EMC TEST REPORT

Product	:	pulse oximeter
Trade mark	:	N/A
Model/Type reference	:	YM101, YM102, YM103, YM201, YM301
Serial number	:	N/A
Ratings	:	DC 3V(2×1.5V⎓ AAA alkaline batteries)
Report number	:	EED32K003314
Date of issue	:	Apr. 26, 2019
Regulations	:	See below

Test Standards	Results
☒ IEC 60601-1-2:2014	PASS
☒ EN 60601-1-2:2015	PASS
☒ IEC 60601-1-11:2015(Clause 12)	PASS
☒ ISO 80601-2-61:2017 (Clause 202)	PASS

Prepared for:

Shenzhen Yimi Life Technology Co.,Ltd
305, Building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, Shenzhen, 518118, China

Prepared by:

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David Wang Check No.: 3177489357

Modification Record

No.	Last Report No.	Modification Description
1	EED32K003314	Initial report

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(Note: N/A means not applicable)

1. GENERAL INFORMATION

Applicant: Shenzhen Yimi Life Technology Co.,Ltd
305,Building A,Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, Shenzhen, 518118, China
Village, Pingshan District, Shenzhen, 518118, China

Manufacturer: Shenzhen Yimi Life Technology Co.,Ltd
305,Building A,Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, Shenzhen, 518118, China

Product: pulse oximeter

Trade mark: N/A

Model/Type reference: YM101, YM102, YM103, YM201, YM301

Serial number: N/A

Report number: EED32K003314

State of Sample(s): Normal

Sample Received Date: Dec. 13, 2018

Sample tested Date: Dec. 13, 2018 to Feb. 20, 2019

The tested sample(s) and the sample information are provided by the client.

2. COMPLIANCE SUMMARY

IEC 60601-1-2:2014 & EN 60601-1-2:2015			
Clause	Requirement + Test	Result - Remark	Verdict
5	Identification, Marking And Documents		Pass
5.1	Marking on the outside of ME equipment or ME equipment parts		N/A
5.2	Accompanying documents	Please refer to user manual.	Pass
5.2.1	Instructions for use	Please refer to user manual.	Pass
5.2.1.1	Requirements applicable to all ME equipment and ME systems		Pass
5.2.1.2	Requirements applicable to all ME equipment and ME systems for which the connector testing exemption specified in 6.2.2.2.c) is used		N/A
5.2.2	Technical description	Please refer to user manual.	Pass

IEC 60601-1-2:2014 & EN 60601-1-2:2015			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2.1	Requirements applicable for all ME equipment and ME systems	Please refer to user manual.	Pass
5.2.2.2	Requirements applicable to ME equipment and ME systems other than those specified for use only in shielded location		N/A
5.2.2.3	Requirements applicable to ME equipment and ME systems specified for use only in shielded location		N/A
5.2.2.4	Requirements applicable to ME equipment and ME systems that intentionally apply RF energy for diagnosis or treatment		N/A
5.2.2.5	Requirements applicable to ME equipment and ME systems that intentionally receive RF electromagnetic energy for the purpose of their operation		N/A
5.2.2.6	Requirements applicable to ME equipment and ME systems that include RF transmitters		N/A

Requirement – Test	Result/Comments	Verdict
Emissions		
Classification		
Class A or B..... :	Class B	—
Group 1 or 2..... :	Group 1	—
CISPR 11, 14-1, or 15..... :	CISPR 11	—
Limits of mains terminal disturbance voltage :	Yes	Pass
Limits for radiated disturbance..... :	Yes	Pass
Limits for disturbance power (if applicable) :	N/A	—
Harmonic Current Emissions per IEC 61000-3-2..:	N/A	—
Voltage Fluctuations and Flicker per IEC 61000-3-3	N/A	—
Immunity		
Electrostatic Discharges (ESD)..... :	Yes	Pass

Radiated RF electromagnetic Fields……..:	Yes	Pass
Electrical Fast Transients and bursts.....:	N/A	—
Surges.....:	N/A	—
Conducted Disturbances, induced by RF fields :	Yes	Pass
Voltage Dips, Interruptions, and variations :	N/A	—
Power-frequency Magnetic Fields.....:	Yes	Pass

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)
Continuous disturbance	3.1
Radiation disturbance	4.9

4. PRODUCT INFORMATION AND TEST SETUP

4.1 PRODUCT INFORMATION

Ratings: DC 3V(2×1.5V⎓ AAA alkaline batteries)

Model difference: All the models have the same circuit diagram and critical component.all the models are identical for the internal except for the following difference, The test model is YM201 and the test results are applicable to the others.

Model	YM101	YM102	YM103	YM201	YM301
Screen size	1.5inch	1.5inch	1.5inch	0.96inch	1.3inch
LED colour	Red	Green	White	Yellow, Blue	Blue

Use environment:
☐ Professional healthcare facility environment.
☒ Home healthcare environment.
☐ Special environment.

EUT description: Intended use:
The pulse oximeter is intended for measure oxygen saturation and pulse rate of adult patients in hospital, hospital type facilities.

Test mode: ON(Spot checking mode)

Main Performance and Technical Specification：

General	
Product Name:	pulse oximeter
Model:	YM201
SpO2:	Measurement range: 0~100% Resolution:1% Accuracy: 70 to 100%: ±2% 0% to 69%: unspecified.
Pulse Rate:	Measurement range: 25~250bpm Resolution:1 bpm Accuracy: ±3bpm
Width*Height*Depth:	57×31×30 mm
Max. weight	<28 g (without the batteries)

Operating conditions:	Temperature (°C):15 to 40 Humidity (non-condensing):15% to 95% Atmospheric pressure (kPa):70 to 106
Storage/transportation Conditions:	Temperature (°C):-20 to 60 Humidity (non-condensing):10% to 95% Atmospheric pressure (kPa):50 to 107.4

4.2 TEST SETUP CONFIGURATION

See test photographs attached in Appendix 1 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.	Spo2 simulator	FLUKE	INDEX 2XLFE	1519028	---	---

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.

5. FACILITIES AND ACCREDITATIONS

5.1 TEST FACLITY

All measurement facilities used to collect the measurement data are located at Hongwei Industrial Zone, 70 Area, Bao'an District, Shenzhen, Guangdong, China. The site and apparatus are constructed in conformance with the requirements of ANSI C63.4 and CISPR 16-1-1 other equivalent standards.

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

CNAS-Lab Code: L1910

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

A2LA-Lab Cert. No. 3061.01

Centre Testing International Group 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.

IC-Registration No.: 7408A

The 3m Alternate Test Site of Centre Testing International Group Co., Ltd. has been registered by Certification and Engineering Bureau of Industry Canada for the performance of radiated measurements.

IC-Registration No.: 7408B

The 10m Alternate Test Site of Centre Testing International Group Co., Ltd. has been registered by Certification and Engineering Bureau of Industry Canada for the performance of radiated measurements.

VCCI

Centre Testing International Group Co., Ltd.
Mains Ports Conducted Interference Measurement VCCI Registration No. is C-20007.
Telecommunication Ports Conducted Disturbance Measurement VCCI Registration No. is T-20008.

3m Alternate

Radiated Emission from 30MHz to 1GHz VCCI Registration No. is R-20006.
Radiated Emission from 1GHz to 6GHz VCCI Registration No. is G-20021.

10m Alternate

Radiated Emission from 30MHz to 1GHz VCCI Registration No. is R-20005.
Radiated Emission from 1GHz to 6GHz VCCI Registration No. is G-10758.

5.2 TEST EQUIPMENT LIST

Instrumentation: The following list contains equipments used at CTI for testing.
The calibrations of the measuring instruments, including any accessories that may effect such calibration, are checked frequently to assure their accuracy. Adjustments are made and correction factors applied in accordance with instructions contained in the manual for the measuring instrument.

Equipment used during the tests:

3M Semi-anechoic Chamber (1)- Radiated disturbance Test				
Equipment	**Manufacturer**	**Model**	**Serial No.**	**Due Date**
3M Chamber & Accessory Equipment	ETS-LINDGREN	FACT-3	3510	06/04/2019
Spectrum Analyzer	Agilent	E4443A	MY45300910	10/31/2019
Receiver	R&S	ESCI	100009	05/24/2019
TRILOG Broadband Antenna	schwarzbeck	VULB 9163	484	06/04/2019
Multi device Controller	ETS-LINGREN	2090	00057230	/

Shielding Room No. 3 - Electrostatic discharge Test (IEC 61000-4-2)				
Equipment	**Manufacturer**	**Model**	**Serial No.**	**Due Date**
ESD Simulator	TESEQ	NSG437	1182	07/24/2019

3M Full-anechoic Chamber - Radio-frequency electromagnetic field Test (IEC 61000-4-3)				
Equipment	**Manufacturer**	**Model**	**Serial No.**	**Due Date**
3M Chamber & Accessory Equipment	ETS-LINDGREN	FACT-3	3510	06/04/2019
ESG Vector signal generators	Agilent	E4438C	MY42082153	01/17/2020
Power Amplifier	AR	150W1000	0322288	01/17/2020
Power Amplifier	AR	25S1G4A	0321112	01/17/2020
Stacked double Log.-Per. Antenna	schwarzbeck	STLP 9128 E special	9128ES-110	/
Horn Antenna	AR	ATH800M5GA	0342530	/
5GHz Indoor Booster	---	JJ55BTA	BCJJ55BTA00 0022	/

Shielding Room No. 2 - Power-frequency magnetic fields Test (IEC 61000-4-8)				
Compact Generator	EM-Test	UCS500M/6B	V0603101093	06/26/2019
Induction Coil	EM-Test	MS100	0106-47	01/15/2020
Current Transformer	EM-Test	MC2630	0106-02	01/15/2020

5.3 LABORATORY ACCREDITATIONS AND LISTINGS

The measuring equipment utilized to perform the tests documented in this report has been calibrated once a year or in accordance with the manufacturer's recommendations, and is traceable under the ISO/IEC/EN 17025 to international or national standards. Equipment has been calibrated by accredited calibration laboratories.

6. RADIATION DISTURBANCE

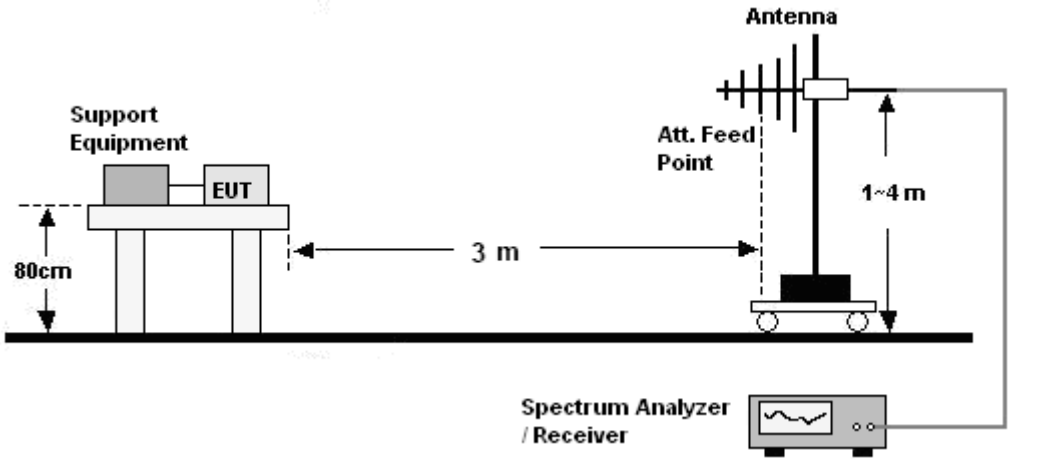
6.1 LIMITS

Limits for Group 1 class B Equipment

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.

6.2 BLOCK DIAGRAM OF TEST SETUP



6.3 TEST PROCEDURE

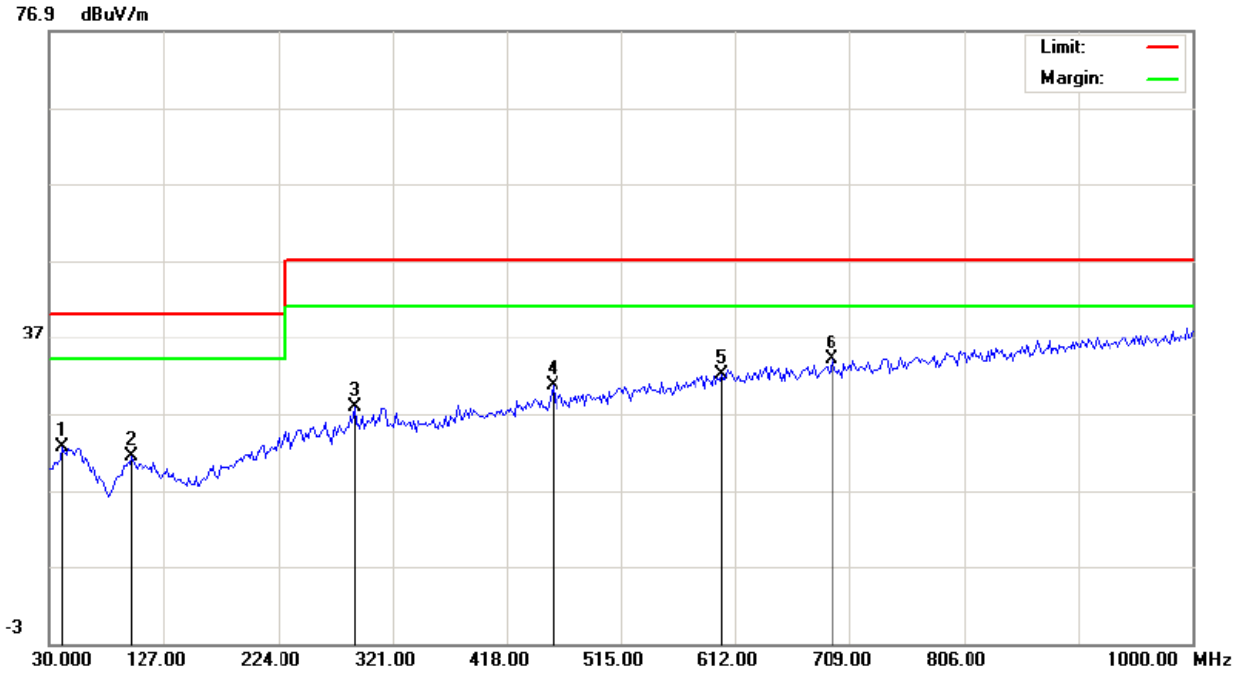
a. The Product was placed on the non-conductive turntable 0.8m above the ground at a chamber.

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.

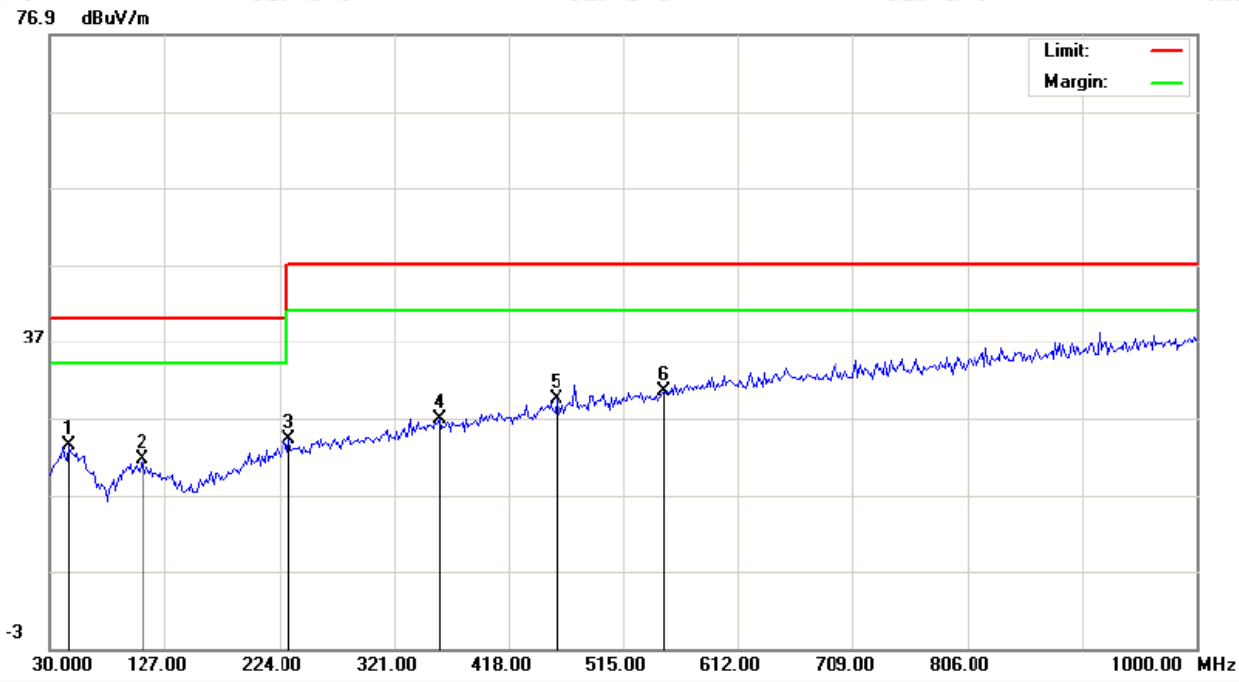
6.4 GRAPHS AND DATA

Product	:	pulse oximeter			
Model/Type reference	:	YM201	**Temperature**	:	22℃
Power	:	DC 3V	**Humidity**	:	50%
Mode	:	ON	**Polarization**	:	Horizontal



No.	Freq.	Reading_Level (dBuV)			Correct Factor	Measurement (dBuV/m)			Limit (dBuV/m)		Margin (dB)			
	MHz	Peak	QP	AVG	dB	peak	QP	AVG	QP	AVG	QP	AVG	P/F	Comment
1	41.3167	8.61	7.90		13.93	22.54	21.83		40.00		-18.17		P	
2	99.5167	8.38	7.80		12.93	21.31	20.73		40.00		-19.27		P	
3	288.6666	11.98	10.90		15.90	27.88	26.80		47.00		-20.20		P	
4	456.8000	10.50	9.90		20.02	30.52	29.92		47.00		-17.08		P	
5	600.6833	8.75	8.30		23.21	31.96	31.51		47.00		-15.49		P	
6	694.4500	9.89	9.50		24.13	34.02	33.63		47.00		-13.37		P	

Product	:	pulse oximeter			
Model/Type reference	:	YM201	**Temperature**	:	22℃
Power	:	DC 3V	**Humidity**	:	50%
Mode	:	ON	**Polarization**	:	Vertical



No.	Freq.	Reading_Level (dBuV)			Correct Factor	Measurement (dBuV/m)			Limit (dBuV/m)		Margin (dB)			
	MHz	Peak	QP	AVG	dB	peak	QP	AVG	QP	AVG	QP	AVG	P/F	Comment
1	46.1667	9.07	8.90		14.42	23.49	23.32		40.00		-16.68		P	
2	107.6000	8.99	8.80		12.53	21.52	21.33		40.00		-18.67		P	
3	232.0833	9.60	9.40		14.63	24.23	24.03		47.00		-22.97		P	
4	359.8000	8.98	8.50		17.90	26.88	26.40		47.00		-20.60		P	
5	458.4167	9.27	8.90		20.05	29.32	28.95		47.00		-18.05		P	
6	548.9500	8.50	8.30		21.97	30.47	30.27		47.00		-16.73		P	

7. IMMUNITY TEST

Immunity Performance Criteria
Required by IEC 60601-1-2:2014
During the immunity tests, the EUT was operated under conditions specified by clause 4.1 of this report. The particular performance criterion for the immunity tests are specified by manufacturer, with reference to the exampls in Annex I of IEC 60601-1-2:2014. The equipment or system shall be able to provide the essential performance and remain safe. The following degradations associated with essential performance and safety shall not be allowed: – malfunction; – non-operation when operation is required; – unwanted operation when no operation is required; – deviation from normal operation that poses an unacceptable RISK to the PATIENT or OPERATOR; – 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. For equipment and systems with multiple functions, the criteria apply to each function, parameter and channel. The equipment and systems may exhibit degradation of performance (e.g. deviation from manufacturer's specifications) that does not affect essential performance or safety.

Required by ISO 80601-2-61:2017(Clause 202)

IEC 60601‑1‑2:2014 applies except as follows:

202.4.3.1 Configurations

Amendment (replace the second dash of 4.3.1 with):

– setting the SpO2 within the calibrated range to be at least 5 % different from that of a noiseinduced value and less than (100 % minus the SpO2 ACCURACY of the PULSE OXIMETER EQUIPMENT).

This shall apply to IMMUNITY testing of PULSE OXIMETER EQUIPMENT.

NOTE The noise‑induced value could be a value, e.g. where R = 1 or R is the ratio of the gain from the IR channel to the gain from the red channel. Other noise‑induced values have been observed.

– setting the pulse rate to be different from that of the noise‑induced signal frequency and within the specified range of the pulse rate display.

The SpO2 and pulse rate signal may be derived from a PATIENT simulator for these tests.

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Additional subclause:

202.8.1.101 Additional general requirements

Under the IMMUNITY TEST LEVELS specified in IEC 60601‑1‑2:2014, 8.9, PULSE OXIMETER EQUIPMENT shall be able to
provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE shall not be allowed:

– component failures;

– changes in programmable parameters or settings;

– reset to default settings; and

– change of operating mode.

The PULSE OXIMETER EQUIPMENT may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE providing the PULSE OXIMETER EQUIPMENT recovers from any disruption within 30 s without OPERATOR intervention.

202.8.2 PATIENT physiological simulation

Amendment (add between the first and second paragraph):

During IMMUNITY testing, the PULSE OXIMETER EQUIPMENT shall be tested at an SpO2 reading within the calibrated range that is at least 5 % different from that of a noise‑induced value and less than (100 % minus the SpO2 ACCURACY of the PULSE OXIMETER EQUIPMENT).

NOTE 2 The noise‑induced value could be a value, e.g. where R = 1 or R is the ratio of the gain from the IR channel to the gain from the red channel. Other noise‑induced values have been observed.

The pulse rate shall be different from that of the noise‑induced signal frequency and within the specified range of the pulse rate display.

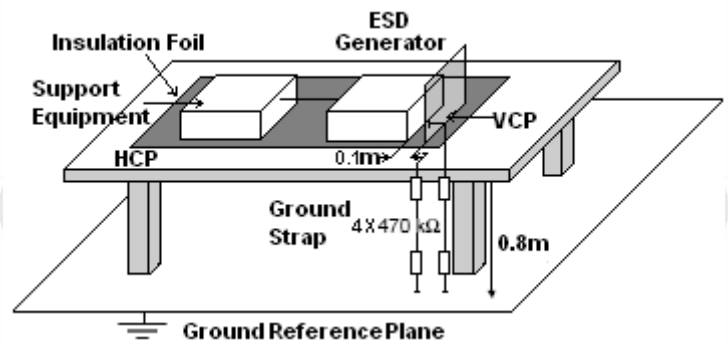
The SpO2 and pulse rate signal may be derived from a PATIENT simulator for these tests.

7.1 ELECTROSTATIC DISCHARGE

7.1.1 TEST SPECIFICATION

Basic Standard	:	IEC 61000-4-2:2008
Test Port	:	Enclosure port
Discharge Impedance	:	330 ohm / 150 pF
Discharge Mode	:	Single Discharge
Discharge Period	:	one second between each discharge

7.1.2 BLOCK DIAGRAM OF TEST SETUP



7.1.3 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.

7.1.4 RESULTS & PERFORMANCE

Product : pulse oximeter
Model/Type reference : YM201
Power : DC 3V **Temperature** : 24℃
Mode : ON **Humidity** : 56%

Discharge Method	Discharge Position	Voltage (±kV)	Min. No. of Discharge per polarity (Each Point)	Meet the Immunity Performance Criteria
Contact Discharge	Conductive Surfaces	8	10	EUT Operated as intended, no degradation of function
	Indirect Discharge VCP	8	10	
	Indirect Discharge HCP	8	10	
Air Discharge	Slots, Apertures, and Insulating Surfaces	2,4,8,15*	10	

*:The product restart by air discharge 15KV in USB port.

Device-Specific Function	Device-Specific Pass/Fail Criteria (Immunity pass/fail criteria)	Detection/Testing Method (how to monitor device-specific functions)	Test results
SpO2 Accuracy	Accuracy: ±2%（70%~100%） Pulse Rate:Accuracy: ±3bpm	Spo2 simulator	Within Range

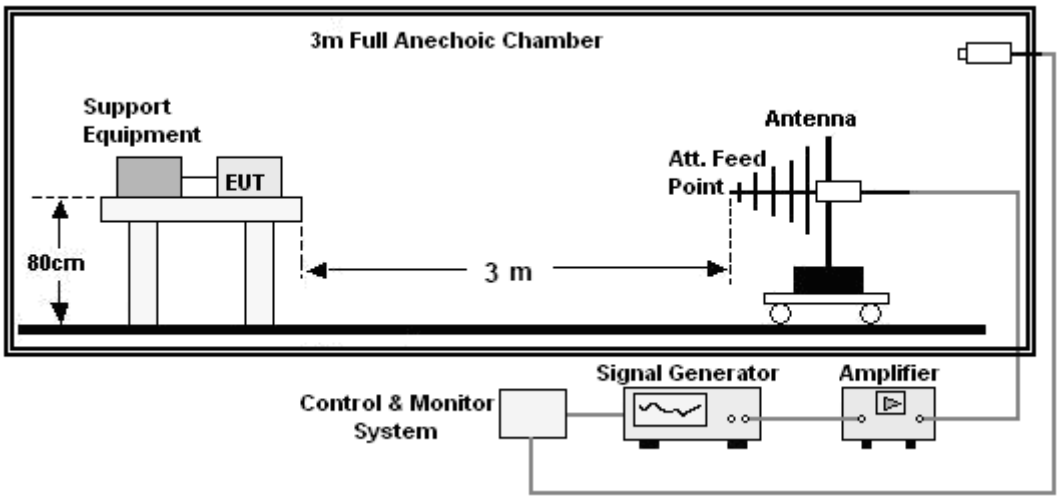
7.2 RADIO FREQUENCY ELECTROMAGNETIC FIELDS

7.2.1 TEST SPECIFICATION

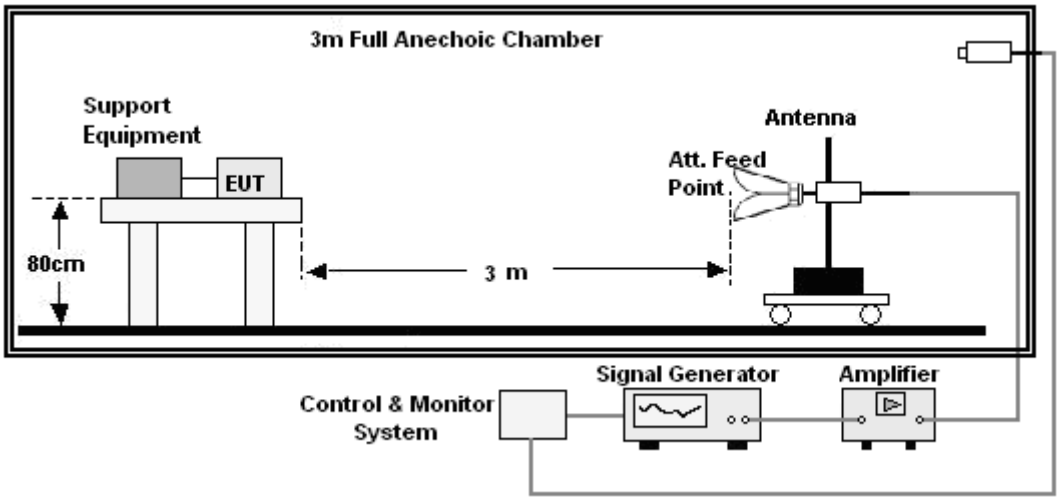
Basic Standard	:	IEC 61000-4-3:2006+A1:2007+A2:2010
Test Port	:	Enclosure port
Step Size	:	1%
Modulation	:	1kHz, 80% AM
Dwell Time	:	1 second
Polarization	:	Horizontal & Vertical

7.2.2 BLOCK DIAGRAM OF TEST SETUP

Below 1GHz:



Above 1GHz:



7.2.3 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. The rate of sweep did not exceed 1.5x 10^{-3} decade/s. Where the frequency range is swept incrementally, the step size was 1%.

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

7.2.4 RESULT & PERFORMANCE

Product : pulse oximeter
Model/Type reference : YM201
Power : DC 3V **Temperature** : 24℃
Mode : ON **Humidity** : 53%

Frequency (MHz)	Position	Field Strength (V/m)	Meet the Immunity Performance Criteria
80 - 2700	Front, Right, Back, Left	10	EUT Operated as intended, no degradation of function.
See the Figure 1	Front, Right, Back, Left	See the Figure 1	EUT Operated as intended, no degradation of function.

☑ There was no observable degradation in performance.

Device-Specific Function	Device-Specific Pass/Fail Criteria (Immunity pass/fail criteria)	Detection/Testing Method (how to monitor device-specific functions)	Test results
SpO2 Accuracy	Accuracy: ±2%（70%~100%） Pulse Rate:Accuracy: ±3bpm	Spo2 simulator	Within Range

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 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 [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

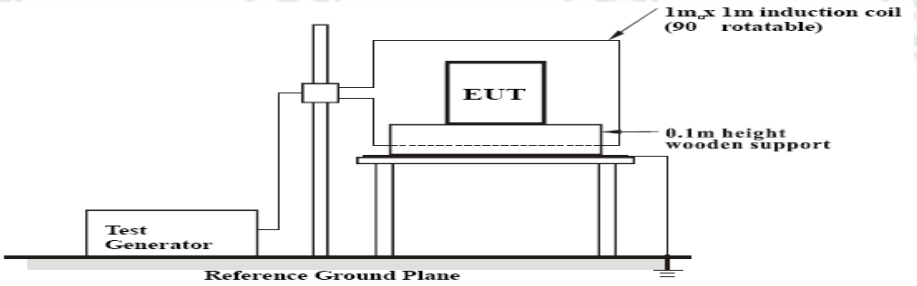
Figure 1

7.3 POWER-FREQUENCY MAGNETIC FIELDS

7.3.1 TEST SPECIFICATION

Basic Standard	:	IEC 61000-4-8:2009
Test Port	:	Enclosure port
Power Frequency	:	50Hz/60Hz
Duration	:	5 Min
Direction	:	X axis Y axis Z axis

7.3.2 BLOCK DIAGRAM OF TEST SETUP



7.3.3 TEST PROCEDURE

a. The Product and support units were located on a table, 0.8m away from ground floor.
b. The Product is configured and connected to satisfy its functional requirements. It shall be place on the GRP with the interposition of a 0.1m thickness insulating support (e.g. dry wood)
c. Setting the parameter of tests and then perform the test software of test simulator.
d. The induction coil shall enclose the Product placed at its centre.

7.3.4 RESULTS & PERFORMANCE

Product	:	pulse oximeter			
Model/Type reference	:	YM201			
Power	:	DC 3V	**Temperature**	:	24℃
Mode	:	ON	**Humidity**	:	56%

Direction	Field Strength (A/m)	Duration (Min)	Meet the Immunity Performance Criteria
X axis	30	5	EUT Operated as intended, no degradation of function.
Y axis	30	5	
Z axis	30	5	

☑ There was no observable degradation in performance.

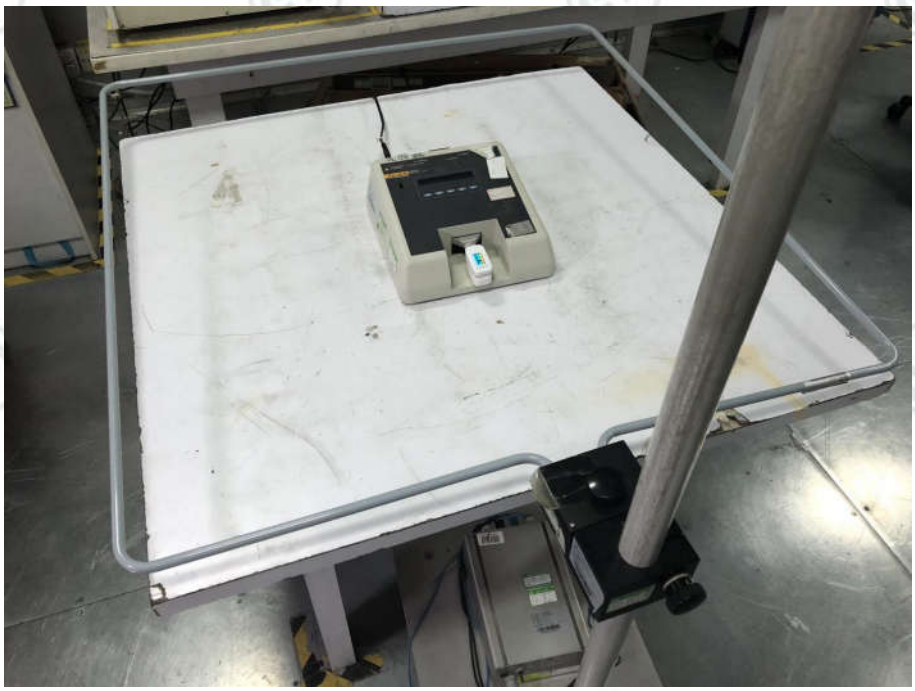
Device-Specific Function	Device-Specific Pass/Fail Criteria (Immunity pass/fail criteria)	Detection/Testing Method (how to monitor device-specific functions)	Test results
SpO2 Accuracy	Accuracy: ±2%（70%~100%） Pulse Rate:Accuracy: ±3bpm	Spo2 simulator	Within Range

APPENDIX 1 PHOTOGRAPHS OF TEST SETUP

Radiation Disturbance Test Setup

Electrostatic Discharge Test Setup

Radio Frequency Electromagnetic Fields Test Setup



Power-frequency magnetic fields

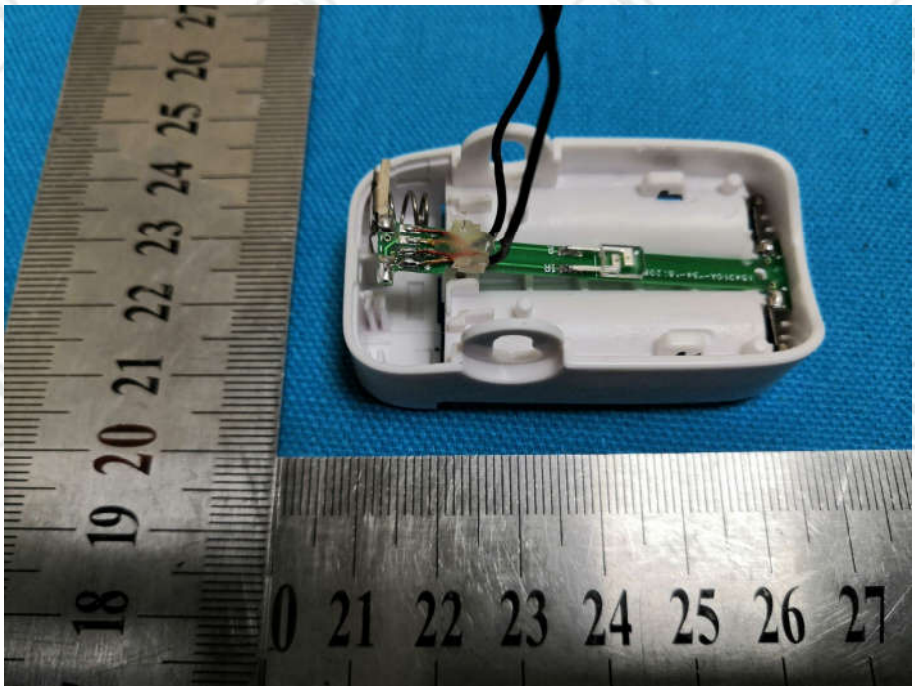
APPENDIX 2 PHOTOGRAPHS OF PRODUCT

View of Product-1

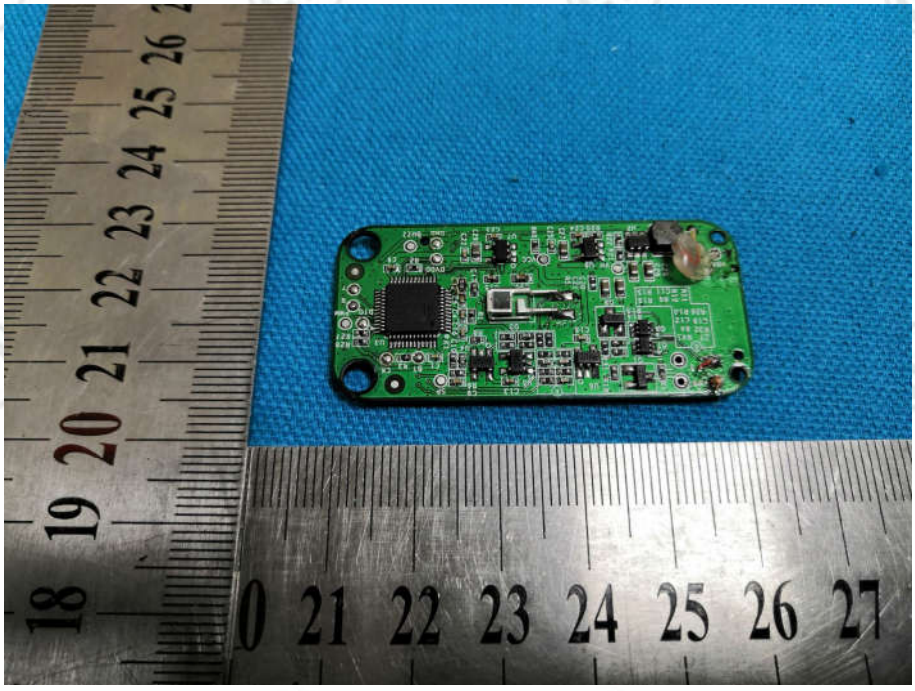
View of Product-2

View of Product-3

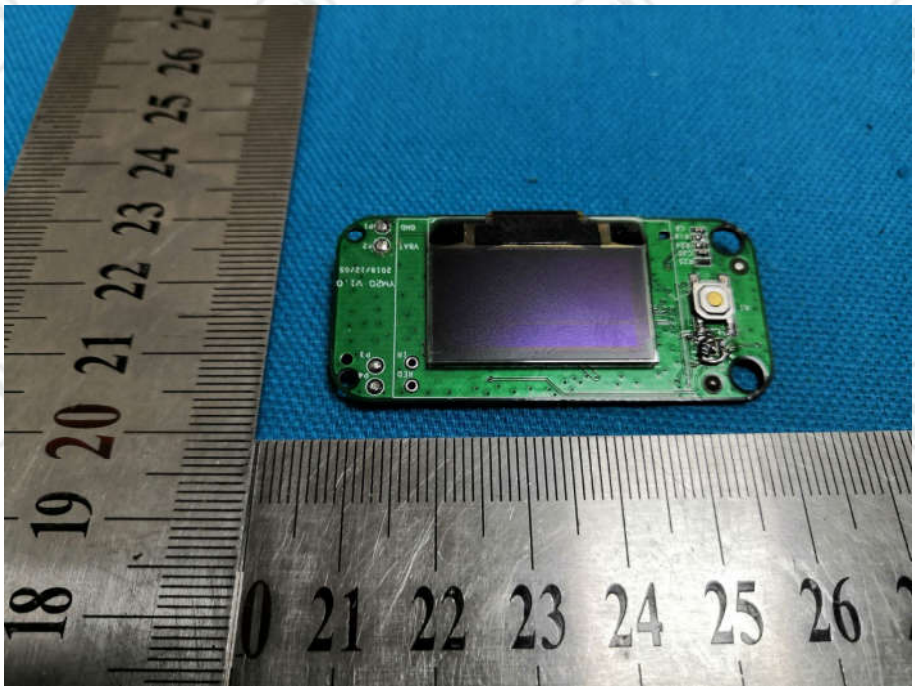
View of Product-4



View of Product-5



View of Product-6



View of Product-7

*** End of Report ***