

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-2111-1166-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	Woermannkehe 1 12359 Berlin GERMANY
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 Pulse Generator
Model(s)	Amvia Stellar DR-T
Additional Model(s)	additional model see family list
Brand Name(s)	BIOTRONIK
Hardware Version(s)	0A
Software Version(s)	ROM: 1.0 / RAM: 1.0
FCC ID	QRI-IPG2267P2
IC	4708A-IPG2267P2
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	2022-01-10	
Report:		
Compiled by	Wilfried Treffke	
Tested by (+ signature) (Responsible for Test)	Wilfried Treffke	
Approved by (+ signature) (Deputy Head of Lab)	Toralf Jahn	
Date of Issue	2022-03-01	
Total number of pages	88	
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 VARIANTS (not tested and not evaluated variants)



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Berlin, 17 January 2022

IPG-2267P2 Family Explanation

1. Family Letter

#	Product Name / PMN	no. of chambers	Connector RA/RV	Connector LV	HVIN Order number
1	Amvia Sky SR-T	1	IS-1	-	460161
2	Amvia Edge SR-T	1	IS-1	-	460164
3	Solvvia Rise SR-T	1	IS-1	-	460228
4	Amvia Sky DR-T	2	IS-1	-	460160
5	Amvia Edge DR-T	2	IS-1	-	460163
6	Solvvia Rise DR-T	2	IS-1	-	460227
7	Amvia Stellar DR-T	2	IS-1	-	460167 (Master)
8	Amvia Sky HF-T	3	IS-1	IS-1	460159
9	Amvia Stellar HF-T	3	IS-1	IS-1	460166
10	Amvia Sky HF-T QP	3	IS-1	IS4 LLLL	460158
11	Amvia Edge HF-T QP	3	IS-1	IS4 LLLL	460162
12	Amvia Stellar HF-T QP	3	IS-1	IS4 LLLL	460165

no HVIN and FVIN for all products

2. Family description

Header difference overview

Variant	Family member's
1	SR-T
2	DR-T
3	HF-T
4	HF-T QP

table 1: PC Board and RF Antenna

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12359 Berlin
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Kommanditgesellschaft:
HRA 6501 B, AG Berlin-Charlottenburg
Komplementärin: BIOTRONIK MT SE
HRB 118866 B, AG Berlin-Charlottenburg

Version History			
Version	Issue Date	Remarks	Revised By
01	2022-03-01	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

REPORT INDEX

1	Equipment (Test Item) Under Test.....	9
1.1	Photos – Equipment External	10
1.2	Photos – Equipment Internal	16
1.3	Photos – Test Setup.....	18
1.4	Photos – Auxiliary/Associated Equipment	20
1.5	Support Equipment.....	21
1.6	Test mode duty cycle	22
1.7	Test Modes	24
1.8	Test Frequencies.....	25
1.9	Sample emission level calculation.....	26
1.10	Simulated human body.....	27
2	Result Summary.....	28
3	Test Conditions and Results	29
3.1	Test Conditions and Results - Occupied bandwidth	29
3.2	Test Conditions and Results - Emission bandwidth.....	43
3.3	Test Conditions and Results - Frequency stability.....	57
3.4	Test Conditions and Results - Transmitter output power.....	59
3.5	Test Conditions and Results - Band-edge and In-band Emissions	61
3.6	Test Conditions and Results - Transmitter unwanted emissions	63
3.7	Test Conditions and Results - Receiver spurious emissions.....	65
ANNEX A	Transmitter output power	67
ANNEX B	Band-edge and In-band Emissions	71
ANNEX C	Transmitter spurious emissions	75
ANNEX D	Receiver spurious emissions	83

1 Equipment (Test Item) Under Test

Description	Implantable Pulse Generator	
Model	Amvia Stellar DR-T	
Additional Model(s)	additional model see family list	
Brand Name(s)	BIOTRONIK	
Serial Number(s)	1000000408 0423321243	Radiated Test Sample ID 38057 Conducted Test Sample ID 38093
Hardware Version(s)	0A	
Software Version(s)	ROM: 1.0 / RAM: 1.0	
PMN	Amvia Stellar DR-T	
HVIN	460167	
FVIN	N/A	
HMN	N/A	
FCC ID	QRI-IPG2267P2	
IC	4708A-IPG2267P2	
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 antenna
	Model	2260
	Manufacturer	BIOTRONIK SE & Co. KG
	Gain	-28.7 dBi (Determined by measurements)
Supply Voltage	V _{NOM}	3.0 VDC
	V _{MIN}	2.5 VDC
	V _{MAX}	3.2 VDC
Operating Temperature	T _{NOM}	37 °C
	T _{MIN}	25 °C
	T _{MAX}	45 °C
AC/DC-Adaptor	Model	None
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

1.5 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE1	Communication Adapter	Biotronik	TelBox II	-
AE2	Programming Head	Biotronik	PGH 3000	-
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment:				

1.6 Test mode duty cycle

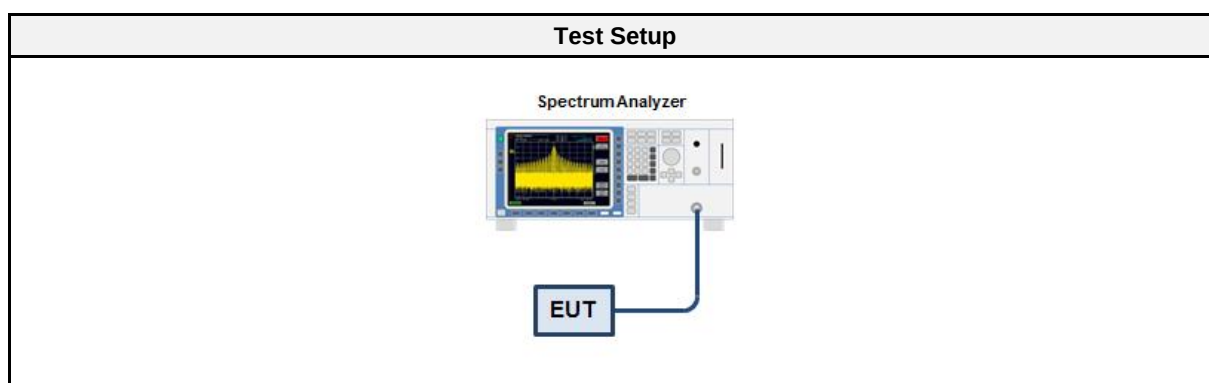
1.6.1 Information

Test Information	
Measurement Method	ANSI C63.10 11.6

1.6.2 Requirements

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

1.6.3 Setup



1.6.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 3	EF00241	2021-07	2023-07

1.6.5 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 $DC = 10 \times \log_{10}(T_{ON} / (T_{ON} + T_{OFF}))$

1.6.6 Results

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

1.7 Test Modes

Mode	Description
Unmodulated	Mode = Transmit Modulation = None
Modulated16	Mode = Transmit Modulation = 2-FSK Power level = maximum Datarate = 16.424kbps
Modulated32	Mode = Transmit Modulation = 2-FSK Power level = maximum Datarate = 32.848kbps
Modulated82	Mode = Transmit Modulation = 2-FSK Power level = maximum Datarate = 82.122kbps
Modulated197	Mode = Transmit Modulation = 2-FSK Power level = maximum Datarate = 197.094kbps
Receive	Mode = Receive Modulation = 2-FSK
Comment:	

1.8 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

1.9 Sample emission level calculation

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

Reading:

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

A.F.:

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

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

Net:

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

Limit:

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

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

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:

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

1.10 Simulated human body

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

Liquid components			
Component		percentage per weight	
Deionized water		52.4	
Bactericide		0.08	
Hydroxy ethyl cellulose (HCE)		1.0	
Sodium chloride		1.4	
Sucrose		45.0	
Tissue parameters – 403.5MHz Measured tissue parameters:			
Component	Target	Measured	Tolerance [%]
Dielectric constant ϵ	62.5	63.07	0.91
Conductivity σ [ms/cm]	9.08	8.9	-1.98

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:				

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

3 Test Conditions and Results

3.1 Test Conditions and Results - Occupied bandwidth

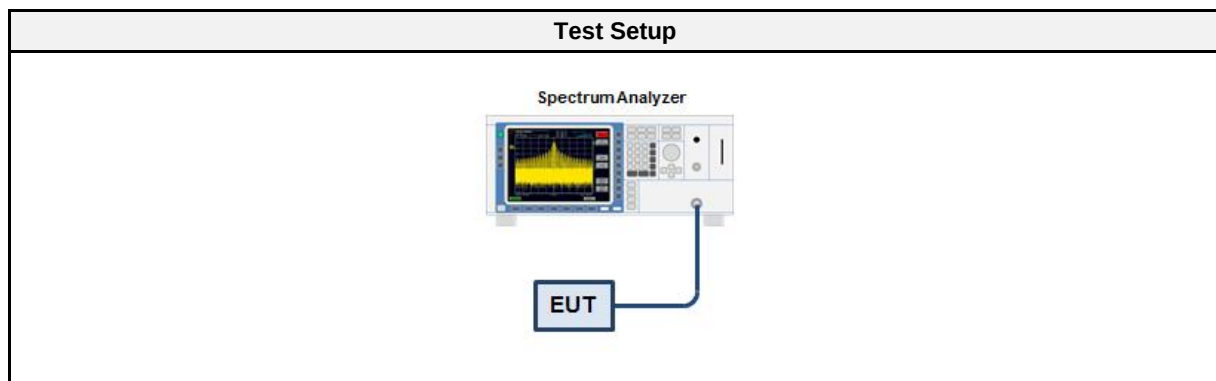
3.1.1 Information

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	2022-01-13

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 3	EF00241	2021-07	2023-07
Cable (diverse)	(diverse)	(diverse)	EF00779	2020-12	2022-02

3.1.5 Procedure

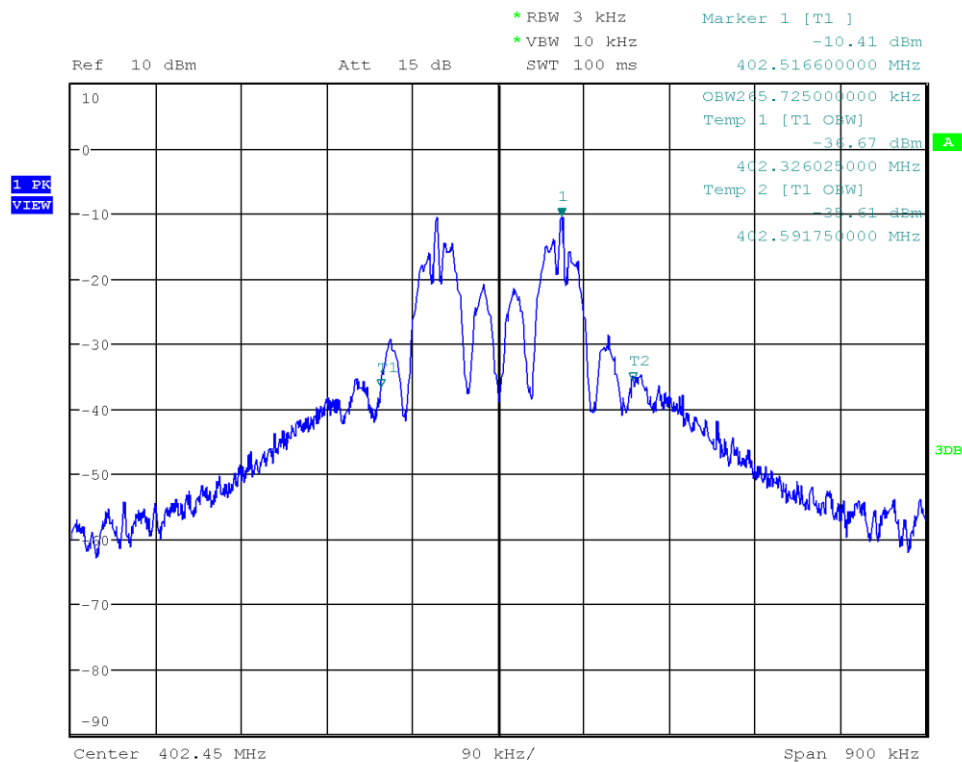
Test Procedure
1. EUT transmitter is activated in test mode under normal conditions 2. The spectrum analyzer is set to peak detection and maximum hold with a span twice the emission spectrum 3. The resolution bandwidth is set 1 % to 5 % of the bandwidth 4. The occupied bandwidth (99%) is measured with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

3.1.6 Results

Test Results		
Mode	Channel [MHz]	Bandwidth [kHz]
Modulated16	402.45	265.725
Modulated32	402.45	246.600
Modulated82	402.45	224.775
Modulated197	402.45	242.550
Modulated16	403.65	255.825
Modulated32	403.65	270.450
Modulated82	403.65	230.400
Modulated197	403.65	243.225
Modulated16	404.85	272.700
Modulated32	404.85	275.175
Modulated82	404.85	235.350
Modulated197	404.85	255.375

Occupied Bandwidth RSS-243

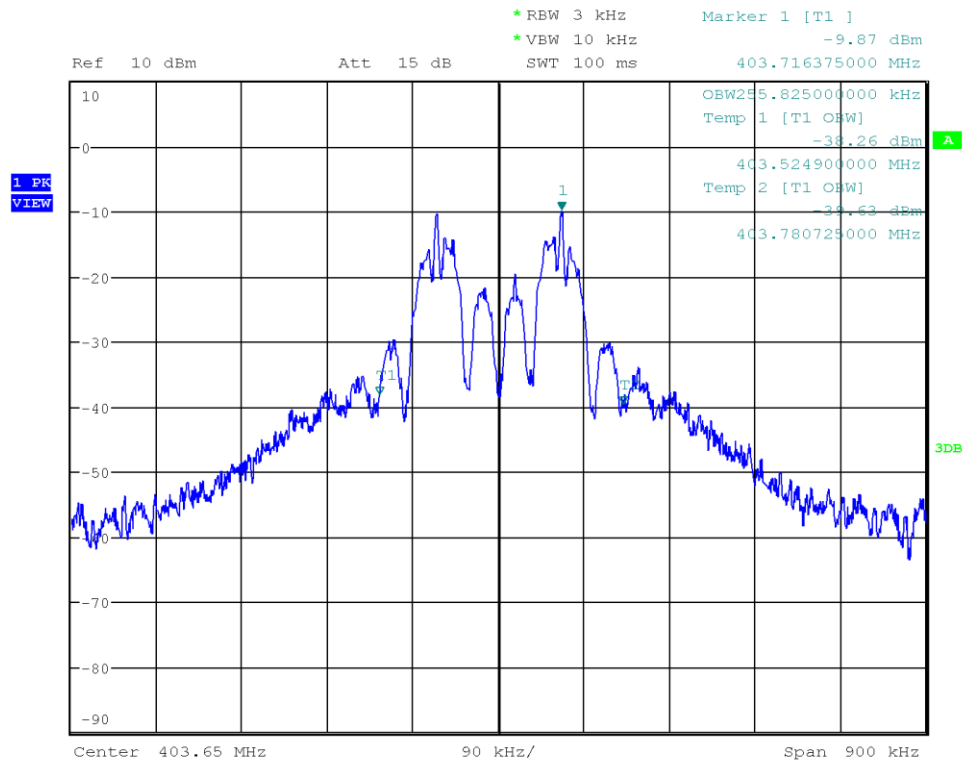
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 265.725



Date: 12.JAN.2022 13:08:07

Occupied Bandwidth RSS-243

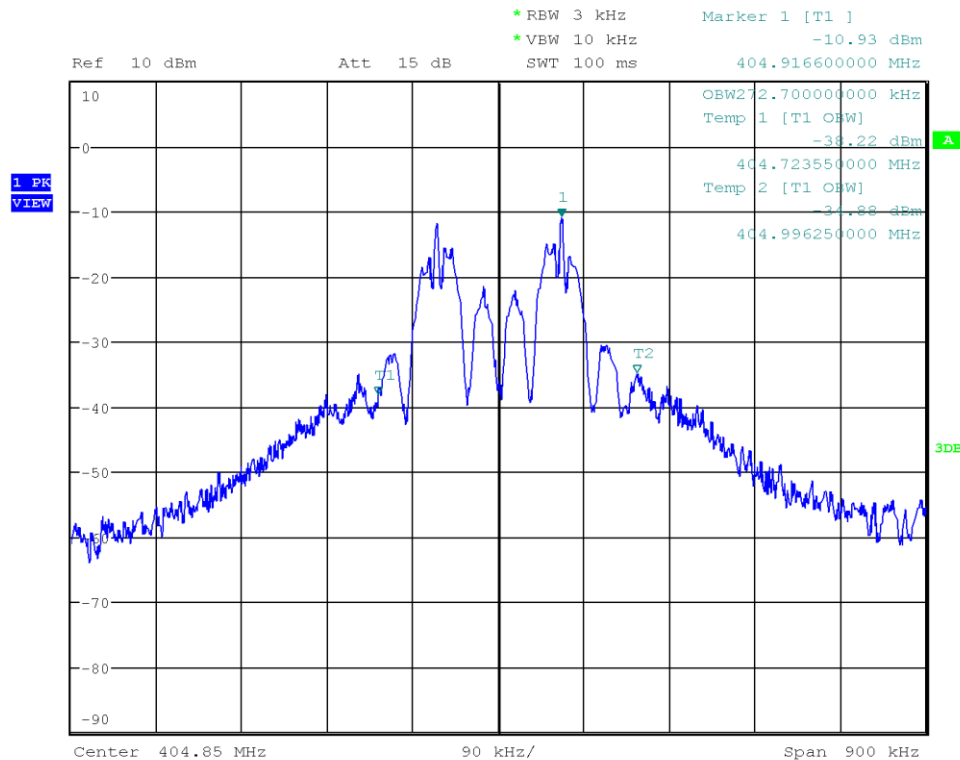
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 255.825



Date: 12.JAN.2022 13:09:44

Occupied Bandwidth RSS-243

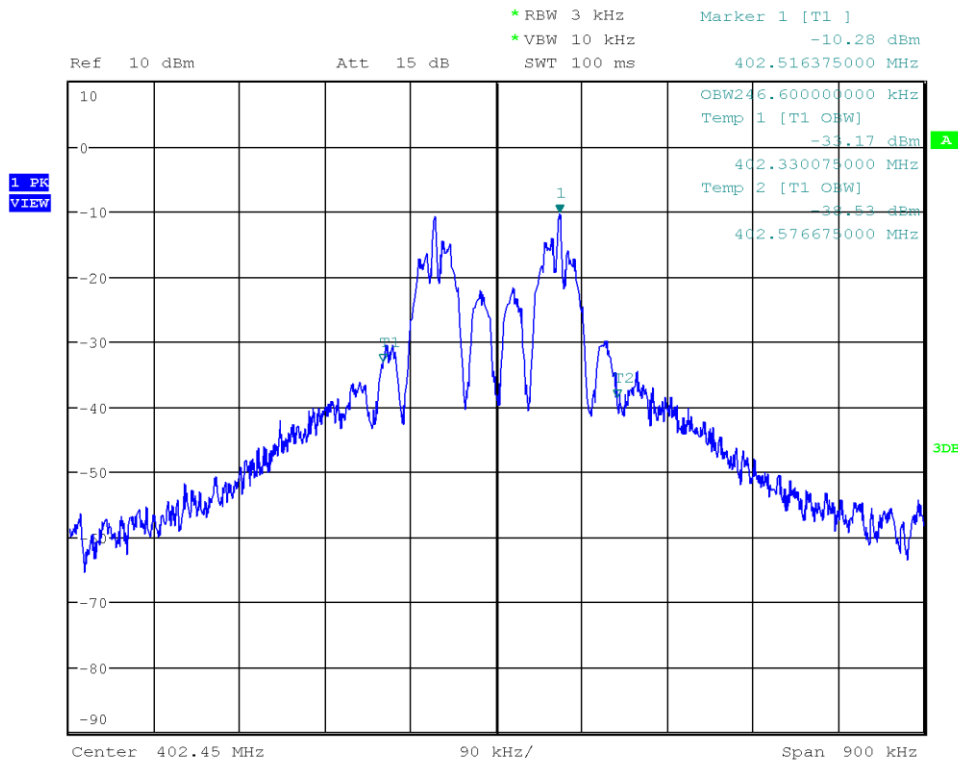
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 16 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 272.700



Date: 12.JAN.2022 13:11:01

Occupied Bandwidth RSS-243

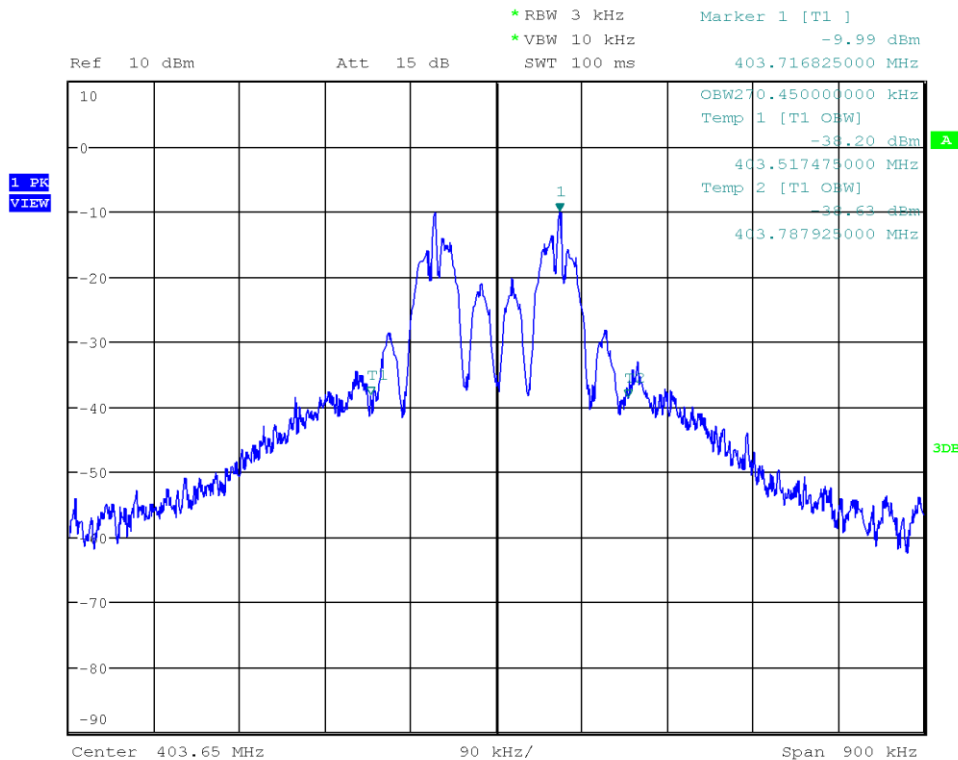
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 32 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 246.600



Date: 12.JAN.2022 13:12:27

Occupied Bandwidth RSS-243

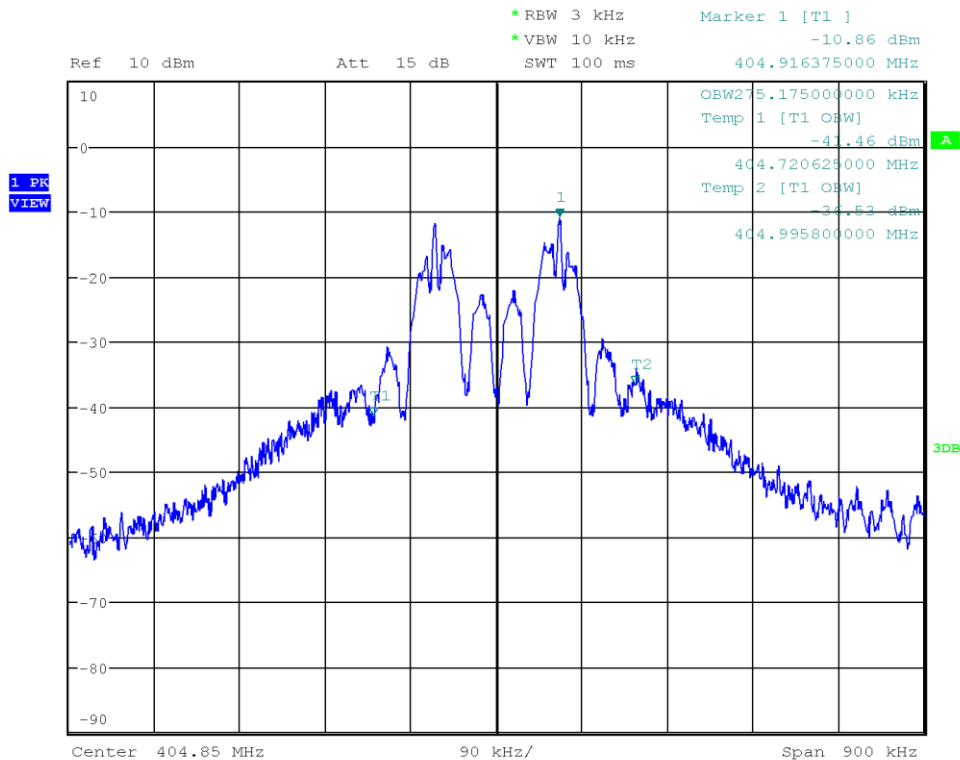
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 32 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 270.450



Date: 12.JAN.2022 13:15:32

Occupied Bandwidth RSS-243

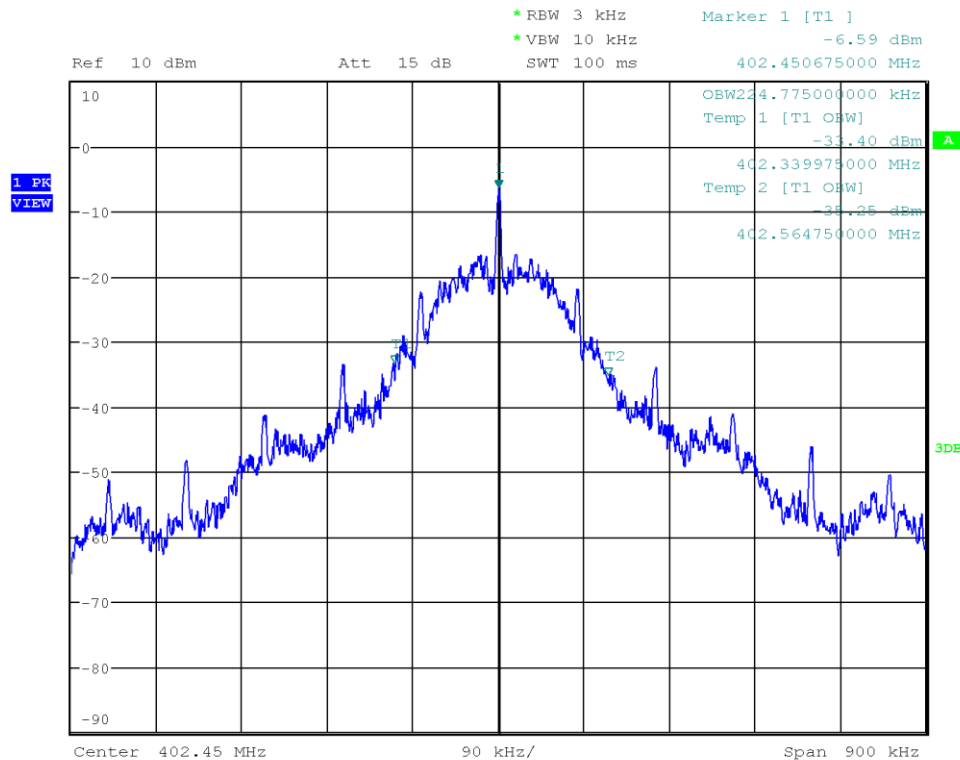
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 32 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 275.175



Date: 12.JAN.2022 13:17:15

Occupied Bandwidth RSS-243

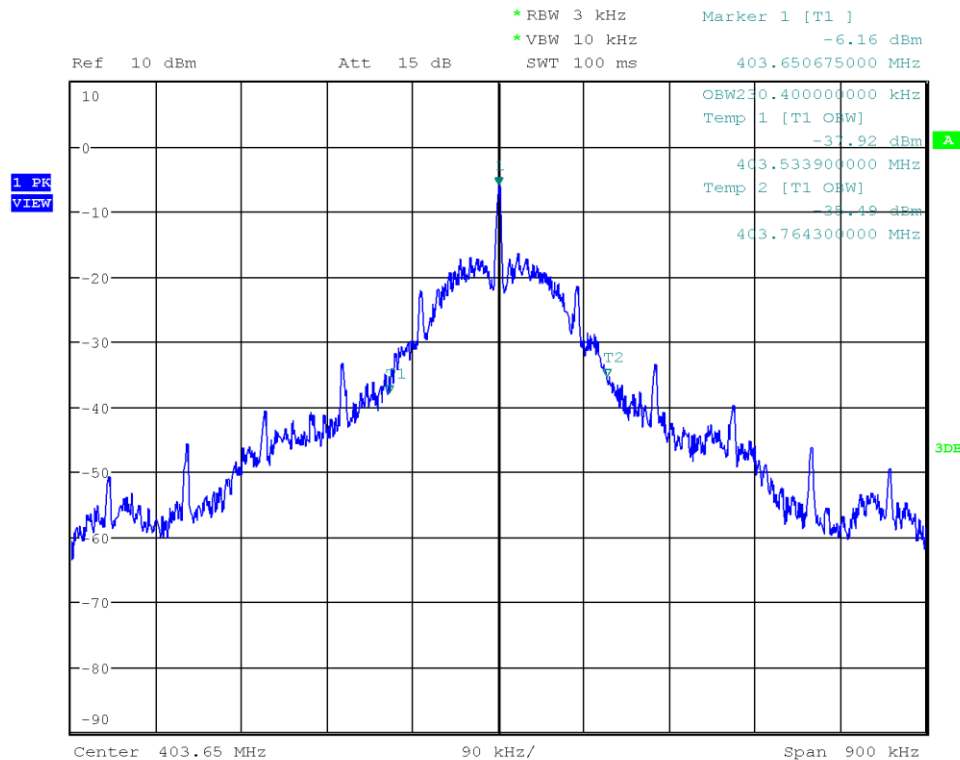
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 82 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 224.775



Date: 12.JAN.2022 13:40:15

Occupied Bandwidth RSS-243

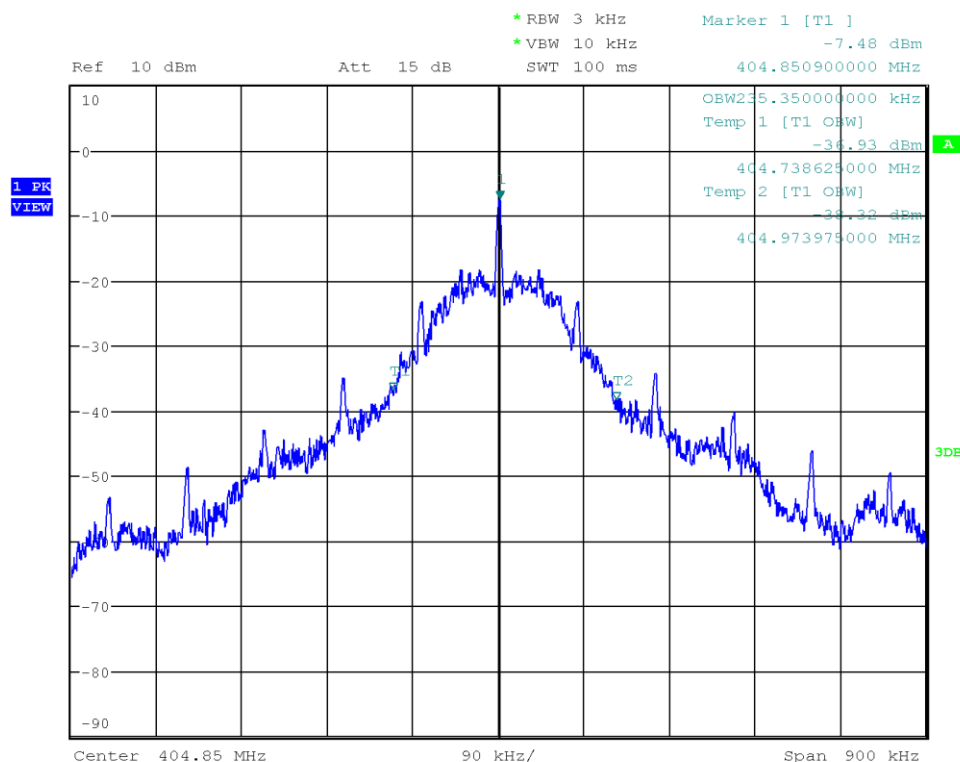
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 82 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 230.400



Date: 12.JAN.2022 13:40:52

Occupied Bandwidth RSS-243

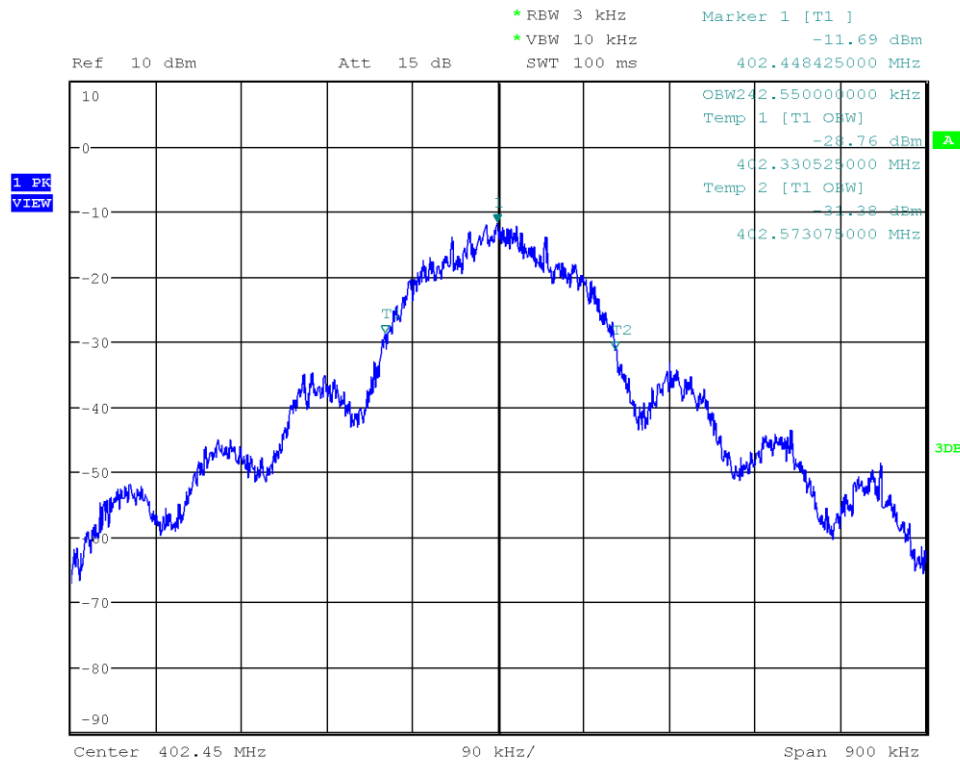
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 82 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 235.350



Date: 12.JAN.2022 13:41:52

Occupied Bandwidth RSS-243

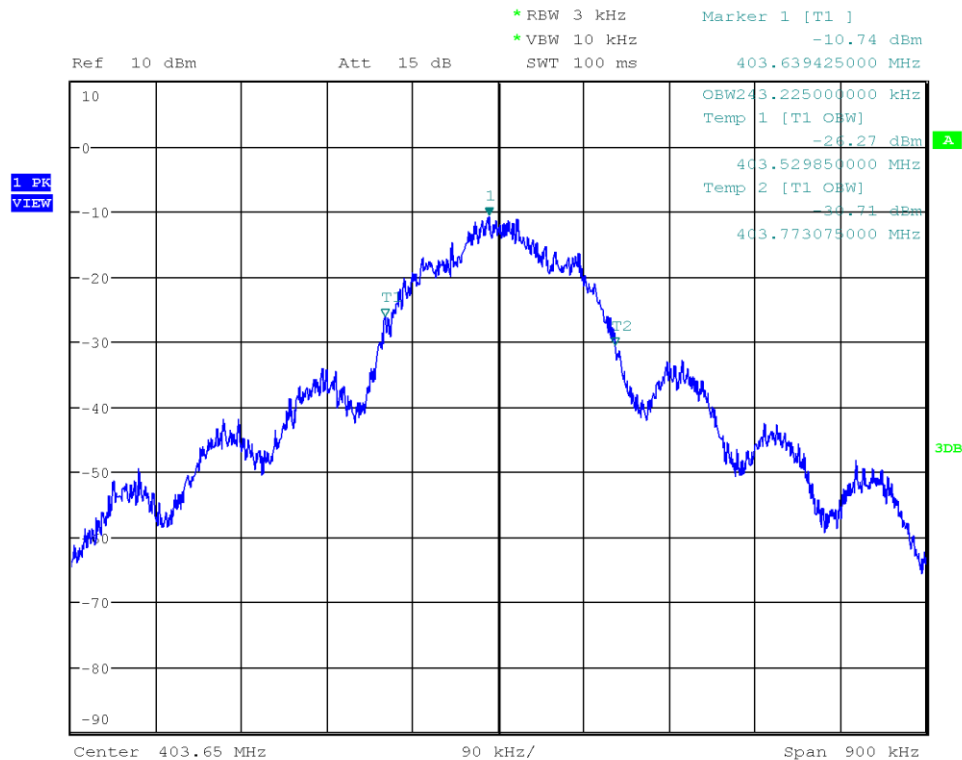
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 197 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 242.550



Date: 12.JAN.2022 13:42:42

Occupied Bandwidth RSS-243

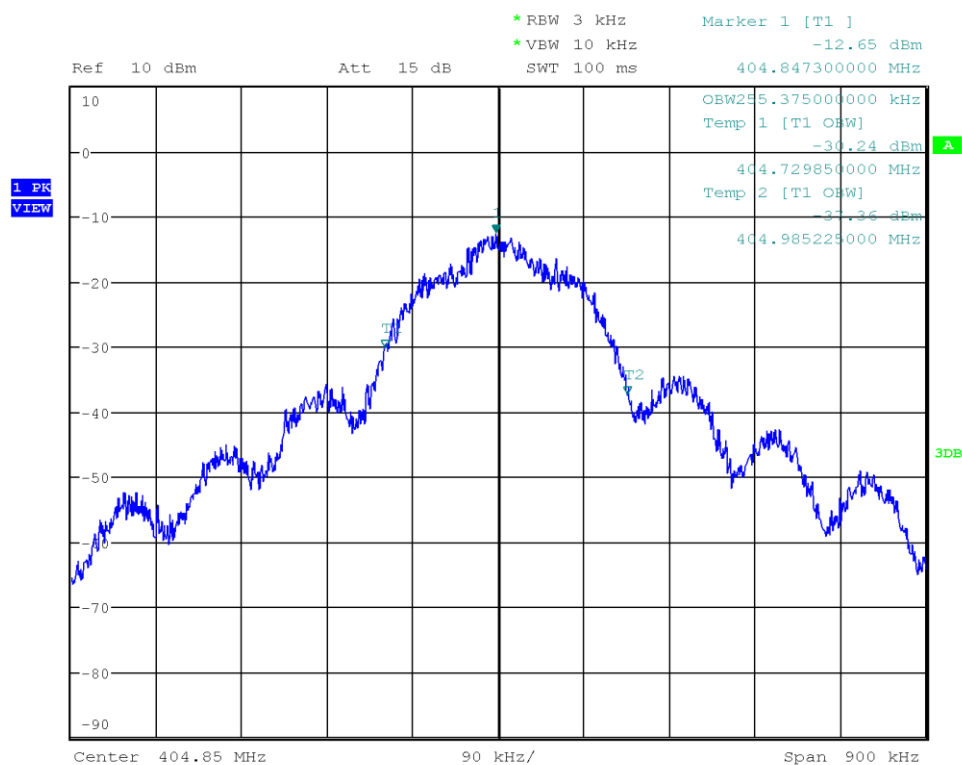
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 197 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 243.225



Date: 12.JAN.2022 13:43:40

Occupied Bandwidth RSS-243

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Method: RSS-Gen Issue 4 6.6 (Occupied Bandwidth)
 Operational Mode: 2FSK, 197 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Occupied Bandwidth [kHz]: 255.375



Date: 12.JAN.2022 13:44:49

3.2 Test Conditions and Results - Emission bandwidth

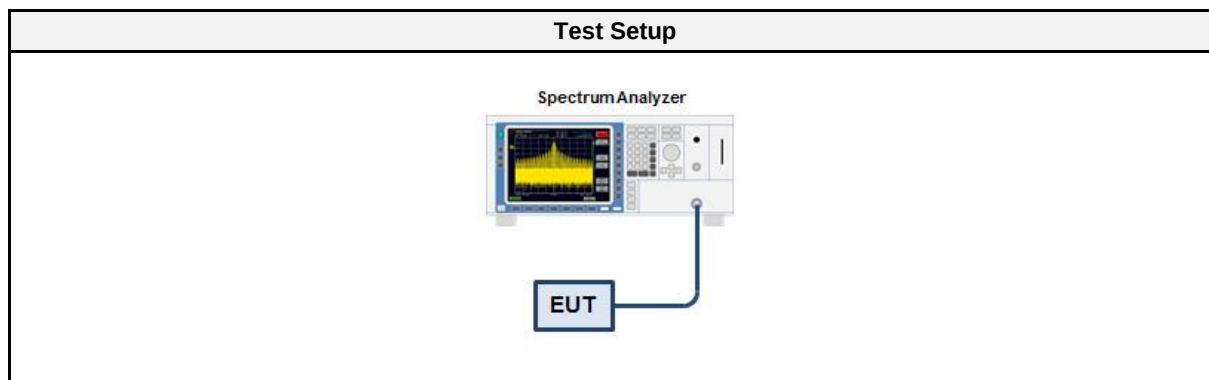
3.2.1 Information

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	2022-01-13

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 3	EF00241	2021-07	2023-07

3.2.5 Procedure

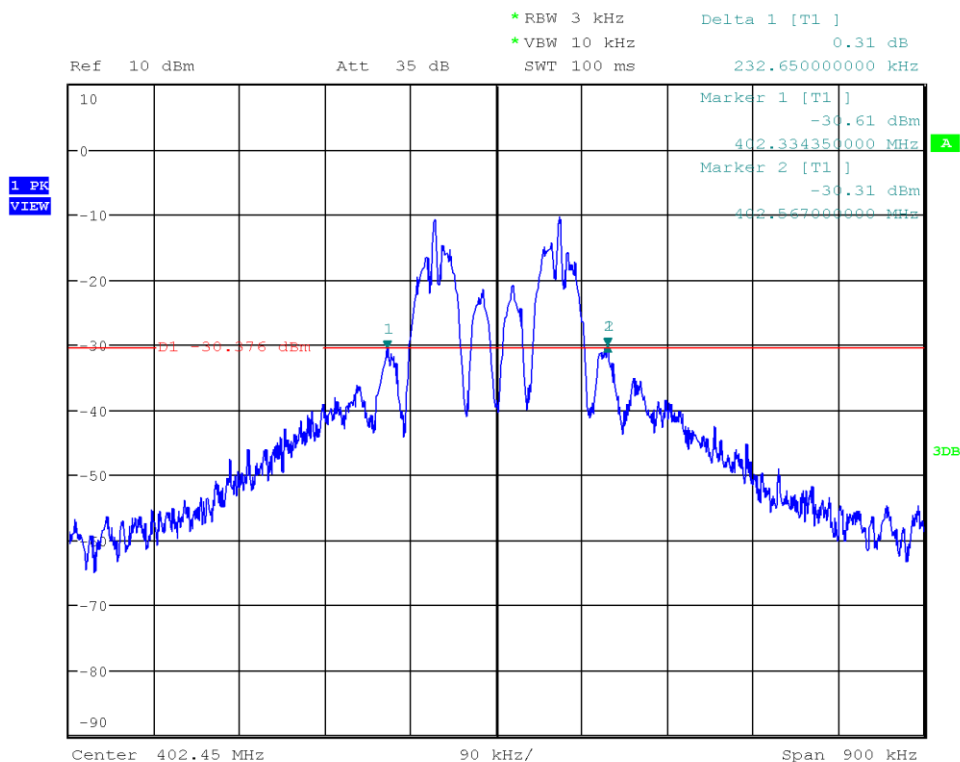
Test Procedure
1. EUT set to test mode 2. Span set to at least twice the emission spectrum 3. Detector set to peak and max hold 4. Envelope peak value of emission spectrum is selected 5. Marker on envelope of spectrum is set to level of -20 dB to the left of the peak 6. Marker on envelope of spectrum 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 [kHz]
Modulated16	402.45	232.650
Modulated32	402.45	232.650
Modulated82	402.45	169.650
Modulated197	402.45	250.200
Modulated16	403.65	229.050
Modulated32	403.65	229.950
Modulated82	403.65	169.425
Modulated197	403.65	247.050
Modulated16	404.85	208.125
Modulated32	404.85	206.775
Modulated82	404.85	170.325
Modulated197	404.85	247.500

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 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: 2022-01-12
 Lower Frequency [MHz]: 402.334
 Upper Frequency [MHz]: 402.567
 20 dB Bandwidth [kHz]: 232.650



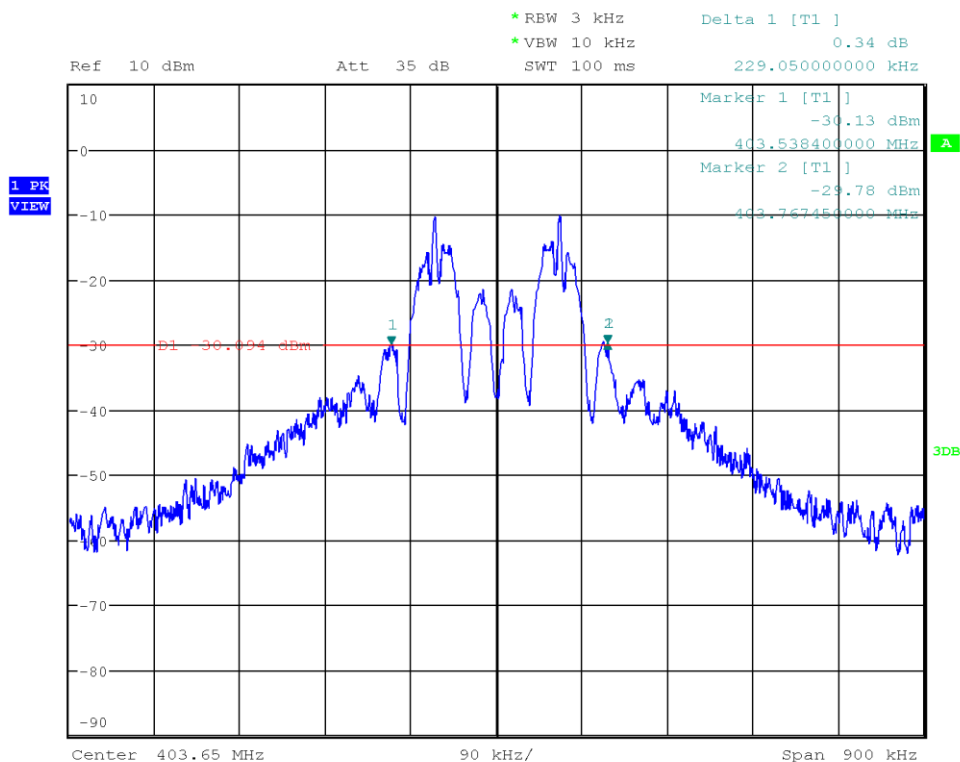
Date: 12.JAN.2022 14:01:32

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 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: 2022-01-12
 Lower Frequency [MHz]: 403.538
 Upper Frequency [MHz]: 403.767
 20 dB Bandwidth [kHz]: 229.050



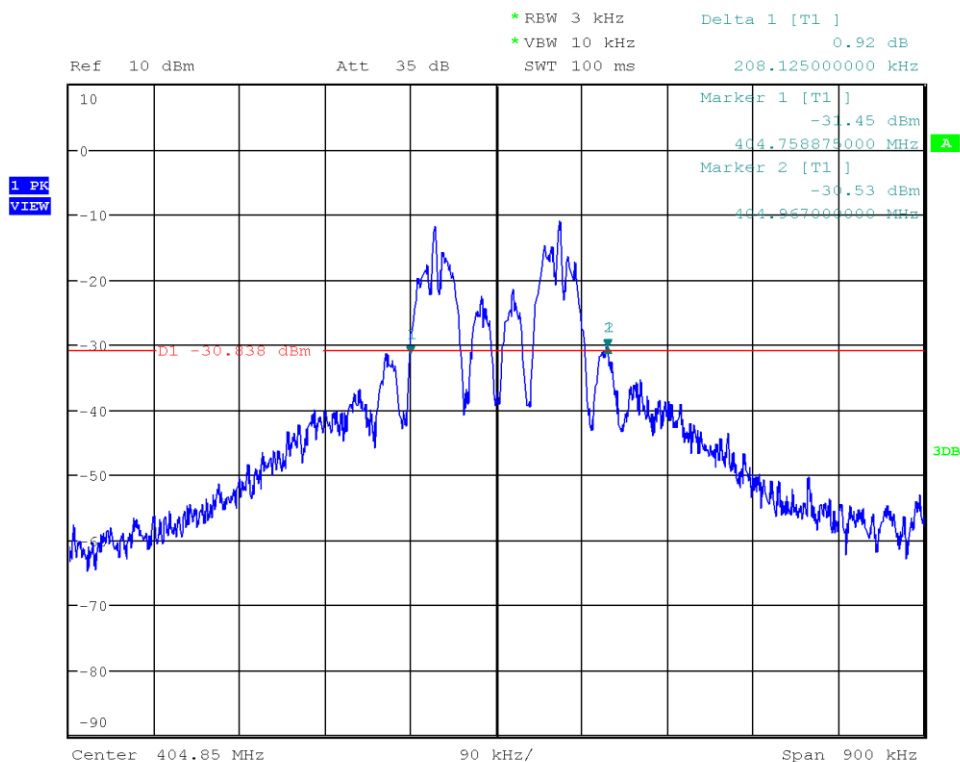
Date: 12.JAN.2022 14:02:23

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 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: 2022-01-12
 Lower Frequency [MHz]: 404.759
 Upper Frequency [MHz]: 404.967
 20 dB Bandwidth [kHz]: 208.125



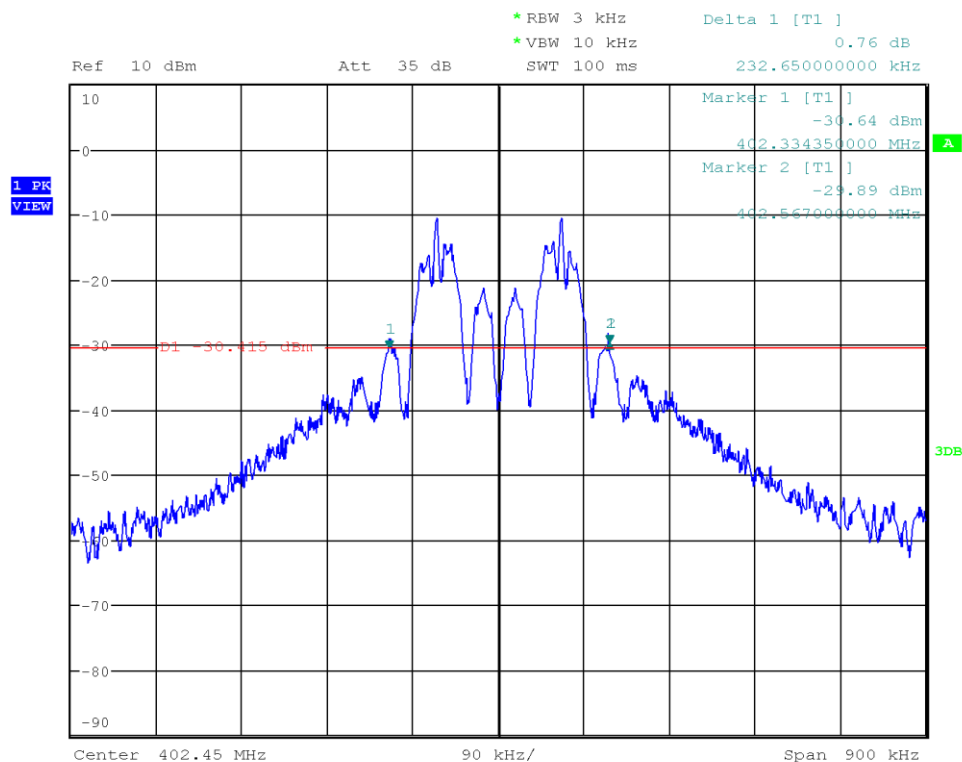
Date: 12.JAN.2022 14:03:07

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 32 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 402.334
 Upper Frequency [MHz]: 402.567
 20 dB Bandwidth [kHz]: 232.650



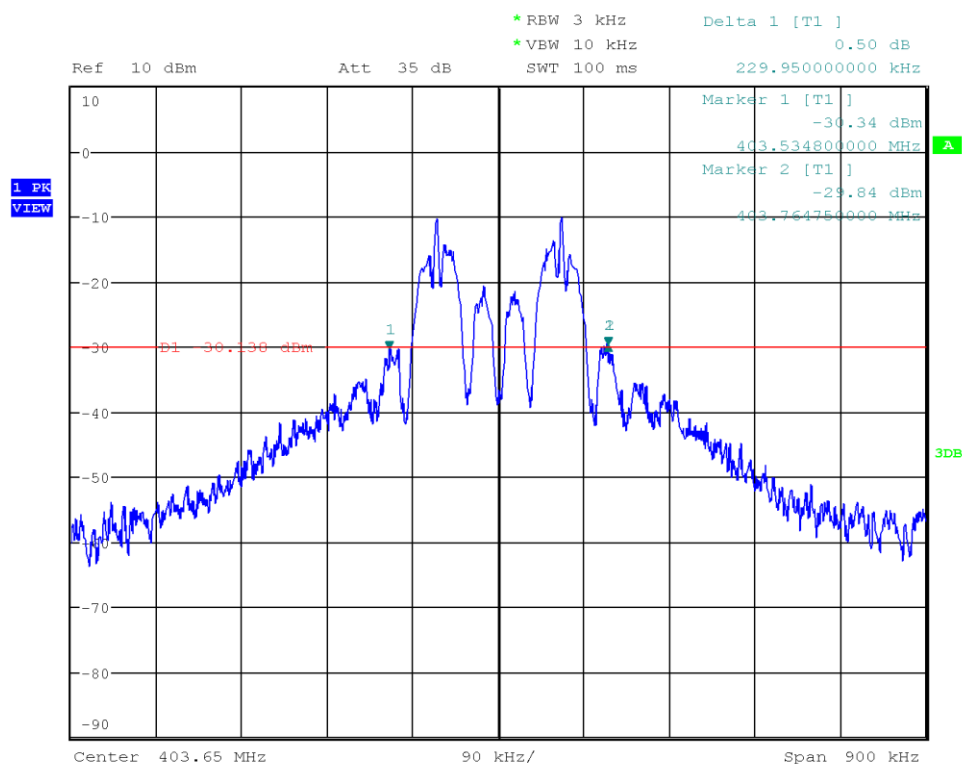
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Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 32 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 403.535
 Upper Frequency [MHz]: 403.765
 20 dB Bandwidth [kHz]: 229.950



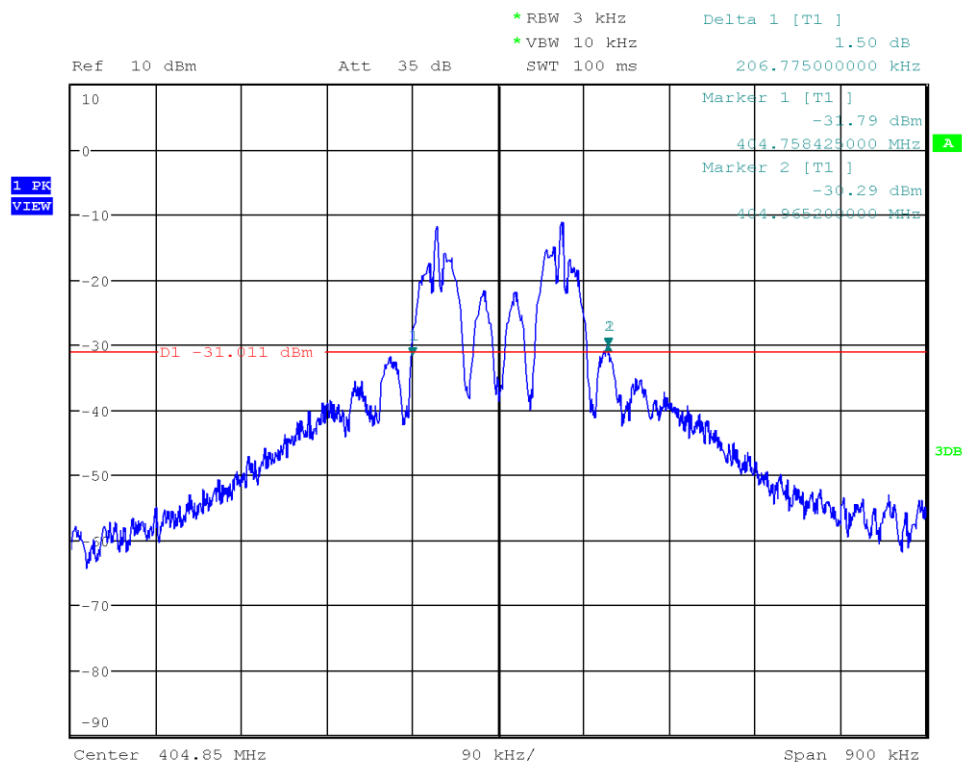
Date: 12.JAN.2022 14:07:28

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 32 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 404.758
 Upper Frequency [MHz]: 404.965
 20 dB Bandwidth [kHz]: 206.775



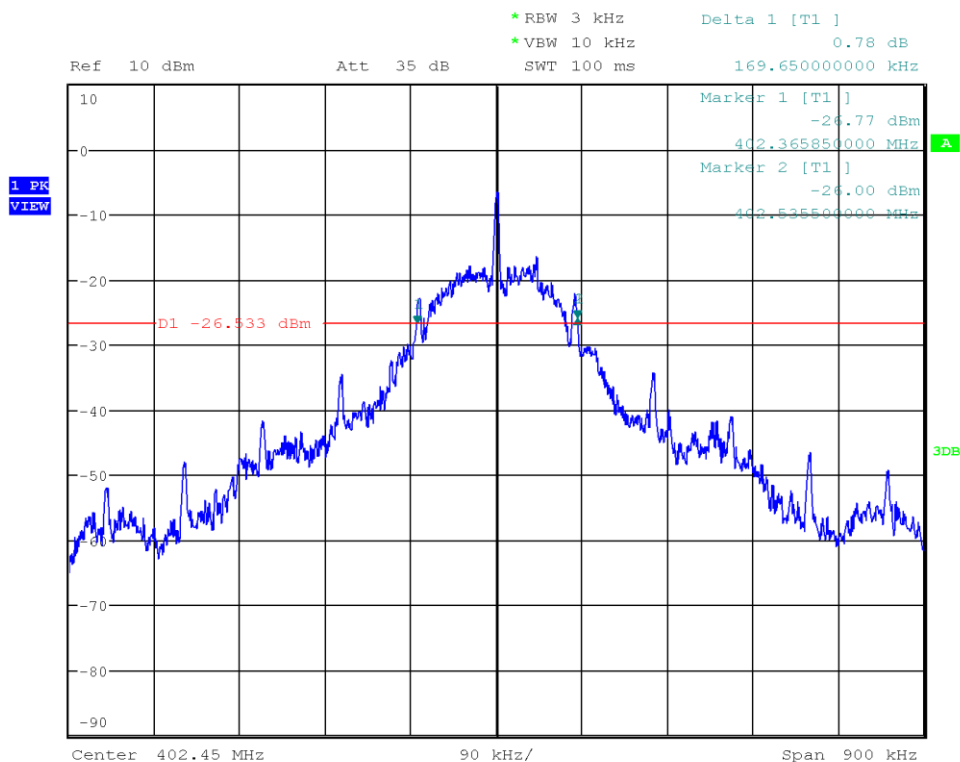
Date: 12.JAN.2022 14:09:03

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 82 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 402.366
 Upper Frequency [MHz]: 402.536
 20 dB Bandwidth [kHz]: 169.650



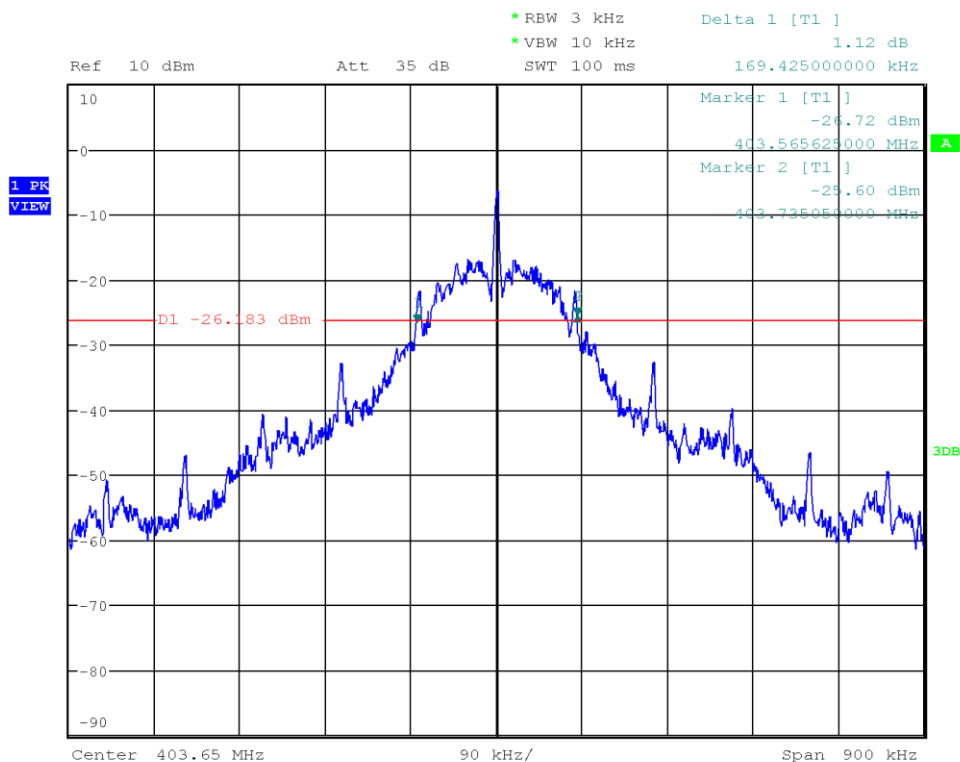
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Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 82 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 403.566
 Upper Frequency [MHz]: 403.735
 20 dB Bandwidth [kHz]: 169.425



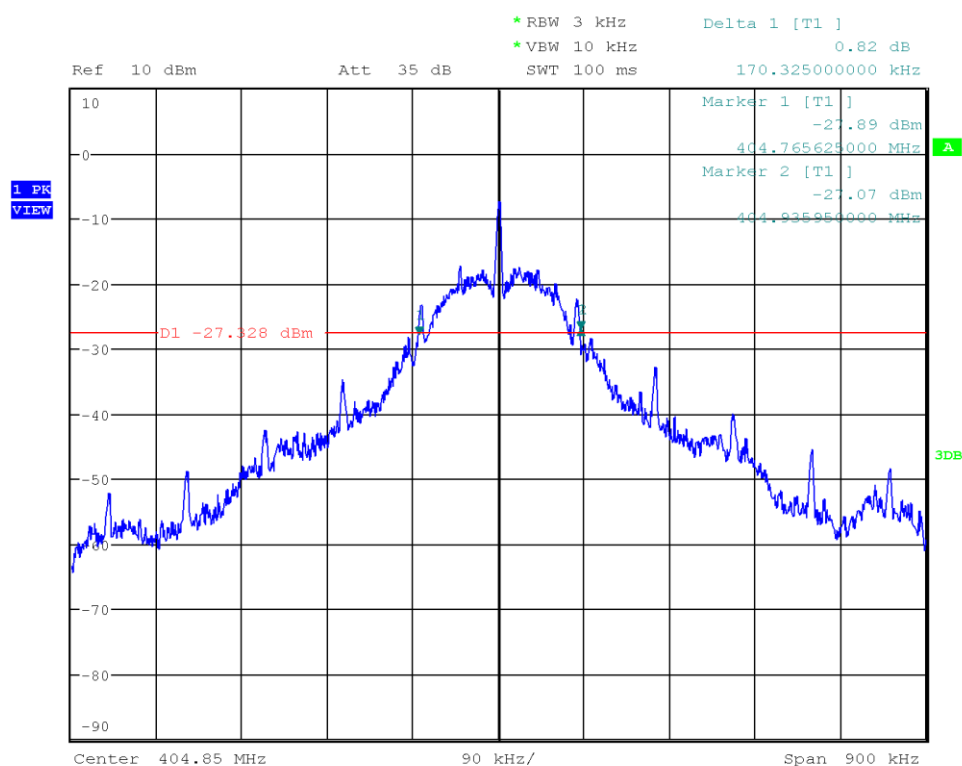
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Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 82 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 404.766
 Upper Frequency [MHz]: 404.936
 20 dB Bandwidth [kHz]: 170.325



Date: 12.JAN.2022 14:13:45

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 197 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 402.326
 Upper Frequency [MHz]: 402.576
 20 dB Bandwidth [kHz]: 250.200



Date: 12.JAN.2022 14:15:08

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 197 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 403.529
 Upper Frequency [MHz]: 403.776
 20 dB Bandwidth [kHz]: 247.050



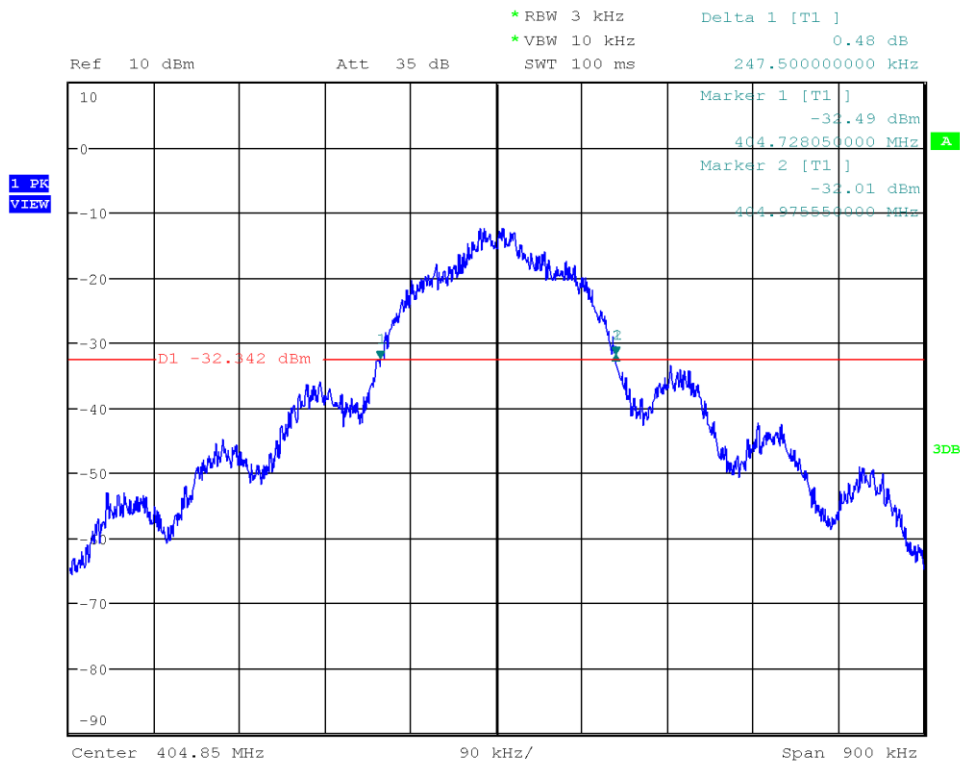
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Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

20 dB Bandwidth FCC

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Reference Standards: FCC 95.627
 Reference Method: 47 CFR § 95.627(a)(6)(i)
 Operational Mode: 2FSK, 197 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom/Vnom
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-12
 Lower Frequency [MHz]: 404.728
 Upper Frequency [MHz]: 404.976
 20 dB Bandwidth [kHz]: 247.500



Date: 12.JAN.2022 14:17:38

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

3.3 Test Conditions and Results - Frequency stability

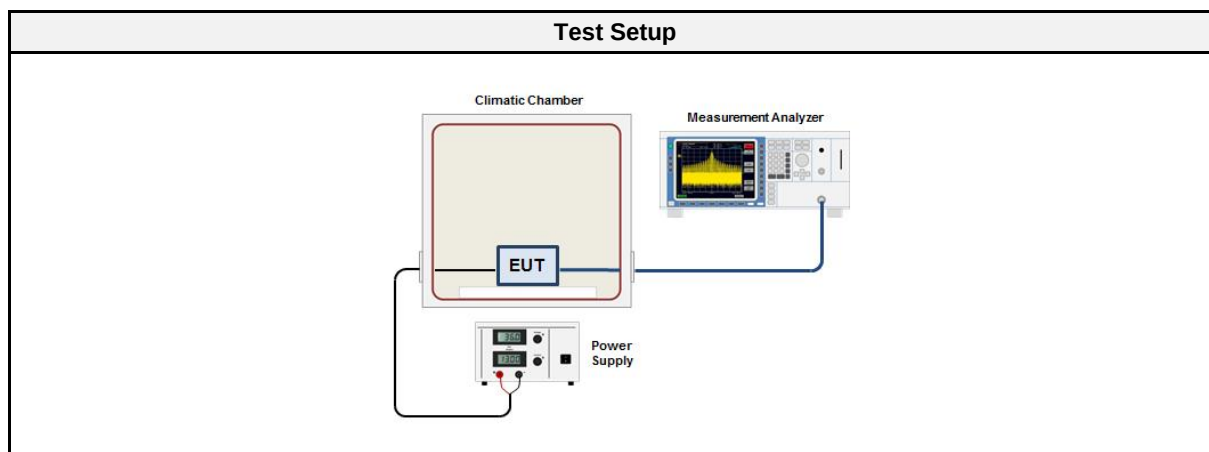
3.3.1 Information

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	2022-01-13

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 3	EF00241	2021-07	2023-07
Climatic chamber	Vötsch	VT 4010	EF00134	2021-06	2022-06
Cable (diverse)	(diverse)	(diverse)	EF00779	2020-12	2022-02

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	3.0	402.449735	-00.66
402.45	25	3.0	402.450474	01.18
402.45	45	3.0	402.449424	-01.43
403.65	37	3.0	403.649822	-00.44
403.65	25	3.0	403.650538	01.33
403.65	45	3.0	403.649507	-01.22
404.85	37	3.0	404.849905	-00.23
404.85	25	3.0	404.850606	01.50
404.85	45	3.0	404.849589	-01.02

3.4 Test Conditions and Results - Transmitter output power

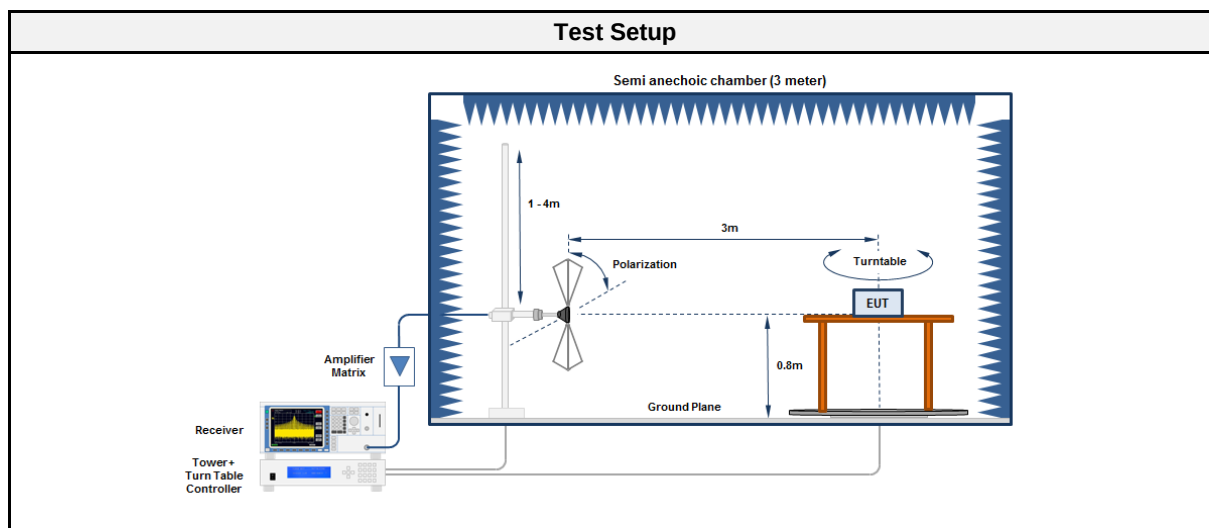
3.4.1 Information

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	2022-01-11

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 Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF01616	2021-09	2022-09
Spectrum Analyzer	R&S	FSU 26	EF01631	2021-07	2022-07
Antenna	R&S	HL 223	EF00187	2019-05	2022-05
Antenna	R&S	HL 223	EF00212	2019-05	2022-05

3.4.5 Procedure

Test Procedure
1. EUT set to test frequency with 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

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	-32.5	pk	-16	-16.50
404.85	-35.5	pk	-16	-19.50

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

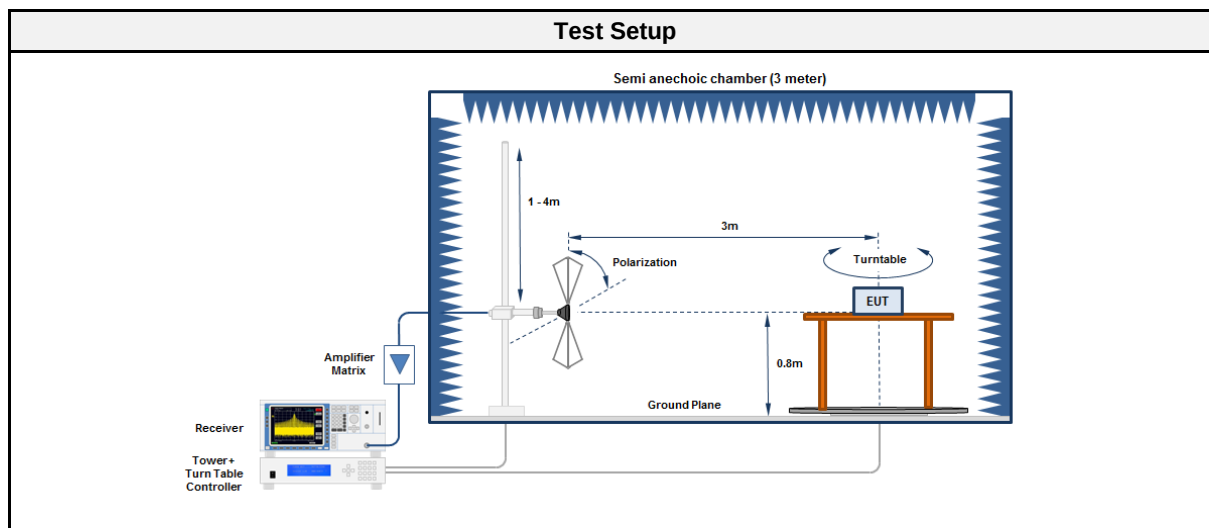
3.5.1 Information

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	2022-01-11

3.5.2 Limits

Limits FCC	
Frequency range	Limit
402 MHz – 250 kHz $\leq f \leq$ 402 MHz	20 dB below maximum permitted output power
402 MHz $< f <$ 150 kHz - f_c	20 dB below transmitter output power
150 kHz $+ f_c < f <$ 405 Mhz	20 dB below transmitter output power
405 MHz $\leq f \leq$ 405 MHz + 250 kHz	20 dB below maximum permitted output power
Limits ISED	
Frequency range	Limit
402 MHz – 250 kHz $< f <$ 150 kHz- f_c	20 dB below maximum permitted output power
150 kHz+ $f_c < f <$ 405 MHz + 250 kHz	20 dB below maximum permitted output power
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 Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF01616	2021-09	2022-09
Spectrum Analyzer	R&S	FSU 26	EF01631	2021-07	2022-07
Antenna	R&S	HL 223	EF00187	2019-05	2022-05
Antenna	R&S	HL 223	EF00212	2019-05	2022-05

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

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	401.793	13.39	ver	59.40	-46.01
402.45	402.293	33.71	ver	54.10	-20.39
402.45	402.609	33.71	ver	54.10	-20.39
402.45	403.237	25.07	ver	54.10	-29.03
404.85	404.691	29.15	ver	44.10	-14.95
404.85	405.002	31.32	ver	59.40	-28.08

3.6 Test Conditions and Results - Transmitter unwanted emissions

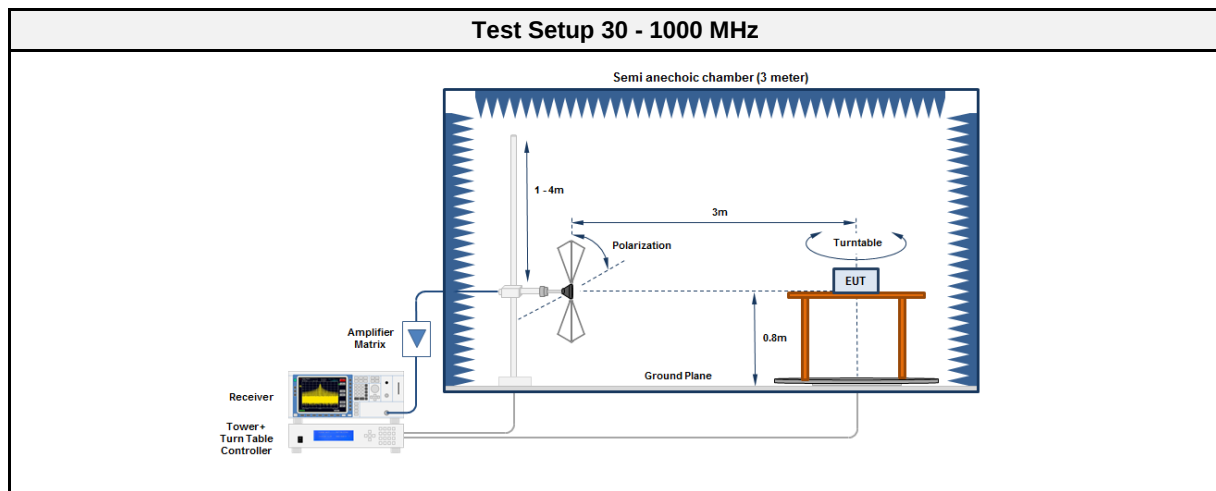
3.6.1 Information

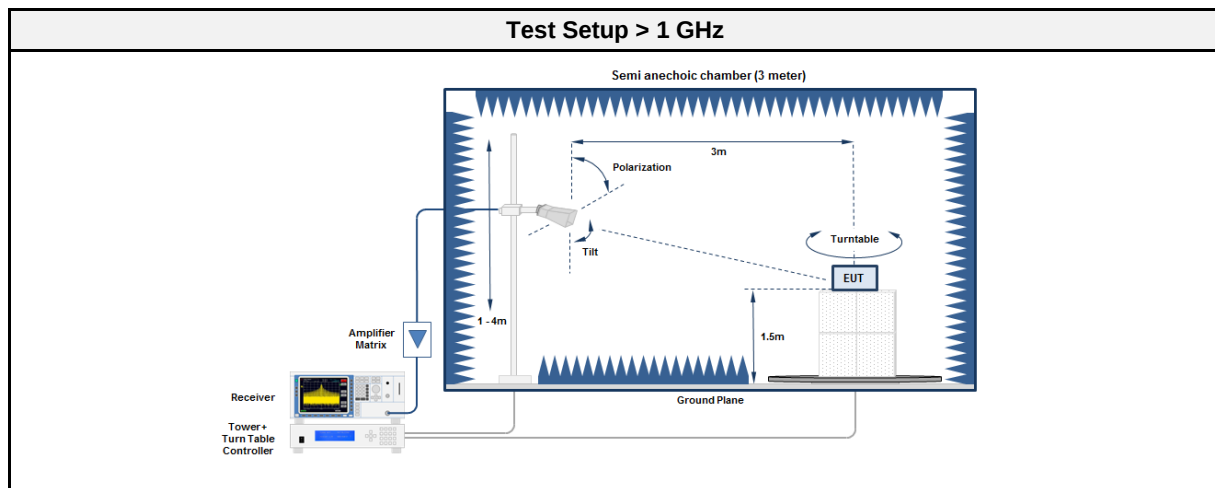
Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.10 6.10
Measurement Uncertainty	± 5.95 dB
Operator	Wilfried Treffke
Date	2022-01-11

3.6.2 Limits

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

3.6.3 Setup





3.6.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2021-02	2024-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2021-07	2022-07
Antenna	R&S	HK 116	EF01564	2020-03	2023-03
Antenna	R&S	HL 223	EF01565	2020-03	2023-03

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2021-02	2024-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2021-07	2022-07
Antenna	Schwarzbeck	BBHA 9120B	EF01678	2021-03	2022-03

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	405.785	23.94	pk	ver	46.00	3	-22.06
404.85	398.475	29.51	pk	ver	46.00	3	-16.49
404.85	405.627	28.83	pk	ver	46.00	3	-17.17

3.7 Test Conditions and Results - Receiver spurious emissions

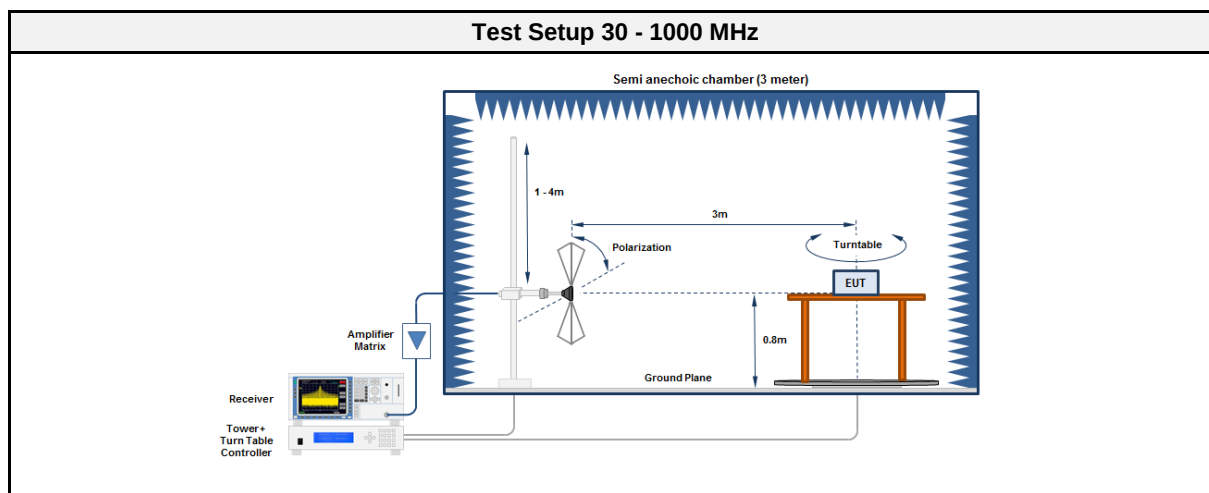
3.7.1 Information

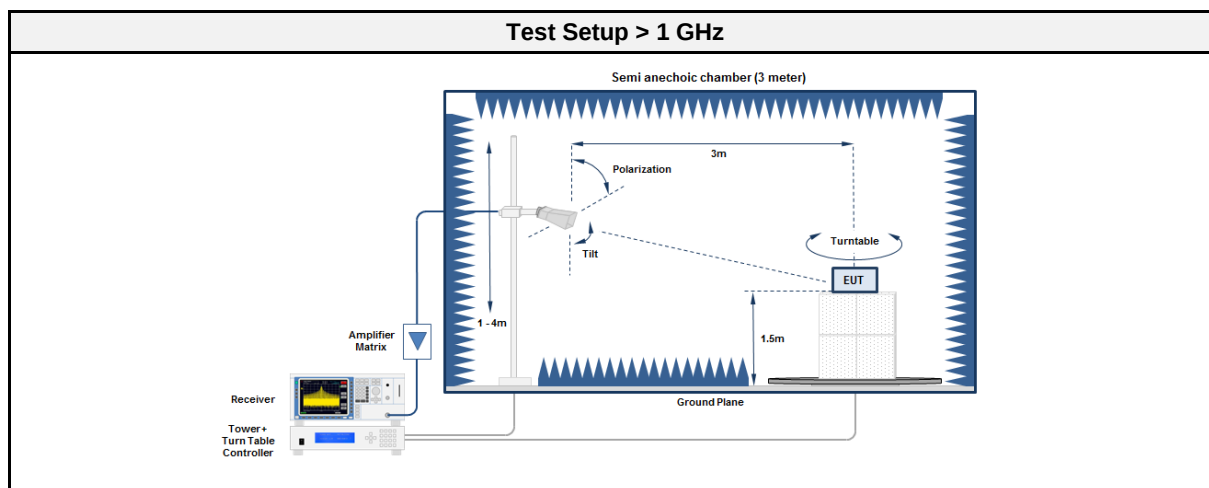
Test Information	
Reference	ISED RSS-243 3.5, 5.6 ISED RSS-Gen 7.3
Measurement Method	ANSI C63.10 6.10
Measurement Uncertainty	± 5.95 dB
Operator	Wilfried Treffke
Date	2022-01-10

3.7.2 Limits

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

3.7.3 Setup





3.7.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2021-02	2024-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2021-07	2022-07
Antenna	R&S	HK 116	EF01564	2020-03	2023-03
Antenna	R&S	HL 223	EF01565	2020-03	2023-03

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2021-02	2024-02
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2021-07	2022-07
Antenna	Schwarzbeck	BBHA 9120B	EF01678	2021-03	2022-03

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	

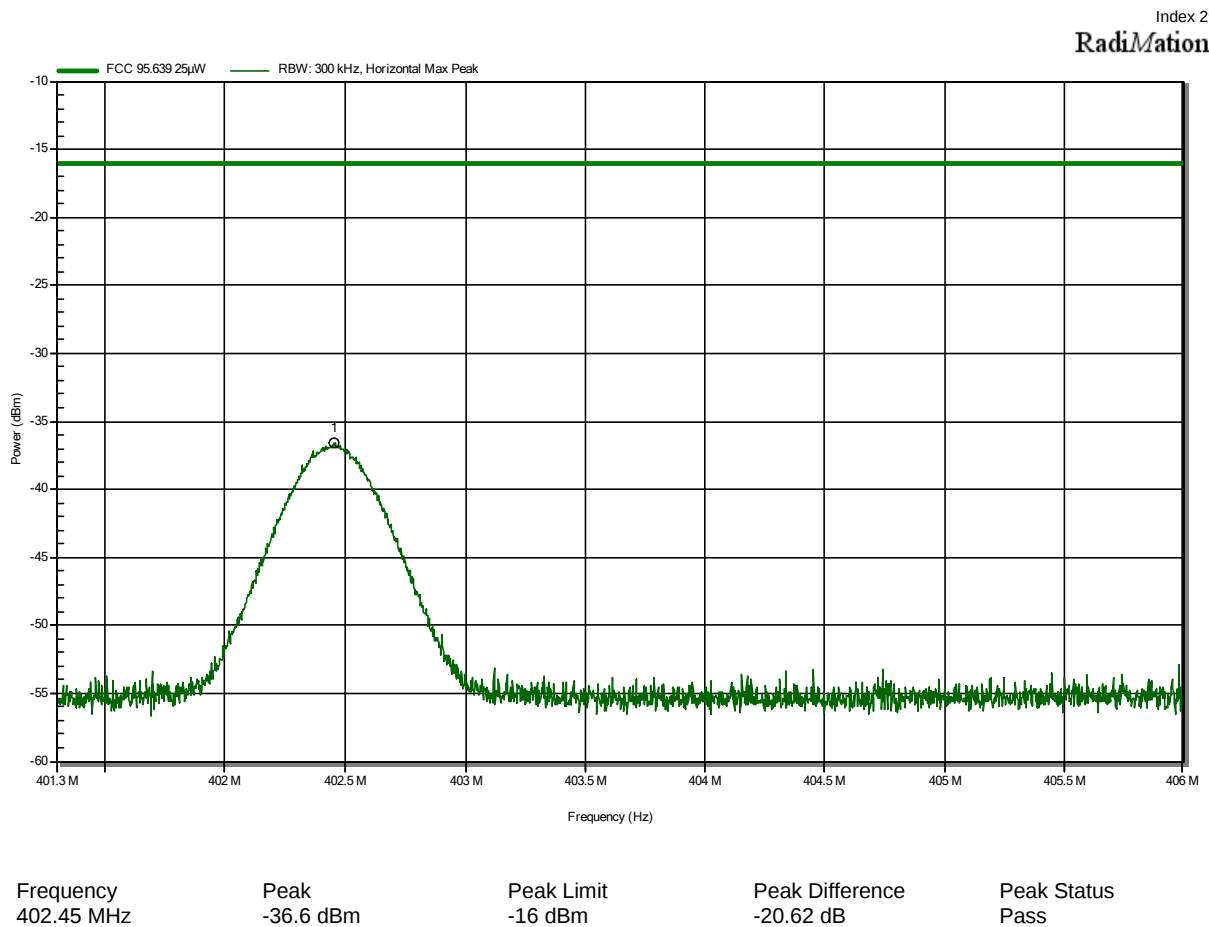
3.7.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Emission Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Margin [dB]
403.65	144.013	31.63	pk	ver	43.50	-11.87
403.65	168	30.53	pk	hor	43.50	-12.97
403.65	359.973	19.52	pk	hor	46.00	-26.48

ANNEX A Transmitter output power

Radiated carrier according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223, Horizontal
 Measurement distance: 3 m
 Mode: Tx; CW; 402.45 MHz
 Test Date: 2022-01-11
 Note: Tx Power EIRP



Test Report No.: G0M-2111-1166-TFC95IMR-V01

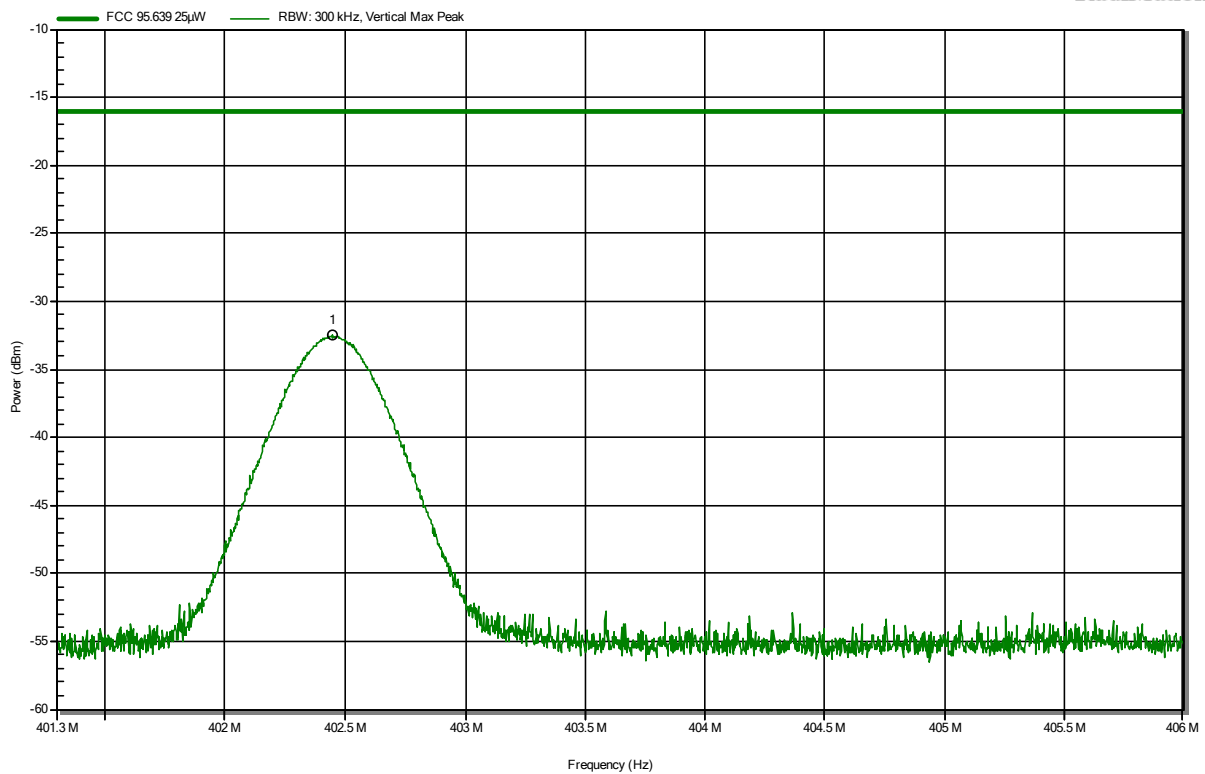
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated carrier according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 402.45 MHz
 Test Date: 2022-01-11
 Note: Tx Power EIRP

Index 30

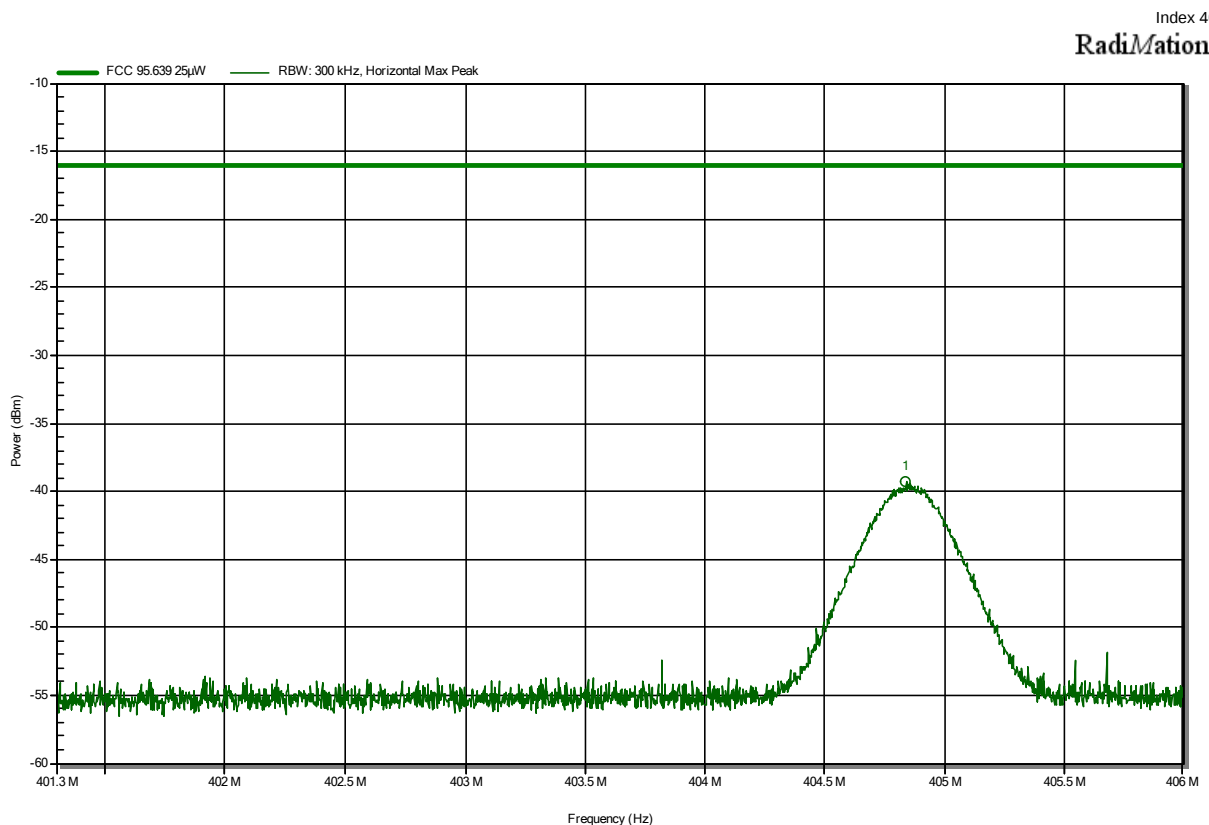
RadiMation



Frequency	Peak	Peak Limit	Peak Difference	Peak Status
402.444 MHz	-32.5 dBm	-16 dBm	-16.52 dB	Pass

Radiated carrier according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223, Horizontal
 Measurement distance: 3 m
 Mode: Tx; CW; 404.85 MHz
 Test Date: 2022-01-11
 Note: Tx Power EIRP



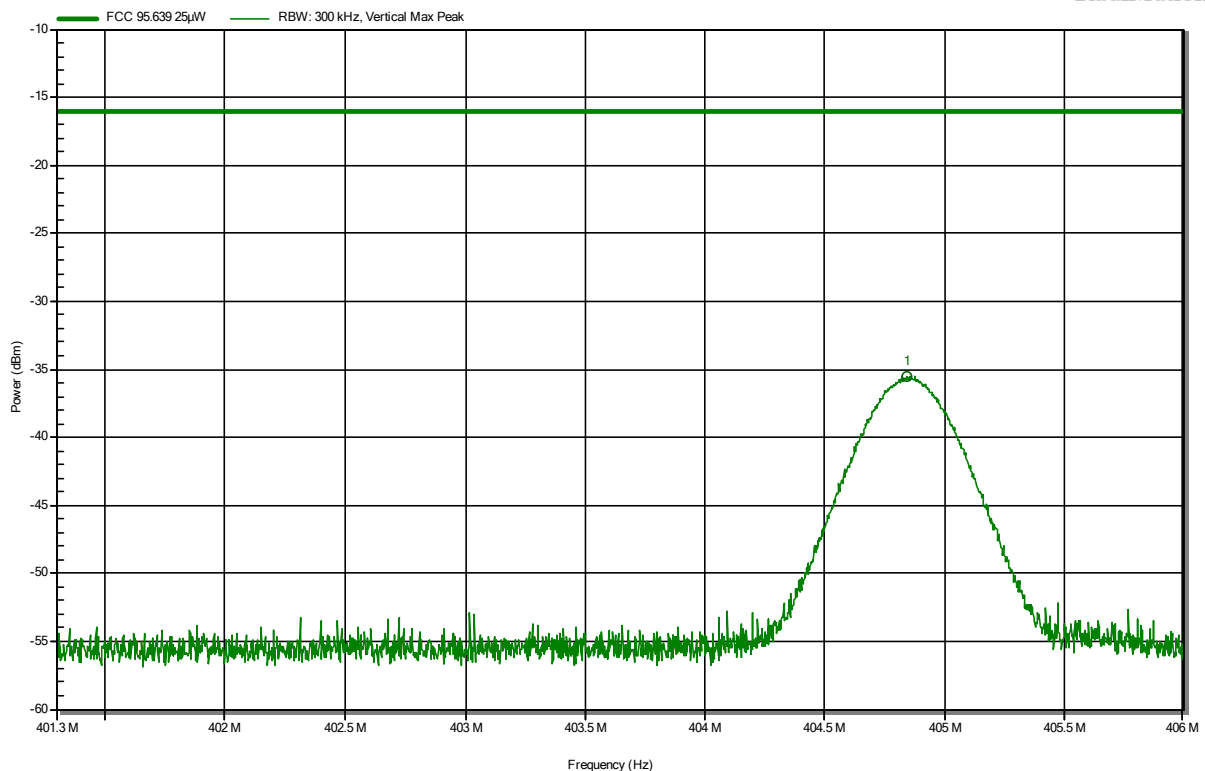
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.84 MHz	-39.3 dBm	-16 dBm	-23.26 dB	Pass

Radiated carrier according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 404.85 MHz
 Test Date: 2022-01-11
 Note: Tx Power EIRP

Index 41

RadiMation

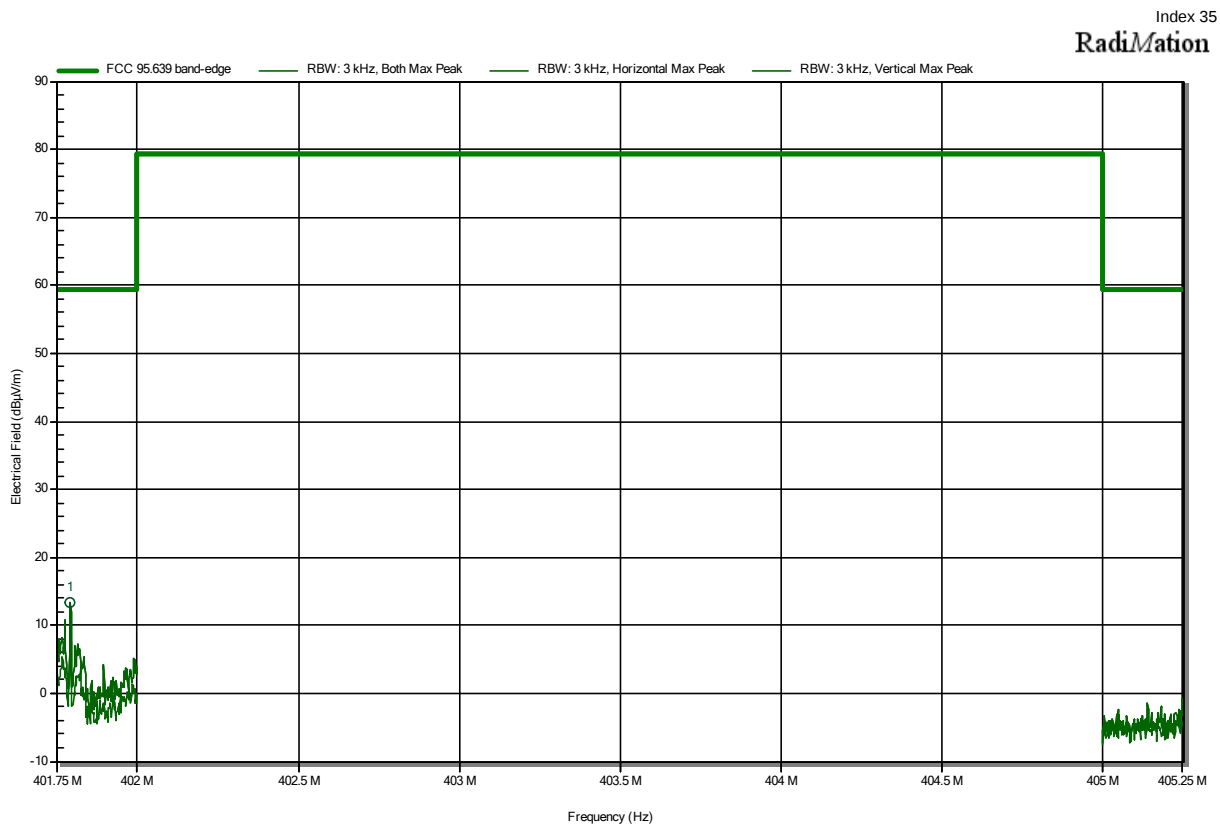


Frequency	Peak	Peak Limit	Peak Difference	Peak Status
404.845 MHz	-35.5 dBm	-16 dBm	-19.54 dB	Pass

ANNEX B Band-edge and In-band Emissions

Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 402.45 MHz
 Test Date: 2022-01-11
 Note: Band-edge



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
401.793 MHz	13.39 dBμV/m	59.4 dBμV/m	-46.01 dB	Pass	Vertical

Test Report No.: G0M-2111-1166-TFC95IMR-V01

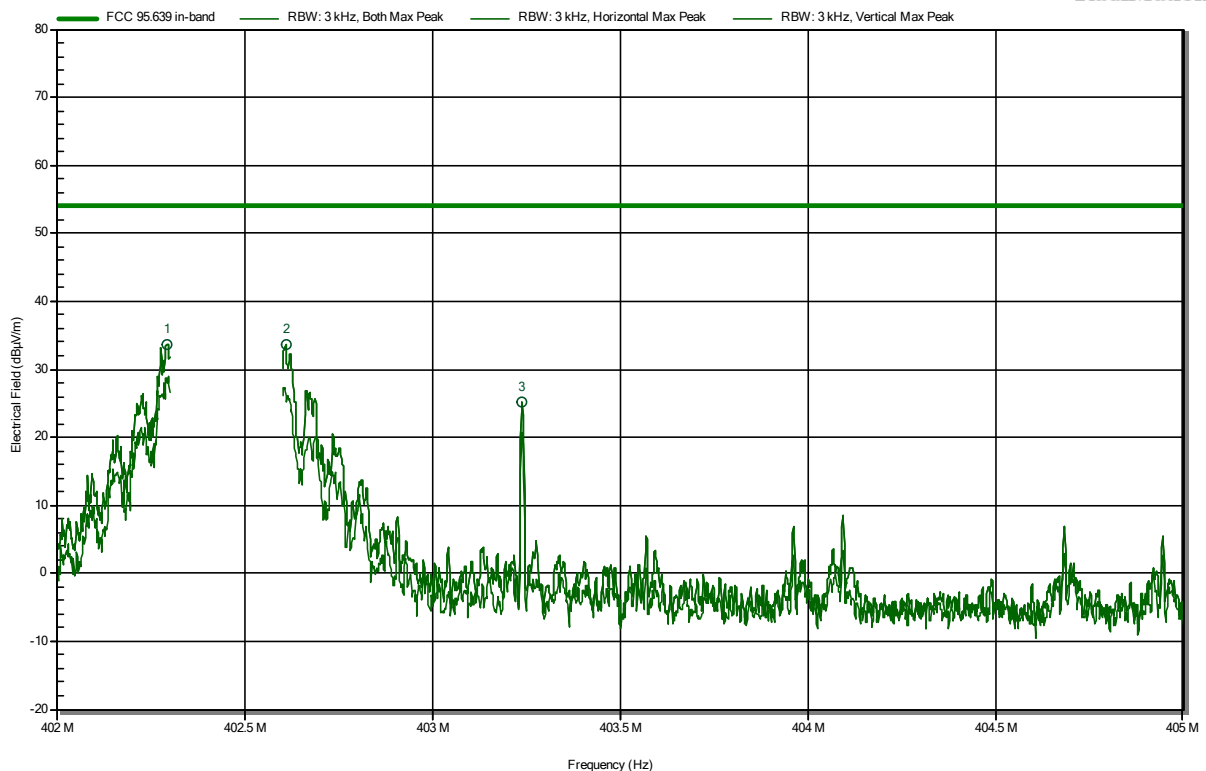
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battrry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 402.45 MHz
 Test Date: 2022-01-11
 Note: In-band emissions

Index 34

RadiMation



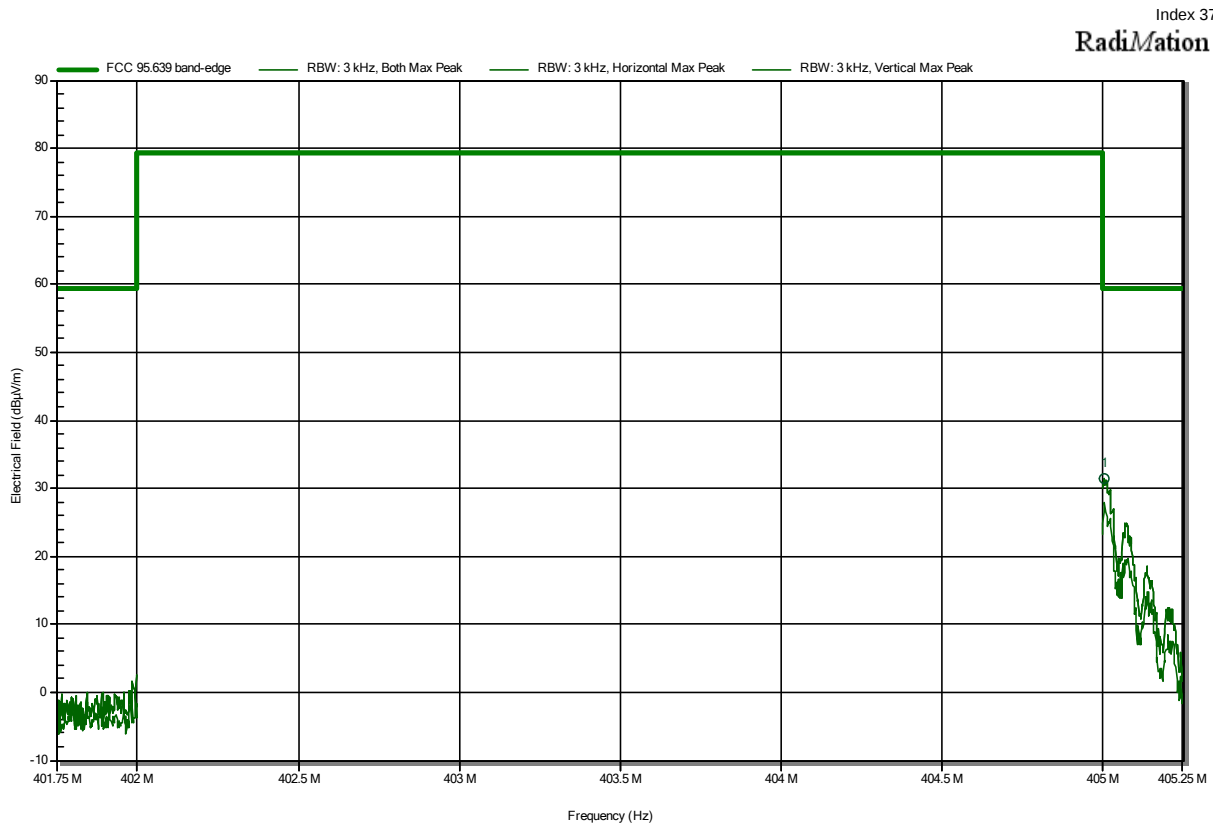
Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
402.293 MHz	33.71 dBμV/m	54.1 dBμV/m	-20.39 dB	Pass	Vertical
402.609 MHz	33.71 dBμV/m	54.1 dBμV/m	-20.39 dB	Pass	Vertical
403.237 MHz	25.07 dBμV/m	54.1 dBμV/m	-29.03 dB	Pass	Vertical

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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

Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

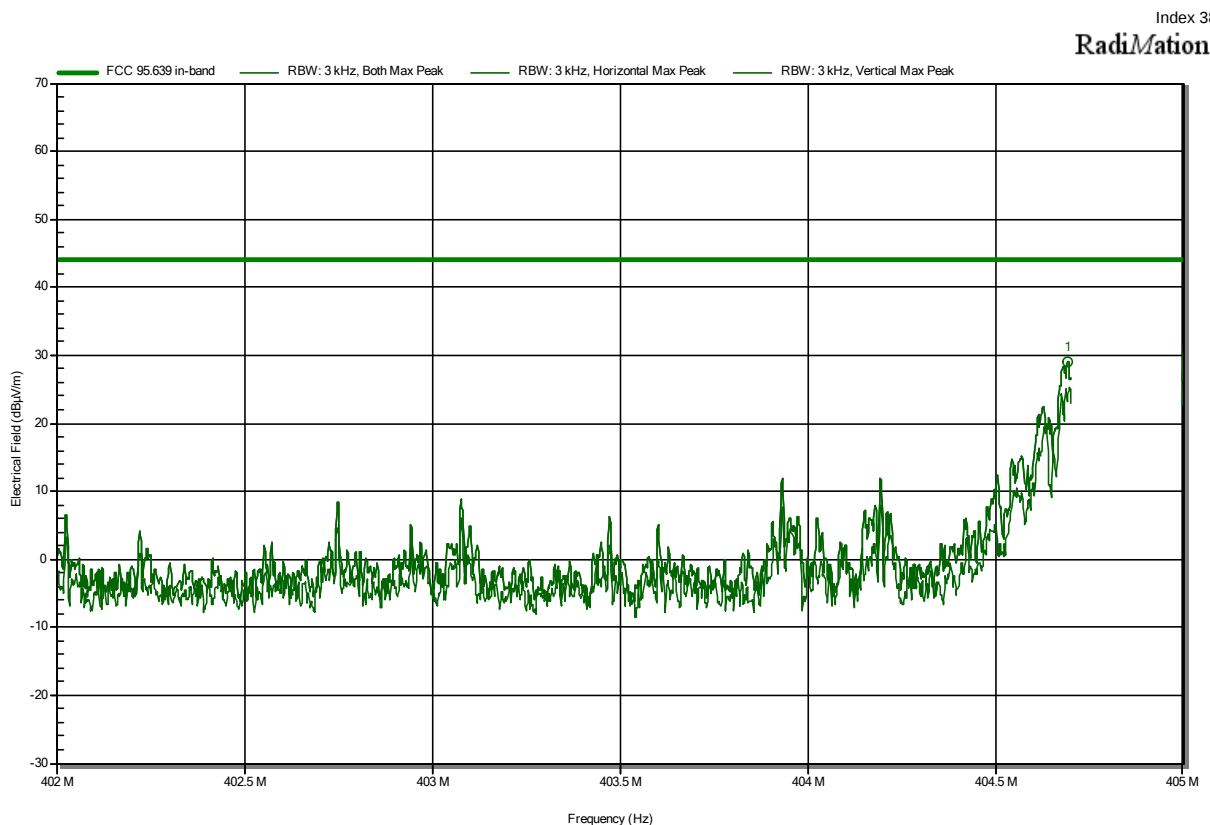
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 404.85 MHz
 Test Date: 2022-01-11
 Note: Band-edge



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
405.002 MHz	31.32 dBµV/m	59.4 dBµV/m	-28.08 dB	Pass	Vertical

Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 404.85 MHz
 Test Date: 2022-01-11
 Note: In-band emissions

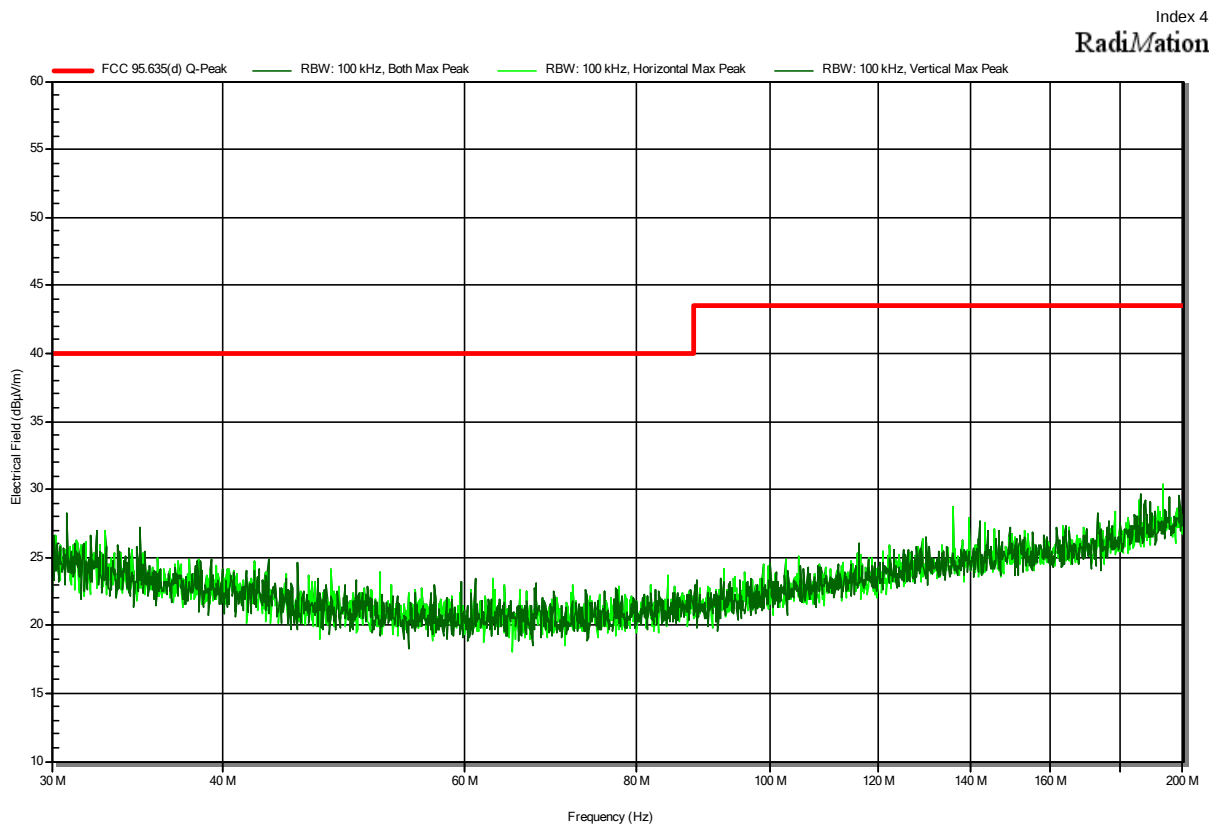


Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
404.691 MHz	29.15 dBμV/m	44.1 dBμV/m	-14.95 dB	Pass	Vertical

ANNEX C Transmitter spurious emissions

Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HK 116
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 402.45 MHz
 Test Date: 2022-01-11
 Note:

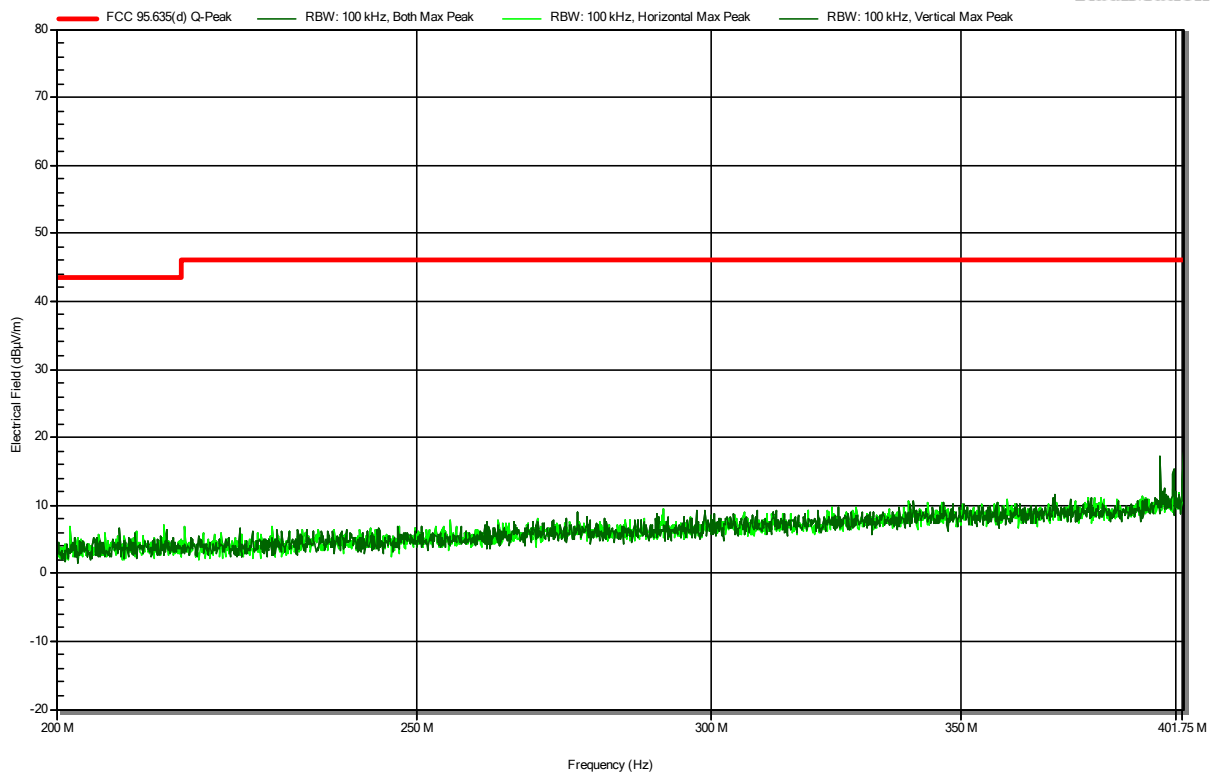


Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 402.45 MHz
 Test Date: 2022-01-11
 Note:

Index 33

RadiMation

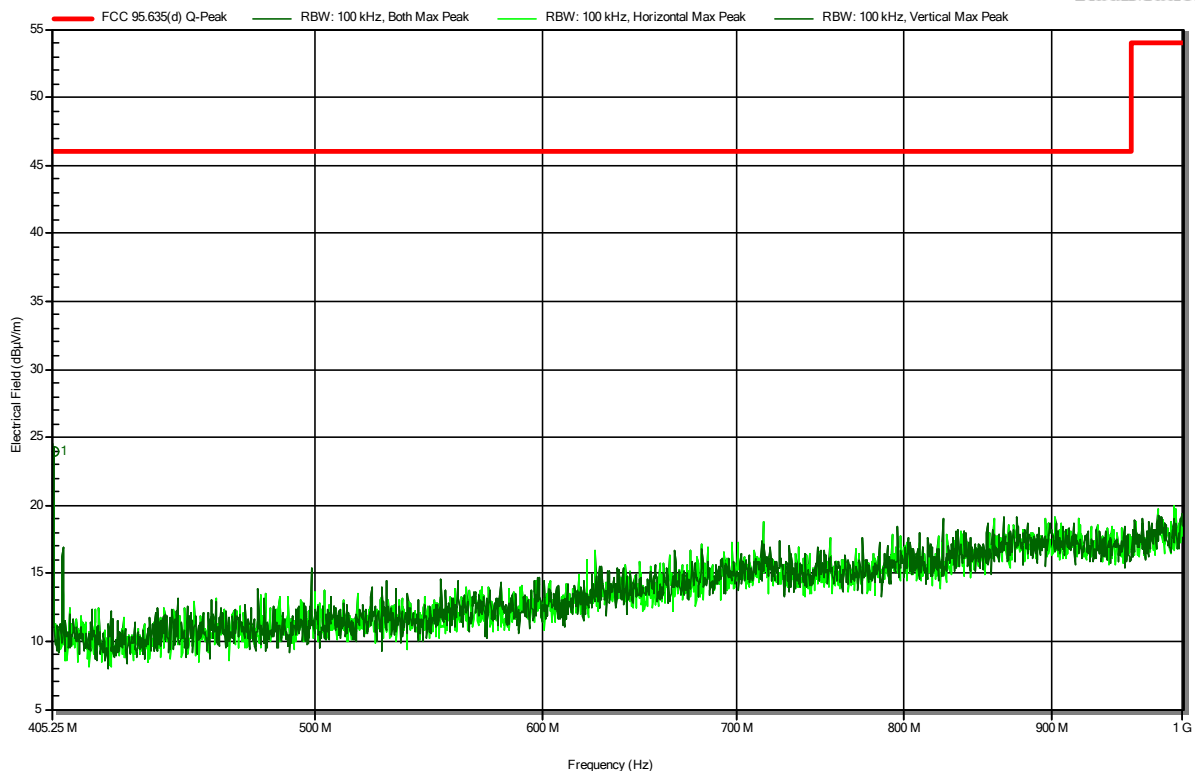


Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 402.45 MHz
 Test Date: 2022-01-11
 Note:

Index 44

RadiMation



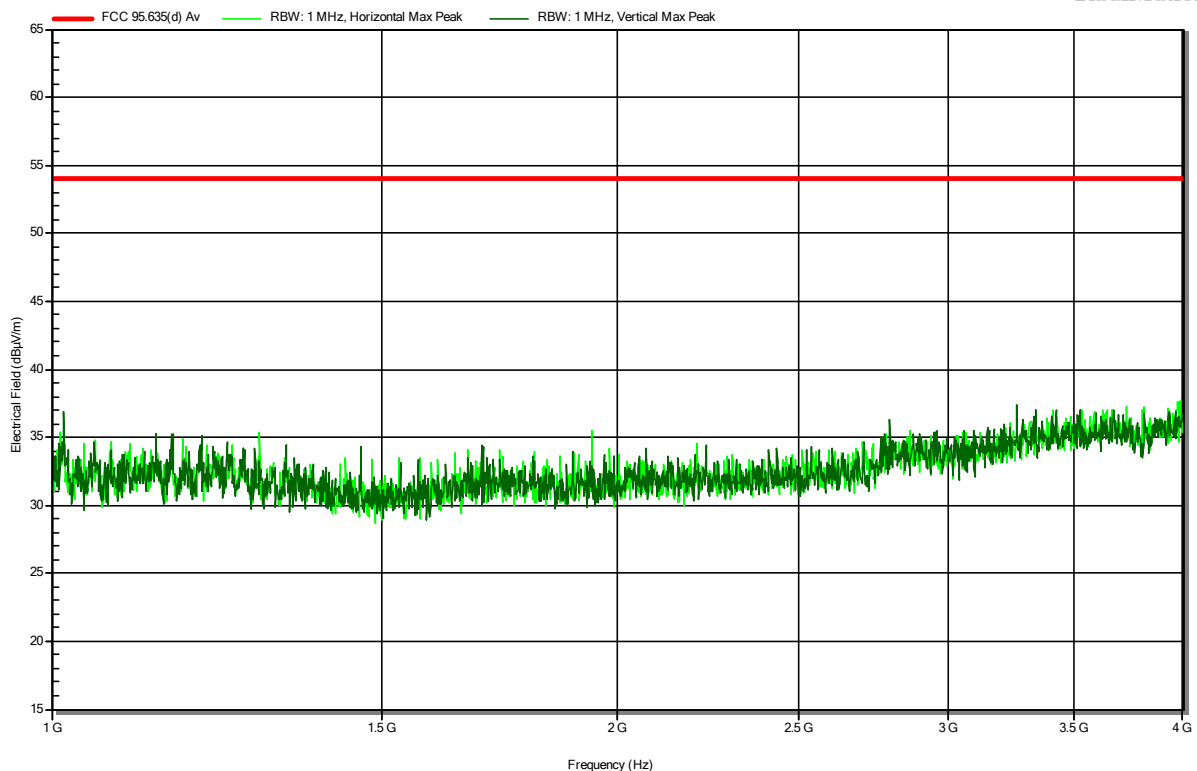
Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
405.785 MHz	23.94 dBμV/m	46 dBμV/m	-22.06 dB	Pass	Vertical

Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 402.45 MHz
 Test Date: 2022-01-11
 Note:

Index 48

RadiMation

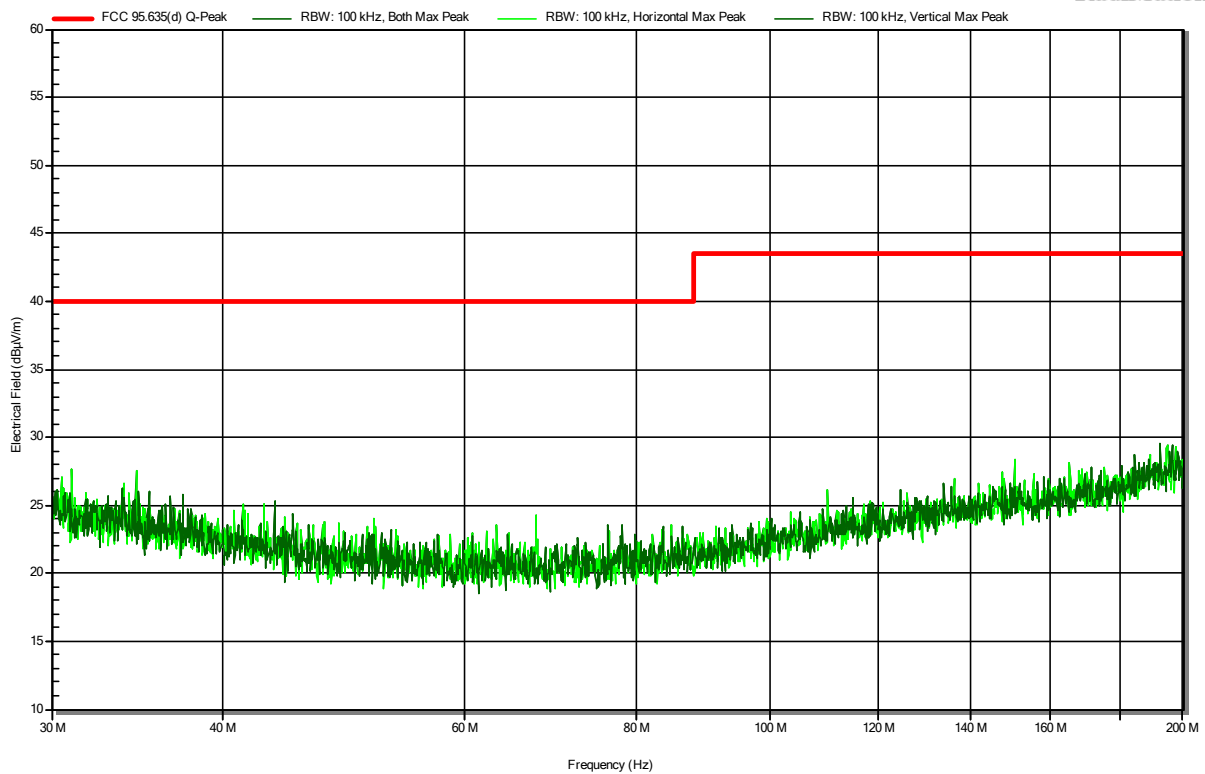


Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HK 116
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 404.85 MHz
 Test Date: 2022-01-11
 Note:

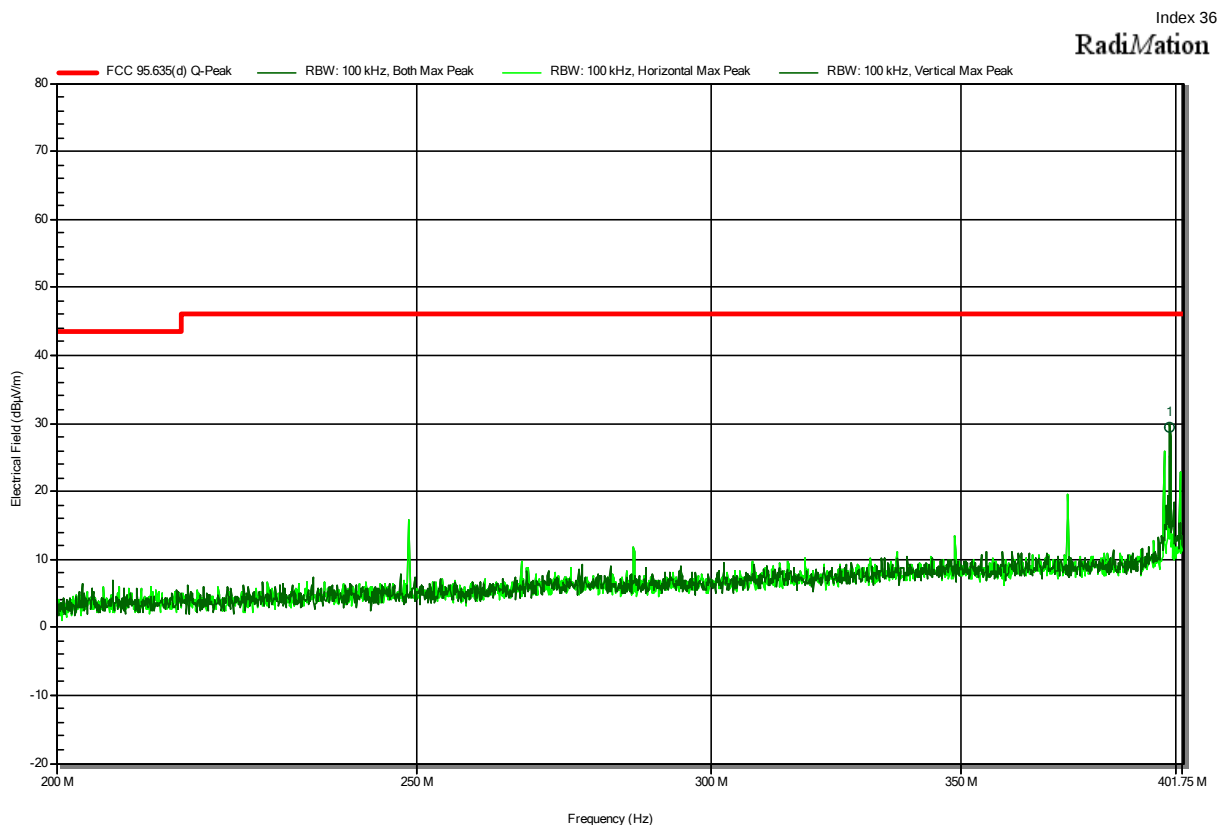
Index 46

RadiMation



Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

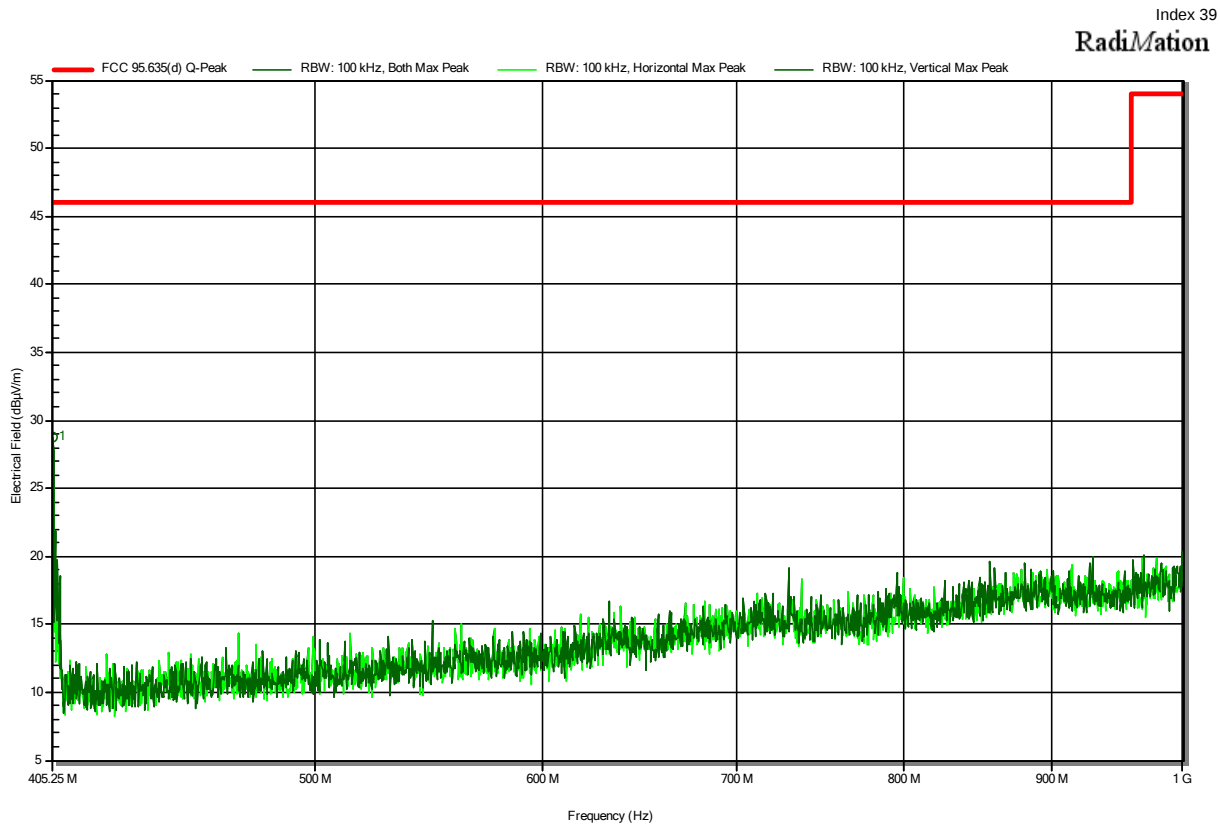
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 404.85 MHz
 Test Date: 2022-01-11
 Note:



Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Polarization
398.475 MHz	29.51 dBμV/m	46 dBμV/m	-16.49 dB	Pass	Vertical

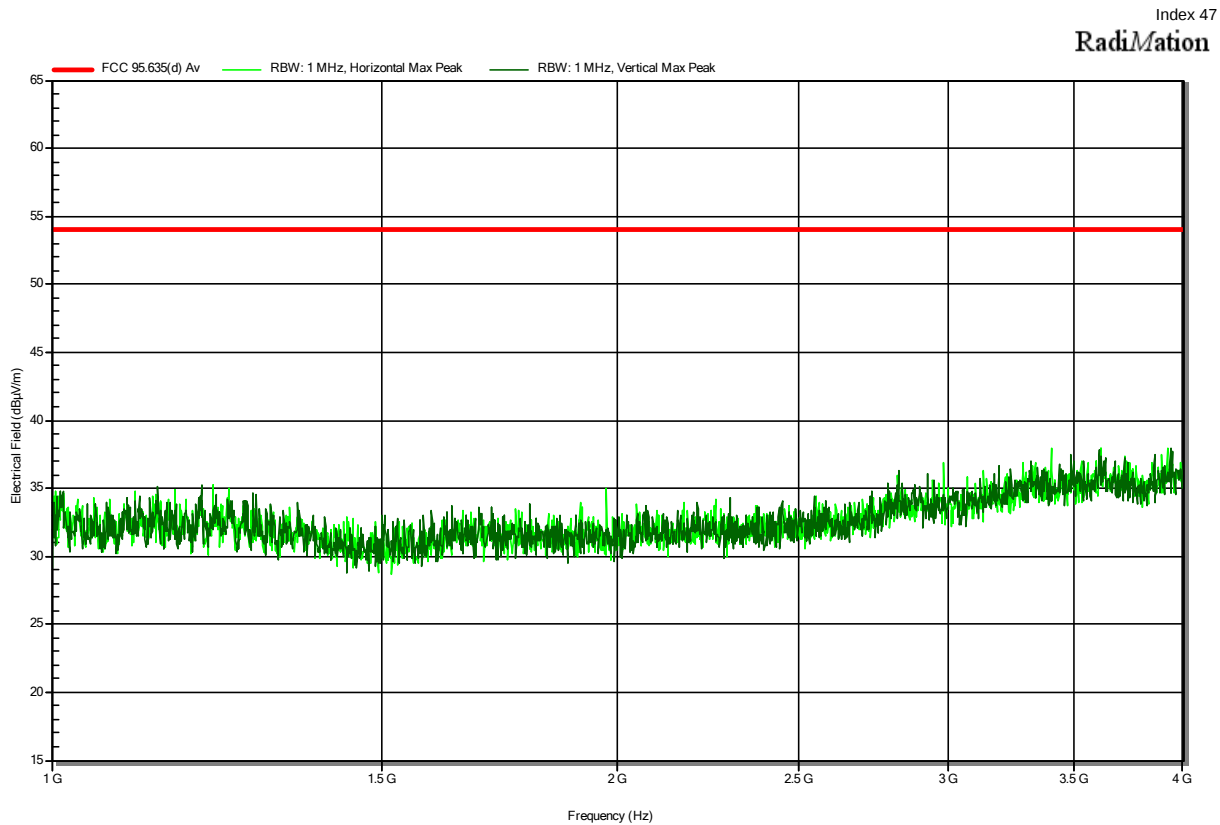
Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 404.85 MHz
 Test Date: 2022-01-11
 Note:



Radiated Spurious Emissions according to FCC part 95 MedRadio (402-405MHz)

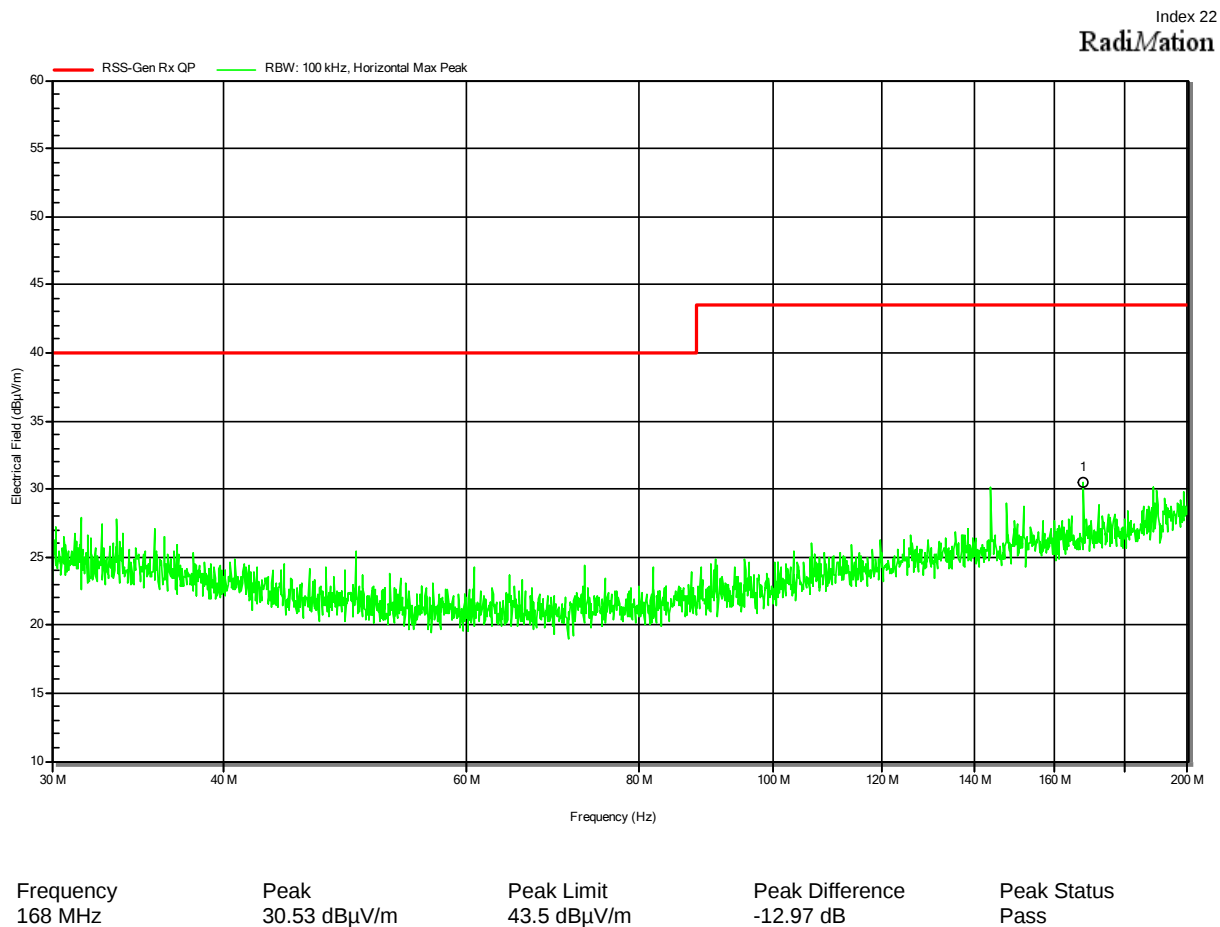
Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Tx; 2FSK; 404.85 MHz
 Test Date: 2022-01-11
 Note:



ANNEX D Receiver spurious emissions

Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HK 116, Horizontal
 Measurement distance: 3 m
 Mode: RX; 2FSK; 403.65 MHz
 Test Date: 2022-01-10
 Note:

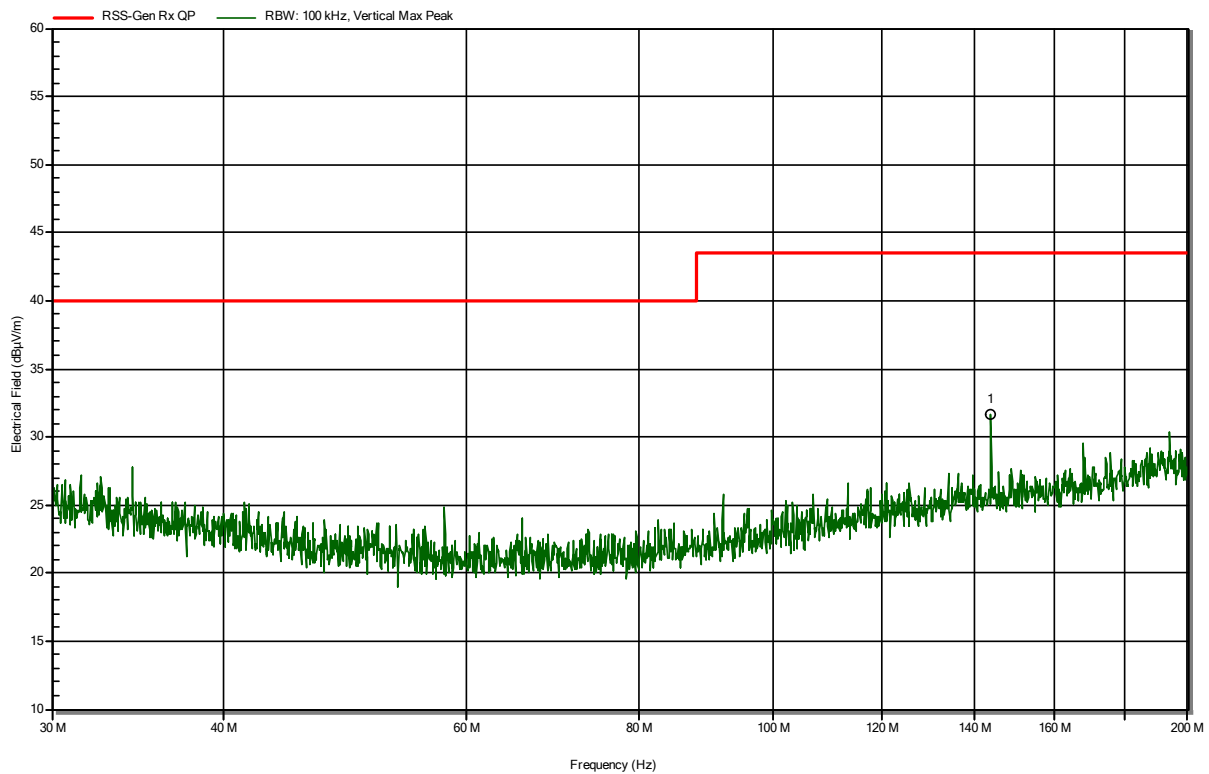


Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Rohde & Schwarz HK 116, Vertical
 Measurement distance: 3 m
 Mode: Rx; 2FSK; 403.65 MHz
 Test Date: 2022-01-10
 Note:

Index 23

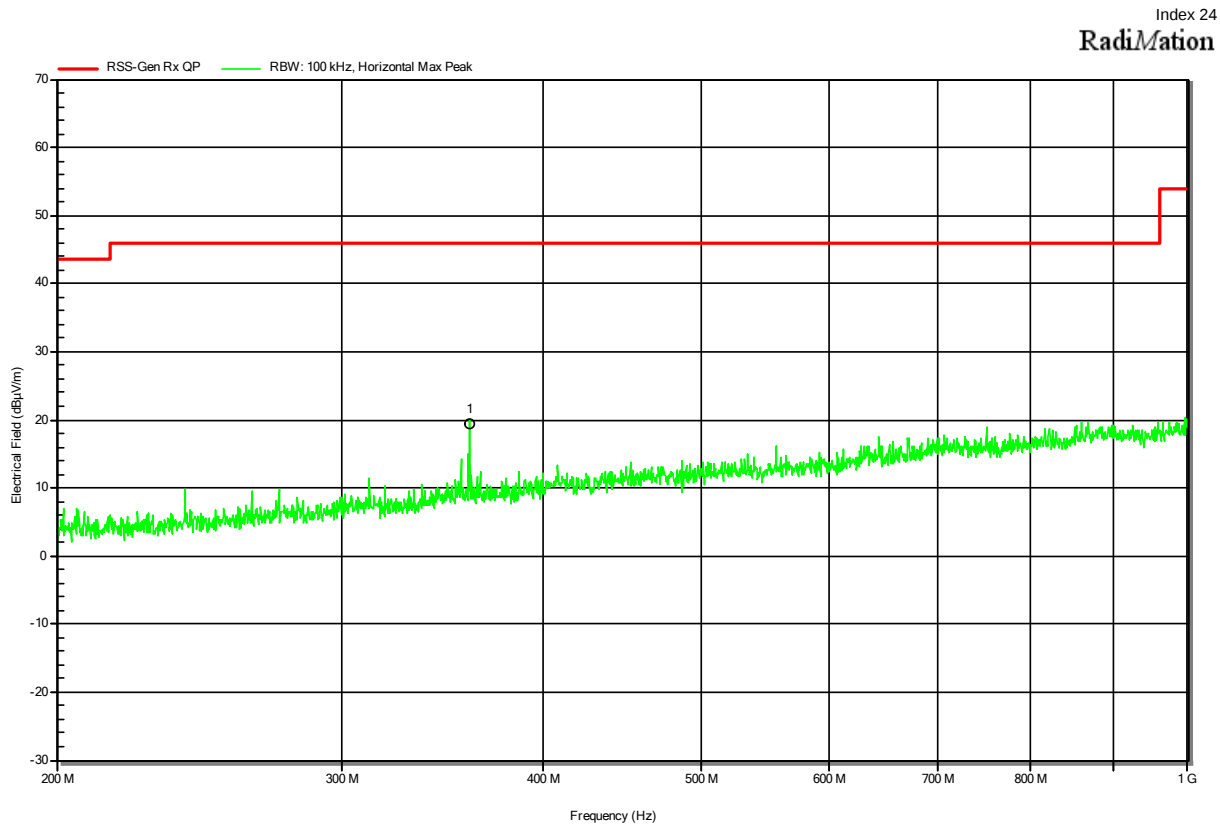
RadiMation



Frequency	Peak	Peak Limit	Peak Difference	Peak Status
144.013 MHz	31.63 dBµV/m	43.5 dBµV/m	-11.87 dB	Pass

Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223, Horizontal
 Measurement distance: 3 m
 Mode: Rx; 2FSK; 403.65 MHz
 Test Date: 2022-01-10
 Note:



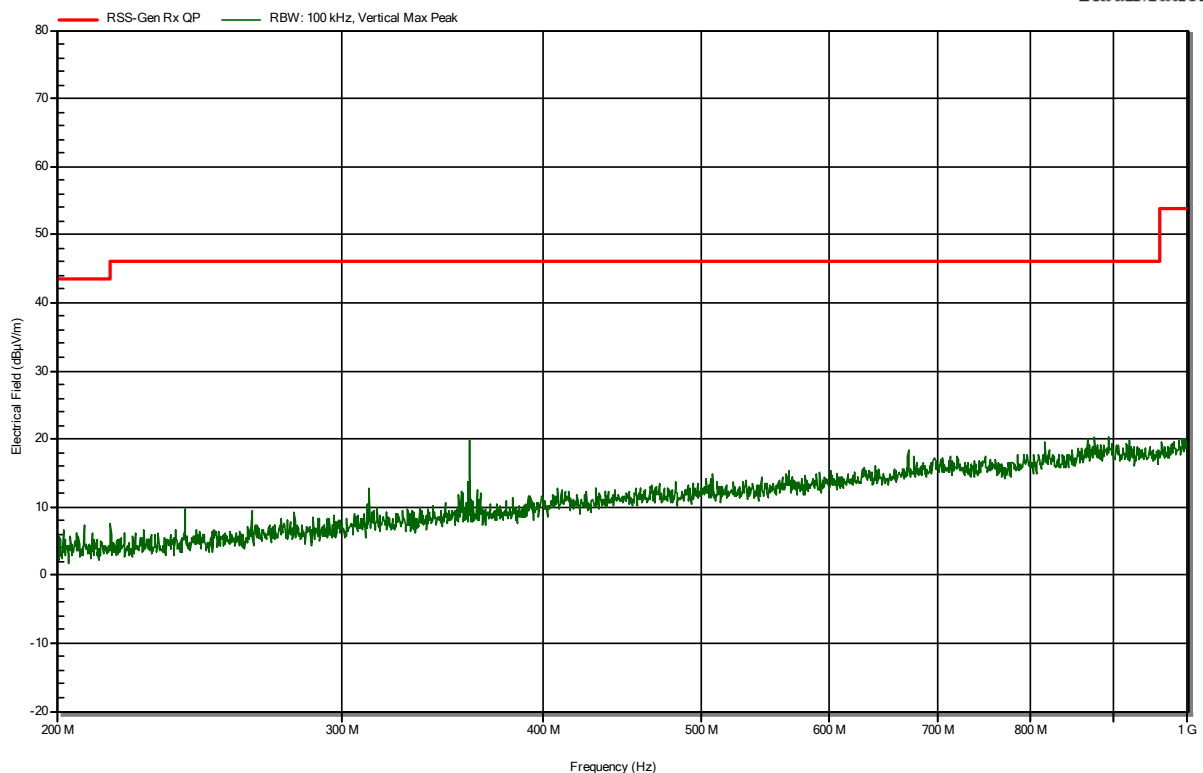
Frequency	Peak	Peak Limit	Peak Difference	Peak Status
359.973 MHz	19.52 dBµV/m	46 dBµV/m	-26.48 dB	Pass

Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3 m
 Mode: Rx; 2FSK; 403.65 MHz
 Test Date: 2022-01-10
 Note:

Index 25

RadiMation

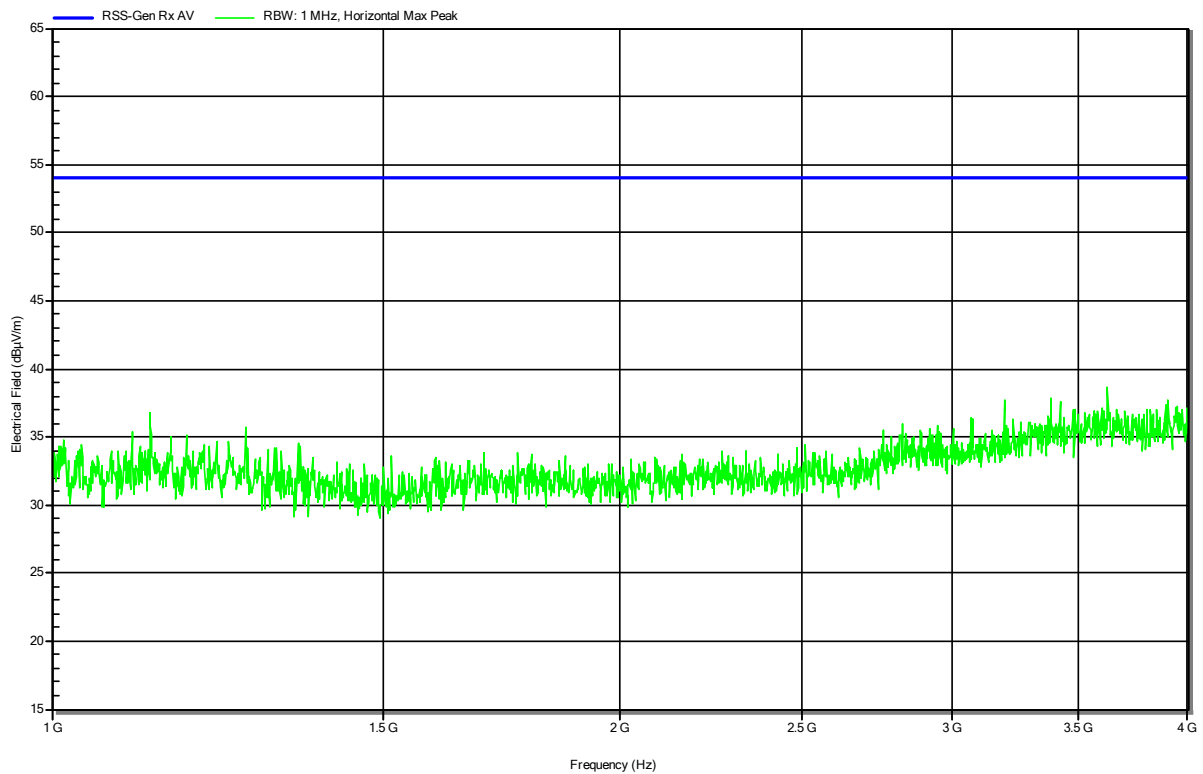


Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battery)
 Antenna: Schwarzbeck BBHA 9120B, Horizontal
 Measurement distance: 3 m
 Mode: Rx; 2FSK; 403.65 MHz
 Test Date: 2022-01-10
 Note:

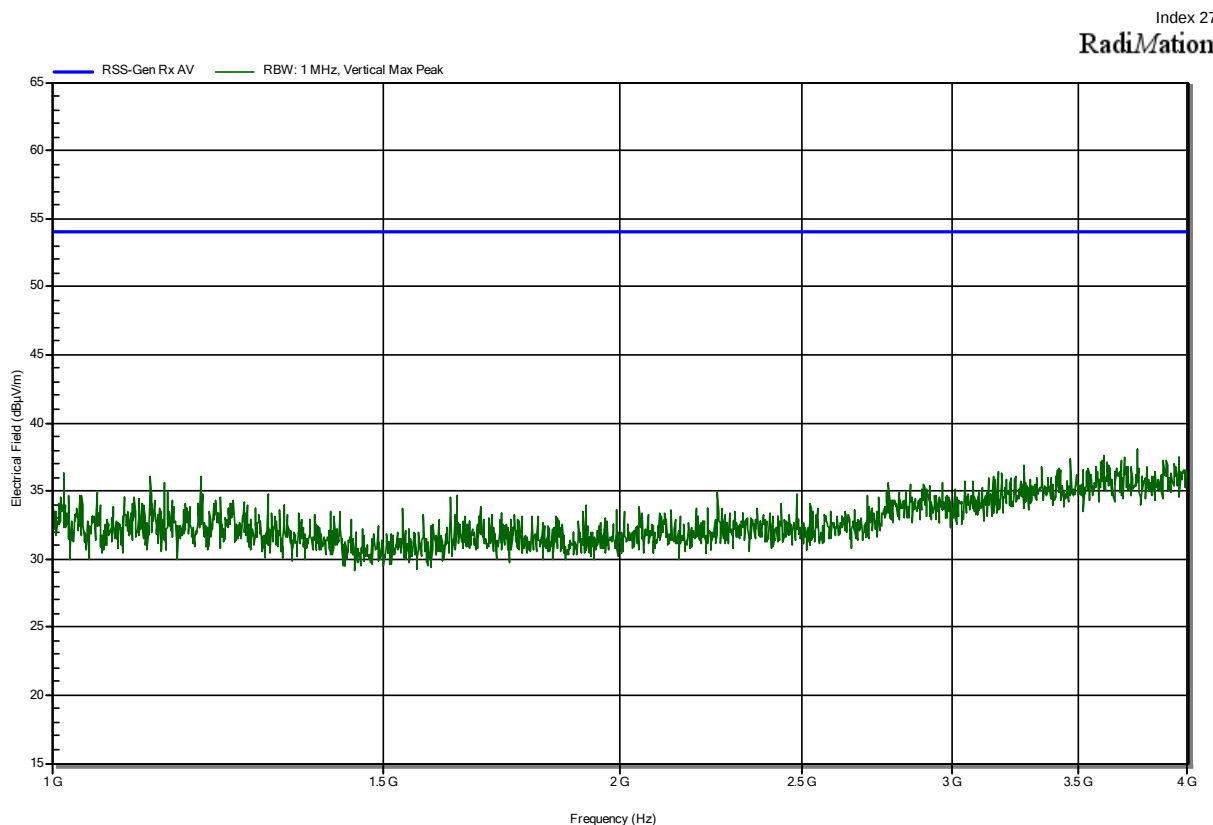
Index 26

RadiMation



Radiated Spurious Emissions according to RSS-243 Issue 3

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38057
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Treffke
 Measurement software: RadiMation, version 2020.1.8
 Test Conditions: Tnom: 23 °Celsius, Vnom: 3.6 VDC (battry)
 Antenna: Schwarzbeck BBHA 9120B, Vertical
 Measurement distance: 3 m
 Mode: Rx; 2FSK; 403.65 MHz
 Test Date: 2022-01-10
 Note:



== = END OF TEST REPORT == =

Test Report No.: G0M-2111-1166-TFC95IMR-V01

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