

# VINNO Technology (Suzhou) Co., Ltd.

# TEST REPORT

## SCOPE OF WORK:

IEC 60601-1-2: 2014 – EMC report

### Model:

VINNO E20, VINNO E10, VINNO E10P,  
VINNO E10E, VINNO X2, VINNO X2P,  
VINNO X2E, VINNO X1, VINNO X1P,  
VINNO X1E, VINNO X3

### REPORT NUMBER

191100498SHA-001 M1

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Report no. 191100498SHA-001 M1

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**Manufacturer** : Same as applicant

**Manufacturing site** : Same as applicant

**Summary****This report is based on the original report: No. 191100498SHA-001 dated Nov 5, 2019.****The equipment complies with the requirements according to the following standard(s) or Specification:****IEC 60601-1-2: 2014:** Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbance - Requirements and tests**PREPARED BY:****REVIEWED BY:**

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## Contents

<b>REVISION HISTORY</b>	<b>5</b>
<b>MEASUREMENT RESULT SUMMARY</b>	<b>6</b>
<b>1 GENERAL INFORMATION</b>	<b>7</b>
1.1 DESCRIPTION OF EQUIPMENT UNDER TEST (EUT)	7
1.2 DESCRIPTION OF TEST FACILITY	8
<b>2 TEST SPECIFICATIONS</b>	<b>9</b>
2.1 NORMATIVE REFERENCES	9
2.2 FREQUENCIES IN THE RADIO-FREQUENCY (RF) RANGE DESIGNATED BY ITU FOR USE AS FUNDAMENTAL ISM FREQUENCIES	10
2.3 VARIANT MODELS	10
2.4 MODE OF OPERATION DURING THE TEST	10
2.5 TEST PERIPHERALS AND ACCESSORY EQUIPMENT USED	12
2.6 RECORD OF CLIMATIC CONDITIONS	13
2.7 INSTRUMENT LIST	14
2.8 MEASUREMENT UNCERTAINTY	15
<b>3 CONDUCTED EMISSION</b>	<b>16</b>
3.1 LIMITS	16
3.2 BLOCK DIAGRAM OF TEST SETUP	19
3.3 TEST PROCEDURE	20
3.4 TEST RESULT	21
<b>4 CONTINUOUS DISTURBANCE POWER</b>	<b>25</b>
4.1 DISTURBANCE POWER LIMITS FOR THE FREQUENCY RANGE 30MHZ TO 300MHZ	25
4.2 BLOCK DIAGRAM OF TEST SETUP	26
4.3 TEST PROCEDURE	26
4.4 TEST RESULT	27
<b>5 RADIATED EMISSION</b>	<b>29</b>
5.1 LIMITS FOR GROUP 1 EQUIPMENT MEASURED ON A TEST SITE	29
5.2 LIMITS FOR GROUP 2 EQUIPMENT MEASURED ON A TEST SITE	30
5.3 LIMITS FOR GROUP 1 AND GROUP 2 CLASS A EQUIPMENT MEASURED IN SITU	32
5.4 BLOCK DIAGRAM OF TEST SET UP	33
5.5 TEST PROCEDURE	34
5.6 TEST RESULT	35
<b>6 HARMONIC CURRENT EMISSION</b>	<b>39</b>
6.1 BLOCK DIAGRAM OF TEST SETUP	39
6.2 TEST PROCEDURE	39
6.3 TEST RESULT	40
<b>7 VOLTAGE FLUCTUATIONS AND FLICKER</b>	<b>44</b>
7.1 BLOCK DIAGRAM OF TEST SETUP	44
7.2 TEST PROCEDURE	44
7.3 TEST RESULT	45
<b>IMMUNITY TEST</b>	<b>47</b>
<b>8 ELECTROSTATIC DISCHARGE (ESD)</b>	<b>49</b>
8.1 SEVERITY LEVEL AND PERFORMANCE CRITERION	49
8.2 BLOCK DIAGRAM OF TEST SETUP	50
8.3 TEST PROCEDURE	51

## TEST REPORT

8.4	TEST RESULT.....	52
<b>9</b>	<b>RADIO FREQUENCY ELECTROMAGNETIC FIELD .....</b>	<b>53</b>
9.1	SEVERITY LEVEL AND PERFORMANCE CRITERION.....	53
9.2	BLOCK DIAGRAM OF TEST SETUP .....	54
9.3	TEST PROCEDURE .....	55
9.4	TEST RESULT.....	56
<b>10</b>	<b>PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATION EQUIPMENT .....</b>	<b>57</b>
10.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	57
10.2	BLOCK DIAGRAM OF TEST SETUP .....	58
10.3	TEST PROCEDURE .....	59
10.4	TEST RESULT .....	59
<b>11</b>	<b>FAST TRANSIENTS, COMMON MODE .....</b>	<b>60</b>
11.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	60
11.2	BLOCK DIAGRAM OF TEST SETUP .....	61
11.3	TEST PROCEDURE .....	61
11.4	TEST RESULT .....	62
<b>12</b>	<b>SURGES.....</b>	<b>63</b>
12.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	63
12.2	BLOCK DIAGRAM OF TEST SETUP .....	64
12.3	TEST PROCEDURE .....	64
12.4	TEST RESULT .....	65
<b>13</b>	<b>CONDUCTED DISTURBANCES INDUCED BY RF FIELDS.....</b>	<b>66</b>
13.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	66
13.2	BLOCK DIAGRAM OF TEST SETUP .....	67
13.3	TEST PROCEDURE .....	67
13.4	TEST RESULT .....	68
<b>14</b>	<b>VOLTAGE DIPS AND INTERRUPTIONS .....</b>	<b>69</b>
14.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	69
14.2	BLOCK DIAGRAM OF TEST SETUP .....	70
14.3	TEST PROCEDURE .....	70
14.4	TEST RESULT .....	71
<b>15</b>	<b>POWER FREQUENCY MAGNETIC FIELD IMMUNITY .....</b>	<b>72</b>
15.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	72
15.2	BLOCK DIAGRAM OF TEST SETUP .....	72
15.3	TEST PROCEDURE .....	72
15.4	TEST RESULT .....	73
<b>16</b>	<b>ELECTRICAL TRANSIENT CONDUCTION ALONG SUPPLY LINES .....</b>	<b>74</b>
16.1	SEVERITY LEVEL AND PERFORMANCE CRITERION .....	74
16.2	BLOCK DIAGRAM OF TEST SETUP .....	75
16.3	TEST PROCEDURE .....	75
16.4	TEST RESULT .....	76
<b>APPENDIX I: PHOTOGRAPH OF TEST SETUP .....</b>		<b>77</b>
<b>APPENDIX II: PHOTOGRAPH OF EQUIPMENT UNDER TEST .....</b>		<b>86</b>
<b>APPENDIX III IEC 60601-1-2 ED4.0 (2014-02) CLAUSE 4 AND CLAUSE 5 WORKSHEET .....</b>		<b>110</b>

### Revision History

Report No.	Version	Description	Date Issued
191100498SHA-001	Rev. 01	Initial issue of report	Nov 5, 2019
191100498SHA-001 M1	Rev. 02	See details on Clause 1.1 on page 7	Jan 17, 2022

## Measurement Result Summary

TEST ITEM	TEST RESULT	NOTE
Conducted emission	Pass	
Continuous disturbance power	NA	<i>The main functions of the product are not performed by motors and switching or regulating devices</i>
Radiation emission	Pass	
Harmonic current emission	Pass	
Voltage fluctuations and flicker	Pass	
Electrostatic discharge	Pass	
RF Electromagnetic Field	Pass	
Proximity fields from RF wireless communications EQUIPMENT	Pass	
Electrical Fast Transients	Pass	
Surge	Pass	
Conducted Disturbances Induced by RF Field	Pass	
Voltage dips and interruptions	Pass	
Power frequency magnetic field immunity	Pass	
Electrical transient conduction along supply line	NA	<i>The product is not intended for vehicular use</i>

Notes: 1: NA =Not Applicable

2: Determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.

3: Additions, Deviations and Exclusions from Standards: None.

## TEST REPORT

### 1 GENERAL INFORMATION

#### 1.1 Description of Equipment Under Test (EUT)

- Product name : ULTRASOUND DIAGNOSTIC SYSTEMS
- Type/Model : VINNO E20, VINNO E10, VINNO E10P, VINNO E10E, VINNO X2, VINNO X2P, VINNO X2E, VINNO X1, VINNO X1P, VINNO X1E, VINNO X3
- Ultrasound Probes : D3-6C, D3-6CE, F2-5C, F4-9E, F4-12L, G1-4P, G4-9E, G4-9M, X4-12L, D2-6C
- Detachable parts : Ultrasound probes, ECG, Medical use printer, Foot switch, Bluetooth adapter, Wireless adapter, USB DVDRW
- Description of EUT : This report is based on the original report: No. 191100498SHA-001 dated Nov 5, 2019 with the following modification:
- Adding new AC inlet without Line filter.
- After evaluation, VINNO E20 and VINNO X1 are tested as representative with typical probe G1-4P.
- These products are divided into eleven models: VINNO E20, VINNO E10, VINNO E10E, VINNO E10P, VINNO X3, VINNO X2, VINNO X2E, VINNO X2P, VINNO X1, VINNO X1E, VINNO X1P. The main difference between the models is software function differences, fit of different probes, minor mechanical differences, No other substantial difference.

Model	Software & Function	Mechanical construction
VINNO E10, VINNO E10E, VINNO E10P	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20	1)Same as VINNO E20, or 2)Same as VINNO E20 except support arm of keyboard can't be lifted
VINNO X3	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20	Same as VINNO E20
VINNO X2, VINNO X2E, VINNO X2P	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20	Same as VINNO E20
VINNO X1, VINNO X1E, VINNO X1P	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20 except model X4-12L	Same as VINNO E20 except support arm of keyboard can't be lifted and can support 15.6" monitor and 8" touch panel
The products with same model names except add an "E" or a "P" are same except software functions difference for commercial use.		

- Rating : 100-240Vac, 50/60Hz, 400 VA
- Trade Mark : VINNO
- Category of EUT : Group 1 Class A
- Intended use : Professional healthcare environment
- EUT type : Floor standing
- Software version : 1.X.X
- Firmware version : 1.X.X
- Sample Number : 0211108-10-001
- Sample received date : 11/8/2021
- Date of test : 11/8/2021~ 11/9/2021

## 1.2 Description of Test Facility

Name : Intertek Testing Services Shanghai  
Address : Building 86, No. 1198 Qinzhou Road(North), Shanghai 200233, P.R. China  
Telephone : 86 21 61278200  
Telefax : 86 21 54262353

The test facility is : CNAS Accreditation Lab  
recognized, certified, Registration No. CNAS L0139  
or accredited by these FCC Accredited Lab  
organizations Designation Number: CN0175  
IC Registration Lab  
Registration code No.: 2042B-1  
VCCI Registration Lab  
Registration No.: R-4243, G-845, C-4723, T-2252  
A2LA Accreditation Lab  
Certificate Number: 3309.02



**TEST REPORT****2 TEST SPECIFICATIONS****2.1 Normative references**

CISPR 11: 2009/+A1: 2010: Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement

CISPR 14-1:2005: Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission

CISPR 32: 2012: Electromagnetic compatibility of multimedia equipment – Emission requirements

IEC 61000-3-2: 2005/+A1: 2008/+A2: 2009: Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current  $\leq 16$  A per phase)

IEC 61000-3-3:2013, Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current  $\leq 16$  A per phase and not subject to conditional connection

IEC 61000-4-2: 2008: Electromagnetic Compatibility (EMC) – Part 4-2: testing and measurement techniques – Electrostatic discharge immunity test

IEC 61000-4-3: 2006/+A1:2007/+A2:2010: Electromagnetic Compatibility (EMC) – Part 4-3: testing and measurement techniques – Radiated, radio frequency, electromagnetic field immunity test

IEC 61000-4-4: 2012: Electromagnetic Compatibility (EMC) – Part 4-4: testing and measurement techniques – Electric fast transient/burst immunity test

IEC 61000-4-5: 2005: Electromagnetic Compatibility (EMC) – Part 4-5: testing and measurement techniques – Surge immunity test

IEC 61000-4-6: 2013: Electromagnetic Compatibility (EMC) – Part 4-6: testing and measurement techniques – Immunity to conducted disturbance, induced by radio frequency field.

IEC 61000-4-8: 2009: Electromagnetic Compatibility (EMC) – Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test

IEC 61000-4-11: 2004: Electromagnetic Compatibility (EMC) – Part 4-11: testing and measurement techniques – Voltage dips, short interruption and voltage variations immunity test

ISO 7637-2: 2011: Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only

## TEST REPORT

### 2.2 Frequencies in the radio-frequency (RF) range designated by ITU for use as fundamental ISM frequencies

Centre Frequency (MHz)	Frequency range (MHz)	Maximum radiation limit
6.780	6.765 – 6.795	Under consideration
13.560	13.553 – 13.567	Unrestricted
27.120	26.957 – 27.283	Unrestricted
40.680	40.66 – 40.70	Unrestricted
433.920	433.05 – 434.79	Unrestricted
915.000	902 – 928	Unrestricted
2450	2400 – 2500	Unrestricted
5800	5725 – 5 875	Unrestricted
24125	24 000 – 24 250	Unrestricted
61250	61000 – 61500	Under consideration
122500	122000 – 123000	Under consideration
245000	244000 – 246000	Under consideration
Note: The term “unrestricted” applies to the fundamental and all other frequency components falling within the designated band.		

### 2.3 Variant Models

☒ The following variant models were not tested as part of this evaluation, but have been identified by the manufacturer as being electrically identical models, depopulated models, or with reasonable similarity to the model(s) tested. Intertek does not make any claims of compliance for samples or variants which were not tested.

Variant model name: VINNO E10/E10P/E10E, VINNO X2, VINNO X1P/X1E, VINNO X3

☐ No variant.

### 2.4 Mode of operation during the test

Within this test report, EUT was tested under following operation modes and tested under its rating voltage and frequency. Other voltage and frequency is specified if used.

#### 2.4.1 EUT Operation Modes

Mode #	Description
1	“Auto scan” mode

## TEST REPORT

### 2.4.2 Nominal input voltages and frequencies under test

Input Used	Voltage (V)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
<input checked="" type="checkbox"/>	230V	AC-50	Single	
<input type="checkbox"/>	120V	AC-60	Single	
<input type="checkbox"/>	380V	AC-50	Three	
<input type="checkbox"/>				Others

### 2.4.3 SIP/SOP and Input/output Ports

PORT No.	Name	Type*	Cable Length	Cable Shielded (Y/N)	Comments**
0	Enclosure	N/E	—	—	
1	Mains	AC	>3m	N	Connected with power supply cord, unshielded
2	USB (5 pcs)	SIP/SOP	<3m	Y	USB port for data transmission, for connection with USB device
3	DVI	SIP/SOP	<3m	Y	DVI port for connection to external display
4	USB port for printer	SIP/SOP	<3m	Y	For connection to external printer
5	S – VIDEO	SIP/SOP	>3m	N	S-Video port for connection to external display
6	VCR audio output	SIP/SOP	>3m	N	Audio port for connection to external sound box
7	Probe	PC	<3m	N	ultrasound diagnostic
8	ECG	PC	>3m	N	Only to be used for reference purposes in normal ultrasound scanning
9	Foot switch	SIP/SOP	>3m	N	Connect to foot switch

#### \*Note

AC= AC Power PORT

DC = DC Power PORT

Batt=Battery

N/E = Non-Electrical

SIP/SOP= SIGNAL INPUT/OUTPUT PORT

PC – PATIENT-Coupled Cable

TP= Telecommunication Ports IC = Interconnecting cable

#### \*\*Note

SIP/SOP lines must include description of use.

PATIENT-coupled cable termination must be described.

Interconnecting cables – describe construction details, ferrites, etc.

**TEST REPORT****2.5 Test peripherals and accessory equipment used**

Item No	Peripheral and accessory	Manufacturer	Model	Description
1	Simulator	-	-	Physiological signal simulator
2	Simulator	-	-	Artificial hand and RC element

## TEST REPORT

### 2.6 Record of climatic conditions

Test Item	Temperature (°C)	Relative Humidity (%)	Pressure (Kpa)
Conducted emission	24	42	NA
Continuous disturbance power	NA	NA	NA
Radiation emission	24	42	NA
Harmonic current emission	24	42	NA
Voltage fluctuations and flicker	24	42	NA
Electrostatic discharge	24	42	101.0
RF Electromagnetic Field	24	42	NA
Proximity fields from RF wireless communications EQUIPMENT	24	42	NA
Electrical Fast Transients	24	42	NA
Surge	24	42	NA
Conducted Disturbances Induced by RF Field	24	42	NA
Voltage dips and interruptions	24	42	NA
Power frequency magnetic field immunity	24	42	NA
Electrical transient conduction along supply line	NA	NA	NA

Notes: NA =Not Applicable

## TEST REPORT

### 2.7 Instrument list

Conducted Emission					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Test Receiver	R&S	ESCS 30	EC 2107	2022-07-09
<input checked="" type="checkbox"/>	A.M.N.	R&S	ESH2-Z5	EC 3119	2019-11-29
Radiated Emission					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Test Receiver	R&S	ESIB 26	EC 3045	2022-10-19
<input checked="" type="checkbox"/>	Bilog Antenna	TESEQ	CBL 6112B	EC 6411	2022-08-06
Harmonics / Flicker / Low-frequency immunity test					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Harmonic-flicker	CI	5001ix-PACS-1	EC 2110	2021-12-08
ESD					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	ESD generator	EM TEST	ditto	EC 2956	2022-07-11
EFT/Surge Voltage Dips/PMF					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Conduct immunity system	EM TEST	UCS 500M6B	EC 2958	2022-03-24
<input checked="" type="checkbox"/>	Automatic transformer	EM TEST	MV2616	EC 2957	2022-03-24
<input checked="" type="checkbox"/>	Capacity clamp	EM TEST	HFK	EC 2959	2021-12-28
<input checked="" type="checkbox"/>	PMF coil	EM TEST	MS 100	EZ6408/EZ6409	2022-06-21
Conducted Immunity					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Signal generator	R&S	SML 01	EC 2338	2019-09-12
<input checked="" type="checkbox"/>	Power amplifier	AR	75A250	EC 3043-1	2019-07-15
<input checked="" type="checkbox"/>	Attenuator	EM TEST	ATT6/75	EC 3043-3	2020-02-11
<input checked="" type="checkbox"/>	CDN	Frankonia	CDN M2M316	EC 5969	2020-03-28
<input checked="" type="checkbox"/>	EM clamp	EM TEST	EM 101	EC 3043-6	2019-11-29
Radiated Immunity					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Power amplifier	AR	250W1000B	EC 5818-2	2022-04-13
<input checked="" type="checkbox"/>	Power amplifier	BONN	BLMA1060-100	EC 5818-4	2022-04-13
<input checked="" type="checkbox"/>	Log-period antenna	AR	AT 1080	EC 3044-7	2022-05-27
<input checked="" type="checkbox"/>	Horn antenna	Schwarzbeck	STLP 9149	EC5881	2022-11-08
<input checked="" type="checkbox"/>	Field meter	AR	FL17000	EC 5818-1	2022-06-14
<input checked="" type="checkbox"/>	Power sensor	Keysight	N1914A	EC 5818-3	2022-04-03
<input checked="" type="checkbox"/>	Signal generator	Agilent	N5181A	EC6171	2022-08-19
Test Site					
Used	Equipment	Manufacturer	Type	Internal no.	Due date
<input checked="" type="checkbox"/>	Shielded room	Zhongyu	-	EC 2838	2022-01-24
<input checked="" type="checkbox"/>	Shielded room	Zhongyu	-	EC 2839	2022-01-24
<input checked="" type="checkbox"/>	Semi-anechoic chamber	Albatross project	-	EC 3048	2022-08-22
<input checked="" type="checkbox"/>	Fully-anechoic chamber	Albatross project	-	EC 3047	2022-08-22

## TEST REPORT

### 2.8 Measurement Uncertainty

Measurement	Frequency	Expanded Uncertainty (k=2) ( $\pm$ )
Conducted emission at mains ports	9kHz ~ 150kHz	3.52 dB
	150kHz ~ 30MHz	3.19 dB
Continuous disturbance voltage at telecom ports	150kHz ~ 30MHz	3.64 dB
Continuous disturbance current at telecom ports	150kHz ~ 30MHz	2.62 dB
Radiated Emissions up to 1 GHz	30MHz ~ 1GHz	4.90 dB
Radiated Emissions above 1 GHz	1GHz ~ 6GHz	5.02 dB
	6GHz ~ 18GHz	5.28 dB
Harmonic current emission	-	3.90%
Voltage fluctuations and flicker	-	10.34%

### 3 Conducted emission

**Test result:** Pass

#### 3.1 Limits

##### 3.1.1 Limits of Mains terminal disturbance voltage limits for class A group 1 equipment measured on a test site

Frequency range (MHz)	Rated input power of ≤ 20 kVA		Rated input power of > 20 kVA	
	Quasi-peak (dBμV)	Average (dBμV)	Quasi-peak (dBμV)	Average (dBμV)
0.15 ~ 0.5	79	66	100	90
0.5 ~ 5	73	60	86	76
5 ~ 30	73	60	90 decreasing linearly with logarithm of frequency to 73	80 60

**Note:**

1. If the limit for the measurement with the average detector is met when using a receiver with a Quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.
2. High-frequency (HF) surgical equipment shall meet the limits of Clause 3.1.1 or 3.1.2 specified for group 1 equipment, in stand-by mode of operation. For high-frequency (HF) surgical equipment operating at frequencies outside designated ISM bands as specified in Clause 2.2, these limits also apply at the operating frequency and inside the designated frequency bands.

##### 3.1.2 Limits of Mains terminal disturbance voltage for class B group 1 and group 2 equipment measured on a test site

Frequency range (MHz)	Quasi-peak (dBμV)	Average (dBμV)
0.15 ~ 0.5	66	56
	decreasing linearly with logarithm of frequency to	
	56	46
0.5 ~ 5	56	46
5 ~ 30	60	50

**Note:**

1. If the limit for the measurement with the average detector is met when using a receiver with a Quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.
2. High-frequency (HF) surgical equipment shall meet the limits of Clause 3.1.1 or 3.1.2 specified for group 1 equipment, in stand-by mode of operation. For high-frequency (HF) surgical equipment operating at frequencies outside designated ISM bands as specified in Clause 2.2, these limits also apply at the operating frequency and inside the designated frequency bands.



## TEST REPORT

### 3.1.3 Limits of Mains terminal disturbance voltage for class A group 2 equipment measured on a test site

Frequency range (MHz)	Rated input power of $\leq 75$ kVA		Rated input power of $> 75$ kVA	
	Quasi-peak (dB $\mu$ V)	Average (dB $\mu$ V)	Quasi-peak (dB $\mu$ V)	Average (dB $\mu$ V)
0.15 ~ 0.5	100	90	130	120
0.5 ~ 5	86	76	125	115
5 ~ 30	90 decreasing linearly with logarithm of frequency to 73	80 60	115	105

Note: If the limit for the measurement with the average detector is met when using a receiver with a Quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.

### 3.1.4 Limits of Mains terminal disturbance voltage for group 1 and group 2 class A equipment measured *in situ*

☐ For group 1 class A or class B PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS tested in situ shall comply with the CISPR 11 limits for equipment measured on a test site. The limit specified in Clause 3.1.1 or 3.1.3 shall be selected.

### 3.1.5 Limits of ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices

#### 3.1.5.1 For mains terminal of electric power tools

Frequency	Rated motor power not exceeding 700W		Rated motor power above 700W and not exceeding 1000W		Rated motor power above 1000W	
(MHz)	dB( $\mu$ V)		dB( $\mu$ V)		dB( $\mu$ V)	
	Quasi-Peak	Average	Quasi-Peak	Average	Quasi-Peak	Average
0.15~0.35	66~59*	59~49*	70~63*	63~53*	76~69*	69~59*
0.35~5	59	49	63	53	69	59
5~30	64	54	68	58	74	64

Notes :

- \* means the limit value decreasing linearly with the logarithm of the frequency.
- If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.

## TEST REPORT

### 3.1.5.2 For mains terminal of other appliance

Frequency range (MHz)	Limits dB( $\mu$ V)	
	Quasi-peak	Average
0.15 ~ 0.5	66 ~ 56 *	59 ~ 46 *
0.5 ~ 5	56	46
5 ~ 30	60	50

Notes:

- \* means the limit decreasing linearly with the logarithm of the frequency in the range 0.15MHz to 0.5MHz.
- If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.

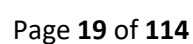
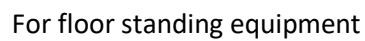
### 3.1.5.3 Limits for Load /Additional Terminal

Frequency range (MHz)	Limits dB( $\mu$ V)	
	Quasi-peak	Average
0.15 ~ 0.5	80	70
0.5 ~ 5	74	64
5 ~ 30	74	64

Notes:

- If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.

For table-top equipment



## **TEST REPORT**

### **3.3 Test Procedure**

Measurement was performed in shielded room, and instruments used were following Clause 7 of CISPR 11.

Detailed test procedure was following Clause 8 of CISPR 11

EUT arrangement and operation conditions were according to Clause 7 of CISPR 11.

Frequency range 150kHz-30MHz was checked and EMI receiver measurement bandwidth was set to 9 kHz.

For ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices:

Measurement was performed in shielded room, and instruments used were following Clause 5 of CISPR 14-1 if applicable.

Detailed test procedure and arrangement was following clause 5 of CISPR 14-1.

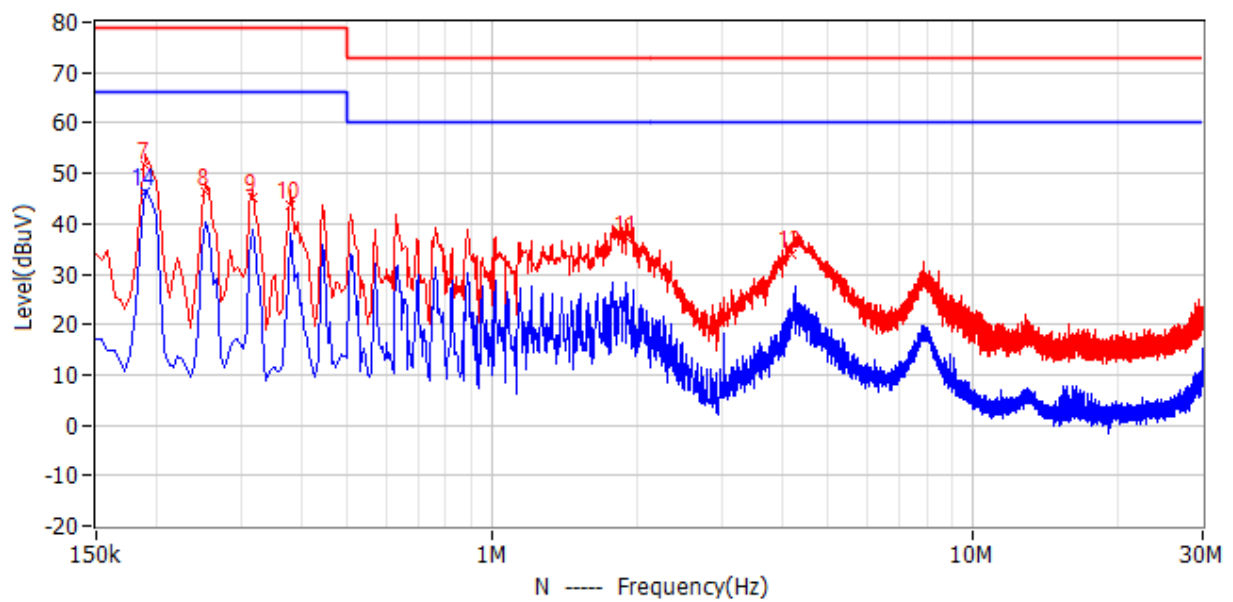
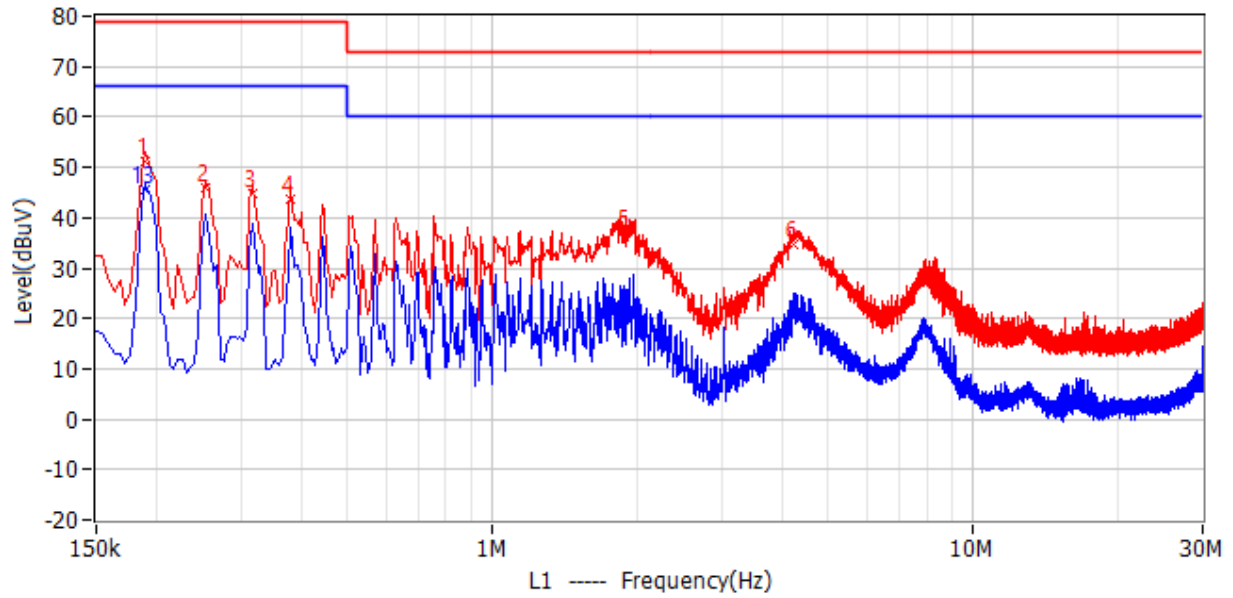
Measurement methods and operation conditions of EUT was according to clause 7 of CISPR 14-1.

## TEST REPORT

### 3.4 Test Result

Test Curve & data:

#### VINNO E20

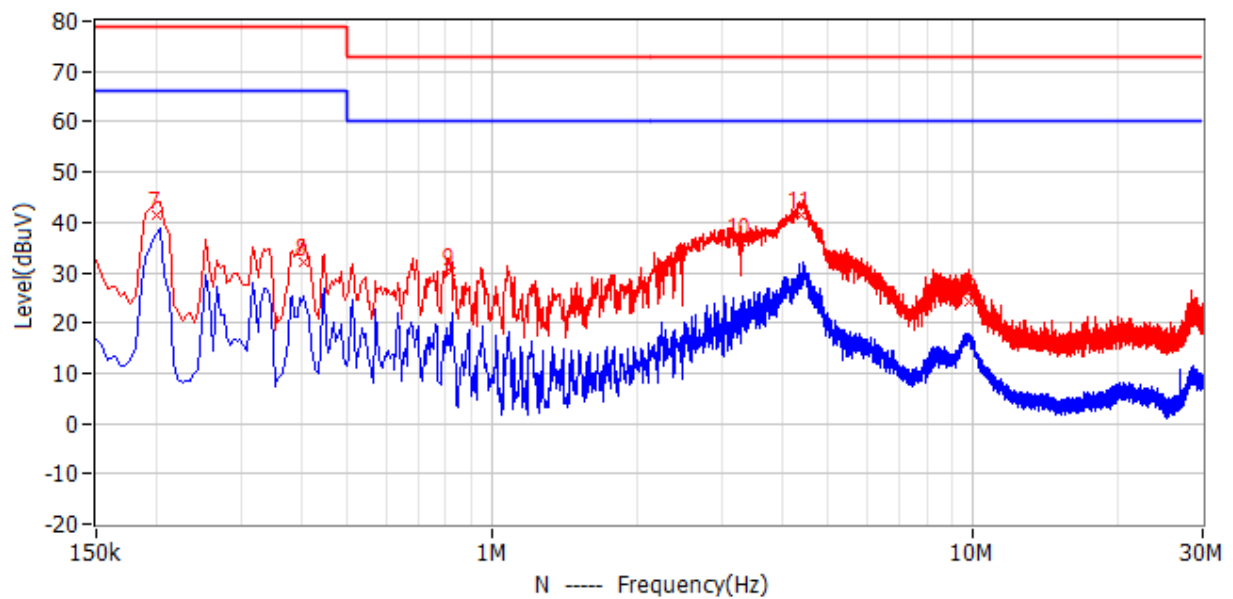
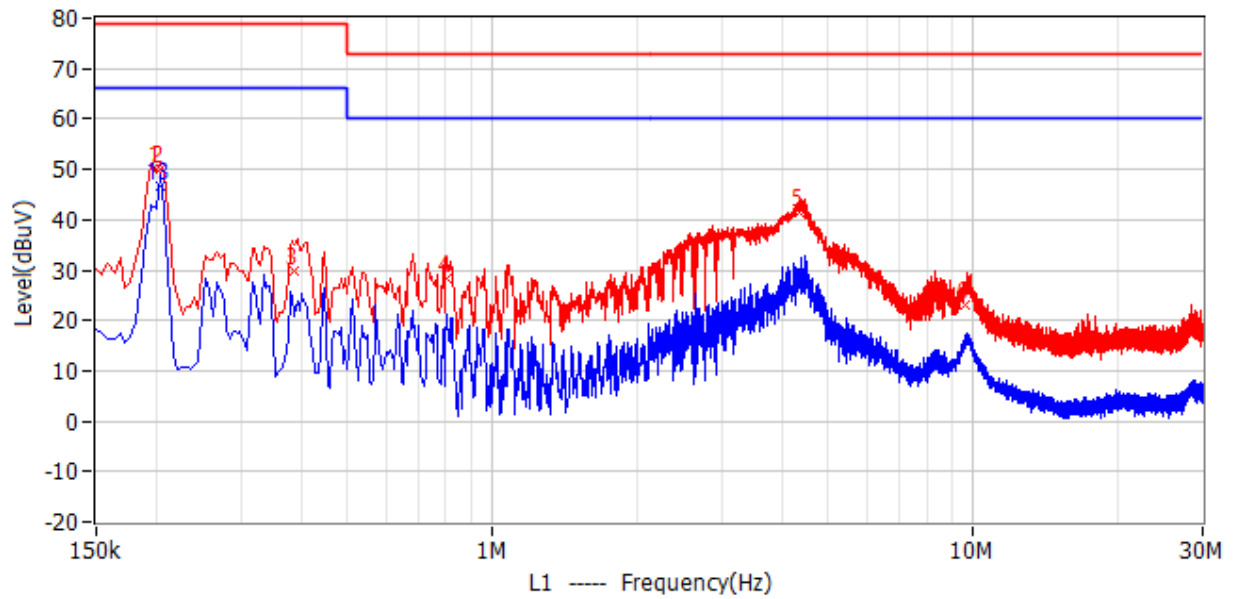


# TEST REPORT

No.	Frequency	Limit dBuV	Level dBuV	Delta dB	Reading dBuV	Factor dB	Detector	Phase
1	190.500kHz	79.0	51.1	-27.9	40.8	10.3	QP	L1
2	253.500kHz	79.0	46.1	-32.9	35.8	10.3	QP	L1
3	316.500kHz	79.0	44.7	-34.3	34.4	10.3	QP	L1
4	379.500kHz	79.0	43.6	-35.4	33.3	10.3	QP	L1
5	1.901MHz	73.0	36.8	-36.2	26.3	10.5	QP	L1
6	4.250MHz	73.0	34.8	-38.2	24.4	10.4	QP	L1
7	190.500kHz	79.0	51.7	-27.3	41.3	10.4	QP	N
8	253.500kHz	79.0	46.2	-32.8	35.9	10.3	QP	N
9	316.500kHz	79.0	45.0	-34.0	34.7	10.3	QP	N
10	379.500kHz	79.0	43.7	-35.3	33.4	10.3	QP	N
11	1.910MHz	73.0	36.9	-36.1	26.5	10.4	QP	N
12	4.200MHz	73.0	34.1	-38.9	23.7	10.4	QP	N
13	190.500kHz	66.0	45.7	-20.3	35.4	10.3	CAV	L1
14	190.500kHz	66.0	46.3	-19.7	35.9	10.4	CAV	N

**TEST REPORT**

**VINNO X1**



# TEST REPORT

No.	Frequency	Limit dBuV	Level dBuV	Delta dB	Reading dBuV	Factor dB	Detector	Phase
1	199.500kHz	79.0	49.9	-29.1	39.5	10.4	QP	L1
2	204.000kHz	79.0	49.9	-29.1	39.5	10.4	QP	L1
3	388.500kHz	79.0	30.0	-49.0	19.7	10.3	QP	L1
4	807.000kHz	73.0	28.5	-44.5	17.9	10.6	QP	L1
5	4.362MHz	73.0	41.5	-31.5	31.1	10.4	QP	L1
6	9.654MHz	73.0	23.1	-49.9	12.2	10.9	QP	L1
7	199.500kHz	79.0	41.5	-37.5	31.1	10.4	QP	N
8	406.500kHz	79.0	31.9	-47.1	21.6	10.3	QP	N
9	816.000kHz	73.0	30.1	-42.9	19.5	10.6	QP	N
10	3.273MHz	73.0	36.0	-37.0	25.6	10.4	QP	N
11	4.376MHz	73.0	41.5	-31.5	31.1	10.4	QP	N
12	9.767MHz	73.0	24.1	-48.9	13.2	10.9	QP	N
13	204.000kHz	66.0	46.6	-19.4	36.2	10.4	CAV	L1



# TEST REPORT

## 4 Continuous Disturbance Power

Test result: NA

☒ Test does not apply. Device under test whose main functions are not performed by motors and switching or regulating devices.

### 4.1 Disturbance Power Limits for the frequency range 30MHz to 300MHz

#### 4.1.1 Limits for electric tools

Frequency	Rated motor power not exceeding 700W		Rated motor power above 700W and not exceeding 1000W		Rated motor power above 1000W	
(MHz)	dB(pW)		dB(pW)		dB(pW)	
	Quasi-peak	Average	Quasi-peak	Average	Quasi-peak	Average
30~300	45~55*	35~45*	49~59*	39~49*	55~65*	45~55*

Notes:

- \* means the limit increasing linearly with the frequency.
- If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement with the receiver with average detector need not be carried out.

#### 4.1.2 Limits for other appliances

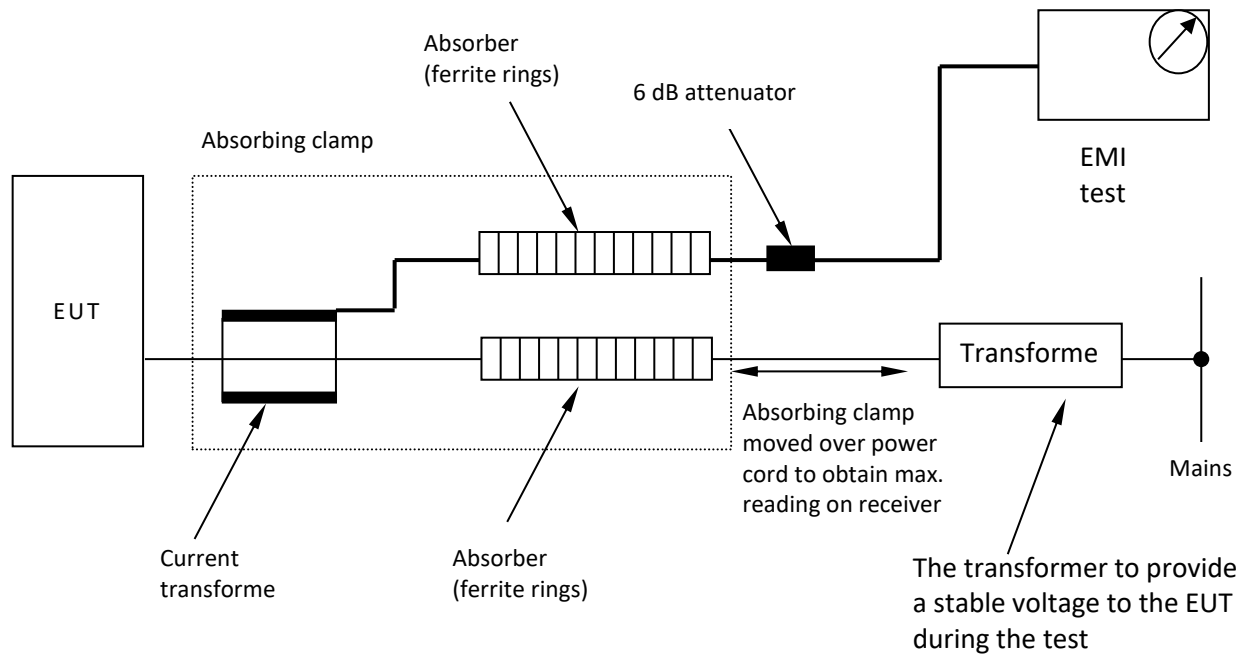
Frequency (MHz)	Quasi-peak dB(pW)	Average dB (pW)
30 ~ 300	45~55*	35 ~ 45*

Notes:

- \* means the limit increasing linearly with the frequency.
- If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement with the receiver with average detector need not be carried out.

## TEST REPORT

### 4.2 Block Diagram of test Setup



### 4.3 Test Procedure

Measurement was performed in shielded room.

Instruments used were following clause 6 of CISPR 14-1.

Detailed test procedure and arrangement was following clause 6 of CISPR 14-1.

Operation conditions of EUT were according to clause 7 of CISPR 14-1.

Frequency range 30MHz – 300MHz was checked and EMI receiver measurement bandwidth was set to 120kHz.

## TEST REPORT

### 4.4 Test Result

Temperature : °C

Relative Humidity : %

At mains lead

Frequency (MHz)	Quasi-peak		Average	
	Disturbance level dB(pW)	Permitted limit dB(pW)	Disturbance level dB(pW)	Permitted limit dB(pW)
30.00				
45.00				
65.00				
90.00				
150.00				
180.00				
220.00				
300.00				
Note: * means the emission level 20dB lower than the relevant limit.				

Remark: 1. Correct Factor = LISN Factor + Cable Loss, the value was added to Original Receiver Reading by the software automatically.

2. Corrected Reading = Original Receiver Reading + Correct Factor

3. Margin = Limit - Corrected Reading

4. If the PK Corrected Reading is lower than AV limit, the AV test can be elided.

Example: Assuming LISN Factor = 10.00dB, Cable Loss = 2.00dB,  
Original Receiver Reading = 10.00dBμV, Limit = 66.00dBμV.  
Then Correct Factor = 10.00 + 2.00 = 12.00dB;  
Corrected Reading = 10dBμV + 12.00dB = 22.00dBμV;  
Margin = 66.00dBμV – 22.00dBμV = 44.00dB.

# TEST REPORT

At auxiliary leads

Frequency (MHz)	Quasi-peak		Average	
	Disturbance level dB(pW)	Permitted limit dB(pW)	Disturbance level dB(pW)	Permitted limit dB(pW)
30.00	-	-	-	-
45.00	-	-	-	-
65.00	-	-	-	-
90.00	-	-	-	-
150.00	-	-	-	-
180.00	-	-	-	-
220.00	-	-	-	-
300.00	-	-	-	-
Note: * means the emission level 20dB lower than the relevant limit.				

- Remark: 1. Correct Factor = LISN Factor + Cable Loss, the value was added to Original Receiver Reading by the software automatically.  
2. Corrected Reading = Original Receiver Reading + Correct Factor  
3. Margin = Limit - Corrected Reading  
4. If the PK Corrected Reading is lower than AV limit, the AV test can be elided.

Example: Assuming LISN Factor = 10.00dB, Cable Loss = 2.00dB,  
Original Receiver Reading = 10.00dBμV, Limit = 66.00dBμV.  
Then Correct Factor = 10.00 + 2.00 = 12.00dB;  
Corrected Reading = 10dBμV + 12.00dB = 22.00dBμV;  
Margin = 66.00dBμV – 22.00dBμV = 44.00dB.

## TEST REPORT

### 5 Radiated emission

Test result: Pass

#### 5.1 Limits for group 1 equipment measured on a test site

##### 5.1.1 Electromagnetic radiation disturbance limits for class A group 1 equipment measured on a test site

Frequency (MHz)	10 m measuring distance rated input power of		3 m measuring distance rated input power of	
	≤ 20 kVA	> 20 kVA	≤ 20 kVA	> 20 kVA
	Quasi-peak (dBμV/m)	Quasi-peak (dBμV/m)	Quasi-peak (dBμV/m)	Quasi-peak (dBμV/m)
30-230	40	50	50	60
230-1000	47	50	57	60
Note: At the transition frequency, the more stringent limit shall apply.				

##### 5.1.2 Electromagnetic radiation disturbance limits for class B group 1 equipment measured on a test site

Frequency (MHz)	10 m measuring distance	3 m measuring distance
	Quasi-peak (dBμV/m)	Quasi-peak (dBμV/m)
30-230	30	40
230-1000	37	47
Note: At the transition frequency, the more stringent limit shall apply.		

## TEST REPORT

### 5.2 Limits for group 2 equipment measured on a test site

Except for the designated frequency range listed in Clause 2.2, the electromagnetic radiation disturbance limits for the frequency range 150 kHz to 1 GHz for group 2 class A equipment are specified in Clause 5.2.1; and for group 2 class B equipment in Clause 5.2.2.

#### 5.2.1 Limits of Electromagnetic radiation disturbance for class A group 2 equipment measured on a test site

Frequency (MHz)	Limits for a measuring distance D from the equipment					
	On a test site D = 30 m		On a test site D = 10 m		On a test site D = 3 m	
	E-field	M-field	E-field	M-field	E-field	M-field
	Quasi-peak (dB $\mu$ V/m)	Quasi-peak (dB $\mu$ A/m)	Quasi-peak (dB $\mu$ V/m)	Quasi-peak (dB $\mu$ A/m)	Quasi-peak (dB $\mu$ V/m)	Quasi-peak (dB $\mu$ A/m)
0.15 – 0.49	–	33,5	–	57,5	–	57,5
0.49 – 1.705	–	23,5	–	47,5	–	47,5
1.705 – 2.194	–	28,5	–	52,5	–	52,5
2.194 – 3.95	–	23,5	–	43,5	–	43,5
3.95 – 20	–	8,5	–	18,5	–	18,5
20 – 30	–	–1,5	–	8,5	–	8,5
30 – 47	58	–	68	–	78	–
47 – 53.91	40	–	50	–	60	–
53.91 – 54.56	40	–	50	–	60	–
54.56 – 68	40	–	50	–	60	–
68 – 80.872	53	–	63	–	73	–
80.872 – 81.848	68	–	78	–	88	–
81.848 – 87	53	–	63	–	73	–
87 – 134.786	50	–	60	–	70	–
134.786 – 136.414	60	–	70	–	80	–
136.414 – 156	50	–	60	–	70	–
156 – 174	64	–	74	–	84	–
174 – 188.7	40	–	50	–	60	–
188.7 – 190.979	50	–	60	–	70	–
190.979 – 230	40	–	50	–	60	–
230 – 400	50	–	60	–	70	–
400 – 470	53	–	63	–	73	–
470 – 1 000	50	–	60	–	70	–

## TEST REPORT

### 5.2.2 Limits of Electromagnetic radiation disturbance for class B group 2 equipment measured on a test site

Frequency (MHz)	Limits for a measuring distance D from the equipment				
	E-field				M-field
	D = 10m		D = 3 m		D = 3 m
	Quasi-peak (dB $\mu$ V/m)	Average (dB $\mu$ V/m)	Quasi-peak (dB $\mu$ V/m)	Average (dB $\mu$ V/m)	Quasi-peak (dB $\mu$ A/m)
0,15 – 30	-	-	-	-	39 Decreasing linearly with the logarithm of frequency to 3
30 – 80,872	30	25	40	35	-
80,872 – 81,848	50	45	60	55	-
81,848 – 134,786	30	25	40	35	-
134,786 – 136,414	50	45	60	55	-
136,414 – 230	30	25	40	35	-
230 – 1 000	37	32	47	42	-

Note 1: The average limits apply to magnetron driven equipment only. If magnetron driven equipment exceeds the quasi-peak limit at certain frequencies, then the measurement shall be repeated at these frequencies with the average detector, and the average limits specified in this table apply.

Note 2: For ISM RF lighting devices operating in dedicated ISM frequency bands as specified in Clause 2.2, the limits of Clause 5.2.2 apply.

### 5.2.3 Limits for group 2 equipment operating at frequencies above 400 MHz measured on a test site within 1 GHz to 18GHz

The limits specified in this clause apply only to RF disturbances appearing outside designated ISM bands as specified in Clause 2.2. The equipment shall meet either the limits of Clause 5.2.3.1 or the limits of both Clause 5.2.3.2 and Clause 5.2.3.3.

#### 5.2.3.1 Peak limits of Electromagnetic radiation disturbance for group 2 equipment producing CW type disturbances and operating at frequencies above 400 MHz

Frequency (MHz)	Limits for a measurement distance of 3 m	
	Peak (dB $\mu$ V/m)	
1-18	Class A	Class B
Within harmonic frequency bands	82	70
Outside harmonic frequency bands	70	70

Note 1: At the upper and lower edge frequency of harmonic frequency bands, the more stringent limit of 70 dB $\mu$ V/m applies.

Note 2: For microwave-powered UV irradiators, the limits specified in this Clause apply.

Note 3: ISM RF lighting devices operating in dedicated ISM frequency bands as specified in Clause 2.2 shall either meet the class B limits of this Clause or the limits of both Clause 5.2.3.2 and 5.2.3.3.

## TEST REPORT

### 5.2.3.2 Peak limits of Electromagnetic radiation disturbance for class B group 2 equipment producing fluctuating disturbances other than CW and operating at frequencies above 400 MHz

Frequency (GHz)	Limits for a measurement distance of 3 m
1-18	Peak (dB $\mu$ V/m)
1 – 2.3	92
2.3 – 2.4	110
2.5 – 5.725	92
5.875 – 11.7	92
11.7 – 12.7	73
12.7 – 18	92
Note 1: At the transition frequency, the more stringent limit shall apply. Note 2: Peak measurements with a resolution bandwidth of 1 MHz and a video signal bandwidth higher or equal to 1 MHz.	

### 5.2.3.3 Electromagnetic radiation disturbance weighted limits for class B group 2 equipment producing fluctuating disturbances other than CW and operating at frequencies above 400 MHz

Frequency (GHz)	Limits for a measurement distance of 3 m
1-18	Peak (dB $\mu$ V/m)
1 – 2.4	60
2.5 – 5.725	60
5.875 – 18	60
Note: Weighted measurements with a RBW of 1 MHz and a VBW of 10 Hz.	

## 5.3 Limits for group 1 and group 2 class A equipment measured in situ

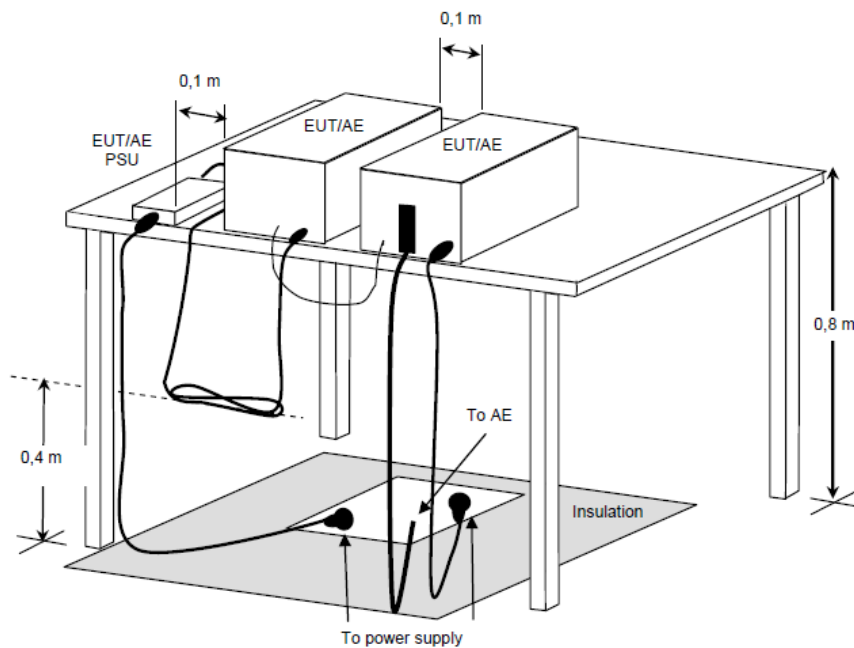
☐ For group 1 class A or class B PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS tested in situ shall comply with the CISPR 11 limits for equipment measured on a test site. The limit specified in Clause 5.1 is selected.



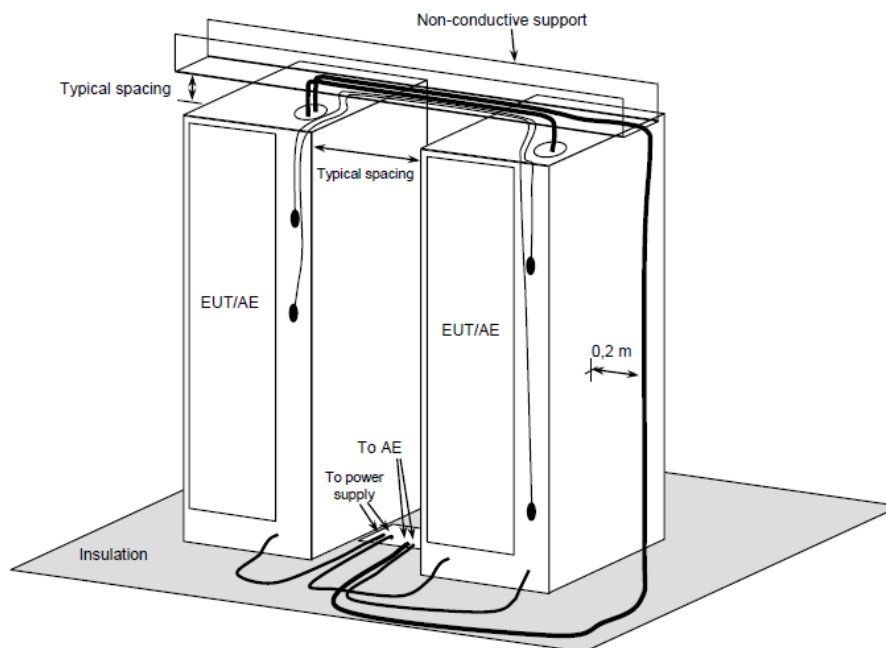
## TEST REPORT

### 5.4 Block diagram of test set up

For table-top equipment



For floor standing equipment



## TEST REPORT

### 5.5 Test Procedure

The measurement was performed in a semi-anechoic chamber.

The distance from EUT to receiving antenna is 10 meters.

Measurement was performed according to clause 8 of CISPR 11.

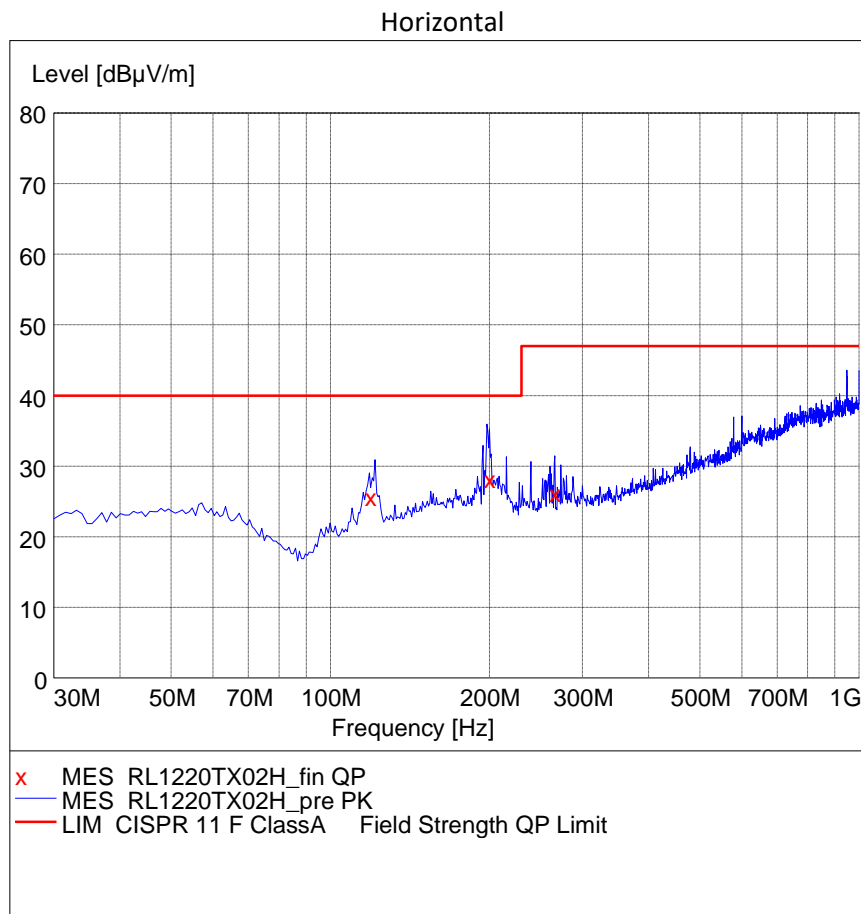
EUT arrangement and operate condition were according to clause 7 of CISPR 11.

The bandwidth setting of measurement below 1GHz on Test Receiver was 120 kHz.

**TEST REPORT**

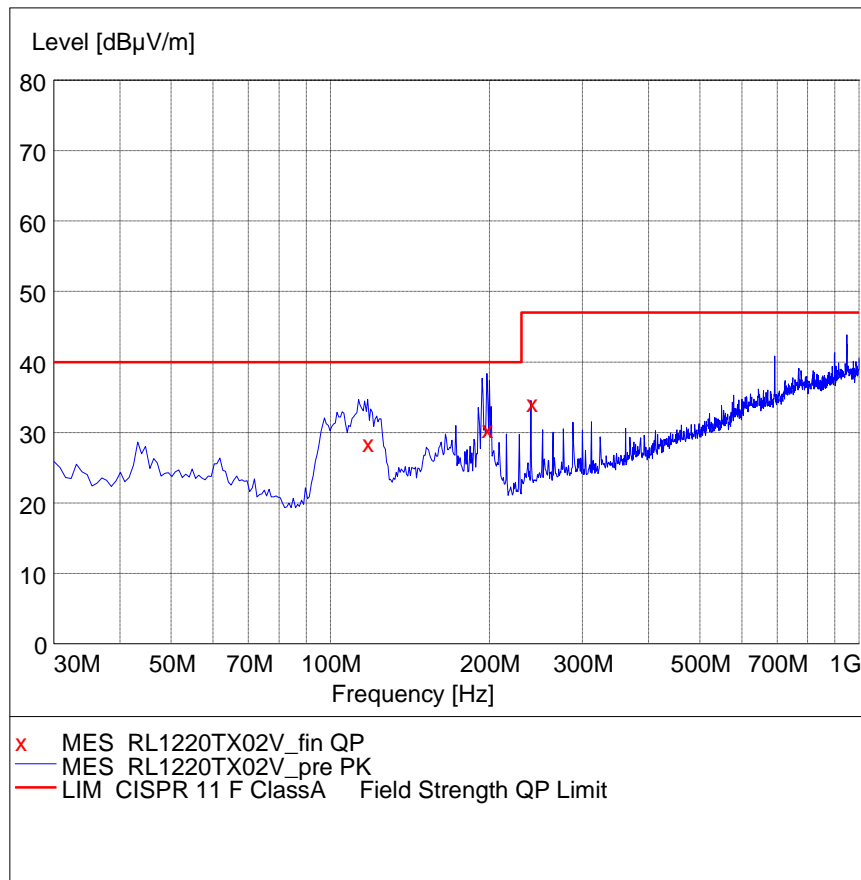
**5.6 Test Result**

**VINNO E20**



Frequency MHz	Level dBµV/m	Height cm	Azimuth deg	Polarisation	Transducer dB	Limit dBµV/m	Margin dB
119.003897	25.9	400.0	270.00	HORIZONTAL	18.33	40.0	14.1
199.859590	28.4	300.0	270.00	HORIZONTAL	18.13	40.0	11.6
265.551436	26.4	400.0	90.00	HORIZONTAL	20.71	47.0	20.6

Vertical

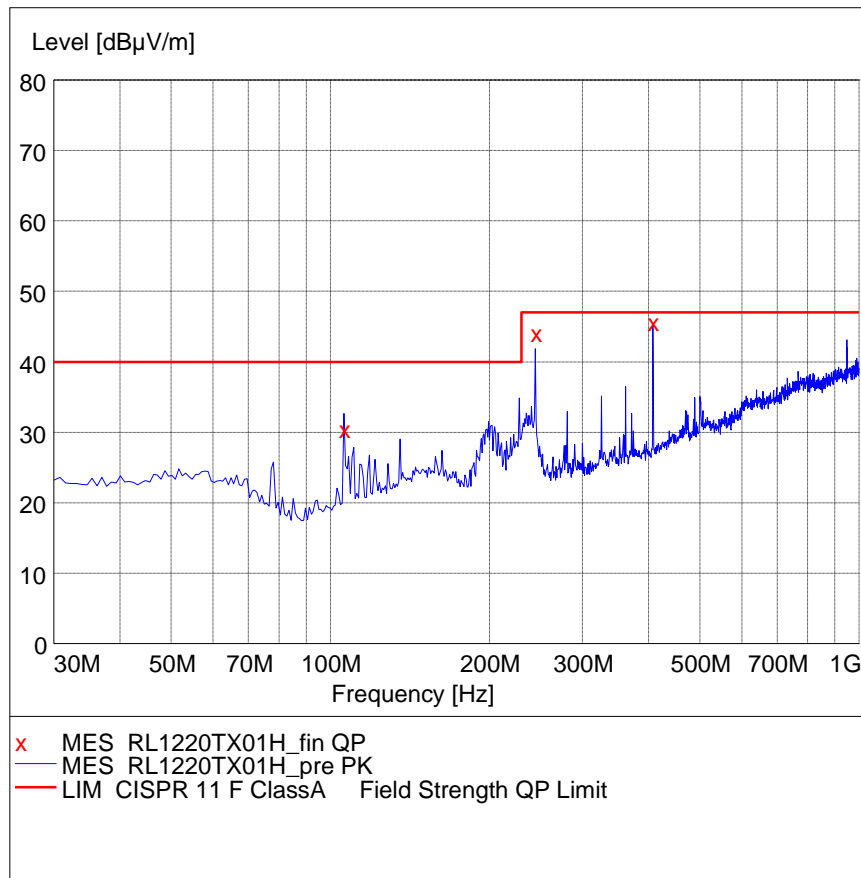


Frequency MHz	Level dBμV/m	Height cm	Azimuth deg	Polarisation	Transducer dB	Limit dBμV/m	Margin dB
117.671974	28.8	100.0	90.00	VERTICAL	18.19	40.0	11.2
197.728179	30.8	100.0	270.00	VERTICAL	18.26	40.0	9.2
239.993590	34.4	100.0	270.00	VERTICAL	19.79	47.0	12.6

**TEST REPORT**

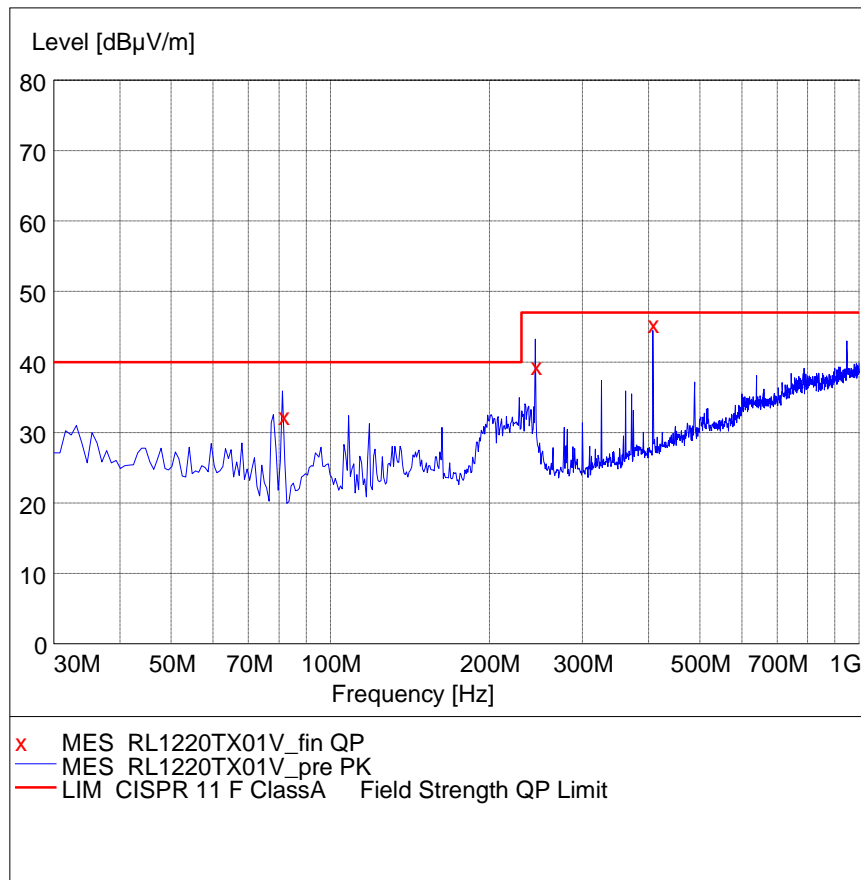
**VINNO X1**

**Horizontal**



Frequency MHz	Level dBμV/m	Height cm	Azimuth deg	Polarisation	Transducer dB	Limit dBμV/m	Margin dB
106.240308	30.7	400.0	270.00	HORIZONTAL	17.48	40.0	9.3
244.512821	44.4	400.0	180.00	HORIZONTAL	19.99	47.0	2.6
407.504590	45.9	200.0	180.00	HORIZONTAL	24.53	47.0	1.1

Vertical



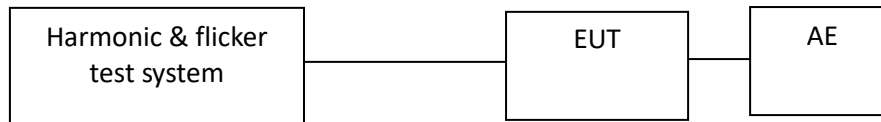
Frequency MHz	Level dBμV/m	Height cm	Azimuth deg	Polarisation	Transducer dB	Limit dBμV/m	Margin dB
81.504462	32.500	200.0	0.00	VERTICAL	15.90	40.0	7.5
244.464462	39.700	400.0	30.00	VERTICAL	19.99	47.0	7.3
407.520615	45.600	300.0	50.00	VERTICAL	24.53	47.0	1.4

## TEST REPORT

### 6 Harmonic current emission

Test result: Pass

#### 6.1 Block diagram of test Setup



#### 6.2 Test Procedure

Harmonics of the fundamental current were measured up to 40 order harmonics using a digital power meter with an analogue output and frequency analyzer which was integrated in the harmonic & flicker test system. The measurements were carried out under steady conditions.

☒ Measuring instrumentation according to IEC 61000-4-7:2002+A1:2008

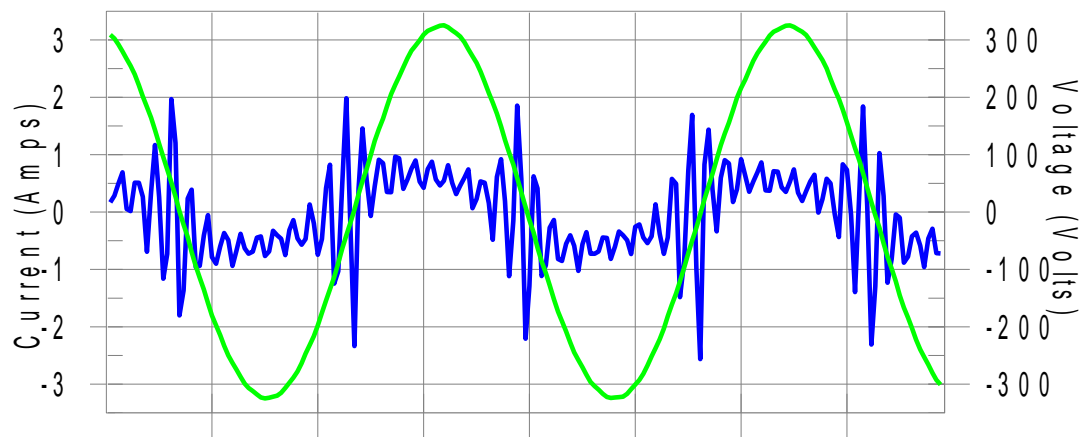
☐ This product is not defined as lighting equipment, and has rated power less than 75W, therefore, no limit applies according to EN 61000-3-2

☐ The product is not intended to connect to the PUBLIC MAINS NETWORK, and this test is not applicable in this environment.

### 6.3 Test Result

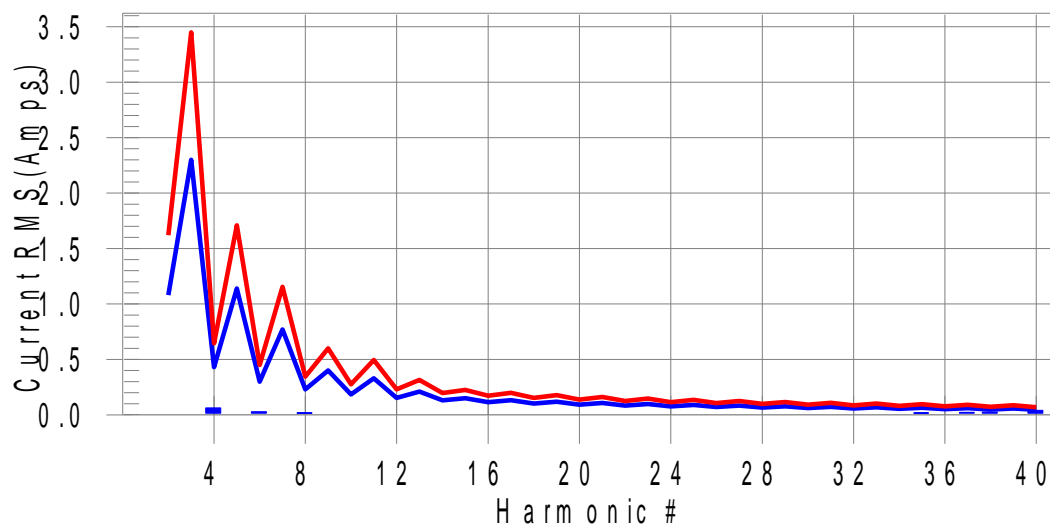
#### VINNO E20

##### Current & voltage waveforms



##### Harmonics and Class A limit line

##### European Limits



**Test result: Pass Worst harmonic was #40 with 59.48% of the limit.**



# TEST REPORT

## Current Test Result Summary (Run time)

THC(A): 0.09    I-THD(%): 2399.86    POHC(A): 0.030    POHC Limit(A): 0.251

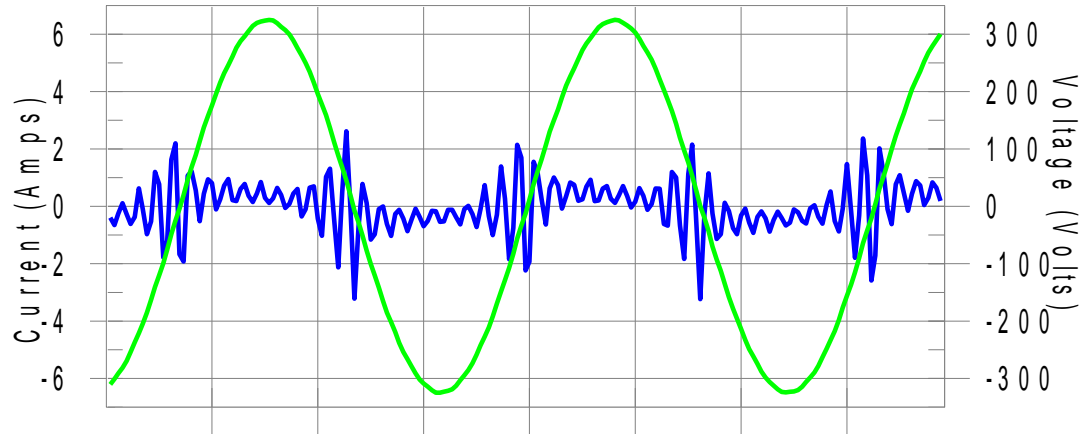
### Highest parameter values during test:

V_RMS (Volts):	229.51	Frequency(Hz):	50.00
I_Peak (Amps):	2.827	I_RMS (Amps):	0.791
I_Fund (Amps):	0.005	Crest Factor:	3.592
Power (Watts):	98.0	Power Factor:	0.550

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.005	1.080	0.4	0.005	1.620	0.33	Pass
3	0.004	2.300	0.2	0.005	3.450	0.14	Pass
4	0.062	0.430	14.5	0.063	0.645	9.70	Pass
5	0.004	1.140	0.4	0.004	1.710	0.25	Pass
6	0.028	0.300	9.4	0.029	0.450	6.39	Pass
7	0.004	0.770	0.5	0.004	1.155	0.38	Pass
8	0.018	0.230	7.9	0.019	0.345	5.37	Pass
9	0.004	0.400	1.0	0.004	0.600	0.74	Pass
10	0.004	0.184	2.2	0.005	0.276	1.64	Pass
11	0.014	0.330	4.2	0.014	0.495	2.83	Pass
12	0.004	0.153	2.5	0.004	0.230	1.74	Pass
13	0.011	0.210	5.1	0.011	0.315	3.45	Pass
14	0.004	0.131	3.1	0.005	0.197	2.38	Pass
15	0.006	0.150	4.1	0.007	0.225	2.93	Pass
16	0.008	0.115	7.0	0.008	0.173	4.84	Pass
17	0.005	0.132	3.4	0.005	0.199	2.51	Pass
18	0.006	0.102	6.2	0.007	0.153	4.43	Pass
19	0.004	0.118	3.2	0.005	0.178	2.59	Pass
20	0.004	0.092	4.7	0.005	0.138	3.53	Pass
21	0.005	0.107	5.0	0.006	0.161	3.76	Pass
22	0.004	0.084	4.2	0.004	0.125	3.10	Pass
23	0.006	0.098	6.1	0.006	0.147	4.33	Pass
24	0.003	0.077	4.3	0.004	0.115	3.31	Pass
25	0.006	0.090	7.1	0.007	0.135	5.01	Pass
26	0.004	0.071	6.3	0.005	0.106	4.92	Pass
27	0.005	0.083	6.1	0.006	0.125	4.50	Pass
28	0.006	0.066	9.8	0.007	0.099	7.11	Pass
29	0.004	0.078	4.7	0.004	0.116	3.68	Pass
30	0.009	0.061	14.3	0.010	0.092	10.54	Pass
31	0.004	0.073	5.8	0.005	0.109	4.42	Pass
32	0.005	0.058	8.5	0.005	0.086	6.32	Pass
33	0.011	0.068	16.4	0.013	0.102	12.46	Pass
34	0.004	0.054	8.0	0.005	0.081	6.25	Pass
35	0.017	0.064	26.3	0.018	0.096	18.96	Pass
36	0.008	0.051	16.2	0.009	0.077	11.48	Pass
37	0.018	0.061	29.3	0.023	0.091	25.62	Pass
38	0.020	0.048	41.7	0.025	0.073	34.17	Pass
39	0.007	0.058	12.2	0.008	0.087	9.57	Pass
40	0.036	0.046	77.2	0.041	0.069	59.48	Pass

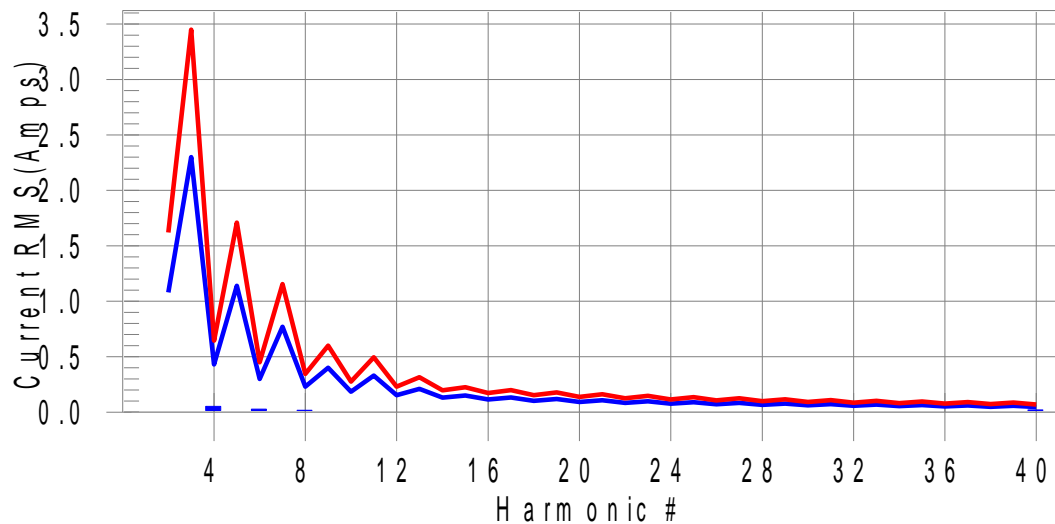
**VINNO X1**

**Current & voltage waveforms**



**Harmonics and Class A limit line**

**European Limits**



**Test result: Pass Worst harmonic was #40 with 29.61% of the limit.**

# TEST REPORT

## Current Test Result Summary (Run time)

THC(A): 0.07    I-THD(%): 2419.63    POHC(A): 0.021    POHC Limit(A): 0.251

### Highest parameter values during test:

V_RMS (Volts):	229.52	Frequency(Hz):	50.00
I_Peak (Amps):	3.340	I_RMS (Amps):	0.894
I_Fund (Amps):	0.006	Crest Factor:	3.865
Power (Watts):	75.7	Power Factor:	0.424

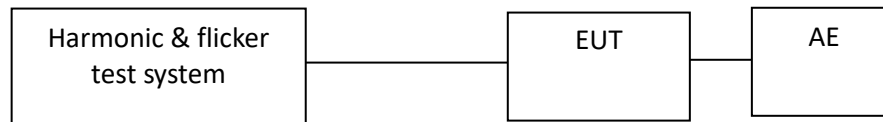
Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.004	1.080	0.3	0.005	1.620	0.31	Pass
3	0.004	2.300	0.2	0.006	3.450	0.17	Pass
4	0.050	0.430	11.7	0.052	0.645	8.10	Pass
5	0.003	1.140	0.3	0.006	1.710	0.32	Pass
6	0.026	0.300	8.7	0.027	0.450	6.03	Pass
7	0.003	0.770	0.5	0.006	1.155	0.51	Pass
8	0.017	0.230	7.2	0.017	0.345	5.00	Pass
9	0.003	0.400	0.8	0.006	0.600	0.98	Pass
10	0.003	0.184	1.6	0.006	0.276	2.07	Pass
11	0.012	0.330	3.7	0.013	0.495	2.65	Pass
12	0.003	0.153	1.8	0.006	0.230	2.41	Pass
13	0.009	0.210	4.5	0.011	0.315	3.45	Pass
14	0.004	0.131	2.9	0.006	0.197	3.11	Pass
15	0.005	0.150	3.1	0.007	0.225	3.08	Pass
16	0.008	0.115	7.3	0.010	0.173	5.69	Pass
17	0.004	0.132	2.7	0.006	0.199	3.06	Pass
18	0.009	0.102	9.3	0.011	0.153	7.16	Pass
19	0.004	0.118	3.4	0.006	0.178	3.50	Pass
20	0.008	0.092	8.3	0.009	0.138	6.87	Pass
21	0.005	0.107	5.1	0.008	0.161	4.77	Pass
22	0.003	0.084	4.0	0.006	0.125	4.74	Pass
23	0.008	0.098	7.7	0.009	0.147	6.32	Pass
24	0.004	0.077	5.8	0.007	0.115	5.99	Pass
25	0.007	0.090	7.7	0.009	0.135	6.76	Pass
26	0.005	0.071	6.6	0.007	0.106	6.63	Pass
27	0.005	0.083	6.3	0.008	0.125	6.27	Pass
28	0.006	0.066	9.5	0.008	0.099	8.38	Pass
29	0.004	0.078	4.7	0.007	0.116	5.82	Pass
30	0.006	0.061	9.9	0.008	0.092	9.11	Pass
31	0.003	0.073	4.7	0.006	0.109	5.87	Pass
32	0.005	0.058	8.2	0.008	0.086	8.88	Pass
33	0.009	0.068	12.5	0.010	0.102	10.17	Pass
34	0.006	0.054	11.6	0.009	0.081	10.67	Pass
35	0.012	0.064	18.4	0.014	0.096	14.12	Pass
36	0.005	0.051	10.1	0.008	0.077	10.66	Pass
37	0.006	0.061	10.6	0.010	0.091	10.57	Pass
38	0.009	0.048	19.3	0.011	0.073	15.13	Pass
39	0.005	0.058	8.3	0.008	0.087	9.67	Pass
40	0.019	0.046	40.5	0.020	0.069	29.61	Pass

## TEST REPORT

### 7 Voltage fluctuations and flicker

Test result: Pass

#### 7.1 Block diagram of test Setup



#### 7.2 Test Procedure

##### 7.2.1 Definition

- Flicker: impression of unsteadiness of visual sensation induced by a lighting stimulus whose luminance or spectral distribution fluctuates with time.
- Pst: Short-term flicker indicator the flicker severity evaluated over a short period (in minutes); Pst=1 is the conventional threshold of irritability
- Plt: long-term flicker indicator; the flicker severity evaluated over a long period (a few hours) using successive Pst values.
- dc: the relative steady-state voltage change
- dmax: the maximum relative voltage change
- d(t): the value during a voltage change

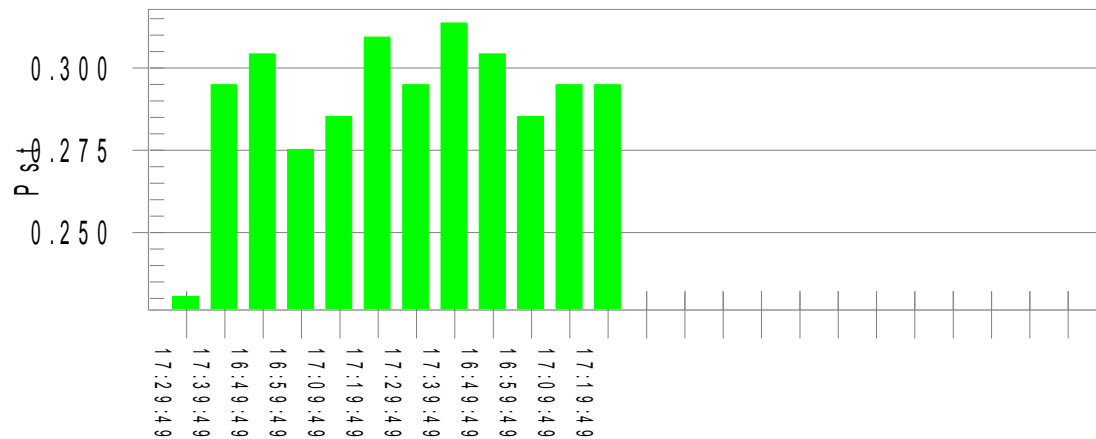
##### 7.2.2 Test Procedure

The following limits apply

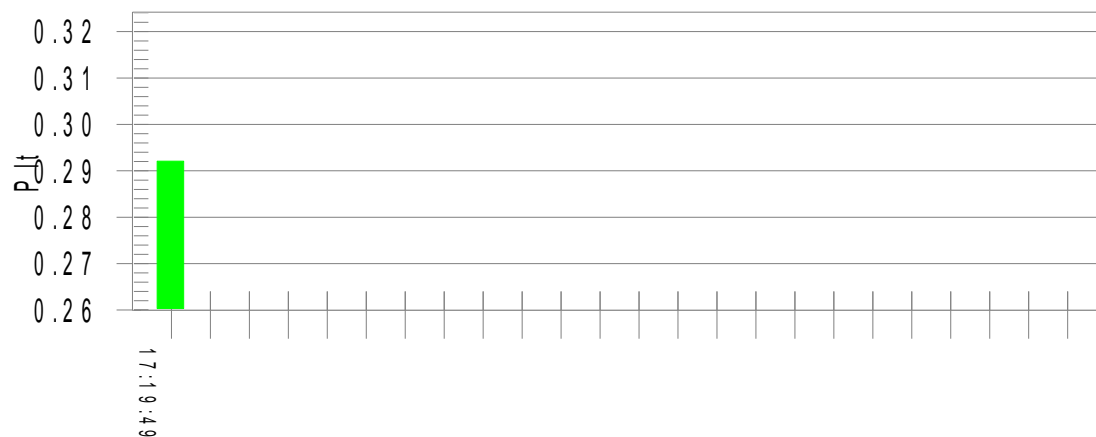
- "Plt" shall not exceed 0.65.
- "Pst" shall not exceed 1.0.
- "dc" shall not exceed 3.3%.
- "d(t)" shall not exceed 3.3% for more than 500ms.
- "dmax" shall not exceed:
  - ☒ 4% without additional conditions,
  - ☐ 6% switched manually or automatically more than twice per day,
  - ☐ 7% attended whilst in use or switched automatically for no more than twice per day or attended while in use.
  - ☐ For manual switch, dmax is measured in accordance with Annex B of standard, average dmax is calculated from 24 times measurement.
  - ☐ The EUT is unlikely to produce significant voltage fluctuations or flicker by technical analysis and evaluation. So it is deemed to fulfil the requirements without testing.
  - ☐ The product is not intended to connect to the PUBLIC MAINS NETWORK, and this test is not applicable in this environment.

### 7.3 Test Result

#### Pst<sub>i</sub> and limit line VINNO E20 European Limits



#### Plt and limit line



#### Parameter values recorded during the test:

Vrms at the end of test (Volt): 229.88

Highest dt (%): 0.85

Time(mS) > dt: 0.0

Highest dc (%): 0.29

Highest dmax (%): 0.58

Test limit (%): 3.30

Test limit (mS): 500.0

Test limit (%): 3.30

Test limit (%): 4.00

Pass

Pass

Pass

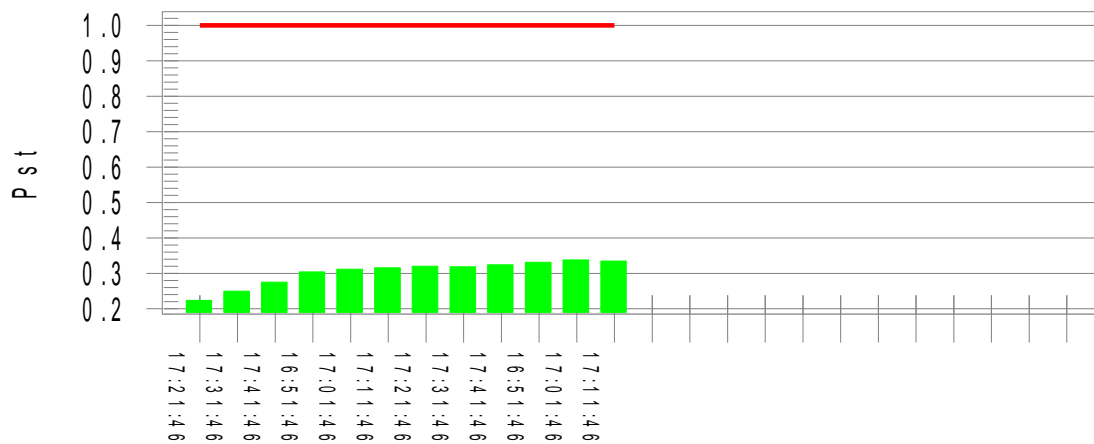
Pass

# TEST REPORT

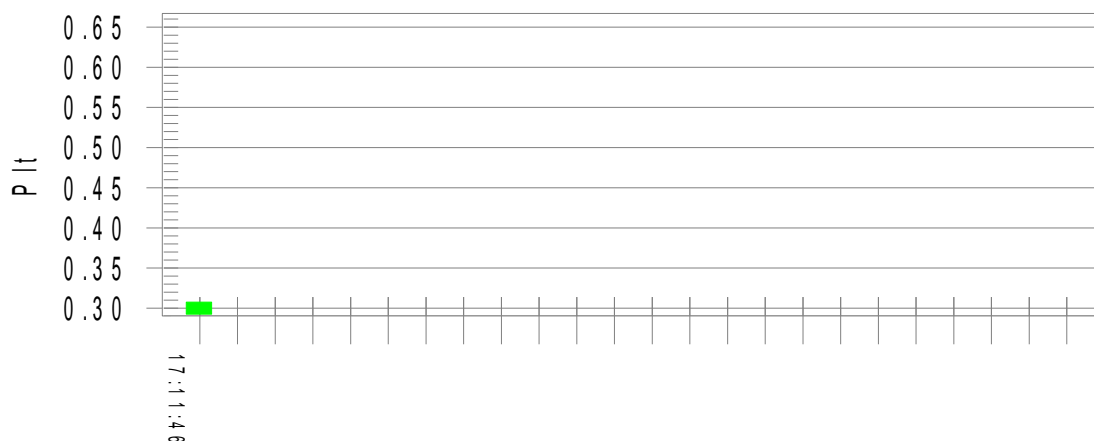
## VINNO X1

### Pst and limit line

### European Limits



### Plt and limit line



### Parameter values recorded during the test:

Vrms at the end of test (Volt): 230.20

Highest dt (%): 0.84

Time(mS) &gt; dt: 0.0

Highest dc (%): -0.29

Highest dmax (%): 0.56

Highest Pst (10 min. period): 0.338

Highest Plt (2 hr. period): 0.308

Test limit (%): 3.30

Pass

Test limit (mS): 500.0

Pass

Test limit (%): 3.30

Pass

Test limit (%): 4.00

Pass

Test limit: 1.000

Pass

Test limit: 0.650

Pass

## Immunity Test

**Performance as required by IEC 60601-1-2 and applicable particular standards. Basic Safety and Essential Performance must be maintained throughout testing.**

### Description of basic safety and essential performance

Product Essential Performance (Expected Performance where RMF identifies no Essential Performance):

No.	Description
1	Display of physiological images
2	Display of physiological traces
3	Display quantified data including distance, angle, square and volume
4	Display ultrasound indices as aid for safe use

### Description of Product Essential/Specific Performance:

No.	Description
1	No component failures
2	No changes in programmable parameters (gain)
3	No reset to factory defaults (manufacturer's presets)
4	No change of operating mode
5	No false alarms
6	No cessation or interruption of any intended operation
7	The disturbance shall not produce noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which may be attributed to a physiological
8	The disturbance shall not produce an error in a display of incorrect numerical values associated with the diagnosis to be performed after 1st dash
9	The disturbance shall not produce an error in a displayed safety related indication
10	The disturbance shall not produce unintended or excessive ultrasound output
11	The disturbance shall not produce unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
12	The disturbance shall not produce unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use
13	Failure of automatic diagnosis or treatment ME equipment or ME systems to diagnose or treat, even if accompanied by an alarm

Description how the basic safety and essential performance were monitored during each test

No.	Description
1	Observing EUT's LCD display

**TEST REPORT****Performance Criteria**

Under the test conditions, the ME EQUIPMENT or ME SYSTEM shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed:

- malfunction;
- non-operation when operation is required;
- unwanted operation when no operation is required;
- deviation from normal operation that poses an unacceptable RISK to the PATIENT or OPERATOR;

The additional immunity performance criteria of IEC 60601-2-37:2015 were considered as below:

- component failures;
- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of operating mode;
- false alarms;
- cessation or interruption of any intended operation, even if accompanied by an alarm;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- \* the disturbance shall not produce noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which may be attributed to a physiological;
- the disturbance shall not produce an error in a display of incorrect numerical values associated with the diagnosis to be performed after dash mark as -\*;
- the disturbance shall not produce an error in a displayed safety related indication;
- the disturbance shall not produce unintended or excessive ultrasound output;
- the disturbance shall not produce unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
- the disturbance shall not produce unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use;

For ME EQUIPMENT and ME SYSTEMS with multiple FUNCTIONS, the criteria apply to each FUNCTION, parameter and channel.

The ME EQUIPMENT or ME SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from MANUFACTURER'S specifications) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.



## TEST REPORT

### 8 Electrostatic Discharge (ESD)

Test result: Pass

#### 8.1 Severity Level and Performance Criterion

##### 8.1.1 Test level

Contact discharge		Air discharge	
Level	Test voltage (kV)	Level	Test voltage (kV)
1	2	1	2
2	4	2	4
3	6	3	8
4	8	4	15
X	Special	X	Special

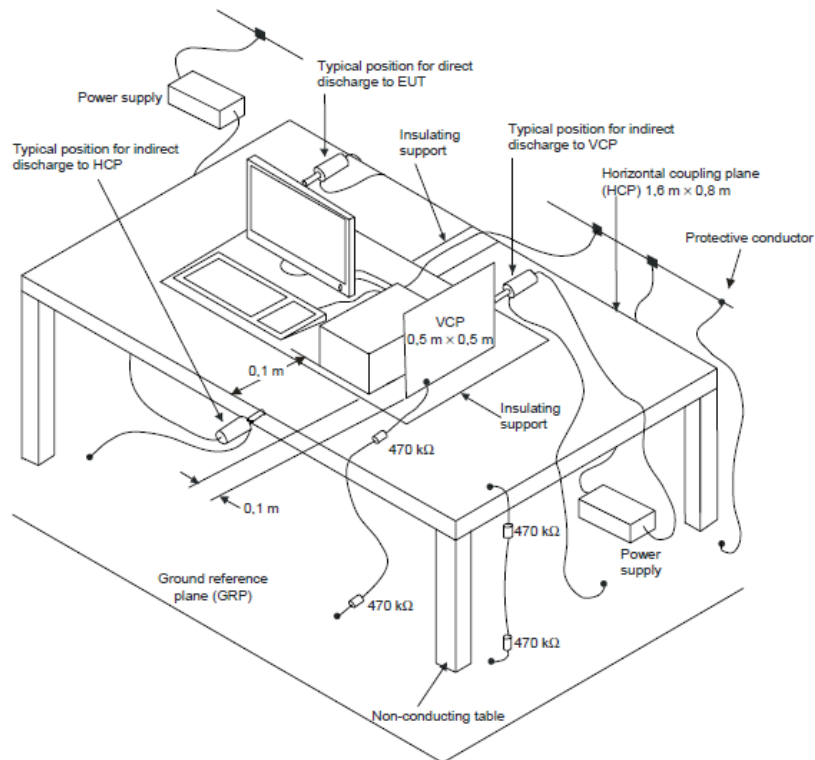
Notes:

- The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shown as "X" may be needed and shall take precedence.
- The yellow rows were the selected test level.

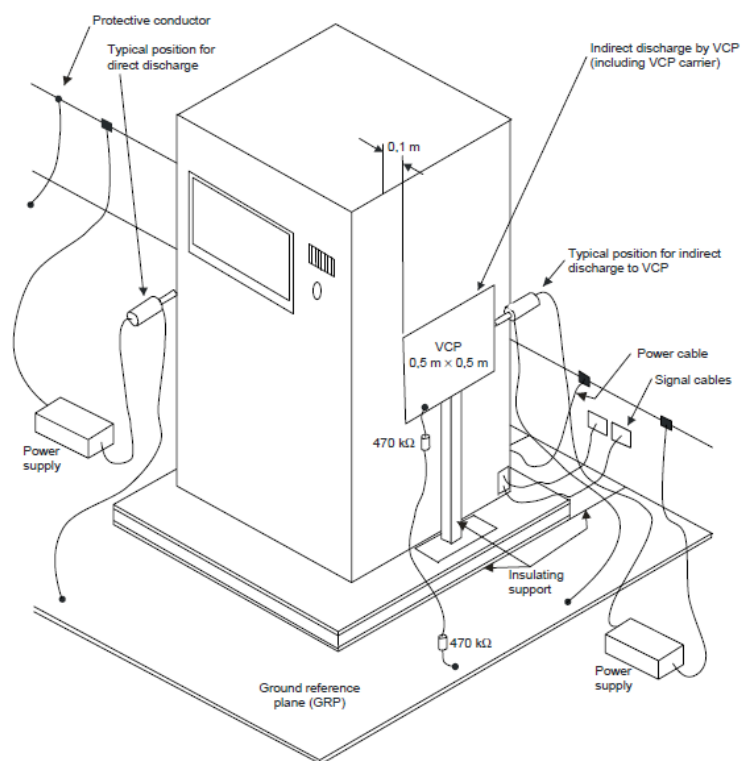
## TEST REPORT

### 8.2 Block diagram of test Setup

For table-top equipment



For floor standing equipment



## TEST REPORT

### 8.3 Test Procedure

Measurement was performed in shielded room.

Measurement procedure was applied according to EN 61000-4-2 Clause 8.

The test method and equipment was specified by EN 61000-4-2 with the modifications by IEC60601-1-2 clause 8.9.

## TEST REPORT

### 8.4 Test Result

Direct discharges were applied at the following selected points:

Test level [kV]	Air/Contact	Polarity (+/-)	Pass/Fail/NA	Comment
8	Contact	+/-	Pass	Accessible metal parts of the EUT
8	Contact	+/-	Pass	All touchable screws of enclosure
2/4/8/15	Air	+/-	Pass	Air gap of the switch, button
2/4/8/15	Air	+/-	Pass	Slots around the EUT
2/4/8/15	Air	+/-	Pass	All probes

Indirect contact discharges were applied to the VCP and the HCP at the following selected points:

For table-top equipment

Position	Description	Point	Pass/Fail/NA
HCP front	0,1m from the front of the EUT	Edge of centre on HCP	NA
HCP back	0,1m from the back of the EUT	Edge of centre on HCP	NA
HCP right	0,1m from the right side of the EUT	Edge of centre on HCP	NA
HCP left	0,1m from the left side of the EUT	Edge of centre on HCP	NA
VCP front	0,1m from the front of the EUT	Edge of centre on VCP	NA
VCP back	0,1m from the back of the EUT	Edge of centre on VCP	NA
VCP right	0,1m from the right of the EUT	Edge of centre on VCP	NA
VCP left	0,1m from the left of the EUT	Edge of centre on VCP	NA

For floor standing equipment

Position	Description	Point	Pass/Fail/NA
CP front	0,1m from the front of the EUT	Edge of centre on VCP	Pass
CP back	0,1m from the back of the EUT	Edge of centre on VCP	Pass
CP right	0,1m from the right of the EUT	Edge of centre on VCP	Pass
CP left	0,1m from the left of the EUT	Edge of centre on VCP	Pass

**Observation:** All the functions were operated as normal after the test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

### 9 Radio frequency electromagnetic field

Test result: Pass

#### 9.1 Severity Level and Performance Criterion

##### 9.1.1 Test level

Level	Test field strength V/m	Intended use environment
1	3	Professional healthcare facility environment
2	10	Home healthcare environment
X	Special	

Note:

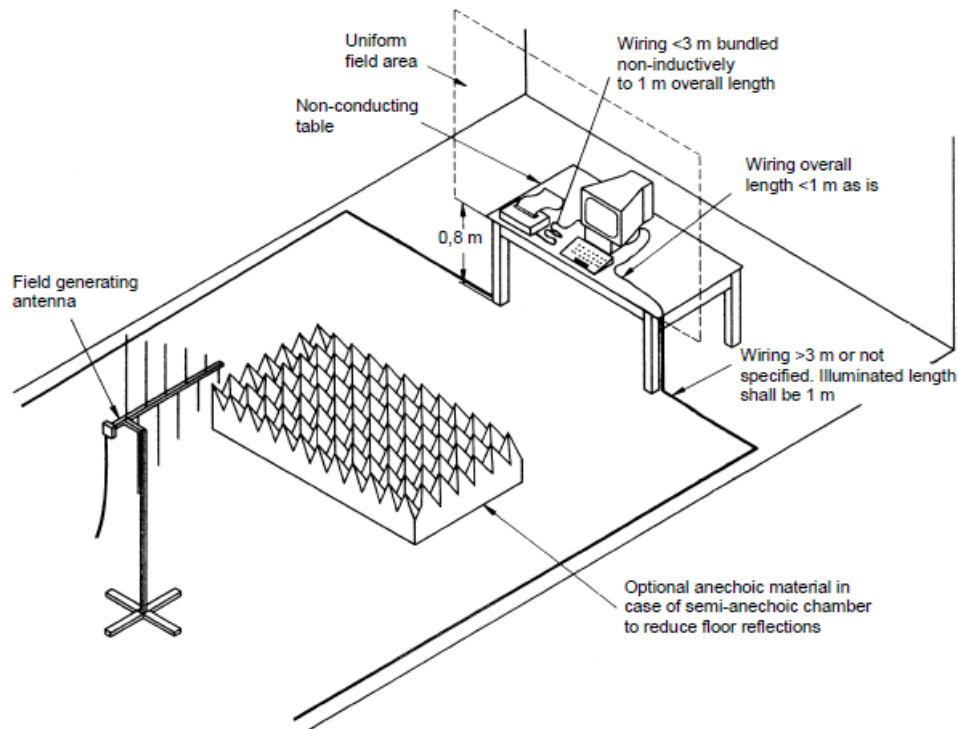
1. "X" is an open test level. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shown as "X" may be needed and shall take precedence.

2. The yellow row is the selected test level.

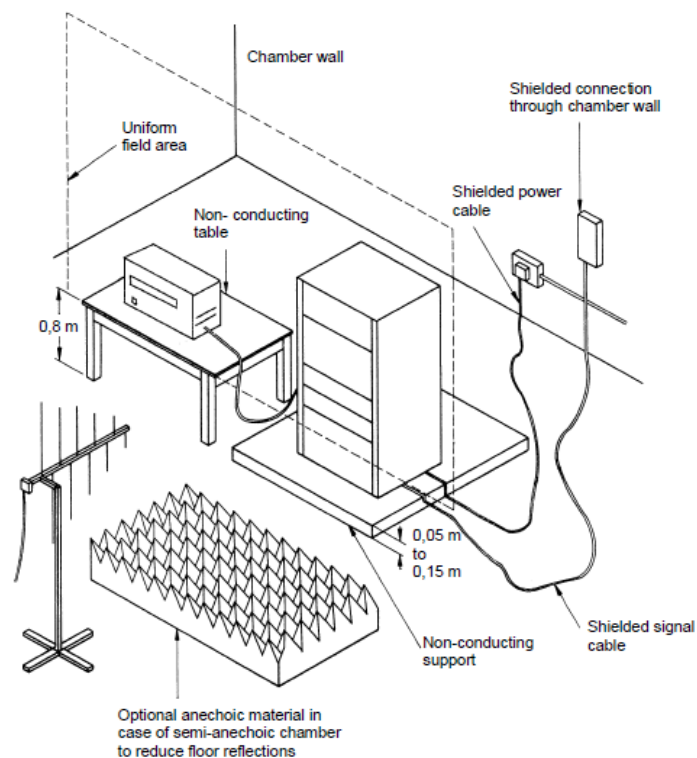
## TEST REPORT

### 9.2 Block diagram of test setup

For table-top equipment



For floor standing equipment



## TEST REPORT

### 9.3 Test Procedure

Measurement was performed in full-anechoic chamber.

Measurement procedure was applied according to EN 61000-4-3 Clause 8.

The test method and equipment was specified by EN 61000-4-3.

Testing of permanently installed large ME equipment or large ME system in situ.

Using the RF sources that are expected to be operating in any of the locations of INTENDED USE.

Testing in the range 80 MHz to 6 GHz at frequencies designated by the International Telecommunications Union (ITU) for ISM use, listed as follows:

Centre Frequency (MHz)	Frequency range (MHz)
433.920	433.05 – 434.79
915.000	902 – 928
2450	2400 – 2500
5800	5725 – 5 875

# TEST REPORT

## 9.4 Test Result

Test no.	Frequency (MHz)	Polarization	Test level (V/m)	Modulation	Dwell time (s)	Exposed location	Pass/Fail/NA
1	80-1000	H & V	3	1 kHz, 80% AM 1 % increment	3	All sides	Pass
2	1000-2700	H & V	3	1 kHz, 80% AM 1 % increment	3	All sides	Pass

Testing of permanently installed large ME equipment or large ME system:

Yes ☐ No ☒

If Yes, include the following information

Frequencies tested									
Power levels of RF test sources									
Modulation of RF test sources									
Test distance used									
Other relevant information related to test									

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** The EUT providing the essential performance and remaining safe.



# TEST REPORT

## 10 Proximity fields from RF wireless communication equipment

Test result: **Pass**

### 10.1 Severity Level and Performance Criterion

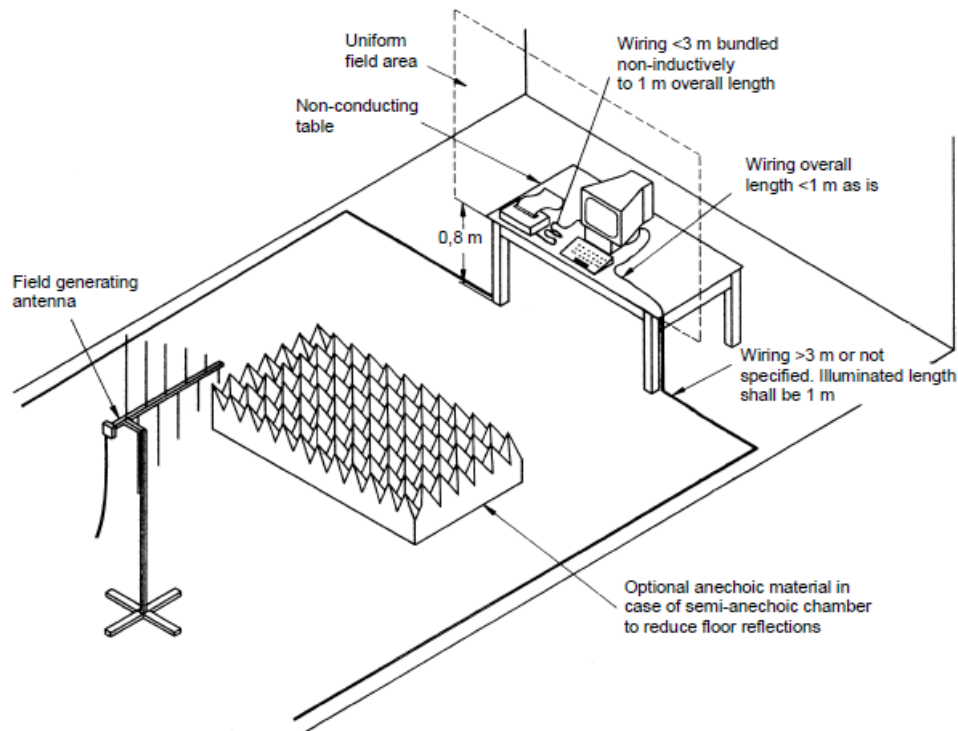
#### 10.1.1 Test level

Test Frequency (MHz)	Modulation	Minimum IMMUNITY Level (V/m)	IMMUNITY Level Applied (V/m)
385	**Pulse Modulation: 18 Hz	27	27
450	<input type="checkbox"/> *FM $\pm$ 5 Hz deviation: 1 kHz sine	28	28
	<input checked="" type="checkbox"/> **Pulse Modulation: 18 Hz		
710 745 780	**Pulse Modulation: 217 Hz	9	9
810 870 930	**Pulse Modulation: 18 Hz	28	28
1720 1845 1970	**Pulse Modulation: 217 Hz	28	28
2450	**Pulse Modulation: 217 Hz	28	28
5240 5500 5785	**Pulse Modulation: 217 Hz	9	9
<p>Note *: As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p> <p>Note **: The carrier shall be modulated using a 50 % duty cycle square wave signal.</p>			

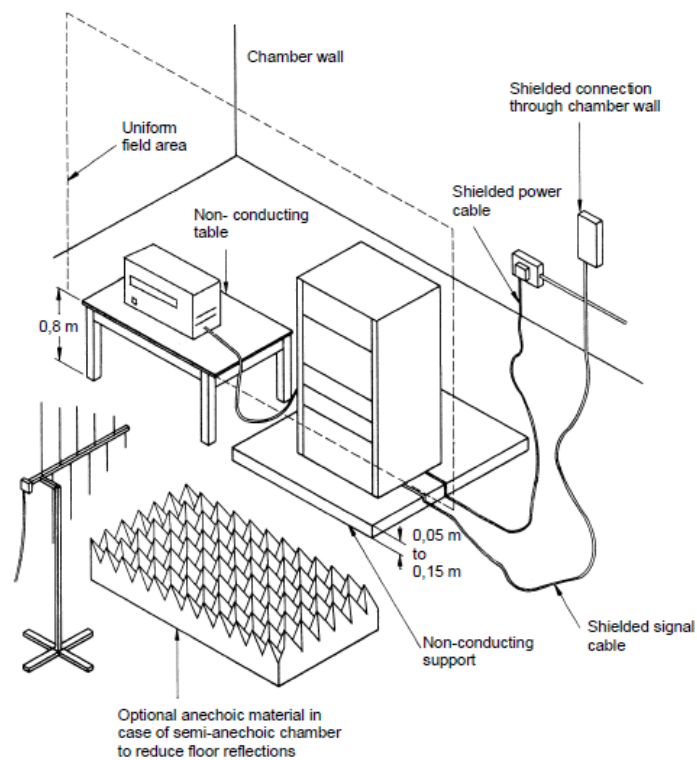
## TEST REPORT

### 10.2 Block diagram of test setup

For table-top equipment



For floor standing equipment



## TEST REPORT

### 10.3 Test Procedure

Measurement was performed in full-anechoic chamber.

Measurement procedure was applied according to EN 61000-4-3 Clause 8.

The test method and equipment was specified by EN 61000-4-3 with the modification of IEC60601-1-2 Clause 8.10.

### 10.4 Test Result

Test frequency (MHz)	Antenna polarization (V/H)	Dwell Time (second)	Exposed location	Result
385	H & V	20	All sides	Pass
450	H & V	20	All sides	Pass
710 745 780	H & V	20	All sides	Pass
810 870 930	H & V	20	All sides	Pass
1720 1845 1970	H & V	20	All sides	Pass
2450	H & V	20	All sides	Pass
5240 5500 5785	H & V	20	All sides	Pass

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

### 11 Fast transients, common mode

Test result: Pass

#### 11.1 Severity Level and Performance Criterion

##### 11.1.1 Test level

Open circuit output test voltage (+/-10%) and repetition rate of the impulses (+/- 20%)			
On A.C and D.C power cables ports		On signal and interconnecting cables ports	
Voltage peak kV	Repetition rate kHz	Voltage peak kV	Repetition rate kHz
2	100	1	100

##### Notes:

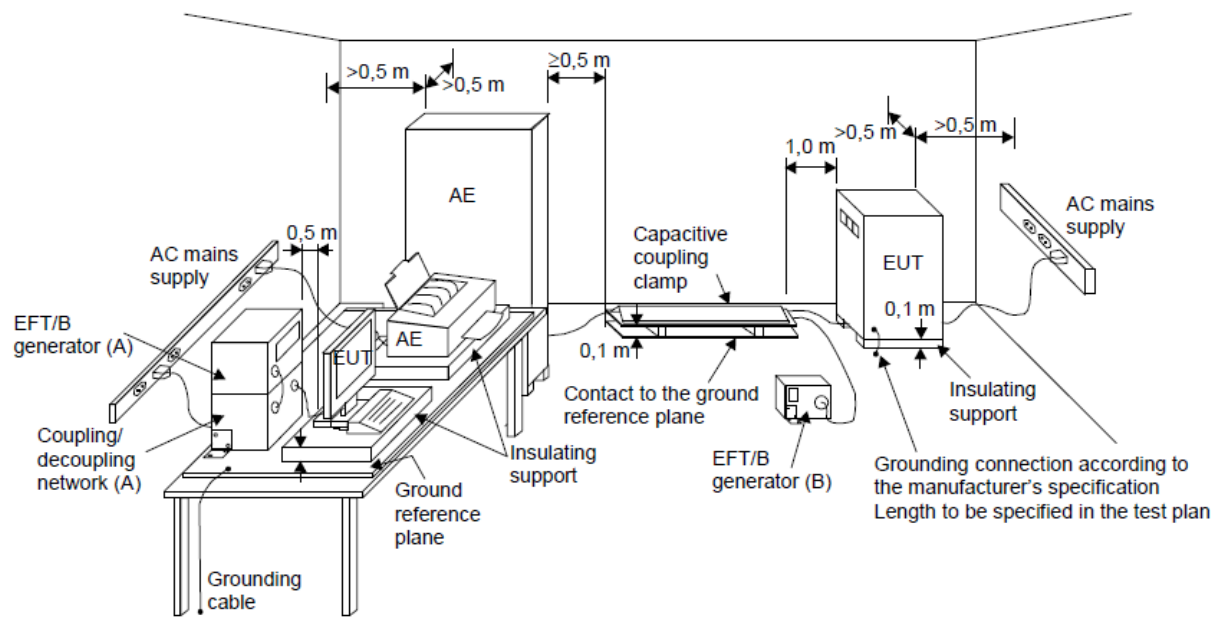
1. The yellow rows were the selected test level.
2. The requirements above shall apply to equipment and systems used in all environments.

When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.

3. Signal and interconnecting cables specified to be (i.e. restricted to) less than 3 m in length by the manufacturer of the equipment or system and all patient-coupled cables are not tested directly. However, the effects of any coupling between cables that are tested directly and cables that are not tested directly shall be taken into account.

## TEST REPORT

### 11.2 Block diagram of test setup



(A) location for supply line coupling

(B) location for signal lines coupling

### 11.3 Test Procedure

Measurement was performed in shielded room.

Measurement procedure was applied according to IEC 61000-4-4 Clause 8.

The test method and equipment was specified by IEC 61000-4-4 with the modification of IEC60601-1-2 Clause 8.9.

## TEST REPORT

### 11.4 Test Result

Test No.	Level (kV)	Polarity (+/-)	Line for test	Pass/Fail/NA
1	2	+/-	AC mains power input ports	Pass
2	2	+/-	DC power input ports	NA
3	1	+/-	Signal/control ports	NA
4	1	+/-	Interconnecting cable ports	NA
Note: For this modification, after technical evaluation, only AC mains power input needs to be further testing. For other ports, see the original report.				

**Observation:** All the functions were operated as normal after the test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

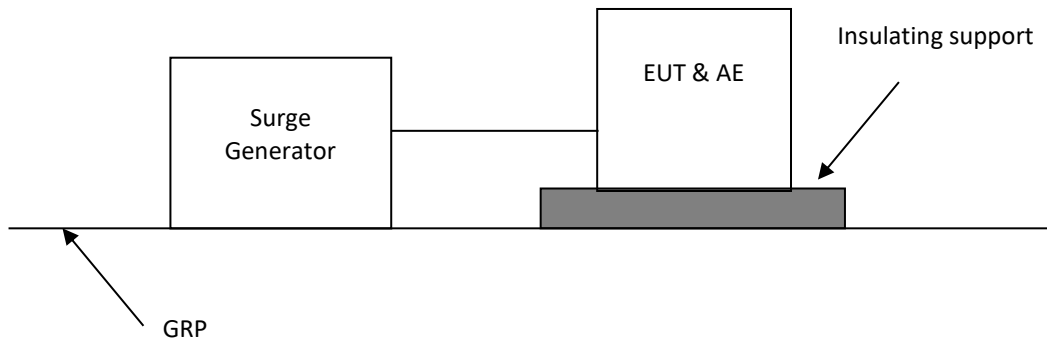
### 12 Surges

Test result: Pass

#### 12.1 Severity Level and Performance Criterion

##### 12.1.1 Test level

Level	Open-circuit test voltage (kV)
1	0.5
2	1.0
3	2.0
4	4.0
X*	Special
Notes: 1. "X" is an open class. This level can be specified in the product specification 2. The yellow rows are the selected level.	

**TEST REPORT****12.2 Block diagram of test setup****12.3 Test Procedure**

Measurement was performed in shielded room.

Measurement procedure was applied according to EN 61000-4-5 Clause 8.

The test method and equipment was specified by EN 61000-4-5 with the modification of IEC60601-1-2 Clause 8.9.



## TEST REPORT

### 12.4 Test Result

Test No.	Level [kV]	Polarity +/-	Line for test	Pass/Fail/NA
1	0.5/1	+/-	AC mains power input port (line to line)	Pass
2	0.5/1/2	+/-	AC mains power input port (line to earth)	Pass
3	0.5/1	+/-	Input d.c. power port (line to line)	NA
4	0.5/1/2	+/-	Input d.c. power port (line to earth)	NA

**Observation:** All the functions were operated as normal after the test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

### 13 Conducted disturbances induced by RF fields

Test result: Pass

#### 13.1 Severity Level and Performance Criterion

##### 13.1.1 Test level

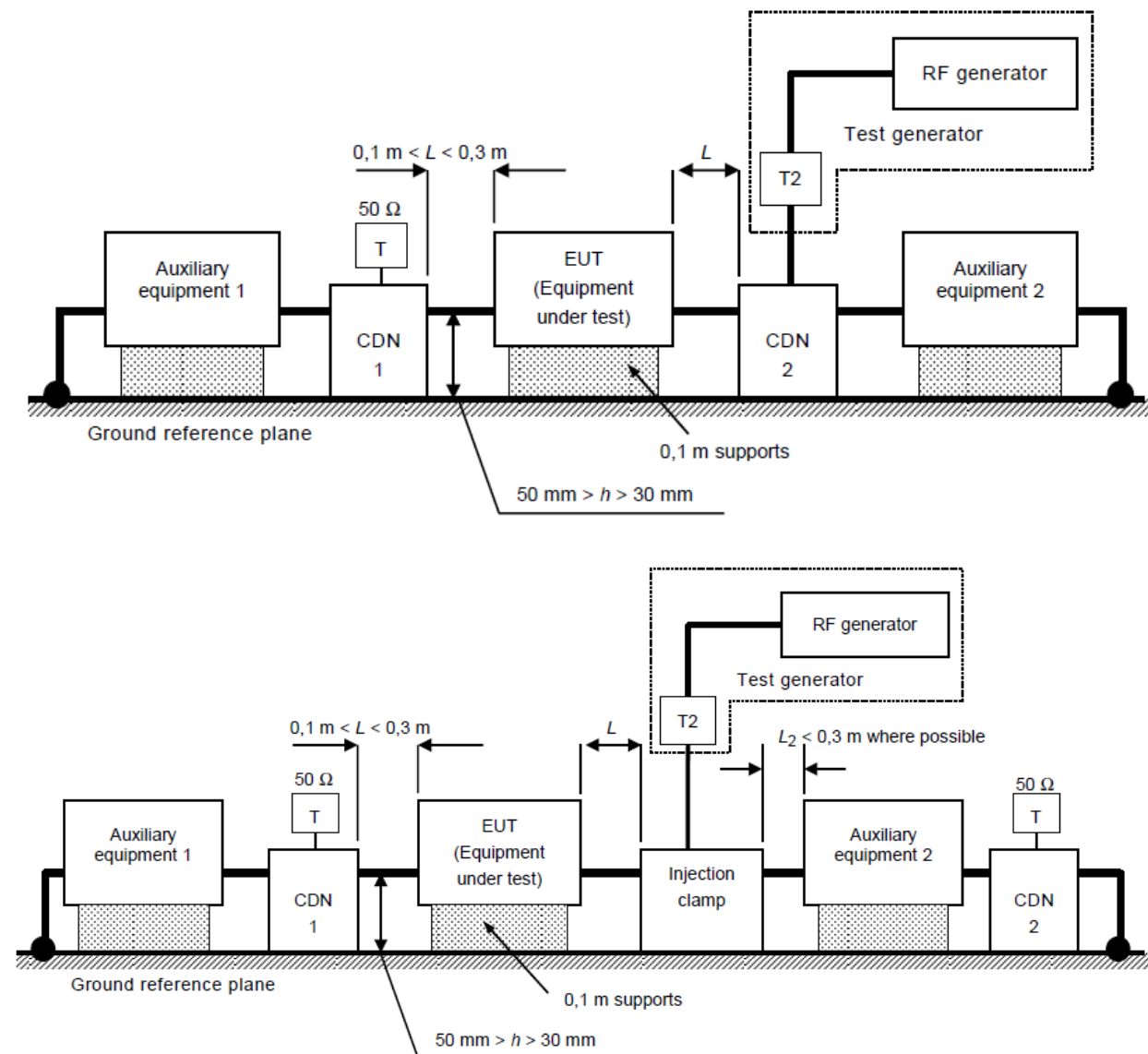
Level	Test field strength V/m	Equipment	Frequency range
1	3	Professional healthcare facility environment	0.15MHz-80MHz
2	3	Home healthcare environment	0.15MHz-80MHz
3	6	Professional healthcare facility environment	In the ISM frequency band
4	6	Home healthcare environment	In the ISM and amateur frequency band

##### Notes:

1. The yellow rows were the selected test level.
2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.
4. "ISM" means the industrial, scientific and medical.
5. For internally powered equipment and systems that cannot be used during battery charging, do not have an option for AC power input and have no connection to ground, telecommunications systems, any other equipment or system or a patient, the start frequency shall be determined from figure B.1 of IEC 61000-4-6, using the maximum dimension of the equipment or system, including the maximum length of each cable connected.

## TEST REPORT

### 13.2 Block diagram of test setup



- T termination  $50\ \Omega$
- T2 power attenuator (6 dB)
- CDN coupling and decoupling network

### 13.3 Test Procedure

Measurement procedure was applied according to EN 61000-4-6 Clause 8.

The test method and equipment was specified by EN 61000-4-6 with the modification of IEC60601-1-2 Clause 8.9.

# TEST REPORT

## 13.4 Test Result

Test No.	Frequency (MHz)	Level (V)	Modulation	Dwell time (s)	Injected point	Pass/Fail/NA
1	0.15~80	3	80%, 1 kHz, AM	3	Input AC mains power port	Pass
	<input checked="" type="checkbox"/> ISM frequency band <input type="checkbox"/> ISM and amateur frequency band	6				
2	0.15~80	3	80%, 1 kHz, AM	3	Input DC power port	NA
	<input type="checkbox"/> ISM frequency band <input type="checkbox"/> ISM and amateur frequency band	6				
3	0.15~80	3	80%, 1 kHz, AM	3	Patient coupling port	NA
	<input type="checkbox"/> ISM frequency band <input type="checkbox"/> ISM and amateur frequency band	6				
4	0.15~80	3	80%, 1 kHz, AM	3	Signal input/output parts PORT	NA
	<input type="checkbox"/> ISM frequency band <input type="checkbox"/> ISM and amateur frequency band	6				
Note: For this modification, after technical evaluation, only AC mains power input needs to be further testing. For other ports, see the original report.						

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

### 14 Voltage dips and interruptions

Test result: Pass

#### 14.1 Severity Level and Performance Criterion

##### 14.1.1 Test level

Voltage Dips (% $U_T$ )**	Cycles	Sync Angle (degrees)
0	0.5*	0; 45; 90; 135; 180; 225; 270; 315
0	1	0
70	25 (50 Hz) 30 (60 Hz)	0
Voltage Interruption % $U_T$	Cycles	Sync Angle [degrees]
0	250 (50 Hz), 300 (60 Hz)	Any

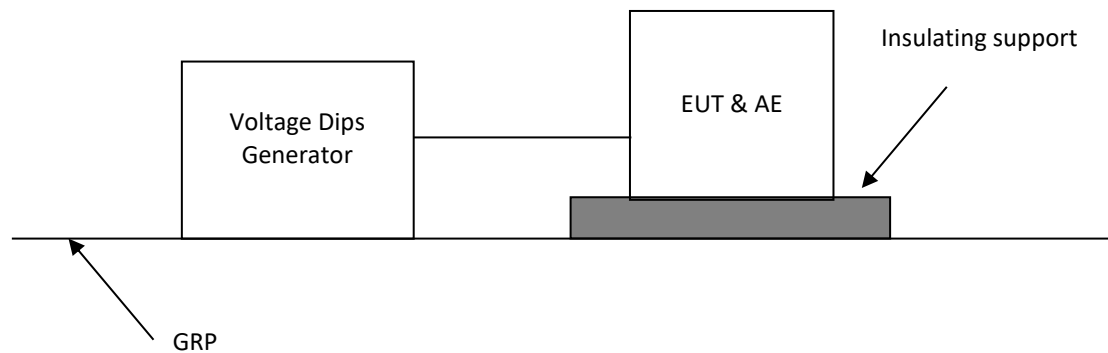
##### Note:

1. If the Rated voltage range <25 % of the lowest rated input voltage, one rated input voltage. Otherwise, minimum and maximum rated voltage.

2. ME equipment and ME systems with power input voltage selection by transformer taps tested at only one tap setting.

Note\* - Only applicable to me equipment with single phase a.c. mains

Note\*\* - Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current  $\leq 16$  A / phase.

**TEST REPORT****14.2 Block diagram of test setup****14.3 Test Procedure**

Measurement was performed in shielded room.

Measurement procedure was applied according to EN 61000-4-11 Clause 8.

The test method and equipment was specified by EN 61000-4-11 with the modification of IEC60601-1-2 Clause 8.9.

**14.4 Test Result**

Supply Voltage Range	Difference of Max Voltage – Min Voltage	25 % of Lowest Rated input Voltage	Test at Min/Max Voltages required (Y/N)	
220V-240V	20V	>20V	N	
Supply Voltage Voltage under Test (V)			<input type="checkbox"/> 100	<input checked="" type="checkbox"/> 230
Frequency (Hz)			60	50
Voltage Dips	Period (Cycles)	Pass/ Fail/ NA		
0	0.5	NA	Pass	
0	1	NA	Pass	
70	25/30 (50/60 Hz)	NA	Pass	
Voltage Interruptions	Period (Cycles)	Pass/ Fail/ NA		
0	250/300 (50/60 Hz)	NA	Pass	

**Observation:** All the functions were operated as normal after test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

### 15 Power frequency magnetic field IMMUNITY

Test result: Pass

☐ Test does not apply. Device under test does not contain magnetically sensitive components or circuitry.

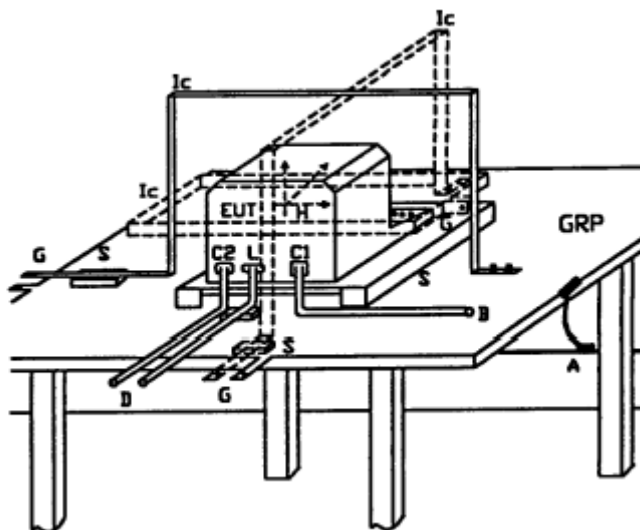
#### 15.1 Severity Level and Performance Criterion

##### 15.1.1 Test level

Level	Magnetic field strength A/m
1	30

Note: The yellow row is the selected test level.

#### 15.2 Block diagram of test setup



#### 15.3 Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-8 clause 7.

The test method and equipment is specified by IEC61000-4-8 with modification of IEC60601-1-2 Clause 8.9.



## TEST REPORT

### 15.4 Test Result

Test No.	Level A/m	Frequency Hz	Axis	Pass/ Fail/ NA
1	30	<input checked="" type="checkbox"/> 50Hz  <input type="checkbox"/> 60Hz	X	Pass
2	30		Y	Pass
3	30		Z	Pass

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** The EUT providing the essential performance and remaining safe.

## TEST REPORT

### 16 Electrical transient conduction along supply lines

Test result: NA

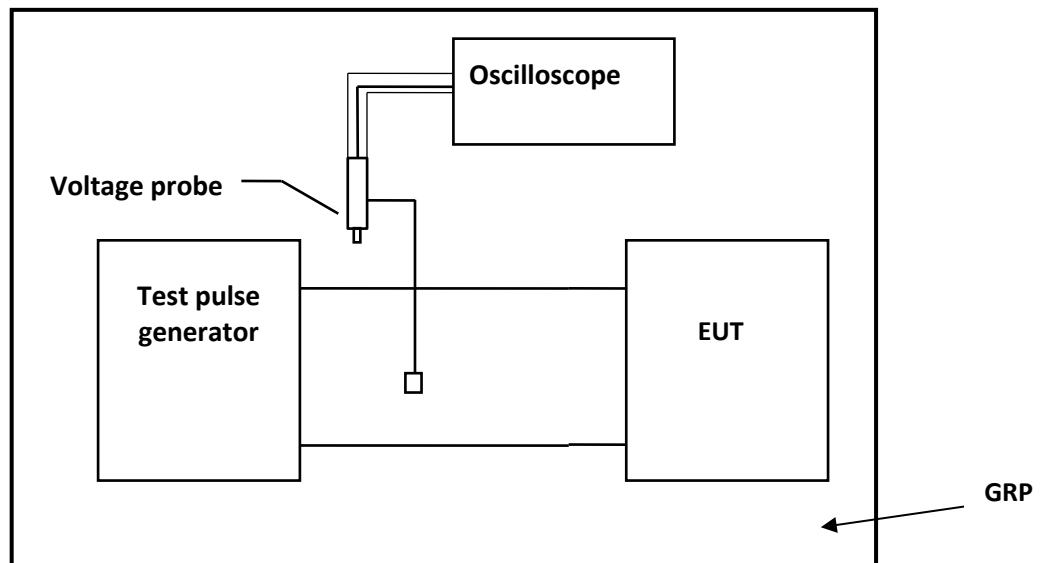
☒ Test does not apply. Device under test is not intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems.

#### 16.1 Severity Level and Performance Criterion

##### 16.1.1 Test level

Application Point	Test pulse and level	Coupling Method
Input d.c. Power ports (transportation)	1 (-150 V)	Direct Injection
	2a (+112 V)	Direct Injection
	2b (10 V for 12 V system; 20 V for 24 V system)	Direct Injection
	3a (-220 V for 12V system; -300 V for 24 V system)	Direct Injection
	3b (+150 V for 12 V system; +300 V for 24 V system)	Direct Injection

## 16.2 Block diagram of test setup



## 16.3 Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to ISO 7637-2 Clause 4.4.

The test method and equipment was specified by ISO 7637-2 with additions and modification of IEC60601-1-2 Clause 8.9.

## TEST REPORT

### 16.4 Test Result

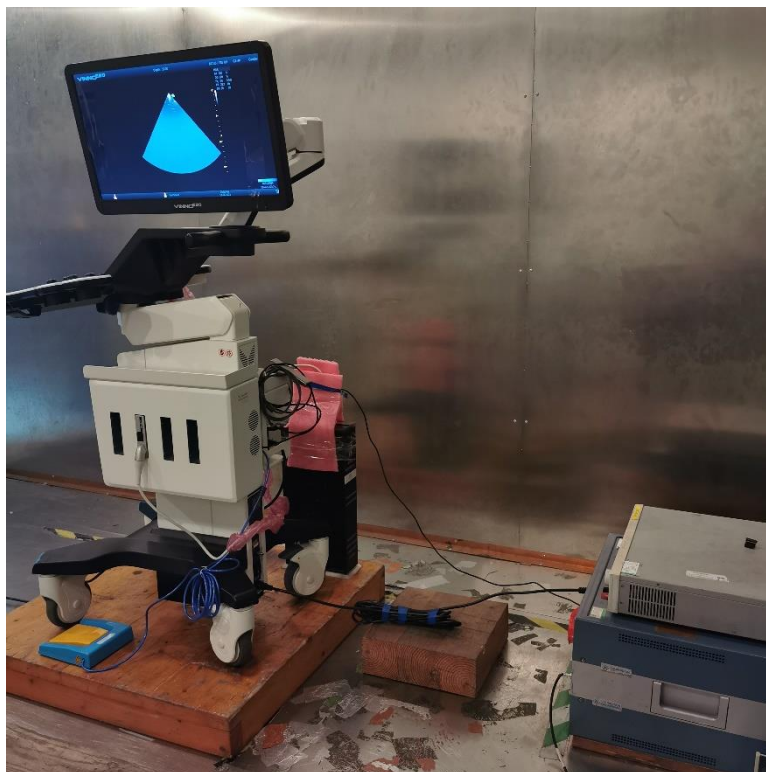
Point of application	Number of Pulses or Application Time	Burst/pulse cycle time	Pass/ Fail/ NA
Mains Pulse 1	10 pulses	0,5 s	NA
Mains Pulse 2a	10 pulses	0,2 s	NA
Mains Pulse 2b	10 pulses	0,5 s	NA
Mains Pulse 3a	20 minutes	90 ms	NA
Mains Pulse 3b	20 minutes	90 ms	NA

**Observation:**

**Conclusion:**

**Appendix I: Photograph of Test setup**

Conducted emission  
VINNO E20

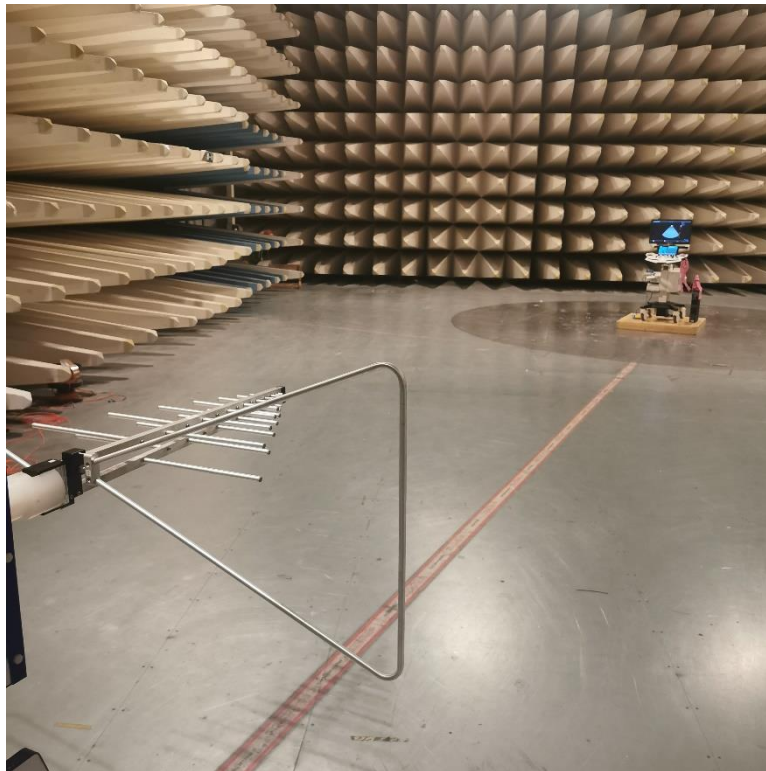


VINNO X1

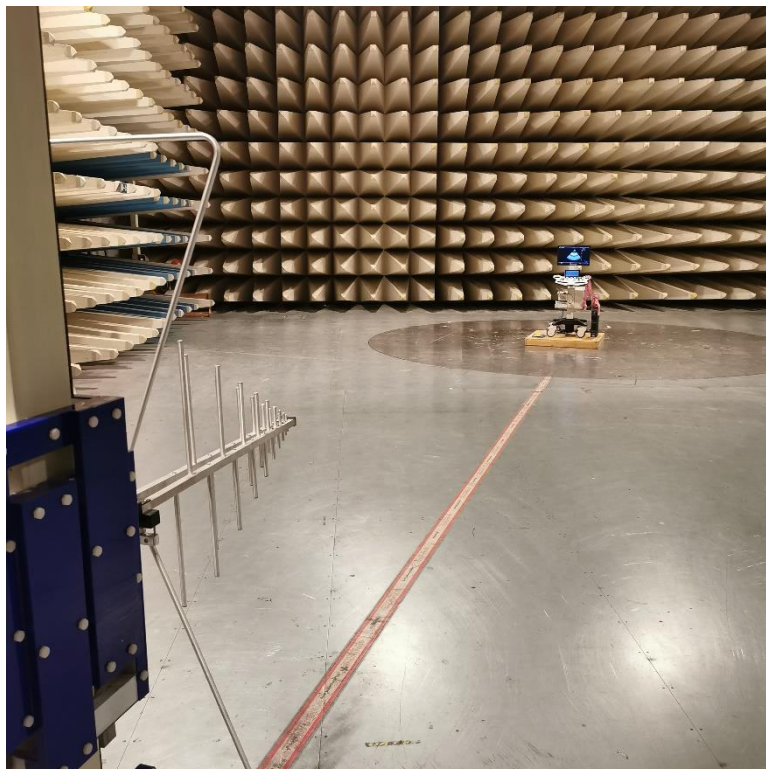


Radiation emission

VINNO E20



VINNO X1





Harmonic current emission & Voltage fluctuations and flicker  
VINNO E20

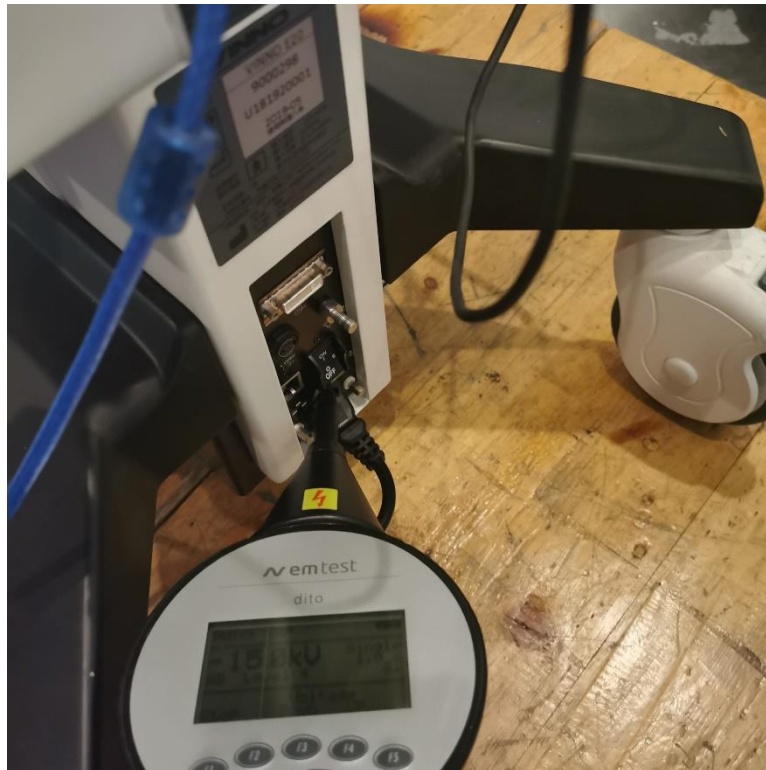


VINNO X1

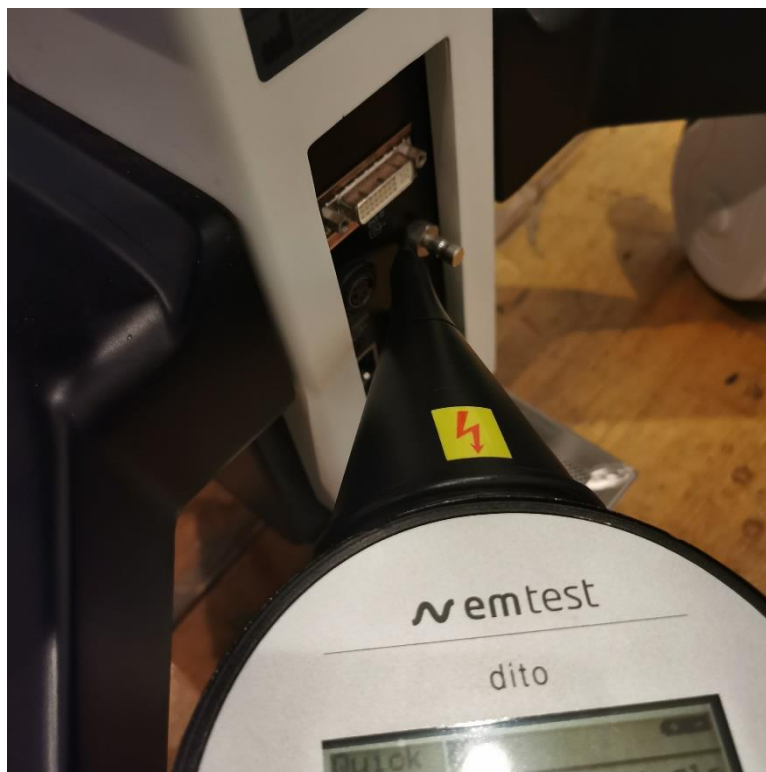


Electrostatic discharge

VINNO E20



VINNO X1





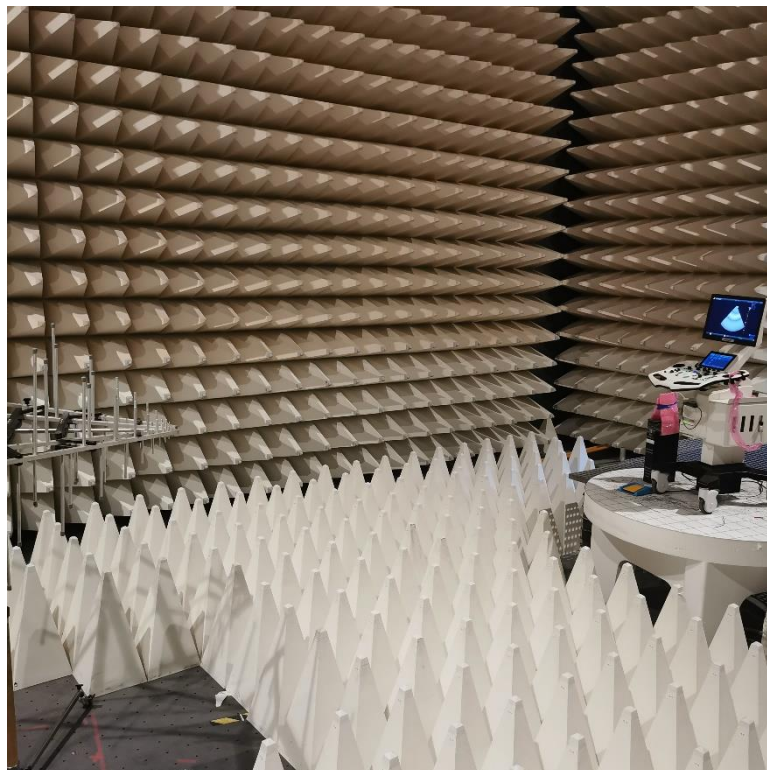
**TEST REPORT**

RF Electromagnetic Field & Proximity fields from RF wireless communications EQUIPMENT  
(Test Frequency Below 1GHz)

VINNO E20



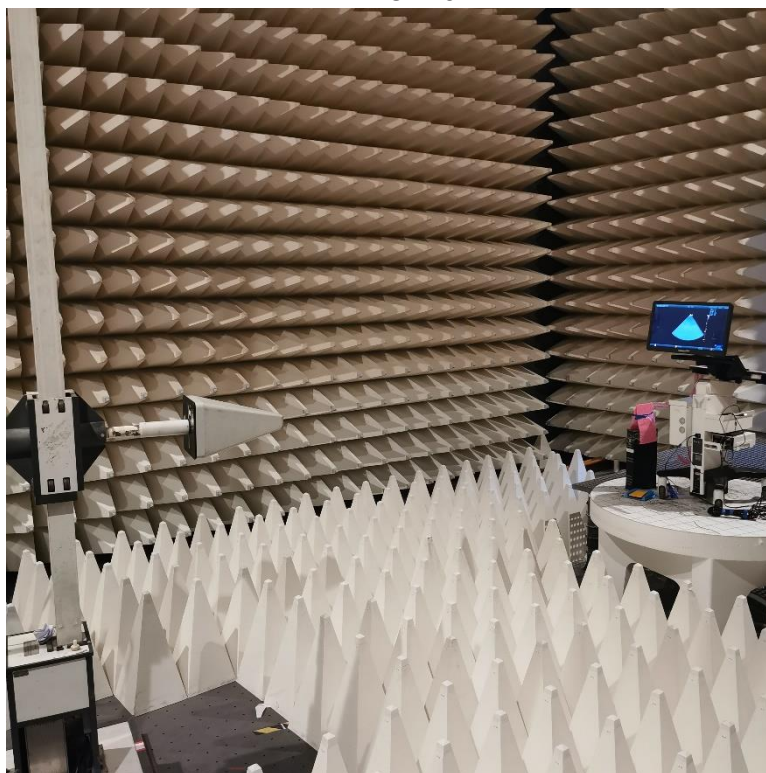
VINNO X1



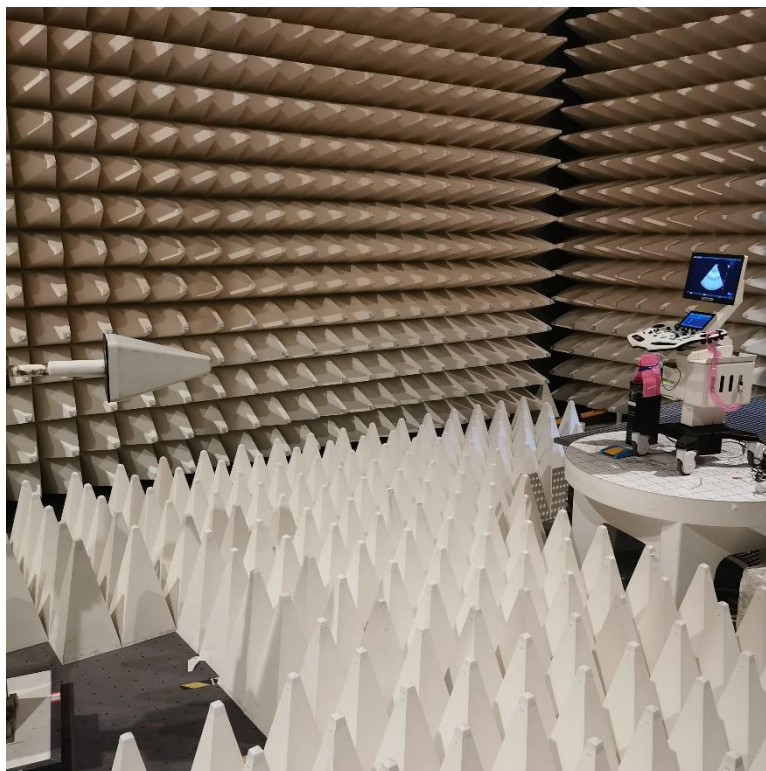
**TEST REPORT**

RF Electromagnetic Field & Proximity fields from RF wireless communications EQUIPMENT  
(Test Frequency Above 1GHz)

VINNO E20



VINNO X1





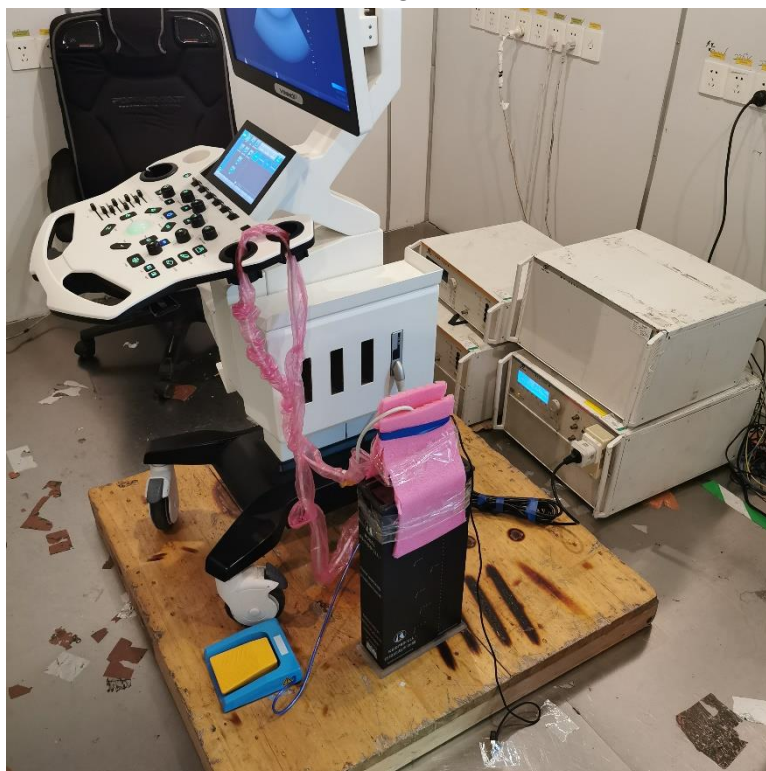
**TEST REPORT**

Electrical Fast Transients & Surge & Voltage dips and interruptions on AC mains terminal

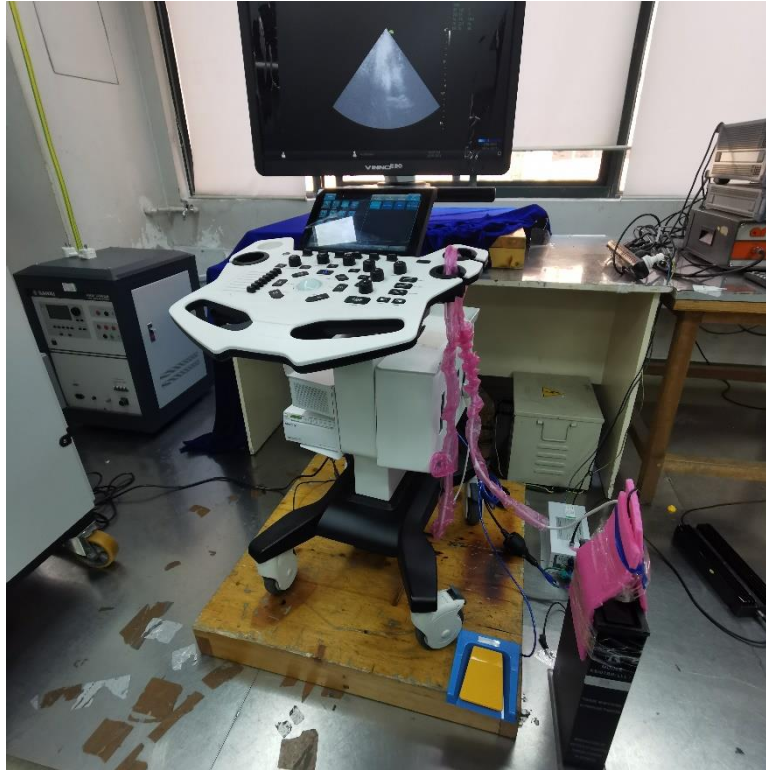
VINNO E20



VINNO X1



Conducted Disturbances Induced by RF Field  
On AC Mains Power Port  
VINNO E20



VINNO X1



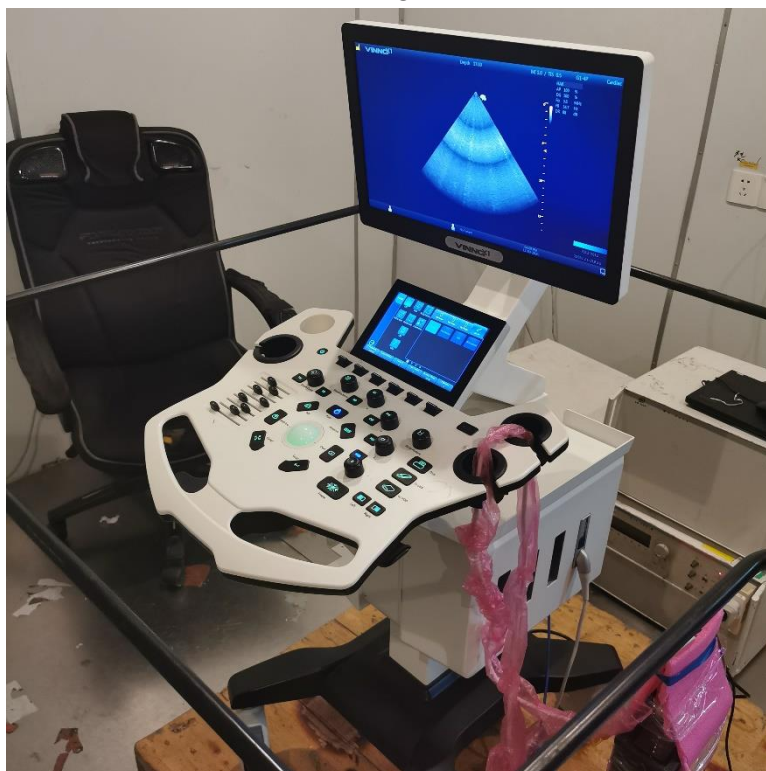


Power frequency magnetic field immunity

VINNO E20



VINNO X1



**Appendix II: Photograph of equipment under test**

**Overall - Front view- VINNO E20 with 21.5" monitor and 10.1" touch panel**



**Overall - Front view- VINNO E20 with 18.5" monitor 10.1" touch panel**



**Overall – Left side view- VINNO E20**



**Overall – Right side view- VINNO E20**



**Overall – Rear view- VINNO E20**



**Overall - Front view- VINNO X1 with 21.5" monitor and 8" touch panel**





**Overall - Front view- VINNO X1 with 18.5" monitor and 8" touch panel**



**Overall - Front view- VINNO X1 with 15.6" monitor and 8" touch panel**



**Overall – Left side view- VINNO X1**



**Overall – Right side view- VINNO X1**



**Overall – Rear view- VINNO X1**



**Control panel with 10.1" touch panel**



**Control panel with 8" touch panel**



**External view – Nameplate and Ports**



**Internal view – Front cover removed**



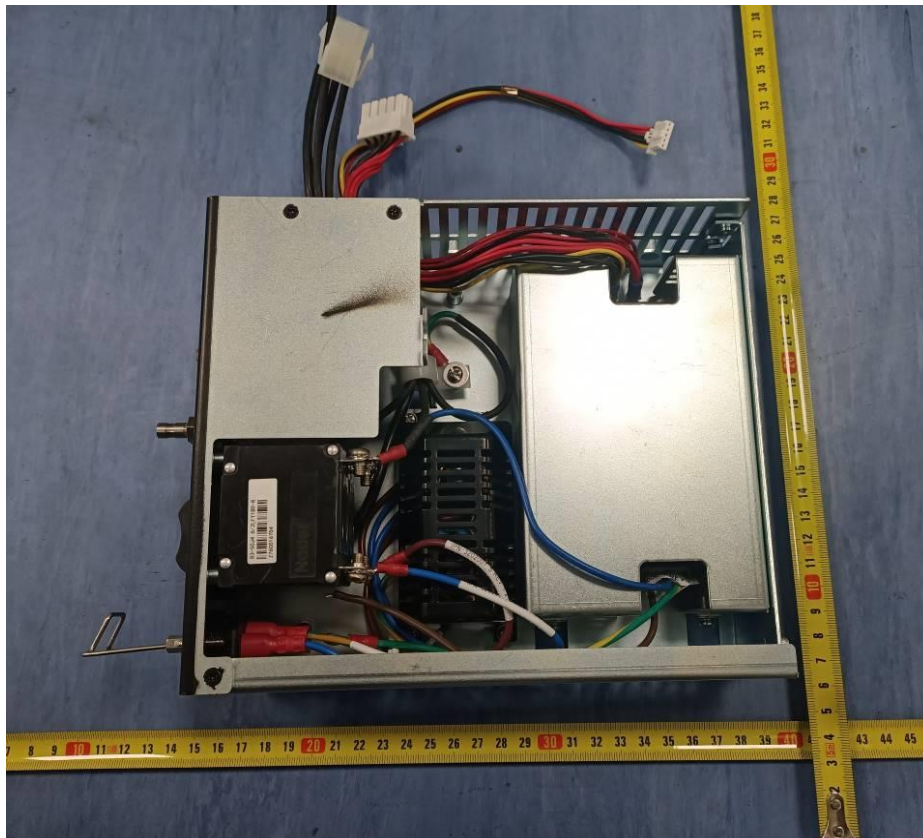
**Internal view – Rear cover removed**



**Internal view – TT enclosure disassembled**



**Internal view – Inlet**

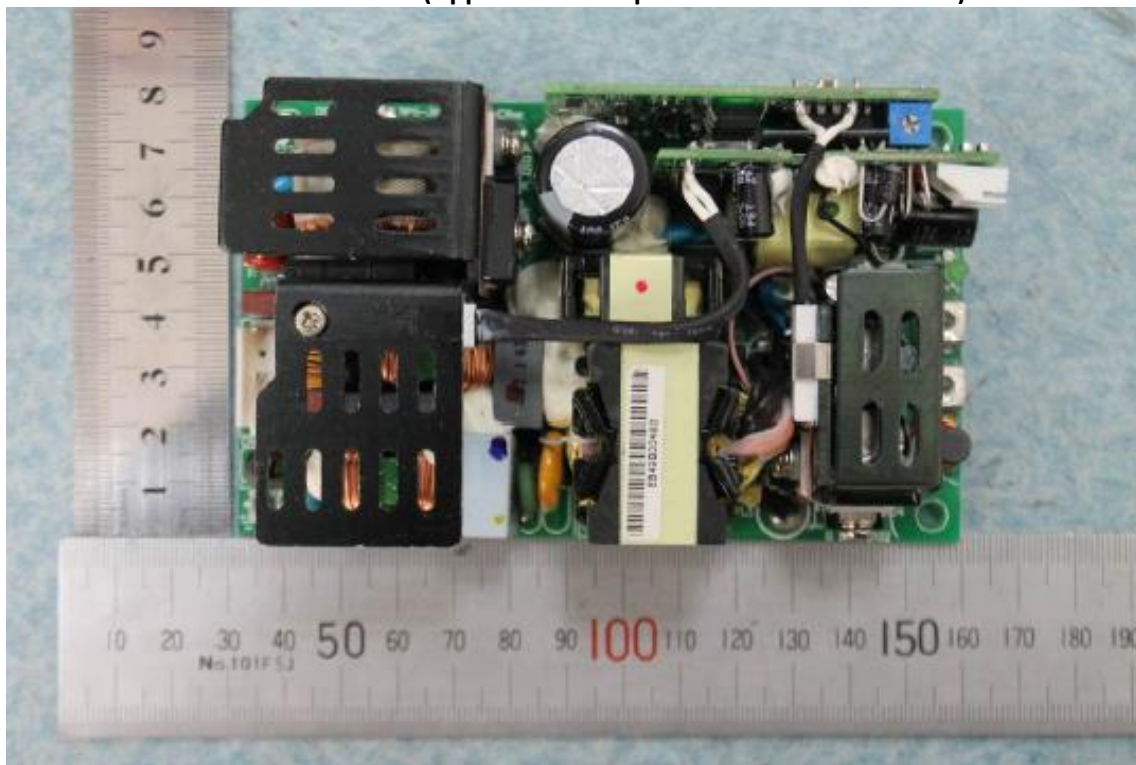




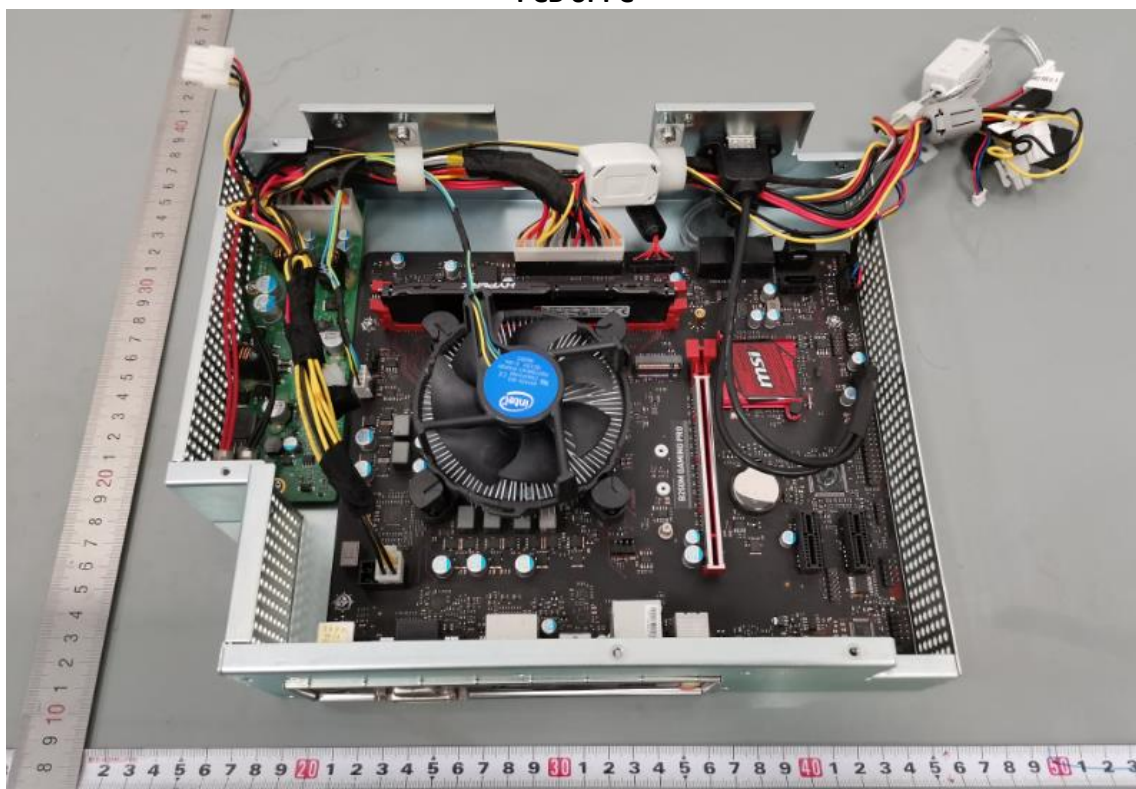
**Internal view - AC mains panel and HDD)**



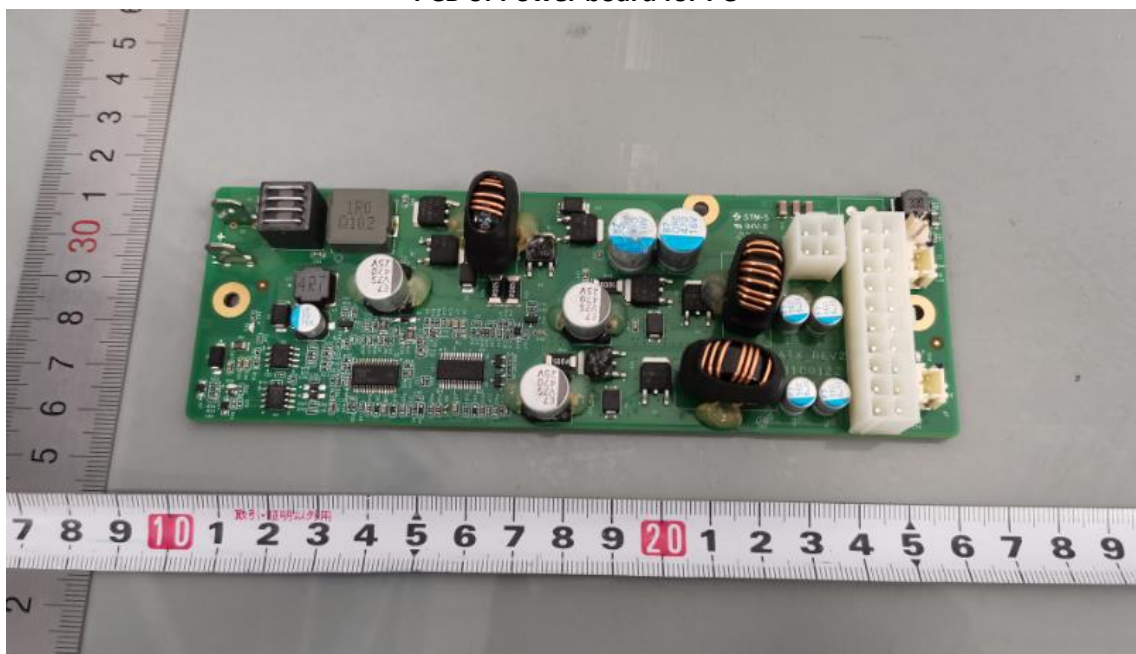
**PCB of ACDC board (Approved SMPS power module RPS-300-12)**



**PCB of PC**



**PCB of Power board for PC**





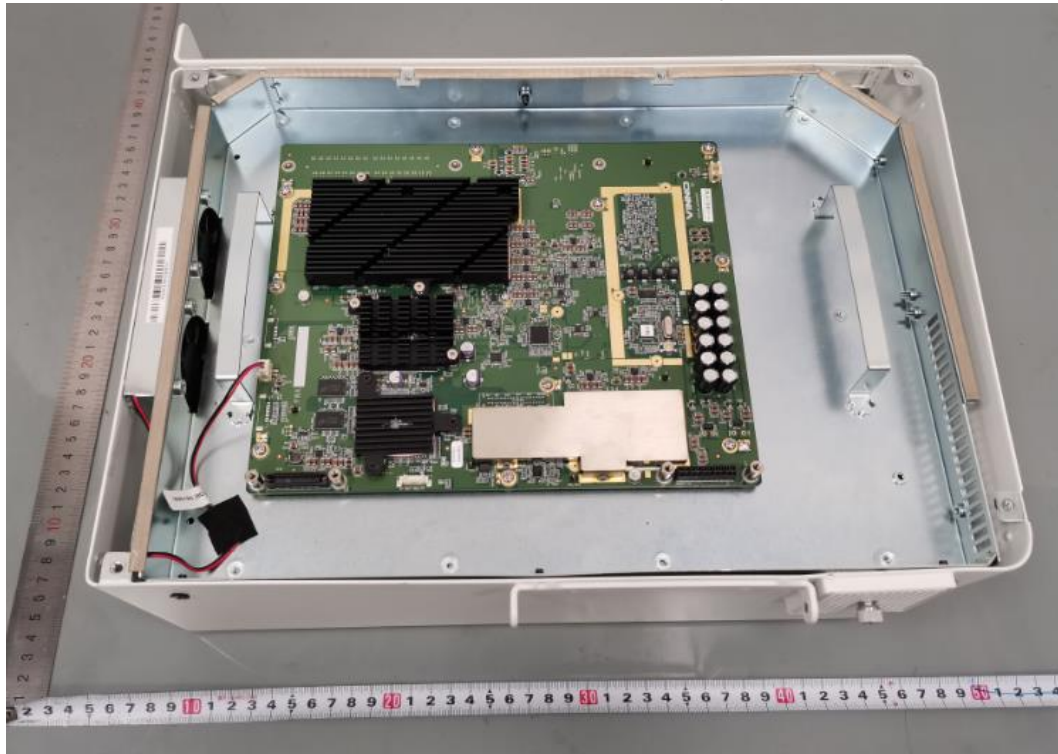
**PCB of T-power board – VINNO E20/X3**



**PCB of T-power board – VINNO X1/X1E/X1P/X2/X2E/X2P/E10/E10E/E10P**



**PCB of T-Main board – VINNO E20/X3**



**PCB of T-Main board – VINNO X1/X1E/X1P/X2/X2E/X2P/E10/E10E/E10P**



**PCB of TT board – 4 Probe Connector**

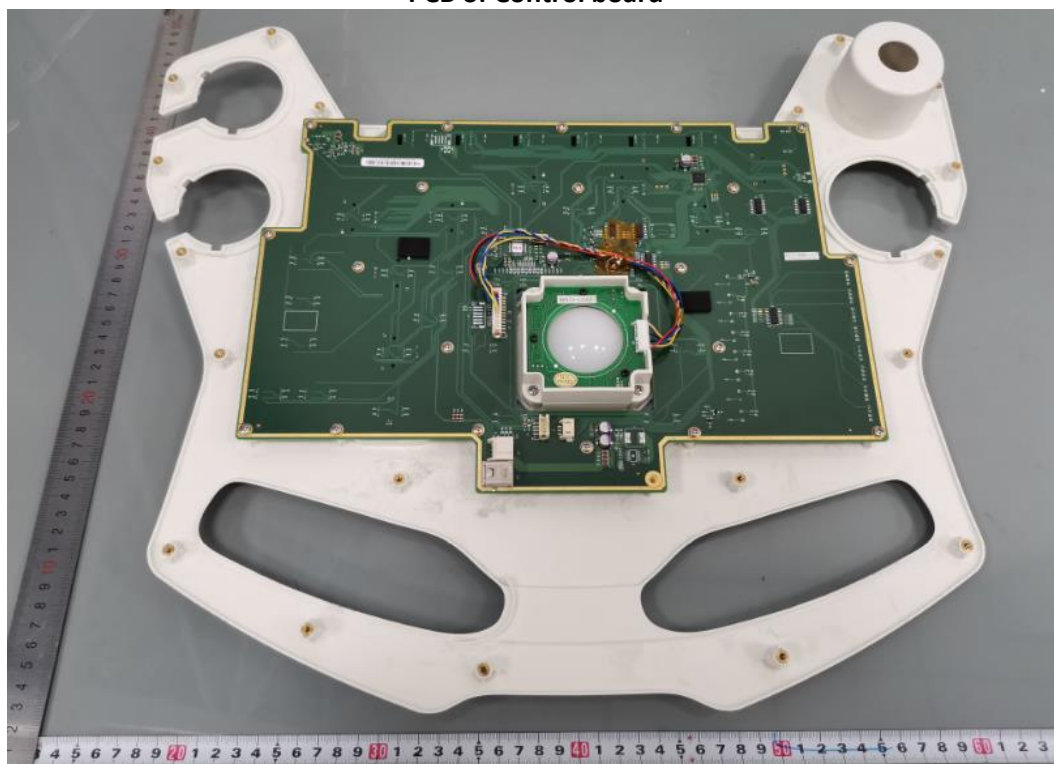


**PCB of TT board – 3 Probe Connector**

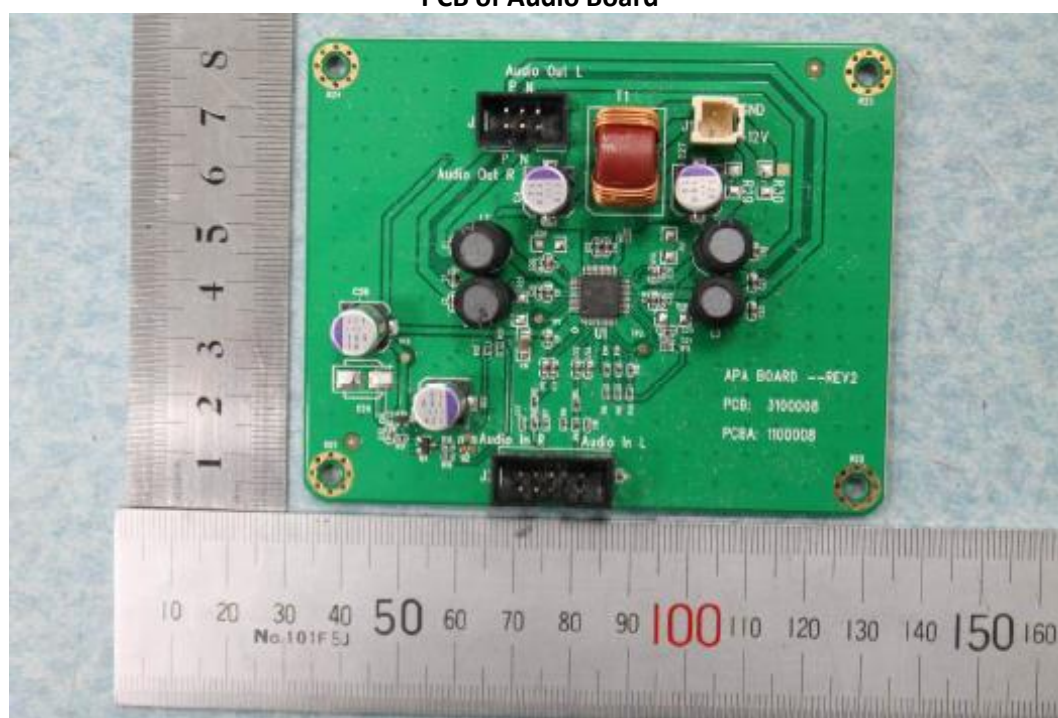




**PCB of Control board**



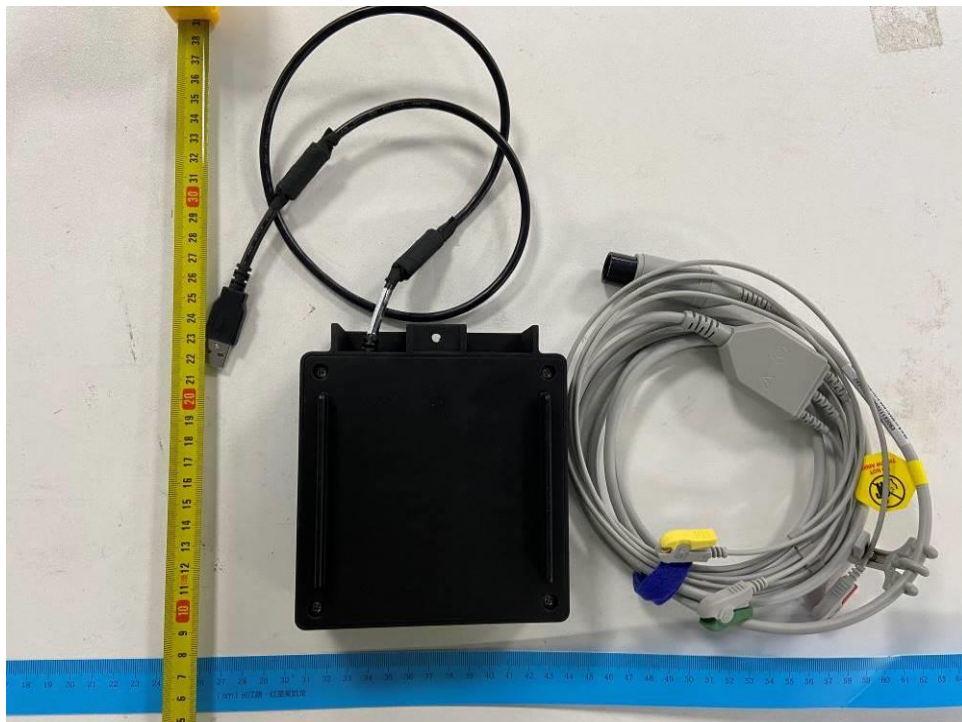
**PCB of Audio Board**



**Front View of ECG module kit and ECG lead**

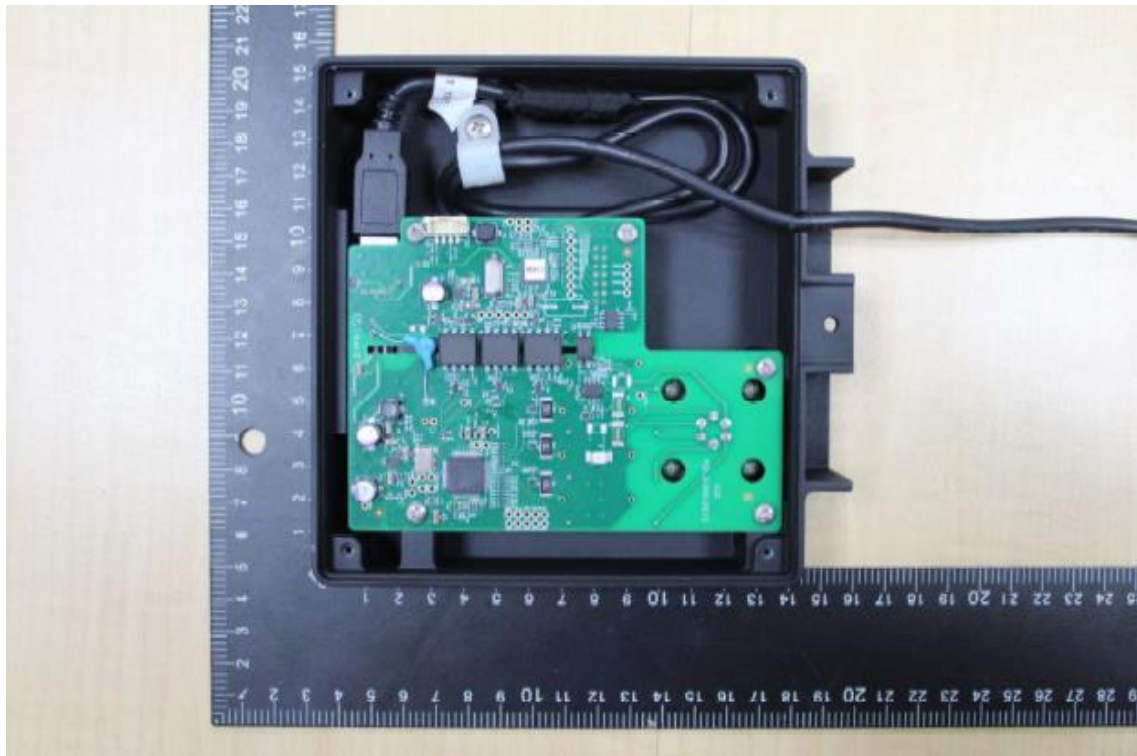


**Rear View of ECG module kit and ECG lead**

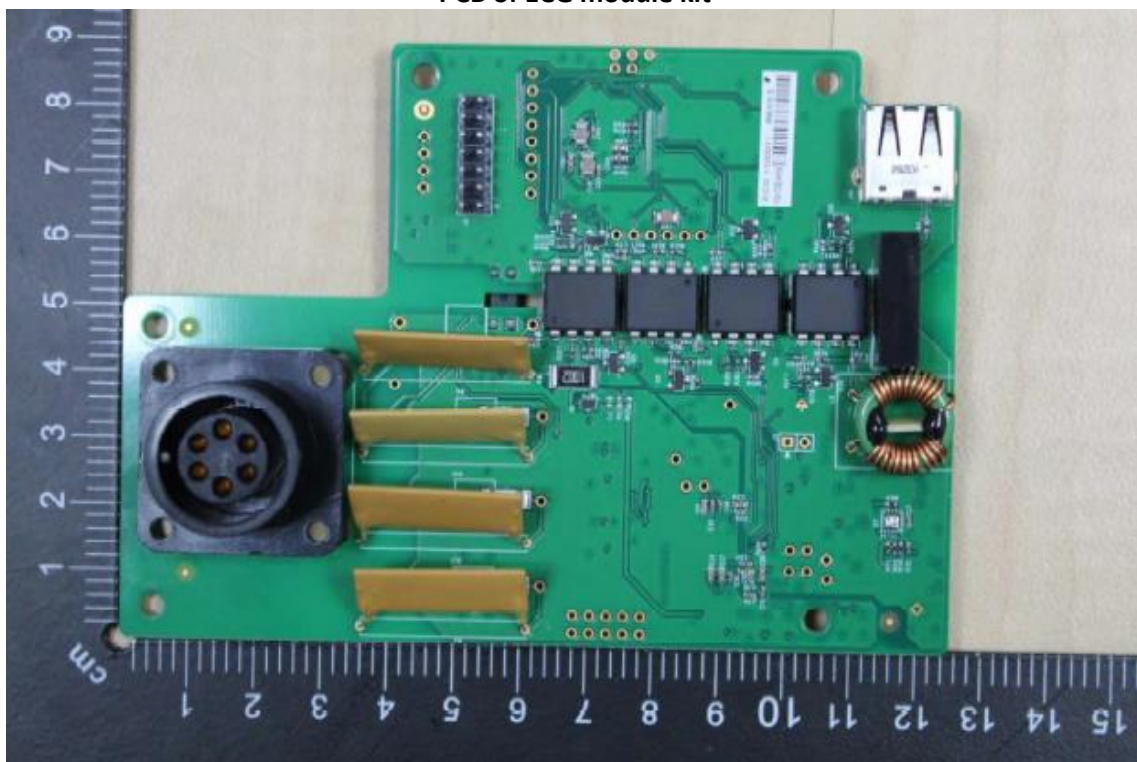




**Internal View of ECG module kit**



**PCB of ECG module kit**



**Optional single-key foot switch (KACON HRF-M5-U IP 68)**



**Optional dual-key foot switch (KACON HRF-M52-U IP68)**



**Optional medical use printer (UP-X898MD)**



**Optional medical use printer (UP-D25MD)**





**View of probe (F2-5C)**



**View of probe (D3-6C)**



**View of probe (D3-6CE)**



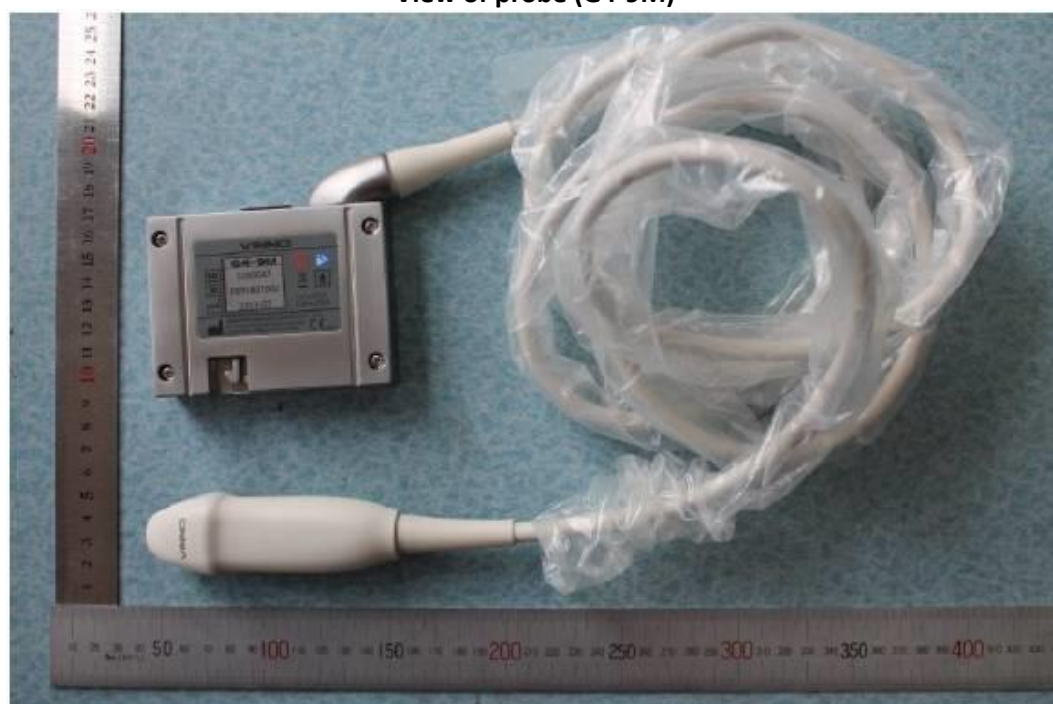
**View of probe (F4-9E)**



**View of probe (G4-9E)**



**View of probe (G4-9M)**





**View of probe (F4-12L)**



**View of probe (X4-12L)**



**View of probe (G1-4P)**



**View of probe (D2-6C)**



**TEST REPORT**
**Appendix III IEC 60601-1-2 ed4.0 (2014-02) Clause 4 and Clause 5 Worksheet**

4	GENERAL REQUIREMENTS		
4.1	RISKS resulting from reasonably foreseeable ELECTROMAGNETIC DISTURBANCES taken into account in the RISK MANAGEMENT PROCESS.	risk management plan (Doc#: RMP-TSUGA, VER#: 7); products intended use and safety feature analysis (Doc#: SFA-TSUGA, VER#: 2); risk assessment and control (Doc#: RMM-TSUGA, VER#: 2); risk management report (Doc#: RMR-TSUGA, VER#: 3)	P
4.2	Non-ME EQUIPMENT used in an ME SYSTEM		N/A
	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	No Non-ME Equipment used	N/A
	non-ME EQUIPMENT used in an ME SYSTEM complies 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 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		P
	ME EQUIPMENT and ME SYSTEMS tested in representative configurations, consistent with INTENDED USE, that are most likely to result in unacceptable RISK as determined by the MANUFACTURER (This was determined using RISK ANALYSIS, experience, engineering analysis, or pretesting). Compliance checked by inspection of the test report and the RISK MANAGEMENT FILE.	See chapter 2 "TEST SPECIFICATIONS" in report and RMF Reference Document	P

**TEST REPORT**

4.3.3	Power input and frequencies	See 2.4 "Mode of operation during the test" and individual test in report	P
<b>5</b>	<b>IDENTIFICATION, MARKING AND DOCUMENTS</b>		
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		N/A
	ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT labelled with a CLEARLY LEGIBLE warning that they should be used only in the specified type of shielded location	NOT for use only in a shielded location	N/A
5.2	<b>ACCOMPANYING DOCUMENTS</b>		
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 determined by RISK ANALYSIS, are listed.	Refer to user manual clause 2.5.5 "Electrical Safety" - Profession healthcare facility	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.	Refer to user manual clause 2.5.5 "Electrical Safety" - Essential performance & In the event of issues relevant to EMC	P
c)	A warning regarding stacking and location close to other EQUIPMENT	Refer to user manual clause 2.5.5 "Electrical Safety" - Use of this equipment adjacent to or stacked with other equipment should be avoided	P
d)	List of cables, transducers and accessories	Refer to user manual clause 2.5.5 "Electrical Safety" - Information of all the cables	P
e)	A warning that other cables and accessories may negatively affect EMC performance	Refer to user manual clause 2.5.5 "Electrical Safety" - Use of accessories, transducers and cables other than	P

# TEST REPORT

f)	A statement that portable RF communications EQUIPMENT including antennas, can effect medical electrical EQUIPMENT. The warning includes 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 manufacturer"	Refer to user manual clause 2.5.5 "Electrical Safety" - Recommended separation distances	P
5.2.1.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11		P
	FOR ME EQUIPMENT and ME SYSTEMS that are classified as class A according to CISPR 11, the instructions for use 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."	Refer to user manual clause 2.5.5 "Electrical Safety" – The EMISSIONS characteristics of this equipment make it suitable for use	P
5.2.2	Technical description		
5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS		
	The technical description describes precautions to be taken to prevent adverse events to the PATIENT and Operator due to electromagnetic disturbances	Reference Document: user manual "Electromagnetic Compatibility (EMC)" section	P
a)	Compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL	Refer to user manual clause 2.5.5 "Electrical Safety" – electromagnetic emissions & electromagnetic immunity	P
b)	Any deviations from this collateral standard and allowances used	No deviation	N/A
c)	All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE	Refer to user manual clause 2.5.5 "Electrical Safety" – General information	P
5.2.2.2	Requirements applicable to ME EQUIPMENT specified for use only in shielded location SPECIAL ENVIRONMENT		
	The technical description includes the following information:		



**TEST REPORT**

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	NOT for use only in a shielded location	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
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 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	Not ME EQUIPMENT that intentionally receives RF electromagnetic energy	N/A
5.2.2.4	Requirements applicable to the ME EQUIPMENT that include RF transmitters the technical description includes the frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER (ERP)..... :	Not ME EQUIPMENT that includes RF transmitters,	N/A
5.2.2.5	Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		
	The technical description includes 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	Not Permanently installed Large ME Equipment or Large ME Systems	N/A

# TEST REPORT

b)	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 SYSTEMS		N/A
5.2.2.6	Requirements applicable to ME EQUIPMENT that claim compatibility with HF Surgical EQUIPMENT		N/A
	Technical description includes a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF Surgery	Not for use with HF SURGICAL EQUIPMENT	N/A

\*\*\*\*\* END \*\*\*\*\*