

EMC TEST REPORT FCC 47 CFR Part 15B, ISED ICES-003 Issue 6	
Report Reference No	G0M-1905-8256-EF0115B-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	    DAKKS - Registration number : D-PL-12092-01-03 (ISED) ISED Testing Laboratory site: 3470A-2 DAKKS - Registration number : D-PL-12092-01-04 (FCC) FCC Filed Test Laboratory, Reg.-No.: 96970
Applicant	BIOTRONIK SE & Co. KG
Address	Woermannkehre 1 12359 Berlin GERMANY
Test Specification	
Standard	47 CFR Part 15 Subpart B ISED ICES-003 Issue 6 ANSI C63.4:2014
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
Model(s)	Renamic Neo
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware Version(s)	A.x
Software Version(s)	Porto_WLAN: 1_0_0, Porto_BT: 15.68.7.p167, WW_BT: V5_1_0006, PGH: RIO_PGHEFW_1_18_x, WW: ULP_LOW_RIO_0_13
FCC-ID	QRI-RENAMICNEO
IC	4708A-RENAMICNEO
Test Result	PASSED

Possible test case verdicts:		
required by standard but not tested	N/T	
not required by standard	N/R	
required by standard but not appl. to test object	N/A	
test object does meet the requirement	P(PASS)	
test object does not meet the requirement	F(FAIL)	
Testing:		
Date of receipt of test item	2019-05-22	
Report:		
Compiled by	Matthias Handrik	
Tested by (+ signature) (Responsible for Test)	Matthias Handrik	
Approved by (+ signature) (Deputy Head of Lab)	Jens Marquardt	
Date of Issue	2020-01-23	
Total number of pages	62	
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:		

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
T _{NOM}	Nominal operating temperature
V _{NOM}	Nominal supply voltage

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2020-01-23	Initial Release	

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1 Equipment (Test Item) Under Test

Description	programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs	
Model	Renamic Neo	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Serial Number(s)	80001103	
Hardware Version(s)	A.x	
Software Version(s)	Porto_WLAN: 1_0_0, Porto_BT: 15.68.7.p167, WW_BT: V5_1_0006, PGH: RIO_PGHFW_1_18_x, WW: ULP_LOW_RIO_0_13	
FCC-ID	QRI-RENAMICNEO	
IC	4708A-RENAMICNEO	
Class	Class B	
Equipment type	Table top	
Highest internal frequency [MHz]	5000	
Radio Module I	Type	COIL RF module
	Model	Unspecified
	Manufacturer	Unspecified
	FCC-ID	Unspecified
	IC	Unspecified
Radio Module II	Type	MICS RF module
	Model	Unspecified
	Manufacturer	Unspecified
	FCC-ID	Unspecified
	IC	Unspecified
Radio Module III	Type	WLAN / Bluetooth module
	Model	CM-T43
	Manufacturer	Compulab
	FCC-ID	Unspecified
	IC	Unspecified
Radio Module IV	Type	Bluetooth Low Energy module
	Model	BlueMod+S50/AP
	Manufacturer	Telit
	FCC-ID	RFR-S50
	IC	4957A-S50
Supply Voltage	V _{NOM}	120 VAC (AC/DC adaptor)
AC/DC-Adaptor	Model	ATM090T-P190
	Vendor	Adapter Tech
	Input	100-240V AC
	Output	19V DC
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

1.1 Equipment Ports

Name	Type	Attributes	Comment
Power	AC	Count: 1 Direction: In Service only: No	
Ethernet	IO	Count: 1 Direction: IO Service only: No	CAT 6 S/FTP
ECG	IO	Count: 1 Direction: In Service only: No	
PSA	IO	Count: 2 Direction: In Service only: No	
Monitor	IO	Count: 1 Direction: In Service only: No	
USB	IO	Count: 4 Direction: IO Service only: No	
Description:			
AC	AC mains power input/output port		
DC	DC power input/output port		
BAT	DC power input port connected to external battery		
IO	Input/Output port		
TP	Telecommunication port		
NE	Non-electrical port		

1.4 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE	External Monitor	Lenovo	ThinkVision T24d-10	
AE	Implant	BIOTRONIK	Ilivia Neo 7 VR-T	SN 60076726
AE	WLAN Router	AVM	Fritz!Box	WLAN 2.4/5GHz
AE	WLAN Router	TP-Link	TP Link	Ethernet
AE	Smartphone	Apple	iPhone SE	Bluetooth LE
AE	Bluetooth Tester	R&S	CBT	Bluetooth
AE	Mouse	DELL	M-UVDEL1	
AE	Keyboard	Lenovo	KU-0906A	
CBL	ECG	BIOTRONIK		
CBL	PSA	BIOTRONIK	PK-67-L	2x
AE	Programing Head	BIOTRONIK		
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
MON	Monitoring Equipment			
CBL	Connecting Cable			
Comment:				

1.5 Operational Modes

Mode #	Description
1	WLAN 2.4 GHz connection to WLAN router (Ping)
2	WLAN 5 GHz connection to WLAN router (Ping)
3	Bluetooth Low Energy connection to Smartphone. App on Smartphone (Telit TIO)
4	Bluetooth connection to Bluetooth Tester. EUT Bluetooth module is set in BT-DUT mode.
5	MICS/ULPAMI connection via Rio Main software on EUT to Implant
6	COIL connection via Rio Main software on EUT to Implant
Comment:	

1.6 EUT Configuration

Configuration #	Description
1	EUT powered via internal battery. External monitor connected via display port, show extended monitor. Ethernet connection to Router (Ping)
2	EUT charging mode. External monitor connected via display port, show extended monitor. Ethernet connection to Router (Ping)
Comment:	

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 analyser in dBµV. Any external preamplifiers used are taken into account through internal analyser 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 analyser. 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:

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

Net:

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

Limit:

This is the FCC Class B radiated emission limit (in units of 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:

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

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:

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

2 Result Summary

FCC 47 CFR Part 15B, ISED ICES-003 Issue 6				
Reference	Requirement	Reference Method	Result	Remarks
Emission				
FCC 15.109 ICES-003, 8, 6.1	Radiated emissions	ANSI C63.4:2014	PASS	
FCC 15.107 ICES-003, 8, 6.2	AC power line conducted emissions	ANSI C63.4:2014	PASS	
Comment:				

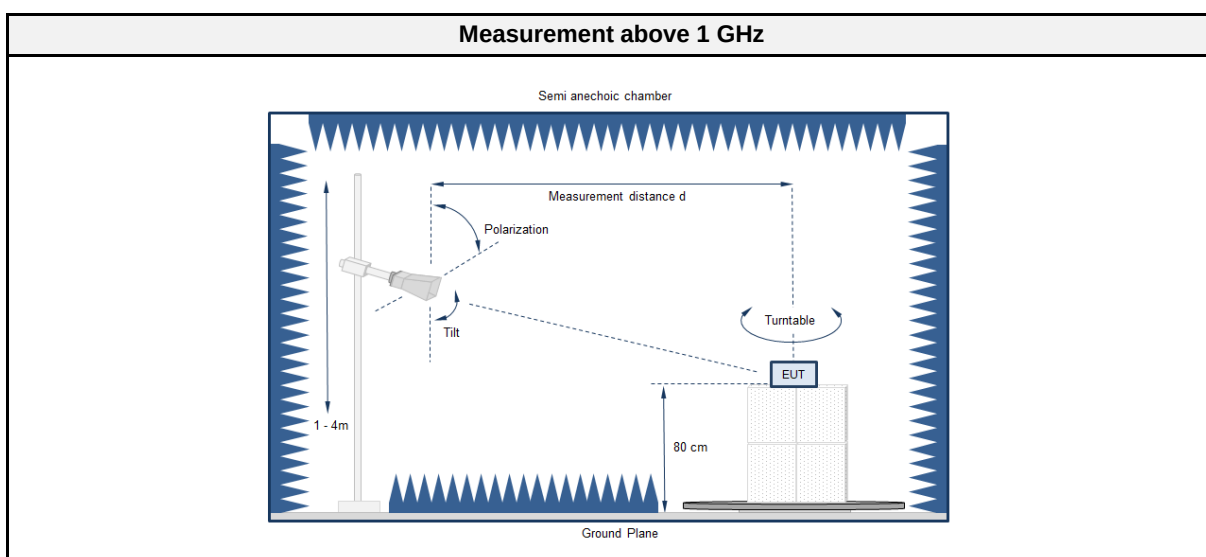
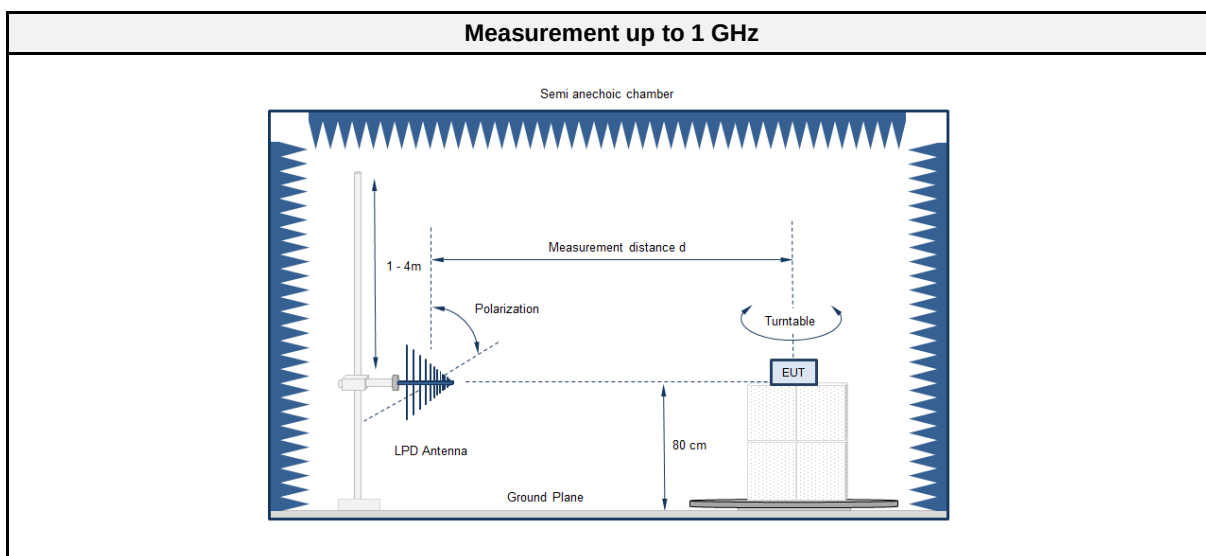
Possible Test Case Verdicts	
PASS	Test object does meet the requirements
FAIL	Test object does not meet the requirements
N/T	Required by standard but not tested
N/R	Not required by standard for the test object

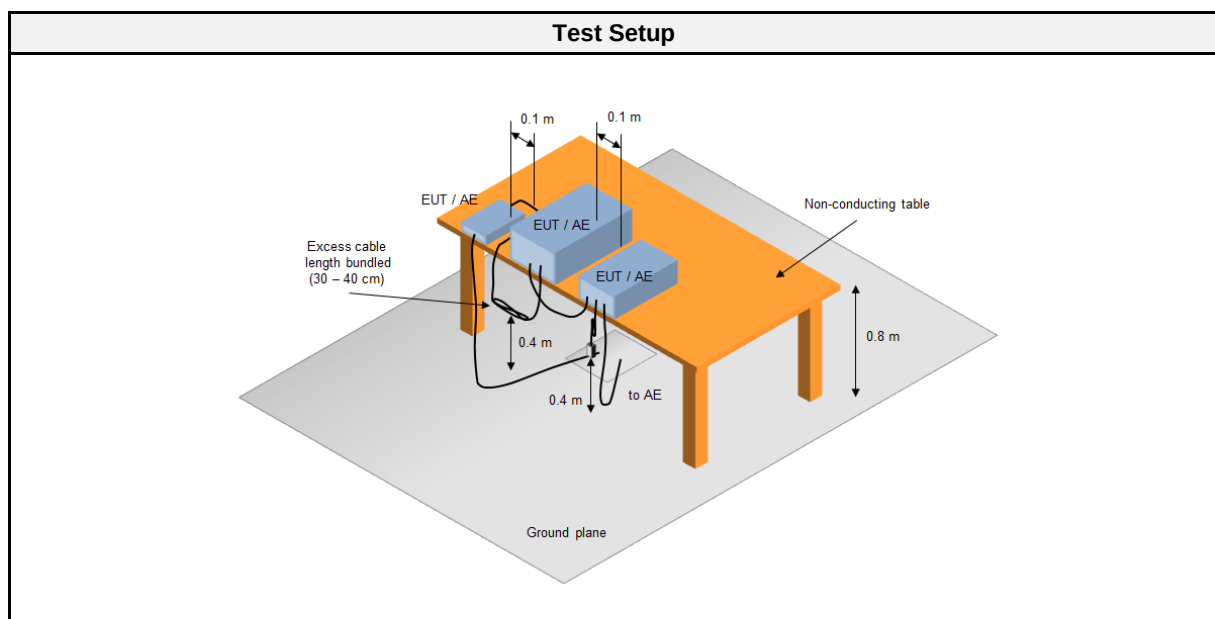
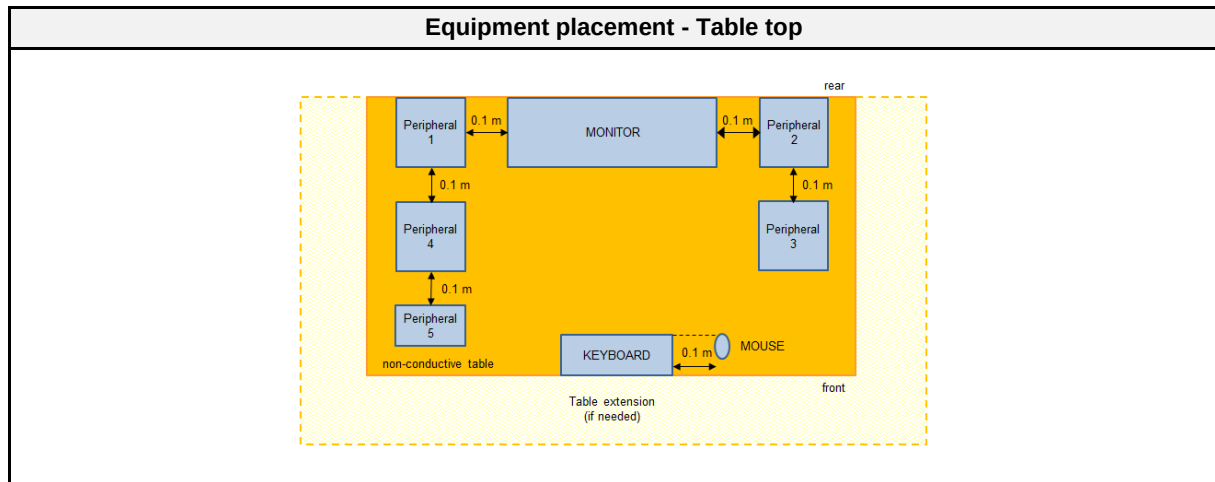
2.1 Test Conditions and Results - Radiated emissions acc. to ANSI C63.4

2.1.1 Information

Test Information	
Reference	FCC 15.109, ICES-003, 8, 6.1
Reference method	ANSI C63.4:2014 Section 8
Equipment class	Class B
Equipment type	Table top
Highest internal frequency [MHz]	5000
Measurement range	30 MHz to 25000 MHz
Temperature [°C]	22
Humidity [%]	42
Operator	Matthias Handrik
Date	2019-09-06

2.1.2 Setup





2.1.3 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	Radimation	2016.1.10

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC1	EF00062	2018-07	2021-07
EMI Test Receiver	Rohde & Schwarz Vertriebs GmbH	ESR7	EF00943	2019-07	2020-07
Spectrum analyzer	Rohde & Schwarz Vertriebs GmbH	FSW43	EF00896	2019-07	2020-07
40GHz High Gain Antenna	Amplifier Research	AT4560	EF00302	2019-05	2020-05
40GHz Standard Gain Horn with Amplifier	Flann Microwave Ltd	22240-25 Amp. CBL26402075	EF00301	2016-11	2019-11
Biconical Antenna	R&S	HK 116	EF00030	2019-04	2022-04
LPD Antenna	R&S	HL 223	EF00187	2019-05	2022-05
Horn antenna	Schwarzbeck	BBHA 9120D (1-18GHz)	EF00018	2016-09	2019-09
Climatic Sensor	Embedded Data Systems, LLC.	2800100000254 17E	EF01054	2019-05	2020-05

2.1.4 Procedure

Exploratory measurement	
1.	The EUT was placed on a non-conductive table at a height of 0.8m.
2.	The EUT and support equipment, if needed, were set up to simulate typical usage.
3.	Cables, of type and length specified by the manufacturer, were connected to at least one port of each type and were terminated by a device or simulating load of actual usage.
4.	The antenna was placed at a distance of 3 or 10 m.
5.	The received signal was monitored at the measurement receiver.
6.	This procedure has to be performed in both antenna polarizations, horizontal and vertical.
7.	The arrangement of the equipment with the maximum emission level is shown on the setup picture at item 1.3

Final measurement	
1.	The EUT was placed on a 0.8 m non-conductive table at a 3 m distance from the receive antenna. The antenna output was connected to the measurement receiver.
2.	A biconical antenna was used for the frequency range 30 – 200 MHz, a logarithmic periodical antenna was used for the frequency range from 200 – 1000 MHz. Above one 1 GHz a Double Ridged Broadband Horn antenna was used. The antenna was placed on an adjustable height antenna mast.
3.	The EUT and cable arrangement were based on the exploratory measurement results.
4.	Emissions were maximized at each frequency by rotating the EUT and adjusting the receive antenna height and polarization. The maximum values were recorded.
5.	The test data of the worst-case conditions were recorded and shown on the next pages.

2.1.5 Limits

Class B @ 3 m		
Frequency [MHz]	Detector	Limit [dB μ V/m]
30 - 88	Quasi-peak	40
88 - 216	Quasi-peak	43.5
216 - 960	Quasi-peak	46
960 - 1000	Quasi-peak	54
> 1000	Peak	74
	Average	54

Class A @ 10 m		
Frequency [MHz]	Detector	Limit [dB μ V/m]
30 - 88	Quasi-peak	39
88 - 216	Quasi-peak	43.5
216 - 960	Quasi-peak	46.5
960 - 1000	Quasi-peak	49.5
> 1000	Peak	69.5
	Average	49.5

2.1.6 Results

Test Results			
Operational mode	EUT Configuration	Verdict	Remark
3; 6	1,2	PASS	Comment
Comment: The shield from used Ethernet cable was connected to chamber ground. EUT display shows on test setup picture Ethernet + WLAN ping but worst case: after visual evaluation on spectrum analyser is operational mode 3, 6 in both EUT configuration.			

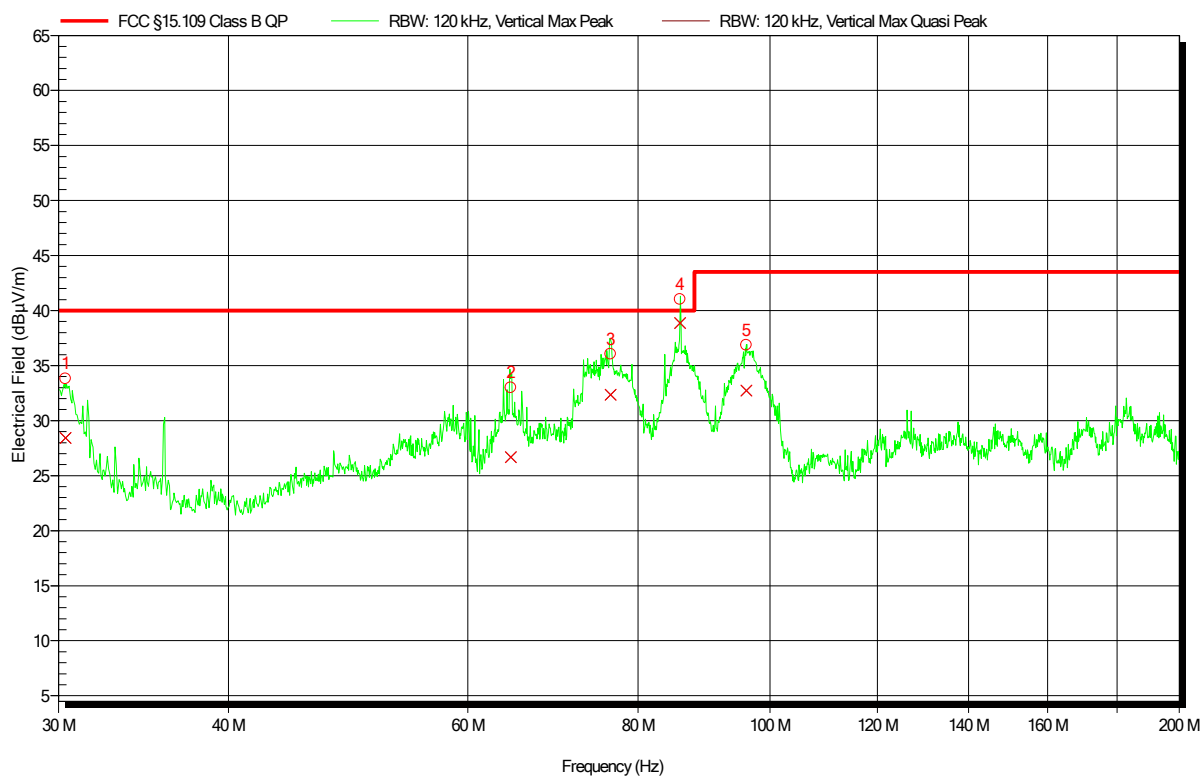
2.1.8 Records

Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
 Antenna: Rohde & Schwarz HK 116, Vertical
 Measurement distance: 3m
 Mode: 3; 6
 Test Date: 2019-09-06
 Note:

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Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	30.36 MHz	28.42 dBµV/m	40 dBµV/m	-11.58 dB	Pass	70 Degree	1 m
2	64.5 MHz	26.69 dBµV/m	40 dBµV/m	-13.31 dB	Pass	70 Degree	1 m
3	76.38 MHz	32.35 dBµV/m	40 dBµV/m	-7.65 dB	Pass	70 Degree	1 m
4	85.92 MHz	38.86 dBµV/m	40 dBµV/m	-1.14 dB	Pass	70 Degree	1 m
5	96.12 MHz	32.72 dBµV/m	43.52 dBµV/m	-10.8 dB	Pass	70 Degree	1 m

Test Report No.: G0M-1905-8256-EF0115B-V01

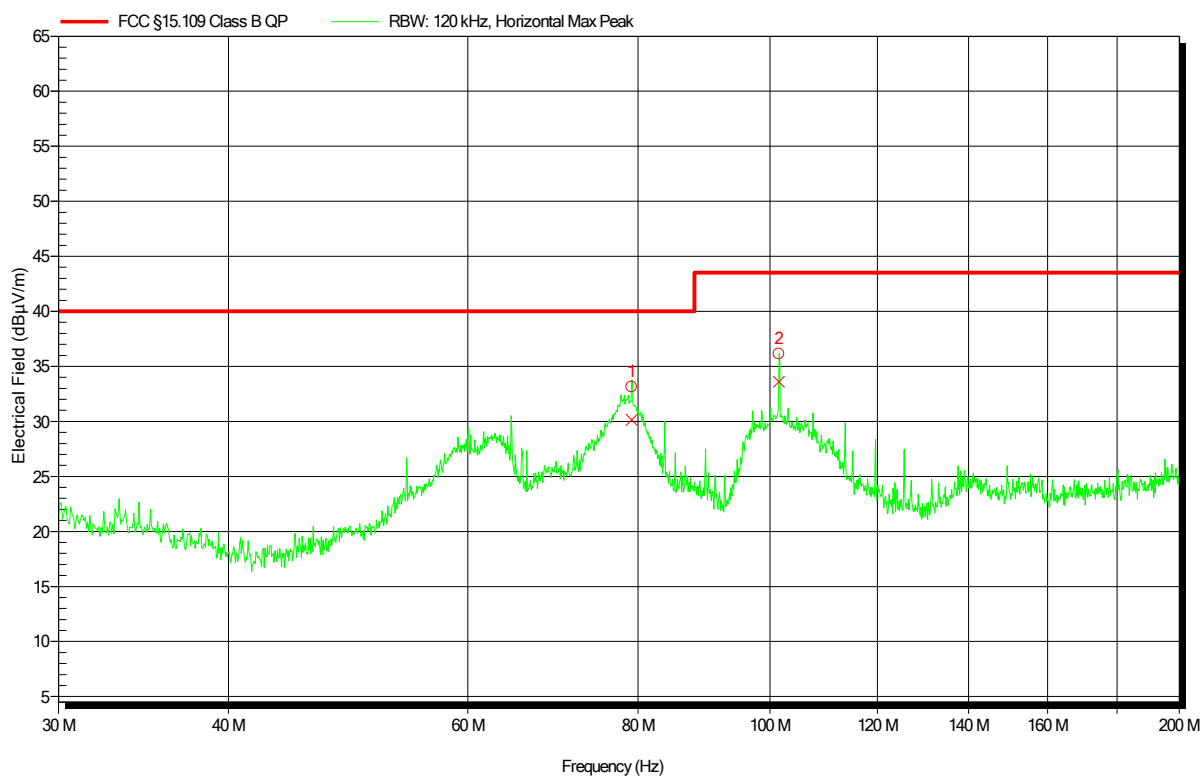
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
 Antenna: Rohde & Schwarz HK 116, Horizontal
 Measurement distance: 3m
 Mode: 3; 6
 Test Date: 2019-09-06
 Note:

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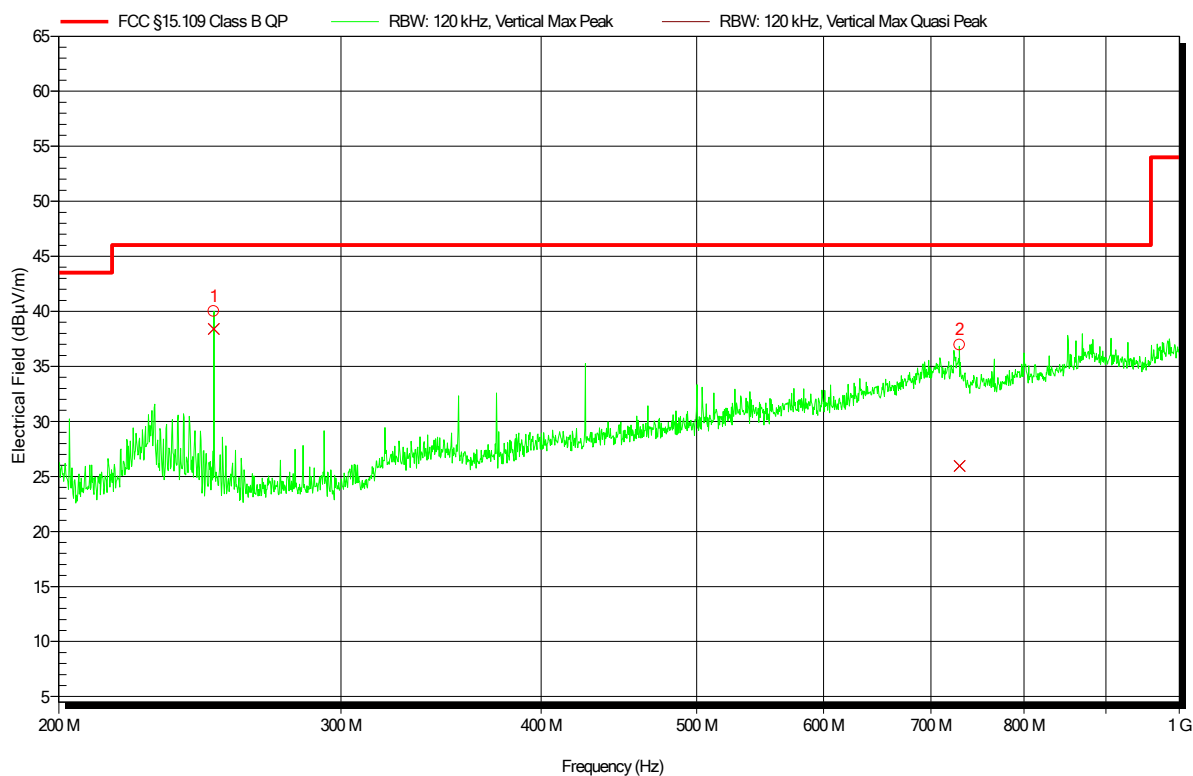
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	79.14 MHz	30.13 dBµV/m	40 dBµV/m	-9.87 dB	Pass	-180 Degree	3.34 m
2	101.574 MHz	33.61 dBµV/m	43.52 dBµV/m	-9.91 dB	Pass	-180 Degree	3.34 m

Radiated emissions according to FCC Part 15b

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Model: Renamic Neo
Test Site: Eurofins Product Service GmbH
Operator: Mr. Handrik
Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
Antenna: Rohde & Schwarz HL 223, Vertical
Measurement distance: 3m
Mode: 3, 6
Test Date: 2019-09-06
Note:

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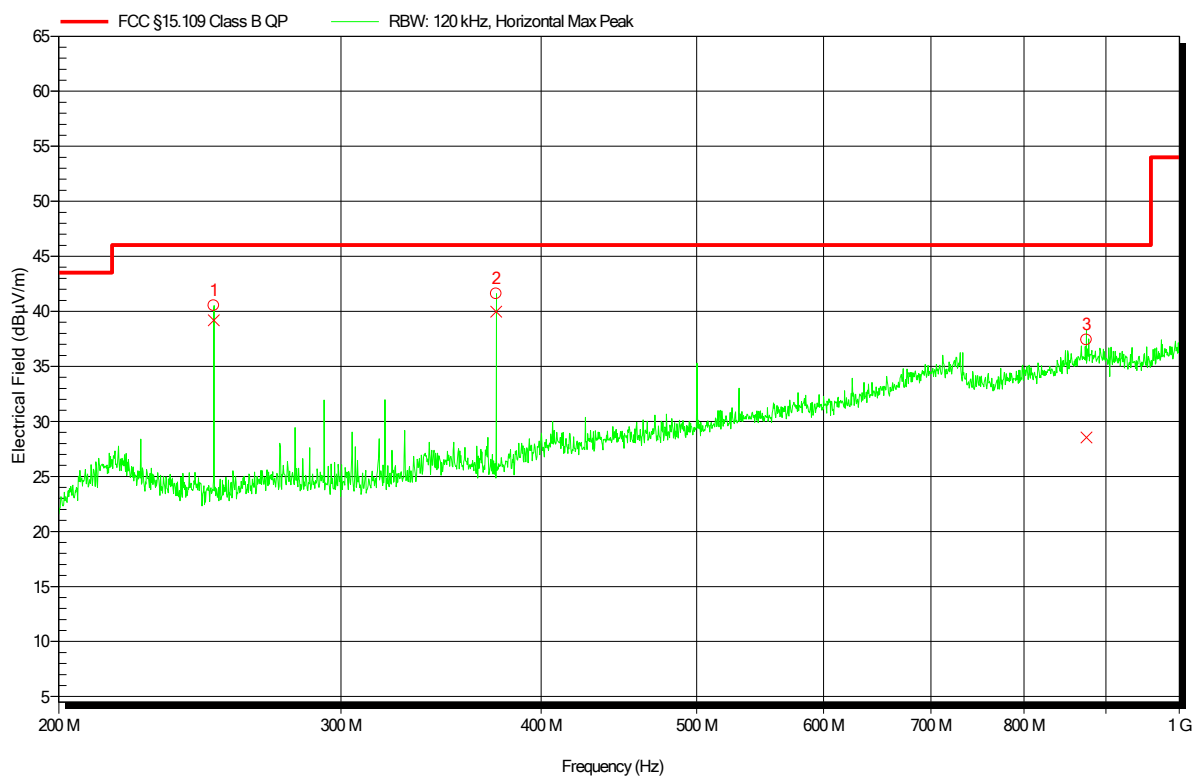
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	250.004 MHz	38.41 dBµV/m	46.02 dBµV/m	-7.61 dB	Pass	-180 Degree	1.10 m
2	729.26 MHz	25.95 dBµV/m	46.02 dBµV/m	-20.07 dB	Pass	-180 Degree	1.10 m

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 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
 Antenna: Rohde & Schwarz HL 223, Horizontal
 Measurement distance: 3m
 Mode: 3; 6
 Test Date: 2019-09-06
 Note:

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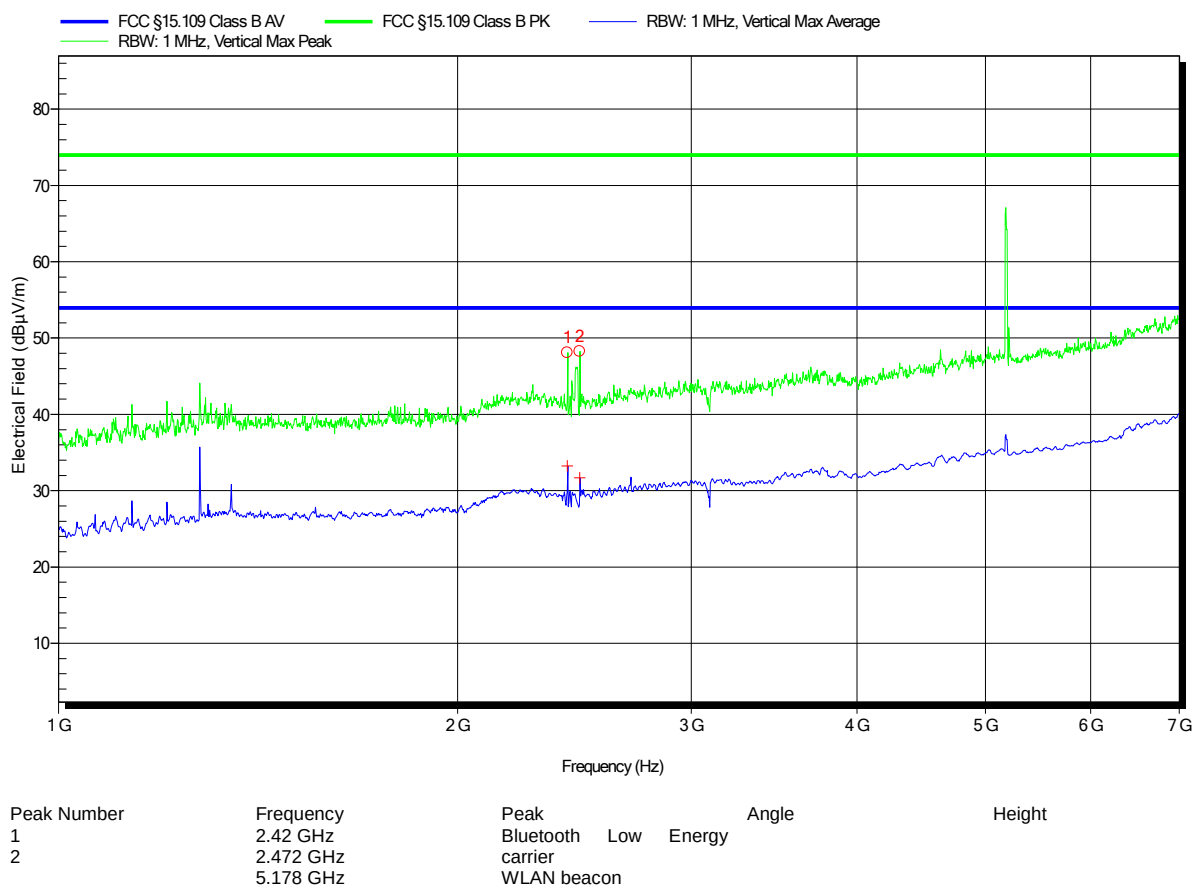
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1	249.998 MHz	39.19 dBµV/m	46.02 dBµV/m	-6.83 dB	Pass	-5 Degree	1 m
2	374.996 MHz	39.97 dBµV/m	46.02 dBµV/m	-6.05 dB	Pass	-5 Degree	1 m
3	874.976 MHz	28.53 dBµV/m	46.02 dBµV/m	-17.49 dB	Pass	-5 Degree	1 m

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 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
 Antenna: Schwarzbeck BBHA 9120D, Vertical
 Measurement distance: 3m
 Mode: 3; 6
 Test Date: 2019-09-06
 Note:

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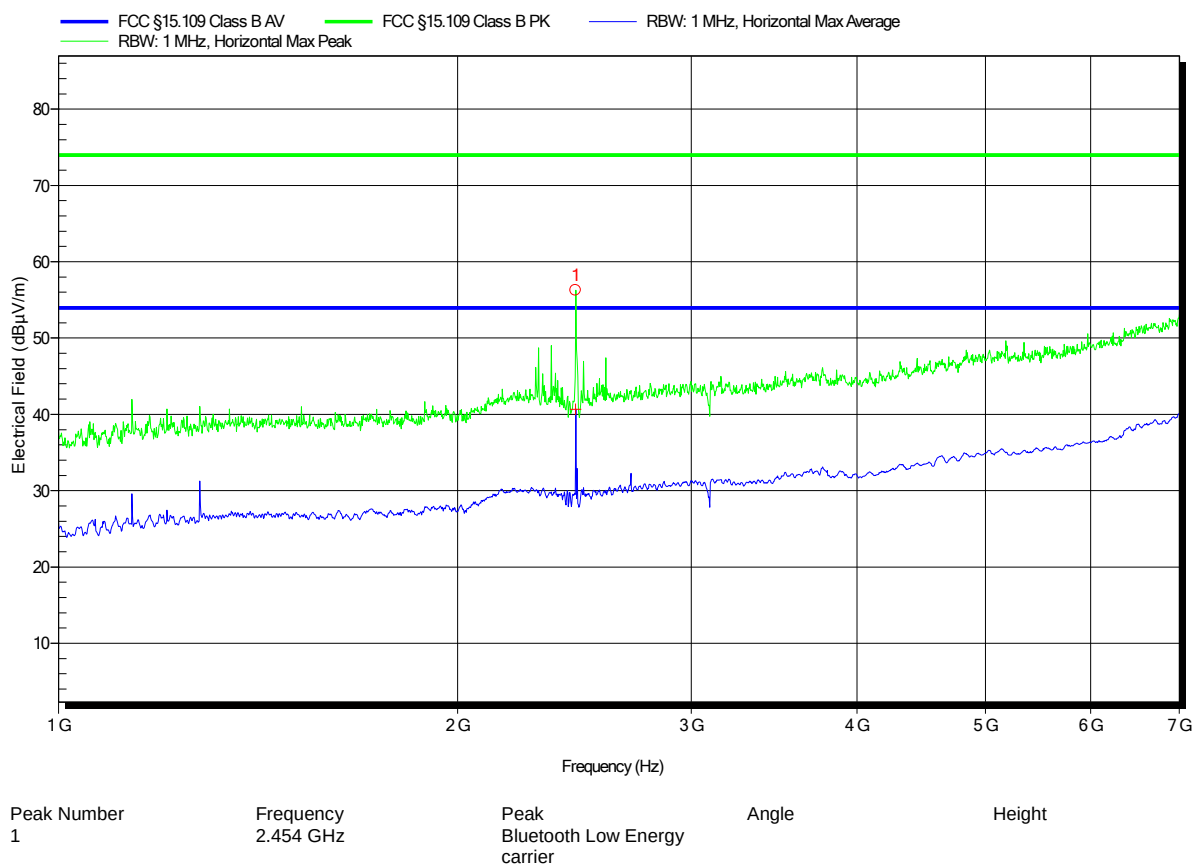


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 Antenna: Schwarzbeck BBHA 9120D, Horizontal
 Measurement distance: 3m
 Mode: 3; 6
 Test Date: 2019-09-06
 Note:

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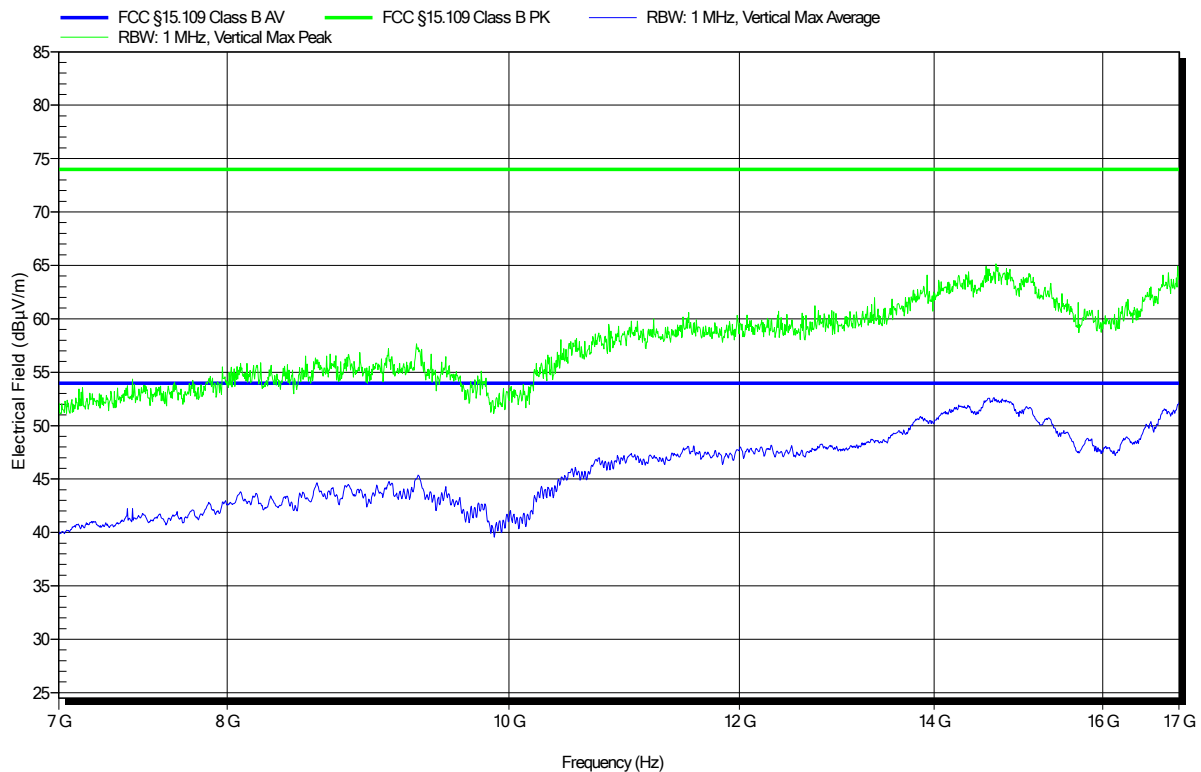


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Operator: Mr. Handrik
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Antenna: Schwarzbeck BBHA 9120D, Vertical
Measurement distance: 3m
Mode: 3, 6
Test Date: 2019-09-06
Note:

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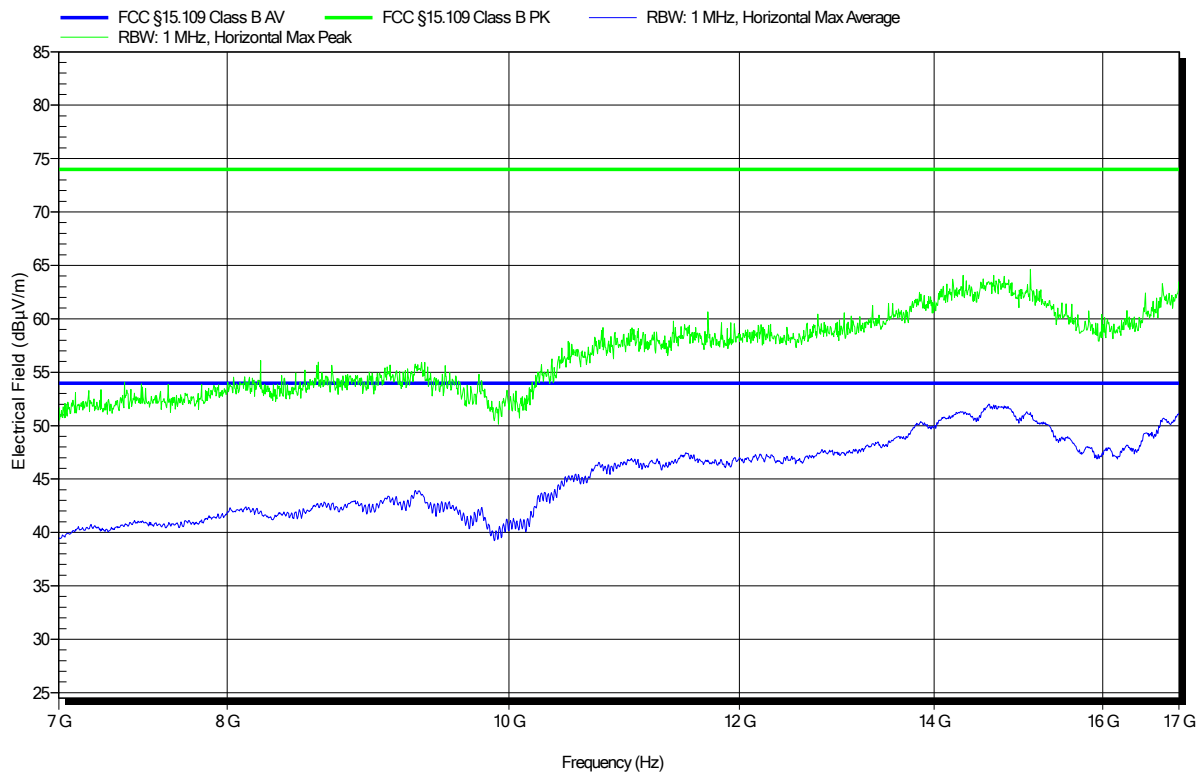


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Operator: Mr. Handrik
Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
Antenna: Schwarzbeck BBHA 9120D, Horizontal
Measurement distance: 3m
Mode: 3, 6
Test Date: 2019-09-06
Note:

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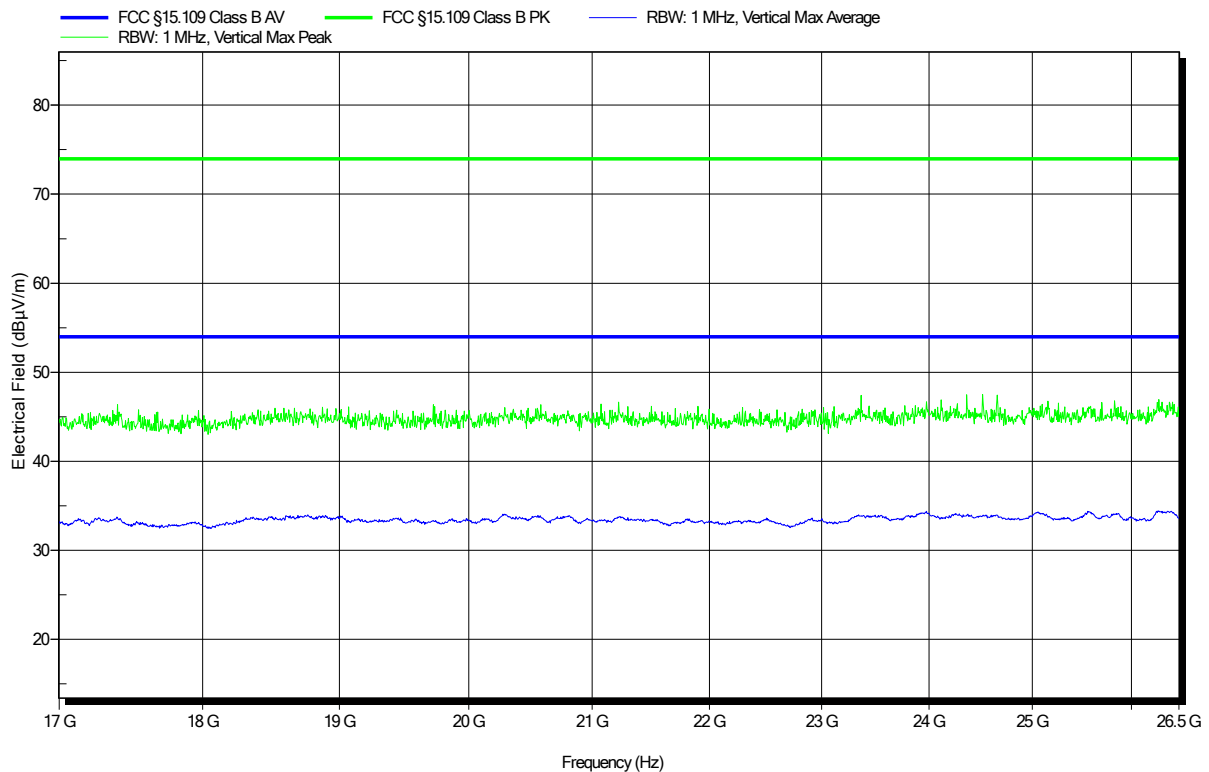


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 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
 Antenna: AT4560, Vertical
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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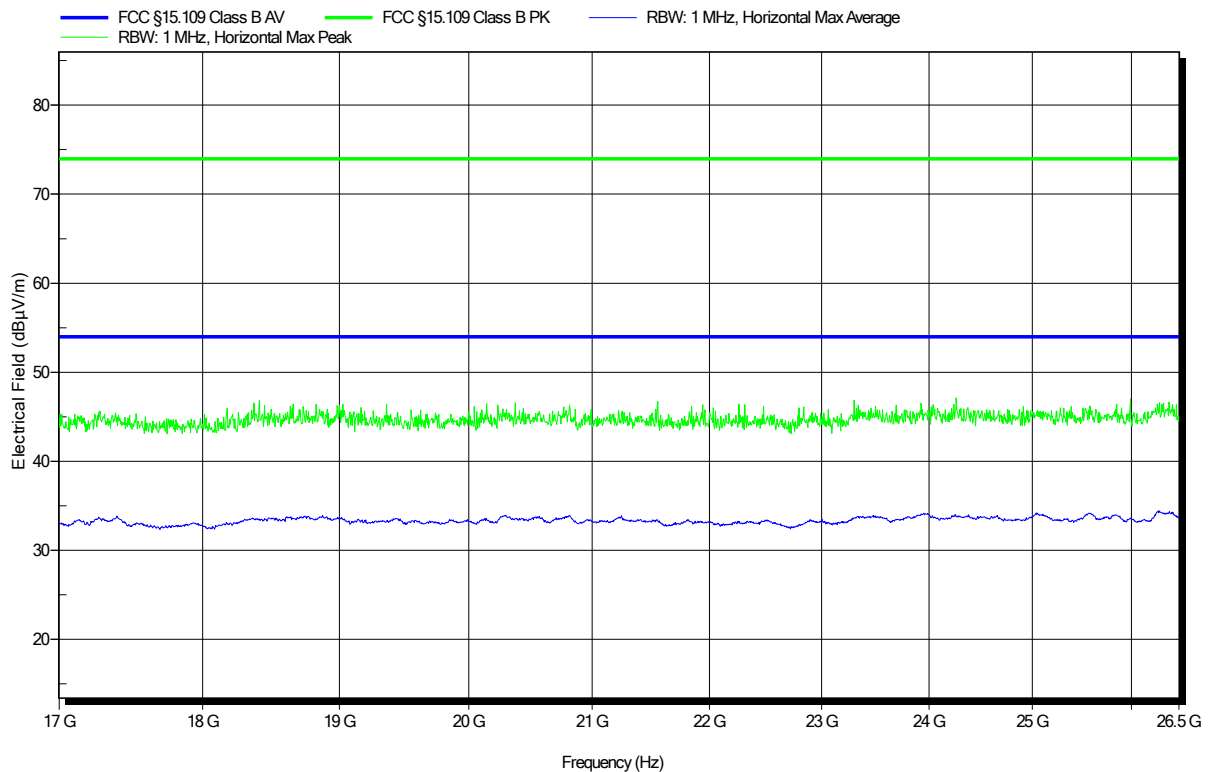


Radiated emissions according to FCC Part 15b

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 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 120V AC (AC/DC adaptor)
 Antenna: AT4560, Horizontal
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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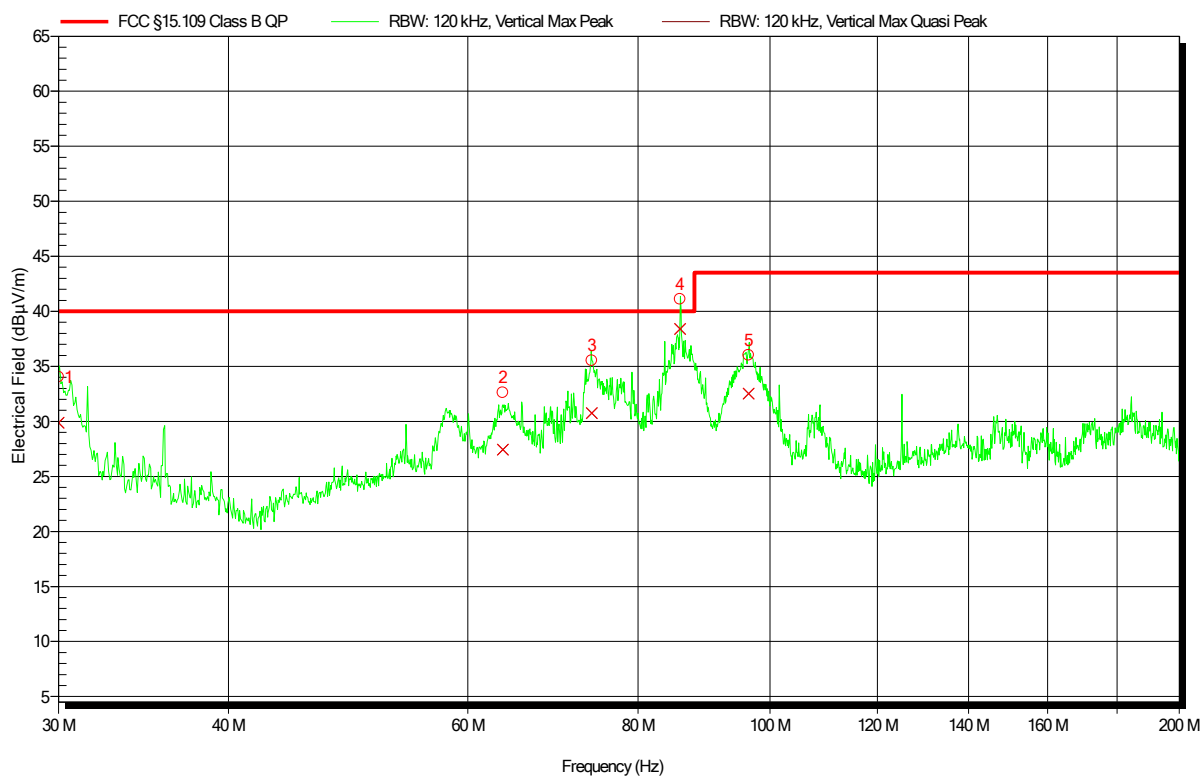


Radiated emissions according to FCC Part 15b

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EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
Model: Renamic Neo
Test Site: Eurofins Product Service GmbH
Operator: Mr. Handrik
Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
Antenna: Rohde & Schwarz HK 116, Vertical
Measurement distance: 3m
Mode: 3, 6
Test Date: 2019-09-06
Note:

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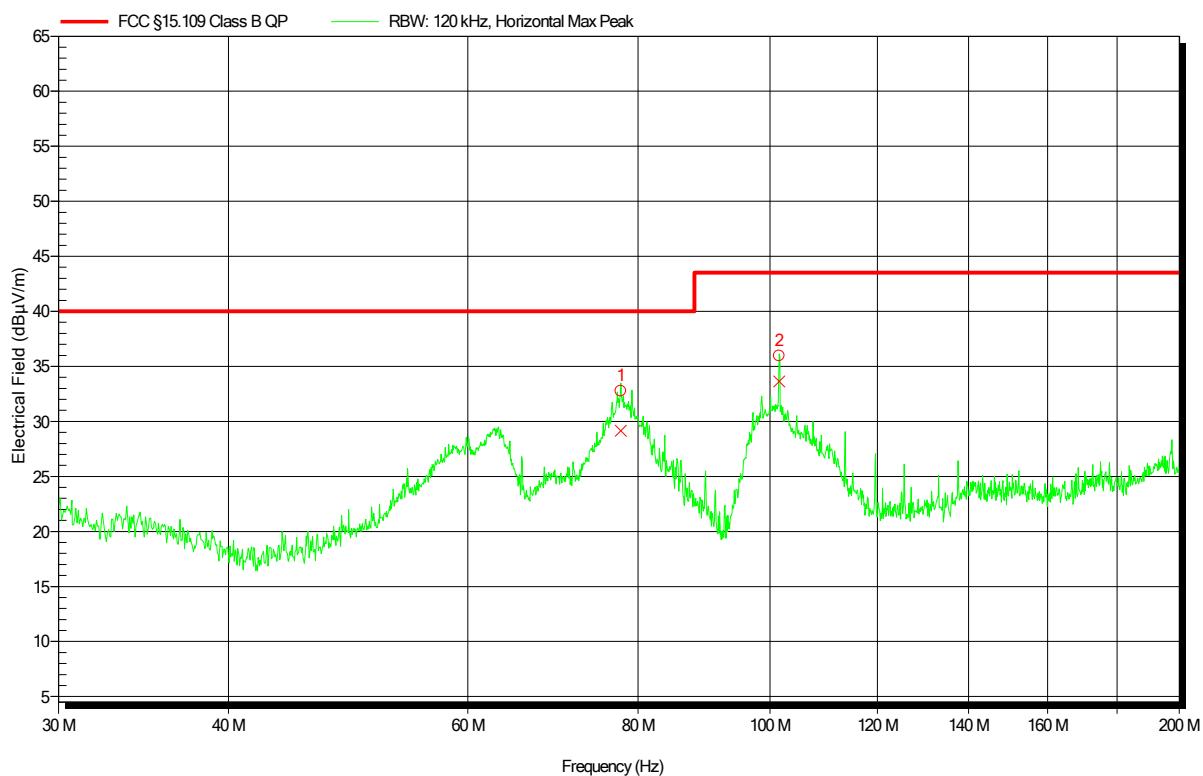
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	30 MHz	29.89 dBμV/m	40 dBμV/m	-10.11 dB	Pass	84 Degree	1 m
2	63.66 MHz	27.45 dBμV/m	40 dBμV/m	-12.55 dB	Pass	84 Degree	1 m
3	73.98 MHz	30.76 dBμV/m	40 dBμV/m	-9.24 dB	Pass	84 Degree	1 m
4	85.926 MHz	38.4 dBμV/m	40 dBμV/m	-1.6 dB	Pass	84 Degree	1 m
5	96.48 MHz	32.53 dBμV/m	43.52 dBμV/m	-10.99 dB	Pass	84 Degree	1 m

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 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: Rohde & Schwarz HK 116, Horizontal
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	77.7 MHz	29.14 dBµV/m	40 dBµV/m	-10.86 dB	Pass	180 Degree	3.68 m
2	101.586 MHz	33.62 dBµV/m	43.52 dBµV/m	-9.9 dB	Pass	180 Degree	3.68 m

Test Report No.: G0M-1905-8256-EF0115B-V01

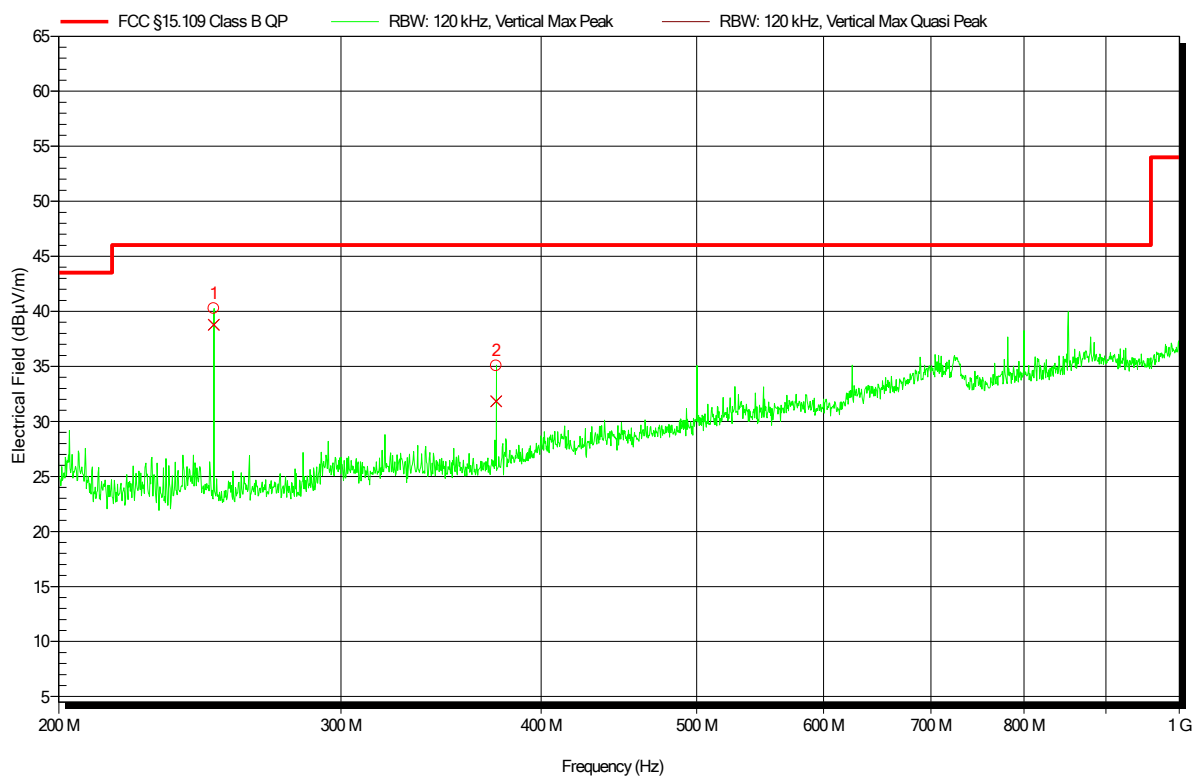
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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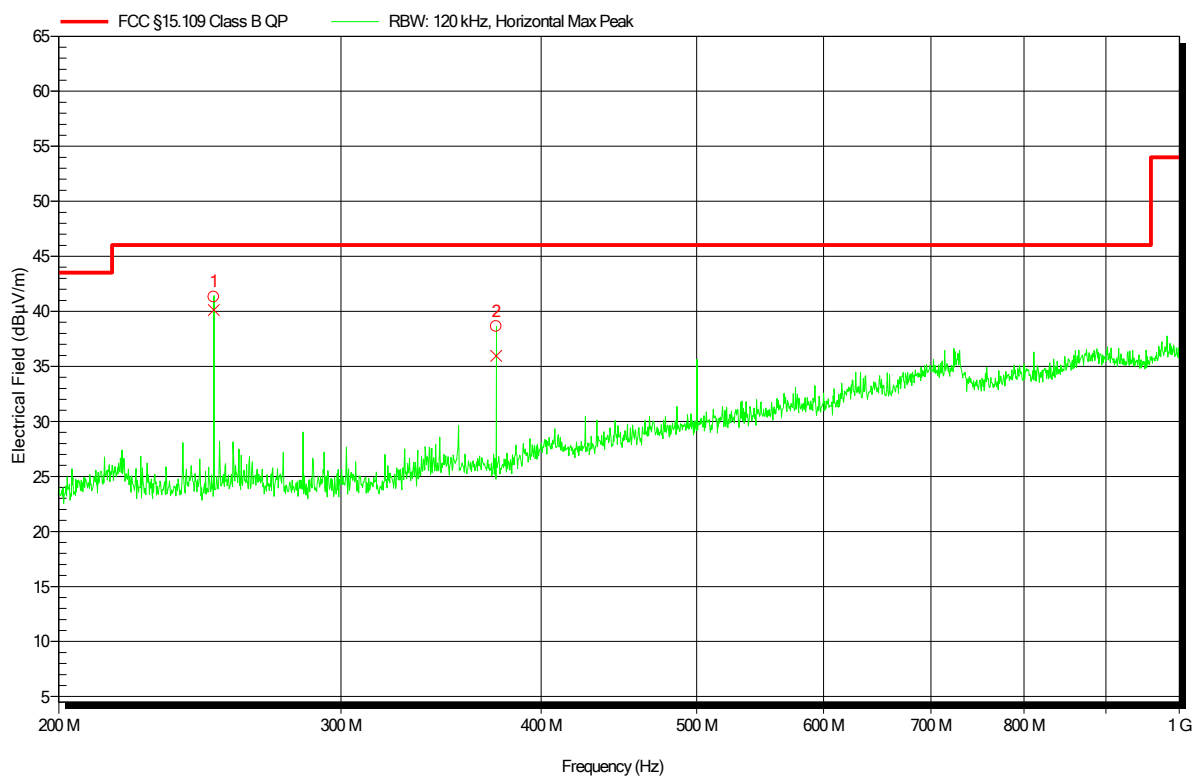
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	249.998 MHz	38.77 dBµV/m	46.02 dBµV/m	-7.25 dB	Pass	-8 Degree	1 m
2	375.002 MHz	31.83 dBµV/m	46.02 dBµV/m	-14.19 dB	Pass	-8 Degree	1 m

Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: Rohde & Schwarz HL 223, Horizontal
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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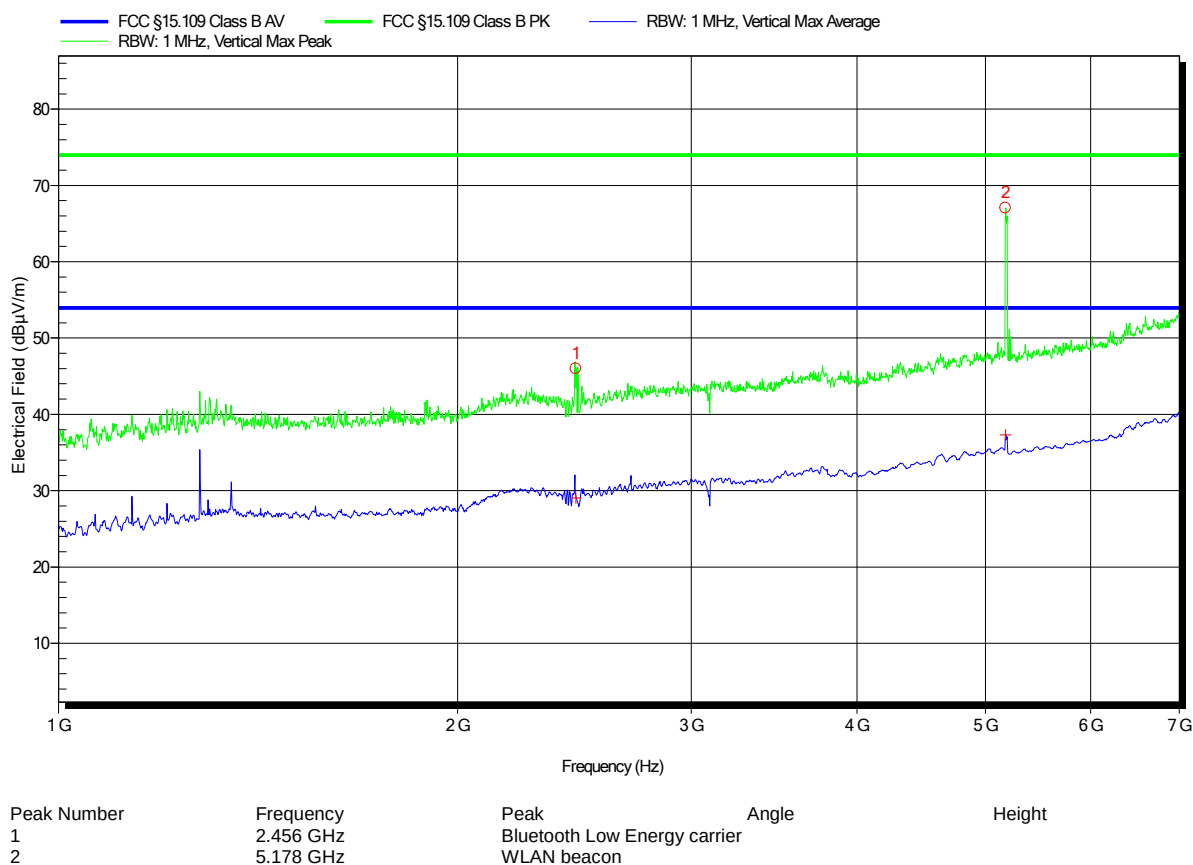
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1	249.998 MHz	40.12 dBµV/m	46.02 dBµV/m	-5.9 dB	Pass	-30 Degree	1.40 m
2	374.996 MHz	35.96 dBµV/m	46.02 dBµV/m	-10.06 dB	Pass	-30 Degree	1.40 m

Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: Schwarzbeck BBHA 9120D, Vertical
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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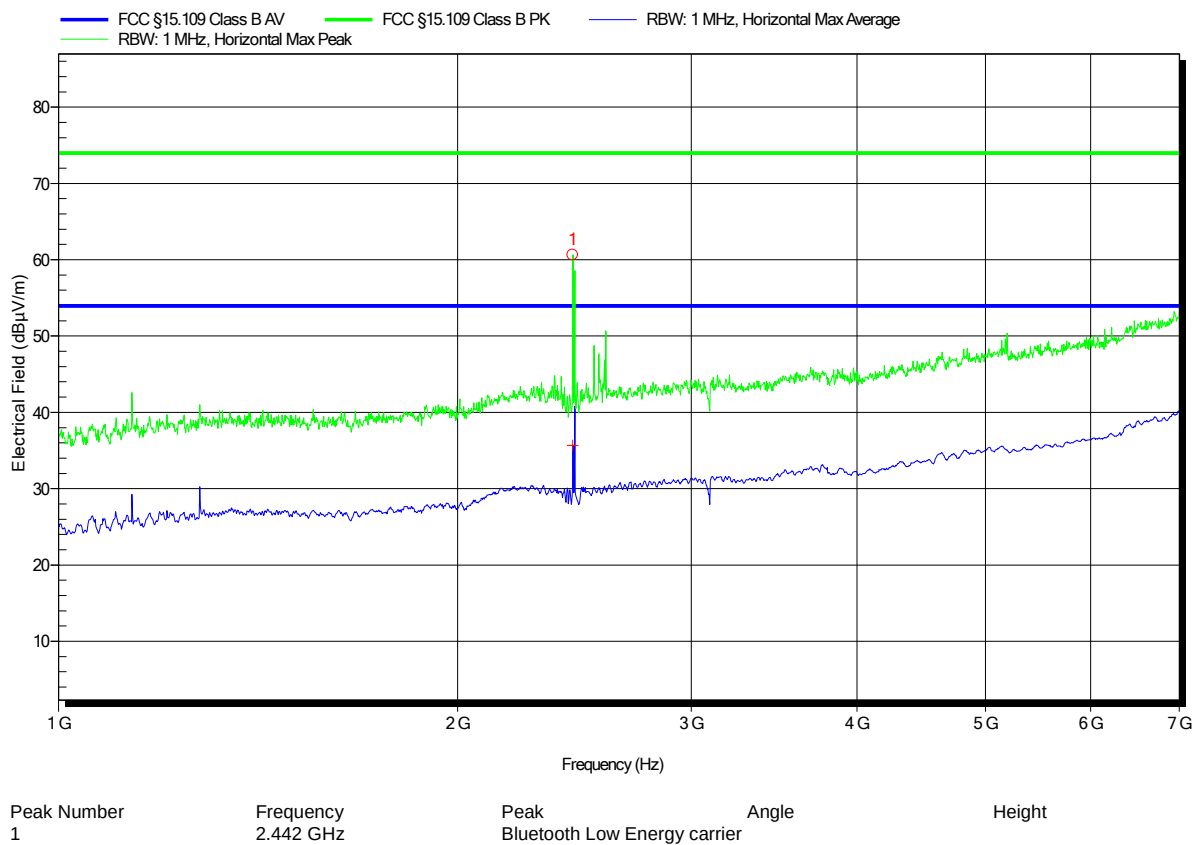


Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
Model: Renamic Neo
Test Site: Eurofins Product Service GmbH
Operator: Mr. Handrik
Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
Antenna: Schwarzbeck BBHA 9120D, Horizontal
Measurement distance: 3m
Mode: 3, 6
Test Date: 2019-09-06
Note:

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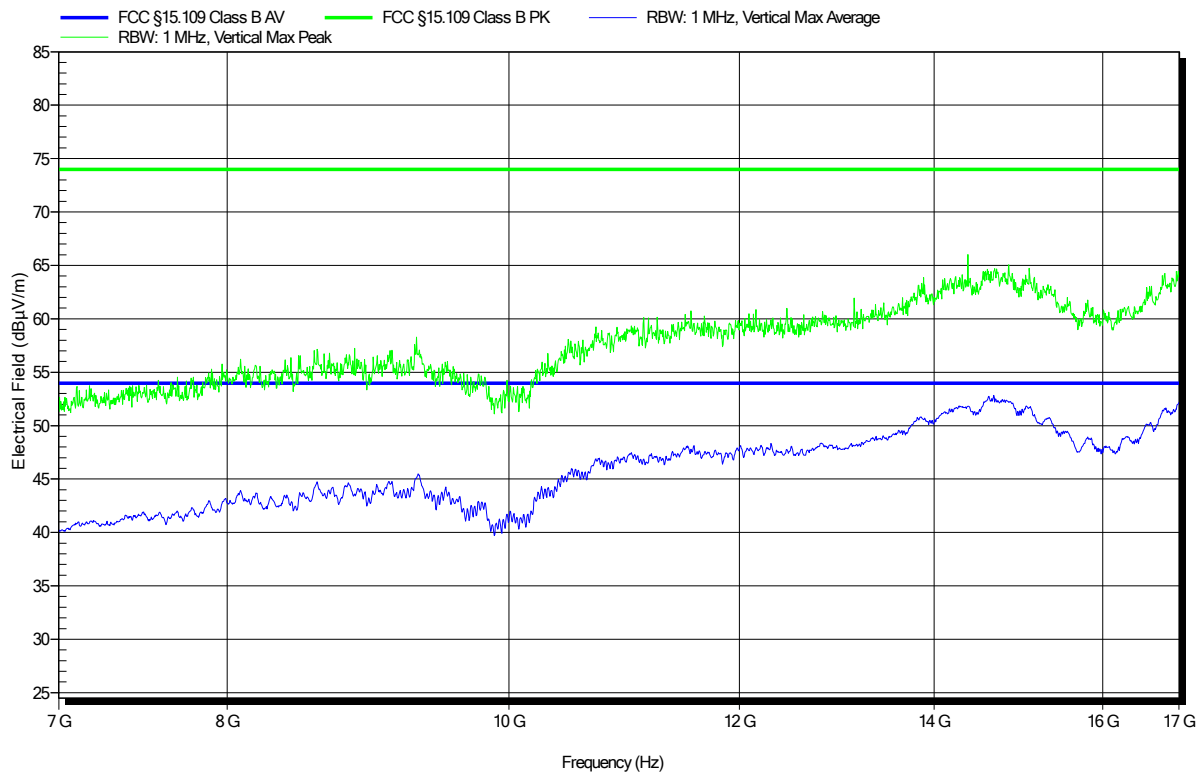


Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
Model: Renamic Neo
Test Site: Eurofins Product Service GmbH
Operator: Mr. Handrik
Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
Antenna: Schwarzbeck BBHA 9120D, Vertical
Measurement distance: 3m
Mode: 3, 6
Test Date: 2019-09-06
Note:

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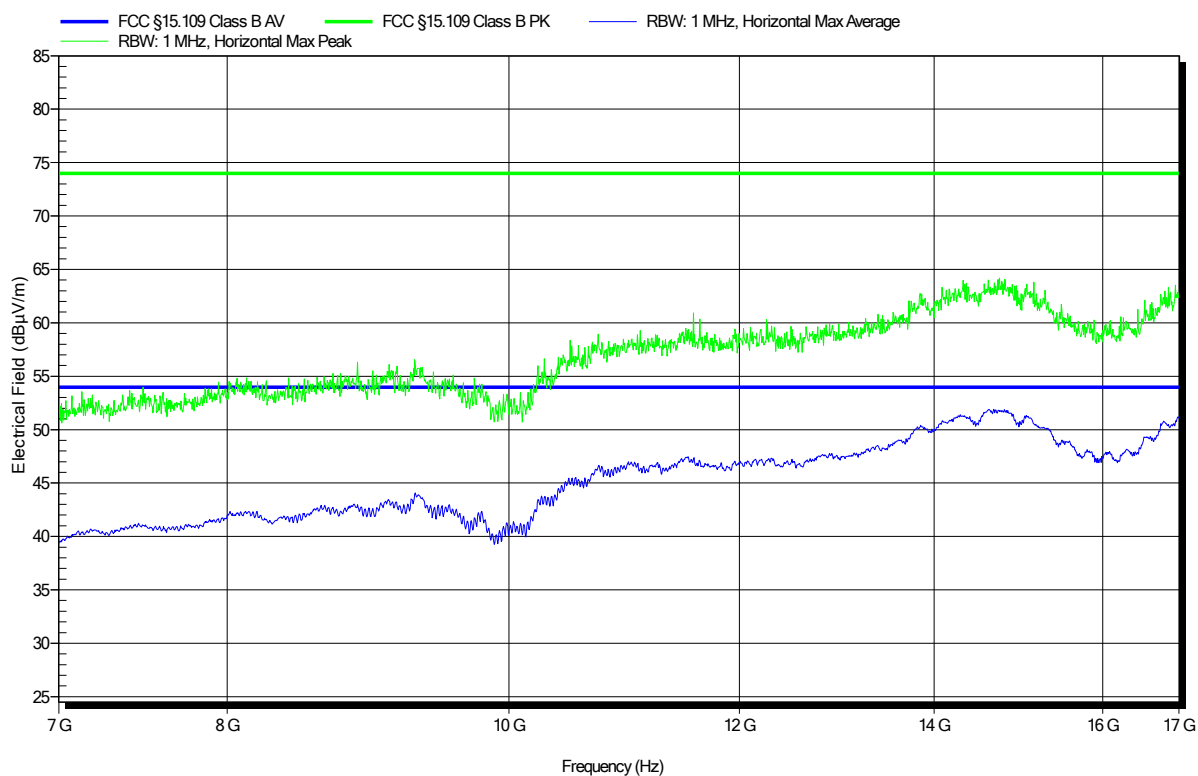


Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: Schwarzbeck BBHA 9120D, Horizontal
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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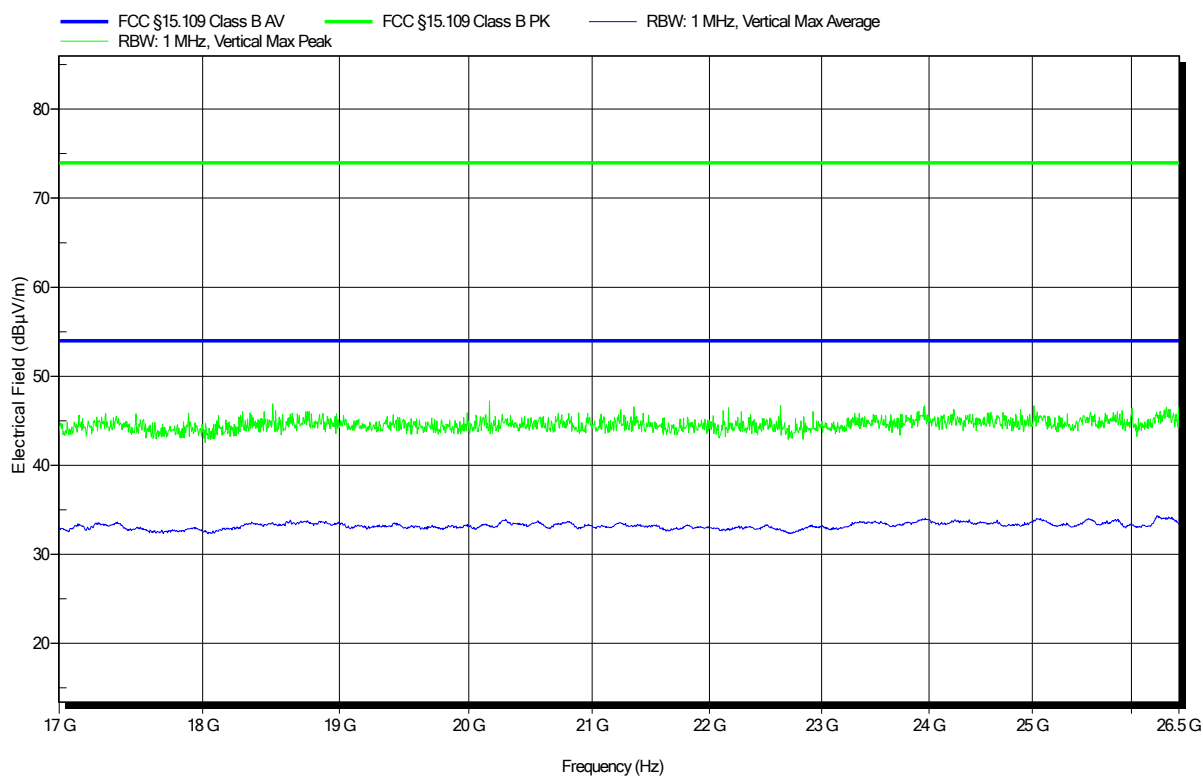


Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: AT4560, Vertical
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

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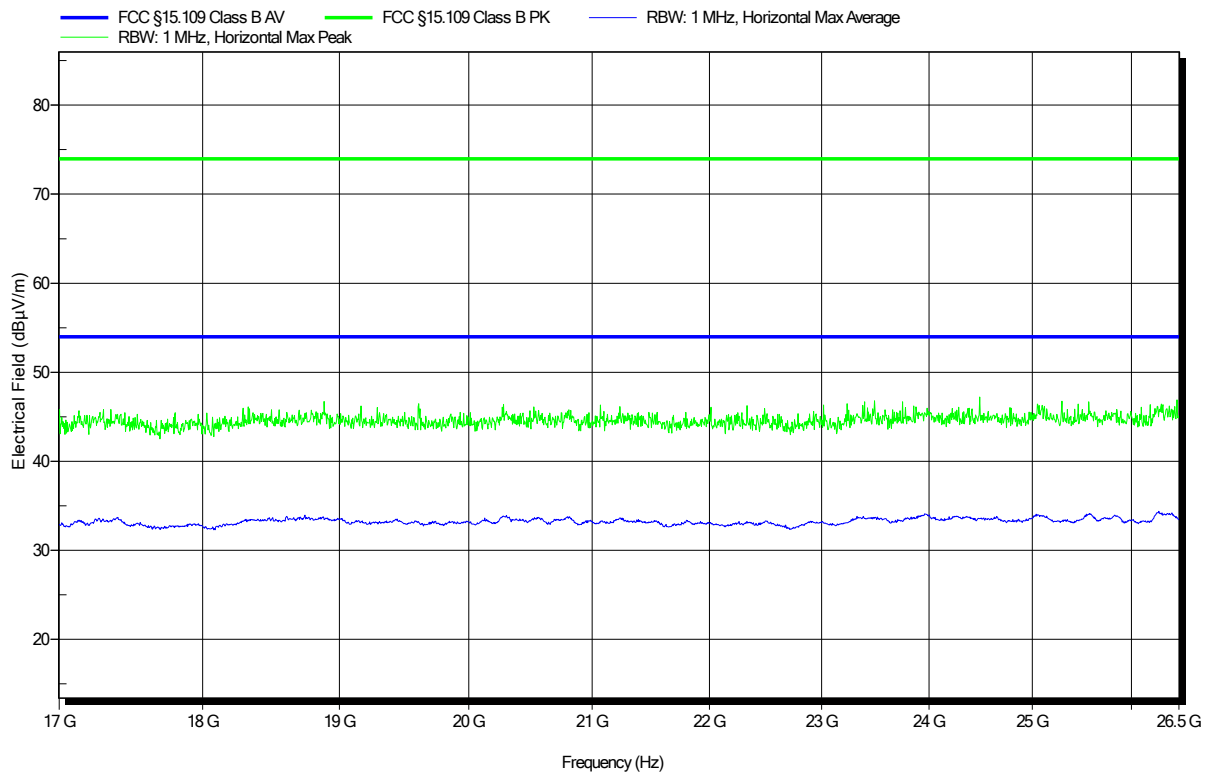


Radiated emissions according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 22°C, Unom: 11.1 V DC (Lithium-Ion)
 Antenna: AT4560, Horizontal
 Measurement distance: 3m
 Mode: 3, 6
 Test Date: 2019-09-06
 Note:

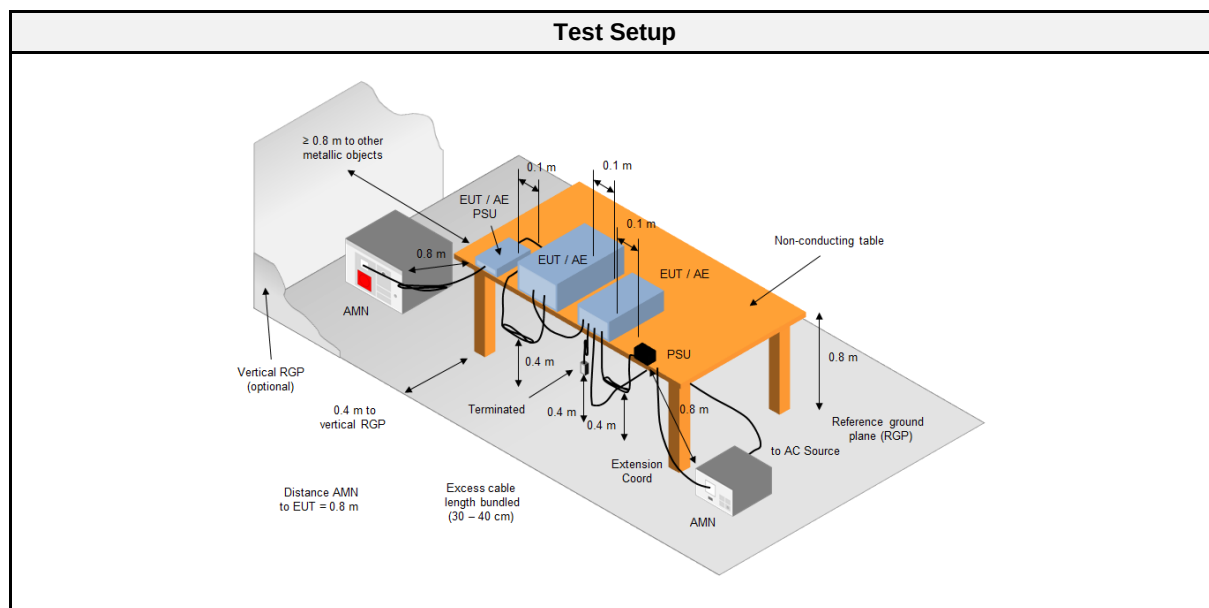
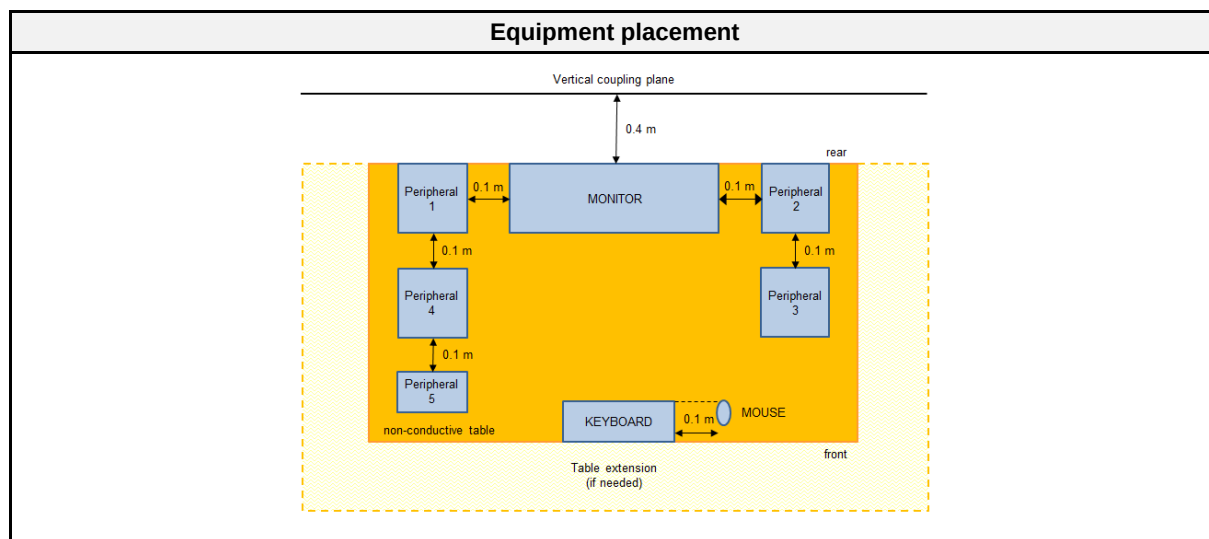
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2.2.1 Information

Test Information	
Reference	FCC 15.107, ICES-003, 8, 6.2
Reference method	ANSI C63.4:2014 Section 12
Measurement range	150 kHz to 30 MHz
Equipment class	Class B
Equipment type	Table top
Temperature [°C]	23
Humidity [%]	43
Operator	Matthias Handrik
Date	2019-09-05

2.2.2 Setup



2.2.3 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	Radimation	2016.1.10

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
AMN	R&S	ESH3-Z5	EF00036	2019-07	2021-07
Pulse Limiter	R&S	ESH3-Z2	EF01063	2019-07	2020-07
CDN	Teseq GmbH - Berlin	ST08A	EF00411	2019-07	2021-07
EMI Test Receiver	Rohde & Schwarz Vertriebs GmbH	ESCS 30	EF00295	2019-07	2020-07
Climatic Sensor	Embedded Data Systems, LLC.	2800100000254 17E	EF01054	2019-05	2020-05

2.2.4 Procedure

Exploratory measurement
1. The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1) 2. The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN. 3. The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length). 4. The LISN measurement port was connected to a measurement receiver 5. I/O cables were bundled not longer than 0.4 m 6. Measurement was performed in the frequency range 0.15 – 30MHz on each current-carrying conductor 7. To maximize the emissions the cable positions were manipulated 8. The worst configuration of EUT and cables is shown on a test setup picture at item 1.3

Final measurement
1. The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1) 2. The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN. 3. The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length). 4. The LISN measurement port was connected to a measurement receiver 5. The EUT and cable arrangement were based on the exploratory measurement results 6. The test data of the worst-case conditions were recorded and shown on the next pages

2.2.5 Limits

Class B		
Frequency [MHz]	Quasi-peak Limit [dBμV]	Average Limit [dBμV]
0.15 - 0.5	66 - 56 *	56 - 46 *
0.5 - 5	56	46
5 - 30	60	50
* Decreases with the logarithm of the frequency		

2.2.6 Results

AC power line conducted emissions					
Port	Coupling	Operational mode	EUT Configuration	Verdict	Remark
Power	AMN	3, 6	2	PASS	
Comment: worst case after visual evaluation on spectrum analyzer					

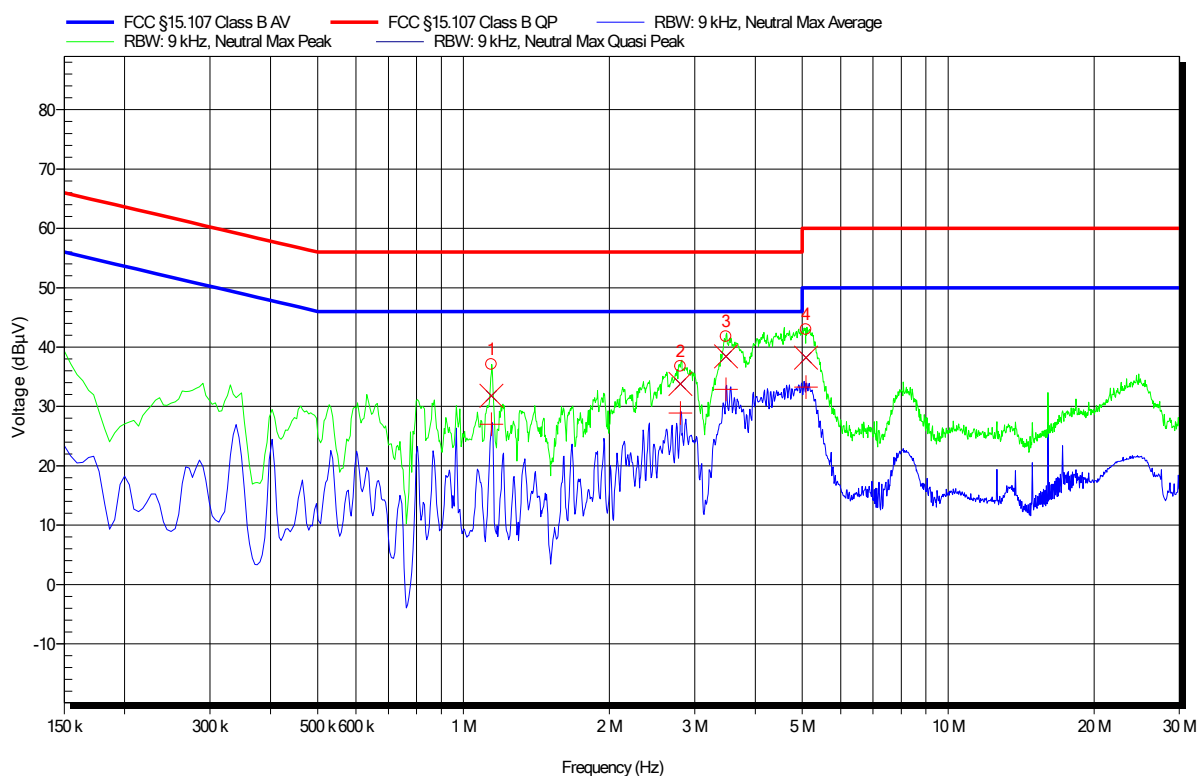
2.2.8 Records

EMI voltage test in the ac-mains according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 23°C, Unom: 120V AC (AC/DC adaptor)
 LISN: ESH3-Z5 (N)
 Mode: 3, 6
 Test Date: 2019-09-05
 Note:

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Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
1	1.143 MHz	31.77 dBµV	56 dBµV	-24.23 dB	Pass
2	2.805 MHz	33.77 dBµV	56 dBµV	-22.23 dB	Pass
3	3.48 MHz	38.42 dBµV	56 dBµV	-17.58 dB	Pass
4	5.091 MHz	38.24 dBµV	60 dBµV	-21.76 dB	Pass

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status
1	1.143 MHz	27 dBµV	46 dBµV	-19 dB	Pass
2	2.805 MHz	28.91 dBµV	46 dBµV	-17.09 dB	Pass
3	3.48 MHz	32.88 dBµV	46 dBµV	-13.12 dB	Pass
4	5.091 MHz	33.24 dBµV	50 dBµV	-16.76 dB	Pass

Test Report No.: G0M-1905-8256-EF0115B-V01

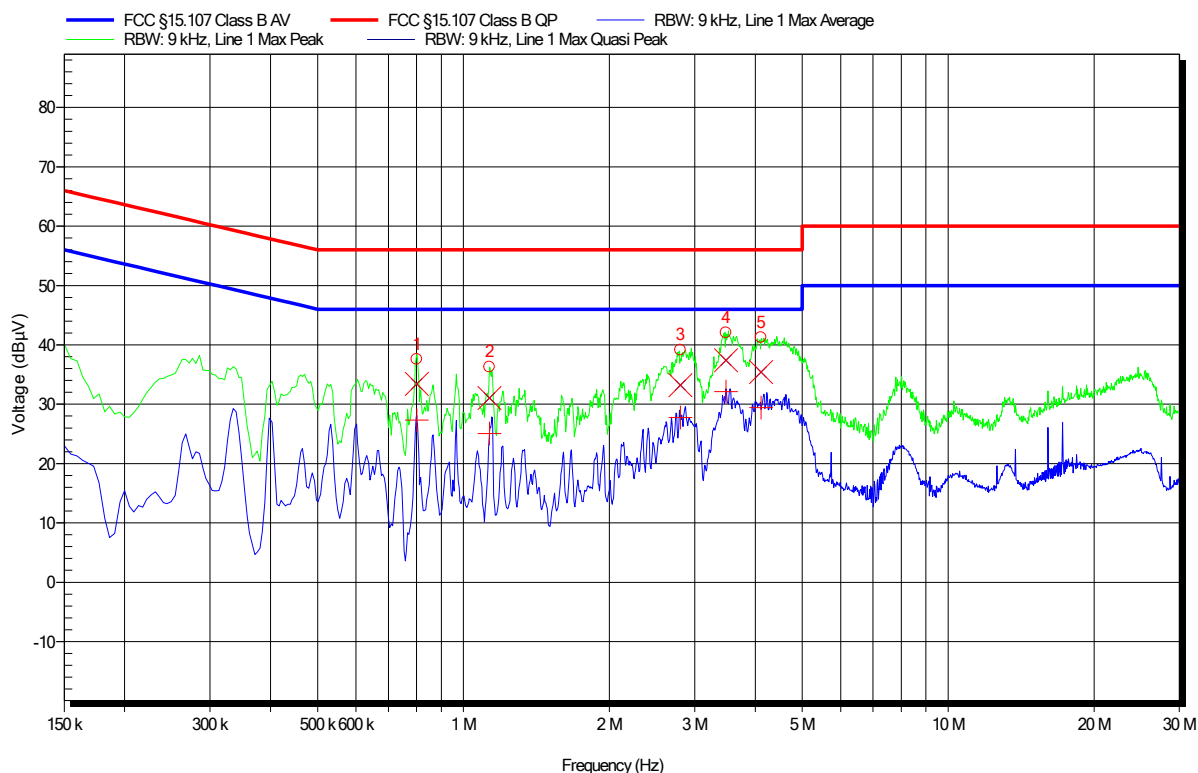
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

EMI voltage test in the ac-mains according to FCC Part 15b

Project number: G0M-1905-8256

Applicant: BIOTRONIK SE & Co. KG
 EUT Name: programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMS
 Model: Renamic Neo
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Handrik
 Test Conditions: Tnom: 23°C, Unom: 120V AC (AC/DC adaptor)
 LISN: ESH3-Z5 (L)
 Mode: 3, 6
 Test Date: 2019-09-05
 Note:

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Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
1	801.6 kHz	33.42 dBμV	56 dBμV	-22.58 dB	Pass
2	1.132 MHz	31.04 dBμV	56 dBμV	-24.96 dB	Pass
3	2.805 MHz	33.18 dBμV	56 dBμV	-22.82 dB	Pass
4	3.48 MHz	37.4 dBμV	56 dBμV	-18.6 dB	Pass
5	4.11 MHz	35.43 dBμV	56 dBμV	-20.57 dB	Pass

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status
1	801.6 kHz	27.34 dBμV	46 dBμV	-18.66 dB	Pass
2	1.132 MHz	25.03 dBμV	46 dBμV	-20.97 dB	Pass
3	2.805 MHz	27.77 dBμV	46 dBμV	-18.23 dB	Pass
4	3.48 MHz	32.14 dBμV	46 dBμV	-13.86 dB	Pass
5	4.11 MHz	29.45 dBμV	46 dBμV	-16.55 dB	Pass