

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-2407-2638-TFC95IMR01-V02
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 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	ICD4200-10 / Implantable Cardioverter Defibrillator
Model(s)	Acticor Sky HF-T QP, additional models see family list
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware Version(s)	0A
Software Version(s)	ROM: 6.0 / RAM: 7.0
FCC ID	QRI-ICD4200P2
IC	4708A-ICD4200P2
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	See test sample identification table on page 7	
Report:		
Compiled by (+ signature) (Test Lab Engineer)	Md Abu Bakar Siddique	
Approved by (+ signature) (Senior Radio Expert)	Radwan Jaafar	
Date of Issue	2025-09-11	
Total number of pages	66	
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:		
None		

ADDITIONAL VARIANTS

The manufacturer declared additional models according to family list.

The model Acticor Sky HF-T QP, with highest transmitter radiated power level was selected for the measurements.

Additional variants have been declared by the manufacturer. The below family explanation was provide by the customer.

4200-10 Family Explanation

1. Family Letter

	Product Name	Type	no. of chambers	Connector RV	Connector LV	HVIN
1	Acticor Sky VR-T	VR	1	DF-4	-	481989
2	Acticor Sky VR-T DX	DX*	1	DF-4	-	481988
3	Acticor Sky DR-T	DR	2	DF-4	-	481987
4	Acticor Sky HF-T	CRT	3	DF-4	IS-1	481986
5	Acticor Sky HF-T QP	CRT	3	DF-4	IS-4	481985
6	Rivacor Sky VR-T	VR	1	DF-4	-	481984
7	Rivacor Sky VR-T DX	DX*	1	DF-4	-	481983
8	Rivacor Sky DR-T	DR	2	DF-4	-	481982
9	Rivacor Sky HF-T	CRT	3	DF-4	IS-1	481991
10	Rivacor Sky HF-T QP	CRT	3	DF-4	IS-4	481990
11	Rivacor Rise VR-T	VR	1	DF-4	-	482020
12	Rivacor Rise VR-T	DX*	1	DF-4	-	482019
13	Rivacor Rise DR-T	DR	2	DF-4	-	482018
14	Rivacor Rise HF-T	CRT	3	DF-4	IS-1	482017
15	Rivacor Rise HF-T QP	CRT	3	DF-4	IS-4	482016
16	Rivacor Aura VR-T	VR	1	DF-4	-	482015
17	Rivacor Aura VR-T	DX*	1	DF-4	-	487199
18	Rivacor Aura DR-T	DR	3	DF-4	IS-4	482014
19	Rivacor Aura HF-T	CRT	3	DF-4	IS-1	482013
20	Rivacor Aura HF-T QP	CRT	3	DF-4	IS-4	482012

*: additional atrial detection (therapy function)

2. Family description

Header difference overview

Variant	Family member's
1	VR-T/DF-4 (DX)
2	DR-T/DF-4
3	HF-T/DF-4
4	HF-T/QP (DF-4 / IS-4)

table 1: header configuration

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2025-03-26	Initial Release	--
02	2025-09-11	- FCC and IC ID are updated in page 7 - EUT and Test setup photos are removed - Separate document is created for photos "G0M-2407-2638-Photos-FCC" - Measurement method "ANSI C63.10" is replaced by "ANSI C63.26" in page 21, 22, 24-32, 33, 51, 55 and 57.	Siddique

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
ANSI	American National Standards Institute
RBW	Resolution bandwidth
RMS	Root mean square
VBW	Video bandwidth
V _{NOM}	Nominal supply voltage
2-FSK	Binary Frequency-shift keying
NRZ	Non Return to Zero
MICS	Medical Implant Communication Service
DC	Duty cycle

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1 Equipment (Test Item) Under Test

Description	ICD4200-10 / Implantable Cardioverter Defibrillator			
Model	Acticor Sky HF-T QP, additional models see family list			
Additional Model(s)	None			
Brand Name(s)	BIOTRONIK			
Sample Identification	EUT #	Sample-ID	Serial Number	Date of receipt
	EUT 1 (Cond.)	50617	938	2025-01-20
	EUT 2 (Rad.)	50612	1000428866	2025-01-20
Hardware Version(s)	0A			
Software Version(s)	ROM: 6.0 / RAM: 7.0			
PMN	Acticor Sky HF-T QP			
HVIN	481985			
FVIN	n/a			
HMN	n/a			
FCC ID	QRI-ICD4200P2			
IC	4708A-ICD4200P2			
Equipment type	End Product			
Radio type	Transceiver			
Assigned frequency bands	402 - 405 MHz			
Radio technology	MedRadio (MICS) active medical implant			
Modulation	2-FSK			
Emission designator	F1D			
Number of channels	9			
Channel spacing	300 kHz			
Spectrum access	Not used			
Number of antenna ports	1			
Antenna	Type	Integrated		
	Model	4200-10		
	Manufacturer	BIOTRONIK SE & Co. KG		
	Gain	-24.24 dBi (note 1)		
Supply Voltage	V _{NOM}	3.0 V DC		
	V _{MIN}	2.5 V DC		
	V _{MAX}	3.2 V DC		
Operating Temperature	T _{NOM}	37°C		
	T _{MIN}	25°C		
	T _{MAX}	45°C		
Dedicated AC/DC-Adaptor	None			
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY			
note 1: Antenna gain measurement result is available in report “G0M-2407-2638-AUT01-V01” issued by Eurofins Product Service GmbH on 2025-03-26				

1.1 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE	Programming Head	BIOTRONIK SE & Co. KG	Renamic PGH	--
AE	Cardio Messenger	BIOTRONIK SE & Co. KG	Cardio Messenger II	--
AE	Communication Adapter	BIOTRONIK SE & Co. KG	TelBox II	--
AE	Laptop	DELL	Latitude 5520	--
SFT	Biotronic Engineering tool	BIOTRONIK SE & Co. KG	2.17328.1.878	--
CBL	USB cable	--	--	--
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment: --				

1.2 EUT Configuration

Configuration #	Description
1	EUT is powered by its internal battery
2	EUT is powered by lab power supply
Comment: -- Configuration # 1 is used for radiated measurements and Configuration # 2 is used for conducted measurements.	

1.3 Test mode duty cycle

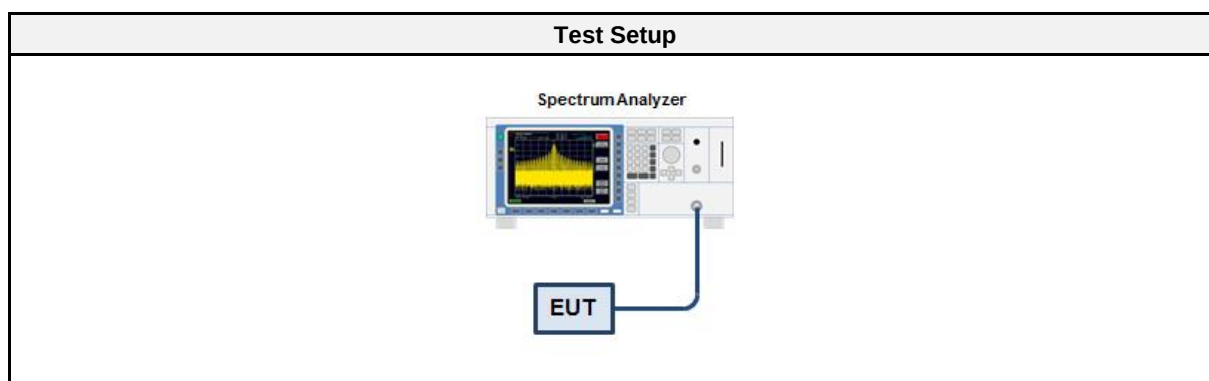
1.3.1 Information

Test Information	
Measurement Method	ANSI C63.10-2020 11.6

1.3.2 Requirements

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

1.3.3 Setup



1.3.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum analyzer	R&S	FSU43	EF01631	2024-07	2025-07

1.3.5 Procedure

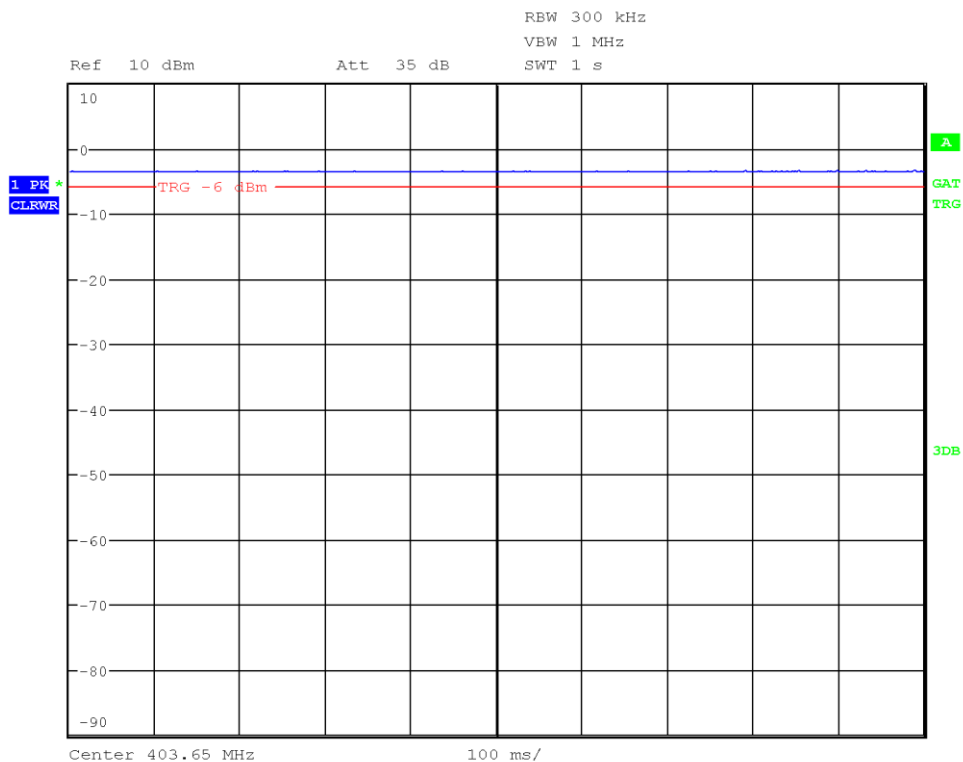
Test Procedure
1. EUT set to test mode 2. Span is set to zero span 3. Detector set to peak 4. Sweep time is set long enough to capture at least 5 bursts 5. Envelope peak value of emission spectrum is selected 6. The maximum burst duration T_{ON} is measured using two markers set to the start and the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

1.3.6 Results

Duty Cycle Results		
Mode	Duty Cycle	Correction Factor [dB]
Unmodulated	1.0	0
Modulated 1	1.0	0
Modulated 2	1.0	0
Modulated 3	1.0	0

Duty cycle

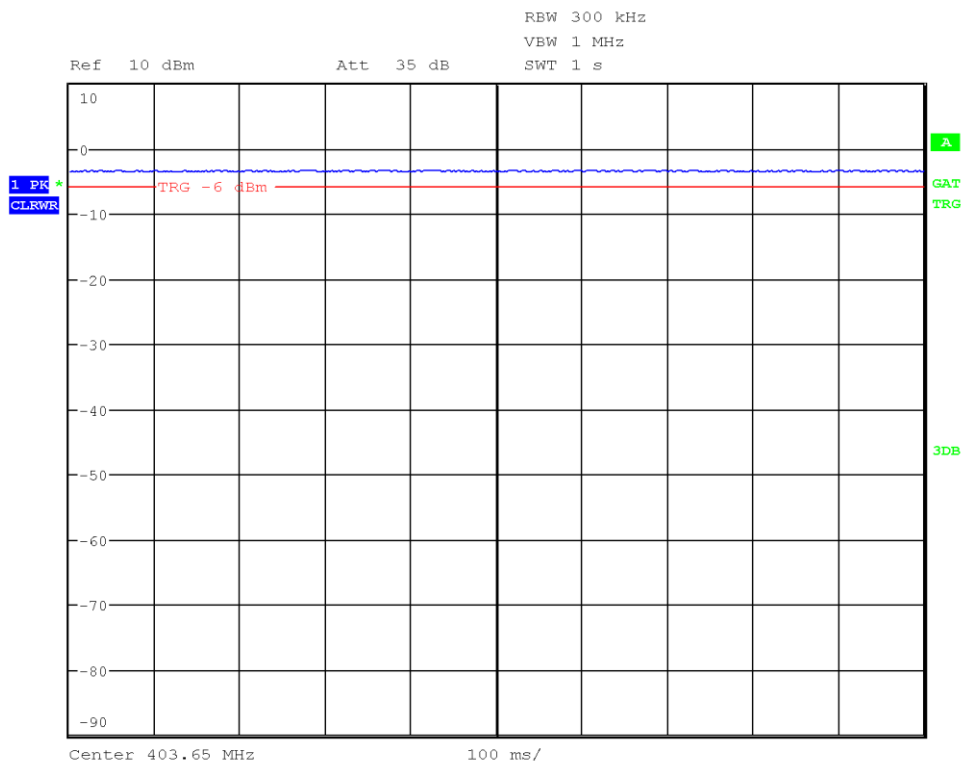
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Operating Conditions: Tnom/Vnom
 Mode: Modulated 1



Date: 21.JAN.2025 18:15:20

Duty cycle

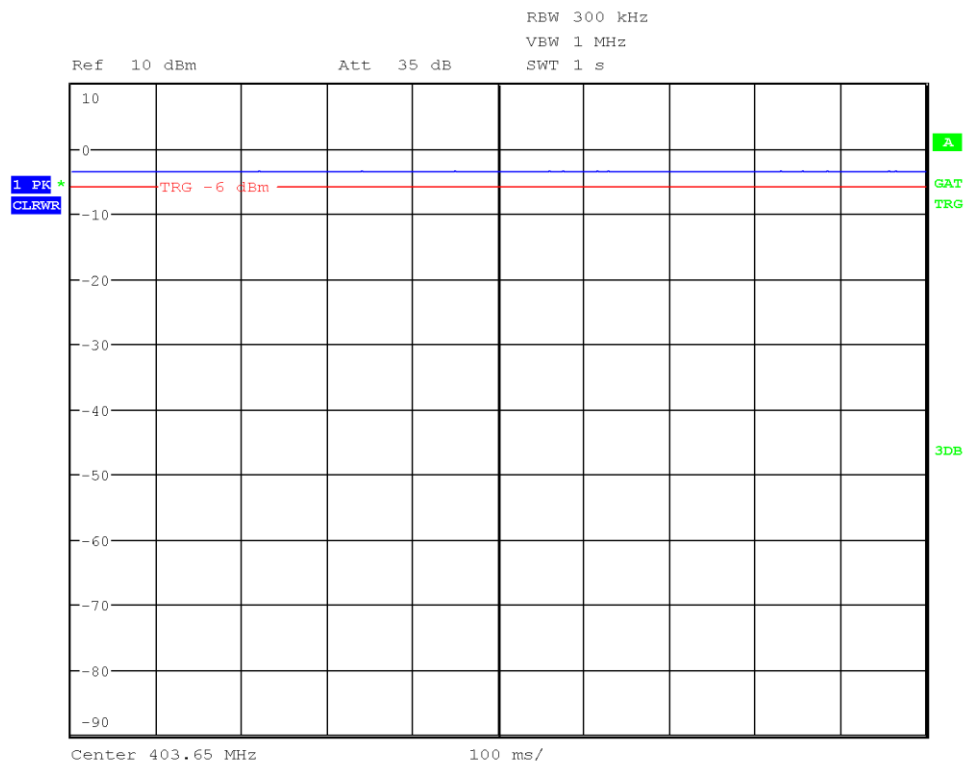
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Operating Conditions: Tnom/Vnom
 Mode: Modulated 2



Date: 21.JAN.2025 18:16:07

Duty cycle

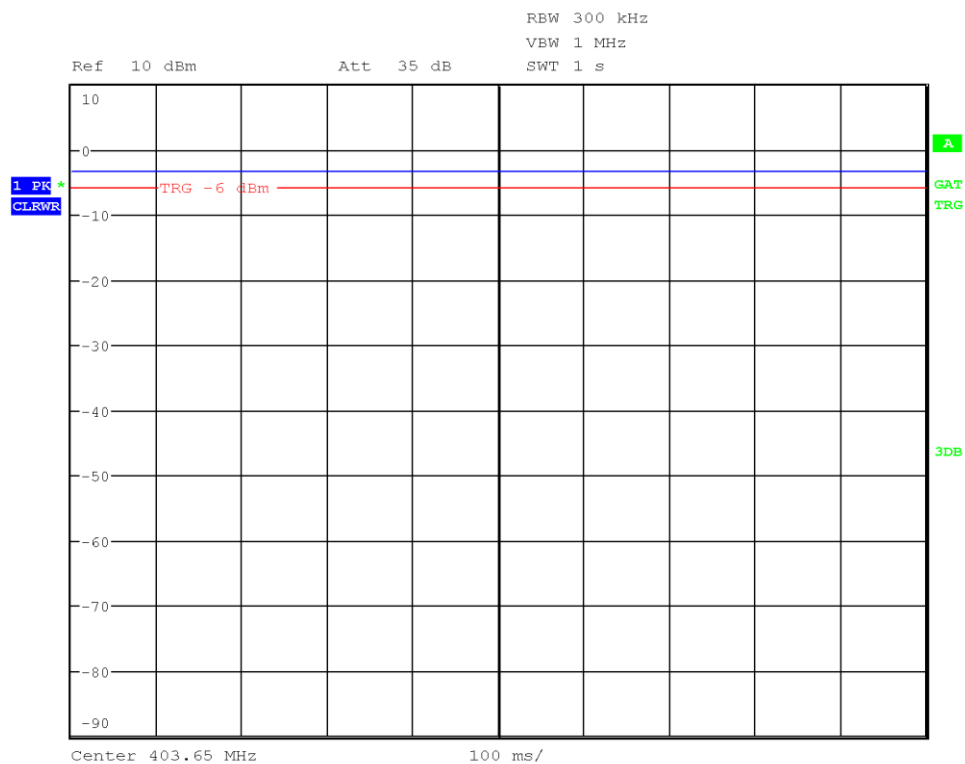
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Operating Conditions: Tnom/Vnom
 Mode: Modulated 3



Date: 21.JAN.2025 18:16:37

Duty cycle

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Operating Conditions: Tnom/Vnom
 Mode: Unmodulated



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1.4 Test Modes

Mode	Description
Unmodulated	Mode = Standalone Transmit Modulation = None Dutycycle = 100 %
Modulated 1	Mode = Standalone Transmit Modulation = 2-FSK Data rate = 16 kBit Dutycycle = 100 %
Modulated 2	Mode = Standalone Transmit Modulation = 2-FSK Data rate = 82 kBit Dutycycle = 100 %
Modulated 3	Mode = Standalone Transmit Modulation = 2-FSK Data rate = 197 kBit Dutycycle = 100 %
Receive	Mode = Standalone Receive Modulation = 2-FSK
Comment:	

1.5 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

1.6 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:

$$\text{Reading} + \text{AF} = \text{Net Reading} \quad : \quad \text{Net reading} - \text{Field strength limit} = \text{Margin}$$

1.7 Measurement Uncertainties

Test case	Maximum measurement uncertainty
Occupied bandwidth	1.3 %
Emission Bandwidth	1.3 %
Frequency stability	0.66 PPM
Transmitter output power	5.95 dB
Band edge compliance	1.8 dB
Transmitter unwanted emissions	5.95 dB
Receiver spurious emissions	5.95 dB
AC power line conducted emissions	3.82 dB

1.8 Simulated human body

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

Liquid components			
Component		percentage per weight	
Deionized water		52.4	
Bactericide		0.08	
Hydroxy ethyl cellulose (HCE)		1.0	
Sodium chloride		1.4	
Sucrose		45.0	
Tissue parameters – 403.5MHz Measured tissue parameters:			
Component	Target	Measured	Deviation
Dielectric constant ϵ	57.2	62.4	5.2
Conductivity σ [mS/cm]	9.3	8.7	-0.6

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 C63.26-2015 5.4.4	N/R	Informational only
FCC 95.2573(a) ISED RSS-243 5.1	Emission Bandwidth	ANSI C63.26-2015 5.4.3 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 C63.26-2015 5.5	PASS	--
FCC 95.2579 ISED RSS-243 3.4, 5.5	Transmitter unwanted emissions	ANSI C63.26-2015 5.5	PASS	--
ISED RSS-243 3.5, 5.6 ISED RSS-Gen 7.3	Receiver spurious emissions	ANSI C63.26-2015 5.5	PASS	--
FCC 15.207 ISED RSS-Gen 7.2, 8.8	AC power line conducted emissions	ANSI C63.10-2020 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

3 Test Conditions and Results

3.1 Test Conditions and Results - Occupied bandwidth

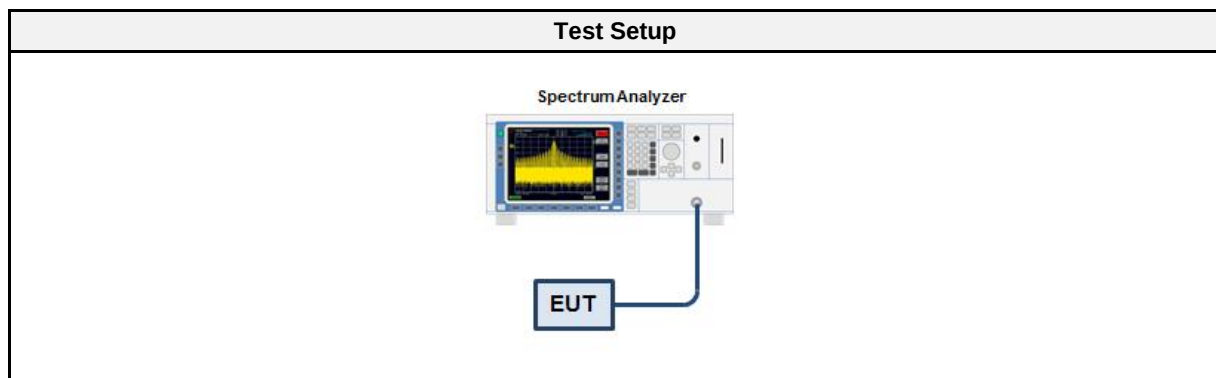
3.1.1 Information

Test Information	
Reference	ISED RSS-243 3.2, RSS-Gen 6.7
Measurement Method	ANSI C63.26 5.4.4
Operator	Florian Voigt
Date	2025-01-21

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 Analyser	R&S	FSU 43	EF01631	2024-07	2025-07
Cable	Huber + Suhner	Sucoflex 100	EF00779 CAABT	2024-04	2025-04

3.1.5 Procedure

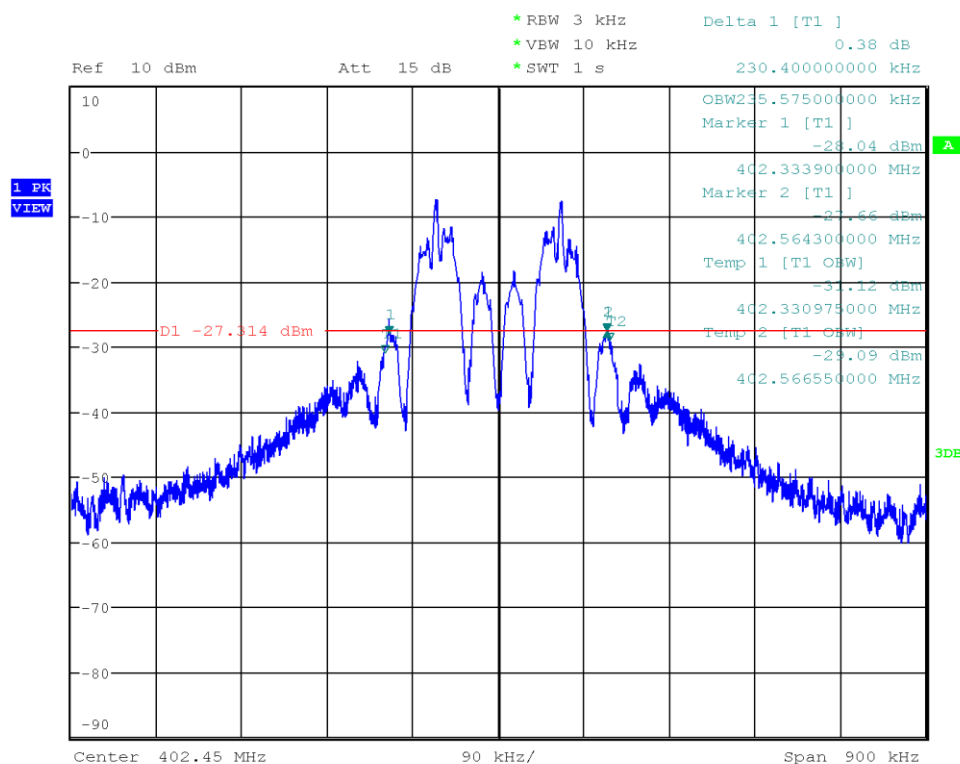
Test Procedure
1. EUT transmitter is activated in test mode under normal conditions 2. The spectrum analyzer is set to peak detection and maximum hold with a span twice the emission spectrum 3. The resolution bandwidth is set 1 % to 5 % of the bandwidth 4. The occupied bandwidth (99%) is measured with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

3.1.6 Results

Test Results		
Mode	Channel [MHz]	Bandwidth [kHz]
Modulated 1	402.45	235.575
Modulated 1	403.65	235.575
Modulated 1	404.85	234.675
Modulated 2	402.45	247.500
Modulated 2	403.65	246.150
Modulated 2	404.85	247.050
Modulated 3	402.45	236.475
Modulated 3	403.65	238.275
Modulated 3	404.85	238.950

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI
 C63.26 5.4
 Operational Mode: 2-FSK, 16 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 235.575
 20 dB Bandwidth [kHz]: 230.400
 Lower 20 dB Frequency [MHz]: 402.334
 Upper 20 dB Frequency [MHz]: 402.564



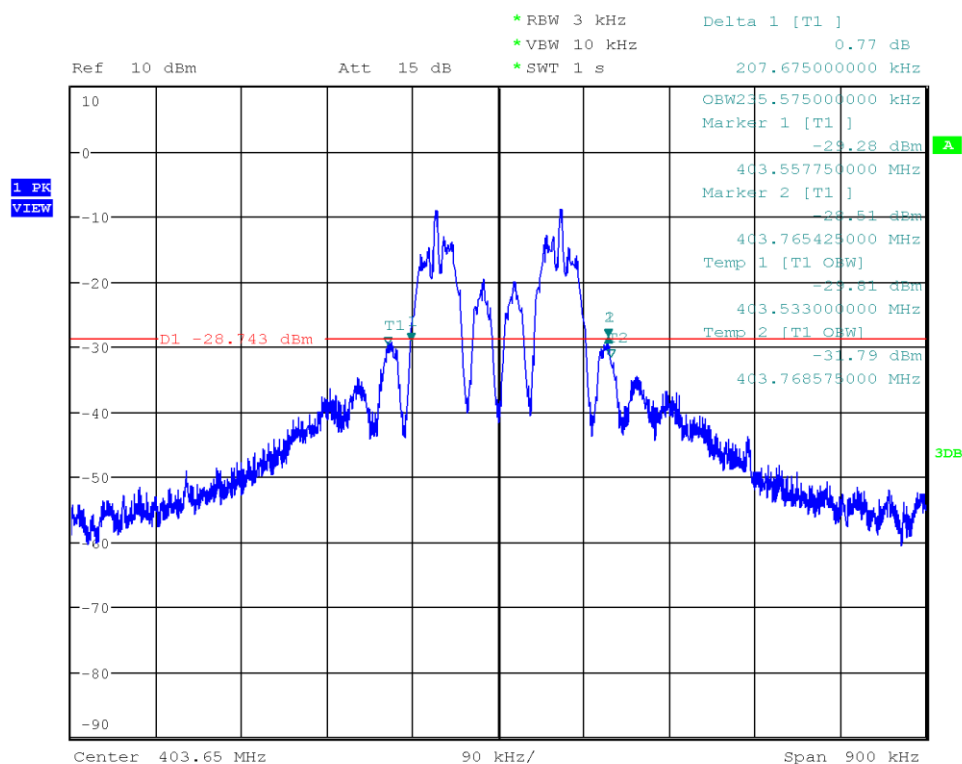
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Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 16 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 235.575
 20 dB Bandwidth [kHz]: 207.675
 Lower 20 dB Frequency [MHz]: 403.558
 Upper 20 dB Frequency [MHz]: 403.765



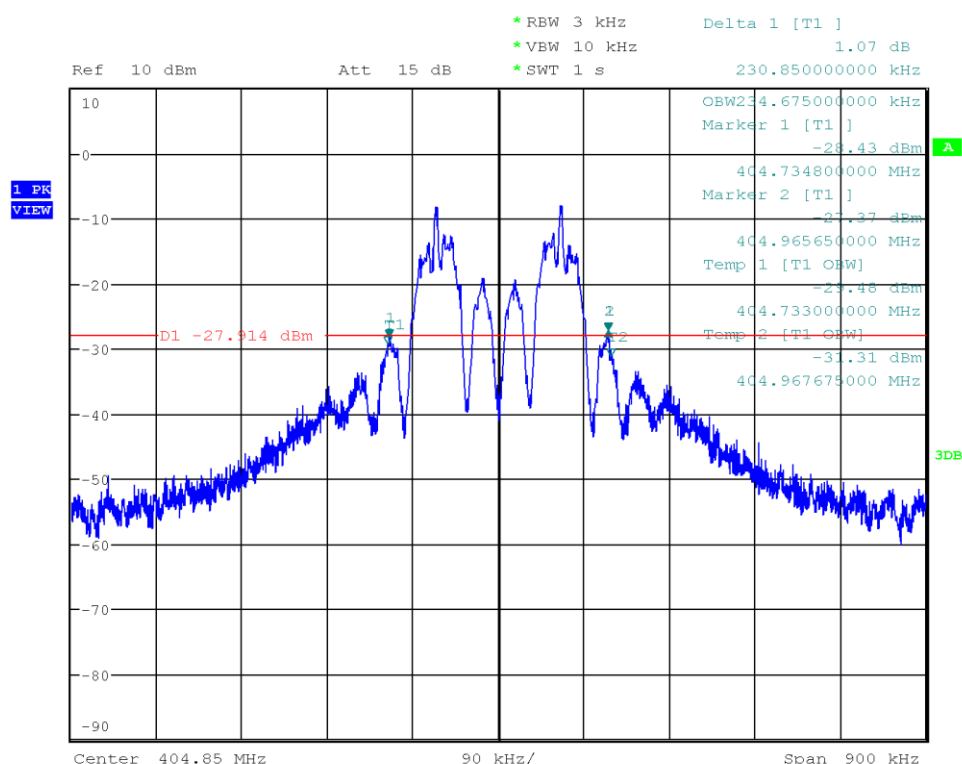
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Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 16 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 234.675
 20 dB Bandwidth [kHz]: 230.850
 Lower 20 dB Frequency [MHz]: 404.735
 Upper 20 dB Frequency [MHz]: 404.966



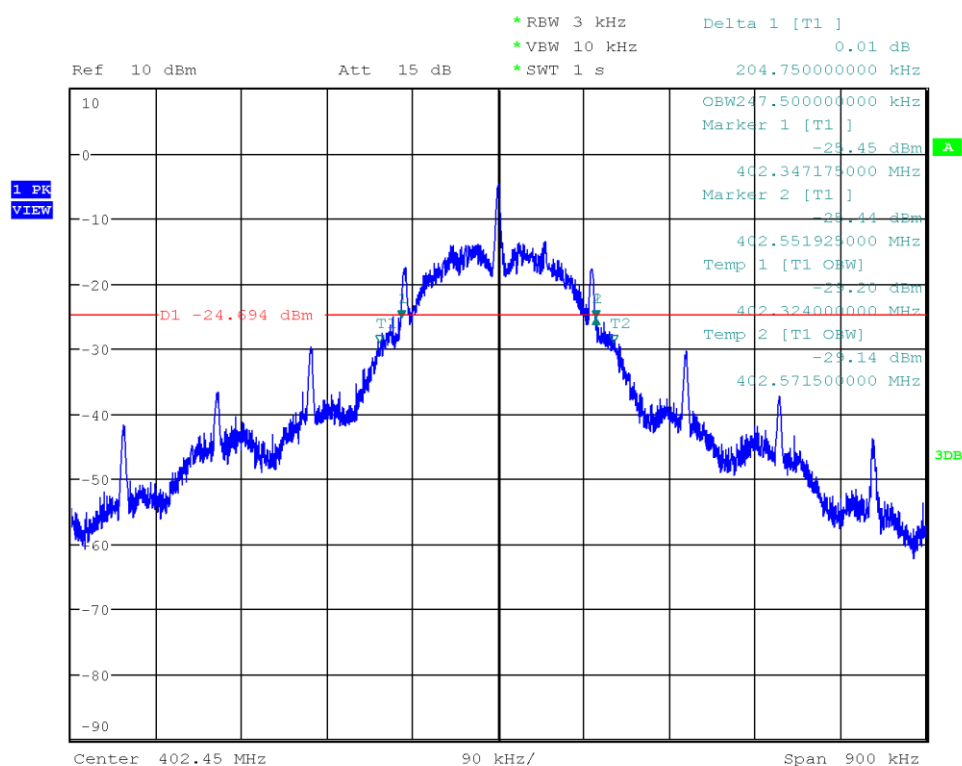
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Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 82 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 247.500
 20 dB Bandwidth [kHz]: 204.750
 Lower 20 dB Frequency [MHz]: 402.347
 Upper 20 dB Frequency [MHz]: 402.552



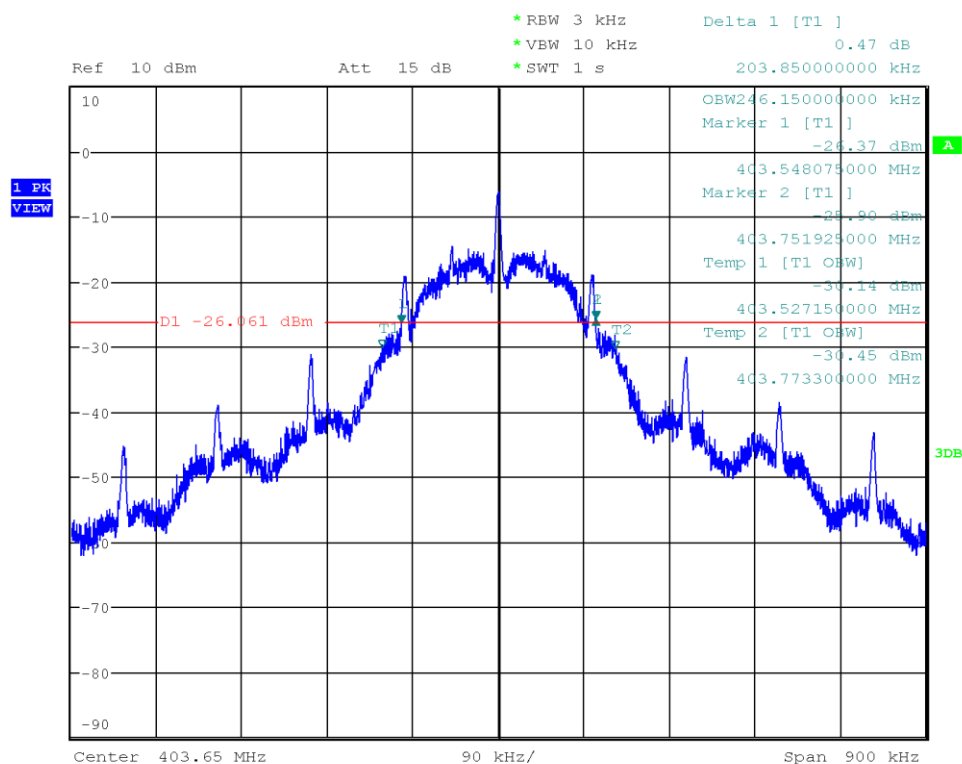
Date: 21.JAN.2025 13:03:57

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Occupied and Emission Bandwidth

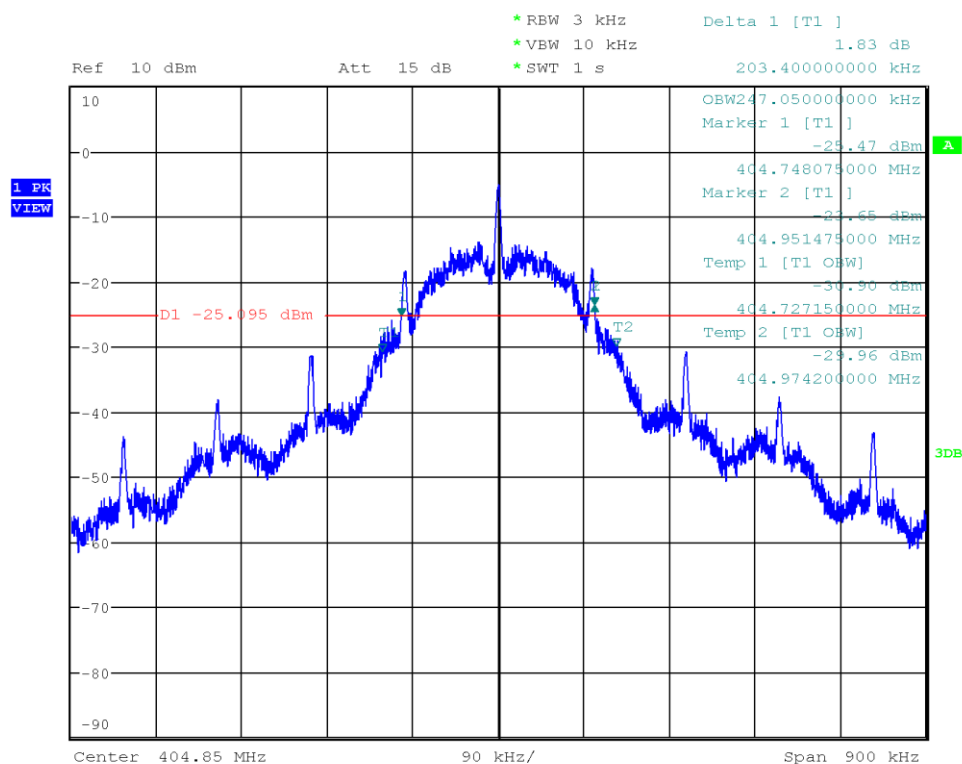
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 82 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 246.150
 20 dB Bandwidth [kHz]: 203.850
 Lower 20 dB Frequency [MHz]: 403.548
 Upper 20 dB Frequency [MHz]: 403.752



Date: 21.JAN.2025 13:04:49

Occupied and Emission Bandwidth

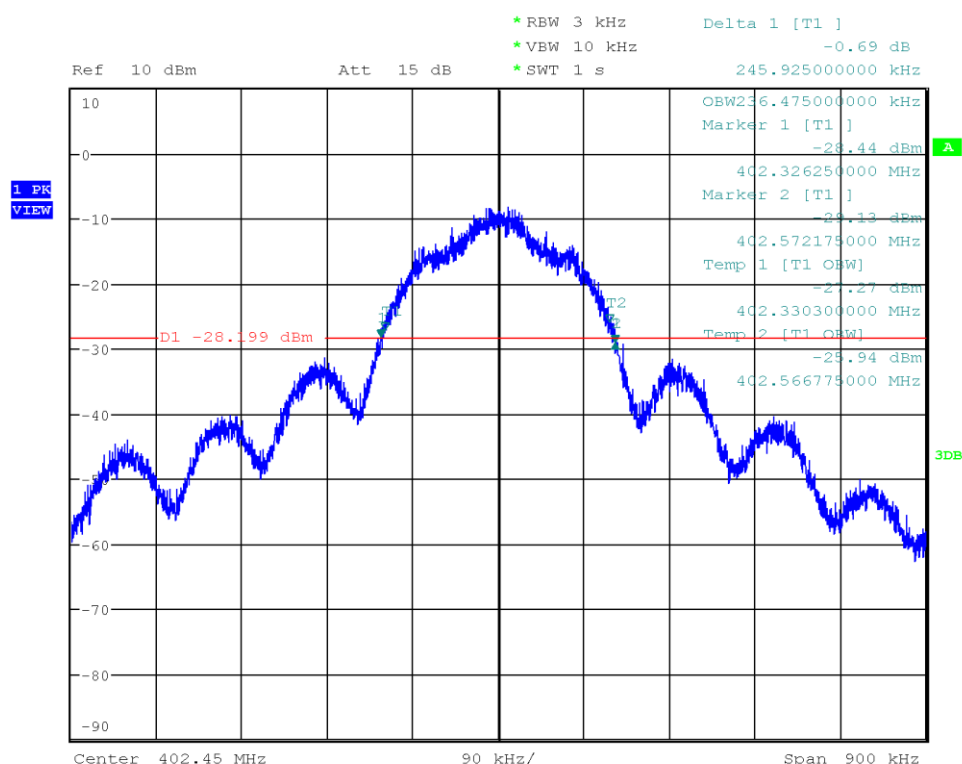
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 82 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 247.050
 20 dB Bandwidth [kHz]: 203.400
 Lower 20 dB Frequency [MHz]: 404.748
 Upper 20 dB Frequency [MHz]: 404.951



Date: 21.JAN.2025 13:05:38

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 197 kbps, Channel: 8, 402.45 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 236.475
 20 dB Bandwidth [kHz]: 245.925
 Lower 20 dB Frequency [MHz]: 402.326
 Upper 20 dB Frequency [MHz]: 402.572



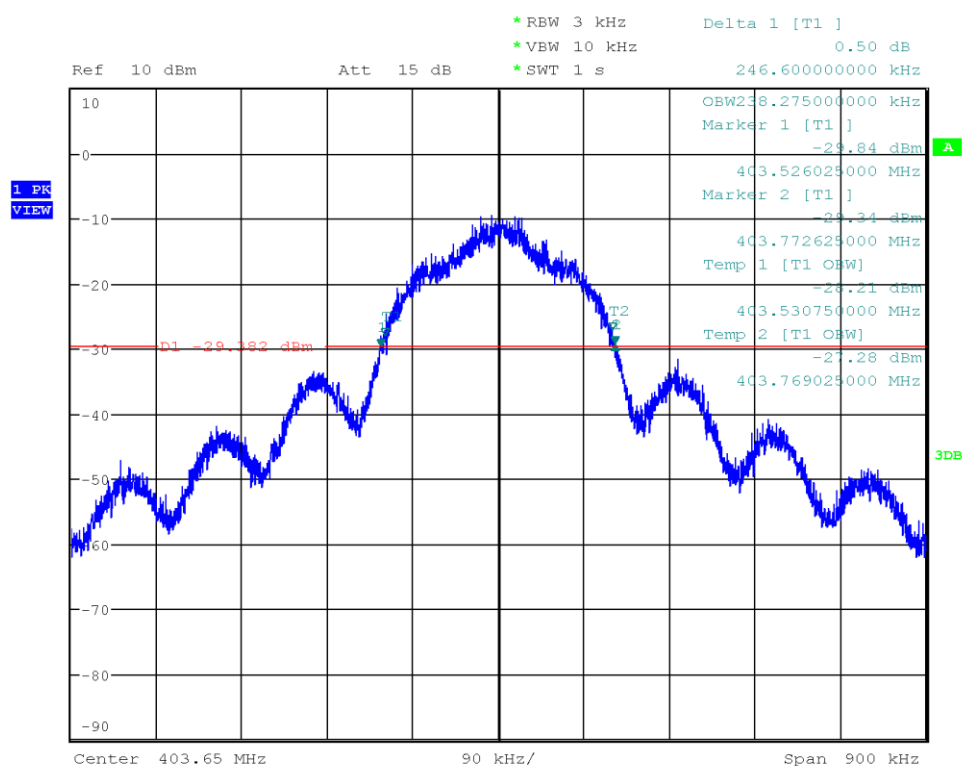
Date: 21.JAN.2025 13:06:40

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 197 kbps, Channel: 0, 403.65 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 238.275
 20 dB Bandwidth [kHz]: 246.600
 Lower 20 dB Frequency [MHz]: 403.526
 Upper 20 dB Frequency [MHz]: 403.773



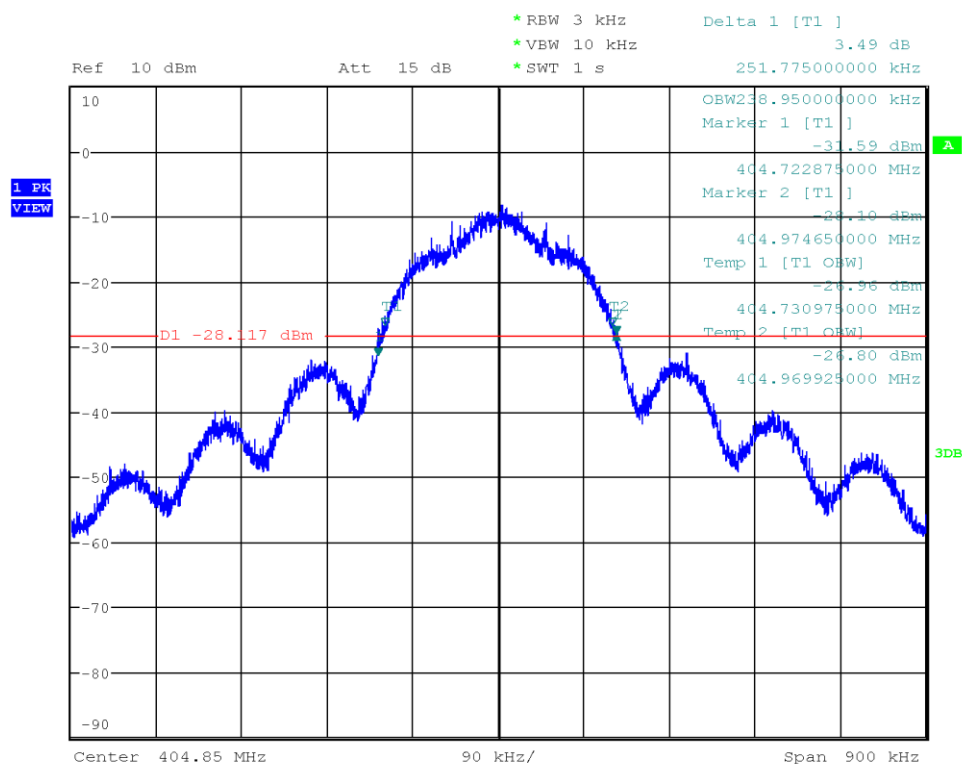
Date: 21.JAN.2025 13:07:56

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Occupied and Emission Bandwidth

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50617
 Reference Method: ANSI C63.26 5.4
 Operational Mode: 2-FSK, 197 kbps, Channel: 7, 404.85 MHz
 Operating Conditions: Tnom / Vnom
 Operator: Florian Voigt
 Test Site: Eurofins Product Service GmbH
 Test Date: 2025-01-21
 Occupied (99%) Bandwidth [kHz]: 238.950
 20 dB Bandwidth [kHz]: 251.775
 Lower 20 dB Frequency [MHz]: 404.723
 Upper 20 dB Frequency [MHz]: 404.975



Date: 21.JAN.2025 13:09:35

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

3.2 Test Conditions and Results - Emission bandwidth

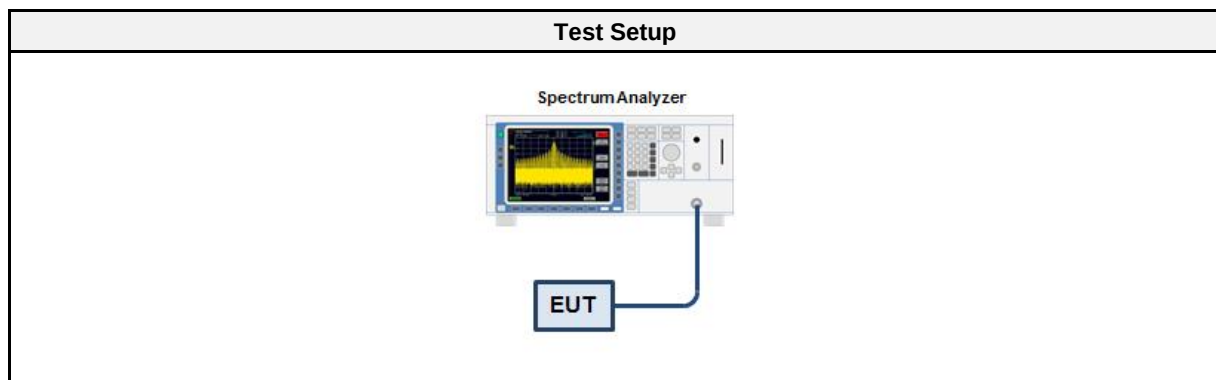
3.2.1 Information

Test Information	
Reference	FCC 95.2573(a) ISED RSS-243 5.1
Measurement Method	ANSI C63.26 5.4.3 ETSI EN 301 839 5.3.2
Operator	Florian Voigt
Date	2025-01-21

3.2.2 Limits

Limits
≤ 300 kHz

3.2.3 Setup



3.2.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyser	R&S	FSU 43	EF01631	2024-07	2025-07
Cable	Huber + Suhner	Sucoflex 100	EF00779 CAABT	2024-04	2025-04

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 1	402.45	230.400
Modulated 1	403.65	207.675
Modulated 1	404.85	230.850
Modulated 2	402.45	204.750
Modulated 2	403.65	203.850
Modulated 2	404.85	203.400
Modulated 3	402.45	245.925
Modulated 3	403.65	246.600
Modulated 3	404.85	251.775

For measurement result display images please see section "Occupied bandwidth" result plots.

3.3 Test Conditions and Results - Frequency stability

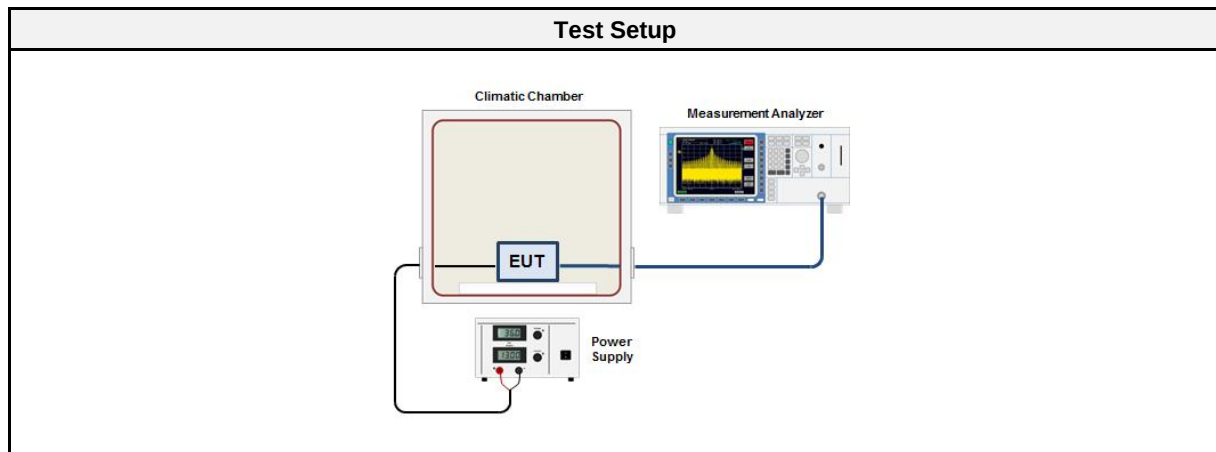
3.3.1 Information

Test Information	
Reference	FCC 95.2565 ISED RSS-243 3.3, 5.3
Measurement Method	ETSI EN 301 839 5.3.1
Operator	Florian Voigt
Date	2025-01-21

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 Analyser	R&S	FSU 43	EF01631	2024-07	2025-07
Cable	Huber + Suhner	Sucoflex 100	EF00779 CAABT	2024-04	2025-04
Climatic chamber	ATT Umweltsimulation	DY110 T	EF01853	2024-09	2025-09

3.3.5 Procedure

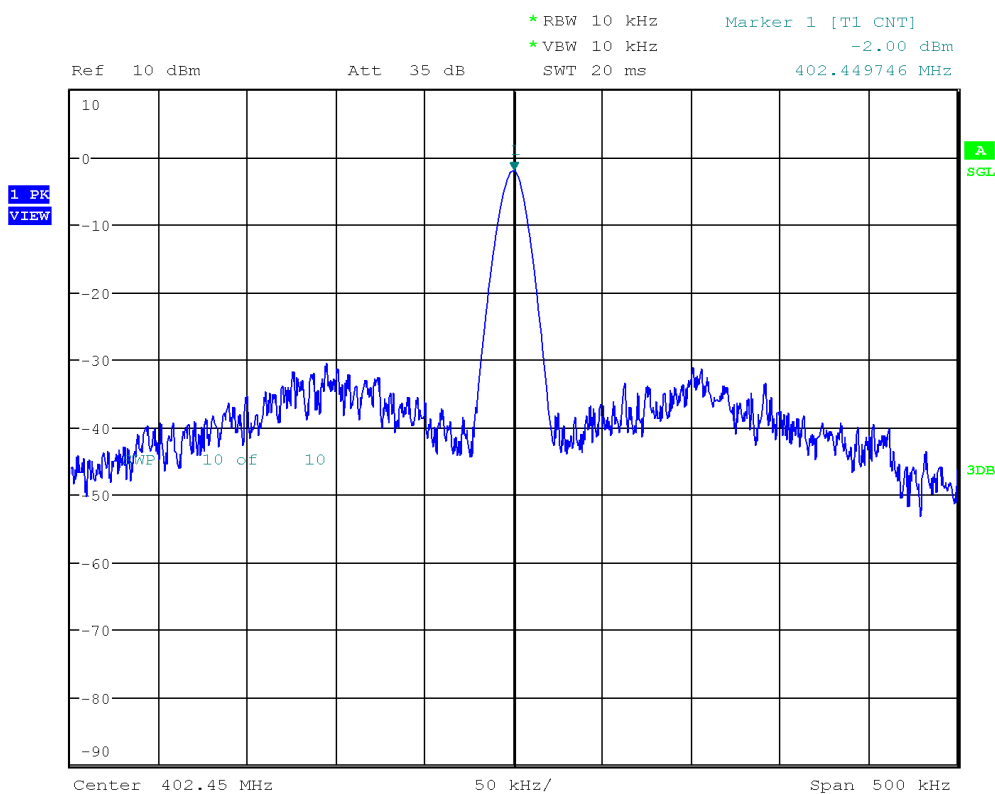
Test Procedure
1. EUT set to test mode with supply voltage and temperature set to nominal conditions 2. EUT transmits without modulation 3. Detector set to peak and max hold 4. Peak of emission is measured using a frequency counter 5. The frequency error is determined as the deviation of the emission 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	402.449746	-0.63
403.65	37	3.0	403.649820	-0.45
404.85	37	3.0	404.849897	-0.25
402.45	25	3.0	402.449735	-0.66
403.65	25	3.0	403.649816	-0.46
404.85	25	3.0	404.849910	-0.22
402.45	45	3.0	402.449642	-0.89
403.65	45	3.0	403.649718	-0.70
404.85	45	3.0	404.849794	-0.51

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	CW, Channel 8, 402.45 MHz
Operating Conditions:	Tnom/Vnom
Operator:	Md Abu Bakar Siddique
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	402.450000
Measured Frequency [MHz]:	402.449746
Frequency Error [kHz]:	-0.254
Frequency Error [ppm]:	-0.63



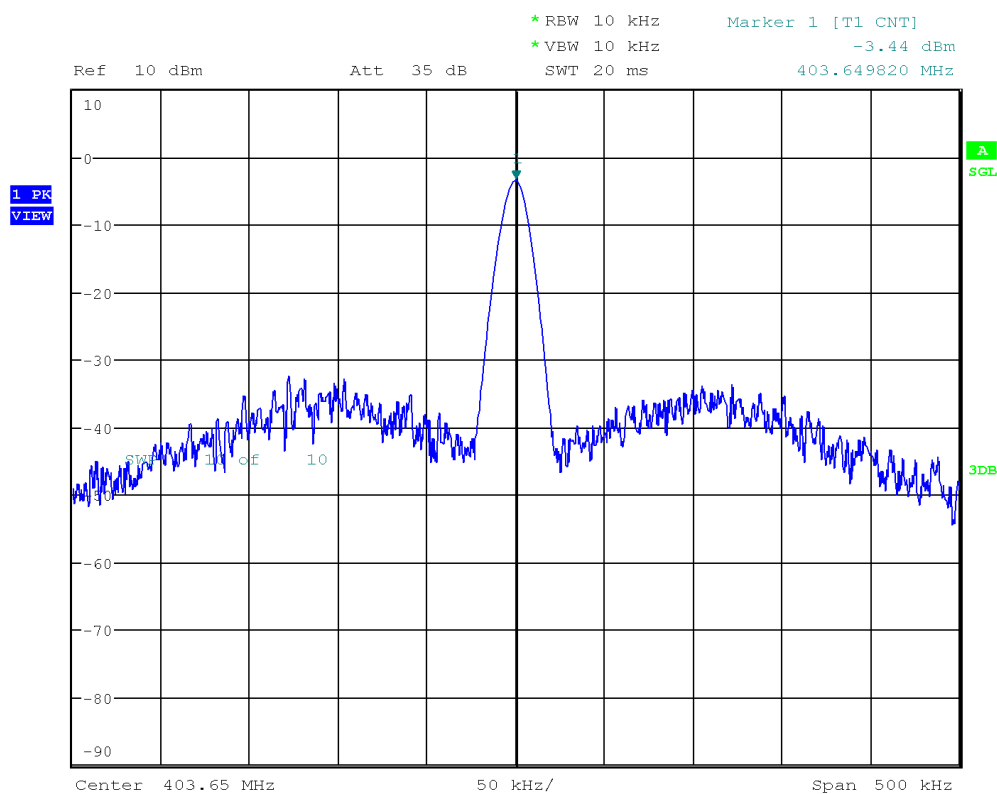
Date: 21.JAN.2025 16:28:25

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	CW, Channel 0, 403.65 MHz
Operating Conditions:	Tnom/Vnom
Operator:	Md Abu Bakar Siddique
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	403.650000
Measured Frequency [MHz]:	403.649820
Frequency Error [kHz]:	-0.180
Frequency Error [ppm]:	-0.45



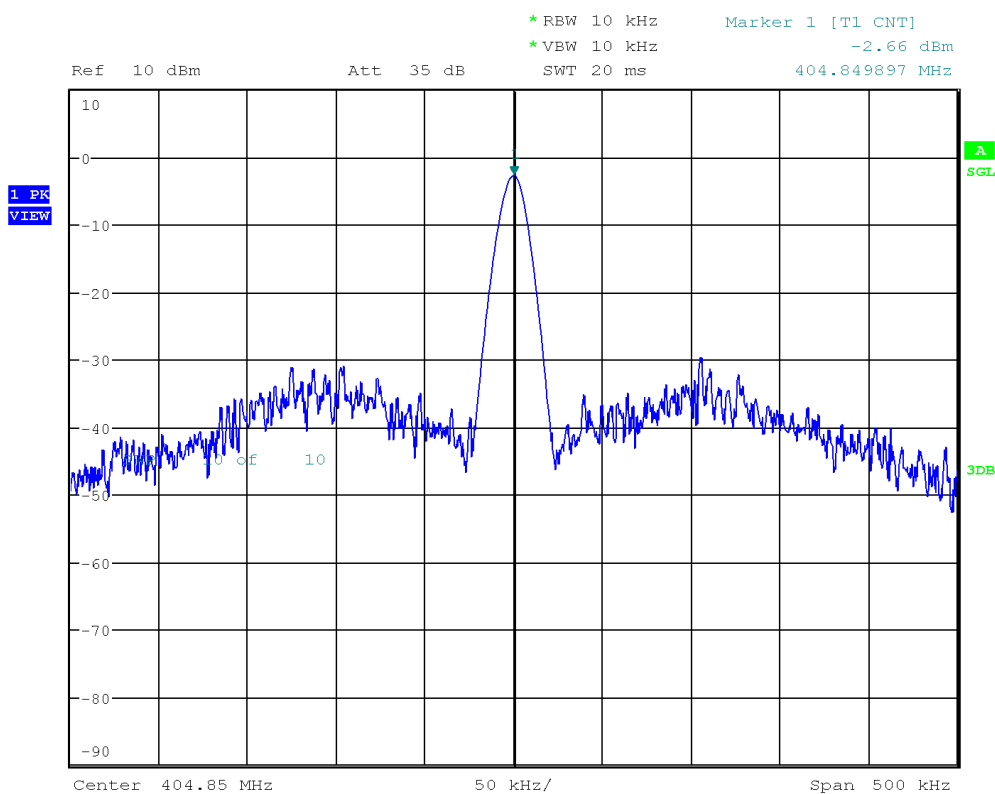
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Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	CW, Channel 7, 404.85 MHz
Operating Conditions:	Tnom/Vnom
Operator:	Md Abu Bakar Siddique
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	404.850000
Measured Frequency [MHz]:	404.849897
Frequency Error [kHz]:	-0.103
Frequency Error [ppm]:	-0.25



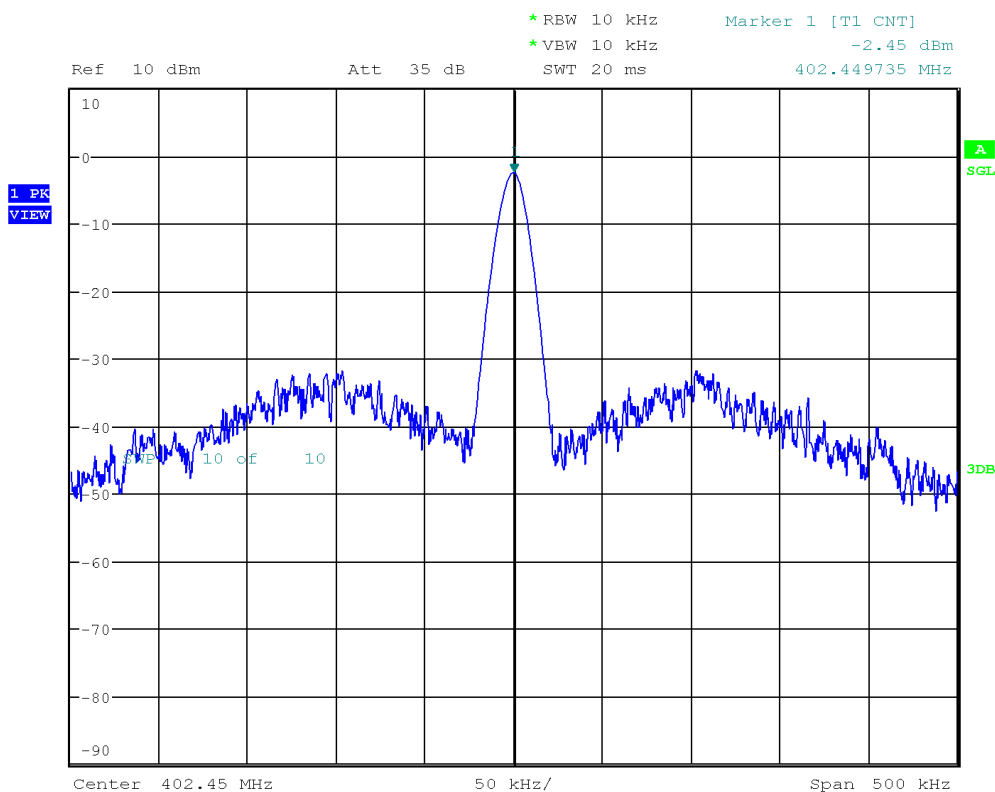
Date: 21.JAN.2025 16:31:18

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	GFSK, Channel 8, 402.45 MHz
Operating Conditions:	Tmin/Vnom
Operator:	Florian Voigt
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	402.450000
Measured Frequency [MHz]:	402.449735
Frequency Error [kHz]:	-0.265
Frequency Error [ppm]:	-0.66



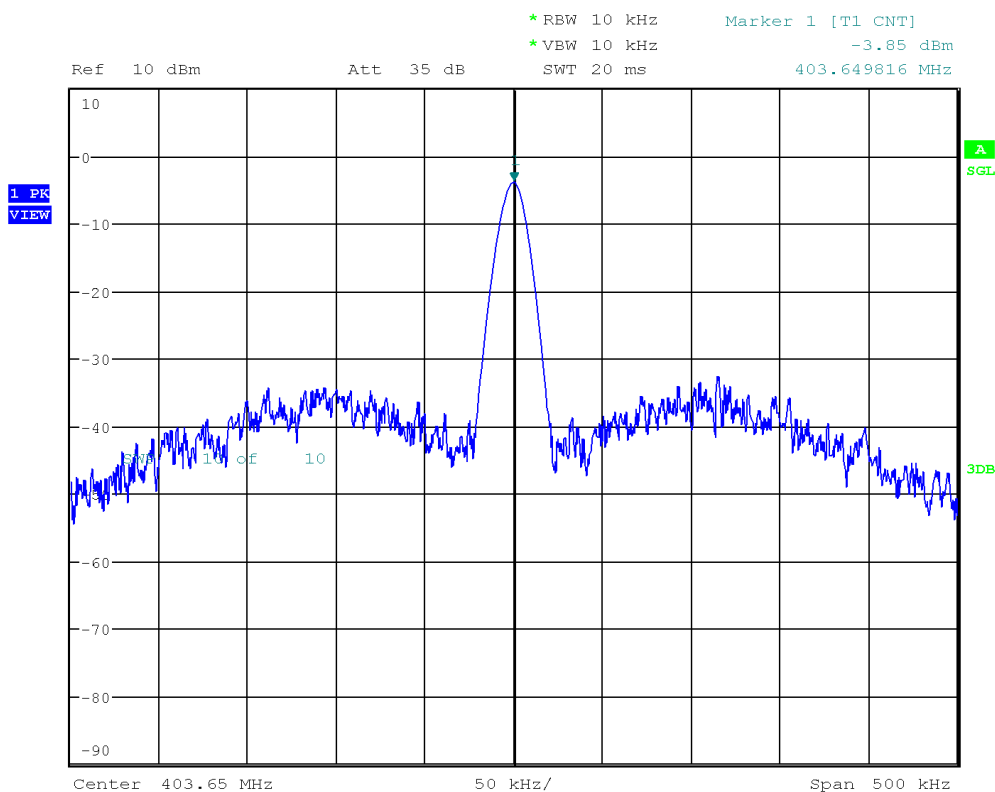
Date: 21.JAN.2025 12:01:27

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	GFSK, Channel 0, 403.65 MHz
Operating Conditions:	Tmin/Vnom
Operator:	Florian Voigt
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	403.650000
Measured Frequency [MHz]:	403.649816
Frequency Error [kHz]:	-0.184
Frequency Error [ppm]:	-0.46



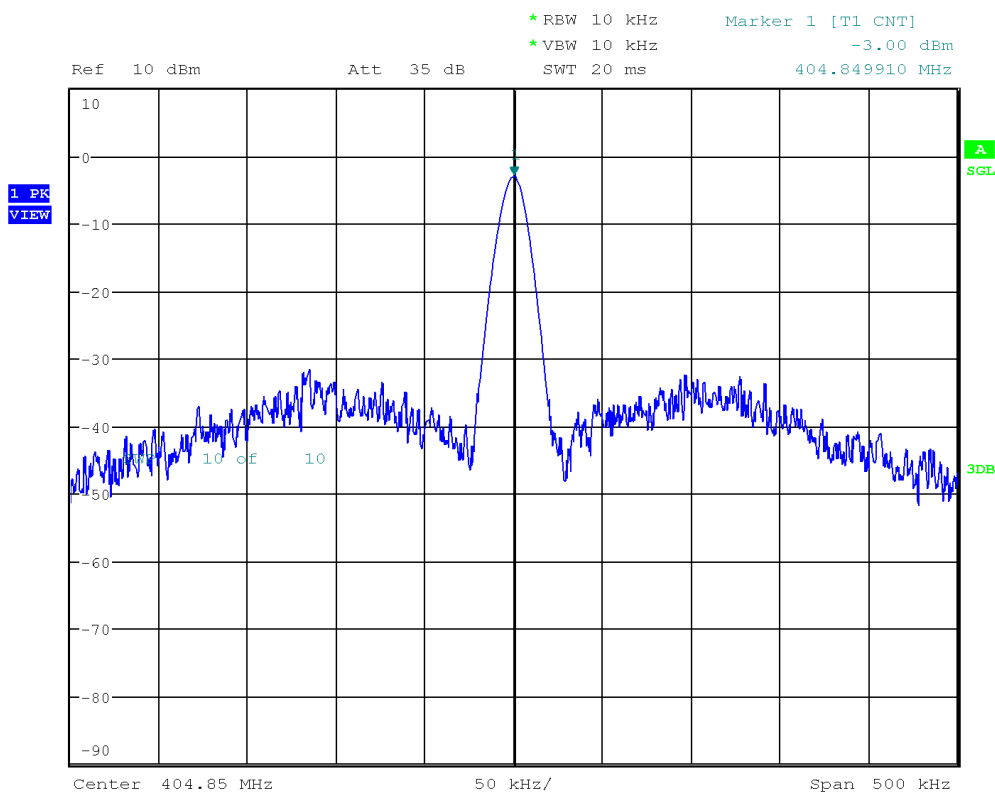
Date: 21.JAN.2025 12:01:58

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	GFSK, Channel 7, 404.85 MHz
Operating Conditions:	Tmin/Vnom
Operator:	Florian Voigt
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	404.850000
Measured Frequency [MHz]:	404.849910
Frequency Error [kHz]:	-0.090
Frequency Error [ppm]:	-0.22



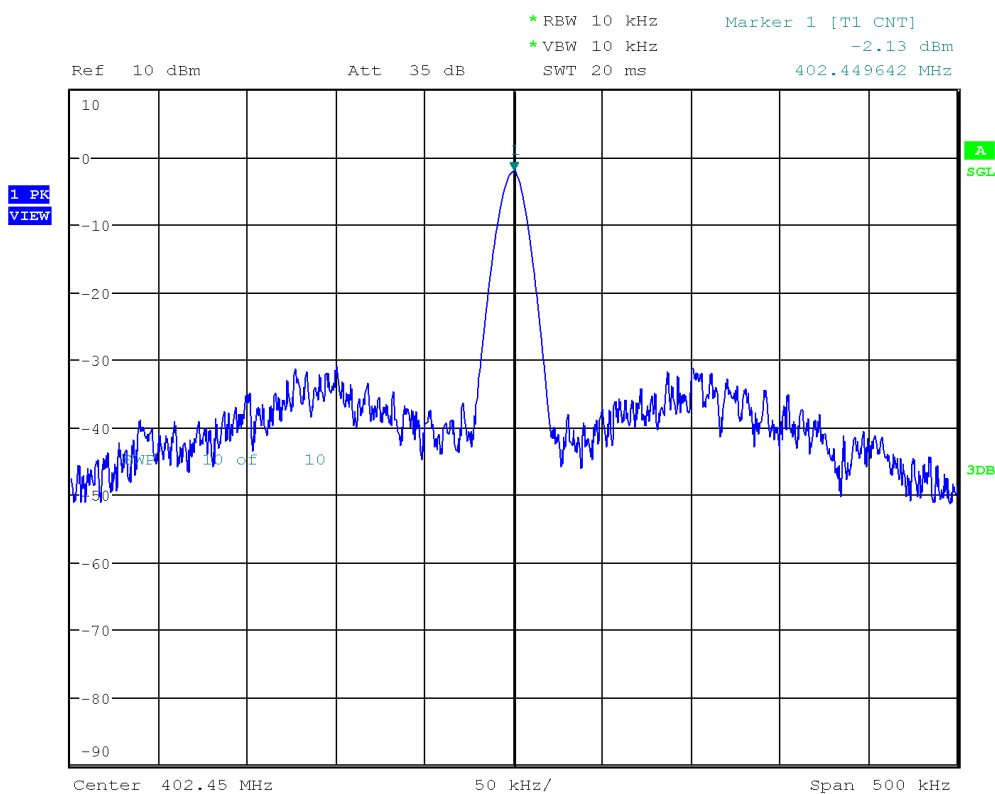
Date: 21.JAN.2025 12:02:21

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	CW, Channel 8, 402.45 MHz
Operating Conditions:	Tmax/Vnom
Operator:	Md Abu Bakar Siddique
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	402.450000
Measured Frequency [MHz]:	402.449642
Frequency Error [kHz]:	-0.358
Frequency Error [ppm]:	-0.89



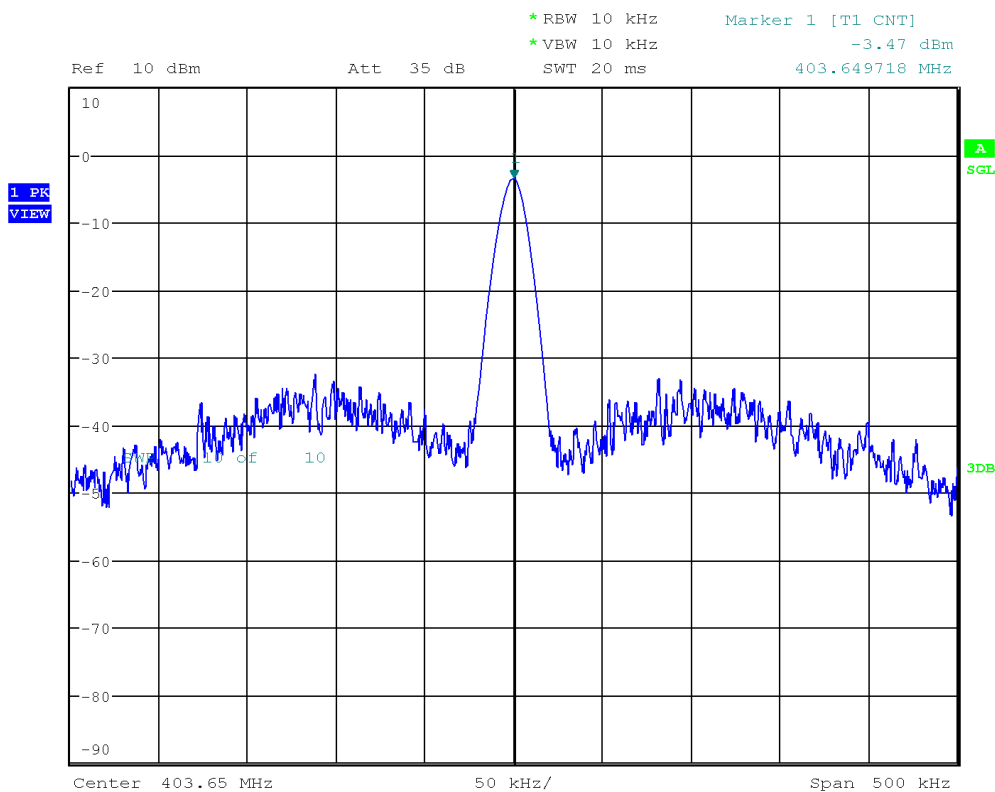
Date: 21.JAN.2025 16:40:21

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	CW, Channel 0, 403.65 MHz
Operating Conditions:	Tmax/Vnom
Operator:	Md Abu Bakar Siddique
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	403.650000
Measured Frequency [MHz]:	403.649718
Frequency Error [kHz]:	-0.282
Frequency Error [ppm]:	-0.70



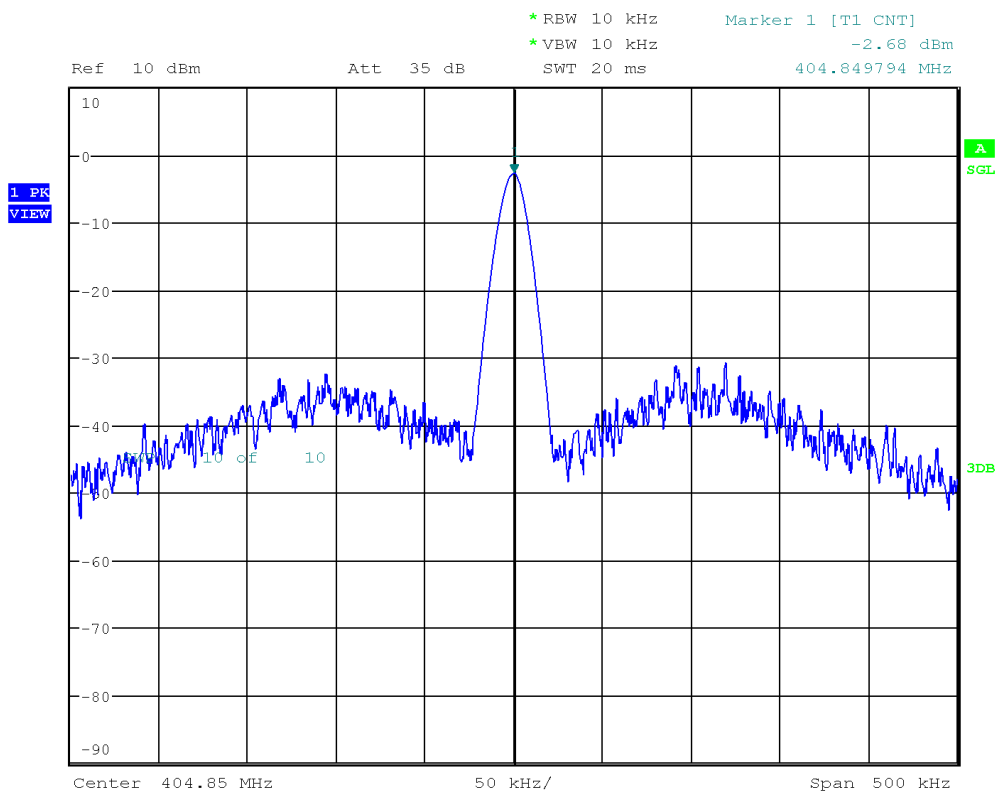
Date: 21.JAN.2025 16:40:49

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

Frequency accuracy

Project Number:	G0M-2407-2638
Applicant:	BIOTRONIK SE & Co. KG
Model Description:	ICD4200-10 / Implantable Cardioverter Defibrillator
Model:	Acticor Sky HF-T QP, additional models see family list
Test Sample ID:	50617
Reference Method:	Spectrum-analyzer build in function Marker Count
Operational Mode:	CW, Channel 7, 404.85 MHz
Operating Conditions:	Tmax/Vnom
Operator:	Md Abu Bakar Siddique
Test Site:	Eurofins Product Service GmbH
Test Date:	2025-01-21
Nominal Frequency [MHz]:	404.850000
Measured Frequency [MHz]:	404.849794
Frequency Error [kHz]:	-0.206
Frequency Error [ppm]:	-0.51



Date: 21.JAN.2025 16:41:10

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

3.4 Test Conditions and Results - Transmitter output power

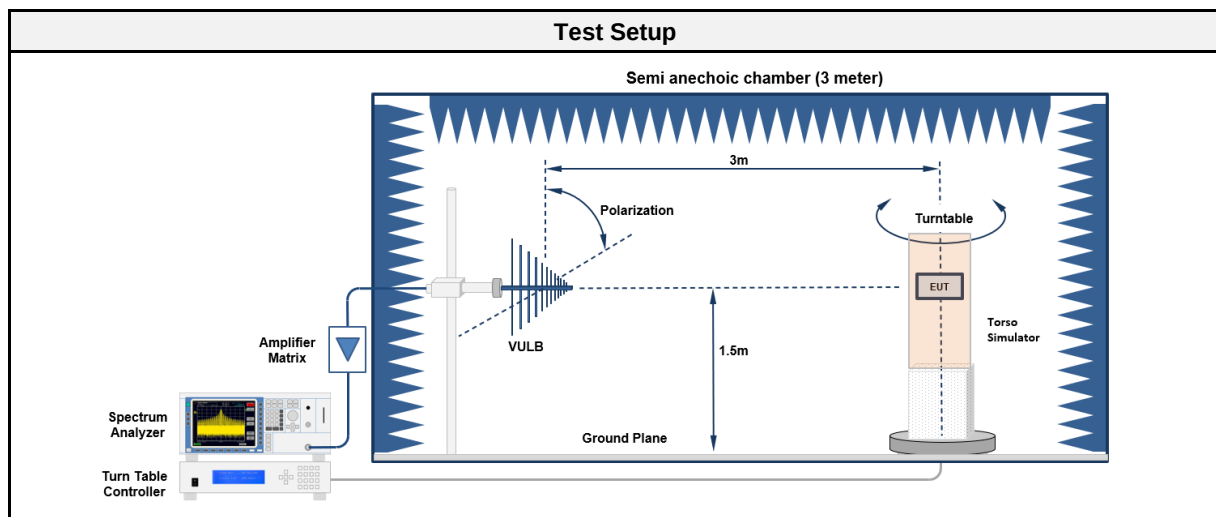
3.4.1 Information

Test Information	
Reference	FCC 95.2567(a), 95.2569 ISED RSS-243 5.4
Measurement Method	EN 301 839 5.3.3
Operator	Md Abu Bakar Siddique
Date	2025-01-29

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
Semi-Anechoic chamber	Frankonia Germany EMC Solutions GmbH	AC 1	EF00062	2024-07	2027-07
Test Receiver	Rohde & Schwarz GmbH & Co. KG - Vertrieb Berlin	ESW44	EF01856	2024-04	2025-04
Trilog Broadband Antenna	Schwarzbeck	VULB 9168	EF01824	2022-10	2025-10
Precision antenna kit	Schwarzbeck	UHAP	EF00017	2023-09	2026-09
Vector Signal Generator	Rohde Schwarz GmbH & Co. KG	SMBV 100A	EF01393	2024-07	2025-07

3.4.5 Procedure

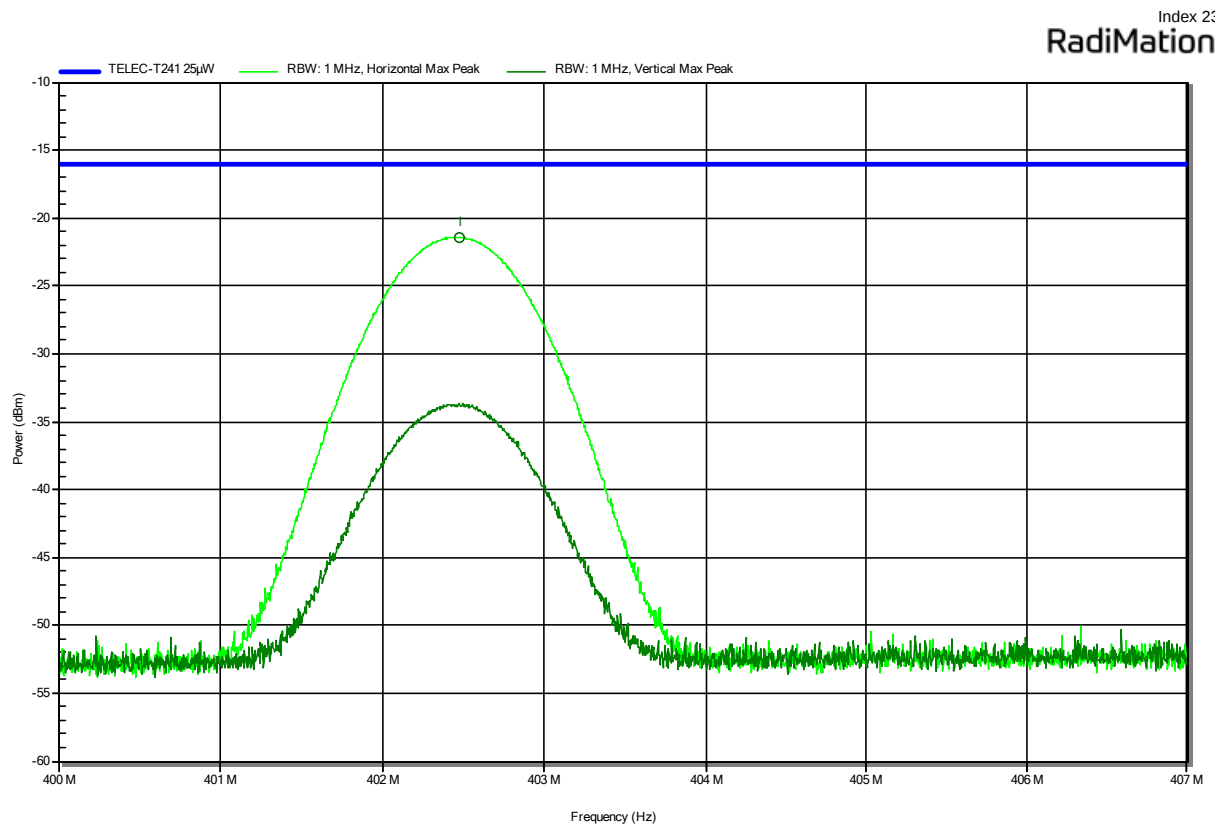
Test Procedure	
1.	EUT is set into test mode with activated transmitter. With unmodulation and under normal test conditions.
2.	The spectrum analyzer is set to peak detection with max hold and RBW = VBW according to frequency range.
3.	The measurement antenna is set to vertical polarization.
4.	The EUT is rotated through 360° in horizontal plane.
5.	Significant emissions are remeasured using the corresponding final detector. The measurement antenna is raised and lowered during remeasurement to get maximum level.
6.	The measurement polarization is set to horizontal polarization and the measurement is repeated.
7.	For significant emissions EUT is replaced by a substitution antenna with connected signal generator.
8.	Signal generator is set to frequency according to significant emission. Measurement antenna is raised and lowered again to capture maximum signal.
9.	Generator level is adjusted to measure same emission power as originally was measured.
10.	Level of generator, compensated by cable loss and substitution antenna gain, is noted as the final measurement result.

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	-26.08	pk	-16	-10.08
403.65	-26.68	pk	-16	-10.68
404.85	-25.88	pk	-16	-9.88
Note: Final measurement is done using substitution method and the results in this table will not correspond to the graphic.				

Radiated carrier according to FCC 47 CFR Part 95I

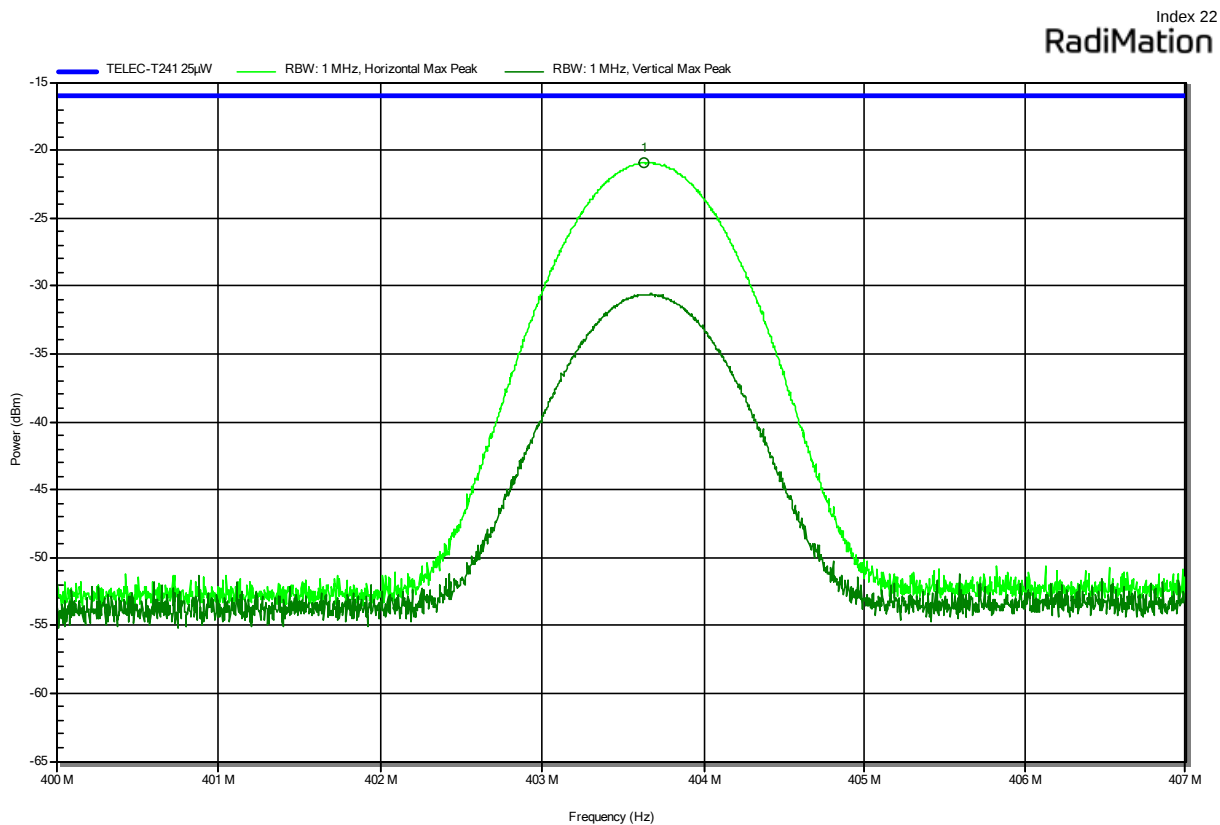
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 24 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 402.45 MHz
 Test Date: 2025-01-29
 Note: Result is substituted and will not correspond to graphic



Frequency (MHz)	Peak (dBm)	Peak Limit (dBm)	Peak Difference (dB)	Peak Status
402.471	-21.4	-16	-5.4	Pass

Radiated carrier according to FCC 47 CFR Part 95I

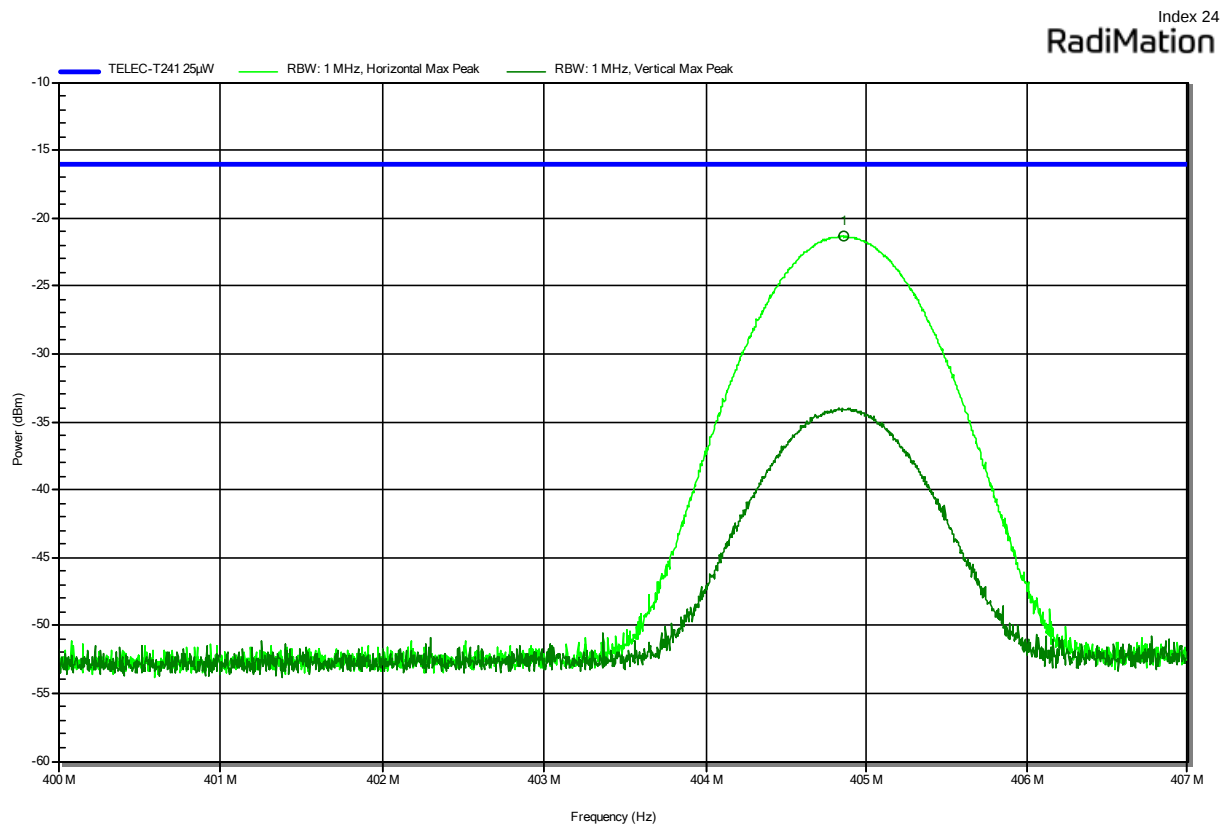
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 24 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168, Horizontal
 Measurement distance: 3 m
 Mode: Tx; CW; 403.65 MHz
 Test Date: 2025-01-29
 Note: Result is substituted and will not correspond to graphic



Frequency (MHz)	Peak (dBm)	Peak Limit (dBm)	Peak Difference (dB)	Peak Status
403.628	-21	-16	-4.97	Pass

Radiated carrier according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 24 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168, Vertical
 Measurement distance: 3 m
 Mode: Tx; CW; 404.85 MHz
 Test Date: 2025-01-29
 Note: Result is substituted and will not correspond to graphic



Frequency (MHz)	Peak (dBm)	Peak Limit (dBm)	Peak Difference (dB)	Peak Status
404.86	-21.4	-16	-5.37	Pass

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

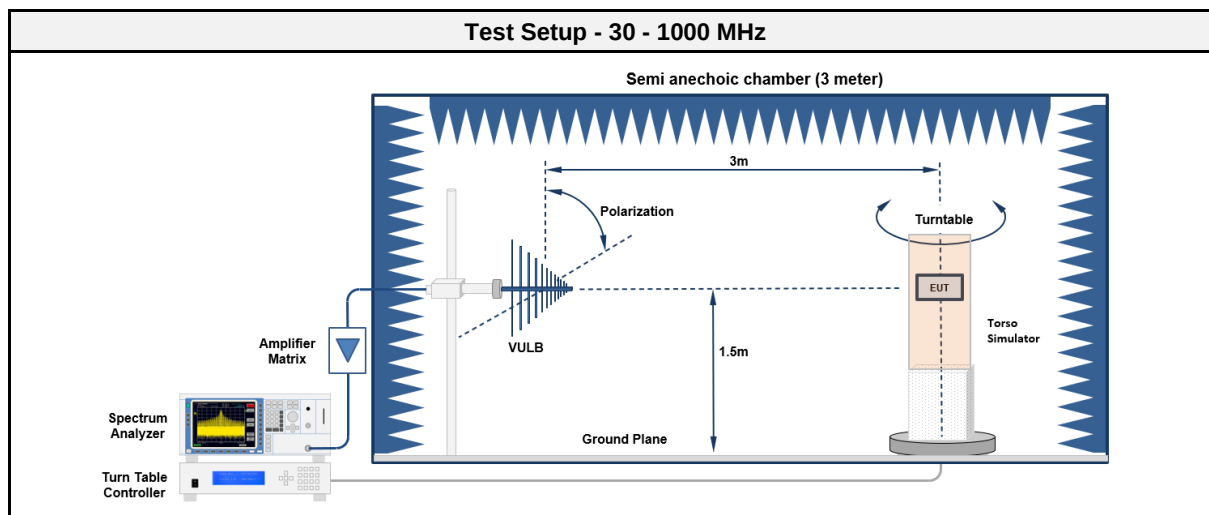
3.5.1 Information

Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.26 5.5
Operator	Md Abu Bakar Siddique
Date	2025-01-29

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 Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic chamber (NSA)	Frankonia	AC1	EF00062	2024-07	2027-07
Trilog Broadband Antenna	Schwarzbeck	VULB 9168	EF01824	2022-10	2025-10
EMI Test Receiver	R&S	ESW 44	EF01856	2024-04	2025-04

3.5.5 Procedure

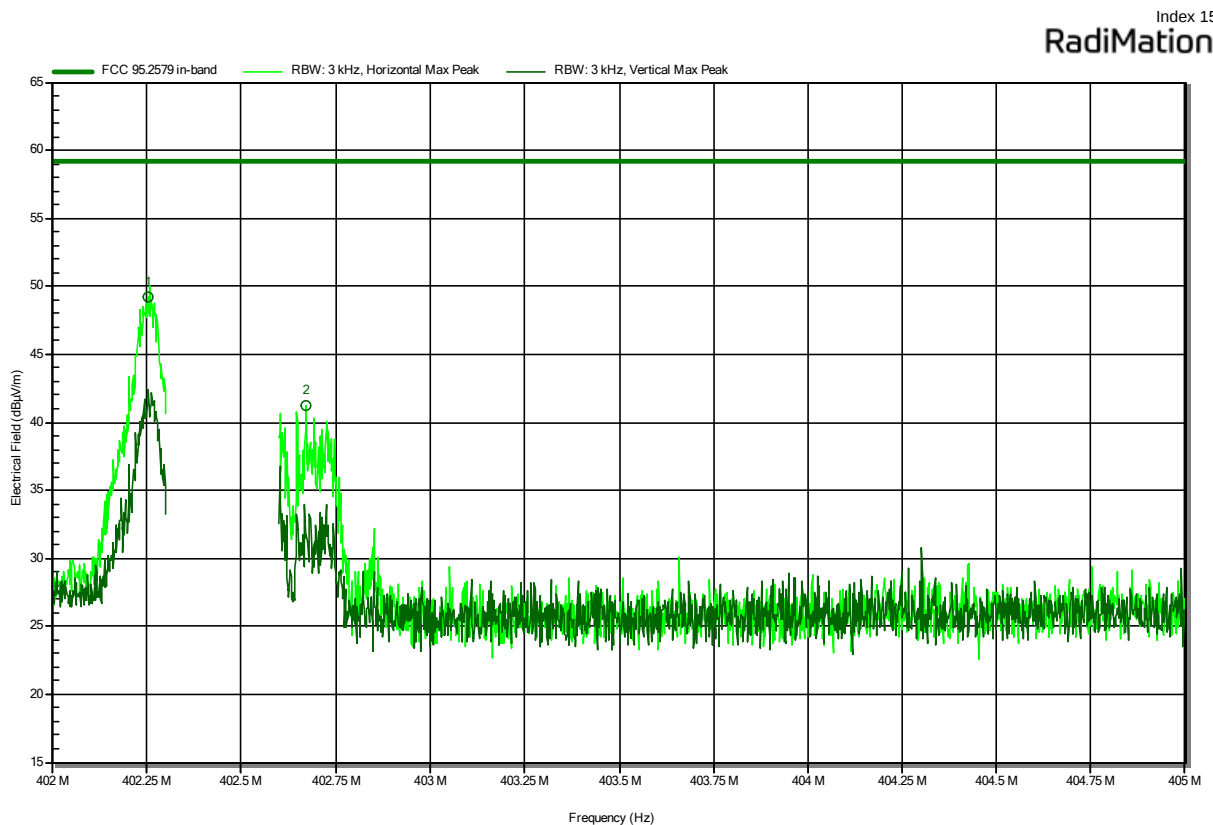
Test Procedure
1. EUT set to test frequency with modulation 2. Measurement polarization is set to vertical 3. Span it set according to measurement range 4. Resolution bandwidth is set to 1% of the emission bandwidth and detector is set to peak 5. During the sweep the EUT is rotated to obtain maximum 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	402.253	49.25	Horizontal	59.2	-9.95
404.85	404.999	44.69	Horizontal	59.2	-14.51

Radiated Spurious Emissions according to FCC 47 CFR Part 95I

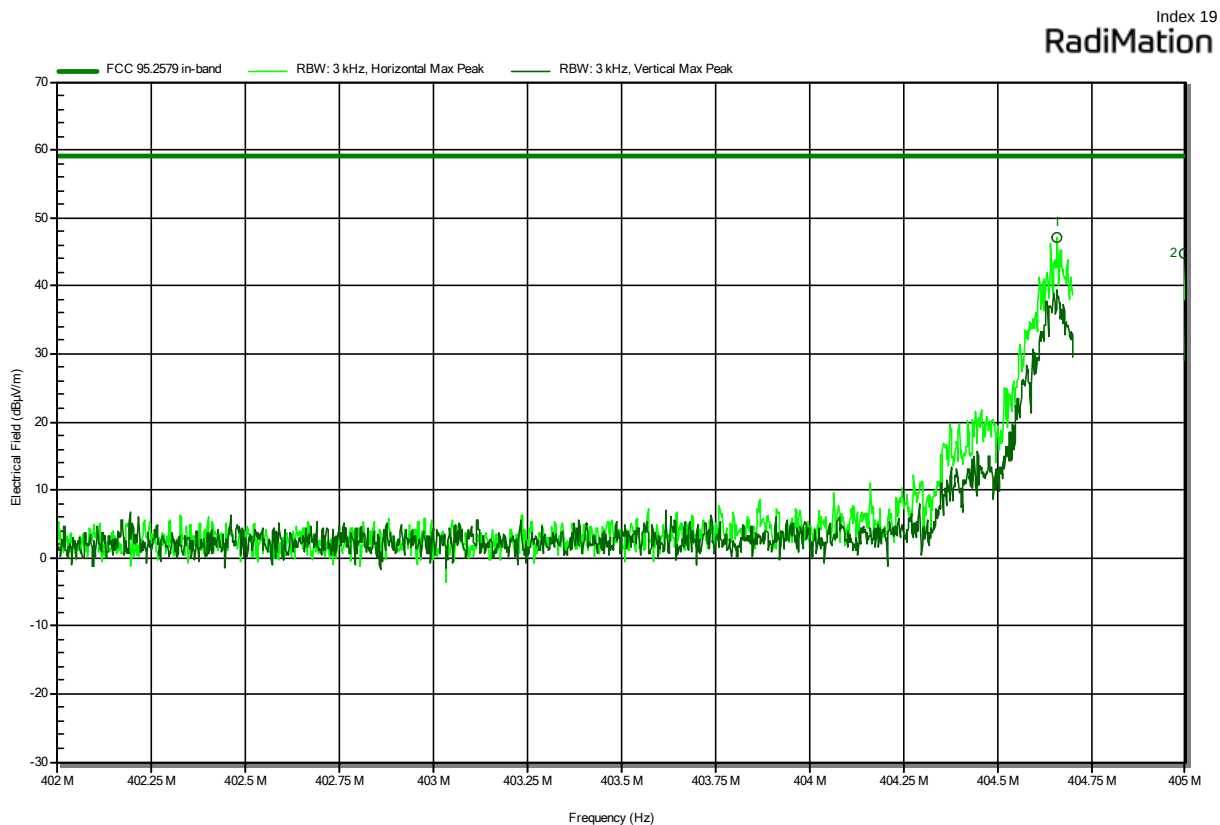
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2025-01-29
 Note: In-band emissions



Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit (dB)	Peak Difference	Peak Status	Polarization
1	402.253	49.25	59.2	-9.95		Pass	Horizontal
2	402.67	41.23	59.2	-17.97		Pass	Horizontal

Radiated Spurious Emissions according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2025-01-29
 Note: In-band emissions



Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit (dB)	Peak Difference	Peak Status	Polarization
1	404.658	47	59.2	-12.2		Pass	Horizontal
2	404.999	44.69	59.2	-14.51		Pass	Horizontal

3.6 Test Conditions and Results - Transmitter unwanted emissions

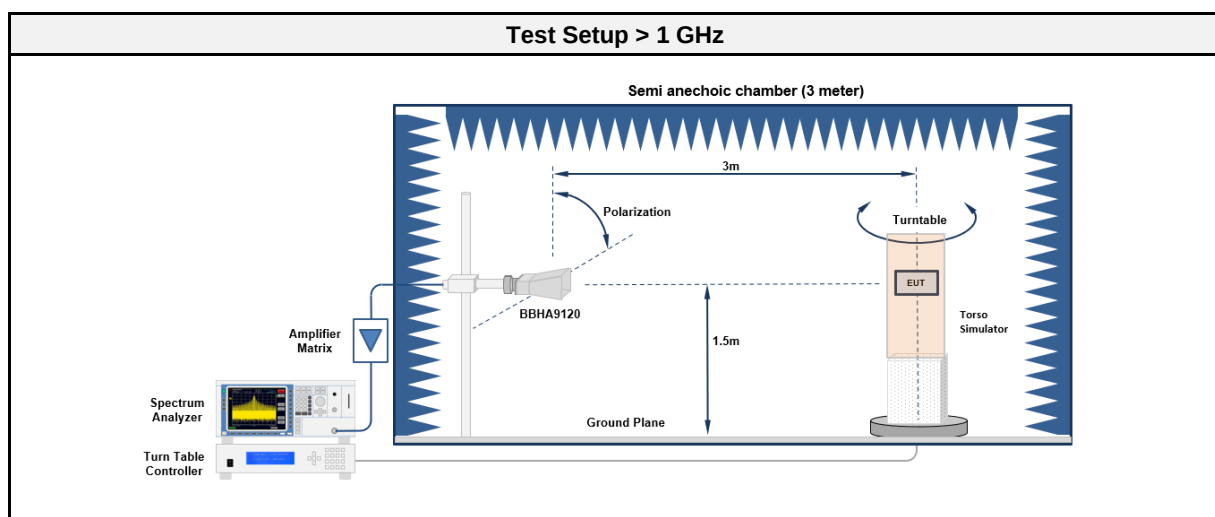
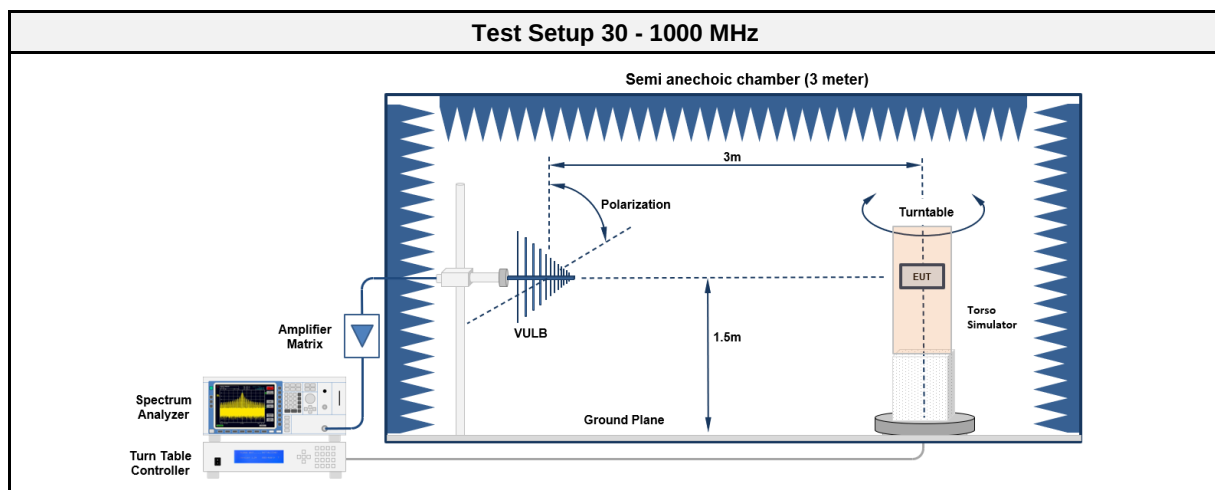
3.6.1 Information

Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.26 5.5
Operator	Md Abu Bakar Siddique
Date	2025-01-28

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



Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

3.6.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic chamber (NSA)	Frankonia	AC1	EF00062	2024-07	2027-07
Trilog Broadband Antenna	Schwarzbeck	VULB 9168	EF01824	2022-10	2025-10
EMI Test Receiver	R&S	ESW 44	EF01856	2024-04	2025-04

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic chamber (SVSWR)	Frankonia	AC1	EF01011	2024-07	2027-07
Horn antenna	Schwarzbeck	BBHA 9120D	EF00019	2023-12	2026-12
EMI Test Receiver	R&S	ESW 44	EF01856	2024-04	2025-04

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]	Distance [m]	Margin [dB]
403.65	405.087	34.63	pk	hor	46	3	-11.37

3.7 Test Conditions and Results - Receiver spurious emissions

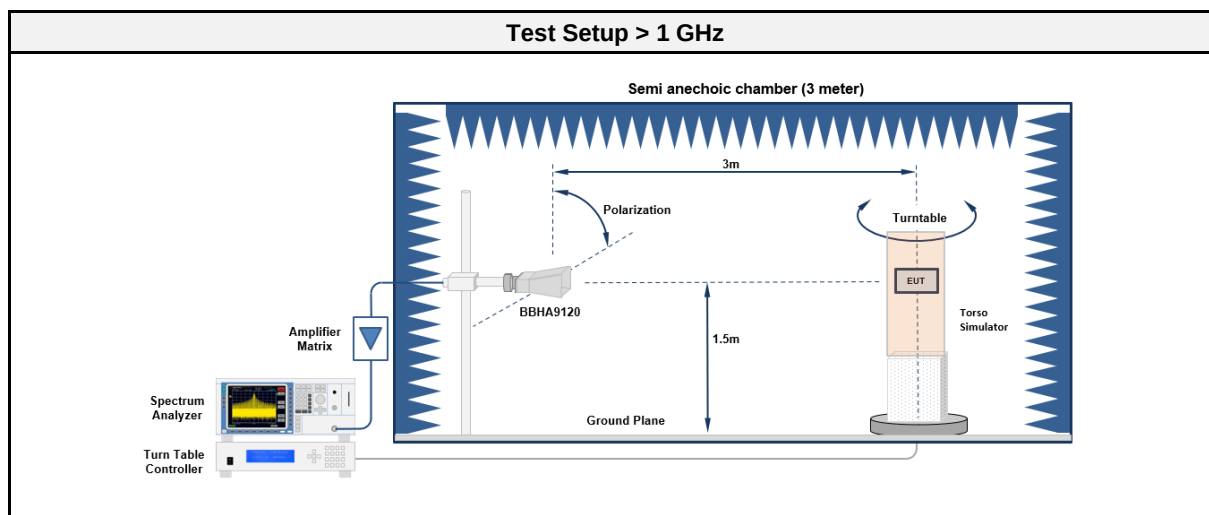
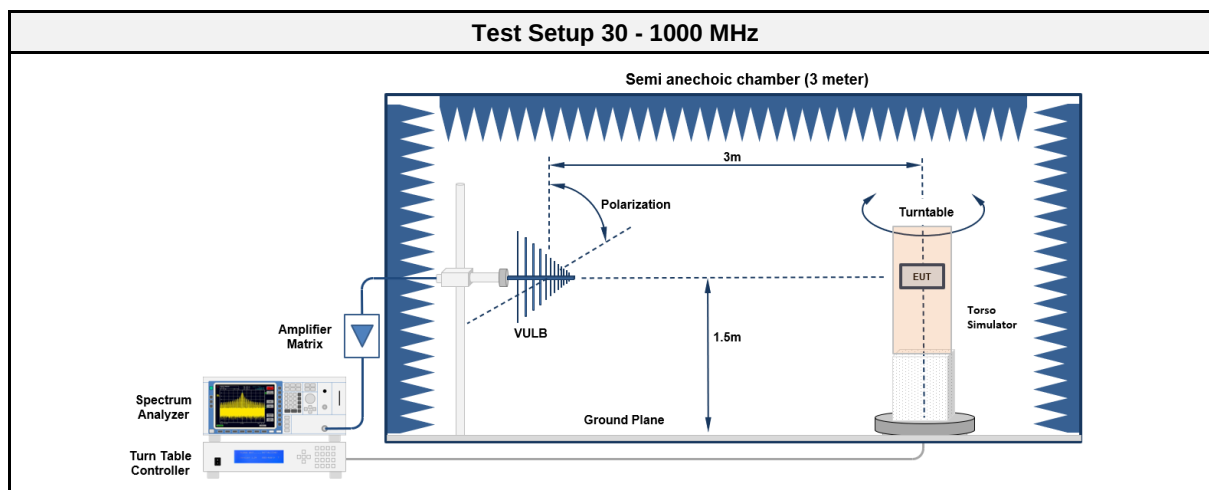
3.7.1 Information

Test Information	
Reference	ISED RSS-243 3.5, 5.6 ISED RSS-Gen 7.3
Measurement Method	ANSI C63.26 5.5
Operator	Md Abu Bakar Siddique
Date	2025-01-28

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



Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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

3.7.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic chamber (NSA)	Frankonia	AC1	EF00062	2024-07	2027-07
Trilog Broadband Antenna	Schwarzbeck	VULB 9168	EF01824	2022-10	2025-10
EMI Test Receiver	R&S	ESW 44	EF01856	2024-04	2025-04

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic chamber (SVSWR)	Frankonia	AC1	EF01011	2024-07	2027-07
Horn antenna	Schwarzbeck	BBHA 9120D	EF00019	2023-12	2026-12
EMI Test Receiver	R&S	ESW 44	EF01856	2024-04	2025-04

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	

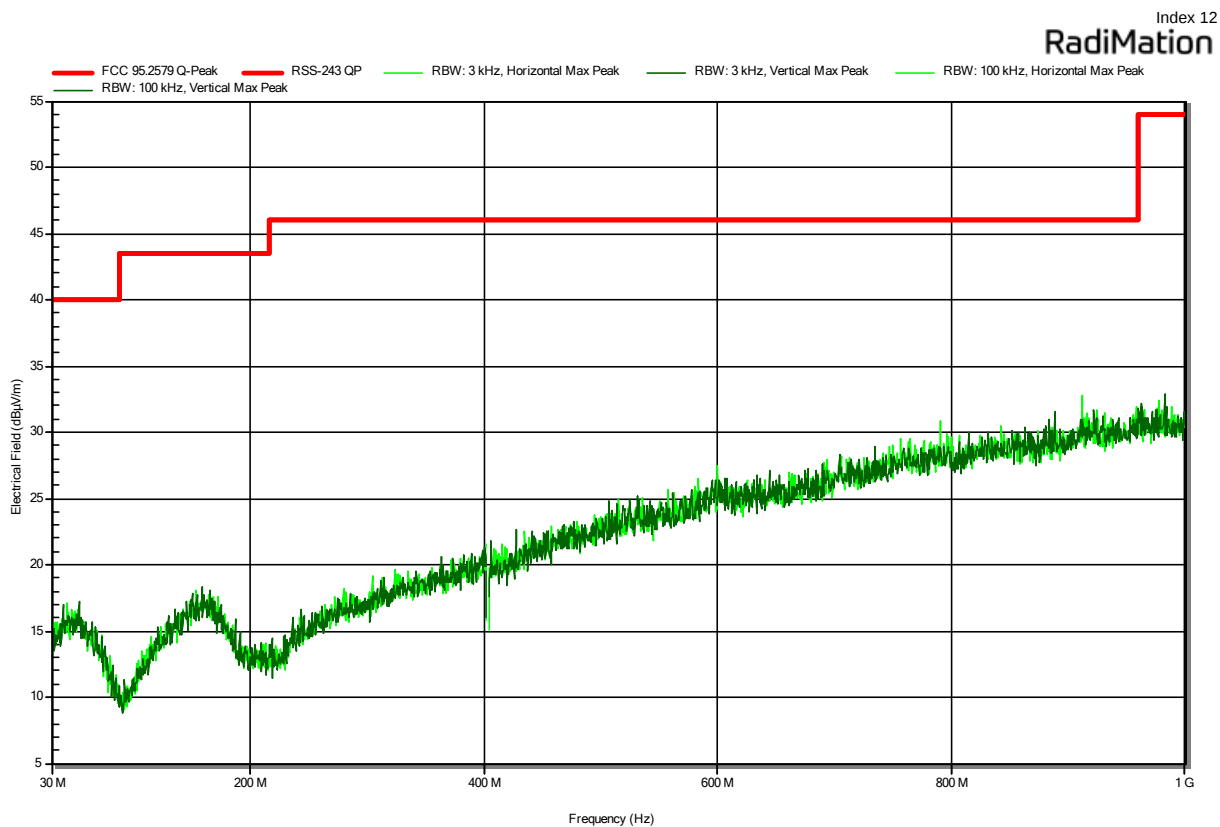
3.7.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Emission Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Margin [dB]
403.65	900.7367	32.8	pk	ver	46	-13.22
403.65	3903.77	40.91	pk	ver	74	-33.09
403.65	3903.77	28.84	avg	ver	53.98	-25.14

ANNEX A Transmitter spurious emissions

Radiated Spurious Emissions according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2025-01-28

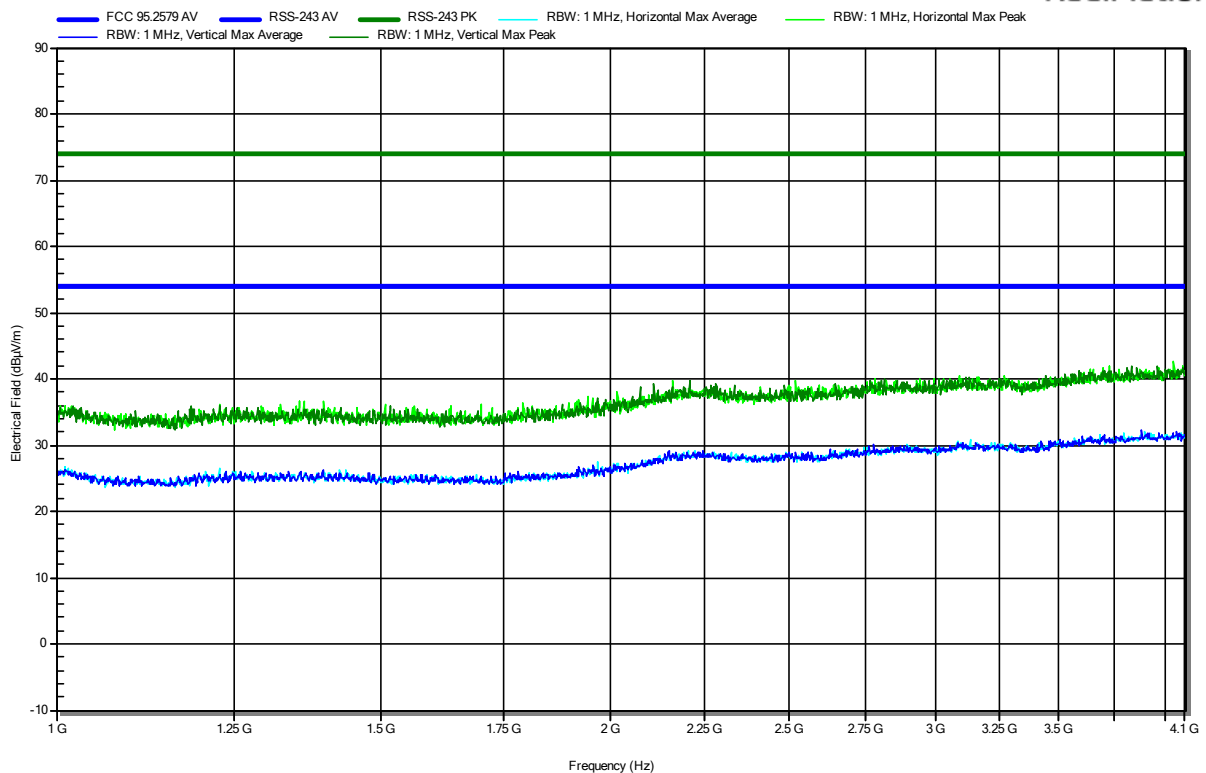


Radiated Spurious Emissions according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck BBHA 9120D
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 402.45 MHz
 Test Date: 2025-01-28

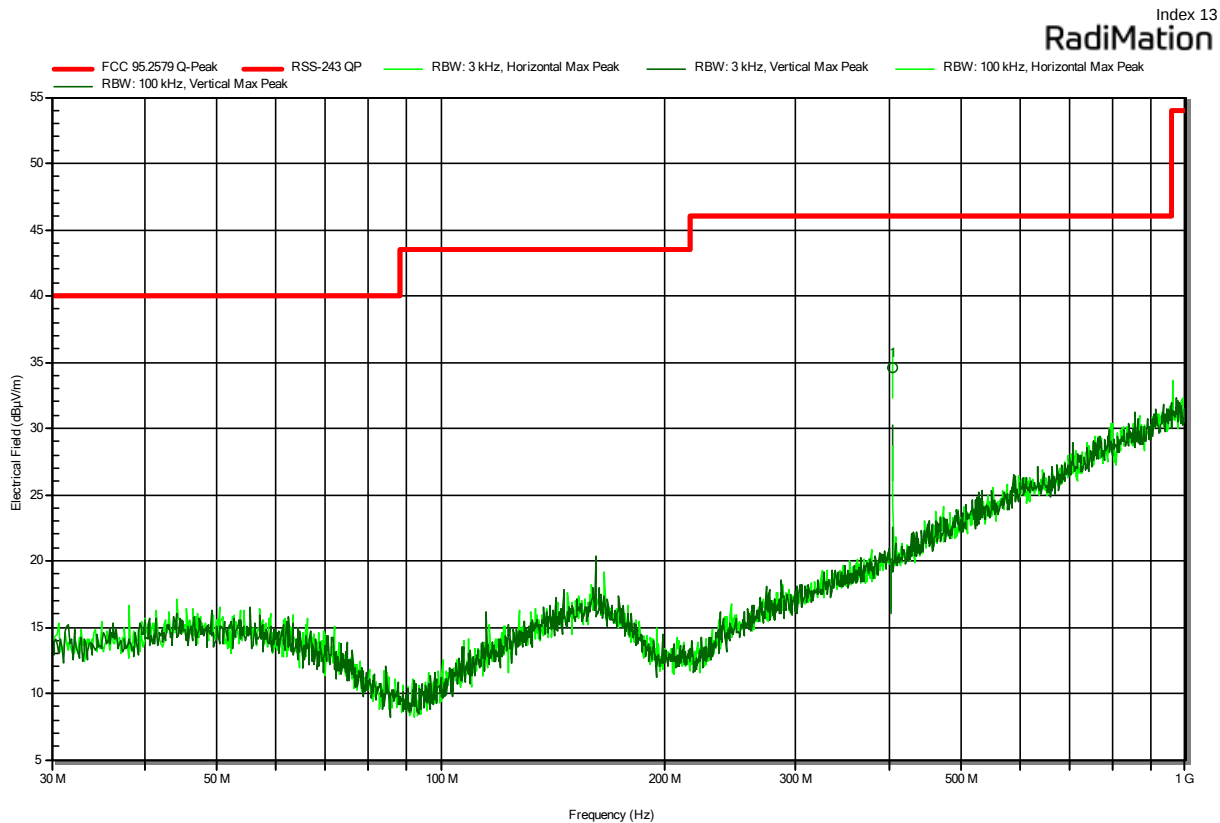
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RadiMation



Radiated Spurious Emissions according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 403.65 MHz
 Test Date: 2025-01-28



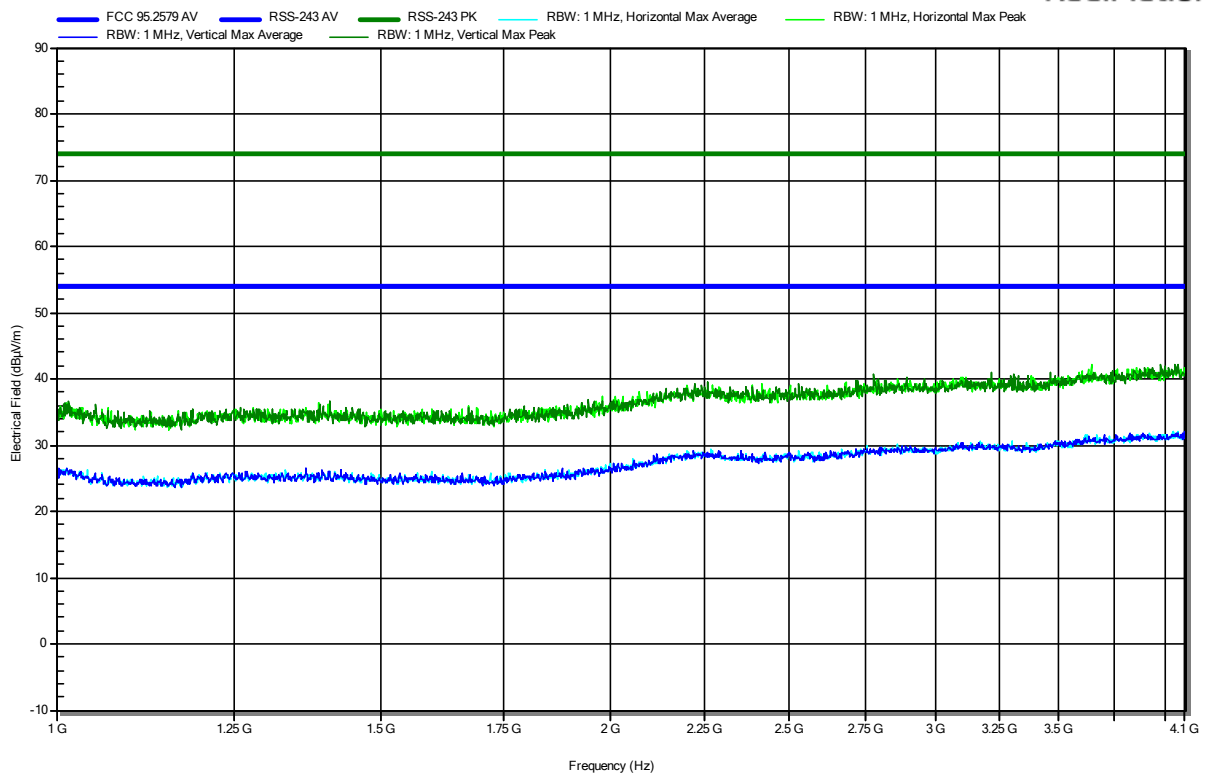
Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak (dBµV/m)	Limit (dB)	Peak Difference (dB)	Peak Status	Polarization
1	405.087	34.63	46	-11.37		Pass	Horizontal

Radiated Spurious Emissions according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck BBHA 9120D
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 403.65 MHz
 Test Date: 2025-01-28

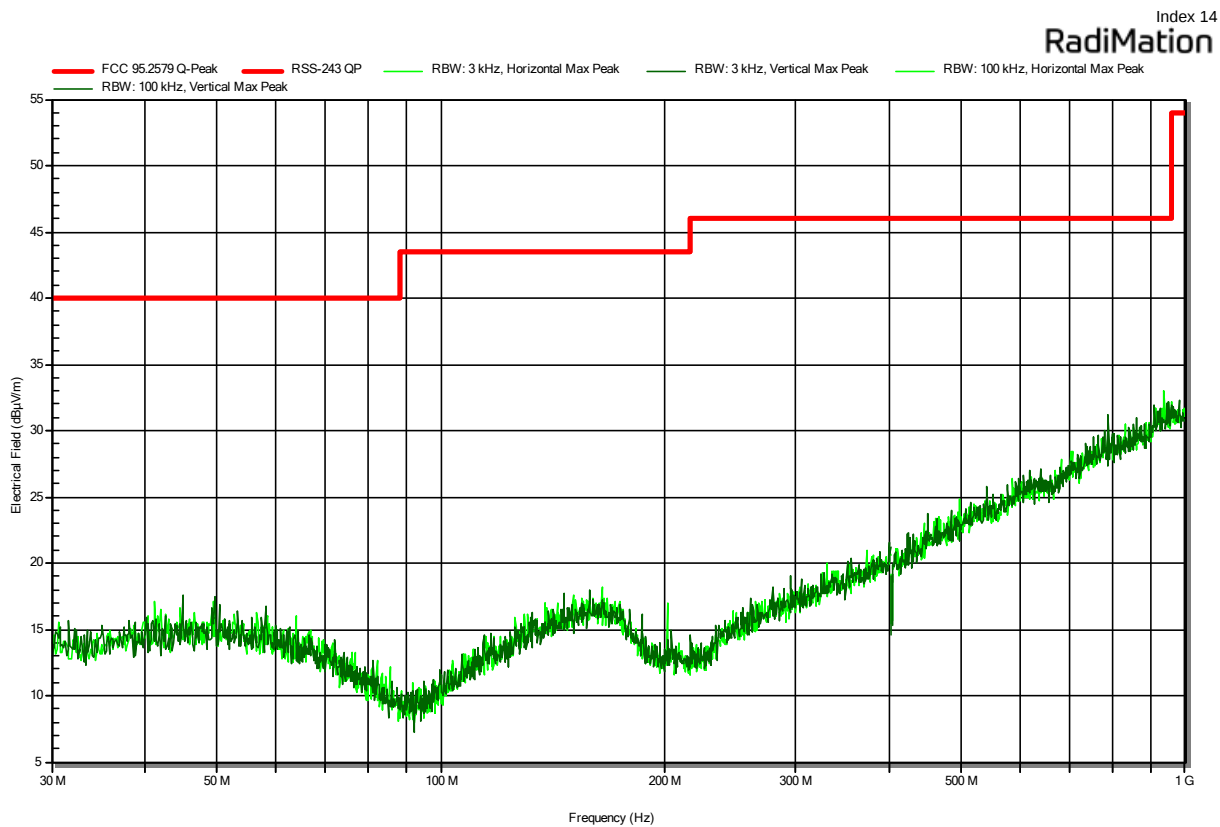
Index 9

RadiMation



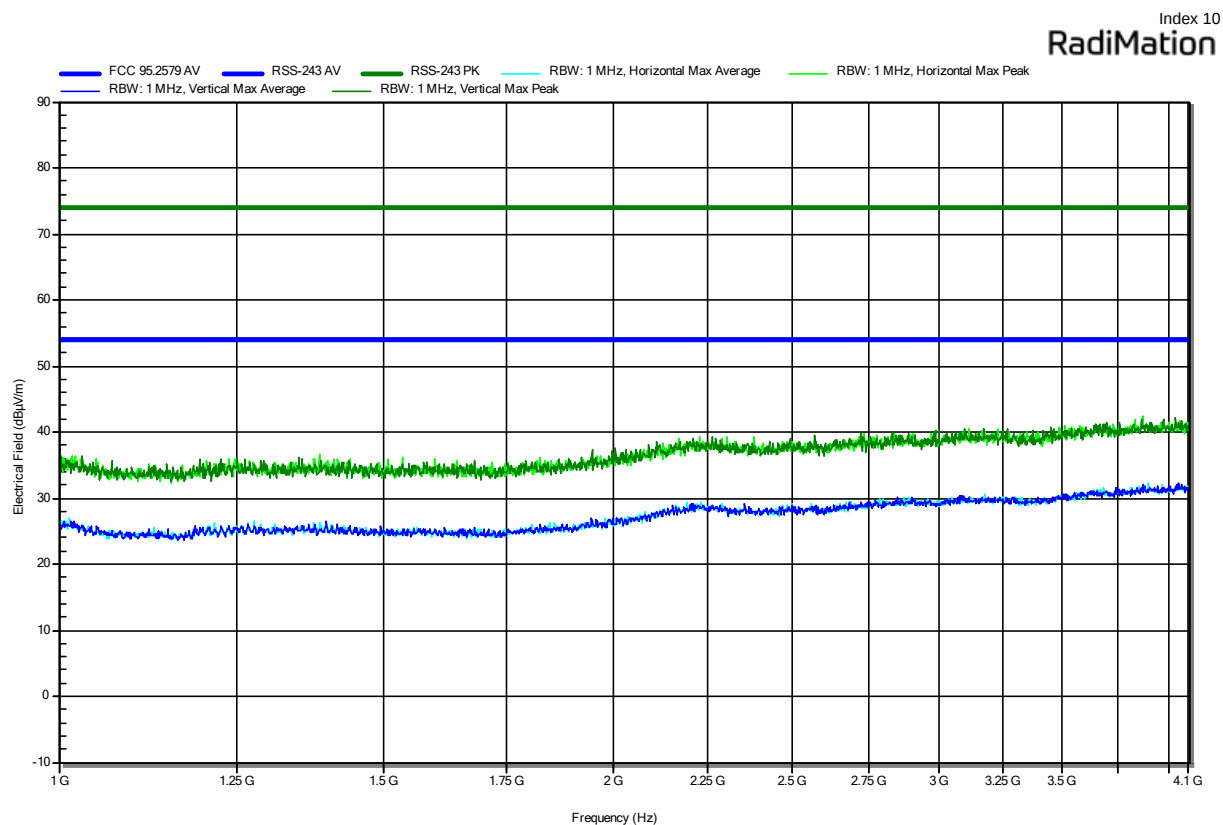
Radiated Spurious Emissions according to FCC 47 CFR Part 95I

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2025-01-28
 Note:



Radiated Spurious Emissions according to FCC 47 CFR Part 95I

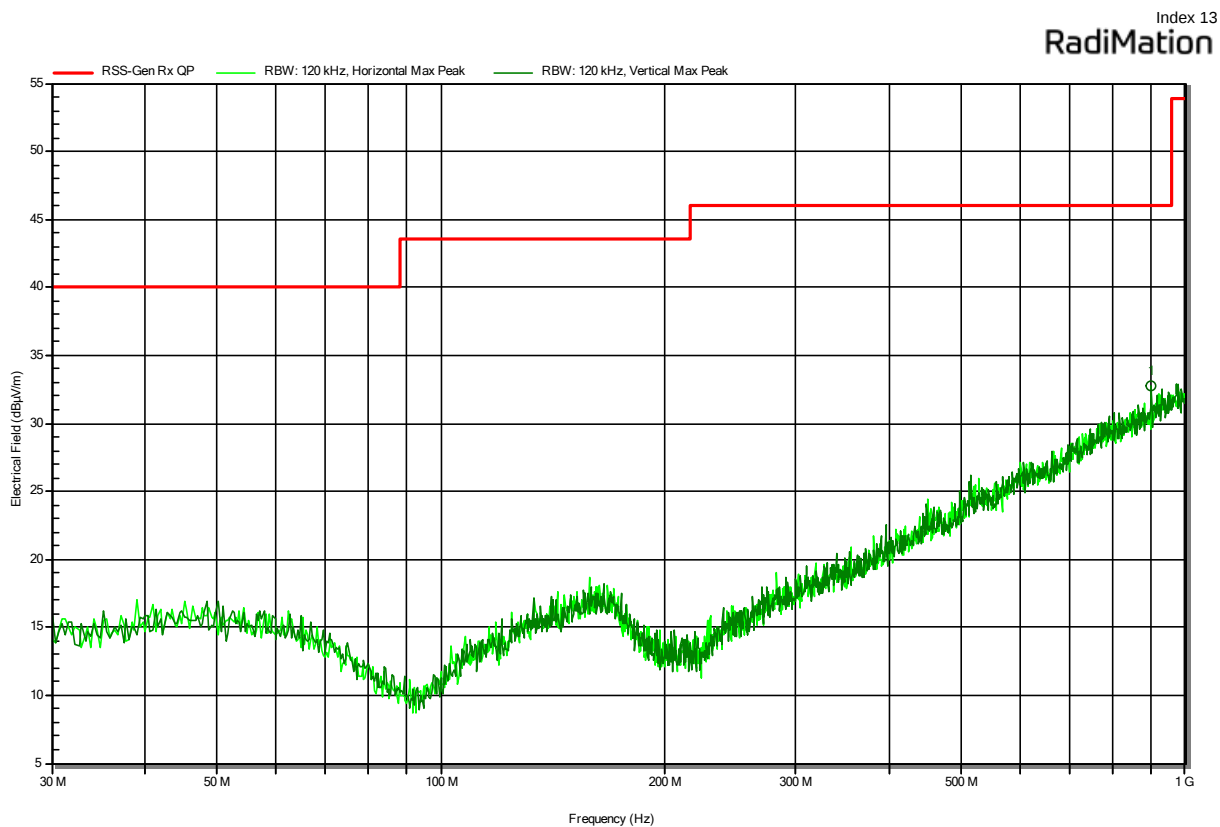
Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck BBHA 9120D
 Measurement distance: 3 m
 Mode: Tx; 2-FSK; 404.85 MHz
 Test Date: 2025-01-28
 Note: AC1



ANNEX B Receiver spurious emissions

Radiated Spurious Emissions according to ISED RSS-Gen

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Rx; 2-FSK; 403.65 MHz
 Test Date: 2025-01-28

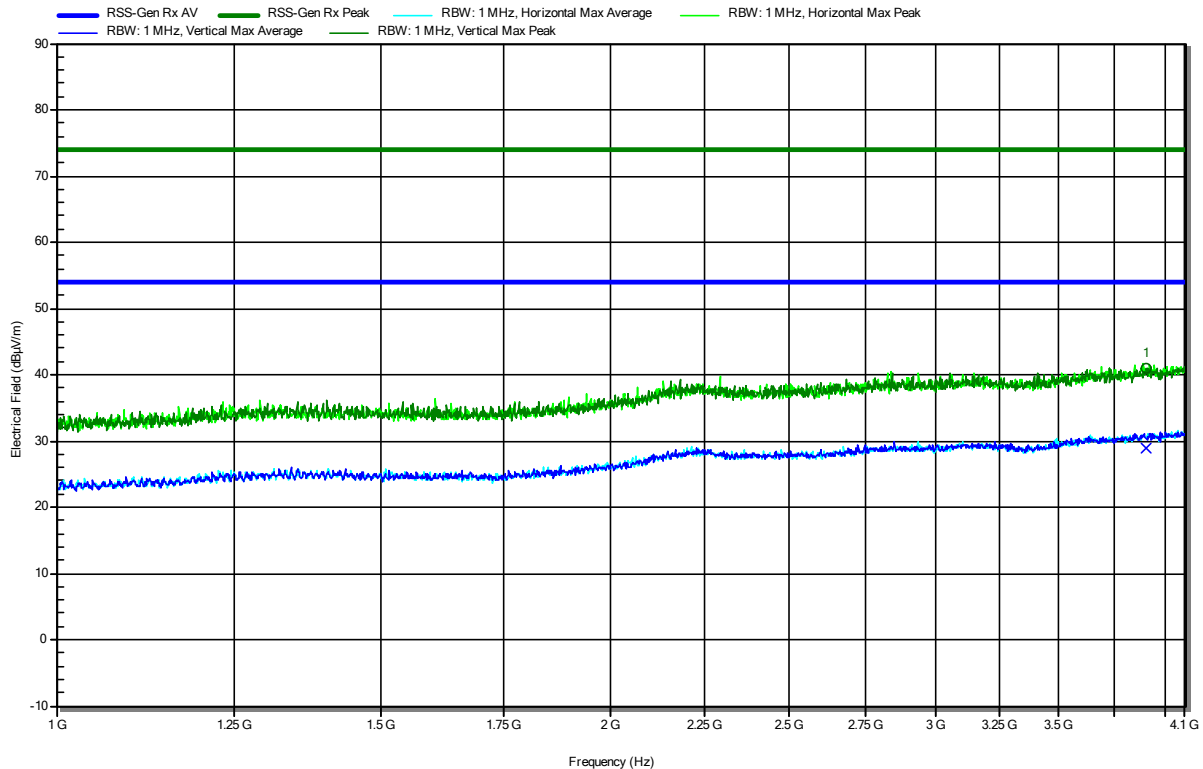


Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak (dBµV/m)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	900.7367	32.8	46		-13.22	Pass	Vertical

Radiated Spurious Emissions according to ISED RSS-Gen

Project Number: G0M-2407-2638
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: ICD4200-10 / Implantable Cardioverter Defibrillator
 Model: Acticor Sky HF-T QP, additional models see family list
 Test Sample ID: 50612
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Siddique
 Measurement software: RadiMation, version 2024.1.6
 Test Conditions: Tnom: 23 °Celsius, Vnom:
 Antenna: Schwarzbeck BBHA 9120D
 Measurement distance: 3 m
 Mode: Rx; 2-FSK; 403.65 MHz
 Test Date: 2025-01-28

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RadiMation



Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak (dBµV/m)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	3903.77	40.91	74		-33.09	Pass	Vertical

Peak Number	Frequency (MHz)	Average (dBµV/m)	Average (dBµV/m)	Limit	Average Difference (dB)	Average Status	Polarization
1	3903.77	28.84	53.98		-25.14	Pass	Vertical

=== End of test report ===

Test Report No.: G0M-2407-2638-TFC95IMR01-V02

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