EMC TEST REPORT

FCC 47 CFR Part 15B, ISED ICES-003 Issue 6

Report Reference No	G0M-1912-8673-EF0115B-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-3 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 Standard(s)	47 CFR Part 15 Subpart B ISED ICES-003 Issue 6 ANSI C63.4:2014+A1:2017
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 PXA320) SN: 1902CE0537
Software Version(s)	1.0.34.7
FCC-ID	2AS5K-TSHW42
IC	25004-TSHW42A
Test Result	**PASSED**

Possible test case verdicts:		
required by standard but not tested	N/T	
not required by standard	N/R	
required by standard but not appl. to test object	N/A	
test object does meet the requirement	P(PASS)	
test object does not meet the requirement	F(FAIL)	
Testing:		
Date of receipt of test item	2020-04-16	
Report:		
Compiled by	Ruslan Colbasiuc	
Tested by (+ signature) (Responsible for Test)	Ruslan Colbasiuc	.....
Approved by (+ signature) (Deputy Head of Lab)	Jens Marquardt	.....
Date of Issue	2020-09-25	
Total number of pages	44	
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:		

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EUT	Equipment Under Test
FCC	Federal Communications Commission
ISED	Innovation, Science and Economic Development Canada
T_{NOM}	Nominal operating temperature
V_{NOM}	Nominal supply voltage

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2020-09-25	Initial Release	-

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1 Equipment (Test Item) Under Test

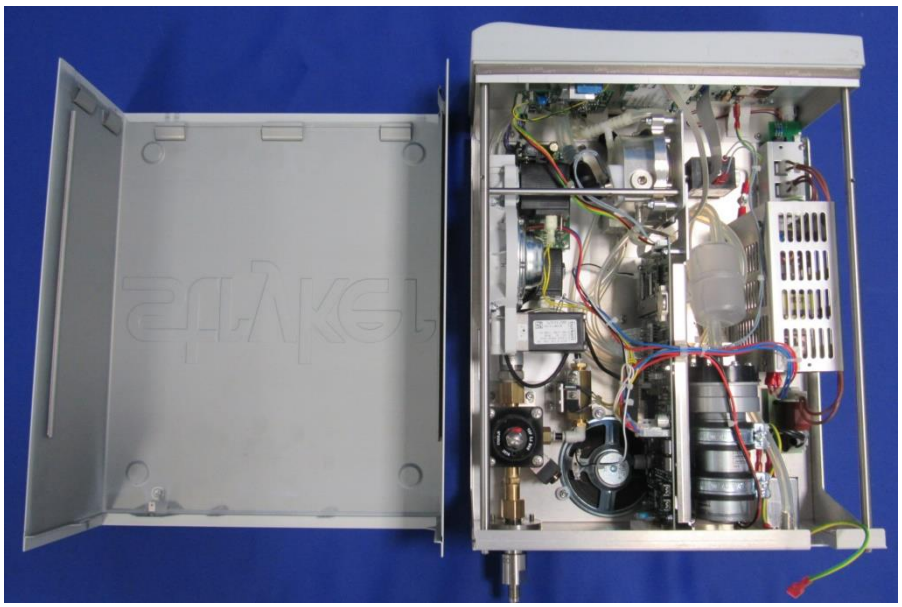
Description	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures	
Model	FM300	
Additional Model(s)	None	
Brand Name(s)	PNEUMOCLEAR™	
Serial Number(s)	1902CE0537	
Hardware Version(s)	hardware traceability is constituted by serial number of device (assembled with processor board Toradex PXA320) SN: 1902CE0537.	
Software Version(s)	1.0.34.7	
FCC-ID	2AS5K-TSHW42	
IC	25004-TSHW42A	
Class	Class B	
Equipment type	Table top	
Highest internal frequency [MHz]	806	
Dimension (cm)	31.8x14.9x42.9	
Radio Module	Type	RFID
	Model	TS-AH20
	Manufacturer	GiS GmbH
	FCC-ID	2AS5K-TSHW42
	IC	25004-TSHW42A
Supply Voltage	V_{NOM}	120 VAC / 60 Hz
Manufacturer	W.O.M. WORLD OF MEDICINE GmbH Salzufer 8 10587 Berlin GERMANY	

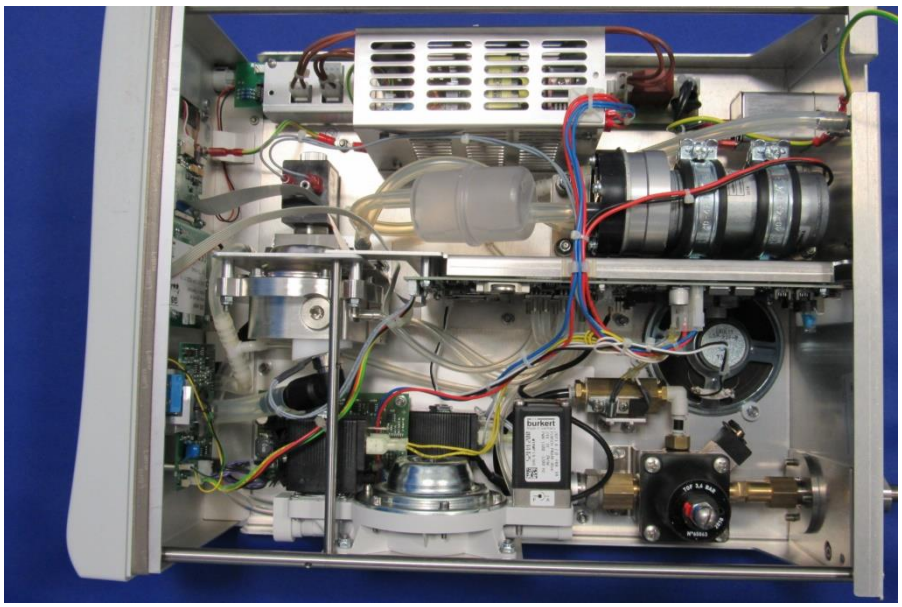
1.1 Equipment Ports

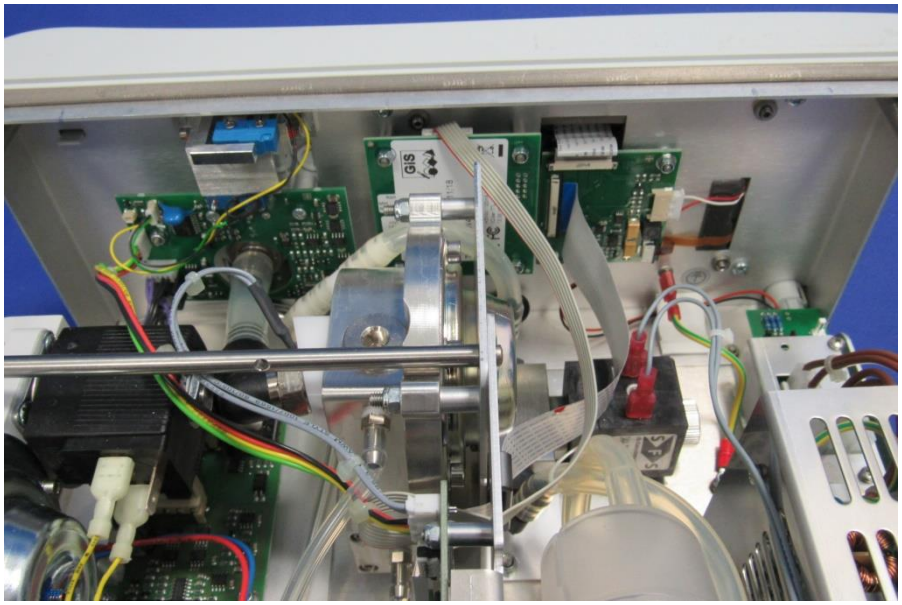
Name	Type	Attributes	Comment
Mains Connection	AC	Count: 1 Direction: In Service only: No	-
SIDNE	IO	Count: 1 Direction: IO Service only: No	USB Type B
USB	IO	Count: 1 Direction: IO Service only: Yes	USB Type A
USB	IO	Count: 1 Direction: IO Service only: Yes	USB Type Mini B
Tube Heater	DC;IO	Count: 1 Direction: IO Service only: No	-
Gas Supply Port	NE	Count: 1 Direction: In Service only: No	-
Gas Insufflation Port	NE	Count: 1 Direction: Out Service only: No	-

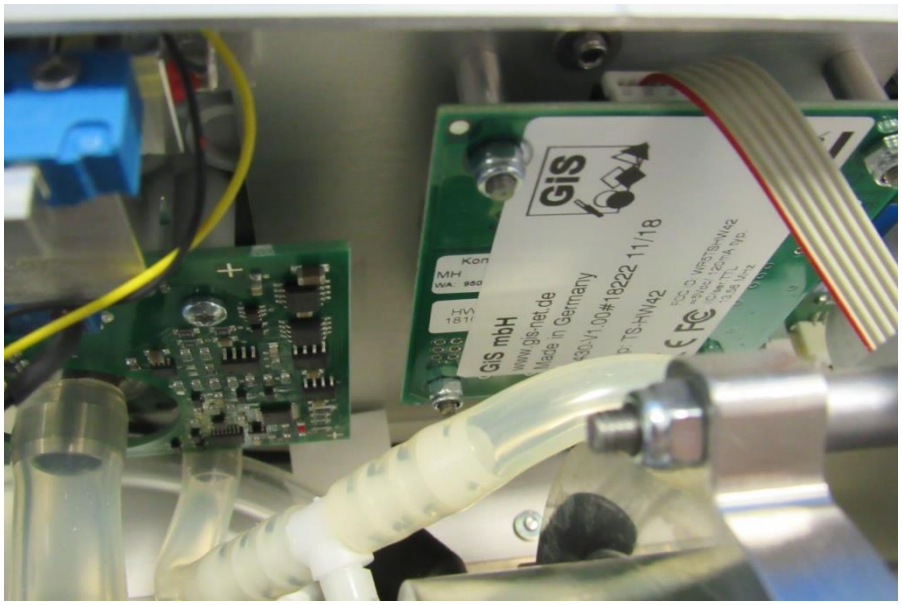
Description:	
AC	AC mains power input/output port
DC	DC power input/output port
BAT	DC power input port connected to external battery
IO	Input/Output port
TP	Telecommunication port
NE	Non-electrical port

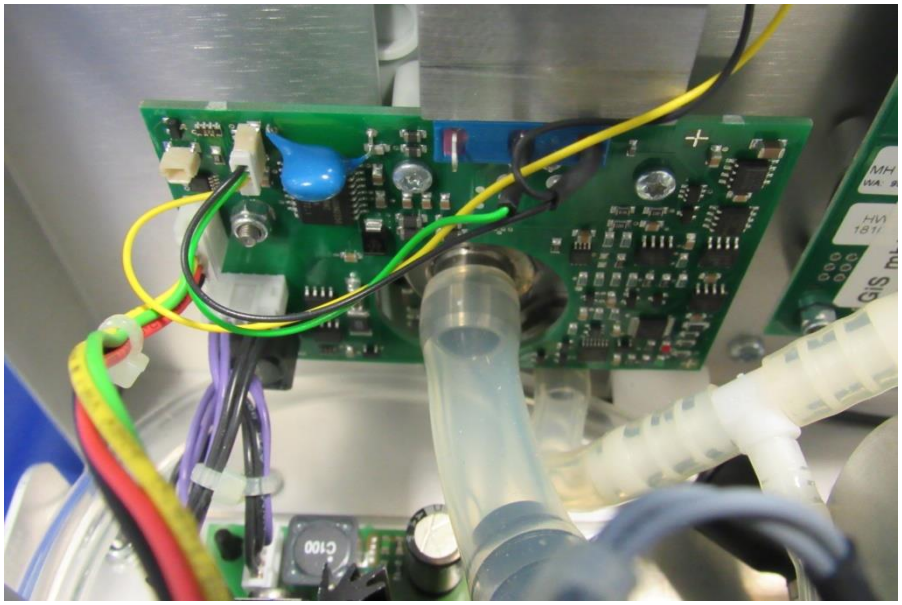
1.2 Equipment Photos - Internal

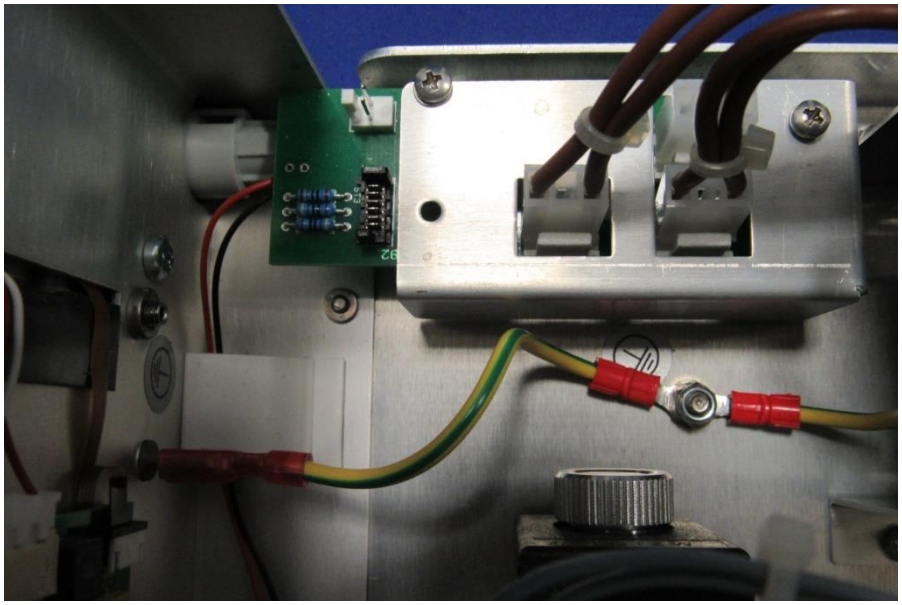
Internal Architecture View 1


Internal Architecture View 2


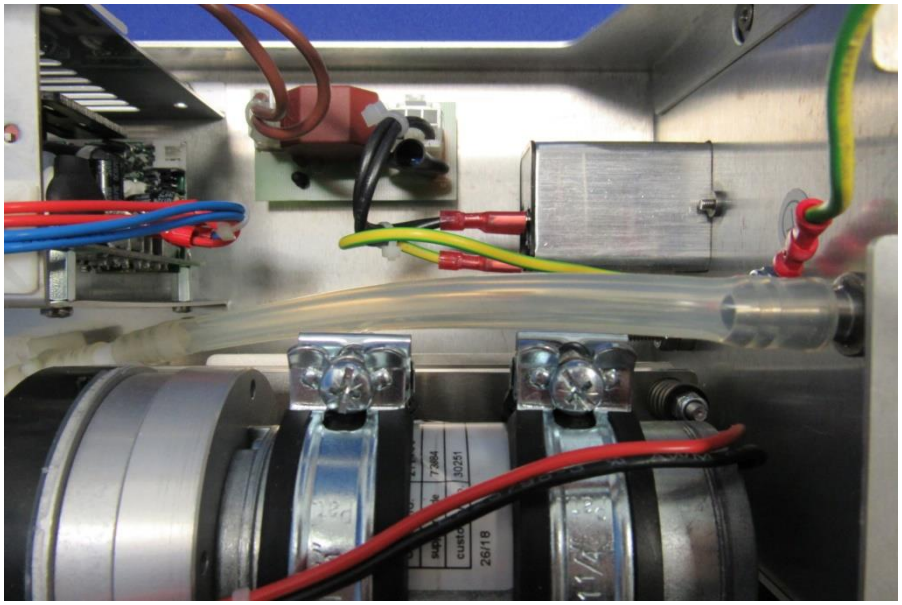
Internal Architecture View 3


Internal Architecture View 4


Internal Architecture View 5


Internal Architecture View 6


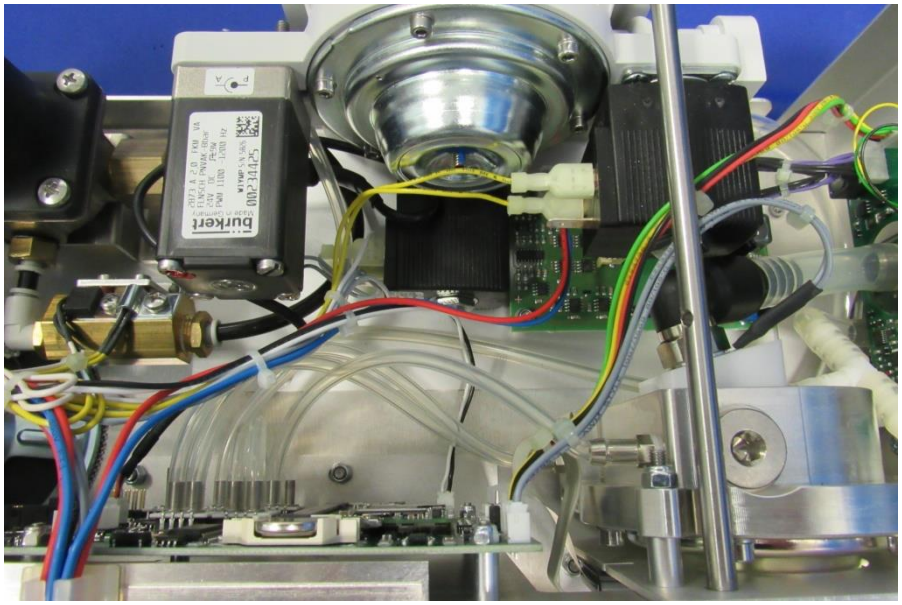
Internal Architecture View 7

Internal Architecture View 8


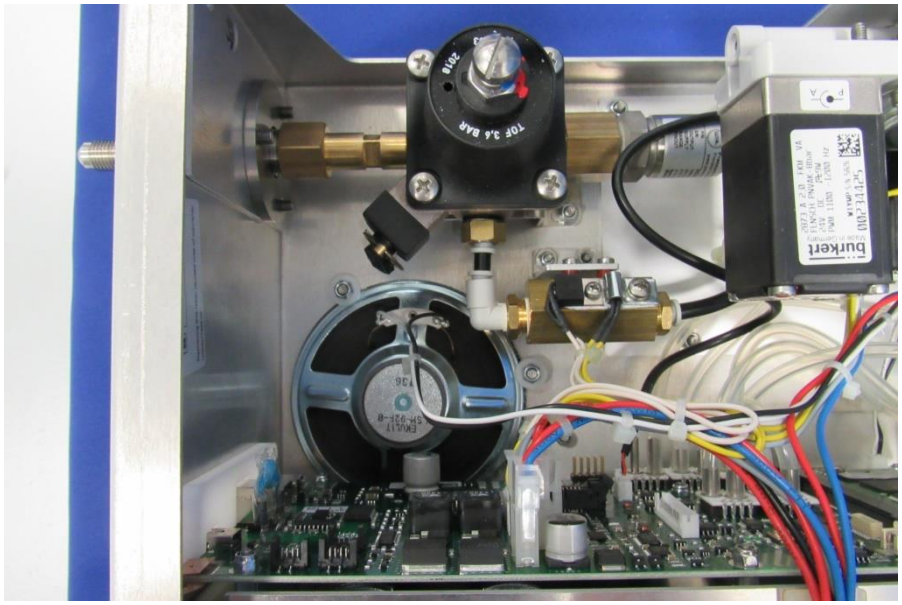
Internal Architecture View 9

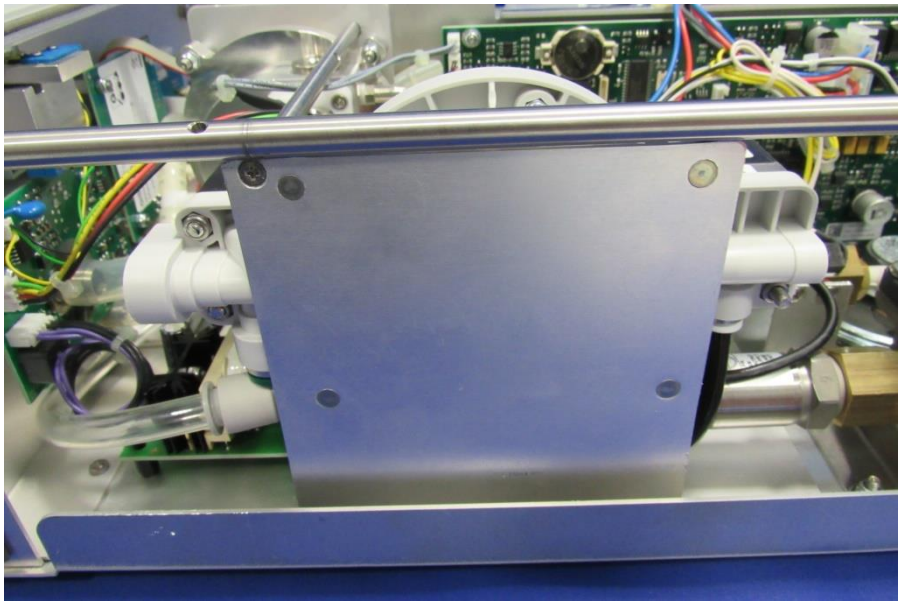
Internal Architecture View 10

Internal Architecture View 11

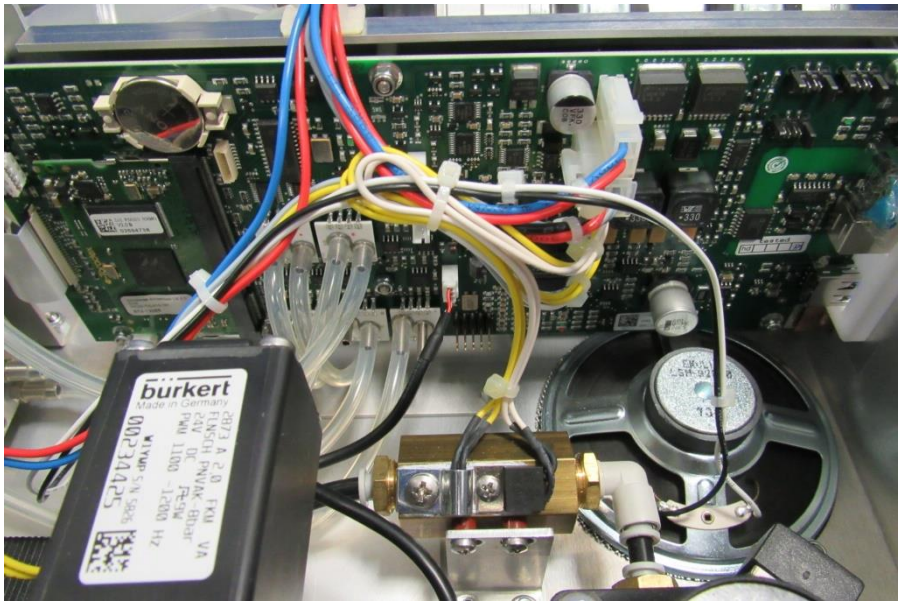


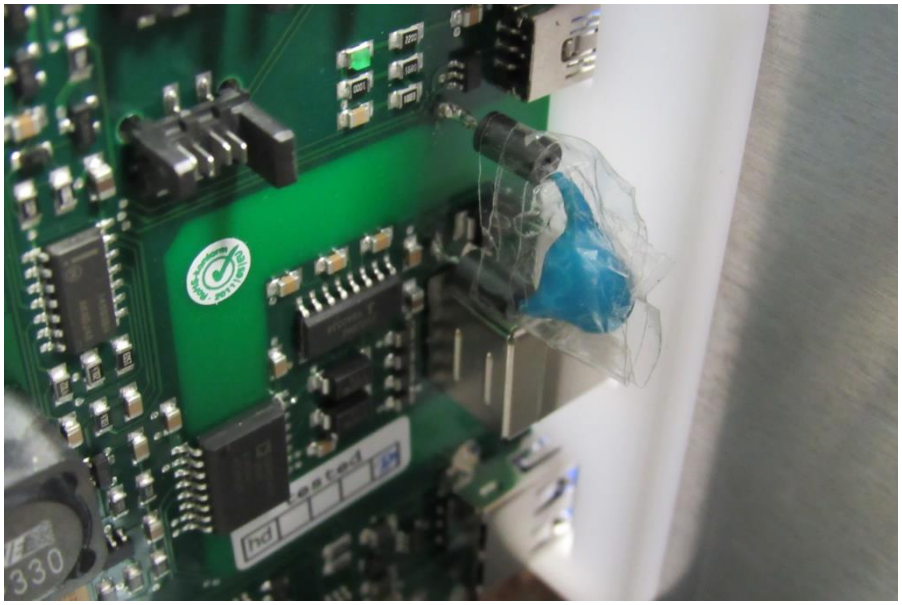
Internal Architecture View 12



Internal Architecture View 13


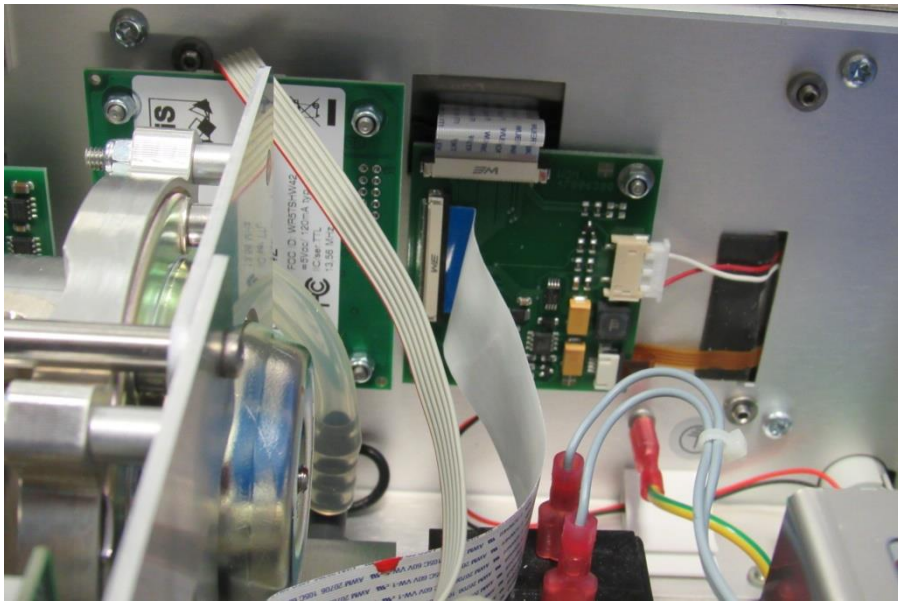
Internal Architecture View 14

Internal Architecture View 15


Internal Architecture View 16


Internal Architecture View 17

Internal Architecture View 18



Internal Architecture View 19

1.3 Equipment Photos – External

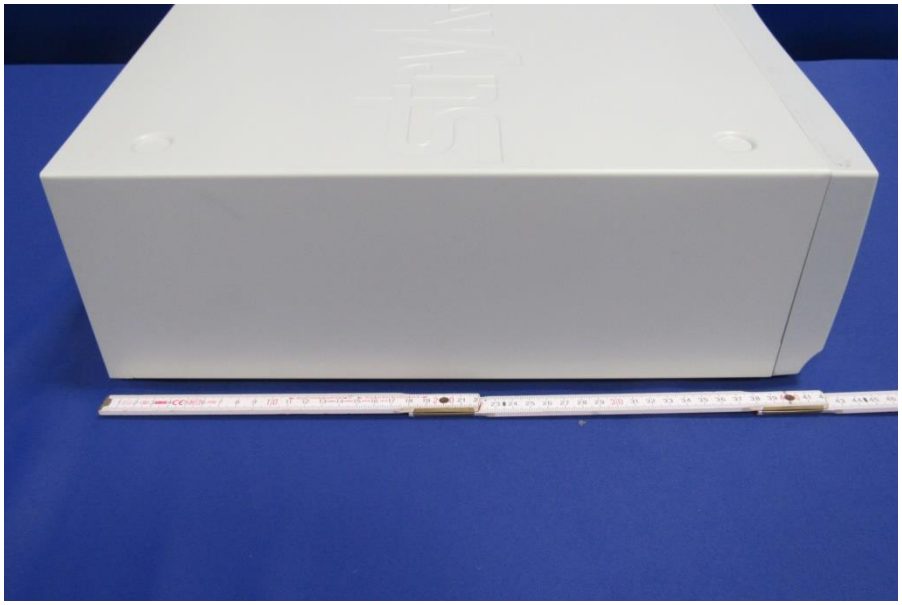
EUT Front View

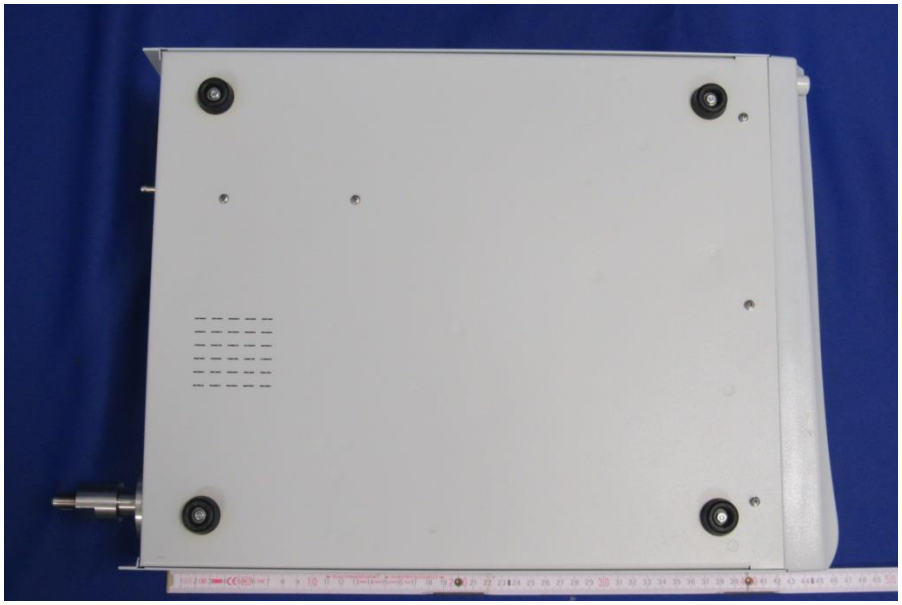
EUT Top View

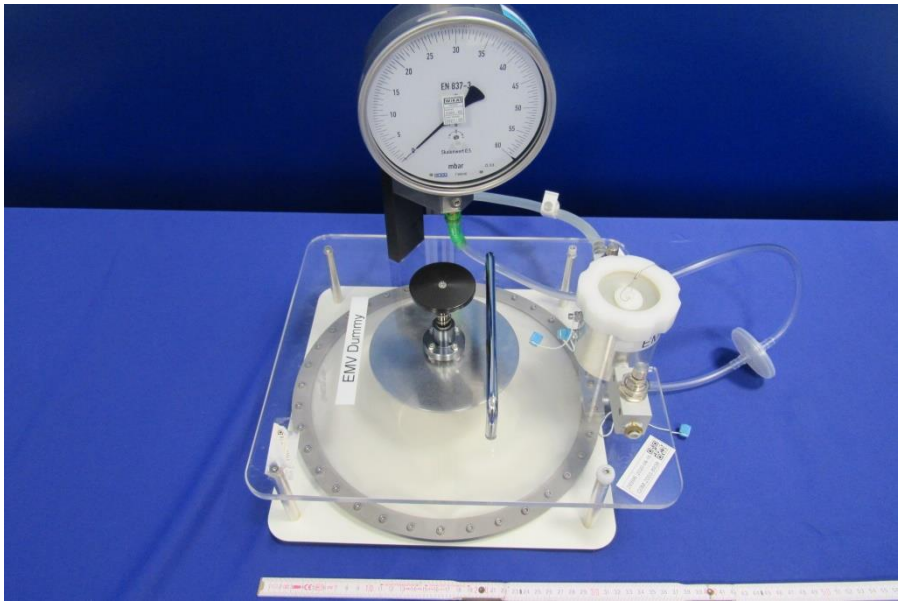
EUT Right Side View

EUT Back Side View

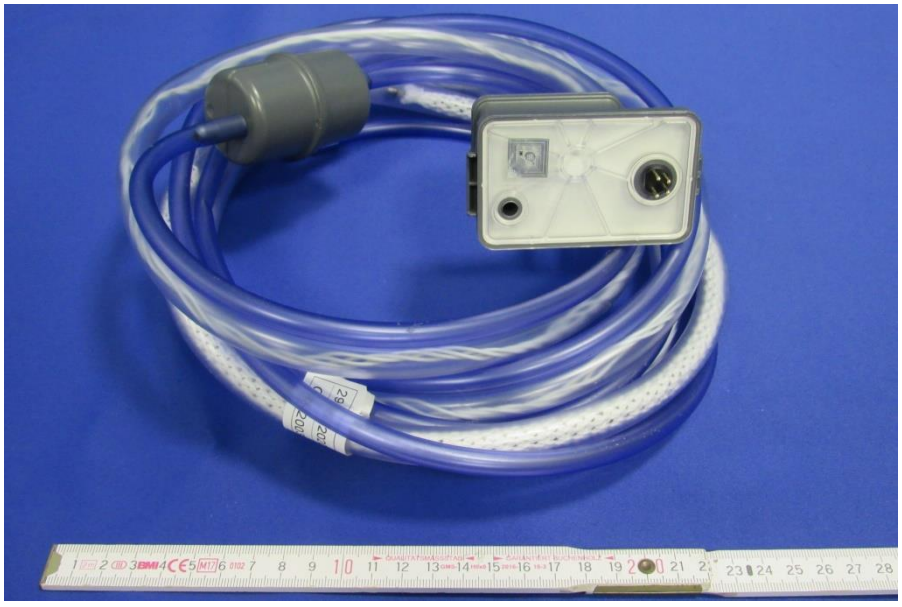
EUT Label

EUT Left Side View


EUT Bottom View


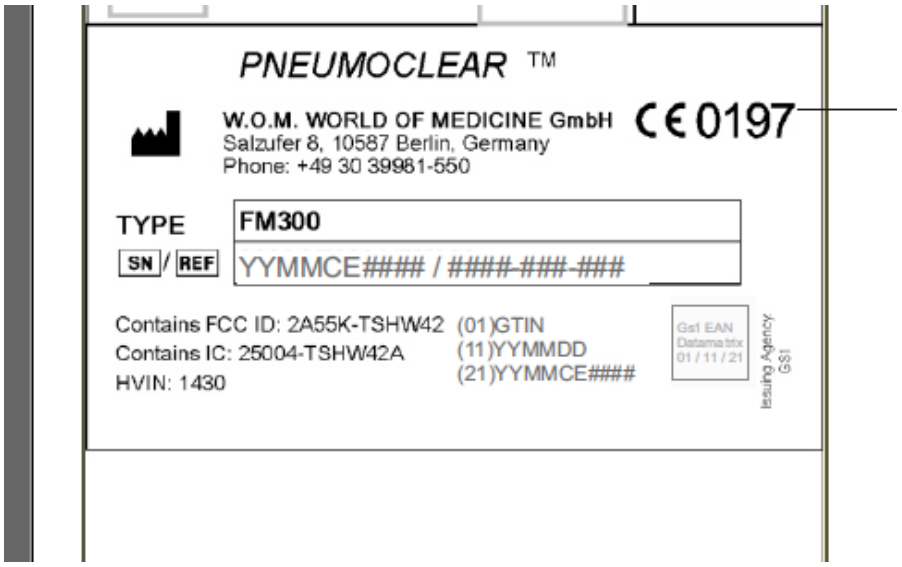
Test Dummy


Gas Tube View 1

Gas Tube View 2 (with RFID TAG)


Gas Tube View 3

EUT Final Label



1.4 Support Equipment

Product Type	Device	Manufacturer	Model	Comment
AE	PNEUMOCLEAR HEATED HUMIDIFIED SMOKE EVACUATION TUBE SET	W.O.M. WORLD OF MEDICINE GmbH	ST298	-
CABL	Power Cord EU 2m	-	1102131	-
CABL	Power Cord cable main US 2.5m	-	1102134	-
CABL	High pressure tube	W.O.M. WORLD OF MEDICINE GmbH	ST216	-
SIM	Abdomnial cavitiy	W.O.M. WORLD OF MEDICINE GmbH	LapDummy Plus	-
AE	CO2 gas tank	-	-	Supply pressure > 15 bar is required
SIM	SIDNE DEVICE CONTROL	STRYKER	SDC3	SN: 16D001594
CABL	USB Cable	-	-	shielded
Description:				
AE	Auxiliary Equipment			
SIM	Simulator			
MON	Monitoring Equipment			
CBL	Connecting Cable			
Comment:				

1.5 Operational Modes

Mode #	Description
1	Advance Mode, Set pressure 15 mmHg; Set flow 20 l/min; Smoke evacuation level 4
Comment:	

1.6 EUT Configuration

Configuration #	Description
1	Insufflator connected with the gas bottle, and gas tube with heater system and RFID Tag. Gas tube connected to the test dummy with mechanical pressure sensor. USB connection with the SYDNE System established. Device powered up with 120 V / 60 Hz.
Comment:	

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 analyser in dBµV. Any external preamplifiers used are taken into account through internal analyser 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 analyser. 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 Analyser (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 15B, ISED ICES-003 Issue 6				
Reference	**Requirement**	**Reference Method**	**Result**	**Remarks**
Emission				
FCC 15.109 ICES-003, 6.2	Radiated emissions	ANSI C63.4:2014 +A1:2017	PASS	-
FCC 15.107 ICES-003, 6.1	AC power line conducted emissions	ANSI C63.4:2014 +A1:2017	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

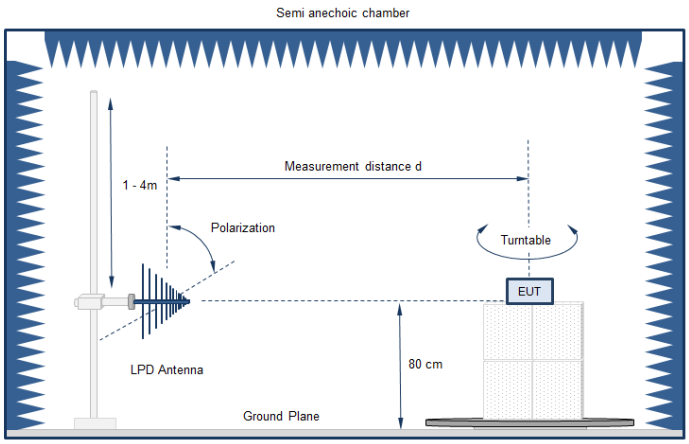
2.1 Test Conditions and Results - Radiated emissions acc. to ANSI C63.4

2.1.1 Information

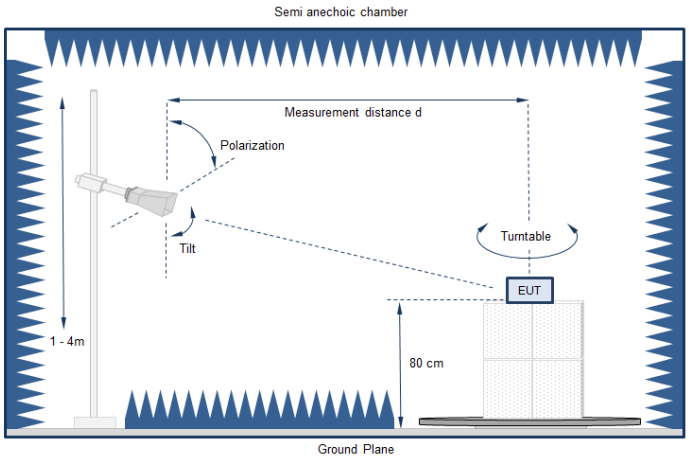
Test Information	
Reference	FCC 15.109, ICES-003, 6.2
Reference method	ANSI C63.4:2014+A1:2017 Section 8
Equipment class	Class B
Equipment type	Table top
Highest internal frequency [MHz]	806
Measurement range	30 MHz to 5 GHz
Temperature [°C]	25
Humidity [%]	55
Operator	Ruslan Colbasiuc
Date	2020-08-13

2.1.2 Setup

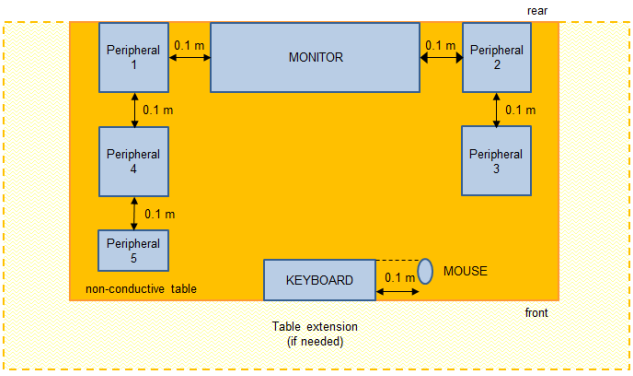
Measurement up to 1 GHz



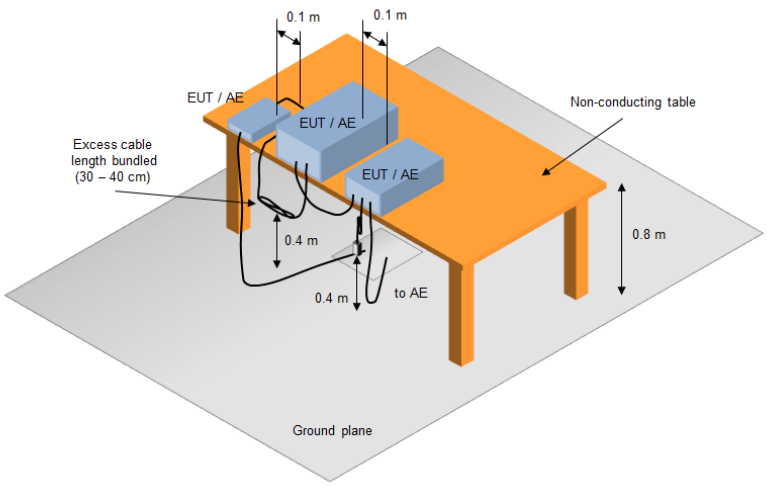
Measurement above 1 GHz



Equipment placement - Table top



Test Setup



2.1.3 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	Radimation	2016.1.10

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC6	EF00910	2020-02	2023-02
EMI Test Receiver	R&S	ESU26	EF00887	2020-07	2021-07
TRILOG Broadband Antenna	Schwarzbeck	VULB 9162	EF00978	2019-10	2022-10
Horn Antenna	ETS-Lindgren	3117	EF00976	2019-03	2022-03
Climatic Sensor	Embedded Data Systems, LLC.	9A00100000254 77E	EF01124	2020-03	2021-03

2.1.4 Procedure

Exploratory measurement
1. The EUT was placed on a non-conductive table at a height of 0.8m. 2. The EUT and support equipment, if needed, were set up to simulate typical usage. 3. Cables, of type and length specified by the manufacturer, were connected to at least one port of each type and were terminated by a device or simulating load of actual usage. 4. The antenna was placed at a distance of 3 or 10 m. 5. The received signal was monitored at the measurement receiver. 6. This procedure has to be performed in both antenna polarizations, horizontal and vertical. 7. The arrangement of the equipment with the maximum emission level is shown on the setup picture at item 1.3

Final measurement
1. The EUT was placed on a 0.8 m non-conductive table at a 3 m distance from the receive antenna. The antenna output was connected to the measurement receiver. 2. A biconical antenna was used for the frequency range 30 – 200 MHz, a logarithmic periodical antenna was used for the frequency range from 200 – 1000 MHz. Above one 1 GHz a Double Ridged Broadband Horn antenna was used. The antenna was placed on an adjustable height antenna mast. 3. The EUT and cable arrangement were based on the exploratory measurement results. 4. Emissions were maximized at each frequency by rotating the EUT and adjusting the receive antenna height and polarization. The maximum values were recorded. 5. The test data of the worst-case conditions were recorded and shown on the next pages.

2.1.5 Limits

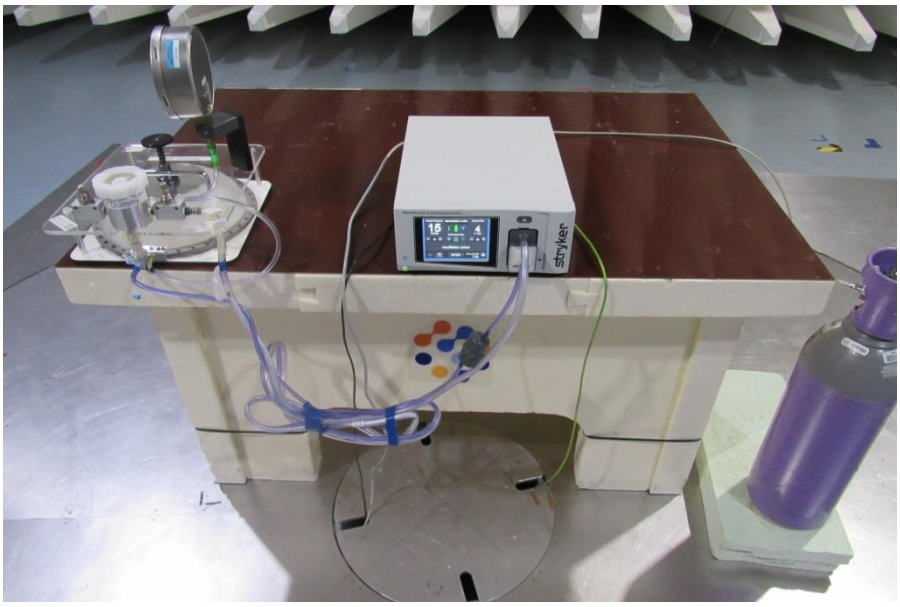
Class B @ 3 m		
Frequency [MHz]	Detector	Limit [dBµV/m]
30 - 88	Quasi-peak	40
88 - 216	Quasi-peak	43.5
216 - 960	Quasi-peak	46
960 - 1000	Quasi-peak	54
> 1000	Peak Average	74 54

2.1.6 Results

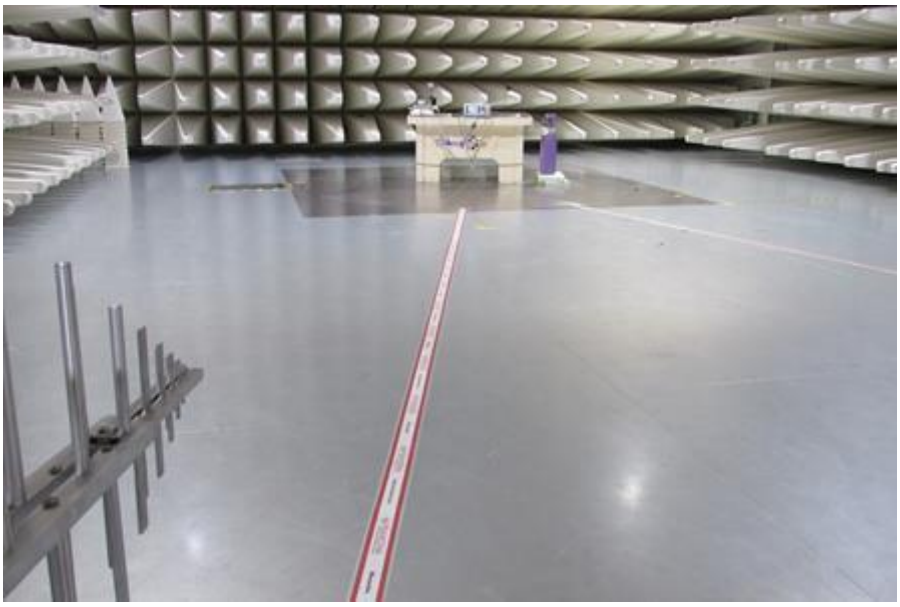
Test Results			
Operational mode	EUT Configuration	Verdict	Remark
1	1	PASS	

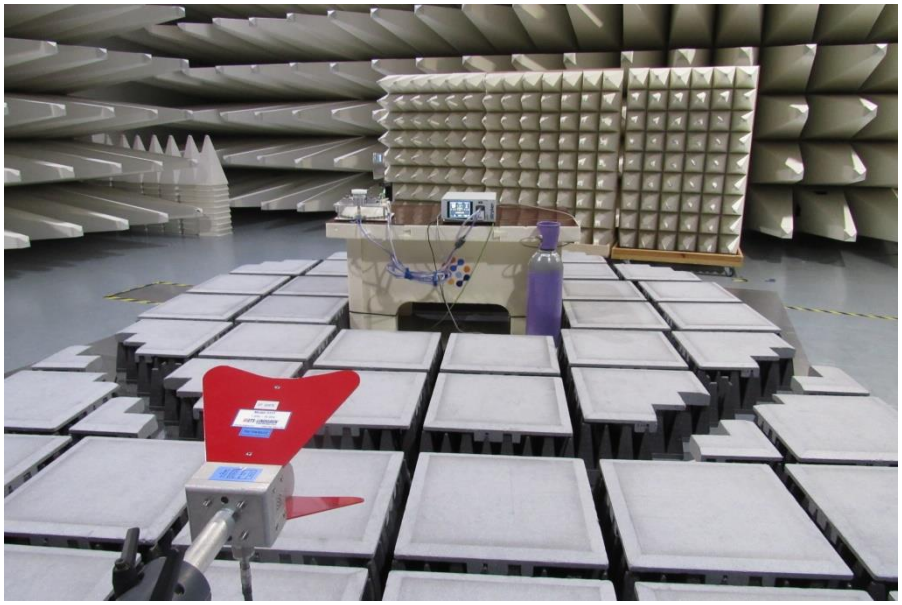
2.1.7 Setup Photos

EUT Table Arrangement for Radiated Emission



Radiated Emission VULB Antenna View



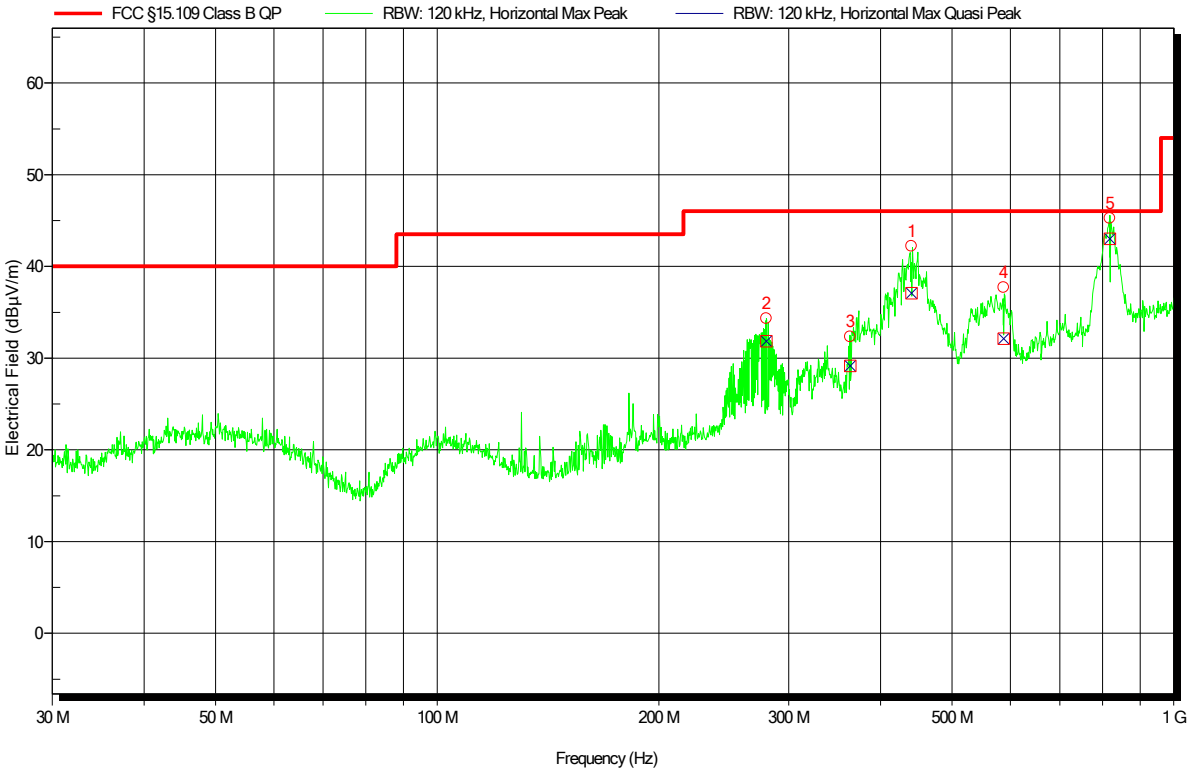
Radiated Emission Horn Antenna View


2.1.8 Records

Radiated emissions according to FCC 15B

Project Number:	G0M-1912-8673
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	29984 / 29985
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Date:	2020-08-13
Operating Conditions:	ambient temperature: 25 °C power input: 120 VAC / 60 Hz
Antenna:	Schwarzbeck VULB 9162, Horizontal
Measurement Distance:	10 m calculated to 3 m
Mode:	1
Note 1:	

Index 1

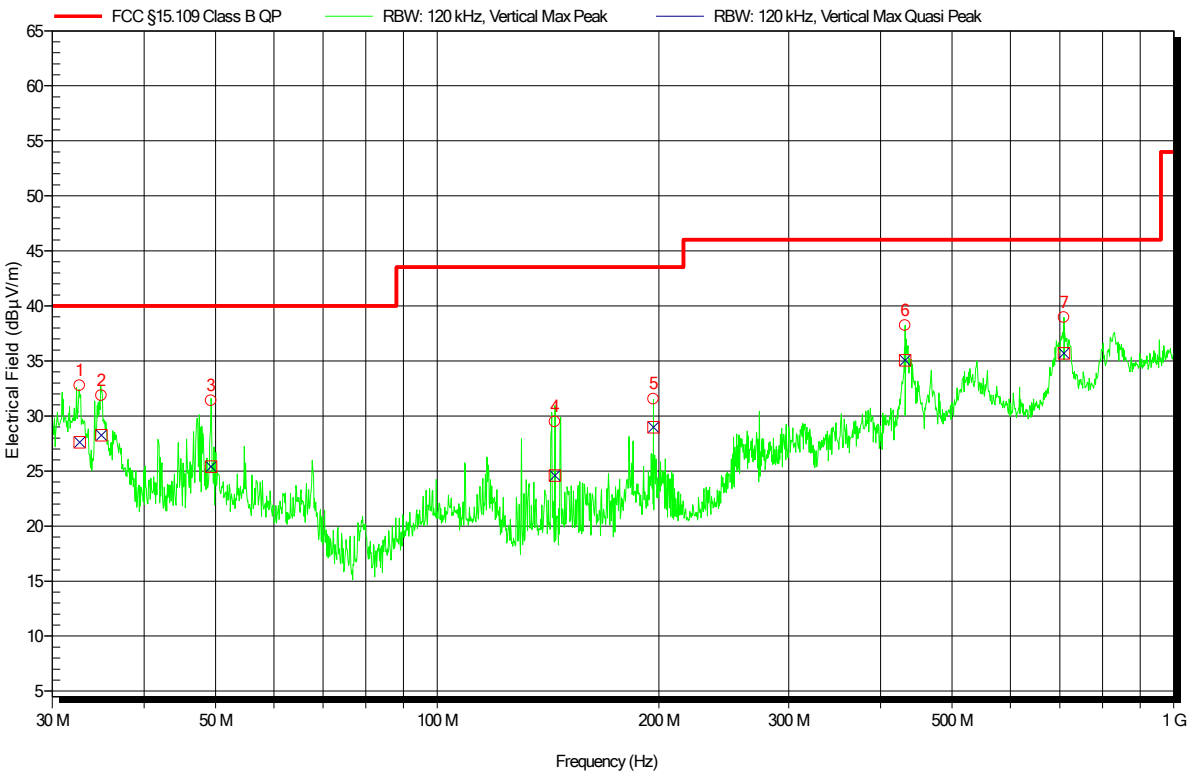


Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	440.46 MHz	37.1 dBµV/m	46 dBµV/m	-9.0 dB	Pass	-130 Degree	2.3 m
2	279.9 MHz	31.9 dBµV/m	46 dBµV/m	-14.2 dB	Pass	-130 Degree	2.3 m
3	363.852 MHz	29.2 dBµV/m	46 dBµV/m	-16.9 dB	Pass	-130 Degree	2.3 m
4	587.28 MHz	32.1 dBµV/m	46 dBµV/m	-13.9 dB	Pass	-130 Degree	2.3 m
5	818.58 MHz	43 dBµV/m	46 dBµV/m	-3.0 dB	Pass	-60 Degree	1 m

Radiated emissions according to FCC 15B

Project Number:	G0M-1912-8673
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	29984 / 29985
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Date:	2020-08-13
Operating Conditions:	ambient temperature: 25 °C power input: 120 VAC / 60 Hz
Antenna:	Schwarzbeck VULB 9162, Vertical
Measurement Distance:	10 m calculated to 3 m
Mode:	1
Note 1:	

Index 2



Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	Angle	Height
1	32.7 MHz	27.6 dBµV/m	40 dBµV/m	-12.4 dB	Pass	-110 Degree	1 m
2	34.98 MHz	28.3 dBµV/m	40 dBµV/m	-11.7 dB	Pass	-110 Degree	1 m
3	49.296 MHz	25.4 dBµV/m	40 dBµV/m	-14.6 dB	Pass	-110 Degree	1 m
4	144.42 MHz	24.6 dBµV/m	43.5 dBµV/m	-18.9 dB	Pass	-110 Degree	1 m
5	196.572 MHz	29 dBµV/m	43.5 dBµV/m	-14.6 dB	Pass	-110 Degree	1 m
6	431.634 MHz	35 dBµV/m	46 dBµV/m	-11.0 dB	Pass	-110 Degree	1 m
7	709.158 MHz	35.7 dBµV/m	46 dBµV/m	-10.3 dB	Pass	-110 Degree	1 m

Radiated emissions according to FCC 15B

Project Number:	G0M-1912-8673
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	29984 / 29985
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Date:	2020-08-13
Operating Conditions:	ambient temperature: 25 °C power input: 120 VAC / 60 Hz
Antenna:	ETS-Lindgren 3117, Vertical
Measurement Distance:	3 m
Mode:	1
Note 1:	Table position 165°, Antenna high 1m

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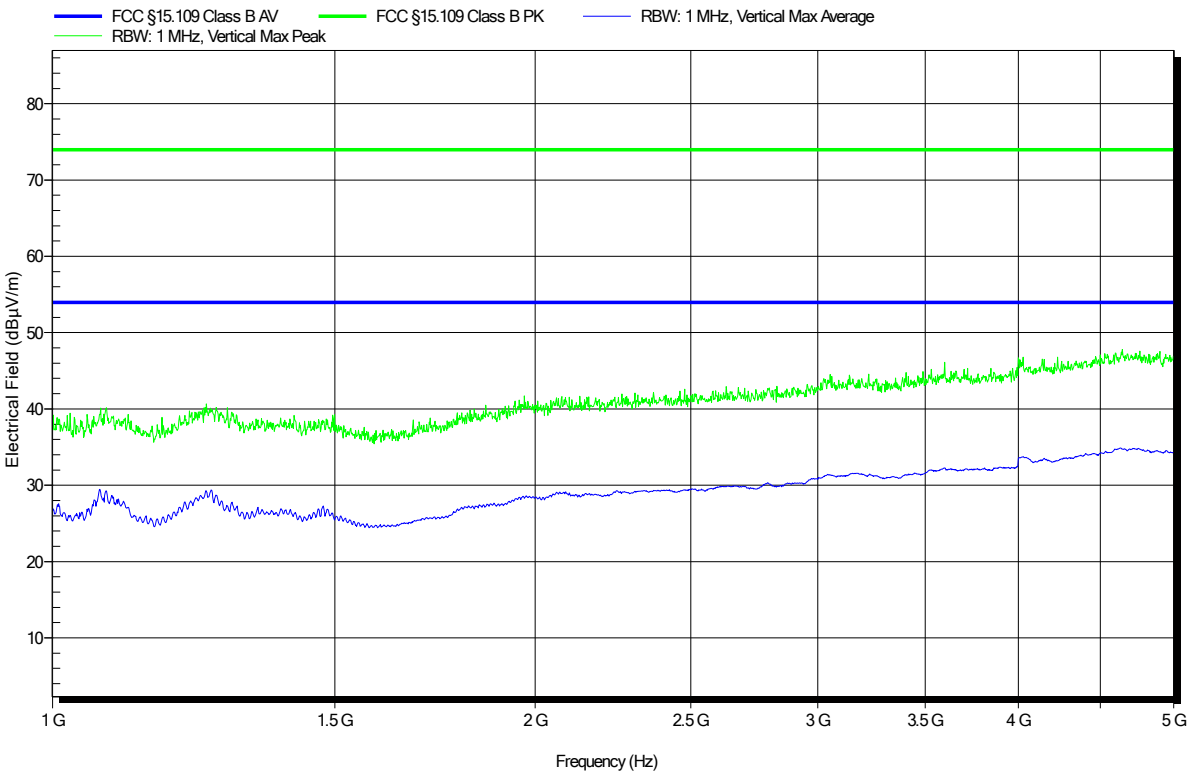

Radiated emissions according to FCC 15B

Project Number:	G0M-1912-8673
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	29984 / 29985
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Date:	2020-08-13
Operating Conditions:	ambient temperature: 25 °C power input: 120 VAC / 60 Hz
Antenna:	ETS-Lindgren 3117, Horizontal
Measurement Distance:	3 m
Mode:	1
Note 1:	

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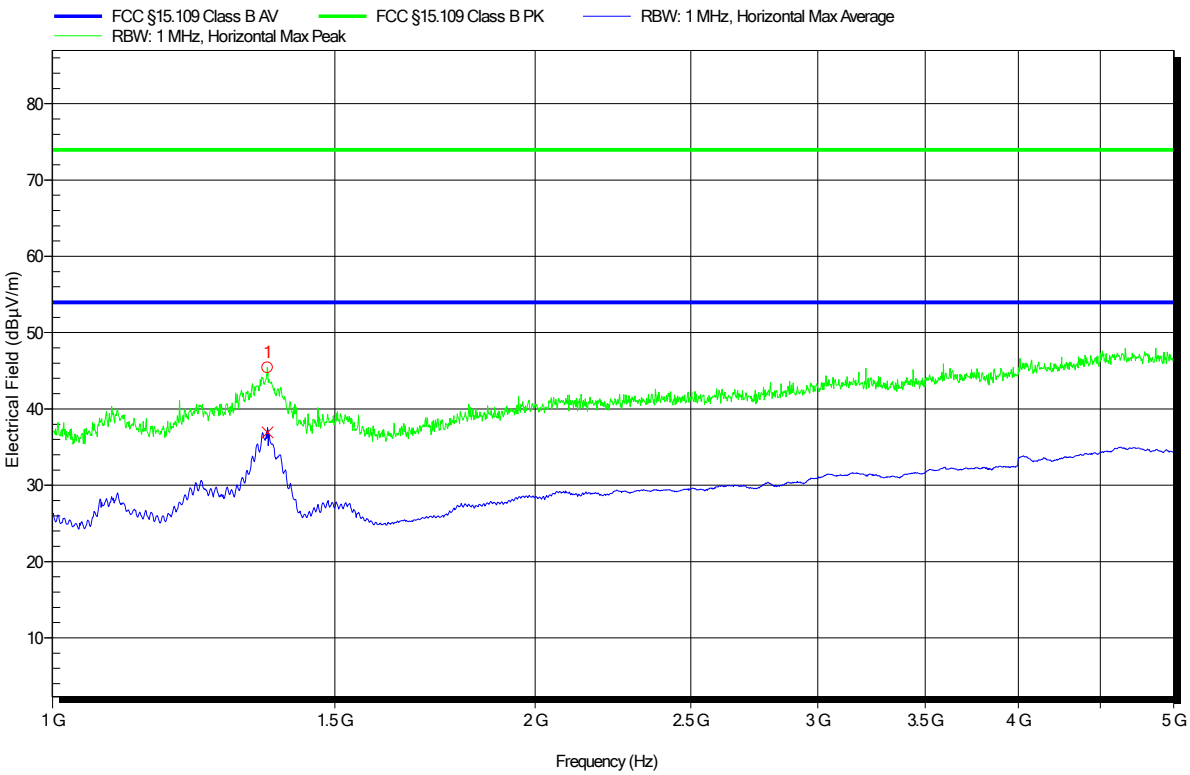


Peak Number	Frequency	Peak	Peak Limit	Peak Difference	Peak Status	Angle	Height
1	1.362 GHz	45.4 dBµV/m	74 dBµV/m	-28.6 dB	Pass	-155 Degree	1 m

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status	Angle	Height
1	1.362 GHz	36.9 dBµV/m	54 dBµV/m	-17.1 dB	Pass	-155 Degree	1 m

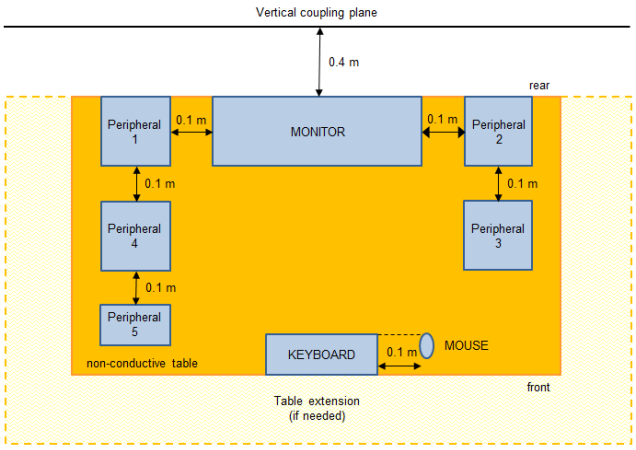
2.2 Test Conditions and Results - Conducted emissions acc. to ANSI C63.4

2.2.1 Information

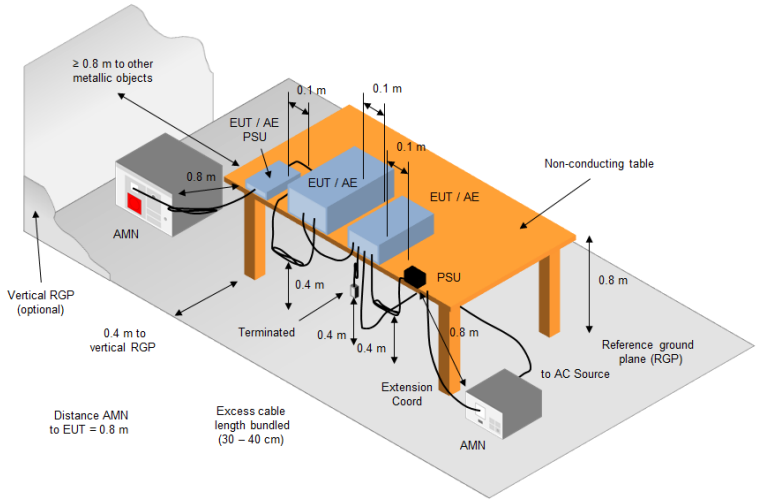
Test Information	
Reference	FCC 15.107, ICES-003, 6.1
Reference method	ANSI C63.4:2014+A1:2017 Section 12
Measurement range	150 kHz to 30 MHz
Equipment class	Class B
Equipment type	Table top
Temperature [°C]	25
Humidity [%]	55
Operator	Ruslan Colbasiuc
Date	2020-08-13

2.2.2 Setup

Equipment placement



Test Setup



2.2.3 Equipment

Test Software			
Description	Manufacturer	Name	Version
EMC Software	DARE Instruments	Radimation	2016.1.10

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
AMN	Schwarzbeck	NSLK 8128	EF00975	2019-07	2021-07
EMI Test Receiver	R&S	ESU26	EF00887	2020-07	2021-07
Climatic Sensor	Embedded Data Systems, LLC.	9A00100000254 77E	EF01124	2020-03	2021-03

2.2.4 Procedure

Exploratory measurement

1. The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
2. The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
3. The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length).
4. The LISN measurement port was connected to a measurement receiver
5. I/O cables were bundled not longer than 0.4 m
6. Measurement was performed in the frequency range 0.15 – 30MHz on each current-carrying conductor
7. To maximize the emissions the cable positions were manipulated
8. The worst configuration of EUT and cables is shown on a test setup picture at item 1.3

Final measurement

1. The EUT was placed on a non conductive table 0.8 m above the reference ground plane and 0.4 m away from the vertical conducting plane (ANSI C63.4: 2014 item 7.3.1)
2. The power cord that is normally supplied or recommended by the manufacturer was connected to the LISN.
3. The distance between the outer edge of the EUT and the LISN shall be set to 0.8 m. A longer power cord shall be bundled to this length (bundling shall not exceed 40 cm in length).
4. The LISN measurement port was connected to a measurement receiver
5. The EUT and cable arrangement were based on the exploratory measurement results
6. The test data of the worst-case conditions were recorded and shown on the next pages

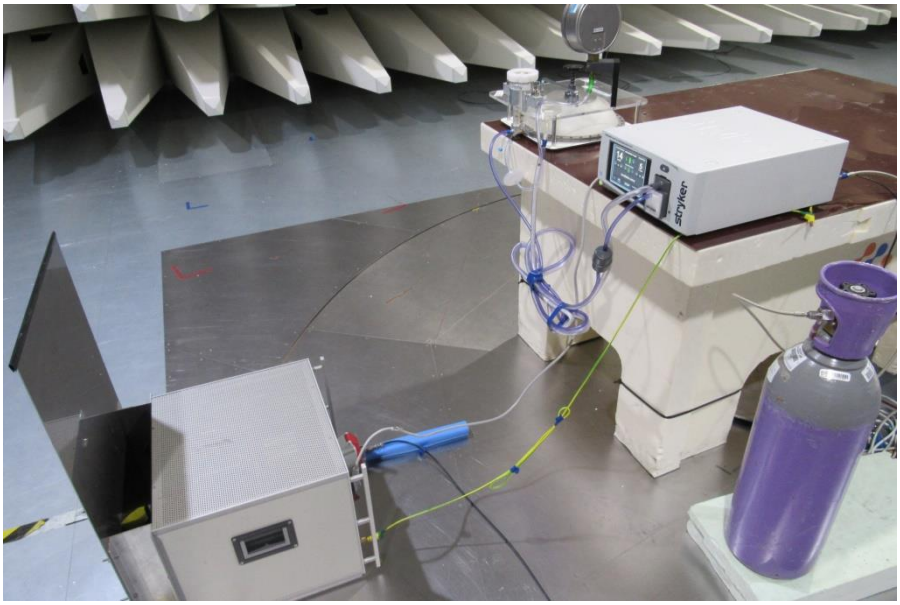
2.2.5 Limits

Class B		
Frequency [MHz]	Quasi-peak Limit [dBµV]	Average Limit [dBµV]
0.15 - 0.5	66 - 56 *	56 - 46 *
0.5 - 5	56	46
5 - 30	60	50
* Decreases with the logarithm of the frequency		

2.2.6 Results

AC power line conducted emissions					
Port	Coupling	Operational mode	EUT Configuration	Verdict	Remark
Mains Connection	AMN	1	1	PASS	-

2.2.7 Setup Photos

Conducted Emission Test Setup


2.2.8 Records

Conducted emissions at the mains power port according to FCC 15B

Project Number:	G0M-1912-8673
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	29984 / 29985
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Date:	2020-08-13
Operating Conditions:	ambient temperature: 25 °C power input: 120 VAC / 60 Hz
LISN:	Schwarzbeck NSLK 8128 (L)
Mode:	1
Applied to Port:	Mains Connection
Note 1:	

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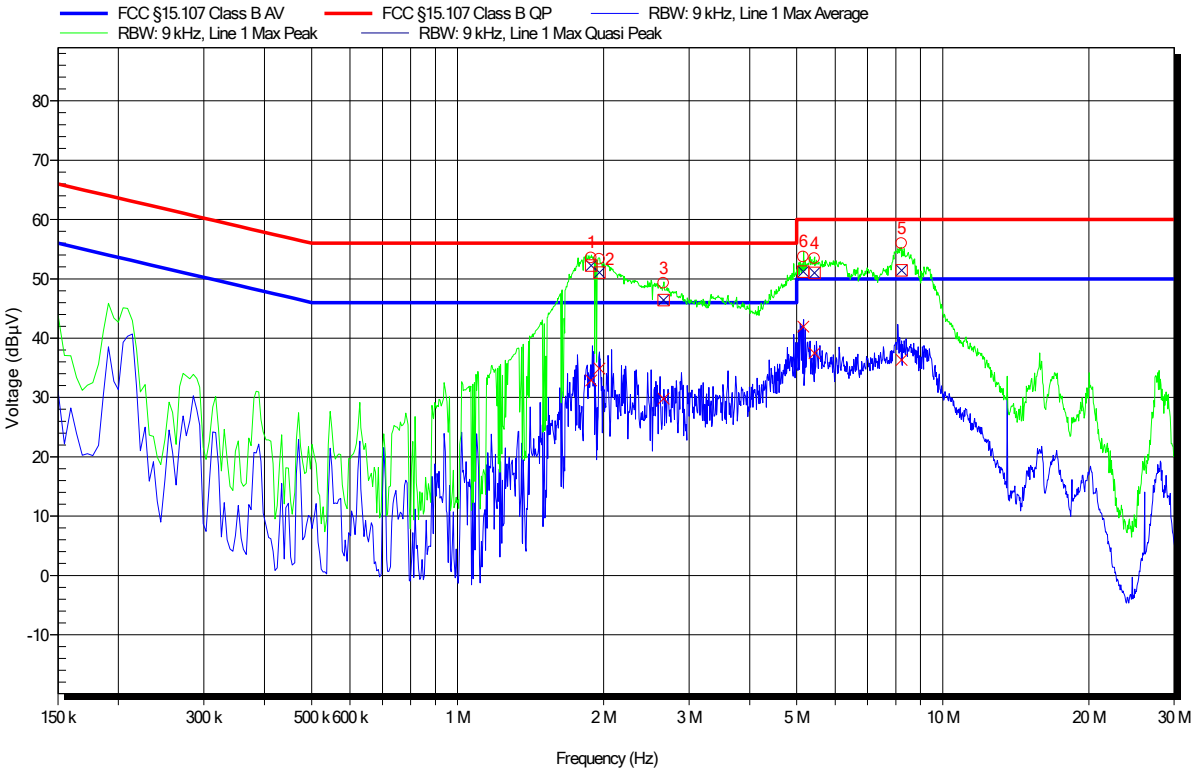

Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	LISN
1	1.886 MHz	52.2 dBµV	56 dBµV	-3.8 dB	Pass	Line 1
2	1.961 MHz	51 dBµV	56 dBµV	-5.0 dB	Pass	Line 1
3	2.66 MHz	46.4 dBµV	56 dBµV	-9.6 dB	Pass	Line 1
4	5.438 MHz	51 dBµV	60 dBµV	-9.0 dB	Pass	Line 1
5	8.232 MHz	51.4 dBµV	60 dBµV	-8.6 dB	Pass	Line 1
6	5.163 MHz	51.2 dBµV	60 dBµV	-8.8 dB	Pass	Line 1

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status	LISN
1	1.886 MHz	32.9 dBµV	46 dBµV	-13.1 dB	Pass	Line 1
2	1.961 MHz	34.9 dBµV	46 dBµV	-11.1 dB	Pass	Line 1
3	2.66 MHz	29.8 dBµV	46 dBµV	-16.2 dB	Pass	Line 1
4	5.438 MHz	37.5 dBµV	50 dBµV	-12.5 dB	Pass	Line 1
5	8.232 MHz	36.3 dBµV	50 dBµV	-13.7 dB	Pass	Line 1
6	5.163 MHz	42 dBµV	50 dBµV	-8.0 dB	Pass	Line 1

Conducted emissions at the mains power port according to FCC 15B

Project Number:	G0M-1912-8673
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Model Description:	Insufflator for Laparoscopy, Vessel Harvesting, Colorectal and Cardiac Procedures
Model:	FM300
Test Sample ID:	29984 / 29985
Test Site:	Eurofins Product Service GmbH
Operator:	Mr. Colbasiuc
Test Date:	2020-08-13
Operating Conditions:	ambient temperature: 25 °C power input: 120 VAC / 60 Hz
LISN:	Schwarzbeck NSLK 8128 (N)
Mode:	1
Applied to Port:	Mains Connection
Note 1:	

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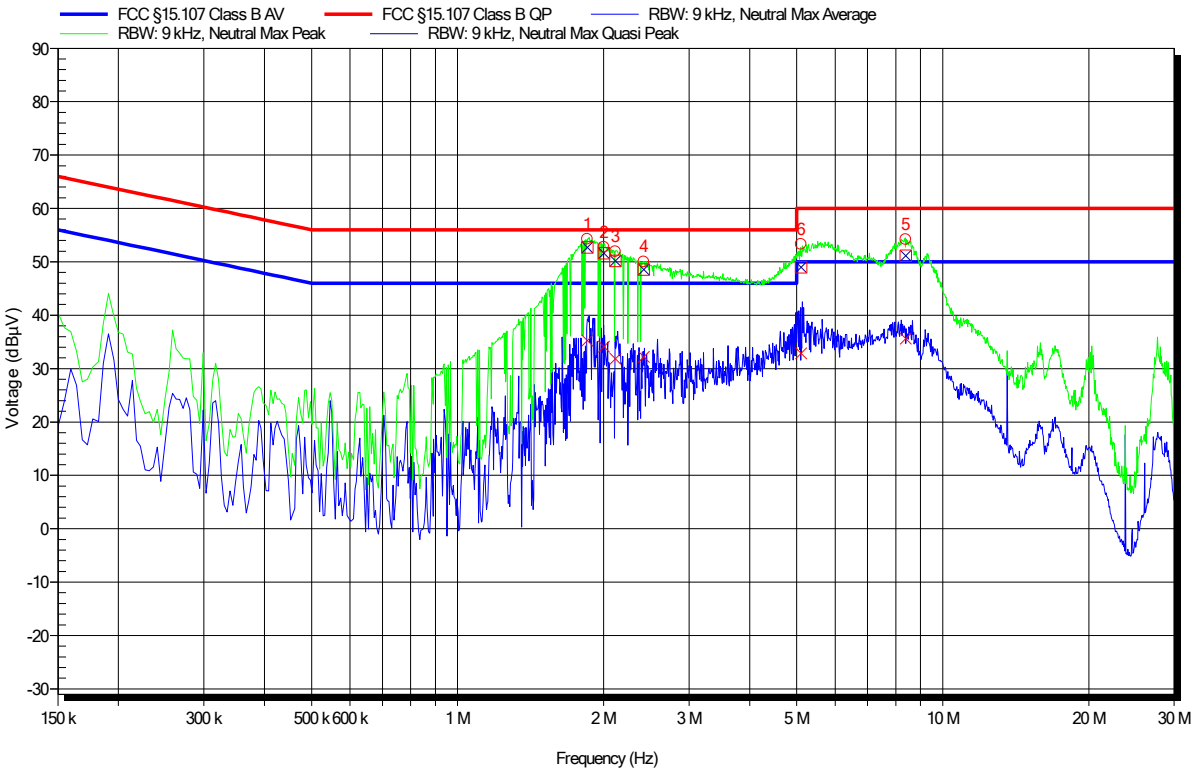

Peak Number	Frequency	Quasi-Peak	Quasi-Peak Limit	Quasi-Peak Difference	Quasi-Peak Status	LISN
1	1.851 MHz	52.7 dBµV	56 dBµV	-3.3 dB	Pass	Neutral
2	2.004 MHz	51.6 dBµV	56 dBµV	-4.4 dB	Pass	Neutral
3	2.116 MHz	50.2 dBµV	56 dBµV	-5.8 dB	Pass	Neutral
4	2.422 MHz	48.6 dBµV	56 dBµV	-7.4 dB	Pass	Neutral
5	8.39 MHz	51.1 dBµV	60 dBµV	-8.9 dB	Pass	Neutral
6	5.105 MHz	49 dBµV	60 dBµV	-11.0 dB	Pass	Neutral

Peak Number	Frequency	Average	Average Limit	Average Difference	Average Status	LISN
1	1.851 MHz	35.2 dBµV	46 dBµV	-10.8 dB	Pass	Neutral
2	2.004 MHz	34.1 dBµV	46 dBµV	-11.9 dB	Pass	Neutral
3	2.116 MHz	31.9 dBµV	46 dBµV	-14.1 dB	Pass	Neutral
4	2.422 MHz	32.2 dBµV	46 dBµV	-13.8 dB	Pass	Neutral
5	8.39 MHz	35.6 dBµV	50 dBµV	-14.4 dB	Pass	Neutral
6	5.105 MHz	32.9 dBµV	50 dBµV	-17.1 dB	Pass	Neutral

End of the Test Report