



EUROFINS PRODUCT SERVICE GMBH



Testing Cert #1983.01

RADIO TEST-REPORT

Compliance Test Report

**Medical Device Radiocommunication Service (MedRadio)
FCC 47 CFR Part 95E & 95I & 15B
RSS 243 Issue 3 & RSS Gen Issue 3**

Implantable Cardioverter Defibrillator

Tach50 Substrate 4140

**FCC ID: QRILUMAXT50
IC: 4708A-LUMAXT50**

TEST REPORT NUMBER: G0M21101-4127-C-3



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1 General Information

1.1 Notes

The results of this test report relate exclusively to the item tested as specified in chapter "Description of test item" and are not transferable to any other test items.

Eurofins Product Service GmbH is not responsible for any generalisations and conclusions drawn from this report. Any modification of the test item can lead to invalidity of test results and this test report may therefore be not applicable to the modified test item.

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Operator:

07.04.2011

W. Treffke



Date

Eurofins-Lab.

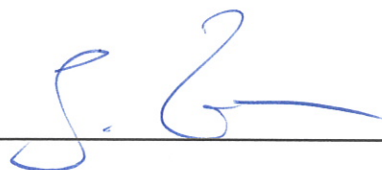
Name

Signature

Technical responsibility for area of testing:

07.04.2011

J. Zimmermann



Date

Eurofins

Name

Signature

1.2 Testing laboratory

EUROFINS PRODUCT SERVICE GMBH
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Germany
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DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-No. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470

Test location, where different:

Name	: ./.
Street	: ./.
Town	: ./.
Country	: ./.
Telephone	: ./.
Fax	: ./.

1.3 Details of approval holder

Name : BIOTRONIK SE & Co. KG
Street : Woermannkehre 1
Town : 12359 Berlin
Country : Germany
Telephone : 030/68905-1213
Fax : 030/68905-5409

Contact : Herr Gunnar Börsch
Telephone : 030/68905-1213

1.4 Application details

Date of receipt of application : 24.01.2011
Date of receipt of test item : 24.01.2011
Date of test : 24. – 26.01.2011

1.5 Test item

Description of test item : Implantable Cardioverter Defibrillator
Type identification : Tach50 Substrate 4140
Tested model : Lumax 740 HF-T
Serial number : 60498675
Hardware Version : Substrate 4140 Rev.: 1C Version 12
Software Version : ROM: 2.2 / RAM: 1.0
Equipment type : Medical implant (MICS transmitter), End product

Technical data

Frequency range : 402 - 405MHz
Number of channels : 9
Channel spacing : 300kHz
Assigned frequency band : 402 – 405MHz, Power limit: 25µW e.i.r.p.
Tested frequencies : F₁ 402.45MHz
F₂ 403.65MHz
F₃ 404.85MHz
Antenna : integrated
Number of antennas : 1
Antenna gain(s) : Unspecified
Duty cycle : N/A (LTB is used for channel selection)
Spectrum access : Listen before talk, not performed by EUT but peripheral device. EUT transmissions only occur only in case of medical events or in a MICS session controlled by peripheral device.

Modulations : 2FSK
Supply voltage : 3.0VDC (Lithium-Battery)

Manufacturer:
(if applicable)

Name : BIOTRONIK SE & Co. KG
Street : Woermannkehre 1
Town : 12359 Berlin
Country : Germany

1.6 Test standards

Technical standard : **FCC 47 CFR Part 95E, most current CFR (eCFR)
Personal Radio Services, Technical Regulations**

**FCC 47 CFR Part 95I, most current CFR (eCFR)
Medical Device Radiocommunication Service
(MedRadio)**

**FCC 47 CFR Part 15B, most current CFR (eCFR)
Unintentional Radiators**

**IC RSS 243 Issue 3 February 2010
Medical Devices Operating in the 401-406MHz
Frequency Band**

**IC RSS Gen Issue 3 December 2010
General Requirements and Information for the
Certification of Radio Apparatus**

1.7 Additional information

In agreement with the customer testing was performed with a Lumax 740 HF-T as a representative for the Lumax 6XX and Lumax 7XX model families.

The approval holder gives the following declarations about the two families:

Variants: Lumax 600/640/700/740 VR-T/ VR-T DX/DR-T/HF-T

The Lumax 6XX and the Lumax 7XX are two model families. Both families use the Tach50 Substrate 4140 electronic module and are therefore identical in hardware. That means that there are also no differences with respect to the RF-part between both families. The transmitter/receiver parts of all models of both families are identical to the tested model. The two families only differ in firmware. The Lumax 7XX family offers additional clinical therapy functions.

Each family offers a 30 joule and a 40 joule model. The joule value is represented by the two XX in the model name; 00 = 30 joule, 40 = 40 joule.

Additionally each family offers the VR-T, DR-T and HF-T variants. The VR-T variant denotes a single chamber header model, the DR-T a dual chamber header model and the HF-T a triple chamber header model.

For VR-T variants (Lumax 6XX and Lumax 7XX) a special DX configuration exists that offers additional diagnostics but uses identical electronic module and antenna.

As described all model variations does not affect the rf-section of the device and for this reason the results given in this test report are supposed to be valid for all the described variations of the two denoted model families.

1.8 Acronyms and Abbreviations

EUT	:	Equipment under Test
TX	:	Transmission
RX	:	Reception
RBW	:	Measurement Resolution Bandwidth
Pol	:	Measurement Polarization
e.i.r.p.	:	Equivalent isotropic radiated power
T_{nom}	:	Nominal Temperature
T_{min}	:	Minimum Temperature
T_{max}	:	Maximum Temperature
V_{nom}	:	Nominal Supply Voltage
V_{min}	:	Minimum Supply Voltage
V_{max}	:	Maximum Supply Voltage
VDC	:	DC voltage
N/A	:	Not applicable

2 Technical test

2.1 Summary of test results

No deviations from the technical specification(s) were ascertained in the course of the tests performed.



or

The deviations as specified in 2.4 were ascertained in the course of the tests performed.



2.2 Test environment

Temperature : 22 ... 26°C

Relative humidity content : 20 ... 75%

Air pressure : 86 ... 103kPa

Extreme conditions parameters:

V_{nom} : 3.0VDC
 V_{min} : 1.6VDC
 V_{max} : 3.2VDC

T_{nom} : 37°C
 T_{min} : 25°C
 T_{max} : 45°C

Other parameter: None

2.3 Test equipment utilized

Measurement Equipment List					
No.	Measurement device:	Type:	Manufacturer:	Last Cal.	Next Cal.
ETS 0271	Spectrum Analyzer	FSEK30	Rohde & Schwarz	19.03.2009	19.03.2011
ETS 0012	Biconical Antenna	HK 116	Rohde & Schwarz	29.01.2010	29.01.2011
ETS 0336	LPD Antenna	HL 223	Rohde & Schwarz	28.01.2010	28.01.2011
ETS 0018	Horn Antenna	BBHA 9120D	Schwarzbeck	26.08.2010	26.08.2011
ETS 0432	Amplifier-Matrix			02.06.2010	02.06.2012
ETS 0278	Power Sensor	NRV-Z31	Rohde & Schwarz	25.11.2010	25.11.2012
ETS 0496	Spectrum Analyzer	FSP30	Rohde & Schwarz	26.08.2010	26.08.2011
ETS 0086	Semi-anechoic chamber	AC1	Frankonia	12.03.2010	12.03.2011

2.4 Simulated human body

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

Liquid components	
Component	Percentage per weight
Deionized water	52.4
Bactericide	0.08
Hydroxy ethyl cellulose (HCE)	1.0
Sodium chloride	1.4
Sucrose	45.0

Measured tissue parameters:

Tissue parameters			
Frequency [MHz]	403.5MHz		
Component	Target	Measured	Tolerance [%]
Dielectric constant ϵ	62.5	63.08	0.93
Conductivity σ [ms/cm]	9.0	8.8	-2.22

2.5 Sample emission level calculation

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

Reading:

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

A.F.:

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

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

Net:

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

Limit:

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

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

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:

$$\begin{array}{rclcl} \text{Reading} & + & \text{AF} & = & \text{Net Reading} & : & \text{Net reading} - \text{FCC limit} = \text{Margin} \\ 21.5 \text{ dB}\mu\text{V} & + & 26 \text{ dB} & = & 47.5 \text{ dB}\mu\text{V/m} & : & 47.5 \text{ dB}\mu\text{V/m} - 57.0 \text{ dB}\mu\text{V/m} = -9.5 \text{ dB} \end{array}$$

2.6 Test results

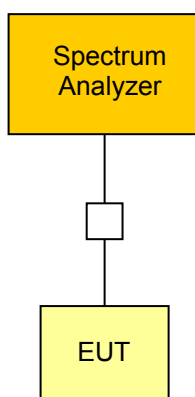
Test case	Clause	Required	Result	Remarks
INFORMATIONAL TRANSMITTER PARAMETERS				
Occupied Bandwidth	RSS-243 3.2 RSS-Gen 4.6.1	<input checked="" type="checkbox"/>		
TRANSMITTER PARAMETERS				
Frequency stability	95.628(e) RSS-243 3.3 RSS-243 5.3 RSS-Gen 4.7	<input checked="" type="checkbox"/>	PASS	
Emission bandwidth	95.628(a)(6)(i) 95.628(d) 95.633(e) RSS-243 3.6	<input checked="" type="checkbox"/>	PASS	
Effective radiated power	95.639(f) RSS-243 5.4	<input checked="" type="checkbox"/>	PASS	
Transmitter spurious emissions	95.635(d) RSS-243 3.4 RSS-243 5.5 RSS-Gen 4.9	<input checked="" type="checkbox"/>	PASS	
AC powerline conducted emissions	15.107 15.207 RSS-Gen 7.2.4	<input type="checkbox"/>	N/A	EUT battery powered
RECEIVER PARAMETERS				
Receiver (unintentional) spurious emissions	15.109 RSS-243 3.5 RSS-243 5.6 RSS-Gen 4.10 RSS-Gen 6.1	<input checked="" type="checkbox"/>	PASS	
MONITORING PARAMETERS				
LBT threshold power level	95.628(a)(3) RSS-243 3.6 RSS-243 5.7.1	<input type="checkbox"/>	N/A	LBT not performed by EUT
Monitoring system bandwidth	95.628(a)(1) RSS-243 3.6 RSS-243 5.7.2	<input type="checkbox"/>	N/A	LBT not performed by EUT
Monitoring system scan cycle time	95.628(a)(2) RSS-243 3.6 RSS-243 5.7.3	<input type="checkbox"/>	N/A	LBT not performed by EUT
Minimum channel monitoring period	95.628(a)(2) RSS-243 3.6 RSS-243 5.7.4	<input type="checkbox"/>	N/A	LBT not performed by EUT
Channel access	95.628(a)(4) RSS-243 3.6 RSS-243 5.7.5	<input type="checkbox"/>	N/A	LBT not performed by EUT
Discontinuation of MICS session	95.628(a)(4) RSS-243 3.6 RSS-243 5.7.6	<input type="checkbox"/>	N/A	LBT not performed by EUT
Use of pre-scanned alternative channel	95.628(a)(5) RSS-243 3.6 RSS-243 5.7.7	<input type="checkbox"/>	N/A	LBT not performed by EUT

3 Transmitter parameters

3.1 Occupied Bandwidth

According to IC RSS-243 Section 3.2 the 99% emission bandwidth occupied by the modulated transmitted signal has to be measured as outlined in RSS-Gen 4.6.1.

3.1.1 Measurement procedure



The EUT is connected to a spectrum analyzer and set to transmission mode with maximum power under normal test conditions. The span of the analyzer is set wide enough to capture all significant emissions of the modulation spectrum. The resolutions bandwidth is set as close as possible to 1% of the selected span without being below 1%. The occupied bandwidth is then measured evaluated by an internal measurement procedure of the analyzer.

3.1.2 Results

Transmitter occupied bandwidth			
Measurement Conditions			
Power occupation :		99%	
Channel [MHz]	Lower edge frequency [MHz]	Upper edge frequency [MHz]	Occupied Bandwidth [kHz]
402.45	402.3366	402.5670	230.400
403.65	403.5384	403.7688	230.400
404.86	404.7186	404.9544	235.800
See attached diagram in Annex			

3.2 Frequency stability

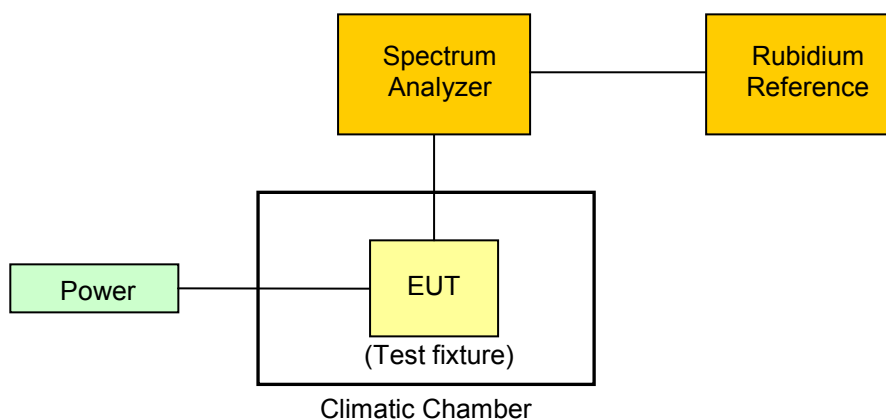
According to FCC 47 CFR 95§628(e) the frequency stability of the device has to be verified at the temperatures of +25°C and +45°C for medical implant devices and 0°C and +55°C for MedRadio programmer/control transmitters and MedRadio body-worn transmitters.

According to IC RSS-243 Section 3.3 the frequency stability of the device has to be verified at the temperatures of +25°C, +37°C and +45°C for internal and body-worn devices, -30°C, +20°C and +50°C for outdoor used devices and 0°C, +20°C and +50°C for indoor used devices.

3.2.1 Limits

Frequency stability limit
±100ppm

3.2.2 Measurement procedure



Measurement:

The EUT is connected to the spectrum analyzer. The supply voltage and ambient temperature of the EUT is set to nominal. The transmitter of the EUT is activated without modulation and the peak carrier frequency is measured. The frequency error is calculated as the deviation from the nominal carrier frequency stated by the provider. The measurement is performed under normal and extreme conditions.

3.2.3 Results

Frequency stability			
Measurement Conditions			
Nominal frequency		403.65MHz	
Modulated		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
Conditions		Frequency [MHz]	Frequency error [ppm]
$T_{nom} = 37^{\circ}\text{C}$	$V_{nom} = 3.0\text{VDC}$	403.652636	6.53
$T_{min} = 25^{\circ}\text{C}$	$V_{nom} = 3.0\text{VDC}$	403.653251	8.05
$T_{max} = 45^{\circ}\text{C}$	$V_{nom} = 3.0\text{VDC}$	403.652637	6.53
See attached diagrams in Annex			
Verdict			PASS

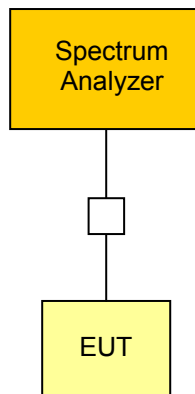
3.3 Emission Bandwidth

According to FCC 47 CFR 95§628(d), 95§633(e)(1) and IC RSS-243 Section 3.6 the maximum authorized emission bandwidth has to be verified.

3.3.1 Limits

Emission bandwidth limit
≤ 300kHz

3.3.2 Measurement procedure



The EUT is connected to a spectrum analyzer and set to transmission mode (using a communication tester if needed) with maximum power under normal test conditions. The resolution bandwidth is set to 1% of the 20dB bandwidth of the emission spectrum ($VBW \geq RBW$). The center frequency is set to the channel center frequency. The span of the analyzer is set to 2 -3 times the 20dB bandwidth. The bandwidth is determined using markers with peak detector and max hold.

3.3.3 Results

Emission bandwidth		
Measurement Conditions		
Channel frequency :	403.65MHz	
Lower edge frequency [MHz]	Upper edge frequency [MHz]	Emission bandwidth [kHz]
403.5358	403.7704	234.600
See attached diagrams in Annex		
Verdict		PASS

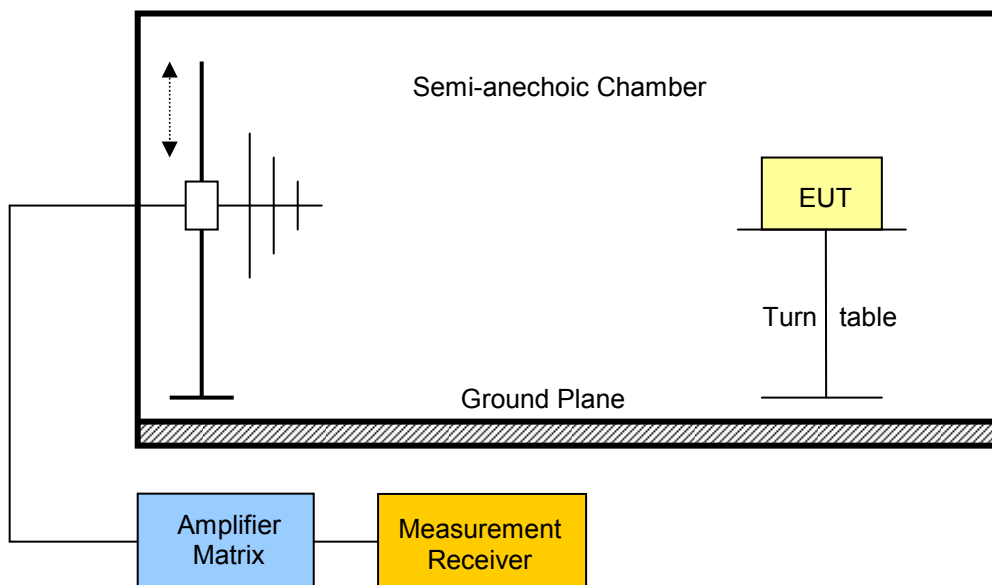
3.4 Equivalent isotropic radiated power

According to FCC 47 CFR 95§639(f) and IC RSS-243 Section 5.4 the maximum effective isotropic radiated power has to be verified.

3.4.1 Limits

Equivalent isotropic radiated power limit
$\leq 25\mu\text{W}$ (-16dBm) e.i.r.p.

3.4.2 Measurement procedure



The EUT is placed on a turn table inside a fully anechoic chamber and activated with normal modulation and highest power level. First the duty cycle of the signal is measured via a spectrum analyzer connected to the measurement antenna. Then the transmitted power is measured by the measurement antenna and a wideband power meter connected to the measurement antenna. The maximum emission is obtained by rotating the EUT through 360°. The measurement procedure is performed for both polarizations of the measurement antenna. The highest power value measured is corrected by the duty cycle and recorded.

3.4.3 Results

Equivalent isotropic radiated power	
Channel [MHz]	Transmitter Power [dBm/ μW] e.i.r.p.
403.65	-34.02 / 0.396
See attached diagrams in Annex	
Verdict	PASS

3.5 Transmitter radiated spurious emissions

The transmitter unwanted emission shall be verified according to FCC 47 CFR 15§635(d) and IC RSS-243 Section 3.4 & 5.5.

3.5.1 Limits

Emissions from a MedRadio transmitter more than 250 kHz outside of the 402–405 MHz band shall be attenuated to a level no greater than the following field strength limits:

Transmitter out-of-band spurious emission limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V}/\text{m}$]	Calculated Limit 3m [$\text{dB}\mu\text{V}/\text{m}$]	Measurement 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

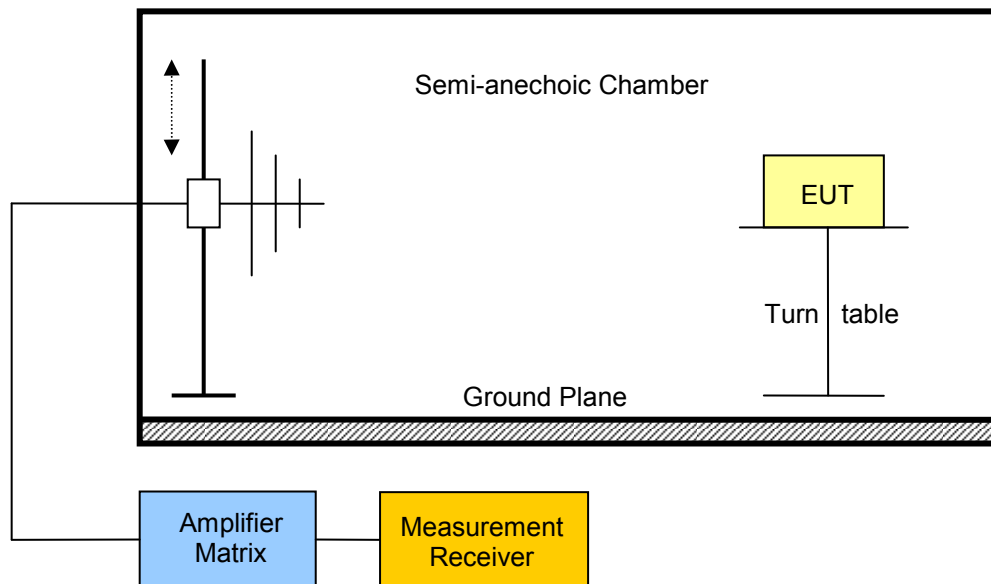
The following in-band and band-edge condition apply:

Emissions within the 402-405 MHz MICS band which are more than 150 kHz away from the centre frequency of the spectrum, and the transmissions that occupy up to 250 kHz above and below the band shall be attenuated at least 20 dB below the maximum transmitter output power. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

The emissions from a MedRadio/MICS transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

Measurement procedure

The spurious emission measurement is performed on 3m a semi-anechoic test site.



The EUT is placed on a non-metallic table. Any emission is received by the measurement antenna and measured via a measurement receiver connected to the antenna. To obtain the maximum emission the EUT is rotated through 360°.

Due to practical reasons the spurious emission level check is first performed with a peak detector and the quasi-peak and average limits.

If any emission is detected that gets close to the emission limit the detector is changed and the quasi-peak or average detector is used. Which detector is used is determined by the emission frequency. If pulsed transmission is used, averaging over the pulse train is used.

The measurement values are also corrected to obtain the field strength values at the defined measurement distances of the emission limits.

The measurement is performed over the frequency range of 30MHz up to the tenth harmonic.

3.5.2 Results

Out-of-band transmitter radiated spurious emissions							
Measurement Conditions							
Measurement distance :		3m					
Modulated :		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No					
Channel Frequency [MHz]	Emission Frequency [MHz]	Pol.	Measured Field Strength [dB μ V/m]	Field Strength [μ V/m]	Limit@3m [dB μ V/m]	Detector	Margin [dB]
403.65	401.700	v	17.54	7.533	46.00	peak	-28.46
	401.700	h	17.44	7.447	46.00	peak	-28.56
See attached diagrams in Annex							
Verdict						PASS	

Transmitter band-edge and in-band emissions			
Measurement Conditions			
Power mode	Peak		
Max. allow power	25 μ W = -16.02dBm = 79.21dB μ V/m @ 3m		
Band-edge limit	79.21dB μ V/m – 20dB = 59.21dB μ V/m		
Max. transmit power	-34.02dBm = 61.21dB μ V/m @ 3m		
In-band limit	61.21dB μ V/m - 20dB = 41.21dB μ V/m		
Channel [MHz]	Lower edge	In-band	Upper edge
402.45	pass	pass	pass
403.65	pass	pass	pass
404.85	pass	pass	pass
See attached diagram in Annex			
Verdict		PASS	

4 Receiver parameters

4.1 Receiver spurious emissions

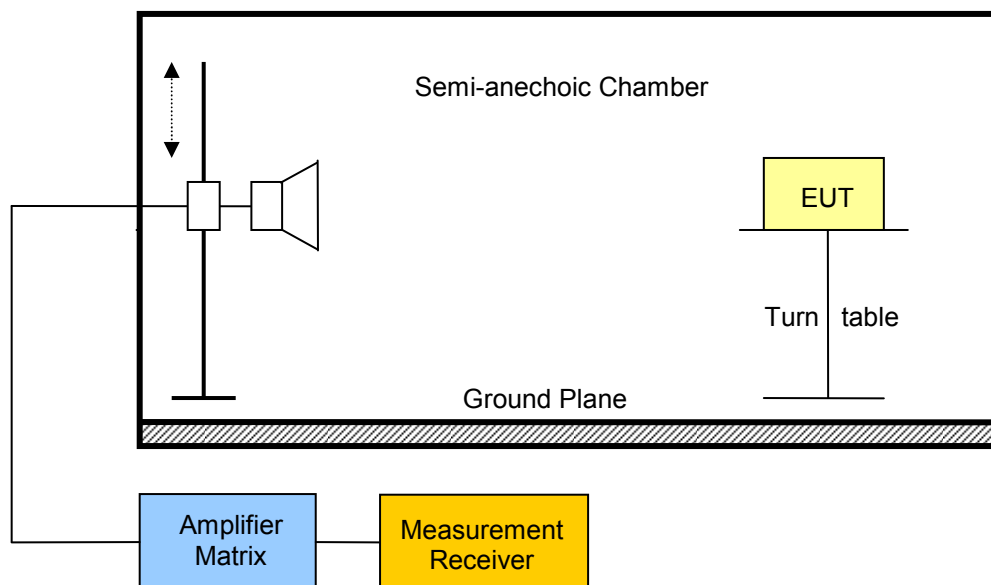
According FCC 47 CFR 15§109 and RSS-243 Section 3.5, RSS-Gen Section 4.10 & 6.1 the emission of unintentional radiators have to comply with limits stated in the rules.

4.1.1 Limits

Receiver (unintentional class B) spurious emission limits @ 3m				
Frequency range [MHz]	Detector	Limit@3m [$\mu\text{V}/\text{m}$]	Calculated Limit @ 3m [$\text{dB}\mu\text{V}/\text{m}$]	Measurement 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

4.1.2 Measurement procedure

The spurious emission measurement is performed on a 3m open area test site.



The eut is placed on a non-metallic table. Any emission is received by a loop antenna and measured via a measurement receiver connected to the loop antenna. To obtain the maximum emission the eut is rotated through 360°.

Due to practical reasons the spurious emission level check is first performed with a peak detector and the quasi-peak and average limits.

If any emission is detected that gets close to the emission limit the detector is changed and the quasi-peak or average detector is used. Which detector is used is determined by the emission frequency. If pulsed transmission is used, averaging over the pulse train is used.

The measurement values are also corrected to obtain the field strength values at the defined measurement distances of the emission limits.

The measurement is performed over the frequency range of 30MHz up to the 3rd harmonic.

4.1.3 Results

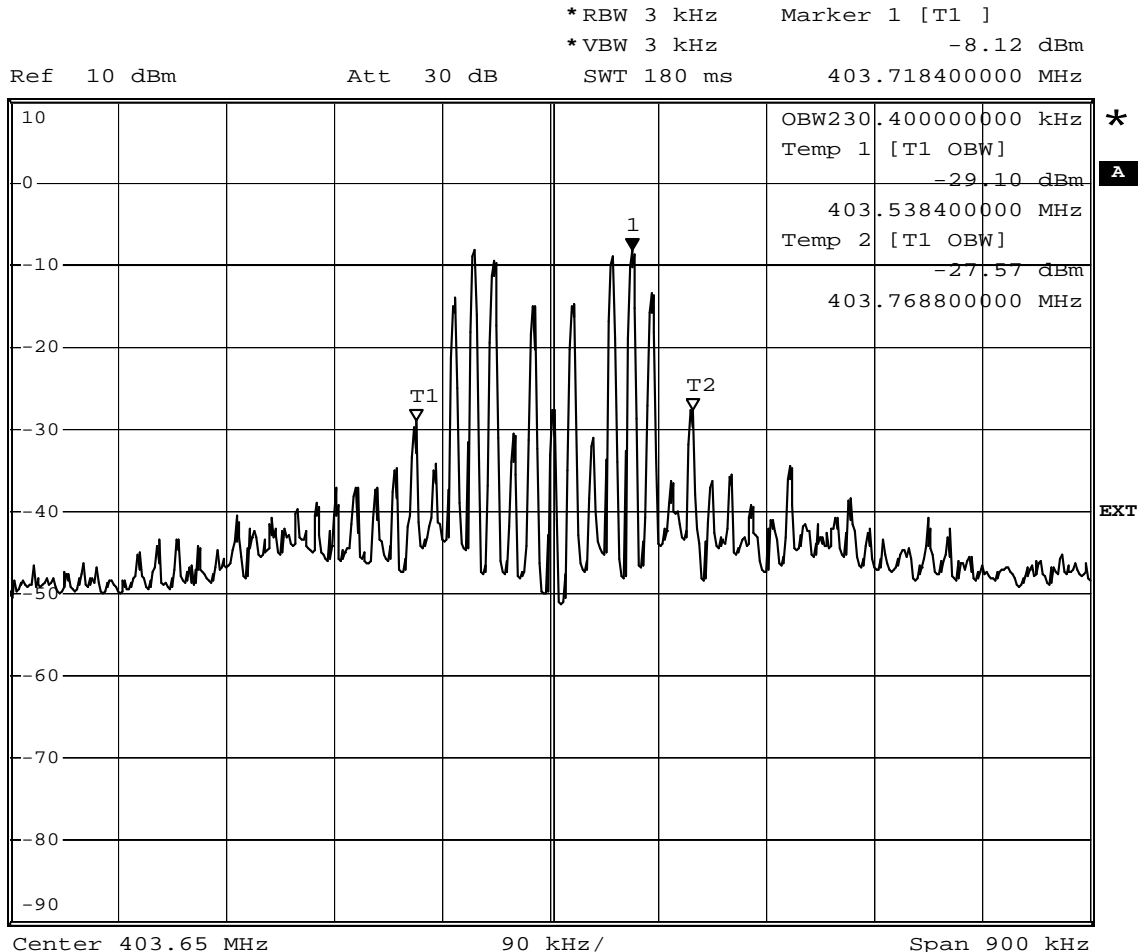
Receiver (unintentional) spurious emissions							
Measurement Conditions							
Measurement distance			3m				
Channel Frequency [MHz]	Emission Frequency [MHz]	Pol.	Measured Field Strength [dB μ V/m]	Field Strength [μ V/m]	Limit@3m [μ V/m]	Detector	Margin [dB]
RX	3817	h	42.74*	137.09*	54	Peak	-11.26
See attached diagrams in Annex							
Verdict						PASS	

* **Note** : The stated emission level corresponds to noise floor. The EUT emits no spurious emissions.

Annex B Occupied Bandwidth

RSS-Gen Occupied frequency bandwidth

EUT	ICD (medical implantable device)
Model	Lumax 6XX /Lumax 7xx
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	Limit: < 300KHz



Comment: Occupied bandwidth: 230.4 KHz
 Date: 26.JAN.2011 14:12:55

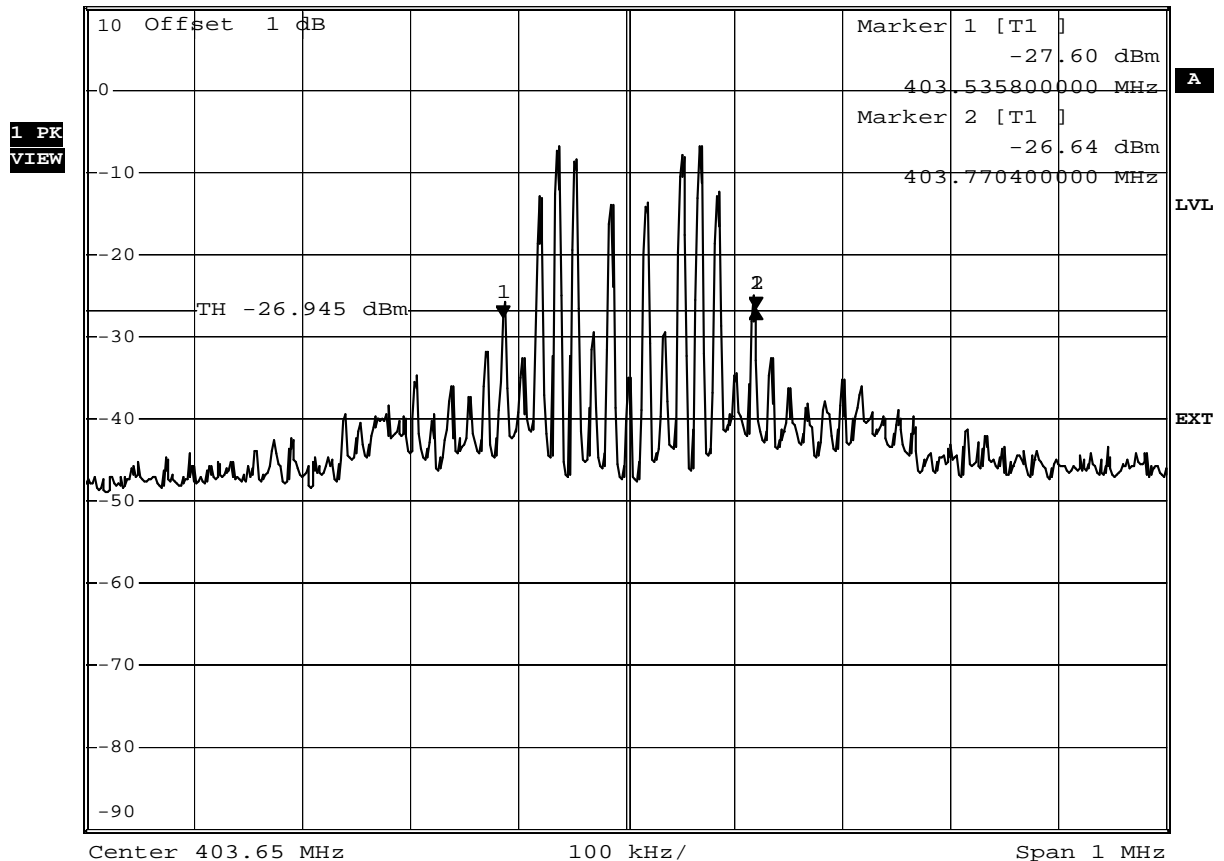
Annex C Emission bandwidth

FCC Part 95.633 Emission bandwidth

EUT	ICD (medical implantable device)
Model	Lumax 6XX /Lumax 7xx
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



*RBW 3 kHz Delta 1 [T1]
 *VBW 10 kHz 0.96 dB
 Ref 10 dBm Att 40 dB SWT 115 ms 234.60000000 kHz



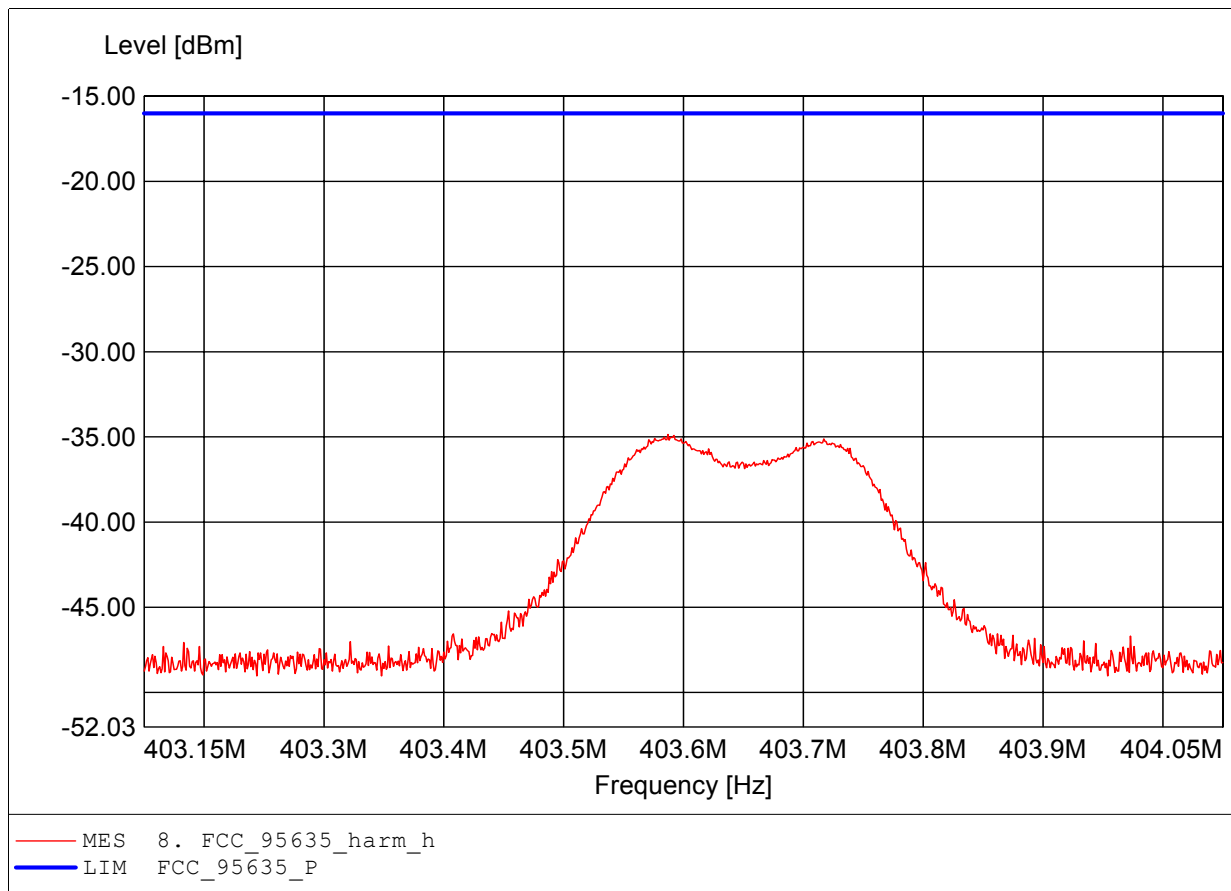
Comment: 20 dB bandwidth: 234.6 KHz
 Date: 26.JAN.2011 14:35:08

Annex D Effective radiated power

Carrier power (dBm)

FCC RULES PART 95, SUBPART i

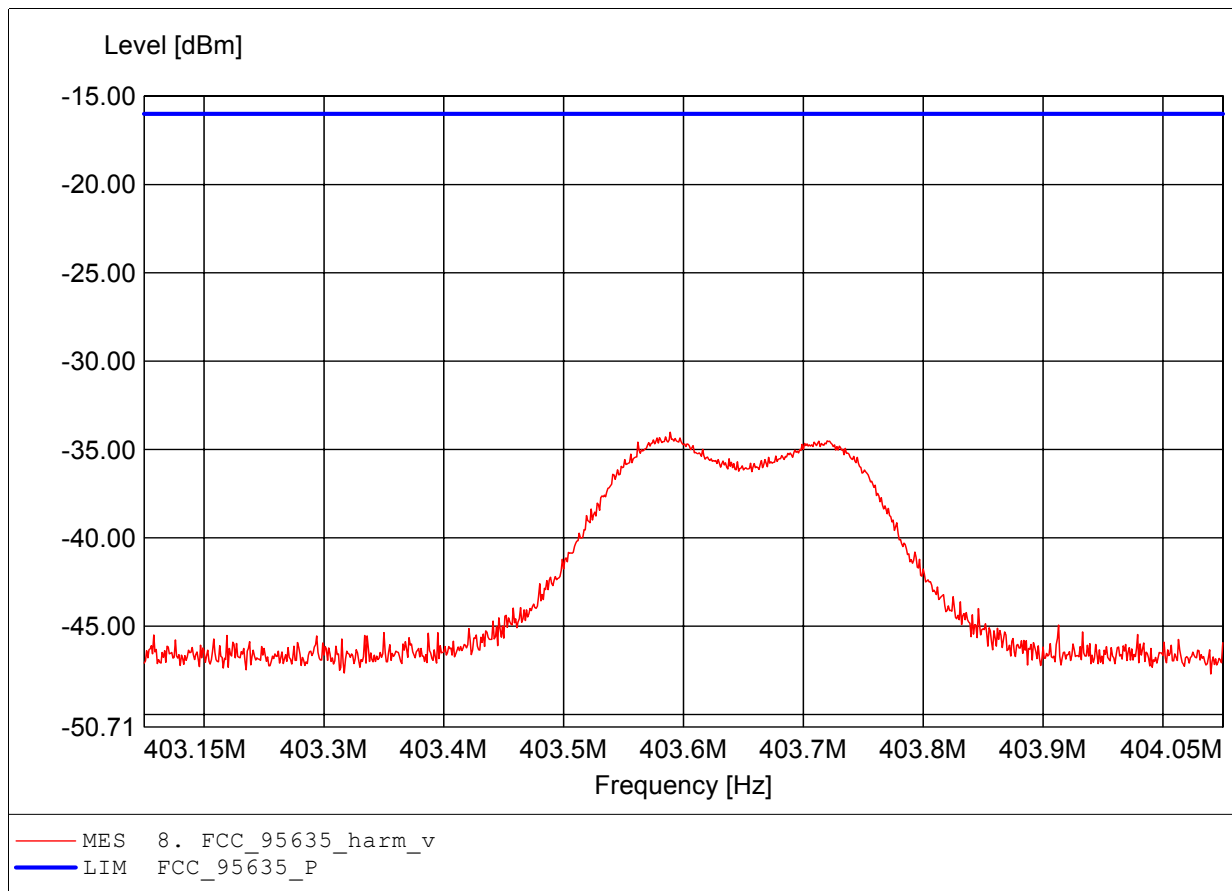
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 403.587MHz, Pmax: -34.86dBm, RBW: 100KHz



Carrier power (dBm)

FCC RULES PART 95, SUBPART i

Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 403.589MHz, Pmax: -34.02dBm, RBW: 100KHz

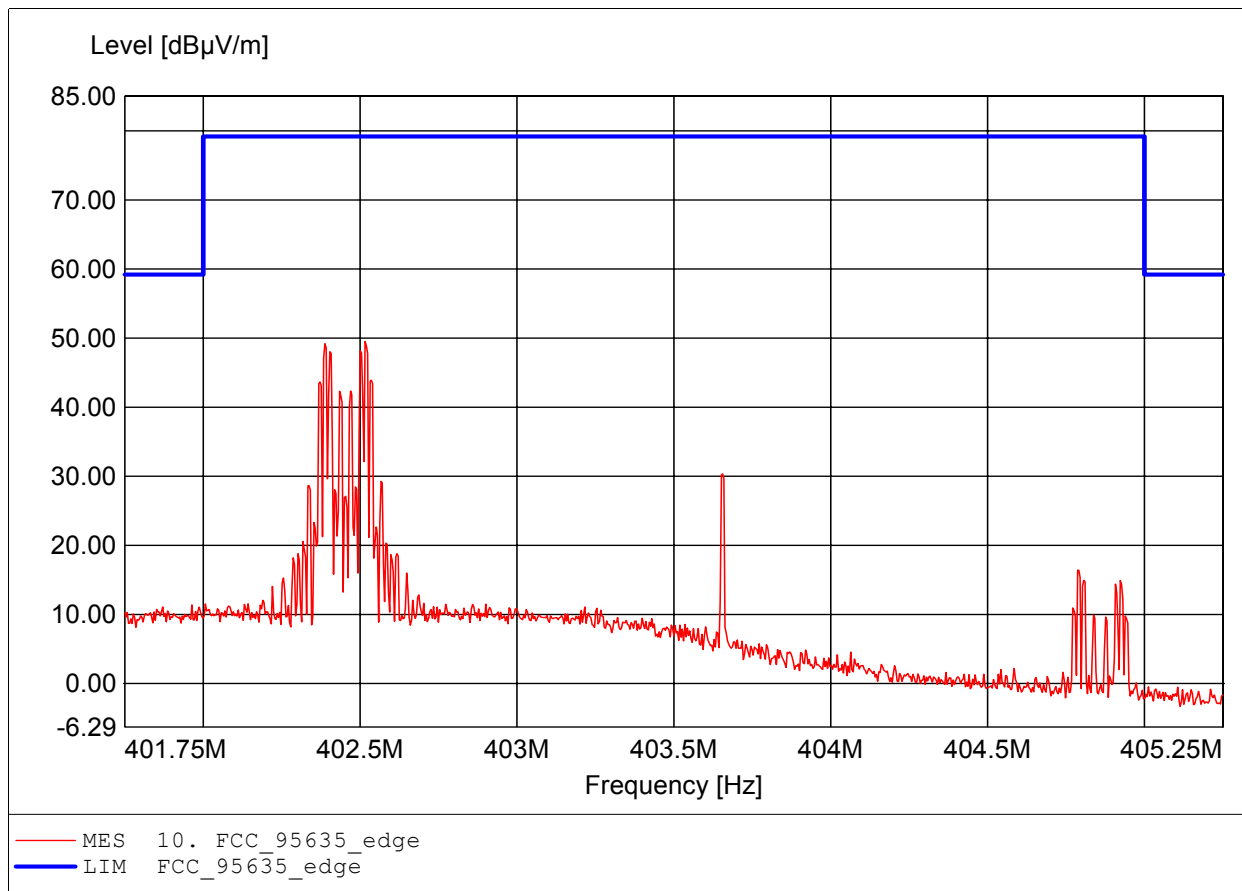


Annex E Transmitter spurious emissions

Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

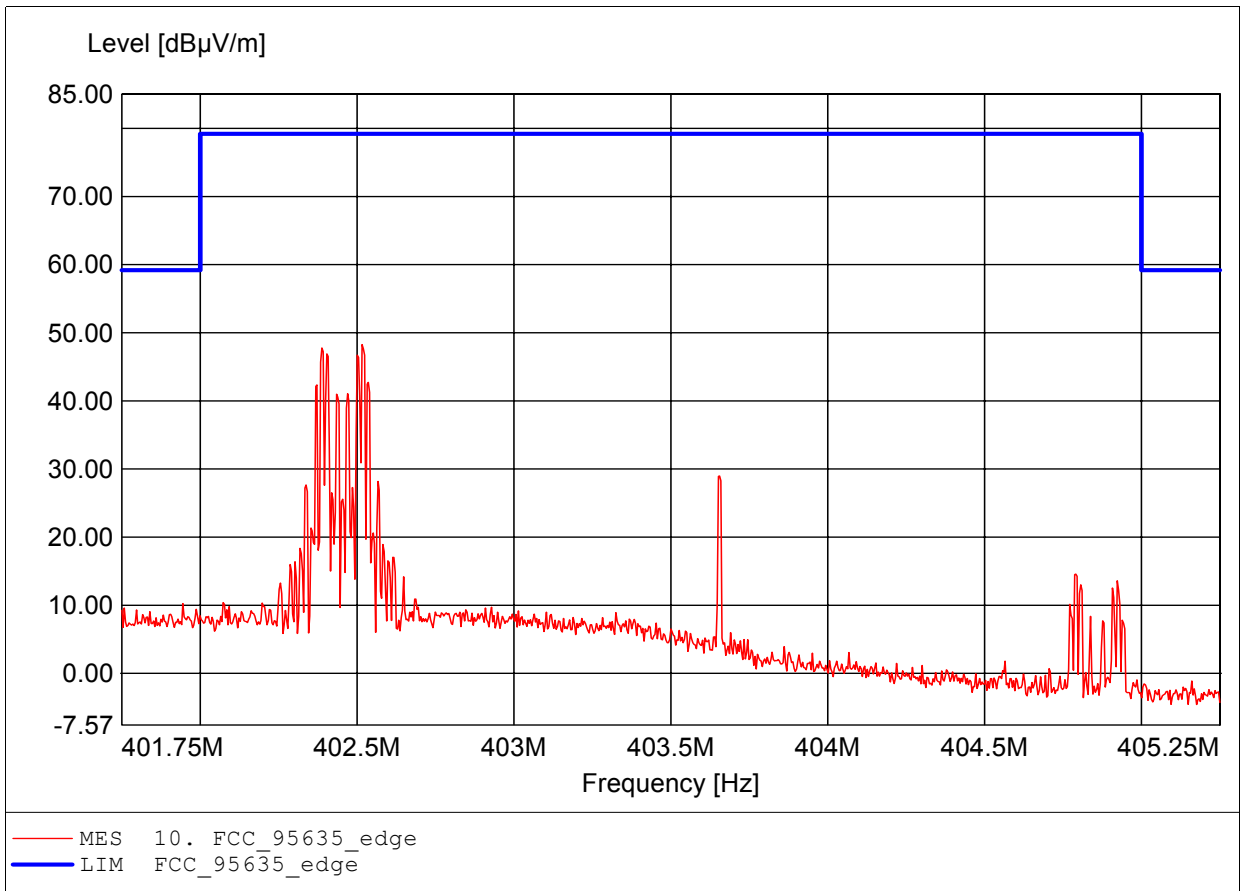
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 402.516MHz, Emax: 49.52dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

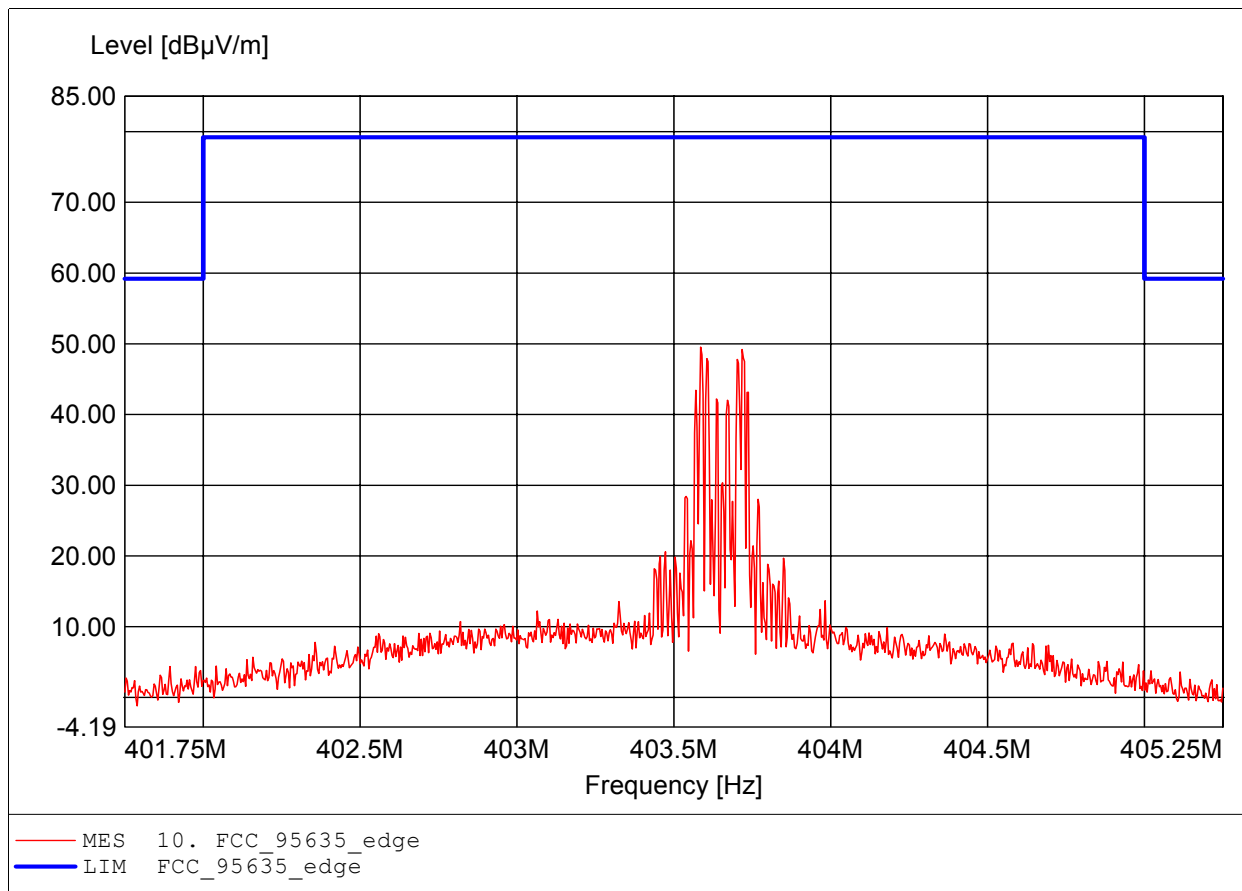
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 402.45MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635 (d) (5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 402.516MHz, Emax: 48.28dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

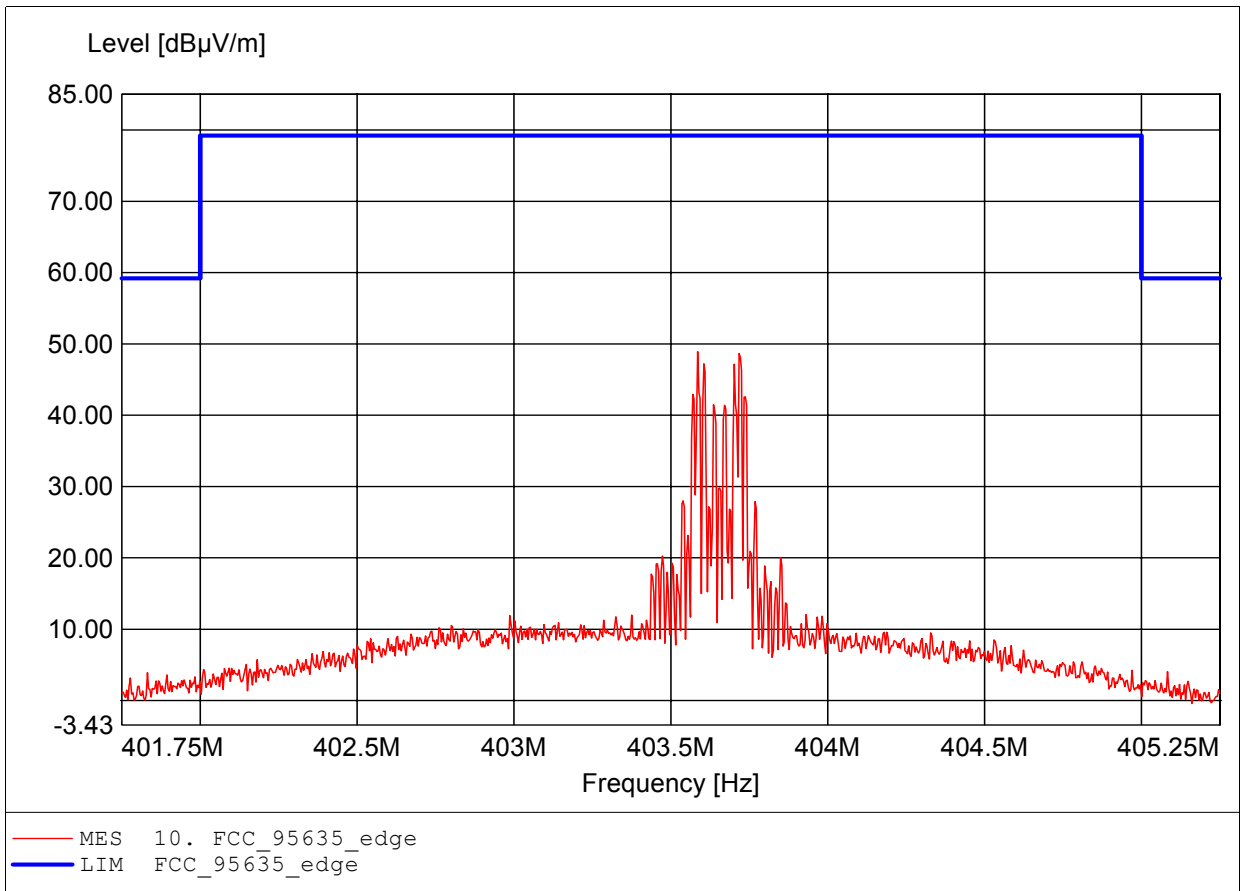
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 403.586MHz, Emax: 49.54dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

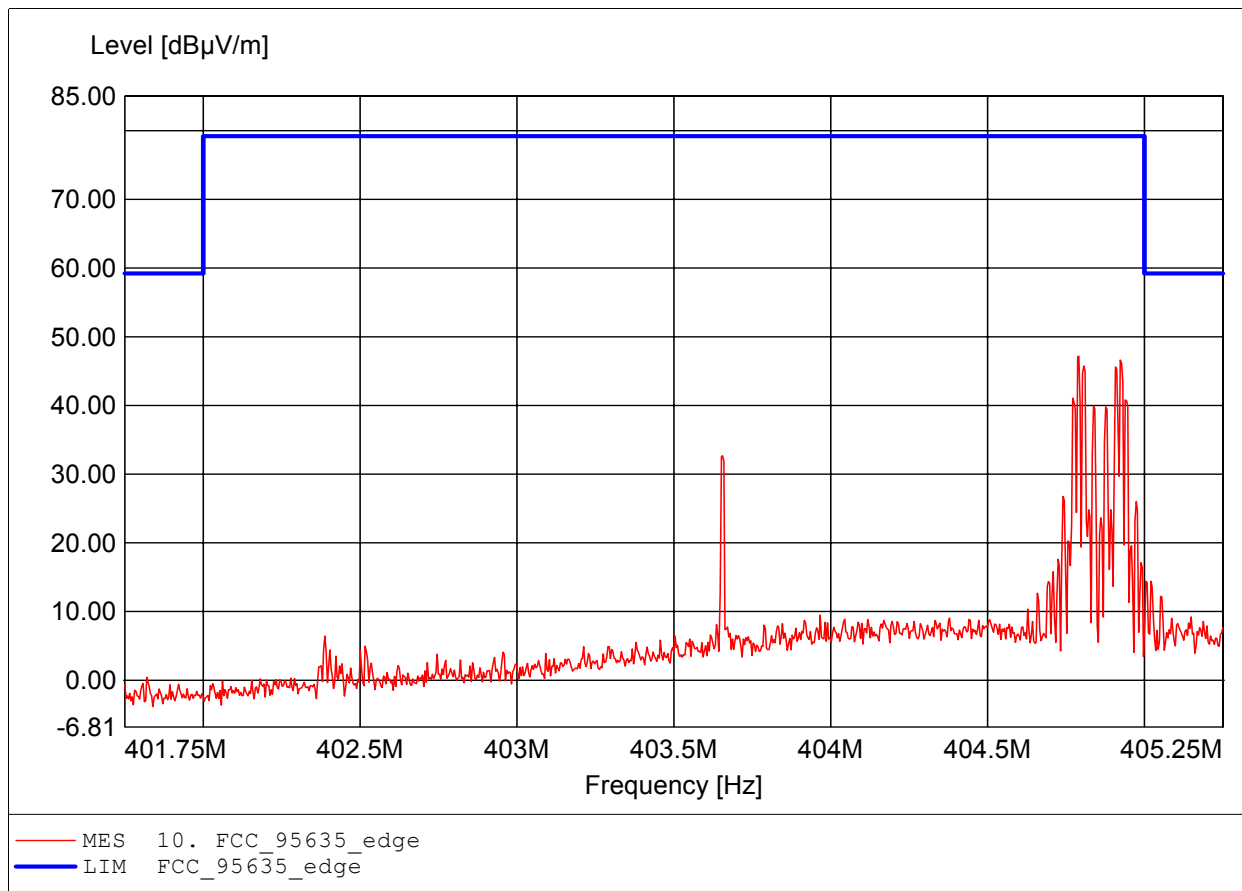
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 403.586MHz, Emax: 48.93dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

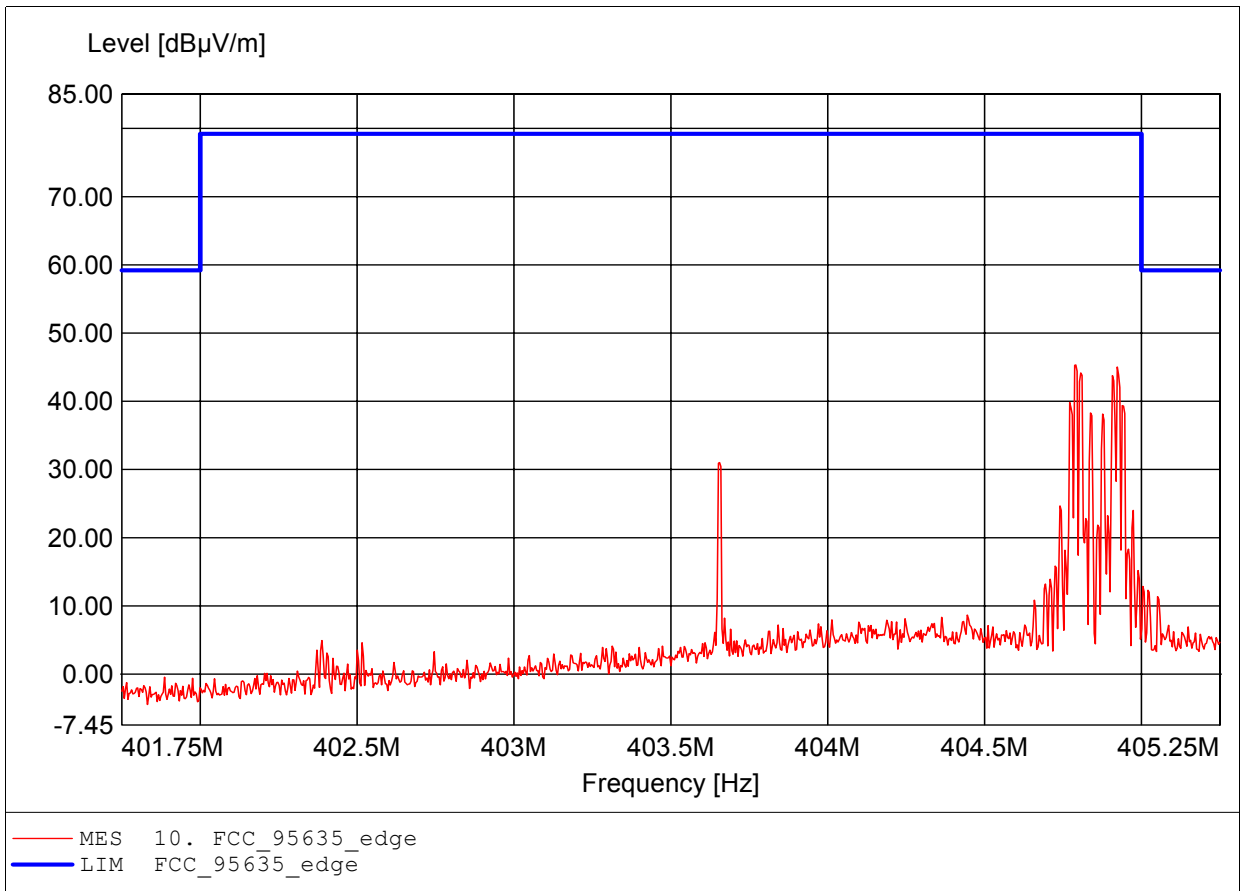
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635 (d) (5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 404.791MHz, Emax: 47.17dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

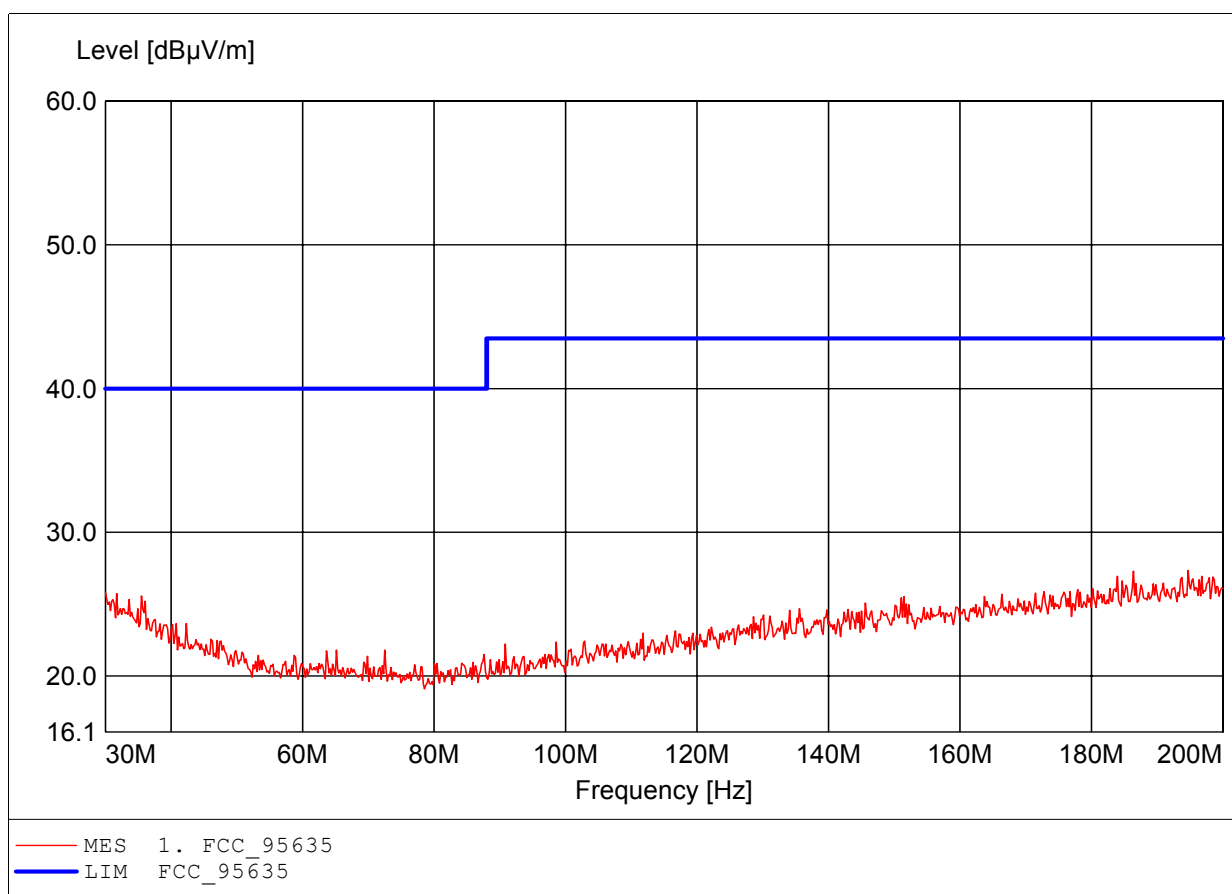
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 404.85MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635 (d) (5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 404.791MHz, Emax: 45.34dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

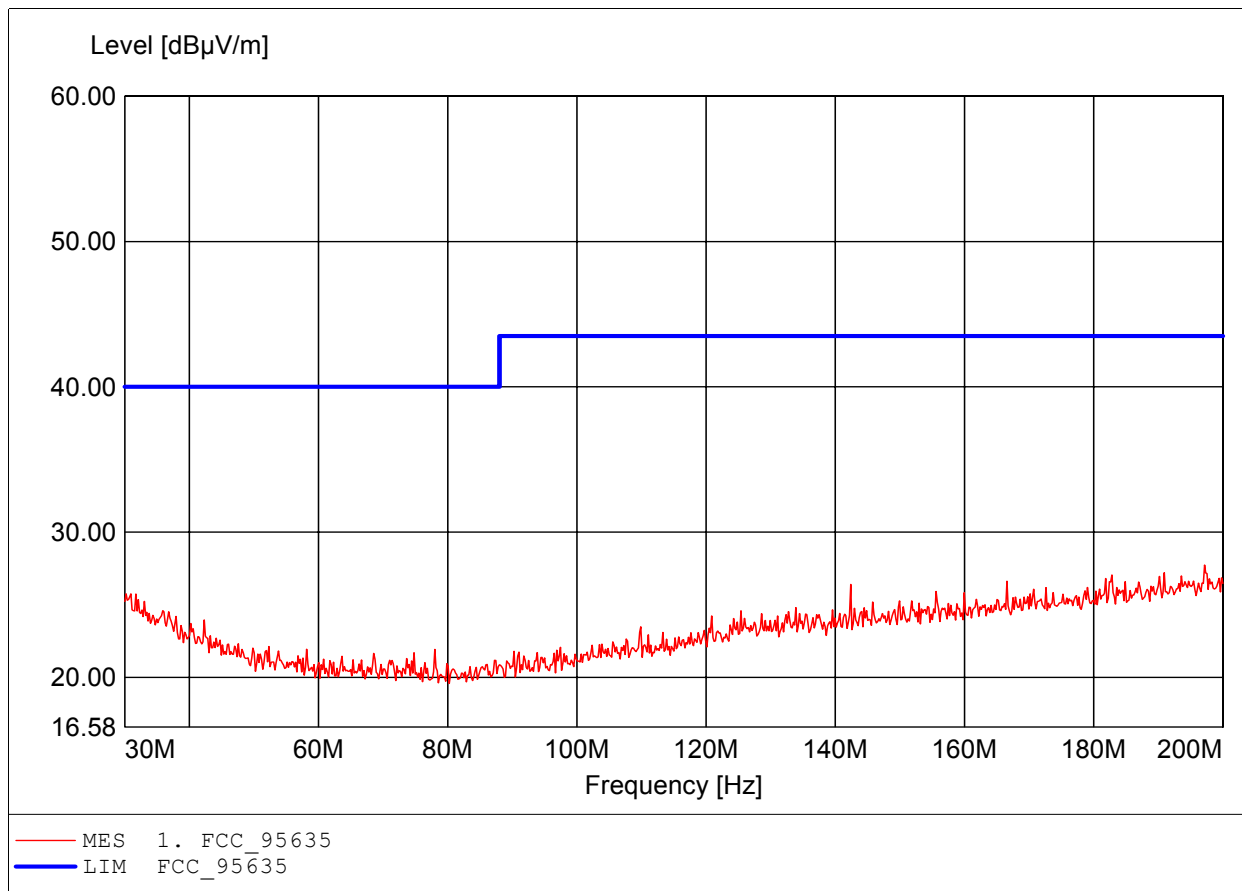
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 194.711MHz, Emax: 27.35dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

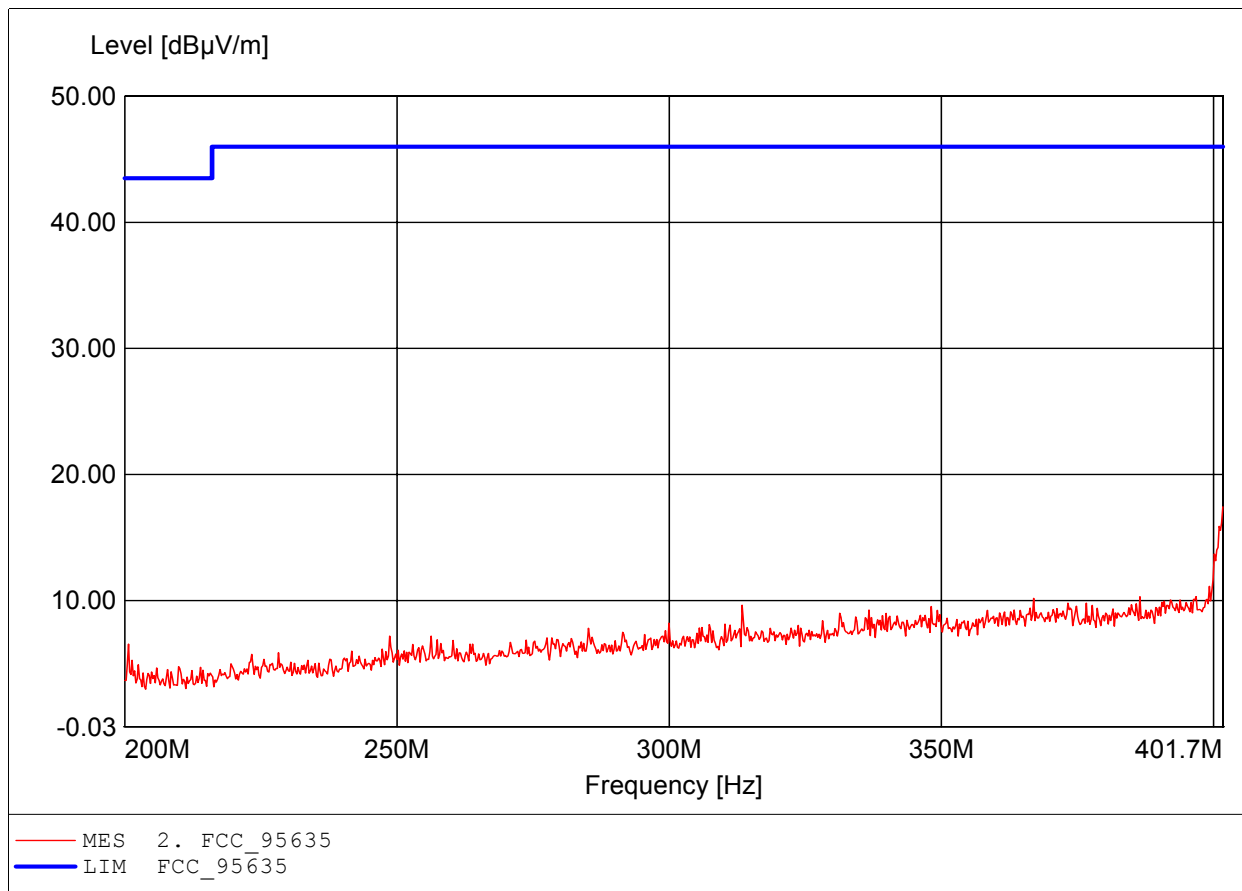
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 197.167MHz, Emax: 27.73dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

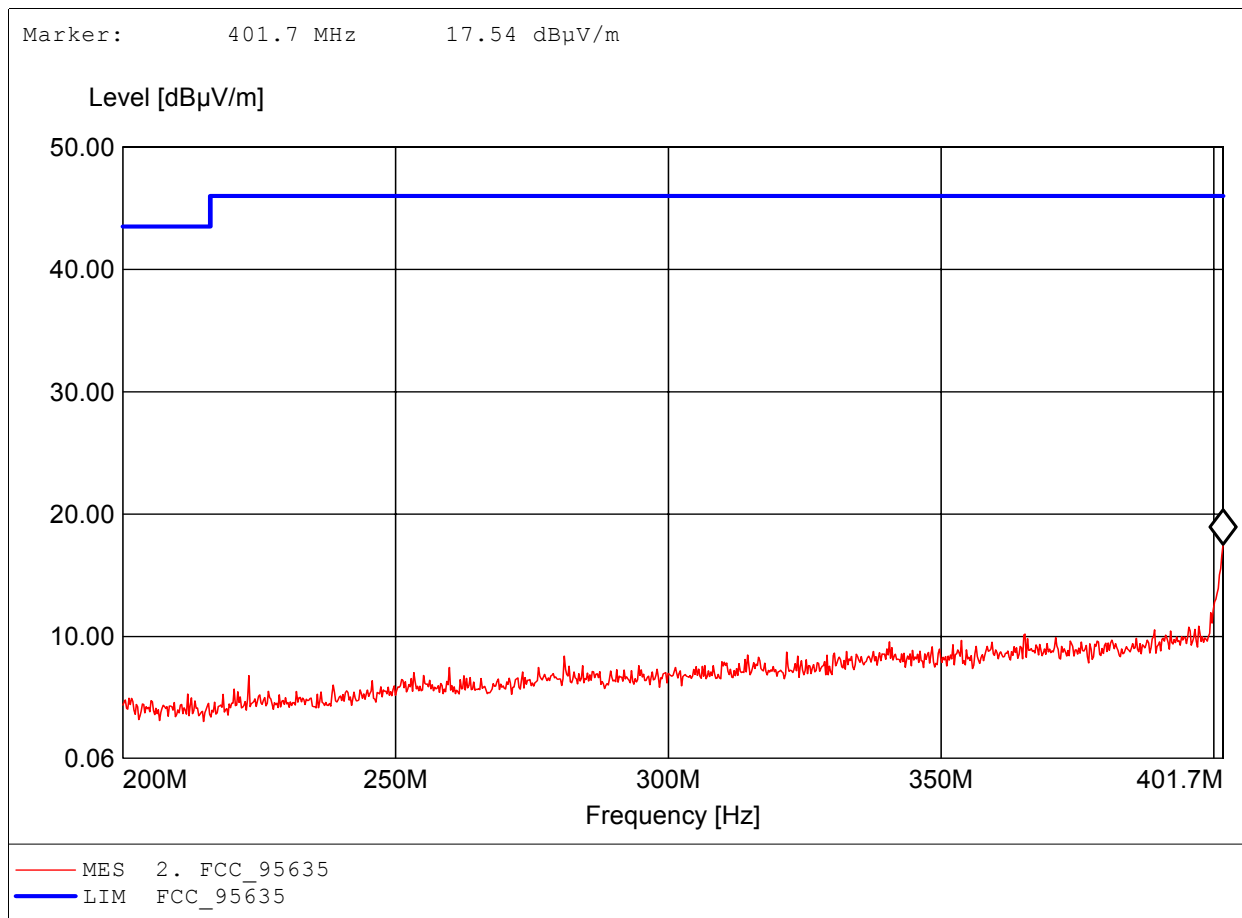
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.700MHz, Emax: 17.44dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

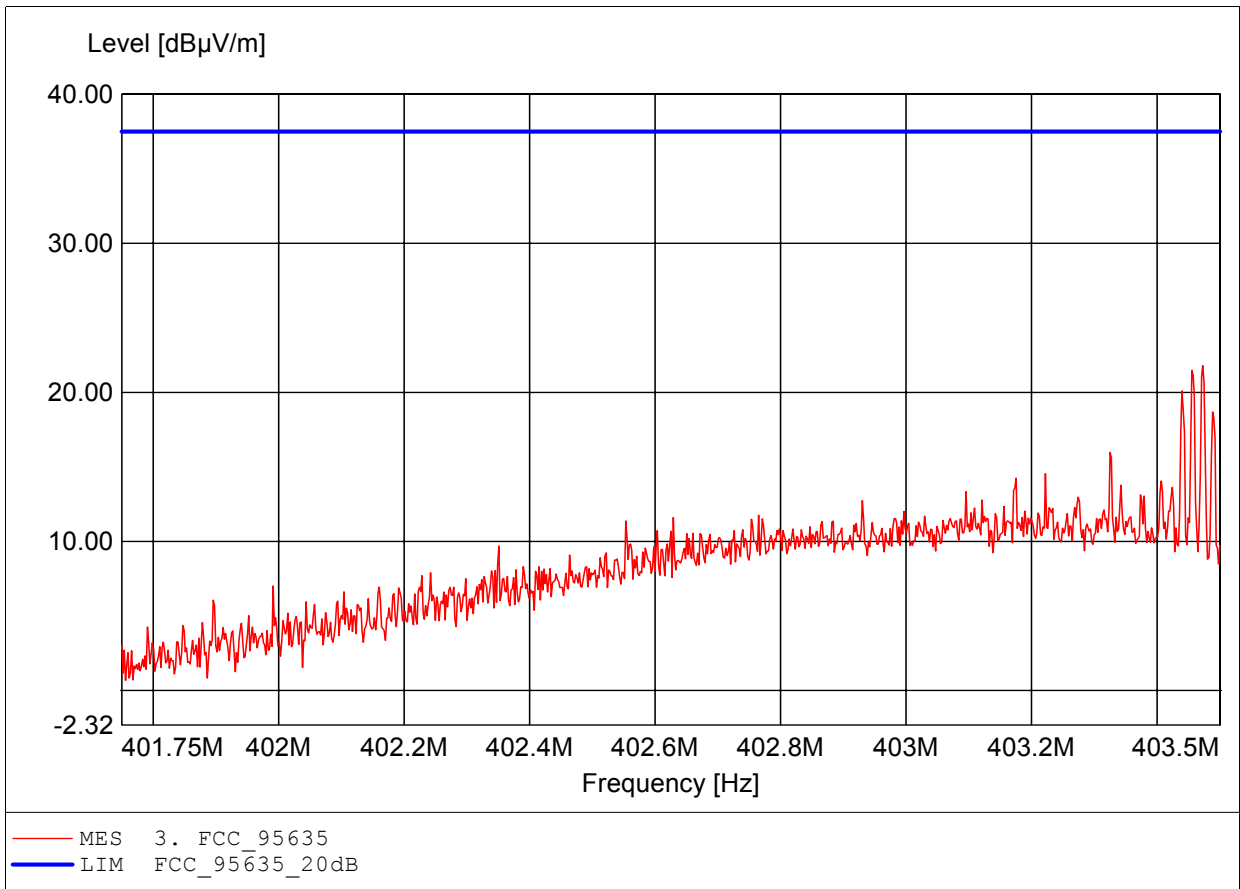
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.700MHz, Emax: 17.54dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

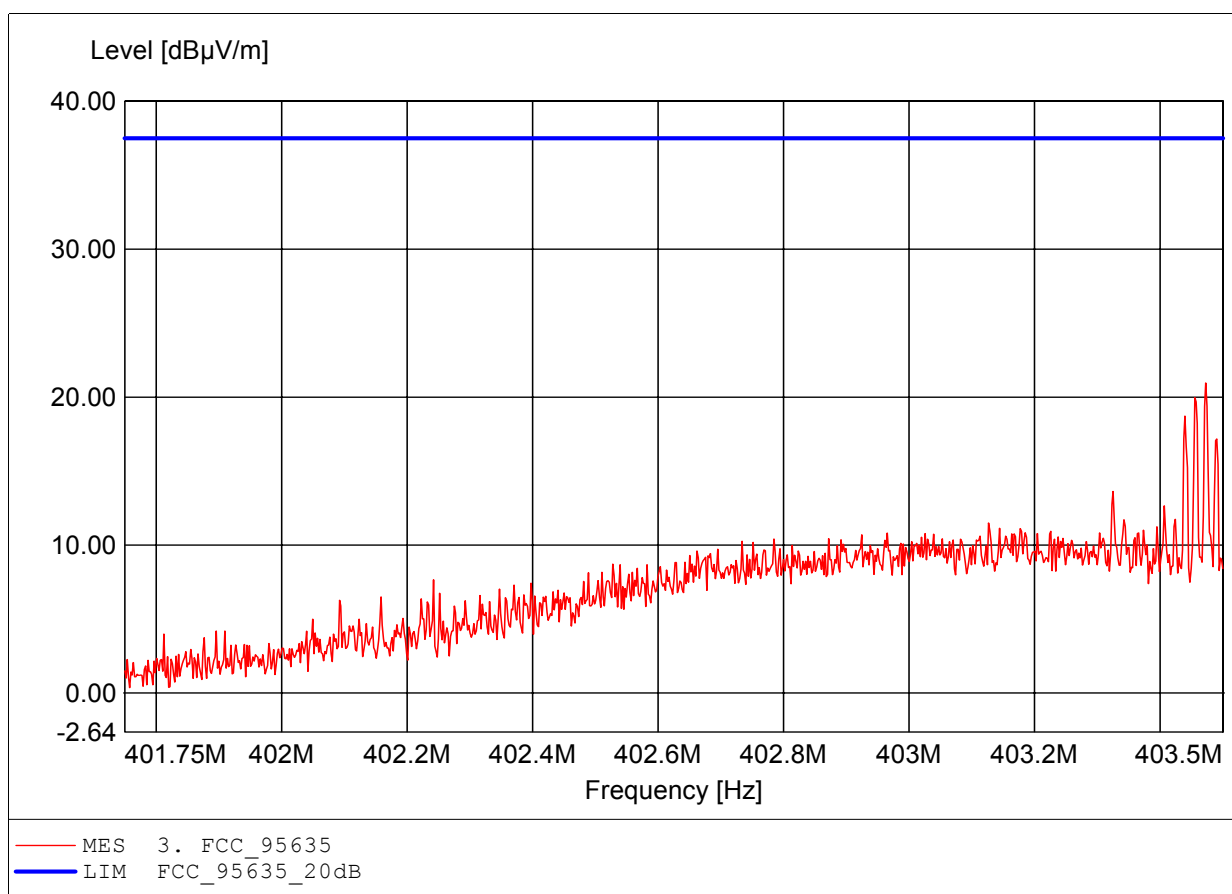
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.473MHz, Emax: 21.81dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

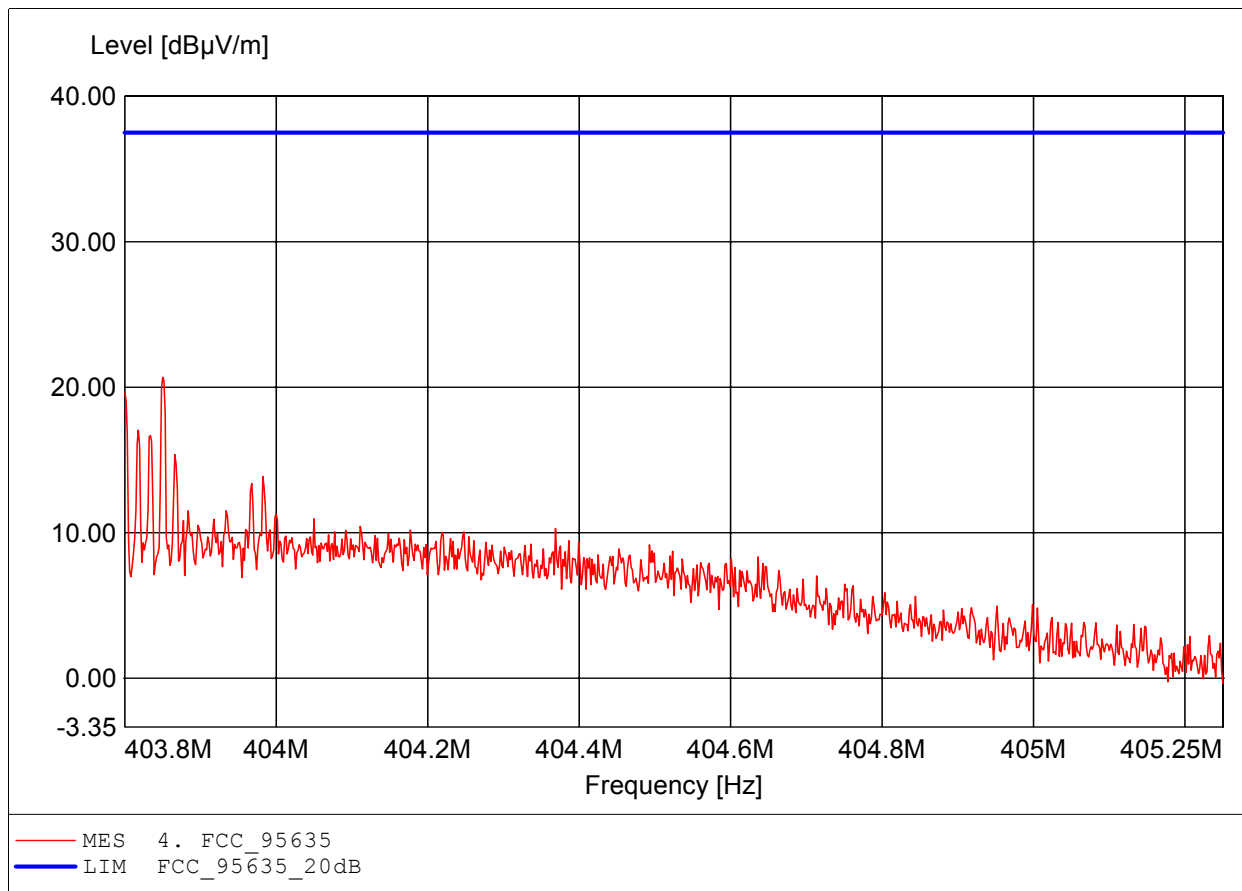
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.473MHz, Emax: 20.95dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

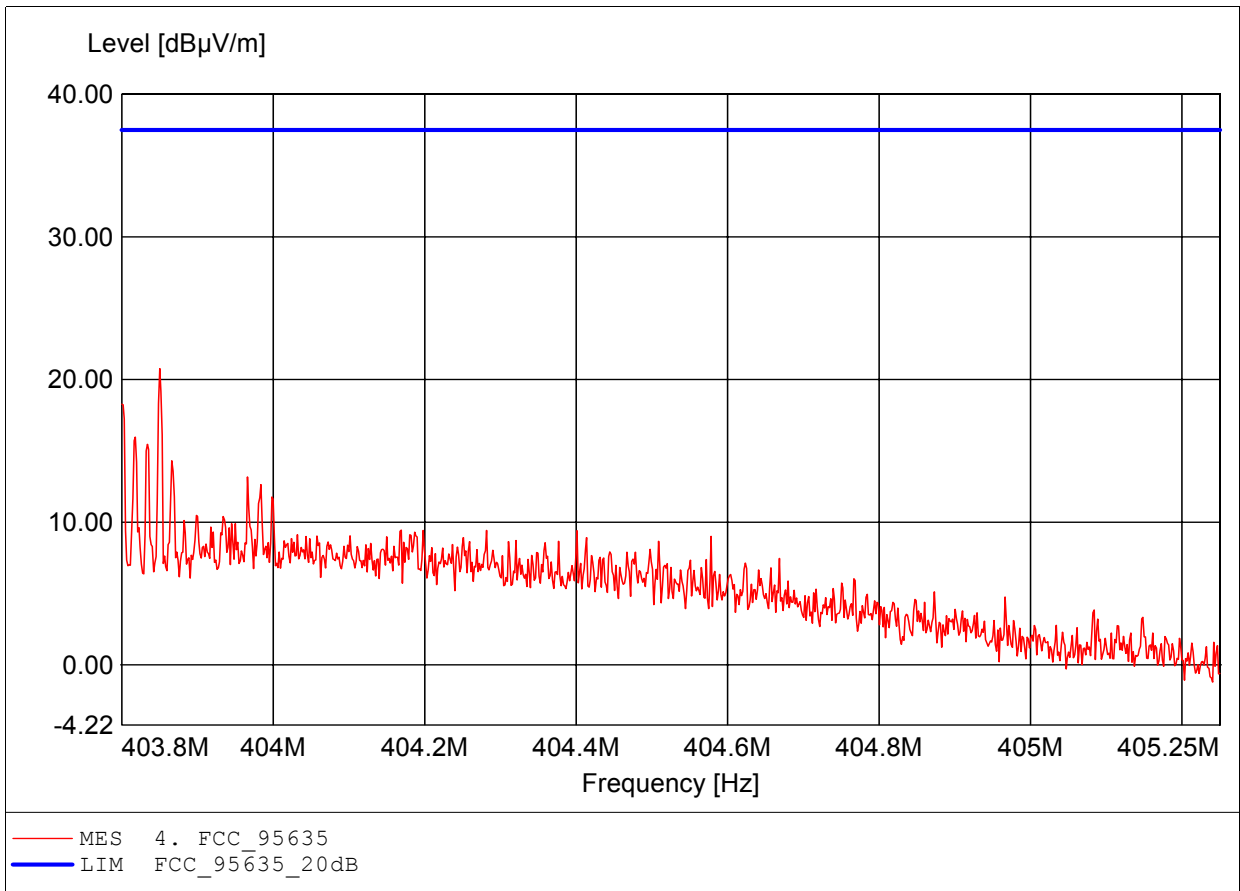
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.850MHz, Emax: 20.69dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

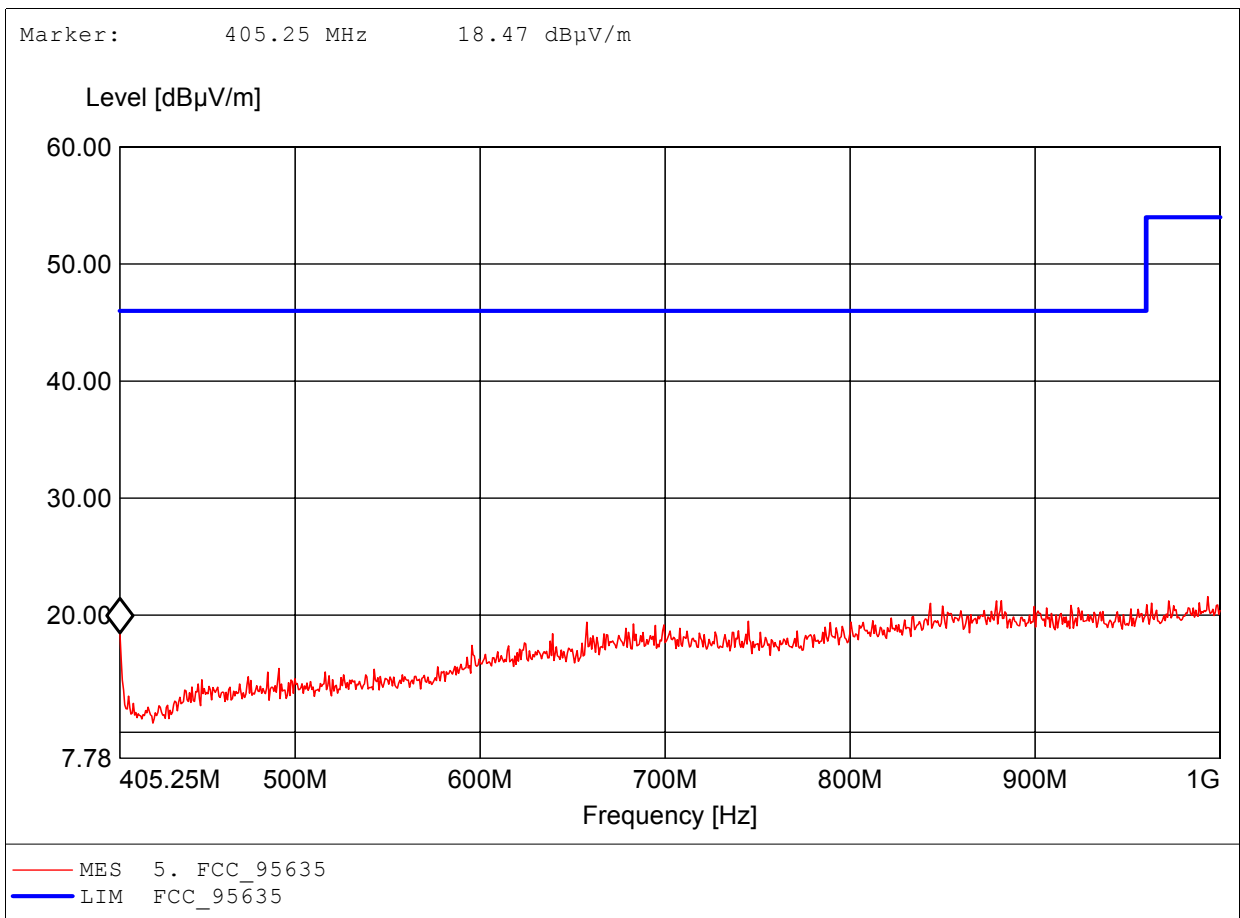
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.850MHz, Emax: 20.76dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

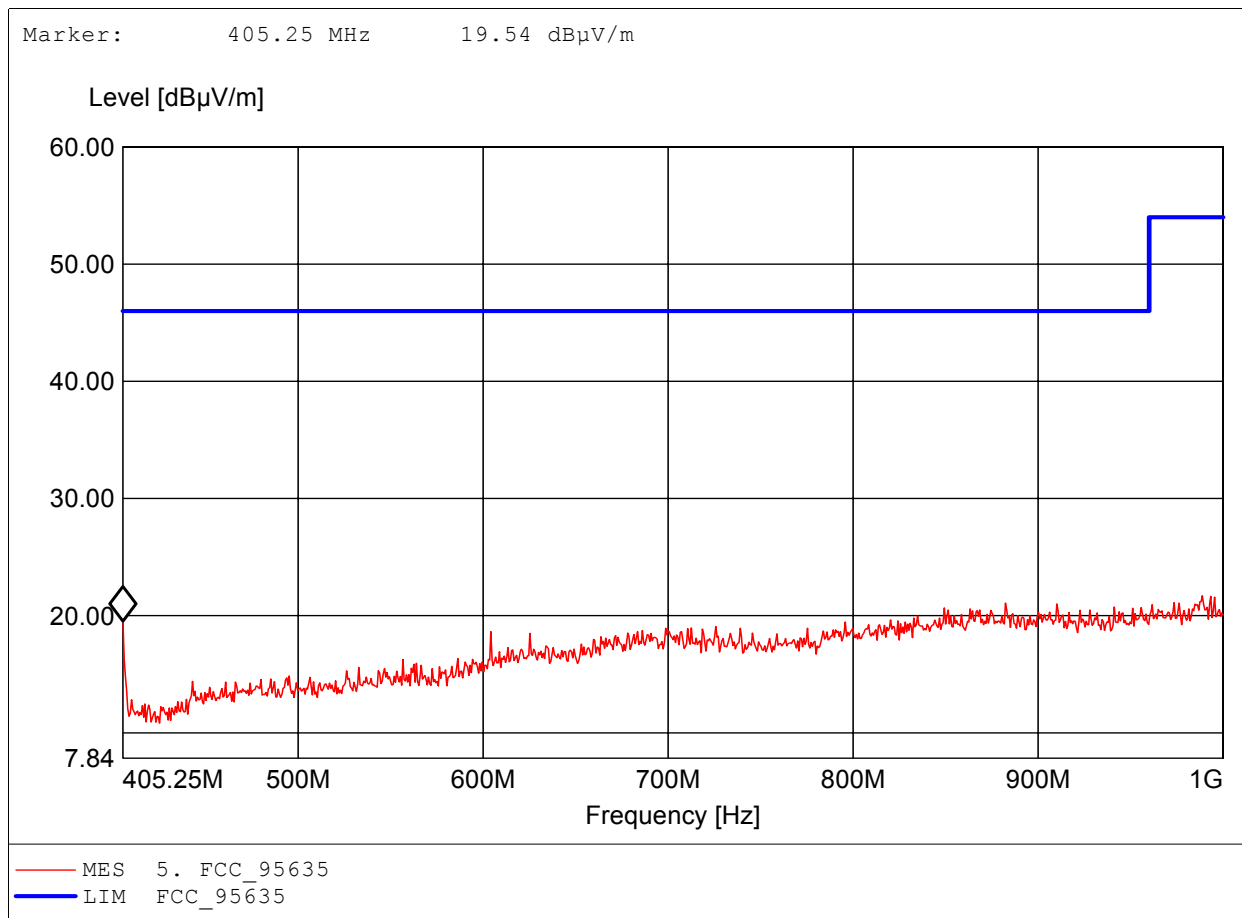
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 993.392MHz, Emax: 21.59dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

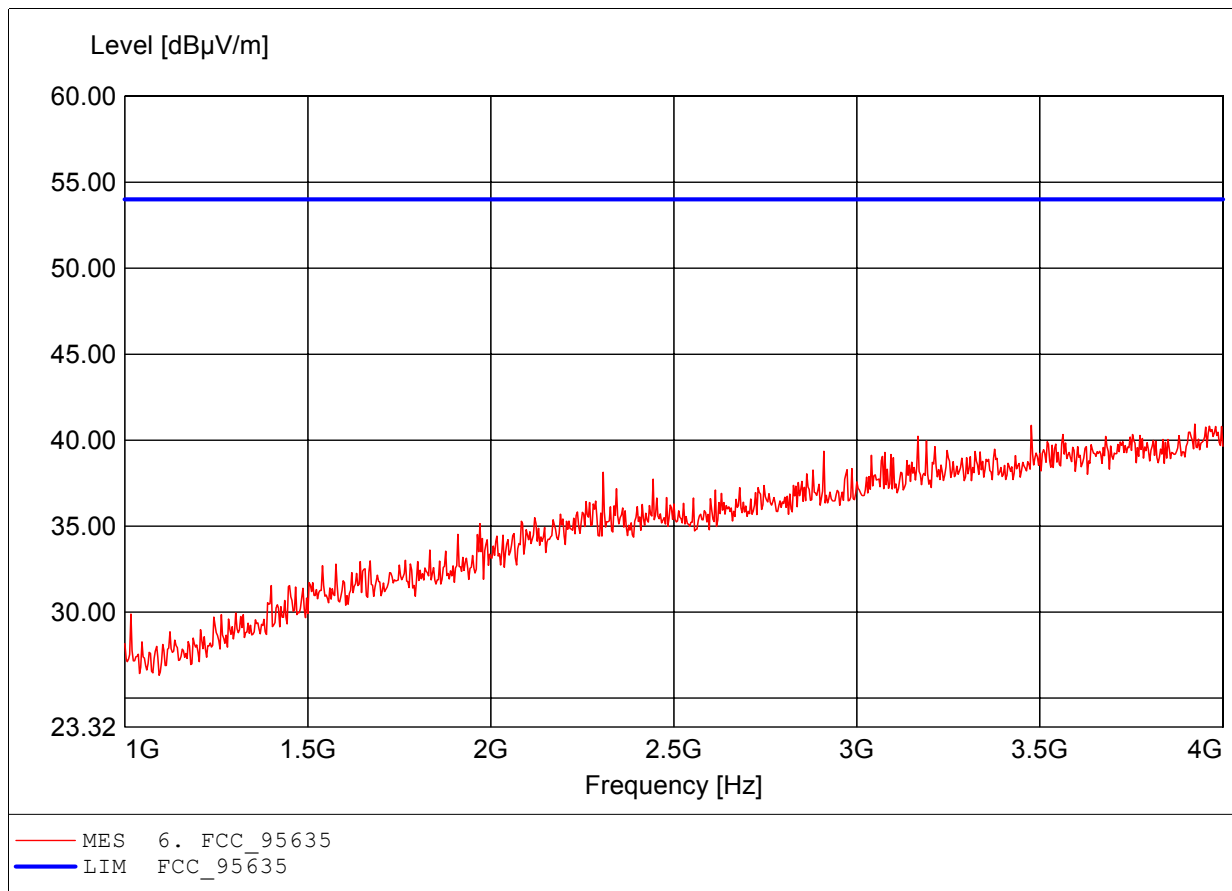
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 988.766MHz, Emax: 21.71dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

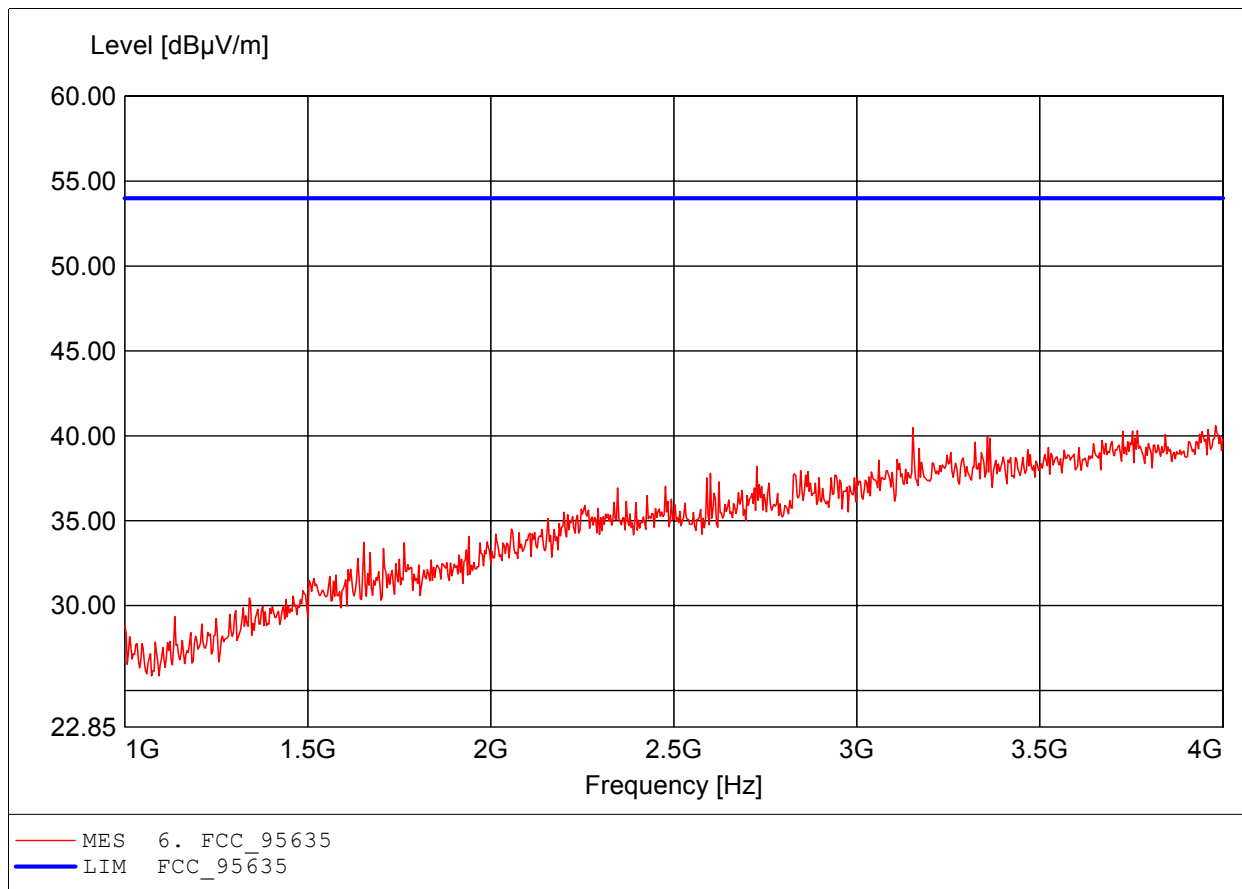
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.923GHz, Emax: 40.94dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

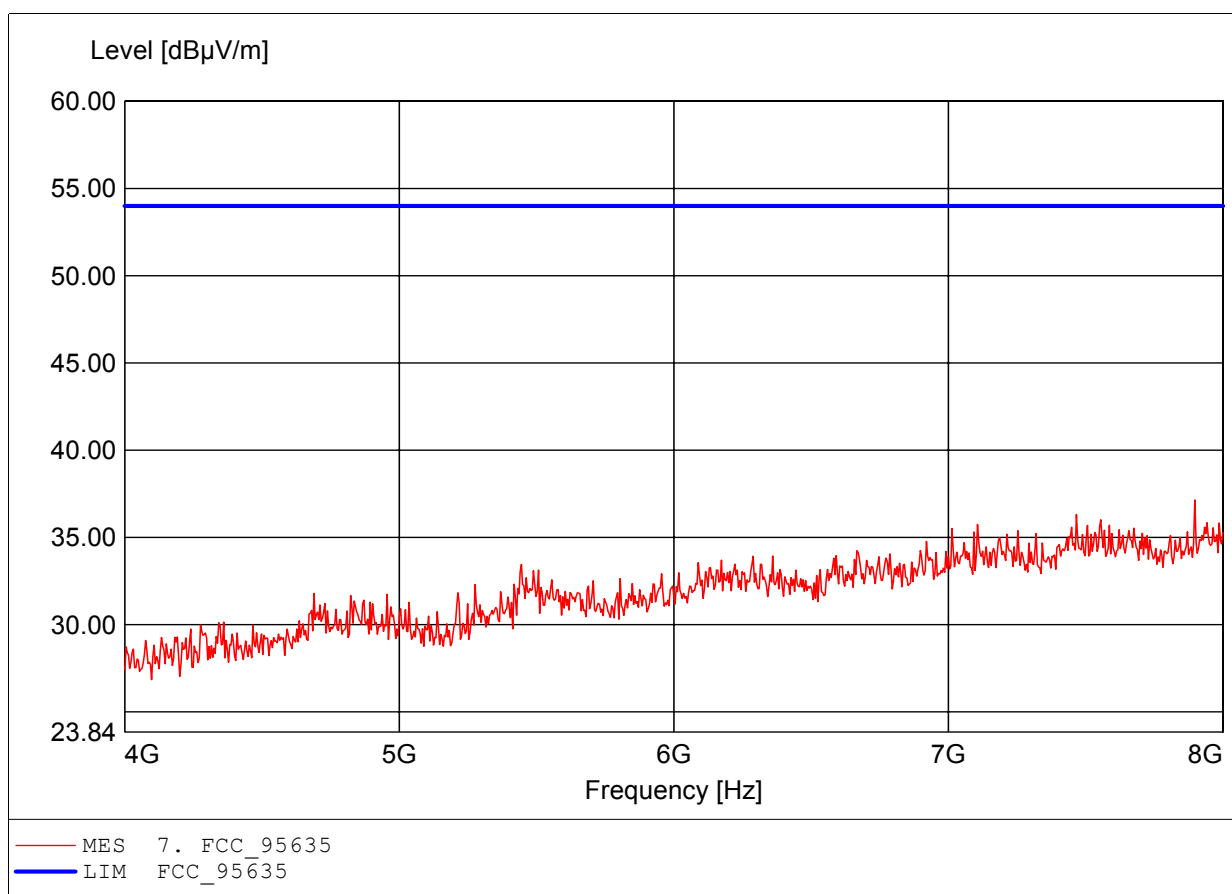
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.980GHz, Emax: 40.60dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

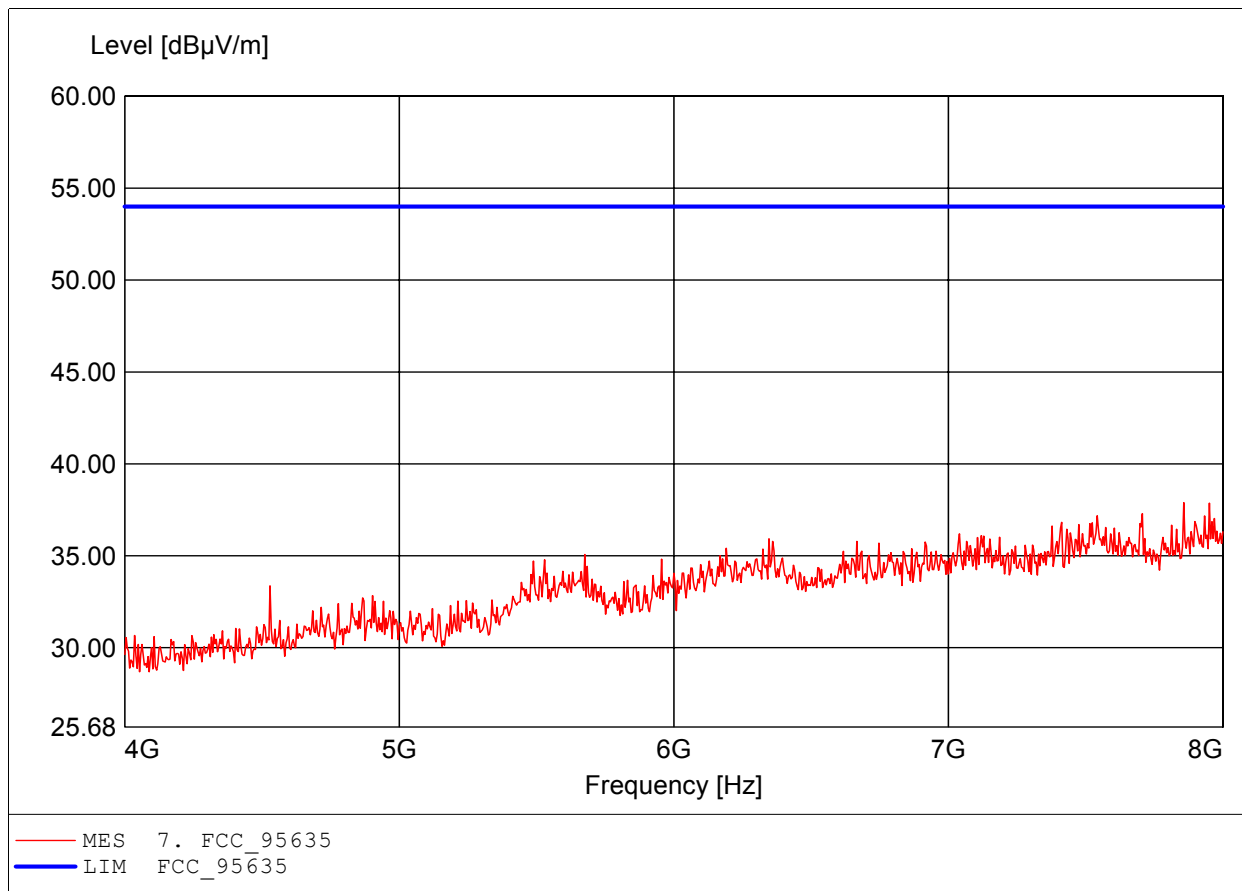
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 7.898GHz, Emax: 37.14dBµV/m, RBW: 1MHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 7.858GHz, Emax: 37.89dBµV/m, RBW: 1MHz

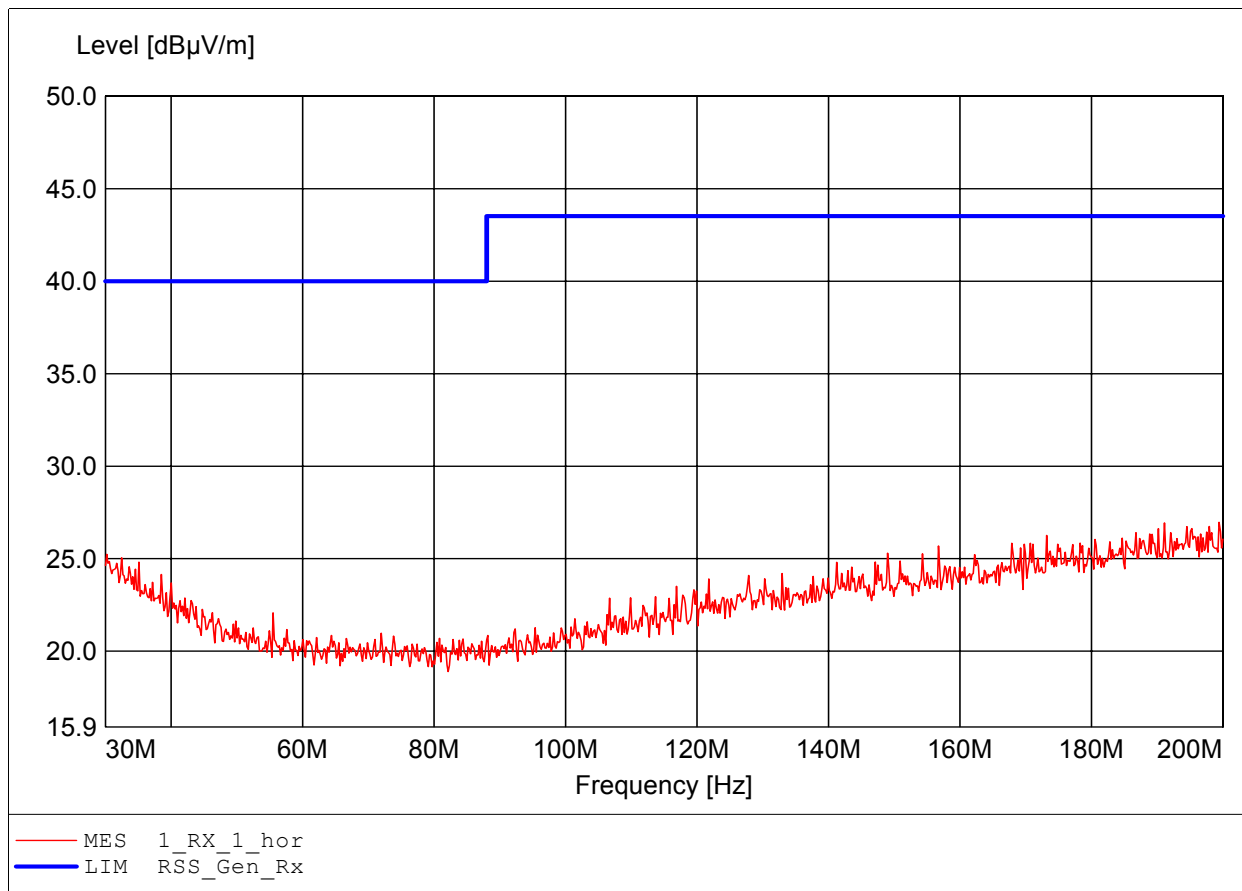


Annex F Receiver/Unintentional spurious emissions

Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

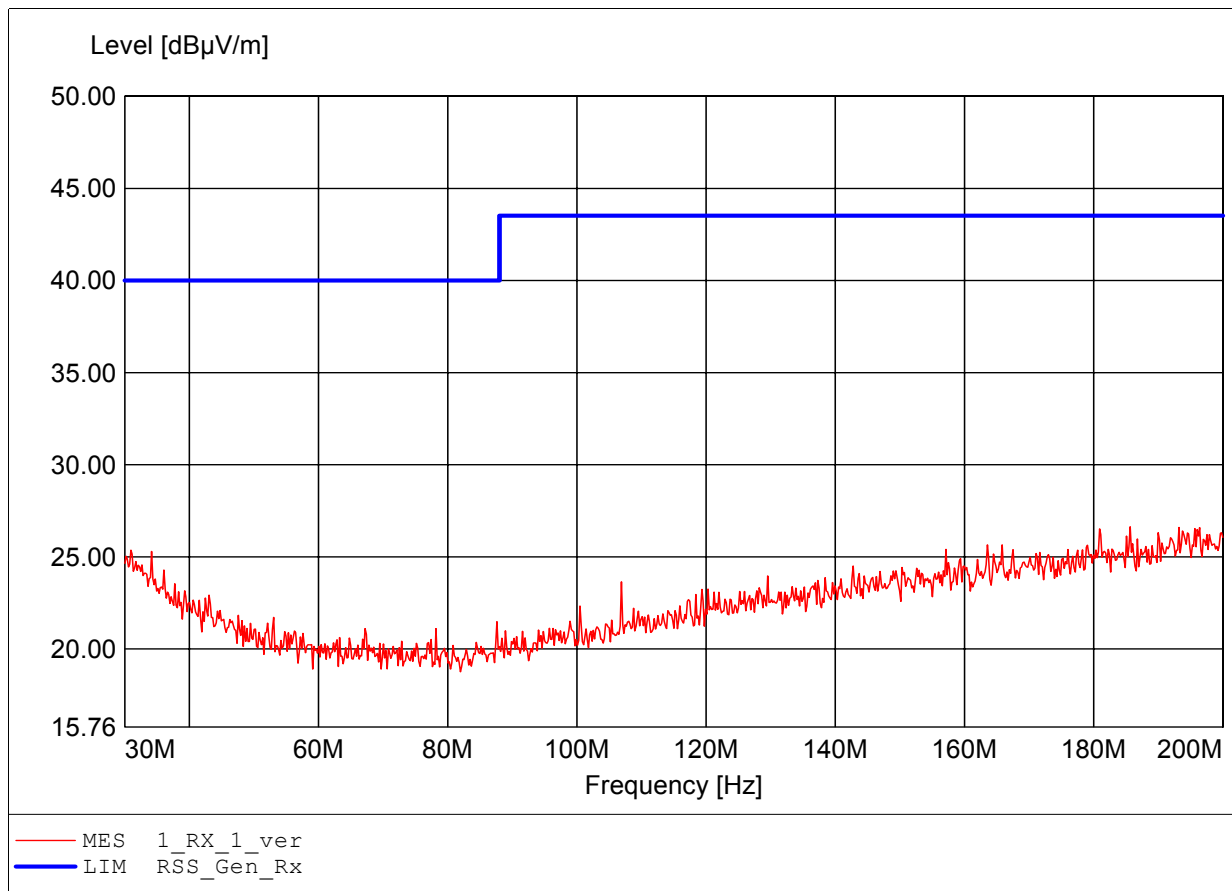
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: Freq. / CH: 1
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:199.433MHz Emax:26.97dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

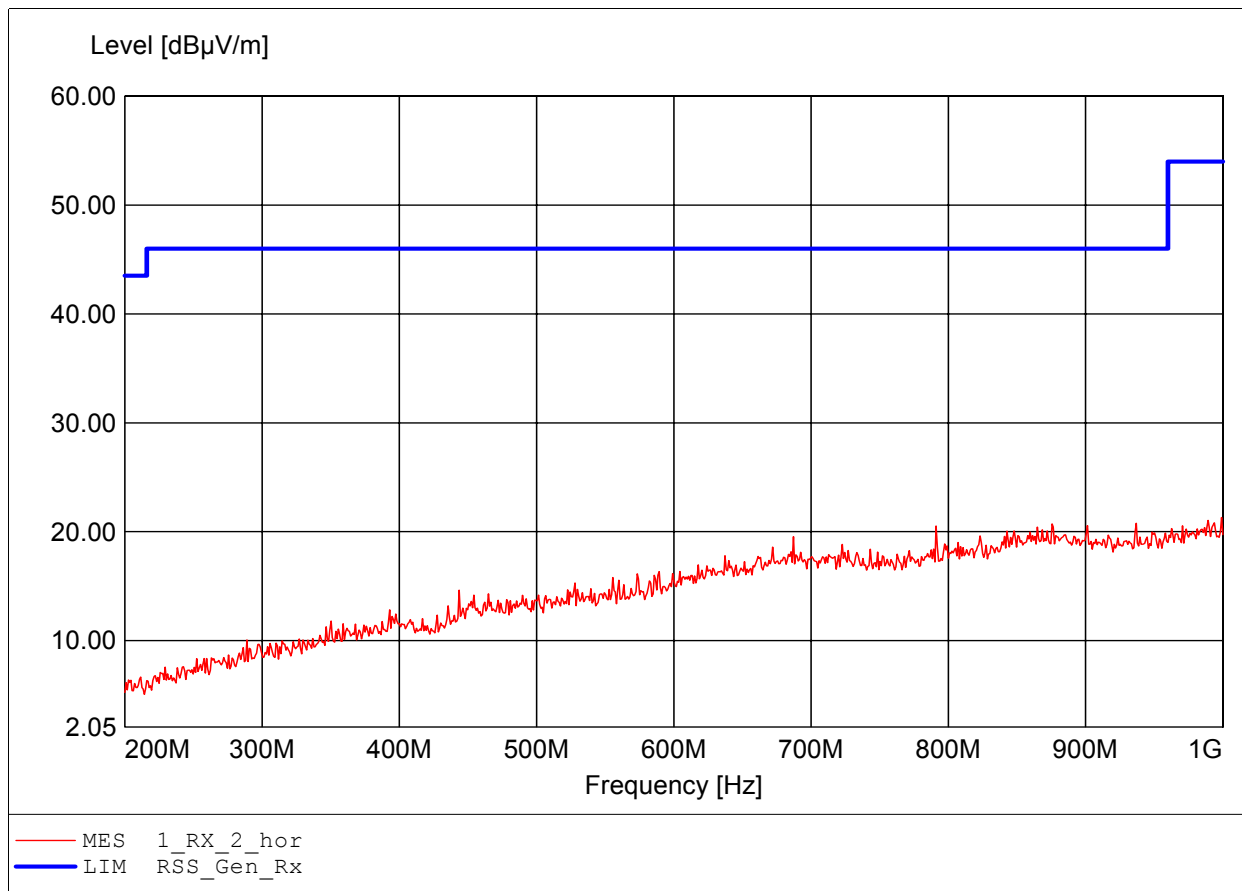
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: Freq. / CH: 1
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:185.644MHz Emax:26.63dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

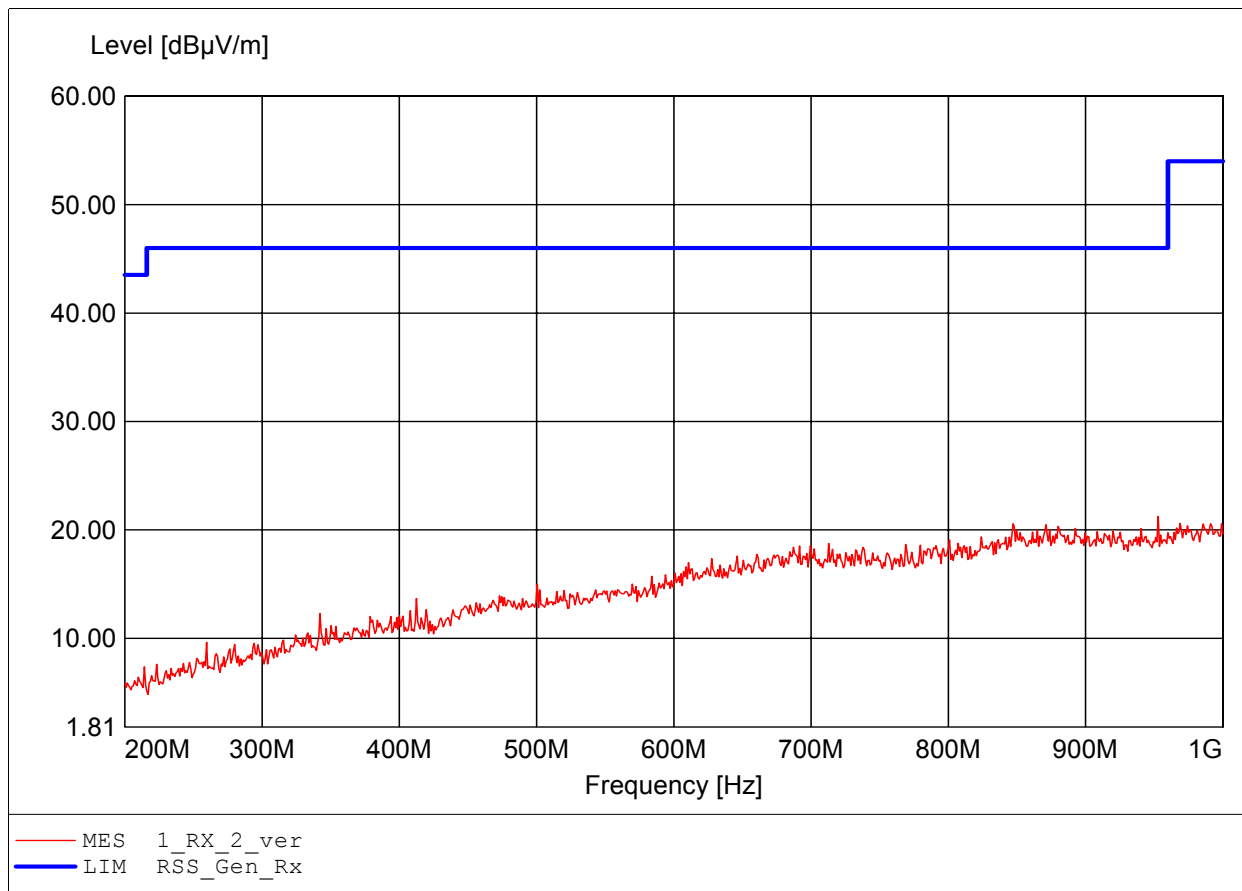
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: Freq. / CH: 1
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.
Comment 2: Freq:999.111MHz Emax:21.30dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

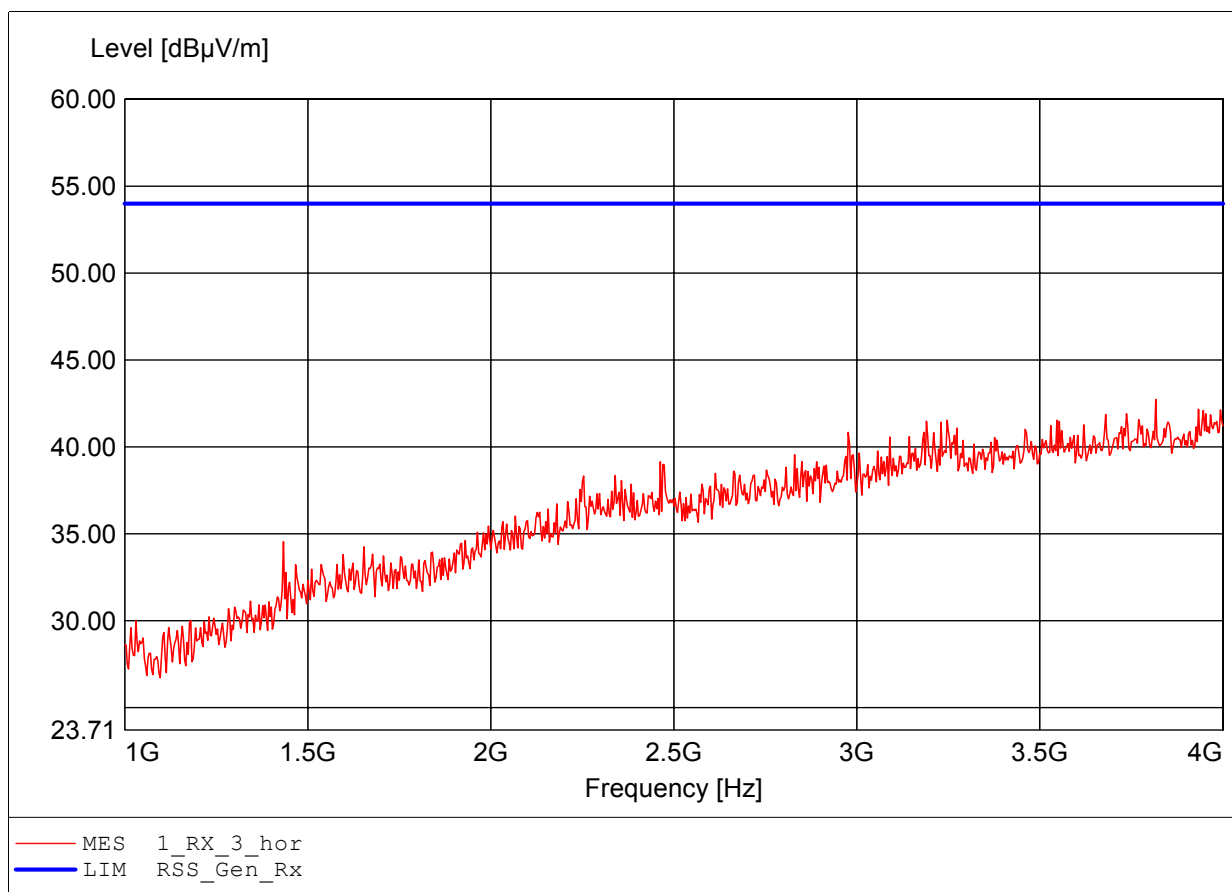
Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: Freq. / CH: 1
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.
Comment 2: Freq:952.889MHz Emax:21.24dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: Freq. / CH: 1
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:3.817GHz Emax:42.74dBµV/m RBW: 1 MHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT: ICD (Implantable Cardioverter Defibrillator)
Model: Lumax 6XX / Lumax 7XX / frequency 403.65MHz
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification: Freq. / CH: 1
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:3.897GHz Emax:41.72dBµV/m RBW: 1 MHz

