RADIO REPORT

FCC 47 CFR Part 15C
ISED Canada RSS-210

Operation within the 13.110 – 14.010 MHz band

Report Reference No	G0M-2010-9360-TFC225RI-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	DAkkS - Registration number : D-PL-12092-01-03 (ISED) ISED Testing Laboratory site: 3470A-2 DAkkS - Registration number : D-PL-12092-01-04 (FCC) FCC Filed Test Laboratory, Reg.-No.: 96970
Applicant	W.O.M. WORLD OF MEDICINE GmbH
Address	Salzufer 8 10587 Berlin GERMANY
Test Specification	47 CFR Part 15C RSS-210, Issue 10, 2019-12 RSS-Gen, Issue 5, Amendment 1, 2019-03
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model(s)	FM300
Additional Model(s)	None
Brand Name(s)	PNEUMOCLEAR™
Hardware Version(s)	Hardware traceability is constituted by serial number of device (assembled with processor board Toradex IMX6) SN: 1902CE0537
Software Version(s)	1.1.1
Contains FCC-ID	2AS5K-TSHW42
Contains IC	25004-TSHW42A
Test Result	**PASSED**

Possible test case verdicts:		
Required by standard but not tested	N/T	
Not required by standard	N/R	
Not applicable to EUT	N/A	
Test object does meet the requirement	P(PASS)	
Test object does not meet the requirement	F(FAIL)	
Testing:		
Test Lab Temperature	20 °C - 30 °C	
Test Lab Humidity	25 % - 55 %	
Date of receipt of test item	2020-09-30	
Report:		
Compiled by	Wilfried Treffke	
Tested by (+ signature) (Responsible for Test)	Wilfried Treffke	W. Treffke .....
Approved by (+ signature) (Head of Lab)	Toralf Jahn	T. J .....
Date of Issue	2020-11-18	
Total number of pages	32	
General Remarks:		
The test results presented in this report relate only to the object tested. **The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.** This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.		
Additional Comments:		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2020-11-18	Initial Release	

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
RBW	Resolution bandwidth
RFID	Radio Frequency Identification
RMS	Root mean square
VBW	Video bandwidth
V_{NOM}	Nominal supply voltage

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1 Equipment (Test Item) Under Test

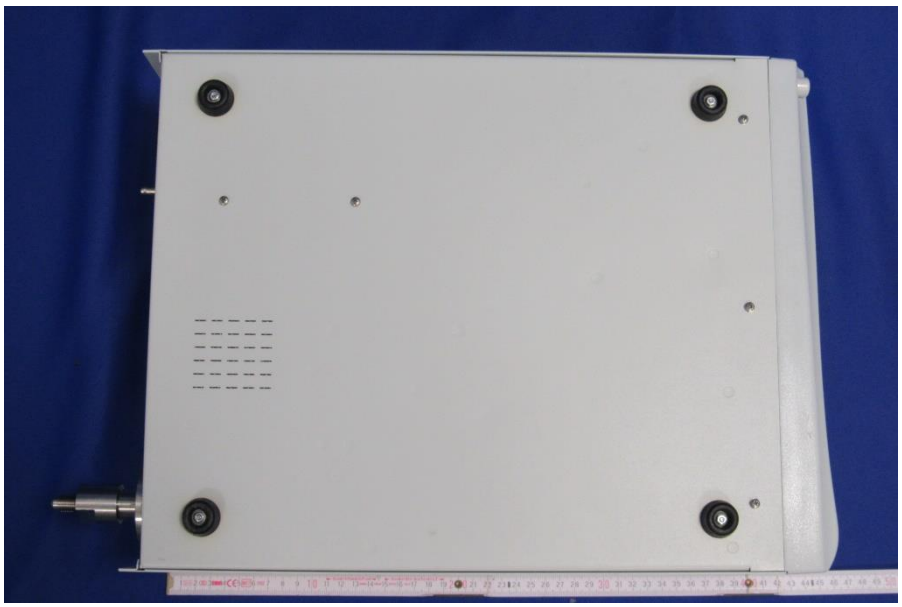
Description	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures	
Model	FM300	
Additional Model(s)	None	
Brand Name(s)	PNEUMOCLEAR™	
Serial Number(s)	1902CE0537	
Hardware Version(s)	Hardware traceability is constituted by serial number of device (assembled with processor board Toradex IMX6) SN: 1902CE0537	
Software Version(s)	1.1.1	
PMN	TS-HW42	
HVIN	1430	
FVIN	-/-	
HMN	FM300	
Contains FCC-ID	2AS5K-TSHW42	
Contains IC	25004-TSHW42A	
Equipment type	End Product	
Radio type	Transceiver	
Assigned frequency bands	13.110 - 14.010 MHz	
Radio technology	RFID	
Modulation	ASK	
Radio Module	Type	RFID Module 13.56MHz
	Model	TS-HW42
	Manufacturer	GiS GmbH
	HW Version	HVIN 1430
	SW Version	unspecified
Antenna	Type	External dedicated
	Model	TS-AH20
	Manufacturer	GiS GmbH
	Gain	not specified
Supply Voltage	V_{NOM}	120 VAC
Operating Temperature	T_{NOM}	25 °C
AC/DC-Adaptor	Model	None
Manufacturer	W.O.M. WORLD OF MEDICINE GmbH Salzufer 8 10587 Berlin GERMANY	

1.1 Photos – Equipment External

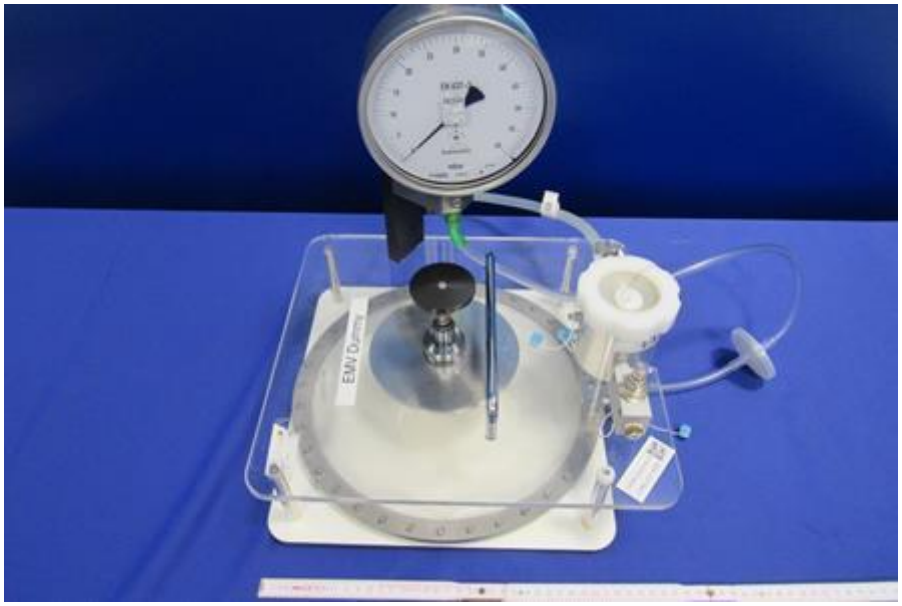
EUT Front Side View

EUT Rear Side View

EUT Side View

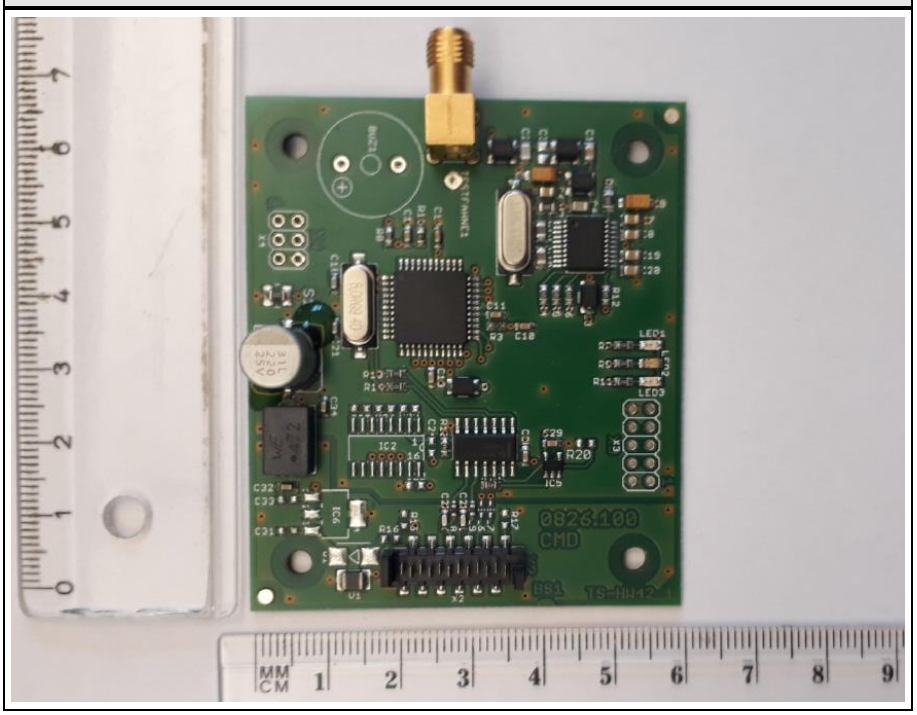
EUT Bottom Side View


AE 1: eHvuamcitduifbieed /heated/smoke

AE 2: Dummy LAP Adult Plus


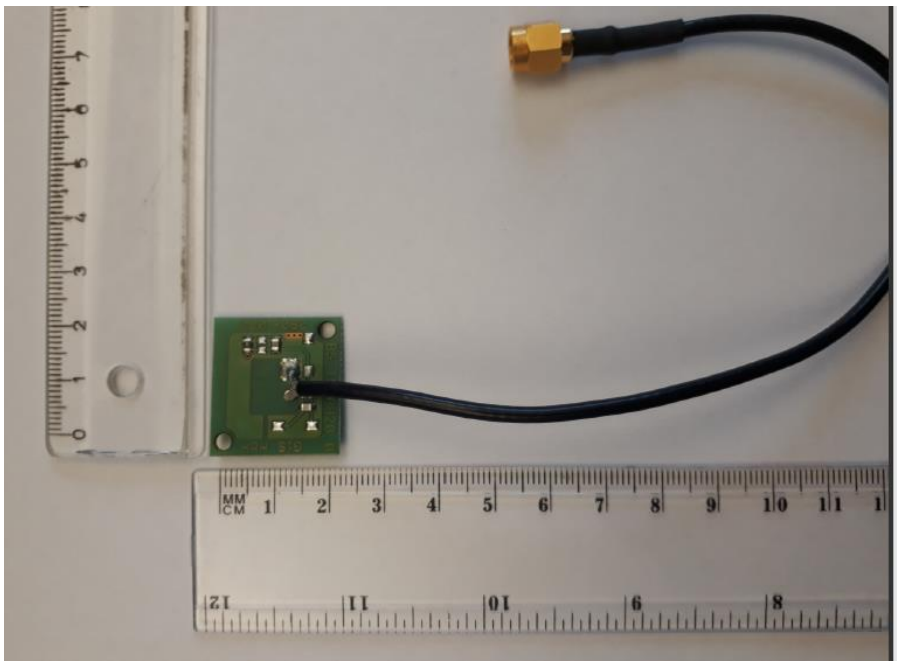
1.2 Photos – Equipment Internal

board RFID top view

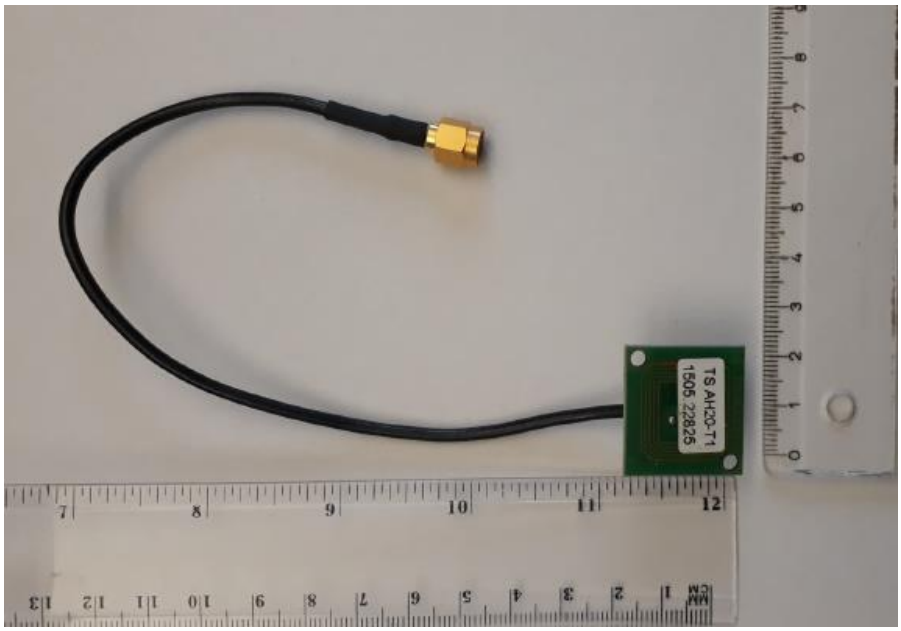


board RFID back view

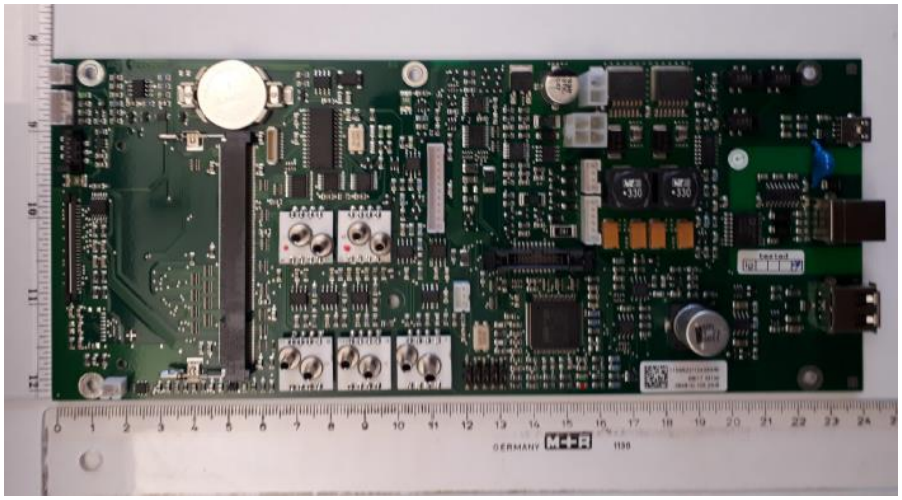
RFID antenna top view



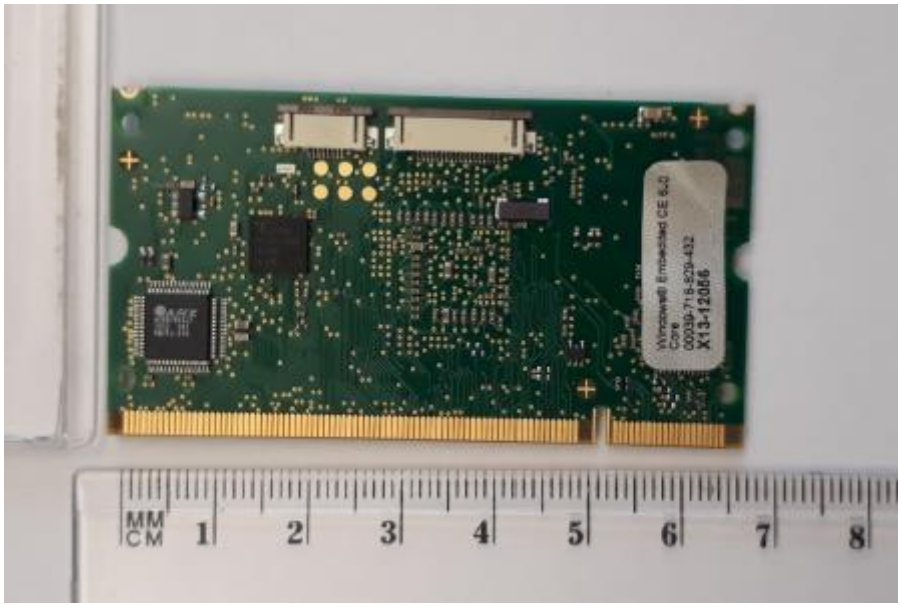
RFID antenna back view



board UNI top view



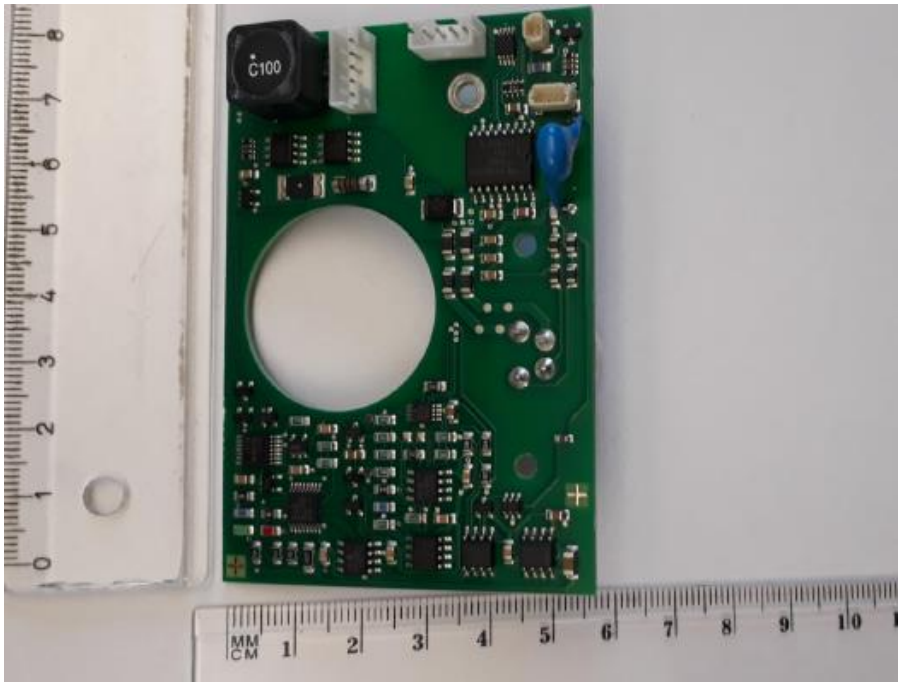
board PXA320 top view



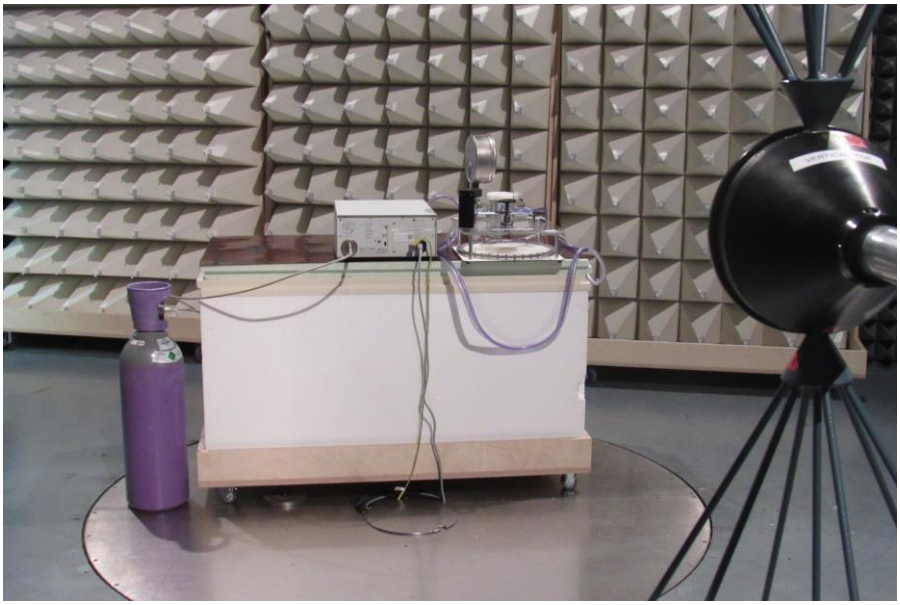
board PXA320 back view

board iMX6 top view

board iMX6 back view

board HPL07


1.3 Photos – Test Setup

Radiated Setup


Conducted Setup

1.4 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE 1	Humidified /heated/smoke evac tube	W.O.M. WORLD OF MEDICINE GmbH	ST298	-
AE 2	Dummy LAP Adult Plus	W.O.M. WORLD OF MEDICINE GmbH	2205477	-
AE 3	High pressure tube	W.O.M. WORLD OF MEDICINE GmbH	ST216	
AE 4	CO2 gas tank	-	-	Food compatible
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
CBL	Connecting Cable			
SFT	Software			
Comment:				

1.5 Test Modes

Mode	Description
Transmit/Receive	Mode = Transmit Modulation = AOK Duty cycle = 100 %
Comment:	

1.6 Test Frequencies

Designator	Mode	Channel	Frequency [MHz]
F1	Tx / Rx	0	13.56

1.7 Sample emission level calculation

The following is a description of terms and a sample calculation, as appears in the radiated emissions data table. The numbers used in the calculation are for example only. There is no direct correlation to the specific data taken for the product described in this document:

Reading:

This is the reading obtained on the spectrum analyzer in dBµV. Any external preamplifiers used are taken into account through internal analyzer settings.

A.F.:

This is the antenna factor for the receiving antenna. It is a conversion factor, which converts electric fields strengths to voltages, which can be measured directly on the spectrum analyzer. It is treated as a loss in dB. Cable losses have been included with the A.F. to simplify the calculations. The antenna factor is used in calculations as follows:

Reading on Analyzer (dBµV) + A.F. (dB/m) = Net field strength (dBµV/m)

Net:

This is the net field strength measurement (as shown above).

Limit:

This is the FCC Class B radiated emission limit (in units of dBµV/m). The FCC limits are given in units of µV/m. The following formula is used to convert the units of µV/m to dBµV/m:

Limit (dBµV/m) = 20*log (µV/m)

Margin:

This is the margin of compliance below the FCC limit. The units are given in dB. A negative margin indicates the emission was below the limit. A positive margin indicates that the emission exceeds the limit.

Example only:

Reading + AF	= Net Reading	:	Net reading - FCC limit	= Margin
+21.5 dBµV + 26 dB/m	= 47.5 dBµV/m	:	47.5 dBµV/m - 57.0 dBµV/m	= -9.5 dB

2 Result Summary

FCC 47 CFR Part 15C, ISED RSS-210				
Product Standard Reference	**Requirement**	**Reference Method**	**Result**	**Remarks**
RSS-Gen 6.7	Occupied Bandwidth	ANSI C63.10-2013	N/T	Module integration
FCC 15.225(a-c) ISED RSS-210 B.6(a)i.	Fundamental in-band field strength emissions	ANSI C63.10-2013	PASS	
FCC 15.225(d) FCC 15.209 ISED RSS-210 B.6(a)iv.	Emission radiated outside the specified frequency band	ANSI C63.10-2013	PASS	
FCC 15.225(e) ISED RSS-210 B.6	Frequency stability	ANSI C63.10-2013	N/T	Module integration
ISED RSS-Gen 4.10 ISED RSS-Gen 7.1	Receiver radiated spurious emissions	ANSI C63.10-2013	N/A	Permanently co-located transmitter
47 CFR 15.207 RSS-Gen 8.8	AC power line conducted emissions	ANSI C63.10-2013	PASS	
Comment:				

Possible Test Case Verdicts	
PASS	Test object does meet the requirements
FAIL	Test object does not meet the requirements
N/T	Required by standard but not tested
N/R	Not required by standard for the test object

3 Test Conditions and Results

3.1 Test Conditions and Results - Fundamental in-band field strength emissions

3.1.1 Information

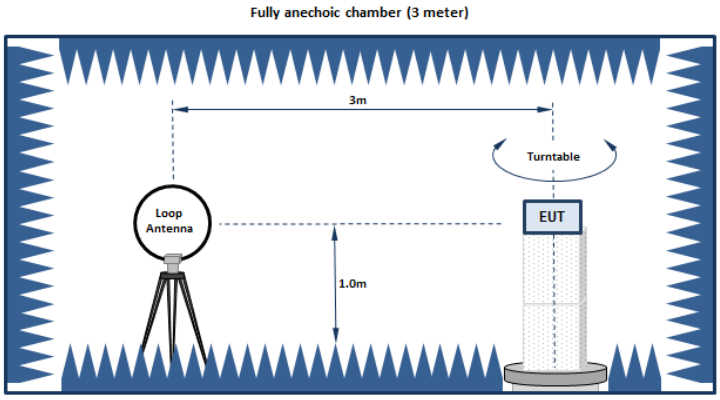
Test Information	
Product Standard Reference	FCC 15.225(a-c) / ISED RSS-210 B.6(a)i.
Measurement Method	Radiated
Measurement Uncertainty	± 5.95 dB

3.1.2 Limits

Limits			
Frequency ragne [MHz]	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
13.553 - 13.567	15848	84	30
13.410 - 13.553 13.567 - 13.710	334	50.5	30
13.110 - 13.410 13.710 - 14.010	106	40.5	30

3.1.3 Setup

Test Setup < 30 MHz



3.1.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic Chamber	Frankonia	AC1	EF00062	2018-07	2021-07
Spectrum Analyzer	R&S	ESCS 30	EF00295	2020-07	2021-07
Antenna	R&S	HFH2-Z2	EF00184	2017-12	2020-12

3.1.5 Procedure

Test Procedure
1. EUT set to test mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector 4. Below 30MHz an extrapolation according ANSI 63.10; 6.4.4.2 is used.

3.1.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Level @ 30 m [dBµV/m]	Detector	Polarization	Limit @ 30 m [dBµV/m]	Margin
13.56	13.56	13.4	pk	ver	84	-70.60

3.2 Test Conditions and Results - Emissions radiated outside the specified frequency band

3.2.1 Information

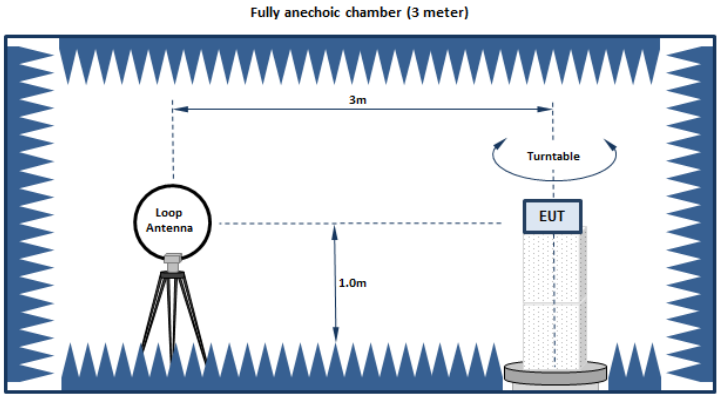
Test Information	
Product Standard Reference	FCC 15.225(d) / ISED RSS-210 B.6(a)iv.
Measurement Method	Radiated
Measurement Uncertainty	± 5.95 dB

3.2.2 Limits

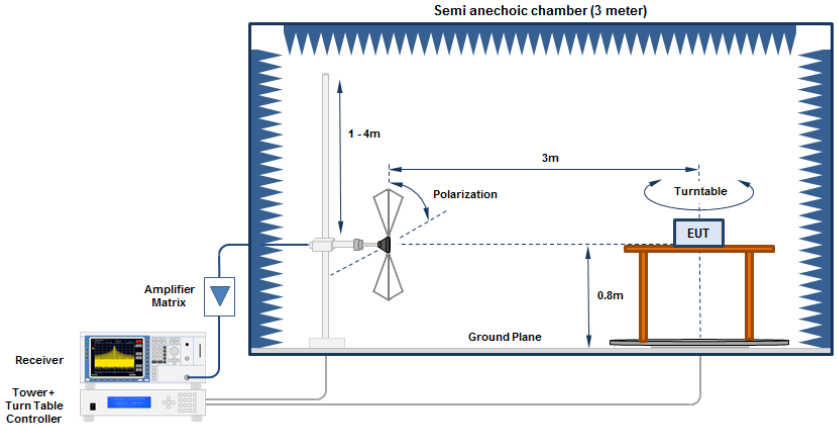
Limits				
Frequency range [MHz]	Detector	Limit [µV/m]	Limit [dBµV/m]	Limit Distance [m]
0.009 - 0.490	Quasi-Peak	2400/F[kHz]	48.5 - 13.8	300
0.490 - 1.705	Quasi-Peak	2400/F[kHz]	13.8 - 2.97	30
1.705 -30	Quasi-Peak	30	29.5	30
30 - 88	Quasi-Peak	100	40	3
88 -216	Quasi-Peak	150	43.5	3

3.2.3 Setup

Test Setup < 30 MHz



Test Setup 30 -216 MHz



3.2.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment ≤ 30MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Semi-Anechoic Chamber	Frankonia	AC1	EF00062	2018-07	2021-07
Measurement Receiver	R&S	ESCS 30	EF00295	2020-07	2021-07
Antenna	R&S	HFH2-Z2	EF00184	2017-12	2020-12

Test Equipment 30 - 216 MHz					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic Chamber	Frankonia	AC1	EF00062	2018-07	2021-07
Measurement Receiver	R&S	N9038A-526/WXP	EF01070	2020-06	2021-06
Antenna	R&S	HK116	EF01564	2020-03	2023-03

3.2.5 Procedure

Test Procedure
1. EUT set to test mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Below 30MHz an extrapolation according ANSI 63.10; 6.4.4.2 is used. 5. Markers are set to maximum emission levels

3.2.6 Results

Test Results						
Channel [MHz]	Emission [MHz]	Level [dBµV/m]	Detector	Polarization	Limit [dBµV/m]	Margin [dB]
13.56	109.503	34.09	Pk	ver	43.5	-9.41
13.56	130.128	33.66	pk	ver	43.5	-9.84
13.56	130.128	30.32	pk	hor	43.5	-13.18

3.3 Test Conditions and Results - AC powerline conducted emissions

3.3.1 Information

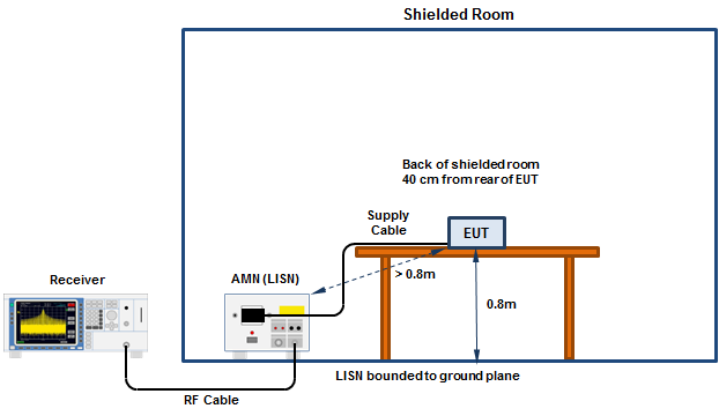
Test Information	
Reference	FCC § 15.207; ISED RSS-Gen, Issue 5
Measurement Method	ANSI C63.10 6.2
Measurement Uncertainty	± 3.82 dB
Operator	Wilfried Treffke
Date	2020-10-13

3.3.2 Limits

Limits		
Frequency [MHz]	Quasi-Peak [dBµV]	Average [dBµV]
0.15 - 0.5	66 - 56*	56 - 46*
0.5 - 5	56	46
5 - 30	60	50
* Limit decreases linearly with the logarithm of the frequency		

3.3.3 Setup

Test Setup



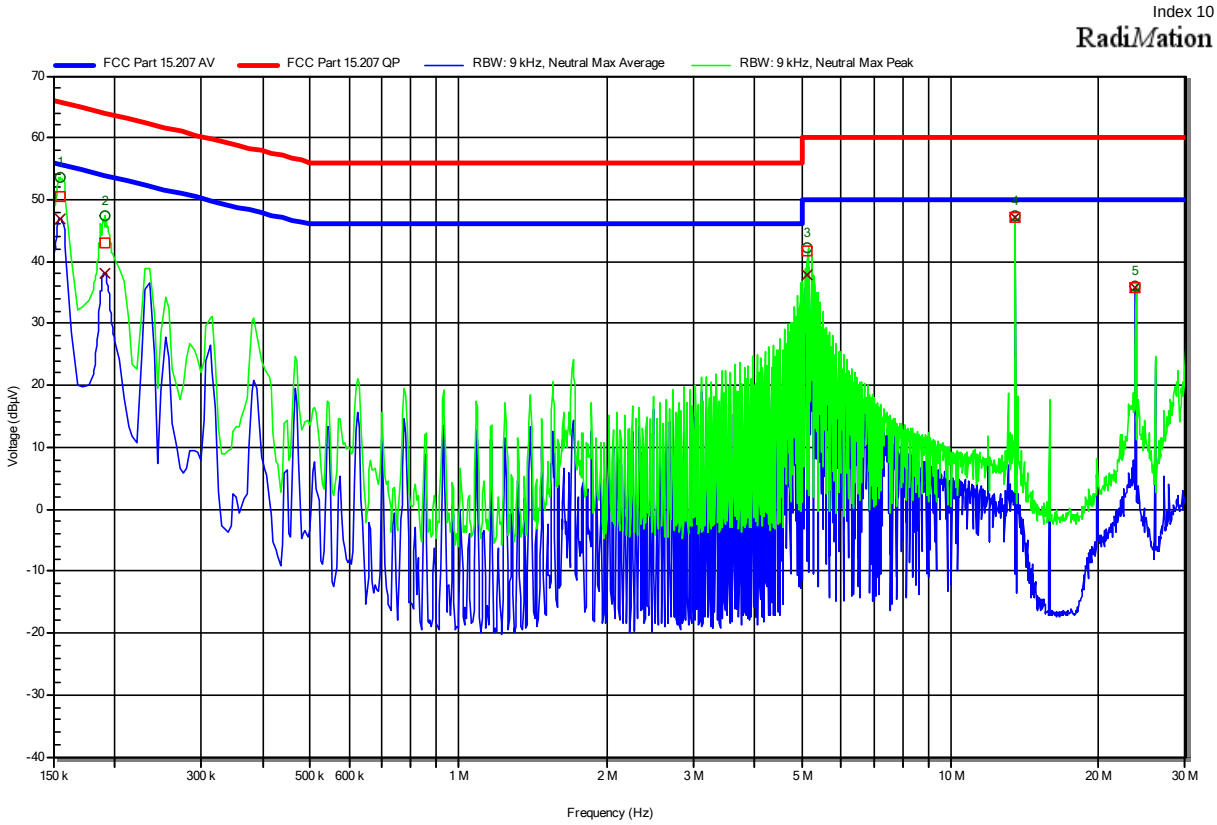
3.3.4 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	RadiMation	2020.1.8

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Test Receiver	R&S	ESR7	EF00943	2020-07	2021-07
Pulse Limiter	R&S	ESH3-Z2	EF01222	2020-07	2021-07
LISN	Schwarzbeck	NSLK 8127 RC	EF01592	2020-07	2021-07

Conducted emissions at the mains power port
according to FCC Part C 15.207

Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Date:	2020-10-13
Operating Conditions:	ambient temperature: 22 °Celsius power input: 120 VAC
LISN:	Schwarzbeck NSLK 8127 RC N
Operational Mode &	RFID; ASK; 13.56 MHz
Applied to Port:	AC mains

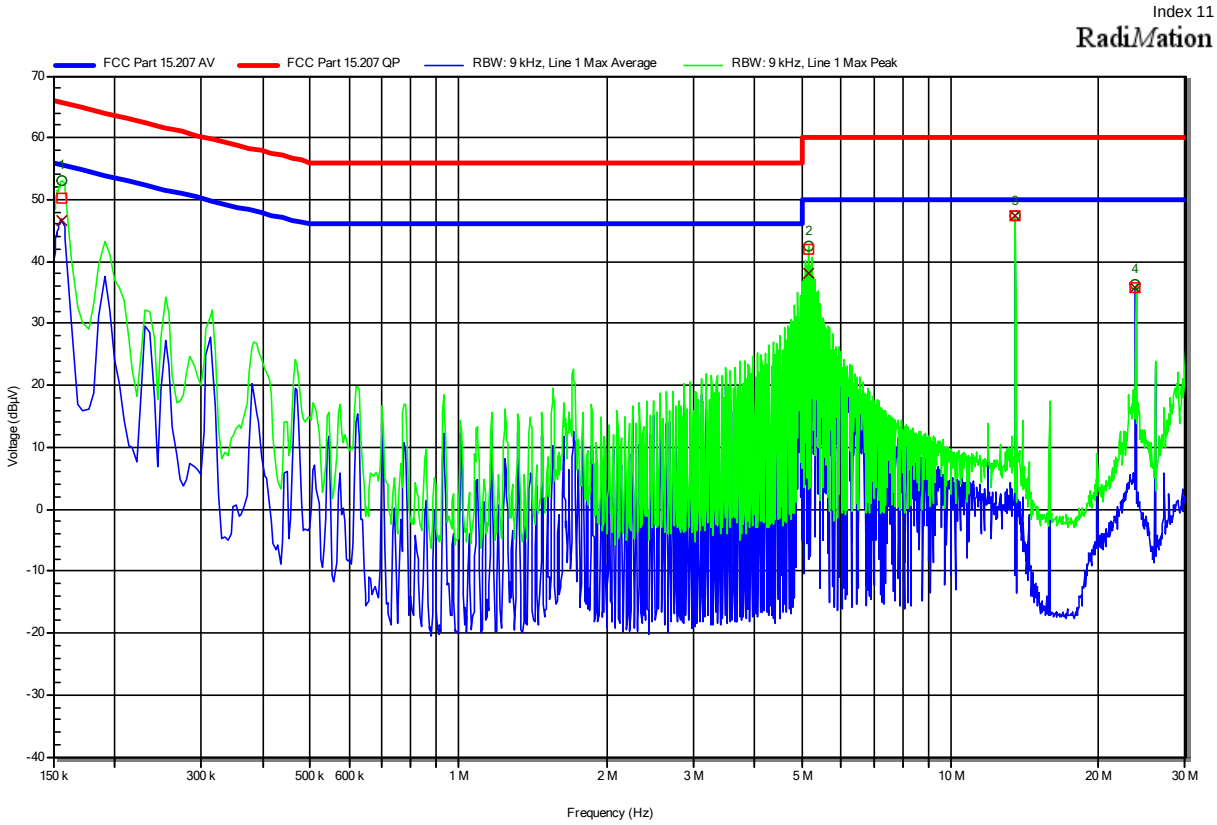


Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	LISN
1	154.95 kHz	50.52 dBµV	65.73 dBµV	-15.21 dB	Pass	Neutral
2	190.95 kHz	43.13 dBµV	64 dBµV	-20.86 dB	Pass	Neutral
3	5.128 MHz	41.72 dBµV	60 dBµV	-18.28 dB	Pass	Neutral
4	13.56 MHz	47.21 dBµV	60 dBµV	-12.79 dB	Pass	Neutral
5	23.788 MHz	35.8 dBµV	60 dBµV	-24.2 dB	Pass	Neutral

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status	LISN
1	154.95 kHz	46.8 dBµV	55.73 dBµV	-8.93 dB	Pass	Neutral
2	190.95 kHz	38.14 dBµV	54 dBµV	-15.86 dB	Pass	Neutral
3	5.128 MHz	37.83 dBµV	50 dBµV	-12.17 dB	Pass	Neutral
4	13.56 MHz	47.16 dBµV	50 dBµV	-2.84 dB	Pass	Neutral
5	23.788 MHz	35.76 dBµV	50 dBµV	-14.24 dB	Pass	Neutral

Conducted emissions at the mains power port
according to FCC Part C 15.207

Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Test Date:	2020-10-13
Operating Conditions:	ambient temperature: 22 °Celsius°C power input: 120 VAC
LISN:	Schwarzbeck NSLK 8127 RC L
Operational Mode &	RFID; ASK; 13.56 MHz
Applied to Port:	AC mains



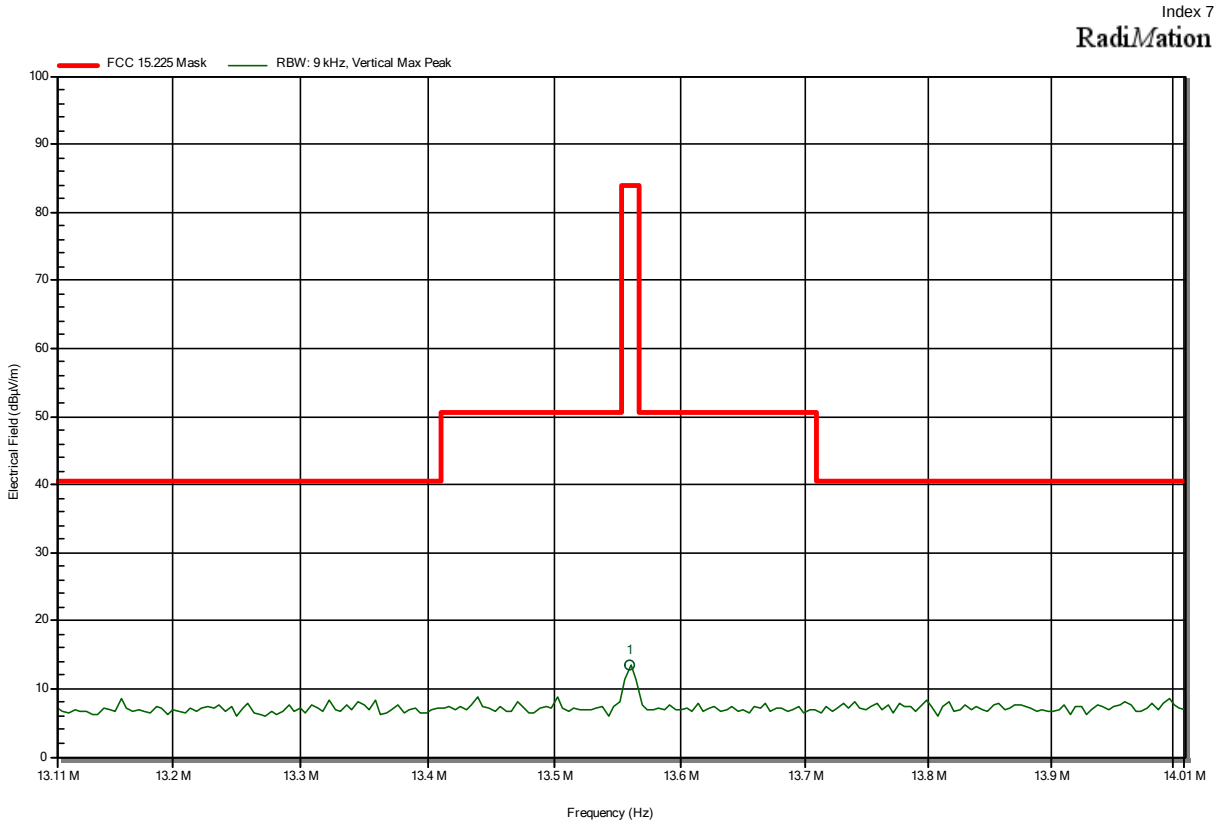
Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	LISN
1	156.3 kHz	50.36 dBµV	65.66 dBµV	-15.29 dB	Pass	Line 1
2	5.134 MHz	41.93 dBµV	60 dBµV	-18.07 dB	Pass	Line 1
3	13.56 MHz	47.34 dBµV	60 dBµV	-12.66 dB	Pass	Line 1
4	23.786 MHz	35.81 dBµV	60 dBµV	-24.19 dB	Pass	Line 1

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status	LISN
1	156.3 kHz	46.54 dBµV	55.66 dBµV	-9.12 dB	Pass	Line 1
2	5.134 MHz	38.05 dBµV	50 dBµV	-11.95 dB	Pass	Line 1
3	13.56 MHz	47.34 dBµV	50 dBµV	-2.66 dB	Pass	Line 1
4	23.786 MHz	35.76 dBµV	50 dBµV	-14.24 dB	Pass	Line 1

ANNEX A Transmitter in-band emissions

Radiated carrier according to FCC 15.225

Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Measurement software:	RadiMation, version 2020.1.8
Test Conditions:	Tnom: 22 °Celsius, Vnom: 120 VAC
Antenna:	HFH2-Z2
Measurement distance:	3 m, converted to 30 m
Mode:	Tx; RFID; ASK; 13.56 MHz
Test Date:	2020-10-13

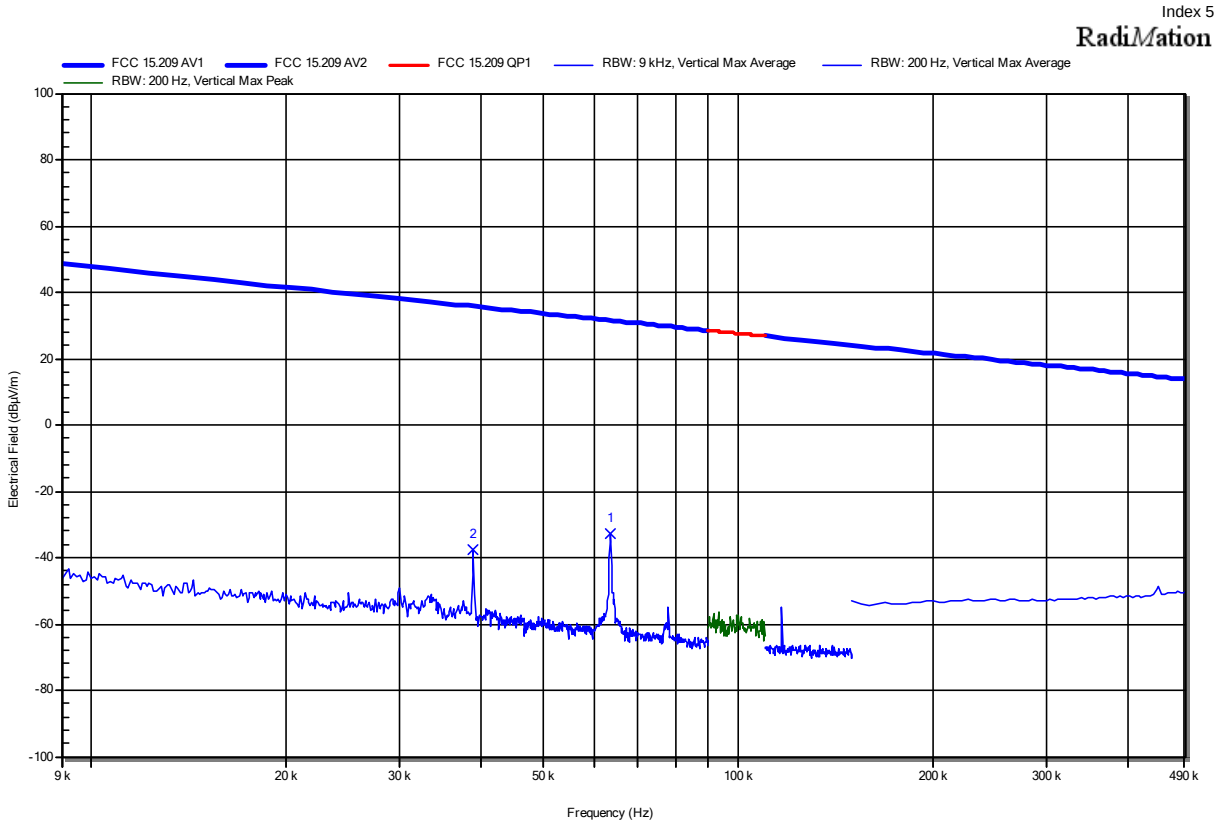


Frequency	Peak	Peak Limit	Peak Difference	Peak Status
13.56 MHz	13.4 dBµV/m	84 dBµV/m	-70.59 dB	Pass

ANNEX B Transmitter radiated spurious emissions

Radiated Spurious Emissions according to FCC 15.225

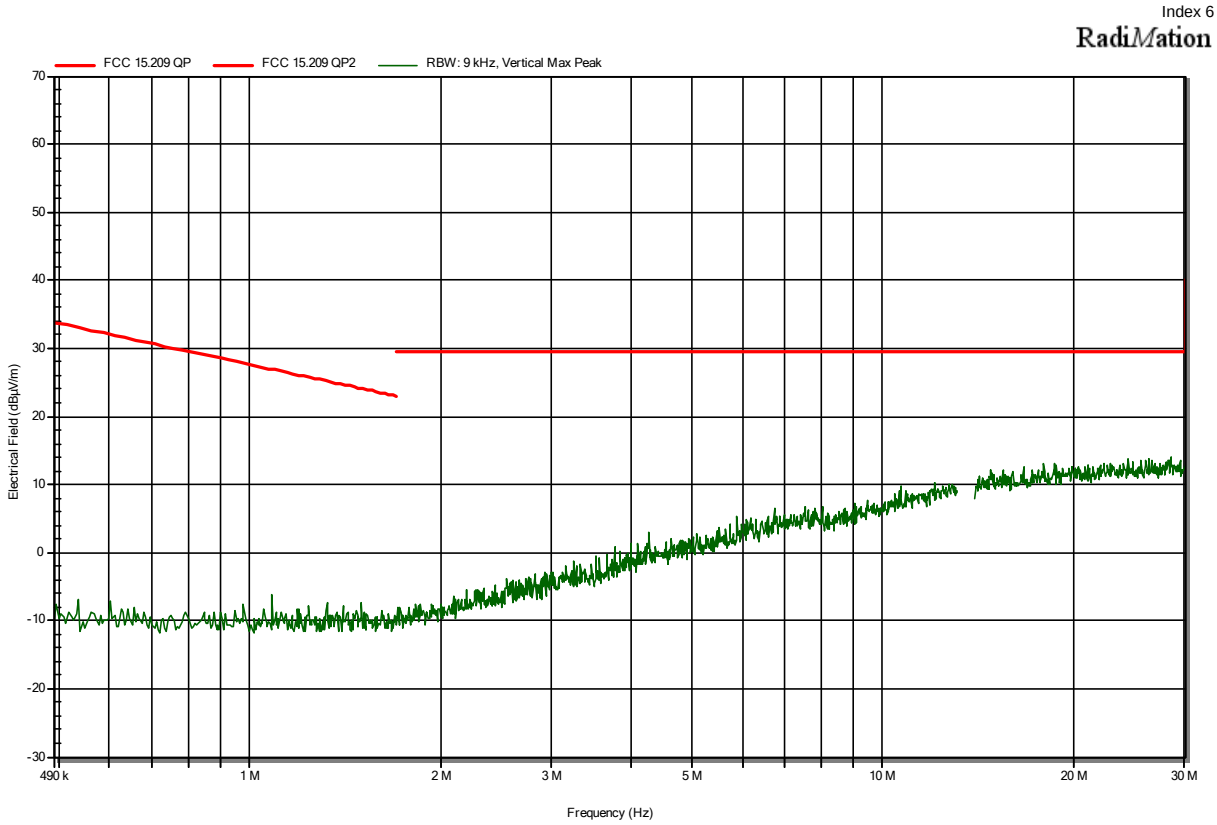
Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Measurement software:	RadiMation, version 2020.1.8
Test Conditions:	Tnom: 22 °Celsius, Vnom: 120 VAC
Antenna:	HFH2-Z2
Measurement distance:	3 m, converted to 300 m
Mode:	Tx; RFID; ASK; 13.56 MHz
Test Date:	2020-10-13



Frequency	Average	Average Limit	Average Difference	Average Status
38.9 kHz	-37.8 dBµV/m	35.8 dBµV/m	-73.56 dB	Pass
63.4 kHz	-32.8 dBµV/m	31.5 dBµV/m	-64.32 dB	Pass

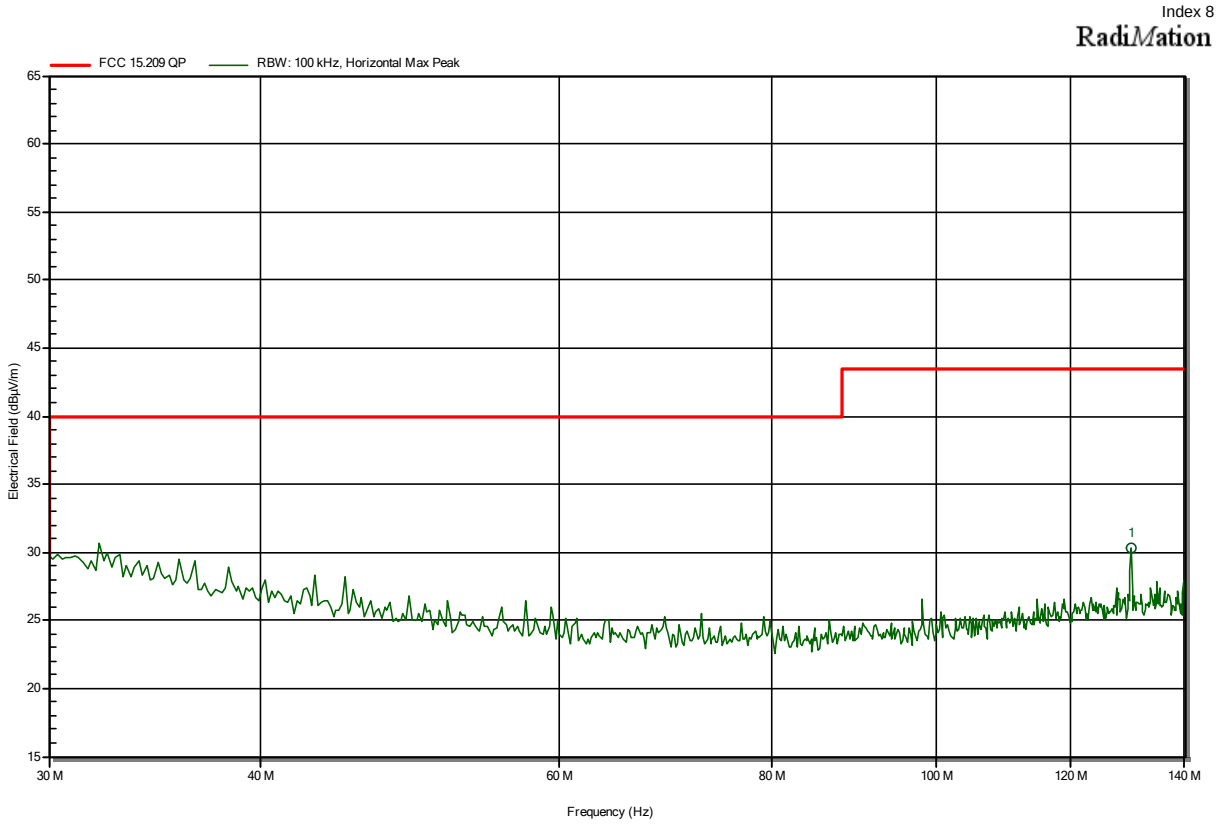
Radiated Spurious Emissions according to FCC 15.225

Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Measurement software:	RadiMation, version 2020.1.8
Test Conditions:	Tnom: 22 °Celsius, Vnom: 120 VAC
Antenna:	HFH2-Z2
Measurement distance:	3 m, converted to 30 m
Mode:	Tx; RFID; ASK; 13.56 MHz
Test Date:	2020-10-13



Radiated Spurious Emissions according to FCC 15.225

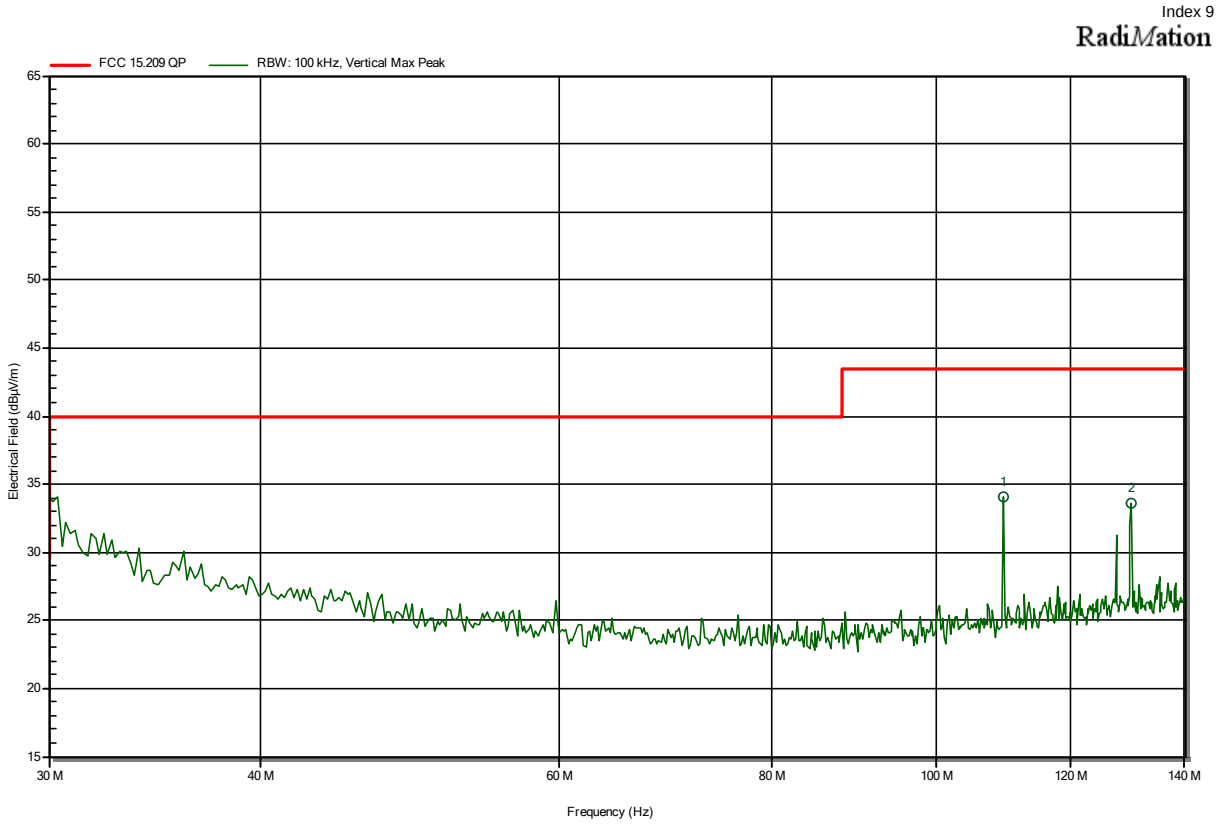
Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Measurement software:	RadiMation, version 2020.1.8
Test Conditions:	Tnom: 22 °Celsius, Vnom: 120 VAC
Antenna:	Rohde & Schwarz HK 116, Horizontal
Measurement distance:	3 m
Mode:	Tx; RFID; ASK; 13.56 MHz
Test Date:	2020-10-13



Frequency	Peak	Peak Limit	Peak Difference	Peak Status
130.128 MHz	30.32 dBµV/m	43.5 dBµV/m	-13.18 dB	Pass

Radiated Spurious Emissions according to FCC 15.225

Project Number:	G0M-2010-9360
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	31468
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Treffke
Measurement software:	RadiMation, version 2020.1.8
Test Conditions:	Tnom: 22 °Celsius, Vnom: 120 VAC
Antenna:	Rohde & Schwarz HK 116, Vertical
Measurement distance:	3 m
Mode:	Tx; RFID; ASK; 13.56 MHz
Test Date:	2020-10-13



Frequency	Peak	Peak Limit	Peak Difference	Peak Status
109.503 MHz	34.09 dBµV/m	43.5 dBµV/m	-9.41 dB	Pass
130.128 MHz	33.66 dBµV/m	43.5 dBµV/m	-9.84 dB	Pass