EMC TEST REPORT

No. 901056-1

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
Tested by request of:	St. Jude Medical AB

SUMMARY

The equipment complies with the requirements of the following standards:

FCC 47 CFR Part 95 (2008) §95.635 – Unwanted radiation
FCC 47 CFR Part 95 (2008) §95.639(f) – Maximum transmitter power
IC RSS-243 Issue 2 (November 2005), 5.4 – Transmitter Output Power
IC RSS-243 Issue 2 (November 2005), 5.5 – Transmitter Unwanted Emissions

Note: Measurements up to 3 GHz have been performed.

Industry Canada listed test facility No. IC 2042G-1

Date of issue: February 13, 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
IC ID:	7067A SJM RF
Equipment:	Medical implant
Type and serial number:	Current DR RF with embedded antenna, s/n: 20 29 62 Current VR RF 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

3. TEST SPECIFICATIONS

3.1 Standards

FCC 47 CFR Part 95 (2008) §95.635 – Unwanted radiation
FCC 47 CFR Part 95 (2008) §95.639(f) – Maximum transmitter power
IC RSS-243, Issue 2 (November 2005), 5.4 – Transmitter Output Power
IC RSS-243, Issue 2 (November 2005), 5.5 – Transmitter Unwanted Emissions

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 of 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)

The sidewall thickness of the torso simulator is 6.1 mm instead of 6.35 mm.

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 79 cm height, with a sidewall thickness of 6,1 mm, bonded to a liquid-tight Plexiglas base. The cylinder was filled with fluid to 76 cm height. 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. The simulator fluid has been made and measured by St. Jude Medical AB to fulfill the standard, the measured values are σ = 0.93 s/m and ε' = 58.4.

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 and a CW during maximum output power measurement. 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	%

4. TEST SUMMARY

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

FCC reference	IC reference	Test	Result
§95.635	5.5	Unwanted radiation, Transmitter Unwanted Emissions	PASS*
§95.639	5.4	Maximum transmitter power, Transmitter Output Power	PASS

* Measurements up to 3 GHz have been performed.

5. UNWANTED RADIATION AND MAXIMUM TRANSMITTER POWER

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.
Test site: Semi-anechoic shielded chamber, 5.7 x 8.7 x 5.4 m (W x L x H)			*30900*
Software:	Rohde & Schwarz	EMC 32	
Measurement receiver:	Rohde & Schwarz	ESCI	12798
Antenna amplifier:	Schaffner	LNA 6000	13129
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. The Plexiglas torso with the EUT was placed on a non-metallic table and the center of the torso and EUT was 1.5 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.

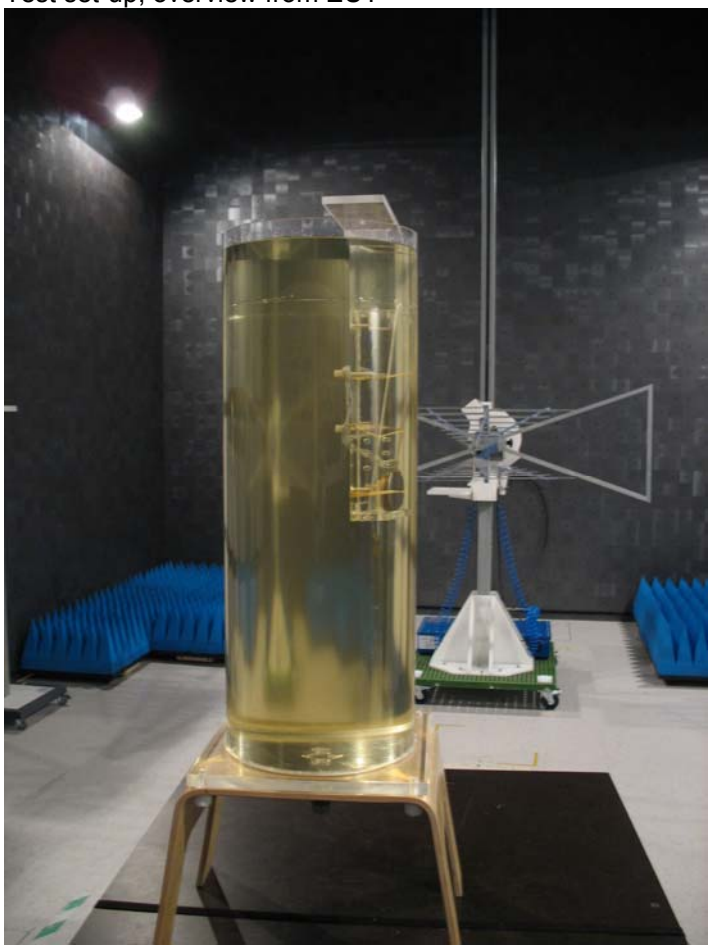
At the frequencies where high disturbance levels were found a search for max disturbance level was performed. With the EUT and antenna in the worst-case configuration new measurements with quasi-peak detector were carried out.

For maximum transmitter power measurement the turntable was turned 360 degrees and the antenna mast was moved from 1 m to 4 m to find the maximum power. The measurement was performed with both horizontal and vertical polarization.

Test set-up photos:

Test set-up, overview from antenna

Test set-up, overview from EUT



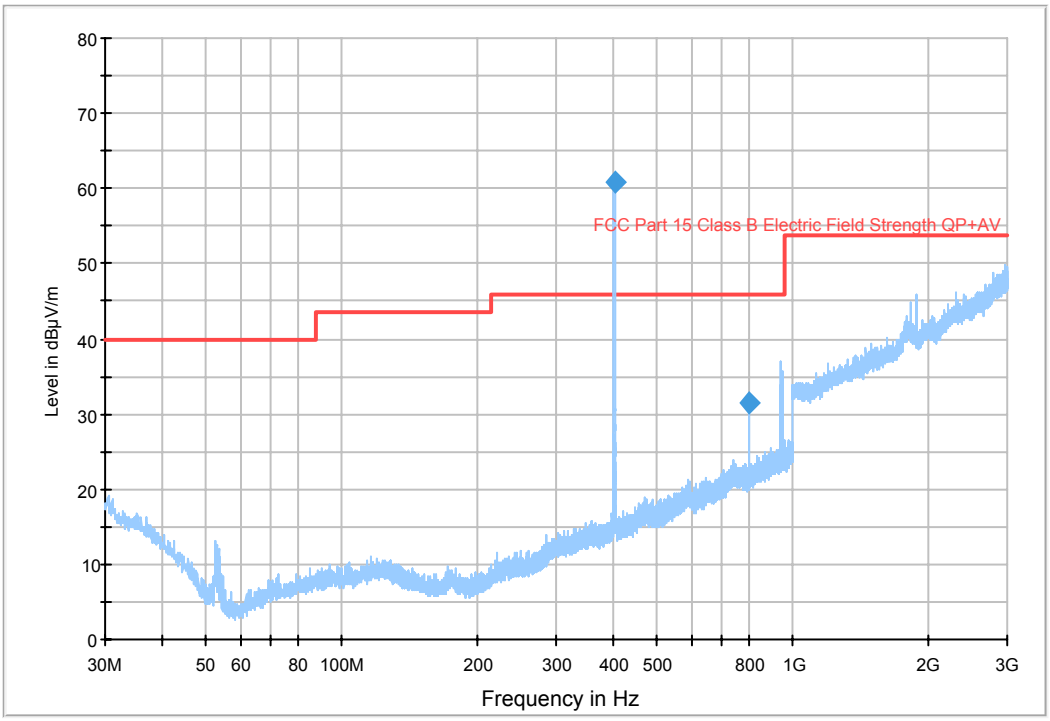
Test set-up, EUT in Plexiglas cylinder

5.4 Test protocol, Unwanted radiation

Semi-anechoic shielded chamber

Date of test: 2009-01-26

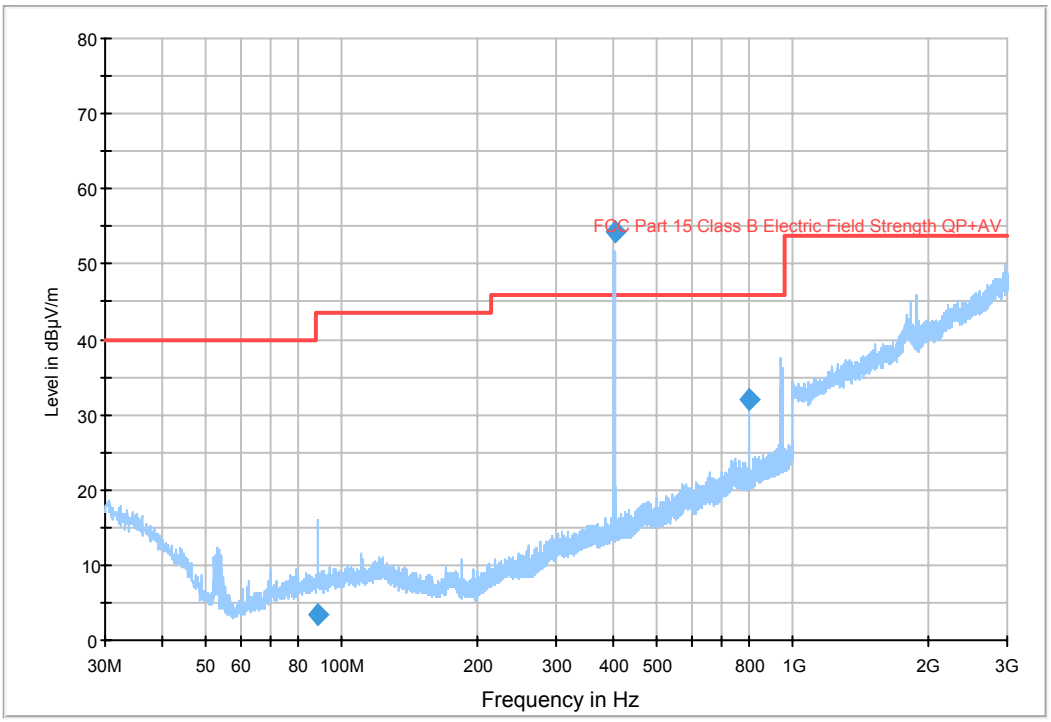
30 – 3000 MHz, max peak at a distance of 3 m, Current DR RF (202962), with embedded antenna, vertical position



Field strength of spurious emissions						
Frequency	RBW	Measured level		Limit		Note
		Peak	QP/AV	Peak	QP/AV	
[MHz]	[kHz]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	
403.649	120	-	60.7	-	-	Carrier, channel 5
807.375	120	-	31.4	-	46.0	

The peaks at 950 MHz and 1850-1900 MHz are ambient disturbances.

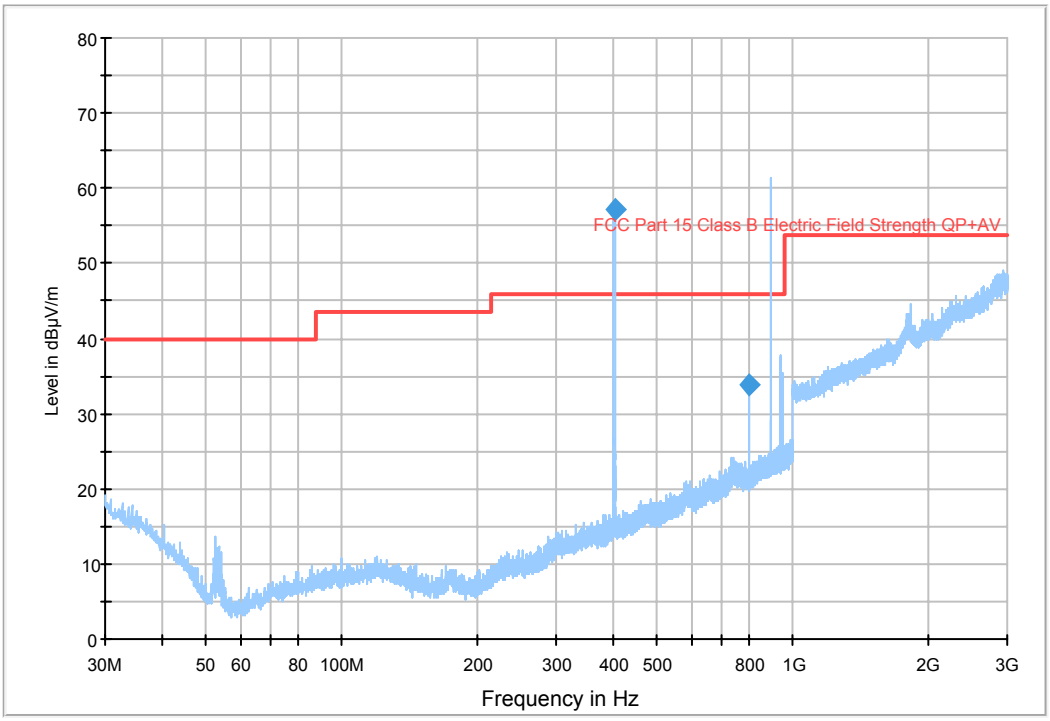
30 – 3000 MHz, max peak at a distance of 3 m, Current DR RF (202962), with embedded antenna, horizontal position



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)]	
88.813	120	-	3.4	-	43.5	
403.649	120	-	54.3	-	-	Carrier, channel 5
807.250	120	-	32.0	-	46.0	

The peaks at 89 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.

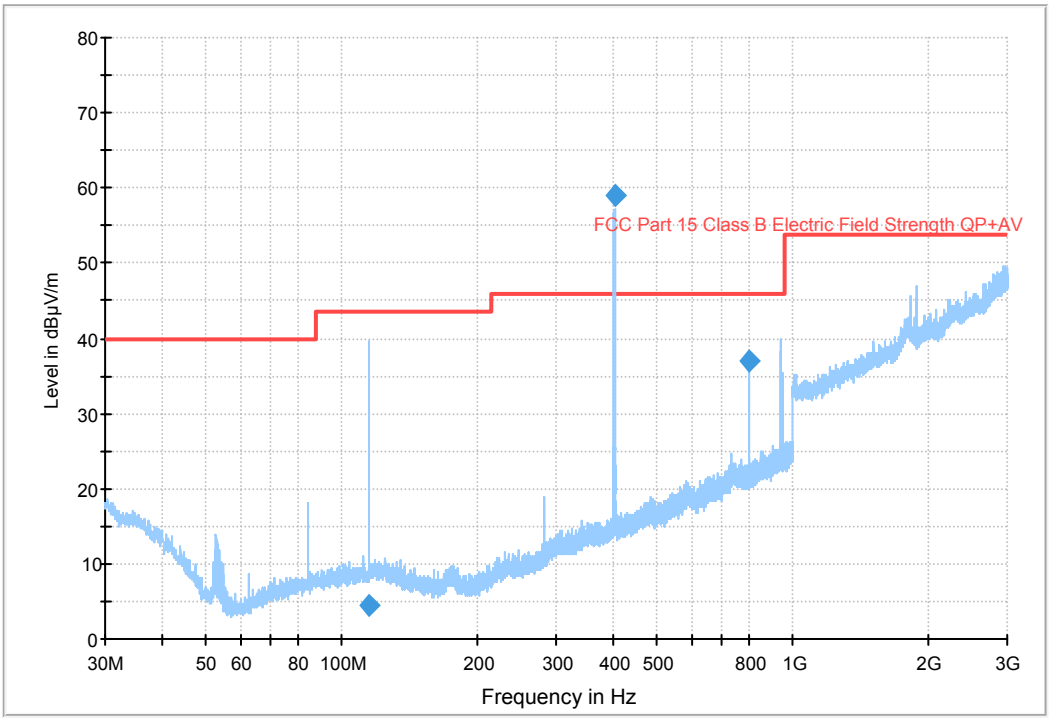
30 – 3000 MHz, max peak at a distance of 3 m, Current VR RF (202961), with embedded antenna, vertical position



Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.650	120	-	57.1	-	-	Carrier, channel 5
807.370	120	-	33.8	-	46.0	

The peaks at 900 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.

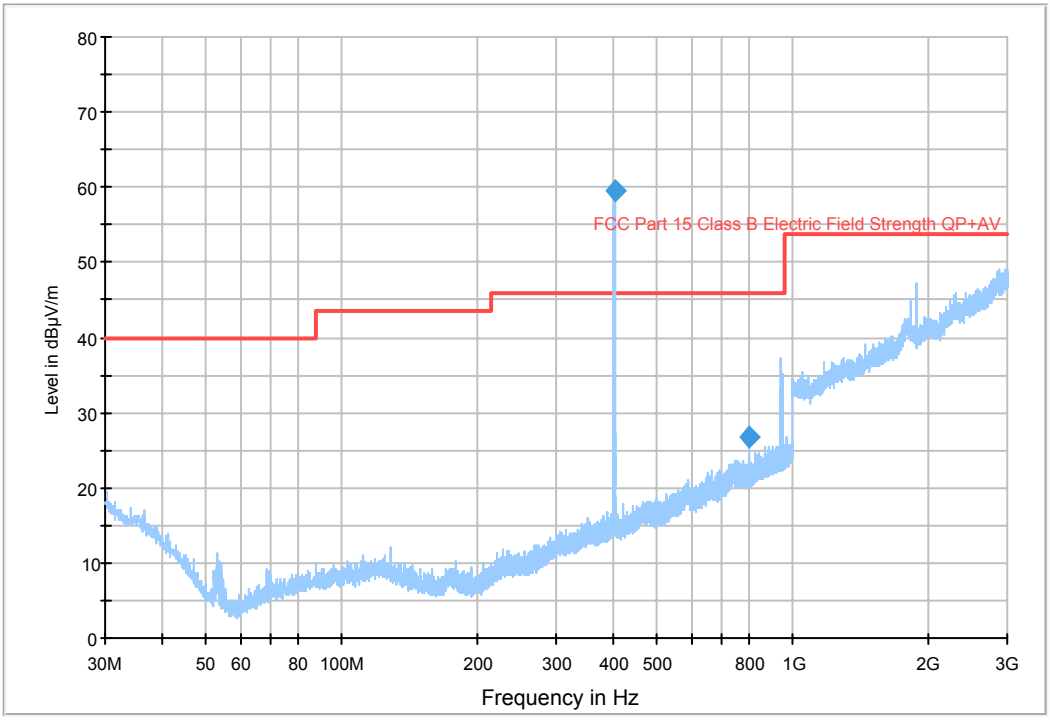
30 – 3000 MHz, max peak at a distance of 3 m, Current VR RF (202961), with embedded antenna, horizontal position



Field strength of spurious emissions						
Frequency	RBW	Measured level		Limit		Note
		Peak	QP/AV	Peak	QP/AV	
[MHz]	[kHz]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	
115.960	120	-	4.5	-	43.5	
403.650	120	-	59.0	-	-	Carrier, channel 5
807.375	120	-	36.9	-	46.0	

The peaks at 83 MHz, 116 MHz, 290 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.

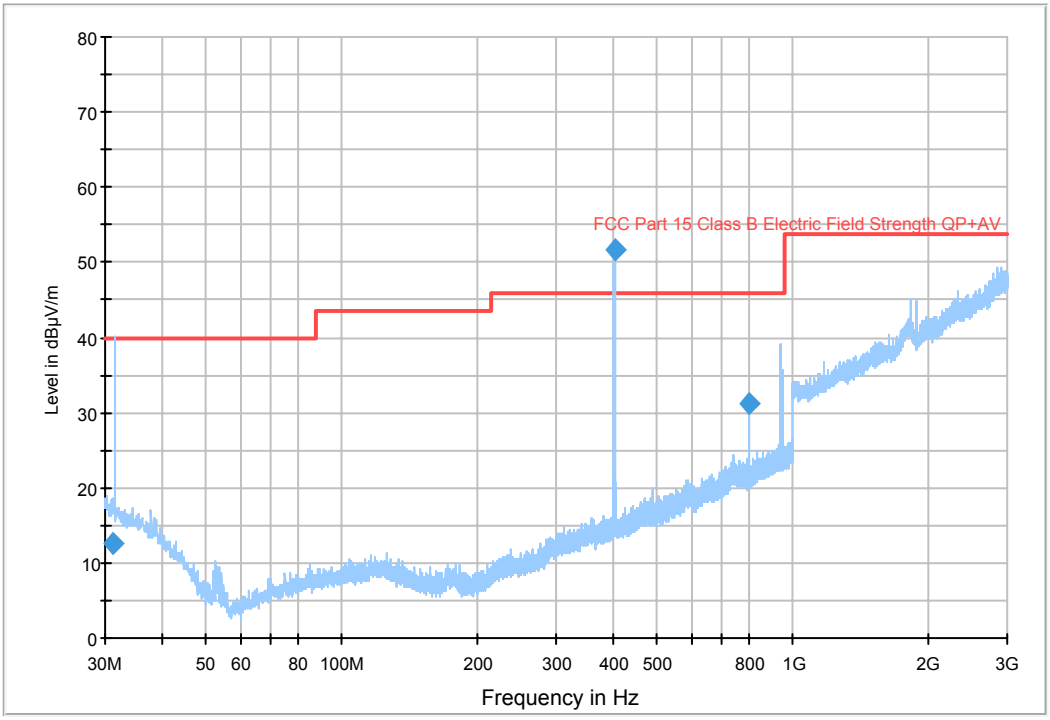
30 – 3000 MHz, max peak at a distance of 3 m, Promote RF (202964), with embedded antenna, vertical position



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)]	
403.650	120	-	59.4	-	-	Carrier, channel 5
807.370	120	-	26.8	-	46.0	

The peaks at 950 MHz and 1850-1900 MHz are ambient disturbances.

30 – 3000 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)]	
31.348	120	-	12.6	-	40.0	
403.650	120	-	51.7	-	-	Carrier, channel 5
807.370	120	-	31.2	-	46.0	

The peaks at 31 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.

Example calculation:

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

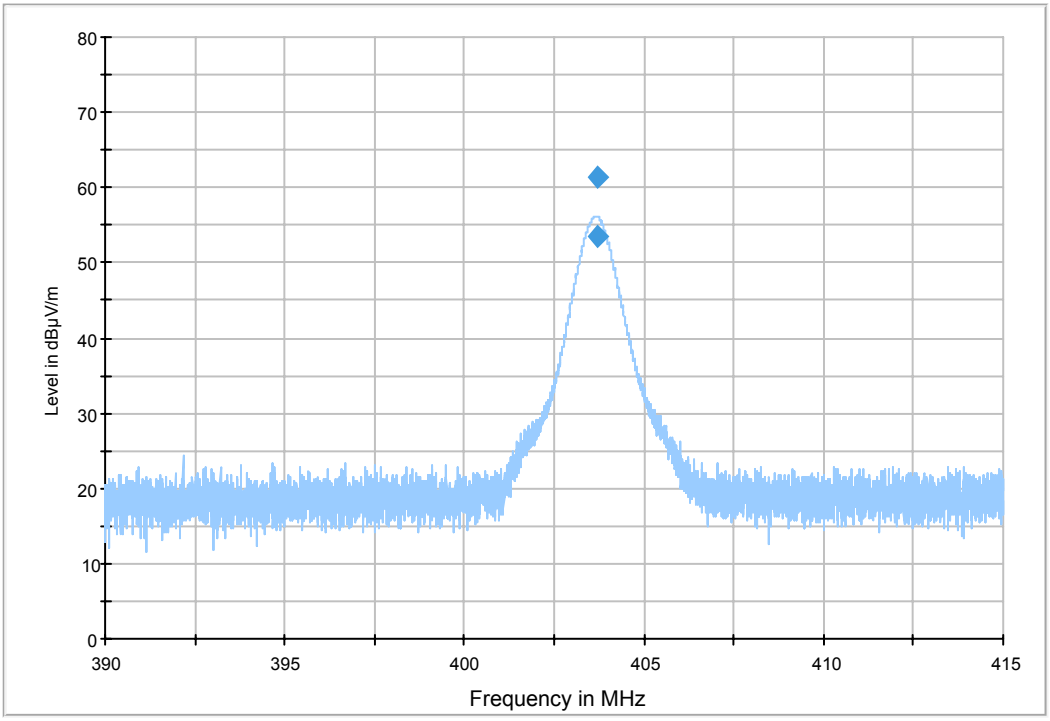
Fulfil requirements: YES

5.5 Test protocol, Maximum transmitter power

Semi-anechoic shielded chamber

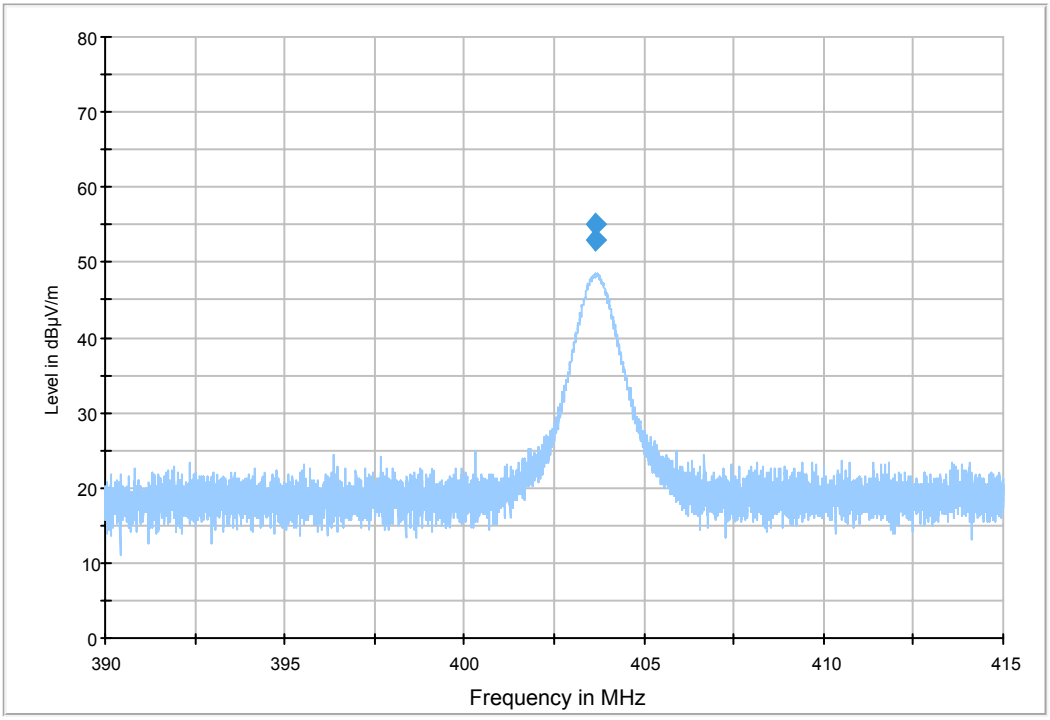
Date of test: 2009-01-27

Maximum transmitter power at a distance of 3 m, Current DR (202962), with embedded antenna, vertical position



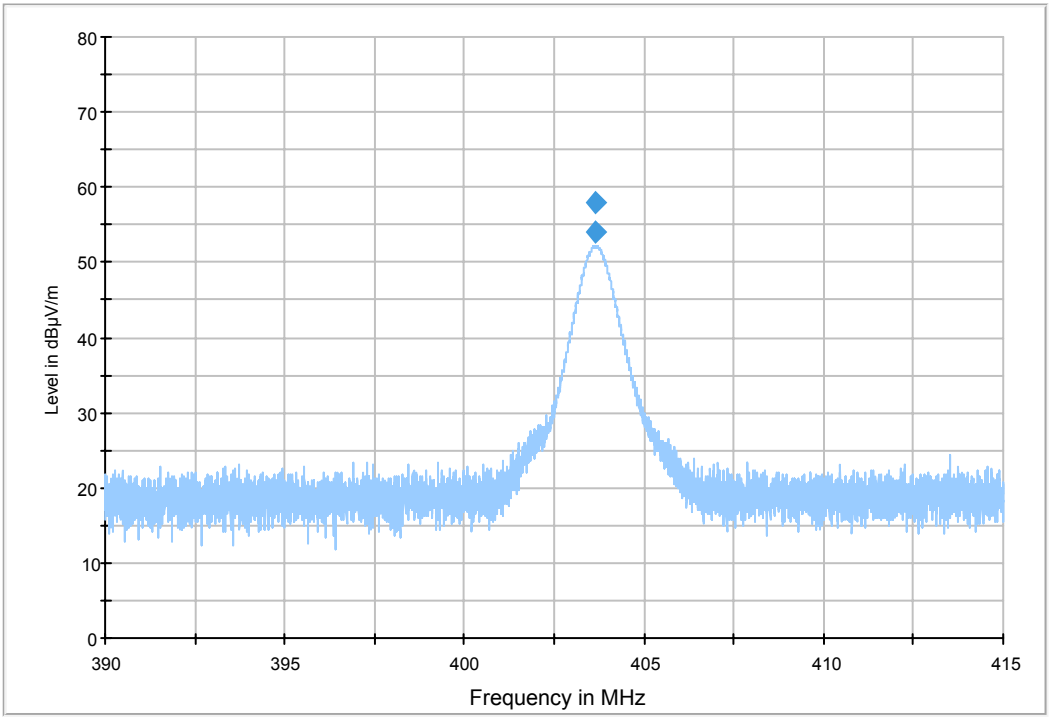
Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
[MHz]	[kHz]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.681	1000	61.3	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Current DR (202962), with embedded antenna, horizontal position



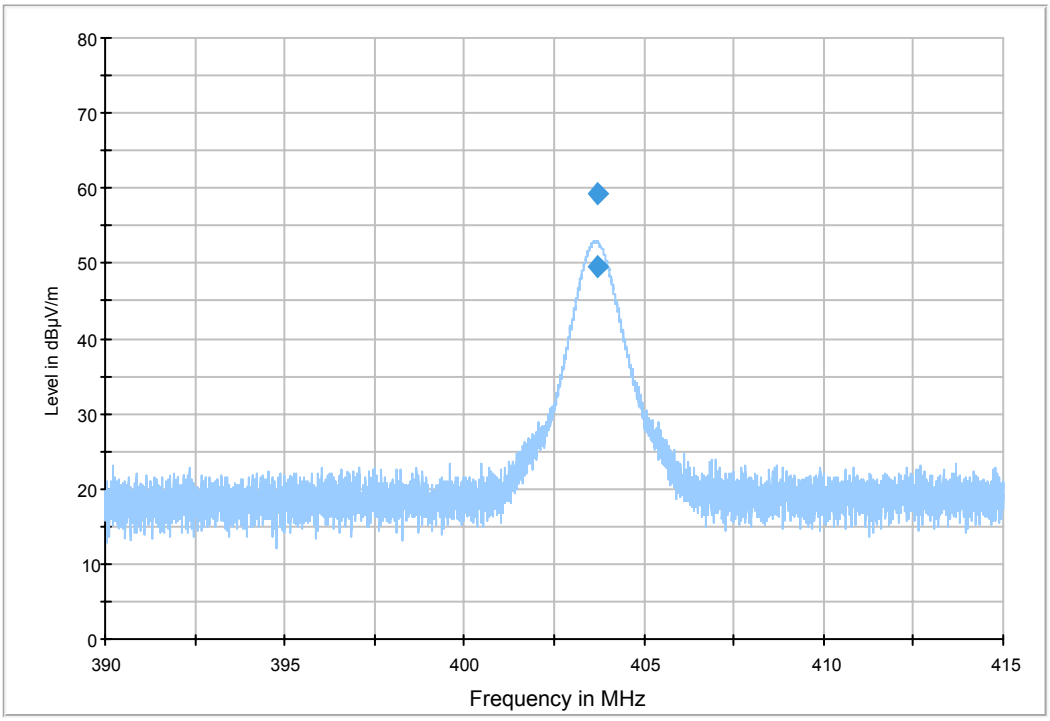
Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
		Peak	QP/AV	Peak	QP/AV	
[MHz]	[kHz]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	
403.628	1000	55.0	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Current VR (202961), with embedded antenna, vertical position



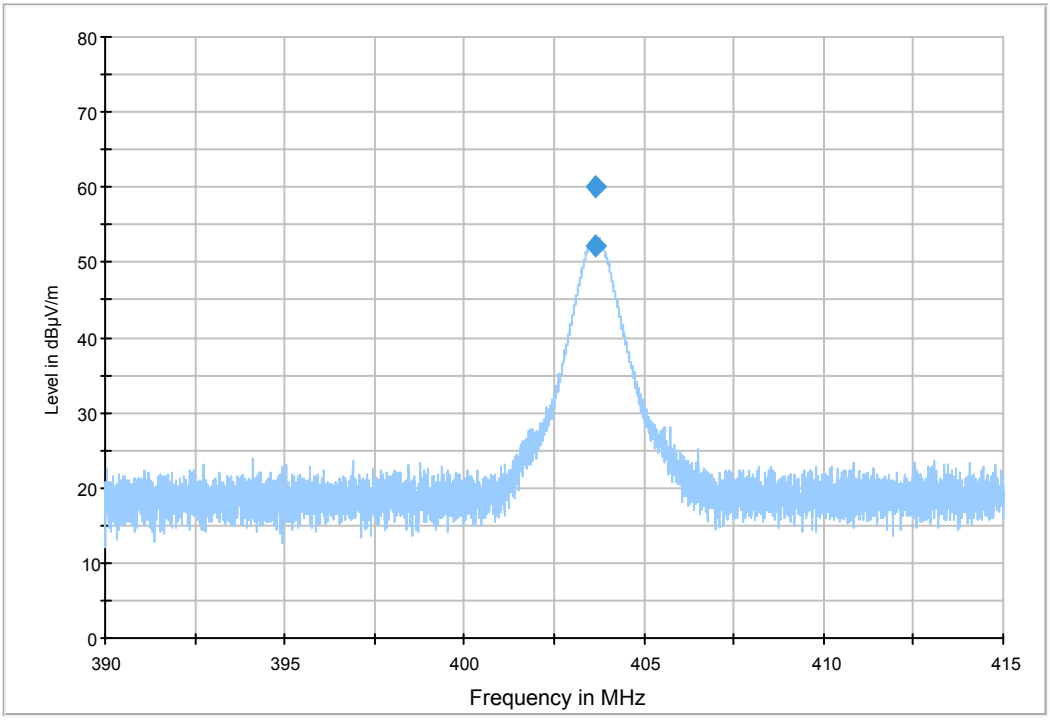
Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
[MHz]	[kHz]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.628	1000	57.9	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Current VR (202961), with embedded antenna, horizontal position



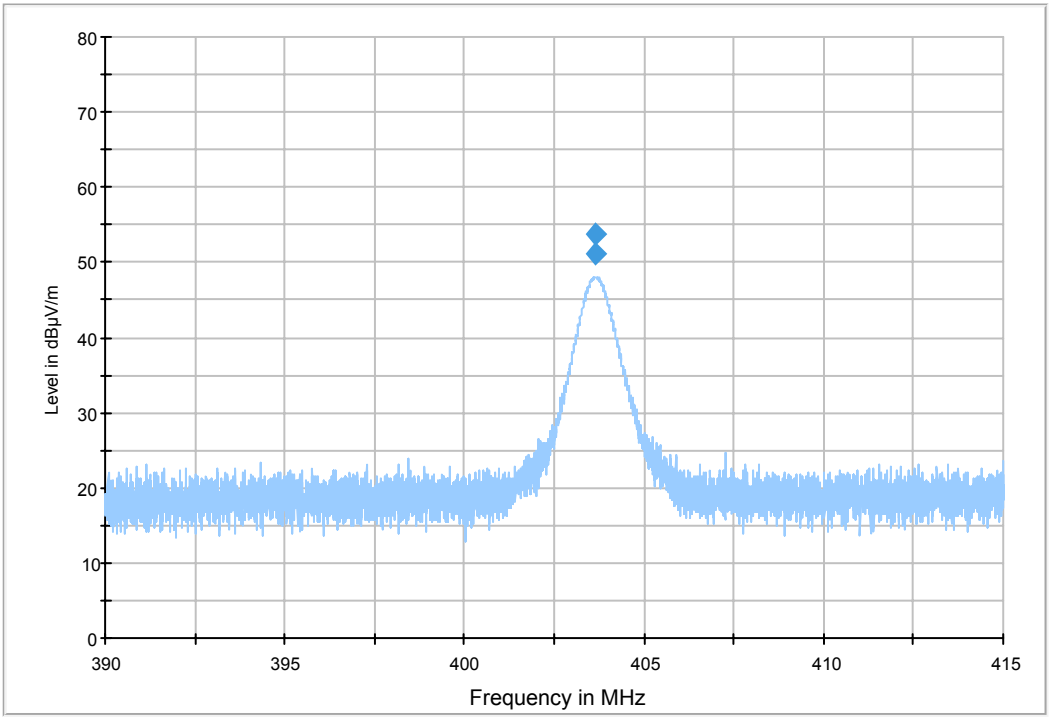
Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
[MHz]	[kHz]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.679	1000	59.3	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Promote RF (202964), with embedded antenna, vertical position



Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
[MHz]	[kHz]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.653	1000	60,0	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Promote RF (202964), with embedded antenna, horizontal position



Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
[MHz]	[kHz]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403.638	1000	53.7	-	85.2	-	

Example calculation:

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

Limit: 25 µW e.i.r.p. correspond to 85.2 dB(µV/m) at 3 m antenna distance.

Fulfil requirements: YES