eurofins | Product Service

FCC TEST REPORT

FCC 47 CFR Part 15C
Industry Canada RSS-310

License exempt radio equipment

Report Reference No. ..... :	G0M-1207-2110-TFC209L-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 3, 2010-12 RSS-Gen, Issue 3, 2010-12 ANSI C63.4:2009
Equipment under test (EUT):	
Product description	ICD / Implantable Cardioverter Defibrillator
Model No.	Ilesto 7 HF-T
Hardware version	Rev.: 0B
Firmware / Software version	ROM: 2.3 / RAM: 2.0
	FCC-ID: QRITACHNXT IC: 4708A-TACHNXT
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:

Date of receipt of test item ..... :	2012-07-18	
Date (s) of performance of tests ..... :	2012-07-18 - 2012-07-20	
Compiled by ..... :	Christian Weber	
Tested by (+ signature)..... : (Testing Manager)	Wilfried Treffke	25. Treffke
Approved by (+ signature) ..... : (Test Lab Manager)	Christian Weber	C. Weber
Date of issue ..... :	2012-09-27	
Total number of pages ..... :	35	

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.

Additional comments:

The report applies to all model stated in the “TACH NXT Family Listing” issued by the Manufacturer 2012-09-19.

	Model Name	Connector	no. of chambers	max. stored energy for shock therapy
1	Ilesto 7 HF-T	DF-1/DF-4	3	40 J
2	Ilesto 7 DR-T	DF-1/DF-4	2	40 J
3	Ilesto 7 VR-T DX	DF-1	1*	40 J
4	Ilesto 7 VR-T	DF-1/DF-4	1	40 J
5	Iforia 7 HF-T	DF-1/DF-4	3	40 J
6	Iforia 7 DR-T	DF-1/DF-4	2	40 J
7	Iforia 7 VR-T DX	DF-1	1*	40 J
8	Iforia 7 VR-T	DF-1/DF-4	1	40 J
9	Ilesto 5 HF-T	DF-1/DF-4	3	40 J
10	Ilesto 5 DR-T	DF-1/DF-4	2	40 J
11	Ilesto 5 VR-T DX	DF-1	1*	40 J
12	Ilesto 5 VR-T	DF-1/DF-4	1	40 J
13	Iforia 5 HF-T	DF-1/DF-4	3	40 J
14	Iforia 5 DR-T	DF-1/DF-4	2	40 J
15	Iforia 5 VR-T DX	DF-1	1*	40 J
16	Iforia 5 VR-T	DF-1/DF-4	1	40 J
17	Iforia 3 HF-T	DF-1/DF-4	3	40 J
18	Iforia 3 DR-T	DF-1/DF-4	2	40 J
19	Iforia 3 VR-T	DF-1/DF-4	1	40 J
20	Idova 7 HF-T	DF-1/DF-4	3	45 J
21	Idova 7 DR-T	DF-1/DF-4	2	45 J
22	Idova 7 VR-T DX	DF-1	1*	45 J
23	Idova 7 VR-T	DF-1/DF-4	1	45 J
24	Innotix 7 HF-T	DF-1/DF-4	3	45 J
25	Innotix 7 DR-T	DF-1/DF-4	2	45 J
26	Innotix 7 VR-T DX	DF-1	1*	45 J
27	Innotix 7 VR-T	DF-1/DF-4	1	45 J

The ulp-ami antenna is built into the headers (DF-1 or DF-4). The antenna of header model DF-1 is slightly different from the antenna built into header DF-4. Evaluation measurements were performed for worst case antenna selection and header DF-1 was selected. Besides the DF-1 header, model ILESTO 7 HF-T, as the most complex model, was selected for the measurements. Hence, the measurements were performed with the following model: “ILESTO 7 HF-T DF-1”.

REPORT INDEX

1 Equipment (Test item) Description

Description	ICD / Implantable Cardioverter Defibrillator	
Model	Ilesto 7 HF-T	
Serial number	None	
Hardware version	Rev.: 0B	
Software / Firmware version	ROM: 2.3 / RAM: 2.0	
FCC-ID	QRITACHNXT	
IC	4708A-TACHNXT	
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	loop 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}	N/A
	V_{MIN}	N/A
AC/DC-Adaptor	Model	N/A
	Vendor	N/A
	Input	N/A
	Output	N/A

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

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSP 30	EF00312	2011-12	2012-12

Field strength emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 5	EF00395	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2012-05	2013-05
Biconical Antenna	R&S	HK 116	EF00012	2010-01	2013-01
LPD Antenna	R&S	HL 223	EF00187	2011-02	2014-02
LPD Antenna	R&S	HL 025	EF00327	2010-02	2013-02

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 4.6.1	Occupied Bandwidth	RSS-Gen 4.6.1	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 2.3 IC RSS-Gen 4.10 6.1	Receiver radiated spurious emissions	ANSI C63.4	PASS	
Remarks:				

3 Test Conditions and Results

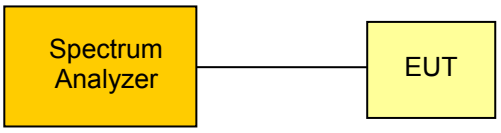
3.1 Test Conditions and Results – Occupied Bandwidth

Occupied Bandwidth acc. IC RSS-Gen	**Verdict: PASS**
Test according to measurement reference	Reference Method
	RSS-Gen 4.6.1
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

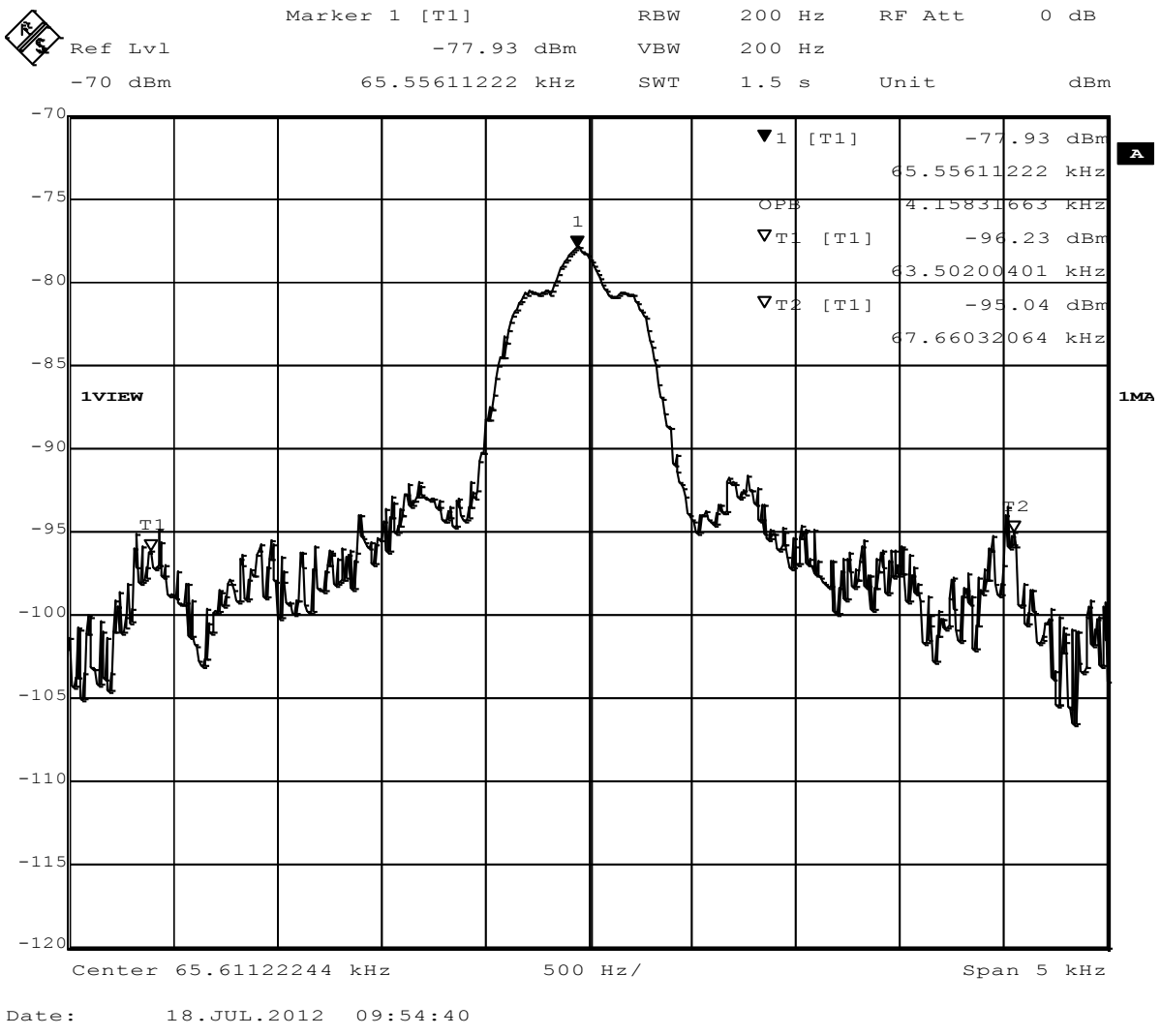
Channel	Frequency [kHz]	Occupied Bandwidth [kHz]
F_{MID}	64	4.16

Comments: Measurement is applicable to all variants

Occupied Bandwidth - F_{MID}

RSS Gen
Occupied Bandwidth

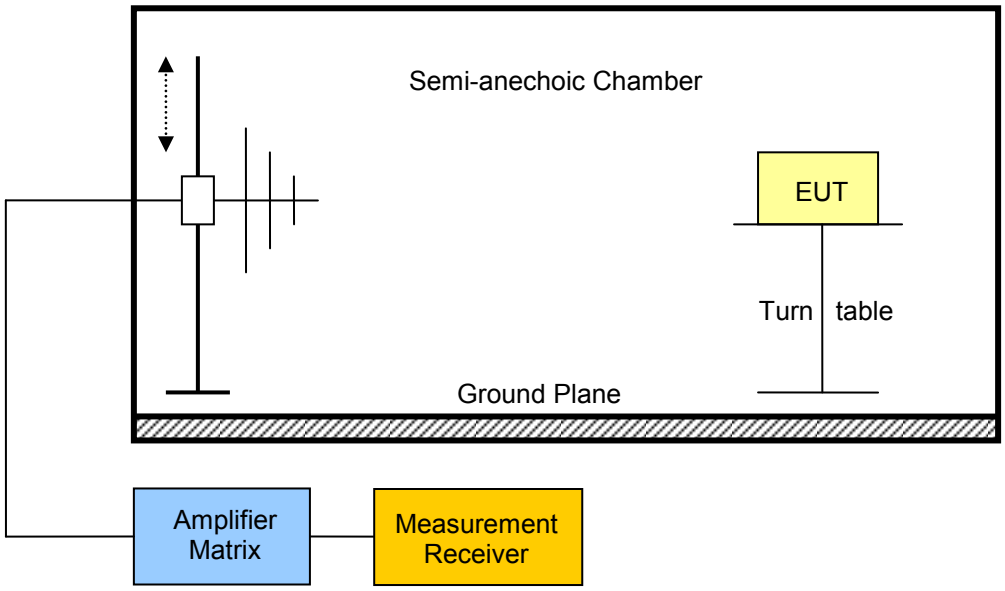
EUT	ICD I Implntable Cardioverter Defibrillator
Model	TACHNXT
Approval Holder	BIOTRONIK SE & Co., KG / G0M-1207-2110
Temperature / Voltage	Tnom / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Treffke
Test Specification	4.4.1 Occupied Bandwidth
Comment 1	near-field measurement, test fixture
Comment 2	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 3	64KHz System



3.2 Test Conditions and Results – Fundamental field strength emissions

Field strength emissions acc. 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	Pol.	Limit [dbµV/m]	Limit distance [m]*	Margin [dB]
F_{MID}	64	100	-35.86	pk	ver	27.6	300	-63.46

Comments: * Physical distance between EUT and measurement antenna.

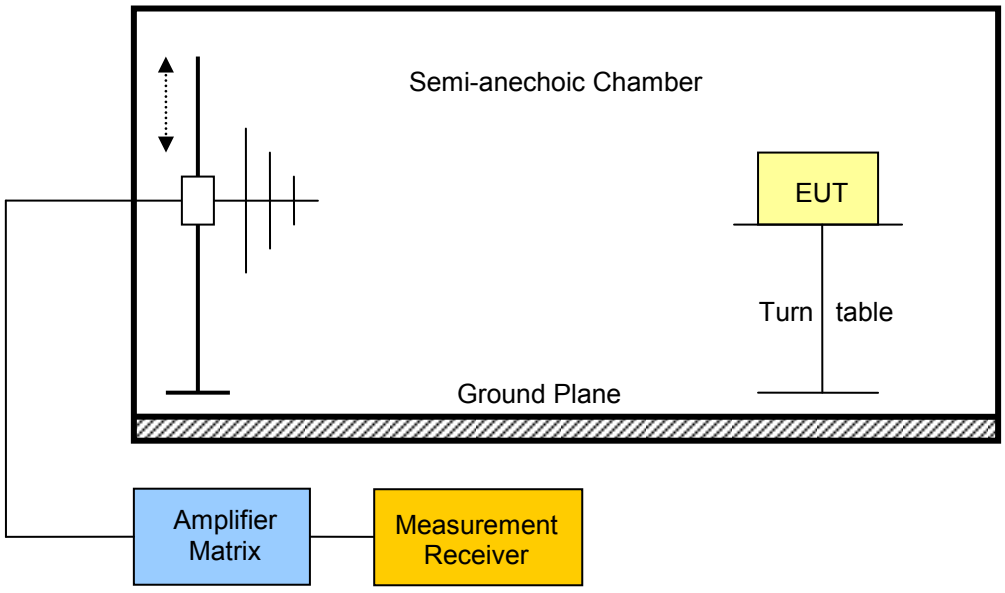
3.4 Test Conditions and Results – Receiver radiated emissions

Receiver radiated emissions acc. 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
	9 kHz – 10th 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]	Emission Level [µV/m]	Det.	Limit [dµV/m]	Margin [µV/m]
F_{MID}	64	12.67	-27.86	0.04	pk	45.55	-73.41

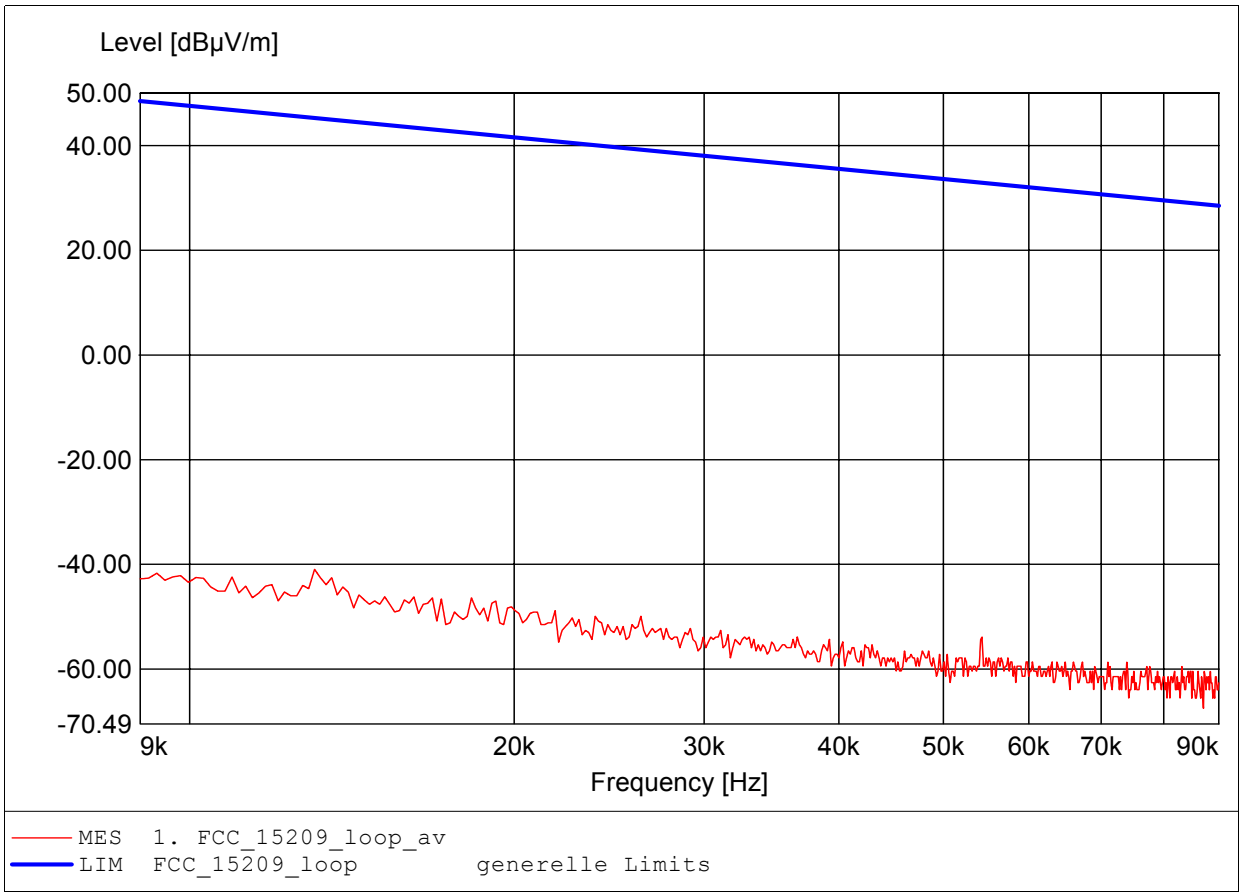
Comments:

ANNEX A Transmitter radiated spurious emissions

Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

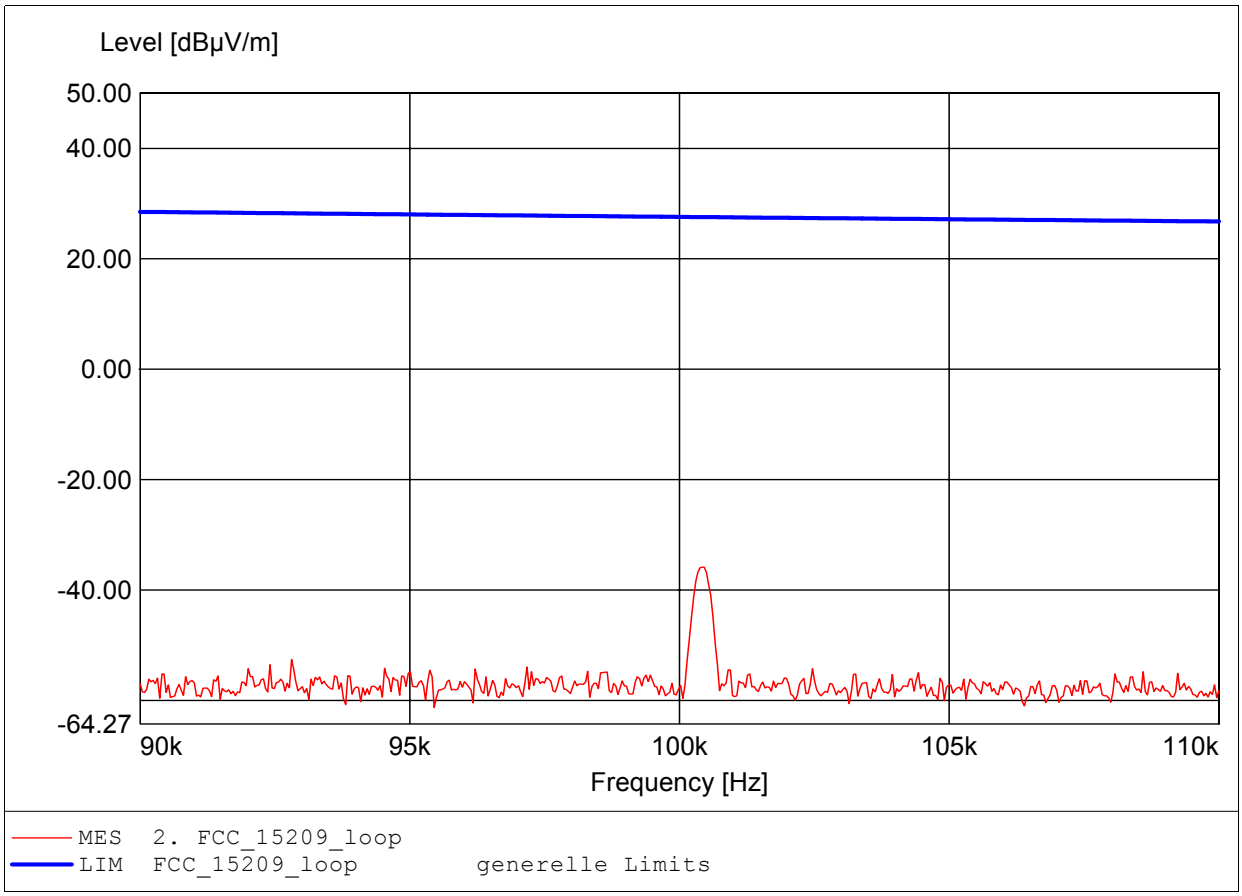
```
Approval Holder:     BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:                 ICD / Implantable Cardioverter Defibrillator
Model:               TACHNXT
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 22°C / Vnom: 3.0VDC  lithium battery
Test Specification: according to §15.209, average detector
Comment 1:           Dist.: 3m corrected to 300m, Ant.: HFH2-Z2
Comment 2:           Freq: 13.058kHz, Emax: -40.96dBµV/m, RBW: 200Hz
```



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

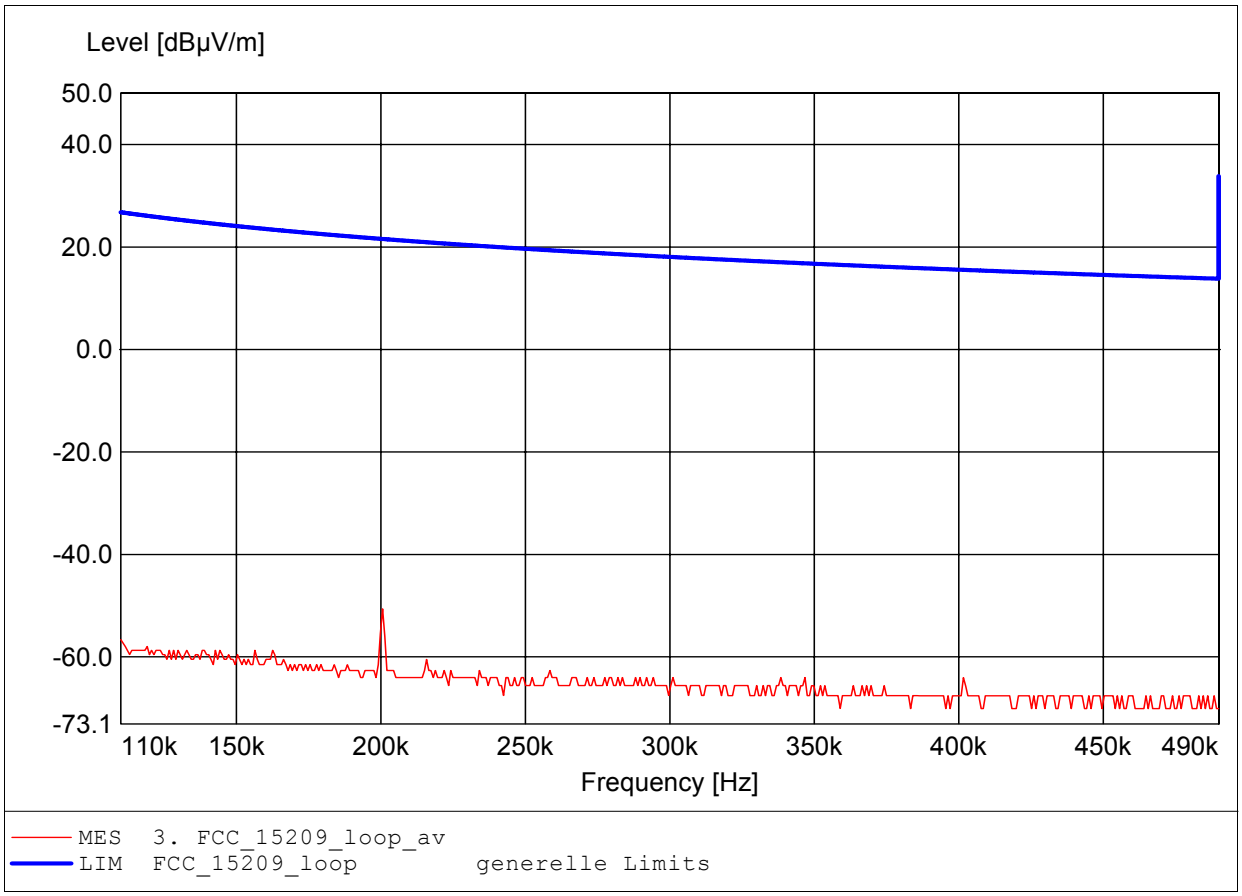
Approval Holder: BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT: ICD / Implantable Cardioverter Defibrillator
Model: TACHNXT
Operator: Eurofins Product Service GmbH / Mr. Treffke
Test Conditions: Tnom: 22°C / Vnom: 3.0VDC lithium battery
Test Specification: according to §15.209, peak detector
Comment 1: Dist.: 3m corrected to 300m, Ant.: HFH2-Z2
Comment 2: Freq: 100.421kHz, Emax: -35.86dBµV/m, RBW: 200Hz



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

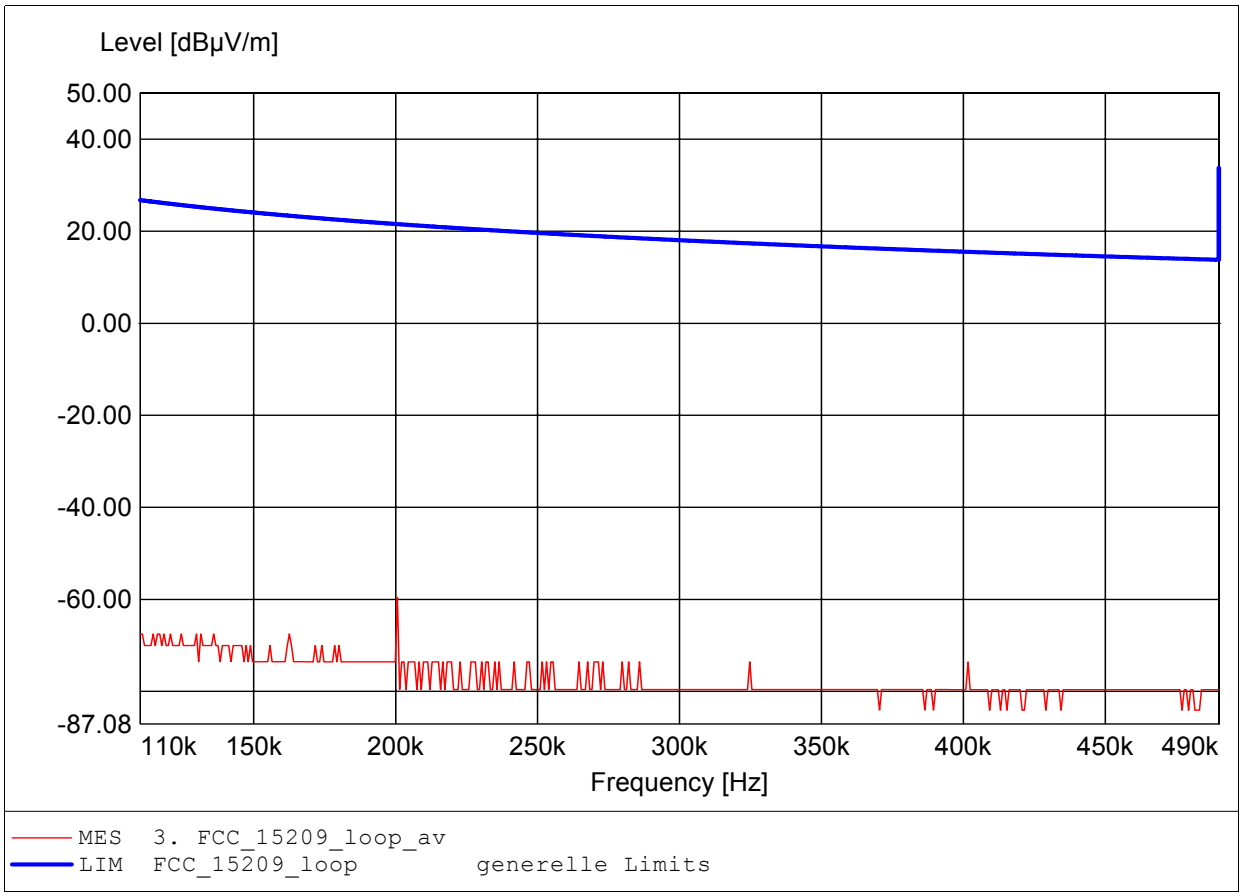
```
Approval Holder:     BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:                 ICD / Implantable Cardioverter Defibrillator
Model:               TACHNXT
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 22°C / Vnom: 3.0VDC  lithium battery
Test Specification: according to §15.209, average detector
Comment 1:           Dist.: 3m corrected to 300m, Ant.: HFH2-Z2
Comment 2:           Freq: 200.621kHz, Emax: -50.64dBµV/m, RBW: 10kHz
```



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

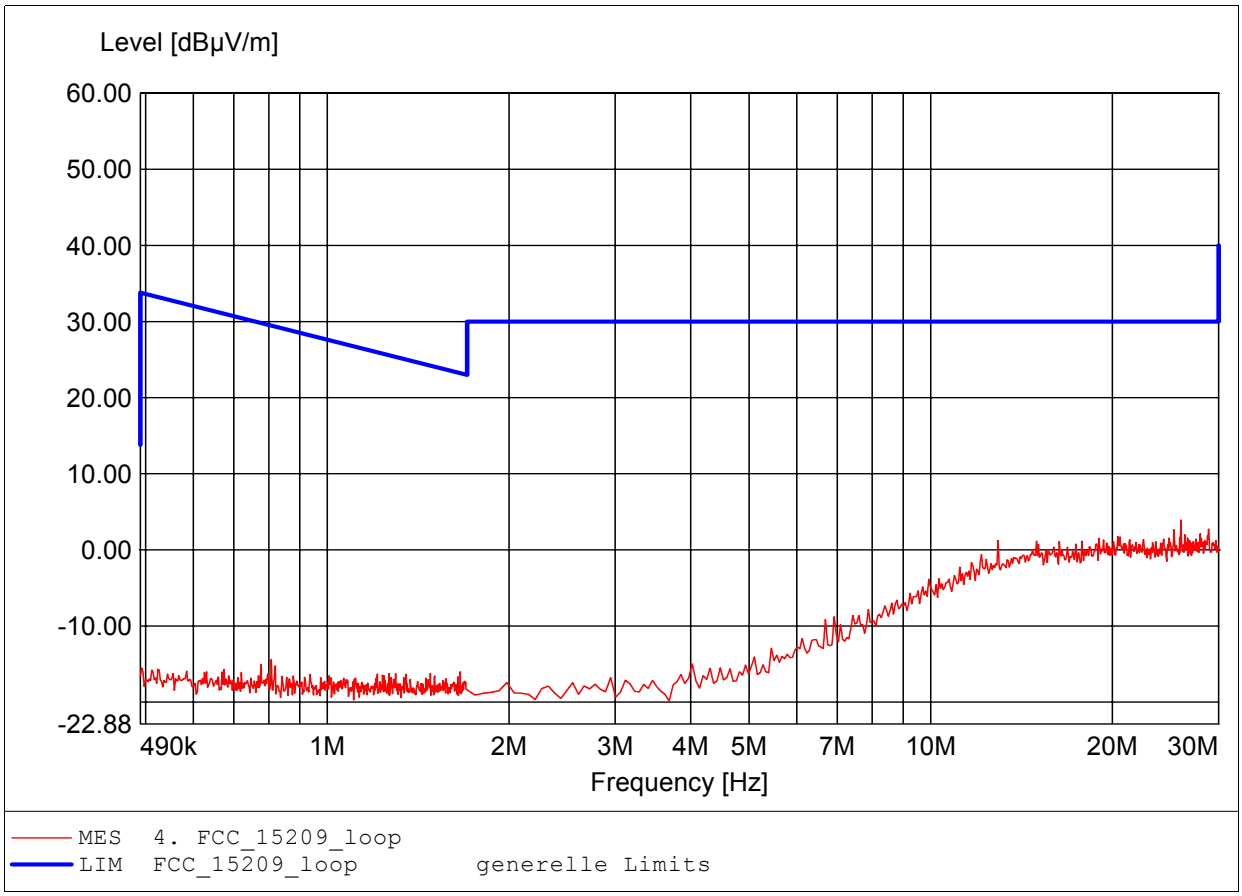
```
Approval Holder:     BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:                 ICD / Implantable Cardioverter Defibrillator
Model:               TACHNXT
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 22°C / Vnom: 3.0VDC  lithium battery
Test Specification: according to §15.209, average detector
Comment 1:           Dist.: 3m corrected to 300m, Ant.: HFH2-Z2
Comment 2:           Freq: 200.621kHz, Emax: -59.59dBµV/m, RBW: 200Hz
```



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

```
Approval Holder:     BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:                 ICD / Implantable Cardioverter Defibrillator
Model:               TACHNXT
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 22°C / Vnom: 3.0VDC  lithium battery
Test Specification: according to §15.209, peak detector
Comment 1:           Dist.: 3m corrected to 30m, Ant.: HFH2-Z2
Comment 2:           Freq: 25.973MHz, Emax: 3.92dBµV/m, RBW: 10kHz
```

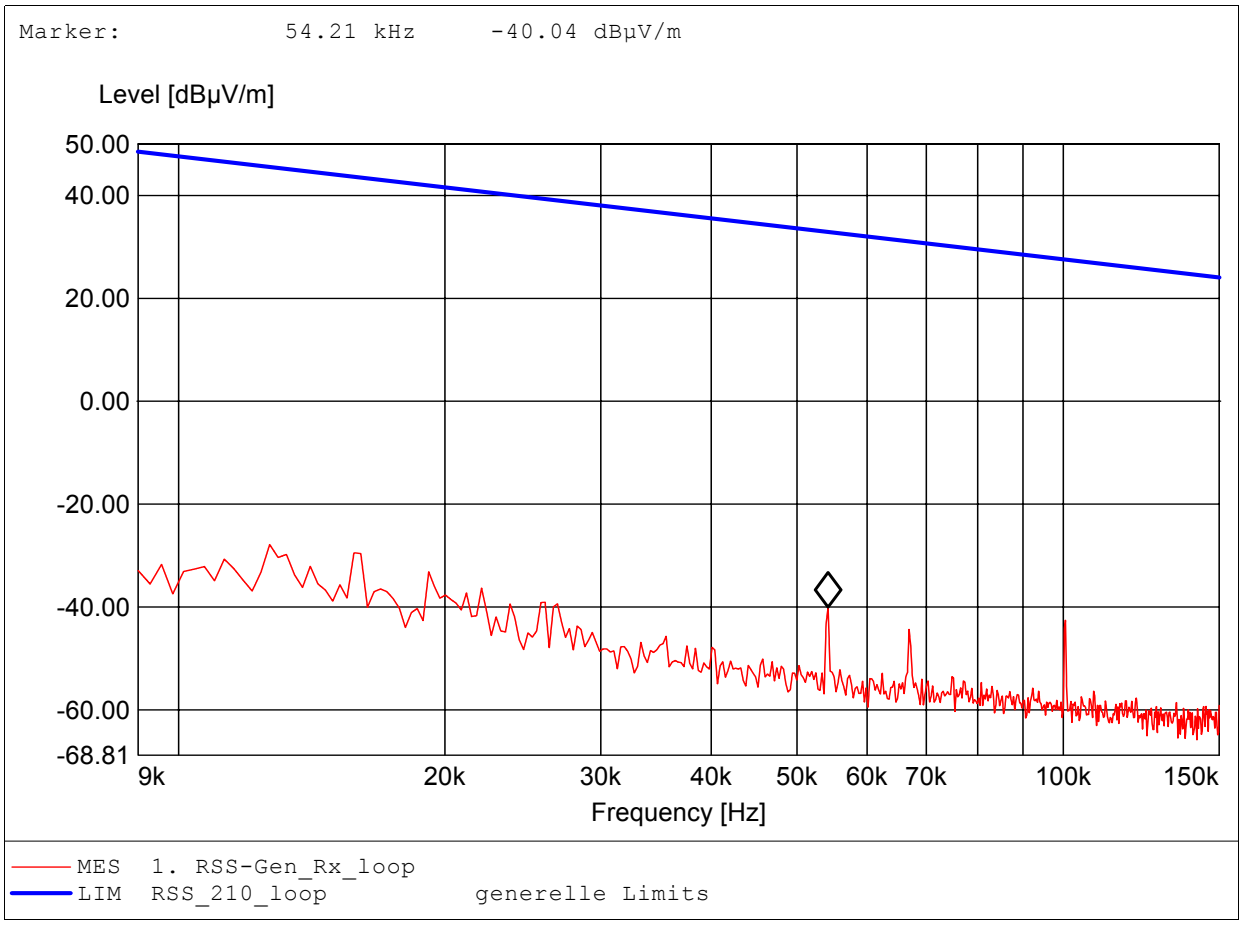


ANNEX B Receiver radiated spurious emissions

Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

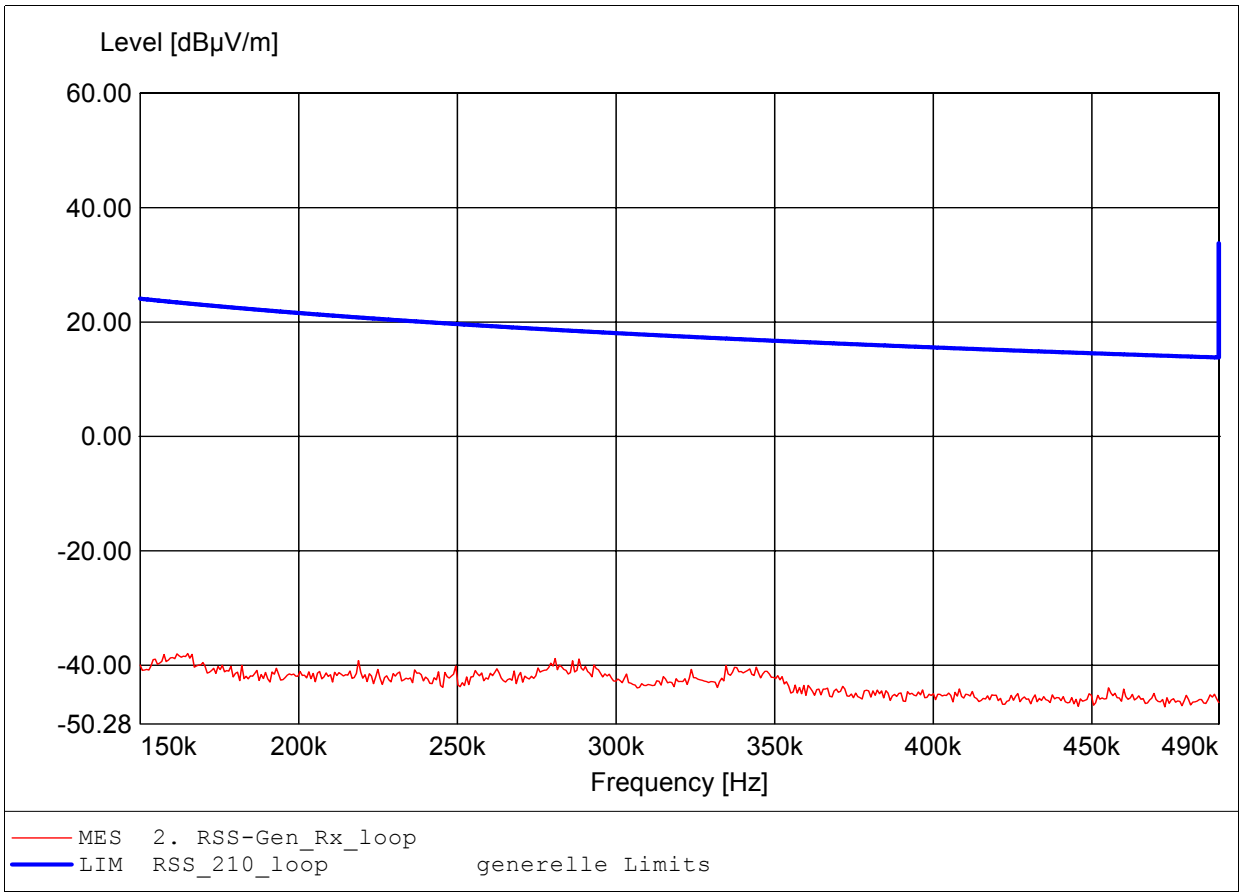
Approval Holder:	BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:	ICD / Implantable Cardioverter Defibrillator
Model:	TACHNXT
Operator:	Eurofins Product Service GmbH / Mr. Treffke
Test Conditions:	Tnom: 22°C / Vnom: 3.0VDC lithium battery
Test Specification:	according to RSS-Gen
Comment 1:	Dist.: 3m converted to 300m, Ant.: HFH2-Z2
Comment 2:	Freq:12.673kHz Emax:-27.86dBµV/m RBW: 200 Hz



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

```
Approval Holder:     BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:                 ICD / Implantable Cardioverter Defibrillator
Model:               TACHNXT
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 22°C / Vnom: 3.0VDC  lithium battery
Test Specification: according to RSS-Gen
Comment 1:           Dist.: 3m converted to 300m, Ant.: HFH2-Z2
Comment 2:           Freq:164.990kHz Emax:-37.97dBµV/m RBW: 10 kHz
```



Field Strength under normal conditions

Standards Industry Canada, RSS-GEN

```
Approval Holder:     BIOTRONIK SE & Co. KG / G0M-1207-2110
EUT:                 ICD / Implantable Cardioverter Defibrillator
Model:               TACHNXT
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 22°C / Vnom: 3.0VDC  lithium battery
Test Specification: according to RSS-Gen
Comment 1:           Dist.: 3m converted to 30m, Ant.: HFH2-Z2
Comment 2:           Freq:681.563kHz Emax:-1.97dBµV/m RBW: 10 kHz
```