

EMC TEST REPORT

FCC 47 CFR Part 15B
Industry Canada ICES-003

Electromagnetic compatibility - Unintentional radiators

Report Reference No. : G0M-1603-5489-EF0115B-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 15 Subpart B
ICES-003, Issue 5:2012
ANSI C63.4:2014

Equipment under test (EUT):

Product description	Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall	
Model No.	Qubic Force	
Additional Models	None	
Hardware version	HWS.A	
Firmware / Software version	FU_MR1.x	
Contains	FCC-ID: QRIQFORCE	IC: 4708A-QFORCE
Test result	Passed	

Test Report No.: G0M-1603-5489-EF0115B-V01

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

Possible test case verdicts:

- not applicable to test object: N/A
- test object does meet the requirement.....: P (Pass)
- test object does not meet the requirement.....: F (Fail)

Testing:

Date of receipt of test item: 2016-04-11

Date (s) of performance of tests: 2016-04-26 - 2016-05-11

Compiled by: Yu Yu

Tested by (+ signature).....: Yu Yu



Approved by (+ signature): Jens Marquardt
Deputy Head of Lab



Date of issue: 2016-05-30

Total number of pages: 31

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.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

Additional comments:

The tested representative configurations, consistent with INTENDED USE, are most likely to result in unacceptable EMC RISK.
Other possible auxiliary equipment are listed in the following tables.

List of Accessories

Accessories: (i.e. power cord / patient cable)	• VK-118/ 0,5m, 5m, 30m; (Ethernet data cable) • VK-119 (RS-232 data cable) • VK-120 (RS-232 null-modem cable) • VK-124 (HDMI cable); Cable for connecting external monitor • PK-147; Cable for connecting a BIOTRONIK ablation catheter (AICath Force); • PK-147; Cable for connecting ablator Stockert EP Shuttle • PK-111; Cable for connecting ablator Osypka HAT 300 Smart • PK-112; Cable for connecting ablator Medtronic Atakr • PK-142; Cable for connecting ablator SJM IBI-1500 • PK-143; Cable for connecting ablator BSC Maestro • PK 150; Cable for connecting ablator Stockert SmartAblate • NK-3 ; Power cord for EU • NK-11 ; Power cord for USA and Japan • NK-16-GB ; Power cord for the United Kingdom • NK-19-CN ; Power cord for China • NK-21-AU, UY; Power cord for Australia and Uruguay • NK-22-AR ; Power cord for Argentina • NK-25-CH ; Power cord for Switzerland • NK-26-CL, IT ; Power cord for Chile and Italy • NK-27-IL ; Power cord for Israel • NK-28-DK ; Power cord for Denmark • NK-33-BR ; Power cord for Brazil
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Cable Information

Cable length/Shielding:

Type	Length	Shielding
VK-118 (Ethernet cable)	0.5 m	Yes
	5.0 m	Yes
	30 m	Yes
VK-119 (RS-232 data cable)	1.8 m	Yes
VK-120 (RS-232 data cable)	1.8 m	Yes
VK-124 (HDMI cable)	5.0 m	Yes
	15.0 m	Yes
PK-111	2.0 m	No
PK-112	2.0 m	No
PK-142	2.5 m	No
PK-143	2.5 m	No
PK-147	2.5 m	No
PK-150	2.5 m	No
NK-3	2,5 m	No
NK-11	3,0 m	No
NK-16-GB	2,0 m	No
NK-19-CN	2,5 m	No
NK-21-AU, UY	2,5 m	No
NK-22-AR	2,5 m	No
NK-25-CH	2,5 m	No
NK-26-CL, IT	2,5 m	No
NK-27-IL	2,5 m	No
NK-28-DK	2,5 m	No
NK-33-BR	2,5 m	No

Version History

Version	Issue Date	Remarks	Revised by
V01	2016-05-30	Initial Release	

REPORT INDEX

1	EQUIPMENT (TEST ITEM) DESCRIPTION	7
1.1	Photos – Equipment external	8
1.2	Photos – Equipment internal	11
1.3	Photos – Test setup	13
1.4	Supporting Equipment Used During Testing	14
1.5	Input / Output Ports	14
1.6	Operating Modes and Configurations	15
1.7	Test Equipment Used During Testing	16
1.8	Sample emission level calculation	17
2	RESULT SUMMARY	18
3	TEST CONDITIONS AND RESULTS	19
3.1	Test Conditions and Results – Radiated emissions	19
3.2	Test Conditions and Results – AC power line conducted emissions	28

1 Equipment (Test item) Description

Description	Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall	
Model	Qubic Force	
Additional Models	None	
Serial number	64300004	
Hardware version	HWS.A	
Software / Firmware version	FU_MR1.x	
Contains FCC-ID	QRIQFORCE	
Contains IC	4708A-QFORCE	
Power supply	100-240V AC 50/60Hz	
Radio module	Type	RFID
	Model	RFIDM 1356 - 001
	Manufacturer	KTS - Kommunikationstechnik & Systeme
	HW Version	2.1
	SW Version	3.17
Manufacturer	Biotronik SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY	
Highest emission frequency	1GHz	
Device classification	Class A	
Equipment type	Tabletop	
Number of tested samples	1	

1.4 Supporting Equipment Used During Testing

Product Type*	Device	Manufacturer	Model No.	Comments (e.g. serial no.)
AE	Catheter	Biotronik	ALCath Force Red	
CABL	Ablation catheter connection	Biotronik	PK-147	Between EUT and ALCath Force
CABL	Ablator connection	Biotronik	PK-147	Between EUT and RF generator
AE	Monitor	Samsung	LE22B350F2WXXC	
AE	USB	Lexar	LJD850-16G	

***Note:** Use the following abbreviations:

AE : Auxiliary/Associated Equipment, or

SIM : Simulator (Not Subjected to Test)

CABL : Connecting cables

1.5 Input / Output Ports

Port #	Name	Type*	Max. Cable Length	Cable Shielded	Comments (e.g. Cat. of Cable)
1	Power	AC	2.5	No	
2	HDMI-Port	I/O	15	Yes	
3	USB	I/O	-	No	For direct plug only
4	Generator input	RF	2.5	No	
5	Catheter	RF	2.5	No	
6	Optical catheter	N/E	2.5	No	
7	Ethernet	TP	30	Yes	Won't be used
8	RS232-DTE	I/O	1.8	Yes	Won't be used
9	RS232-DCE	I/O	1.8	Yes	Won't be used
10	AUX output(typo)	I/O	-	No	Won't be used

***Note:** Use the following abbreviations:

AC : AC power port

DC : DC power port

N/E : Non electrical

I/O : Signal input or output port

TP : Telecommunication port

1.6 Operating Modes and Configurations

Mode #	Description
1	Measuring and displaying the contact force of the catheter tip

Configuration #	EUT Configuration
1	Generator input port is connected with PK-147 Catheter port is connected with PK-147 and catheter AICath Force Optical Catheter port is connected with catheter AICath Force HDMI port is connected with VK-124(15m) to external monitor Binary interface 1 (RS-232 port) is connected with a null-modem cable (VK-120) Binary interface 2 (RS-232 port) is connected with a serial data cable (VK-119) USB-stick on USB- port Ethernet interface is connected with VK-118 (30 m)
2	Generator input port is connected with PK-147 Catheter port is connected with PK-147 and catheter AICath Force Optical Catheter port is connected with catheter AICath Force HDMI port is connected with VK-124(15m) to external monitor Binary interface 1 (RS-232 port) is connected with a null-modem cable (VK-120) Binary interface 2 (RS-232 port) is connected with a serial data cable (VK-119) Ethernet interface is connected with VK-118 (30 m)

1.7 Test Equipment Used During Testing

Measurement Software			
Description	Manufacturer	Name	Version
EMC Test Software	Dare Instruments	Radimation	2015.1.12

Radiated emissions – 3m Chamber					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Biconical Antenna	R&S	HK 116	EF00012	2016-02	2019-02
LPD-Antenne	R&S	HL 223	EF00187	2014-03	2017-03
Horn antenna	Schwarzbeck	BBHA 9120D	EF00018	2013-09	2016-09
EMI Test Receiver	R&S	ESU26	EF00887	2016-01	2017-01

Conducted emissions					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
AMN	R&S	ESH2-Z5	EF00182	2014-11	2016-11
AMN	R&S	ESH3-Z5	EF00036	2014-12	2016-12
EMI Test Receiver	R&S	ESR7	EF00943	2015-09	2016-09
Cable	-	RG58/U	-	System Cal.	System Cal.

1.8 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 μ 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 μ V/m). The FCC limits are given in units of μ V/m. The following formula is used to convert the units of μ V/m to dB μ 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:

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

2 Result Summary

FCC 47 CFR Part 15B, Industry Canada ICES-003				
Product Specific Standard	Requirement – Test	Reference Method	Result	Remarks
47 CFR 15.109 ICES-003 Item 6.2	Radiated emissions	ANSI C 63.4	PASS	-
47 CFR 15.107 ICES-003 Item 6.1	AC power line conducted emissions	ANSI C63.4	PASS	-
Remarks:				

3 Test Conditions and Results

3.1 Test Conditions and Results – Radiated emissions

Radiated emissions acc. FCC 47 CFR 15.109 / ICES-003				Verdict: PASS		
Laboratory Parameters:		Required prior to the test		During the test		
Ambient Temperature		15 to 35 °C		22.4 °C		
Relative Humidity		30 to 60 %		35 %		
Test according referenced standards		Reference Method				
		ANSI C63.4				
Sample is tested with respect to the requirements of the equipment class		Equipment class				
		A				
Test frequency range determined from highest emission frequency		Highest emission frequency				
		1 GHz				
Fully configured sample scanned over the following frequency range		Frequency range				
		30 MHz to 5 GHz				
Operating mode		1				
Configuration		1				
Limits and results Class A						
Frequency [MHz]	Quasi-Peak [dBµV/m]	Result	Average [dBµV/m]	Result	Peak [dBµV/m]	Result
30 – 88	39.085	PASS	-		-	-
88 – 216	43.522	PASS	-		-	-
216 – 960	46.444	PASS	-		-	-
960 – 1000	49.542	PASS	-		-	-
> 1000	-	-	54	PASS	74	PASS
Comments:						

Test Procedure:

The test site is in accordance with ANSI C63-4:2014 requirements and is listed by FCC.
The measurement procedure is as follows:

Exploratory measurement:

- The EUT was placed on a non-conductive table at a height of 0.8m.
- The EUT and support equipment were set up to simulate typical usage.
- Cables, of type and length specified by the manufacturer, were connected to at least one port of each type and were terminated by a device or simulating load of actual usage.
- The antenna was placed at a distance of 3 or 10 m.
- The received signal was monitored at the measurement receiver.
 - Cables not bundled were manipulated within the range of likely arrangements to produce the highest emission amplitude
 - To maximize the suspected emissions the EUT is rotated 360 degrees. If the signal exceeds the previous amplitude, go back to the corresponding azimuth and manipulate the cables again for maximizing the emissions if possible.
 - Move the antenna from 1 to 4m to maximize the suspected highest amplitude signal.
- This procedure has to be performed in both antenna polarizations, horizontal and vertical.
- The arrangement of the equipment with the maximum emission level is shown on the setup picture at item 1.3.

Final measurement:

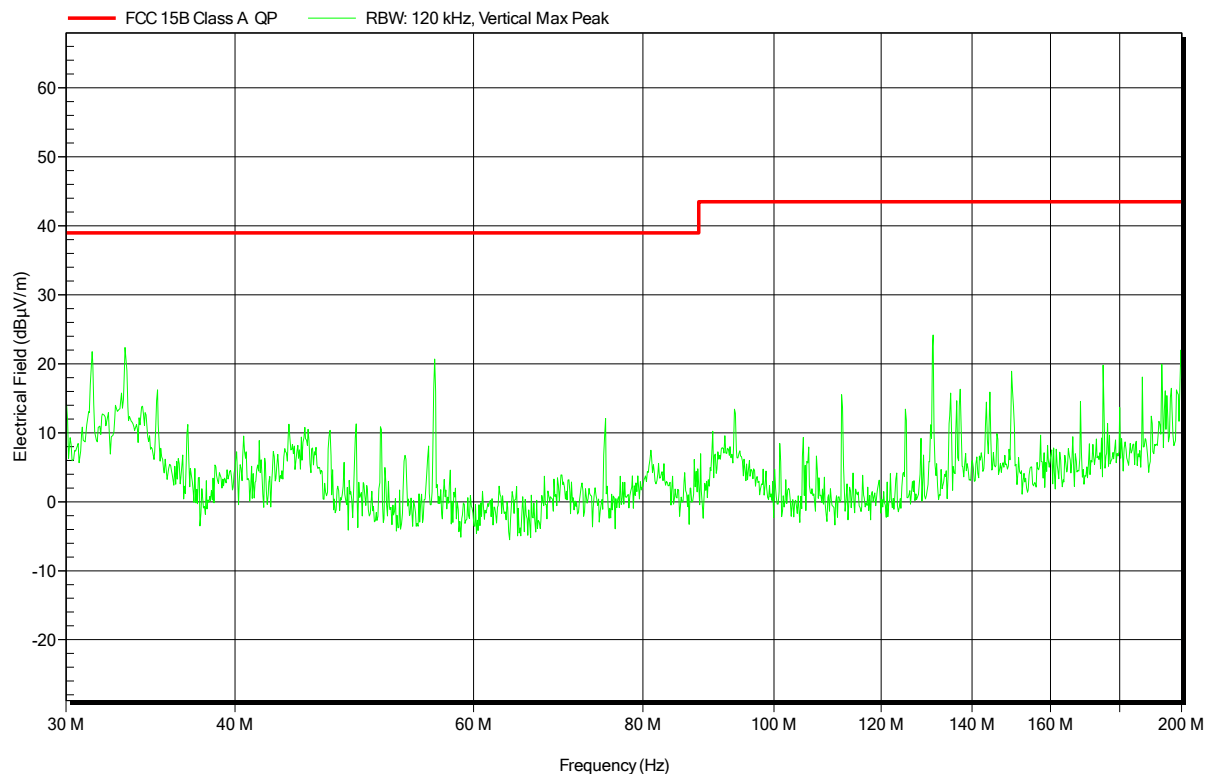
- The EUT was placed on a 0.8 m non-conductive table at a 3 m distance from the receive antenna. The antenna output was connected to the measurement receiver
- A biconical antenna was used for the frequency range 30 – 200 MHz, a logarithmic periodical antenna was used for the frequency range from 200 – 1000 MHz. Above one 1 GHz a Double Ridged Broadband Horn antenna was used. The antenna was placed on an adjustable height antenna mast
- The EUT and cable arrangement were based on the exploratory measurement results
- Emissions were maximized at each frequency by rotating the EUT and adjusting the receive antenna height and polarization. The maximum values were recorded.
- The test data of the worst-case conditions were recorded and shown on the next pages.

Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant:	Biotronik SE & Co. KG
EUT Name:	Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
Model:	Qubic Force
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Yu
Test Conditions:	Tnom: 22.4°C, Unom: 120V AC
Antenna:	Rohde & Schwarz HK 116, Vertical
Measurement distance:	3m, converted to 10m
Mode:	1
Test Date:	2016-04-26
Note:	

Index 4



Test Report No.: G0M-1603-5489-EF0115B-V01

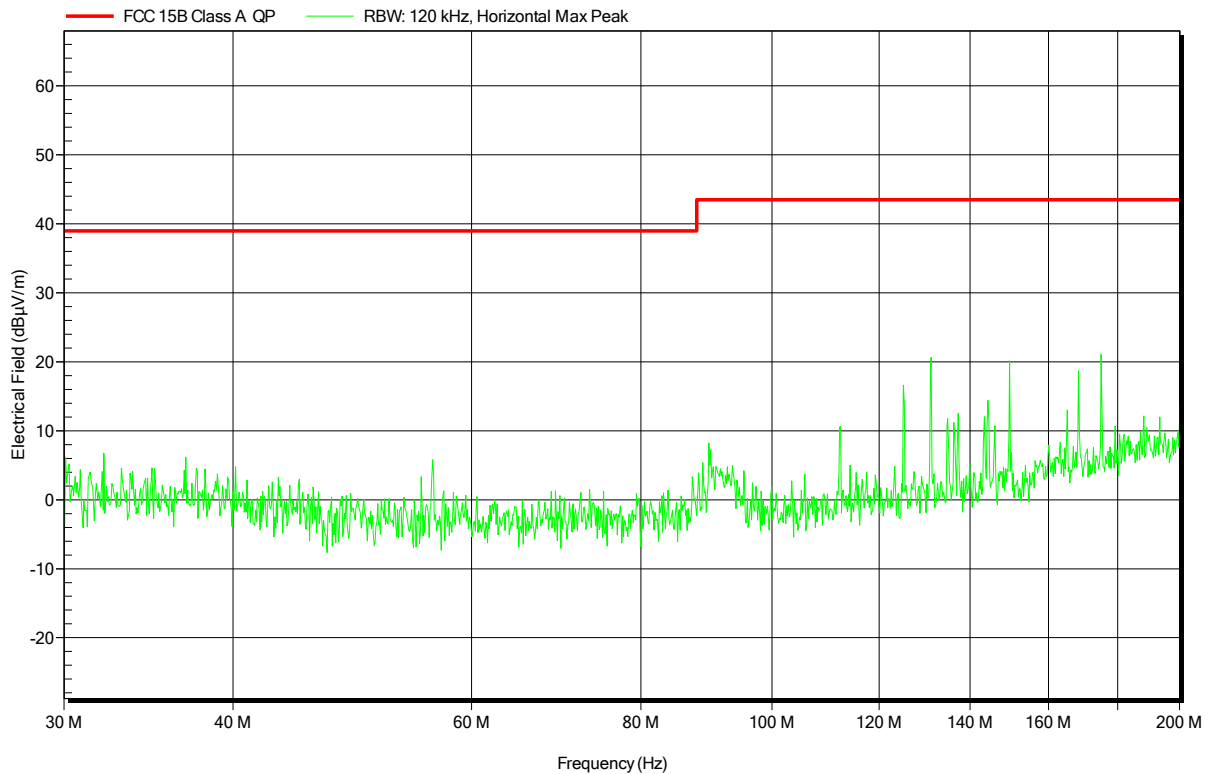
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant:	Biotronik SE & Co. KG
EUT Name:	Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
Model:	Qubic Force
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Yu
Test Conditions:	Tnom: 22.4°C, Unom: 120V AC
Antenna:	Rohde & Schwarz HK 116, Horizontal
Measurement distance:	3m, converted to 10m
Mode:	1
Test Date:	2016-04-26
Note:	

Index 3



Test Report No.: G0M-1603-5489-EF0115B-V01

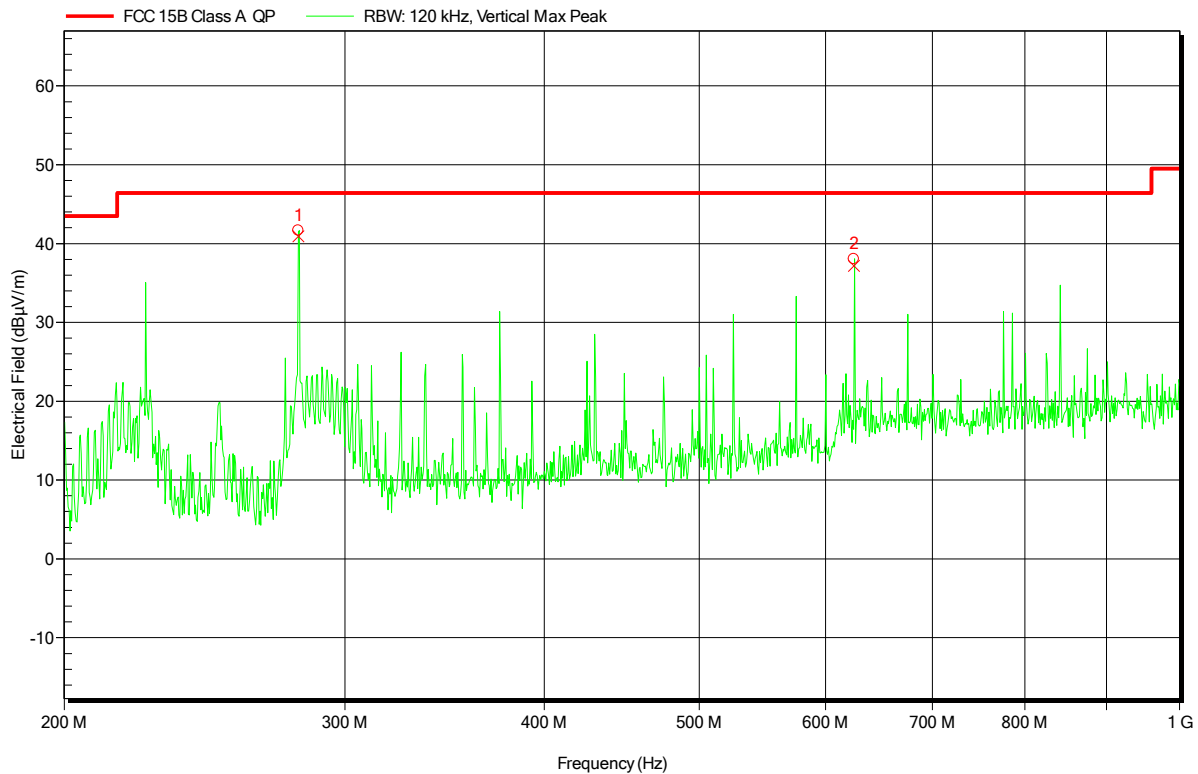
Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
 EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
 Model: Qubic Force
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Yu
 Test Conditions: Tnom: 22.4°C, Unom: 120V AC
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3m, converted to 10m
 Mode: 1
 Test Date: 2016-04-26
 Note:

Index 13



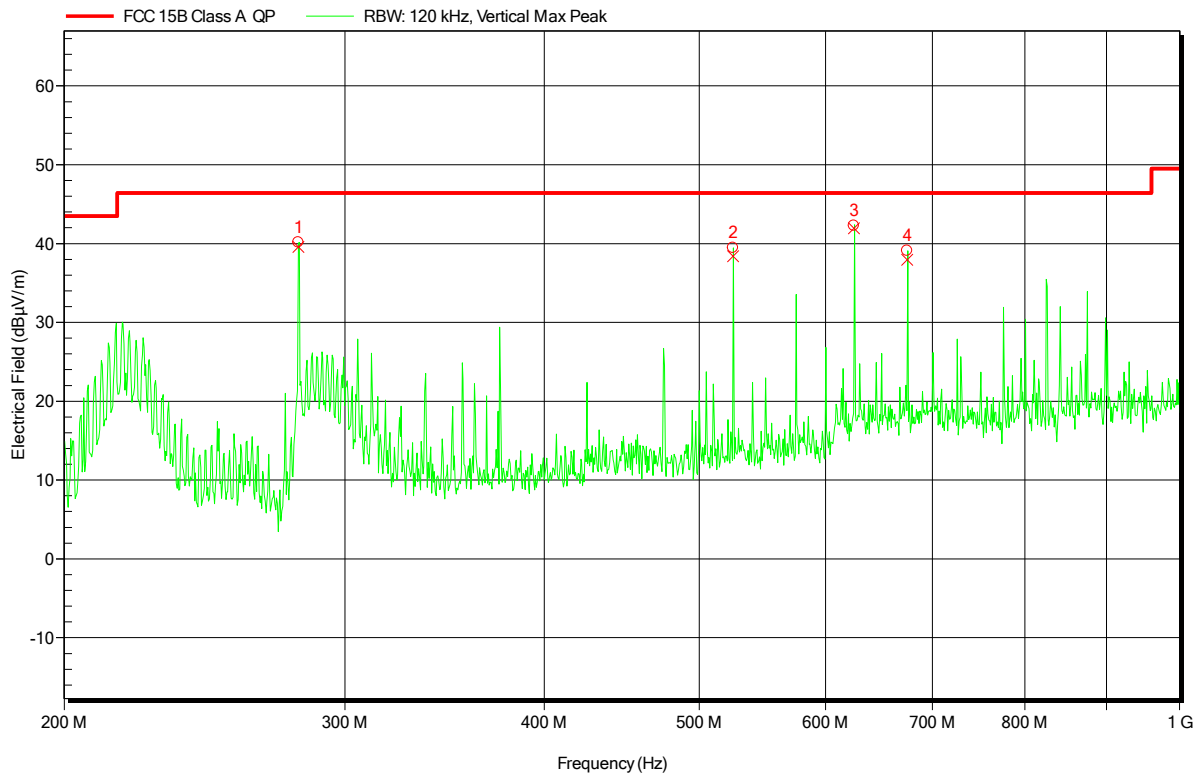
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	280.502 MHz	40.9 dBµV/m	46.4 dBµV/m	-5.5 dB	Pass	60 Degree	1 m
2	624.986 MHz	37.19 dBµV/m	46.4 dBµV/m	-9.21 dB	Pass	60 Degree	1 m

Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
 EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
 Model: Qubic Force
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Yu
 Test Conditions: Tnom: 22.4°C, Unom: 120V AC
 Antenna: Rohde & Schwarz HL 223, Vertical
 Measurement distance: 3m, converted to 10m
 Mode: 1
 Test Date: 2016-04-26
 Note:

Index 14



Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	280.502 MHz	39.57 dBµV/m	46.4 dBµV/m	-6.83 dB	Pass	290 Degree	1 m
2	524.99 MHz	38.4 dBµV/m	46.4 dBµV/m	-8 dB	Pass	290 Degree	1 m
3	624.986 MHz	41.92 dBµV/m	46.4 dBµV/m	-4.48 dB	Pass	290 Degree	1 m
4	674.99 MHz	37.93 dBµV/m	46.4 dBµV/m	-8.47 dB	Pass	290 Degree	1 m

Test Report No.: G0M-1603-5489-EF0115B-V01

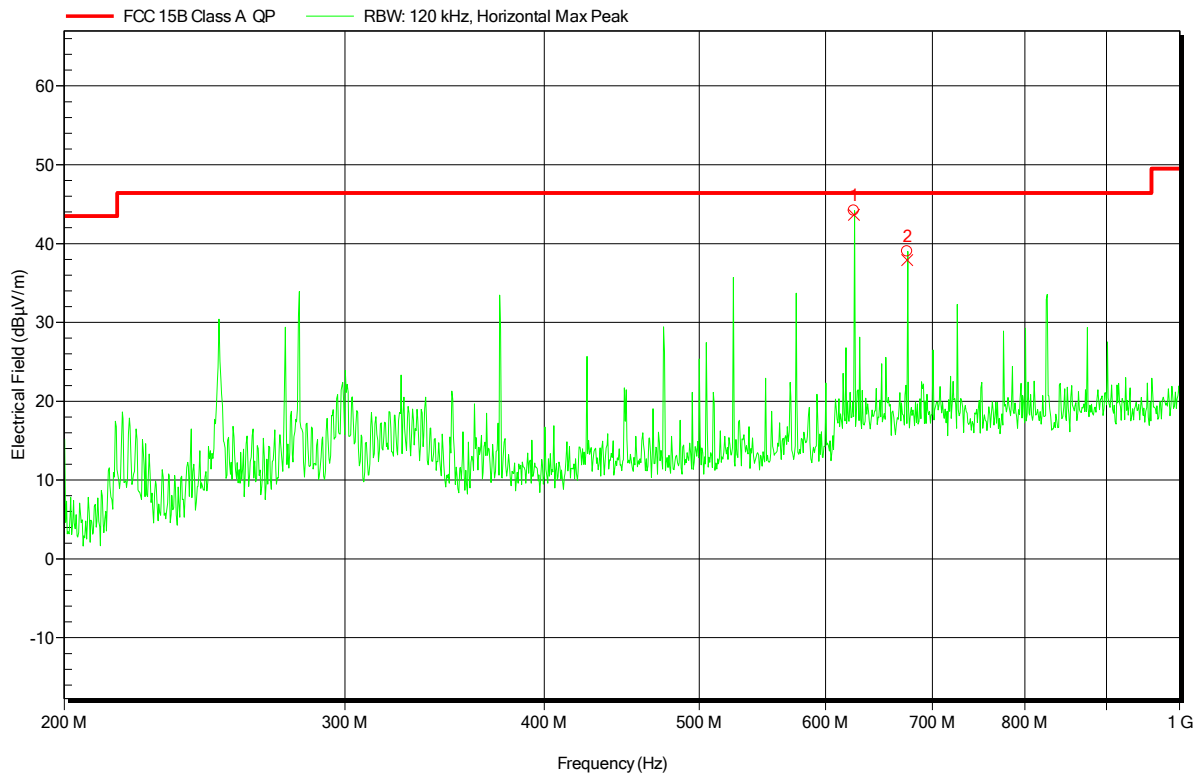
Eurofins Product Service GmbH
 Storkower Str. 38c, D-15526 Reichenwalde, Germany

Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
Model: Qubic Force
Test Site: Eurofins Product Service GmbH
Operator: Mr. Yu
Test Conditions: Tnom: 22.4°C, Unom: 120V AC
Antenna: Rohde & Schwarz HL 223, Horizontal
Measurement distance: 3m, converted to 10m
Mode: 1
Test Date: 2016-04-26
Note:

Index 12



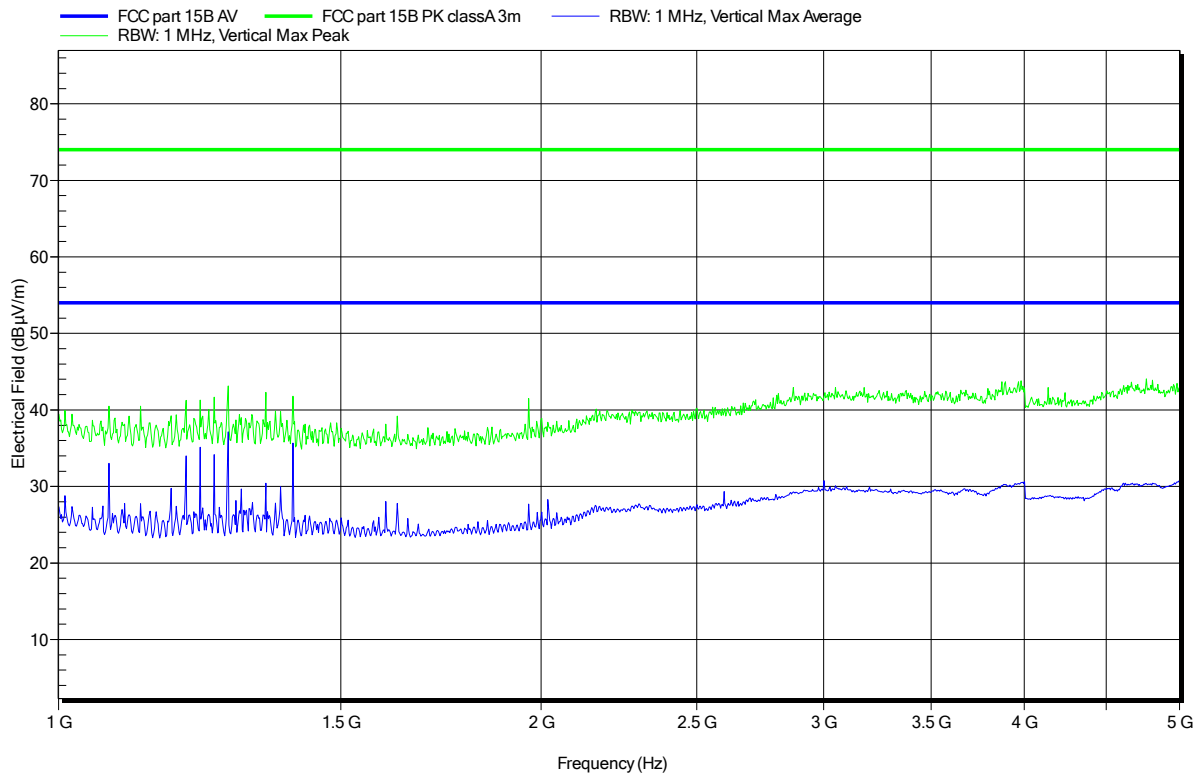
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	624.985 MHz	43.63 dBµV/m	46.4 dBµV/m	-2.77 dB	Pass	197 Degree	1 m
2	674.985 MHz	37.9 dBµV/m	46.4 dBµV/m	-8.5 dB	Pass	197 Degree	1 m

Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
 EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
 Model: Qubic Force
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Yu
 Test Conditions: Tnom: 22.4°C, Unom: 120V AC
 Antenna: Schwarzbeck BBHA 9120D, Vertical
 Measurement distance: 3m
 Mode: 1
 Test Date: 2016-04-26
 Note:

Index 18

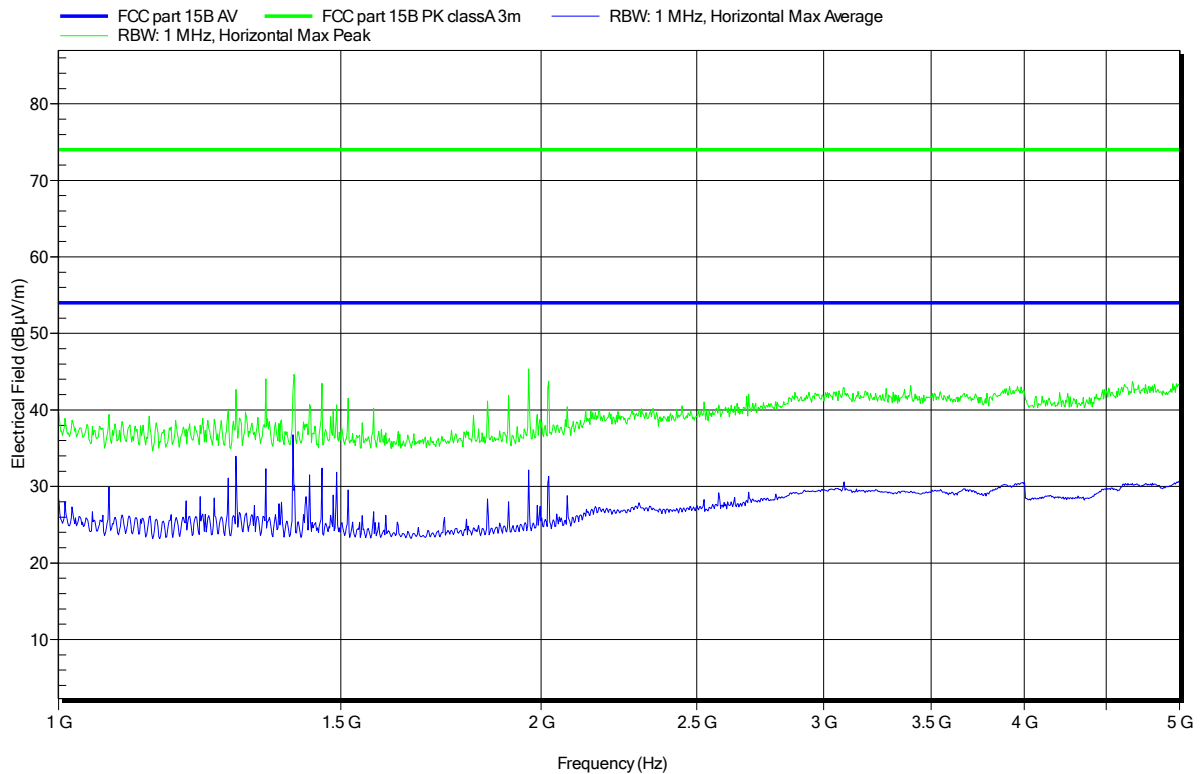


Spurious emissions under normal conditions according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
 EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
 Model: Qubic Force
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Yu
 Test Conditions: Tnom: 22.4°C, Unom: 120V AC
 Antenna: Schwarzbeck BBHA 9120D, Horizontal
 Measurement distance: 3m
 Mode: 1
 Test Date: 2016-04-26
 Note:

Index 19



3.2 Test Conditions and Results – AC power line conducted emissions

Conducted emissions acc. FCC 47 CFR 15.107 / ICES-003				Verdict: PASS	
Laboratory Parameters:		Required prior to the test		During the test	
Ambient Temperature		15 to 35 °C		22.4 °C	
Relative Humidity		30 to 60 %		35 %	
Test according referenced standards		Reference Method			
		ANSI C63.4			
Fully configured sample scanned over the following frequency range		Frequency range			
		0.15 MHz to 30 MHz			
Sample is tested with respect to the requirements of the equipment class		Equipment class			
		A			
Points of Application		Application Interface			
AC Mains		LISN			
Operating mode		1			
Configuration		2			
Limits and results Class A					
Frequency [MHz]		Quasi-Peak [dBμV]	Result	Average [dBμV]	Result
0.15 to 0.5		66	PASS	79	PASS
5 to 30		60	PASS	73	PASS
Comments:					
* Limit decreases linearly with the logarithm of the frequency.					

Test Procedure:

The test site is in accordance with ANSI C63-4:2014 requirements and is listed by FCC.
The measurement procedure is as follows:

Exploratory measurement:

- The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
- The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
- The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length).
- The LISN measurement port was connected to a measurement receiver
- I/O cables were bundled not longer than 0.4 m
- Measurement was performed in the frequency range 0.15 – 30MHz on each current-carrying conductor
- To maximize the emissions the cable positions were manipulated
- The worst configuration of EUT and cables is shown on a test setup picture at item 1.3

Test Procedure:**Final measurement:**

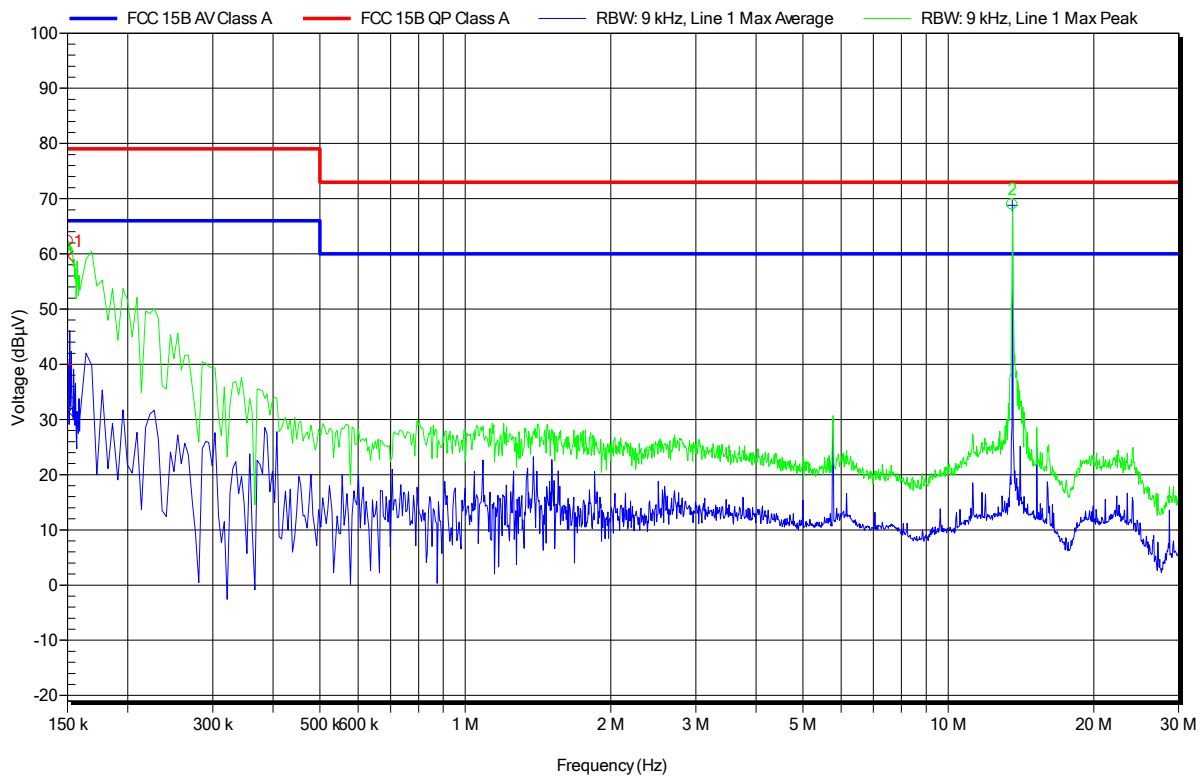
- The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
- The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
- The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length).
- The LISN measurement port was connected to a measurement receiver
- The EUT and cable arrangement were based on the exploratory measurement results
- The test data of the worst-case conditions were recorded and shown on the next pages.

EMI voltage test in the ac-mains according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
 EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
 Model: Qubic Force
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Yu
 Test Conditions: Tnom: 22.4°C, Unom: 120V AC
 LISN: ESH2-Z5 L
 Mode: 1
 Test Date: 2016-05-02
 Note:

Index 53



Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
1	150.45 kHz	59.54 dBμV	79 dBμV	-19.46 dB	Pass
2	13.56 MHz RFID carrier				Pass

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status
1	150.45 kHz	39.94 dBμV	66 dBμV	-26.06 dB	Pass
2	13.56 MHz RFID carrier				Pass

Test Report No.: G0M-1603-5489-EF0115B-V01

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EMI voltage test in the ac-mains according to FCC Part 15b

Project number: G0M-1603-5489

Applicant: Biotronik SE & Co. KG
 EUT Name: Measuring device for visualization of the contact force of the ablation catheter tip on the cardiac wall
 Model: Qubic Force
 Test Site: Eurofins Product Service GmbH
 Operator: Mr. Yu
 Test Conditions: Tnom: 22.4°C, Unom: 230CAC
 LISN: ESH2-Z5 N
 Mode: 1
 Test Date: 2016-05-02
 Note:

Index 55

