

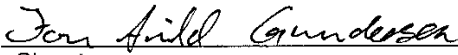
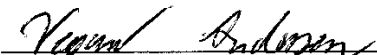


APPENDIX TO TEST REPORT, NEMKO REF. NO. 2000 43151

This Appendix consists of this cover page and additional test report page(s) to the original test report.

Equipment / Product	Power supplies for medical electric equipment	
Name and address of the applicant	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 U.S.A.	
Name and address of the manufacturer	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 U.S.A.	
Name and address of the factory	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 U.S.A.	
Trademark	 GlobTek, Inc.	
Model/type	GT500160-30	
Rating and principal characteristics	Input voltage 100 - 240 V~, 50 / 60 Hz, 1.4 A max; Class I. Output 30 VDC, 2 A maximum.	
Serial no	Prototypes.	
Modification on Appliances:	Addition of a new model GT500160-30.	
Modification to Clause:	Additional Information, Summary of Testing, Personnel, Content of the Test Report, 6.1, 7.1, 15b, 19.4, 20, 42, 57.9, 19.4f Appendix 1 (Earth Leakage), 19.4g Appendix 2 (Enclosure Leakage), 19.4f Appendix 3 (Patient Leakage).	
The test results relate only to the sample(s) tested.		
Name and address of the testing laboratory	 P.O. BOX 73 BLINDERN, N - 0314 OSLO, NORWAY	Telephone (+47) 22 96 03 30 Fax (+47) 22 96 05 50
Tested by	 Signature Jon Arild Gundersen	23 July 2001 date
Verified by	 Signature Vegard Andersen	23 July 2001 date
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Verdicts are placed in the column to the right: P = Pass, F = Fail, N = Not applicable, — = Considered/Information.

Due to Nemko's computerised handling of test reports the layout of this form is modified compared to the original TRF published by EMEDCA; 1992-12-01. The content fully covers the original TRF.

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Issue Nemko 97-12-18

ADDITIONAL INFORMATION

DESCRIPTION OF EQUIPMENT UNDER TEST:

This Appendix should always be used together with the original Test Report, Nemko Ref. No. 2000 43151.

This model G1500160-30 is identical in construction to the model GT500148-24 covered by the original report, except the model GT500160-30 output voltage divider network has been adjusted to produce a 30V output.

NAME AND ADDRESS OF PRODUCTION-SITES (FACTORIES):

See original report.

INFORMATION ABOUT THE STANDARDS / DOCUMENTS CONSIDERED:

See original report.

TESTED ACCORDING TO NATIONAL REQUIREMENTS FOR THE FOLLOWING COUNTRIES:

See original report.

LIST OF APPENDIXES / ENCLOSURES TO THE TEST REPORT:

See original report.

PERSONNEL - INITIALS USED THROUGHOUT THIS TRF:

Initials:	Full name:	Signatures:
JAG	Jon Arild Gundersen	<i>Jon Arild Gundersen</i>
VA	Vegard Andersen	<i>Vegard Andersen</i>

CONTENT OF THE TEST REPORT:

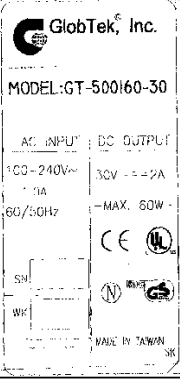
- This Part 1 TRF contains **11** pages, numbered from **1** to **11**.

SUMMARY OF TESTING:

The alternative construction on the equipment complies with the mentioned standards.

Clause	Remarks	Information/Comments
		<i>Due to the similar construction of the model GT-500160-30 to the previously tested and reported models, only the tests relevant to the revised electrical output ratings were conducted.</i>
19.4	<i>The equipment is a power supply for medical use. There is no applied part in the equipment.</i>	<i>For the purpose of this clause, the equipment output is regarded as applied part type B</i>

3	GENERAL REQUIREMENTS		
3.1	EQUIPMENT when transported, stored, installed, operated in NORMAL USE and maintained according to the instructions of the manufacturer, causes no SAFETY HAZARD which could reasonably be fore- seen and which is not connected with its intended application in NORMAL CONDITION and in S.F.C.	<i>The equipment causes no hazards when used according the manufacturers instructions.</i>	—

6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside		
6.1 a	Markings of Mains operated EQUIPMENT		P
6.1 f	Model or type reference	GT-500160-30	P
6.1 p	Rated output voltage and current or power, output frequency (where applicable)	30 VDC, 2 A	P

7 POWER INPUT					
7.1	Steady state current or power input does not exceed the marked rating by more than specified				
	Equipment:	N-18			
	Initials Tester / Date:	JAG / June 2001			
	50 Hz	Power input: 100-240VAC, max. 1.4 A			
Power input	Function	$U_{\text{Nlower}} = 90 \text{ V}$	$U_{\text{N}} = 100 \text{ V}$	$U_{\text{N}} = 240 \text{ V}$	$U_{\text{Nupper}} = 264 \text{ V}$
Input current	Normal operation (A)	1,2	1,1	0,47	0,43
Input power	Normal operation (W)	69	69	68	69
Input power	Normal operation (VA)	110	113	113	113
	60 Hz	Power input: 100-240VAC, max. 1.4 A			
Power input	Function	$U_{\text{Nlower}} = 90 \text{ V}$	$U_{\text{N}} = 100 \text{ V}$	$U_{\text{N}} = 240 \text{ V}$	$U_{\text{Nupper}} = 264 \text{ V}$
Input current	Normal operation (A)	1,1	1,1	0,48	0,44
Input power	Normal operation (W)	69	69	68	68
Input power	Normal operation (VA)	103	106	116	117

15 LIMITATION OF VOLTAGE AND/OR ENERGY											
15 b	Equipment with mains plug so designed that the voltage 1 sec. after disconnection does not exceed 60 V	See table below									
	Equipment:	N28, N79									
	Initials Tester / Date:	JAG / May 2001									
	Maximum residual voltage in the mains plug 1 second after disconnection (measured in the least favourable position of the on-off switch, if any):										
	Remark: pins 1 and 2 are Line and Neutral supply pins. Note! PE is equal to enclosure.										
Measurement no.	1	2	2	4	5	6	7	8	9	10	
Voltage between pins 1 and 2 (Limit 60 V)	30	30	30	30	30	30	30	30	30	30	
Voltage between pin 1 and PE (Limit 60 V)	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	
Voltage between pin 2 and PE (Limit 60 V)	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENTS AUXILIARY CURRENTS			
19.2	Single fault conditions (tests see 19.4)			
19.3	Allowable values (see 19.4)			
19.4	Tests before humidity preconditioning treatment			
	<i>See comment below.</i>			
	Equipment:	N65, N72, N88, N69		
	Initials Tester / Date:	JAG / May 2001		
Type of leakage current	In normal condition		In single fault condition	
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)
Earth leakage current	500	108	1000	211
Enclosure leakage current	100	3.6	500	3.5
Patient leakage current (p.l.c.), a.c.:	B, BF: 100 CF: 10	4.7	B, BF: 500 CF: 50	32.4
Patient leakage current (p.l.c.), d.c.:	B, BF: 10 CF: 10	0	B, BF: 50 CF: 50	0
Comments	The listed values are the maximum values			
19.4	Tests after humidity preconditioning treatment			
	Equipment:	N65, N72, N88, N69		
	Initials Tester / Date:	JAG / May 2001		
Type of leakage current	In normal condition		In single fault condition	
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)
Earth leakage current	500	162	1000	296
Enclosure leakage current	100	1.5	500	1.4
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	5.7	B, BF: 500 CF: 50	32.6
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	0	B, BF: 50 CF: 50	0
Comments	The listed values are the maximum values.			

20	DIELECTRIC STRENGTH (at operating temperature)					
	Overall compliance with Clause 20					P
	Equipment:		High voltage supply : 6			
	Initials Tester / Date:		JAG / June 2001			
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations	
All equipment types	A-a ₁		250 VAC	1 500 VAC		
	A-a ₂		250 VAC	4000 VAC		
	A-e		250 VAC	4000 VAC		
	A-f		250 VAC	1 500 VAC		
*) IEC 60601-1 does not require to measure this						

20	DIELECTRIC STRENGTH (after humidity preconditioning treatment)					
	Overall compliance with Clause 20					P
	Equipment:		Humidity room : N3205 High voltage supply : 6			
	Initials Tester / Date:		JAG / June 2001			
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations	
All equipment types	A-a ₁		250 VAC	1 500 VAC		
	A-a ₂		250 VAC	4000 VAC		
	A-e		250 VAC	4000 VAC		
	A-f		250 VAC	1 500 VAC		
*) IEC 60601-1 does not require to measure this						

42	EXCESSIVE TEMPERATURES				
42.1 - 42.2	Determination of the temperature with thermocouples:				P
	Equipment:	N18, N19, N93			
	Initials Tester / Date:	JAG / June 2001			
Quantity	Rated	Frequency	Used	Frequency	
Supply voltage, V	100-240VAC	50/60Hz	264 / 90 VAC	50 Hz	
Output power, VA	60	—	59	—	
Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Model GT500148-12	
1. Ambient, T = 26 / 23 °C	—	—	—		
2. Transformer T1, winding	72 / 67	112 / 107	130	Class B insulation. Tab Xa	
3. Transformer T1, core	74 / 69	114 / 109	—	Tab. Xa	
4. L1 winding	47 / 67	87 / 107	130	Class B materials. Tab Xa	
5. L2 winding	53 / 76	93 / 116	130	Class B materials. Tab Xa	
6. L3 winding	54 / 52	94 / 92	130	Class B materials. Tab Xa	
7. L4 winding	45 / 44	85 / 84	130	Class B materials. Tab Xa	
8. L5 winding	28 / 42	68 / 82	130	Class B materials. Tab Xa	
9. C9	52 / 62	92 / 102	—	Tab. Xa	
10. C1	42 / 52	82 / 92	—	Tab. Xa	
11. C25	54 / 51	94 / 91	—	Tab. Xa	
12. PWB (near Q1)	63 / 70	103 / 110	—	UL 94V-0	
13. Enclosure, top	36 / 35	76 / 75	85	Tab. Xa	
14. Enclosure, bottom	35 / 35	75 / 75	85	Tab. Xa	
Comments	According to IEC 60601-1 clause 42.1, table Xa and Xb, 40°C or 25°C is added to the temperature rise for determination of the final temperature T.				

57	MAINS PARTS, COMPONENTS AND LAY-OUT		
57.9	Mains supply transformers (refer to table below)		
57.9.1 a	Short-circuit test(s) at 90 to 110 percent of rated supply voltage / voltage range	Primary side current regulator operated. Output cycled. No hazard.	P
<p><i>For switch mode power supplies:</i> A short circuit was applied across the output leads, input 264 VAC.</p> <p><i>Results:</i> No excessive temperature rises where observed after 2.0 hours. Maximum temperature (T1 winding) was measured to 112°C (24.2°C ambient). Secondary output current cycled from 0 to 10 A (momentary). Dielectric test was conducted at 4000 VAC for one min. No breakdown.</p>			
57.9.1 b	Overload		
<p><i>For switch mode power supplies:</i> A resistor connected directly across output, input 264 VAC; resistance decrease to just before foldback. Output load used was electric resistor with automatic regulation of the resistance to keep current at a preset level.</p> <p><i>Results:</i> No excessive temperature rises where observed after 2.5 hours. Maximum temperature (T1 winding) was measured to 116°C (23.3°C ambient). Maximum secondary output current is 3.2A with 19.2 VDC. Dielectric test was conducted at 4000 VAC for one min. No breakdown.</p>			
	Equipment:	N22, N25, 38	
	Initials Tester / Date:	JAG / June 2001	

19.4 f	APPENDIX 1				
Fig. 16 in IEC 60601-1	Measurement of the earth leakage current	FOR MAINS OPERATED EQUIPMENT			P

(Measuring supply circuit with one side of the supply mains at approximately earth potential (fig. 10)).

Switch positions	NC (S1 = 1) Measured (μA)		SFC (S1 = 0) Measured (μA)		Additional SFC* (see Clause 17.a)* (S1 = 1) Measured (μA)	
	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
S5						
1	108	160	209	296	—	—
0	100	156	211	296	—	—

¹ and ² = Before and after humidity preconditioning treatment.

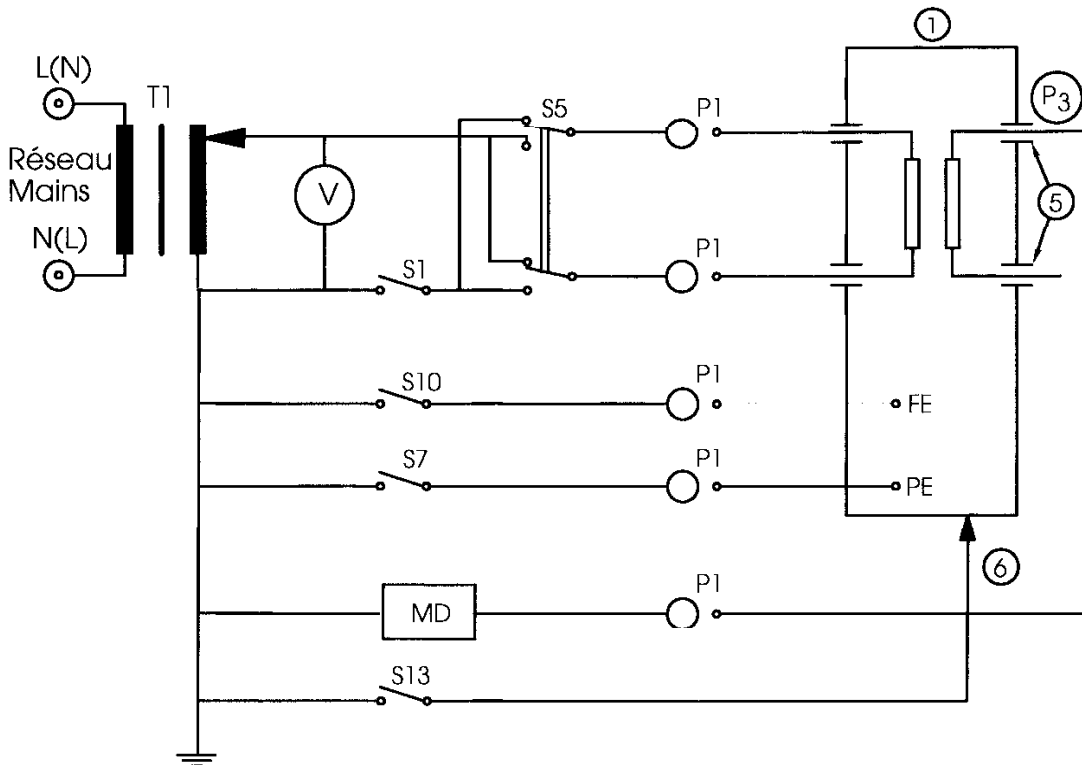
Note:	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above	Additional SFC not used for measuring earth leakage current.
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19.4 g	APPENDIX 2			
Fig. 18 in IEC 60601-1	Measurement of the enclosure leakage current	FOR MAINS OPERATED EQUIPMENT		P

Switch position	NC S1 = 1, S7 = 1 Measured (μA)		SFC S1 = 0, S7 = 1 Measured (μA)		SFC S1 = 1, S7 = 0 Measured (μA)		Additional SFC* S1 = 1, S7 = 1 Measured (μA)	
S5	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
1	3.6	1.5	1.8	0.9	3.4	1.4	—	—
0	3.6	1.5	1.8	0.9	3.5	1.4	—	—

¹ and ² = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above
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19.4 h	APPENDIX 3								
Fig. 20 in IEC 60601-1	Measurement of the patient leakage current	FOR MAINS OPERATED EQUIPMENT. This test is not applicable, as this equipment has no applied part. For the purpose of this test the output terminal of the power supply is regarded as applied part type B.				N			
									
Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)		
S5	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	
1	4.7	5.6	8.8	10.4	32.4	32.4	—	—	
00	4.7	5.7	0.7	10.4	32.3	32.0	—	—	
¹ and ² = Before and after humidity preconditioning treatment.									
Values are maximum measured from positive and return output leads.									
Note:	S7 not used for Class II equipment		NC = Normal Conditions SFC = Single Fault Condition		1 = Switch Closed 0 = Switch Open		* = describe additional SFC according to Sub-clause 17 a in notes above		