

<b>FCC TEST REPORT</b> <b>FCC 47 CFR Part 15C</b> <b>Industry Canada RSS-310</b> <b>License exempt radio equipment</b>	
<b>Report Reference No.</b> .....	G0D-1611-6014-TFC209LP-V01
<b>Testing Laboratory</b> .....	Eurofins Product Service GmbH
Address .....	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation .....	<div style="display: flex; justify-content: center; align-items: center;">   </div> <p style="text-align: center; margin-top: 5px;">                     A2LA Accredited Testing Laboratory, Certificate No.: 1983.01                      FCC Filed Test Laboratory, Reg.-No.: 96970                      IC OATS Filing assigned code: 3470A                 </p>
<b>Applicant's name</b> .....	Biotronik SE & Co. KG
Address .....	Woermannkehre 1 12359 Berlin GERMANY
<b>Test specification:</b>	
Standard .....	47 CFR Part 15C RSS-310, Issue 4, 2015-07
Test scope .....	complete Radio compliance test
<b>Equipment under test (EUT):</b>	
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
<b>Test result</b>	<b>Passed</b>
<b>Possible test case verdicts:</b>	

Test Report No.: G0D-1611-6014-TFC209LP-V01

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

- 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) ..... : Wilfried Treffke  
 (Responsible for Test)

*W. Treffke*

Approved by (+ signature) ..... : Christian Weber  
 (Head of Lab)

*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:**

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.

**Additional comments:**

## 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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BIOTRONIK SE & Co. KG  
 Woermannkehr 1  
 12359 Berlin Germany  
 Tel +49 (0) 30 68905-0  
 Fax +49 (0) 30 6852804

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

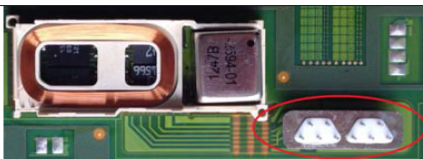
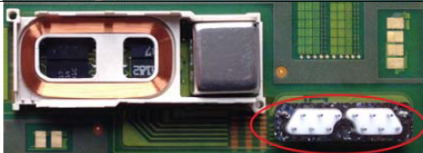
table 1: PC Board and RF Antenna

### 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 feedthrough with 12 pols instead of 10 pols. QP means a quadruple left ventricular lead.

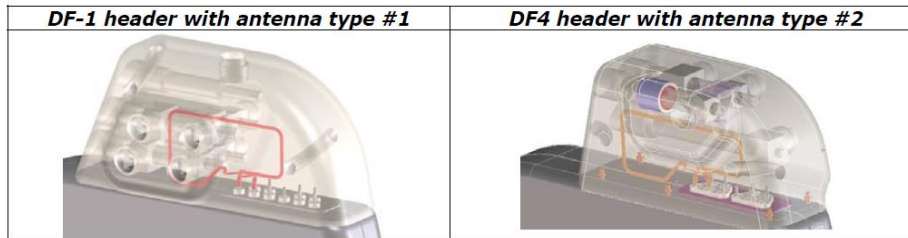
<p>PC Board #1 10pol feedthrough Schematic file SCH-0143_0A.pdf</p>	
<p>PC Board #2 12pol feedthrough Schematic file SCH-0142_0A.pdf</p>	

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Woermannkehrre 1  
12359 Berlin Germany  
Tel +49 (0) 30 68905-0  
Fax +49 (0) 30 6852804

**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.



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## Version History

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

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## REPORT INDEX

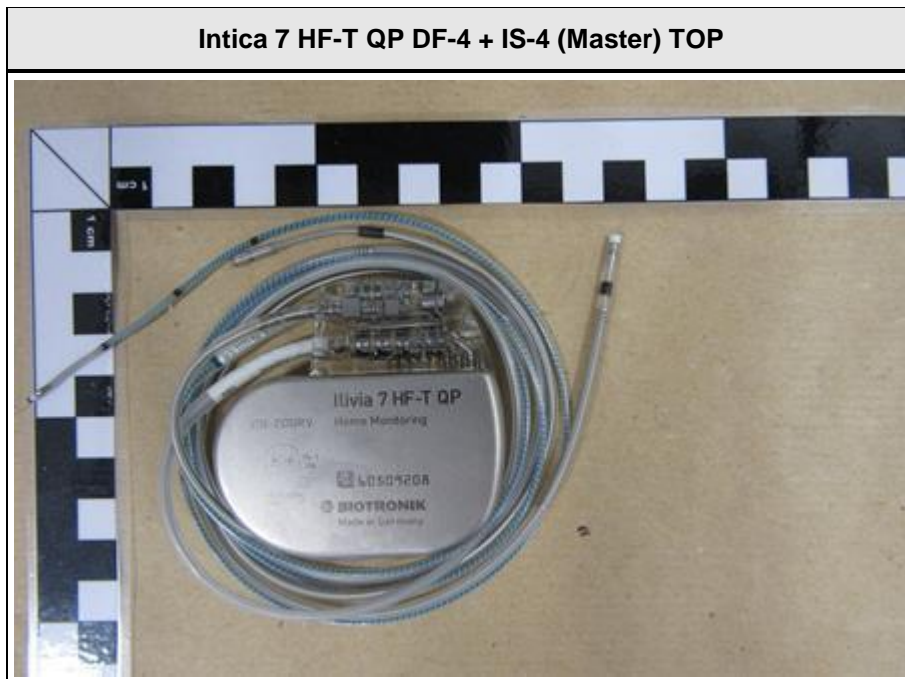
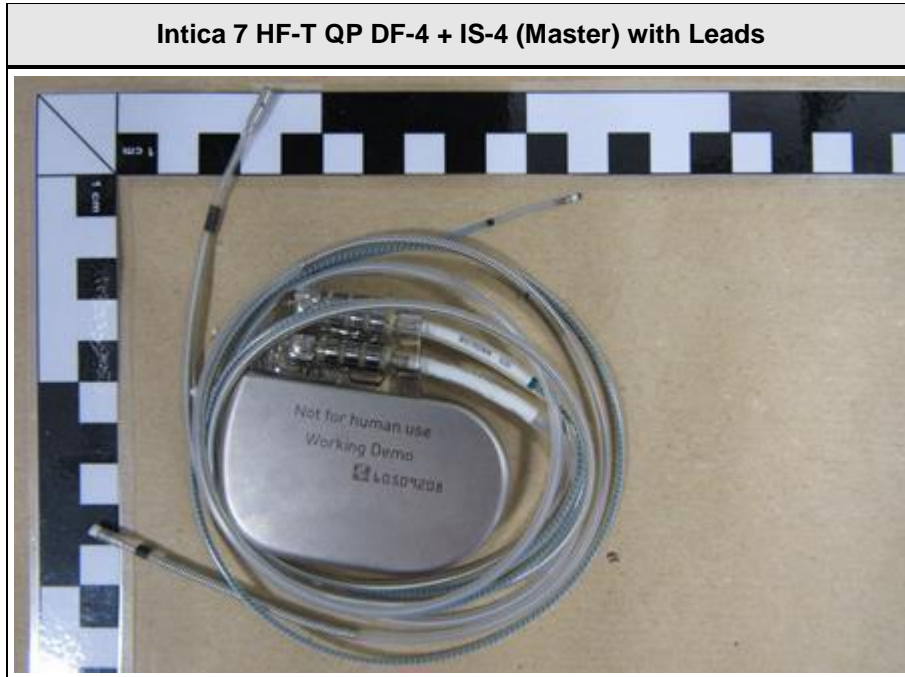
<b>1</b>	<b>EQUIPMENT (TEST ITEM) DESCRIPTION</b>	<b>9</b>
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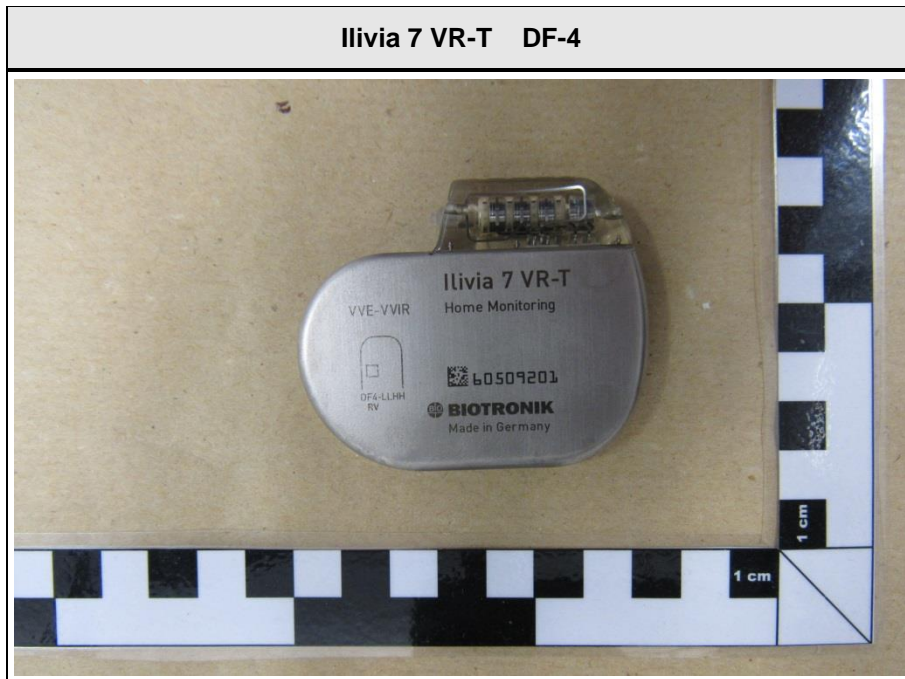


## 1 Equipment (Test item) Description

<b>Description</b>	ICD / Implantable Cardioverter Defibrillator TachNT2	
<b>Model</b>	Intica 7 HF-T QP	
<b>Additional Model(s)</b>	Additional Models according to Family Letter	
<b>Brand Name(s)</b>	BIOTRONIK	
<b>Serial number</b>	60509208 (HVIN 404630)	
<b>Hardware version</b>	Rev.: 0A	
<b>Software / Firmware version</b>	ROM: 5.0 / RAM: 4.1.0	
<b>PMN</b>	N/A	
<b>HVIN</b>	N/A	
<b>FVIN</b>	N/A	
<b>HMN</b>	N/A	
<b>FCC-ID</b>	QRITACHNT2	
<b>IC</b>	N/A	
<b>Equipment type</b>	End product	
<b>Radio type</b>	Transceiver	
<b>Radio technology</b>	custom	
<b>Operating frequency range</b>	64 kHz	
<b>Frequency range</b>	$F_{MID}$	64 kHz
<b>Modulations</b>	OOK	
<b>Number of channels</b>	1	
<b>Channel spacing</b>	None	
<b>Number of antennas</b>	1	
<b>Antenna</b>	Type	integrated
	Model	unspecified
	Manufacturer	Biotronik SE & Co. KG
	Gain	unspecified
<b>Manufacturer</b>	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
<b>Power supply</b>	$V_{NOM}$	3.0 VDC (Lithium-Battery)
	$V_{MIN}$	N/A
	$V_{MIN}$	N/A
<b>AC/DC-Adaptor</b>	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

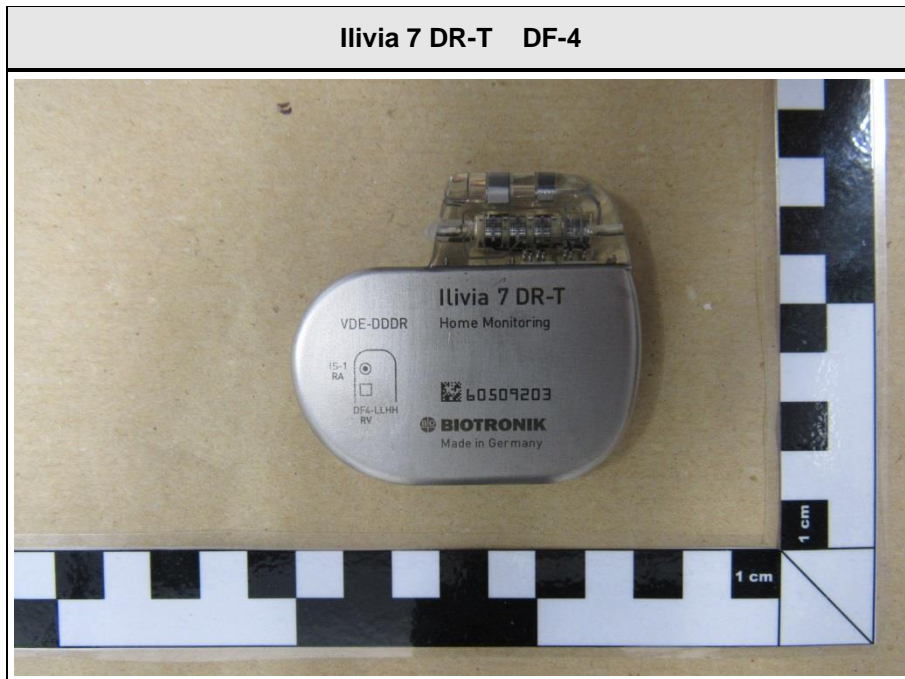
1.1 Photos – Equipment External











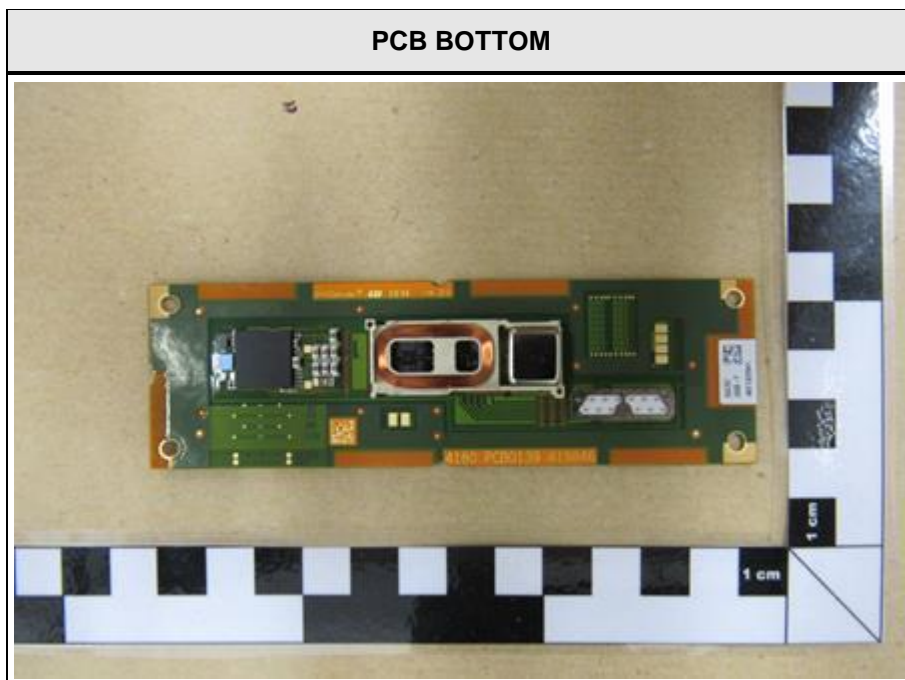
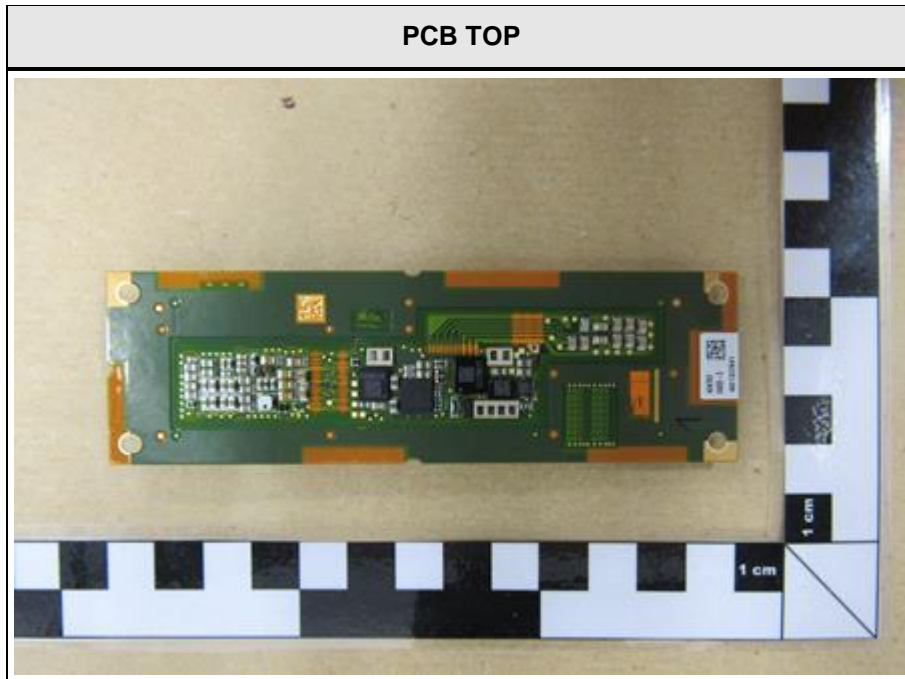
Ilivia 7 HF-T DF-4



Intica 7 HF-T QP DF-1

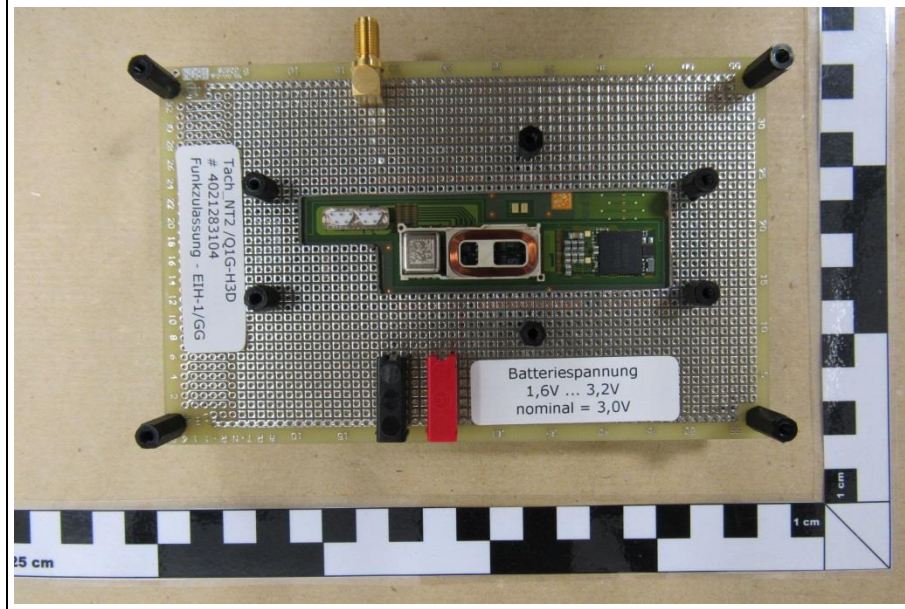


1.2 Photos – Equipment internal

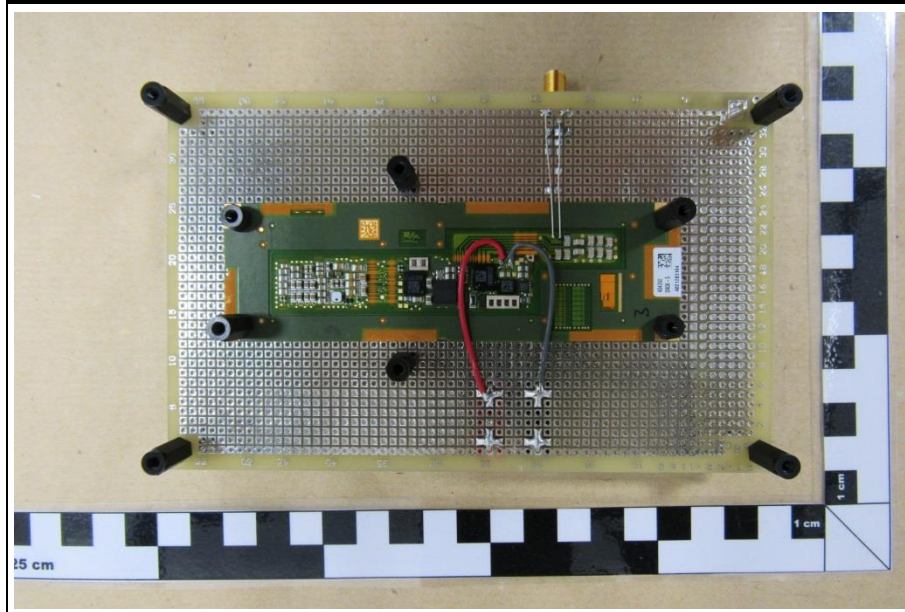




**CONDUCTED TEST SAMPLE TOP**

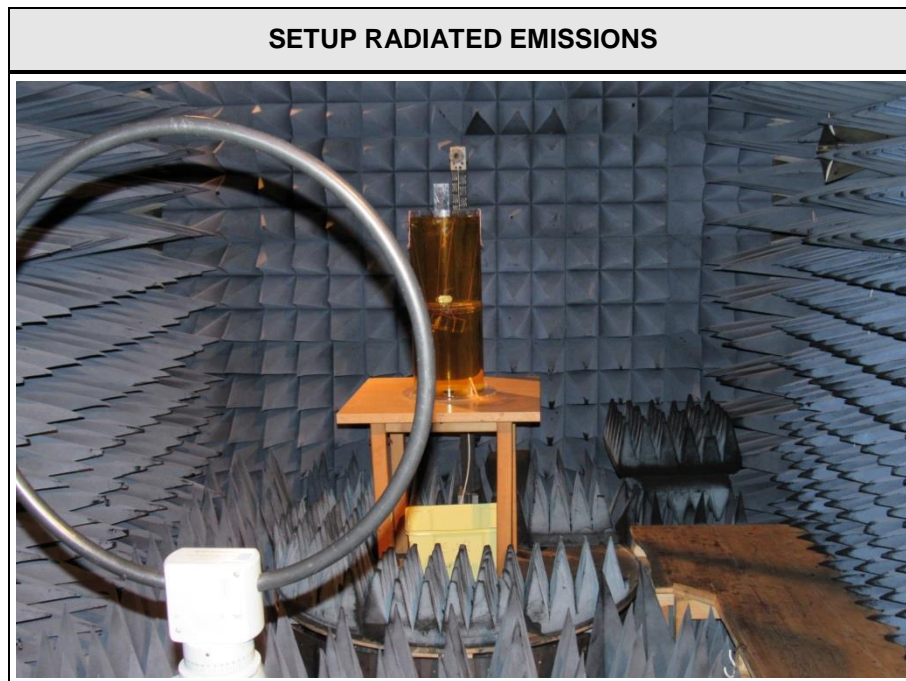


**CONDUCTED TEST SAMPLE BOTTOM**





1.3 Photos – Test setup



#### 1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
None				
<b>*Note:</b> 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**

<b>Measurement Software</b>			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2015.2.4

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

<b>Field strength emissions</b>					
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 dB $\mu$ V. 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 dB $\mu$ V/m). The FCC limits are given in units of  $\mu$ V/m. The following formula is used to convert the units of  $\mu$ V/m to dB $\mu$ V/m:

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

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:

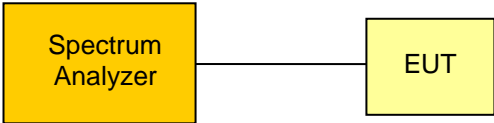
$$\begin{array}{rclcl} \text{Reading} & + & \text{AF} & = & \text{Net Reading} & : & \text{Net reading - FCC limit} & = & \text{Margin} \\ 21.5 \text{ dB}\mu\text{V} & + & 26 \text{ dB} & = & 47.5 \text{ dB}\mu\text{V/m} & : & 47.5 \text{ dB}\mu\text{V/m} - 57.0 \text{ dB}\mu\text{V/m} & = & -9.5 \text{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

## 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 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	
<b>Remarks:</b>				

### 3 Test Conditions and Results

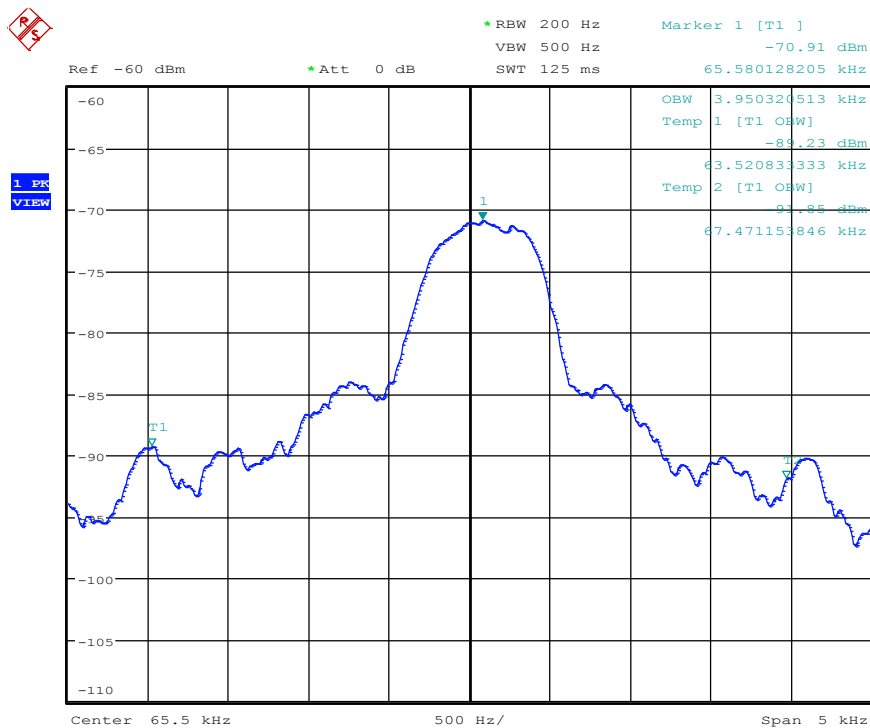
#### 3.1 Test Conditions and Results – Occupied Bandwidth

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 <sub>MID</sub>	
EUT test mode	Single	
<b>Limits</b>		
None (Informational only)		
<b>Test setup</b>		
 <pre> graph LR     SA[Spectrum Analyzer] --- EUT[EUT]             </pre>		
<b>Test procedure</b>		
<ol style="list-style-type: none"> <li>1. EUT set to test mode (Communication tester is used if needed)</li> <li>2. Span set to at least twice the emission spectrum</li> <li>3. Resolution bandwidth set to 1 % of span</li> <li>4. Occupied Bandwidth (99 %) measurement with spectrum analyzer built in measurement function</li> </ol>		
<b>Test results</b>		
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]
F <sub>MID</sub>	64	3.95
Comments:		

**Occupied Bandwidth - F<sub>MID</sub>**
**Occupied Bandwidth acc. to RSS-Gen**

Project Number: GOD-1611-6014

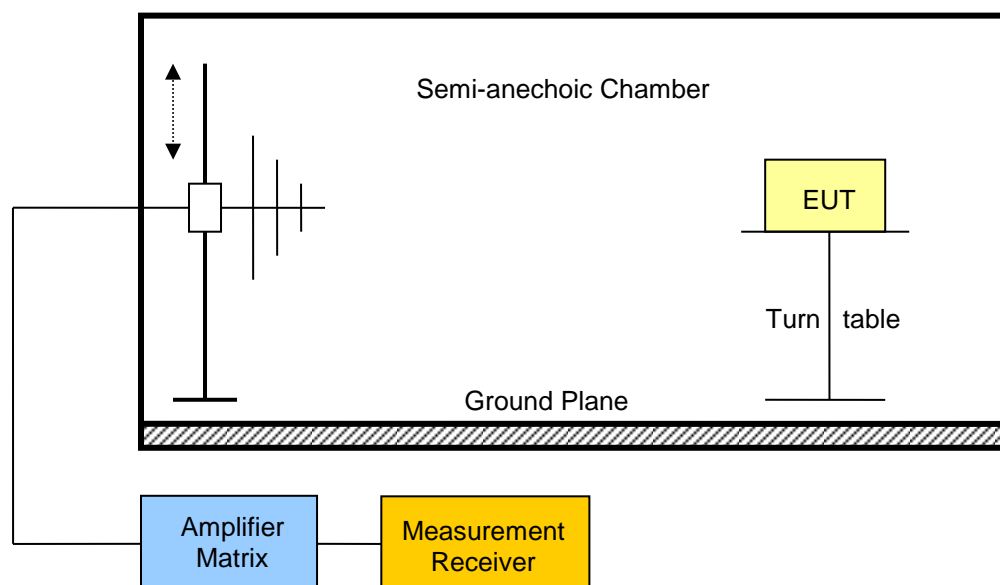
Applicant: Biotronik SE & Co. KG  
 EUT Name: ICD / Implantable Cardioverter Defibrillator  
 Model: TachNT2 (Intica 7 HF-T QP DF-4 + IS-4)  
 Test Site: Eurofins Product Service GmbH  
 Operator: Wilfried Treffke  
 Test Conditions: Tnom / Vnom  
 Mode: Tx 64 kHz  
 Test Date: 2016-11-23  
 Verdict: 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



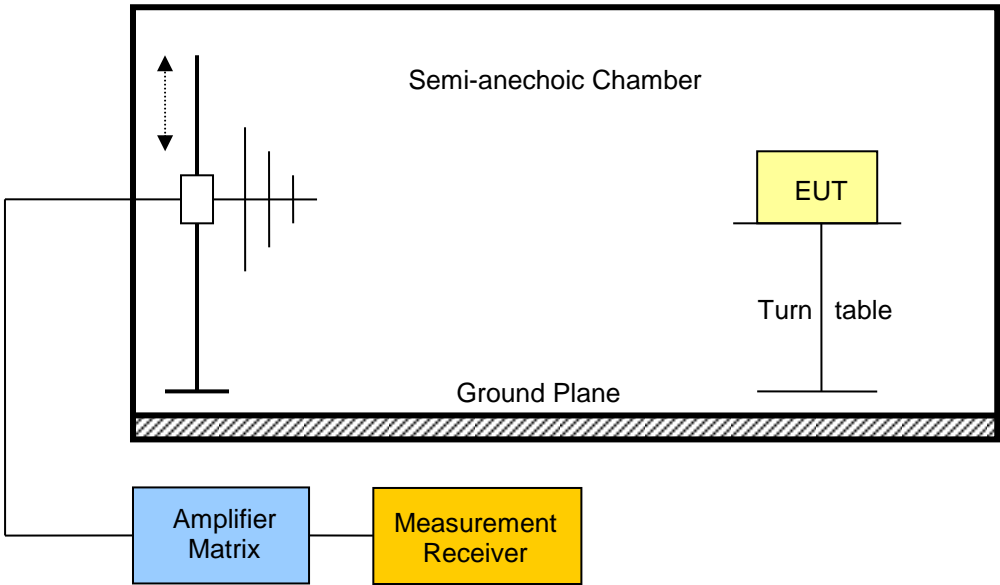


**3.2 Test Conditions and Results – Fundamental field strength emissions**

<b>Field strength emissions acc. to FCC 47 CFR 15.201 / IC RSS-310</b>				<b>Verdict: PASS</b>
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 – 10 <sup>th</sup> Harmonic			
EUT test mode	Single			
<b>Limits</b>				
Frequency range [MHz]	Detector	Limit [ $\mu$ V/m]	Limit [dB $\mu$ 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
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							
<ol style="list-style-type: none"> <li>1. EUT set to test mode</li> <li>2. Span it set according to measurement range</li> <li>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</li> <li>4. Markers are set to maximum emission levels</li> </ol>							
Test results							
Channel	Frequency [kHz]	Emission [kHz]	Level [db $\mu$ V/m]	Detector	Limit [db $\mu$ V/m]	Limit distance [m]*	Margin [dB]
F <sub>MID</sub>	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 – 5 <sup>th</sup> Harmonic			
EUT test mode	Receive			
Limits				
Frequency range [MHz]	Detector	Limit [ $\mu\text{V}/\text{m}$ ]	Limit [ $\text{dB}\mu\text{V}/\text{m}$ ]	Limit Distance [m]
0.009 – 0.490	Quasi-Peak	$2400/F[\text{kHz}]$	48.5 – 13.8	300
0.490 – 1.705	Quasi-Peak	$2400/F[\text{kHz}]$	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				
 <p>The diagram illustrates the test setup within a Semi-anechoic Chamber. A Ground Plane is located at the bottom. An Amplifier Matrix is connected to the chamber. A Measurement Receiver is connected to the Amplifier Matrix. The EUT (Equipment Under Test) is placed on a Turn table inside the chamber. A vertical antenna is positioned to receive signals from the EUT.</p>				

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 [dB $\mu$ V/m]	Det.	Limit [dBd $\mu$ V/m]	Margin [dB $\mu$ V/m]
F <sub>MID</sub>	64	64.9	-53.4	pk	31.3	84.7
Comments:						