

EMC

Measurement and Test Report

For

GlobTek, Inc.

186 Veterans Dr. Northvale, NJ 07647 USA

Test Standards:	<u>EN 60601-1-2:2015</u>
Product Description:	<u>Power Supply for Medical Use</u>
Tested Model:	<u>GT-500160-30</u>
Report No.:	<u>WTX19X09063416E</u>
Tested Date:	<u>2019-09-12 to 2019-09-17</u>
Issued Date:	<u>2019-09-17</u>
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TABLE OF CONTENTS

1. GENERAL INFORMATION	4
1.1 PRODUCT DESCRIPTION FOR EQUIPMENT UNDER TEST (EUT).....	4
1.2 TEST STANDARDS.....	5
1.3 TEST METHODOLOGY	5
1.4 EUT SETUP AND OPERATION MODE	6
1.5 PERFORMANCE CRITERIA FOR EMS	6
1.6 TEST EQUIPMENT LIST AND DETAILS	7
2. SUMMARY OF TEST RESULTS	8
3. CONDUCTED DISTURBANCE.....	9
3.1 MEASUREMENT UNCERTAINTY	9
3.2 TEST PROCEDURE.....	9
3.3 BASIC TEST SETUP BLOCK DIAGRAM.....	9
3.4 ENVIRONMENTAL CONDITIONS	10
3.5 SUMMARY OF TEST RESULTS/PLOTS	10
3.6 CONDUCTED EMISSIONS TEST DATA.....	10
4. RADIATED DISTURBANCE	13
4.1 MEASUREMENT UNCERTAINTY	13
4.2 TEST PROCEDURE.....	13
4.3 CORRECTED AMPLITUDE & MARGIN CALCULATION.....	14
4.4 ENVIRONMENTAL CONDITIONS	14
4.5 SUMMARY OF TEST RESULTS/PLOTS	14
5. HARMONIC CURRENT EMISSIONS	17
5.1 TEST PROCEDURE.....	17
5.2 TEST STANDARDS	17
5.3 HARMONIC CURRENT EMISSIONS TEST DATA.....	17
6. VOLTAGE FLUCTUATION AND FLICKER	18
6.1 TEST PROCEDURE.....	18
6.2 TEST STANDARDS	18
6.3 VOLTAGE FLUCTUATION AND FLICKER TEST DATA.....	18
7. ELECTROSTATIC DISCHARGES (ESD)	20
7.1 TEST PROCEDURE.....	20
7.2 ELECTROSTATIC DISCHARGE IMMUNITY TEST DATA	20
8. CONTINUOUS RADIATED DISTURBANCES (R/S)	21
8.1 TEST PROCEDURE.....	21
8.2 CONTINUOUS RADIATED DISTURBANCES TEST DATA.....	21
9. ELECTRICAL FAST TRANSIENTS (EFT)	22
9.1 TEST PROCEDURE.....	22
9.2 ELECTRICAL FAST TRANSIENTS TEST DATA	22
10. SURGES	23
10.1 TEST PROCEDURE.....	23
10.2 SURGE TEST DATA.....	23
11. CONTINUOUS CONDUCTED DISTURBANCES (C/S).....	24
11.1 TEST PROCEDURE	24
11.2 CONTINUOUS CONDUCTED DISTURBANCES TEST DATA	24
12. POWER-FREQUENCY MAGNETIC FIELDS (PFMF)	25
12.1 TEST PROCEDURE	25
12.2 POWER-FREQUENCY MAGNETIC FIELD TEST DATA	25
13. VOLTAGE DIPS AND INTERRUPTIONS.....	26
13.1 TEST PROCEDURE	26
13.2 VOLTAGE DIPS AND INTERRUPTIONS TEST DATA	26
EXHIBIT 1 - PRODUCT LABELING	27

PROPOSED CE LABEL FORMAT	27
PROPOSED LABEL LOCATION ON EUT	27
EXHIBIT 2 - EUT PHOTOGRAPHS.....	28
EXHIBIT 3 - TEST SETUP PHOTOGRAPHS	31

1.GENERAL INFORMATION

1.1 Product Description for Equipment Under Test (EUT)

Client Information

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

Manufacturer 1 : GlobTek, Inc.
Address of manufacturer 1 : 186 Veterans Dr. Northvale, NJ 07647 USA

Manufacturer 2 : GlobTek (Suzhou) Co., Ltd
Address of manufacturer 2 : Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215021, China

General Description of EUT	
Product Name:	Power Supply for Medical Use
Trade Name:	 GlobTek, Inc.
Model No.:	GT-500160-30
Adding Model(s):	/
<i>Note: The test data is gathered from a production sample, provided by the manufacturer.</i>	

Technical Characteristics of EUT	
Rated Voltage:	AC 100-240V, 50-60Hz
Rated Current:	/
Rated Power:	60W
Power Adaptor Model:	GT-500160-30 Input: AC 100-240V, 50-60Hz, 1.6-0.7A Output: DC 30V, 2.0A, 60W
Class of Equipment:	/
Highest Internal Frequency:	/

1.2 Test Standards

The tests were performed according to following standards:

EN 60601-1-2:2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Maintenance of compliance is the responsibility of the manufacturer. Any modification of the product maybe which result in lowering the emission/immunity should be checked to ensure compliance has been maintained.

1.3 Test Methodology

All measurements contained in this report were conducted with the standards EN 60601-1-2 for Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

1.4 EUT Setup and Operation Mode

The equipment under test (EUT) was configured to measure its highest possible emission/immunity level. The test modes were adapted according to the operation manual for use, more detailed description as follows:

Test Mode List:

Test Mode	Description	Remark	Power Supply Mode
TM1	Full load	/	AC 230V/50Hz

EUT Cable List and Details

Cable Description	Length (M)	Shielded/Unshielded	With Core/Without Core
/	/	/	/

Auxiliary Equipment List and Details

Description	Manufacturer	Model	Serial Number
/	/	/	/

Special Cable List and Details

Cable Description	Length (M)	Shielded/Unshielded	With Core/Without Core
/	/	/	/

1.5 Performance Criteria for EMS

All the test data has been collected, reduced, and analyzed within this report in accordance with Immunity requires the following as specific performance criteria:

- A. The apparatus shall continue to operate as intended during and after the test. The manufacturer specifies some minimum performance level. The performance level may be specified by the manufacturer as a permissible loss of performance.
- B. The apparatus shall continue to operate as intended after the test. This indicates that the EUT does not need to function at normal performance levels during the test, but must recover. Again some minimal performance is defined by the manufacturer. No change in operating state or loss or data is permitted.
- C. Temporary loss of function is allowed. Operation of the EUT may stop as long as it is either automatically reset or can be manually restored by operation of the controls.

1.6 Test Equipment List and Details

Description	Manufacturer	Model	Serial No.	Cal. Date	Due. Date
Spectrum Analyzer	Rohde & Schwarz	FSP	836079/035	2019-04-30	2020-04-29
EMI Test Receiver	Rohde & Schwarz	ESVB	825471/005	2019-04-30	2020-04-29
Amplifier	Agilent	8447F	3113A06717	2019-04-30	2020-04-29
Amplifier	C&D	PAP-1G18	2002	2019-04-30	2020-04-29
Trilog Broadband Antenna	Schwarz beck	VULB9163	9163-333	2019-05-05	2021-05-04
Trilog Broadband Antenna	Schwarz beck	VULB9163(B)	9163-333	2019-05-05	2021-05-04
Horn Antenna	ETS	3117	00086197	2019-05-05	2021-05-04
Loop Antenna	Schwarz beck	FMZB 1516	9773	2019-05-05	2021-05-04
EMI Test Receiver	Rohde & Schwarz	ESPI	101611	2019-04-30	2020-04-29
EMI Test Receiver	Rohde & Schwarz	ESPI	101391	2019-04-30	2020-04-29
Pulse Limiter	Rohde & Schwarz	ESH3-Z2	100911	2019-04-30	2020-04-29
AC LISN	Schwarz beck	NSLK8126	8126-224	2019-04-30	2020-04-29
8-WIRE LISN	Schwarz beck	8158	CAT3-8158-0059	2019-04-30	2020-04-29
8-WIRE LISN	Schwarz beck	8158	CAT5-8158-0117	2019-04-30	2020-04-29
PMF Generator	LIONCEL	PMF-801C-C	0171101	2019-04-30	2020-04-29
PMF Antenna	LIONCEL	PMF-801C-A	0180302	2019-04-30	2020-04-29
Instantaneous PMF Generator Module	LIONCEL	PMF-801C-T	0171001	2019-04-30	2020-04-29
Digital Power Analyzer	California Instrument	CTS	72831	2019-04-30	2020-04-29
Power Source	California Instrument	5001IX-CTS-400	25965	2019-04-30	2020-04-29
ESD Generator	LIONCEL	ESD-203B	0170901	2019-05-05	2020-05-04
Amplifier	Agilent	8447D	2944A10179	2019-04-30	2020-04-29
Transient 2000	EMC PARTNER	TRA2000	863	2019-05-21	2020-05-20
Couple Clamp	EMC PARTNER	CN-EFT1000	513	2019-05-21	2020-05-20
CS Immunity Tester	SCHAFFNER	NSG2070	1123	2019-04-30	2020-04-29
Attenuator	EMTEST	MA-5100/6BF2	1009	2019-04-30	2020-04-29
CDN	Luthi	L-801M2/M3	2665	2019-04-30	2020-04-29
Signal Generator	R&S	SMB100A	105942	2019-09-09	2020-09-08
Power Meter	R&S	NRP2	102031	2019-09-09	2020-09-08
RF Power Amplifier	BONN Elektronik	BLWA0830-160/100/40D	128740	2019-09-09	2020-09-08
RF Power Amplifier	NJNT	NTWPAS-2560025	2560025	2019-09-09	2020-09-08
Antenna	SCHWARZBECK	STLP9128D	043	2017-09-11	2020-09-10
Antenna	SCHWARZBECK	BBHA 9120 D	667	2017-09-11	2020-09-10
CS Generator	MARCONI	2024	112260/042	2019-05-31	2020-05-30
Attenuator	FRANKONIA	75-A-FFN-06	1001698	2019-05-31	2020-05-30
CDN	FRANKONIA	CDN M2+M3	A3027019	2019-05-31	2020-05-30
EM Injection	FCC	F-203I-23mm	91536	2019-05-31	2020-05-30

Clamp					
RF POWER AMPLIFIER	FRANKONIA	FLL-75	102A1109	2019-05-31	2020-05-30

2. SUMMARY OF TEST RESULTS

Standards	Description of Test Item	Result
EN 60601-1-2	Conducted Disturbance	Compliant
	Radiated Disturbance	Compliant
	Harmonic Current Emission EN 61000-3-2	Compliant
	Voltage Fluctuation and Flicker EN 61000-3-3	Compliant
	Electrostatic Discharge Immunity in accordance with EN 61000-4-2	Compliant
	Continuous Radiated Disturbances Immunity in accordance with EN 61000-4-3	Compliant
	Electrical Fast Transient/Burst Immunity in accordance with EN 61000-4-4	Compliant
	Surges Immunity in accordance with EN 61000-4-5	Compliant
	Continuous Conducted Disturbances Immunity in accordance with EN 61000-4-6	Compliant
	Power-frequency Magnetic Fields Immunity in accordance with EN 61000-4-8	Compliant
	Voltage Dips/Interruptions Immunity in accordance with EN 61000-4-11	Compliant

3. Conducted Disturbance

3.1 Measurement Uncertainty

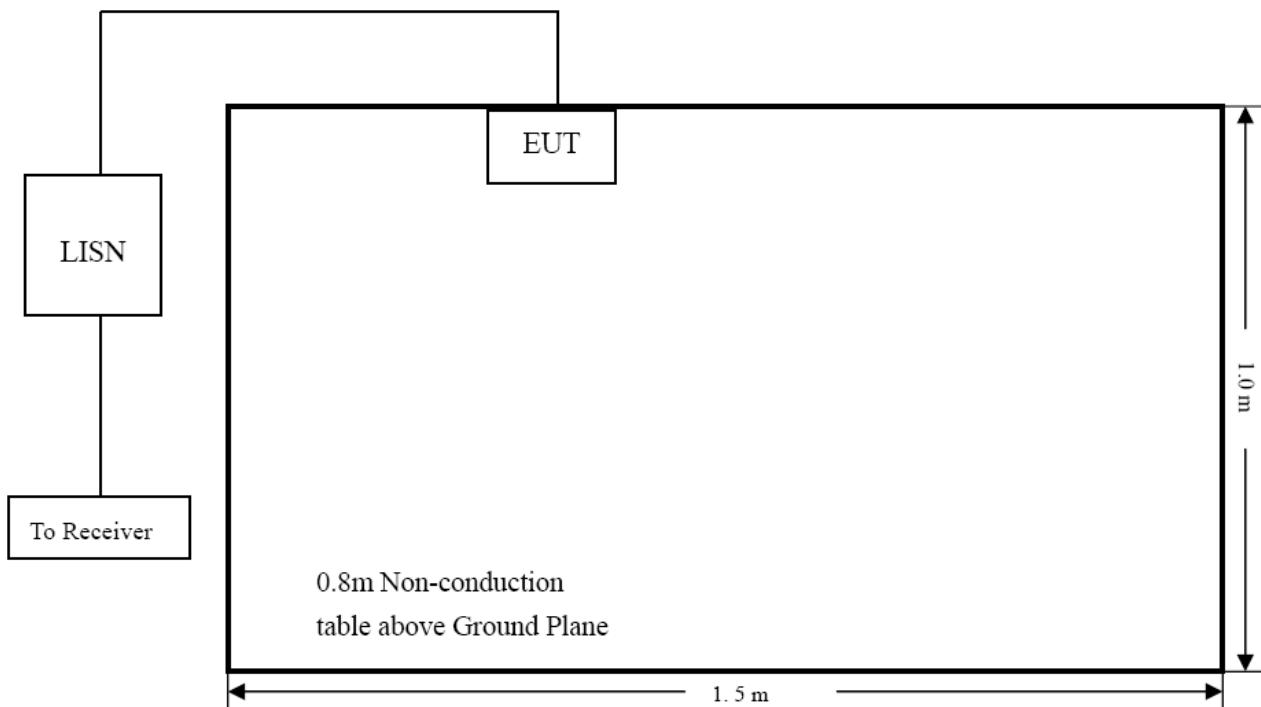
Base on NIS 81, The Treatment of Uncertainty in EMC Measurements, the best estimate of the uncertainty of any conducted emissions measurement

Measurement uncertainty		
Parameter	Conditions	Uncertainty
Conducted Emissions	Conducted	9-150kHz $\pm 3.74\text{dB}$
		0.15-30MHz $\pm 3.34\text{dB}$

3.2 Test Procedure

Test is conducting under the description of EN55022 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement.

3.3 Basic Test Setup Block Diagram



3.4 Environmental Conditions

Temperature:	22 °C
Relative Humidity:	55 %
ATM Pressure:	1015 mbar

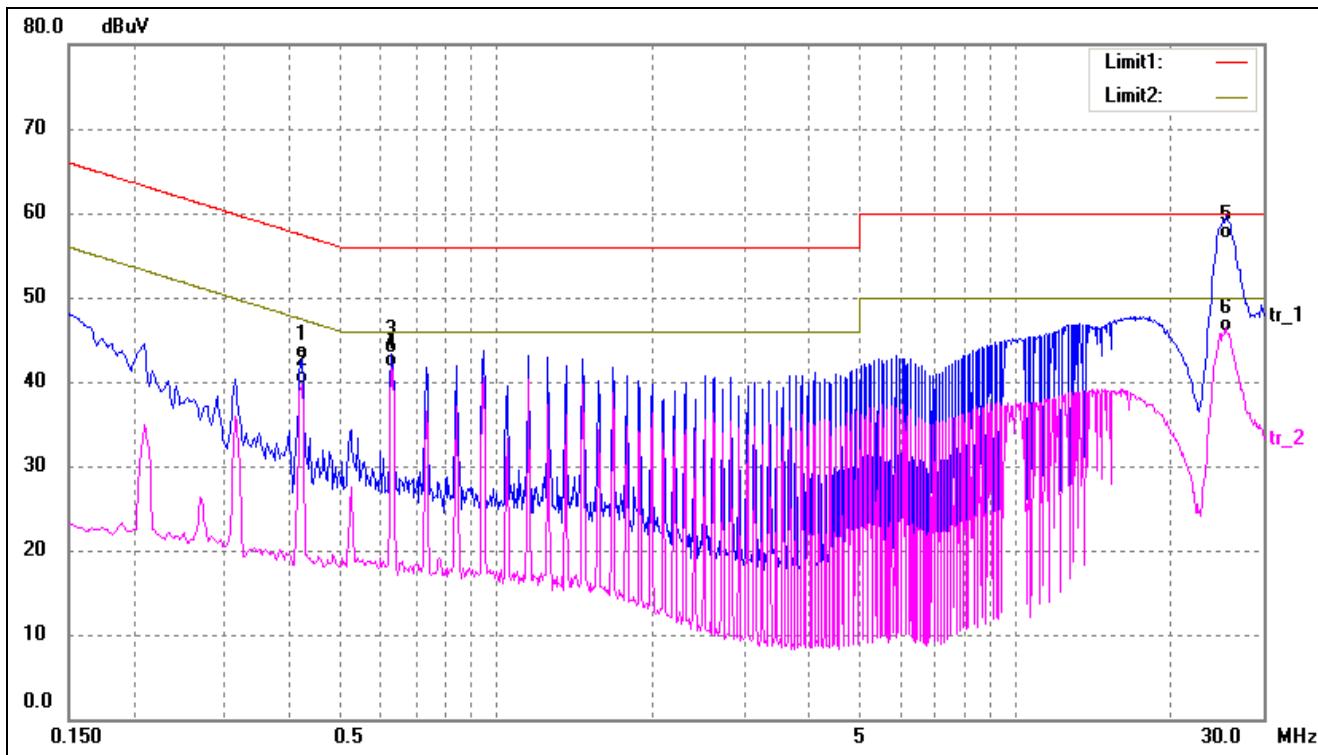
3.5 Summary of Test Results/Plots

According to the data in section 3.6, the EUT complied with the EN 60601-1-2 conducted margin for a Class B device, with the *worst* margin reading of:

-3.04 dB at 25.4020 MHz in the **Line** mode, **QP** detector, **0.15-30 MHz**

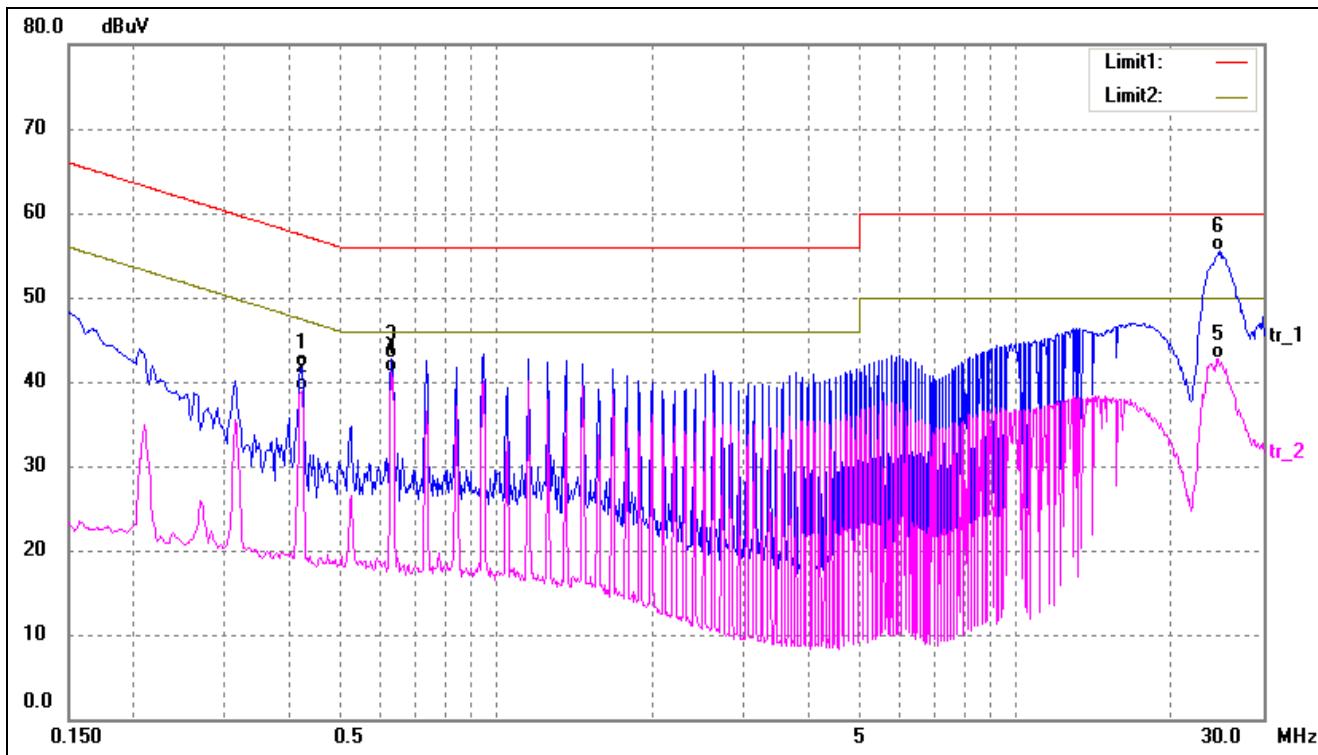
3.6 Conducted Emissions Test Data

Test mode:	TM1	Polarity:	Line
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No.	Frequency (MHz)	Reading (dBuV)	Correct (dB/m)	Result (dBuV)	Limit (dBuV)	Margin (dB)	Detector
1	0.4220	32.72	10.01	42.73	57.41	-14.68	QP
2	0.4220	29.78	10.01	39.79	47.41	-7.62	AVG
3	0.6300	33.31	10.05	43.36	56.00	-12.64	QP
4	0.6300	31.63	10.05	41.68	46.00	-4.32	AVG
5*	25.4020	46.04	10.92	56.96	60.00	-3.04	QP
6	25.4020	34.89	10.92	45.81	50.00	-4.19	AVG

Test mode:	TM1	Polarity:	Neutral
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No.	Frequency (MHz)	Reading (dBuV)	Correct (dB/m)	Result (dBuV)	Limit (dBuV)	Margin (dB)	Detector
1	0.4220	31.63	10.01	41.64	57.41	-15.77	QP
2	0.4220	28.96	10.01	38.97	47.41	-8.44	AVG
3	0.6300	32.59	10.05	42.64	56.00	-13.36	QP
4	0.6300	30.99	10.05	41.04	46.00	-4.96	AVG
5	24.6500	31.80	10.90	42.70	50.00	-7.30	AVG
6*	24.7540	44.54	10.90	55.44	60.00	-4.56	QP

4. Radiated Disturbance

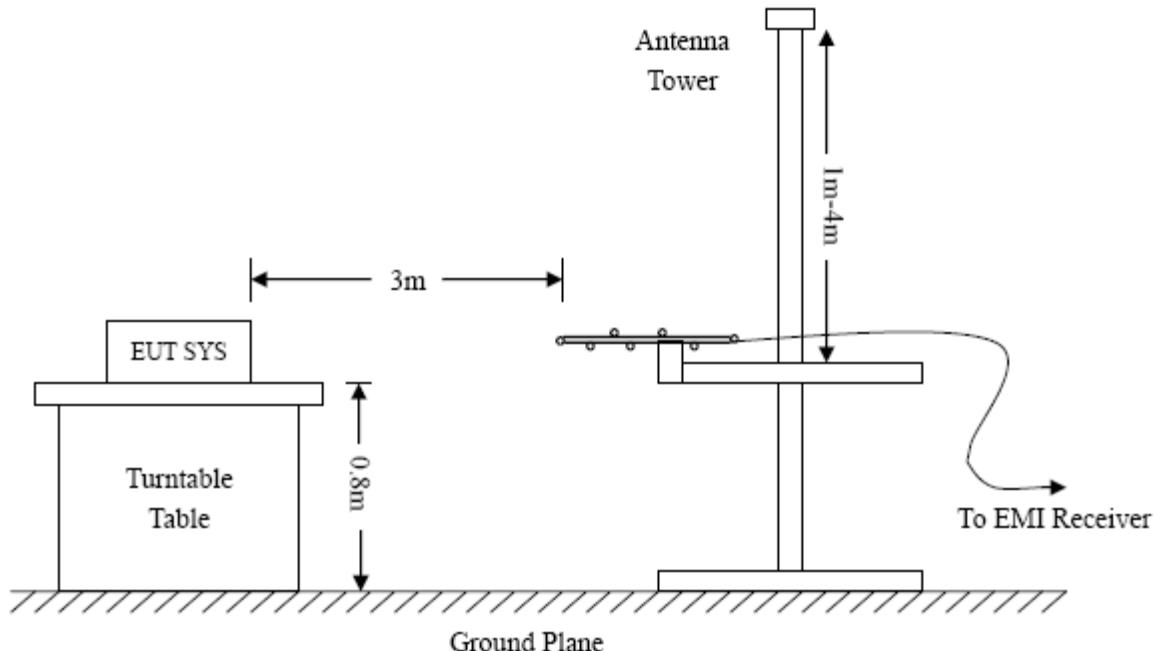
4.1 Measurement Uncertainty

Base on NIS 81, The Treatment of Uncertainty in EMC Measurements, the best estimate of the uncertainty of any radiation emissions measurement

Measurement uncertainty		
Parameter	Conditions	Uncertainty
Radiated Emissions	Radiated	30-200MHz $\pm 4.52\text{dB}$
		0.2-1GHz $\pm 5.56\text{dB}$
		1-6GHz $\pm 3.84\text{dB}$
		6-18GHz $\pm 3.92\text{dB}$

4.2 Test Procedure

Test is conducting under the description of EN55022 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement.



4.3 Corrected Amplitude & Margin Calculation

The Corrected Amplitude is calculated by adding the Antenna Factor and the Cable Factor, and subtracting the Amplifier Gain from the Amplitude reading. The basic equation is as follows:

$$\begin{aligned}\text{Corr. Ampl.} &= \text{Indicated Reading} + \text{Correct} \\ \text{Correct} &= \text{Ant.Factor} + \text{Cable Loss} - \text{Ampl.Gain}\end{aligned}$$

The “Margin” column of the following data tables indicates the degree of compliance with the applicable limit. For example, a margin of -6dB μ V means the emission is 6dB μ V below the maximum limit for Class B device. The equation for margin calculation is as follows:

$$\text{Margin} = \text{Corr. Ampl.} - \text{EN 60601-1-2 Class B Limit}$$

4.4 Environmental Conditions

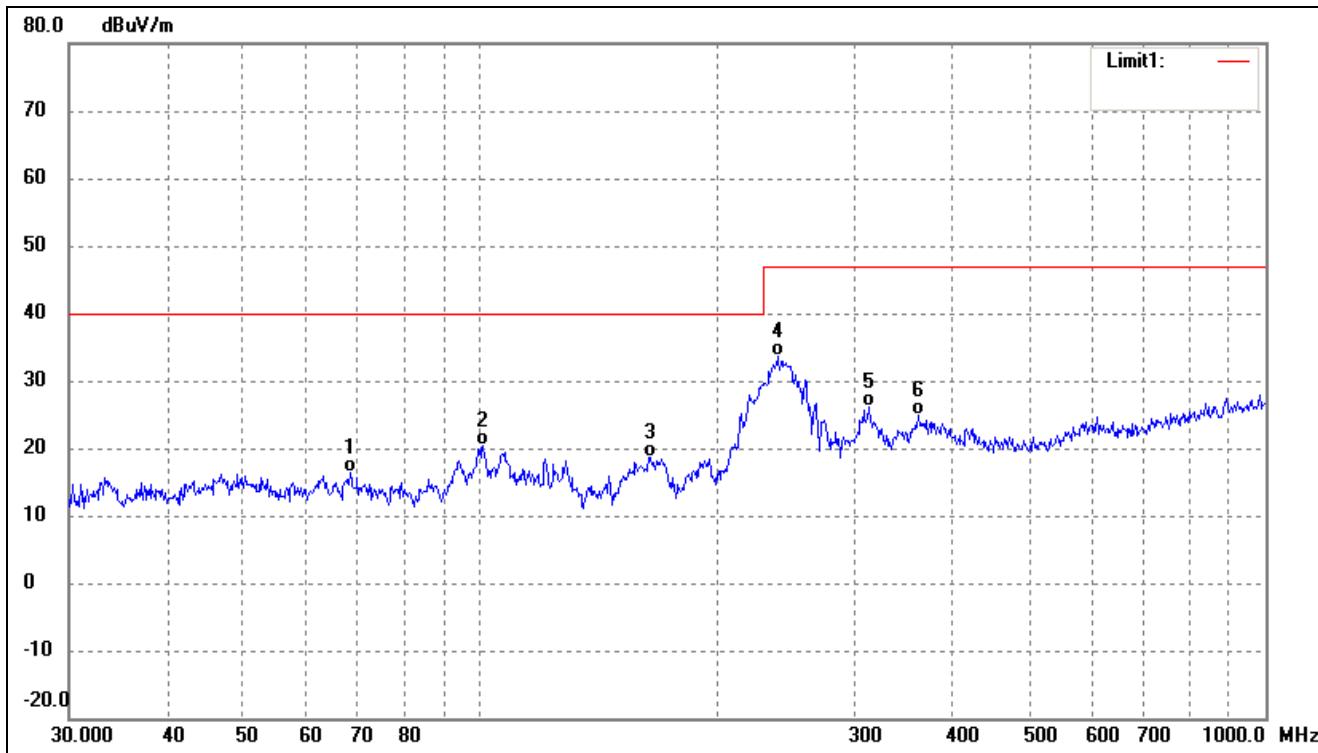
Temperature:	23° C
Relative Humidity:	53%
ATM Pressure:	1011 mbar

4.5 Summary of Test Results/Plots

According to the data in section 4.5, the EUT complied with the EN 60601-1-2 Class B standards, and had the worst margin is:

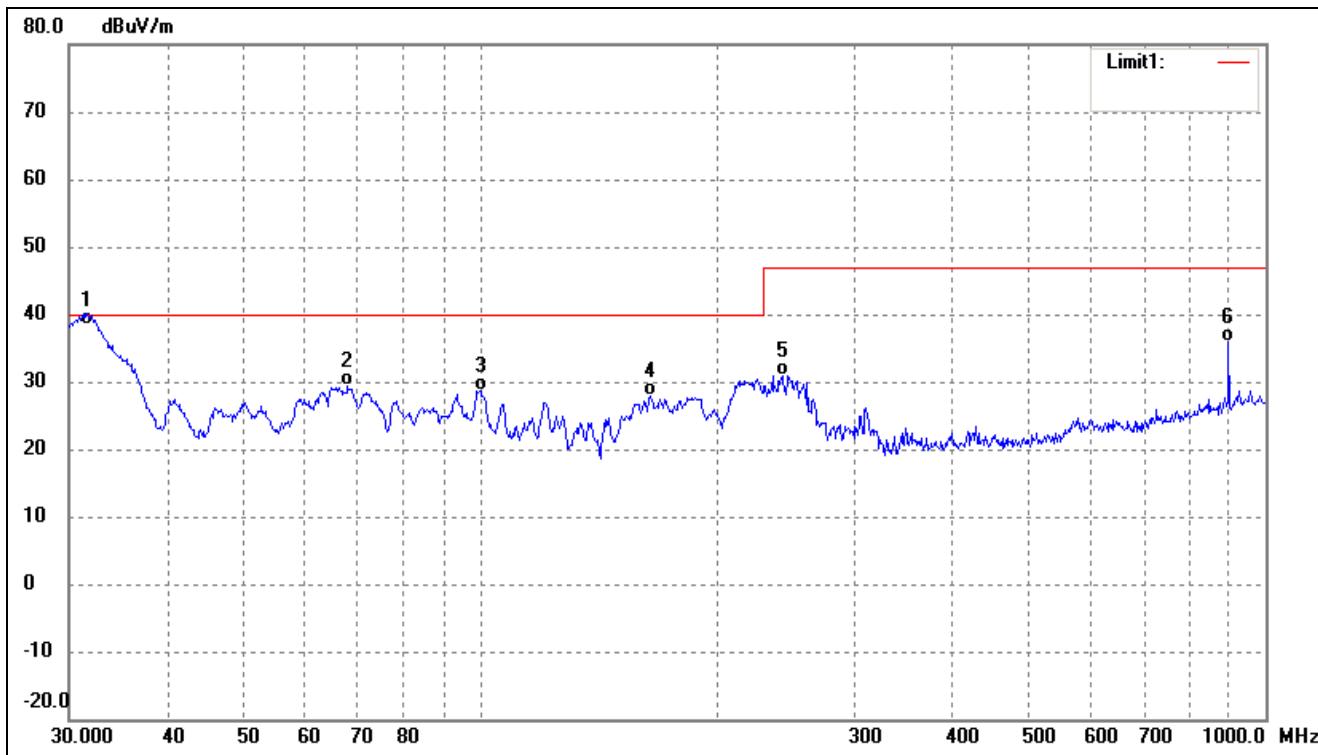
-1.50 dB at 31.6202 MHz in the Vertical polarization, 30 MHz to 1 GHz, 3 Meters

Test mode:	TM1	Polarity:	Horizontal
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No.	Frequency (MHz)	Reading (dBuV/m)	Correct dB/m	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Degree (°)	Height (cm)	Remark
1	68.3908	31.12	-14.83	16.29	40.00	-23.71	357	100	QP
2	100.9339	33.43	-13.17	20.26	40.00	-19.74	97	100	QP
3	164.9075	33.80	-15.18	18.62	40.00	-21.38	214	100	QP
4	239.1473	45.15	-11.57	33.58	47.00	-13.42	101	100	QP
5	312.1794	35.54	-9.30	26.24	47.00	-20.76	184	100	QP
6	361.7139	32.76	-7.83	24.93	47.00	-22.07	235	100	QP

Test mode:	TM1	Polarity:	Vertical
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No.	Frequency (MHz)	Reading (dBuV/m)	Correct dB/m	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Degree (°)	Height (cm)	Remark
1	31.6202	52.67	-14.17	38.50	40.00	-1.50	231	100	QP
2	67.9129	44.08	-14.72	29.36	40.00	-10.64	90	100	QP
3	100.2286	41.93	-13.18	28.75	40.00	-11.25	85	100	QP
4	164.9075	43.05	-15.18	27.87	40.00	-12.13	97	100	QP
5	242.5253	42.26	-11.39	30.87	47.00	-16.13	203	100	QP
6	896.9965	36.61	-0.62	35.99	47.00	-11.01	313	100	QP

5. Harmonic Current Emissions

5.1 Test Procedure

Test is conducting under the description of EN 61000-3-2.

5.2 Test Standards

EN61000-3-2, Clause 7.1 Limits for Class A equipment.

Environmental Conditions

Temperature:	22 °C
Relative Humidity:	48%
ATM Pressure:	1022 mbar

5.3 Harmonic Current Emissions Test Data

According to Clause 7 of EN 61000-3-2, the rated power of the EUT is less than 75W, belong to 'equipment with a rated power of 75W or less', therefore 'limits are not specified in this edition of the standards'. It is deemed to fully fit the requirements of the standards.

Result: The EUT is compliant with the requirements of this section.

6. Voltage Fluctuation and Flicker

6.1 Test Procedure

Test is conducting under the description of EN 61000-3-3.

6.2 Test Standards

EN61000-3-3, Limit : Clause 5.

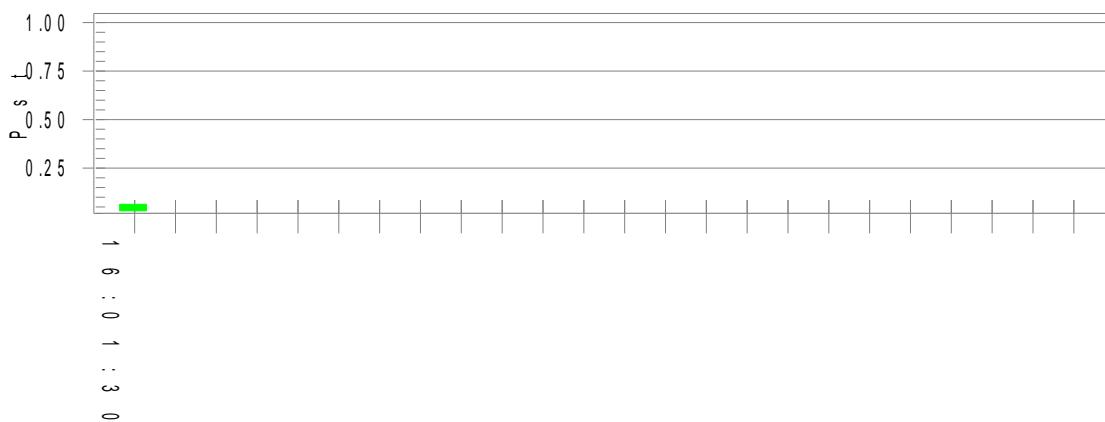
Environmental Conditions

Temperature:	22 °C
Relative Humidity:	48%
ATM Pressure:	1022 mbar

6.3 Voltage Fluctuation and Flicker Test Data

Test mode:

TM1

Flicker Test Summary per EN/IEC61000-3-3 Ed. 3.0 (2013) (Run time)**Test Result: Pass****Status: Test Completed****Pst_s and limit line****European Limits****Plt and limit line****Parameter values recorded during the test:**

Vrms at the end of test (Volt): 229.95

T-max (mS):	0	Test limit (mS):	500.0	Pass
Highest dc (%):	0.00	Test limit (%):	3.30	Pass
Highest dmax (%):	0.00	Test limit (%):	4.00	Pass
Highest Pst (10 min. period):	0.064	Test limit:	1.000	Pass
Highest Plt (2 hr. period):	0.028	Test limit:	0.650	Pass

7. Electrostatic Discharges (ESD)

7.1 Test Procedure

Test is conducting under the description of EN 61000-4-2.

Test Performance

Performance Criterion: B

Environmental Conditions

Temperature:	26 °C
Relative Humidity:	55%
ATM Pressure:	1011 mbar

7.2 Electrostatic Discharge Immunity Test Data

Table 1: Electrostatic Discharge Immunity (Air Discharge)

EN 61000-4-2 Test Points	Test Levels (Kv)									
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15
Shell crack	A	A	A	A	A	A	A	A	/	/
indicator light	A	A	A	A	A	A	A	A	/	/

Table 2: Electrostatic Discharge Immunity (Direct Contact)

EN 61000-4-2 Test Points	Test Levels (Kv)									
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15
/	/	/	/	/	/	/	/	/	/	/

Table 3: Electrostatic Discharge Immunity (Indirect Contact HCP & VCP)

EN 61000-4-2 Test Points	Test Levels (kV)									
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15
HCP (6 Sides)	A	A	A	A	/	/	/	/	/	/
VCP (4 Sides)	A	A	A	A	/	/	/	/	/	/

Test Result: Pass

8. Continuous Radiated Disturbances (R/S)

8.1 Test Procedure

Test is conducting under the description of EN 61000-4-3.

Test Performance

Performance Criterion: A

Environmental Conditions

Temperature:	25 °C
Relative Humidity:	52%
ATM Pressure:	1010 mbar

8.2 Continuous Radiated Disturbances Test Data

Frequency step: 1% of fundamental

Dwell time: 1 second

Modulation: AM by 1kHz sine wave with 80% modulation depth

Frequency Range(MHz)	Field (V/m)	Front		Rear		Left Side		Right Side	
		VERT	HORI	VERT	HORI	VERT	HORI	VERT	HORI
80-2700	3	A	A	A	A	A	A	A	A

Test Result: Pass

9. Electrical Fast Transients (EFT)

9.1 Test Procedure

Test is conducting under the description of EN 61000-4-4.

Test Performance

Performance Criterion: B

Environmental Conditions

Temperature:	22 °C
Relative Humidity:	53%
ATM Pressure:	1011 mbar

9.2 Electrical Fast Transients Test Data

EN 61000-4-4 Test Points		Test Levels (kV)							
		+0.5	-0.5	+1.0	-1.0	+2.0	-2.0	+4.0	-4.0
Power Supply	L1	/	/	/	/	A	A	/	/
	L2	/	/	/	/	A	A	/	/
	PE	/	/	/	/	A	A	/	/
	L1+L2	/	/	/	/	A	A	/	/
	L1 + PE	/	/	/	/	A	A	/	/
	L2 + PE	/	/	/	/	A	A	/	/
	L1+L2+PE	/	/	/	/	A	A	/	/
Signal ports	/	/	/	/	/	/	/	/	/

Test Result: Pass

10. Surges

10.1 Test Procedure

Test is conducting under the description of EN 61000-4-5.

Test Performance

Performance Criterion: B

Environmental Conditions

Temperature:	25 °C
Relative Humidity:	53%
ATM Pressure:	1011 mbar

10.2 Surge Test Data

Repetition frequency for 100 KHz

Level	Voltage	Poll	Path	Pass	Fail
1	0.5kV	±	L-N	/	/
2	1kV	±	L-N	A	/
3	2kV	±	L-PE, N-PE	A	/
4	4kV	±	L-N, L-PE, N-PE	/	/

Test Result: Pass

11. Continuous Conducted Disturbances (C/S)

11.1 Test Procedure

Test is conducting under the description of EN 61000-4-6.

Test Performance

Performance Criterion: A

Environmental Conditions

Temperature:	25 °C
Relative Humidity:	53%
ATM Pressure:	1011 mbar

11.2 Continuous Conducted Disturbances Test Data

Sweep frequency range: 150kHz~80MHz

Frequency step: 1% of fundamental

Dwell time: 1 second

Level	Voltage Level (e.m.f.) U_0	Modulation:	Pass	Fail
1	1	AM 80%, 1kHz sinewave	/	/
2	3	AM 80%, 1kHz sinewave	A	/
3	10	AM 80%, 1kHz sinewave	/	/
X	Special	/	/	/

Test Result: Pass

12. Power-Frequency Magnetic Fields (PFMF)

12.1 Test Procedure

Test is conducting under the description of EN 61000-4-8.

Test Performance

Performance Criterion: A

Environmental Conditions

Temperature:	25 °C
Relative Humidity:	50%
ATM Pressure:	1011 mbar

12.2 Power-Frequency Magnetic Field Test Data

Level	Magnetic Field Strength (r.m.s) A/m	Frequency Hz	Induction Coil Postion	Pass	Fail
1	3	50	X, Y, Z	/	/
2	10	50	X, Y, Z	/	/
3	30	50	X, Y, Z	A	/
X	Special	/		/	/

Test Result: Pass

13. Voltage Dips and Interruptions

13.1 Test Procedure

Test is conducting under the description of EN 61000-4-11.

Test Performance

Performance Criterion: B/C

Environmental Conditions

Temperature:	25 °C
Relative Humidity:	50%
ATM Pressure:	1011 mbar

13.2 Voltage Dips And Interruptions Test Data

U: Voltage dips in % U_T (U_T is rated voltage for the EUT)

T: Test duration

Level	U	T	Phase Angle	N	Pass	Fail
1	100%	10ms	0/90/180/270	3	B	/
2	60%	100ms	0/90/180/270	3	B	/
3	30%	500ms	0/90/180/270	3	B	/
4	100%	5000ms	0/90/180/270	3	B	/

Test Result: Pass

EXHIBIT 1 - PRODUCT LABELING

Proposed CE Label Format

Power Supply for Medical Use

Model: GT-500160-30

Brand: GlobTek

Importer Name: XXX

Importer Address: XXX

GlobTek, Inc.

186 Veterans Dr. Northvale, NJ 07647 USA

GlobTek (Suzhou) Co., Ltd

Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215021, China



Specifications: Text is Black in color and is justified. Labels are printed in indelible ink on permanent adhesive backing or silk-screened onto the EUT or shall be affixed at a conspicuous location on the EUT. The 'CE' marking must be affixed to the EUT or to its data plate. Where this is not possible or not warranted on account of the nature of the apparatus, it must be affixed to the packaging, if any, and to the accompanying documents. The 'CE' marking is allowed less than 5 mm but must clear. If the 'CE' marking is reduced or enlarged the proportions given in the above graduated drawing must be respected. The Importer name, address and Manufacturer name and address should indicate on marking label or packaging or in a document accompanying

Proposed Label Location on EUT

CE Label Location



EXHIBIT 2 - EUT PHOTOGRAPHS

EUT View 1



EUT View 2



EUT View 3**EUT View 4**

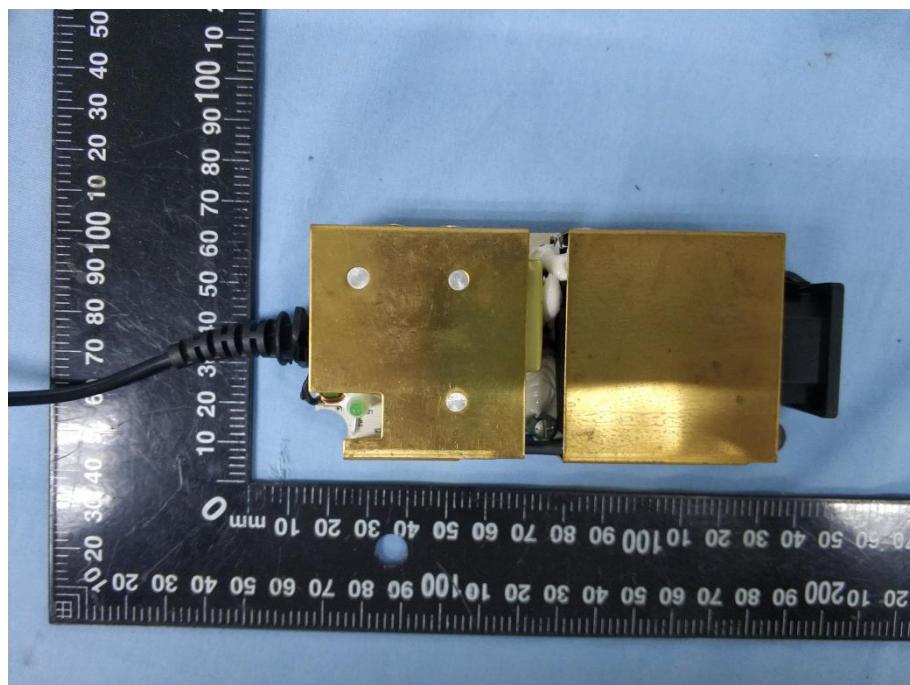
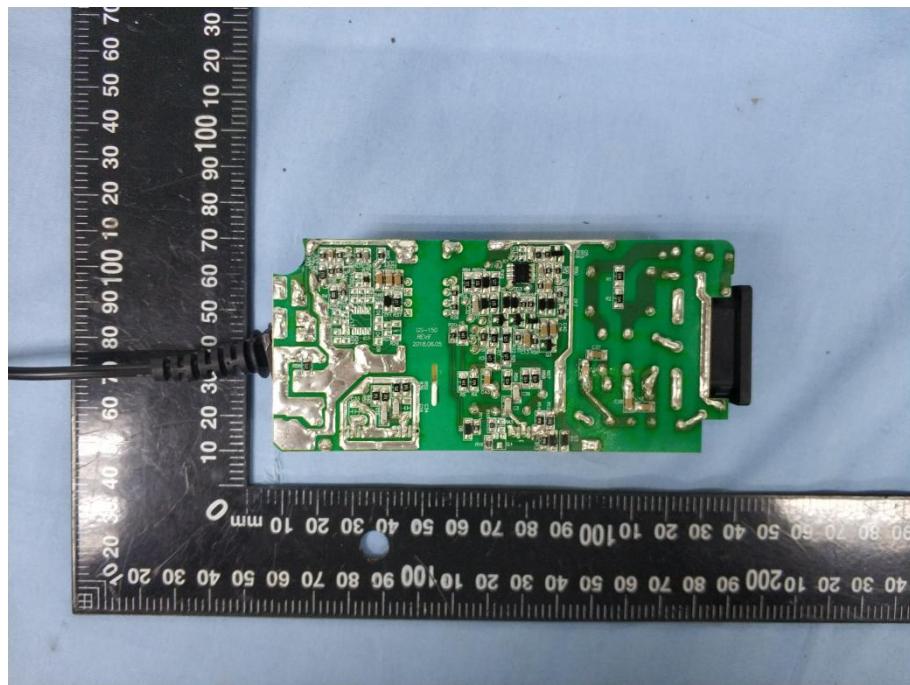
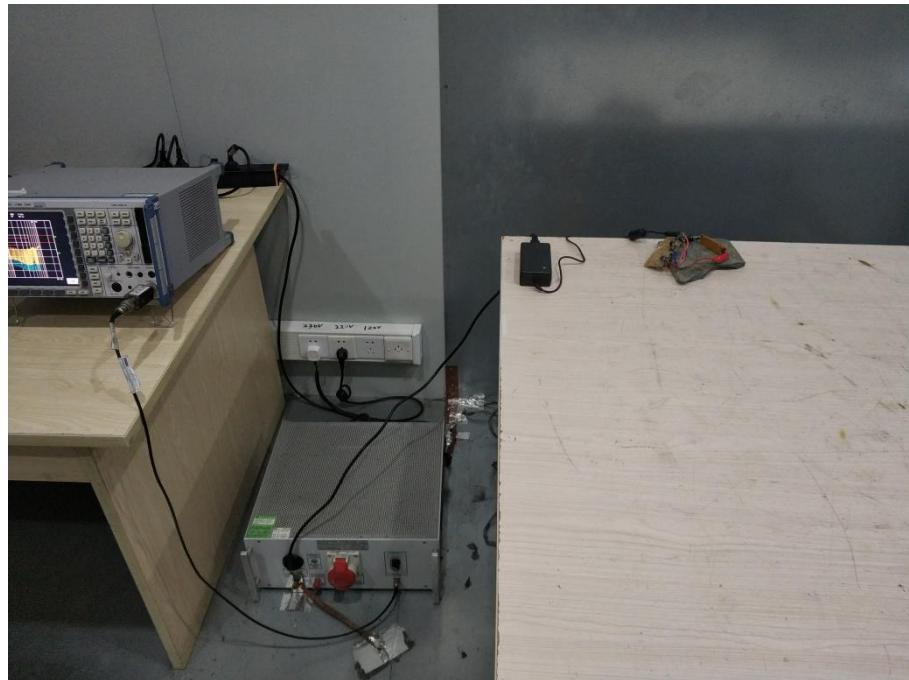
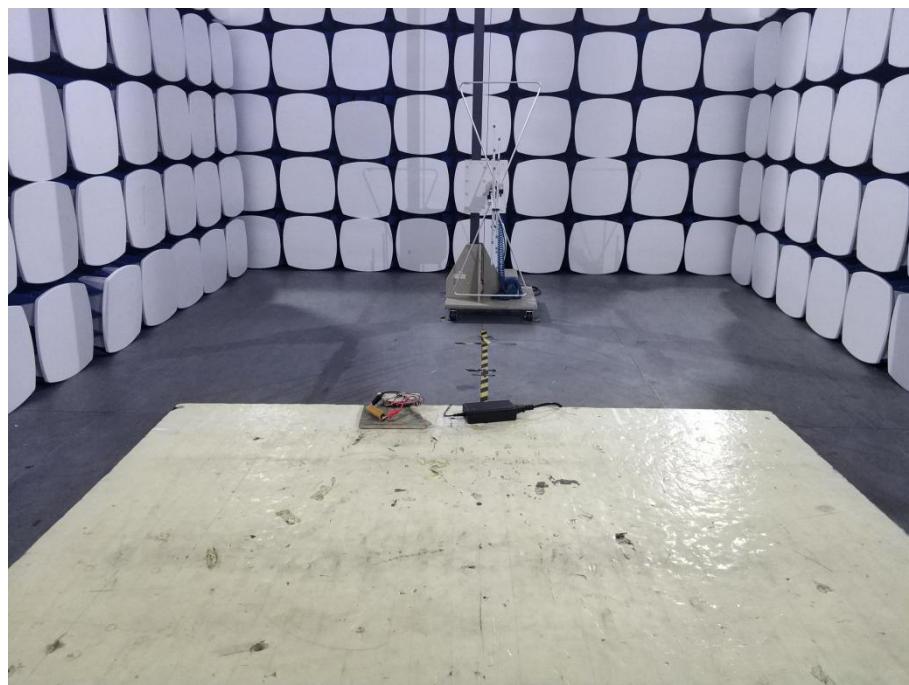
EUT Housing and Board View 1**EUT Housing and Board View 2**

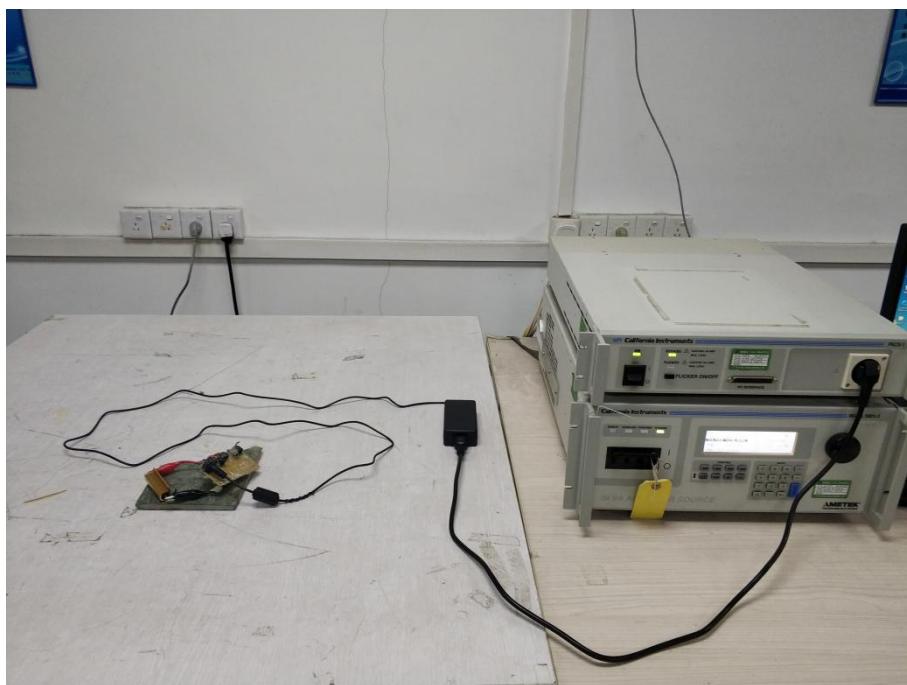
EXHIBIT 3 - TEST SETUP PHOTOGRAPHS

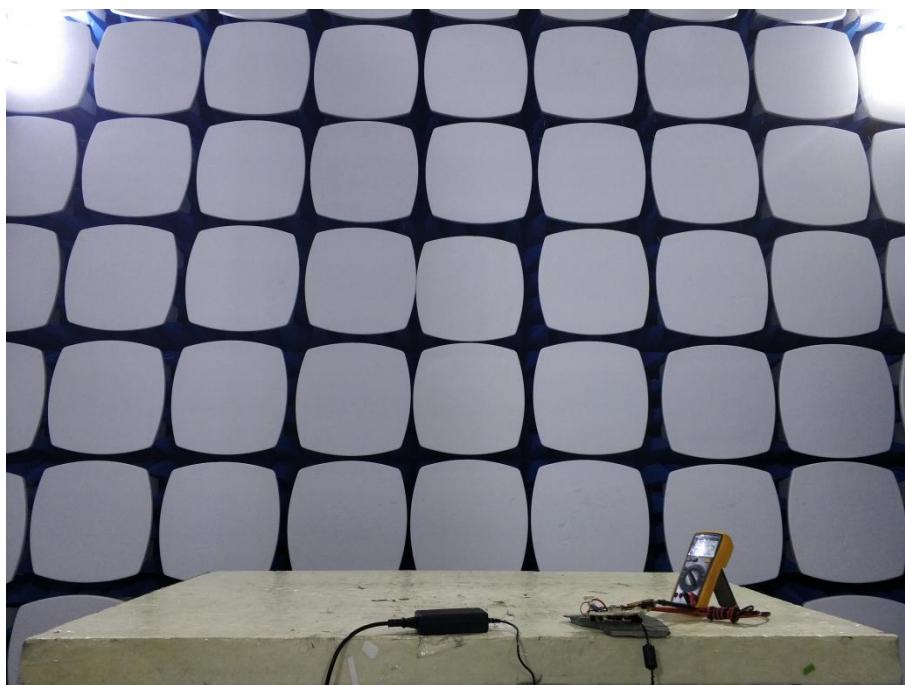
Conduction Emission Test View

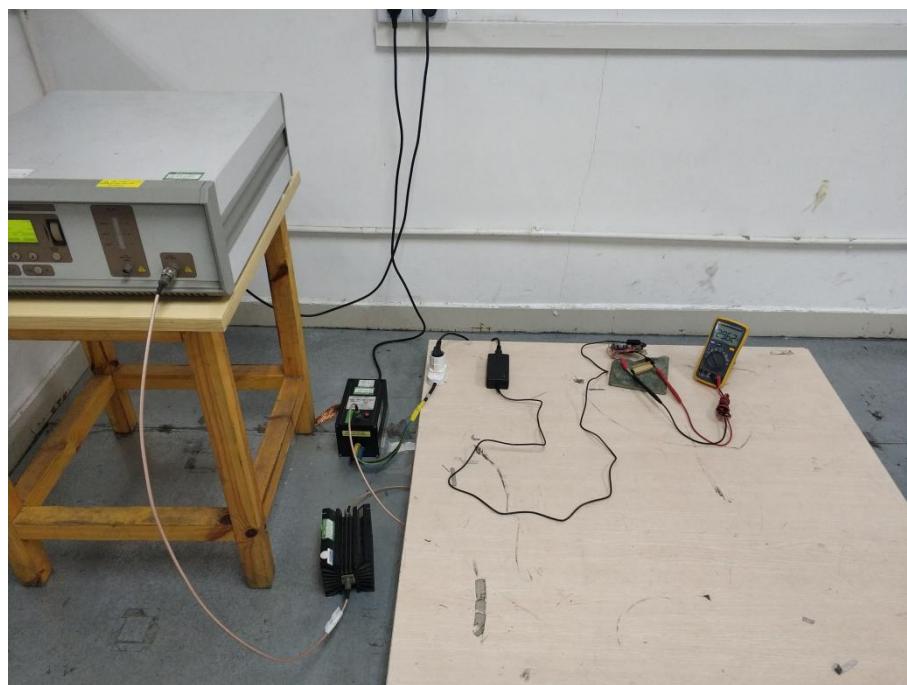
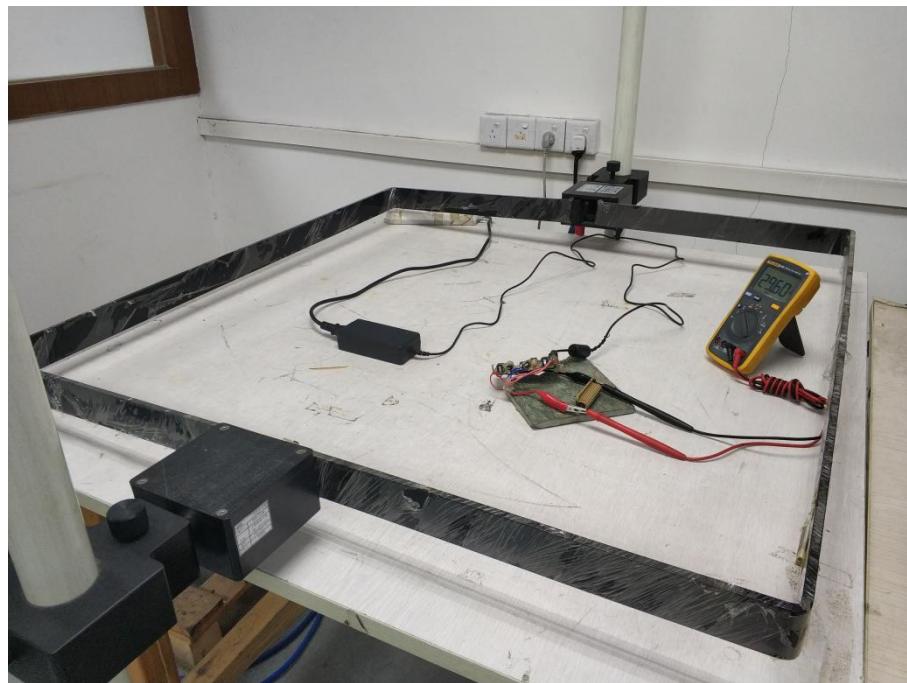


Radiation Emission Test View



Harmonic/Flicker Test View**EN 61000-4-2 Test View**

EN 61000-4-3 Test View**EN 61000-4-4/5/11 Test View**

EN 61000-4-6 Test View**EN 61000-4-8 Test View**

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