Shenzhen Huatongwei International Inspection Co., Ltd.
Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China
Phone: 86-755-26748078 Fax: 86-755-26748089 http://www.szhtw.com.cn

TEST REPORT

IEC 60601-1-2

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

Report Reference No. ..... :	**TRE18090108 R/C: 32373**	
Compiled by (printed name+signature) .....:	File administrators Tracy Tian	Tracy tian
Supervised by (printed name+signature) .....:	Technique principal Tony Jiang	Tony Jiang
Approved by (printed name+signature) .....:	Manager Tiger Jiang	tiger jiang
Date of issue.....:	2018-12-11	
Testing Laboratory Name .....:	**Shenzhen Huatongwei International Inspection Co., Ltd.**	
Address.....:	Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China	
Testing location/ procedure .....:	Full application of Harmonised standards ☒ Partial application of Harmonised standards ☐ Other standard testing methods ☐	
Applicant's name.....:	**SUNS Electric(Zhangzhou) Co., Ltd.**	
Address.....:	No.169 Wengjiao Road, Jiaomei Town, Taishang Investment Zone, Zhangzhou, Fujian Province, P.R. China	
Test specification:		
Standard .....:	**IEC 60601-1-2: 2014**	
Non-standard test method……..:	N/A	
Test Report Form No.....:	HTWEMCCE_1B	
TRF Originator.....:	Shenzhen Huatongwei International Inspection Co., Ltd.	
Master TRF.....:	Dated 2014-06	

Test item description ..... :	**Foot Switch**
Trade Mark .....:	SUNS
Manufacturer.....:	SUNS Electric(Zhangzhou) Co., Ltd.
Model/Type reference.....:	FSB-66-10-RF
Listed models.....:	Refer to chapter 2.3 for details
Ratings.....:	3.0Vd.c.
Result.....:	**Positive**

EMC -- T E S T R E P O R T

Test Report No. : TRE18090108	2018-12-11 Date of issue

Equipment under Test	:	**Foot Switch**
Model /Type	:	FSB-66-10-RF
Listed Models	:	Refer to chapter 2.3 for details
Applicant	:	SUNS Electric(Zhangzhou) Co., Ltd.
Address	:	No.169 Wengjiao Road, Jiaomei Town, Taishang Investment Zone, Zhangzhou, Fujian Province, P.R. China
Manufacturer	:	SUNS Electric(Zhangzhou) Co., Ltd.
Address	:	No.169 Wengjiao Road, Jiaomei Town, Taishang Investment Zone, Zhangzhou, Fujian Province, P.R. China

Test Result according to the standards on page 4:	**Positive**

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.

Contents

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 B apparatus according to the standard of CISPR 11: 2015+A1: 2016 clause 5.2.

2 . SUMMARY

2.1. General Remarks

Date of receipt of test sample : 2018-12-04

Testing commenced on : 2018-12-04

Testing concluded on : 2018-12-11

2.2. Equipment Under Test

Power supply system utilised

Power supply voltage : o 230V / 50 Hz o 120V / 60Hz
o 12 V DC o 24 V DC
■ Other (specified in blank below)

3.0Vd.c.(internal battery)

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

The EUT is a foot switch.

It's applicable for use with medical equipment.

Tests were carried out on model FSB-66-10-RF to represent all other foot switches series: FS-2, FS-6, FS-7, FS-8, FS-9, FCP, FSB, FSR, FWC series. All these foot switch models use exactly the same PCB circuit and RF receiver.

LOT No.: 2018-10-22

2.4. EUT operation mode

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

Test with frequency wireless supplied by 12V battery.

The EUT is measuring during the test.

Test program (customer specific)

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

2.5. EUT configuration

The following peripheral devices and interface cables were connected during the measurement:

■ - supplied by the manufacturer

o - supplied by the lab

■ Frequency wireless Manufacture : SUNS Electric(Zhangzhou) Co., Ltd.
M/N : RCV-RF-10A-6

2.6. IMMUNITY pass/fail criteria:

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.

During the test, frequency wireless is abnormal response.

3. TEST ENVIRONMENT

3.1. Address of the test laboratory

Shenzhen Huatongwei International Inspection Co., Ltd.
Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China
Tel: 86-755-26748019 Fax: 86-755-26748089

3.2. Test Facility

The test facility is recognized, certified, or accredited by the following organizations:

CNAS-Lab Code: L1225

Shenzhen Huatongwei International Inspection Co., Ltd. has been assessed and proved to be in compliance with CNAS-CL01 Accreditation Criteria for Testing and Calibration Laboratories (identical to ISO/IEC 17025: 2005 General Requirements) for the Competence of Testing and Calibration Laboratories,

A2LA-Lab Cert. No. 3902.01

Shenzhen Huatongwei International Inspection Co., Ltd. EMC Laboratory has been accredited by A2LA for technical competence in the field of electrical testing, and proved to be in compliance with ISO/IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories and any additional program requirements in the identified field of testing.

FCC-Registration No.: 762235

Shenzhen Huatongwei International Inspection Co., Ltd. EMC Laboratory has been registered and fully described in a report filed with the FCC (Federal Communications Commission). The acceptance letter from the FCC is maintained in our files. Registration No: 762235.

IC-Registration No.: 5377B-1, 5377B-2

Two 3m Alternate Test Site of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered by Certification and Engineering Bureau of Industry Canada for the performance of radiated measurements with Registration No. 5377B.

ACA

Shenzhen Huatongwei International Inspection Co., Ltd. EMC Laboratory can also perform testing for the Australian C-Tick mark as a result of our A2LA accreditation.

VCCI

Radiated disturbance above 1GHz measurement of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: G-20007.

Main Ports Conducted Interference Measurement of Shenzhen Huatongwei International Inspection Co., Ltd. Has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: C-20001.

Telecommunication Ports Conducted Interference Measurement of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: T-20001.

The 3m Semi-anechoic chamber (9.1m×6.4m×6.0m) of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.:R-4398.

3.3. Environmental conditions

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

Temperature:	22-25°C
Humidity:	40-58 %
Atmospheric pressure:	950-1050mbar

3.4. Test Description

Emission Measurement		
Radiated Emission	IEC 60601-1-2: 2014 CISPR 11: 2015+A1: 2016	PASS
Conducted Disturbance (0.15-30MHz)	IEC 60601-1-2: 2014 CISPR 11: 2015+A1: 2016	N/A
Harmonic Current	IEC 60601-1-2: 2014 IEC 61000-3-2: 2014	N/A
Voltage Fluctuation and Flicker	IEC 60601-1-2: 2014 IEC 61000-3-3: 2013	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 IEC61000-4-3: 2006+A1: 2007+A2: 2010	PASS
Electrical Fast Transient/Burst Test	IEC 60601-1-2: 2014 IEC 61000-4-4: 2012	N/A
Surge Test	IEC 60601-1-2: 2014 IEC 61000-4-5: 2014	N/A
Conducted Susceptibility Test	IEC 60601-1-2: 2014 IEC 61000-4-6: 2013	N/A
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	N/A

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		N/A
	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.		N/A
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

3.5. 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 Shenzhen 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 Shenzhen Huatongwei laboratory is reported:

Test	Range	Measurement Uncertainty	Notes
Radiated Emission	30~1000MHz	4.28 dB	(1)

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

3.6. Equipments used during the Test

Radiated Emission/ Radiated power						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Ultra-Broadband Antenna	SCHWARZBECK	VULB9163	538	4/5/2017	4/4/2020
2	Emi Test Receiver	R&S	ESCI	100900	2018/10/28	2019/10/28
3	Pre-amplifer	SCHWARZBECK	BBV 9742	N/A	11/14/2018	11/14/2019
4	Turntable	Maturo Germany	TT2.0-1T	/	N/A	N/A
5	Antenna Mast	Maturo Germany	CAM-4.0-P-12	/	N/A	N/A
6	Test Software	R&S	ES-K1	/	N/A	N/A

Electrostatic Discharge						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	ESD Simulator	DITO	0301-04	P1251107888	2018/8/17	2019/8/17

RF Field Strength Susceptibility						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	Next Cal.
1	Signal Generator	R&S	SMB100A	114360	8/21/2018	8/21/2019
2	Amplifier	R&S	BBA150-BC500	102664	8/21/2018	8/21/2019
3	Amplifier	R&S	BBA150 D200	102728	1/31/2018	1/31/2019
4	Amplifier	R&S	BBA150 E200	102729	1/31/2018	1/31/2019
5	Power Head	R&S	NRP18A	101010	8/21/2018	8/21/2019
6	Power Head	R&S	NRP18A	101011	8/21/2018	8/21/2019
7	Transmit Antenna	Schwarzbeck	STLP9129	00044	7/12/2017	7/12/2020
8	Field Probe	ETS-LINDGREN	HI-6153	00130812	2018/1/17	2019/1/16
9	Test Software	R&S	EMC32	100916	NA	NA

Power Frequency Magnetic Field Susceptibility						
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	NextCal.
1	Ultra Compact Simulator	EM TEST	UCS500M6	202304/060	2018/10/27	2019/10/27
2	Motor Driven Voltage Transformer	EM TEST	MV2616	302205	2018/10/27	2019/10/27
3	Current Transformer	EM TEST	MC2630	D5101	2018/11/2	2019/11/2
4	Magnetic Coil	EM TEST	MS100	0010230A	2018/11/2	2019/11/2
5	Test Software	EM TEST	ISM IEC	N/A	N/A	N/A

4. TEST CONDITIONS AND RESULTS

4.1. Radiated Emission

For test instruments and accessories used see section 3.6.

4.1.1. Description of the test location

Test location: Shielded room No. 6

4.1.2. Limits of disturbance (Class B)

Frequency (MHz)	Distance (Meters)	Field Strengths Limits (dBμV/m)
30 ~ 230	3	40
230 ~ 1000	3	47

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 turned on and measuring 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**

Band Width: 120kHz

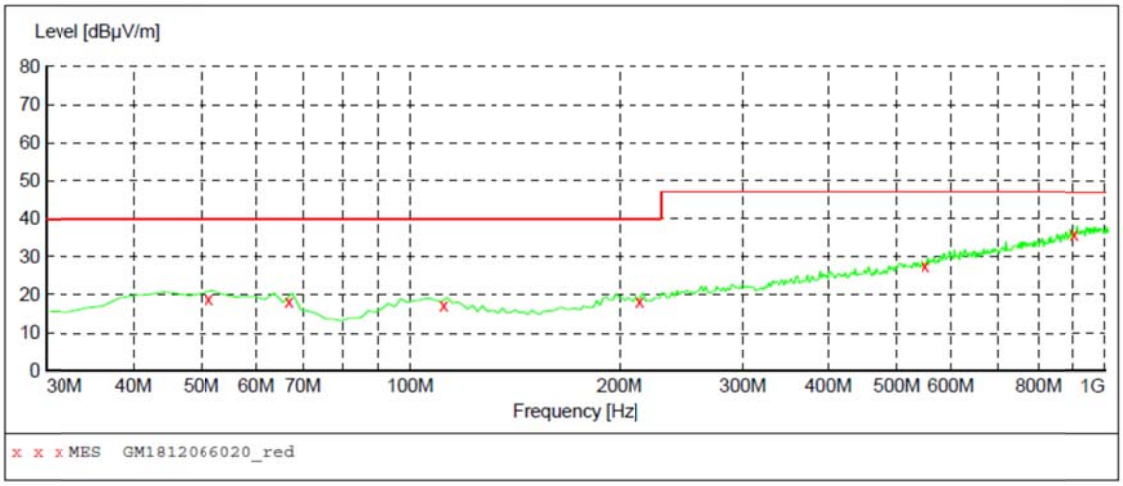
Frequency Range: 30MHz to 1000MHz

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

Margin=limit-level

Level=read values+transducer

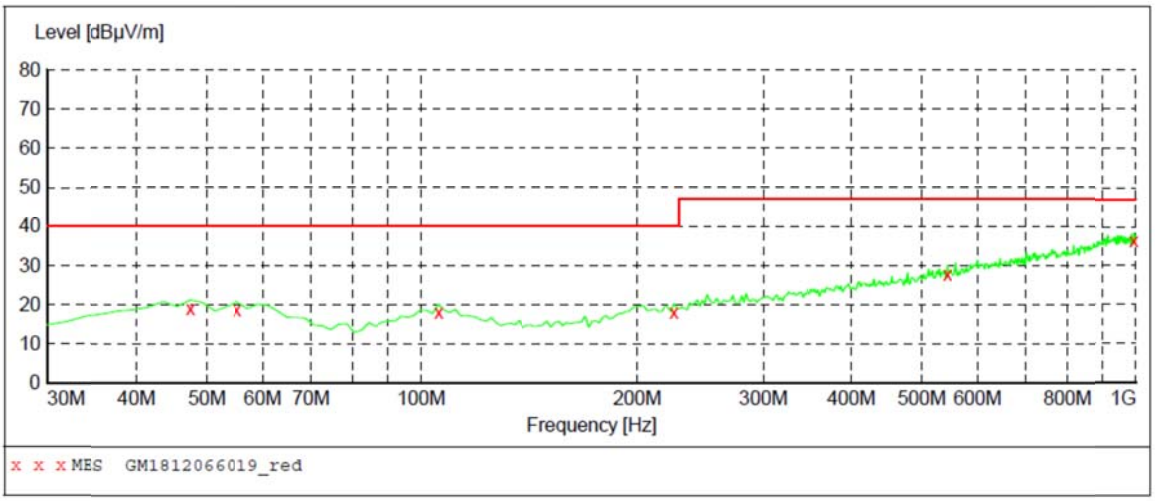
Transducer=antenna factor+pre-amplifier factor+cable loss



MEASUREMENT RESULT: "GM1812066020_fin"

12/6/2018 1:17PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
51.340000	19.00	-8.8	40.0	21.0	QP	300.0	7.00	HORIZONTAL
66.860000	18.30	-11.9	40.0	21.7	QP	100.0	237.00	HORIZONTAL
111.480000	17.20	-10.9	40.0	22.8	QP	100.0	140.00	HORIZONTAL
214.300000	18.40	-10.0	40.0	21.6	QP	300.0	7.00	HORIZONTAL
549.920000	27.50	-0.1	47.0	19.5	QP	100.0	116.00	HORIZONTAL
903.000000	36.00	7.6	47.0	11.0	QP	300.0	238.00	HORIZONTAL



MEASUREMENT RESULT: "GM1812066019_fin"

12/6/2018 1:32PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
47.460000	19.10	-8.7	40.0	20.9	QP	100.0	351.00	VERTICAL
55.220000	18.70	-9.1	40.0	21.3	QP	100.0	77.00	VERTICAL
105.660000	18.00	-10.3	40.0	22.0	QP	100.0	292.00	VERTICAL
225.940000	18.10	-9.3	40.0	21.9	QP	100.0	39.00	VERTICAL
542.160000	27.80	-0.3	47.0	19.2	QP	100.0	196.00	VERTICAL
994.180000	36.30	8.5	47.0	10.7	QP	100.0	151.00	VERTICAL

4.2. Conducted disturbance

The test is not applicable to the EUT.

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 3.6.

4.5.1. Description of the test location and date

Test location: Shielded room No. 4

Date of test: 2018-12-07

Operator: QUANHAOI DENG

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 ± 2kV, ± 4kV, ±8kV and ±15kV for air discharge and ± 8kV for contact discharge.

4.5.3. Description of the test set-up

4.5.3.1. Operating Condition

The EUT is turned on and measuring during the test and the results of the maximum susceptive results are recorded.

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:

Contact discharge voltage:	■ 8 kV			
Number of discharges:	■ 10	□ 25		
Air discharge voltage:	■ 2 kV	■ 4 kV	■ 8 kV	■ 15 kV
Number of discharges:	■ 10	□ 25		
Type of discharge:	Direct discharge	■ Air discharge ■ Contact discharge		
	Indirect discharge	■ Contact discharge		
Polarity:	■ Positive	■ Negative		
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

No change of the mode. The temperature measurement is in of the accuracy range. No degradation of function. Comply with IEC 60601-1-2: 2014.

4.6. Radiated, radio-frequency, electromagnetic field

For test instruments and accessories used see section 3.6.

4.6.1. Description of the test location and date

Test location: Shielded room No. 7

Date of test: 2018-12-06

Operator: BAOJIN LING

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 10V/m.

4.6.3. Description of the test set-up

4.6.3.1. Operating Condition

The EUT is turned on and measuring during the test and the results of the maximum susceptive results are recorded.

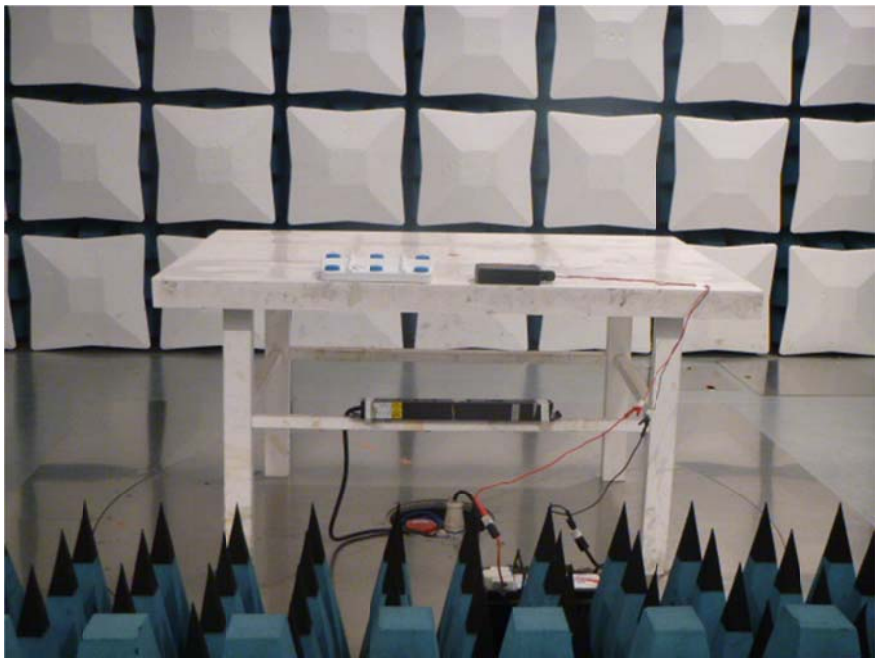
4.6.3.2. Test Procedure

EUT and its auxiliary instrument are placed on a turntable 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:

Frequency range: ■ 80 MHz to 2700 MHz

Field strength: ■ 10 V/m

EUT - antenna separation: ■ 3 m

Modulation: ■ AM: 80 %
■ sinusoidal 1KHz

Frequency step: ■ 1 % with 3s dwell time

Antenna polarisation: ■ horizontal ■ vertical

Test specifications for ENCLOSURE PORT IMMUNITY to 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	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
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

No change of the mode. The temperature measurement is in of the accuracy range. No degradation of function. Comply with IEC 60601-1-2: 2014.

4.7. Electrical fast transients / Burst

The test is not applicable to the EUT.

4.8. Surge

The test is not applicable to the EUT.

4.9. Conducted disturbances induced by radio-frequency fields

The test is not applicable to the EUT.

4.10. Magnetic Field Immunity

For test instruments and accessories used see section 3.6.

4.10.1. Description of the test location and date

Test location: Shielded room No. 8

Date of test: 2018-12-06

Operator: QUANHAOI DENG

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

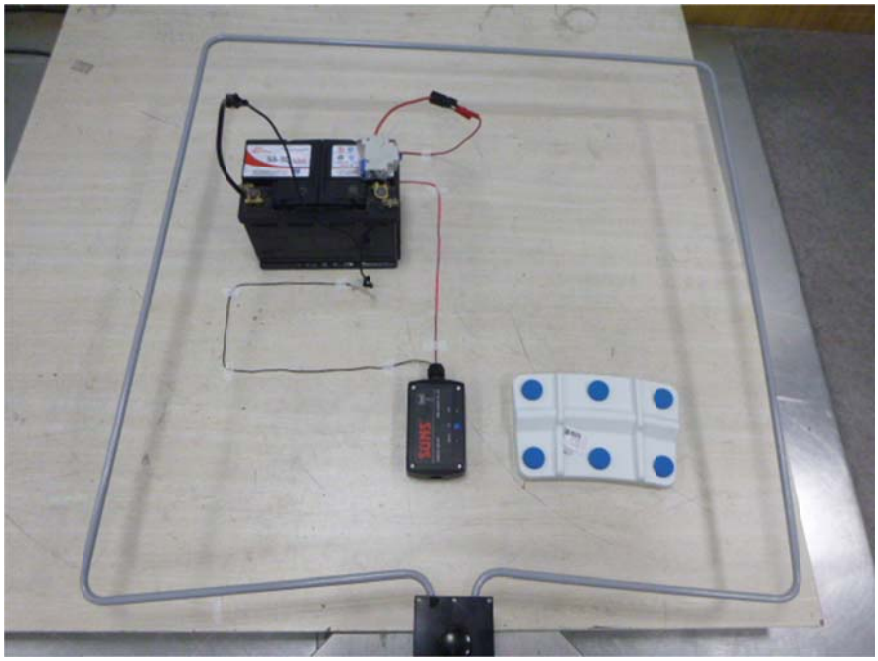
The EUT is turned on and measuring during the test and the results of the maximum susceptive results are recorded.

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 frequency:	■ 50 Hz	■ 60 Hz	
Continuous field:	■ 30 A/m		
Test duration:	■ 5 mins		
Antenna factor:	0.917 A/m		
Axis:	■ x-axis	■ y-axis	■ z-axis

4.10.5. Test result

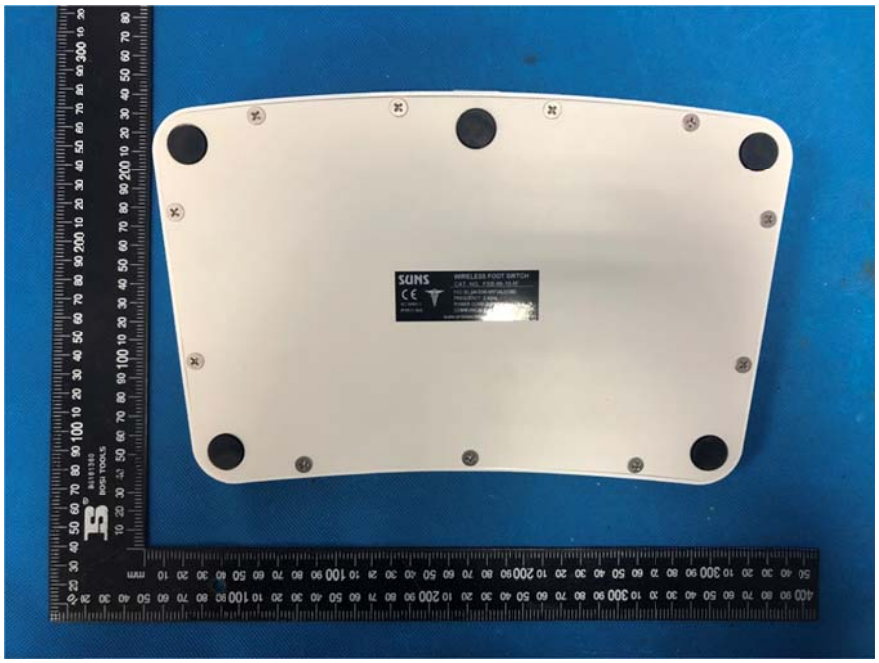
No change of the mode. The temperature measurement is in of the accuracy range. No degradation of function. Comply with IEC 60601-1-2: 2014.

4.11. Voltage Dips and Interruptions

The test is not applicable to the EUT.

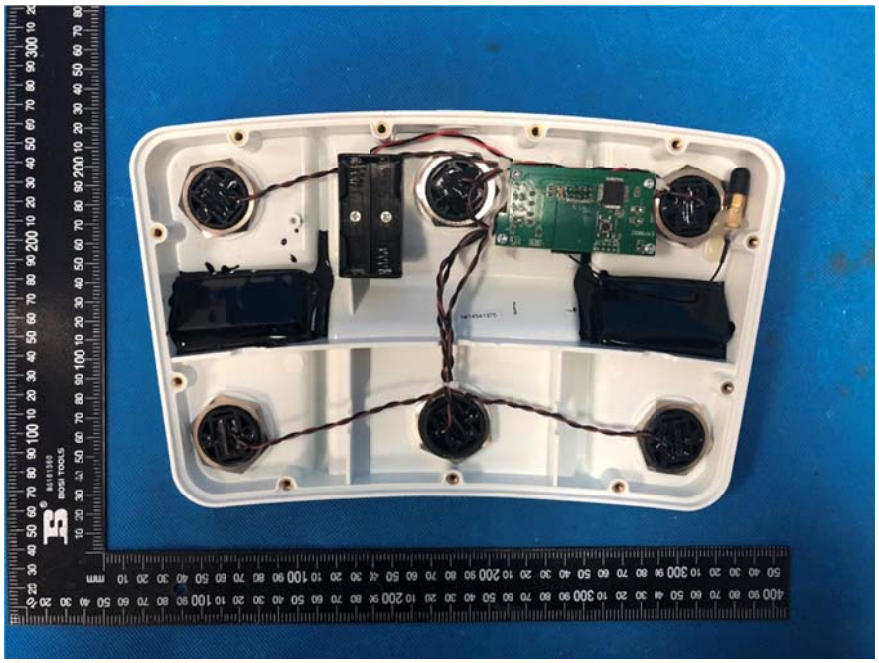
5. External and Internal Photos of the EUT

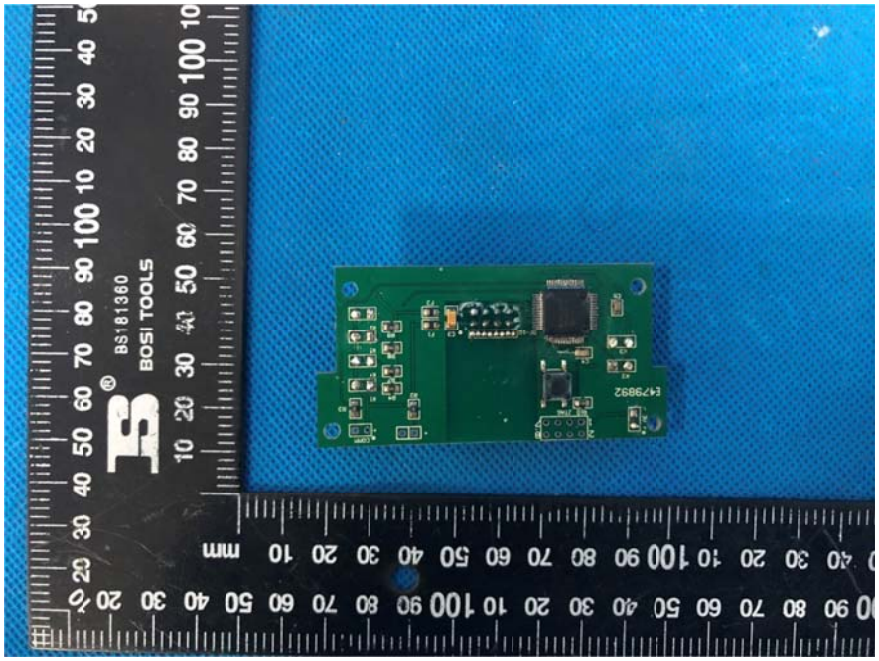
5.1. External Photos of the EUT

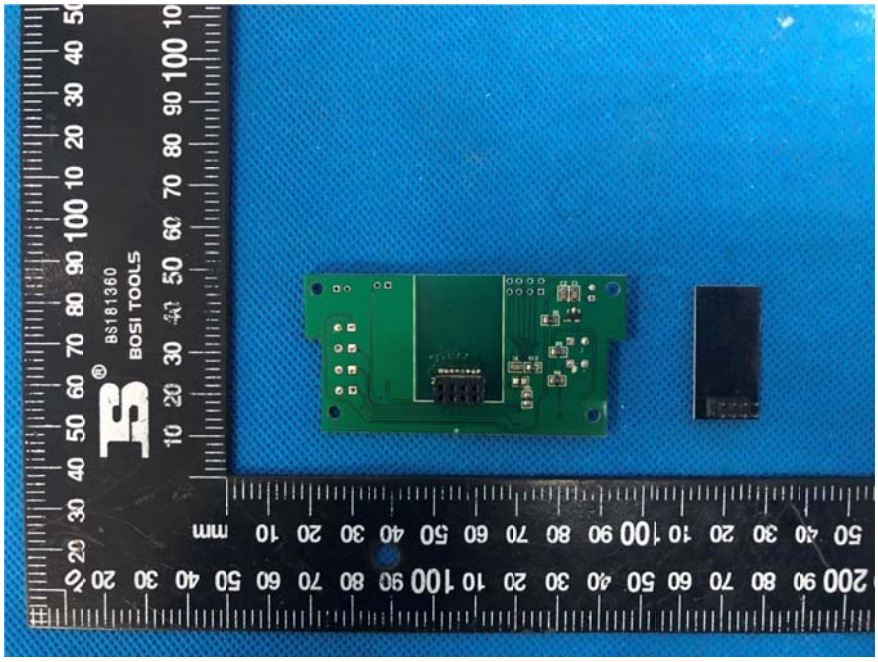



SUNS
SUNS ELECTRIC CO., LTD
WIRELESS RECEIVER
CONNECTED
SYNC
POWER

5.2. Internal photos of the EUT







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