

## EMC TEST REPORT

### No. 130300591SHA-001

Applicant: GlobTek, Inc.  
186 Veterans Dr. Northvale, NJ 07647 USA

Manufacturer: GlobTek (Suzhou) Co., Ltd  
Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial  
Park, Suzhou, JiangSu 215021, China

Equipment: Medical Power Supply

Type/Model: GTM43033-\*\*\* (see annex for details)

**TEST RESULT: PASS**

## SUMMARY

The equipment complies with the requirements according to the following standard:

**EN 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

Date of issue: May 28, 2012

Prepared by:



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Reviewed by:



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## 1. GENERAL INFORMATION

### 1.1 Description of Equipment Under Test (EUT)

|                          |                                                                                                         |
|--------------------------|---------------------------------------------------------------------------------------------------------|
| EUT                      | : Medical Power Supply                                                                                  |
| Description of EUT       | : This EUT have series models. We tested these models and listed its worst test data as representative. |
| Model number             | : GTM43033-*** (see annex for details)                                                                  |
| Rating                   | : Input: 100-240V~, 50-60Hz, 0.3A;<br>Output: see annex                                                 |
| Mains lead               | : None                                                                                                  |
| Data cable               | : None                                                                                                  |
| Sample received date     | : 2013-03-12                                                                                            |
| Sample identification No | : /                                                                                                     |
| Date of test             | : 2013-03-19                                                                                            |

### 1.2 Description of Client

|               |                                                                                                                              |
|---------------|------------------------------------------------------------------------------------------------------------------------------|
| Applicant:    | GlobTek, Inc.<br>186 Veterans Dr. Northvale, NJ 07647 USA                                                                    |
| Manufacturer: | GlobTek (Suzhou) Co., Ltd<br>Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial<br>Park, Suzhou, JiangSu 215021, China |

### 1.3 Description of Test Facility

|                                     |           |                                                                           |
|-------------------------------------|-----------|---------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Name      | Intertek Testing Service Shanghai                                         |
|                                     | Address   | Building 86, No. 1198 Qinzhou Road(North),<br>Shanghai 200233, P.R. China |
|                                     | Telephone | 86 21 61278200                                                            |
|                                     | Telefax   | 86 21 54262353                                                            |
| Subcontractor:                      |           |                                                                           |
| <input type="checkbox"/>            | Name      | Shanghai Institute of Measurement Technology                              |
|                                     | Address   | 716 Yishan Road, Shanghai 200233, P.R. China                              |
|                                     | Telephone | 86 21 64700066                                                            |
| <input type="checkbox"/>            | Name      | Jiangsu Electronic Products Supervision and<br>Inspection Institute       |
|                                     | Address   | No. 10, Geixiang, Zhongqiao, Wuxi, P.R. China                             |
|                                     | Telephone | 0510-85140037                                                             |

## 2. TEST SPECIFICATIONS

### 2.1 Standards

**EN 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

### 2.2 Mode of operation during the test / Test peripherals used

Within this test report, EUT was tested under all available operation modes and tested under its rating voltage and frequency. Other voltage and frequency is specified if used.

### 2.3 Instrument list

| Selected                            | Instrument            | EC no.     | Model         | Valid until date |
|-------------------------------------|-----------------------|------------|---------------|------------------|
| <input checked="" type="checkbox"/> | EMI test receiver     | EC 2107    | ESCS 30       | 2013-10-17       |
| <input checked="" type="checkbox"/> | A.M.N.                | EC 3119    | ESH2-Z5       | 2013-10-9        |
| <input type="checkbox"/>            | A.M.N.                | EC 3394    | ENV 216       | 2013-10-19       |
| <input type="checkbox"/>            | Voltage probe         | EC 3405    | ESH2-Z3       | 2013-10-11       |
| <input checked="" type="checkbox"/> | Absorbing clamp       | EC 2108    | MDS 21        | 2013-10-11       |
| <input type="checkbox"/>            | Tri-loop              | EC 3384    | HXYZ 9170     | 2013-12-18       |
| <input checked="" type="checkbox"/> | Harmonic/Flicker sys. | EC 2110    | 5001ix/PACS-1 | 2013-10-21       |
| <input checked="" type="checkbox"/> | CDN                   | EC 2113-1  | M216          | 2013-12-05       |
| <input type="checkbox"/>            | CDN                   | EC 2113-2  | M316          | 2013-12-05       |
| <input type="checkbox"/>            | Click meter           | EC 2253    | CL55C         | 2013-12-19       |
| <input checked="" type="checkbox"/> | Signal generator      | EC 2338    | SML 01        | 2013-11-7        |
| <input type="checkbox"/>            | Lum. Meter            | EC 2451    | TES 1332      | 2013-12-2        |
| <input checked="" type="checkbox"/> | ESD Gun               | EC 2956    | ditto         | 2013-10-20       |
| <input checked="" type="checkbox"/> | Motorise Variac       | EC 2957    | MV 2616       | 2013-10-20       |
| <input checked="" type="checkbox"/> | Immunity system       | EC 2958    | UCS500M6      | 2013-10-22       |
| <input type="checkbox"/>            | Capacitive clamp      | EC 2959    | HFK           | 2013-10-20       |
| <input type="checkbox"/>            | Immunity system       | EC 2960    | TSS500M       | 2013-11-27       |
| <input type="checkbox"/>            | Immunity system       | EC 2961    | TSS500M4      | 2013-10-11       |
| <input checked="" type="checkbox"/> | Power amplifier       | EC 3043-1  | 75A250        | 2013-12-16       |
| <input type="checkbox"/>            | CDN                   | EC 3043-2  | T2            | 2013-10-9        |
| <input checked="" type="checkbox"/> | Attenuator            | EC 3043-3  | ATT6/75       | 2013-10-9        |
| <input type="checkbox"/>            | CDN                   | EC 3043-4  | T4            | 2013-10-9        |
| <input type="checkbox"/>            | DDC                   | EC 3043-5  | DC2600        | 2013-10-9        |
| <input type="checkbox"/>            | EM clamp              | EC 3043-6  | EM 101        | 2013-10-10       |
| <input checked="" type="checkbox"/> | Power sensor          | EC 3043-7  | PH 2000       | 2013-10-19       |
| <input checked="" type="checkbox"/> | Power meter           | EC 3043-8  | PM 2002       | 2013-10-19       |
| <input type="checkbox"/>            | Attenuator            | EC 3043-9  | 68-6-44       | 2013-10-9        |
| <input type="checkbox"/>            | Impedance             | EC 3043-10 | R100          | 2013-10-9        |
| <input type="checkbox"/>            | Impedance             | EC 3043-11 | R100          | 2013-10-9        |
| <input type="checkbox"/>            | Impedance             | EC 3043-12 | R50           | 2013-10-9        |
| <input checked="" type="checkbox"/> | Signal generator      | EC 3044-1  | SMR20         | 2013-12-16       |
| <input checked="" type="checkbox"/> | Power amplifier       | EC 3044-2  | 150W1000      | 2013-12-16       |

|                                     |                        |           |                 |            |
|-------------------------------------|------------------------|-----------|-----------------|------------|
| <input checked="" type="checkbox"/> | Field sensor           | EC 3044-3 | FP6001          | 2013-10-9  |
| <input checked="" type="checkbox"/> | Power amplifier        | EC 3044-4 | 25S1G4          | 2013-12-16 |
| <input checked="" type="checkbox"/> | DDC                    | EC 3044-5 | DC6180A         | 2013-12-05 |
| <input type="checkbox"/>            | DDC                    | EC 3044-6 | DC7144A         | 2013-10-9  |
| <input checked="" type="checkbox"/> | Log-periodical antenna | EC 3044-7 | AT1080          | 2013-12-8  |
| <input type="checkbox"/>            | Horn antenna           | EC 3044-8 | AT4002          | 2013-12-24 |
| <input checked="" type="checkbox"/> | Field meter            | EC 3044-9 | FM5004          | 2013-10-9  |
| <input checked="" type="checkbox"/> | EMI test receiver      | EC 3045   | ESIB26          | 2013-10-21 |
| <input checked="" type="checkbox"/> | Broadband antenna      | EC 4206   | CBL 6112D       | 2013-12-18 |
| <input checked="" type="checkbox"/> | Fully anechoic chamber | EC 3047   | -               | 2013-12-5  |
| <input checked="" type="checkbox"/> | Semi anechoic chamber  | EC 3048   | -               | 2013-12-5  |
| <input type="checkbox"/>            | Horn antenna           | EC 3049   | HF906           | 2013-12-8  |
| <input type="checkbox"/>            | ISN                    | EC 3754   | FCC-TLISN-T2-02 | 2013-10-9  |
| <input type="checkbox"/>            | ISN                    | EC 3755   | FCC-TLISN-T4-02 | 2013-10-9  |
| <input type="checkbox"/>            | ISN                    | EC 3756   | FCC-TLISN-T8-02 | 2013-10-9  |
| <input type="checkbox"/>            | Current probe          | EC 3221   | EZ-17           | 2013-10-11 |
| <input type="checkbox"/>            | Pre-amplifier          | EC 3222   | pre-amp 18      | 2013-12-17 |
| <input checked="" type="checkbox"/> | Shielded room          | EC 2838   | GB88            | 2014-1-11  |
| <input checked="" type="checkbox"/> | Shielded room          | EC 2839   | GB88            | 2014-1-11  |
| <input type="checkbox"/>            | Oscilloscope           | EC 3515   | DPO 4504        | 2013-10-17 |
| <input type="checkbox"/>            | TV generator           | EC 3555   | TG39            | 2013-10-5  |



## 2.4. Test Summary

**This report applies to tested sample only. This report shall not be reproduced in part without written approval of Intertek Testing Service Shanghai Limited.**

| TEST ITEM                                     | RESULT | NOTE |
|-----------------------------------------------|--------|------|
| Mains terminal continuous disturbance voltage | Pass   | -    |
| Continuous disturbance power*                 | Pass   | -    |
| Radiated emission                             | Pass   | -    |
| Harmonic Currents                             | Pass   | -    |
| Flicks                                        | Pass   | -    |
| Electrostatic Discharge (ESD)                 | Pass   | -    |
| Electric Fast Transient /Burst (EFT/B)        | Pass   | -    |
| Surge                                         | Pass   | -    |
| Injected Current                              | Pass   | -    |
| RF electromagnetic field susceptibility       | Pass   | -    |
| Voltage dips and interruption                 | Pass   | -    |
| Magnetic Fields                               | NA     | -    |

Notes: 1: NA =Not Applicable

\* : According to clause 7.1.4 of the standard EN55014-1, a test at 160 kHz (conducted emission) and at 50 MHz (disturbance power) was made over a range of 0,9 to 1,1 times the rated voltage, and the worst test data is listed in relevant clause of the report.

## Emission Test

### Classification for Equipment and Systems

Equipment and systems, except as specified in 1 through 3 below, shall be classified as group 1 or group 2 and class A or class B in accordance with CISPR11, based on their intended use, as specified by the manufacturer.

Equipment and systems shall comply with CISPR requirements, based upon their classification, with the exceptions and clarifications specified in 4 and 5 below.

1. *Simple electrical components*

Medical electrical equipment containing only simple electrical components like motors and switches and not utilizing any electronic circuitry that generates or uses frequencies above 9 kHz (e.g. some dental drills, some ventilators, some operating tables) may be classified in accordance with CISPR14-1. Classification to CISPR14-1, however, is limited to stand-alone equipment and is not applicable to systems or sub-systems.

2. *Lighting equipment*

Lighting equipment used in medical applications (e.g. equipment for illumination of x-ray films, lighting devices for operating theatres) may be classified in accordance with CISPR 15. Classification to CISPR 15, however, is limited to stand-alone equipment and is not applicable to systems or sub-systems.

3. *Information technology equipment (ITE)*

ITE connected to equipment and systems may be classified in accordance with CISPR 22 with the following restriction: CISPR 22 class B equipment may be used with CISPR 11 class a or class b systems, but CISPR 22 class A equipment may only be used with CISPR 11 class a systems.

4. *Equipment and systems specified for use only in a shielded location*

- For equipment and systems that are specified for use only in a shielded location, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification meets the requirements in EN60601-1-2.
- For equipment and systems that are specified for use only in a shielded location, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that exit the shielded location, provided the minimum RF filter attenuation specification meets the requirements specified.

Moreover, the outside of equipment and systems shall be labeled with a warning that they should be used only in the specified type of shielded location.

### 5. Equipment and systems that include radio equipment

Equipment and systems that include radio equipment and have been tested and found to comply with applicable national radio regulations are exempt from testing to CISPR electromagnetic disturbance requirements, provided the emissions limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR electromagnetic disturbance limits. Equipment and systems that include RF transmitters are exempt from the emissions requirements of this standard in the dedicated transmission band of the transmitter. Otherwise, and for equipment and systems intended only for countries with no national radio regulations, the emissions requirements of this standard shall apply.

Moreover, equipment and systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with the following symbol for non-ionizing radiation.

Symbol for Non-Ionizing Radiation: 

### Classification

| Emission                                        | Compliance |         |
|-------------------------------------------------|------------|---------|
| RF emissions<br>CISPR 11                        | Group 1    | Group 2 |
| RF emissions<br>CISPR 11                        | Class A    | Class B |
| RF emissions<br>CISPR 22                        | Group 1    | Group 2 |
| RF emissions<br>CISPR 22                        | Class A    | Class B |
| RF emissions<br>CISPR 14-1                      | Complies   |         |
| RF emissions<br>CISPR 15                        | Complies   |         |
| Used only in a<br>shielded location<br>CISPR 11 | Complies   |         |
| Including radio<br>equipment                    | Complies   |         |
| Notes: The gray rows were the selected objects. |            |         |

**Basic EMC standard for emission test**

IEC 61000-3-2:2005/+A1:2008: Limits for harmonic current emissions (equipment input current  $\leq 16\text{A}$  per phase)

IEC 61000-3-3:2008: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current  $\leq 16\text{A}$

CISPR 11:2003/+A1:2004/+A2:2006: Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement

CISPR 14-1:2005: Electromagnetic compatibility-Requirements for household appliances, electric tools and similar apparatus Part 1: Emission

CISPR 15:2005/+A2:2008: Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment

CISPR 22:2005/+A1:2005/+A2:2006: Information technology equipment – Radio disturbance characteristics Limits and methods of measurement.

### 3. Mains Terminal Continuous Disturbance Voltage

**Test result: Pass**

#### 3.1 Terminal Voltage Limits for the frequency range 148.5kHz to 30MHz

3.1.1 Limits for household appliances, electric power tools and similar devices at mains terminals

For household appliance

| Frequency range<br>(MHz)                                                                                                                                                                                                                                                                                                                                                                                      | Limits dB(μV) |           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-----------|
|                                                                                                                                                                                                                                                                                                                                                                                                               | Quasi-peak    | Average   |
| 0.15 ~ 0.5                                                                                                                                                                                                                                                                                                                                                                                                    | 66 ~ 56 *     | 59 ~ 46 * |
| 0.5 ~ 5                                                                                                                                                                                                                                                                                                                                                                                                       | 56            | 46        |
| 5 ~ 30                                                                                                                                                                                                                                                                                                                                                                                                        | 60            | 50        |
| <p>Note : 1. * means the limit decreasing linearly with the logarithm of the frequency in the range 0.15MHz to 0.5MHz</p> <p>2. If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.</p> |               |           |

For electric power tools

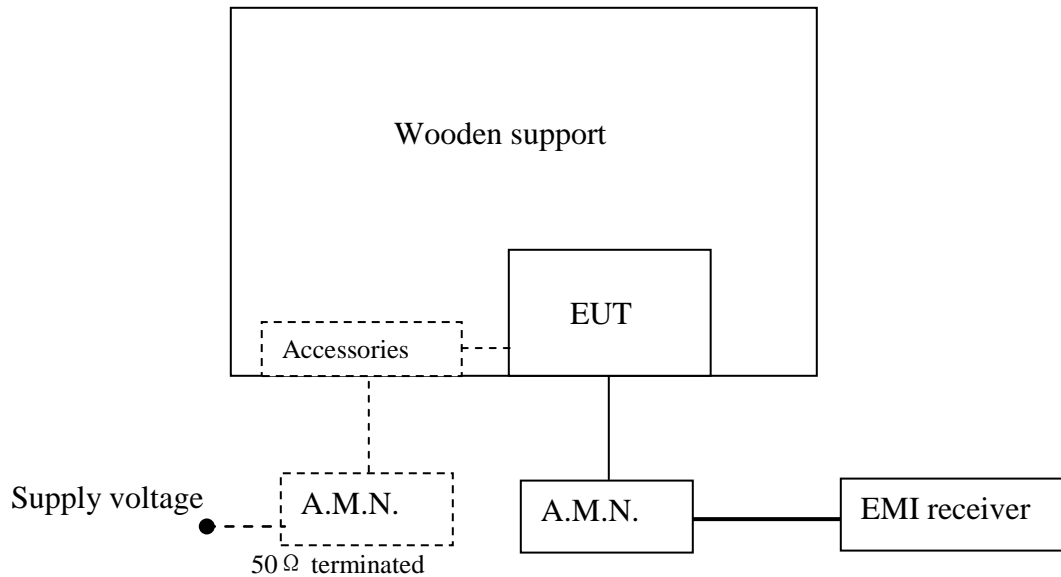
| Frequency<br>(MHz)                                                                                                                                                                                                                                                                                                                                                                     | Rated motor power<br>not<br>exceeding 700W |         | Rated motor power<br>above 700W and not<br>exceeding 1000W |         | Rated motor power<br>above 1000W |         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------|------------------------------------------------------------|---------|----------------------------------|---------|
|                                                                                                                                                                                                                                                                                                                                                                                        | dB(μV)                                     |         | dB(μV)                                                     |         | dB(μV)                           |         |
|                                                                                                                                                                                                                                                                                                                                                                                        | Quasi-Peak                                 | Average | Quasi-Peak                                                 | Average | Quasi-Peak                       | Average |
| 0.15-0.35                                                                                                                                                                                                                                                                                                                                                                              | 66-59*                                     | 59-49*  | 70-63*                                                     | 63-53*  | 76-69*                           | 69-59*  |
| 0.35-5                                                                                                                                                                                                                                                                                                                                                                                 | 59                                         | 49      | 63                                                         | 53      | 69                               | 59      |
| 5-30                                                                                                                                                                                                                                                                                                                                                                                   | 64                                         | 54      | 68                                                         | 58      | 74                               | 64      |
| <p>Notes : 1. * means the limit value decreasing linearly with the logarithm of the frequency.</p> <p>2. If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out.</p> |                                            |         |                                                            |         |                                  |         |

### 3.1.2 Limits for household appliances and similar devices at additional terminals

| Frequency range<br>(MHz)                                                                                                                                                                                                                                                           | Limits dB( $\mu$ V) |         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------|
|                                                                                                                                                                                                                                                                                    | Quasi-peak          | Average |
| 0.15 ~ 0.5                                                                                                                                                                                                                                                                         | 80                  | 70      |
| 0.5 ~ 5                                                                                                                                                                                                                                                                            | 74                  | 64      |
| 5 ~ 30                                                                                                                                                                                                                                                                             | 74                  | 64      |
| Note: 1. If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement using the receiver with an average detector need not be carried out. |                     |         |

### 3.2 Test setup

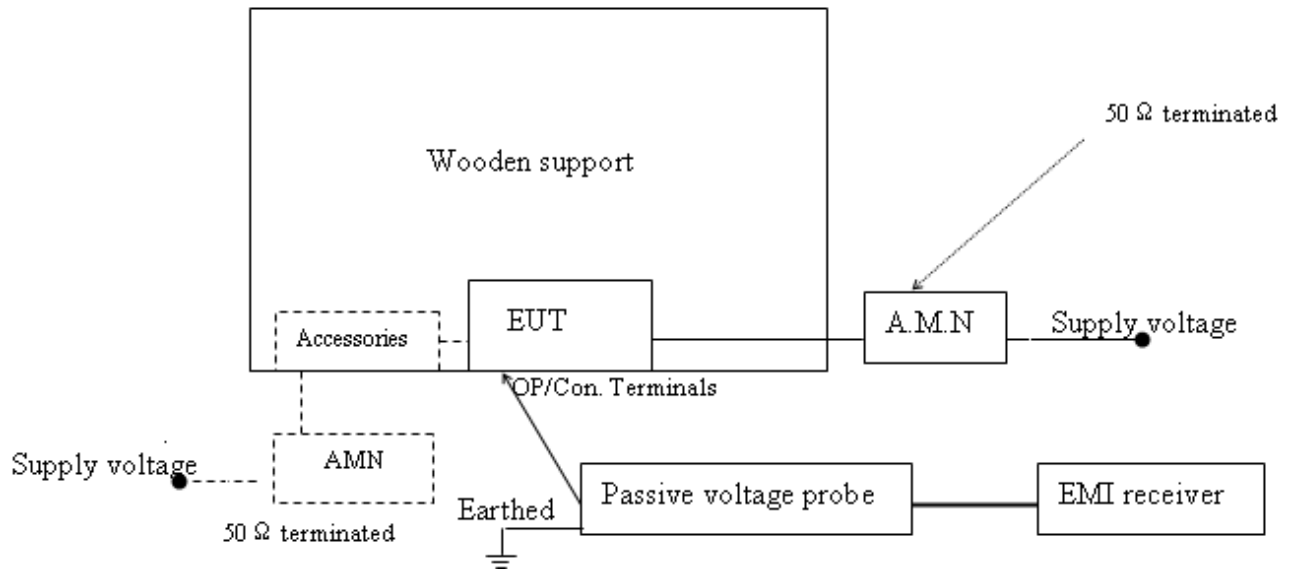
☒ At mains terminal



☒ For table top equipment, wooden support is 0.8m height table

☐ For floor standing equipment, wooden support is 0.1m height rack.

☐ At output and control terminals



Note: — : power line  
 — : signal line  
 - - - - - : means the test setup while available

### 3.3 Test Setup and Test Procedure

Measurement was performed in shielded room, and instruments used were following clause 5.1.1, 5.1.2, 5.1.3, 5.1.4 and 5.1.5 of EN 55014-1 if applicable.

Detailed test procedure and arrangement was follow EN 55014-1 clause 5.2.

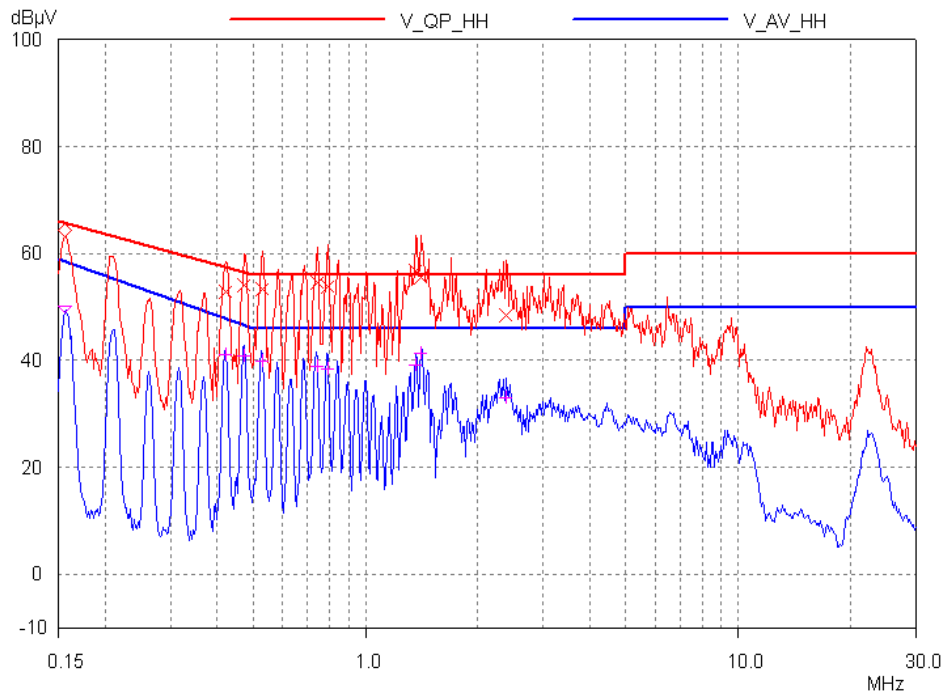
Measurement methods and operation conditions of EUT was according to clause 7 of EN 55014-1'.

Frequency range 150kHz – 30MHz was checked and EMI receiver measurement bandwidth was set to 9kHz.



### 3.4 Test Protocol

Temperature : 20°C  
Relative Humidity : 40 %



| Frequency<br>(MHz) | Quasi-peak                  |                           | Average                     |                           |
|--------------------|-----------------------------|---------------------------|-----------------------------|---------------------------|
|                    | Disturbance level<br>dB(μV) | Permitted limit<br>dB(μV) | Disturbance level<br>dB(μV) | Permitted limit<br>dB(μV) |
| 0.42               | 52.72                       | 57.45                     | 41.06                       | 47.88                     |
| 0.47               | 54.01                       | 56.45                     | 40.81                       | 46.59                     |
| 0.52               | 53.36                       | 56.00                     | 39.80                       | 46.00                     |
| 0.74               | 54.51                       | 56.00                     | 38.84                       | 46.00                     |
| 0.79               | 53.80                       | 56.00                     | 38.40                       | 46.00                     |
| 1.36               | 55.98                       | 56.00                     | 39.04                       | 46.00                     |

Note: \* means the emission level 20dB below the relevant limit.

### 3.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty at mains terminal:  $\pm 1.99\text{dB}$

Measurement uncertainty at load/control terminal:  $\pm 1.99\text{dB}$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

## 4. Continuous Disturbance Power

**Test result: PASS**

### 4.1 Disturbance Power Limits for the frequency range 30MHz to 300MHz

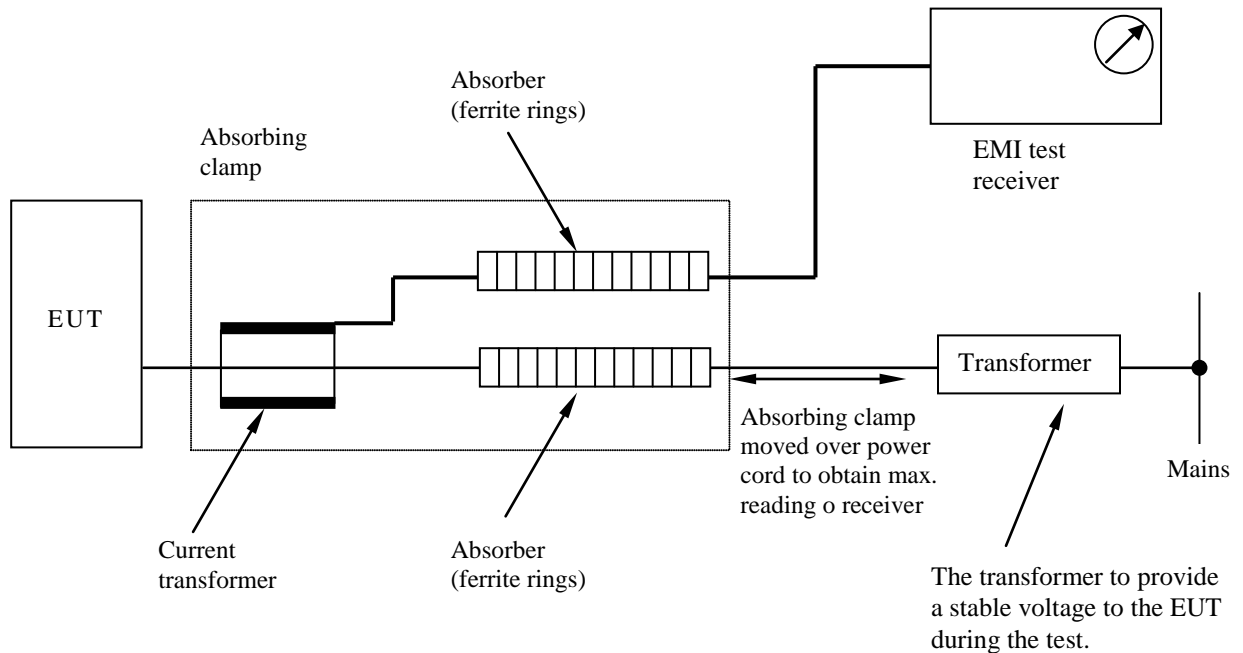
#### 4.1.1 Limits for household and similar appliances

| Frequency (MHz)                                                                                                                                                                                                                                                                                                                                        | Quasi-peak<br>dB(pW) | Average<br>dB (pW) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------|
| 30 to 300                                                                                                                                                                                                                                                                                                                                              | 45 to 55*            | 35 to 45*          |
| <p>Note: 1. * means the limit increasing linearly with the frequency.<br/>2. If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement with the receiver with average detector need not be carried out.</p> |                      |                    |

#### 4.1.2 Limits for electric tools

| Frequency                                                                                                                                                                                                                                                                                                                                               | Rated motor power<br>not exceeding 700W |         | Rated motor power<br>above 700W and not<br>exceeding 1000W |         | Rated motor power<br>above 1000W |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|---------|------------------------------------------------------------|---------|----------------------------------|---------|
| (MHz)                                                                                                                                                                                                                                                                                                                                                   | dB(pW)                                  |         | dB(pW)                                                     |         | dB(pW)                           |         |
|                                                                                                                                                                                                                                                                                                                                                         | Quasi-peak                              | Average | Quasi-peak                                                 | Average | Quasi-peak                       | Average |
| 30-300                                                                                                                                                                                                                                                                                                                                                  | 45-55*                                  | 35-45*  | 49-59*                                                     | 39-49*  | 55-65*                           | 45-55*  |
| <p>Notes: 1. * means the limit increasing linearly with the frequency.<br/>2. If the limit for the measurement with the average detector is met when using a receiver with a quasi-peak detector, the equipment under test shall be deemed to meet both limits and the measurement with the receiver with average detector need not be carried out.</p> |                                         |         |                                                            |         |                                  |         |

## 4.2 Block Diagram of Test Setup



## 4.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Instruments used were follow EN 55014-1 clause 6.1.

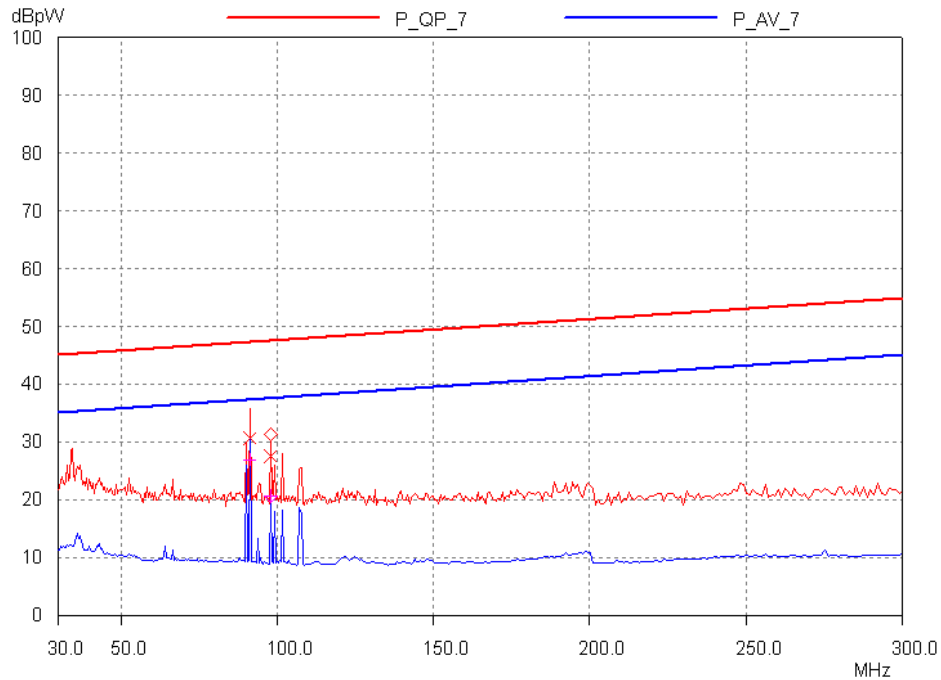
Detailed test procedure and arrangement was follow EN 55014-1 clause 6.2 and 6.3.

Operation conditions of EUT were according to EN 55014-1 clause 7.

Frequency range 30MHz – 300MHz was checked and EMI receiver measurement bandwidth was set to 120kHz.

#### 4.4 Test Protocol and Wave Form

Temperature : 20°C  
Relative Humidity : 40 %



| Frequency<br>(MHz) | Quasi-peak                  |                           | Average                     |                           |
|--------------------|-----------------------------|---------------------------|-----------------------------|---------------------------|
|                    | Disturbance level<br>dB(μV) | Permitted limit<br>dB(μV) | Disturbance level<br>dB(μV) | Permitted limit<br>dB(μV) |
| 31.22              | *                           | 45.05                     | *                           | 35.05                     |
| 37.21              | *                           | 45.27                     | *                           | 35.27                     |
| 58.66              | *                           | 46.06                     | *                           | 36.06                     |
| 91.37              | 30.72                       | 47.27                     | 26.97                       | 37.27                     |
| 97.79              | 27.53                       | 47.51                     | 20.68                       | 37.51                     |
| 259.01             | *                           | 53.48                     | *                           | 43.48                     |

Note: \* means the emission level 20dB below the relevant limit.

#### **4.5 Measurement Uncertainty**

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of mains lead and auxiliary lead:  $\pm 4.12\text{dB}$

The measurement uncertainty is given with a confidence of 95%,  $k=2$

The measurement uncertainty is traceable to internal procedure TI-036.

## 5. Radiated emission

### Test result: PASS

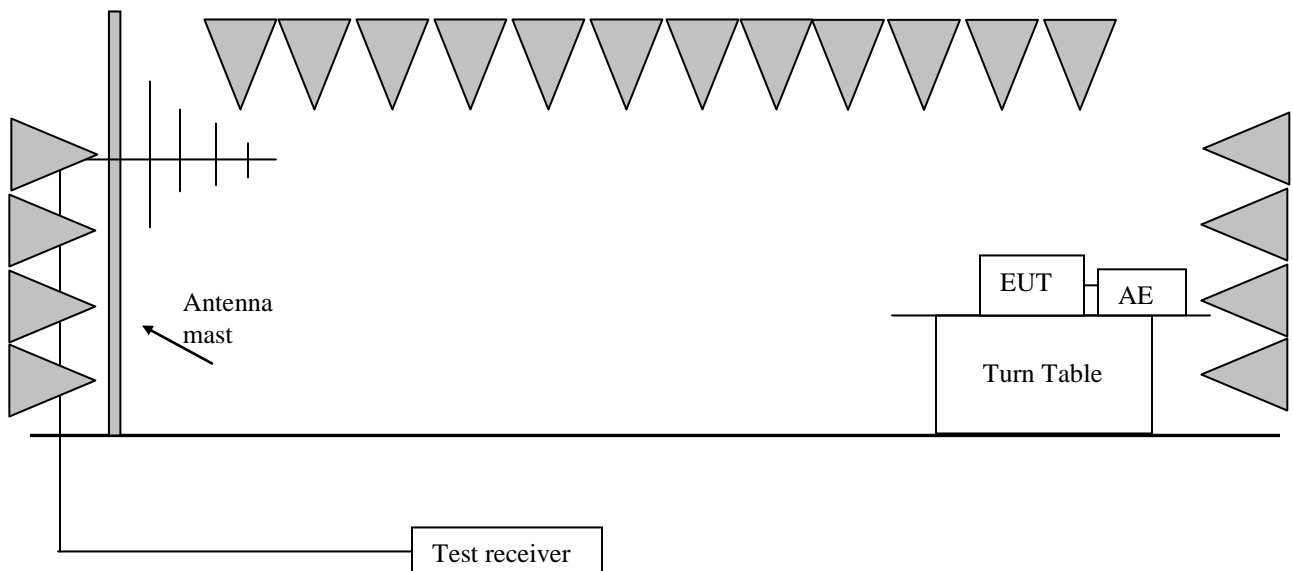
☒ As for in the disturbance power test all emission readings from the EUT are lower than the applicable limits (Table 2a) reduced by the margin (Table 2b) and the maximum clock frequency is less than 30MHz, the EUT is deemed to comply with the Radiated Emission requirement without test.

### 5.1 Radiated emission limit from frequency range 30MHz – 1000MHz

| Frequency (MHz) | Permitted limit in dB $\mu$ V/m<br>(Quasi-peak)<br>of Measurement Distance 3m | Permitted limit in dB $\mu$ V/m<br>(Quasi-peak)<br>of Measurement Distance 10M |
|-----------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 30-230          | 40                                                                            | 30                                                                             |
| 230-1000        | 47                                                                            | 37                                                                             |

Note: for the measurement distance other than 3m and 10m, the limit is varied according to 20dB/10 decades.

### 5.2 Block diagram and test set up



The measurement was applied in a 3 m semi-anechoic chamber.  
Measurement was performed according to CISPR 22.  
Setting of EUT is according to EN 55014-1 clause 7.3.6.2.3  
The bandwidth setting on R&S Test Receiver ESI26 was 120kHz.  
The frequency range from 30MHz to 1000MHz was checked.

### 5.3 Test Protocol

Temperature : °C  
Relative humidity : %

Horizontal Polarization:

Vertical Polarization:

| Polarization                | Frequency<br>(MHz) | Emission level<br>(dB $\mu$ V/m) | Limits<br>(dB $\mu$ V/m) | Margin<br>(dB $\mu$ V/m) |
|-----------------------------|--------------------|----------------------------------|--------------------------|--------------------------|
| Horizontal                  |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
| Vertical                    |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
|                             |                    |                                  |                          |                          |
| Note: * means margin >20dB. |                    |                                  |                          |                          |

### 5.4 Measurement uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of radiated emission is:  $\pm 5.31$ dB

The measurement uncertainty is given with a confidence of 95%, k=2.

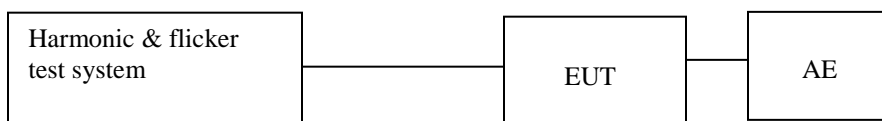
The measurement uncertainty is traceable to internal procedure TI-036.



## 6. Harmonics

**Test result:** **Pass**

### 6.1 Block Diagram of Test Setup



### 6.2 Test Setup and Test Procedure

Harmonics of the fundamental current were measured up to 40 order harmonics using a digital power meter with an analogue output and frequency analyser which was integrated in the harmonic & flicker test system. The measurements were carried out under steady conditions.

- ☒ This product is not defined as lighting equipment, and has rated power less than 75W, therefore, no limit apply according to EN 61000-3-2
- ☐ Professional equipment with a total rated power greater than 1 kW, therefore, no limit apply according to EN 61000-3-2
- ☐ Symmetrically controlled heating elements with a rated power less than or equal to 200 W, therefore, no limit apply according to EN 61000-3-2
- ☐ Independent dimmers for incandescent lamps with a rated power less than or equal to 1kW, therefore, no limit apply according to EN 61000-3-2

### 6.3 Test Protocol

Temperature : °C

Relative Humidity : %

### 6.4 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of harmonic test is:  $\pm 5\%$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

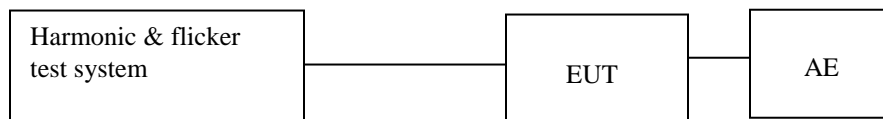
### 6.5 Additions, Deviations and Exclusions from Standards

None

## 7. Voltage Fluctuations-Flicker

**Test result**                      **Pass**

### 7.1 Block Diagram of Test Setup



### 7.2 Test Setup and Test Procedure

#### 7.2.1 Definition

- Flicker:** impression of unsteadiness of visual sensation induced by a lighting stimulus whose luminance or spectral distribution fluctuates with time.
- Pst:** Short-term flicker indicator The flicker severity evaluated over a short period (in minutes); Pst=1 is the conventional threshold of irritability
- Plt:** long-term flicker indicator; the flicker severity evaluated over a long period (a few hours) Using successive Pst values.
- dc:** the relative steady-state voltage change
- dmax:** the maximum relative voltage change
- d(t):** the value during a voltage change

#### 7.2.2 Test condition

The EUT was set to produce the most unfavorable sequence of voltage changes.

### 7.3 Test Protocol

The tested object operated under the operating condition specified in IEC61000-3-3.

The following limits apply

- “dc” shall not exceed 3.3%.
- “dmax” shall not exceed 4/6/7%
- “d(t)” shall not exceed 3.3% for more than 500ms.



The product no means to generate voltage fluctuation higher than the relevant limit, therefore, it is deemed to fulfill the requirements according to EN61000-3-3 without test.

Temperature : °C

Relative Humidity : %

### 7.4 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of voltage fluctuation and flicker is:  $\pm 12\%$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

### 7.5 Additions, deviations and exclusions from standards

None

## Immunity Test

### Performance criteria

The equipment or system shall be able to provide the essential performance and remain safe. The following degradations associated with essential performance and safety shall not be allowed:

- 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 is indistinguishable from physiologically produced signals or the noise interferes with interpretation of physiologically-produced signals;
- Artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- 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.

### Operating Mode and Configuration

During immunity testing, each function of the equipment or system that is associated with essential performance shall be tested in the mode that is most critical from a patient outcome perspective, based upon a risk analysis, using equipment options, cable layout and accessories in a typical configuration, consistent with normal use. This risk analysis is not required if all modes of the equipment or system are tested. If the equipment or system is not rated for continuous duty, the operating mode may instead be selected such that reliable operation is obtained for the applicable test duration.

### **Basic EMC standard for immunity test**

IEC 61000-4-2: 1995/+A1:1998/+A2:2000: Electromagnetic Compatibility (EMC) – Part 4-2: testing and measurement techniques – Electrostatic discharge immunity test

IEC 61000-4-3: 2006/+A1:2007: Electromagnetic Compatibility (EMC) – Part 4-3: testing and measurement techniques – Radiated, radio frequency, electromagnetic field immunity test

IEC 61000-4-4: 2004: Electromagnetic Compatibility (EMC) – Part 4-4: testing and measurement techniques – Electric fast transient/burst immunity test

IEC 61000-4-5: 2005: Electromagnetic Compatibility (EMC) – Part 4-5: testing and measurement techniques – Surge immunity test

IEC 61000-4-6:2003/+A1:2004/+A2:2006: Electromagnetic Compatibility (EMC) – Part 4-6: testing and measurement techniques – Immunity to conducted disturbance, induced by radio frequency field.

IEC 61000-4-11: 2004: Electromagnetic Compatibility (EMC) – Part 4-11: testing and measurement techniques – Voltage dips, short interruption and voltage variations immunity test

IEC 61000-4-8: 1994/+A1: 2001: Electromagnetic Compatibility (EMC) – Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test

## 9. Electrostatic Discharge (ESD)

**Test result** **PASS**

### 9.1 Severity Level

#### 9.1.1 Test level

| Contact discharge                                                                                                                                                                                                                                                                                                                            |                    | Air discharge |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------|--------------------|
| Level                                                                                                                                                                                                                                                                                                                                        | Test voltage<br>kV | Level         | Test voltage<br>kV |
| 1                                                                                                                                                                                                                                                                                                                                            | 2                  | 1             | 2                  |
| 2                                                                                                                                                                                                                                                                                                                                            | 4                  | 2             | 4                  |
| 3                                                                                                                                                                                                                                                                                                                                            | 6                  | 3             | 8                  |
| <p>Notes: 1. The gray rows were the selected test level.</p> <p>2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.</p> |                    |               |                    |

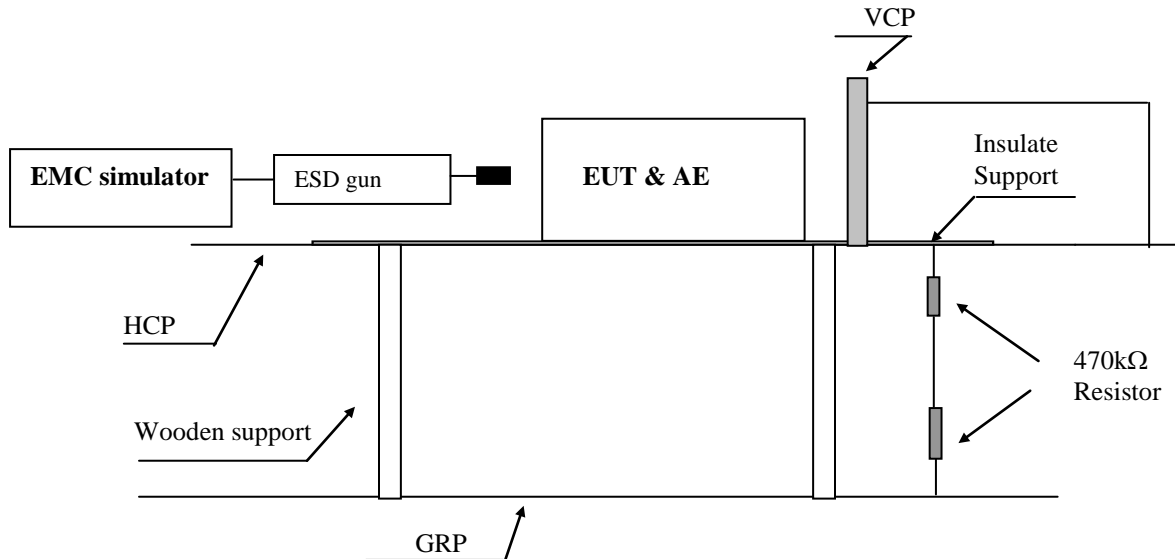
#### 9.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

| Discharge Class                                | Highest Compliance Level | Electromagnetic Environment |
|------------------------------------------------|--------------------------|-----------------------------|
| Contact discharge                              | 6                        | All environments            |
|                                                | Others                   | Others                      |
| Air discharge                                  | 8                        | All environments            |
|                                                | Others                   | Others                      |
| Notes: The gray rows were the selected object. |                          |                             |

## 9.2 Block Diagram of Test Setup

☒ For table-top equipment



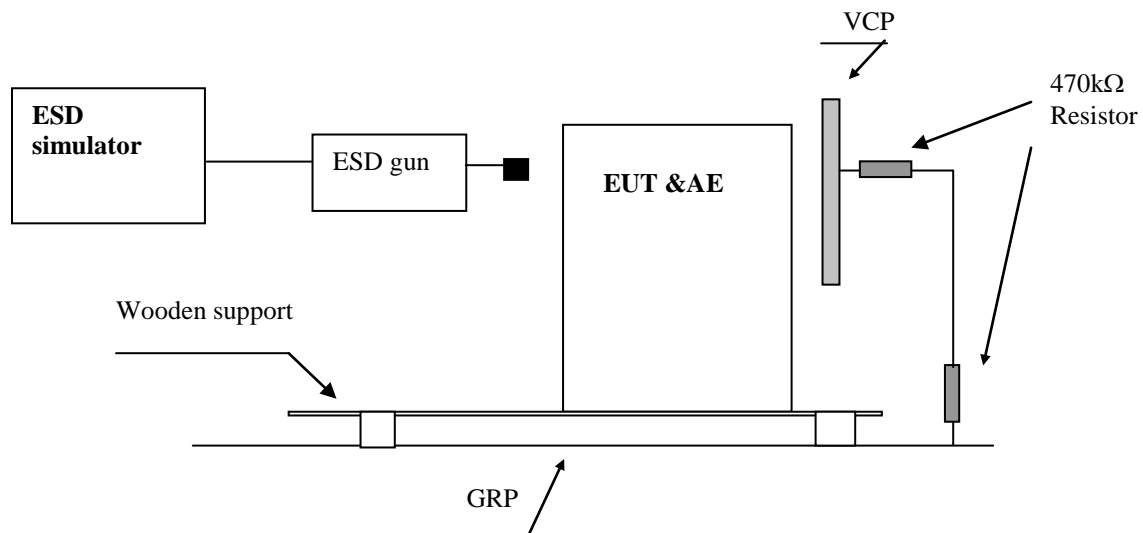
Note: HCP means Horizontal Coupling Plane

VCP means Vertical Coupling Plane

GRP means Ground Reference Plane

Wooden support is a 0.8m height table

☐ For floor standing equipment



Note: VCP means Vertical Coupling Plane

GRP means Ground Reference Plane

Wooden support is a 0.1m height rack



### 9.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-2 clause

7.1.

The test method is specified by IEC61000-4-2 with the modifications by IEC60601-1-2 clause 36.202.2(b).

### 9.4 Test Protocol

Temperature: 26°C

Relative Humidity: 41%

Atmospheric Pressure: 101.2kPa

Direct discharge was applied at the following selected points:

| Test point # | Test level [kV] | Air/Contact | Polarity (+/-) | Pass/Fail | Comment                           |
|--------------|-----------------|-------------|----------------|-----------|-----------------------------------|
| A            | 2/4/6           | Contact     | +/-            | Pass      | all touchable screws of enclosure |
| B            | 2/4/6           | Contact     | +/-            | Pass      | Accessible metal parts of the EUT |
| C            | 2/4/8           | Air         | +/-            | Pass      | Air gap of the switch, button     |
| D            | 2/4/8           | Air         | +/-            | Pass      | Slots around the EUT              |

Indirect contact discharges were applied to the VCP and the HCP at the following selected points:

☒ For table top equipment

| Point | Description                         | Point                        | Result |
|-------|-------------------------------------|------------------------------|--------|
| HCP f | 0,1m from the front of the EUT      | Edge of centre,corner on HCP | P      |
| HCP b | 0,1m from the back of the EUT       | Edge of centre,corner on HCP | P      |
| HCP r | 0,1m from the right side of the EUT | Edge of centre,corner on HCP | P      |
| HCP l | 0,1m from the left side of the EUT  | Edge of centre,corner on HCP | P      |
| VCP f | 0,1m from the front of the EUT      | Edge of centre,corner on VCP | P      |
| VCP b | 0,1m from the back of the EUT       | Edge of centre,corner on VCP | P      |
| VCP r | 0,1m from the right of the EUT      | Edge of centre,corner on VCP | P      |
| VCP l | 0,1m from the left of the EUT       | Edge of centre,corner on VCP | P      |

☐ For floor standing equipment

| Point | Description                    | Point                        | Result |
|-------|--------------------------------|------------------------------|--------|
| VCP f | 0,1m from the front of the EUT | Edge of centre,corner on VCP | -      |
| VCP b | 0,1m from the back of the EUT  | Edge of centre,corner on VCP | -      |
| VCP r | 0,1m from the right of the EUT | Edge of centre,corner on VCP | -      |
| VCP l | 0,1m from the left of the EUT  | Edge of centre,corner on VCP | -      |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe.

## 9.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of ESD test is:  $\pm 6.8 \%$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

## 9.6 Additions, deviations and exclusions from standards

None

## 10. Electromagnetic field susceptibility

**Test result**                      **Pass**

### 10.1 Severity Level

#### 10.1.1 Test level

| Level | Test field strength V/m | Equipment                     |
|-------|-------------------------|-------------------------------|
| 1     | 3                       | Not life-supporting equipment |
| 2     | 10                      | Life-supporting equipment     |

Notes: 1. The gray rows were the selected test level.  
 2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.  
 3. “Life-supporting equipment” means the equipment or system that includes at least one function that is intended to actively keep alive or resuscitate patients and the failure is likely to lead to serious injury or death of a patient.

#### 10.1.2 Class of equipment

| Equipment                     | Used Location               | Construction                                         |
|-------------------------------|-----------------------------|------------------------------------------------------|
| Not life-supporting equipment | Not Only in Shield Location | Not Including Receivers of RF Electromagnetic Energy |
| Life-supporting equipment     | Only in Shield Location     | Including Receivers of RF Electromagnetic Energy     |

Notes: The gray rows were the selected object.

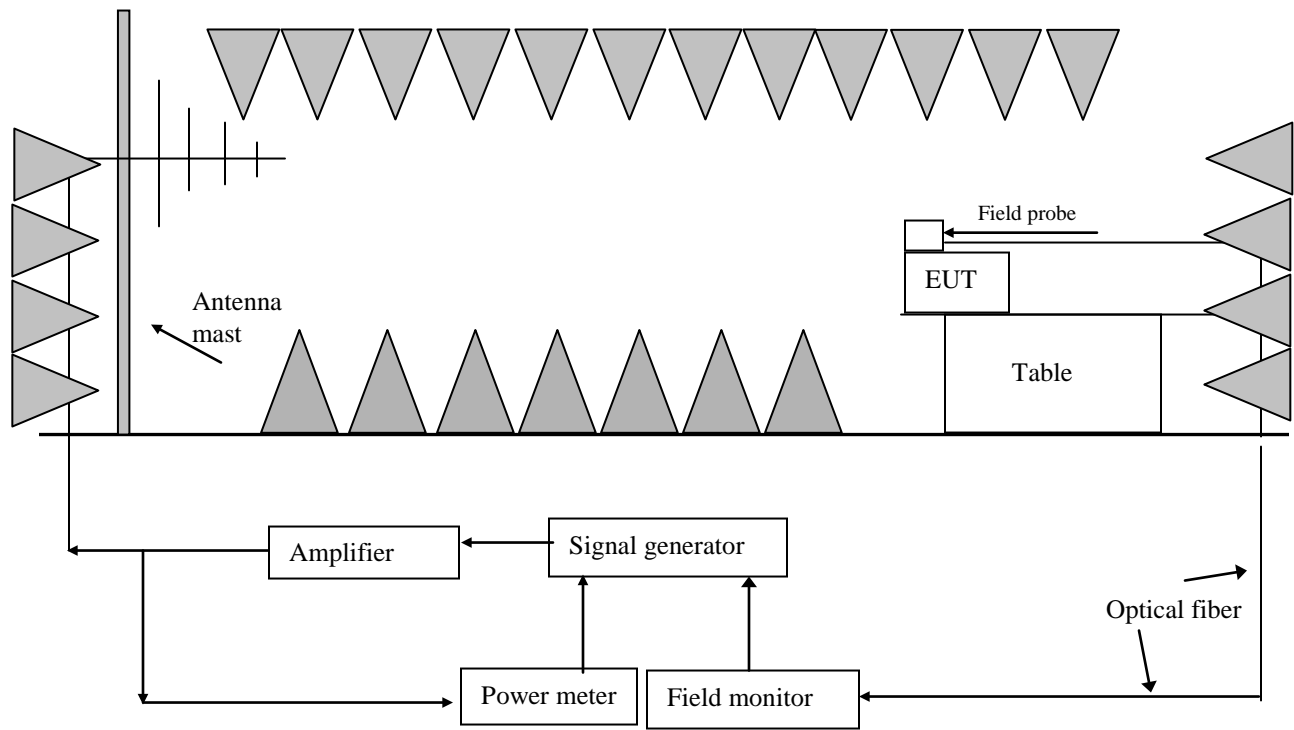
### 10.1.3 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

| Equipment                     | Highest Compliance Level | Electromagnetic Environment |
|-------------------------------|--------------------------|-----------------------------|
| Not life-supporting equipment | 3                        | All environments            |
|                               | Others                   | Others                      |
| Life-supporting equipment     | 10                       | All environments            |
|                               | Others                   | Others                      |

Notes: The gray rows were the selected object.

## 10.2 Block diagram of test setup



## 10.3 Test Setup and Test Procedure

Measurement was performed in full-anechoic chamber.

Measurement and setting of EUT was applied according to IEC61000-4-3 clause 7.

The test method and equipment is specified by IEC61000-4-3 with additions and modifications by IEC60601-1-2 clause 36.202.3(b).

#### 10.4 Test Protocol

Temperature: 26°C

Relative Humidity: 41%

| Test no.: | Frequency<br>(MHz) | Polarization | Test level<br>V/m | Exposed<br>location | Result |
|-----------|--------------------|--------------|-------------------|---------------------|--------|
| 1         | 80-2500            | H & V        | 3                 | All surfaces        | Pass   |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe

#### 10.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of radiated susceptibility test is:  $\pm 4.7\text{dB}$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

#### 10.6 Additions, deviations and exclusions from standards

None

## 11. Electric Fast Transient/Burst Immunity Test

**Test result**
**Pass**

### 11.1 Severity Level

#### 11.1.1 Test level

| Open circuit output test voltage (+/-10%) and repetition rate of the impulses (+/- 20%)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                        |                                            |                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------------------------|------------------------|
| On A.C and D.C power cables ports                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                        | On signal and interconnecting cables ports |                        |
| Voltage peak<br>kV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Repetition rate<br>kHz | Voltage peak<br>kV                         | Repetition rate<br>kHz |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 5                      | 1                                          | 5                      |
| <p>Notes: 1. The gray rows were the selected test level.</p> <p>2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.</p> <p>3. Signal and interconnecting cables specified to be (i.e. restricted to) less than 3 m in length by the manufacturer of the equipment or system and all patient-coupled cables are not tested directly. However, the effects of any coupling between cables that are tested directly and cables that are not tested directly shall be taken into account.</p> |                        |                                            |                        |

#### 11.1.2 Compliance Level

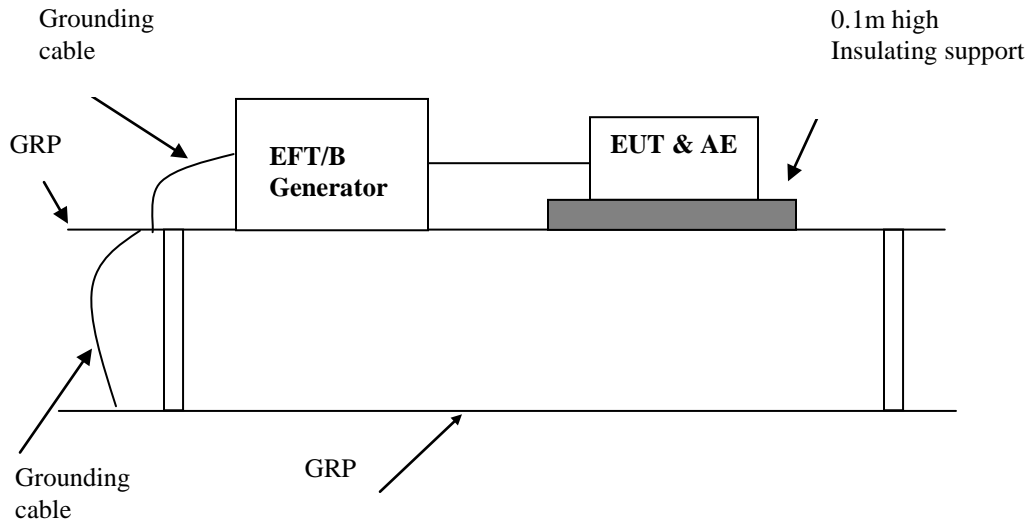
Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

| Cables Class                                   | Highest Compliance Level | Electromagnetic Environment |
|------------------------------------------------|--------------------------|-----------------------------|
| A.C and D.C power cables ports                 | 2                        | All environments            |
|                                                | Others                   | Others                      |
| Signal and interconnecting cables ports        | 1                        | All environments            |
|                                                | Others                   | Others                      |
| Notes: The gray rows were the selected object. |                          |                             |

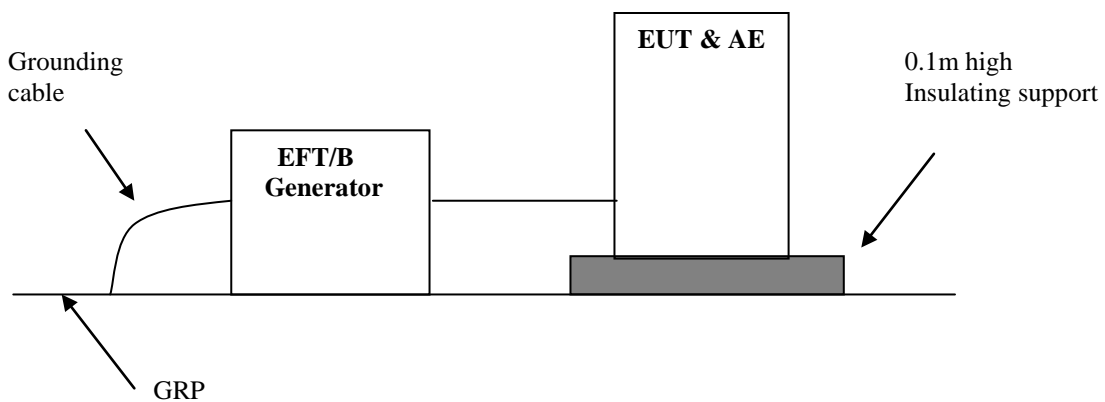
## 11.2 Block Diagram of Test Setup

### 11.2.1 Block Diagram for input a.c./d.c. power line

☒ For table-top equipment



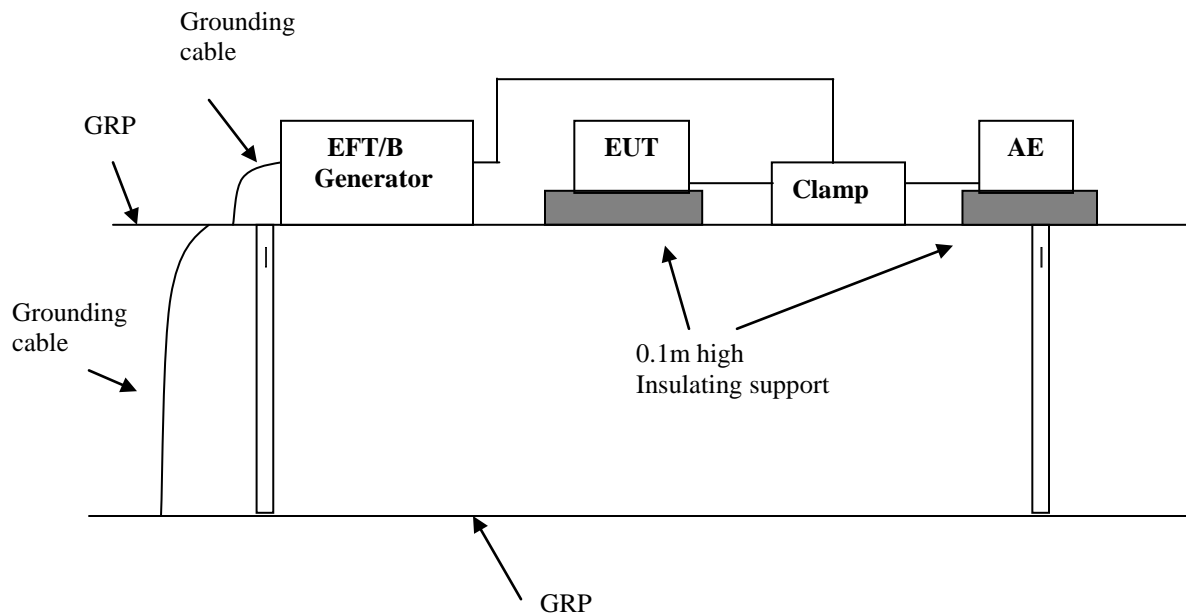
☐ For floor standing equipment



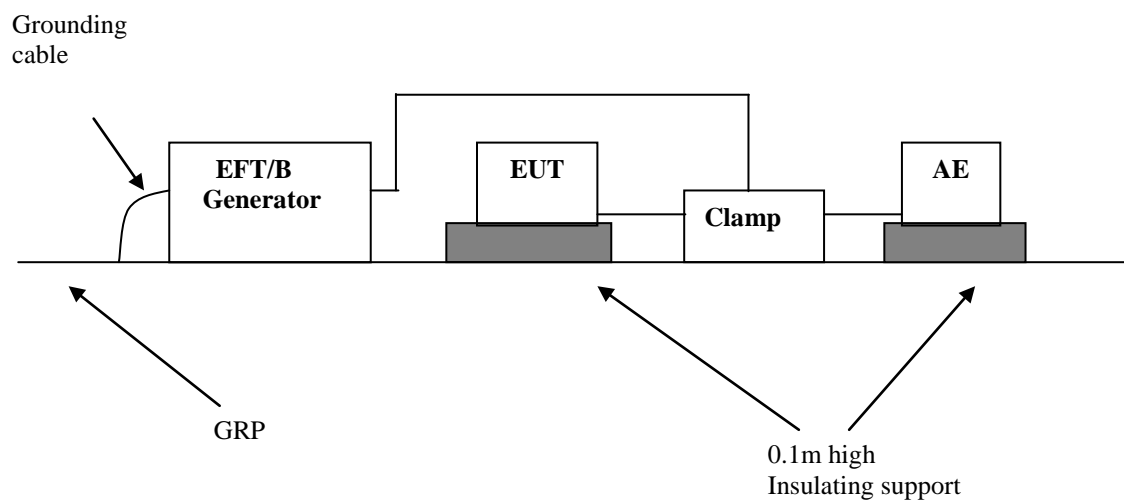


### 11.2.2 Block Diagram for output a.c./d.c. power line or signal/control lines

☐ For table-top equipment



☐ For floor standing equipment



### 11.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-4 clause 7.2.

The test method and equipment is specified by IEC61000-4-4 with additions and modifications by IEC60601-1-2 clause 36.202.4(b).

### 11.4 Test Protocol

Temperature: 26°C  
Relative Humidity: 40%

| Test No.<br>#                 | Level<br>[kV] | Polarity<br>+/- | Line for test             | Pass/<br>Fail |
|-------------------------------|---------------|-----------------|---------------------------|---------------|
| 1                             | 2             | +/-             | L                         | Pass          |
| 2                             | 2             | +/-             | N                         | Pass          |
| 3                             | 2             | +/-             | PE                        | NA            |
| 4                             | 2             | +/-             | L-N                       | Pass          |
| 5                             | 2             | +/-             | L-PE                      | NA            |
| 6                             | 2             | +/-             | N-PE                      | NA            |
| 7                             | 2             | +/-             | L,N,PE                    | NA            |
| 8                             | 1             | +/-             | Signal cables             | NA            |
| 9                             | 1             | +/-             | interconnecting<br>cables | NA            |
| Note: NA means Not Applicable |               |                 |                           |               |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe

### 11.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of EFT test at main terminal is:  $\pm 17.3\%$

Measurement uncertainty of EFT test at signal/telecom terminal is:  $\pm 17.4\%$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

### 11.6 Additions, deviations and exclusions from standards

None

## 12. Surge Immunity Test

**Test result** **Pass**

### 12.1 Severity Level

#### 12.1.1 Test level

| Level | Open-circuit test voltage +/-10%<br>kV |                              |
|-------|----------------------------------------|------------------------------|
|       | A.C power line(s) to ground            | A.C power line(s) to line(s) |
| 1     | 0.5                                    | 0.5                          |
| 2     | 1                                      | 1                            |
| 3     | 2                                      | Not applicable               |

Notes: 1. The gray rows were the selected test level.  
2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.  
3. All other cables except AC power line are not tested directly. the determination of compliance with this requirement shall be based on the response of the equipment or system, considering each surge individually, taking into account the effects of any coupling between cables that are tested directly and cables that are not tested directly.

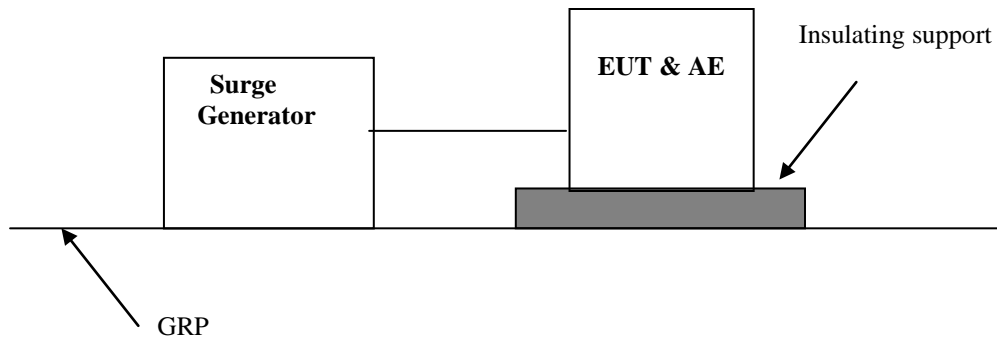
#### 12.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

| Test Items                   | Highest Compliance Level | Electromagnetic Environment |
|------------------------------|--------------------------|-----------------------------|
| A.C power line(s) to ground  | 2                        | All environments            |
|                              | Others                   | Others                      |
| A.C power line(s) to line(s) | 1                        | All environments            |
|                              | Others                   | Others                      |

Notes: The gray rows were the selected object.

## 12.2 Block Diagram of Test Setup



## 12.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-5 clause 7.

The test method and equipment is specified by IEC61000-4-5 with modifications by IEC60601-1-2 clause 36.202.5(b).

## 12.4 Test Protocol

Temperature: 26°C

Relative Humidity: 40%

| Test No.                          | Test level<br>kV | Phase<br>°           | Polarity  | Diff. /<br>Com. | Result |
|-----------------------------------|------------------|----------------------|-----------|-----------------|--------|
| 1                                 | 0.5              | 0°,90°,<br>180°,270° | +/-, L-PE | Com.            | NA     |
| 2                                 | 0.5              | 0°,90°,<br>180°,270° | +/-, N-PE | Com.            | NA     |
| 3                                 | 1                | 0°,90°,<br>180°,270° | +/-, L-PE | Com.            | NA     |
| 4                                 | 1                | 0°,90°,<br>180°,270° | +/-, N-PE | Com.            | NA     |
| 5                                 | 2                | 0°,90°,<br>180°,270° | +/-, L-PE | Com.            | NA     |
| 6                                 | 2                | 0°,90°,<br>180°,270° | +/-, N-PE | Com.            | NA     |
| 7                                 | 0.5              | 0°,90°,<br>180°,270° | +/-, L-N  | Diff.           | Pass   |
| 8                                 | 1                | 0°,90°,<br>180°,270° | +/-, L-N  | Diff.           | Pass   |
| Notes: "NA" means not applicable. |                  |                      |           |                 |        |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe

## 12.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of surge test at main terminal is:  $\pm 18.8\%$

Measurement uncertainty of surge test at signal/telecom terminal is:  $\pm 19.3\%$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

## 12.6 Additions, deviations and exclusions from standards

None

### 13. Immunity to Conducted Disturbances, Induced by Radio-frequency Fields

**Test result**

**Pass**

#### 13.1 Severity Level

##### 13.1.1 Test level

| Level | Test field strength<br>V/m | Equipment                     | Frequency range           |
|-------|----------------------------|-------------------------------|---------------------------|
| 1     | 3                          | Not life-supporting equipment | 0.15MHz-80MHz             |
| 2     | 3                          | Life-supporting equipment     | 0.15MHz-80MHz             |
| 3     | 10                         | Life-supporting equipment     | In the ISM frequency band |

Notes: 1. The gray rows were the selected test level.

2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.
3. “Life-supporting equipment” means the equipment or system that includes at least one function that is intended to actively keep alive or resuscitate patients and the failure is likely to lead to serious injury or death of a patient.
4. “ISM” means the industrial, scientific and medical.
5. For internally powered equipment and systems that cannot be used during battery charging, do not have an option for AC power input and have no connection to ground, telecommunications systems, any other equipment or system or a patient, the start frequency shall be determined from figure B.1 of IEC 61000-4-6, using the maximum dimension of the equipment or system, including the maximum length of each cable connected.

### 13.1.2 Class of equipment

| Equipment                                      | Used Location               | Construction                                         |
|------------------------------------------------|-----------------------------|------------------------------------------------------|
| Not life-supporting equipment                  | Not Only in Shield Location | Not Including Receivers of RF Electromagnetic Energy |
| Life-supporting equipment                      | Only in Shield Location     | Including Receivers of RF Electromagnetic Energy     |
| Notes: The gray rows were the selected object. |                             |                                                      |

### 13.1.3 Compliance Level

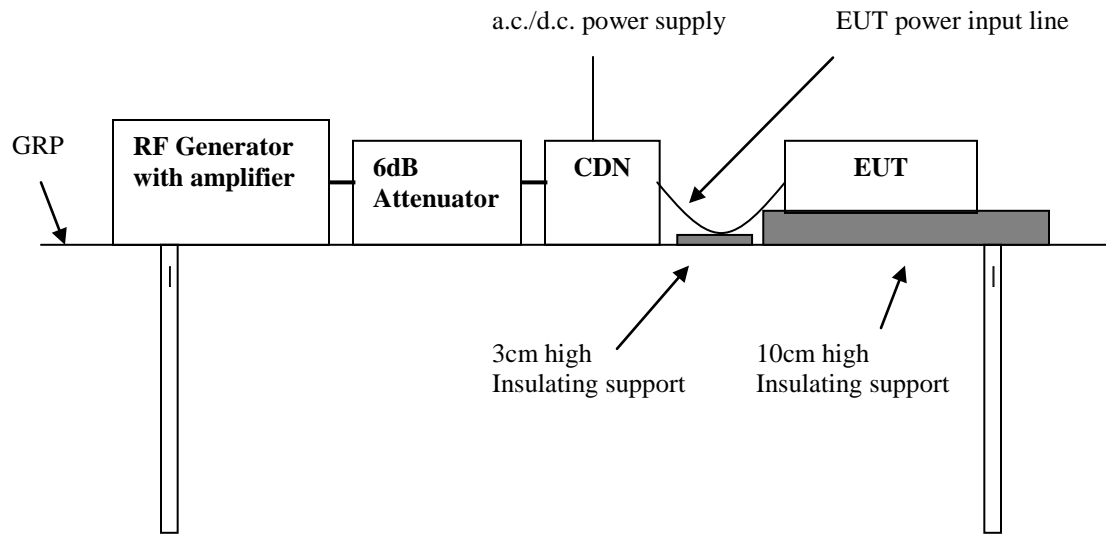
Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

| Frequency range                                | Equipment                     | Highest Compliance Level | Electromagnetic Environment |
|------------------------------------------------|-------------------------------|--------------------------|-----------------------------|
| 0.15MHz-80MHz                                  | Not life-supporting equipment | 3                        | All environments            |
|                                                |                               | Others                   | Others                      |
| 0.15MHz-80MHz                                  | Life-supporting equipment     | 3                        | All environments            |
|                                                |                               | Others                   | Others                      |
| In the ISM frequency band                      | Life-supporting equipment     | 10                       | All environments            |
|                                                |                               | Others                   | Others                      |
| Notes: The gray rows were the selected object. |                               |                          |                             |

## 13.2 Diagram of Test Setup

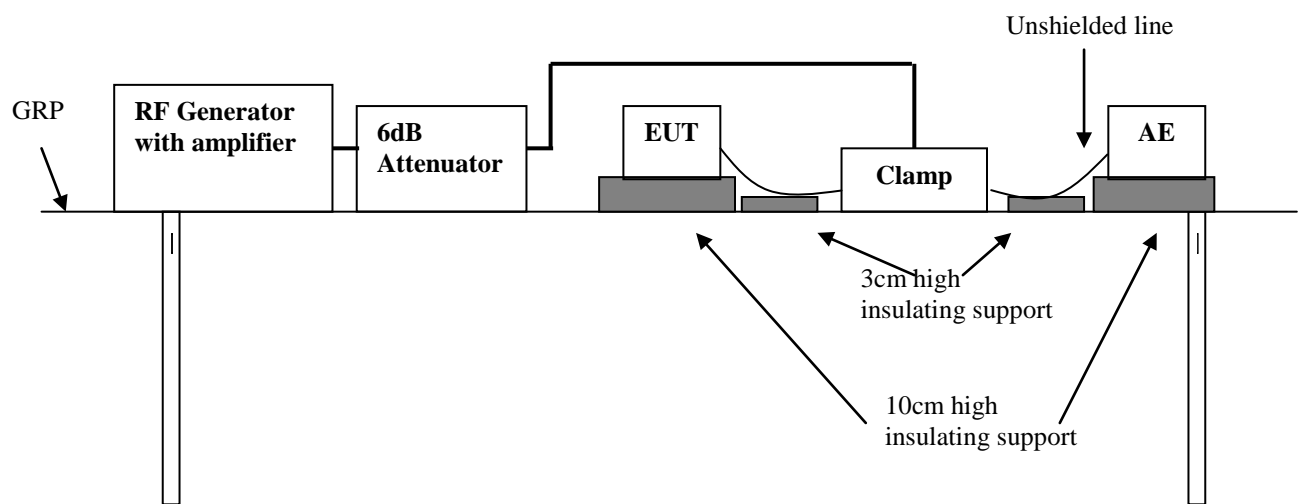
### 13.2.1 Block Diagram for a.c./d.c input power line

☒ Block Diagram for a.c./d.c input power line



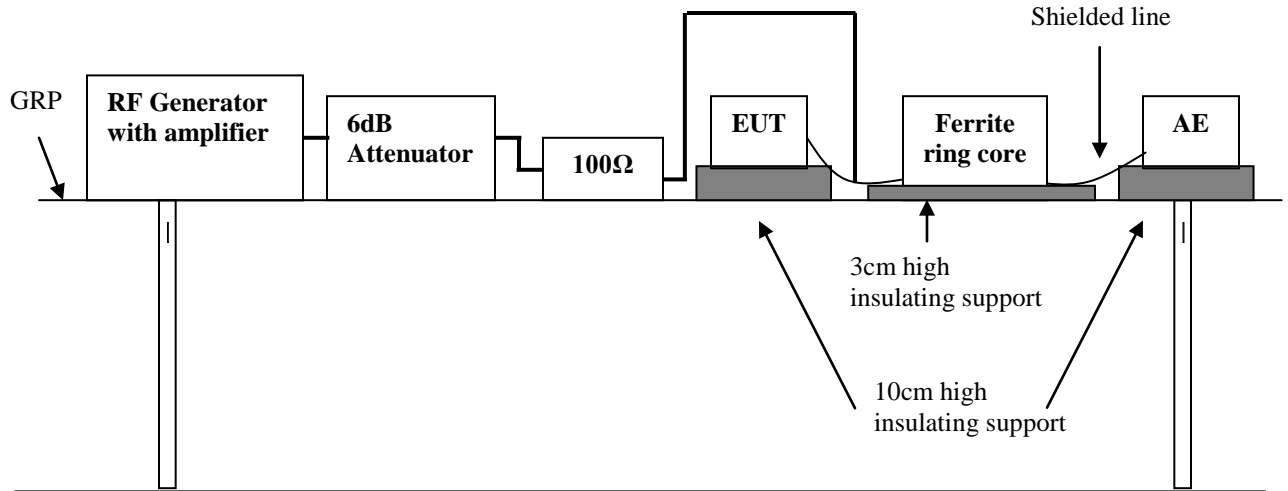
### 13.2.2 Block Diagram for output a.c./d.c. power line or signal/control lines

☐ Unshielded line





☐ Shielded line



### 13.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-6 clause 7.

The test method and equipment is specified by IEC61000-4-6 with additions and modifications by IEC60601-1-2 clause 36.202.6(b).

### 13.4 Test Protocol

Temperature: 26°C  
Relative Humidity: 40%

| Test No.                          | Frequency (MHz)    | Level V (e.m.f.) | Amplitude modulation | Injected point | Result |
|-----------------------------------|--------------------|------------------|----------------------|----------------|--------|
| 1                                 | 0.15~80            | 3                | 1kHz<br>80%          | L-N            | Pass   |
| 2                                 | 0.15~80            | 3                | 2Hz<br>80%           | L-N-PE         | NA     |
| 3                                 | ISM frequency band | 10               | 1kHz<br>80%          | L-N-PE         | NA     |
| 2                                 | ISM frequency band | 10               | 2Hz<br>80%           | L-N-PE         | NA     |
| Notes: "NA" means not applicable. |                    |                  |                      |                |        |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe

### 13.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of injected current test at main terminal as well as unshielded signal terminal is:  $\pm 2.9\text{dB}$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

### 13.6 Additions, deviations and exclusions from standards

None

## 14. Voltage Dips, Short Interruptions and Voltage Variations Immunity Test

**Test result**

**Pass**

### 14.1 Severity Level

#### 14.1.1 Test level

Immunity Test Levels for Voltage Dips

| Test level<br>% UT | Voltage dip<br>% UT | Duration<br>(in period) |
|--------------------|---------------------|-------------------------|
| 0                  | 100                 | 0.5                     |
| 40                 | 60                  | 5                       |
| 70                 | 30                  | 25                      |

- Notes:
- For 0.5 period, the test shall be made in positive and negative polarity, i.e. starting at 0° and 180° respectively.
  - The gray rows are selected test level.
  - Equipment and systems with a rated input power of 1kVA or less and all life supporting equipment and systems shall comply with the requirements.
  - For equipment and systems that are not life-supporting and for which the rated input power is greater than 1kVA and the rated input current is less than or equal to 16A per phase, deviation from performance criteria is allowed, provided the equipment or system remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention.
  - Equipment and systems that are not life-supporting and for which the rated input current exceeds 16A per phase are exempt from the testing specification.

Immunity Test Level for Voltage Interruption

| Test level<br>% UT | Voltage Interruption<br>% UT | Duration<br>(s) |
|--------------------|------------------------------|-----------------|
| 0                  | 100                          | 5               |

- Notes:
- The gray rows are selected test level.
  - Equipment and systems are allowed a deviation from the performance criteria at this immunity test level, provided the equipment or system remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention. Life-supporting equipment and systems for which this allowance for a deviation from the performance criteria shall provide an alarm complying with applicable international standards to indicate cessation or interruption of an intended operation related to essential performance.

#### 14.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

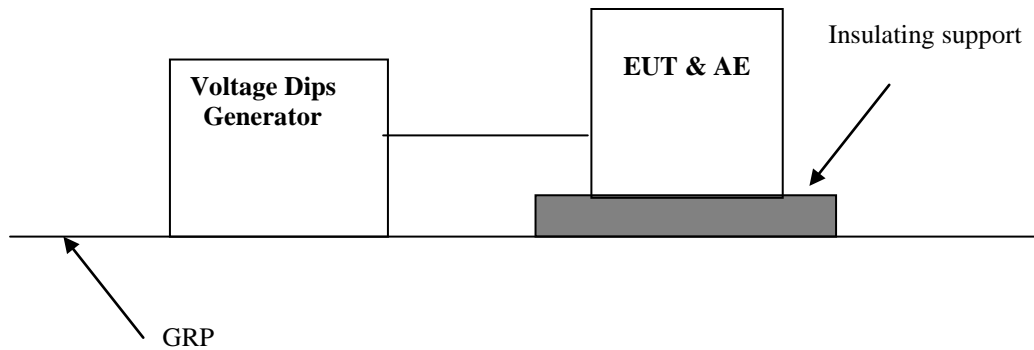
##### Compliance Level for Voltage Dips

| Equipment                                                                                  | Highest Compliance Level<br>(Duration in period)) | Electromagnetic Environment |
|--------------------------------------------------------------------------------------------|---------------------------------------------------|-----------------------------|
| With rated input power ≤1kVA<br>or life-supporting equipment                               | 0.5, 5, 25                                        | All environments            |
|                                                                                            | Others                                            | Others                      |
| Not life-supporting & rated input power<br>higher than 1kVA & rated input<br>current ≤ 16A | 0.5, 5, 25                                        | All environments            |
|                                                                                            | Others                                            | Others                      |
| Not life-supporting & Rated input<br>current ≥ 16A                                         | Exempt                                            |                             |
| Notes: The gray rows were the selected object.                                             |                                                   |                             |

##### Compliance Level for Voltage Interruption

| Equipment                                      | Highest Compliance Level<br>(Duration in Seconds) | Electromagnetic Environment |
|------------------------------------------------|---------------------------------------------------|-----------------------------|
| All                                            | 5                                                 | All environments            |
|                                                | Others                                            | Others                      |
| Notes: The gray rows were the selected object. |                                                   |                             |

## 14.2 Block diagram of test setup



## 14.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-11 clause 7.

The test method and equipment is specified by IEC61000-4-11 with additions and modifications by IEC60601-1-2 clause 36.202.7(b).

#### 14.4 Test Protocol

Temperature: 26°C  
Relative Humidity: 40%

##### For Voltage Dips

| Test no. | Voltage dip<br>% UT    | Test level<br>% UT | Duration in periods of<br>rated frequency | Pass/<br>Fail |
|----------|------------------------|--------------------|-------------------------------------------|---------------|
| 1        | 30%                    | 70%                | 25                                        | Pass          |
| 2        | 60%                    | 40%                | 5                                         | Pass          |
| 3        | 100% pos half<br>cycle | 0                  | 0,5                                       | Pass          |
| 4        | 100% neg half<br>cycle | 0                  | 0,5                                       | Pass          |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe

##### For Voltage Interruption

| Test no. | Voltage dip<br>% UT | Test level<br>% UT | Duration<br>( Seconds ) | Pass/<br>Fail |
|----------|---------------------|--------------------|-------------------------|---------------|
| 1        | 100%                | 0                  | 5                       | Pass          |

**Observation:** All the functions were operated as normal during and after test.

**Conclusion:** providing the essential performance and remaining safe

#### 14.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of voltage dips and interruption test is:  $\pm 10.8\%$

The measurement uncertainty is given with a confidence of 95%,  $k=2$ .

The measurement uncertainty is traceable to internal procedure TI-036.

#### 14.6 Additions, deviations and exclusions from standards

None

## 15. Magnetic Fields Immunity Test

**Test result**                      **NA**

This test is applicable only to apparatus containing devices susceptible to magnetic fields.

### 15.1 Severity Level

#### 15.1.1 Test level

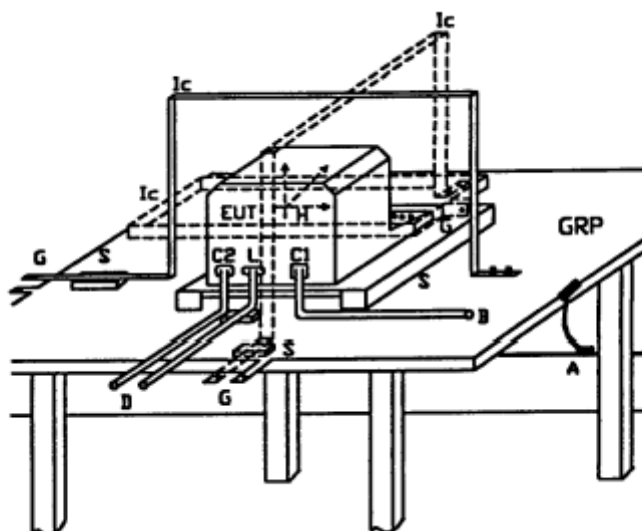
| Level                                          | Magnetic field strength A/m |
|------------------------------------------------|-----------------------------|
| 1                                              | 3                           |
| Note: The gray row is the selected test level. |                             |

#### 15.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

| Highest Compliance Level<br>A/m                | Electromagnetic Environment |
|------------------------------------------------|-----------------------------|
| 3                                              | All environments            |
| Others                                         | Others                      |
| Notes: The gray rows were the selected object. |                             |

## 15.2 Diagram of Test Setup



## 15.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-8 clause 7.

The test method and equipment is specified by IEC61000-4-3 with modifications by IEC60601-1-2 clause 36.202.8(b).

## 15.4 Test Protocol

Temperature : °C

Relative Humidity: %

| Test No. | Level<br>A/m | Axis | Result | Comment |
|----------|--------------|------|--------|---------|
| 1        | 3            | X    |        | -       |
| 2        | 3            | Y    |        | -       |
| 3        | 3            | Z    |        | -       |

**Observation:**

**Conclusion:**

## 15.5 Measurement Uncertainty

The measurement uncertainty for magnetic fields test is under consideration.

## 15.6 Additions, deviations and exclusions from standards

None



# **Annex:**

## **Models and rating list:**

| Model         | Rated output voltage range | Max. rated output current | Max. rated output power |
|---------------|----------------------------|---------------------------|-------------------------|
| GTM43033-*03  | 3Vdc                       | 2A                        | 6W                      |
| GTM43033-*04* | 3.1-4V                     | 1.94A                     | 6W                      |
| GTM43033-*06* | 4.1-6V                     | 1.46A                     | 6W                      |
| GTM43033-*12* | 6.1-12V                    | 0.98A                     | 6W                      |
| GTM43033-*15* | 12.1-15V                   | 0.50A                     | 6W                      |
| GTM43033-*18* | 15.1-18V                   | 0.40A                     | 6W                      |
| GTM43033-*24* | 18.1-24V                   | 0.33A                     | 6W                      |
| GTM43033-*36* | 24.1-36V                   | 0.25A                     | 6W                      |
| GTM43033-*48* | 36.1-48V                   | 0.16A                     | 6W                      |

**Appendix I: Photograph of equipment under test**



