

# EMC TEST REPORT

**No. 903213-1****EQUIPMENT UNDER TEST**

Equipment: Medical implant

Type / model: Accent SR RF, model PM1210  
Accent DR RF, model PM2212  
Anthem RF, model PM3212

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 Subpart I (2008)  
IC RSS-243 Issue 2 (November 2005)

Note: Only selected tests has been performed on the above mentioned models by the request of the client, the whole sequence of tests has been performed on implant model 2207DR at Intertek Boxborough, test report 3114493BOX-001 (2007-01-24 to 2007-01-25)

Date of issue: April 6, 2009

Tested by:



Stefan Andersson

Approved by:



Niklas Boström

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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, according to the manufacturer, of the EUT measured at Intertek Kista (Date of test 2009-01-30)**

Equipment: Medical implant  
Type and serial number: Accent SR RF, s/n: 1274081  
Accent DR RF, s/n: 1274101  
Anthem RF, s/n: 1274122  
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 Identification, according to the manufacturer, of the EUT measured at Intertek Boxborough, test report 3114493BOX-001 (Date of test 2007-01-24 to 2007-01-25)**

FCC ID: RIASJMRF  
IC ID: 7067A SJM RF  
Equipment: Medical implant  
Type and serial number: 2207DR, s/n: 201275, UEN396  
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

**2.3 Modifications during the test**

No modifications have been made during the tests.



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### 3. TEST SPECIFICATIONS

#### 3.1 Standards

FCC 47 CFR Part 95 Subpart I (2008)

IC RSS-243, Issue 2 (November 2005)

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

The following measurements have been performed at Intertek Kista by request of the client:

- FCC 47 CFR Part 95 (2008) §95.635 – Unwanted radiation more than 250 kHz removed from MICS band has been performed up to 3 GHz.
- IC RSS-243, Issue 2 (November 2005), 5.5 – Transmitter Unwanted Emissions more than 250 kHz removed from MICS band has been performed up to 3 GHz.
- FCC 47 CFR Part 95 (2008) §95.639(f) – Maximum transmitter power
- IC RSS-243, Issue 2 (November 2005), 5.4 – Transmitter Output Power

The whole sequence of tests has been performed on implant 2207DR with serial number: 201275, UEN396. (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  $\sigma = 0.93$  s/m and  $\epsilon' = 58.4$ .

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. Channel 5 (403.65 MHz) was utilized for testing. A fresh battery was used during all tests.



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### 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   | IC reference | Test  | Result | Note |
|-----------------|--------------|---|--------|------|
| §95.639(f)      | 5.4          | Maximum Transmitter Power                                       | PASS   | 1    |
| §95.633(e)      | 5.1          | Emission Bandwidth  | PASS   | 2    |
| §95.635         | 5.5          | Unwanted Radiation more than 250 kHz removed from the MICS band | PASS   | 2, 3 |
| §95.635         | 5.5          | Unwanted Radiation within 250 kHz of the MICS band              | PASS   | 2    |
| §95.628(e)      | 5.3          | Frequency Error   | PASS   | 2    |
| §95.628(a)(1-4) | 5.7          | MICS Operation  | N/A    | 4    |

- 1) Performed at Intertek Kista on implant Accent SR RF, Accent DR RF and Anthem RF
- 2) Performed at Intertek Boxborough, test report 3114493BOX-001, on implant 2207DR
- 3) Performed up to 3 GHz at Intertek Kista on implant Accent SR RF, Accent DR RF and Anthem RF
- 4) MICS Programmer/Controller test only



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## 5. UNWANTED RADIATION AND MAXIMUM TRANSMITTER POWER

### 5.1 Measurement uncertainty

Radiated emission, field strength, 30 – 1 000 MHz:  $\pm 4.6$  dB

Radiated emission, field strength, 1 000 – 3 000 MHz:  $\pm 6.2$  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>Semi-anechoic shielded chamber "Björkhallen", 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:   | Schaffner       | LNA 6000 | 13129     |
| Antenna, bilog:  | Rohde & Schwarz |          | 30711     |

### 5.3 Test site

The tests in Kista were performed at the following test location:

Intertek Semko AB  
Torshamnsgatan 43  
Box 1103, SE-164 22 Kista, Sweden

The test location has two test sites. Both sites are semi anechoic chambers and they are named "Björkhallen" and "Stora Hallen". "Björkhallen" is a 3m semi anechoic chamber and "Stora Hallen" is a 10m semi anechoic chamber with the possibility to measure at 3m or 10m distance.

For both chambers the information required by Section 2.948 of the FCC Rules has been uploaded to the FCC and has been registered by FCC with No. 90913

"Björkhallen" has been registered by Industry Canada with test site id 2042G-1

"Stora Hallen" has been registered by Industry Canada with test site id 2042G-2

All tests in this report were performed in "Björkhallen" except the tests performed at Boxborough.



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#### 5.4 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

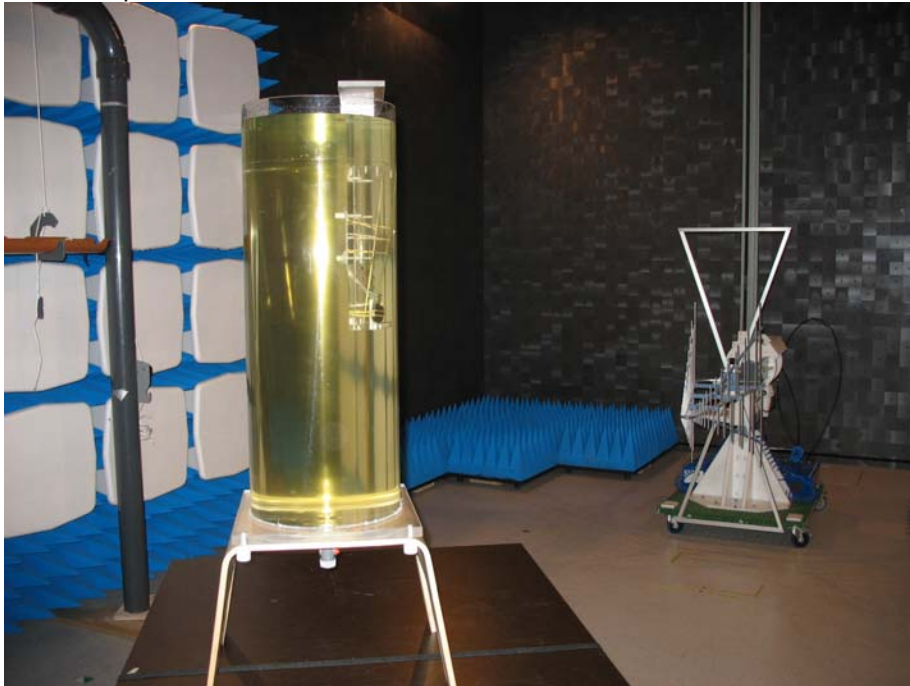


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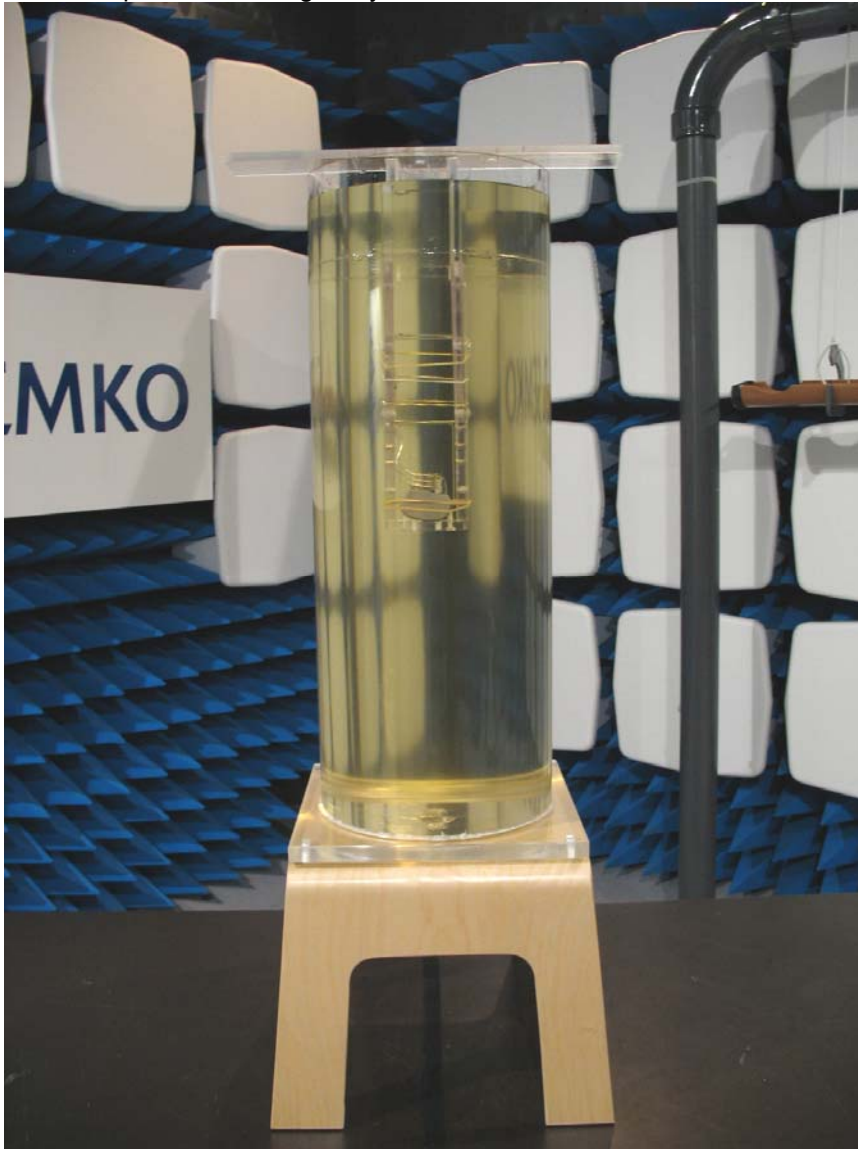
Test set-up, overview from EUT



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Test set-up, EUT in Plexiglas cylinder



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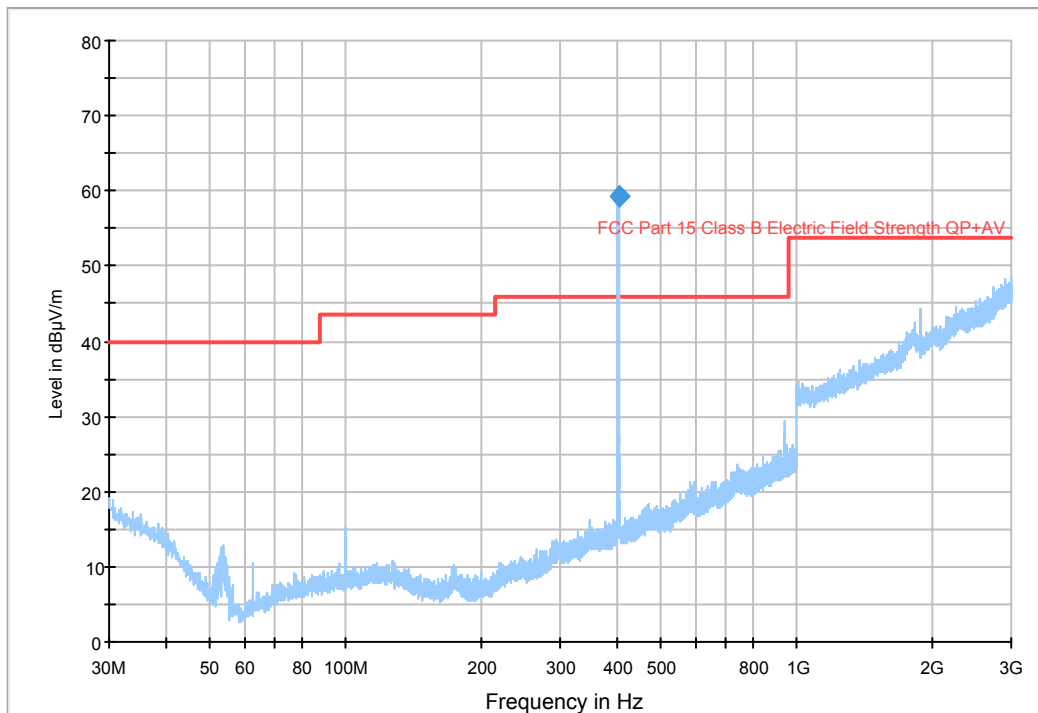
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## 5.5 Test protocol, Unwanted radiation

Semi-anechoic shielded chamber

Date of test: 2009-01-30

30 – 3000 MHz, max peak at a distance of 3 m, Accent SR RF (1274081), vertical position



| Field strength of spurious emissions |              |                    |                     |                    |                     |                    |
|--------------------------------------|--------------|--------------------|---------------------|--------------------|---------------------|--------------------|
| Frequency<br>[MHz]                   | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note               |
|                                      |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |                    |
| 403.650                              | 120          | -                  | 59.2                | -                  | -                   | Carrier, channel 5 |

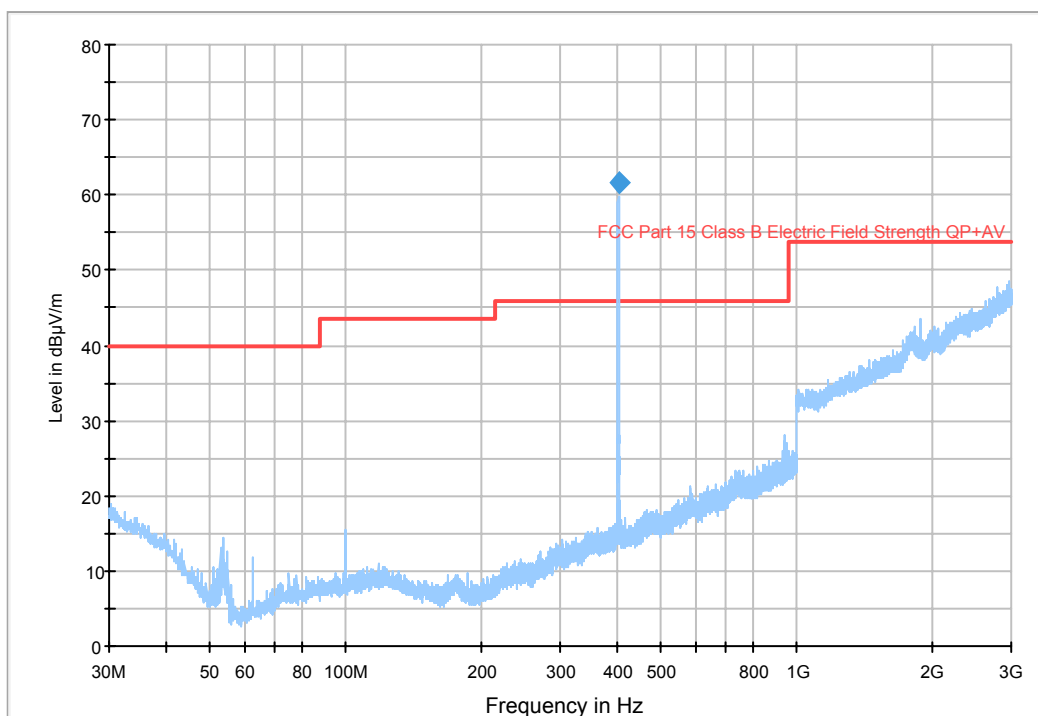
The peaks at 62 MHz, 100 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.



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30 – 3000 MHz, max peak at a distance of 3 m, Accent SR RF (1274081), horizontal position



| Field strength of spurious emissions |              |                    |                     |                    |                     |                    |
|--------------------------------------|--------------|--------------------|---------------------|--------------------|---------------------|--------------------|
| Frequency<br>[MHz]                   | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note               |
|                                      |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |                    |
| 403.650                              | 120          | -                  | 61.6                | -                  | -                   | Carrier, channel 5 |

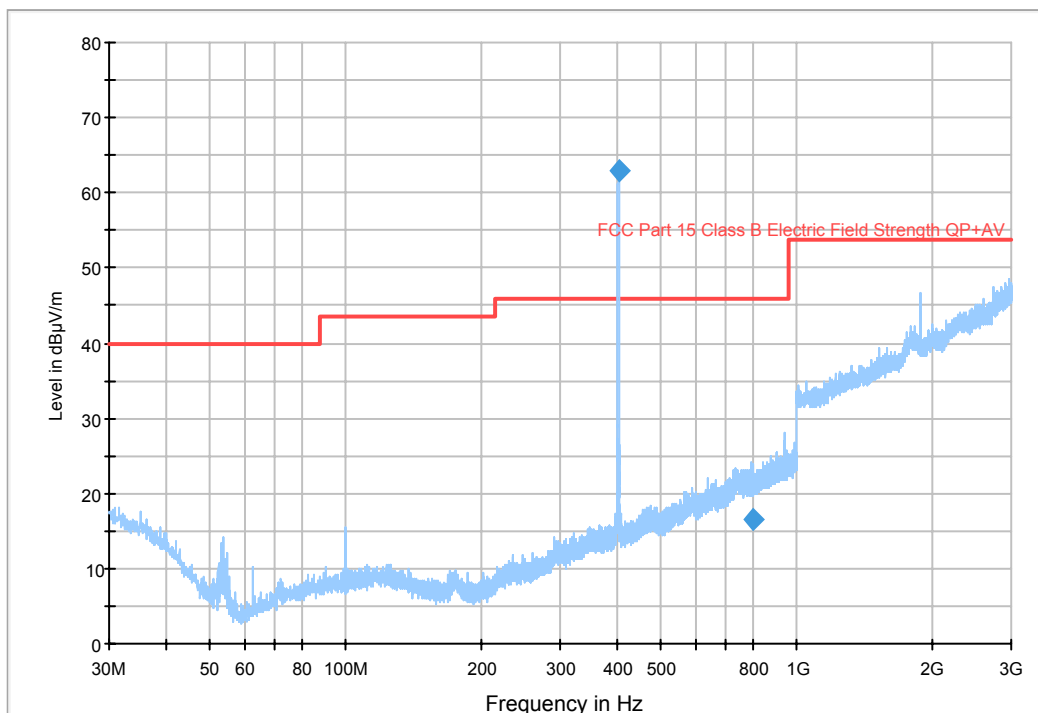
The peaks at 62 MHz, 100 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.



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30 – 3000 MHz, max peak at a distance of 3 m, Accent DR RF (1274101), vertical position



| Field strength of spurious emissions |              |                    |                     |                    |                     |                    |
|--------------------------------------|--------------|--------------------|---------------------|--------------------|---------------------|--------------------|
| Frequency<br>[MHz]                   | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note               |
|                                      |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |                    |
| 403.649                              | 120          | -                  | 62.9                | -                  | -                   | Carrier, channel 5 |
| 807.580                              | 120          | -                  | 16.7                | -                  | 46.0                |                    |

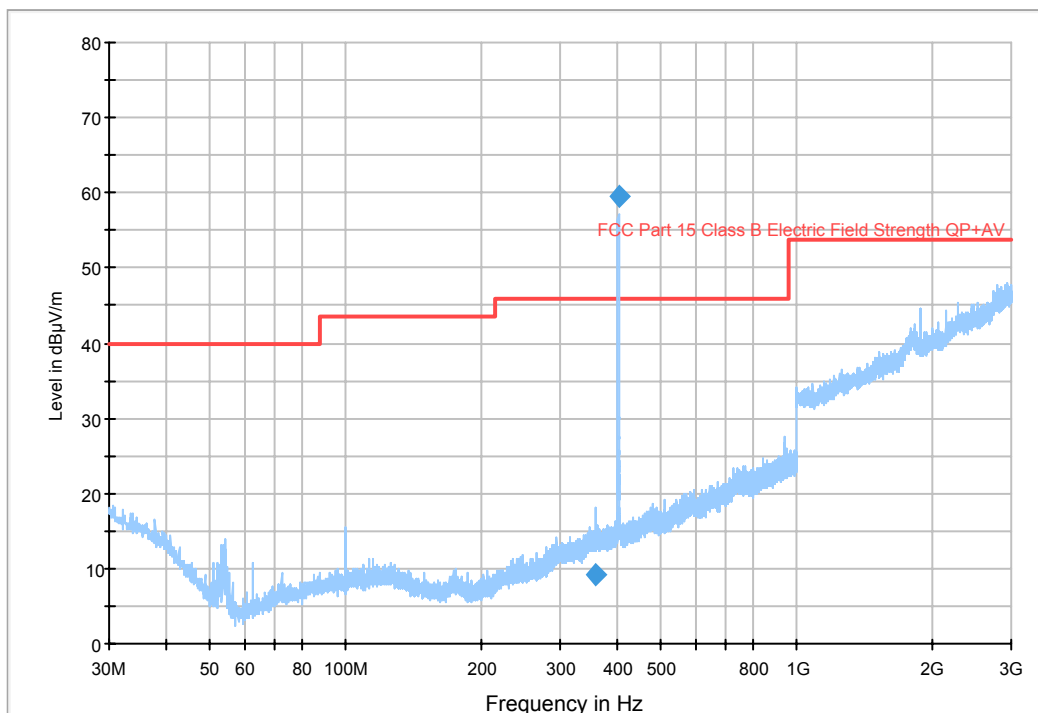
The peaks at 62 MHz, 100 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.



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30 – 3000 MHz, max peak at a distance of 3 m, Accent DR RF (1274101), horizontal position



| Field strength of spurious emissions |              |                    |                     |                    |                     |                    |
|--------------------------------------|--------------|--------------------|---------------------|--------------------|---------------------|--------------------|
| Frequency<br>[MHz]                   | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note               |
|                                      |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |                    |
| 358.821                              | 120          | -                  | 9.1                 | -                  | 46.0                |                    |
| 403.650                              | 120          | -                  | 55.9                | -                  | -                   | Carrier, channel 5 |

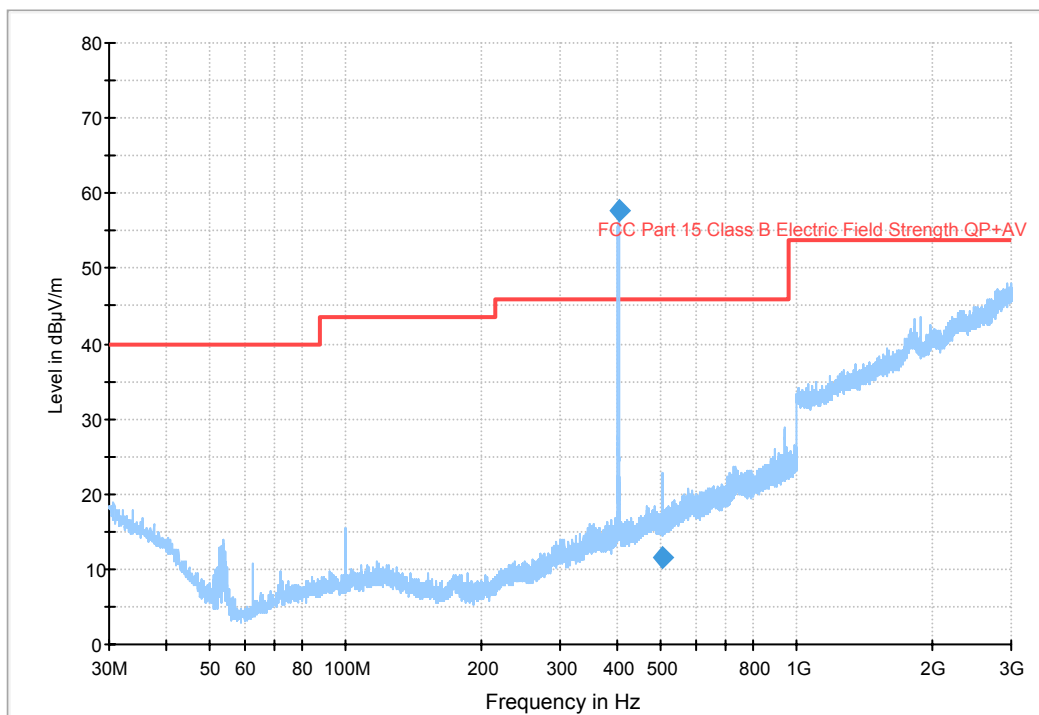
The peaks at 62 MHz, 100 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.



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30 – 3000 MHz, max peak at a distance of 3 m, Anthem RF (1274122), vertical position



| Field strength of spurious emissions |              |                          |                           |                          |                           |                    |
|--------------------------------------|--------------|--------------------------|---------------------------|--------------------------|---------------------------|--------------------|
| Frequency<br>[MHz]                   | RBW<br>[kHz] | Measured level           |                           | Limit                    |                           | Note               |
|                                      |              | Peak<br>[dB( $\mu$ V/m)] | QP/AV<br>[dB( $\mu$ V/m)] | Peak<br>[dB( $\mu$ V/m)] | QP/AV<br>[dB( $\mu$ V/m)] |                    |
| 403.650                              | 120          | -                        | 57.6                      | -                        | -                         | Carrier, channel 5 |
| 504.740                              | 120          | -                        | 11.6                      | -                        | 46.0                      |                    |

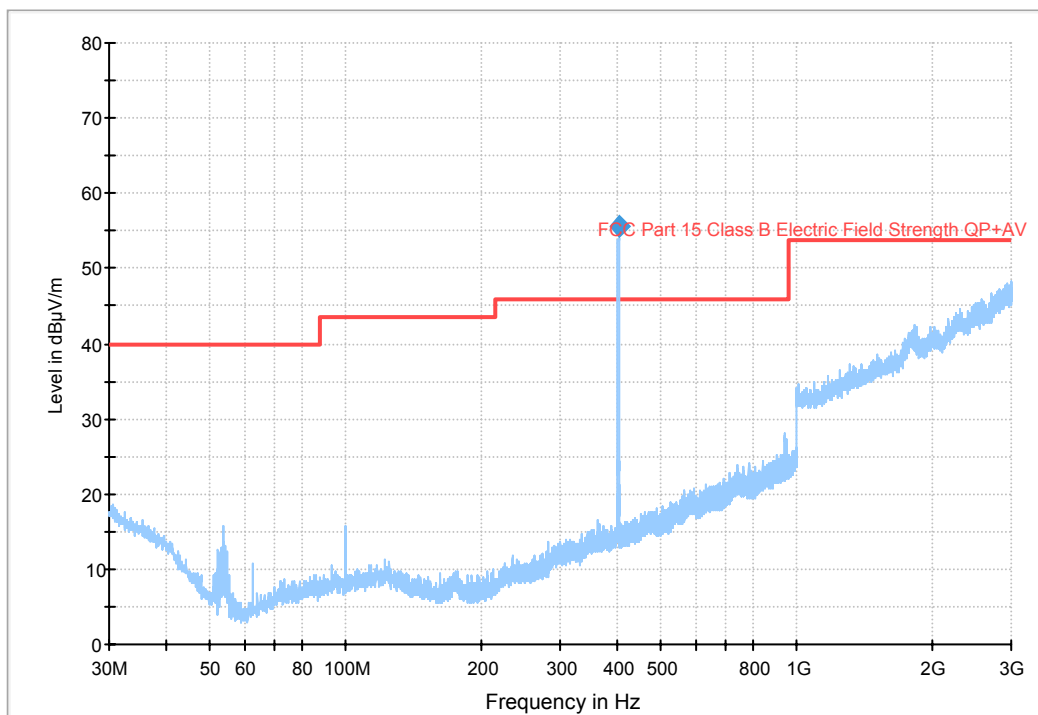
The peaks at 62 MHz, 100 MHz, 950 MHz and 1850-1900 MHz are ambient disturbances.



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30 – 3000 MHz, max peak at a distance of 3 m, Anthem RF (1274122), horizontal position



| Field strength of spurious emissions |              |                    |                     |                    |                     |                    |
|--------------------------------------|--------------|--------------------|---------------------|--------------------|---------------------|--------------------|
| Frequency<br>[MHz]                   | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note               |
|                                      |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |                    |
| 403.649                              | 120          | -                  | 55.5                | -                  | -                   | Carrier, channel 5 |

The peaks at 62 MHz, 100 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]

## 5.6 Limit, Unwanted radiation

Unwanted radiation more than 250 kHz removed from the MICS band (402-405 MHz) at 3 meters test distance must not exceed 40.0 dBμV/m in the range of 30-88 MHz, 43.5 dBμV/m in the range of 88-216 MHz, 46.0 dBμV/m in the range of 216-960 MHz and 54.0 dBμV/m above 960 MHz

Fulfil requirements: YES



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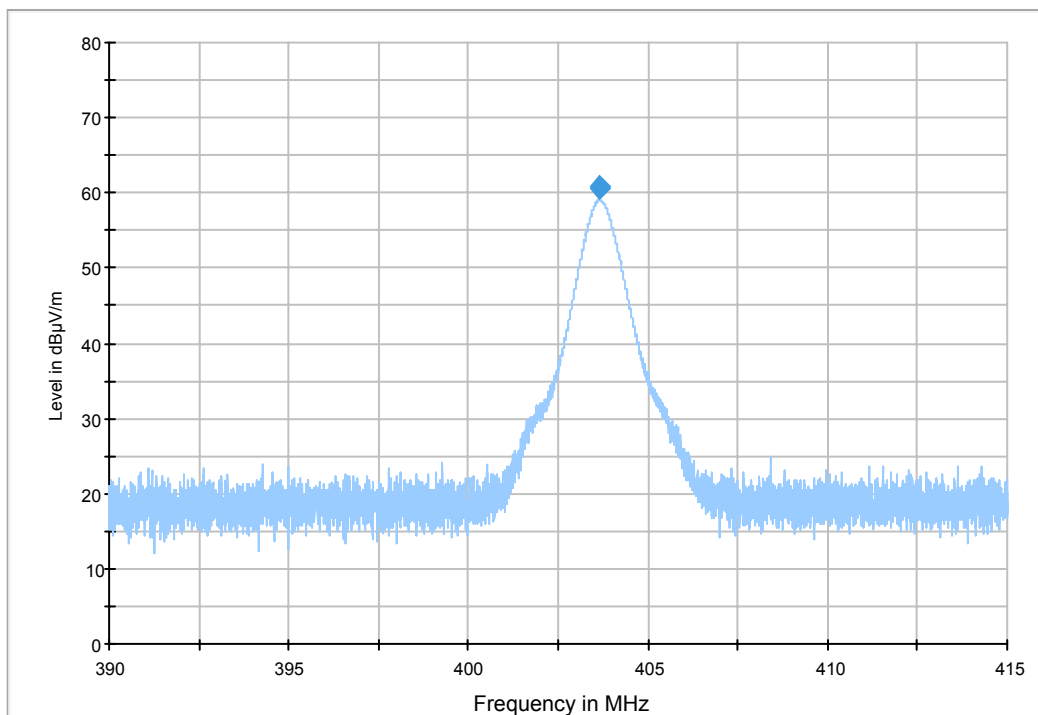


## 5.7 Test protocol, Maximum transmitter power

Semi-anechoic shielded chamber

Date of test: 2009-01-30

Maximum transmitter power at a distance of 3 m, Accent SR RF (1274081), vertical position



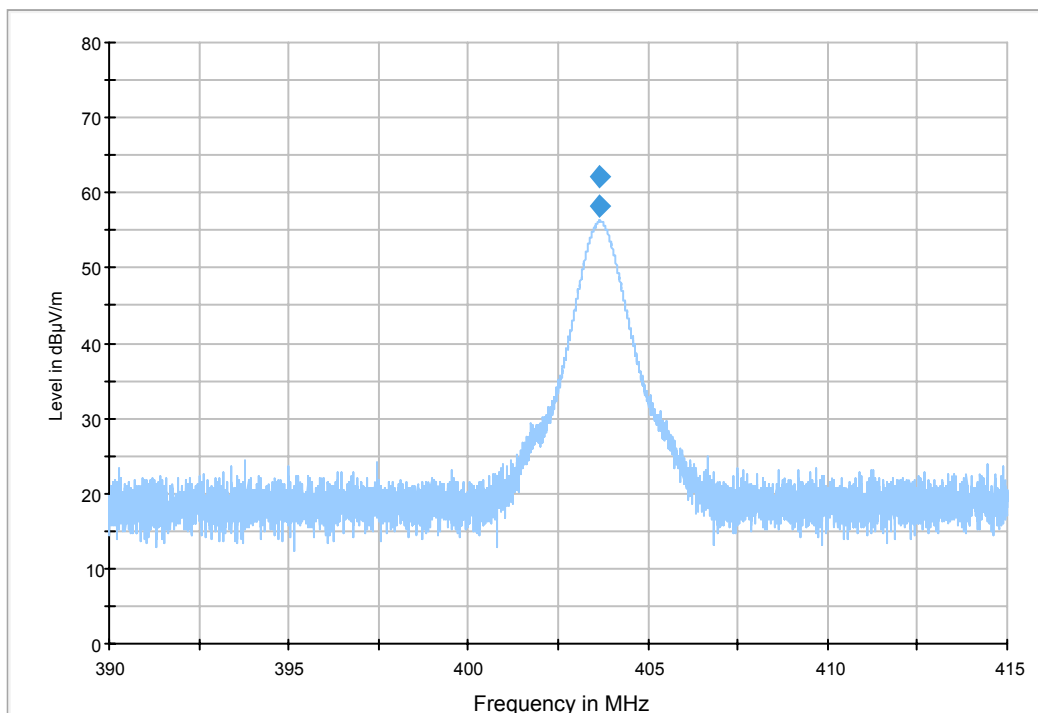
| Maximum transmitting power |              |                    |                     |                    |                     |      |
|----------------------------|--------------|--------------------|---------------------|--------------------|---------------------|------|
| Frequency<br>[MHz]         | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note |
|                            |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |      |
| 403.663                    | 1000         | 60.9               | -                   | 85.2               | -                   |      |



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Maximum transmitter power at a distance of 3 m, Accent SR RF (1274081), horizontal position



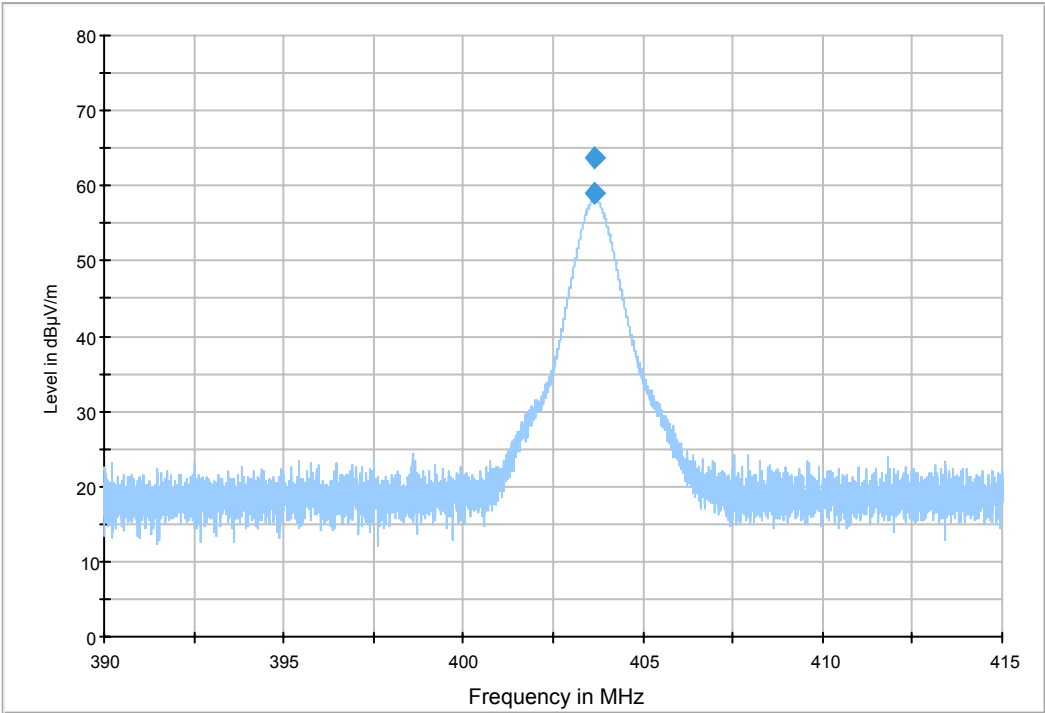
| Maximum transmitting power |              |                    |                     |                    |                     |      |
|----------------------------|--------------|--------------------|---------------------|--------------------|---------------------|------|
| Frequency<br>[MHz]         | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note |
|                            |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |      |
| 403.638                    | 1000         | 62.2               | -                   | 85.2               | -                   |      |



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Maximum transmitter power at a distance of 3 m, Accent DR RF (1274101), vertical position



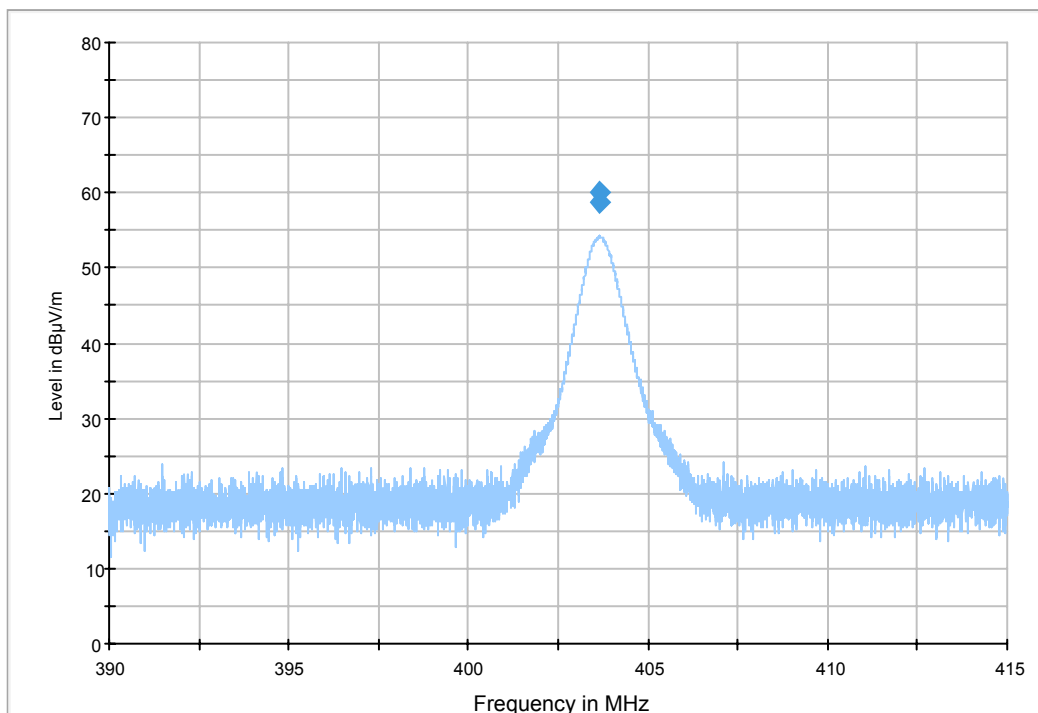
| Maximum transmitting power |              |                    |                     |                    |                     |      |
|----------------------------|--------------|--------------------|---------------------|--------------------|---------------------|------|
| Frequency<br>[MHz]         | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note |
|                            |              | Peak<br>[dB(µV/m)] | QP/AV<br>[dB(µV/m)] | Peak<br>[dB(µV/m)] | QP/AV<br>[dB(µV/m)] |      |
| 403.659                    | 1000         | 63.9               | -                   | 85.2               | -                   |      |



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Maximum transmitter power at a distance of 3 m, Accent DR RF (1274101), horizontal position



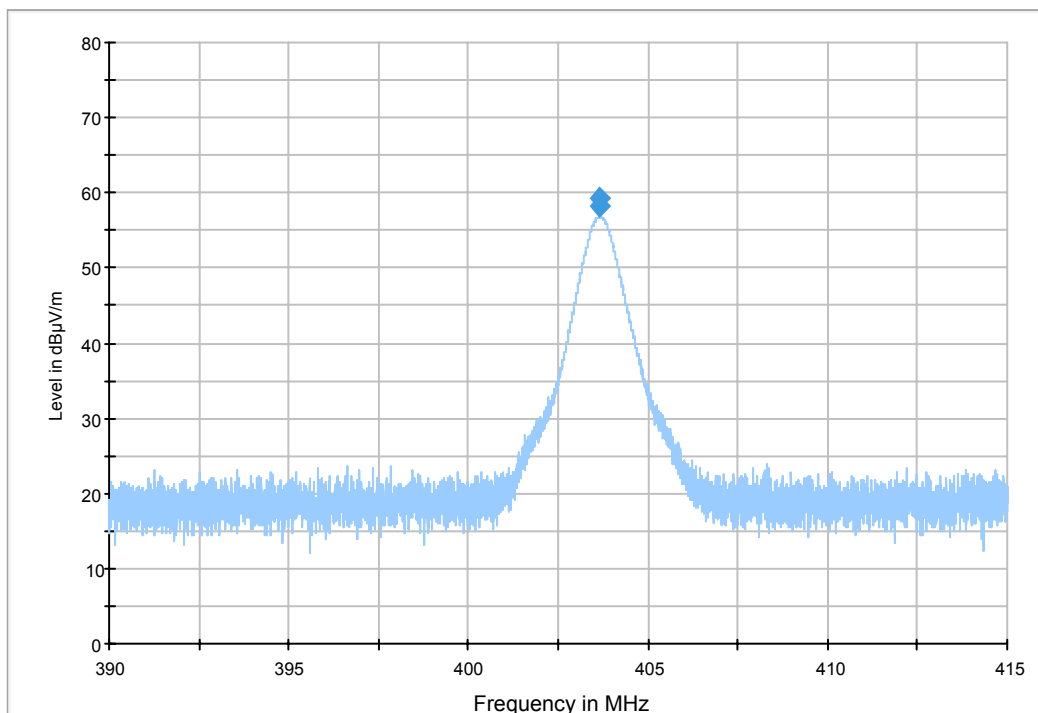
| Maximum transmitting power |              |                    |                     |                    |                     |      |
|----------------------------|--------------|--------------------|---------------------|--------------------|---------------------|------|
| Frequency<br>[MHz]         | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note |
|                            |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |      |
| 403.669                    | 1000         | 60.0               | -                   | 85.2               | -                   |      |



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 Registered in Sweden: No SE556024059901, Registered office: As address

Maximum transmitter power at a distance of 3 m, Anthem RF (1274122), vertical position



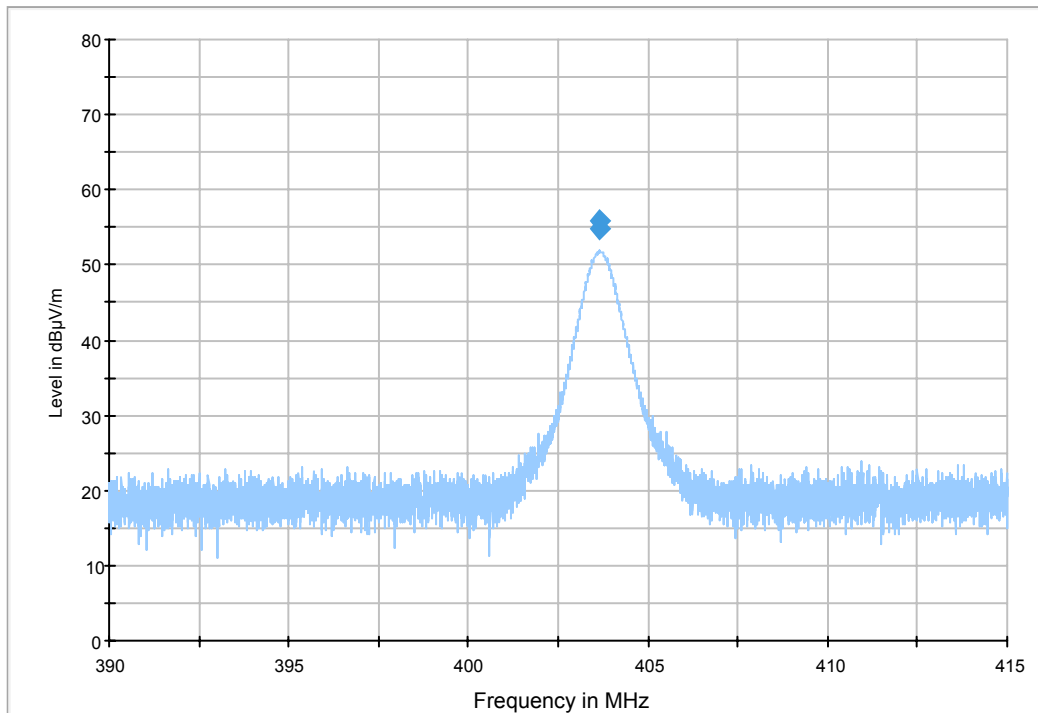
| Maximum transmitting power |              |                    |                     |                    |                     |      |
|----------------------------|--------------|--------------------|---------------------|--------------------|---------------------|------|
| Frequency<br>[MHz]         | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note |
|                            |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |      |
| 403.669                    | 1000         | 59.2               | -                   | 85.2               | -                   |      |



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Maximum transmitter power at a distance of 3 m, Anthem RF (1274122), horizontal position



| Maximum transmitting power |              |                    |                     |                    |                     |      |
|----------------------------|--------------|--------------------|---------------------|--------------------|---------------------|------|
| Frequency<br>[MHz]         | RBW<br>[kHz] | Measured level     |                     | Limit              |                     | Note |
|                            |              | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] | Peak<br>[dB(μV/m)] | QP/AV<br>[dB(μV/m)] |      |
| 403.659                    | 1000         | 55.8               | -                   | 85.2               | -                   |      |

Example calculation:

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

### 5.8 Limit, Maximum transmitter power

Maximum allowed transmitting power is 25 μW e.i.r.p. which correspond to 85.2 dB(μV/m) at 3 m antenna distance.

**Fulfil requirements: YES**



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