# EMC TEST REPORT

For

Longnan Renzhong Medical Equipment Co., Ltd

Product Name: INFRARED BODY THERMOMETER

Model No.: YK001, YK002, YK003, YK004

| | | |
|---|---|---|
| Prepared for | : | Longnan Renzhong Medical Equipment Co., Ltd |
| Address | : | Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi province, China |
| Testing Laboratory | : | SHENZHEN CTO TECHNOLOGY CO., LTD |
| Address | : | 9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China |
| Report No. | : | CTO200312012URE |
| Date of Receiver | : | Mar. 09, 2020 |
| Number of tested samples | : | 1 |
| Date of Test | : | Mar. 09, 2020 – Mar. 12, 2020 |
| Date of Report | : | Mar. 12, 2020 |

***Note:*** *This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of SHENZHEN CTO TECHNOLOGY CO., LTD*

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# 1. GENERAL INFORMATION

## 1.1. Description of Device (EUT)

| | | |
|---|---|---|
| EUT | : | INFRARED BODY THERMOMETER |
| Trade Name | : | AFK |
| Model | : | YK001 |
| Supplementary Model | : | YK002, YK003, YK004 |
| Voltage Rating | : | Battery: DC 1.5V×2(AAA) |
| Applicant | : | Longnan Renzhong Medical Equipment Co., Ltd |
| Address | : | Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi province, China |
| Manufacturer | : | Longnan Renzhong Medical Equipment Co., Ltd |
| Address | : | Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi province, China |
| Test Standards | : | EN 60601-1-2:2015<br>EN 55011:2016/A1:2017<br>EN 61000-3-2:2019<br>EN 61000-3-3:2013+A1:2019 |
| Date of Receiver | : | Mar. 09, 2020 |
| Date of Test | : | Mar. 09, 2020–Mar. 12, 2020 |
| Test Results | : | Pass |
| Test Engineer | : | |
| Reviewed By | : | |

## 1.2. Test Standards

| Test Standards | |
|---|---|
| EN 60601-1-2:2015 | Electromagnetic compatibility - Requirements and tests |
| EN 55011:2016/A1:2017 | Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement |
| EN 61000-3-2:2019 | Electromagnetic compatibility(EMC)-Part 3-2:Limits-Limits for harmonic current emissions(equipment input current ≤16A per phase) |
| EN 61000-3-3:2013+A1:2019 | Electromagnetic compatibility(EMC)-Part 3-3:Limits-Limitation of voltage changes,Voltage fluctuations and fliker in public low-voltage supply systems. For equipment with Rated current ≤ 16A per phase and not subject to conditional connection |

## 1.3. Test Summary

P Indicates that the test is applicable
N/A Indicates that the test is not applicable

| Standard | Test Items | Status |
|---|---|---|
| EN 55011:2016/A1:2017 | Disturbance Voltage at The Mains Terminals (150KHz To 30MHz) | N/A |
| | Radiated Disturbances (30MHz To 1000MHz) | P |
| EN 61000-3-2:2019 | Harmonic Current | N/A |
| EN 61000-3-3:2013+A1:2019 | Voltage Fluctuations | N/A |
| EN 61000-4-2:2009 | Electrostatic discharge Immunity | P |
| EN 61000-4-3:2006+A2:2010 | Radiated Susceptibility (80MHz to 1GHz) | P |
| EN 61000-4-4:2012 | Electrostatic Fast Transient/Burst Immunity | N/A |
| EN 61000-4-5:2014+A1:2017 | Surge Immunity | N/A |
| EN 61000-4-6:2014+AC:2015 | Conducted Susceptibility (150KHz to 80MHz) | N/A |
| EN 61000-4-8:2010 | Power Frequency Magnetic Field Immunity (50/60Hz) | P |
| EN 61000-4-11:2004+A1:2017 | Voltage Dips Short Interruptions Immunity Tests | N/A |

## 1.4.Test Methodology

All measurements contained in this report were conducted with CISPR 16-1, radio disturbance and immunity measuring apparatus, and CISPR16-2, Method of measurement of disturbances and immunity.
All measurement required was performed at laboratory of SHENZHEN CTO TECHNOLOGY CO., LTD

## 1.5.EUT operation mode

1.5.1 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none.<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

1.5.2 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use.

## 1.6.Test Facility

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

SHENZHEN CTO TECHNOLOGY 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: 2017 General Requirements) for the Competence of Testing and Calibration Laboratories.

The facility also complies with the radiated and AC line conducted test site criteria set forth in CISPR 16-1, CISPR16-2.

# 2. MEASURING DEVICE AND TEST EQUIPMENT

## 2.1.For Power Line Conducted Emission

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Test Receiver | Rohde & Schwarz | ESPI TEST RECEIVER | ID:1164.6607K03-102109-MH | Dec. 11, 2019 |
| 2. | L.I.S.N | Rohde & Schwarz | ESH3-Z5.831.5518.52 | 9561-G071 | Dec. 11, 2019 |
| 3. | 50ΩCoaxial Switch | Anritsu | MP59B | M20531 | N/A |
| 4. | Pulse Limiter | SCHWARZ BECK | VTSD 9561-F Pulse limiter 10dB Ateennator | 561-G071 | Dec. 11, 2019 |
| 5. | Cable | SCHWARZ BECK | N/A | N/A | Dec. 11, 2019 |

## 2.2.For Radiated Emission Measurement

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Test Receiver | Rohde & Schwarz | ESPI TEST RECEIVER | ID:1164.6607K03-102109-MH | Dec. 11, 2019 |
| 2. | Bilog Antenna | Sunol Sciences | Model JB6 Antenna | A090414 | Dec. 11, 2019 |
| 3. | 50ΩCoaxial Switch | Anritsu | MP59B | M20531 | N/A |
| 4. | control | Positioning Controller | Model MF-7802 | MF780208362 | Dec. 11, 2019 |
| 5. | Cable | SCHWARZ BECK | N/A | N/A | Dec. 11, 2019 |
| 6. | Cable | SCHWARZ BECK | N/A | N/A | Dec. 11, 2019 |

## 2.3.For Harmonic Current / Flicker Measurement

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Coupling decoupling network | SCHAFFNER | M016 | 20812 | Dec. 11, 2019 |
| 2. | PC | N/A | P2L97 | N/A | Dec. 11, 2019 |

## 2.4. For Electrostatic Discharge Immunity Test

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | ESD Tester | Prima | ESD61002A | 144305 | Dec. 11, 2019 |

## 2.5. For RF Strength Susceptibility Test

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Signal Generator | HP | 8648A | 3625U00573 | Dec. 11, 2019 |
| 2. | Amplifier | AR | 500A100 | 17034 | NCR |
| 3. | Amplifier | AR | 100W/1000M1 | 17028 | NCR |
| 4. | Isotropic Field Monitor | AR | FM2000 | 16829 | NCR |
| 5. | Isotropic Field Probe | AR | FP2000 | 16755 | Dec. 11, 2019 |
| 6. | Biconic Antenna | EMCO | 3108 | 9507-2534 | NCR |
| 7. | Log-periodic Antenna | AR | AT1080 | 16812 | NCR |
| 8. | PC | N/A | 486DX2 | N/A | N/A |

## 2.6. For Electrical Fast Transient /Burst Immunity Test

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Burst Tester | HTEC | HEFT 51 | 144303 | Dec. 11, 2019 |
| 2. | Coupling Clamp | HTEC | IP-4A | 147147 | Dec. 11, 2019 |

## 2.7. For Surge Immunity Test

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Surge Tester | HTEC | HCWG | 144302 | Dec. 11, 2019 |

## 2.8. For Injected Current Susceptibility Test

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Simulator | EMTEST | CWS500C | 0900-12 | Dec. 11, 2019 |
| 2. | CDN | EMTEST | CDN-M2 | 5100100100 | Dec. 11, 2019 |
| 3. | CDN | EMTEST | CDN-M3 | 0900-11 | Dec. 11, 2019 |
| 4. | Injection Clamp | EMTEST | F-2031-23MM | 368 | Dec. 11, 2019 |
| 5. | Attenuator | EMTEST | ATT6 | 0010222A | Dec. 11, 2019 |

## 2.9. For Magnetic Field Immunity Test

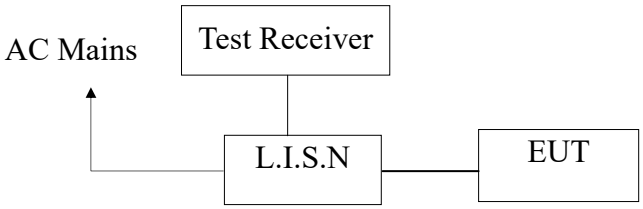
| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Magnetic Field Tester | HTEC | HPFM T | 144301 | Dec. 11, 2019 |

## 2.10. For Voltage Dips and Interruptions Test

| Item | Equipment | Manufacturer | Model No. | Factory Number | Last Cal. |
|---|---|---|---|---|---|
| 1. | Dips Tester | HTEC | HPFS | 144304 | Dec. 11, 2019 |

# 3. POWER LINE CONDUCTED EMISSION MEASUREMENT

## 3.1.Block Diagram of Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 3.2.Measuring Standard

EN 55011:2016/A1:2017

Power Line Conducted Emission Limits (Class B)

| Frequency (MHz) | Limit (dBμV) | |
|---|---|---|
| | Quasi-Peak Level | Average Level |
| 0.15 ~ 0.50 | 66.0 ~ 56.0 * | 56.0 ~ 46.0 * |
| 0.50 ~ 5.00 | 56.0 | 46.0 |
| 5.00 ~ 30.00 | 60.0 | 50.0 |
| NOTE1-The lower limit shall apply at the transition frequencies.<br>NOTE2-The limit decreases linearly with the logarithm of the frequency in the range 0.15MHz to 0.50MHz. | | |

## 3.3.EUT Configuration on Measurement

The following equipments are installed on Conducted Emission Measurement to meet CISPR 11 requirements and operating in a manner which tends to maximize its emission characteristics in a normal application.

## 3.4.Operating Condition of EUT

### 3.4.1. EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none .<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

3.4.2. The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use.

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

## 3.5. Test Procedure

The EUT is put on the plane 0.8m high above the ground by insulating support and connected to the AC mains through Line Impedance Stability Network (L.I.S.N). This provided a 50ohm coupling impedance for the tested equipments. Both sides of AC line are investigated to find out the maximum conducted emission according to the CISPR 11 regulations during conducted emission measurement.

The bandwidth of the field strength meter (R&S Test Receiver ESCS30) is set at 9KHz in 150KHz~30MHz and 200Hz in 9KHz~150KHz.

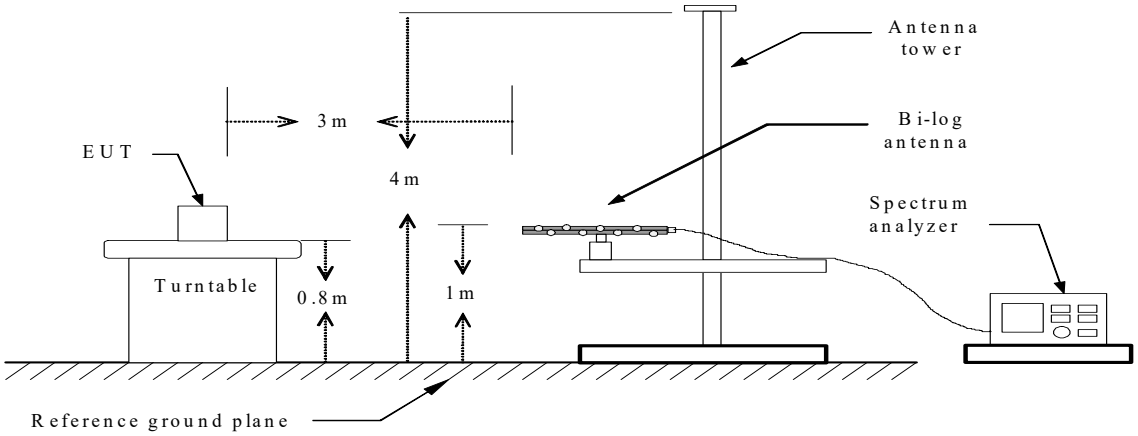
The frequency range from 150kHz to 30MHz is investigated .

Conduction Uncertainty: Uc = ± 2.72 dB

# 4. RADIATED EMISSION MEASUREMENT

## 4.1.Block Diagram of Test

### 4.1.1.Block diagram of test setup (In chamber)




## 4.2.Measuring Standard

EN 55011:2016/A1:2017

## 4.3.Radiated Emission Limits

All emanations from a class B device or system, including any network of conductors and apparatus connected thereto, shall not exceed the level of field strengths specified below:

| FREQUENCY (MHz) | DISTANCE (Meters) | FIELD STRENGTHS LIMIT (dBμV/m) |
|---|---|---|
| 30 ~ 230 | 3 | 40 |
| 230 ~ 1000 | 3 | 47 |

Note: (1) The smaller limit shall apply at the combination point between two frequency bands.

(2) Distance refers to the distance in meters between the measuring instrument antenna and the closed point of any part of the EUT.

## 4.4.EUT Configuration on Test

The CISPR 11 regulations test method must be used to find the maximum emission during radiated emission measurement.

## 4.5.Operating Condition of EUT

4.5.1.Setup the EUT and simulators as shown in Section4.1.

4.5.2.During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena.

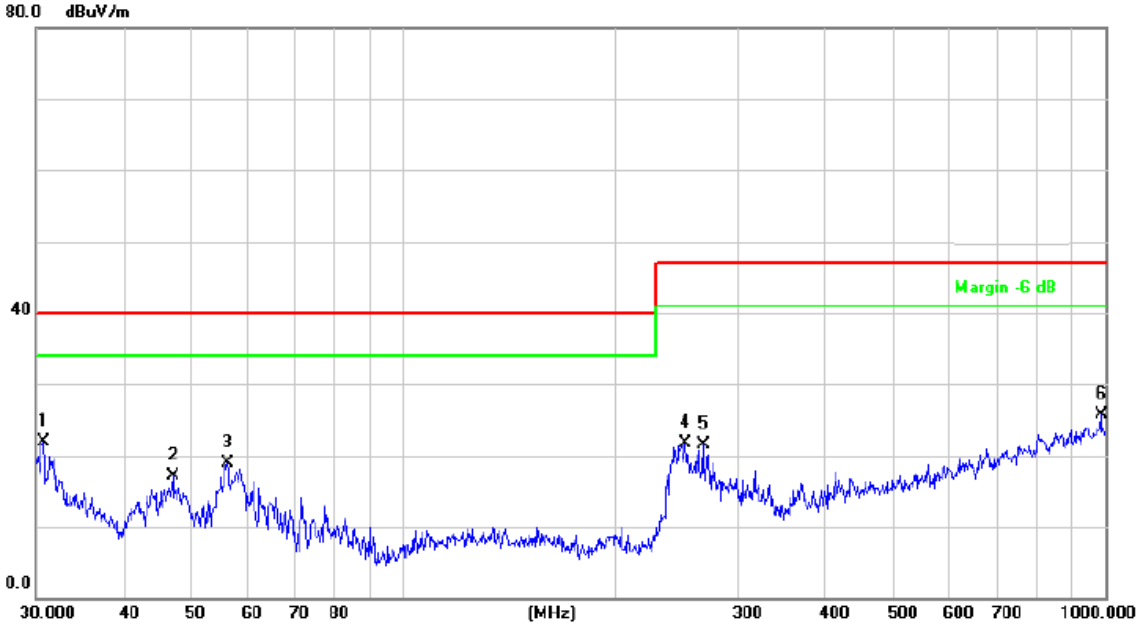
## 4.6.Test Procedure

The EUT is placed on a turn table which is 0.8 meter high above the ground. The turn table can rotate 360 degrees to determine the position of the maximum emission level. The EUT is set 3 meters away from the receiving antenna which is mounted on a antenna tower. The antenna can be moved up and down from 1 to 4 meters to find out the maximum emission level. Bilog antenna (calibrated by Dipole Antenna) is used as a receiving antenna. Both horizontal and vertical polarization of the antenna are set on test.

The bandwidth of the Receiver (ESCI 3) is set at 120KHz below 1 GHz.
Above 1 GHz (1MHz resolution bandwidth)

# Radiated Emission Test Data

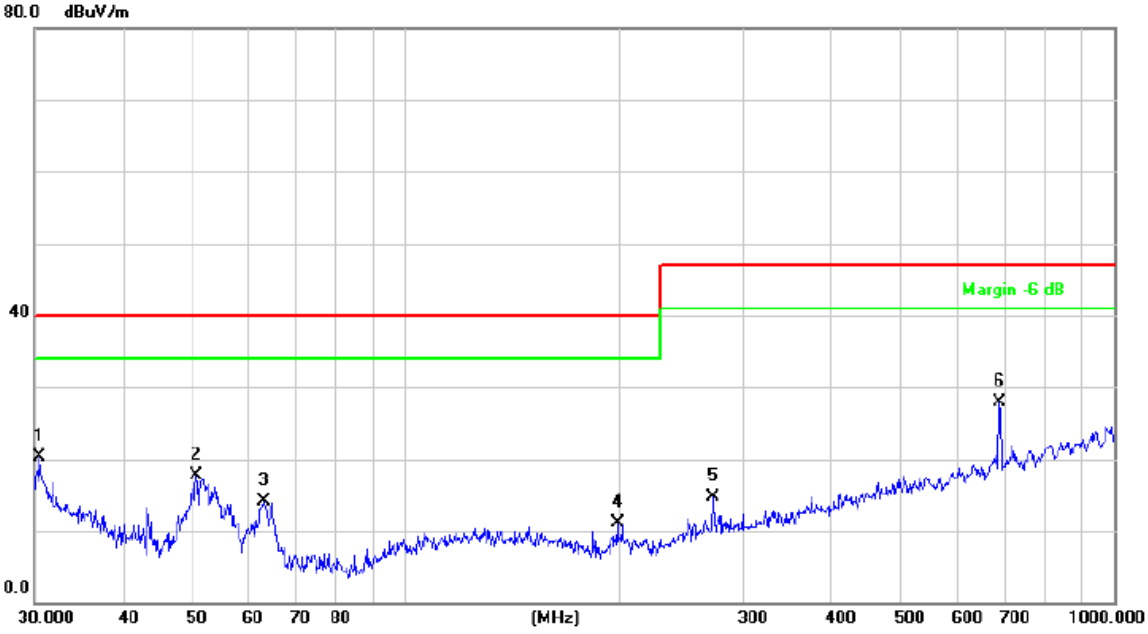
| | | | |
|---|---|---|---|
| EUT : | INFRARED BODY THERMOMETER | Temperature: | 20℃ |
| M/N : | YK001 | Humidity : | 50% |
| Test Voltage : | DC 1.5V×2(AAA) | Test Mode : | ON |
| Test Engineer : | Bill | Polarization : | Horizontal |




| No. | Mk. | Freq. | Reading Level | Correct Factor | Measure-ment | Limit | Over | | Antenna Height | Table Degree | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | MHz | dBuV | dB/m | dBuV/m | dBuV/m | dB | Detector | cm | degree | Comment |
| 1 | * | 30.7455 | 26.02 | -4.14 | 21.88 | 40.00 | -18.12 | QP | | | |
| 2 | | 46.9948 | 33.46 | -16.32 | 17.14 | 40.00 | -22.86 | QP | | | |
| 3 | | 56.1974 | 37.75 | -18.88 | 18.87 | 40.00 | -21.13 | QP | | | |
| 4 | | 252.0627 | 34.85 | -13.16 | 21.69 | 47.00 | -25.31 | QP | | | |
| 5 | | 267.5455 | 33.26 | -11.66 | 21.60 | 47.00 | -25.40 | QP | | | |
| 6 | | 986.0717 | 24.27 | 1.36 | 25.63 | 47.00 | -21.37 | QP | | | |

# Radiated Emission Test Data

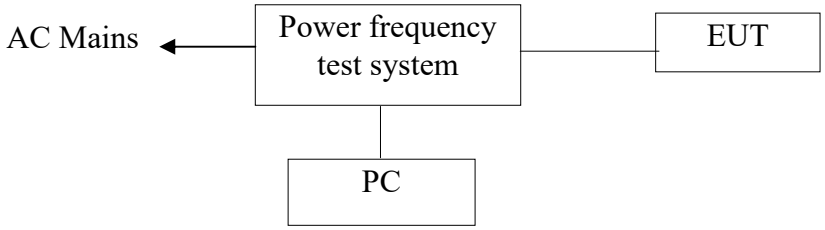
| | | | |
|---|---|---|---|
| EUT : | INFRARED BODY THERMOMETER | Temperature: | 20℃ |
| M/N : | YK001 | Humidity : | 50% |
| Test Voltage : | DC 1.5V×2(AAA) | Test Mode : | ON |
| Test Engineer : | Bill | Polarization : | Vertical |




| No. | Mk. | Freq. | Reading Level | Correct Factor | Measure-ment | Limit | Over | | Antenna Height | Table Degree | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | MHz | dBuV | dB/m | dBuV/m | dBuV/m | dB | Detector | cm | degree | Comment |
| 1 | | 30.5305 | 25.73 | -5.34 | 20.39 | 40.00 | -19.61 | QP | | | |
| 2 | | 50.7637 | 36.42 | -18.62 | 17.80 | 40.00 | -22.20 | QP | | | |
| 3 | | 63.3132 | 33.07 | -18.88 | 14.19 | 40.00 | -25.81 | QP | | | |
| 4 | | 199.2855 | 24.14 | -13.00 | 11.14 | 40.00 | -28.86 | QP | | | |
| 5 | | 271.3245 | 26.54 | -11.79 | 14.75 | 47.00 | -32.25 | QP | | | |
| 6 | * | 689.5643 | 31.28 | -3.43 | 27.85 | 47.00 | -19.15 | QP | | | |

# 5. HARMONIC CURRENT EMISSION MEASUREMENT

## 5.1Block Diagram of Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 5.2 Measuring Standard

EN 60601-1-2:2015(EN 61000-3-2:2019)

## 5.3Operation Condition of EUT

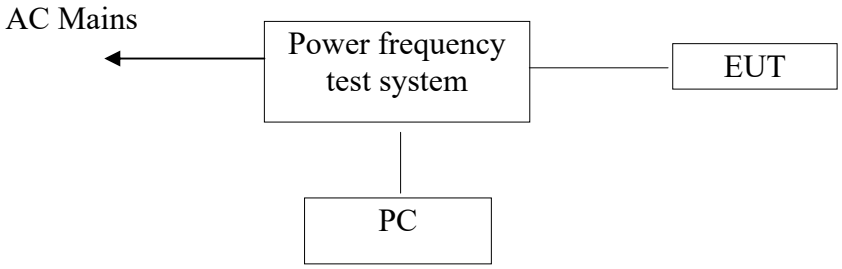
5.3.1 Setup the EUT and simulators as shown in Section5.1.
5.3.2 Turn on the power of all equipments.
5.3.3 Let the EUT only works in charging mode (see 1.5) and test it.

## 5.4 Description of test Equipment

N/A

# 6. VOLTAGE FLUCTUATION AND FLICKER MEASUREMENT

## 6.1 Block Diagram of Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 6.2 Measuring Standard

EN 60601-1-2:2015(EN 61000-3-3:2013+A1:2019)

## 6.3 Operation Condition of EUT

6.3.1 Setup the EUT and simulators as shown in Section6.1.
6.3.2 Turn on the power of all equipments.
6.3.3 Let the EUT only works in charging mode (see 1.5) and test it.

# 7. ELECTROMAGNETIC SUSCEPTIBILITY TEST RESULTS

## 7.1 Performance Criteria Description in Annex A of EN 60601-1-2

Under the test conditions specified in A.1, the ME EQUIPMENT or ME SYSTEM shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed:
– component failures;
– changes in programmable parameters;
– reset to factory defaults (MANUFACTURER'S presets);
– change of operating mode;
– false alarms;
– cessation or interruption of any intended operation, even if accompanied by an alarm;
– initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
– 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 and ME SYSTEMS to diagnose or treat, even if accompanied by an alarm.

For ME EQUIPMENT and ME SYSTEMS with multiple FUNCTIONS, the criteria apply to each FUNCTION, parameter and channel. The ME EQUIPMENT or ME SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from MANUFACTURER'S specifications) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

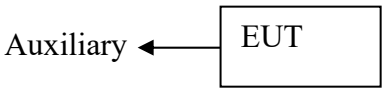
## 7.2 Essential performance

The deviation of distance, Temperature range do not deviate by more than ±10%

# 8. ELECTROSTATIC DISCHARGE IMMUNITY TEST

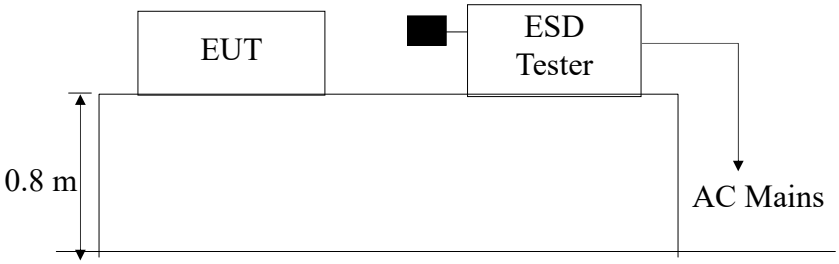
## 8.1 Block Diagram of Test Setup

### 8.1.1 Block Diagram of the EUT and the simulators




(EUT: INFRARED BODY THERMOMETER)

### 8.1.2 Block diagram of ESD test setup




(EUT: INFRARED BODY THERMOMETER)

## 8.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-2: 2009 )
Severity Level: 4 / Air Discharge: ±2KV, ±4KV, ±8KV, ±15KV Level: 3 / Contact Discharge: ±8KV)

## 8.3 Severity Levels and Performance Criterion

### 8.3.1 Severity level

| 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 |

8.3.2Performance criterion: Comply with EN 60601-1-2: 2014

## 8.4 Operating Condition of EUT

8.4.1 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none .<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

8.4.2 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use.

## 8.5 Test Procedure

8.5.1 Air Discharge**:**

This test is done on a non-conductive surface. The round discharge tip of the discharge electrode shall be approached as fast as possible to touch the EUT. After each discharge, the discharge electrode shall be removed from the EUT. The generator 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.

8.5.2 Contact Discharge**:**

All the procedure shall be same as Section 7.4.1. except that the tip of the discharge electrode shall touch the EUT before the discharge switch is operated.

8.5.3 Indirect discharge for horizontal coupling plane

At least 10 single discharges (in the most sensitive polarity) shall be applied at the front edge of each HCP opposite the center point of each unit (if applicable) of the EUT and 0.1m from the front of the EUT. The long axis of the discharge electrode shall be in the plane of the HCP and perpendicular to its front edge during the discharge.

8.5.4 Indirect discharge for vertical coupling plane

At least 10 single discharge (in the most sensitive polarity) shall be applied to the center of one vertical edge of the coupling plane. The coupling plane, of dimensions 0.5m X 0.5m, is placed parallel to, and positioned at a distance of 0.1m from the EUT. Discharges shall be applied to the coupling plane, with this plane in sufficient different positions that the four faces of the EUT are completely illuminated.

# Electrostatic Discharge Test Result

| | | | |
|---|---|---|---|
| EUT : | INFRARED BODY THERMOMETER | Temperature: | 20℃ |
| M/N : | YK001 | Humidity : | 50% |
| Test Voltage: | DC 1.5V×2(AAA) | Test Mode : | ON |
| Test Engineer : | Bill | Test Date : | 2020-03-11 |

Air Discharge: ±2KV,±4KV,±8KV,±15KV # For each point positive 10 times and negative 10 times discharge.
Contact Discharge: ±8KV # For each point positive 10 times and negative 10 times discharge.

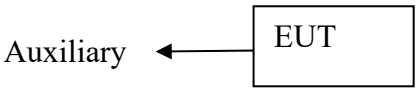
| Location | Discharge Points | Kind<br>A-Air Discharge<br>C-Contact Discharge | Result |
|---|---|---|---|
| HCP | 4 Points | C | PASS |
| VCP | 4 Points | C | PASS |
| Metal | 10 Points | C | PASS |
| Button | 10 Points | A | PASS |
| Slot | 20 Points | A | PASS |
| Screen | 10 Points | A | PASS |
| / | / | / | / |

| | |
|---|---|
| Note:<br>Test result:Device worked normally after power on and remained functionally stable after the test, The EUT is normal, no obvious change. Comply with EN 60601-1-2: 2014 | Test Equipment :ESD Tester Model: ESD61002A |

# 9. RF FIELD STRENGTH SUSCEPTIBILITY TEST

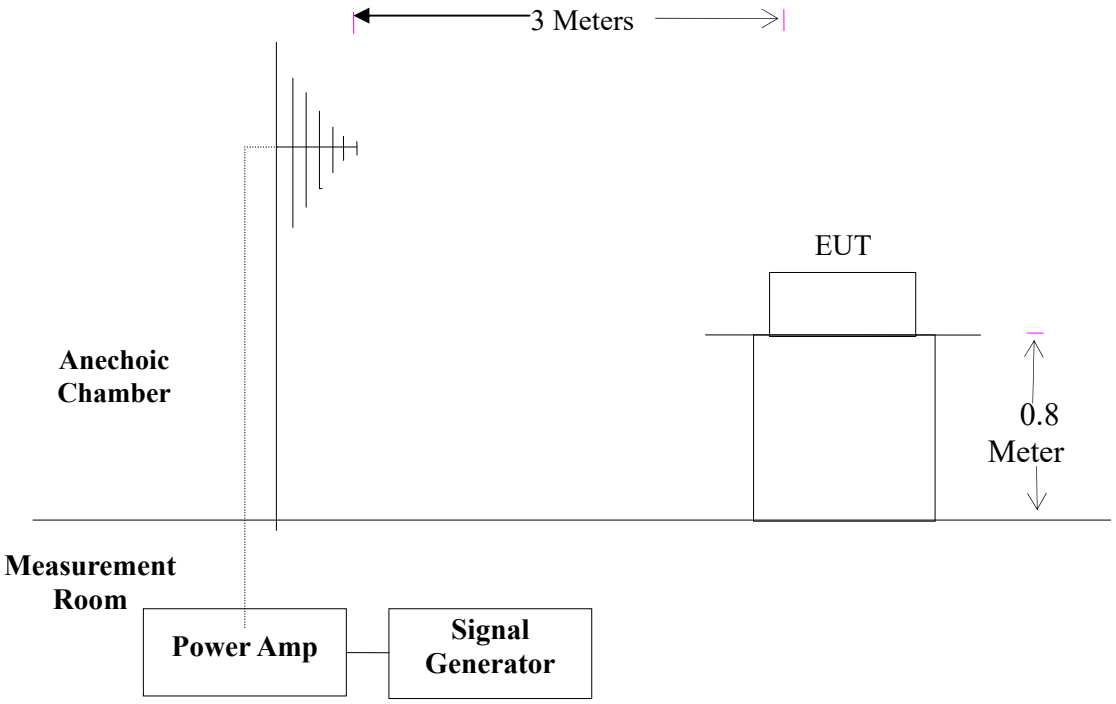
## 9.1 Block Diagram of Test

### 9.1.1 Block diagram of connection between the EUT and Load




(EUT: INFRARED BODY THERMOMETER)

### 9.1.2 Block diagram of RS test setup




(EUT: INFRARED BODY THERMOMETER)

## 9.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-3:2006+A2:2010: (Severity Level: 3, 10V / m))

## 9.3 Severity Levels and Performance Criterion

### 9.3.2 Severity Levels

| Level | Field Strength V/m |
|---|---|
| 1. | 1 |
| 2. | 3 |
| 3. | 10 |
| X | Special |

9.3.3 Performance Criterion : Comply with EN 60601-1-2: 2014

## 9.4 Operating Condition of EUT

9.4.1 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none .<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

9.4.2 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use

## 9.5Test Procedure

The EUT are placed on a table which is 0.8 meter high above the ground. The EUT is set 3 meters away from the transmitting antenna which is mounted on an antenna tower. Both horizontal and vertical polarization of the antenna are set on test. Each of the four sides of the EUT must be faced this transmitting antenna and measured individually.
In order to judge the EUT performance, a CCD camera is used to monitor its screen.
All the scanning conditions are as following:

| Condition of Test | Remark |
|---|---|
| 1. Fielded Strength | 10V/m (Severity Level 3) |
| 2. Radiated Signal | Modulated |
| 3. Scanning Frequency | 80-1000MHz, 1000-2700MHz |
| 4. Sweep time of radiated | 0.0015 Decade/s |
| 2. Dwell Time | 3 Sec. |

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 18Hz | 1.8 | 0.3 | 27 |
| 450 | 430-470 | GMRS 460, FRS 460 | FM ± 5KHz deviation 1KHz sine | 2 | 0.3 | 28 |
| 710 | 704-787 | LTE Band 13,17 | Pulse modulation 217Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800-900 | GSM 800/900, TETRA800, IDEN820, CDMA850, LTE Band5 | Pulse modulation 18Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700-1990 | GSM 1800, CDMA1900 ;GSM 1900; DECT; TLE Band 1,3,4,25, UMTS | Pulse modulation 217Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400-2570 | Bluetooth, WLAN, 802,11b/g/n, RF ID 2450, LTE Band 7 | Pulse modulation 217Hz | 2 | 0.3 | 28 |
| 5240 | 5100-5800 | WLAN 802.11a/n | Pulse modulation 217Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

| Tabulated Results for Proximity Fields From RF Wireless Communications Equipment | | | | |
|---|---|---|---|---|
| Side of the equipment under test | Frequency Band (MHz) | Antenna polarization (V/H) | Dwell Time (second) | Result |
| Front | 380 – 380 | H | 1S | 1 |
| | 430 – 470 | H | 1S | 1 |
| | 704 – 787 | H | 1S | 1 |
| | 800 – 960 | H | 1S | 1 |
| | 1700 – 1990 | H | 1S | 1 |
| | 2400 – 2570 | H | 1S | 1 |
| | 5100 – 5800 | H | 1S | 1 |
| Front | 380 – 380 | V | 1S | 1 |
| | 430 – 470 | V | 1S | 1 |
| | 704 – 787 | V | 1S | 1 |
| | 800 – 960 | V | 1S | 1 |
| | 1700 – 1990 | V | 1S | 1 |
| | 2400 – 2570 | V | 1S | 1 |
| | 5100 – 5800 | V | 1S | 1 |
| Back | 380 – 380 | H | 1S | 1 |
| | 430 – 470 | H | 1S | 1 |
| | 704 – 787 | H | 1S | 1 |
| | 800 – 960 | H | 1S | 1 |
| | 1700 – 1990 | H | 1S | 1 |
| | 2400 – 2570 | H | 1S | 1 |
| | 5100 – 5800 | H | 1S | 1 |
| Back | 380 – 380 | V | 1S | 1 |
| | 430 – 470 | V | 1S | 1 |
| | 704 – 787 | V | 1S | 1 |
| | 800 – 960 | V | 1S | 1 |
| | 1700 – 1990 | V | 1S | 1 |
| | 2400 – 2570 | V | 1S | 1 |
| | 5100 – 5800 | V | 1S | 1 |
| Left | 380 – 380 | H | 1S | 1 |
| | 430 – 470 | H | 1S | 1 |
| | 704 – 787 | H | 1S | 1 |
| | 800 – 960 | H | 1S | 1 |
| | 1700 – 1990 | H | 1S | 1 |
| | 2400 – 2570 | H | 1S | 1 |

| Tabulated Results for Proximity Fields From RF Wireless Communications Equipment | | | | |
|---|---|---|---|---|
| Side of the equipment under test | Frequency Band (MHz) | Antenna polarization (V/H) | Dwell Time (second) | Result |
| | 5100 – 5800 | H | 1S | 1 |
| Left | 380 – 380 | V | 1S | 1 |
| | 430 – 470 | V | 1S | 1 |
| | 704 – 787 | V | 1S | 1 |
| | 800 – 960 | V | 1S | 1 |
| | 1700 – 1990 | V | 1S | 1 |
| | 2400 – 2570 | V | 1S | 1 |
| | 5100 – 5800 | V | 1S | 1 |
| Right | 380 – 380 | H | 1S | 1 |
| | 430 – 470 | H | 1S | 1 |
| | 704 – 787 | H | 1S | 1 |
| | 800 – 960 | H | 1S | 1 |
| | 1700 – 1990 | H | 1S | 1 |
| | 2400 – 2570 | H | 1S | 1 |
| | 5100 – 5800 | H | 1S | 1 |
| Right | 380 – 380 | V | 1S | 1 |
| | 430 – 470 | V | 1S | 1 |
| | 704 – 787 | V | 1S | 1 |
| | 800 – 960 | V | 1S | 1 |
| | 1700 – 1990 | V | 1S | 1 |
| | 2400 – 2570 | V | 1S | 1 |
| | 5100 – 5800 | V | 1S | 1 |
| Results Descriptions:<br>X - Not performed nor required. 1 – Compliant - No observed response from EUT. | | | | |
| Supplementary information: none.<br>Note: Description of the response should detail observations during testing. | | | | |
| Test result:Device worked normally after power on and remained functionally stable after the test, The EUT is normal, no obvious change. Comply with EN 60601-1-2: 2014 | | | | |

# RF Field Strength Susceptibility Test Results

| | | | |
|---|---|---|---|
| EUT : | INFRARED BODY THERMOMETER | Temperature : | 22℃ |
| M/N : | YK001 | Humidity : | 50 % |
| Test Voltage: | DC 1.5V×2(AAA) | Test Mode : | ON |
| Field Strength : | 10 V/m | Test Date : | 2020-03-11 |
| Test Engineer: | Bill | Frequency Range: | 80 MHz to1000 MHz<br>1000MHz to 2700MHz |

| | | | | | | |
|---|---|---|---|---|---|---|
| Modulation: | ☐None | | ☐ Pulse | ☑AM 1KHz | 80% | |
| | Frequency Rang 1: 80~ 1000MHz | | | Frequency Rang 2: 1000MHz~2700MHz | | |
| Steps | 1 | / | % | # | / | % |
| | Horizontal | Vertical | | Horizontal | Vertical | |
| Front | PASS | PASS | | PASS | PASS | |
| Right | PASS | PASS | | PASS | PASS | |
| Rear | PASS | PASS | | PASS | PASS | |
| Left | PASS | PASS | | PASS | PASS | |

Test Equipment **:**

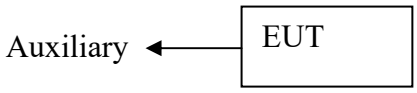
1. Signal Generator : 2031 (MARCONI)
2. Power Amplifier : 500A100 & 100W/1000M1 (A&R)
3. Power Antenna : 3108 (EMCO) & AT1080 (A&R)
4. Field Monitor : FM2000 (A&R)

Note:
Test result:Device worked normally after power on and remained functionally stable after the test, The EUT is normal, no obvious change. Comply with EN 60601-1-2: 2014

# 10. ELECTRICAL FAST TRANSIENT/BURST IMMUNITY TEST

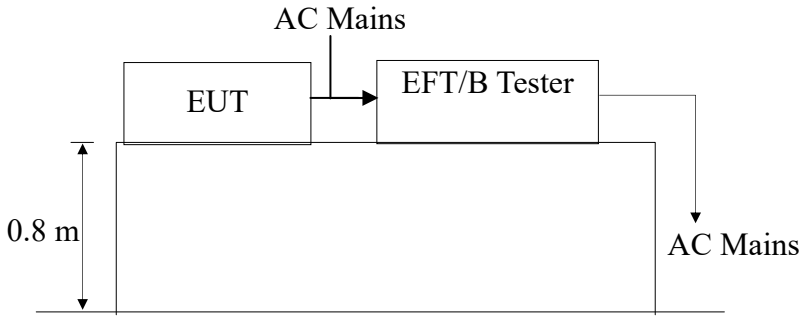
## 10.1 Block Diagram of Test Setup

### 10.1.1.Block Diagram of the EUT




(EUT: INFRARED BODY THERMOMETER)

### 10.1.2.EFT Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 10.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-4:2012, Severity Level, Level 3**:** 2KV)

## 10.3 Severity Levels and Performance Criterion

### 10.3.1 Severity level

| Open Circuit Output Test Voltage ±10% | | |
|---|---|---|
| Level | On Power Supply Lines | On I/O (Input/Output) Signal data and control lines |
| 1. | 0.5 KV | 0.25 KV |
| 2. | 1 KV | 0.5 KV |
| 3. | 2 KV | 1 KV |
| 4. | 4 KV | 2 KV |
| X | Special | Special |

10.3.2 Performance criterion **:** Comply with EN 60601-1-2:2015

## 10.4 Test Procedure

The EUT is put on the table which is 0.8 meter high above the ground. 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.

10.4.1 For input and output AC power ports**:**

The EUT is connected to the power mains by using a coupling device which couples the EFT interference signal to AC power lines. Both polarities of the test voltage should be applied during compliance test and the duration of the test is 2 mins.

10.4.2 For signal lines and control lines ports**:**

No I/O ports. It's unnecessary to test.

10.4.3 For DC output line ports**:**

It's unnecessary to test.

## 10.5 Operating Condition of EUT

10.5.1 Setup the EUT as shown in Section 10.1.

10.5.2 Turn on the power of all equipments.

10.5.3 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none.<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

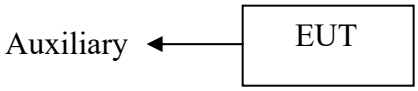
10.5.4 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use

Note: It's unnecessary to test.

# 11. SURGE IMMUNITY TEST

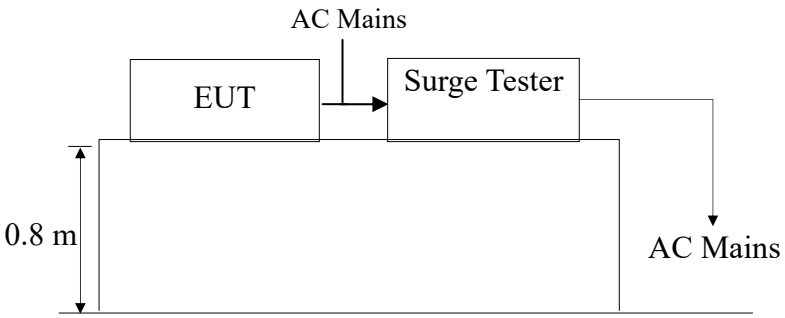
## 11.1 Block Diagram of Test Setup

### 11.1.1 Block Diagram of the EUT




(EUT: INFRARED BODY THERMOMETER)

### 11.1.2. Surge Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 11.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-5: 2014+A1:2017)Severity Level**:** Line to Line: Level 1, ± 0.5KV,Level 2, ±1.0KV, Line to ground: Level 1, ±0.5KV,Level 2, ±1.0KV, Level 3, ±2.0KV)

## 11.3 Severity Levels and Performance Criterion

### 11.3.1.Severity level

| Severity Level | Open-Circuit Test Voltage KV |
|---|---|
| 1 | 0.5 |
| 2 | 1.0 |
| 3 | 2.0 |
| 4 | 4.0 |
| * | Special |

11.3.2 Performance criterion **:** Comply with EN 60601-1-2: 2014

## 11.4 Operating Condition of EUT

11.4.1 Setup the EUT as shown in Section 11.1.

11.4.2. Turn on the power of all equipments.

11.4.3. EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none.<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

11.4.4. The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use

## 11.5 Test Procedure

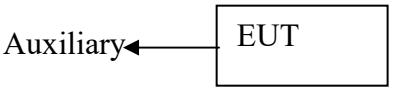
1) Set up the EUT and test generator as shown on Section 10.1.2.
2) For line to line coupling mode, provide a 1.0 KV 1.2/50us voltage surge (at open-circuit condition) and 8/20us current surge to EUT selected points.
3) At least 5 positive and 5 negative (polarity) tests with a maximum 1/min repetition rate are conducted during test.
4) Different phase angles are done individually.
5) Record the EUT operating situation during compliance test and decide the EUT immunity criterion for above each test.

Note: It's unnecessary to test.

# 12. INJECTED CURRENTS SUSCEPTIBILITY TEST

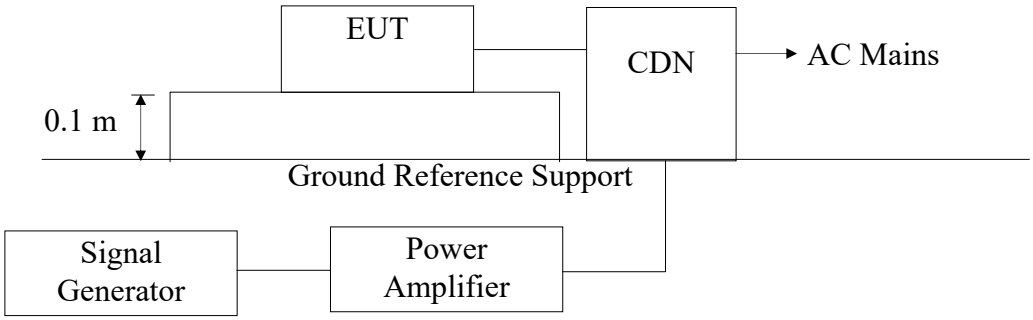
## 12.1 Block Diagram of Test Setup

### 12.1.1 Block Diagram of the EUT




(EUT: INFRARED BODY THERMOMETER)

### 12.1.2 Block Diagram of Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 12.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-6: 2014+AC:2015, Severity Level: Level 2, 3V (0.15MHz ~ 80MHz,6V in ISM and amateur radio bands between 0.15MHz and 80 MHz 80% AM at 1KHz)

## 12.3 Severity Levels and Performance Criterion

### 12.3.1 Severity level

| Level | Field Strength V |
|---|---|
| 1 | 1 |
| 2 | 3 |
| 3 | 10 |
| X | Special |

12.3.2 Performance criterion**:** Comply with EN 60601-1-2:2015

## 12.4 Operating Condition of EUT

12.4.1 Setup the EUT as shown in Section 12.1.

12.4.2 Turn on the power of all equipments.

12.4.3 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none.<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

12.4.4 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use

## 12.5 Test Procedure

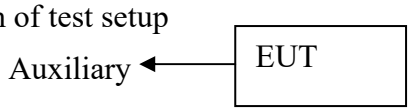
1) Set up the EUT, CDN and test generators as shown on Section 11.1.2.
2) Let the EUT work in test mode and measure it.
3) The EUT are placed on an insulating support 0.1m high above a ground reference plane. CDN (coupling and decoupling device) is placed on the ground plane about 0.3m from EUT. Cables 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).
4) The disturbance signal described below is injected to EUT through CDN.
5) The EUT operates within its operational mode(s) under intended climatic conditions after power on.
6) The frequency range is swept from 150KHz to80MHz using 3V signal level, and with the disturbance signal 80% amplitude modulated with a 1KHz sine wave.
7) The rate of sweep shall not exceed $1.5*10^{-3}$decades/s. Where the frequency is swept incrementally, the step size shall not exceed 1% of the start and thereafter 1% of the preceding frequency value.
8) Recording the EUT operating situation during compliance testing and decide the EUT immunity criterion.

Note: It's unnecessary to test.

# 13. MAGNETIC FIELD SUSCEPTIBILITY TEST

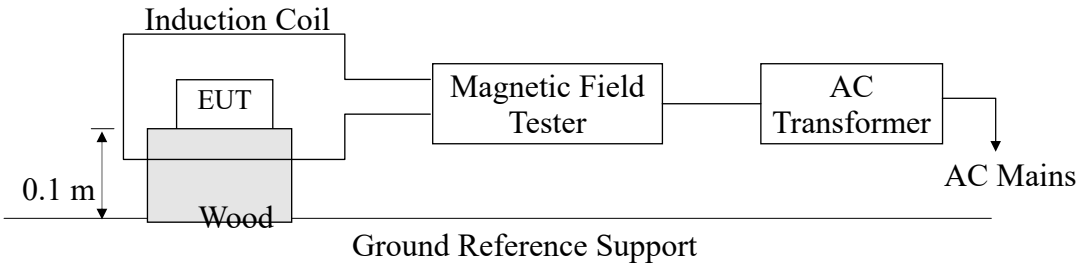
## 13.1 Block Diagram of Test

13.1.1 Block diagram of test setup




(EUT: INFRARED BODY THERMOMETER)

13.1.2 Magnetic field test setup




## 13.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-8: 2010, Severity Level: Level 4, 30A / m)

## 13.3 Severity Levels and Performance Criterion

13.3.1 Severity Levels

| Level | Field Strength A/m |
|---|---|
| 1 | 1 |
| 2 | 3 |
| 3 | 10 |
| 4 | 30 |
| 5 | 100 |
| X | Special |

13.3.2 Performance Criterion : Comply with EN 60601-1-2:2015

## 13.4 Operating Condition of EUT

13.4.1 Setup the EUT as shown in Section 13.1.
13.4.2 Turn on the power of all equipments.
13.4.3 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none.<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

13.4.3 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use

## 13.5 Test Procedure

The EUT is placed in the middle of a induction coil (1*1m), under which is a 1*1*0.1m (high) table, this small table is also placed on a larger table,0.8 m above the ground. Both horizontal and vertical polarization of the induction coil are set on test, so that each side of the EUT is affected by the magnetic field. Also can reach the same aim by change the position of the EUT.

# Magnetic Field Immunity Test Result

| | | | | | |
|---|---|---|---|---|---|
| EUT : | INFRARED BODY THERMOMETER | | | Temperature: | 20℃ |
| M/N : | YK001 | | | Humidity : | 50% |
| Test Voltage : | DC 1.5V×2(AAA) | | | Test Mode : | ON |
| Test Engineer : | Bill | Test frequency: 50/60Hz | | Test Date : | 2020-03-11 |
| Test Level (A/M) | Testing Duration | Coil Orientation | Result | | |
| 30 | 5 mins | X | Pass | | |
| 30 | 5 mins | Y | Pass | | |
| 30 | 5 mins | Z | Pass | | |
| Test Level (A/M) | Testing Duration | Coil Orientation | Result | | |
| / | / | / | / | | |
| / | / | / | / | | |
| / | / | / | / | | |

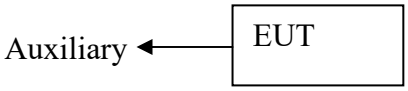
Test Equipment :Magnetic Field Tester Model: HPFM T

Note:
Test result:Device worked normally after power on and remained functionally stable after the test, The EUT is normal, no obvious change. Comply with EN 60601-1-2:2015

# 14. VOLTAGE DIPS AND INTERRUPTIONS TEST

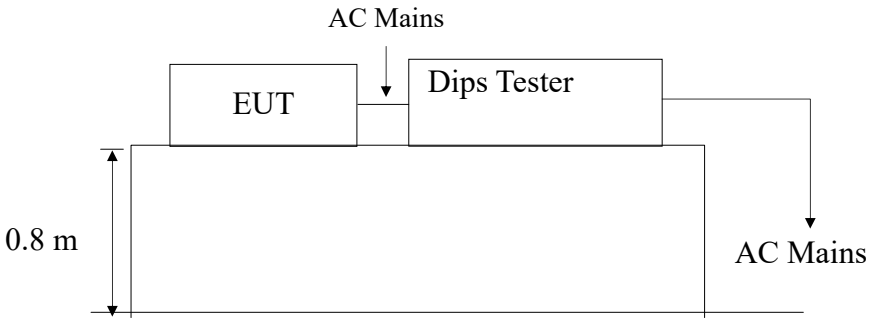
## 14.1 Block Diagram of Test Setup

### 14.1.1 Block Diagram of the EUT




(EUT: INFRARED BODY THERMOMETER)

### 14.1.2 Dips Test Setup




(EUT: INFRARED BODY THERMOMETER)

## 14.2 Test Standard

EN 60601-1-2:2015 (EN 61000-4-11: 2004+A1:2017)

## 14.3 Severity Levels and Performance Criterion

### 14.3.1 Severity level

| Test Level %UT | Voltage dip and short interruptions %UT | Duration (in period) |
|---|---|---|
| 0 | 100 | 0,5<br>0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° |
| 0 | 100 | 1<br>25<br>30<br>250<br>300<br>* |
| 70 | 30 | |
| 0 | 100 | |

14.3.2 Performance criterion **:** Comply with EN 60601-1-2: 2014

## 14.4 Operating Condition of EUT

14.4.1 Setup the EUT as shown in Section 14.1.

14.4.2 Turn on the power of all equipments.

14.4.3 EUT Operation Modes:

| Mode # | Description |
|---|---|
| ON | The product is in the measured state |
| Supplementary information: none.<br>Remark:<br>During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena. | |

13.4.3 The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use

## 14.5 Test Procedure

1) Set up the EUT and test generator as shown on Section 13.1.2.
2) The interruptions is introduced at selected phase angles with specified duration.
3) Record any degradation of performance.

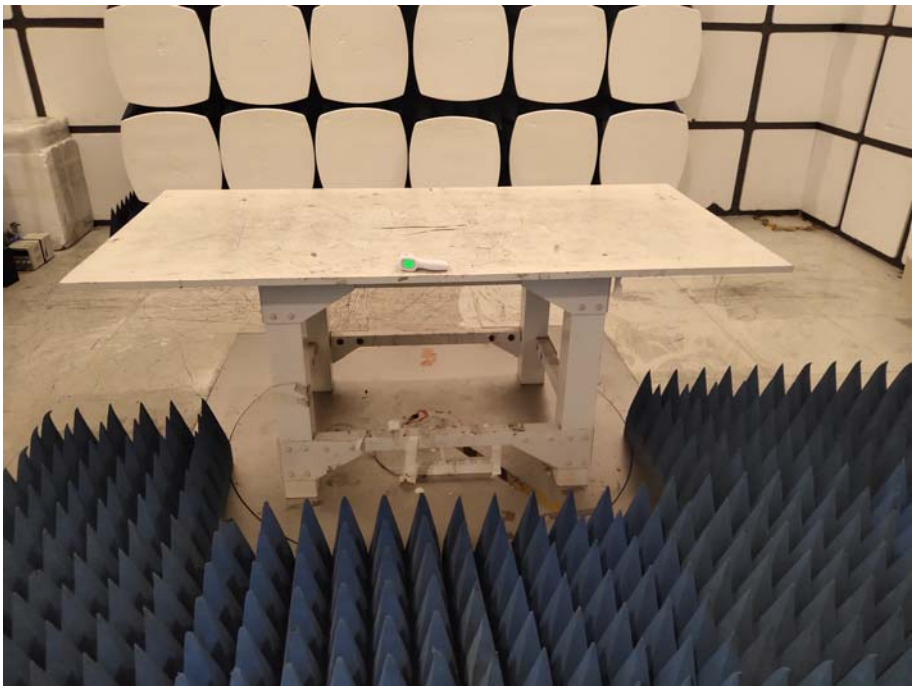
Note:It's unnecessary to test.

# 15. PHOTOGRAPH

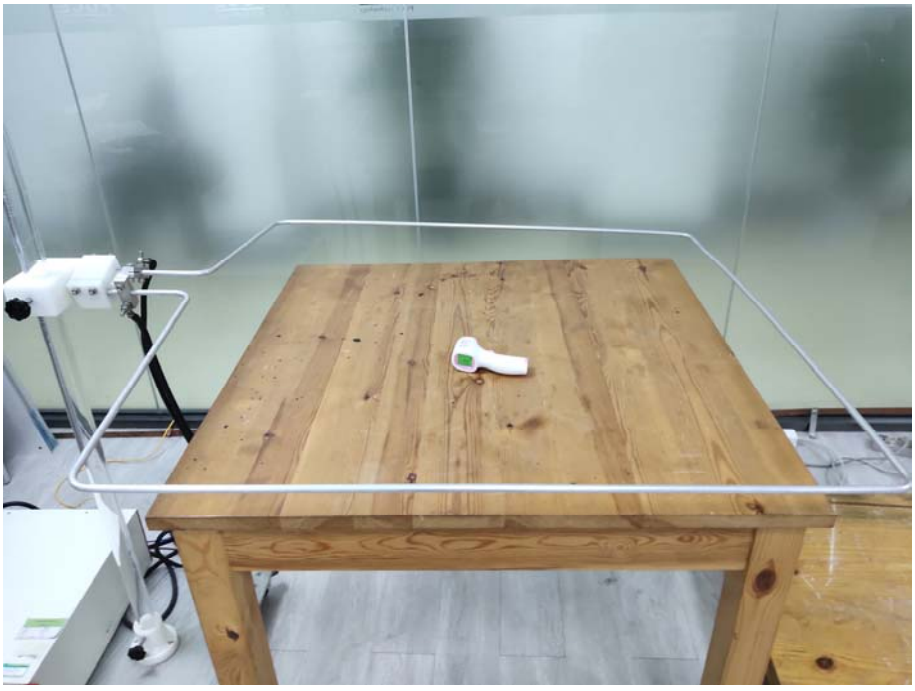
## 15.1 Photo of Radiated Emission


## 15.2 Photo of Electrostatic Discharges Immunity

## 15.3 Photo Of Rf Field Strength Susceptibility Immunity



## 15.4 Photo of Magnetic Field Immunity



# APPENDIX 1

**Photo documentation**


**Fig.1**

**Fig.2**

**Fig.3**

**Fig.4**

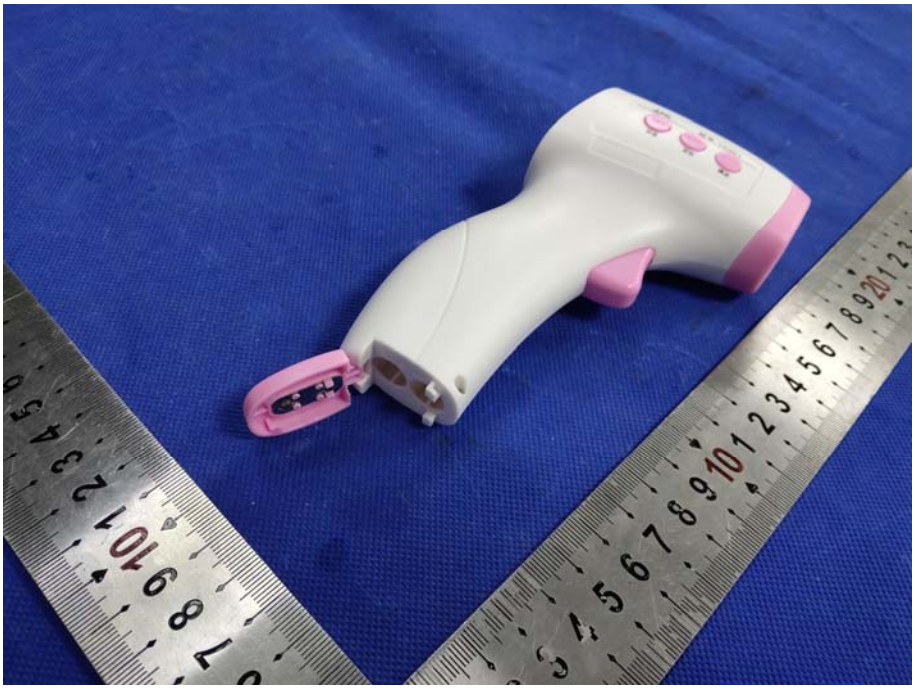


Fig.5

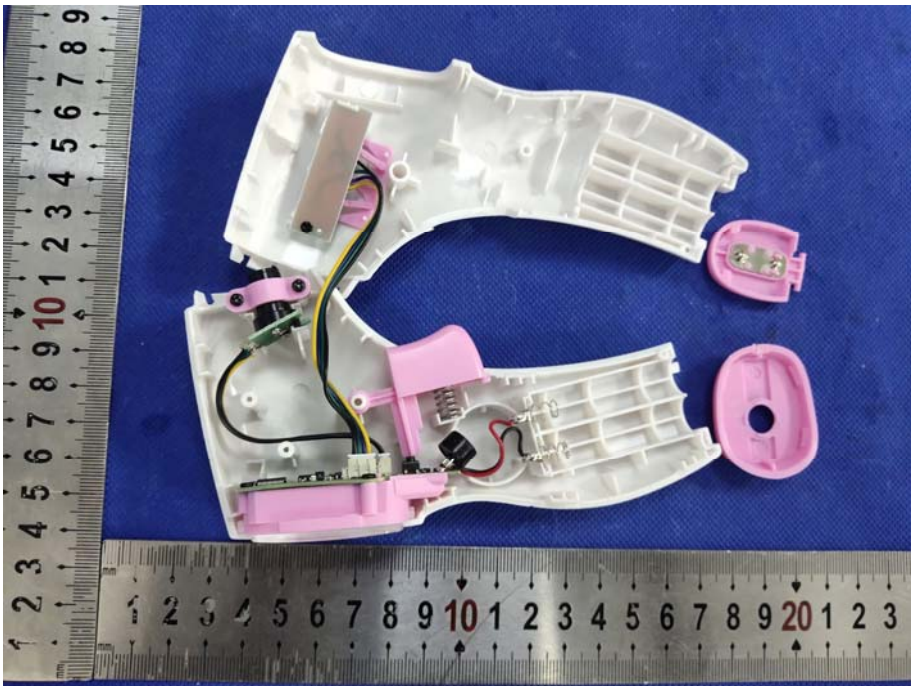


Fig.6

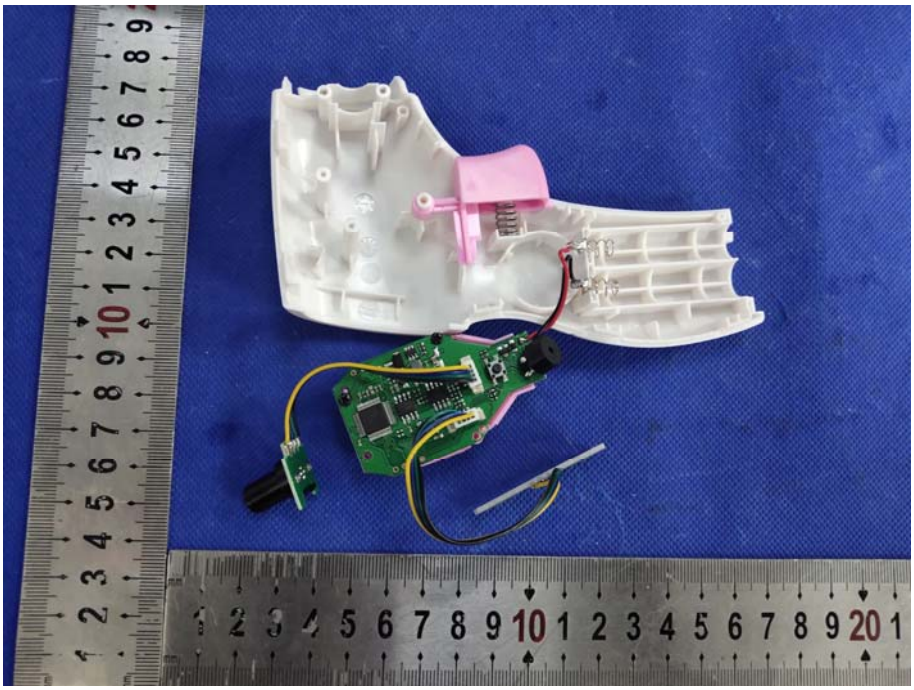


**Fig.7**

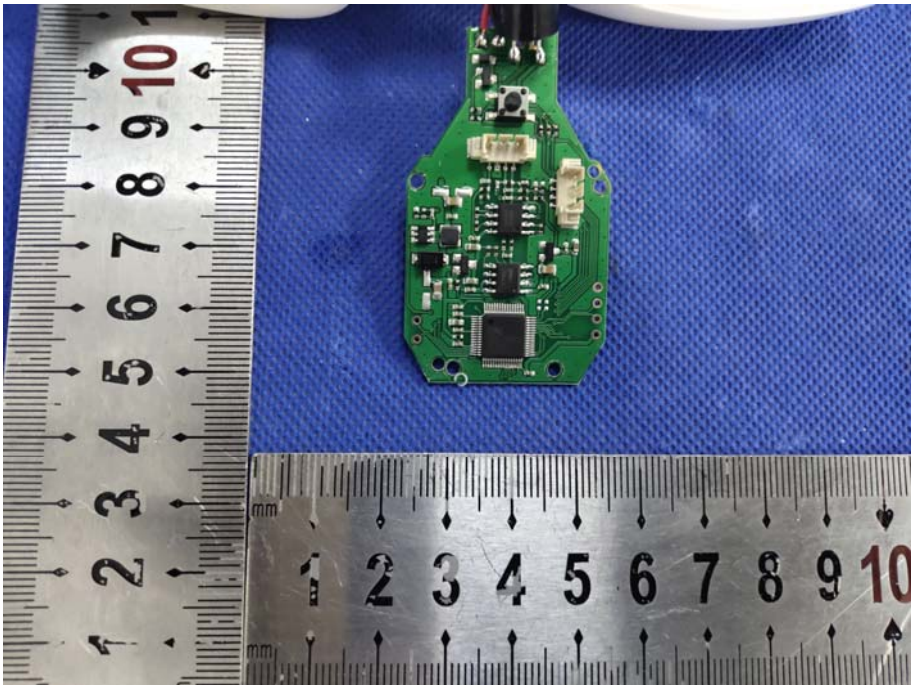


**Fig.8**

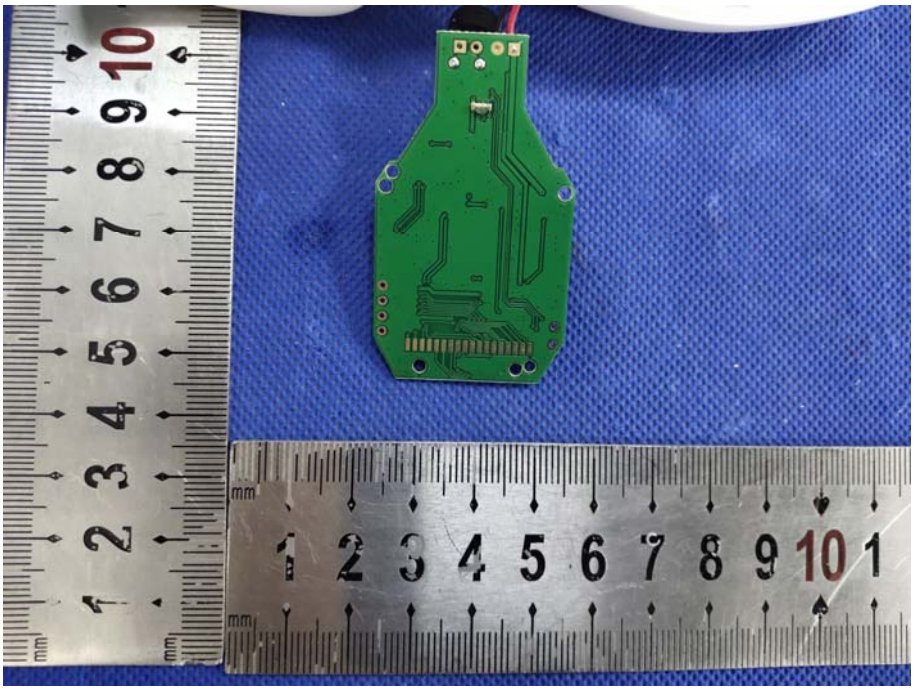


Fig.9

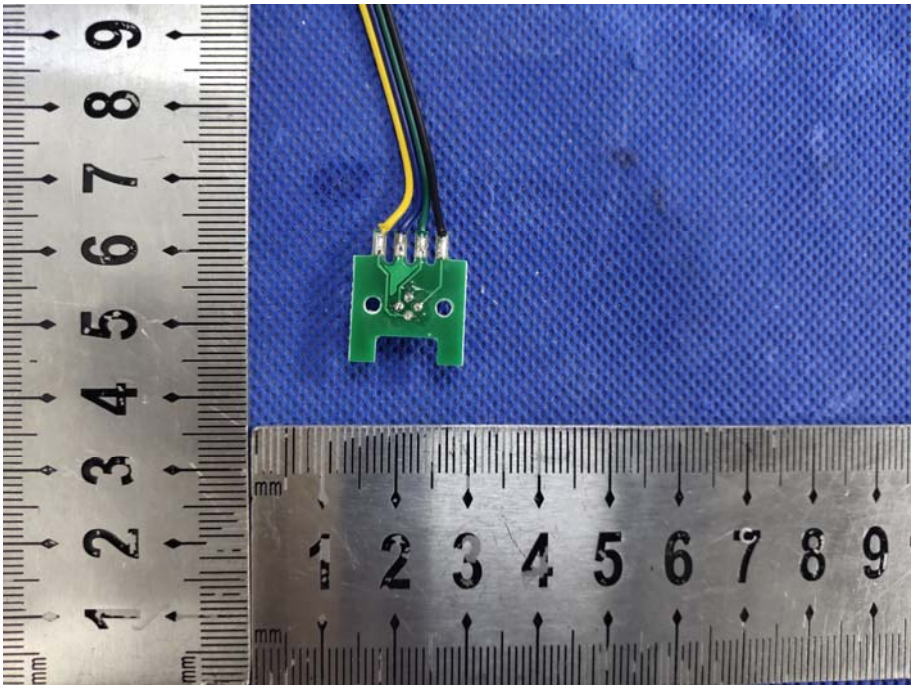


Fig.10

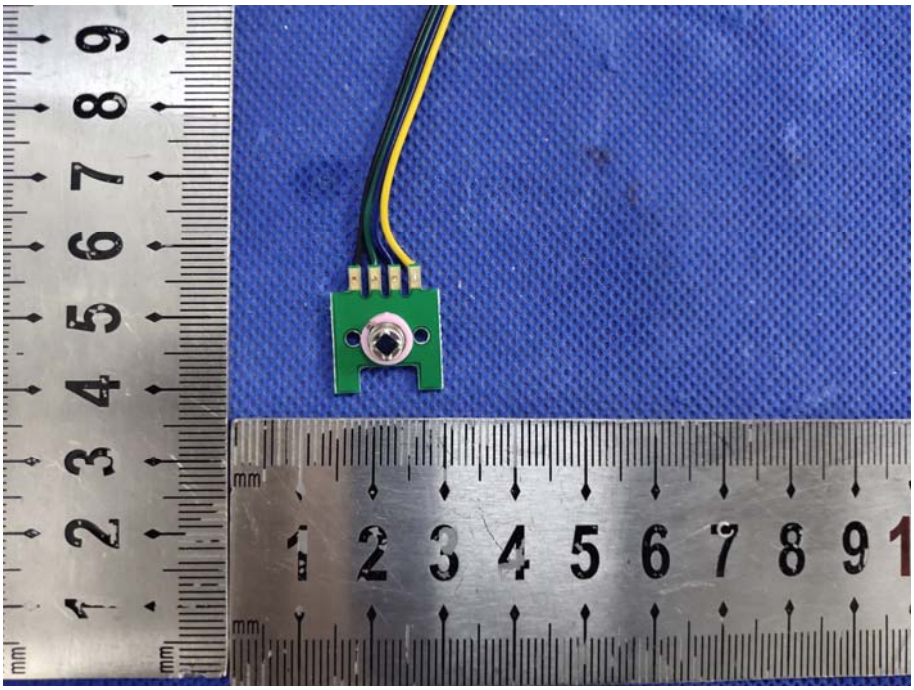


Fig.11

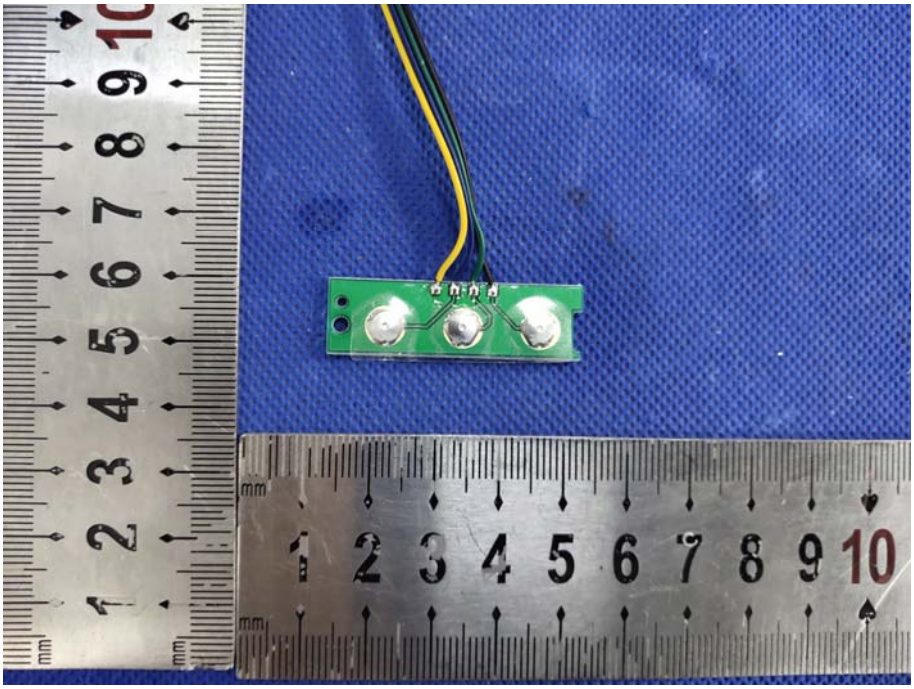


Fig.12

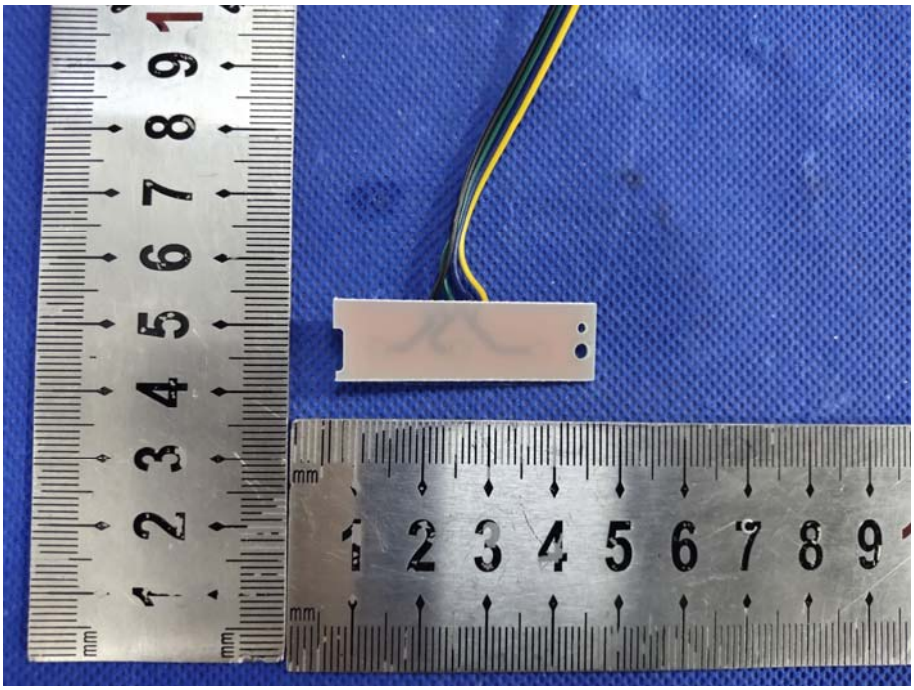



**Fig.13**

# APPENDIX 2

Compliance Summar

| EN 60601-1-2 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **4** | **GENERAL REQUIREMENTS** | | |
| 4.1 | Risk management process for ME equipment and ME systems. | | P |
| | | | |
| **5** | **IDENTIFICATION, MARKING AND DOCUMENTS** | | |
| 5.1 | Equipment specified for use only in shielded location has appropriate marking/warning labels | | N/A |
| 5.2 | Accompanying Documents | | |
| 5.2.1 | Instructions for use | | |
| 5.2.1.1 | General | | |
| a) | A statement of the environments the ME equipment will be used. Relevant exclusions, as determined by Risk Analysis, shall also be listed. | | P |
| b) | The essential performance of ME equipment and a description of what the operator can expect if the Essential Performance is lost or degraded due to EM disturbances. | | P |
| c) | A warning regarding stacking and location close to other equipment | | P |
| d) | List of cables, transducers and accessories | | P |
| e) | A warning that other cables and accessories may negatively affect EMC performance | | P |
| f) | A statement that portable RF communications equipment. Including antennas, can effect medical electrical equipment. The warning should include a use distance such as "…be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer" | | P |
| 5.2.1.2 | Required statement from standard for Class A equipment | | N/A |
| 5.2.2 | Technical description | | P |
| 5.2.2.1 | All equipment and systems | | P |
| | Describe precautions to be taken to prevent adverse events to the Patient and Operator due to electromagnetic disturbances | | P |
| a) | Compliance information for each test | | P |
| b) | Statement of any deviations from standards used | | N/A |
| c) | Statements to maintain basic safety and essential performance in regards to EMC | | P |

*********THE END OF REPORT*********