UL TEST REPORT AND PROCEDURE

Standard:	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Switching Power Adapter
Model:	GT(M) 91120-WWVV-X.X-T2 series where "M" is for Medical, WW is the rated output wattage designation, with a maximum value of "30"; VV is the standard rated output voltage designation, with a maximum value of "48"; -X.X denotes the optional deviation, subtracted or added from standard output voltage in 0.1 volt increments or blank to indicate the no voltage different;
Rating:	Input:100-240 Vac, 50-60 Hz, 1.5A Output: Refer to ID 07-06
Applicant Name and Address:	GLOBTEK (HONG KONG) LTD UNIT 1402, BENSON TOWER 74 HUNG TO RD KWUN TONG KOWLOON HONG KONG

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of Underwriters Laboratories Inc. ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

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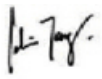
Any information and documentation involving UL Mark services are provided on behalf of Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.

Prepared by:	Steve Chiu Underwriters Laboratories Inc.	
Reviewed by:	Calvin Tang Underwriters Laboratories Inc.	

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

Electronic components mounted to PWB, and housed in plastic enclosure, with Class II appliance inlet, which intended to provide electrical power to medical electrical equipment.

Model Differences

N/A

Technical Considerations

- Classification of installation and use : N/A - Recognized Power Supply
- Supply connection : Appliance coupler
- Accessories and detachable parts included in the evaluation : None
- Options included : None
- The product was investigated to the following additional standards:: IEC 60601-1:1988 + A1:1991 + A2:1995, CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA)
- The product was not investigated to the following standards or clauses:: Clause 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 48, Biocompatibility (ISO 10993-1), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4)
- The product is Classified only to the following hazards:: Casualty, Fire, Shock,
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock:: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- This power supply has not been evaluated for patient connected applications.
- The secondary output circuits of Transformer T1 output is SELV and not at hazardous energy levels.
- The power supply was evaluated as Double Insulation between Primary and Secondary, Double Insulation between Primary and Enclosure. See insulation diagram for details.
- The Temperature Test was performed in an ambient of 40 Deg.C.
- The maximum working voltage present is 242 V rms; 795 V pk-pk. The electric strength tests in the end-product shall be based on this value.
- Consideration should be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The primary transformer (T1) incorporates a Class 130 (B) insulation system.
- The Clearances and Creepage Distances have additionally been assessed for suitability up to 3000 m elevation.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The AC inlet of this switching power supply is polarised type. The suitability need evaluated in the end product.
- The need for conduction Patient leakage current tests should be considered as part of the end product evaluation.
- This power supply has been evaluated as a Class II, 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. An additional evaluation shall be made if the power supply is intended for use in other than Class II equipment.
- This power supply has not been provided with a power supply cord; these items must be considered in the end use product.

Additional Information

The label is a draft of an artwork for marking plate pending approval by National Certification Bodies and it shall not be affixed to products prior to such an approval.

Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File

Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Direct current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Class II equipment	
Output	Rated output voltage, power, frequency.
Special Instructions to UL Representative N/A	

Production-Line Testing Requirements			
Test Exemptions - The following models are exempt from the indicated test			
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
N/A	--	--	--
Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
N/A			
Sample and Test Specifics for Follow-Up Tests at UL			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Model	Samples	Test	Test Details
N/A	--	--	--

TABLE: List of Critical Components

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Enclosure	Sabic Innovative Plastics B V	HF500R(f2)	Rated min V-0, 125 degC Overall 45.3 by 100.3 by 35.2 mm, min 2.0mm thickness.	QMFZ2 (E45329)	UL
Appliance -Inlet	Zhejiang Leci Electronics Co Ltd	DB-8	Rated 5A, 250Vac, 105 degC	AXUT2/8 (E302229)	UL
Appliance –Inlet – Alternate	Kunshan DLK Electronics Technology Co Ltd	CDJ-2	Rated 2.5A, 250Vac, 125 degC	AXUT2/8 (E317189)	UL
Appliance –Inlet – Alternate	Shenzhen Delikang Electronics Technology Co Ltd	CDJ-2	Rated 2.5A, 250Vac, 125 degC	AXUT2/8 (E217394)	UL
Appliance –Inlet – Alternate	Rich Bay Co Ltd	R-201SN90	Rated 2.5A, 250Vac, 105 degC	AXUT2/8 (E184638)	UL
Appliance –Inlet – Alternate	Sun Fair Electric Wire & Cable (HK) Co Ltd	S-01	Rated 2.5A, 250Vac.	AXUT2/8 (E226643)	UL
Appliance –Inlet – Alternate	Inalways Corp	0721 series	Rated 2.5A, 250Vac, 105 degC	AXUT2/8 (E94191)	UL
Fuse (F1) and (F2)	Walter Electronic Co Ltd.	ICP	Rated 3.15A, 250Vac, provided with tubing (YDPU2/8), marked with VW-1, min 300V, 105 degC.	JDYX/7 (E56092)	UL, cUL
Fuse (F1) and (F2) - Alternate	Zhong Shan Lanbao Electrical Co Ltd	RTI-10	Rated 3.15A, 250Vac, provided with tubing (YDPU2/8), marked with VW-1, min 300V, 105 degC.	JDYX/7 (E213695)	UL, cUL
Fuse (F1) and (F2) - Alternate	Various	Various	Rated 3.15A, 250Vac, provided with tubing (YDPU2/8), marked with VW-1, min 300V, 105 degC.	JDYX/7	UL, cUL
Varistor (MOV)	Thinking Electronic Industrial Co Ltd	TVR10471K, TVR07471K, TVR14471K	Rated 300Vac.	VZCA2/8 (E314979)	UL, cUL
Varistor (MOV) - Alternate (Optional)	Joyin Co Ltd	7N471K, 10N471K,	Rated 300Vac.	VZCA2/8 (E325508)	UL, cUL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
		14N471K			
Varistor (MOV) - Alternate (Optional)	Centra Science Corp	CNRV-07D471K, CNRV-10D471K, CNRV-14D471K	Rated 300Vac.	VZCA2/8 (E316325)	UL, cUL
Varistor (MOv) - Alternate (Optional)	Success Electronics Co Ltd	SVR-07D471K, SVR-10D471K, SVR-14D471K	Rated 300Vac.	VZCA2/8 (E330256)	UL, cUL
Varistor (MOv) - Alternate (Optional)	Brightking （Shenzhen） Co Ltd	07D471K, 10D471K, 14D471K	Rated 300Vac.	VZCA2/8 (E327997)	UL, cUL
Varistor (MOV) - Alternate (Optional)	Walsin Technology Corp.	VZ07D471K, VZ10D471K, VZ14D471K	Rated 300Vac.	VZCA2/8 (E309297)	UL, cUL
Varistor (MOV) - Alternate (Optional)	Lien Shun Electronics Co Ltd	07D471K, 10D471K, 14D471K	Rated 300Vac.	VZCA2/8 (E315524)	UL, cUL
Bleeder Resistors (R1A, R1B)	--	--	Min. 0.499M ohm , 1/4W	-	-
X-Capacitor (CX1) (Optional)	Cheng Tung Industrial Co., Ltd.	CTX	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E193049)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	Winday Electronic Industrial Co Ltd	MPX	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E302125)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	ULTRA TECH XIPHI ENTERPRISE CO LTD	HQX	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E183780)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	Okaya Electric Industries Co. LTD	RE series	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E47474)	UL, cUL
X-Capacitor (CX1) - Alternate	VISHAY Capacitors Belgium N V	F1772	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2 (E100682	UL, cUL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
(Optional)				)	
X-Capacitor (CX1) - Alternate (Optional)	Tenta Electric Industrial Co Ltd	MEX	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOKY2/8 (E186475)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	DAIN ELECTRONICS CO LTD	MEX, MPX, NPX	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E147776)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	Sinhua Electronics (Huzhou) Co. Ltd.	MPX	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E237560)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	FOSHAN SHUNDE CHUANG GE ELECTRONIC INDUSTRIAL CO LTD	MKP-X2	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E308832)	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	SHUN DE DAHUA ELECTRIC CO LTD	HD	Rated 0.33uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 (E227157)	UL, cUL
Y-Capacitors (CY1) – (Optional)	WELSON INDUSTRIAL CO LTD	WD	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2/8 (E104572)	UL
Y-Capacitors (CY1) – Alternate (Optional)	SUCCESS ELECTRONICS CO LTD	SE, SB	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2 (E114280)	--
Y-Capacitors (CY1) - Alternate (Optional)	TDK CORP	CD	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2 (E37861)	UL
Y-Capacitors (CY1) - Alternate (Optional)	WALSIN TECHNOLOGY CORP	AH	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2/8 (E146544)	UL
Y-Capacitors (CY1) - Alternate (Optional)	JYA-NAY CO LTD	JN	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2/8 (E201384)	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Y-Capacitors (CY1) - Alternate (Optional)	KUNSHAN WANSHENG ELECTRONICS CO LTD	CT7	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2/8 (E249006)	UL
Y-Capacitors (CY1) - Alternate (Optional)	MURATA MFG CO LTD	KX	Rated 470pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2 (E37921)	UL
Line Filter (LF1)	Various	Various	Open-type construction with ferrite core. Copper wire (OBMW2), rated min. 130degC. See illustration *ID4-12 for details.	-	-
Diode (D1, D2, D3, D4)	--	--	Rated min 2A, min 1000V	-	-
Transistor (Q1)	--	--	Rated min 7A, min600V	-	-
Electrolytic Capacitor (C2)	--	--	Rated 68uF, Min 400V, fully tubed by tubing (YDPU2) 120 degC, VW-1.	-	-
Transformer (T1)	Top Nation Electronic Ltd	GT-3005001 for 5-7.5V GT-3009001 for 7.6V to 10.5V GT-3012001 for 10.6V to 14.5V GT-3015001 for 14.6V to 19.5V GT-3024001 for 19.6V to 24V GT-3048001 for 24.1V to 48V	(OBJY2) Class B insulation system, (E218387), designated M7A90. Open type construction with ferrite core. See enclosed illustration ID 4-11 for construction.	-	-
Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 degC min. MW -75 Type.	OBMW2	UL
Secondary winding used in T1	Furukawa Electric Co Ltd.	TEX-E	Rated 130 degC Triple insulated wire	OBJT2 (E206440)	UL
Bobbin used in T1	HITACHI CHEMICAL	CP-J-8800	Phenolic, rated V-0, 150 degC, min 0.39 mm thick	QMFZ2 (E42956)	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
	CO LTD				
Insulation Tape used in T1	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F	Rated 130 degC	OANZ2 (E17385)	UL
Insulation Tape wrapping over transformer	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F	Rated 130 degC. Min. two layers, minimum 22 mm width.	OANZ2 (E17385)	UL
Varnish used in T1	KYOCERA CHEMICAL CORP	TVB2180T++	Rated 130 degC	OBOR2 (E83702)	UL
Varnish used in T1 - Alternate	HITACHI CHEMICAL CO LTD	WP-2952F-2G	Rated 130 degC	OBOR2 (E72979)	UL
Tube	NIKKAN INDUSTRIES CO LTD	S-693-600	Rated 600V, 200 Degree C,	UZFT2 (E72406)	UL
Transformer (T1) - Alternate	Top Nation Electronic Ltd	GT-3005001 for 5-7.5V GT-3009001 for 7.6V to 10.5V GT-3012001 for 10.6V to 14.5V GT-3015001 for 14.6V to 19.5V GT-3024001 for 19.6V to 24V GT-3048001 for 24.1V to 48V	(OBJY2) Class B insulation system, (E140166), designated SPB-6. Open type construction with ferrite core. See enclosed illustration ID 4-11 for construction.	-	-
Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 degC min. MW -75 or MW28 Type.	OBMW2	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Secondary winding used in T1	Furukawa Electric Co Ltd.	TEX-E	Rated 130 degC Triple insulated wire	OBJT2 (E206440)	UL
Bobbin used in T1	HITACHI CHEMICAL CO LTD	CP-J-8800	Phenolic, rated V-0, 150 degC, min 0.39 mm thick	QMFZ2 (E42956)	UL
Insulation Tape used in T1	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F(#), (#) is replaced with suffix B-1, B-2, W-1, W-2, Y-1 or Y-2	Rated 130 degC	OANZ2 (E17385)	UL
Insulation Tape wrapping over transformer	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F(#), (#) is replaced with suffix B-1, B-2, W-1, W-2, Y-1 or Y-2	Rated 130 degC. Min. two layers, minimum 22 mm width.	OANZ2 (E17385)	UL
Varnish used in T1	KYOCERA CHEMICAL CORP	TVB2180T++	Rated 130 degC	OBOR2 (E83702)	UL
Varnish used in T1 - Alternate	HITACHI CHEMICAL CO LTD	WP-2952F-2G	Rated 130 degC	OBOR2 (E72979)	UL
Tube	NIKKAN INDUSTRIES CO LTD	E651U-1	Rated 300V, 200 Degree C, VW-1	YDTU2 (E88468)	UL
Tube - Alternate	NIKKAN INDUSTRIES CO LTD	S-693-600	Rated 600V, 200 Degree C, VW-1	UZFT2 (E72406)	UL
Tube - Alternate	NIKKAN INDUSTRIES CO LTD	S-693F-1, S-693VF-1	Rated 300V, 200 Degree C,VW-1	UZIQ2 (E55258)	UL
Tube - Alternate	SUMITOMO ELECTRIC FINE POLYMER INC	Sumitube F2	Rated 600V, 125 degC, VW-1	YDPU2 (E48762)	UL
Tube - Alternate	ZEUS INDUSTRIAL PRODUCTS INC	TFE-TW-300	Rated 300V, 200degC, VW-1	YDPU2 (E64007)	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Tube - Alternate	FURUKAWA ELECTRIC CO LTD	PI-Tube	Rated 600V, 200degC, VW-1.	YDTU2 (E58401)	UL
Opto-couplers (U2)	Everlight Electronics Co Ltd	EL817	Rated min. 110degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8 (E214129)	UL
Opto-couplers (U2) - Alternate	Cosmo Electroncis Corp	K1010, KP1010	Rated min. 115degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8 (E169586)	UL
Opto-couplers (U2) - Alternate	Lite-On Technology Corp.	LTV-357T LTV357 LTV-817	Rated min. 115degC Provide min 3750Vac isolation test voltage rating.	FPQU2/8 (E113898)	UL
Opto-couplers (U2) - Alternate	Fairchild	H11A817B, F0D817B	Rated min. 110degC Provide min 5000Vac isolation test voltage rating.	FPQU2/8 (E90700)	UL
Heat Sink - HS1	--	--	Aluminium. Shaped as shown. Secured to PWB by soldering. See ID4-18 for dimension	-	-
Heat Sink - HS2	--	--	Aluminium. Shaped as shown. Secured to PWB by soldering.See ID 4-19 for dimension	-	-
Insulation tape provided on HS2	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350T-1	Provided between primary component C2, C7, CX1 and HS2. Overall measured 42 mm by 18 mm. Min 3 layers or 3 Wraps.	OANZ2/8 (E17385)	UL
DC output cord	Various	Various	Rated min 60V, 24AWG min, 80degC marked with VW-1	AVLV2/8	UL, cUL
Label Artwork	Dongguan Xianquan Printing Co Ltd	Type XQ03	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2 (MH27594)	UL
Label Artwork - Alternate	Fan JA Paper Printing Co Ltd	Type FJ-03-3	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2 (MH19546)	UL
Label Artwork	Fan JA Paper	Type FJ07	Rated min 80 deg C Suitable for use on the plastic	PGDQ2 (	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
	Printing Co Ltd		enclosure	MH19546)	
Label Artwork	Dongguan Xianquan Printing Co Ltd	Type XQ004-B	Rated min 80 deg C Suitable for use on the plastic enclosure	PGJI2 (MH47303)	UL
Label Artwork	E-Lin Adhesive Label Co Ltd	Type EL-15	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2 (MH45549)	UL
PWB	Various	Various	Min V-1, 130 degC.	ZPMV2/8	UL
Thermal Pad	Pioneer Material Precision Tech	PMP-P-300	Provided between Transformer and Heatsink. Rated V-0, 150 degC. Overall measured 50mm by 38 mm, 1.5 mm thick	QMFZ2 (E153203)	UL
Insulator	SKC Co LTD	SH71S	Provided between PWB and Enclosure. Rated VTM-2, 105 degC. Overall measured 91.07mm by 39.72 mm, 0.43 mm thick	QMFZ2 (E74359)	UL

Enclosures

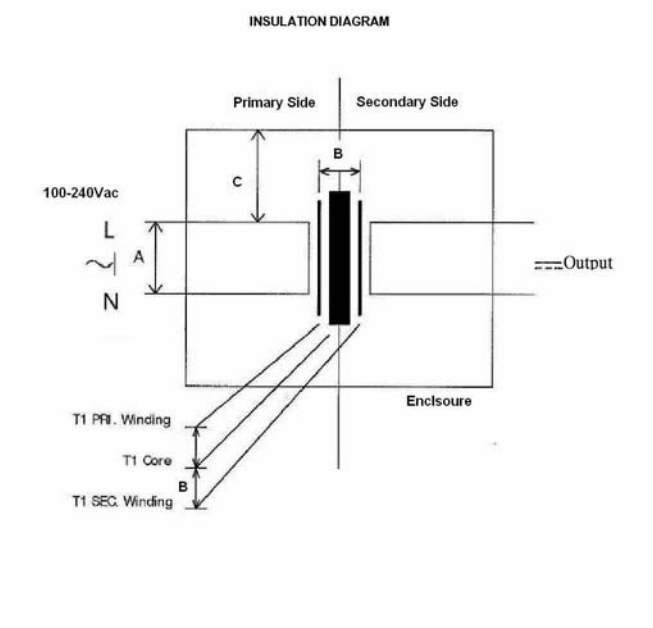
Type	Supplement Id	Description
Collateral		
Particular		
Photographs	3-01	External View 1 of Unit
Photographs	3-02	External View 2 of Unit
Photographs	3-03	Bottom View of Unit
Photographs	3-04	Internal View 1 of Unit
Photographs	3-06	Internal View 2 of Unit
Photographs	3-07	PWB Component Side 1
Photographs	3-10	PWB Component Side 2
Photographs	3-11	PWB Layout Side
Diagrams	4-11	T1 specification
Diagrams	4-12	Choke LF1 specification
Diagrams	4-18	Heatsink 1 dimension drawing
Diagrams	4-19	Heatsink 2 dimension drawing
Schematics + PWB	5-01	PWB Layout
Manuals		
Miscellaneous	7-06	Output List

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		Pass
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 foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
5	**CLASSIFICATION**		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		N/A
	Class II equipment		Pass
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		Pass
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - no applied parts	Adaptor is not an end product and is intended to supply medical electrical system by its output. No applied parts.	Pass
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)..... :	Ordinary equipment. No protection against ingress of water provided.	N/A
5.4	Methods of sterilization or disinfection	To be determined in the end product.	N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures		Pass
	Category AP equipment	Not AP equipment	N/A
	Category APG equipment	Not APG equipment	N/A
5.6	Mode of operation:		Pass
	-continuous operation		Pass
	-short-time operation, specified operation; period. :		-
	-intermittent operation, specified operation; rest period..... :		-
	-continuous operation with short-time, stated permissible loading time..... :		-
	-continuous operation with intermittent, stated permissible loading/rest time..... :		-

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM



IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: to insulation diagram						
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
(A)	BOP	240 V rms	3.0	1.6	4.3	4.3	A-f: L-N before fuse
(B)	DI/RI	240 V rms	8.0	5.0	21.3	14.5	A-a2: T1 Primary to Secondary
(B)	DI/RI	240 V rms	8.0	5.0	17	10.3	A-a2: T1 Pin 1(Primary) to R21 (Secondary)
(B)	DI/RI	240 V rms	8.0	5.0	8.0	8.0	A-a2: U2 Primary pin to Secondary pin
(B)	DI/RI	240 V rms	8.0	5.0	12	9.5	A-a2: CY1 Primary pin to Secondary pin
(C)	DI/RI	240 V rms	8.0	5.0	20.0	20.0	A-a2:Primary circuit - Enclosure

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional.
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6	**IDENTIFICATION, MARKING AND DOCUMENTS**		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
6.1c	Markings of the specific power supply affixed		N/A
6.1d	If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N/A
6.1e	Name and/or trademark of the manufacturer or supplier ..... :	"Globtek (Hong Kong) Ltd" or "E341350"	Pass
6.1f	Model or type reference..... :	See Cover page	Pass
6.1g	Rated supply voltages or voltage range(s)	100-240Vac	Pass
	Number of phases ..... :	Single phases	Pass
	Type of current ..... :	AC	Pass
6.1h	Rated frequency or rated frequency range(s) (Hz) :	50-60Hz	Pass
6.1j	Rated power input (VA, W or A) ..... :	1.5A	Pass
6.1k	Power output of auxiliary mains socket - outlets		N/A
6.1l	Class II symbol	Provided on product label	Pass
	Symbol for degree of protection against ingress of water provided ..... :	IPX0	N/A
	Symbol for protection against electric shock..... :	No applied parts	N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
6.1m	Mode of operation (if no marking, suitable for continuous operation)	Continuous.	N/A
6.1n	Types and rating of external accessible fuses ..... :	Fuse is not accessible from the outside of the equipment	N/A
6.1p	Ratings of external output:..... :	See Cover page	Pass
6.1q	Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents	Not used	N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
6.1r	Anaesthetic-proof symbol: AP or APG ..... :	Not AP or APG type	N/A
6.1s	Dangerous voltage symbol		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6.1t	Special cooling requirements		N/A
6.1u	Limited mechanical stability		N/A
6.1v	Protective packing requirement(s)		N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
6.1y	Potential equalization terminal	Not such terminal provided	N/A
	- Functional earth terminal	Not such terminal provided	N/A
6.1z	Removable protective means		N/A
	Durability of marking test	(see appended table 6.1)	Pass
6.2	Marking on the inside of equipment or equipment parts		N/A
6.2a	Nominal voltage of permanently installed equipment	Not permanently installed equipment	N/A
6.2b	Maximum power loading for heating elements or holders for heating lamps	No such device provided	N/A
6.2c	Dangerous voltage symbol	No such device provided	N/A
6.2d	Type of battery and mode of insertion	No such components provided	N/A
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
6.2e	Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N/A
6.2f	Protective earth terminal	Class II equipment	N/A
6.2g	Functional earth terminal		N/A
6.2h	Supply neutral conductor in permanently installed equipment (N)		N/A
6.2j	Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
6.2k	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
6.2l	Statement for suitable wiring materials at temperatures over 75°C	Not permanently connected equipment.	N/A
6.2n	Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6.3a	Mains switch clearly identified		N/A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	No Mains switch provided.	N/A
6.3b	Indication of different positions of control devices and switches		N/A
6.3c	Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
6.3f	The functions of operator controls and indicators are identified		N/A
6.3g	Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	In accordance with Appendix D.	Pass
6.5	Colors of the insulation of conductors		N/A
6.5a	Protective earth conductor has green/yellow insulation		N/A
6.5b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
6.5c	Only protective or functional earthing, or potential equalization conductors are green/yellow		N/A
6.5d	Color of neutral conductor ..... :	Intergrated in PWB	N/A
6.5e	Colors of phase conductor(s) ..... :	Intergrated in PWB	N/A
	- Compliance with IEC 227 and IEC 245		N/A
6.5f	Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		N/A
6.6a	In accordance with ISO ISO/R 32		N/A
6.6b	Identification of connection point		N/A
6.7	Indicator lights and push-buttons		N/A
6.7a	Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N/A
	- Yellow used to indicate caution or attention required		N/A
	- Green used to indicate ready for action		N/A
6.7b	Color red used only for push-buttons by which a		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	function is interrupted in case of emergency		
6.8	ACCOMPANYING DOCUMENTS		N/A
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	To be determined in end application.	N/A
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		N/A
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents		N/A
6.8.2	Instructions for use		N/A
6.8.2a	General information provided in instructions for use		N/A
	- state the function and intended application of the equipment		N/A
	- include an explanation of: the function of controls, displays and signals		N/A
	- the sequence of operation		N/A
	- the connection and disconnection of detachable parts and accessories		N/A
	- the replacement of material which is consumed during operation		N/A
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		N/A
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N/A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		N/A
	General information provided in instructions:		N/A
	- information for the safe performance of routine maintenance		N/A
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		N/A
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6.8.2c	Signal output or signal input parts intended only for connection to specified equipment described		N/A
6.8.2d	Details about acceptable cleaning, disinfection or sterilization methods included		N/A
6.8.2e	Warning statement for mains operated equipment with additional power source		N/A
6.8.2f	A warning to remove primary batteries if equipment is not likely to be used for some time		N/A
6.8.2g	Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N/A
6.8.2h	Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		N/A
6.8.2j	Identification of any risks associated with the disposal of waste products, residues, etc.		N/A
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		N/A
6.8.3a	All characteristics essential for safe operation provided		N/A
6.8.3b	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		N/A
6.8.3c	Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N/A
6.8.3d	Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		N/A
7	**POWER INPUT**		Pass
	Power Input Measurements		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

10	**ENVIRONMENTAL CONDITIONS**		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	To be determined in end application.	N/A
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	Not hand-held equipment	N/A
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA	Single phase, 100-240 Vac.	Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz	50-60 Hz.	Pass
10.2.2b	Internal replaceable electrical power source specified		N/A

14	**REQUIREMENTS RELATED TO CLASSIFICATION**		Pass
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection		Pass
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	AC power source	N/A
14.5a	Dual classification for internally powered equipment with a means of connection to supply mains	Not Internally powered equipment	N/A
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Not internally powered equipment.	N/A
14.6c	Applied parts intended for direct cardiac application are of type CF		N/A

15	**LIMITATION OF VOLTAGE AND/OR ENERGY**		Pass
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	(see appended table 15b)	Pass
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging	Not manual discharging	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
16	**ENCLOSURES AND PROTECTIVE COVERS**		Pass
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	Equipment is provided with plastic enclosure without any openings.	Pass
	Insertion or removal of lamps - protection against contact with live parts provided	No lamps	N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No openings	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ohm		N/A
	- separated from live parts by one of the means described in Sub-clause 17g		N/A
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N/A
16e	Removable enclosures protecting against contact with live parts		Pass
	- Removal possible only with the aid of a tool		Pass
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts..... :		N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
17	**SEPARATION**		Pass
17a	Separation method of the applied part from live parts:		N/A
	1) basic insulation: applied part earthed	No applied part.	N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		N/A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17g	Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		Pass
	5) by protective impedances limiting current to accessible part		N/A
	- Additional leakage current test in single fault conditions		N/A
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
18	**PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION**		N/A
19	**CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS**		Pass
19.1b	Leakage currents	(see appended table 19)	Pass
	- earth leakage current		N/A
	- enclosure leakage current		Pass
	- patient leakage current		N/A
	- patient auxiliary current		N/A
20	**DIELECTRIC STRENGTH**		Pass
	Overall compliance with Clause 20	(see appended table 20)	Pass
21	**MECHANICAL STRENGTH**		Pass
21a	Sufficient rigidity of an enclosure tested by: force of 45 N		Pass
21b	Sufficient strength of an enclosure tested by: impact hammer	Test covered by Ball Impact, see Sub-clause 55, Ball Drop Test.	Pass
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test		N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test		N/A
21.5	Hand held equipment or equipment parts are safe after drop test		N/A
21.6	Portable and mobile equipment is able to withstand rough handling		N/A
22	**MOVING PARTS**		N/A
23	**SURFACES, CORNERS AND EDGES**		Pass
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	No rough surfaces, sharp corners or sharp edges.	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
24	**STABILITY IN NORMAL USE (see appended table 24)**		N/A
25	**EXPELLED PARTS**		N/A
28	**SUSPENDED MASSES**		N/A
29	**X-RADIATION**		N/A
36	**ELECTROMAGNETIC COMPATIBILITY**		N/A
37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**		N/A
42	**EXCESSIVE TEMPERATURES**		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 42)	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient	(see appended table 42)	Pass
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No such parts.	N/A
43	**FIRE PREVENTION**		Pass
	Strength and rigidity necessary to avoid a fire hazard	Strength and rigidity of the enclosure was tested according to clause 21. For material sources refer to appended to table 56.	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION**		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity	(see appended table 44)	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	Ordinary protection (IPX0) only considered. Other IP must be considered in end use.	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		N/A
45	**PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE**		N/A
48	**BIOCOMPATIBILITY**		N/A
49	**INTERRUPTION OF THE POWER SUPPLY**		N/A
51	**PROTECTION AGAINST HAZARDOUS OUTPUT**		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
52	**ABNORMAL OPERATION AND FAULT CONDITIONS**		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	(see appended table 52)	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		N/A
52.5.2	Failure of thermostats presents no safety hazards	No thermostats presents	N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	(see appended table 19)	Pass
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	No opening	N/A
52.5.6	Locking of moving parts presents no safety hazard	No moving parts	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No such components used	N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	Pass
52.5.10	Overload of heating elements presents no safety hazard	No such components used	N/A
52.5.10f	Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No such components used	N/A
52.5.10h	Equipment with three-phase motors can safely operate with one phase disconnected		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
56	**COMPONENTS AND GENERAL ASSEMBLY**		Pass
	List of critical components		Pass
56.1b	Ratings of components not in conflict with the conditions of use in equipment	The components are used according to their ratings.	Pass
	Ratings of mains components are identified		Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely		Pass
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Internal wire is secured and/or Insulated to prevent accidental detachment resulting in a safety hazards.	Pass
56.3a	Connectors provide separation required by Sub-clause 17g		N/A
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		N/A
	Medical gas connections not interchangeable		N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken		N/A
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		N/A
56.4	Connections of capacitors		Pass
	Not connected between live parts and non-protectively earthed accessible parts		Pass
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		Pass
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		Pass
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		Pass
56.6	Temperature and overload control devices		N/A
56.6a	Thermal cut-outs which have to be reset by a		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	soldering not fitted in equipment		
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
56.6b	Thermostats with varying temperature settings clearly indicated		N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		N/A
56.7a	Battery compartments:		N/A
	- adequately ventilated		N/A
	- accidental short-circuiting is prevented		N/A
56.7b	Incorrect polarity of connection prevented		N/A
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		N/A
	- to indicate that equipment is energized		N/A
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		N/A
56.10	Actuating parts of controls		N/A
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N/A
56.10c	Stops are provided on rotating controls:		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		N/A
56.11a	Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N/A
56.11b	Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being		N/A
56.11c	Devices not change their setting when inadvertently placed		N/A
56.11d	Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
56.11e	Adequate strain relief at the cord entry provided		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
57	**MAINS PARTS, COMPONENTS AND LAYOUT**		Pass
57.1	Isolation from supply mains		Pass
57.1a	Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Appliance inlet provided as disconnecting device.	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		N/A
57.1d	Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328	No switches.	N/A
57.1f	Mains switches not incorporated in a power supply cord	No switches.	N/A
57.1h	Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		Pass
57.1m	Fuses and semiconductor devices not used as isolating devices		Pass
57.2	Mains connectors and appliance inlets		Pass
57.2e	Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		N/A
57.2g	Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		Pass
57.3	Power supply cords		N/A
57.3a	Not more than one connection to a particular supply mains	Investigated in the end product	N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
57.3b	Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
57.3c	Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		N/A
57.3d	Stranded conductors not soldered if fixed by any		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	clamping means		
57.4	Connection of power supply cords		N/A
57.4a	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods		N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
57.5b	Terminals closely grouped with any protective earth terminal		N/A
	Mains terminal devices accessible only with use of a tool		N/A
	Mains terminal devices located or shielded that,		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		
57.5c	Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
57.5d	Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		Pass
	Fuses or over-current releases provided accordingly for Class I and Class II	F1, F2 are provided for each conductor.	Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		Pass
	Protective earth conductor not fused		N/A
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		Pass
57.8a	Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC Publications 227 or 245, treated as bare conductor		Pass
57.8b	Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		Pass
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		Pass
57.9	Mains supply transformers		Pass
57.9.1	Overheating		Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	(see appended table 57.9.1a)	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	(see appended table 57.9.1b)	Pass
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
57.9.4	Construction		Pass
57.9.4a	Separation of primary and secondary windings	Double Insulation provided.	Pass
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation		Pass
57.9.4c	Means provided to prevent displacement of end turns		Pass
57.9.4d	Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
57.9.4e	Insulation between the primary and secondary in transformers with double insulation		Pass
	- 1 insulation layer having a thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		Pass
57.9.4g	Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A
57.10	Creepage distances and air clearances		Pass
57.10a	Values: compliance with at least the values of Table XVI	(refer to insulation diagram)	Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
57.10b	Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard	(see appended table insulation diagram)	Pass
57.10c	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
58	**PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS**		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
59	**CONSTRUCTION AND LAYOUT**		Pass
59.1	Internal wiring		Pass
59.1a	Cables and wiring protected against contact with a moving part		N/A
	Wiring having basic insulation only protected by additional fixed sleeving		Pass
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
59.1b	Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A
59.1c	Insulating sleeving adequately secured		Pass
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
59.1d	Aluminum wires of less than 16 mm2 cross-section not used		N/A
59.1f	Connecting cords between equipment parts considered as belonging to the equipment		N/A
59.2	Insulation		Pass
59.2b	Mechanical strength and resistance to heat and fires retained by all types of insulation		Pass
59.2c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		N/A
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard		N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed		N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	prevent the loss of oil during transport		
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

Enclosure

National Differences

Canada
USA

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

Canada - Differences to IEC 60601-1:1988 + A1:1991 + A2:1995			
6	Canadian difference to this clause no longer applicable		N/A
6.61	Point of connection of gas cylinders:		N/A
6.61	- is gas specific		N/A
6.61	- is non-interchangeable		N/A
6.61	- is identified		N/A
56.3a	Medical gas inlet connectors:		N/A
56.3a	- are gas specific		N/A
56.3a	- are non-interchangeable		N/A
56.3a	- are DISS type complying with CGA V-5		N/A
56.3a	- are configured to permit the supply from assemblies complying with CAN/CSA - Z5359-04 (replaces Z305.2)		N/A
56.6a	Where consequential loss of function caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings provided		N/A
57.2g	Mains plug of non-permanent installed equipment:		N/A
57.2g	- if molded on type - hospital grade complying with CSA C22.2, No. 21		N/A
57.2g	- hospital grade disassembly type complying with CSA C22.2, No. 42		N/A
57.2g	- if Class II equipment - polarized hospital grade CSA configuration 1-15P	Investigated in the end product	N/A
57.3b	Detachable power supply cords:		N/A
57.3b	- unlikely to be detached accidentally		N/A
57.3b	- impedance of earth contacts presents no safety hazard		N/A
57.3b	- possibility of replacement by a cord which could make equipment hazards minimized		N/A
57.3b	- complies with CSA C22.2 NO. 21		N/A
57.3b	- not smaller than No. 18 AWG		N/A
57.3b	- minimum serviceability of Type SJ for mobile equipment or Type SV for other		N/A
57.9	Canadian difference to this clause no longer applicable		Pass
58.2	Canadian difference to this clause no longer		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
	applicable		
59.1	Connecting cables comply with Canadian Electrical Code, Part I		N/A
60	Canadian difference to this clause no longer applicable		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

USA - Differences to IEC 60601-1:1988 + A1:1991 + A2:1995			
3.100.1a	Printed wiring boards comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.	See Table Critical Components.	Pass
3.100.1b	Lithium batteries comply with U.S. National or internationally harmonized component standards	Lithium battery does not provided.	N/A
3.100.1c	Optical isolators comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.	See Table Critical Components.	Pass
3.100.1d	Wiring and tubing comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.	See Table Critical Components.	Pass
3.100.1e	CRT's > 5 inches comply with U.S. National or internationally harmonized component standards	Not provided.	N/A
3.101.1	Primary circuit components up to isolation transformer meet U.S. national or international harmonized component standards		N/A
6	a) All words except the signal words in "CAUTION", WARNING", and "DANGER" markings at least 1.6 mm (1/16 inch) high		N/A
6	b) Signal words "CAUTION", WARNING", and "DANGER" at least 2.8 mm (7/64 inch)		N/A
6	c) Letters in contrast color to the background		N/A
6	Equipment capable of emitting ionizing radiation provided with warning statement		N/A
6	If equipment produced in more than one factory, factory identification marked on the equipment		N/A
6	Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped		N/A
6.2l	Statement for suitable wiring materials at temperatures over 60 ºC		N/A
6.6a	Identification of the content of gas cylinders in accordance with the color coding requirement of ANSI/NFPA99.		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
6.8	Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage	To be determined in end application.	N/A
10.2.2a	Rated voltage not exceeding 250 Vdc or single phase ac or 600 V polyphase ac for equipment up to 4kVA	Single phase, 100-240 Vac.	Pass
10.2.2a	Rated voltage not exceeding 600 V for all other equipment		N/A
14	Fixed equipment and permanent equipment is Class I	Not fixed and premanent equipment	N/A
18m	Earthing of X-ray equipment: All parts operating at over 600 V ac, 850 V dc, or 850 V peak are enclosed in protectively earthed enclosures		N/A
18m	Earthing of X-ray equipment: Connections from high-voltage equipment to other high voltage components made with high voltage shielded cables		N/A
18n	Accessible non-current carrying conductive parts are protectively earthed		N/A
19	Enclosure and earth leakage currents comply with U.S. limits		Pass
22	When risk of injury can occur, end stops are provided		N/A
22	End stops have mechanical strength as determined by the test		N/A
22.4	Dangerous movements of equipment parts which may cause physical injury to the patient or operator are possible only by the continuous activation by the operator		N/A
22.7a	Emergency off switch has red actuator		N/A
22.7a	Emergency off switch: once actuated, maintains the equipment in "off" condition until action, different from that used to actuate, is performed		N/A
22.7a	Emergency off switch is readily accessible to operator		N/A
22.7b	Emergency off switch is marked with word "STOP" or symbol 5110 of IEC 878 in compliance with U.S. Clause 6		N/A
22.7b	Emergency off switch: separate and independent of		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
	the intended movement control		
28.3	No evidence of damage to a safety catch after test		N/A
28.3	Safety catch marking provided		N/A
28.4	No damage to structural parts as a result of loading test		N/A
42	Insulation systems with measured temperatures exceeding Class A 105°C (based on 40°C ambient) comply with UL1446		Pass
55	Polymeric enclosures and external combustible surfaces		Pass
55	Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C		N/A
55	External combustible surface of more than 9.47 m2 or single dimension of 3.7 m have flame spread rating not exceeding 75 (Steiner Tunnel Test)		N/A
55	External combustible surface of more than 4.74 m2 but not exceeding 9.47 m2 have flame spread rating not exceeding 75 (Radiant Panel or Steiner Tunnel Test)		N/A
55	Polymeric enclosures for transportable equipment rated 94V-2 or better		Pass
55	Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better		N/A
55	Polymeric enclosures withstand 6.78 Nm impact test		Pass
55	Polymeric enclosures: no deformation after mold stress test		Pass
55	Polymeric enclosures of hand-held equipment withstands 1.22 m drop test	Not a hand-held unit.	N/A
56.3a	Connector, pin, plug attached to patient connected lead or contact cannot engage any part on the equipment, including separable cord set		N/A
56.3a	Connector, pin, plug attached to patient connected lead or contact cannot make contact with live parts of power receptacle outlet (if product can be used without professional supervision)		N/A
57	Permanently connected equipment provided with field wiring provision in accordance with NEC, ANSI/NFPA 70		N/A
57.2	Power cord mains plug is "Hospital Grade" type	Appliance inlet provided only.	N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
57.2	Grounding reliability marking provided		N/A
57.2	Plug for radiography equipment acceptable for current not less than 50 % of maximum input		N/A
57.2	Plug acceptable for use with current not less than 125 % of rated current		N/A
57.2	Plug acceptable for voltage for which the equipment is configured when shipped		N/A
57.2	Polarized plug wired such that the center contact of edison-base lampholder, single-pole switch or single-pole overcurrent device connected in ungrounded side		N/A
57.3b	Detachable power supply cord unlikely to become detached accidentally		N/A
57.3b	Flexible cord is of type acceptable for application		N/A
57.3b	Flexible cord not smaller than 18 AWG		N/A
57.3b	Flexible cord complies with serviceability requirements		N/A
57.5b	If leads are provided for connection to branch circuit, the free end is in separate compartment		N/A
57.5b	If leads are provided for connection to branch circuit, the free length of leads inside field-wiring compartment is at least 152 mm long		N/A
58.2	Connections are mechanically secured in addition to soldering		N/A
59.1	Installation of connecting cords between parts of equipment in compliance with NEC		N/A
59.1	Cable type acceptable for external interconnection		N/A
400	Oxygen		N/A
400.1	At least one of the following three requirements is satisfied:		N/A
400.1.1	Electrical components separated by barrier per 400.2		N/A
400.1.2	Compartments with electrical components ventilated per 400.3		N/A
400.1.3	Electrical components comply with 400.4 so that cannot be a source of ignition		N/A
400.2	Barrier required by 400.1 is sealed at all joints and holes		N/A
400.3	Ventilation required by 400.1 is such that oxygen		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
	content does not exceed 4% above ambient		
400.4	Under N.C. and S.F.C. the product of the value of no load rms voltage and short circuit rms current less than 10 VA		N/A
400.4	Surface temperature of components below 300°C in N.C. and S.F.C		N/A
400.5	External exhaust gas outlets located at least 20 cm from any electrical component mounted on the outside		N/A
400.6	Hospital beds intended for use with oxygen administering equipment provided with required markings		N/A
400.7	Pendant controls on hospital beds with oxygen administering equipment marked as required		N/A
400.8	Instructions for installation are in compliance with requirements of this clause		N/A
600.1	Separate power units packed with equipment		N/A
600.1	Separate power units provided with correlation marking		N/A
600.2.1	Direct plug-in unit construction and performance comply with required sections of UL1310		N/A
600.2.2	Direct plug-in unit external temperature rise during overheating test do not exceed 65°C		N/A
600.2.3	If direct plug-in unit provided with a mounting tab - unit marked as required by UL1310		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6.1	**TABLE: marking durability**	Pass
Marking tested		Remarks
Label, Type XQ03, by Dongguan Xianquan Printing Co Ltd		Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;
Label, Type FJ-03-3, by Dongguan Xianquan Printing Co Ltd		Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;
Label, Type FJ07, by Fan JA Paper Printing Co Ltd		Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;
Label, XQ004-B, Fan JA Paper Printing Co Ltd		Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;
Label, EL-15, E-Lin Adhesive Label Co Ltd		Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;
supplementary information: -		

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

7	**TABLE: power input**					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Model GT(M)91120-3007.5-2.5-T2		-	-	-	-	-
Maximum Normal Load/--		90	50	473.61	25.327	Max. normal load
Maximum Normal Load/--		90	60	477.38	25.296	Max. normal load
Maximum Normal Load/1.5A		100	50	436.21	25.107	Max. normal load
Maximum Normal Load/1.5A		100	60	440.66	25.117	Max. normal load
Maximum Normal Load/1.5A		240	50	253.61	25.08	Max. normal load
Maximum Normal Load/1.5A		240	60	253.78	24.96	Max. normal load
Maximum Normal Load/ --		264	50	235.62	24.21	Max. normal load
Maximum Normal Load/ --		264	60	237.76	24.43	Max. normal load
Model GT(M)91120-3048-T2		-	-	-	-	-
Maximum Normal Load/--		90	50	637.2	35.34	Max. normal load
Maximum Normal Load/--		90	60	643.8	35.34	Max. normal load
Maximum Normal Load/1.5A		100	50	591.5	35.33	Max. normal load
Maximum Normal Load/1.5A		100	60	599.1	35.45	Max. normal load
Maximum Normal Load/1.5A		240	50	332.92	35.81	Max. normal load
Maximum Normal Load/1.5A		240	60	336.86	35.83	Max. normal load
Maximum Normal Load/ --		264	50	317.55	36.07	Max. normal load
Maximum Normal Load/ --		264	60	318.28	26.06	Max. normal load
supplementary information: Max. normal load: 5Vdc, 4A, Model GT(M)or-91120-3005-T2 ; Max. normal load: 48Vdc, 0.625A, Model GT(M)or-91120-3048-T2 ;						

15b	**TABLE: residual voltage in attachment plug**										Pass
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
Supply Pins (pin 1 and pin 2)	10	9	11	11	10	12	11	11	10	9	Pass
supplementary information: -											

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

15c	**TABLE: residual voltage or energy in capacitors**				N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
supplementary information:					

17h1	**TABLE: defibrillation-proof applied parts**				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
supplementary information:					

17h2	**TABLE: defibrillation-proof recovery time**			N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks
supplementary information:				

18	**TABLE: protective earthing**				N/A
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
supplementary information:					

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

19	**TABLE: leakage current**				Pass
Type of leakage current and test condition (including single faults)		Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Model GT(M)91120-3048-T2		-	-	-	-
EN, NC, S1 = 1, S5 = N		264	60	0.0058/0.0059	MD1 between Enclosure and Earth /100uA
EN, NC, S1 = 1, S5 = R,		264	60	0.0052/0.0054	MD1 between Enclosure and Earth/100uA
EN, SFC (Neutral Open), S1 = 0, S5 = N		264	60	0.0054/0.0055	MD1 between Enclosure and Earth/250uA
EN, SFC (Neutral Open), S1 = 0, S5 = R		264	60	0.0050/0.0051	MD1 between Enclosure and Earth/250uA
EN, NC, S1 = 1, S5 = N		264	60	0.44/0.44	MD1 between Output connector and Earth/100uA
EN, NC, S1 = 1, S5 = R,		264	60	0.46/0.46	MD1 between Output connector and Earth /100uA
EN, SFC (Neutral Open), S1 = 0, S5 = N		264	60	0.50/0.51	MD1 between Output connector and Earth/150uA
EN, SFC (Neutral Open), S1 = 0, S5 = R		264	60	0.50/0.51	MD1 between Output connector and Earth/150uA
Model GT(M)91120-3007.5-2.5-T2		-	-	-	-
EN, NC, S1 = 1, S5 = N		264	60	0.0057/0.0057	MD1 between Enclosure and Earth /100uA
EN, NC, S1 = 1, S5 = R,		264	60	0.0053/0.0054	MD1 between Enclosure and Earth/100uA
EN, SFC (Neutral Open), S1 = 0, S5 = N		264	60	0.0054/0.0056	MD1 between Enclosure and Earth/250uA
EN, SFC (Neutral Open), S1 = 0, S5 = R		264	60	0.0051/0.0051	MD1 between Enclosure and Earth/250uA
EN, NC, S1 = 1, S5 = N		264	60	0.200/0.200	MD1 between Output connector and Earth/100uA
EN, NC, S1 = 1, S5 = R,		264	60	0.200/0.200	MD1 between Output connector and Earth /100uA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	0.220/0.220	MD1 between Output connector and Earth/150uA
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	0.220/0.220	MD1 between Output connector and Earth/150uA

supplementary information:

-- Output terminal leakage current is measured for reference only. -- All measured leakage currents did not exceed allowable limits.

ER - Earth leakage current	A - After humidity conditioning
EN - Enclosure leakage current	B - Before humidity conditioning
P - Patient leakage current	1 - Switch closed or set to normal polarity
PM - Patient leakage current with mains on the applied parts	0 - Switch open or set to reversed polarity
PA - Patient auxiliary current	NC - Normal condition
Fig. 15 - refers to Fig. 15 in IEC601-1	SFC - Single fault condition
MD - Measuring device	

20	**TABLE: dielectric strength**			Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks
Area	-	-	-	-
Area B, Primary – Secondary Output	(A-a2) DI/RI	281.1	4125	No breakdown
Area B, T1 Core - Secondary	(A-a2) DI/RI	281.1	4125	No breakdown
Area B, Triple Wire (Furukawa Electric / TEX-E) *	(A-a2) DI/RI *1.5	281.1	6187	No breakdown
Area B, TWO layer tape (3M Company / 1350F)	(A-a2) DI/RI	281.1	4125	No breakdown
Area C, Primary - Enclosure (without cover)	(A-a2) DI/RI	281.1	4125	No breakdown

supplementary information:

1.5 times of DI/RI voltage for Primary -secondary

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

21	**TABLE: mechanical strength**		Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Enclosure, Top, above T1	Force Test	No Damage	
Enclosure, Bottom, above Label	Force Test	No Damage	
Enclosure, Side, above parting line	Force Test	No Damage	
Enclosure, Bottom, above removable cover	Force Test	No Damage	
Enclosure, Front, near Inlet	Force Test	No Damage	
Enclosure, Back, near output cord	Force Test	No Damage	
Power supply whole unit	Drop Test	No Damage	
supplementary information: -			

24	**TABLE: - stability**		N/A
Part under test	Test condition	Remarks	
supplementary information:			

29	**TABLE: X - radiation**			N/A
Part under test	Test condition	Measured radiation (mR)	Remarks	
supplementary information:				

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

42	**TABLE: normal temperature**	Pass
Supply voltage: See below Ambient temperature: See below	Test Condition: See below	

Measuring location	Measured temperature (°C)	Remarks
Supply Voltage: 90VAC, 60Hz, Label face down, model Model GT(M)91120-3048-T2	-	-
AMBIENT	40	--
AC inlet body	62.01	85
AC inlet Pin	76.05	155
F1	64.03	130
F2	69.2	130
LF1 Winding	108.51	130
C2	103.88	120
D4	106.58	130
CX1	72.9	100
Q1	114.55	130
T1 Core	117.2	130
T1 winding	110.69	120
CY1	90.27	100
U2	98.71	110
D7	105.28	130
LF2	80.22	130
OUTPUT WIRE, Inside near LF2	73.9	80
PWB near Q1	109.95	130
PWB near R11	106.4	130
ENCLOSURE, Inside, above T1	70.19	125
ENCLOSURE, Outside above Label	68.79	85
Supply Voltage: 90VAC, 60Hz, Label face up, model Model GT(M)91120-3048-T2	-	-
AMBIENT	40	--
AC inlet body	64.09	85
AC inlet Pin	80.59	155
F1	68.54	130
F2	72.56	130
LF1 Winding	110.69	130
C2	105.12	120
D4	110.1	130
CX1	76.11	100
Q1	116.29	130
T1 Core	118.07	130
T1 winding	110.47	120
CY1	90.4	100

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U2	100.36	110
D7	105.84	130
LF2	82.65	130
OUTPUT WIRE, Inside near LF2	76.08	80
PWB near Q1	112.22	130
PWB near R11	109.26	130
ENCLOSURE, Inside, above T1	65.24	125
ENCLOSURE, Outside above Label	69.2	85
Supply Voltage: 90VAC, 60Hz, Label face up, model Model GT(M)91120-3007.5-2.5-T2	-	-
AMBIENT	40	--
AC inlet body	56.03	85
AC inlet Pin	66.59	155
F1	60.52	130
F2	62.95	130
LF1 Winding	88.78	130
C2	87.35	120
D4	90.03	130
CX1	64.8	100
Q1	94.42	130
T1 Core	95.32	130
T1 winding	96.32	120
CY1	79.47	100
U2	87.07	110
D7	98.96	130
LF2	82.87	130
OUTPUT WIRE, Inside near LF2	72.62	80
PWB near Q1	92.86	130
COR - indicates measurements taken using change-of-resistance method		
supplementary information: Max normal load 12V, 5A		

44	**TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection**	Pass

Test type and condition	Part under test	Remarks
Humidity: 93%, Temperature: 25degree C, 48 hrs	Power Supply whole Unit	Pass
Preconditioning: 25.5 degC, 4 hrs	Power Supply whole Unit	Pass
Post-Conditioning: 26.7 degC, 50.9 % 1 hrs	Power Supply whole Unit	Pass
supplementary information: --		

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Clause	Requirement + Test	Result - Remark	Verdict

45	**TABLE: hydrostatic pressure and pressure-relief device cycling test**		N/A
Test type and condition	Part under test	Test pressure	Remarks
supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

52	**TABLE: abnormal operation**	Pass
Test type, condition and clause reference	Observed results	Remarks
Model GT(M)91120-3048-T2	--	--
Diode D1	Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A T1= - °C	Test Time: 1 sec Fuse opened immediately
Diode C2	Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A T1= - °C	Test Time: 1 sec Fuse opened immediately
R11	Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A T1= - °C	Test Time: 1sec Fuse opened immediately Q1 damaged
U2B (Pri pin 1-2)	Final Input: 264Vac, 20mA to 120mA, 3W to 20W Final Output: 29V, 0.18A T1= 54.64 °C	Test Time: 7hrs Input and output bouncing
U2A(Sec pin 3-4)	Final Input: 264Vac, 32mA, 0.6W Final Output: 0V, 0A	Test Time: 1 hr Unit shut down
Mosfet Q1 (G-D)	Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A T1= - °C	Test Time: 1sec Fuse opened immediately R11, R12, R13 and R14 damaged
Mosfet Q1 (S-D)	Final Input: 264Vac, 0mA, 0W Final Output: 0V, 0V T1= - °C	Test Time: 1sec Fuse opened immediately R11, R12, R13 and R14 damaged
Mosfet Q1 (G-S)	Final Input: 264Vac, 33mA, 0.6W Final Output: 0V, 0A T1= - °C	Test Time: 1 hr Unit shut down
T1 Pin1-2 (Primary)	Final Input: 264Vac, 0mA, 0W Final Output: 0V, 0A T1= 127.22°C	Test Time: 30mins Input and output bouncing Fuse open after run for 30mins R9, R11, R12, R13 and R14 damaged
T1 Pin3-5 (Primary) Repeat with fuse type: ICP 3.15A	Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A T1= - °C	Test Time: 15mins No hazard Fuse (F1) opened R11, R12 damaged
D7	Final Input: 264Vac, 31.1mA, 0.11W	Test Time: 1 hr

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	Final Output: 0V, 0A T1: -°C	Unit shut down No hazard
R20	Final Input: 264Vac, 34.64mA, 0.59W Final Output: 0V, 0A T1= - °C	Test Time: 1 hr Unit shut down No hazard
U2A(Sec pin 3-4)	Final Input: 264Vac, 30mA, 0.6W Final Output: 0V, 0A T1= - °C	Test Time: 15mins Unit shut down
D7	Final Input: 264Vac, 30mA, 0.6W Final Output: 0V, 0A T1= - °C	Test Time: 1 hrs Unit shut down
R20	Final Input: 264Vac, 35mA, 0.7W Final Output: 0V, 0A T1= - °C	Test Time: 15mins Unit shut down
Output Short	Final Input: 264Vac, 34mA Final Output: - T1= - °C Unit shut down	Test Time: 15mins
Output overload	Final Input: 264Vac, 106.28mA Final Output: 4.65V, 5A T1= 109.64°C Output bouncing at 5.1A	Test Time: 6.5hrs
supplementary information: -		

56.10	**TABLE: actuating parts and controls**	N/A
Part under test	Torque applied	Remarks
supplementary information:		

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Clause	Requirement + Test	Result - Remark	Verdict

56.11b	**TABLE: foot operated control devices-loading**	N/A
Part under test	Observed results	Remarks
supplementary information:		

57.4	**TABLE: cord anchorages**			N/A
Cord under test	Mass of equipment	Pull	Torque	Remarks
supplementary information:				

57.4b	**TABLE: cord bending**		N/A
Cord under test	Test mass	Measured curvature	Remarks
supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

57.9.1a	**TABLE: transformer short circuit**						Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks	
		Primary	Secondary	Ambient			
Model GT(M)911 20-3007.5-2.5-T2	--	--	--	--	--	--	
T1 Sec winding (Pin TA – TB)	OPP	-	22.9	15mins	Final Input:264V, 38mA, 0.67W Enclosure, above T1: - Unit shut down	T1 Sec winding (Pin TA – TB)	
Model GT(M)911 20-3048-T2	--	--	--	--	--	--	
T1 Sec winding (Pin TA – TB)	OPP	-	22.9	15mins	Final Input:264V, 35mA, 0.77W Enclosure, above T1: - Unit shut down	T1 Sec winding (Pin TA – TB)	
supplementary information: -							

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Clause	Requirement + Test	Result - Remark	Verdict

57.9.1b	**TABLE: overload**						Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
Model GT(M)911 20-3007.5-2.5-T2	--	--	--	--	--	--	--
T1 Sec winding (Pin TA – TB)	OPP	110.51	--	25	8.5hrs	--	Final Input: 264Vac, 107.89mA Enclosure (outside), above T1: 77.02°C
Model GT(M)911 20-3048-T2	--	--	--	--	--	--	--
T1 Sec winding (Pin TA – TB)	OPP	154.93		25	8.5hrs	--	Final Input: 264Vac, 113.14mA Enclosure (outside), above T1: 89.31°C
supplementary information: -							

57.9.2	**TABLE: transformer dielectric strength**			N/A
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks
supplementary information:				

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Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
Cl. 16E	Low Voltage Reliability	Unit shutdown immediately	Pass
Cl. 55	Ball Drop, Enclosure	No Damage	Pass
Cl.55	No Damage	No Damage	Pass
Cl. 52.4.1	Power Availability	Maximum VA: 51.6 VA	Pass
Cl. 59.2	Measured 1.1mm impression	Ball Pressure, T1 Bobbin, type CP-J-8800 by Hitachi Chemical Co Ltd	Pass
Cl. 59.2	Measured 1.0mm impression	Ball Pressure, Enclosure, Type HF500R by Sabic Innovative Plastics B V	Pass
supplementary information: -			