FCC TEST REPORT

FCC 47 CFR Part 15C
Industry Canada RSS-310

License exempt radio equipment

Report Reference No. ..... :	G0M-1509-5046-TFC209LP-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 4, 2014-11 ANSI C63.4:2014
Test scope…….. ..... :	complete Radio compliance test (C2PC)
Equipment under test (EUT):	
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
Test result	**Passed**

Possible test case verdicts:

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

Testing:

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 .....
(Responsible for Test)

Approved by (+ signature) ..... : Christian 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
excellence for life

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To whom it may concern

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Berlin, October 20, 2015

Gentlemen,

Herewith we, BIOTRONIK SE & 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

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Company nameBIOTRONIK SE & CO. KG
Phone No.: +49 (0) 30 68905 1291

Sincerely,

Signature
Dirk König
Manager Regulatory Affairs
BIOTRONIK SE & CO. KG

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

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

Certification Number: **QRIPRIMUSNXT**

Model	Description
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.

Version History

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

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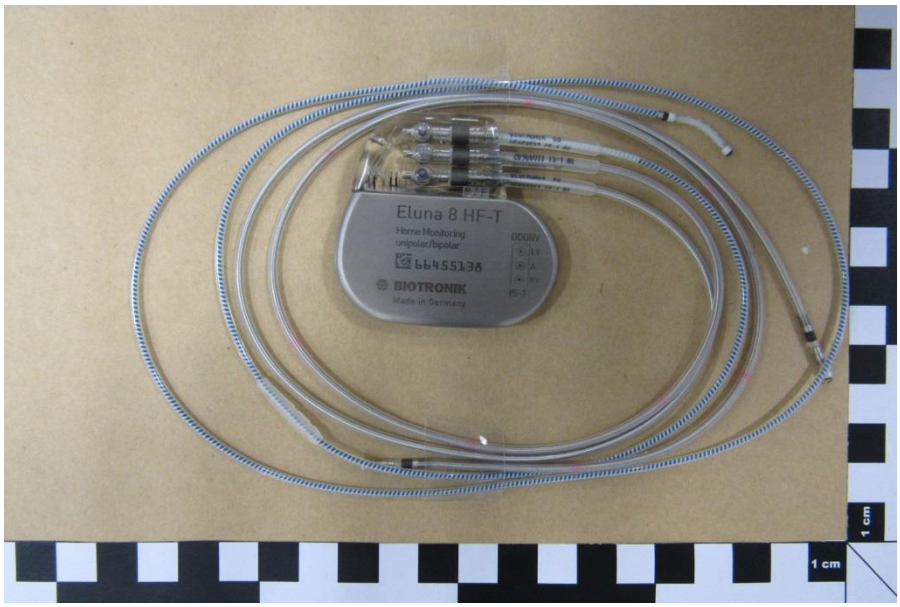
1 Equipment (Test item) Description

Description	Pacemaker family PRIMUS NXT	
Model	Eluna 8 HF-T	
Additional Model(s)	see page5: List of Models to be included in the family	
Brand Name(s)	BIOTRONIK	
Serial number	66455138	
Hardware version	ASM-0217_0B with BOM-0288_06_396062 (2230-04)	
Software / Firmware version	7300RomRev_01.02/7474RamRev_04.02	
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	unspecified
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
Power supply	V_{NOM}	3.0 VDC (Lithium-Battery)
	V_{MIN}	N/A
	V_{MIN}	N/A
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

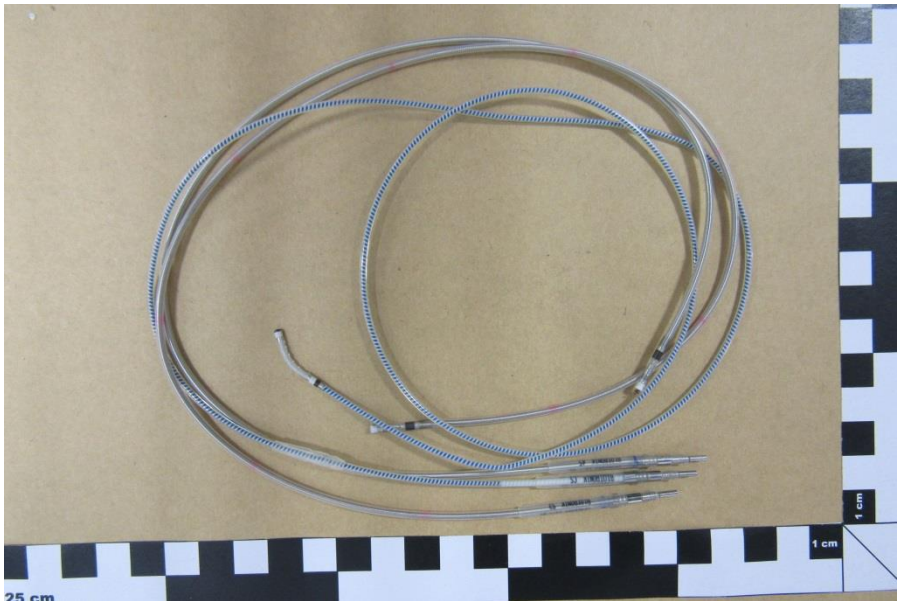
1.1 Photos – Equipment External

ELUNA 8 HF-T (Master) with Leads


ELUNA 8 HF-T (Master) TOP

ELUNA 8 HF-T (Master) BOTTOM

LEADS



ADDITIONAL MODEL NXT_DRT_FRONT

ADDITIONAL MODEL NXT_DRT_BACK

ADDITIONAL MODEL NXT_SRT_FRONT

ADDITIONAL MODEL NXT_SRT_BACK

1.2 Photos – Test setup

SETUP RADIATED EMISSIONS

1.3 Photos – Auxiliary/Associated Equipment

AE1: PROGRAMER 64kHz

1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE1	Programer	Biotronik	USB TelBox	64kHz system

***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 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

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2014.1.15

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

Field strength emissions					
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 dBµV. Any external preamplifiers used are taken into account through internal analyzer settings.

A.F.:

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

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

Net:

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

Limit:

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

Limit (dBµV/m) = 20*log (µV/m)

Margin:

This is the margin of compliance below the FCC limit. The units are given in dB. A negative margin indicates the emission was below the limit. A positive margin indicates that the emission exceeds the limit.

Example only:

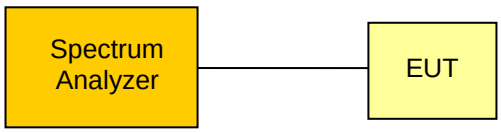
Reading	+	AF	=	Net Reading	:	Net reading - FCC limit = Margin
21.5 dBµV	+	26 dB	=	47.5 dBµV/m	:	47.5 dBµV/m - 57.0 dBµV/m = -9.5 dB

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	
Remarks:				

3 Test Conditions and Results

3.1 Test Conditions and Results – Occupied Bandwidth

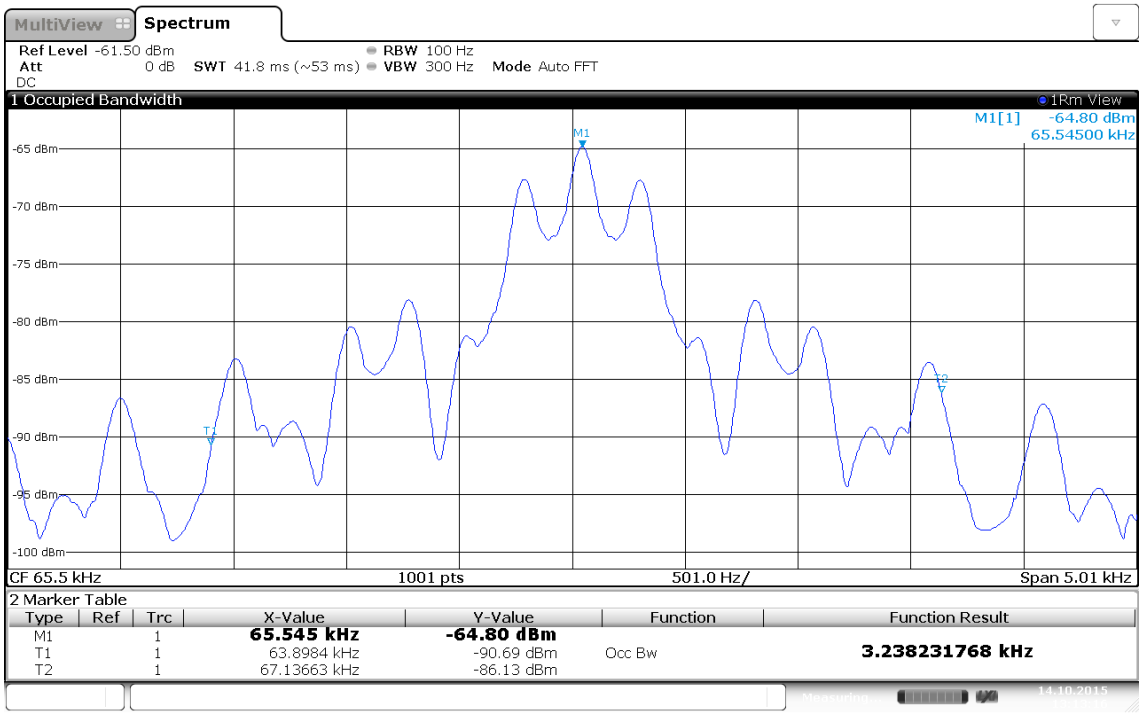
Occupied Bandwidth acc. to IC RSS-Gen		**Verdict: PASS**
Test according to measurement reference	Reference Method	
	RSS-Gen 6.6	
Test frequency range	Tested frequencies	
	F_{MID}	
EUT test mode	Single	
Limits		
None (Informational only)		
Test setup		
		
Test procedure		
1. EUT set to test mode (Communication tester is used if needed) 2. Span set to at least twice the emission spectrum 3. Resolution bandwidth set to 1 % of span 4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function		
Test results		
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]
F_{MID}	64	3.238
Comments: Measurement is applicable to all variants		

Occupied Bandwidth - F_{MID}

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



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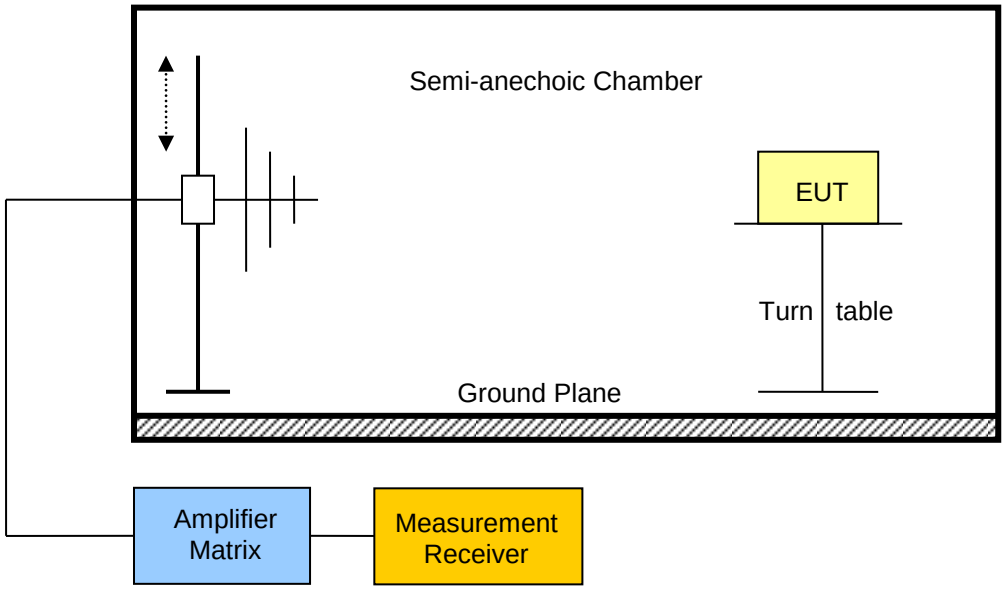
3.2 Test Conditions and Results – Fundamental field strength emissions

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 – 10th Harmonic		
EUT test mode		Single		
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/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

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

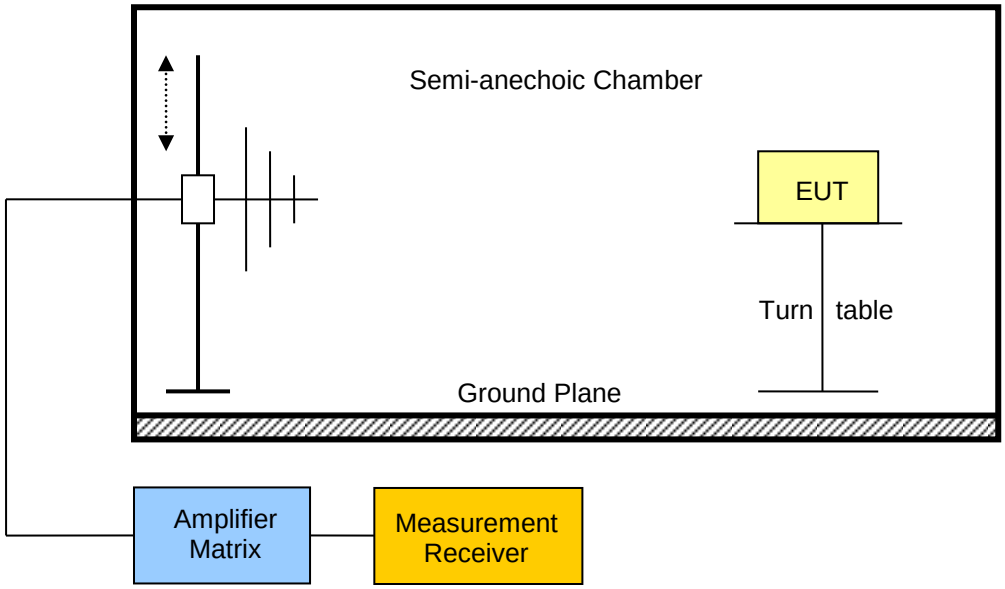
Test results

Channel	Frequency [kHz]	Emission [kHz]	Level [dbµV/m]	Detector	Pol.	Limit [dbµV/m]	Limit distance [m]*	Margin [dB]
F_{MID}	64	100.32	-61.50	pk	ver	27.60	3	-89.06
F_{MID}	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 – 5th Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/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 [dbµV/m]	Det.	Limit [dBdµV/m]	Margin [dBµV/m]
F_{MID}	64	100.36	-60.60	pk	27.6	-88.17
F_{MID}	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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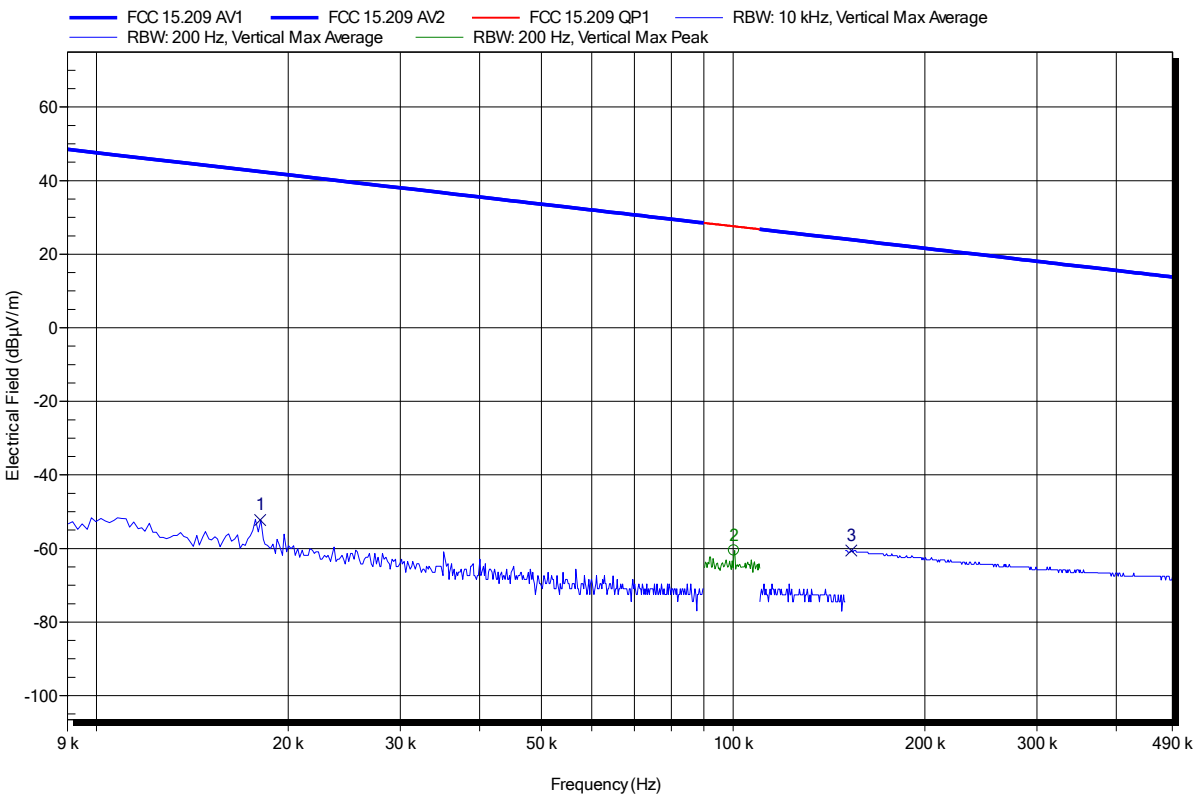

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
100.36 kHz	-60.6 dBµV/m	27.6 dBµV/m	-88.17 dB	Pass

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

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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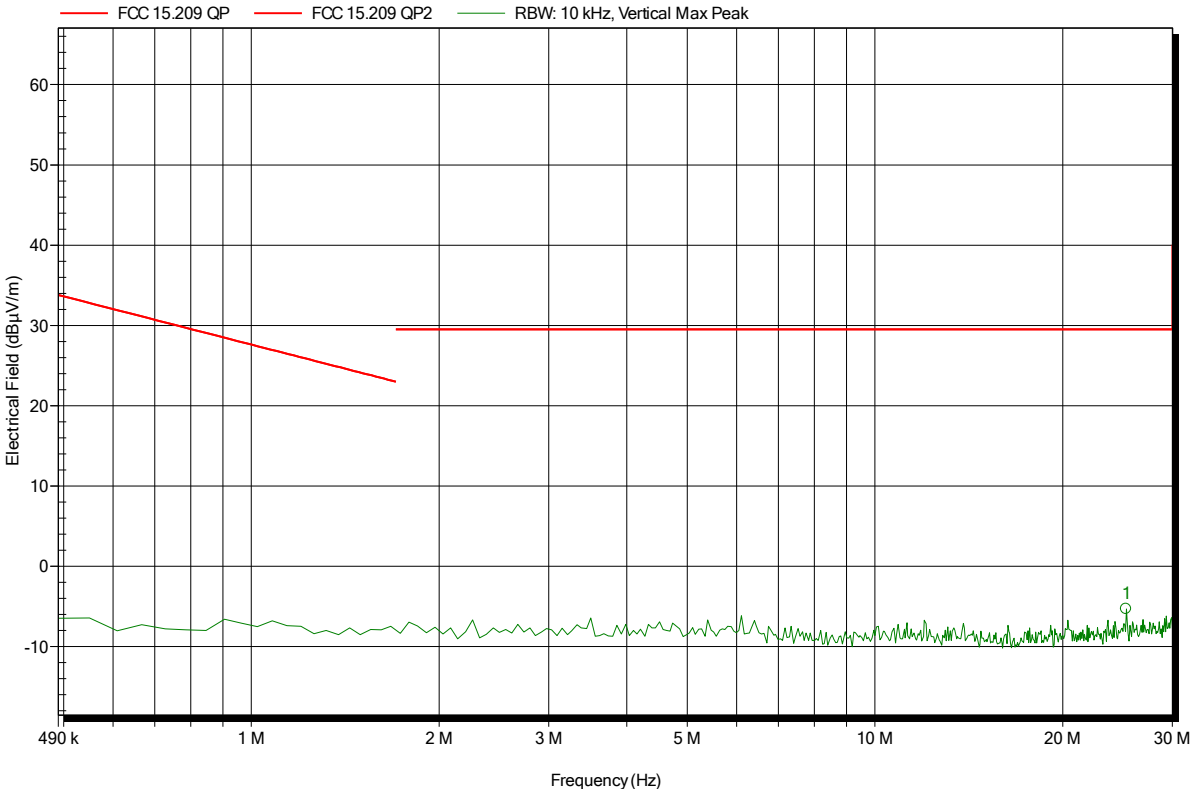

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
25.278 MHz	-5.3 dBµV/m	29.5 dBµV/m	-34.81 dB	Pass

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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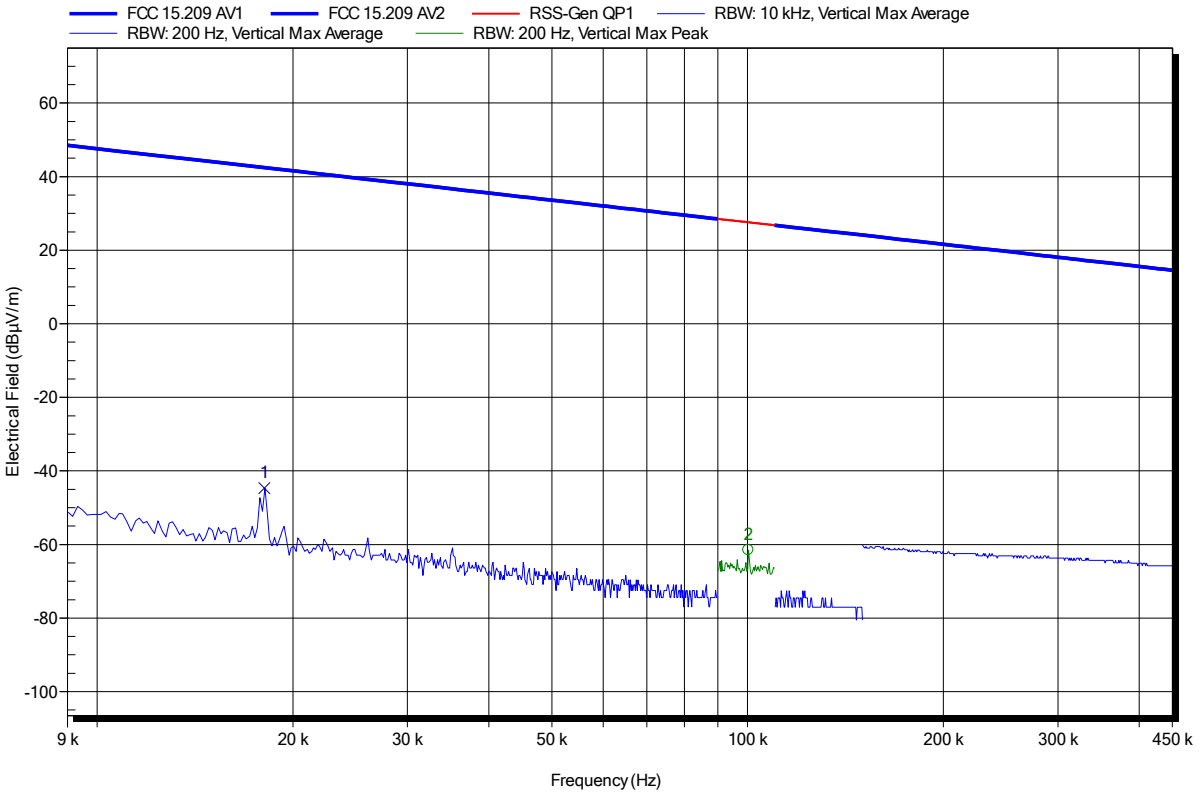

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
100.32 kHz	-61.5 dBµV/m	27.6 dBµV/m	-89.06 dB	Pass

Frequency	Average	Average Limit	Average Difference	Average Status
18.072 kHz	-44.7 dBµV/m	42.4 dBµV/m	-87.13 dB	Pass

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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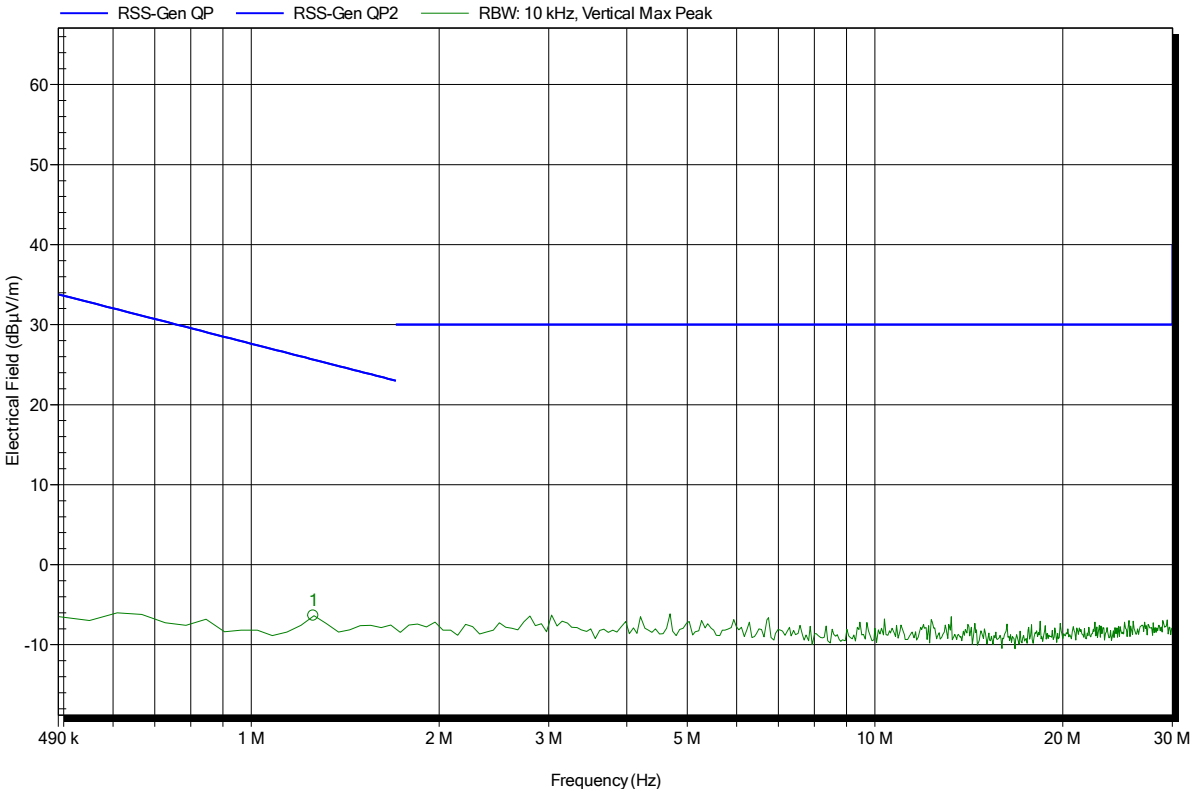

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
1.257 MHz	-6.4 dBµV/m	25.6 dBµV/m	-32.01 dB	Pass