

EMC TEST REPORT				
FCC 47 CFR Part 15B Industry Canada ICES-003				
Electromagr	etic 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, RegNo.: 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			



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	Yu Yu			
Approved by (+ signature) Deputy Head of Lab	Narquardt			
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, with laboratory.	out the written approval of the Issuing testing			

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



### **Cable Information**

Cable length/Shielding:

Туре	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	



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### 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		
	Туре	RFID	
	Model	RFIDM 1356 - 001	
Radio module	Manufacturer	KTS - Kommunikationstechnik & Systeme	
	HW Version	2.1	
	SW Version	3.17	
	Biotronik SE & Co. K	G	
Manufacturer	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	ABL Ablation catheter 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 :	AE : Auxiliary/Associated Equipment, or					
SIM : Simulator (Not Subjected to Test)						

CABL : Connecting cables

### 1.5 Input / Output Ports

Port #	Name	Туре*	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			
	Generator input port is connected with PK-147			
	Catheter port is connected with PK-147 and catheter AlCath Force			
	Optical Catheter port is connected with catheter AICath Force			
	HDMI port is connected with VK-124(15m) to external monitor			
1	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)			
	Generator input port is connected with PK-147			
	Catheter port is connected with PK-147 and catheter AlCath Force			
	Optical Catheter port is connected with catheter AlCath Force			
2	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 SoftwareDare InstrumentsRadimation2015.1.12					

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  $dB\mu V$ . 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:

Reading on Analyzer  $(dB\mu V) + A.F. (dB) = Net field strength (dB\mu V/m)$ 

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  $dB\mu V/m$ :

Limit (dB
$$\mu$$
V/m) = 20\*log ( $\mu$ 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:



### 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:	Re	Required prior to the test During the test					
Ambient T	emperature	15 to 35 °C		22.4 °C				
Relative	Humidity	30 to 60 %				35 %		
Test accordi	ng referenced			Referenc	e Metho	d		
stan	dards			ANSI	C63.4			
Sample is tested	with respect to the			Equipme	ent class			
requirements of th	ne equipment class			ŀ	4			
Test frequency ran	ge determined from			Highest emiss	ion freq	uency		
highest emiss	sion frequency	1 GHz						
Fully configured sa	ample scanned over	Frequency range						
the following fi	requency range	30 MHz to 5 GHz						
Operati	ng mode	1						
Config	juration			1	1			
	L	imits a	nd r	esults Class A				
Frequency [MHz]	Quasi-Peak [dBµV/r	n] Res	sult	Average [dBµV/m]	Result	Peak [dBµV/m]	Result	
30 – 88	39.085	PA	SS	-		-	-	
88 – 216	43.522	PA	SS	-		-	-	
216 – 960	46.444	PA	SS	-		-	-	
960 - 1000	49.542	PA	SS	-		-	-	
> 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:

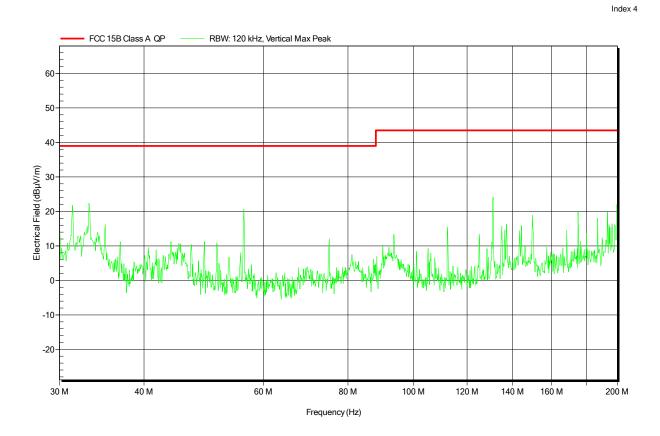
- The EUT was placed on a 0.8 m non-conductive table at a 3 m distance from the receive antenna. The antenna output was connected to the measurement receiver
- A biconical antenna was used for the frequency range 30 200 MHz, a logarithmic periodical antenna was used for the frequency range from 200 – 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:	

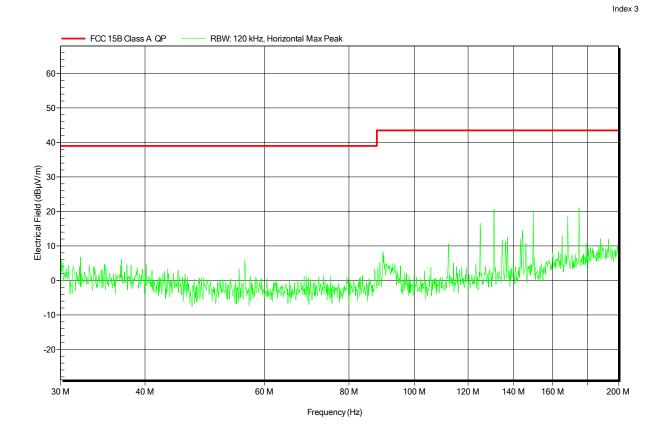




### Spurious emissions under normal conditions according to FCC Part 15b

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:	





### 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:	

FCC 15B Class A QP RBW: 120 kHz, Vertical Max Peak 60 50 40 Electrical Field (dBµV/m) 30 20 WWW 10 0 -10 800 M 300 M 400 M 500 M 600 M 700 M 1 G 200 M Frequency (Hz) Frequency Peak Number Quasi-Peak Quasi-Peak Quasi-Peak Quasi-Peak Angle Height Limit Difference Status 280.502 MHz 624.986 MHz 46.4 dBµV/m 60 Degree 40.9 dBµV/m -5.5 dB Pass 1 m 1 2 37.19 dBµV/m  $46.4 \text{ dB}\mu\text{V/m}$ -9.21 dB Pass 60 Degree 1 m

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

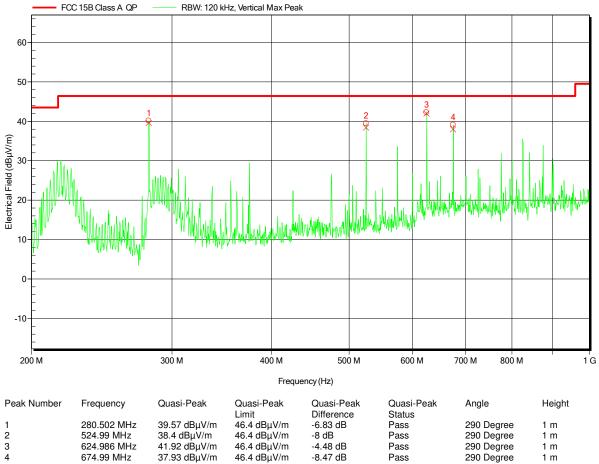


### Spurious emissions under normal conditions according to FCC Part 15b

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:	

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### 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:	

FCC 15B Class A QP RBW: 120 kHz, Horizontal Max Peak 60 50 Ģ 40 Electrical Field (dBµV/m) 30 20 **,**М 10 0 -10 800 M 300 M 400 M 500 M 600 M 700 M 1 G 200 M Frequency (Hz) Peak Number Frequency Quasi-Peak Quasi-Peak Quasi-Peak Quasi-Peak Angle Height Limit Difference Status 46.4 dBµV/m 624.985 MHz 43.63 dBµV/m -2.77 dB Pass 197 Degree 1 m 1 2 674.985 MHz 37.9 dBµV/m  $46.4 \text{ dB}\mu\text{V/m}$ -8.5 dB Pass 197 Degree 1 m

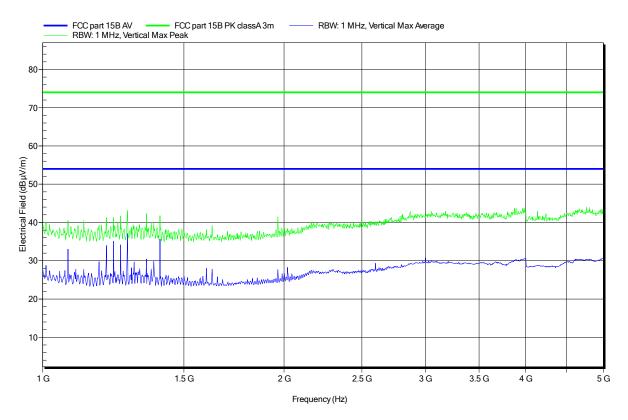
Test Report No.: G0M-1603-5489-EF0115B-V01



### 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: Note:	2016-04-26

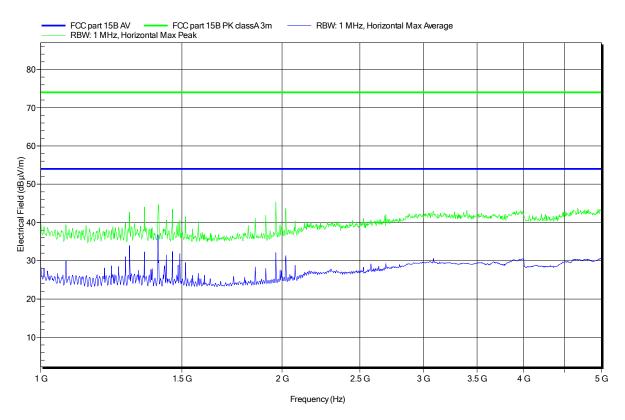




### Spurious emissions under normal conditions according to FCC Part 15b

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:	





### 3.2 Test Conditions and Results – AC power line conducted emissions

Conducted emission	s acc. FCC 47	CFR 15.	107 / ICES-003		Verdict: PASS		
Laboratory Para	imeters:	Required prior to the test		Durin	g the test		
Ambient Temp	erature		15 to 35 °C		22	2.4 °C	
Relative Hun	nidity		30 to 60 %		35 %		
Test according re	ferenced		Reference Method				
standard	S			ANSI C	63.4		
Fully configured sample	e scanned over		Fi	requency	/ range		
the following freque			0.15	5 MHz to	30 MHz		
Sample is tested with	respect to the	Equipment class					
requirements of the eq	uipment class			Α			
Points of Application		Application Interface					
AC Mains				LISI	N		
Operating m	ode			1			
Configurati	on			2			
	L	imits and	d results Class A				
Frequency [MHz]	Quasi-Peak [	dBµV]	Result	Avera	age [dBµV]	Result	
0.15 to 0.5	66		PASS		79	PASS	
5 to 30	60		PASS		73	PASS	
Comments: * Limit decreases linearly w	vith the logarithm o	f the frequ	ency.			·	



#### 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.

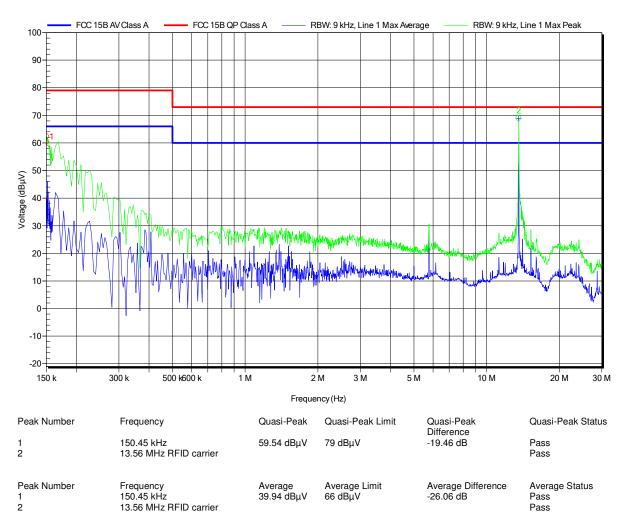


#### EMI voltage test in the ac-mains according to FCC Part 15b

Project number: G0M-1603-5489

Applicant:	Biotronik SE & Co. KG
EUT Name:	Measuring device for visualization of the contact force of the ablation
Lot Name.	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
Noto:	

Note:





### 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:	

