
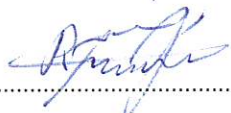


RADIO REPORT FCC 47 CFR Part 15C ISED RSS-310 License exempt radio equipment	
Report Reference No	G0M-2210-1712-TFC209LP-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	 <p>DAkkS - Registration number : D-PL-12092-01-03 (ISED) ISED Testing Laboratory site: 3470A DAkkS - Registration number : D-PL-12092-01-04 (FCC) FCC Filed Test Laboratory, Reg.-No.: 96970</p>
Applicant	BIOTRONIK SE & Co. KG
Address	Woermannkehre 1 12359 Berlin DE
Test Specification	47 CFR Part 15C RSS-310, Issue 5, 2020-01 RSS-Gen, Issue 5, Amendment 2, 2021-02
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	Implantable Cardiac Monitor
Model(s)	BIOMONITOR IV
Additional Model(s)	None
Brand Name(s)	BIOTRONIK
Hardware Version(s)	BOM-0578_01_474897 (2610-30), SCH-0295_0B, ASM-0929_0C
Software Version(s)	ROM: 7748ROMRev_1.03 / RAM: 7341RamRev_3.01
FCC ID	QRI-BM2610P2
IC	4708A-BM2610P2
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 °C - 30 °C	
Test Lab Humidity	25 % - 55 %	
Date of receipt of test item	2022-12-14	
Report:		
Compiled by	Wilfried Treffke	
Tested by (+ signature) (Responsible for Test)	Wilfried Treffke	
Approved by (+ signature) (Test Lab Engineer)	Radwan Jaafar	
Date of Issue	2023-02-16	
Total number of pages	25	
General Remarks:		
<p>The test results presented in this report relate only to the object tested.</p> <p>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.</p> <p>This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.</p>		
Additional Comments:		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2023-02-16	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	Implantable Cardiac Monitor	
Model	BIOMONITOR IV	
Additional Model(s)	None	
Brand Name(s)	BIOTRONIK	
Serial Number(s)	95043357(radiated test sample)	
Test Sample Id(s)	42363 (radiated test sample)	
Hardware Version(s)	BOM-0578_01_474897 (2610-30), SCH-0295_0B, ASM-0929_0C	
Software Version(s)	ROM: 7748ROMRev_1.03 / RAM: 7341RamRev_3.01	
PMN	BIOMONITOR IV	
HVIN	471155	
FVIN	N/A	
HMN	N/A	
FCC ID	QRI-BM2610P2	
IC	4708A-BM2610P2	
Equipment type	End Product	
Radio type	Transceiver	
Assigned frequency bands	9 - 315 kHz	
Operating frequency range	9 - 90 kHz	
Radio technology	custom	
Modulation	OOK	
Number of antenna ports	1	
Antenna	Type	Internal
	Model	loop coil antenna
	Manufacturer	BIOTRONIK SE & Co. KG
	Gain	unspecified
Supply Voltage	V_{NOM}	2.7 VDC
Operating Temperature	T_{NOM}	25 °C
AC/DC-Adaptor	Model	None
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin DE	

1.5 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE1	USB Telbox	Biotronik	Telbox II (087)	to set the test mode
AE2	Programming Wand	Biotronik	Renamic PGH	to set the test mode
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment:				

1.6 Test mode duty cycle

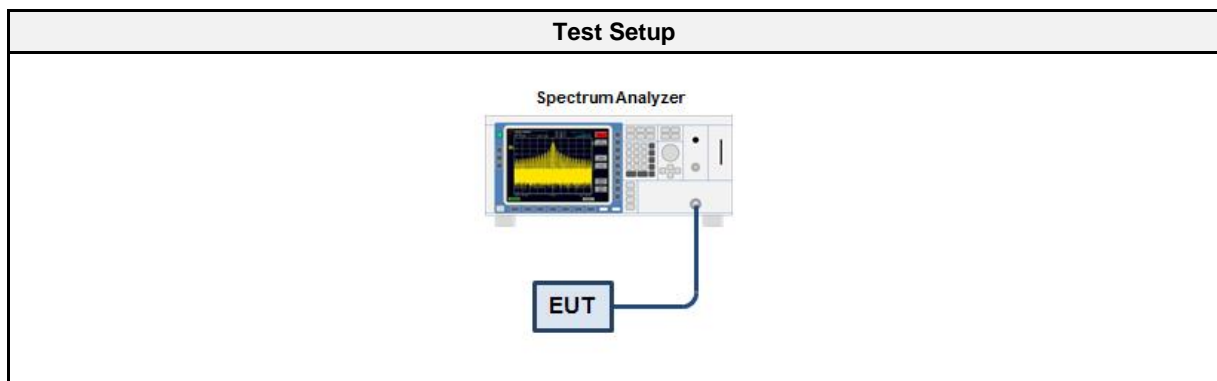
1.6.1 Information

Test Information	
Measurement Method	ANSI C63.10 11.6

1.6.2 Requirements

Requirements	
Duty cycle	Duty cycle correction
≥ 98 %	No correction required
< 98 %	Correction required ($10 \times \text{Log}_{10}(1/\text{DC})$)

1.6.3 Setup



1.6.4 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08

1.6.5 Procedure

Test Procedure
<ol style="list-style-type: none"> 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 $\text{DC} = T_{ON} / (T_{ON} + T_{OFF})$ 9. The duty cycle correction is calculated by $\text{DC} = 10 \times \text{Log}_{10}(T_{ON} / (T_{ON} + T_{OFF}))$

1.6.6 Results

Duty Cycle Results		
Mode	Duty Cycle	Correction Factor [dB]
Transmit	50 % (test mode)	3

1.7 Test Modes

Mode	Description
Transmit	Mode = Transmit Modulation = OOK Duty cycle = 50 % (test mode)
Receive	Mode = Receive Modulation = OOK
Comment:	

1.8 Test Frequencies

Designator	Mode	Channel	Frequency [kHz]
F1	Tx / Rx	1	64

1.9 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-210				
Product Standard Reference	Requirement	Reference Method	Result	Remarks
ISED RSS-Gen 6.7 Issue 5 A2	Occupied Bandwidth	ANSI C63.10-2013	N/R	Information only
FCC 15.35(c) ISED RSS-Gen 6.10 Issue 5 A2	Duty Cycle	ANSI C63.10-2013	N/R	Information only
FCC 15.201(a) FCC 15.209 ISED RSS-310 10.6	Field strength emissions	ANSI C63.10-2013	PASS	
ISED RSS-310 10.6 ISED RSS-Gen 7.1 Issue 5 A2	Receiver radiated spurious emissions	ANSI C63.10-2013	PASS	
Comment: The Decision Rule is applied on the basis of ETSI TR 102 273 and ETSI TR 100 028. These standards provide guidance on how to calculate and apply measurement uncertainty whilst providing maximum uncertainties allowance. In all cases due consideration will be given to ILAC-G8:09/2019. Where a result is considered conditional in respect of its proximity to the limit line, the customer would be made aware of situation so that they can make an informed decision on how to proceed.				

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

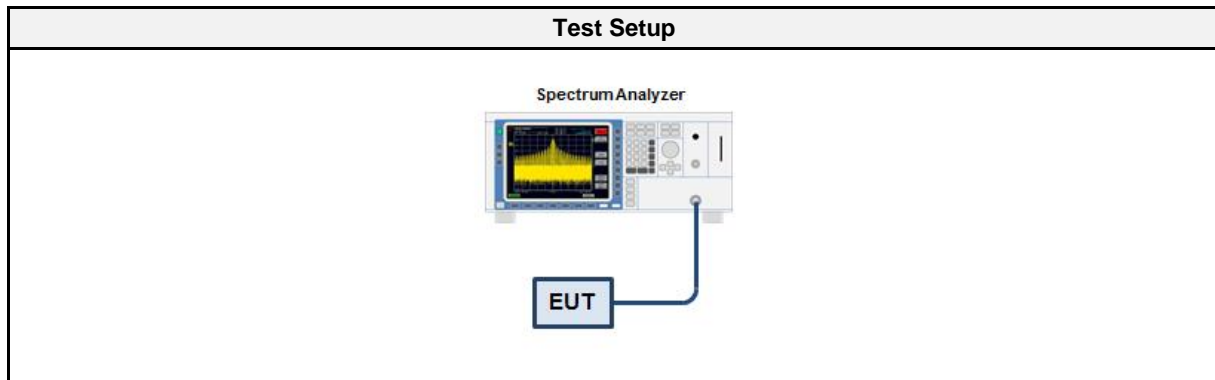
3.1.1 Information

Test Information	
Reference	ISED RSS-Gen 6.7
Measurement Method	ANSI C63.10 6.9.3
Measurement Uncertainty	$\pm 1.26 \%$
Operator	Wilfried Treffke
Date	2022-12-14

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 26	EF01003	2022-07	2023-07
Cable	Gigalane	SMS111B	EF00779 CAAZ	2022-02	2023-02

3.1.5 Procedure

Test Procedure
<ol style="list-style-type: none"> 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

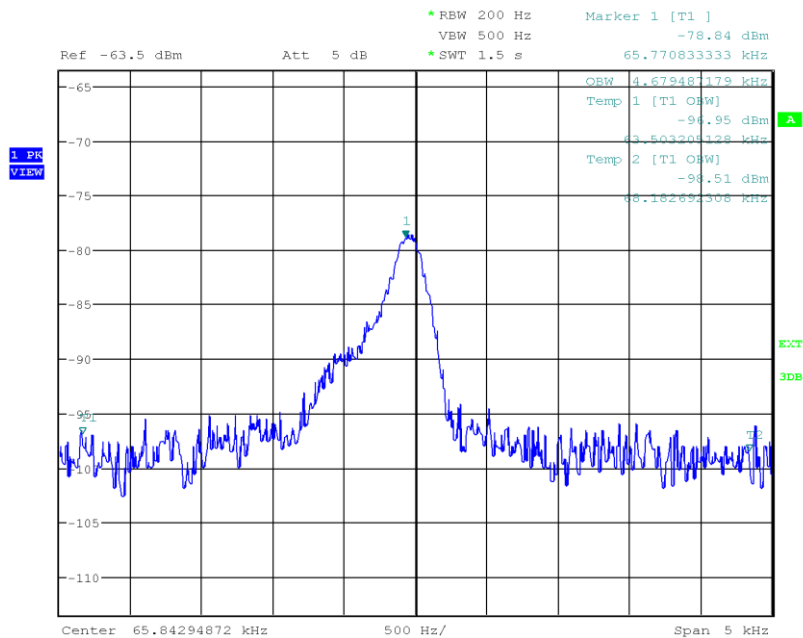
3.1.6 Results

Test Results		
Mode	Channel [kHz]	Bandwidth [kHz]
Transmit	64	4.68

Occupied Bandwidth - F_{MID}

Occupied Bandwidth

Project Number: G0M-2210-1712
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: BM4 / Implantable Cardiac Monitors
 Model: BIOMONITOR IV
 Test Sample ID: 42363
 Operator: W. Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-12-14
 Operating Conditions: Tnom/Vnom
 Mode: 64 kHz
 Note 1: Tnom / Vnom
 Note 2: Eurofins Product Service GmbH



3.2 Test Conditions and Results - Fundamental field strength emissions

3.2.1 Information

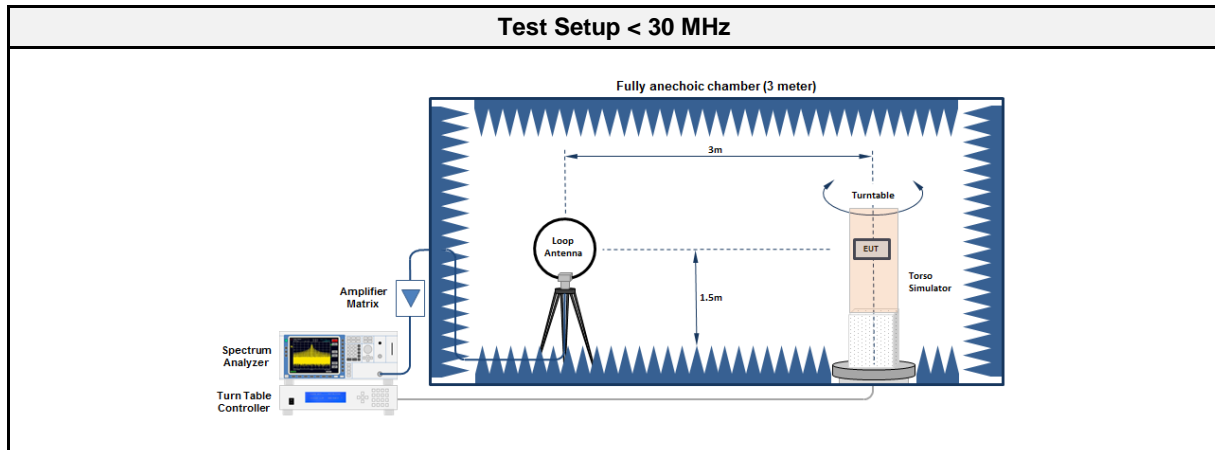
Test Information	
Reference	FCC 15.201(a) + 15.209 / ISED RSS-310 10.6
Measurement Method	ANSI C63.10
Measurement Uncertainty	± 5.95 dB
Operator	Wilfried Treffke
Date	2022-12-14

3.2.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V}/\text{m}$]	Limit [$\text{dB}\mu\text{V}/\text{m}$]	Limit Distance [m]
0.009 - 0.090	Average	2400/F	48.5 - 28.5	300
0.090 - 0.110	Quasi-Peak	2400/F	28.5 - 26.8	300
0.110 - 0.490	Average	2400/F	26.8 - 13.8	300
0.490 - 1.705	Quasi-Peak	24000/F	33.8 - 23.0	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

Note: F [kHz]

3.2.3 Setup



3.2.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC2	EF00196	-	-
Loop Antenna	R&S	HFH2-Z2	EF00184	2021-01	2024-01
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08

3.2.5 Procedure

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

3.2.6 Results

Test Results							
Channel [kHz]	Emission [kHz]	Level [dB μ V/m]	Detector	Pol.	Limit [dB μ V/m]	Limit distance [m]*	Margin [dB]
64	66.06	-40.3	PK	ver	31.2	3	-71.5
Comment	*Physical distance =3 m, converted to 300 m						

3.3 Test Conditions and Results - Receiver radiated emissions

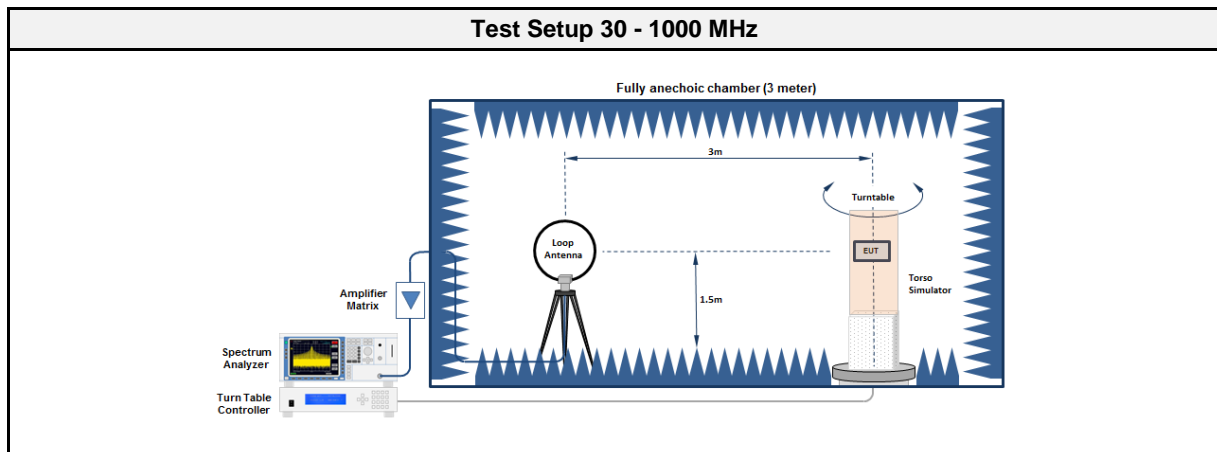
3.3.1 Information

Test Information	
Reference	ISED RSS-310 10.6
Measurement Method	ANSI C63.10
Measurement Uncertainty	± 5.95 dB
Operator	Wilfried Treffke
Date	2022-12-14

3.3.2 Limits

Limits				
Frequency range [MHz]	Detector	Limit [$\mu\text{V}/\text{m}$]	Limit [$\text{dB}\mu\text{V}/\text{m}$]	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 Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC2	EF00196	-	-
Loop Antenna	R&S	HFH2-Z2	EF00184	2021-01	2024-01
Spectrum Analyzer	R&S	FSW 43	EF00896	2022-08	2023-08

3.3.5 Procedure

Test Procedure	
<ol style="list-style-type: none"> 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 [dB μ V/m]	Det.	Pol.	Limit [dB μ V/m]	Margin [dB]
64	66.06	-40.3	PK	ver	31.2	71.5

=== END OF TEST REPORT ===