



TEST REPORT

IEC 60601-1-2: 2007

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

Report Reference No...... : TRE11120111 R/C: 81181

Compiled by

(printed name+signature): Belial

Supervised by

(printed name+signature): Jony Yu

Approved by

(printed name+signature): Tony Jiang

Belial
Jony Yu
Tony Jiang

Date of issue.....: Dec. 30, 2011

Testing Laboratory Name: **Shenzhen Huatongwei International Inspection Co., Ltd.**

Address.....: Keji Nan No.12 Road, Hi-tech Park, Shenzhen, China

Testing location/ procedure: Full application of Harmonised standards
 Partial application of Harmonised standards
 Other standard testing methods

Applicant's name.....: **Foshan YaYou Medical Equipment Co., Ltd.**

Address.....: NO.2 Building, No.1 Huafu Bei Road, Zhangcha Street, Chancheng District, Foshan City, Guangdong Province, China

Test specification:

Standard: **IEC 60601-1-2: 2007**

Non-standard test method.....: /

Test Report Form No......: HTWEMCCE_1B

TRF Originator.....: Shenzhen Huatongwei International Inspection Co., Ltd.

Master TRF.....: Dated 2014-06

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Test item description: Complete Dental Unit

Trade Mark:



Manufacturer: Foshan YaYou Medical Equipment Co., Ltd.

Model/Type reference.....: A8000-IA

Listed models: A8000- I B, A8000- II, A6800, A6600, A5000, A3600, A3000, A1000, A880, A800

Ratings.....: 230Va.c. 50/60Hz 1200VA

Result.....: **Positive**

Report version information

Revised date: 2015-05-05 Clause 2.3 /3

EMC -- TEST REPORT

| | |
|--------------------------------------|---------------|
| Test Report No. : TRE11120111 | Dec. 30, 2011 |
| | Date of issue |

Equipment under Test : Complete Dental Unit

Model /Type : A8000-IA

Listed Models : A8000- I B, A8000- II , A6800, A6600, A5000, A3600, A3000, A1000, A880, A800

Applicant : Foshan YaYou Medical Equipment Co., Ltd.

Address : NO.2 Building, No.1 Huafu Bei Road, Zhangcha Street, Chancheng District, Foshan City, Guangdong Province, China

Manufacturer : Foshan YaYou Medical Equipment Co., Ltd.

Address : NO.2 Building, No.1 Huafu Bei Road, Zhangcha Street, Chancheng District, Foshan City, Guangdong Province, 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.

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1. TEST STANDARDS

The tests were performed according to following standards:

[IEC 60601-1-2: 2007](#) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Remark: This EUT is ranged to the Group 1 Class B apparatus according to the standard of CISPR 11: 2010 clause 5.2

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
- AC power cord for EUT
 - Length(m) : 1.4
 - Shield : Unshielded
 - Detachable : Detachable
- Foot pedal Cable
 - Length(m) : 1.6
 - Shield : Shielded
 - Detachable : Detachable
- Control Cable
 - Length(m) : 0.8
 - Shield : Shielded
 - Detachable : Undetachable

2.6. Compliance criteria

Under the test conditions specified in 6.2.1.10 of IEC 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 Nan No.12 Road, Hi-tech Park, Shenzhen, China
Tel: 86-755-26748019 Fax: 86-755-26748089

3.2. Test Facility

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

CNAS-Lab Code: L1225

Shenzhen Huatongwei International Inspection Co., Ltd. has been assessed and proved to be in compliance with CNAS-CL01 Accreditation Criteria for Testing and Calibration Laboratories (identical to ISO/IEC 17025: 2005 General Requirements) for the Competence of Testing and Calibration Laboratories, Date of Registration: February 28, 2015. Valid time is until February 27, 2018.

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 Sept 30, 2015.

FCC-Registration No.: 662850&317478

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, 2012, valid time is until Jun. 01, 2015. Registration 317478, Renewal date Jul. 18, 2014, valid time is until Jul. 18, 2017.

IC-Registration No.: 5377A&5377B

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 Dec. 31, 2013, valid time is until Dec. 31, 2016.

Two 3m Alternate Test Site of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered by Certification and Engineering Bureau of Industry Canada for the performance of radiated measurements with Registration No. 5377B on Dec.03, 2014, valid time is until Dec.03, 2017.

ACA

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

VCCI

The 3m Semi-anechoic chamber (12.2m×7.95m×6.7m) of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.:R-2484. Date of Registration: Dec. 20, 2012. Valid time is until Dec. 29, 2015.

Radiated disturbance above 1GHz measurement of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: G-292. Date of Registration: Dec. 24, 2013. Valid time is until Dec. 23, 2016.

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, 2012. Valid time is until Dec. 19, 2015.

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, 2013. Valid time is until May 06, 2016.

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, 2016.

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 | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 CISPR 11: 2010 | PASS |
| Conducted Disturbance (0.15-30MHz) | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 CISPR 11: 2010 | PASS |
| Harmonic Current | IEC 60601-1-2: 2007 IEC 61000-3-2: 2014 | PASS |
| Voltage Fluctuation and Flicker | IEC 60601-1-2: 2007 IEC 61000-3-3: 2013 | PASS |
| Immunity Measurement | | |
| Electrostatic Discharge | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-2: 2008 | PASS |
| RF Field Strength Susceptibility (80~2500MHz) | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-3: 2010 | PASS |
| Electrical Fast Transient/Burst Test | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-4: 2012 | PASS |
| Surge Test | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-5: 2014 | PASS |
| Conducted Susceptibility Test | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-6: 2013 | PASS |
| Power Frequency Magnetic Field Susceptibility Test | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-8: 2009 | PASS |
| Voltage Dips and Interruptions Test | IEC 60601-1-2: 2007 ISO 80601-2-61: 2011 Clause 202 IEC 61000-4-11: 2004 | PASS |

Note: "N/A" means "not applicable".

The measurement uncertainty is not included in the test result.

| IEC 60601-1-2: 2007 | | | |
|---------------------|---|-----------------------------|---------|
| 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 | Please refer to User manual | PASS |
| e) | A justification for each immunity compliance level below 60601 test level | | N/A |
| f) | Table 2, completed as appropriate | | PASS |
| g) | The performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE. | Please refer to User manual | PASS |
| 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 | Please refer to User manual | PASS |

| | | | |
|----------|--|-----------------------------|------|
| a) | ME EQUIPMENT or ME SYSTEM shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or SYSTEM | Please refer to User manual | PASS |
| b) | Table 3 or 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 | Please refer to User manual | 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 IEC61000-4-6 and IEC61000-4-3 test | Please refer to User manual | 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 Table 5 or in columns 2 through 4 in Table 6 | Please refer to User manual | 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" | Please refer to User manual | 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 | (see 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) |
| Conducted Disturbance | 0.15~30MHz | 3.35dB | (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. | Next Cal. |
| 1 | Ultra-Broadband Antenna | R&S | HL562 | 100015 | 11/8/2014 | 11/7/2017 |
| 2 | Emi Test Receiver | R&S | ESI 26 | 100009 | 11/1/2014 | 10/31/2015 |
| 3 | Pre-Amplifier | CD | PAP-0102 | 12004 | 11/1/2014 | 10/31/2015 |
| 4 | Turntable | ETS | 2088 | 2149 | N/A | N/A |
| 5 | Antenna Mast | ETS | 2075 | 2346 | N/A | N/A |
| 6 | Test Software | R&S | ES-K1 | / | N/A | N/A |

| Conducted Disturbance | | | | | | |
|-----------------------|-------------------|--------------|-----------|------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | EMI Test Receiver | R&S | ESCS30 | 100038 | 11/1/2014 | 10/31/2015 |
| 2 | Artificial Mains | R&S | ESH3-Z5 | 100049 | 11/1/2014 | 10/31/2015 |
| 3 | Pulse Limiter | R&S | ESH3-Z2 | 100449 | 11/1/2014 | 10/31/2015 |
| 4 | Test Software | R&S | ES-K1 | / | N/A | N/A |

| Harmonic Current | | | | | | |
|------------------|-------------------------------|------------------------|-----------|-------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Purified Power Source | CALIFORNIA INSTRUMENTS | HFS500 | 54513 | 11/1/2014 | 10/31/2015 |
| 2 | Harmonic And Flicker Analyzer | EM TEST | DPA500N | V1106108797 | 11/1/2014 | 10/31/2015 |
| 3 | Test Software | EM TEST | DPA | / | NA | NA |

| Voltage Fluctuation and Flicker | | | | | | |
|---------------------------------|-------------------------------|------------------------|-----------|-------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Purified Power Source | CALIFORNIA INSTRUMENTS | HFS500 | 54513 | 11/1/2014 | 10/31/2015 |
| 2 | Harmonic And Flicker Analyzer | EM TEST | DPA500N | V1106108797 | 11/1/2014 | 10/31/2015 |
| 3 | Test Software | EM TEST | DPA | / | NA | NA |

| Electrostatic Discharge | | | | | | |
|-------------------------|----------------|--------------|-----------|------------|------------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | ESD Simulator | EM TEST | DITO | 0301-04 | 11/19/2014 | 11/18/2015 |

| RF Field Strength Susceptibility | | | | | | |
|----------------------------------|--------------------------|--------------|-----------|------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Signal Generator | IFR | 2032 | 203002/100 | 11/1/2014 | 10/31/2015 |
| 2 | Amplifier | AR | 150W1000 | 301584 | 11/1/2014 | 10/31/2015 |
| 3 | Dual Directional Coupler | AR | DC6080 | 301508 | 11/1/2014 | 10/31/2015 |
| 4 | Power Head | AR | PH2000 | 301193 | 11/1/2014 | 10/31/2015 |
| 5 | Power Meter | AR | PM2002 | 302799 | 11/1/2014 | 10/31/2015 |
| 6 | Transmit Antenna | AR | AT1080 | 28570 | 11/1/2014 | 10/31/2015 |
| 7 | Power Amplifier | AR | 25S1G4A | 0325511 | 11/1/2014 | 10/31/2015 |
| 8 | Dual Directional Coupler | AR | DC7144A | 0325100 | 11/1/2014 | 10/31/2015 |
| 9 | Microwave Horn Antenna | AR | AT4002A | 0324848 | 11/1/2014 | 10/31/2015 |
| 10 | Test Software | AR | SW1004 | / | NA | NA |

| Electrical Fast Transient/Burst | | | | | | |
|---------------------------------|---|--------------|-----------|-----------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Electrical Fast Transient/Burst Generator | EM TEST | UCS500N5E | P130511113 5 | 11/1/2014 | 10/31/2015 |
| 2 | Test Software | EM TEST | ISM IEC | / | NA | NA |

| Surge | | | | | | |
|-------|------------------|--------------|------------|-----------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Surge Generator | EM TEST | VCS500N10T | P131811830 9 | 11/1/2014 | 10/31/2015 |
| 2 | Coupling Network | EM TEST | CNV501S4.1 | P141313287 4 | 11/1/2014 | 10/31/2015 |
| 3 | Test Software | EM TEST | IEC | / | NA | NA |

| Conducted Susceptibility | | | | | | |
|--------------------------|--------------------------|--------------|------------|------------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Signal Generator | IFR | 2023A | 202304/060 | 11/1/2014 | 10/31/2015 |
| 2 | Amplifier | AR | 75A250 | 302205 | 11/1/2014 | 10/31/2015 |
| 3 | Dual Directional Coupler | AR | DC2600 | 302389 | 11/1/2014 | 10/31/2015 |
| 4 | 6db Attenuator | EMTEST | ATT6/75 | 0010230A | 11/1/2014 | 10/31/2015 |
| 5 | CDN | EMTEST | CDN M3/32A | 5100103200 23 | 11/1/2014 | 10/31/2015 |
| 6 | Test Software | AR | SW1004 | / | NA | NA |

| Power Frequency Magnetic Field Susceptibility | | | | | | |
|---|----------------------------------|--------------|-----------|------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Ultra Compact Simulator | EM TEST | UCS500M6 | 202304/060 | 11/1/2014 | 10/31/2015 |
| 2 | Motor Driven Voltage Transformer | EM TEST | MV2616 | 302205 | 11/1/2014 | 10/31/2015 |
| 3 | Current Transformer | EM TEST | MC2630 | 302389 | 11/1/2014 | 10/31/2015 |
| 4 | Magnetic Coil | EM TEST | MS100 | 0010230A | 11/1/2014 | 10/31/2015 |
| 5 | Test Software | EM TEST | ISM IEC | / | NA | NA |

| Voltage Dips and Interruptions | | | | | | |
|--------------------------------|-----------------------|------------------------|-----------|------------|-----------|------------|
| Item | Test Equipment | Manufacturer | Model No. | Serial No. | Last Cal. | Next Cal. |
| 1 | Purified Power Source | CALIFORNIA INSTRUMENTS | HFS500 | 54513 | 11/1/2014 | 10/31/2015 |
| 2 | Test Software | EM TEST | DPA | / | NA | NA |

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 (dB μ V/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

Old



New



4.1.4. Test result

The requirements are **Fulfilled**

Band Width: 120kHz

Frequency Range: 30MHz to 1000MHz

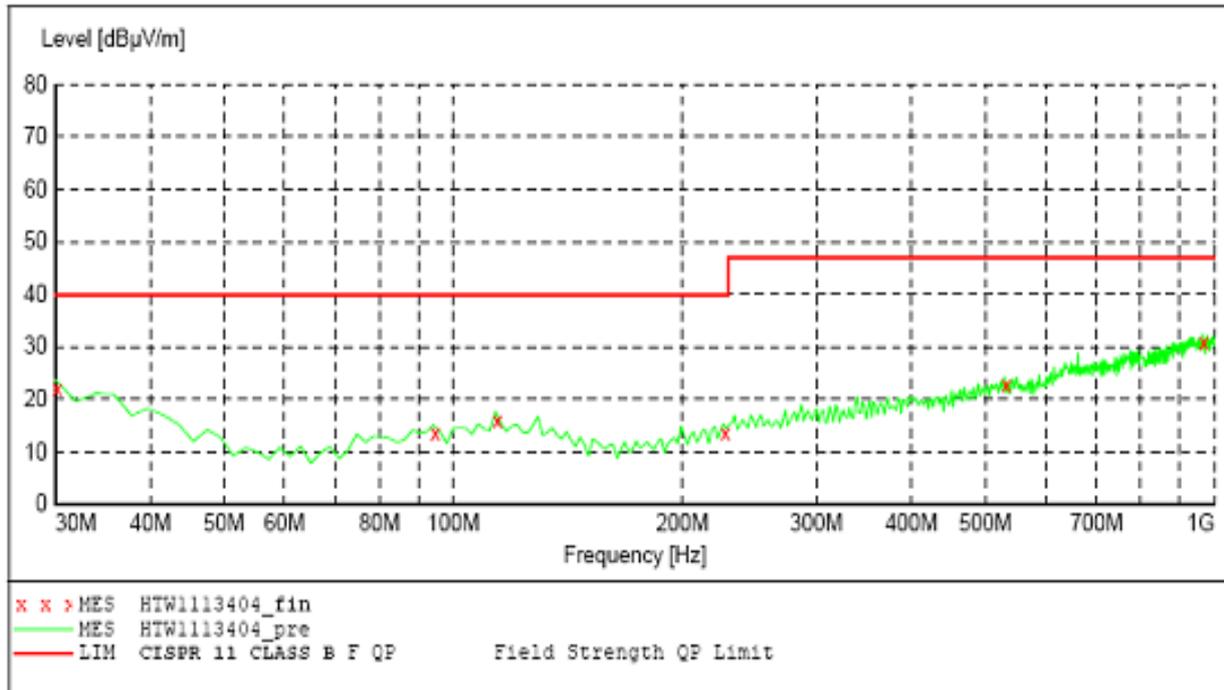
Remarks: The limits are kept. For detailed results, please see the following page(s).

Margin=limit-level

Level=read values+transducer

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

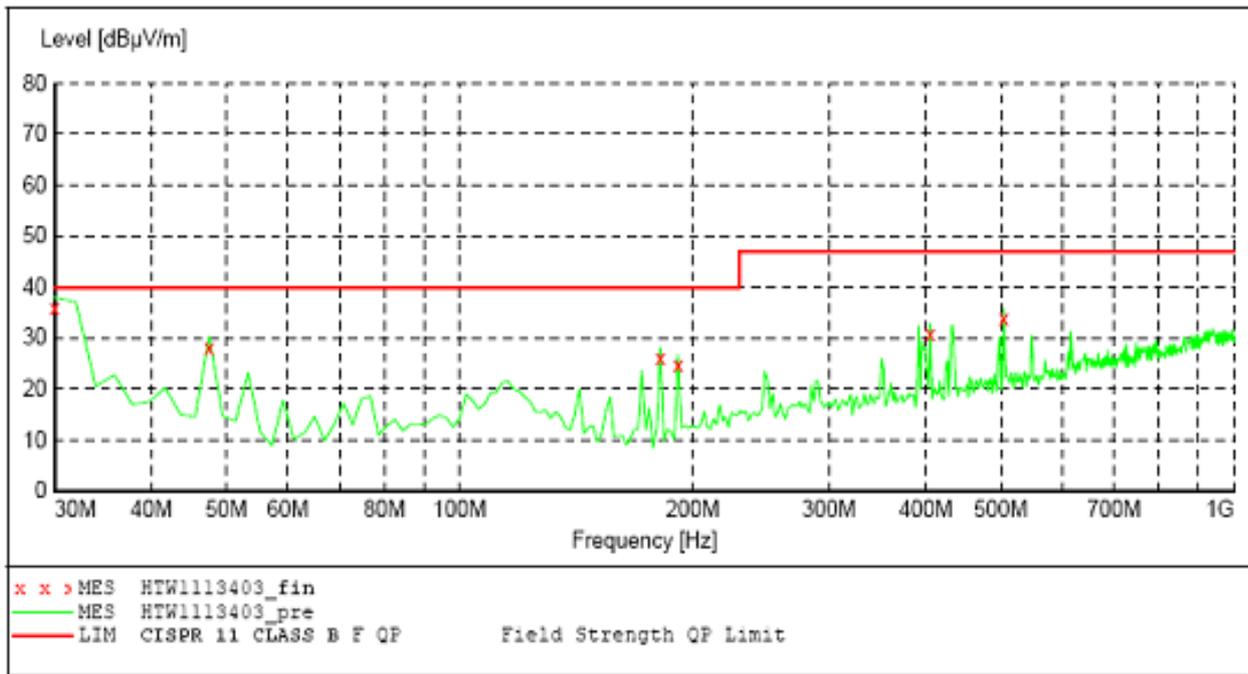
Old



MEASUREMENT RESULT: "HTW1113404_fin"

11/13/2009 9:02AM

| Frequency MHz | Level dBµV/m | Transd dB | Limit dBµV/m | Margin dB | Det. | Height cm | Azimuth deg | Polarization |
|------------------|-----------------|--------------|-----------------|--------------|------|--------------|----------------|--------------|
| 30.000000 | 21.70 | -4.7 | 40.0 | 18.3 | QP | 100.0 | 65.00 | HORIZONTAL |
| 94.150000 | 13.10 | -13.9 | 40.0 | 26.9 | QP | 100.0 | 196.00 | HORIZONTAL |
| 113.590000 | 15.60 | -13.0 | 40.0 | 24.4 | QP | 100.0 | 229.00 | HORIZONTAL |
| 226.330000 | 13.30 | -13.6 | 40.0 | 26.7 | QP | 300.0 | 0.00 | HORIZONTAL |
| 529.580000 | 22.30 | -5.8 | 47.0 | 24.7 | QP | 300.0 | 207.00 | HORIZONTAL |
| 963.070000 | 30.50 | 2.7 | 47.0 | 16.5 | QP | 100.0 | 276.00 | HORIZONTAL |

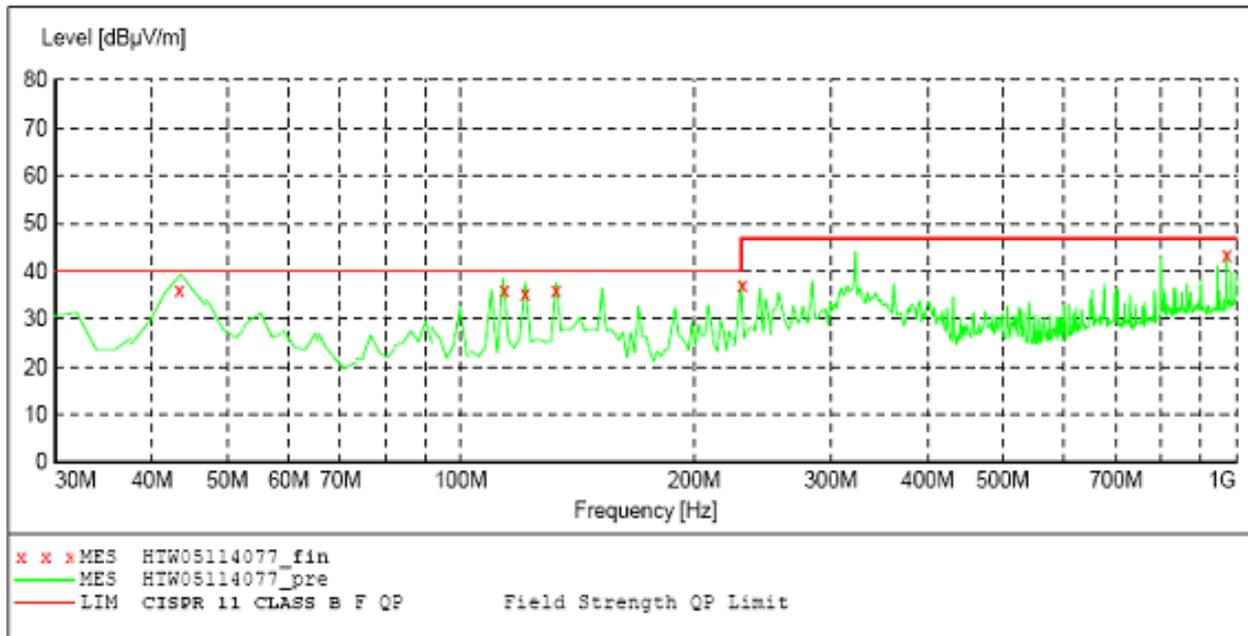


MEASUREMENT RESULT: "HTW1113403_fin"

11/13/2009 8:40AM

| Frequency MHz | Level dBµV/m | Transd dB | Limit dBµV/m | Margin dB | Det. | Height cm | Azimuth deg | Polarizatio |
|------------------|-----------------|--------------|-----------------|--------------|------|--------------|----------------|-------------|
| 30.000000 | 36.00 | -4.7 | 40.0 | 4.0 | QP | 100.0 | 229.00 | VERTICAL |
| 47.490000 | 28.30 | -14.6 | 40.0 | 11.7 | QP | 100.0 | 324.00 | VERTICAL |
| 181.620000 | 26.10 | -16.6 | 40.0 | 13.9 | QP | 100.0 | 236.00 | VERTICAL |
| 191.340000 | 24.70 | -16.0 | 40.0 | 15.3 | QP | 100.0 | 330.00 | VERTICAL |
| 405.170000 | 30.80 | -8.6 | 47.0 | 16.2 | QP | 100.0 | 229.00 | VERTICAL |
| 504.310000 | 33.80 | -6.5 | 47.0 | 13.2 | QP | 100.0 | 56.00 | VERTICAL |

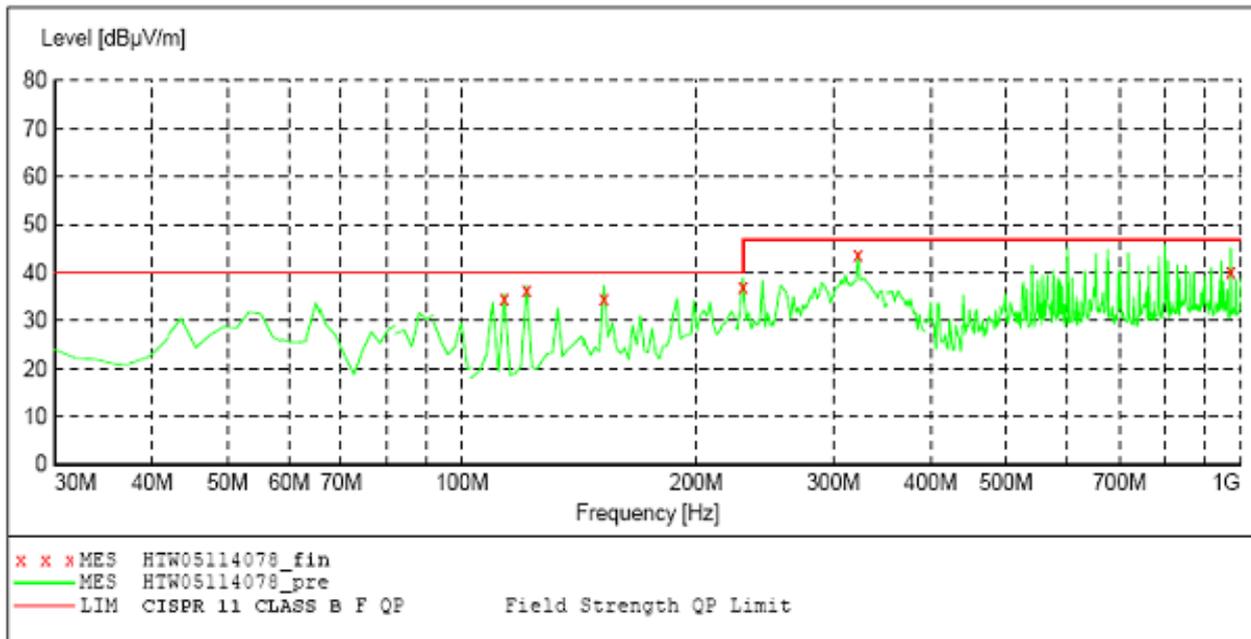
New



MEASUREMENT RESULT: "HTW05114077_fin"

5/11/2013 5:37PM

| Frequency MHz | Level dBµV/m | Transd dB | Limit dBµV/m | Margin dB | Det. | Height cm | Azimuth deg | Polarization |
|------------------|-----------------|--------------|-----------------|--------------|------|--------------|----------------|--------------|
| 43.580000 | 36.90 | -11.1 | 40.0 | 3.1 | QP | 300.0 | 102.00 | VERTICAL |
| 113.420000 | 37.00 | -17.2 | 40.0 | 3.0 | QP | 300.0 | 116.00 | VERTICAL |
| 121.180000 | 36.50 | -22.4 | 40.0 | 3.5 | QP | 300.0 | 0.00 | VERTICAL |
| 136.420000 | 36.20 | -18.1 | 40.0 | 3.8 | QP | 300.0 | 31.00 | VERTICAL |
| 229.820000 | 37.00 | -17.9 | 40.0 | 3.0 | QP | 300.0 | 167.00 | VERTICAL |
| 969.820000 | 36.80 | -18.0 | 40.0 | 3.2 | QP | 300.0 | 354.00 | VERTICAL |



MEASUREMENT RESULT: "HTW05114078_fin"

5/11/2013 5:49PM

| Frequency MHz | Level dBµV/m | Transd dB | Limit dBµV/m | Margin dB | Det. | Height cm | Azimuth deg | Polarization |
|------------------|-----------------|--------------|-----------------|--------------|------|--------------|----------------|--------------|
| 113.420000 | 35.20 | -18.1 | 40.0 | 4.8 | QP | 100.0 | 68.00 | HORIZONTAL |
| 121.180000 | 36.90 | -17.9 | 40.0 | 3.1 | QP | 100.0 | 42.00 | HORIZONTAL |
| 152.220000 | 35.50 | -21.1 | 40.0 | 4.8 | QP | 100.0 | 280.00 | HORIZONTAL |
| 229.820000 | 35.90 | -18.0 | 40.0 | 4.1 | QP | 100.0 | 300.00 | HORIZONTAL |
| 322.940000 | 43.40 | -14.6 | 47.0 | 3.6 | QP | 100.0 | 261.00 | HORIZONTAL |
| 972.840000 | 39.90 | -3.8 | 47.0 | 7.1 | QP | 100.0 | 21.00 | HORIZONTAL |

4.2. Conducted disturbance

For test instruments and accessories used see section 3.6.

4.2.1. Description of the test location

Test location: Shielded room No. 3

4.2.2. Limits of disturbance

Limit of conducted disturbance at the mains ports(Class B)

| Frequency Range (MHz) | Limits (dBuV) | |
|-----------------------|---------------|---------|
| | Quasi-Peak | Average |
| 0.150~0.500 | 66~56 | 56~46 |
| 0.5000~5.000 | 56 | 46 |
| 5.000~30.000 | 60 | 50 |

Note: (1) The tighter limit shall apply at the edge between two frequency bands.

4.2.3. Description of the test set-up

4.2.3.1. Operating Condition

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

4.2.3.2. Test Configuration and Procedure

EUT is placed on the grounded reference plane. Connect the power line of the EUT to the LISN which is connected to receiver by coaxial line, then disturbance of the neutral line and live line can be detected by the receiver.

4.2.3.3. Photo of the test set-up

Old



New



4.2.4. Test result

The requirements are **Fulfilled**

Band Width: 9kHz

Frequency Range: 150kHz to 30MHz

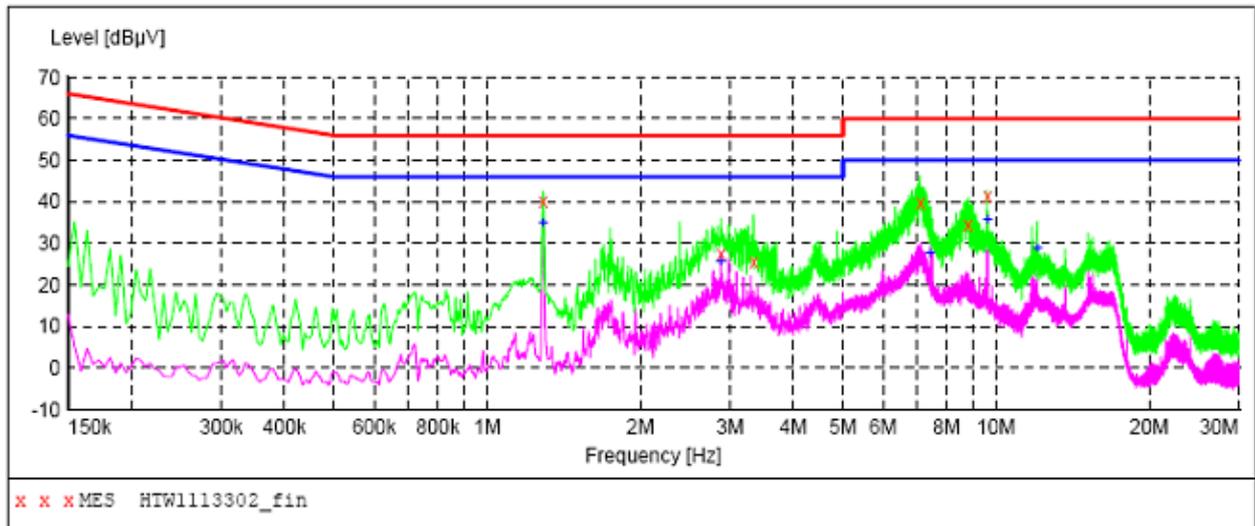
Remarks: The limits are kept. For detailed results, please see the following page(s).

Margin=limit-level

Level=read values+transducer

Transducer=insertion loss of LISN+cable loss+insertion loss of pulse limiter

Old



MEASUREMENT RESULT: "HTW1113302_fin"

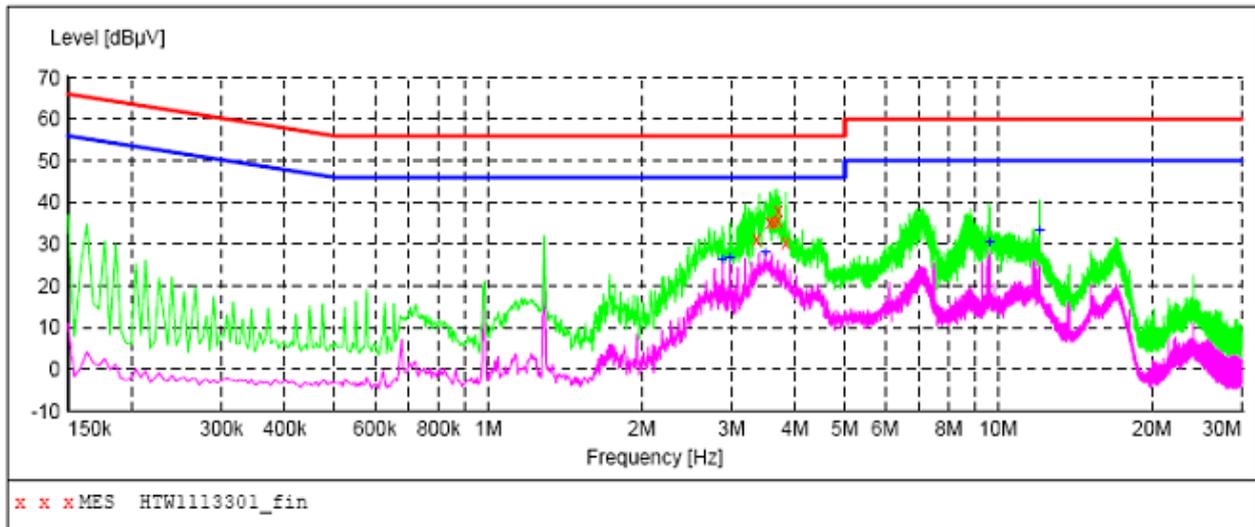
11/13/2009 8:51AM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 1.288500 | 40.10 | 10.3 | 56 | 15.9 | QP | L1 | GND |
| 2.886000 | 27.40 | 10.4 | 56 | 28.6 | QP | L1 | GND |
| 3.345000 | 25.50 | 10.4 | 56 | 30.5 | QP | L1 | GND |
| 7.116000 | 39.90 | 10.4 | 60 | 20.1 | QP | L1 | GND |
| 8.821500 | 34.50 | 10.6 | 60 | 25.5 | QP | L1 | GND |
| 9.622500 | 41.50 | 10.6 | 60 | 18.5 | QP | L1 | GND |

MEASUREMENT RESULT: "HTW1113302_fin2"

11/13/2009 8:51AM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 1.288500 | 34.90 | 10.3 | 46 | 11.1 | AV | L1 | GND |
| 2.877000 | 25.50 | 10.4 | 46 | 20.5 | AV | L1 | GND |
| 7.435500 | 27.50 | 10.5 | 50 | 22.5 | AV | L1 | GND |
| 9.622500 | 35.80 | 10.6 | 50 | 14.2 | AV | L1 | GND |
| 12.070500 | 28.90 | 10.6 | 50 | 21.1 | AV | L1 | GND |



MEASUREMENT RESULT: "HTW1113301_fin"

11/13/2009 8:48AM

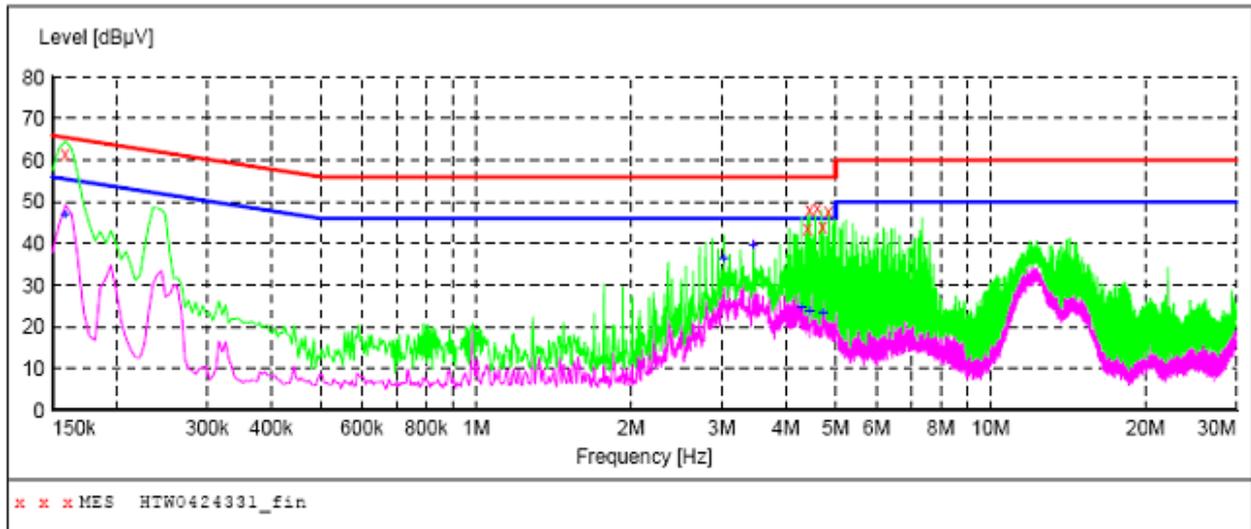
| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 3.363000 | 31.30 | 10.4 | 56 | 24.7 | QP | N | GND |
| 3.570000 | 35.20 | 10.4 | 56 | 20.8 | QP | N | GND |
| 3.633000 | 35.40 | 10.4 | 56 | 20.6 | QP | N | GND |
| 3.700500 | 35.80 | 10.4 | 56 | 20.2 | QP | N | GND |
| 3.709500 | 38.10 | 10.4 | 56 | 17.9 | QP | N | GND |
| 3.835500 | 30.60 | 10.4 | 56 | 25.4 | QP | N | GND |

MEASUREMENT RESULT: "HTW1113301_fin2"

11/13/2009 8:48AM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 2.881500 | 26.30 | 10.4 | 46 | 19.7 | AV | N | GND |
| 2.985000 | 26.70 | 10.4 | 46 | 19.3 | AV | N | GND |
| 3.498000 | 27.90 | 10.4 | 46 | 18.1 | AV | N | GND |
| 9.622500 | 30.50 | 10.6 | 50 | 19.5 | AV | N | GND |
| 12.070500 | 33.10 | 10.6 | 50 | 16.9 | AV | N | GND |

New



MEASUREMENT RESULT: "HTW0424331_fin"

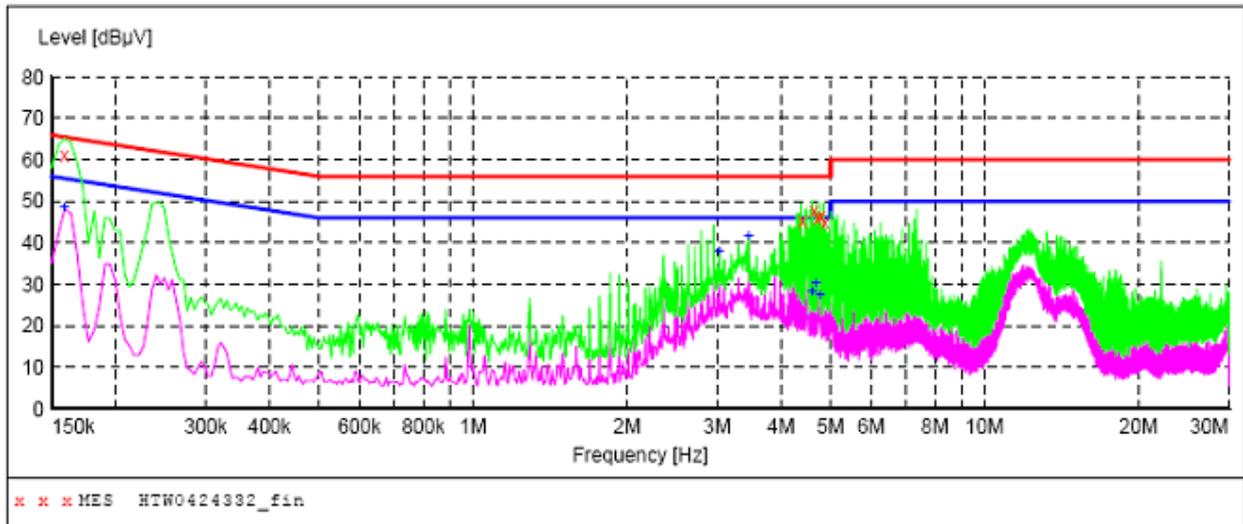
4/24/2013 5:02PM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 0.159000 | 62.80 | 10.2 | 66 | 3.2 | QP | L1 | GND |
| 4.402500 | 45.10 | 10.2 | 56 | 10.9 | QP | L1 | GND |
| 4.443000 | 49.60 | 10.2 | 56 | 6.4 | QP | L1 | GND |
| 4.600500 | 50.00 | 10.2 | 56 | 6.0 | QP | L1 | GND |
| 4.717500 | 45.50 | 10.2 | 56 | 10.5 | QP | L1 | GND |
| 4.839000 | 49.00 | 10.2 | 56 | 7.0 | QP | L1 | GND |

MEASUREMENT RESULT: "HTW0424331_fin2"

4/24/2013 2:11PM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 0.159000 | 48.30 | 10.2 | 56 | 7.2 | AV | L1 | GND |
| 3.025500 | 37.70 | 10.2 | 46 | 8.3 | AV | L1 | GND |
| 3.457500 | 40.90 | 10.2 | 46 | 5.1 | AV | L1 | GND |
| 4.290000 | 25.70 | 10.2 | 46 | 20.3 | AV | L1 | GND |
| 4.447500 | 25.20 | 10.2 | 46 | 20.8 | AV | L1 | GND |
| 4.722000 | 24.70 | 10.2 | 46 | 21.3 | AV | L1 | GND |



MEASUREMENT RESULT: "HTW0424332_fin"

4/24/2013 5:04PM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 0.159000 | 62.20 | 10.2 | 66 | 3.8 | QP | N | GND |
| 4.407000 | 45.20 | 10.2 | 56 | 10.8 | QP | N | GND |
| 4.641000 | 47.70 | 10.2 | 56 | 8.3 | QP | N | GND |
| 4.717500 | 46.10 | 10.2 | 56 | 9.9 | QP | N | GND |
| 4.798500 | 46.30 | 10.2 | 56 | 9.7 | QP | N | GND |
| 4.875000 | 44.70 | 10.2 | 56 | 11.3 | QP | N | GND |

MEASUREMENT RESULT: "HTW0424332_fin2"

4/24/2013 5:04PM

| Frequency MHz | Level dBµV | Transd dB | Limit dBµV | Margin dB | Detector | Line | PE |
|------------------|---------------|--------------|---------------|--------------|----------|------|-----|
| 0.159000 | 48.40 | 10.2 | 56 | 7.1 | AV | N | GND |
| 3.025500 | 37.80 | 10.2 | 46 | 8.2 | AV | N | GND |
| 3.457500 | 41.60 | 10.2 | 46 | 4.4 | AV | N | GND |
| 4.605000 | 28.20 | 10.2 | 46 | 17.8 | AV | N | GND |
| 4.677000 | 30.10 | 10.2 | 46 | 15.9 | AV | N | GND |
| 4.762500 | 27.30 | 10.2 | 46 | 18.7 | AV | N | GND |

4.3. Harmonic current

For test instruments and accessories used see section 3.6.

4.3.1. Description of the test location

Test location: Shielded room No. 2

4.3.2. Limits of harmonic current

Test configuration and procedure see clause 7.1 of standard IEC 61000-3-2: 2014.

4.3.3. Description of the test set-up

4.3.3.1. Operating Condition

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

4.3.3.2. Photo of the test set-up



4.3.4. Test result

The requirements are **Fulfilled**

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

Test Report of HTW

| | |
|-----------------------|---|
| Standard used: | IEC 61000-3-2 Ed.3 Quasi-stationary Equipment class A <= 150% of the limit |
| Observation time: | 150s |
| Windows width: | 10 periods – (IEC 61000-4-7: 2009) |
| Customer: | Foshan YaYou Medical Equipment Co., Ltd. |
| Mains supply voltage: | AC 230V/50Hz |
| E. U. T.: | Complete dental unit M/N: A8000-IA |
| Date of test: | 11:03 22.Sep 2009 |
| Tester: | Nada |

| | |
|--------------------|------|
| Test Result | |
| E. U. T.: | PASS |
| Power Source: | PASS |

E. U. T. Result***Check harmonics 2..40 [exception odd 21..39]:***

| | |
|--|------|
| Harmonic(s) > 150%: | |
| Order (n): | None |
| Harmonic(s) with average > 100%: | |
| Order (n): | None |

Check odd harmonics 21..39:

| | |
|--|------|
| All Partial Odd Harmonics below partial limits. | |
| Harmonic(s) > 150%: | |
| Order (n): | None |
| Harmonic(s) with average > 150%: | |
| Order (n): | None |

Power Source Result

| | |
|------------------------------------|------|
| First dataset out of limit: | |
| DS (time): | None |
| Harmonic(s) out of limit: | |
| Order (n): | None |

Average harmonic current results

| Hn | I _{eff} [A] | % of Limit | Limit [A] | Result |
|----|----------------------|------------|-----------|--------|
| 1 | 98.957E-3 | | | |
| 2 | 2.357E-3 | 0.218 | 1.08 | PASS |
| 3 | 41.063E-3 | 1.785 | 2.30 | PASS |
| 4 | 1.875E-3 | 0.436 | 430.00E-3 | PASS |
| 5 | 28.491E-3 | 2.499 | 1.14 | PASS |
| 6 | 1.203E-3 | 0.401 | 300.00E-3 | PASS |
| 7 | 23.658E-3 | 3.073 | 770.00E-3 | PASS |
| 8 | 788.046E-6 | 0.343 | 230.00E-3 | PASS |
| 9 | 7.552E-3 | 1.888 | 400.00E-3 | PASS |
| 10 | 461.385E-6 | 0.251 | 184.00E-3 | PASS |
| 11 | 3.995E-3 | 1.210 | 330.00E-3 | PASS |
| 12 | 457.608E-6 | 0.298 | 153.33E-3 | PASS |
| 13 | 7.725E-3 | 3.678 | 210.00E-3 | PASS |
| 14 | 417.235E-6 | 0.317 | 131.43E-3 | PASS |
| 15 | 9.421E-3 | 6.281 | 150.00E-3 | PASS |
| 16 | 358.603E-6 | 0.312 | 115.00E-3 | PASS |
| 17 | 9.190E-3 | 6.944 | 132.35E-3 | PASS |
| 18 | 421.296E-6 | 0.412 | 102.22E-3 | PASS |
| 19 | 8.418E-3 | 7.108 | 118.42E-3 | PASS |
| 20 | 328.852E-6 | 0.357 | 92.00E-3 | PASS |
| 21 | 6.253E-3 | 3.891 | 160.71E-3 | PASS |
| 22 | 346.364E-6 | 0.414 | 83.64E-3 | PASS |
| 23 | 4.432E-3 | 3.020 | 146.74E-3 | PASS |
| 24 | 315.263E-6 | 0.411 | 76.66E-3 | PASS |
| 25 | 3.849E-3 | 2.851 | 135.00E-3 | PASS |
| 26 | 287.436E-6 | 0.406 | 70.77E-3 | PASS |
| 27 | 3.961E-3 | 3.169 | 124.99E-3 | PASS |
| 28 | 293.072E-6 | 0.446 | 65.71E-3 | PASS |
| 29 | 3.900E-3 | 3.351 | 116.39E-3 | PASS |
| 30 | 313.874E-6 | 0.512 | 61.33E-3 | PASS |
| 31 | 3.599E-3 | 3.306 | 108.87E-3 | PASS |
| 32 | 293.304E-6 | 0.510 | 57.50E-3 | PASS |
| 33 | 3.459E-3 | 3.382 | 102.27E-3 | PASS |
| 34 | 281.766E-6 | 0.521 | 54.12E-3 | PASS |
| 35 | 3.453E-3 | 3.580 | 96.44E-3 | PASS |
| 36 | 290.054E-6 | 0.568 | 51.11E-3 | PASS |
| 37 | 3.272E-3 | 3.587 | 91.21E-3 | PASS |
| 38 | 313.540E-6 | 0.648 | 48.42E-3 | PASS |
| 39 | 3.034E-3 | 3.506 | 86.53E-3 | PASS |
| 40 | 299.282E-6 | 0.651 | 46.00E-3 | PASS |

Maximum harmonic current results

| Hn | I _{eff} [A] | % of Limit | Limit [A] | Result |
|----|----------------------|------------|-----------|--------|
| 1 | 272.691E-3 | | | |
| 2 | 20.836E-3 | 1.286 | 1.62 | PASS |
| 3 | 165.073E-3 | 4.785 | 3.45 | PASS |
| 4 | 8.092E-3 | 1.255 | 645.00E-3 | PASS |
| 5 | 93.585E-3 | 5.473 | 1.71 | PASS |
| 6 | 7.532E-3 | 1.674 | 450.00E-3 | PASS |
| 7 | 53.958E-3 | 4.672 | 1.15 | PASS |
| 8 | 4.201E-3 | 1.218 | 345.00E-3 | PASS |
| 9 | 21.850E-3 | 3.642 | 600.00E-3 | PASS |
| 10 | 2.936E-3 | 1.064 | 276.00E-3 | PASS |
| 11 | 17.761E-3 | 3.588 | 495.00E-3 | PASS |
| 12 | 2.527E-3 | 1.099 | 229.99E-3 | PASS |
| 13 | 19.958E-3 | 6.336 | 315.00E-3 | PASS |
| 14 | 1.596E-3 | 0.810 | 197.15E-3 | PASS |
| 15 | 13.180E-3 | 5.858 | 225.00E-3 | PASS |
| 16 | 1.541E-3 | 0.894 | 172.50E-3 | PASS |
| 17 | 9.428E-3 | 4.749 | 198.52E-3 | PASS |
| 18 | 1.464E-3 | 0.955 | 153.33E-3 | PASS |
| 19 | 9.613E-3 | 5.412 | 177.63E-3 | PASS |
| 20 | 976.813E-6 | 0.708 | 138.00E-3 | PASS |
| 21 | 7.811E-3 | 4.860 | 160.71E-3 | PASS |
| 22 | 954.260E-6 | 0.761 | 125.46E-3 | PASS |
| 23 | 5.703E-3 | 3.886 | 146.74E-3 | PASS |
| 24 | 896.038E-6 | 0.779 | 114.99E-3 | PASS |
| 25 | 5.313E-3 | 3.936 | 135.00E-3 | PASS |
| 26 | 755.728E-6 | 0.712 | 106.16E-3 | PASS |
| 27 | 4.380E-3 | 3.504 | 124.99E-3 | PASS |
| 28 | 749.101E-6 | 0.760 | 98.57E-3 | PASS |
| 29 | 4.070E-3 | 3.497 | 116.39E-3 | PASS |
| 30 | 692.906E-6 | 0.753 | 92.00E-3 | PASS |
| 31 | 3.719E-3 | 3.416 | 108.87E-3 | PASS |
| 32 | 650.054E-6 | 0.754 | 86.25E-3 | PASS |
| 33 | 3.689E-3 | 3.607 | 102.27E-3 | PASS |
| 34 | 643.529E-6 | 0.793 | 81.18E-3 | PASS |
| 35 | 3.596E-3 | 3.729 | 96.44E-3 | PASS |
| 36 | 592.405E-6 | 0.773 | 76.66E-3 | PASS |
| 37 | 3.381E-3 | 3.707 | 91.21E-3 | PASS |
| 38 | 587.885E-6 | 0.809 | 72.63E-3 | PASS |
| 39 | 3.334E-3 | 3.852 | 86.53E-3 | PASS |
| 40 | 570.530E-6 | 0.827 | 69.00E-3 | PASS |

Maximum harmonic voltage results

| Hn | Ueff [V] | Ueff [%] | Limit [%] | Result |
|----|-----------|----------|-----------|--------|
| 1 | 229.99 | 99.994 | | |
| 2 | 155.14E-3 | 0.067 | 0.2 | PASS |
| 3 | 422.33E-3 | 0.184 | 0.9 | PASS |
| 4 | 49.22E-3 | 0.021 | 0.2 | PASS |
| 5 | 20.18E-3 | 0.009 | 0.4 | PASS |
| 6 | 46.20E-3 | 0.020 | 0.2 | PASS |
| 7 | 39.55E-3 | 0.017 | 0.3 | PASS |
| 8 | 27.05E-3 | 0.012 | 0.2 | PASS |
| 9 | 24.44E-3 | 0.011 | 0.2 | PASS |
| 10 | 21.26E-3 | 0.009 | 0.2 | PASS |
| 11 | 18.17E-3 | 0.008 | 0.1 | PASS |
| 12 | 14.09E-3 | 0.006 | 0.1 | PASS |
| 13 | 25.20E-3 | 0.011 | 0.1 | PASS |
| 14 | 13.31E-3 | 0.006 | 0.1 | PASS |
| 15 | 12.46E-3 | 0.005 | 0.1 | PASS |
| 16 | 19.67E-3 | 0.009 | 0.1 | PASS |
| 17 | 20.79E-3 | 0.009 | 0.1 | PASS |
| 18 | 17.31E-3 | 0.008 | 0.1 | PASS |
| 19 | 16.21E-3 | 0.007 | 0.1 | PASS |
| 20 | 15.81E-3 | 0.007 | 0.1 | PASS |
| 21 | 13.13E-3 | 0.006 | 0.1 | PASS |
| 22 | 15.17E-3 | 0.007 | 0.1 | PASS |
| 23 | 13.12E-3 | 0.006 | 0.1 | PASS |
| 24 | 12.58E-3 | 0.005 | 0.1 | PASS |
| 25 | 12.10E-3 | 0.005 | 0.1 | PASS |
| 26 | 12.17E-3 | 0.005 | 0.1 | PASS |
| 27 | 12.08E-3 | 0.005 | 0.1 | PASS |
| 28 | 13.28E-3 | 0.006 | 0.1 | PASS |
| 29 | 14.87E-3 | 0.006 | 0.1 | PASS |
| 30 | 12.47E-3 | 0.005 | 0.1 | PASS |
| 31 | 9.44E-3 | 0.004 | 0.1 | PASS |
| 32 | 11.10E-3 | 0.005 | 0.1 | PASS |
| 33 | 13.61E-3 | 0.006 | 0.1 | PASS |
| 34 | 10.82E-3 | 0.005 | 0.1 | PASS |
| 35 | 17.26E-3 | 0.008 | 0.1 | PASS |
| 36 | 8.32E-3 | 0.004 | 0.1 | PASS |
| 37 | 7.15E-3 | 0.003 | 0.1 | PASS |
| 38 | 7.98E-3 | 0.003 | 0.1 | PASS |
| 39 | 14.17E-3 | 0.006 | 0.1 | PASS |
| 40 | 14.21E-3 | 0.006 | 0.1 | PASS |

4.4. Voltage Fluctuation and Flicker

For test instruments and accessories used see section 3.6.

4.4.1. Description of the test location

Test location: Shielded room No. 2

4.4.2. Limits of voltage fluctuation and flicker

Test configuration and procedure see clause 5 of standard IEC 61000-3-3: 2013.

4.4.3. Description of the test set-up

4.4.3.1. Operating Condition

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

4.4.3.2. Photo of the test set-up



4.4.4. Test result

The requirements are **Fulfilled**

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

Test Report of HTW

| | |
|----------------------|--|
| Standard used: | IEC 60601-1-2: 2007 IEC 61000-3-3: 2013 |
| Short time (Pst): | 10 mins |
| Observation time: | 120 mins (12 Flicker measurement) |
| Customer: | Foshan YaYou Medical Equipment Co., Ltd. |
| Flickermeter: | AC 230V/ 50Hz |
| Ambient Temperature: | 23°C |
| Humidity: | 51% |
| Barometric Pressure: | 1017mbar |
| E. U. T.: | Complete dental unit M/N: A8000-IA |
| Date of test: | 11:08 22.Sep 2009 |
| Tester: | Nada |

| | |
|-------------|------|
| Test Result | PASS |
|-------------|------|

Maximum Flicker results

| | EUT values | Limit | Result |
|----------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| Plt | 0.028 | 0.65 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.222 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

Detail Flicker data

| Flicker measurement 1 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.222 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 2 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.064 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 3 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.069 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 4 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.064 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 5 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.066 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 6 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.067 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 7 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.061 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 8 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.065 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 9 | EUT values | Limit | Result |
|-----------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.064 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 10 | EUT values | Limit | Result |
|------------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.066 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 11 | EUT values | Limit | Result |
|------------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.065 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

| Flicker measurement 12 | EUT values | Limit | Result |
|------------------------|------------|-------|--------|
| Pst | 0.028 | 1.00 | PASS |
| dc [%] | 0.000 | 3.30 | PASS |
| dmax [%] | 0.064 | 4.00 | PASS |
| dt [s] | 0.000 | 0.50 | PASS |

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: May 13, 2013

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 IEC 60601-1-2: 2007 at immunity test levels of $\pm 2\text{KV}$, $\pm 4\text{KV}$ and $\pm 8\text{KV}$ for air discharge and $\pm 2\text{KV}$, $\pm 4\text{KV}$ and $\pm 6\text{KV}$ 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 susceptible 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

Old



New



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
- Contact discharge
- Indirect discharge ■ Contact discharge
- Negative

Polarity:

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 IEC 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: Nov. 24, 2009

Operator: Nada

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 IEC 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 susceptible results are recorded.

4.6.3.2. Test Procedure

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

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

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

4.6.3.3. Photo of the test set-up



4.6.4. Test specification:

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

4.6.5. Test result

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

4.7. Electrical fast transients / Burst

For test instruments and accessories used see section 3.6.

4.7.1. Description of the test location and date

Test location: Shielded room No. 1

Date of test: May 13, 2013

Operator: Jony

4.7.2. Severity levels of electrical fast transients / Burst

| Open circuit output test voltage and repetition rate of the impulses | | |
|--|-------------------|----------------------------|
| Level | On power port, PE | |
| | V peak(KV) | Repetition Frequency (kHz) |
| 1. | 0.5 | 5 or 100 |
| 2. | 1 | 5 or 100 |
| 3. | 2 | 5 or 100 |
| 4. | 4 | 5 or 100 |
| X | Special | Special |

Note: equipment and systems shall comply with the requirements of 6.2.4 of IEC 60601-1-2: 2007 at immunity test levels of $\pm 2\text{KV}$ for a.c. power lines.

4.7.3. Description of the test set-up**4.7.3.1. Operating Condition**

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

4.7.3.2. Test Requirements

EUT and its simulators shall be placed above the ground reference plane which is a minimum 1m*1m with minimum 0.65mm thickness. 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.

4.7.3.3. Test Configuration and Procedure

For AC power input ports:

EUT is connected to coupling/decoupling network which couples the EFT signal to power input lines. During the test, both positive and negative polarities of the test voltage should be applied and the duration of the test can't be less than 1mins.

The EUT is unnecessary to test on these signal / control lines.

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

4.7.3.4. Photo of the test set-up

Old



New



4.7.4. Test specification:

Coupling network: 0.5 kV 1 kV 2 kV

Coupling clamp: 0.5 kV 1 kV

Burst frequency: 5.0 kHz

Coupling duration: 60 s

Polarity: positive negative

4.7.5. Coupling points

Cable description: AC power line : L, N, PE, L-N, L-PE, N-PE, L-N-PE

Screening: screened unshielded

Status: detachable undetachable

Signal transmission: analogue digital

Length: 1.4 m

4.7.6. Test result

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

4.8. Surge

For test instruments and accessories used see section 3.6.

4.8.1. Description of the test location and date

Test location: Test location No. 1

Date of test: Nov. 24, 2009

Operator: Nada

4.8.2. Severity levels of surge

| Level | Test Voltage (KV) |
|-------|-------------------|
| 1 | 0.5 |
| 2 | 1.0 |
| 3 | 2.0 |
| 4 | 4.0 |
| * | Special |

Note: equipment and systems shall comply with the requirements of 6.2.5 of IEC 60601-1-2: 2007 at immunity test levels of $\pm 0.5KV$, $\pm 1KV$ and $\pm 2KV$ for a.c. power line(s) to earth and $\pm 0.5KV$ and $\pm 1KV$ for a.c. power line(s) to line(s).

4.8.3. Description of the test set-up

4.8.3.1. Operating Condition

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

4.8.3.2. Test Configuration and Procedure

In this test, the 1.2/50us & 8/20us surge generator must be used for AC power ports. The voltage for line to earth coupling mode is twice of that for line to line. At least 5 positive and 5 negative (polarity) surge signal with a maximum 1/min repetition rate are injected to AC power lines from 3 different phase angles (0°, 90°, 180°, 270°) during the test.

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

4.8.3.3. Photo of the test set-up

**4.8.4. Test specification:**

Pulse amplitude-Power line sym.:
Source impedance: $2 \Omega + 18\mu\text{F}$

0.5 kV 1 kV 2 kV 4 kV

Pulse amplitude-Power line unsym.:
Source impedance: $12 \Omega + 9\mu\text{F}$

0.5 kV 1 kV 2 kV 4 kV

Number of surges:

5 Surges/Phase angle

Phase angle:

0° 90° 180° 270°

Repetition rate:

60 s

Polarity:

positive negative

4.8.5. Coupling points

| | | |
|----------------------|--|---|
| Cable description: | <u>AC power line: L-N, L-PE, N-PE</u> | |
| Screening: | <input type="radio"/> screened | <input checked="" type="radio"/> unscreened |
| Status: | <input checked="" type="checkbox"/> detachable | <input type="checkbox"/> undetachable |
| Signal transmission: | <input checked="" type="checkbox"/> analogue | <input type="checkbox"/> digital |
| Length: | <input checked="" type="checkbox"/> 1.4 m | |

4.8.6. Test result

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

4.9. Conducted disturbances induced by radio-frequency fields

For test instruments and accessories used see section 3.6.

4.9.1. Description of the test location and date

Test location: Shielded room No. 2

Date of test: May 13, 2013

Operator: Jony

4.9.2. Severity levels of conducted disturbances induced by radio-frequency fields discharge

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

Note: equipment and systems shall comply with the requirements of 6.2.6 of IEC 60601-1-2: 2007 at immunity test levels of 0.5V_{rms} over the frequency range beginning at the start frequency and extending to 80 MHz.

4.9.3. Description of the test set-up

4.9.3.1. Operating Condition

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

4.9.3.2. Test Configuration and Procedure

For AC power input lines:

—EUT is placed on an insulating support above a ground reference plane. It must be 0.3m away the CDN (coupling and decoupling network) of which the bottom is made of metallic material and placed directly on the ground plane. 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). The disturbance signal amplified by amplifier is injected to EUT through CDN.

For Signal Line and Control Line:

—EUT is placed on an insulating support above a ground reference plane. The EM clamp is directly placed on the ground reference plane with its metallic bottom contacting the plane. Cables between EUT and auxiliary equipment are put through the EM clamp. The disturbance signal amplified by amplifier is injected to EUT through EM clamp.

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

4.9.3.3. Photo of the test set-up

Old



New



4.9.4. Test specification:

| | |
|-------------------------|---------------------------------|
| <u>Frequency range:</u> | ■ 0.15 MHz to 80 MHz |
| <u>Test voltage :</u> | ■ 3 V |
| <u>Modulation:</u> | ■ AM: 80 % ■ sinusoidal 1kHz |
| <u>Frequency step:</u> | ■ 1 % with 3 s dwell time |

4.9.5. Coupling points

| | | |
|----------------------|--|---|
| Cable description : | <u>AC power line, Signal line</u> | |
| Screening: | <input type="radio"/> screened | <input checked="" type="radio"/> unscreened |
| Status: | <input checked="" type="checkbox"/> detachable | <input type="checkbox"/> undetachable |
| Signal transmission: | <input checked="" type="checkbox"/> analogue | <input type="checkbox"/> digital |
| Length: | ■ 1.4 m | |

4.9.6. Test result

No degradation of function comply with IEC 60601-1-2: 2007.

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: May 13, 2013

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 IEC 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 susceptible 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

New



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 | | |
| <u>Axis:</u> | ■ x-axis | ■ y-axis | ■ z-axis |

4.10.5. Test result

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

4.11. Voltage Dips and Interruptions

For test instruments and accessories used see section 3.6.

4.11.1. Description of the test location and date

Test location: Test location No. 1

Date of test: Nov. 24, 2009

Operator: Nada

4.11.2. Severity levels of voltage dips and interruptions

| Test Level for Voltage Dips | | |
|-----------------------------|---|----------------------|
| Test Level (%Ut) | Voltage Dip And Short Interruptions (%Ut) | Duration (In Period) |
| <5 | >95 | 0.5 |
| 40 | 60 | 5 |
| 70 | 30 | 25 |

| Test Level for Voltage Interruption | | |
|-------------------------------------|---|----------------------|
| Test Level (%Ut) | Voltage Dip And Short Interruptions (%Ut) | Duration (In Period) |
| <5 | >95 | 250 |

4.11.3. Description of the test set-up

4.11.3.1. Operating Condition

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

4.11.3.2. Test Configuration and Procedure

EUT is connected to the simulator according to the test photo. When conducting this test, the power supply shall be set at the minimum and maximum rated input voltages and test voltage changes shall be step changes and start at the phase angle of 0° and 180°.

4.11.3.3. Photo of the test set-up



4.11.4. Test specification:

Nominal Mains Voltage (V_N): ■ 230 V AC

Number of voltage fluctuations: ■ 3

Level of reduction(dip) / duration: ■ 100 % / 10ms ■ 60 % / 100ms ■ 30 % / 500ms

Nominal Mains Voltage (V_N): ■ 230 V AC

Number of Interruptions: ■ 3

Duration of the Interruption: ■ 5000 ms

4.11.5. Test result

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

5. External and Internal Photos of the EUT

5.1. External photos of the EUT







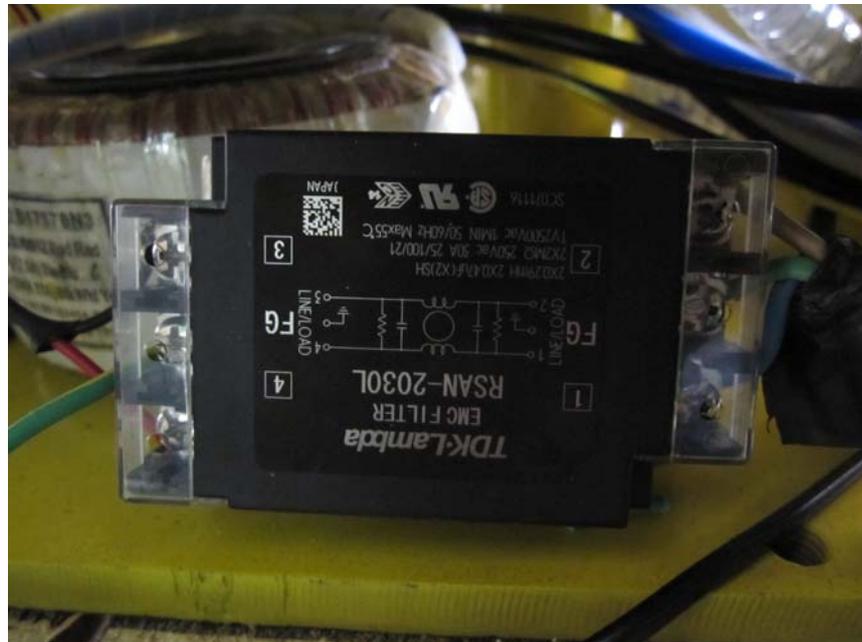
New



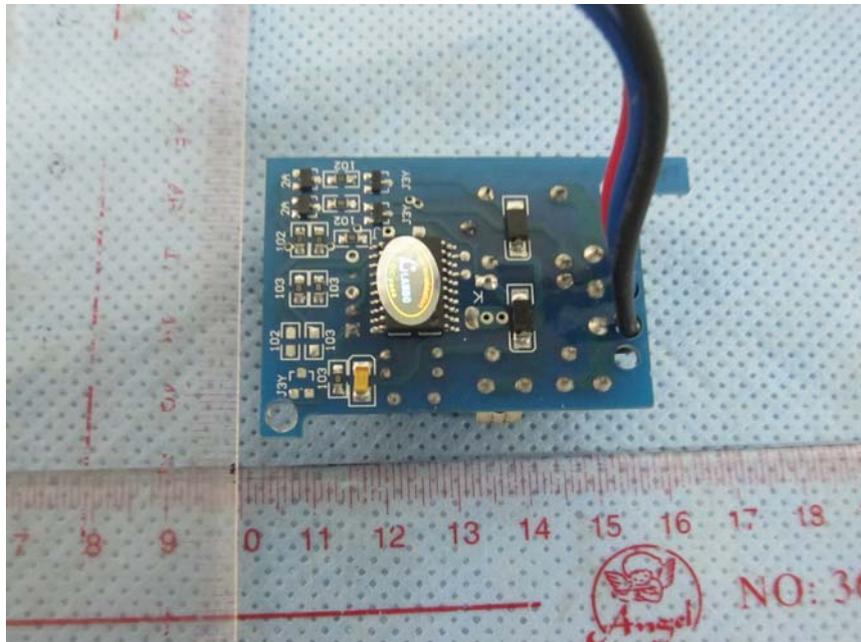
5.2. Internal photos of the EUT



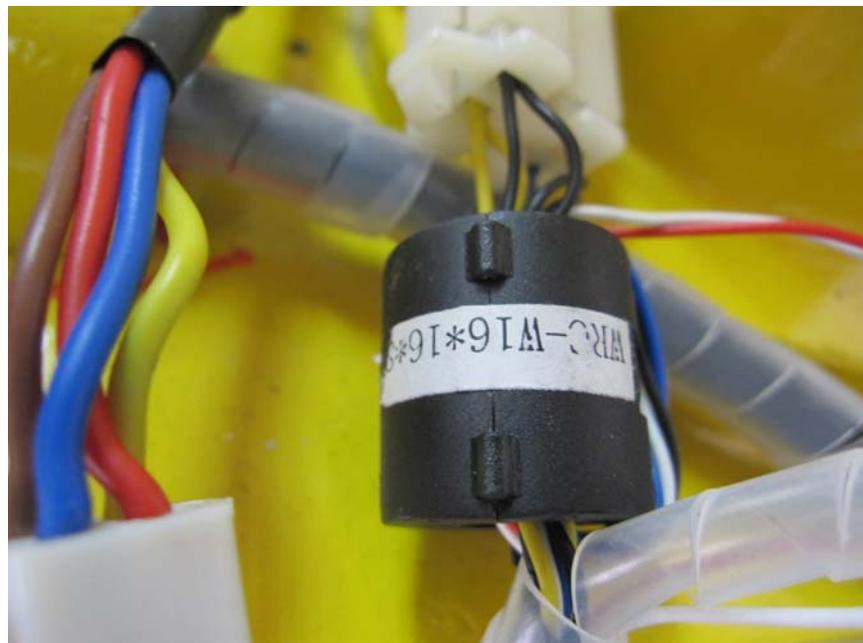
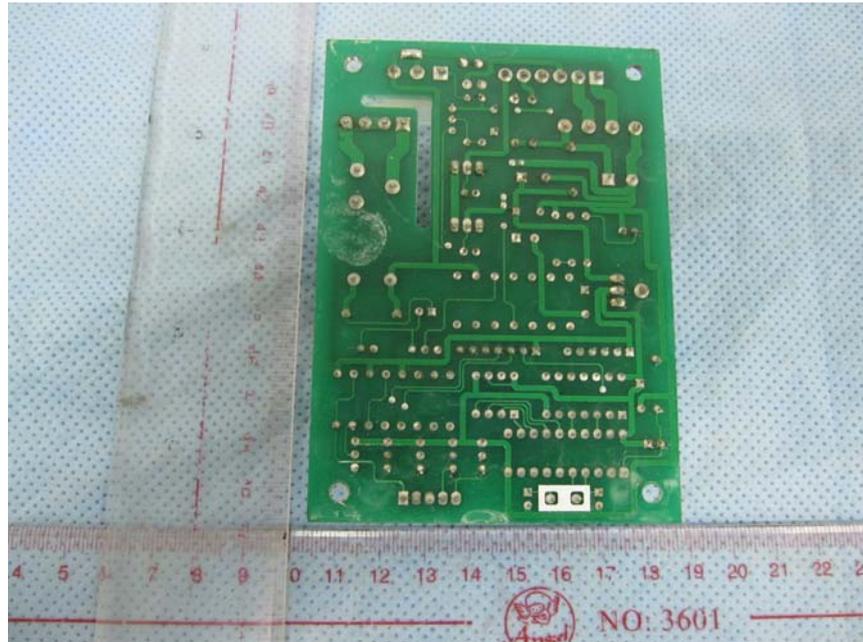


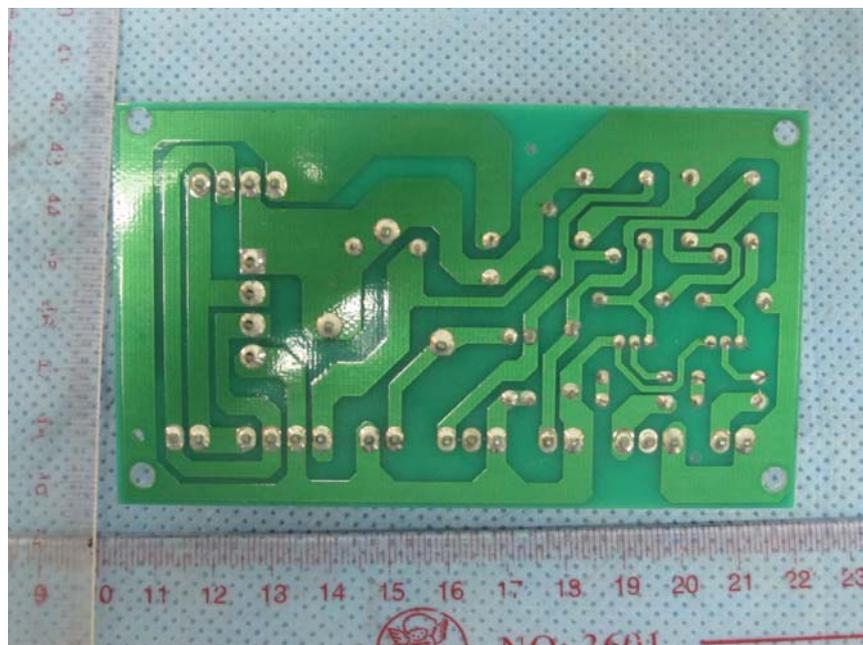
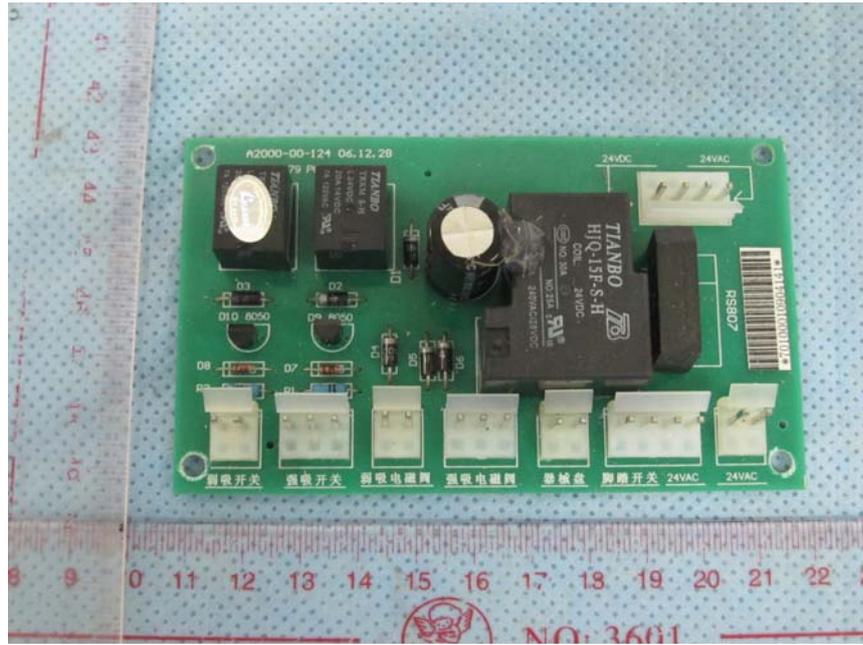




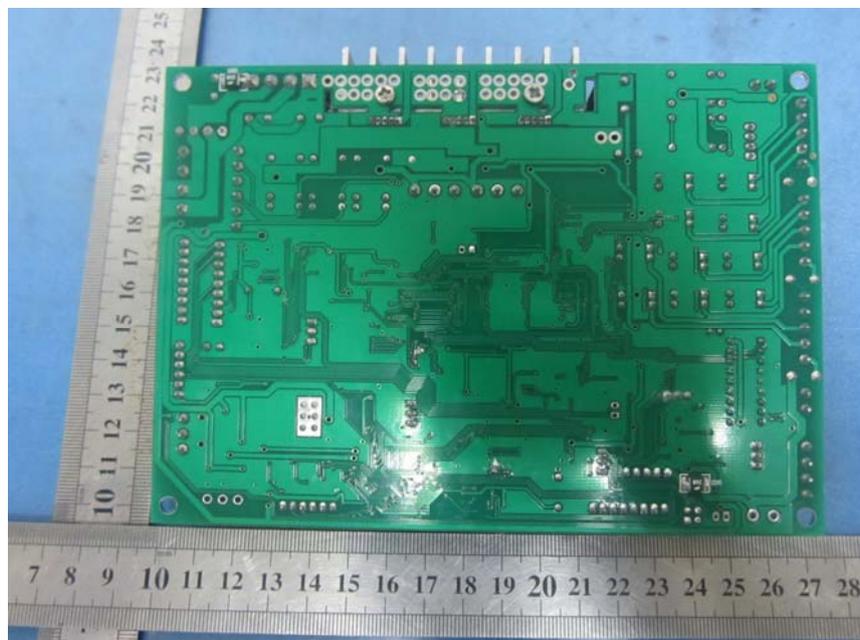
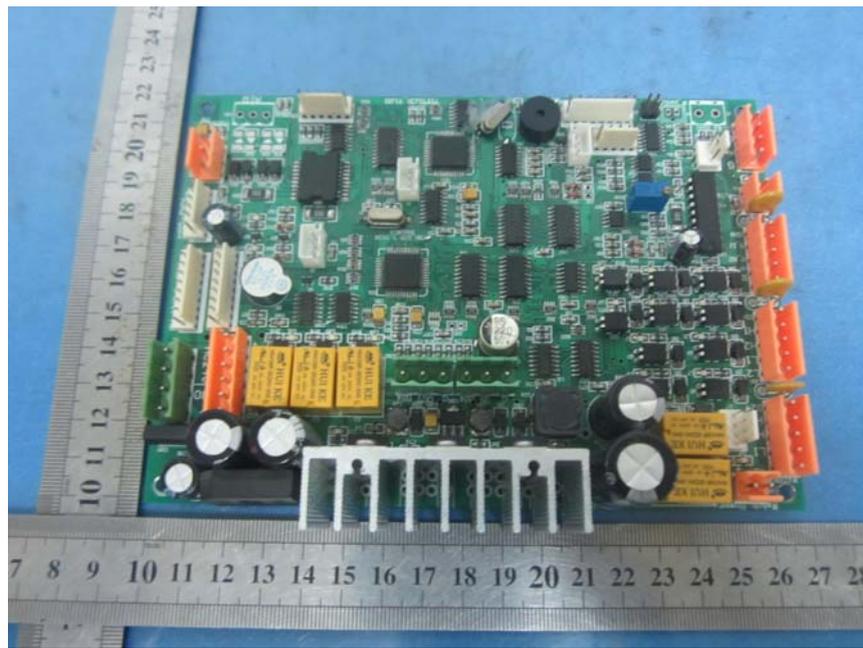


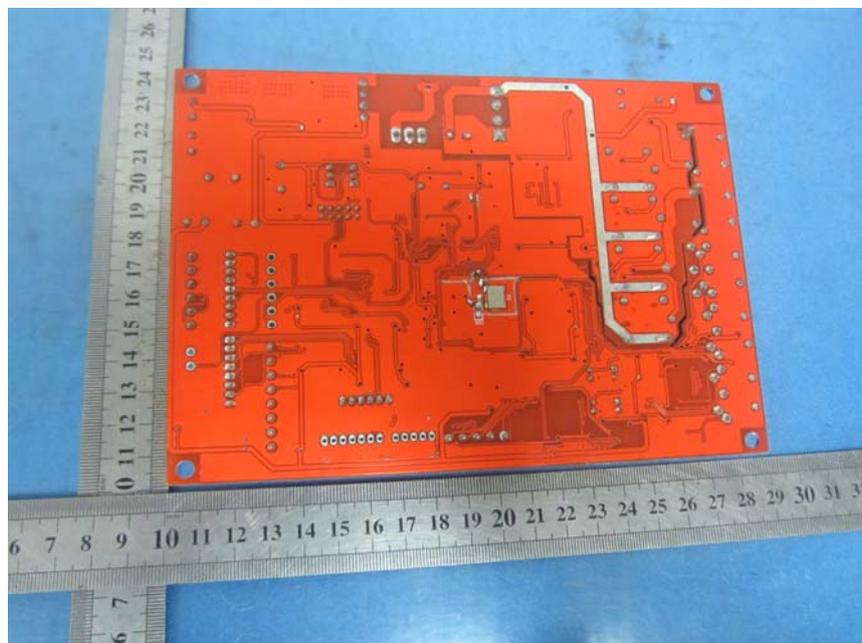
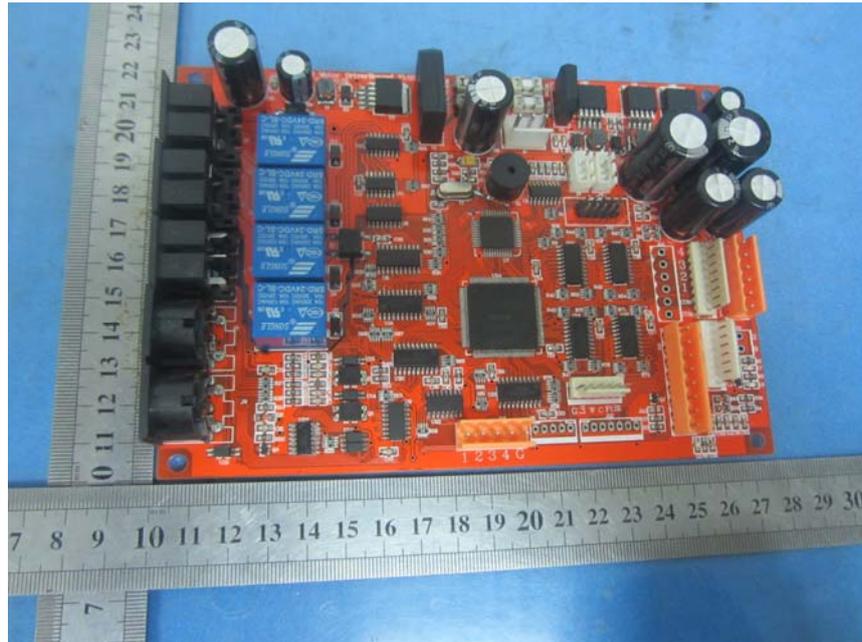


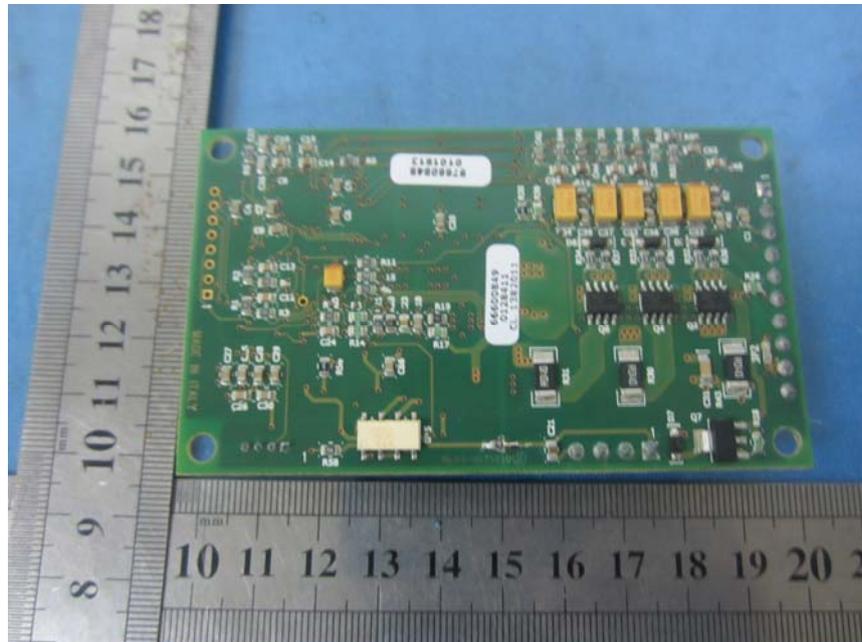
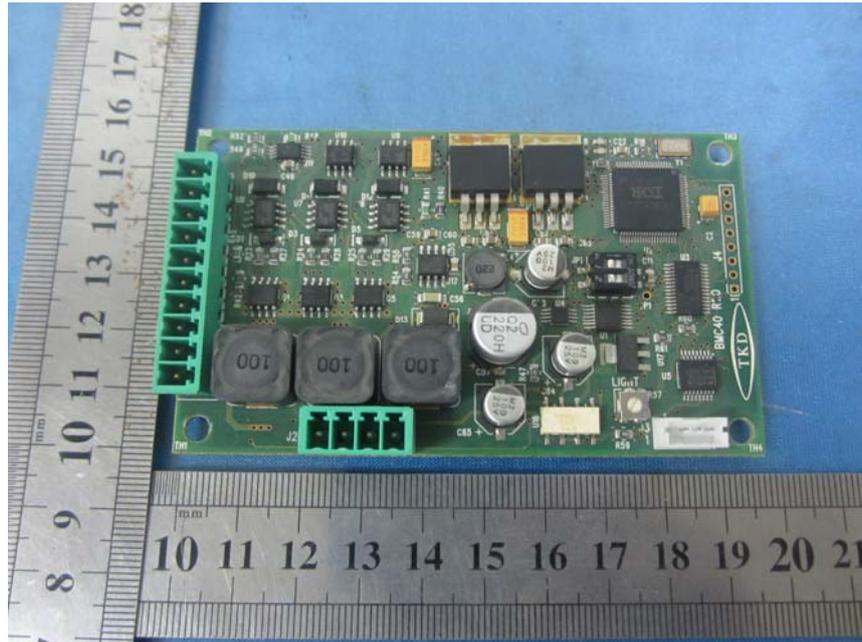


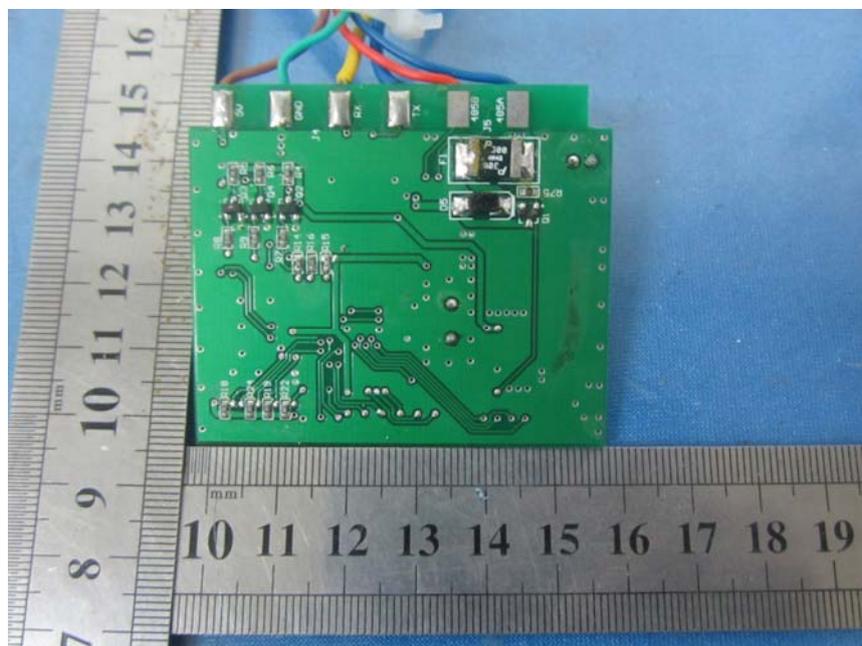
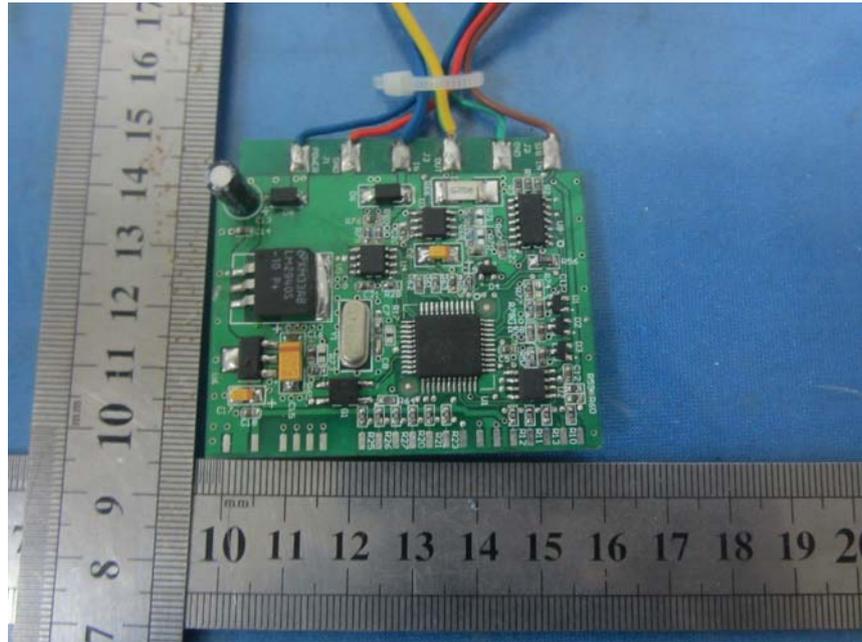


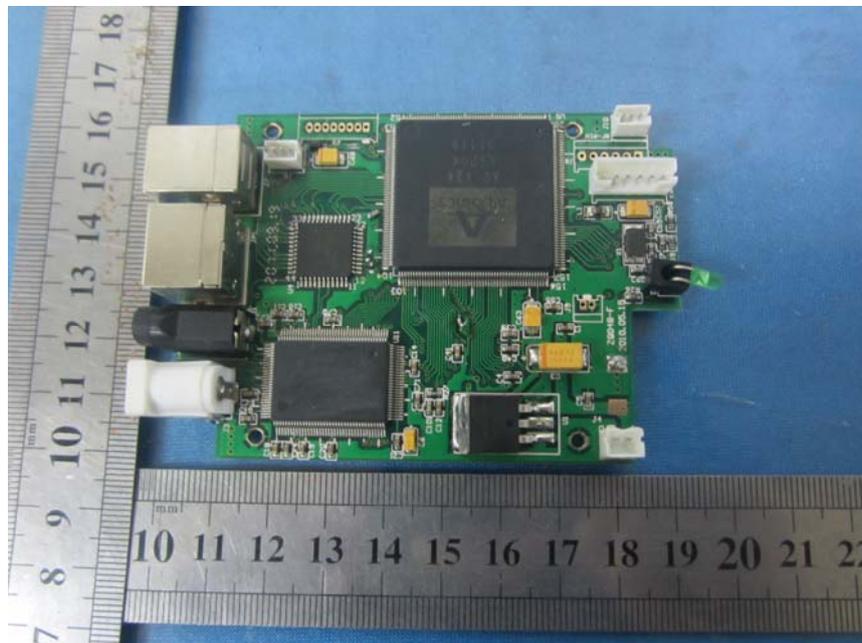
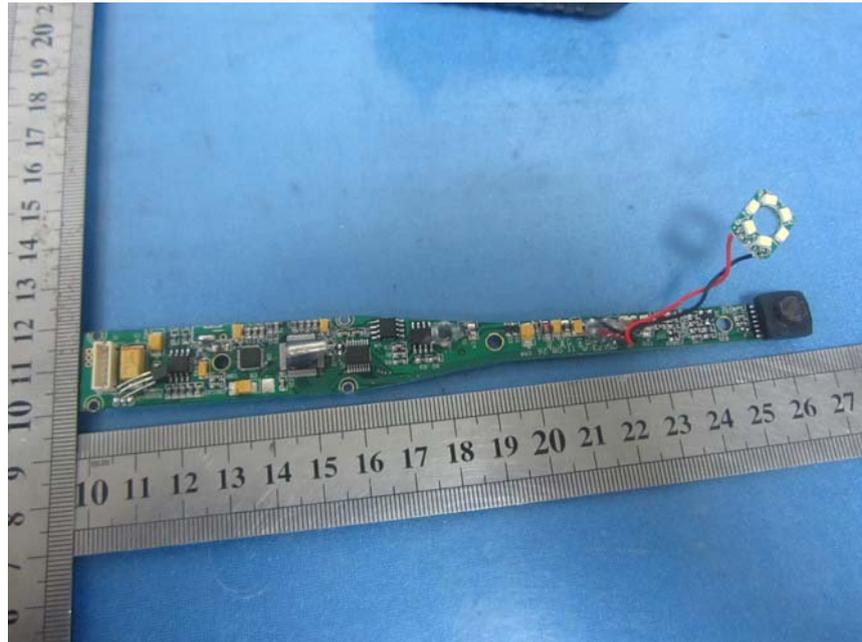
New

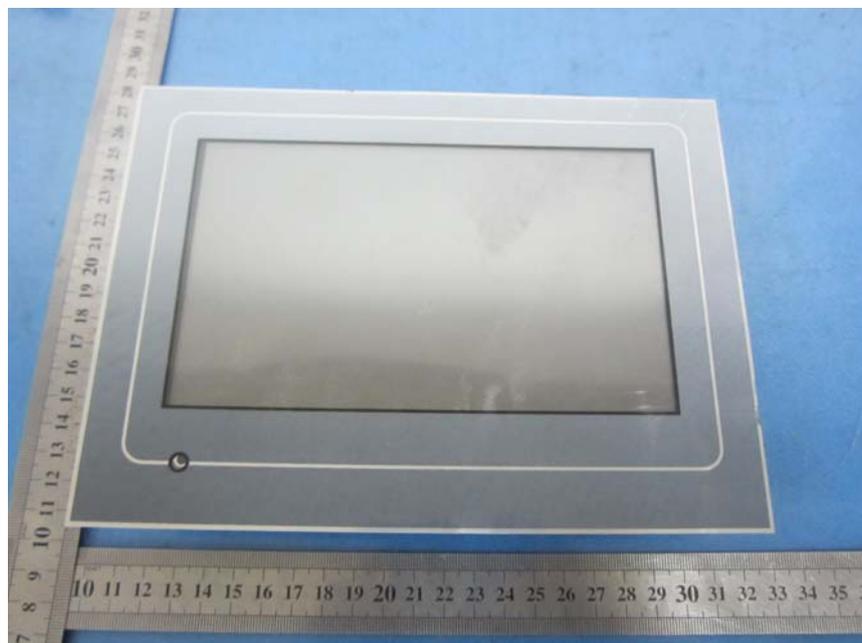
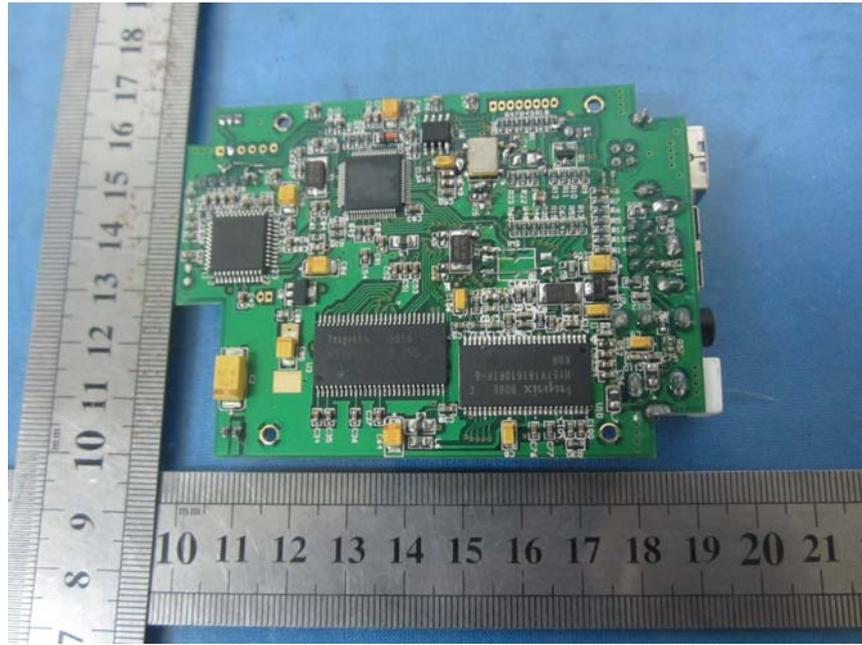


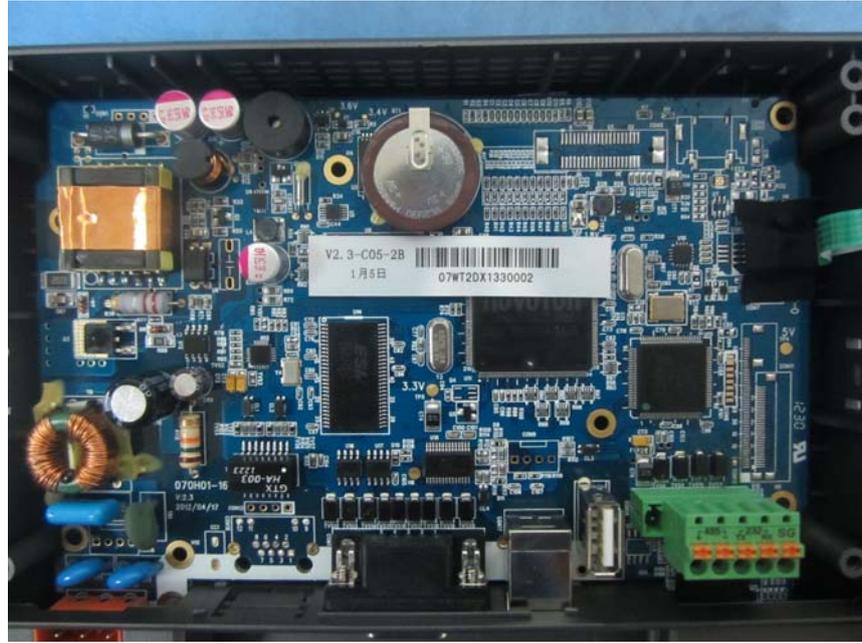












..... End of Report.....

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 A8000-IA Complete Dental Unit is intended for use in the electromagnetic environment specified below. The customer or the user of A8000-IA Complete Dental Unit should assure that it is used in such an environment. | | |
| 3 | Emissions test | Compliance | Electromagnetic environment - guidance |
| 4 | RF emissions CISPR 11 | Group 1 | The A8000-IA Complete Dental Unit 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 CISPR 11 | Class B | The A8000-IA Complete Dental Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| 6 | Harmonic emissions IEC 61000-3-2 | Class A | |
| 7 | Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

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

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|--|
| The A8000-IA Complete Dental Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A8000-IA Complete Dental Unit should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 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 IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | 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 IEC 61000-4-11 | < 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec | < 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the A8000-IA Complete Dental Unit requires continued operation during power mains interruptions, it is recommended that the A8000-IA Complete Dental Unit be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | N/A | 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 A8000-IA Complete Dental Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A8000-IA Complete Dental Unit should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 V | Portable and mobile RF communications equipment should be used no closer to any part of the A8000-IA Complete Dental Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ 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 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 Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |
| 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 A8000-IA Complete Dental Unit is used exceeds the applicable RF compliance level above, the A8000-IA Complete Dental Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the A8000-IA Complete Dental Unit. ^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 A8000-IA Complete Dental Unit | | | |
|--|--|---|--|
| The A8000-IA Complete Dental Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the A8000-IA Complete Dental Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A8000-IA Complete Dental Unit 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 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. | | | |