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FCC TEST REPORT

FCC 47 CFR Part 95I

Medical Device Radiocommunication Service (MedRadio)

Industry Canada RSS-243

Medical Devices Operating in the 401 – 406 MHz Frequency Band

Report Reference No. ..... :	G0M-1304-2799-TFC95IM-V02
Testing Laboratory ..... :	Eurofins Product Service GmbH
Address ..... :	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation ..... :	A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Filed Test Laboratory, Reg.-No.: 96970 IC OATS Filing assigned code: 3470A
Applicant's name ..... :	Biotronik SE & Co. KG
Address ..... :	Woermannkehre 1 12359 Berlin GERMANY
Test specification:	
Standard..... :	47 CFR Part 95E 47 CFR Part 95I 47 CFR Part 15C 47 CFR Part 2 RSS-243, Issue 3, 2010-02 RSS-Gen, Issue 3, 2010-12 ANSI C63.4:2009 EN 301 839-1 V1.3.1:2009-10
Equipment under test (EUT):	
Product description	IPG / Implantable Pulse Generator
Model No.	Eluna 8-HF-T
Addition Models	see family listing on page 3
Hardware version	6082220-03 Rev 0A
Firmware / Software version	GTR-12-0173-A
	FCC-ID: QRIPRIMUSNXT IC: 4708A-PRIMUSNXT
Test result	**Passed**

Possible test case verdicts:

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

Testing:

Date of receipt of test item ..... :	2013-05-06	
Date (s) of performance of tests ..... :	2013-05-10 – 2013-05-17	
Compiled by ..... :	Antje Bartusch	
Tested by (+ signature)..... : (Testing Manager)	Wilfried Treffke	W. Treffke
Approved by (+ signature) ..... : (Test Lab Manager)	Christian Weber	C. Weber
Date of issue ..... :	2013-12-09	
Total number of pages ..... :	81	

General remarks:

The test results presented in this report relate only to the object tested.

The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

Additional comments:

The report applies to all model stated in the “Primus NXT Family Listing” issued by the Manufacturer.

Model	Description
Eluna 8 SR-T	One chamber , Coil telemetry and RF Transceiver
Eluna 8 DR-T	Two chamber , Coil telemetry and RF Transceiver
Eluna 8 HF-T	Three chambers , Coil telemetry and RF Transceiver
Epyra 6 SR-T	One chamber , Coil telemetry and RF Transceiver
Epyra 6 DR-T	Two chambers , Coil telemetry and RF Transceiver
Epyra 8 SR-T	One chamber , Coil telemetry and RF Transceiver
Epyra 8 DR-T	Two chambers , Coil telemetry and RF Transceiver
Epyra 8 HF-T	Three chambers , Coil telemetry and RF Transceiver
Etrinsa 6 SR-T	One chamber , Coil telemetry and RF Transceiver
Etrinsa 6 DR-T	Two chambers , Coil telemetry and RF Transceiver
Etrinsa 8 SR-T	One chamber , Coil telemetry and RF Transceiver
Etrinsa 8 DR-T	Two chambers , Coil telemetry and RF Transceiver
Etrinsa 8 HF-T	Three chambers , Coil telemetry and RF Transceiver

The BIOTRONIK PRIMUS NXT family of products includes the following models:
Eluna, Epyra and Etrinsa.
All models comprise identical internal electronic including a low frequency telemetry coil and packaged in titanium cases with a header where the leads connect.
The T Devices include additional an internal RF Transceiver and an antenna within the header.
The internal electronic of HF-T devices differs slightly from SR and DR devices to include the third channel electronic. Therefore the device under test is three chambers model Eluna 8 HF-T.
The PRIMUS NXT models contain a different therapeutic feature set. The feature differences comprising only software.

Evaluation measurements were performed for worst case with the Eluna 8-HF-T, as the most complex model, was selected for the measurements.

Version History

Version	Issue Date	Remarks		Revised by
01	2013-08-05	Initial Release		
02	2013-12-10	Replaced document: Replaced by: Reason: The standards were updated.	G0M-1304-2799-TFC95IM-V01 G0M-1304-2799-TFC95IM-V02	A. Bartusch

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1 Equipment (Test item) Description

Description	IPG / Implantable Pulse Generator	
Model	Eluna 8-HF-T	
Serial number	None	
Hardware version	6082220-03 Rev 0A	
Software / Firmware version	GTR-12-0173-A	
FCC-ID	QRIPRIMUSNXT	
IC	4708A-PRIMUSNXT	
Equipment type	End product	
Radio type	Transceiver	
Number of Radios	2 Transceivers are built into the device	
Radio technology	MedRadio (MICS) programmer / control tranmitter	
Operating frequency range	402 45- 405.85 MHz	
Assigned frequency band	402 - 405 MHz	
Main test frequencies	F_{LOW}	402.45 MHz
	F_{MID}	403.65 MHz
	F_{HIGH}	404.85 MHz
Modulations	2FSK	
Emission designator	F1D	
Number of channels	9	
Channel spacing	300 kHz	
Spectrum access	Listen before transmit (channel access controlled by ULP-AMI-P device outside the human body)	
Number of antennas	1	
Antenna	Type	integrated
	Model	loop antenna
	Manufacturer	Biotronik SE & Co. KG
	Gain	-21.6 dBi (Determined by measurements)
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
Power supply	V_{NOM}	2.8 VDC
	V_{MIN}	2.5 VDC
	V_{MAX}	3.2 VDC
Temperature	T_{NOM}	37 °C
	T_{MIN}	25 °C
	T_{MAX}	45 °C

1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
None				

***Note:** Use the following abbreviations:

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.5 Test Modes:

Mode #	Description	
Unmodulated	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Spreading = None Modulation = None Duty cycle = 100 % Power level = Maximum
Modulated	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone transmit Modulation = FSK Duty cycle = 100 % Power level = Maximum
Receive	General conditions:	EUT powered by battery
	Radio conditions:	Mode = standalone receive Modulation = FSK

1.6 Test Equipment Used During Testing

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00151	2012-12	2013-12

Emission Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00151	2012-12	2013-12

Frequency Stability					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00151	2012-12	2013-12

Effective radiated power					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Fully-anechoic chamber	Frankonia	AC 4	EF00200	2008-09	2013-09
Spectrum Analyzer	R&S	FSEK30	EF00168	2012-12	2013-12
LPD Antenna	R&S	HL 223	EF00212	2013-02	2016-02

Radiated spurious emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 5	EF00395	calibration	calibration
Spectrum Analyzer	R&S	FSIQ26	EF00151	2012-12	2013-12
Biconical Antenna	R&S	HK 116	EF00012	2013-02	2016-02
LPD Antenna	R&S	HL 223	EF00187	2011-02	2014-02
LPD Antenna	R&S	HL 025	EF00327	2013-02	2016-02

Discontinuation of MICS or MEDS session					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSIQ26	EF00151	2012-12	2013-12

1.7 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:

Reading on Analyzer (dBµV) + A.F. (dB) = Net field strength (dBµV/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:

Limit (dBµV/m) = 20*log (µV/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	=	47.5 dBµV/m	:	47.5 dBµV/m - 57.0 dBµV/m = -9.5 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	52.3
Bactericide	0.09
Hydroxy ethyl cellulose (HCE)	1.0
Sodium chloride	1.4
Sucrose	45.0

Measured tissue parameters:

Tissue parameters – 403.5MHz			
Component	Target	Measured	Tolerance [%]
Dielectric constant ε	62.5	63.11	0.97
Conductivity σ [ms/cm]	9.0	8.7	-3.33

2 Result Summary

FCC 47 CFR Part 95E, 95I, 15C, IC RSS-243, IC RSS-Gen				
Product Specific Standard Section	**Requirement – Test**	**Reference Method**	**Result**	**Remarks**
FCC § 2.1047 FCC § 2.1049 IC RSS-243 3.2 IC RSS-Gen 4.6	Occupied bandwidth	RSS-Gen 4.6.1	PASS	Informational only
FCC § 95.627(d) FCC § 95.633(e) IC RSS-243 3.6, 5.1	Emission bandwidth	FCC § 95.628(a)(6)(i) FCC § 95.633(e)(3)	PASS	
FCC § 95.627(e) FCC § 2.1055 IC RSS-243 3.3, 5.3 RSS-Gen 4.7	Frequency stability	EN 301 839-1 8.1	PASS	
FCC § 95.639(f) FCC § 2.1046 IC RSS-243 § 5.4	Transmitter output power	EN 301 839-1 8.3	PASS	
FCC § 95.635(d) IC RSS-243 § 3.4, 5.5	Band edge compliance	FCC § 95.635(d) ANSI C63.4	PASS	
FCC § 95.635(d) FCC § 2.1051 FCC § 2.1053 FCC § 2.1057 IC RSS-243 § 3.4, 5.5 RSS-Gen 4.9	Transmitter unwanted emissions	FCC § 95.635(d) ANSI C63.4	PASS	
IC RSS-243 3.5, 5.6 IC RSS-Gen 4.10 6.1	Receiver spurious emissions	ANSI C63.4	PASS	
FCC § 15.207 IC RSS-Gen 7.2.4	AC power line conducted emissions	ANSI C63.4	N/A	EUT battery powered
FCC § 95.627(a)(3) IC RSS-243 3.6, 5.7.1	System threshold power levels	EN 301 839-1 10.1	N/R	Applies only to equipment by which LBT is performed
FCC § 95.627(a)(1) IC RSS-243 3.6, 5.7.2	Monitoring system bandwidth	EN 301 839-1 10.2	N/R	Applies only to equipment by which LBT is performed
FCC § 95.627(a)(2) IC RSS-243 3.6, 5.7.3	Scan cycle time	EN 301 839-1 10.3	N/R	Applies only to equipment by which LBT is performed
FCC § 95.627(a)(2) IC RSS-243 3.6, 5.7.4	Minimum channel monitoring period	EN 301 839-1 10.3	N/R	Applies only to equipment by which LBT is performed
FCC § 95.627(a)(4) IC RSS-243 3.6, 5.7.5	Channel Access	EN 301 839-1 10.4	N/R	Applies only to equipment by which LBT is performed
FCC § 95.627(a)(4) IC RSS-243 3.6, 5.7.6	Discontinuation of MICS or MEDS session	EN 301 839-1 10.5	PASS	
FCC § 95.627(a)(5) IC RSS-243 3.6, 5.7.7	Use of the pre-scanned alternate channel	EN 301 839-1 10.6	N/A	
Remarks:				

3 Test Conditions and Results

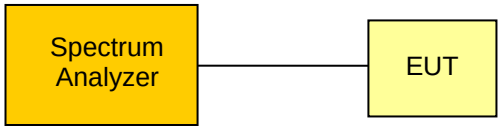
3.1 Test Conditions and Results – Occupied Bandwidth – Modulation Characteristics

Occupied Bandwidth acc. IC RSS-243, FCC § 2.1049, FCC § 2.1047	**Verdict: PASS**
Test according to measurement reference	Reference Method
	FCC § 2.1049 / FCC § 2.1047 / RSS-Gen 4.6.1
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated

Limits

None (Informational only)

Test setup



Test procedure

1. EUT set to test mode (Communication tester is used if needed)
2. Span set to at least twice the emission spectrum
3. Resolution bandwidth set to 1 % of span
4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function

Test results

Channel	Frequency [MHz]	Occupied Bandwidth [kHz]
F_{LOW}	402.45	178.2
F_{MID}	403.65	180.0
F_{HIGH}	404.85	178.2

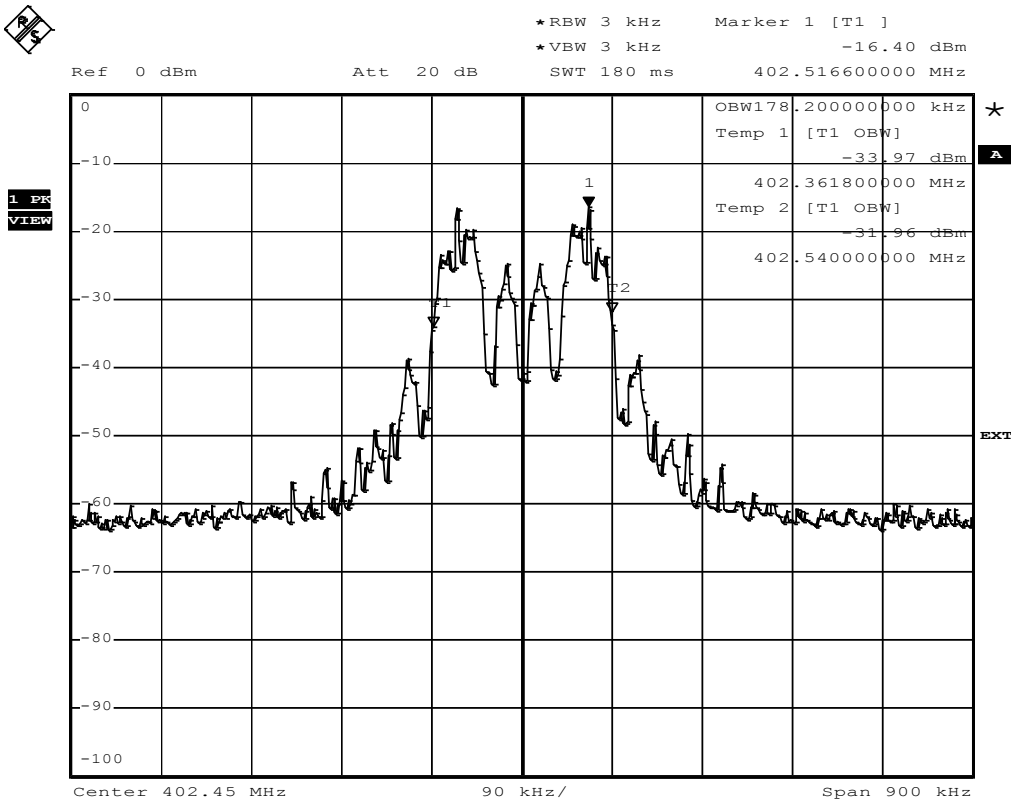
Comments:

Modulation characteristics:
The equipment meet the modulation characteristics according to FCC § 2.1047 (d) and § 95.1209 for digital data transmission (2FSK) and no voice mode.

Occupied Bandwidth – F_{LOW}

RSS-Gen
Occupied frequency bandwidth

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 402.45 MHz
Comment 3	

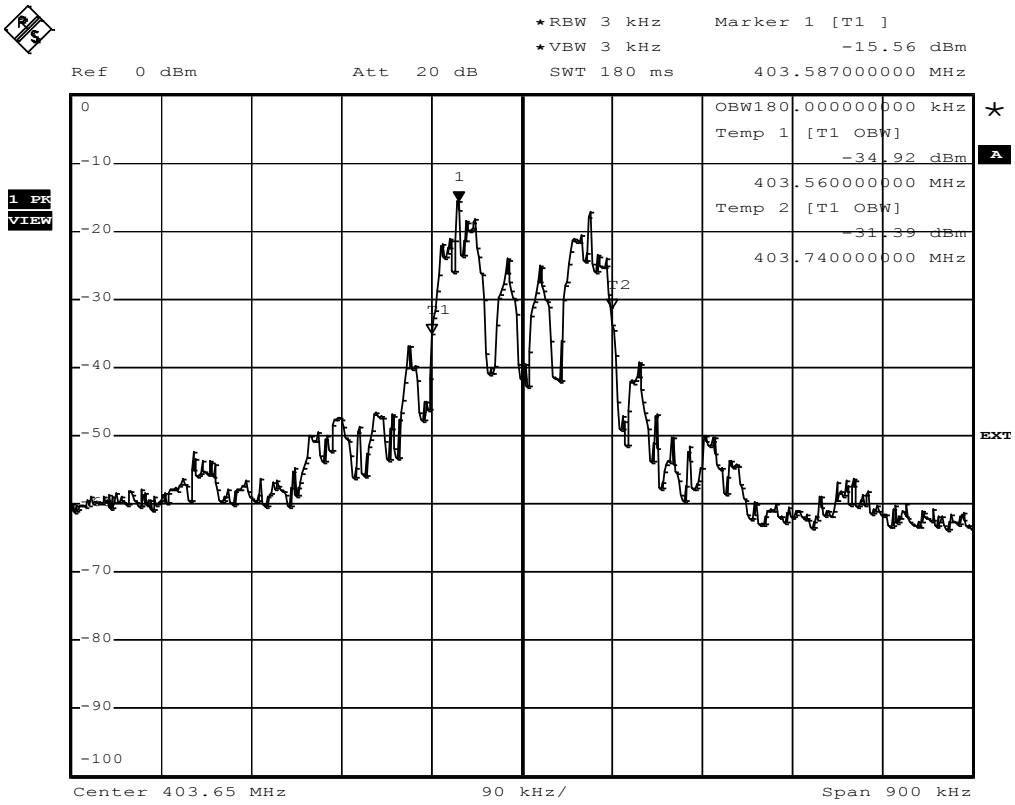


Comment: Occupied bandwidth: 178.2 KHz
Date: 15.MAY.2013 14:54:04

Occupied Bandwidth - F_{MID}

RSS-Gen
Occupied frequency bandwidth

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 403.65 MHz
Comment 3	

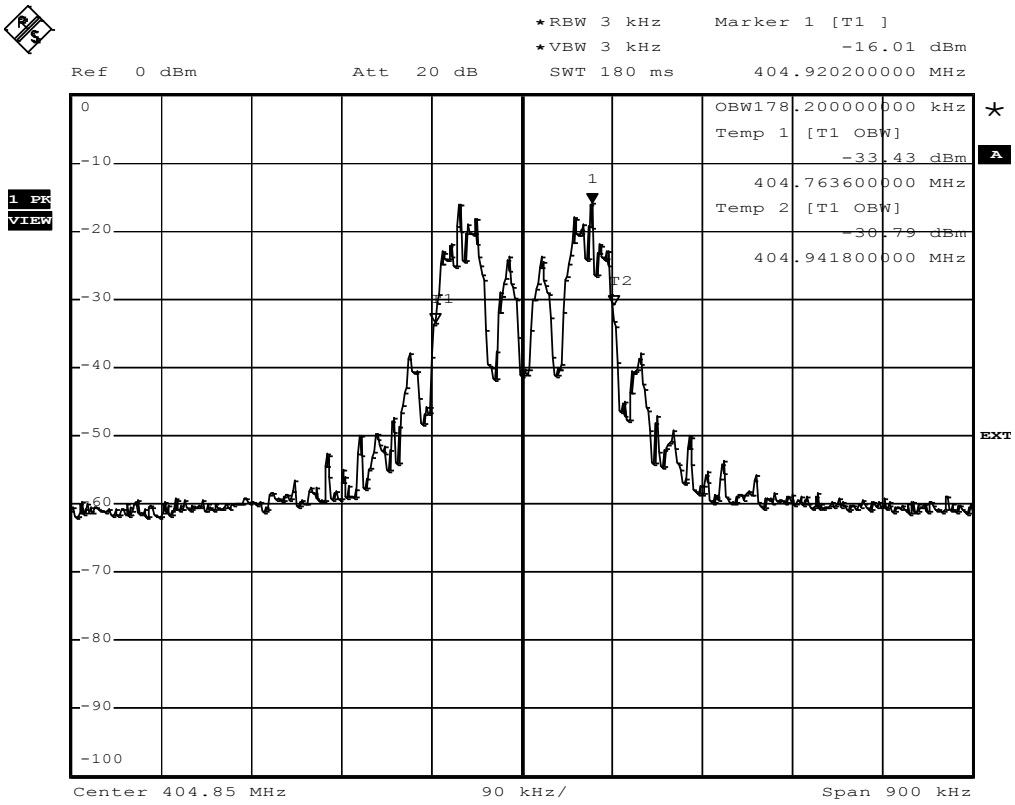


Comment: Occupied bandwidth: 180 KHz
Date: 15.MAY.2013 15:38:31

Occupied Bandwidth - F_{HIGH}

RSS-Gen
Occupied frequency bandwidth

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 404.85 MHz
Comment 3	



Comment: Occupied bandwidth: 178.2 KHz
Date: 15.MAY.2013 15:22:47

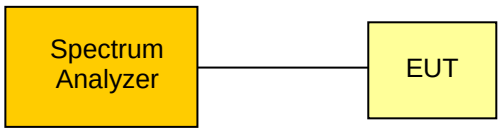
3.2 Test Conditions and Results – Emission Bandwidth

Emission Bandwidth acc. FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC § 95.627(d) / FCC § 95.633(e) / IC RSS-243 3.3 5.1
Test according to measurement reference	Reference Method
	FCC § 95.627(a)(6)(i) / FCC § 95.633(e)(3)
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated

Limits

≤ 300 kHz

Test setup



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. 20 dB Emission Bandwidth is determined by marker frequency separation

Test results

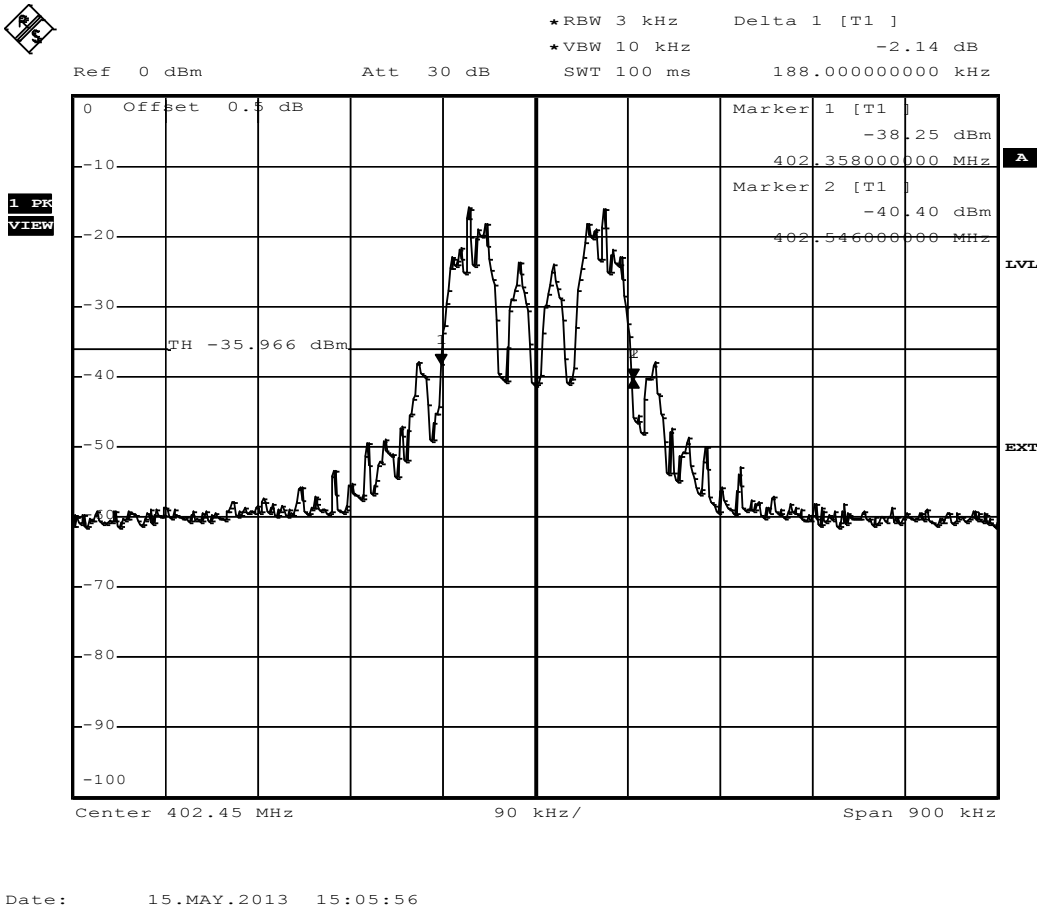
Channel	Frequency [MHz]	Emission Bandwidth [kHz]	Limit [kHz]	Result
F_{LOW}	402.45	188.0	≤ 300	PASS
F_{MID}	403.65	188.0	≤ 300	PASS
F_{HIGH}	404.85	187.6	≤ 300	PASS

Comments:

Emission Bandwidth – F_{LOW}

FCC Part 95.633
Emission bandwidth

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.633
Comment 1	20 dB Emission bandwidth
Comment 2	Channel: 402.45 MHz
Comment 3	Pass

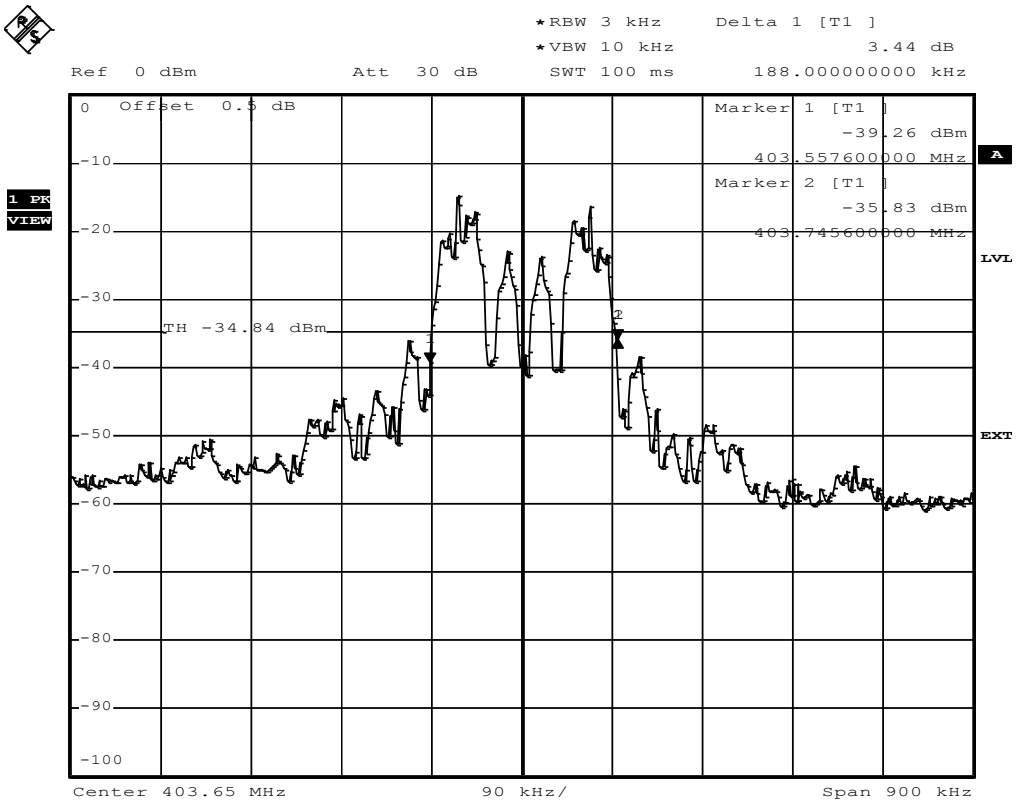


Date: 15.MAY.2013 15:05:56

Emission Bandwidth – F_{MID}

FCC Part 95.633
Emission bandwidth

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.633
Comment 1	20 dB Emission bandwidth
Comment 2	Channel: 403.65 MHz
Comment 3	Pass

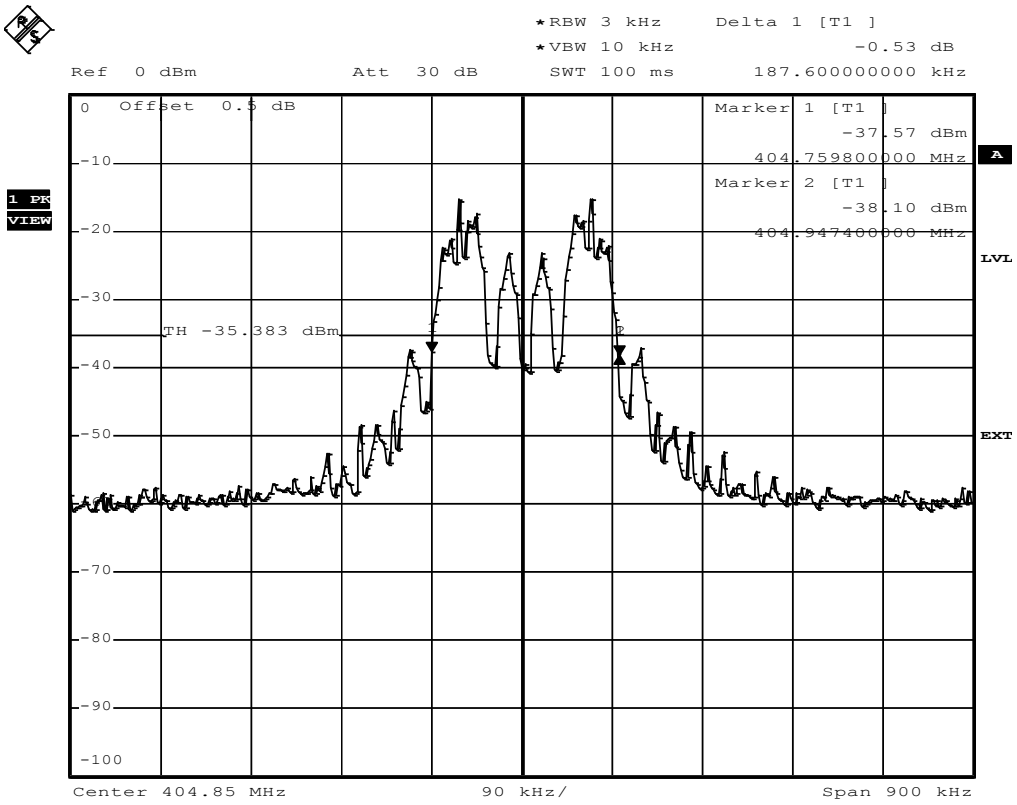


Comment: 20 dB bandwidth: 188 KHz
Date: 15.MAY.2013 15:50:33

Emission Bandwidth – F_{HIGH}

FCC Part 95.633
Emission bandwidth

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.633
Comment 1	20 dB Emission bandwidth
Comment 2	Channel: 404.85 MHz
Comment 3	Pass



Comment: 20 dB bandwidth: 187.6 KHz
Date: 15.MAY.2013 15:30:42

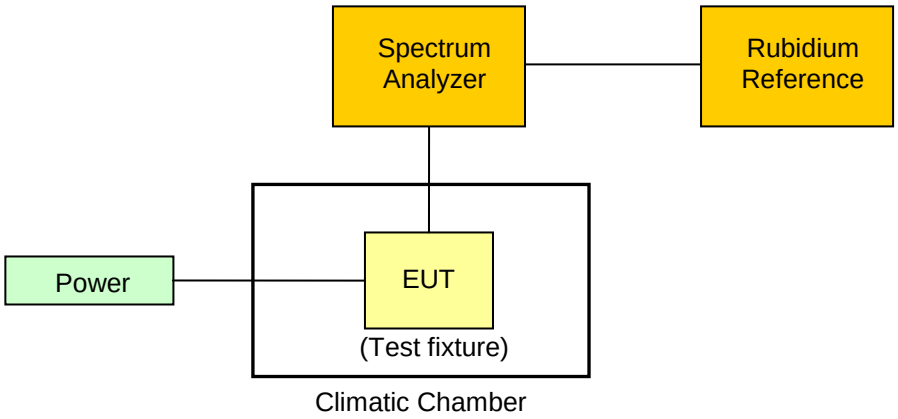
3.3 Test Conditions and Results – Frequency stability

Frequency stability acc. FCC Part 95 / FCC Part 2 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC § 95.627(e) / FCC § 2.1055 IC RSS-243 3.3 5.3 / RSS-Gen 4.7
Test according to measurement reference	Reference Method
	EN 301 839-1 8.1
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Unmodulated

Limits

≤ ±100 ppm

Test setup



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.

Test results					
Channel	Nominal Frequency [MHz]	Temperature	Supply voltage	Frequency [MHz]	Drift [ppm]
F_{MID}	403.65	T_{NOM} = 37 °C	V_{NOM} = 2.8 VDC	403.652286	05.66
F_{MID}	403.65	T_{NOM} = 37 °C	V_{MIN} = 2.5 VDC	403.652416	-05.99
F_{MID}	403.65	T_{MIN} = 25 °C	V_{NOM} = 2.8 VDC	403.652127	05.27
F_{MID}	403.65	T_{MIN} = 25 °C	V_{MIN} = 2.5 VDC	403.651826	-04.52
F_{MID}	403.65	T_{MAX} = 45 °C	V_{NOM} = 2.8 VDC	403.652352	05.83
F_{MID}	403.65	T_{MAX} = 45 °C	V_{MIN} = 2.5 VDC	403.652039	-05.05
Comments:					

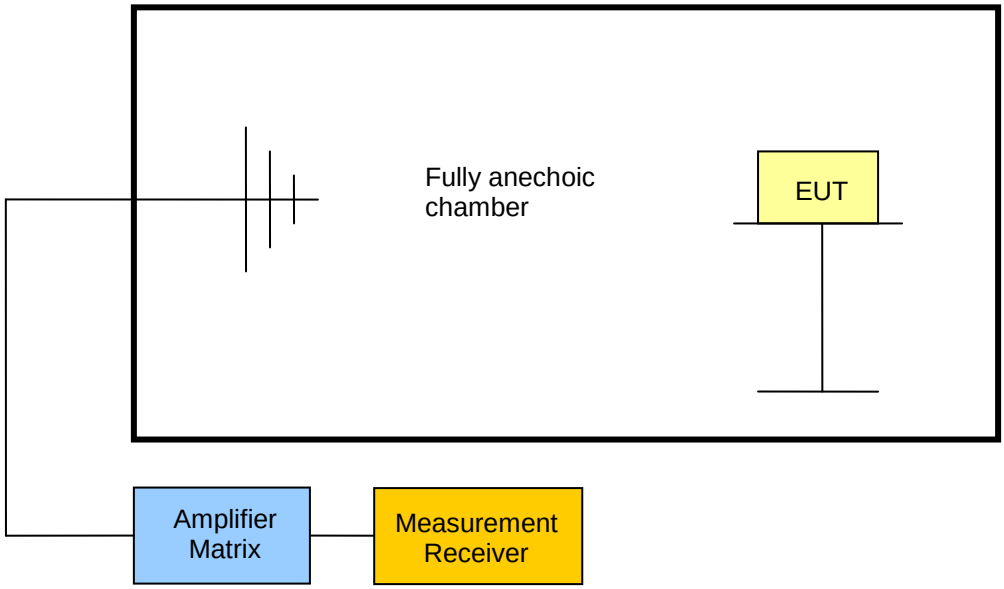
3.4 Test Conditions and Results – Transmitter output power

Transmitter output power acc. FCC Part 2 / FCC Part 95 / IC RSS-243	Verdict: PASS
EUT requirement rule parts and clause	Reference
	FCC § 2.1046 / FCC § 95.639(f) / IC RSS-243 5.4
Test according to measurement reference	Reference Method
	EN 301 839-1 8.3
Test frequency range	Tested frequencies
	F_{LOW} / F_{MID} / F_{HIGH}
EUT test mode	Modulated

Limits

≤ 25 µW (-16 dBm) e.i.r.p.

Test setup



Test procedure

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

Test results					
Channel	Frequency [MHz]	Emission Level [dbm e.i.r.p.]	Detector	Limit [dbm e.i.r.p.]	Margin [dB]
F_{LOW}	402.45	-31.9	pk	-16	-15.90
F_{MID}	403.65	-30.9	pk	-16	-14.90
F_{HIGH}	404.85	-31.4	pk	-16	-15.40
Comments: conducted measurements at the output terminal according to FCC § 2.1046 are not applicable. Specific radiated test procedure for implants according to FCC § 95.639(f) takes precedence.					

3.5 Test Conditions and Results – Band-edge compliance

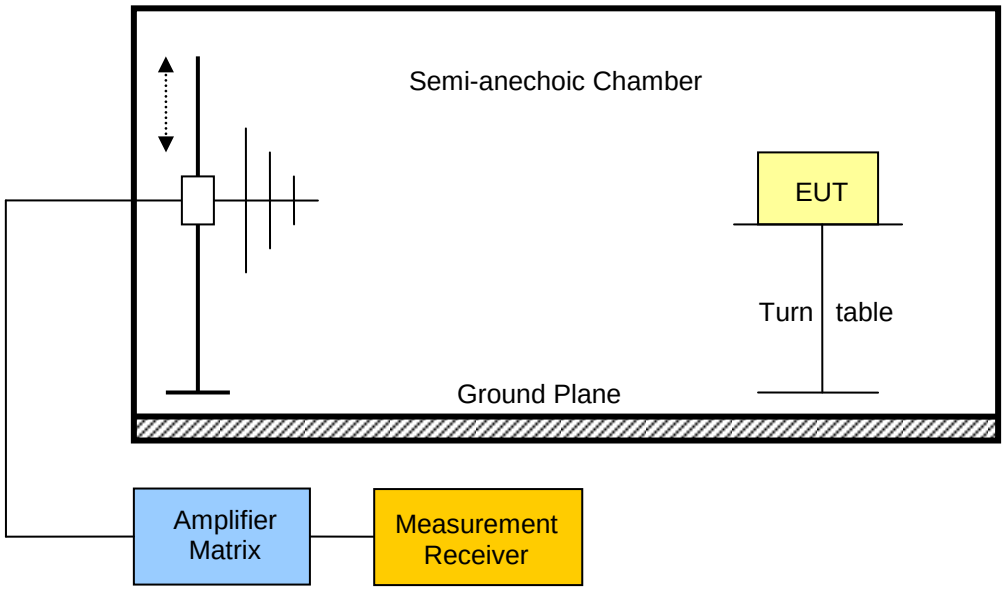
Band-edge compliance acc. FCC Part 95 / IC RSS-243	**Verdict: PASS**
EUT requirement rule parts and clause	Reference
	FCC § 95.635(d) / IC RSS-243 3.5 5.5 / RSS-Gen 4.9
Test according to measurement reference	Reference Method
	FCC § 95.635(d) / ANSI C 63.4
Test frequency range	Tested frequencies
	F_{LOW} / F_{HIGH}
EUT test mode	Modulated

Limits - FCC	
Frequency range	Limit
402 MHz – 250 kHz ≤ f ≤ 402 MHz	20 dB below maximum permitted output power
402 MHz < f < 150 kHz - f_C	20 dB below transmitter output power
150 kHz + f_C < f < 405 Mhz	20 dB below transmitter output power
405 MHz ≤ f ≤ 405 MHz + 250 kHz	20 dB below maximum permitted output power

Limits - IC	
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

Because the FCC limits are more stringent than the Industry Canada limits, the FCC limits are used to show compliance with the band-edge emission requirements.

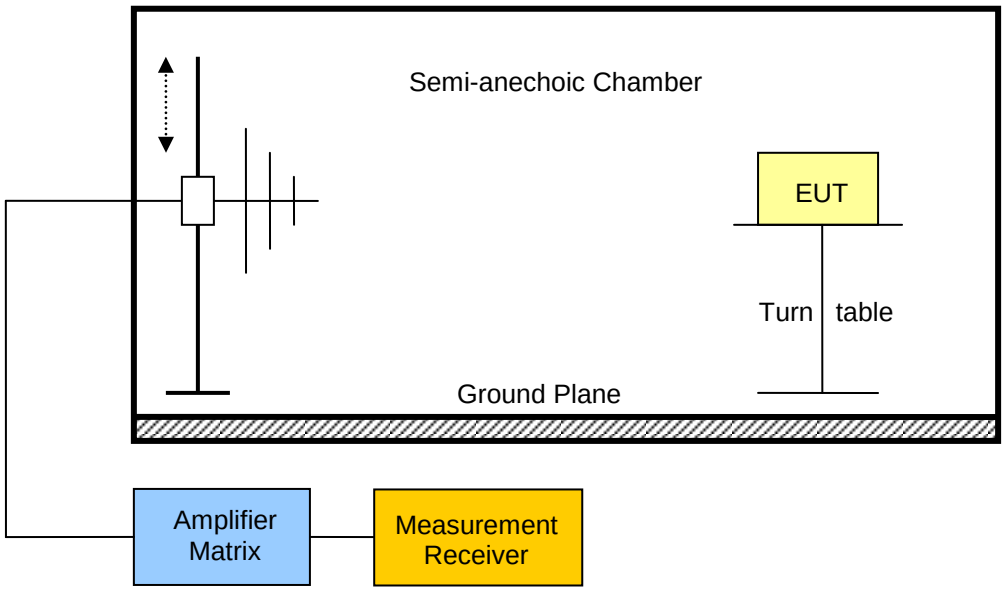
Test setup



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		
Test results		
Channel	Frequency [MHz]	Result
F_{LOW}	402.45	PASS
F_{HIGH}	404.85	PASS
Comments: see attached diagrams		

3.6 Test Conditions and Results – Transmitter unwanted emissions

Transmitter unwanted emissions acc. FCC Part 2 / FCC Part 95 IC RSS-243				**Verdict: PASS**
Test according referenced standards		Reference Method		
		FCC § 2.1051 / FCC § 2.1053 / FCC § 2.1057 / FCC § 95.635(d) / IC RSS-243 3.4 5.5 / IC RSS-Gen 4.9		
Test according to measurement reference		Reference Method		
		FCC 95.635(d) / ANSI C 63.4		
Test frequency range		Tested frequencies		
		30 MHz – 10th Harmonic		
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
30 – 88	Quasi-Peak	100	40	3
88 – 216	Quasi-Peak	150	43.5	3
216 – 960	Quasi-Peak	200	46	3
960 – 1000	Quasi-Peak	500	54	3
> 1000	Average	500	54	3
Test setup				

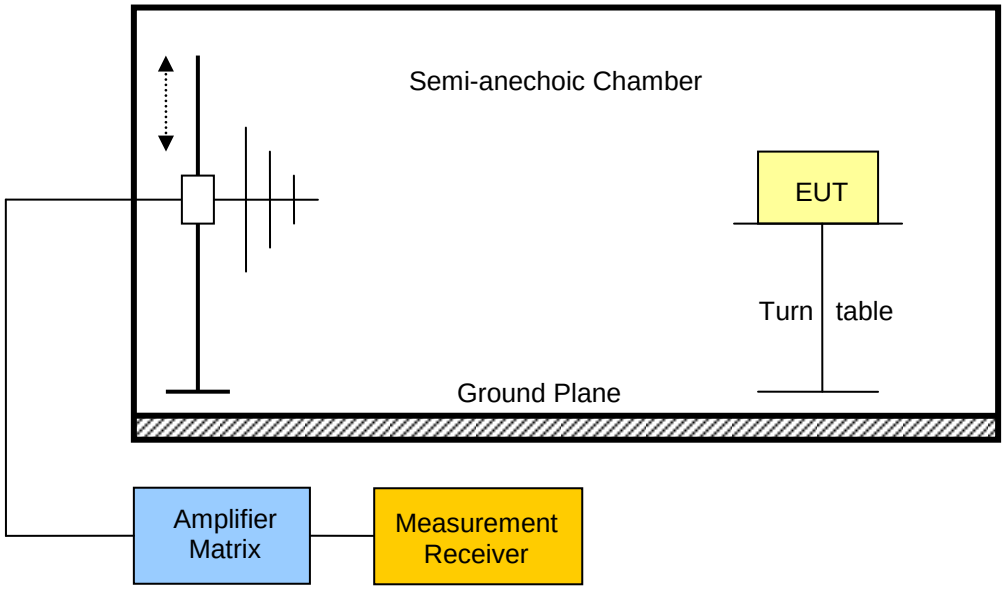


Test procedure
1. EUT set to test mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to peak emission levels within restricted bands

Test results – Transmitter & Antenna 1									
Channel	Frequency [MHz]	Mode	Emission [MHz]	Level [dbµV/m]	Det.	Pol.	Limit [dbµV/m]	Limit dist. [m]*	Margin [dB]
No significant spurious emissions									
Comments: * Physical distance between EUT and measurement antenna. The implant has no antenna terminals.									

3.7 Test Conditions and Results – Receiver spurious emissions

Receiver spurious emissions acc. IC RSS-243				**Verdict: PASS**
Test according referenced standards	Reference Method			
	IC RSS-243 3.5 5.6 / IC RSS-Gen 4.10 6.1			
Test according to measurement reference	Reference Method			
	ANSI C 63.4			
Test frequency range	Tested frequencies			
	30 MHz – 3th Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
30 – 88	Quasi-Peak	100	40	3
88 – 216	Quasi-Peak	150	43.5	3
216 – 960	Quasi-Peak	200	46	3
960 – 1000	Quasi-Peak	500	54	3
> 1000	Average	500	54	3
Test setup				



Test procedure
1. EUT set to receive mode (Communication tester is used if needed) 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to peak emission levels

Test results

Channel	Frequency [MHz]	Emission [MHz]	Emission Level [dbµV/m]	Emission Level [µV/m]	Det.	Pol.	Limit [µV/m]	Margin [µV/m]
No significant spurious emissions								

Comments:
* Physical distance between EUT and measurement antenna.
** Emission level corresponds to ambient noise floor

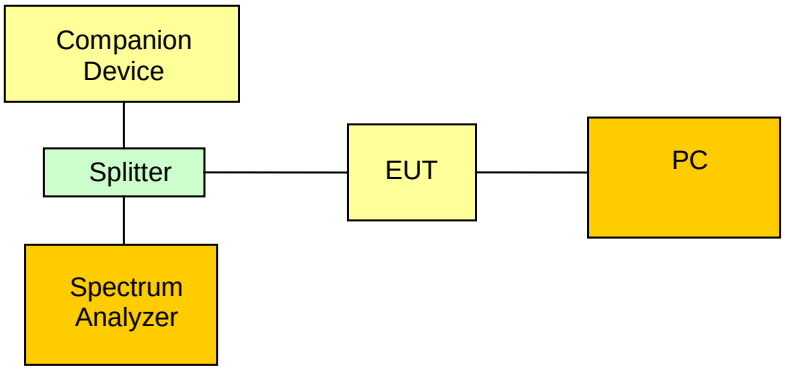
3.8 Test Conditions and Results – Discontinuation of MICS or MEDS session

Discontinuation of MICS or MEDS session acc. FCC Part 95 / IC RSS-243	Verdict: PASS
Test according to measurement reference	Reference Method
	FCC § 95.627(a)(4) / IC RSS-243 3.6, 5.7.6
Test frequency range	Tested frequencies
	F_{MID}

Limits

When the communication connection is interrupted for 5 s or longer, the transmission shall be terminated.

Test setup



Test procedure

1. A communication session is established between the EUT and a companion device
2. The communication is monitored by a spectrum analyser
3. The communication session is interrupted
4. All transmissions after the interruptions are monitored and recorded

Test results – Home monitoring mode

Channel	Frequency [MHz]	Transmission time [s]	Time Limit [s]	Margin [s]
F_{MID}	403.65	3.84	5	-1.16

Test results – Programming mode

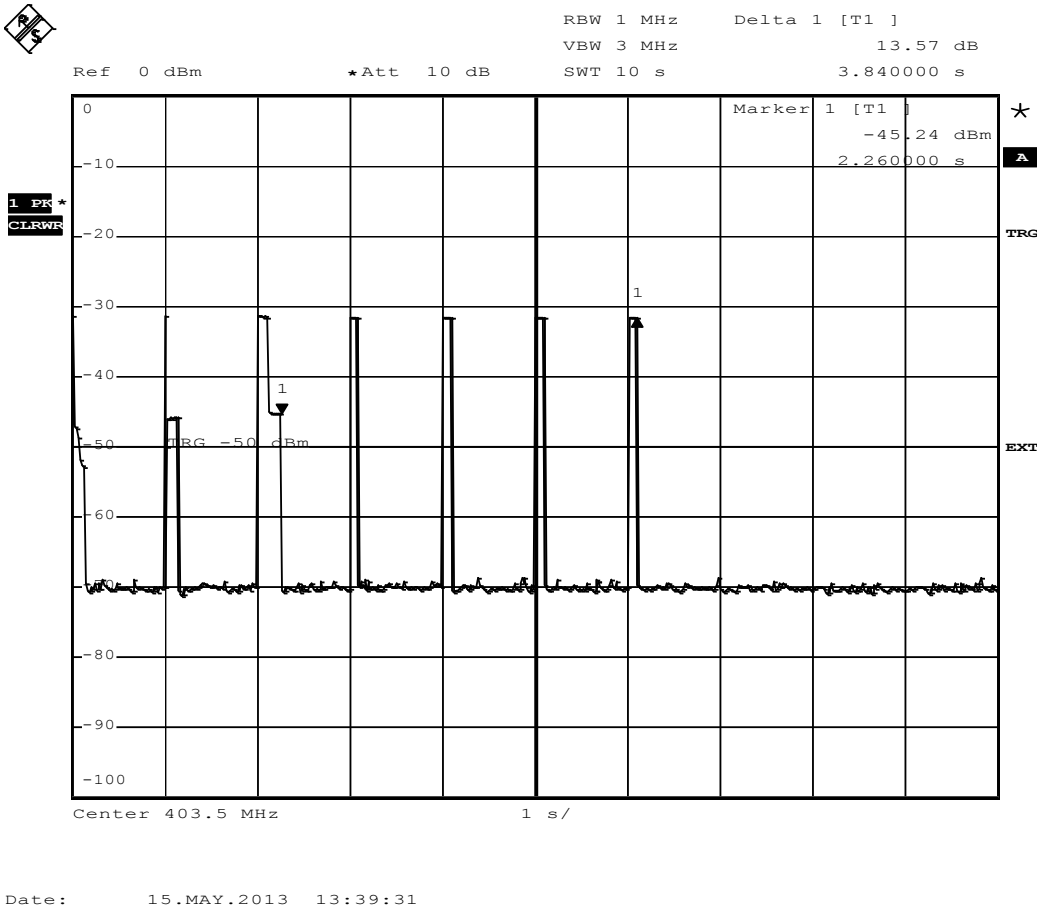
Channel	Frequency [MHz]	Transmission time [s]	Time Limit [s]	Margin [s]
F_{MID}	403.65	0.792	5	-04.21

Comments:

Discontinuation of MICS or MEDS session – F_{MID} (Home monitoring mode)

FCC Part 95.627
Discontinuation of MICS session if a silent period greater than or equal 5s occurs

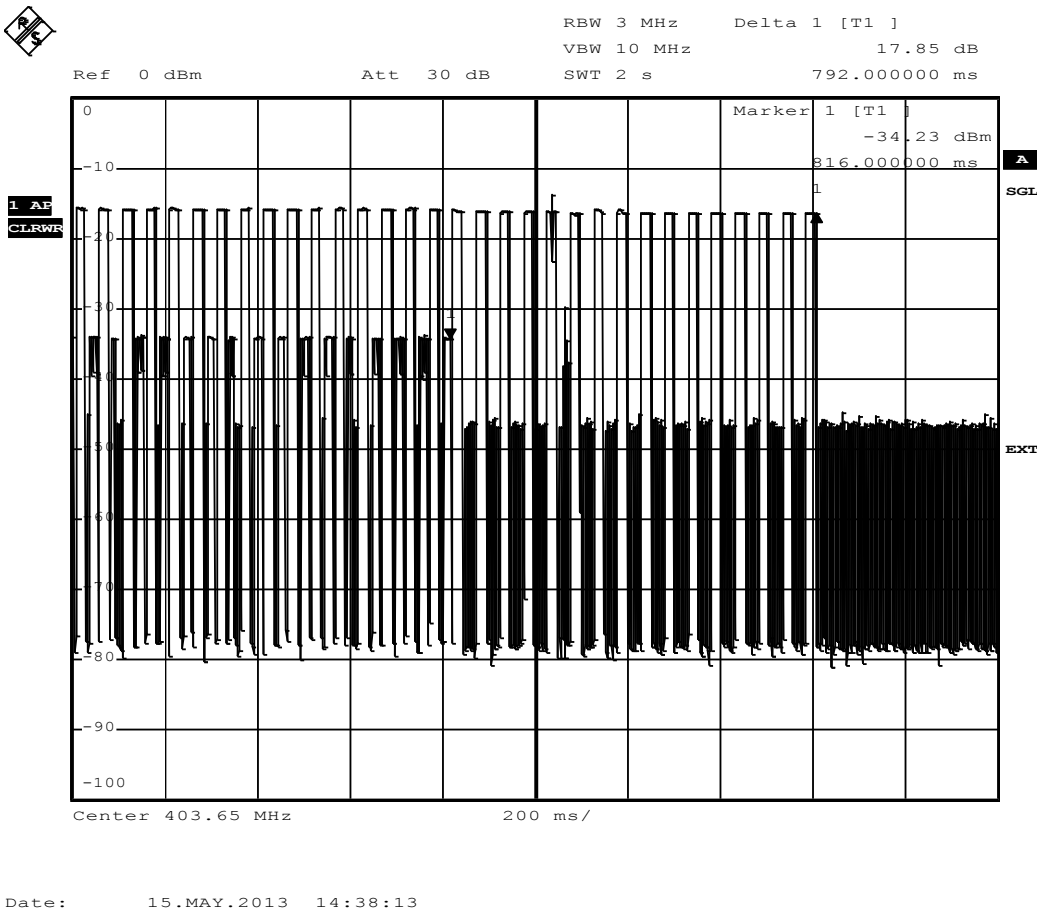
EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.627 / EN 301 839-1
Comment 1	Discontinuation of MICS session if a silent period greater than or equal 5s occurs
Comment 2	No communication after 3.84 msec silent period @ communication channel
Comment 3	mode: home monitoring



Discontinuation of MICS or MEDS session – F_{MID} (Programming mode)

FCC Part 95.627
Discontinuation of MICS session if a silent period greater than or equal 5s occurs

EUT	IPG / Implantable Pulse Generator
Model	Primus NXT / G0M-1304-2799
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	FCC Part 95.627 / EN 301 839-1
Comment 1	Discontinuation of MICS session if a silent period greater than or equal 5s occurs
Comment 2	No communication after 792 msec silent period @ communication channel
Comment 3	mode: wireless wand

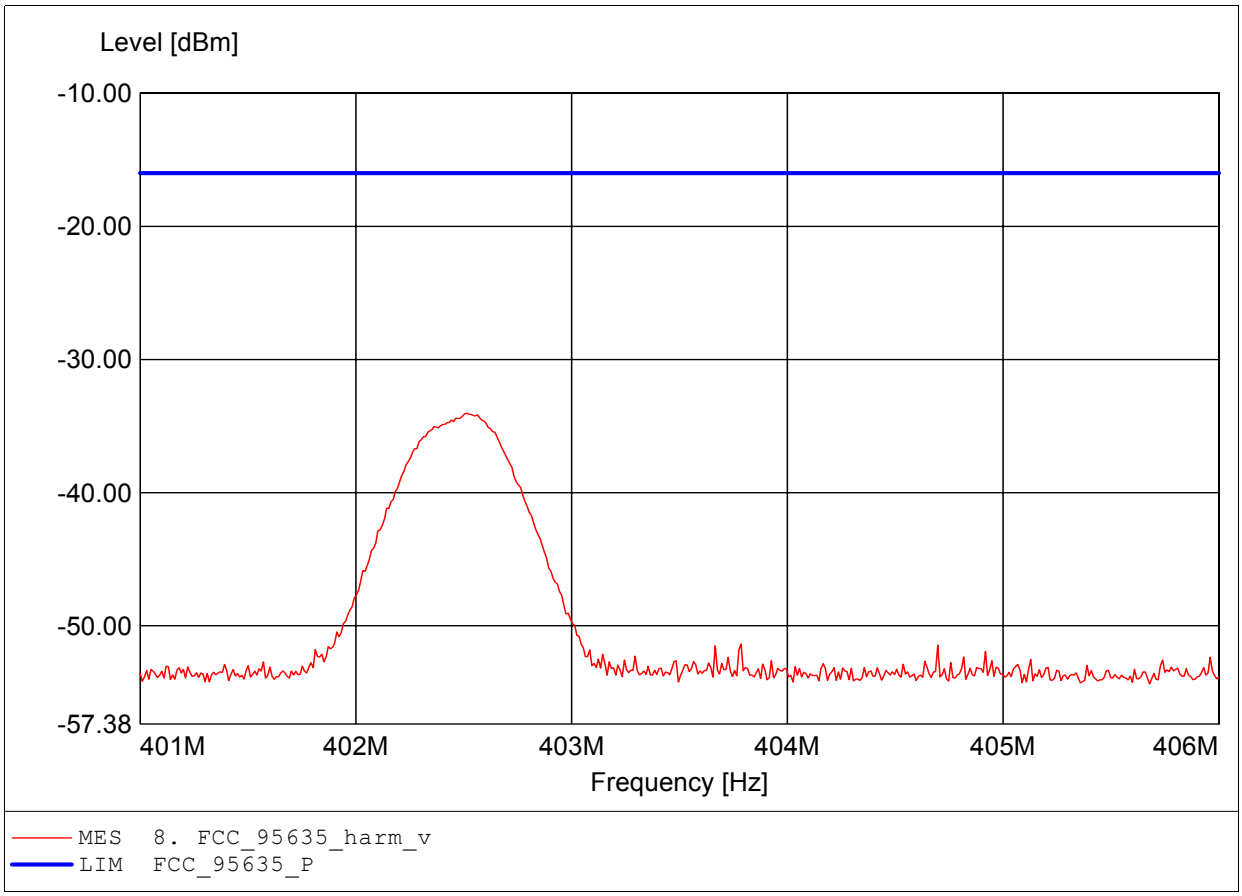


ANNEX A Transmitter radiated power

Carrier power (dBm)

FCC RULES PART 95, SUBPART i

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 402.513MHz, Pmax: -34.03dBm, RBW: 300KHz



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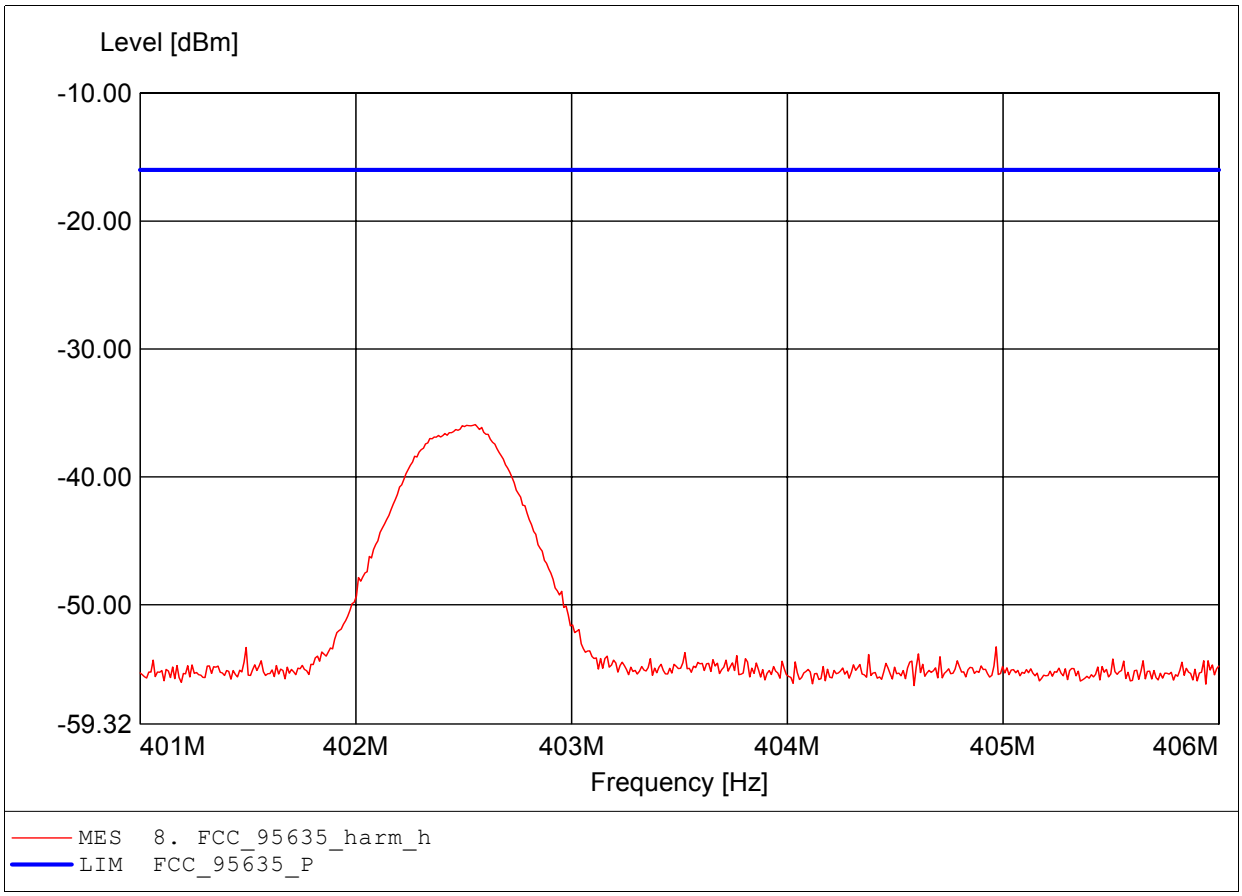
Carrier power (dBm)

FCC RULES PART 95, SUBPART i

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 402.553MHz, Pmax: -35.90dBm, RBW: 300KHz



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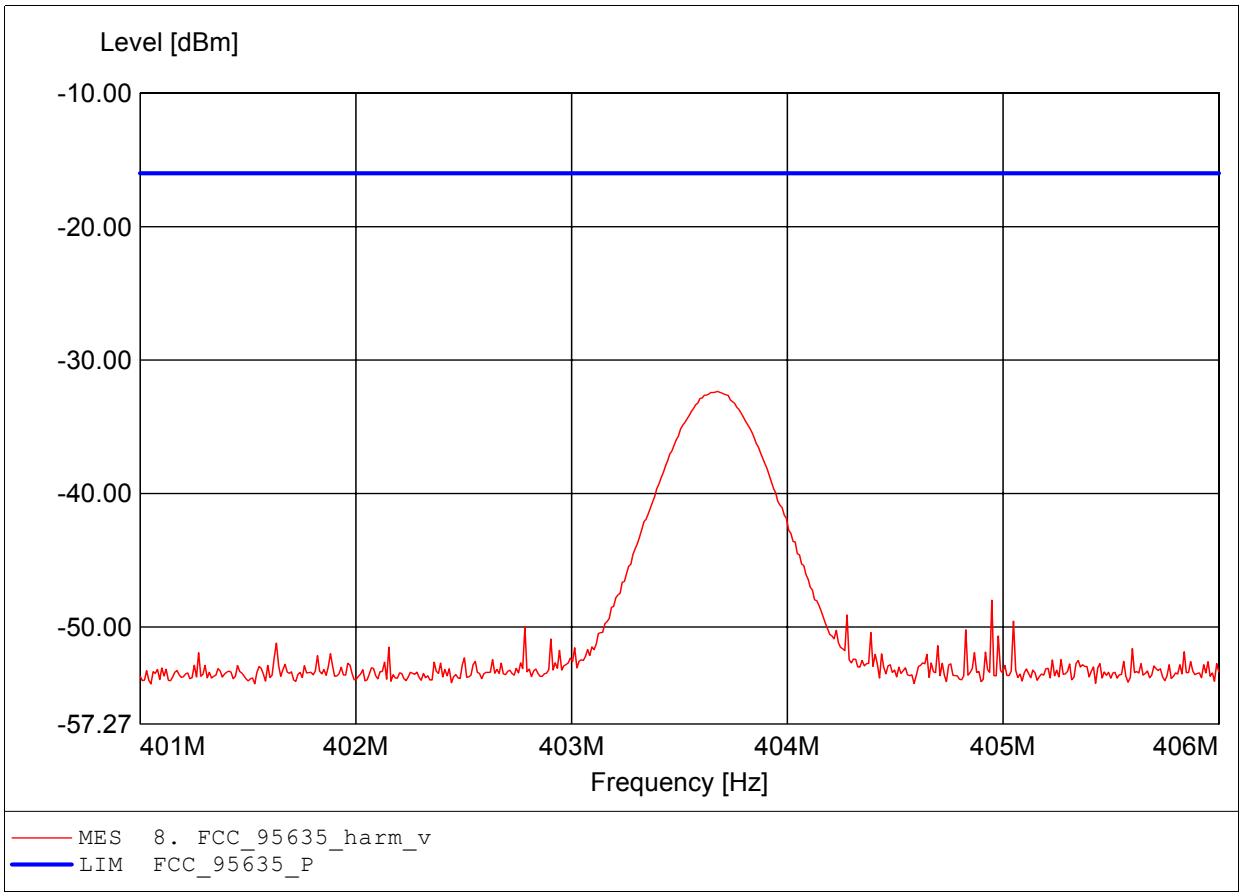
Carrier power (dBm)

FCC RULES PART 95, SUBPART i

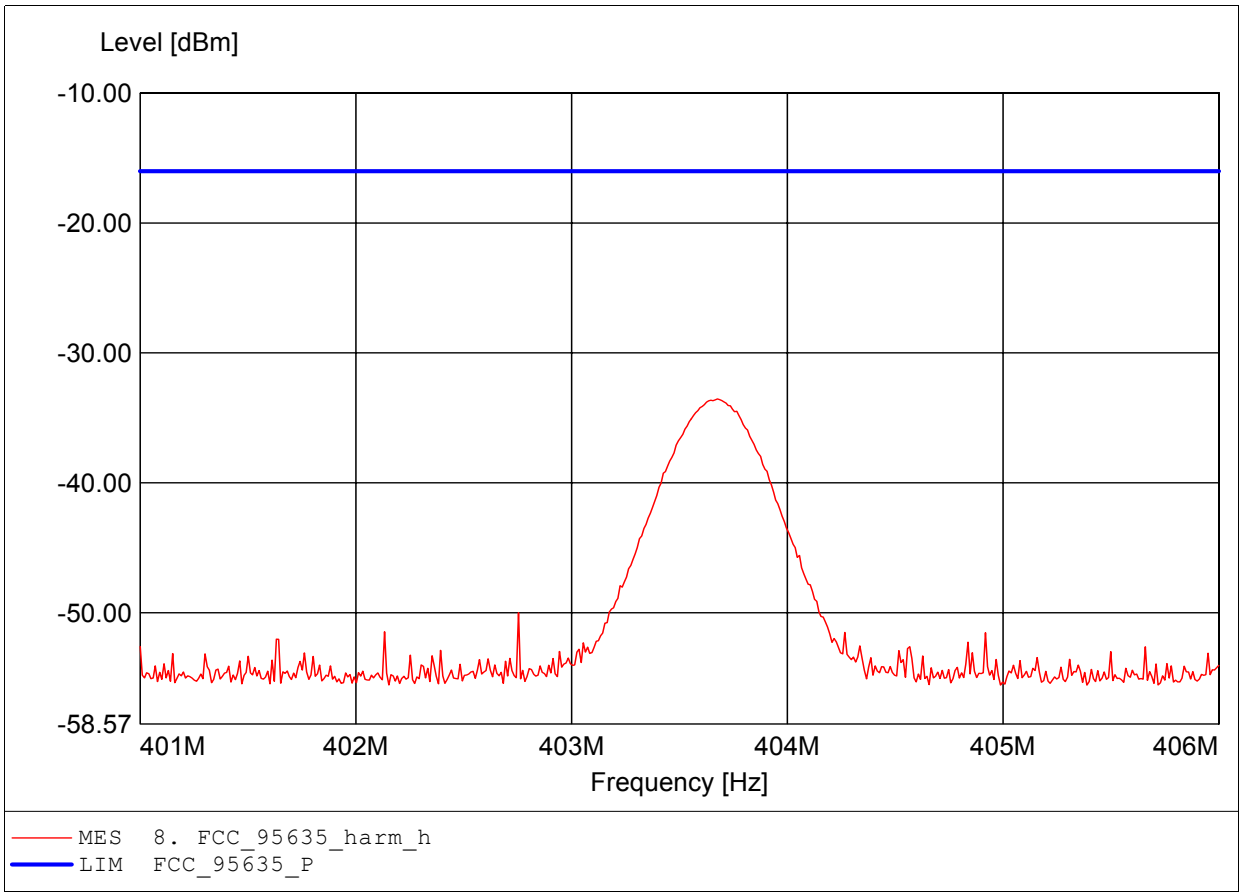
Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 403.675MHz, Pmax: -32.34dBm, RBW: 300KHz



Carrier power (dBm)

FCC RULES PART 95, SUBPART i

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 403.675MHz, Pmax: -33.54dBm, RBW: 300KHz



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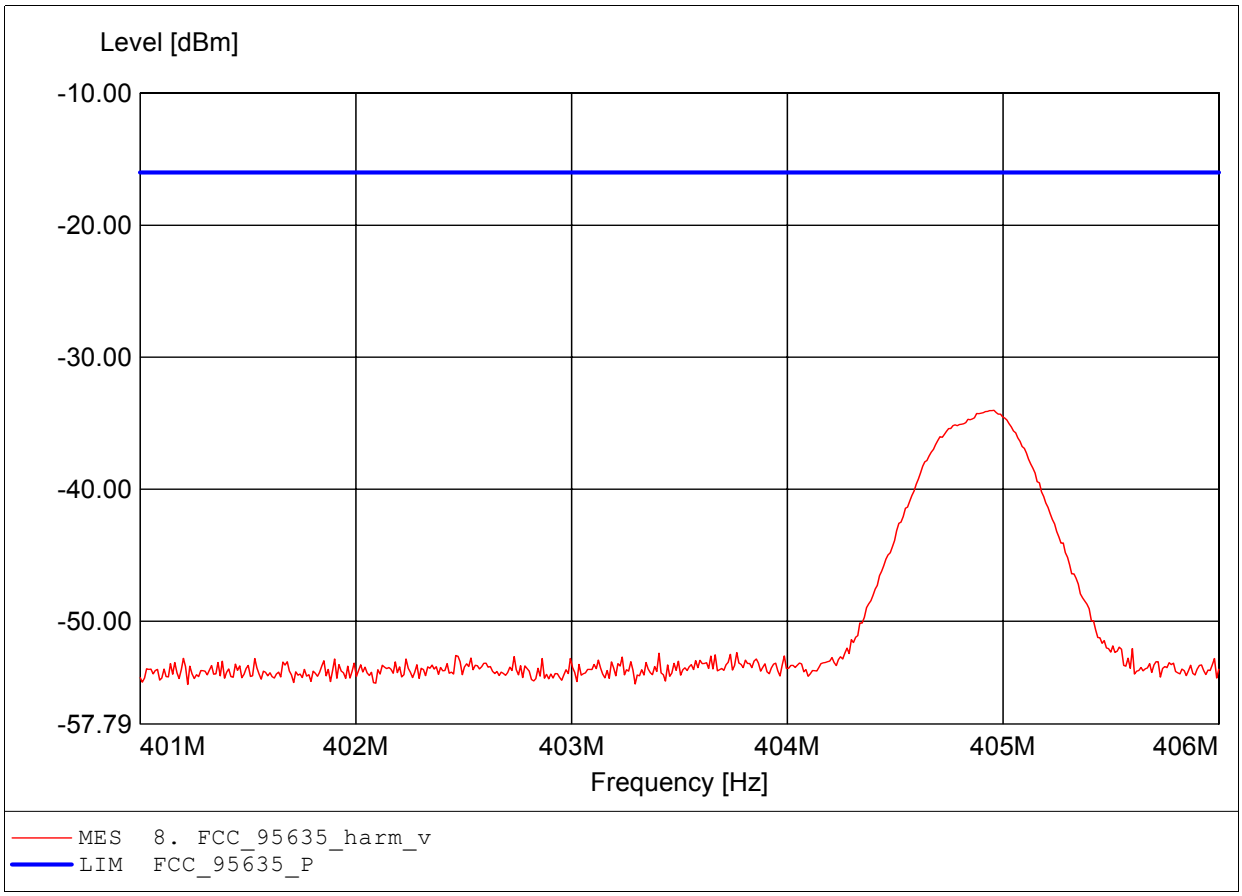
Carrier power (dBm)

FCC RULES PART 95, SUBPART i

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 404.958MHz, Pmax: -34.02dBm, RBW: 300KHz



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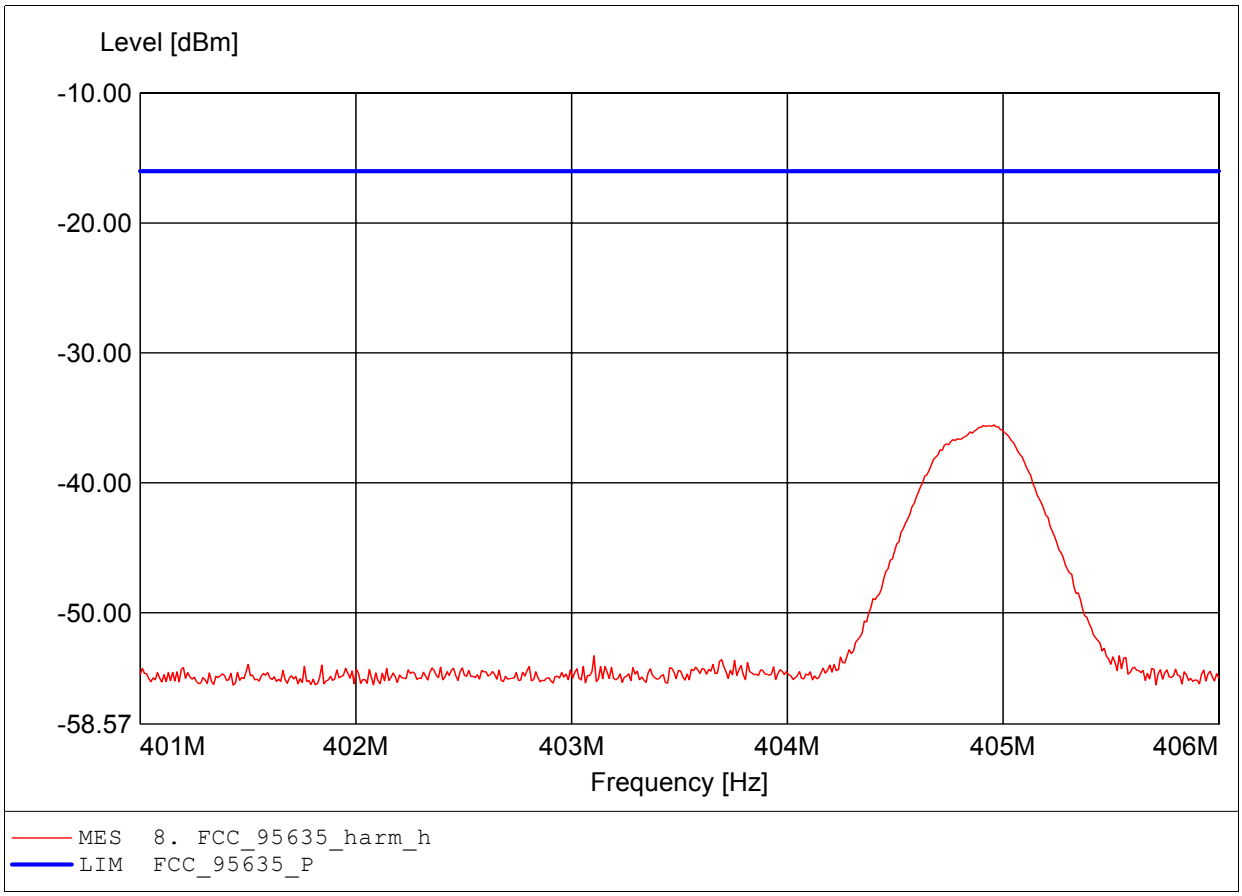
Carrier power (dBm)

FCC RULES PART 95, SUBPART i

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 404.958MHz, Pmax: -35.54dBm, RBW: 300KHz



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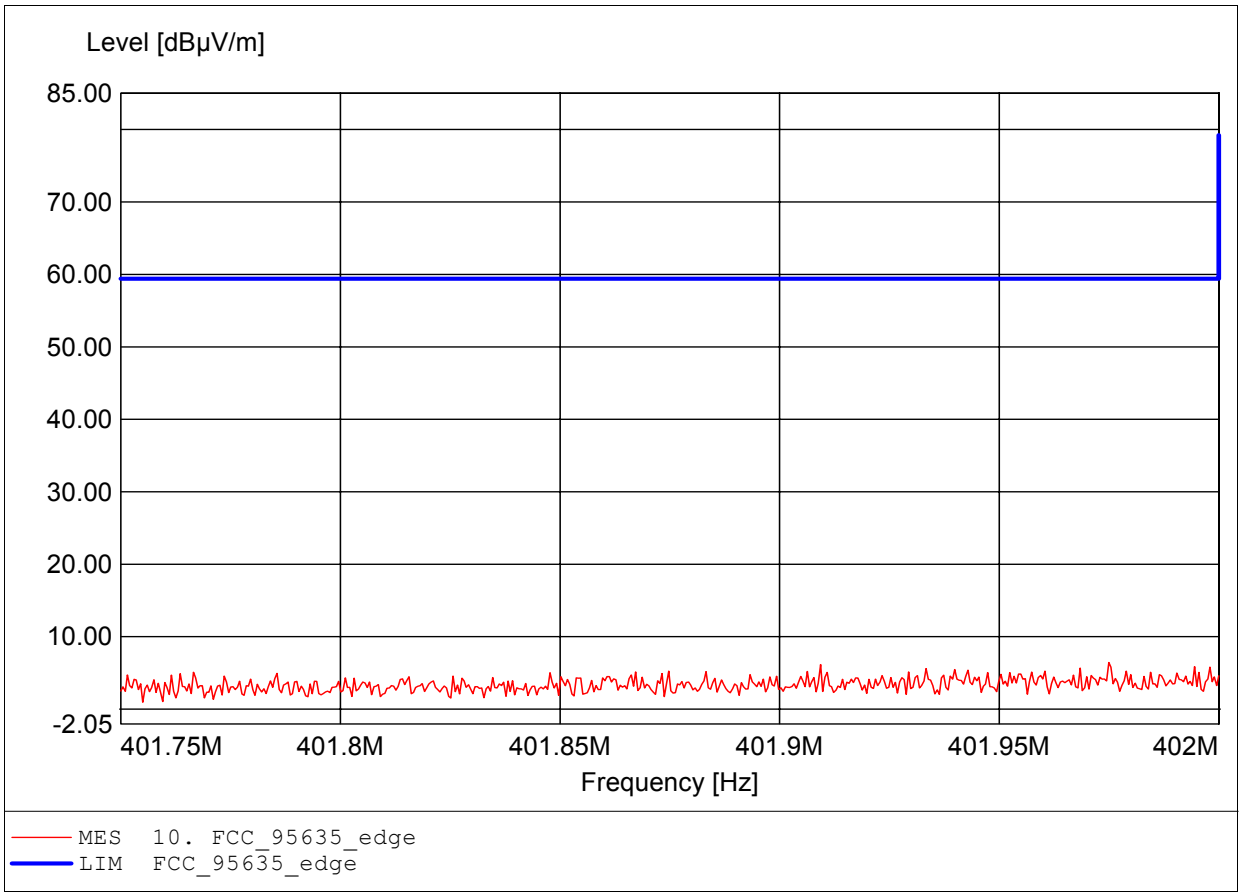
ANNEX B Transmitter band-edge

Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 401.975MHz, Emax: 6.44dBµV/m, RBW: 3kHz



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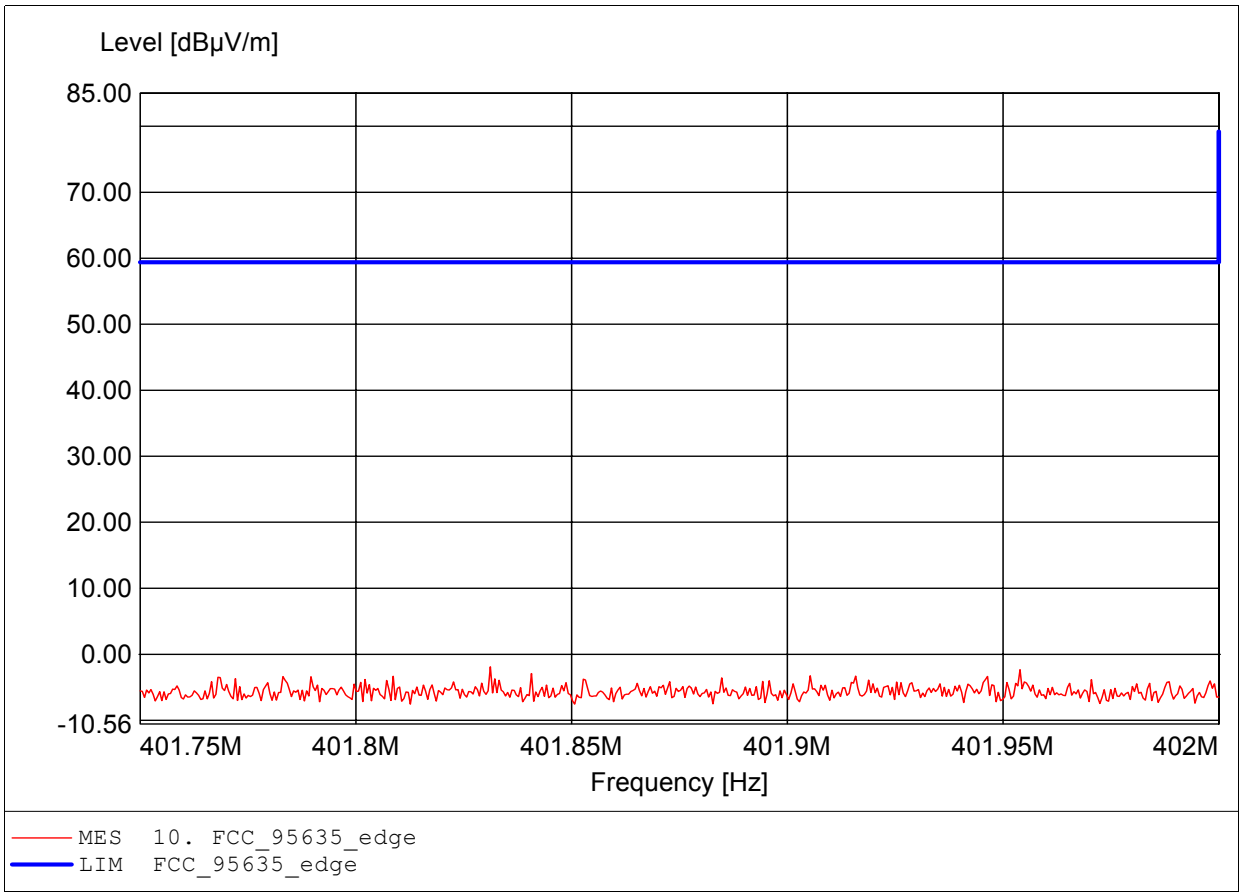
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 401.831MHz, Emax: -1.91dBµV/m, RBW: 3kHz



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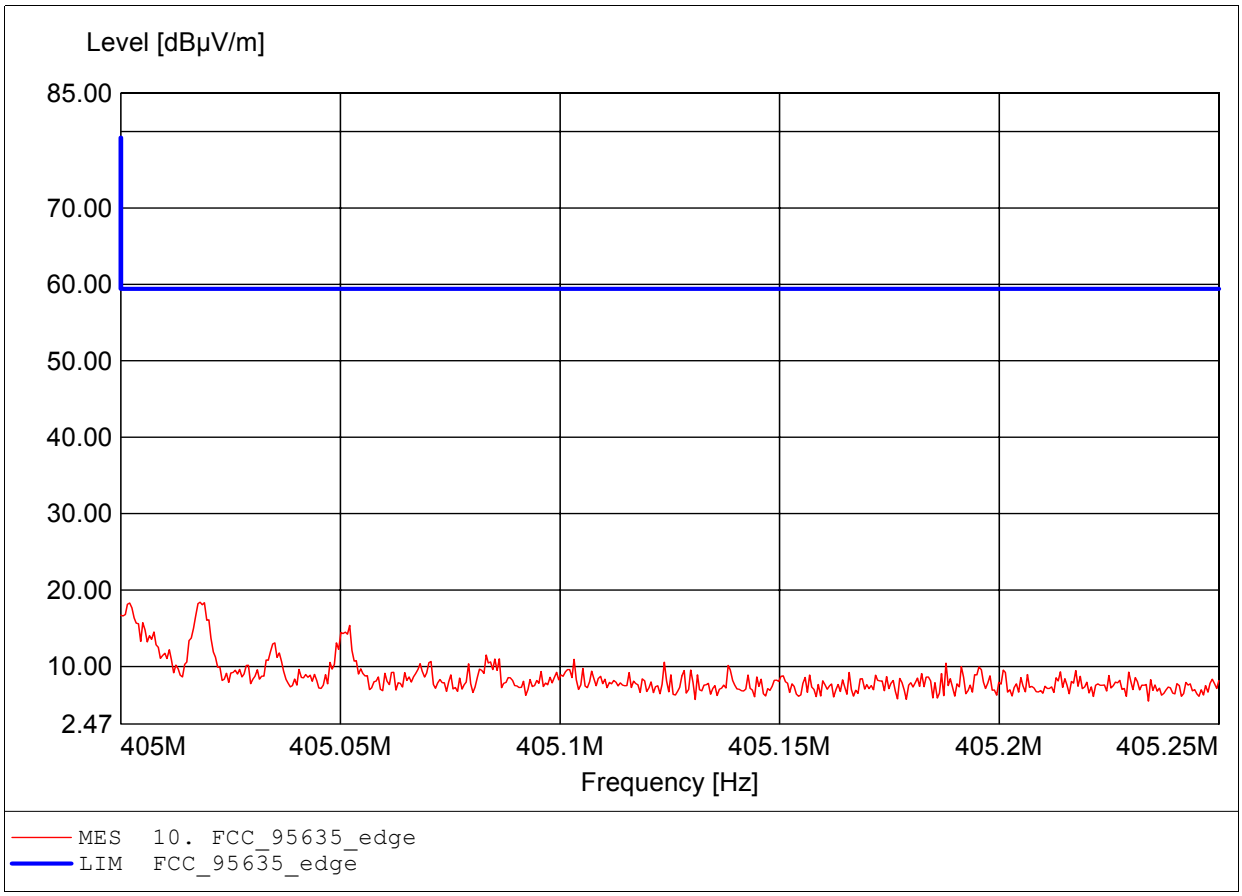
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 405.018MHz, Emax: 18.40dBµV/m, RBW: 3kHz



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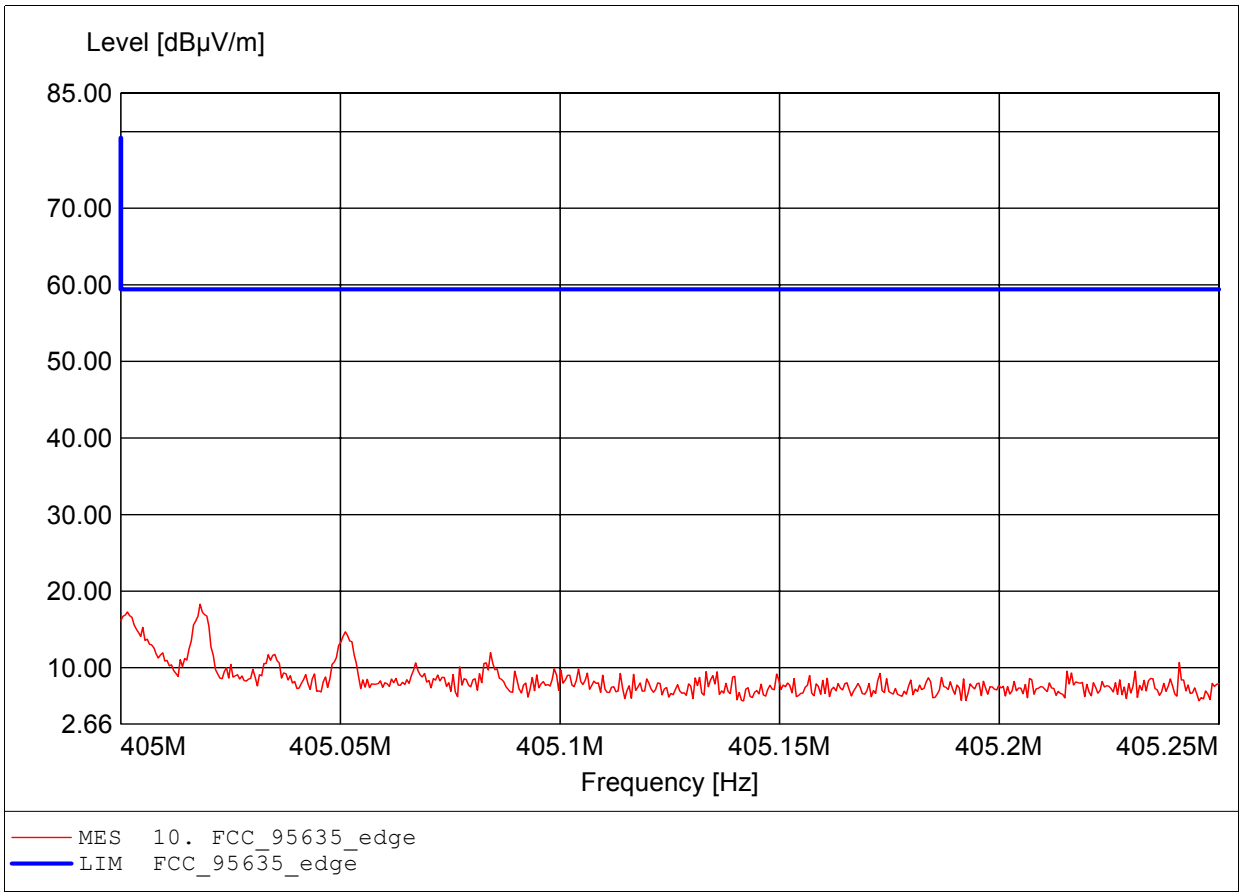
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 405.018MHz, Emax: 18.31dBµV/m, RBW: 3kHz



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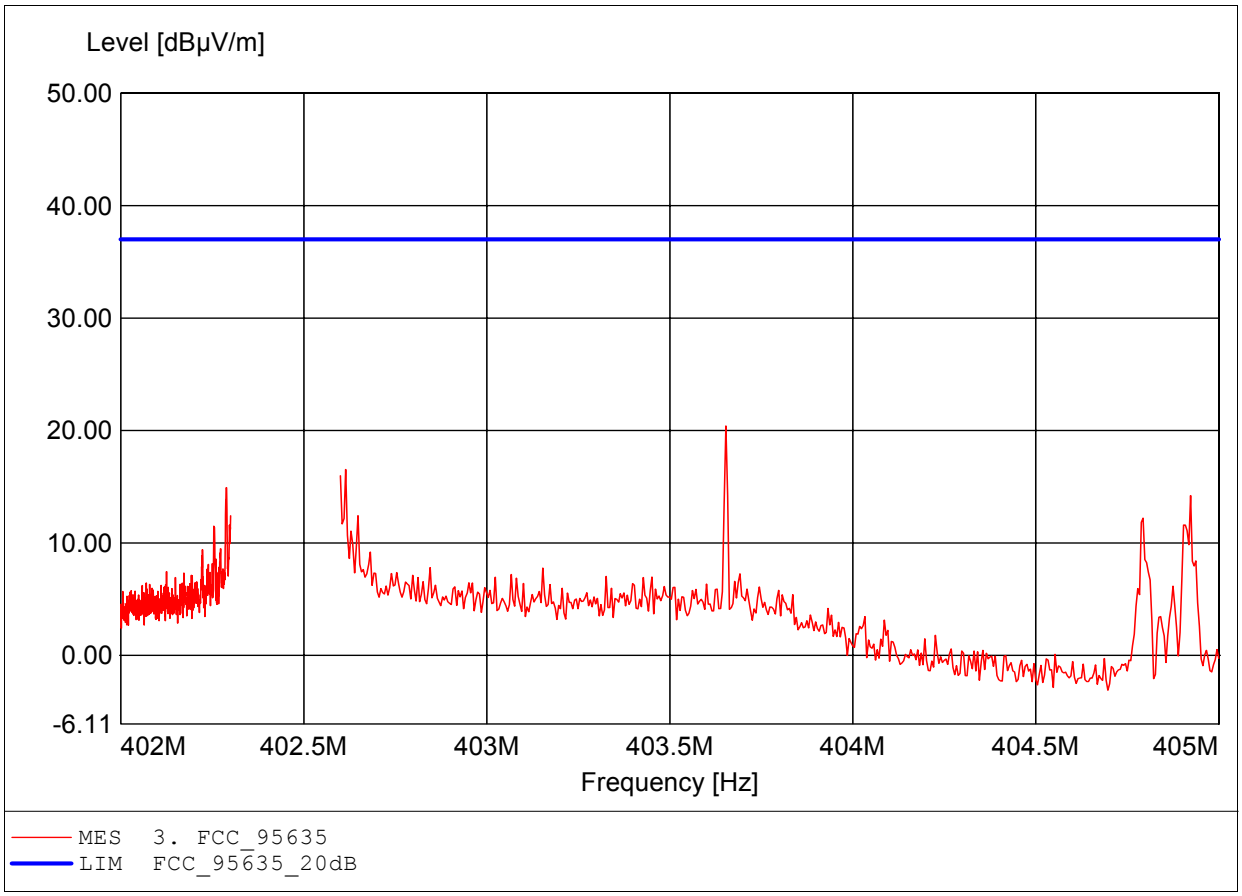
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.653MHz, Emax: 20.40dBµV/m, RBW: 3kHz



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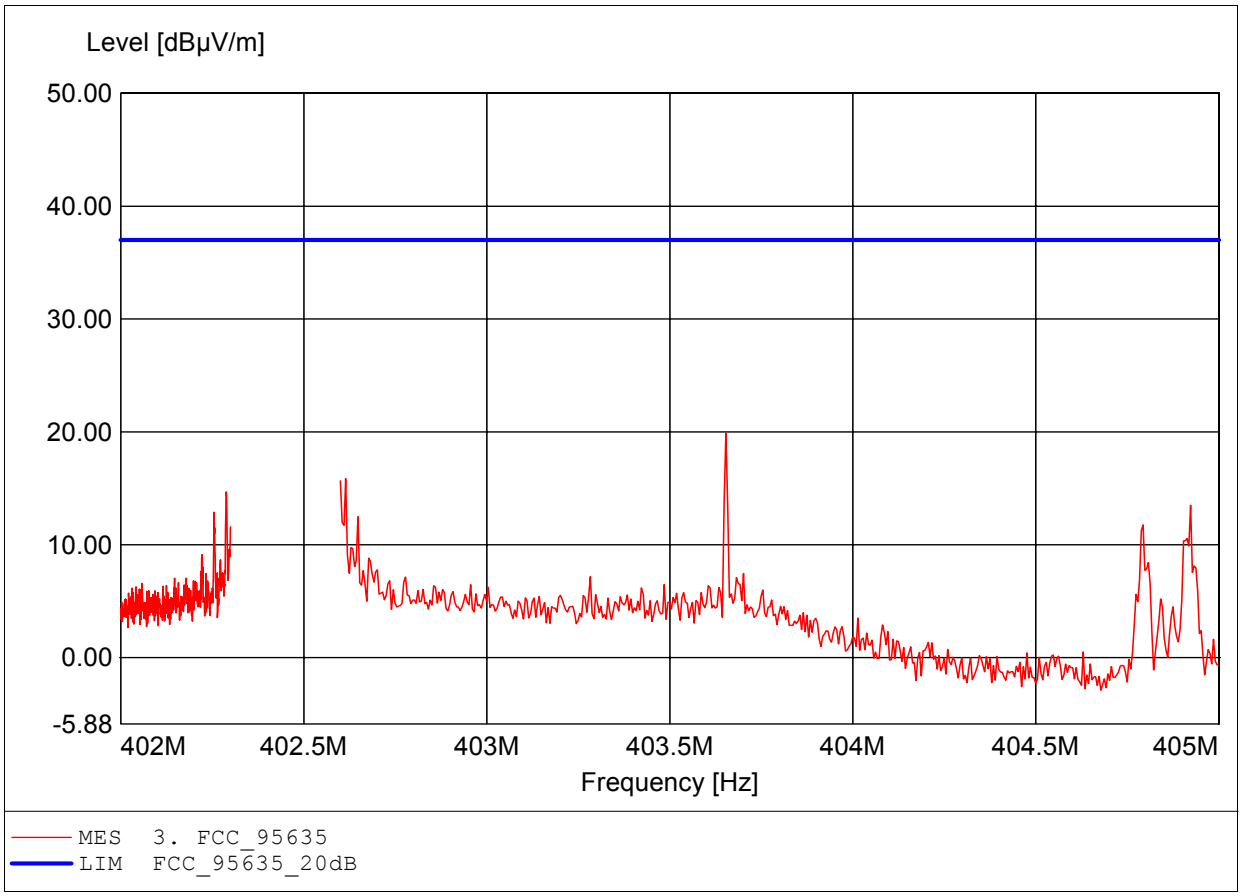
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.653MHz, Emax: 19.91dBµV/m, RBW: 3kHz



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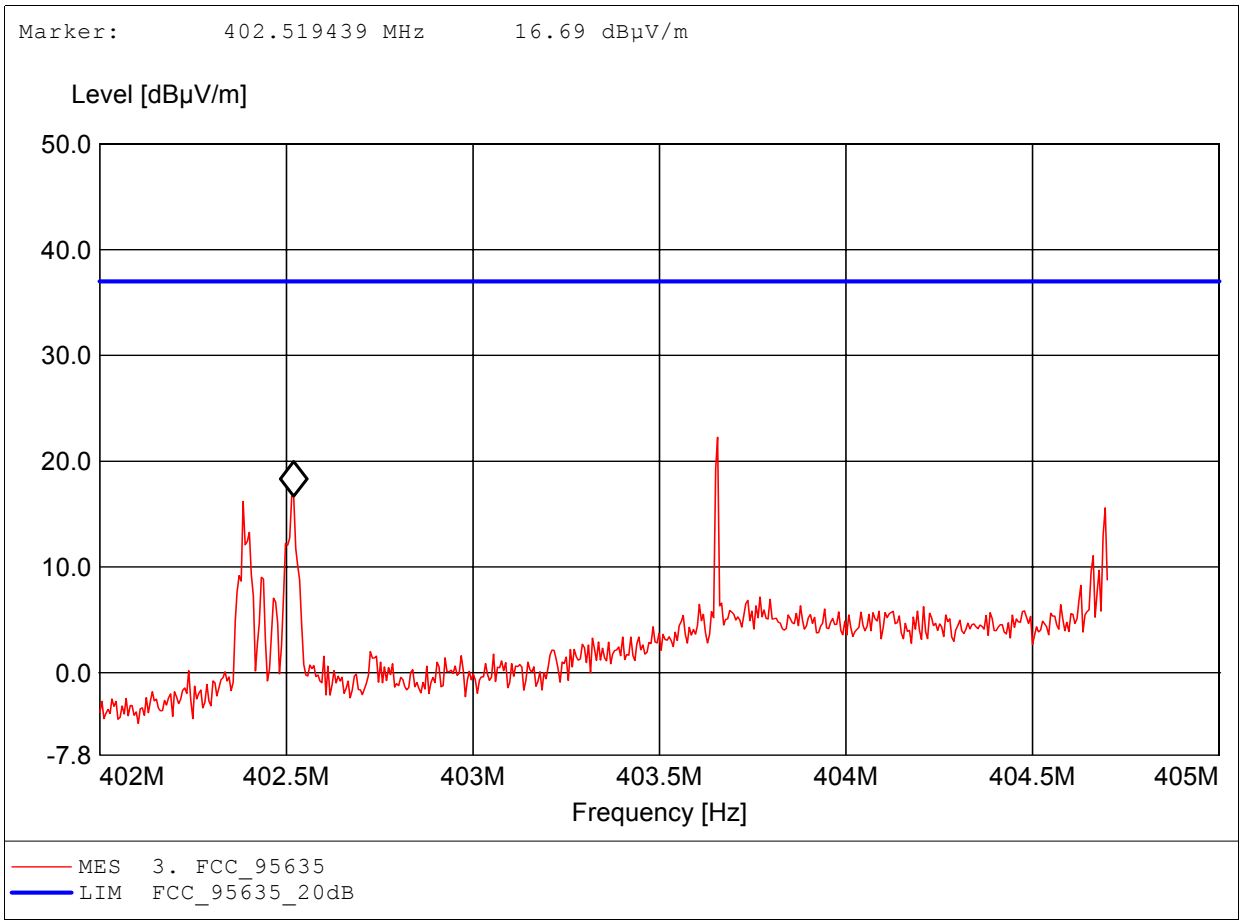
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.656MHz, Emax: 22.25dBµV/m, RBW: 3kHz



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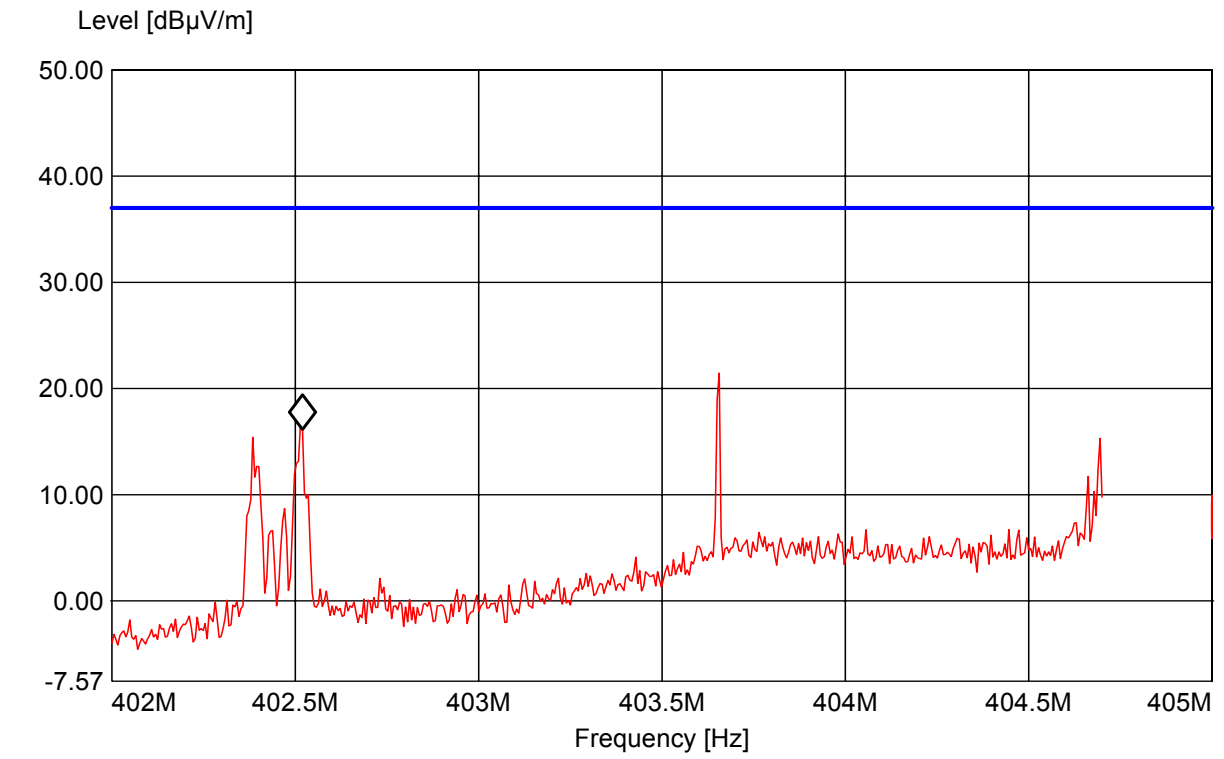
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.656MHz, Emax: 21.44dBµV/m, RBW: 3kHz

Marker: 402.519439 MHz 16.13 dBµV/m



MES 3. FCC_95635
LIM FCC_95635_20dB

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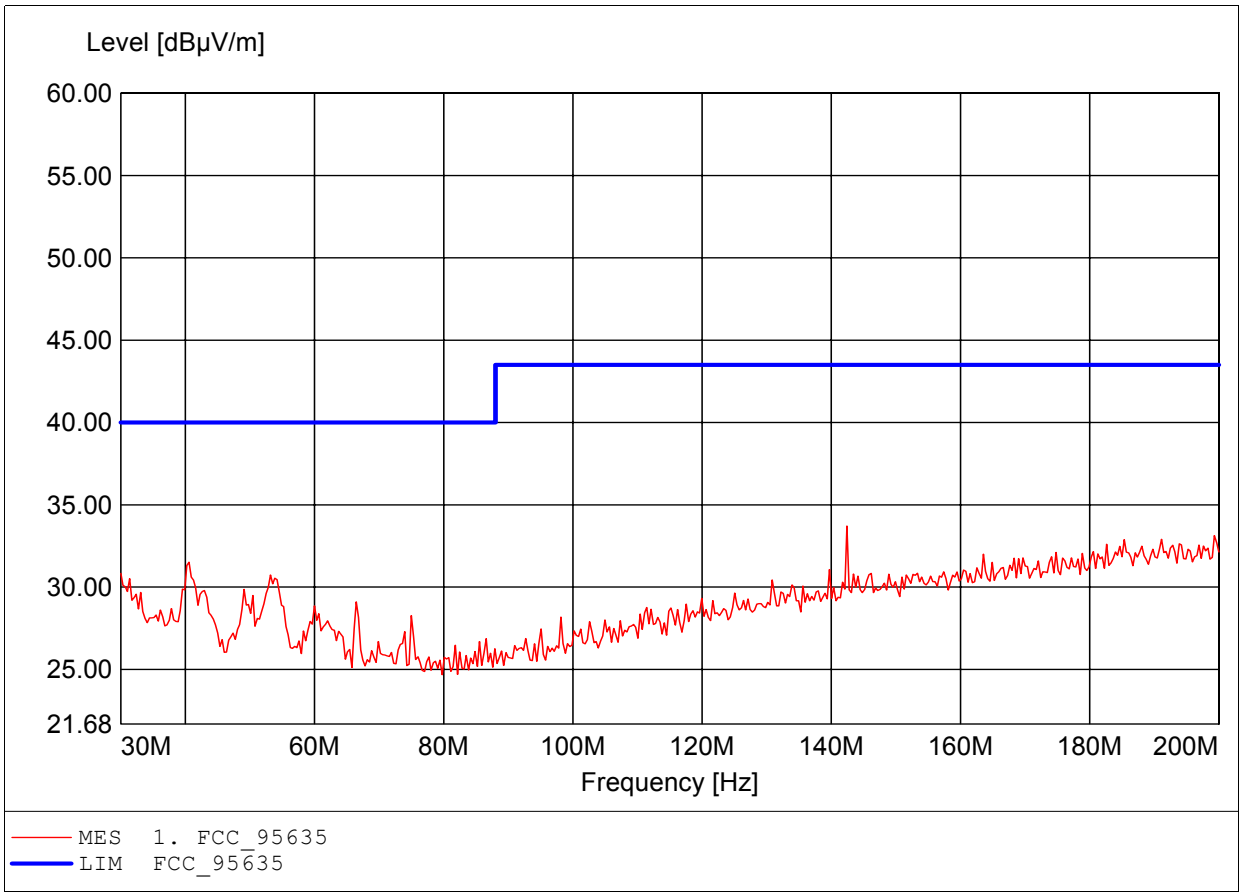
ANNEX C Transmitter radiated spurious emissions

Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 142.425MHz, Emax: 33.71dBµV/m, RBW: 100kHz



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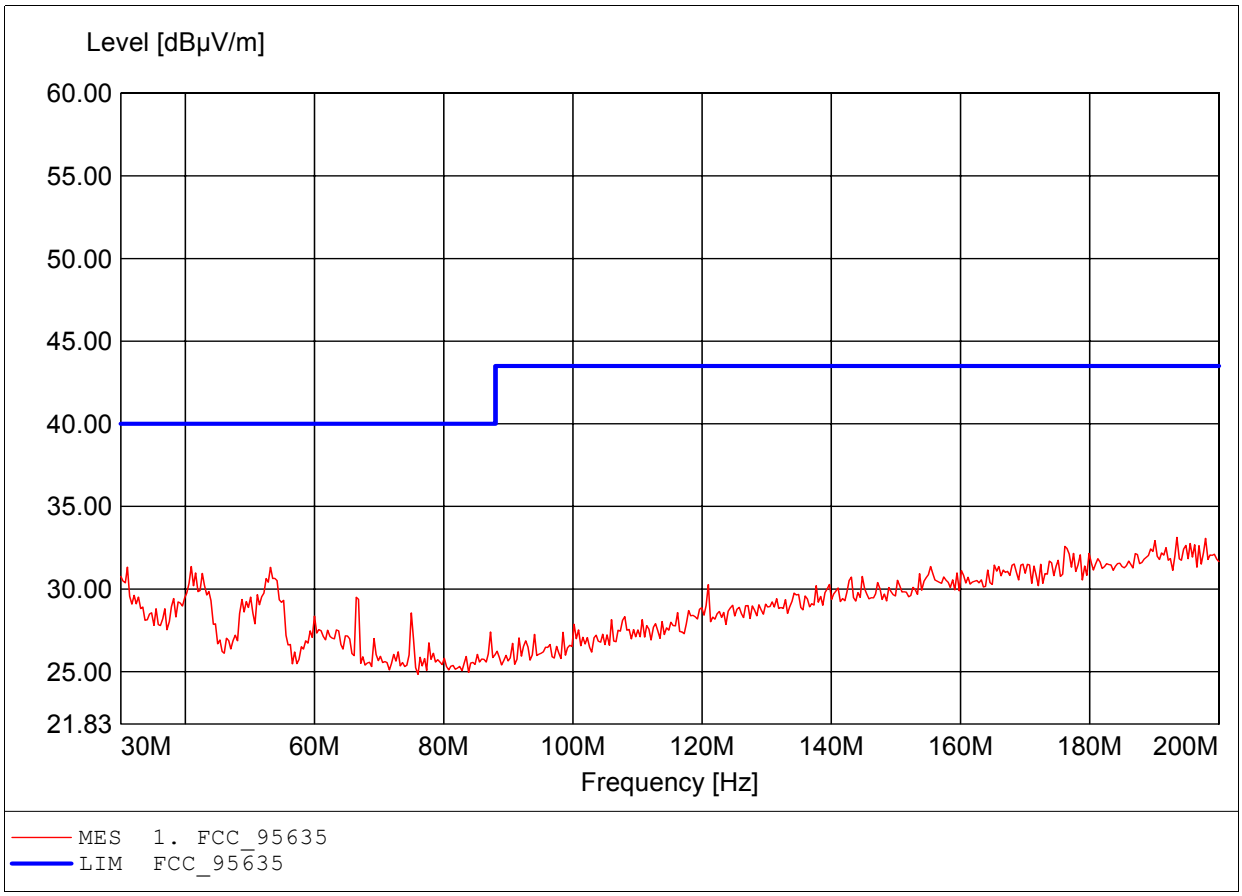
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 193.527MHz, Emax: 33.13dBµV/m, RBW: 100kHz



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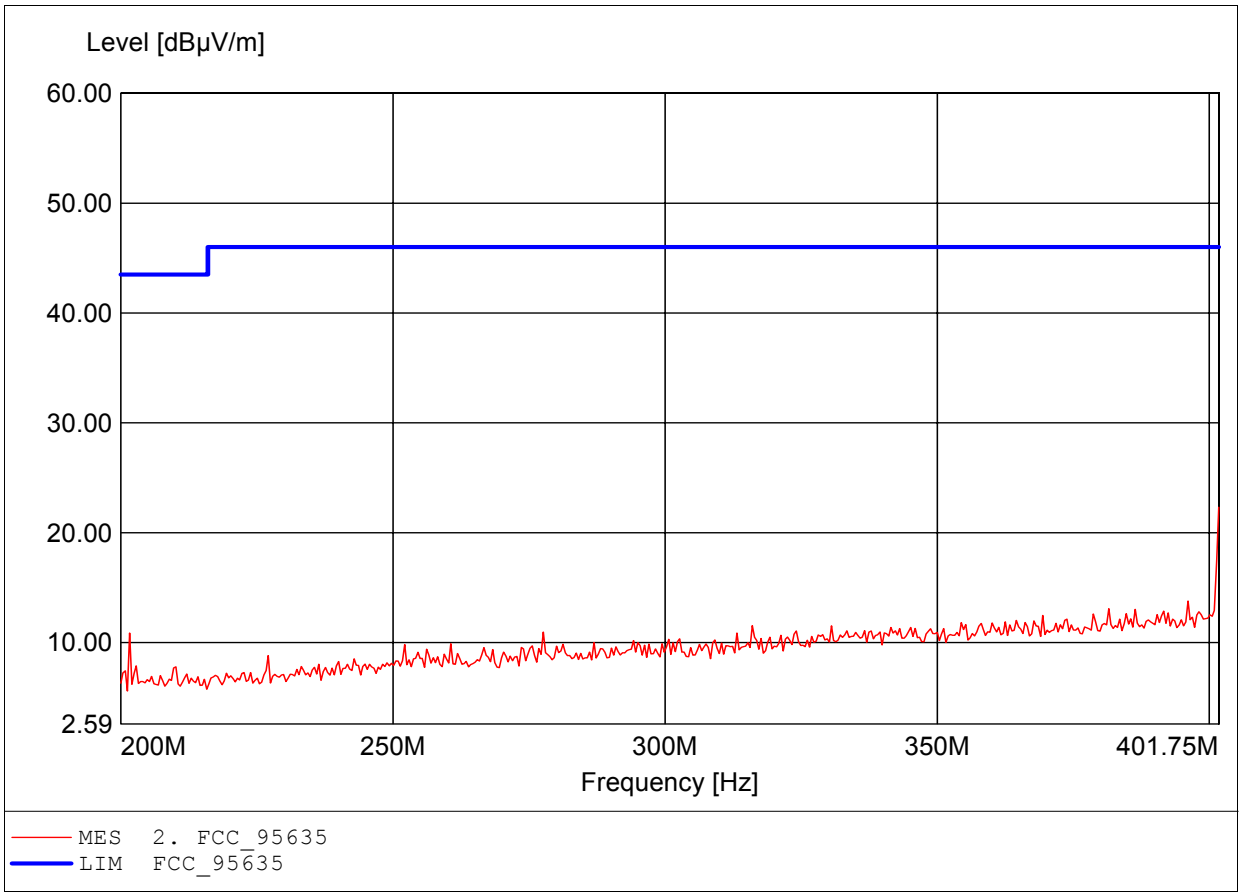
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.750MHz, Emax: 22.31dBµV/m, RBW: 100kHz



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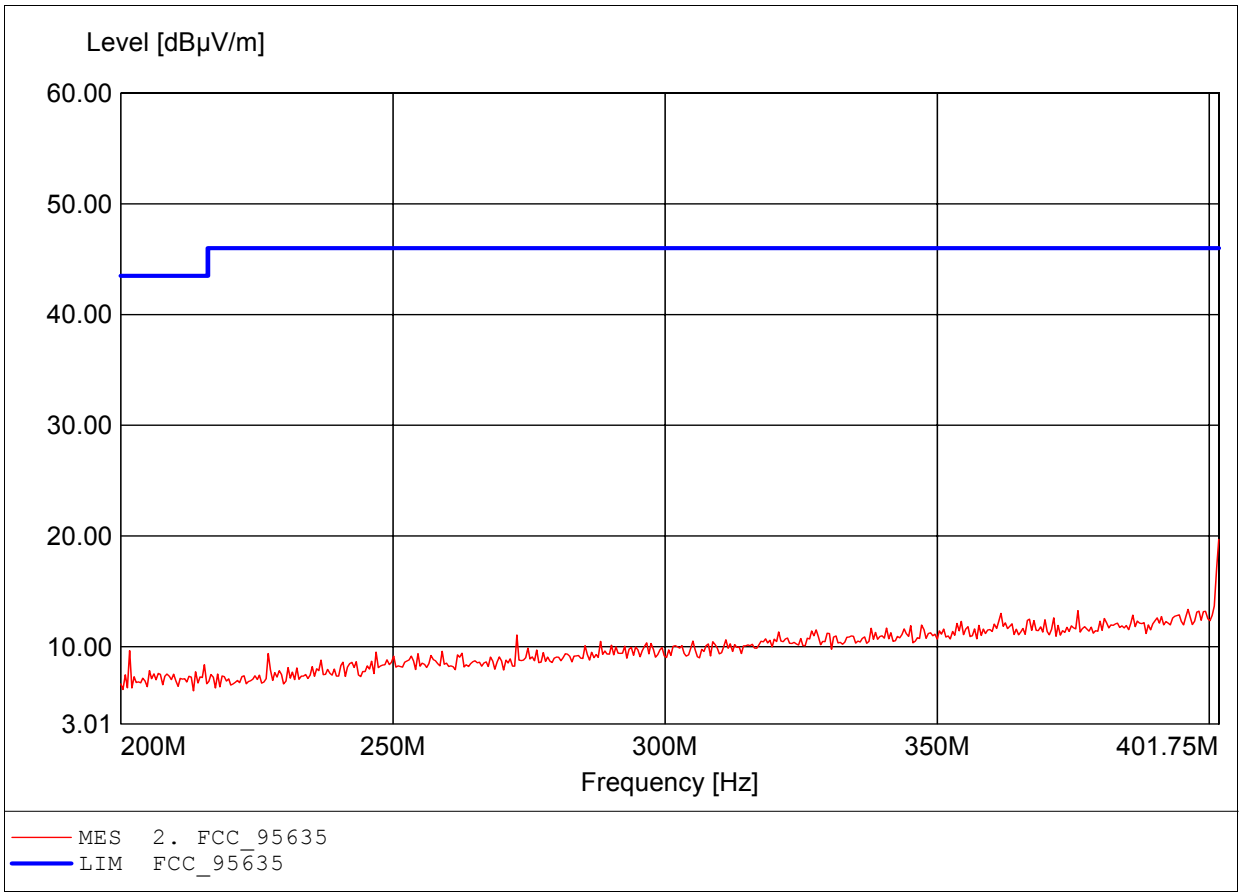
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.750MHz, Emax: 19.67dBµV/m, RBW: 100kHz



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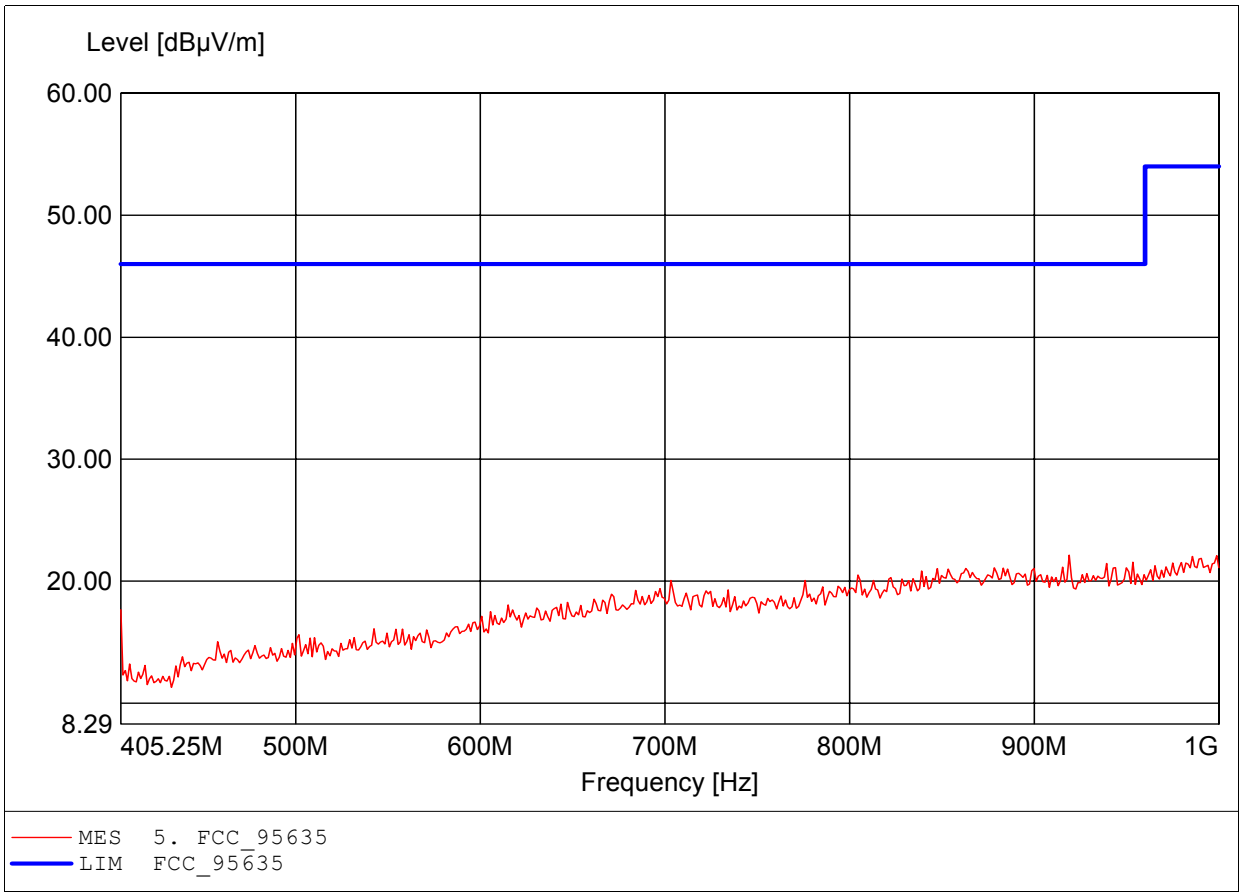
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 918.952MHz, Emax: 22.13dBµV/m, RBW: 100kHz



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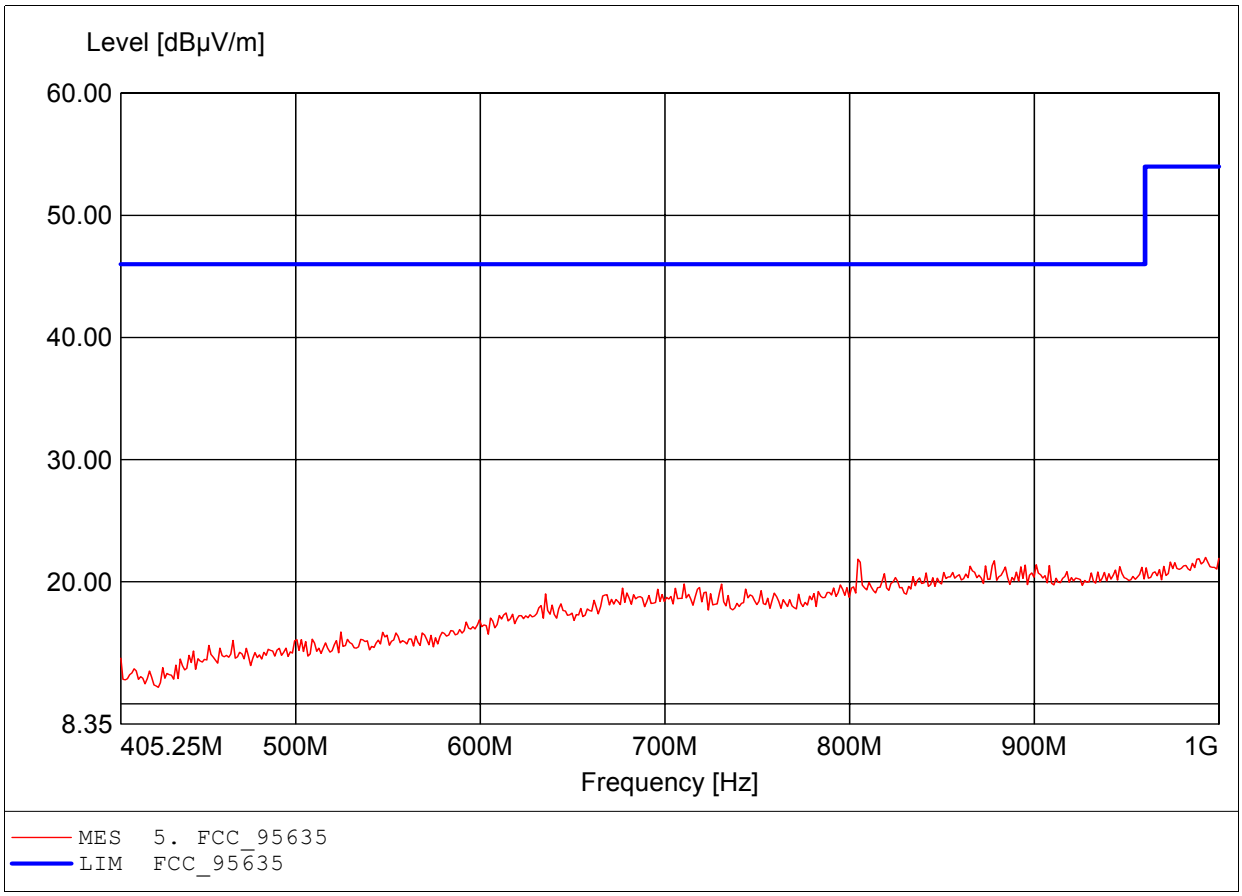
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 992.849MHz, Emax: 21.98dBµV/m, RBW: 100kHz



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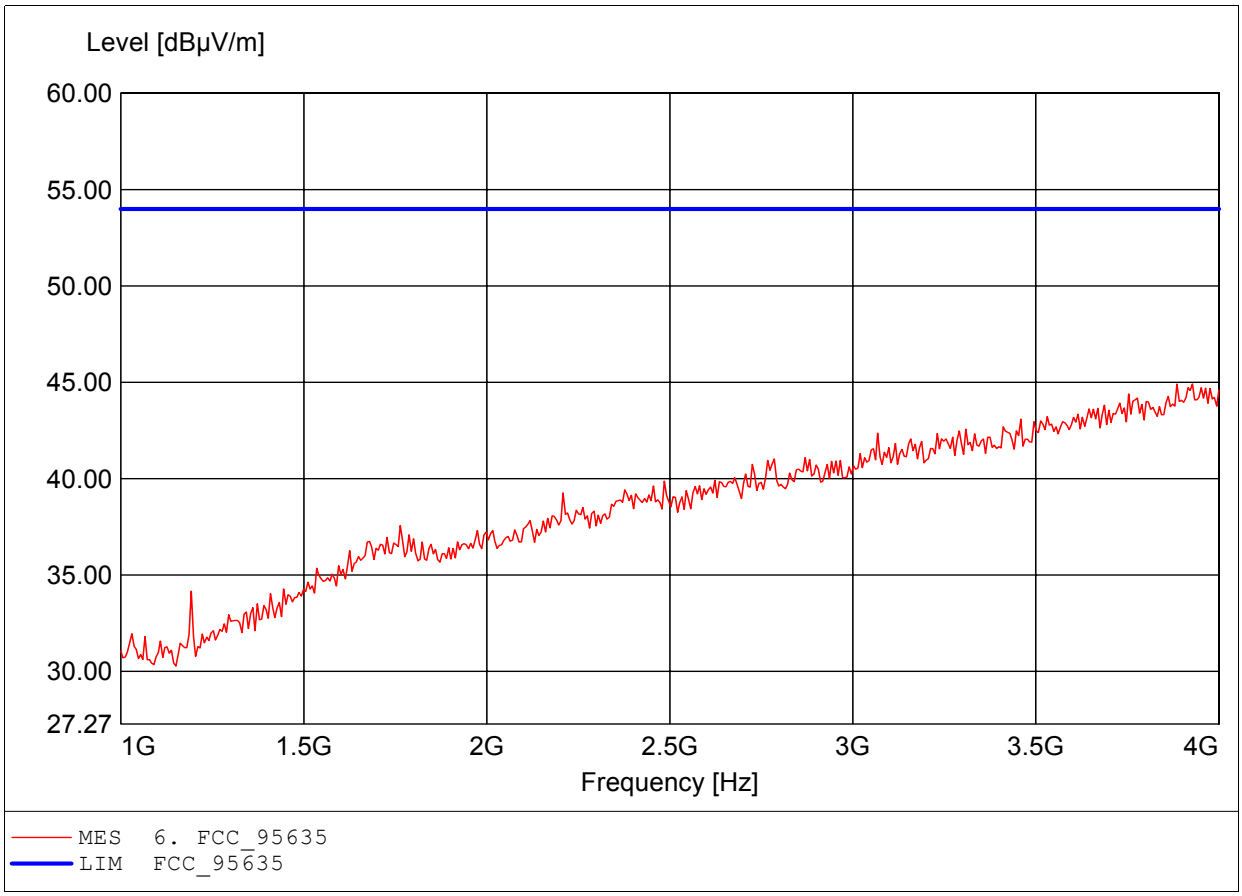
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.928GHz, Emax: 44.92dBµV/m, RBW: 100kHz



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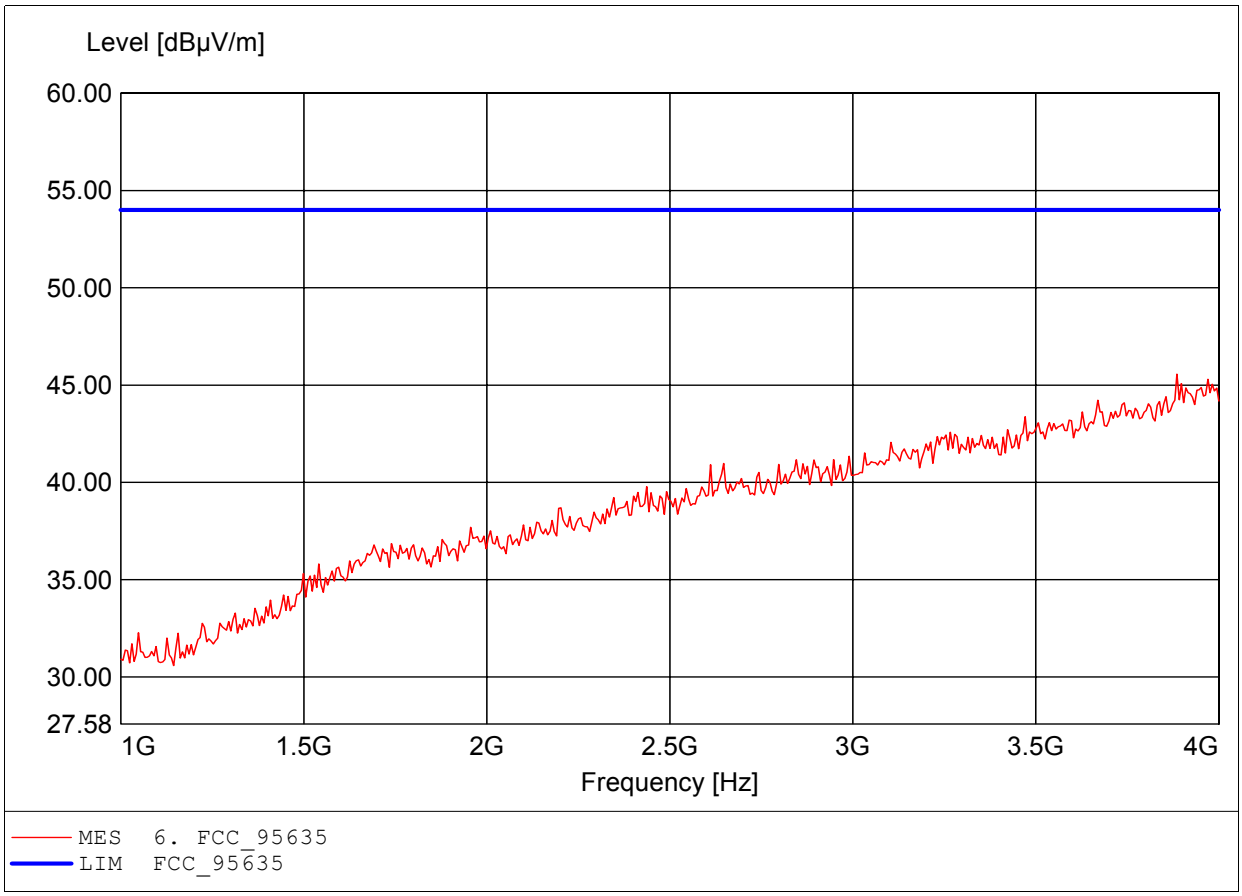
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.886GHz, Emax: 45.57dBµV/m, RBW: 100kHz



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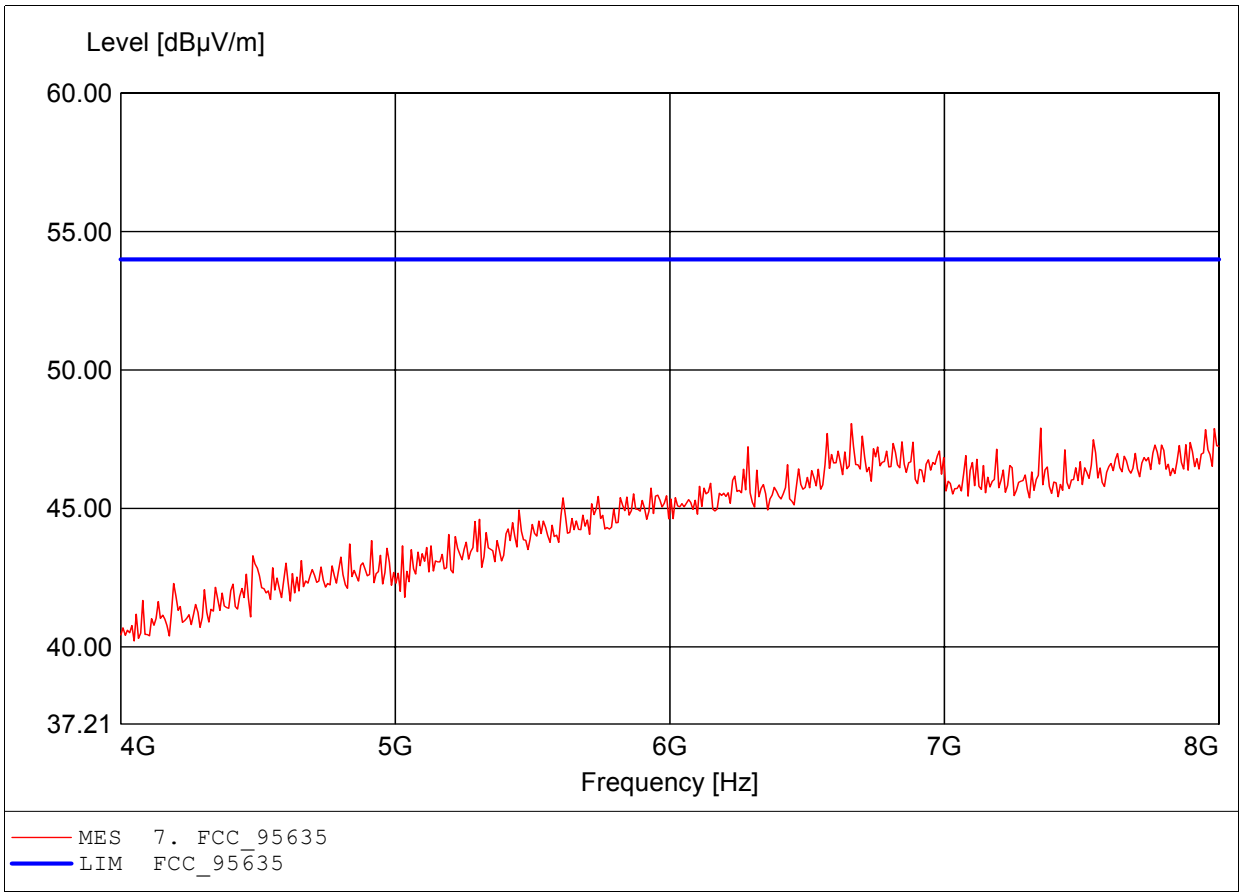
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 6.661GHz, Emax: 48.07dBµV/m, RBW: 1MHz



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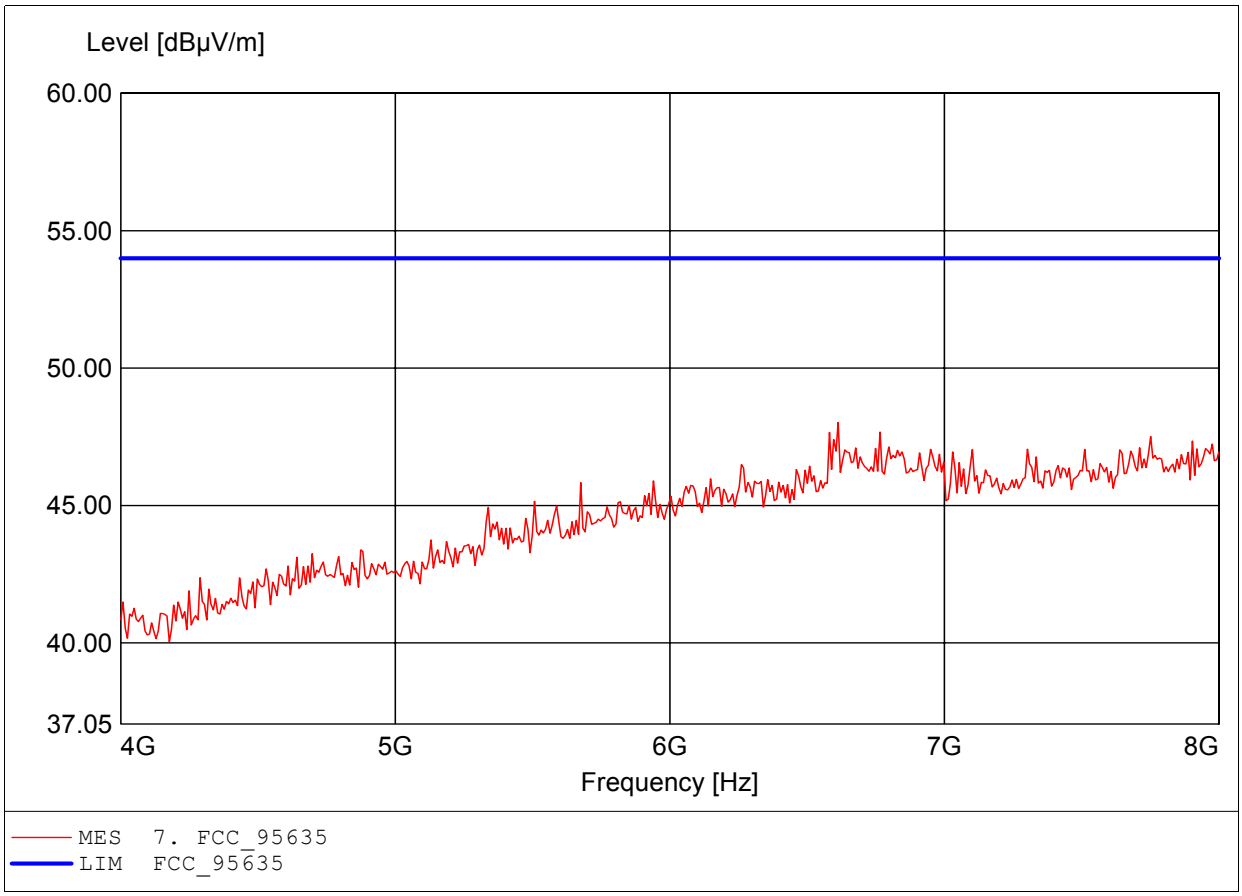
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 6.613GHz, Emax: 48.02dBµV/m, RBW: 1MHz



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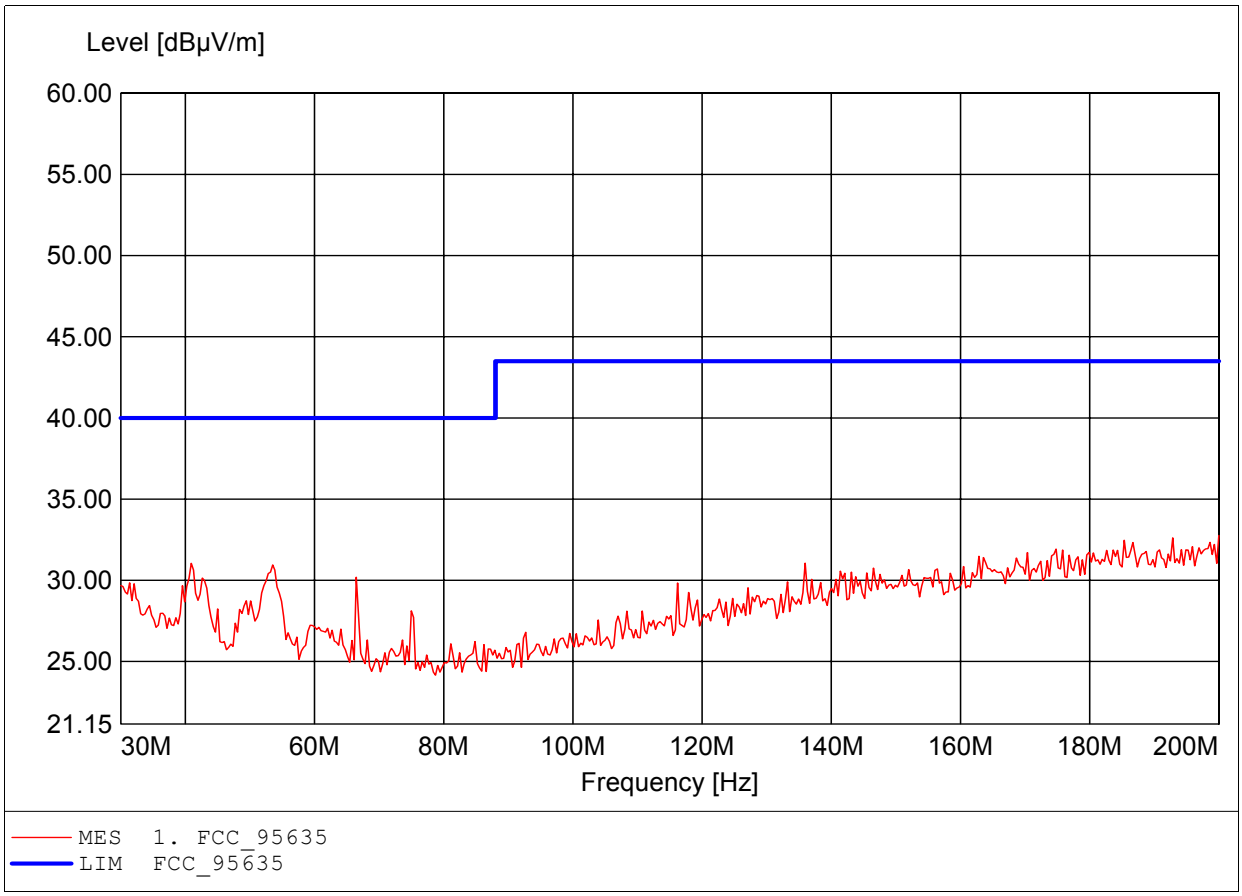
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 200.000MHz, Emax: 32.77dBµV/m, RBW: 100kHz



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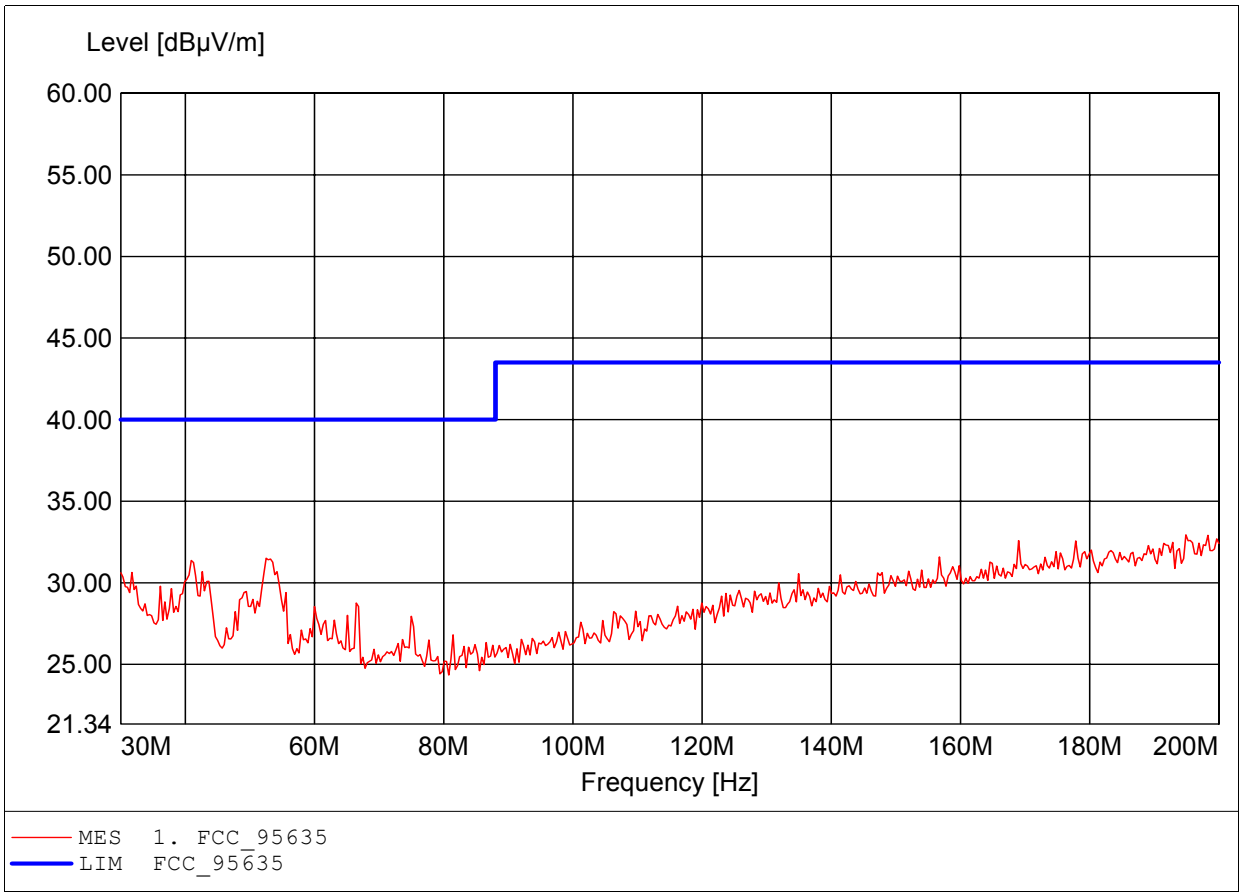
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 194.890MHz, Emax: 32.94dBµV/m, RBW: 100kHz



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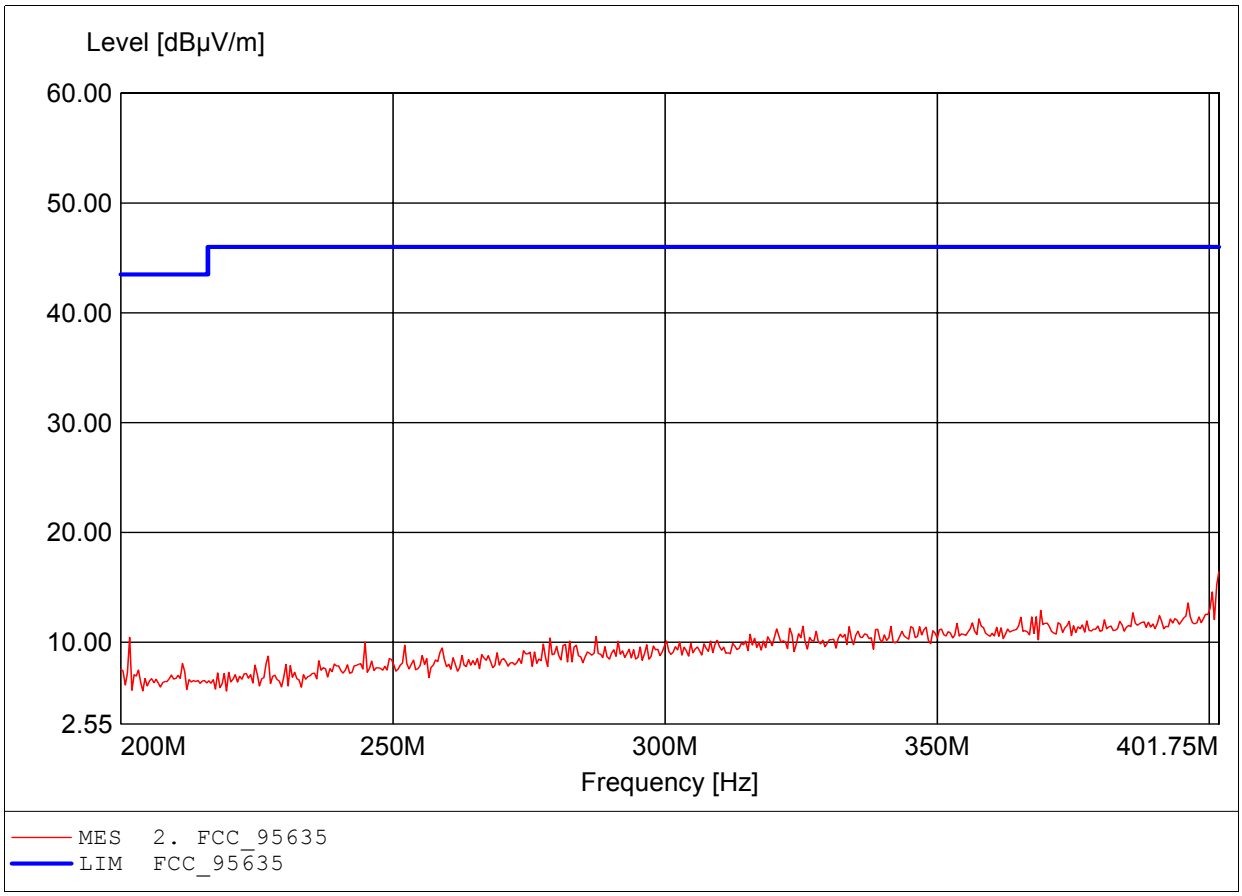
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.750MHz, Emax: 16.41dBµV/m, RBW: 100kHz



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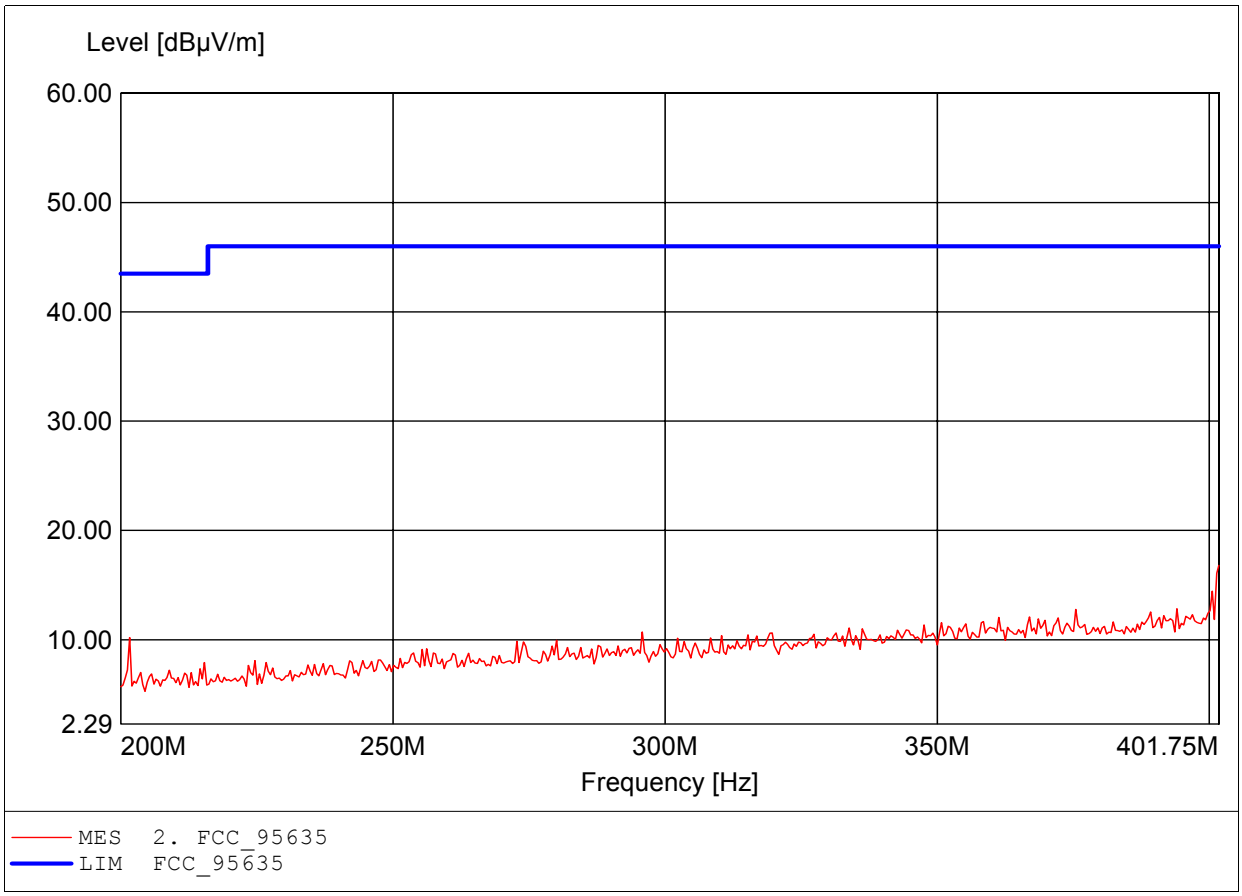
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.750MHz, Emax: 16.81dBµV/m, RBW: 100kHz



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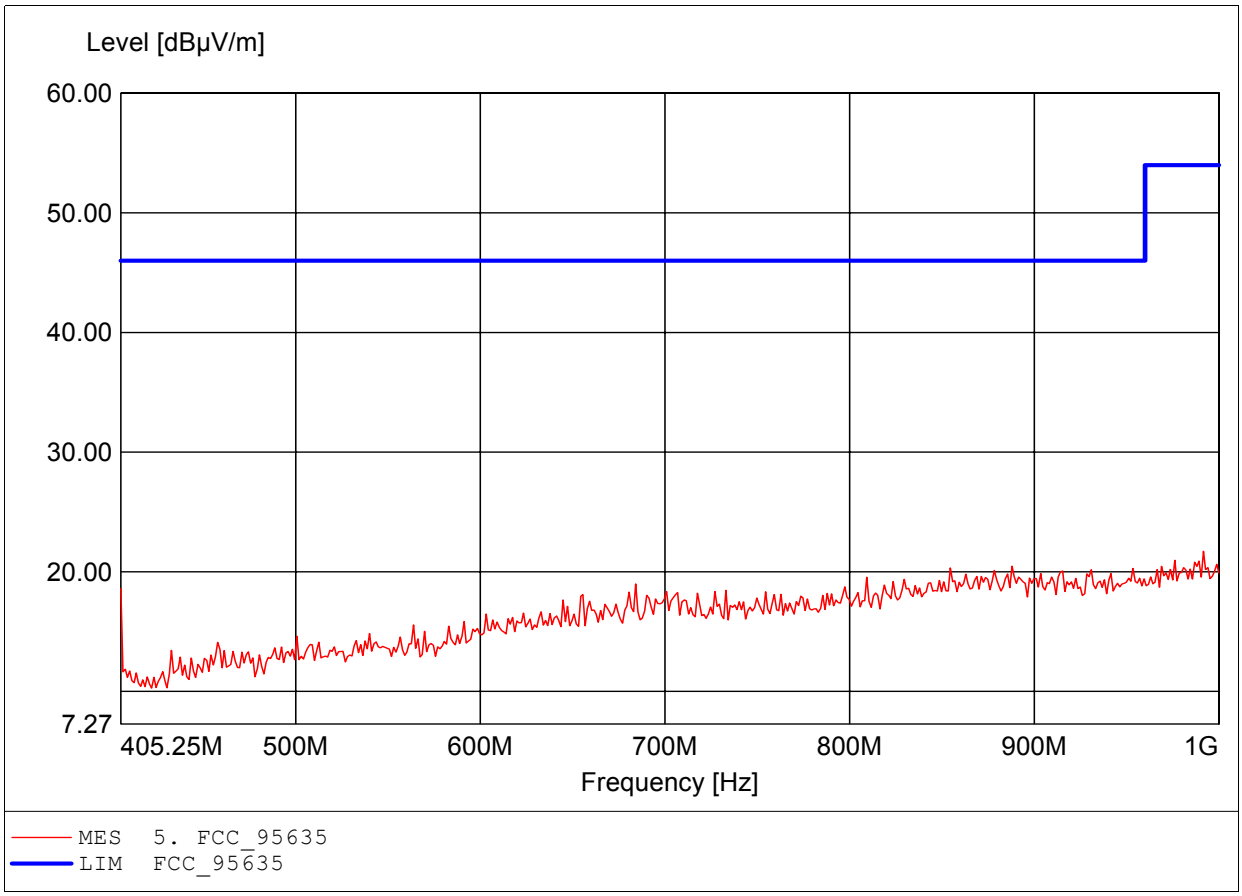
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 991.657MHz, Emax: 21.71dBµV/m, RBW: 100kHz



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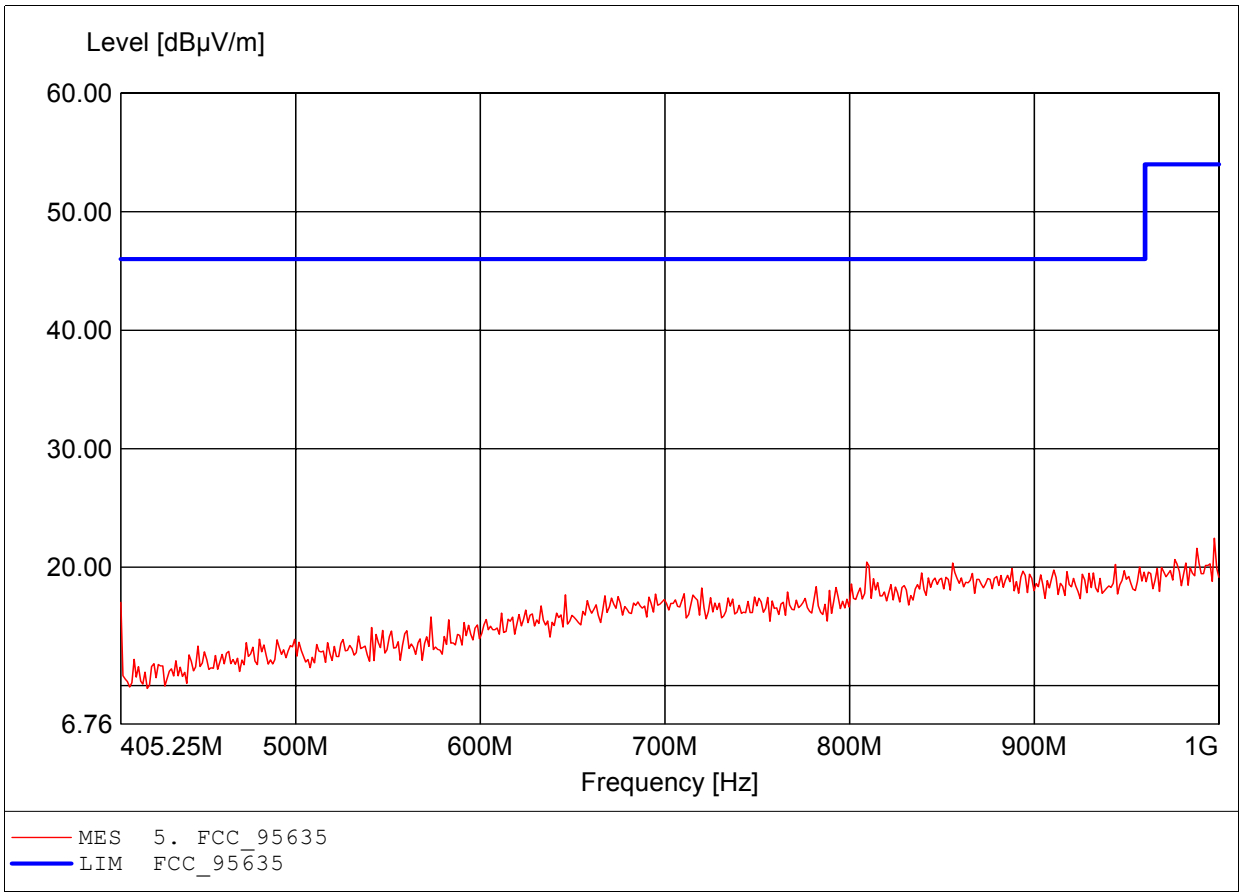
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 997.616MHz, Emax: 22.45dBµV/m, RBW: 100kHz



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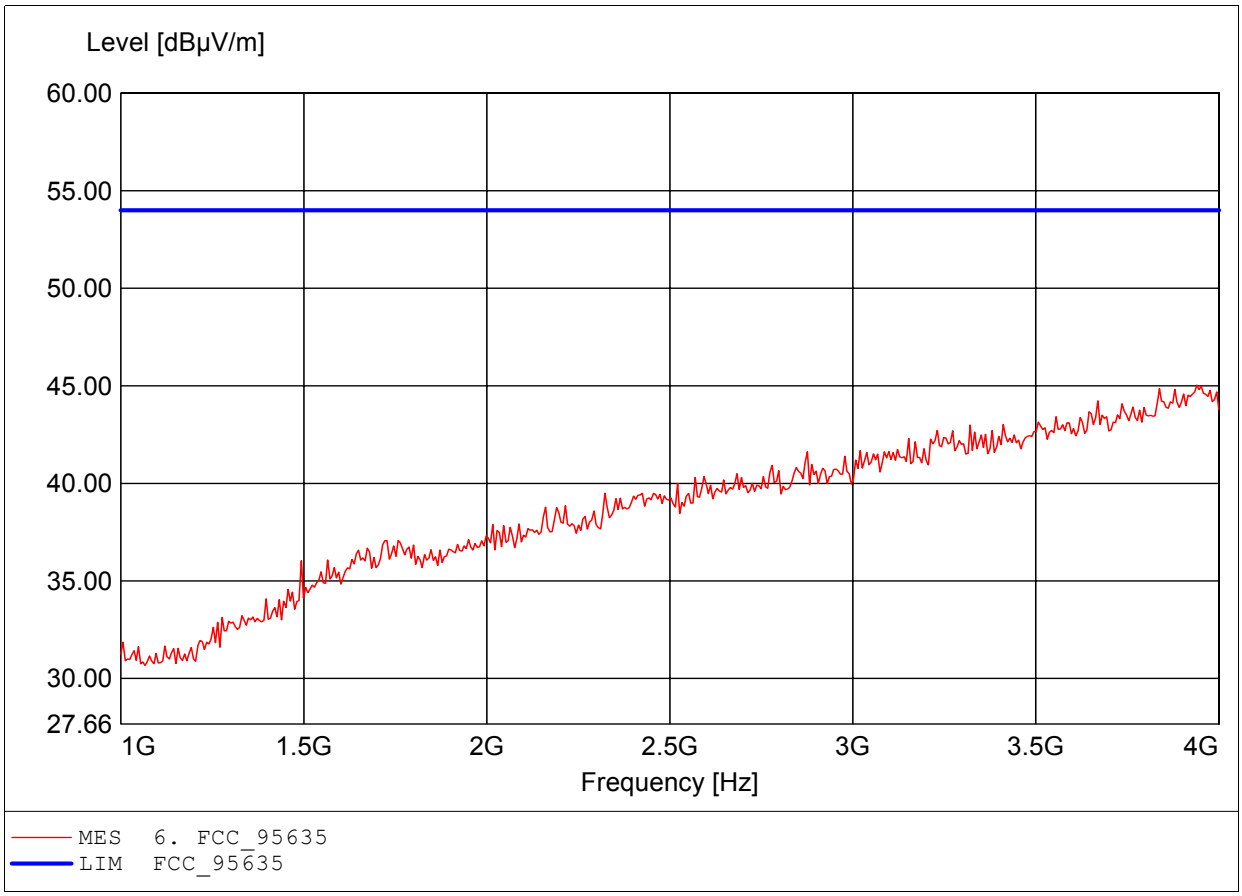
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.940GHz, Emax: 45.04dBµV/m, RBW: 100kHz



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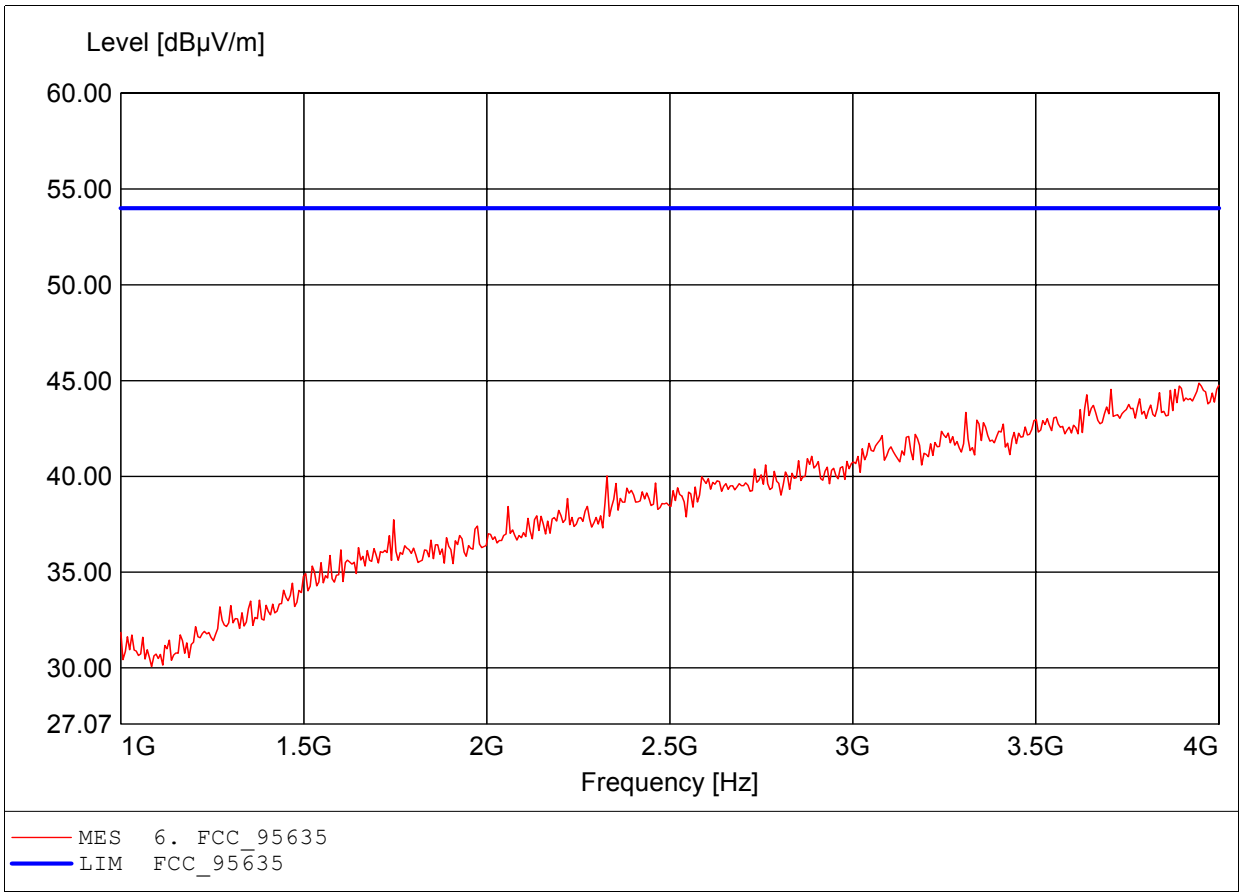
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.946GHz, Emax: 44.86dBµV/m, RBW: 100kHz



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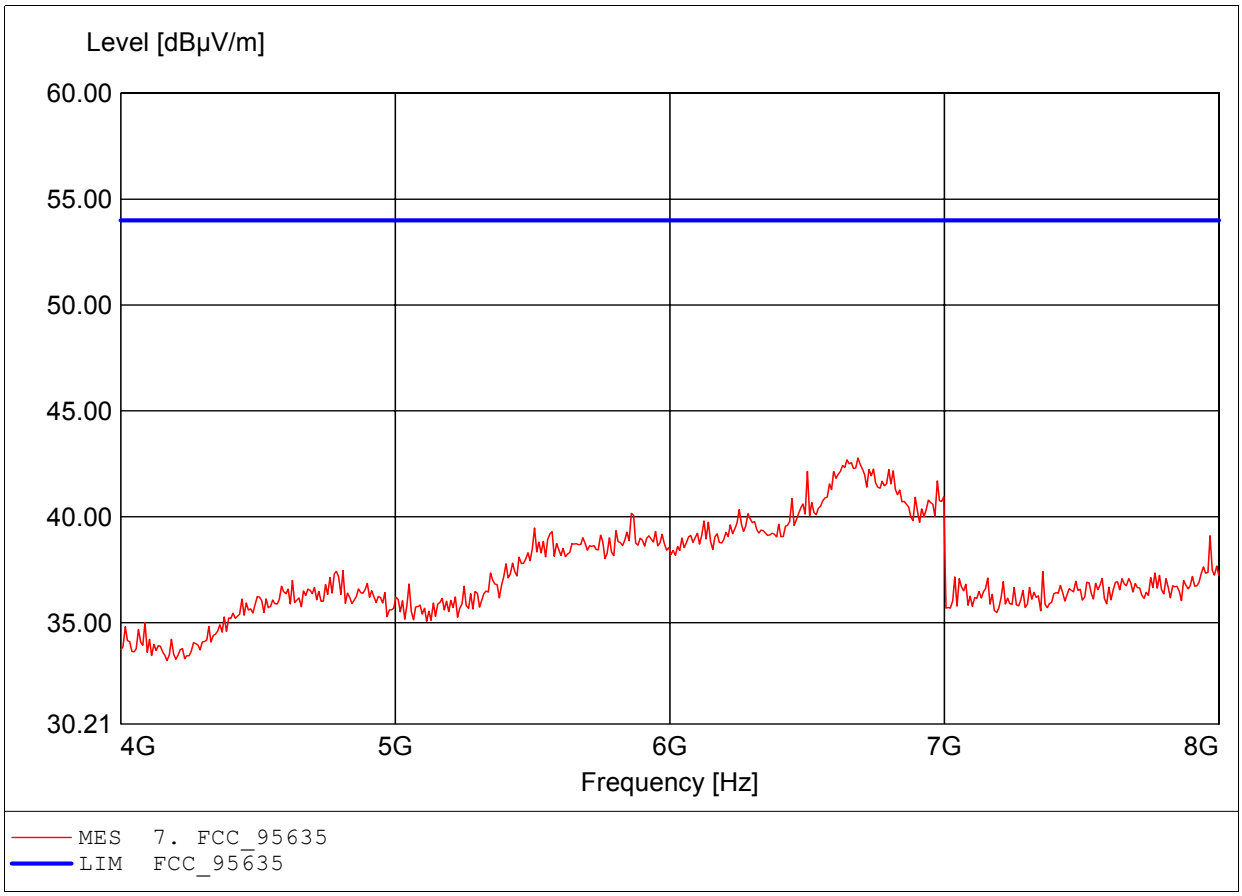
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 6.685GHz, Emax: 42.78dBµV/m, RBW: 1MHz



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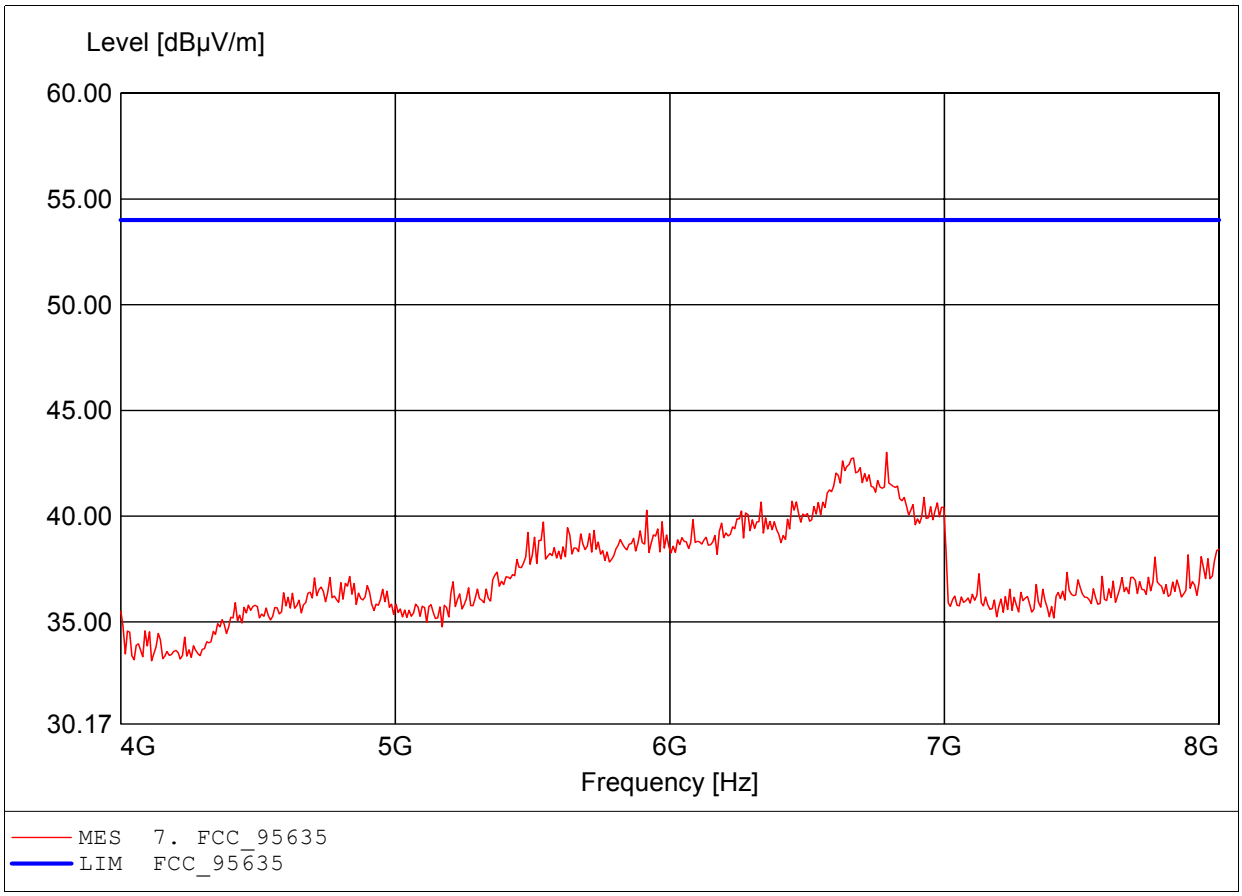
Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Tx 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 6.790GHz, Emax: 43.01dBµV/m, RBW: 1MHz



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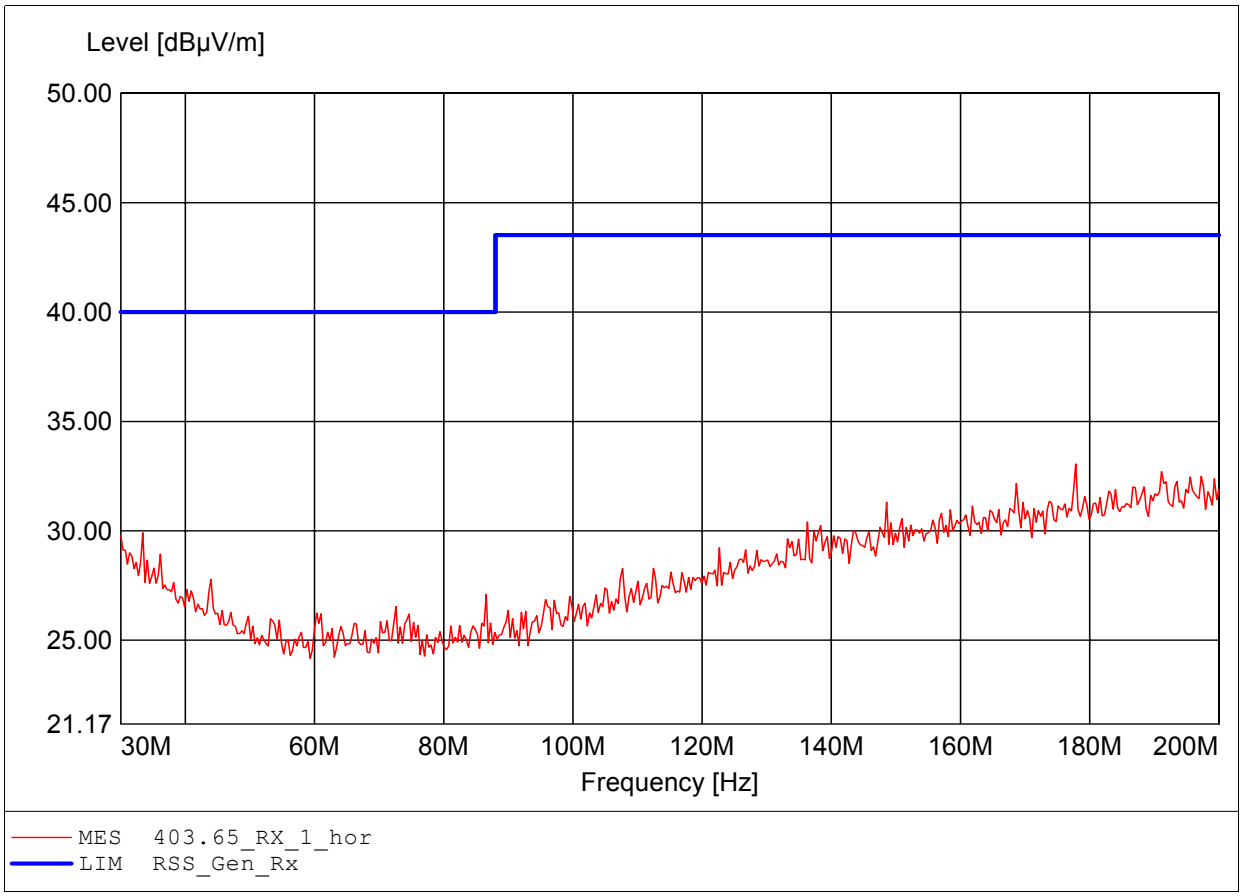
ANNEX D Receiver radiated spurious emissions

Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65Hz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: Freq. / CH: 403.65
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:177.856MHz Emax:33.05dBµV/m RBW: 100 kHz



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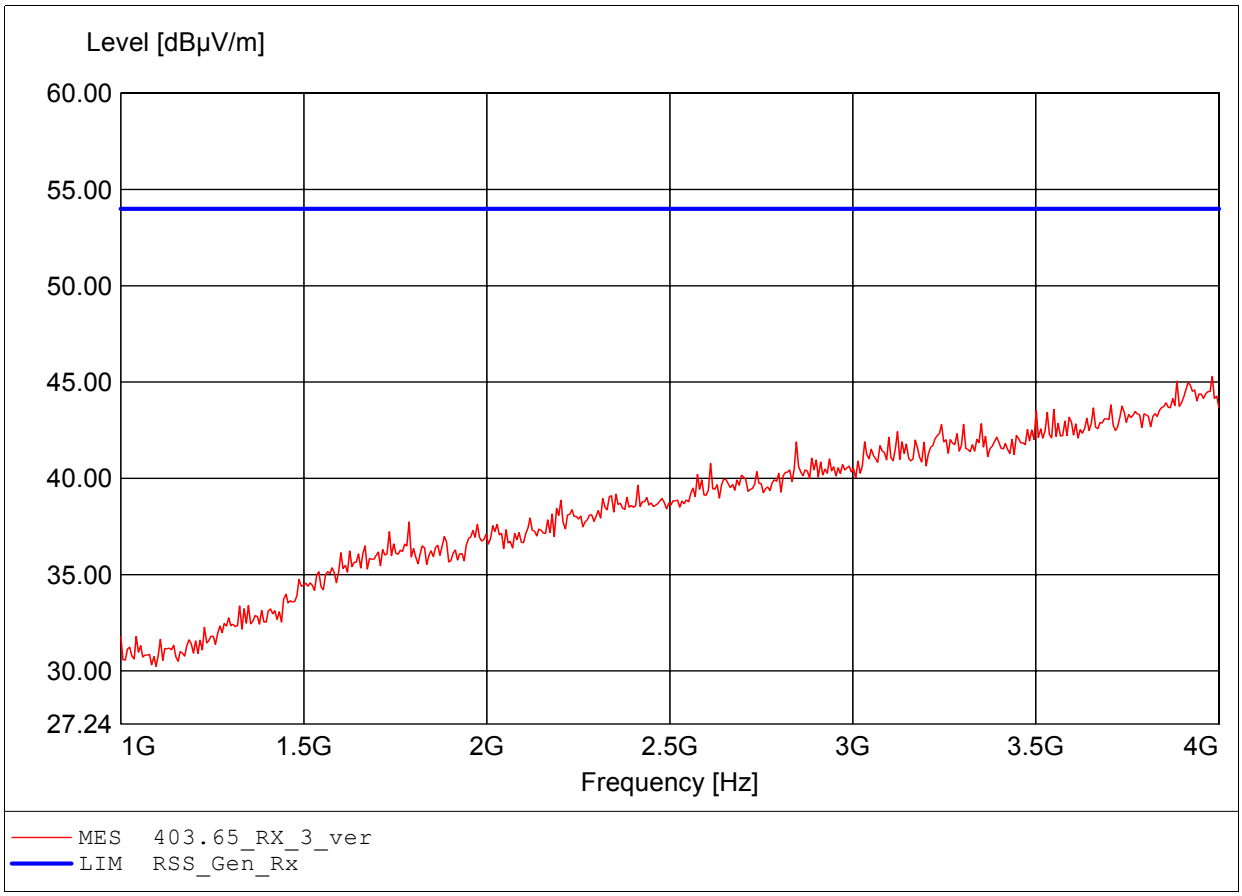
Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65Hz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: Freq. / CH: 403.65
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:3.982GHz Emax:45.30dBµV/m RBW: 1 MHz



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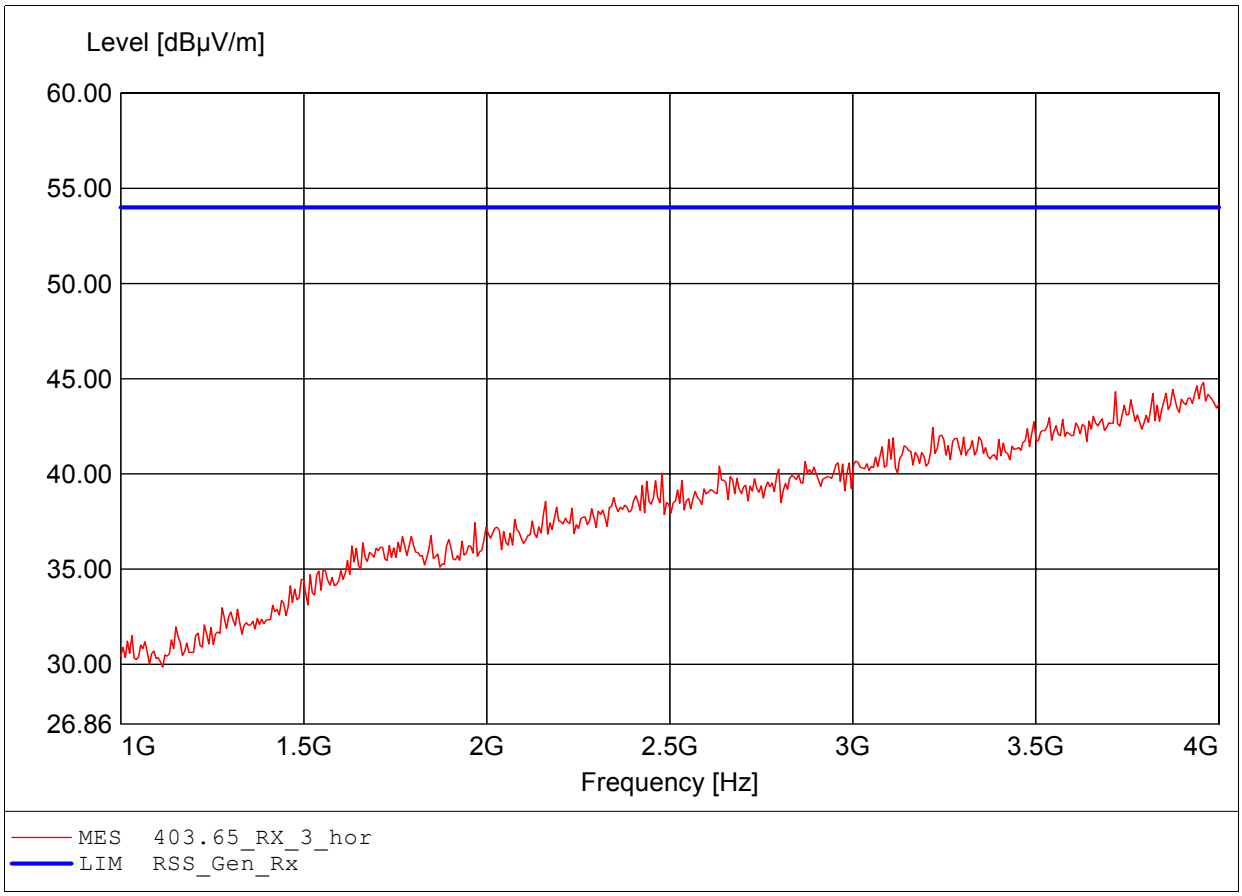
Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder:	BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT:	IPG / Implantable Pulse Generator
Model:	Eluna 8 HF-T / Rx 403.65Hz
Operator:	Eurofins Product Service GmbH / Mr. Treffke
Test Conditions:	Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification:	Freq. / CH: 403.65
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.
Comment 2:	Freq:3.958GHz Emax:44.80dBµV/m RBW: 1 MHz



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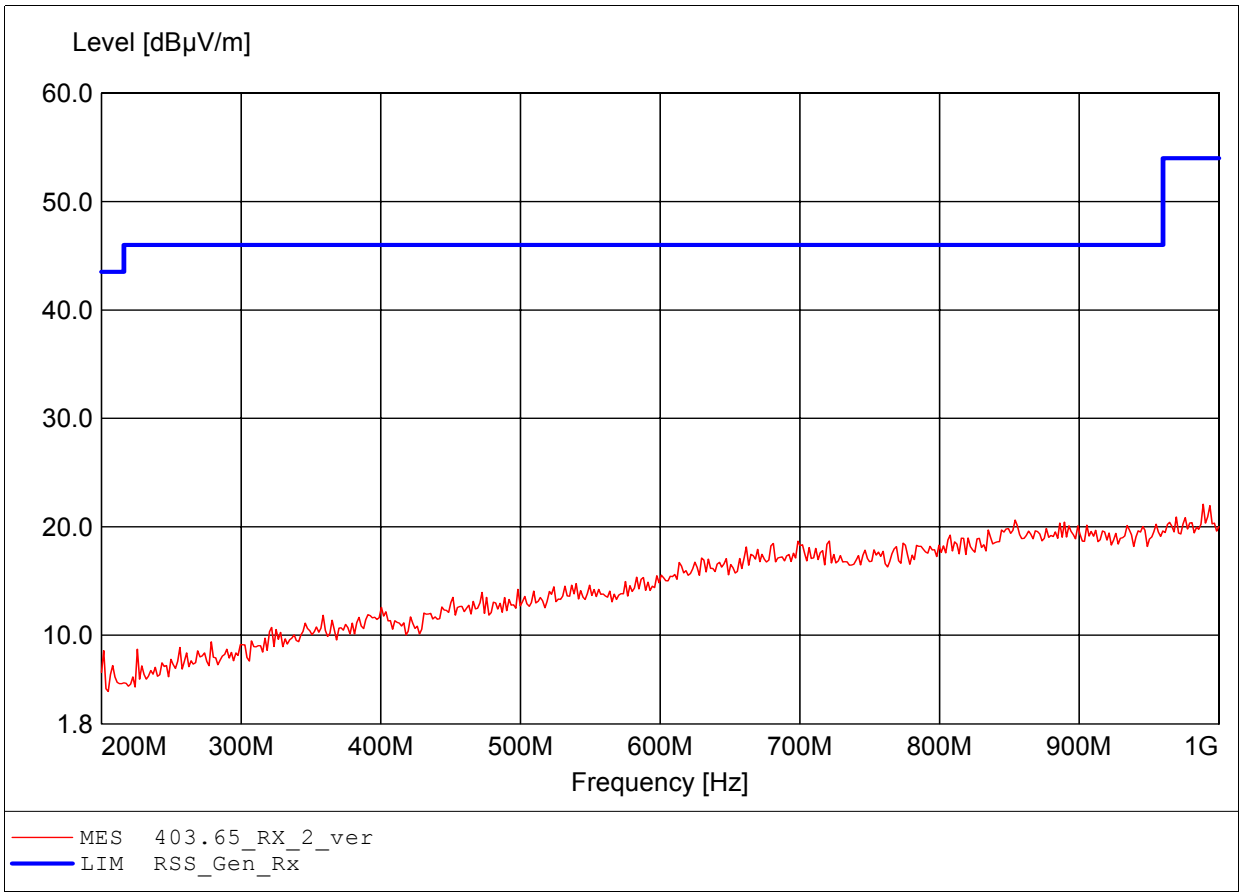
Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65Hz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: Freq. / CH: 403.65
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.
Comment 2: Freq:988.778MHz Emax:22.07dBµV/m RBW: 100 kHz



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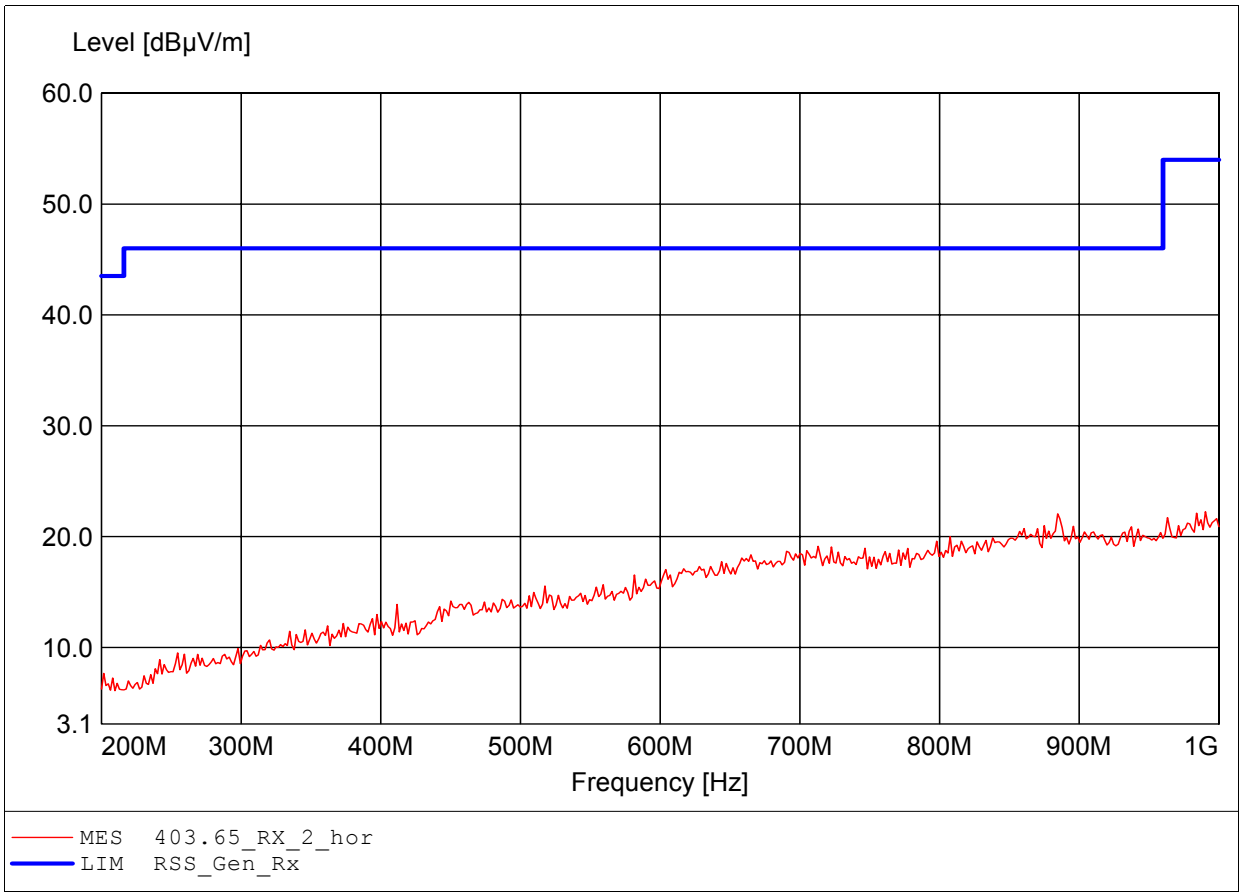
Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65Hz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: Freq. / CH: 403.65
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.
Comment 2: Freq:990.381MHz Emax:22.24dBµV/m RBW: 100 kHz



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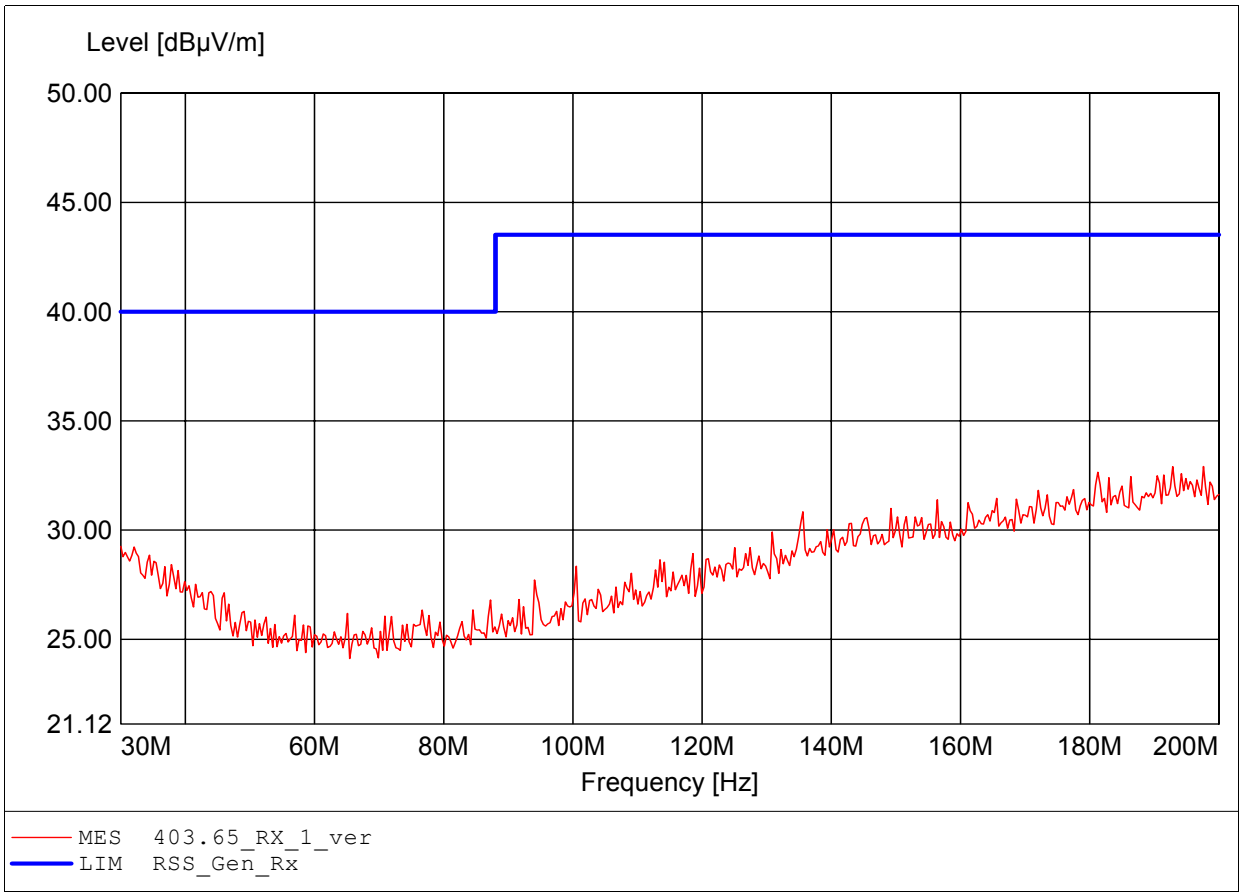
Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: BIOTRONIK SE & Co. KG / G0M-1304-2799
EUT: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T / Rx 403.65Hz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 2.8 VDC lithium battery
Test Specification: Freq. / CH: 403.65
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:197.615MHz Emax:32.91dBµV/m RBW: 100 kHz



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