

Test Report

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

Product : Medical Power Supply

Brand Name/Trade Name : G GlobTek, Inc.

Model No. : GT*9X1001P-*****, 8016-000101
The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety;
The 2nd "*" can be "01" to "100", denotes the rated output wattage designation from 1W to 100W, which with interval of 1W;
The 3rd "*" can be "12" to "54" or "12.0" to "54.0", denote the standard rated output voltage designation from 12V to 54V, with interval of 0.1V;
The 4th "*" --T2 means desktop class II with C8 AC inlet
--T2A means desktop class II with C18 AC inlet
--T3 means desktop class I with C14 AC inlet
--T3A means desktop class I with C6 AC inlet
--TP means desktop class II with power supply cord
--TP3 means desktop class I with power supply cord
The 5th "*" is optional, when the 4th "*" is -TP or -TP3, it can be:
EU means power supply cord with EU plug,
NA means power supply cord with USA plug,
AU means power supply cord with Australian plug.
The 6th * denotes any six character = 0-9 or A-Z or ()[] or – or blank for marketing purposes.

Electrical Rating : For GT*9X1001P-*****.
Input: 100-240V~,50-60Hz or 50/60 Hz, 1.5A; 115Vac, 400Hz, 1.5A
Output: 12.0-54.0V===, Max.8.33A, Max. 100.0W

For 8016-000101:
Input: 100-240V~,50/60Hz, 1.5A; 115Vac, 400Hz, 1.5A
Output: 15.0V===, 4.0 A, 120W(peak)

Manufacturer : same as applicant

Model No. of Manufacturer : /

No. of Samples : 240809-22-001~002

Date of receipt of test item : 2024-08-09

Date (s) of performance of test : 2024-08-12 to 2024-08-21

Date of issue : 2024-10-08

Service Requested : IP54 test

Method : IEC 60529:1989+AMD1:1999+AMD2:2013

Conclusion : The testing of submitted sample comply with the above safety standard clause/requirement (refer to page 3-4).

Test Report

Prepared and checked by:
Eurofins Electrical Testing Service (Shanghai) Co.,
Ltd.

Reviewed by
Eurofins Electrical Testing Service (Shanghai) Co.,
Ltd.



Jack Gan
Project Manager



Jackie Zhao
Reviewer

- The results reported in this test report shall refer only to the sample actually checked and shall not refer or be deemed to refer to bulk from which such a sample may be said to have been obtained.
- This report shall not be reported except in full without prior authorization from Eurofins Electrical Testing Service (Shanghai) Co., Ltd.
- The services are provided subject to the terms and condition of the company, which can be furnished upon request.

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Test Method

Test means for the tests for protection against solid foreign objects

First characteristic numeral	Test means	Test force	Test conditions, see
0	No test required	--	--
1	Rigid sphere without handle or guard 50 ₀ ^{+0,2} mm diameter	50 N ± 10 %	13.2 of IEC 60529
2	Rigid sphere without handle or guard 12,5 ₀ ^{+0,2} mm diameter	30 N ± 10 %	13.2 of IEC 60529
3	Rigid steel rod 2,5 ₀ ^{+0,05} mm diameter with edges free from burrs	3 N ± 10 %	13.2 of IEC 60529
4	Rigid steel rod 1,0 ₀ ^{+0,05} mm diameter with edges free from burrs	1 N ± 10 %	13.2 of IEC 60529
5	Dust chamber figure 2, with or without underpressure	--	13.4 + 13.5 of IEC 60529
6	Dust chamber figure 2, with underpressure	--	13.4 + 13.5 of IEC 60529

Test means and main test conditions for the tests for protection against water

Second characteristic numeral	Test means	Water flow rate	Duration of test	Test conditions, see
0	No test required	--	--	--
1	Drip box Figure 3 Enclosure on turntable	0,51+ 0 mm/min	10 min	14.2.1 of IEC 60529
2	Drip box Figure 3 Enclosure in 4 fixed positions of 15° tilt	0,53+ 0 mm/min	2,5 min for each position of tilt	14.2.2 of IEC 60529
3	Oscillating tube Figure 4 Spray ± 60° from vertical, distance max. 200 mm or Spray nozzle Figure 5 Spray ± 60° from vertical	0,07 l/min ± 5 % per hole, multiplied by number of holes 10 l/min ± 5 %	10 min 1 min/mx at least 5 min	14.2.3 a) 14.2.3 b) of IEC 60529
4	As for numeral 3 Spray ± 180° from vertical	As for numeral 3		14.2.4 of IEC 60529
5	Water jet hose nozzle Figure 6 Nozzle 6,3 mm diameter, distance 2,5 m to 3 m	12,5 l/min ± 5 %	1 min/mx at least 3 min	14.2.5 of IEC 60529
6	Water jet hose nozzle Figure 6 Nozzle 12,5 mm diameter, distance 2,5 m to 3 m	100 l/min ± 5 %	1 min/mx at least 3 min	14.2.6 of IEC 60529
7	Immersion tank Water-level on enclosure: 0,15 m above top 1 m above bottom	--	30 min	14.2.7 of IEC 60529
8	Immersion tank Water-level: by agreement	--	by agreement	14.2.8 of IEC 60529

Remark:

Enclosure of all models are identical, and model 8016-000101 was subject to the tests.

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Acceptance conditions

For protection against water: see clause 14.3 of IEC 60529:1989+AMD1:1999+AMD2:2013 and
Clause 11.6.5 of IEC 60601-1:2005+AMD1:2012+AMD2:2020.

For protection against solid foreign objects: Clause 13.5.2 of IEC 60529:1989+AMD1:1999+AMD2:2013

Requirements from product standard:

Test results

The sample comply with the requirements of IP54 of IEC 60529:1989+AMD1:1999+AMD2:2013

Remark:

Clause 8.7.4, 8.8.3 of IEC 60601-1:2005+AMD1:2012+AMD2:2021 were checked after IP54 test.

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8.7	TABLE: leakage current			P
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
To be evaluated in end-product				
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
For 8016-000101, Enclosure to enclosure:				
NC, S1=1, S5=1	264	60	3.43	A, frequency-weighted
NC, S1=1, S5=0	264	60	3.52	A, frequency-weighted
SFC, S1=0, S5=1	264	60	2.13	A, frequency-weighted
SFC, S1=0, S5=0	264	60	2.06	A, frequency-weighted
NC, S1=1, S5=1	264	60	22.68	A, non-frequency-weighted
NC, S1=1, S5=0	264	60	22.59	A, non-frequency-weighted
SFC, S1=0, S5=1	264	60	8.62	A, non-frequency-weighted
SFC, S1=0, S5=0	264	60	8.47	A, non-frequency-weighted
NC, S1=1, S5=1	122	400	1.27	A, frequency-weighted
NC, S1=1, S5=0	122	400	1.32	A, frequency-weighted
SFC, S1=0, S5=1	122	400	1.42	A, frequency-weighted
SFC, S1=0, S5=0	122	400	1.23	A, frequency-weighted
NC, S1=1, S5=1	122	400	11.12	A, non-frequency-weighted
NC, S1=1, S5=0	122	400	11.25	A, non-frequency-weighted
SFC, S1=0, S5=1	122	400	4.86	A, non-frequency-weighted
SFC, S1=0, S5=0	122	400	4.92	A, non-frequency-weighted
For 8016-000101, Output to enclosure:				
NC, S1=1, S5=1	264	60	3.45	A, frequency-weighted
NC, S1=1, S5=0	264	60	3.68	A, frequency-weighted
SFC, S1=0, S5=1	264	60	2.95	A, frequency-weighted
SFC, S1=0, S5=0	264	60	2.74	A, frequency-weighted
NC, S1=1, S5=1	264	60	23.21	A, non-frequency-weighted
NC, S1=1, S5=0	264	60	23.37	A, non-frequency-weighted
SFC, S1=0, S5=1	264	60	11.96	A, non-frequency-weighted
SFC, S1=0, S5=0	264	60	12.06	A, non-frequency-weighted
NC, S1=1, S5=1	122	400	1.32	A, frequency-weighted
NC, S1=1, S5=0	122	400	1.26	A, frequency-weighted

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Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
SFC, S1=0, S5=1	122	400	1.28	A, frequency-weighted
SFC, S1=0, S5=0	122	400	1.34	A, frequency-weighted
NC, S1=1, S5=1	122	400	15.49	A, non-frequency-weighted
NC, S1=1, S5=0	122	400	15.62	A, non-frequency-weighted
SFC, S1=0, S5=1	122	400	5.39	A, non-frequency-weighted
SFC, S1=0, S5=0	122	400	5.43	A, non-frequency-weighted
For 8016-000101, Output to earth:				
NC, S1=1, S5=1	264	60	6.74	A, frequency-weighted
NC, S1=1, S5=0	264	60	6.69	A, frequency-weighted
SFC, S1=0, S5=1	264	60	1.96	A, frequency-weighted
SFC, S1=0, S5=0	264	60	1.80	A, frequency-weighted
NC, S1=1, S5=1	264	60	77.3	A, non-frequency-weighted
NC, S1=1, S5=0	264	60	78.0	A, non-frequency-weighted
SFC, S1=0, S5=1	264	60	11.62	A, non-frequency-weighted
SFC, S1=0, S5=0	264	60	11.54	A, non-frequency-weighted
NC, S1=1, S5=1	122	400	2.08	A, frequency-weighted
NC, S1=1, S5=0	122	400	2.27	A, frequency-weighted
SFC, S1=0, S5=1	122	400	1.25	A, frequency-weighted
SFC, S1=0, S5=0	122	400	1.28	A, frequency-weighted
NC, S1=1, S5=1	122	400	31.95	A, non-frequency-weighted
NC, S1=1, S5=0	122	400	31.86	A, non-frequency-weighted
SFC, S1=0, S5=1	122	400	5.48	A, non-frequency-weighted
SFC, S1=0, S5=0	122	400	5.12	A, non-frequency-weighted
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
To be evaluated in end-product				
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
To be evaluated in end-product				
Fig. 17 - Patient leakage current with external voltage on Signal	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA

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Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Input/Output part (SIP/SOP)				SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
To be evaluated in end-product				
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
To be evaluated in end-product				
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
To be evaluated in end-product				
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
To be evaluated in end-product				
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
To be evaluated in end-product				
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
To be evaluated in end-product				
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
To be evaluated in end-product				

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Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks		
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC		
To be evaluated in end-product						
Supplementary information:						
<p>Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5; Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6; Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7 Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values. Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).</p> <p>Fig. 14 - Touch Current (TC): For CLASS II ME equipment, the PROTECTIVE EARTH CONNECTION and S7 are not used.</p>						
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device </td> <td style="width: 50%; border: none;"> A - After IP54 testing B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition </td> </tr> </table>					ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device	A - After IP54 testing B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition
ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device	A - After IP54 testing B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition					

Test Report

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				P
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s ¹⁾	Dielectric breakdown after 1 minute Yes/No ²⁾
		PEAK WORKING VOLTAGE (U) V _{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Insulation between L and N before fuses	1 MOOP	339	-	1500	D) No
B (Secondary circuit to core of transformer)	1 MOPP	432.8	-	1620	D) No
C (Primary circuit to secondary circuit)	2 MOPP	432.8	-	4240	D) No
D (Primary circuit to enclosure surface)	2 MOPP	339	-	4000	D) No
E (CY1)	1 MOPP	339	-	1500	D) No
F (CY2)	1 MOPP	339	-	1500	D) No
H (Primary circuit to core of transformer)	1 MOPP	432.8	-	1620	D) No
Supplementary information:					
¹ Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used. ² A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).					

Test Report

Photo 1.

Description: Sample before IP5X test



Photo 2

Description: Sample after IP5X test



Test Report

Photo 3

Description: Sample internal view after IP5X test



Photo 4

Description: Sample before IPX4 test



Test Report

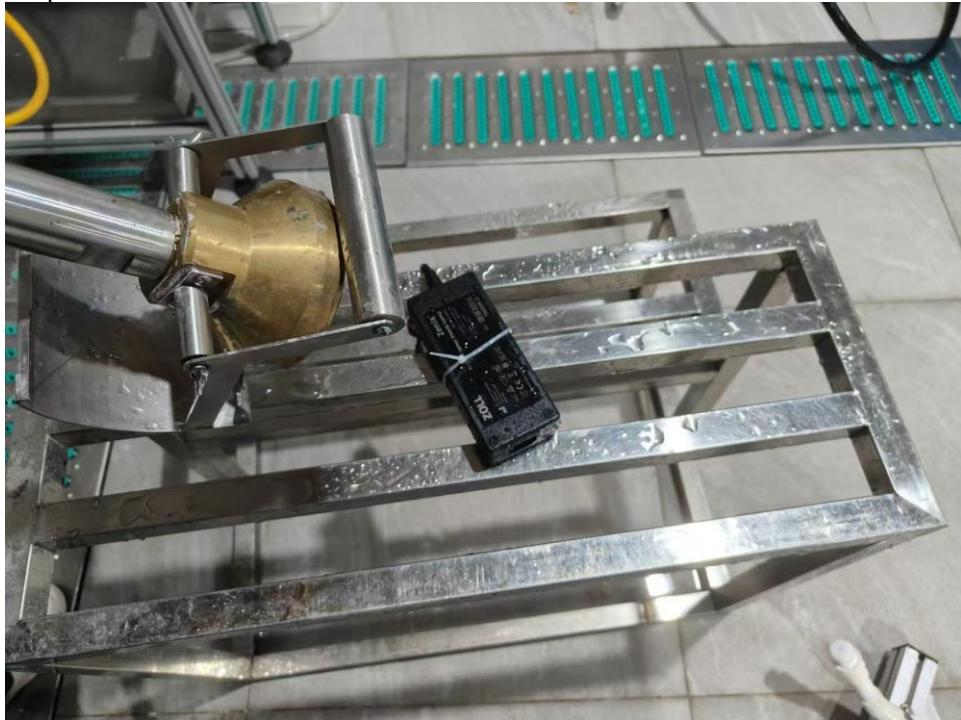
Photo 5

Description: Sample undergo IPX4 test



Photo 6

Description: Sample after IPX4 test



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Photo 7

Description: Sample internal view after IPX4 test



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