



<b>FCC TEST REPORT</b> <b>FCC 47 CFR Part 15C</b> <b>Industry Canada RSS-310</b> <b>License exempt radio equipment</b>	
<b>Report Reference No.</b> .....	G0M-1509-5046-TFC209LP-V01
<b>Testing Laboratory</b> .....	Eurofins Product Service GmbH
Address .....	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation .....	<div style="display: flex; align-items: center; justify-content: center;">   </div> <p style="text-align: center; margin-top: 5px;">                     A2LA Accredited Testing Laboratory, Certificate No.: 1983.01                      FCC Filed Test Laboratory, Reg.-No.: 96970                      IC OATS Filing assigned code: 3470A                 </p>
<b>Applicant's name</b> .....	Biotronik SE & Co. KG
Address .....	Woermannkehre 1 12359 Berlin GERMANY
<b>Test specification:</b>	
Standard .....	47 CFR Part 15C RSS-310, Issue 3, 2010-12 RSS-Gen, Issue 4, 2014-11 ANSI C63.4:2014
Test scope .....	complete Radio compliance test (C2PC)
<b>Equipment under test (EUT):</b>	
Product description	Pacemaker family PRIMUS NXT
Model No.	Eluna 8 HF-T
Additional Model(s)	see page5: List of Models to be included in the family
Brand Name(s)	BIOTRONIK
Hardware version	ASM-0217_0B with BOM-0288_06_396062 (2230-04)
Firmware / Software version	7300RomRev_01.02/7474RamRev_04.02
	FCC-ID: QRIPRIMUSNXT      IC: 4708A-PRIMUSNXT
<b>Test result</b>	<b>Passed</b>

**Possible test case verdicts:**

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

**Testing:**

Test Lab Temperature ..... : 20 – 23 °C

Test Lab Humidity ..... : 32 – 38 %

Date of receipt of test item ..... : 2015-10-02

Date (s) of performance of tests ..... : 2015-10-05 – 2015-10-08

Compiled by ..... : Wilfried Treffke

Tested by (+ signature) ..... : Wilfried Treffke *W. Treffke*  
 (Responsible for Test) .....

Approved by (+ signature) ..... : Christian Weber *C. Weber*  
 (Head of Lab) .....

Date of issue ..... : 2015-11-11

Total number of pages ..... : 31

**General remarks:**

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

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

**Additional comments:**

Family Explanation Primus NXT

All devices feature the two RF-Telemetry functions Home Monitoring and wireless Wand.

RF-Telemetry functions are using the MICS-Band (402MHz – 405MHz).

A „T“ inside the name of the device represents a device containing Home Monitoring capabilities.

HF-T are triple-chamber devices. (Master for all tests)

DR-T are dual-chamber devices.

SR-T are single-chamber devices.

DR are dual-chamber without home monitoring.

SR are single-chamber without home capabilities.

*All of these differences are only relevant in terms of medical aspects. They do not interfere with the RF-performance.*

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

BIOTRONIK SE &amp; Co. KG · Postfach 470255 · 12311 Berlin

To whom it may concern

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dirk.koenig@biotronik.com  
www.biotronik.com

Berlin, October 20, 2015

Gentlemen,

Herewith we, BIOTRONIK SE &amp; Co. KG, declare the following changes that were done to the already approved product family PRIMUS NXT (FCC-ID: QRIPRIMUSNXT)

The major change filed under application is:

- Change 1: The SAW filter was changed from the Vectron 403A to the Vectron 403B.  
Change 2: Matching components for the SAW filter were changed (L804 was 11nH and is now 36nH, L808 was 27nH and is now 30nH).  
Change 3: The antenna design was modified to improve manufacturability. The electrical length remains the same.

According to our internal design validation no difference in conducted output power was observed as part of the design change.

If you have any questions regarding this application, please feel free to contact

Contact name Dirk König  
Company name BIOTRONIK SE & CO. KG  
Phone No.: +49 (0) 30 68905 1291

Sincerely,

Signature  
Dirk König  
Manager Regulatory Affairs  
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HRA 6501 B, AG Berlin-Charlottenburg  
Komplementärin: BIOTRONIK MT SE  
HRB 118866 B, AG Berlin-Charlottenburg

**PRIMUS NXT product family  
Family Certification  
List of the models to be included in the family**

**Applicant:** BIOTRONIK SE & Co. KG

**Certification Number:** QRIPRIMUSNXT

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

The BIOTRONIK PRIMUS NXT family of products includes the following models:

**Eluna, Epyra and Etrinsa.**

All models comprise identical internal electronic including a low frequency telemetry coil and packaged in titanium cases with a header where the leads connect.

All devices include additional an internal RF Transceiver and an antenna within the header.

The internal electronic of HF-T devices differs slightly from SR and DR devices to include the third channel electronic. Therefore the device under test is three chambers model **Eluna 8 HF-T**.

The PRIMUS NXT models contain a different therapeutic feature set. The features differ only by the number of connectable leads and software.

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## Version History

Version	Issue Date	Remarks	Revised by
01	2015-11-11	Initial Release	

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## REPORT INDEX

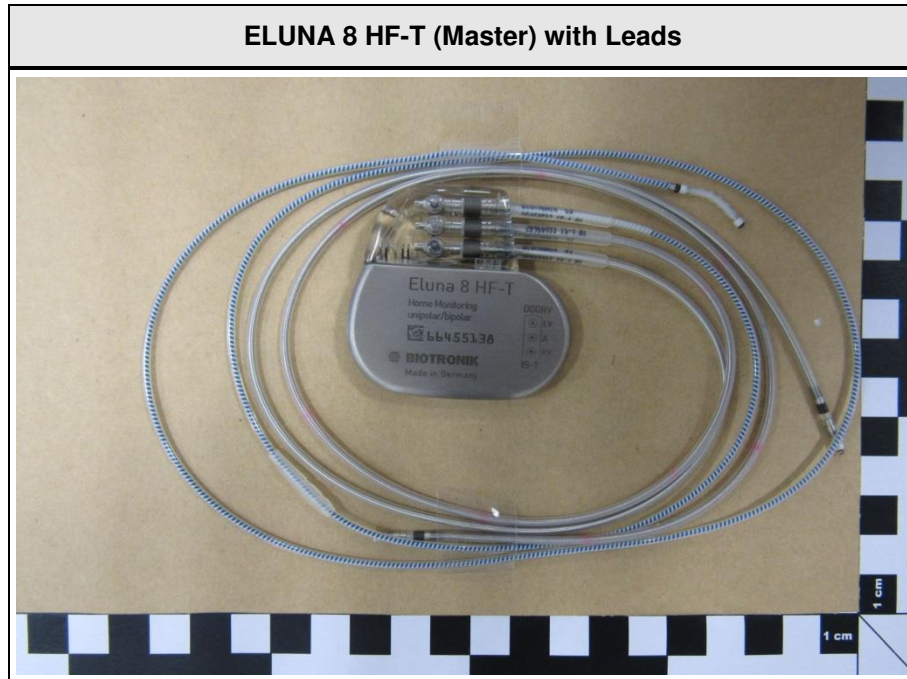
<b>1</b>	<b>EQUIPMENT (TEST ITEM) DESCRIPTION</b>	<b>8</b>
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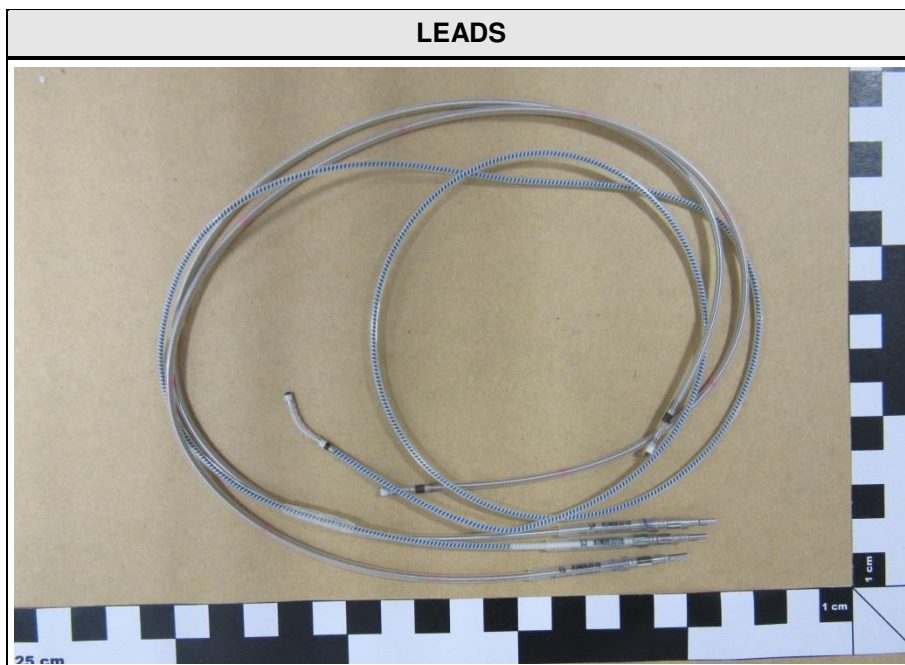
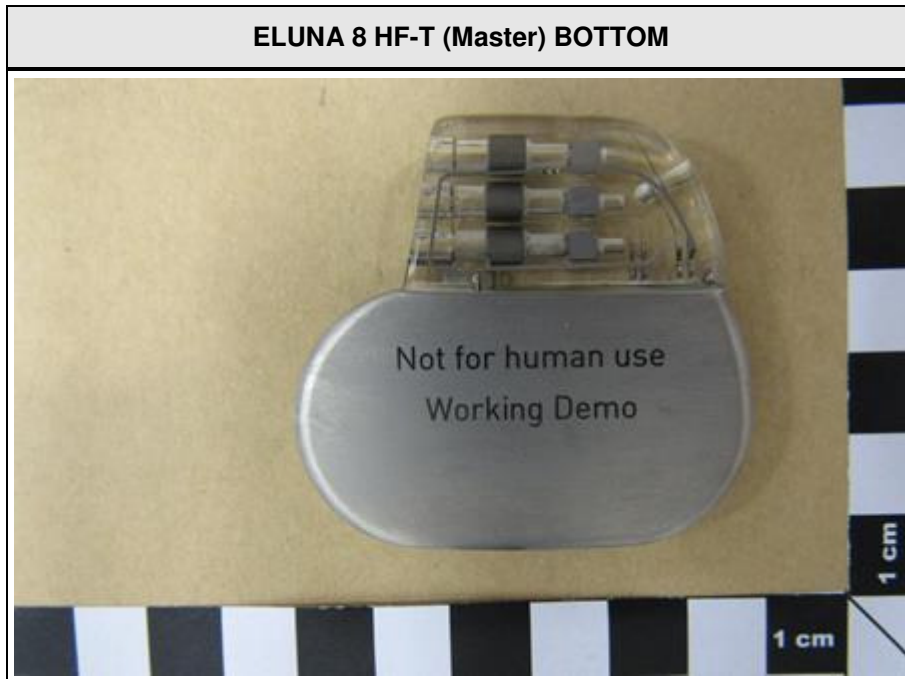
## 1 Equipment (Test item) Description

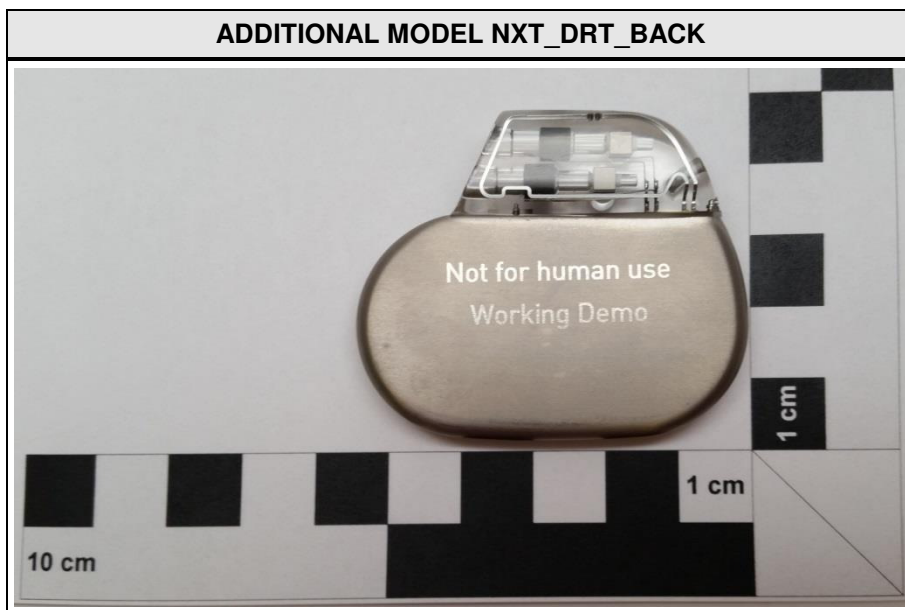
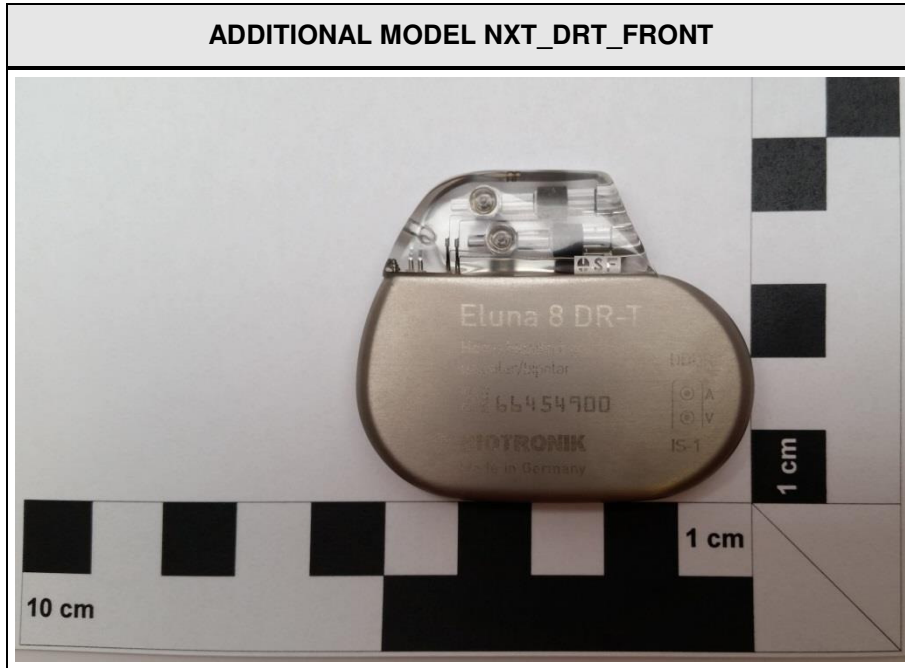
<b>Description</b>	Pacemaker family PRIMUS NXT	
<b>Model</b>	Eluna 8 HF-T	
<b>Additional Model(s)</b>	see page5: List of Models to be included in the family	
<b>Brand Name(s)</b>	BIOTRONIK	
<b>Serial number</b>	66455138	
<b>Hardware version</b>	ASM-0217_0B with BOM-0288_06_396062 (2230-04)	
<b>Software / Firmware version</b>	7300RomRev_01.02/7474RamRev_04.02	
<b>FCC-ID</b>	QRIPRIMUSNXT	
<b>IC</b>	4708A-PRIMUSNXT	
<b>Equipment type</b>	End product	
<b>Radio type</b>	Transceiver	
<b>Radio technology</b>	custom	
<b>Operating frequency range</b>	64 kHz	
<b>Frequency range</b>	$F_{MID}$	64 kHz
<b>Modulations</b>	OOK	
<b>Number of channels</b>	1	
<b>Channel spacing</b>	None	
<b>Number of antennas</b>	1	
<b>Antenna</b>	Type	integrated
	Model	loop antenna
	Manufacturer	Biotronik SE & Co. KG
	Gain	unspecified
<b>Manufacturer</b>	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
<b>Power supply</b>	$V_{NOM}$	3.0 VDC (Lithium-Battery)
	$V_{MIN}$	N/A
	$V_{MIN}$	N/A
<b>AC/DC-Adaptor</b>	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

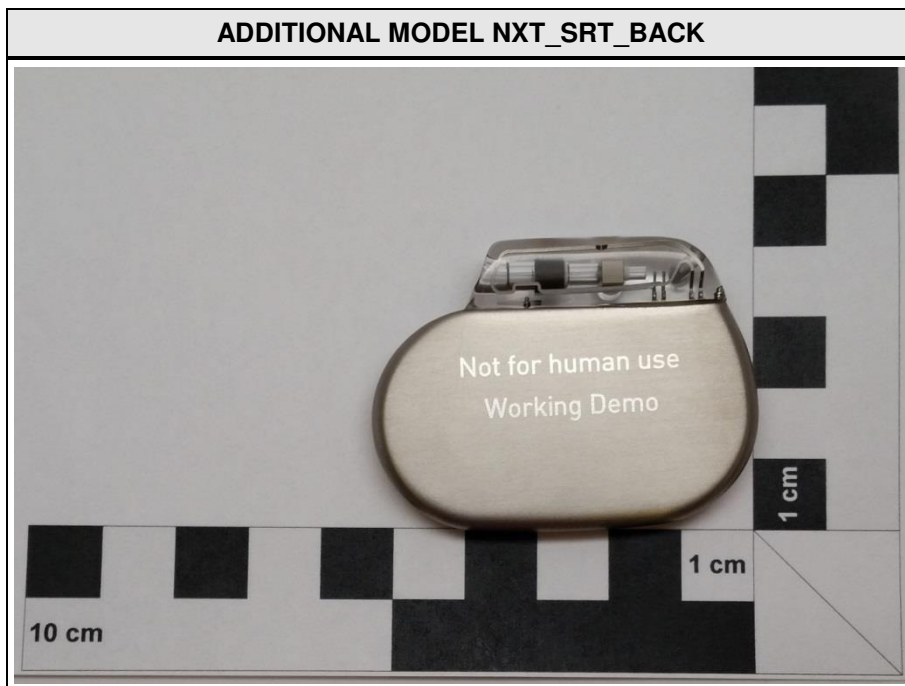
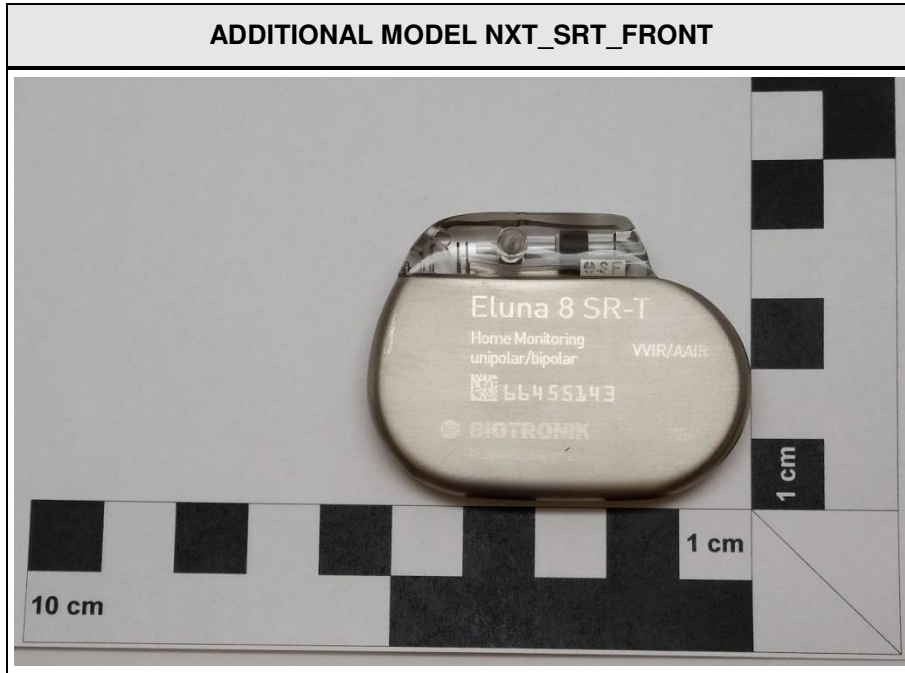


1.1 Photos – Equipment External

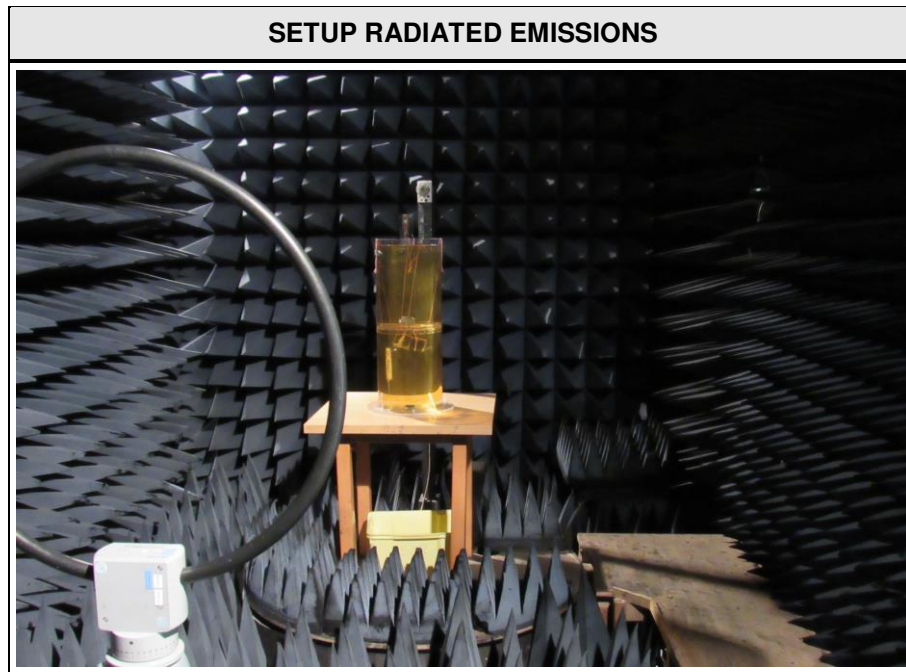








1.2 Photos – Test setup



1.3 Photos – Auxiliary/Associated Equipment



**1.4 Supporting Equipment Used During Testing**

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Programer	Biotronik	USB TelBox	64kHz system
<p><b>*Note:</b> Use the following abbreviations:</p> <p>AE : Auxiliary/Associated Equipment, or</p> <p>SIM : Simulator (Not Subjected to Test)</p> <p>CABL : Connecting cables</p>				

**1.5 Test Modes**

Mode #	Description	
Single	General conditions:	EUT powered by fully charged battery
	Radio conditions:	Mode = standalone transmit Modulation = OOK Power level = Maximum
Receive	General conditions:	EUT powered by fully charged battery
	Radio conditions:	Mode = standalone receive Modulation = OOK



**1.6 Test Equipment Used During Testing**

<b>Measurement Software</b>			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2014.1.15

<b>Occupied Bandwidth</b>					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSP 30	EF00312	2015-02	2016-02

<b>Field strength emissions</b>					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 1	EF00062	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2015-04	2016-04
Loop antenna	R&S	HFH2-Z2	EF00184	2014-11	2016-11

## 1.7 Sample emission level calculation

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

Reading:

This is the reading obtained on the spectrum analyzer in dB $\mu$ 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 $\mu$ V/m). The FCC limits are given in units of  $\mu$ V/m. The following formula is used to convert the units of  $\mu$ V/m to dB $\mu$ 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:

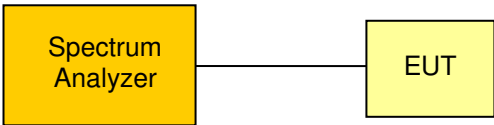
$$\begin{array}{rclcl} \text{Reading} & + & \text{AF} & = & \text{Net Reading} & : & \text{Net reading - FCC limit} & = & \text{Margin} \\ 21.5 \text{ dB}\mu\text{V} & + & 26 \text{ dB} & = & 47.5 \text{ dB}\mu\text{V/m} & : & 47.5 \text{ dB}\mu\text{V/m} - 57.0 \text{ dB}\mu\text{V/m} & = & -9.5 \text{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

## 2 Result Summary

FCC 47 CFR Part 15C, IC RSS-310				
Product Specific Standard Section	Requirement – Test	Reference Method	Result	Remarks
RSS-Gen 6.6	Occupied Bandwidth	RSS-Gen 6.6	N/R	Informational only
FCC 15.201(a), FCC 15.209 IC RSS-310 3.7	Field strength emissions	ANSI C63.4	PASS	
IC RSS-310 2.3 IC RSS-Gen 7.1	Receiver radiated spurious emissions	ANSI C63.4	PASS	
<b>Remarks:</b>				

### 3 Test Conditions and Results

#### 3.1 Test Conditions and Results – Occupied Bandwidth

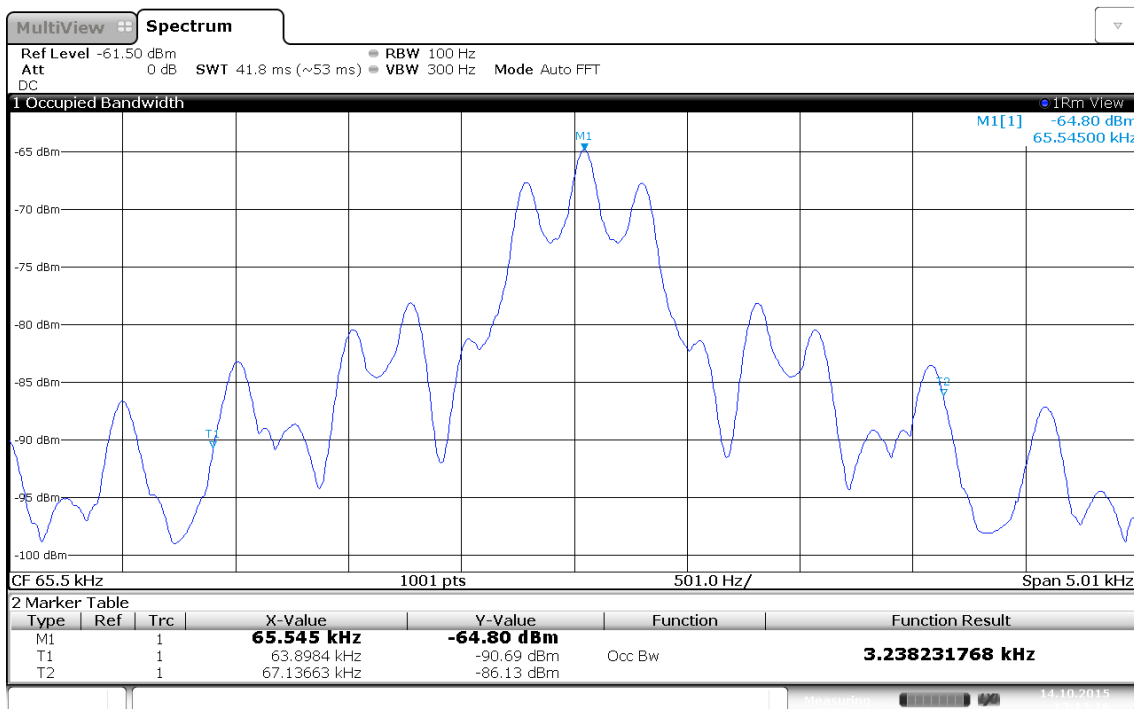
Occupied Bandwidth acc. to IC RSS-Gen		Verdict: PASS
Test according to measurement reference	Reference Method	
	RSS-Gen 6.6	
Test frequency range	Tested frequencies	
	F <sub>MID</sub>	
EUT test mode	Single	
<b>Limits</b>		
None (Informational only)		
<b>Test setup</b>		
 <pre> graph LR     SA[Spectrum Analyzer] --- EUT[EUT]             </pre>		
<b>Test procedure</b>		
<ol style="list-style-type: none"> <li>1. EUT set to test mode (Communication tester is used if needed)</li> <li>2. Span set to at least twice the emission spectrum</li> <li>3. Resolution bandwidth set to 1 % of span</li> <li>4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function</li> </ol>		
<b>Test results</b>		
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]
F <sub>MID</sub>	64	3.238
Comments: Measurement is applicable to all variants		

Occupied Bandwidth - F<sub>MID</sub>

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1509-5046

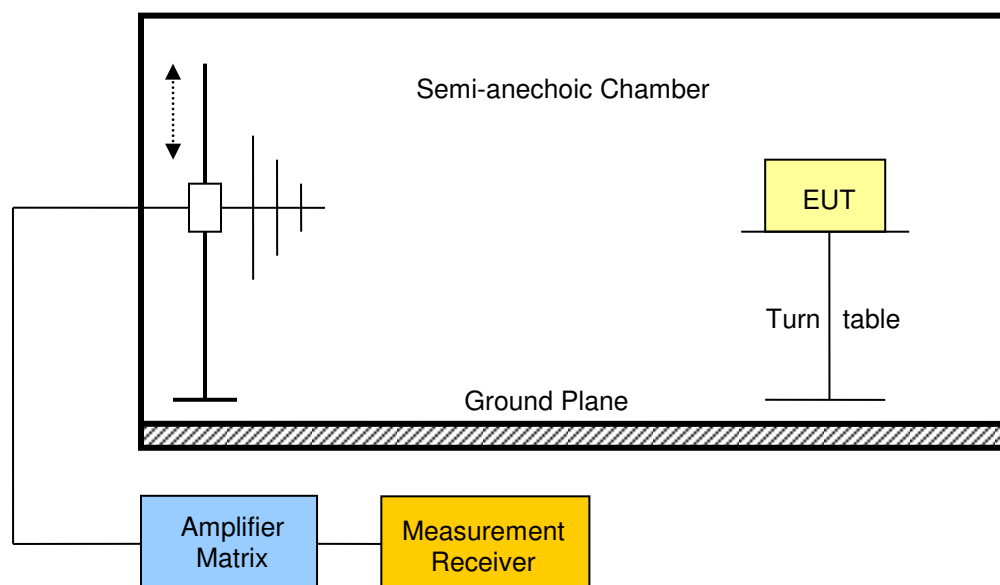
Applicant: Biotronik SE & Co. KG  
 EUT Name: Pacemaker family PRIMUS NXT  
 Model: Eluna 8 HF-T  
 Test Site: Eurofins Product Service GmbH  
 Operator: Wilfried Treffke  
 Test Conditions: Tnom / Vnom  
 Mode: Tx 64 kHz  
 Test Date: 2015-10-14  
 Verdict: NONE (INFORMATION ONLY)  
 Note 1: A spectrum analyzer with an integrated 99% power bandwidth function is used  
 Note 2: Near-field measurement test fixture / 64 kHz system



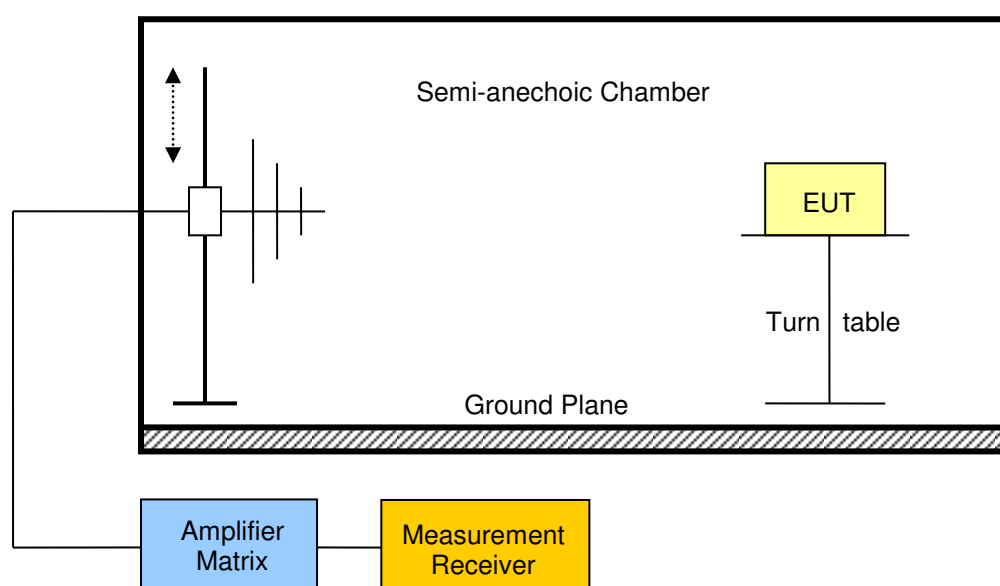
Date: 14.OCT.2015 13:13:16

**3.2 Test Conditions and Results – Fundamental field strength emissions**

Field strength emissions acc. to FCC 47 CFR 15.201 / IC RSS-310				Verdict: PASS
Test according referenced standards	Reference Method			
	FCC 15.201(a) + 15.209 / IC RSS-310 3.7			
Test according to measurement reference	Reference Method			
	ANSI C63.4			
Test frequency range	Tested frequencies			
	9 kHz – 10 <sup>th</sup> Harmonic			
EUT test mode	Single			
Limits				
Frequency range [MHz]	Detector	Limit [ $\mu$ V/m]	Limit [dB $\mu$ V/m]	Limit Distance [m]
0.009 – 0.490	Quasi-Peak	2400/F[kHz]	48.5 – 13.8	300
0.490 – 1.705	Quasi-Peak	2400/F[kHz]	13.8 – 1.4	30
1.705 – 30	Quasi-Peak	30	29.5	30
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 emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector.				

Test setup								
								
Test procedure								
<ol style="list-style-type: none"> <li>1. EUT set to test mode</li> <li>2. Span it set according to measurement range</li> <li>3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz</li> <li>4. Markers are set to maximum emission levels</li> </ol>								
Test results								
Channel	Frequency [kHz]	Emission [kHz]	Level [db $\mu$ V/m]	Detector	Pol.	Limit [db $\mu$ V/m]	Limit distance [m]*	Margin [dB]
F <sub>MID</sub>	64	100.32	-61.50	pk	ver	27.60	3	-89.06
F <sub>MID</sub>	64	1257	-06.40	pk	ver	25.60	3	-32.01
Comments: * Physical distance between EUT and measurement antenna.								

### 3.4 Test Conditions and Results – Receiver radiated emissions

Receiver radiated emissions acc. to IC RSS-310				Verdict: PASS
Test according referenced standards	Reference Method			
	IC RSS-310 3.7			
Test according to measurement reference	Reference Method			
	ANSI C63.4			
Test frequency range	Tested frequencies			
	30 MHz – 5 <sup>th</sup> Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [ $\mu\text{V}/\text{m}$ ]	Limit [ $\text{dB}\mu\text{V}/\text{m}$ ]	Limit Distance [m]
0.009 – 0.490	Quasi-Peak	$2400/F[\text{kHz}]$	48.5 – 13.8	300
0.490 – 1.705	Quasi-Peak	$2400/F[\text{kHz}]$	13.8 – 1.4	30
1.705 – 30	Quasi-Peak	30	29.5	30
30 – 88	Quasi-Peak	100	40	3
88 – 216	Quasi-Peak	150	43.5	3
216 – 960	Quasi-Peak	200	46	3
960 – 1000	Quasi-Peak	500	54	3
> 1000	Average	500	54	3
Test setup				
				



Test procedure						
1. EUT set to receive mode (Communication tester is used if needed) 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to peak emission levels						
Test results						
Channel	Frequency [kHz]	Emission [kHz]	Emission Level [dB $\mu$ V/m]	Det.	Limit [dBd $\mu$ V/m]	Margin [dB $\mu$ V/m]
F <sub>MID</sub>	64	100.36	-60.60	pk	27.6	-88.17
F <sub>MID</sub>	64	25278	-05.30	pk	29.5	-34.81
Comments:						

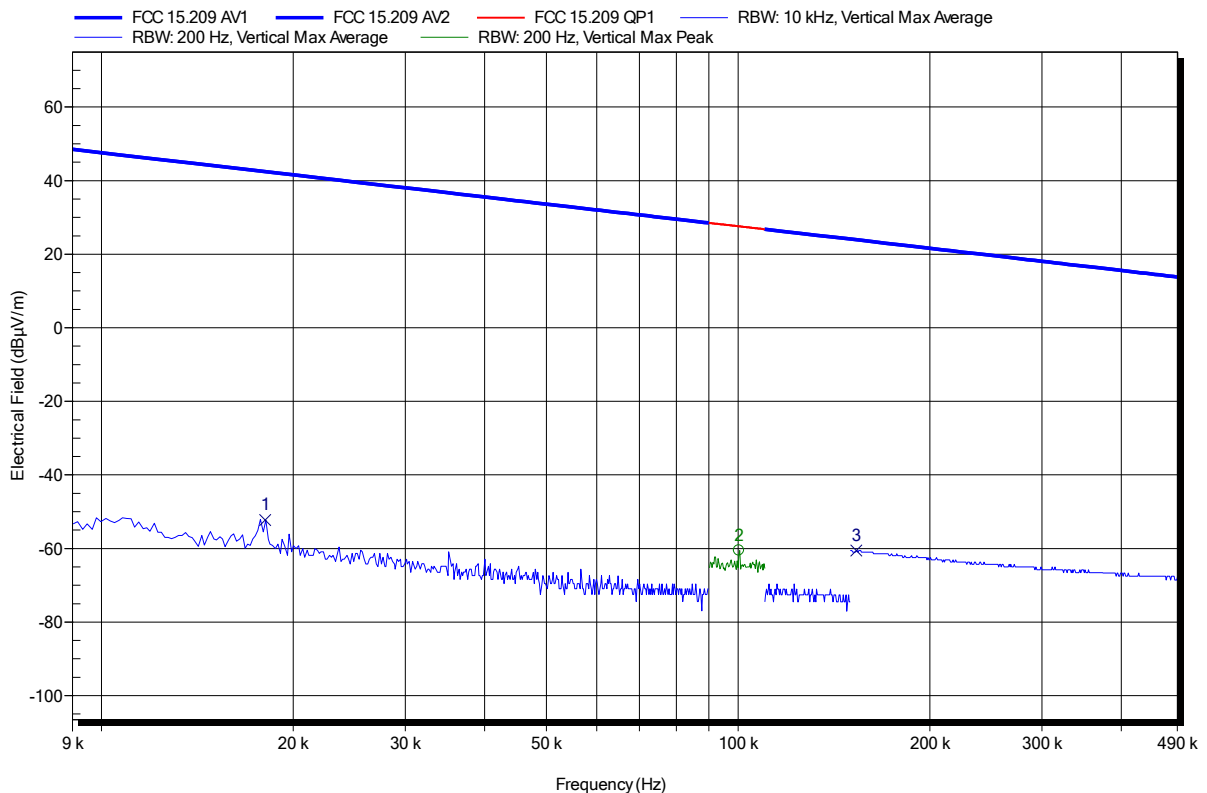
## ANNEX A Transmitter radiated spurious emissions

### Spurious emissions according to FCC 15.209

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG  
 EUT Name: Pacemaker family PRIMUS NXT  
 Model: Eluna 8 HF-T  
 Test Site: Eurofins Product Service GmbH  
 Operator: Treffke  
 Test Conditions: Tnom: 25°C, Vnom: 3V DC battery  
 Antenna: Rohde & Schwarz HFH 2-Z2  
 Measurement distance: 3 m converted to 300 m  
 Mode: TX; 64 kHz  
 Test Date: 2015-10-07  
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
100.36 kHz	-60.6 dBµV/m	27.6 dBµV/m	-88.17 dB	Pass
18.072 kHz	Average	Average Limit	Average Difference	Average Status
153.4 kHz	-52.3 dBµV/m	42.4 dBµV/m	-94.71 dB	Pass
	-60.6 dBµV/m	23.9 dBµV/m	-84.46 dB	Pass

Test Report No.: G0M-1509-5046-TFC209LP-V01

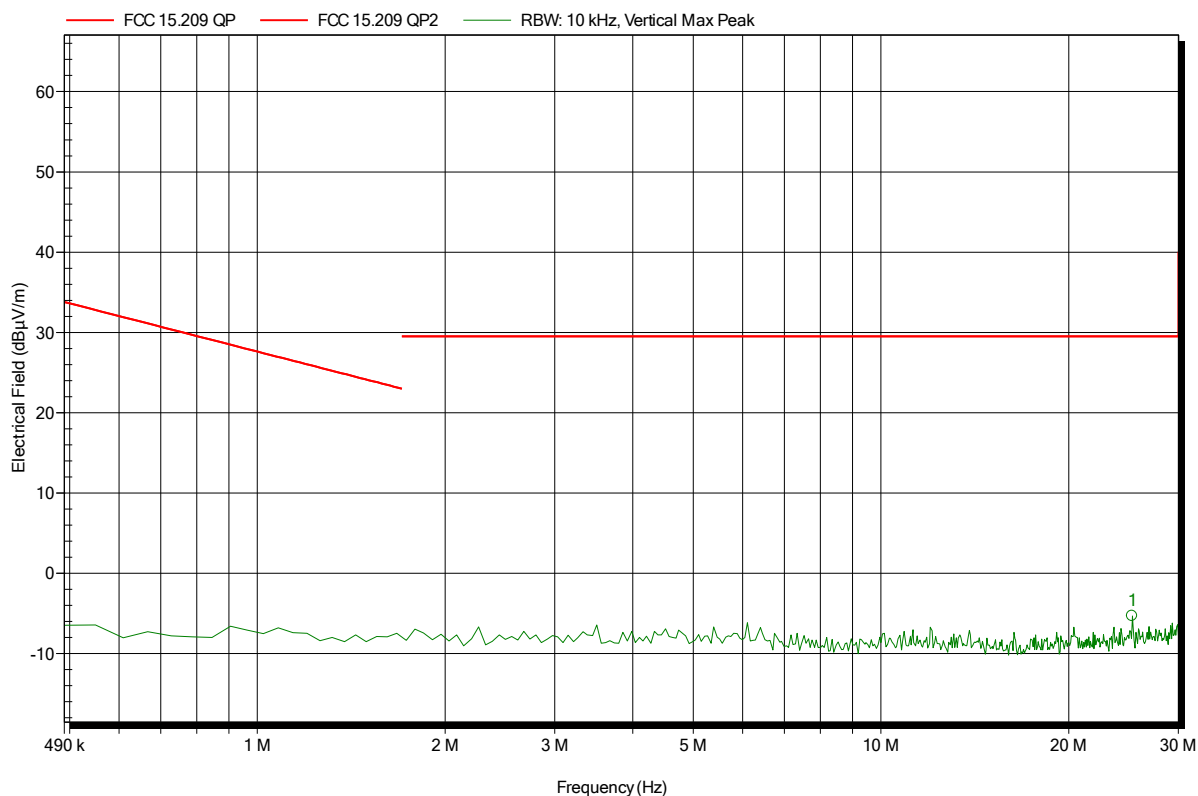
Eurofins Product Service GmbH  
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

**Spurious emissions according to FCC 15.209**

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG  
 EUT Name: Pacemaker family PRIMUS NXT  
 Model: Eluna 8 HF-T  
 Test Site: Eurofins Product Service GmbH  
 Operator: Treffke  
 Test Conditions: Tnom: 25°C, Vnom: 3V DC battery  
 Antenna: Rohde & Schwarz HFH 2-Z2  
 Measurement distance: 3 m converted to 30 m  
 Mode: TX; 64 kHz  
 Test Date: 2015-10-07  
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
25.278 MHz	-5.3 dBµV/m	29.5 dBµV/m	-34.81 dB	Pass

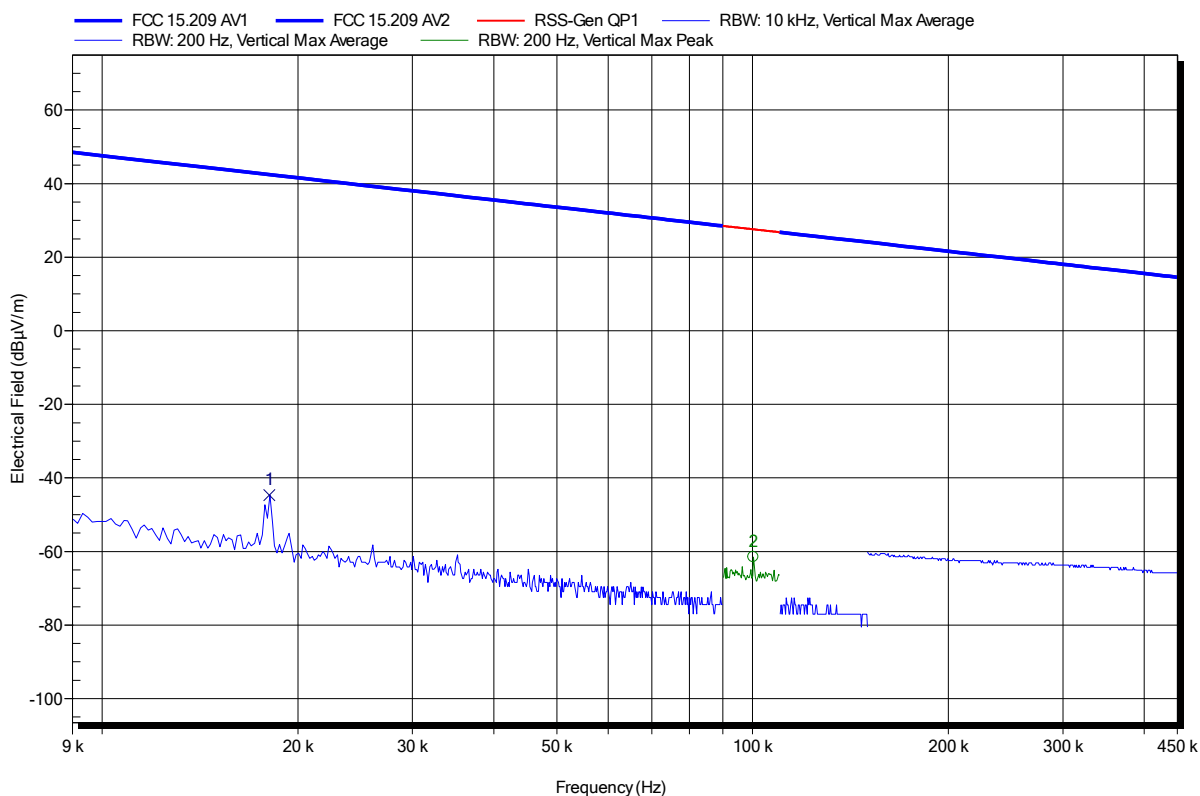
## ANNEX B Receiver radiated spurious emissions

### Spurious emissions according to RSS-Gen

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG  
 EUT Name: Pacemaker family PRIMUS NXT  
 Model: Eluna 8 HF-T  
 Test Site: Eurofins Product Service GmbH  
 Operator: Treffke  
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery  
 Antenna: Rohde & Schwarz HFH 2-Z2  
 Measurement distance: 3 m converted to 300 m  
 Mode: RX; 64 kHz  
 Test Date: 2015-10-07  
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
100.32 kHz	-61.5 dBµV/m	27.6 dBµV/m	-89.06 dB	Pass
Frequency	Average	Average Limit	Average Difference	Average Status
18.072 kHz	-44.7 dBµV/m	42.4 dBµV/m	-87.13 dB	Pass

Test Report No.: G0M-1509-5046-TFC209LP-V01

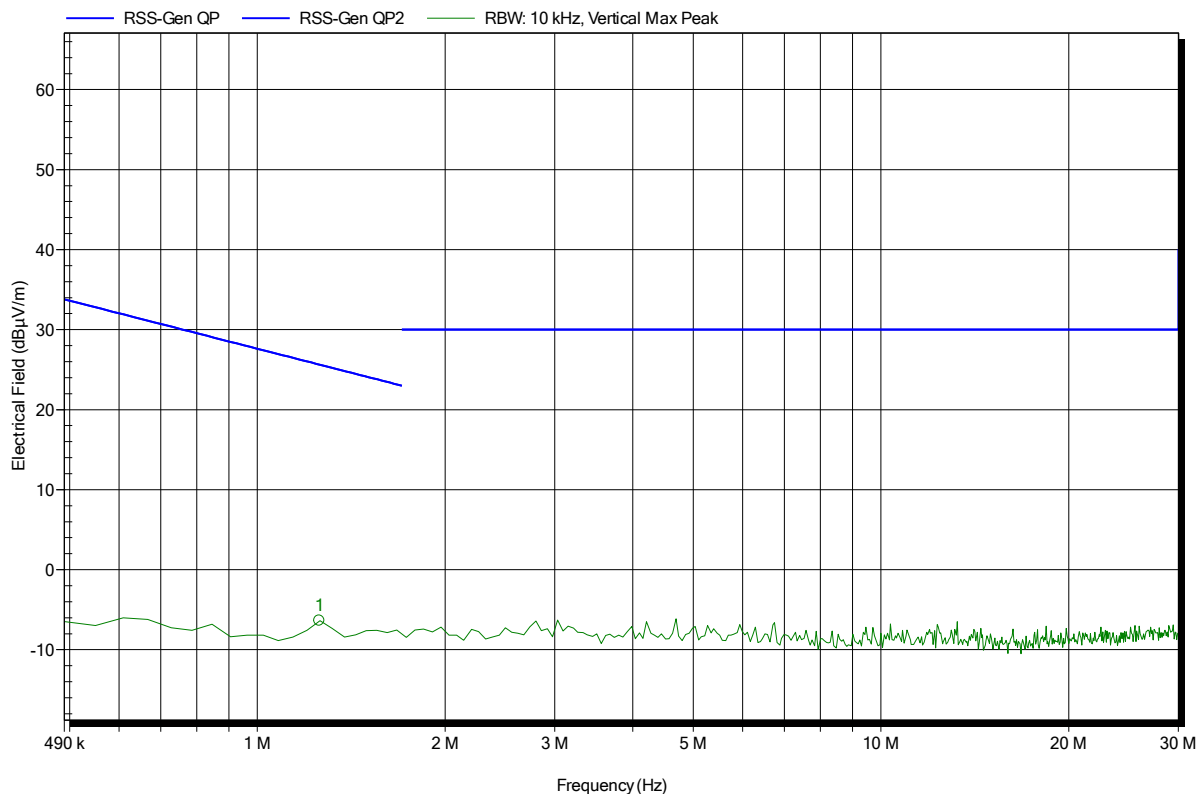
Eurofins Product Service GmbH  
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

**Spurious emissions according to RSS-Gen**

Project number: G0M-1509-5046

Applicant: Biotronik SE & Co. KG  
 EUT Name: Pacemaker family PRIMUS NXT  
 Model: Eluna 8 HF-T  
 Test Site: Eurofins Product Service GmbH  
 Operator: Treffke  
 Test Conditions: Tnom: 25°C, Vnom: 3 V DC battery  
 Antenna: Rohde & Schwarz HFH 2-Z2  
 Measurement distance: 3 m converted to 30 m  
 Mode: RX; 64 kHz  
 Test Date: 2015-10-07  
 Note:

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Frequency	Peak	Peak Limit	Peak Difference	Peak Status
1.257 MHz	-6.4 dBµV/m	25.6 dBµV/m	-32.01 dB	Pass