



- 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.
- FCC Registration Number: NL0002 / 375449
- ISED CABid: NL0003 / Company number: 27051

Test report No:
2285019.0506A-RSM

Partial Test Report

USA FCC Part 15.247, 15.225, 15.209

CANADA RSS-247, RSS-210, RSS-Gen

(*) Identification of item tested	Apparatus intended for ophthalmic surgery
(*) Trademark	VIRTUOSO
(*) Model and /or type reference	EQ00.R02
(*) Features	RFID 13.56MHz and BT-EDR.
Other identification of the product	FCC ID: 2BNUMIRIS Contains FCC ID: SQGBT700 Contains IC: 3147A-BT700
(*) 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	USA FCC Part 15.247 (10-1-24) Edition: Operation within the bands 902 - 928 MHz, 2400 - 2483.5 MHz, and 5725 - 5850 MHz. USA FCC Part 15.209 (10-1-24) Edition: Radiated emission limits; general requirements. USA FCC Part 15.225 (10-1-24 Edition): Operation within the band 13.110 -14.010. CANADA RSS-Gen Issue 5 (April 2018), Amendment 1 (March 2019) and Amendment 2 (February 2021). CANADA RSS-247 Issue 4, (July 2025). CANADA RSS-210 Issue 11 (June 2024). ANSI C63.10-2020+Cor. 1-2023+C63.10a-2024 + Errata to C63.10a-2024: American National Standard for Testing Unlicensed Wireless Devices. - Transmitter out of band radiated emission with simultaneous transmissions. Guidance for Performing Compliance Measurements on Digital Transmission System, Frequency Hopping Spread Spectrum System, and Hybrid Systems Devices Operating Under Section 15.247 of the FCC Rules. 558074 D01 Meas Guidance v05r02 dated April 2, 2019.
Verdict Summary	IN COMPLIANCE
Tested by (name / position & signature)	Alberto Serrano Criado Technical Professional EMC/Wireless Supervised by Jose Carlos Luque Technical Professional EMC/Wireless
Approved by (name / position & signature)	Sedat Eser Technical Professional EMC/Wireless
Date of issue	2026-01-13
Report template No	TRF_RSM_FCC R1.0 (*) "Data provided by the applicant"

INDEX

	page
Competences and Guarantees.....	3
General conditions.....	3
Uncertainty	3
Environmental conditions	4
Possible test case verdicts.....	4
Definition of symbols used in this test report.....	4
Abbreviations.....	4
Data provided by the applicant.....	5
Document History	5
Conclusion, Remarks and Comments	5
1 General Information	6
1.1 General Description of the Item(s)	6
1.2 Derived models	12
1.3 Test data.....	12
2 Description of Test Setup	13
2.1 Sample(s) used for tests.....	13
2.2 Operating mode(s) used for tests	13
2.3 Port(s) of the EUT	13
2.4 Test Configuration / Block diagram used for tests	14
2.5 Test conditions.....	14
3 Verdict summary section	18
3.1 Standards	18
3.2 Overview of results – BT BR and EDR 2.4 GHz.....	18
3.3 Deviation(s) from the Standard(s) / Test Specification(s).....	18
4 Test Results HFS mode	19
4.1 Product Information.....	19
4.2 Emission limitations radiated (Transmitter)	20
Annex A: Used Equipment	26
Annex B: Similarity declaration.....	27
Annex C: Photographs.....	33

COMPETENCES AND GUARANTEES

The DEKRA is a testing laboratory competent to carry out the tests described in this report.

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.

IMPORTANT: No parts of this report may be reproduced or quoted out of context, in any form or by any means, except in full, without the previous written permission of DEKRA.

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

Uncertainties have been calculated according to the DEKRA internal document AM#2224. 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.

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	86 kPa – 106 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
DUT	: Device Under Test
QP	: Quasi-Peak
PK	: Peak
AV	: Average
SAC	: Semi-Anechoic Chamber
OATS	: Open Area Test Site
RBW	: Resolution Bandwidth
VBW	: Video Bandwidth
Tx	: Transmitter
Rx	: Receiver
N/A	: Not Applicable
N/M	: Not Measured
RGP	: Reference Ground Plane
TX	: Transmission
RX	: Reception

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 same as the model under test.
3. Similarity declaration in Annex B.

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
2285019.0506-RSM	2025-03-19	First release.
2285019.0506A-RSM	2026-01-13	Second release. It was updated the version of ANSI C63.10 and RSS-247 and FCC Part 15C to the last version. This revision of the test report cancels and replaces the test report with a reference number 2285019.0506-RSM.

CONCLUSION, REMARKS AND COMMENTS

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

- Transmitter out of band radiated emissions with simultaneous transmissions:

The test results stated in this report of model " EQ00.R02 " are also representative for models in chapter 1.2.

1 GENERAL INFORMATION

1.1 General Description of the Item(s)

Description of the item.....:	A multifunctional surgical equipment for use in anterior and posterior segment ophthalmic surgeries
Model / Type number	EQ00.R02
Reference number	IR230113
Trademark	VIRTUOSO®
Manufacturer.....:	Vitrec
Address	Seggelant-Noord 2, 3237 MG Vierpolders, The Netherlands

Operating frequency range(s) – Tx :	RFID: 13.56MHz BT BR and EDR: 2400-2483.5 MHz
Operating frequency range(s) – Rx :	RFID: 13.56MHz BT BR and EDR: 2400-2483.5 MHz
Type of Modulation.....:	RFID: ASK BT BR and EDR: GFSK, PI/4-DQPSK, 8DPSK
Number of channel.....:	RFID: 1 BT BR and EDR: 79
Antenna type.....:	RFID: PCB Antenna BT BR and EDR: Internal/Integrated/PCB antenna
Antenna gain.....:	RFID : H-field@3m= 6.47 dBuA/m BT BR and EDR: 0.5 dBi

Rated power supply.....:	Voltage and Frequency			Power connection type				
				L1	L2	L3	N	PE
	☒	AC: 100 – 240 V, 50/60 Hz		☒	☐	☐	☒	☒
	☐	DC:						
	☒	Battery: for Remote control	☒	Rechargeable battery: for foot pedal				
Rated Power	500VA / 6A							
Clock frequencies.....:	See screenshot below a)							
Other parameters.....:	RFID 13.56MHz, BT 2.4 GHz							
Software version	11.0.x							
Hardware version.....:	DMR02776							
Dimensions in cm (W x H x D).....:	64.0 x 171.0 x 75.5							
Mounting position.....:	☐	Table top equipment						
	☐	Wall/Ceiling mounted equipment						
	☒	Floor standing equipment						
	☐	Hand-held equipment						
	☐	Other:						

a)

Frequency (MHz)	Description	Frequency (MHz)	Description
25	Clock frequency references (FPGA, DSP, Ethernet switch)	0.65	Boost Converter Diathermy
100	Internal FPGA	10	SPI clock ADC's (ADC1, ADC2, ADC5, ADC6, ADC7, ADC8)
25	RGMII interface	0.5	SPI clock Pressure sensors
0.1152	UART	1.25	SPI clock Pump
0.5	RS232 UART Laser	10	SPI clock Vitrectomy ADC
0.5	RS232 Video Overlay	1	SPI clock Diathermy ADC
0.1	PWM PSD LED's	1	SPI clock Phaco ADC
1	PWM Illumination LED Drivers	1	SPI clock Laser I/O ADC (ADC4)
0.035	PWM BLDC Motors	2.1	SPI clock Laser ID transceiver
0.025	PWM FAN's	1	SPI clock ADuM devices
0.04	PWM Phaco		
0.2	PWM Diathermy		

Intended use of the Equipment Under Test (EUT)

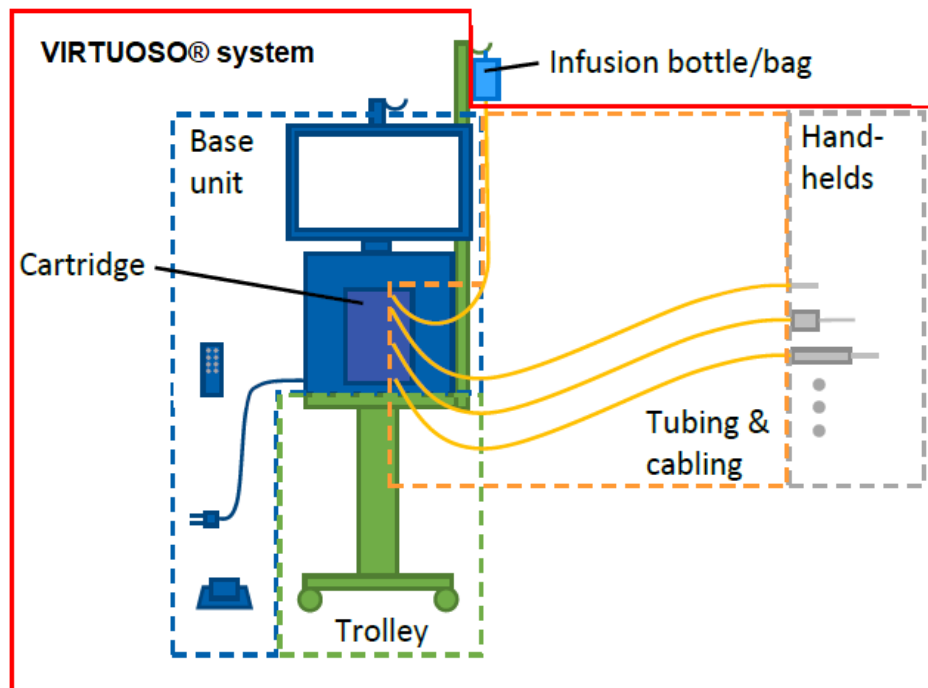
The VIRTUOSO® system is an equipment intended for anterior and posterior segment ophthalmic surgery. The system capabilities include:

- 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:

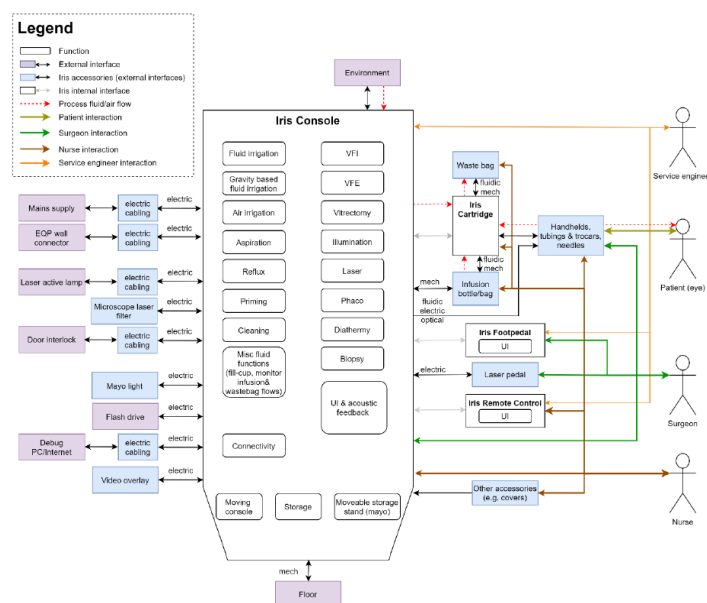
- Base unit: the desktop part of the system, including touch screen, foot pedal(s) and remote control. The base unit also encloses two (2) Bluetooth radio modules used for communication with the foot pedal and the remote control units and RFID interface related to laser function.
- Cartridge: disposable 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:



No	Module/parts of test item	Type	Manufacturer
1	Mainboard	D664301_F	Demcon
2	Laser Frontpanel	D242197_D	Demcon
3	Footpedal	2X0783 Rev 0	Vitrec
4	Remote control	D745561_A	Demcon

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.	Similarity declaration	Declaration of Similarity - Option 1	2024-12-10

Modifications to the test item during testing	☒	N/A	☐	Refers Chapter
---	-------------------------------------	-----	--------------------------	----------------

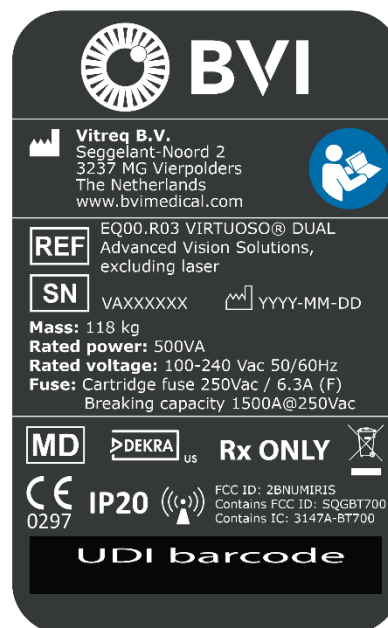
Copy of marking plate:



EQ00.R02



EQ00.R01



EQ00.R03

1.2 Derived models

See Annex B.

1.3 Test data

Test Location	DEKRA Certification B.V., Netherlands
Date (start)	2024-10-17
Date (finish)	2024-10-18

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	Module / parts of test item	Type	Serial number	Remark(s) / Changes
01	100781 / 1-1	VIRTUOSO® Main System (Full surgical unit)	EQ00.R02	IR230113	See 1
02	100781 / 1-3	Footpedal	2X0783 Rev 0	PROT_7	See 2
03	105379 / 1-1	Remote control	D745561_A	0000.0006 (T1)	See 3
Supplementary information: 1. Base unit of Virtuoso system. Radiated sample. 2. Foot Pedal of Virtuoso system. Radiated sample. 3. Remote control of Virtuoso system. Radiated sample.					

2.2 Operating mode(s) used for tests

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

Operating mode	Description of the operating mode	Used for testing
1	EUT ON. TX continuous modulated carrier at 2402 MHz BT GFSK (DH5) Main system setting 47 (Module 1). TX continuous modulated carrier at 2480 MHz BT GFSK (DH5) Main system setting 47 (Module 2). TX continuous modulated carrier at 2441 MHz BT GFSK (DH5) Foot Pedal setting 47 (Module 1). TX continuous modulated carrier at 2478 MHz BT GFSK (DH5) Remote Control setting 47 (Module 1).	☒
Supplemental information: ---		

The following power settings were used for BDR/EDR:

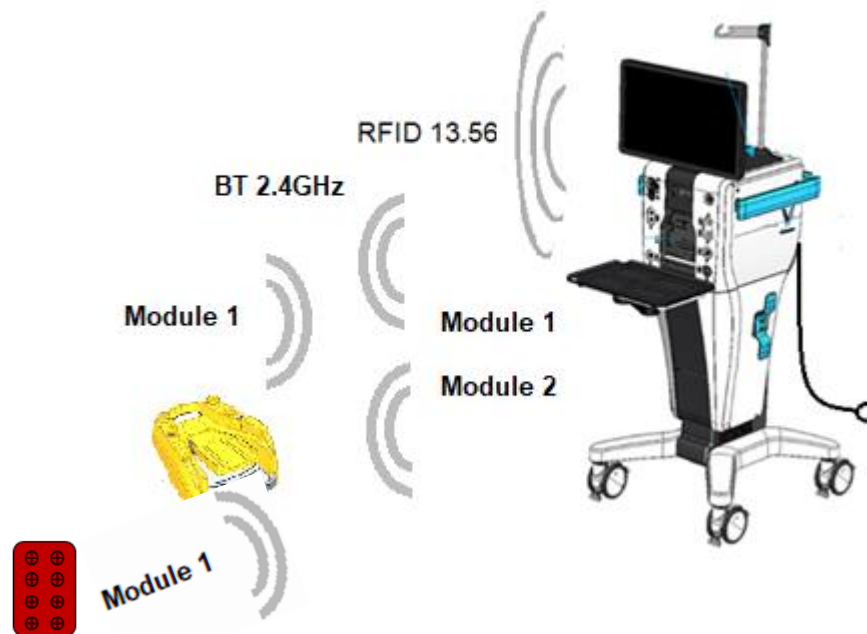
Modulation Mode	Test Frequency (MHz)			
	2402	2441	2478	2480
GFSK / 1Mbps	48	48	48	48

2.3 Port(s) of the EUT

Port name and description	Connected to / Termination	Cable		
		Length used during test [m]	Attached during test	Shielded
Enclosure	--	--	☐	☐
			☐	☐
Supplemental information: ---				

2.4 Test Configuration / Block diagram used for tests

The following block diagram has been used during the tests:



2.5 Test conditions

Power supply (V) of Main System:

Vnom= 230 Vac.

Vmin= N/A

Vmax= N/A

Type of Power Supply: AC main power.

Power supply (V) of foot pedal:

Vnom= 7.2Vdc.

Vmin= N/A

Vmax= N/A

Type of Power Supply of Footpedal: Internal battery

Power supply (V) of remote control:

Vnom= 3Vdc.

Vmin= N/A

Vmax= N/A

Type of Power Supply of Remote Control: Two 'AAA' batteries

Temperature (°C):

Tn = +15° to +35°.

Tmin= N/A

Tmax= N/A

The Virtuoso system is placed inside an anechoic chamber on a turntable.

TEST Setup

All radiated tests were performed in a semi-anechoic chamber. The used measurement antenna's are:

- Loop antenna situated at a distance of 3 m for the range between 9 KHz to 30 MHz.
- Ultralog antenna situated at a distance of 3 m for the range between 30 MHz to 1000 MHz.
- Double ridge horn antenna is situated at a distance of 3 m for the frequency range of 1 GHz to 26 GHz.
- Double ridge horn antenna is situated at a distance of 1 m for the frequency range of 18 GHz to 26 GHz.

The equipment under (Main System) test was set up on a non-conductive platform at a height of 0,2 m above the ground plane and the situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height (Ultralog antenna and Double ridge horn antenna) was varied from 1 to 4 meters to find the maximum radiated emission.

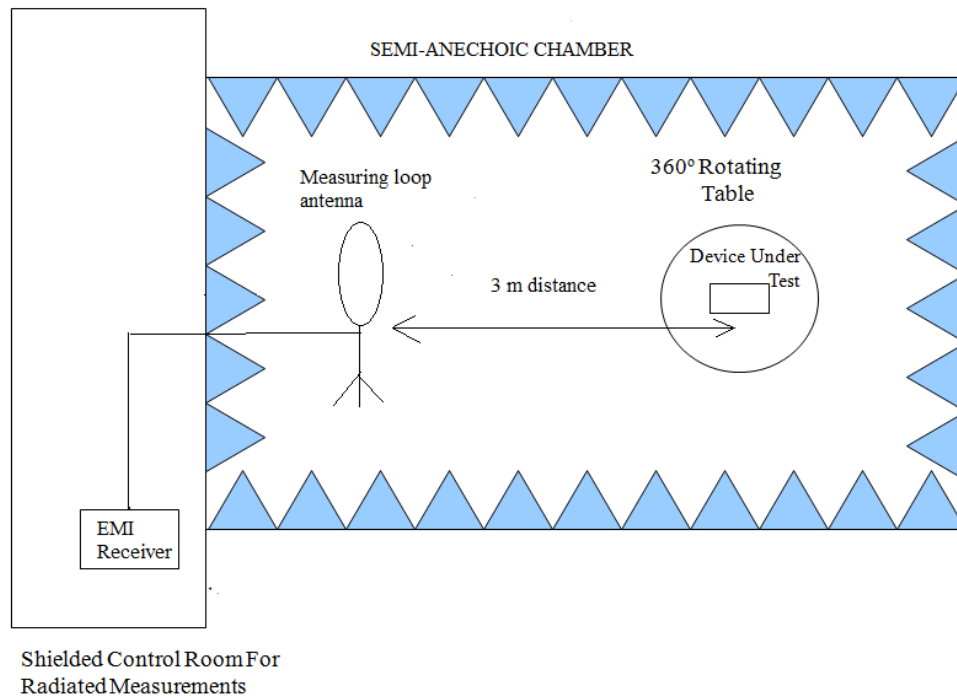
The equipment under (Foot pedal) test was set up on a non-conductive platform at a height of 1,5 m above the ground plane and the situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height (Ultralog antenna and Double ridge horn antenna) was varied from 1 to 4 meters to find the maximum radiated emission.

The equipment under (Remote control) test was set up on a non-conductive platform at a height of 1,5 m above the ground plane and the situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height (Ultralog antenna and Double ridge horn antenna) was varied from 1 to 4 meters to find the maximum radiated emission.

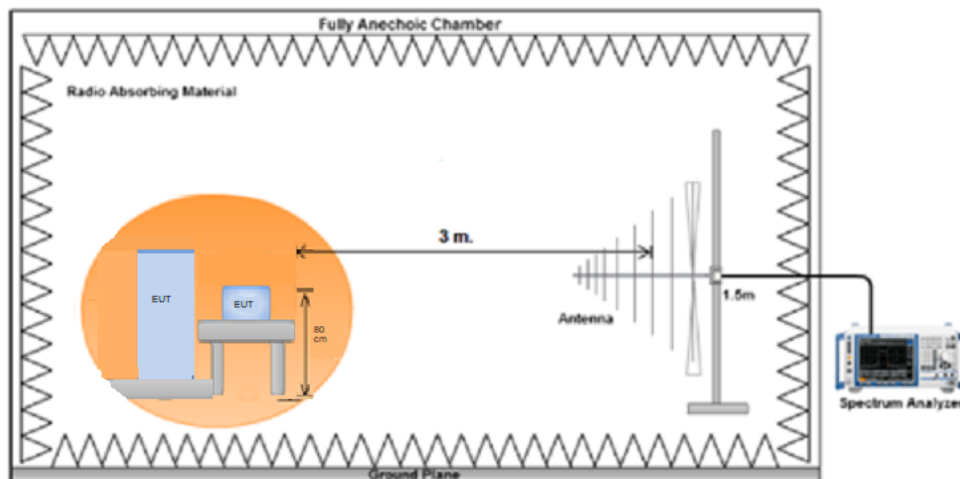
Measurements were made in both horizontal and vertical planes of polarization.

A resolution bandwidth / video bandwidth of 100 kHz / 300 kHz was used for frequencies below 1 GHz and 1 MHz / 3 MHz for frequencies above 1 GHz.

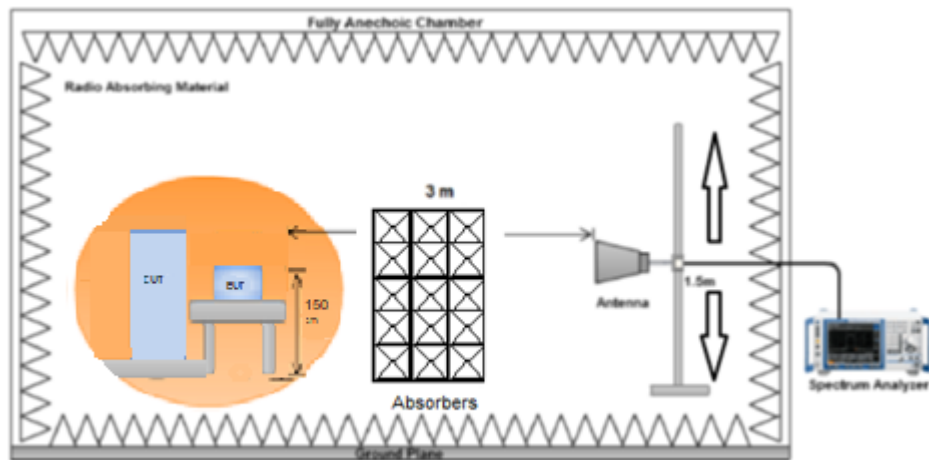
Radiated measurements setup from 9 KHz to 30 MHz



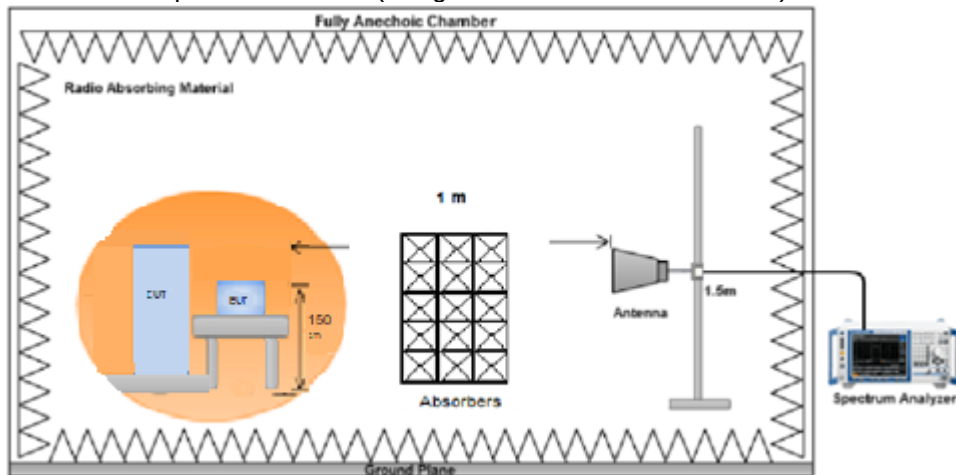
Radiated measurements setup from 30 MHz to 1 GHz



Radiated measurements setup from 1 GHz to 18 GHz (tilting of the antenna is not shown):



Radiated measurements setup above 18 GHz (tilting of the antenna is not shown):



3 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.

3.1 Standards

Standard	Year	Description
FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart C Clause 15.247	2024-01	Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.
RSS-247	2025-07	Digital Transmission System (DTSS), Frequency Hopping System (HFSS) and License-Exempt Local Area Network (LE-LAN) Devices
FCC Rules & Regulations 47 CFR Chapter I - Part 15 Subpart C Clause 15.225	2024-01	Operation within the bands 13.110-14.010MHz..
RSS-210	2024-06	Licence-Exempt Radio Apparatus: Category I Equipment

3.2 Overview of results – BT BR and EDR 2.4 GHz

Test case	Standard	Verdict	Remarks
Emission limitations radiated (Transmitter)	FCC 15.247 Subclause (d), 15.225 Subclause (d) / RSS-210 Clause B.6 (a.iv), RSS-247 Subclause 6.6 and RSS-Gen	Pass	See 1
Supplementary information and remarks: (1) Only Co-Location radiated spurious emission test was requested.			

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

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

4 TEST RESULTS HFS MODE

4.1 Product Information

The following information is provided by the supplier, in accordance with clause 5.3.1:

Information	Description
Modulation	RFID: ASK BT BR and EDR: GFSK, PI/4-DQPSK, 8DPSK
Frequency band/Range	RFID: 13.110MHz to 14.010 MHz BT BR and EDR: 2400 MHz to 2483.5 MHz
Maximum RF OutFHsFHput Power (e.i.r.p.)	RFID: +23 dBm BT BR and EDR: +18 dBm
Operation mode 1: Single Antenna Equipment	RFID: Single antenna BT BR and EDR: Single antenna
- Operating Frequency Range	RFID: 13.56MHz BT BR and EDR: 2402 MHz to 2480 MHz
- Channel Spacing	RFID: N/A. BT BR and EDR: 1MHz
- Number of Channels	RFID: 1 channel BT BR and EDR: 79 Channels
Extreme operating conditions	
- Temperature range	0°C – 35°C
Antenna type	RFID: PCB Antenna BT BR and EDR: Internal/Integrated/PCB antenna
Antenna gain "Antenna port 1"	RFID : H-field@3m= 6.47 dBuA/m BT BR and EDR: 0.5 dBi
Nominal Voltage	
- Supply Voltage	Main system: AC: 100 – 240 V, 50/60 Hz Foot pedal: Internal battery Remote control: Internal batteries
- Type of power source	Main system: Bluetooth BDR/EDR and RFID. Foot pedal: Bluetooth BDR/EDR Remote control: Bluetooth BDR/EDR
Equipment type	Main system: FHSS and RFID Foot pedal: FHSS Remote control: FHSS

4.2 Emission limitations radiated (Transmitter)

SPECIFICATION FCC 15.225 and RSS-210:

Field strength of any emissions appearing outside of the band 13.110 MHz - 14.010 MHz band shall not exceed the general radiated emission limits in 15.209/RSS-Gen:

Frequency Range (MHz)	Field strength (μV/m)	Field strength (dBμV/m)	Measurement distance (m)
0.009-0.490	2400/F(kHz)	-	300
0.490-1.705	24000/F(kHz)	-	30
1.705 - 30.0	30	29.54	30
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
Above 960	500	54	3

SPECIFICATION FCC 15.247 and RSS-247:

Radiated emissions which fall in the restricted bands, as defined in §15.205(a), must also comply with the radiated emission limits specified in §15.209(a) (see §15.205(c)):

Frequency Range (MHz)	Field strength (μV/m)	Field strength (dBμV/m)	Measurement distance (m)
0.009-0.490	2400/F(kHz)	-	300
0.490-1.705	24000/F(kHz)	-	30
1.705 - 30.0	30	-	30
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
960 - 25000	500	54	3

The emission limits shown in the above table are based on measurements employing CISPR quasi-peak detector except for the frequency bands 9-90 kHz, 110-490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector.

For average radiated emission measurements above 1000 MHz, there is also a limit corresponding to 20 dB above the indicated values in the table is specified when measuring with peak detector function.

RESULTS:

The situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height was varied (in TILT mode) from 1 to 4 meters to find the maximum radiated emission.

Measurements were made in both horizontal and vertical planes of polarization.

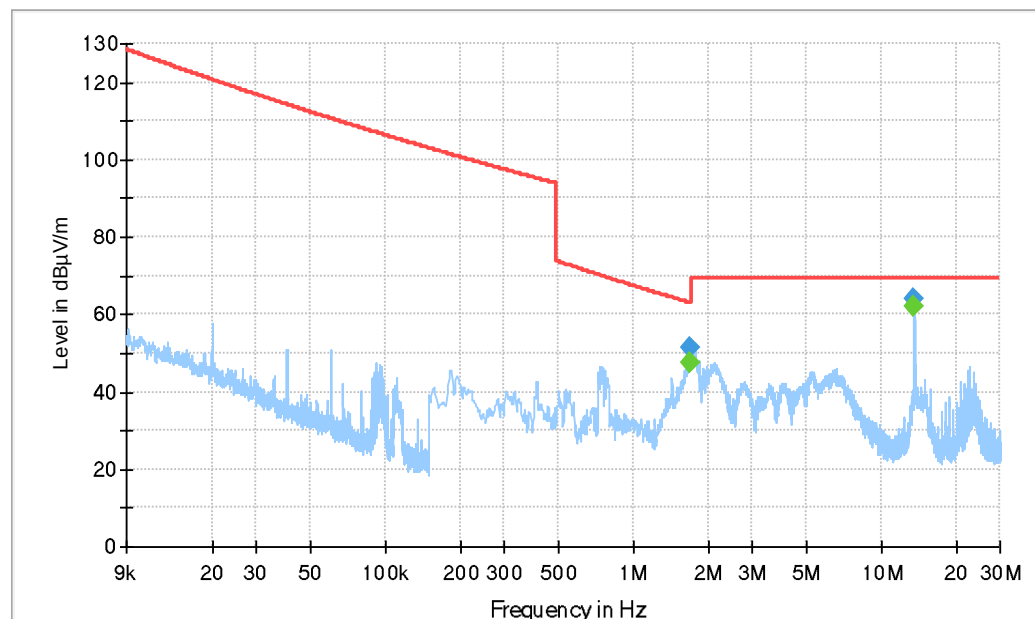
All tests were performed in a semi-anechoic chamber at a distance of 3 m for the frequency range 30 MHz-18 GHz and at distance of 1 m for the frequency range 18 GHz-26 GHz.

The field strength is calculated by adding correction factor to the measured level from the spectrum analyzer. This correction factor includes antenna factor, cable loss and pre-amplifiers gain.

Measurement data:

Common Information

EUT/Sample # / OM# : Main system + Footpedal + Remote Control / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment : EUT ON. Simultaneous TX. Mainsystem with BT BR GFSK Module
 1: Low channel. BT BR GFSK Module 2: High channel. RFID in TX
 13.56MHz. Foot pedal with BT BR GFSK Module 1: Mid channel.
 Remote control with BT GFSK Module 1: 2478 MHz. Axis X.



◆ Preview Result 1-PK+ Final_Result PK+ ◆ 08-1_FCC Part 15.225 E-Field_dBuv Final_Result QPK

Final_Result

Frequency (MHz)	MaxPeak (dBµV/m)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol
1.700283	---	47.68	---	---	1000.0	9.000	100.0	V
1.700283	51.49	---	62.99	11.50	1000.0	9.000	100.0	V
13.559822	---	61.91	---	---	1000.0	9.000	100.0	V
13.559822	64.10	---	69.54	5.44	1000.0	9.000	100.0	V

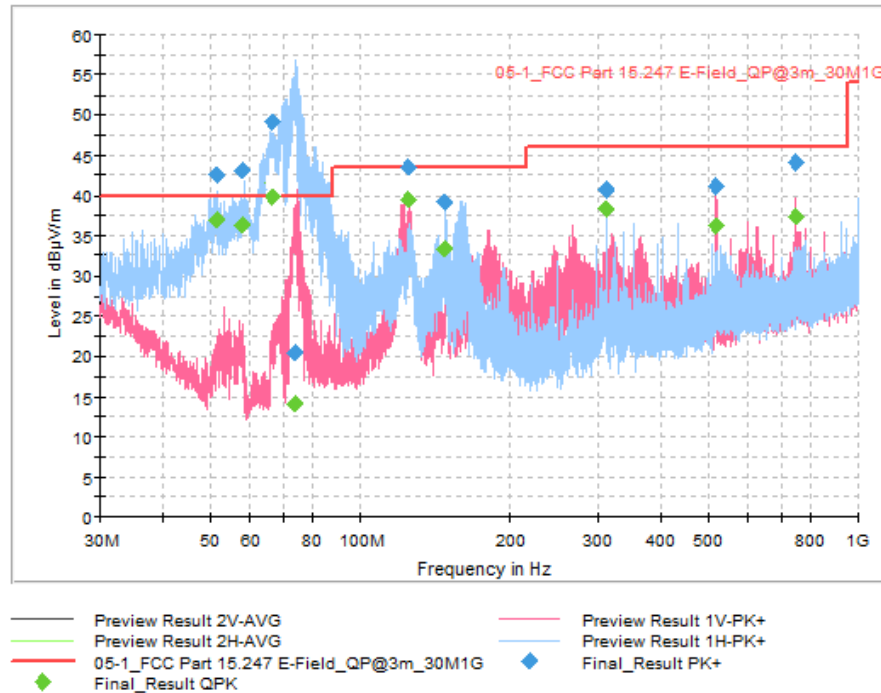
Supplementary information:

- 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.
- The signal near the limit belongs to RFID carrier. Axis-X was the worst orientation of the Loop antenna.

Measurement data:

Common Information

EUT/Sample # / OM# : Main system + Footpedal + Remote Control / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment : EUT ON. Simultaneous TX. Mainsystem with BT BR GFSK Module
 1: Low channel. BT BR GFSK Module 2: High channel. RFID in TX
 13.56MHz. Foot pedal with BT BR GFSK Module 1: Mid channel.
 Remote control with BT GFSK Module 1: 2478 MHz.



Final Result PK+

Frequency (MHz)	MaxPeak (dBµV/m)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Comment
51.471333	42.44	120.000	100.0	H	274.0	This broadband noise is due to the operation of a pump that operates discontinuously. It is not related to RF Simultaneous Transmission.
57.661167	43.02	120.000	275.0	H	310.0	
66.614167	49.12	120.000	100.0	H	71.0	
73.644333	20.53	120.000	280.0	H	107.0	
125.006166	43.58	120.000	258.0	V	266.0	
147.917667	39.08	120.000	100.0	H	186.0	
311.877167	40.66	120.000	113.0	V	233.0	
517.676667	41.05	120.000	100.0	V	211.0	
750.018667	44.11	120.000	145.0	V	140.0	

Final Result QPK

Frequency (MHz)	QuasiPeak (dBµV/m)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Comment
51.471333	36.97	120.000	100.0	H	274.0	The QP value was measured when the pump was not running.
57.661167	36.41	120.000	275.0	H	310.0	
66.614167	39.92	120.000	100.0	H	71.0	
73.644333	14.05	120.000	280.0	H	107.0	
125.006166	39.45	120.000	258.0	V	266.0	
147.917667	33.35	120.000	100.0	H	186.0	
311.877167	38.43	120.000	113.0	V	233.0	
517.676667	36.20	120.000	100.0	V	211.0	
750.018667	37.27	120.000	145.0	V	140.0	

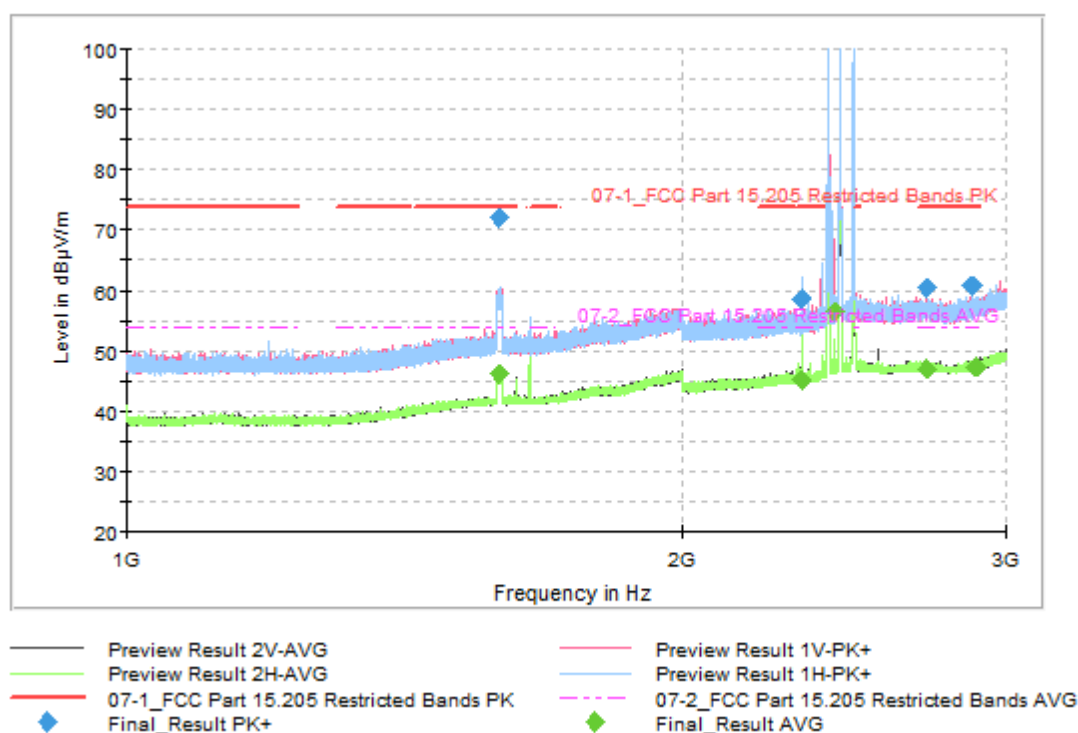
Supplementary information:

- 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.
- In addition to the simultaneous transmission, the equipment is running a discontinuous process outside the transmission.

Measurement data:

Common Information

EUT/Sample # / OM# : Main system + Footpedal + Remote Control / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment : EUT ON. Simultaneous TX. Mainsystem with BT BR GFSK Module
 1: Low channel. BT BR GFSK Module 2: High channel. RFID in TX
 13.56MHz. Foot pedal with BT BR GFSK Module 1: Mid channel.
 Remote control with BT GFSK Module 1: 2478 MHz.



Final Result

Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol
1594.066667	72.12	---	74.00	1.88	2000.0	1000.000	103.0	H
1594.466667	---	46.19	54.00	7.81	2000.0	1000.000	104.0	V
2323.800000	58.47	---	74.00	15.53	2000.0	1000.000	256.0	H
2323.866667	---	45.13	54.00	8.87	2000.0	1000.000	189.0	H
2721.600000	---	47.04	54.00	6.96	2000.0	1000.000	218.0	V
2721.666667	60.58	---	74.00	13.42	2000.0	1000.000	189.0	V
2874.666667	60.68	---	74.00	13.32	2000.0	1000.000	300.0	H
2890.066667	---	47.40	54.00	6.60	2000.0	1000.000	329.0	H

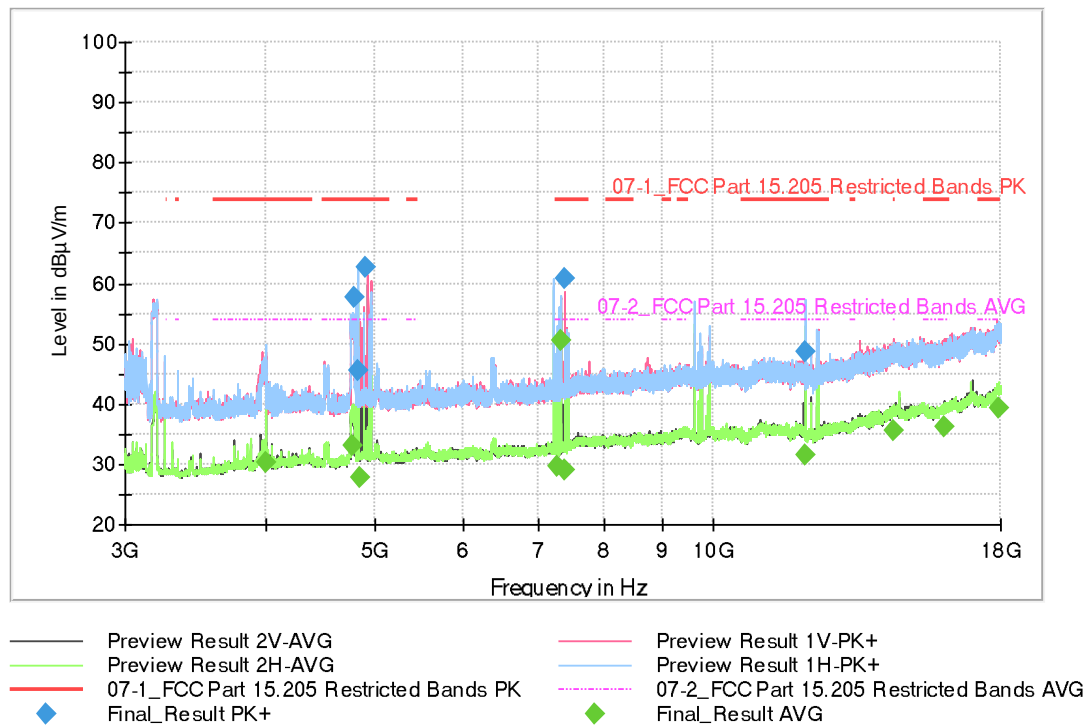
Supplementary information:

- 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.
- The signals above the limit of RSE belong to 4 carrier of BT BR transmitting simultaneously.

Measurement data:

Common Information

EUT/Sample # / OM# : Main system + Footpedal + Remote Control / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment : EUT ON. Simultaneous TX. Mainsystem with BT BR GFSK Module 1: Low channel. BT BR GFSK Module 2: High channel. RFID in TX 13.56MHz. Foot with BT BR GFSK Module 1: Mid channel. Remote control with BT GFSK Module 1: 2478 MHz.



Final Result

Frequency (MHz)	MaxPeak (dBμV/m)	Average (dBμV/m)	Limit (dBμV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol
3999.888333	---	30.36	54.00	23.64	2000.0	1000.000	104.0	V
4769.281667	---	33.16	54.00	20.84	2000.0	1000.000	173.0	H
4787.113333	57.80	---	74.00	16.20	2000.0	1000.000	121.0	H
4827.245000	45.66	---	74.00	28.34	2000.0	1000.000	139.0	H
4852.925000	---	27.93	74.00	26.07	2000.0	1000.000	171.0	H
4904.486667	62.58	---	74.00	11.42	2000.0	1000.000	154.0	V
7274.915000	---	29.66	54.00	24.34	2000.0	1000.000	139.0	H
7322.463333	---	50.65	54.00	3.35	2000.0	1000.000	100.0	H
7364.568333	---	29.17	54.00	24.83	2000.0	1000.000	189.0	V
7379.781667	60.71	---	74.00	13.29	2000.0	1000.000	197.0	V
12056.131667	48.68	---	74.00	25.32	2000.0	1000.000	156.0	H
12064.670000	---	31.59	54.00	22.41	2000.0	1000.000	138.0	H
14482.590000	---	35.42	54.00	18.58	2000.0	1000.000	400.0	V
16066.615000	---	36.07	54.00	17.93	2000.0	1000.000	400.0	V
17959.725000	---	39.15	54.00	14.85	2000.0	1000.000	317.0	H

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# : Main system + Footpedal + Remote Control / 01 / 01
 Voltage/Frequency : 120 Vac / 60 Hz
 Port/Terminal under test : Enclosure
 Remark/Comment : EUT ON. Simultaneous TX. Mainsystem with BT BR GFSK Module 1: Low channel. BT BR GFSK Module 2: High channel. RFID in TX 13.56MHz. Foot pedal with BT BR GFSK Module 1: Mid channel. Remote control with BT GFSK Module 1: 2478 MHz.



— Preview Result 2V-AVG
 — Preview Result 2H-AVG
 * Critical_Freqs AVG
 — 07-1_FCC Part 15.205 Restricted Bands PK
 ◆ Final_Result PK+

— Preview Result 1V-PK+
 — Preview Result 1H-PK+
 * Critical_Freqs PK+
 — 07-2_FCC Part 15.205 Restricted Bands AVG
 ◆ Final_Result AVG

Final_Result

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Height (cm)	Pol
20454.666667	57.52	74.00	16.48	150.0	H
19427.466667	56.34	74.00	17.66	150.0	H
23958.933333	56.92	74.00	17.08	150.0	H
23665.066667	58.20	74.00	15.80	150.0	V
18586.933333	55.55	74.00	18.45	150.0	H
21305.600000	57.35	74.00	16.65	150.0	H
22863.466667	57.76	74.00	16.24	150.0	V
22863.466667	57.76	74.00	16.24	150.0	V
22469.866667	57.28	74.00	16.72	150.0	V

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.

ANNEX A: USED EQUIPMENT

Test equipment used - Radiated Spurious Emissions (9KHz - 26 GHz)				
Equipment	Manufacturer	Model	Dekra ID	Cal. Due
EMI Test Receiver	Rohde-Schwarz	ESU26	126351	2025-09-24
Anechoic Chamber	Comtest	SAC-5m	129683	2026-09-05
Coaxial cable (5m)	Huber&Suhner	SUCOFLEX 126EA	134187	2025-12-18
Antenna	Rohde-Schwarz	HL562E	135981	2025-03-25
Highpass filter	Wainwright instruments	WHKX10-2700-3000-18000-40SS	132561B	2025-10-04
Double Horn Ridge antenna	Rohde-Schwarz	HF 907	134928	2025-07-08
Pre-Amplifier (1- 18 GHz)	BONN	BLMA 1-18-5G	134808	2025-09-10
Coaxial cable (5m)	Huber&Suhner	SUCOFLEX 102EA	134189	2025-10-07
Antenna Horn	ETS-LINDGREN	3116C	132585	2026-11-02
Pre-Amplifier (18- 40 GHz)	BONN	BLMA 18-40-5G	134807	2025-09-10
Highpass filter	Wainwright instruments	WHW2-13500-18000-34000-40CC	132561E	2025-10-04
Test-Control Software	Rohde-Schwarz	EMC32 V10.60.20	500000	---
Active Loop Antenna	Rohde-Schwarz	HFH2-Z2E	134139	2026-12-07

ANNEX B: SIMILARITY DECLARATION

Title:

Declaration of Similarity

Product:

0412 - Iris system



Declaration of Similarity

Name legal manufacturer: Vitreq B.V.

Address: Seggelant-Noord 2

Postal code & City: 3237 MG Vierpolders

Country: Netherlands

9 December 2024

We, DEMCON Life Sciences & Health Enschede B.V., declare,

That the VIRTUOSO® system of model EQ00.R02 and EQ00.R01 and EQ00.R03 use similar hardware (HW) and similar software (SW)

1. HARDWARE SIMILARITY BETWEEN EQ00.R02, EQ00.R01 AND EQ00.R03

This is manifested in using:

- Equivalent schematic/circuit diagrams
- Equivalent functional block diagrams
- Same Printed Circuit Boards (PCB) of the main board and the antennas

Doc. ID: / Version: / Document status:

TMPL-2-145 / 8.0 / Released

Confidential

Declaration of Similarity

Page 1 of 6

Title:

Declaration of Similarity

Product:

0412 - Iris system



- Same PCB Layouts of the mainboard and the antennas
- Same chip sets
- Same Radio frequency antennas with same RF assemblies, like matching circuits
- Same Bluetooth and RFID chipset and related PCB assemblies and part values
- The electrical rating are equal: supply voltage range, current consumption, operating temperature ranges and others

1.1 Hardware impact on EQ00.R03:

The part numbers difference are caused by the laser module (ARC purchase part) and the laser off button not being present:

- 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.
- 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.

These modifications do not influence the radio frequency characteristics of the VIRTUOSO® system model EQ00.R03.

1.2 Hardware impact on EQ00.R01:

A VIRTUOSO® system model EQ00.R01 does NOT contain the functionality related to VFIE, Illumination and Laser.

- 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.

Doc. ID: / Version: / Document status:

TMPL-2-145 / 8.0 / Released

Confidential

Declaration of Similarity

Page 2 of 6

Title:

Declaration of Similarity

Product:

0412 - Iris system



- 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.

These modifications do not influence the radio frequency characteristics of the VIRTUOSO® system model EQ00.R01.

2. SOFTWARE AND FIRMWARE SIMILARITY BETWEEN EQ00.R02, EQ00.R01 AND EQ00.R03

This is manifested using:

The software bundle for all three configurations is the same.

The difference between the three variants lies on a configuration text file which contains information about the variant of the VIRTUOSO® system being used. Depending on this, the following happens:

2.1 Software and Firmware impact on EQ00.R03:

- 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 switched on.
- The GUI is adapted to hide all laser functionality. It is not possible to add a laser step.

Doc. ID: / Version: / Document status:

TMPL-2-145 / 8.0 / Released

Confidential

Declaration of Similarity

Page 3 of 6

Title:

Declaration of Similarity

Product:

0412 - Iris system



The above mentioned text configuration file does not have differences in the Radio Frequency behavior.

2.2 Software and Firmware impact on EQ00.R01:

- 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.
- The GUI is 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.

The above mentioned txt configuration file does not have differences in the Radio Frequency behavior.

Title:

Declaration of Similarity

Product:

0412 - Iris system



3. POTENTIAL LEVERAGING OF TESTS RESULTS

This declaration is intended to allow the leveraging of the tests results from the VIRTUOSO® system model EQ00.R02 to the VIRTUOSO® system models EQ00.R01 and EQ00.R03

Following, a list of test reports which could be leveraged according to our understanding.

- 1) Test report No: 2285019.0504-RSM
- 2) Test report No: 2285019.0505-RSM
- 3) Test report No: 2285019.0506-RSM
- 4) Test report No: 2285019.0507-RSM

3.1 Argumentation for the leveraging

As can be seen in the above list of differences and equalities, the hardware of all three models is equal in many points. The differences lie on subsystems and functionalities not related to the Radio Frequency part of the system.

Especially concerning the Bluetooth and RFID, the chip sets are equal, the main PCB, PCB layout and the antenna are equal between models EQ00.R01, EQ00.R02, and EQ00.R03. The antenna matchings and antenna gain of the Bluetooth and RFID antennas are equal with the same part values.

On behalf of *Vitrex B.V.*

Doc. ID: / Version: / Document status:

TMPL-2-145 / 8.0 / Released

Confidential

Declaration of Similarity

Page 5 of 6

Title:

Declaration of Similarity

Product:

0412 - Iris system



.....

Sheila Chin

Senior Director, R&D

Date: 2024-12-09

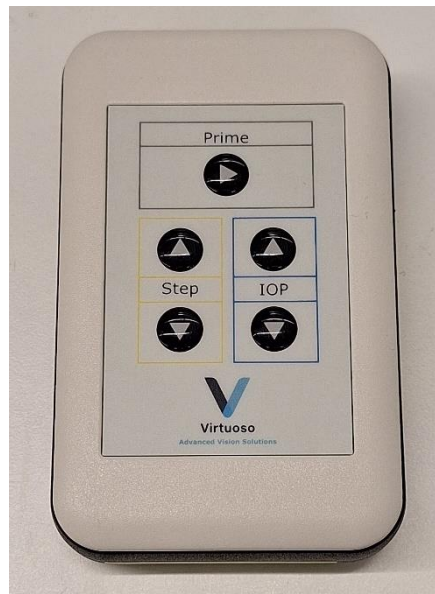
ANNEX C: PHOTOGRAPHS

Test Photo(s): Sample

Test samples



Main system



Remote control



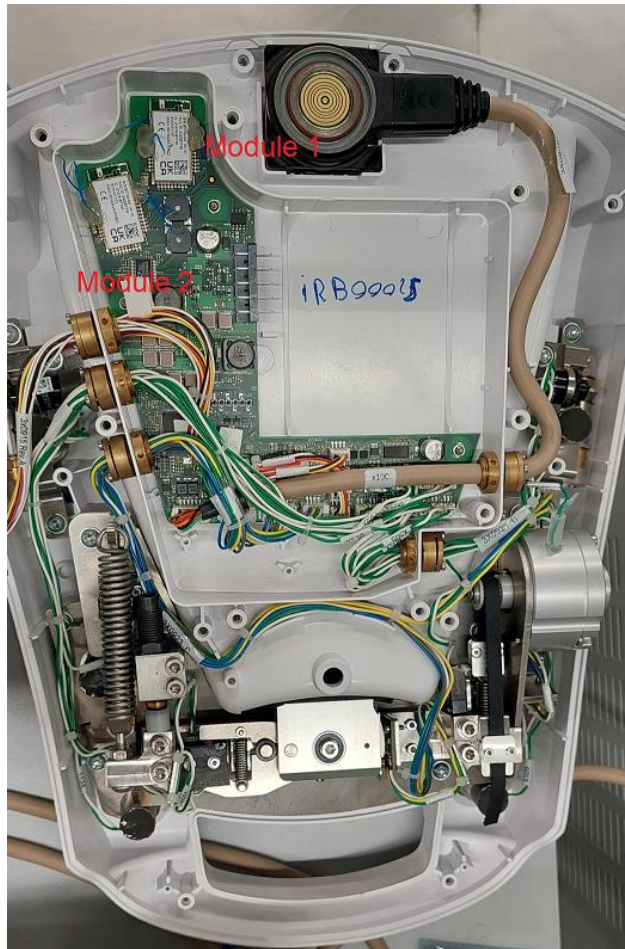
Foot pedal

Test Photo(s): Modules of the samples

Test samples



Main system



Foot Pedal



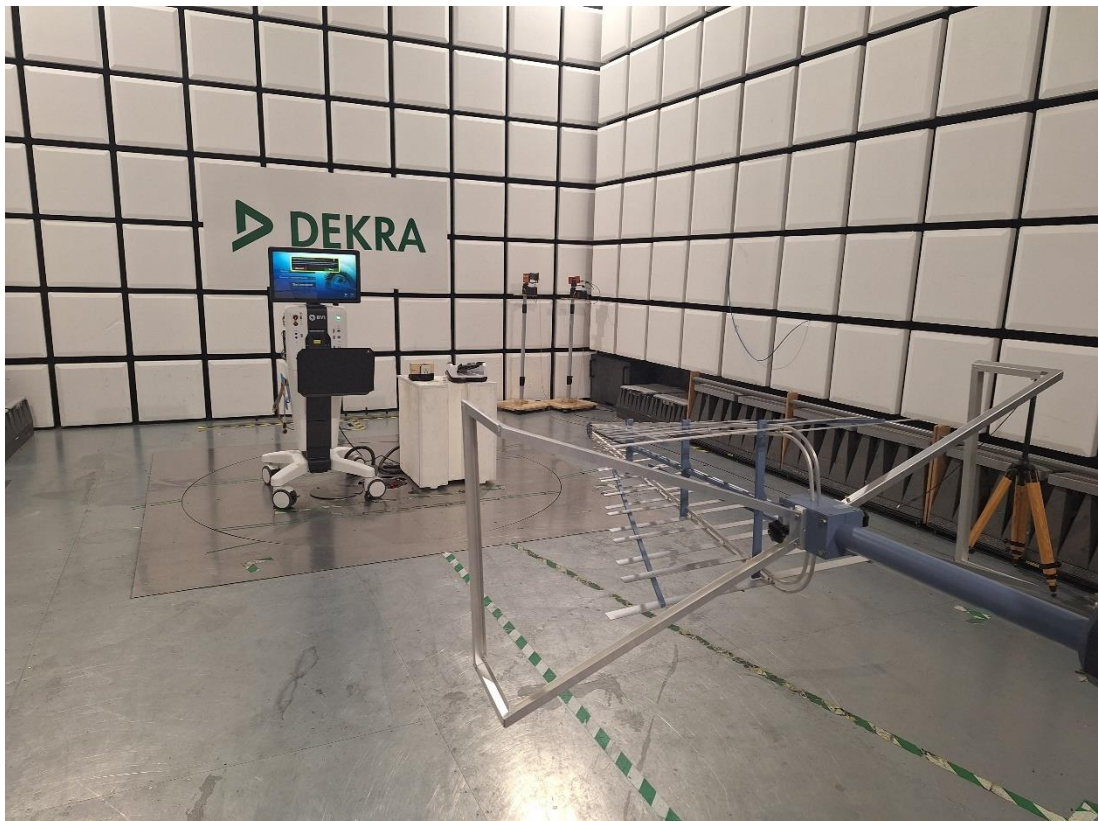
Remote control

Test Photo(s): OM#01

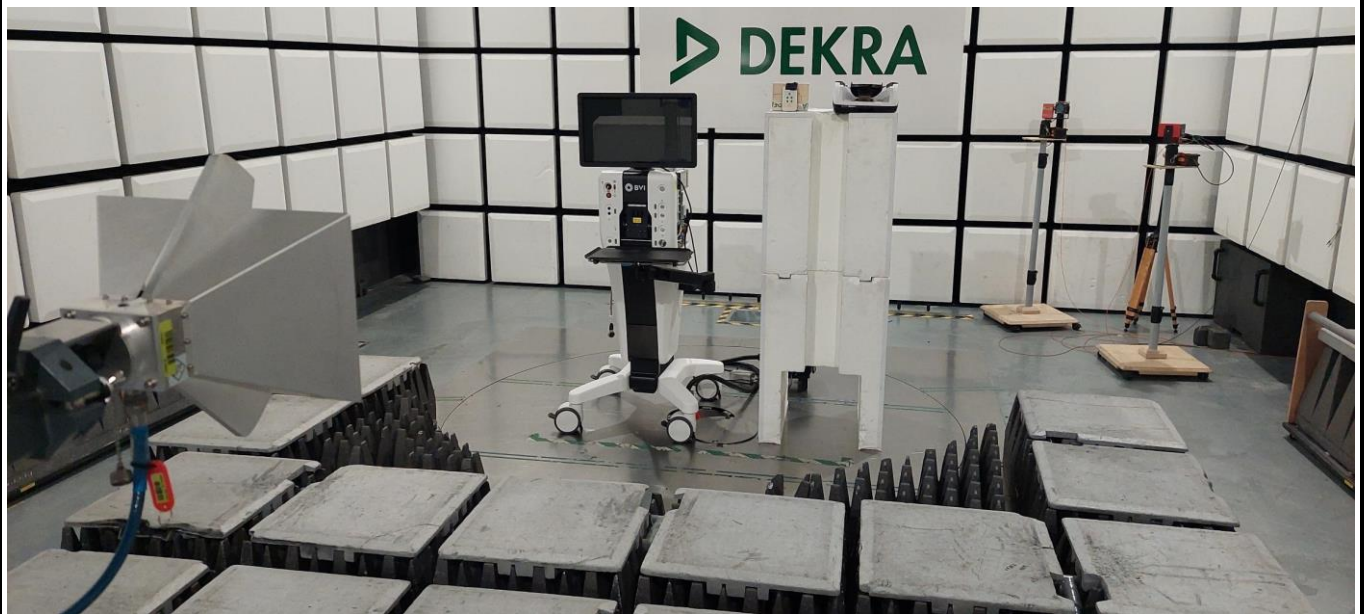
Test set-up below 30 MHz



Test set-up 30 MHz - 1 GHz



Test set-up 1 – 18 GHz



Test set-up 18 – 26 GHz



End of the report