

File E172861
Project 02ME05550

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REPORT

on

COMPONENT- POWER SUPPLIES FOR USE WITH MEDICAL EQUIPMENT

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DESCRIPTION

PRODUCT COVERED:

USR, CNR - Component - Power Supplies, GTM3 series, see Table 1 for models covered.

ELECTRICAL RATINGS:

All models are rated 120 V, 60 Hz. See table 1 for output ratings.

CLASSIFICATION:

1. Protection against electric shock (5.1, 5.2):
Class I or Class II based on provided attachment plug configuration.
2. Applied Parts:
There are no Applied Parts.
3. Protection against harmful ingress of water (5.3):
Ordinary.
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.

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

General - The product covered by this report is Medical Equipment, intended for use under direct or indirect professional medical supervision.

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

CNR - Refers to evaluation per CAN/ CSA C22.2 No. 601.1- M90

Compliance regarding Electromagnetic Compatibility (Clause 36) is not covered by this report.

Connection to SIP/SOP's - Not applicable, the product has no SIP/SOP's.

Function of Equipment - This Power Supply is intended for use in (or with) with professional medical and dental equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.

MODEL DIFFERENCES:

These are plug-in component power supplies with isolating type transformers housed in a thermoplastic enclosure. These products can be assembled as direct plug-ins with grounded or ungrounded input supply blades or as desktop types with grounded power supply cord.

The series includes four different transformer core/enclosure sizes.

Within each core size, for a given output voltage, models are available in 50 mA output current increments and the maximum values are limited to the values listed in Table 1.

The model number designation consists of:

GTM-3AA-BB-CCCC-D where:

GTM-3	- is the series name
AA	- indicates the transformer core/enclosure size and may be 35, 41, 48, 57.
BB	- indicates the rated output voltage in Volts - note 1
CCCC	- indicates the rated output current in mA - note 1
D	- letter D indicates DC output

Note 1 - See table 1 for rated output voltage and current of models covered.

CONSTRUCTION DETAILS:

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

Internal Wiring - Unless otherwise specified, all internal wiring is Recognized Component appliance wiring material (AVLV2), insulation 1/32 in. (0.8 mm) thick minimum, rated 300 V, 105°C minimum (UL Style 1015), or 1/64 in (0.4 mm) thick cross-linked PVC insulation (UL Style 1007).

Tubing - Unless otherwise specified, Recognized Component extruded tubing, electrical (YDPU2), rated min 600 V, 105°C.

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.

The following markings are provided:

"Caution - Indoor Use Only".


Recognized Company's name or File No. "E172861", model number, date or dating system that provides the period of manufacture, complete electrical ratings, and location of manufacturer.

The following IEC Symbols shown in Sec. Gen. (ILLS. 1 and 2) are provided:

Table DI: Nos. 1, 4, 7 or 10, 14.

Additional Markings:

For Class I equipment, (applies to equipment supplied with grounding pin), if UL Listed cord is provided the appliance itself or the power supply cord is provided with the following or equivalent text: "Grounding Reliability Can Only Be Achieved When The Equipment Is Connected To An Equivalent Receptacle Marked 'Hospital Only' Or 'Hospital Grade'."

For Class II equipment (applies to equipment not supplied with grounding Pin), 'Class II' or the symbol 6041 -1-IEC-5172 shall be used.

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, Sub-clause 57.10.
2. These products meet Reinforced Insulation requirements between primary and secondary circuits. If provided with a Hospital Grade plug, Basic Insulation is provided between primary and secondary circuits.
3. The Power Supply was considered as a Class II device with no Applied Parts. If provided with a Hospital Grade plug, the Power Supply was considered as a Class I device with no Applied Parts. Outputs are less than 25 V ac/60 V dc.
4. All transformers employ a Class A (105°C) electrical insulation system.
5. For Class I equipment supplied with a power supply cord, a UL Listed power supply cord provided with a "Hospital Only" or "Hospital Grade" attachment plugs shall be used in the end-use application in the US. See Sub-clauses 57.2 and 57.3 of US differences in UL2601-1.
6. Output cords terminate in non-polarized connectors and are single insulated with or without outer jackets.
7. 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.
8. The required markings are as noted above. All other markings deemed necessary must be evaluated as part of the end product evaluation and so described in the end product report.
9. Accompanying documentation such as a user manual is not provided.
10. With regard to CSA C22.2 No. 125, the risk class of the equipment is not indicated.
11. Optional secondary current fuse, when provided, is not relied upon for protection from fire or electric shock or for compliance with UL2601-1.
12. When optional secondary current fuse is provided, a Temperature Test must be repeated in the end product to verify normal operation.

Table 1

<u>Model</u>	<u>Output</u>		<u>Input</u>	<u>Output</u>	<u>Thermal</u>
	<u>Volts</u>	<u>mA (max)</u>	<u>Fuse mA</u>	<u>Fuse mA</u>	<u>Cut-out °C</u>
GTM335-3-600	3.0	600	160	NA	115
GTM335-4-600	4.0	600	160	NA	115
GTM335-5-500	5.0	500	160	NA	115
GTM335-6-500	6.0	500	160	NA	115
GTM335-7-400	7.0	400	160	NA	115
GTM335-7.5-400	7.5	400	160	NA	115
GTM335-9-300	9.0	300	160	NA	115
GTM335-12-250	12.0	250	160	NA	115
GTM335-14-200	14.0	200	160	NA	115
GTM335-15-200	15.0	200	160	NA	115
GTM335-18-150	18.0	150	160	NA	115
GTM335-21-150	21.0	150	160	NA	115
GTM335-24-100	24.0	100	160	NA	115
GTM341-3-1300	3.0	1300	250	NA	130
GTM341-4-1300	4.0	1300	250	NA	130
GTM341-5-1000	5.0	1000	250	NA	130
GTM341-6-900	6.0	900	250	NA	130
GTM341-7-800	7.0	800	250	NA	130
GTM341-7.5-800	7.5	800	250	NA	130
GTM341-9-650	9.0	650	250	NA	130
GTM341-12-600	12.0	600	375	NA	130
GTM341-14-450	14.0	450	250	NA	130
GTM341-15-450	15.0	450	250	NA	130
GTM341-18-350	18.0	350	250	NA	130
GTM341-21-300	21.0	300	250	NA	130
GTM341-24-300	24.0	300	250	NA	130

Table 1 cont.

<u>Model</u>	<u>Output</u>		<u>Input</u>	<u>Output</u>	<u>Thermal</u>
	<u>Volts</u>	<u>mA (max)</u>	<u>Fuse mA</u>	<u>Fuse mA</u>	<u>Cut-out °C</u>
GTM348-3-1500	3.0	1500	350	NA	130
GTM348-3.3-1500	3.3	1500	350	NA	130
GTM348-4-1000	4.0	1000	350	NA	130
GTM348-4-1500	4.0	1500	350	NA	130
GTM348-4.5-1500	4.5	1500	350	NA	130
GTM348-5-1200	5.0	1200	350	NA	130
GTM348-5-1400	5.0	1400	350	NA	130
GTM348-6-1200	6.0	1200	350	NA	130
GTM348-6-1400	6.0	1400	350	NA	130
GTM348-7-1100	7.0	1100	350	NA	130
GTM348-7-1300	7.0	1300	350	NA	130
GTM348-7.5-900	7.5	900	350	NA	130
GTM348-7.5-1100	7.5	1100	350	NA	130
GTM348-7.5-1300	7.5	1300	350	NA	130
GTM348-9-1000	9.0	1000	350	NA	130
GTM348-9-1200	9.0	1200	350	NA	130
GTM348-10-700	10.0	700	350	NA	130
GTM348-10-900	10.0	900	350	NA	130
GTM348-10-1100	10.0	1100	350	NA	130
GTM348-11-1000	11.0	1000	350	NA	130
GTM348-12-800	12.0	800	350	NA	130
GTM348-12-1200	12.0	1200	500	NA	130
GTM348-13.5-850	13.5	850	350	NA	130
GTM348-13.5-1000	13.5	1000	350	NA	130
GTM348-14-500	14.0	500	350	NA	130
GTM348-14-600	14.0	600	350	NA	130
GTM348-14-800	14.0	800	350	NA	130
GTM348-15-800	15.0	800	350	NA	130
GTM348-15-900	15.0	900	350	NA	130
GTM348-16-900	16.0	900	350	NA	130
GTM348-18-350	18.0	350	350	NA	130
GTM348-18-450	18.0	450	350	NA	130
GTM348-18-500	18.0	500	350	NA	130
GTM348-18-550	18.0	550	350	NA	130
GTM348-18-700	18.0	700	350	NA	130
GTM348-20-500	20.0	500	350	NA	130
GTM348-21-300	21.0	300	350	NA	130
GTM348-21-400	21.0	400	350	NA	130
GTM348-21-500	21.0	500	350	NA	130
GTM348-21-600	21.0	600	350	NA	130
GTM348-24-350	24.0	350	350	NA	130
GTM348-24-450	24.0	450	350	NA	130
GTM348-24-550	24.0	550	350	NA	130
GTM348-28-450	28.0	450	350	NA	130
GTM348-36-300	36.0	300	350	NA	130
GTM348-48-200	48.0	200	350	NA	130

Table 1 cont.

<u>Model</u>	<u>Output</u>		<u>Input</u>	<u>Output</u>	<u>Thermal</u>
	<u>Volts</u>	<u>mA (max)</u>	<u>Fuse mA</u>	<u>Fuse mA</u>	<u>Cut-out °C</u>
GTM357-3-2500	3.0	2500	350	NA	130
GTM357-4-2300	4.0	2300	350	NA	130
GTM357-5-2300	5.0	2300	350	NA	130
GTM357-6-2200	6.0	2200	350	NA	130
GTM357-7-2000	7.0	2000	350	NA	130
GTM357-7.5-2000	7.5	2000	500	NA	130
GTM357-9-1800	9.0	1800	500	NA	130
GTM357-10-1500	10.0	1500	500	NA	130
GTM357-12-1400	12.0	1400	500	NA	130
GTM357-12-1500	12.0	1500	500	NA	130
GTM357-14-1300	14.0	1300	500	NA	130
GTM357-15-1300	15.0	1300	500	NA	130
GTM357-16.5-1300	16.5	1300	500	NA	130
GTM357-17.8-1500	17.8	1500	500	NA	130
GTM357-18-1100	18.0	1100	500	NA	130
GTM357-20-1000	20.0	1000	500	NA	130
GTM357-21-1000	21.0	1000	500	NA	130
GTM357-24-800	24.0	800	500	NA	130
GTM357-28-700	28.0	700	500	NA	130
GTM357-36-500	36.0	500	500	NA	130
GTM357-48-350	48.0	350	350	NA	130

MODEL GTM-3 Series

FIG. 1 (M02-12873)

FIG. 2 (M02-12874)

Fig. 1 shows an overhead external view of the plug-in unit.

Fig. 2 shows an external view of the input pin configurations.

1. Enclosure (plug-in models) - R/C (QMFZ2), GE Plastics, designated ABS, Type KJW, rated 94V-0, 85°C, min. 2.8 mm thick. Sonically welded or secured by screws. Shaped as shown.
 - a. GTM335 models - measures approx. 64 by 44 by 39 mm.
 - b. GTM341 models - measures approx. 74 by 52 by 40 mm.
 - c. GTM348 models - measures approx. 82 by 58 by 49 mm.
 - d. GTM357 models - measures approx. 85 by 65 by 56 mm.
2. Input blades (plug-in models) - Non-polarized, molded into enclosure. See Sec. Gen. for details.
3. Grounding pin (plug-in models, optional) - molded into enclosure. See Sec. Gen. for details.
4. Enclosure (desktop models, not shown) - same as Item 1 above, except dimensioned as follows:
 - a. GTM335 models - measures approx. 74 by 52 by 40 mm.
 - b. GTM341 models - measures approx. 74 by 52 by 40 mm.
 - c. GTM348 models - measures approx. 82 by 58 by 49 mm.
 - d. GTM357 models - measures approx. 85 by 65 by 56 mm.
5. Input cord (desktop models, not shown) - Listed, 2-prong polarized, or 3-prong, or Hospital Grade plug, equipped with integrally molded strain relief measuring approx. 16 by 14 by 29 mm, which is secured by enclosure base, cover and integral slot measuring approx. 11 by 10 mm.
6. Output Cable - Listed, Types SPT-1 or SPT-2, rated min. 60°C provided with tubing R/C, (QMFZ2), rated min V-0, 105°C on leads inside enclosure. Terminates in non-standard connector. See Conditions of Acceptability for further details.

Alternate - R/C (AVLV2), AWM Styles 2464 or 2468, 20 gauge, rated min. 80°C provided with tubing R/C, (QMFZ2), rated min V-0, 105°C on leads inside enclosure.

Alternate - Listed, Types SPT-1 or SPT-2, rated 105°C.
7. Output Strain Relief (all models) - Integrally molded with output cord. Secured by enclosure base, cover and integral slot measuring approx. 9 by 6 mm.

MODEL GTM-3 SERIES

Fig. 3 (M02-12875)

Fig. 3 shows an internal view of the power supply.

1. Printed Wiring Board - R/C (QMFZ2), rated 94V-0 min., 130°C. Secondary windings of transformer soldered to board. See Sec. Gen. for details.
2. Input Line Fuse - Listed, see Table 1 for specific ratings. Maintain min. 1.0 mm clearance between fuse and input blade, min. 1.6 mm clearance between line and neutral fuses. Mechanically secured before soldering.
3. Input Neutral Fuse - same as Item 2 above. Optional for Class II (ungrounded) units.
4. Capacitor - Electrolytic type, rated 470 - 6800 uF, min. 85°C. Voltage rating must exceed output voltage rating.
5. Rectifying Diodes - Mounted as shown, soldered min. 5.5 mm above pwb.
6. Grounding wire (Class I units only) - R/C (AVLV2), Style 1015 or 1007, rated 300 V, 105°C. One end mechanically secured and soldered to Grounding pin or provided as part of power supply cord, other end attached to transformer core using screw and locking washer.
7. Output Fuse (optional, not shown) - Listed or R/C, ratings not specified.

8. Transformer - For GTM335 models:

- A. Thermal fuse - R/C (XCMQ2), Aupo Electronics, Type A2, rated 250 V ac, 115°C. Insulated from primary winding by two layers of insulating tape, 0.025 mm thick each and 1 layer of insulating grade paper. Mechanically secured and soldered in series with winding.
- B. Bobbin - R/C (QMFZ2), DuPont, designated Zytel, Type 101L, min. 0.71 mm thick, rated 94V-2, 130°C. Separate primary and secondary bobbins held together by bobbin holder, minimum thickness 1 mm.
- C. Core - Steel, measuring approx. 35 by 30 by 14.6 mm.
- D. Primary Outer Wrap - 2 layers PET insulating tape, R/C (OANZ2), Chyun Yih, or Four Pillars, rated 130°C, 0.025 mm thick. Also provided by bobbin.
- E. Primary to Secondary Insulation - Formed by each of the bobbins and bobbin holder.
- F. Primary to Core Insulation - Formed by each of the bobbins and bobbin holder, including molded side walls.
- G. Crossover Lead Insulation - 1 layer polyester tape R/C (OANZ2), 3M, No. 44, measuring 0.12 mm thick, 1 layer polyester tape, R/C (OANZ2), Chyun Yih, Cat. No. P-244-1, rated 130°C, 0.16 mm thick.
- H. Windings - Enameled copper wire.

9. Transformer - For GTM341 models, same as Item 6 A - G above except for the following:

- A. Thermal fuse - R/C (XCMQ2), Aupo Electronics, Type A4, rated 250 V ac, 130°C.
- B. Core - Steel, measuring approx 41 by 33 by 24.6 mm.

10. Transformer - For GTM348 models, same as Item 6 A - G above except for the following:
 - A. Thermal fuse - R/C (XCMQ2), Aupo Electronics, Type A4, rated 250 V ac, 130°C.
 - B. Core - Steel, measuring approx. 48 by 40 by 31 mm.
11. Transformer - For GTM357 models, same as Item 6 A - G above except for the following:
 - A. Thermal Fuse - R/C (XCMQ2), Aupo Electronics, Type A4, rated 250 V ac, 130°C.
 - B. Core - Steel, measuring approx. 57 by 48 by 26 mm.