

RF-EXPOSURE REPORT

FCC 47 CFR Part 2.1091
ISED RSS-102

Maximum permissible exposure

Report Reference No	G0M-2010-9360-TFC091MP-V01
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	  A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Test Firm Designation Number: DE0008 ISED Testing Laboratory site: 3470A-2
Applicant	W.O.M. WORLD OF MEDICINE GmbH
Address	Salzufer 8 10587 Berlin GERMANY
Test Specification	According to FCC/ISED rules
Standard	FCC 47 CFR 2.1091 ISED RSS-102
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
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	Charline Graf
Tested by (+ signature) (Responsible for Test)	Charline Graf 
Approved by (+ signature) (Head of Lab)	Toralf Jahn 
Date of Issue	2020-12-14
Total number of pages	16
General Remarks:	
<p>The test results presented in this report relate only to the object tested.</p> <p>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.</p> <p>This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.</p>	
Additional Comments:	

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2020-12-14	Initial Release	

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EIRP	Equivalent Isotropic Radiated Power
EUT	Equipment Under Test
MPE	Maximum Permissible Exposure

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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
Environment	General public

1.1 Reference Documents

Document Type	Document No.	Issued by	Date
Radio Test Report FCC 47 CFR Part 15 C ISED Canada RSS-210	G0M-2010-9360- TFC225RI-V01	Eurofins Product Service GmbH	2020-11-18

1.2 Power density radiation sources

None

1.3 Field strength radiation sources

Mode	Operating Frequency [MHz]	Maximum electric field strength [V/m]	Maximum magnetic field strength [A/m]	Measurement distance [m]
RFID 13.56 MHz	13.56	1.3	0.015	0.2
Comment:				

1.4 Concurrent Sources

No concurrent radiation sources

2 Result Summary

FCC MPE Evaluation - Single radiation sources					
Product Standard Reference	Requirement	Reference Method	Mode	Distance [m]	Verdict
47 CFR 2.1091	Maximum permissible exposure	FCC KDB 447498	RFID 13.56 MHz	0.20	PASS
Comment:					

ISED MPE Evaluation - Single radiation sources					
Product Standard Reference	Requirement	Reference Method	Mode	Distance [m]	Verdict
ISED RSS-102	Maximum permissible exposure	ISED RSS-102	RFID 13.56 MHz	0.20	PASS
Comment:					

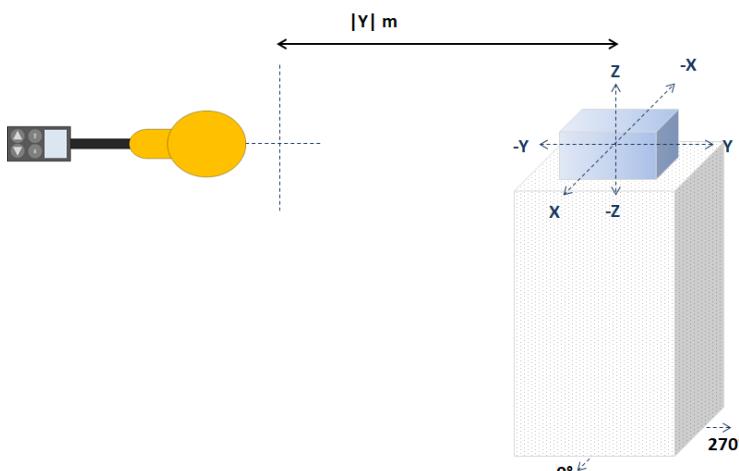
3 Radiated Field Measurement

3.1 Test Conditions and Results – Electric and magnetic field strength

3.1.1 Information

Test Information	
Measurement Method	Radiated only
Operator	Charline Graf
Date	2020-12-14

3.1.2 Setup

Exposition of measurements along six planes in 3D space	
	<p>All shown planes in 3D space represent the dimensions of the Equipment Under Test. The point of origin is equal to the location of the RFID system respectively the centre of the antenna in the Equipment Under Test.</p>

3.1.3 Equipment

Test Equipment					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Anechoic chamber	Frankonia	AC1	EF00062	2018-07	2021-07
Exposure Level Tester	Narda Safety Test Solutions	ELT-400	EF00605	2020-11	2021-11
Magnetic field probe 100 cm ²	Narda Safety Test Solutions	2300/90.10	EF00606	2020-11	2021-11
EM Radiation Monitor	Narda Safety Test Solutions	EMR-02	EF00058	2020-11	2021-11

3.1.4 Procedure

Test Procedure	
1.	EUT transmitter is activated in test mode under normal conditions.
2.	The perimeter of the EUT is scanned with an electric and magnetic field probe at a fixed distance.
3.	The electric and magnetic field strength is measured.
4.	The maximum field strength values are recorded.

3.1.5 Results

Test Results			
Measurement position	Distance x or y or z [m]	Max. electric field strength [V/m]	Max. magnetic field strength [A/m]
X/Y/Z plane +x	0.2	1.3	0.015

4 RF-Exposure classification

RF-Exposure Categories	
Fixed	A fixed device is defined as a device physically secured at one fixed location and cannot be easily re-located.
Mobile	A mobile device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that a separation distance of at least 20 centimeters is normally maintained between the transmitter's radiating structure(s) and the body of the user or nearby persons.
Portable	A portable device is defined as a transmitting device designed to be used so that the radiating structure(s) of the device is/are within 20 centimeters of the body of the user.

RF-Exposure Categories	
Occupational / Controlled	Limits apply in situations in which persons are exposed as a consequence of their employment provided those persons are fully aware of the potential for exposure and can exercise control over their exposure. Limits for occupational/controlled exposure also apply in situations when an individual is transient through a location where occupational/controlled limits apply provided he or she is made aware of the potential for exposure.
General population / Uncontrolled	Exposures apply in situations in which the general public may be exposed, or in which persons that are exposed as a consequence of their employment may not be fully aware of the potential for exposure or cannot exercise control over their exposure.

5 RF-Exposure limits

FCC Limits – General Population / Uncontrolled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.3 – 1.34	614	1.63	1000	30
1.34 – 30	824/f	2.19/f	1800/f ²	30
30 – 300	27.5	0.073	2	30
300 – 1500	-	-	f/150	30
1500 – 100000	-	-	10.0	30

FCC Limits – Occupational / Controlled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.3 – 3.0	614	1.63	1000	6
3.0 – 30	1842/f	4.89/f	9000/f ²	6
30 – 300	61.4	0.163	10.0	6
300 – 1500	-	-	f/30	6
1500 – 100000	-	-	50	6

ISED Limits – General Population / Uncontrolled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.003 – 10	83	90	-	Instantaneous
0.1 – 10	-	0.73/f	-	6
1.1 – 10	87/f ^{0.5}	-	-	6
10 – 20	27.46	0.0728	2	6
20 – 48	58.07/f ^{0.5}	0.1540/f ^{0.25}	8.944/f ^{0.5}	6
48 – 300	22.06	0.05852	1.291	6
300 – 6000	3.142·f ^{0.3417}	0.008335·f ^{0.3417}	0.02619·f ^{0.6834}	6
6000 – 15000	61.4	0.163	10	6
15000 – 150000	61.4	0.163	10	616000/f ^{1.2}
150000 – 300000	0.158·f ^{0.5}	4.21·10 ⁻⁴ ·f ^{0.5}	6.67·10 ⁻⁵ ·f	616000/f ^{1.2}

ISED Limits – Occupational / Controlled Exposure				
Frequency range [MHz]	Electric field strength [V/M]	Magnetic field strength [A/M]	Power density [W/m ²]	Averaging time [min]
0.003 – 10	170	180	-	Instantaneous
0.1 – 10	-	1.6/f	-	6
1.1 – 10	193/f ^{0.5}	-	-	6
10 – 20	61.4	0.163	10	6
20 – 48	129.8/f ^{0.5}	0.3444/f ^{0.25}	44.72/f ^{0.5}	6
48 – 300	49.33	0.1309	6.455	6
300 – 6000	15.60·f ^{0.25}	0.04138·f ^{0.25}	0.6455·f ^{0.5}	6
6000 – 15000	137	0.364	50	6
15000 – 150000	137	0.364	50	616000/f ^{1.2}
150000 – 300000	0.354·f ^{0.5}	9.40·10 ⁻⁴ ·f ^{0.5}	3.33·10 ⁻⁵ ·f	616000/f ^{1.2}

6 RF-Exposure Evaluation

Evaluation Relations
$\lambda[m] = \frac{c \left[\frac{m}{s} \right]}{f[Hz]} ; R_{FF}[m] \geq \frac{2 \cdot D[m]^2}{\lambda[m]}$
$S[W/m^2] = \frac{P_{E.I.R.P.}[W]}{4\pi R[m]^2} ; R[m] = \sqrt{\frac{P_{E.I.R.P.}[W]}{4\pi S[W/m^2]}}$
$DCC [dB] = 10 \cdot \log_{10} \left(\frac{DC[\%]}{100} \right)$
$\sum_{i=1}^N \frac{S_i \left[\frac{W}{m^2} \right]}{S_{Li} \left[\frac{W}{m^2} \right]} + \sum_{j=1}^M \left(\frac{E_j \left[\frac{V}{m} \right]}{E_{Lj} \left[\frac{V}{m} \right]} \right)^2 + \sum_{k=1}^O \left(\frac{H_k \left[\frac{A}{m} \right]}{H_{Lk} \left[\frac{A}{m} \right]} \right)^2 < 1$

Evaluation Procedure
<u>Standalone operation evaluation:</u>
For each radio and frequency band the worst case transmission mode with the highest peak conducted or radiated power is evaluated at the frequency that results in the most restrictive rf-exposure limit. From the peak power values, antenna gains and duty cycles taken from the reference documents, the source average radiated power values are calculated. From the average radiated power the power densities at antenna far-field distance is calculated. The distance from the radiation source for compliance power density is calculated. If the separation distance is lower than the far-field distance, the far-field distance is given as compliance separation distance because the plane wave power density assessment is only valid in the far-field of the radiation source.
For radiation sources for which the average electric and magnetic fields are measured using field probes, the measured field strength values are compared to the reference limits. For those sources no calculations are performed. Compliance with the reference values is determined with the near field measurements.
<u>Concurrent operation evaluation:</u>
First the evaluation distance is set to an appropriate value. For all radiation sources for which power densities are calculated, the power densities at the evaluation distance are calculated and for all other sources the electric or magnetic field strengths are measured using field probes. Finally the ratios of the power densities and/or field strength values and the corresponding limits are calculated and summed and the sum is compared to the maximum of 1.

7 Single Source Evaluation Results - FCC

RFID 13.56 MHz	
Evaluation distance [m]	0.20
Transmission Mode	
Transmission Frequency (f) [MHz]	13.56
Electric field strength	
Compliance field strength limit [V/m]	60.77
Measured field strength [V/m]	1.30
Field strength ratio	0.00
Magnetic field strength	
Compliance field strength limit [A/m]	0.16
Measured field strength [A/m]	0.02
Field strength ratio	0.01
Compliance	
Verdict	PASS
Comment:	

8 Single Source Evaluation Results - ISED

RFID 13.56 MHz	
Evaluation distance [m]	0.20
Transmission Mode	
Transmission Frequency (f) [MHz]	13.56
Electric field strength	
Compliance field strength limit [V/m]	27.46
Measured field strength [V/m]	1.30
Field strength ratio	0.00
Magnetic field strength	
Compliance field strength limit [A/m]	0.07
Measured field strength [A/m]	0.02
Field strength ratio	0.04
Compliance	
Verdict	PASS
Comment:	

==== END OF TEST REPORT ====