

RADIO TEST REPORT

No. 1118080-2

EQUIPMENT UNDER TEST

Equipment: Medical implant

Type / model: Ellipse™ VR, Model CD1275-36
Ellipse™ ST VR, Model CD1273-36Q
Ellipse™ DR, Model CD2275-36
Ellipse™ ST DR, Model CD2273-36Q

See appendix A for a list of other model names with identical hardware

Manufacturer: St. Jude Medical

Tested by request of: St. Jude Medical AB

SUMMARY

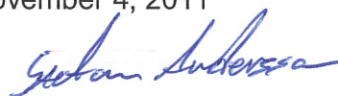
All selected test cases specified in this report comply with the requirements according to the following standards:

FCC 47 CFR Part 95 (2010)
IC RSS-243 Issue 3 (February 2010)

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

Date of issue: November 4, 2011

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: Per Burström

2. EQUIPMENT UNDER TEST (EUT)

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

Equipment: Medical implant
Type and serial number*: Ellipse™ VR, Model CD1275-36, S/N 206009
Ellipse™ ST VR, Model CD1273-36Q, S/N 206021
Ellipse™ DR, Model CD2275-36, S/N 206016
Ellipse™ ST DR, Model CD2273-36Q, S/N 206028
See appendix A for a list of models with identical hardware

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 and 2 FSK fallback

*Conducted tests was measured on Ellipse™ VR, Model CD1275-36 with wire access instead of battery and with SMA connector to RF antenna feed-through, s/n: 206036.

2.2 Modifications during the test

No modifications have been made during the tests

3. TEST SPECIFICATIONS

3.1 Standards

FCC 47 CFR Part 95 (2010)
IC RSS-243, Issue 3 (February 2010)

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 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 and mode of operation

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 $\sigma = 0.85$ s/m and $\epsilon' = 56.0$.

Target value: $\sigma = 0.93$ s/m and $\epsilon' = 57.0$ (according to FCC OET 65C).

The measured values are within 10 % from target values.

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.

Mode of operation:

Spurious emission and effective radiated power of the fundamental emission:

The EUT can transmit with 2FSK and 2FSK Fallback modulation. Spurious emission and effective radiated power of the fundamental emission was performed with 2FSK modulation which has the highest measured output power.

Frequency stability:

The EUT was transmitting without modulation.

Emission bandwidth and emission close to MICS band:

These tests were performed with 2FSK and 2FSK fallback modulation.

A fresh battery was used during radiated tests. During conducted tests the EUT was connected to a DC supply.

3.4 Operating environment

The tests in semi-anechoic chamber were performed under the following environmental conditions:

Air temperature: 20-25 °C
Relative humidity: 40-60 %

The conducted tests were performed under the following environmental conditions:

Normal condition:
Air temperature: 37 °C
Relative humidity: 40-60 %

Extreme condition:
Air temperature: 25-45 °C
Relative humidity: 40-60 %

4. TEST SUMMARY

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

FCC reference	IC reference	Test	Result
§95.635(d)	5.5	Unwanted radiation, Transmitter Unwanted Emissions	PASS
§95.639(f)	5.4	Maximum transmitter power, Transmitter Output Power	PASS
§95.633(e)	5.1	Emission Bandwidth	PASS
§95.628	5.3	Frequency error	PASS
§95.628(a)(b)	5.7	MICS operation and duty cycle requirement	NA*

* Only applicable for MICS controller/programmer

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 – 4 100 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	Intertek 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	N/A
Measurement receiver:	Rohde & Schwarz	ESU40	13178
Antenna amplifier:	μ COMP NORDIC	N/A	30939
Antenna, bilog:	Chase	CBL6111B	12474
Antenna, horn:	EMCO	3115	3006

5.3 Measurement set-up

Test site: Semi-anechoic shielded chamber (30 – 4100 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.

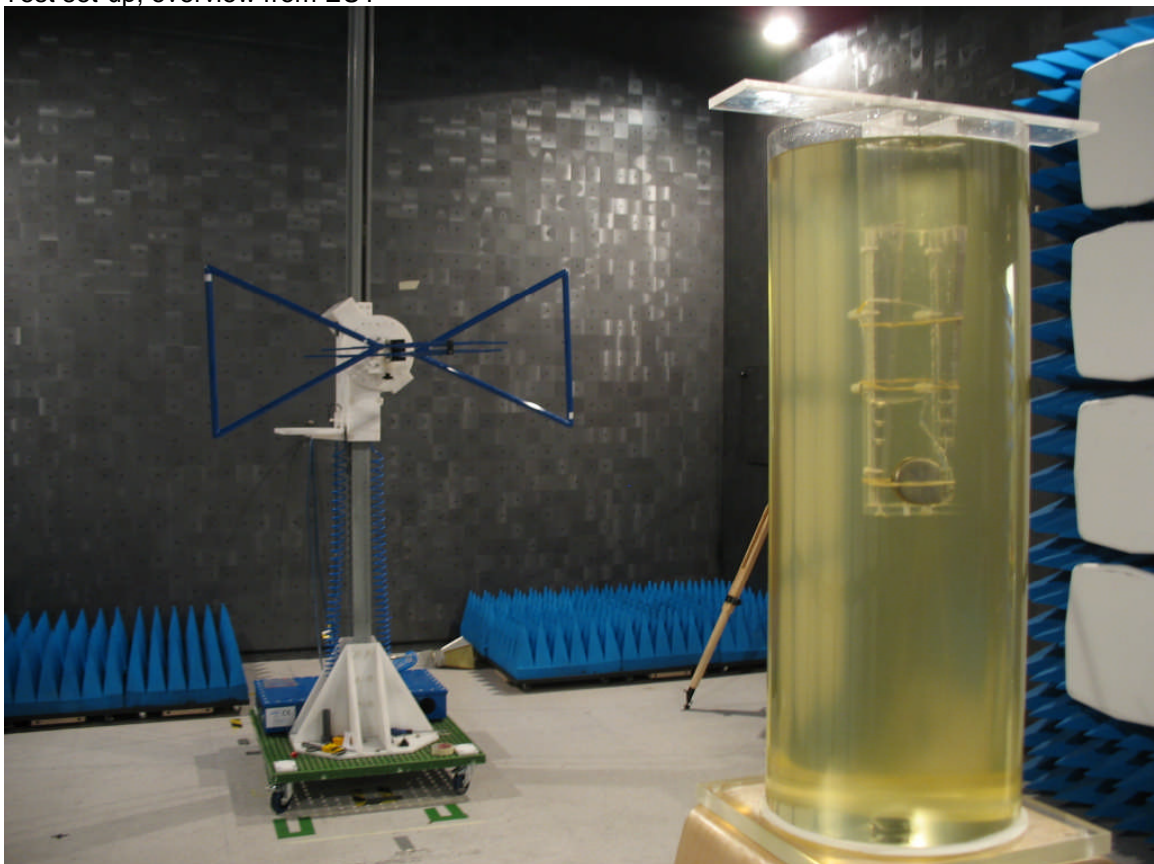
An overview sweep with peak detection of the electric field intensity was performed with the measurement receiver in max-hold and with the antenna placed 1.5 m, 2.5 m and 3.5 m above the floor. The polarization was horizontal and vertical. The measurements were repeated with the EUT rotated in 90-degree steps below 1 GHz and 45-degree steps above 1 GHz.

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.

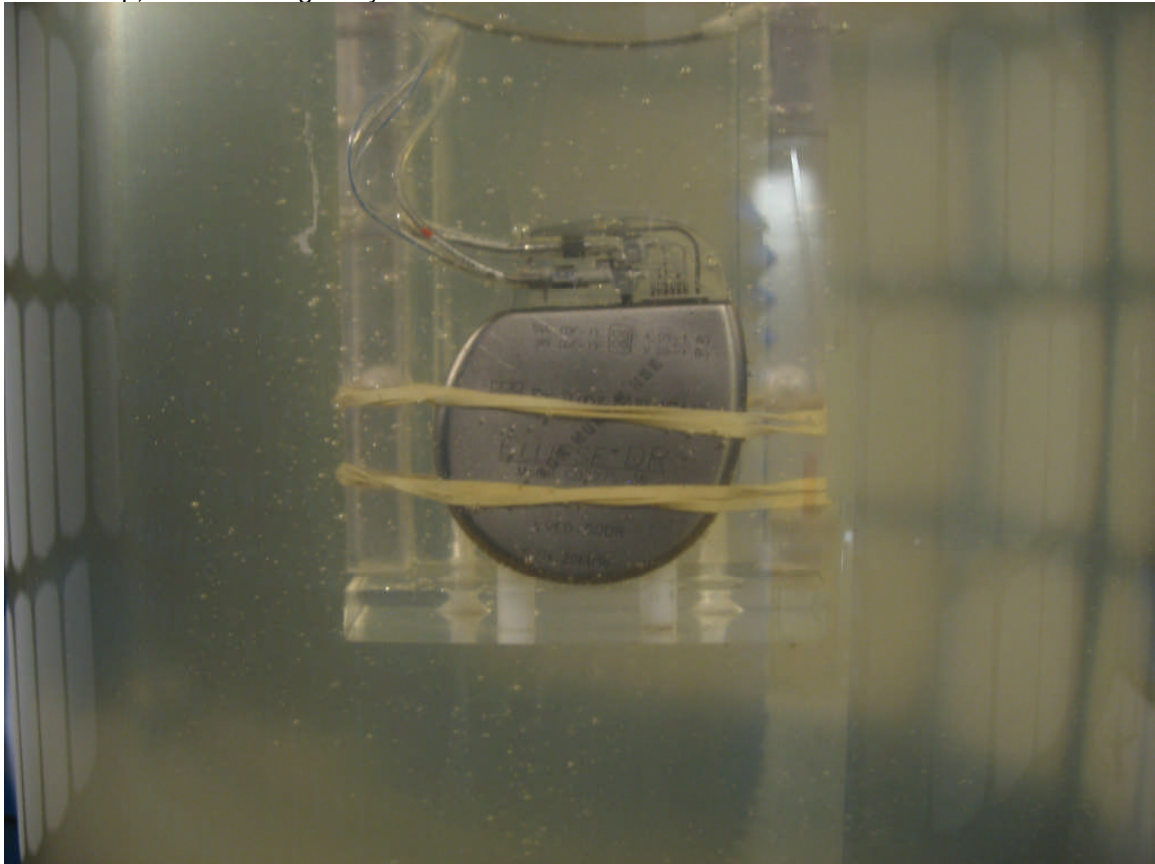
For maximum transmitter power measurement the turntable was turned 360 degrees and the antenna mast was moved from 1 m to 4 m to find the maximum power. The measurement was performed with both horizontal and vertical polarization.

Test set-up photos:

Test set-up, overview from EUT



Test set-up, EUT in Plexiglas cylinder



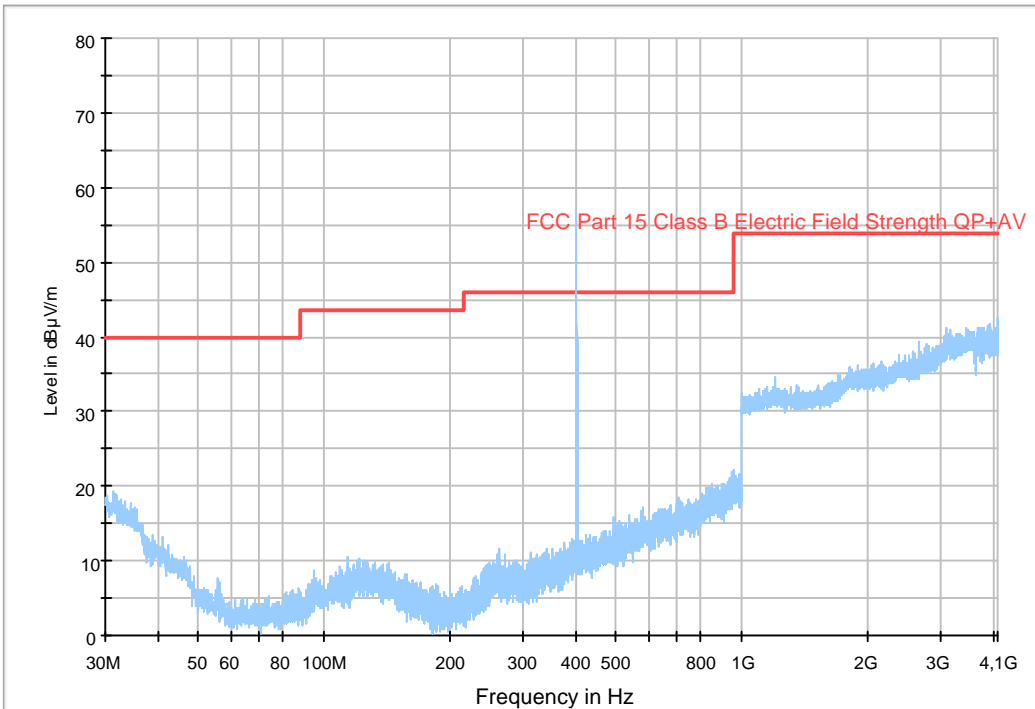
5.4 Test protocol, Unwanted radiation

Semi-anechoic shielded chamber

Date of test: 2011-10-14 and 2011-10-17

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ VR, Model CD1275-36, S/N 206009, vertical position

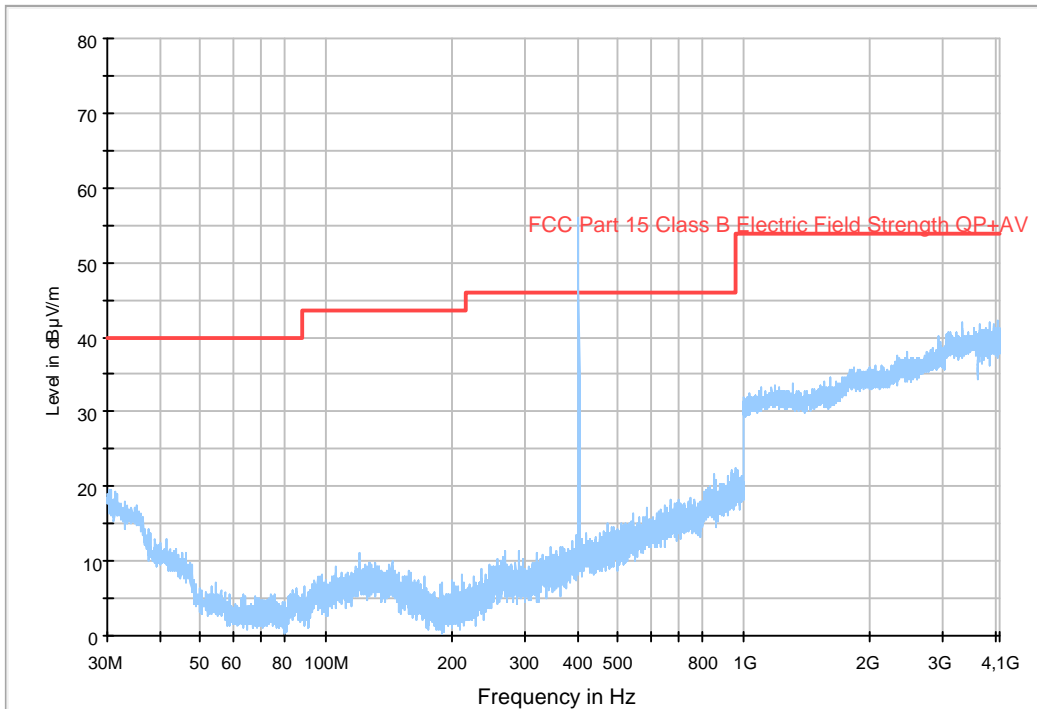
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ VR, Model CD1275-36, S/N 206009, horizontal position

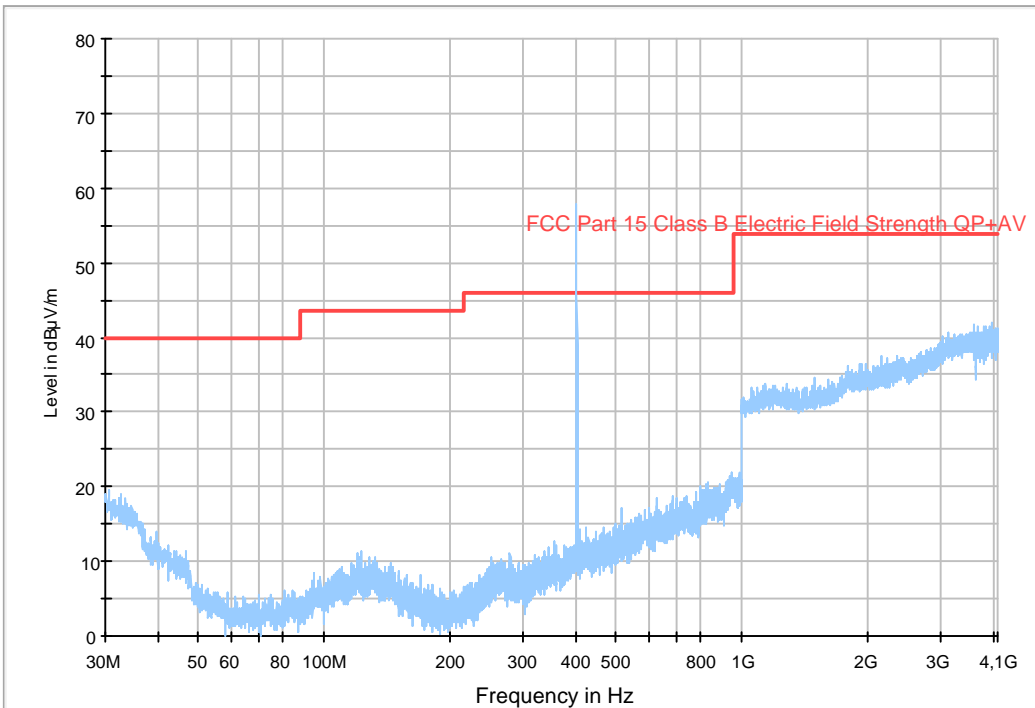
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ ST VR, Model CD1273-36Q, S/N 206021, vertical position

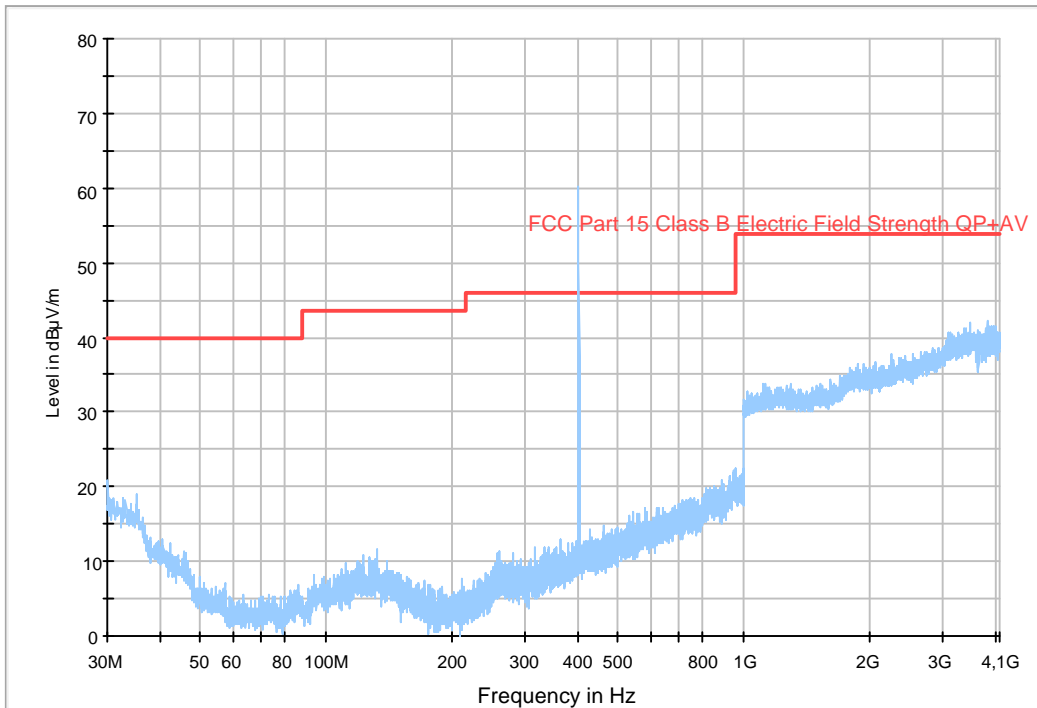
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ ST VR, Model CD1273-36Q, S/N 206021, horizontal position

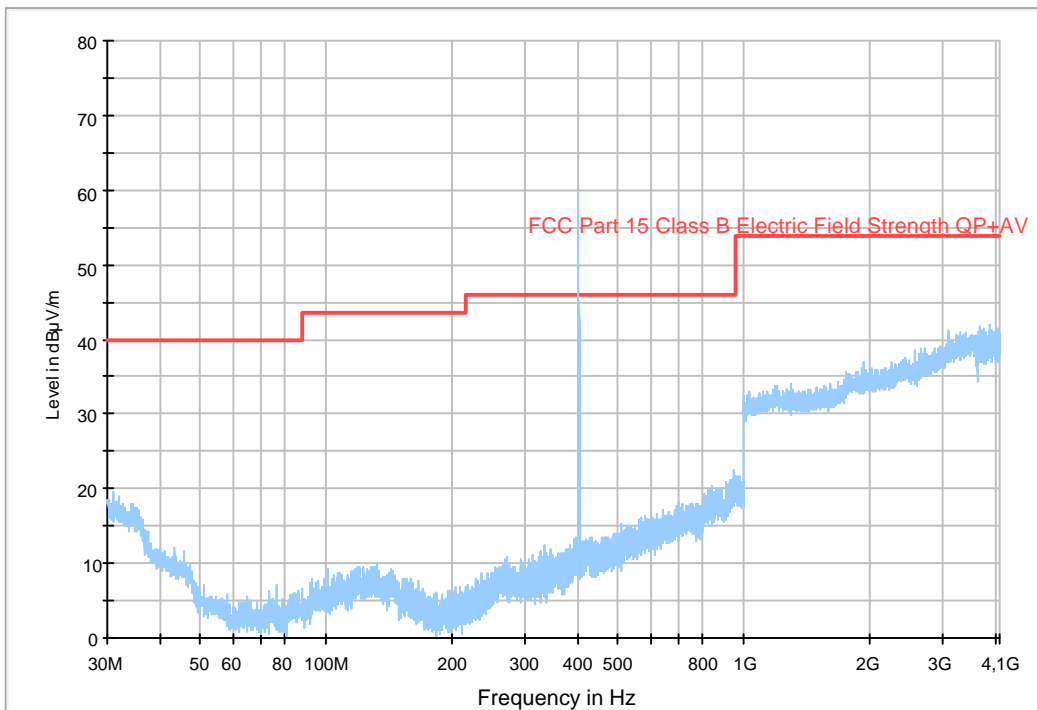
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ DR, Model CD2275-36, S/N 206016, vertical position

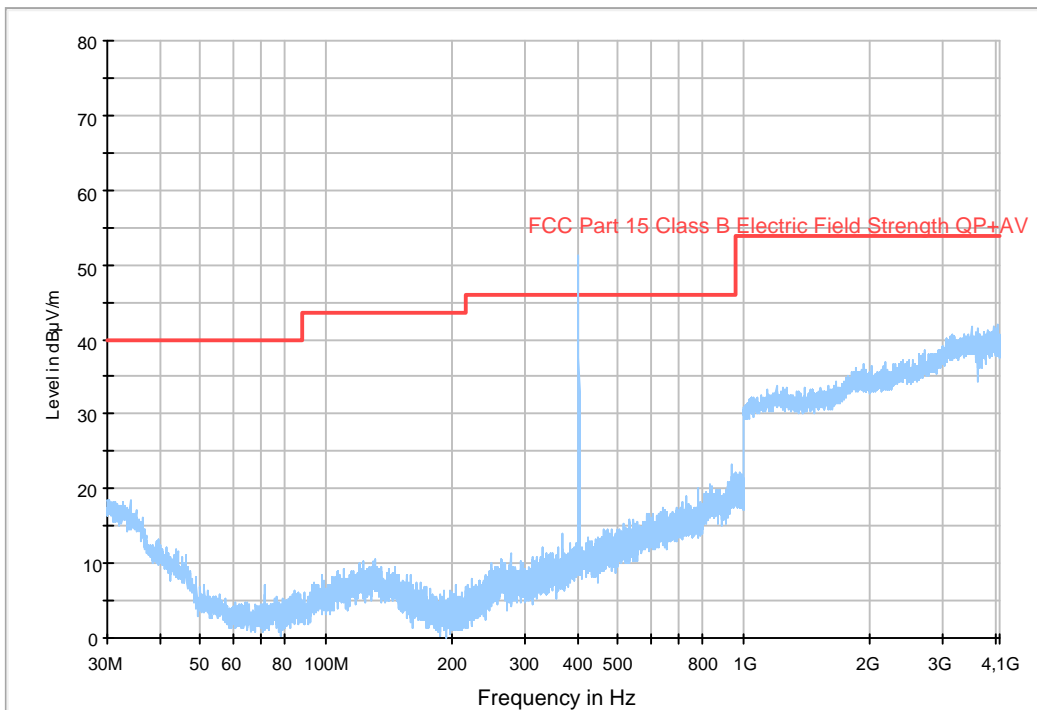
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ DR, Model CD2275-36, S/N 206016, horizontal position

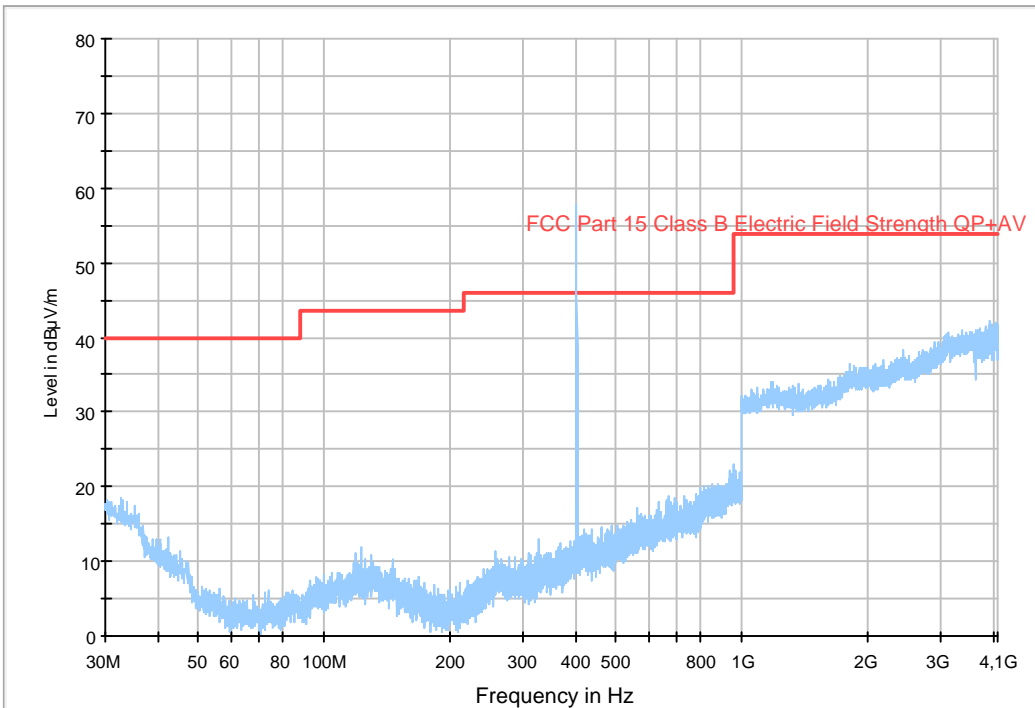
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ ST DR, Model CD2273-36Q, S/N 206028, vertical position

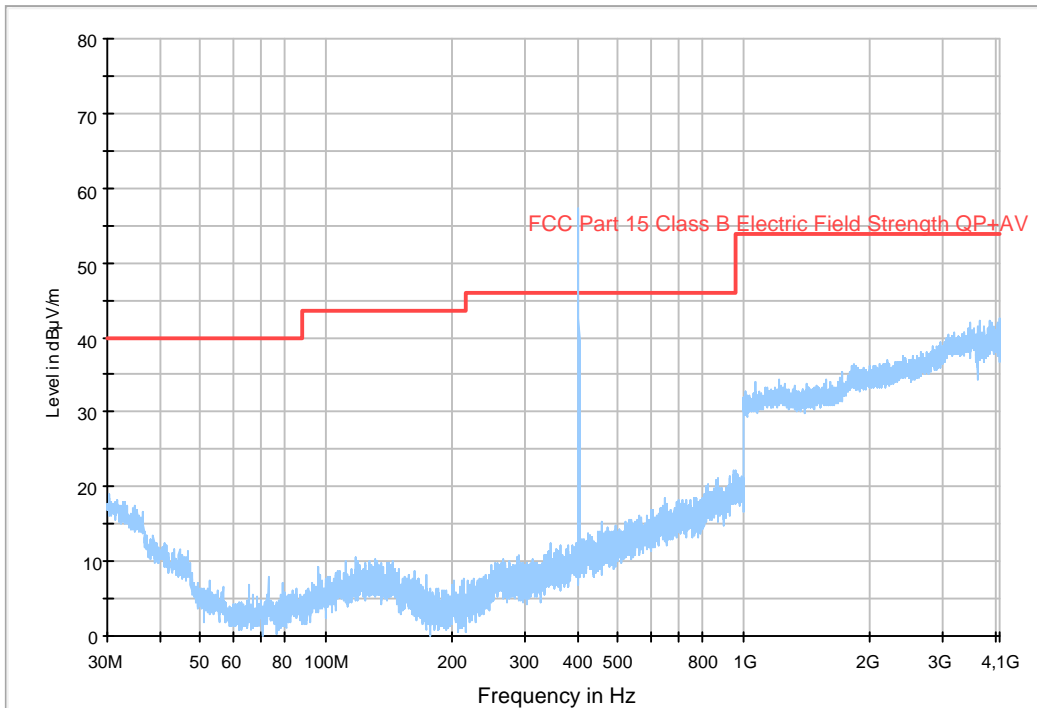
1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

30 – 4100 MHz, max peak at a distance of 3 m, Ellipse™ ST DR, Model CD2273-36Q, S/N 206028, horizontal position

1 mics spur 30M-1G-4G w.uComp preamp_110523



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	-	-	-	-	-	Carrier
30 - 4100	-	-	-	-	-	No peaks above noise floor

Example calculation:

$$\text{Measured level [dB}\mu\text{V/m]} = \text{Analyzer reading [dB}\mu\text{V]} + \text{cable loss [dB]} - \text{preamplifier gain [dB]} + \text{antenna factor [1/m]}$$

Fulfil requirements: YES

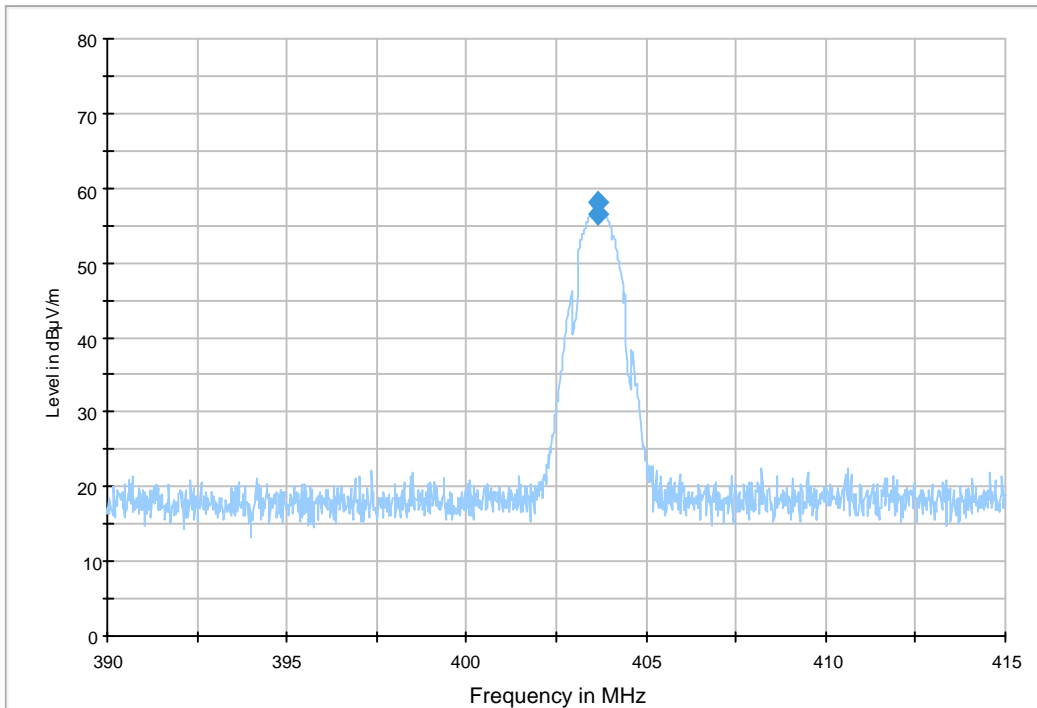
5.5 Test protocol, Maximum transmitter power

Semi-anechoic shielded chamber

Date of test: 2011-05-24 and 2011-05-25

Maximum transmitter power at a distance of 3 m, Ellipse™ VR, Model CD1275-36, S/N 206009, vertical position

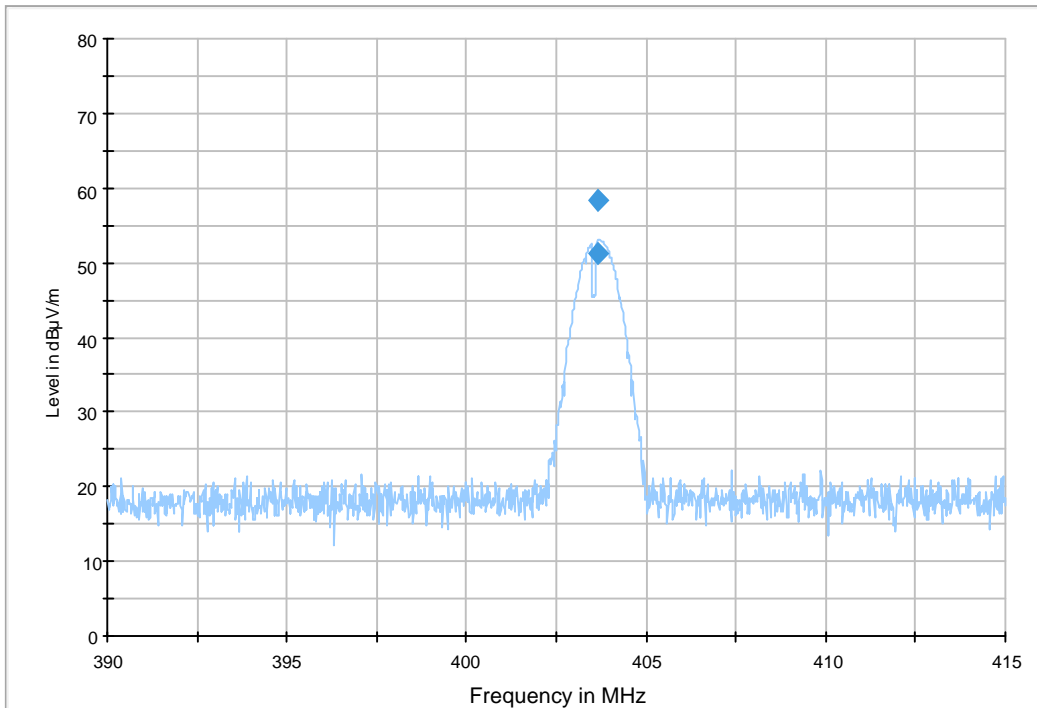
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	58.1	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ VR, Model CD1275-36, S/N 206009, horizontal position

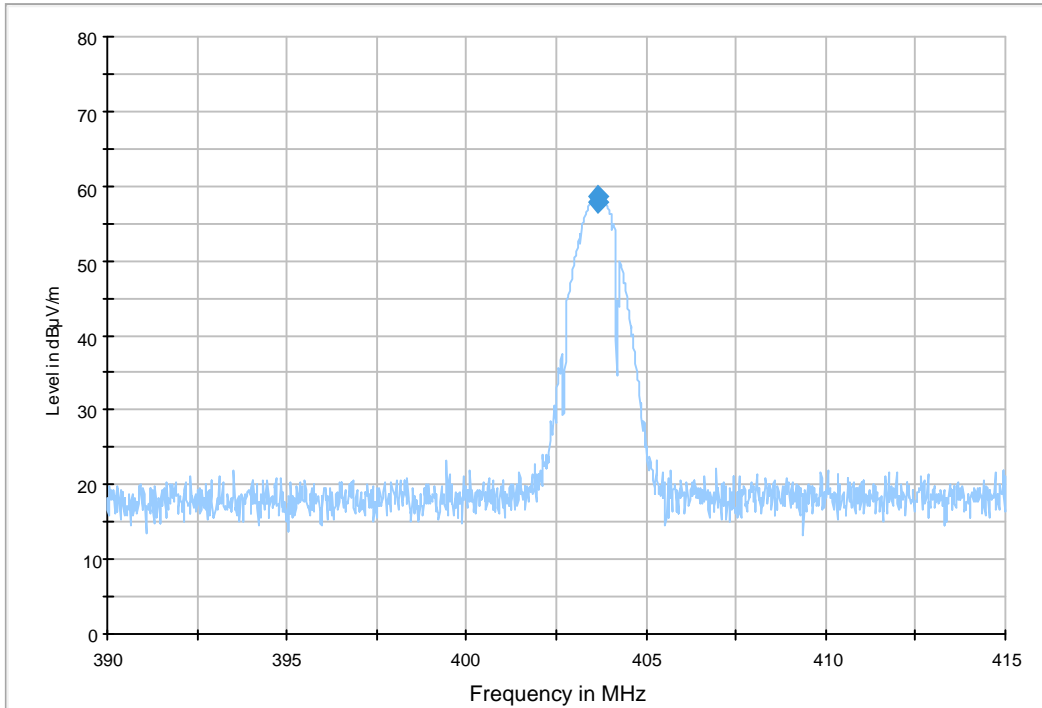
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	58.3	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ ST VR, Model CD1273-36Q, S/N 206021, vertical position

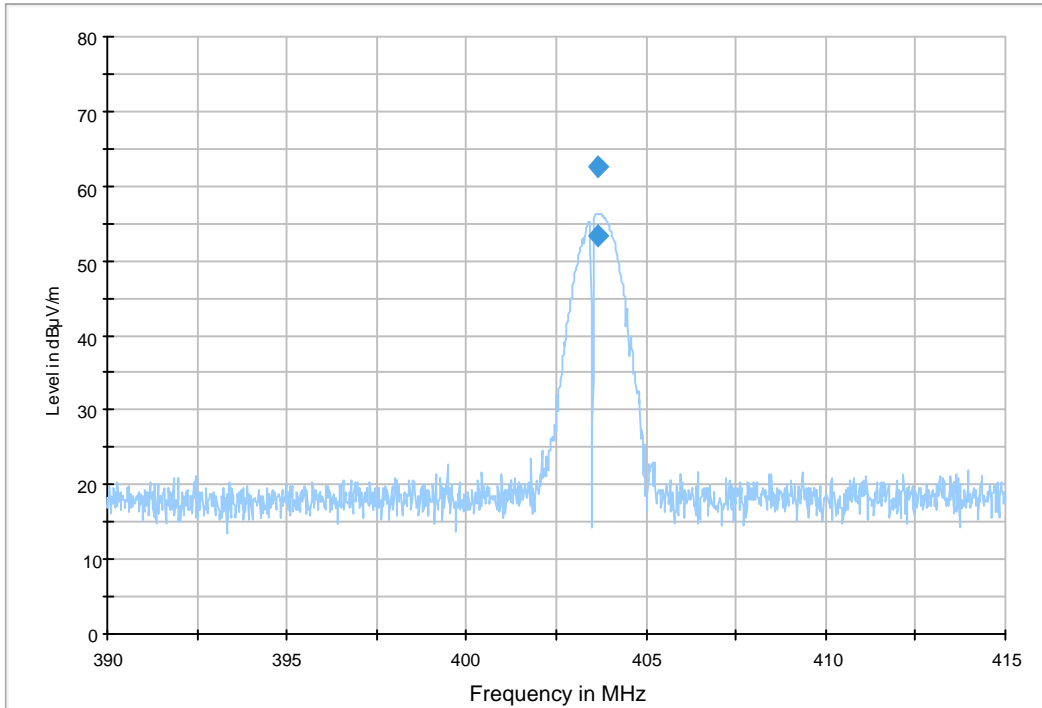
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	58.6	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ ST VR, Model CD1273-36Q, S/N 206021, horizontal position

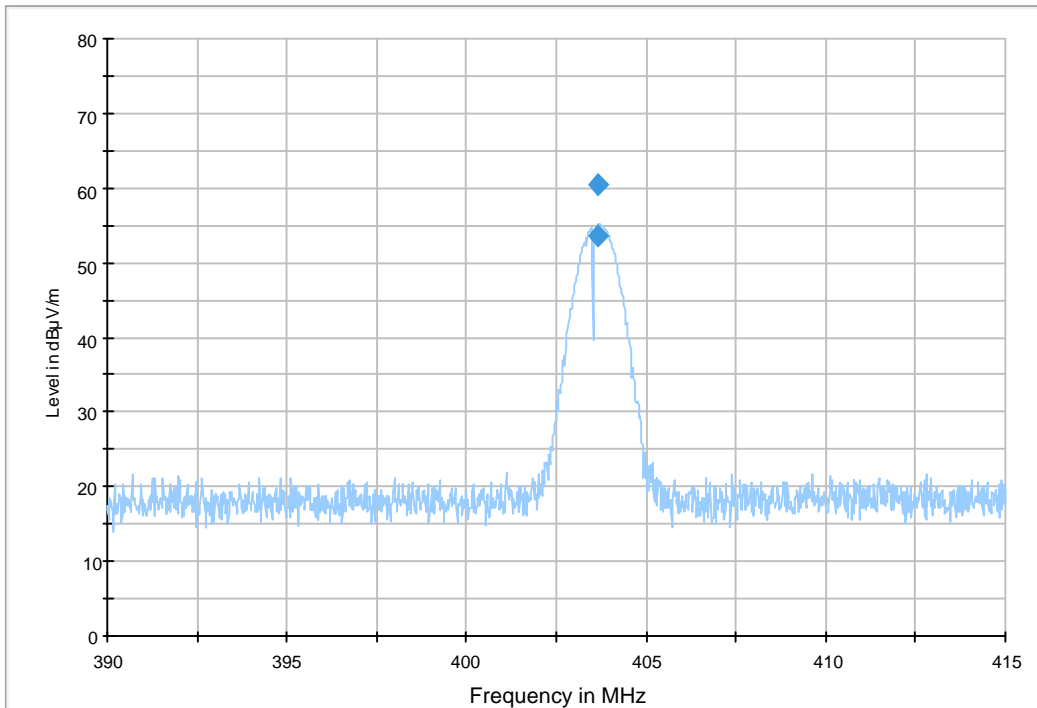
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	62.7	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ DR, Model CD2275-36, S/N 206016, vertical position

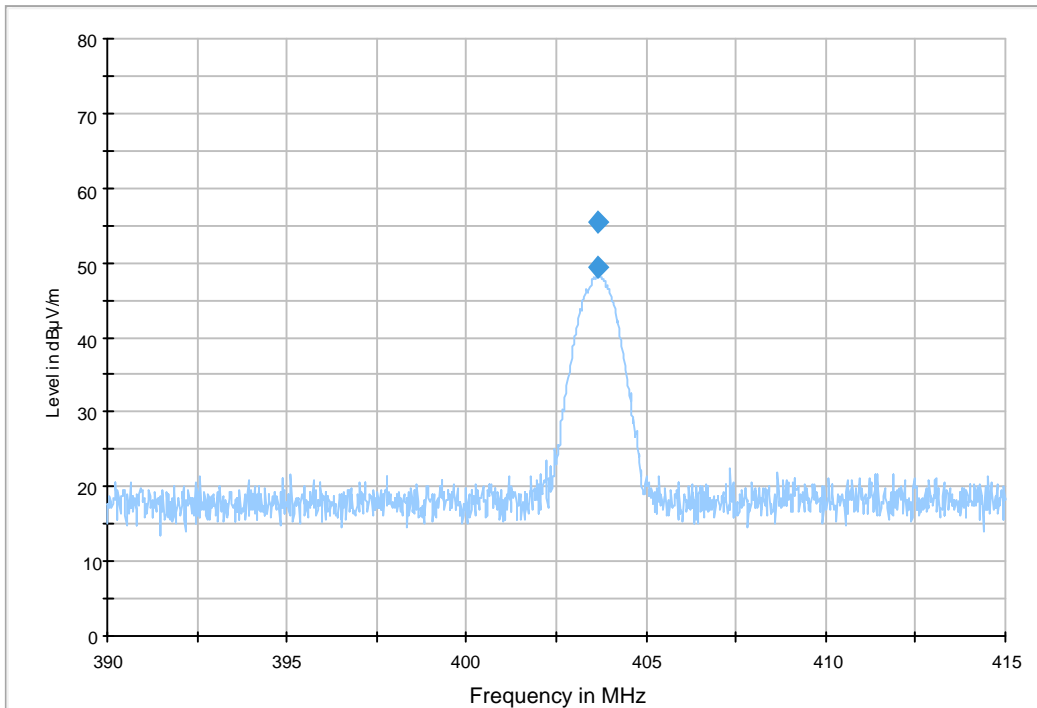
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	60.4	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ DR, Model CD2275-36, S/N 206016, horizontal position

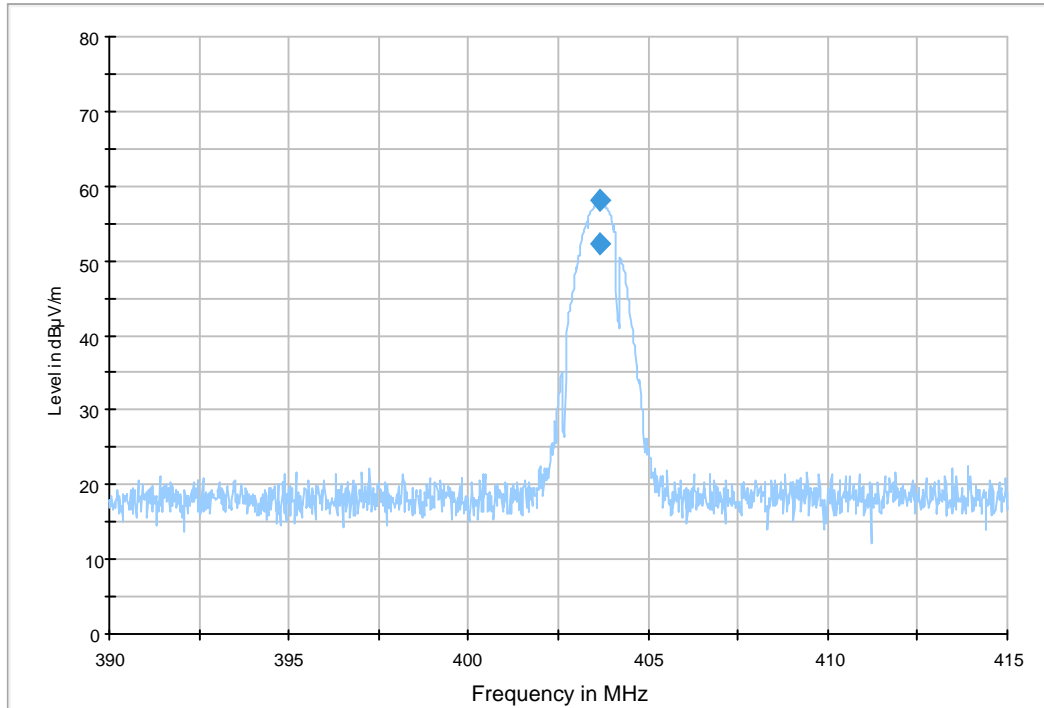
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	55.4	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ ST DR, Model CD2273-36Q, S/N 206028, vertical position

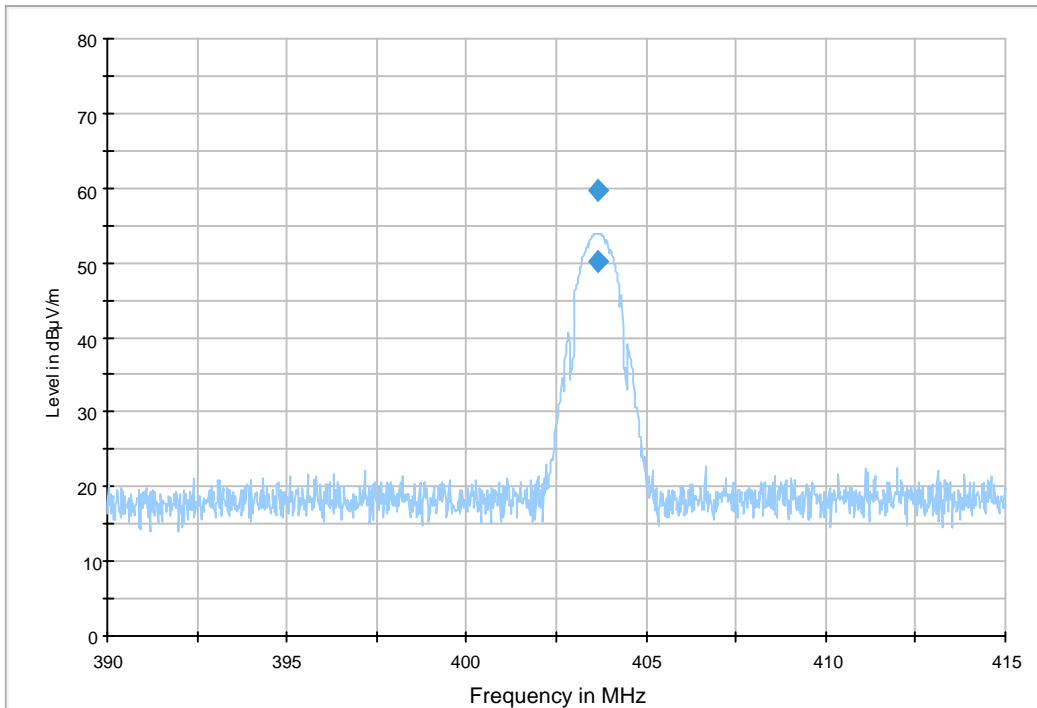
1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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	1000	58.1	-	85.2	-	

Maximum transmitter power at a distance of 3 m, Ellipse™ ST DR, Model CD2273-36Q, S/N 206028, horizontal position

1 mics tx power 405M w.uComp preamp_110523



Maximum transmitting power						
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)]	
403.620	1000	59.7	-	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

6. FREQUENCY ERROR

6.1 Measurement uncertainty

Frequency uncertainty at 400 MHz < 1 Hz

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%.

6.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
Frequency counter:	Philips	PM6685R	5616

6.3 Test protocol

Date of test: 2011-10-04

Test conditions		Frequency (MHz)	Frequency drift (kHz)
		Middle channel	
T _{nom} 37°C	V _{nom} 2,8 V	403,6520	-
T _{min} 25°C	V _{min} 2,35 V	403,6506	-1,4
	V _{max} 2,8 V	403,6507	-1,3
T _{max} 45°C	V _{min} 2,35 V	403,6511	-0,9
	V _{max} 2,8 V	403,6511	-0,9

6.4 Limit

The frequency error shall not exceed ±100 ppm (40 kHz) under normal and extreme condition.

Fulfil requirements: Yes

7. EMISSION BANDWIDTH

7.1 Measurement uncertainty

Frequency uncertainty at 400 MHz < 1 Hz

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%.

7.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
Measurement receiver:	Rohde & Schwarz	FSIQ	12793
Rubidium oscillator	Datum	N/A	40032


7.3 Test protocol

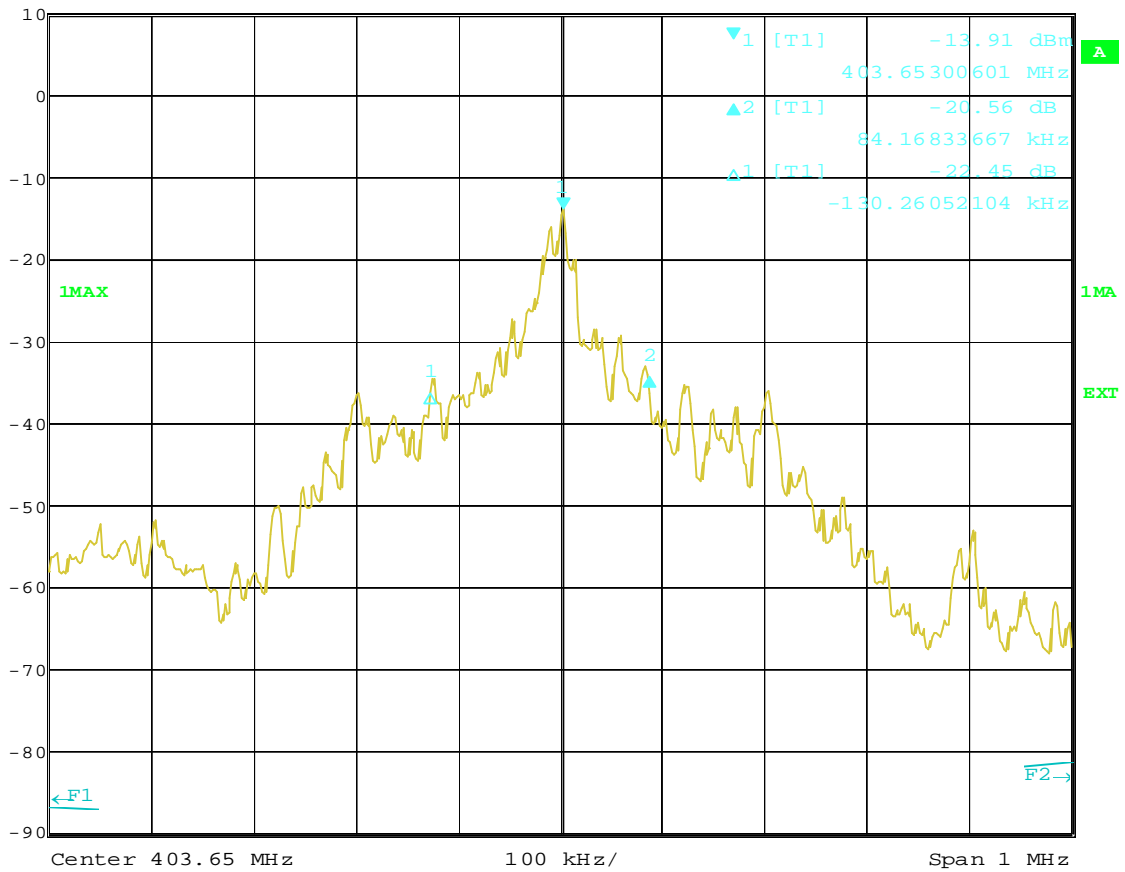
Date of test: 2011-10-04

20 dB Bandwidth:

Middle Channel. 2FSK

Test conditions		Emission bandwidth
T _{nom} 37°C	V _{nom} 2.8 V	214.4 kHz

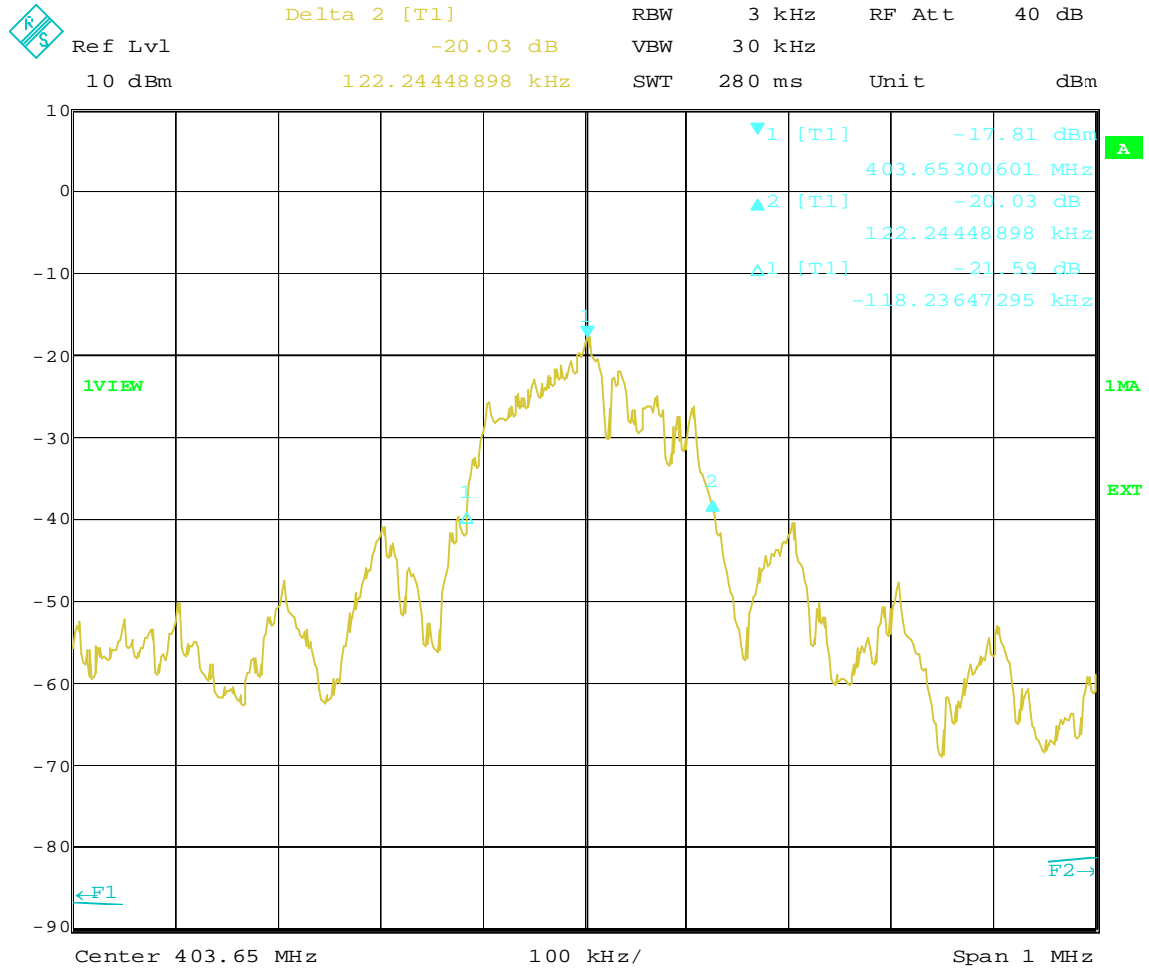

Delta 2 [T1]
RBW 3 kHz
RF Att 40 dB
Ref Lvl -20.56 dB
VBW 30 kHz
10 dBm
84.16833667 kHz
SWT 280 ms
Unit dBm



Date: 4.OCT.2011 14:04:55

Middle Channel. 2FSK fallback

Test conditions		Emission bandwidth
T _{nom} 37°C	V _{nom} 2,8 V	240,5 kHz



Date: 4.OCT.2011 13:59:13

7.4 Limits

The maximum permitted emission bandwidth shall be 300 kHz.

Fulfil requirements: Yes

8. UNWANTED EMISSION WITHIN MICS BAND

8.1 Measurement uncertainty

Measurement uncertainty: < 1 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%.


8.2 Test equipment

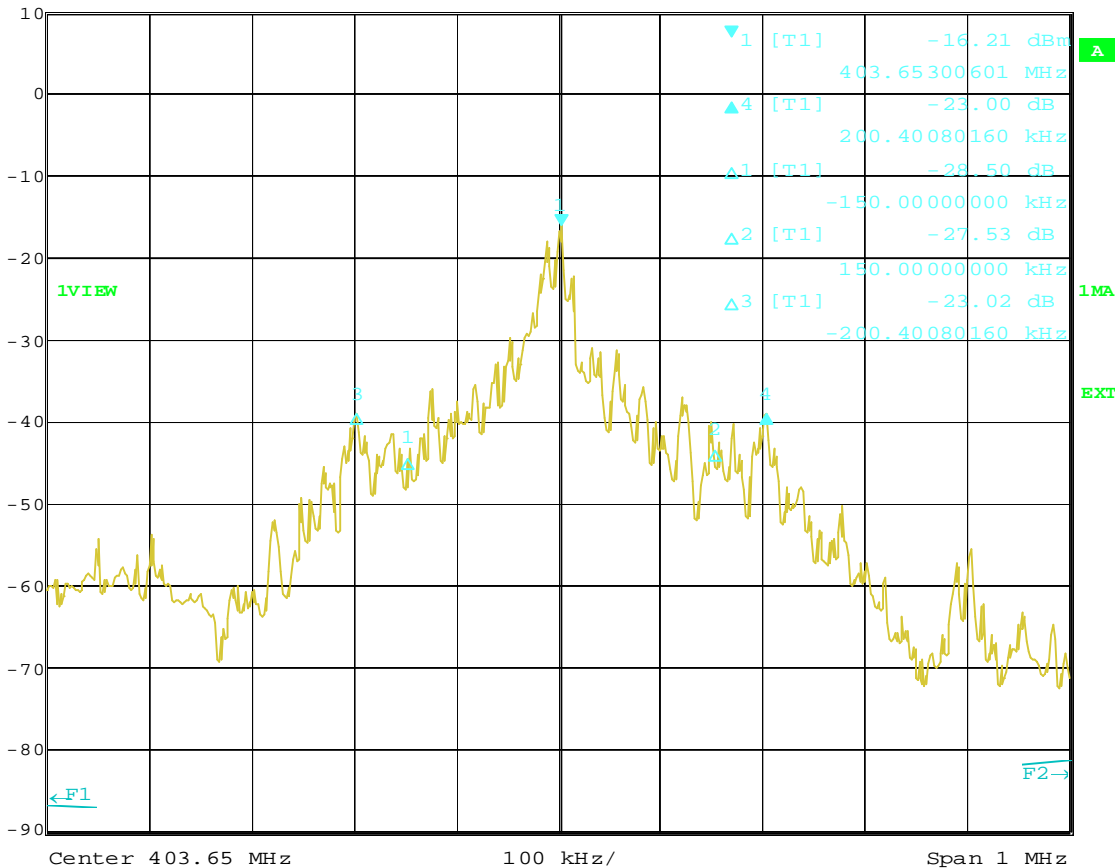
Equipment	Manufacturer	Type	SEMKO No.
Measurement receiver:	Rohde & Schwarz	FSIQ	12793
Rubidium oscillator	Datum	N/A	40032

8.3 Test protocol

Date of test: 2011-10-04

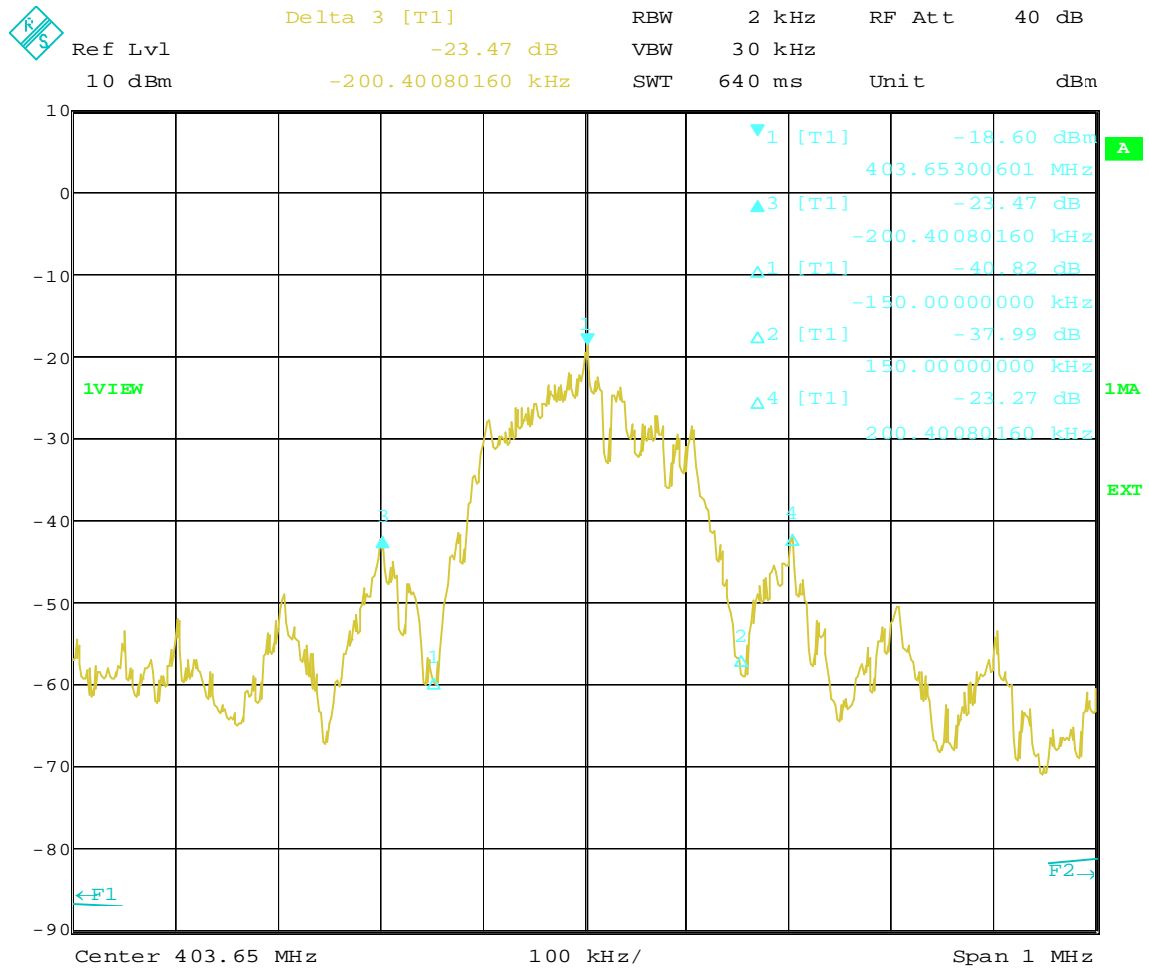
Middle Channel. 2FSK

	Delta 4 [T1]	RBW	2 kHz	RF Att	40 dB
Ref Lvl	-23.00 dB	VBW	30 kHz		
10 dBm	200.40080160 kHz	SWT	640 ms	Unit	dBm



Date: 4.OCT.2011 14:08:15

Middle Channel. 2FSK fallback



Date: 4.OCT.2011 14:13:50

8.4 Limits

Emission within MICS band more than 150 kHz away from center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20 dB.

Fulfil requirements: Yes

9. UNWANTED EMISSION CLOSE TO MICS BAND

9.1 Measurement uncertainty

Measurement uncertainty: < 1 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%.


9.2 Test equipment

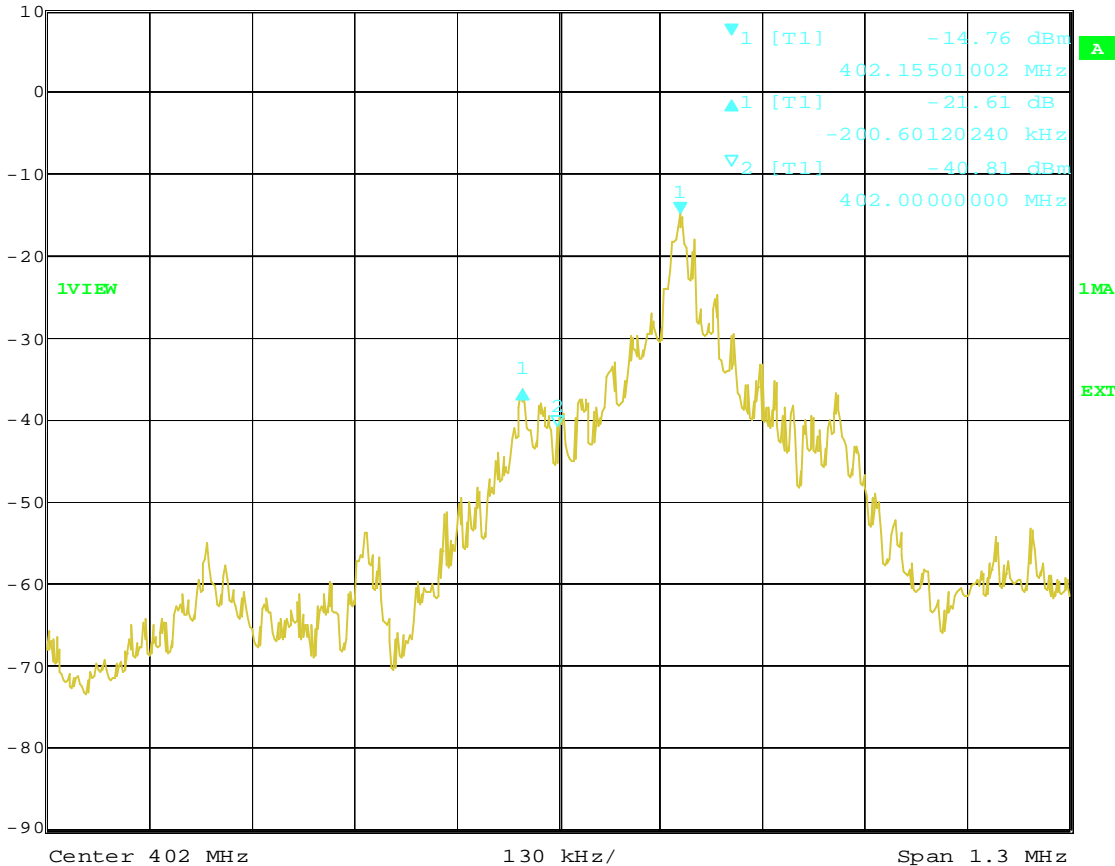
Equipment	Manufacturer	Type	SEMKO No.
Measurement receiver:	Rohde & Schwarz	FSIQ	12793
Rubidium oscillator	Datum	N/A	40032

9.3 Test protocol

Date of test: 2011-10-04

Low Channel. 2FSK

	Delta 1 [T1]	RBW	2 kHz	RF Att	40 dB
	Ref Lvl	-21.61 dB	VBW	30 kHz	
	10 dBm	-200.60120240 kHz	SWT	820 ms	Unit dBm

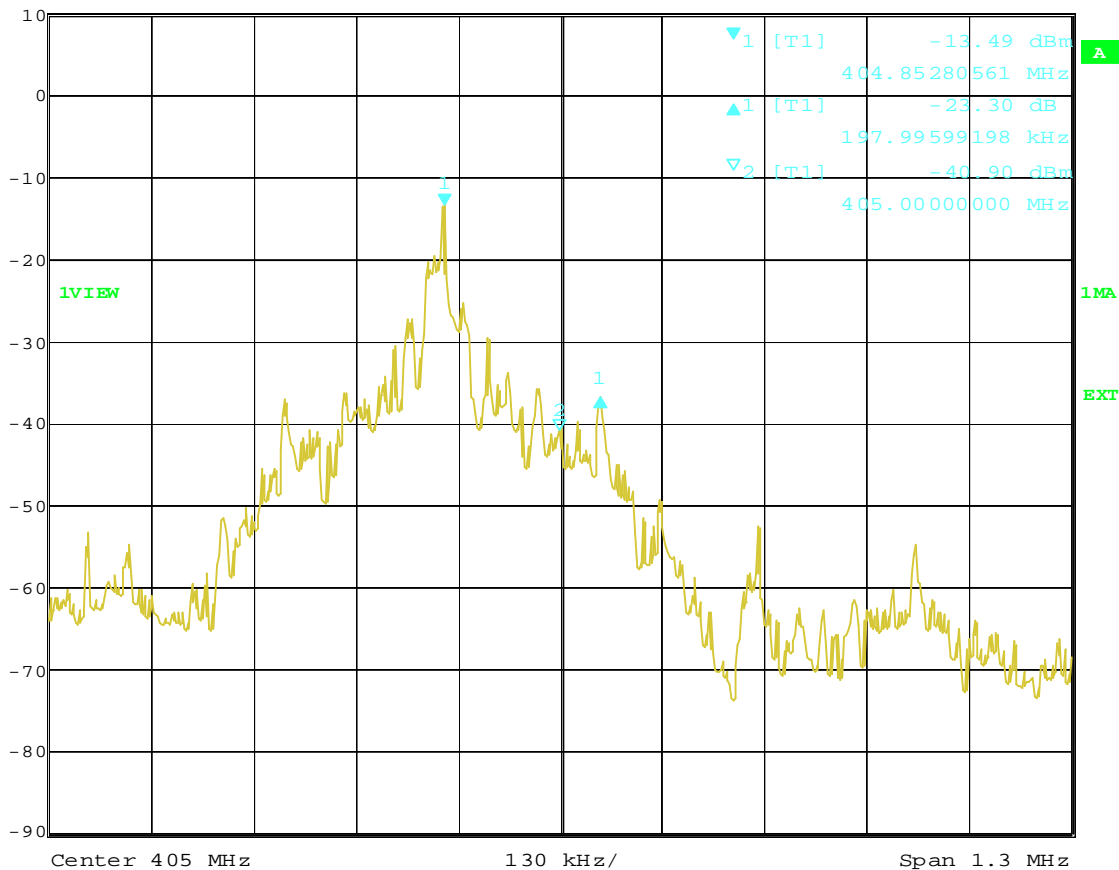


Date: 4.OCT.2011 14:18:32

High Channel. 2FSK




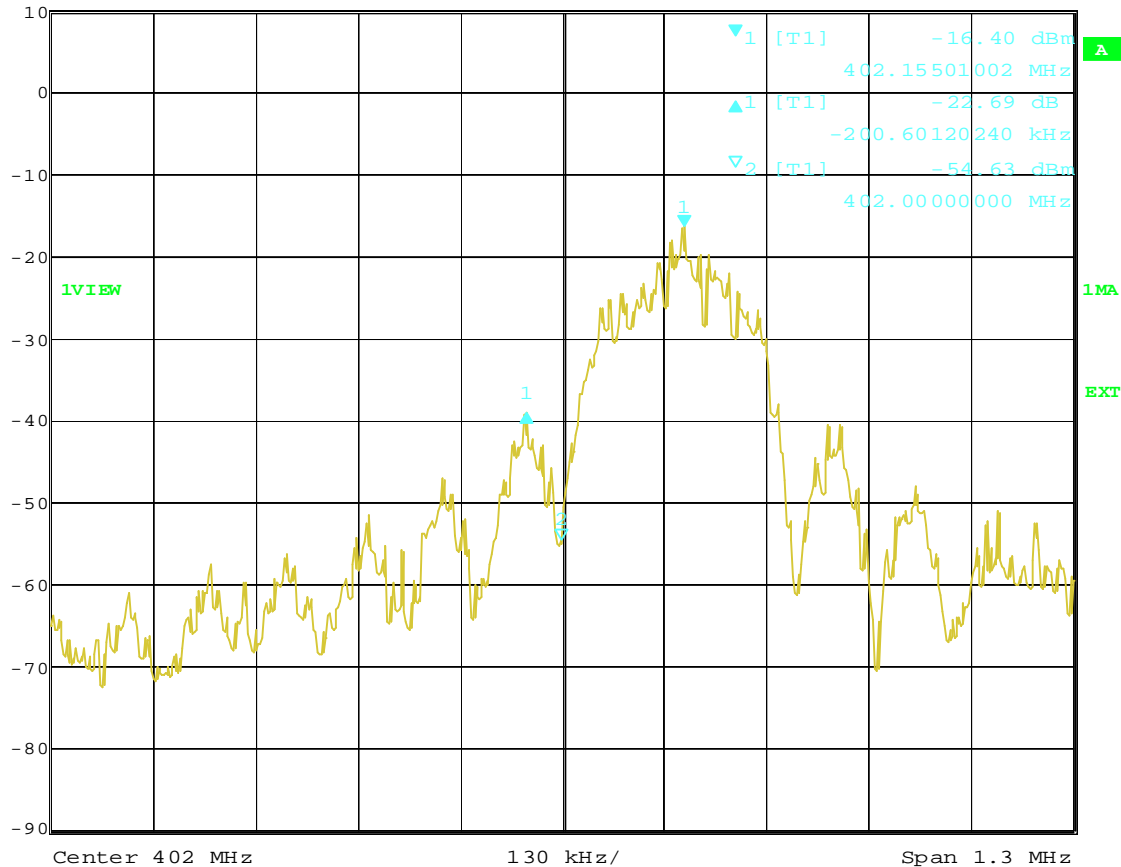
Delta 1 [T1]	RBW	2 kHz	RF Att	40 dB
Ref Lvl	-23.30 dB	VBW	30 kHz	
10 dBm	197.99599198 kHz	SWT	820 ms	Unit dBm



Date: 4.OCT.2011 14:21:25


Low Channel. 2FSK fallback

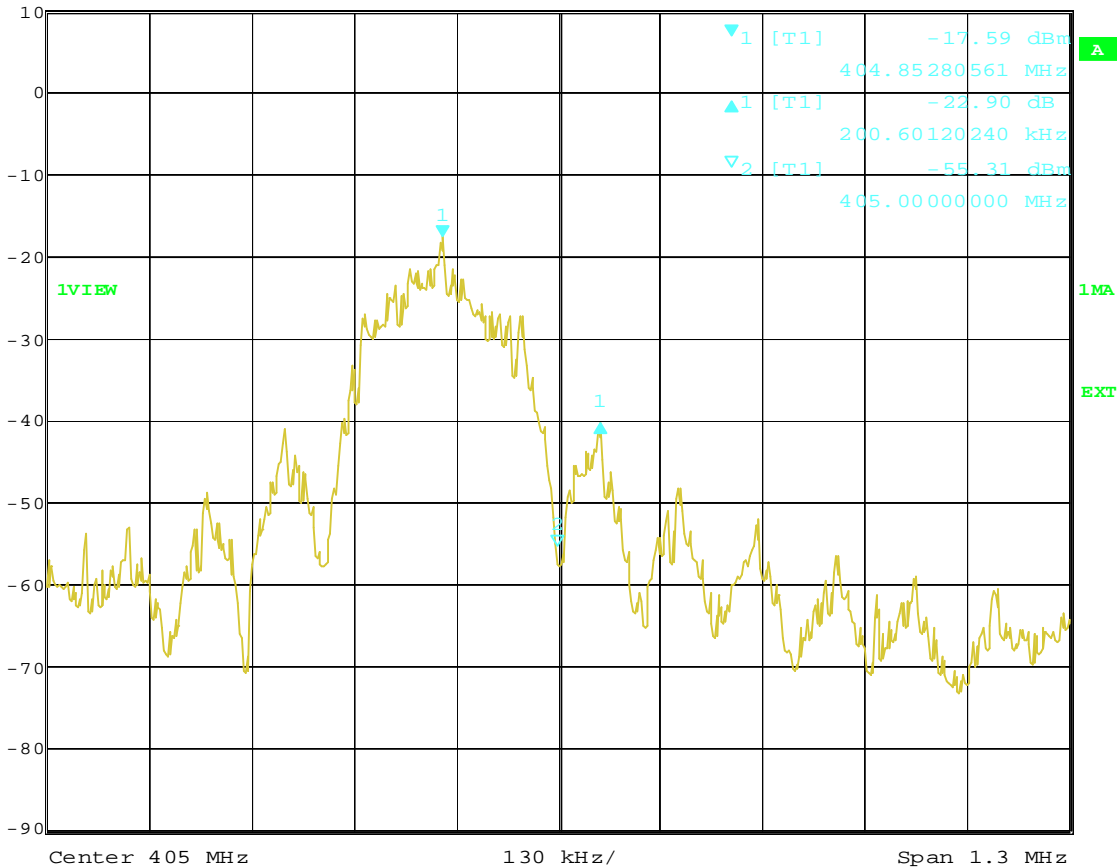
	Delta 1 [T1]	RBW	2 kHz	RF Att	40 dB
Ref Lvl	-22.69 dB	VBW	30 kHz		
10 dBm	-200.60120240 kHz	SWT	820 ms	Unit	dBm



Date: 4.OCT.2011 14:24:31

High Channel. 2FSK fallback

	Delta 1 [T1]	RBW	2 kHz	RF Att	40 dB
Ref Lvl	-22.90 dB	VBW	30 kHz		
10 dBm	200.60120240 kHz	SWT	820 ms	Unit	dBm



Date: 4.OCT.2011 14:23:01

9.4 Limits

Emission 250 kHz or less that are above and below the MICS band will be attenuated below the maximum permitted output power by at least 20 dB.

Fulfil requirements: Yes

APPENDIX A

According to the manufacturer the hardware of the following models are identical with the tested samples:

Tested model:

Ellipse™ VR, Model CD1275-36

Hardware identical with:

Ellipse™ ST VR, Model CD1273-36
Ellipse™ VR, Model CD1277-36
Ellipse™ VR, Model CD1279-36
Ellipse™ ST VR, Model CD1309-36
Ellipse™ VR, Model CD1311-36

Ellipse™ ST VR, Model CD1273-36Q

Ellipse™ VR, Model CD1275-36Q
Ellipse™ VR, Model CD1277-36Q
Ellipse™ VR, Model CD1279-36Q
Ellipse™ ST VR, Model CD1309-36Q
Ellipse™ VR, Model CD1311-36Q

Ellipse™ DR, Model CD2275-36

Ellipse™ ST DR, Model CD2273-36
Ellipse™ DR, Model CD2277-36
Ellipse™ DR, Model CD2279-36
Ellipse™ ST DR, Model CD2309-36
Ellipse™ DR, Model CD2311-36

Ellipse™ ST DR, Model CD2273-36Q

Ellipse™ DR, Model CD2275-36Q
Ellipse™ DR, Model CD2277-36Q
Ellipse™ DR, Model CD2279-36Q
Ellipse™ ST DR, Model CD2309-36Q
Ellipse™ DR, Model CD2311-36Q