

April 20, 2012

Attention:
Federal Communication Commission
7435 Oaklands Mills Rd.
Colombia, MD 21036

Responses to questions, correspondence Reference Number 41515 related to Class II Permissive change for FCC ID: RIASJMRF

Dear Sir,

Please find responses to the FCC questions dated Apr. 3, 2012 below:

Q1a: The warning statement at pages numbered as 13-14 is outdated, i.e. 47 CFR part 95 was changed circa 2009 (also changed in Jan. 2012, mainly to incorporate "MMN" device provisions, i.e. separate from the earlier changes from MICS to MedRadio); please apply what is now numbered as 95.1215(a). (<http://ecfr.gpoaccess.gov/>).

A1a: SJM has incorporated the suggested changes. Please reference page 14 of the attached User Manual (Attachment 1).

Q1b: We note that 2nd-last paragraph at page numbered 13 appears to be text as required by 95.1217(a)(1), i.e. for MedRadio programmer / control transmitters. BUT we notice also the para. is preceded by "Canada only"; however the page layout is somewhat ambiguous whether ALL the text following "Canada only" is for Canada only, i.e. whether Canada-only also includes the subsequent 90.1215(a) FCC text. Please revise to disambiguate.

A1b: SJM has incorporated the suggested changes. Please reference page 15 of the attached User Manual (Attachment 1).

Q1c: Page marked 13 mentions 95.1201-95.1219, which was the section range for 95 subpart I (eye) at least till 2008 CFR, however the 2009 FR changed subpart I to be 95.1201-95.1221.

A1c: SJM has incorporated the suggested changes. Please reference page 14 of the attached User Manual (Attachment 1).

Q2: Revised EMC/radio report includes equation as follows.

$$P [\text{uW}] = 25 * (10^{(U[\text{dB}(\text{uV}/\text{m})]) / 20 } / 18200)^2$$

As written that equation has a misplaced parenthesis;
revised is as follows.

$$P [\text{uW}] = 25 * (10^{(U[\text{dB}(\text{uV}/\text{m})] / 20) } / 18200)^2$$

As stated at report pg 22(39), for 62.7 dBuV/m the latter equation does give 0.1405 uW.

However the basis / derivation of that equation is unclear.

Rather we suggest to use e.g. as mentioned at 47 CFR 15.503(k), i.e.

$$\text{EIRP [dBm]} = E [\text{dBuV/m}] - 95.2$$

This last equation gives 0.56 uW EIRP, which because it does not exceed 0.63 uW rated power of the preceding filings under this FCC ID means 2.1043(a) does remain applicable (i.e. output power did not increase).

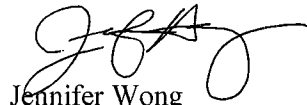
Unless if we might have made an error in the preceding discussion, please revise emc/radio report similarly for showing appropriate conversion from field strength to EIRP [95.628(g)(3), 2.911(b), 2.1033(c)(7), 2.1033(c)(14), 2.1046(c)].

A2: As suggested by FCC, the EMC/radio report has been revised to include an updated equation and result based on FCC § 95.628(g)(3). The following updated equation takes into account the reflecting floor of the semi anechoic test chamber that was used during testing:

$$\text{EIRP [dBm]} = E [\text{dBuV/m}] - 101.2$$

The report has also been revised to show the conversion from field strength to EIRP without floor reflex, per 47 CFR 15.503(k). Please reference the revised report in Attachment 2.

Sincerely,



Jennifer Wong
Regulatory Affairs Specialist
St. Jude Medical
CA, USA

Enclosures: Two attachments

Ellipse™

Tiered-therapy Cardioverter/Defibrillator

Fortify Assura™

Tiered-therapy Cardioverter/Defibrillator

Quadra Assura™

Cardiac Resynchronization Device, Tiered-therapy Cardioverter/Defibrillator

Unify Assura™

Cardiac Resynchronization Device, Tiered-therapy Cardioverter/Defibrillator



Covered by one or more of the following US patents: 5,318,591

Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

ST. JUDE MEDICAL, the nine-squares symbol, and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Unless otherwise noted, ® or ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical, Inc. or its subsidiaries.

Device Description

This manual describes the following St. Jude Medical® pulse generators:

Table 1. Single-chamber pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Ellipse VR	CD1275-36	Single-chamber ICD with RF telemetry	DF-1/IS-1	36 J
Ellipse VR	CD1275-36Q	Single-chamber ICD with RF telemetry	DF4-LLHH	36 J
Ellipse VR	CD1311-36	Single-chamber ICD with RF telemetry	DF-1/IS-1	36 J
Ellipse VR	CD1311-36Q	Single-chamber ICD with RF telemetry	DF4-LLHH	36 J

Table 1. Single-chamber pulse-generator descriptions

Fortify Assura VR	CD1257-40	Single-chamber ICD with RF telemetry	DF-1/IS-1	40 J
Fortify Assura VR	CD1257-40Q	Single-chamber ICD with RF telemetry	DF4-LLHH	40 J

Table 2. Dual-chamber pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Ellipse DR	CD2275-36	Dual-chamber ICD with RF telemetry	DF-1/IS-1	36 J

Table 2. Dual-chamber pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Ellipse DR	CD2275-36Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/ IS-1	36 J
Ellipse DR	CD2311-36	Dual-chamber ICD with RF telemetry	DF-1/IS-1	36 J
Ellipse DR	CD2311-36Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/ IS-1	36 J
Fortify Assura DR	CD2257-40	Dual-chamber ICD with RF telemetry	DF-1/IS-1	40 J
Fortify Assura DR	CD2257-40Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/ IS-1	40 J

Table 3. CRT-D pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Quadra Assura	CD3265-40	CRT-D with RF telemetry	DF-1/IS-1/ IS4-LLLL	40 J
Quadra Assura	CD3265-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J
Unify Assura	CD3257-40	CRT-D with RF telemetry	DF-1/IS-1	40 J
Unify Assura	CD3257-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS-1	40 J

The pulse generator, along with compatible, commercially available leads, constitutes the implantable portion of the ICD and CRT-D systems. The lead systems are implanted using either transvenous or transthoracic techniques. The St. Jude Medical Merlin[®] Patient Care System (PCS) with software model 3330 version 14.1 (or greater), a Merlin[®] Antenna (for devices with RF communication), and a telemetry wand constitute the external portion of the ICD and CRT-D

systems.

Models with the “Q” suffix” are functionally equivalent in all respects to the same model without the “Q” suffix, except for the header. Models without the Q” suffix use DF-1 lead connectors for the high-voltage leads, and models with the Q” suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead.

SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connectors comply with ISO 27186:2010(E). SJ4-LLLL is equivalent to IS4-LLLL. SJ4 and IS4 connectors comply with ISO 27186:2010(E).

Indications and Usage

St. Jude Medical® ICDs and CRT-Ds are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

AF Suppression™ pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction.

In patients indicated for an ICD, CRT-Ds are also intended:

- to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical

therapy (as defined in the clinical trials section included in the Merlin PCS on-screen help) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration

- to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure

Contraindications

Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Warnings and Precautions

Resuscitation Availability. Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

Lead system. Do not use another manufacturer's lead system without demonstrated compatibility as undersensing cardiac activity and failure to deliver necessary therapy may result.

Avoiding shock during handling. Disable tachyarrhythmia therapy (Enable/ Disable Tachy Therapy) or program tachyarrhythmia therapies Off during surgical implant and explant or post-

mortem procedures as well as when disconnecting leads as the device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.

Additional pacemaker implanted. These devices provide bradycardia pacing. If another pacemaker is used, it should have a bipolar pacing reset mode and be programmed for bipolar pacing to minimize the possibility of the output pulses being detected by the device.

Modifying the device. This device has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by St. Jude Medical Inc. could void the user's authority to operate this device.

Suboptimal radio frequency (RF) communication. The Merlin PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the Merlin PCS and the Merlin Antenna. Below is a list of potential causes to suboptimal radio communication:

Table 4. Possible causes and solutions for suboptimal RF communication

Possible Causes	Solutions
The Merlin Antenna orientation/location is suboptimal.	Move or reorient the Merlin Antenna slightly. Make sure that the front of the Merlin Antenna faces the implantable device.
People or objects interfere with the communication between the Merlin Antenna and the device.	Make sure that the space between the Merlin Antenna and the device is free from interfering objects/people.
The Merlin Antenna is too far away from the device.	Move the Merlin Antenna closer to the device.
Someone is holding the Merlin Antenna.	Place the Merlin Antenna on a flat surface. Do not hold the Merlin Antenna.

Table 4. Possible causes and solutions for suboptimal RF communication

Possible Causes	Solutions
Other products in the vicinity are causing electromagnetic interference (EMI).	Power off or remove equipment that could cause EMI.
The Merlin Antenna cable is wound around the Merlin Antenna.	Make sure the Merlin Antenna cable is not wound around the Merlin Antenna.

Sterilization, Storage and Handling

Resterilization. Do not resterilize and re-implant explanted pulse generators.

Use before date. Do not implant the device after the "use before" date because the battery may have reduced longevity.

If package is damaged. Do not use the device or accessories if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to St. Jude Medical.

Device storage. Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage. Store the device between 10° and 45°C because temperatures outside this range may damage the device.

Temperature Equilibration. After cold storage, allow the device to reach room temperature before charging the capacitors, programming, or implanting the device because cold temperature may affect initial device function.

Follow-up Testing

Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Implantation and Device Programming

Do not position a magnet over the device as that suspends detection and treatment (unless the device has been programmed to ignore the magnet).

Replace the device when the battery reaches the elective replacement indicator (ERI).

Implant the pulse generator no deeper than 5 cm to ensure reliable data transmission. For patient comfort, do not implant the pulse generator within 1.25 cm of bone unless you cannot avoid it.

Exercise caution when turning the setscrew, which may be backed out of the connector if turned counterclockwise for more than two rotations.

Program the device parameters as specified in the Merlin[®] PCS on-screen help.

The results of the DAVID Study demonstrated that, for patients with standard indications for ICD therapy, no indication for cardiac pacing and an EF < 40%, dual-chamber pacing offers no clinical advantage over backup VVI pacing and may be associated with worsening heart failure.¹ When programming the device to dual-chamber pacing modes, give particular attention to setting the pacing parameters (such as the A-V delay) to promote intrinsic conduction and minimize the amount of ventricular pacing.

Pulse Generator Explant and Disposal

Interrogate the device and turn all therapies off before explanting, cleaning or shipping the device to prevent unwanted shocks.

Return all explanted pulse generators and leads to St. Jude Medical.

Never incinerate the device because of the potential for explosion. Explant the device before cremation.

¹ Wilkoff BL, Cook JR, Epstein AE, Greene L, Hallstrom AP, Hsia H, Kutalek SP, Sharma A. Dual-Chamber Pacing or Ventricular Backup Pacing in Patients With an Implantable Defibrillator: The Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial. JAMA. December 25, 2002; Vol 288, No. 24:3115-3123.

Environmental and Medical Therapy Hazards

Instruct patients to avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause device malfunction or damage, resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

Hospital and Medical Environments

Electrosurgical cautery. Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If electrocautery is necessary, keep the current path and groundplate as far away from the pulse generator and leads as possible.

External defibrillation. External defibrillation may damage the pulse generator or may result in temporary and/or permanent myocardial damage at the electrode-tissue interface as well as temporarily or permanently elevated pacing capture thresholds. Minimize current flowing through the pulse generator and lead system by following these precautions when using external defibrillation on a patient with a pulse generator:

- Position defibrillation paddles as far from the pulse generator as possible (minimum of 13 cm)
- Use the lowest clinically appropriate energy output
- Confirm pulse generator function following any external defibrillation

High radiation sources. Do not direct high radiation sources such as cobalt 60 or gamma radiation

at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

Lithotripsy. Lithotripsy may permanently damage the pulse generator. Avoid it unless the therapy site is not near the pulse generator and leads.

Diathermy. Avoid diathermy, even if the device is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the pulse generator.

Magnetic resonance imaging (MRI). MRI for patients with implantable pulse generators has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decision to use MRI with ICD/CRT-D patients. MRI may cause device malfunction or injury to the patient.

Ultrasound therapy. Diagnostic and therapeutic ultrasound treatment is not known to affect the function of the pulse generator.

Transcutaneous Electrical Nerve Stimulation (TENS). TENS may interfere with device function. To reduce interference, place the TENS electrodes close to one another and as far from the device/lead system as possible. Monitor cardiac activity during TENS use.

Radiofrequency ablation. RF ablation in a patient with a pulse generator may cause device malfunction or damage.

Minimize RF ablation risks by:

- Programming all tachyarrhythmia therapies off

- Avoiding direct contact between the ablation catheter and the implanted lead or pulse generator
- Positioning the groundplate so that the current pathway does not pass near the pulse generator system, i.e., place the groundplate under the patient's buttocks or legs
- Having external defibrillation equipment available.

RF Operating Frequencies. Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 301 839-2
- USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1221 Subpart I
- FCC ID: RIASJMRF.

WARNING

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (that is., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations,

including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

The following is applicable to Canada only:

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.

Home and Occupational Environments

High-voltage power transmission lines. High-voltage power transmission lines may generate enough EMI to interfere with pulse generator operation if approached too closely.

Communication equipment. Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with pulse generator operation if approached too closely.

Home appliances. Home appliances in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

Industrial equipment. A variety of industrial equipment produce EMI of sufficient field strength and modulation characteristics to interfere with proper operation of the pulse generator. These include, but are not limited to: arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

Electronic Article Surveillance

Advise patients that the Electronic Article Surveillance/Anti-theft (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with the device. It is very unlikely that these systems will interact with their device significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

Metal Detectors

Advise patients that metal detector security systems such as those found in airports and government buildings emit signals that may interact with ICDs and CRT-Ds. It is very unlikely that these systems will interact with their device significantly. To minimize the possibility of interaction,

advise patients to simply walk through these areas at a normal pace and avoid lingering. Even so, the ICD and CRT-D systems contain metal that may set off the airport security system alarm. If the alarm does sound, the patient should present security personnel with their patient identification card. If security personnel perform a search with a handheld wand, the patient should ask that they perform the search quickly, stressing that they should avoid holding the wand over the device for a prolonged period.

Cellular Phones

The pulse generator has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of AAMI PC69. This testing covered the operating frequencies (450 MHz - 3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. Based on the results of this testing, the pulse generator should not be affected by the normal operation of cellular phones.

Potential Adverse Events

Possible adverse events (in alphabetical order) associated with the system, include, but are not limited to the following:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Allergic reaction

- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Death
- Erosion
- Exacerbation of heart failure
- Excessive fibrotic tissue growth
- Extracardiac stimulation (phrenic nerve, diaphragm, chest wall)
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles

- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation.

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD or CRT-D system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear of losing shock capability
- Imagined shocking (phantom shock).

Clinician Use Information

WARNING

For devices without the Low Frequency Attenuation Filter, the default Atrial Sensitivity setting and the lowest possible setting of Ventricular Sensitivity, 0.2 mV, may be more susceptible to EMI, according to testing required by CENELEC standard prEN45502-2-2. The devices comply with the electromagnetic

compatibility requirements of CENELEC standard prEN45502-2-2 at atrial and ventricular sensitivities of 0.3 mV and less sensitive settings.

For devices with the Low Frequency Attenuation Filter, the default Atrial Sensitivity setting, the lowest possible setting of Ventricular Sensitivity, 0.2 mV, and the Ventricular Sensitivity setting of 0.3 mV when the Low Frequency Attenuation Filter is On, may be more susceptible to EMI, according to testing required by CENELEC standard EN45502-2-2. The devices comply with the electromagnetic compatibility requirements of CENELEC standard EN45502-2-2 at atrial sensitivities of 0.3 mV, ventricular sensitivities of 0.3mV (Low Frequency Attenuation Filter OFF) or ventricular sensitivities of 0.4 mV (Low Frequency Attenuation Filter On), and less sensitive settings.

Physician Training

Physicians should be familiar with sterile pulse generator implant procedure and with follow-up evaluation and management of patients with an ICD or CRT-D (or should refer the patient to such a physician).

Maintaining Device Effectiveness

Device Storage

FOR SINGLE USE ONLY. Do not resterilize and re-implant explanted pulse generators.

St. Jude Medical has sterilized the pulse generator with ethylene oxide prior to shipment. Contact St. Jude Medical if resterilization is necessary.

Do not implant the device when:

- It has been dropped on a hard surface because this could have damaged pulse generator components.
- The sterility indicator within the inner package is purple, because it might not have been sterilized.
- Its storage package has been pierced or altered, because this could have rendered it non-sterile.
- It has been stored or transported outside the environmental temperature limits.

Storage limits: 10° to 45°C.

Transportation limits: -20° to 60°C.

An electrical reset condition may occur at temperatures below -20°C.

After cold storage, allow the device to reach room temperature before charging the capacitors, programming, or implanting the device because cold temperature may affect initial device function.

- Its "use before" date has expired, because this can adversely affect pulse generator longevity or device sterility.

Do not resterilize the pulse generator using an autoclave, gamma-irradiation, organic cleaning agents (e.g., alcohol, acetone, etc.), or ultrasonic cleaners.

Sterilization Instructions

Contact St. Jude Medical if resterilization is necessary.

Directions for Use

Pulse generator operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the Patient Registration Form and return it to St. Jude Medical as it provides necessary information for warranty purposes and patient tracking.

Copies of this user's manual can be obtained by contacting your St. Jude Medical representative.

Radiopaque Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code.

Table 5. X-ray ID codes for the device models described in this manual

Device Model	X-ray ID Model Code
CD1275-36/36Q, CD1311-36/36Q, CD2275-36/36Q, CD2311-36/36Q	KF
CD1257-40/40Q, CD2257-40/40Q, CD3257-40/40Q, CD3265-40/40Q	KC

Package Contents

The pulse generator is supplied in a sterile tray for introduction into the operating field. The tray contains:

- One pulse generator (with all tachyarrhythmia therapies off) with pre-installed setscrews
- Torque driver.

The outer box contains:

- Literature.

Technical Support

St. Jude Medical Cardiac Rhythm Management Division maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local St. Jude Medical representative.

Additional Information

For additional information on this device, see the programmer's on-screen help.

Cardiac Rhythm Management Division

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100056454



April 2012
Art 60031731/B

RADIO TEST REPORT

No. 1118080-2 ed. 3

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

Manufacturer: See appendix A for a list of other model names with identical hardware
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: April 18, 2012

Tested by:


Stefan Andersson

Approved by:


Henric Larsson
On behalf of
Niklas Boström

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Revision History

Edition	Date	Description
1	2011-11-04	First release
2	2012-02-16	Result for output power in section 5.5 is also listed in microwatt EIRP
3	2012-04-18	Equation in section 5.5 corrected. As suggested by the FCC, equation and results according to §15.503(k) added

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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	FSU40	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.

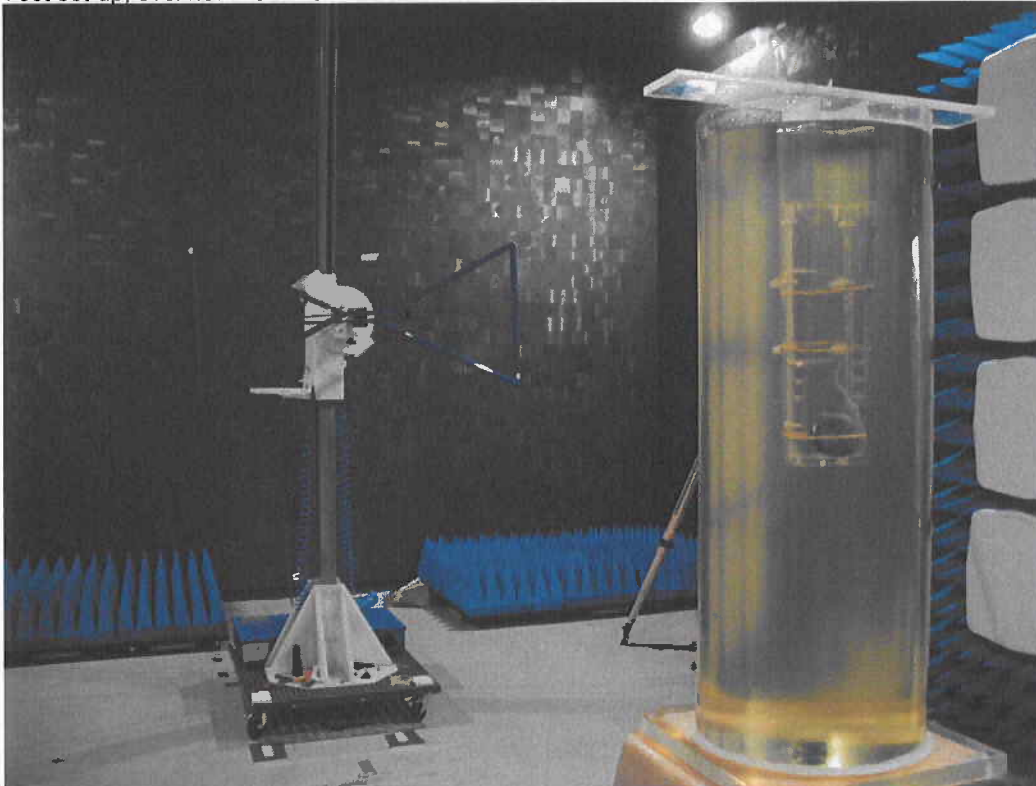
An overview sweep with peak detection of the electric field intensity was performed with the measurement receiver in max-hold and with the antenna placed 1.5 m, 2.5 m and 3.5 m above the floor. The polarization was horizontal and vertical. The measurements were repeated with the EUT rotated in 90-degree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

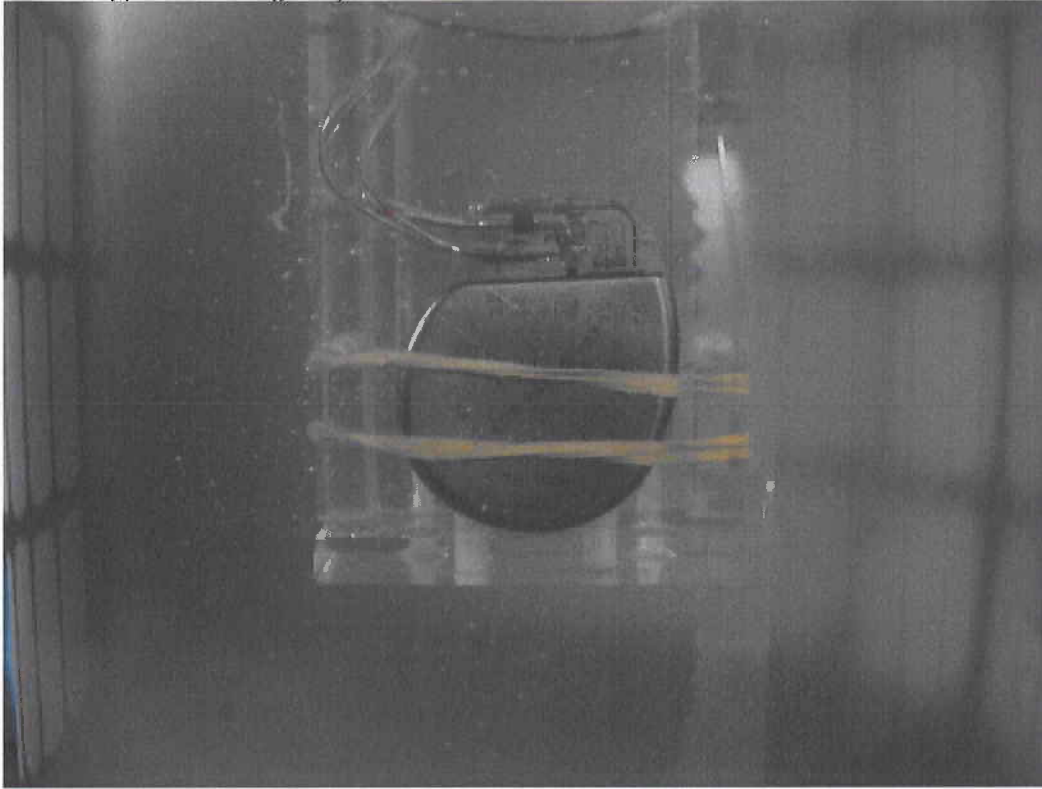
For maximum transmitter power measurement the turntable was turned 360 degrees and the antenna mast was moved from 1 m to 4 m to find the maximum power. The measurement was performed with both horizontal and vertical polarization.

Test set-up photos:

Test set-up, overview from EUT



Test set-up, EUT in Plexiglas cylinder



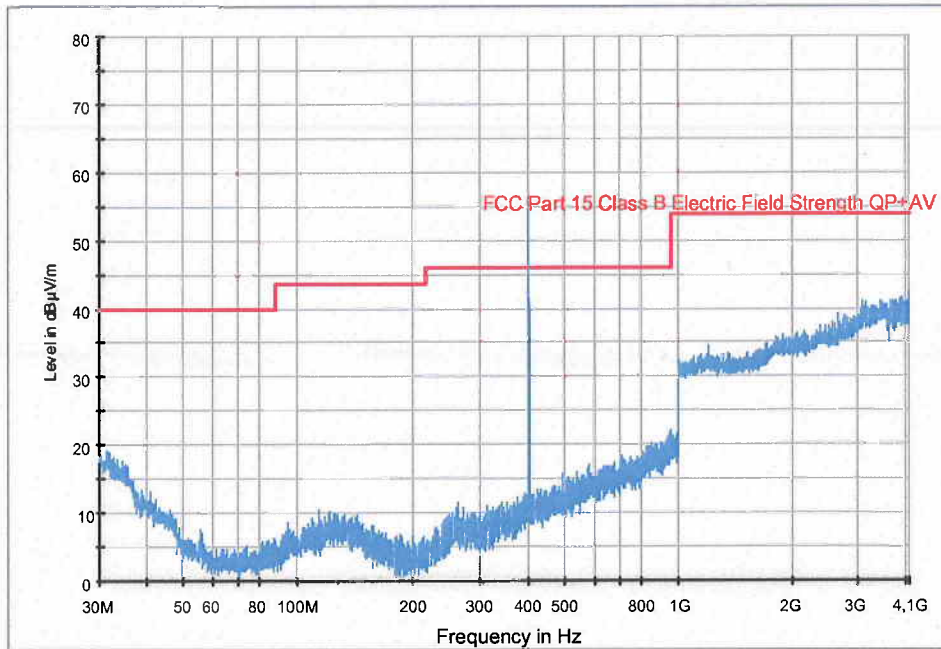
5.4 Test protocol, Unwanted radiation

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

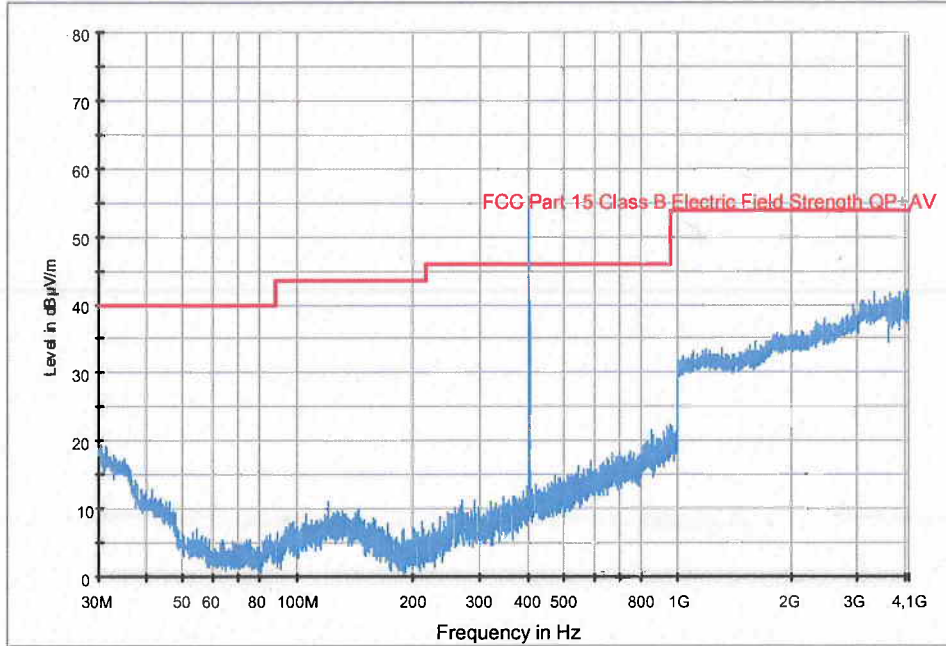
1 mics spur 30M-1G-4G w.uComp preamp_110523



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

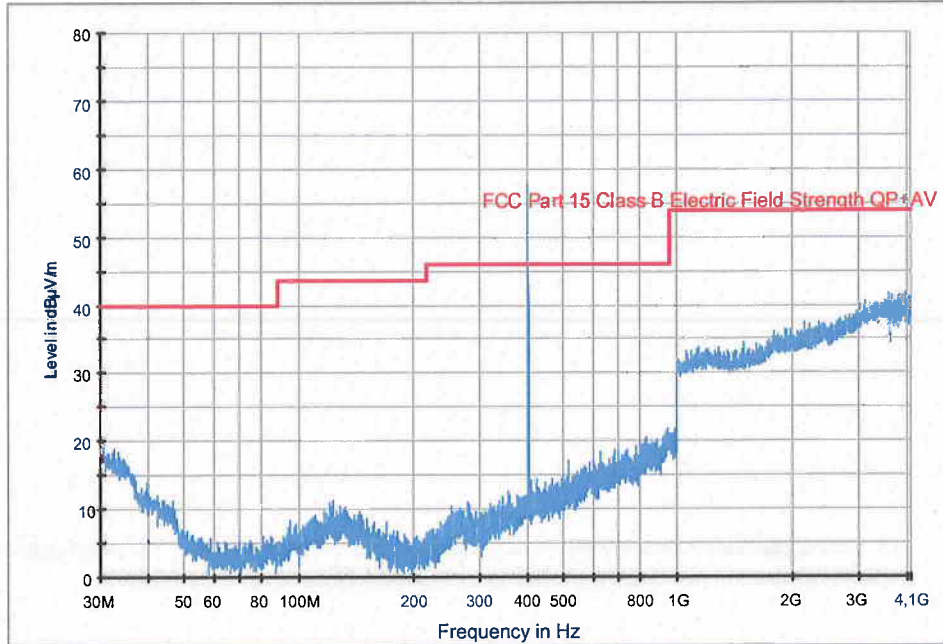
1 mics spur 30M-1G-4G w.uComp preamp_110523



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

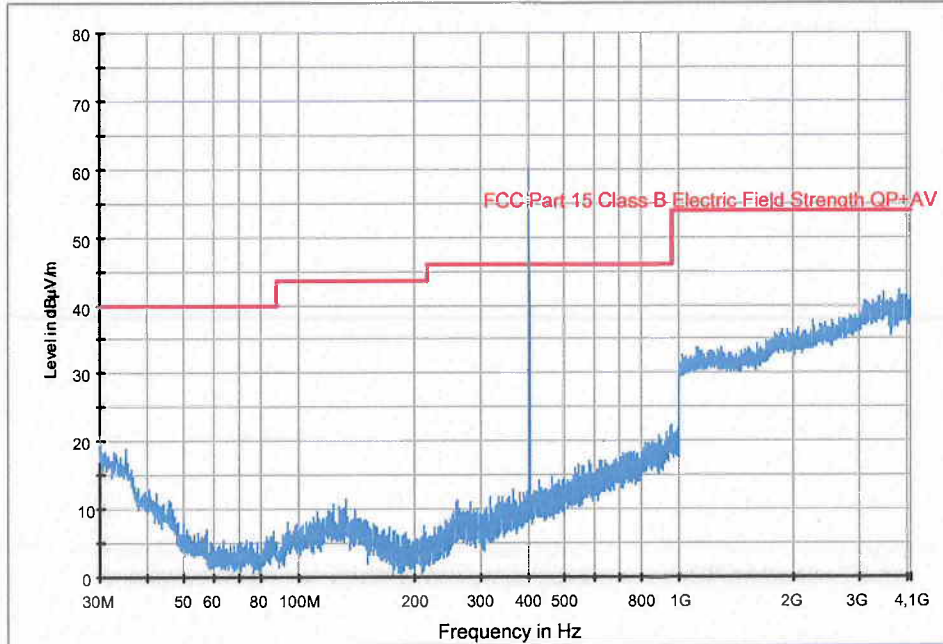
1 mics spur 30M-1G-4G w.uComp preamp_110523



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

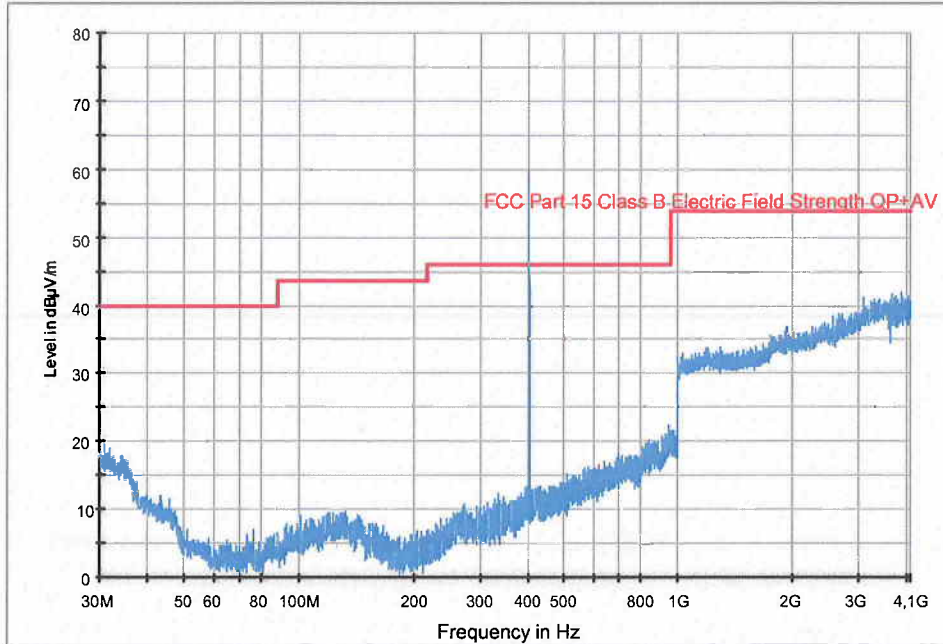
1 mics spur 30M-1G-4G w.uComp preamp_110523



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

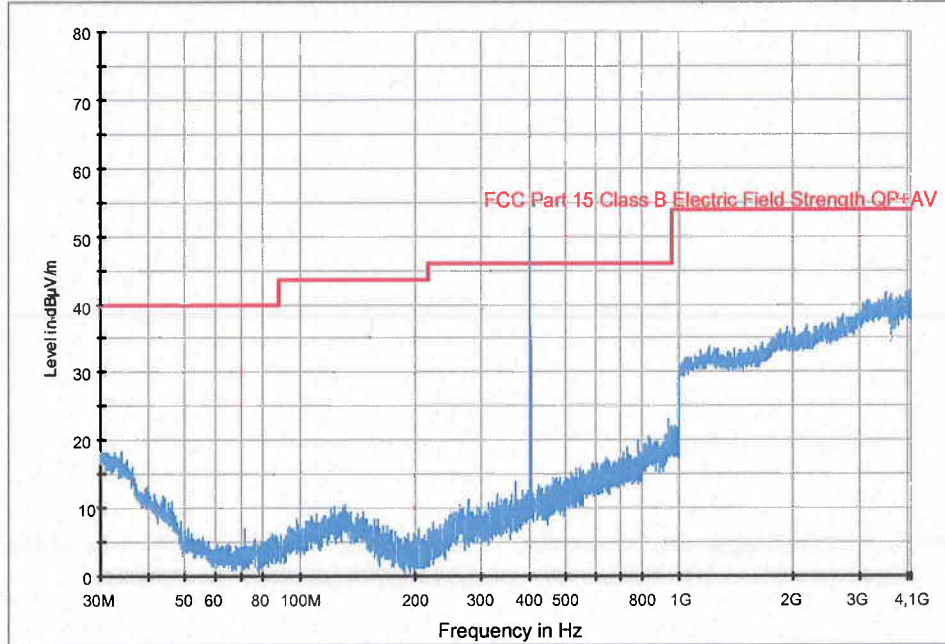
1 mics spur 30M-1G-4G w.uComp preamp_110523



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

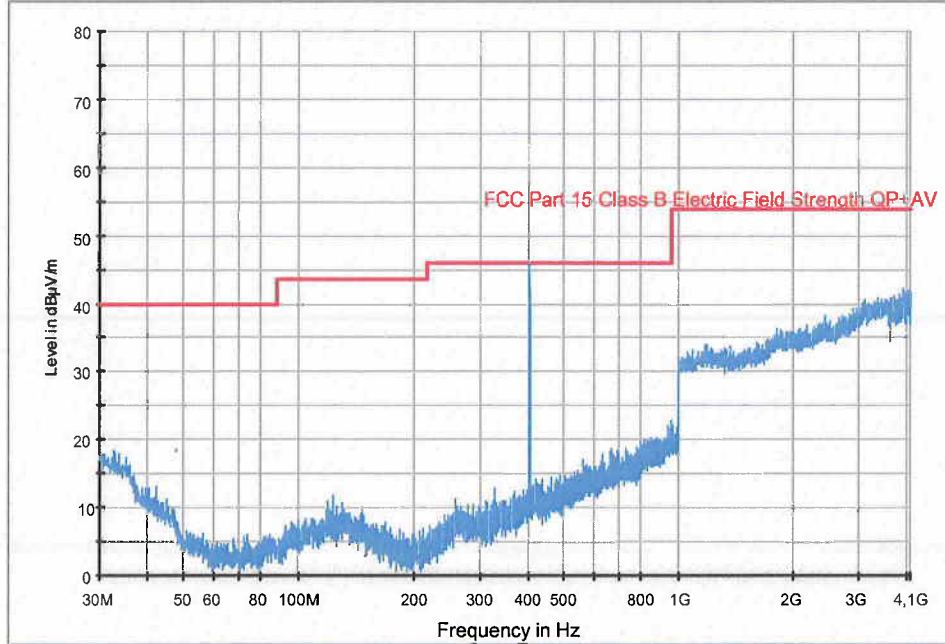
1 mics spur 30M-1G-4G w.uComp preamp_110523



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

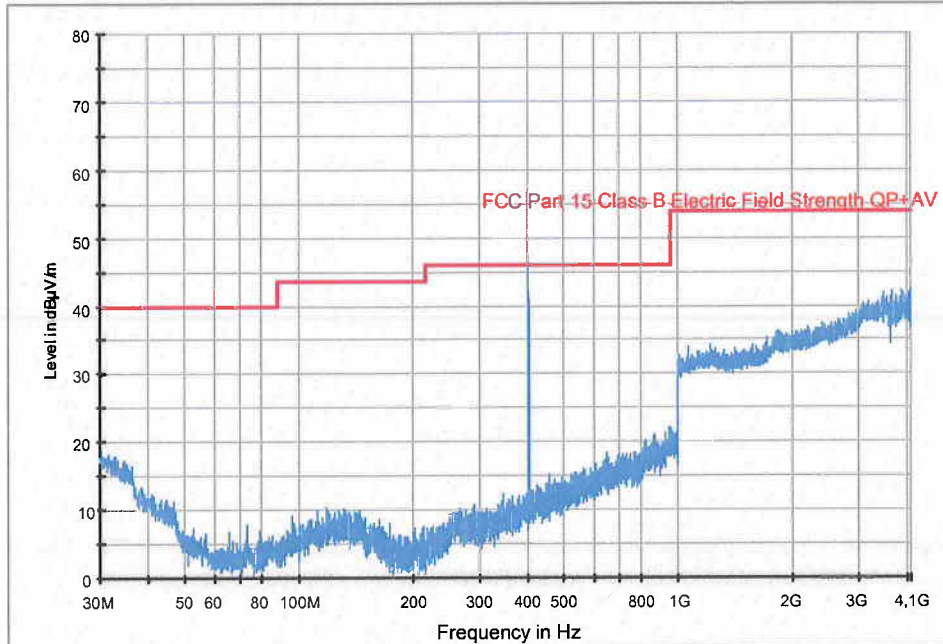
1 mics spur 30M-1G-4G w.uComp preamp_110523



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:

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

Fulfil requirements: YES

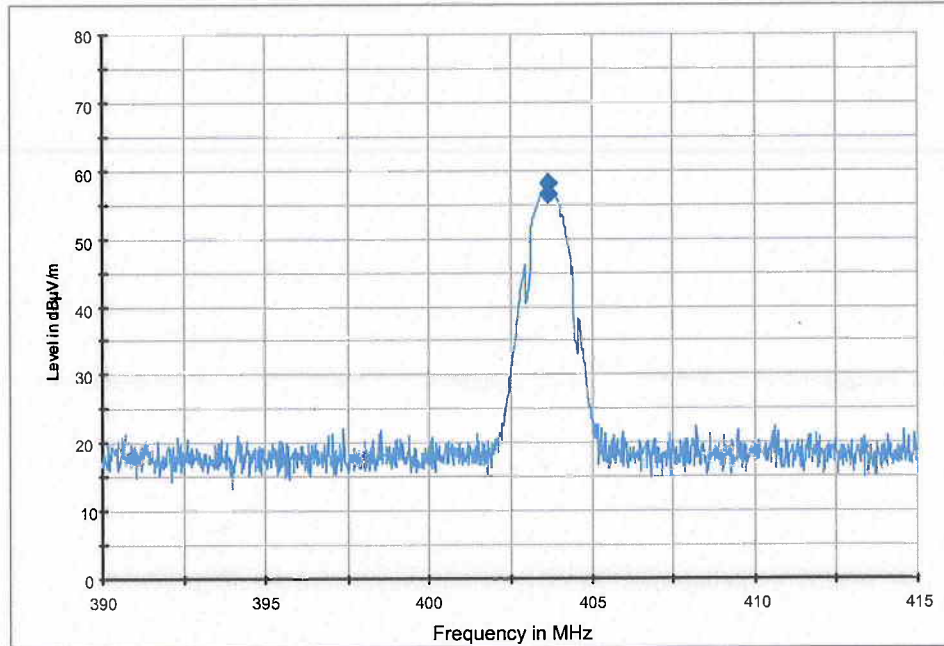
5.5 Test protocol, Maximum transmitter power

Semi-anechoic shielded chamber

Date of test: 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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):

25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

$$EIRP [dBm] = E [dB\mu V/m] - 101.2 \Rightarrow EIRP [\mu W] = 1000 * 10^{((E [dB\mu V/m] - 101.2)/10)}$$

$$P = 0.0487 \mu W \text{ EIRP}$$

According to FCC §15.503(k):

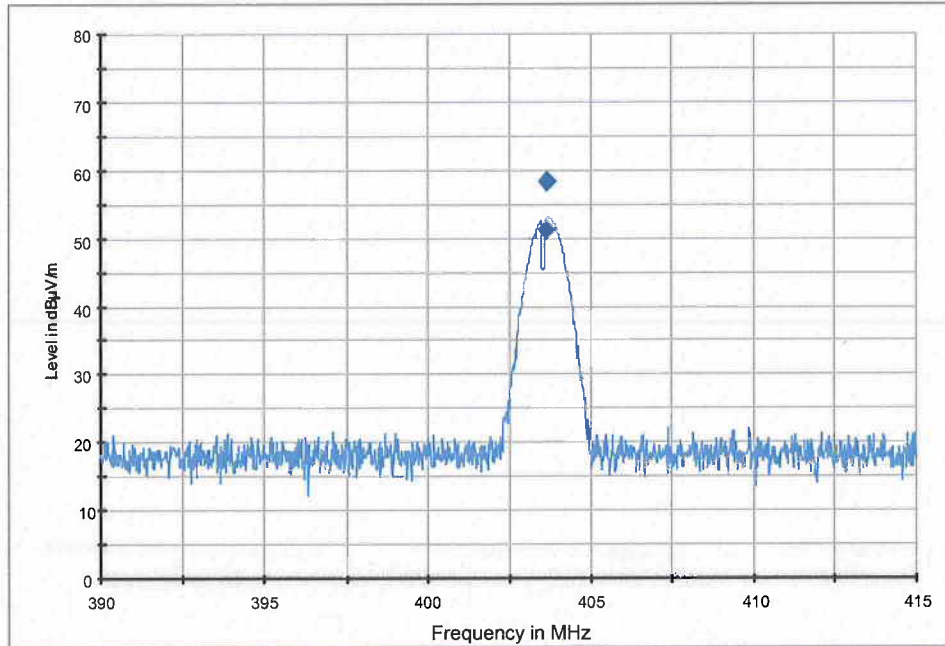
$$EIRP [dBm] = E [dB\mu V/m] - 95.2 \Rightarrow EIRP [\mu W] = 1000 * 10^{((E [dB\mu V/m] - 95.2)/10)}$$

(This equation is not counting with the reflecting floor in the chamber)

$$P = 0.195 \mu W \text{ EIRP}$$

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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 101.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 101.2)/10)}$$

$$P = 0.0510 \mu\text{W EIRP}$$

According to FCC §15.503(k):

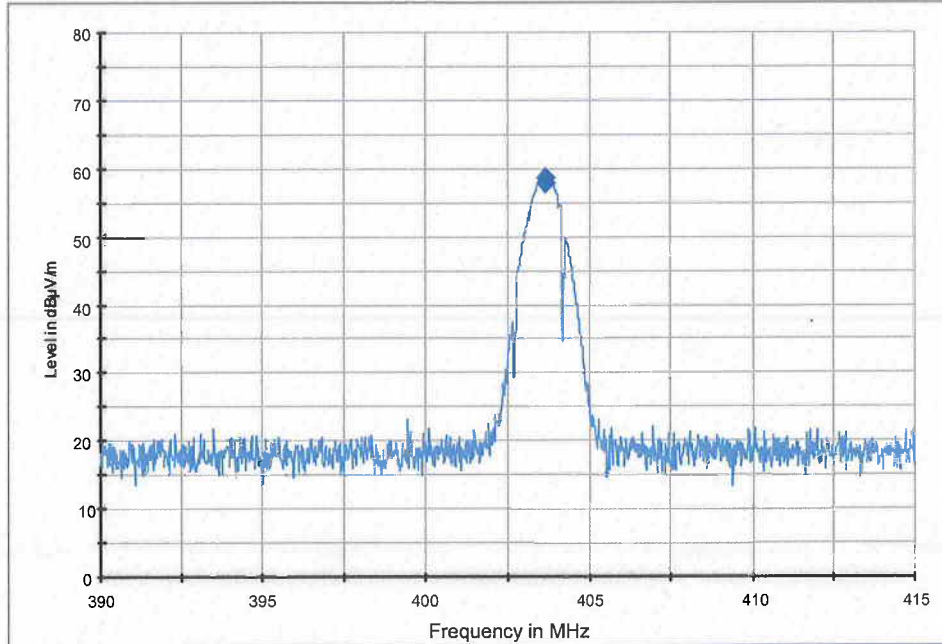
$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 95.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 95.2)/10)}$$

(This equation is not counting with the reflecting floor in the chamber)

$$P = 0.204 \mu\text{W EIRP}$$

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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):

25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 101.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 101.2)/10)}$$

$$P = 0.0547 \mu\text{W EIRP}$$

According to FCC §15.503(k):

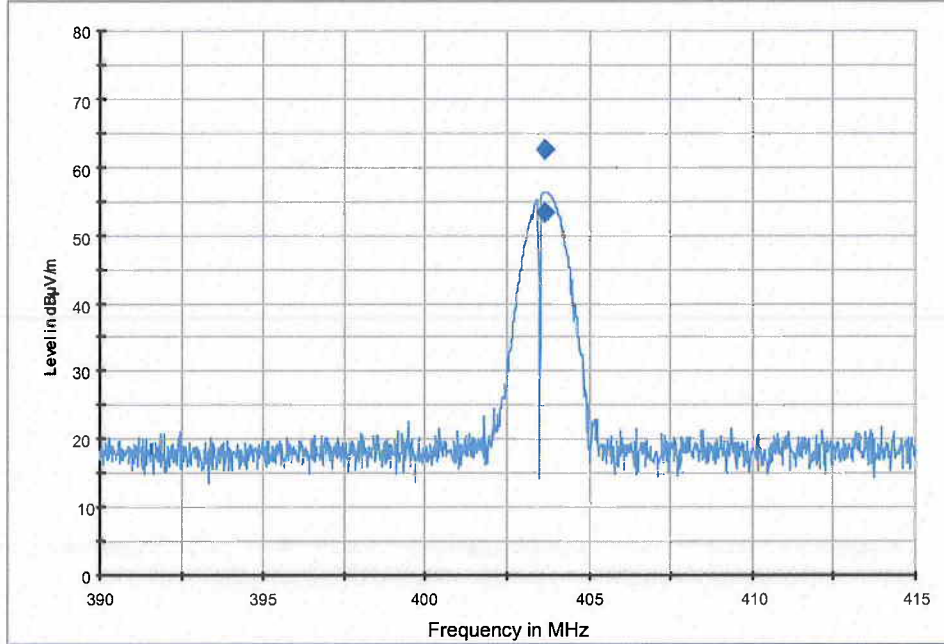
$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 95.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 95.2)/10)}$$

(This equation is not counting with the reflecting floor in the chamber)

$$P = 0.219 \mu\text{W EIRP}$$

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	-	

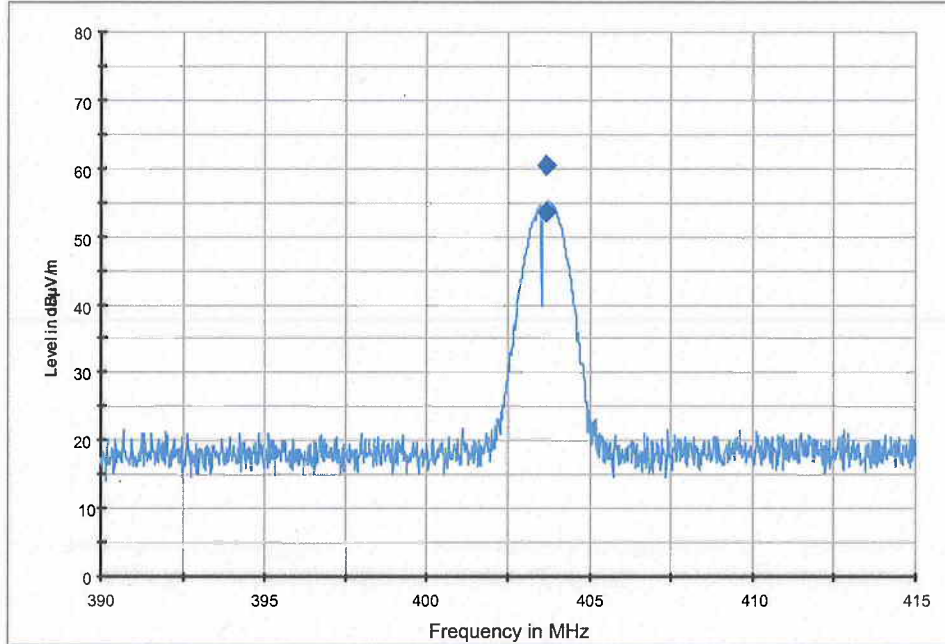
Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
 25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).
 $EIRP [dBm] = E [dB\mu V/m] - 101.2 \Rightarrow EIRP [\mu W] = 1000 * 10^{((E [dB\mu V/m] - 101.2)/10)}$
 $P = 0.141 \mu W$ EIRP

According to FCC §15.503(k):
 $EIRP [dBm] = E [dB\mu V/m] - 95.2 \Rightarrow EIRP [\mu W] = 1000 * 10^{((E [dB\mu V/m] - 95.2)/10)}$
 (This equation is not counting with the reflecting floor in the chamber)
 $P = 0.562 \mu W$ EIRP

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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):

25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

$$EIRP [dBm] = E [dB\mu V/m] - 101.2 \Rightarrow EIRP [\mu W] = 1000 * 10^{((E [dB\mu V/m] - 101.2)/10)}$$

$$P = 0.0828 \mu W \text{ EIRP}$$

According to FCC §15.503(k):

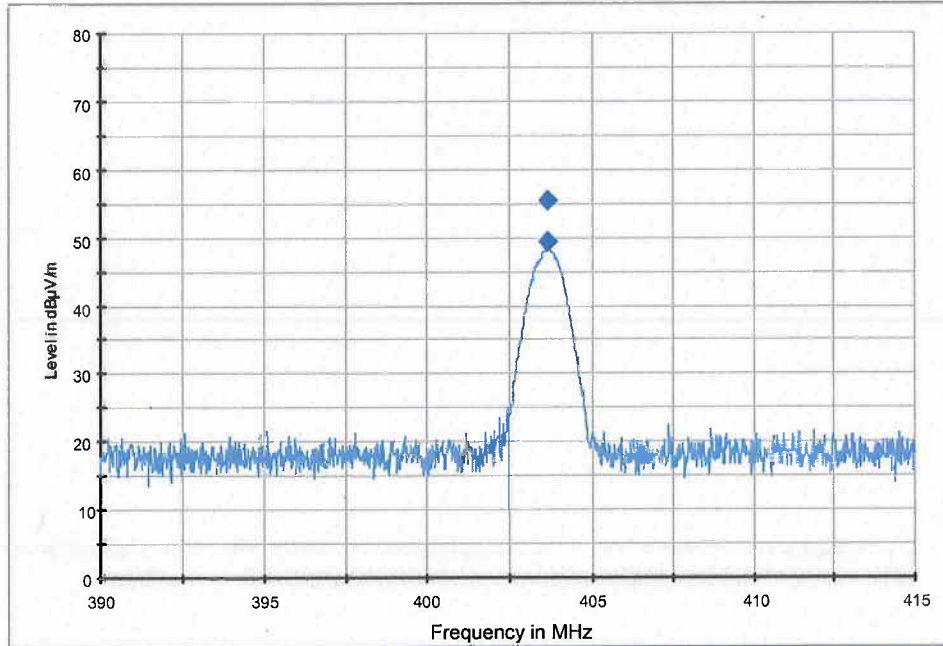
$$EIRP [dBm] = E [dB\mu V/m] - 95.2 \Rightarrow EIRP [\mu W] = 1000 * 10^{((E [dB\mu V/m] - 95.2)/10)}$$

(This equation is not counting with the reflecting floor in the chamber)

$$P = 0.331 \mu W \text{ EIRP}$$

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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

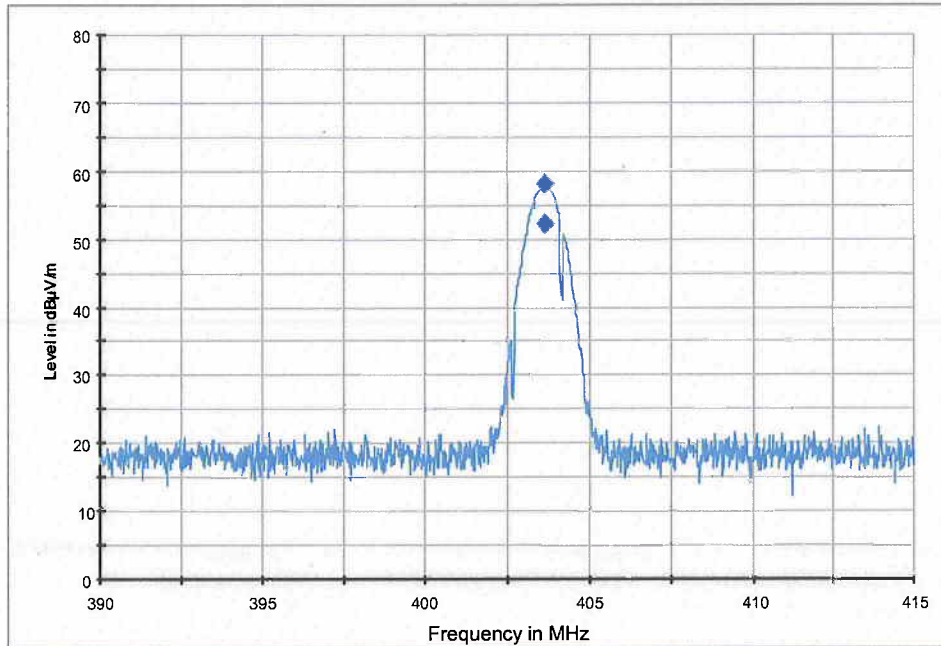
$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 101.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 101.2)/10)}$$

$$P = 0.0262 \mu\text{W EIRP}$$

According to FCC §15.503(k):
EIRP [dBm] = E [dBµV/m] - 95.2 => EIRP [µW] = 1000*10^((E [dBµV/m] - 95.2)/10)
(This equation is not counting with the reflecting floor in the chamber)
P = 0.105 µW EIRP

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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):

25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 101.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 101.2)/10)}$$

$$P = 0.0487 \mu\text{W EIRP}$$

According to FCC §15.503(k):

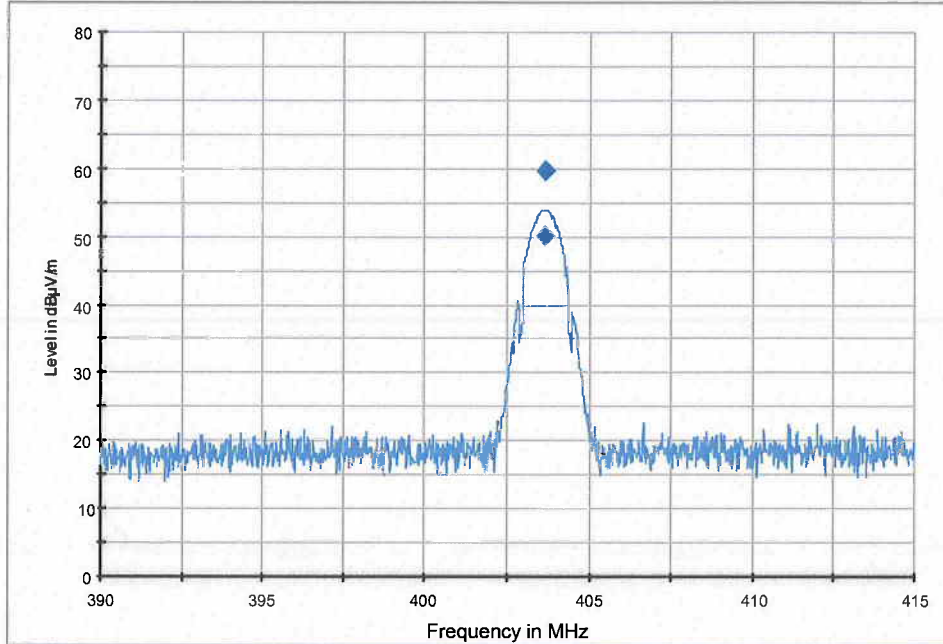
$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 95.2 \Rightarrow \text{EIRP } [\mu\text{W}] = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 95.2)/10)}$$

(This equation is not counting with the reflecting floor in the chamber)

$$P = 0.195 \mu\text{W EIRP}$$

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	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).

$$\text{EIRP [dBm]} = E \text{ [dB}\mu\text{V/m]} - 101.2 \Rightarrow \text{EIRP [\mu W]} = 1000 \cdot 10^{((E \text{ [dB}\mu\text{V/m]} - 101.2)/10)}$$

$$P = 0.0704 \mu\text{W EIRP}$$

According to FCC §15.503(k):
EIRP [dBm] = E [dBµV/m] - 95.2 ⇒ EIRP [µW] = 1000*10^((E [dBµV/m] - 95.2)/10)
(This equation is not counting with the reflecting floor in the chamber)
P = 0.282 µW EIRP

Example calculation, measured level:

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

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: Rubidium oscillator	Rohde & Schwarz Datum	FSIQ N/A	12793 40032

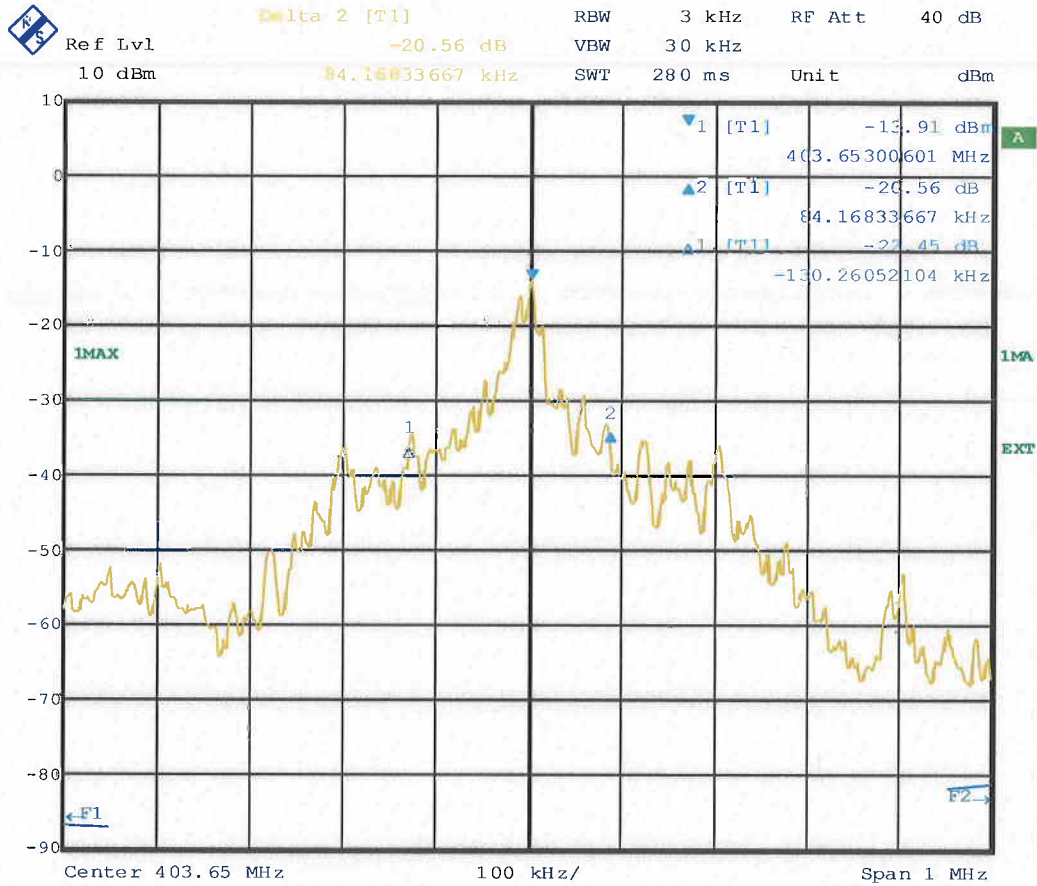
7.3 Test protocol

Date of test: 2011-10-04

20 dB Bandwidth:

Middle Channel. 2FSK

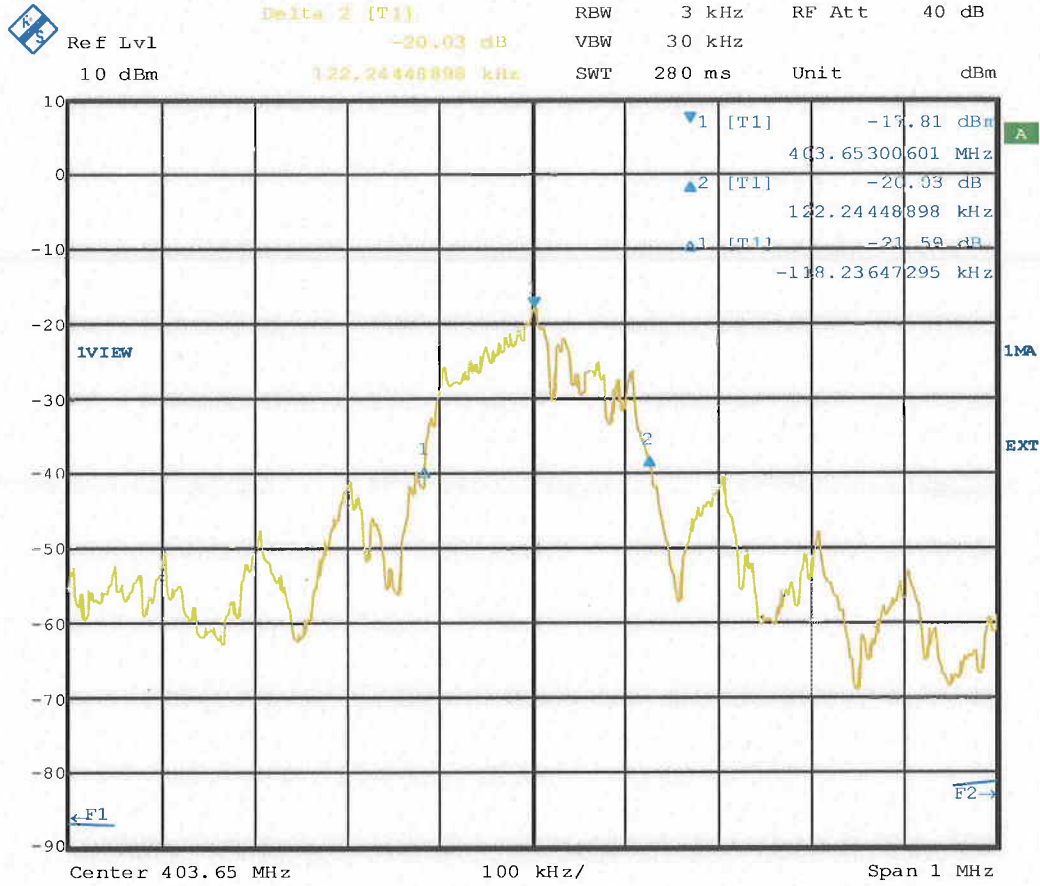
Test conditions		Emission bandwidth
T _{nom} 37°C	V _{nom} 2.8 V	214.4 kHz



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%.

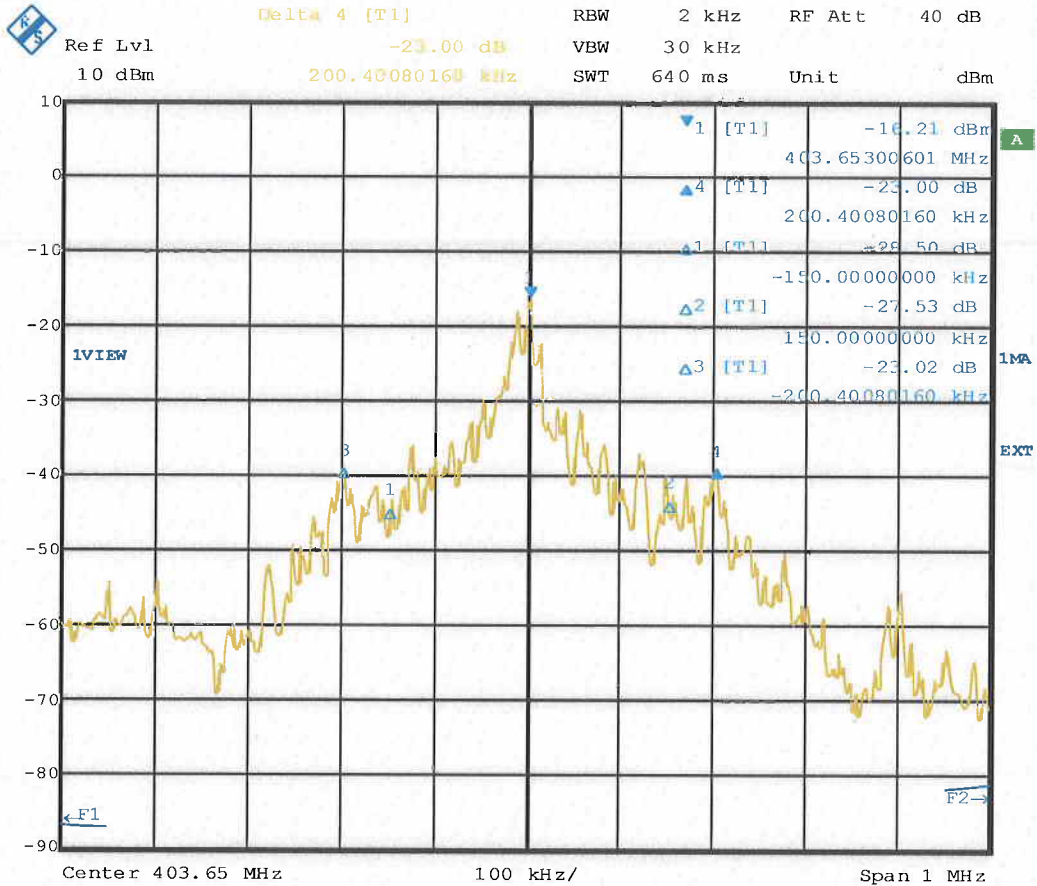
8.2 Test equipment

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

8.3 Test protocol

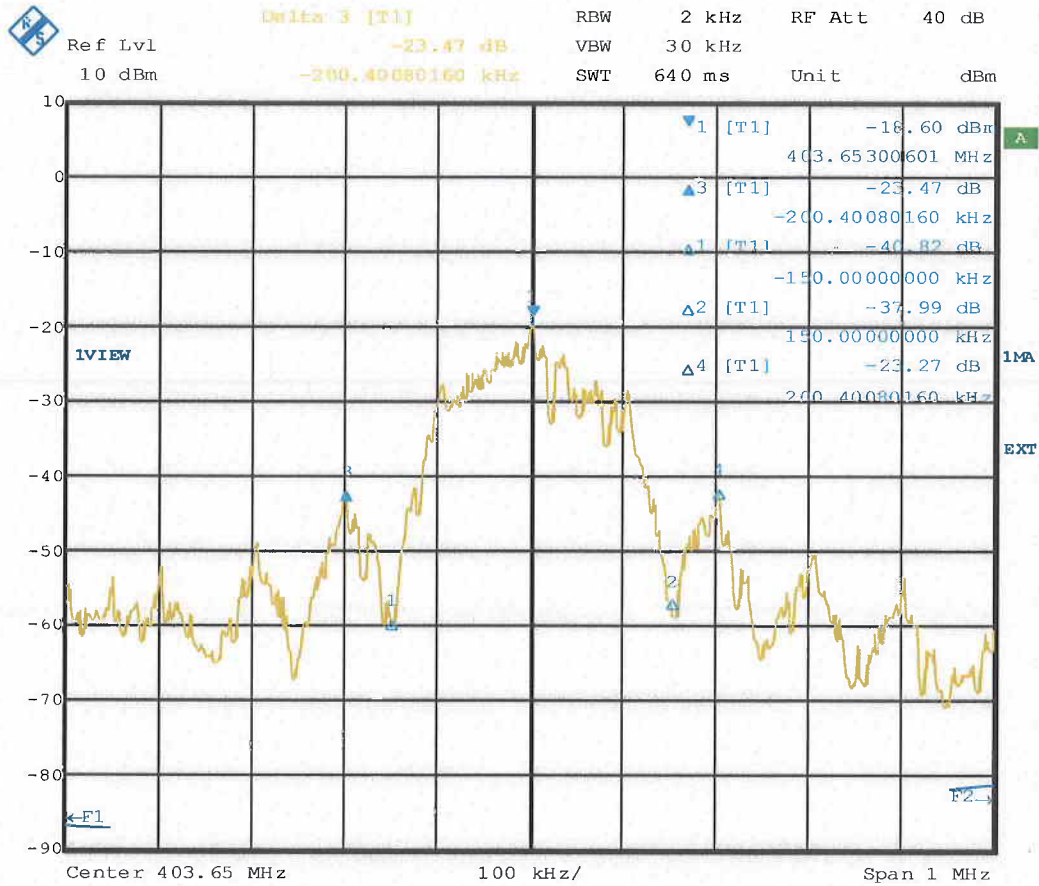
Date of test: 2011-10-04

Middle Channel. 2FSK



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%.

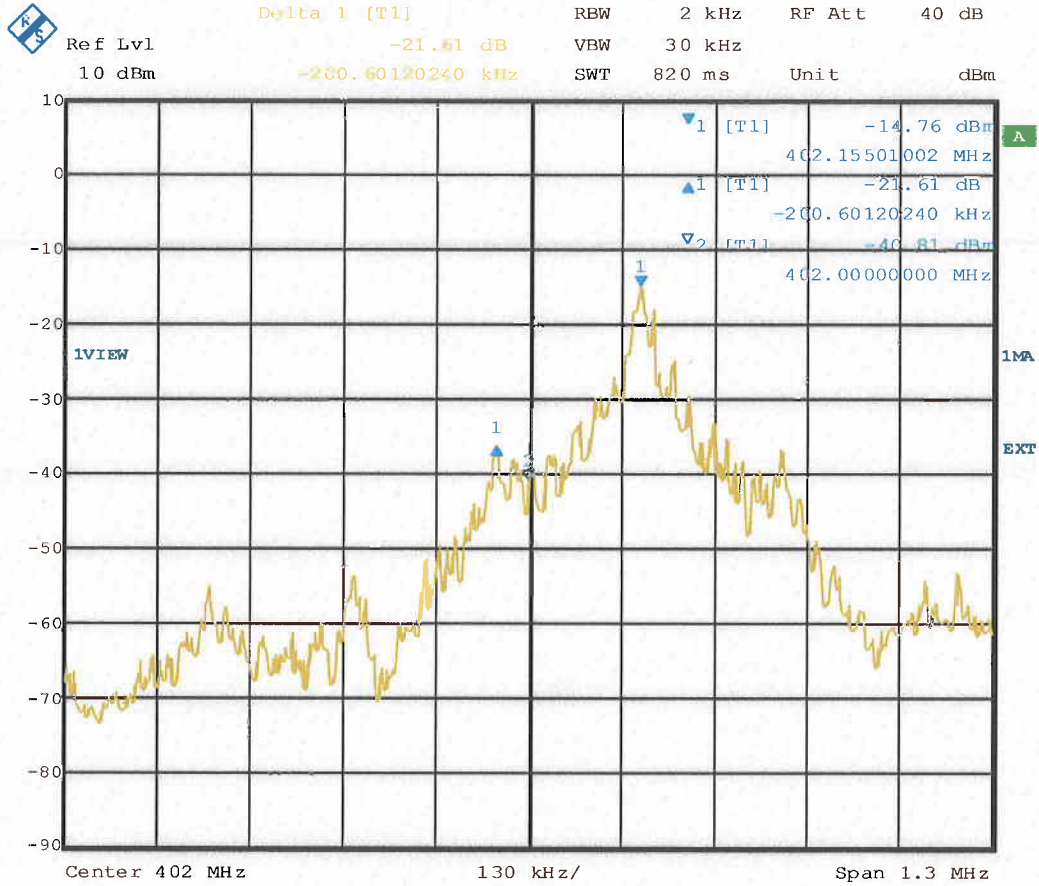
9.2 Test equipment

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

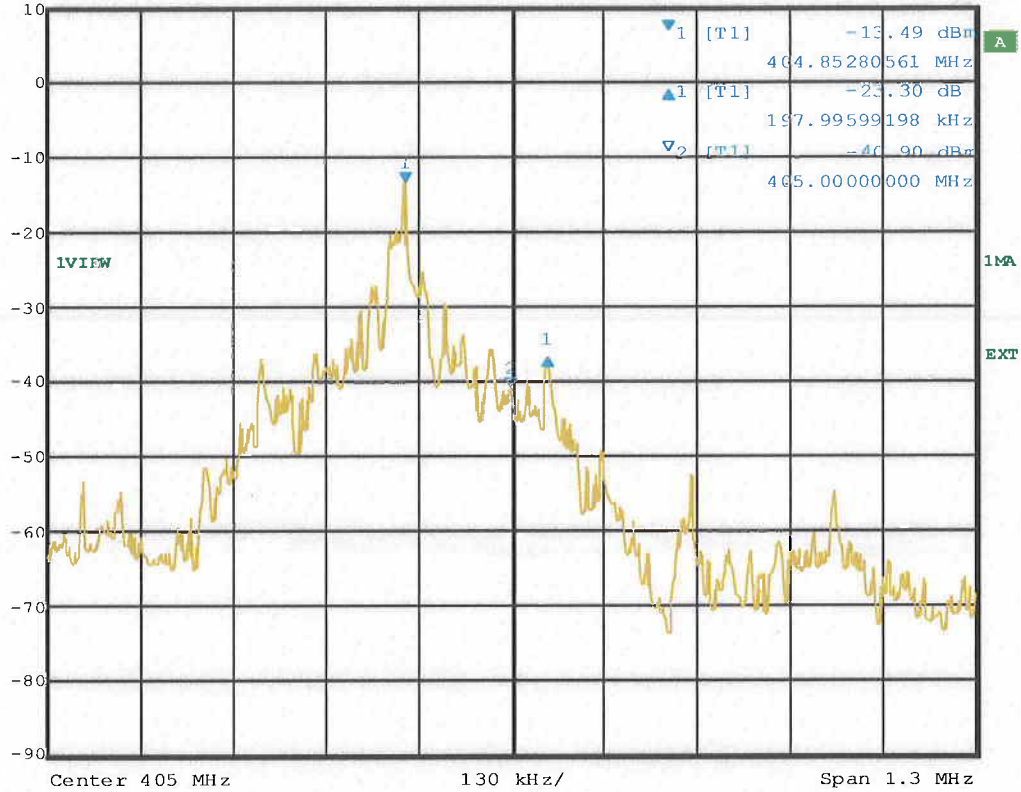


Date: 4.OCT.2011 14:18:32

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

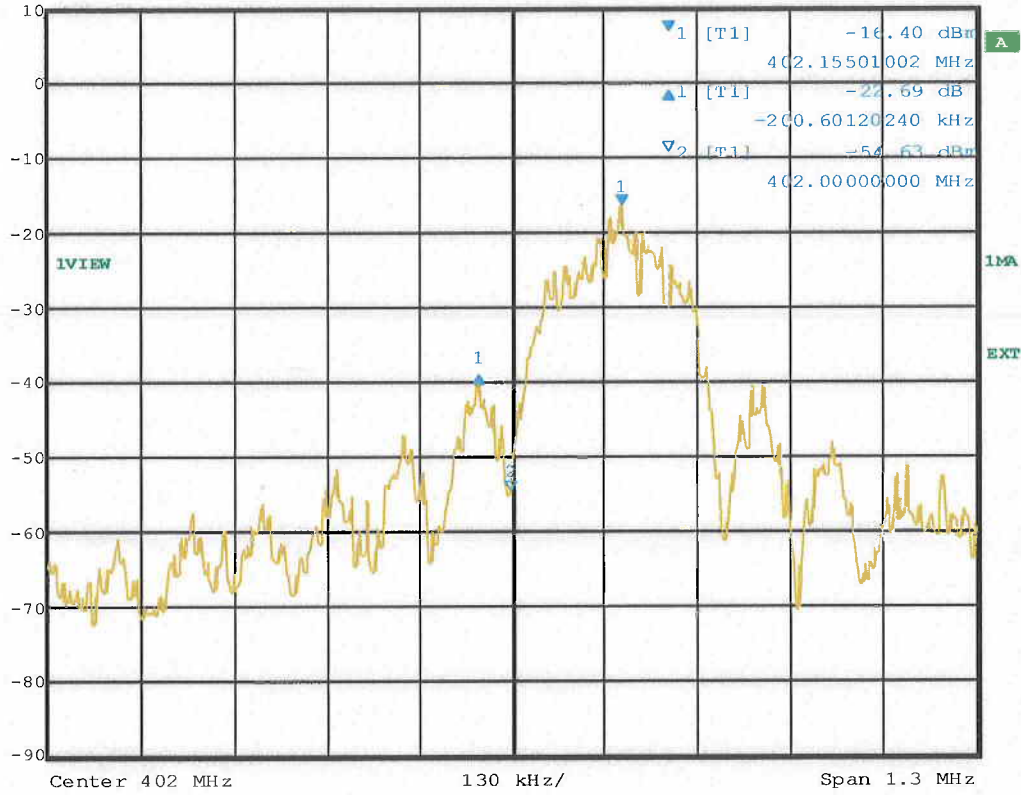


Date: 4.OCT.2011 14:21:25

Low Channel. 2FSK fallback

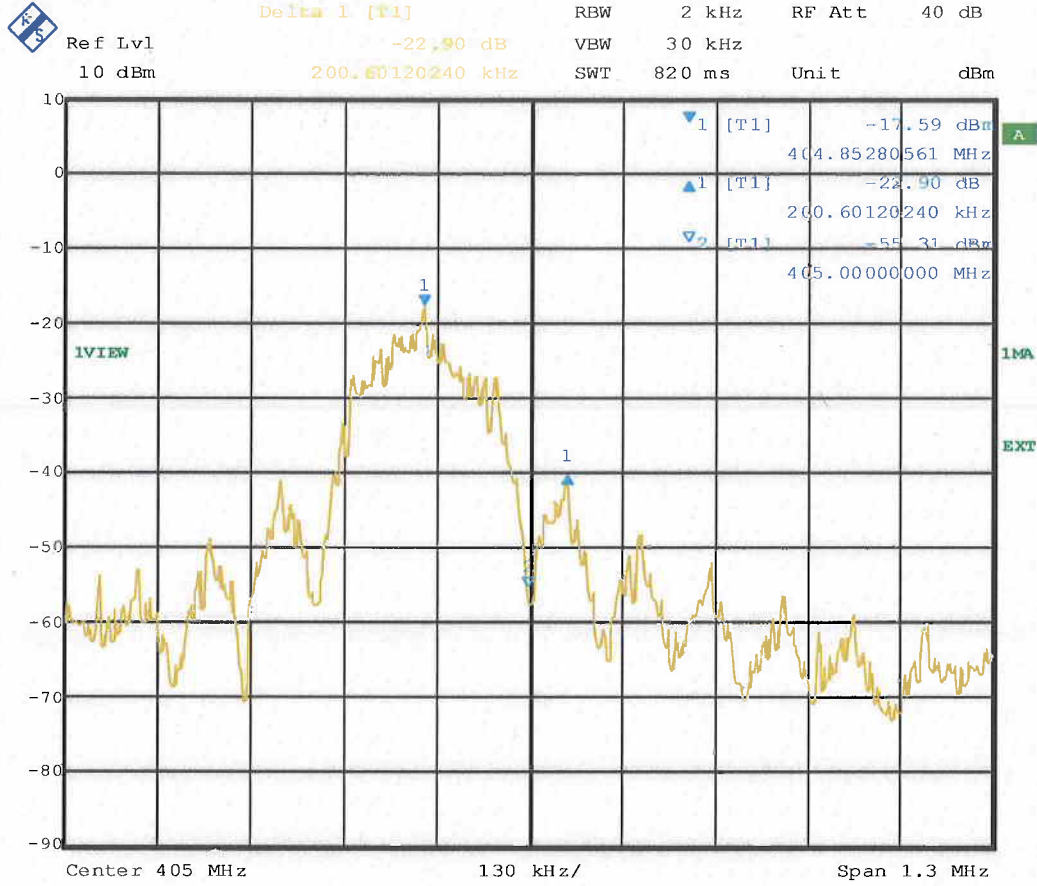


Delta 1 [T1] RBW 2 kHz RF Att 40 dB
 Ref Lvl -22.69 dB VBW 30 kHz
 10 dBm -200.60120240 kHz SWT 820 ms Unit dBm



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

High Channel. 2FSK fallback



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