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# **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: GTM91120-WWVV-X.X-AB series, GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL. M can be "M" or "-" for market identification and not related to saftey 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; A:T is External/Desktop model. F is Open Frame. P is Encapsulated: when A=T, B can be 2 or 3A, 2 presents Class II, 3A presents Class I; when A=F, B can be Blank or W, W means class II equipment, Blank means class I: when A=P, B can be 2 or 3, 2 means class II equipment, 3 means class I equipment. Rating: Input:100-240 Vac, 50-60 Hz, 1.5A Model GTM91120-WWVV-X.X-AB Output: Refer to ID 07-06 Model GTM91128LI1CEL Output: 4.2V, 1000mA; Model GTM91128LI2CEL Output: 8.4V, 1000mA; Model GTM91128LI3CEL Output: 12.6V, 1000mA; 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 UL LLC ('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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UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

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

Prepared by: Steve Chiu Reviewed by: Calvin Tang

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## **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 -
  - 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.

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## **Product Description**

For model GTM91120-WWVV-X.X-AB series, Electronic components mounted to PWB, and housed in plastic enclosure, with Class II appliance inlet or Class I Inlet, with alternate construction of Open Frame or Encapsulated which intended to provide electrical power to medical electrical equipment.

For models GTM91128LI1CEL, GTM91128LI2CEL, GTM91128LI3CEL, Electronic components mounted to PWB, and housed in plastic enclosure, with Class II appliance inlet, which intended to provide electrical power to battery pack used in medical electrical equipment. Models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL is External/Desktop model.

#### **Model Differences**

Model GTM91120-WWVV-X.X-T3A is identical to Model GTM91120-WWVV-X.X-T2 except the Class Type.

Model GTM91120-WWVV-X.X-PB is identical to Model GTM91120-WWVV-X.X-TB except the Enclosure Construction and with Encapsulation Construction.

Model GTM91120-WWVV-X.X-FB is identical to Model GTM91120-WWVV-X.X-TB except the Enclosure Construction and PWB Layout.

Models GTM91128LI1CEL, GTM91128LI2CEL, GTM91128LI3CEL are identical to Model GTM91120-WWVV-X.X-F2 except employ additional output battery charging circuit, output rating, PWB size and Plastic enclosure.

# **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

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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 UL LLC. When installed in an end-product, consideration must be given to the following:

- This power supply has not been evaluated for non 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 Basic Insulation between Primary and Earthing (Class I), 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 I and 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 I and Class II equipment.
- This power supply has not been provided with a power supply cord; these items must be considered

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in the end use product.

- The Protective bonding wire should not be connected to other equipment as earthing protection.
- During testing, the testing battery is rated 3.7V 1000mAh, 1S-1P, (for model GTM91128LI1CEL) and 11.1V, 1000mAh, 3S-1P (for GTM91128LI1CEL). The suitability of the battery rating and configuration should be considered at end system.
- The filed connection of the output wire of models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL is not evaluated.

#### 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.

SR8152030, no-test require for correction Critical Component Table, due to typographical error.

Project 10CA43386 (Revision)

- Add Model GTM91120-WWVV-X.X-T3A Series
- Add alternate sourece of AC Inet type SO-222 and SC-12S
- Revise model desigantion to GTM91120-WWVV-X.X-AB series

Project 10CA43385 (Revision)

- Add Model GTM91120-WWVV-X,X-P2 Series
- Add Model GTM91120-WWVV-X.X-FW Series

Project 10CA43677 (Revision)

- Add Model GTM91120-WWVV-X.X-P3 Series
- Add Model GTM91120-WWVV-X.X-F Series
- Add Insulation Tape, Type 1350F, 1350-1, 35660Y, LY-20 for HS2
- Correct the model designation of Label to Type FJ-03-1
- Correct the rating of CX1 to 0.47uF and CY1 to 3300pF
- Cancel the description of min 3 layers of insulation tape 1350T-1 (1350T-1 already with 3 layers construction)

Project 11CA59755 (Revision)

- Add Models GTM91128LI1CEL, GTM91128LI2CEL, GTM91128LI3CEL
- Add Alternate Transformer from Shandong Boam Electric Co Ltd

#### **Additional Standards**

The product fulfills the requirements of: The product fulfills the requirements of: CAN/CSA C22.2 No. 601.1-M90 (R1997), CAN/CSA C22.2 No. 601.1S1-94, and CAN/CSA C22.2 No. 601.1B-98 (National Differences for Canada)

#### 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

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N/A

Supply Connection	Voltage range, ac/dc, phases	s if more than single phase	
Alternating current	$\sim$		
Direct current			
Supply Frequency	Rated frequency range in her	rtz	
Power Input	Amps, VA, or Watts		
Class II equipment			
Output	Rated output voltage, power,	frequency.	
Special Instructions	to UL Representative		
N/A			
Production-Line Test	ing Requirements		
Test Exemptions - Th	e following models are exempt f	from the indicated test	
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
N/A			
	ent Test Exemptions - The follo the circuitry during either Dielect		
	N	/A	
Sample and Test Spe	cifics for Follow-Up Tests at L	<u>JL</u>	
The following tests sha	all be conducted in accordance v	vith the Generic Inspection	Instructions
Model	Samples	Test	Test Details

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# **TABLE: List of Critical Components**

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Enclosure (For Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	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
Enclosure (For Encapsulation only)	Sabic Innovative Plastics B V	HF500R(f2)	Rated min V-0, 125 degC Overall 97 by 46 by 32 mm, min 2.0mm thickness.	QMFZ2 (E45329)	UL
Appliance –Inlet (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Zhejiang Leci Electronics Co Ltd	DB-8	Rated 5A, 250Vac, 105 degC	AXUT2/8 (E302229)	UL
Appliance –Inlet – Alternate (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Kunshan DLK Electronics Technology Co Ltd	CDJ-2	Rated 2.5A, 250Vac, 125 degC	AXUT2/8 (E317189)	UL
Appliance –Inlet – Alternate (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Shenzhen Delikang Electronics Technology Co Ltd	CDJ-2	Rated 2.5A, 250Vac, 125 degC	AXUT2/8 (E217394)	UL
Appliance –Inlet – Alternate (For Class II Desktop construction and models	Rich Bay Co Ltd	R-201SN90	Rated 2.5A, 250Vac, 105 degC	AXUT2/8 (E184638)	UL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)					
Appliance –Inlet – Alternate (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Sun Fair Electric Wire & Cable (HK) Co Ltd	S-01	Rated 2.5A, 250Vac.	AXUT2/8 (E226643)	UL
Appliance –Inlet – Alternate (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Inalways Corp	0721 series	Rated 2.5A, 250Vac, 105 degC	AXUT2/8 (E94191)	UL
Appliance –Inlet – Alternate (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Tecx-unions Technology Corp	SO-222 series	Rated 2.5A, 250Vac, 75 degC	AXUT2 (E220004)	UL
Appliance –Inlet – Alternate (For Class II Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Supercom Electronics Co Ltd	SC-12S series	Rated 2.5A, 250Vac, 75 degC	AXUT2/8 (E152973)	UL
Appliance -Inlet - (For	Supercom	SC-14	Rated 2.5A, 250Vac, 75 degC	AXUT2/8	UL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Class I Desktop construction only)	Electronics Co Ltd			(E152973)	
Appliance –Inlet – Alternate (For Class I Desktop construction only)	Tecx-Unions Technology Corp	TU-333	Rated 2.5A, 250Vac, 105degC,	AXUT2/8 (E220004)	UL
Appliance –Inlet – Alternate (For Class I Desktop construction only)	Zhejiang Leci Electronics Co Ltd	DB-6	Rated 5A, 250Vac, 105DegC	AXUT2/8 (E302229)	UL
Appliance –Inlet – Alternate (For Class I Desktop construction only)	Rich Bay Co Ltd	R-30790	Rated 2.5A, 250Vac, 105 degC	AXUT2/8 (E184638)	UL
Appliance –Inlet – Alternate (For Class I Desktop construction)	Sun Fair Electric Wire & Cable (HK) Co Ltd	S-02	Rated 2.5A, 250Vac,	AXUT2/8 (E226643)	UL
Appliance –Inlet – Alternate (For Class I Desktop construction only)	Kunshan DLK Electronics Technology Co Ltd	CDJ-2	Rated 2.5A, 250Vac, 105 degC	AXUT2/8 (E317189)	UL
Appliance –Inlet – Alternate (For Class I Desktop construction only)	Inalways Corp.	0724	Rated 2.5A, 250Vac, 65 degC	AXUT2/8 (E94191)	UL
Input connector (For Open Frame Construction only)	Various	Various	Rated min 240Vac, 1.5A, 85 degC.	ECBT2/8	UL,cUL
Input Lead Wire (For Encapsulation construction only)	Various	Various	Rated min 300V, 105DegC, min 18AWG, VW-1.	AVLV2/8	UL, cUL
Earthing Conductor (For	Various	Various	Yellow and Green in Color, provided between inlet	AVLV2/8	UL, cUL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
class I model only and except for Open Frame construction)			and PWB secondary side. Rated min 300V, 105 degC, VW-1		
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	TVR10471, TVR07471, TVR14471	Rated 300Vac.	VZCA2/8 (E314979)	UL, cUL
Varistor (MOV) - Alternate (Optional)	Joyin Co Ltd	7N471K, 10N471K, 14N471K	Rated 300Vac.	VZCA2/8 (E325508)	UL, cUL
Varistor (MOV) - Alternate (Optional)	Centra Science Corp	CNR07D471K, CNR10D471K, CNR14D471K	Rated 300Vac.	VZCA2/8 (E316325)	UL, cUL
Varistor (MOv) - Alternate (Optional)	Success Electronics Co Ltd	SVR07D471K, SVR10D471K, SVR14D471K	Rated 300Vac.	VZCA2/8 (E330256)	UL, cUL
Varistor (MOv) - Alternate (Optional)	Brightking (Shenzhen) Co Ltd	471KD07, 471KD10, 471KD14	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,	Rated 300Vac.	VZCA2/8 ( E315524)	UL, cUL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
		14D471K			
Bleeder Resistors (R1A, R1B)			Min. 0.499M ohm , 1/4W	-	-
X-Capacitor (CX1) (Optional)	Cheng Tung Industrial Co., Ltd.	CTX	Rated 0.47uF 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 0.47uF 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 0.47uF 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 0.47uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 ( E47474 )	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	VISHAY Capacitors Belgium N V	F1772	Rated 0.47uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2 ( E100682 )	UL, cUL
X-Capacitor (CX1) - Alternate (Optional)	Tenta Electric Industrial Co Ltd	MEX	Rated 0.47uF 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 0.47uF 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 0.47uF 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 0.47uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	FOWX2/8 ( E308832 )	UL, cUL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
X-Capacitor (CX1) - Alternate (Optional)	SHUN DE DAHUA ELECTRIC CO LTD	HD	Rated 0.47uF max. Min 250Vac, 100degC, marked X1 or X2 (meets IEC 60384-14)	E227157 ` )	UL, cUL
Y-Capacitors (CY1) – (Optional)	WELSON INDUSTRIAL CO LTD	WD	Rated 2200pF 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 2200pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2 ( E114280 )	
Y-Capacitors (CY1) - Alternate (Optional)	TDK CORP	CD	Rated 2200pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2 ( E37861 )	UL
Y-Capacitors (CY1) - Alternate (Optional)	WALSIN TECHNOLOGY CORP	АН	Rated 2200pF 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 2200pF max. Min 250V, 105degC, marked with Y1 or Y2 (meets IEC 60384-14)	FOWX2/8 ( E201384 )	UL
Y-Capacitors (CY1) - Alternate (Optional)	KUNSHAN WANSHENG ELECTRONICS CO LTD	CT7	Rated 2200pF 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 2200pF 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.	-	-

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
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, (E212542), 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 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	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	KYOĆERA 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

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Tube	NIKKAN INDUSTRIES CO LTD	S-693-600	Rated 600V, 200 Degree C,	UZFT2 (E72406)	UL
Transformer (T1) - Alternate	XEPEX ELECTRONIC CO 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
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	TVB2180T++	Rated 130 degC	OBOR2 (E83702)	UL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
	CHEMICAL CORP				
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
Tube - Alternate	FURUKAWA ELECTRIC CO LTD	PI-Tube	Rated 600V, 200degC, VW-1.	YDTU2 (E58401)	UL
Transformer (T1) - Alternate	Shan Dong Boam Electric Co 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, (E252329), designated BOAM. Open type construction with ferrite core. See enclosed illustration ID 4-12 for construction.	-	-
Primary winding used in	Various	Various	Polyurethane with or without overcoat Polyamide,	OBMW2	UL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
T1			130 degC min. MW -75 or MW28 Type.		
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)	UL93947
Varnish used in T1	Noroo Paint & Coatings Co Ltd	DVB-2085	Rated 130 degC	OBOR2 ( E93947)	UL
Tube in T1	Great Holding Industrial Co Ltd	TFL	Rated 150V, 200 Degree C, VW-1	YDTU2 (E156256)	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	-	-

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
			dimension		
Heat Sink - HS2 (For Desktop Construction only)			Aluminium. Shaped as shown. Secured to PWB by soldering.See ID 4-19 for dimension	-	-
Heat Sink – HS2 (Alternate) (For Open Frame and Encapsulation construction and model GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)			Aluminium. Shaped as shown. Secured to PWB by soldering.See ID 4-21 for dimension	-	-
Insulation tape provided on HS2 (For Desktop Construction only)	3M COMPANY  ELECTRICAL  MARKETS DIV  (EMD)	1350T-1	Provided between primary component C2, C7, CX1, U2 and HS2. Overall measured 42 mm by 18 mm.	OANZ2 (E17385)	UL
Insulation tape provided on HS2 (For Open Frame and Encapsulation and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350T-1	Provided between primary component C2, C7, CX1, U2 and HS3. Overall measured 42 mm by 18 mm.	OANZ2 (E17385)	UL
Insulation tape provided on HS2 (For Open Frame and Encapsulation and models GTM91128LI1CEL,	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F, 1350-1	Provided between primary component C2, C7, CX1, U2 and HS3. Overall measured 42 mm by 18 mm. Min 3 layers or 3 wraps.	OANZ2 (E17385)	UL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
GTM91128LI2CEL and GTM91128LI3CEL only) - Alternate					
Insulation tape provided on HS2 (For Open Frame and Encapsulation and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only) - Alternate	Symbio Inc	35660Y	Provided between primary component C2, C7, CX1, U2 and HS3. Overall measured 42 mm by 18 mm. Min 3 layers or 3 wraps.	OANZ2 (E50292)	UL
Insulation tape provided on HS2 (For Open Frame and Encapsulation and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only) - Alternate	Shang Shu Liang Yi Tape Industry Co Ltd	LY-20	Provided between primary component C2, C7, CX1, U2 and HS3. Overall measured 42 mm by 18 mm. Min 3 layers or 3 wraps.	OANZ2 (E246820)	UL
DC output cord (For Desktop construction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)	Various	Various	Rated min 60V, 24AWG min, 80degC marked with VW-1	AVLV2/8	UL, cUL
Input connector (For Open Frame Construction only)	Various	Various	Constructed with thermoplastic (QMFZ2), rated min V-2.		
Label (Provided if not using engraving or	Dongguan Xianquan Printing Co Ltd	Type XQ03	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2 ( MH27594 )	UL

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Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
silkscreen)					
Label (Provided if not using engraving or Silkscreen) - Alternate	Fan JA Paper Printing Co Ltd	Type FJ-03-1	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2 ( MH19546 )	UL
Label (Provided if not using engraving or Silkscreen) - Alternate	Fan JA Paper Printing Co Ltd	Type FJ07	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2 ( MH19546 )	UL
Label (Provided if not using engraving or Silkscreen) - Alternate	Dongguan Xianquan Printing Co Ltd	Type XQ004-B	Rated min 80 deg C Suitable for use on the plastic enclosure	PGJI2 ( MH47303 )	UL
Label (Provided if not using engraving) - Alternate	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 (For Desktop construction only)	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 (Optional) (For Desktop construction only)	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
Encapsulation (For Encapsulation construction only)	Dong Guan Shi Pai Hua Chuang Material FTY	808A/B	Rated V-0, 90 degC.	QMFZ2	UL

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# **Enclosures**

<u>Type</u>	Supplement Id	<u>Description</u>
Collateral		
Particular		
Photographs	3-01	External View 1 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-02	External View 2 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-03	Bottom View of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-04	Internal View 1 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-06	Internal View 2 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-07	PWB Component Side 1 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-10	PWB Component Side 2 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-11	PWB Layout Side of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-12	External View of Model GTM91120-WWVV-X.X-T3A series
Photographs	3-13	Internal View 1 of Model GTM91120-WWVV-X.X-T1 series
Photographs	3-14	Internal View 2 of Model GTM91120-WWVV-X.X-T2 series
Photographs	3-15	Top View of GTM91120-WWVV-X.X-P2 series
Photographs	3-16	PWB component side of Model GTM91120-WWVV-X.X-P2 series
Photographs	3-17	PWB Layout side of Model GTM91120-WWVV-X.X-P2 and GTM91120-WWVV-X.X-P3 series
Photographs	3-18	PWB Component Side of Model GTM91120-WWVV-X.X-FW series
Photographs	3-19	PWB Layout side of Model GTM91120-WWVV-X.X-FW and GTM91120-WWVV-X.X-F series
Photographs	3-20	PWB component side of Model GTM91120-WWVV-X.X-P3 series
Photographs	3-21	PWB component side of Model GTM91120-WWVV-X.X-F series
Photographs	3-22	Overalll review of Models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL.
Photographs	3-23	Internal View of models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL.
Photographs	3-24	PWB component side of GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL.
Photographs	3-25	PWB Layout side of GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL.
Diagrams	4-11	T1 specification
Diagrams	4-12	Choke LF1 specification
Diagrams	4-18	Heatsink 1 dimension drawing

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Diagrams	4-19	Heatsink 2 (for Desktop Construction only) dimension drawing
Diagrams	4-21	Heatsink 2 (for Open frame and Encapsulation for struction and models GTM91128LI1CEL, GTM91128LI2CEL and GTM91128LI3CEL only)
Diagrams	4-22	T1 Specification from Shandong Boam Electric Co Ltd
Schematics + PWB	5-01	PWB Layout of Desktop and Encapsulation Construction
Schematics + PWB	5-05	PWB Layout of Open Frame Construction
Schematics + PWB	5-06	PWB Layout of model GTM91128LI1CEL, GTM91128LI2CELand GTM91128LI3CEL
Manuals		
Miscellaneous	7-06	Output List GTM91120-WWVV-X.X-AB series

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		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

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	IEC	60601	
Clause	Requirement + Test	Result - Remar	k Verdict

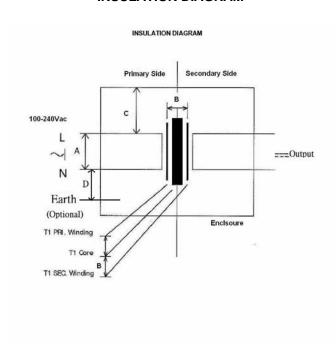
5	CLASSIFICATION		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		N/A
	Class II equipment		Pass
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		Pass
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - 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.	Pass
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:		-

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		IEC 60601		
Clause	Requirement + Test		Result - Remark	Verdict

# **INSULATION DIAGRAM**



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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: to i	nsulation d	iagram				
Area	Insulation type: operational / basic / supplementary / double / reinforced	Referenc e 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	6.0	A-a2:Primary circuit - Enclosure (For desk top model)
(D)	BI	240Vrms	4.0	2.5	5.0	5.0	A-a1: Inlet Earth pin - L/N pin

#### **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.

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	IEC	60601	
Clause	Requirement + Test	Result - Remar	k Verdict

6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside of equipment or equipment p	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
6.11	Class II symbol	Provided on product label for class II construction only	Pass
	Symbol for degree of protection against ingress of water provided:	IPX0 for desktop construction only	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

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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict
			•
6.1s	Dangerous voltage symbol		N/A
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 pa	arts	Pass
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
	<ul> <li>Marking referring to accompanying documents used for battery not intended to be changed by the operator</li> </ul>		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	Appliance inlet provided.	Pass
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
6.21	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

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		IEC 60601		
Clause	Requirement + Test		Result - Remark	Verdict

6.3	Marking of controls and instruments		N/A
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		Pass
6.5a	Protective earth conductor has green/yellow insulation		Pass
6.5b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		Pass
6.5c	Only protective or functional earthing, or potential equalization conductors are green/yellow		Pass
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

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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict
	·		

6.7b	Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
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

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	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		N/A

7	POWER INPUT	Pass	l
	Power Input Measurements	Pass	l

N/A

equipment parts designated by the manufacturer

Environmental conditions for transport and storage

specified in accompanying documents and marked

as repairable provided

on packaging

6.8.3d

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	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

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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict

16	<b>ENCLOSURES AND PROTECTIVE COVERS</b>		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 ha	ndles, 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

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	IEC	C 60601		
Clause	Requirement + Test	Res	ult - Remark	Verdict

17	SEPARATION		Pass
17a	Separation method of the applied part from live part	S:	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
	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 app	plied parts so designed that:	N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	<ul> <li>after exposure to the defibrillation voltage, the equipment continues to perform its intended function</li> </ul>		N/A

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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict

18	PROTECTIVE EARTHING, FUNCTIONAL EARTHI	NG AND POTENTIAL	N/A
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		N/A
18b	Protective earth terminals suitable for connection to the protective earth conductor	No accessible earthing conductor part.	N/A
18e	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table DI		N/A
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part <= 0.1 Ohm		N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part <= 0.1 Ohm		N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part <= 0.2 Ohm		N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ohm, the allowable value of the enclosure leakage current is not exceeded in single fault condition		N/A
18k	Functional earth terminal not used to provide protective earthing		N/A
181	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

19 CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUX		IENT AUXILIARY CURRENTS	Pass
19.1b	Leakage currents	(see appended table 19)	Pass
	- earth leakage current		Pass
	- 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	

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IEC 60601			
Clause	Requirement + Test	Result - Remar	k Verdict

22	MOVING PARTS		N/A
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No such parts.	N/A
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N/A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or other safeguards are removable only with a tool		N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		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

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IEC 60601				
Clause	Requirement + Test		Result - Remark	Verdict

24	STABILITY IN NORMAL USE (see appended table 24)	N/A
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	N/A
24.3	Equipment overbalances when tilted through an angle of 10°	N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport	N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position	N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°	N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:	N/A
	- suitable handling devices (grips etc.), or	N/A
	- instructions for lifting and handling during assembly	N/A
24.6b	On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons	N/A

25	EXPELLED PARTS	
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	N/A

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	IEC 60601				
Clause	Requirement + Test	Result - Remark	Verdict		
28	SUSPENDED MASSES		N/A		
28.3	Suspension system with safety device		N/A		
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4		N/A		
	Safety device has safety factors complying with Sub-clause 28.4.2		N/A		
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N/A		
28.4	Suspension systems of metal without safety devices		N/A		
	Total load does not exceed the safe working load		N/A		
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N/A		
	3) Safety factors not less than 8 where impairment is expected		N/A		
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N/A		
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N/A		
29	X-RADIATION		N/A		
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure <= 130 nC/kg (0.5 mR)		N/A		

37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT	N/A
	Requirements for category AP and APG equipment (Cl. 37 - 41)	N/A

N/A

N/A

Not evaluated by Underwriters

Laboratories Inc.

**ELECTROMAGNETIC COMPATIBILITY** 

Equipment complies with IEC 601-1-2

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

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IEC 60601				
Clause	Requirement + Test		Result - Remark	Verdict

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION  Equipment contain a liquid reservoir:		Pass
44.2			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

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IEC 60601				
Clause	Requirement + Test	Result - Remark	Verdict	

45	PRESSURE VESSELS AND PARTS SUBJECT TO	PRESSURE N/A
45.2	Pressure vessel with pressure volume greater than 200 kPa x I and pressure greater than 50 kPa withstand the hydraulic test pressure	N/A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts	N/A
45.7	Unless excessive pressure can not occur, pressure-relief device provided	N/A
45.7a	a) Pressure-relief device connected as close as possible to the pressure vessel	N/A
45.7b	b) Readily accessible for inspection	N/A
45.7c	c) Not capable of being adjusted or rendered inoperative without a tool	N/A
45.7d	d) Discharge opening located that the released material is not directed towards person	N/A
45.7e	e) Discharge opening located that operation will not deposit material which may cause a safety hazard	N/A
45.7f	f) Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure	N/A
45.7g	g) No shut-off valve between a pressure-relief device and the parts intended to be protected	N/A
45.7h	h) Minimum number of cycles of operation: 100.000	N/A

48	BIOCOMPATIBILITY		N/A
	· ·	Not evaluated by Underwriters Laboratories Inc.	N/A

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IEC 60601				
Clause	Requirement + Test		Result - Remark	Verdict

49	INTERRUPTION OF THE POWER SUPPLY		N/A
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No automatic resetting devices.	N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		N/A
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N/A

51	PROTECTION AGAINST HAZARDOUS OUTPUT	N/A
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	N/A

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

52	ABNORMAL OPERATION AND FAULT CONDITION	ONS	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

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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 cutouts		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

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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):	
	- 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

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56.11d

56.11e

	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	

N/A

N/A

N/A

Foot-operated control devices are at least IPX 1

Adequate strain relief at the cord entry provided

- For surgical use, electrical switching parts are IPX

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	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

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	IEC 60601			
Clause	Requirement + Test	Result - Remar	k 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

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IEC 60601

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57.9.1

57.9.1a

57.9.1b

57.9.2

Overheating

inoperative

tests

excessive temperature

excessive temperature

External to the transformer protective devices

Short-circuit of secondary windings not caused

The dielectric strength of the electrical insulation of

a mains supply transformer such that it passes

Overload of secondary windings not caused

connected in such a way that failure of any component cannot render the protective devices

	IEC 0000 I		
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

Pass

Pass

Pass

Pass

N/A

(see appended table 57.9.1a)

(see appended table 57.9.1b)

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	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 trainsulation	nsformers with double	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
	<ul> <li>three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation</li> </ul>		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

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	IEC 60601			
Clause	Requirement + Test	Result - Remar	k Verdict	

58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS	N/A
58.1	Clamping means of the protective earth terminal	N/A
	Not be able to loosen without the aid of a tool	N/A
	Screws for internal earth connections are covered or protected against loosening from outside	N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	N/A
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing	N/A
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	N/A

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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

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	prevent the loss of oil during transport		
l .	prevent the loss of oil during transport		

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2012-07-21

## **Enclosure**

## **National Differences**

Canada USA Issue Date: 2011-10-03 Page 2 of 9 Report Reference # E341350-A3-UL

IEC 60601		
SubClause Difference + Test	Result - Remark	Verdict

	Canada - Differences to IEC 60601-1:1988 + A1:1	991 + 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	nvestigated 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	Protective earth connections comply with CSA		N/A

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	IEC 60601		
SubClause	Difference + Test	Result - Remark	Verdict

	C22.2 No. 04	
59.1	Connecting cables comply with Canadian Electrical Code, Part I	N/A
60	Canadian difference to this clause no longer applicable	N/A

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	IEC 60601		
SubClause	Difference + Test	Result - Remark	Verdict

	USA - Differences to IEC 60601-1:1988 + A1:1	991 + A2:1995	
1.1	Section 5 Safety hazards resulting from intended physiological function of and ionizing radiation resulting from equipment covered by this standard are not considered. Such equipment is subject to US FDA requirements and US Federal Radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.		N/A
2.4.1	High voltage X-Ray installations Long Time and Momentary ratings definitions Clause 6, 6.2 and product markings shall agree with the NEC.		N/A
2.10.100	X-Ray INSTALLATIONS (MOMENTARY RATING): A rating based on an operating interval that does not exceed 5 secs. (See also 2.10DV.13 in UL 60601-1)		N/A
2.10.101	X-Ray INSTALLATIONS (LONG-TIME RATING): A rating based on an operating interval of 5 minutes or longer. (See also 2.10DV.12 in UL 60601-1)		N/A
2.10.102	Equipment shall comply with ANSI/AAMI Safety Current Limits (SCL) and ANSI/NFPA 99 Health Care Facilities Standards. X-ray equipment need only comply with the Clause 19 requirements in UL 2601-1. (See also 19.5DV.1 in UL 60601-1)		N/A
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 also 3.10DV.1.1 a) in UL 60601-1)	See Table Critical Components.	Pass
3.100.1b	Lithium batteries comply with U.S. National or internationally harmonized component standards (See also 3.10DV.1.1 b) in UL 60601-1)	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 also 3.10DV.1.1 c) in UL 60601-1)	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	See Table Critical Components.	Pass

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	IEC 60601		
SubClause	Difference + Test	Result - Remark	Verdict

	Hazard.(See also 3.10DV.1.1 d) in UL 60601-1)		
3.100.1e	CRT's > 5 inches comply with U.S. National or internationally harmonized component standards (See also 3.10DV.1.1 e) in UL 60601-1)	Not provided.	N/A
3.101.1	Primary connected components up to isolation transformer meet U.S. national or international harmonized component standards(See also 3.10DV.2 in UL 60601-1)		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 (See also 6DV.1 a) in UL 60601-1)		N/A
6	b) Signal words "CAUTION", WARNING", and "DANGER" at least 2.8 mm (7/64 inch) (See also 6DV.1 b) in UL 60601-1)		N/A
6	c) Letters in contrast color to the background (See also 6DV.1 c) in UL 60601-1)		N/A
6	Equipment capable of emitting ionizing radiation provided with warning statement (See also 6DV.2 in UL 60601-1)		N/A
6	If equipment produced in more than one factory, factory identification marked on the equipment (See also 6DV.3) in UL 60601-1)		N/A
6	Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped (See also 6DV.4 in UL 60601-1)		N/A
6.2l	Statement for suitable wiring materials at temperatures over 60 °C (See also 6.2DV in UL 60601-1)		N/A
6.6a	Identification of the content of gas cylinders in accordance with the color coding requirement of ANSI/NFPA99.(See also 6.5DV in UL 60601-1)		N/A
6.8	Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage(See also 6.8DV in UL 60601-1)	To be determined in end application.	N/A
10.2.2a	Replace "500V" with "600V" associated with the first dash (2nd bullet). (see also 2.2.2DV in UL60601-1.)	Single phase, 100-240 Vac.	Pass
10.2.2a	Replace "500V" with "600V" associated with the first dash (3rd bullet).(see also 2.2.2DV in UL60601-1.)		N/A
14	Fixed equipment and permanent equipment is Class I (see also 14DV in UL60601-1)	Not fixed and premanent equipment	N/A

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		IEC 60601		
SubClause	Difference + Test		Result - Remark	Verdict

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 (see also 18DV in UL60601-1)	N/A
18m	Earthing of X-ray equipment: Connections from high-voltage equipment to other high voltage components made with high voltage shielded cables (see also 18DVm in UL 60601-1)	N/A
18n	Accessible non-current carrying conductive parts are protectively earthed (see also 18DVn in UL60601-1)	N/A
19	Enclosure and earth leakage currents comply with U.S. limits (see also 19.5DV in UL 60601-1)	Pass
22	When risk of injury can occur, end stops are provided (see also 22DV.1 in UL60601-1)	N/A
22	End stops have mechanical strength as determined by the test (see 22DV.2-4 in UL60601-1)	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 (see also 22.4DV in UL60601-1)	N/A
22.7a	Emergency off switch has red actuator (see also 22.7DV a1) in UL60601-1)	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 (see also 22.7DV a2) in UL60601-1)	N/A
22.7a	Emergency off switch is readily accessible to operator (see also 22.7DV a3) in UL60601-1)	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 the intended movement control (see also 22.7DV in UL60601-1)	N/A
28.3	No evidence of damage to a safety catch after test (see also 28.3DV in UL60601-1)	N/A
28.3	Safety catch marking provided (see also 28.3DV in UL60601-1)	N/A
28.4	No damage to structural parts as a result of loading test (see also 28.4DV.1&2 in UL60601-1)	N/A
	·	

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		IEC 60601		
SubClause	Difference + Test		Result - Remark	Verdict

42	Insulation systems with measured temperatures exceeding Class A 105°C (based on 40°C ambient) during normal use and normal conditions shall comply with UL1446		Pass		
55	Polymeric enclosures and external combustible surf UL60601-1)	aces (see also 55DV.1 in	Pass		
55	Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C (see also 55DV.2 in UL60601-1)		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)(see also 55DV.3.1 in UL60601-1)				
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)(see also 55DV.3.2 in UL60601-1)		N/A		
55	Polymeric enclosures for transportable equipment rated 94V-2 or better (see also 55DV.4.1 in UL60601-1)		Pass		
55	Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better (see also 55DV.4.1 in UL60601-1)		N/A		
55	Polymeric enclosures withstand 6.78 Nm impact test (see also 55DV.4.3 in UL60601-1)		Pass		
55	Polymeric enclosures: no deformation after mold stress test (see also 55DV.4.1 in UL60601-1)		Pass		
55	Polymeric enclosures of hand-held equipment withstands 1.22 m drop test (see also 55DV.4.4 in UL 60601-1)	Not a hand-held unit.	N/A		
56.3a	The likelihood of a patient connected lead or part being misused so as to introduce a safety hazard shall be investigated. Connector, pin, plug attached to patient connected lead or contact cannot engage any part on the equipment, including separable cord set (see also 56.3DV.1 in UL60601-1)		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) (see also 56.3DV.2 in UL60601-1)		N/A		

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		IEC 60601		
SubClause	Difference + Test		Result - Remark	Verdict

57	All equipment installations are required to be permanently connected equipment provided with field wiring provision in accordance with NEC, ANSI/NFPA 70 (see also 57DV.1 in UL60601-1)		N/A	
57.2	Power cord mains plug is "Hospital Grade" type (see also 57.2DV.1 in UL60601-1)	Appliance inlet provided only.	N/A	
57.2	Grounding reliability marking provided (see also 57.2DV.2 in UL60601-1)		N/A	
57.2	Radiographic control disconnect mains plugs shall be acceptable for a current not less than 50 percent of the maximum input current measured. (see also 57.2DV.3 in uL60601-1)			
57.2	Except for X-Ray equipment mains plugs shall be rated not less than 125% of rated current of the equipment (see also 57.2DV.4 in UL 60601-1)			
57.2	Plug acceptable for voltage for which the equipment is configured when shipped (see also 57.2DV.4 in UL60601-1)			
57.2	Where a polarized mains plug is used with edison-base lampholders or any single-pole protective device, it shall be connected in the ungrounded side of the line, except if it is in addition to the one in the ungrounded side. (see also 57.2DV.5&6 in UL60601-1)		N/A	
57.3b	A detachable power cord for non-permanently installed equipment shall be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safty hazard. (see also 57.3DVb) in UL60601-1)		N/A	
57.3b	Flexible cord is of type acceptable for application (see also 57.3DVb) 1) in UL60601-1)		N/A	
57.3b	Flexible cord not smaller than 18 AWG (57.3DVb) 2) in UL60601-1)		N/A	
57.3b	Flexible cord complies with serviceability requirements (57.3DVb) 2) in UL60601-1)		N/A	
57.5b	If leads are provided for connection to branch circuit, the free end is in separate compartment (see also 57.5DV in UL60601-1)		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 (see also 57.5DV in UL60601-1)		N/A	

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	IEC 60601		
SubClause	Difference + Test	Result - Remark	Verdict

58.2	Connections shall be made mechanically secure as well as bing soldered. (see also 58.2DV in UL60601-1)	N/A
59.1	Power supply cords and internal wiring including interconnection cords between equipment shall meet the requirements of NEC.	N/A
59.1	Cable type acceptable for external interconnection	N/A
400	For equipment which uses oxygen or recommends use with oxygen, special safety hazards associated with use of oxygen addressed in accordance with Clause 400. These requirements are based on oxygen-related requirements from IEC60601-2-19, particular requirements for the safety of baby incubators. (see also 43.2DV in UL60601-1)	N/A
600.1	Separate power units packed with equipment or provided with correlation marking (see also 60DV.1.1.1 in UL60601-1)	N/A
600.2.1	Direct plug-in unit construction and performance comply with required sections of UL1310 (see also 60DV.1.2.2 in UL60601-1)	N/A
600.2.2	Direct plug-in unit external temperature rise during overheating test does not exceed 65°C (60DV.1.2.3.2 in UL60601-1)	N/A
600.2.3	If direct plug-in unit provided with a mounting tab - unit marked as required by UL1310 (see also 60DV.1.2.4 in UL60601-1)	N/A

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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict

6.1	6.1 TABLE: marking durability			
Marking test	ed	Remarks		
		Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;		
Test with distilled water, Duration 15s; Test with methylated spirit, Duration 15s; Test with isopropyl alcohol, Duration 15s;		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, XQ00	4-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:				

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		IEC 60601		
Clause	Requirement + Test		Result - Remark	Verdict

7 TABLE: power input	ut				Pass
Operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Model GTM91120-3007.5-2.5-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 GTM91120-3048-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
Model GTM91120-3007.5-2.5- P2	-	-	-	-	-
Maximum Normal Load/	90	50	0.521	25.3	Max. normal load
Maximum Normal Load/	90	60	0.515	25.2	Max. normal load
Maximum Normal Load/1.5A	100	50	0.472	25.1	Max. normal load
Maximum Normal Load/1.5A	100	60	0.458	25.0	Max. normal load
Maximum Normal Load/1.5A	240	50	0.231	24.8	Max. normal load
Maximum Normal Load/1.5A	240	60	0.236	24.9	Max. normal load
Maximum Normal Load/	264	50	0.219	24.8	Max. normal load
Maximum Normal Load/	264	60	0.223	24.9	Max. normal load
Model GTM91120-3048-P2	-	-	-	-	-
Maximum Normal Load/	90	50	0.730	36.6	Max. normal load
Maximum Normal Load/	90	60	0.715	36.5	Max. normal load
Maximum Normal Load/1.5A	100	50	0.643	36.4	Max. normal load
Maximum Normal Load/1.5A	100	60	0.645	36.3	Max. normal load
Maximum Normal Load/1.5A	240	50	0.325	37.9	Max. normal load
Maximum Normal Load/1.5A	240	60	0.323	36.9	Max. normal load
Maximum Normal Load/	264	50	0.310	38.1	Max. normal load
Maximum Normal Load/	264	60	0.303	36.9	Max. normal load
Model GTM91128LI1CEL					
Maximum Normal Load/	90	50	0.1551	6.66	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/	90	60	0.1539	6.67	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/1.5A	100	50	0.1429	6.69	Max. normal load, 4.2V, 1000mA

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	IEC 60601		
Clause	Requirement + Test	Result - Remark	Verdict

Maximum Normal Load/1.5A	100	60	0.1425	6.67	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/1.5A	240	50	0.0850	6.99	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/1.5A	240	60	0.0905	6.92	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/	264	50	0.0835	7.03	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/	264	60	0.0964	7.09	Max. normal load, 4.2V, 1000mA
Maximum Normal Load/	90	50	0.1839	8.03	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/	90	60	0.1800	8.01	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/1.5A	100	50	0.1678	7.99	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/1.5A	100	60	0.1640	7.95	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/1.5A	240	50	0.0964	8.30	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/1.5A	240	60	0.1058	8.31	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/	264	50	0.0936	8.35	Max. normal load, Charging Discharged battery (1S-1P)
Maximum Normal Load/	264	60	0.1014	8.38	Max. normal load, Charging Discharged battery (1S-1P)
Model GTM91128LI3CEL					
Maximum Normal Load/	90	50	0.3217	14.94	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/	90	60	0.3137	14.96	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/1.5A	100	50	0.2933	14.92	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/1.5A	100	60	0.2873	14.94	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/1.5A	240	50	0.1533	15.26	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/1.5A	240	60	0.1590	15.17	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/	264	50	0.1442	15.23	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/	264	60	0.1542	15.46	Max. normal load, 12.6V, 1000mA
Maximum Normal Load/	90	50	0.3115	14.39	Max. normal load, Charging Discharged battery (3S-1P)
Maximum Normal Load/	90	60	0.3084	14.40	Max. normal load, Charging Discharged battery (3S-1P)
Maximum Normal Load/1.5A	100	50	0.2846	14.31	Max. normal load, Charging

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					Discharged battery (3S-1P)
Maximum Normal Load/1.5A	100	60	0.2799	14.36	Max. normal load, Charging
					Discharged battery (3S-1P)
Maximum Normal Load/1.5A	240	50	0.1483	14.54	Max. normal load, Charging
					Discharged battery (3S-1P)
Maximum Normal Load/1.5A	240	60	0.1524	14.44	Max. normal load, Charging
					Discharged battery (3S-1P)
Maximum Normal Load/	264	50	0.1401	14.58	Max. normal load, Charging
					Discharged battery(3S-1P)
Maximum Normal Load/	264	60	0.1472	14.90	Max. normal load, Charging
					Discharged battery (3S-1P)

supplementary information:

Max. normal load: 5Vdc, 4A, Model GTM 91120-3007.5-2.5-AB Series; Max. normal load: 48Vdc, 0.625A, Model GTM 91120-3048-AB Series;

15b	TABLE: reside	ual vol	tage in	attach	ment <sub> </sub>	olug						Pass
Voltage mea	asured				Мє	easurer	nents [	V ]				Remarks
between:		1	2	3	4	5	6	7	8	9	10	
Supply Pins 2)	( pin 1 and pin	10	9	11	11	10	12	11	11	10	9	Model GTM91120- WWVV- X.X-T2
pin 1 and Ea	arthing pin)	0	0	0	0	0	0	0	0	0	0	Model GTM91120- WWVV- X.X-T3A
pin 2 and Ea	arthing pin)	0	0	0	0	0	0	0	0	0	0	Model GTM91120- WWVV- X.X-T3A
supplement	ary information:									•	•	

15c	TABLE: residual voltage	ABLE: residual voltage or energy in capacitors				
Capacitor ar	nd its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
supplementa	ary information:					

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Clause	Requirement + Test		Result - Remark	Verdict

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
supplementa	ry information:				

17h2	TABLE: defibrillation-proof recovery time					N/A
Applied part with test volt		Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Rema	rks
supplementa	ary information:					

18	TABLE: protective earthing					N/A
Test location		Test current (A)	Measured voltage (V)	Resistance (ohms)	F	Remarks
supplementa	ary information:					
No accessib	le earthing part					

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Clause	Requirement + Test	Result - Remark	Verdict

19	TABLE: leakage current				Pass
	kage current and test condition ingle faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
	191120-3048-T2	-	-	-	-
	= 1, S5 = N	264	60	28 /29	MD1 between Enclosure and Earth /500uA
EN, NC, S1	= 1, S5 = R,	264	60	28 /29	MD1 between Enclosure and Earth/500uA
EN, SFC (N	Neutral Open), S1 = 0, S5 = N	264	60	28 /29	MD1 between Enclosure and Earth/500uA
EN, SFC (N	leutral Open), S1 = 0, S5 = R	264	60	28 /29	MD1 between Enclosure and Earth/500uA
EN, NC, S1	= 1, S5 = N	264	60	245 /237	MD1 between Output connector and Earth/500uA
EN, NC, S1	= 1, S5 = R,	264	60	245 /237	MD1 between Output connector and Earth /500uA
EN, SFC (N	Neutral Open), S1 = 0, S5 = N	264	60	359 /388	MD1 between Output connector and Earth/500uA
EN, SFC (N	leutral Open), S1 = 0, S5 = R	264	60	359 /388	MD1 between Output connector and Earth/500uA
Model GTM	191120-3007.5-2.5-T2	-	-	-	-
, ,	= 1, S5 = N	264	60	9 /10	MD1 between Enclosure and Earth /500uA
	= 1, S5 = R,	264	60	9 /10	MD1 between Enclosure and Earth/500uA
	Neutral Open), S1 = 0, S5 = N	264	60	9 /10	MD1 between Enclosure and Earth/500uA
EN, SFC (N	leutral Open), S1 = 0, S5 = R	264	60	9 /10	MD1 between Enclosure and Earth/500uA
EN, NC, S1	= 1, S5 = N	264	60	93 /91	MD1 between Output connector and Earth/500uA
EN, NC, S1	= 1, S5 = R,	264	60	93 /91	MD1 between Output connector and Earth /500uA

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EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	131 /129	MD1 between
				Output connector
				and Earth/50uA
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	131 /129	MD1 between
				Output connector
				and Earth/500uA
Model GTM91120-3005-T1	Earth			
	Leakage			
ER, NC, S1 = 1, S5 = N	264	60	85 /87	500uA
ER, NC, S1 = 1, S5 = R	264	60	85 /87	500uA
ER, SFC (Neutral Open), S1 = 0, S5 = N	264	60	121 /124	500uA
ER, SFC (Neutral Open), S1 = 0, S5 = R	264	60	121 /124	500uA
Enclosure Leakage				
EN, NC, S1 = 1, S5 = N	264	60	7 /8	MD1 between
214, 140, 01 - 1, 05 - 14	204		' '	Enclosure and Earth
				/500uA
EN, NC, S1 = 1, S5 = R,	264	60	7 /8	MD1 between
LIN, INC, 31 - 1, 33 - 11,	204	00	1 70	Enclosure and
				Earth/500uA
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	7 /8	MD1 between
Liv, 31 6 (Neutral Open), 31 - 0, 33 - N	204	00	1 70	Enclosure and
				Earth/500uA
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	7 /8	MD1 between
EN, SEC (Neutral Open), ST = 0, SS = R	204	60	7 /0	
				Enclosure and
EN, NC, S1 = 1, S5 = N	264	60	84 /85	Earth/500uA
EIN, INC, ST = 1, SS = IN	204	60	04 /03	MD1 between
				Output connector
EN, NC, S1 = 1, S5 = R,	004	00	04 /05	and Earth/500uA
EN, NC, SI = 1, SS = R,	264	60	84 /85	MD1 between
				Output connector
ENLOGO (Novitral Open) C4 = 0 C5 = N	004	00	400 /400	and Earth /500uA
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	120 /122	MD1 between
				Output connector
ENLOGO (Novitral Organ) C4 = 0, C5 = D	004	00	120 /122	and Earth/500uA
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	120/122	MD1 between
				Output connector
May 1-1 OTMO4400 0040 T4	<b>—</b> 41-			and Earth/500uA
Model GTM91120-3048-T1	Earth			
ED NO. 04 - 4. 05 - N	Leakage	00	000 /007	500A
ER, NC, S1 = 1, S5 = N	264	60	226 /227	500uA
ER, NC, S1 = 1, S5 = R	264	60	226 /227	500uA
ER, SFC (Neutral Open), S1 = 0, S5 = N	264	60	344 /346	500uA
ER, SFC (Neutral Open), S1 = 0, S5 = R	264	60	344 /346	500uA
Enclosure Leakage				
EN, NC, S1 = 1, S5 = N	264	60	7 /8	MD1 between
				Enclosure and Earth
				/500uA
EN, NC, S1 = 1, S5 = R,	264	60	7 /8	MD1 between

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	T	ı	1	1
				Enclosure and
				Earth/500uA
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	7 /8	MD1 between
				Enclosure and
				Earth/500uA
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	7 /8	MD1 between
				Enclosure and
				Earth/500uA
EN, NC, S1 = 1, S5 = N	264	60	84 /85	MD1 between
				Output connector
				and Earth/500uA
EN, NC, S1 = 1, S5 = R,	264	60	84 /85	MD1 between
				Output connector
				and Earth /500uA
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	120 /122	MD1 between
				Output connector
				and Earth/500uA
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	120 /122	MD1 between
				Output connector
				and Earth/500uA
Model GTM91120-3048-FW				
Enclosure Leakage				
EN, NC, S1 = 1, S5 = N	264	60	45.7/46.3	MD1 between
				Output connector
				and Earth
EN, NC, S1 = 1, S5 = R,	264	60	45.4/46.0	MD1 between
				Output connector
				and Earth
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	96.2/96.4	MD1 between
				Output connector
				and Earth
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	95.8/95.8	MD1 between
				Output connector
				and Earth
Model GTM91120-3048-P2				
Enclosure Leakage				
EN, NC, S1 = 1, S5 = N	264	60	4.2/3.7	MD1 between
				Enclosure and Earth
EN, NC, S1 = 1, S5 = R,	264	60	5.0/4.6	MD1 between
				Enclosure and Earth
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	12.8/10.5	MD1 between
				Enclosure and Earth
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	12.7/11.3	MD1 between
				Enclosure and Earth
EN, NC, S1 = 1, S5 = N	264	60	22.0/21.8	MD1 between
				Output connector
				and Earth
EN, NC, S1 = 1, S5 = R,	264	60	21.9/21.8	MD1 between
				Output connector

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				and Earth
EN, SFC (Neutral Open), S1 = 0, S5 = N	264	60	57.7/57.5	MD1 between
				Output connector
				and Earth
EN, SFC (Neutral Open), S1 = 0, S5 = R	264	60	63.3/63.0	MD1 between
				Output connector
				and Earth

## supplementary information:

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

ER - Earth leakage current

EN - Enclosure leakage current

P - Patient leakage current

PM - Patient leakage current with mains on the applied parts

PA - Patient auxiliary current

Fig. 15 - refers to Fig. 15 in IEC601-1

MD - Measuring device

A - After humidity conditioning

B - Before humidity conditioning

1 - Switch closed or set to normal polarity

0 - Switch open or set to reversed polarity

NC - Normal condition

SFC - Single fault condition

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Clause	Requirement + Test		Result - Remark	Verdict

20	TABLE: di	electric 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)	Ren	narks
Area		Model GTM91120-WWVV-X.X-T2 series, Class II	-	-	-	
Area B, Prin Secondary (		(A-a2) DI/RI	281.1	4125	No breakdov	vn
Area B, T1 ( Secondary		(A-a2) DI/RI	281.1	4125	No breakdov	vn
Area B, Trip (Furukawa E TEX-E) *		(A-a2) DI/RI *1.5	281.1	6187	No breakdov	vn
Area B, TWo tape (3M Co 1350F)		(A-a2) DI/RI	281.1	4125	No breakdov	vn
Area Ć, Prin Enclosure (v cover)		(A-a2) DI/RI	281.1	4125	No breakdov	vn
Area		Model GTM91120-WWVV-X.X-T1 series, Class I	-	-	-	
Area B, Prim Secondary (	Output	(A-a2) DI/RI	281.1	4125	No breakdov	vn
Area C, Prin Enclosure (v cover)		(A-a2) DI/RI	281.1	4125	No breakdov	vn
Area D, Prin Earthing	nary –	(A-a1)BI	281.1	1563	No breakdov	vn
Area		Model GTM91120-WWVV-X.X-P2 series, Class II	-	-	-	
Area B, Prin Secondary (		DI/RI	281.1	4125	No breakdov	vn
Area C, Prin Enclosure		DI/RI	281.1	4125	No breakdov	vn
Area		Model GTM91120-WWVV-X.X-F2 series, Class II	-	-	-	
Area B, Prin Secondary (	•	DI/RI	281.1	4125	No breakdov	vn
Area B, TWo tape (3M Co 1350F, 1350 35660Y, LY	O layer ompany / )-1,	(A-a2) DI/RI	281.1	4125	No breakdov	vn
supplementa	ary informati	ion:				

1.5 times of DI/RI voltage for Primary -secondary

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21	TABLE: mechanical strength				
Part under t	est	Test (impact, drop, force, handle, rough handling, mobile)	Remark	S	
Enclosure,	Top, above T1	Force Test	No Damage		
Enclosure, l Label	Bottom, above	Force Test	No Damage		
Enclosure, Sline	Side, above parting	Force Test	No Damage		
Enclosure, I removable of	Bottom, above cover	Force Test	No Damage		
Enclosure, I	Front, near Inlet	Force Test	No Damage		
Enclosure, E	Back, near output	Force Test	No Damage		
Power supp	ly whole unit	Drop Test	No Damage		
supplement	ary information:		-		

24 TABLE: - stability			N/A	
Part under test		Test condition	Remark	S
supplementary information:				

29	TABLE: X - radiat	ion			N/A
Part under to	est	Test condition	Measured radiation (mR)	Remark	S
supplementa	ary information:				

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Clause	Requirement + Test		Result - Remark	Verdict

42	ΓABLE: normal tempera	ature			Pass
Supply voltage	e: See below	Test Condition: See be	low		
Ambient temp	erature: See below				
Measuring loo	cation		Measured temperature (°C)	Remark	S
Supply Voltag 90VAC, 60H	je: z, Label face down, Mod	el GTM91120-3048-T2	-	-	
AMBIENT	,		40		
AC inlet body			62.01	100	
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	
	RE, Inside near LF2		73.9	80	
PWB near Q1			109.95	130	
PWB near R1			106.4	130	
	, Inside, above T1		70.19	125	
	, Outside above Label		68.79	85	
Supply Voltag 90VAC, 60H	e: z, Label face up, Model (	GTM91120-3048-T2	-	-	
AMBIENT			40		
AC inlet body			64.09	130	
AC inlet Pin			80.59	155	
F1			68.54	130	
F2			72.56	130	
LF1 Winding			110.69	130	
C2			105.12	120	
C2 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	
U2 D7			100.36	110	
D7			105.84	130	

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Clause Requirement + Test	Result - R	emark Verdict			
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 GTM91120-3007.5-2.5- T2	-	-			
AMBIENT	40				
AC inlet body	56.03	T1 Core			
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			
Supply Voltage: 90VAC, 60Hz, Model GTM91120-3048-P2					
AMBIENT	27.5	40			
INPUT WIRE	46.2	59.5			
F1	47.5	60.8			
F2	46.9	60.2			
LF1 Winding	59.5	72.8			
C2	59.2	72.5			
D4	64.2	77.5			
CX1	49.7	63.0			
Q1	61.3	74.6			
T1 Core	63.1	76.3			
T1 winding	64.8	78.1			
CY1	57.4	70.7			
U2	58.7	70.0			
D7	62.1	75.4			
LF2	50.8	64.1			
OUTPUT WIRE, Inside near LF2	48.7	62.0			
PWB near Q1	61.4	74.7			
PWB near R11	61.9	75.2			

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IEC 60601				
Clause	Requirement + Test	Result - F	Remark	Verdict
		,		,
	RE, Inside, near Label	58.6	71.9	
<b>ENCLOSUF</b>	RE, Outside above Label	55.5	68.8	
Supply Volta	Supply Voltage:			
264VAC, 6	60Hz, Model GTM91120-3048-P2			
AMBIENT		27.3	40	
INPUT WIR	E	41.9	55.0	
F1		43.7	56.8	
F2		42.4	55.6	
LF1 Winding		50.4	63.6	
C2		56.4	69.6	
D4		55.9	69.1	
CX1		47.0	60.2	
Q1		62.4	75.6	
T1 Core		65.8	79.0	
T1 winding		68.4	81.6	
CY1		60.7	73.9	
U2		62.8	76.0	
D7		70.0	83.2	
LF2		54.7	67.8	
OUTPUT W	IRE, Inside near LF2	52.0	65.1	
PWB near C	,	61.8	75.0	
PWB near F		57.2	70.4	
	RE, Inside, near Label	60.0	73.2	
	RE, Outside above Label	54.6	67.8	
Supply Volta	,			
	60HZ, MODEL GTM91120-3007.5-2.5-P2			
AMBIENT	,	25.6	40.0	
INPUT WIR	E	40.1	54.7	
F1		40.5	55.1	
F2		38.2	52.8	
LF1 Winding		46.2	60.8	
C2		54.6	69.2	
D4		50.4	65.0	
CX1		44.6	59.2	
Q1		57.1	71.7	
T1 Core		62.5	77.0	
T1 winding		64.5	79.0	
CY1		55.9	70.5	
U2		59.6	74.2	
D7		70.5	85.1	
LF2		61.5	76.1	
	IRE, Inside near LF2	55.0	69.5	
PWB near C	•	57.4	72.0	
PWB near F		54.0	68.6	
	RE, Inside, near Label	52.0	66.6	
ENCLOSUE	RE, Outside above Label	46.6	61.2	
Supply Volta				
Supply Volte	49V.			

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Clause	Requirement + Test		Result - Remark	Verdict

90VAC, 60HZ, MODEL GTM91120-3048-FW		
AMBIENT	40.0	40
INPUT CONNECTOR BODY	55.9	85
INPUT CONNECTOR PIN	51.5	155
F1	53.4	130
LF1 Winding	81.8	130
C2	77.6	85
D4	90.2	105
CX1	71.7	100
Q1	84.1	130
T1 Core	88.2	120
T1 winding	90.3	120
CY1	65.3	85
U2	70.0	100
D7	84.0	105
LF2	56.6	130
OUTPUT connector	46.1	80
PWB near Q1	81.7	130
PWB near R11	82.9	130
Supply Voltage:		
264VAC, 60HZ, MODEL GTM91120-3048-FW		
AMBIENT	40.0	40
INPUT CONNECTOR BODY	49.4	85
INPUT CONNECTOR PIN	47.4	155
F1	48.0	130
LF1 Winding	58.2	130
C2	67.5	85
D4	66.9	105
CX1	59.4	100
Q1	82.8	130
T1 Core	96.5	120
T1 winding	98.4	120
CY1	68.1	85
U2	75.4	100
D7	99.4	105
LF2	59.8	130
OUTPUT Connector, Inside near LF2	47.6	80
PWB near Q1	79.5	130
PWB near R11	74.0	130
Supply Voltage:		
264VAC, 60HZ, MODEL GTM91120-3007.5-2.5-FW		
AMBIENT	40.0	40
Input Connector body	47.6	85
Input Connector Pin	47.6	155
F1	47.7	130
LF1 Winding	56.7	130
C2	63.1	85

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	IEC 60601			
Clause	Requirement + Test	Result - F	Remark	Verdict
D4		61.9	105	
CX1		55.0	100	
Q1		80.1	130	
T1 Core		86.2	120	
T1 winding		87.5	120	
CY1		69.5	85	
U2		68.5	100	
D7		96.4	105	
LF2		91.0	130	
OUTPUT Co	onnector, Inside near LF2	54.9	80	
PWB near C	21	78.6	130	
PWB near R		71.1	130	
Model GTM	91128LI3CEL			
	on: Input: 90V, 60 Hz, Load: 12.6Vdc, 1000mA,			
	y discharged battery(3S-1P)			
AMBIENT		40	40	
AC INLET B		50.3	85	
AC INLET P	IN	51.3	155	
F1		51.9	130	
LF1 Winding		69.2	130	
C2		72.0	120	
D4		72.8	105	
CX1		64.1	100	
Q1		76.7	130	
T1 Core		77.2	130	
T1 winding		79.0	120	
CY1		66.2	85	
U2		74.5	100	
Charging PV	VB near R1	73.9	130	
	VB near U100	100.1	130	
<b>OUTPUT W</b>	IRE, Inside near LF2	57.2	80	
Main PWB n		76.4	130	
ENCLOSUR	RE, Inside, above T1	62.7	125	
	RE, Outside above Label	61.8	85	
	91128LI3CEL, Test Condition: Input: 264V, 60			
	2.6Vdc, 1000mA,charging fully discharged			
battery((3S-	1P)			
AMBIENT		40.0	40	
AC INLET B		49.1	85	
AC INLET P	IN	51.8	155	
F1		53.7	130	
LF1 Winding		64.1	130	
C2		72.8	120	
D4		69.8	105	
CX1		57.3	100	
Q1		79.9	130	
T1 Core		82.5	130	
T1 winding		83.4	120	

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	70.1 76.7 81.2 98.1 58.5 80.5 68.9 56.7	85 100 130 130 80 130	Verdict
Charging PWB near R1 Charging PWB near U100 OUTPUT WIRE, Inside near LF2 Main PWB near Q1 ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	76.7 81.2 98.1 58.5 80.5 68.9	100 130 130 80	
Charging PWB near R1 Charging PWB near U100 OUTPUT WIRE, Inside near LF2 Main PWB near Q1 ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	76.7 81.2 98.1 58.5 80.5 68.9	100 130 130 80	
Charging PWB near R1 Charging PWB near U100 OUTPUT WIRE, Inside near LF2 Main PWB near Q1 ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128L11CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	81.2 98.1 58.5 80.5 68.9	130 130 80	
Charging PWB near U100 OUTPUT WIRE, Inside near LF2 Main PWB near Q1 ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	98.1 58.5 80.5 68.9	130 80	
Charging PWB near U100 OUTPUT WIRE, Inside near LF2 Main PWB near Q1 ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	58.5 80.5 68.9	80	
Main PWB near Q1 ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	80.5 68.9		
ENCLOSURE, Inside, above T1 ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	68.9	130	
ENCLOSURE, Outside above Label Model GTM91128LI1CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN			
Model GTM91128L11CEL, Test Condition: Input: 90V #, 60 Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P) AMBIENT AC INLET BODY AC INLET PIN	56.7	125	
Hz, Load: 4.2Vdc, 1000mA, charging fully discharged battery(1S-1P)  AMBIENT  AC INLET BODY  AC INLET PIN		85	
battery(1S-1P)  AMBIENT  AC INLET BODY  AC INLET PIN			
AMBIENT AC INLET BODY AC INLET PIN			
AC INLET BODY AC INLET PIN			
AC INLET PIN	40.0	40	
	45.6	85	
T4	46.8	155	
F1	47.7	130	
LF1 Winding	55.2	130	
C2	61.1	120	
D4	59.1	105	
CX1	52.8	100	
Q1	68.8	130	
T1 Core	69.8	130	
T1 winding	71.1	120	
CY1	64.1	85	
U2	66.9	100	
Charging PWB near R1	68.7	130	
Charging PWB near U100	95.2	130	
OUTPUT WIRE, Inside near LF2	55.9	80	
Main PWB near Q1	68.8	130	
ENCLOSURE, Inside, above T1	56.4	125	
ENCLOSURE, Outside above Label	52.3	85	
COR - indicates measurements taken using change-of-resistance	e method		
supplementary information:			
Max Normal Load: 5V, 12A; 48V, 0.625A.			

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IEC 60601				
Clause	Requirement + Test		Result - Remark	Verdict

TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection					
Test type and condition Part under test Rer					
Power Supply whole Unit	Pass				
Power Supply whole Unit	Pass				
Power Supply whole Unit	Pass				
Post-Conditioning: 26.7 degC, 50.9 % 1 hrs  Power Supply whole Unit Pass supplementary information:					
	Part under test Power Supply whole Unit Power Supply whole Unit	Part under test Re Power Supply whole Unit Pass  Power Supply whole Unit Pass			

45	TABLE: hydrostatic pressure and pressure-relief device cycling test						
Test type and condition Part under test Test pressure				Re	emarks		
supplementa	supplementary information:						

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IEC 60601					
Clause	Requirement + Test		Result - Remark	Verdict	

52	TABLE: abnormal operation		Pass
Test type, c	condition and clause reference	Observed results	Remarks
Model GT(N	И)91120-3048-T2		
Diode D1		Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A	Test Time: 1 sec
		T1= - °C	Fuse opened immediately
Diode C2		Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A	Test Time: 1 sec
		T1= -°C	Fuse opened immediately
R11		Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A	Test Time: 1sec
		T1= -°C	Fuse opened immediately Q1 damaged
U2B (Pri pin 1-2)		Final Input: 264Vac, 20mA to 120mA, 3W to 20W	Test Time: 7hrs
		Final Output: 29V, 0.18A T1= 54.64 °C	Input and output bouncing
U2A(Sec pi	n 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 (I	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 (	• ,	Final Input: 264Vac, 0A, 0W Final Output: 0V, 0A	Test Time: 15mins No hazard
•	n fuse type: ICP 3.15A	T1= - °C	Fuse (F1) opened R11, R12 damaged
D7		Final Input: 264Vac, 31.1mA, 0.11W	Test Time: 1 hr

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IEC 60601				
Clause	Requirement + Test		Result - Remark	Verdict

	Final Output: 0V, 0A	Unit shut down
R20	T1: -°C Final Input: 264Vac, 34.64mA, 0.59W	No hazard Test Time: 1 hr
1120	Final Output: 0V, 0A	Unit shut down
	T1= - °C	No hazard
U2A(Sec pin 3-4)	Final Input: 264Vac, 30mA, 0.6W	Test Time: 15mins
02/\(\000 \pi\\\ 0 -4)	Final Output: 0V, 0A  T1= - °C	Unit shut down
D7	Final Input: 264Vac, 30mA, 0.6W	Test Time: 1 hrs
	Final Output: 0V, 0A T1= - °C	Unit shut down
R20	Final Input: 264Vac, 35mA, 0.7W	Test Time: 15mins
	Final Output: 0V, 0A T1= - °C	Unit shut down
Output Short	Final Input: 264Vac, 34mA	Test Time: 15mins
·	Final Output: -	
	T1= - °C	
	Unit shut down	
Output overload	Final Input: 264Vac, 106.28mA	Test Time: 6.5hrs
	Final Output: 4.65V, 5A	
	T1= 109.64°C	
	Output bouncing at 5.1A	
Power Supper Short Circuit	Final Input: 0.066 A	Unit Shut down
Model: GTM91128LI1CEL	Final Output: 0 A	
	T1= 47.3 °C	
Power Supper Short Circuit	Final Input: 0.0543 A	Unit Shut down
Model: GTM91128LI3CEL	Final Output: 0 A	
	T1= 54.4 °C	
Power Supply Unit GTM91128LI1CEL	Max Voltage:4.146V	Pass.
	Max Current at 1 min: 1.314A	
	Max Power at 1 min: 5.06W	
Power Supply Unit GTM91128LI3CEL	Max Voltage:12.548V	Pass.
	Max Current at 1 min: 9.82A	
	Max Power at 1 min: 11.84W	i

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IEC 60601						
Clause	Requirement + Test	Result	- Remark	Verdict		
56.10	TABLE: actuating parts and conti	TABLE: actuating parts and controls				
Part under	Part under test Torque applied Remarks					
supplemen	supplementary information:					

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

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

57.4b	57.4b TABLE: cord bending				
Cord under test		Test mass	Measured curvature	Remarks	
supplementa	ary information:				

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		IEC 60601		
Clause	Requirement + Test		Result - Remark	Verdict

57.9.1a	TABLE: tra	nsformer	short circuit				Pass
Winding	Protection	Measu	red temperatu	ıres (°C)	Test	Remarks	
under test		Primary	Secondary	Ambient	duration		
Model GTM 91120- 3007.5- 2.5-T2							
T1 Sec winding (Pin TA – TB)	OPP	-		22.9	15mins	Final Input:264V, 38mA, 0 Enclosure, above T1: - Unit shut down	.67W
Model GTM 91120- 3048-T2							
T1 Sec winding (Pin TA – TB)	OPP	-		22.9	15mins	Final Input:264V, 35mA, 0 Enclosure, above T1: - Unit shut down	.77W
Model GTM 91120- 3007.5- 2.5-F2	-	-	-	-	-	-	
T1 Sec winding (Pin TA – TB)	OPP			24.1	10 mins	Final Input:0.07A↔0.13A. Down	Unit Shut
Model GTM 91120- 3048-F2	-	-	-	-	-	-	
T1 Sec winding (Pin TA – TB)	OPP			24.1	10 min	Final Input:0.07A↔0.14A. Down	Unit Shut
Model GTM 91120- 3007.5- 2.5-F2							
T1 Sec winding (Pin TA – TB)	OPP			24.1	10 min	Final Input:0.07A↔0.13A. Down	Unit Shunt
Model							

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	IEC 60601							
Clause	Requirement + Test			Res	Result - Remark			
GTM 91120- 3048-F2								
T1 Sec winding (Pin TA – TB)	OPP			24.1	10 min	Final Input:0.07A↔0. Down	14A. Unit Shunt	
supplement	tary information	n:						

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		IEC 60601		
Clause	Requirement + Test		Result - Remark	Verdict

57.9.1b	TABLE: ov	erload					Pass
Winding		Measu	red temperatu	ıres (°C)	Test	Test current	,
under test	Protection	Primary	Secondary	Ambient	duration	or thermal cutout temp.	Remarks
Model GTM9112 0-3007.5- 2.5-T2							
T1 Sec winding (Pin TA – TB)	OPP	110.51	ł	25	8.5hrs		Final Input: 264Vac, 107.89mA Enclosure (outside), above T1: 77.02°C
Model GTM9112 0-3048-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
Model GTM9112 0-3007.5- 2.5-FW			-				
T1 Sec winding (Pin TA – TB)	OPP	78.7	1	25.0	6hr18:59		Final Input: 0.07A↔0.13A
Model GTM9112 0-3048- FW			1				
T1 Sec winding (Pin TA – TB)	OPP	100.7	1	25.0	6hr18:30		Final Input:0↔0.08A
Model GTM9112 0-3007.5- 2.5-P2			1				
T1 Sec winding (Pin TA – TB)	OPP	143.3		25.7	30hr11:5 0		Final Input: 0.136A
Model GTM9112 0-3048-P2							
T1 Sec	OPP	77.8°C		25.6°C	17:21:09		Final

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			IEC 60	601			
Clause	Requirement + Test			R	esult - Rema	Verdict	
winding (Pin TA – TB)						Input:0.137	<b>′</b> ↔0.07A
supplement	tary information:						
-							

57.9.2 TABLE: transformer dielectric strength						N/A	
		Test voltage applied to	Test voltage	Test frequency	Remarks		
supplementa	supplementary information:						

	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
CI.55	Drop Impact	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: