

File E172861  
Project 02ME17432

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REPORT

on

COMPONENT - MEDICAL ELECTRICAL EQUIPMENT

Under The  
RECOGNITION PROGRAM

Globtek Inc.  
Northvale, NJ

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## DESCRIPTION

## PRODUCT COVERED:

USR/CNR: Component - Power Supply, Medical Electrical Equipment, Model Family GT(M)-21097(CC)-YZ-X.X, where M designates versions with medical safety approval; CC designates versions with constant current output, I<sub>o</sub>; Y = maximum output power, P<sub>o</sub>; Z = base open circuit output voltage, V<sub>o</sub>, and X.X = optional deviation subtracted from base output (voltage/current) to provide output (voltage/current) in 0.1 volt/amps increments.

## ELECTRICAL RATINGS:

Input: 100-240 V ac, 50-60 Hz, 1.6 A maximum

## Output:

YZ	P <sub>o</sub>	V <sub>o</sub>	Max I <sub>o</sub>
2003	20	3.3	6.0
3005	30	5	6.0
4509	45	9	5.0
5012	50	12	4.17
5015	50	15	3.3
5018	50	18	2.8
5024	50	24	2.1
5048	50	48	1.1

## CLASSIFICATION:

1. Protection against electric shock (5.1, 5.2)

Class II with Functional Earth.

2. Applied Parts:

There are no Applied Parts

3. Protection against harmful ingress of water (5.3)

Ordinary, IPX0

4. Degree of safety in the presence of flammable anesthetics mixture with air or with oxygen or with nitrous oxide (5.5)

Not suitable

5. Mode of operation (5.6)

Continuous

## ACCESSORIES:

None

## MODEL DIFFERENCES:

Basic generic model described, internal secondary component differences account for specific output voltage and/or current characteristics.

## ENGINEERING CONSIDERATIONS (NOT FOR FIELD REPRESENTATIVE'S USE):

General - The product covered by this Report is a component power supply intended for use in/with medical electrical equipment.

USR - Refers to evaluation per to UL 2601-1, 2<sup>nd</sup> Edition including Amendments 1 and 2.

CNR - Refers to evaluation per CAN/ CSA C22.2 N0. 601.1- M90

Connection to SIP/ SOPs - Not applicable, the product has no SIP/ SOPs

Function of Equipment - This Power Supply is intended for use in/with professional medical and dental equipment where Underwriters Laboratories Inc determines the acceptability of the combination.

Considerations - The product is provided with an appliance inlet, but evaluated without a detachable Power Supply cord. All electrical components are housed within a plastic enclosure.

Disconnect Device - The following component is considered the equipment disconnect device: Appliance inlet.

Compliance regarding Electromagnetic Compatibility (Clause 36), Biocompatibility (Clause 48) and Software Reliability (Sub- Clause 52.1) is not covered by this report.

Conditions of Acceptability - When installed in the end-use equipment, the following are among the considerations to be made.

1. This product has been judged on the basis of the required spacing in the Second Edition of the standard for Medical Electrical Equipment, UL 2601-1, CL. 57.10.
2. A Listed detachable Power Supply cord provided with a "Hospital Only" or "Hospital Grade" attachment plug shall be used in the end-use application in US. A KAM Certified Power Supply cord shall be used in Europe.
3. The Power Supply was considered as a Class II device with a Functional Earth and no Applied Parts.
4. The Temperature Test was conducted with simulated load on an open bench. Consideration should be given to measuring the temperature on transformer windings when the power supply is installed or used in the end-use equipment.
5. This product has been evaluated for Double Insulation Primary to Secondary and Basic Insulation Primary to Ground; outputs are less than 60 V dc.
6. Accompanying documentation such as a user manual is not provided.
7. With regard to CSA C22.2 No. 125, the risk class of the equipment is not indicated.

Engineering References - The following Illustrations are provided for engineering references only:

ILL. 1 - PWB Trace Pattern.

CONSTRUCTION DETAILS:

Except for items specifically addressed in this Section, all Section General requirements apply.

Markings - Refer to Section General, "Markings" for further details. Unless otherwise noted, all markings described in this Procedure are provided on a Recognized Component Marking and Labeling System suitable for adhesion to the surface involved. R/C PGDQ2, manufactured by Colorful Printing Co., Type C-100 or Graphtex, Inc., Type ML 1842 metalized Mylar stock used with R/C PGJI2, printing system using Type RHQ thermal transfer ribbon ink manufactured by EPC Identification System, used with any suitable thermal transfer printer.

The following IEC Symbols shown in Section General (Ills. 1 and 2) are provided on the label:

Table DI: Nos. 1, 4, 7 and 14.

Additional Markings - The following markings are provided on the Label:

- Recognized Company's Name or File Number, model number, and optional input and output electrical ratings.
- "WARNING - For use only with xx" where xx = specific end use product.
- CN Product Marking - Month and year of manufacturing.
- Identity of manufacturer - "MADE IN CHINA" or "MADE IN USA"

MODEL GT(M)-21097(CC)-YZ-X.X

FIG. 1 (M02-04881)

General - Figure 1 shows overall external top and bottom views.

1. Enclosure - R/C QMFZ2, Teijin Chemicals, Type LN-1250#, rated 94V-0. Overall measures 118 by 32 by 60 mm, minimum 2.0 mm thick. Constructed of two parts secured together by ultrasonic welding.

Alternate - Same as above, except GE Plastics, Type GE-100 or C6200, overall 118 by 39 by 60 mm, minimum 2.0 mm thick.

2. Appliance Inlet - Listed or R/C AXUT2, rated minimum 250 V, 10 A. Secured to Printed Wiring Boards by soldering.
3. Output Cable - R/C AVLV2, Style No. 1185, AWM, No. 18 AWG, VW-1, 80°C, 300 V, one end is soldered to Printed Wiring Boards, the other end is molded with connector barrel type.

Alternate - Same as above, except cable Style No. SPT-1, 18 AWG, VW-1, 105°C.

Alternate - Same as above, except cable, Style No. 2464, AWM, No. 20 AWG, VW-1, minimum 80°C, 300 V.

4. Output Cable Strain Relief - Molded on the Output Cable, Fig. 1, Item 3, through the Enclosure, Fig. 1, Item 1, opening overall 11 by 8 mm.

MODEL GT(M)-21097(CC)-YZ-X.X

FIG. 2 (M02-04879)

FIG. 3 (M02-04880)

General - Figure 2 shows internal, top views of unit, with and without heat sink. Figure 3 shows bottom views of pc board, with and without bottom shield.

1. Fuse (F1, F2) - Listed JDYX, rated 250 V, 1.6 A, fuse body and leads entirely sleeved with R/C sleeving and/or tubing, see Section General for appropriate types. Fuse current and voltage rating are permanently marked adjacent to fuse, soldered to printed wiring boards.
2. Line Choke (LF1) - Rating 130°C. Open-type construction. Ferrite core, size 24.3 by 24.3 by 4 mm, coil of copper-magnet wire on three-flange bobbin, R/C QMFZ2, phenolic, rated minimum 94V-1, and 100°C, minimum 0.71 mm thick.
3. Line Choke (LF2) - Rating 130°C. Optional. Toroidal-type construction. Ferrite core, size 13.2 mm OD, 6.4 mm ID, 6.7 mm thick, coil of copper magnet wire-wound on the core.
4. X-Capacitor (C24) - (Optional). (Line-to-Line) R/C FOWX2 or FOKY2, marked X1 to indicate compliance with IEC 384-14, rated minimum 250 V, maximum 0.47  $\mu$ F.
5. Y-Capacitors (CY1, CY2, CY3) - (Optional). (Line-to-Ground) R/C FOWX2 or FOKY2, marked Y2 to comply with IEC 384-14, rated minimum 250 V, maximum 4700 pF.
6. Bulk Capacitor (C22) - Rated 150  $\mu$ F maximum, 400 V, minimum 95°C. Electrolytic type, provided with integral pressure relief.
7. Bleeder Resistors (R11, R16) - SMD type, rated 470 kilohm or 1 M $\Omega$ , 1/8 W.
8. Bridge Diode (BD1) - Rated 600 V, minimum 2 A.

9. Class B insulation system. Type 04-B173. Open-type construction. Core: Ferrite core. Overall 28.6 by 19.6 by 19 mm thick. Coil: Copper magnet wire-wound concentrically on two-flanged bobbin. Bobbin: R/C QMFZ2, phenolic, minimum 0.71 mm thick. Leads exit directly through integral flanges in bobbin and are mechanically secured and soldered to pins that are molded into bobbin.

<u>Location</u>	<u># Layer</u>	<u>Total Thickness (mm)</u>	<u>Material</u>
Outer wrap	2 layer	minimum 0.050	polyester tape
Pri/Sec	1 layer	minimum 0.075	polyester tape, Secondary triple wire, R/C (OCDT2), Furukawa Electric, Type TEX-E.
Pri/Core	Bobbin	0.71 mm	R/C QMFZ2, phenolic
Sec/Core	Bobbin	0.71 mm	R/C QMFZ2, phenolic. Primary leadouts sleeved with tubing.

10. Transistor (Q3) - Rated minimum 600 V, 8.5 A. Secured to Heat Sink, Fig. 2, Item 12, by metal clamp, the body of transistor covered with tubing, see Section General for Insulation Tubing.
11. Heat Sink (for Q3) - Aluminum, size maximum 110 by 53 by 25 mm, 1.5 mm thick. Secured to printed wiring boards by soldering, provides ground continuity between pc board grounds. R/C (OANZ2), polyester tape, one layer adhesive to the heat sink between the heat sink and primary parts C24, LF2 and primary edge of printed wiring boards providing basic insulation distance
12. Optical Isolator (U2) - R/C FPQU2, (Philips, Type CNX82A), rated isolation 3000 V ac. (Meet reinforced requirement, internal creepage minimum 5 mm distance, and insulation thickness minimum 0.4 mm.)



13. Earthing - R/C AVLV2, No. 18 AWG, green/yellow lead; one lead mechanically secured then soldered to earthing terminal of Appliance Inlet, Fig. 1, Item 2. Other end terminates into the trace of the printed wiring board, directly connected to L2 to heat sink.
14. Printed Wiring Board - See Section General. Refer to Ill. 1 for trace pattern and slot location.
15. Inductor (L2) - Optional. Toroidal-type construction. Ferrite core, size 10 mm OD, 8 mm ID, 2.4 mm thick, coil of copper magnet wire, 0.8 mm minimum wound on the core.
16. Bottom Shield and Insulator - R/C QMFZ2 insulator, manufactured by Toshiba, P/N TSE21B2U, 0.5 mm thick with 0.1 mm thick copper layer, overall measuring approximately 90 mm x 50 mm with 5.0 mm margin of insulator provided all sides.

TEST RECORD NO. 1

SAMPLES:

Samples of the GT(M) 21097 (CC) - YZ-X.X family as indicated below and constructed as described herein, was submitted by the manufacturer for examination and test.

GENERAL:

Due to similarity of these devices to Model GT-21097-XY Family Listed for this manufacturer, and Model GTM21097CC-3015 Recognized Component for this manufacturer, only the following tests were considered necessary.

The following tests were conducted:

7.1 - Power Input Test  
15B - Voltage Limitation (Part 1)  
19 - Leakage Current Test  
20.4 - Dielectric Voltage Withstand  
42 - Temperature  
Mechanical Abuse - Ball Drop Test: (IEC 60601-1, Sub-Clause 55, US Deviation)  
Humidity Pre-Conditioning

Additional Tests Performed for UL1310 Coverage:

Leakage Current Test  
Maximum Output Voltage Test  
Maximum Input Test  
Output Current and Power Test:  
Calibration of Overcurrent Protection Devices Test  
Full-load Output Current Test  
Abnormal Tests: General  
Output Loading Test Methods A/BO  
Output Loading Test Methods C3.2/C4/C5 (CSA Fuse/Reset/Foldback)  
Output Loading Test Results A/B  
Output Loading Test Results C3.2  
Output Loading Test Results C4/C5  
Transformer Burnout Test (Switching)  
Dielectric Voltage Withstand Test After Transformer Burnout Test  
Component Breakdown Test - Abnormal:  
Dielectric Voltage Withstand Test After Component Breakdown Test  
Output Connector Security Test

The test methods and results of the above tests have been reviewed and found in accordance with the requirements in UL 2601-1, UL 60950 and UL 1310.

## CONCLUSION

Samples of the component covered by this Report been found to comply with the requirements covering the class and the component(s) are judged to be eligible for Component Recognition and Follow-Up Service. Under the Service the manufacturer is authorized to use the Recognized Marking described in the Follow-Up Service Procedure on such components which comply with said Procedure and any other applicable requirements of Underwriters Laboratories Inc. Only those components which properly bear the Recognized Marking are considered as Recognized Components by Underwriters Laboratories Inc.

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