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TEST REPORT

IEC 60601-1-2:2014

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

Report Reference No. : CSTEM21080077 report verification



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Date of issue : Aug.31 , 2021

Testing Laboratory Name : CCIC Huatongwei International Inspection(Suzhou) Co., Ltd.

Address..... : Room 101,Building G, Ruoshui Road 388, Industrial Park, Suzhou, Jiangsu, China

Testing location/ procedure : Full application of Harmonised standards ☒
Partial application of Harmonised standards ☐
Other standard testing methods ☐

Applicant's name : Shanghai Huifeng Medical Instrument Co., Ltd.

Address..... : Building No.2,No.885,Qiuxing Road,Nicheng Town,Pudong New Area,Shanghai, China 201306

Test specification:

Standard : IEC 60601-1-2:2014

Non-standard test method..... : N/A

Test Report Form No. : HTWEMCCE_1B

TRF Originator : CCIC Huatongwei International Inspection(Suzhou) Co., Ltd.

Master TRF..... : Dated 2019-06

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Test item description..... : Operating Table

Trade Mark..... : /

Manufacturer..... : Shanghai Huifeng Medical Instrument Co., Ltd.

Model/Type reference..... : HFEOT99C

Listed models..... : HFEOT99X HFEOT99 HFEOT2000 HFEOT99D HFEOT99S
HFEOT100 HFEPB99B HFEPB99 HFOOT99 HFOOT99A
HFEPB99A MT600 HFMH3008A HFMH3008AB HFMS3001B
HFMH700A HFMPB06B HFMPB06C

Ratings..... : Input: AC 200V-240V,50Hz,360VA

Result..... : Positive

EMC -- TEST REPORT

Test Report No. : CSTEM21080077	Aug.31 , 2021 Date of issue
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Equipment under Test : Operating Table

Model /Type : HFEOT99C

Listed Model : HFEOT99X HFEOT99 HFEOT2000 HFEOT99D HFEOT99S
HFEOT100 HFEPB99B HFEPB99 HFOOT99 HFOOT99A
HFEPB99A MT600 HFMH3008A HFMH3008AB HFMS3001B
HFMH700A HFMPB06B HFMPB06C

Sample Number : YPST21060335002

Serial Number : HF20210700541

Applicant : Shanghai Huifeng Medical Instrument Co., Ltd.

Address : Building No.2, No.885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China 201306

Manufacturer : Shanghai Huifeng Medical Instrument Co., Ltd.

Address : Building No.2, No.885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China 201306

Test Result according to the standards on page 4:	Positive
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The test report merely corresponds to the test sample.
It is not permitted to copy extracts of these test result without the written permission of the test laboratory.

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1. TEST STANDARDS

The tests were performed according to following standards:

[IEC 60601-1-2: 2014](#) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.

Remark: This EUT is ranged to the Group 1 Class A apparatus according to the standard of CISPR11: 2015+A1: 2016 clause 5.2.



2. SUMMARY

2.1. General Remarks:

Date of receipt of test sample : Jul. 22, 2021

Testing commenced on : Aug. 05, 2021

Testing concluded on : Aug.08, 2021

2.2. Equipment Under Test

Power supply system utilised

Power supply voltage : ☒ 230V / 50 Hz ☐ 110V / 60Hz
☐ 12 V DC ☐ 24 V DC
☐ Other (specified in blank below)

2.3. Short description of the Equipment under Test (EUT)

The table adopts electric hydraulic pressure and telecontroller to finish all the actions. The operating is formed by head plate and back plate, waist plate, buttocks plate and leg plate.

The difference between HFEOT99C and HFEOT99X HFEOT99 HFEOT2000 HFEOT99D HFEOT99S HFEOT100 HFEPB99B HFEPB99 HFOOT99 HFOOT99A HFEPB99A MT600 HFMH3008A HFMH3008AB HFMS3001B HFMH700A HFMPB06B HFMPB06C is passive structure and color size.

Model HFEOT99C differs from HFEOT99X HFEOT99 HFEOT2000 HFEOT99D HFEOT99S HFEOT100 HFEPB99B HFEPB99 HFOOT99 HFOOT99A HFEPB99A MT600 HFMH3008A HFMH3008AB HFMS3001B HFMH700A HFMPB06B HFMPB06C only in passive structure and color size, no other special instructions. This test is only based on HFEOT99C.

2.4. EUT operation mode:

The equipment under test was operated during the measurement under the following conditions:

The operating table moves up and down

Emissions tests.....	:According to EN 60601-1-2, searching for the highest disturbance.
Immunity tests.....	:According to EN 60601-1-2, searching for the highest susceptibility.
Harmonics current.....	: Not performed according to IEC 61000-3-2
Voltage fluctuation.....	: Not performed according to IEC 61000-3-3

2.5. EUT configuration:

No peripheral devices and interface cables were connected during the measurement.

2.6. Compliance criteria

The general principles (performance criteria) for the evaluation of the immunity test results are the following.

Examples of test failures:

- 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;
- component failures;
- change in programmable parameters;
- reset to factory defaults (MANUFACTURER's presets);
- change of operating mode;
- a FALSE POSITIVE ALARM CONDITION;
- a FALSE NEGATIVE ALARM CONDITION (failure to alarm);
- cessation or interruption of any intended operation, even if accompanied by an ALARM SIGNAL;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an ALARM SIGNAL;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring;
- artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
- failure of automatic diagnosis or treatment ME EQUIPMENT or ME SYSTEM to diagnose or treat, even if accompanied by an ALARM SIGNAL.
 - The Indicator lamp cannot break down.
 - The keys cannot be malfunction.
 - The work mode cannot be change.
 - The power out cannot be control.
 - The screen is out of control.
- The screen cannot display image

3. TEST ENVIRONMENT

3.1. Address of the test laboratory

CCIC Huatongwei International Inspection(Suzhou) Co., Ltd.
Room 101,Building G, Ruoshui Road 388, Industrial Park, Suzhou, Jiangsu, China

3.2. Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

Temperature: 18-22° C

Humidity: 48-52 %RH

Atmospheric pressure: 1000-1020mbar

3.3. Test Description

Emission Measurement		
Radiated Emission	IEC 60601-1-2:2014 CISPR11:2015+A1:2016	PASS
Conducted Disturbance (0.15-30MHz)	IEC 60601-1-2:2014 CISPR11:2015+A1:2016	PASS
Harmonic Current	IEC 60601-1-2:2014 IEC 61000-3-2: 2018	N/A
Voltage Fluctuation and Flicker	IEC 60601-1-2:2014 IEC 61000-3-3: 2017	N/A
Immunity Measurement		
Electrostatic Discharge	IEC 60601-1-2:2014 IEC 61000-4-2: 2008	PASS
RF Field Strength Susceptibility (80~2700MHz)	IEC 60601-1-2:2014 IEC 61000-4-3: 2006+A1: 2007+A2: 2010	PASS
Electrical Fast Transient/Burst Test	IEC 60601-1-2:2014 IEC 61000-4-4: 2012	PASS
Surge Test	IEC 60601-1-2:2014 IEC 61000-4-5: 2014	PASS
Conducted Susceptibility Test	IEC 60601-1-2:2014 IEC 61000-4-6: 2013	PASS

Power Frequency Magnetic Field Susceptibility Test	IEC 60601-1-2:2014 IEC 61000-4-8: 2009	PASS
Voltage Dips and Interruptions Test	IEC 60601-1-2:2014 IEC 61000-4-11: 2004 +A1:2017	PASS

Note: "N/A" means "not applicable".

The measurement uncertainty is not included in the test result.

IEC 60601-1-2:2014			
Clause	Requirement + Test	Result - Remark	Verdict
5	ME EQUIPMENT and ME SYSTEMS identification, marking and documents		PASS
5.1	Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT		N/A
	In addition to the requirements of 7.2 of the general standard, ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT shall be labelled with a CLEARLY LEGIBLE warning that they should be used only in the specified type of shielded location.		N/A
5.2	ACCOMPANYING DOCUMENTS		PASS
5.2.1	Instructions for use		PASS
5.2.1.1	General		PASS
a)	a statement of the environments for which the ME EQUIPMENT or ME SYSTEM is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.	Please refer to User manual	PASS
b)	the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).	Please refer to User manual	PASS

c)	a warning statement to the effect that "WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally." The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM may provide a description or list of equipment with which the ME EQUIPMENT or ME SYSTEM has been tested in a stacked or adjacent configuration and with which stacked or adjacent use resulted in normal operation.	Please refer to User manual	PASS
d)	a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE). Transducers and cables specified by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components need not be listed.	Please refer to User manual	PASS
e)	a warning statement to the effect that "WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."	Please refer to User manual	PASS
f)	a warning statement to the effect that: "WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result." In the above warning, "[ME EQUIPMENT or ME SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.	Please refer to User manual	PASS
	If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in 8.10.		N/A

5.2.1.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS classified class A according to CISPR 11		PASS
	In addition to the requirements of 7.9.2 of the general standard, for ME EQUIPMENT and ME SYSTEMS that are classified class A according to CISPR 11, the instructions for use shall include the following 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.		PASS
5.2.2	Technical description		PASS
5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS		PASS
	In addition to the requirements of 7.9.3 of the general standard, the technical description shall describe precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES. For all ME EQUIPMENT and ME SYSTEMS, the technical description shall include the following information:		
a)	the compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL.	Please refer to User manual	PASS
b)	any deviations from this collateral standard and allowances used.		N/A
c)	all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.	Please refer to User manual	PASS
5.2.2.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT		N/A
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location (see 7.1.5), the technical description shall include the following information:		N/A
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 the performance of this equipment, interference with other equipment or interference with radio services";		N/A
b)	specifications for the 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)	recommended 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 receives RF electromagnetic energy for the purpose of its operation		N/A
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation (RF receivers), the technical description shall include the following information:		N/A
	– each frequency or frequency band of reception; – the preferred frequency or frequency band, if applicable; – the bandwidth of the receiving section of the ME EQUIPMENT in those bands.		
5.2.2.4	Requirements applicable to ME EQUIPMENT that includes RF transmitters		N/A
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that includes RF transmitters, the technical description shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER		N/A
5.2.2.5	Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS		N/A
	In addition to the requirements of 7.9.3 of the general standard, for PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS for which the exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used, the technical description shall include the following information:		N/A
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 6 000 MHz;		N/A
b)	a warning to the effect that “WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation”;		N/A
c)	a list of the frequencies and modulations used to test the IMMUNITY of the ME EQUIPMENT or ME SYSTEM.		N/A
5.2.2.6	Requirements applicable to ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT		N/A

	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT, the technical description shall include a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery.	N/A
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3.4. Statement of the measurement uncertainty

The data and results referenced in this document are true and accurate. The reader is cautioned that there may be errors within the calibration limits of the equipment and facilities. The measurement uncertainty was calculated for all measurements listed in this test report acc. to CISPR 16 - 4 „Specification for radio disturbance and immunity measuring apparatus and methods – Part 4: Uncertainty in EMC Measurements“ and is documented in the Suzhou Huatongwei International Inspection Co., Ltd quality system acc. to DIN EN ISO/IEC 17025. Furthermore, component and process variability of devices similar to that tested may result in additional deviation. The manufacturer has the sole responsibility of continued compliance of the device.

Hereafter the best measurement capability for CCIC Huatongwei International Inspection(Suzhou) laboratory is reported:

Test	Range	Measurement Uncertainty	Notes
Radiated Emission	30~1000MHz	4.66dB	(1)
Conducted Disturbance	0.15~30MHz	2.80dB	(1)

- (1) This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

3.5. Equipments Used during the Test

Radiated Emission/ Radiated power						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Trilog Broadband Antenna	SCHWARZB ECK	VULB9163	01173	9/12/2018	9/11/2021
2	Emi Test Receiver	R&S	ESI26	100009	7/15/2021	7/14/2022
3	Pre-amplifier	SCHWARZB ECK	BBV 9744	00105	7/15/2021	7/14/2022
4	Turntable	MF	N/A	N/A	N/A	N/A
5	Antenna Mast	MF	N/A	N/A	N/A	N/A

Conducted Disturbance						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	EMI Test Receiver	R&S	ESCI	100106	7/15/2021	7/14/2022
2	3P LISN	SCHWARZB ECK	NNLK 8121RC	06168	7/15/2021	7/14/2022
3	Pulse Limiter	SCHWARZB ECK	VTSD 9561-F	00452	7/15/2021	7/14/2022

Electrostatic Discharge						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	ESD Simulator	EM TEST	Ditto	/	7/18/2021	7/17/2022

Electrical Fast Transient/Burst						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Multifunction Immunity Test System	EM TEST	NX5 bspt-1-300-16	P1807214325	7/15/2021	7/14/2022
2	Coupling Clamp	EM TEST	HFK	1501-14	7/15/2021	7/14/2022

Surge						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Multifunction Immunity Test System	EM TEST	NX5 bspt-1-300-16	P1807214325	7/15/2021	7/14/2022

RF Field Strength Susceptibility						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Signal Generator	Keysight	N5171B	MY59100289	7/15/2021	7/14/2022
2	Amplifier	AR	150W1000	301584	09/07/2020	09/06/2021
3	Dual Directional Coupler	AR	DC6080	301508	7/15/2021	7/14/2022
4	Power Head	AR	PH2000	301193	7/15/2021	7/14/2022
5	Power Meter	AR	PM2002	302799	7/15/2021	7/14/2022
6	Transmit Antenna	AR	AT1080	28570	10/28/2018	10/27/2021
7	Dual Directional Coupler	AR	DC7144A	0325100	7/15/2021	7/14/2022
8	Microwave Horn Antenna	AR	AT4002A	0324848	10/28/2018	10/27/2021
9	Power Amplifier	AR	25S1G4A	0325511	09/07/2020	09/06/2021

Conducted Susceptibility						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Signal Generator	TESEQ	NSG 4070C-80	50504	3/11/2021	3/10/2022
2	Fixed Attenuator r	TESEQ	ATN 6150	/	3/11/2021	3/10/2022
3	CDN	TESEQ	CDN M016	50738	3/11/2021	3/10/2022

4	Current Injection Probe	TESEQ	CIP 9136A	51670	3/11/2021	3/10/2022
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Power Frequency Magnetic Field Susceptibility

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Multifunction Immunity Test System	EM TEST	NX5 bspt-1-300-16	P180721432 5	7/15/2021	7/14/2022
2	Current Transformer	EM TEST	MC2630	P181621510 3	7/15/2021	7/14/2022
3	Magnetic Field Antenna	EM TEST	MS100N	P180321371 8	7/15/2021	7/14/2022

Voltage Dips and Interruptions

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Multifunction Immunity Test System	EM TEST	NX5 bspt-1-300-16	P180721432 5	7/15/2021	7/14/2022
2	Voltage Regulators	EM TEST	NX-1 -260-16	P182822178 8	7/15/2021	7/14/2022

4. TEST CONDITIONS AND RESULTS

4.1. Radiated Emission

For test instruments and accessories used see section 3.5.

4.1.1. Description of the test location

Test location: Anechoic Chamber

Date of test: Aug. 05, 2021

Operator: Kang.Yang

4.1.2. Limits of disturbance (Class A)

Frequency (MHz)	Distance (Meters)	Field Strengths Limits (dB μ V/m)
30 ~ 230	3	50
230 ~ 1000	3	57

Note: (1) The tighter limit shall apply at the edge between two frequency bands.

(2) Distance refers to the distance in meters between the test instrument antenna and the closest point of any part of the E.U.T.

4.1.3. Description of the test set-up

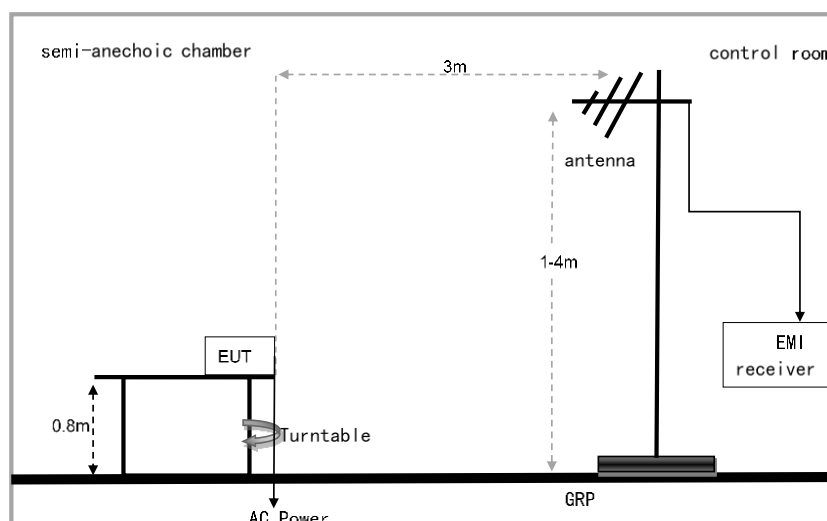
4.1.3.1. Operating Condition

The EUT is working during the test, and the maximum emanating results are recorded.

4.1.3.2. Test Configuration and Procedure

EUT is tested in Semi-Anechoic Chamber. EUT is placed on a nonmetal table above a grounded turntable. The turntable can rotate 360 degrees to determine the azimuth of the maximum emission level. EUT is set 3 meters away from the center of receiving antenna. The antenna can move up and down from 1 to 4 meter to find out the maximum emission level. Both horizontal and vertical polarizations of the antenna are set on the test.

4.1.3.3. Photos of the test set-up





4.1.4. Test result

The requirements are **Fulfilled**

Test voltage: AC 230V/50Hz

Band Width: 120kHz

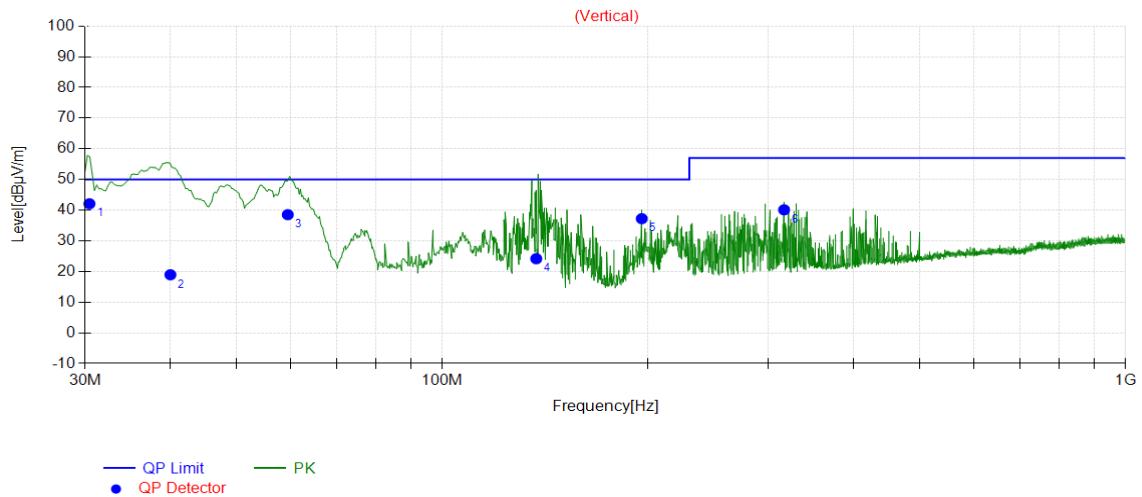
Frequency Range: 30MHz to 1000MHz

Remarks: The limits are kept. For detailed results, please see the following page(s).

Margin=limit-level

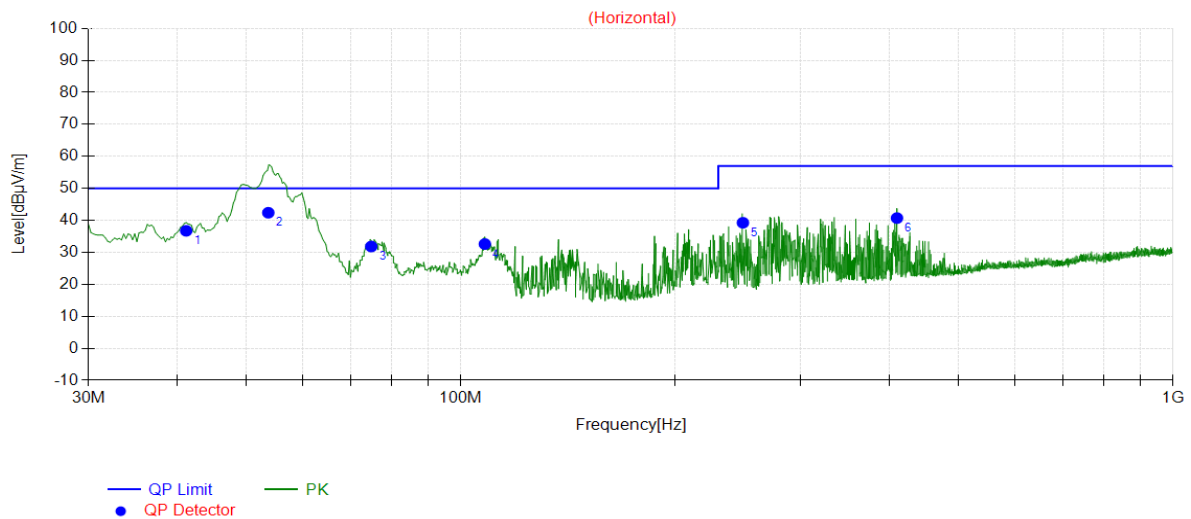
Level=read values+transducer

Transducer=antenna factor+pre-amplifier factor+cable loss+ attenuator factor



Final Data List

NO	Freq. [MHz]	Factor [dB]	QP Value [dBμV/m]	QP Limit [dBμV/m]	QP Margin [dB]	Height [cm]	Angle [°]	Polarity
1	30.4500	-14.19	42.09	50.00	7.91	105	74.4	Vertical
2	40.0025	-12.14	18.94	50.00	31.06	344	182	Vertical
3	59.4175	-12.72	38.53	50.00	11.47	144	201	Vertical
4	137.2375	-17.38	24.17	50.00	25.83	103	197.9	Vertical
5	195.8700	-14.03	37.22	50.00	12.78	100	358	Vertical
6	316.3925	-10.97	40.11	57.00	16.89	100	48	Vertical



Final Data List

NO	Freq. [MHz]	Factor [dB]	QP Value [dBμV/m]	QP Limit [dBμV/m]	QP Margin [dB]	Height [cm]	Angle [°]	Polarity
1	41.1550	-11.74	36.75	50.00	13.25	200	127	Horizontal
2	53.6750	-11.34	42.38	50.00	7.62	310	253.1	Horizontal
3	74.8625	-17.17	31.84	50.00	18.16	200	92	Horizontal
4	108.0850	-13.60	32.60	50.00	17.40	300	347	Horizontal
5	248.9775	-12.49	39.26	57.00	17.74	200	191	Horizontal
6	409.7550	-8.92	40.71	57.00	16.29	100	341	Horizontal

4.2. Conducted disturbance

For test instruments and accessories used see section 3.5.

4.2.1. Description of the test location

Test location: Conductive Test Room

Date of test: Aug. 05, 2021

Operator: Kang.Yang

4.2.2. Limits of disturbance

Limit of conducted disturbance at the mains ports (Class A)

Frequency Range (MHz)	Limits (dBuV)	
	Quasi-Peak	Average
0.150~0.500	79	66
0.500~30.000	73	60

Note: (1) The tighter limit shall apply at the edge between two frequency bands.

4.2.3. Description of the test set-up

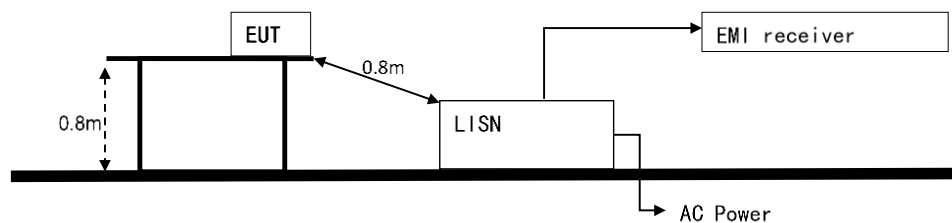
4.2.3.1. Operating Condition

The EUT is working during the test, and the maximum emanating results are recorded.

4.2.3.2. Test Configuration and Procedure

EUT is placed on a nonmetal table above the grounded reference plane. Connect the power line of the EUT to the LISN which is connected to receiver by coaxial line, then disturbance of the neutral line and live line can be detected by the receiver.

4.2.3.3. Photo of the test set-up





4.2.4. Test result

The requirements are **Fulfilled**

Test voltage: AC 230V/50Hz

Band Width: 9kHz

Frequency Range: 150kHz to 30MHz

Remarks: The limits are kept. For detailed results, please see the following page(s).

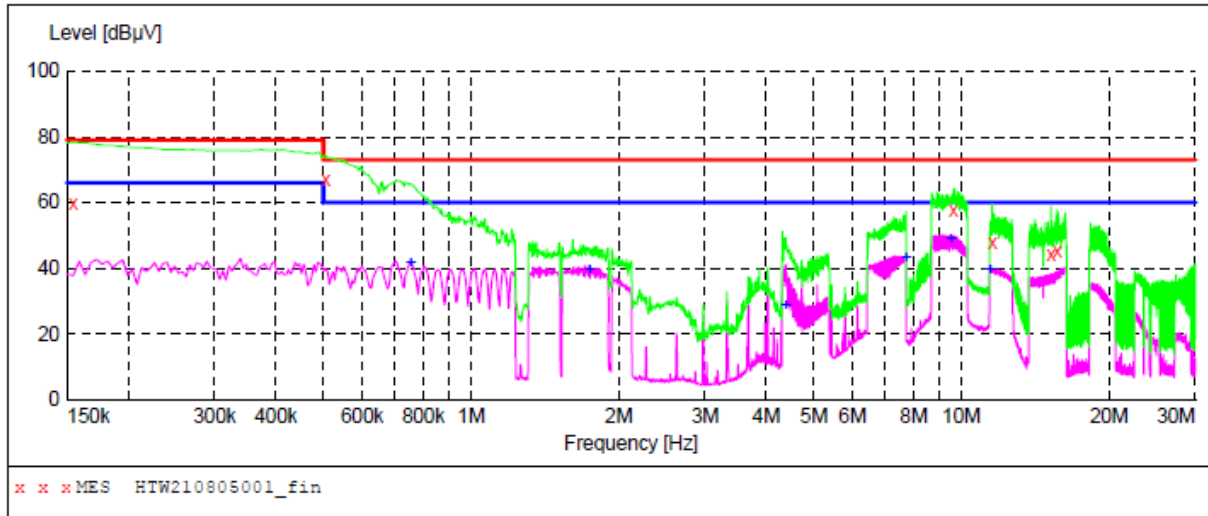
Margin=limit-level

Level=read values+transducer

Transducer=insertion loss of LISN+cable loss+insertion loss of pulse limiter

SCAN TABLE: "Voltage (150K-30M) FIN"

Short Description: 150K-30M Voltage



MEASUREMENT RESULT: "HTW210805001_fin"

05/08/2021 10:17

Frequency MHz	Level dBμV	Transd dB	Limit dBμV	Margin dB	Detector	Line	PE
0.154500	59.70	9.4	79	19.3	QP	L1	GND
0.505500	66.80	9.2	73	6.2	QP	L1	GND
9.636000	57.80	9.5	73	15.2	QP	L1	GND
11.562000	47.70	9.4	73	25.3	QP	L1	GND
15.216000	44.20	9.2	73	28.8	QP	L1	GND
15.702000	45.10	9.2	73	27.9	QP	L1	GND

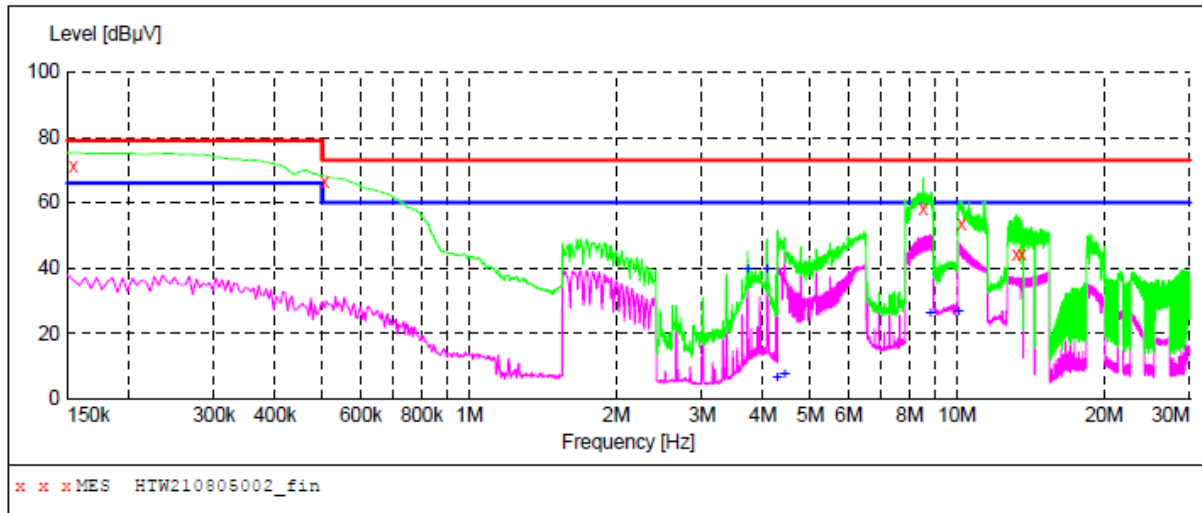
MEASUREMENT RESULT: "HTW210805001_fin2"

05/08/2021 10:17

Frequency MHz	Level dBμV	Transd dB	Limit dBμV	Margin dB	Detector	Line	PE
0.753000	41.60	9.2	60	18.4	AV	L1	GND
1.743000	39.40	9.3	60	20.6	AV	L1	GND
4.380000	28.60	9.3	60	31.4	AV	L1	GND
7.710000	42.90	9.5	60	17.1	AV	L1	GND
9.514500	49.10	9.5	60	10.9	AV	L1	GND
11.445000	39.50	9.4	60	20.5	AV	L1	GND

SCAN TABLE: "Voltage (150K-30M) FIN"

Short Description: 150K-30M Voltage



MEASUREMENT RESULT: "HTW210805002_fin"

05/08/2021 10:27

Frequency MHz	Level dBμV	Transd dB	Limit dBμV	Margin dB	Detector	Line	PE
0.154500	71.30	9.4	79	7.7	QP	N	GND
0.505500	66.70	9.2	73	6.3	QP	N	GND
8.533500	58.30	9.5	73	14.7	QP	N	GND
10.212000	53.60	9.5	73	19.4	QP	N	GND
13.231500	44.40	9.3	73	28.6	QP	N	GND
13.591500	44.30	9.3	73	28.7	QP	N	GND

MEASUREMENT RESULT: "HTW210805002_fin2"

05/08/2021 10:27

Frequency MHz	Level dBμV	Transd dB	Limit dBμV	Margin dB	Detector	Line	PE
3.723000	39.40	9.2	60	20.6	AV	N	GND
4.078500	39.30	9.3	60	20.7	AV	N	GND
4.285500	6.30	9.3	60	53.7	AV	N	GND
4.434000	7.60	9.3	60	52.4	AV	N	GND
8.803500	26.20	9.5	60	33.8	AV	N	GND
10.054500	26.40	9.5	60	33.6	AV	N	GND

4.3. Harmonic current

The test is not applicable to the EUT.

4.4. Voltage Fluctuation and Flicker

The test is not applicable to the EUT.

4.5. Electrostatic discharge

For test instruments and accessories used see section 3.5.

4.5.1. Description of the test location and date

Test location: ESD Room

Date of test: Aug. 06, 2021

Operator: Kang.Yang

4.5.2. Severity levels of electrostatic discharge

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

Note: equipment and systems shall comply with the requirements of 8.9 of IEC 60601-1-2:2014 at immunity test levels of $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$, $\pm 15\text{kV}$ for air discharge and $\pm 8\text{kV}$ for contact discharge.

4.5.3. Description of the test set-up

4.5.3.1. Operating Condition

The EUT is working during the test, and Table shift normal, controller control normal, indicator normal. The marks are the electrostatic discharge position.

4.5.3.2. Test Configuration and Procedure:

Air Discharge:

- This test is done on a non-conductive surfaces. The round discharge tip of the Electrostatic Discharge simulator shall be approached as fast as possible then to touch the EUT. After each discharge, the simulator shall be removed from the EUT. The simulator is then re-triggered for a new single discharge and repeated 10 times for each pre-selected test point. This procedure shall be repeated until all the air discharge completed

Contact Discharge:

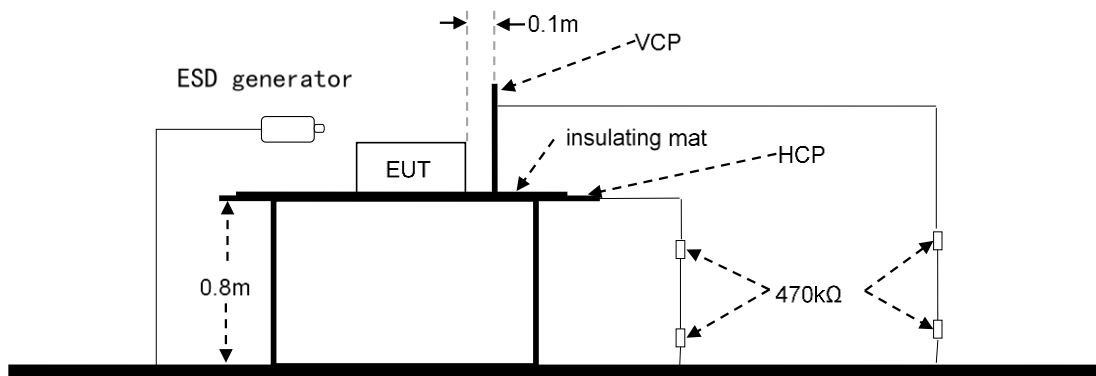
- All the procedure shall be same as air discharge, except using the acute discharge tip. The top end of the Electrostatic Discharge simulator is touch the EUT all the time when the simulator is re-triggered for a new single discharge and repeated 10 times for each pre-selected test point.

Indirect Discharge:

- The vertical coupling plane(VCP) is placed 0.1m away from EUT. The top end of Electrostatic Discharge simulator should aim at the center of one border of the VCP for at least 10 times discharge.
- The top end of Electrostatic Discharge simulator should place at the point 0.1m away from EUT on the horizontal coupling plane(HCP). At least 10 times discharge should be done for every pre-selected point around EUT.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.5.3.3. Photo of the test set-up



4.5.4. Test specification:

- Test voltage: ☒ AC 230V/50Hz ☐ AC 120V/60Hz
- Contact discharge voltage: ☒ 2 kV ☒ 4 kV ☒ 6kV ☒ 8 kV
- Number of discharges: ☒ 10 ☐ 25
- Air discharge voltage: ☒ 2 kV ☒ 4 kV ☒ 8kV ☒ 15 kV
- Number of discharges: ☒ 10 ☐ 25
- Type of discharge: Direct discharge ☒ Air discharge
Indirect discharge ☒ Contact discharge
☒ Positive ☒ Negative
- Polarity:
- Discharge location: ☒ see photo documentation of the test set-up
☒ all external locations accessible by hand
☒ horizontal coupling plane (HCP)
☒ vertical coupling plane (VCP)

4.5.5. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

4.6. Radiated, radio-frequency, electromagnetic field

For test instruments and accessories used see section 3.5.

4.6.1. Description of the test location and date

Test location: 3m Anechoic Chamber

Date of test: Aug. 06, 2021

Operator: Kang.Yang

4.6.2. Severity levels of radiated, radio-frequency, electromagnetic field

Level	Field Strength (V/m)
1.	1
2.	3
3.	10
X	Special

Note: equipment and systems shall comply with the requirements of 8.9 of IEC 60601-1-2:2014 at immunity test levels of 3V/m.

4.6.3. Description of the test set-up

4.6.3.1. Operating Condition

The EUT is working during the test, and Table shift normal, controller control normal, indicator normal.

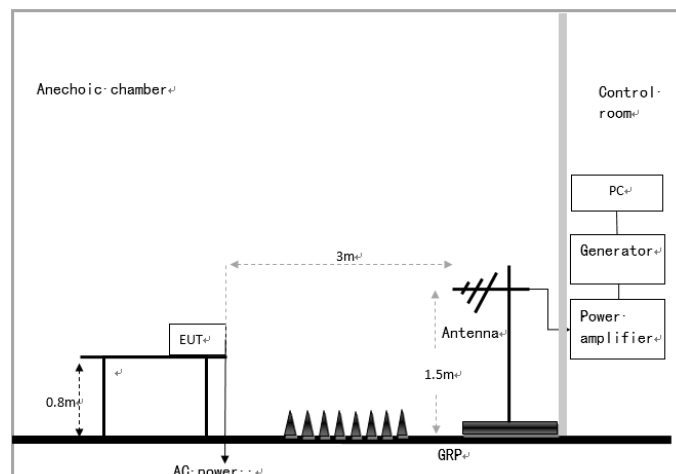
4.6.3.2. Test Procedure

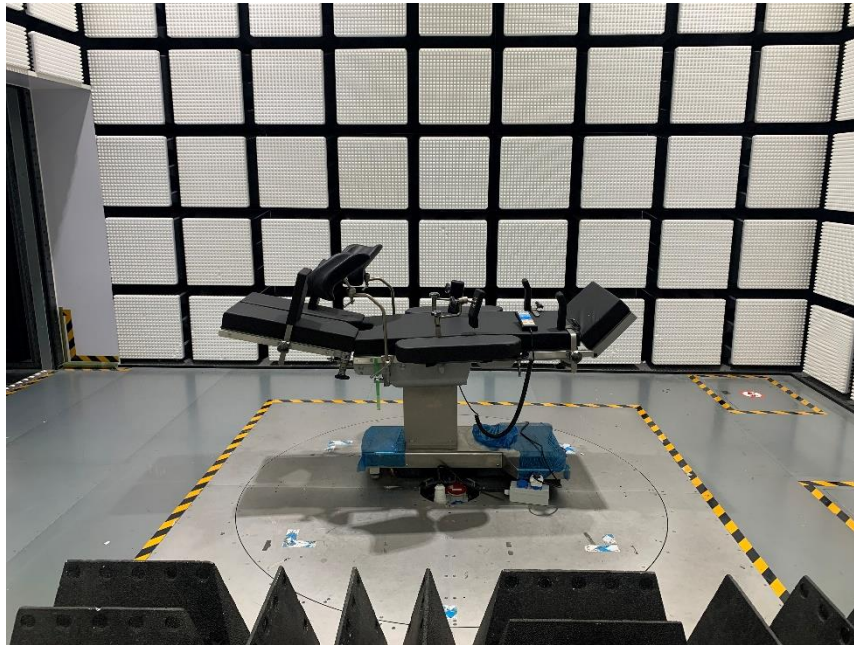
EUT and its auxiliary instrument are placed on a turntable which is 0.8 meter above ground. Transmitting antenna mounted on an antenna mast is set 3 meter away from the EUT. During the test, each of the four sides of EUT will face the transmitting antenna with the turntable cycled. Both horizontal and vertical polarization of the antenna are set on test and measured individually.

In order to judge the performance of the EUT, a set of monitor system is used.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.6.3.3. Photo of the test set-up





4.6.4. Test specification:

Test voltage:

- AC 230V/50Hz ☐ AC 120V/60Hz

Frequency range:

- 80 MHz to 2700 MHz

Field strength:

- 3 V/m

EUT - antenna separation:

- 3 m

Modulation:

- AM: 80 %
■ sinusoidal 1kHz

Frequency step:

- 1 % with 3 s dwell time

Antenna polarisation:

- horizontal ■ vertical

Communications Equipment Frequency:

- Tabulated Results for Proximity Fields From RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870	800 – 960	GSM 800/900,	Pulse modulation	2	0.3	28

930		TETRA 800, iDEN 820, CDMA 850, LTE Band 5	18 Hz			
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

4.6.5. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

4.7. Electrical fast transients / Burst

For test instruments and accessories used see section 3.5.

4.7.1. Description of the test location and date

Test location: EMS Integrate Room

Date of test: Aug. 07, 2021

Operator: Kang.Yang

4.7.2. Severity levels of electrical fast transients / Burst

Open circuit output test voltage and repetition rate of the impulses				
Level	On power port, PE		On I/O signal, data and control ports	
	V peak(kV)	Repetition rate (kHz)	Voltage peak	Repetition rate (kHz)
1	0.5	5	0.25	5
2	1	5	0.5	5
3	2	5	1	5
4	4	5	2	5
X	Special	Special	Special	Special

Note: equipment and systems shall comply with the requirements of 8.9 of IEC 60601-1-2:2014 at immunity test levels of $\pm 2\text{kV}$ for a.c. power lines.

4.7.3. Description of the test set-up

4.7.3.1. Operating Condition

The EUT is working during the test, and Table shift normal, controller control normal, indicator normal.

4.7.3.2. Test Requirements

EUT shall be placed above the ground reference plane. This reference ground plane shall project beyond the EUT by at least 0.1m on all sides and the minimum distance between EUT and all other conductive structure, except the ground plane beneath the EUT, shall be more than 0.5m.

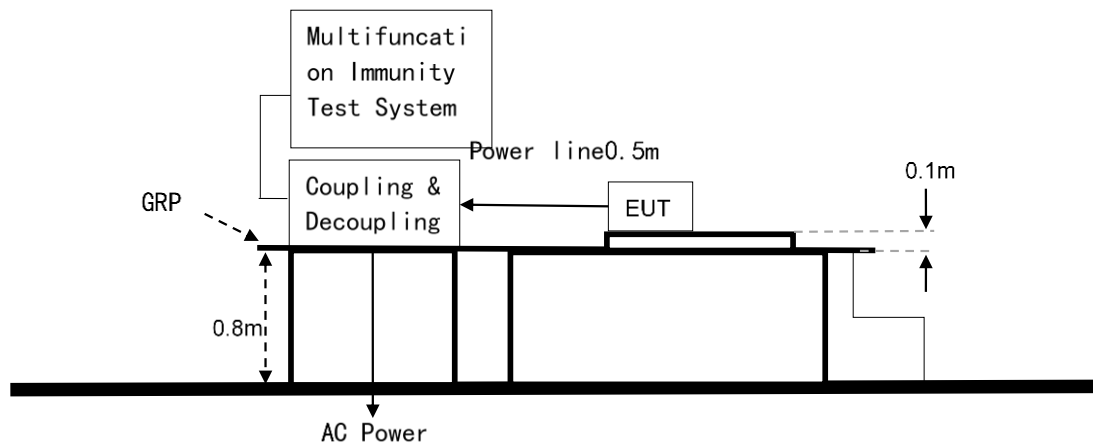
4.7.3.3. Test Configuration and Procedure

For AC power input ports:

—EUT is connected to coupling/decoupling network which couples the EFT signal to power input lines. During the test, both positive and negative polarities of the test voltage should be applied and the duration of the test can't be less than 1min.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.7.3.4. Photo of the test set-up





4.7.4. Test specification:

Coupling network:

■ 0.5 kV ■ 1 kV ■ 2 kV

Coupling clamp:

■ 0.5 kV ■ 1 kV

Test power supply

■ AC 230V/50Hz □ AC 120V/60Hz

Burst frequency:

■ 100.0 kHz

Coupling duration:

■ 60 s

Polarity:

■ positive ■ negative

4.7.5. Coupling points

Cable description:

AC power line : L, N, PE, L+N, L+PE, N+PE, L+N+PE; signal line

Screening:

○ screened ■ unscreened

Status:

○ passive ■ active

Signal transmission:

■ analogue ○ digital

Length:

■ /

4.7.6. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

4.8. Surge

For test instruments and accessories used see section 3.5.

4.8.1. Description of the test location and date

Test location: EMS Integrate Room

Date of test: Aug. 13, 2021

Operator: Kang.Yang

4.8.2. Severity levels of surge

Level	Test Voltage (kV)
1	0.5
2	1.0
3	2.0
4	4.0
*	Special

Note: Equipment and systems shall comply with the requirements of 8.9 of IEC60601-1-2: 2014 at immunity test levels of $\pm 0.5\text{kV}$ and $\pm 1\text{kV}$ for a.c. power line(s) to line(s); and $\pm 0.5\text{kV}$, $\pm 1\text{kV}$, $\pm 2\text{kV}$ for a.c. power line(s) to ground.

4.8.3. Description of the test set-up

4.8.3.1. Operating Condition

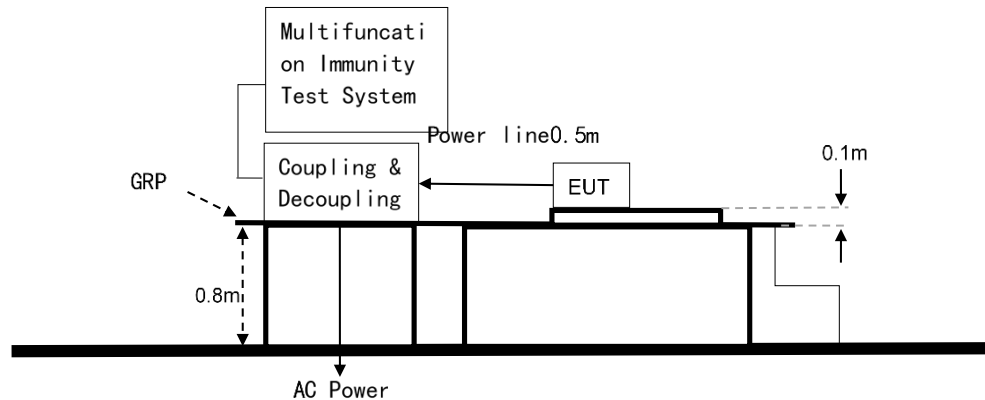
The EUT is working during the test, and Table shift normal, controller control normal, indicator normal.

4.8.3.2. Test Configuration and Procedure

In this test, the 1.2/50us & 8/20us surge generator must be used for AC power ports. The voltage for line to earth coupling mode is twice of that for line to line. At least 5 positive and 5 negative (polarity) surge signal with a maximum 1/min repetition rate are injected to AC power lines from 4 different phase angles (0° , 90° , 180° , 270°) during the test.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.8.3.3. Photo of the test set-up



4.8.4. Test specification:

Pulse amplitude-Power line sym.:
Source impedance: $2 \Omega + 18 \mu\text{F}$

☒ 0.5 kV ☒ 1 kV ☐ 2 kV ☐ 4 kV

Pulse amplitude-Power line unsym.:
Source impedance: $12 \Omega + 9 \mu\text{F}$

☒ 0.5 kV ☒ 1 kV ☒ 2 kV ☐ 4 kV

Test power supply

☒ AC 230V/50Hz ☐ AC 120V/60Hz

Number of surges:

☒ 5 Surges/Phase angle

Phase angle:

☒ 0° ☒ 90° ☒ 180° ☒ 270°

Repetition rate:

☒ 60 s

Polarity:

☒ positive ☒ negative

4.8.5. Coupling points

Cable description:

AC power line: L-N , L+PE,N+PE

Screening:

☐ screened

☒ unscreened

Status:

☐ passive

☒ active

Signal transmission:

☒ analogue

☐ digital

Length:

☒ /

4.8.6. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

4.9. Conducted disturbances induced by radio-frequency fields

For test instruments and accessories used see section 3.5.

4.9.1. Description of the test location and date

Test location: EMS Integrate Room

Date of test: Aug. 08, 2021

Operator: Kang.Yang

4.9.2. Severity levels of conducted disturbances induced by radio-frequency fields discharge

Level	Field Strength (V)
1.	1
2.	3
3.	10
X	Special

Note: equipment and systems shall comply with the requirements of 8.9 of IEC 60601-1-2: 2014 and IEC 60601-1-2:2014 at immunity test levels of 3Vrms range beginning at the start frequency and extending to 80MHz, 6Vrms in the ISM frequency band.

4.9.3. Description of the test set-up

4.9.3.1. Operating Condition

The EUT is working during the test, and Table shift normal, controller control normal, indicator normal.

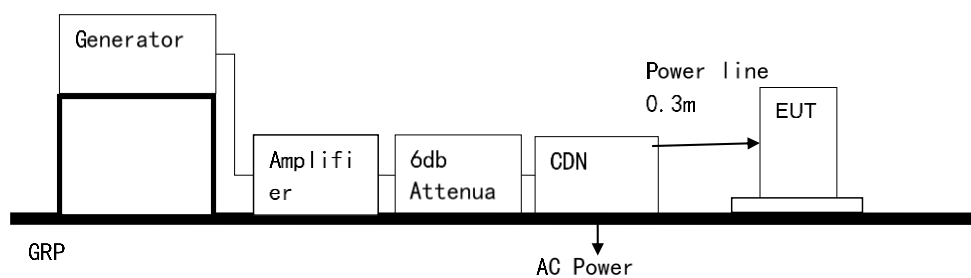
4.9.3.2. Test Configuration and Procedure

For AC power input lines:

- EUT is placed on an insulating support of 0.1m high above a ground reference plane. It must be 0.3m away the CDN (coupling and decoupling network) of which the bottom is made of metallic material and placed directly on the ground plane. Cables between CDN and EUT are as short as possible, and their height above the ground reference plane shall be between 30 and 50 mm (where possible). The disturbance signal amplified by amplifier is injected to EUT through CDN.
- EUT is placed on an insulating support of 0.1m high above a ground reference plane. The Current clamp is directly placed on the ground reference plane with its metallic bottom contacting the plane. Cables between EUT and auxiliary equipment are put through the Current clamp. The disturbance signal amplified by amplifier is injected to EUT through Current clamp.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.9.3.3. Photo of the test set-up





4.9.4. Test specification:

Test voltage:

- AC 230V/50Hz

Frequency range:

- 0.15 MHz to 80 MHz

Test strength :

- 3 V

Frequency range:

- Professional healthcare facility environment
The ISM (industrial, scientific and medical) band between 0.15MHz and 80MHz:
6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, 40.66 MHz to 40.70 MHz
- ☐ Home healthcare environment
The amateur radio bands between 0.15MHz and 80MHz:
1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7.0 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14.0 MHz to 14.2 MHz, 8.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, 50.0 MHz to 54.0 MHz

Test strength :

- 6 V

Modulation:

- AM: 80 %
- sinusoidal 1 kHz

Frequency step:

- 1 % with 1 s dwell time

4.9.5. Coupling points

Cable description :

AC power line;signal line

Screening:

- | | |
|--------------------------------|-------------------------------|
| ☐ screened | ■ unscreened |
| ☐ passive | ■ active |
| ■ analogue | ☐ digital |
| ■ / | |

Status:

Signal transmission:

Length:

4.9.6. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

4.10. Magnetic Field Immunity

For test instruments and accessories used see section 3.5.

4.10.1. Description of the test location and date

Test location: EMS Integrate Room

Date of test: Aug. 08, 2021

Operator: Kang.Yang

4.10.2. Severity levels of magnetic field immunity

Level	Magnetic Field Strength (A/m)
1	1
2	3
3	10
4	30
5	100
X.	Special

Note: equipment and systems shall comply with the requirements of 8.9 of IEC 60601-1-2:2014 at immunity test levels of 30A /m.

4.10.3. Description of the test set-up

4.10.3.1. Operating Condition

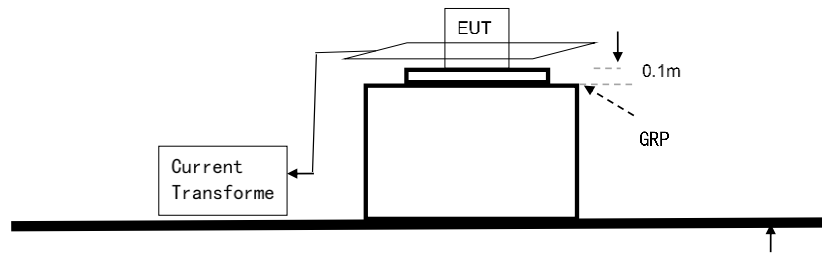
The EUT is working during the test, and Table shift normal, controller control normal, indicator normal.

4.10.3.2. Test Configuration and Procedure:

EUT is placed on an insulating support of 0.1m high above a table of 0.8m high. There is a minimum 1m*1m ground metallic plane put on this table. EUT is put in the center of the magnetic coil then three orientations of the magnetic coil, X, Y and Z, shall be rotated in order to expose the EUT to the difference polarization magnetic field.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.10.3.3. Photo of the test set-up



4.10.4. Test specification:

Test voltage:

■ AC 230V/50Hz

Test frequency:

■ 50 Hz

■ 60 Hz

Continuous field:

■ 30A/m

Test duration:

■ 5m

Antenna factor:

0.917 A/m

Axis:

■ x-axis

■ y-axis

■ z-axis

4.10.5. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

4.11. Voltage Dips and Interruptions

For test instruments and accessories used see section 3.5.

4.11.1. Description of the test location and date

Test location: EMS Integrate Room

Date of test: Aug. 08, 2021

Operator: Kang.Yang

4.11.2. Severity levels of voltage dips and interruptions

Test Level for Voltage Dips		
Test Level (%Ut)	Voltage Dip And Short Interruptions (%Ut)	Duration (In Period)
0	100	0.5
0	100	1
70	30	25
70	30	30

Test Level for Voltage Interruption		
Test Level (%Ut)	Voltage Dip And Short Interruptions (%Ut)	Duration(In Period)
0	100	250
0	100	300

4.11.3. Description of the test set-up

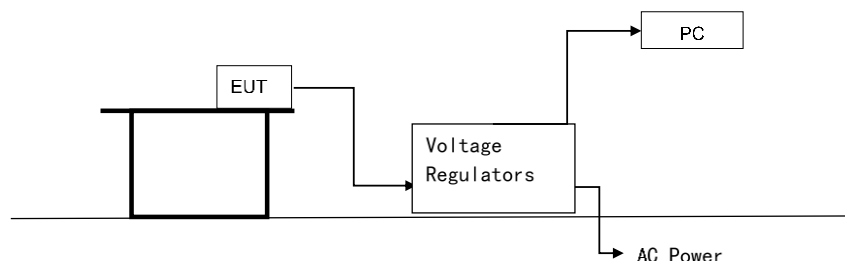
4.11.3.1. Operating Condition

The EUT is working during the test, and Table shift normal, controller control normal, indicator normal.

4.11.3.2. Test Configuration and Procedure

EUT is connected to the simulator according to the test photo. When conducting this test, the power supply shall be set at the minimum and maximum rated input voltages and test voltage changes shall be step changes at the phase angle of 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° .

4.11.3.3. Photo of the test set-up





4.11.4. Test specification:

Nominal Mains Voltage (V_N):

■ AC 230V/50Hz

Number of voltage fluctuations:

■ 3

Level of reduction(dip) / duration:

■ 100 % / 10ms ■ 100 % / 20ms ■ 30 % / 500ms

Nominal Mains Voltage (V_N):

■ AC 230V/50Hz

Number of Interruptions:

■ 3

Duration of the Interruption:

■ 5000 ms

4.11.5. Test result

During and after the test, Table shift normal, controller control normal, indicator normal. Comply with IEC 60601-1-2:2014.

5. External and Internal Photos of the EUT



Figure1 : External photo of EUT



Figure2 : External photo of EUT

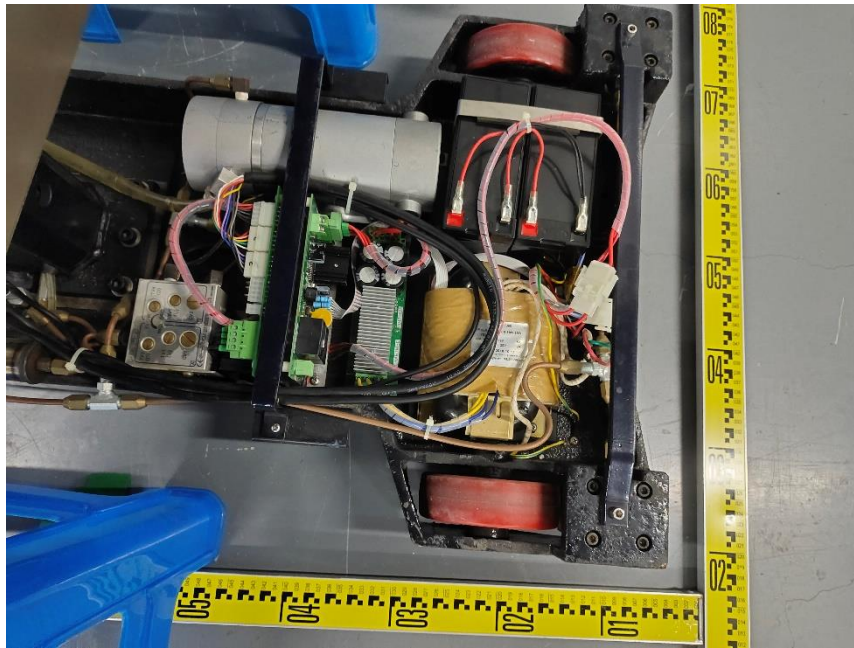


Figure3 : Internal photo of EUT

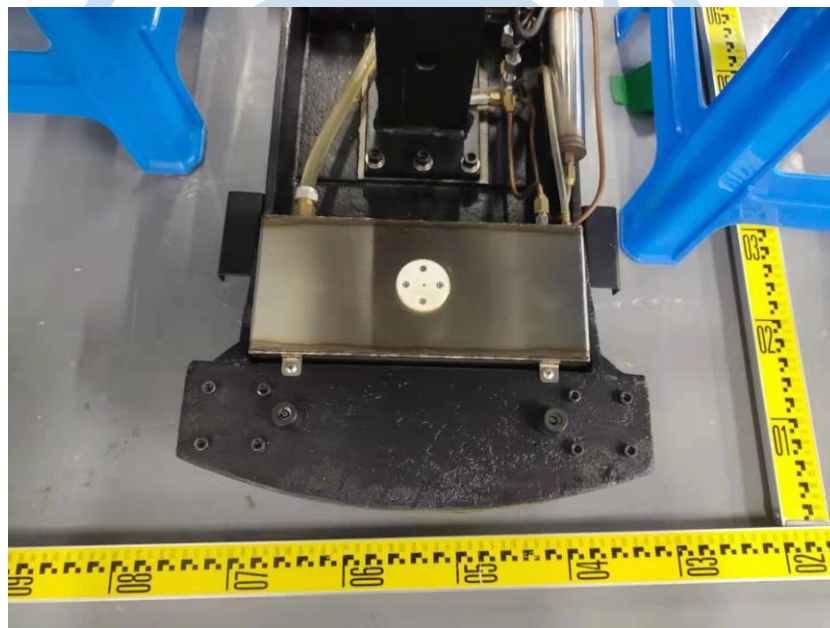


Figure 4 : Internal photo of EUT

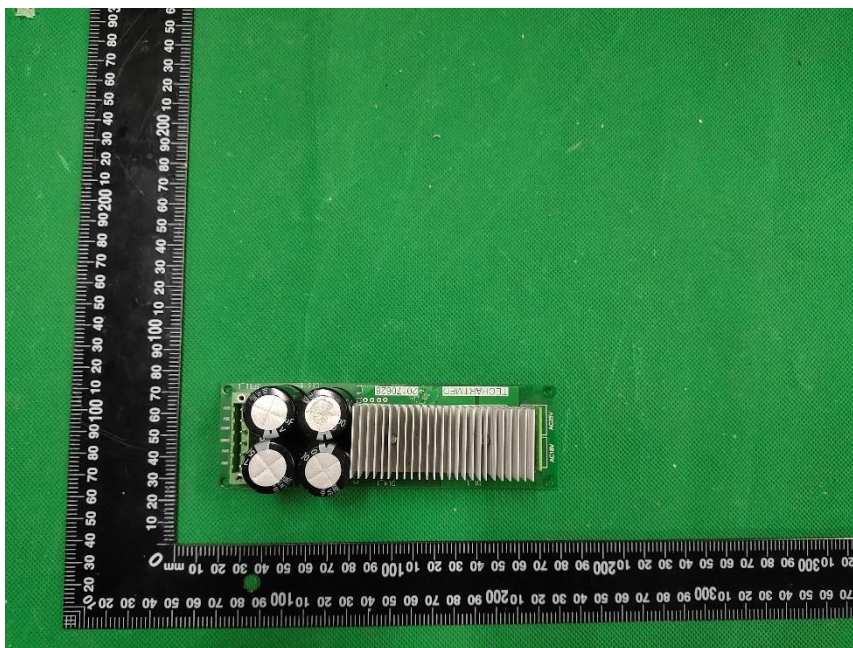


Figure5 : Internal photo of EUT

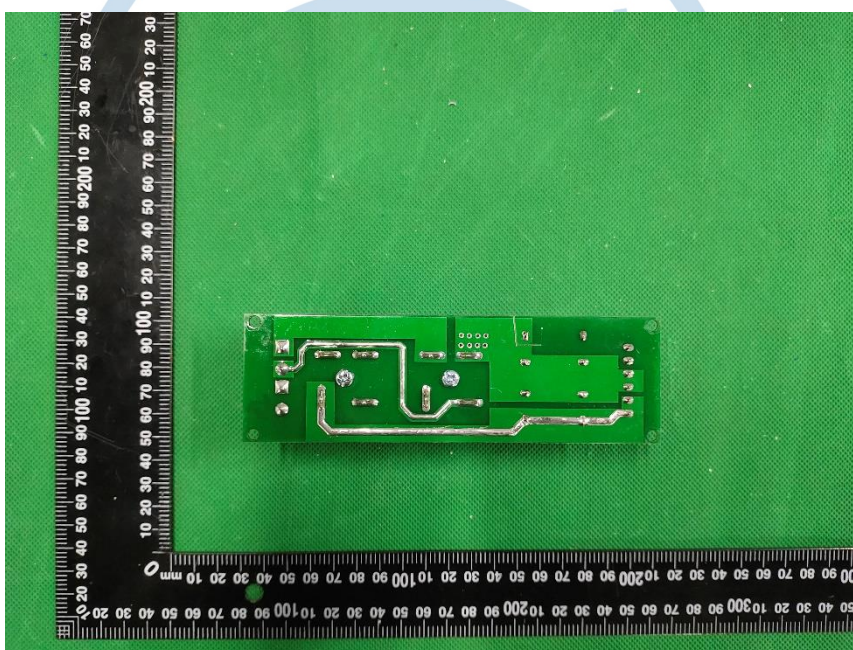


Figure6 : Internal photo of EUT

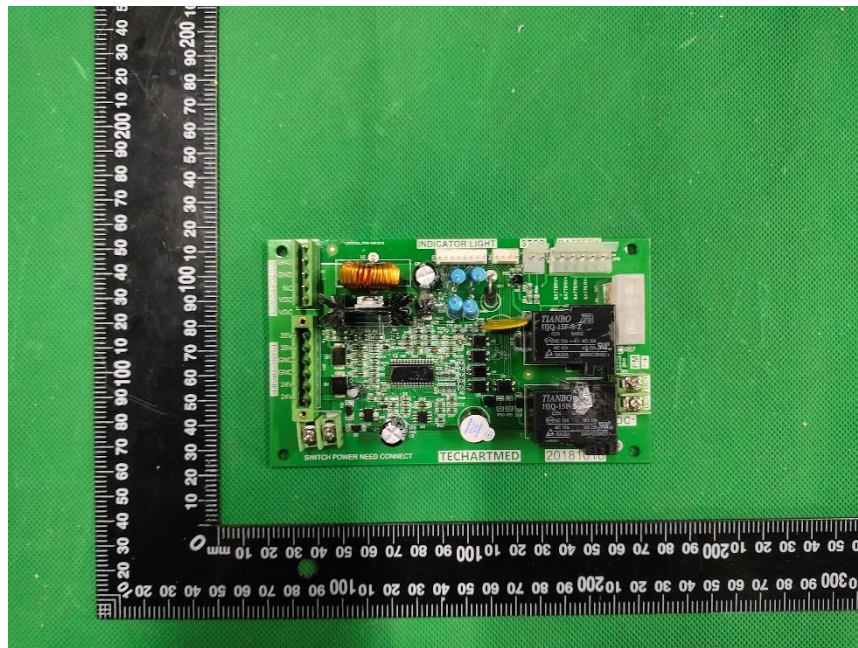


Figure7 : Internal photo of EUT

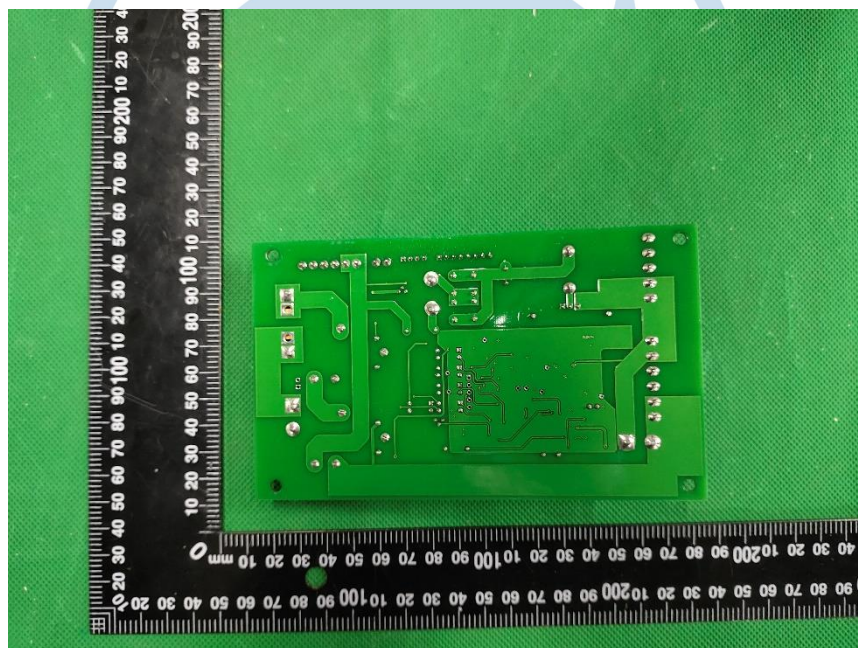


Figure8 : Internal photo of EUT

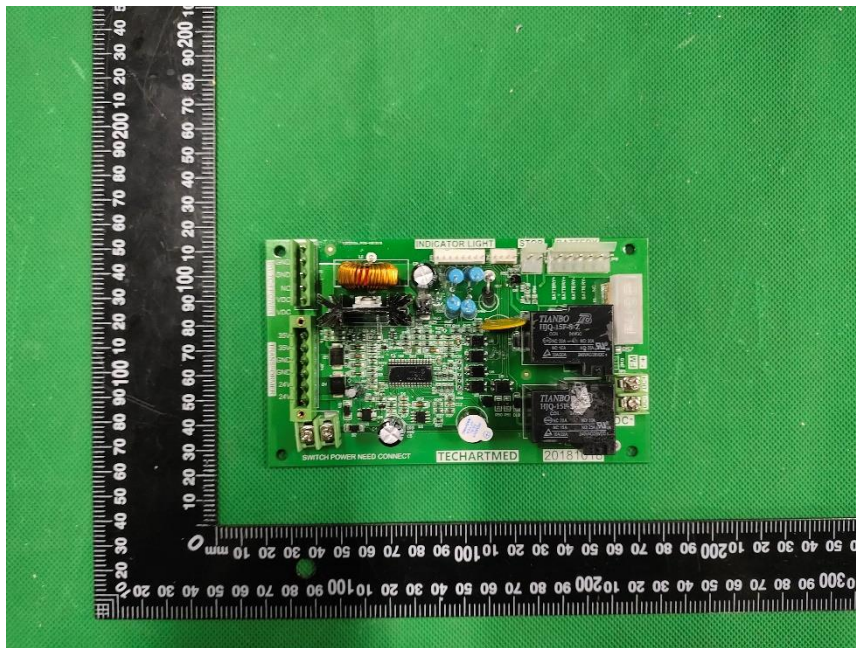


Figure9 : Internal photo of EUT

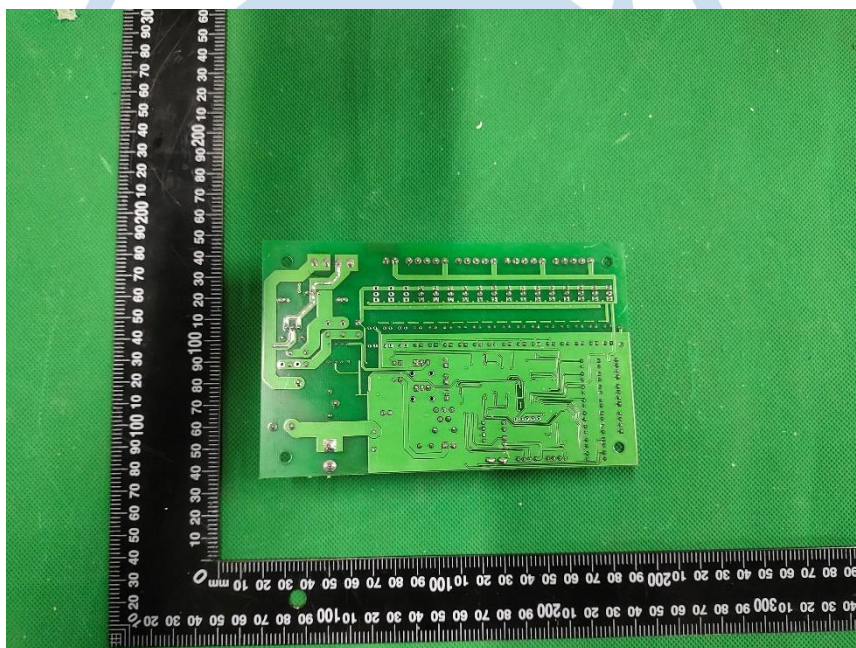


Figure10 : Internal photo of EUT

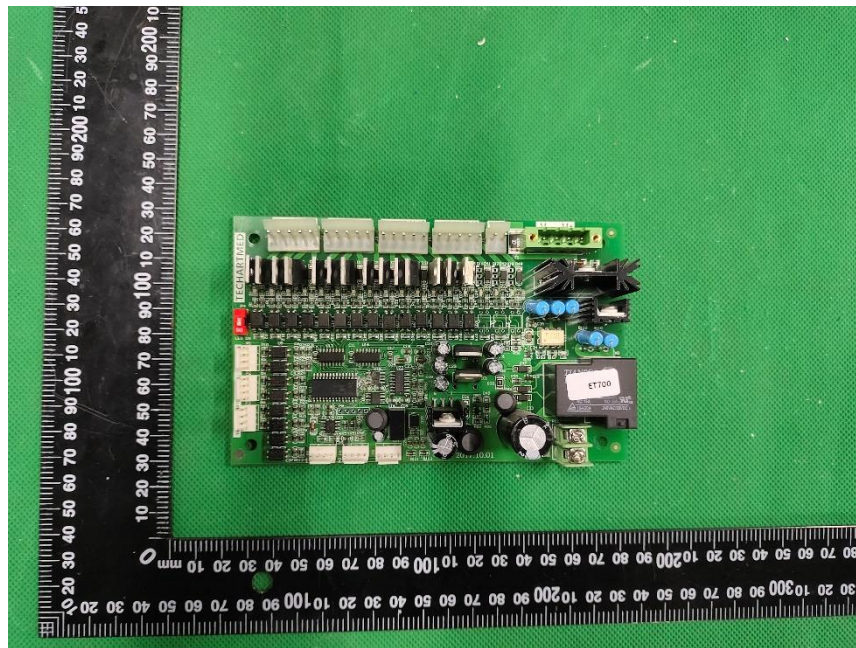


Figure11 : Internal photo of EUT

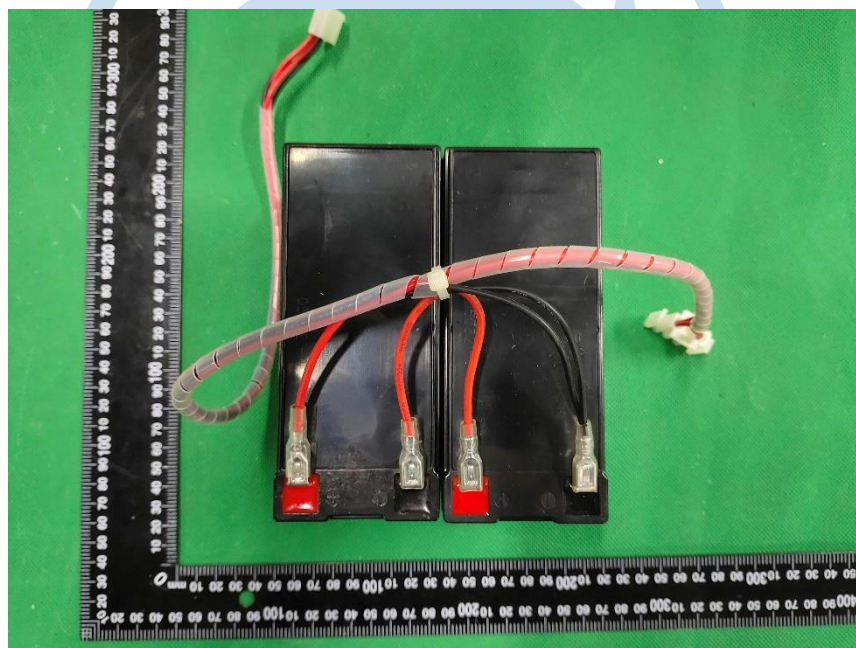


Figure12 : Internal photo of EUT

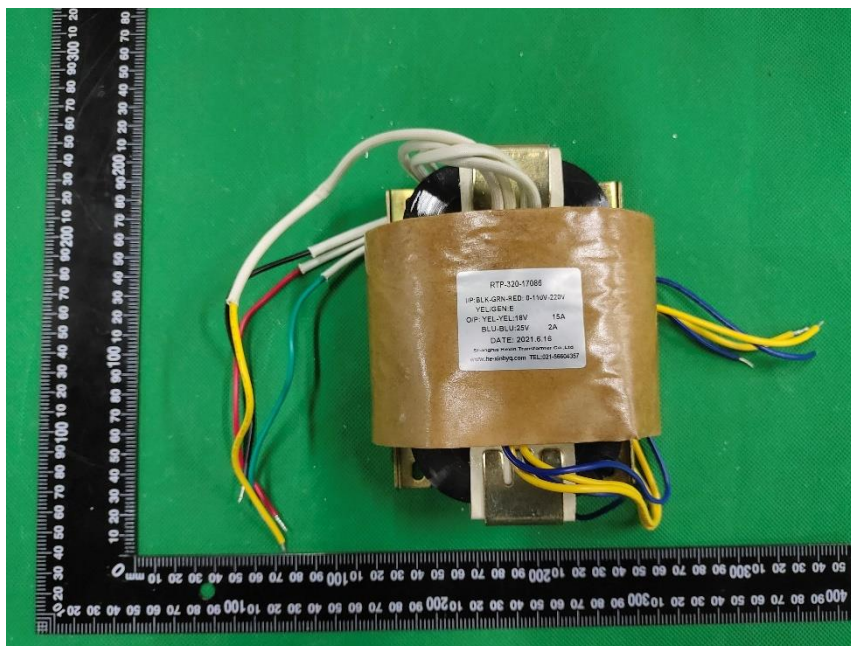


Figure13 : Internal photo of EUT

HFMED[®]

Operating Table

Type:: HFEOT99C

Power Supply: 200-240V~, 50Hz

Input power: 360VA.

Main fuse: F5AL-250V

Battery Rated Voltage: 24V

Battery Nominal Capacity: 7.0Ah

SN HF20210700541

2021-07

2031-06

MD IPX4

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Fax: +86-021-58085105

Figure 5: Nameplate

..... End of Report.....