eurofins | Product Service

FCC TEST REPORT

FCC 47 CFR Part 15C
Industry Canada RSS-310

License exempt radio equipment

Report Reference No. ..... :	G0D-1611-6014-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 4, 2015-07
Test scope…….. ..... :	complete Radio compliance test
Equipment under test (EUT):	
Product description	ICD / Implantable Cardioverter Defibrillator TachNT2
Model No.	Intica 7 HF-T QP
Additional Model(s)	Additional Models according to Family Letter
Brand Name(s)	BIOTRONIK
Hardware version	Rev.: 0A
Firmware / Software version	ROM: 5.0 / RAM: 4.1.0
	FCC-ID: QRITACHNT2 IC: N/A
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 ..... :	2016-11-21	
Date (s) of performance of tests ..... :	2016-11-23	
Compiled by ..... :	Wilfried Treffke	
Tested by (+ signature) ..... : (Responsible for Test)	Wilfried Treffke	W. Treffke .....
Approved by (+ signature) ..... : (Head of Lab)	Christian Weber	C. Weber .....
Date of issue ..... :	2017-01-17	
Total number of pages ..... :	28	

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.

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Additional comments:	Additional comments:
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 RF-Telemetry. HF-T are triple-chamber devices. DR-T are dual-chamber devices. VR-T are single chamber devices without additional atrial detection. All variants are available with DF-1 and DF-4. All of these differences are only relevant in terms of medical aspects. They do not interfere the RF Performance. Antenna pattern measurements were performed for worst case antenna selection and the Intica 7 HF-T QP Ser. 60509208 (HVIN 404630) was selected. Besides the model Intica 7 HF-T QP Ser. 60509208 (HVIN 404630), as the most complex model, was selected for the measurements.	

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TachNT2 Family Explanation (G0D-1611-6014)

1. Family Letter

	Product Name	Type	no. of chambers	Connector	Battery	HVIN
1	Ilivia 7 HF-T	CRT	3	DF-1	GB	404601
2	Ilivia 7 HF-T	CRT	3	DF-1	LiS	406035
3	Ilivia 7 HF-T	CRT	3	DF-4	GB	404602
4	Ilivia 7 HF-T	CRT	3	DF-4	LiS	406036
5	Ilivia 7 HF-T QP	CRT	3	DF-1 + IS-4	GB	404620
6	Ilivia 7 HF-T QP	CRT	3	DF-4 + IS-4	GB	404621
7	Ilivia 7 HF-T QP	CRT	3	DF-4 + IS-4	LiS	406038
8	Ilivia 7 DR-T	DR	2	DF-1	GB / LiS	404622
9	Ilivia 7 DR-T	DR	2	DF-4	GB / LiS	404623
10	Ilivia 7 VR-T DX	DX*	1	DF-1	GB / LiS	404624
11	Ilivia 7 VR-T	VR	1	DF-1	GB / LiS	404625
12	Ilivia 7 VR-T	VR	1	DF-4	GB / LiS	404626
13	Intica 7 HF-T	CRT	3	DF-1	GB	404627
14	Intica 7 HF-T	CRT	3	DF-1	LiS	406039
15	Intica 7 HF-T	CRT	3	DF-4	GB	404628
16	Intica 7 HF-T	CRT	3	DF-4	LiS	406040
17	Intica 7 HF-T QP	CRT	3	DF-1 + IS-4	GB	404629
18	Intica 7 HF-T QP	CRT	3	DF-4 + IS-4	GB	404630
19	Intica 7 HF-T QP	CRT	3	DF-4 + IS-4	LiS	406042
20	Intica 7 DR-T	DR	2	DF-1	GB / LiS	404631
21	Intica 7 DR-T	DR	2	DF-4	GB / LiS	404632
22	Intica 7 VR-T DX	DX*	1	DF-1	GB / LiS	404633
23	Intica 7 VR-T	VR	1	DF-1	GB / LiS	404634
24	Intica 7 VR-T	VR	1	DF-4	GB / LiS	404635
25	Inlexa 7 HF-T	CRT	3	DF-1	GB	404636
26	Inlexa 7 HF-T	CRT	3	DF-1	LiS	406043
27	Inlexa 7 HF-T	CRT	3	DF-4	GB	404637
28	Inlexa 7 HF-T	CRT	3	DF-4	LiS	406044
29	Inlexa 7 HF-T QP	CRT	3	DF-1 + IS-4	GB	404638
30	Inlexa 7 HF-T QP	CRT	3	DF-4 + IS-4	GB	404639
31	Inlexa 7 HF-T QP	CRT	3	DF-4 + IS-4	LiS	406046
32	Inlexa 7 DR-T	DR	2	DF-1	GB / LiS	404640
33	Inlexa 7 DR-T	DR	2	DF-4	GB / LiS	404641
34	Inlexa 7 VR-T DX	DX*	1	DF-1	GB / LiS	404642
35	Inlexa 7 VR-T	VR	1	DF-1	GB / LiS	404643
36	Inlexa 7 VR-T	VR	1	DF-4	GB / LiS	404644
37	Intica 5 HF-T	CRT	3	DF-1	GB / LiS	404683
38	Intica 5 HF-T	CRT	3	DF-4	GB / LiS	404684
39	Intica 5 HF-T QP	CRT	3	DF-1 + IS-4	GB / LiS	406932

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40	Intica 5 HF-T QP	CRT	3	DF-4 + IS-4	GB / LiS	404685
41	Intica 5 DR-T	DR	2	DF-1	GB / LiS	404686
42	Intica 5 DR-T	DR	2	DF-4	GB / LiS	404678
43	Intica 5 VR-T DX	DX*	1	DF-1	GB / LiS	404688
44	Intica 5 VR-T	VR	1	DF-1	GB / LiS	404689
45	Intica 5 VR-T	VR	1	DF-4	GB / LiS	404690
46	Inlexa 3 HF-T	CRT	3	DF-1	GB / LiS	404699
47	Inlexa 3 HF-T	CRT	3	DF-4	GB / LiS	404700
48	Inlexa 3 HF-T QP	CRT	3	DF-1 + IS-4	GB / LiS	416037
49	Inlexa 3 HF-T QP	CRT	3	DF-4 + IS-4	GB / LiS	416038
50	Inlexa 3 DR-T	DR	2	DF-1	GB / LiS	404701
51	Inlexa 3 DR-T	DR	2	DF-4	GB / LiS	404702
52	Inlexa 3 VR-T	VR	1	DF-1	GB / LiS	404703
53	Inlexa 3 VR-T	VR	1	DF-4	GB / LiS	404704

*: additional atrial detection (therapy function)

2. Family description

Header difference overview

Variant	***Family member's***	***PC Board***	***RF-Antenna***
1	VR-T/DF-1 (DX)	#1	#1
2	VR-T/DF-4	#1	#2
3	DR-T/DF-1	#1	#1
4	DR-T/DF-4	#1	#2
5	HF-T/DF-1	#1	#1
6	HF-T/DF-4	#1	#2
7	HF-T/QP (DF-1 / IS-4)	#2	#2
8	HF-T/QP (DF-4 / IS-4)	#2	#2

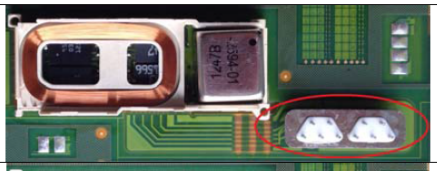
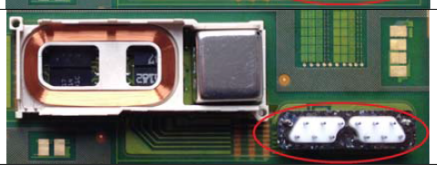
table 1: PC Board and RF Antenna

Battery vendor

Due to marketing reasons it was necessary to have different hardware identification numbers for the battery suppliers within the Ilivia 7 / Intica 7 / Inlexa 7 families for CRT models. The different battery vendors do not affect the RF and EMC performance.

2.1 PC-Board

All family devices are using the same electronic. This means all active and all passive electrical components are the same. The variant #7 and #8 HF-T QP header device are providing two additional electrical connections to the header. Therefore the variant #7 and #8 are using a different printed circuit board. The difference are the two wires MID3 and PROXIMAL4 (please refer schematic's) and a different feedtrough with 12 pols instead of 10 pols. QP means a quadruple left ventricular lead.

PC Board #1 10pol feedtrough Schematic file SCH-0143_0A.pdf	
PC Board #2 12pol feedtrough Schematic file SCH-0142_0A.pdf	

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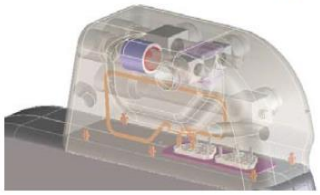
2.2 RF-Antenna

The family members are equipped with two different RF antennas. All DF-1 header based devices are using the same antenna type #1. All DF4 header based devices are using also the same antenna, but type #2.

DF-1 header with antenna type #1	***DF4 header with antenna type #2***
	

Version History

Version	Issue Date	Remarks	Revised by
01	2017-01-17	Initial Release	

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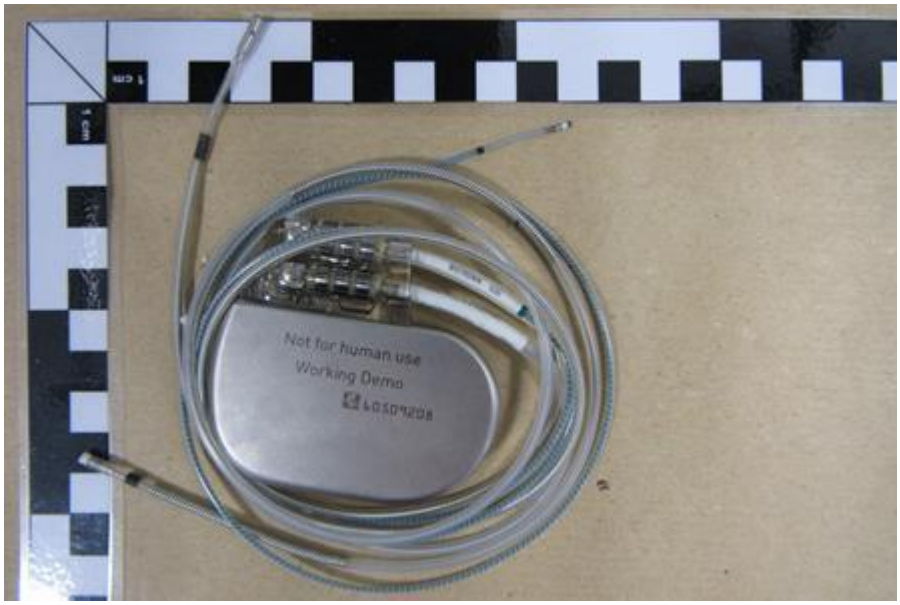
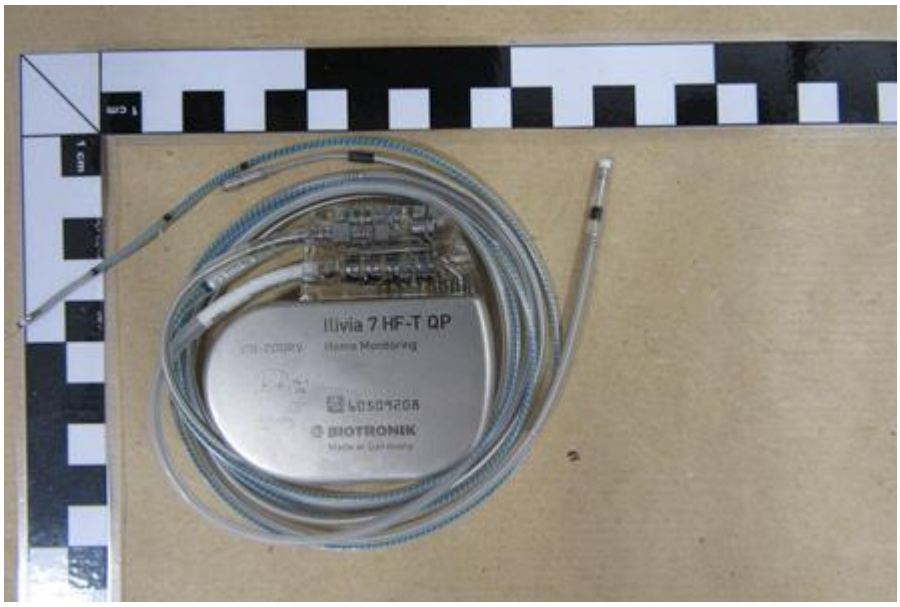
1 Equipment (Test item) Description

Description	ICD / Implantable Cardioverter Defibrillator TachNT2	
Model	Intica 7 HF-T QP	
Additional Model(s)	Additional Models according to Family Letter	
Brand Name(s)	BIOTRONIK	
Serial number	60509208 (HVIN 404630)	
Hardware version	Rev.: 0A	
Software / Firmware version	ROM: 5.0 / RAM: 4.1.0	
PMN	N/A	
HVIN	N/A	
FVIN	N/A	
HMN	N/A	
FCC-ID	QRITACHNT2	
IC	N/A	
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	unspecified
	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

Intica 7 HF-T QP DF-4 + IS-4 (Master) with Leads


Intica 7 HF-T QP DF-4 + IS-4 (Master) TOP


Ilivia 7 VR-T DF-4

Ilivia 7 VR-T DF-1

Ilivia 7 VR-T DX DF-1

Ilivia 7 DR-T DF-1

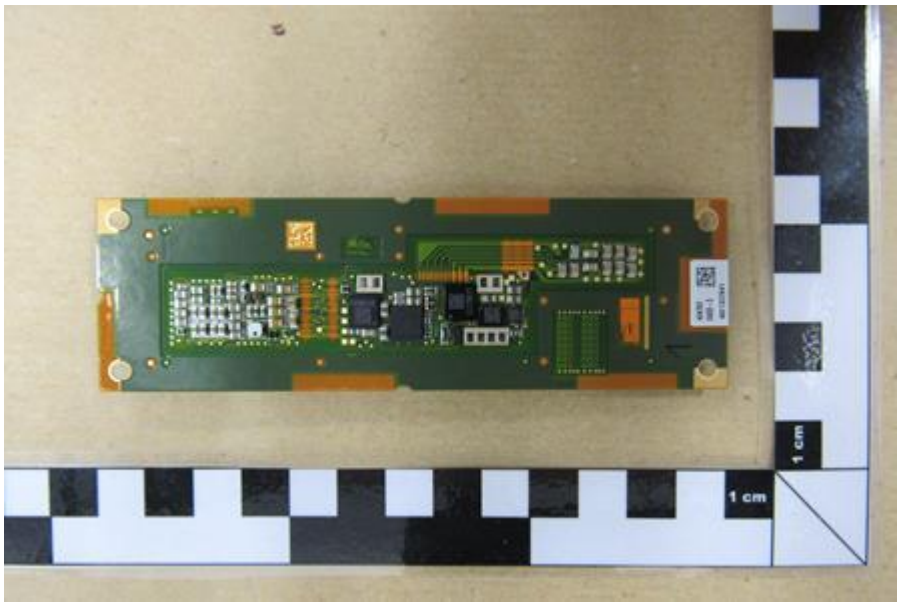
Ilivia 7 DR-T DF-4

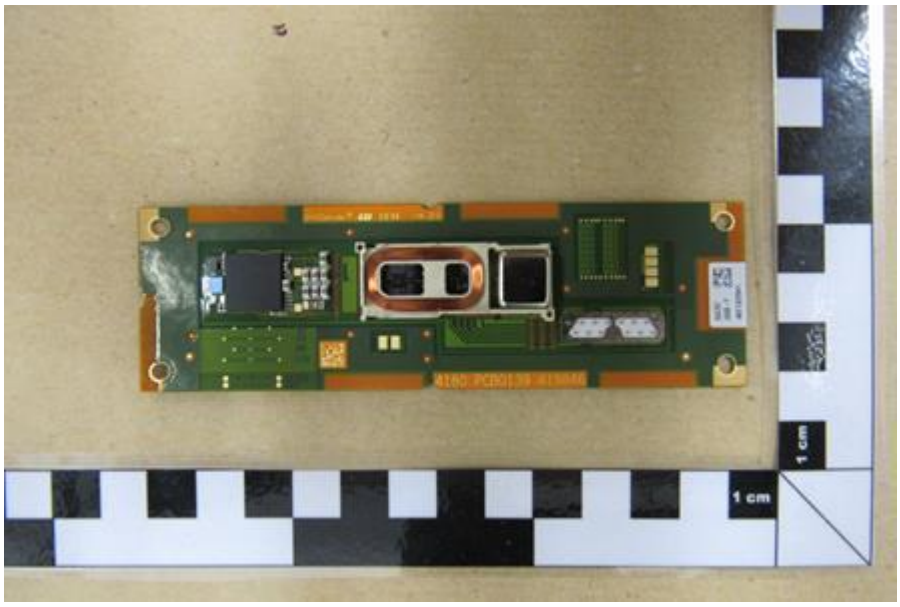
Ilivia 7 HF-T DF-1

Ilivia 7 HF-T DF-4

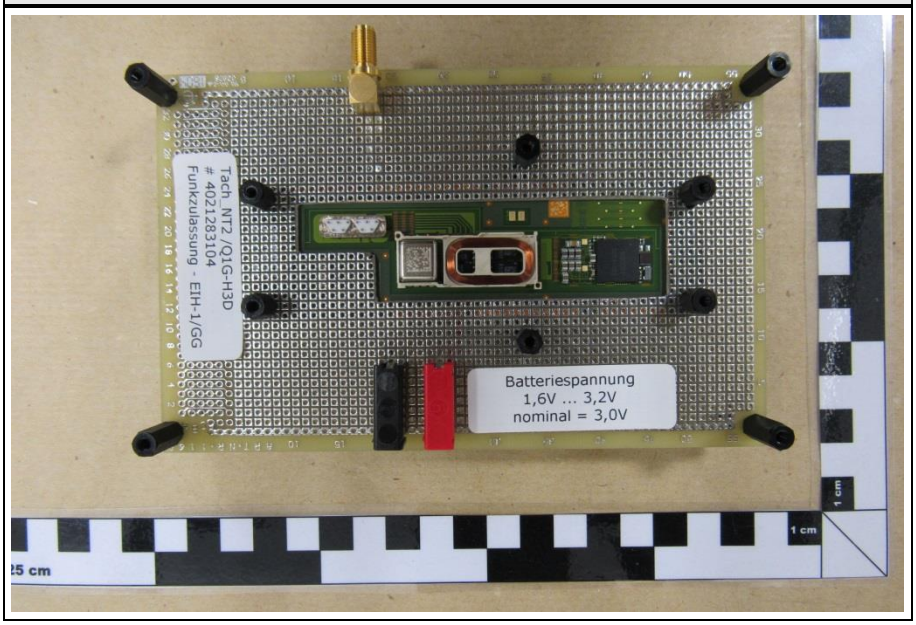
Intica 7 HF-T QP DF-1

1.2 Photos – Equipment internal

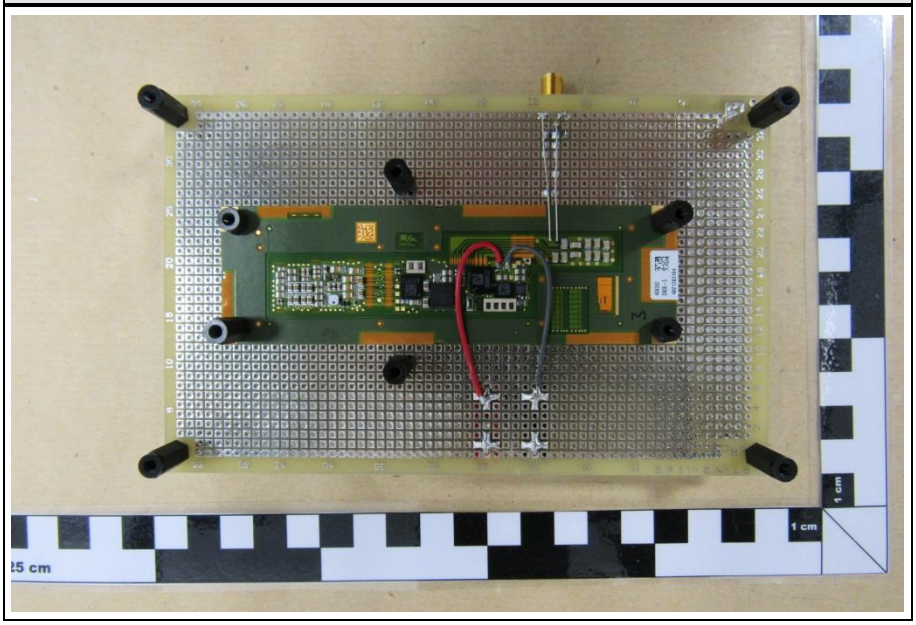
PCB TOP


PCB BOTTOM


CONDUCTED TEST SAMPLE TOP



CONDUCTED TEST SAMPLE BOTTOM



1.3 Photos – Test setup

SETUP RADIATED EMISSIONS

1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
None				

***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	2015.2.4

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSP 30	EF00312	2016-02	2017-02

Field strength emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC 2	EF00196	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2016-04	2017-04
Biconical Antenna	R&S	HK 116	EF00012	2016-05	2019-05
LPD Antenna	R&S	HL 223	EF00187	2016-05	2019-05
LPD Antenna	R&S	HL 025	EF00327	2015-10	2018-10

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:

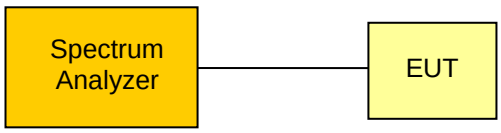
Reading	+	AF	=	Net Reading	:	Net reading - FCC limit = Margin
21.5 dBµV	+	26 dB	=	47.5 dBµV/m	:	47.5 dBµV/m - 57.0 dBµV/m = -9.5 dB

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 2.6 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

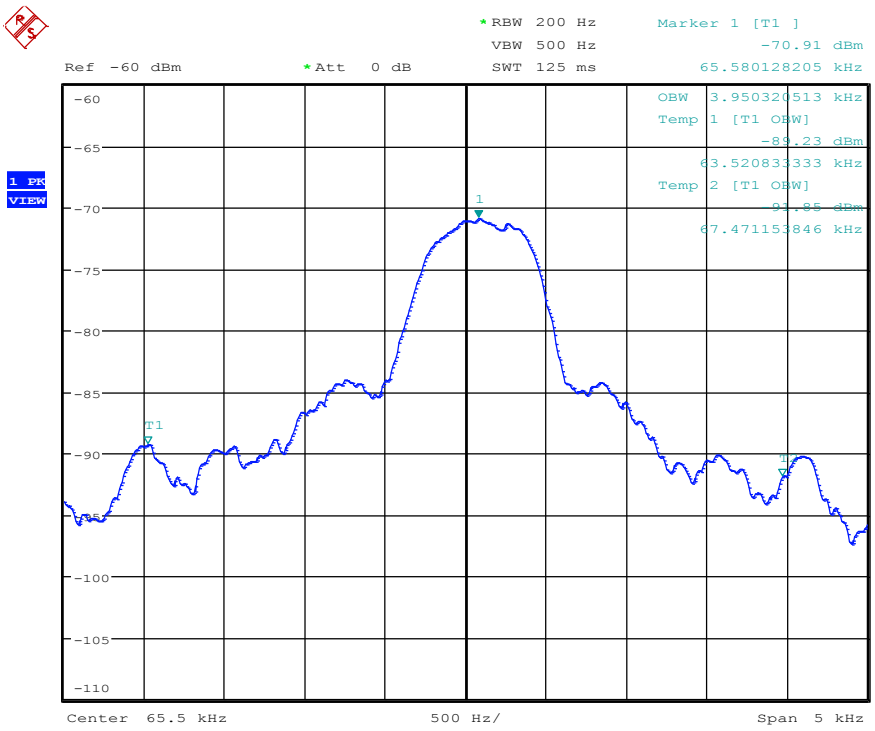
Occupied Bandwidth acc. to IC RSS-Gen		**Verdict: PASS**
Test according to measurement reference	Reference Method	
	RSS-Gen 6.6	
Test frequency range	Tested frequencies	
	F_{MID}	
EUT test mode	Single	
Limits		
None (Informational only)		
Test setup		
		
Test procedure		
1. EUT set to test mode (Communication 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	3.95
Comments:		

Occupied Bandwidth - F_{MID}

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0D-1611-6014

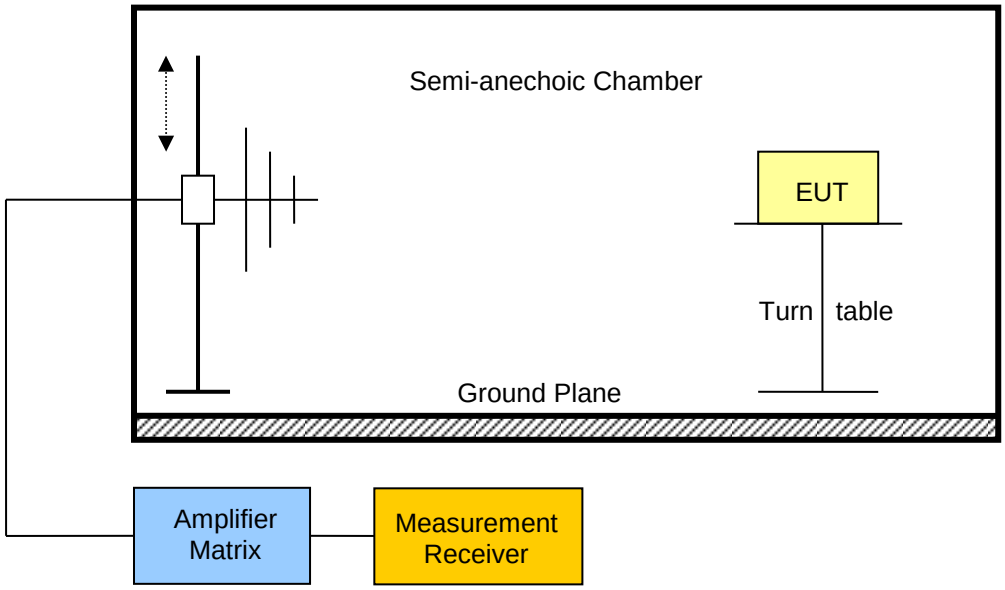
Applicant:	Biotronik SE & Co. KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 64 kHz
Test Date:	2016-11-23
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with an integrated 99% power bandwidth function is used
Note 2:	Near-field measurement test fixture / 64 kHz system



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

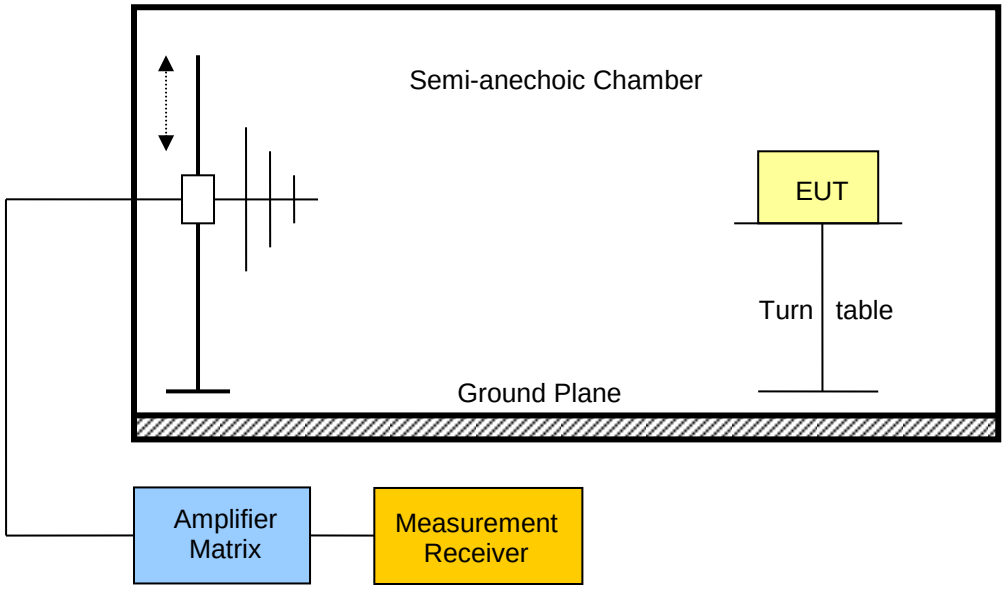
Test results

Channel	Frequency [kHz]	Emission [kHz]	Level [dbµV/m]	Detector	Limit [dbµV/m]	Limit distance [m]*	Margin [dB]
F_{MID}	64	65	-53.0	pk	31.3	3	-84.30

Comments: * Physical distance between EUT and measurement antenna.

3.3 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	64.9	-53.4	pk	31.3	84.7
Comments:						