eurofins | Product Service

FCC TEST REPORT

FCC 47 CFR Part 15C
Industry Canada RSS-310

License exempt radio equipment

Report Reference No.....:	G0M-1412-4360-TFC209LP-V02
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 4, 2014-11 ANSI C63.4:2009
Equipment under test (EUT):	
Product description	ICD / Implantable Cardioverter Defibrillator
Model No.	Inlexa 1 HF-T
Additional Model(s)	Inlexa 1 DR-T (SN: 60508939) Inlexa 1 VR-T (SN: 60508940)
Brand Name(s)	Inlexa 1
Hardware version	Rev.: 01
Firmware / Software version	ROM: 4.1 / RAM: 3.0
	FCC-ID: QRITACHBORAX IC: 4708A-TACHBORAX
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 ..... : 2015-01-26

Date (s) of performance of tests ..... : 2015-01-26

Compiled by ..... : Wilfried Treffke

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

Approved by (+ signature) ..... : Christian Weber C. Weber

Date of issue ..... : 2016-02-12

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.

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.
All of these differences are only relevant in terms of medical aspects. They do not interfere the RF performance.

Evaluation measurements were performed for worst case antenna selection and the Inlexa 1 HF-T was selected. The model Inlexa 1 HF-T, as the most complex model, was selected for the measurements.

Tach_Borax Family Explanation (G0M-1412-4360)

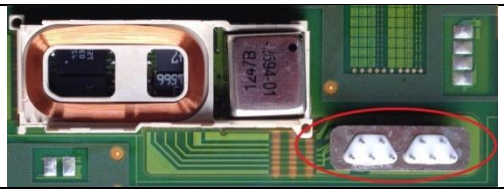
1. Family Letter

	Product Name	Type	no. of chambers	Connector	max.stored energy	SN
1	**Inlexa 1 HF-T**	**CRT**	**3**	**DF-1**	**40J**	**60508938 (Master)**
2	**Inlexa 1 DR-T**	**DR**	**2**	**DF-1**	**40J**	**60508939**
3	**Inlexa 1 VR-T**	**VR**	**1**	**DF-1**	**40J**	**60508940**

2. Family description

2.1 PC-Board

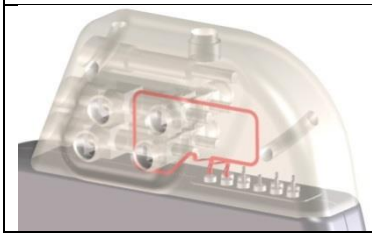
All family devices are using the same electronic. This means all active and all passive electrical components are the same.

PC Board (4190) **10pol feedtrough** **Schematic file SCH-0160_01.pdf**	

2.2 RF-Antenna

The family members are equipped with the identical RF antenna.

DF-1 header with antenna



Signature: *Date:* 2/12/2016

Mark Briesemeister
Junior Manager Regulatory Affairs
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin
Germany

Version History

Version	Issue Date	Remarks	Revised by
01	2015-01-30	Initial Release	
02	2016-02-12	Certification numbers corrected	C. Weber

REPORT INDEX

1 Equipment (Test item) Description

Description	ICD / Implantable Cardioverter Defibrillator	
Model	Inlexa 1 HF-T	
Additional Model(s)	additional models according to family letter	
Brand Name(s)	Inlexa 1	
Serial number	60508938	
Hardware version	Rev.: 01	
Software / Firmware version	ROM: 4.1 / RAM: 3.0	
FCC-ID	QRITACHBORAX	
IC	4708A-TACHBORAX	
Equipment type	End product	
Radio type	Transceiver / Inductive Loop Coil Transmitter	
Radio technology	ULP-AMI	
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	Tach_Borax Coil
	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

MASTER EUT TOP (Inlexa 1 HF-T)

MASTER EUT BOTTOM (Inlexa 1 HF-T)

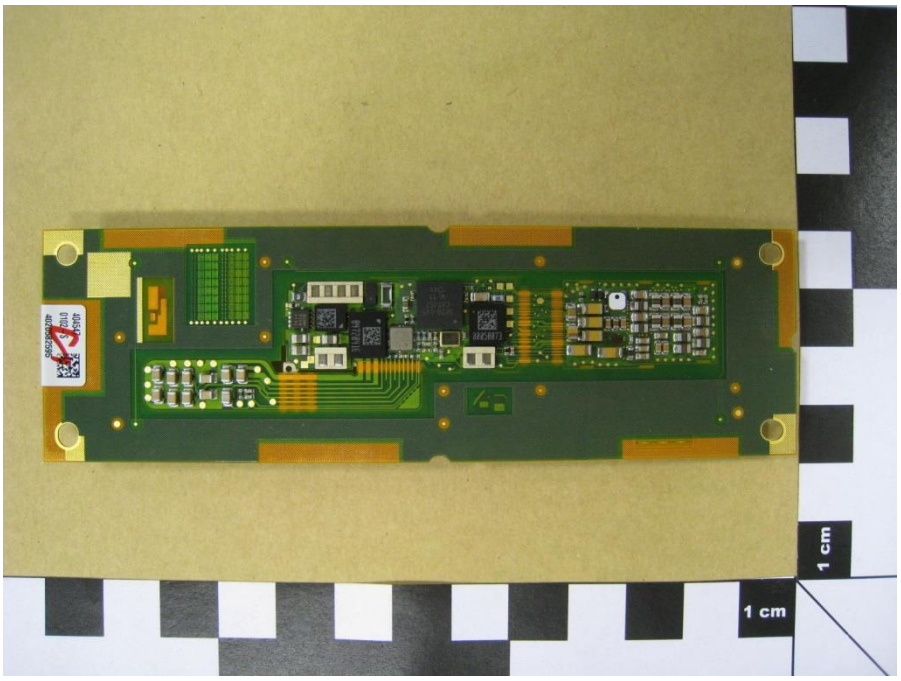
VARIANT Inlexa 1 VR-T

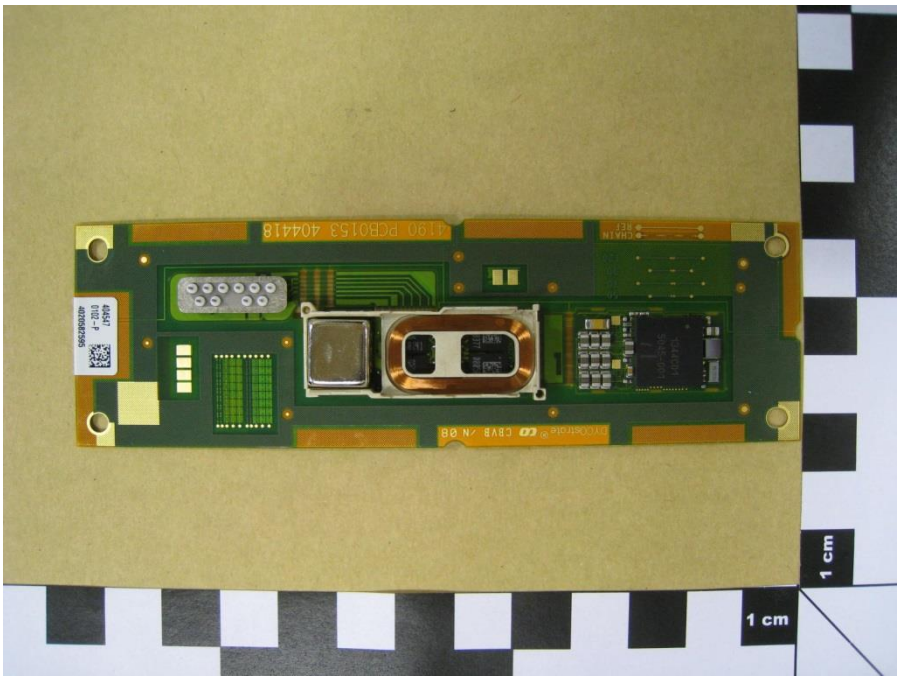
VARIANT Inlexa 1 DR-T

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

AE WIRELESS WAND TelBoxII


1.2 Photos – Equipment internal

PCB TOP


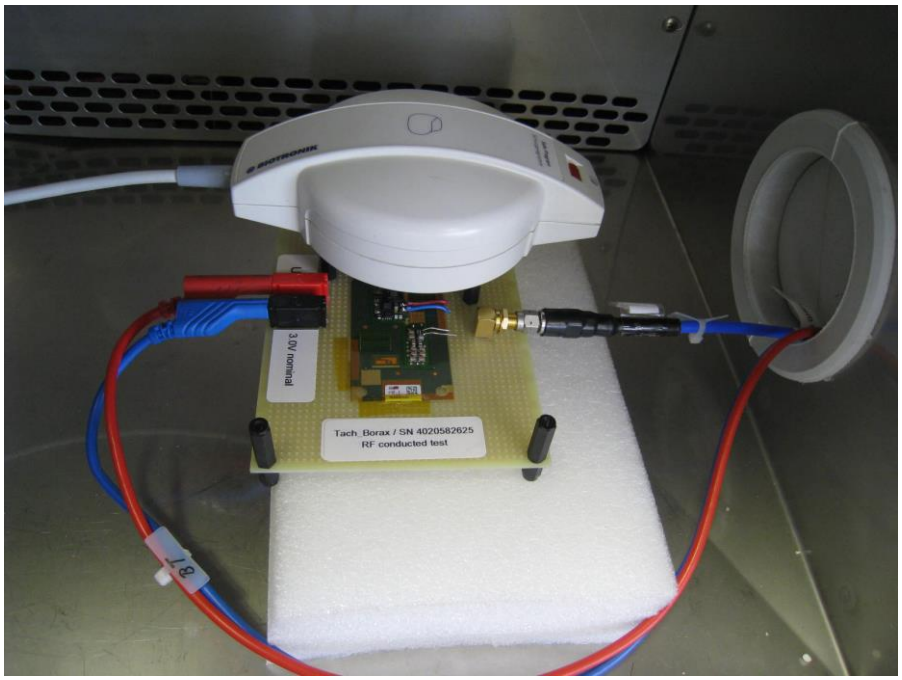
PCB BOTTOM


EUT OPEN


397994
MICRO ENERGY TECHNOLOGIES
MST
AEL 100101
1000000114

1.3 Photos – Test setup

Test setup – Radiated emissions EUT


CONDUCTED SETUP


1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments
AE	Enginnering communication box	BIOTRONIK	TelBoxII	for test mode
AE	Electrode	Biotronik	Linox Smart	-

***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	2014-01-15

Occupied Bandwidth					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Spectrum Analyzer	R&S	FSP 30	EF00312	2014-02	2015-02

Field strength emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-anechoic chamber	Frankonia	AC 5	EF00395	-	-
Spectrum Analyzer	R&S	FSIQ26	EF00242	2014-03	2015-03
Biconical Antenna	R&S	HK 116	EF00012	2013-02	2016-02
LPD antenna	R&S	HL 223	EF00212	2013-02	2016-02
LPD Antenna	R&S	HL 025	EF00327	2013-02	2016-02

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

1.8 Simulated human body

For radiated tests the implant was placed in a simulated human body.

Liquid components	
Component	percentage per weight
Deionized water	52.4
Bactericide	0.08
Hydroxy ethyl cellulose (HCE)	1.0
Sodium chloride	1.4
Sucrose	45.0

Measured tissue parameters:

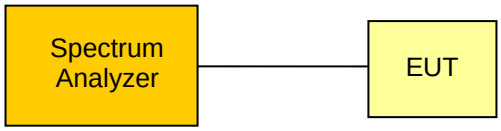
Tissue parameters – 403.5MHz			
Component	Target	Measured	Tolerance [%]
Dielectric constant ε	62.5	63.01	0.82
Conductivity σ [ms/cm]	9.0	8.9	-1.11

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 2.3 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

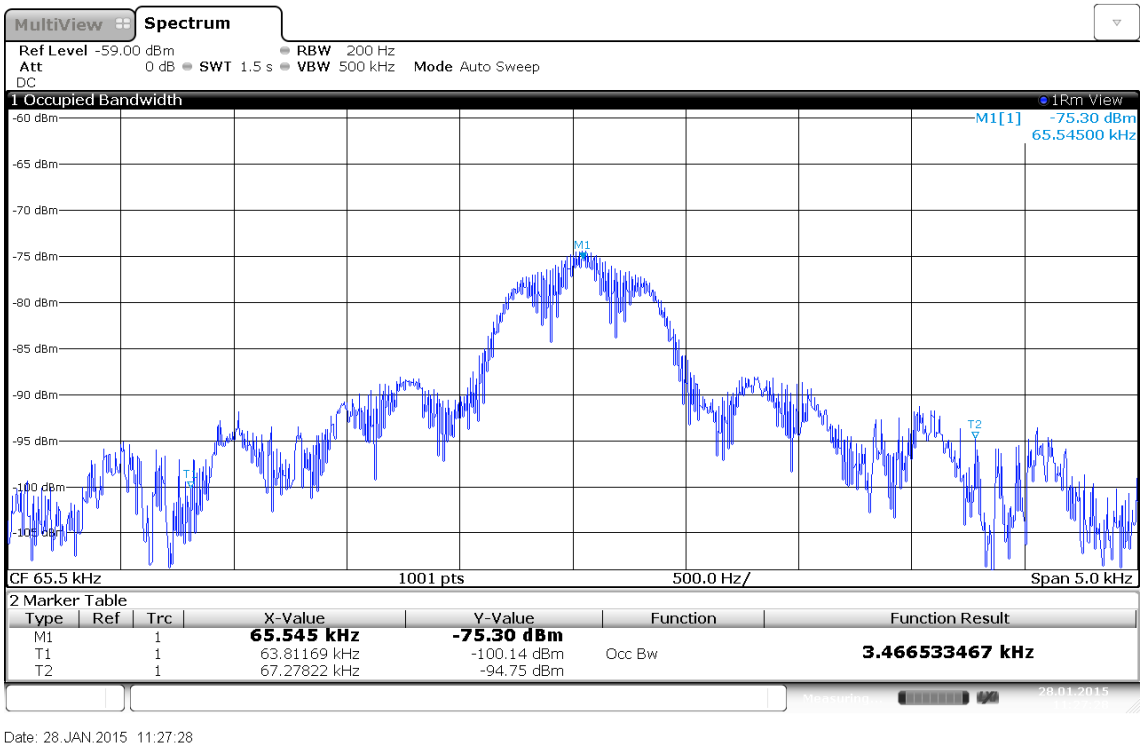
Occupied Bandwidth acc. to IC RSS-Gen		**Verdict: PASS**
Test according to measurement reference	Reference Method	
	RSS-Gen 6.6	
Test frequency range	Tested frequencies	
	F_{MID}	
EUT test mode	Single	
Limits		
None (Informational only)		
Test setup		
		
Test procedure		
1. EUT set to test mode (Communication 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	3.5
Comments: Measurement is applicable to all variants		

Occupied Bandwidth - F_{MID}

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1412-4360

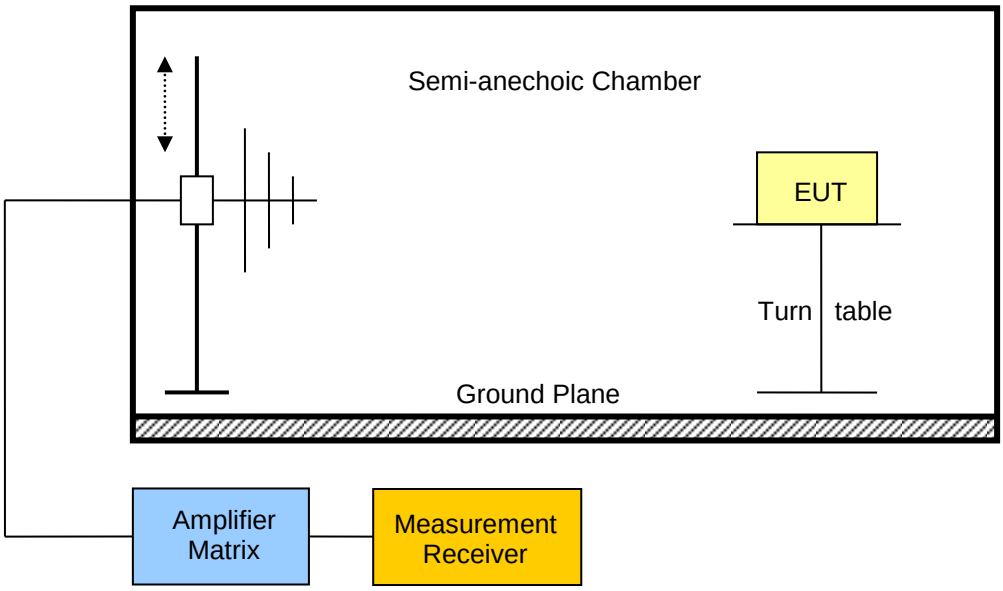
Applicant:	Biotronic SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Inlexa 1
Test Site:	Eurofins Product Service GmbH
Operator:	Wilfried Treffke
Test Conditions:	Tnom / Vnom
Mode:	Tx 64 kHz
Test Date:	2015-01-28
Verdict:	NONE (INFORMATION ONLY)
Note 1:	A spectrum analyzer with 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	Pol.	Limit [dbµV/m]	Limit distance [m]*	Margin [dB]
F_{MID}	64	100.36	-58.90	pk	ver	27.60	300	-86.50
F_{MID}	64	48.528	-63.5	av	ver	33.9	300	-97.40

Comments: * Physical distance between EUT and measurement antenna.

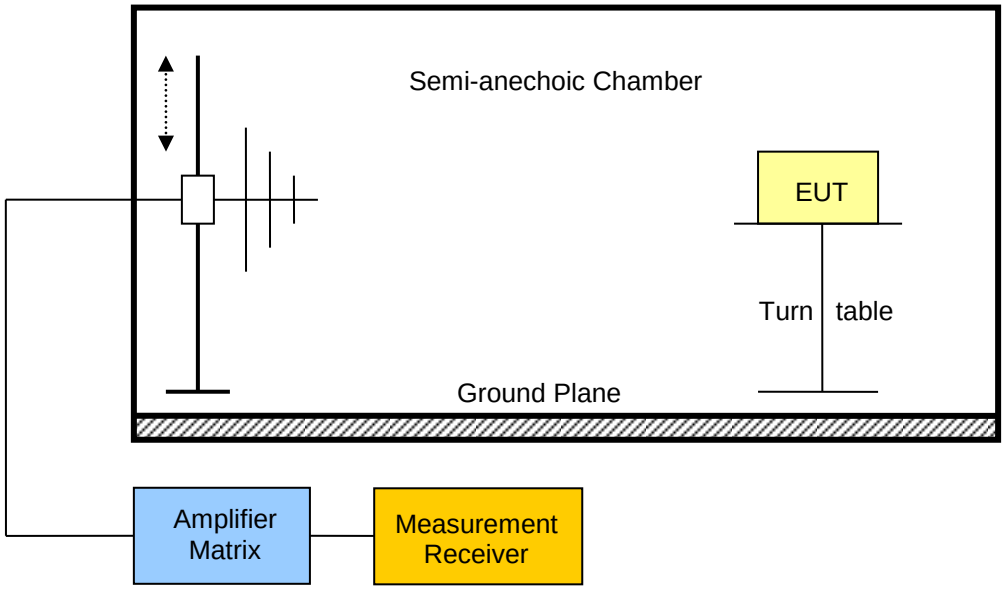
3.4 Test Conditions and Results – Receiver radiated emissions

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
	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]	Det.	Limit [dBdµV/m]	Margin [dBµV/m]
F_{MID}	64	94.68	-62.90	pk	28.1	-91.0 dB
F_{MID}	64	64.40	-66.50	av	31.4	-97.9 dB
F_{MID}	64	417.00	-65.10	av	15.2	-80.3 dB

Comments:

ANNEX A Transmitter radiated spurious emissions

Spurious emissions according to FCC 15.209

Project number: G0M-1412-4360

Applicant:	BIOTRONIK SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Inlexa 1
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC lithium battery
Antenna:	Rohde & Schwarz HFH 2-Z2
Measurement distance:	3 m converted to 300 m
Mode:	TX; 64 kHz
Test Date:	2015-01-26
Note:	

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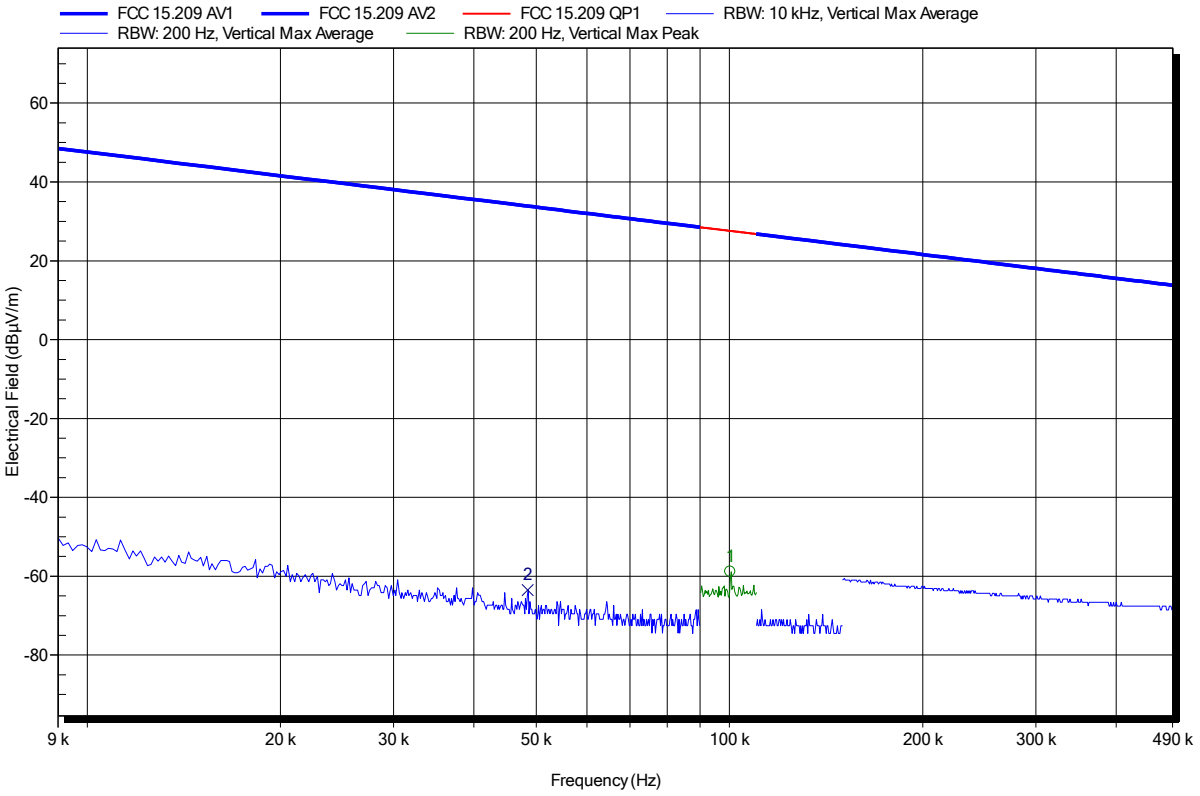

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
100.36 kHz	-58.9 dBµV/m	27.6 dBµV/m	-86.48 dB	Pass

Frequency	Average	Average Limit	Average Difference	Average Status
48.528 kHz	-63.5 dBµV/m	33.9 dBµV/m	-97.41 dB	Pass

Spurious emissions according to FCC 15.209

Project number: G0M-1412-4360

Applicant:	BIOTRONIK SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Inlexa 1
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC lithium battery
Antenna:	Rohde & Schwarz HFH 2-Z2
Measurement distance:	3 m converted to 30 m
Mode:	TX; 64 kHz
Test Date:	2015-01-26
Note:	

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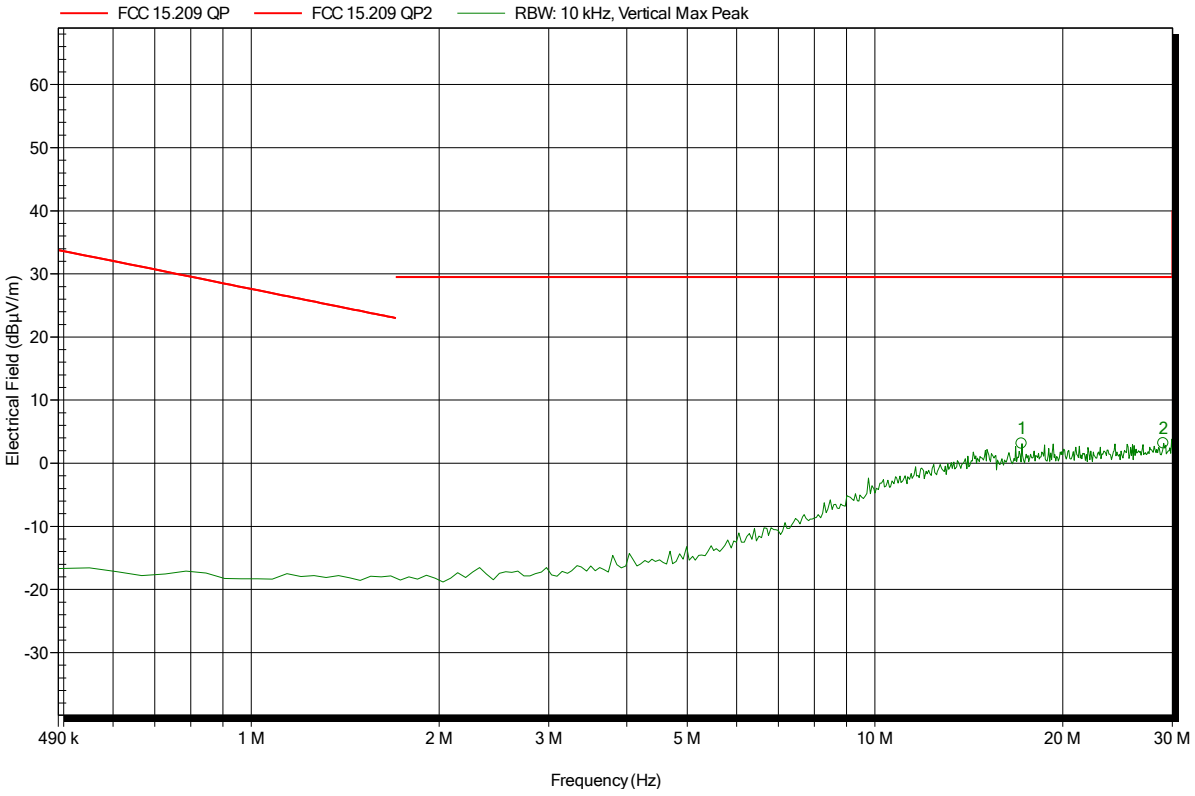

ANNEX B Receiver radiated spurious emissions

Spurious emissions according to RSS-Gen

Project number: G0M-1412-4360

Applicant:	BIOTRONIK SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Inlexa 1
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC lithium battery
Antenna:	Rohde & Schwarz HFH 2-Z2
Measurement distance:	3 m converted to 300 m
Mode:	RX; 64 kHz
Test Date:	2015-01-26
Note:	

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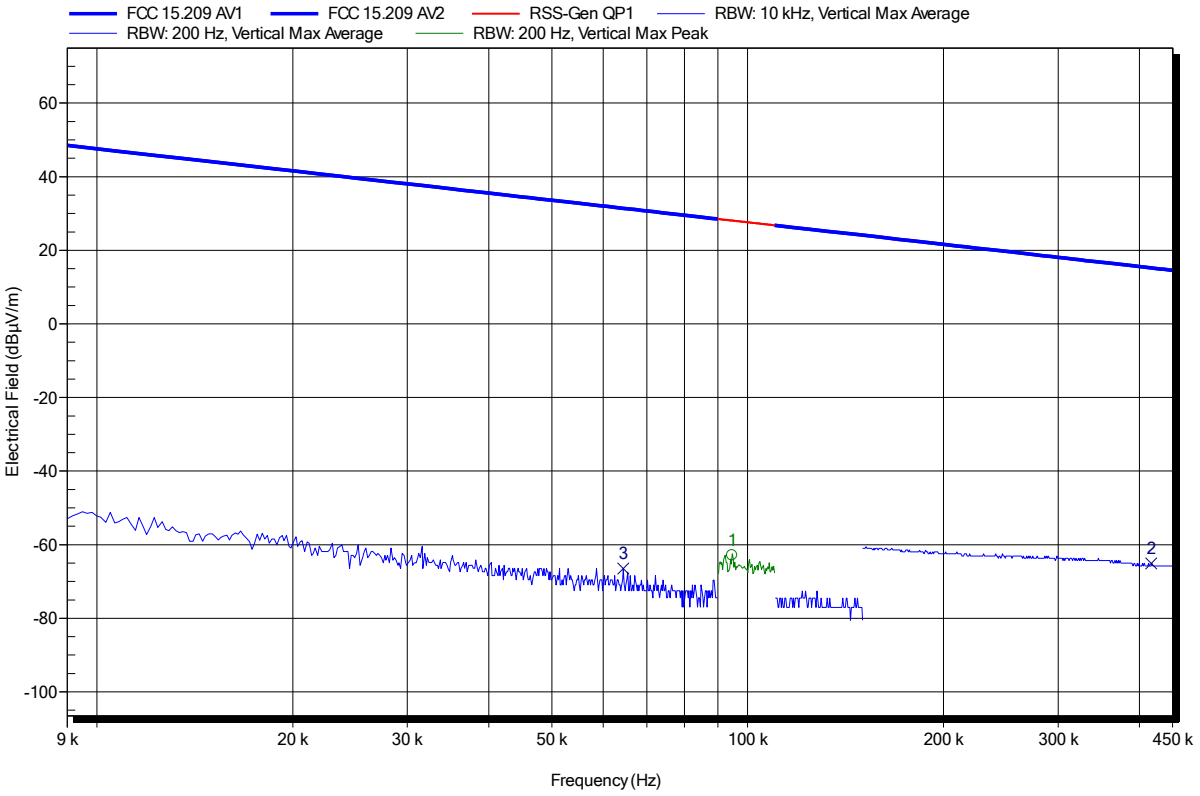

Frequency	Peak	Peak Limit	Peak Difference	Peak Status
94.68 kHz	-62.9 dBµV/m	28.1 dBµV/m	-90.96 dB	Pass

Frequency	Average	Average Limit	Average Difference	Average Status
64.404 kHz	-66.5 dBµV/m	31.4 dBµV/m	-97.89 dB	Pass
417 kHz	-65.1 dBµV/m	15.2 dBµV/m	-80.27 dB	Pass

Spurious emissions according to RSS-Gen

Project number: G0M-1412-4360

Applicant:	BIOTRONIK SE & Co.KG
EUT Name:	ICD / Implantable Cardioverter Defibrillator
Model:	Inlexa 1
Test Site:	Eurofins Product Service GmbH
Operator:	Treffke
Test Conditions:	Tnom: 25°C, Vnom: 3.0 VDC lithium battery
Antenna:	Rohde & Schwarz HFH 2-Z2
Measurement distance:	3 m converted to 30 m
Mode:	RX; 64 kHz
Test Date:	2015-01-26
Note:	

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