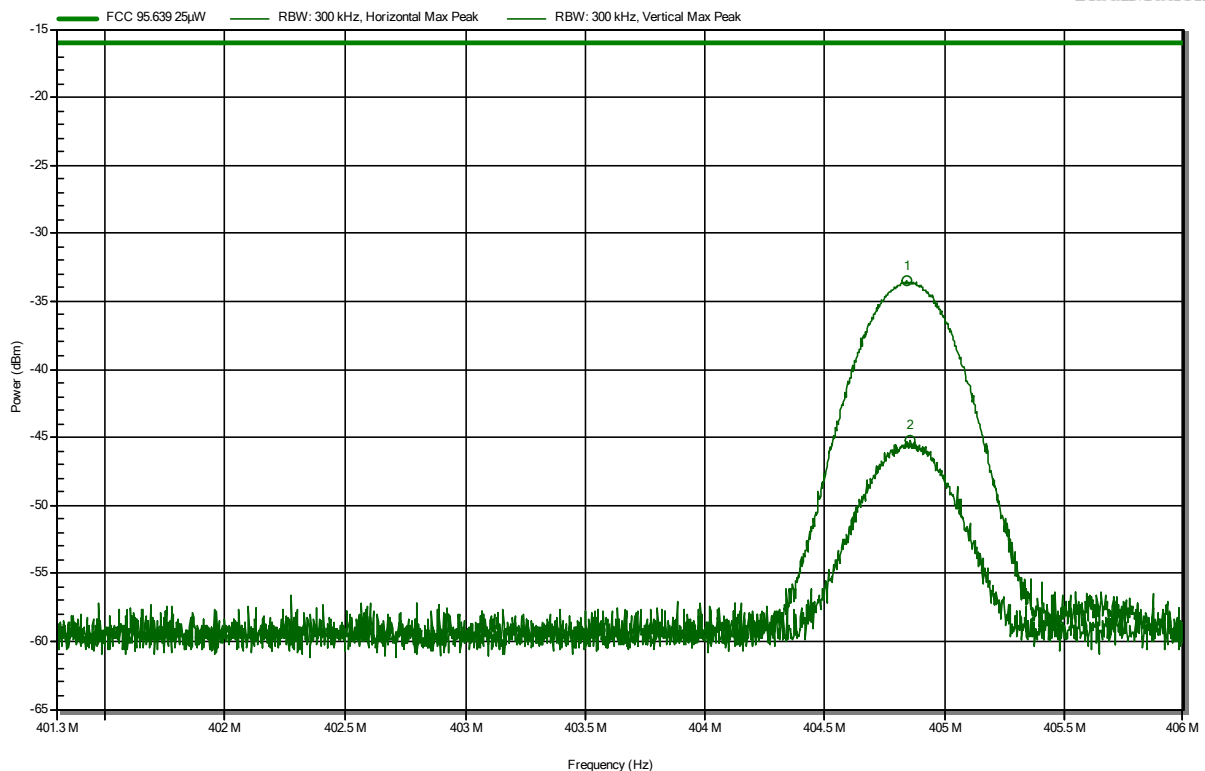
Peak
 50.23 dB μ V/m
 62.17 dB μ V/m

Radiated carrier according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 404.85 MHz
 Test Date: 2022-12-14
 Note: Tx Power EIRP

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RadiMation



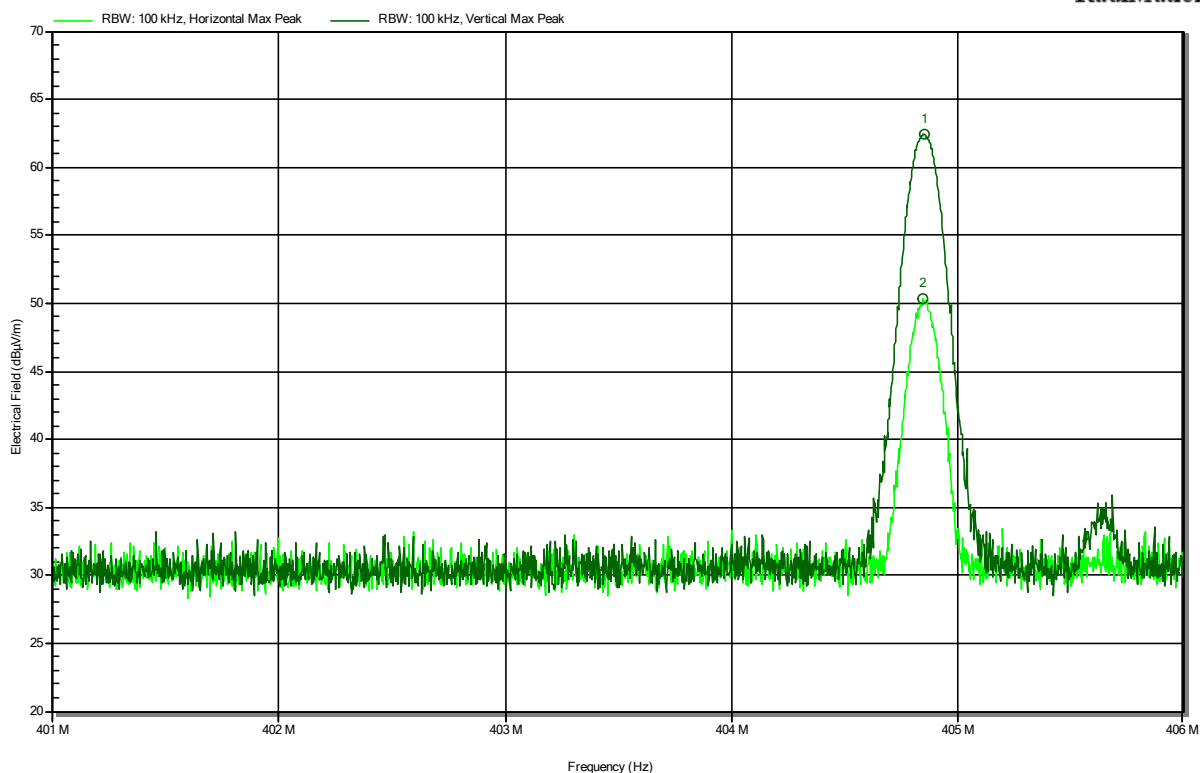
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.84 MHz	-33.5 dBm	-16 dBm	-17.52 dB	Pass
404.858 MHz	-45.3 dBm	-16 dBm	-29.26 dB	Pass

Radiated carrier according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 404.85 MHz
 Test Date: 2022-12-14
 Note: Power dB μ V/m ERP

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RadiMation



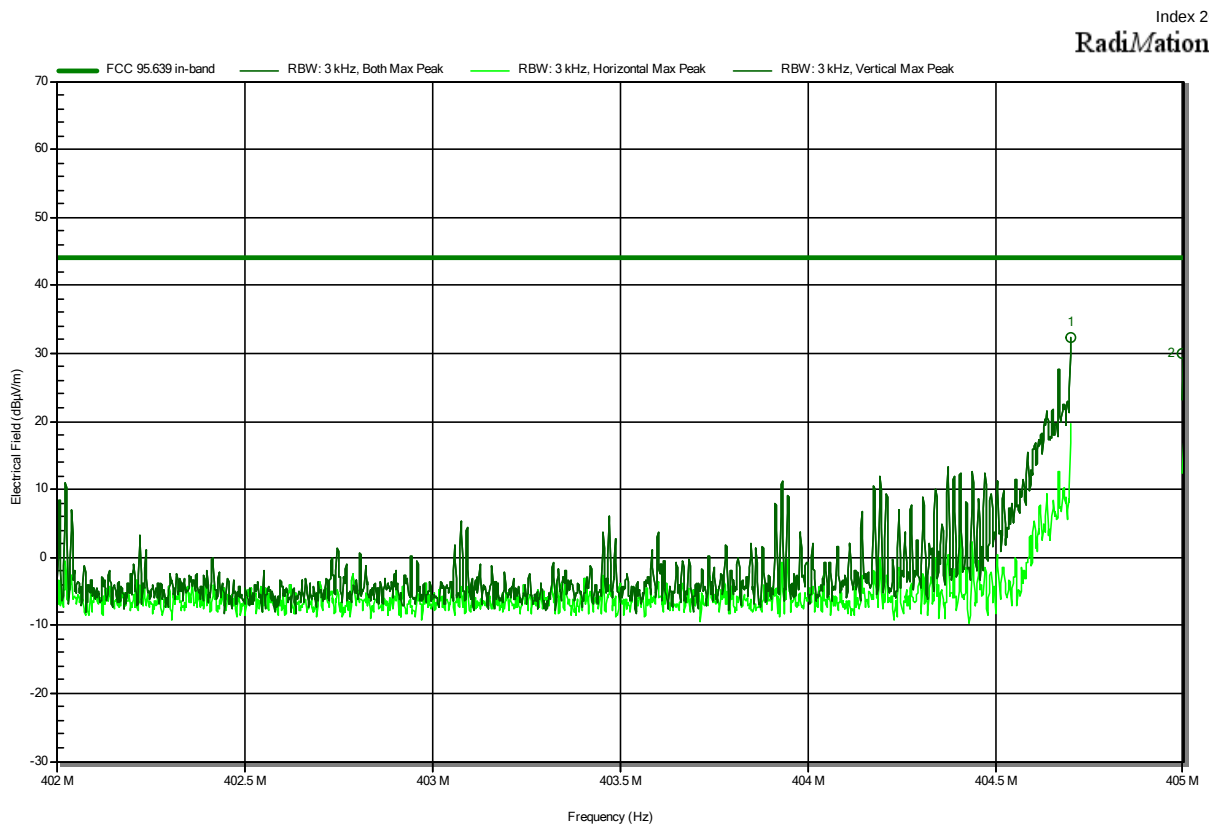
Frequency
 404.846 MHz
 404.848 MHz

Peak
 50.38 dB μ V/m
 62.45 dB μ V/m

ANNEX B Band-edge and In-band Emissions

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2022-12-14
 Note: In-band emissions



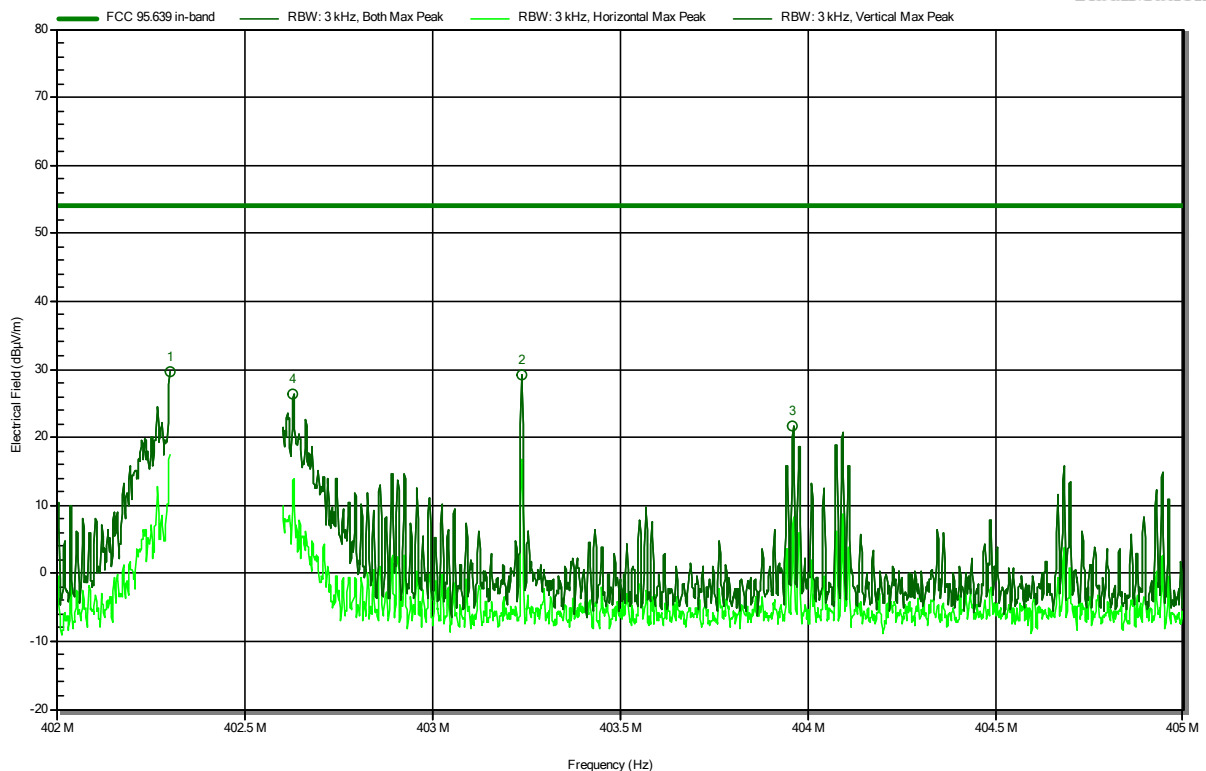
Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
404.7 MHz	32.43 dBμV/m	44.1 dBμV/m	-11.67 dB	Pass	Vertical
404.999 MHz	29.99 dBμV/m	44.1 dBμV/m	-14.11 dB	Pass	Vertical

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2022-12-14
 Note: In-band emissions

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RadiMation



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
402.3 MHz	29.74 dBμV/m	54.1 dBμV/m	-24.36 dB	Pass	Vertical
402.629 MHz	26.44 dBμV/m	54.1 dBμV/m	-27.66 dB	Pass	Vertical
403.236 MHz	29.21 dBμV/m	54.1 dBμV/m	-24.89 dB	Pass	Vertical
403.959 MHz	21.66 dBμV/m	54.1 dBμV/m	-32.44 dB	Pass	Vertical

Test Report No.: G0M-2210-1712-TFC95IMR-V01

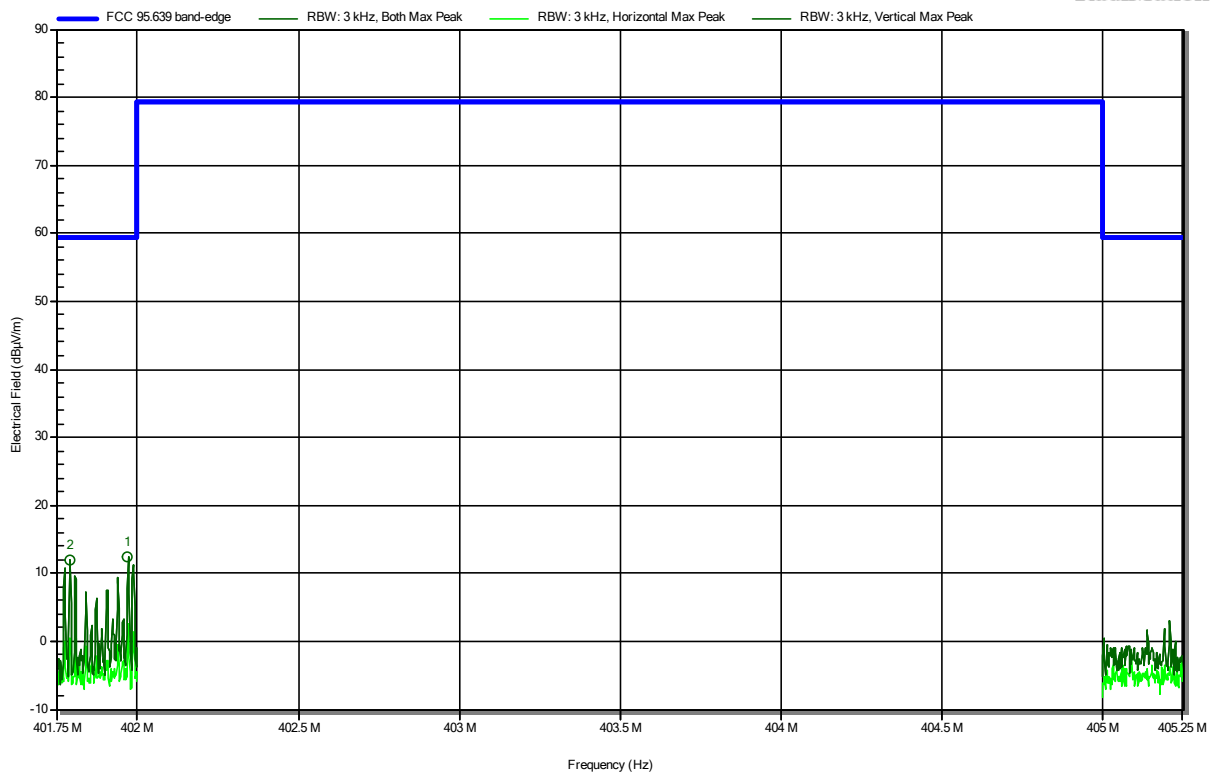
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2022-12-14
 Note: Band-edge

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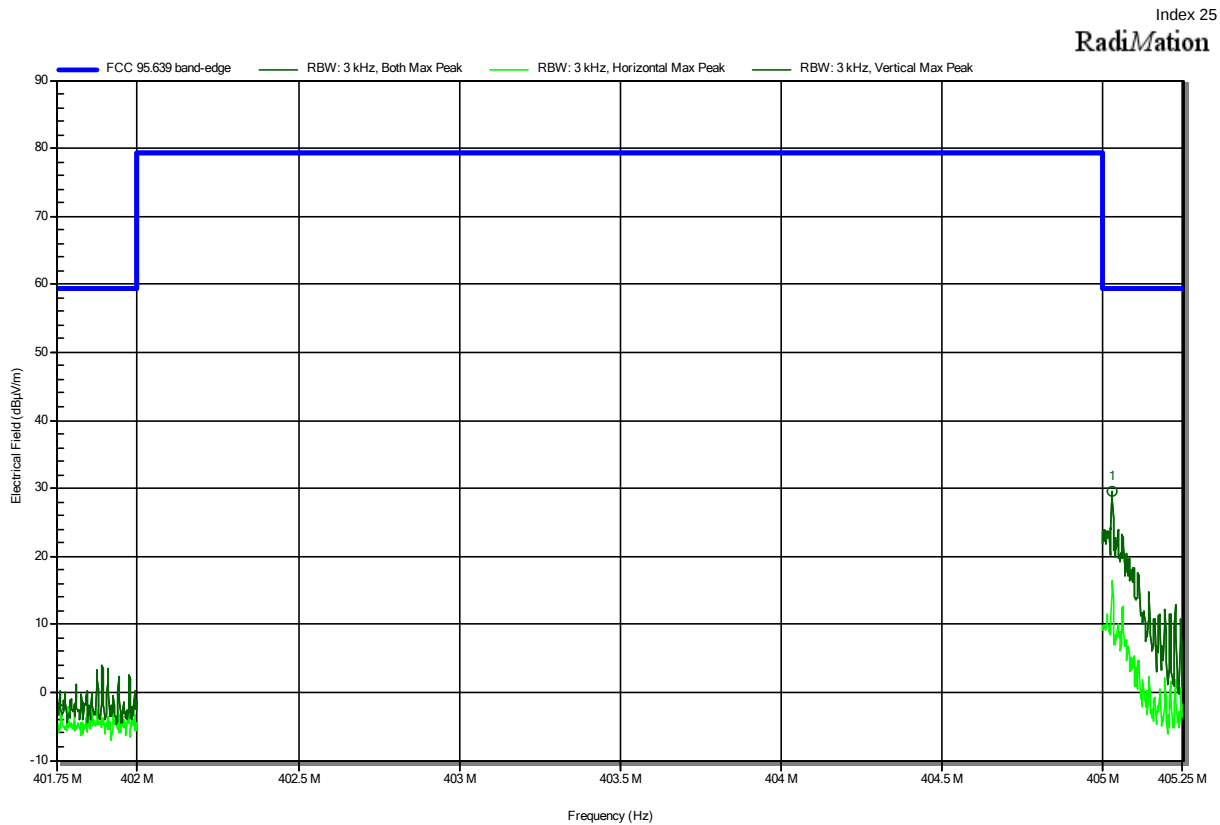
RadiMation



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
401.791 MHz	12.01 dBμV/m	59.4 dBμV/m	-47.39 dB	Pass	Vertical
401.971 MHz	12.44 dBμV/m	59.4 dBμV/m	-46.96 dB	Pass	Vertical

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2022-12-14
 Note: Band-edge

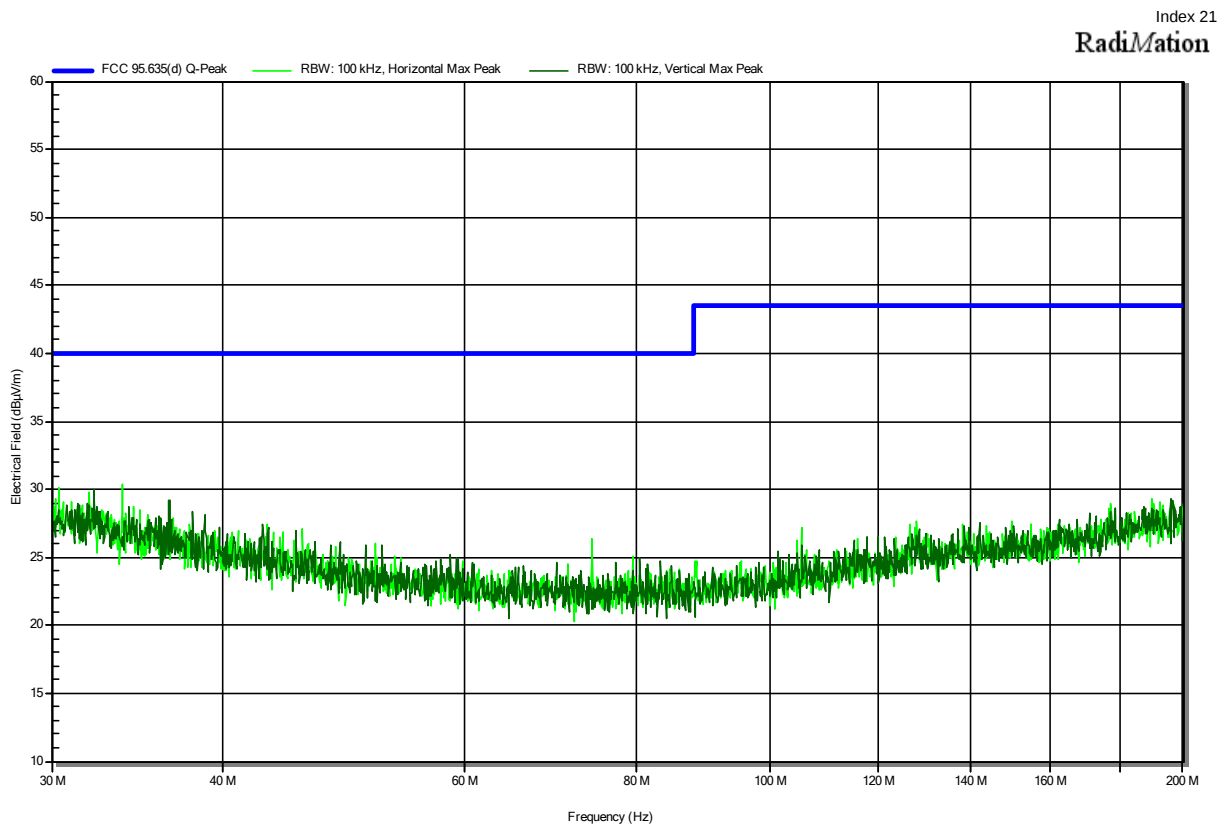


Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
405.028 MHz	29.45 dBµV/m	59.4 dBµV/m	-29.95 dB	Pass	Vertical

ANNEX C Transmitter spurious emissions

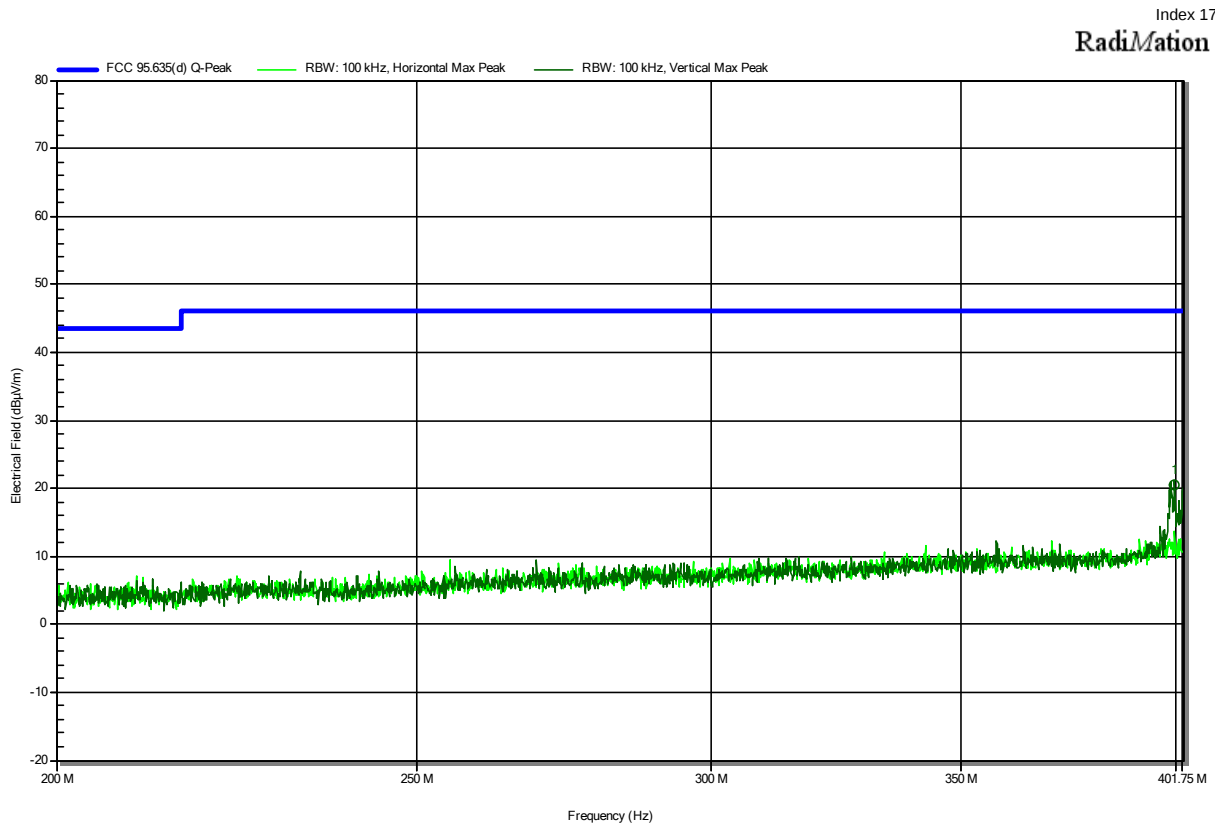
Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HK 116
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2022-12-14
 Note:



Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

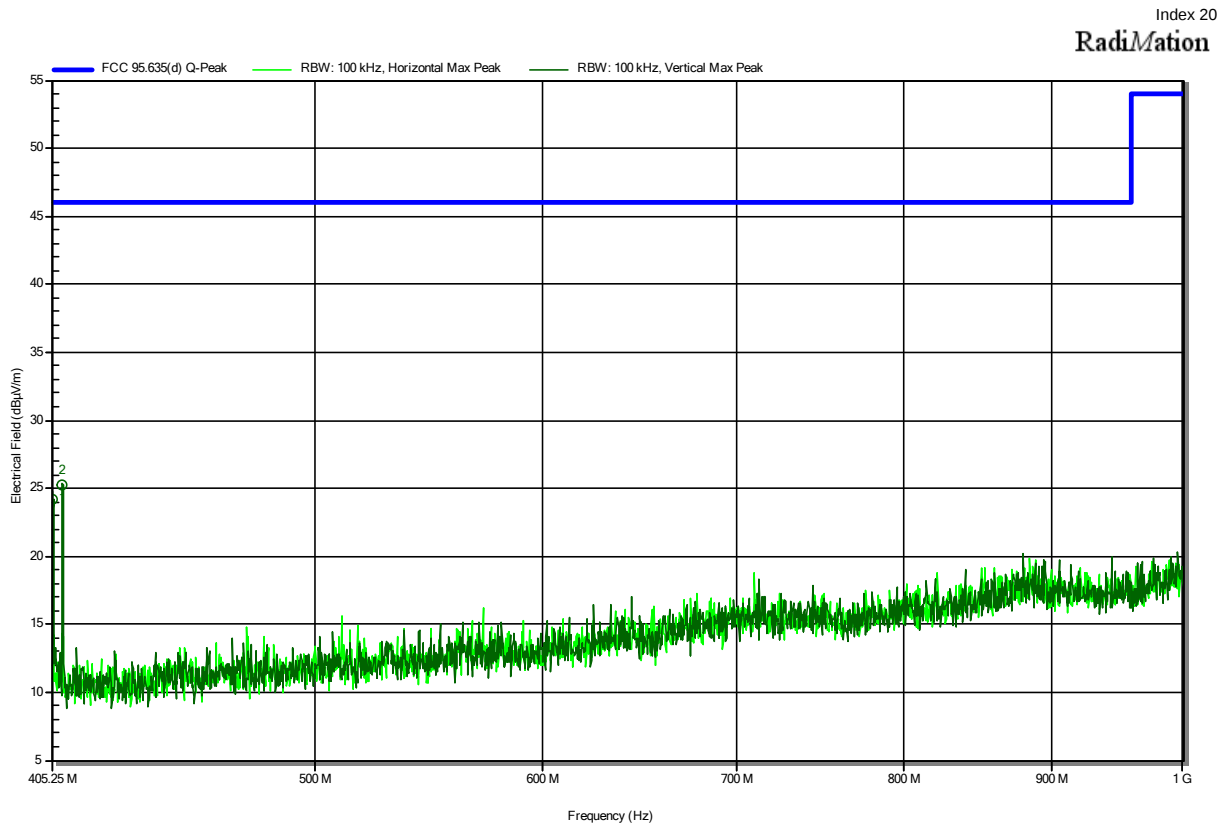
Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2022-12-14
 Note:



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
399.632 MHz	20.48 dBµV/m	46 dBµV/m	-25.52 dB	Pass	Vertical

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

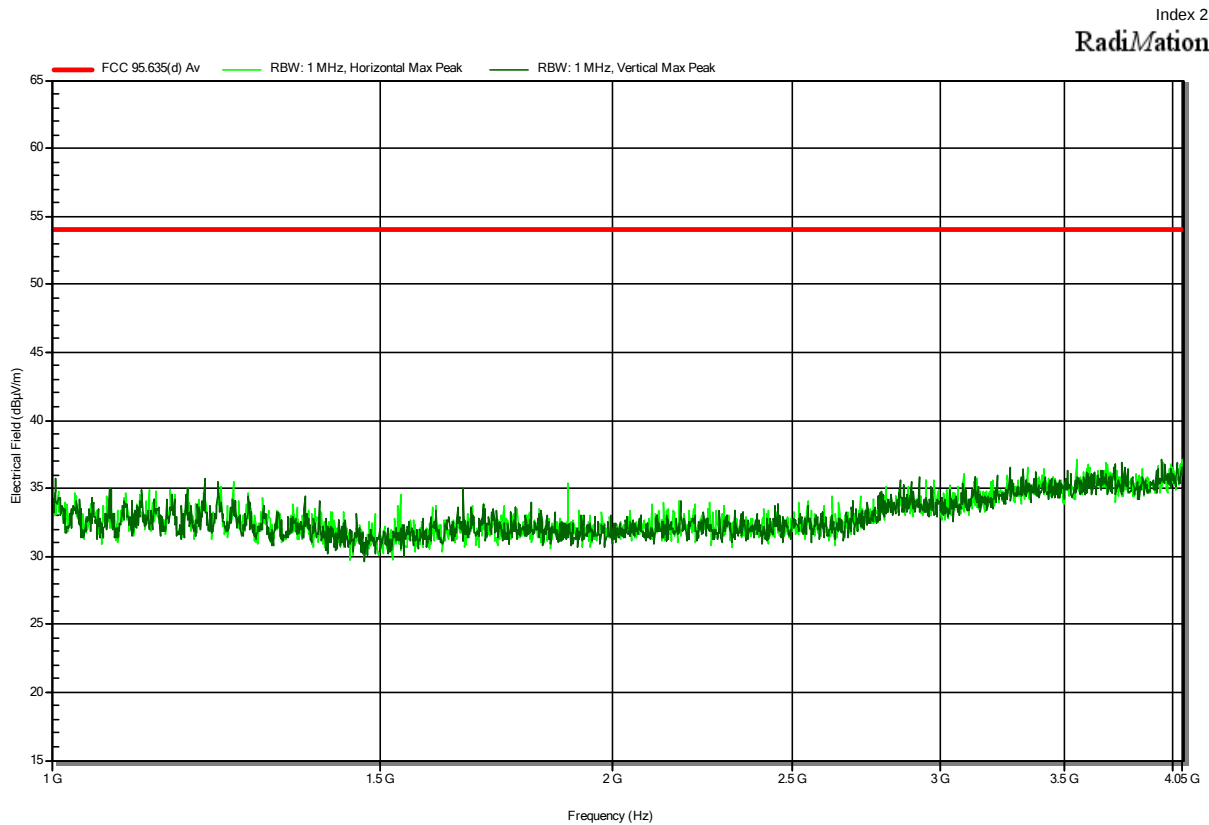
Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2022-12-14
 Note:



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
405.409 MHz	24.24 dBµV/m	46 dBµV/m	-21.76 dB	Pass	Vertical
408.7 MHz	25.29 dBµV/m	46 dBµV/m	-20.71 dB	Pass	Vertical

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2022-12-14
 Note:

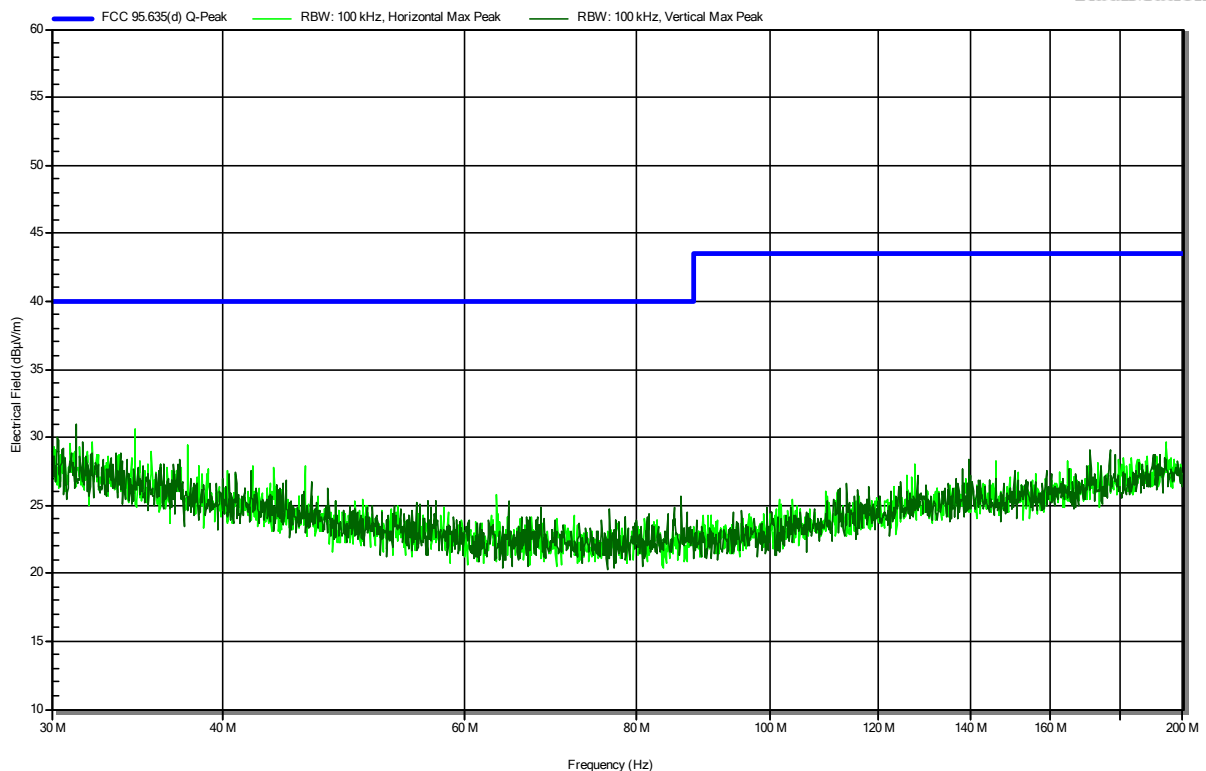


Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HK 116
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2022-12-14
 Note:

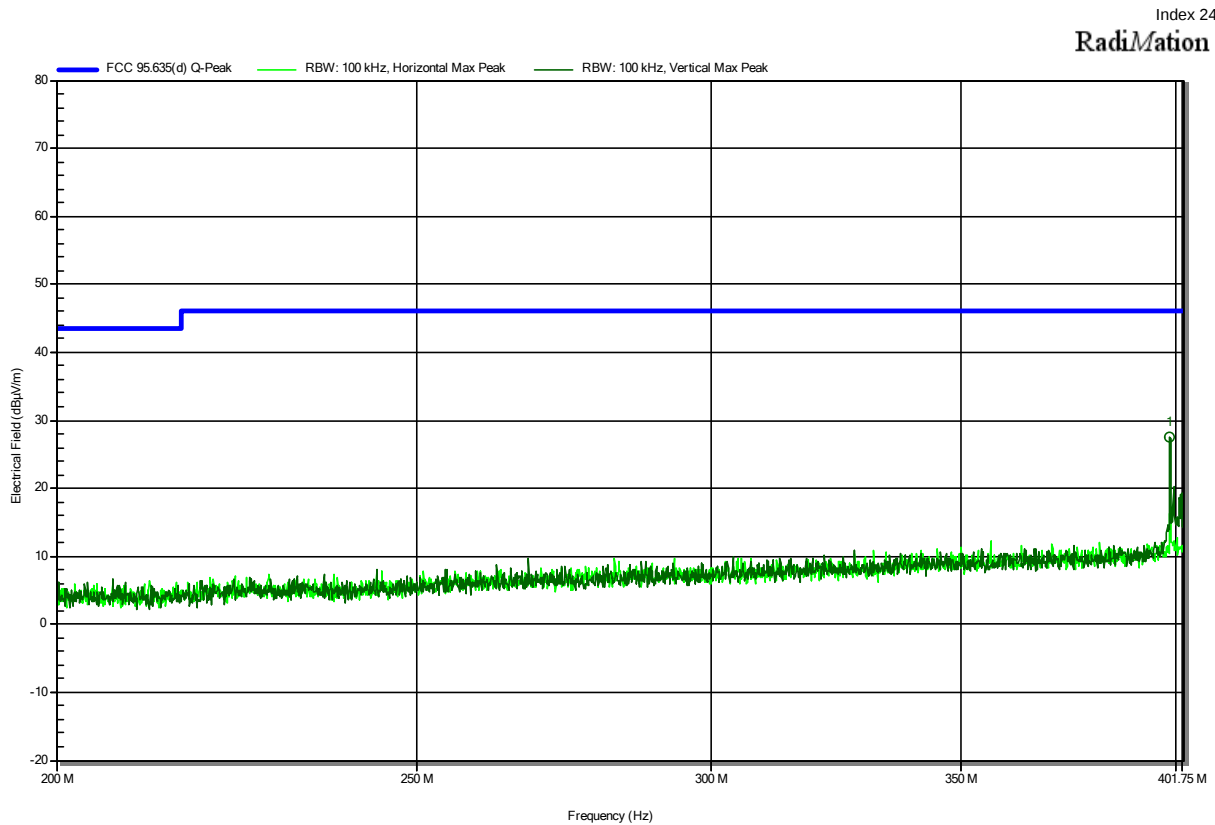
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RadiMation



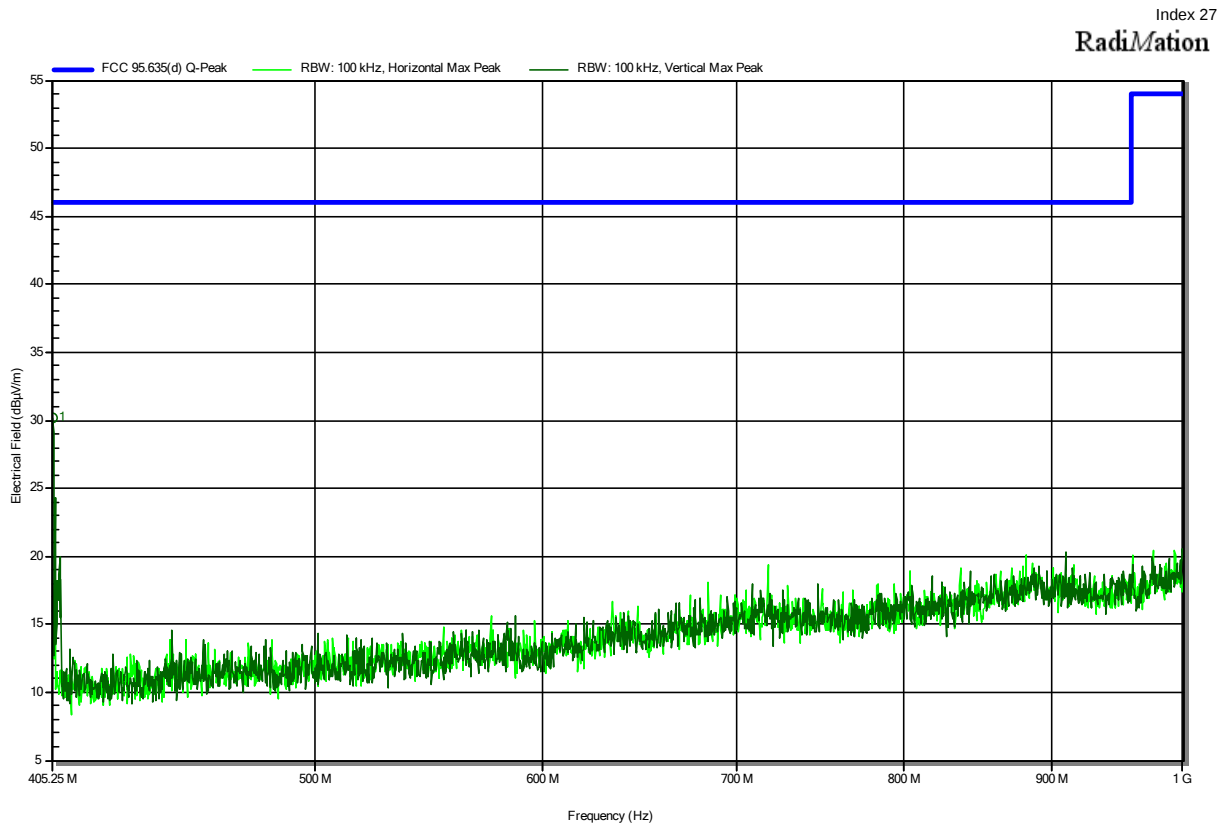
Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2022-12-14
 Note:



Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

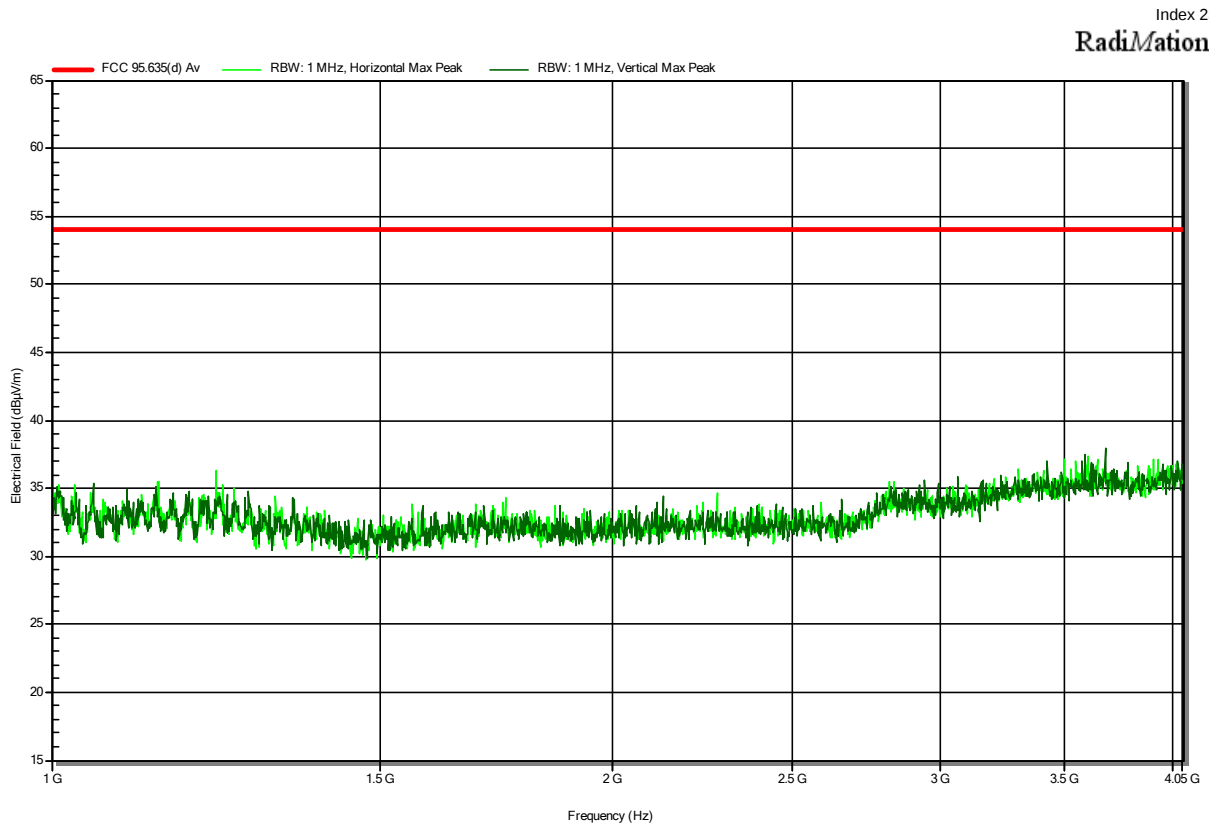
Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2022-12-14
 Note:



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
405.627 MHz	30.13 dBµV/m	46 dBµV/m	-15.87 dB	Pass	Vertical

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

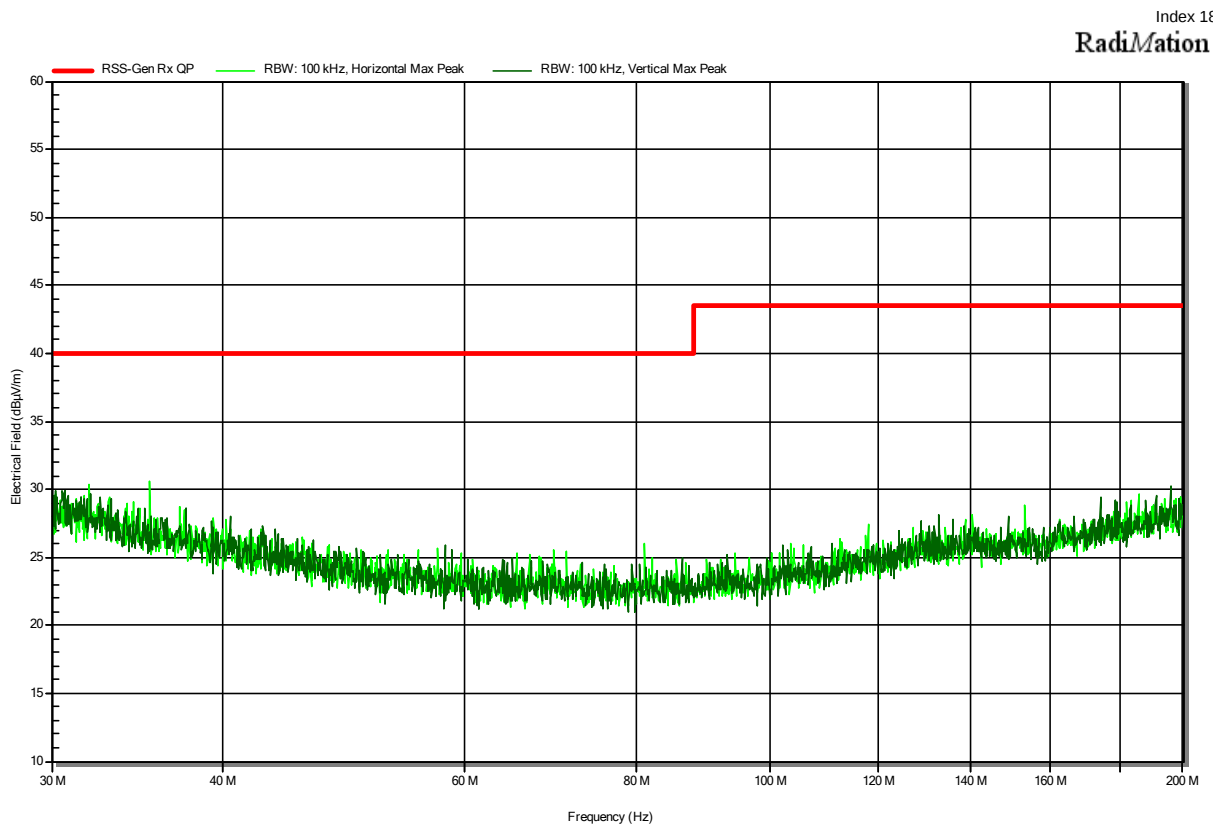
Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2022-12-14
 Note:



ANNEX D Receiver spurious emissions

Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HK 116
 Measurement distance: 3 m
 Mode: RX; 402.45 MHz
 Test Date: 2022-12-15
 Note:

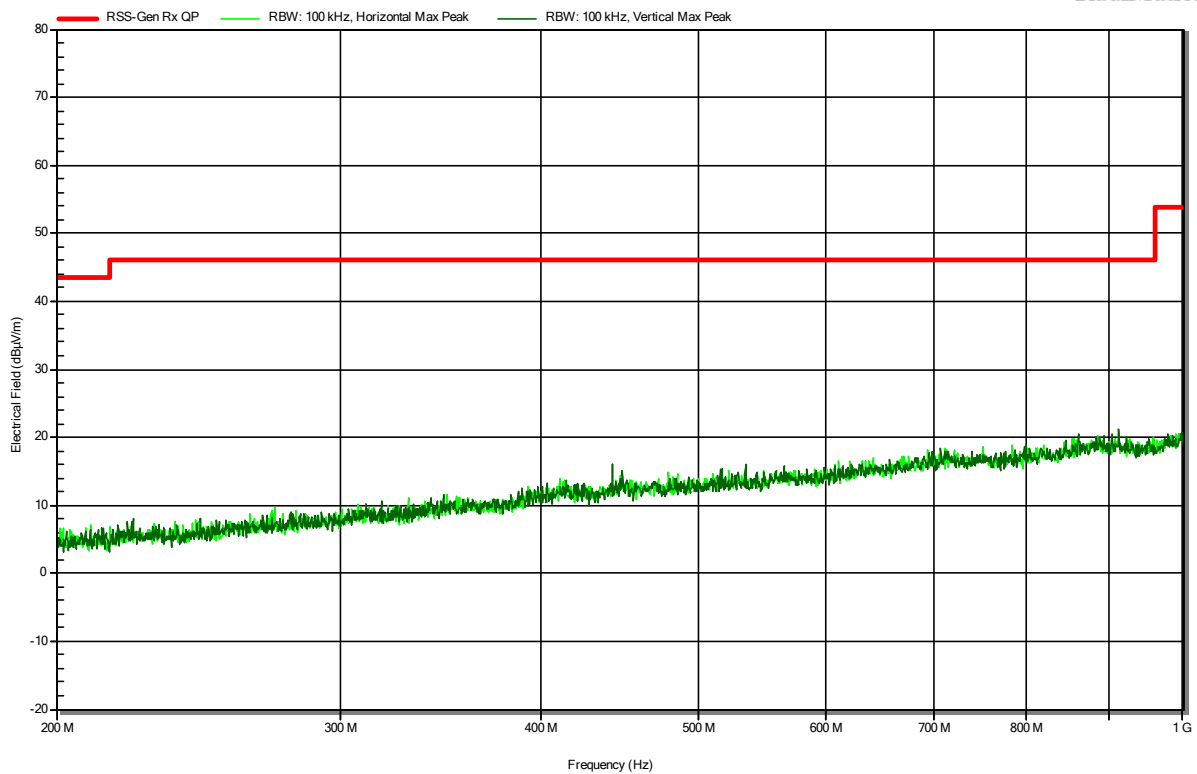


Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Rx; 402.45 MHz
 Test Date: 2022-12-15
 Note:

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RadiMation

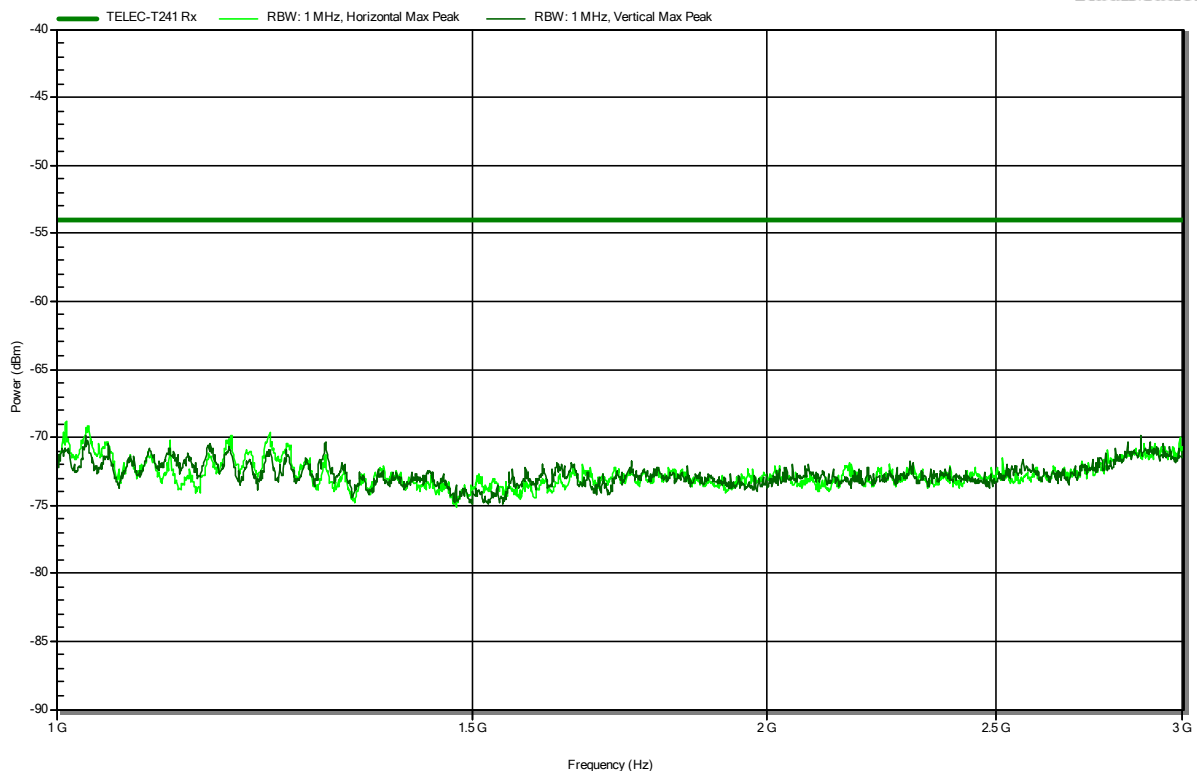


Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Cardiac Monitor
 Model: BIOMONITOR IV
 Test Sample ID: 42364
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 25 °Celsius, Vnom: 3.0 VDC
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Rx; 403.65 MHz
 Test Date: 2022-12-15
 Note: Rx

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RadiMation



=== END OF TEST REPORT ===

Test Report No.: G0M-2210-1712-TFC95IMR-V01

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