

**TEST REPORT CONCERNING THE COMPLIANCE OF A
Low Power Communication Device Transmitter,
APPLICANT Given Imaging,
BRAND PillCam™ MODEL Colon 2
WITH 47 CFR PART 15 (10-1-15 Edition) and
THE REQUIREMENTS OF INDUSTRY CANADA:
RSS-GEN (ISSUE 4, NOVEMBER 2014) AND
RSS-210 (ISSUE 9, AUGUST 2016).**

17011002.fcc02
May 02, 2017

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MEASUREMENT/TECHNICAL REPORT

Given Imaging
Brand: PillCam™ Model: Colon 2

FCC ID: O8PCAPDH-2
IC: 4752A-CAPDH2

This report concerns: Original grant/certification ~~Class 2 change~~ Verification

Equipment type: Part 15 Low Power Communication Device Transmitter

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The data taken for this test and report herein was done in accordance with 47 CFR Part 15 (10-1-15 Edition), RSS-GEN, RSS-210 and the measurement procedures of ANSI C63.10-2013. TÜV Rheinland Nederland at Leek, The Netherlands, certifies that the data is accurate and contains a true representation of the emission profile of the Equipment Under Test (EUT) on the date of the test as noted in the test report. I have reviewed the test report and find it to be an accurate description of the test(s) performed and the EUT so tested.

Date: May 02, 2017

Signature:



E. van der Wal
Senior Engineer TÜV Rheinland Nederland B.V.

Description of test item

Test item : Low Power Communication Device Transmitter
Manufacturer : Given Imaging
Brand : PillCam™
Model : Colon 2
Serial number, ID : 4YN-DSG-L (all tests except Occ BW) and 4NT-DAG-Z (Occ BW)
Revision : --
FCC ID : O8PCAPDH-2
IC : 4752A-CAPDH2
Receipt date : January 10, 2017

Applicant information

Applicant's representative : Janet Gavidia
Company : Given Imaging
Address : 15 Hampshire Street
Postal code : 02048
City : Mansfield, MA
Country : United States of America
Telephone number : 408.992.1632
E-mail : janet.gavidia@covidien.com

Test(s) performed

Location : Leek
Test(s) started : January 10, 2017
Test(s) completed : January 11, 2017
Purpose of test(s) : Equipment Authorization (original certification)
Test specification(s) : 47 CFR Part 15 (10-1-15 Edition), Subpart C section 15.209 (a);(c) and RSS-GEN (ISSUE 4, NOVEMBER 2014) AND RSS-210 (ISSUE 9, AUGUST 2016).

Test engineer(s) : R. van der Meer



Report written by : R. van der Meer



Report date : May 02, 2017

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The test results relate only to the item(s) tested.

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1 General information.

1.1 Product description.

1.1.1 Introduction.

The Given Imaging product Brand PillCam™ Model Colon 2, hereafter referred to as EUT, is a low power image transmitter enclosed in a capsule and is intended for gastrointestinal imaging. The transmitter operates at 434.1 MHz and is internally powered (3.1VDC) by two 1.55V silver oxide batteries. The model Colon 2 is part of a family range of products. The other identical models that are part of this family are models UGI, SBC and Crohns capsules.

The content of this report and measurement results have not been changed other than the way of presenting the data.

1.2 Related submittal(s) and/or Grant(s).

1.2.1 General.

This test report supports the original certification in equipment authorization files under
FCC ID: O8PCAPDH-2 and IC: 4752A-CAPDH2 .

1.3 Test results summary

The EUT was tested in accordance with the specifications given in the table below and found to comply with standard requirements.

Test Standard		Description	Page	Pass / Fail
47 CFR Part 15 (10-1-15 Edition)	RSS-Gen Issue 4, November 2016 RSS-210 Issue 9, August 2016			
15.209(a),(c)	RSS-Gen(8.9) and RSS-210(4.3-4.4)	Radiated emissions	10 - 15	Pass
15.215(c)	RSS-Gen(6.6)	Occupied bandwidth and Bandwidth of the emission	16 - 17	Pass

Table 1: testspecifications

Testmethods: ANSI C63.10-2013 and RSS-Gen Issue 4, November 2014

2 Tested system details.

2.1 Test system

Details and an overview of the system and all of its components, as it has been tested, may be found below.

EUT	:	Low Power Communication Device Transmitter
Manufacturer	:	Given Imaging
Brand	:	PillCam™
Model	:	Colon 2
Serial number, ID	:	4YN-DSG-L and (all tests except Occ BW) and 4NT-DAG-Z (Occ BW only)
Operating frequency	:	434.1 MHz
Modulation	:	MSK
Voltage input rating	:	1.50 – 3.10 Vdc
Voltage output rating	:	n.a.
Current input rating	:	--
Antenna	:	Internal
Remarks	:	n.a.
Interface cable(s)	:	n.a.
Operating configuration	:	continuously transmitting
Mode	:	Low Frame Rate and High Frame Rate



Photograph of the EUT

2.2 Description of input and output ports.

The EUT is tested stand-alone it has no input ports and no output ports.



Figure 1. Basic set-up for testing, EUT tested stand alone



Photograph of the test setup

2.3 Test methodology.

The test methodology used is based on the requirements of 47 CFR Part 15 (10-1-15 Edition), sections 15.209(a),(c), RSS-Gen Issue 4 and RSS-210 Issue 9. The test methods, which have been used, are based on ANSI C63.10-2013. A human torso simulator for implantables was used which was 76cm in height and the diameter was 30cm and sidewall thickness of 0.635mm. The EUT was placed on a low-loss mounting grid at a height of 150cm. The human torso simulator was fully filled with tissue equivalent liquid.

Radiated emission tests above 30 MHz were performed at a measurement distance of 3 meters.

The receiver is switching automatically to the right bandwidth in accordance with CISPR 16. This is implemented in the receiver. The antenna factors are programmed in the test receiver. The receiver automatically calculates the appropriate correction factor for the utilized antenna and cable loss. The total correction is automatically added to the measured value.

2.4 Test facility.

The Federal Communications Commission and Industry Canada has reviewed the technical characteristics of the test facilities at TÜV Rheinland Nederland B.V., located in Leek, 9351VT Eiberkamp 10, The Netherlands, and has found these test facilities to be in compliance with the requirements of 47 CFR Part 15, section 2.948.

The description of the test facilities has been filed at the Office of the Federal Communications Commission under registration number 90828. The facility has been added to the list of laboratories performing these test services for the public on a fee basis.

The description of the test facilities has been filed to Industry Canada under registration number 2932G-2. The facility has been added to the list of laboratories performing these test services for the public on a fee basis.

2.5 Test conditions.

Normal test conditions:

Temperature (*)	: +15°C to +35°C
Relative humidity(*)	: 20 % to 75 %
Supply voltage	: 3.1Vdc Battery operated only, new batteries used during testing
Air pressure	: 950 – 1050 hPa

*When it was impracticable to carry out the tests under these conditions, a note to this effect stating the ambient temperature and relative humidity during the tests are stated separately.

2.6 Measurement Uncertainty

Compliance of the product is based on the measured value. However, the measurement uncertainty is included for informational purposes.

The expanded uncertainty ($k = 2$) for radiated emissions below 1000 MHz has been determined to be: 5.22 dB at 3m.
The expanded uncertainty ($k = 2$) for radiated emissions above 1000 MHz has been determined to be: 5.22 dB at 3m

3 System test configuration.

3.1 Justification.

This report covers the EUT as a stand-alone transmitter. Test regarding the digital device part of the EUT is covered in section 5 of this report. On request by the applicant the tests were performed with the EUT inside a human body simulating liquid. The simulating liquid container and the liquid were provided by the applicant. human torso simulating liquid. The simulating liquid container and the liquid were provided by the applicant. See section 2.3 and 4.1 for more details.

Fluid properties of the tissue simulating fluid as provided by the applicant: Epsilon: 60.6 Sigma: 1.2.

The EUT was configured for continues transmission. The frequency range was investigated from 30 MHz to 5000 MHz (covering up to the 10th harmonic of the EUT's fundamental frequency). The EUT's design and use is such that the wanted and unwanted emissions fall within the general field strength limits specified in 15.209 and RSS-Gen. The tested model Colon 2 is part of the PillCam™ family range of products. A by the applicant delivered "Similarity Declaration" and a "PillCam Family Brochure" is part of the technical documentation package.

The justification and manipulation of cables and equipment in order to simulate a worst-case behavior of the test setup has been carried out as prescribed in ANSI C63.10-2013.

3.2 EUT mode of operation.

The EUT has been tested while continuously transmitting. The intentional radiator tests have been performed with a complete functioning EUT.

3.3 Special accessories.

No special accessories are used and/or needed to achieve compliance.

3.4 Equipment modifications.

No modifications have been made to the equipment in order to achieve compliance.

3.5 Product Labeling

The product labeling information is available in the technical documentation package.

3.6 Block diagram of the EUT.

The block diagram is available in the technical documentation package.

3.7 Schematics of the EUT.

The schematics are available in the technical documentation package.

4 Radiated emission data.

4.1 Radiated field strength measurements (30 MHz – 5 GHz, E-field)

RESULT: PASS

Date of testing: 2017-01-10
Frequency range: 30MHz - 5GHz

Requirements:

FCC 15.205 and 15.209.

Radiated emissions must comply with the radiated emission limits specified in FCC 15.209(a), and RSS-Gen Section 8.9 Table 4, see Table 2 below.

Frequency (MHz)	Field strength (μV/meter)	Field strength (dBμV/m)	Measurement distance (meters)
30-88	100	40.0	3
88-216	150	43.5	3
216-960	200	46.0	3
Above 960	500	54.0	3

Table 2: applicable limits

Test procedure:

ANSI C63.4-2014.

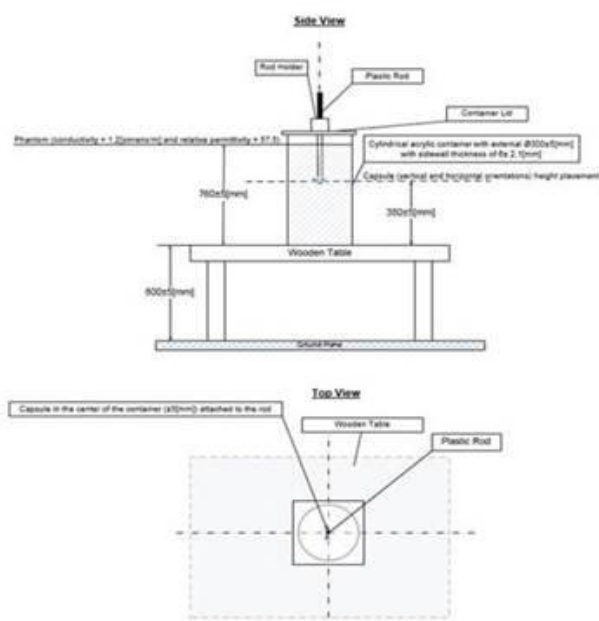


Figure 2: test setup

The EUT was placed on a nonconductive turntable 0.8m above the ground plane and the EUT placed 70 cm above that (so the EUT is at a height of 150cm) in a tank containing Human tissue simulating liquid (see Figure 2). Before final measurements of radiated emissions were performed, the EUT was scanned to determine its emission spectrum profile. The physical arrangement of the test system and the associated cabling were varied in order to ensure that maximum emission amplitudes were attained. The EUT was placed in vertical position.

The spectrum was examined from 30MHz to the 10th harmonic of the highest fundamental transmitter frequency (5GHz). Final E-field radiated emission measurements were made at 3m distance.

At each frequency where a spurious emission was found, the EUT was rotated 360° and the antenna was raised and lowered from 1 to 4m in order to determine the emission's maximum level. Measurements were taken using both horizontal and vertical antenna polarizations. The six highest emission amplitudes relative to the appropriate limit were recorded in this report. Field strength values of radiated emissions at frequencies not listed in the tables are more than 20 dB below the applicable limit

Measurement uncertainty is 5.22 dB.

4.1.1 Radiated field strength measurements (30 MHz – 1000 MHz, E-field)

The results of the radiated emission tests, carried out in accordance with 47 CFR Part 15 section 15.209 and RSS-Gen are depicted in Table 3.

Frequency [MHz]	EUT Orientation	Antenna Orientation	Level [dBμV/m]	Limit [dBμV/m]	Margin [dB]	Verdict [Pass/Fail]
31.94 noise	Horizontal	Horizontal	23.8	40.0	16.2	Pass
350.10 noise	Horizontal	Horizontal	21.8	46.0	24.2	Pass
434.18 Fundamental	Vertical	Horizontal	28.8	46.0	17.2	Pass
458.74 noise	Vertical	Horizontal	25.6	46.0	20.4	Pass
868.4 *H ⁵ -noise	Horizontal	Horizontal	34.1	46.0	11.9	Pass
967.02 noise	Horizontal	Vertical	35.1	46.0	10.9	Pass

Table 3 Radiated emissions of the EUT in the frequency range 30 – 1000 MHz.

Notes:

1. Tested on ID: 4YN-DSG-L
2. From pre-test the worst case situation proved to be the Low Frame Rate mode and this mode is used for final tests.
3. The six worst case values relative to the applicable limit were noted.
4. A Quasi-peak detector was used with a resolution bandwidth of 120 kHz.
5. The harmonic of the fundamental is in the noise.
6. Liquid temperature was 18.4 °C
7. A selection of plots are provided on the next page.

Used test equipment and ancillaries:

A00257	A00258	A00314	A00450	A00447	A00235	A00466	A00472	A00445

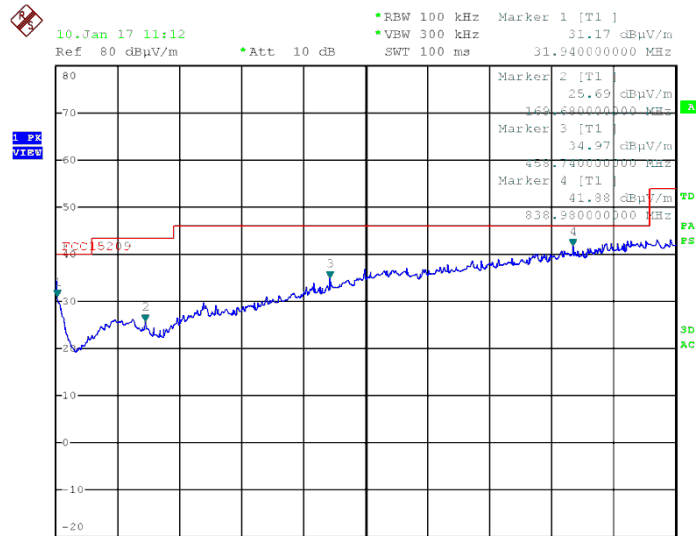
Test engineer

Signature :



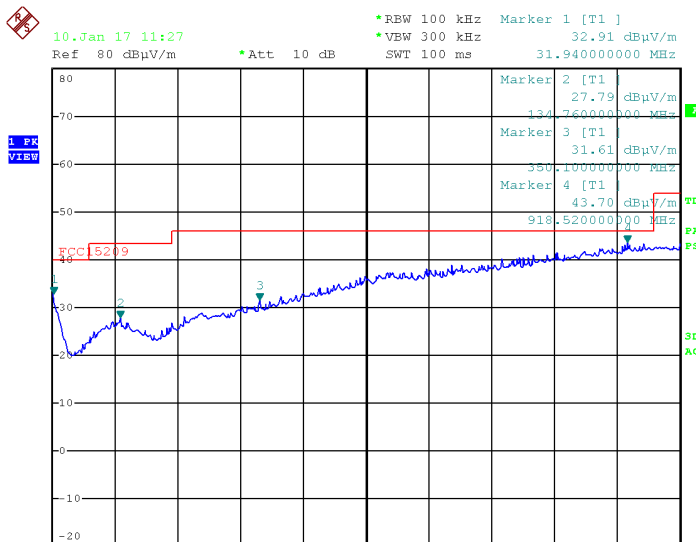
Name : Richard van der Meer

Date : January 10, 2017



ORI
Date: 10.JAN.2017 11:12:42

Plot 1a Radiated emissions (Peak values) of the EUT in the frequency range 30 – 1000 MHz,
EUT Vertical, Antenna Horizontal



ORI
Date: 10.JAN.2017 11:27:05

Plot 1b Radiated emissions (Peak values) of the EUT in the frequency range 30 – 1000 MHz,
EUT Horizontal, Antenna Horizontal

4.1.2 Radiated field strength measurements (1 GHz – 5 GHz, E-field)

Frequency [MHz]	EUT Orientation	Antenna Orientation	Detector	Bandwidth (MHz)	Level [dBm]	Limit [dBm]	Result
1040.24 ^{*R}	Vertical	Vertical	Pk	1	-70.1	--41.2 (Av) -21.2 (Pk)	Pass
1080.74 ^{*R}	Vertical	Vertical	Pk	1	-69.0	-41.2 (Av) -21.2 (Pk)	Pass
1320.21 ^{*R}	Vertical	Vertical	Pk	1	-67.1	-41.2 (Av) -21.2 (Pk)	Pass
1379.7 ^{*R}	Vertical	Horizontal	Pk	1	-67.2	-41.2 (Av) -21.2 (Pk)	Pass
1441.19 ^{*R}	Vertical	Horizontal	Pk	1	-57.6	-41.2 (Av) -21.2 (Pk)	Pass
1559.68	Vertical	Horizontal	Pk	1	-68.5	-41.2 (Av) -21.2 (Pk)	Pass

Table 4 Radiated emissions of the EUT in the frequency range 1 – 5 GHz

Notes:

- Tested on ID: 4YN-DSG-L
- *R refers to a frequency in a restricted band,
- Field strength values of radiated emissions not listed in the tables above are more than 20 dB below the applicable limit.
- Measurement uncertainty is +/- 5.22 dB.
- The levels are expressed in dBm which are derived from $\text{dBm} = E(\text{dB}\mu\text{V/m}) - 95.2\text{dB}$. Where Peak (Pk) values where at least 6 dB under the Average (Av) limits, Av value was not tested. Where Average values were tested, Average values were measured using a 10Hz Video Bandwidth
- worst case values noted, these are of the EUT in Low Frame Rate mode.
- Liquid temperature was 18.4 °C
- a selection of plots is provided on the next pages

Used test equipment and ancillaries:

A00450	A00257	A00235	A00337	A00258	A00444	A00009	A00247	A00255
A00472								

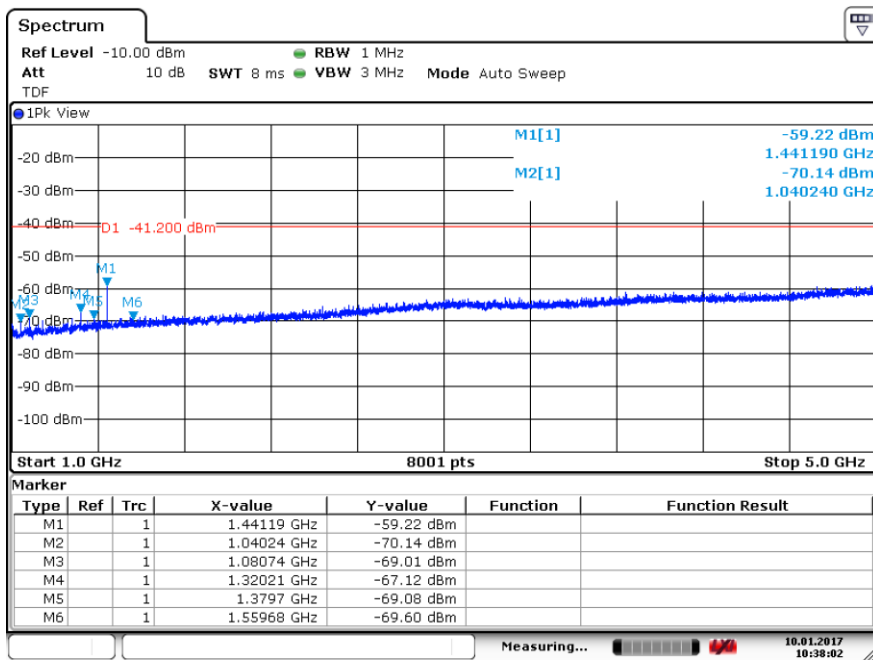
Test engineer

Signature :



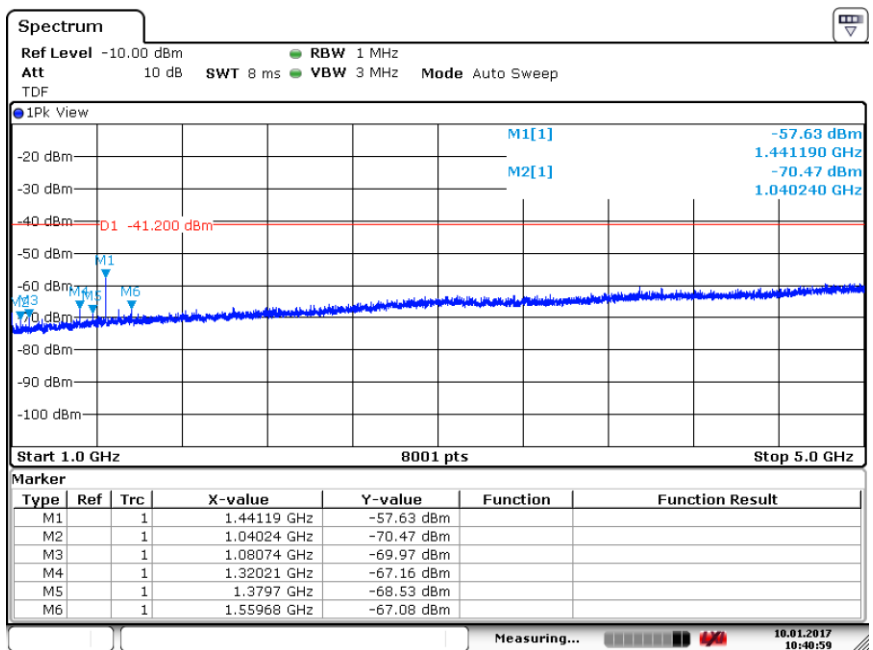
Name : Richard van der Meer

Date : January 10, 2017



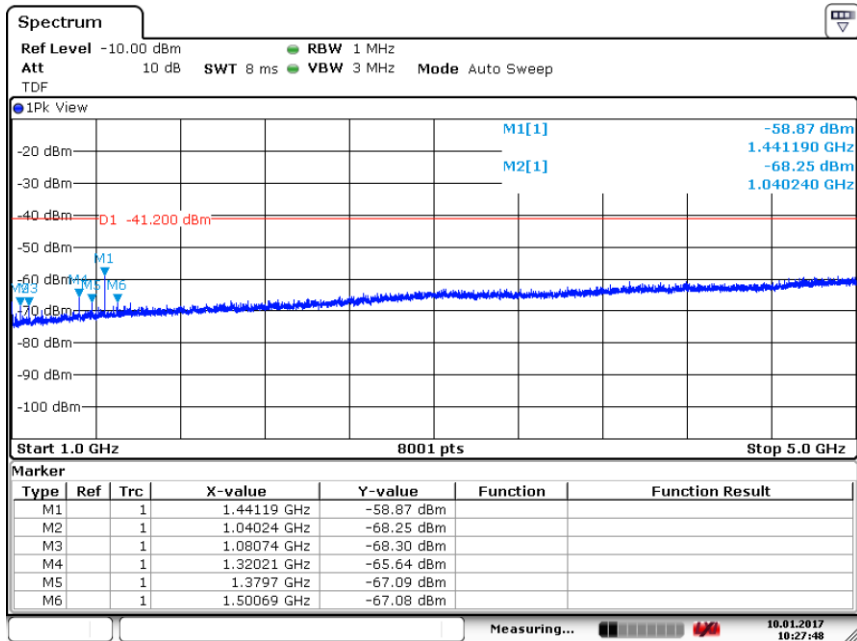
Date: 10.JAN.2017 10:38:02

Plot Radiated unwanted emissions in the range 1 – 5 GHz
(Peak values, EUT Vertical, Antenna Vertical position shown).



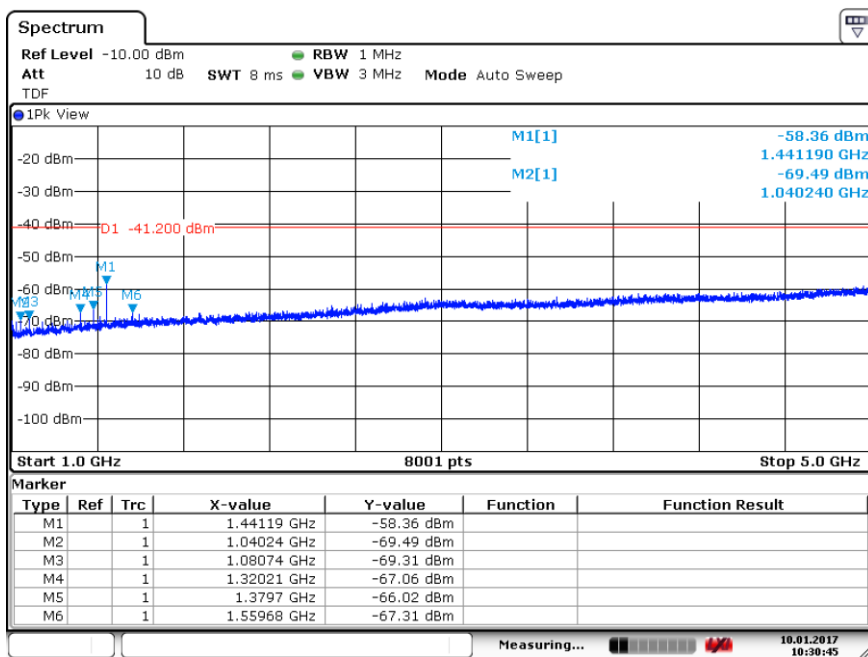
Date: 10.JAN.2017 10:40:58

Plot Radiated unwanted emissions in the range 1 – 5 GHz
(Peak values, EUT vertical, Antenna Horizontal position shown).



Date: 10.JAN.2017 10:27:47

Plot Radiated unwanted emissions in the range 1 – 5 GHz
(Peak values, EUT Horizontal, Antenna Horizontal position shown).



Date: 10.JAN.2017 10:30:44

Plot Radiated unwanted emissions in the range 1 – 5 GHz
(Peak values, EUT Horizontal, Antenna Vertical position shown).

5 Radiated field strength measurements (30 MHz – 1 GHz, E-field), Part 15B / ICES-003 verification

Frequency [MHz]	EUT Orientation	Antenna Orientation	Level [dBμV/m]	Limit [dBμV/m]	Margin [dB]	Verdict [Pass/Fail]
31.94 noise	Horizontal	Horizontal	23.8	40.0	16.2	Pass
350.10 noise	Horizontal	Horizontal	21.8	46.0	24.2	Pass
434.18 Fundamental	Vertical	Horizontal	28.8	46.0	17.2	Pass
458.74 noise	Vertical	Horizontal	25.6	46.0	20.4	Pass
868.4 *H*5-noise	Horizontal	Horizontal	34.1	46.0	11.9	Pass
967.02 noise	Horizontal	Vertical	35.1	46.0	10.9	Pass

Table 5: Radiated emissions of the EUT.

The results of the radiated emission tests, carried out in accordance with 47 CFR Part 15 section 15.109(a) and ICE-003 section 6.2 are depicted in Table 5. The reported results are the same as for the 15.209 as those were already within 15.109 Class B limits.

Notes:

1. Tested on ID: 4YN-DSG-L
2. Measurement uncertainty is ± 5.22 dB
3. The reported field strength values are the six worst case values (relative to the applicable limit) at the indicated frequency.
4. The receiving antenna was varied in horizontal and vertical orientations and also in height (between 1m and 4m).
5. The harmonic of the fundamental is in the noise
6. A Quasi-peak detector was used with a resolution bandwidth of 120 kHz.

Used test equipment and ancillaries:

A00257	A00258	A00314	A00450	A00447	A00235	A00466	A00472	

Test engineer

Signature : 

Name : Richard van der Meer
Date : January 10, 2017

6 Plot of the carrier bandwidth

6.1 Bandwidth of the emission

RESULT: PASS

Date of testing: 2017-01-12

Requirements:

For 99% Bandwidth: RSS-Gen Section 6.6: No requirement is given

Testprocedure: ANSI C63.10-2013

For 99% Bandwidth:
RSS-Gen.

The transmitter shall be operated at its maximum carrier power measured under normal test conditions. The span of the analyzer shall be set to capture all products of the modulation process, including the emission skirts. The resolution bandwidth shall be set as close to 1% of the selected span as is possible without being below 1%. The video bandwidth shall be set to 3 times the resolution bandwidth. Video averaging is not permitted. Where practical, a sampling detector shall be used given that a peak or peak hold may produce a wider bandwidth than actual.

Testresults:

Tested on ID: 4NT-DAG-Z

Power supply voltage: 2.90V.

The Spectrum analyzers automated function for 99% BW was used.

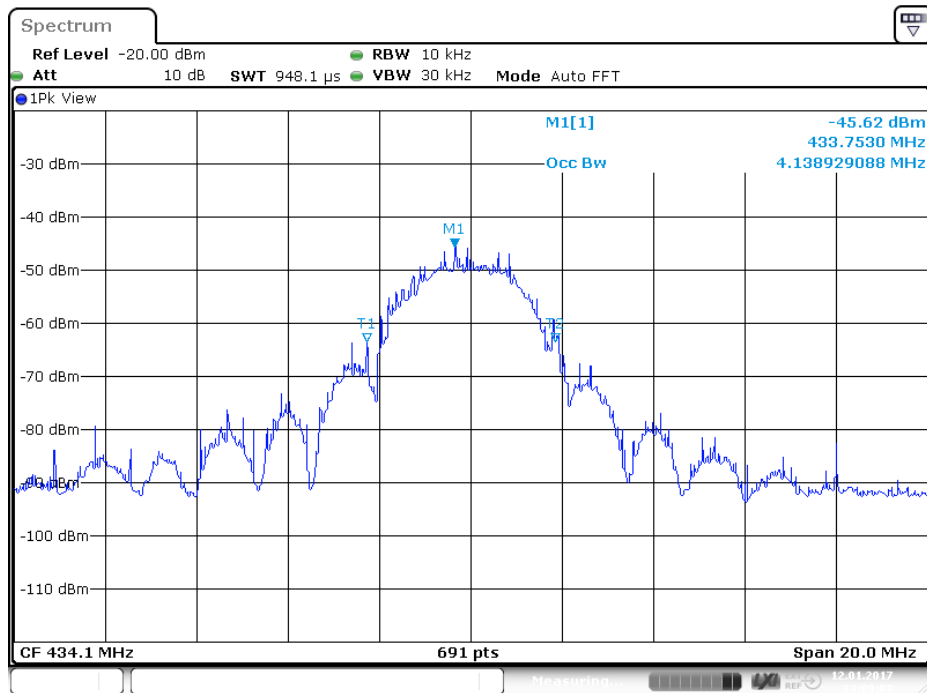
Measurement uncertainty is +/- 26kHz.

See plots on the next page.

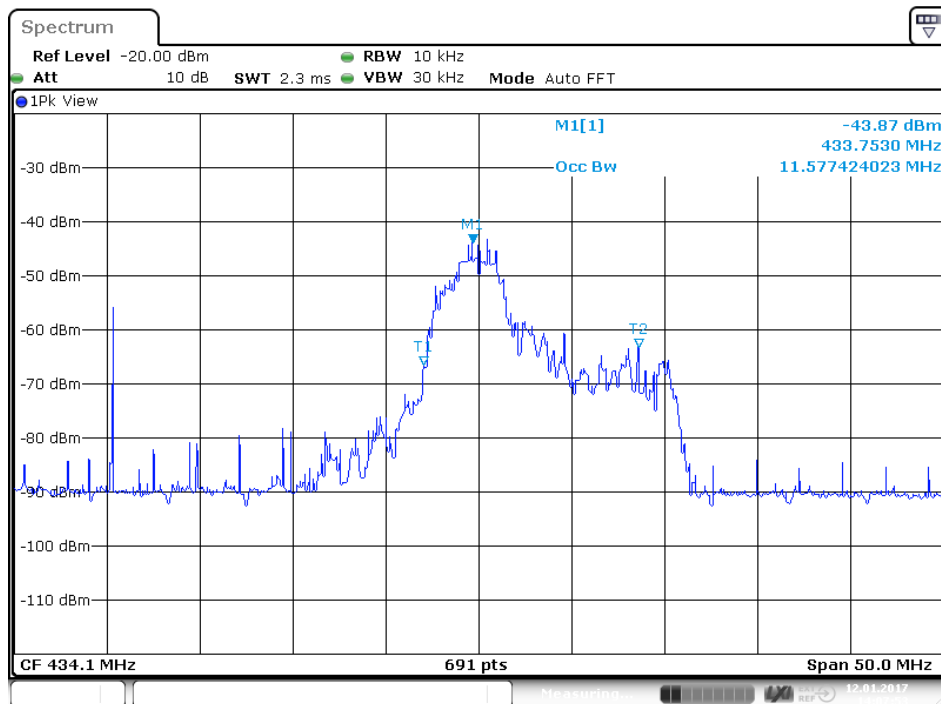
Used test equipment and ancillaries:

A00266	A01744	A00444	A01634				

The complete list of used equipment can be found in section 7 of this testreport.



Plot A1 is of the 99% bandwidth in the Low Frame Rate mode.



Plot A2 is of the 99% bandwidth in the High Frame Rate mode

7 List of utilized test equipment.

Kind of Equipment	Manufacturer	Model Name	Inventory number	Calibration date (mm/yyyy)	Calibration due date (mm/yyyy)
For Radiated Emissions					
Measurement Receiver	Rohde & Schwarz	ESCI	A00314	03/2016	03/2017
RF Cable S-AR	Gigalink	APG0500	A00447	01-26/2016	01-26/2017
Controller	Maturo	SCU/088/ 8090811	A00450	N/A	N/A
Controller	EMCS	DOC202	A00257	N/A	N/A
Test facility	Comtest	FCC listed: 90828 IC: 2932G-2	A00235	04/2014	04/2017
Spectrum Analyzer	Rohde & Schwarz	FSV	A00337	06/2016	06/2017
Antenna mast	EMCS	AP-4702C	A00258	N/A	N/A
Amplifier for A00209	EMCS	--	A00378	N/A	N/A
Temperature-Humiditymeter	Extech	SD500	A00444 / A00445	04/2016	04/2017
Guidehorn 1-18 GHz	EMCO	3115	A00009	04/2016	04/2017
Biconilog Testantenna	Teseq	CBL 6111D	A00466	06/2016	06/2017
Preamplifier 0.5 - 18 GHz	Miteq	AMF-5D-005180- 28-13p	A00247	N/A	N/A
Filterbox	EMCS	RFS06S	A00255	02/2016	02/2017
Liquid temperature meter	YCT	YC-727	A00472	02/2016	02/2017
Spectrum Analyzer	Rohde & Schwarz	FSV	A01744	07/2015	07/2018
Power supply	Wolfsen	EA-3005	A00266	12/2016	12/2017
Digital Voltmeter	Keysight	34461A	A01634	02/2016	02/2017

Conformance of the used measurement and test equipment with the requirements of ISO/IEC 17025:2005 has been confirmed before testing. NA= Not Applicable

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