

RADIO REPORT FCC 47 CFR Part 15C ISED Canada RSS-210 License exempt radio equipment	
Report Reference No	G0M-1905-8256-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 Test Firm Designation Number: DE0008 ISED Testing Laboratory site: 3470A-2
Applicant	BIOTRONIK SE & Co. KG
Address	Woermannkehre 1 12359 Berlin GERMANY
Test Specification	According to FCC/ISED rules
Standard	47 CFR Part 15C RSS-210, Issue 9, 2016-08
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)	RIO_PGFW_1_18_x
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	
not applicable to EUT	N/A	
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	2019-05-22	
Report:		
Compiled by	Wilfried Treffke	
Tested by (+ signature) (Responsible for Test)	Wilfried Treffke	
Approved by (+ signature) (Head of Lab)	Christian Weber	
Date of Issue	2019-12-17	
Total number of pages	32	
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:		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2019-12-17	Initial Release	

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
RBW	Resolution bandwidth
RMS	Root mean square
VBW	Video bandwidth
V _{NOM}	Nominal supply voltage

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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)	80001071	
Hardware Version(s)	A.x	
Software Version(s)	RIO_PGHEW_1_18_x	
PMN	Renamic Neo	
HVIN	Renamic Neo	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRI-RENAMICNEO	
IC	4708A-RENAMICNEO	
Equipment type	End Product	
Radio type	Transceiver	
Operating frequency range	64 kHz	
Radio technology	ULP-AMI	
Modulation	OOK	
Number of antenna ports	1	
Antenna type	Inductive loop coil transmitter	
Antenna	Type	Integrated
	Model	Programming Head
	Manufacturer	BIOTRONIK SE & Co KG
	Gain	Not specified
Supply Voltage	V _{NOM}	120 VAC
Operating Temperature	T _{NOM}	25 °C
AC/DC-Adaptor	Model	ATM090T-P190
	Vendor	Adapter Tech
	Input	100 VAC – 240 VAC
	Output	19 VDC
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	

1.4 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE 1	Companion device for coil telemetry	BIOTRONIK SE & Co KG	Implant	-
AE 2	Programing head	BIOTRONIK SE & Co KG	Renamic PGH	-
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment:				

1.5 Test mode duty cycle

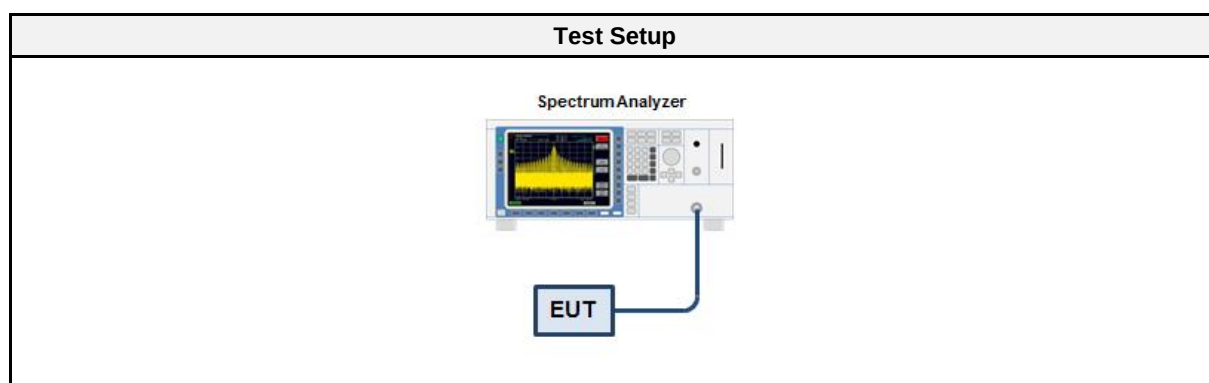
1.5.1 Information

Test Information	
Measurement Method	ANSI C63.10 11.6

1.5.2 Requirements

Requirements	
Duty cycle	Duty cycle correction
$\geq 98 \%$	No correction required
$< 98 \%$	Correction required ($10 \times \log_{10}(1/DC)$)

1.5.3 Setup



1.5.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 3	EF00241	2017-07	2019-07

1.5.5 Procedure

Test Procedure
1. EUT set to test mode 2. Span is set to zero span 3. Detector set to peak 4. Sweep time is set long enough to capture at least 5 bursts 5. Envelope peak value of emission spectrum is selected 6. The maximum burst duration T_{ON} is measured using two markers set to the start and the end of the longest burst 7. The minimum idle duration T_{OFF} is measured using two markers set to the start and the end of the shortest idle period 8. The duty cycle is calculated by $DC = T_{ON} / (T_{ON} + T_{OFF})$ 9. The duty cycle correction is calculated by $DC = 10 \times \log_{10}(T_{ON} / (T_{ON} + T_{OFF}))$

1.5.6 Results

Duty Cycle Results		
Mode	Duty Cycle	Correction Factor [dB]
Transmit	1 (100%)	0

1.6 Test Modes

Mode	Description
Transmit	Mode = Transmit Modulation = OOK Duty cycle = 100 %
Receive	Mode = Receive Modulation = OOK
Comment:	

1.7 Test Frequencies

Designator	Mode	Channel	Frequency [kHz]
F1	Tx/RX	F1	64

1.8 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:

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

Net:

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

Limit:

This is the FCC Class B radiated emission limit (in units of 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 = 47.5 dBμV/m	:	47.5 dBμV/m	- 57.0 dBμV/m	= -9.5 dB

2 Result Summary

FCC 47 CFR Part 15C, ISED RSS-247				
Product Standard Reference	Requirement	Reference Method	Result	Remarks
ISED RSS-Gen 6.6 Issue 5	Occupied Bandwidth	ANSI C63.10-2013	N/R	Informational only
FCC 15.35(c) ISED RSS-Gen 6.10 Issue 5	Duty Cycle	ANSI C63.10-2013	N/R	Information only
FCC 15.209 ISED RSS-210 4.3, 4.4 Issue 9	Fundamental field strength emissions	ANSI C63.10-2013	PASS	
ISED RSS-210 3.1 Issue 9 ISED RSS-Gen 7.1 Issue 5	Receiver radiated spurious emissions	ANSI C63.10-2013	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

3 Test Conditions and Results

3.1 Test Conditions and Results - Occupied bandwidth

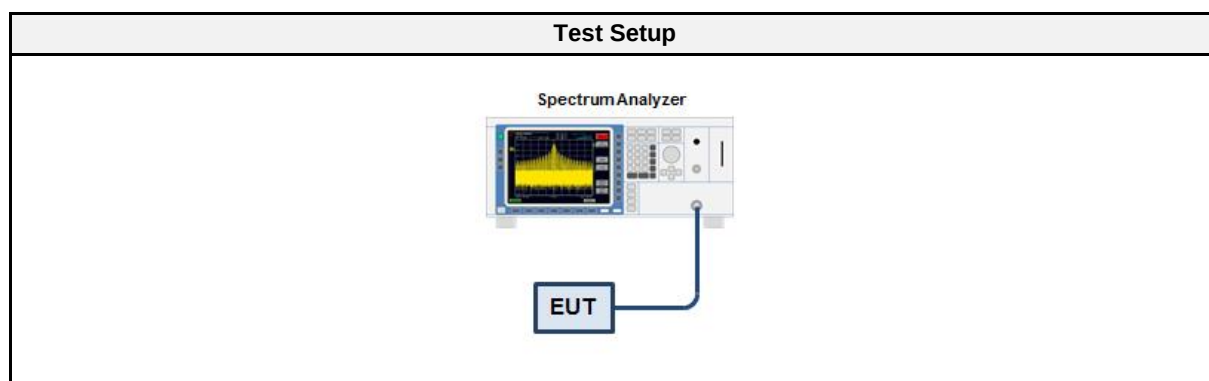
3.1.1 Information

Test Information	
Reference	ISED RSS-Gen 6.6
Measurement Method	ANSI C63.10 6.9.3
Operator	Wilfried Treffke
Date	2019-07-09

3.1.2 Limits

Limits
None (Informational only)

3.1.3 Setup



3.1.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 3	EF00241	2017-07	2019-07

3.1.5 Procedure

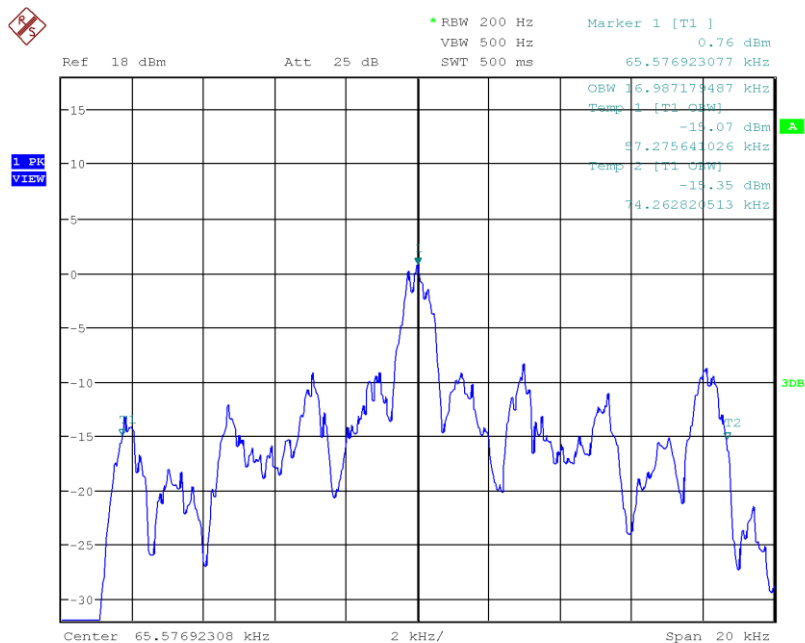
Test Procedure
1. EUT transmitter is activated in test mode under normal conditions 2. The spectrum analyzer is set to peak detection and maximum hold with a span twice the emission spectrum 3. Resolution bandwidth set to 1% to 5% of Occupied Bandwidth 4. The occupied bandwidth (99%) is measured with the build-in analyzer function

3.1.6 Results

Test Results		
Mode	Channel [kHz]	Bandwidth [kHz]
Transmit	64	17.0

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1905-8256
 Applicant: Biotronik SE & Co.KG
 Model Description: Renamic Neo Programming
 Model: Renamic Neo
 Test Sample ID: 24166
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2019-07-09
 Operating Conditions: Tnom/Vnom
 Mode: Tx 64 kHz
 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: 9.JUL.2019 04:38:57

3.2 Test Conditions and Results - Fundamental field strength emissions

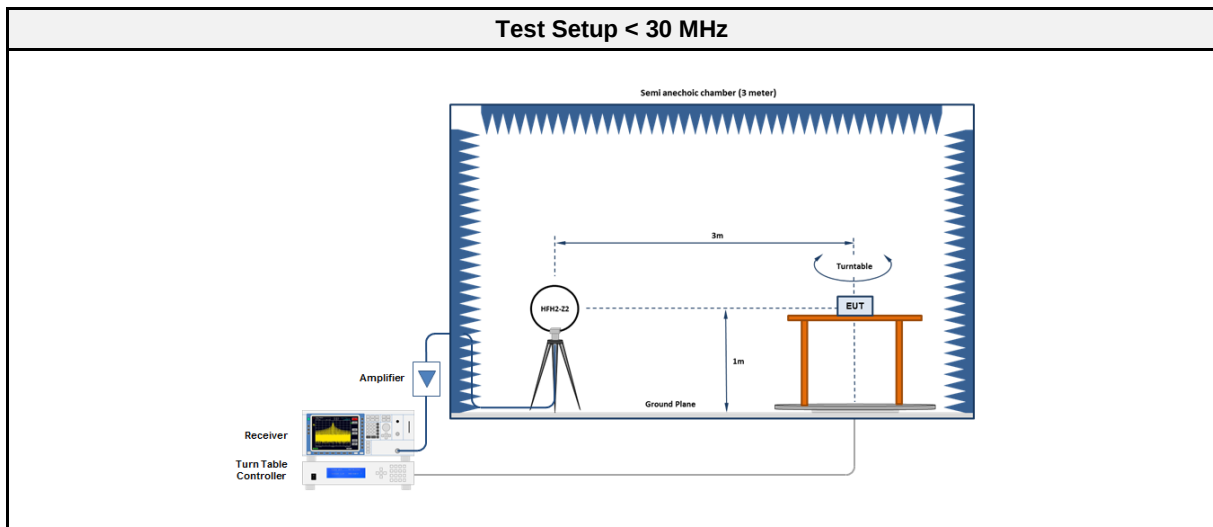
3.2.1 Information

Test Information	
Reference	FCC 15.209 / ISSED RSS-210 4.3, 4.4
Measurement Method	ANSI C63.10
Operator	Select operator from list
Date	2019-07-09

3.2.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V/m}$]	Limit [$\text{dB}\mu\text{V/m}$]	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

3.2.3 Setup



3.2.4 Equipment

Test Equipment >30 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	-	-
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2018-08	2019-08
Loop Antenna	R&S	HFH2-Z2	EF00184	2017-12	2019-12

3.2.5 Procedure

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

3.2.6 Results

Test Results						
Channel [kHz]	Emission [kHz]	Level [dBμV/m]	Detector Pol.	Limit [dBμV/m]	Limit distance [m]*	Margin [dB]
64	65.5	-65.9	AV	31.3	3	-97.19
Comments: * Physical distance between EUT and measurement antenna						

3.3 Test Conditions and Results - Receiver radiated emissions

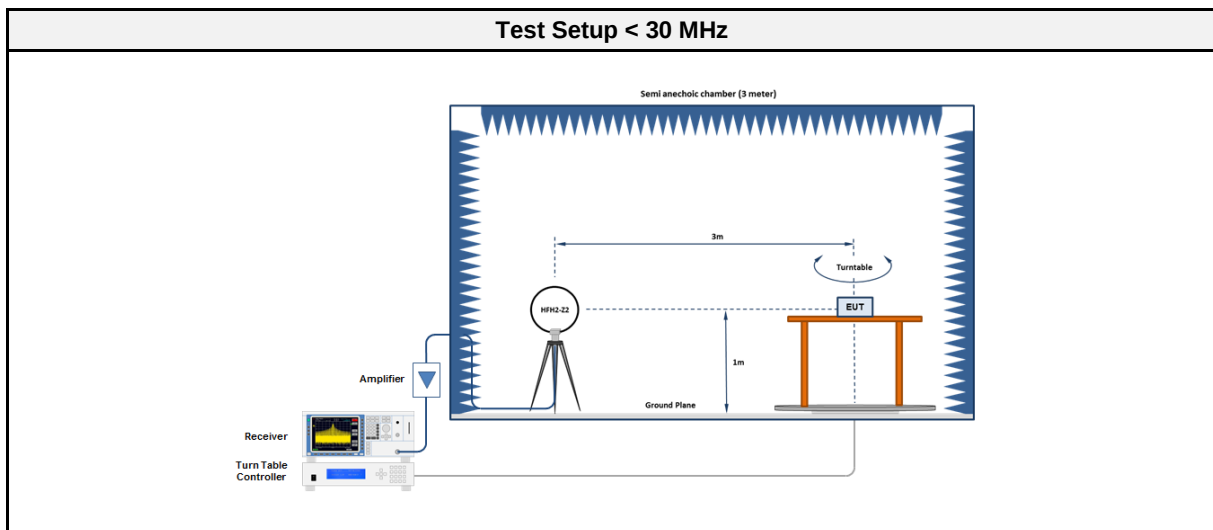
3.3.1 Information

Test Information	
Reference	ISED RSS-210 3.1
Measurement Method	ANSI C63.10
Operator	Wilfried Treffke
Date	2019-07-09

3.3.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V/m}$]	Limit [$\text{dB}\mu\text{V/m}$]	Limit Distance [m]
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

3.3.3 Setup



3.3.4 Equipment

Test Equipment >30 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	-	-
Measurement Receiver	Agilent	N9038A-526/WXP	EF01070	2018-08	2019-08
Loop Antenna	R&S	HFH2-Z2	EF00184	2017-12	2019-12

3.3.5 Procedure

Test Procedure
1. EUT set to receive mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peakdetector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to peak emission levels

3.3.6 Results

Test Results					
Channel [kHz]	Emission [MHz]	Level [dBμV/m]	Det. Pol.	Limit [dBμV/m]	Margin [dB]
64	65.5	-62	AV	31.2	-93.20