TEST REPORT

Product Name:	Oximeter
Trademark:	N/A
Model Number:	H8
Prepared For:	Shenzhen Huidu Technology Co., Ltd.
Address:	floor 2, building 22, nibaizhang Industrial Zone, Loucun community, Xinhu street, Guangming District, Shenzhen, China
Manufacturer:	Shenzhen Huidu Technology Co., Ltd.
Address:	floor 2, building 22, nibaizhang Industrial Zone, Loucun community, Xinhu street, Guangming District, Shenzhen, China
Prepared By:	Shenzhen BCTC Testing Co., Ltd.
Address:	BCTC Building & 1-2F, East of B Building, Pengzhou Industrial, Fuyuan 1st Road, Qiaotou Community, Fuyong Street, Bao'an District, Shenzhen, China
Sample Received Date:	Apr. 25, 2020
Sample tested Date:	Apr. 28, 2020 to Apr. 29, 2020
Issue Date:	Apr. 30, 2020
Report No.:	BCTC2004002149E
Test Standards	EN 60601-1-2:2015
Test Results	PASS

Compiled by:	Reviewed by:	Approved by:
Blake Cai	Eric Yang	Zero Zhou/Manager

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(NOTE: N/A MEANS NOT APPLICABLE)

1. VERSION

Report No.	Issue Date	Description	Approved
BCTC2004002149E	Apr. 30, 2020	Original	Valid

2. TEST SUMMARY

The Product has been tested according to the following specifications:

EMISSION		
Standard	**Test Item**	**Test result**
CISPR 11	Conducted emissions from the AC mains power ports	N/A[1]
CISPR 11	Radiated emissions	Pass

IMMUNITY (EN 60601-1-2)		
Standard	**Test Item**	**Test result**
IEC 61000-4-2	Electrostatic discharge (ESD)	Pass
IEC 61000-4-3	Continuous RF electromagnetic field disturbances(RS)	Pass
IEC 61000-4-4	Electrical fast transients/burst (EFT)	N/A[1]
IEC 61000-4-5	Surges	N/A[1]
IEC 61000-4-6	Continuous induced RF disturbances (CS)	N/A[1]
IEC 61000-4-8	Power frequency magnetic field (PFMF)	N/A[2]
IEC 61000-4-11	Voltage dips and interruptions (DIPS)	N/A[1]

Remark:
1. EUT is a DC port powered.
2. The Product doesn't contain any device susceptible to magnetic fields.

3. MEASUREMENT UNCERTAINTY

Where relevant, the following measurement uncertainty levels have been estimated for tests performed on the Product as specified in CISPR 16-4-2. This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

Test item	Value (dB)
Conducted Emission (150kHz-30MHz)	3.20
Radiated Emission(30MHz~1GHz)	4.80

4. PRODUCT INFORMATION AND TEST SETUP

4.1 Product Information

Ratings: DC 3V

Cable of Product

No.	Cable Type	Quantity	Provider	Length (m)	Specification	Note
1	--	--	Applicant	**---**	Shielded	With a ferrite ring in mid Detachable
2	--	--	BCTC	--	Unshielded	--

4.2 Test Setup Configuration

See test photographs attached in EUT TEST SETUP PHOTOGRAPHS for the actual connections between Product and support equipment.

4.3 Support Equipment

No	Device Type	Brand	Model	Series No.	Data Cable	Power Cord
1.	---	---	---	---	---	---

Notes:

1. All the equipment/cables were placed in the worst-case configuration to maximize the emission during the test.
2. Grounding was established in accordance with the manufacturer's requirements and conditions for the intended use.

4.4 Test Mode

Test item	Test Mode	Test Voltage
Radiated emissions(30MHz-1GHz) Class B	Working	DC 3V*
Electrostatic discharge (ESD) B ☒Air Discharge: ±2kV,±4kV,±8kV,±15kV ☒Contact Discharge: ±8kV ☒HCP & VCP: ±8kV	Working	DC 3V
Continuous RF electromagnetic field disturbances(RS) 80MHz-2700MHz, table 9 3V/m,80% AM Front, Rear, Left, Right H/V	Working	DC 3V
All test mode were tested and passed, only Radiated Emissionsshows (*) is the worst case mode which were recorded in this report.		

5. TEST FACILITY AND TEST INSTRUMENT USED

5.1 Test Facility

All measurement facilities used to collect the measurement data are located at BCTC Building & 1-2F, East of B Building, Pengzhou Industrial, Fuyuan 1st Road, Qiaotou Community, Fuyong Street, Bao'an District, Shenzhen, China. The site and apparatus are constructed in conformance with the requirements of ANSI C63.4 and CISPR 16-1-1 other equivalent standards.

5.2 Test Instrument Used

Radiated emissions Test (966 chamber)					
Equipment	**Manufacturer**	**Model#**	**Serial#**	**Last Cal.**	**Next Cal.**
966 chamber	ChengYu	966 Room	966	Jun. 19, 2018	Jun. 18, 2021
Receiver	R&S	ESR3	102075	Jun. 13, 2019	Jun. 12, 2020
Receiver	R&S	ESRP	101154	Jun. 13, 2019	Jun. 12, 2020
Amplifier	Schwarzbeck	BBV9718	9718-309	Jun. 25, 2019	Jun. 24, 2020
Amplifier	Schwarzbeck	BBV9744	9744-0037	Jun. 25, 2019	Jun. 24, 2020
TRILOG Broadband Antenna	schwarzbeck	VULB 9163	VULB9163-942	Jun. 22, 2019	Jun. 21, 2020
Horn Antenna	SCHWARZBECK	BBHA9120D	1201	Jun. 22, 2019	Jun. 21, 2020
Software	Frad	EZ-EMC	FA-03A2 RE	\	\

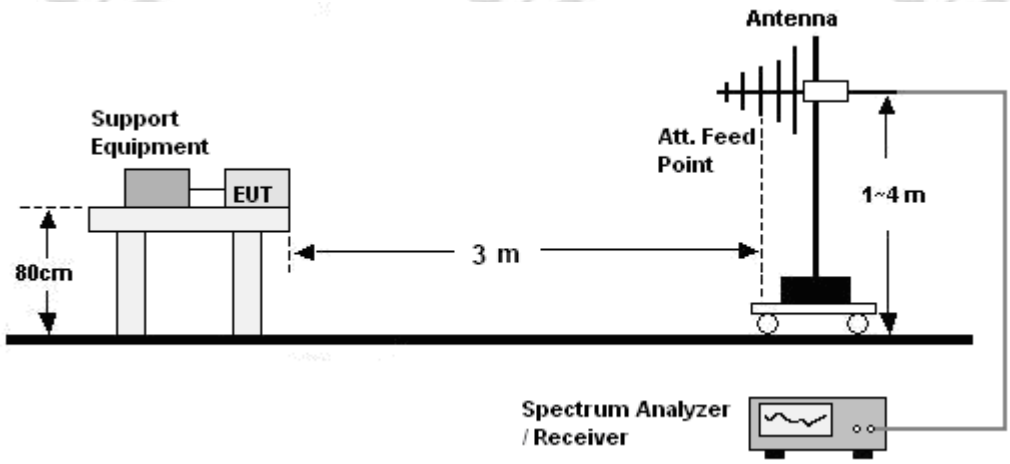
Electrostatic discharge Test					
Equipment	**Manufacturer**	**Model#**	**Serial#**	**Last Cal.**	**Next Cal.**
ESD Tester	KIKISUI	KES4201A	UH002321	Jul. 12, 2019	Jul. 10, 2020

Continuous RF electromagnetic field disturbances Test					
Equipment	**Manufacturer**	**Model#**	**Serial#**	**Last Cal.**	**Next Cal.**
Power meter	Keysight	E4419	GB42421440	Jun. 17, 2019	Jun. 16, 2020
Power sensor	Keysight	E9300A	US39211305	Jun. 17, 2019	Jun. 16, 2020
Power sensor	Keysight	E9300A	US39211659	Jun. 17, 2019	Jun. 16, 2020
Amplifier	SKET	HAP-801000M-250W	\	Jun. 25, 2019	Jun. 24, 2020
Amplifier	SKET	HAP-801000M-75W	\	Jun. 25, 2019	Jun. 24, 2020
Amplifier	SKET	HAP-801000M-50W	\	Jun. 25, 2019	Jun. 24, 2020
Stacked double Log.-Per. Antenna	Schwarzbeck	STLP 9129	077	\	\
Field Probe	Narda	EP-601	80256	Jul. 07, 2019	Jul. 06, 2020
Signal Generator	Aglilent	N5181A	MY50143748	Jun. 13, 2019	Jun. 12, 2020
Software	SKET	EMC-S	1.2.0.18	\	\

6. RADIATED EMISSIONS TEST

6.1 Block Diagram Of Test Setup

30MHz ~ 1GHz:



6.2 Limits

Limits for class B group 1

Frequency (MHz)	Quasi-peak limits at 3m dB(μV/m)
30-230	40
230-1000	47

Note: The lower limit shall apply at the transition frequencies.

6.3 Test Procedure

30MHz ~ 1GHz:

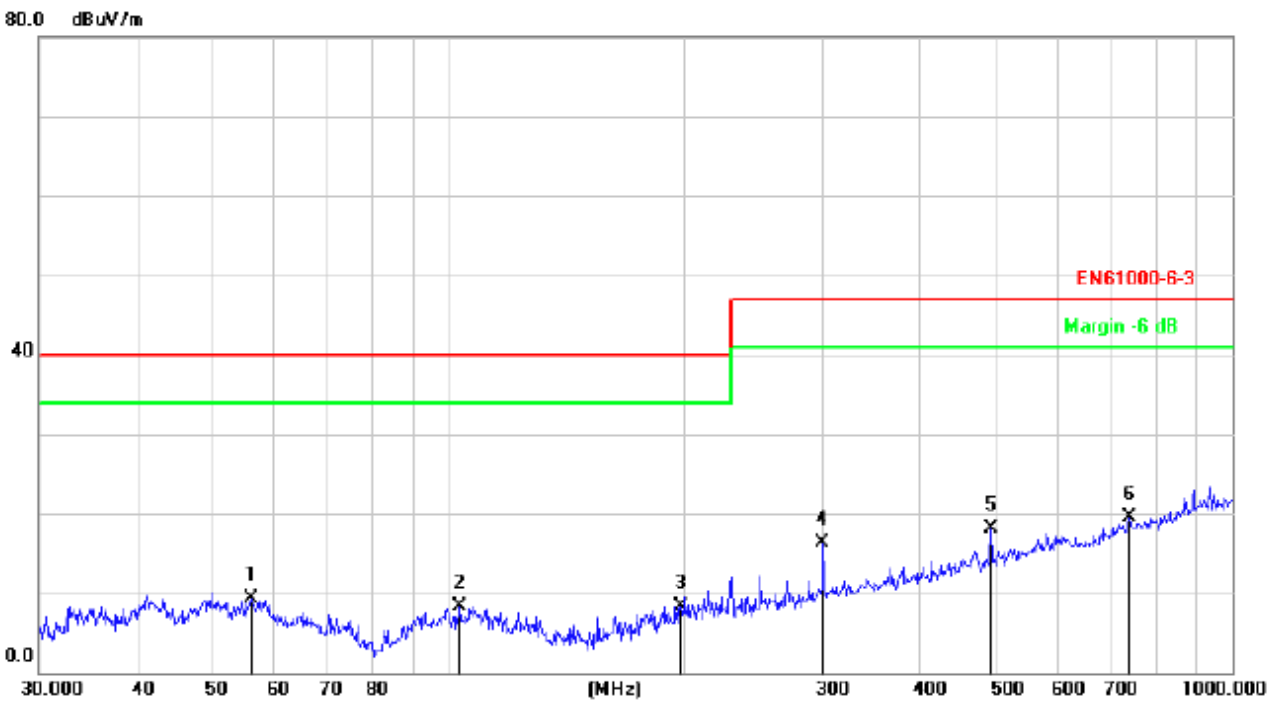
a. The Product was placed on the nonconductive turntable 0.8 m above the ground in a semi anechoic chamber.

b. Set the spectrum analyzer/receiver in Peak detector, Max Hold mode, and 120 kHz RBW. Record the maximum field strength of all the pre-scan process in the full band when the antenna is varied between 1~4 m in both horizontal and vertical, and the turntable is rotated from 0 to 360 degrees.

c. For each frequency whose maximum record was higher or close to limit, measure its QP value: vary the antenna's height and rotate the turntable from 0 to 360 degrees to find the height and degree where Product radiated the maximum emission, then set the test frequency analyzer/receiver to QP Detector and specified bandwidth with Maximum Hold Mode, and record the maximum value.

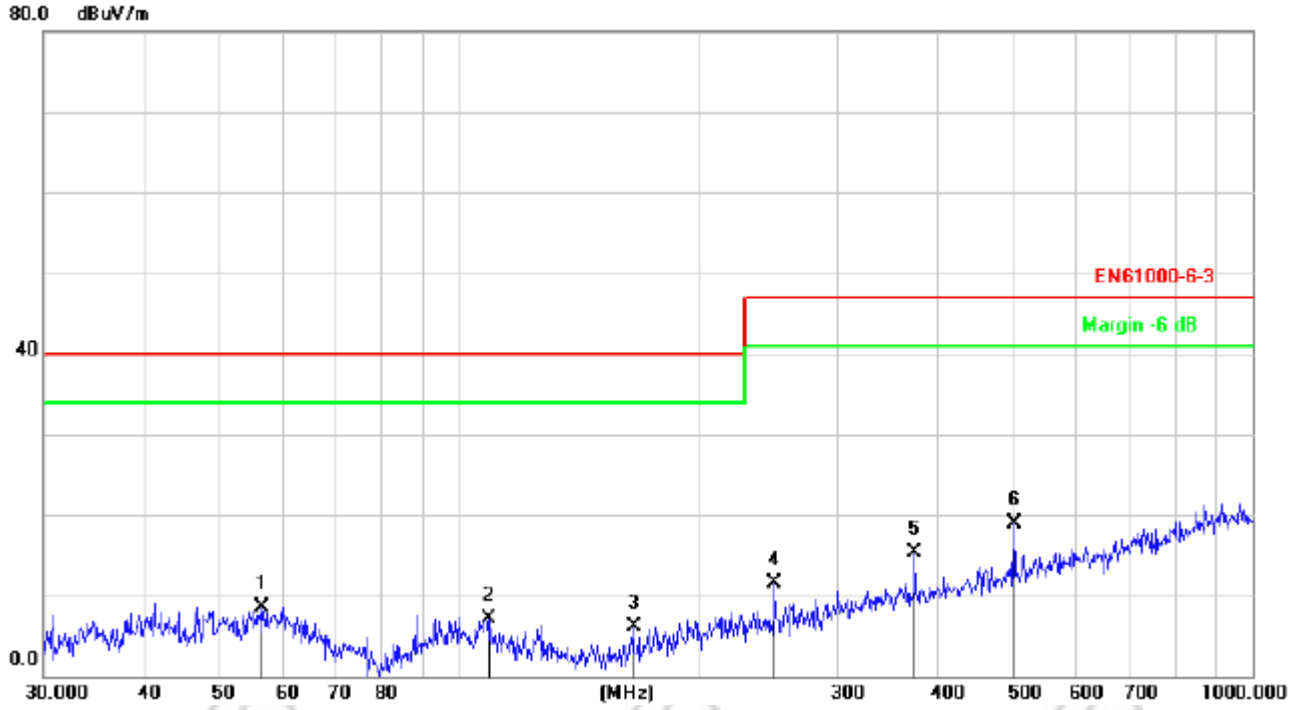
6.4 Test Results

Temperature:	23 ℃	Relative Humidity:	54%
Pressure:	101kPa	Phase :	Horizontal
Test Voltage :	DC 3V	Test Mode:	Working



No.	Mk.	Freq.	Reading Level	Correct Factor	Measure-ment	Limit	Over		Antenna Height	Table Degree	
		MHz	dBuV	dB	dBuV/m	dB/m	dB	Detector	cm	degree	Comment
1		56.0007	24.70	-15.49	9.21	40.00	-30.79	QP			
2		103.4421	24.71	-16.50	8.21	40.00	-31.79	QP			
3		197.8928	24.80	-16.43	8.37	40.00	-31.63	QP			
4		300.3672	29.85	-13.59	16.26	47.00	-30.74	QP			
5		492.4685	27.13	-9.09	18.04	47.00	-28.96	QP			
6	*	739.6604	24.10	-4.51	19.59	47.00	-27.41	QP			

Temperature:	23 ℃	Relative Humidity:	54%
Pressure:	101kPa	Phase :	Vertical
Test Voltage :	DC 3V	Test Mode:	Working



No.	Mk.	Freq.	Reading Level	Correct Factor	Measure-ment	Limit	Over		Antenna Height	Table Degree	
		MHz	dBuV	dB	dBuV/m	dB/m	dB	Detector	cm	degree	Comment
1		56.3948	24.02	-15.53	8.49	40.00	-31.51	QP			
2		109.4116	23.97	-16.89	7.08	40.00	-32.92	QP			
3		166.0680	24.60	-18.47	6.13	40.00	-33.87	QP			
4		250.3012	26.73	-15.14	11.59	47.00	-35.41	QP			
5		375.9385	26.94	-11.64	15.30	47.00	-31.70	QP			
6	*	501.1790	27.82	-8.91	18.91	47.00	-28.09	QP			

Remark:
Factor = Antenna Factor + Cable Loss – Pre-amplifier.

7. IMMUNITY TEST OF GENERAL THE PERFORMANCE CRITERIA

I.2.3 IMMUNITY pass/fail criteria determination

The functions to be tested and the specific, detailed IMMUNITY pass/fail criteria should be derived from one or more sources. This includes identification of:

- the HAZARDS;
- the functions to be tested for IMMUNITY to verify freedom from unacceptable RISK;
- the criteria on which to base the pass/fail decision;
- operating modes;
- characteristics of simulated PATIENT physiological signals;
- specification of locations of INTENDED USE;
- the characteristics of the test, where these are at the discretion of the MANUFACTURER.

Part 2 standards in the IEC 60601 family can specify particular ESSENTIAL PERFORMANCE and IMMUNITY pass/fail criteria.

IMMUNITY pass/fail criteria can specify degradations that are acceptable because they do not result in unacceptable RISK.

I.3.1 General examples

The following are examples that can be used to develop pass/fail criteria. For ME EQUIPMENT and ME SYSTEMS with multiple functions, the pass/fail criteria should be applied to each function, parameter and channel.

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.

Example of performance during and after the applied testing stimulus required to pass the test:

– for a mammography system, the compression full release and associated command remains fully operational;
– for ULTRASOUND DIAGNOSTIC EQUIPMENT, the probe heating, dissipative power and temperature shall remain within specifications;
– safety-related functions perform as intended;
– false operation of alarms, "fail safe" modes and similar functions do not occur.

NOTE This might require performing the test twice – once to ensure the functions occur as expected and again to ensure they do not occur falsely.

Examples of acceptable degradation:

– an imaging system displays an image that could be altered, but in a way that would not affect the diagnosis or treatment;
– a heart rate monitor displays a heart rate that could be in error, but by an amount that is not clinically significant;
– a PATIENT monitor exhibits a small amount of noise or a transient on a waveform and the noise or transient would not affect diagnosis, treatment or monitoring.

Examples of ME EQUIPMENT and ME SYSTEMS with multiple functions:

– multi-parameter monitors;
– anaesthesia system with monitors;
– ventilators with monitors;
– multiple instances of the same function (e.g. multiple invasive blood pressure sensors).

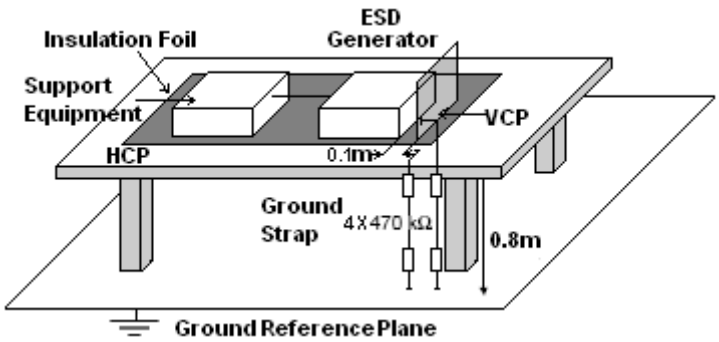
Failure of therapy equipment to terminate a treatment at the intended time can be considered cessation or interruption of an intended operation related to ESSENTIAL PERFORMANCE. If the effect of the test signal on an ME EQUIPMENT or ME SYSTEM is so brief as to be transparent to the PATIENT or OPERATOR and does not affect diagnosis, monitoring or treatment of the PATIENT, this can be considered not to be cessation or interruption of an intended operation. For example, if in response to the IMMUNITY TEST LEVEL a ventilator stops pumping for 50 ms and then resumes operation such that accuracy is within acceptable limits, this would not be considered cessation or interruption of an intended operation.

8. ELECTROSTATIC DISCHARGE (ESD)

8.1 Test Specification

Test Port	Enclosure port
Discharge Impedance	330 ohm / 150 pF
Discharge Mode	Single Discharge
Discharge Period	one second between each discharge

8.2 Block Diagram of Test Setup



8.3 Test Procedure

a. Electrostatic discharges were applied only to those points and surfaces of the Product that are accessible to users during normal operation.

b. The test was performed with at least ten single discharges on the pre-selected points in the most sensitive polarity.

c. The time interval between two successive single discharges was at least 1 second.

d. The ESD generator was held perpendicularly to the surface to which the discharge was applied and the return cable was at least 0.2 meters from the Product.

e. Contact discharges were applied to the non-insulating coating, with the pointed tip of the generator penetrating the coating and contacting the conducting substrate.

f. Air discharges were applied with the round discharge tip of the discharge electrode approaching the Product as fast as possible (without causing mechanical damage) to touch the Product. After each discharge, the ESD generator was removed from the Product and re-triggered for a new single discharge. The test was repeated until all discharges were complete.

g. At least ten single discharges (in the most sensitive polarity) were applied to the Horizontal Coupling Plane at points on each side of the Product. The ESD generator was positioned vertically at a distance of 0.1 meters from the Product with the discharge electrode touching the HCP.

h. At least ten single discharges (in the most sensitive polarity) were applied to the center of one vertical edge of the Vertical Coupling Plane in sufficiently different positions that the four faces of the Product were completely illuminated. The VCP (dimensions 0.5m x 0.5m) was placed vertically to and 0.1 meters from the Product.

8.4 Test Results

Temperature:	26 ℃	Relative Humidity:	54%
Pressure:	101kPa	Test Mode:	Working
Test Voltage :	DC 3V		

Discharge Method	Discharge Position	Voltage (±kV)	Min. No. of Discharge per polarity (Each Point)	Performance Criterion
Contact Discharge	Conductive Surfaces	8	10	Meet the requirement
	Indirect Discharge HCP	8	10	Meet the requirement
	Indirect Discharge VCP	8	10	Meet the requirement
Air Discharge	Slots, Apertures, and Insulating Surfaces	2,4,8,15	10	Meet the requirement

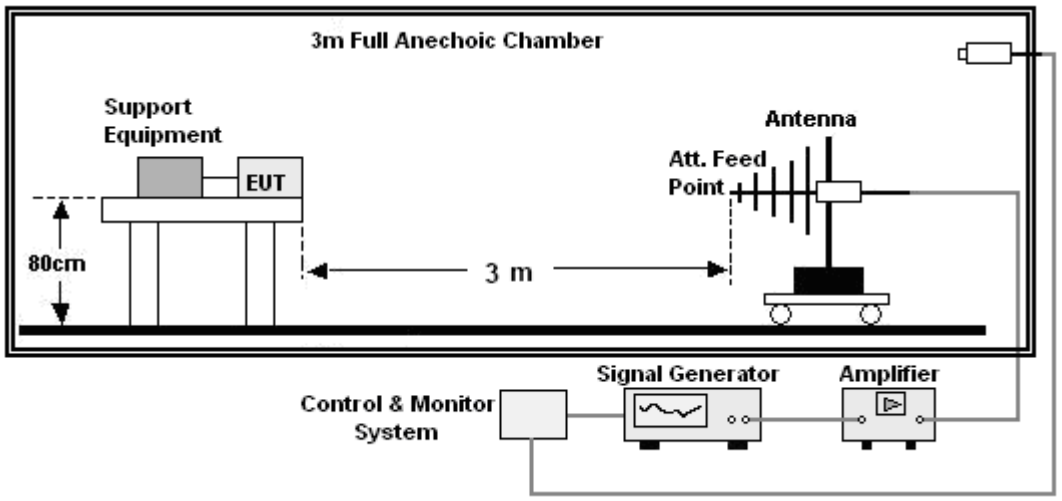
9. CONTINUOUS RF ELECTROMAGNETIC FIELD DISTURBANCES (RS)

9.1 Test Specification

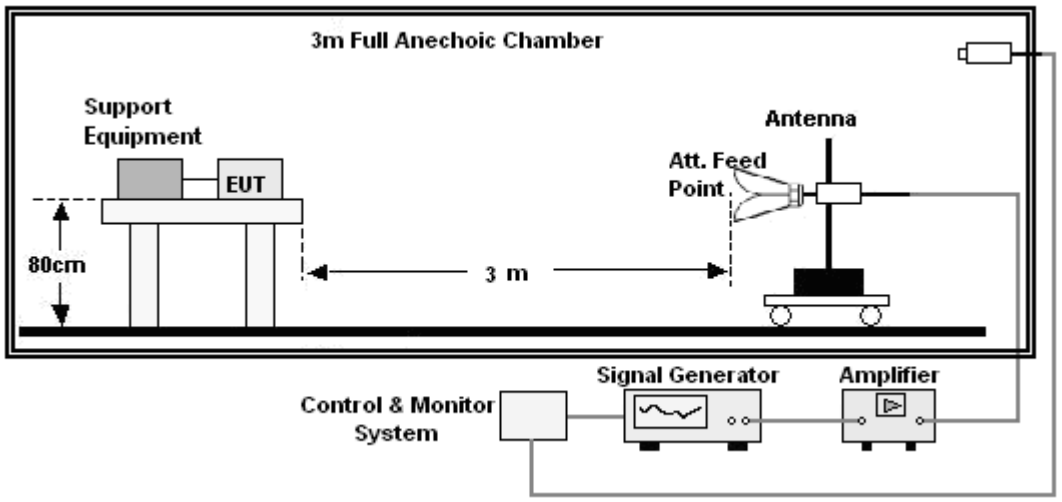
Test Port	:	Enclosure port
Step Size	:	1%
Modulation	:	1kHz, 80% AM
Dwell Time	:	1 second
Polarization	:	Horizontal & Vertical

9.2 Block Diagram of Test Setup

Below 1GHz:



Above 1GHz:



9.3 Test Procedure

a. The testing was performed in a fully-anechoic chamber. The transmit antenna was located at a distance of 3 meters from the Product.

b. The frequency range is swept from 80MHz to 2700MHz, with the signal 80% amplitude modulated with a 1 kHz sine wave, and the step size was 1%.

c. The dwell time at each frequency shall not be less than the time necessary for the EUT to be exercised and to be able to respond, but should not exceed 5 s at each of the frequencies during the scan.

d. The test was performed with the Product exposed to both vertically and horizontally polarized fields on each of the four sides.

9.4 Test Results

Temperature:	26 ℃	Relative Humidity:	54%
Pressure:	101kPa	Test Mode:	Working
Test Voltage :	DC 3V		

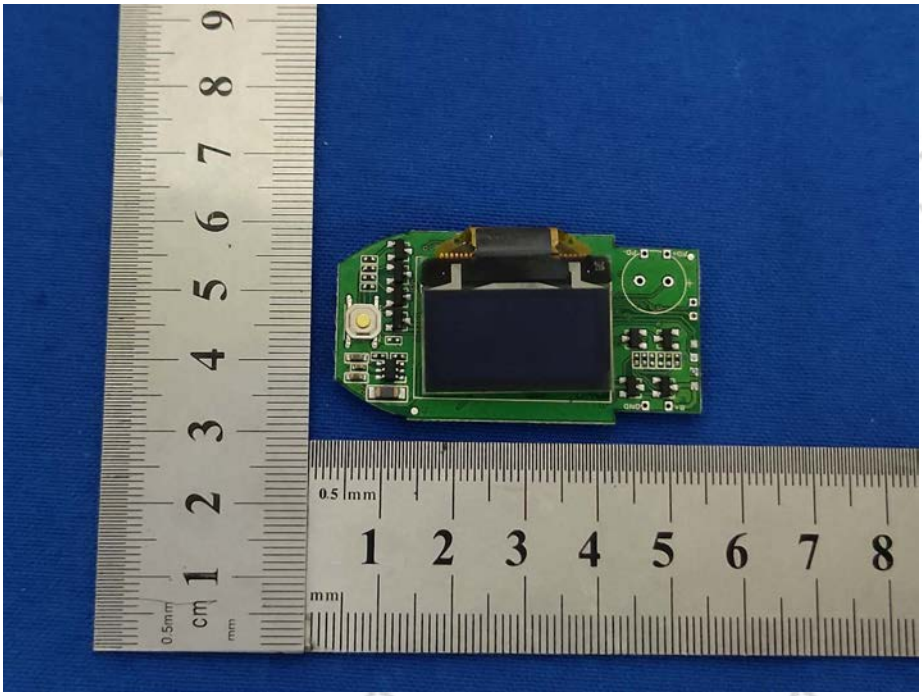
Frequency	Position	Field Strength (V/m)	Performance Criterion
80 - 2700MHz,	Front, Right, Back, Left	10	Meet the requirement

10. EUT PHOTOGRAPHS

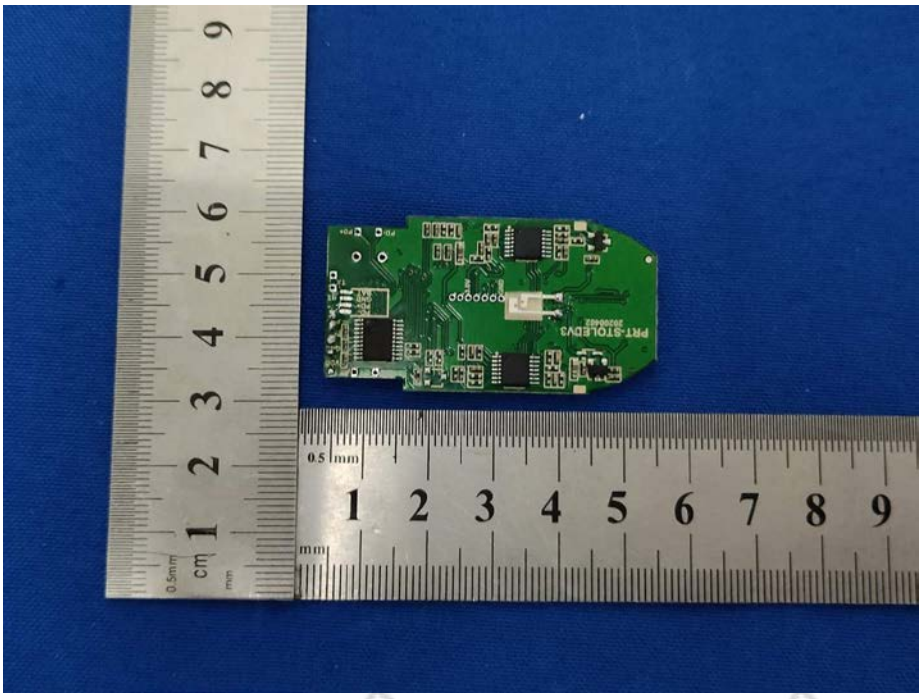
EUT Photo 1

EUT Photo 2

EUT Photo 3

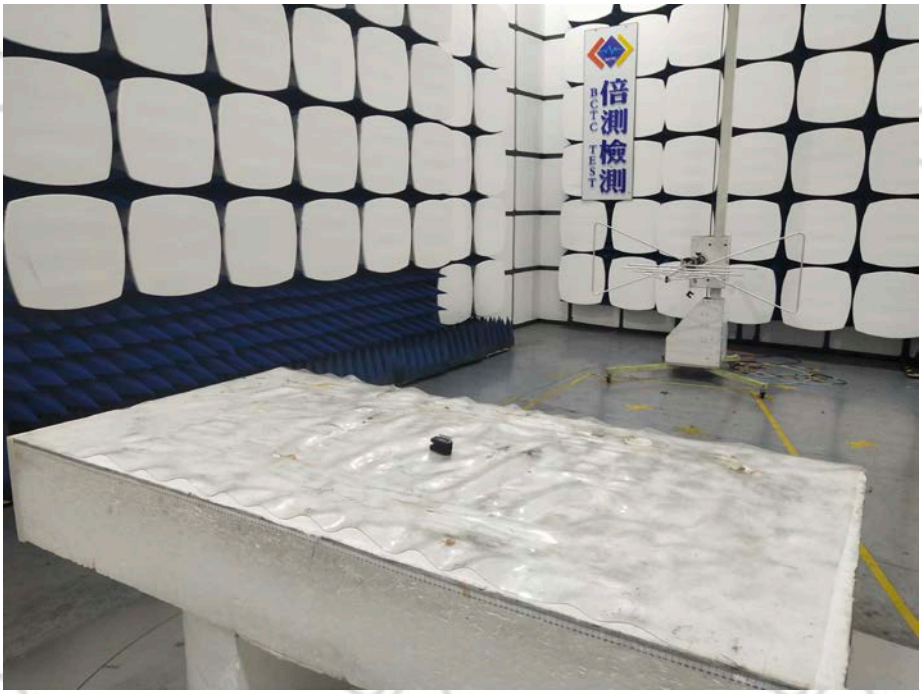


EUT Photo 4

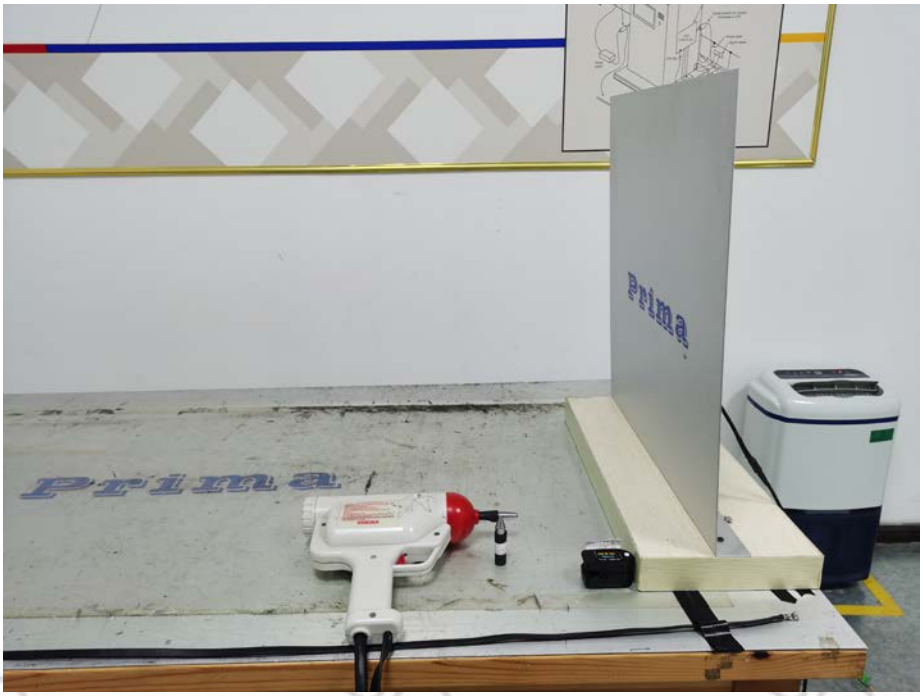


11. EUT TEST SETUP PHOTOGRAPHS

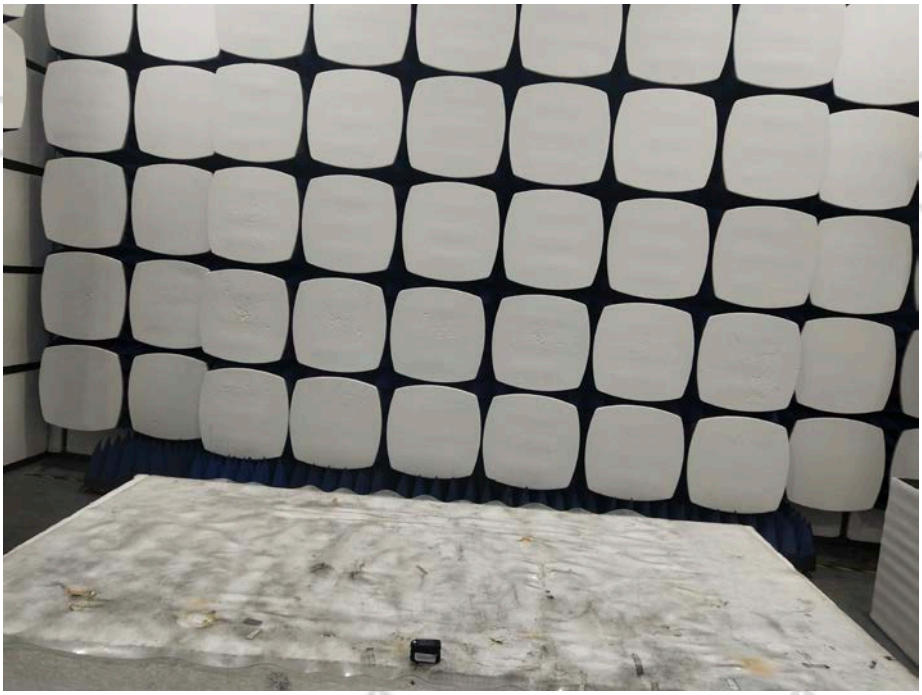
Radiated emissions



ESD



RS



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