



EUROFINS PRODUCT SERVICE GMBH



RADIO TEST - REPORT

**EUROPEAN STANDARD EN 301 839
FCC RULES PART 95I
IC RADIO STANDARDS RSS-243**

FCC ID:QRIPRIMUS

Pacemaker, medical implant

PRIMUS

TEST REPORT NUMBER : G0M20810-2039-T-47_rev01



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TABLE OF CONTENT

1	General information	3
1.1	Notes	3
1.2	Testing laboratory	4
1.3	Details of approval holder	5
1.4	Application details	5
1.5	Test item	5
1.6	Test standards	6
2	Technical test	6
2.1	Summary of test results	6
2.2	Test environment	6
2.3	Test information	7
2.4	Test equipment utilized	8
2.5	Test results	9
3	Transmitter parameter	10
3.1	Frequency error	10
3.2	Emission bandwidth, Occupied bandwidth	11
3.3	Effective radiated power (e.r.p.)	12
3.4	Spurious emissions	13
3.5	Frequency stability under low voltage conditions	15
3.6	Unwanted radiation	15
3.7	Conducted measurements at AC power line	19
4	Receiver parameter	20
4.1	Spurious radiation	20
4.2	Discontinuation of MICS session	22
Annex A	Pictures	23
Annex B	Frequency Error	26
Annex C	20dB Emission bandwidth, Occupied bandwidth	34
Annex D	Radiated Power under normal conditions	41
Annex E	Spurious Radiation mode: TX	44
Annex F	Frequency stability under low voltage condition	51
Annex G	Unwanted radiations FCC RULES Part 95	53
Annex H	In-Band Emissions FCC RULES §95.635 (d) (4)	71
Annex I	Band Edge Emissions FCC RULES §95.635 (d) (5)	76
Annex J	Receiver spurious emission	79
Annex K	Discontinuation of MICS session	94
	Revision History	96

1 General Information

1.1 Notes

The purpose of conformity testing is to increase the probability of adherence to the essential requirements or conformity specifications, as appropriate.

The complexity of the technical specifications, however, means that full and thorough testing is impractical for both technical and economic reasons.

Furthermore, there is no guarantee that a test sample which has Passed all the relevant tests conforms to a specification.

Neither is there any guarantee that such a test sample will interwork with other genuinely open systems.

The existence of the tests nevertheless provides the confidence that the test sample possesses the qualities as maintained and that its performance generally conforms to representative cases of communications equipment.

This report covers test results according to EN 301 839-1 (ULP-AMI), FCC 95I (MICS) and RSS 243 (Active medical Implants) which are similar or the same related to test procedure and limits.

The test results of this test report relate exclusively to the item tested as specified in 1.5.

The test report may only be reproduced or published in full.

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Operator:

12.01.2010

W. Treffke



Date

Eurofins.

Name

Signature

Technical responsibility for area of testing:

12.01.2010

J. Zimmermann



Date

Eurofins

Name

Signature

1.2 Testing laboratory

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Germany

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1.2.1 Details of accreditation status

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

1.2.2 Test location, where different from Eurofins:

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

1.3 Details of approval holder

Name: Biotronik GmbH & Co. KG
Street: Woermannkehre 1
Town: 12359 Berlin
Country: Germany
Telephone: +1 503 6354016
Fax: +1 503 6359610

Contact: Mr. Brian P. Sutton
Telephone: +1 503 6354016

1.4 Application details

Date of receipt of application: 20.10.2008
Date of receipt of test item: 20.10.2008
Date of test: 20.10.2008 - 24.10.2008

1.5 Test item

Description of test item: Pacemaker, medical implant
Type identification: PRIMUS
Frequency range: 402 MHz – 405 MHz
Antenna: integrated
Antenna gain: -35 dBi
Operating mode: duplex
Kind of modulation: 2FSK
Number of channels: 9
Duty cycle: < 1%
Software: 3147197
Hardware: 359529-15102008
Power supply: 2.8 V DC (battery)
Serial number: 66000122
Photos: see Annex

Manufacturer:

Name: Biotronik GmbH & Co. KG
Street: Woermannkehre 1
Town: 12359 Berlin
Country: Germany

1.6 Test standards

Technical standard : EN 301 839-1; (ULP-AMI)
EN 301 839-2, (ULP-AMI)
FCC Part 95 Subpart I - Medical Implant Communications (MICS)
RSS-243 Iss2 (Active Medical Implants)

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 2.5 were ascertained in the course of the tests performed.

2.2 Test environment

Temperature: 18 ... 25 °C

Relative humidity content 20 ... 75 %

Air pressure: 860 ... 1030 hPa

Details of power supply: 2.8 V DC (battery)

Extreme conditions parameters:

Voltage	V_{nom}	: 2.8 V, DC
	V_{min}	: 2.5 V, DC
	V_{max}	: 3.2 V, DC
Temperature	T_{nom}	: 37 °C
	T_{min}	: +25 °C
	T_{max}	: +45 °C

Other parameters: Test Temperature T: 25 °C

2.3 Test information

For radiated tests the implant was placed in a simulated human body.
 Find Information of liquid preparation for simulated human body below.
 This device is considered as a specific low power equipment for "implant medical telemetry".

Reference: EN 301 839-1/-2.

Reference: Book: Simulated Biological Materials for Electromagnetic Radiation Absorption Studies;
 G. Hartsgrrove, A. Kraszewski and A. Surowiec

Compounding of liquid considered for simulated human body

Table 1.(A)

Components	Muscle Percentage per weight
Deionized water	52,4
Bactericide	0,08
Hydroxy Ethyl Cellulose (HEC)	1,0
Sodium chloride	1,4
Sucrose	45,0

Tolerance:

Measured electrical characteristics of liquid preparation for simulated human body

According to Table 2 Dielectric Constant and Conductivity of Tissue Equivalent Materials at Selected Frequencies,

	Measured Tissue Parameters		
	403,5MHz Muscle		
	Target	Measured	Tolerance in %
Dielectric Constant: ϵ	62,5	63,08	+0,93
Conductivity: σ [mS/cm]	9,0	8,8	-2.22

Dielectric parameters of the simulating liquids were verified to a tolerance of $\pm 5\%$.

Test equipment used: A005, ETS0468, ETS0469

2.4 Test equipment utilized

No.	Test equipment	Type	Manufacturer
ETS 0004	Spectrum- and Network-Analyzer	FSMS 26	R & S
ETS 0012	Biconical Antenna	HK 116	R & S
ETS 0013	LPD Antenna	HL 223	R & S
ETS 0015	Log Periodic Antenna	HL 025	R & S
ETS 0086	Semi-Anechoic chamber	AC 1	Frankonia
ETS 0087	Climatic cell	HC 4033	Heraeus
ETS 0291	Loop antenna	HFH2-Z2	R & S
ETS 0309	Anechoic chamber	AC 2	Frankonia
ETS 0496	Spectrum Analyzer	FSP	R & S
A 005	Human Torso Simulator		
ETS 0468	Network Analyzer 300 kHz to 3 GHz	8753C	Agilent
ETS 0469	Dielectric Probe Kit	85070C	Agilent

2.5 Test results (enclosure)
 1st test

 test after modification

 production test

Test case	Sub-clause EN	Sub-clause FCC	Sub-clause RSS-243	Test re- quest	Test results	
					pas- sed	failed
<i>TRANSMITTER PARAMETERS</i>						
Frequency error	8.1	95.628 (e)	3.3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Emission bandwidth	8.2	95.633 (e)	3.2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Effective radiated power	8.3	95.639(f)	5.4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Spurious emissions	8.4			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Frequency stability under low voltage conditions	8.5			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Unwanted radiation		95.635 (d)	3.4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Conducted emission (AC_power_line)		15.207		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>RECEIVER PARAMETERS</i>						
Spurious radiation	9.1	15.109	3.5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Monitoring system threshold power level	10.1	95.628 (a)(3)	5.7.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Monitoring system bandwidth	10.2	95.628 (a)(1)	5.7.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scan cycle time	10.3.1.1 10.3.3.1	95.628 (a)(2)	5.7.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Minimum channel monitoring period	10.3.1.2 10.3.3.2	95.628 (a)(2)	5.7.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Channel access	10.4	95.628 (a)(4)	5.7.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discontinuation of MICS session	10.5	95.628 (a)(4)	5.7.6 (f)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Use of pre-scanned alternate channel	10.6	95.628 (a)(5)	5.7.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3 Transmitter Parameters

3.1 Frequency error

**EN 301 839- 8.1; FCC 95.628(e)
RSS-243 – 3.3**

The frequency error is the difference between the frequency of the device under normal and extreme test conditions.

The measurements were performed as described in subclause 8.1.1 for the middle frequency within the band 402 MHz to 405 MHz, using a spectrum analyser and an environmental chamber.

Test conditions		Low frequency 402,45 MHz	Center frequency 403,65MHz	High frequency 404,85 MHz
$T_{nom} = 37\text{ °C}$	$V_{nom} = 2.8\text{ V}$	402,452240 8.5477 ppm	403,653264 8.09 ppm	404,854344 7.7658 ppm
$T_{min} = +25\text{ °C}$	$V_{min} = 2.5\text{ V}$	--	403,652677 6.63	--
	$V_{max} = 3.2\text{ V}$	--	403,652912 7.21 ppm	--
$T_{max} = +45\text{ °C}$	$V_{min} = 2.5\text{ V}$	--	403,652651 6.57	--
	$V_{max} = 3.2\text{ V}$	--	403,652831 7.01 ppm	--
Maximum frequency drift (ppm)		-7,4 ppm		
Measurement uncertainty		< 10^{-7} Hz		

Comment: See attached measurement diagrams, "Frequency Error" in Annex B.

Limits acc. subclause 8.1.2	Frequency error shall not exceed $\pm 100\text{ppm}$ ($\pm 40,36\text{ kHz}$)
-----------------------------	---

Test equipment used: ETS 0087, ETS 0496;

3.2 Emission bandwidth EN 301 839- 8.2; FCC 95.633(e)
Occupied bandwidth RSS-243 – 3.2

The emission bandwidth of the device under test is measured as the width of the signal between the points on either side of carrier centre frequency that are 20 dB down relate to the maximum level of the modulated carrier.

The measurements were performed as described in subclause 8.2.1.1 for the middle frequency within the band 402 MHz to 405 MHz.

Test conditions		Inside the assigned frequency band		
		402 MHz to 405 MHz		
$T_{\min} = 25\text{ °C}$	$V_{\text{nom}} = 2.8\text{ V}$	Low channel 402,45 MHz	Middle channel 403,65 MHz	High channel 404,85
Maximum radiated bandwidth (Hz)		180,60 kHz	182,00 kHz	180,00 kHz
Occupied bandwidth (kHz)		178,20 kHz	178,20 kHz	178,20 kHz
Measurement uncertainty		$\pm 1 \times 10^{-7}$		

Comment: See attached measurement diagram, „20dB Emission bandwidth“ and “Occupied bandwidth” in Annex C.

Limits acc. subclause 8.2.2	Maximum permitted emission bandwidth shall be 300 kHz
-----------------------------	---

Test equipment used: ETS 0496

3.3 Effective radiated power
**EN 301 839-8.3; FCC 95.639(f)
RSS-243 – 5.4**

The effective radiated power is the power radiated within the emission bandwidth of the EUT in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate.

The measurements were performed as described in subclause 8.3 for the middle frequency within the band 402 MHz to 405 MHz.

These tests are performed in a fully anechoic chamber equipped with suitable antennas, turn table, spectrum analyzer and control computer. All antenna gains, cable loss and applicable correction factors are calculated for final results.

Test instruction:

The EUT was adjusted so, that it transmits continuous unmodulated.

		Effective radiated power		Equivalent Isotropic Radiated Power	
		Center frequency 403,65MHz			
		dBm	μ W	dBm	μ W
$T_{\min} = 25\text{ }^{\circ}\text{C}$	$V_{\text{nom}} = 2.8\text{ V}$	-38,47	0,142	-36.33	0.232
Measurement uncertainty		$\pm 3\text{ dB}$			

Comment: See attached measurement diagrams, „Radiated Power under normal conditions“ in Annex D

The reported values are measured as effective radiated power.

Since EIRP is equivalent to ERP modified by dipole antenna gain; i.e. $EIRP = ERP + 2.14\text{dB}$, these ERP values can be converted to EIRP by attending 2.14dB to the reported measurements. All transmitter and receiver parameters (power, spurious emissions, unwanted radiation and spurious radiation) continue to be within the applicable regulatory limits.

Limits acc. subclause 8.3.2	The effective radiated power shall not exceed $25\mu\text{W}$ ETSI: Radiated Power $\leq 25\mu\text{W}$ ERP (-16dBm) FCC: Radiated Power $\leq 25\mu\text{W}$ EIRP (-16dBm)
-----------------------------	---

Test equipment used: ETS 0004; ETS 0012, ETS 0013, ETS 0015, ETS 0291, ETS 0309;

3.4 Spurious emissions

EN 301 839- 8.4

Spurious emissions are emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation.

Active medical implants shall have the effective radiated power (ERP) of their spurious emissions using the specified test fixture (simulated man).

These tests are performed in a fully anechoic chamber equipped with suitable antennas, turn table, spectrum analyzer and control computer. All antenna gains, cable loss and applicable correction factors are calculated for final results.

Test instruction:

The EUT was adjusted so, that it transmits continuous modulated.

TX mode	Frequency range	Limit	Spurious emissions	
operating	25 MHz - 47 MHz	250 nW	-71 dBm	79,433 pW
	47 MHz - 74 MHz	4 nW	-73 dBm	50,119 pW
	74 MHz - 87,5 MHz	250 nW	-71 dBm	79,433 pW
	87,5 MHz - 118 MHz	4 nW	-71 dBm	79,433 pW
	118 MHz - 174 MHz	250 nW	-64 dBm	398,107 pW
	174 MHz - 230 MHz	4 nW	-63 dBm	501,187 pW
	230 MHz - 470 MHz	250 nW	-81 dBm	7,943 pW
	470 MHz - 862 MHz	4 nW	-77 dBm	19,953pW
	862 MHz - 1 GHz	250 nW	-75 dBm	31,623 pW
	1 GHz - 4 GHz	1 μ W	-48,98 dBm	12,647 nW
standby	< 1GHz	2 nW	--	--
	> 1 GHz	20 nW	--	--
Measurement uncertainty		\pm 6dB		

Remark: Standby mode was not tested because the spurious emission values of operating mode were below the limits for standby mode.

Comment: See attached diagrams in Annex E.

Limits acc. subclause 8.4.2

State	47 MHz to 74 MHz 87,5 MHz to 118 MHz 174 MHz to 230 MHz 470 MHz to 862 MHz	Other frequencies below 1GHz	Frequencies above 1 GHz
operating	4 nW (-54dBm)	250 nW (-36dBm)	1 μ W (-30dBm)
standby	2 nW (-57dBm)	2 nW (-57dBm)	20 nW (-47dBm)

Test equipment used: ETS 0004; ETS 0012, ETS 0013, ETS 0015, ETS 0291, ETS 0309;

3.5 Frequency stability under low voltage conditions EN 301 839 - 8.5

Applicable for battery operating equipment only

The frequency stability under low voltage conditions is the ability of the equipment to remain within its permitted frequency limits when the battery voltage falls below the lower extrem voltage level.

Test instruction:
The EUT must be adjusted so, that it transmits continuous unmodulated.

The measured carrier frequency = 403,646 MHz

Test conditions		Center frequency 403,65MHz
$T_{min} = 25\text{ °C}$	$V_{low} = 1,5\text{ V}$	403,650789
Frequency drift (ppm)		1,95 ppm
Measurement uncertainty		$< 10^{-7}\text{ Hz}$

Comment: See attached diagram in Annex F "Frequency stability under low voltage conditions"

The EUT remain on the nominal operating frequency, within the limits stated in clause 8.1.2 whilst the radiated power is greater than the spurious emission limits (-36 dBm).

Limits acc. subclause 8.5.2	<p>Transmit with a carrier frequency within the limits of ± 100 ppm whilst the radiated or conducted power is below the spurious emission limits; or</p> <p>Automatically cease to function below the provider's declared operating voltage</p>
-----------------------------	--

Test equipment used: ETS 0496

3.6 Unwanted radiation

FCC 95.635 (d); RSS-243-3.4

The intention of these tests is to prove whether the sample meets the requirements to save the spectrum against unwanted radiations.

The radiated test under this sub-clause are performed according to ANSI 63.4 in a semianechoic chamber. Such factors like antenna correction, cable loss, external attenuation etc. are already included in the provided measurement results. This is done by using validated test software and calibrated test system according to the accreditation requirements.

Out-of-band emissions

FCC 95.635(d)(1); RSS-243-5.5

The sample complies with the requirements

Comment: See attached diagrams in Annex G, all other noted test plots do not contain significant test results in relation to the limits, no spurious was found after the limit. The EUT does meet the FCC requirements.

Limits acc. FCC 95.635 (d)(1)

Frequency (MHz)	Field strength ($\mu\text{V}/\text{m}$)	Measurement distance (m)
30 - 88	100	3
88 -216	150	3
216 - 960	200	3
960 and above	500	3

Test equipment used: ETS 0004; ETS 0012, ETS 0013, ETS 0015, ETS 0291, ETS 0309;

The unwanted radiation measurements shall be performed with usual test modulation.

In-band emissions**FCC 95.635(d)(4); RSS-243-5.5**

Emissions within the MICS band (402 – 405 MHz) more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20 dB.

The sample complies with the requirements

max. measured power = 55,36dB μ V/m

55,36 dB μ V/m – 20dB = 35,36 dB μ V/m \triangleq limit line

Comment: See attached diagrams in Annex H, all other noted test plots do not contain significant test results in relation to the limits. The EUT does meet the FCC requirements.

Test equipment used: ETS 0004; ETS 0012, ETS 0013, ETS 0015, ETS 0291, ETS 0309;

The unwanted radiation measurements shall be performed with usual test modulation.

Band-edge emissions

FCC 95.635(d)(5)

Emissions 250 kHz or less that are above and below the MICS band (402 – 405 MHz) will be attenuated below the maximum permitted output power by at least 20 dB (-16 dBm e.i.r.p.).

The sample complies with the requirements

Band edge: 20dB under allowed radiated power 25μW

$$25\mu W \triangleq 9100\mu V/m \triangleq 79,2dB\mu V/m$$

$$79,2dB\mu V/m - 20dB = 59,2 dB\mu V/m$$

Comment: See attached diagrams in Annex I, all other noted test plots do not contain significant test results in relation to the limits. The EUT does meet the FCC requirements.

Test equipment used: ETS 0004; ETS 0012, ETS 0013, ETS 0015, ETS 0291, ETS 0309;

The unwanted radiation measurements shall be performed with usual test modulation.

3.7 Conducted measurement at AC power line FCC Part15

For an intentional radiator which is designed to be connected to the public utility (AC) power line, the radio frequency voltage that is conducted back onto the AC line on any frequency or frequencies within the band 150 kHz to 30 MHz shall not exceed the limits in the table below. Compliance with this provision shall be based on the measurement of the radio frequency voltage between each power line and ground at the power terminals.

This measurement was transact first with instrumentation using an average and peak detector and a 10 kHz bandwidth. If the peak detector achieves a calculated level, the measurement is repeated by an instrumentation using a quasi-peak detector.

Frequency	Level	
	quasi-peak	average
150 kHz	--	--

Comment: not applicable.

Limits:

Frequency of Emission (MHz)	Conducted Limit (dBuV)	
	Quasi Peak	Average
0.15-0.5	66 to 56	56 to 46
0.5-5	56	46
5-30	60	50

Test equipment used: --

4 Receiver Parameter

4.1 Spurious radiation

EN 301 839-9.1

FCC 15.109

RSS-243 – 3.5

Spurious radiations from the receiver are components at any frequency, generated and radiated by active receiver circuitry and antenna.

Test instruction:

The EUT is adjusted to receive but does not transmit.

Frequency range	Maximum spurious radiation [dBm]
25 MHz - 200 MHz	-65,95
200 MHz - 1 GHz	-76,45
1 GHz - 4 GHz	-58,59
Measurement uncertainty	±6dB

Limits acc. subclause 9.1.2	The spurious emission shall not exceed 2nW (-57 dBm) below 1GHz 20nW (-47 dBm) above 1GHz
-----------------------------	---

Comment: See attached diagrams "Receiver spurious emissions" in Annex J.

Test equipment used: ETS 0004; ETS 0012, ETS 0013, ETS 0015, ETS 0291, ETS 0309;

Test Results – RSS -Gen

Device Frequency	Frequency marker indication [MHz]	Antenna polarization	Worst case emission level [$\mu\text{V/m}$]	Compliance limit [$\mu\text{V/m}$]	Results [$\mu\text{V/m}$]
403,65 MHz	199,244	V	22,05	150	<u>-127,95</u>
	198,111	H	24,86	150	<u>-125,14</u>
	976,889	V	11,87	500	<u>-488,13</u>
	980,444	H	11,61	500	<u>-488,39</u>
	3957,000	V	129,57	500	<u>-370,43</u>
	3987,000	H	147,23	500	<u>-352,77</u>
	7778,000	V	138,36	500	<u>-361,64</u>
	7956,000	H	137,09	500	<u>-362,91</u>

Limits

	Spurious frequency	Field strength
	MHz	microvolt/m at 3 meter
FCC IC	30 - 88	100
	88 - 216	150
	216 - 960	200
	above 960	500

See attached diagrams in Annex J.

Test equipment: ETS 0014, ETS 0294, ETS 0295, ETS 0310, ETS 0416, ETS 0484

4.2 Discontinuation of MICS session EN 301 839-10.5 FCC 95.628 (a)(4)

MICS system shall cease transmission in the event that the communication session is interrupted for a period of 5s or more.

Check, whether communication switching off, after 5s break

All channels are occupied, except channel 0.
Measure time up to communication switching off.

Test conditions		Center frequency 403,65 MHz Measured time up to communication switching off
T = 25 °C	V _{nom} = 2.8 V	< 4s
Measurement uncertainty		<1µs

Comment: See attached measurement diagrams, "Discontinuation of MICS session if a silent period greater then or equal 5s occurs" in Annex K.

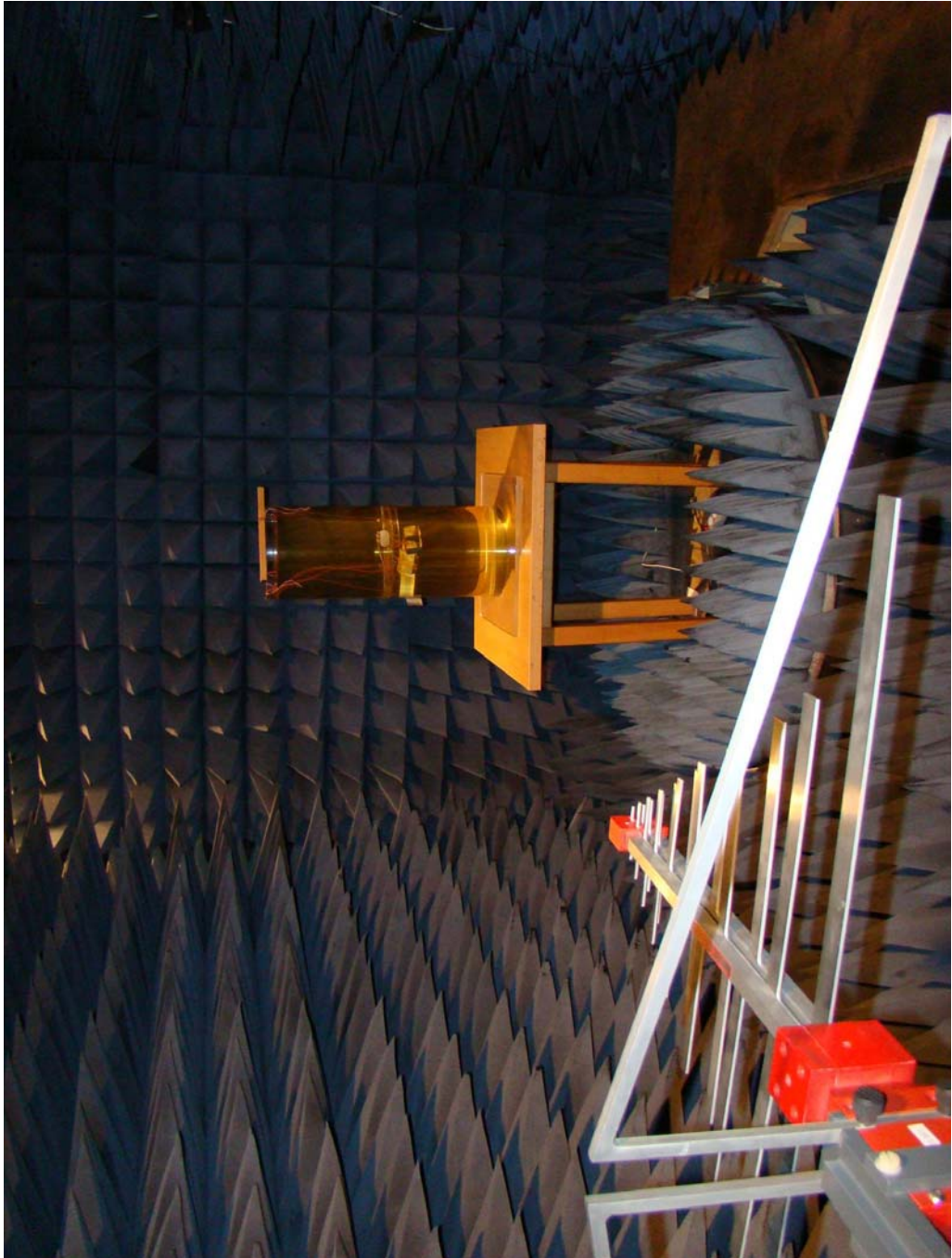
Limit acc. subclause 10.5.2	Time up to communication switching off must be ≤ 5s.
------------------------------------	--

Test equipment used: ETS 0253

Annex A Pictures





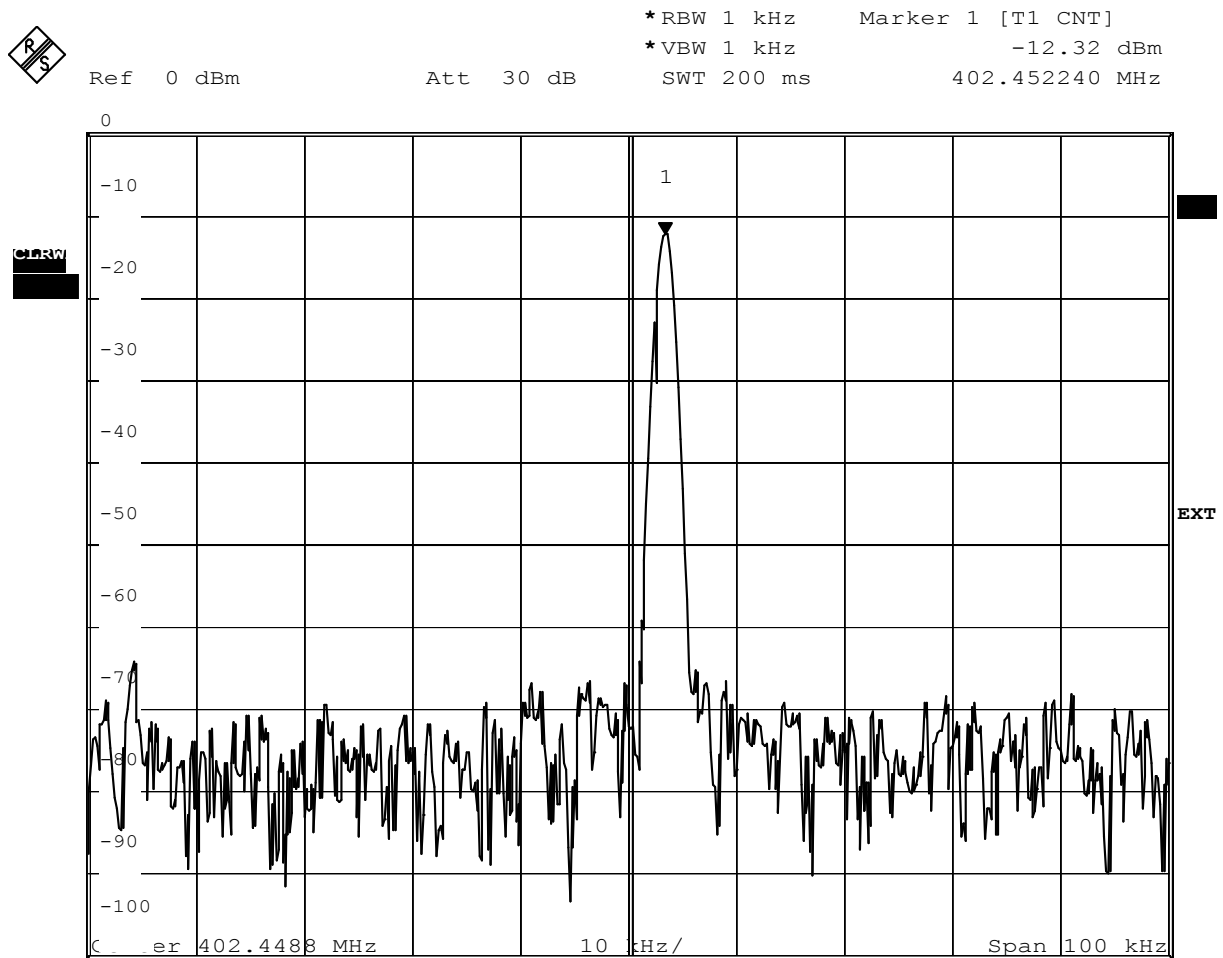


Annex B

Measurement diagrams “Frequency Error”

FCC Part 95.628 / EN 301 839 v1.1.1 / RSS-434
Frequency Error / Frequency deviation

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.628 e / EN 301 839-1 8.1 / RSS-243 3.3
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 402.4488 MHz / 8.5477 ppm
Comment 3	Limit +/-100 ppm



Date: 21.OCT.2008 09:31:40

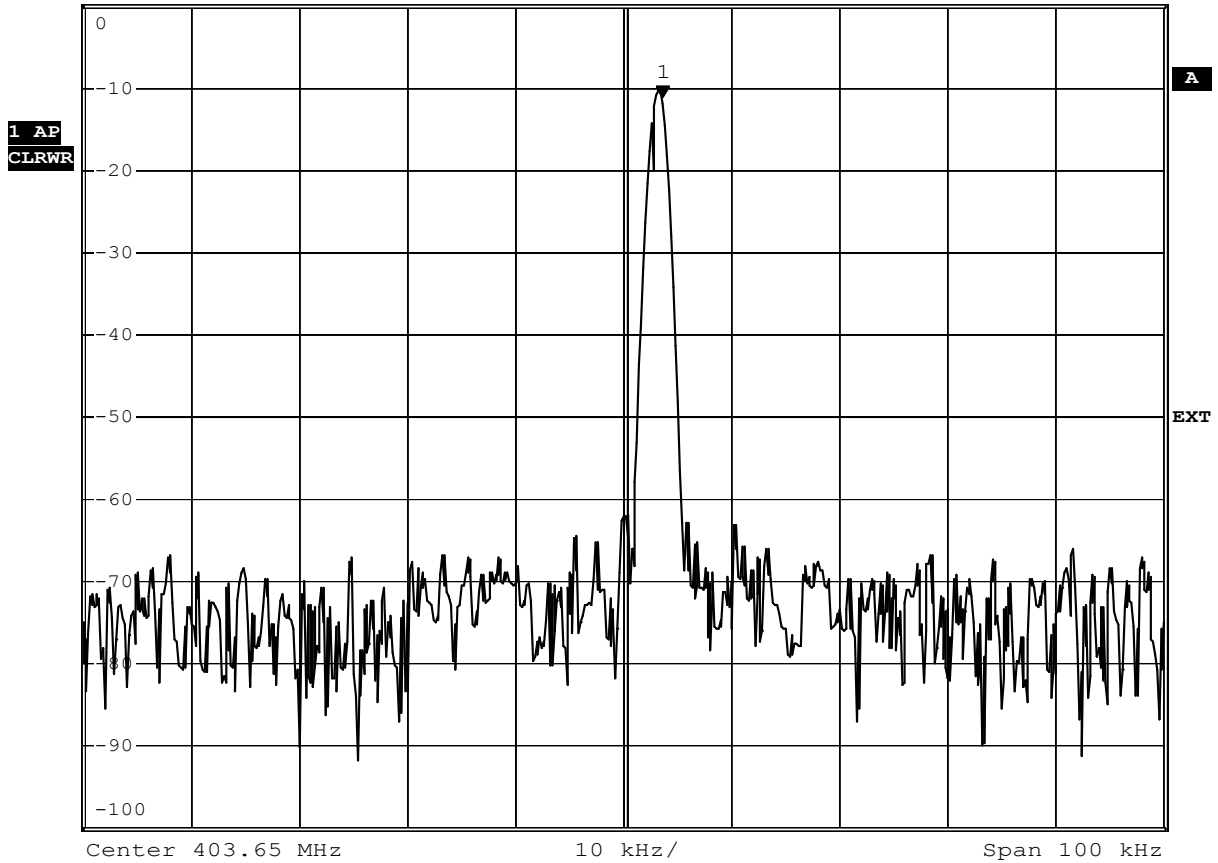
Measurement diagram

FCC Part 95.628 / EN 301 839 v1.1.1 / RSS-434
Frequency Error / Frequency deviation

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.628 e / EN 301 839-1 8.1 / RSS-243 3.3
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 403.65 MHz / 8.09 ppm
Comment 3	Limit +/-100 ppm



*RBW 1 kHz Marker 1 [T1 CNT]
 *VBW 1 kHz -11.09 dBm
 Ref 0 dBm Att 30 dB SWT 200 ms 403.653264 MHz



Date: 21.OCT.2008 09:13:42

Measurement diagram

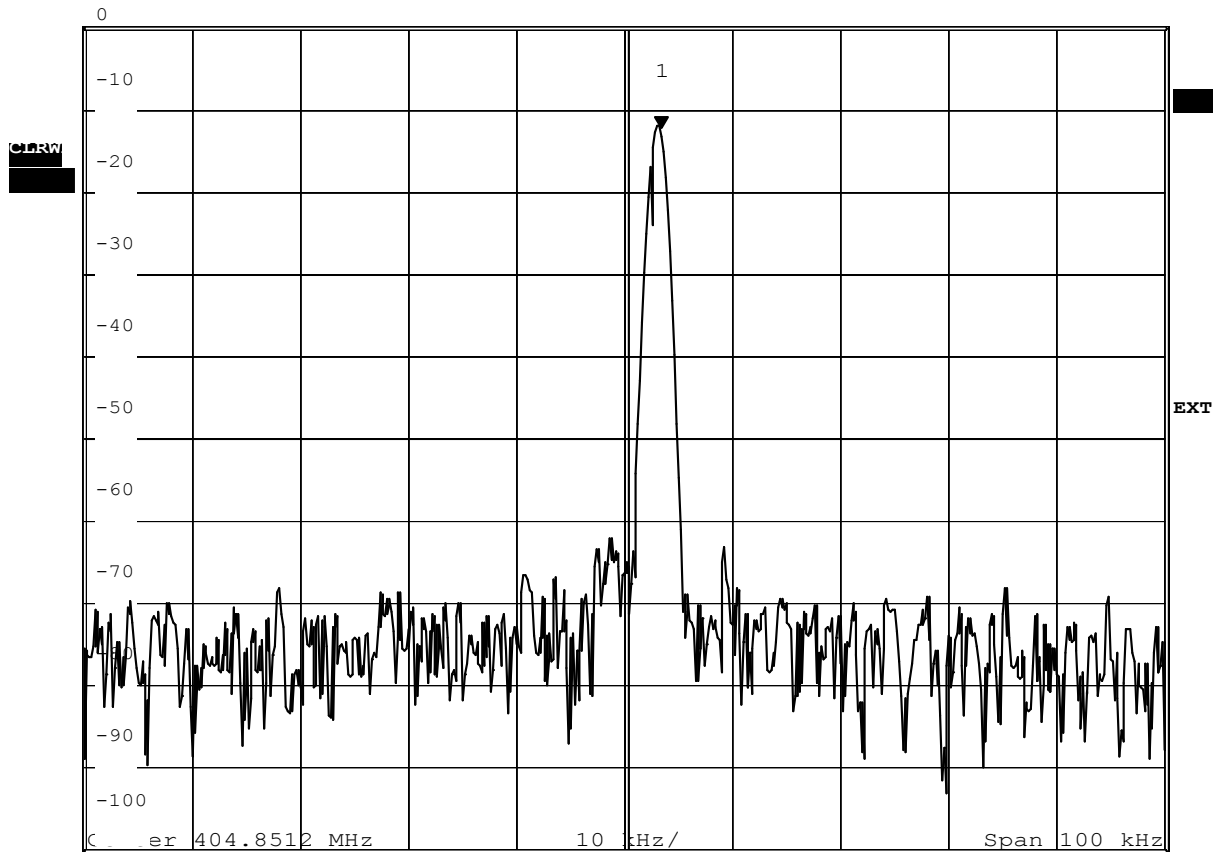
Eurofins ETS Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

FCC Part 95.628 / EN 301 839 v1.1.1 / RSS-434
Frequency Error / Frequency deviation

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.628 e / EN 301 839-1 8.1 / RSS-243 3.3
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 404.8512 MHz / 7.7658 ppm
Comment 3	Limit +/-100 ppm



Ref	0 dBm	Att	30 dB	*RBW	1 kHz	Marker 1 [T1 CNT]	
				*VBW	1 kHz		-12.29 dBm
				SWT	200 ms		404.854344 MHz

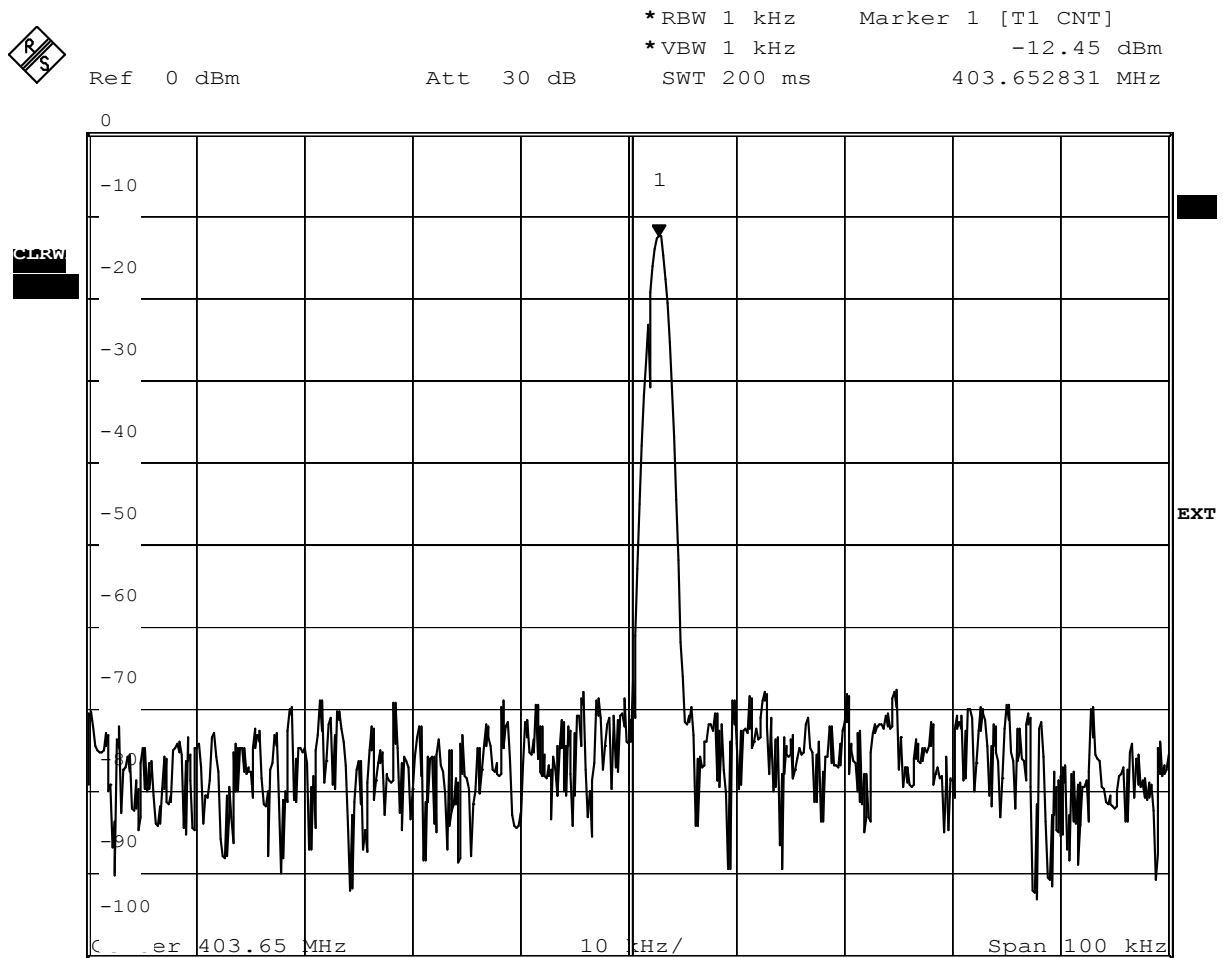


Date: 21.OCT.2008 09:49:09

Measurement diagram

FCC Part 95.628 / EN 301 839 v1.1.1
Frequency Error / Frequency deviation

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	45°C / Umax: 3.2 V DC
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.628 e / EN 301 839-1 8.1
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 403.65 MHz / 7.01 ppm
Comment 3	Limit +/-100 ppm



Date: 22.OCT.2008 08:00:13

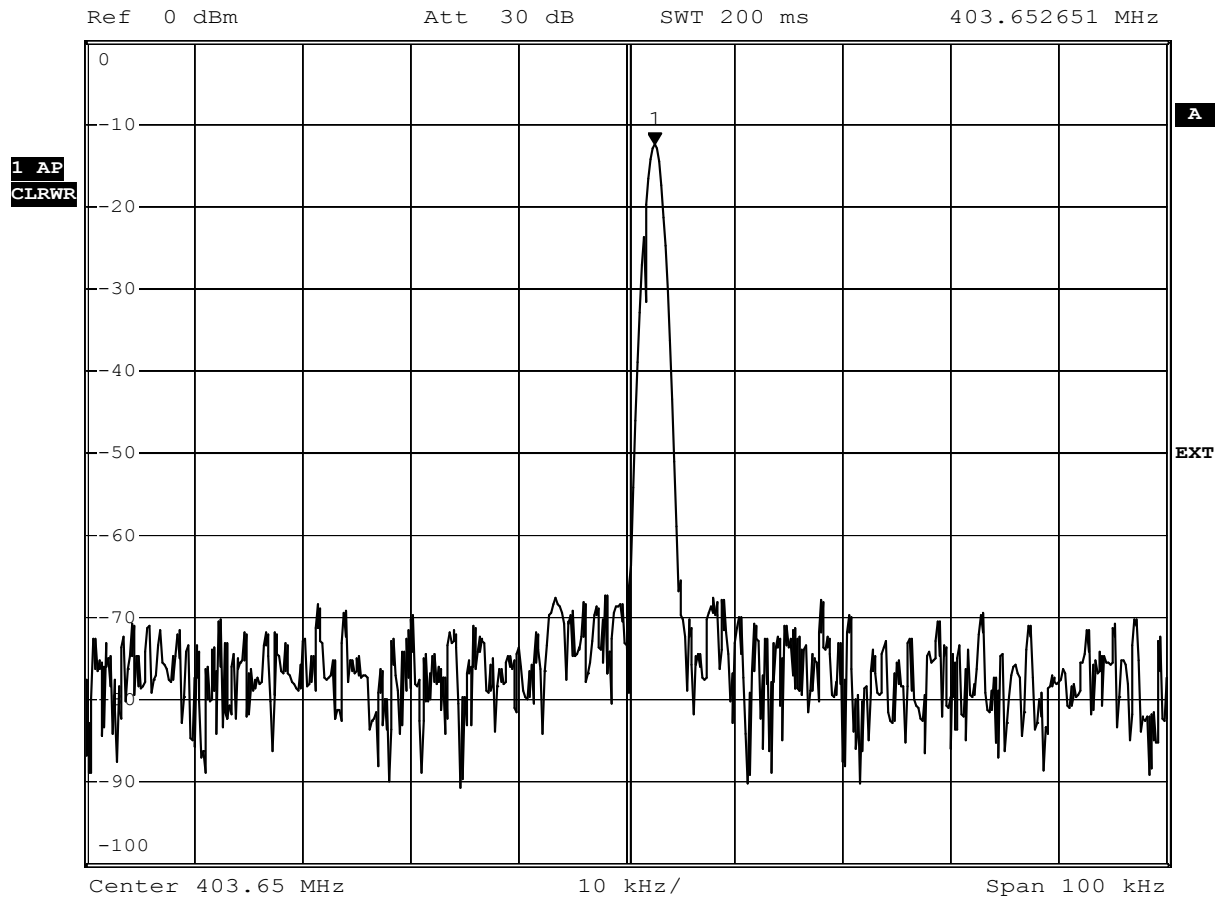
Measurement diagram

FCC Part 95.628 / EN 301 839 v1.1.1
Frequency Error / Frequency deviation

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	45°C / Umin: 2.5 V DC
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.628 e / EN 301 839-1 8.1
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 403.65 MHz / 6.57 ppm
Comment 3	Limit +/-100 ppm



*RBW 1 kHz Marker 1 [T1 CNT]
 *VBW 1 kHz -12.59 dBm
 SWT 200 ms 403.652651 MHz

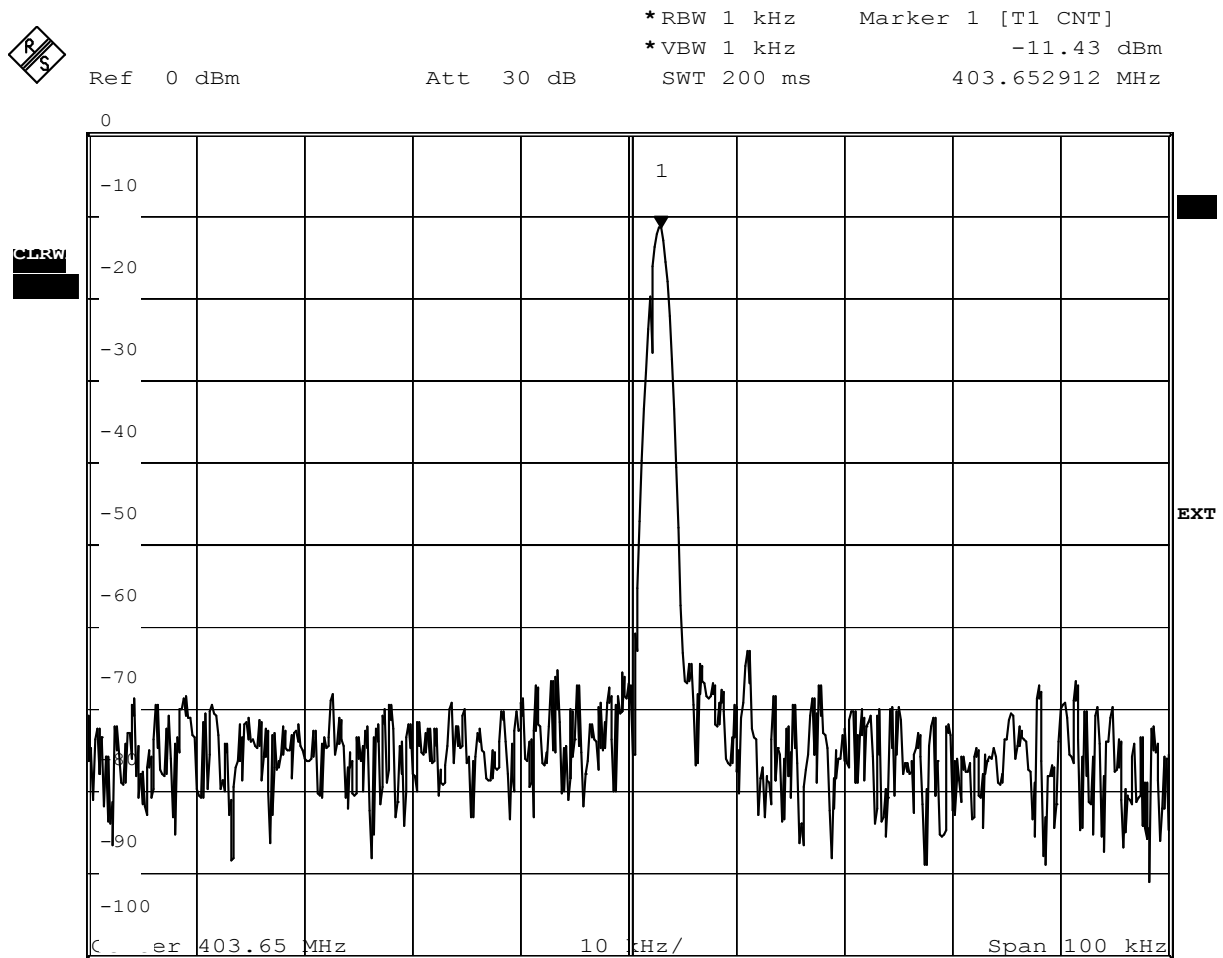


Date: 22.OCT.2008 08:03:51

Measurement diagram

RSS-243
Frequency Stability

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	37°C / Umax: 3.2 V DC
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	RSS-243 3.3 Frequency Stability
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 403.65 MHz / 7.21 ppm
Comment 3	Limit +/-100 ppm



Date: 22.OCT.2008 07:20:11

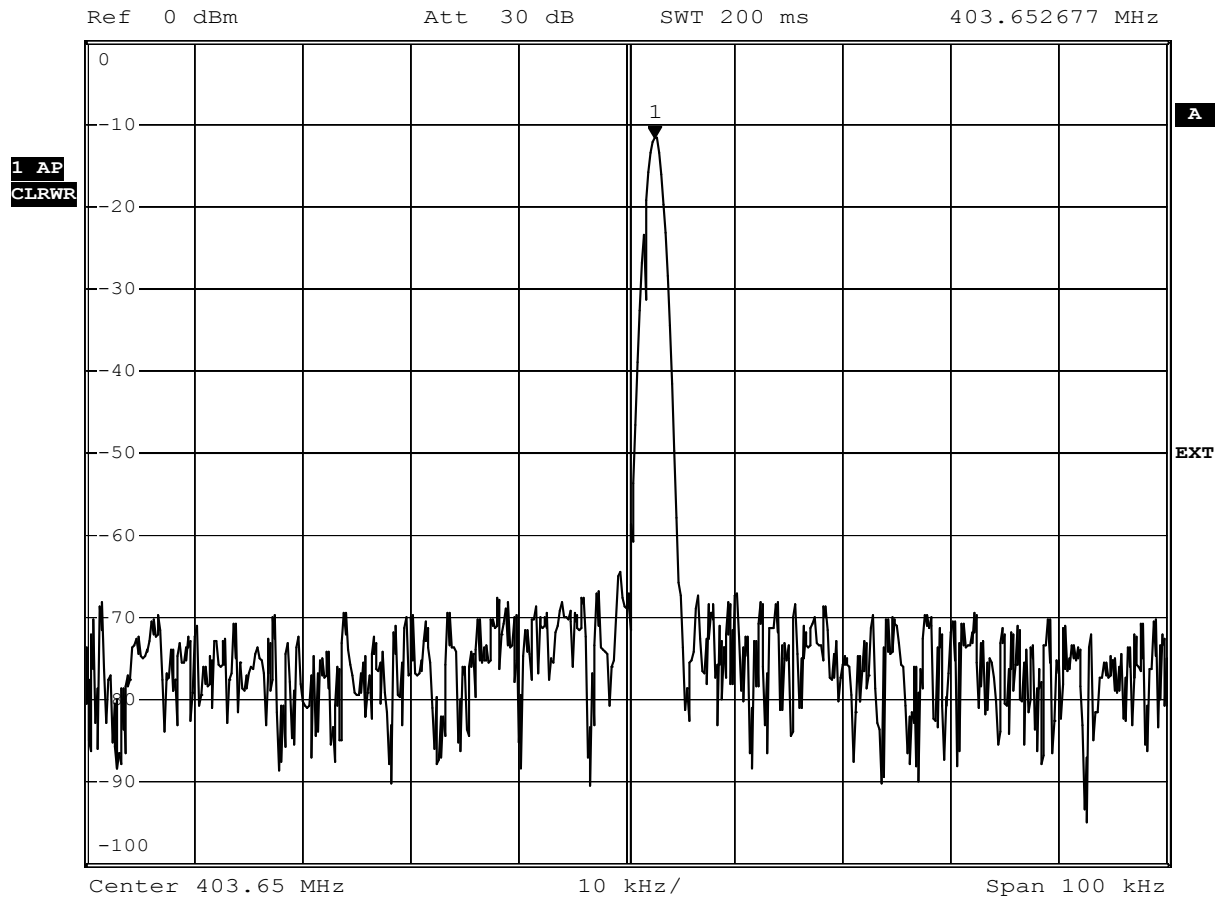
Measurement diagram

RSS-243
Frequency Stability

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	37°C / Umin: 2.5 V DC
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	RSS-243 3.3 Frequency Stability
Comment 1	Frequency Error (signal count function of analyzer)
Comment 2	f: 403.65 MHz / 6.63 ppm
Comment 3	Limit +/-100 ppm



*RBW 1 kHz Marker 1 [T1 CNT]
 *VBW 1 kHz -11.64 dBm
 SWT 200 ms 403.652677 MHz



Date: 22.OCT.2008 07:14:50

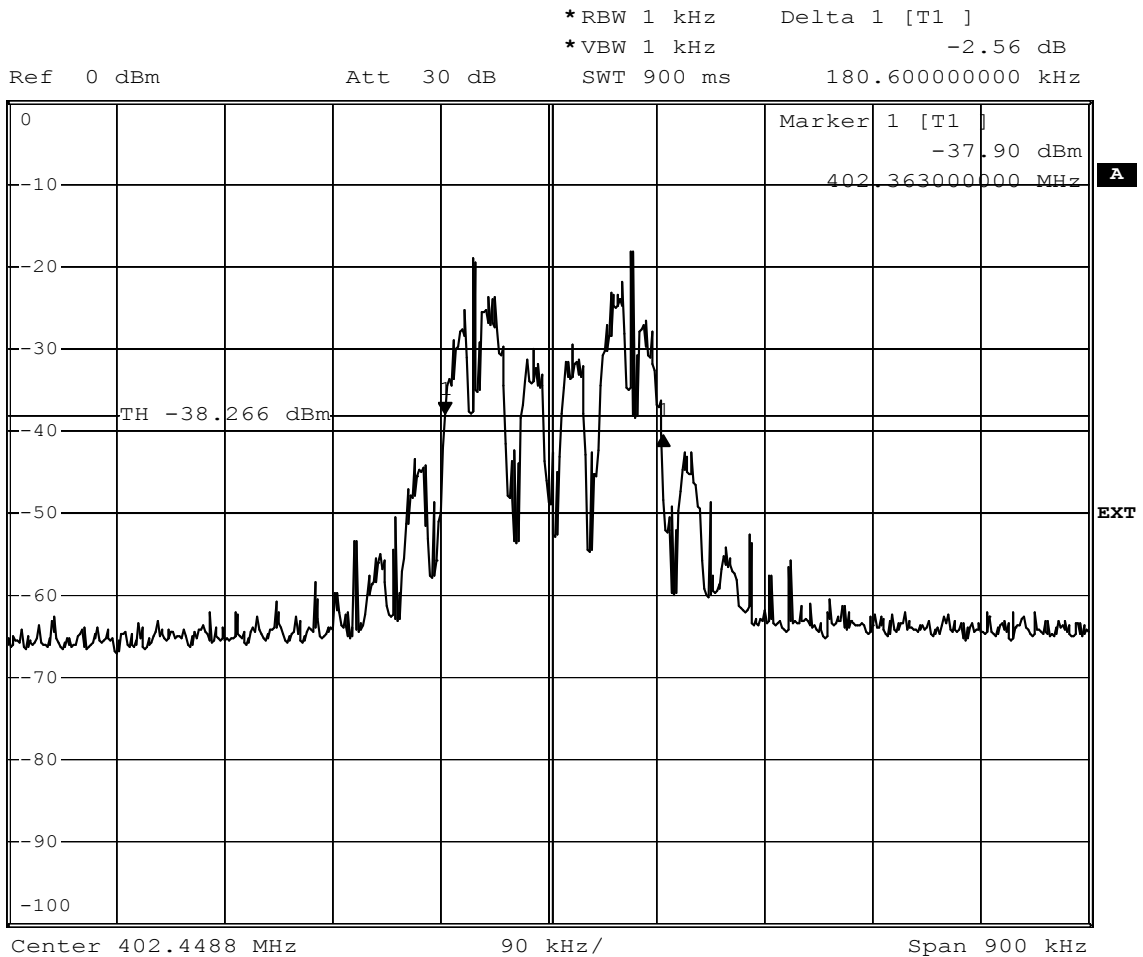
Measurement diagram

Annex C

Measurement diagrams “20dB Emission bandwidth”; “Occupied Bandwidth”

FCC Part 95.633 / EN 301 839 v1.1.1
Emission bandwidth / Maximum radiation bandwidth

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.633 e / EN 301 839-1 8.2
Comment 1	20 dB Emission bandwidth
Comment 2	f high-flow Bandwidth: 180.6 kHz
Comment 3	Limit 300KHz

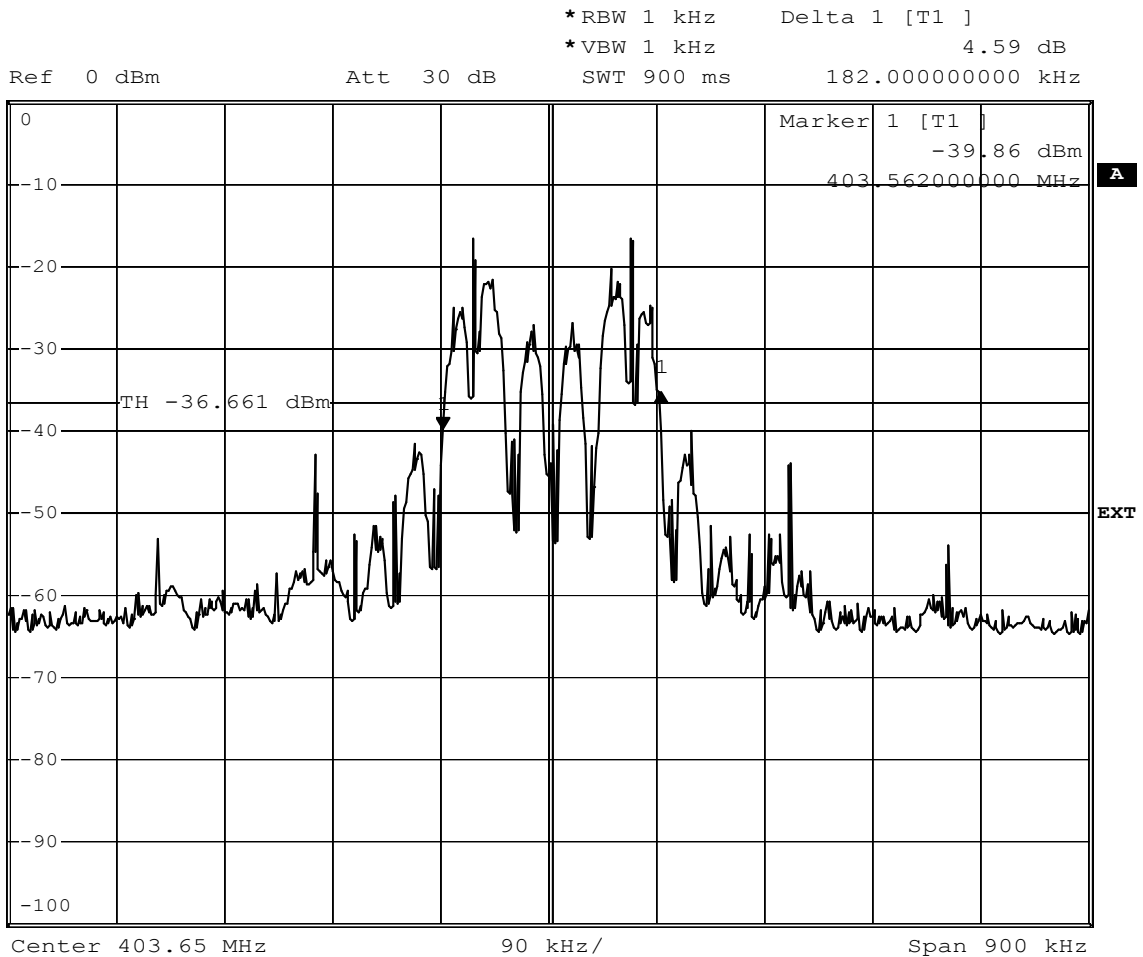


Date: 21.OCT.2008 10:28:12

Measurement diagram

FCC Part 95.633 / EN 301 839 v1.1.1
Emission bandwidth / Maximum radiation bandwidth

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.633 e / EN 301 839-1 8.2
Comment 1	20 dB Emission bandwidth
Comment 2	f high-flow Bandwidth: 182 kHz
Comment 3	Limit 300KHz

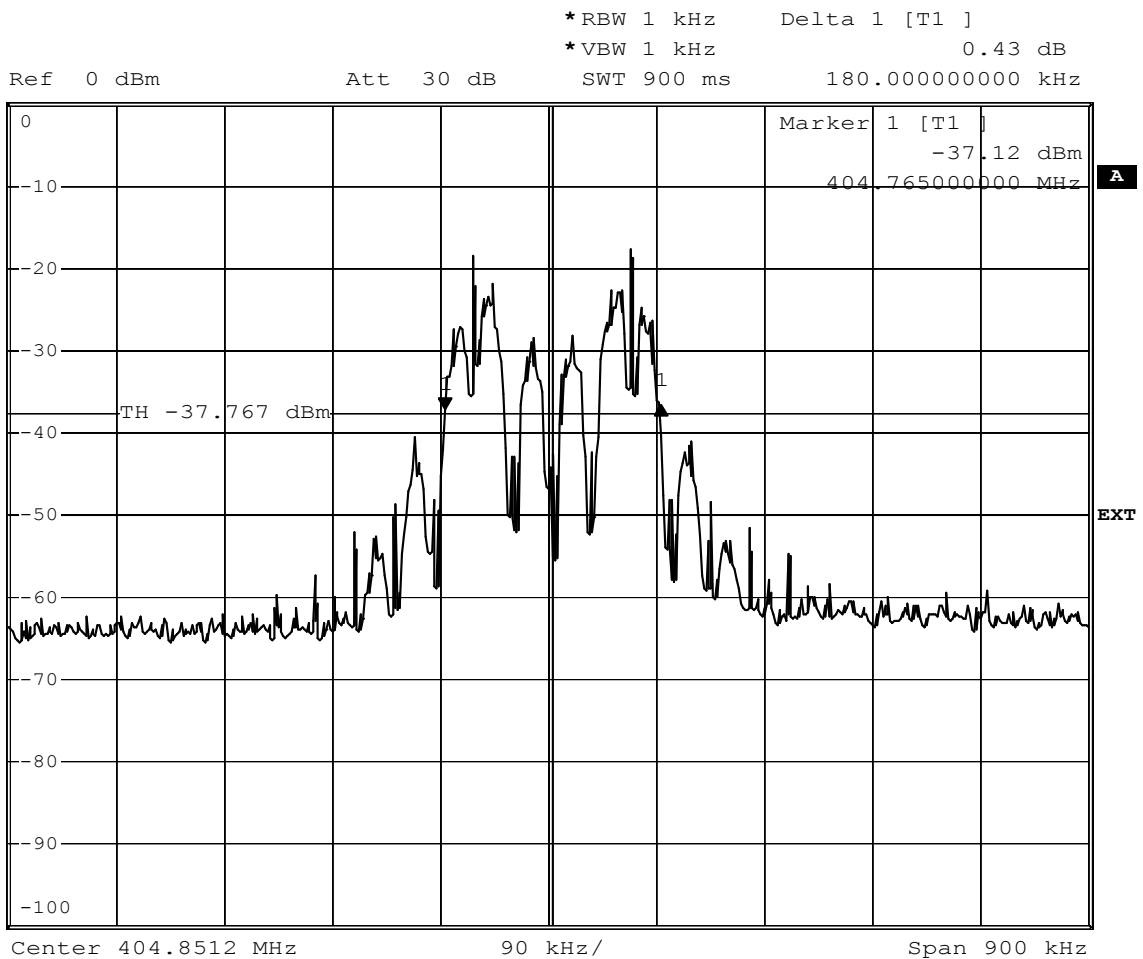


Date: 21.OCT.2008 11:13:18

Measurement diagram

FCC Part 95.633 / EN 301 839 v1.1.1
Emission bandwidth / Maximum radiation bandwidth

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC Part 95.633 e / EN 301 839-1 8.2
Comment 1	20 dB Emission bandwidth
Comment 2	f high-flow Bandwidth: 180 kHz
Comment 3	Limit 300KHz

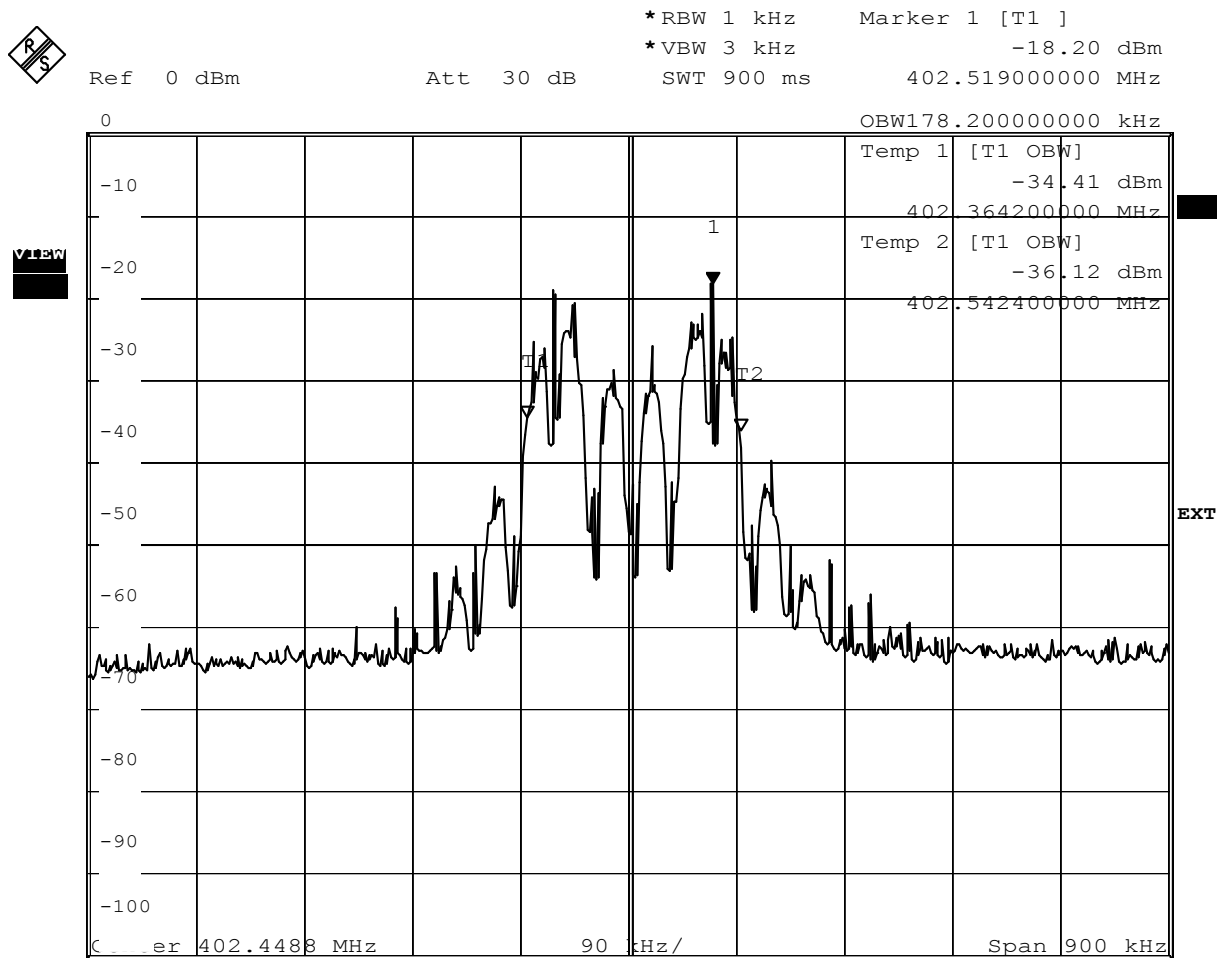


Date: 21.OCT.2008 11:29:59

Measurement diagram

RSS-243
Occupied bandwidth

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	RSS-Gen Occupied bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Occupied frequency bandwidth: 178.2 kHz
Comment 3	

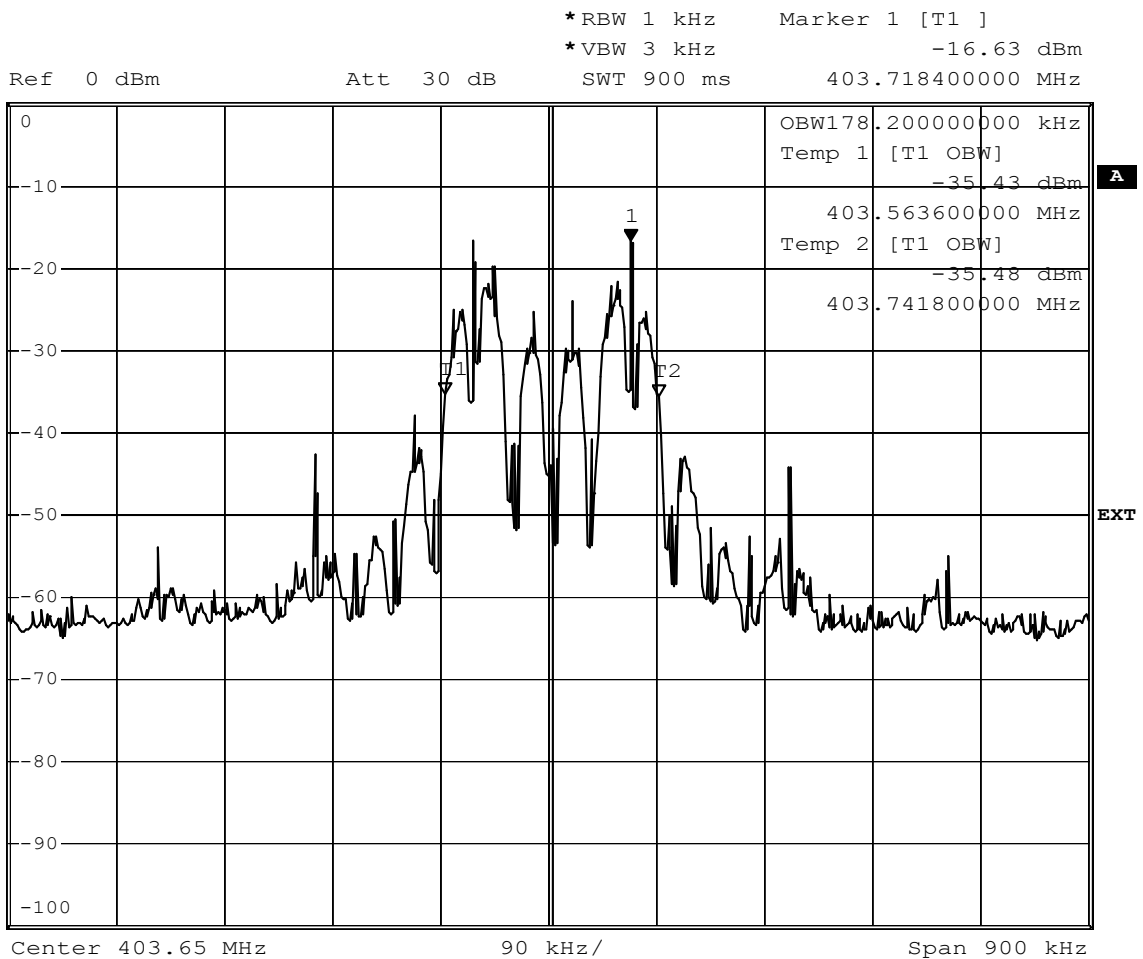


Comment: Occupied bandwidth: 178.2 KHz
Date: 21.OCT.2008 10:53:09

Measurement diagram

RSS-243
Occupied bandwidth

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	RSS-Gen Occupied bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Occupied frequency bandwidth: 178.2 kHz
Comment 3	

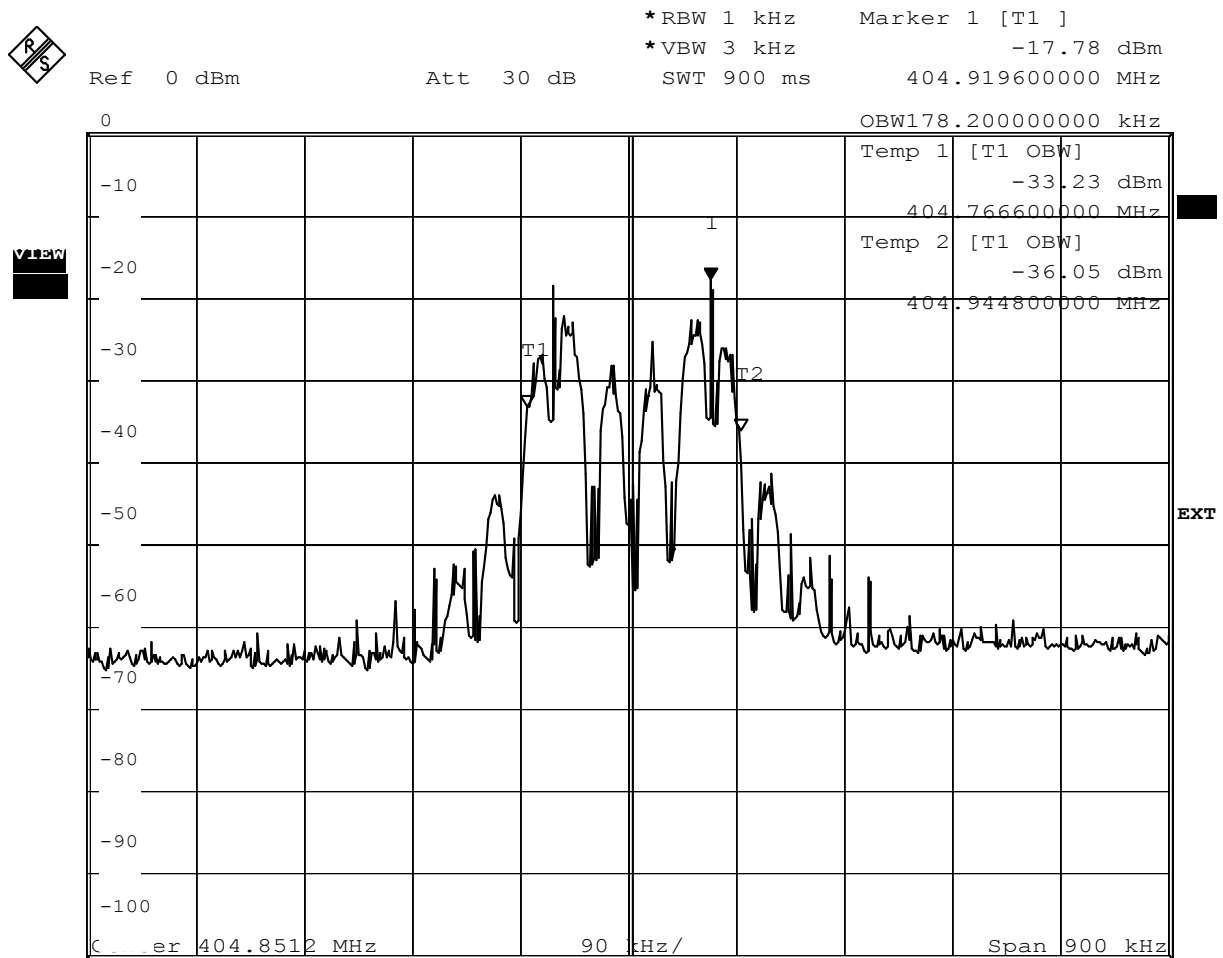


Comment: Occupied bandwidth: 178.2 KHz
 Date: 21.OCT.2008 10:57:39

Measurement diagram

RSS-243
Occupied bandwidth

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: 2.8 V DC (Battery)
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	RSS-Gen Occupied bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Occupied frequency bandwidth: 178.2 kHz
Comment 3	



Comment: Occupied bandwidth: 178.2 KHz
Date: 21.OCT.2008 12:14:33

Measurement diagram

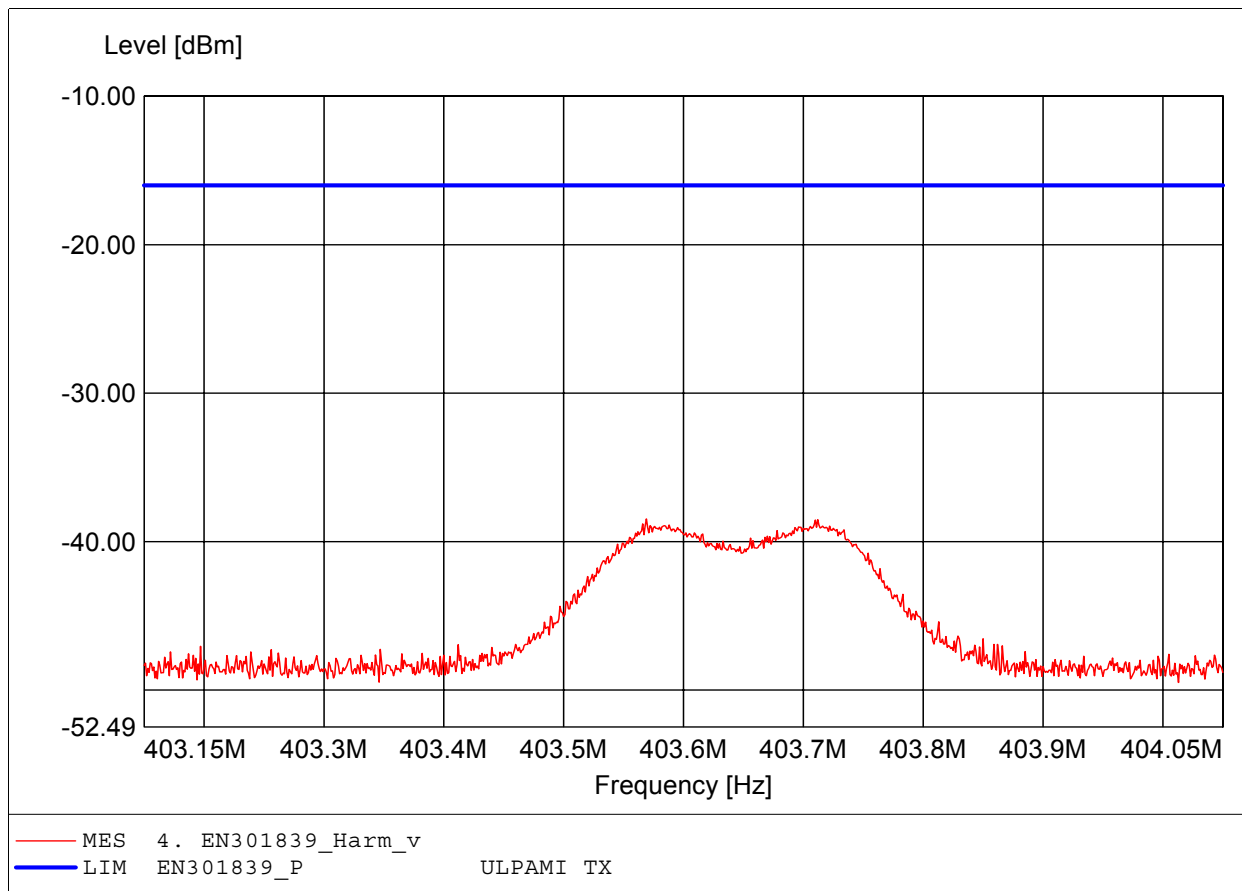
Annex D

Measurement diagrams “Radiated Power under normal conditions”

Radiated power under normal conditions

ULPAMI in accordance to the EN 301 839

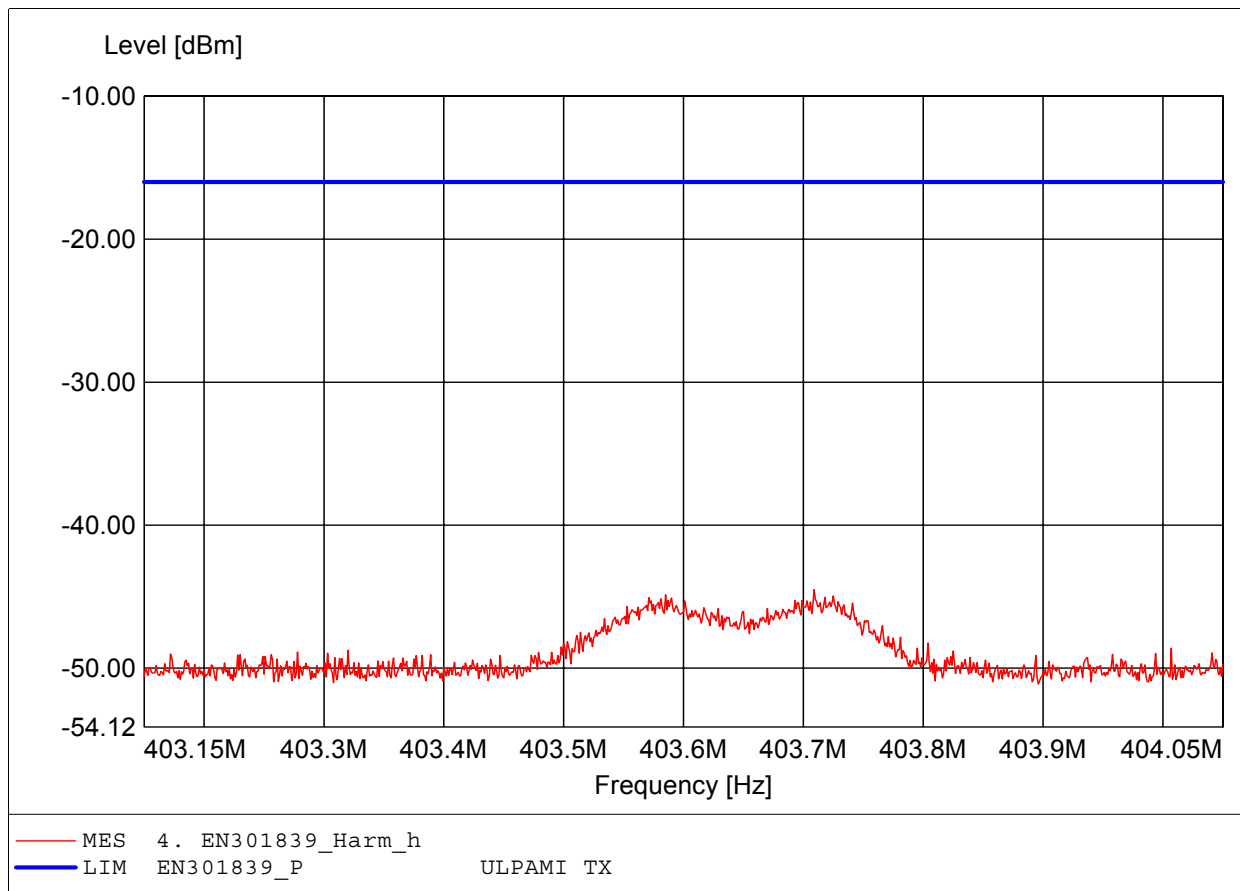
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 3m, Ant.: HL 025,
Comment 2: Freq:403.569MHz Pmax:-38.47dBm RBW: 10 MHz



Radiated power under normal conditions

ULPAMI in accordance to the EN 301 839

Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 3m, Ant.: HL 025,
Comment 2: Freq:403.709MHz Pmax:-44.52dBm RBW: 10 MHz



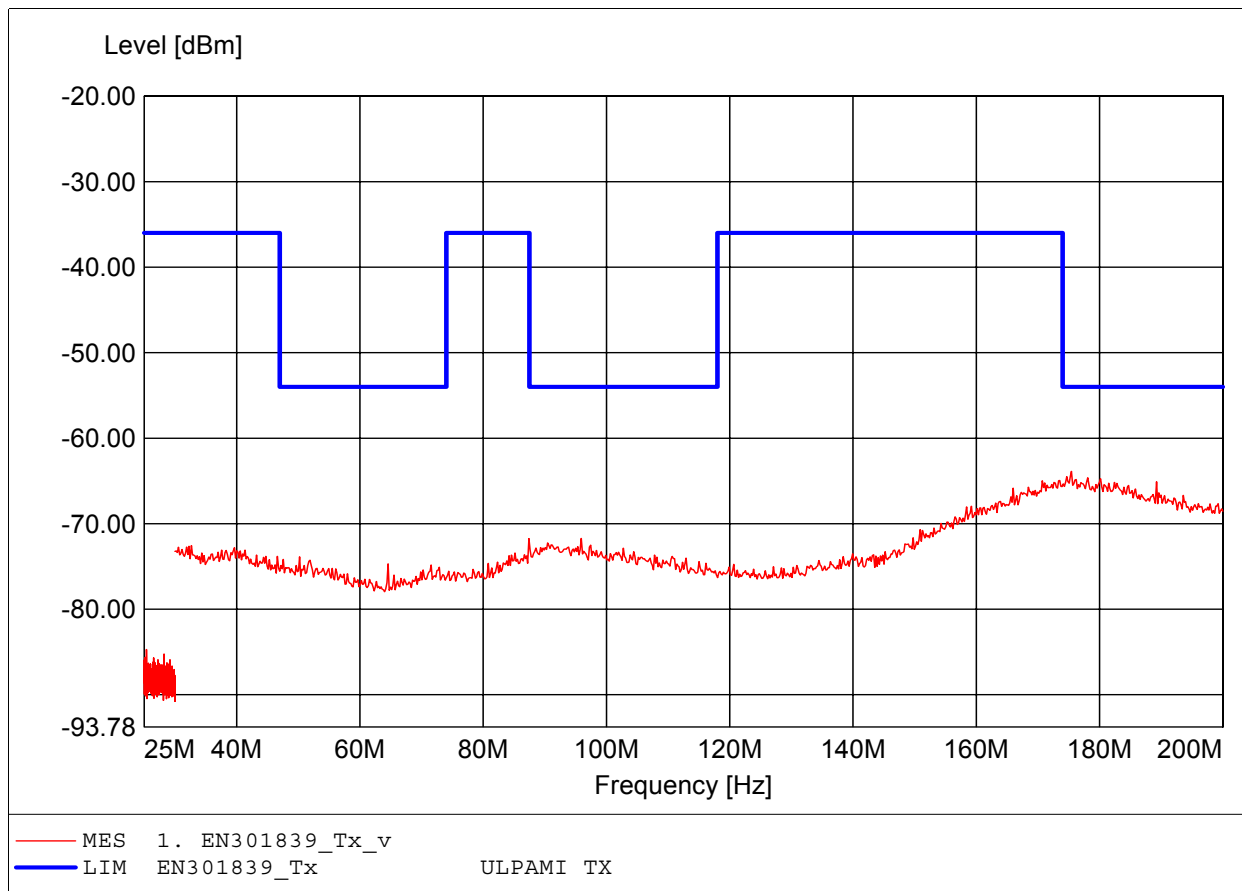
Annex E

Measurement diagrams “Spurious Radiation mode: TX”

Spurious radiation

ULPAMI in accordance to the EN 301 839

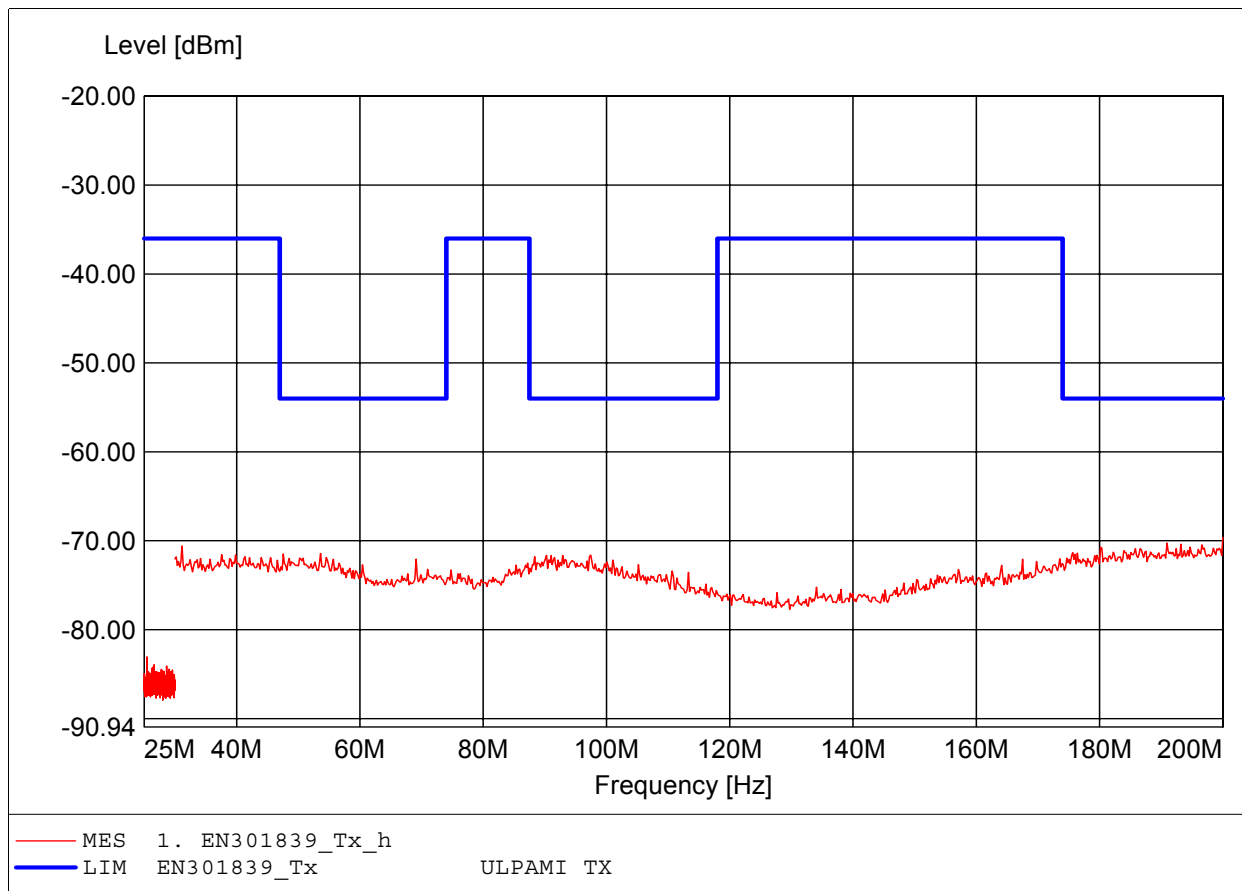
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:175.444MHz Pmax:-63.89dBm RBW: 10/100 kHz



Spurious radiation

ULPAMI in accordance to the EN 301 839

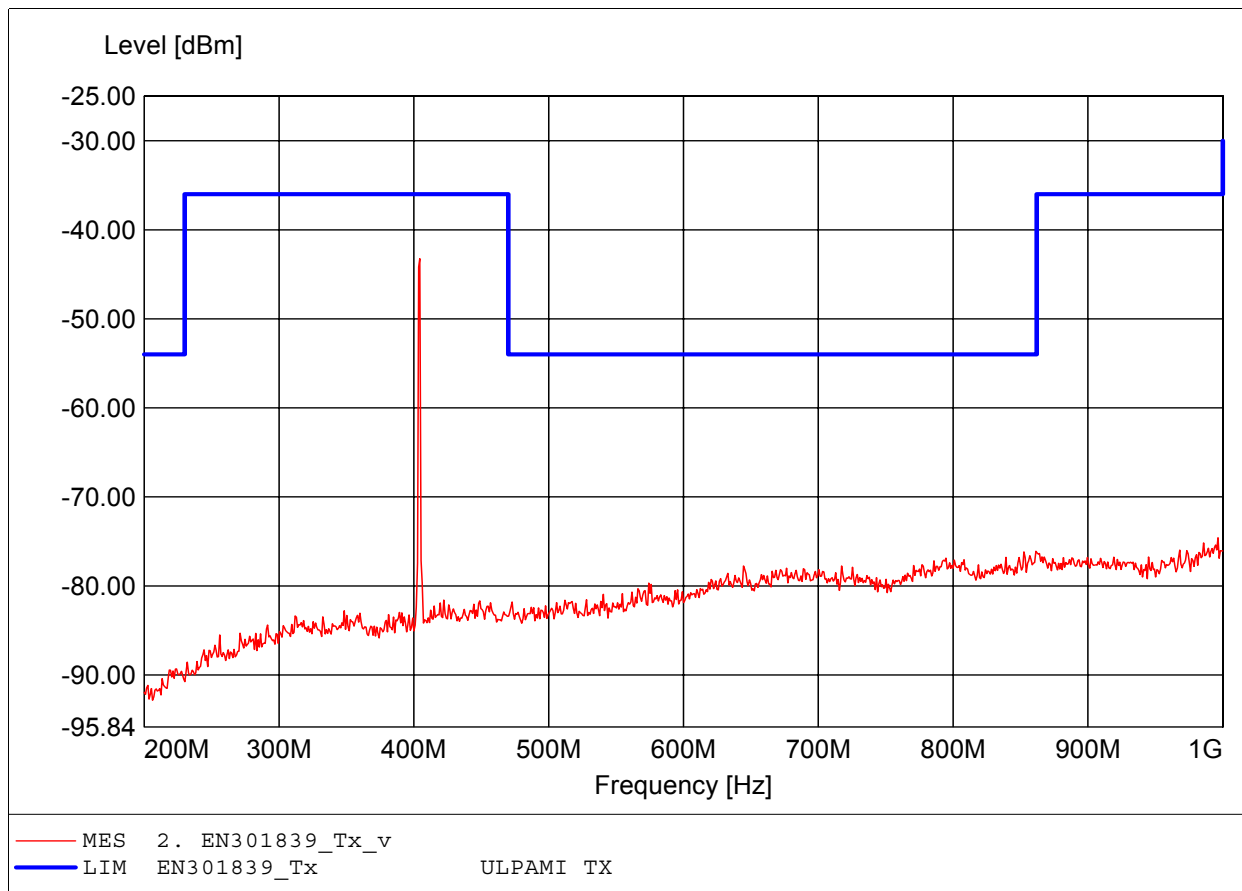
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:200.000MHz Pmax:-69.62dBm RBW: 10/100 kHz



Spurious radiation

ULPAMI in accordance to the EN 301 839

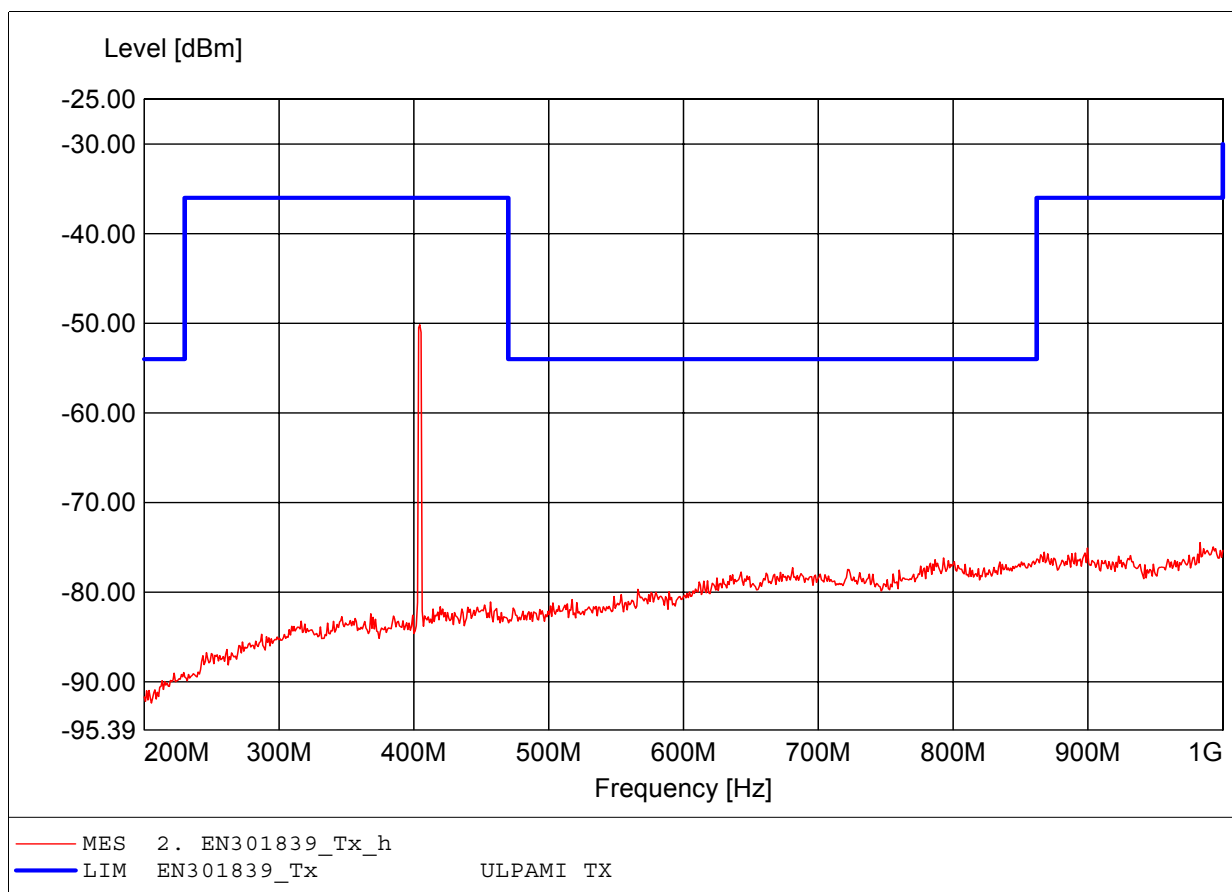
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.: 0.2-1 GHz
Comment 2: Freq:404.444MHz Pmax:-43.25dBm RBW: 100 kHz



Spurious radiation

ULPAMI in accordance to the EN 301 839

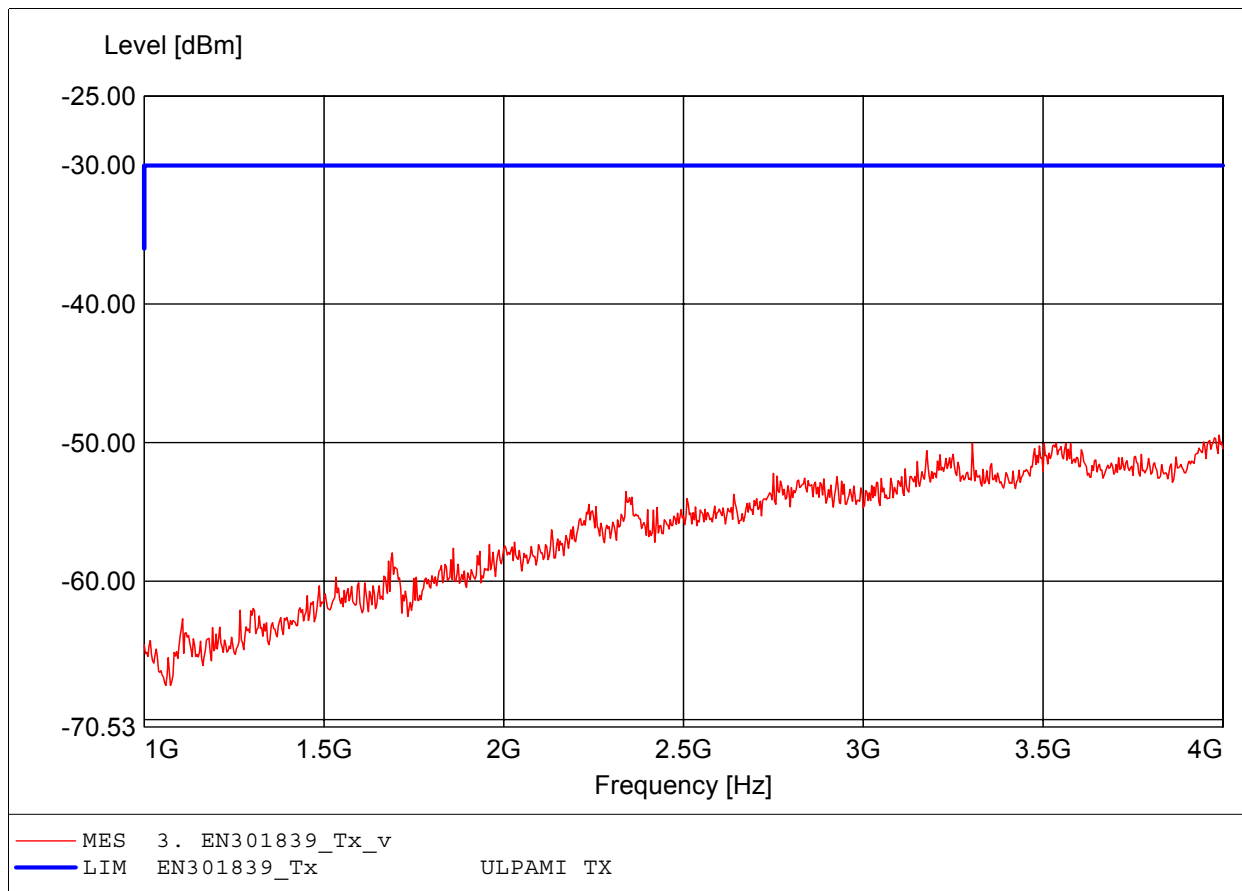
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.: 0.2-1 GHz
Comment 2: Freq:404.444MHz Pmax:-50.18dBm RBW: 100 kHz



Spurious radiation

ULPAMI in accordance to the EN 301 839

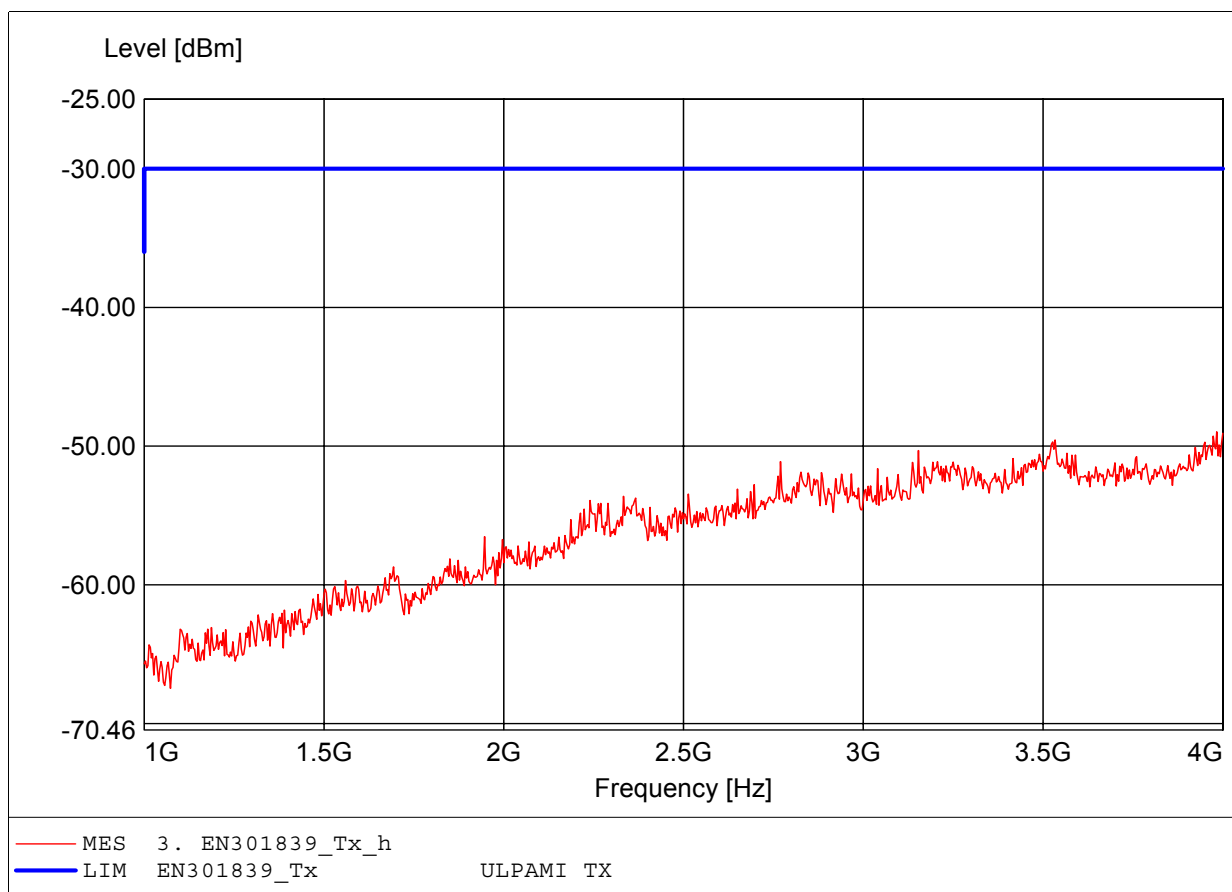
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 1m, Ant.: HL 025, ampl.: 1-4 GHz
Comment 2: Freq:3.990GHz Pmax:-49.46dBm RBW: 1 MHz



Spurious radiation

ULPAMI in accordance to the EN 301 839

Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: Tx
Comment 1: Dist.: 1m, Ant.: HL 025, ampl.: 1-4 GHz
Comment 2: Freq:3.983GHz Pmax:-48.98dBm RBW: 1 MHz



Annex F

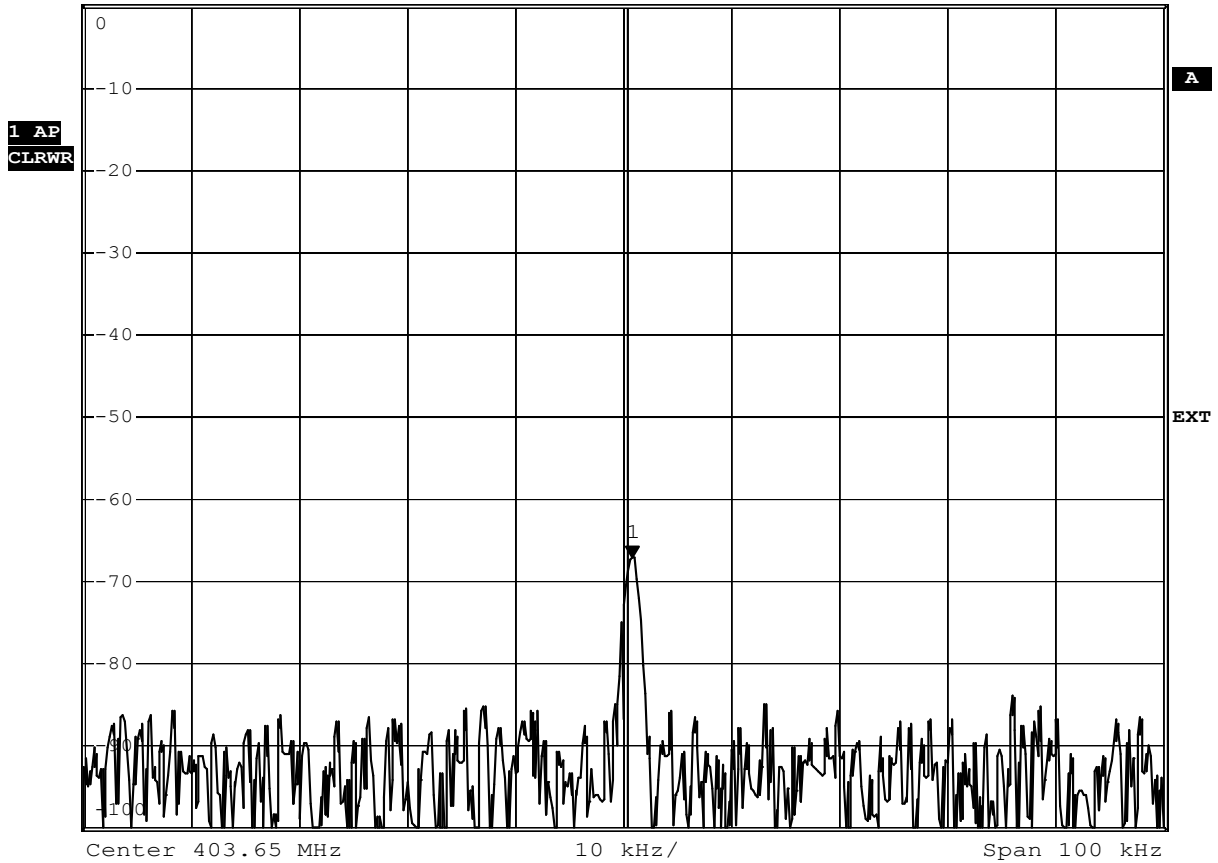
Measurement diagram “ Frequency stability under low voltage condition”

EN 301 839 v1.1.1
Frequency stability under low voltage conditions

EUT	Pacemaker
Model	PRIMUS
Approval Holder	Biotronik GmbH
Temperature / Voltage	25°C / Unom: low voltage condition : 1.5 V D
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	EN 301 839-1 8.2
Comment 1	EN 301 839 8.5 Frequency stability under low voltage conditions
Comment 2	f: 403.65 MHz => 1.95 ppm
Comment 3	Limit: +/- 100 ppm



*RBW 1 kHz Marker 1 [T1 CNT]
 *VBW 1 kHz -66.95 dBm
 Ref 0 dBm Att 30 dB SWT 200 ms 403.650789 MHz



Date: 21.OCT.2008 12:44:17

Measurement diagram

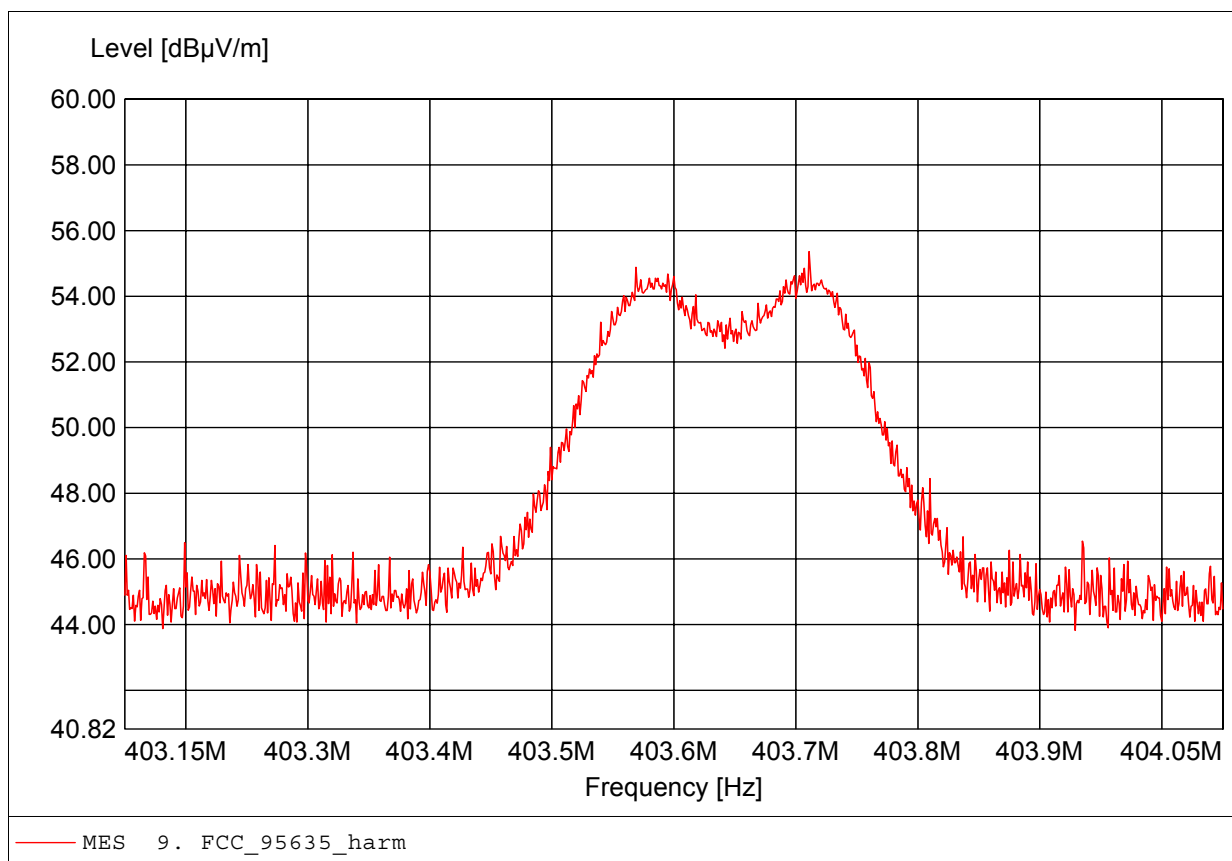
Annex G

Measurement diagrams “ Unwanted radiations FCC RULES Part 95”

Carrier power (dBµV/m)

FCC RULES PART 95, SUBPART i

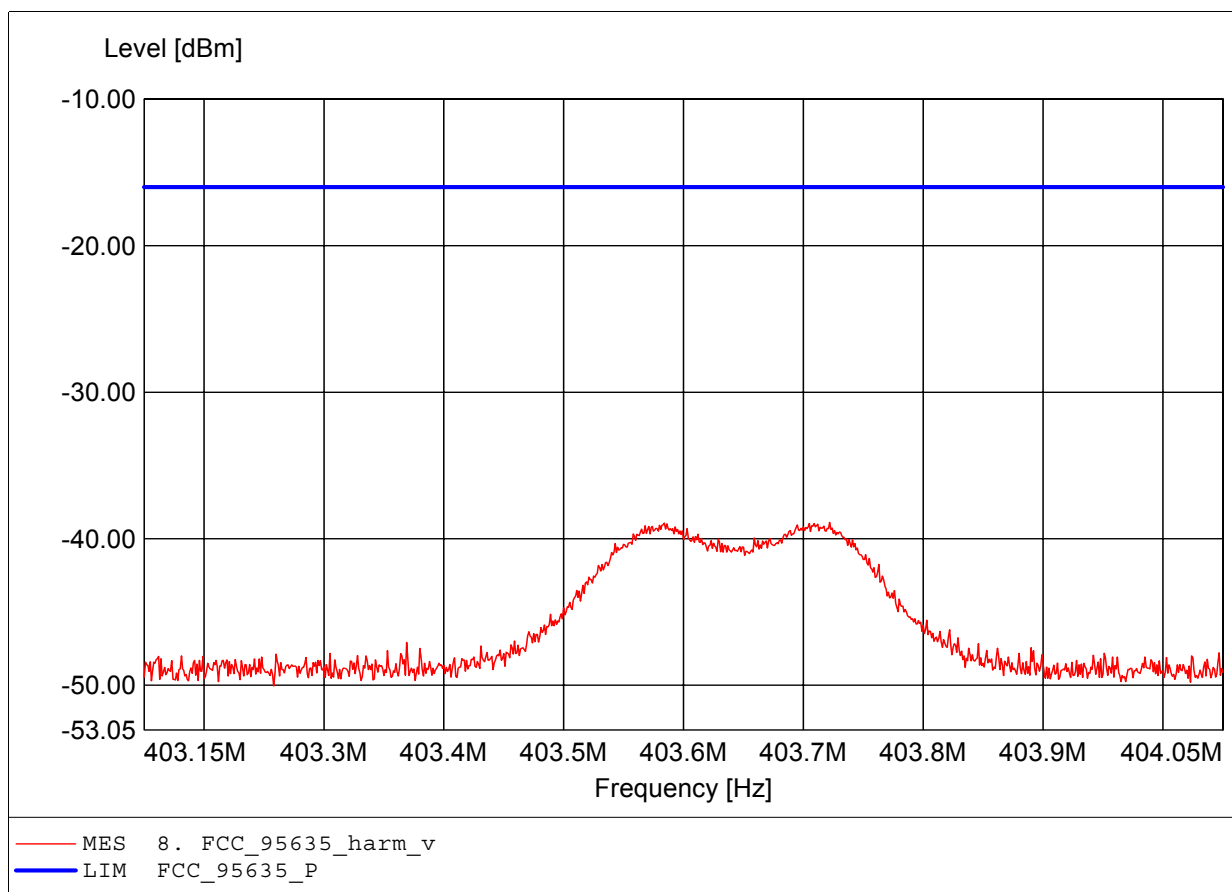
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 403.711MHz, Emax: 55.36dBµV/m, RBW: 100kHz



Carrier power (dBm)

FCC RULES PART 95, SUBPART i

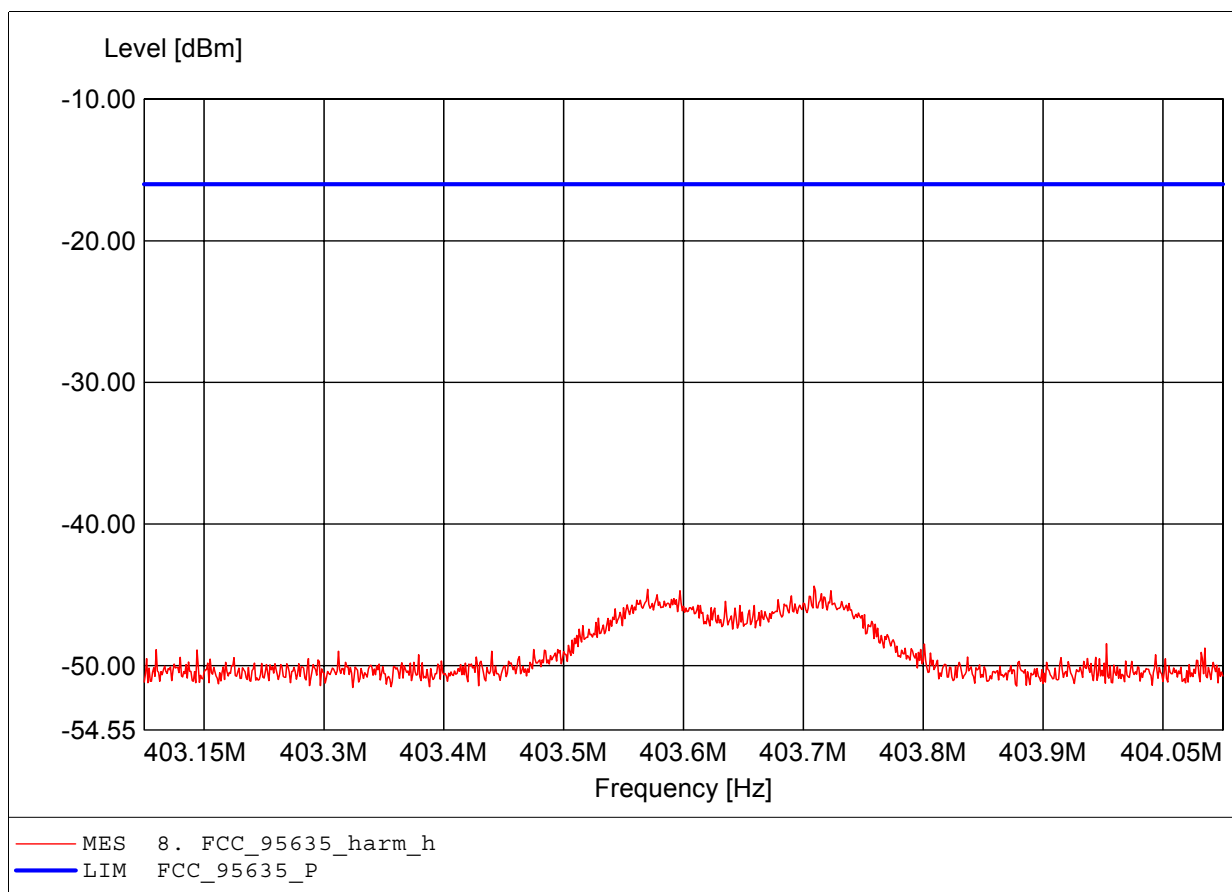
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 403.722MHz, Pmax: -38.88dBm, RBW: 100KHz



Carrier power (dBm)

FCC RULES PART 95, SUBPART i

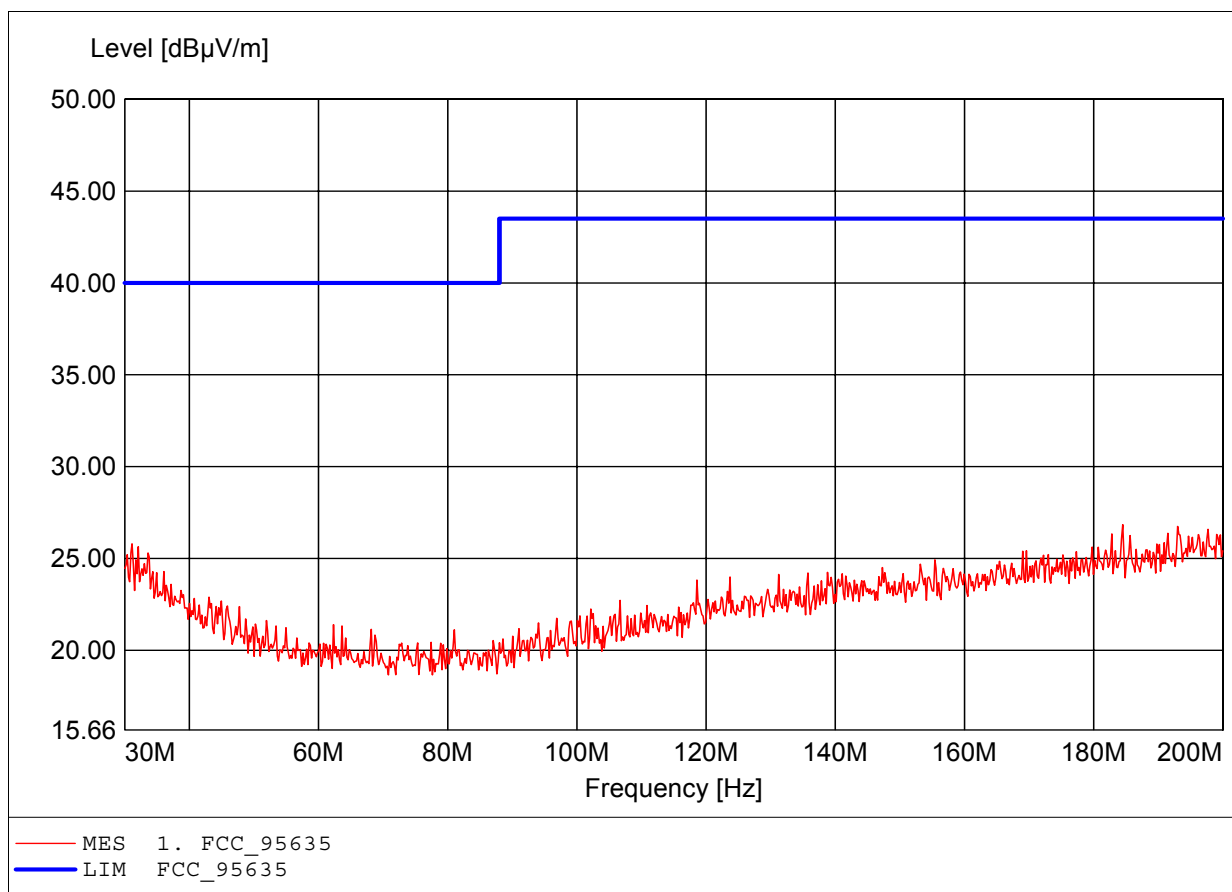
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.639, peak detector
Comment 1: Dist.: 3m, Ant.: HL223
Comment 2: Freq: 403.709MHz, Pmax: -44.39dBm, RBW: 100KHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

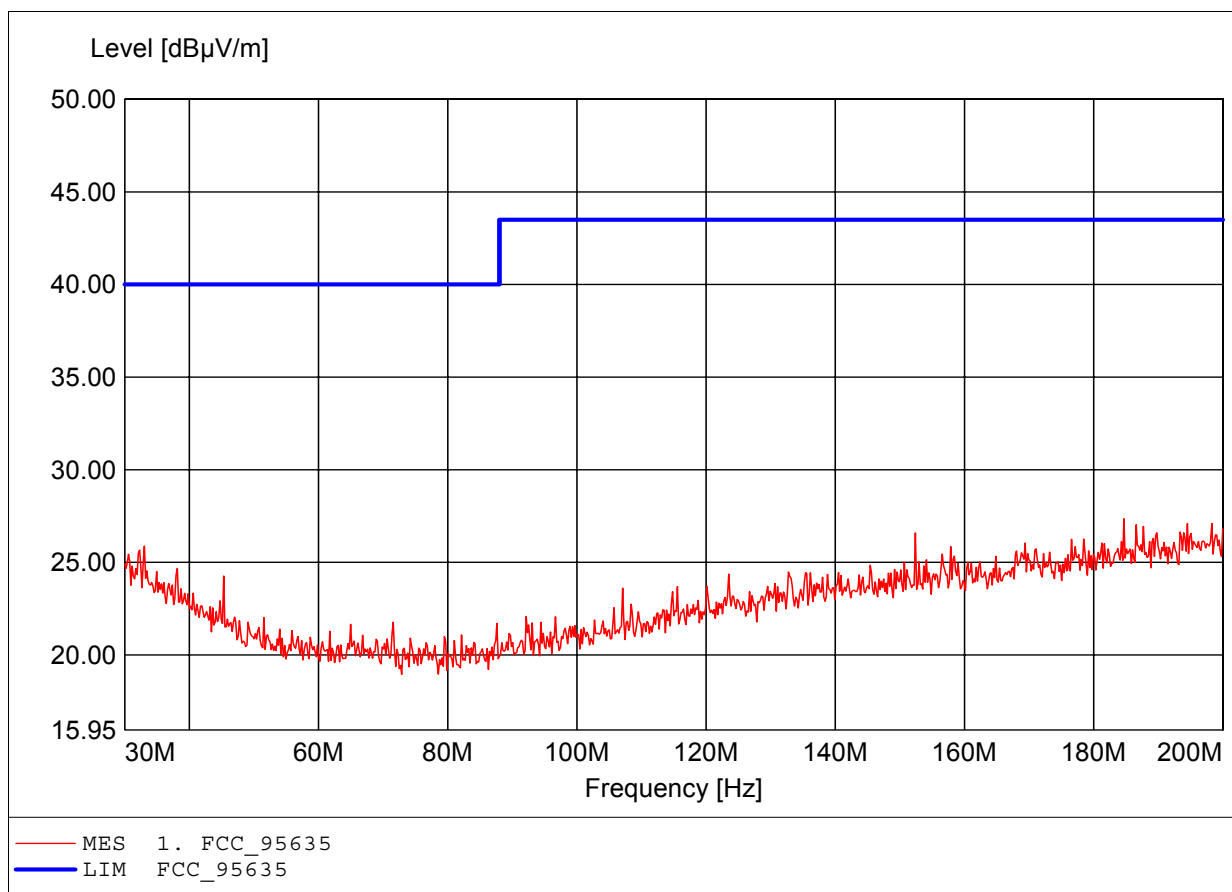
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 184.511MHz, Emax: 26.84dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

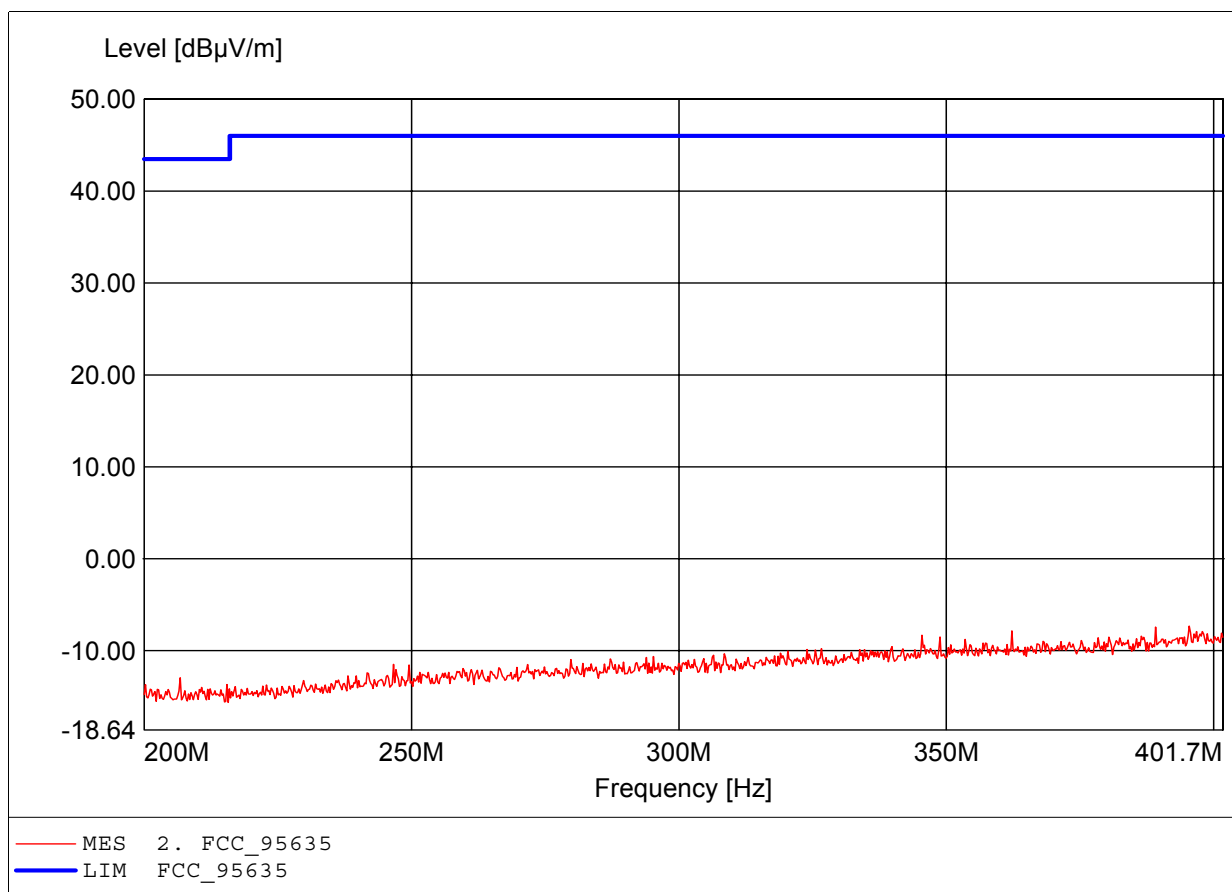
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq: 184.700MHz, Emax: 27.35dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

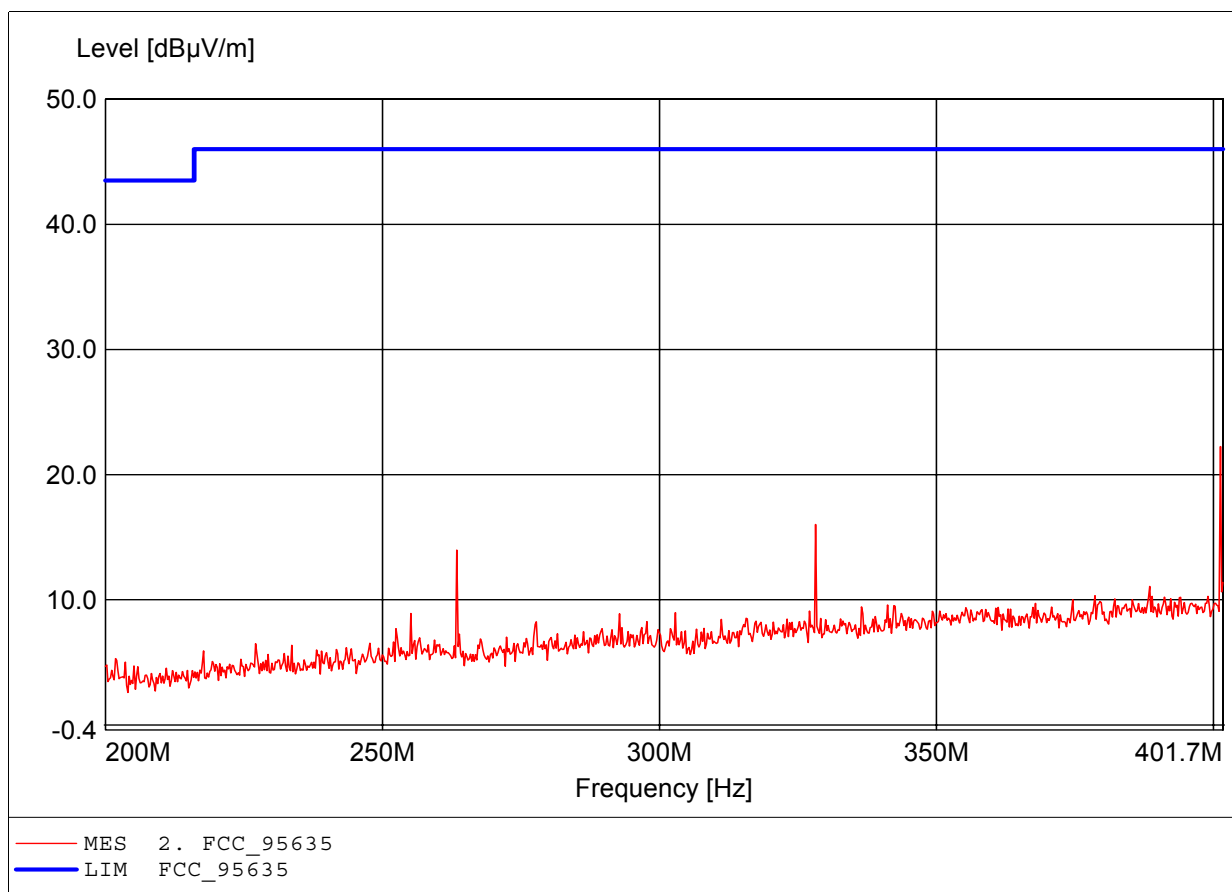
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 395.425MHz, Emax: -7.34dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

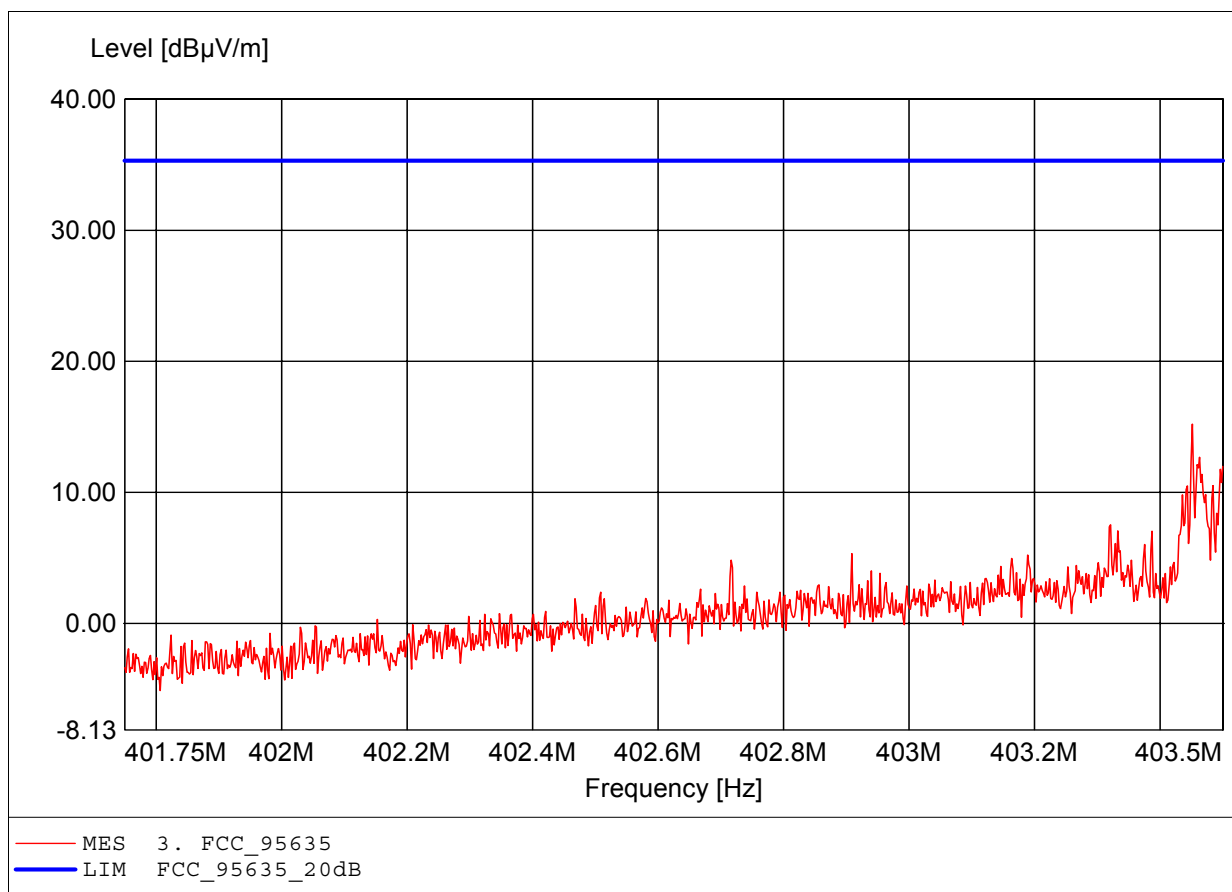
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 401.252MHz, Emax: 22.25dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

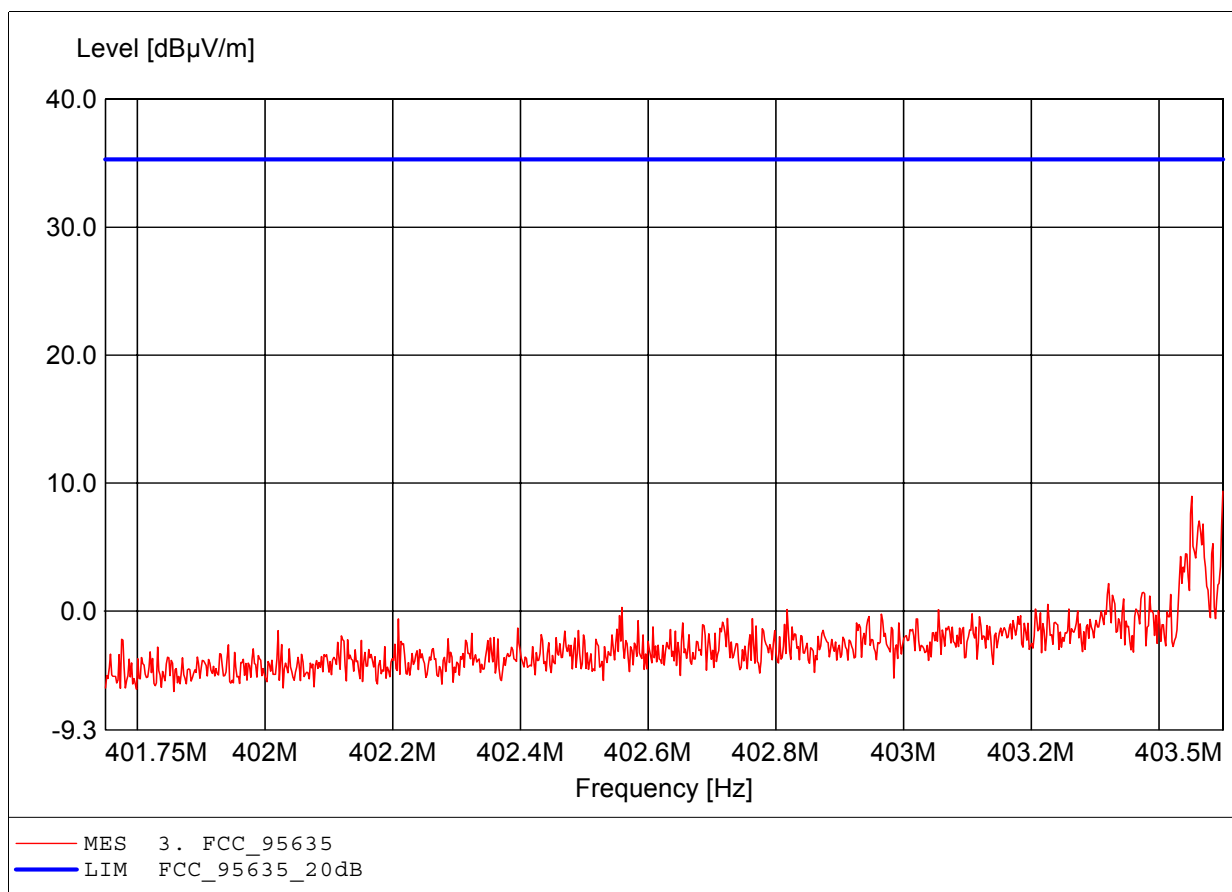
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.451MHz, Emax: 15.21dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

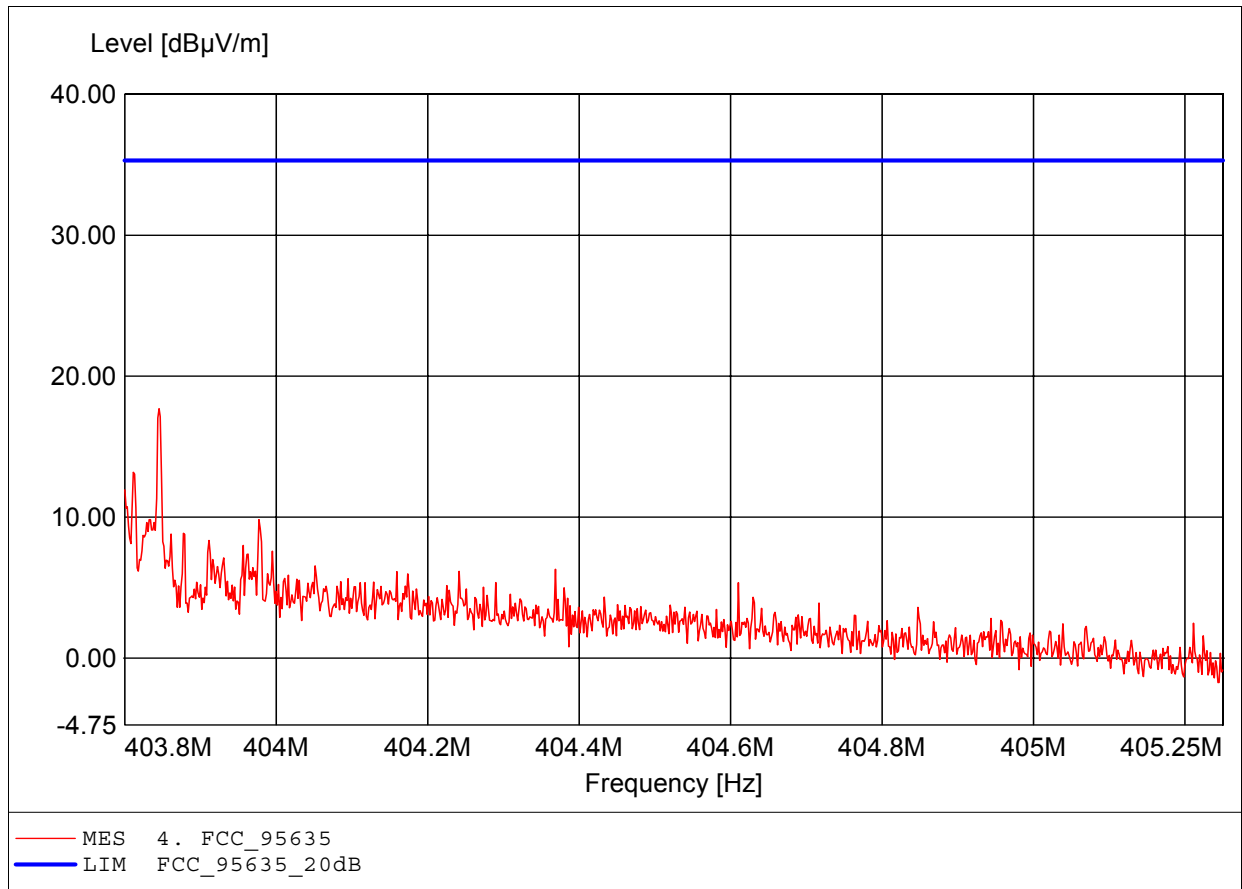
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.500MHz, Emax: 9.37dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

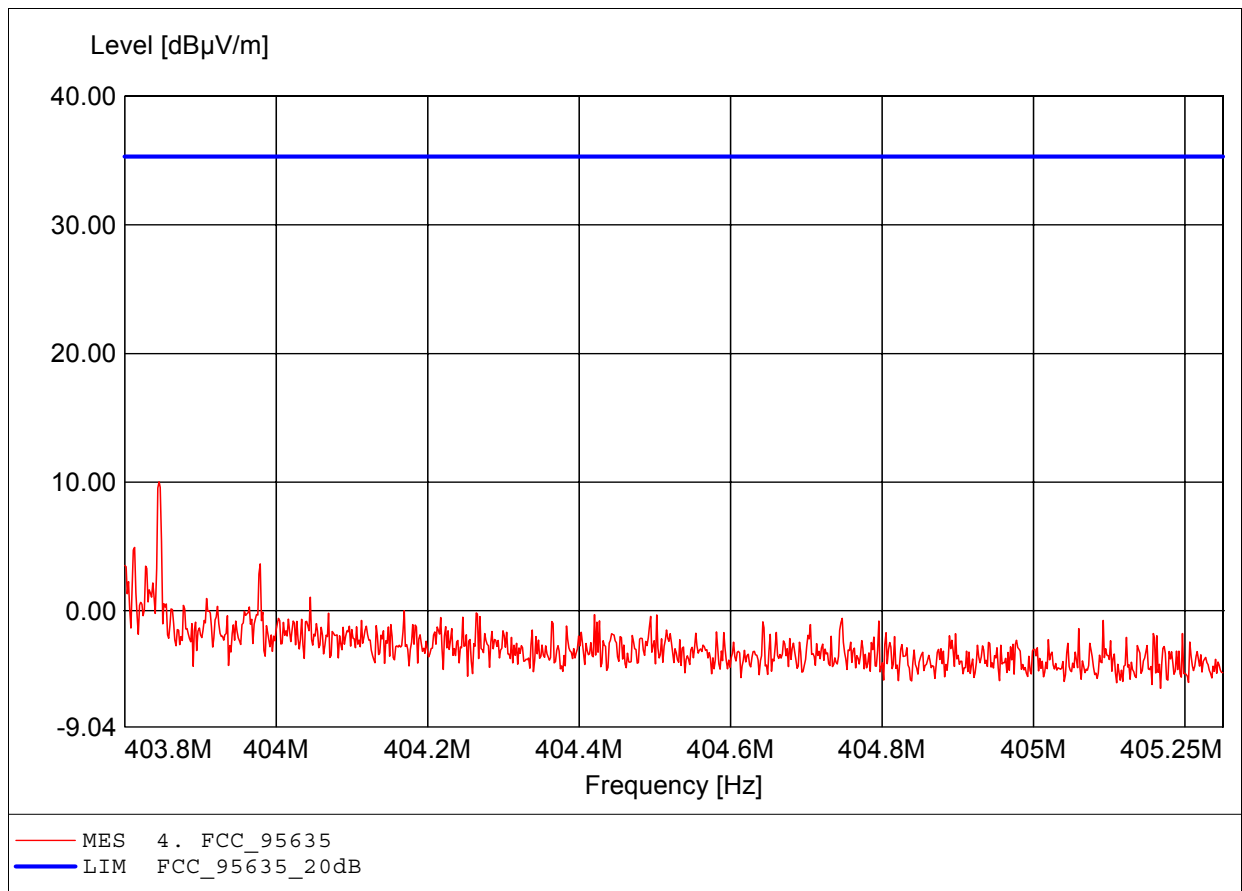
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.845MHz, Emax: 17.69dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

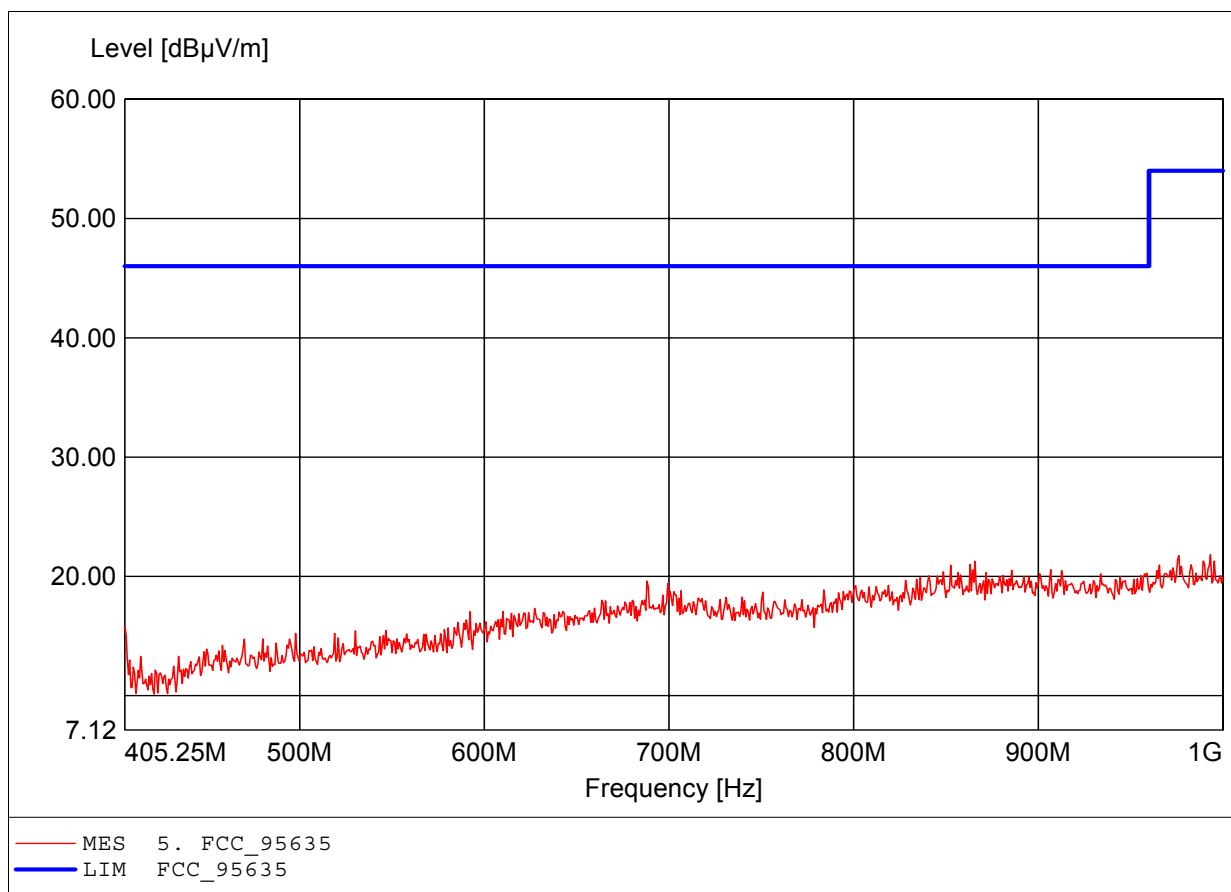
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.845MHz, Emax: 10.02dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

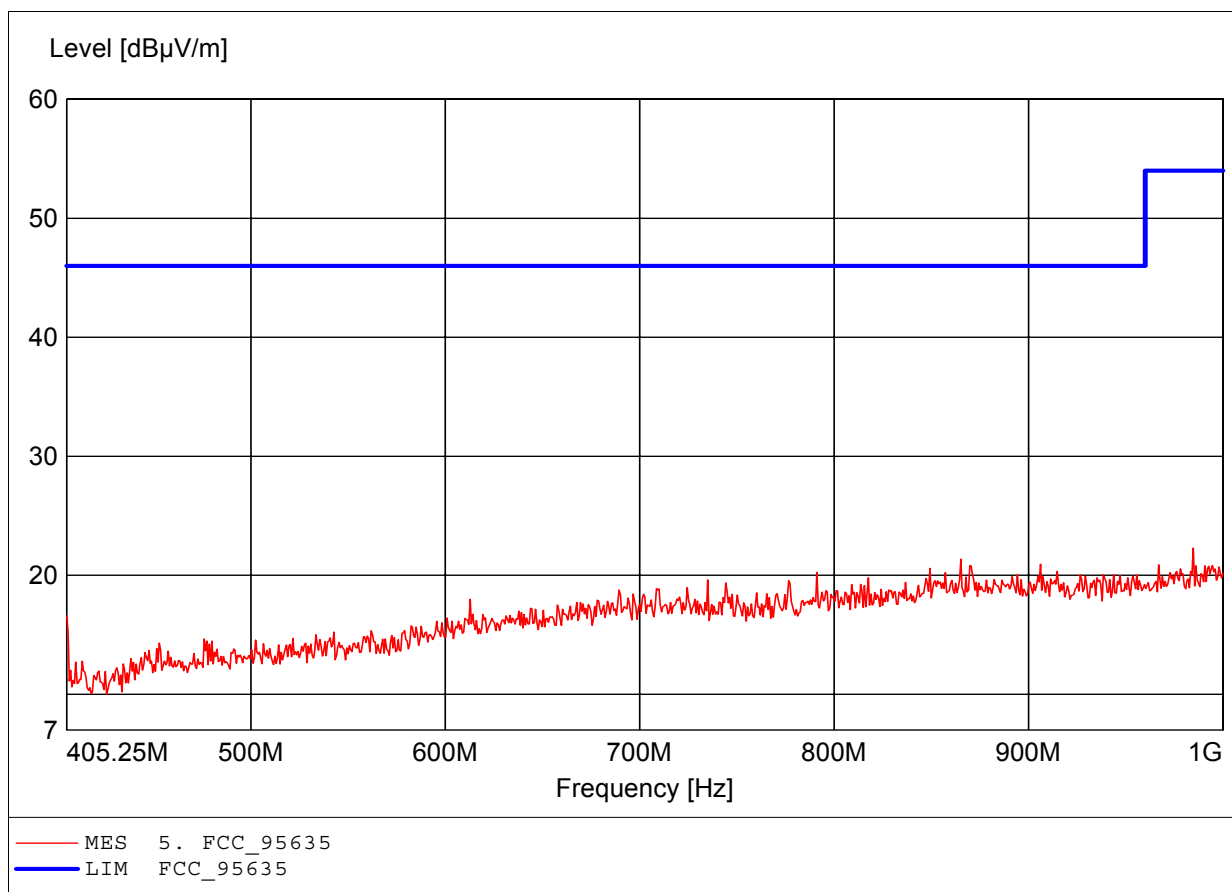
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 993.392MHz, Emax: 21.82dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

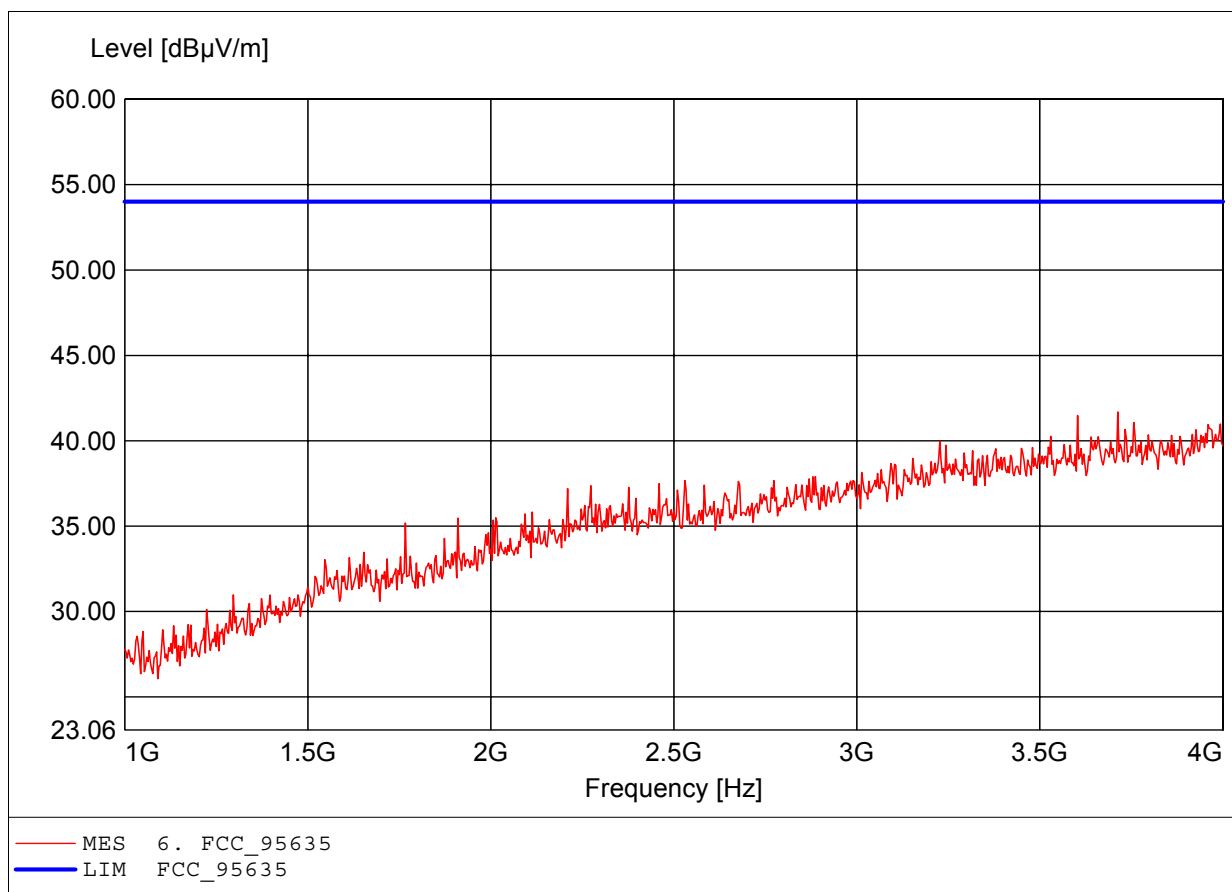
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 984.801MHz, Emax: 22.29dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

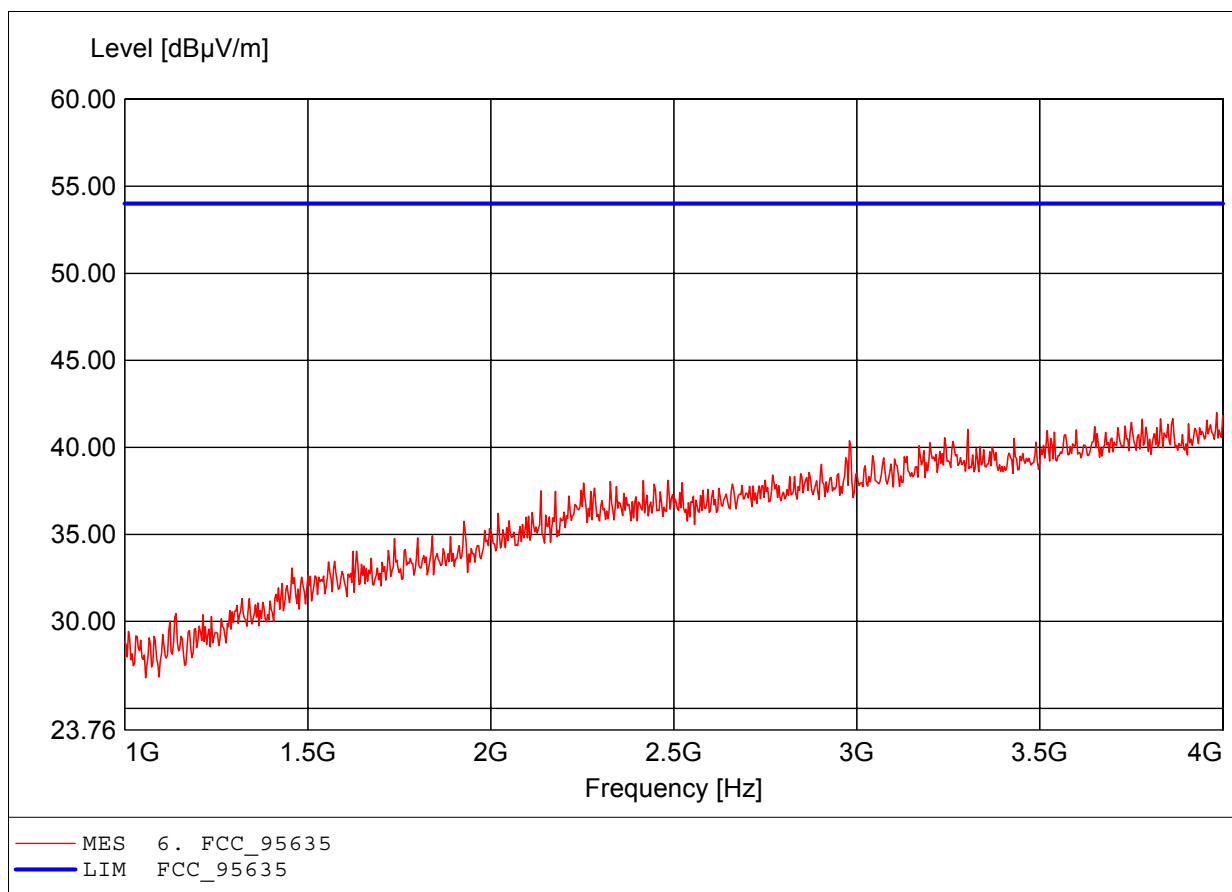
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.713GHz, Emax: 41.69dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

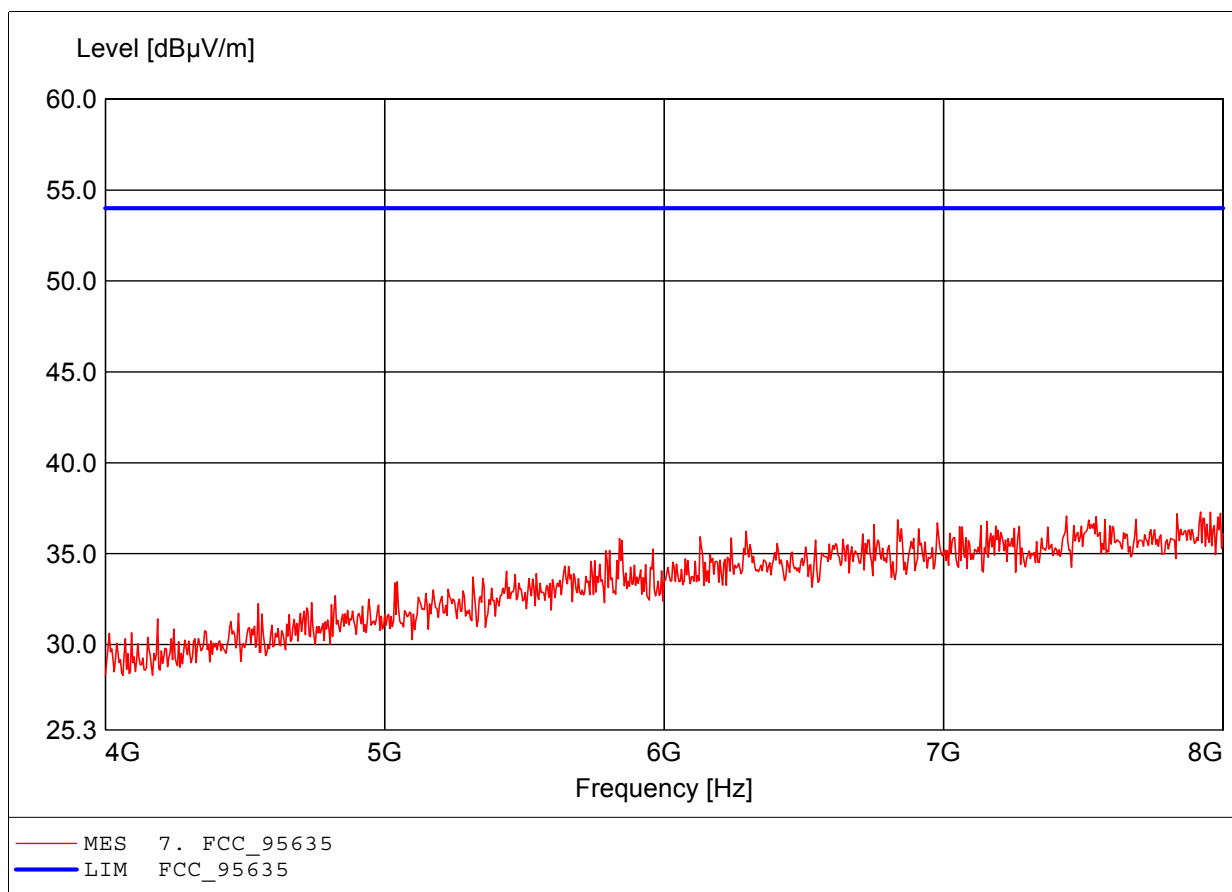
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 3.983GHz, Emax: 41.99dBµV/m, RBW: 100kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

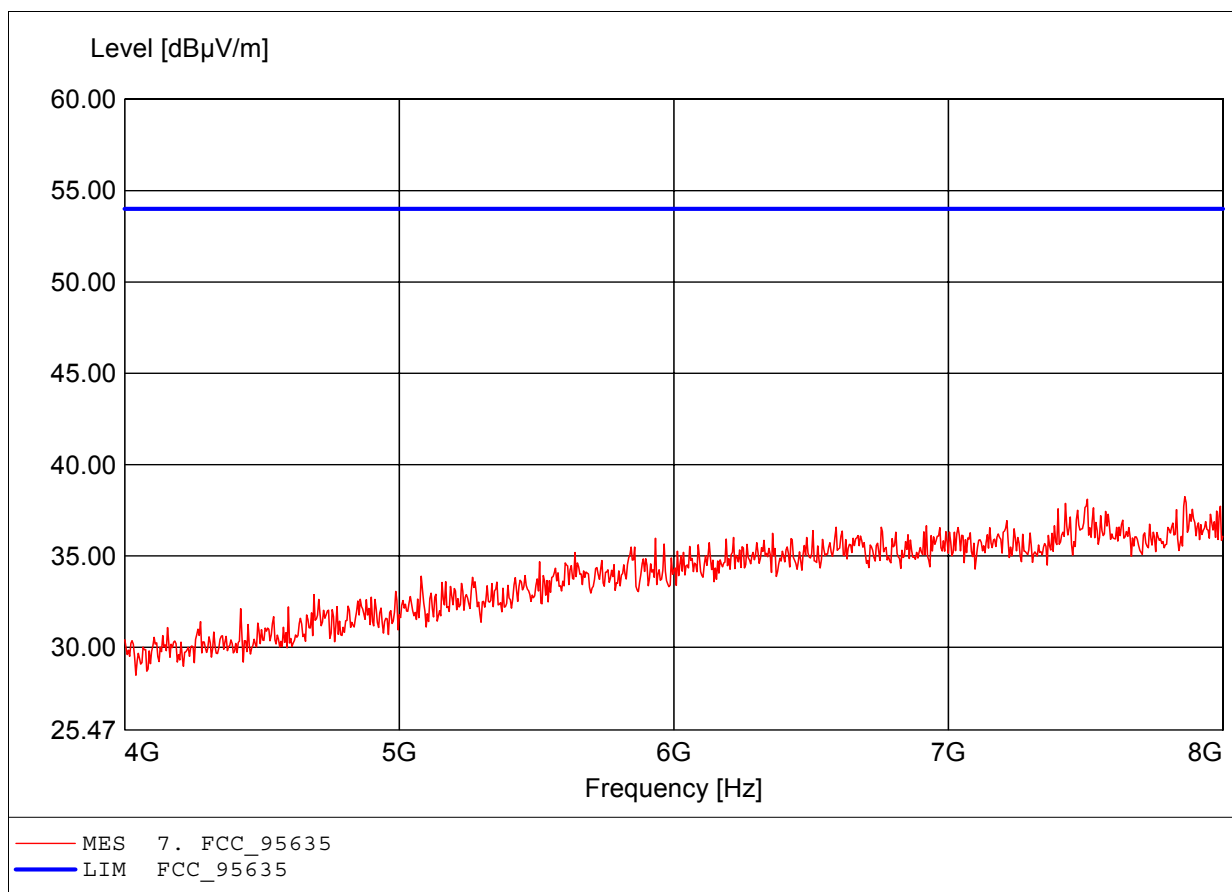
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 7.920GHz, Emax: 37.29dBµV/m, RBW: 1MHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 025, amplif.
Comment 2: Freq: 7.862GHz, Emax: 38.25dBµV/m, RBW: 1MHz



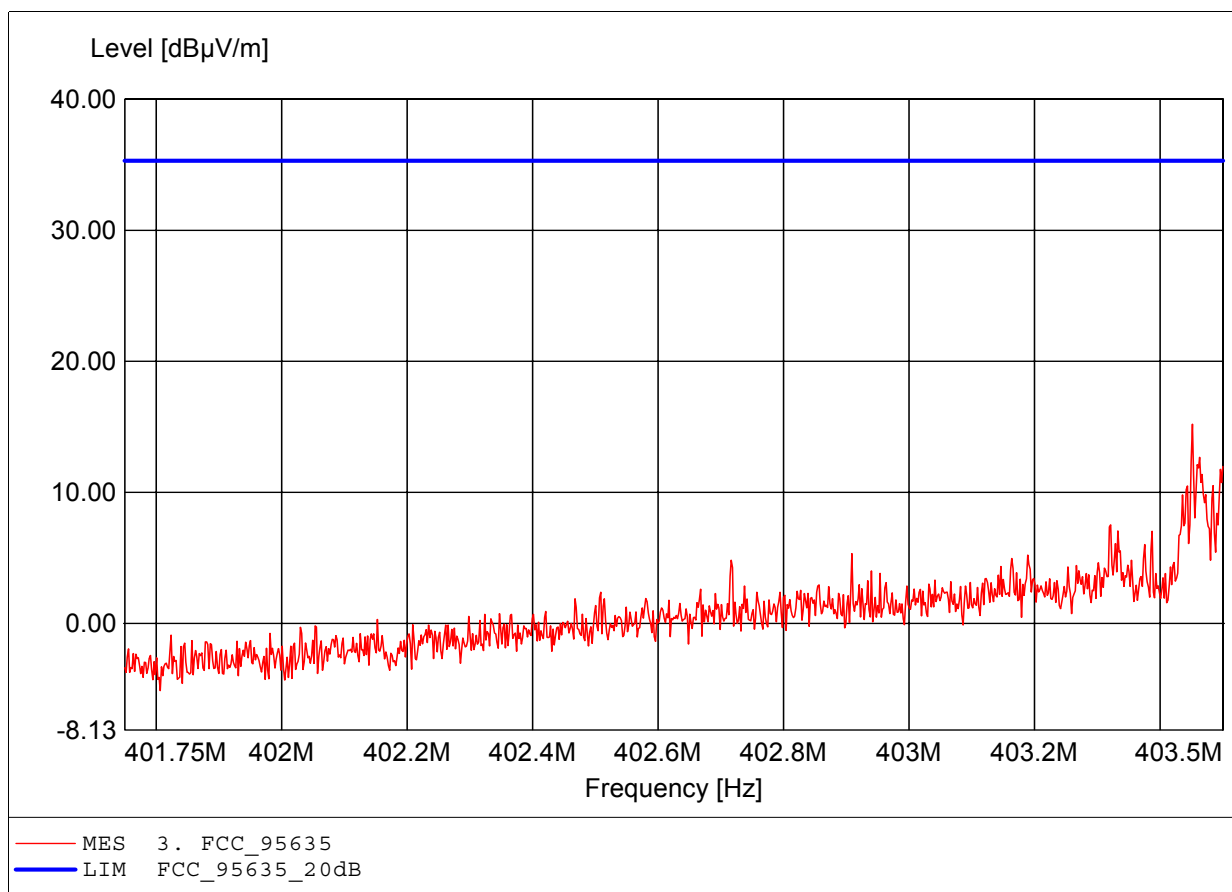
Annex H

Measurement diagrams FCC RULES §95.635 (d) (4) “In-Band Emissions”

Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

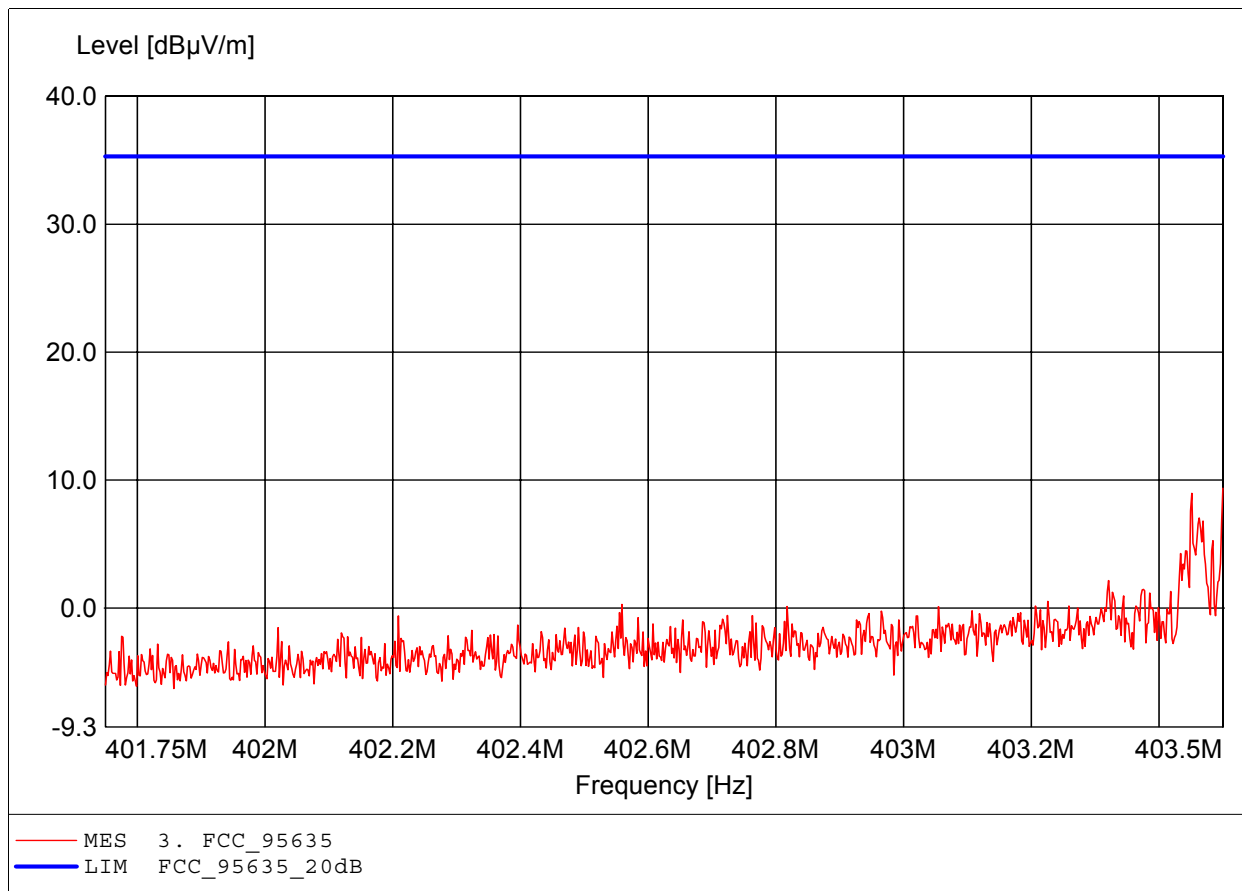
Approval Holder: BiotronicGmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.451MHz, Emax: 15.21dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

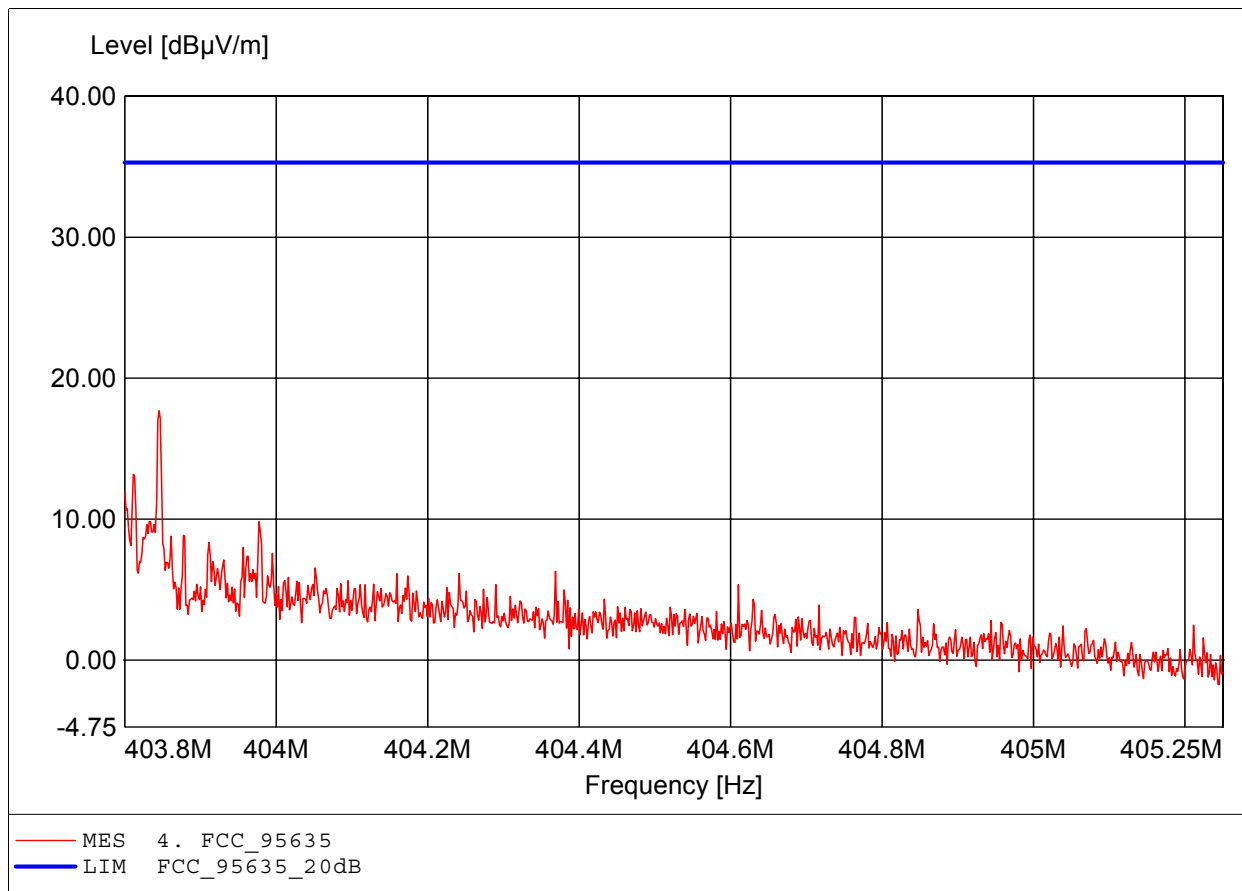
Approval Holder: BiotronicGmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.500MHz, Emax: 9.37dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

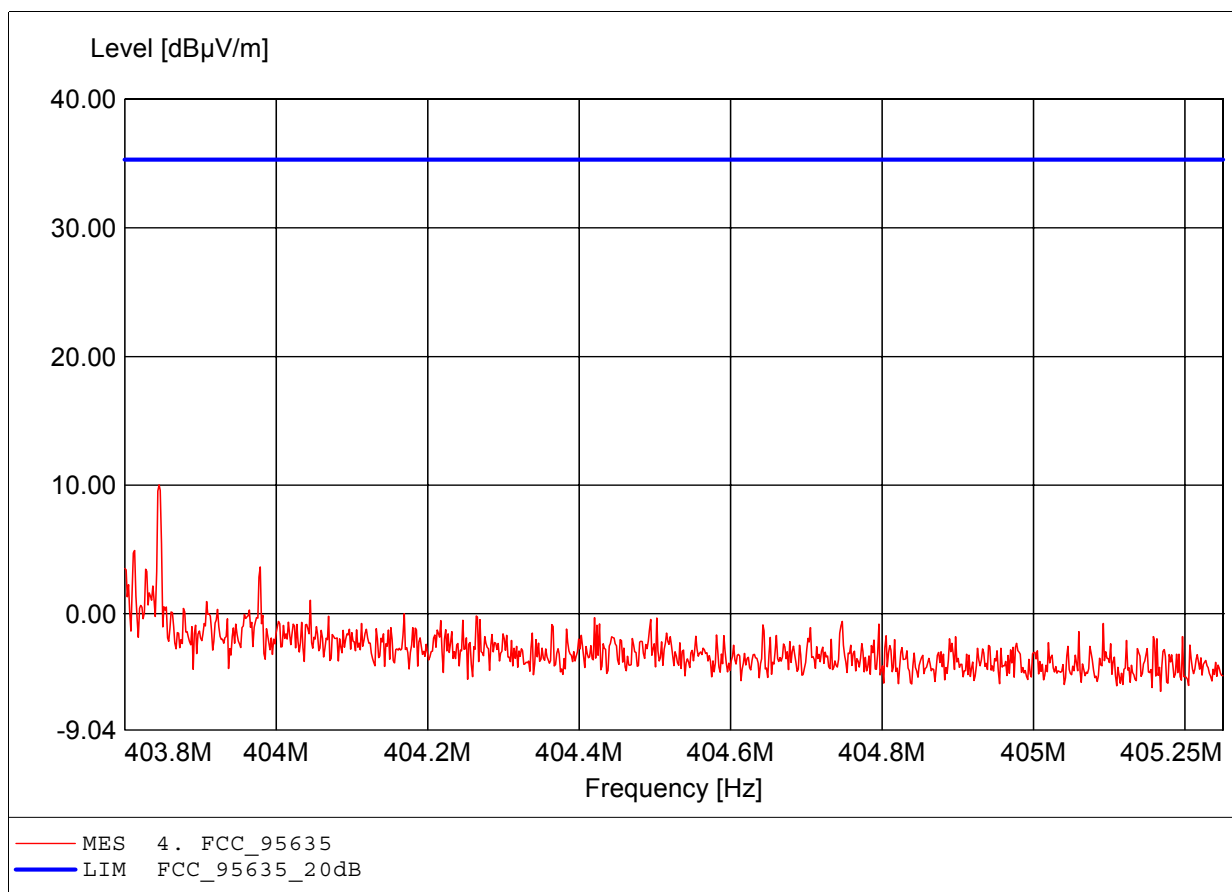
Approval Holder: BiotronicGmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.845MHz, Emax: 17.69dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BiotronicGmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635, peak detector
Comment 1: Dist.: 3m, Ant.: HL 223, amplif.
Comment 2: Freq: 403.845MHz, Emax: 10.02dBµV/m, RBW: 3kHz



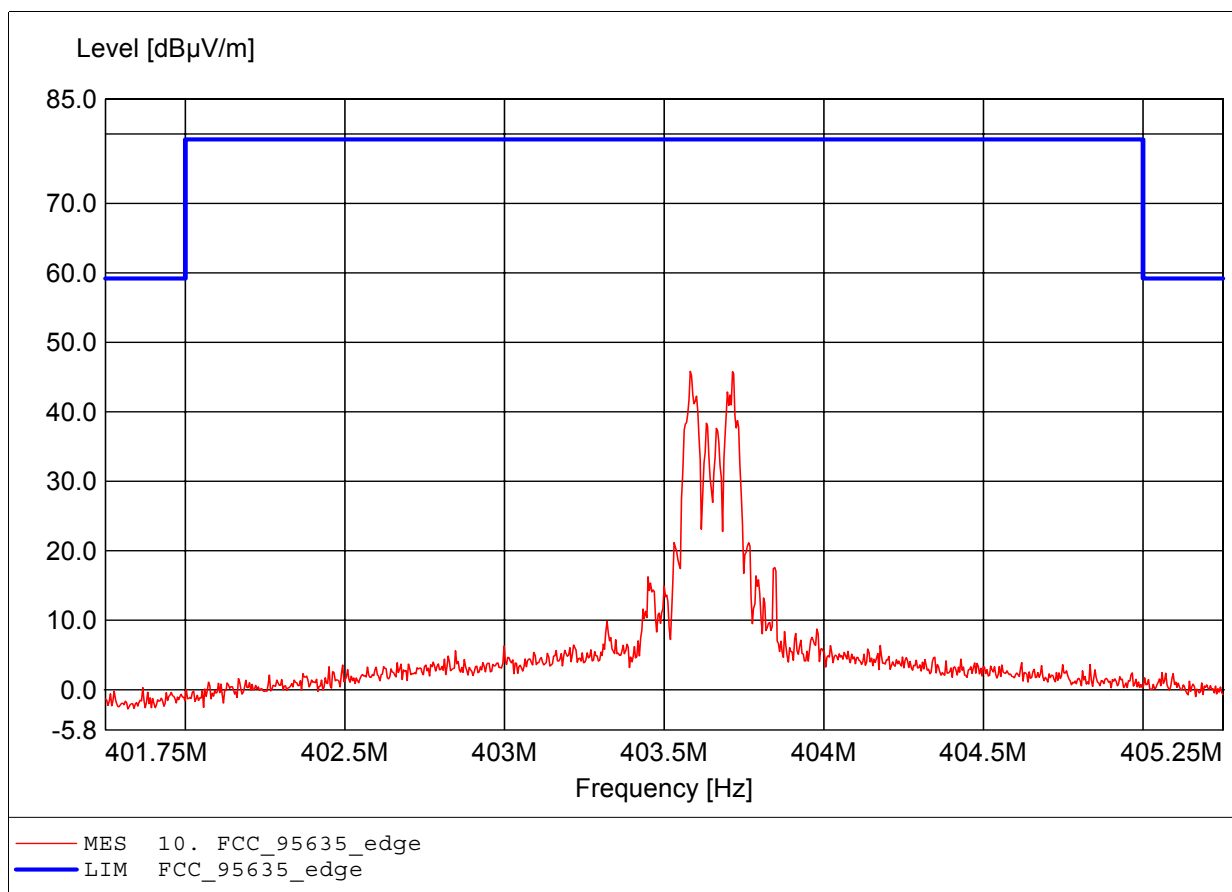
Annex I

Measurement diagrams FCC RULES §95.635 (d) (5) “Band Edge Emissions”

Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

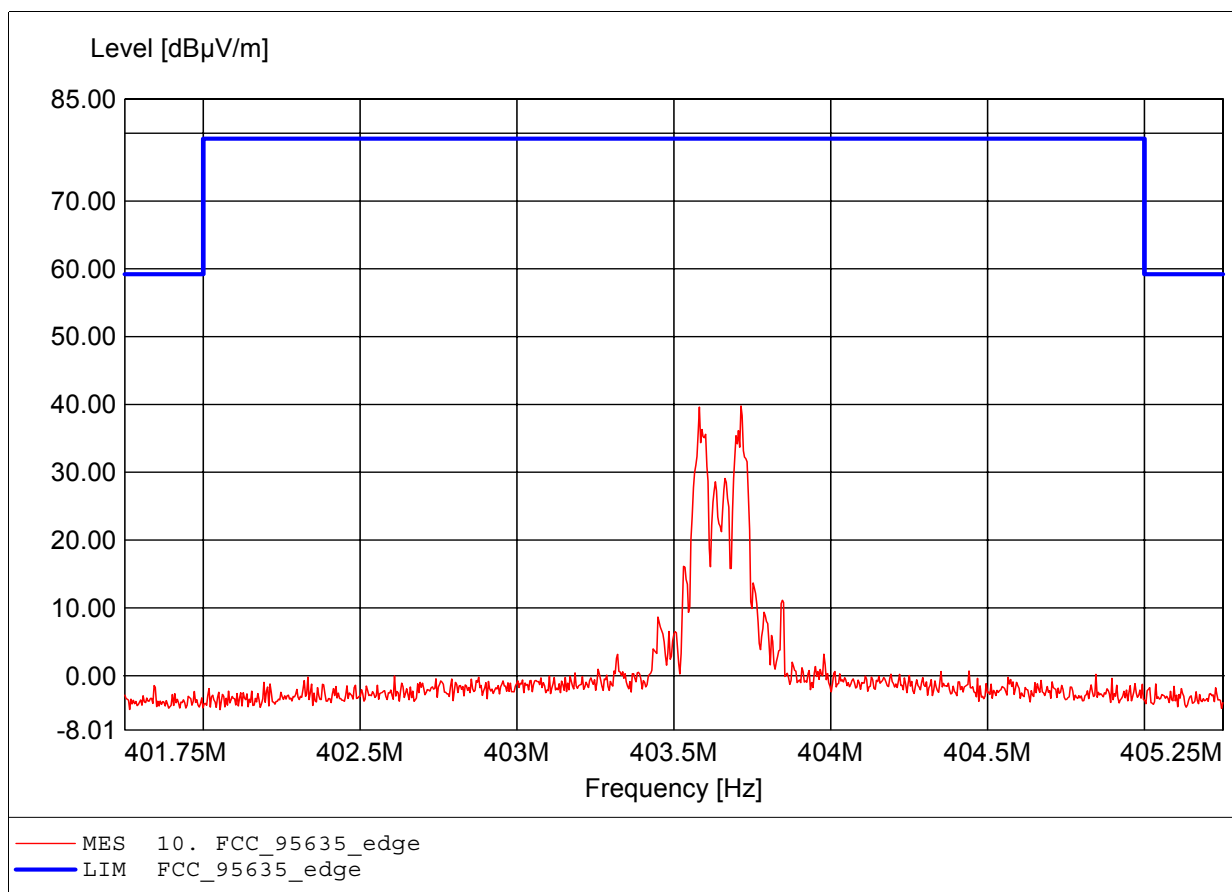
Approval Holder: BiotronicGmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 403.582MHz, Emax: 45.83dBµV/m, RBW: 3kHz



Spurious emissions Field Strength Tx

FCC RULES PART 95, SUBPART D

Approval Holder: BiotronicGmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §95.635 (d)(5), peak detector
Comment 1: Dist.: 3m, Ant.: HL 223
Comment 2: Freq: 403.714MHz, Emax: 39.79dBµV/m, RBW: 3kHz



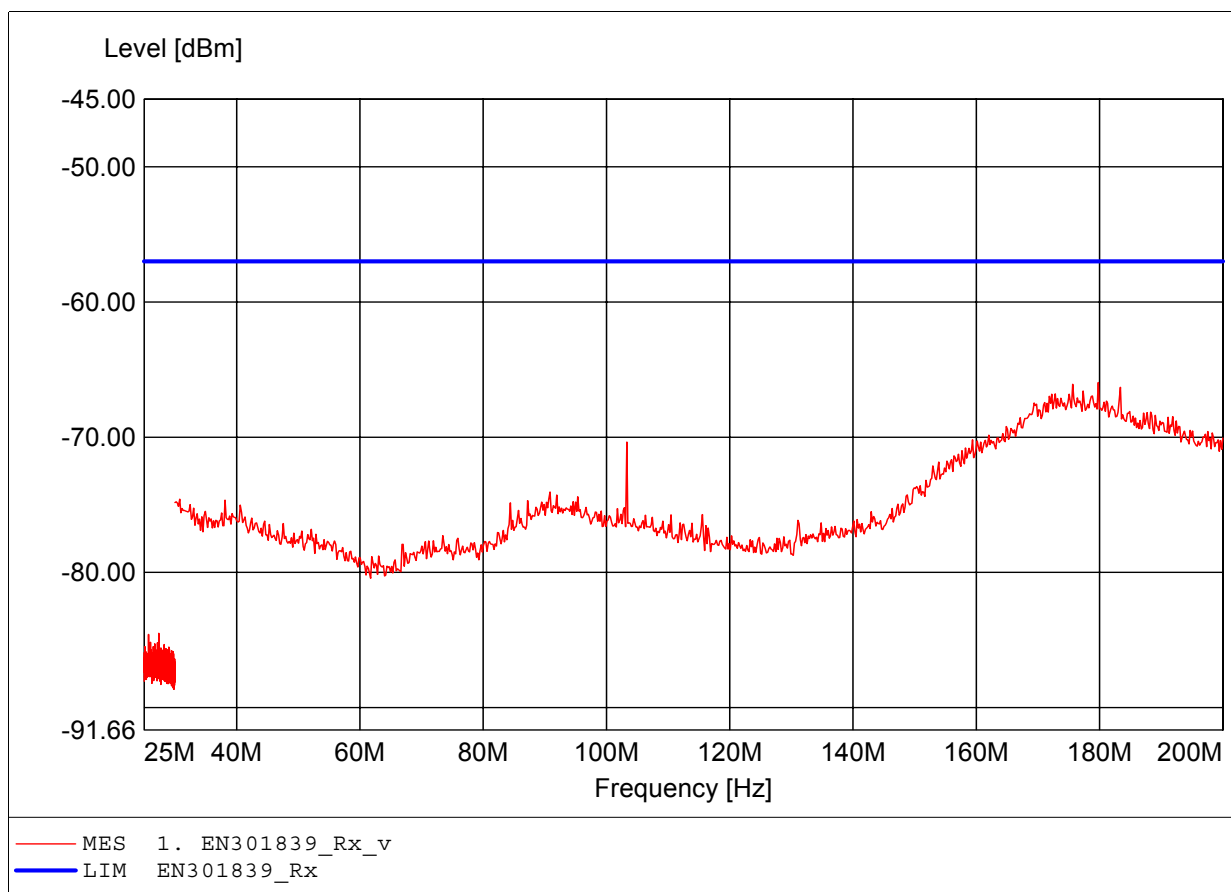
Annex J

Measurement diagrams Receiver Spurious emissions EN 301 839; RSS-Gen

Receiver spurious emissions

in accordance to the EN 301 839

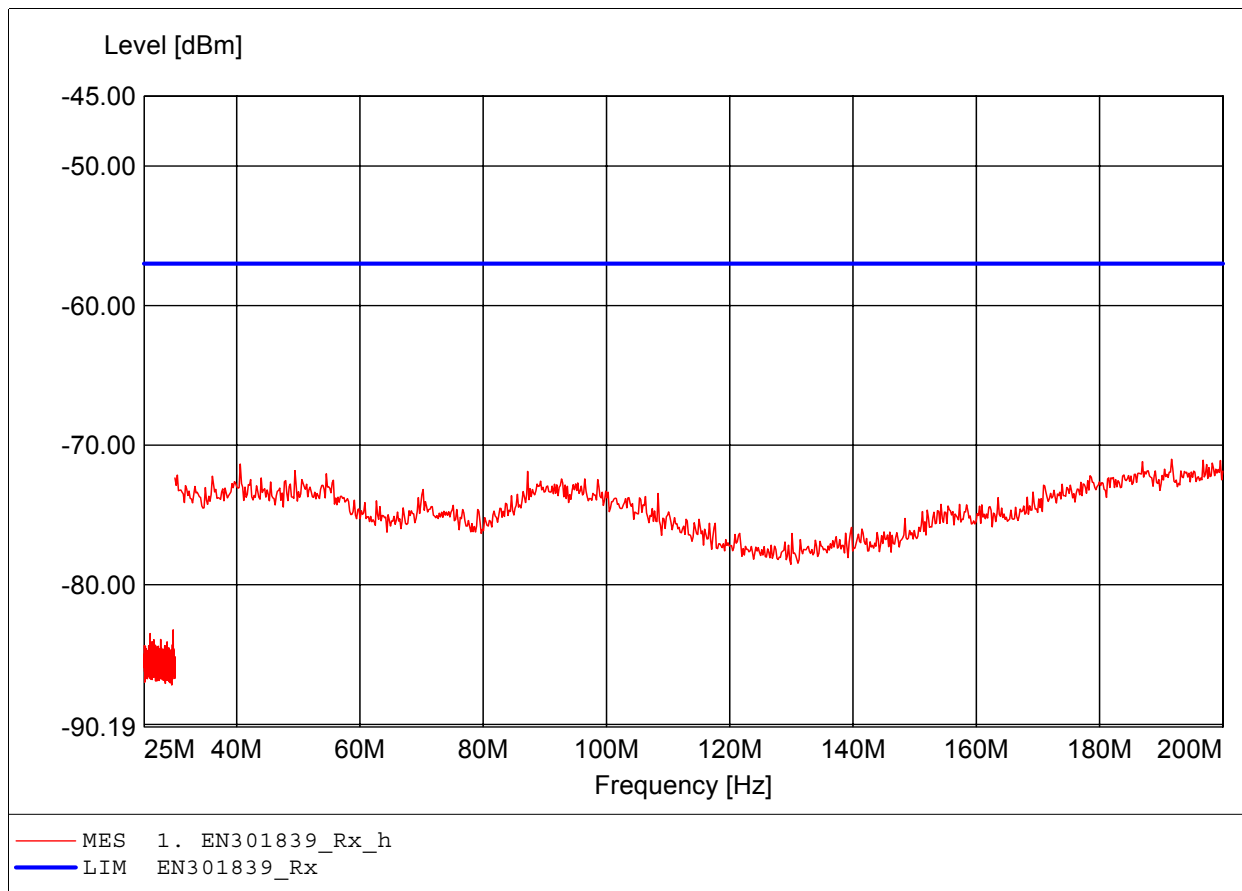
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: RX
Comment 1: Dist.: 3m, Ant.: HK 116, ampl.: None
Comment 2: Freq:179.789MHz Pmax:-65.95dBm RBW: 10/100 kHz



Receiver spurious emissions

in accordance to the EN 301 839

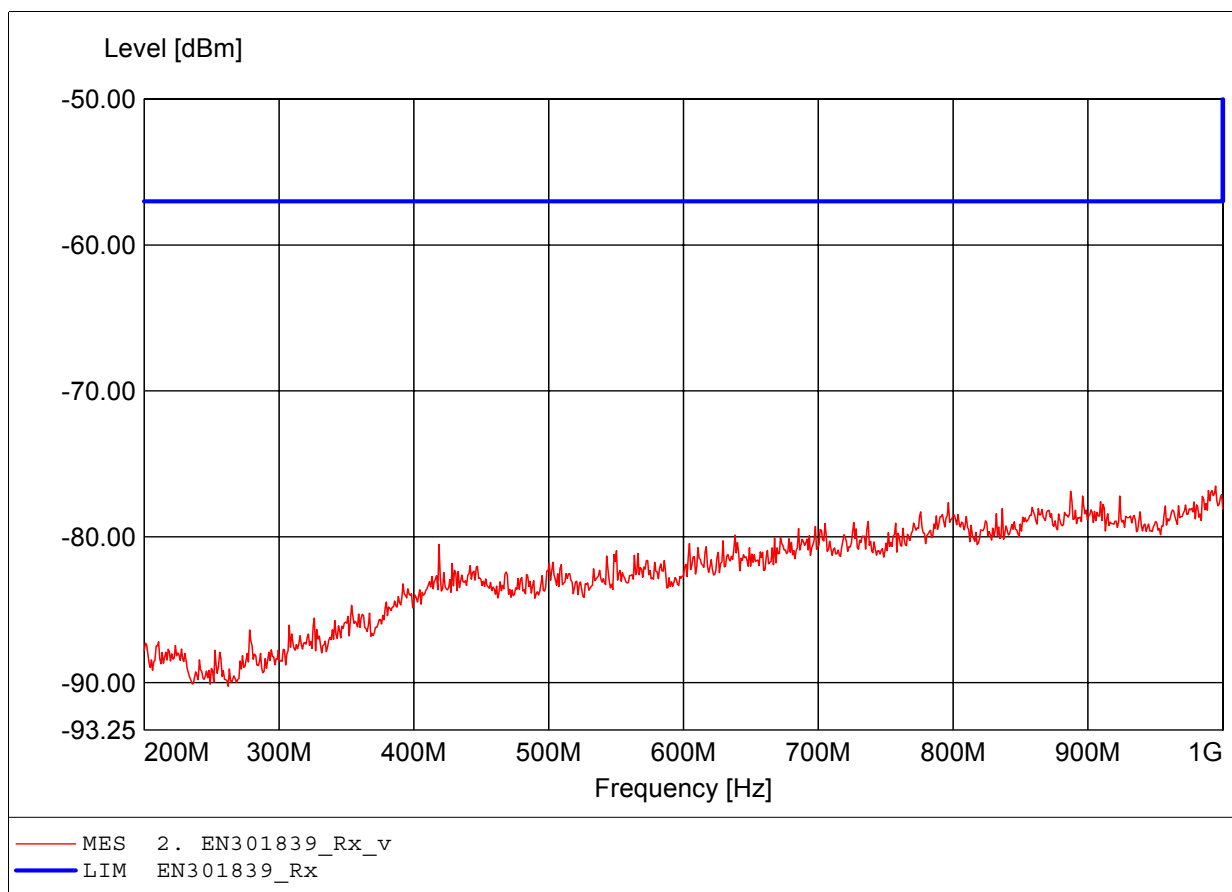
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: RX
Comment 1: Dist.: 3m, Ant.: HK 116, ampl.: None
Comment 2: Freq:191.689MHz Pmax:-71.00dBm RBW: 10/100 kHz



Receiver spurious emissions

in accordance to the EN 301 839

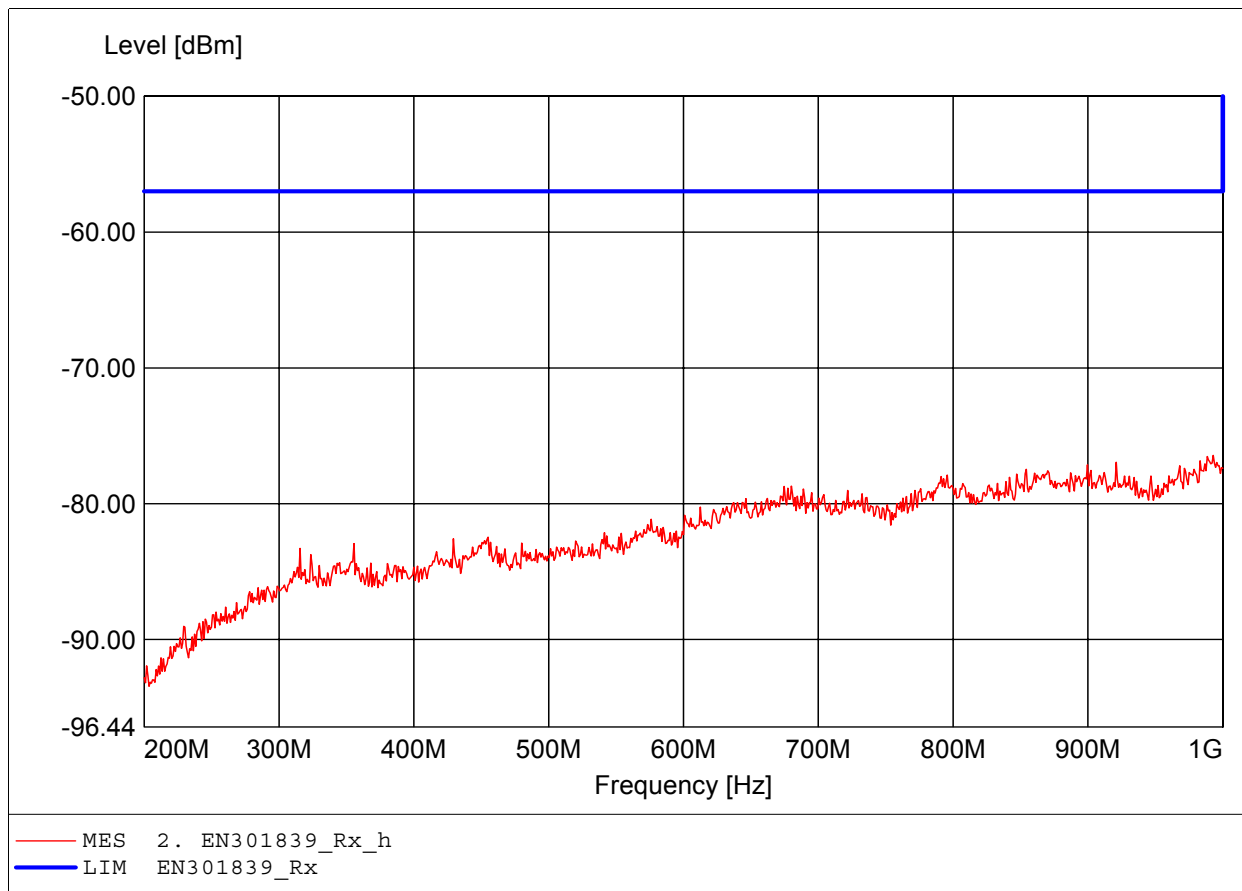
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: RX
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.: 0.1-1GHz
Comment 2: Freq:994.667MHz Pmax:-76.53dBm RBW: 100 kHz



Receiver spurious emissions

in accordance to the EN 301 839

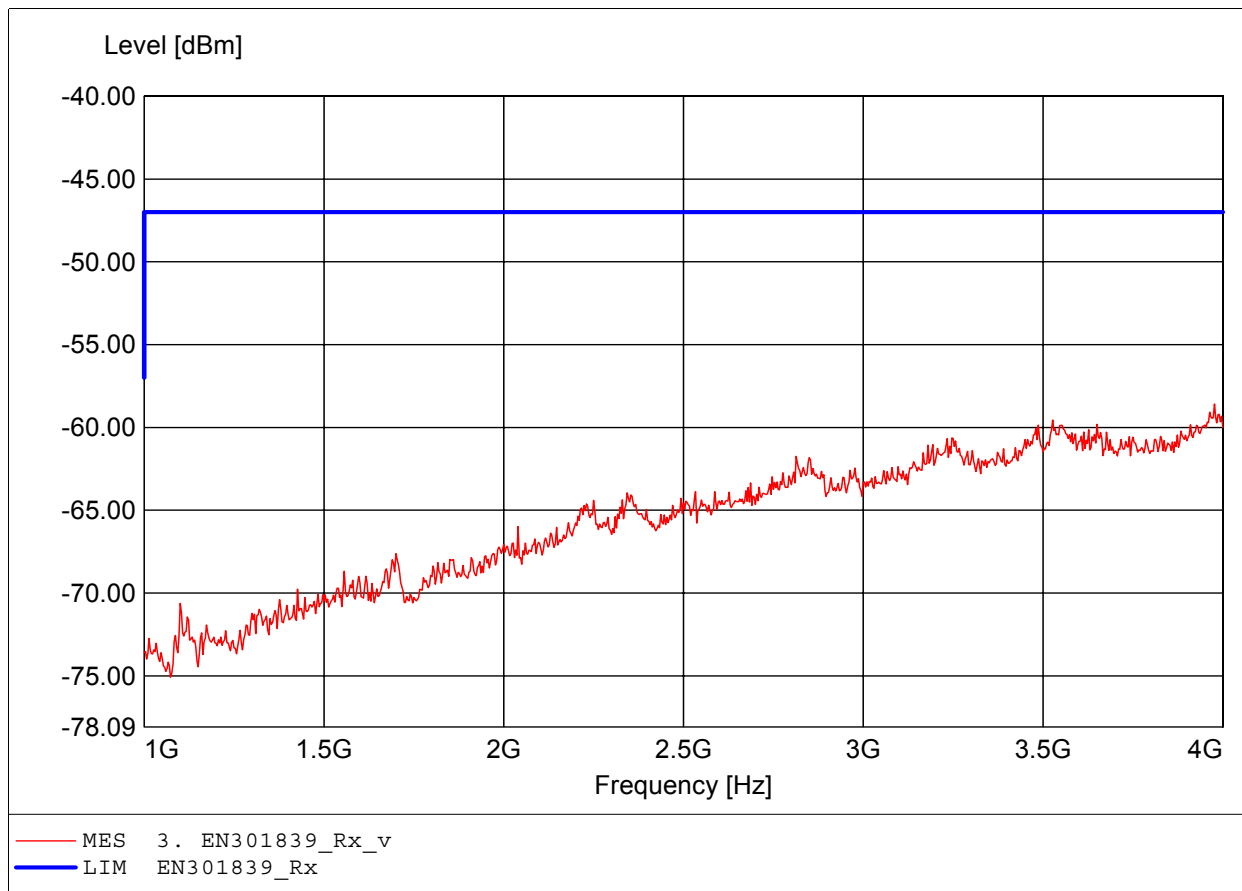
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: RX
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.: 0.1-1GHz
Comment 2: Freq:992.889MHz Pmax:-76.45dBm RBW: 100 kHz



Receiver spurious emissions

in accordance to the EN 301 839

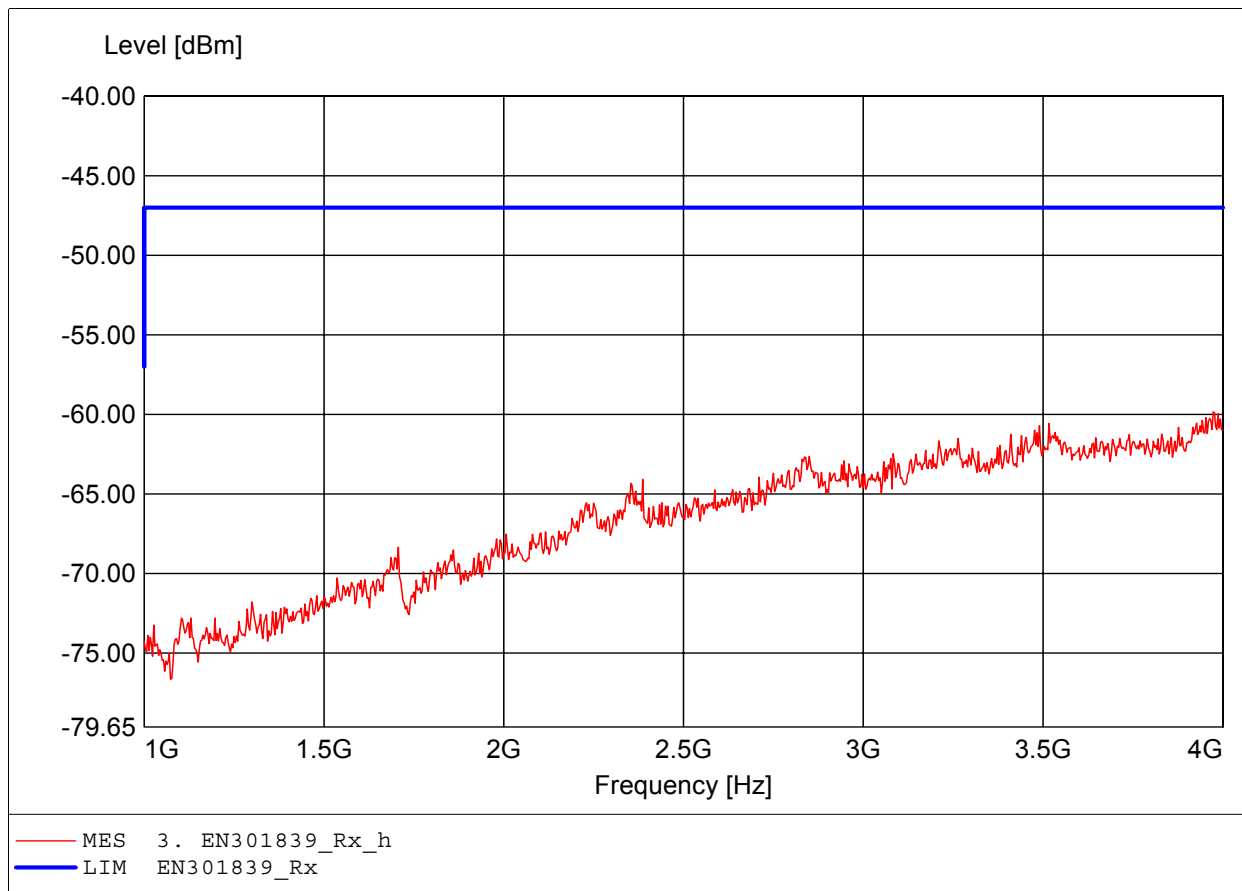
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: RX
Comment 1: Dist.: 3m, Ant.: HL 025, ampl.: 1-4GHz
Comment 2: Freq:3.977GHz Pmax:-58.59dBm RBW: 1 MHz



Receiver spurious emissions

in accordance to the EN 301 839

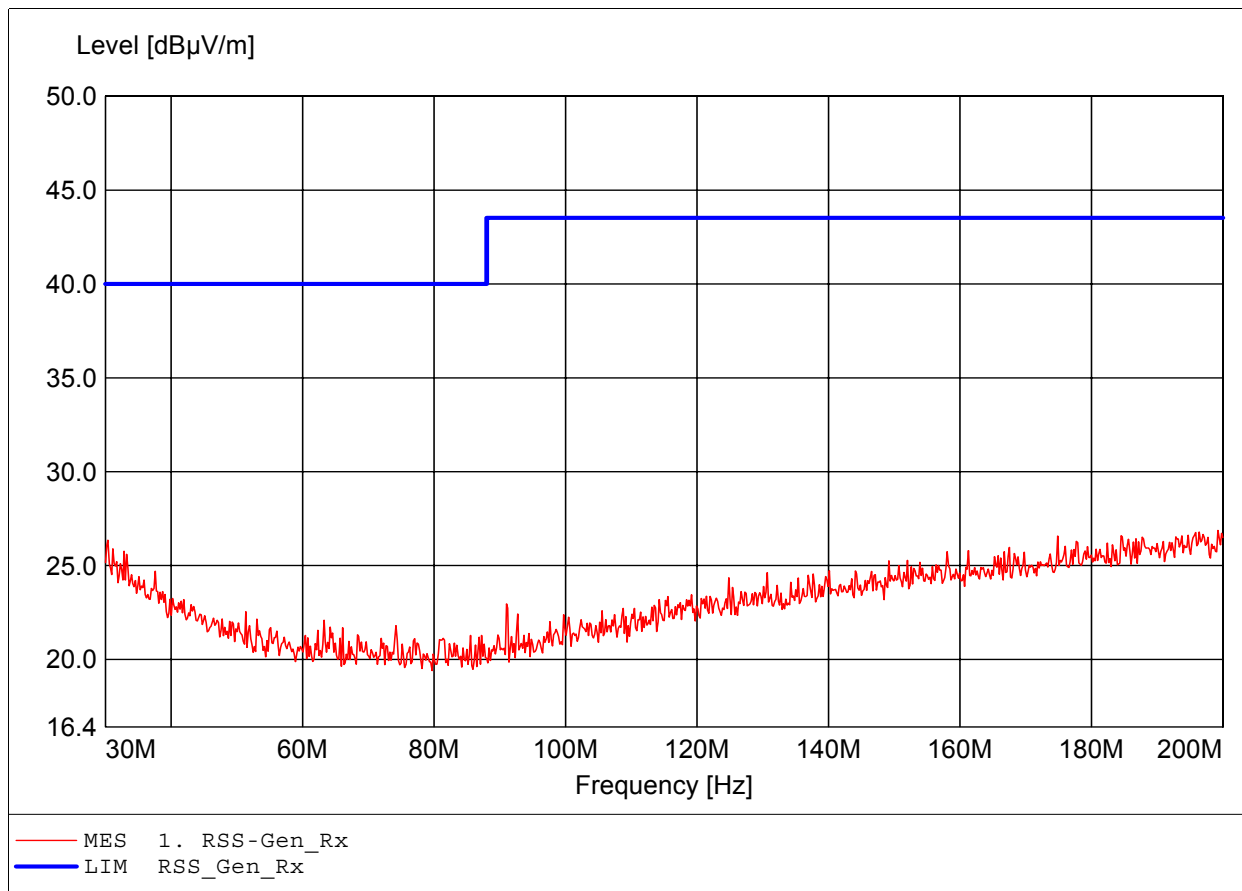
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: Fully anechoic chamber / mode: RX
Comment 1: Dist.: 3m, Ant.: HL 025, ampl.: 1-4GHz
Comment 2: Freq:3.973GHz Pmax:-59.84dBm RBW: 1 MHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

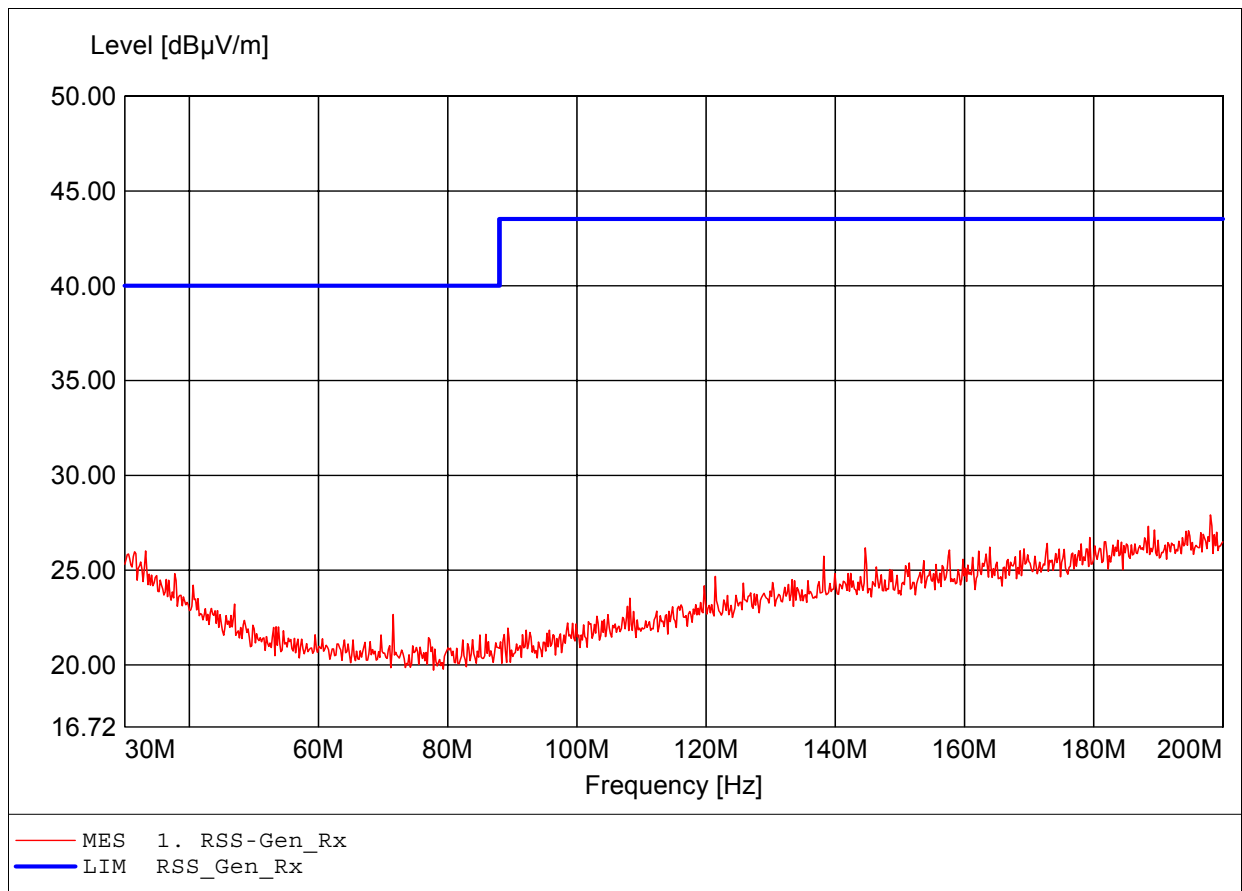
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to RSS-Gen
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:199.244MHz Emax:26.87dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

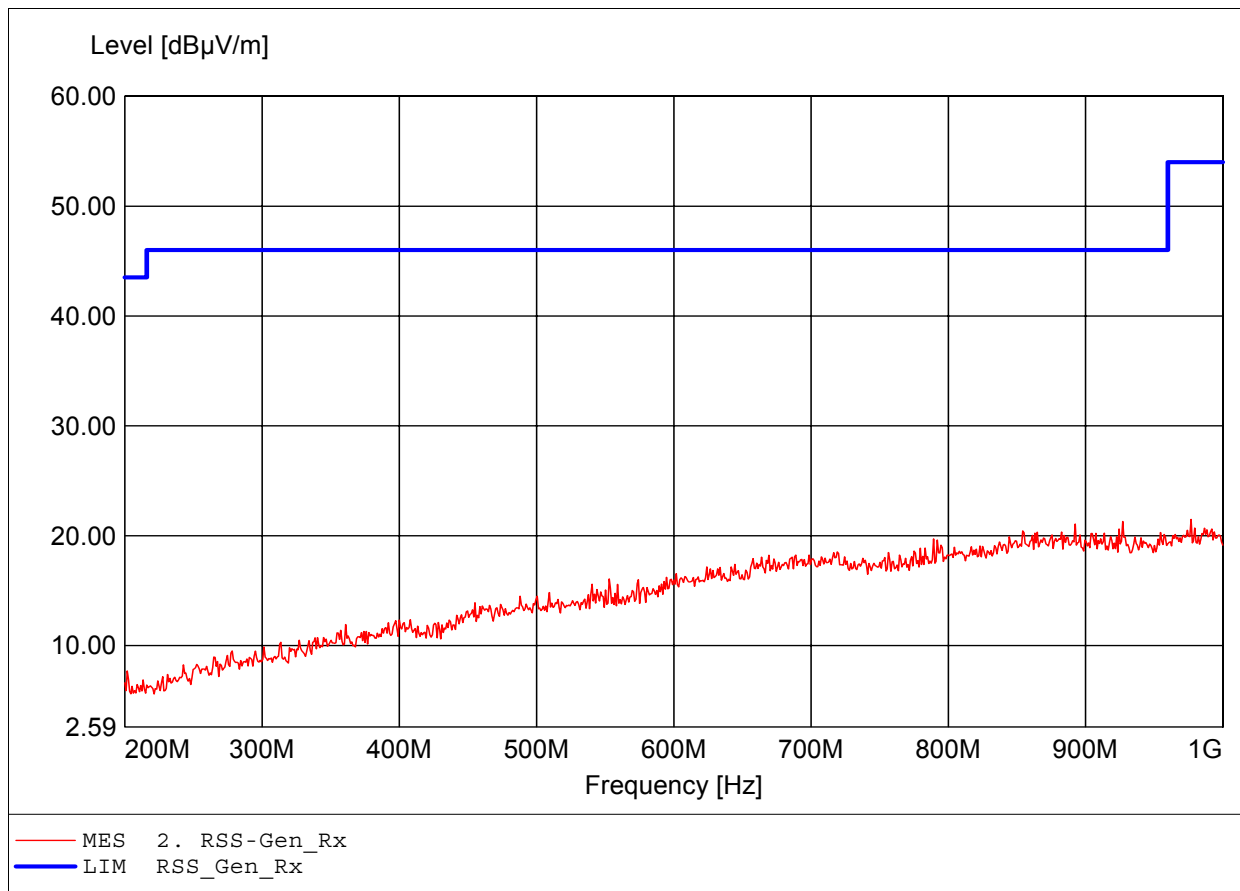
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to RSS-Gen
Comment 1: Dist.: 3m, Ant.: HK 116
Comment 2: Freq:198.111MHz Emax:27.91dBuV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

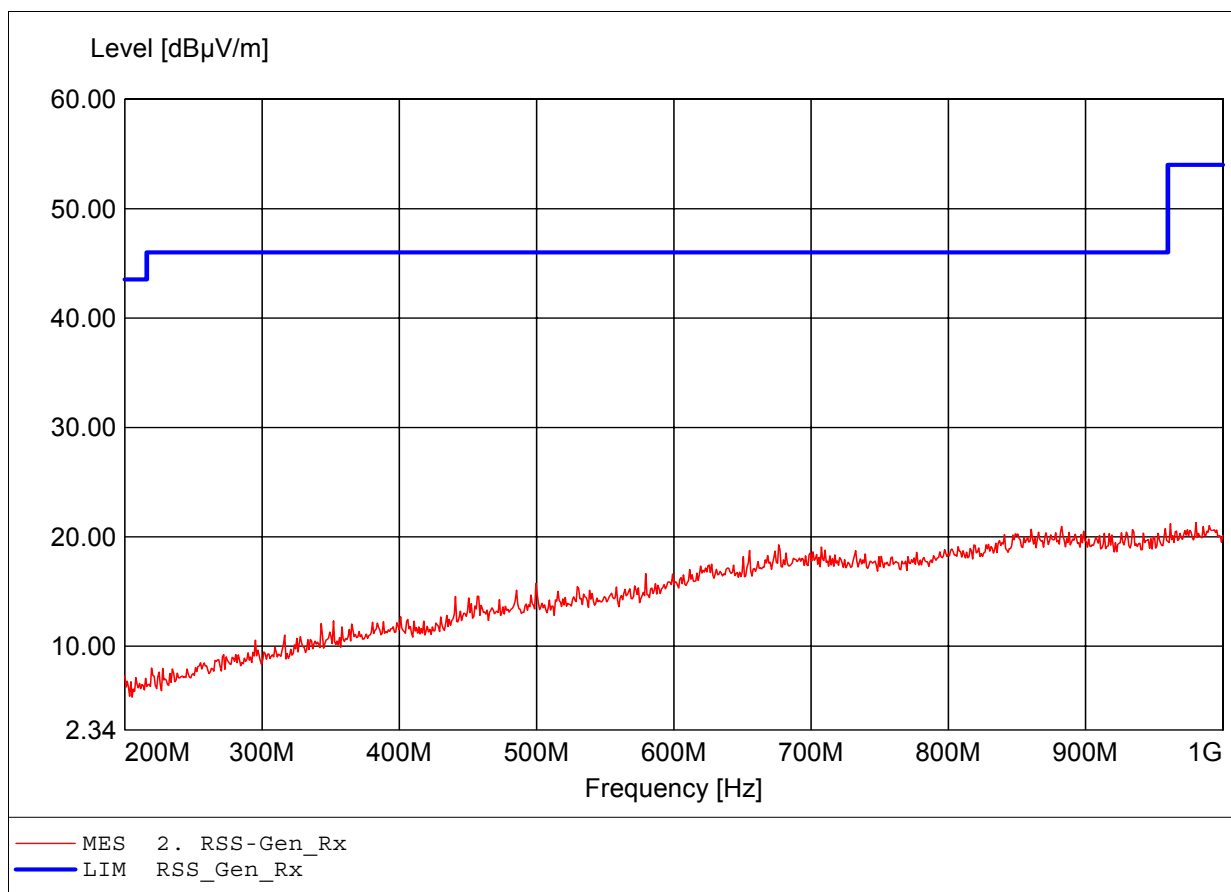
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to RSS-Gen
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.
Comment 2: Freq:976.889MHz Emax:21.49dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

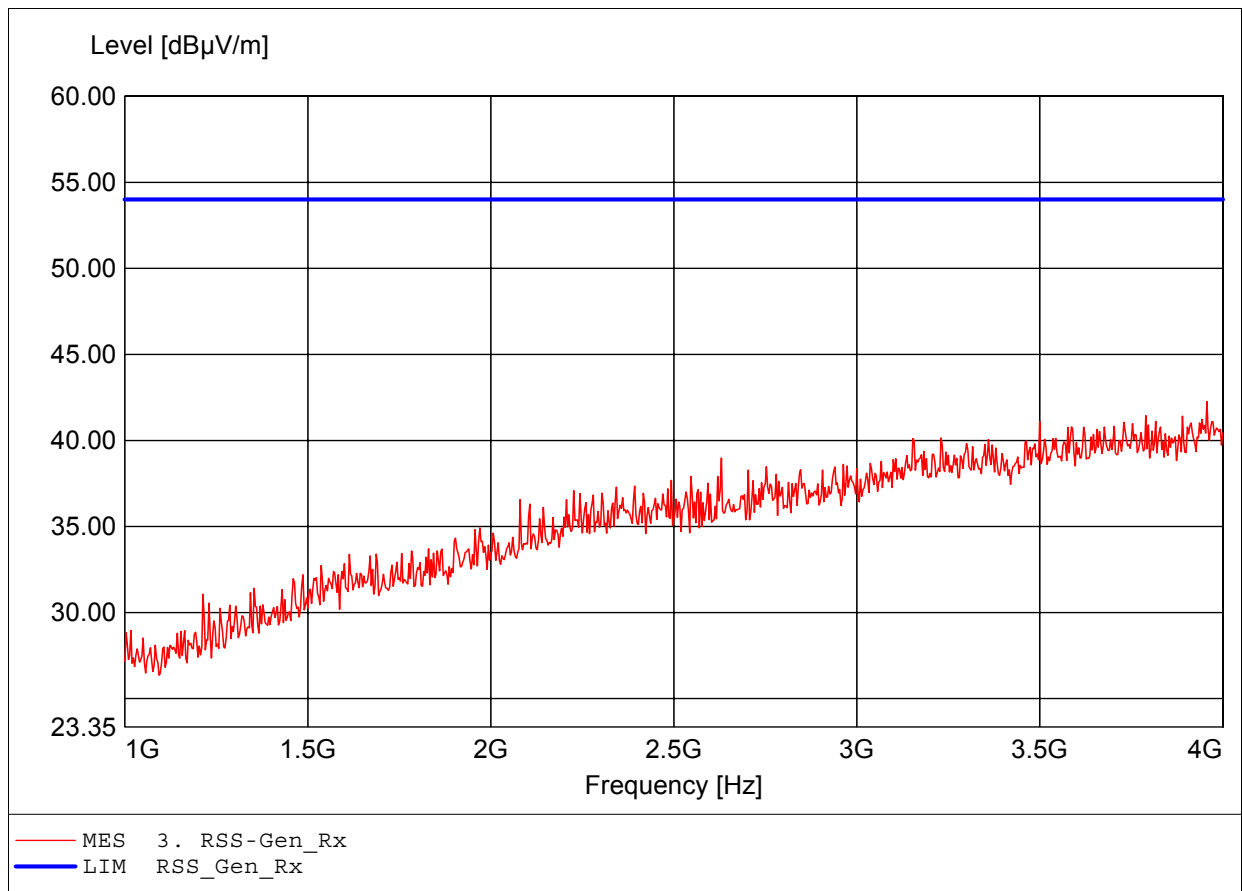
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to RSS-Gen
Comment 1: Dist.: 3m, Ant.: HL 223, ampl.
Comment 2: Freq:980.444MHz Emax:21.30dBµV/m RBW: 100 kHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

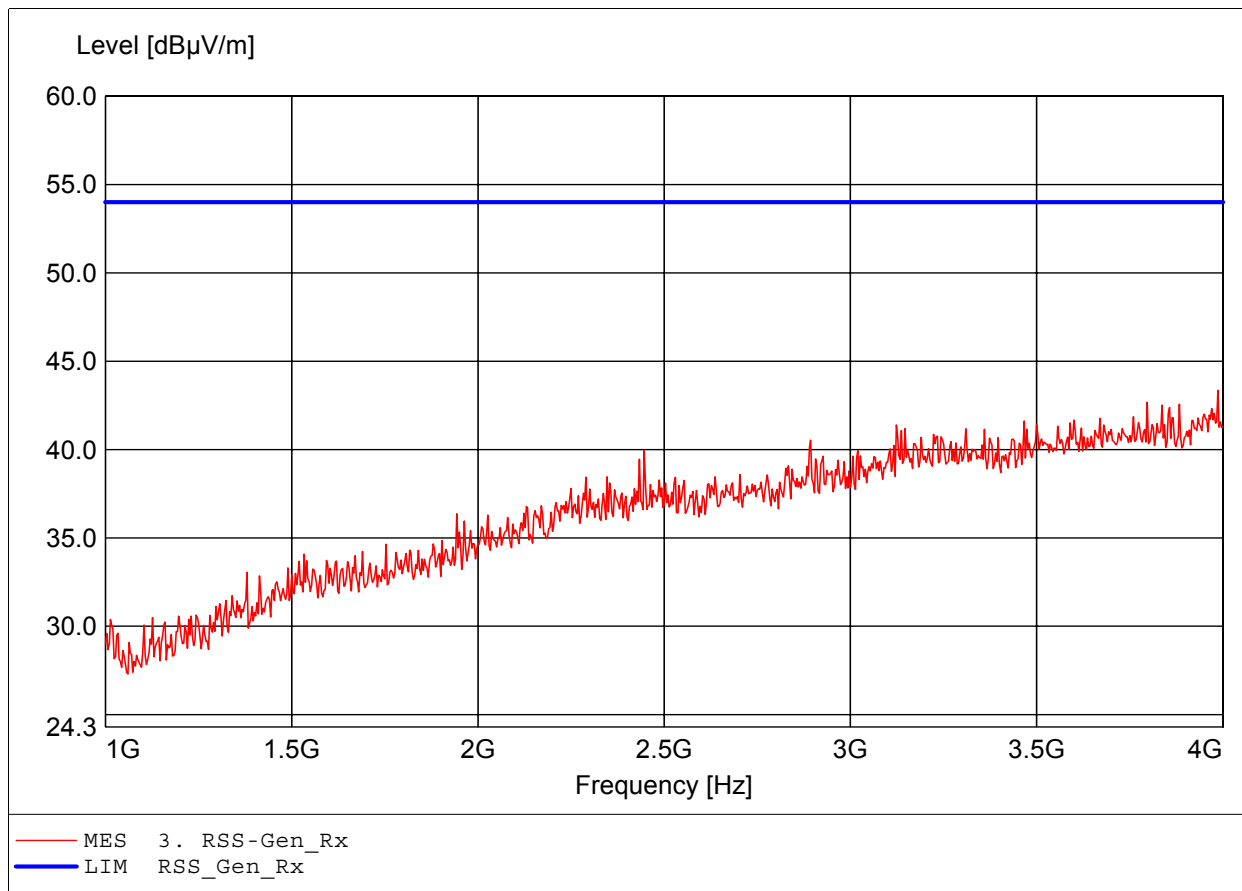
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §15109, peak detector
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:3.957GHz Emax:42.25dBµV/m RBW: 1 MHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

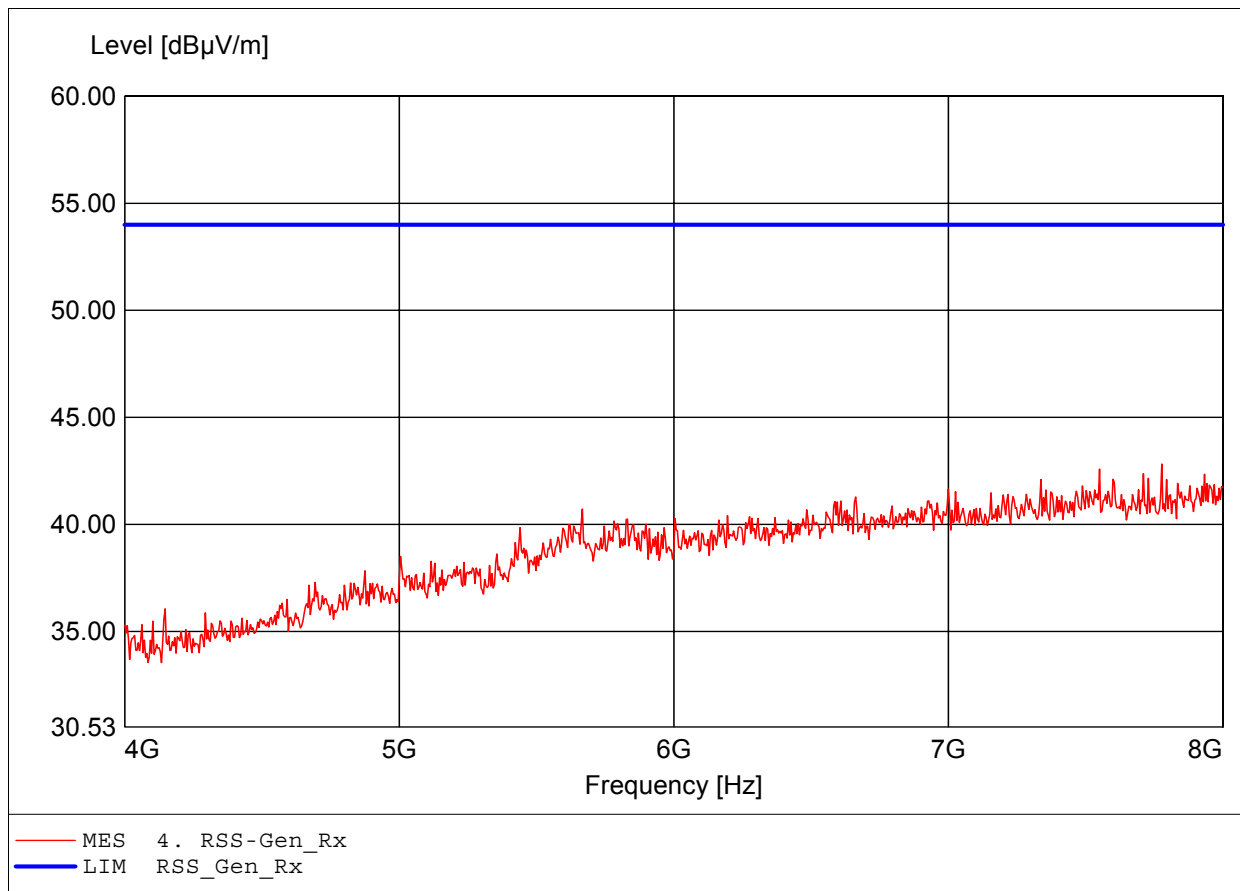
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §15109, peak detector
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:3.987GHz Emax:43.36dBµV/m RBW: 1 MHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

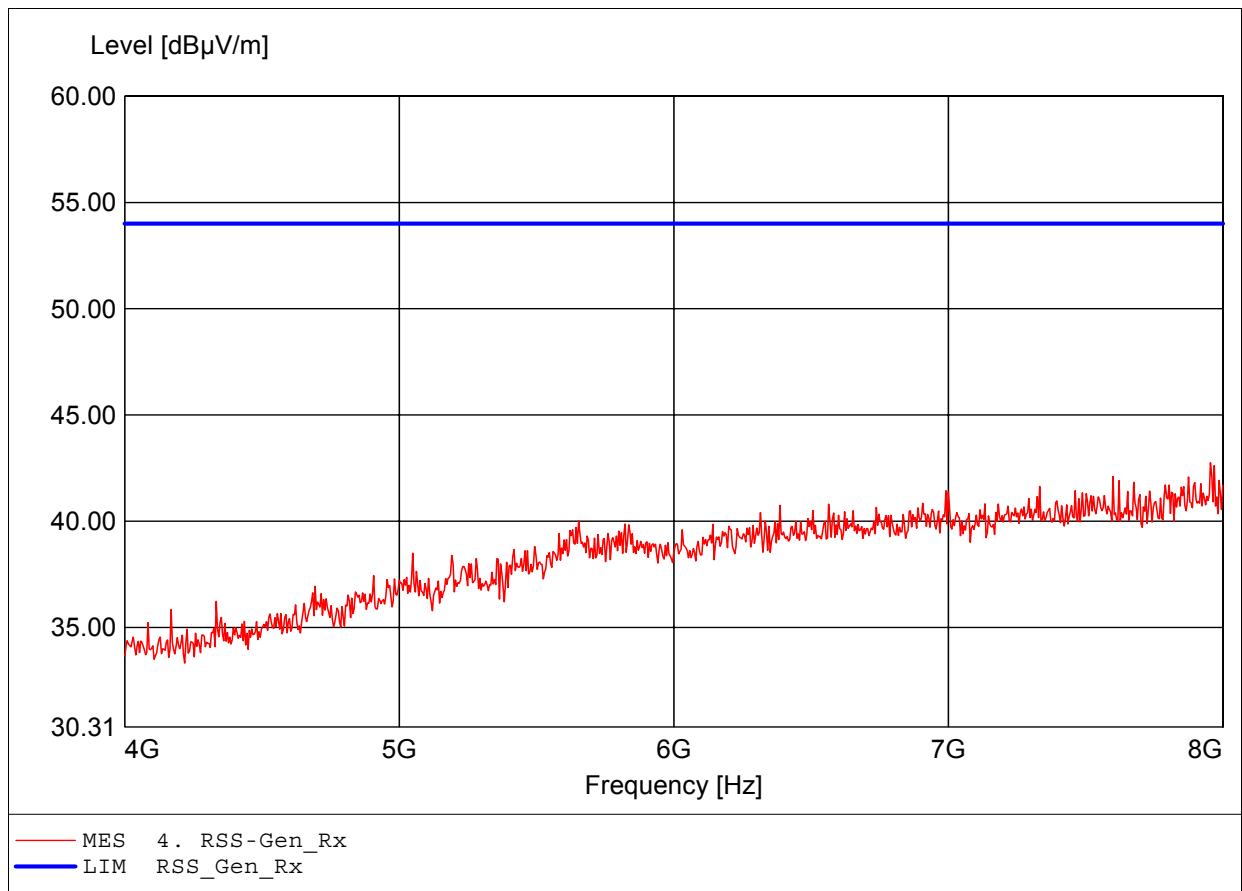
Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §15109, peak detector
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:7.778GHz Emax:42.82dBµV/m RBW: 1 MHz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

Approval Holder: Biotronik GmbH & Co., KG
EUT : Pacemaker Implant / Frequency 403.65 MHz
Model: PRIMUS
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: 25°C / Vnom.: 2.8V DC (Battery)
Test Specification: according to §15109, peak detector
Comment 1: Dist.: 3m, Ant.: HL025, ampl.
Comment 2: Freq:7.956GHz Emax:42.74dBµV/m RBW: 1 MHz



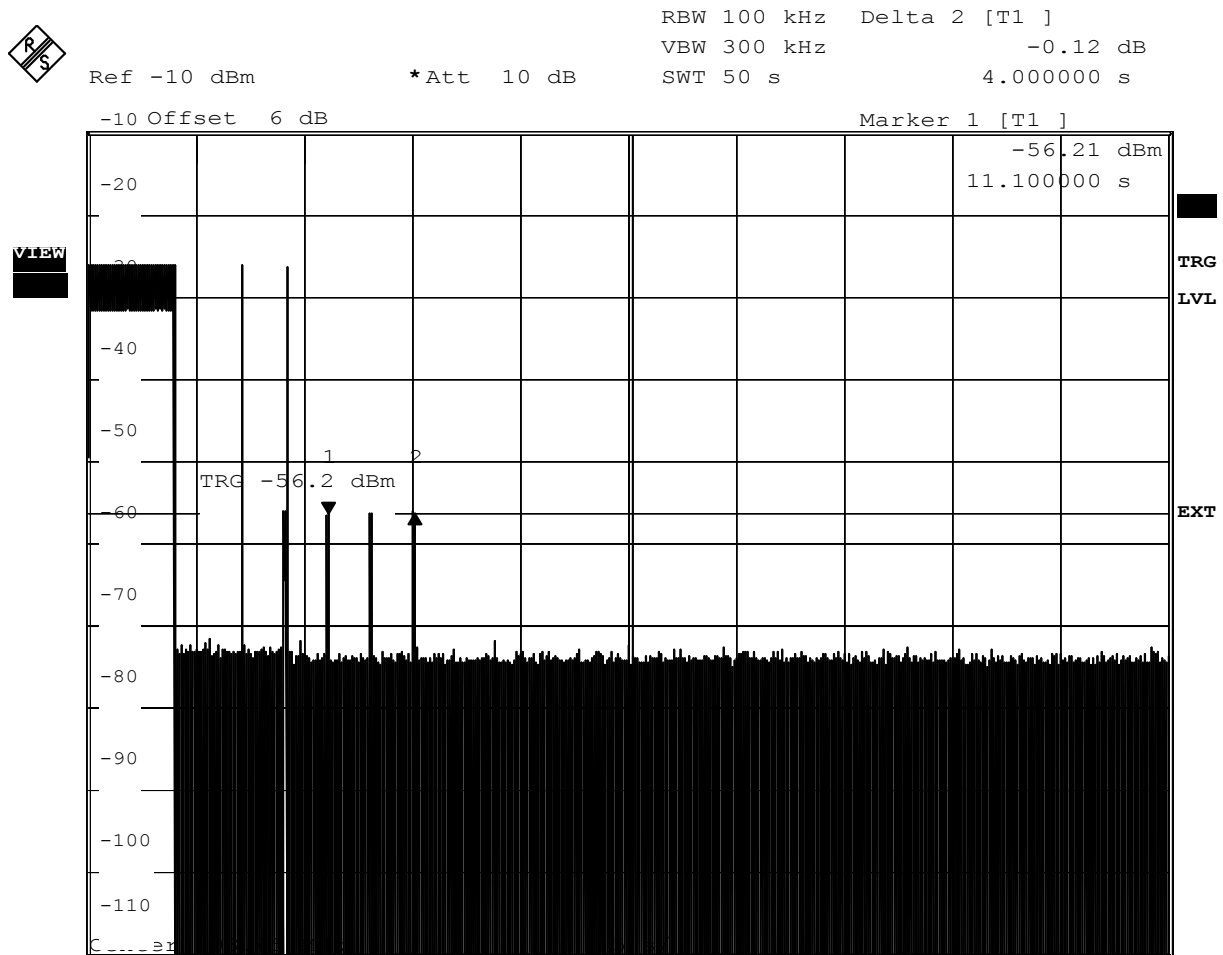
Annex K

Discontinuation of MICS session

FCC part 95.628 / EN 301 839 v1.1.1 / RSS-243
Discontinuation of MICS session if a silent period greater than or equal to 5 s occurs

EUT Pacemaker
 Model PRIMUS
 Approval Holder Biotronik GmbH
 Temperature / Voltage 25°C / Unom: 2.8 V DC (Battery)
 Test Site / Operator Eurofins Product Service GmbH / Mr. Handrik
 Test Specification FCC part 95.628 / EN 301 839-1 10.5 / RSS-243 5.7.6
 Comment 1 Discontinuation of MICS session if a silent period greater than or equal to 5 s occurs

Comment 2
 Comment 3



Date: 21.OCT.2008 14:15:32

Measurement diagram

Revision History

Revision	Issue Date	Revision	Revised by
01	12.01.2010	Replaced document:: G0M20810-2039-T-47 Replaced by: G0M20810-2039-T-47_rev01 Reason: Page 7: Point 2.3 Test information Source of target values added <ul style="list-style-type: none">Page 12: Point 3.3 Effective radiated power EIRP values completed	A. Bartusch
