





FCC TEST REPORT FCC 47 CFR Part 15C ISED RSS-310 License exempt radio equipment	
Report Reference No.	G0M-2111-1166-TFC209LP-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's name	BIOTRONIK SE & Co. KG
Address	Woermannkehre 1 12359 Berlin GERMANY
Test specification:	
Standard	47 CFR Part 15C RSS-310, Issue 4, 2015-07
Test scope	complete Radio compliance test
Equipment under test (EUT):	
Product description	Implantable Pulse Generator
Model No.	Amvia Stellar DR-T
Additional Model(s)	additional model see family list
Brand Name(s)	BIOTRONIK
Hardware version	0A
Firmware / Software version	ROM: 1.0 / RAM: 1.0
	FCC-ID: QRI-IPG2267P2 IC: 4708A-IPG2267P2
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 : 2022-01-10

Date (s) of performance of tests : 2022-01-10 - 2022-01-13

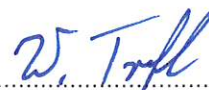

Compiled by : Wilfried Treffke

Tested by (+ signature) : Wilfried Treffke
(Responsible for Test)

Approved by (+ signature) : Toralf Jahn
(Deputy Head of Lab)

Date of issue : 2022-03-01

Total number of pages : 29



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:

Test Report No.: G0M-2111-1166-TFC209LP-V01

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

ADDITIONAL VARIANTS (not tested and not evaluated variants)



BIOTRONIK SE & Co. KG · Postfach 470255 · 12311 Berlin

Tel +49 (0) 30 68905-1291
Fax +49 (0) 30 68905-961291
dirk.koenig@biotronic.com
www.biotronic.com

Berlin, 17 January 2022

IPG-2267P2 Family Explanation

1. Family Letter

#	Product Name / PMN	no. of chambers	Connector RA/RV	Connector LV	HVIN Order number
1	Amvia Sky SR-T	1	IS-1	-	460161
2	Amvia Edge SR-T	1	IS-1	-	460164
3	Solvix Rise SR-T	1	IS-1	-	460228
4	Amvia Sky DR-T	2	IS-1	-	460160
5	Amvia Edge DR-T	2	IS-1	-	460163
6	Solvix Rise DR-T	2	IS-1	-	460227
7	Amvia Stellar DR-T	2	IS-1	-	460167 (Master)
8	Amvia Sky HF-T	3	IS-1	IS-1	460159
9	Amvia Stellar HF-T	3	IS-1	IS-1	460166
10	Amvia Sky HF-T QP	3	IS-1	IS4 LLLL	460158
11	Amvia Edge HF-T QP	3	IS-1	IS4 LLLL	460162
12	Amvia Stellar HF-T QP	3	IS-1	IS4 LLLL	460165

no HVIN and FVIN for all products

2. Family description

Header difference overview

Variant	Family member's
1	SR-T
2	DR-T
3	HF-T
4	HF-T QP

table 1: PC Board and RF Antenna

BIOTRONIK SE & Co. KG
Wormannstraße 1
12359 Berlin
Steuer-Nr.: 30/005/75408
USt-Ident.Nr.: DE136651322

Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6844060
info@biotronic.com
www.biotronic.com

Geschäftsführende Direktoren:
Dr. Daniel Böhrer
Dr. Thomas Kraft
Stephan Schulz-Gohritz

Kommanditgesellschaft:
HRA 6501 B, AG Berlin-Charlottenburg
Komplementärin: BIOTRONIK MT SE
HRB 118866 B, AG Berlin-Charlottenburg

Test Report No.: G0M-2111-1166-TFC209LP-V01

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

Version History

Version	Issue Date	Remarks	Revised by
01	2022-03-01	Initial Release	

REPORT INDEX

1	EQUIPMENT (TEST ITEM) DESCRIPTION	8
1.1	Photos – Equipment External	9
1.2	Photos – Equipment Internal	15
1.3	Photos – Test Setup	17
1.4	Photos – Auxiliary/Associated Equipment	18
1.2	Supporting Equipment Used During Testing	19
1.3	Test Modes	20
1.4	Test Equipment Used During Testing	21
1.5	Sample emission level calculation	22
2	RESULT SUMMARY	23
3	TEST CONDITIONS AND RESULTS	24
3.1	Test Conditions and Results – Occupied Bandwidth	24
3.2	Test Conditions and Results – Fundamental field strength emissions	26
3.3	Test Conditions and Results – Receiver radiated emissions	28

1 Equipment (Test item) Description

Description	Implantable Pulse Generator	
Model	Amvia Stellar DR-T	
Additional Model(s)	additional model see family list	
Brand Name(s)	BIOTRONIK	
Serial number	1000000408 0423321243	Radiated Test Sample ID 38057 Conducted Test Sample ID 38093
Hardware version	0A	
Software / Firmware version	ROM: 1.0 / RAM: 1.0	
PMN	Amvia Stellar DR-T	
HVIN	460167	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRI-IPG2267P2	
IC	4708A-IPG2267P2	
Equipment type	End product	
Radio type	Transceiver	
Radio technology	custom	
Operating frequency	64 kHz	
Modulations	OOK	
Number of channels	1	
Channel spacing	None	
Number of antennas	1	
Antenna	Type	integrated
	Model	Coil 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}	2.5 VDC
	V _{MIN}	3.2 VDC
Operating Temperature	T _{NOM}	37 °C
	T _{MIN}	25 °C
	T _{MAX}	45 °C
AC/DC-Adaptor	Model	None

1.2 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model	Comments
AE1	Communication Adapter	Biotronik	TelBox II	-
AE2	Programming Head	Biotronik	PGH 3000	-
<p>*Note: Use the following abbreviations:</p> <p>AE : Auxiliary/Associated Equipment, or</p> <p>SIM : Simulator (Not Subjected to Test)</p> <p>CABL : Connecting cables</p>				

1.3 Test Modes

Mode #	Description	
Transmit	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

1.4 Test Equipment Used During Testing

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2020.1.8

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSU 3	EF00241	2021-07	2023-07
Climatic chamber	Vötsch	VT 4010	EF00134	2021-06	2022-06

Field strength emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF00196	-	-
Loop Antenna	R&S	HFH2-Z2	EF00184	2021-01	2024-01
Spectrum Analyzer	R&S	FSU 43	EF01631	2021-07	2022-07

1.5 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:

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

2 Result Summary

FCC 47 CFR Part 15C, IC RSS-310				
Product Specific Standard Section	Requirement – Test	Reference Method	Result	Remarks
RSS-Gen 6.6	Occupied Bandwidth	RSS-Gen 6.6	N/R	Informational only
FCC 15.201(a), FCC 15.209 ISED RSS-310 3.7	Field strength emissions	ANSI C63.10	PASS	
ISED RSS-310 2.6 ISED RSS-Gen 7.1	Receiver radiated spurious emissions	ANSI C63.10	PASS	
Remarks:				

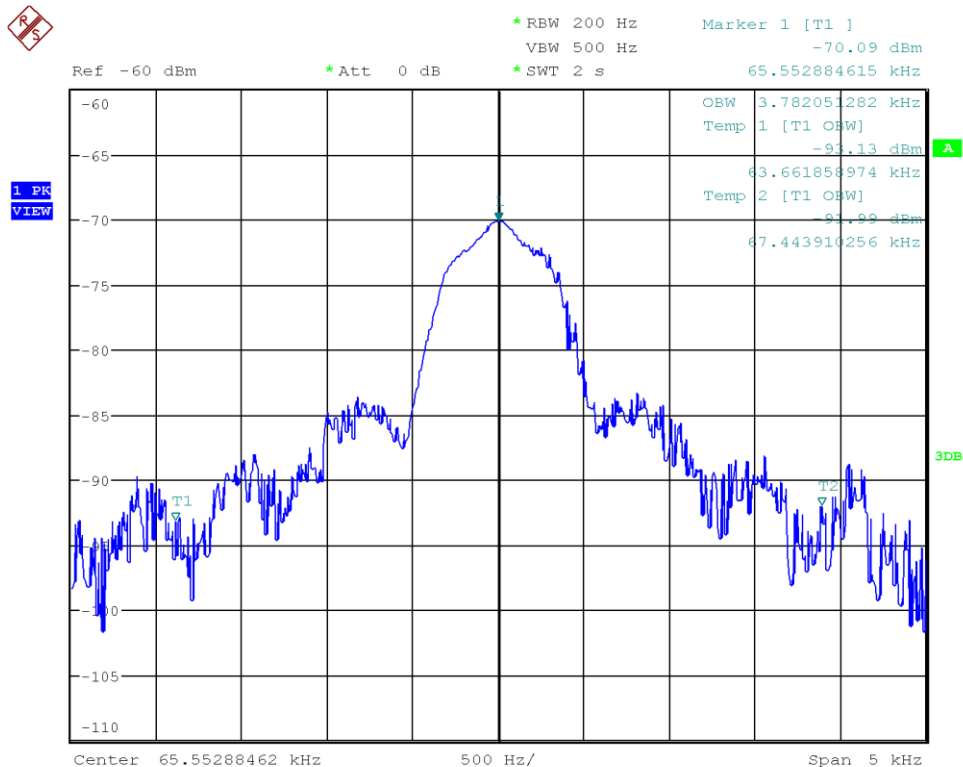
3 Test Conditions and Results

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	Transmit		
Limits			
None (Informational only)			
Test setup			
<div><div>Spectrum Analyzer</div><div>EUT</div></div>			
Test procedure			
<div>1. EUT set to test mode (Communication tester is used if needed)</div> <div>2. Span set to at least twice the emission spectrum</div> <div>3. Resolution bandwidth set to 1% to 5% of Occupied Bandwidth</div> <div>4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function</div>			
Test results			
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]	
F _{MID}	64	3.78	
Comments: Measurement is applicable to all variants			

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-2111-1166
 Applicant: BIOTRONIK SE & Co. KG
 Model Description: Implantable Pulse Generator
 Model: Amvia Stellar DR-T
 Test Sample ID: 38093
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2022-01-13
 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



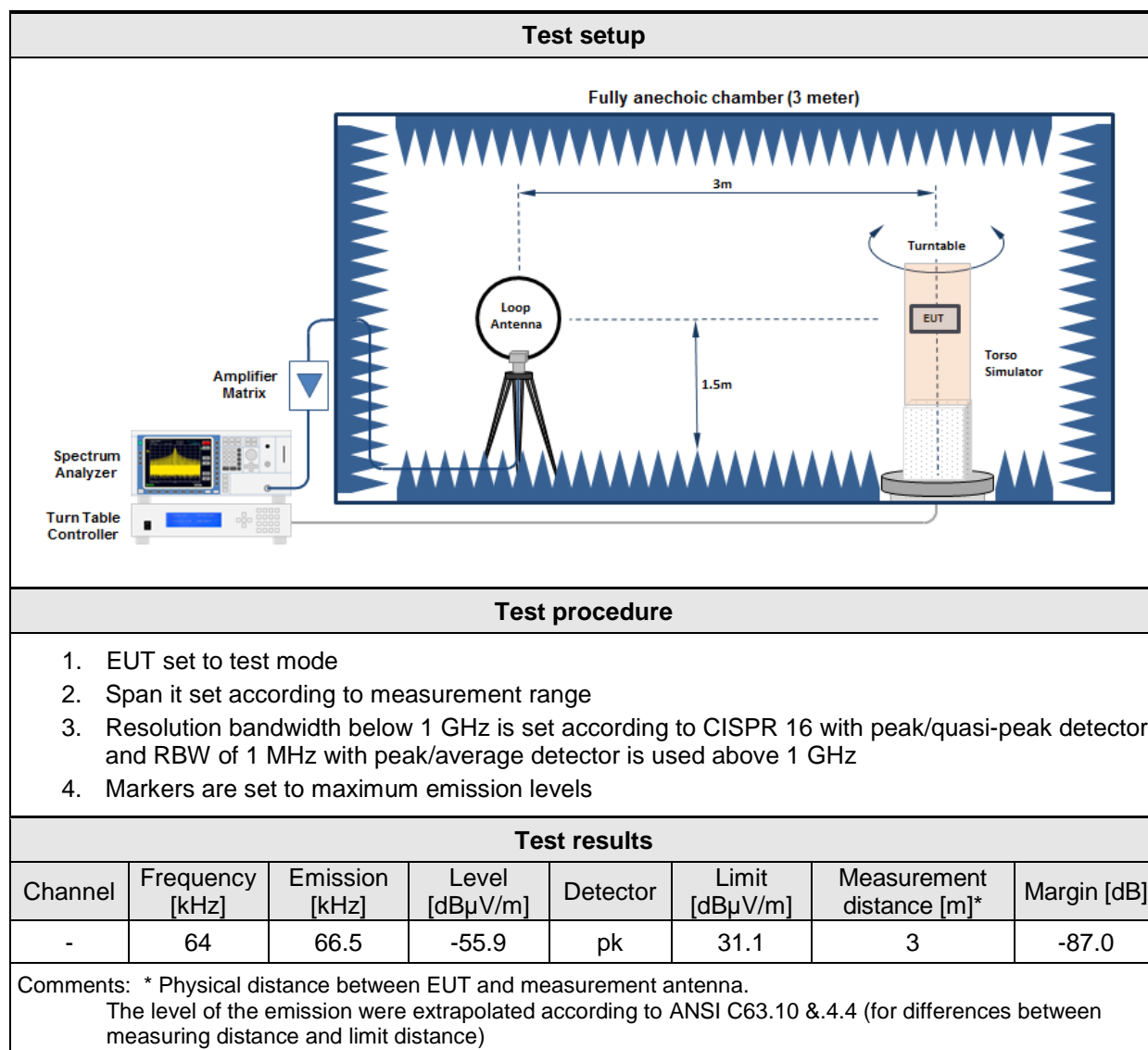
Date: 13.JAN.2022 09:21:48

Test Report No.: G0M-2111-1166-TFC209LP-V01

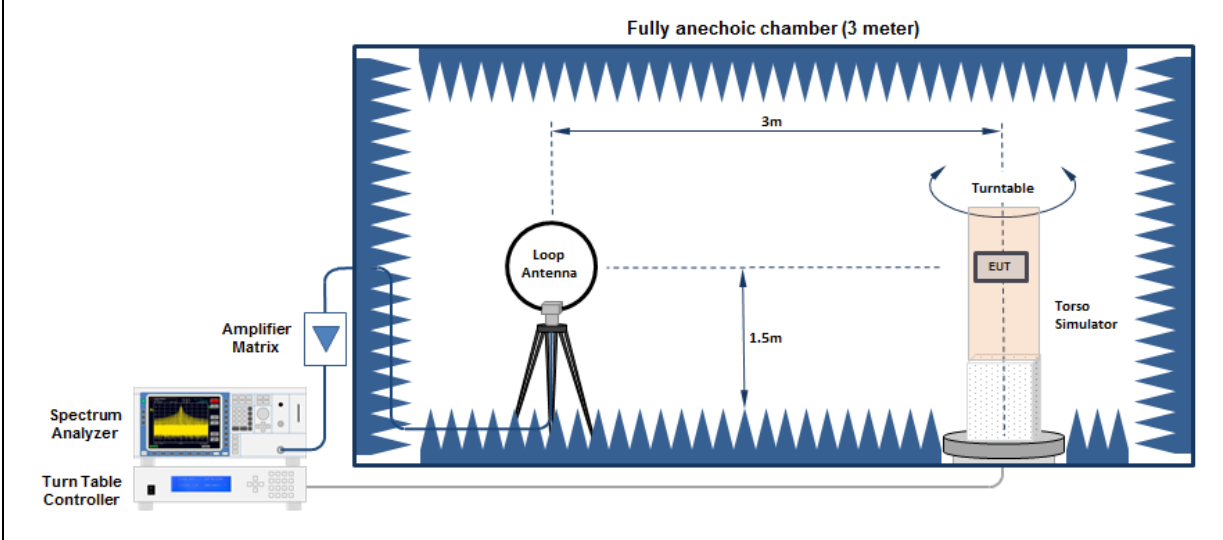
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

3.2 Test Conditions and Results – Fundamental field strength emissions

Field strength emissions acc. to FCC 47 CFR 15.201+15.209 / ISED RSS-310				Verdict: PASS
Test according referenced standards		Reference Method		
		FCC 15.201(a) + 15.209 / ISED RSS-310 3.7		
Test according to measurement reference		Reference Method		
		ANSI C63.10		
Test frequency range		Tested frequencies		
		9 kHz – 10 th 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.				



3.3 Test Conditions and Results – Receiver radiated emissions

Receiver radiated emissions acc. to ISED RSS-310				Verdict: PASS
Test according referenced standards	Reference Method			
	ISED RSS-310 3.7			
Test according to measurement reference	Reference Method			
	ANSI C63.10			
Test frequency range	Tested frequencies			
	30 MHz – 5 th 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
Test setup				
				

Test procedure							
<ol style="list-style-type: none"> 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]	Level [dB μ V/m]	Detector	Limit [dB μ V/m]	Measurement distance [m]*	Margin [dB]
-	64	66.5	-55.3	pk	31.1	3	-86.4
Comments: * Physical distance between EUT and measurement antenna. The level of the emission were extrapolated according to ANSI C63.10 & 4.4 (for differences between measuring distance and limit distance)							

=== END OF TEST REPORT ===

Test Report No.: G0M-2111-1166-TFC209LP-V01

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