



- The RvA is a signatory to the EA MLA.
- The RvA is a signatory to the ILAC MRA.
- The RvA is a signatory to the IAF MLA.

Test report No:
2285019.0509A-EMC

TEST REPORT

FCC Rules & Regulations 47 CFR Chapter I - Part 15 & ICES-003

(*) Identification of item tested	Apparatus intended for ophthalmic surgery
(*) Trademark	VIRTUOSO
(*) Model and /or type reference	EQ00.R02
(*) Features	100 – 240 Vac, 50 / 60 Hz, 500 VA RFID 13.56 MHz, Bluetooth 2.4 GHz
(*) Derived model(s)	EQ00.R01, EQ00.R03
(*) Applicant's name / address	DEMCON Life Sciences & Health Enschede B.V. Institutenweg 25, 7521 PH Enschede, Netherlands
Test method requested, standard	FCC Rules and Regulations 47 CFR Chapter I Part 15 Subpart B (20-11-24 Edition) ICES-003 Issue 7 (15-10-20)
Verdict Summary	IN COMPLIANCE (refer to chapter 3 for details)
Tested by (name / position & signature)	Johan van den Berg Technical Professional EMC Supervised by Sedat Eser Technical Professional EMC
Approved by (name / position & signature)	Sky Zhang Technical Professional EMC
Date of issue	2025-12-11
Report template No	TRF_EMC_FCC_ISED R2.0 (*) "Data provided by the applicant"

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Competences and Guarantees

The DEKRA Certification B.V. EMC laboratory has been designated by the “Radio communications Agency of the Netherlands” as a Conformity Assessment Body for all products addressed by Parts 15 and Part 18 of the FCC rules per designation AT-EZ/EU-USA/MRA002 since December 1, 2005.

In order to assure the traceability to other national and international laboratories, DEKRA has a calibration and maintenance program for its measurement equipment.

DEKRA guarantees the reliability of the data presented in this report, which is the result of the measurements and the tests performed to the item under test on the date and under the conditions stated in the report and it is based on the knowledge and technical facilities available at DEKRA at the time of performance of the test.

DEKRA is liable to the client for the maintenance of the confidentiality of all information related to the item under test and the results of the test.

The results presented in this Test Report apply only to the particular item under test established in this document.

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GENERAL CONDITIONS

1. This report is only referred to the item that has undergone the test.
2. This report does not constitute or imply on its own an approval of the product by the Certification Bodies or Competent Authorities.
3. This document is only valid if complete; no partial reproduction can be made without previous written permission of DEKRA.
4. This test report cannot be used partially or in full for publicity and/or promotional purposes without previous written permission of DEKRA.

UNCERTAINTY

For all measurements where guidance for the calculation of the instrumentation uncertainty of a measurement is specified in EN 55016-4-2 (CISPR 16-4-2), EN/IEC 61000-4 series or a product standard, the measurement instrumentation uncertainty has been calculated and applied in accordance with these standards.

Uncertainties have been calculated according to the DEKRA internal document AMS#1167. The reported expanded uncertainties are based on a standard uncertainty multiplied by a coverage factor of $k=2$, providing a level of confidence of approximately 95%. Refer to the Annex 1 for further information.

CONFORMITY ASSESSMENT

For all EMI (emission) tests (when included in this report), as measurement uncertainties (U_{LAB}) are less than the values U_{CISPR} given in CISPR 16-4-2 (EN 55016-4-2) (Table-1), compliance with the limits is determined by comparing measurement results directly with corresponding limits without taking into consideration of measurement uncertainties.

ENVIRONMENTAL 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:

Ambient temperature	15 °C – 35 °C
Relative Humidity air	30% - 60%
Atmospheric pressure	81 kPa - 110 kPa

If explicitly required in the basic standard or applied product / product family standard the climatic values are recorded and documented separately in this test report.

POSSIBLE TEST CASE VERDICTS

Test case does not apply to test object	N/A
Test object does meet requirement	P (Pass) / PASS
Test object does not meet requirement	F (Fail) / FAIL
Not measured	N/M

DEFINITION OF SYMBOLS USED IN THIS TEST REPORT

☒ Indicates that the listed condition, standard or equipment is applicable for this report/test/EUT.			
☐ Indicates that the listed condition, standard or equipment is not applicable for this report/test/EUT.			
Decimal separator used in this report	☐	Comma (,)	☒ Point (.)

ABBREVIATIONS

For the purposes of the present document, the following abbreviations apply:

EUT	: Equipment Under Test	Rx	: Receiver
QP	: Quasi-Peak	N/A	: Not Applicable
CAV	: CISPR Average	N/M	: Not Measured
AV	: Average	S#	: Sample number
PK	: Peak	OM#	: Operating mode number
CDN	: Coupling Decoupling Network	Conf#	: Configuration number
SAC	: Semi-Anechoic Chamber	V _m	: Measured voltage
OATS	: Open Area Test Site	CF	: Correction factor
BW	: Bandwidth	V _{RX}	: Voltage measured by the receiver
U _N	: Nominal voltage	FS	: Field Strength
Tx	: Transmitter		

DATA PROVIDED BY THE APPLICANT

The following data has been provided by the client:

1. Information relating to the description of the sample('Identification of the item tested', 'Trademark', 'Model and/or type reference tested', 'Features' and 'Derived model(s)').
2. Derived models not tested. These models have been declared by the applicant as being the similar as the model under test.

DEKRA Certification B.V. declines any responsibility with respect to the information provided by the applicant and that may affect the validity of results.

DOCUMENT HISTORY

Report nr.	Date	Description
2285019.0509-EMC	2024-12-17	First release.
2285019.0509A-EMC	2025-12-11	Second release. Some typos were corrected. This revision of the test report cancels and replaces the test report with a reference number 2285019.0509-EMC.

REMARKS AND COMMENTS

The equipment under test (EUT) does meet the EMC requirements of the stated standard(s)/test(s).

The test results stated in this report of model EQ00.R02 are also representative for models EQ00.R01 and EQ00.R03. Refer to chapter 2.6 for more details.

The tests described in this report do not result in the right to use any approval mark as conferred by DEKRA. As far as the tests were based on certain specifications, these are mentioned in the report.

1 GENERAL INFORMATION

1.1 General Description of the Item(s)

Description of the item.....:	Apparatus intended for ophthalmic surgery
Model / Type number	EQ00.R02
Serial number.....:	IR230112
Trademark	VIRTUOSO
Manufacturer.....:	Vitrex B.V.
Address	Seggelant-Noord 2, 3237 MG Vierpolders, Netherlands

Rated power supply.....:	Voltage and Frequency		Power connection type				
			L1	L2	L3	N	PE
	☒	AC: 100 – 240 V, 50/60 Hz	☒	☐	☐	☒	☒
	☐	DC:					
	☐	Battery:					
Rated Power	500 VA						
Clock frequencies.....:	100 MHz						
Other parameters.....:	RFID 13.56 MHz, BT 2.4 GHz						
Software version	EFT : 11.0.4 ESD : 11.0.6 All other tests : 11.0.X						
Hardware version.....:	DMR02776						
Dimensions in mm (W x H x D)....:	640 x 1710 x 755						
Mounting position.....:	☐	Table top equipment					
	☐	Wall/Ceiling mounted equipment					
	☒	Floor standing equipment					
	☐	Hand-held equipment					
	☐	Other:					

RF interface 1 (Base unit):

Technology	RFID 13.56 MHz
Frequency band / range(s)	13.533 – 13.567 MHz
Maximum chipset/conducted output power.....:	+23 dBm
Type of Modulation(s).....:	ASK (8% to 30%)
Number of channels	1
Channel spacing	N/A
Channel bandwidth	200-500kHz
Type of antenna	PCB Antenna
Antenna gain.....:	N/A

RF interface 2 (Base unit):

Technology	Bluetooth 2.4 GHz
Frequency band / range(s)	2.402 – 2.480 GHz
Maximum chipset/conducted output power	+ 18 dBm
Type of Modulation(s).....	GFSK / 1Mbps
Number of channels	0 - 78
Channel spacing	1 MHz
Channel bandwidth	0.95 MHz @ BR-1Mbps
Type of antenna	Internal/Integrated/PCB antenna
Antenna gain.....	0.5 dBi

RF interface 3 (Base unit):

Technology	Bluetooth 2.4 GHz
Frequency band / range(s)	2.402 – 2.480 GHz
Maximum chipset/conducted output power	+ 18 dBm
Type of Modulation(s).....	GFSK / 1Mbps
Number of channels	0 - 78
Channel spacing	1 MHz
Channel bandwidth	0.95 MHz @ BR-1Mbps
Type of antenna	Internal/Integrated/PCB antenna
Antenna gain.....	0.5 dBi

RF interface 4 (Foot pedal):

Technology	Bluetooth 2.4 GHz
Frequency band / range(s)	2.402 – 2.480 GHz
Maximum chipset/conducted output power	+ 18 dBm
Type of Modulation(s).....	GFSK / 1Mbps
Number of channels	0 - 78
Channel spacing	1 MHz
Channel bandwidth	0.95 MHz @ BR-1Mbps
Type of antenna	Internal/Integrated/PCB antenna
Antenna gain.....	0.5 dBi

RF interface 5 (Remote control):

Technology	Bluetooth 2.4 GHz
Frequency band / range(s)	2.402 – 2.480 GHz
Maximum chipset/conducted output power	+ 18 dBm
Type of Modulation(s).....	GFSK / 1Mbps
Number of channels	0 - 78
Channel spacing	1 MHz
Channel bandwidth	0.95 MHz @ BR-1Mbps
Type of antenna	Internal/Integrated/PCB antenna
Antenna gain.....	0.5 dBi

Intended use of the Equipment Under Test (EUT)

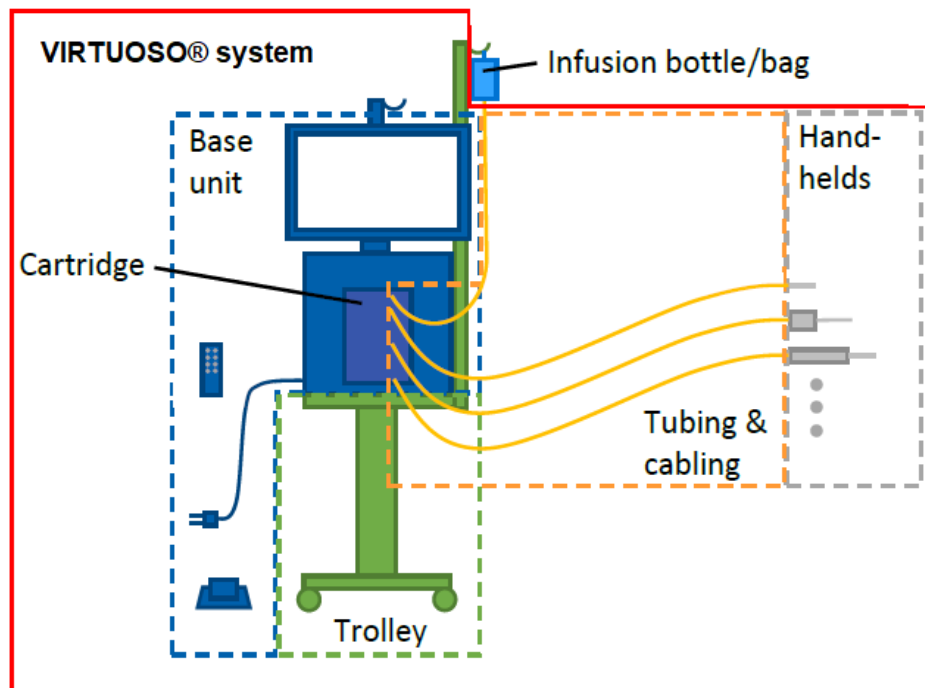
The VIRTUOSO® system is an equipment intended for anterior and posterior segment ophthalmic surgery. The system capabilities include:

- fluid irrigation,
- air irrigation,
- fluid/air aspiration, phaco-emulsification,
- diathermy,
- vitrectomy,
- viscous fluid injection,
- viscous fluid extraction,
- illumination, and
- laser coagulation.

System overview:

The following figures give a definition of the various parts of the VIRTUOSO® system, including the system boundaries. The different blocks contain the following elements:

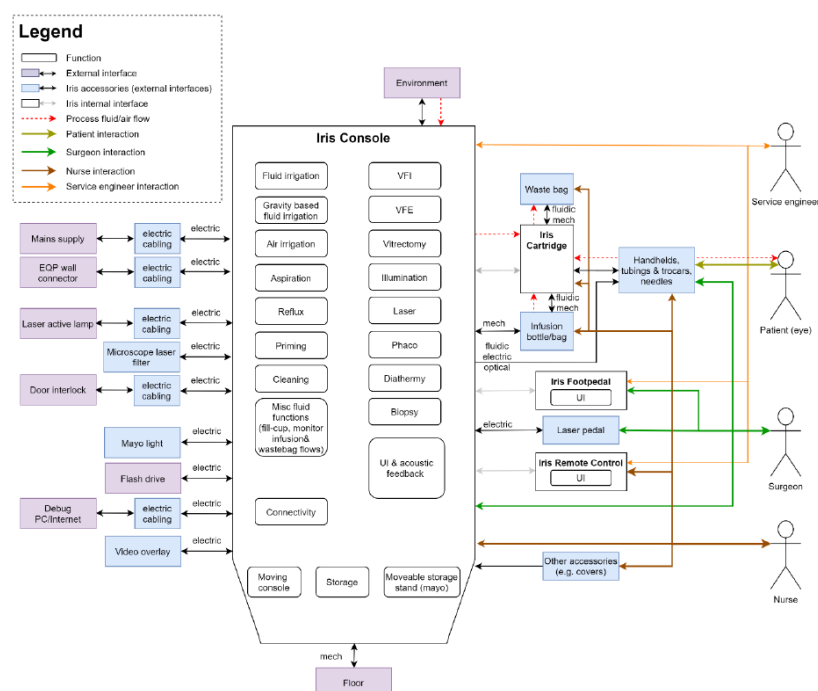
- Base unit: the desktop part of the system, including touch screen, foot pedal(s) and remote control. The base unit also encloses two (2) Bluetooth radio modules used for communication with the foot pedal and the remote control units and RFID interface related to laser function.
- Cartridge: disposable part of irrigation/aspiration pump function
- Trolley: the movable trolley (also contains Air Supply parts)
- Tubing & cabling: all electrical cables, optical fibers and disposable tubes that are connected to the cartridge, base unit, infusion bottle/bag and the handhelds
- Handhelds: all instruments connected to the tubing or base unit, including light or laser fibers



The battery operated foot pedal is a separate unit which can be connected with a cable (length = 4 m) or a BT RF connection. In the wired configuration the foot pedal is powered via the cable. In the wireless configuration the foot pedal is battery powered.

A battery operated remote control can be connected via Bluetooth connection.

Block diagram demonstration of the system:



Copy of marking plate:



No	Module/parts of test item	Type	Manufacturer
1	VIRTUOSO® Main System (Full surgical unit)	EQ00.R02	Vitrec B.V.
2	Mainboard	D664301_F	Demcon
3	Laser Frontpanel	D242197_D	Demcon
4	Footpedal	2X0783 Rev 0	Vitrec
5	Remote Control	D643741_B	Demcon
6	Laser foot switch	MKFS 2S-MED	Steute

No	Documents as provided by the applicant - Description	File name	Issue date
1	General information form	20240604 Iris surgery system - 01 General information form v1.0	2024-06-17
2	EMC Test Plan	PRD0412-5-93_6.0_EMC test plan	2024-07-11
3	Instruction for use (IFU)	IFUS-94000029 Version 04 GP	2024-08-01

1.2 Classification

The device under test (DUT) is classified as:

☒	Class A	A digital device that is marketed for use in a commercial, industrial or business environment, exclusive of a device which is marketed for use by the general public or is intended to be used in the home.
☐	Class B	A digital device that is marketed for use in a residential environment notwithstanding use in commercial, business and industrial environments. Examples of such devices include, but are not limited to, personal computers, calculators, and similar electronic devices that are marketed for use by the general public.

1.3 Test data

Test Location	DEKRA Certification B.V., Netherlands
Date (start)	2024-04-05
Date (finish)	2024-06-02

2 DESCRIPTION OF TEST SETUP

2.1 Sample(s) used for tests

During the tests the following sample(s) has(have) been used.

Sample	Logistics number	Model number	Serial number	Remark(s) / Changes
01	102677/1-1	Iris system	IR230112	---
<u>Supplementary information:</u> ---				

2.2 Operating mode(s) used for tests

During the tests the following operating mode(s) has(have) been used.

Operating mode	Operating mode description	Sup. Info / Remark
01	EMC Test mode	See 1
02	Operating mode.	See 2
<u>Supplementary information:</u> 1. The EMC test mode actuates all functions simultaneously. It was analyzed by risk management that this mode will maximize EMC disturbance. A python test script running on a PC connected via the Ethernet port actuates all functions and monitor/log different parameters. See table below for further details regarding emission testing. This modes establish continuous communication link between the Iris system and the foot pedal and also remote control devices. The radio functions does not have an IDLE or STANDBY mode. 2. The RF section turned off, in order to verify the emissions from the device's internal circuitry.		

2.3 Port(s) of the EUT

Port name and description	Connected to / Termination	Cable			Sup. Info / Remark
		Length used during test [m]	Attached during test	Shielded	
AC mains power input	AC power grid	4	Yes	No	---
Potential Equalization	Earth	3	Yes	No	---
Foot pedal	Iris device	3	Yes	Yes	See 1
LIO (Laser foot pedal)	Iris device	3	Yes	No	See 2
Ethernet	Control PC	3	Yes	No	See 3
Laser interlock/lamp	Iris device	3	Yes	No	See 4
Laser filter	Iris device	3	Yes	No	See 5
Phaco handpiece	Iris device	2	Yes	Yes	See 6
Diathermy handpiece	Iris device	3.5	Yes	No	See 7
2 x power LED lamps	Iris device	0.4	Yes	No	See 8
USB	Iris device	N/A	No	Yes	See 9
<u>Supplementary information:</u>					

- 1) 24V power for four pedal+full duplex RS422 data.
- 2) External LIO switch (Laser foot pedal cable).
- 3) Isolated Gbit port.
- 4) External contact (interlock) + internal contact (lamp).
- 5) External contact.
- 6) Max 475Vrms / 40 kHz..
- 7) Max 60Vrms / 200 kHz.
- 8) 5V USB-A connector (no data). This port is only used to mount a LED lamp and is not part of the EMC testing.
- 9) Isolated USB 2.0. This port is used to plug in memory stick for maintenance purposes and is not part of the EMC testing.

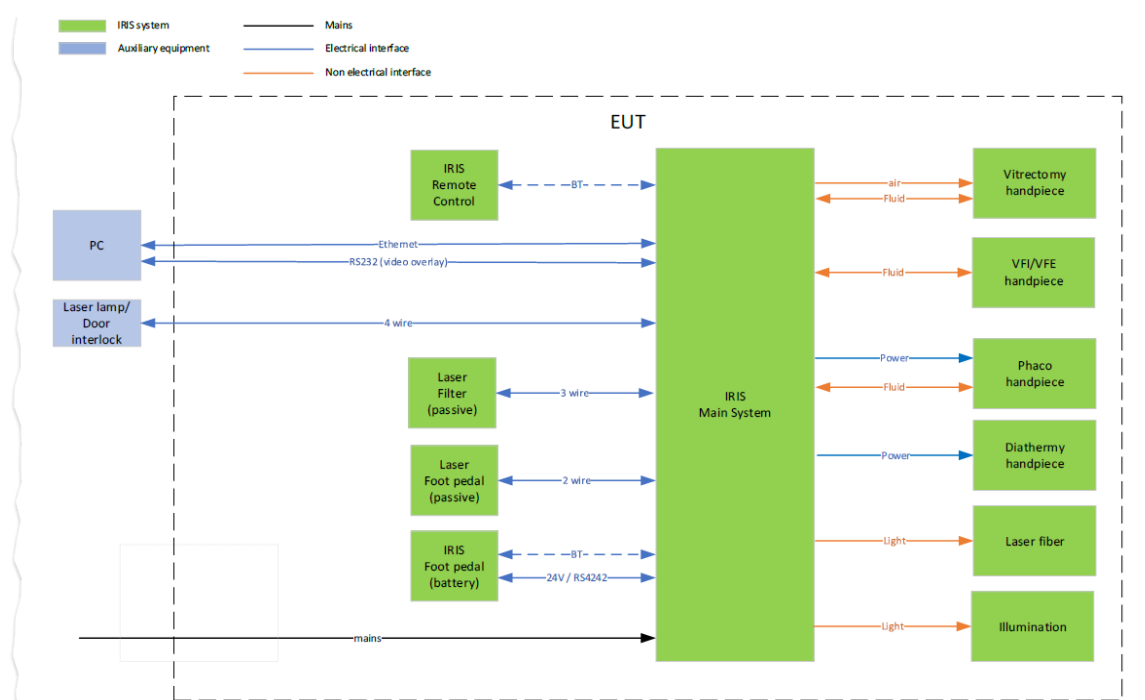
2.4 Support / Auxiliary equipment / unit / software for the EUT

The EUT has been tested with the following auxiliary equipment / unit / software:

Auxiliary equipment / unit / software	Type / Version	Manufacturer	Supplied by
Test/control PC	ZBook 15 G3	HP	Applicant
Laser door interlock/lamp termination box	D489455_A	Demcon	Applicant
<u>Supplementary information:</u>			

2.5 Test Configuration / Block diagram used for tests

The following test setup / configuration / block diagram has been used during the tests

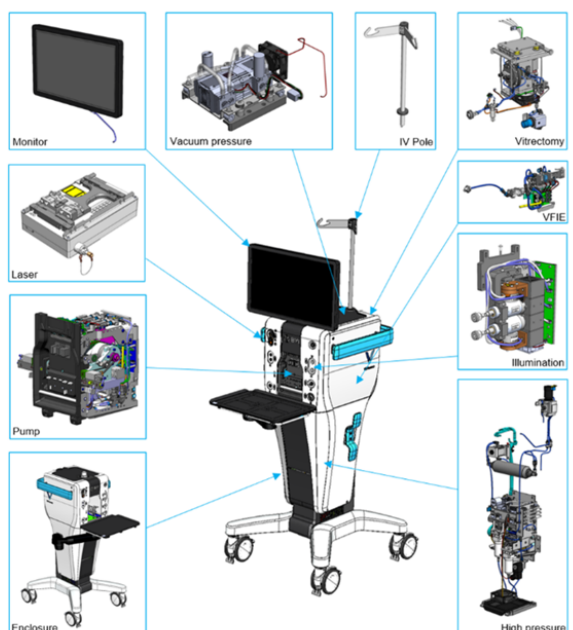


The items, in the test configuration, colored in green are part of the EUT (incl. cables/ports), while the items colored in blue are the simulators, accessories and auxiliary equipment used as part of the EMC test setup for simulation. During testing the system was controlled via auxiliary control PC connected via ethernet port of the system which was running specific Python script provided by the applicant to activate and also monitor the functions.

2.6 EUT variants/configurations

The EUT has the following variants/configurations. The table below shows the differences between the configurations.

System configurations				
VIRTUOSO® Configurations				
(Sub)system(s)		Anterior	Excluding Laser	EQ00.R02 Dual Full (full system)
Pump		x	x	x
Air		x	x	x
Vitrectomy		x	x	x
Illumination			x	x
Laser				x
Infusion Pole		x	x	x
Monitor		x	x	x
Enclosure	Anterior	x		
	Excluding laser		x	
Dual Full				x
		x	x	x
Trolley & Mayo		x	x	x



'Anterior': EQ00.R01 and 'Excluding laser': EQ00.R03

Additional information about the configurations:

- Full surgical unit: All functions and subsystems are present. This design document typically describes the full surgical unit, as the full surgical unit is considered the most complex system.
- Full surgical unit excluding laser: The laser module (ARC purchase part) and the laser off button are not present:
 - On hardware this has the following impact:
 - The laser module, laser off button and related cabling are not placed.
 - The enclosure front have a configuration that does not contain a laser port, laser off button and related labelling. Laser door interlock and microscope laser filter connections on the back are present. Labelling on the back of the system is different.
 - Mainboard & Peripherals are able to function in the absence of a laser module and the laser off button. Laser door interlock, laser active lamp signal and microscope laser filter connections on the back are present. On the front panel PCA the RFID components and laser icon are present.
 - For software and firmware this has the following impact:
 - The software and firmware are able to function in the absence of a laser module and the laser off button. Microscope laser filter / dongle, door interlock and RFID laser fiber detection may or may not be active and are not influencing the functionality. The laser active lamp and the laser icon are never be switched on. The GUI is adapted to hide all laser functionality. It is not possible to add a laser step.

- Anterior unit: An anterior VIRTUOSO® unit does NOT contain the functionality related to VFIE, Illumination and Laser.
 - On hardware this has the following impact:
 - The Laser module, laser off button, Illumination subsystem and related cabling are not placed.
 - Parts of the VFIE subsystem that are needed for venting of the High Pressure Supply and Vacuum Supply are placed.
 - The enclosure front has a configuration that does not contain a laser port, laser off button, VFIE connector, illumination ports and related labelling. Laser door interlock and microscope laser filter connections on the back are present. Labelling on the back of the Iris system is different.
 - Mainboard & Peripherals are able to function in the absence of a laser module, the laser off button, the illumination subsystem and parts of the VFIE subsystem. Laser door interlock and microscope laser filter connections on the back are present. The RFID components, the laser icon, the VFIE icon and the illumination icons on the front are still present.
 - For software and firmware this has the following impact:
 - The software and firmware are able to function in the absence of a laser module, the laser off button, the illumination subsystem and parts of the VFIE subsystem. Microscope laser filter / dongle, door interlock and RFID laser fiber detection may or may not be active and are not influencing the functionality. The laser active lamp, the laser icon, the VFIE icon and the illumination icons are never switched on. VFIE functionality with respect to venting of the High Pressure Supply and Vacuum Pressure Supply subsystems are still available. Also, the GUI must be adapted to hide all laser, VFI, VFE and Illumination functionality. It is not possible to add a laser, VFI or VFE step. Next to that, it will only be possible to select anterior procedures and anterior steps.

3 MEASUREMENT PROCEDURE

3.1 Conducted emissions

In accordance with section 15.107 of 47CFR Part 15B and clause 3.2.1 of ICES-003, the conducted radio frequency disturbance voltages between each of the power lines (live and neutral) and the ground terminal have been determined over the frequency range from 150 kHz to 30 MHz using test configuration described at chapter 5.1. The test set-up was in accordance with the requirements of ANSI C63.4.

The measurement result/emission level (V_m) is calculated by adding correction factor (CF) to the measured level (V_{RX}) from the receiver. This correction factor includes cable loss (L_{CABLE}) and the insertion loss (IL) of the LISN.

$$CF (dB) = L_{CABLE} (dB) + IL (dB)$$

$$V_m (dB\mu V) = V_{RX} (dB\mu V) + CF (dB)$$

Sample Calculation:

$$CF (dB) : 1.2 \text{ dB} + 0.8 \text{ dB} = 2.0 \text{ dB}$$

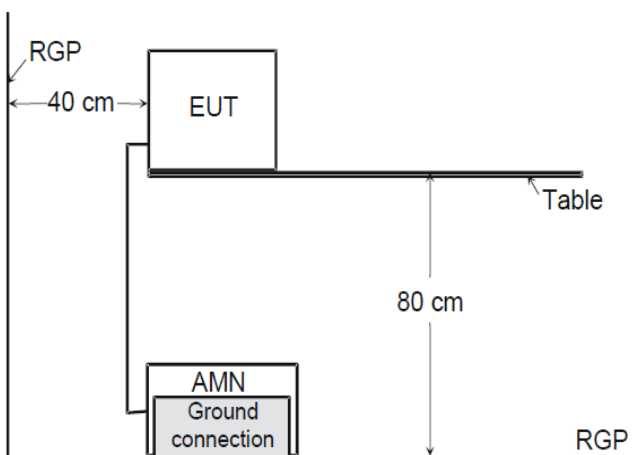
$$V_m (dB) : 43.4 \text{ dB}\mu V + 1.2 \text{ dB} = 44.6 \text{ dB}\mu V/m.$$

Important Note: This is a sample calculation only for the purpose of demonstration, and does not reflect data in this report.

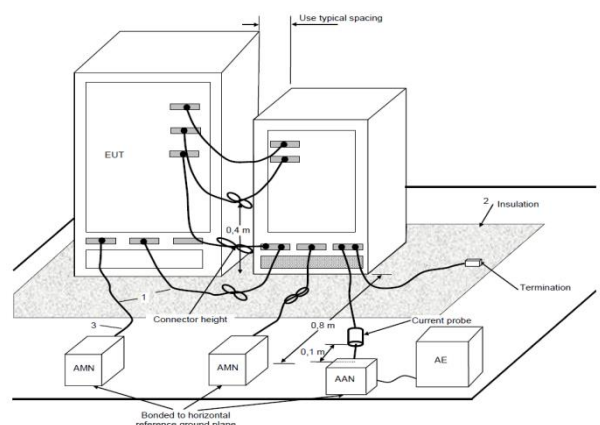
The AC power line conducted emission measurements were performed at the line voltage of 120 V_{AC} and at the power frequency of 60 Hz.

The initial step in collecting conducted data was a peak scan measurement over the frequency range of interest. The significant peaks were marked and these peaks were re-measured using a quasi peak and average detectors.

This procedure was implemented by using EMI test receiver and control software (see used equipment section).



Test setup for "Table-top" EUT.



Test setup for "Floor-standing" EUT.

3.2 Radiated emissions

The field strength level of radiated emissions from digital device has been determined according to the section 15.109 of 47CFR Part 15B and clause 3.2.2. of ICES-003.

Measurements have been performed in a Semi Anechoic Chamber (SAC) at 3 meter measurement distance using the test setup described chapter 5.2. The field strength (FS) is calculated by adding correction factor to the measured level from the spectrum analyzer. This correction factor includes antenna factor (AF), cable loss (L_{CABLE}) and pre-amplifiers gain (PA_{GAIN}). Final measurements are made with the Azimuth, Polarisation, Height, and EUT Cables positioned for maximum radiation.

$$CF \text{ (dB)} = AF(\text{dB/m}) + L_{\text{CABLE}} \text{ (dB)} - PA_{\text{GAIN}} \text{ (dB)}$$

$$FS \text{ (dB}\mu\text{V/m)} = V_{\text{RX}} \text{ (dB}\mu\text{V)} + CF \text{ (dB)}$$

Sample Calculation:

$$CF \text{ (dB)} : 11.8 \text{ (dB/m)} + 2.3 \text{ (dB)} - 20.8 \text{ (dB)} = - 6.7 \text{ dB}$$

$$FS \text{ (dB}\mu\text{V/m)} : 39.8 \text{ (dB}\mu\text{V)} - 6.7 \text{ (dB)} = 33.1 \text{ dB}\mu\text{V/m.}$$

Important Note: This is a sample calculation only for the purpose of demonstration, and does not reflect data in this report.

The measurements have been conducted in accordance with the methodology as described in ANSI C63.4, as required by sections 15.31 and 15.33 of 47CFR Part 15B and clause 2.3 and 3.2.2 of ICES-003.

The frequency band in which the DUT is operating is 2480 MHz. Thus, according to the table below, the frequency range of interest was 30 MHz – 18 GHz.

Highest frequency generated or used in the device or on which the device operates or tunes (MHz)	Upper frequency of measurement range (MHz)
Below 1.705	30
1.705 to 108	1000
108 to 500	2000
500 to 1000	5000
Above 1000	5 th harmonic of the highest frequency or 40 GHz, whichever is lower.

4 VERDICT SUMMARY SECTION

This chapter presents an overview of standards and results. Refer to the next chapters for details of measured test results and applied test levels.

For the DUT the following measurement clauses are applicable:

47CFR Chapter I - Part 15 Subpart B & ICES-003 unintentional radiators	
☐	Section 15.107 (a) Conducted emissions – Class B / Section 3.2.1 Conducted emission ICES-003 – Class B
☒	Section 15.107 (b) Conducted emissions – Class A / Section 3.2.1 Conducted emission ICES-003 – Class A
☐	Section 15.109 (a) Radiated emissions – Class B / Section 3.2.2 Radiated emission ICES-003 – Class B
☒	Section 15.109 (b) Radiated emissions – Class A / Section 3.2.2 Radiated emission ICES-003 – Class A

4.1 Standards

Standard	Year	Description
FCC Part 15 Subpart B	20-11-24 Edition	FCC Rules and Regulations 47 CFR Chapter I Part 15 Subpart B - Radio Frequency Devices.
ICES-003 Issue 7	October 15, 2020	Information Technology Equipment (Including Digital Apparatus) — Limits and Methods of Measurement
ANSI C63.4	2014	American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.

4.2 Deviation(s) from the Standard(s) / Test Specification(s)

The following deviation(s) was / were made from the published requirements of the listed standards:

- No deviations.

4.3 Overview of results

FCC Rules and Regulations 47 CFR Chapter I - Part 15 Subpart B				
Section	Requirement – Test case	Basic standard	Verdict	Remark
15.107	Conducted emissions	ANSI C63.4	PASS	---
15.109	Radiated emissions (30-1000 MHz)	ANSI C63.4	PASS	---
15.109	Radiated emissions (above 1 GHz)	ANSI C63.4	PASS	---
Supplementary information:				

5 TEST RESULTS

5.1 Conducted disturbance voltage – Mains port	VERDICT: PASS
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Standard	FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart B Clause 15.107 / ICES-003 Clause 3.2.1
Basic standard	ANSI C63.4
Supplementary information / Remark:	

Limits – Class A

47 CFR Chapter I - Part 15 Subpart B Clause 15.107(b) / ICES-003 Clause 3.2.1				
Frequency range [MHz]	Limit: QP [dB(μV) ¹⁾	Limit: AV [dB(μV) ¹⁾	IF BW	Detector(s)
0.15 - 0.50	79	66	9 kHz	QP, CAV
0.50 - 30.0	73	60	9 kHz	QP, CAV
¹⁾ At the transition frequency, the lower limit applies.				

Performed measurements

The following configuration(s) and parameter(s) was/were used for testing:

Test set-up		Table-top. Equipment on a table of 80 cm height. 40 cm. distance to VGP.
		Table-top. Equipment on a table of 40 cm height. 40 cm. distance to HGP.
	X	Floor-standing. Equipment on the floor (insulated from ground plane).
	X	Artificial hand applied.
		Other:

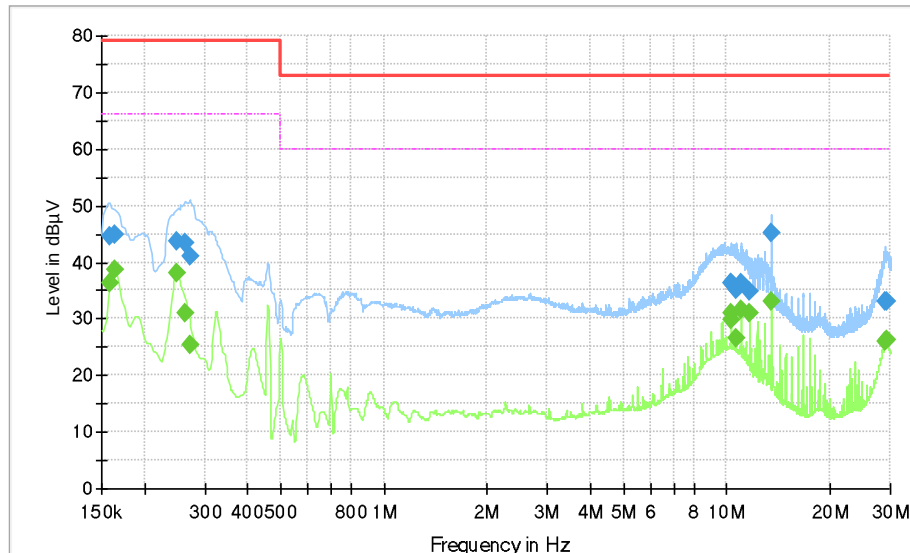
S#	OM#	Conf#	[V]/[Hz] (mains)	Detector	Frequency range	Port/Terminal	Method	P/F	Sup. Info/ Remark
01	01	---	120/60	QP/CAV	150 kHz - 30 MHz	AC Mains	AMN/LISN	P	---
01	02	---	120/60	QP/CAV	150 kHz - 30 MHz	AC Mains	AMN/LISN	P	---
Supplementary information / Remark:									

Test equipment used					
Equipment	Manufacturer	Model	Dekra ID	Cal. Date	Cal. Due
Artificial Mains Network	Rohde-Schwarz	ESH2-Z5	128201	calibration	2025 WK39
Coaxial Cable	Huber&Suhner	RG 223-U	128370	calibration	2025 WK39
EMI Test Receiver	Rohde&Schwarz	ESR 7	132185	calibration	2025 WK39
ISN	Teseq	T8-Cat.6	127033	calibration	2025 WK40
Pulse Limiter	Rohde&Schwarz	ESH3-Z2	116978	calibration	2025 WK39
Test-Control Software	Rohde-Schwarz	EMC32 V10.60.20	500005	---	---

Measurement data:

Common Information

EUT/Sample # / OM# : Iris System / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : AC Mains input
 Remark/Comment :



◆ Preview Result 2-AVG Final_Result QPK
 ◆ Preview Result 1-PK+ Final_Result CAV

Final_Result

Frequency (MHz)	QuasiPeak (dBµV)	CAverage (dBµV)	Limit (dBµV)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Line	PE	Corr. (dB)	Comment
0.159000	---	36.42	66.00	29.58	3000.0	9.000	L1	GND	10.0	
0.159000	44.61	---	79.00	34.39	3000.0	9.000	L1	GND	10.0	
0.163500	---	38.67	66.00	27.33	3000.0	9.000	L1	GND	10.0	
0.163500	44.73	---	79.00	34.27	3000.0	9.000	L1	GND	10.0	
0.249000	---	37.99	66.00	28.01	3000.0	9.000	L1	GND	10.0	
0.249000	43.59	---	79.00	35.41	3000.0	9.000	L1	GND	10.0	
0.262500	---	31.02	66.00	34.98	3000.0	9.000	L1	GND	10.0	
0.262500	43.54	---	79.00	35.46	3000.0	9.000	L1	GND	10.0	
0.271500	---	25.50	66.00	40.50	3000.0	9.000	L1	GND	10.0	
0.271500	41.13	---	79.00	37.87	3000.0	9.000	L1	GND	10.0	
10.333500	---	30.97	60.00	29.03	3000.0	9.000	L1	GND	10.3	
10.333500	36.45	---	73.00	36.55	3000.0	9.000	L1	GND	10.3	
10.335750	---	29.72	60.00	30.28	3000.0	9.000	N	GND	10.4	
10.335750	36.20	---	73.00	36.80	3000.0	9.000	N	GND	10.4	
10.659750	---	26.53	60.00	33.47	3000.0	9.000	N	GND	10.4	
10.659750	35.10	---	73.00	37.90	3000.0	9.000	N	GND	10.4	
10.979250	---	31.63	60.00	28.37	3000.0	9.000	L1	GND	10.4	
10.979250	36.35	---	73.00	36.65	3000.0	9.000	L1	GND	10.4	
11.625000	---	31.04	60.00	28.96	3000.0	9.000	L1	GND	10.4	
11.625000	34.70	---	73.00	38.30	3000.0	9.000	L1	GND	10.4	
13.560000	---	33.17	60.00	26.83	3000.0	9.000	N	GND	10.5	RFID
13.560000	45.03	---	73.00	27.97	3000.0	9.000	N	GND	10.5	RFID
29.143500	---	26.10	60.00	33.90	3000.0	9.000	L1	GND	10.6	
29.143500	33.08	---	73.00	39.92	3000.0	9.000	L1	GND	10.6	
29.240250	---	26.17	60.00	33.83	3000.0	9.000	L1	GND	10.6	
29.240250	33.02	---	73.00	39.98	3000.0	9.000	L1	GND	10.6	

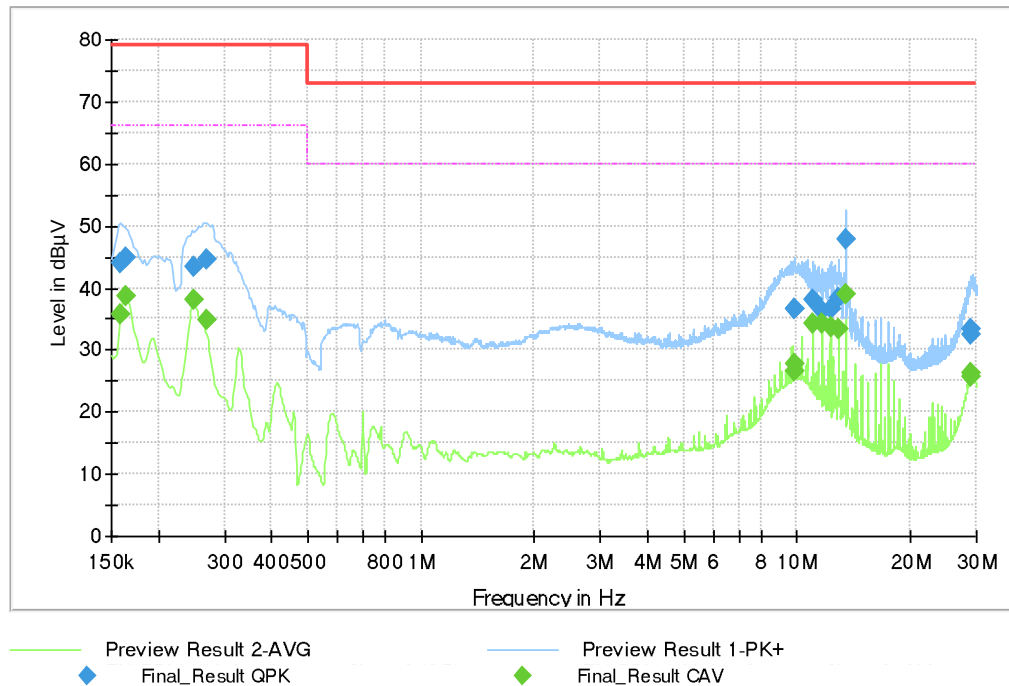
Supplementary information:

- The "Margin" is with reference to the emissions limit. A positive number indicates that the emission measurement is below the limit. A negative number indicates that the emission measurement exceeds the limit.
- The given graph is the combination of max-hold function of each line.

Measurement data:

Common Information

EUT/Sample # / OM# : Iris System / 01 / 02
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : AC Mains input
 Remark/Comment :



Final_Result

Frequency (MHz)	QuasiPeak (dBμV)	CAverage (dBμV)	Limit (dBμV)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Line	PE	Corr. (dB)
0.159000	44.05	---	79.00	34.95	3000.0	9.000	L1	GND	10.0
0.159000	---	35.77	66.00	30.23	3000.0	9.000	L1	GND	10.0
0.163500	44.72	---	79.00	34.28	3000.0	9.000	L1	GND	10.0
0.163500	---	38.82	66.00	27.18	3000.0	9.000	L1	GND	10.0
0.249000	43.38	---	79.00	35.62	3000.0	9.000	L1	GND	10.0
0.249000	---	38.02	66.00	27.98	3000.0	9.000	L1	GND	10.0
0.269250	---	34.92	66.00	31.08	3000.0	9.000	L1	GND	10.0
0.269250	44.47	---	79.00	34.53	3000.0	9.000	L1	GND	10.0
9.827250	---	26.66	60.00	33.34	3000.0	9.000	N	GND	10.3
9.827250	36.46	---	73.00	36.54	3000.0	9.000	N	GND	10.3
9.874500	---	27.63	60.00	32.37	3000.0	9.000	L1	GND	10.3
9.874500	36.56	---	73.00	36.44	3000.0	9.000	L1	GND	10.3
10.979250	---	34.11	60.00	25.89	3000.0	9.000	L1	GND	10.4
10.979250	37.98	---	73.00	35.02	3000.0	9.000	L1	GND	10.4
11.625000	36.45	---	73.00	36.55	3000.0	9.000	L1	GND	10.4
11.625000	---	34.16	60.00	25.84	3000.0	9.000	L1	GND	10.4
12.270750	---	33.63	60.00	26.37	3000.0	9.000	L1	GND	10.4
12.270750	36.73	---	73.00	36.27	3000.0	9.000	L1	GND	10.4
12.916500	---	33.32	60.00	26.68	3000.0	9.000	N	GND	10.5
12.916500	38.24	---	73.00	34.76	3000.0	9.000	N	GND	10.5
13.560000	---	38.99	60.00	21.01	3000.0	9.000	N	GND	10.5
13.560000	47.80	---	73.00	25.20	3000.0	9.000	N	GND	10.5
28.954500	---	25.72	60.00	34.28	3000.0	9.000	N	GND	10.3
28.954500	32.50	---	73.00	40.50	3000.0	9.000	N	GND	10.3
29.150250	---	26.16	60.00	33.84	3000.0	9.000	L1	GND	10.6
29.150250	33.26	---	73.00	39.74	3000.0	9.000	L1	GND	10.6

Supplementary information:

- The "Margin" is with reference to the emissions limit. A positive number indicates that the emission measurement is below the limit. A negative number indicates that the emission measurement exceeds the limit.
- The given graph is the combination of max-hold function of each line.

5.2 Radiated emissions (30 - 1000 MHz)	VERDICT: PASS
---	----------------------

Standard	FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart B Clause 15.109 / ICES-003 Clause 3.2.2
Basic standard	ANSI C63.4
Supplementary information / Remark:	

Limits : FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart B / Class A

Frequency [MHz]	Limit: QP [dB(μV/m) ¹⁾			IF BW [kHz]	Detector
	@3 m.	@5 m.	@10 m.		
30 - 88	49.5	45.1	39.0	120	QP
88 - 216	54.0	49.5	43.5	120	QP
216 - 960	56.9	52.4	46.4	120	QP
960 - 1000	60.0	55.5	49.5	120	QP
¹⁾ At the transition frequency, the lower limit applies.					

Limits : ICES-003 / Class A

Frequency [MHz]	Limit: QP [dB(μV/m) ¹⁾			IF BW [kHz]	Detector
	@3 m.	@5 m.	@10 m.		
30 - 88	50.0	46.0	40.0	120	QP
88 - 216	54.0	49.5	43.5	120	QP
216 - 230	56.9	52.4	46.4	120	QP
216 - 960	57.0	53.0	47.0	120	QP
960 - 1000	60.0	55.5	49.5	120	QP
¹⁾ At the transition frequency, the lower limit applies.					

Performed measurements

The following configuration(s) and parameter(s) was/were used for testing:

Port under test	Enclosure (with cabling)		
Test method	X	Semi Anechoic Chamber	
		Open Area Test Site (OATS)	
		In-Situ (at user/manufacturer premises)	
		GTEM cell	
		Other:	
Test set-up		Equipment on a table of 80 cm height	
	X	Equipment on the floor (insulated from the reference ground plane)	
	X	Other:	The foot pedals connected to the system were placed on the floor (insulated from the ground plane), while remote control device, laser lamp, laser interlock and Diathermy load were placed on a non-conductive support of a height of 80 cm above the ground floor.

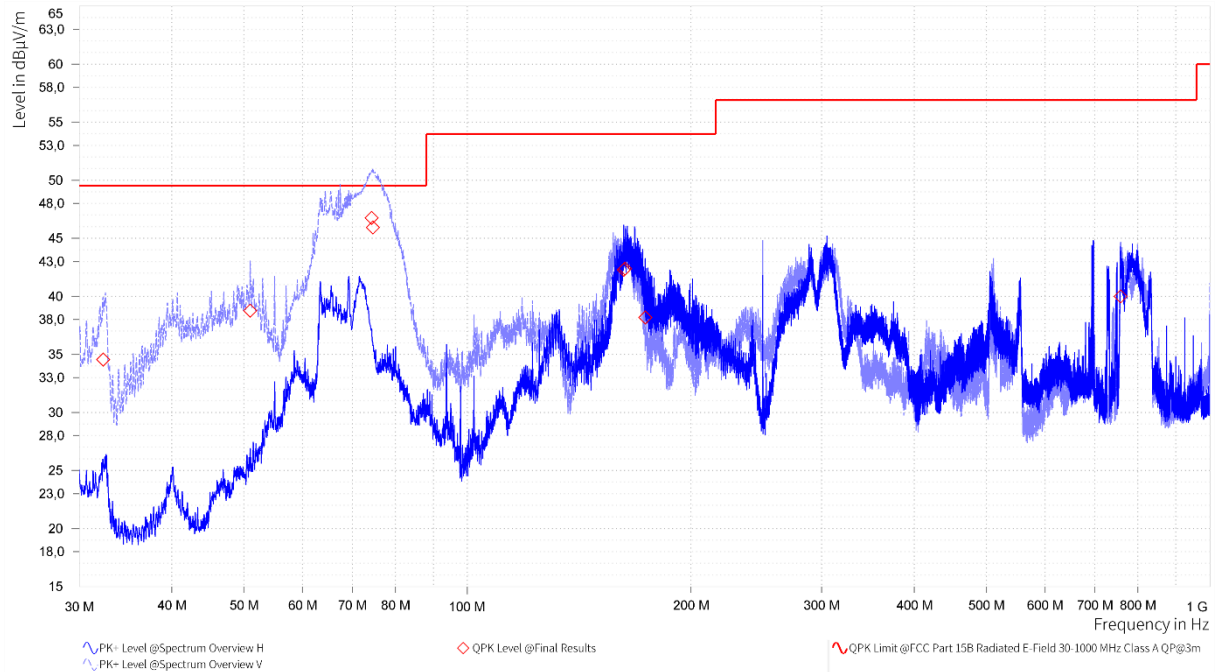
S#	OM#	Conf#	[V]/[Hz] (mains)	Detector	Frequency range	Antenna polar. / axis	Measurement distance	P/F	Sup. Info / Remark
01	01	---	120/60	QP	30 - 1000 MHz	H/V	3 m.	P	---
01	02	---	120/60	QP	30 - 1000 MHz	H/V	3 m.	P	---
Supplementary information / Remark:									

Test equipment used					
Equipment	Manufacturer	Model	Dekra ID	Cal. Date	Cal. Due
Anechoic Chamber	Comtest	SAC-5m	129683	calibration	2026 WK08
Antenna	Rohde-Schwarz	HL562E	132292	calibration	2025 WK48
Coaxial cable	Huber&Suhner	SUCOFLEX 126EA	134187	calibration	2025 WK39
EMI Test Receiver	Rohde-Schwarz	ESU26	126351	calibration	2025 WK39
Test-Control Software	Rohde-Schwarz	EMC32 V10.60.20	500000	---	---

Measurement data:

Common Information

EUT/Sample # / OM# : Iris System / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment :



EMI Final Results

Frequency [MHz]	QPK Level [dBµV/m]	QPK Limit [dBµV/m]	QPK Margin [dB]	Correction [dB]	Polarization	Azimuth [deg]	Antenna Height [m]	Meas. BW [kHz]	Meas. Time [s]
32,310	34,54	49,50	14,96	18,10	V	1	1,00	120,000	2,000
51,000	38,75	49,50	10,75	6,32	V	360	1,18	120,000	2,000
74,310	46,76	49,50	2,74	9,07	V	357	1,18	120,000	2,000
74,610	45,94	49,50	3,56	9,10	V	23	1,13	120,000	2,000
162,480	42,27	54,00	11,73	9,58	H	115	1,70	120,000	2,000
163,080	42,38	54,00	11,62	9,70	V	21	2,26	120,000	2,000
173,610	38,18	54,00	15,82	12,17	H	59	1,96	120,000	2,000
758,610	39,98	60,00	20,02	21,69	V	190	1,60	120,000	2,000

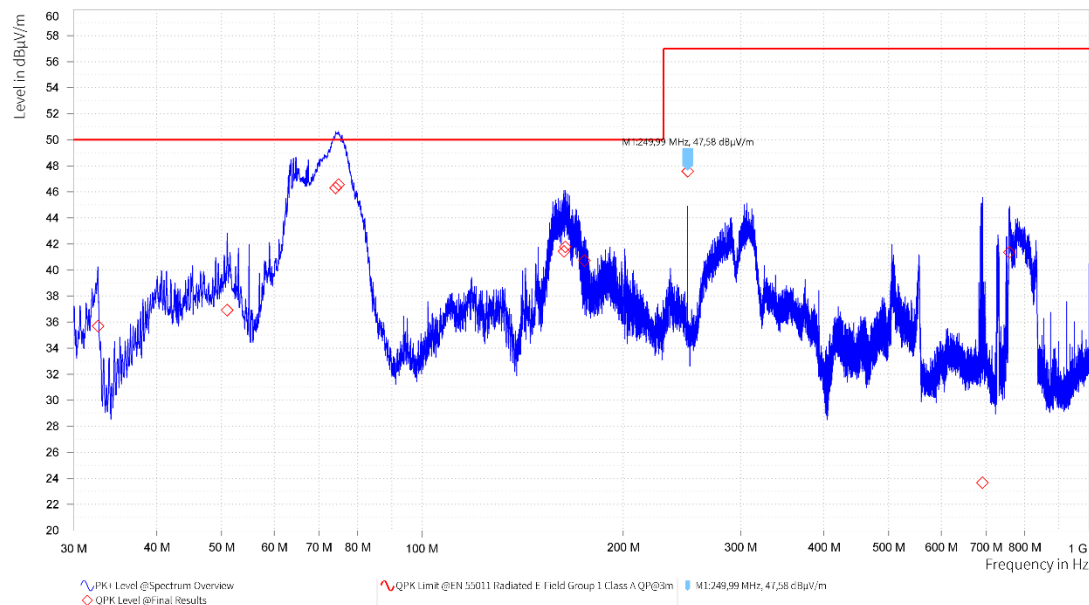
Supplementary information:

- The "Azimuth/Pol/Height" indicates the turn-table azimuth, the antenna polarisation and the antenna height where the maximum emissions level was measured.
- The "Margin" is with reference to the emissions limit. A positive number indicates that the emission measurement is below the limit. A negative number indicates that the emission measurement exceeds the limit.

Measurement data:

Common Information

EUT/Sample # / OM# : Iris System / 01 / 02
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment :



EMI Final Results

Frequency [MHz]	QPK Level [dBµV/m]	QPK Limit [dBµV/m]	QPK Margin [dB]	Correction [dB]	Polarization	Azimuth [deg]	Antenna Height [m]	Meas. BW [kHz]	Meas. Time [s]
32,640	35,70	50,00	14,30	17,93	V	38	1,04	120,000	2,000
51,000	36,92	50,00	13,08	6,32	V	329	1,18	120,000	2,000
74,160	46,29	50,00	3,71	9,05	V	11	1,59	120,000	2,000
74,880	46,55	50,00	3,45	9,13	V	3	1,23	120,000	2,000
163,080	41,43	50,00	8,57	9,70	V	47	2,08	120,000	2,000
163,860	41,77	50,00	8,23	9,86	V	10	1,94	120,000	2,000
175,020	40,72	50,00	9,28	11,51	H	5	1,13	120,000	2,000
249,990	47,58	57,00	9,42	11,13	V	235	1,00	120,000	2,000
691,290	23,66	57,00	33,34	20,88	H	326	2,86	120,000	2,000
759,180	41,36	57,00	15,64	21,69	V	203	1,49	120,000	2,000

Supplementary information:

- The "Azimuth/Pol/Height" indicates the turn-table azimuth, the antenna polarisation and the antenna height where the maximum emissions level was measured.
- The "Margin" is with reference to the emissions limit. A positive number indicates that the emission measurement is below the limit. A negative number indicates that the emission measurement exceeds the limit.

5.3	Radiated emissions (1 - 18 GHz)	VERDICT: PASS
-----	--	----------------------

Standard	FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart B Clause 15.109 / ICES-003 Clause 3.2.2
Basic standard	ANSI C63.4
Supplementary information / Remark:	

Limits : FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart B / Class A

Frequency [GHz]	Limit ^{1) 2)} : AV [dB(μV/m)]			IF BW [MHz]	Detector
	@3 m.	@5 m.	@10 m.		
1 – 40 GHz	60	55.5	49.5	1	AV

¹⁾ At the transition frequency. the lower limit applies.

²⁾ Above 1 GHz. the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test (section 15.35.b).

Limits : ICES-003 / Class A

Frequency [GHz]	Limit ^{1) 2)} : PK&AV [dB(μV/m)]		IF BW [MHz]	Detector
	AV@3 m.	PK@3 m.		
1 – 40 GHz	60	80	1	AV

¹⁾ At the transition frequency. the lower limit applies.

Performed measurements

The following configuration(s) and parameter(s) was/were used for testing:

Port under test	Enclosure (with cabling)		
Test method	X	Absorber-lined Semi Anechoic Chamber (SAC)	
		Absorber-lined Open Area Test Site (OATS)	
		In-Situ (at user/manufacturer premises)	
		Other:	
Test set-up		Equipment on a table of 80 cm height	
	X	Equipment on the floor (insulated from the reference ground plane)	
	X	Other:	The foot pedals connected to the system were placed on the floor (insulated from the ground plane), while remote control device, laser lamp, laser interlock and Diathermy load were placed on a non-conductive support of a height of 80 cm above the ground floor.

S#	OM#	Conf#	[V]/[Hz] (mains)	Detector	Frequency range	Antenna polar. / axis	Measurement distance	P/F	Sup. Info / Remark
01	01	---	120/60	P/AV	1 -18 GHz	H/V	3 m	P	---

Supplementary information / Remark:

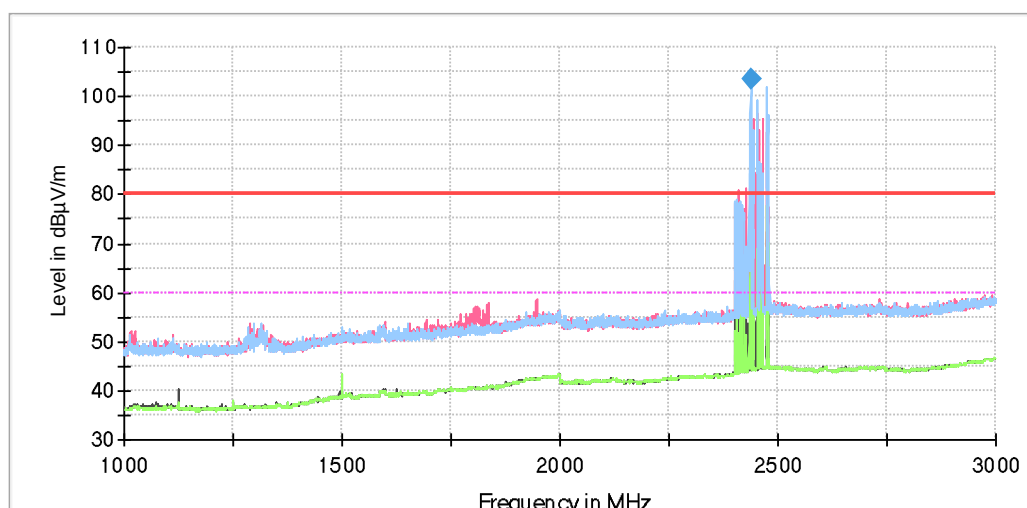
Since the clock frequency of the DUT is 100 MHz, this test is not required.

Test equipment used					
Equipment	Manufacturer	Model	Dekra ID	Cal. Date	Cal. Due
Anechoic Chamber	Comtest	SAC-5m	129683	calibration	2026 WK08
Antenna	Antenna Research Association	DRG-118A	118369	calibration	2025 WK35
Coaxial cable	Huber&Suhner	SUCOFLEX 126EA	134187	calibration	2025 WK39
Coaxial cable	Huber&Suhner	SUCOFLEX 126EA	134185	calibration	2025 WK39
EMI Test Receiver	Rohde-Schwarz	ESU26	126351	calibration	2025 WK39
Highpass filter	Wainwright instruments	WHKX10-2700-3000-18000-40SS	132561C	calibration	2025 WK40
Pre-Amplifier	Bonn Elektronik	BLMA 0118-5A	134808	calibration	2025 WK44
Test-Control Software	Rohde-Schwarz	EMC32 V10.60.20	500000	---	---

Measurement data:

Common Information

EUT/Sample # / OM# : Iris System / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment :



— Preview Result 2V-AVG
 — Preview Result 1V-PK+
 — Preview Result 2H-AVG
 — Preview Result 1H-PK+
 — 01-1_FCC Part 15 Class A E-Field_PK@3m_1G40G
 — 01-2_FCC Part 15 Class A E-Field_AV@3m_1G40G
 ◆ Final_Result PK+
 ◆ Final_Result CAV

Final Result

Frequency (MHz)	MaxPeak (dBμV/m)	Limit (dBμV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth h (kHz)	Height (cm)	Pol	Azimuth (deg)	Comment
2438.0000	103.62	80.00	-23.62	2000.0	1000.000	126.0	H	254.0	Bluetooth

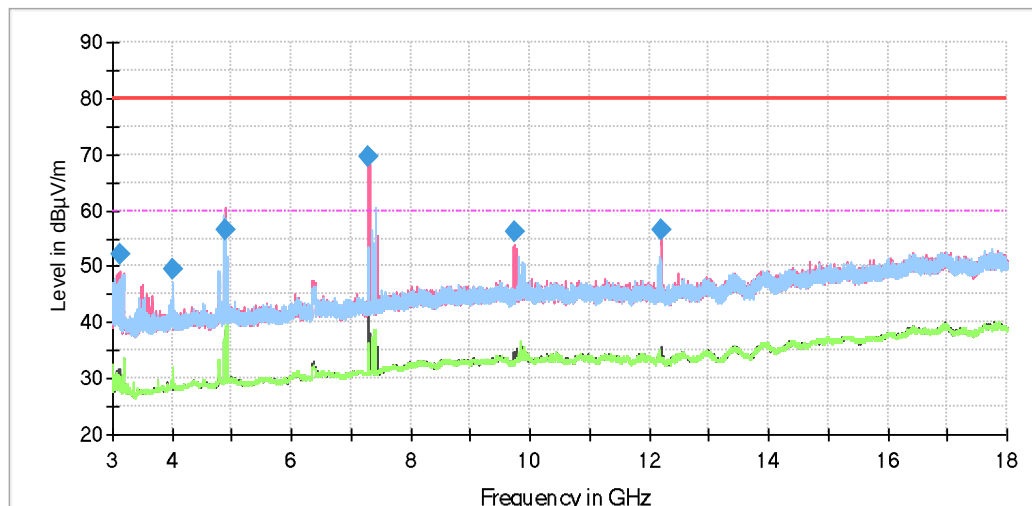
Supplementary information:

- The "Azimuth/Pol/Height" indicates the turn-table azimuth, the antenna polarisation and the antenna height where the maximum emissions level was measured.
- The "Margin" is with reference to the emissions limit. A positive number indicates that the emission measurement is below the limit. A negative number indicates that the emission measurement exceeds the limit.

Measurement data:

Common Information

EUT/Sample # / OM# : Iris System / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment :



— Preview Result 2V-AVG
 — Preview Result 1V-PK+
 — Preview Result 2H-AVG
 — Preview Result 1H-PK+
 — 01-1_FCC Part 15 Class A E-Field_PK@3m_1G40G
 — 01-2_FCC Part 15 Class A E-Field_AV@3m_1G40G
 ◆ Final_Result PK+
 ◆ Final_Result CAV

Final Result

Frequency (MHz)	MaxPeak (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)
3111.00000	52.17	80.00	27.83	2000.0	1000.000	150.0	V	186.0
4000.00000	49.54	80.00	30.46	2000.0	1000.000	137.0	H	212.0
4890.25000	56.54	80.00	23.46	2000.0	1000.000	356.0	V	267.0
7290.25000	69.44	80.00	10.56	2000.0	1000.000	100.0	V	303.0
9728.00000	56.27	80.00	23.73	2000.0	1000.000	283.0	V	269.0
12194.0000	56.40	80.00	23.60	2000.0	1000.000	120.0	V	271.0

Supplementary information:

- The "Azimuth/Pol/Height" indicates the turn-table azimuth, the antenna polarisation and the antenna height where the maximum emissions level was measured.
- The "Margin" is with reference to the emissions limit. A positive number indicates that the emission measurement is below the limit. A negative number indicates that the emission measurement exceeds the limit.

6 ANNEX 1 - MEASUREMENT UNCERTAINTIES

The table(s) below show(s) measurement uncertainties of the EMC test set-ups. The reported expanded uncertainties are based on a standard uncertainty multiplied by a coverage factor of $k=2$, providing a level of confidence of approximately 95%.

Emission tests	Uncertainty	Ucisp
RF Conducted disturbance (mains port) 150 kHz–30 MHz / AMN: R&S ESH2-Z5	2.15 dB	3.40 dB
Radiated emissions; 30 MHz – 1000 MHz (Horz.), SAC@3m, With HYBRID antenna	3.81 dB	5.21 dB
Radiated emissions; 30 MHz – 1000 MHz (Vert.), SAC@3m, With HYBRID antenna	5.56 dB	6.21 dB
Radiated emissions; 1 – 6 GHz (Horz.), with DRG Horn antenna SAC@3m	4.61 dB	5.18 dB
Radiated emissions; 1 – 6 GHz (Vert.), with DRG Horn antenna SAC@3m	4.76 dB	5.18 dB
Radiated emissions; 6 – 18 GHz (Horz.), with DRG Horn antenna SAC@3m	5.31 dB	5.48 dB
Radiated emissions; 6 – 18 GHz (Vert.), with DRG Horn antenna SAC@3m	5.48 dB	5.48 dB

End of the report