



Descriptive Report and Test Results

MASTER CONTRACT: 171413

REPORT: 1851838

PROJECT: 1851838

Edition 1: November 29, 2006; Project 1851838 - Montreal
Issued by Abdelkrim Kassou, Jr. Eng.

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Attachment 1*: CB Certificate SIQ (SI-1679), Test Report (T223-0253/06)

*To CSA Main file only

PRODUCTS

CLASS 5311 20 - POWER SUPPLIES - Component Type - For Use in Medical Equipment

CLASS 5311 96 - POWER SUPPLIES - Component Acceptance - Certified to US Standards

Direct plug in power supply, rated input: 100-240 Vac, 50-60 Hz, 0.5 A, Models:

- GTM41076-0605; Output: 5 Vdc, 1.2 A
- GTM41076-0606; Output: 6 Vdc, 1.0 A
- GTM41076-0607; Output: 7 Vdc, 0.85 A
- GTM41076-0609; Output: 9 Vdc, 0.66 A
- GTM41076-0612; Output: 12 Vdc, 0.5 A
- GTM41076-0615; Output: 15 Vdc, 0.4 A
- GTM41076-0618; Output: 18 Vdc, 0.33 A
- GTM41076-0620; Output: 20 Vdc, 0.3 A
- GTM41076-0624; Output: 24 Vdc, 0.25 A
- GTM41076-0630; Output: 30 Vdc, 0.16 A

Note (*):

- *The units were evaluated as components where the suitability of the combination must be determined with the end use product.*
- *Models differences: Turns ratio of the main transformer and few passive components on the secondary side*

APPLICABLE REQUIREMENTS

CAN/CSA Standard C22.2 No. 601.1-M90 - Medical Electrical Equipment

UL Standard 60601-1, 1st Edition - Medical Electrical Equipment, Part 1: General Requirements for Safety

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CONDITIONS OF ACCEPTABILITY

1. This component has been judged on the basis of the required spacings in the Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety, CAN/CSA-C22.2 No. 601.1-M90 and UL 60601-1, 1st Edition, which covers the end-use product for which the component is designed.
2. The power supply complies with requirements for reinforced Insulation between primary to secondary.
3. The system requires a manual for the medical applications. This product is shipped without a manual, because it was considered as part of an overall product.
4. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
5. The temperature test was performed in a raised ambient of 40 °C.
6. The power supply has been evaluated as Class II equipment, continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
7. Under normal and single fault conditions, the outputs do not exceed 60 V dc.

MARKINGS

On the Equipment Exterior:

Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- the CSA Mark  with the NRTL/C or C US indicator adjacent to it and the optional reference to CAN/CSA Standard C22.2 No. 601-1, UL 60601-1, or IEC 60601-1.
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).
- Complete electrical ratings; (in volts, hertz and amperes) with the IEC 417-5032 alternating current symbol ~ adjacent to the marked voltage and dc current symbol IEC 417-5031 for each model.

Note 1: Bilingual Markings for products with CSA Mark or CSA Mark and the C US indicator.

Note 2: Jurisdictions in Canada may require these markings to be also in French. It is the responsibility of the Customer to provide bilingual marking, where applicable, in accordance with the requirements of the Provincial Regulatory Authorities. It is the responsibility of the Customer to determine this requirement and have bilingual wording added to the "Markings".

Marking Method: The above markings are lasered or made via silk screening, die stamping, moulding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or other equivalent permanent means that can pass the label rub test under Clause 6.1.

ALTERATIONS

- 1- Markings, as described above, appear on each unit.

FACTORY TEST

1-DIELECTRIC STRENGTH

Equipment: The equipment at the conclusion of manufacture, before shipment, shall withstand for one minute, without breakdown, the application of 4000Vac between the primary side and the secondary side of the equipment.

Note: Although AC voltages are quoted above, coupling components within the product may require the tests be conducted using DC voltages. Where DC voltages are used, the test values are increased by 1.414 times the AC voltages. The test period may be shortened by using a potential 20 percent higher for one second.

Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury.

INTRODUCTION:

Notes: Unless stated otherwise:

Agency Approvals: "C" or "CSA" or "Certified" = CSA Certified, "UR" = UL Recognized, "UL" = UL Listed, "CUL" = UL Listed to Canadian Standards.

: The asterisk "" adjacent to "C" or "L" indicates the Agency Mark appears on the component. An asterisk behind any other test house's name denotes that their monogram appears on the component.

±: The "+" preceding the "manufacturer's name" denotes a Certified component that can be interchanged for one from another Certified source provided that it has an equivalent or better electrical rating, the same terminal orientation, and that 3mm (120V) or 4mm (240V) min spacing is maintained from live parts to protectively earthed parts.

SELV: All references to "SELV" denote Extra Low Voltage secondary circuits or components operating at less than 30V rms or 42.4V p-p.

Dimensions: (dim) All dimensions specified are approximations only, and shown in millimeters (mm).

Spacings: All spacings between terminals, between pwb conductive traces, and between other bare live parts and ground, conform to Standard.

CRITICAL COMPONENTS LIST

object/part No.	manufac- turer/trademark	type/model	technical data	standard	mark(s) of conformity ¹⁾
Overall external view of unit					
1- Enclosure (electrical, mechanical, fire)	GE Plastics China	SE1X	V-1 @ 1,5mm thickness; overall approx. 74 by 43,5 by 34mm, 2.0mm thick; 105°C	UL94	UR (E161723)
	GE Plastics China	C2950	V-1 @ 1,5mm thickness; overall approx. 74 by 43,5 by 34mm, 2.0mm thick; 75°C	UL94	UR (E161723)
	Chi Mei	PA-765A	V-1 @ 1,5mm thickness; overall approx. 74 by 43,5 by 34mm, 2.0mm thick; 80°C	UL94	UR (E56070)
2- Exchangeable input blade US	GE Plastics China	SE1X	125 Vac, 15 A V-1; 105°C Solid copper, brass or bronze. 2-blade configuration.	UL1310	Accepted
3- Output cable with moulded connector and strain relief	+ Dongguan GlobTek or equivalent	UL2468, SPT-1, SPT-2, 1185, 2464	20AWG; VW-1; 80°C; 300V; one conductor and shield or two conductor minimum; polarized connector or open ends	-----	UR E205058
Overall internal view of unit					
4- PCB	GlobTek	GT(M) 41076 PCB	Paper phenolic, paper epoxy or glass epoxy. Overall approx. 67,8 by 35,7 by 1,6 mm; V-1, 105°C	UL94	UR
5- Fuse (F1)	+ Walter	2010	Time delay 1A; 250Vac; soldered to PCB	-----	UL VDE
6- Fuse (F2)	+ Walter	2010	Time delay 1A; 250Vac; soldered to PCB	-----	UL VDE
7- Varistor (ZNR) (line to line)	Joyin	JVR- 07N471K	8mmOD min. 250Vac 1200A Surge Current	IEC 61051	CSA UR VDE
8- Bleeder resistors (R1, R1A)	Compostar	1206	0,25W; 1MOhms	--	accepted
9- X-capacitor (CX1) (line to neutral)	+ Cheng tung Industrial or Ultra Tech Xiphi or Tenta or equivalent	CTX UTX MEX	Min. 250Vac, 0,22µF; min. X2	IEC 60384- 14	cURus VDE

object/part No.	manufac- turer/trademark	type/model	technical data	standard	mark(s) of conformity ¹⁾
10- EMC inductor (NF1)	YAO Sheng or GlobTek or equivalent	NF00001D	Open type construction 32mH; 1A <u>core</u> : ferrite, 15 by 15 by 3mm <u>coil</u> : copper magnet wire wound on bobbin <u>bobbin</u> (QMFZ2, min 94V- 2): + Chang Chun, T373J and T375J, RTI, 94V-0, min. thickness (UL E59481S) 130 °C	--	Accepted
11- Diodes (D5- D8)	Liteon	1N4007	1A; 1000V	--	Accepted
12- Bulk (C2)	Samxon	KM	400V; 22μF; 105 °C	--	Accepted
13- Transformer (T1) for models: 5Vdc-7Vdc	Xepex or GlobTek	XF00336	Open type construction In: 100-240Vac, 0.5 A Out: 7Vdc, 1.2 A <u>core</u> : ferrite, EE-19, bottom wrapped with one layer polyester insulation foil <u>coil, primary</u> : enamelled magnet copper wire wound on bobbin <u>coil, secondary</u> : triple insulated wire wound on bobbin <u>bobbin</u> (QMFZ2, min. 94V- 1): + Chang Chun, phenolic, T375J; 150 °C; 94V-0; min. 0,45mm thick (UL E59481) <u>triple insulated wire</u> : +Great Leoflon; TRW-B approved according to Annex U of IEC 60950-1 by UL (UL E211989) UL insulation system (OBJY2) class B provided UL E243347. class B	--	Accepted
14- Transformer (T1) for models: 9Vdc-18Vdc	Xepex	XF00337	Open type construction In: 100-240Vac, 0.5 A Out: 18Vdc, 0.33 A <u>core</u> : ferrite, EE-19, bottom wrapped with one layer polyester insulation foil <u>coil, primary</u> : enamelled magnet copper wire wound on bobbin <u>coil, secondary</u> : triple	--	Accepted

object/part No.	manufac- turer/trademark	type/model	technical data	standard	mark(s) of conformity ¹⁾
			insulated wire wound on bobbin <u>bobbin</u> (QMFZ2, min. 94V- 1): + Chang Chun, phenolic, T375J; 150 °C; 94V-0; min. 0,45mm thick (UL E59481) <u>triple insulated wire</u> : +Great Leoflon; TRW-B approved according to Annex U of IEC 60950-1 by UL (UL E211989) UL insulation system (OBJY2) class B provided UL E243347. class B		
15- Transformer (T1) for models: 20-30Vdc	Xepex	XF00338	Open type construction In: 100-240Vac, 0.5 A Out: 30Vdc, 0.16 A <u>core</u> : ferrite, EE-19, bottom wrapped with one layer polyester insulation foil <u>coil, primary</u> : enamelled magnet copper wire wound on bobbin <u>coil, secondary</u> : triple insulated wire wound on bobbin <u>bobbin</u> (QMFZ2, min. 94V- 1): + Chang Chun, phenolic, T375J; 150 °C; 94V-0; min. 0,45mm thick (UL E59481) <u>triple insulated wire</u> : +Great Leoflon; TRW-B approved according to Annex U of IEC 60950-1 by UL (UL E211989) UL insulation system (OBJY2) class B provided UL E243347. class B	--	accepted
16- Bridging capacitor (CY1)	+ TDK or equivalent	CD85- E2GA102M YAS	400Vac; 1000pF; min. Y1	(FOWX2 or FOKY2) IEC 60384- 14	UR E37861 VDE
17- Optical isolator (PC1)	Liteon	LTV-817-V- B	Rated insulation min. 5300Vac	IEC 60950	VDE
18- Inductor (L1)	Yao Sheng or GölobTek	RC00010	Open type construction 4µH; 2A	--	Accepted

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object/part No.	manufac- turer/trademark	type/model	technical data	standard	mark(s) of conformity ¹⁾
			<u>core</u> : ferrite; 6mm OD by 8mm <u>coil</u> : enamelled magnet copper wire wound on core 120°C		
19 Diode (ZD2)	Panjit	ZMM series	Max. 38V; 0,5W	--	Accepted

TEST REPORT

Edition 1 - Project 1851838

The following tests were conducted at SIQ. These tests were conducted with satisfactory results, referenced to CB certificate (SI-1679) and SIQ test report (T223-0253/06)

Tests were performed according to the test requirements of CAN/CSA C22.2 No 601-1-M90 (AM1+AM2) and UL Standard 60601-1, 1st Edition.

Details of these results are kept in the CSA Montreal Principal file:

General Requirements, Cl. 3
Humidity, Clause 4.10
Classification, Cl. 5
Marking, Cl. 6
Label Rub Test, Clause 6.1(z)
Power Input, Cl. 7
Requirements Related to Classification Cl. 14
Enclosures and Protective Covers Cl. 16
Separation Cl. 17
Continuous Leakage Current, Cl. 19
Dielectric Strength, Cl. 20
Mechanical Strength, Cl. 21
Stability, Cl. 24
Excessive Temperature, Cl. 42
Interruption of The Power Supply, Cl. 49
Abnormal Operation Fault Condition, Cl. 52
Transformer Short Circuit & Overload, Clause 57.9
Induced Dielectric Strength Test on Transformer, Clauses 57.9.2
Creepage Distance and Air Clearance, Cl. 57.10
Construction and Layout Cl. 59