EUROFINS PRODUCT SERVICE GMBH

Testing Cert #1983.01

TEST- REPORT

Compliance Test Report

FCC PART 15 SUBPART C
IC RSS 310 ISSUE 3

Implantable Cardioverter Defibrillator

FCC ID: QRILUMAXT50
IC : 4708A-LUMAXT50

Tach50 Substrate 4140

TEST REPORT NUMBER: G0M21101-4127-C-1

Eurofins Product Service GmbH
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Germany

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1 General Information

1.1 Notes

The results of this test report relate exclusively to the item tested as specified in chapter "Description of test item" and are not transferable to any other test items.

Eurofins Product Service GmbH is not responsible for any generalisations and conclusions drawn from this report. Any modification of the test item can lead to invalidity of test results and this test report may therefore be not applicable to the modified test item.

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Operator:

Date	Eurofins-Lab.	Name	Signature
07.04.2011		W. Treffke	W. Treffke

Technical responsibility for area of testing:

Date	Eurofins	Name	Signature
07.04.2011		J. Zimmermann	

1.2 Testing laboratory

EUROFINS PRODUCT SERVICE GMBH
Storkower Strasse 38c
D-15526 Reichenwalde b. Berlin
Germany
Telefon : +49 33631 888 00
Telefax : +49 33631 888 660

DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-NO. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470

Test location, where different:

Name	: ./.
Street	: ./.
Town	: ./.
Country	: ./.
Telephone	: ./.
Fax	: ./.

1.3 Details of approval holder

Name	: BIOTRONIK SE & Co. KG
Street	: Woermannkehre 1
Town	: 12359 Berlin
Country	: Germany
Telephone	: 030/68905-1213
Fax	: 030/68905-5409
Contact	: Herr Gunnar Börsch
Telephone	: 030/68905-1213

1.4 Application details

Date of receipt of application	: 24.01.2011
Date of receipt of test item	: 24.01.2011
Date of test	: 24.01.2011

1.5 Test item

Description of test item	: Implantable Cardioverter Defibrillator
Type identification	: Tach50 Substrate 4140
Tested model	: Lumax 740 HF-T
Serial number	: 60498675
Hardware version	: Substrate 4140 Rev.: 1C Version 12
Software version	: ROM: 2.2 / RAM: 1.0

Technical data

Frequency range	: 32kHz
Tested frequencies	: F_1 32kHz
Antenna	: non-removable connected to device
Power supply	: 3VDC (Lithium-Battery)
Modulation	: OOK
Transmitter type	: End product

Manufacturer:
(if applicable)

Name	: BIOTRONIK SE & Co. KG
Street	: Woermannkehre 1
Town	: 12359 Berlin
Country	: Germany

1.6 Test standards

Technical standard	: **FCC PART 15 SUBPART C § 15.201 / 15.209** **IC RSS 310 ISSUE 3 / RSS-Gen ISSUE 3**

1.7 Additional information

In agreement with the customer testing was performed with a Lumax 740 HF-T as a representative for the Lumax 6XX and Lumax 7XX model families.

The approval holder gives the following declarations about the two families:

Variants: Lumax 600/640/700/740 VR-T/ VR-T DX/DR-T/HF-T

The Lumax 6XX and the Lumax 7XX are two model families. Both families use the Tach50 Substrate 4140 electronic module and are therefore identical in hardware. That means that there are also no differences with respect to the RF-part between both families. The transmitter/receiver parts of all models of both families are identical to the tested model. The two families only differ in firmware. The Lumax 7XX family offers additional clinical therapy functions.

Each family offers a 30 joule and a 40 joule model. The joule value is represented by the two XX in the model name; 00 = 30 joule, 40 = 40 joule.

Additionally each family offers the VR-T, DR-T and HF-T variants. The VR-T variant denotes a single chamber header model, the DR-T a dual chamber header model and the HF-T a triple chamber header model.

For VR-T variants (Lumax 6XX and Lumax 7XX) a special DX configuration exists that offers additional diagnostics but uses identical electronic module and antenna.

As described all model variations does not affect the rf-section of the device and for this reason the results given in this test report are supposed to be valid for all the described variations of the two denoted model families.

1.8 Acronyms and abbreviations

EUT	:	Equipment under Test
TX	:	Transmission
RX	:	Reception
RBW	:	Measurement Resolution Bandwidth
Pol	:	Measurement Polarization
T_{nom}	:	Nominal Temperature
T_{min}	:	Minimum Temperature
T_{max}	:	Maximum Temperature
V_{nom}	:	Nominal Supply Voltage
V_{min}	:	Minimum Supply Voltage
V_{max}	:	Maximum Supply Voltage
VDC	:	DC voltage
N/A	:	Not applicable

2 Technical test

2.1 Summary of test results

No deviations from the technical specification(s) were ascertained in the course of the tests performed. ☒

or

The deviations as specified in 2.4 were ascertained in the course of the tests performed. ☐

2.2 Test environment

Temperature	: 22	...	26°C
Relative humidity content	: 20	...	75%
Air pressure	: 86	...	103kPa

Extreme conditions parameters:

V_{nom} : 3VDC

T_{nom} : 25°C

2.3 Test equipment utilized

Measurement Equipment List					
No.	**Measurement device:**	**Type:**	**Manufacturer:**	**Last Cal.**	**Next Cal.**
ETS 0178	Open area test side	10m	Eurofins Product Service	08.10.2010	08.10.2012
ETS 0291	Loop antenna	HFH2-Z2	Rohde & Schwarz	06.04.2010	06.04. 2011
ETS 0496	Spectrum Analyzer	FSP30	Rohde & Schwarz	26.08.2010	26.08.2011

2.4 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			
Frequency [MHz]	403.5MHz		
Component	**Target**	**Measured**	**Tolerance [%]**
Dielectric constant ε	62.5	63.08	0.93
Conductivity σ [ms/cm]	9.0	8.8	-2.22

2.5 Test results

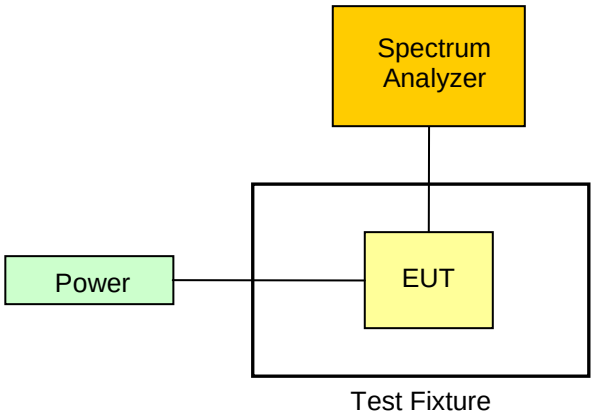
Test case	Subclause	Required	Test passed	Test failed
INFORMATIONAL TRANSMITTER PARAMETERS				
Occupied Bandwidth	IC RSS Gen. 4.6.1	☒		
TRANSMITTER PARAMETERS				
Radiated spurious emissions	FCC § 15.201 FCC § 15.209 IC RSS 310 3.7 IC RSS Gen 4.9 & 7.2.5	☒	☒	☐

3 Transmitter parameters

3.1 Occupied Bandwidth

The 99% emission bandwidth occupied by the modulated transmitted signal has to be reported as calculated or measured.

3.1.1 Measurement procedure



The eut is connected to a spectrum analyzer and set to transmission mode with maximum power under normal test conditions. The span of the analyzer is set wide enough to capture all significant emissions of the modulation spectrum. The resolutions bandwidth is set as close as possible to 1% of the selected span without being below 1%. The occupied bandwidth is than measured evaluated by an internal measurement procedure of the analyzer.

3.1.2 Results

Transmitter occupied bandwidth		
Measurement Conditions		
Nominal frequency :	32kHz	
Power occupation :	99%	
Lower edge frequency [kHz]	**Upper edge frequency [kHz]**	**Occupied Bandwidth [kHz]**
30.868	34.928	4.06
See attached diagram in Annex		
Verdict		**PASS**

3.2 Transmitter spurious emissions

The unwanted emissions of intentional operators have to comply with the field strength emission limits.

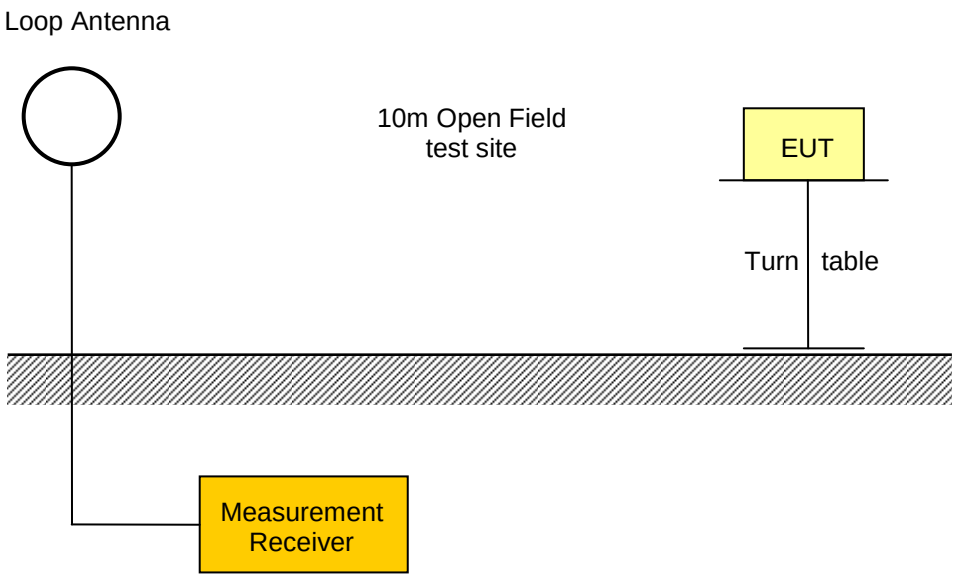
3.2.1 Limits

The following table lists all spurious emission limits in the frequency range of 9kHz to 30MHz.

Tranmitter spurious emission limits				
Tx-state	**Frequency range [MHz]**	**Limit [µV/m]**	**Calculated Limit [dBµV/m]**	**Measurement Distance [m]**
Operational	0.009 – 0.490	2400/F[kHz]	48.5 – 13.8	300
	0.490 – 1.705	2400/F[kHz]	33.8 - 23	30
	1.705 – 30.0	30	29.5	30
	30 – 88	100	40	3
	88 – 216	150	43.5	3
	216 – 960	200	46	3
	> 960	500	54	3

3.2.2 Measurement procedure

The spurious emission measurement is performed on a 10m open area test site.



The eut is placed on a non-metallic table. Any emission is received by a loop antenna and measured via a measurement receiver connected to the loop antenna. To obtain the maximum emission the eut is rortated through 360°.

Due to pratical reasons the spurious emission level check is first performed with a peak detector and the quasi-peak and average limits.

If any emission is detected that gets close to the emission limit the detector is changed and the quasi-peak or average detector is used. Which detector is used is determined by the emission frequency. If pulsed transmission is used, averaging over the pulse train is used.

The measurement values are also corrected to obtain the field strength values at the defined measurement distances of the emission limits.

The measurement is performed over the frequency range of 9kHz to 30MHz.

3.2.3 Results

Transmitter spurious Emissions					
Measurement Conditions					
Nominal frequency :	32kHz				
Modulated :	☒ Yes ☐ No				
Pulsed :	☒ Yes ☐ No				
Emission Frequency [kHz]	**Measured Field Strength * [dBµV/m]**	**Limit Measurement Distance [m]**	**Detektor**	**Limit [dBµV/m]**	**Margin [dB]**
48	-52.04	300	Peak	33.98	86.01
See attached diagrams in Annex					
Verdict				**PASS**	

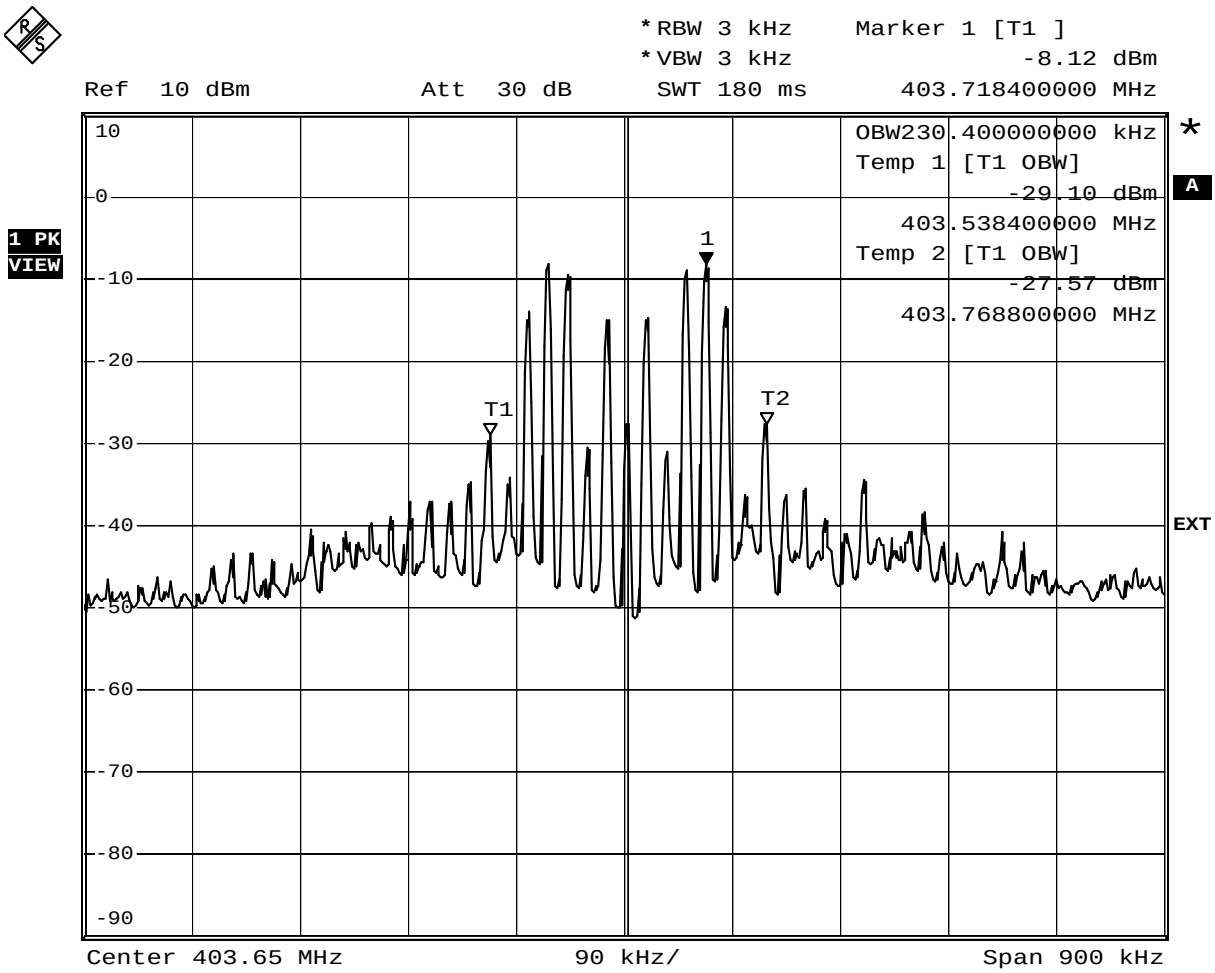
*** Note :** The measured field strength values are corrected to reflect the field strength values at the measurement distance stated in the table.

Comment : All measured emission levels up to the then harmonic are more than 40dB below the corresponding spurious limit. According 47 CFR 15§201 and RSS310 Devices operating below 490kHz whose emission are all at least 40dB below the spurious limit only need to be verified.

Annex B Occupied bandwidth

RSS-Gen
Occupied frequency bandwidth

EUT	ICD (medical implantable device)
Model	Lumax 6XX /Lumax 7xx
Approval Holder	Biotronik SE & Co. KG
Temperature / Voltage	25°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr Treffke
Test Specification	Occupied frequency bandwidth
Comment 1	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 2	Carrier channel: 403.65 MHz
Comment 3	Limit: < 300KHz



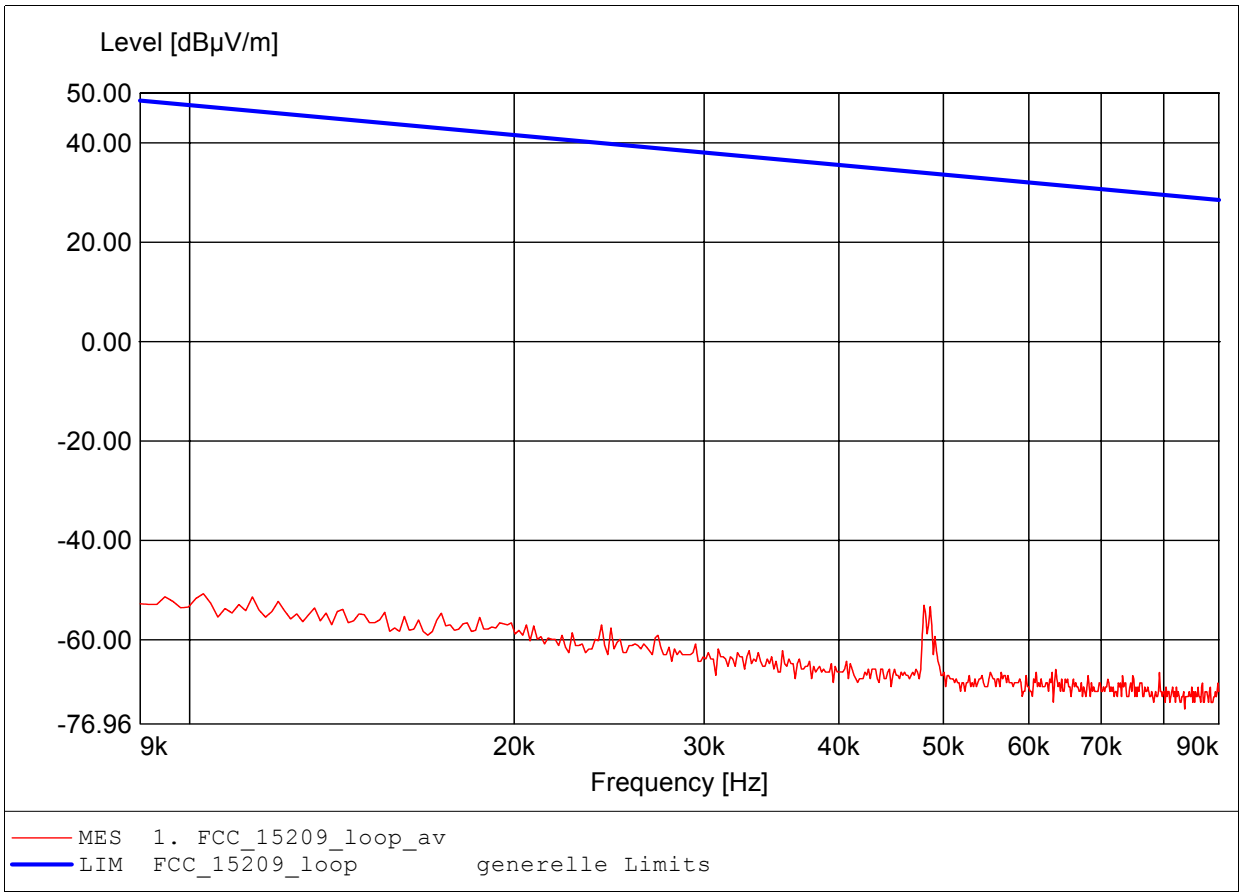
Comment: Occupied bandwidth: 230.4 KHz
Date: 26.JAN.2011 14:12:55

Annex C Transmitter radiated spurious emissions

Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

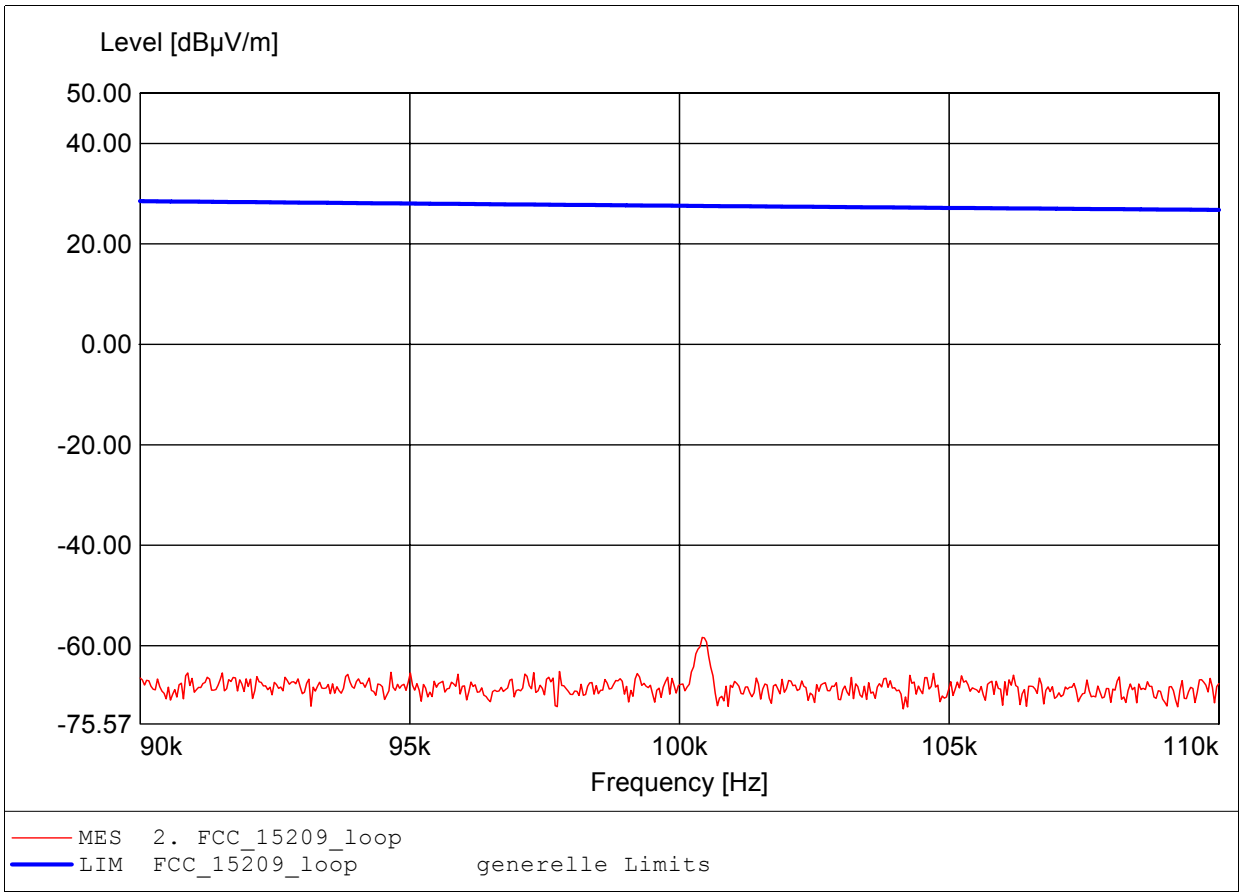
Approval Holder:	Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT:	ICD (Implantable Cardioverter Defibrillator)
Model:	Lumax 6XX / Lumax 7XX
Operator:	Eurofins Product Service GmbH / Mr. Treffke
Test Conditions:	Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification:	according to §15.209, average detector
Comment 1:	Dist.: 3m corrected to 300m, Ant.: HFH2-Z2
Comment 2:	Freq: 10.299kHz, Emax: -50.74dBµV/m, RBW: 200Hz



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

Approval Holder:	Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT:	ICD (Implantable Cardioverter Defibrillator)
Model:	Lumax 6XX / Lumax 7XX
Operator:	Eurofins Product Service GmbH / Mr. Treffke
Test Conditions:	Tnom: 25°C / Vnom: 3.0 V DC (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: -58.34dBµV/m, RBW: 200Hz



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

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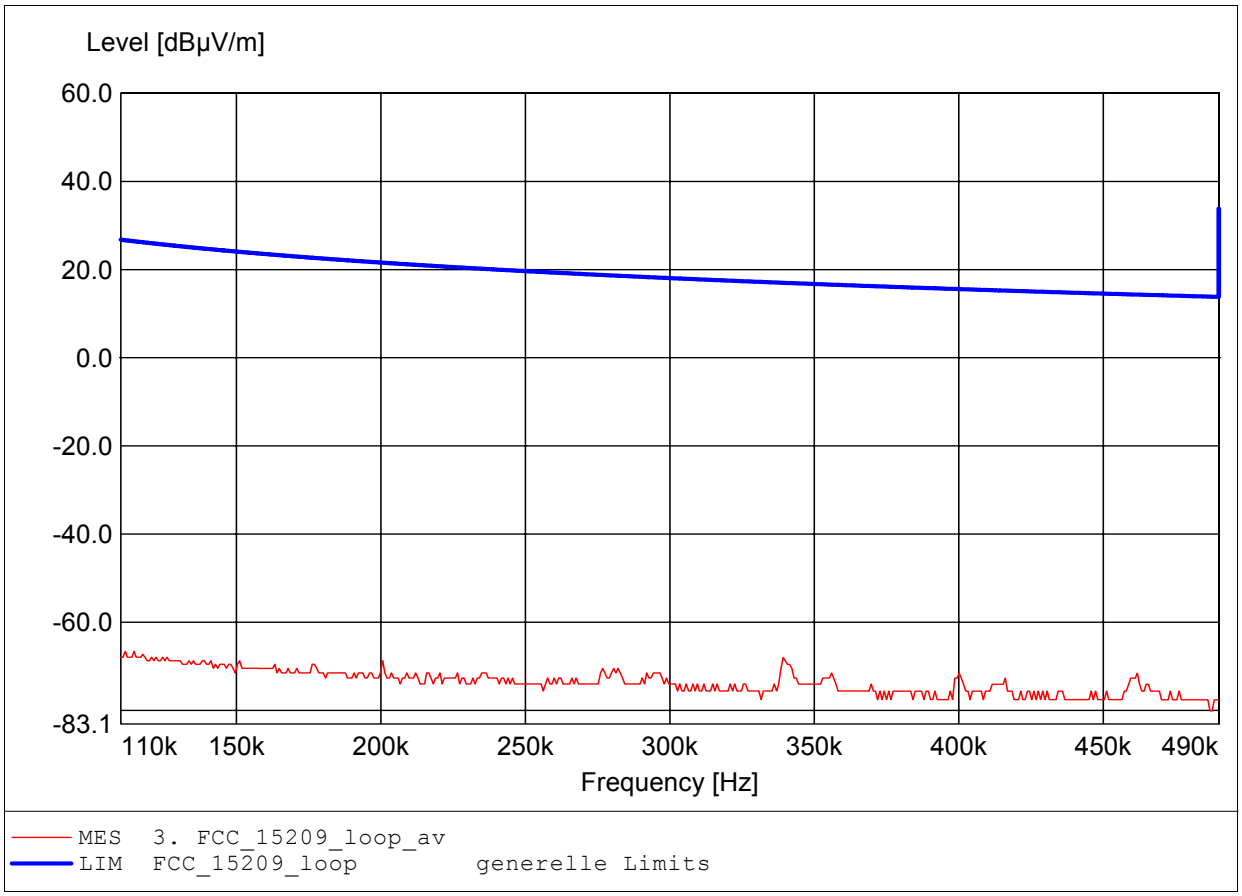
Approval Holder:     Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT:                 ICD (Implantable Cardioverter Defibrillator)
Model:               Lumax 6XX / Lumax 7XX
Operator:            Eurofins Product Service GmbH   /   Mr. Treffke
Test Conditions:     Tnom: 25°C / Vnom: 3.0 V DC  (battery)
Test Specification: according to §15.209, average detector
Comment 1:           Dist.: 3m corrected to 300m, Ant.: HFH2-Z2
Comment 2:           Freq: 111.523kHz, Emax: -66.64dBµV/m, RBW: 200Hz
```



Spurious emissions Field Strength Tx

FCC RULES PART 15, SUBPART C

Approval Holder:	Biotronik SE & Co. KG / Ord.: G0M21101-4127
EUT:	ICD (Implantable Cardioverter Defibrillator)
Model:	Lumax 6XX / Lumax 7XX
Operator:	Eurofins Product Service GmbH / Mr. Treffke
Test Conditions:	Tnom: 25°C / Vnom: 3.0 V DC (battery)
Test Specification:	according to §15.209, peak detector
Comment 1:	Dist.: 3m corrected to 30m, Ant.: HFH2-Z2
Comment 2:	Freq: 25.746MHz, Emax: 3.43dBµV/m, RBW: 10kHz