



EUROFINS PRODUCT SERVICE GMBH



Testing Cert #1983.01

# TEST - REPORT

FCC RULES PART 15 / SUBPART B  
IC RSS-GEN ISSUE 2

SafeSync Module

ECM

Test report no.: G0M21010-3780-C-3



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# 1 General Information

## 1.1 Notes

The purpose of conformity testing is to increase the probability of adherence to the essential requirements or conformity specifications, as appropriate.

The tests were carried out and passed in accordance to the standards:

**FCC part 15B**

**IC RSS-Gen Issue 2**

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.

The test report may only be reproduced or published in full. Reproducing or publishing extracts of the report requires the prior written approval of the Eurofins Product Service GmbH.

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**Important Notes:**

Proper labeling is required for each device. Devices shall be labeled in accordance with labeling requirements pursuant to section 15.19 and section 2.1074 of the FCC rules.

Devices subject to a Declaration of Conformity shall be uniquely identified by the responsible party.

This identification shall not be of a format which could be confused with the FCC Identifier required on certified, notified type accepted or type approved equipment.

The responsible party shall maintain adequate identification records to facilitate positive identification for each device.

The user manual or instruction manual shall included also a warning statement that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**Reference Section 15.21**

Furthermore information to the user regarding to the interference potential of the device and about simple measures that can be taken to correct interference is required.

**Reference Section 15.105**

The responsible party must warrant that each unit of equipment marketed under a Declaration of Conformity is identical to the unit tested and found acceptable with the standards and that the records maintained by the responsible party continue to reflect the equipment being produced under the Declaration of Conformity within the variation that can be expected due to quantity production and testing on a statistical basis.

**1.2 Operator:**

30.05.2011

M. Klein



Date

Eurofins -Lab.

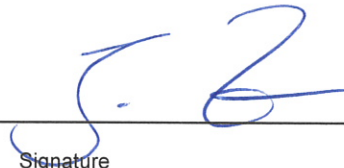
Name

Signature

Technical responsibility for area of testing:

30.05.2011

J. Zimmermann



Date

Eurofins

Name

Signature

## 1.3 Testing laboratory

### 1.3.1 Location

EUROFINS PRODUCT SERVICE GMBH  
STORKOWER STR. 38c  
D- 15526 REICHENWALDE B. BERLIN  
GERMANY  
Telephone: + 49 33631 888-00  
Telefax: + 49 33631 888-660

### 1.3.2 Details of accreditation status

**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 3470A

### 1.3.3 Test location, where different

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

## 1.4 Details of applicant

Name : BIOTRONIK SE & Co. KG  
Street : Woermannkehre 1  
Town : 12359 Berlin  
Country : Germany  
Telephone : 030/68905-1213

Contact : Herr Wolfgang Buske  
Telephone : 030/689054440

## 1.5 Application details

Date of receipt of application : 18.10.2010  
Date of receipt of test item : 18.10.2010  
Date of test : 18 - 19.10.2010

## 1.6 Test item

### 1.6.1 Description of test item

Type of product : SafeSync Module  
Type identification : ECM  
Hardware Version : HW0000\_0002\_0000  
Software Version : C\_1\_X\_X  
Photos : Please find in Annex.  
Power supply : 5VDC (supplied via USB-Bus)  
Antenna type : internal antenna  
Additional information : ./.

### 1.6.2 Manufacturer (if different from applicant in point 1.4)

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

### 1.6.3 Frequency behavior

Highest clock Frequency	500MHz < f < 1000MHz
-------------------------	----------------------

### 1.7 Test standards

**FCC part 15B  
IC RSS-Gen Issue 2**



## 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 2.3 were ascertained in the course of the tests performed.



### 2.2 Test environment

Temperature	: 23 °C
Relative humidity content	: 44 %
Air pressure	: 1017 hPa
Details of power supply	: 5VDC
Other parameters	: ./.

## 2.3 Test results

 1<sup>st</sup> test

 test after modification

 production test

Test Emission / Immunity			Done	Test passed	Test failed
Conducted Emission	FCC part 15.107	RSS-Gen 7.2.2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Radiated Emission	FCC part 15.109	RSS-Gen 7.2.3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

## 2.4 Test equipment utilized

No.	Test Equipmen	Type	Manufacturer
ETS 0001	ESD Gun	SESD 30000	Schlöder
ETS 0008	Antenna	Loop antenna	Siemens
ETS 0012	Biconical Antenna	HK 116	R & S
ETS 0013	LPD Antenna	HL 223	R & S
ETS 0014	Log Periodical Antenna	HL 025	R & S
ETS 0038	RF amplifier	150L	Amplifier Research
ETS 0032	Controller	HD 050	Heinrich Deisel
ETS 0039	Absorbing clamp	MDS 21	R & S
ETS 0040	Artificial Mains Network	ESH3-Z5	R & S
ETS 0041	T-Artificial Mains Network	ESH3-Z4	R & S
ETS 0042	Artificial Mains	ESH3-Z6	R & S
ETS 0045	Vehicle LISN	NNBM 8126D	Schwarzbeck
ETS 0052	Audio analyzer	UPA 4	R & S
ETS 0056	Ultra Compact Simulator	UCS 500 M4	EM Test
ETS 0057	Motor Variac	MV 2616	EM Test
ETS 0058	Capacitive coupling clamp	E 502 B	Keytek/ EMC
ETS 0059	Kikusui amplifier	PCR 2000L	Keytek/ EMC
ETS 0064	CDN IEC 61000-4-6		Keytek/ EMC
ETS 0066	EM Injection Clamp		FCC/ EMC
ETS 0076	Feeding bridge A	SBA 1000	ESP
ETS 0082	PC system		Esotronic
ETS 0085	Shielded room	SR 1	Frankonia
ETS 0086	Semi-Anechoic chamber	AC 1	Frankonia
ETS 0088	Color TV pattern Generator	PM 5518-TX VPS	Philips
ETS 0092	Power Amplifier	150W1000	AR Amplifier Research
ETS 0102	CDN	M3-801/6	MEB
ETS 0103	Magnetic field test set	MF1000	EMC-Partner
ETS 0148	RF Current Probe	F-65	FCC
ETS 0155	Signal Generator	SMG	R & S
ETS 0157	TV and Sat-Signalgenerator	VTG 700	Grundig
ETS 0161	Harmonic / Flicker Analyzer	HFA 3000	Schlöder
ETS 0178	Open area test side	10m	ETS
ETS 0233	Direction coupler	RK 100	MEB
ETS 0276	Audio Analyzer	UPL 16	R & S
ETS 0282	RF bridge 75 Ohm	86207 A	HP
ETS 0287	EMI Test receiver	ESHS10	R & S
ETS 0288	Artificial mains	ESH2-Z5	R & S
ETS 0292	RF Generator	SMHU	R & S
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0300	RF amplifier	75 A 250	Ar
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0401	MPEG2 Generator	DVG	R & S
ETS 0402	TV Messender	SFQ	R & S
ETS 0409	Stripline	DC220	Schwarzbeck
ETS 0428	4-WIRE ISN with B1	ENY41	R & S
ETS 0448	RF Power Amplifier	AR 60S1G3	AR Amplifier Research
ETS 0472	Antenna	BTA-H	Frankonia
ETS 0474	EMI Test Receiver	ESCS 30	R&S
ETS 0485	Radio Communication Tester	CMU 200	R&S

## 2.4.1 Conducted Emission

### 2.4.1.1 Test Equipment

- ETS 0040
- ETS 0085
- ETS 0474
- Software: Radimation Version 5.5.12

### 2.4.1.2 Test Procedures

- Test configuration

The test configuration is contained inside of a shielded chamber and corresponds to the standard ANSI C.63.4: 2003. The equipment under test is placed in the facility on a wooden table 0.8m high. The equipment under test is connected with the artificial mains network (AMN) in a distance of 0,8m and also 0,8m from other subassembly and metallic area. The measurement receiver is placed in a special room adjacent to the chamber. The observation of the equipment under test is realized by 3 video cameras and by a microphone.

- Test parameters and marginal conditions

The tests are carried out with nominal impedance by  $50 \Omega / 50 \mu\text{H}$  of the AMN in a frequency range 150 kHz to 30 MHz. This measurement was transacted first with instrumentation using an average and peak detector and a 10 kHz bandwidth. If the peak detector achieves a calculated level, the measurement is repeated by an instrumentation using a quasi-peak detector, Further information please find in test report.

## 2.4.2 Spurious Emission

### 2.4.2.1 Test Equipment

- ETS 0012
- ETS 0013
- ETS 0086
- ETS 0474
- Software: Radimation Version 5.5.12

### 2.4.2.2 Test Procedures

- Test configuration

The test configuration corresponds to the standard ANSI C 63.4: 2003. The equipment under test is placed on a non metallic table with 0,8 m height. The power supply and the RF connection points are close to the equipment under test at the floor inside a connection box. The cables to this connection box are shielded and below the double floor. The receiving antenna is placed in a height at 1,0 to 4,0 m, in a distance of 3 m. The measurement receiver is placed in a special room. The observation of the equipment under test is realized by 3 video cameras and by a microphone.

- Test parameters and marginal conditions

The test are carried out with horizontal and vertical polarization of the antenna in a frequency range of 30 MHz to 5 000 MHz. Further information please find in the test protocol.

## 2.5 Test protocols

### Conducted Emission

# Emission

Standard : FCC part 15.107; RSS-Gen 7.2.2

Reg.-no. : G0M21010-3780-C-3

Device : SafeSync Module ECM

Date : 20.05.2011

Class : B

Frequency Range	Limit dB $\mu$ V		Passed	Failed	Number of rechecks
	Quasi-peak	Average			
150 kHz - 500 kHz AC	66 to 56*	56 to 46*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0
500 kHz - 5 MHz AC	56	46	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0
5 MHz - 30 MHz AC	60	50	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0

\* Decreases with logarithm of the frequency

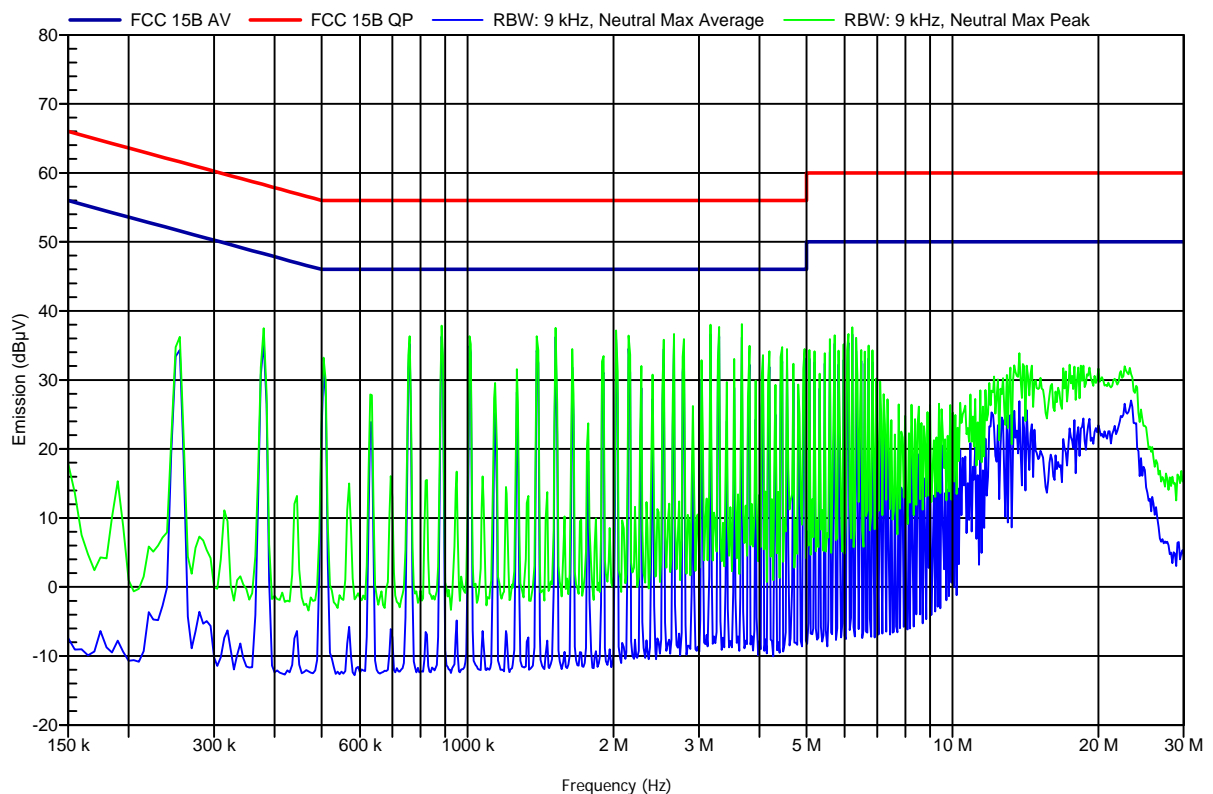
Uncertainty:  $U_{\text{lab(cond)}} = 3.8 \text{ dB}$ .

Comment: See attached diagrams.

**EMI voltage test in the ac-mains according to FCC PART 15 B**

Order number: G0M21010-3780

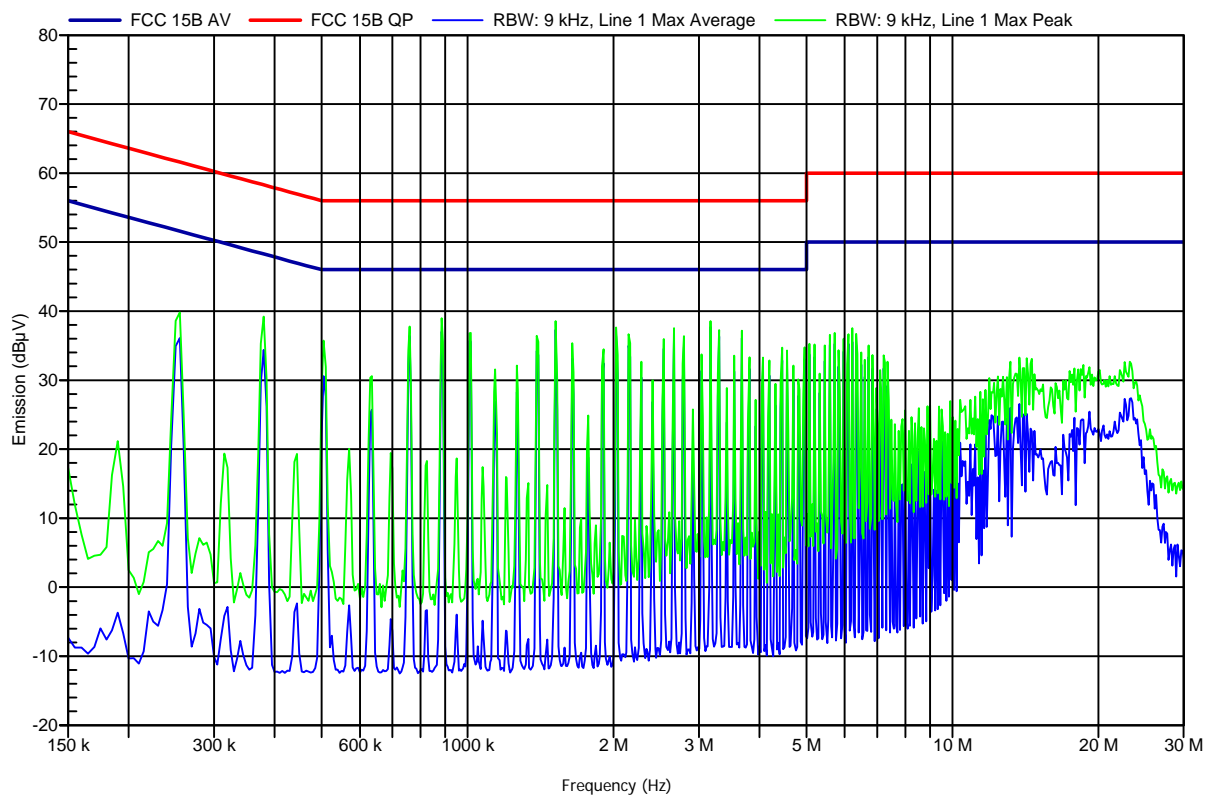
Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module L  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 LISN: ESH2-Z5 N  
 Mode: usb-data-link  
 ULPAMI TX-mode  
 Test Date: 19.10.2010  
 Note:



**EMI voltage test in the ac-mains according to FCC PART 15 B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 LISN: ESH2-Z5 L  
 Mode: usb-data-link  
 ULPAMI TX-mode  
 Test Date: 19.10.2010  
 Note:





**Radio Noise Field Strength**

# Emission

Standard : FCC part 15.109; RSS-Gen 7.2.3

Reg.-no. : G0M21010-3780-C-3

Device : SafeSync Module ECM

Date : 20.05.2011

Class : B

Frequency Range Polarization	Limit $\mu\text{V/m}$	Passed	Failed	Number of rechecks
30 MHz - 88 MHz	100	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0
88 MHz - 216 MHz	150	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0
216 MHz - 960 MHz	200	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0
960 MHz - 5000 MHz	500	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0

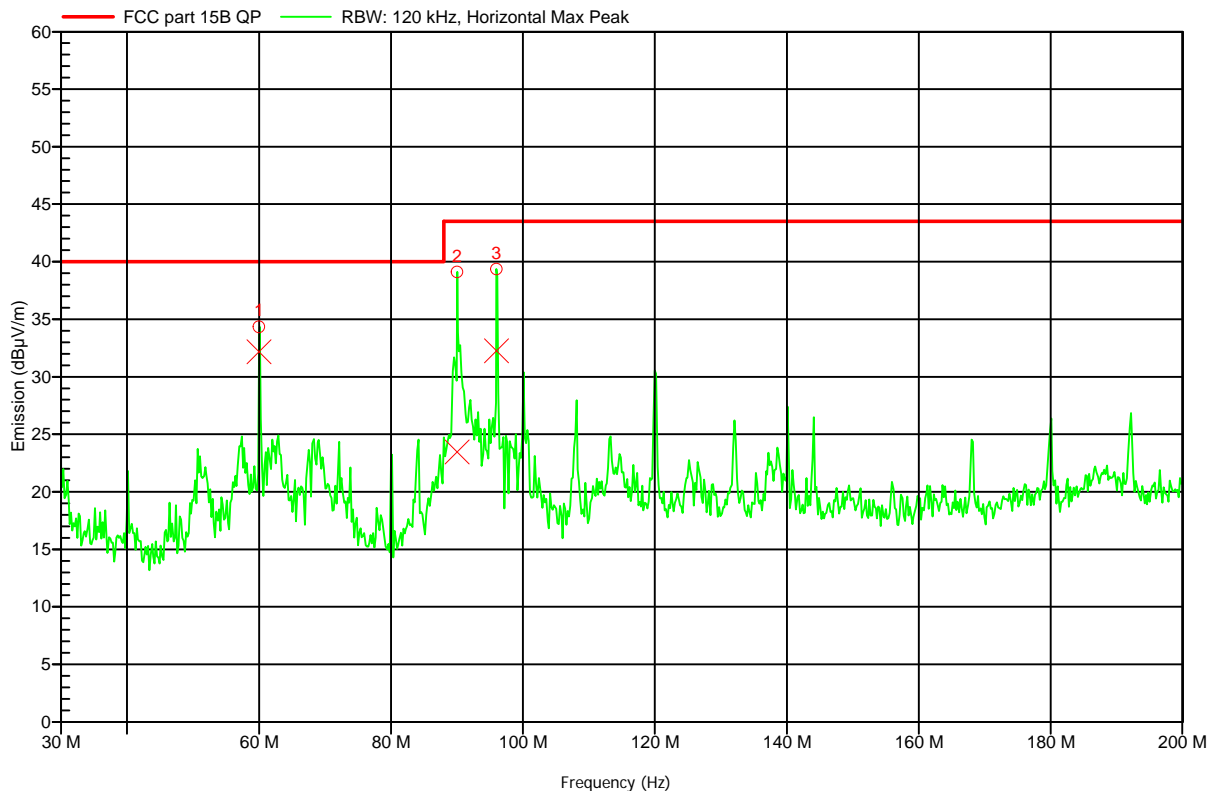
Uncertainty:  $U_{\text{lab(rad)}} = 5.3 \text{ dB}$

Comment: See attached diagrams.

**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 Measurement Distance: 3m  
 Antenna: Rohde & Schwarz HK 116, Horizontal  
 Mode: usb-data-link, ULPAMI-link  
 Test Date: 18.10.2010  
 Note:

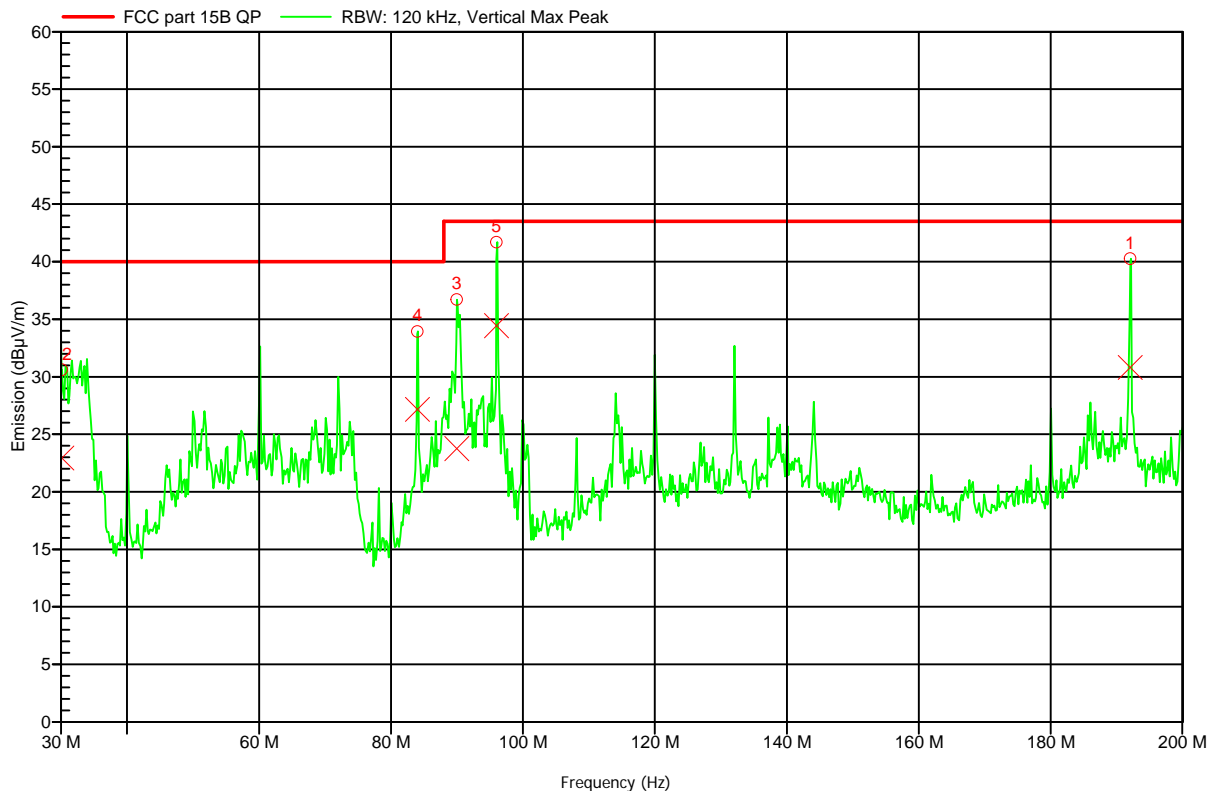


Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
60,01 MHz	32,16 dBµV/m	40 dBµV/m	-7,84 dB	Pass
90,035 MHz	23,46 dBµV/m	43,5 dBµV/m	-20,04 dB	Pass
96 MHz	32,24 dBµV/m	43,5 dBµV/m	-11,26 dB	Pass

**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 Measurement Distance: 3m  
 Antenna: Rohde & Schwarz HK 116, Vertical  
 Mode: usb-data-link, ULPAMI-link  
 Test Date: 18.10.2010  
 Note:



Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
30,115 MHz	22,93 dBµV/m	40 dBµV/m	-17,07 dB	Pass
84,005 MHz	27,16 dBµV/m	40 dBµV/m	-12,84 dB	Pass
89,985 MHz	23,75 dBµV/m	43,5 dBµV/m	-19,75 dB	Pass
96,005 MHz	34,43 dBµV/m	43,5 dBµV/m	-9,07 dB	Pass
192,055 MHz	30,81 dBµV/m	43,5 dBµV/m	-12,69 dB	Pass

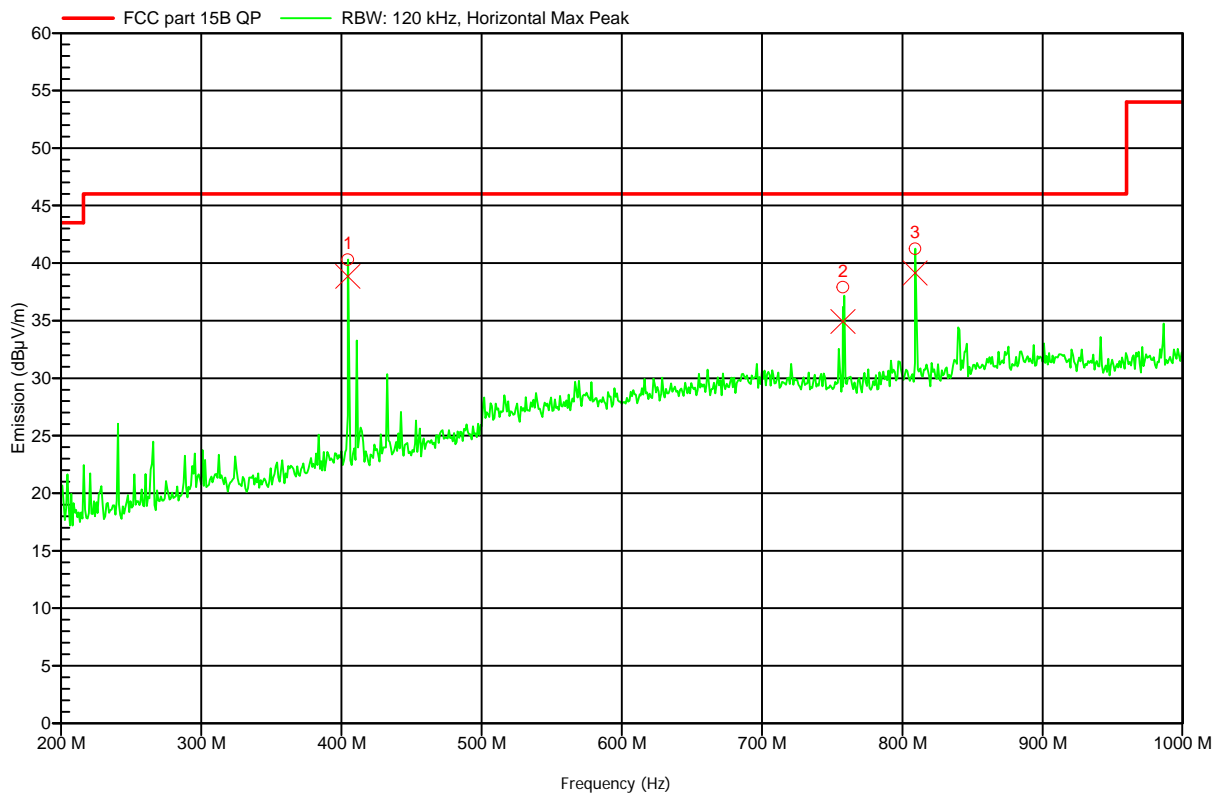
**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 Measurement Distance: 3m  
 Antenna: Rohde & Schwarz HL 223, Horizontal  
 Mode: usb-data-link, ULPAMI-link, with notch-filter

Test Date: 18.10.2010

Note:

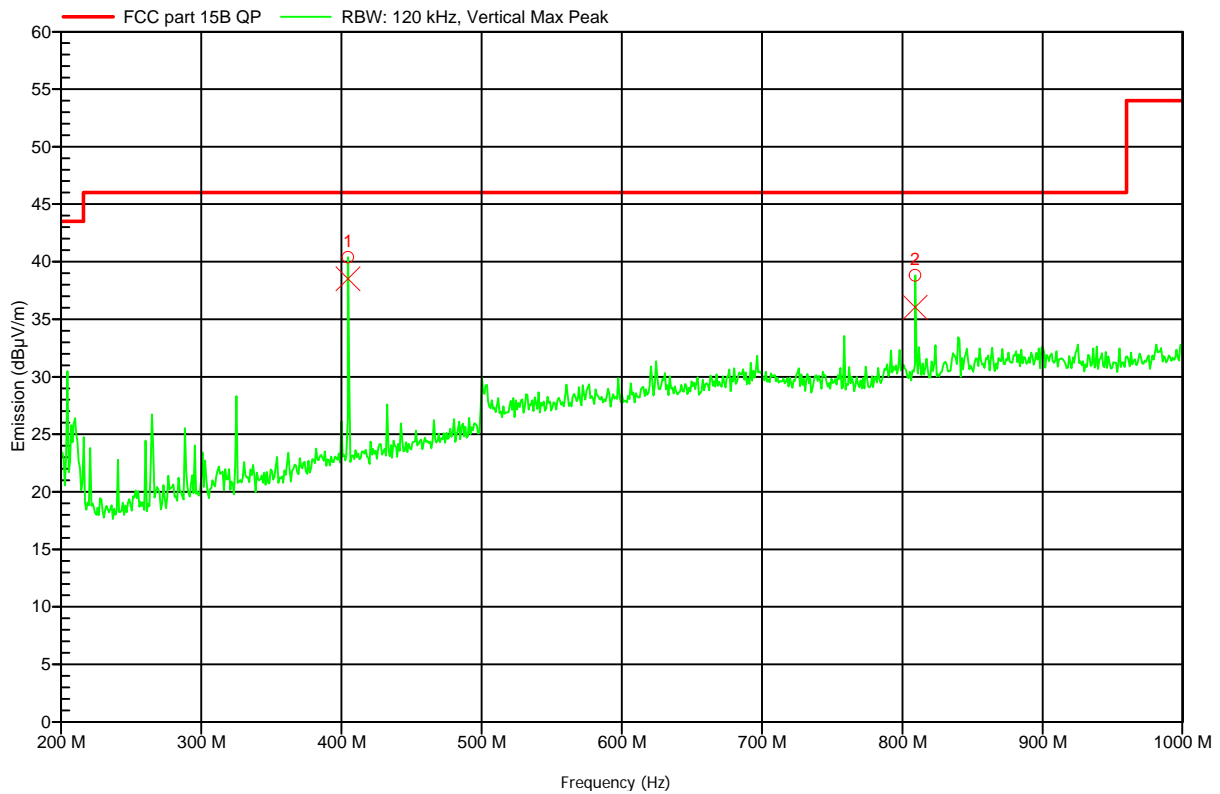


Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
404,565 MHz	38,86 dBµV/m	46 dBµV/m	-7,14 dB	Pass
757,65 MHz	34,94 dBµV/m	46 dBµV/m	-11,06 dB	Pass
809,125 MHz	39,14 dBµV/m	46 dBµV/m	-6,86 dB	Pass

**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 Measurement Distance: 3m  
 Antenna: Rohde & Schwarz HL 223, Vertical  
 Mode: usb-data-link, ULPAMI-link, with notch-filter  
 Test Date: 18.10.2010  
 Note:



Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status
404,58 MHz	38,51 dBµV/m	46 dBµV/m	-7,49 dB	Pass
809,11 MHz	36,04 dBµV/m	46 dBµV/m	-9,96 dB	Pass

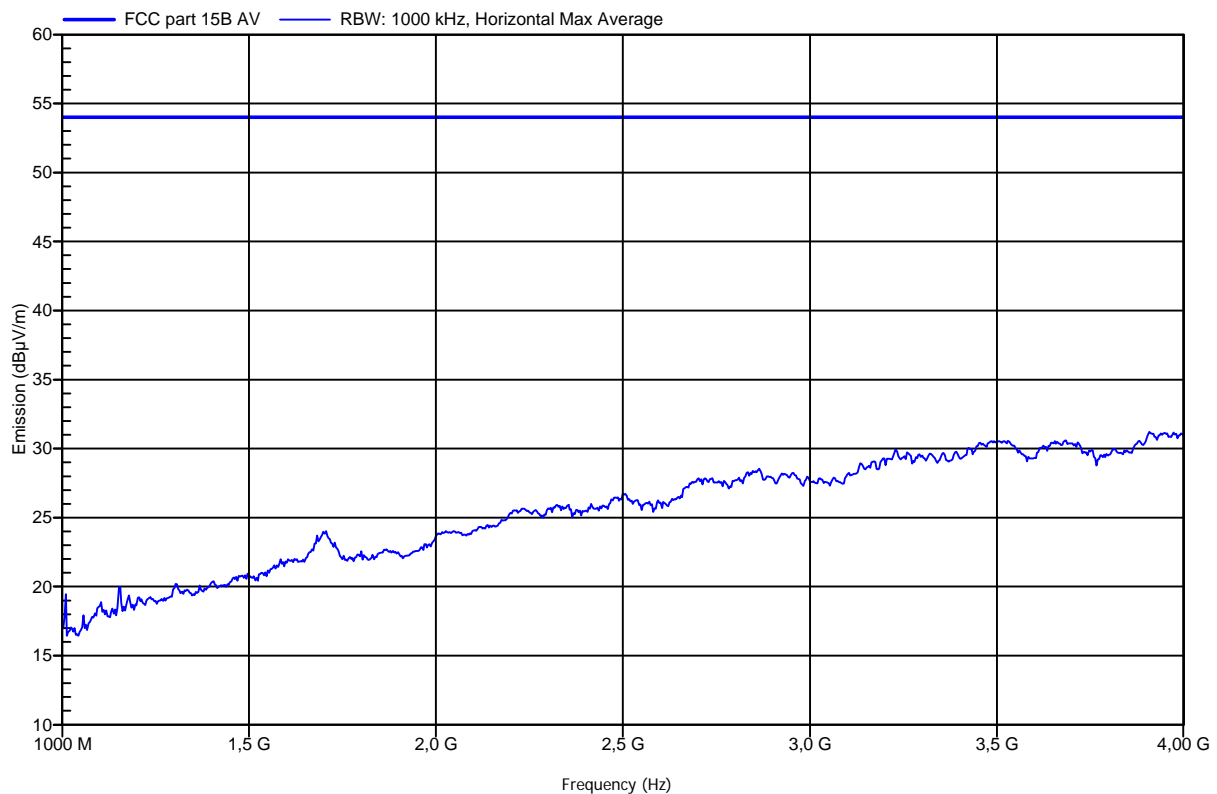
**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer:	Biotronik SE & CO. KG
EUT Name:	SafeSync Module
Model:	ECM
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Pflug
Test Conditions:	Tnom: 23°C, Unom: 120 VAC (feeding over USB)
Measurement Distance:	3m
Antenna:	Rohde & Schwarz HL 025, Horizontal
Mode:	usb-data-link, ULPAMI

Test Date: 19.10.2010

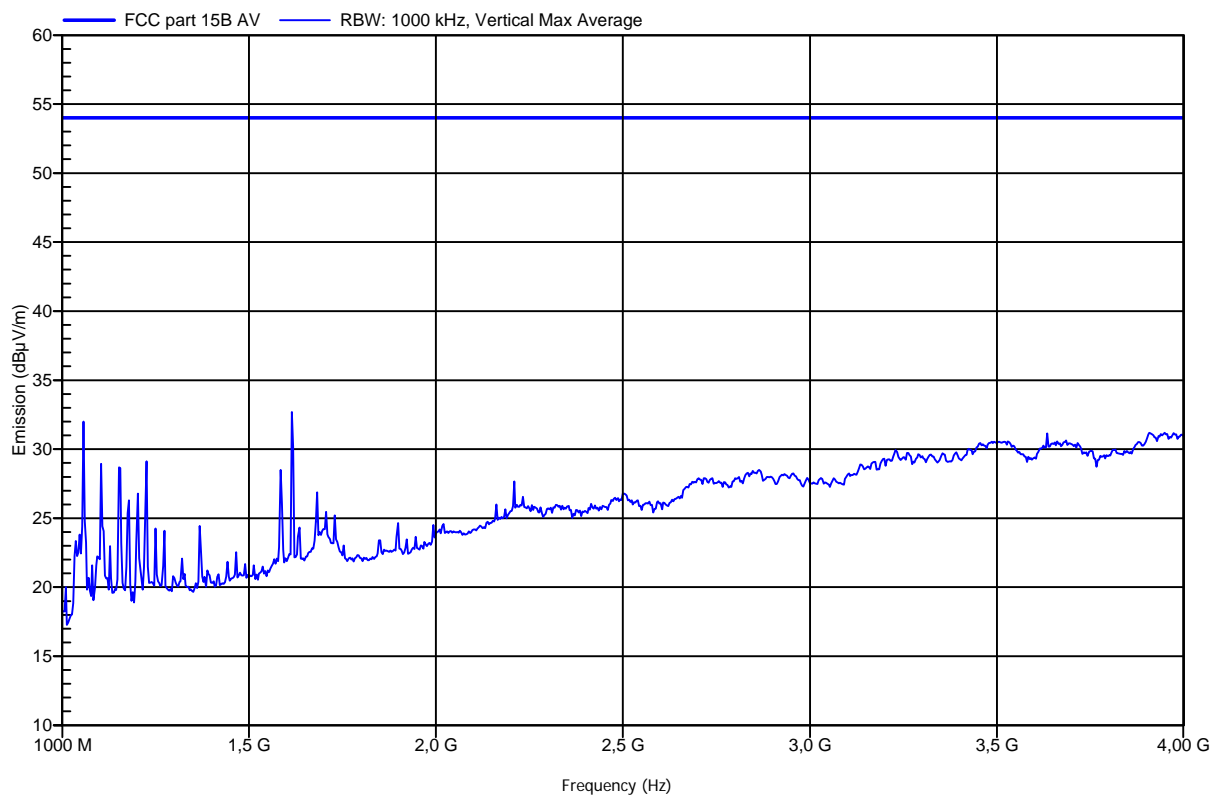
Note



**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

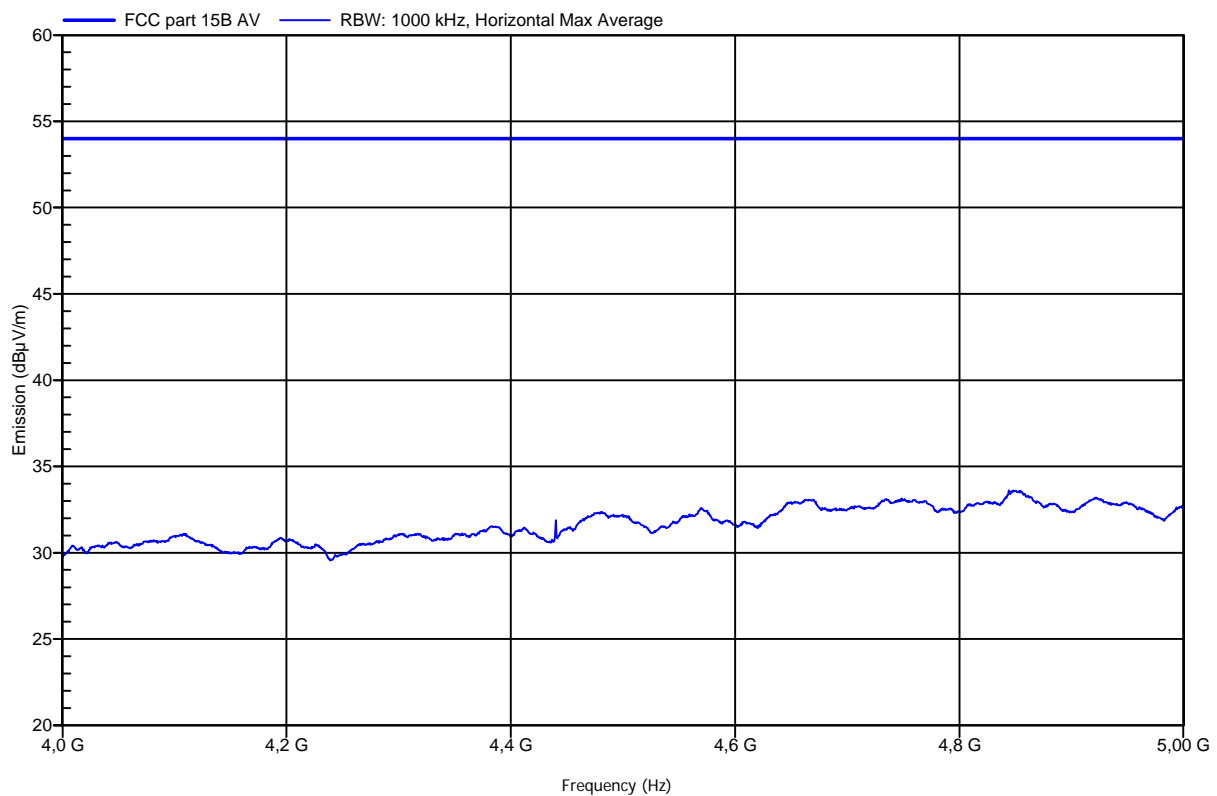
Manufacturer:	Biotronik SE & CO. KG
EUT Name:	SafeSync Module
Model:	ECM
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Pflug
Test Conditions:	Tnom: 23°C, Unom: 120 VAC (feeding over USB)
Measurement Distance:	3m
Antenna:	Rohde & Schwarz HL 025, Vertical
Mode:	usb-data-link, ULPAMI
Test Date:	19.10.2010
Note	



**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
 EUT Name: SafeSync Module  
 Model: ECM  
 Test Site: Eurofins Product Service GmbH  
 Operator: Mr. Pflug  
 Test Conditions: Tnom: 23°C, Unom: 120 VAC (feeding over USB)  
 Measurement Distance: 3m  
 Antenna: Rohde & Schwarz HL 025, Horizontal  
 Mode: usb-data-link, ULPAMI  
 Test Date: 19.10.2010  
 Note

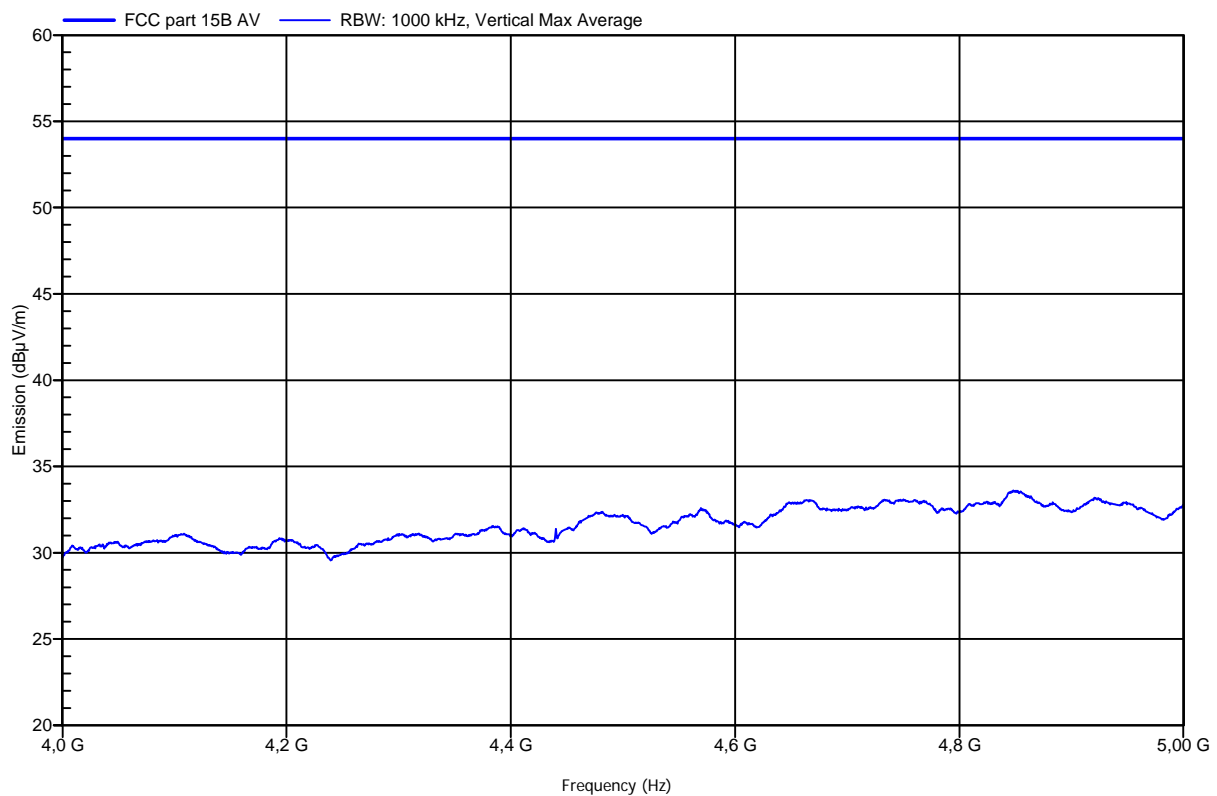




**Spurious emissions under normal conditions according to FCC part 15B**

Order number: G0M21010-3780

Manufacturer: Biotronik SE & CO. KG  
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 Measurement Distance: 3m  
 Antenna: Rohde & Schwarz HL 025, Vertical  
 Mode: usb-data-link, ULPAMI  
 Test Date: 19.10.2010  
 Note



### 3 Normative references

- /1/ FCC part 15  
Radio Frequency Devices
- /2/ CISPR 22  
Limits and Methods of Measurement of Radio Interference Characteristics of Information Technology Equipment
- /3/ ANSI C 63.4  
American National Standard for Methods of Measurement of Radio-Noise Emission from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz
- /4/ IC RSS-Gen Issue 2  
General Requirements and Information for the Certification of Radio communication Equipment