

FCC TEST REPORT

**FCC 47 CFR Part 15C
Industry Canada RSS-310
License exempt radio equipment**

Report Reference No. : G0M-1304-2799-TFC209L-V01

Testing Laboratory : Eurofins Product Service GmbH

Address : Storkower Str. 38c
15526 Reichenwalde
Germany

Accreditation :



A2LA Accredited Testing Laboratory, Certificate No.: 1983.01
FCC Filed Test Laboratory, Reg.-No.: 96970
IC OATS Filing assigned code: 3470A

Applicant's name : BIOTRONIK SE & Co. KG

Address : Woermannkehre 1
12359 Berlin
GERMANY

Test specification:

Standard : 47 CFR Part 15C
RSS-310, Issue 3, 2010-12
RSS-Gen, Issue 3, 2010-12
ANSI C63.4:2009

Equipment under test (EUT):

Product description	IPG / Implantable Pulse Generator	
Model No.	Eluna 8-HF-T	
Hardware version	6082220-03 Rev 0A	
Firmware / Software version	GTR-12-0173-A	
	FCC-ID: QRIPRIMUSNXT	IC: 4708A-PRIMUSNXT
Test result	Passed	

Test Report No.: G0M-1304-2799-TFC209L-V01

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

Possible test case verdicts:

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

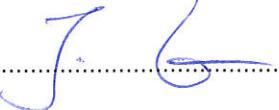
Testing:

Date of receipt of test item: 2013-05-06

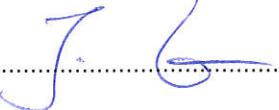
Date (s) of performance of tests: 2013-05-10 – 2013-05-16

Compiled by: Antje Bartusch

Tested by (+ signature).....: Wilfried Treffke
(Testing Manager)

Approved by (+ signature): Jens Zimmermann
(Test Lab Manager)



Date of issue: 2013-07-30

Total number of pages: 24

General remarks:

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

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

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

Additional comments:

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

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

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

Eluna, Epyra and Etrinsa .

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

The T Devices include additional an internal RF Transceiver and an antenna within the header.

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

The PRIMUS NXT models contain a different therapeutic feature set. The feature differences comprising only software.

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

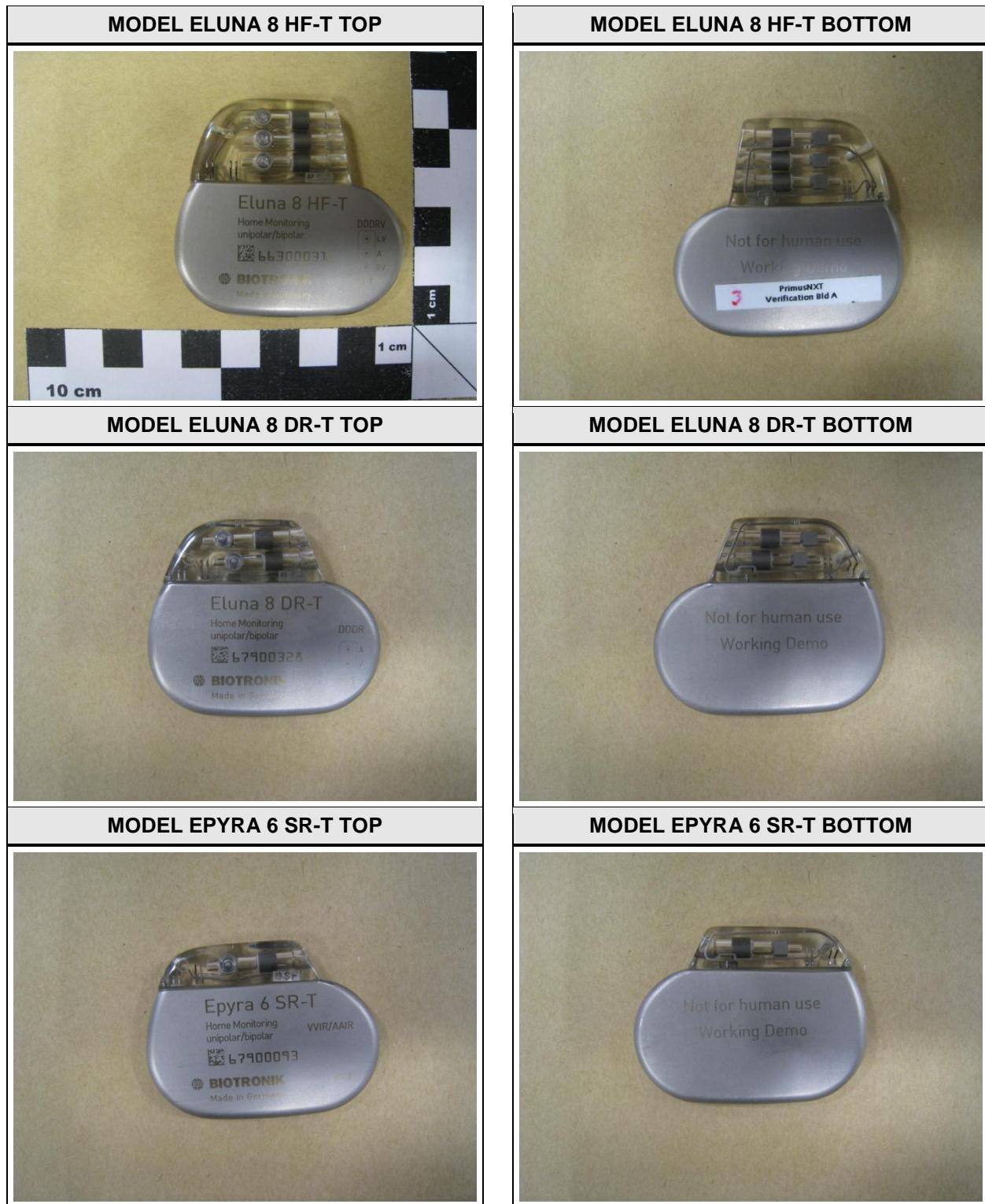
REPORT INDEX

1 EQUIPMENT (TEST ITEM) DESCRIPTION	5
1.1 Photos – Equipment External	6
1.2 Photos – Equipment Internal	7
1.3 Photos – Test setup	9
1.4 Supporting Equipment Used During Testing	10
1.5 Test Modes	11
1.6 Test Equipment Used During Testing	12
1.7 Sample emission level calculation	13
2 RESULT SUMMARY	14
3 TEST CONDITIONS AND RESULTS	15
3.1 Test Conditions and Results – Occupied Bandwidth	15
3.2 Test Conditions and Results – Fundamental field strength emissions	18
3.4 Test Conditions and Results – Receiver radiated emissions	20
ANNEX A Transmitter radiated spurious emissions	22
ANNEX B Receiver radiated spurious emissions	24

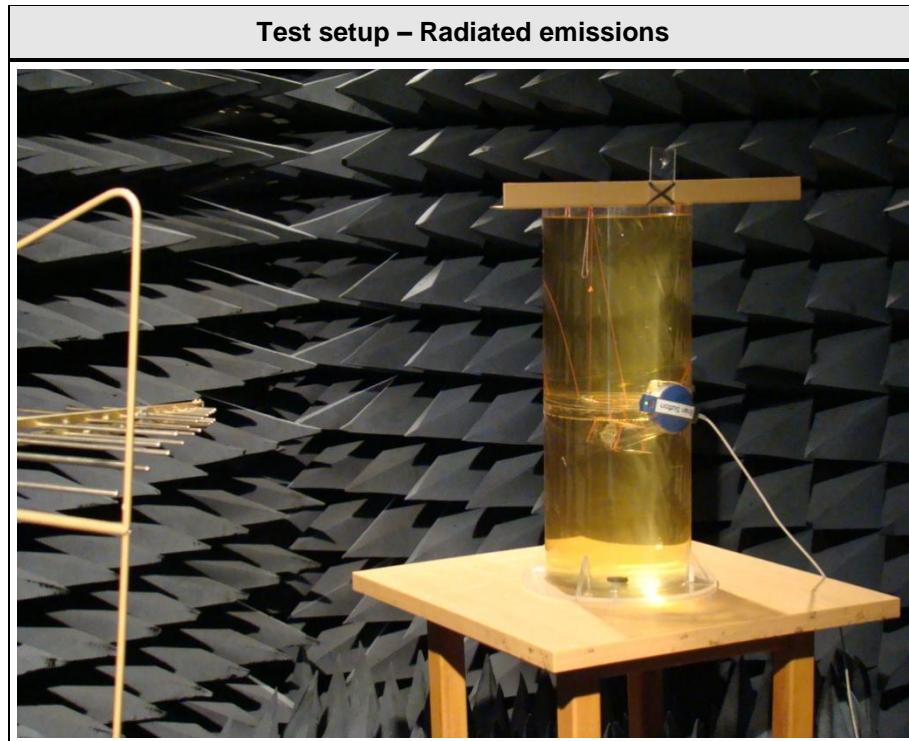
1 Equipment (Test item) Description

Description	IPG / Implantable Pulse Generator	
Model	Eluna 8-HF-T	
Serial number	None	
Hardware version	6082220-03 Rev 0A	
Software / Firmware version	GTR-12-0173-A	
FCC-ID	QRIPRIMUSNXT	
IC	4708A-PRIMUSNXT	
Equipment type	End product	
Radio type	Transceiver	
Radio technology	custom	
Operating frequency range	64 kHz	
Frequency range	F_{MID}	64 kHz
Modulations	OOK	
Number of channels	1	
Channel spacing	None	
Number of antennas	1	
Antenna	Type	integrated
	Model	loop antenna
	Manufacturer	Biotronik SE & Co. KG
	Gain	-21.6 dBi (Determined by measurements)
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
Power supply	V_{NOM}	2.8 VDC (Lithium-Battery)
	V_{MIN}	N/A
	V_{MAX}	N/A
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

1.1 Photos – Equipment External



1.3 Photos – Test setup



1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
	None			

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

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.5 Test Modes

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

1.6 Test Equipment Used During Testing

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSP 30	EF00312	2013-01	2014-01

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

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 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:

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

2 Result Summary

FCC 47 CFR Part 15C, IC RSS-310				
Product Specific Standard Section	Requirement – Test	Reference Method	Result	Remarks
RSS-Gen 4.6.1	Occupied Bandwidth	RSS-Gen 4.6.1	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 4.10 6.1	Receiver radiated spurious emissions	ANSI C63.4	PASS	
Remarks:				

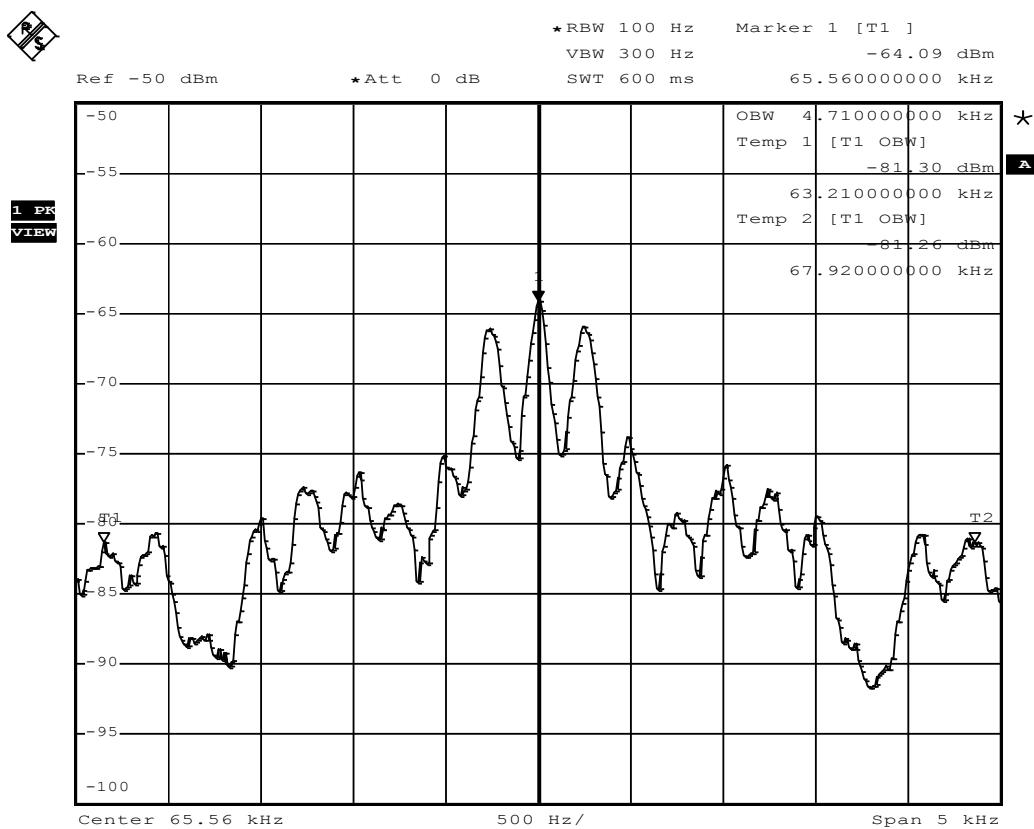
3 Test Conditions and Results

3.1 Test Conditions and Results – Occupied Bandwidth

Occupied Bandwidth acc. IC RSS-Gen		Verdict: PASS	
Test according to measurement reference	Reference Method		
	RSS-Gen 4.6.1		
Test frequency range	Tested frequencies		
	F_{MID}		
EUT test mode	Single		
Limits			
None (Informational only)			
Test setup			
 <pre> graph LR SA[Spectrum Analyzer] --- EUT[EUT] </pre>			
Test procedure			
<ol style="list-style-type: none"> 1. EUT set to test mode (Communication tester is used if needed) 2. Span set to at least twice the emission spectrum 3. Resolution bandwidth set to 1 % of span 4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function 			
Test results			
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]	
F_{MID}	64	5 kHz	4.71
F_{MID}	64	20 kHz	19.44
Comments: Measurement is applicable to all variants			

Occupied Bandwidth - F_{MID}
RSS-Gen
Occupied frequency bandwidth

EUT IPG / Implantable Pulse Generator
 Model Primus NXT / G0M-1304-2799
 Approval Holder Biotronik SE & Co. KG
 Temperature / Voltage 25°C / Vnom
 Test Site / Operator Eurofins Product Service GmbH / Mr Treffke
 Test Specification Occupied frequency bandwidth
 Comment 1 A spectrum analyzer with an integrated 99% power bandwidth function is used
 Comment 2 Carrier channel: 64 kHz
 Comment 3



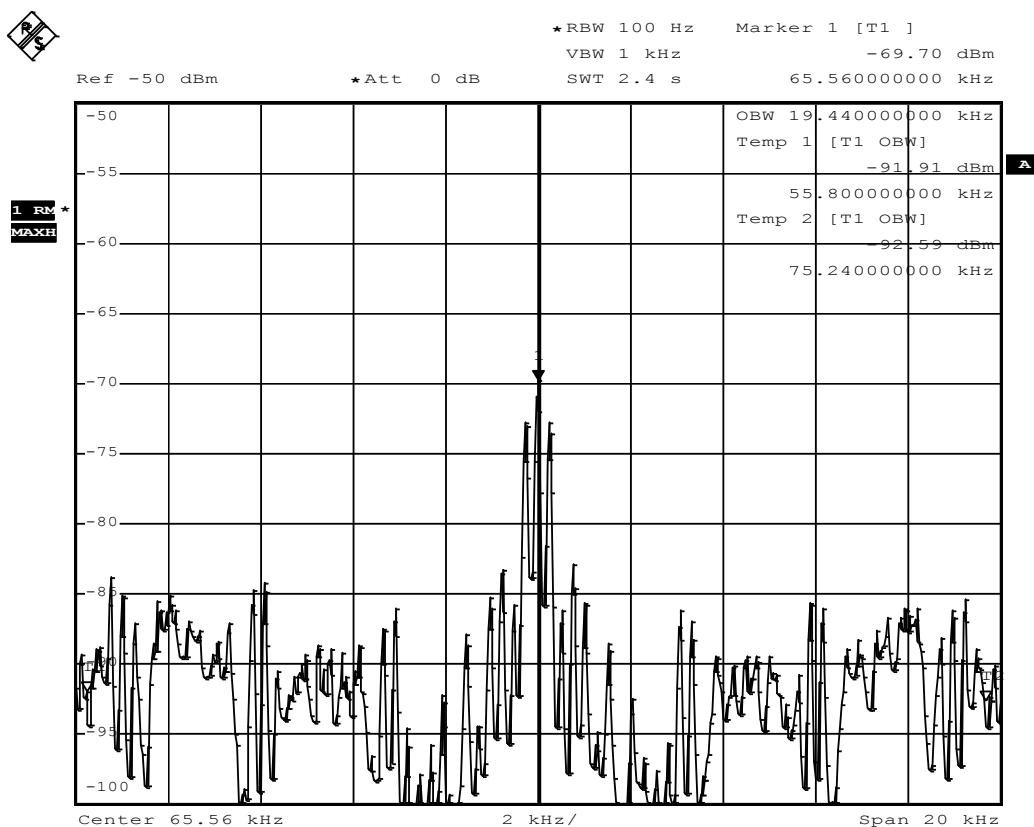
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Test Report No.: G0M-1304-2799-TFC209L-V01

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Occupied Bandwidth - F_{MID}
RSS-Gen
Occupied frequency bandwidth

EUT IPG / Implantable Pulse Generator
 Model Primus NXT / G0M-1304-2799
 Approval Holder Biotronik SE & Co. KG
 Temperature / Voltage 25°C / Vnom
 Test Site / Operator Eurofins Product Service GmbH / Mr Treffke
 Test Specification Occupied frequency bandwidth
 Comment 1 A spectrum analyzer with an integrated 99% power bandwidth function is used
 Comment 2 Carrier channel: 64 kHz
 Comment 3



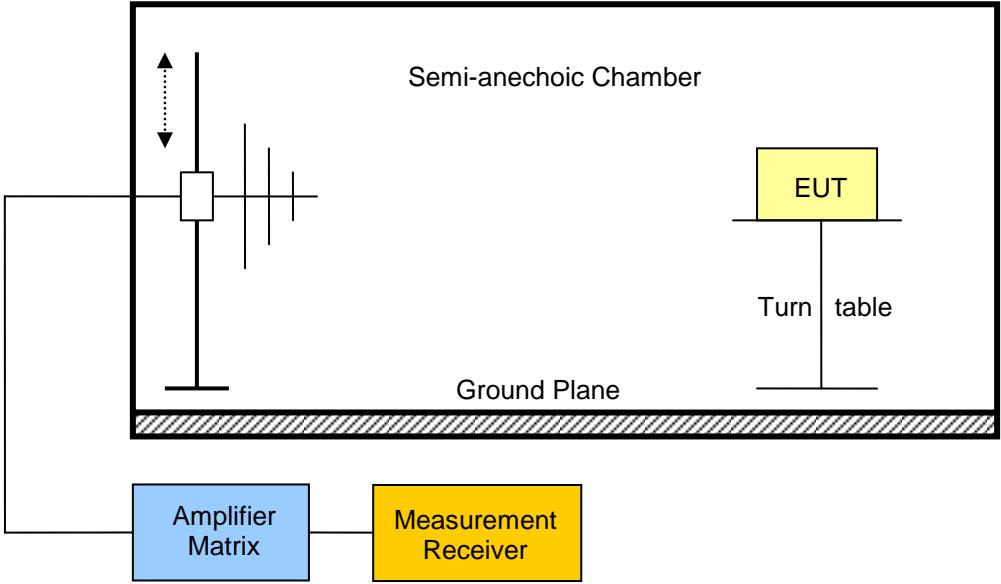
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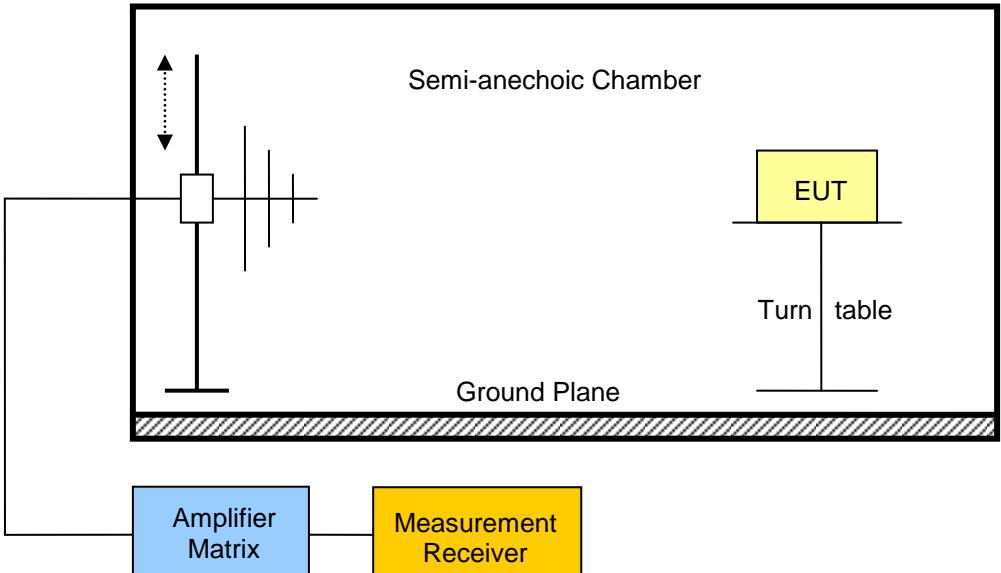
 Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

3.2 Test Conditions and Results – Fundamental field strength emissions

Field strength emissions acc. 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 th Harmonic				
EUT test mode		Single				
Limits						
Frequency range [MHz]	Detector	Limit [μ V/m]	Limit [dB μ 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"> 1. EUT set to test mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to maximum emission levels 								
Test results								
Channel	Frequency [kHz]	Emission [kHz]	Level [dB μ V/m]	Detector	Pol.	Limit [dB μ V/m]	Limit distance [m]*	Margin [dB]
No significant spurious emission								
Comments: * Physical distance between EUT and measurement antenna.								

3.4 Test Conditions and Results – Receiver radiated emissions

Receiver radiated emissions acc. 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		
		9 kHz – 10 th Harmonic		
EUT test mode		Receive		
Limits				
Frequency range [MHz]	Detector	Limit [μ V/m]	Limit [dB μ 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
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 μ V/m]	Emission Level [μ V/m]	Det.	Limit [d μ V/m]	Margin [μ V/m]
No significant spurious emission							
Comments:							

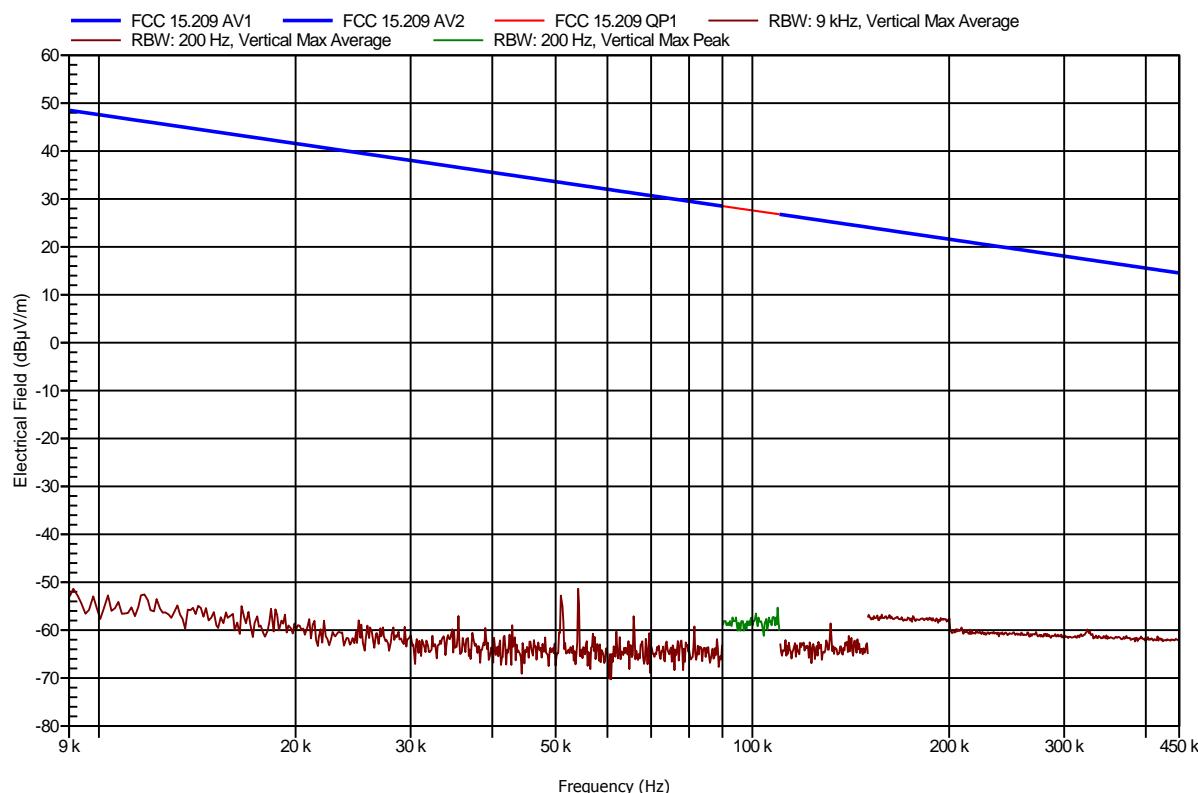
ANNEX A Transmitter radiated spurious emissions

Spurious emissions according to FCC 15.209

Project number: G0M-1304-2799

Manufacturer: BIOTRONIK SE & Co. KG
 EUT Name: IPG / Implantable Pulse Generator
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: $T_{nom}: 25^{\circ}\text{C}$, $V_{nom}: 2.8 \text{ V DC}$ lithium battery
 Antenna: Rohde & Schwarz HFH 2-Z2
 Measurement distance: 3 m converted to 300 m
 Mode: TX; 64 kHz
 Test Date: 2013-05-13
 Note: FCC 15.209

Index 5



Test Report No.: G0M-1304-2799-TFC209L-V01

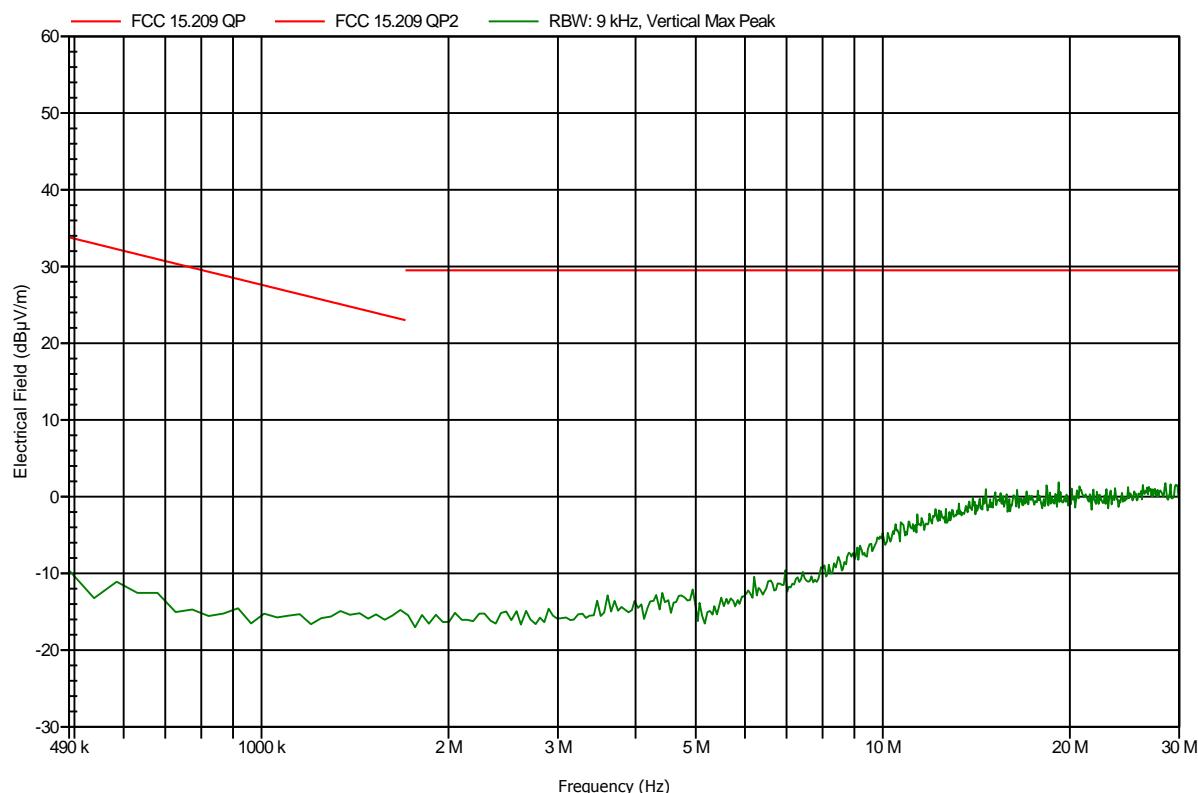
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions according to FCC 15.209

Project number: G0M-1304-2799

Manufacturer: BIOTRONIK SE & Co. KG
EUT Name: IPG / Implantable Pulse Generator
Model: Eluna 8 HF-T
Test Site: Eurofins Product Service GmbH
Operator: Treffke
Test Conditions: T_{nom} : 25°C, V_{nom} : 2.8 V DC lithium battery
Antenna: Rohde & Schwarz HFH 2-Z2
Measurement distance: 3 m converted to 30 m
Mode: TX; 64 kHz
Test Date: 2013-05-13
Note: FCC 15.209

Index 6



Test Report No.: G0M-1304-2799-TFC209L-V01

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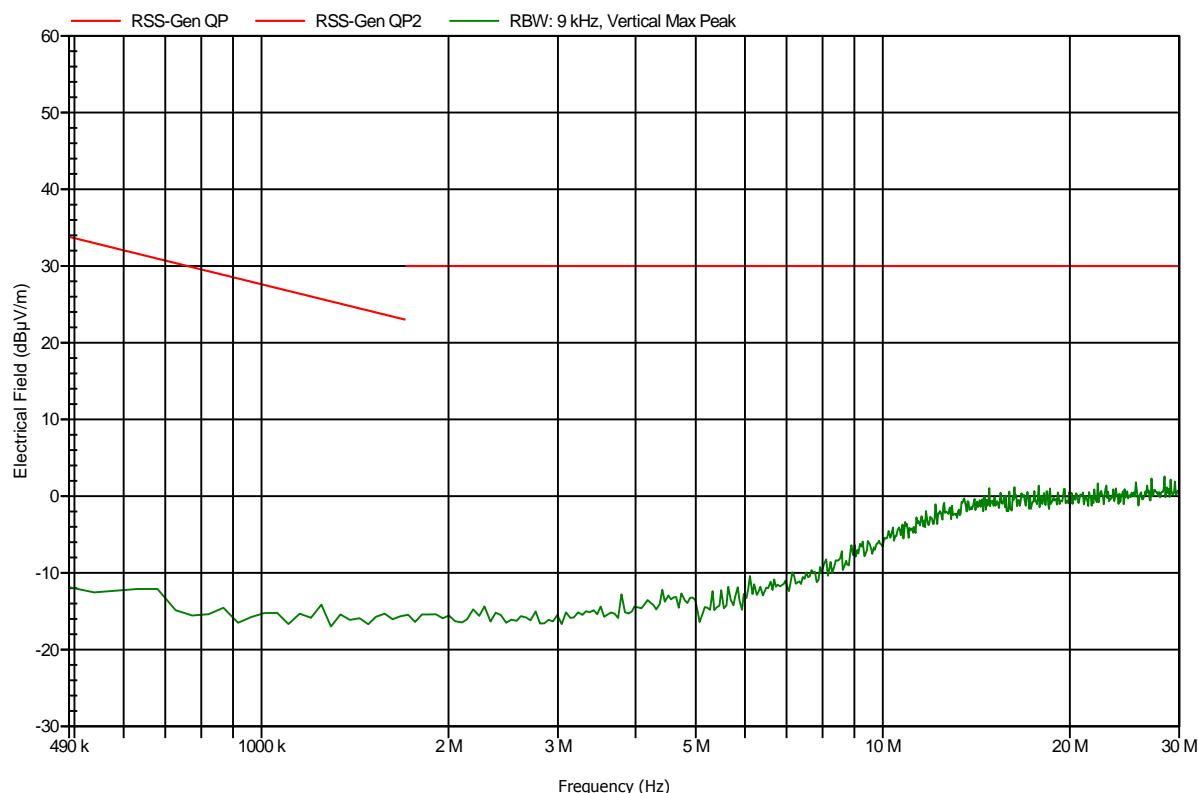
ANNEX B Receiver radiated spurious emissions

Spurious emissions according to RSS-GEN

Project number: G0M-1304-2799

Manufacturer: BIOTRONIK SE & Co. KG
 EUT Name: IPG / Implantable Pulse Generator
 Model: Eluna 8 HF-T
 Test Site: Eurofins Product Service GmbH
 Operator: Treffke
 Test Conditions: $T_{nom}: 25^{\circ}\text{C}$, $V_{nom}: 2.8 \text{ V DC}$ lithium battery
 Antenna: Rohde & Schwarz HFH 2-Z2
 Measurement distance: 3 m converted to 30 m
 Mode: RX; 64 kHz
 Test Date: 2013-05-13
 Note: RSS 310

Index 12



Test Report No.: G0M-1304-2799-TFC209L-V01

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