

EMC TEST REPORT

No. 816799-1

EQUIPMENT UNDER TEST

Equipment: Medical implant

Type / model: Current DR RF with embedded antenna, Model 2207
Current VR RF with embedded antenna, Model 1207
Promote RF with embedded antenna, Model 3207

Manufacturer: St. Jude Medical AB

Tested by request of: St. Jude Medical AB

SUMMARY

The equipment complies with the requirements of the following standard:

47 CFR Part 95 (2008) §95.635 – Unwanted radiation

Note: Measurements up to 3 GHz have been performed.

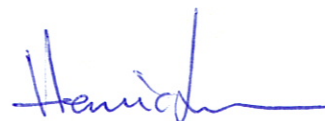
Date of issue: December 15, 2008

Tested by:



Stefan Andersson

Approved by:



Henric Larsson

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1. CLIENT INFORMATION

The EUT has been tested by request of

Company: St. Jude Medical AB
SE-175 84 Järfälla
Sweden

Name of contact: Hans Andersen

2. EQUIPMENT UNDER TEST (EUT)

2.1 Identification of the EUT according to the manufacturer/client declaration

FCC ID: RIASJMRF

Equipment: Medical implant

Type and serial number: Current DR with embedded antenna, s/n: 20 29 63
Current VR with embedded antenna, s/n: 20 29 61
Promote RF with embedded antenna, s/n: 20 29 64

Manufacturer: St.Jude Medical

Rating/Supplying voltage: Battery

External antenna connector: No

Frequency range: 402-405 MHz

Number of channels: 10

Modulation characteristics: 2 FSK

2.2 Modifications during the test

No modifications have been made during the tests

2.3 Purpose of the test

A new device antenna configuration is introduced to existing RF implant models. The original device loop antenna is a thin round wire on the surface of the device header. The new configuration is an embedded loop antenna consisting of a flat wire routed inside the epoxy header.

The purpose of this test is to confirm that the characteristics reported by the manufacturer have not been degraded by the change related to the RF-implants, now equipped with embedded antennas



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3. TEST SPECIFICATIONS

3.1 Standards

47 CFR Part 95 (2008) §95.635 – Unwanted radiation

Measurements methods according to ANSI C63.4-2003 - Methods of Measurements of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

3.2 Additions, deviations and exclusions from standards

Measurements according to *47 CFR Part 95 (2008) §95.635 – Unwanted radiation* have been performed up to 3 GHz to confirm that the characteristics have not been affected by the change related to the RF-implants.

The whole sequence of tests had been performed prior to the changes were implemented (see Intertek Emission Test Report No. 3114493BOX-001, date of issue: February 16, 2007)

No other additions, deviations or exclusions have been made from standards.

3.3 Test setup

Test setup:

The EUT was suspended in a Plexiglas torso simulator comprised of a vertical cylinder 30 cm diameter by 76 cm height, with a sidewall thickness of 6,35 mm, bonded to a liquid-tight Plexiglas base. The simulator was constructed in accordance with FCC 95.639(a)(2)(i) and EN 301 839-1 A1.1.3. These are also references for the simulator fluid.

During testing the EUT was centered vertically in the Plexiglas cylinder and 6 cm from the sidewall. A plastic jig was used to position the EUT both vertically and horizontally in the cylinder. The electrodes were placed as a vertical coil of approximately 7 cm in diameter above the EUT.

EUT was transmitting a modulated carrier during the spurious emission tests. A fresh battery was used during all tests.

3.4 Operating environment

The tests were performed under the following environmental conditions:

Air temperature: 20-25 °C
Relative humidity: 20-45 %



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4. TEST SUMMARY

The results in this report apply only to the sample tested.

FCC reference	Test	Result	Note
§95.635	Unwanted radiation	PASS	1

1) Measurements up to 3 GHz have been performed.



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5. RADIATED SPURIOUS EMISSIONS

5.1 Measurement uncertainty

Radiated emission, field strength, 30 – 1 000 MHz: ± 4,6 dB
 Radiated emission, field strength, 1 000 – 3 000 MHz: ± 6,2 dB

The measurement uncertainty describes the overall uncertainty of the given measured value during operation of the EUT.

Measurement uncertainty is calculated in accordance with EA-4/02-1997. The measurement uncertainty is given with a confidence of 95%.

5.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
<i>Test site: Semi-anechoic shielded chamber, 5.7 x 8.7 x 5.4 m (W x L x H)</i>			30900
Software:	Rohde & Schwarz	EMC 32	
Measurement receiver:	Rohde & Schwarz	ESCI	12798
Antenna amplifier:	SEMKO		7992/7993
Antenna amplifier:	Hewlet Packard	8449B	6685
Antenna, bilog:	Rohde & Schwarz		30711



5.3 Measurement set-up

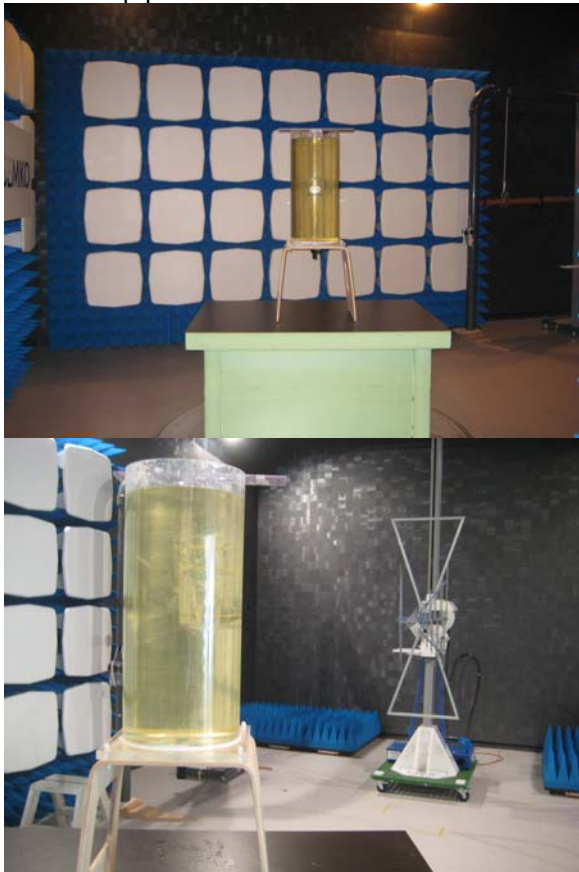
Test site: Semi-anechoic shielded chamber (30 – 3000 MHz)

The radiated disturbance electric field intensity was measured in a semi-anechoic chamber at a distance of 3 m and the Plexiglas torso with the EUT was placed on a non-metallic table, 0,8 m above the reference ground plane. The specified test mode was enabled. Test set-up photos are given below.

An overview sweep with peak detection of the electric field intensity was performed with the measurement receiver in max-hold and with the antenna placed 1,5 m, 2,5 m and 3,5 m above the floor. The polarization was horizontal and vertical. The measurements were repeated with the EUT rotated in 90-degree steps.

At the frequencies where high disturbance levels were found a search for max disturbance level was performed. With the EUT and antenna in the worst-case configuration new measurements with quasi-peak detector were carried out.

Test set-up photos:



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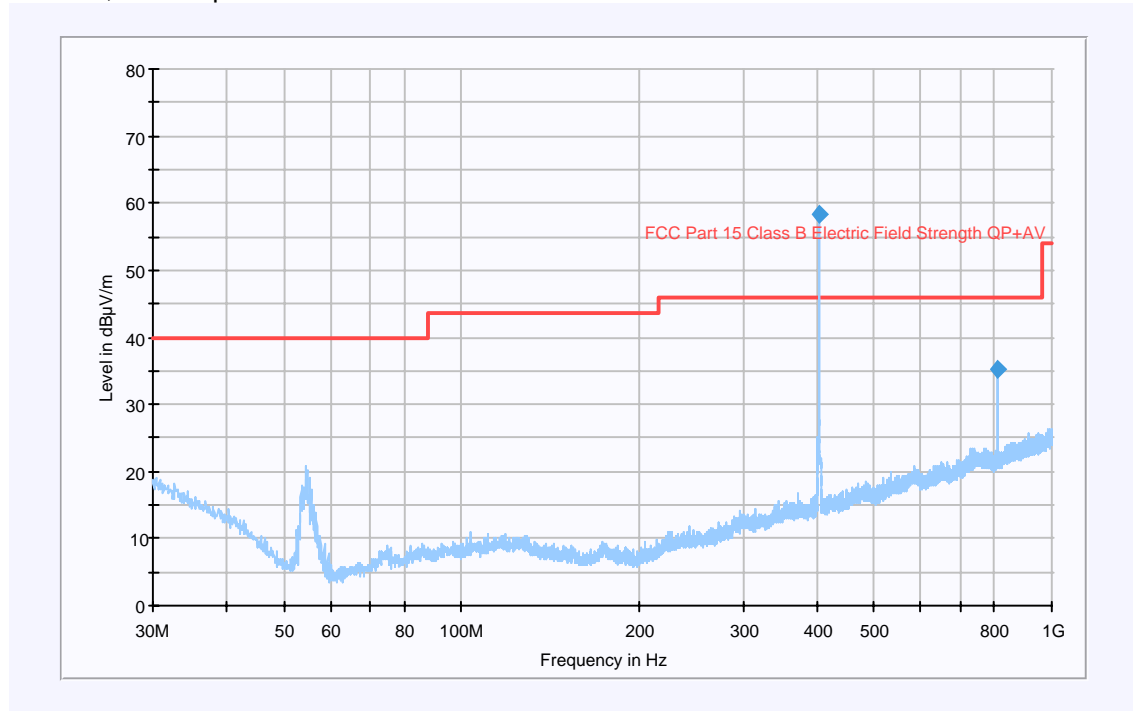
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5.4 Test protocol

Semi-anechoic shielded chamber

Date of test: 2008-11-14, 2008-11-17 & 2008-11-18

30 – 1000 MHz, max peak at a distance of 3 m, Current DR RF (202963), with embedded antenna, vertical position



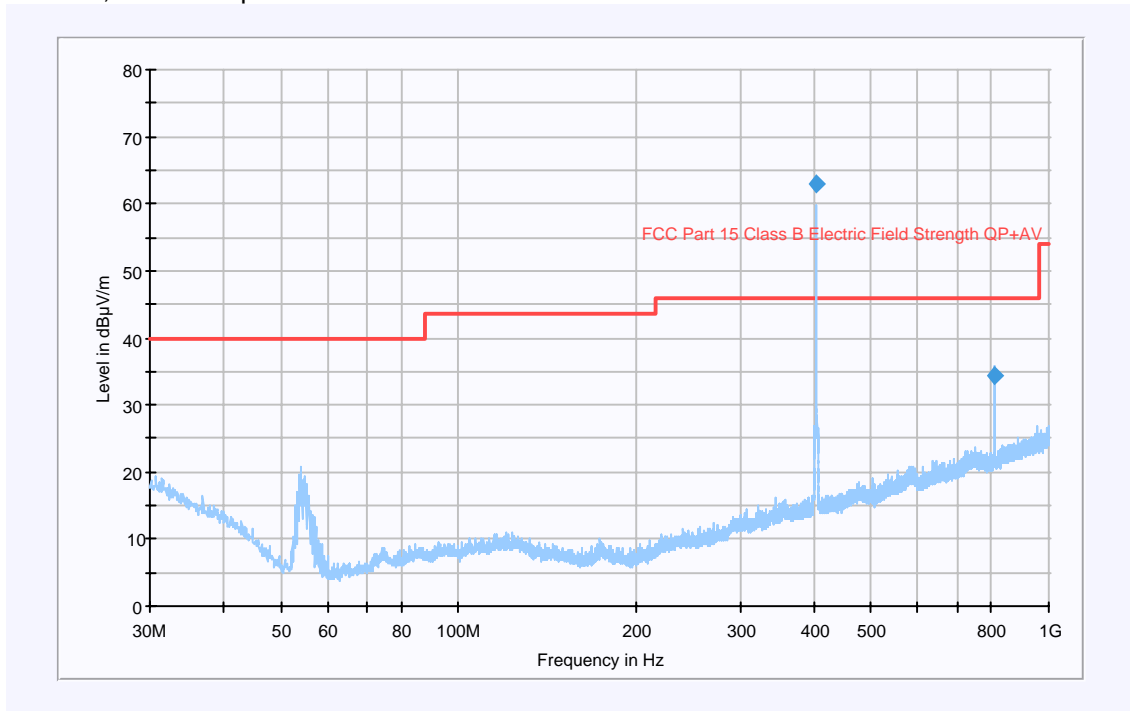
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.670000	120	-	58.2	-	-	Carrier, channel 6
807.220000	120	-	35.3	-	46	



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30 – 1000 MHz, max peak at a distance of 3 m, Current DR RF (202963), with embedded antenna, horizontal position



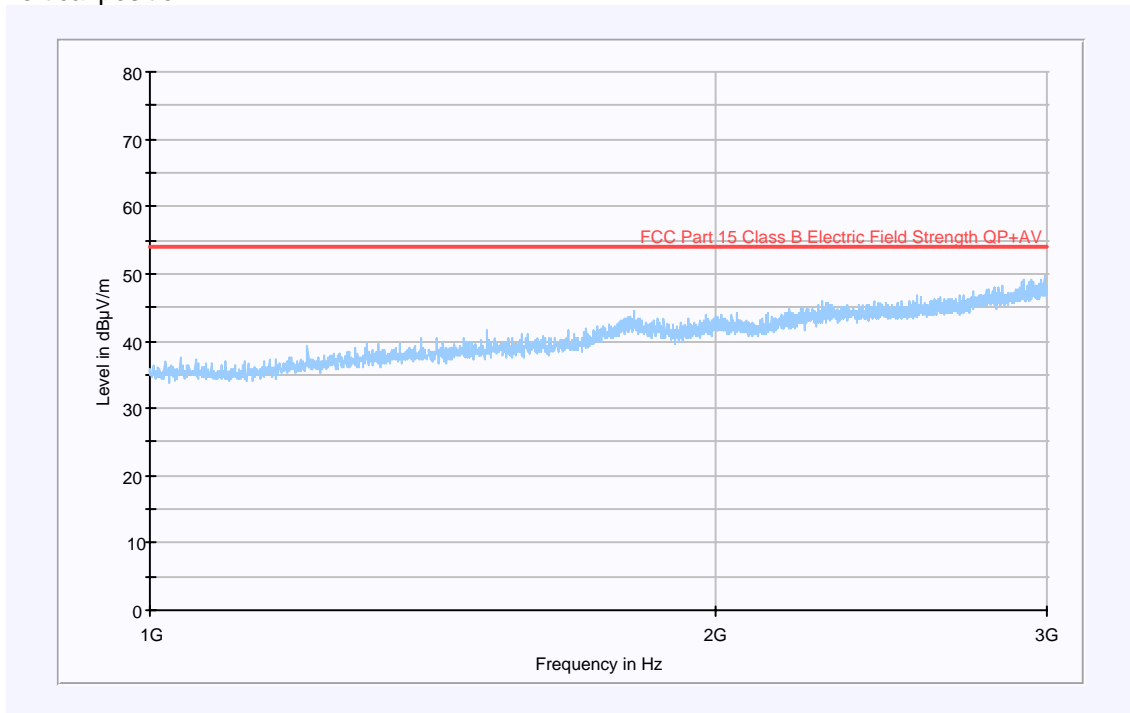
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(μV/m)]	QP/AV [dB(μV/m)]	Peak [dB(μV/m)]	QP/AV [dB(μV/m)]	
403.630000	120	-	63.0	-	-	Carrier, channel 6
807.380000	120	-	34.3	-	46	



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1 – 3 GHz, max peak at a distance of 3 m, Current DR RF (202963), with embedded antenna, vertical position



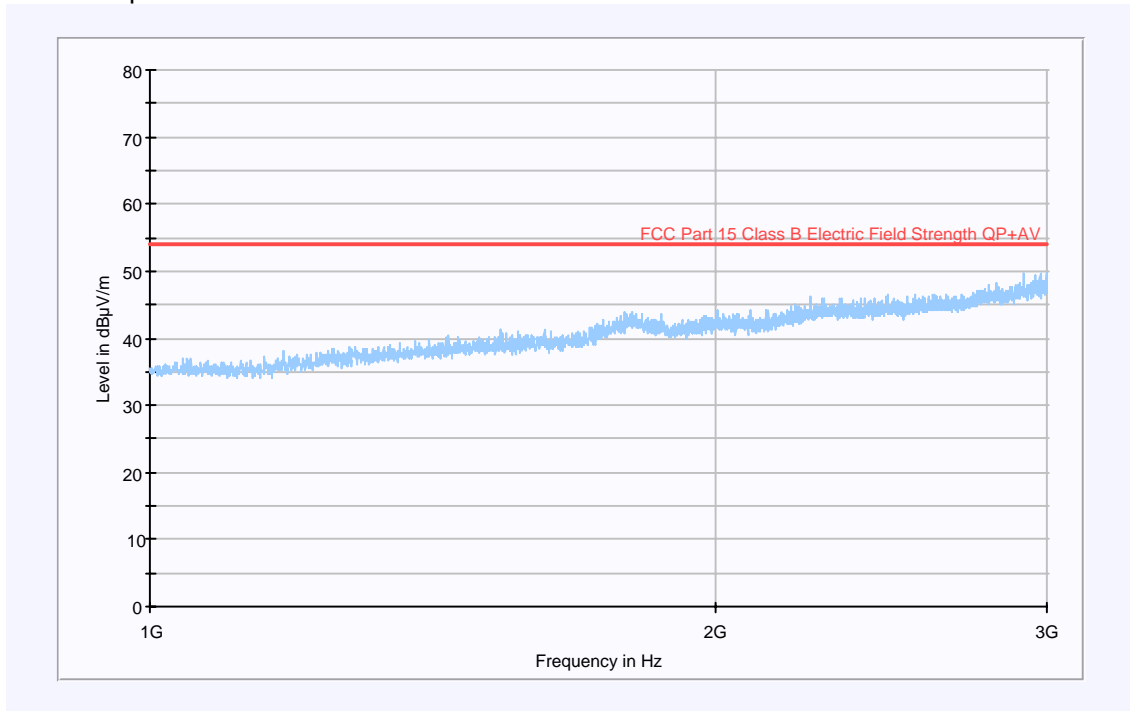
Field strength of spurious emissions						
Frequency [GHz]	RBW [MHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
1 - 3	1	-	-	-	54	No peaks above the noise floor were found



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1 – 3 GHz, max peak at a distance of 3 m, Current DR RF (202963), with embedded antenna, horizontal position



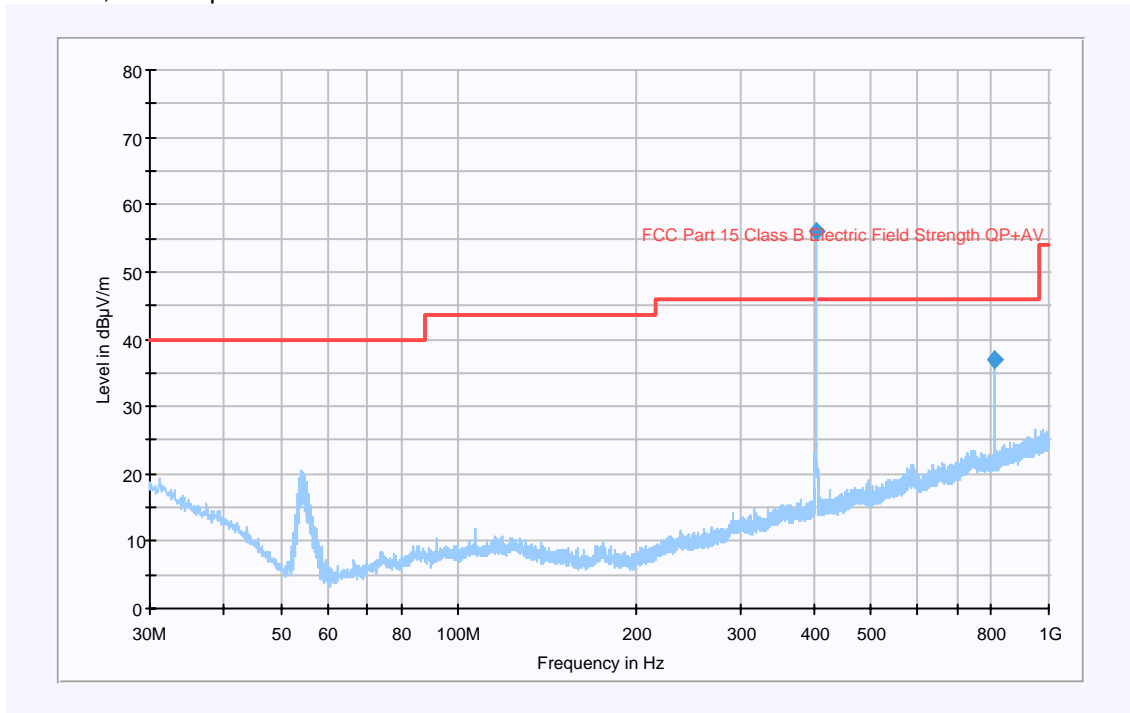
Field strength of spurious emissions						
Frequency [GHz]	RBW [MHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
1 - 3	1	-	-	-	54	No peaks above the noise floor were found



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30 – 1000 MHz, max peak at a distance of 3 m, Current VR RF (202961), with embedded antenna, vertical position



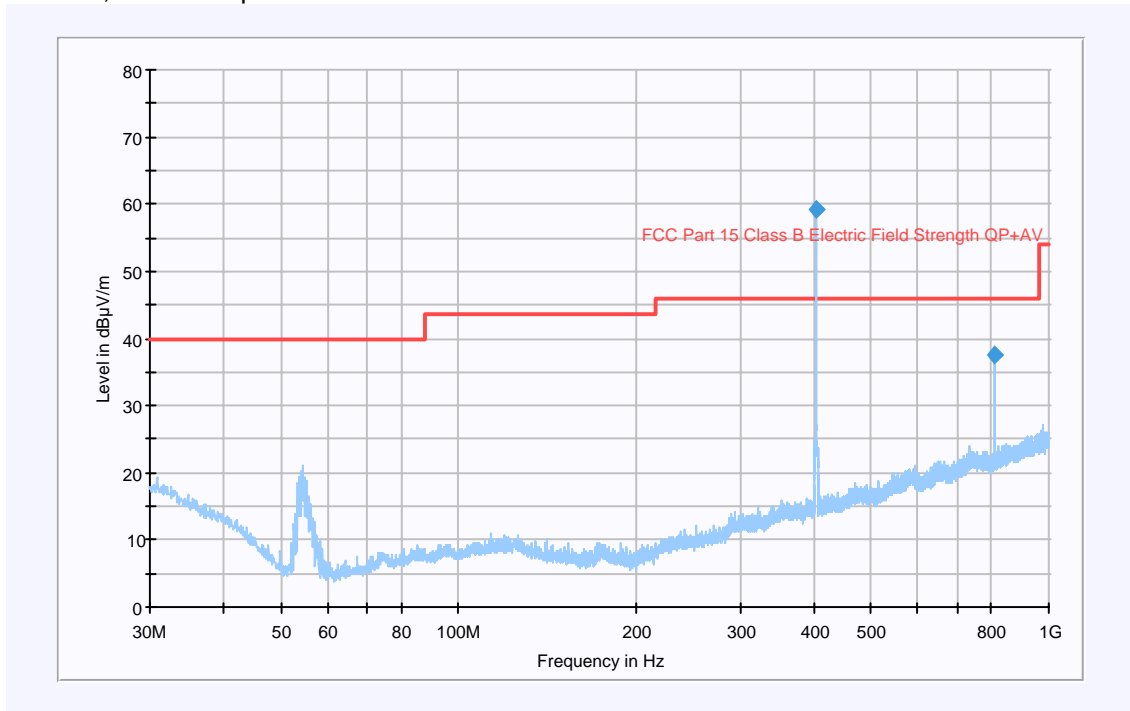
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
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403.630000	120	-	56.0	-	-	Carrier, channel 6
807.230000	120	-	37.0	-	46	



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30 – 1000 MHz, max peak at a distance of 3 m, Current VR RF (202961), with embedded antenna, horizontal position



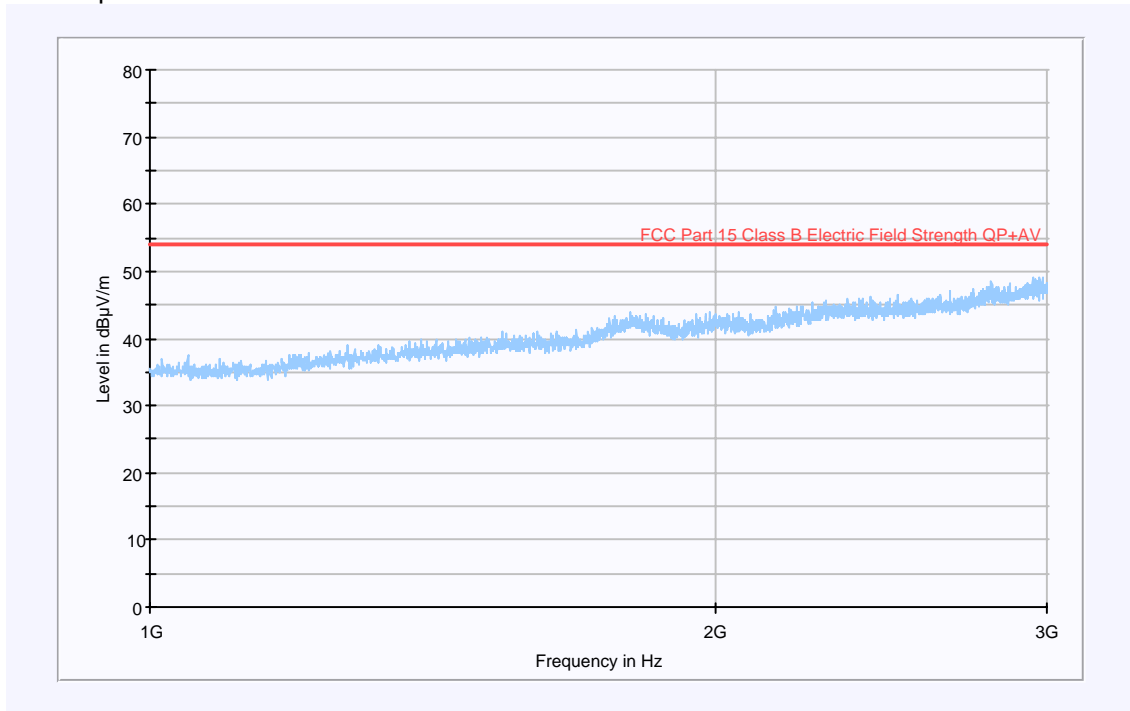
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.630000	120	-	59.1	-	-	Carrier, channel 6
807.230000	120	-	37.5	-	46	



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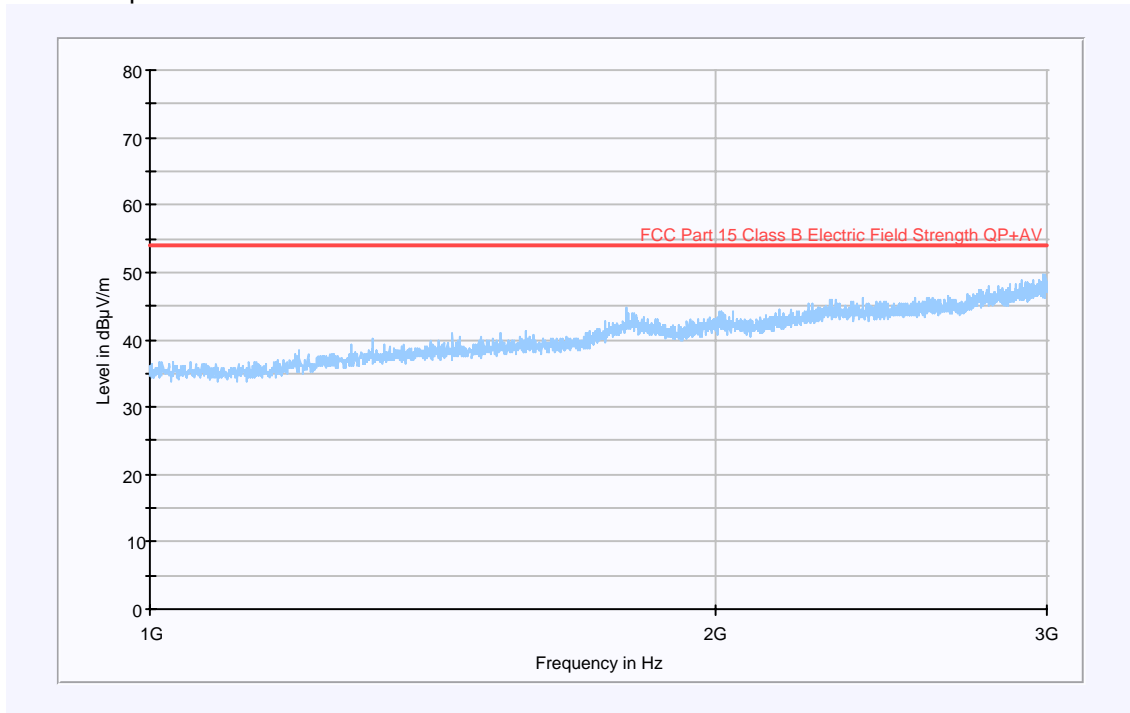
Field strength of spurious emissions						
Frequency [GHz]	RBW [MHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
1 - 3	1	-	-	-	54	No peaks above the noise floor were found



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1 – 3 GHz, max peak at a distance of 3 m, Current VR RF (202961), with embedded antenna, horizontal position



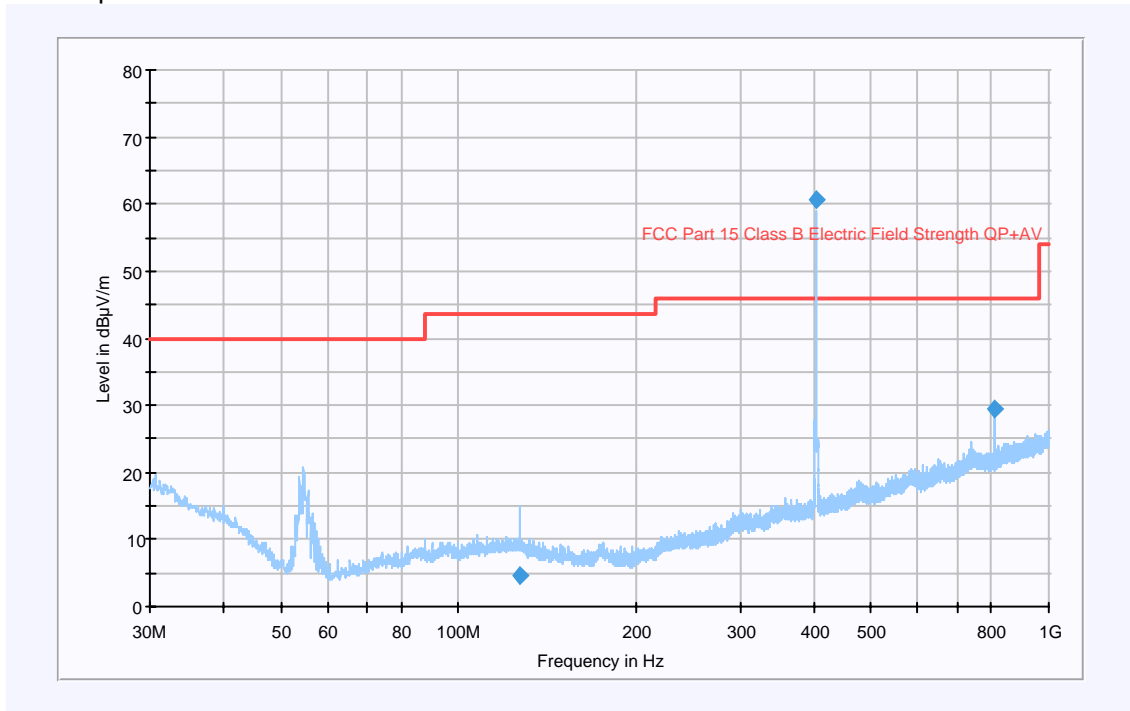
Field strength of spurious emissions						
Frequency [GHz]	RBW [MHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
1 - 3	1	-	-	-	54	No peaks above the noise floor were found



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30 – 1000 MHz, max peak at a distance of 3 m, Promote RF (202964), with embedded antenna, vertical position



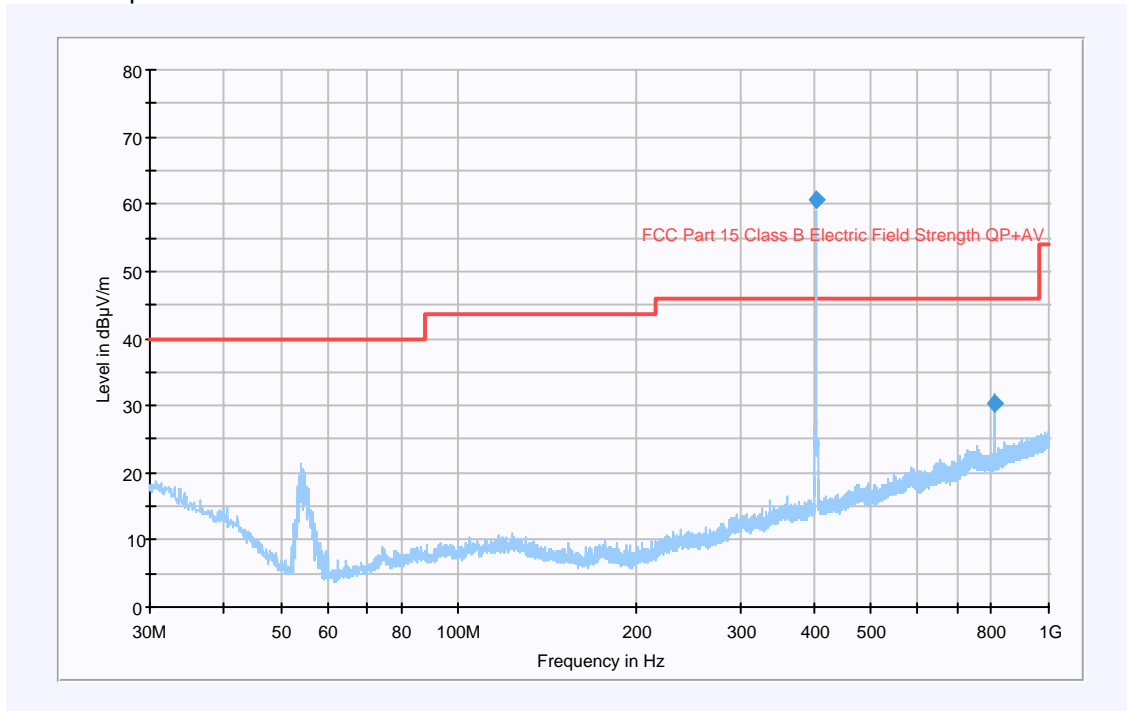
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
126.700000	120	-	4.6	-	43.5	Ambient transient
403.630000	120	-	60.7	-	-	Carrier, channel 6
807.345000	120	-	29.5	-	46	



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30 – 1000 MHz, max peak at a distance of 3 m, Promote RF (202964), with embedded antenna, horizontal position



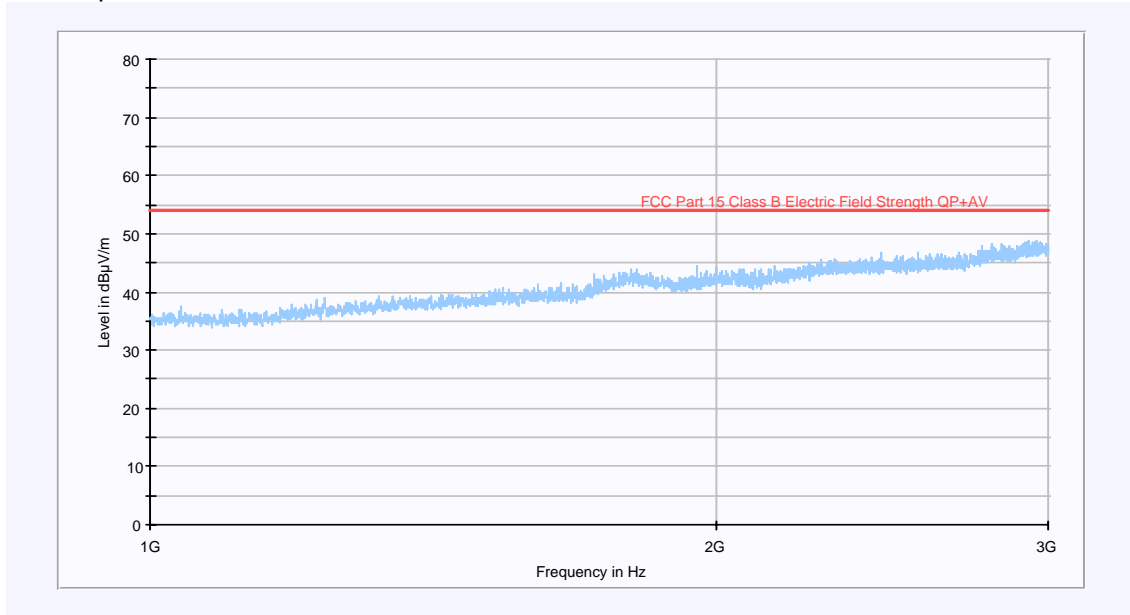
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.630000	120	-	60.6	-	-	Carrier, channel 6
807.380000	120	-	30.2	-	46	



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1 – 3 GHz, max peak at a distance of 3 m, Promote RF (202964), with embedded antenna, vertical position



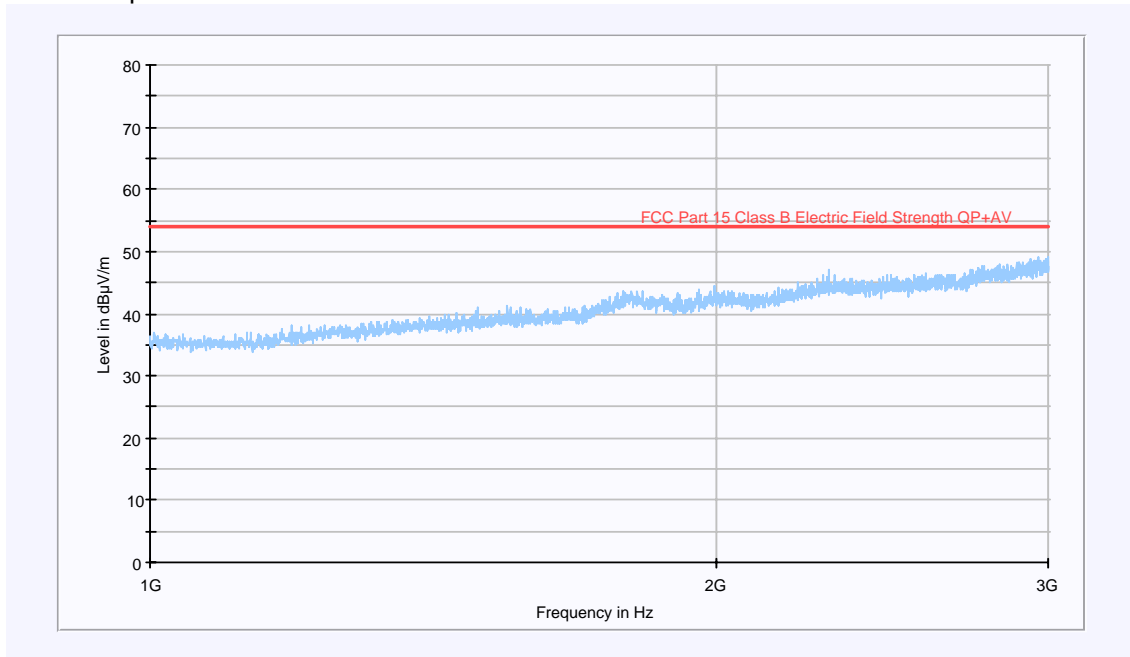
Field strength of spurious emissions						
Frequency [GHz]	RBW [MHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
1 - 3	1	-	-	-	54	No peaks above the noise floor were found



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1 – 3 GHz, max peak at a distance of 3 m, Promote RF (202964), with embedded antenna, horizontal position



Field strength of spurious emissions						
Frequency [GHz]	RBW [MHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
1 - 3	1	-	-	-	54	No peaks above the noise floor were found

Example calculation:

Measured level [dBµV/m] = Analyzer reading [dBµV] + cable loss [dB] – preamplifier gain [dB] + antenna factor [1/m]

Fulfil requirements: YES



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