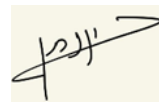


TEST REPORT IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: ELECTROMAGNETIC disturbances – Requirements and tests	
Report Number	E250570.01
Date of issue	15 June 2022
Total number of pages	85
Name of Testing Laboratory preparing the Report	I.T.L. (Product Testing) Ltd.
Applicant's name	Flight Medical Innovations Ltd..
Address	7 Hatnufa St. Petach Tikva 4951025 , PO box 3172, Israel
Test specification:	
Standard	IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
Test procedure	PM120
Non-standard test method	N/A
TRF template used	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.	IEC60601_1_2J_EMC
Test Report Form(s) Originator	CSA Group
Master TRF	Dated 2021-11-11
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General disclaimer: The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

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Test item description..... :	Life Support Ventilator	
Trade Mark..... :	Ventoux	
Manufacturer	Flight Medical Innovations Ltd.	
Model/Type reference	VC3 (12") / VC2 (8") VT1 (Transport)	
Ratings	100 – 240VAC; 50 – 60 Hz; 1.25 A Max.	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
☐ Testing Laboratory:	I.T.L. (Product Testing) Ltd.	
Testing location/ address..... :	1 Bat Sheva St., Lod 7120101 Israel	
Tested by (name, function, signature)..... :		
Approved by (name, function, signature).... :		
☐ Testing procedure: CTF Stage 1:		
Testing location/ address..... :		
Tested by (name, function, signature)..... :	Jonathan Cohen	
Approved by (name, function, signature).... :	Moshe Zohar	
☐ Testing procedure: CTF Stage 2:		
Testing location/ address..... :		
Tested by (name + signature)		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature).... :		
☐ Testing procedure: CTF Stage 3:		
☐ Testing procedure: CTF Stage 4:		
Testing location/ address..... :		
Tested by (name, function, signature)..... :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature).... :		
Supervised by (name, function, signature) :		

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List of Attachments (including a total number of pages in each attachment):**Attachment 1 Declarations (2 page)****Attachment 2 worst case (6 pages)****Summary of testing:****Tests performed (name of test and test clause):**

Tests for: VC3 (12")

Clause 7.1 Radiated disturbances

Clause 7.2.1 AC-Mains Harmonics

Clause 8.9 Electrostatic Discharges

Clause 8.9 Radiated RF EM fields

Clause 8.9 Electrical fast transients / bursts

Clause 8.9 Surges

Clause 8.9 Conducted disturbances induced by RF fields

Clause 8.9 RATED power frequency magnetic fields

Clause 8.9 Voltage dips

Clause 8.9 Voltage interruptions

Clause 8.10 IMMUNITY to proximity fields from RF wireless communications equipment

Clause 8.10 Immunity to proximity magnetic fields

Tests for VC2 (8"):

Clause 7.1 Radiated EMISSIONS

Clause 8.9 Electrostatic Discharges

Clause 8.9 Electrical fast transients / bursts

Testing location:

I.T.L. (PRODUCT TESTING) LTD.

1 Batsheva St., Lod Israel 7120101

Summary of compliance with National Differences (List of countries addressed): N/A☒ **The product fulfils the requirements of IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020**

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Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Bottom Name Plate:



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Test item particulars: Classification of installation and use.....: Portable Type of Applied Part.....: Type BF applied part	
Possible test case verdicts: - test case does not apply to the test object.....: N/A - test object does meet the requirement.....: P (Pass) - test object does not meet the requirement.....: F (Fail)	
Testing.....: N/A Date of receipt of test item 21/06/2021 Date (s) of performance of tests 21/06/2021 – 17/4/2022	
General remarks: "(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. Throughout this report a ☒ comma / ☐ point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-2:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided :	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) : Same as applicant	
General product information (GPI) and other remarks: For test equipment description refer to item 1.1	

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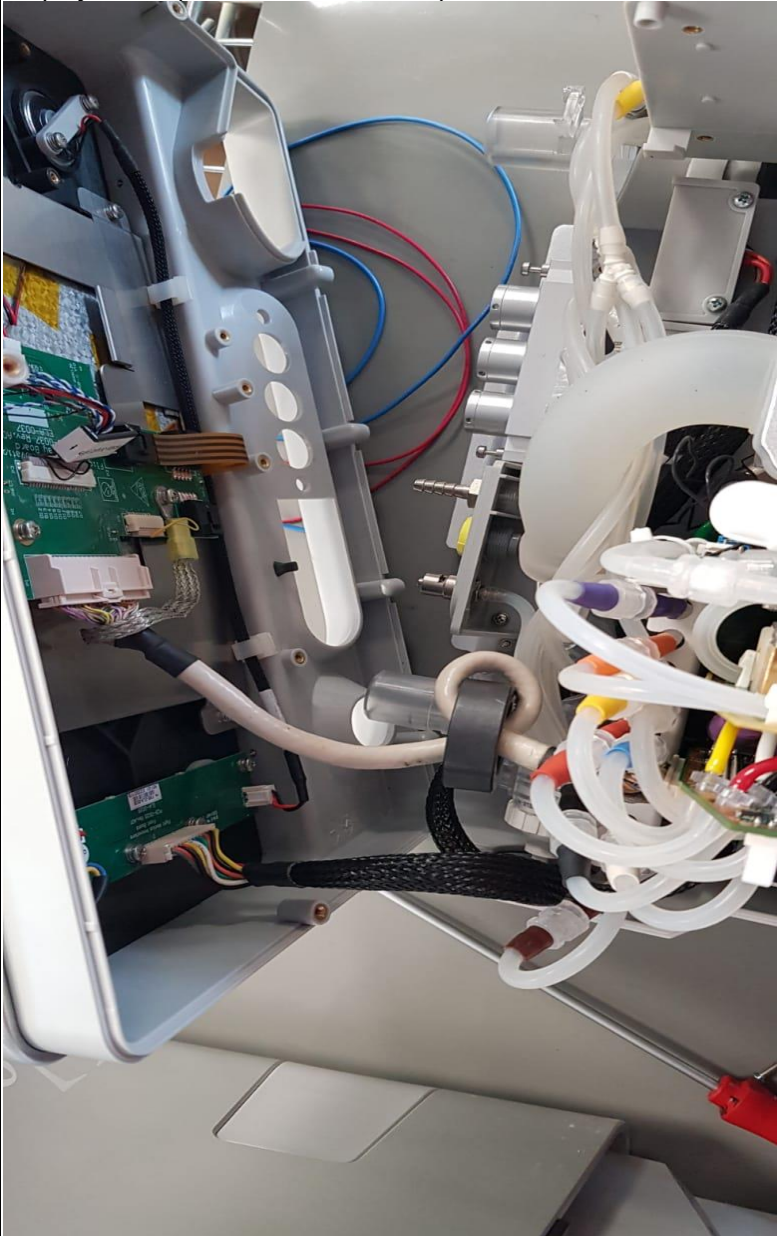
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1 General description of test item

Description	Life Support Ventilator			
Serial number.....	SN VX-12-xxx; 12" screen - SN VX-8-xxx			
Brand name.....	Flight Medical Innovations Ltd.			
Prototype or production version.....	Production			
Units tests and rationale for selected sample size	One sample of each screen size is required for type testing			
Intended use	The Ventoux Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the Ventoux is applicable for adult, and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg. The Ventoux Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospitals, sub-acute emergency rooms, as well as for transport and emergency response applications.			
Intended ENVIRONMENT	Professional healthcare facility			
PORT	AC power port	Cable		
		Specified length [m]	Attached during test	Shielded
	AC Mains	<3m	☒	☐
PORT	DC power port	Cable		
		Specified length [m]	Attached during test	Shielded
	DC Input	<3m	☐	☐
PORT	PATIENT COUPLING PORT	Cable		
		Specified length [m]	Attached during test	Shielded
	Pulse Oximeter	<3m	☒	☐
	Nebulizer Port	<3m	☒	☐
	Capnography Port	<3m	☒	☐
PORT	SIP / SOP PORT	Cable		
		Specified length [m]	Attached during test	Shielded
	USB	<3m	☐	☒
	Remote Alarm – RJ11	<3m	☒	☐
	Lan RJ45	<3m	☒	☒

Supplemental information to the PORTS	-				
Rated power supply		Voltage and frequency	1 ph/ PE	2 ph/N/PE	3 ph/N/PE
	☒	AC: 100 V – 240 V / 50 - 60 Hz	☒ / ☒	☐ / ☐ / ☐	☐ / ☐ / ☐
	☐	DC:			
Rated power	300W Max.				
Protection class	Class 2				
Other parameters	N/A				
Software version	SW Version 1.1				
Hardware version	HW Version A.01				
Dimensions (W x H x D)	34Wx26Dx25H Cm for VC2 (8"), 34Wx26Dx30H Cm for VC3 (12")				
Mounting position:	☒	Table top equipment			
	☐	Wall/Ceiling mounted equipment			
	☐	Floor standing equipment			
	☐	Hand-held equipment			
	☐	Other:			
Modules / parts	Module / parts of test item		Type	Manufacturer	
	EUT enclosure		Plastic	COVESTRO DEUTSCHLA ND AG	
Operating modes	No.	Operating mode of test item	Applied for testing		
			EMISSION	IMMUNITY	
	1	Active Operating configuration – Assist Control, Volume Control, Target Volume 500 ml, Breath Rate 15 bpm, Inhalation Time 1 sec., PEEP 0 cmH2O, no triggers, no oxygen mixing.	☒	☒	
Supplemental information to the operating modes	N/A				
Supporting equipment (not part of the test item)	Accessory / Auxiliary / Simulator		Type	Manufacturer	
	Patient Circuit		Dual Link	Flight Medical	
	Remote Alarm		RJ-45	-	
Documents as provided by the applicant	Description		File name	Issue date	
	Risk management file / Risk analysis		DOC-0428 Rev A02	-	
	Instruction for use (IFU)		DOC-0468 Rev A01	-	

	Technical description	-	-
	Test plan	DOC-0701	-

Modifications to the test item during testing.....:	Corrective Action for radiated emissions - Cable between Main board and Display board (LVDS communication) 
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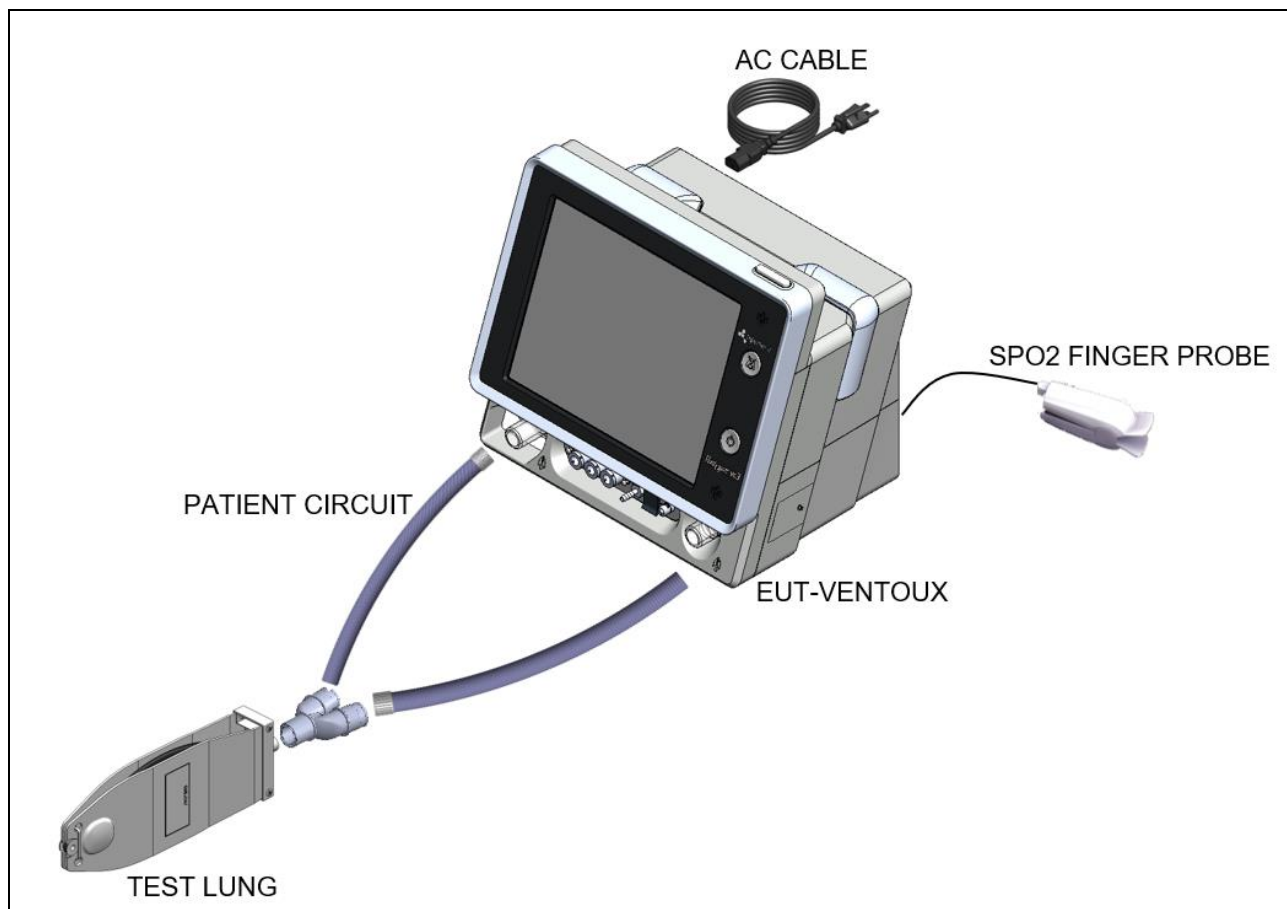
	 ESD corrective action: the machine stops respire after the ESD check, alarm and red led showed up right after it stops. The screen has frozen. Fixed with Apoxy ☒ Manufacturer provided declaration statement. ☐ Manufacturer did not provide declaration statement.
--	--

1.1 Photos of the test item

Photo of test item :	
-----------------------------------	--



1.2 Block diagram of the ME equipment and ME system and all peripherals and auxiliary equipment used



2 Verdict summary section

IEC 60601-1-2 referenced emission standards			
Clause	Requirement – Test case	Basic standard	Verdict
7.1	Terminal disturbance voltages	CISPR 11:2015 +A1:2016 + A2:2019	P
7.1	Radiation disturbance	CISPR 11:2015 +A1:2016 + A2:2019	P
7.1	Terminal disturbance voltages	CISPR 14-1:2016	N/A
7.1	Disturbance Power	CISPR 14-1:2016	N/A
7.1	Radiated disturbances	CISPR 14-1:2016	N/A
7.2.1	AC-Mains Harmonics	IEC 61000-3-2:2005 +A1:2008 +A2:2009	P
7.2.2	AC-Mains Voltage fluctuations and flicker	IEC 61000-3-3:2013	P
IEC 60601-1-2 referenced immunity standards			
Clause	Requirement – Test case	Basic standard	Verdict
8.9	ELECTROSTATIC DISCHARGE	IEC 61000-4-2:2008	P
8.9	Radiated RF EM fields	IEC 61000-4-3:2006 +A1:2007 +A2:2010	P
8.9	Electrical fast transients / bursts	IEC 61000-4-4:2012	P
8.9	Surges	IEC 61000-4-5:2014+A1:2017	P
8.9	Conducted disturbances induced by RF fields	IEC 61000-4-6:2013	P
8.9	RATED power frequency magnetic fields	IEC 61000-4-8:2009	P
8.9	Voltage dips	IEC 61000-4-11:2004 + A1:2017	P
8.9	Voltage interruptions	IEC 61000-4-11:2004 + A1:2017	P
8.9	Electrical transient conduction along supply lines	ISO 7637-2: 2011	N/A
8.10	IMMUNITY to proximity fields from RF wireless communications equipment	IEC 60601-1-2:2014 Table 9	P
8.11	Immunity to proximity magnetic fields	IEC 61000-4-39:2017	P
Supplementary information: N/A			

3 Test conditions

3.1 General

Environmental reference conditions	The climatic conditions during the tests are within the limits specified by the manufacturer for the operation of the EUT and the test equipment. The climatic conditions during the tests were within the following limits:		
	Temperature	Humidity	Atmospheric pressure
	15 °C to 35 °C	30 % to 60 %	86 kPa to 106 kPa
	If explicitly required in the basic standard or applied product standard the climatic values are recorded and documented separately in this test report i.e. at the supplementary information of each test.		
Measurement uncertainties..... :	For all measurements where guidance for the calculation of the instrumentation uncertainty of a measurement is specified in CISPR 16-4-2, IEC 61000-4 series or a product standard, the measurement instrumentation uncertainty has been calculated and applied in accordance with these standards. See statement of measurement uncertainty at the end of the report. In all cases if the test laboratory uncertainty is larger than the value for U_{CISPR} given in CISPR 16-4-2 the uncertainty is included in the test report annex. In case the standards in the IEC 61000-4 series or the product standard requires the indication of the uncertainty in the report these uncertainty values are included in Section 11.		

3.2 Specific test conditions for IEC 60601-1-2 BASIC SAFETY, ESSENTIAL PERFORMANCE

Description of BASIC SAFETY and ESSENTIAL PERFORMANCE

Basic safety relies on the integrity of the enclosure.

The following are the essential performance criteria that the Ventoux must meet following any test

- The ventilator will continue to ventilate according to its parameter settings.
Or
Should the ventilator stop operating, then Audio and Visual warning alarms are produced by the device.
- DOC-0540 - Essential Performance Document based on ISO 80601-2-12

Description how the BASIC SAFETY and ESSENTIAL PERFORMANCE were monitored during each test (Note: for some aspects of BASIC SAFETY this monitoring might be carried out before and after the test)			
ESSENTIAL PERFORMANCE Requirement	Pass Criteria	Fail Criteria	Monitored Indicators
Delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or generation of an ALARM CONDITION:			
oxygen level ALARM CONDITIONS	19>FiO₂<25 - Set FiO₂ LOW alarm to 25 – verify alarm on**	FiO ₂ <19 / FiO ₂ >25 / unexpected Fio ₂ alarm*	- Actual FiO₂ - Alarms on the screen - Audio alarm - Video alarm
AIRWAY PRESSURE	PIP end gauge reading error is within 20% of PCV.	PIP end gauge reading error is more than 20% of PCV.	PIP
expired volume	Error of DELIVERED VOLUME of individual breaths smaller than 35 % and error of the DELIVERED VOLUME averaged over a one minute interval smaller than 25 %.	Error of DELIVERED VOLUME of individual breaths greater than 35 % and error of the DELIVERED VOLUME averaged over a one minute interval greater than 25 %.	- Mechanical lung internal volume indicator - Actual VTe - Actual MVe
reset to default settings	Ventilator does not reset to default settings	Ventilator resets to default settings	- Ventilation mode - Rate - Ti, Vt, PC,PS - PEEP - TriggerFiO₂ - FiO₂Ventilation mode - Slope - PS TermPSV flow term - PS Ti - Waveform
change of operating mode	- When off, ventilator stays off - When on, ventilator stays on - When in settings mode, ventilator stays in settings mode When in charging mode, ventilator stays in charging mode	- When off, ventilator does not stay off - When on, ventilator does not stay on - When in settings mode, ventilator does not stay in settings mode When in charging mode, ventilator does not stay in charging mode	Ventilator mode as reflected by LEDs, screen and mechanical test lung
initiation of an unintended operation	- No change in the display that indicates unintended operation - Alarm reset LED does not change state	- Change in the display that indicates unintended operation - Alarm reset LED changes state	- Ventilator display - Alarm reset LED

3.3 Specific test conditions for IEC 60601-1-2 TEST LEVELS for SPECIAL ENVIRONMENTS

☒ Not Applicable

EM DISTURBANCE levels	TEST LEVEL	Justification for SPECIAL ENVIRONMENTS identified
Conducted RF EMISSIONS		
Radiated RF EMISSIONS		
Harmonic Distortion		
Voltage Fluctuations and Flicker		
IMMUNITY TEST LEVELS		
ELECTROSTATIC DISCHARGES		
Radiated RF EM Fields		
Proximity Wireless fields		
Electrical Fast Transients and bursts		
Surges		
Conducted Disturbances, induced by RF fields		
Rated Power-frequency Magnetic Field		
Voltage Dips and Interruptions		
Proximity magnetic fields		
Supplemental Information: - The resulting final IMMUNITY TEST LEVELS are to be rounded to the nearest whole number or, if a decimal, to a single significant digit - Details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS are to be described in the table below.		
IMMUNITY	Details of the methods and data sources used in determining the appropriate IMMUNITY TEST LEVELS noted above for IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS	
ELECTROSTATIC DISCHARGES		
Radiated RF EM Fields		
Proximity Wireless fields		
Electrical Fast Transients and bursts		
Surges		
Conducted Disturbances, induced by RF fields		
Rated Power-frequency Magnetic Field		
Voltage Dips and Interruptions		
Proximity magnetic fields		

4 EMISSION**4.1 Disturbance Voltage**
☐ Not Applicable.

Tested by	Jonathan Cohen	
Test date	21/06/2021	
Test location (stand).....	ITL lab	
Applied limit class or ENVIRONMENT:	☒	Class A according to applied standard
	☐	Class B according to applied standard
	☐	General Limits (CISPR 14-1 Table 5)
	☐	Limits for mains port of tools (CISPR 14-1 Table 6)
	☐	Other:
Applied limit group.....	☒	Group 1 according to applied standard
	☐	Group 2 according to applied standard
Test set-up description.....	☒	Set-up Type A (40 cm distance to vertical ground plane, 80 cm over ground plane)
	☐	Set-up Type B (40 cm distance to horizontal ground plane)
	☐	Floor standing equipment set-up (10 cm over ground plane)
	☐	Other:
	☐	Artificial hand applied
Supplementary test set-up description		
Test method applied.....	☒	Artificial mains network
	☐	Artificial mains network used as voltage probe

	☐	Voltage probe
	☐	Current probe and capacitive voltage probe (CVP)
	☐	ISN
	☐	In situ CDN (150 Ohm and current probe)
	☐	Other:
All used mains voltage and frequency	Voltage:	Frequency:
	100 V	60 Hz
	240 V	50 Hz
Supplementary information		

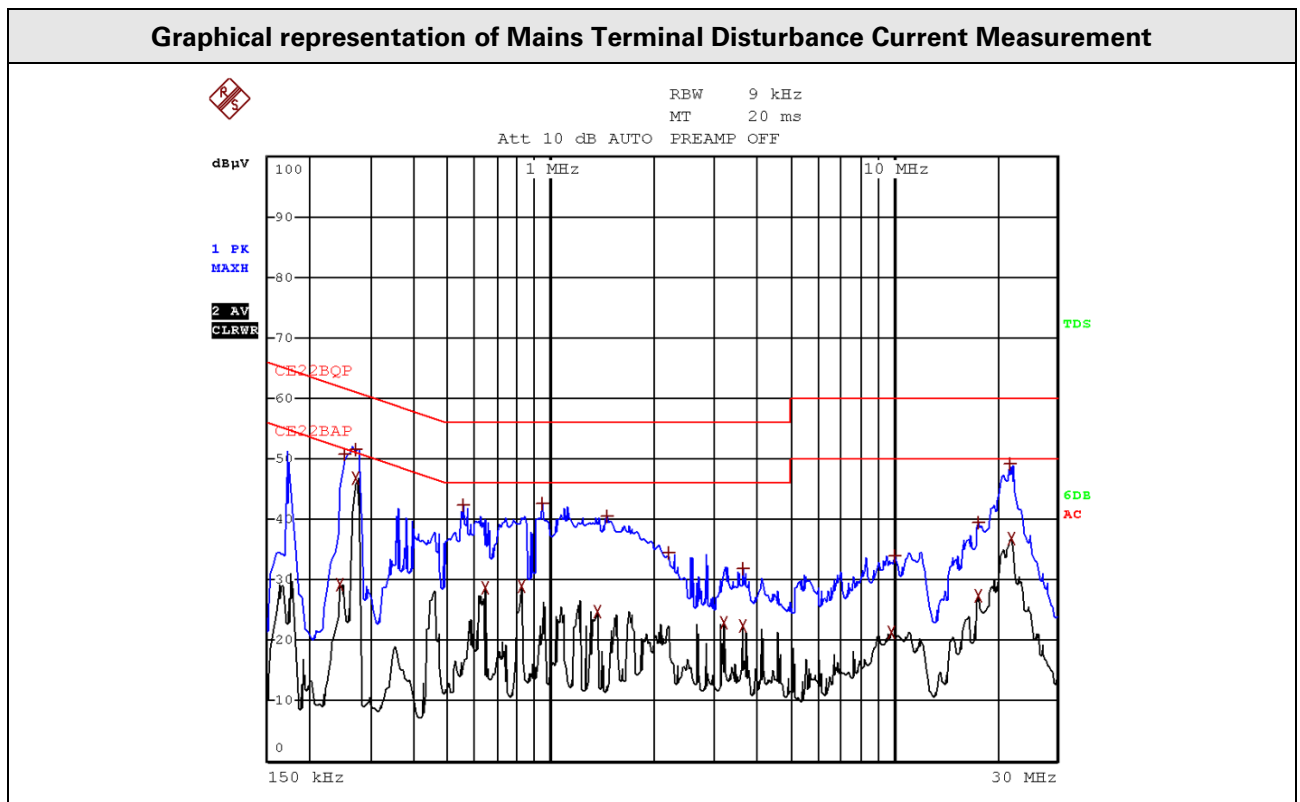
A) Test Conditions and Results – Conducted EMISSIONS				
CISPR 11: 2009 +A1: 2010	TEST: Limits of mains terminal disturbance voltage			Verdict
				P
Laboratory Parameters	Required prior to the test		During the test	
Ambient Temperature	10 to 40 °C		22°C	
Relative Humidity	10 to 90 %		43%	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line		Measurement Point	
	150 kHz to 30 MHz		Mains	
EQUIPMENT mode	Power interface mode		1,2	
	EUT configurations mode		1	
	Operation mode		1	
Limits – Group 1 - Class A				
Power interface mode:1				
Frequency (MHz)	Limit dB (µV)			
	Quasi-Peak	Result*	Average	Result*
0.15 to 0.50	79	-11.19	66	-15.53
0.50 to 30	73	-17.05	60	-15.84
Power interface mode:2				
Frequency (MHz)	Limit dB (µV)			
	Quasi-Peak	Result*	Average	Result*
0.15 to 0.50	79	-8.29	79	-2.64
0.50 to 30	73	-17.51	73	-14.51
Limits - Group 2 - Class A				
Frequency (MHz)	Limit dB (µV)			
	Quasi-Peak	Result*	Average	Result*

0.15 to 0.50	100		90	
0.50 to 5	86		76	
5 to 30	90 to 70		80 to 60	
Limits - Group 2 - Class A Mains supply currents in excess of 100 A per phase				
Frequency (MHz)	Limit dB (μV)			
	Quasi-Peak	Result*	Average	Result*
0.15 to 0.50	130		120	
0.50 to 5	125		115	
5 to 30	115		105	
Limits - Group 1 and 2 - Class B Charging Mode				
Frequency (MHz)	Limit dB (μV)			
	Quasi-Peak	Result*	Average	Result*
0.15 to 0.50	66 to 56		56 to 46	
0.50 to 5	56		46	
5 to 30	60		50	
Supplementary information: * - The result in tables may be a minimum margin to the limit. EUT powered at one of the Nominal input voltages and frequencies.				

Power interface mode:1

EDIT PEAK LIST (Final Measurement Results)				
Trace1:	CE22BQP			
Trace2:	CE22BAP			
Trace3:	---			
TRACE	FREQUENCY	LEVEL dBμV	DELTA LIMIT dB	
2 Average	246 kHz	30.63	-21.26	
1 Quasi Peak	254 kHz	42.54	-19.07	
1 Quasi Peak	274 kHz	49.80	-11.19	
2 Average	274 kHz	35.20	-15.78	
1 Quasi Peak	554 kHz	35.14	-20.85	
2 Average	642 kHz	23.03	-22.96	
2 Average	826 kHz	22.91	-23.08	
1 Quasi Peak	946 kHz	37.72	-18.27	
2 Average	1.366 MHz	12.25	-33.74	
1 Quasi Peak	1.466 MHz	32.25	-23.74	
1 Quasi Peak	2.214 MHz	25.19	-30.80	
2 Average	3.206 MHz	20.71	-25.28	
2 Average	3.634 MHz	18.40	-27.59	
1 Quasi Peak	3.638 MHz	26.50	-29.49	
2 Average	9.806 MHz	20.81	-29.18	
1 Quasi Peak	10.038 MHz	27.64	-32.35	
2 Average	17.602 MHz	26.49	-23.50	
1 Quasi Peak	17.614 MHz	31.64	-28.35	
1 Quasi Peak	21.942 MHz	42.95	-17.05	
2 Average	22.134 MHz	34.15	-15.84	

Charging Mode - Phase



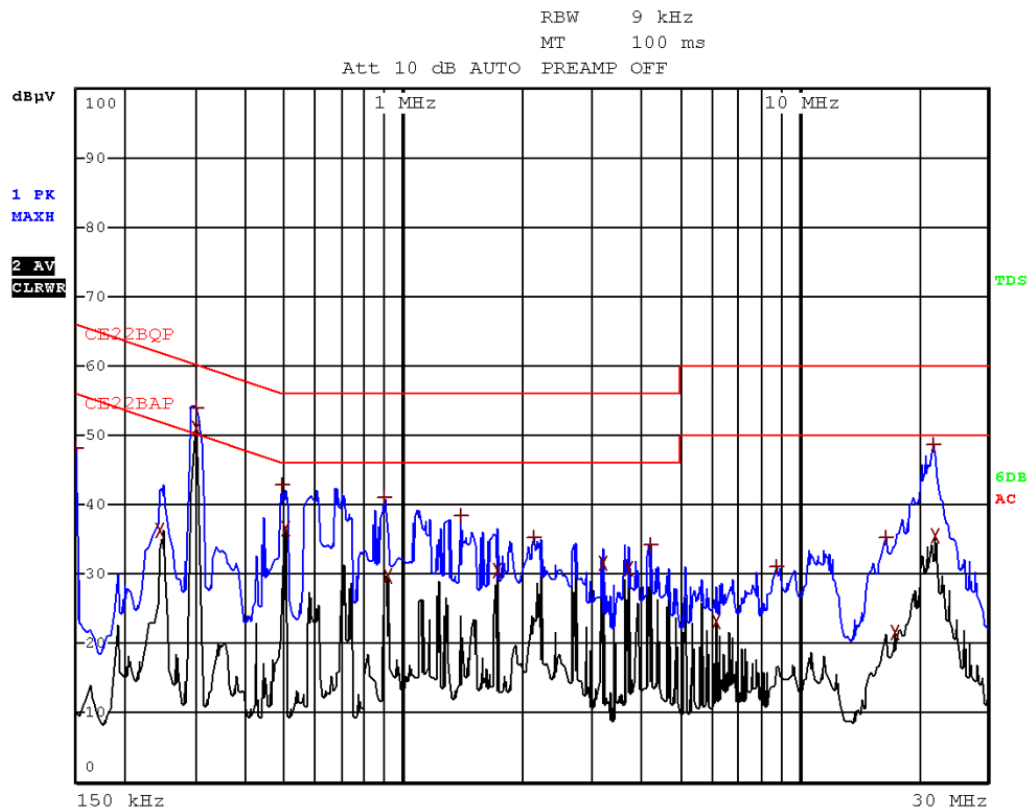
Tabulated Results for Input/Output Terminal Disturbance Current								
Terminal	Test Frequency (MHz)	Meter Reading dB (μV)	Detector (Pk/QP/Av)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB (μA)	Limit 1 dB (μA)	Margin (dB)

Supplementary information:
Note: This table is to be used for combined correction factors (Gain/Loss and Transducer). Use column "Terminal" to identify the Line and /or Neutral that was tested. Other table formats are allowed as long as all information is included.

EDIT PEAK LIST (Final Measurement Results)				
Trace1:	CE22AQP			
Trace2:	CE22AAP			
Trace3:	---			
	TRACE	FREQUENCY	LEVEL dBμV	DELTA LIMIT dB
2	Average	242 kHz	27.57	-38.42
1	Quasi Peak	254 kHz	45.22	-33.77
1	Quasi Peak	270 kHz	45.07	-33.92
2	Average	290 kHz	50.46	-15.53
1	Quasi Peak	666 kHz	37.78	-35.21
2	Average	682 kHz	26.69	-33.30
1	Quasi Peak	1.042 MHz	26.39	-46.60
2	Average	1.074 MHz	25.86	-34.13
2	Average	1.262 MHz	24.02	-35.97
1	Quasi Peak	1.274 MHz	34.50	-38.49
1	Quasi Peak	2.158 MHz	27.55	-45.44
2	Average	2.186 MHz	22.14	-37.85
2	Average	3.642 MHz	19.84	-40.15
1	Quasi Peak	3.746 MHz	21.42	-51.57
2	Average	9.654 MHz	16.73	-43.27
1	Quasi Peak	9.878 MHz	23.53	-49.46
2	Average	17.182 MHz	16.66	-43.33
1	Quasi Peak	17.63 MHz	31.05	-41.94
2	Average	21.802 MHz	28.68	-31.32
1	Quasi Peak	21.826 MHz	37.12	-35.87

Charging Mode – Neutral

Graphical representation of Input/Output Terminal Disturbance Current Measurement

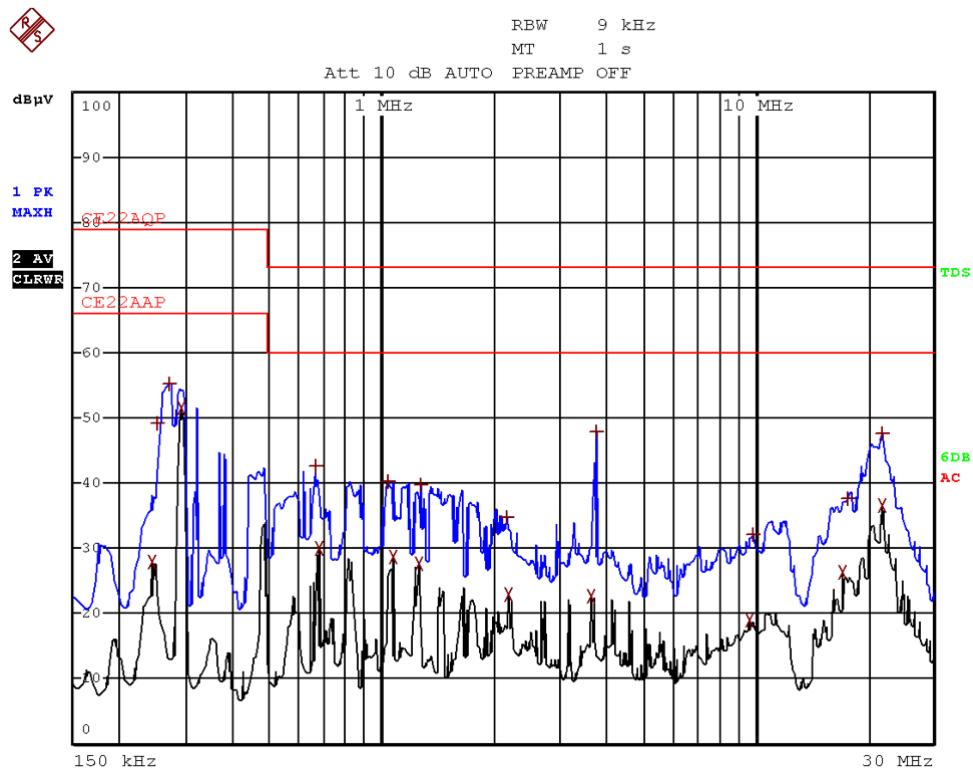


Power interface mode: 2

EDIT PEAK LIST (Final Measurement Results)				
Trace1:	CE22BQP			
Trace2:	CE22BAP			
Trace3:	---			
TRACE	FREQUENCY	LEVEL dBμV	DELTA LIMIT dB	
1 Quasi Peak	246 kHz	40.77	-21.11	
2 Average	246 kHz	36.61	-15.27	
1 Quasi Peak	302 kHz	48.25	-11.93	
2 Average	306 kHz	44.97	-5.10	
1 Quasi Peak	590 kHz	38.48	-17.51	
2 Average	734 kHz	28.35	-17.64	
1 Quasi Peak	1.114 MHz	33.50	-22.49	
2 Average	1.238 MHz	29.49	-16.50	
1 Quasi Peak	1.274 MHz	24.83	-31.16	
2 Average	1.734 MHz	30.58	-15.41	
1 Quasi Peak	2.202 MHz	31.51	-24.48	
2 Average	3.218 MHz	29.62	-16.37	
2 Average	3.714 MHz	30.19	-15.80	
1 Quasi Peak	4.206 MHz	25.52	-30.47	
2 Average	6.19 MHz	20.07	-29.92	
1 Quasi Peak	8.922 MHz	22.43	-37.56	
1 Quasi Peak	17.538 MHz	30.68	-29.31	
2 Average	17.658 MHz	19.47	-30.52	
1 Quasi Peak	21.862 MHz	40.66	-19.33	
2 Average	21.862 MHz	32.48	-17.51	

Charging Mode - Phase

Graphical representation of Mains Terminal Disturbance Current Measurement

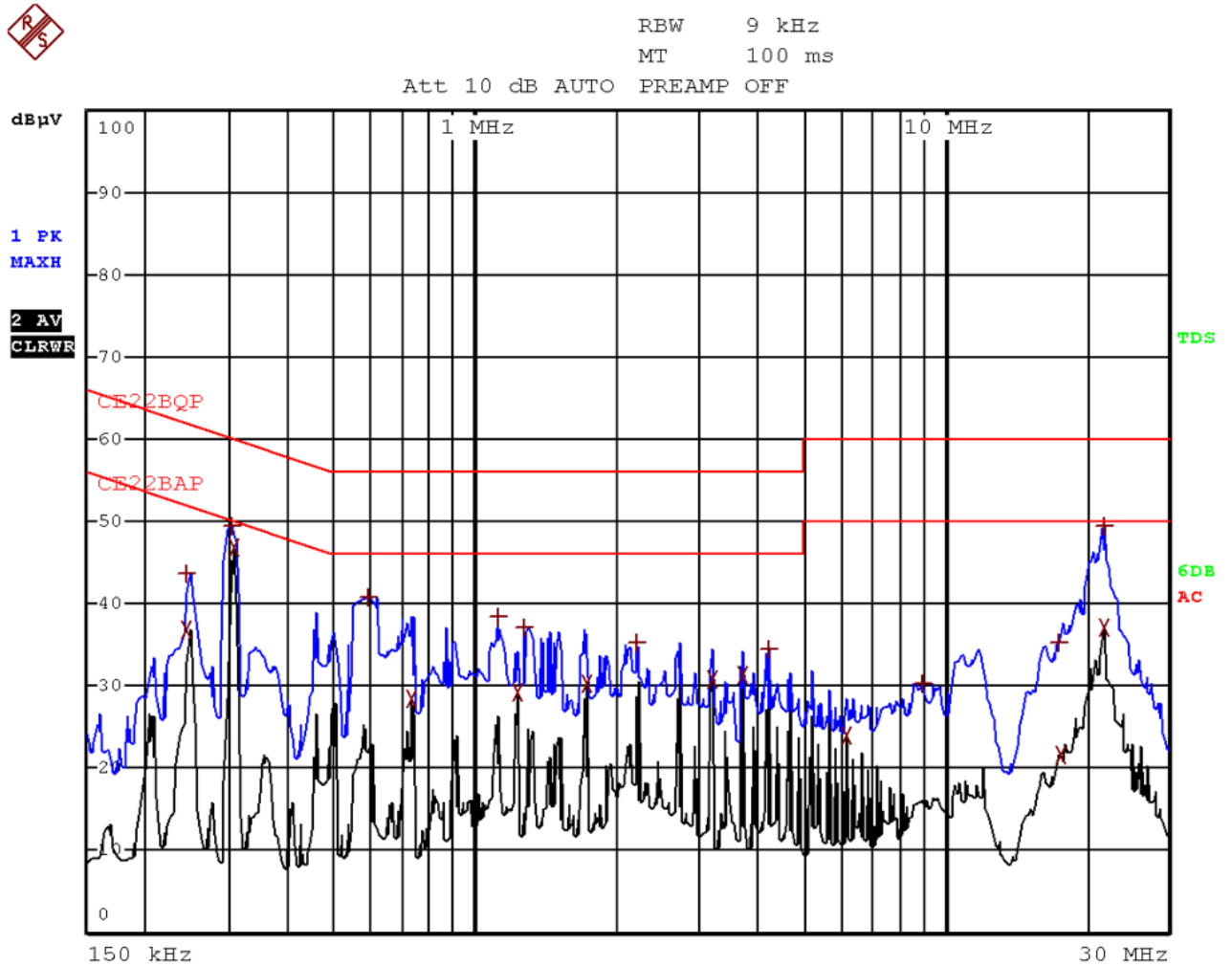


Tabulated Results for Input/Output Terminal Disturbance Current								
Terminal	Test Frequency (MHz)	Meter Reading dB (μV)	Detector (Pk/QP/Av)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB (μA)	Limit 1 dB (μA)	Margin (dB)

Supplementary information:
Note: This table is to be used for combined correction factors (Gain/Loss and Transducer). Use column "Terminal" to identify the Line and /or Neutral that was tested. Other table formats are allowed as long as all information is included.

EDIT PEAK LIST (Final Measurement Results)				
Trace1:	CE22BQP			
Trace2:	CE22BAP			
Trace3:	---			
	TRACE	FREQUENCY	LEVEL dBμV	DELTA LIMIT dB
1	Quasi Peak	150 kHz	14.17	-51.82
2	Average	246 kHz	36.59	-15.29
1	Quasi Peak	298 kHz	52.00	-8.29
2	Average	298 kHz	47.65	-2.64
1	Quasi Peak	494 kHz	40.50	-15.59
2	Average	506 kHz	31.48	-14.51
1	Quasi Peak	898 kHz	35.79	-20.20
2	Average	914 kHz	26.96	-19.03
1	Quasi Peak	1.402 MHz	27.92	-28.07
2	Average	1.73 MHz	30.51	-15.48
1	Quasi Peak	2.138 MHz	29.16	-26.83
2	Average	3.21 MHz	27.84	-18.15
2	Average	3.702 MHz	21.12	-24.87
1	Quasi Peak	4.198 MHz	27.58	-28.41
2	Average	6.17 MHz	9.82	-40.17
1	Quasi Peak	8.774 MHz	24.50	-35.49
1	Quasi Peak	16.51 MHz	28.44	-31.55
2	Average	17.546 MHz	20.16	-29.84
1	Quasi Peak	21.814 MHz	39.52	-20.47
2	Average	22.046 MHz	32.30	-17.69

Charging Mode – Neutral

Graphical representation of Input/Output Terminal Disturbance Current Measurement

Test set-up photo :



Discontinuous disturbances (clicks)

☒ Not Applicable

Disturbance power

☒ Not Applicable

4.2 Radiation Measurements

☐ Not Applicable

Tested by	Yonatan Cohen	
Test date	21/06/2021	
Test location (stand).....	ITL lab	
Applied limit class.....	☒	Class A according to applied standard
	☐	Class B according to applied standard
	☐	Other:
Applied limit Group	☒	Group 1 according to applied standard
	☐	Group 2 according to applied standard
	☐	Other:
Test set up description	☒	Equipment on a table 80 cm height
	☐	Equipment on the floor (isolated from ground plane)
	☐	Other:
Supplementary test set up description	N/A	
Test method applied.....	☒	OATS with measurement distance [m]: 10
	☐	SAC with measurement distance [m]:
	☐	Alternative Test Site
Supplementary information	Tested on VC3 (12") / VC2 (8")	

Test set-up photo	30-200MHz  200-1000MHz
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Test Conditions and Results – Radiated EMISSIONS				
CISPR 11: 2009 +A1: 2010		TEST: Limits for radiated disturbance 0.15 MHz –1 GHz		Verdict
Test site:	☒ OATS	☐ SAC	☐ Alternative Test Site	P
Laboratory Parameters:		Required prior to the test	During the test	
Ambient Temperature		10 to 40 °C	30°C	
Relative Humidity		10 to 90 %	35%	
Fully configured sample scanned over the following frequency range		Frequency range	Measurement Distance	
		☐ 0.15 MHz – 1 GHz	☐ 3 m ☐ 10 m	
		☒ 30 MHz – 1 GHz	☐ 3 m ☒ 10 m	
		☒ 30 MHz – 1 GHz	☐ 3 m ☒ 10 m	
EQUIPMENT mode		Power interface mode	1,2	
		EUT configurations mode	1	
		Operation mode	1	
Limits – Group 1 Class A Charging Mode				
Power interface mode: 1				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		40	-1.7	
230 to 1000		47	-10.9	
Power interface mode: 2				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		40	-0.1	
230 to 1000		47	-10.5	
Limits – Group 1 Class B Charging Mode				
Frequency (MHz)		Limit dB (µV/m)		
		Quasi-Peak	Results *	
30 to 230		30		
230 to 1000		37		
Limits – Group 2 Class A				
Frequency (MHz)		Limits Below 30MHz dB (µA/m); Above 30MHz dB (µV/m)		
		Quasi-Peak	Results *	
0.15 to 30		See standard		
30 to 1000		See standard		
Limits – Group 2 Class B				

Frequency (MHz)	Limits Below 30MHz dB ($\mu\text{A/m}$); Above 30MHz dB ($\mu\text{V/m}$)		
	Quasi-Peak	Average**	Results *
0.15 to 30	39 to 3***	-	
30 to 80.872	30	25	
80,872 to 81,848	50	45	
81,848 to 134,786	30	25	
134,786 to 136,414	50	45	
136,414 to 230	30	25	
230 to 1000	37	32	
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies. * - The result in this table may be a minimum margin to the limit. ** - The Average Limits Apply To Magnetron Driven EQUIPMENT Only. *** - Decreases linearly with the logarithm of frequency			

Result for VC3 (12")

Frequency (MHz)	Antenna Polarization		Azimuth (Degrees)	Antenna Height (cm)	Peak Reading (dB $\mu\text{V/m}$)	QP Reading (dB $\mu\text{V/m}$)	Limit (dB $\mu\text{V/m}$)	Margin (dB)
	Hor.	Ver.						
111.02		X	0	140	34.8	27.8	40	-12.2
115.04		X	170	160	29.1	33.9	40	-6.1
129.3	X		100	220	44.5	39.4	40	-0.6
193.97	X		110	120	45.5	39.9	40	-0.1
209.93	X		340	140	34.8	29.6	40	-10.4
250.025	X		330	120	41.2	36.5	47	-10.5
274.92	X		200	110	34.3	29.9	47	-17.1

Result for VC2 (8")

Frequency (MHz)	Antenna Polarization		Azimuth (Degrees)	Antenna Height (cm)	Peak Reading (dB $\mu\text{V/m}$)	QP Reading (dB $\mu\text{V/m}$)	Limit (dB $\mu\text{V/m}$)	Margin (dB)
	Hor.	Ver.						
172.90	X		63	329.4	37.4	31.9	40.0	-8.1
173.82	X		63	329.4	35.8	31.1	40.0	-8.9
191.70	X		226	272.0	36.0	31.0	40.0	-9.0
599.00	X		30	201.4	40.8	36.1	47.0	-10.9

132.82		X	103	100.0	39.8	35.4	40.0	-4.6
133.81		X	108	100.0	40.4	35.6	40.0	-4.4
171.54		X	121	100.0	42.6	37.8	40.0	-2.2
189.61		X	142	100.0	42.5	37.9	40.0	-2.1
190.63		X	142	100.0	42.9	38.3	40.0	-1.7
192.61		X	142	100.0	42.9	37.8	40.0	-2.2

5 Harmonics IEC 61000-3-2

☐ Not Applicable

Tested by	Yonatan Cohen	
Test date	21/06/2021	
Test location (stand)	ITL lab	
Test set up description	Normal tests set up	
Limit classification in accordance with the standard	☒	Class A
	☐	Class B
	☐	Class C with power > 25 W
	☐	Class C with power < 25 W Option a)
	☐	Class C with power < 25 W Option b)
	☐	Class D
Observation period	Description	Period selected T_{obs}
	☒ Quasi stationary	2.5 min
	☐ Short cyclic	$T_{obs} \geq 10$ cycles =
	☐ Random	$T_{obs} =$
	☐ Long cyclic	Full program cycle or 2.5 min. with highest THC $T_{obs} =$
Control principle used in the sample	Automatically switch	
Supplementary information	N/A	

Test Conditions and Results – Harmonic Current Emissions		
IEC 61000-3-2:2005 +A1: 2008 +A2: 2009	TEST: Limits for harmonic current emissions (EQUIPMENT input current ≤ 16 A per phase)	Verdict
		P
Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	22°C
Relative Humidity	30 to 60 %	48%
EQUIPMENT mode	Power interface mode	1
	EUT configurations mode	1
	Operation mode	1
Classification of EQUIPMENT		Class A
Supplementary information:		

Tabulated Results for Harmonic Current EMISSIONS

Supply Meets EN Requirements

Load Power : 0.1 kW 0.066 kVA Power Factor 0.803
Load Current : 0.3 Arms 0.5 Apk Crest Factor 1.671

Measurement Standard : EN61000-4-7:2002+A1:2009

Limits Applied : EN61000-3-2:2014 No Limits - Actual Power Professional, below Minimum Threshold.

Harmonic Number	Limit Current Amp	Average (filtered) Amp	% Limit	max. Value (Filtered) Amp	% Limit	Assessment
Fundamental :		0.266				
2 :	-	0.002	-	0.004	-	-
3 :	-	0.081	-	0.092	-	-
4 :	-	0.001	-	0.001	-	-
5 :	-	0.024	-	0.027	-	-
6 :	-	0.001	-	0.001	-	-
7 :	-	0.017	-	0.018	-	-
8 :	-	0.001	-	0.001	-	-
9 :	-	0.011	-	0.011	-	-
10 :	-	0.001	-	0.001	-	-
11 :	-	0.009	-	0.010	-	-
12 :	-	0.001	-	0.001	-	-
13 :	-	0.010	-	0.012	-	-
14 :	-	0.001	-	0.001	-	-
15 :	-	0.006	-	0.008	-	-
16 :	-	0.001	-	0.001	-	-
17 :	-	0.005	-	0.005	-	-
18 :	-	0.001	-	0.001	-	-
19 :	-	0.005	-	0.005	-	-
20 :	-	0.001	-	0.001	-	-
21 :	-	0.005	-	0.005	-	-
22 :	-	0.001	-	0.001	-	-
23 :	-	0.004	-	0.005	-	-
24 :	-	0.001	-	0.002	-	-
25 :	-	0.004	-	0.005	-	-
26 :	-	0.001	-	0.001	-	-
27 :	-	0.004	-	0.004	-	-
28 :	-	0.001	-	0.001	-	-
29 :	-	0.004	-	0.004	-	-
30 :	-	0.001	-	0.001	-	-
31 :	-	0.003	-	0.004	-	-
32 :	-	0.001	-	0.001	-	-
33 :	-	0.003	-	0.004	-	-
34 :	-	0.001	-	0.001	-	-
35 :	-	0.002	-	0.002	-	-
36 :	-	0.001	-	0.001	-	-
37 :	-	0.003	-	0.004	-	-
38 :	-	0.001	-	0.001	-	-
39 :	-	0.002	-	0.004	-	-
40 :	-	0.001	-	0.001	-	-
21 - 39 :	-	0.011	-	0.012	-	-

Tabulated Results for Harmonic Current EMISSIONS

Equipment Under Test : ventoux 12
Serial Number :
Tested by : yonatan

	Nominal	Measured Low	Measured High	Deviation	Allowed Deviation	Result
Supply Voltage	: 230	230.11	230.13	+0.13	4.60	PASS
Supply Frequency	: 50	50.00	50.01	+0.01	0.25	PASS
Crest Phase	: 90.0	89.5	89.6	-0.5	3.0	PASS
Crest Factor	: 1.414	1.413	1.413	-0.001	-0.014/+0.006	PASS
Fundamental Voltage	: 230.11	-	-	-	-	-

Harmonic	Harmonic Voltage	Harmonic Ratio	Limit	Result
2	0.14	0.065	0.20	PASS
3	0.04	0.026	0.90	PASS
4	0.02	0.008	0.20	PASS
5	0.01	0.006	0.40	PASS
6	0.00	0.000	0.20	PASS
7	0.00	0.002	0.30	PASS
8	0.00	0.000	0.20	PASS
9	0.00	0.003	0.20	PASS
10	0.00	0.001	0.10	PASS
11	0.00	0.000	0.10	PASS
12	0.00	0.000	0.10	PASS
13	0.00	0.003	0.10	PASS
14	0.00	0.000	0.10	PASS
15	0.00	0.000	0.10	PASS
16	0.00	0.000	0.10	PASS
17	0.00	0.000	0.10	PASS
18	0.00	0.000	0.10	PASS
19	0.00	0.000	0.10	PASS
20	0.00	0.000	0.10	PASS
21	0.00	0.002	0.10	PASS
22	0.00	0.000	0.10	PASS
23	0.00	0.001	0.10	PASS
24	0.00	0.000	0.10	PASS
25	0.00	0.000	0.10	PASS
26	0.00	0.000	0.10	PASS
27	0.00	0.000	0.10	PASS
28	0.00	0.000	0.10	PASS
29	0.00	0.000	0.10	PASS
30	0.00	0.000	0.10	PASS
31	0.00	0.000	0.10	PASS
32	0.00	0.000	0.10	PASS
33	0.00	0.000	0.10	PASS
34	0.00	0.000	0.10	PASS
35	0.00	0.003	0.10	PASS
36	0.00	0.000	0.10	PASS
37	0.00	0.003	0.10	PASS
38	0.00	0.000	0.10	PASS
39	0.00	0.000	0.10	PASS
40	0.00	0.000	0.10	PASS

6 Voltage fluctuation and flicker☐ Not Applicable

Tested by	Yonatan Cohen	
Test date	21/06/2021	
Test Location (stand)	ITL lab	
Test set up description	Normal tests set up	
Test method	☒	4.2.2 Measurement with Flickermeter according IEC 61000-4-15
	☐	4.2.3 Simulation
	☐	4.2.4 Analytical method
	☐	4.2.5 Use of $P_{st} = 1$ curve
Observation time selected	☒	10 minutes
	☐	120 minutes
	☐	24 times switching according to annex B
Limit for d_{max} applied	☒	4 %
	☐	6 %
	☐	7 %
Supplementary information	N/A	

Test Conditions and Results – Voltage changes, voltage fluctuations and flicker			
IEC 61000-3-3: 2013		Test Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	Verdict
			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	22°C	
Relative Humidity	30 to 60 %	48%	
EQUIPMENT mode	Power interface mode :	1	
	EUT configurations mode :	1	
	Operation mode :	1	
Control Method of EQUIPMENT (see below) :			
1 - without additional conditions			
2 - switched manually, or switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.			
3 - attended while in use, or switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a			

few tens of seconds) or manual restart, after a power supply interruption.

Supplementary information:

7 IMMUNITY

7.1 Information specific for IEC 60601-1-2

IMMUNITY Pass/Fail Criteria		
Product Function related to Basic Safety and Essential performance	Pass/Fail Criteria description (see EMC test sections for any additional Part 2 P/F criteria)*	Part 2 reference (if applicable)
oxygen level ALARM CONDITIONS	• $19 > FiO_2 < 25$ Set FiO_2 LOW alarm to 25 – verify alarm on**	
AIRWAY PRESSURE	PIP end gauge reading error is within 20% of PCV.	
expired volume	Error of DELIVERED VOLUME of individual breaths smaller than 35 % and error of the DELIVERED VOLUME averaged over a one minute interval smaller than 25 %.	
reset to default settings	Ventilator does not reset to default settings	
change of operating mode	• When off, ventilator stays off • When on, ventilator stays on • When in settings mode, ventilator stays in settings mode When in charging mode, ventilator stays in charging mode	
initiation of an unintended operation	• No change in the display that indicates unintended operation • Alarm reset LED does not change state	
oxygen level ALARM CONDITIONS	• $19 > FiO_2 < 25$ Set FiO_2 LOW alarm to 25 – verify alarm on**	
AIRWAY PRESSURE	PIP end gauge reading error is within 20% of PCV.	
expired volume	Error of DELIVERED VOLUME of individual breaths smaller than 35 % and error of the DELIVERED VOLUME averaged over a one minute interval smaller than 25 %.	
reset to default settings	Ventilator does not reset to default settings	
change of operating mode	• When off, ventilator stays off • When on, ventilator stays on • When in settings mode, ventilator stays in settings mode When in charging mode, ventilator stays in charging mode	
initiation of an unintended operation	• No change in the display that indicates unintended operation • Alarm reset LED does not change state	

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Note: Specific, detailed IMMUNITY pass/fail criteria, are based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. These pass/fail criteria must be included in the RISK MANAGEMENT FILE

7.2 Electrostatic Discharge

☐ Not Applicable

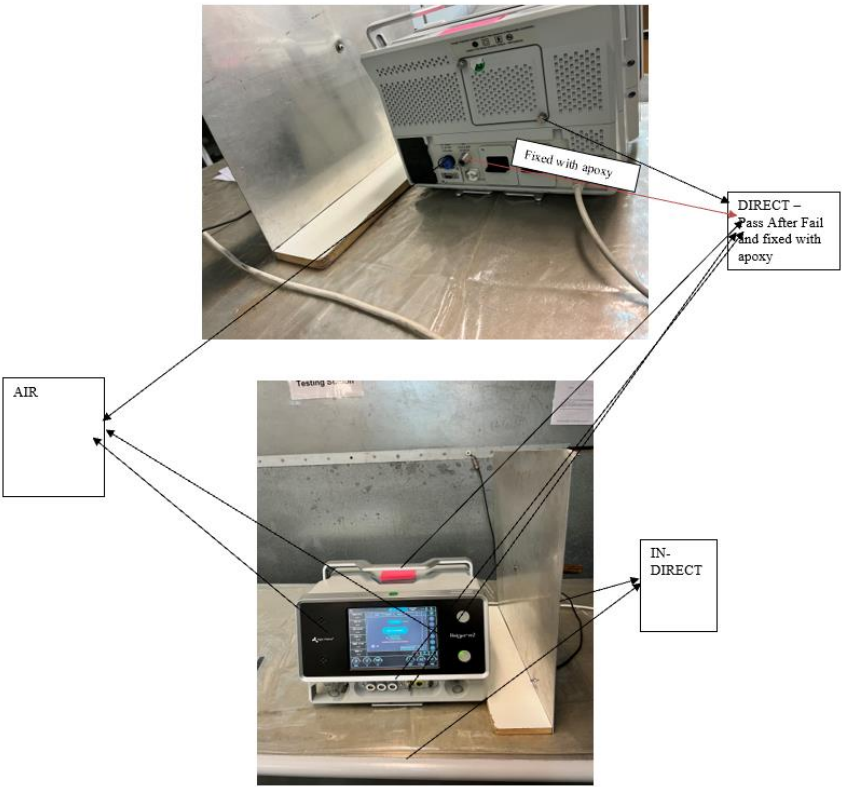
Tested by	Yonatan Cohen		
Test date	21/06/2021		
Test location (Stand)	ITL lab		
Test set up	☒	Table top equipment	
	☐	Floor standing equipment	
	☐	Wall or ceiling mounted equipment (Treated as table top)	
Supplementary test set up description.....	N/A		
Size of horizontal coupling plate ..	1,6 x 0,8 m		
Number of DISCHARGES for each test point.....	10 positive / 10 negative		
DISCHARGE interval	1s		
Environmental conditions	Temperature:	23°C	(Range: 15 °C to 35 °C)
	Humidity:	55%	(Range: 30 % to 60 %)
	Atmospheric pressure:	101.3kPa	(Range: 86 kPa to 106 kPa)
Supplementary information	Tested on VC3 (12") / VC2 (8")		

Test set-up photo :



Result for VC3 (12")

Photo or drawing of selected test points..... :



Fixed with apoxy

DIRECT – Pass After Fail and fixed with apoxy

AIR

IN-DIRECT

Test results for ELECTROSTATIC DISCHARGE						
No.	Location of DISCHARGE	Type	Polarity	TEST LEVEL [kV]	Operating mode	Observations
1	Nebulizer port	Con	P / N	8	1	Pass
2	Screen metal Frame	Con	P / N	8	1	Pass
3	Handle	Con	P / N	8	1	Pass
4	Air filter screens	Con	P / N	8	1	Pass
5	O2 regulator	Con	P / N	8	1	Pass
6	Silent & On/Off buttons	Air	P / N	2, 4, 8, 15	1	Pass
7	Speakers	Air	P / N	2, 4, 8, 15	1	Pass
8	DC power inlet cover	Air	P / N	2, 4, 8, 15	1	Pass
HCP = Horizontal coupling plate; VCP = Vertical coupling plate						
N= Negative; P= Positive						
Con= Conducted Discharge; Air= Air Discharge						
Supplementary information: N/A						

Result for VC2 (8")

Photo or drawing of selected test points..... :



Fixed with apoxy



IN-DIRECT

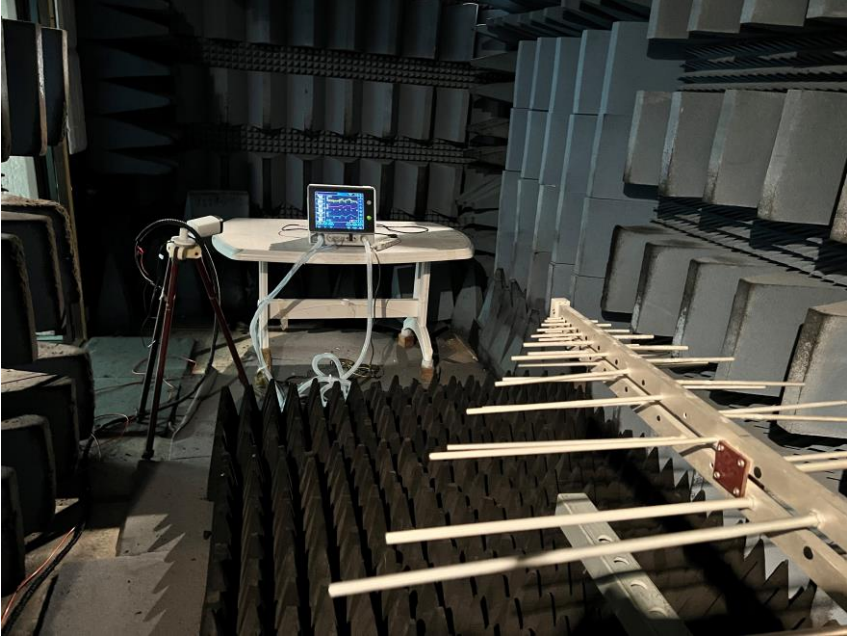
AIR

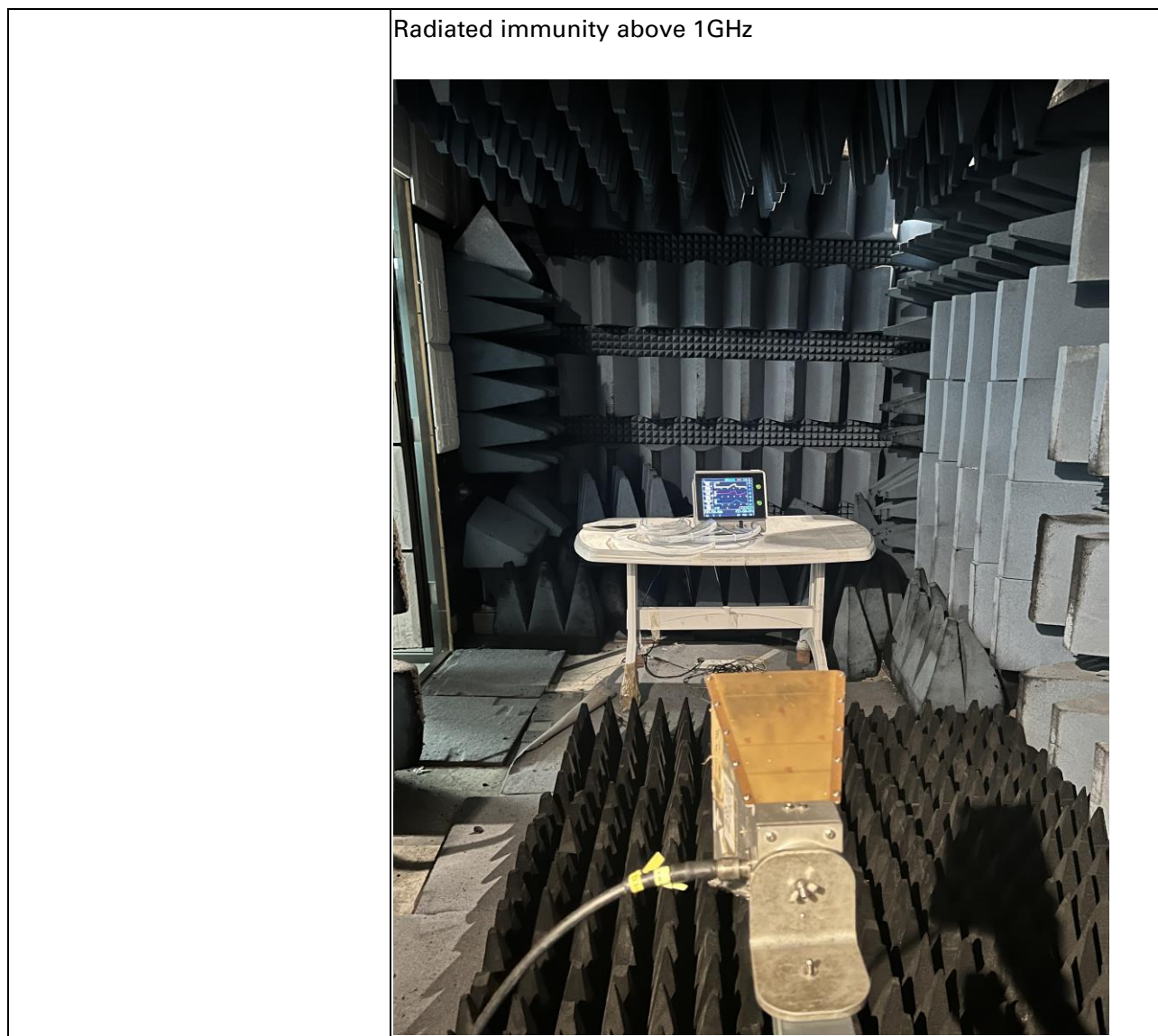
DIRECT - Pass After Fail and fixed with apoxy

Test results for ELECTROSTATIC DISCHARGE						
No.	Location of DISCHARGE	Type	Polarity	TEST LEVEL [kV]	Operating mode	Observations
1	Nebulizer port	Con	P / N	8	1	Pass
2	Screen metal Frame	Con	P / N	8	1	Pass
3	Handle	Con	P / N	8	1	Pass
4	Air filter screens	Con	P / N	8	1	Pass
5	O2 regulator	Con	P / N	8	1	Pass
6	Silent & On/Off buttons	Air	P / N	2, 4, 8, 15	1	Pass
7	Speakers	Air	P / N	2, 4, 8, 15	1	Pass
8	DC power inlet cover	Air	P / N	2, 4, 8, 15	1	Pass
HCP = Horizontal coupling plate; VCP = Vertical coupling plate N= Negative; P= Positive Con= Conducted Discharge; Air= Air Discharge						
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)						

7.3 Radiated RF EM fields

☐ Not Applicable.

Tested by	Yonatan Cohen
Test date	21/06/2021
Test location (Stand)	ITL lab
Test set-up	☒ Equipment on the table (0,8 m height) ☐ Equipment standing on floor (0,05 – 0,15 m height)
Supplementary test set up description	N/A
Exposed side of EUT	☒ 0 ° (Front) ☐ 90 ° ☐ 180 ° (Rear) ☐ 270 ° ☐ Top ☐ Bottom
Reason for not exposing a side ...	The EUT is a table top where exposing top and bottom is technically not feasible.
Distance Antenna to EUT	3 m
Step size [%]	1 %
Supplementary information	Tested on VC3 (12")
Test set-up photo	Radiated immunity below 1GHz 

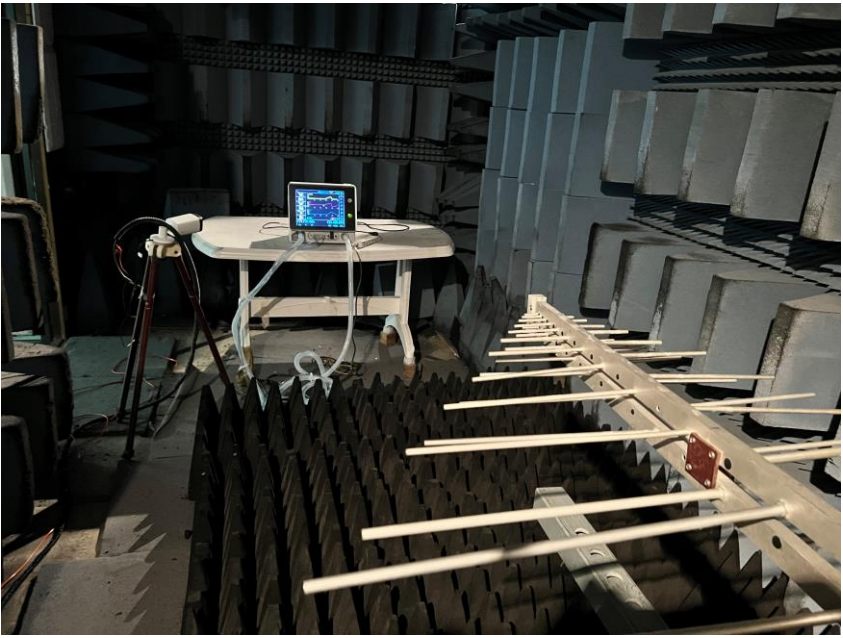


Test results for Radiated RF EM fields						
Frequency range / discrete frequencies	TEST LEVEL [V/m]	Polarisation	Modulation	Operation mode	Dwell time [s]	Observations
80 – 1000 MHz	10	H	AM 1 kHz 80 %	1	3	Pass
1,0 – 2,7 GHz	10	H	AM 1 kHz 80 %	1	3	Pass
80 – 1000 MHz	10	V	AM 1 kHz 80 %	1	3	Pass
1,0 – 2,7 GHz	10	V	AM 1 kHz 80 %	1	3	Pass
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)						

7.4 Proximity fields From RF wireless communications equipment

☐ Not Applicable

Tested by	Yonatan Cohen	
Test date	21/06/2021	
Test location (Stand)	ITL lab	
Test set-up	☒	Equipment on the table (0,8 m height)
	☐	Equipment standing on floor (0,05 – 0,15 m height)
Supplementary test set up description	N/A	
Exposed side of EUT	☒	0 ° (Front)
	☐	90 °
	☐	180 ° (Rear)
	☐	270 °
	☐	Top
	☐	Bottom
Reason for not exposing a side ...	The EUT is a table top where exposing top and bottom is technically not feasible.	
Distance Antenna to EUT	3 m	
Supplementary information	Tested on VC3 (12")	

Test set-up photo	
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Test results for Proximity fields From RF wireless communications equipment

Frequency range / discrete frequencies [MHz]	TEST LEVEL [V/m]	Polarisation	Modulation	Operation mode	Dwell time [s]	Observations
385	27	H	Pulse	1	3	Pass
450	28	H	Pulse	1	3	Pass
710 745 780	9	H	Pulse	1	3	Pass
810 870 930	28	H	Pulse	1	3	Pass
1720 1845	28	H	Pulse	1	3	Pass

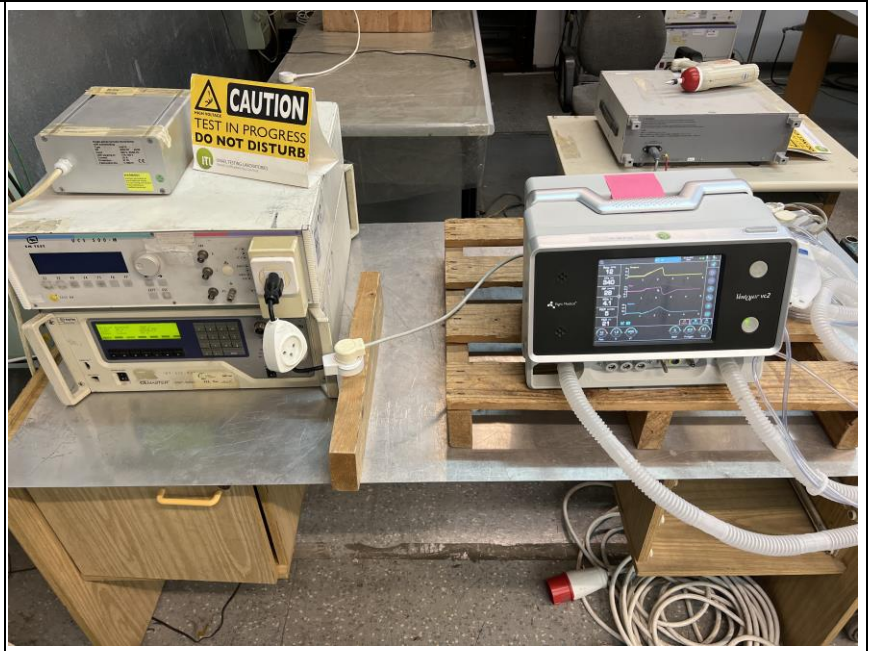
Test results for Proximity fields From RF wireless communications equipment						
Frequency range / discrete frequencies [MHz]	TEST LEVEL [V/m]	Polarisation	Modulation	Operation mode	Dwell time [s]	Observations
1970						
2450	28	H	Pulse	1	3	Pass
5240 5500 5785	9	H	Pulse	1	3	Pass
385	27	V	Pulse	1	3	Pass
450	28	V	Pulse	1	3	Pass
710 745 780	9	V	Pulse	1	3	Pass
810 870 930	28	V	Pulse	1	3	Pass
1720 1845 1970	28	V	Pulse	1	3	Pass
2450	28	V	Pulse	1	3	Pass
5240 5500 5785	9	V	Pulse	1	3	Pass
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)						

7.5 Electrical fast transients / bursts

☐ Not Applicable.

Tested by	Yonatan Cohen
Test date	21/06/2021
Test location (stand)	ITL lab
Test set-up	☒ Equipment on the table ($0,1 \pm 0,01$) m above ground plane
	☐ Equipment standing on floor at ($0,1 \pm 0,05$) m above ground plane
	☐ Artificial hand applied. Location see photo.
Supplementary test set up description	N/A
Repetition frequency	100 kHz
Test time	1 min
Supplementary information	Tested on VC3 (12") / VC2 (8")

Test set-up photo



Result for VC3 (12")

Test results Electrical fast transients / bursts						
PORT	Coupling	Level [kV]	Polarity	Operating mode	Mains voltage / frequency	Observation
Mains	CDN	2	P/N	1	230 V / 50 Hz	None
SIP/SOP	Clamp	2	N	1	230 V / 50 Hz	None
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)						

Result for VC2 (8")

Test results Electrical fast transients / bursts						
PORT	Coupling	Level [kV]	Polarity	Operating mode	Mains voltage / frequency	Observation
Mains	CDN	2	P/N	1	230 V / 50 Hz	None
SIP/SOP	Clamp	2	N	1	230 V / 50 Hz	None
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)						

7.6 Surges Line-to-line, Surges Line-to-ground

☐ Not Applicable

Tested by	Yonatan Cohen
Test date	21/06/2021
Test location (Stand)	ITL lab
Test set up description	Normal test set up
Repetition rate	1 / min
Number of pulses for each coupling	5
Supplementary information	Tested on VC3 (12")

Test set-up photo

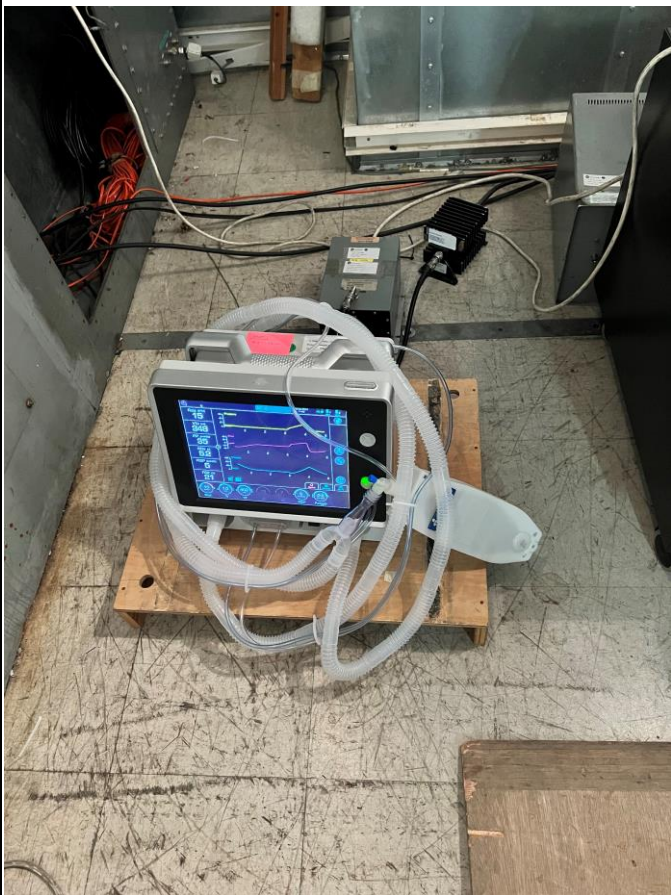


Test results for Surges Line-to-line, Surges Line-to-ground								
PORT	Coupling	CDN (figure no.)	Level [kV]	Polarity	Phase angles [°]	Operating mode	Mains voltage / frequency	Observation
Mains	L1 - N	Mains	1	P / N	0, 90, 180, 270	1	230 V / 50 Hz	None
Mains	L1 – PE N – PE	Mains	2	P / N	0, 90, 180, 270	1	220 V / 60 Hz	None
Lower TEST LEVELS:			☒	The lower TEST LEVELS are tested.				
			☐	The lower TEST LEVELS are not tested (Table 5 table footnote j) applies.)				
Legend: Polarity: P = Positive, N = Negative CDN: Mains = Mains Coupling Network, Signal/Control: e.g. F9 = Figure No. 9 from IEC 61000-4-5								
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)								

7.7 Conducted disturbances induced by RF Fields

☐ Not Applicable

Tested by	Yonatan Cohen	
Test date	21/06/2021	
Test location (Stand)	ITL lab	
Test set-up	☒	Equipment located (0,1 ± 0,05) m above ground plane
	☐	Elevated ground plane according to Annex F (IEC 61000-4-6)
	☐	Artificial hand applied. Location see photo.
Supplementary test set up description	N/A	
Modulation	☒	80 % AM with 1 kHz
	☐	Other:
Step size	1 %	
Supplementary information	Tested on VC3 (12")	

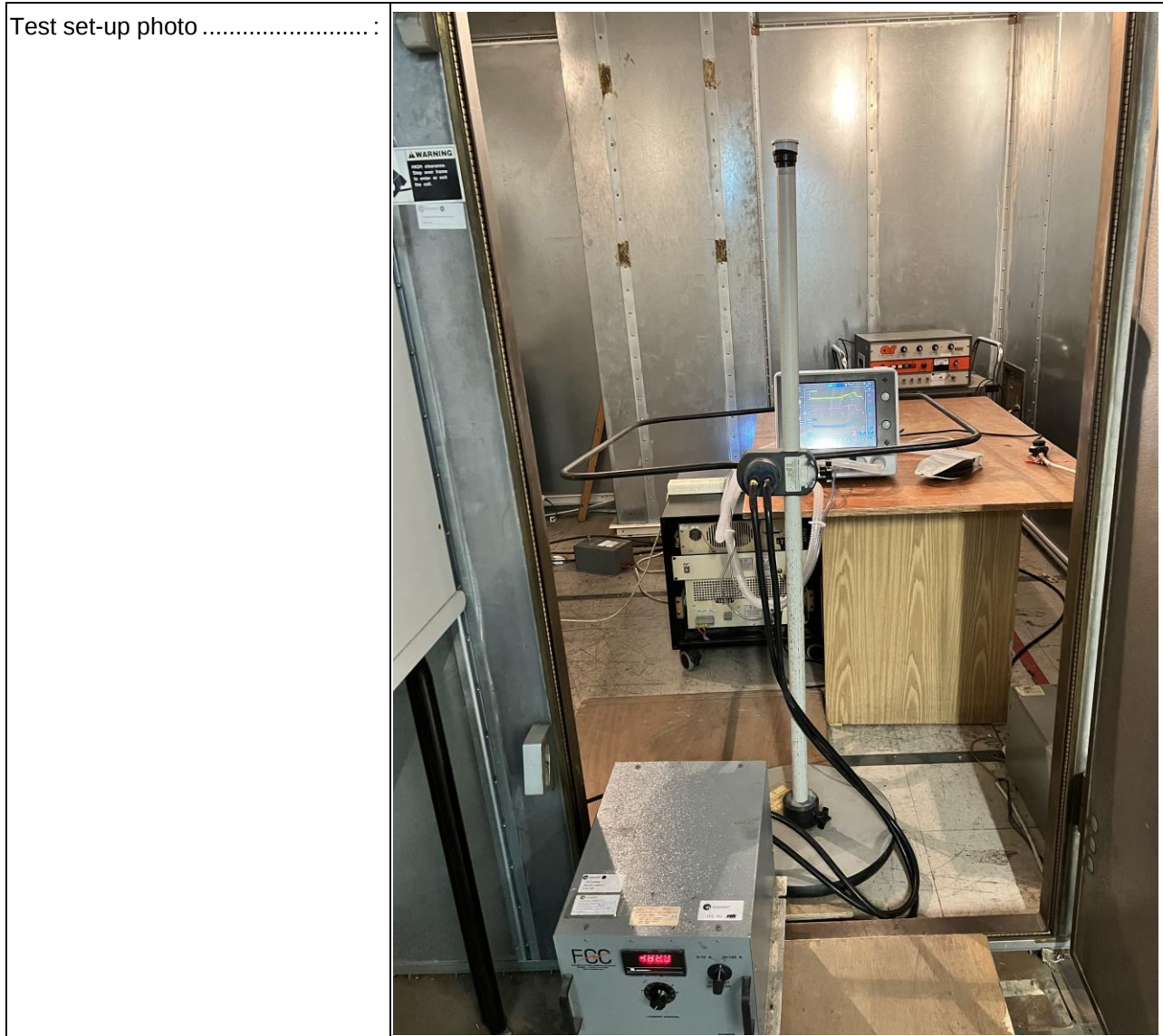
Test set-up photo	
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Test results for Conducted disturbances induced by RF Fields								
Frequency range / discrete frequencies	TEST LEVEL [V]	PORT under test	CDN type	Cable length used [m]	PORT with terminated CDN	Operating mode	Dwell time [s]	Observations
0,15 - 80 MHz	3	Mains	M3	0,3	RS232	1	3	--
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)								

7.8 RATED power frequency magnetic fields

☐ Not Applicable

Tested by	Yonatan Cohen	
Test date	21/06/2021	
Test location (Stand)	ITL lab	
Test set-up	☐	0,1 m above metal surface (floor standing devices)
	☐	Homogeneous field (Helmholtz coil). Dimensions:
	☒	Single Coil. Dimensions: 1 x 1 m
	☐	Single Coil. Dimensions: 1 x 2,6 m
	☐	Other (Describe):
Observations during test	None	
Supplementary information	Tested on VC3 (12")	



Test results for RATED power frequency magnetic fields							
Test frequency	TEST LEVEL [A/m]	Test time [s]		Axis	Operating mode	Mains voltage / frequency	Observations
50 Hz	30	10		x	1	230 V / 50 Hz	None
60 Hz	30	10		y	1	230 V / 50 Hz	None
60 Hz	30	10		z	1	230 V / 50 Hz	None
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)							

7.9 Voltage dips and voltage interruptions

☐ Not Applicable

Tested by	Yonatan Cohen
Test date	21/06/2021
Test location (Stand)	ITL lab
Test set up description	Normal test set up
Repetition rate	10 s
Number of dips or interruptions.....	3
Supplementary information	Tested on VC3 (12")

Test voltage requirements			
Supply Voltage Range	Difference of Max Voltage – Min Voltage	25 % of highest Rated input Voltage	Voltage Dips Test at Min/Max Voltages required (Y/N)
110 - 230	120	25	Y

Test results voltage dips for 0% of U_N for 0,5 cycles and phase angles of 0 °, 45 °, 90 °, 135 °, 180°, 225 °, 270° and 315 °				
U_N [V]	Frequency [Hz]	TEST LEVEL U_T [V]	Operating mode	Observations
230	50	0	2	None
110	60	0	2	None
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)				

Test results voltage dips for 0% of U_N for 1 cycle and phase angles of 0 °				
U_N [V]	Frequency [Hz]	TEST LEVEL U_T [V]	Operating mode	Observations
230	50	0	2	None
110	60	0	2	None
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)				

Test results voltage dips for 70% of U_N for 25 / 30 cycles and phase angles of 0 °				
U_N [V]	Frequency [Hz]	TEST LEVEL U_T [V]	Operating mode	Observations
230	50	161	2	None
110	60	77	2	None
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry				

Test results voltage dips for 70% of U_N for 25 / 30 cycles and phase angles of 0 °				
U_N [V]	Frequency [Hz]	TEST LEVEL U_T [V]	Operating mode	Observations
and cuff pressure control (for tests)				

Voltage interruptions for 0% of U_N for 250 / 300 cycles				
U_N [V]	Frequency [Hz]	TEST LEVEL U_T [V]	Operating mode	Observations
230	50	0	2	
110	60	0	2	
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)				

Test set-up photo :

7.10 Electrical transient conduction along supply lines

☒ Not Applicable

7.11 Proximity magnetic fields

☐ Not Applicable

Tested by	Yonatan Cohen
Test date	21/06/2021
Supplementary information	ITL lab

Magnetic field immunity 9 kHz to 150 kHz		
Test location (stand)	ITL EMC floor	
Test set up description	Normal test set up	
Selected window size	☒	100 mm x 100 mm (maximum)
	☐	Other: --
Test distance d	☒	(50 ± 3) mm
	☐	Other: -- 0.15m
Frequencies applied	☒	30 kHz
	☒	134,2 kHz
Supplementary information.....		

Magnetic field immunity 150 kHz to 26 MHz		
Test location (stand)	ITL EMC floor	
Test set up description	Normal test set up	
Selected windows size	☒	80 mm x 80 mm (maximum)
	☐	Other: e.g. Testing at selected points only (See result table)
Test distance d	☒	(50 ± 3) mm
	☐	Other: -- 0.15m
Frequency applied	13,56 MHz	
Supplementary information.....	Tested on VC3 (12")	

Test results						
Frequencies	Test Level [A/m]	Point / Window	Modulation	Operating mode	Dwell time [s]	Observations
30 kHz	8	All points on photo below	CW	1	3	none
134,2 kHz	65	All points on photo below	Pulse modulation 2,1 kHz	1	3	none
13,56 MHz	7,5	All points on photo below	Pulse modulation 50 kHz	1	3	none
Supplementary information: Configuration: HW configuration – With Oxygen mixer, capnography, oximetry and cuff pressure control (for tests)						

Test set-up photo :



Photo or drawing of locations of application :



7.12 Specialized Emissions and Immunity tests

☒ Not Applicable

SP	TABLE: Additional or special tests conducted		
Standard	CLAUSE AND NAME OF TEST	Test type and condition	Observed results
Supplementary information: N/A			

8 Accompanying documents as required by IEC 60601-1-2

Clause	Requirement + Test	Result - Remark	Verdict
Note: For items that require a presence check of the RISK MANAGEMENT PROCESS OR RISK MANAGEMENT FILE, use PC in the Verdict column when the item is confirmed as present in the associated documents.			
4	GENERAL REQUIREMENTS		
4.1	RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES shall be taken into account in THE RISK MANAGEMENT PROCESS.	RMF Reference Document: DOC-0428 Rev A02 Clause:4.1 Risk No:2	P
4.2	Non-ME EQUIPMENT used in an ME SYSTEM		
	Check 16.1 of general standard, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard		N/A
	Non- ME EQUIPMENT used in an ME SYSTEM shall comply with IEC and ISO EMC standards applicable to that equipment, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard		N/A
	Non- ME EQUIPMENT used in an ME SYSTEM for which the intended EM ENVIRONMENT could result in the loss of BASIC SAFETY OR ESSENTIAL PERFORMANCE of the ME SYSTEM due to the non- ME EQUIPMENT shall be tested according to the requirements of this collateral standard, checked by inspection of the RISK MANAGEMENT FILE and OBJECTIVE EVIDENCE of compliance with the respective EMC standards, or by the tests of this collateral standard		N/A
4.3.1	Configurations		
	ME EQUIPMENT and ME SYSTEMS shall be tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK. as determined by the MANUFACTURER. This shall be determined using RISK ANALYSIS, experience, engineering analysis, or pretesting. Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.		N/A
4.3.3	Power input and frequencies	See appended Item 1	P

Clause	Requirement + Test	Result - Remark	Verdict
Note: For items that require a presence check of the RISK MANAGEMENT PROCESS or RISK MANAGEMENT FILE, use PC in the Verdict column when the item is confirmed as present in the associated documents.			
5	IDENTIFICATION, MARKING AND DOCUMENTS		
5.1	Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT		
	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT shall be labelled with a CLEARLY LEGIBLE warning that they should be used only in the specified type of shielded location		N/A
5.2	ACCOMPANYING DOCUMENTS		
5.2.1	Instructions for use		
5.2.1.1	General		
a)	A statement of the ENVIRONMENTS for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed.	RMF Reference Document: DOC-0428 Rev A02 Clause:4.9 Risk No:143 - 147	P
b)	The ESSENTIAL PERFORMANCE of ME EQUIPMENT and a description of what the operator can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM disturbances.	Section 14.1.1 EMC statement of Essential Performance in the UM	P
c)	A warning regarding stacking and location close to other equipment	Section 14.1.1 EMC statement of Essential Performance in the UM	P
d)	List of cables, transducers and accessories	Section 14.1.1 EMC statement of Essential Performance in the UM	P
e)	A warning that other cables and accessories may negatively affect EMC performance	Section 14.1.1 EMC statement of Essential Performance in the UM	P
f)	A statement that portable RF communications equipment. Including antennas, can effect ME EQUIPMENT. The warning should include a use distance such as "...be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer"	Section 14.1.1 EMC statement of Essential Performance in the UM	P
5.2.1.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11		

Clause	Requirement + Test	Result - Remark	Verdict
Note: For items that require a presence check of the RISK MANAGEMENT PROCESS OR RISK MANAGEMENT FILE, use PC in the Verdict column when the item is confirmed as present in the associated documents.			
	ME EQUIPMENT and ME SYSTEMS that are classified class A according to CISPR 11, the instructions for use shall include the following note: NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		P
5.2.2	Technical description		
5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS		
	The technical description shall describe precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES	See 14.4 – table in the UM	P
a)	Compliance for each EMISSION and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL	14.4 – Tables 1, 2 & 3 in the UM	P
b)	Any deviations from this collateral standard and allowances used		N/A
c)	All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE	14.4 – Table 5 in the UM	P
5.2.2.2	Requirements applicable to ME EQUIPMENT specified for use only in shielded location SPECIAL ENVIRONMENT		
	The technical description shall include the following information:		
a)	A warning to the effect that: WARNING: Failure to use this equipment in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services		N/A
b)	Specifications for shielded location including: – minimum RF shielding effectiveness; – for each cable that enters or exits the shielded location, the minimum RF filter attenuation; and – the frequency range(s) over which the specifications apply		N/A
c)	Test methods for measurement of RF shielding effectiveness and RF filter attenuation		N/A

Clause	Requirement + Test	Result - Remark	Verdict
Note: For items that require a presence check of the RISK MANAGEMENT PROCESS OR RISK MANAGEMENT FILE, use PC in the Verdict column when the item is confirmed as present in the associated documents.			
d)	one or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location: – a specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the ME EQUIPMENT OR ME SYSTEM; – a list of specific equipment allowed; – a list of types of equipment prohibited.		N/A
5.2.2.3	Requirements applicable to ME EQUIPMENT that intentionally receive RF electromagnetic energy shall include the following information: - each frequency or frequency of reception - the preferred frequency or frequency band, if applicable, and - the bandwidth of the receiving section of the ME EQUIPMENT in those bands		N/A
5.2.2.4	Requirements applicable to the ME EQUIPMENT that include RF transmitters the technical description shall include: Frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER		N/A
5.2.2.5	Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		
	The technical description shall include the following information:		
a)	A statement that an exemption has been used and that the equipment has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 6 GHz		N/A
b)	A warning to the effect that "WARNING: This equipment has been tested for radiated RF IMMUNITY only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation"		N/A
c)	A list of the frequencies and modulations used to test the IMMUNITY of the ME EQUIPMENT OR ME SYSTEM		N/A
5.2.2.6	Requirements applicable to ME EQUIPMENT that claim compatibility with HF SURGICAL EQUIPMENT		
	The technical description shall include in the technical description a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery		N/A

Clause	Requirement + Test	Result - Remark	Verdict
6.1	Documentation of tests - General		
	The documentation of tests shall contain all information necessary to facilitate adequate planning (test plan) and execution of tests	See appended Item 1	P
6.2	Test Plan		
	Prior to the start of formal testing, a detailed test plan shall be provided to the test laboratory. Note: title / name / version of test plan in remark section.	See appended Item 1	P

7	ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS		
Clause	Requirement + Test	Result - Remark	Verdict
7.1.1	Protection of radio services and other equipment - General		
	Unless otherwise specified herein, ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 11		P
7.1.2	Operating modes		
	During EMISSIONS testing, ME EQUIPMENT or ME SYSTEM shall be tested in the modes that maximize EMISSIONS. In addition to active modes, inclusion of standby mode should be considered. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report	See appended Item 1	P
7.1.3	Multimedia Equipment		
	Multimedia equipment connected to ME EQUIPMENT or ME SYSTEM shall comply with CISPR 32. If CISPR 32 class A equipment is supplied as part of the ME SYSTEM, the ME SYSTEM shall be classified class A		N/A
7.1.4	Subsystems		
	Compliance with CISPR 11 may be demonstrated by testing each subsystem of an ME SYSTEM on a subsystem basis, provided the requirements of CISPR 11 for evaluation of equipment that interacts with other equipment to form a system are met		N/A
7.1.5	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT		
	For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the ELECTROMAGNETIC radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification		N/A

7	ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS		
Clause	Requirement + Test	Result - Remark	Verdict
	For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that enter or exit the shielded location, provided the minimum RF filter attenuation specification		N/A
a)	The specified RF shielding effectiveness and RF filter attenuation shall; - be expressed in dB; - be rounded to the nearest integer; and - be at least 20 dB.		N/A
b)	The RF shielding effectiveness and RF filter attenuation specification shall include the frequency range over which the RF shielding effectiveness and RF filter attenuation apply, and this frequency range shall be at least one decade in width		N/A
c)	The specified value(s) for minimum RF filter attenuation shall be identical to the specified value(s) for minimum RF shielding effectiveness in each frequency range for which they are specified		N/A
d)	In frequency ranges for which the minimum RF shielding effectiveness and RF filter attenuation are not specified or are specified to be less than 20 dB, the RF shielding effectiveness and RF filter attenuation shall be assumed to be 0 dB for the purpose of this collateral standard		N/A
7.1.6	ME EQUIPMENT and ME SYSTEMS that include radio equipment		
	ME EQUIPMENT and ME SYSTEMS that include radio equipment (e.g. RF transmitters, receivers, transceivers) and have been tested together with the radio equipment and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements.		P
7.1.7	ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices		
	ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices may be classified in accordance with CISPR 14-1		N/A
7.1.8	ME EQUIPMENT and ME SYSTEMS containing X-ray generators		

7	ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS		
Clause	Requirement + Test	Result - Remark	Verdict
	For diagnostic X-ray generators and ME SYSTEMS that include X-ray generators operating in INTERMITTENT MODE, the quasi-peak limits to discontinuous radiated and conducted DISTURBANCES can be relaxed by 20 dB		N/A
7.1.12	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods: – on a test site as a system; – on a test site on a subsystem basis; – <i>in situ</i> as a system at the premises of a RESPONSIBLE ORGANIZATION		N/A
	TEST METHOD SELECTED		
7.2	Protection of the PUBLIC MAINS NETWORK		
7.2.1	Harmonic distortion		
	If the ME EQUIPMENT OR ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase is intended to be connected a PUBLIC MAINS NETWORK it shall comply with the requirements of IEC 61000-3-2 Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.	See Appended Item 5	P
7.2.2	Voltage fluctuations and flicker		
	If the ME EQUIPMENT OR ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase is intended to be connected a PUBLIC MAINS NETWORK it shall comply with the requirements of IEC 61000-3-3. Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the test report.	See Appended Item 6	P

Clause	Requirement + Test	Result - Remark	Verdict
Note: For items that require a presence check of the RISK MANAGEMENT PROCESS or RISK MANAGEMENT FILE, use PC in the Verdict column when the item is confirmed as present in the associated documents.			
8	ELECTROMAGNETIC IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS		
	For ME EQUIPMENT and ME SYSTEMS for which the INTENDED USE includes types of transportation or other locations as in the HOME HEALTHCARE ENVIRONMENT if additional IMMUNITY tests or IMMUNITY TEST LEVELS that are higher these additional tests to these higher IMMUNITY TEST LEVELS shall be documented		N/A
	ME EQUIPMENT or ME SYSTEMS intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT for the HOME HEALTHCARE ENVIRONMENT. If locations in the EMERGENCY MEDICAL SERVICES ENVIRONMENT are identified for which the specifications are for the HOME HEALTHCARE ENVIRONMENT are not adequate, then Annex E may be used to determine appropriate IMMUNITY TEST LEVELS		N/A
	Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The pass/fail criteria and the monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE	RMF Reference Document: DOC-0428 Rev A02	P
8.2	PATIENT physiological simulation		
	If a PATIENT simulation is required to verify normal operation of the ME EQUIPMENT or ME SYSTEM, it shall be provided during IMMUNITY testing		N/A
	Prior to the beginning of the test, the amplitude of simulated PATIENT physiological signals shall be adjusted to be consistent with normal operation of the ME EQUIPMENT or ME SYSTEM, as specified by the MANUFACTURER		N/A
8.5	Subsystems		
	When subsystems are tested to demonstrate compliance, normal operating conditions are simulated		N/A
	The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed.		N/A
8.6	Permanently installed LARGE ME EQUIPMENT and LARGE ME SYSTEMS		
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods:		N/A

Clause	Requirement + Test	Result - Remark	Verdict
Note: For items that require a presence check of the RISK MANAGEMENT PROCESS OR RISK MANAGEMENT FILE, use PC in the Verdict column when the item is confirmed as present in the associated documents.			
8	ELECTROMAGNETIC IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS		
	- on a test site as a system; - on a test site on a subsystem basis; <i>in situ</i> as a system at the premises of a RESPONSIBLE ORGANIZATION		
	Test Method selected		Test Method selected
8.7	Operating Modes		
	Operating Modes and settings	RMF Reference Document: DOC-0428 Rev A02 Clause: 4.5 Risk No: 84, 85, 86,104,105	P
8.8	Non- ME EQUIPMENT		
	Non- ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM. Compliance is checked by inspection of the test report and the RISK MANAGEMENT FILE.		N/A
8.9	IMMUNITY TEST LEVELS		
	IMMUNITY TEST LEVELS based on ENVIRONMENT location of INTENDED USE	RMF Reference Document: DOC-0428 Rev A02 Clause: 4.1 Risk No: 2	P
8.10	IMMUNITY to proximity fields from RF wireless communication equipment		
	ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall, be tested as specified in Table 9 as per IEC 61000-4-3	RMF Reference Document: DOC-0428 Rev A02 Clause: 4.1 Risk No: 2	P

9 List of test equipment

Equipment used					
Equipment	Manufacturer	Type	Inventory number	Last calibration	Calibration due date
LISN	Solar Electronics	8028-50-TS-24-BNC	007-010-001	30/06/2021	30/06/2022
Cable CE Chamber 5M	Telrad	RJ214	ITL1705	25/04/2021	25/04/2022
Transient Limiter	HP	11947A	3107A03041	14/09/2021	14/09/2022
EMI Test Receiver	Rohde & Schwarz	ESC17	100724	20/02/2022	20/02/2023
EMI Receiver	HP	8542E	3906A00276	22/02/2022	22/02/2023
EMI Receiver Filter	HP	85420E	3906A00276	22/02/2022	22/02/2023
Biconical Antenna	EMCO	3110B	9912-3337	27/04/2021	27/04/2023
Log-periodic Antenna	EMCO	3146	9505-4081	27/04/2021	27/04/2024
EMC Analyzer	HP	8593 EM	3826A00265	22/02/2022	20/02/2023
Harmonics Flicker & Power Analyzer	Laplace Instruments	AC2000A	439269	03/05/2021	03/05/2022
AC Power Supply 0-400Hz	KIKUSUI	PCR1000M	TK000848	NCR	NCR
ESD Simulator	KIKUSUI	KES4021A	UG002517	19/01/2022	19/01/2023
Isotropic Field Prob	AR	FP2080	23190	18/07/2021	18/07/2023
Isotropic Field Monitor	AR	FM-2000	23294	NCR	NCR
Biconilog Antenna	EMCO	3142B	1078	04/07/2021	04/07/2022
Horn Antenna	ETS	3115	29845	25/05/2021	25/05/2024
RF Amplifier	AR	100W1000 M1	19842	NCR	NCR
RF Amplifier	Microwave Power Equipment Inc.	PA-47-0-800/6000	0002	NCR	NCR
Signal Generator	HP	8657A	3430U2142	22/02/2022	20/02/2023
Signal Generator	HP	83731A	3339A00600	22/02/2022	20/02/2023
Signal / frequency Generator	Wiltron	6747B	278007	02/05/2021	02/05/2022
Transient Generator	KeyTek	CEMASTER	9612436	21/02/2022	21/02/2023
Capacitive Clamp	Keytek	-	-	NCR	NCR
Surge Generator	CDI	CDI 1000i	3153	21/02/2022	21/02/2024
RF Amplifier	IFI	M100	M612-0208	NCR	NCR
Current Injection Probe (10KHz-230MHz)	FCC	F-120-9A	111592	28/07/2021	28/07/2022

CDN	FCC	FCC-801-M3-25	90	27/01/2022	27/01/2023
Magnetic Loop	FCC	F-1000-4-8-G-125A + L-1M	9837+9836	01/01/2022	01/01/2023

* Calibration interval extended based on sufficient calibration data and experience of use (see IEC60601-1-2J:2015 clause 8.3)

10 Statement of Measurement Uncertainty

Statement concerning the uncertainty of the measurement systems used for the tests	
☒	Internal procedure used for type testing through which traceability of the measuring uncertainty has been established: ITL #1911 Calculations leading to the reported values below are on file with the NCB and testing laboratory that conducted the testing. For MIU details for emission (according to CISPR 11 and CISPR 14-1) see table below.
☐	Statement not required by the standard used for type testing:
Supplementary information: N/A	

Parameter/ Measurement / test method	Requirement U_{CISPR}	Calculated U of M U_{lab}
Conducted Emission	EN 55011/CISPR11, EN55022/CISPR 22, ANSI C63.4	± 3.44 dB
Radiated Emission	EN 55011/CISPR11, EN55022/CISPR 22, ANSI C63.4	± 4.98 dB
ESD	EN/IEC 61000-4-2	± 10 %
Radiated Immunity	EN/IEC 61000-4-3	± 2.2 dB
EFT/B	EN/IEC 61000-4-4	± 10 %
Conductive Surges	EN/IEC 61000-4-5	± 9 %
Conducted RF Disturbances	EN/IEC 61000-4-6	± 2.4 dB
Voltage Dips and Short Interruptions	EN/IEC 61000-4-11	± 6 %

Attachment 1 Declarations

Date May 18, 2022

Declaration Letter for the implementation of an EMC suppressing ferrite into the Ventoux device as part of its Manufacture

This is to you inform that we **Flight Medical Innovations Ltd.** 7 Hatnufa St. Petach Tikva 4951025 , PO box 3172, Israel have implemented the process of adding an EMC suppressing ferrite into the Ventoux to the cable between the display board to main board as indicated in the photo below.



Ferrite used: WE-TOP EMI Suppression Toroidal Ferrite.



74270151.pdf

Signature

Name : Ken Raichman

Designation : Director of QA & Regulatory Affairs

Flight Medical Innovations Ltd, 7 Hatnufa St. Petach Tikva 4951025 , PO box 3172, Israel Tel: +972 3 6731660, Fax: +972 3 6731690



Ventoux – Compliance Declaration

We, Flight Medical Innovations, declare that the Ventoux 8" (VC2) ventilator is identical to the Ventoux 12" (VC3) ventilator in all respects (electrically and mechanically) except for the size of the Display Screen, where the VC2 has an 8" screen and the VC3 has a 12" screen.

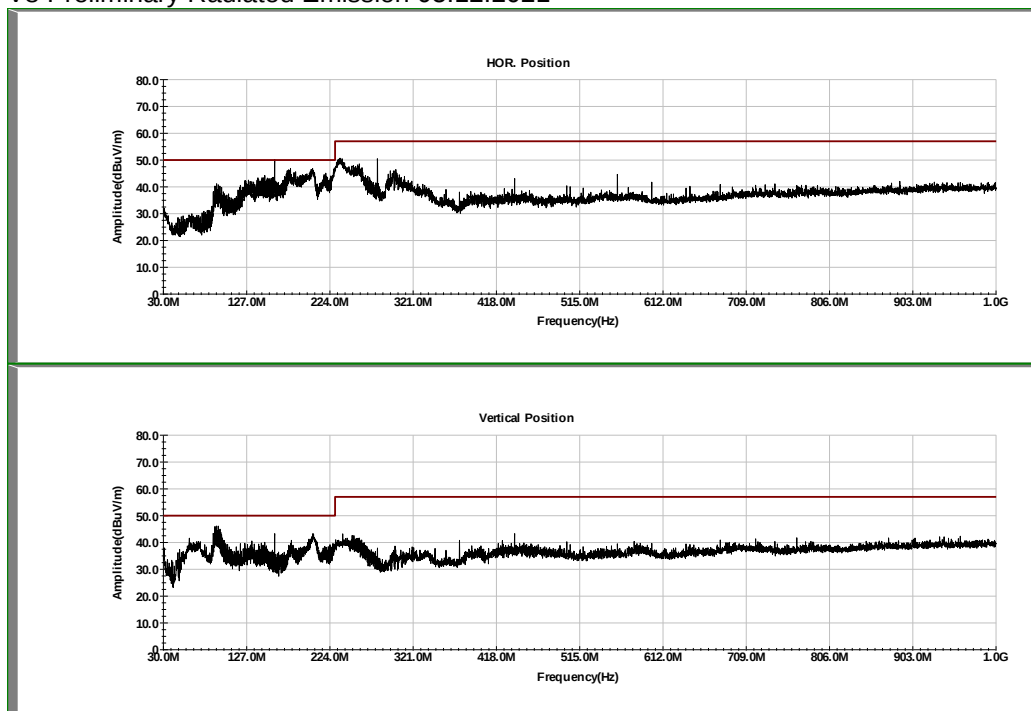
Date: 06.04.2022

A handwritten signature in blue ink, appearing to read "Ken Raichman", written over a horizontal line.

Ken Raichman,
Regulatory & QA Manager

Attachment 2 worst case

V8 Preliminary Radiated Emission 05.12.2021

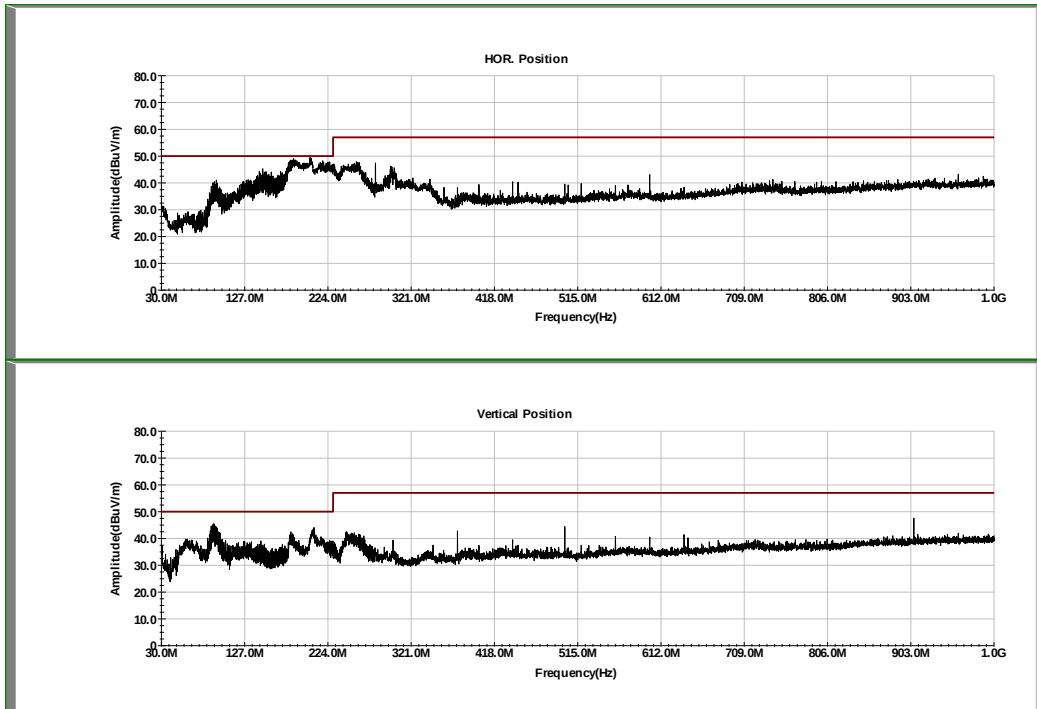


TOP Peaks

06:50:28 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
159.66 MHz	50.21	50.0	0.207	50.21	43.29	269.400	180.100
178.09 MHz	46.87	50.0	-3.130	46.87	40.28	89.400	90.300
179.06 MHz	46.87	50.0	-3.130	46.87	40.80	89.400	60.100
203.79 MHz	46.87	50.0	-3.131	46.87	43.26	329.300	180.100
204.28 MHz	46.81	50.0	-3.187	46.81	43.31	1.400	180.100
224.00 MHz	46.74	50.0	-3.263	46.74	39.14	179.300	120.200
235.80 MHz	50.71	57.0	-6.287	50.71	42.36	1.400	-0.400
238.87 MHz	50.70	57.0	-6.304	50.70	43.20	1.400	330.700
261.02 MHz	50.58	57.0	-6.424	50.58	40.93	179.300	90.300
269.10 MHz	50.53	57.0	-6.468	50.53	37.53	29.400	90.300
277.03 MHz	50.49	57.0	-6.511	50.49	36.69	1.400	90.300
279.29 MHz	50.48	57.0	-6.524	50.48	37.84	1.400	300.300
279.45 MHz	50.40	57.0	-6.598	50.40	37.92	29.400	300.300
299.82 MHz	46.37	57.0	-10.628	46.37	38.63	269.400	300.300
300.79 MHz	46.44	57.0	-10.558	46.44	38.42	239.200	300.300

TEST 2



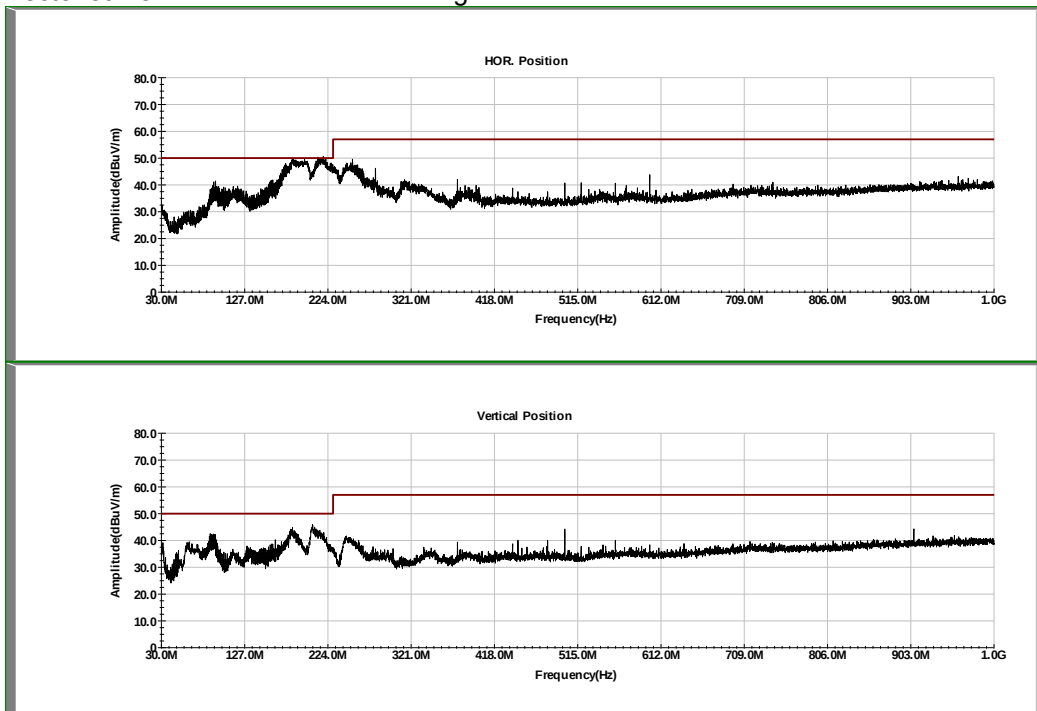
TOP Peaks

07:20:57 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
91.11 MHz	45.51	50.0	-4.491	40.28	45.51	179.000	30.200
148.02 MHz	45.24	50.0	-4.759	45.24	37.51	89.200	30.200
180.83 MHz	45.50	50.0	-4.503	45.50	42.45	89.200	30.200
203.63 MHz	49.37	50.0	-0.629	49.37	43.83	328.900	180.300
207.83 MHz	49.25	50.0	-0.747	49.25	44.08	328.900	210.000
229.82 MHz	48.64	50.0	-1.364	48.64	39.09	149.200	150.200
245.83 MHz	48.19	57.0	-8.813	48.19	42.51	29.100	-0.200
257.14 MHz	47.87	57.0	-9.130	47.87	41.64	29.100	-0.200
265.87 MHz	47.69	57.0	-9.312	47.69	40.96	1.500	90.200
272.82 MHz	47.54	57.0	-9.457	47.54	37.70	89.200	90.200
279.45 MHz	47.40	57.0	-9.596	47.40	38.10	179.000	300.100
297.23 MHz	46.24	57.0	-10.759	46.24	39.16	209.400	300.100
299.82 MHz	45.84	57.0	-11.157	45.84	39.31	179.000	330.300
301.28 MHz	45.62	57.0	-11.381	45.62	39.26	209.400	90.200
906.40 MHz	47.61	57.0	-9.390	42.73	47.61	328.900	90.200

215.00 MHz Hor-pol Peak=46.3dBuV/m, QP=42.8dBuV/m

Vectorious 8' test for worst case testing

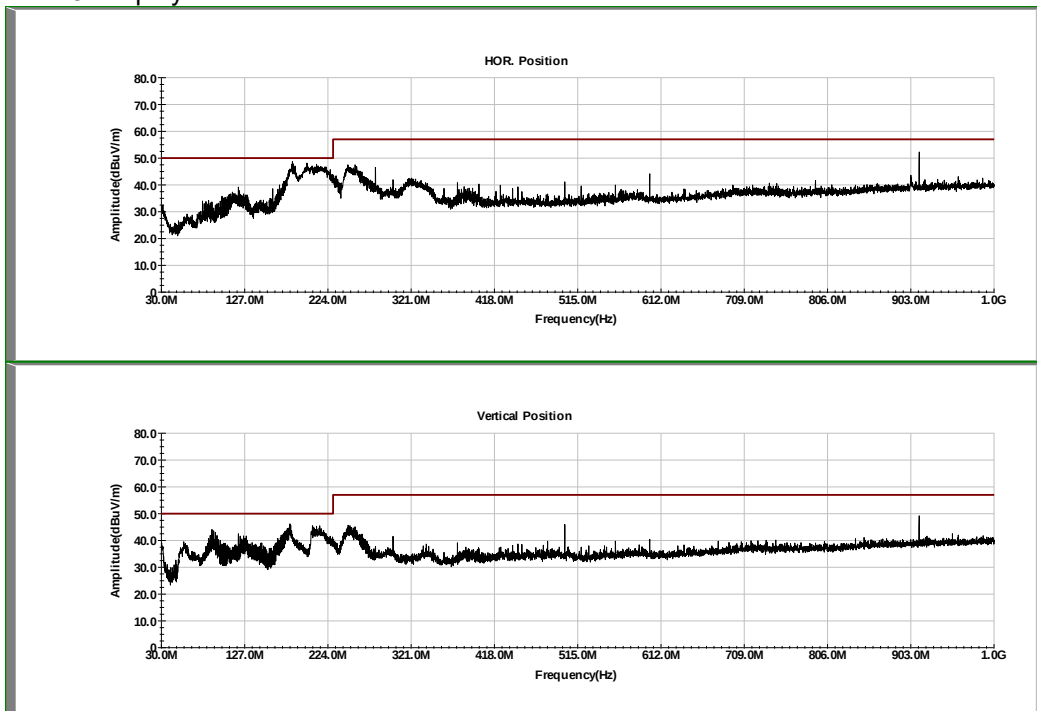


TOP Peaks

07:57:38 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
86.91 MHz	42.52	50.0	-7.478	38.71	42.52	119.300	30.000
162.73 MHz	42.88	50.0	-7.124	42.88	40.22	299.100	150.200
182.61 MHz	49.90	50.0	-0.096	49.90	44.75	299.100	210.100
182.77 MHz	49.91	50.0	-0.093	49.91	44.79	329.200	330.000
206.05 MHz	50.38	50.0	0.376	50.38	45.98	179.200	30.000
218.66 MHz	50.63	50.0	0.630	50.63	44.60	179.200	30.000
245.50 MHz	49.83	57.0	-7.175	49.83	41.67	269.300	240.400
252.62 MHz	49.61	57.0	-7.388	49.61	41.34	269.300	90.000
279.45 MHz	46.21	57.0	-10.786	46.21	40.10	-0.200	300.000
499.80 MHz	44.23	57.0	-12.772	40.69	44.23	209.400	330.000
499.96 MHz	44.22	57.0	-12.783	40.70	44.22	209.400	330.000
519.04 MHz	42.85	57.0	-14.151	40.81	42.85	29.300	90.000
598.90 MHz	43.79	57.0	-13.208	43.79	40.50	29.300	300.000
906.56 MHz	44.31	57.0	-12.689	43.24	44.31	149.000	60.400
958.13 MHz	43.15	57.0	-13.851	43.15		269.300	-0.300

Final 8" display

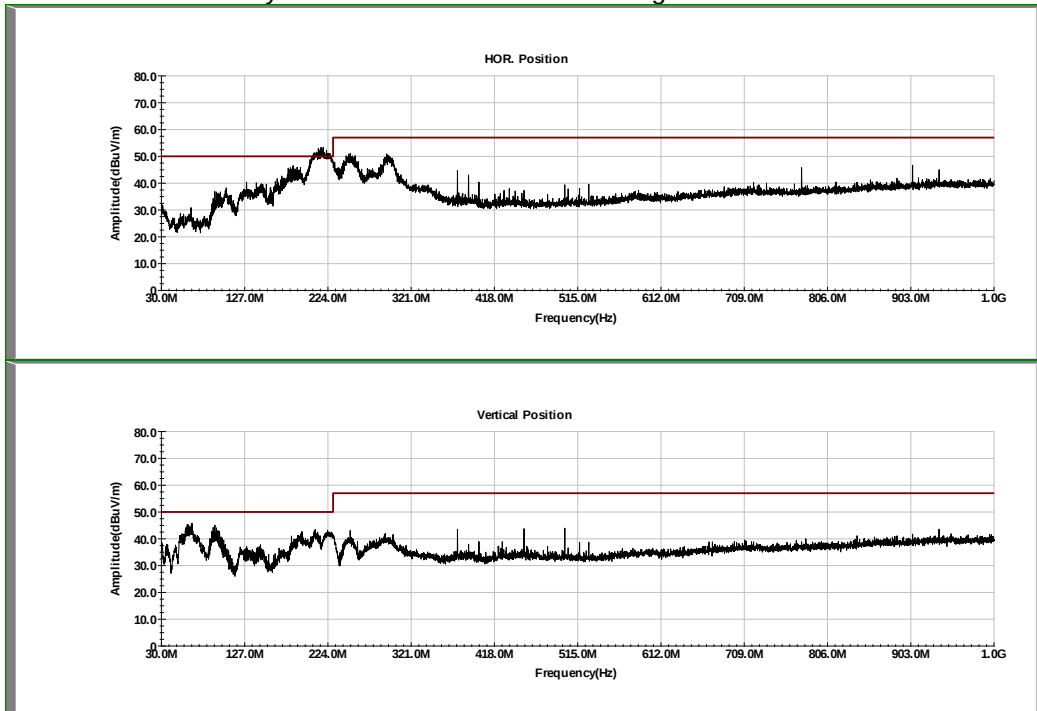


TOP Peaks

08:26:20 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
88.85 MHz	44.12	50.0	-5.879	33.65	44.12	89.100	120.100
90.95 MHz	43.61	50.0	-6.394	33.06	43.61	269.200	90.000
179.70 MHz	47.39	50.0	-2.606	47.39	46.18	269.200	150.300
182.61 MHz	48.67	50.0	-1.326	48.67	46.10	269.200	150.300
199.59 MHz	48.15	50.0	-1.853	48.15	45.66	149.000	270.300
206.05 MHz	48.07	50.0	-1.930	48.07	45.49	1.800	-0.100
247.44 MHz	47.58	57.0	-9.425	47.58	45.68	29.300	-0.100
255.69 MHz	47.48	57.0	-9.523	47.48	45.03	29.300	-0.100
279.29 MHz	46.44	57.0	-10.564	46.44	43.16	1.800	30.100
499.80 MHz	45.97	57.0	-11.032	41.13	45.97	209.300	-0.100
519.04 MHz	43.94	57.0	-13.063	39.61	43.94	29.300	60.400
598.90 MHz	44.14	57.0	-12.858	44.14	40.36	29.300	60.400
791.93 MHz	45.78	57.0	-11.221	41.58	45.78	209.300	90.000
912.70 MHz	52.27	57.0	-4.734	52.27	49.17	329.000	30.100
912.86 MHz	52.28	57.0	-4.720	52.28		299.000	150.300

Worst case Preliminary Radiated Emission V12-1 configuration

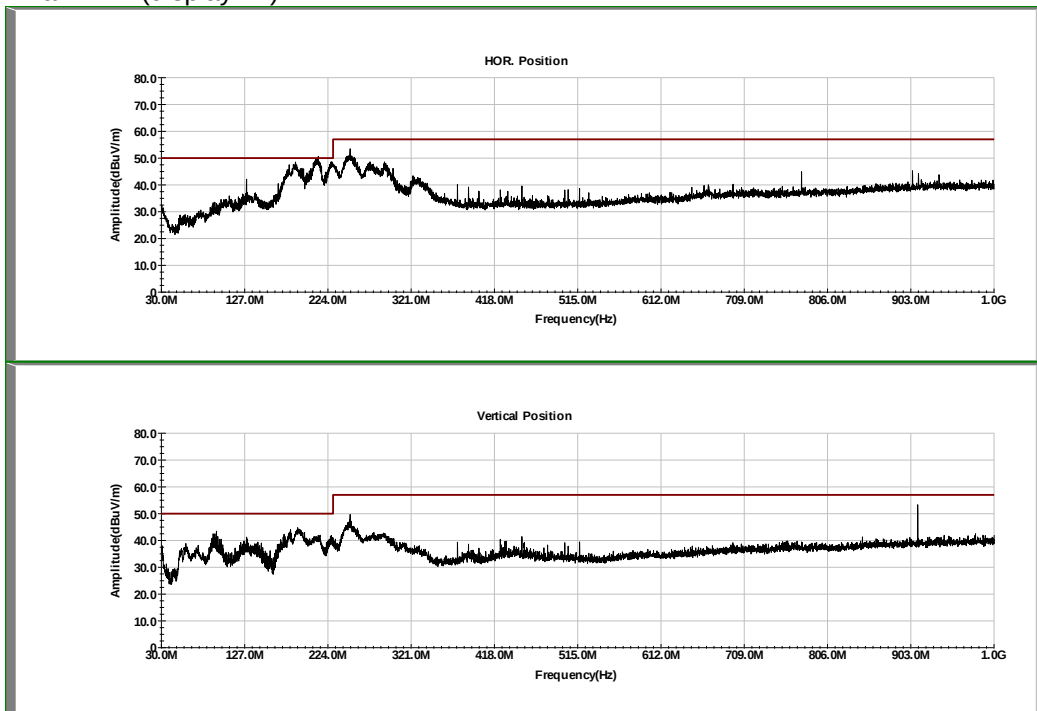


TOP Peaks

05:50:43 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
64.60 MHz	45.46	50.0	-4.539	30.89	45.46	119.400	180.000
65.57 MHz	45.88	50.0	-4.122	31.10	45.88	119.400	180.000
92.24 MHz	45.09	50.0	-4.913	36.89	45.09	89.200	-0.200
92.40 MHz	45.08	50.0	-4.918	36.91	45.08	299.000	-0.200
183.42 MHz	46.54	50.0	-3.463	46.54	40.43	89.200	-0.200
193.77 MHz	48.56	50.0	-1.440	48.56	42.71	299.000	210.300
209.29 MHz	51.60	50.0	1.596	51.60	43.51	29.200	240.100
218.66 MHz	53.43	50.0	3.430	53.43	43.28	-0.100	90.300
223.51 MHz	53.06	50.0	3.063	53.06	43.16	89.200	120.000
249.87 MHz	51.07	57.0	-5.927	51.07	43.08	329.000	330.300
290.77 MHz	50.93	57.0	-6.069	50.93	42.00	209.500	150.400
292.55 MHz	50.92	57.0	-6.076	50.92	42.03	209.500	120.000
775.77 MHz	45.76	57.0	-11.243	45.76	41.67	329.000	210.300
905.10 MHz	46.69	57.0	-10.310	46.69	43.20	149.000	120.000
935.82 MHz	45.04	57.0	-11.961	45.04	43.57	149.000	240.100

Final V12-1(display #1)



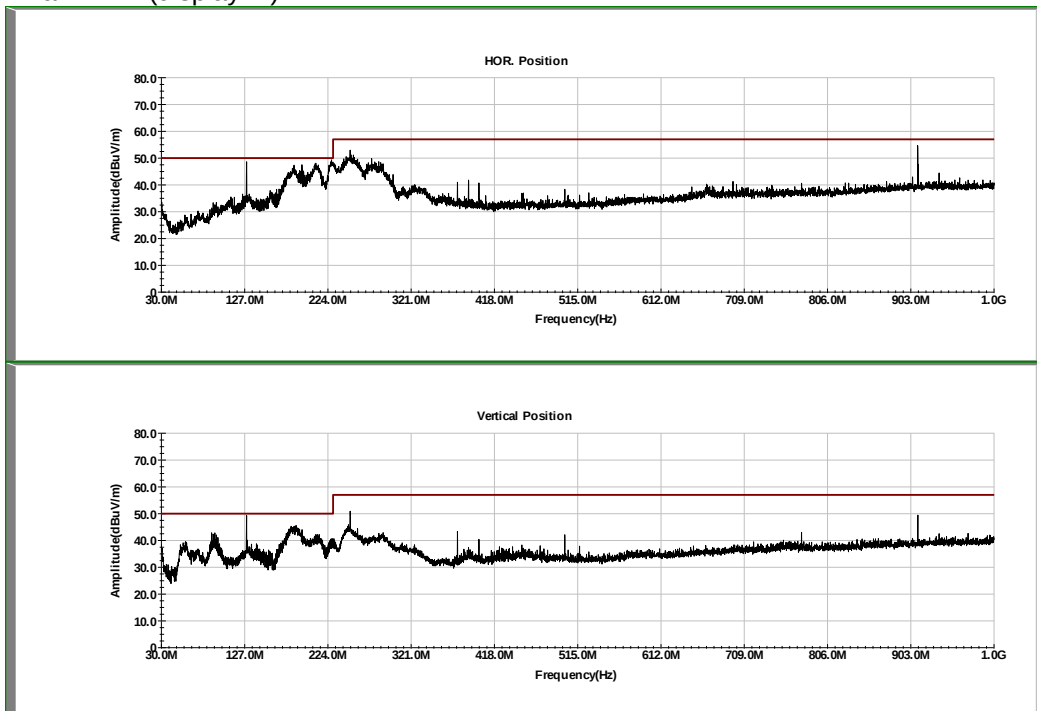
TOP Peaks

08:52:17 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
94.18 MHz	43.45	50.0	-6.545		43.45	209.400	120.000
109.06 MHz	42.52	50.0	-7.478	35.88	42.52	89.000	150.300
129.26 MHz	42.11	50.0	-7.895	42.11	41.26	209.400	150.300
186.17 MHz	48.52	50.0	-1.481	48.52	44.06	269.200	240.000
188.76 MHz	48.73	50.0	-1.274	48.73	44.75	299.300	270.000
212.84 MHz	50.66	50.0	0.660	50.66	46.70	239.200	179.900
227.72 MHz	48.62	50.0	-1.380	48.62	47.90	239.200	0.000
249.87 MHz	53.48	57.0	-3.517	53.48	49.69	1.800	300.200
289.96 MHz	48.59	57.0	-8.406	48.59	46.37	179.200	330.400
323.10 MHz	43.62	57.0	-13.378	43.42	43.62	179.200	240.000
449.85 MHz	41.42	57.0	-15.583	39.62	41.42	119.200	179.900
775.77 MHz	48.56	57.0	-8.439	44.93	48.56	329.100	179.900
904.94 MHz	53.12	57.0	-3.880	45.26	53.12	209.400	179.900
911.08 MHz	53.34	57.0	-3.664	44.39	53.34	269.200	270.000
911.89 MHz	44.27	57.0	-12.727	44.27		89.000	30.000

211.1MHz Peak=51.4dBuV/m, QP=46.9dBuV/m.

Final V12-2 (display#2)



TOP Peaks

09:30:11 PM, Sunday, December 05, 2021

	1	2	3	4	5	6	7
Frequency	Max Peaks	Limit EN	Delimit	Peak_Hor	Peak_Ver	Angle Hor	Angle Ver
Hz	dBuV/m	dBuV/m	dB	dBuV/m	dBuV/m	deg.	deg.
111.00 MHz	46.09	50.0	-3.910	35.51	46.09	209.300	240.300
115.04 MHz	46.80	50.0	-3.203	35.37	46.80	269.200	180.000
129.26 MHz	49.29	50.0	-0.715	48.61	49.29	209.300	180.000
140.74 MHz	44.13	50.0	-5.872	44.13	38.75	119.100	150.400
184.55 MHz	47.33	50.0	-2.667	47.33	44.56	209.300	270.200
187.14 MHz	47.38	50.0	-2.618	47.38	45.52	239.300	270.200
193.77 MHz	47.51	50.0	-2.491	47.51	46.09	119.100	240.300
209.93 MHz	48.08	50.0	-1.915	48.08	47.49	269.200	180.000
249.87 MHz	52.95	57.0	-4.047	52.95	50.93	329.300	300.100
274.92 MHz	49.79	57.0	-7.214	49.79	49.41	179.200	270.200
775.77 MHz	46.27	57.0	-10.728	46.27	43.01	329.300	210.200
910.92 MHz	54.68	57.0	-2.325	54.68	49.40	239.300	-0.100
911.24 MHz	51.17	57.0	-5.827	51.17	49.42	239.300	60.000
911.57 MHz	47.67	57.0	-9.330	47.67		209.300	30.300
935.98 MHz	44.45	57.0	-12.549	44.45		149.300	210.200

129.3 MHz Peak=54.9dBuV/m, QP=51.5dBuV/m

End of the Report