

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-2403-2480-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-2 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	According to FCC/ISED rules
Standard	47 CFR Part 95I RSS-243, Issue 3, 2010-02 RSS-Gen, Issue 5, Amendment 2, 2021-02
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	CardioMessenger Smart / Telemonitorig System
Model(s)	CardioMessenger Smart 4G
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware Version(s)	CardioMessenger Smart 4G mit LP1 Rev Cx
Software Version(s)	ULP_HIGH_1_37_0, ULP_LOW_1_17_0, M0C.400005, SMARTAPP 1.x
FCC-ID	QRI-CMSMART4GWW2
IC	4708A-CMSMART4GWW2
Test Result	PASSED

Test Report No.: G0M-2403-2480-TFC95IMR-V01

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

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 - 23 °C	
Test Lab Humidity	32 – 38 %	
Date of receipt of test item	2024-10-10	
Report:		
Compiled by	Azamat Ibraimov	
Tested by (+ signature) (Responsible for Test)	Azamat Ibraimov	
Approved by (+ signature) (Senior Radio Expert)	Radwan Jaafar	
Date of Issue	2025-02-07	
Total number of pages	51	
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		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2025-02-07	Initial Release	--

ABBREVIATIONS AND ACRONYMS

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

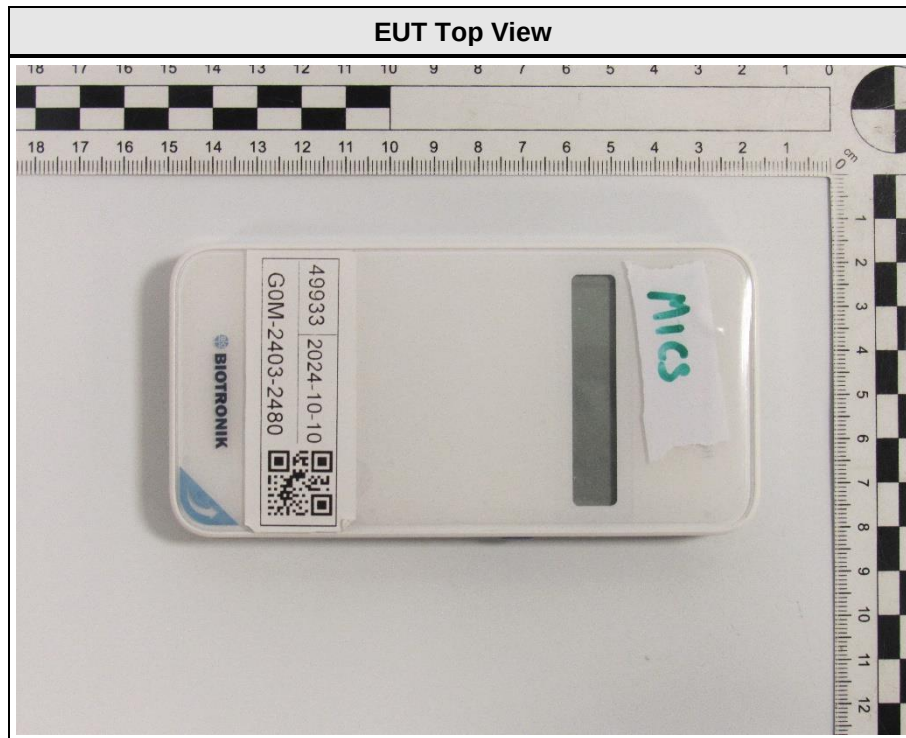
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1 Equipment (Test Item) Under Test

Description	CardioMessenger Smart / Telemonitorig System	
Model	CardioMessenger Smart 4G	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Sample-ID	49933	
Serial Number(s)	91244970	
Hardware Version(s)	CardioMessenger Smart 4G mit LP1 Rev Cx	
Software Version(s)	ULP_HIGH_1_37_0, ULP_LOW_1_17_0, M0C.400005, SMARTAPP 1.x	
PMN	CardioMessenger Smart 4G	
HVIN	CMSMART4GWW2	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRI-CMSMART4GWW2	
IC	4708A-CMSMART4GWW2	
Equipment type	End Product	
Radio type	Transceiver	
Assigned frequency bands	402 - 405 MHz	
Radio technology	MedRadio (MICS) programmer / control transmitter	
Modulation	2-FSK	
Emission designator	F1D	
Number of channels	9	
Channel spacing	300 kHz	
Spectrum access	LBT/AFA	
Number of antenna ports	1	
Antenna	Type	Integrated
	Model	PCB-Antenna
	Manufacturer	BIOTRONIK SE & Co. KG
	Gain	0.37 dBi (by antenna pattern measurement, refer to Annex C)
Supply Voltage	V _{NOM}	3.7 V DC via internal rechargeable lithium battery 5 V DC via external AC/DC adaptor
Operating Temperature	T _{NOM}	25 °C
	T _{MIN}	-20 °C
	T _{MAX}	55 °C
AC/DC-Adaptor 1	Model	GTM96180-1107-2.0
	Vendor	GlobTek
	Input	100-240 VAC
	Output	5 VDC
AC/DC-Adaptor 2	Model	FW8000
	Vendor	Friwo
	Input	100-240 VAC
	Output	5 VDC
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

1.1 Photos – Equipment External

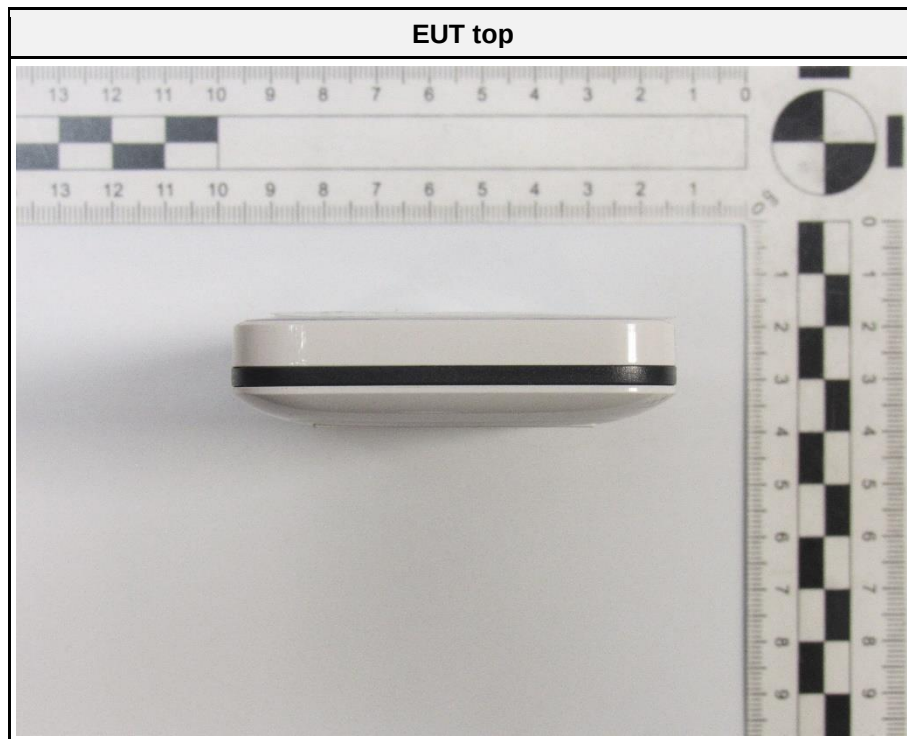


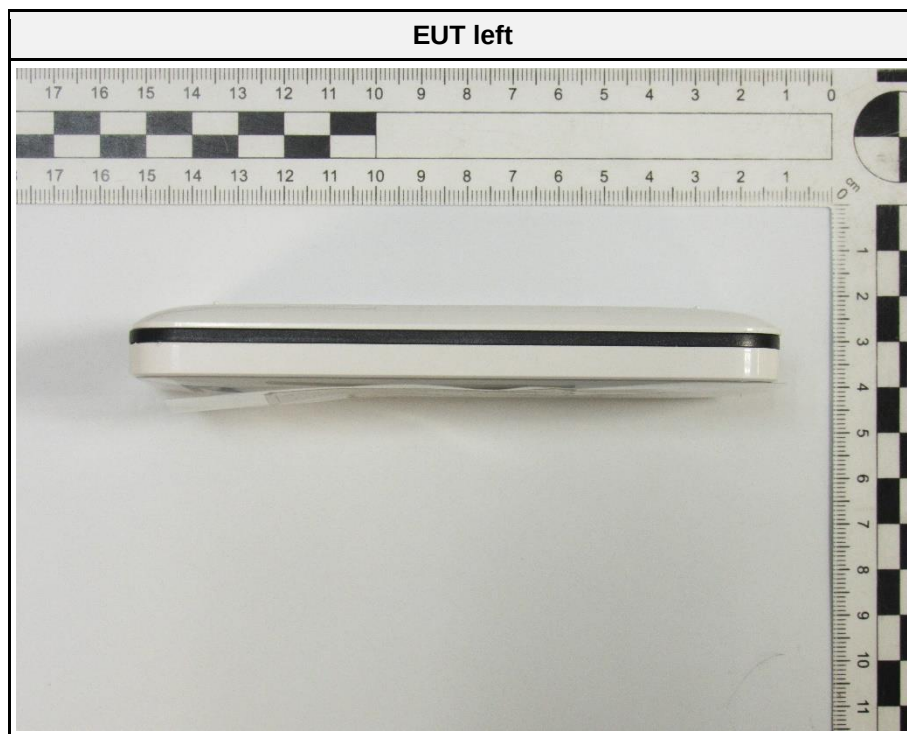
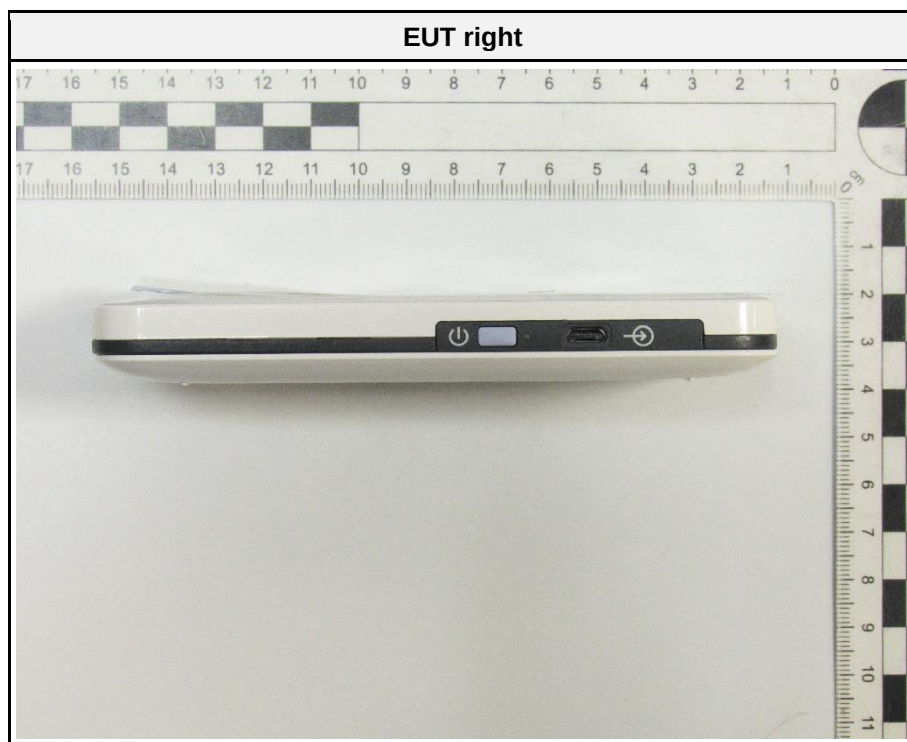
EUT Perspective 1



EUT Perspective 2

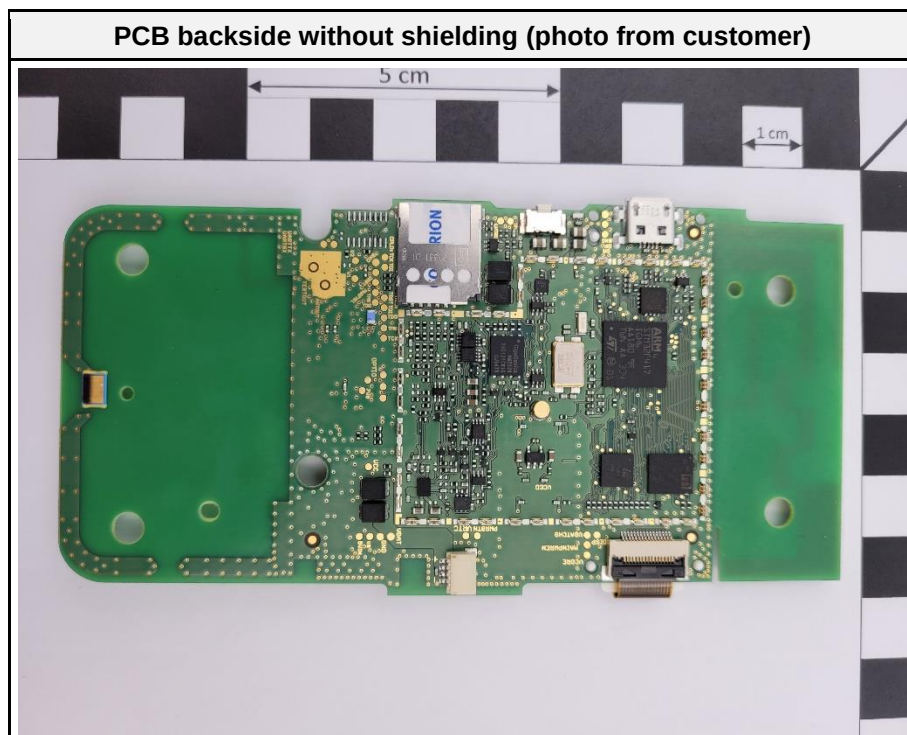
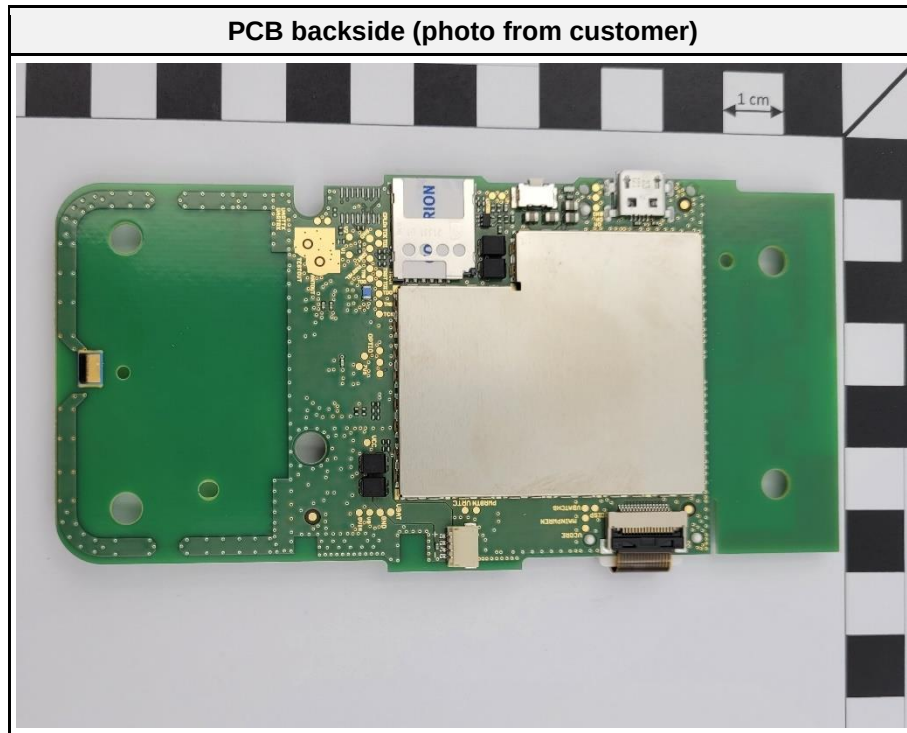




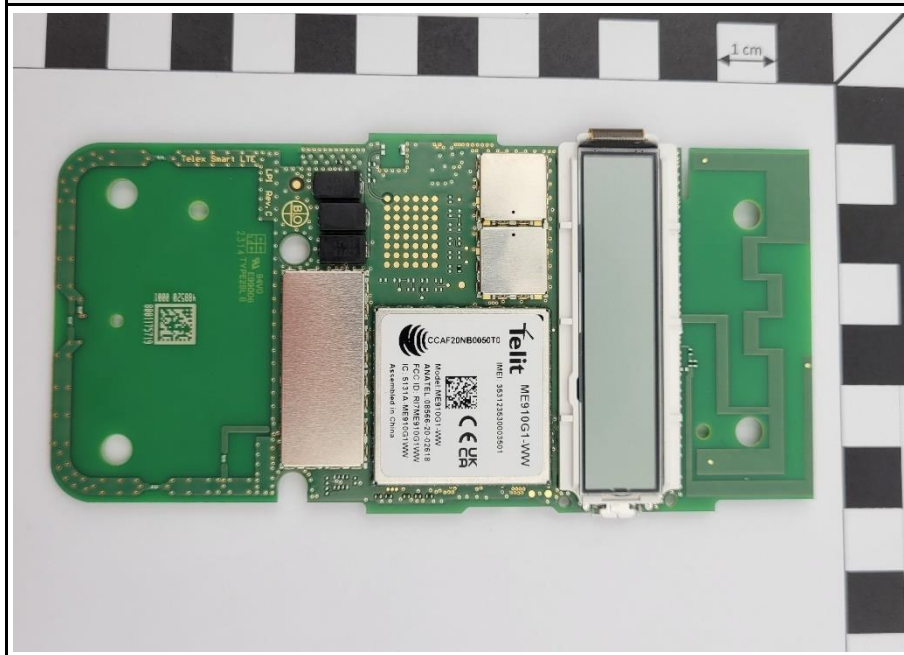




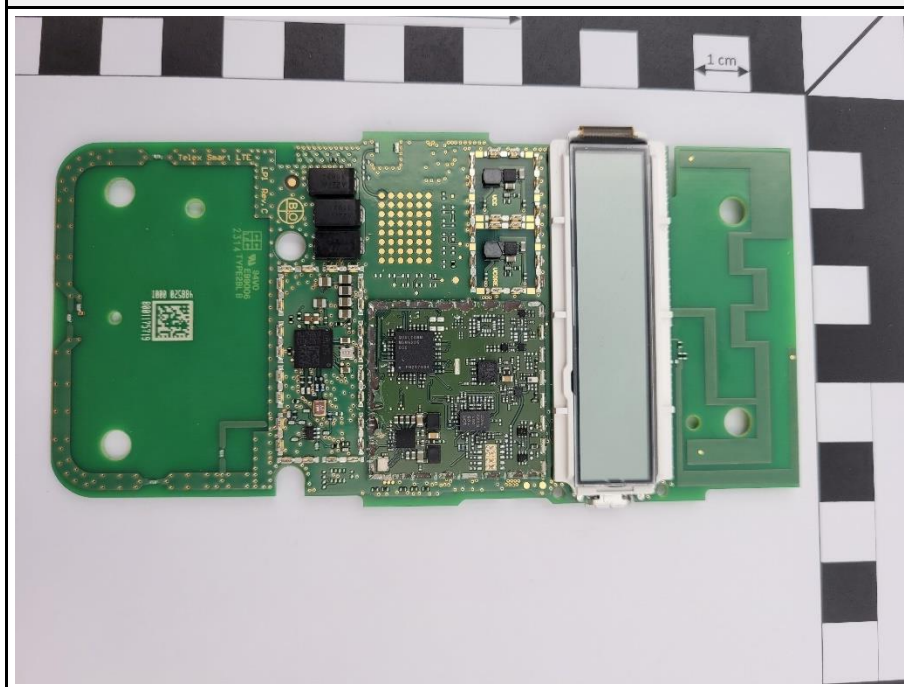
1.2 Photos – Equipment Internal



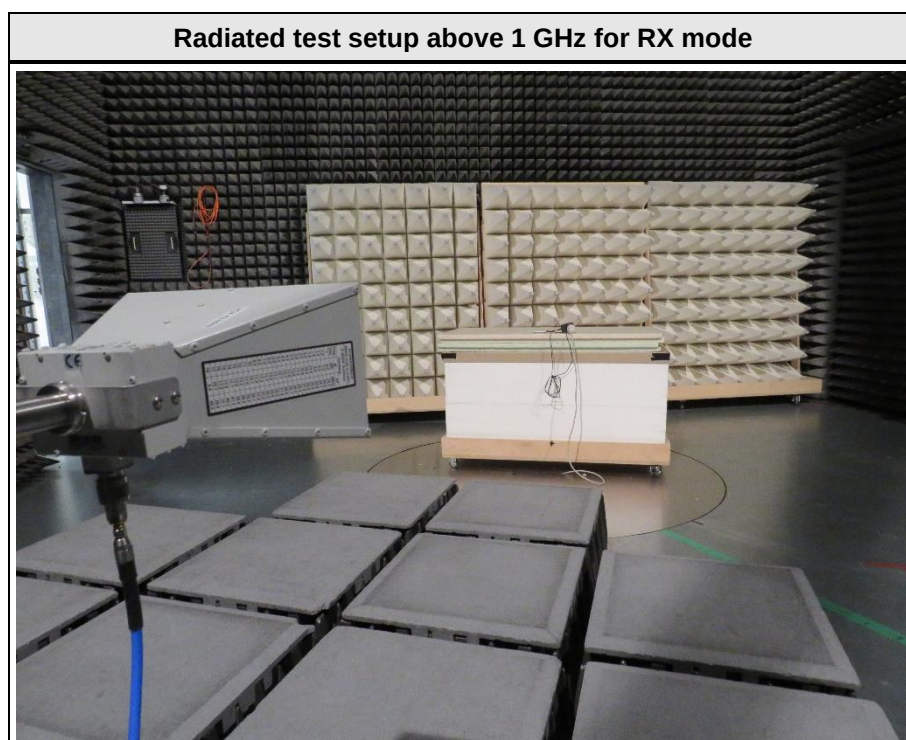
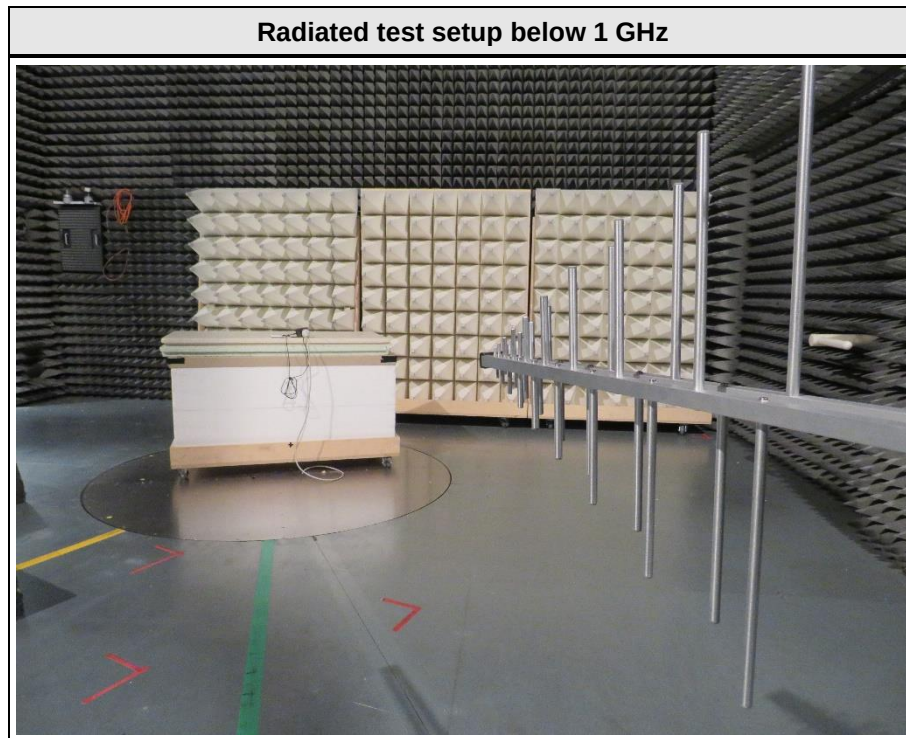
PCB frontside (photo from customer)



PCB frontside without shielding (photo from customer)



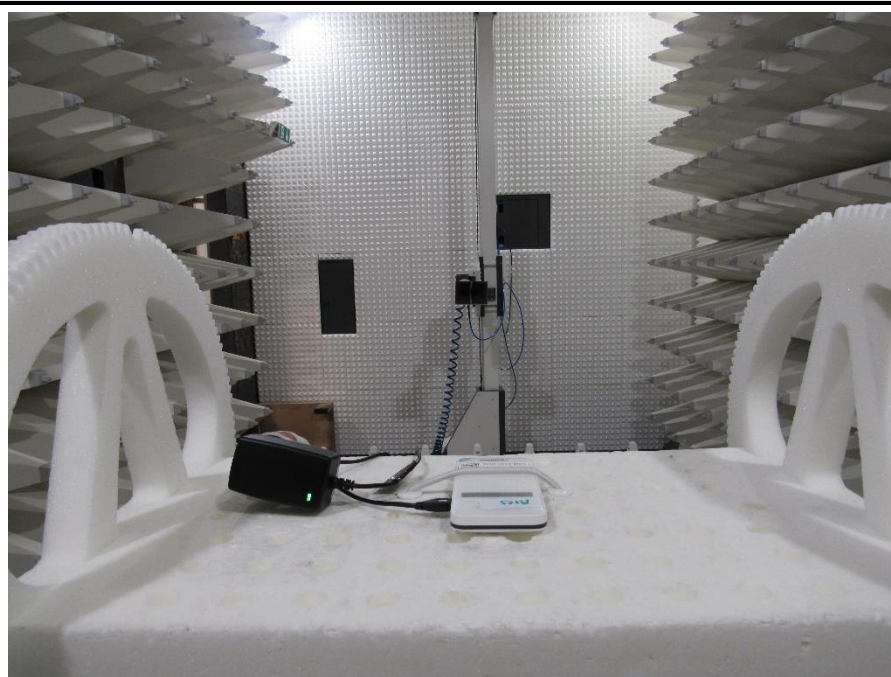
1.3 Photos – Test Setup



Radiated test setup above 1 GHz for TX mode



Radiated test setup above 1 GHz for TX mode



1.4 Support Equipment.

Product Type	Device	Manufacturer	Model	Comment
AE	Notebook	Lenovo	T440	For configuring test modes
CBL	USB A to Micro	---	---	Connection between Notebook and EUT
SFT	---	SW provided by applicant	MICS tool	For test mode activation
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment: --				

1.5 Test mode duty cycle

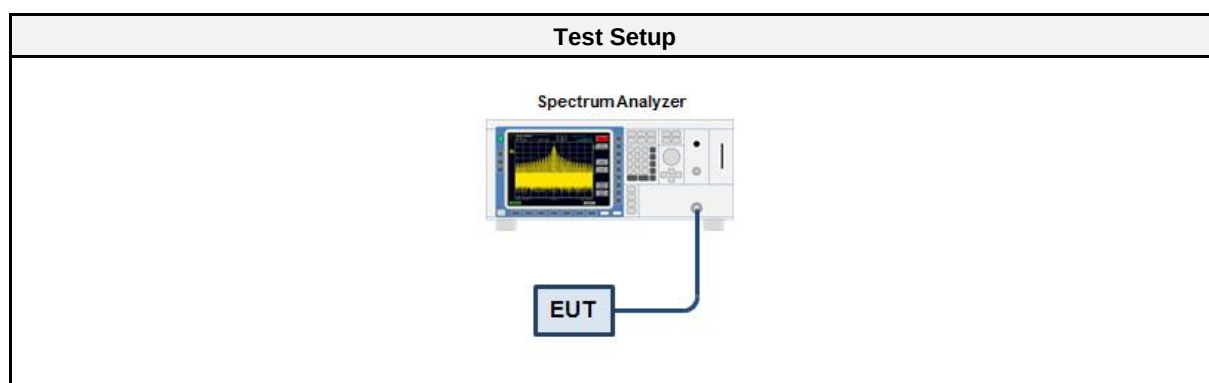
1.5.1 Information

Test Information	
Measurement Method	ANSI C63.10 11.6

1.5.2 Requirements

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

1.5.3 Setup



1.5.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 26	EF01631	2024-07	2025-07

1.5.5 Procedure

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

1.5.6 Results

Duty Cycle Results		
Mode	Duty Cycle	Correction Factor [dB]
Modulated	1.0 (100%)	0

1.6 Test Modes

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

1.7 Test Frequencies

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

1.8 Sample emission level calculation

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

Reading:

This is the reading obtained on the spectrum analyzer in 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

1.9 Measurement Uncertainties

Test case	Maximum measurement uncertainty
Transmitter output power (radiated)	5.3 dB
Band edge compliance	5.3 dB
Transmitter unwanted emissions	5.3 dB
Receiver spurious emissions	5.3 dB

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	N/T	Note 1
FCC 95.2565 ISED RSS-243 3.3, 5.3	Frequency stability	ETSI EN 301 839 5.3.1	N/T	Note 1
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/T	Note 1
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/T	Note 1
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/T	Note 1
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/T	Note 1
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/T	Note 1
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/T	Note 1
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/T	Note 1
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	
Note 1: Integration of certified module. Full test report: G0M-1908-8377-TFC95IMR-V02 from 2021-08-25 issued by Eurofins Product Service GmbH.				
Comment: The Decision Rule is applied on the basis of ETSI TR 102 273 and ETSI TR 100 028. These standards provide guidance on how to calculate and apply measurement uncertainty whilst providing maximum uncertainties allowance. In all cases due consideration will be given to ILAC-G8:09/2019. Where a result is considered conditional in respect of its proximity to the limit line, the customer would be made aware of situation so that they can make an informed decision on how to proceed.				

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

Test Report No.: G0M-2403-2480-TFC95IMR-V01

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

3 Test Conditions and Results

3.1 Test Conditions and Results - Transmitter output power

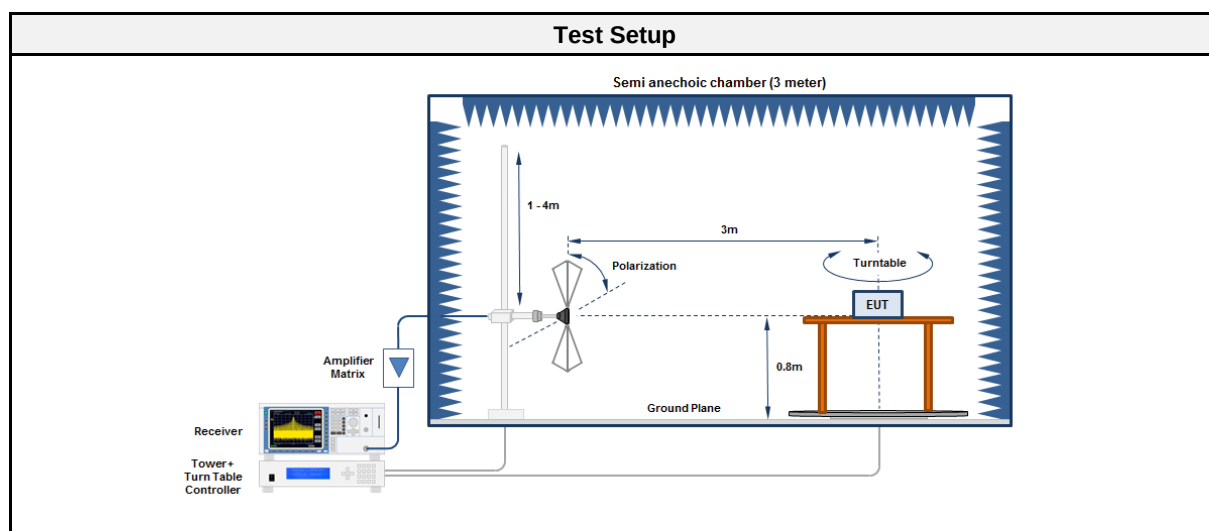
3.1.1 Information

Test Information	
Reference	FCC 95.2567(a), 95.2569 ISED RSS-243 5.4
Measurement Method	EN 301 839 5.3.3
Test Mode	Unmodulated
Operator	Azamat Ibraimov
Date	2024-10-10

3.1.2 Limits

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

3.1.3 Setup



3.1.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2024-07	2027-07
Test Receiver	R&S	ESW44	EF01856	2024-04	2025-04
Antenna	R&S	HL 223	EF00187	2022-06	2025-06

3.1.5 Procedure

Test Procedure	
1.	EUT set to test frequency with continuous wave.
2.	Measurement polarization is set to vertical
3.	Span it set according to measurement range and detector is set to peak and max hold
4.	Resolution bandwidth is set two be at least twice the emission bandwidth
5.	During the sweep the EUT is rotated to obtain maximum emission level
6.	Measurement is repeated with horizontal measurement polarization

3.1.6 Results

Test Results				
Channel [MHz]	Emission Level [dBm e.i.r.p.]	Detector	Limit [dBm e.i.r.p.]	Margin [dB]
402.45	-16.8	pk	-16	-0.8
403.65	-17.9	pk	-16	-1.9
404.85	-17.5	pk	-16	-1.5

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

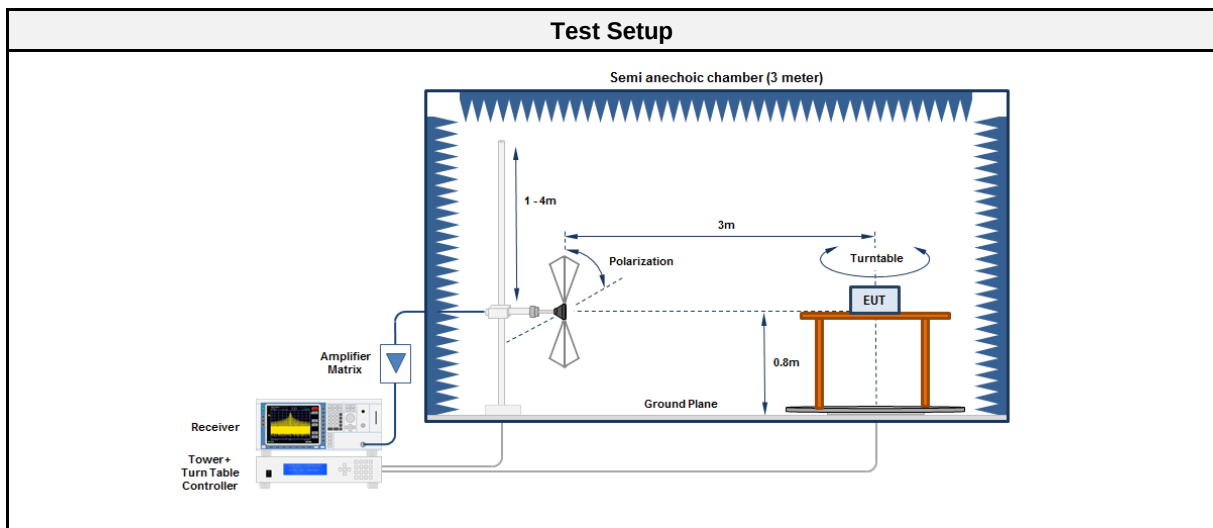
3.2.1 Information

Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.10 6.10
Test Mode	Modulated
Operator	Azamat Ibraimov
Date	2024-10-15

3.2.2 Limits

Limits	
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

3.2.3 Setup



3.2.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2024-07	2027-07
Test Receiver	R&S	ESW44	EF01856	2024-04	2025-04
Antenna	R&S	HL 223	EF00187	2022-06	2025-06

3.2.5 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

3.2.6 Results

Test Results					
Channel [MHz]	Emission [MHz]	Level [dB μ V/m]	Pol.	Limit [dB μ V/m]	Margin [dB]
404.85	405.036	51.2	Hor	59.2	-8
402.45	402.264	46.68	Hor	59.2	-12.52
402.45	402.657	45.39	Hor	59.2	-13.81
404.85	404.628	51.53	Hor	59.2	-7.67
404.85	404.999	46.1	Hor	59.2	-13.1

3.3 Test Conditions and Results - Transmitter unwanted emissions

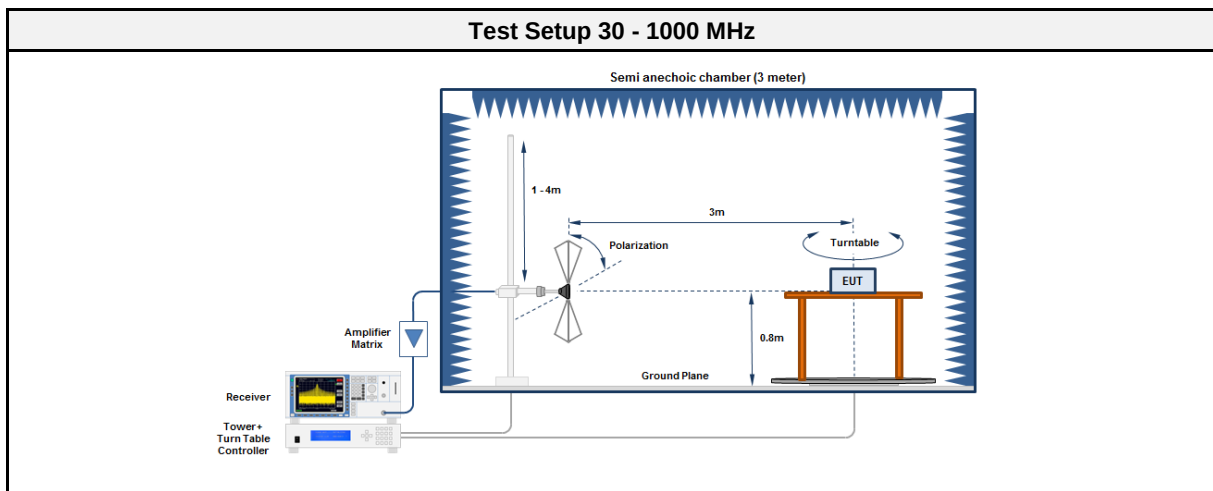
3.3.1 Information

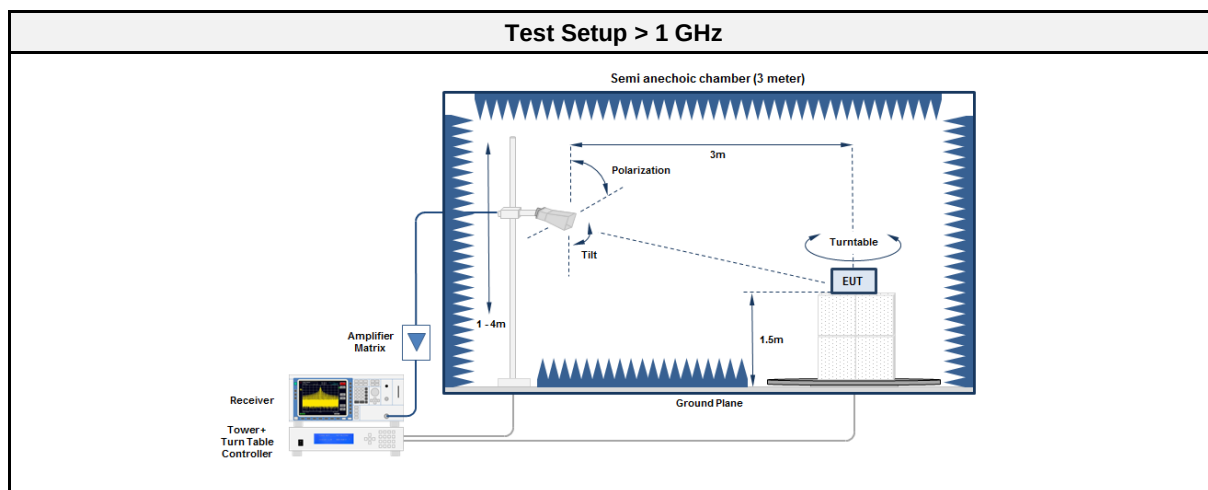
Test Information	
Reference	FCC 95.2579 ISED RSS-243 3.4, 5.5
Measurement Method	ANSI C63.10 6.10
Test Mode	Modulated
Operator	Azamat Ibraimov
Date	2024-10-16

3.3.2 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

3.3.3 Setup





3.3.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2024-07	2027-07
Test Receiver	R&S	ESW44	EF01856	2024-04	2025-04
Antenna	Schwarzbeck	VULB 9168	EF01824	2022-10	2025-10
Antenna	R&S	HL 223	EF00212	2022-08	2025-08

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC2	EF01616	2024-07	2025-07
Spectrum Analyzer	R&S	FSU 26	EF00896	2024-07	2025-07
Horn antenna	Schwarzbeck	BBHA 9120B	EF01678	2024-05	2027-05

3.3.5 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

3.3.6 Results

Test Results							
Channel [MHz]	Emission [MHz]	Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Limit dist. [m]	Margin [dB]
402.45	34.709	33.28	pk	Ver	40	3	-6.72
402.45	125.292	34.38	pk	Ver	43.5	3	-9.12
402.45	139.666	34.21	pk	Ver	43.5	3	-9.29
402.45	401.455	40.77	QP	Hor	46	3	-5.23
404.85	117.113	34.28	pk	Ver	43.5	3	-9.22
404.85	34.213	29.81	pk	Ver	40	3	-10.19
404.85	42.268	30.29	pk	Ver	40	3	-9.71
404.85	401.35	33.77	QP	Hor	46	3	-12.23
402.45	405.448	33.06	pk	Hor	46	3	-12.94
404.85	809.878	27.36	pk	Hor	46	3	-18.64
404.85	405.25	44.65	QP	Hor	46	3	-1.35
402.45	2425.672	37.44	pk	Hor	54	3	-16.56
404.85	2479.758	35.88	pk	Ver	54	3	-18.12

3.4 Test Conditions and Results - Receiver spurious emissions

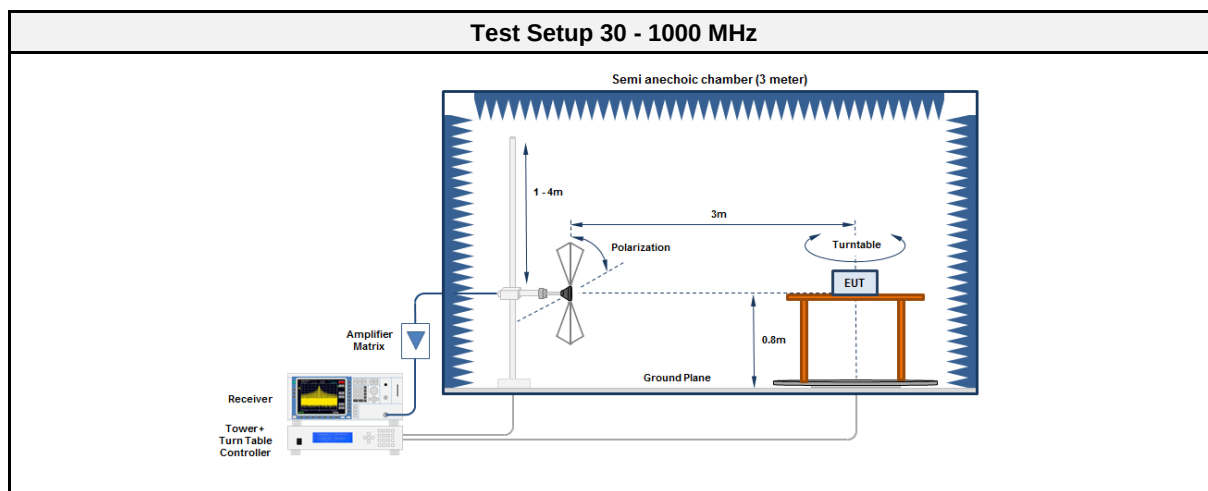
3.4.1 Information

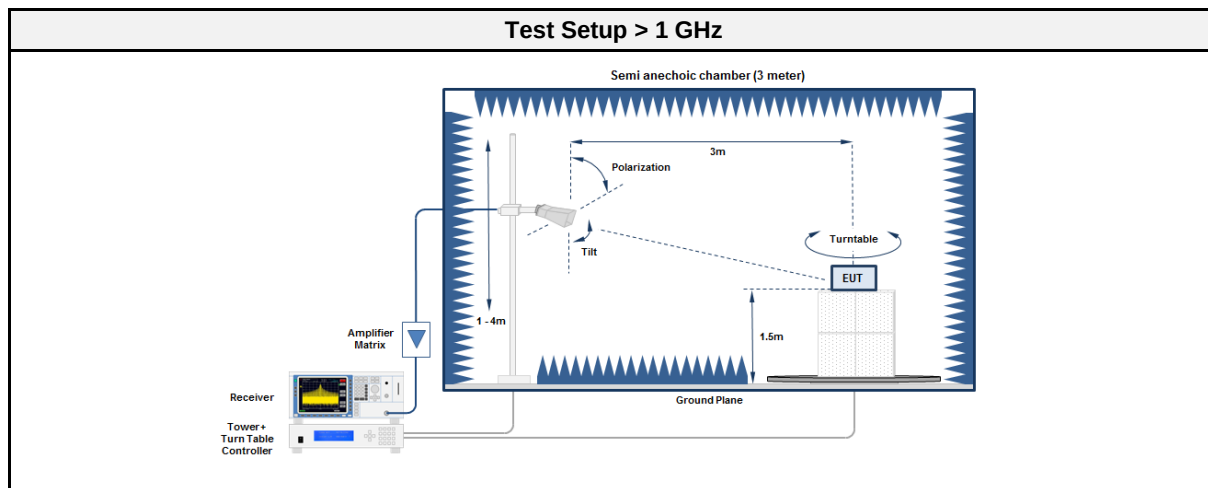
Test Information	
Reference	ISED RSS-243 3.5, 5.6 ISED RSS-Gen 7.3
Measurement Method	ANSI C63.10 6.10
Test Mode	Receive
Operator	Azamat Ibraimov
Date	2024-10-14

3.4.2 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

3.4.3 Setup





3.4.4 Equipment

Test Equipment 30 - 1000 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2024-07	2027-07
Test Receiver	R&S	ESW44	EF01856	2024-04	2025-04
Antenna	Schwarzbeck	VULB 9168	EF01824	2022-10	2025-10

Test Equipment > 1 GHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic chamber	Frankonia	AC 1	EF01011	2023-11	2024-11
Test Receiver	Rohde & Schwarz	ESW44	EF01856	2024-04	2025-04
Horn antenna	Schwarzbeck	BBHA 9120D	EF01561	2021-11	2024-11

3.4.5 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

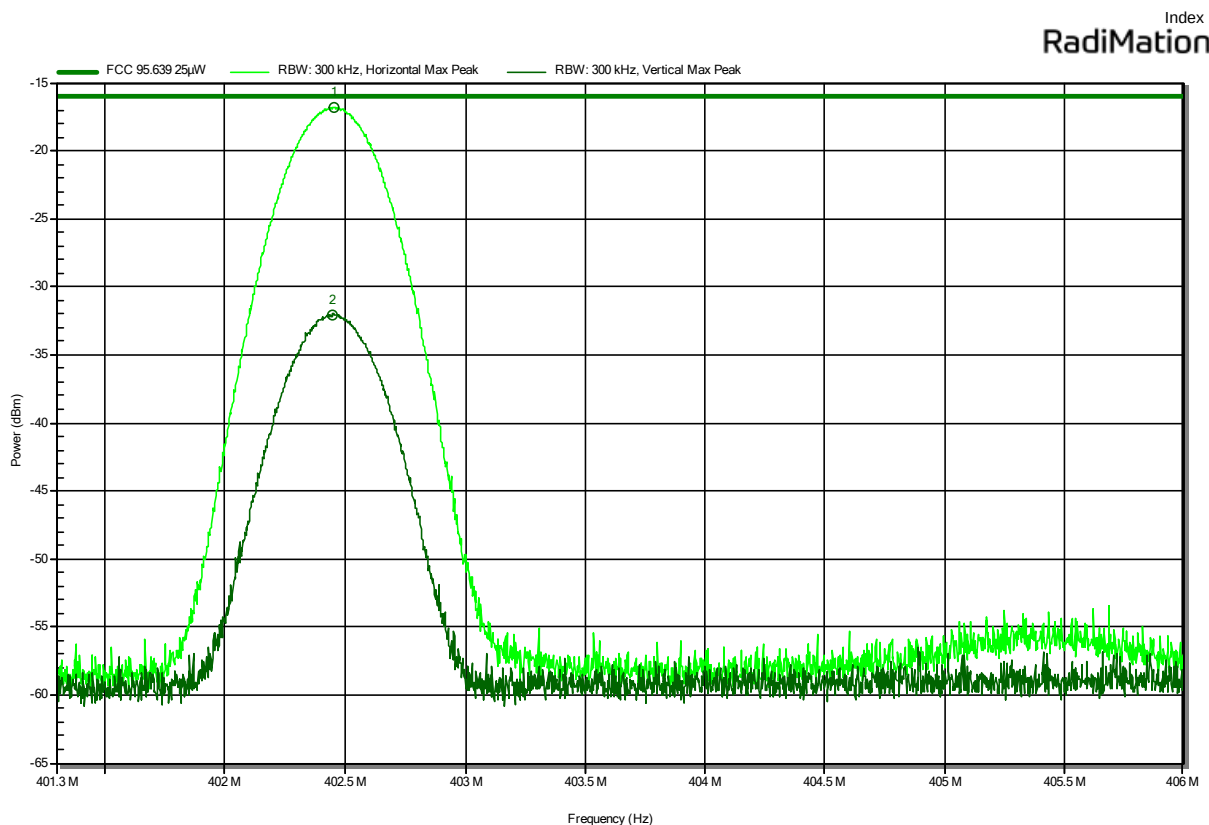
3.4.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Emission Level [dBμV/m]	Det.	Pol.	Limit [dBμV/m]	Margin [dB]
403.65	37.1133	28.6	pk	ver	40	-11.38
403.65	115.36	26.2	pk	ver	43.5	-17.34
403.65	140.2567	26.5	pk	ver	43.5	-17.02

ANNEX A Transmitter output power

Radiated carrier according to 47 CFR Part 95 Subpart I

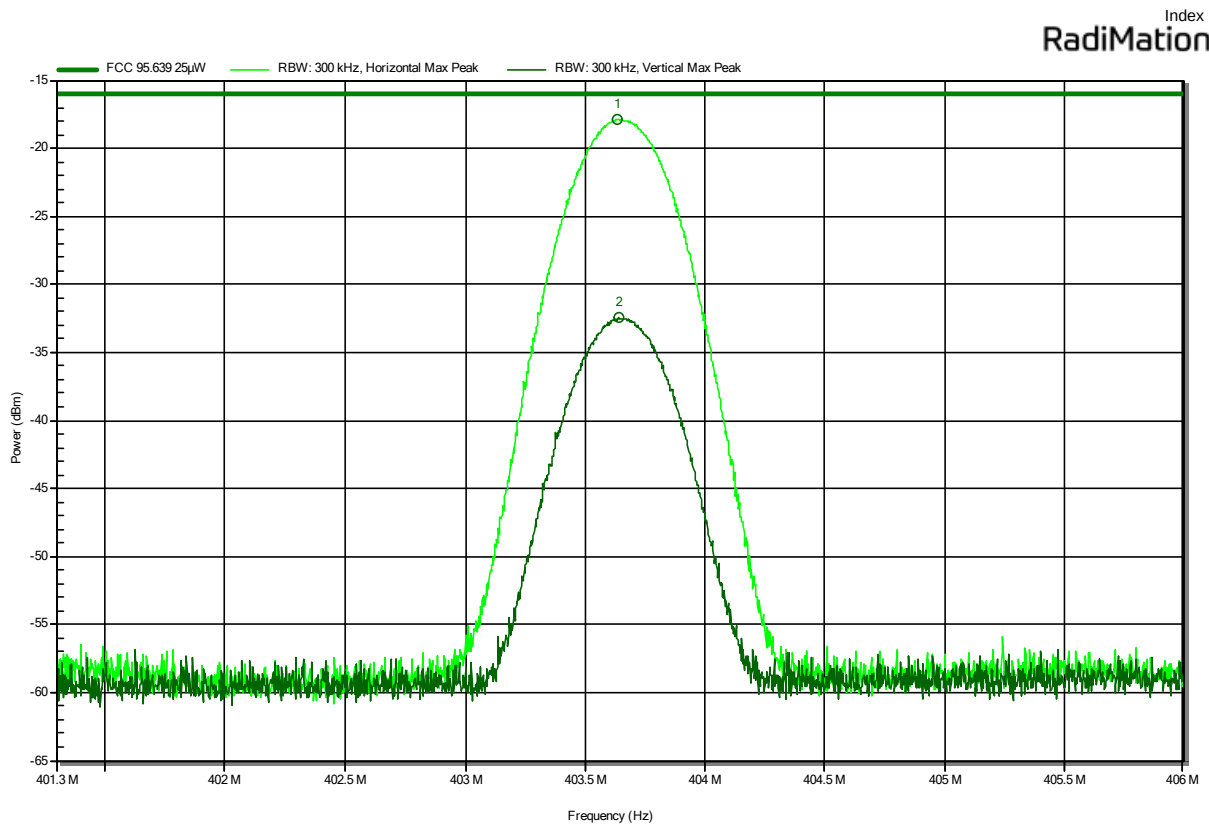
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; CW_402.45 MHz
 Test Date: 2024-10-10
 Note: Tx Power EIRP



Peak Number	Frequency (MHz)	Peak (dBm)	Peak (dBm)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	402.456	-16.8	-16		-0.78	Pass	Horizontal
2	402.448	-32	-16		-16.04	Pass	Vertical

Radiated carrier according to 47 CFR Part 95 Subpart I

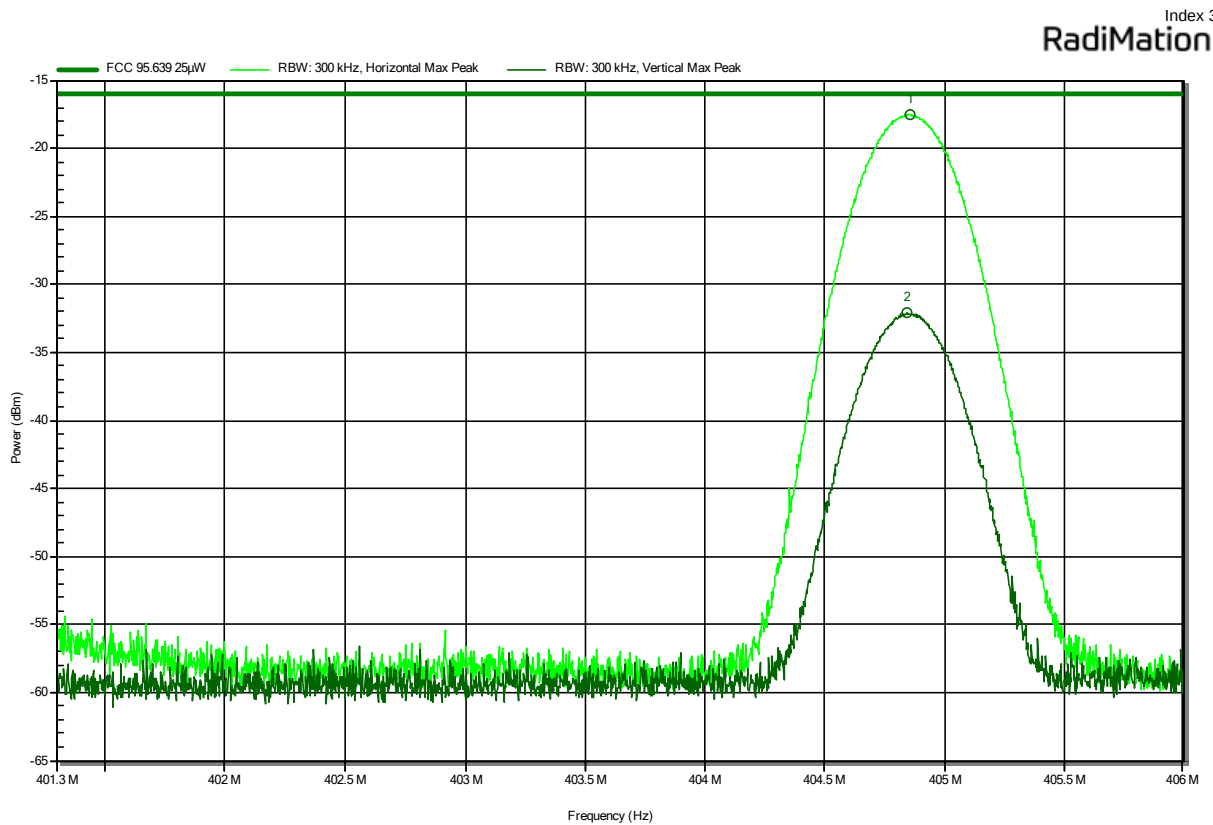
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; CW_403.65 MHz
 Test Date: 2024-10-10
 Note: Tx Power EIRP



Peak Number	Frequency (MHz)	Peak (dBm)	Peak (dBm)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	403.631	-17.9	-16		-1.88	Pass	Horizontal
2	403.638	-32.5	-16		-16.46	Pass	Vertical

Radiated carrier according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; CW_404.85 MHz
 Test Date: 2024-10-10
 Note: Tx Power EIRP

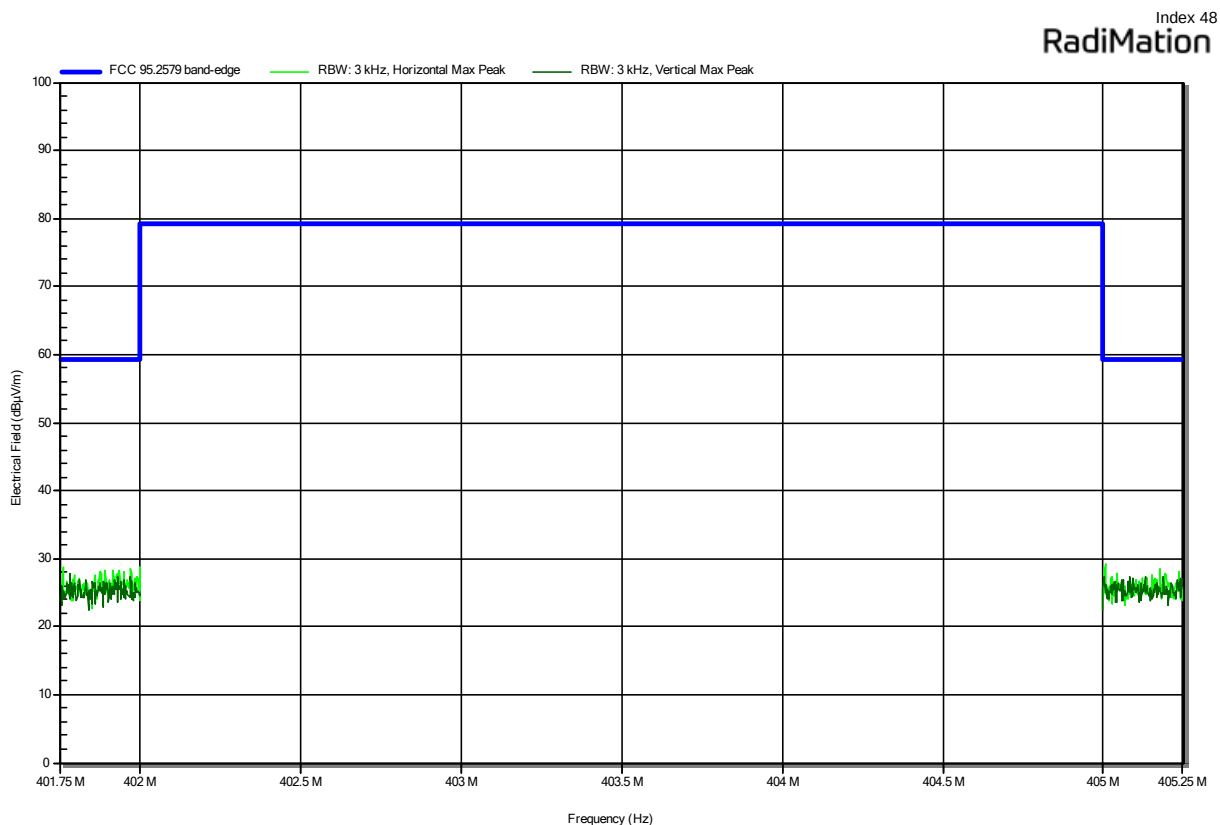


Peak Number	Frequency (MHz)	Peak (dBm)	Peak (dBm)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	404.856	-17.5	-16		-1.51	Pass	Horizontal
2	404.844	-32.1	-16		-16.12	Pass	Vertical

ANNEX B Band-edge and In-band Emissions

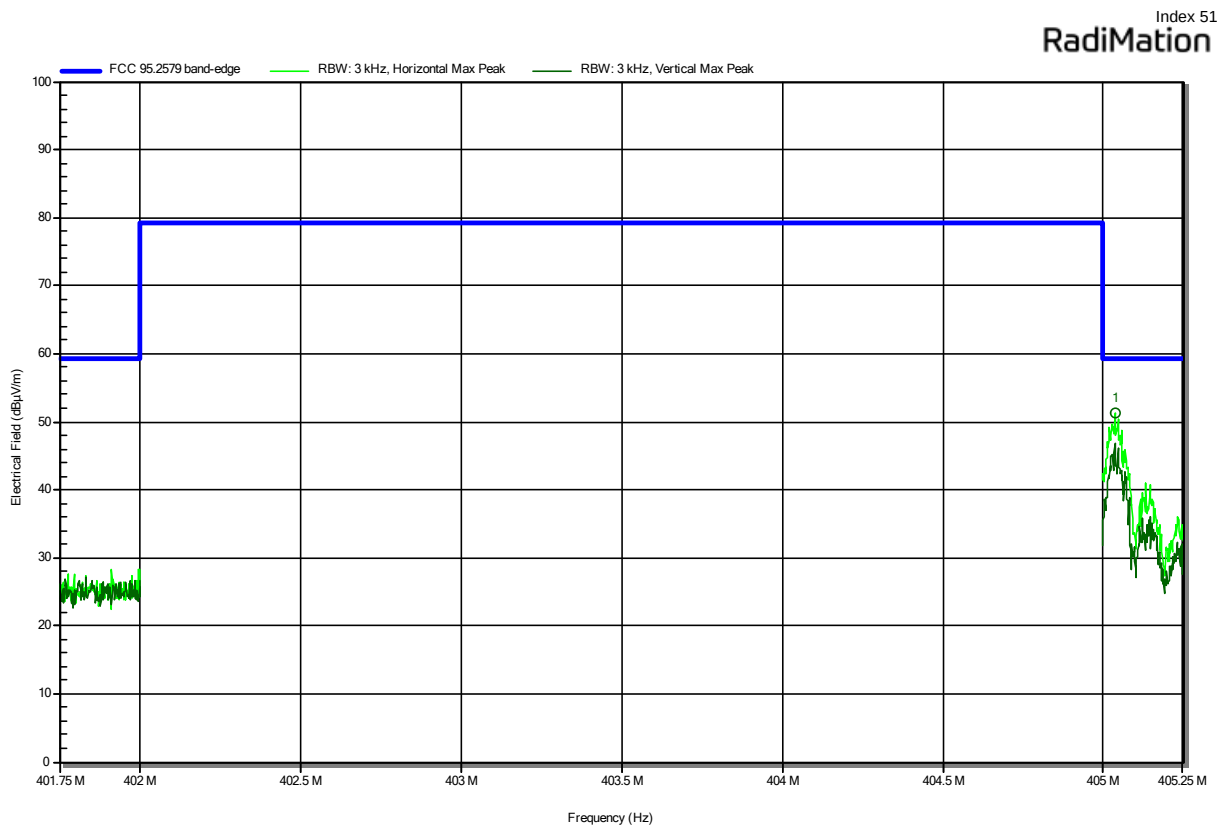
Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_402.45 MHz
 Test Date: 2024-10-15



Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

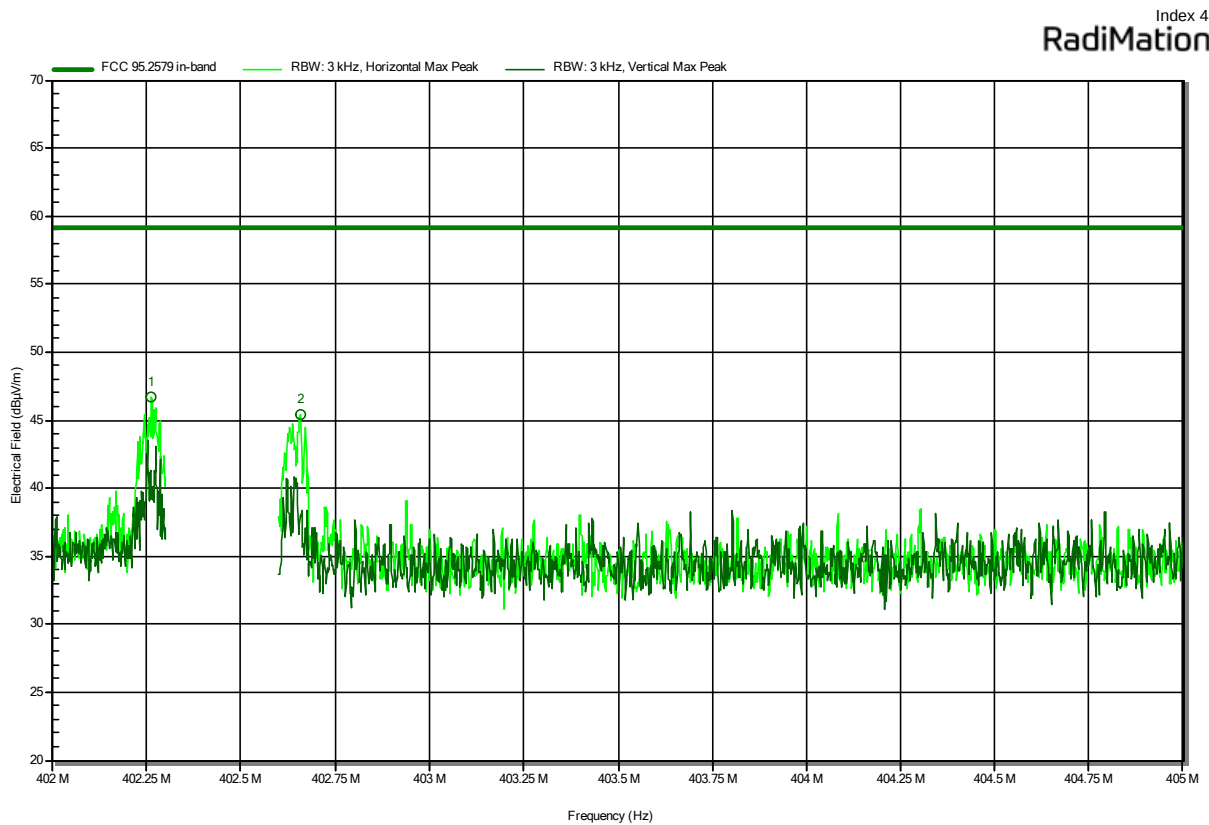
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_404.85 MHz
 Test Date: 2024-10-15
 Note:



Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak Limit (dBµV/m)	Peak Difference (dB)	Peak Status	Polarization
1	405.036	51.2	59.2	-8	Pass	Horizontal

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

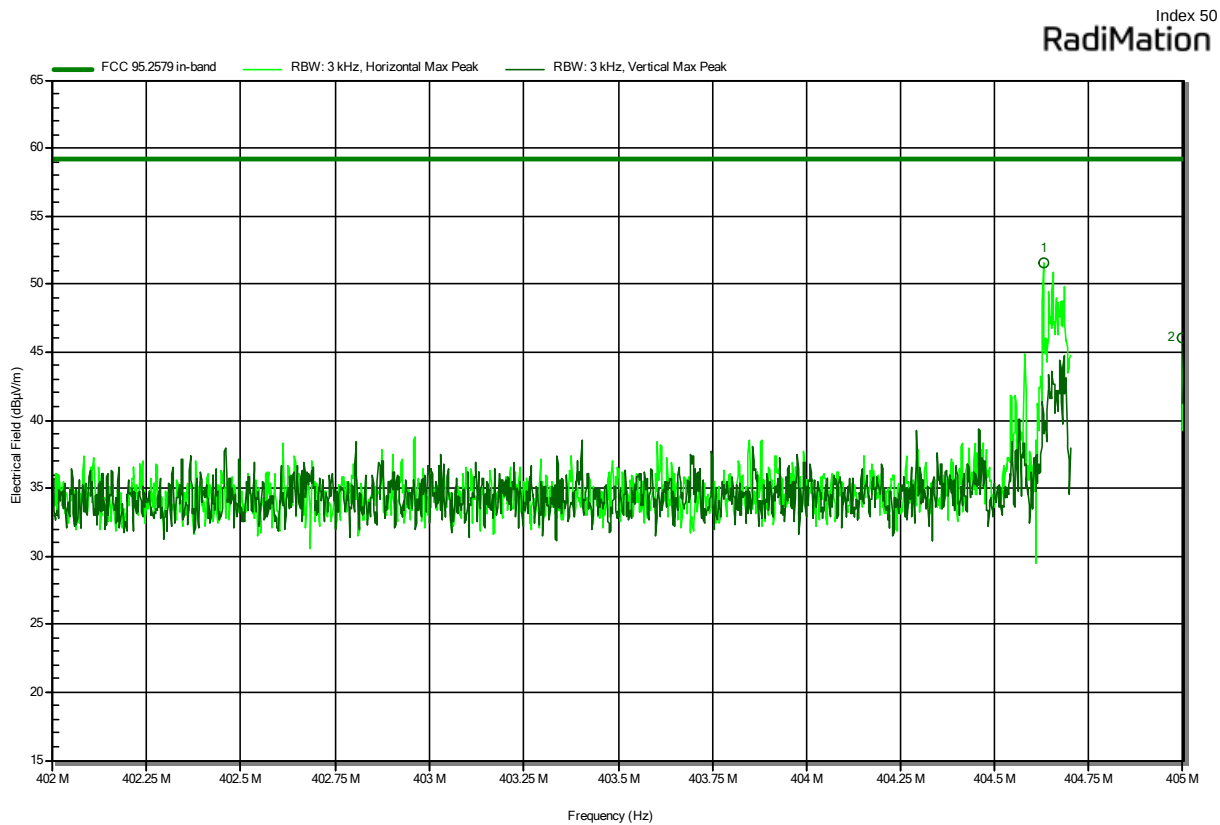
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_402.45 MHz
 Test Date: 2024-10-15



Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit (dB)	Peak Difference	Peak Status	Polarization
1	402.264	46.68	59.2	-12.52		Pass	Horizontal
2	402.657	45.39	59.2	-13.81		Pass	Horizontal

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_404.85 MHz
 Test Date: 2024-10-15



Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak Limit (dBµV/m)	Peak Difference (dB)	Peak Status	Polarization
1	404.628	51.53	59.2	-7.67	Pass	Horizontal
2	404.999	46.1	59.2	-13.1	Pass	Horizontal

ANNEX C Antenna Pattern

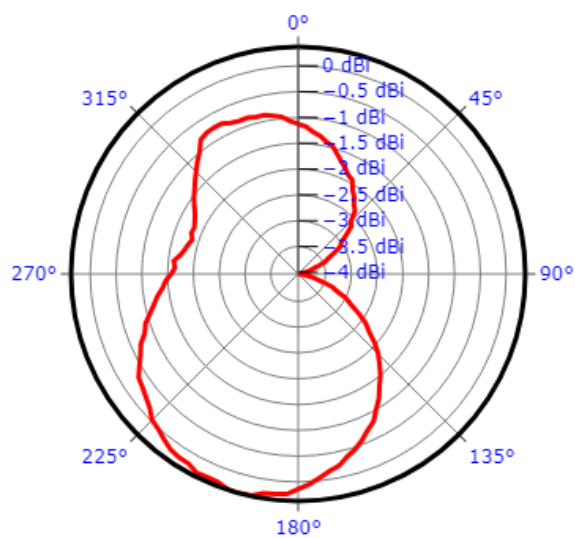
Project Number:	G0M-2403-2480
Product:	CardioMessenger Smart / Telemonitoring System
Model:	CardioMessenger Smart 4G
EUT Antenna:	Integrated PCB-antenna
Operating Conditions:	Tnom / Vnom
Operating Frequency:	403.65 MHz
Detector:	RMS
RBW:	1 MHz
VBW:	3 MHz
Sweep Time:	100 ms
Operator:	A. Ibraimov
Date:	2024-10-11

Result Summary

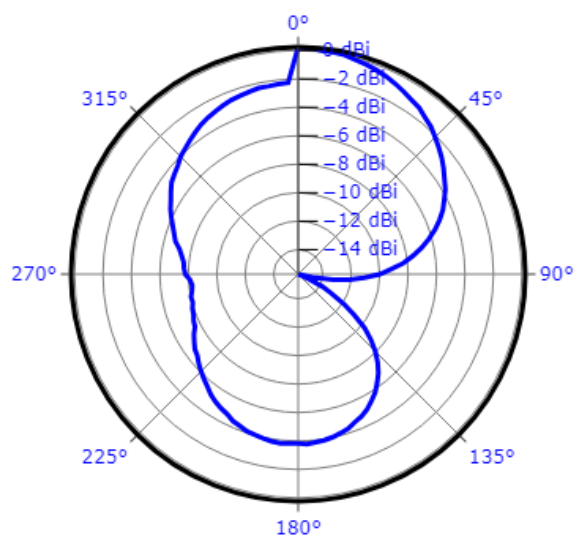
Antenna Polarization	Half power beamwidth ϕ [°]	Half power beamwidth θ [°]	Max. antenna gain [dBi]
Horizontal	279	75	0.37
Vertical	108	96	-1.47

Polarization horizontal

Polar radiation pattern at $\theta = -9^\circ$

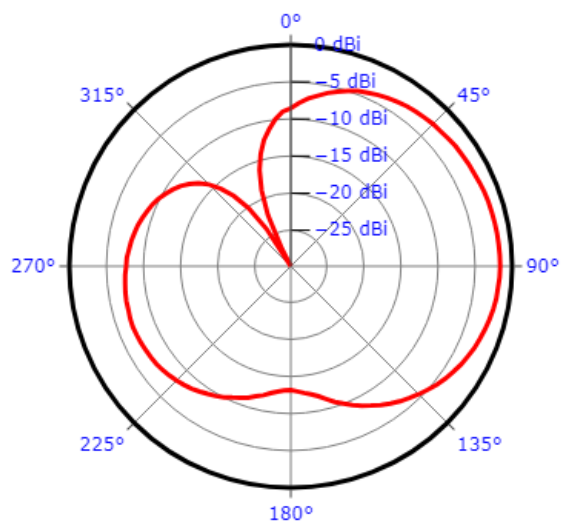


Polar radiation pattern at $\phi = 200^\circ$

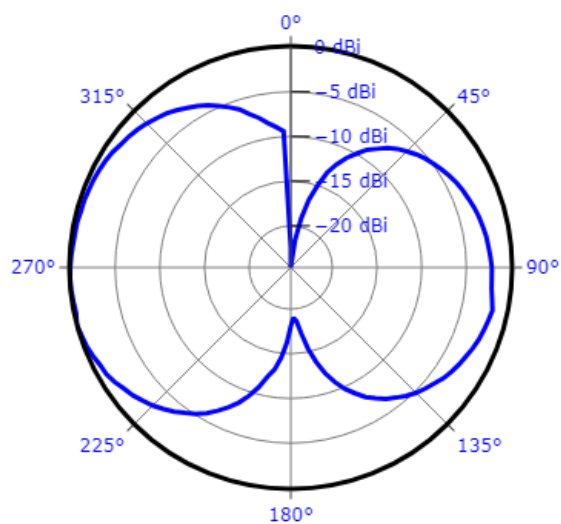


Polarization vertical

Polar radiation pattern at $\theta = 98^\circ$



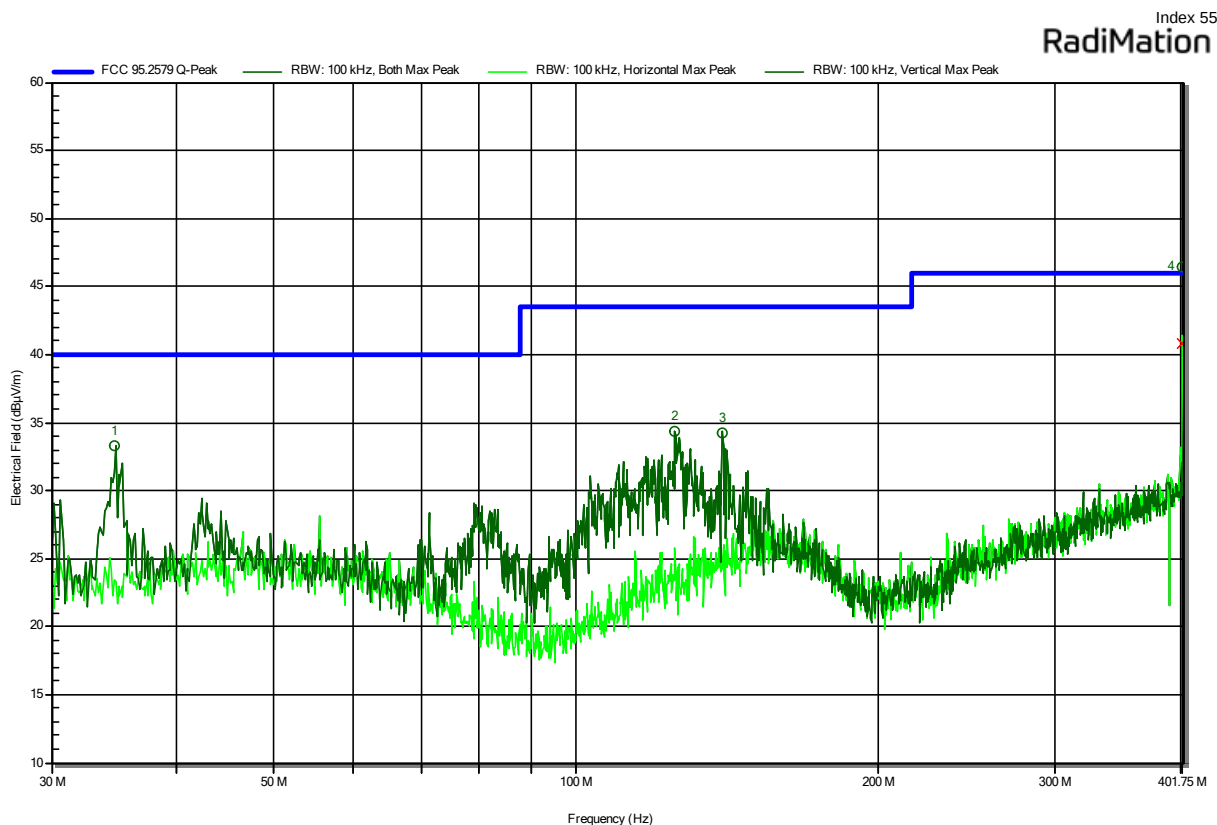
Polar radiation pattern at $\phi = 86^\circ$



ANNEX D Transmitter spurious emissions

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_402.45 MHz
 Test Date: 2024-10-16



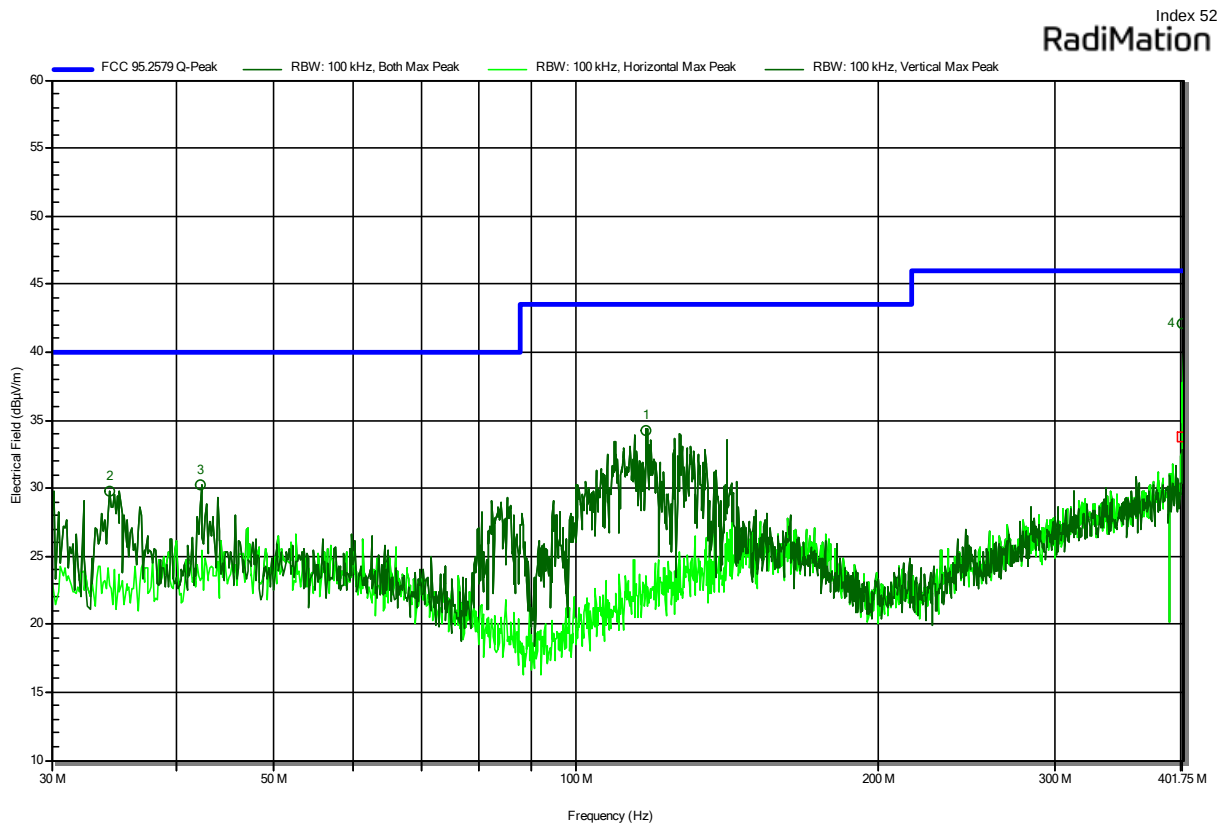
Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak Limit (dBµV/m)	Peak Difference (dB)	Peak Status	Polarization
1	34.709	33.28	40	-6.72	Pass	Vertical
2	125.292	34.38	43.5	-9.12	Pass	Vertical
3	139.666	34.21	43.5	-9.29	Pass	Vertical
Peak Number	Frequency (MHz)	Quasi-Peak (dBµV/m)	Quasi-Peak Limit (dBµV/m)	Quasi-Peak Difference (dB)	Quasi-Peak Status	Polarization
4	401.455	40.77	46	-5.23	Pass	Horizontal

Test Report No.: G0M-2403-2480-TFC95IMR-V01

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

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

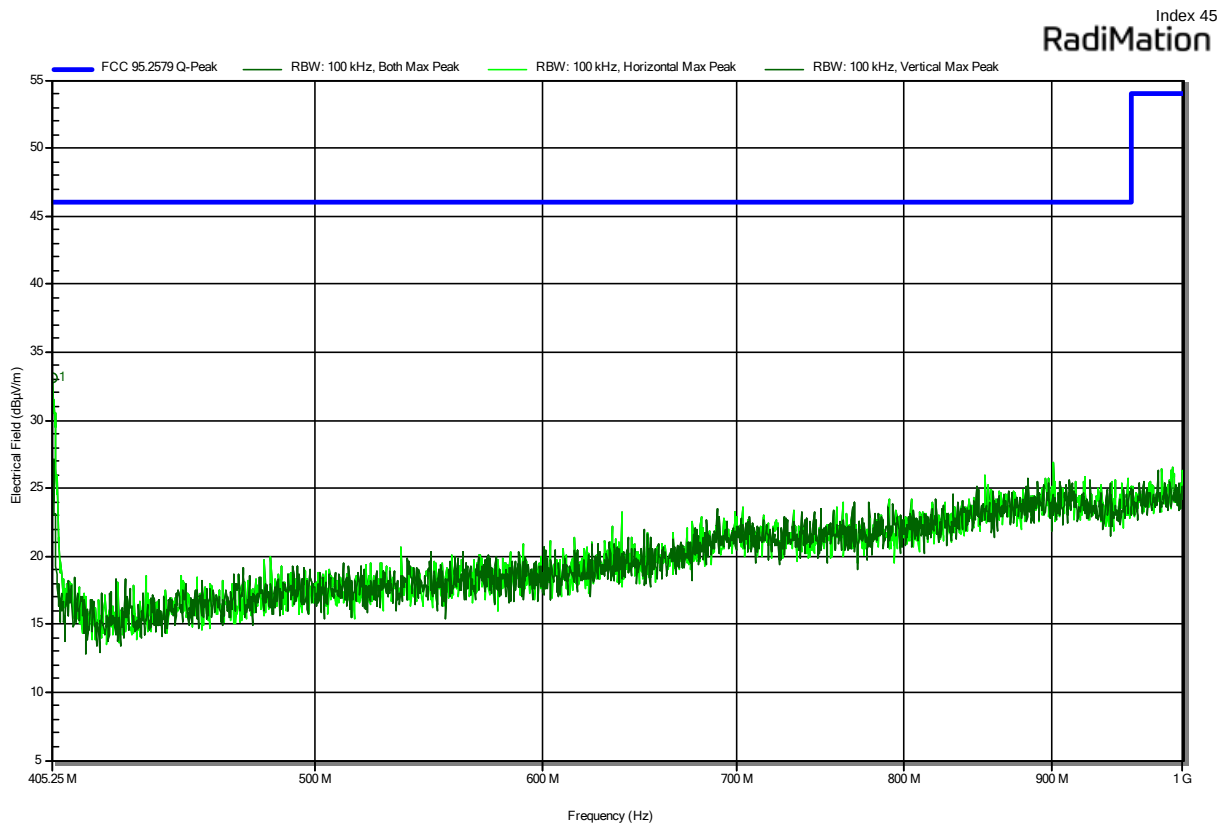
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_404.85 MHz
 Test Date: 2024-10-16



Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak Limit (dBμV/m)	Peak Difference (dB)	Peak Status	Polarization
1	117.113	34.28	43.5	-9.22	Pass	Vertical
2	34.213	29.81	40	-10.19	Pass	Vertical
3	42.268	30.29	40	-9.71	Pass	Vertical
Peak Number	Frequency (MHz)	Quasi-Peak (dBμV/m)	Quasi-Peak Limit (dBμV/m)	Quasi-Peak Difference (dB)	Quasi-Peak Status	Polarization
4	401.35	33.77	46	-12.23	Pass	Horizontal

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

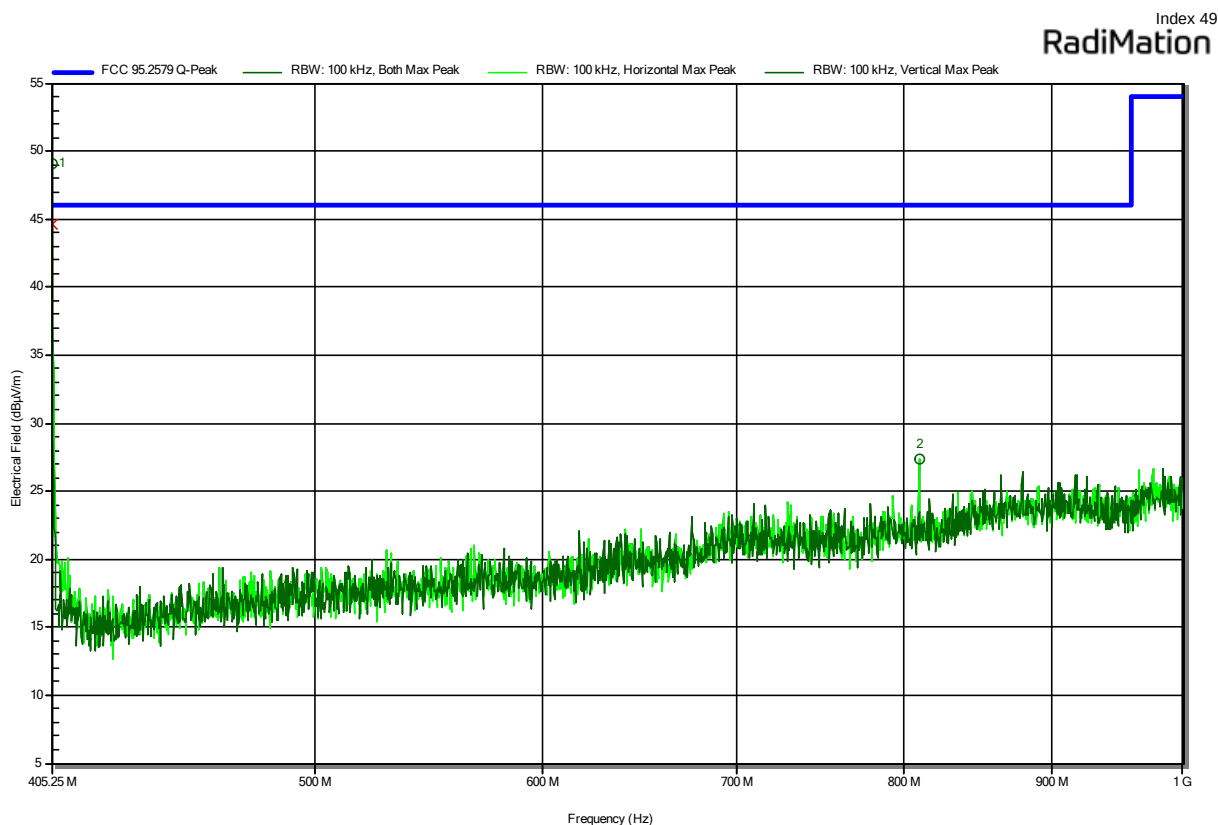
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_402.45 MHz
 Test Date: 2024-10-15



Peak Number	Frequency (MHz)	Peak (dBµV/m)	Peak Limit (dBµV/m)	Peak Difference (dB)	Peak Status	Polarization
1	405.448	33.06	46	-12.94	Pass	Horizontal

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Rohde & Schwarz HL 223
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_404.85 MHz
 Test Date: 2024-10-15

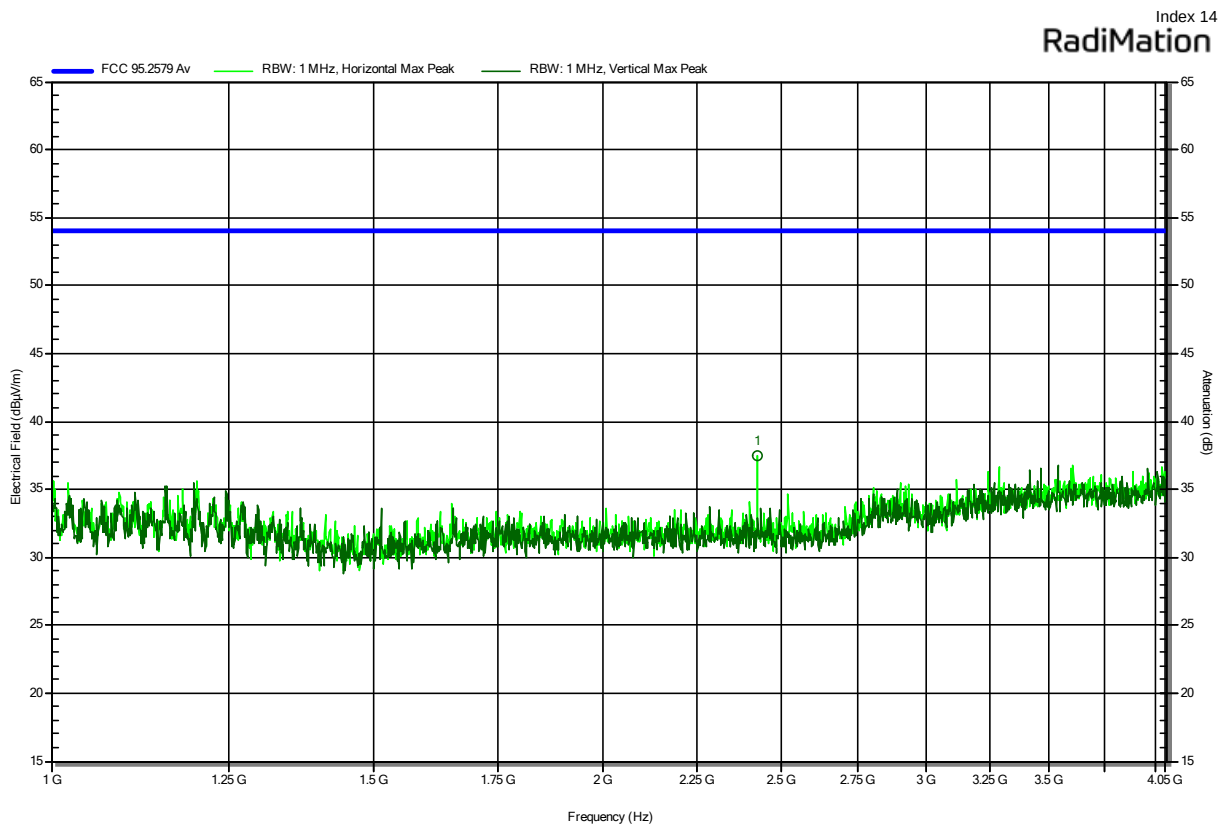


Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit	Peak Difference (dB)	Peak Status	Polarization
2	809.878	27.36	46		-18.64	Pass	Horizontal

Peak Number	Frequency (MHz)	Quasi-Peak (dBμV/m)	Quasi-Peak Limit (dBμV/m)	Quasi-Peak Difference (dB)	Quasi-Peak Status	Polarization
1	405.25	44.65	46	-1.35	Pass	Horizontal

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

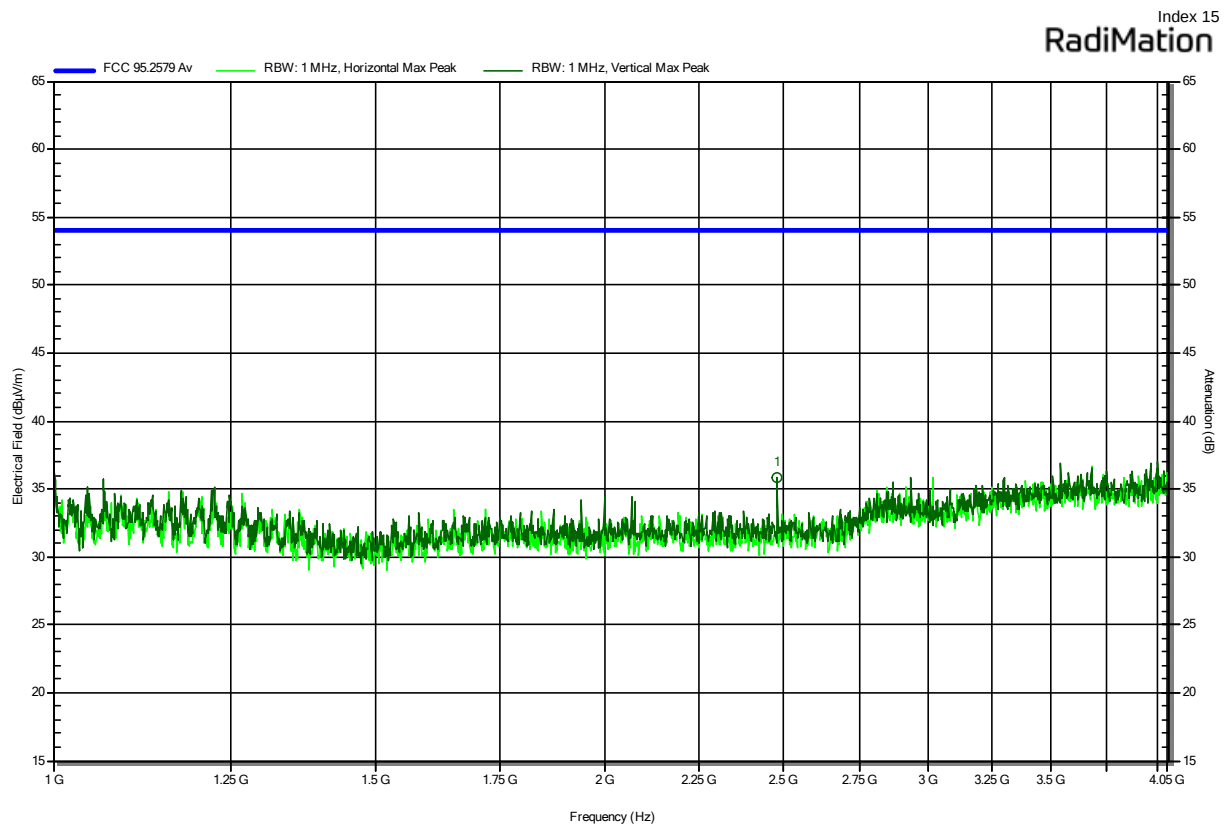
Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2024.1.3
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_402.45 MHz
 Test Date: 2024-10-11



Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit (dB)	Peak Difference	Peak Status	Polarization
1	2425.672	37.44	54	-16.56		Pass	Horizontal

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID: 49933
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibrahimov
 Measurement software: RadiMation, version 2024.1.3
 Test Conditions: Tnom: 25 °Celsius, Vnom: 5V AC/DC adaptor
 Antenna: Schwarzbeck BBHA 9120B
 Measurement distance: 3 m
 Mode: Tx; 2FSK_197 kbps_404.85 MHz
 Test Date: 2024-10-11

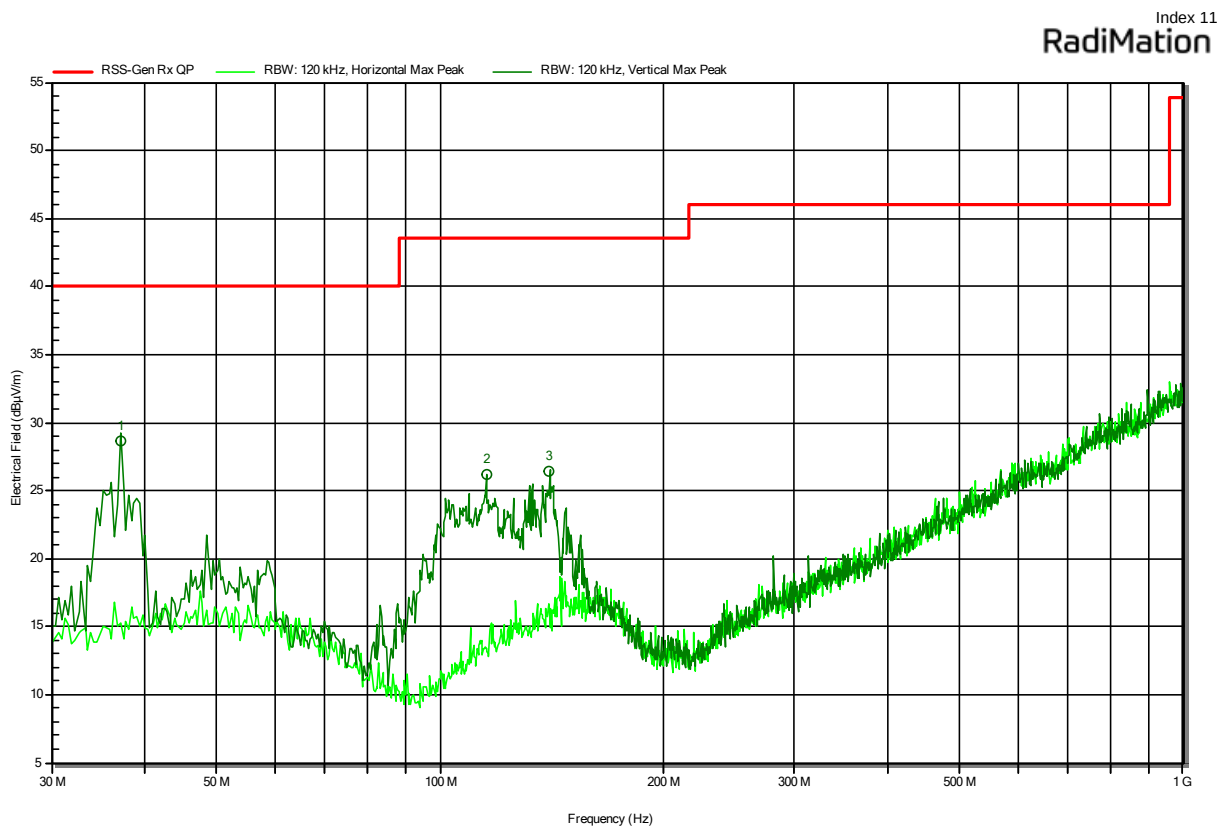


Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	2479.758	35.88	54		-18.12	Pass	Vertical

ANNEX E Receiver spurious emissions

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID:
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom:
 Antenna: Schwarzbeck VULB 9168
 Measurement distance: 3 m
 Mode: Rx; 403.65 MHz
 Test Date: 2024-10-14



Peak Number	Frequency (MHz)	Peak (dBμV/m)	Peak (dBμV/m)	Limit	Peak Difference (dB)	Peak Status	Polarization
1	37.1133	28.6	40		-11.38	Pass	Vertical
2	115.36	26.2	43.5		-17.34	Pass	Vertical
3	140.2567	26.5	43.5		-17.02	Pass	Vertical

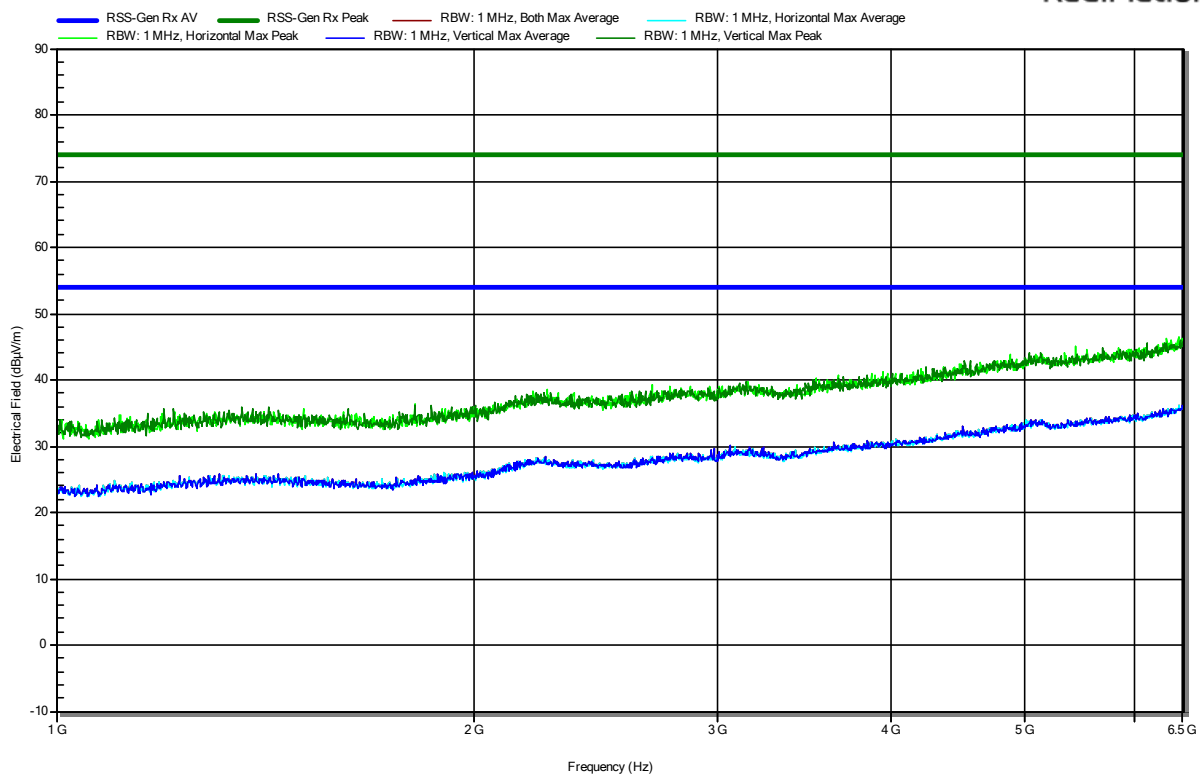
Test Report No.: G0M-2403-2480-TFC95IMR-V01

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

Radiated Spurious Emissions according to 47 CFR Part 95 Subpart I

Project Number: G0M-2403-2480
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: CardioMessenger Smart / Telemonitorig System
 Model: CardioMessenger Smart 4G
 Test Sample ID:
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Ibraimov
 Measurement software: RadiMation, version 2023.2.6
 Test Conditions: Tnom: 25 °Celsius, Vnom:
 Antenna: Schwarzbeck BBHA 9120D
 Measurement distance: 3 m
 Mode: Rx; 403.65 MHz
 Test Date: 2024-10-14

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RadiMation



== = END OF TEST REPORT == =