**Shenzhen Huatongwei International Inspection Co., Ltd.**
Keji S,12th , Road, Hi-tech Industrial Park, Shenzhen, Guangdong, China
Phone:86-755-26748019 Fax:86-755-26748089 http://www.szhtw.com.cn

CNASL1225

# TEST REPORT

## EN 60601-1-2: 2007

## Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

| | |
|---|---|
| **Report Reference No. ..... :** | **TRE11120098** |
| Compiled by ( position+printed name+signature) . : | File administrators Vivi Zhou |
| Supervised by ( position+printed name+signature) . : | Technique principal Sam Wang |
| Approved by ( position+printed name+signature) . : | Manager Tony Jiang |
| Date of issue ..... : | Jan. 09, 2012 |
| **Testing Laboratory Name**..... : | **Shenzhen Huatongwei International Inspection Co., Ltd.** |
| Address..... : | Keji S, 12th, Road, Hi-tech Industrial Park, Shenzhen, Guangdong, China |
| Testing location/ procedure..... : | Full application of Harmonised standards ☒<br>Partial application of Harmonised standards ☐<br>Other standard testing methods ☐ |
| **Applicant's name** ..... : | **Ningbo Ourui New Material Technology Development Co.,Ltd.** |
| Address..... : | No. 9 Xiahengdai Road Lanjiang Street, Yuyao, Zhejiang, China |
| **Test specification:** | |
| Standard..... : | **EN 60601-1-2: 2007** |
| Non-standard test method……..: | / |
| **Test Report Form No**. ..... : | HTWEMCCE_1A |
| TRF Originator ..... : | Shenzhen Huatongwei International Inspection Co., Ltd. |
| Master TRF ..... : | Dated 2006-06 |



| | |
|---|---|
| **Test item description..... :** | Blood Pressure Monitor (Upper arm type) |
| Manufacturer..... : | Ningbo Ourui New Material Technology Development Co.,Ltd. |
| Model/Type reference ..... : | ORA211 |
| Listed models..... : | ORA210 |
| Ratings..... : | DC 6V, 500mA, 3W |
| Result..... : | **Positive** |

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

| Test Report No. : | TRE11120098 | Jan. 09, 2012<br>Date of issue |
|---|---|---|

| | | |
|---|---|---|
| Equipment under Test | : | Blood Pressure Monitor (Upper arm type) |
| Model /Type | : | ORA211 |
| Listed Model | : | ORA210 |
| **Applicant** | : | Ningbo Ourui New Material Technology Development Co.,Ltd. |
| Address | : | No. 9 Xiahengdai Road Lanjiang Street, Yuyao, Zhejiang, China |
| **Manufacturer** | : | Ningbo Ourui New Material Technology Development Co.,Ltd. |
| Address | : | No. 9 Xiahengdai Road Lanjiang Street, Yuyao, Zhejiang, 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:

EN 60601-1-2: 2007 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.

Remark: This EUT is ranged to the Group 1 Class B apparatus according to the standard of EN 55011: 2009 clause 5.2

# 2. SUMMARY

■ – Specified by manufacturer
O – Not specified

## 2.1. General Remarks

Date of receipt of test sample : Dec. 27, 2011

Testing commenced on : Dec. 30, 2011

Testing concluded on : Jan. 05, 2012

## 2.2. Equipment Under Test

### Power supply system utilised

Power supply voltage : o 230V / 50 Hz o 115V / 60Hz
■ 6 V DC o 24 V DC
o Other (specified in blank below)

/

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

The EUT is an Blood Pressure Monitor (Upper arm type), and this EUT is ranged to the Group 1 Class B apparatus according to the standard of EN 55011: 2009 clause 5.2.

| Blood Pressure Monitor (Upper arm type) differences in Table | | | | |
|---|---|---|---|---|
| Model Name | | ORA211 | ORA210 | |
| Measurement methods | Oscillometric | Yes | Yes | |
| Blood pressure measuring range | 30-280mmHG | Yes | Yes | |
| Pulse measurement range | 40-195 pulse/min | Yes | Yes | |
| Pressure accuracy | +/-3mmHG | Yes | Yes | |
| Pulse accuracy | +/-5% | Yes | Yes | |
| Inflatable | Micro pump automatic inflatable | Yes | Yes | |
| Pressure detection | Semiconductor | Yes | Yes | |
| Memory | | 2*90 | 2*90 | |
| Power supply | | 6V 4*AA | 6V 4*AA | |
| Time | | Yes | Yes | |

| | | | | |
|---|---|---|---|---|
| Average | | Yes | Yes | |
| Voice | | Yes | No | |
| Blood partition Tips | | Yes | Yes | |
| Armband size | | 22-32cm | 22-32cm | |
| Display Size | | 57.5*58mm | 57.5*58mm | |
| | |  |  | |

Serial number: prototype

## 2.4. EUT operation mode

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

Test program (customer specific)

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

o NIBP Simulator Manufacturer： FLUKE

M/N： BP Pump 2

## 2.6. Compliance criteria

Under the test conditions specified in 6.2.1.10 of EN 60601-1-2: 2007, the equipment of 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:

- 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;
- artifact or distortion in an image in which the artifact would interfere with diagnosis, treatment or monitoring;
- failure of automatic diagnosis or treatment equipment and systems to diagnose or treat, even if accompanied by an alarm.

For equipment and systems with multiple functions, the criteria apply to each function, parameter and channel.
The equipment or system may exhibit degradation of performance (e.g. deviation from manufacturer's specifications) that does not affect essential performance or safety.

# 3. TEST ENVIRONMENT

## 3.1. Address of the test laboratory

Shenzhen Huatongwei International Inspection Co., Ltd.
Keji S, 12th, Road, Hi-tech Industrial Park, Shenzhen, Guangdong, China
Tel: 86-755-26715686 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, Date of Registration: Mar. 30, 2009. Valid time is until Mar. 29, 2012.

### A2LA-Lab Cert. No. 2243.01

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. Valid time is until Sep. 30, 2013.

### FCC-Registration No.: 662850

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 662850, Renewal date Jul. 01, 2009, valid time is until Jun. 30, 2012.

## IC-Registration No.: 5377A

The 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. 5377A on Jan. 25, 2011, valid time is until Jan. 24, 2014.

## 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.

## NEMKO-Aut. No.: ELA125

Shenzhen Huatongwei International Inspection Co., Ltd. has been assessed the quality assurance system, the testing facilities, qualifications and testing practices of the relevant parts of the organization. The quality assurance system of the Laboratory has been validated against ISO/IEC 17025 or equivalent. The laboratory also fulfils the conditions described in Nemko Document NLA-10, the authorization is valid through Oct. 07, 2013.

## VCCI

The 3m Semi-anechoic chamber (12.2m×7.95m×6.7m) and Shielded Room (8m×4m×3m) of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: G-292. Date of Registration: Dec. 24, 2010. Valid time is until Dec. 23, 2013.

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-2726. Date of Registration: Dec. 20, 2009. Valid time is until Dec. 19, 2012.

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-1837. Date of Registration: May 07, 2010. Valid time is until May 06, 2013.

## DNV

Shenzhen Huatongwei International Inspection Co., Ltd. has been found to comply with the requirements of DNV towards subcontractor of EMC and safety testing services in conjunction with the EMC and Low voltage Directives and in the voluntary field. The acceptance is based on a formal quality Audit and follow-ups according to relevant parts of ISO/IEC Guide 17025 (2005), in accordance with the requirements of the DNV Laboratory Quality Manual towards subcontractors. Valid time is until Aug. 24, 2013.

## 3.3. Environmental conditions

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

| | |
|---|---|
| Temperature: | 22-25 ° C |
| Humidity: | 40-54 % |
| Atmospheric pressure: | 950-1050mbar |

## 3.4. Test Description

| | | |
|---|---|---|
| Emission Measurement | | |
| Radiated Emission | EN 60601-1-2: 2007<br>EN 55011: 2009 | PASS |
| Conducted Disturbance<br>(0.15-30MHz) | EN 60601-1-2: 2007<br>EN 55011: 2009 | N/A |
| Harmonic Current | EN 60601-1-2: 2007<br>EN 61000-3-2: 2006+A1: 2009+A2: 2009 | N/A |
| Voltage Fluctuation and Flicker | EN 60601-1-2: 2007<br>EN 61000-3-3: 2008 | N/A |
| Immunity Measurement | | |
| Electrostatic Discharge | EN 60601-1-2: 2007<br>EN 61000-4-2: 2009 | PASS |
| RF Field Strength Susceptibility<br>(80~2500MHz) | EN 60601-1-2: 2007<br>EN 61000-4-3: 2006 | PASS |
| Electrical Fast Transient/Burst Test | EN 60601-1-2: 2007<br>EN 61000-4-4: 2004+A1: 2010 | N/A |
| Surge Test | EN 60601-1-2: 2007<br>EN 61000-4-5: 2006 | N/A |
| Conducted Susceptibility Test | EN 60601-1-2: 2007<br>EN 61000-4-6: 2009 | N/A |
| Power Frequency Magnetic Field Susceptibility Test | EN 60601-1-2: 2007<br>EN 61000-4-8: 2010 | PASS |
| Voltage Dips and Interruptions Test | EN 60601-1-2: 2007<br>EN 61000-4-11: 2004 | N/A |

Note: “N/A” means “not applicable”.
The measurement uncertainty is not included in the test result.

| EN 60601-1-2 | | | |
|---|---|---|---|
| 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 |
| 5.1.1 | RF equipment marked with symbol IEC 60417-5140 | | N/A |
| 5.1.2 | Equipment for which the connector testing exemption is used marked with symbol IEC 60417-5134 | | N/A |
| 5.1.3 | Equipment specified for use only in shielded location has appropriate marking | | N/A |
| 5.2 | ACCOMPANYING DOCUMENTS | | PASS |
| 5.2.1 | Instructions for use | | PASS |
| 5.2.1.1 | All equipment and systems: | | PASS |
| a) | A statements that medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information | Please refer to User manual | PASS |
| b) | A statement that RF communications equipment can effect medical electrical equipment | Please refer to User manual | PASS |
| 5.2.1.2 | Equipment for which the connector testing exemption is used: | | N/A |
| a) | A reproduction of the ESD warning symbol (IEC 60417-5134) | | N/A |
| b) | A warning that pins of connectors marked with the warning symbol shall not be touched and connections shall not be made without special precautions | | N/A |
| c) | A specification of precautionary procedures | | N/A |
| d) | A recommendation that all staff receive explanation and training in ESD procedures | | N/A |
| e) | A specification of the minimum contents of ESD precautions procedure training | | N/A |
| 5.2.1.3 | For equipment and systems without a manual sensitivity adjustment and for which the manufacturer specifies a minimum amplitude or signal: | | PASS |
| a) | The minimum amplitude or value of signal | Please refer to User manual | PASS |
| b) | A warning that operation of the equipment below that value may cause incorrect results | Please refer to User manual | PASS |
| 5.2.1.4 | Requirements applicable to TYPE A PROFESSIONAL SYSTEMS | | N/A |
| 5.2.2 | TECHNICAL DESCRIPTION | | PASS |
| 5.2.2.1 | All equipment and systems: | | PASS |
| a) | List of cables and accessories | Please refer to User manual | PASS |
| b) | A warning that other cables and accessories may affect EMC performance | Please refer to User manual | PASS |
| c) | Table 1, modified as appropriate | Please refer to User manual | PASS |
| d) | A warning regarding stacking and location close to other equipment | | N/A |
| e) | A justification for each immunity compliance level below 60601 test level | | N/A |
| f) | Table 2, completed as appropriate | | N/A |
| 5.2.2.2 | Equipment not specified for use only in shielded location | | PASS |
| | Table 3 and Table 5 shall be used for LIFE-SUPPORTING , Table 4 and Table 6 shall be used are not LIFE-SUPPORTING , selected and completed as appropriate | | PASS |
| a) | ME EQUIPMENT or ME SYSTEM shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or SYSTEM | | PASS |

| | | | |
|---|---|---|---|
| b) | Table 3or Table 4,as applicable shall be filled in with the IMMUNITY COMPLIMENT LEVEL in accordance with the requirements of 5.2.2 and 6.2 | | PASS |
| c) | The expressions of Table 3 Table 4 and Table 5 Table 6,as applicable, shall be calculated,the results substituted in place of the COMPLIANCE LEVELS for IEC61000-4-6and IEC61000-4-3 test | | PASS |
| d) | Table 5 and Table 6,as applicable,shall be completed by calculating the distance corresponding to each entry in columns 2 through 5 in Table5 or in columns 2 through 4 in Table 6 | | PASS |
| e) | If,according to 6.2 or the scope of the EMC basic standard not apply to,the corresponding entries shall state “not applicable” | | PASS |
| 5.2.2.3 | Equipment specified for use only in shielded location | | N/A |
| a) | A warning that equipment should be used only in the specified type of shielded location | | N/A |
| b) | Tables modified if disturbance allowance according in 6.1.1.1 d) is used | | N/A |
| c) | A specification of allowed emission of other equipment located within the shielded location | | N/A |
| d) | Table 7 shall be used for LIFE-SUPPORTING, Table 8 shall be used are not LIFE-SUPPORTING | | N/A |
| 5.2.2.4 | Equipment that intentionally apply RF energy | | N/A |
| 5.2.2.5 | Equipment that intentionally receive RF energy | | N/A |
| 5.2.2.6 | Equipment that includes RF transmitters | | N/A |
| 5.2.2.7 | Requirements of cables and accessories | Please refer to User manual | PASS |
| 5.2.2.8 | Requirements applicable to large permanently installed equipment and systems | | N/A |
| 5.2.2.9 | Requirements applicable to equipment that has no essential performance | | N/A |
| 5.2.2.10 | Requirements applicable to TYPE A PROFESSIONAL SYSTEMS | | N/A |
| 6 | ELECTROMAGNETIC COMPATIBILITY | (se appended table) | |

## 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 | 4.65dB | (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 | | | | | |
|---|---|---|---|---|---|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. |
| 1 | ULTRA-BROADBAND ANTENNA | ROHDE & SCHWARZ | HL562 | 100015 | 2011/05 |
| 2 | EMI TEST RECEIVER | ROHDE & SCHWARZ | ESI 26 | 100009 | 2011/10 |
| 3 | RF TEST PANEL | ROHDE & SCHWARZ | TS / RSP | 335015/ 0017 | 2011/10 |
| 4 | TURNTABLE | ETS | 2088 | 2149 | 2011/10 |
| 5 | ANTENNA MAST | ETS | 2075 | 2346 | 2011/10 |
| 6 | EMI TEST SOFTWARE | ROHDE & SCHWARZ | ESK1 | N/A | 2011/10 |

| Electrostatic Discharge | | | | | |
|---|---|---|---|---|---|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. |
| 1 | ESD 30 System | EM TEST | ESD 30C | V0511100210 | 2011/10 |

| RF Field Strength Susceptibility | | | | | |
|---|---|---|---|---|---|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. |
| 1 | SIGNAL GENERATOR | IFR | 2032 | 203002/100 | 2011/10 |
| 2 | AMPLIFIER | AR | 150W1000 | 301584 | 2011/10 |
| 3 | DUAL DIRECTIONAL COUPLER | AR | DC6080 | 301508 | 2011/10 |
| 4 | POWER HEAD | AR | PH2000 | 301193 | 2011/10 |
| 5 | POWER METER | AR | PM2002 | 302799 | 2011/10 |
| 6 | TRANSMITTING AERIAL | AR | AT1080 | 28570 | 2011/10 |
| 7 | POWER AMPLIFIER | AR | 25S1G4A | 0325511 | 2011/10 |
| 8 | DUAL DIRECTIONAL COUPLER | AR | DC7144A | 0325100 | 2011/10 |
| 9 | TRANSMITTING AERIAL | AR | AT4002A | 0324848 | 2011/10 |

| Power Frequency Magnetic Field Susceptibility | | | | | |
|---|---|---|---|---|---|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. |
| 1 | ULTRA COMPACT SIMULATOR | EM TEST | UCS500M6 | 202304/060 | 2011/10 |
| 2 | MOTOR DRIVEN VOLTAGE TRANSFORMER | EM TEST | MV2616 | 302205 | 2011/10 |
| 3 | CURRENT TRANSFORMER | EM TEST | MC2630 | 302389 | 2011/10 |
| 4 | MAGNETIC COIL | EM TEST | MS100 | 0010230A | 2011/10 |

# 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. 4

### 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

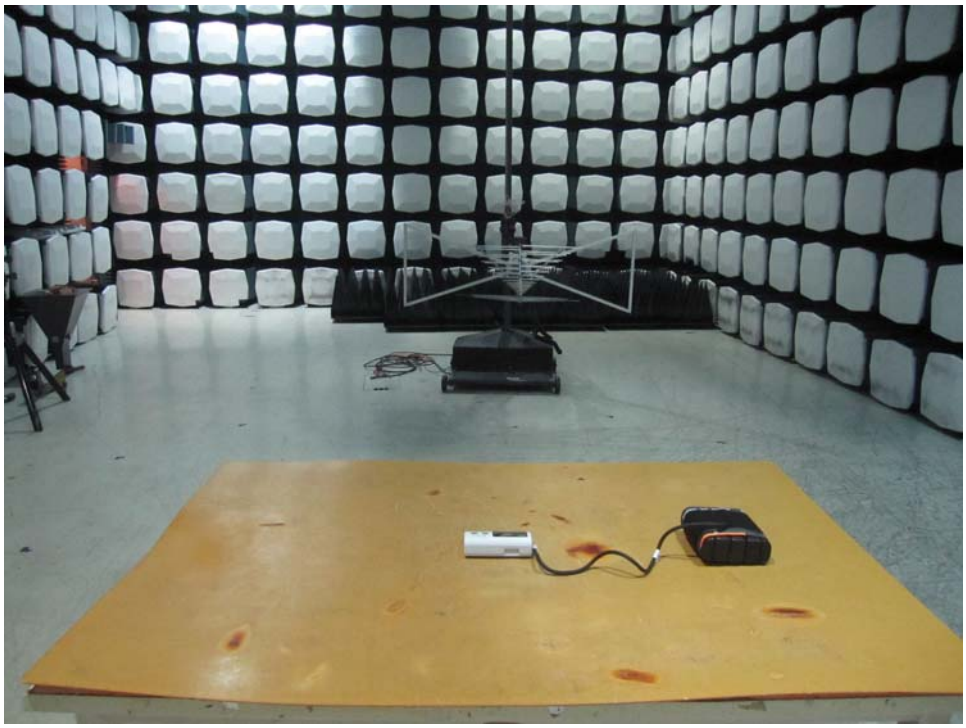
4.1.3.1. Operating Condition

The EUT is turned on 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

*SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO.,LTD*

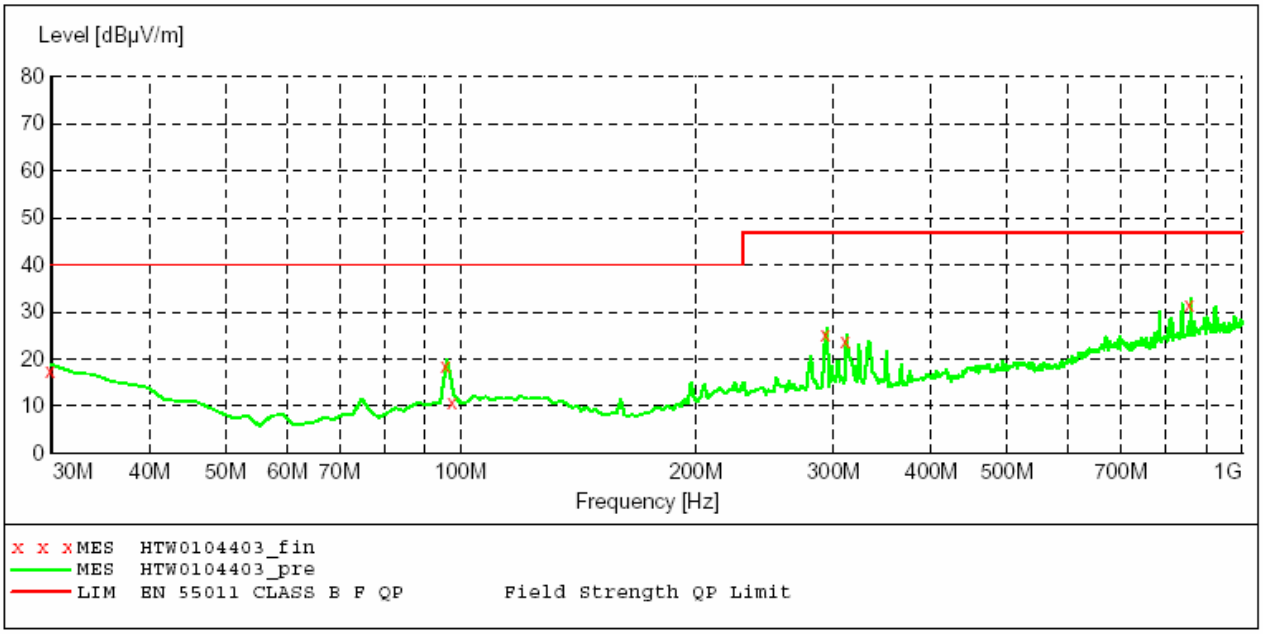
*RADIATED EMISSION EN 55011 CLASS B*

EUT: Blood Pressure Monitor(Upper arm type) M/N:ORA211
Manufacturer: Ningbo Ourui New Material Technology Development Co.,Ltd.
Operating Condition: ON
Test Site: 3M CHAMBER
Operator: JONY
Test Specification: DC 6V
Comment:
Start of Test: 1/4/2012 / 9:00:34AM

*SCAN TABLE: "test Field(30M-1G)QP"*

Short Description: Field Strength(30M-1G)

| Start Frequency | Stop Frequency | Step Width | Detector | Meas. Time | IF Bandw. | Transducer |
|---|---|---|---|---|---|---|
| 30.0 MHz | 1.0 GHz | 60.0 kHz | QuasiPeak | 1.0 s | 120 kHz | HL562 |




*MEASUREMENT RESULT: "HTW0104403_fin"*

1/4/2012 9:12AM

| Frequency MHz | Level dBµV/m | Transd dB | Limit dBµV/m | Margin dB | Det. | Height cm | Azimuth deg | Polarization |
|---|---|---|---|---|---|---|---|---|
| 30.000000 | 17.80 | -11.3 | 40.0 | 22.2 | QP | 100.0 | 319.00 | VERTICAL |
| 96.090000 | 18.90 | -19.9 | 40.0 | 21.1 | QP | 100.0 | 0.00 | VERTICAL |
| 98.030000 | 11.30 | -19.9 | 40.0 | 28.7 | QP | 100.0 | 14.00 | VERTICAL |
| 294.360000 | 25.50 | -17.4 | 47.0 | 21.5 | QP | 100.0 | 50.00 | VERTICAL |
| 311.860000 | 24.10 | -16.3 | 47.0 | 22.9 | QP | 100.0 | 91.00 | VERTICAL |
| 860.040000 | 32.00 | -7.5 | 47.0 | 15.0 | QP | 100.0 | 3.00 | VERTICAL |

*SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO.,LTD*

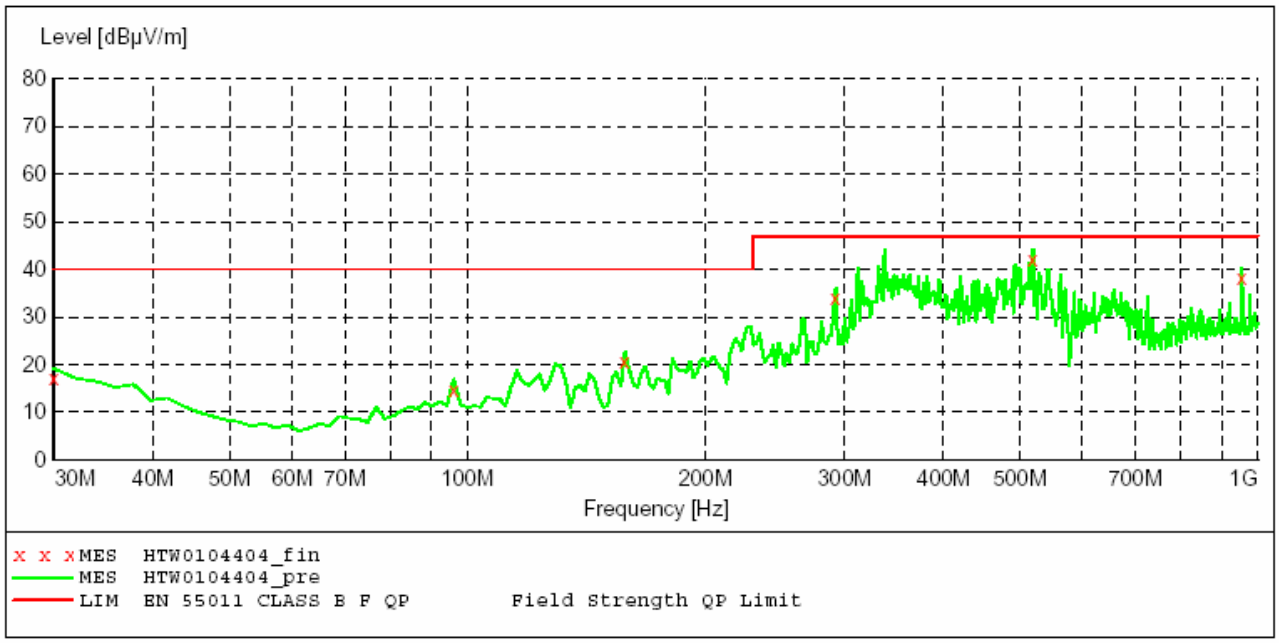
*RADIATED EMISSION EN 55011 CLASS B*

EUT: Blood Pressure Monitor(Upper arm type) M/N:ORA211
Manufacturer: Ningbo Ourui New Material Technology Development Co.,Ltd.
Operating Condition: ON
Test Site: 3M CHAMBER
Operator: JONY
Test Specification: DC 6V
Comment:
Start of Test: 1/4/2012 / 9:12:39AM

*SCAN TABLE: "test Field(30M-1G)QP"*

Short Description: Field Strength(30M-1G)

| Start Frequency | Stop Frequency | Step Width | Detector | Meas. Time | IF Bandw. | Transducer |
|---|---|---|---|---|---|---|
| 30.0 MHz | 1.0 GHz | 60.0 kHz | QuasiPeak | 1.0 s | 120 kHz | HL562 |




*MEASUREMENT RESULT: "HTW0104404_fin"*

1/4/2012 9:24AM

| Frequency MHz | Level dBµV/m | Transd dB | Limit dBµV/m | Margin dB | Det. | Height cm | Azimuth deg | Polarization |
|---|---|---|---|---|---|---|---|---|
| 30.000000 | 17.20 | -11.3 | 40.0 | 22.8 | QP | 100.0 | 39.00 | HORIZONTAL |
| 96.090000 | 14.90 | -19.9 | 40.0 | 25.1 | QP | 100.0 | 151.00 | HORIZONTAL |
| 158.290000 | 20.70 | -22.8 | 40.0 | 19.3 | QP | 100.0 | 39.00 | HORIZONTAL |
| 292.420000 | 34.00 | -17.4 | 47.0 | 13.0 | QP | 100.0 | 133.00 | HORIZONTAL |
| 519.850000 | 42.30 | -12.9 | 47.0 | 4.7 | QP | 100.0 | 3.00 | HORIZONTAL |
| 955.290000 | 38.30 | -7.1 | 47.0 | 8.7 | QP | 100.0 | 181.00 | HORIZONTAL |

## 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. 1

Date of test: Jan. 05, 2012

Operator: Jony

### 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 6.2.2 of EN 60601-1-2: 2007 at immunity test levels of ± 2KV, ± 4KV and ±8KV for air discharge and ± 2KV, ± 4KV and ± 6KV for contact discharge.

### 4.5.3. Description of the test set-up

4.5.3.1. Operating Condition

The EUT is turned on 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 25 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: | ■ 2 kV | ■ 4 kV | ■ 6 kV |
| Number of discharges: | ■ 10 | □ 25 | |
| Air discharge voltage: | ■ 2 kV | ■ 4 kV | ■ 8 kV |
| Number of discharges: | □ 10 | ■ 25 | |
| Type of discharge: | Direct discharge | ■ Air discharge<br>■ 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 degradation of function. Comply with EN 60601-1-2: 2007.

## 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. 4

Date of test: Jan. 05, 2012

Operator: Jony

### 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 6.2.3 of EN 60601-1-2: 2007 at immunity test levels of 3V/m.

### 4.6.3. Description of the test set-up

4.6.3.1. Operating Condition

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

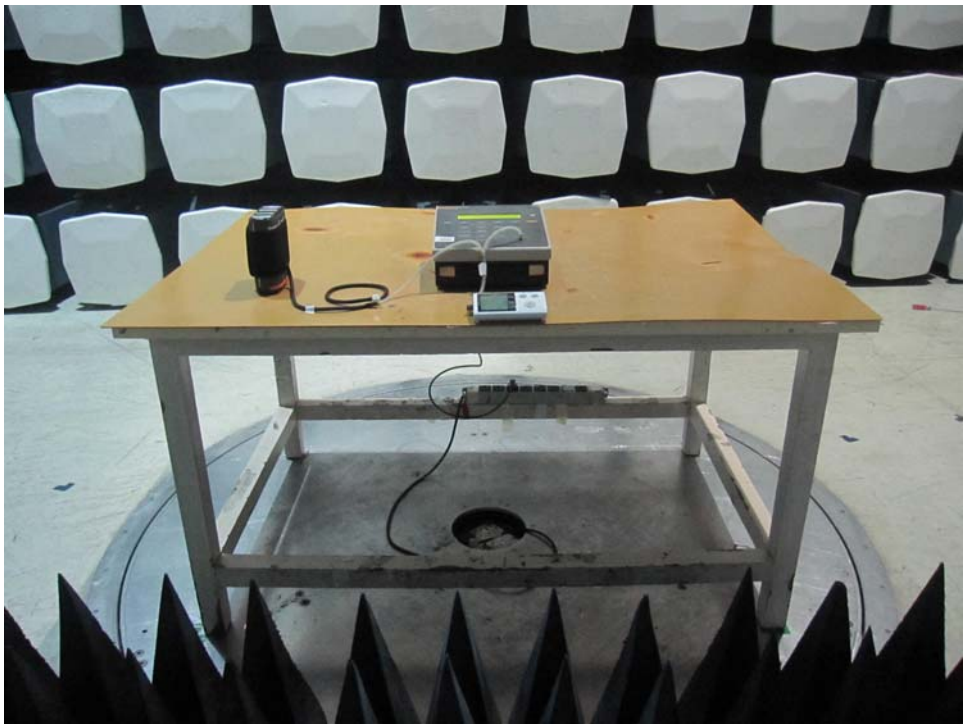
4.6.3.2. Test Procedure

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

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

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

4.6.3.3. Photo of the test set-up



**4.6.4. Test specification:**

| | |
|---|---|
| Frequency range: | ■ 80 MHz to 2500 MHz |
| Field strength: | ■ 3 V/m |
| EUT - antenna separation: | ■ 3 m |
| Modulation: | ■ AM: 80 %<br>■ sinusoidal 2Hz |
| Frequency step: | ■ 1 % with 3s dwell time |
| Antenna polarisation: | ■ horizontal ■ vertical |

**4.6.5. Test result**

No degradation of function. Comply with EN 60601-1-2: 2007.

## 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. 1

Date of test: Jan. 05, 2012

Operator: Jony

### 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 6.2.8 of EN 60601-1-2: 2007 at immunity test levels of 3A /m.

### 4.10.3. Description of the test set-up

4.10.3.1. Operating Condition

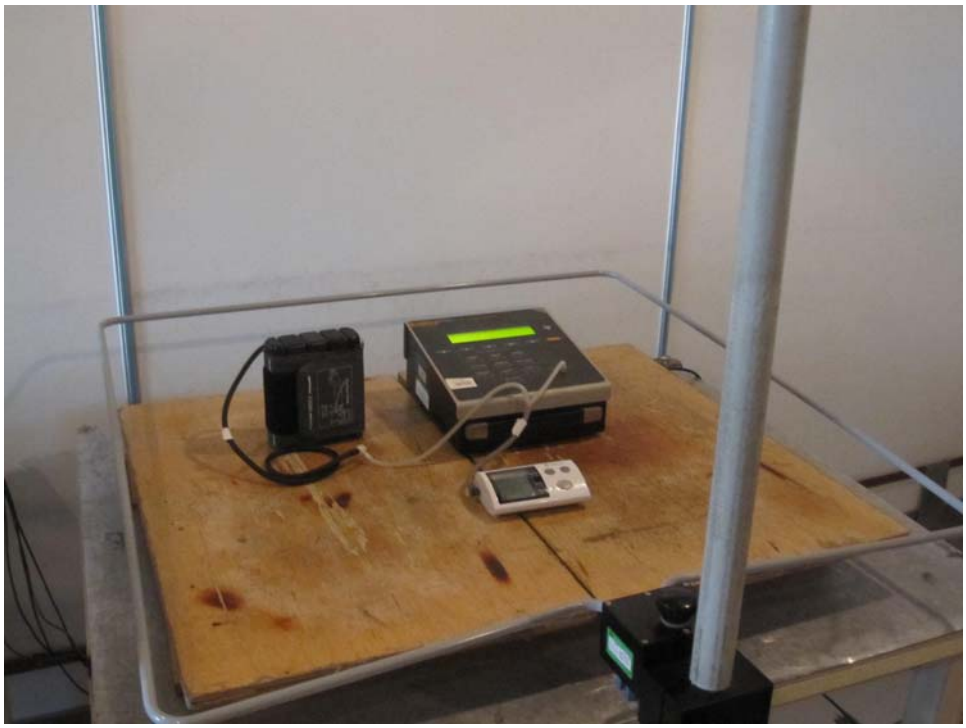
The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

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: | ■ 3 A/m | | |
| Test duration: | ■ 5 mins | | |
| Antenna factor: | 0.917 A/m | | |
| Axis: | ■ x-axis | ■ y-axis | ■ z-axis |

**4.10.5. Test result**

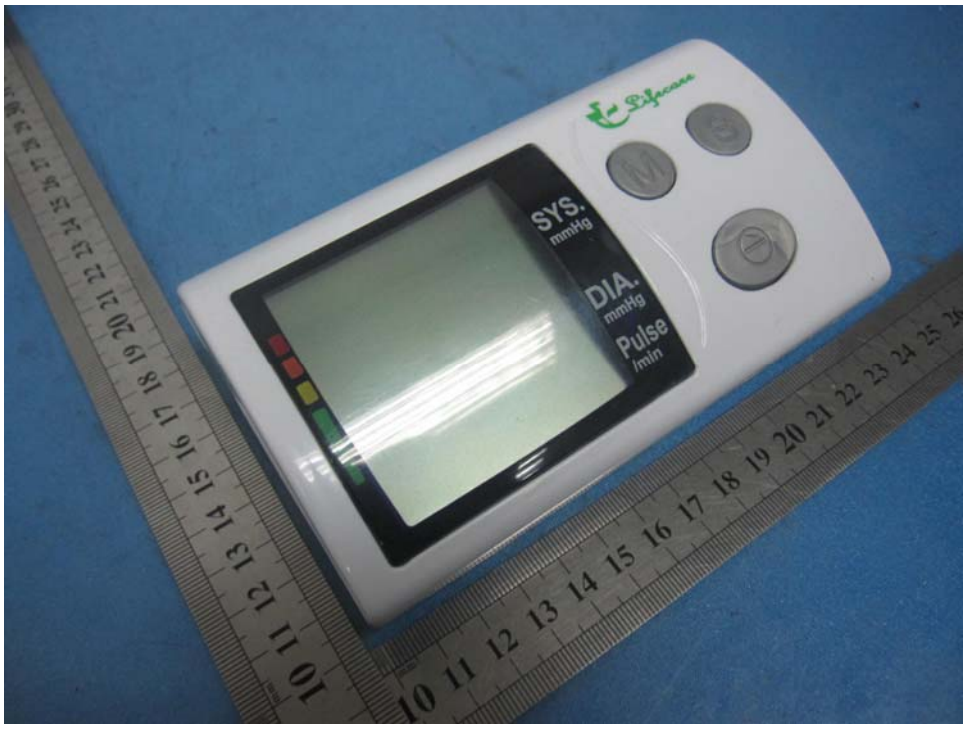
No degradation of function. Comply with EN 60601-1-2: 2007.

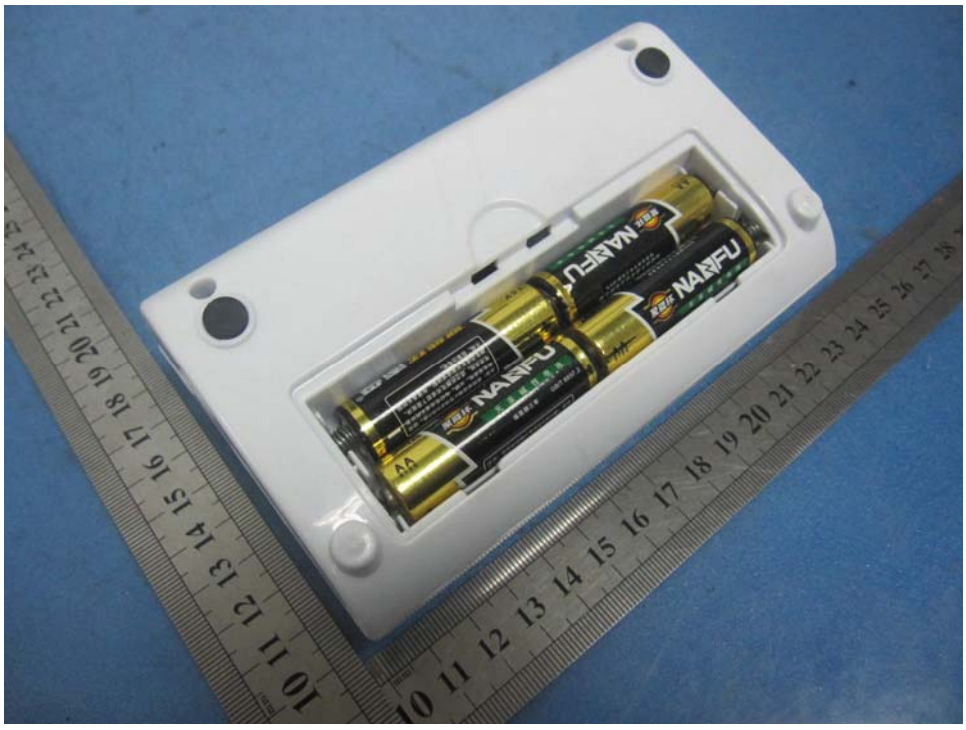
## 4.11. Voltage Dips and Interruptions

The test is not applicable to the EUT.

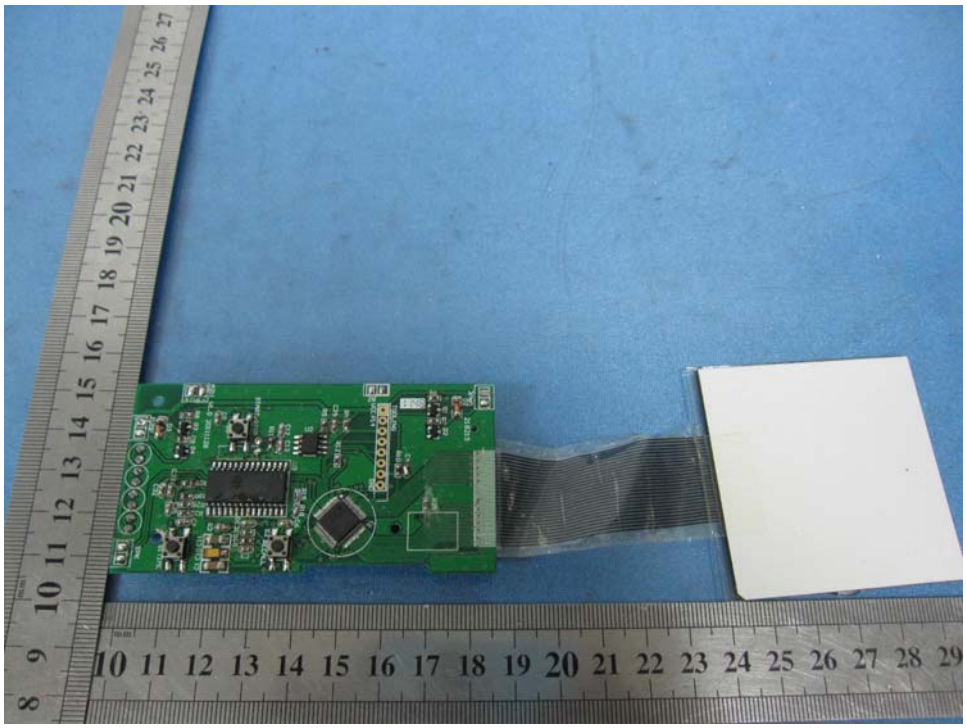
# 5. External and Internal Photos of the EUT

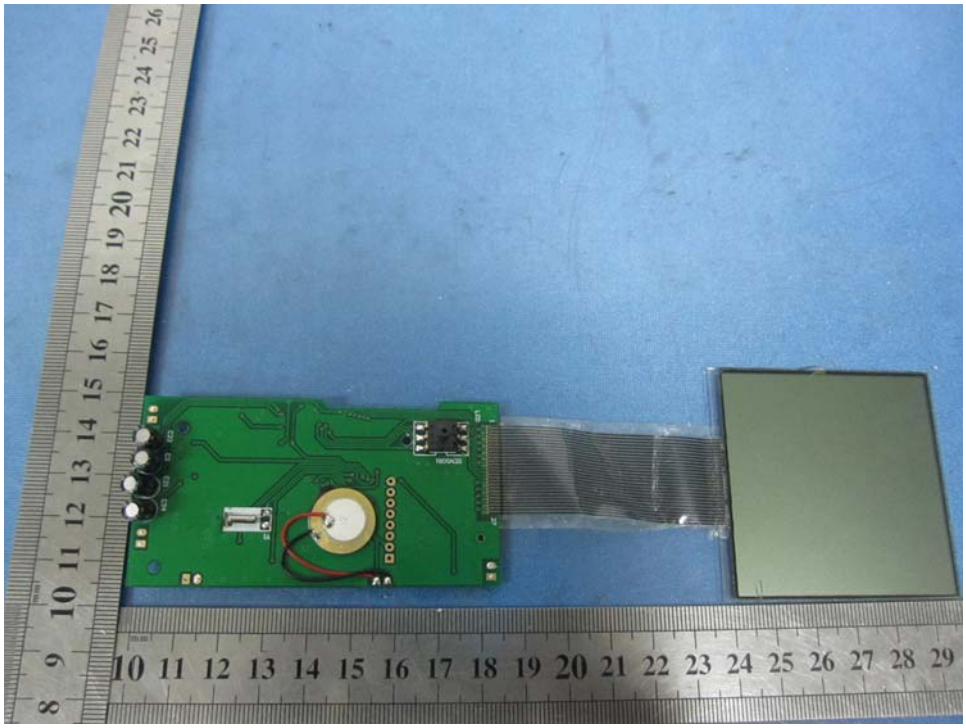
## 5.1. External photos of the EUT



## 5.2. Internal photos of the EUT





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

# Annex of Report

**Manufacturer's Declaration of the EUT**
**(altogether 5 pages)**

## Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

| Row | | | |
|---|---|---|---|
| 1 | Guidance and manufacturer´s declaration – electromagnetic emission | | |
| 2 | The ORA211 Blood Pressure Monitor (Upper arm type) is intended for use in the electromagnetic environment specified below. The customer or the user of ORA211 Blood Pressure Monitor (Upper arm type) should assure that it is used in such an environment. | | |
| 3 | Emissions test | Compliance | Electromagnetic environment - guidance |
| 4 | RF emissions<br>EN 55011 | Group 1 | The ORA211 Blood Pressure Monitor (Upper arm type) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| 5 | RF emissions<br>EN 55011 | Class B | The ORA211 Blood Pressure Monitor (Upper arm type) is suitable f or use in all establishments, including domestic establishments and those directlyconnected to the public low-voltage power supplynetwork that supplies buildings used for domestic purposes. |
| 6 | Harmonic emissions<br>EN 61000-3-2 | N/A | |
| 7 | Voltage fluctuations / flicker emissions<br>EN 61000-3-3 | N/A | |

## Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

| Guidance and manufacturer´s declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The ORA211 Blood Pressure Monitor (Upper arm type) is intended for use in the electromagnetic environment specified below. The customer or the user of the ORA211 Blood Pressure Monitor (Upper arm type) should assure that it is used in such an environment. | | | |
| **Immunity test** | **EN 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD)<br><br>EN 61000-4-2 | ± 6 kV contact<br><br>± 8 kV air | ± 6 kV contact<br><br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrostatic transient / burst<br><br>EN 61000-4-4 | ± 2 kV for power supply lines<br><br>± 1 kV for input/output lines | N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>EN 61000-4-5 | ± 1 kV differential mode<br><br>± 2 kV common mode | N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>EN 61000-4-11 | < 5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 0.5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$ )<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$ )<br>for 25 cycles<br><br>< 5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 5 sec | N/A | Mains power quality should be that of a typical commercial or hospital environment. If the user of the ORA211 Blood Pressure Monitor (Upper arm type) requires continued operation during power mains interruptions, it is recommended that the ORA211 Blood Pressure Monitor (Upper arm type) be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>EN 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE | $U_T$ is the a. c. mains voltage prior to application of the test level. | | |

## Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

**Guidance and manufacturer´s declaration – electromagnetic immunity**

The ORA211 Blood Pressure Monitor (Upper arm type) is intended for use in the electromagnetic environment specified below. The customer or the user of the ORA211 Blood Pressure Monitor (Upper arm type) should assure that it is used in such an environment.

| Immunity test | EN 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Conducted RF<br>EN 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | N/A | Portable and mobile RF communications equipment should be used no closer to any part of the ORA211 Blood Pressure Monitor (Upper arm type), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = [\frac{3.5}{V_1}]\sqrt{P}$ |
| Radiated RF<br>EN 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz<br>$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz<br>where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b]<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ORA211 Blood Pressure Monitor (Upper arm type) is used exceeds the applicable RF compliance level above, the ORA211 Blood Pressure Monitor (Upper arm type) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ORA211 Blood Pressure Monitor (Upper arm type).

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

## Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

**Recommended separation distances between portable and mobile RF communications equipment and the ORA211 Blood Pressure Monitor (Upper arm type)**

The ORA211 Blood Pressure Monitor (Upper arm type) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ORA211 Blood Pressure Monitor (Upper arm type) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ORA211 Blood Pressure Monitor (Upper arm type) as recommended below, according to the maximum output power of the communications equipment

| Rated maximum output of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ | 80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ | 800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ |
| 0.01 | / | 0.12 | 0.23 |
| 0.1 | / | 0.38 | 0.73 |
| 1 | / | 1.2 | 2.3 |
| 10 | / | 3.8 | 7.3 |
| 100 | / | 12 | 23 |

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.