



Test Protocol

IEC 60601-1:1988 incl A1:1991 and A2:1995

EN 60601-1:1990 incl A1:1993 and A2:1995

Version: CB 01.10.1996

TÜV Product Service

☐ BLD ☒ DAN ☐ HAN ☐ HMB ☐ MUC ☐ NBL ☐ SDG ☐ TYO ☐

Manufacturer: Globtek, Inc

Equipment GTM35/41/48/57 Series of Power Supplies

Project No.: 091-024777-000

☒ Initial testing

☐ Retesting

Remarks: See Attachment 2 "Description of the range of assessed devices"

Note: This assessment excludes testing for compliance with

clauses 36 (EMC) and 48 (Biocompatibility)

TMP (Testing at Manufacturers Premises)

Test Report related to this Test Protocol: 091-024777-000



Test Report Form IEC 60601-1		Report No: 091-024777-000	
Testing station: TUV Product Service			
Address: 5 Cherry Hill Drive, Danvers, MA 01923			
Tel:	1-(978)-739-7041	Tested by:	<i>Allyson Taylor</i> Date: 2/27/02
Fax:	1-(978)-774-9987	Checked by:	<i>Prakash Matharu</i> Date: 03/05/02

IEC Publication 60601-1, 2nd ed., 1988 (EN 60601-1, 1990),

Including Amendment No. 1 (1991) and Amendment No. 2 (1995)

MEDICAL ELECTRICAL EQUIPMENT

PART 1: GENERAL REQUIREMENTS FOR SAFETY

Equipment: Range of low voltage DC Power Supplies

Trade Mark: Globtek Inc

Model: GTM35/41/48/57 Series (See Appendix 2)

Manufacturer: Globtek, Inc

Serial no: N/A - No serial number marked

Date of equipment receipt: 7 January 2002

Rated voltage: See Attachment 2

Rated current: See Attachment 2

Rated power: See Attachment 2

☒ Transportable equipment

☐ Permanently installed equipment

Accompanying units and accessories:

Single page user manual

Client: Globtek, Inc

Address: 186 Veterans Drive, Northvale, NJ 07647

Contact person and phone: Prakash Matharu - 1-(201)-784-1000



LIST OF ATTACHMENTS PROVIDING FURTHER INFORMATION ON THE EQUIPMENT TESTED AND THE TEST METHODS

KEPT
IN N/A
FILE

The following attachments are added to this TRF or kept in file at the Test Laboratory mentioned at the cover page:

- | | | | |
|--|------------------------------|-------------------------------------|-------------------------------------|
| • Statements on calibrations and measurement uncertainties (where relevant) of the measurement and test equipment as identified throughout this TRF:
Document title/identification: _____ | Att. No. _____ | ☒ | ☐ |
| • List of worksheets which describe measurement procedures or test methods where practicable:
Document title/identification: _____ | Att. No. _____ | ☐ | ☒ |
| • List of equipment or units tested and/or accompanying units and accessories (in case not all individual units can be mentioned on the front-page):
Document title/identification: "Description of the range of devices assessed" | Att. No. <u>Attachment 2</u> | ☒ | ☐ |
| • Technical design documents of components having basic, supplementary or reinforced insulation (e.g. transformer specification mentioning the insulation class of the insulation materials applied - A to H).
Document title/identification: _____ | Att. No. _____ | ☒ | ☐ |
| | Att. No. _____ | ☐ | ☒ |
| • Description of safety systems (specifying for example safety circuits, redundant circuits, double circuits, hardware/software safety measures, temperature controls, etc.).
Document title/identification: _____ | Att. No. _____ | ☒ | ☐ |
| | Att. No. _____ | ☐ | ☒ |
| | Att. No. _____ | ☐ | ☒ |



PERSONNEL - INITIALS USED THROUGHOUT THIS TRF

initials used in this TRF	full name (block capitals; clearly readable)	signature
	Antony C. Young-Taylor	
	Uwe Degenhardt	

N/A

This TRF contains 90 pages, numbered 0 to 89☐This TRF contains 0 photographs☒This TRF contains 8 enclosures / attachments, numbered 1 to 8☐This TRF is a part of a document or report with identification 091-024777-000☐



Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
3	GENERAL REQUIREMENTS				
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 and in S.F.C.			☒	☐
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.	No alternative means employed		☐	☒
5	CLASSIFICATION				
5.1	Class I EQUIPMENT	☐			
	Class II EQUIPMENT	☒			
	Internally powered equipment	☐			
5.2	Type B APPLIED PART	☐			
	Type BF APPLIED PART	☐			
	Type CF APPLIED PART	☐			
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.J)			☐	☒
5.4	Classification according to the method(s) of sterilisation or disinfection recommended by the manufacturer	Not a complete end use device		☐	☒

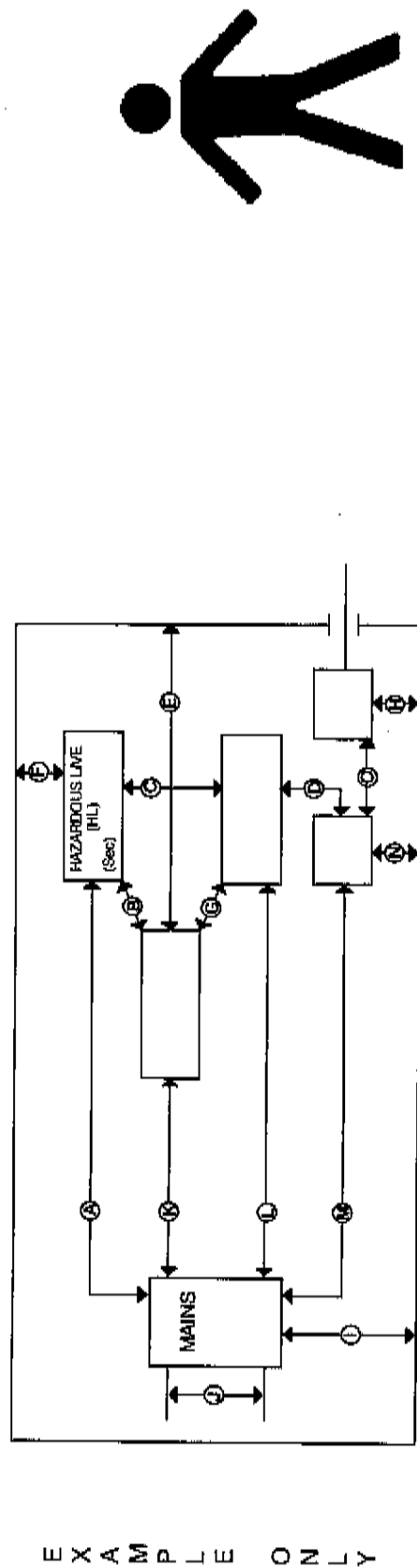


Requirements / Description	Comments / Observation	Compliance Yes No N/A
5.5 Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	☒	
Anaesthetic proof (AP)	☐	
Anaesthetic proof (APG)	☐	
5.6 Mode of operation:	☒	
Continuous operation	☐	
Short-time operation, specified operation period:	☐	
Intermittent operation, specified operation/ rest period:	☐	
Continuous operation with short-time loading. Permissible loading time stated:	☐	
Continuous operation with intermittent loading. Permissible loading/ rest time stated:	☐	

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

INSULATION DIAGRAM (Refer to table on next page)

Protection against electric shock - Block diagram of system



NOTE - Above is an example of a pictorial which should be created on page 8 of this TRF to assist the reader in the analysis of the equipment



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

TABLE TO INSULATION DIAGRAM ON PREVIOUS PAGE

Area	Test. Refer to 20.1 + 20.2	Insulation type Basic/Double/ Reinforced Ins.	Maximum circuit voltage	Required distances / mm		Dielectric strength test voltage Refer to 20.3
				Air Clearance	Creepage	
A						
B						
C						
D						
E	E	A	L E	O N L	Y	
F						
G						
H						
I						
J						
K						
L						
M						
N						
O	A-a1	Basic	230	2,5 mm	4 mm	1500 V
NOTE - Above is an example of a table which should be created on page 9 in this TRF to assist the reader in the analysis of the equipment						



Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A

INSULATION DIAGRAM (Refer to table on next page)
Protection against electric shock-Block diagram of system

or see Att. No. _____



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

TABLE TO INSULATION DIAGRAM ON PREVIOUS PAGE

Area	Test. Refer to 20.1 + 20.2	Insulation type Basic/Double/ Reinforced Ins.	Maximum circuit voltage	Required distance / mm		Dielectric strength test voltage Refer to 20.3
				Clearance	Creepage	
A	A-f	Basic	230/120	1.6/1.0	3.0/2.0	1500/1000VAC
B	A-f	Basic	230/120	1.6/1.0	3.0/2.0	1500/1000VAC
C	A-a1	Basic	230/120	2.5/1.6	4.0/3.0	1500/1000VAC
D	A-a2	Double	230/120	5.0/3.2	8.0/6.0	4000/3000VAC
E	A-a2	Double	230/120	5.0/3.2	8.0/6.0	4000/3000VAC
F	17 g.4	Double	230/120	5.0/3.2	8.0/6.0	4000/3000VAC
G	17 g.4	Double	230/120	5.0/3.2	8.0/6.0	4000/3000VAC
H						
I						
J						
K						
L						
M						
N						
O						



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A

6 IDENTIFICATION, MARKING AND DOCUMENTS

6.1 Marking on the outside of Equipment or Equipment parts

a)	Markings of mains operated equipment are permanently affixed and clearly legible	☒	☐	☐
b)	Markings of internally powered equipment are permanently affixed and clearly legible	☐	☐	☒
c)	Markings of the specific power supply are affixed	☐	☐	☒
d)	If the size of the equipment doesn't allow all markings, then at least the specific markings e), f), g), h), i), j) are affixed	☐	☐	☒
	All other markings present in accompanying documents	☐	☐	☒
e)	Name and/or trademark of the manufacturer or supplier	☒	☐	☐
f)	Model or type reference	☒	☐	☐
g)	Rated supply voltage(s) or voltage range(s)	☒	☐	☐
	Number of phases	☐	☐	☒
	Type of current	☒	☐	☐
h)	Rated frequency or rated frequency range(s) in Hz	☒	☐	☐
i)	Rated power input (VA, W or A)	☒	☐	☐
k)	Power output of auxiliary mains socket outlets	☐	☐	☒



Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
l)	Class II symbol 	All marked (Class II and Class II with functional earth)		☒	☐
	Symbol for degree of protection provided: IP X (1-8) of IEC Publication 529	Not protected		☐	☒
	If the protection against defibrillation is partly in the patient cable, is the symbol 14 of Table DI marked near the relevant outlet.	Not defibrillation protected		☐	☒
	Symbol for protection against electric shock: Type B 	No applied part		☐	☒
	Type BF or CF  or 	No applied part		☐	☒
	Symbol for protection of DEFILIBRATION-PROOF APPLIED PARTS  or  or 	No applied part		☐	☒
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous		☐	☒
	n) Types and rating of external accessible fuses	No external fuses		☐	☒
	p) Rated output voltage and current or power, output frequency (where applicable)	See Attachment 2		☒	☐
	q) Symbol for physiological effect(s): Attention, consult accompanying documents 	On device rating label		☒	☐
	Non-ionizing radiation 			☐	☒
	or symbols as adopted by ISO or IEC Publ. 417			☐	☒



Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
r)	Anaesthetic-proof symbol:  Type AP  Type APG			☐	☒
s)	Dangerous voltage symbol 	No such voltages		☐	☒
t)	Special cooling requirements	None		☐	☒
u)	Limited mechanical stability			☐	☒
v)	Protective packing requirement(s). Marking(s) for unpacking safety hazard(s) Equipment or accessories supplied sterile marked as sterile			☐	☒
y)	Potential equalisation terminal 			☐	☒
z)	Functional earth terminal 	No user or service access		☐	☒
	Removable protective means	No such means		☐	☒
	Durability of markings			☒	☐
6.2 Marking on the inside of EQUIPMENT or EQUIPMENT parts					
a)	Nom. voltage of permanently installed equipment	Not permanently installed		☐	☒
b)	Maximum power loading for heating elements or holders for heating lamps	No heating elements		☐	☒



Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
c)  Dangerous voltage parts		☐	☒
d) Type of battery and mode of insertion	No batteries	☐	☒
Battery not intended to be changed by the operator		☐	☒
e) Fuse type and rating or reference		☐	☒
f)  Protective earth terminal		☐	☒
g)  Functional earth terminal		☐	☒
h) Supply neutral conductor in permanently installed equipment (N)		☐	☒
i) Markings required in Sub-clause 6.2. f), h), k) and l) shall not be affixed to parts which have to be removed and remain visible after connection		☐	☒
k) The supply connections are clearly marked adjacent to the terminals or in accompanying documents (for small equipment)		☐	☒
l) Statement for suitable wiring materials (at temperatures over 75°C) locates at or near the point of the supply connections		☐	☒
Statement is clearly discernible		☐	☒
n) Capacitors and/or circuit parts are marked as required in Sub-clause 15 c)		☐	☒
6.3 Marking of controls and instruments			
a) Mains switch clearly identified	Not provided	☐	☒



Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
'ON' and 'OFF' positions marked according to Symbols 15 and 16 of Table DI or indicated by an adjacent indicator light or other unambiguous means			
b) Positions of controls and other switches		☐	☒
c) Indication of the direction of setting devices		☐	☒
f) Functions of operator controls and indicators are identified		☐	☒
g) Numeric indications of parameters are according ISO 1000		☐	☒
6.4 Symbols			
Symbols used comply with appendix D or IEC- publication 417 and/or 878 or ISO publications (if applicable)			
	Class II, AC, DC	☒	☐
6.5 Colours of insulation of conductors			
a) Protective earth conductor has green/yellow insulation	No protective earth	☐	☒
b) All insulation of internal protective earth conductors are green/yellow, at least their terminations		☐	☒
c) Only protective earth or potential equalisation or functional earth conductors are green/yellow	Functional earth connector	☒	☐
d) Colour of neutral conductor:	Black - No user or service access	☐	☒
e) Colours of phase conductors:	/ /	☐	☒
Compliance with IEC 227 and IEC 245	22 AWG - UL 1015 wire	☒	☐
f) Additional protective earthing in multi-conductor cords are marked green/yellow at the ends of the additional conductors	No additional earth	☐	☒

EC 60601-1: 1988 + A1: 1991 + A2: 1995Report No: 091-024777-000Page 14 of 89



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A

6.6 Medical gas cylinders and connections

- a) In accordance with ISO/R32
- b) Identification of connection point

No gas connection

☐ ☐ ☒

☐ ☐ ☒

6.7 Indicator lights and push-buttons

- a) On indicator lights the colour red is used exclusively to indicate a warning of danger and/or a need for urgent action
- b) Colour red is used only for unilluminated push-buttons by which a function is interrupted in case of emergency

Not required - See Working Group Recommendation No 47

☐ ☐ ☒

No such devices

☐ ☐ ☒

6.8 Accompanying documents

- 6.8.1 Equipment is accompanied at least by:

- instructions for use
- technical description
- an address to which the user can refer

All classifications specified in item 5 are included in both the instructions for use and the technical description if separable

Single page each model - Example Doc No:910-0040 Rev.A

Section C - Specifications

GlobTek - Northdale NJ 07647

Class II only - Self evident from marking

☒ ☐ ☐

☒ ☐ ☐

☒ ☐ ☐

☐ ☐ ☒



Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
Warning statements and explanations of warning symbols are provided in accompanying documents	Flammable anaesthetic warning + Cautions	☒	☐
Language of accompanying documents:	English	☒	☐
All markings specified in Sub-clause 6.1 shall be included in full in accompanying documents		☒	☐
6.8.2 Instructions for use			
a) General information			
Instructions for use shall:	Self evident	☒	☐
• state the function and Intended application of the equipment		☐	☒
• include an explanation of:		☒	☐
– the function of controls, displays and signals		☒	☐
– the sequence of operation		☒	☐
– the connection and disconnection of detachable parts and accessories		☒	☐
– the replacement of material which is consumed during operation		☐	☒
• include: Indications of recognised accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance		
		Yes	No	N/A
- provide the user or operator with information regarding potential electromagnetic or other interference - instruct the user or operator concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance The instructions shall: – provide information for the safe performance of routine maintenance – identify the parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	<u>Requirement for end use equipment</u> <u>Requirement for end use equipment</u> <u>None</u> <u>None</u> <u>None used</u> <u>No SIP/SOP's</u>	☐	☐	☒
Explanation of figures, symbols, warning statements and abbreviations on the equipment		☐	☐	☒
c) Signal output and signal input parts Signal output or signal input parts intended only for connection to specified equipment		☐	☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
d) Cleaning, disinfection and sterilisation of parts in contact with the patient Details about cleaning or disinfection or sterilisation methods that may be used for equipment parts which come into contact with the patient during normal use	No patient contact	☐	☒
e) Mains operated equipment with additional power source A warning statement referring to the necessity for periodical checking or replacement of an additional power source If Class I equipment a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment is operated from its internal electrical power source	No additional power source	☐	☒
f) Removal of primary batteries A warning to remove batteries if equipment is not likely to be used for some time, unless there is no risk of a safety hazard arising	No batteries	☐	☒
g) Rechargeable batteries Instructions to ensure safe use and adequate maintenance	No batteries	☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
h) Equipment with a specified power supply or battery charger		☐	☒
Identification of power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		☐	☒
j) Environmental protection		☐	☒
Identify any risks associated with the disposal or waste products, residues, etc.		☐	☒
Provide advice on minimizing these risks	No special risk	☐	☒
6.8.3 Technical description			
a) General			
All data, which is essential for safe operation including:		☒	☐
• data mentioned in Sub-clause 6.1;		☐	☒
• all characteristics of the equipment, including range(s), accuracy and precision of the displayed values		☐	☒
A statement whether particular measures or particular conditions are to be observed for installing equipment and bringing equipment into use		☐	☒

Section C - Specifications



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance		
		Yes	No	N/A
b) Replacement of fuses and other parts				
Required type and rating of fuses utilised in the mains supply circuit external to permanently installed equipment	No accessible fuses	☐	☐	☒
Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		☐	☐	☒
c) Circuit diagrams, component part lists, etc.				
A statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc.	Not user serviceable	☐	☐	☒
d) Environmental conditions for transport and storage				
A specification of the permissible environmental conditions for transport and storage which shall be repeated on the outside of the packaging of the equipment	Requirement for end use equipment	☐	☐	☒



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

7 POWER INPUT

Power Input	Function	$U_N =$	$U_N + 10\%$	$U_N - 10\%$
Input Current	Normal operation	A	A	A
	Standby	A	A	A
Input power	Normal operation	W	W	W
Input power	Normal operation	VA	VA	VA
Power factor	cos Ø			

Test equipment: 4039, 4023, 4025, 4096, 4027, 4062

Initials tester: AWD

Date: 24 Feb 2003

7.1 Rated steady state input current or power:

WNA/A

See Attachment 3

☒ ☐ ☐

10 ENVIRONMENTAL CONDITIONS

The equipment complies with all requirements under the environmental conditions of clause 10.

☒ ☐ ☐



Requirements / Description	Comments / Observation	Compliance	
Yes	No	N/A	
b) If equipment is fitted with a device for changing over from class I to class II protection, the following requirements are fulfilled: The change-over device indicates the selected class clearly A tool for change-over is necessary The equipment complies with all requirements for the selected class at any given time Class II position: The device interrupts the connection of protective earth conductor to equipment or changes it into functional earth conductor (compliance with 18)		☐	☒
		☐	☒
		☐	☒
		☐	☒
14.4 Class I and II equipment		☒	☐
a) Equipment is provided with additional protection according to the rules of Class I or Class II		☒	☐
b) No safety hazard develop, when a connection with the wrong polarity is made in equipment specified for power supply from an external d.c. power source (e.g. for use in ambulances)		☐	☒
14.5 Internally powered equipment		☐	☒
b) For connection to a supply mains the equipment complies with the requirements for Class I or II equipment	Not internally powered	☐	☒
14.6 Types B, BF and CF applied parts		☐	☒
c) Applied parts which are specified in the accompanying documents as suitable for direct cardiac application are of type CF	No applied part	☐	☒



Requirements / Description	Comments / Observation	Compliance Yes No N/A
----------------------------	------------------------	--------------------------

15 LIMITATION OF VOLTAGE AND/OR ENERGY

b) Interference suppression capacitors

Capacitance between each line and protective earth.

Measured value _____pF

Capacitance between line and neutral.

Measured value _____μF 0,1μF

No charge retention devices in primaries

Test equipment: _____

Initials tester: _____ Date: _____

Maximum residual voltage in the mains plug 1second after disconnection (measured in the least favourable position of the on-off switch, if any):

Measurement no.	1	2	3	4	5	6	7	8	9	10
Voltage between pins 1 and 2 (Limit 60 V)										
Voltage between pin 1 and Enclosure (Limit 60 V)										
Voltage between pins 2 and Enclosure (Limit 60 V)										

Remark: Pins 1 and 2 are Line and Neutral supply pins.

Test equipment: By inspection of circuits

Initials tester: _____ Date: _____



PRODUCT SERVICE

Compliance

Yes No N/A

Comments / Observation

Requirements / Description

c) Residual voltage or energy in capacitors:

Capacitor and its location	Working voltage V	Capacitance value μF	Residual voltage V	Residual energy mJ	☐	☐	☒
					☐	☐	☒
					☐	☐	☒
					☐	☐	☒
					☐	☐	☒
					☐	☐	☒

Test equipment: _____

Initials tester: _____

Date: _____

Means of discharging capacitors:

- automatic
- non-automatic (included and marked)

☐☐☐☐☒



Compliance
Yes No N/A

Comments / Observation

16 ENCLOSURES AND PROTECTIVE COVERS

a) There is protection against accidental contact with live parts, and with parts which can become live in single fault conditions

This requirement applies for all position of equipment when it is operated as in normal use, even after opening of lids and doors and removal of parts without the use of a tool or according to the instructions for use.

During the insertion or removal of lamps, protection against contact with live parts of lamp shall be ensured if the replacement of the lamp is possible without the use of a tool.

☒ ☐ ☐

See Working Group Recommendations 47 and 8

☒ ☐ ☐

☐ ☐ ☒

No such lamps

Test equipment: _____

Initials tester: _____ Date: _____

Location of opening	Test result (finger, pin, hook)
No openings	N/A

☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒

b) Openings in top covers (test rod)

No openings

☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

- c) Conductive parts of actuating mechanism of electrical controls after the removal of handles, knobs, levers etc. have either resistance to the protective earth terminal $\leq 0.2 \Omega$ or the separation from live parts complies with 17 g
- d) Protection of internal parts of the equipment with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by external means

☐ ☐ ☒

No such parts

☐ ☐ ☒

Can be disconnected

Test equipment: _____

Initials tester: _____ Date: _____

Location of part	Covering	Warning notice	Remarks

☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒

- e) Protective enclosures are removable only with the aid of tool or an automatic device makes these parts not live, when the enclosure is opened or removed

Some models glued - others require a tool

☐ ☐ ☒

- f) Basic insulation or live parts or parts not protectively earthed and separated from the mains by basic insulation only are inaccessible to the test rod through openings for adjustment of pre-set controls

No openings

☐ ☐ ☒



PRODUCT SERVICE

Compliance

Yes No N/A

Comments / Observation

Requirements / Description

17 SEPARATION (also refer to the insulation diagram at the end of clause 5 in this TRF)

a) Separation method of the applied part from live parts:

- 1) Basic insulation - applied part earthed
- 2) By protectively earthed metal part (e.g. screen)
- 3) By separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure
- 4) By double or reinforced insulation
- 5) By protective impedances limiting current to applied part
- 6) Other method

No applied part

☐ ☐ ☒

Test equipment:

Date:

Initials tester:

Additional leakage current test according to 17.a):

Fault condition (description)	Earth leakage current (μ A)	Enclosure leakage current (μ A)	Patient leakage current (μ A)	Patient auxiliary current (μ A)
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒

c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed

☐ ☐ ☒

d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)

☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

g) Separation method of accessible parts other than applied parts from live parts

- ☐ 1) Basic insulation - accessible part earthed
☐ 2) By protectively earthed conductive part (e.g. screen)
☐ 3) By separate earthed intermediate circuit
☒ 4) By double or reinforced insulation
☐ 5) By protective impedances limiting current to accessible part
☐ 6) Other method

☒ ☐ ☐

Test equipment: _____

Additional leakage current test according to 17.g):

Initials tester: _____ Date: _____

Fault condition (description)	Earth leakage current (μA)	Enclosure leakage current (μA)	Patient leakage current (μA)	Patient auxiliary current (μA)
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒

h) Arrangements used to isolate defibrillation-proof applied parts are so designed that:

- no hazardous electrical energies do appear during a discharge of a cardiac defibrillator
- after exposure to the defibrillator voltage, the equipment shall continue to perform its intended function

Not defibrillation protected

Not defibrillation protected

☐ ☐ ☒

☐ ☐ ☒



Requirements / Description		Comments / Observation	Compliance	
			Yes	No N/A
18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALISATION			
a)	Accessible parts of Class I equipment separated from live parts by basic insulation only are connected by sufficiently low impedance to the protective earth terminal	No such parts	☐	☒
b)	The protective earth terminal is suitable for the protective conductor in the installation either by a protective earth conductor in a power supply cord and by a suitable plug or by a fixed and permanently installed protective earth conductor	Not protectively earthed	☐	☒
e)	Potential equalization	Not provided	☐	☒
	Equipment provided with connection of a potential equalization conductor		☐	☐
	This connection complies with following requirements:		☐	☐
	• readily accessible		☐	☐
	• no possibility to accidental disconnection in normal use		☐	☐
	• conductor is detachable without the use of a tool		☐	☐
	• power supply cord does not include potential equalization conductor		☐	☐
	• connection is marked with symbol 		☐	☐



Requirements / Description	Comments / Observation	Compliance Yes No N/A
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- f) Impedance of protective earthing system:
Impedance between any protectively earthed accessible metal part and:
- 1) protective earth terminal (PE)
(requirement: $R < 0.1 \Omega$),
 - 2) protective contact in appliance inlet
(requirement: $R < 0.1 \Omega$)
 - 3) protective contact in the mains plug
(requirement: $R < 0.2 \Omega$),
- are tabled below

Test equipment: _____
Initials tester: _____ Date: _____

Accessible part and its location	R (Ω) measured against (numbers see above)		
	1 PE	2 Inlet	3 Plug

☐	☐	☒
☐	☐	☒
☐	☐	☒
☐	☐	☒
☐	☐	☒
☐	☐	☒
☐	☐	☒



Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
g) If the impedance of protective earth connections other than in 18.1.f exceeds 0.1 Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition		☐	☒
k) Functional earth terminals are not used to provide protective earthing		☒	☐
l) For Class II equipment with isolated internal screens and with a power supply cord: - the third conductor is used only as functional earth of these screens and is coloured green/ yellow - insulation of such screens and all internal wiring connected to them is double insulation or reinforced insulation (see also 20.3) - marking of functional earth terminal is distinguished from protective earth terminal and is noted in accompanying documents		☐	☒
		☐	☒
		☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

19 **CONTINUOUS LEAKAGE CURRENTS AND PATIENTS: AUXILIARY CURRENTS**
(before humidity preconditioning treatment)

Test equipment: 4077, 4024, 4033, 4032

Initials tester: AVP Date: 1/29/02

Type of leakage current	In normal condition		In single fault condition		Compliance
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)	
Earth leakage current	500	4.5 (120V/60hz)	1000	5.7 (120V/60Hz)	☒ ☐ ☐
Enclosure leakage current	100	1.5 (230V/50Hz)	500	1.5 (230V/50Hz)	☒ ☐ ☐
Enclosure leakage current (110% mains voltage on any SIP or SOP)	-	-	5000		☐ ☐ ☒
Patient leakage current	d.c.	10	50		☐ ☐ ☒
	a.c.	B, BF: 100 CF: 10	B, BF: 500 CF: 50		☐ ☐ ☒
Patient leakage current (110% mains voltage on any SIP or SOP)	-	-	B: 5000		☐ ☐ ☒
Patient leakage current (110% mains voltage on any F-type applied part)	-	-	BF: 5000 CF: 50		☐ ☐ ☒
Patient leakage current (110% mains voltage on any accessible metal part not protectively earthed)	-	-	B: 5000		☐ ☐ ☒
Patient auxiliary current	d.c.	10	50		☐ ☐ ☒
	a.c.	B, BF: 100 CF: 10	B, BF: 500 CF: 50		☐ ☐ ☒

Limits for permanently installed equipment and some other limits: See Table IV of IEC601-1.



Requirements / Description	Comments / Observation	Compliance Yes No N/A
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19 CONTINUOUS LEAKAGE CURRENTS AND PATIENTS: AUXILIARY CURRENTS

(After humidity preconditioning treatment)

Test equipment: 4077, 4024, 4033, 4032

Initials tester: PUA Date: 1/31/02

Type of leakage current	In normal condition		In single fault condition		Measured max. value (µA)			
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)				
Earth leakage current	500	5.0 (120V/60Hz)	1000	5.5 (120V/60Hz)		☒	☐	☐
Enclosure leakage current	100	1.5 (230V/50Hz)	500	1.5 (230V/50Hz)		☒	☐	☐
Enclosure leakage current (110% mains voltage on any SIP or SOP)	-	-	5000			☐	☐	☒
Patient leakage current			50			☐	☐	☒
	B, BF: 100 CF: 10		B, BF: 500 CF: 50			☐	☐	☒
Patient leakage current (110% mains voltage on any SIP or SOP)	-	-	B: 5000			☐	☐	☒
Patient leakage current (110% mains voltage on any F-type applied part)	-	-	BF: 5000 CF: 50			☐	☐	☒
Patient leakage current (110% mains voltage on any accessible metal part not protectively earthed)	-	-	B: 5000			☐	☐	☒
Patient auxiliary current			50			☐	☐	☒
	B, BF: 100 CF: 10		B, BF: 500 CF: 50			☐	☐	☒

Limits for permanently installed equipment and some other limits: See Table IV of IEC 601-1.



PRODUCT SERVICE

Requirements / Description		Comments / Observation	Compliance	
			Yes	No N/A
21	MECHANICAL STRENGTH			
a)	Rigidity of enclosure (45 N testforce)		☒	☐
b)	Strength of enclosure part and any component there on (Impact hammer test)	T/E 004048	☒	☐
c)	On portable equipment carrying handles or grips withstand the requirements of the loading test	Test force _____ N (Four times the weight of equipment)	☐	☒
21.3	No damage to parts of patient support and/or immobilisation system after the loading test (1350 N and 2700 N tests) When a breakdown of a patient support constitutes a safety hazard, the requirements of Clause 28 are met	No patient support	☐	☒
21.5	Hand-held equipment or equipment parts are safe after drop test (dropping height 1 m)	Not hand held	☐	☒
21.6	Portable and mobile equipment is able to withstand rough handling.			
a)	portable equipment dropping three times	Drop height: 5cm All models <10kg	☒	☐
b)	Mobile equipment travel 20 times over a descending step 20 mm high		☐	☒



PRODUCT SERVICE

Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
22	MOVING PARTS				
22.2					
a)	Moving parts of transportable equipment are provided with guards which form an integral part of the equipment	No moving parts		☐	☒
b)	Moving parts of stationary equipment are provided with similar guards as above unless it is evident that equivalent protection is separately provided during installation			☐	☒
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			☐	☒
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the control of operator			☐	☒
22.6	Parts of equipment subject to mechanical wear, likely to result in a safety hazard, are accessible for inspection			☐	☒
22.7	To remove an unexpected safety hazard caused by an electrically produced mechanical movement, there are means for emergency switching of a relevant part			☐	☒
	Operation of an emergency switching means does not introduce a further safety hazard			☐	☒
	Devices for emergency stopping means are able to break the full load current			☐	☒
	Means for stopping of movements do operate as a result of one single action			☐	☒
IEC 60601-1: 1988 + A1: 1991 + A2: 1995		Report No: 091-024777-000		Page 38 of 89	



Requirements / Description		Comments / Observation	Compliance	
			Yes	No N/A
The means for emergency switching are readily identifiable and accessible			☐	☒
Current breaking capability			☐	☒
23	SURFACES, CORNERS AND EDGES			
	There are no rough surfaces, sharp corners, flange or frame edges and burrs which may cause damage in the equipment		☒	☐
24	STABILITY IN NORMAL USE			
24.1	Equipment does not overbalance, when tilted through an angle of 10°	Secured by interface with wall outlet	☒	☐
24.3	If equipment overbalances when tilted 10°: - it does not overbalance when tilted through an angle of 5° in any position of normal use, excluding transport - The equipment carries a warning notice for transport - It does not overbalance when tilted through an angle of 10° in the condition specified for transport		☐ ☐ ☐	☒ ☒ ☒



Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
24.6 Grips and other handling devices					
a)	Equipment or its parts with a mass of more than 20 kg is provided with			☐	☒
	- suitable handling devices (grips etc.) - instructions for lifting and handling during assembly			☐	☒
b)	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			☐	☒
25 EXPELLED PARTS					
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No such parts		☐	☒
25.2	Display vacuum tubes with a face dimension of 16 cm or larger are intrinsically safe with respect to effects of implosion of tubes and to mechanical impact, or the enclosure of the equipment is provided with adequate protection against implosion.	No such parts		☐	☒
Certificate of the test provided				☐	☒
IEC 60601-1: 1988 + A1: 1991 + A2: 1995		Report No: 091-024777-000		Page 40 of 89	



PRODUCT SERVICE

Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
28	SUSPENDED MASSES				
28.3	Where the integrity of the system is in doubt, is a safety device provided, unless excess travel in the event of breakdown is limited	No suspended masses		☐	☒
	Suspension systems include a safety device with adequate safety factors to protect user or patient from hazards	No suspended masses		☐	☒
	If after activation of a safety device the equipment can still be used, the activation of the device, e.g. a secondary rope, becomes obvious to the operator			☐	☒
28.4	If a safety device is not provided does the construction comply with the following:			☐	☒
	1) the TOTAL LOAD does not exceed the SAFE WORKING LOAD			☐	☒
	2) Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the SAFETY FACTOR of all supporting parts is not less than 4			☐	☒
	3) Where impairment by wear, corrosion, material fatigue or ageing is expected, the SAFETY FACTOR is not less than 8			☐	☒



Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
4) Where metal having a specific elongation at break of less than 5% is used in supporting components, the SAFETY FACTOR is not less than 1.5 times those given in 2) and 3) above				☐	☒
5) Sheaves, sprockets, bandwheels and guides are so designed that the SAFETY FACTORS of this sub-clause shall be maintained for a specified minimum life till replacement of the ropes, chains and bands				☐	☒
29 X-RADIATION					
29.1 For diagnostic X-ray equipment - See Collateral Standard IEC 601-1-3					
For radiotherapy equipment - No general requirement, see relevant Particular Standard					
29.2 For equipment not intended to produce X-radiation for diagnostic and therapeutic purposes, ionizing radiation emitted by vacuum tubes excited by voltages exceeding 5 kV does not produce an exposure exceeding 130 nC/kg (0.5 mR)		No x-rays		☐	☒
36 ELECTROMAGNETIC COMPATIBILITY					
The equipment complies with the requirements of IEC 601-1-2		System component only - Not a complete medical device		☐	☒
IEC 60601-1: 1988 + A1: 1991 + A2: 1995		Report No: 091-024777-000		Page 42 of 89	



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
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37 - 41 Requirements for category AP and APG equipment (clauses 39..41), see additional test report form, Attachment No _____

☐ ☐ ☒

Not AP or APG

42. EXCESSIVE TEMPERATURES

Ambient temp. during measurements: 22°C

Humidity: 35 %

Atmospheric pressure: 1018mbar hPa

Test equipment: 4039,4023, 4025, 4096,4027, 4062

Initials tester: AWG Date: 1/21/02

Quantity	Rated	Used in test	Remarks
Supply voltage, V		See Attachment 5	
Supply power, VA			
Output power, VA			



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

Determination of the temperature rise of copper windings by the resistance method:

$$\Delta t = \frac{R_2 - R_1}{R_1} (234.5 + t_1) - (t_2 - t_1)$$

Test equipment: _____ Date: _____
Initials tester: _____

$$T = 40 + \Delta t$$

Winding	R ₁ Ω	R ₂ Ω	Room temperature °C		Final temperature		Allowed °C	Remarks			
			t ₁	t ₂	Δt	T			☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒
									☐	☐	☒



Requirements / Description	Comments / Observation	Compliance Yes No N/A	
42.3 Surface temperatures of applied parts not intended to supply heat to a patient do not exceed 41°C	<u>No applied part</u>	☐	☒
42.5 Guards for preventing contact with hot accessible surfaces are removable only with the aid of a tool	<u>No such guards</u>	☐	☒
43 FIRE PREVENTION			
Strength and rigidity of the equipment are sufficient to avoid fire hazards (see 21)		☒	☐
44 OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILISATION, DISINFECTION AND COMPATIBILITY			
44.2 Overflow			
If equipment contains a liquid reservoir:			
• The equipment is electrically safe after 15% overflow steadily over a period of 1 min	<u>No liquid reservoir</u>	☐	☒
• Transportable equipment is electrically safe after additionally having been tilted through 15° in least favourable direction(s) (if necessary with refilling)		☐	☒
44.3 Spillage			
Safety of the equipment does not change in consequence of spillage test performed by the method mentioned in the standard (200 ml of water).	<u>Does not require the use of liquids in normal use</u>	☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
44.4 Leakage Safety of the equipment does not change in consequence of leakage test performed by the method mentioned in the standard (drops of water).	No liquids present	☐ ☐ ☒
44.5 Humidity Checked by the pre-conditioning treatment and tests (see 4.10)		☒ ☐ ☐
44.6 Ingress of liquids (see IEC 529) Enclosures designed to give protection against ingress of water provide protection in accordance with IEC 529 Protective index (IPX) stated by the manufacturer (1-8):	Not protected IPX0	☐ ☐ ☒
44.7 Cleaning, sterilisation and disinfection Method specified by the manufacturer: Default method of IEC 601-1: No signs of damage and/or deterioration Pass dielectric strength test	☒ ☐ ☐ Requirement for end use equipment	☐ ☐ ☒ ☐ ☐ ☒
IEC 60601-1: 1988 + A1: 1991 + A2: 1995 Report No: 091-024777-000 Page 47 of 89		



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A

45 PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE

45.2 Pressure vessel covered by a National Standard: Yes ☐ No ☐

Title: _____

If No, default hydraulic pressure Test is required:

Hydraulic test pressure: Required _____ kPa Measured: _____ kPa

Results of the test: _____

☐ ☐ ☒

45.3 The maximum pressure to which part can be subjected in normal condition and single fault condition does not exceed the maximum permissible.

The used maximum pressure is the highest of the following:

a) Marked maximum supply pressure from an external source ☐

b) Pressure setting of a pressure relief device provided as a part of the assembly ☐

c) Maximum pressure that can be developed by an air compressor included in the assembly ☐

☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance	
		Yes	No N/A
45.7 Equipment does incorporated pressure-relief device(s) where excessive pressure could occur:	No pressure vessels	☐	☒
a) Connected as close as possible to the pressure vessel or parts of system it is intended to protect		☐	☒
b) Readily accessible for inspection, maintenance and repair		☐	☒
c) Not capable of being adjusted or rendered inoperative without a tool		☐	☒
d) Its discharge opening located and directed so, that released materials is not directed towards any person		☐	☒
e) Operation of device does not deposit material on parts causing possible safety hazard		☐	☒
f) Ensures that the pressure does not exceed the maximum permissible working pressure by more than 10%, if a failure occurs in the control of the supply pressure		☐	☒
g) No shut-off valve between the pressure-relief device and the parts it is intended to protect		☐	☒
h) Minimum number of cycles of operation is 100,000		☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
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49 INTERRUPTION OF POWER SUPPLY

49.1 If automatically resetting thermal cut-outs and overcurrent releases are used, they give a safe condition by such resetting

Single use devices in primaries of transformers

☐ ☐ ☒

49.2 Interruption and restoration of the power supply do not result in hazards other than interruption of intended function

☒ ☐ ☐

49.3 Means are provided for removal of mechanical constraints on patients in case of a supply mains failure

☐ ☐ ☒

51 PROTECTION AGAINST HAZARDOUS OUTPUT

51.4 In multi-purpose equipment providing both low and high intensity outputs for different treatments means are provided to minimise the possibility of the accidental selection of high output

No such outputs

☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

52 ABNORMAL OPERATION AND FAULT CONDITIONS

.1 Equipment is so designed and manufactured that even in a single fault condition no safety hazard as described under 52.4 exists (see 3.1 and 13) Refer to Table at the end of 52.

Additionally the safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4

☐ ☐ ☒

No PEMS

.5.2 Failure of thermostats

No thermostats

☐ ☐ ☒

.5.3 Short-circuiting one part of a double insulation

☐ ☐ ☒

.5.5 Impairment of cooling

No cooling requirement

☐ ☐ ☒

.5.6 Locking of moving parts (see also 52.5.8).

No moving parts

☐ ☐ ☒



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

5.7 Interruption and short-circuiting of motor capacitors
(see also 52.5.8)

Duration of the test min

Voltage V

Loading

Final temperature of winding °C

No motor capacitors

☐☐☒

Test equipment:

Initials tester:

Date:

Open circuited or short-circuited capacitors									
Capacitor and winding	Short circuit	Open circuit	R ₁ ↓	R ₂ ↓	t ₁ s°C	t ₂ s°C	Δ t s°C	Final t s°C	☐ ☐ ☒
									☐ ☐ ☒
									☐ ☐ ☒
									☐ ☐ ☒

Notes:



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
.5.8 Additional tests for motor operated equipment: Duration of operating time:	<u>Not motor operator</u>	
.5.9 Failure of components	<u>Short circuit applied to outputs under clause 57.9</u>	☐ ☐ ☒
.5.10 Overload		☒ ☐ ☐
a) Equipment with heating element: 1. Thermostats (see 52.5.10c-d) 2. Equipment with heating elements with short-time rating (see 52.5.10c-e) 3. Other equipment (see 52.5.10c) Equipment having motors, which are a part of equipment (see 52.5.5 ... 52.5.8 and 52.5.10f... 2.5.10h)	☐ ☐ ☐ 	☐ ☐ ☒
b)		☐ ☐ ☒



PRODUCT SERVICE

Compliance
Yes No N/A

Requirements / Description		Comments / Observation	
Test No. from 52.5	Applied single fault condition (refer to 52.5) ¹⁾	Observed result (e.g. hazards which arise or not) ²⁾	
	Short circuit output	See Attachment 5	☒ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐
			☐ ☐ ☐

- 1)
Mention circuit/component concerned (e.g. regulator, capacitor, wiring, etc.) and mention the fault condition (e.g. disconnected, short-circuited, etc.) Mention creepage-distances separately if applicable (refer to the text of 52.5 above 52.5.1 in the 601-1 standard)
- 2)
Mention for example safety hazards according to 3.1 and 13 and 52.4

Comments / Observation

Compliance
Yes No N/A

COMPONENTS AND GENERAL ASSEMBLY LIST OF CRITICAL COMPONENT PARTS (see

[illegible]

Codes Table;

PC = Power Cord (Set)

OI = Opto Isolator

TB = Terminal Block

J = Feed Through

RF = RF1 Filter

PF = Primary Fuse

SF = Secondary Fuse

XF = Fuse Holder



RF Choke

$$R = \text{Resistor}$$

MS = Mains Switch

S = Interlock

SI = Safety Interlock

CB = Circuit Breaker

VS = Voltage Selector

7

- Transformer
- Vari

TP = Thermal Protection

SSR = Solid State Relay

DS - Damsel Candidate

13 - Motor

Mr. - Motor Controller

By = Balance

Notes: 1) List all different supplies of above components; 2) Most critical components are: mains part, applied part



Requirements / Description		Comments / Observation		Compliance	
				Yes	No N/A
56.1 General					
b)	Component markings are according with conditions of use (refer to table in 56 on previous page)			☒	☐
d)	The movement of components is prevented			☒	☐
f)	Fixing of wiring			☒	☐
	Conductors and connectors are secured and/or insulated so that accidental detachment does not result in a safety hazard			☒	☐
56.3 Connections - General					
a)	Construction of connectors			☒	☐
	Incorrect interconnection of accessible connectors (electrical, hydraulic, pneumatic, gas), removable without the use of a tool, is prevented were a hazard may be caused			☒	☐
	Accessible parts are separated from live parts (see 17.g)			☒	☐
	Plugs for connection of patient circuit cannot be connected to other outlets			☒	☐
	Medical gas connections are not interchangeable			☐	☒
b)	Accessible conductive parts are prevented from becoming live when connection between different part of the equipment, by means of detachable flexible cords, is loosened or broken			☐	☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
c) Any connector in a lead having a conductive connection to a patient is constructed in such a manner that no conductive connection of that part can contact earth or possibly hazardous voltage	No patient connection	☐ ☐ ☒
56.4 Capacitors Capacitors not connected between live parts and not-protectively earthed accessible parts Capacitors between the mains part and protectively earthed accessible metal parts, compliance with IEC 384-14 or equivalent The enclosure of capacitors connected to the mains part and provided with only basic insulation are not secured directly to non-protectively earthed accessible metal parts Capacitors or other spark suppression devices are not connected between the contacts of thermal cut-outs	No such capacitors	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☒ ☒ ☐ ☐
56.5 Protective devices Protective devices which operate by producing a short circuit which results in operation of an over-current protection device in supply mains system not used		☒ ☐ ☐



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
Yes No N/A		
56.6 Temperature and overload control devices		
a) Thermal cut-outs with a safety function which require soldering to reset are not used		☒ ☐ ☐
Thermal safety devices are provided to prevent temperature limits being exceeded	<u>Transformer primaries</u>	☒ ☐ ☐
An independent non-selfresetting thermal cut-out is provided where the failure of a thermostat may cause a hazard	<u>No thermostats</u>	☐ ☐ ☒
The operating temperature of the above thermal cut-out is between the upper limit of the first thermostat and the safe limit for the function		☐ ☐ ☒
There is an audible alarm where loss of function due to operation of thermal cut-out could present a safety hazard		☐ ☐ ☒
Test of thermal cut-outs and overcurrent releases	<u>Approved devices</u>	☐ ☐ ☒
	<u>See Attachment 5</u>	☒ ☐ ☐
Heated liquid containers are protected against dangerous overheating when containers empty	<u>No liquid containers</u>	☐ ☐ ☒
Where means are provided for varying the temperature setting of thermostats, the temperature setting is clearly indicated	<u>No such devices</u>	☐ ☐ ☒
The temperature setting is clearly indicated		☐ ☐ ☒
The operating temperature of cut-outs is clearly indicated		☐ ☐ ☒
b)		



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
Yes No N/A		
56.7 Batteries		
a) Battery compartments are:		
1) Adequately ventilated	No batteries	☐ ☐ ☒
2) Accidental short-circuiting is prevented		☐ ☐ ☒
b) Incorrect polarity of connection prevented (Obs! Lithium batteries)		☐ ☐ ☒
56.8 Indicators		
Unless indication is provided by other means, from the normal operation position, indicator lights are used (colours: see 6.7):		
• To indicate that equipment is energised	Not required - See Working Group 14 Recommendations	☐ ☐ ☒
• To indicate the operation of non-luminous heaters if a safety hazard could result	No such heaters	☐ ☐ ☒
• To indicate when output exists if a safety hazard could result	No such hazardous outputs	☐ ☐ ☒
• Charging mode indicator is provided	No such mode	☐ ☐ ☒
56.10 Actuating parts of controls		
b) Actuating parts are adequately secured to prevent them working loose during normal use	No such parts/controls	☐ ☐ ☒
Controls are secured to prevent movement relative to scale marking (safety related only)	No such parts/controls	☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

Detachable indicating devices are prevented from incorrect connection without the use of a tool

☐ No such devices ☐ ☐ ☒

Rotating controls	Gripping diameter of the knob mm	Test torque Nm	Remarks	
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒
Pull controls	Axial pull, test force, Nm		Remarks	☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒
				☐ ☐ ☒

- c) Stops are provided on rotating controls:
- To prevent an unexpected change from maximum to minimum where this could produce a hazard
 - To prevent damage to wiring
- No rotating controls ☐ ☐ ☒
- ☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
----------------------------	------------------------	--------------------------

56.11 Cord connected hand-held and foot-operated control devices

- | | | |
|----|--|---|
| a) | Voltage on cord connected control devices do not exceed 25 V a.c. or 60 V d.c.
Measured voltage _____ V | ☐ ☐ ☒ |
| b) | The means of isolation from mains part (according 17g):
No safely hazard as a result of a free fall test
Foot-operated control devices: An actuating force of 1350 N doesn't damage the device | ☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒ |
| c) | No change of control setting when inadvertent placed in an abnormal position | ☐ ☐ ☒
☐ ☐ ☒ |
| d) | IP-classification of foot-operated control device:

At least IPX1 according to IEC 529
Specified for use in operating rooms IPX8 | ☐ ☐ ☒
☐ ☐ ☒
☐ ☐ ☒ |
| e) | Provided with adequate means of anchorage cords (see the test of 57.4)

Displacement _____ mm | ☐ ☐ ☒ |



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
57 MAINS PARTS, COMPONENTS AND LAY-OUT		
57.1 Isolation from supply mains		
a) Means of isolation:		
Incorporated in equipment	☒	
External	☐	
The equipment has a means for simultaneous disconnection of all supply poles		
Means of external isolation are specified in accompanying documents	<u>Wall outlet connector</u>	☒ ☐ ☐
d) Switches that are used to comply with subclause 57.1 a) complies with the creepage distances and air clearances as specified in IEC Publication 328		☐ ☐ ☒
f) Mains switches are not incorporated in flexible leads		☐ ☐ ☒
g) The directions of movement of their actuators (IEC 447)		☐ ☐ ☒
h) If there is a suitable plug device to isolate the non-permanently installed equipment from the supply mains, it is considered as a means of compliance with 57.1.a		☒ ☐ ☐
m) Fuses and semiconductor devices are not used as isolating devices		☒ ☐ ☐



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A
57.2 Mains connectors and appliance inlets		
e) Auxiliary mains sockets outlets:		
• cannot accept a mains plug (only applied to non-permanently installed equipment)		☐ ☐ ☒
• are properly marked		☐ ☐ ☒
g) Except where a functional earth needs to be provided Class I appliance inlets are not used in Class II equipment		☐ ☐ ☒
57.3 Power supply cords		
a) there is only one connection to a particular supply mains		☒ ☐ ☐
Alternative connections to a different supply do not cause safety hazards when more than one connection is made simultaneously		☐ ☐ ☒
The mains plug has only one power supply cord		☐ ☐ ☒
Equipment, not intended to be permanently connected to fixed wiring, is provided with a power supply cord or an appliance inlet		☒ ☐ ☐
b) Supply cables are sufficiently robust to comply with the requirements of IEC 227, designation 53, or IEC 245, designation 53		☒ ☐ ☐
PVC cords are not used for equipment having external metal parts with a temperature exceeding 75°C	No such temperatures	☐ ☐ ☒

Page 64 of 89



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

Screws associated with cable replacement are not used to secure other components

☐ ☐ ☒

Conductors of the power supply cord are so arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals

☐ ☐ ☒

Cable displacement with force indicated in Table XVIII
N/m

☐ ☐ ☒

b) For other than stationary equipment, the power supply cord is adequately protected against excessive bending

Results of bending test:

☒ ☐ ☐

c) There is sufficient space inside the equipment to allow the supply cable conductors to be introduced and connected

Not rewirable

☐ ☐ ☒

Any covers can be fitted without risk of damage to the conductors or their insulation

☐ ☐ ☒

It is possible to check that conductors are correctly connected before the cover is fitted

☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance Yes No N/A
57.5 Mains Terminal Devices and wiring of mains part		
a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Pins molded into case or approved plug	☒ ☐ ☐
If a conductor break away, barriers are provided such that creepage distance and air clearances cannot reduced		☒ ☐ ☐
They are not used to fix any other component (other than internal conductors unlikely to be displaced)		☒ ☐ ☐
b) Equipment with rewirable cords and terminals including any protective earth terminal are closely grouped to allow easy connection	Not re-wireable	☐ ☐ ☒
Protective earth conductor, see 58		
Marking of mains terminals, see 6.2		
They are inaccessible without the use of a tool		☐ ☐ ☒
Mains terminal devices are so located or shielded that there is no risk of accidental contact between live parts and accessible conductive parts and for Class II equipment between live parts and conductive parts if wire should escape		☐ ☐ ☒
Single strand of wire (8 mm). Test result:		☐ ☐ ☒
IEC 60601-1: 1988 + A1: 1991 + A2: 1995 Report No: 091-024777-000 Page 66 of 89		



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

c)	Tightening or loosening of clamping means of conductor does not::		☐	☐	☒
	Subject internal wiring to stress				
	Reduce creepage distances and air clearances below allowable limits		☐	☐	☒
	Cross-sectional area of the conductor used in the test: _____ mm ²		☐	☐	☒
d)	Effective connection to mains terminals does not require special preparation of cables		☐	☐	☒
	Conductors are not damaged or displaced when tightening or loosening of clamping screws or nuts		☐	☐	☒

57.6 Mains Fuses and Over-current Releases

Current rating of fuses etc. is :		☒	☐	☐
• sufficient (see table in 56)		☒	☐	☐
• not greater than rating of mains components		☒	☐	☐



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
		Yes No N/A
There are fuses or over-current releases in each supply lead for class I equipment and for class II equipment having a functional earth according to 18.1		
There is at least one mains fuse for other single phase class II equipment	Some models are Class II with functional earth	☒ ☐ ☐
A protective earth conductor is not fused	No protective earth	☒ ☐ ☐
No fuse is fitted in neutral conductor of permanently installed equipment	Not permanently installed	☐ ☐ ☒
57.8 Wiring of Mains Part		
a) Is insulation of all individual conductors at least equivalent to that required by IEC 227 or 245. If not, specify conductors to be considered as bare		☒ ☐ ☐
b) The cross-sectional area of wiring between the mains terminal and fuse		
Measured area: 0.75 mm ² Cu (see Sub-clause 57.3.c)	Test equipment: 4099	☒ ☐ ☐
	Initials tester: <u>AWB</u> Date: 21/02	
The cross-sectional area of other wiring in the mains part and sizes of tracks on printed wiring circuits are sufficient	Primary windings	☒ ☐ ☐



PRODUCT SERVICE

Requirements / Description

Comments / Observation

Compliance

Yes No N/A

57.9 Mains supply transformers (refer to table below)

Identification, reference, marking (e.g. T1, T2, etc.)	Manufacturer and type	Total rated power VA	Insulation material class	Nominal rated voltages and currents of the windings	General construction *)	Protection devices (manufacturer, type and rating, location)
GTM35 Series	Globtek	Output 2.4VA	E	120V or 230V 3 to 24VDC	Single bobbin with imperforate partition	Primary fuse (various values) Primary thermal cut out -1150C
GTM41 Series	Globtek	Output 7.2VA	E	120V or 230V 3 to 24VDC	Single bobbin with imperforate partition	Primary fuse (various values) Primary thermal cut out -1300C
GTM48 Series	Globtek	Output 9.6VA	E	120V or 230V 3 to 48VDC	Single bobbin with imperforate partition	Primary fuse (various values) Primary thermal cut out -1300C
GTM57 Series	Globtek	Output 16.8VA	E	120V or 230V 3 to 48VDC	Single bobbin with imperforate partition	Primary fuse (various values) Primary thermal cut out -1300C

*) A construction diagram like the example on the following page has to be added to this test report for each transformer mentioned above in a separate attachment.
Fill in the attachment number on the following page

IEC 60601-1: 1988 + A1: 1991 + A2: 1995

Report No: 091-02477-000

Page 69 of 89



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

^{*)}To the note on the previous page::
A construction diagram has been added in an attachment to this test report for each transformer, mentioned in the table on the previous page.

Document title/identification:

See Attachment 6

ATT. NR.



PRODUCT SERVICE

Requirements / Description

Comments / Observation

Compliance

Yes No N/A

page distances and air clearances of transformers

Insulation between :	Ref. voltage (V)	Air clearance (mm)		Creepage distance (mm)		Notes	
		Required	Measured	Required	Measured		
Primary - Primary							☐ ☐ ☒
Primary - Primary							☐ ☐ ☒
Primary - Secondary 1						See Attachment 7	☒ ☐ ☐
Primary - Secondary 2							☐ ☐ ☒
Primary - Secondary 3							☐ ☐ ☒
Primary - Core						See Attachment 7	☒ ☐ ☐
Secondary - Core							☐ ☐ ☒
Primary- Live Volt							☐ ☐ ☒
							☐ ☐ ☒
							☐ ☐ ☒
							☐ ☐ ☒



PRODUCT SERVICE

Requirements / Description

Comments / Observation

Compliance

Yes No N/A

57.9.1 Overheating

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

☐ ☐ ☒

Test equipment: _____

Initials tester: _____

Date: _____

a) Short-circuit

Supply voltage: _____ V

Winding under test *)	Comments
	See Attachment 5

☒ ☐ ☐ ☐
☐ ☐ ☐ ☐
☐ ☐ ☐ ☐
☐ ☐ ☐ ☐

*) Test under the conditions specified in clause 42. (Specify test voltages)

b) Overload

Tests under the conditions specified in clause 42 until steady thermal conditions are obtained

Results: see table below See Attachment 5

☒ ☐ ☐

Loading of a section or winding of the transformer:

- with fuses which comply with IEC 127, 241
- with fuses which do not comply with IEC 127, 241

☐ ☐



PRODUCT SERVICE

Requirements / Description

Comments / Observation

Compliance

Yes No N/A

- short-circuit current is less than test current ☒
- thermal out-cuts ☒
- overcurrent releases ☒
- not provided with a protective device for limitation of the winding temperature ☐

Test equipment: See Attachment 5

Initials tester:

Date:

[illegible]



Requirements / Description		Comments / Observation		Compliance	
				Yes	No / N/A
57.9.2	Dielectric strength			☒	☐
The electrical insulation between primary winding and other windings, screens and the core of the transformer(s) have been investigated by the tests performed as described in clause 20					
Insulation between turns and layers, test performed according to 57.9.2:					
Voltage used in test:		<u>5xsecondary</u> V			
Frequency used in test:		<u>250</u> Hz			
Test results:		<u>No breakdown or deterioration of insulation</u>		☒	☐
57.9.4	Construction			☒	☐
a)	One of the following methods is used to separate primary from patient connected windings and non-protective earthed secondary windings:			☒	☐
• separate bobbins or formers		☐			
• one bobbin or former with imperforate insulation partition		☒			
• one bobbin or former with concentric windings and having an imperforate protective copper screen with thickness of not less than 0.13 mm.		☐			
• one bobbin with concentric windings separated by double or reinforced insulation		☐			

IEC 60601-1: 1988 + A1: 1991 + A2: 1995

Report No: 091-024777-000

Page 74 of 89



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A
c) Means are provided to prevent displacement of end turns	<u>Bobbin cheeks</u>	☒ ☐ ☐
d) An earthed screen has a minimum overlap of 3mm and with a width at least equal to the axial length of the primary winding		☐ ☐ ☒
e) The double or reinforced insulation between the primary and secondary winding: Number of insulation layer(s) <u>2</u> ; total thickness <u>1.14</u> mm Result of voltage test:		☒ ☐ ☐
f) The Creepage distances between the primary and secondary windings: <u> </u> mm at location <u> </u> <u> </u> mm at location <u> </u> Notes: See Attachment 7		☒ ☐ ☐
g) For toroidal transformers: - the exit of wires from internal windings is provided with double sleeving complying with requirements for double insulation - its total thickness is at least 0.3mm extending at least 20mm outside the winding	<u> </u> Measured thickness <u> </u> mm	☐ ☐ ☒ ☐ ☐ ☒



Requirements / Description		Comments / Observation		Compliance	
				Yes No N/A	
<u>57.10 Creepage distances and air clearance</u>					
a) Values (refer to table in 57.10 on the next page)					
Creepage distances and air clearances comply at least with the values in the table in 57.10 on the next page		See Attachment 7		☒	☐
Creepage distances for slot insulation of motors are at least 50% of the values in the table with a minimum of 2 mm at 250 V				☐	☒
Creepage distances and air clearances between defibrillator-proof applied parts and other parts are not less than 4 mm				☐	☒



PRODUCT SERVICE

Compliance
Yes No N/A

Requirements / Description

Comments / Observation

Creepage distances and air clearances ¹⁾							
	Insulation between	Ref. voltage (V)	Air clearance / mm		Creepage distance/ mm		Notes
			Required	Measured	Required	Measured	
Basic insulation between parts of opposite polarity	A-f						See Attachment 7
Basic or supplementary insulation	A-a						☐ ☐ ☐
	A-b						☐ ☐ ☐
	A-c						☐ ☐ ☐
	A-j						☐ ☐ ☐
	B-d						☐ ☐ ☐
	B-c						☐ ☐ ☐
	A-a						☐ ☐ ☐
Double insulation or reinforced insulation	A-e						☐ ☐ ☐
	A-k						☐ ☐ ☐
	B-a						☐ ☐ ☐
	B-e						☐ ☐ ☐

¹⁾ See explanatory notes on next page (if any)

IEC 60601-1: 1988 + A1: 1991 + A2: 1995

Report No: 091-024777-000



Requirements / Description	Comments / Observation	Compliance
		Yes No N/A

Explanatory notes to table on previous page:

Page 79 of 89



Requirements / Description		Comments / Observation		Compliance	
59 CONSTRUCTION AND LAYOUT				Yes No N/A	
59.1 Internal wiring					
a)	Internal cables and wiring: - are protected against contact with moving parts or friction with sharp corners and edges - are protected by additional fixed sleeving, if there is movement relative to metal parts where it is in direct contact with them - and components are not likely to be damaged by opening or assembling the equipment			☒	☐ ☐
b)	Guiding rollers or moveable leads are such that the leads are not bent around a radius of less than five times the outer diameter of the lead			☐	☐ ☒
c)	Insulation: - Insulating sleeving can only be removed by breaking or cutting or is secured at both ends - if the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 or 245 - Insulated conductors, which are subject to temperatures greater than 70°C, have an insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation			☒	☐ ☐
d)	Aluminium wires below 16 mm ² cross section are not in use	No aluminium wires used		☐	☐ ☐ ☒

IEC 60601-1: 1988 + A1: 1991 + A2: 1995

Report No: 091-024777-000

Page 80 of 89



PRODUCT SERVICE

Requirements / Description	Comments / Observation	Compliance
Yes No N/A		
59.2 Insulation		
b) Resistance to moisture test (see clause 44)		☒ ☐ ☐
Dielectric strength test (see clause 20)	Common enclosure material - ABS 94V-O - E121562(R)	☒ ☐ ☐
Ball-pressure test		☒ ☐ ☐
c) Insulation is not likely to be impaired by deposition of dirt or dust resulting from wear of parts within the equipment		☐ ☐ ☒
Ceramic materials specified in this subclause are not used as supplementary or reinforced insulation		☐ ☐ ☒
Rubber materials used as supplementary insulation in class II equipment are resistant to ageing (oxygen test) and		
creepage distances are not reduced below those values specified in 57.10 despite any cracks in such insulation		☐ ☐ ☒
Insulating materials in which heating elements are embedded are not used as reinforced insulation		☐ ☐ ☒
59.3 Excessive current and voltage protection		
Fuse elements replaceable without opening the enclosure are fully enclosed in a fuseholder	Internal fuses only	☐ ☐ ☒
Live parts of fuseholders are shielded to prevent electric shock when replacing fuses (if replaceable without the use of a tool)		☐ ☐ ☒
Protective devices between an isolated applied part and the body of the equipment do not operate below 500 Vrms		☐ ☐ ☒



Requirements / Description	Comments / Observation	Compliance Yes No N/A
59.4 Oil containers		
Oil containers in portable equipment are adequately sealed to prevent oil loss in any position and the oil container design allows for the expansion of oil	No oil containers	☐ ☐ ☒
Oil containers in mobile equipment are sealed to prevent loss of oil during transport		☐ ☐ ☒
An oil level indicator is provided on partially sealed oil-filled equipment or parts		☐ ☐ ☒



Certain 120V models have a functional earth connection to the transformer laminations

Test Frequency f = 50 Hz



0 = Switch open

Switch Positions			NC (S1 = 1)		SFC (S1 = 0)	
S5	S10	S12	Measured μA		Measured μA	
			Before ¹	After ²	Before ¹	After ²
1	1	1	N/A	N/A	N/A	N/A
1	1	0	N/A	N/A	N/A	N/A
1	0	1	N/A	N/A	N/A	N/A
1	0	0	3.2	3.4	4.6	4.7
0	1	1	N/A	N/A	N/A	N/A
0	1	0	N/A	N/A	N/A	N/A
0	0	1	N/A	N/A	N/A	N/A
0	0	0	4.5	5.0	5.7	5.5

¹ and ² = Before and After humidity preconditioning treatment.



PRODUCT SERVICE

APPENDIX 2 : Sub-clause 19.4.g :

MEASUREMENT OF THE ENCLOSURE LEAKAGE CURRENT

Notes : GTM3T57-12-1500D

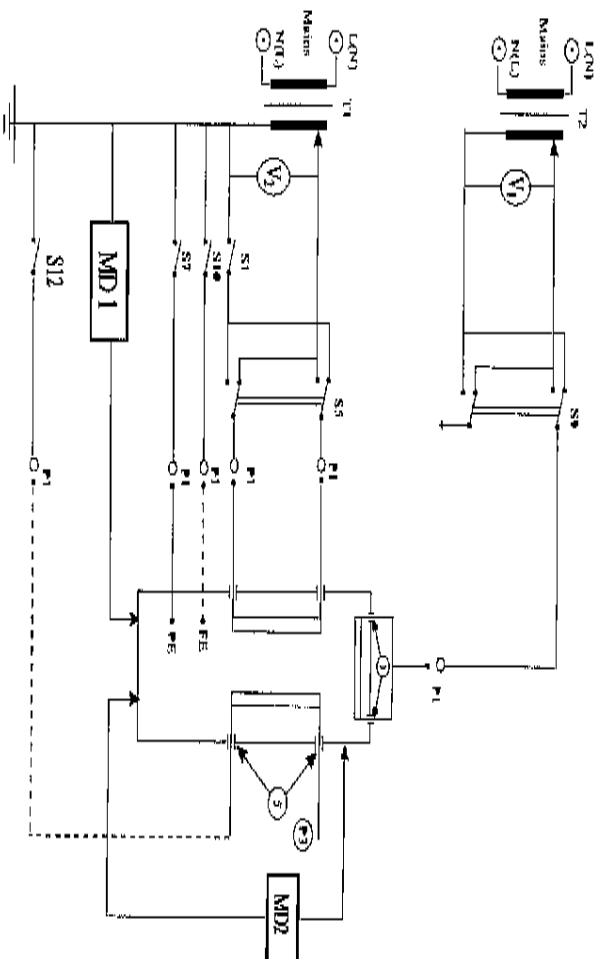
Results are typical for the range

Worst case results recorded

T/E 4077, 4024, 4033, 4032

Test Voltage U= 230 V

Test Frequency f= 50 Hz



Switch Positions		NC S1 = 1, S7 = 1 Measured μA	SFC S1 = 0, S7 = 1 Measured μA	SFC S1 = 1, S7 = 0 Measured μA	Additional SFC S1 = 1 S7 = 1 Measured μA		
S5	S10 S12	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
1	1 1	N/A	N/A	N/A	N/A	N/A	N/A
1	1 0	N/A	N/A	N/A	N/A	N/A	N/A
1	0 1	N/A	N/A	N/A	N/A	N/A	N/A
1	0 0	1.5	1.5	1.5	1.5	1.5	1.5
0	1 1	N/A	N/A	N/A	N/A	N/A	N/A
0	1 0	N/A	N/A	N/A	N/A	N/A	N/A
0	0 1	N/A	N/A	N/A	N/A	N/A	N/A
0	0 0	1.5	1.5	1.5	1.5	1.5	1.5

and ² = Before and After humidity preconditioning treatment.

Remarks:
S7 not used for class II equipment

NC = Normal Condition
SFC = Single Fault condition
1 = Switch closed
0 = Switch open
* = described additional SFC according to Sub-clause 17g in notes above.



PRODUCT SERVICE

APPENDIX 3 : Sub-clause 19.2.c:

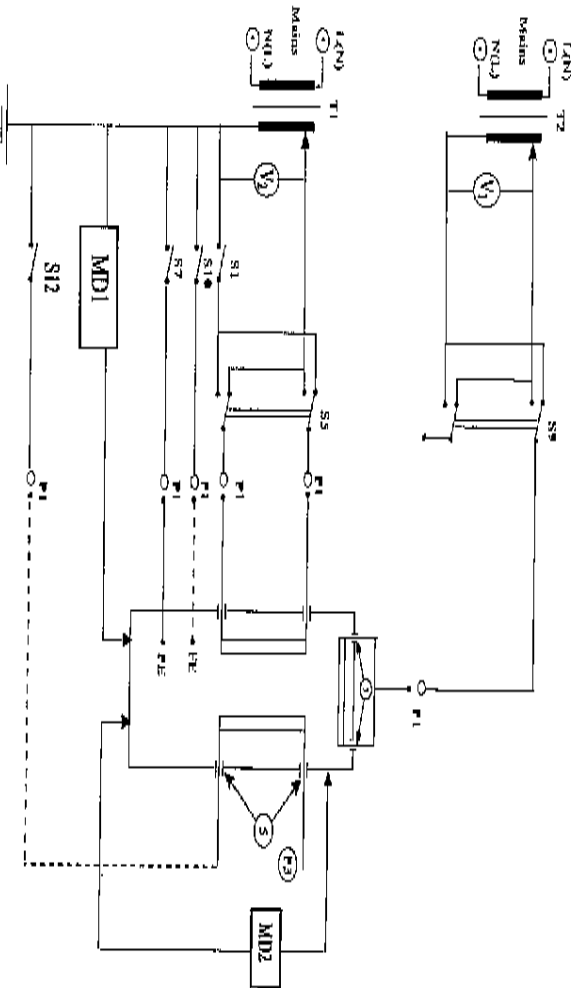
MEASUREMENT OF THE ENCLOSURE LEAKAGE CURRENT WITH 110% MAINS VOLTAGE ON ANY SIGNAL INPUT OR SIGNAL OUTPUT PART

Notes :

No SIP/SOP's

Test Voltage U= V

Test Frequency f= Hz



Switch Positions	NC S1 = 1, S7 = 1		SFC S1 = 0, S7 = 1		SFC S1 = 1, S7 = 0		Additional SFC S1 = 1 S7 = 1	
	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
S5	S10	S12	Measured μA	Measured μA	Measured μA	Measured μA	Measured μA	Measured μA
1	1	1	N/A	N/A	N/A	N/A	N/A	N/A
1	1	0	N/A	N/A	N/A	N/A	N/A	N/A
1	0	1	N/A	N/A	N/A	N/A	N/A	N/A
1	0	0	N/A	N/A	N/A	N/A	N/A	N/A
0	1	1	N/A	N/A	N/A	N/A	N/A	N/A
0	1	0	N/A	N/A	N/A	N/A	N/A	N/A
0	0	1	N/A	N/A	N/A	N/A	N/A	N/A
0	0	0	N/A	N/A	N/A	N/A	N/A	N/A

¹ and ² = Before and After humidity preconditioning treatment.

Remarks:

S7 not used for classII equipment

NC = Normal Condition

SFC = Single Fault condition

1 = Switch closed

0 = Switch open

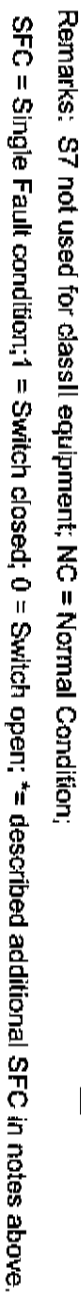
* = described additional SFC according to Sub-clause 17. in notes above.

MEASUREMENT OF THE PATIENT LEAKAGE CURRENT

No applied part

Test Voltage $U =$ V

Test Frequency = Hz

¹ and ² = before and after humidity preconditioning treatment.

MEASUREMENT OF THE PATIENT LEAKAGE CURRENT WITH $\pm 10\%$ MAINS VOLTAGE ON A SIGNAL INPUT OR SIGNAL OUTPUT PART

No applied part

Test Frequency = Hz

Switch positions	measured μA
1	0.00
2	0.00
3	0.00
4	0.00
5	0.00
6	0.00
7	0.00
8	0.00
9	0.00
10	0.00
11	0.00
12	0.00
13	0.00
14	0.00
15	0.00
16	0.00
17	0.00
18	0.00
19	0.00
20	0.00
21	0.00
22	0.00
23	0.00
24	0.00
25	0.00
26	0.00
27	0.00
28	0.00
29	0.00
30	0.00
31	0.00
32	0.00
33	0.00
34	0.00
35	0.00
36	0.00
37	0.00
38	0.00
39	0.00
40	0.00
41	0.00
42	0.00
43	0.00
44	0.00
45	0.00
46	0.00
47	0.00
48	0.00
49	0.00
50	0.00
51	0.00
52	0.00
53	0.00
54	0.00
55	0.00
56	0.00
57	0.00
58	0.00
59	0.00
60	0.00
61	0.00
62	0.00
63	0.00
64	0.00
65	0.00
66	0.00
67	0.00
68	0.00
69	0.00
70	0.00
71	0.00
72	0.00
73	0.00
74	0.00
75	0.00
76	0.00
77	0.00
78	0.00
79	0.00
80	0.00
81	0.00
82	0.00
83	0.00
84	0.00
85	0.00
86	0.00
87	0.00
88	0.00
89	0.00
90	0.00
91	0.00
92	0.00
93	0.00
94	0.00
95	0.00
96	0.00
97	0.00
98	0.00
99	0.00
100	0.00

0 = Switch open

Page 88 of 89



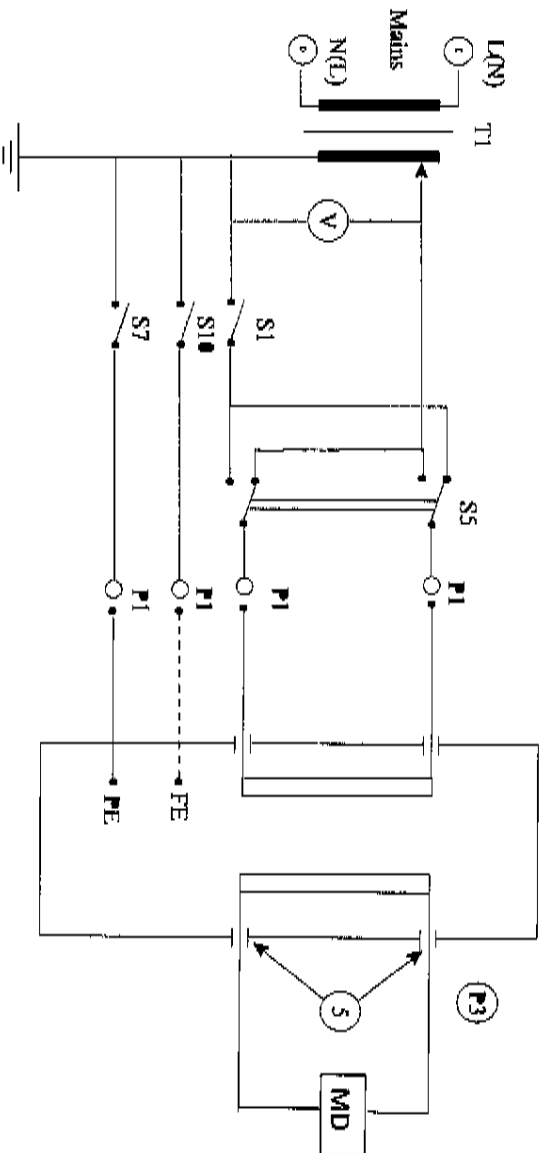
APPENDIX 7 : Sub-clause 19.4.j):
MEASUREMENT OF THE PATIENT AUXILIARY
CURRENT

Notes : _____

No applied part _____

Test Voltage U= V

Test Frequency f= Hz



Remarks: S7 not used for classII equipment; NC = Normal Condition; SFC = Single Fault condition;
1 = Switch closed; 0 = Switch open; * = described additional SFC in notes above.

Switch Positions	NC S1 = 1, S7 = 1 measured µA				SFC S1 = 0, S7 = 1 measured µA				SFC S1 = 1, S7 = 0 Measured µA				Additional SFC S1 = 1, S7 = 1 Measured µA			
	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
S5	S10	d.c.	a.c.	d.c.	a.c.	d.c.	a.c.	d.c.	a.c.	d.c.	a.c.	d.c.	a.c.	d.c.	a.c.	d.c.
1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
0	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

¹ and ² = Before and After humidity preconditioning treatment

Attachment 2

Description of the range of devices covered

The range of devices covered by this assessment consists of four basic transformer/enclosure sizes, ie 35, 41, 48 and 57.

The model designations are given as follows:

GTM3TA4-BB-CCCC (AA is Case Size, BB is O/P Volts, CCCC is O/P Current in mA)

The T indicates that the input voltage is 230VAC – No T indicates that the input voltage is 120VAC

All 120VAC models can have Input Plug as Nema 1-15P or Nema 5-15P

All 230VAC models can have Input Plug as Euro (CEE 7/16, 2 or 3 Pin), Schuko (CEE 7/7), British (BS1363), Australian (AS3112)

All models can be table top with input cord.

Models with DC output will have D at the end of the model number.

The available models are summarized in the following table

Model No:	Out Put	
	Volts	mA
GTM335-3-600	3.0	600
GTM341-3-1300	3.0	1300
GTM348-3-1500	3.0	1500
GTM357-3-2500	3.0	2500
GTM348-3-3-1500	3.3	1500
GTM335-4-600	4.0	600
GTM341-4-1300	4.0	1300
GTM348-4-1000	4.0	1000
GTM348-4-1500	4.0	1500
GTM357-4-2300	4.0	2300
GTM348-4.5-1500	4.5	1500
GTM335-5-500	5.0	500
GTM341-5-1000	5.0	1000
GTM348-5-1200	5.0	1200
GTM348-5-1400	5.0	1400
GTM357-5-2300	5.0	2300
GTM335-6-500	6.0	500
GTM341-6-900	6.0	900
GTM348-6-1200	6.0	1200
GTM348-6-1400	6.0	1400
GTM357-6-2200	6.0	2200
GTM335-7-400	7.0	400
GTM341-7-800	7.0	800

Attachment 2

Model No:	Out Put	Volts	mA
GTM348-7-1100	7.0	1100	
GTM348-7-1300	7.0	1300	
GTM357-7-2000	7.0	2000	
GTM335-7.5-400	7.5	400	
GTM341-7.5-800	7.5	800	
GTM348-7.5-900	7.5	900	
GTM348-7.5-1100	7.5	1100	
GTM348-7.5-1300	7.5	1300	
GTM357-7.5-2000	7.5	2000	
GTM335-9-300	9.0	300	
GTM341-9-650	9.0	650	
GTM348-9-1000	9.0	1000	
GTM348-9-1200	9.0	1200	
GTM357-9-1800	9.0	1800	
GTM348-10-700	10.0	700	
GTM348-10-900	10.0	900	
GTM348-10-1100	10.0	1100	
GTM357-10-1500	10.0	1500	
GTM348-11-1000	11.0	1000	
GTM335-12-250	12.0	250	
GTM341-12-600	12.0	600	
GTM348-12-800	12.0	800	
GTM348-12-1200	12.0	1200	
GTM357-12-1400	12.0	1400	
GTM357-12-1500	12.0	1500	
GTM348-13.5-850	13.5	850	
GTM348-13.5-1000	13.5	1000	
GTM335-14-200	14.0	200	
GTM341-14-450	14.0	450	
GTM348-14-500	14.0	500	
GTM348-14-600	14.0	600	
GTM348-14-800	14.0	800	
GTM357-14-1300	14.0	1300	
GTM335-15-200	15.0	200	
GTM341-15-450	15.0	450	
GTM348-15-800	15.0	800	
GTM348-15-900	15.0	900	
GTM357-15-1300	15.0	1300	
GTM348-16-900	16.0	900	
GTM357-16.5-1300	16.5	1300	
GTM335-18-150	18.0	150	
GTM341-18-350	18.0	350	
GTM348-18-350	18.0	350	
GTM348-18-450	18.0	450	
GTM348-18-500	18.0	500	
GTM348-18-550	18.0	550	
GTM348-18-700	18.0	700	
GTM357-17.8-1500	17.8	1500	
GTM357-18-1100	18.0	1100	

Attachment 2

Model No:	Out Put	Volts	mA
GTM348-20-500		20.0	500
GTM357-20-1000		20.0	1000
GTM335-21-150		21.0	150
GTM341-21-300		21.0	300
GTM348-21-300		21.0	300
GTM348-21-400		21.0	400
GTM348-21-500		21.0	500
GTM348-21-600		21.0	600
GTM357-21-1000		21.0	1000
GTM335-24-100		24.0	100
GTM341-24-300		24.0	300
GTM348-24-350		24.0	350
GTM348-24-450		24.0	450
GTM348-24-550		24.0	550
GTM357-24-800		24.0	800
GTM348-28-450		28.0	450
GTM357-28-700		28.0	700
GTM348-36-300		36.0	300
GTM357-36-500		36.0	500
GTM348-48-200		48.0	200
GTM357-48-350		48.0	350
GTM335-3-600		3.0	600
GTM341-3-1300		3.0	1300
GTM348-3-1500		3.0	1500
GTM357-3-2500		3.0	2500
GTM348-3-3-1500		3.3	1500
GTM335-4-600		4.0	600
GTM341-4-1300		4.0	1300
GTM348-4-1000		4.0	1000
GTM348-4-1500		4.0	1500
GTM357-4-2300		4.0	2300
GTM348-4-5-1500		4.5	1500
GTM335-5-500		5.0	500
GTM341-5-1000		5.0	1000
GTM348-5-1200		5.0	1200
GTM348-5-1400		5.0	1400
GTM357-5-2300		5.0	2300
GTM335-6-500		6.0	500
GTM341-6-900		6.0	900
GTM348-6-1200		6.0	1200
GTM348-6-1400		6.0	1400
GTM357-6-2200		6.0	2200
GTM335-7-400		7.0	400
GTM341-7-800		7.0	800
GTM348-7-1100		7.0	1100
GTM348-7-1300		7.0	1300
GTM357-7-2000		7.0	2000
GTM335-7-5-400		7.5	400
GTM341-7-5-800		7.5	800

Attachment 2

Model No:	Out Put	
	<i>Volts</i>	<i>mA</i>
GTM3T48-7.5-900	7.5	900
GTM3T48-7.5-1100	7.5	1100
GTM3T48-7.5-1300	7.5	1300
GTM3T57-7.5-2000	7.5	2000
GTM3T35-9-300	9.0	300
GTM3T41-9-650	9.0	650
GTM3T48-9-1000	9.0	1000
GTM3T48-9-1200	9.0	1200
GTM3T57-9-1800	9.0	1800
GTM3T48-10-700	10.0	700
GTM3T48-10-900	10.0	900
GTM3T48-10-1100	10.0	1100
GTM3T57-10-1500	10.0	1500
GTM3T48-11-1000	11.0	1000
GTM3T35-12-250	12.0	250
GTM3T41-12-600	12.0	600
GTM3T48-12-800	12.0	800
GTM3T48-12-1200	12.0	1200
GTM3T57-12-1400	12.0	1400
GTM3T57-12-1500	12.0	1500
GTM3T48-13.5-850	13.5	850
GTM3T48-13.5-1000	13.5	1000
GTM3T35-14-200	14.0	200
GTM3T41-14-450	14.0	450
GTM3T48-14-500	14.0	500
GTM3T48-14-600	14.0	600
GTM3T48-14-800	14.0	800
GTM3T57-14-1300	14.0	1300
GTM3T35-15-200	15.0	200
GTM3T41-15-450	15.0	450
GTM3T48-15-800	15.0	800
GTM3T48-15-900	15.0	900
GTM3T57-15-1300	15.0	1300
GTM3T48-16-900	16.0	900
GTM3T57-16.5-1300	16.5	1300
GTM3T35-18-150	18.0	150
GTM3T41-18-350	18.0	350
GTM3T48-18-350	18.0	350
GTM3T48-18-450	18.0	450
GTM3T48-18-500	18.0	500
GTM3T48-18-550	18.0	550
GTM3T48-18-700	18.0	700
GTM3T57-17.8-1500	17.8	1500
GTM3T57-18-1100	18.0	1100
GTM3T48-20-500	20.0	500
GTM3T57-20-1000	20.0	1000
GTM3T35-21-150	21.0	150
GTM3T41-21-300	21.0	300
GTM3T48-21-300	21.0	300

Attachment 2

Model No:	Out Put	
	<i>Volts</i>	<i>mA</i>
GTM3T48-21-400	21.0	400
GTM3T48-21-500	21.0	500
GTM3T48-21-600	21.0	600
GTM3T57-21-1000	21.0	1000
GTM3T35-24-100	24.0	100
GTM3T41-24-300	24.0	300
GTM3T48-24-350	24.0	350
GTM3T48-24-450	24.0	450
GTM3T48-24-550	24.0	550
GTM3T57-24-800	24.0	800
GTM3T48-28-450	28.0	450
GTM3T57-28-700	28.0	700
GTM3T48-36-300	36.0	300
GTM3T57-36-500	36.0	500
GTM3T48-48-200	48.0	200
GTM3T57-48-350	48.0	350

The power supplies are being evaluated to selected requirements of EN60601-1 and UL2601-1 as a component for use with a medical device. It is the responsibility of the medical device manufacturer to ensure that the device with which this component is used complies with all applicable requirements of EN60601-1 and UL2601-1.

Attachment 3

Power Input

Models from throughout the range were sampled and the power consumption compared to the marked rating.

Model number	Power input	Marked rating	Compliance
GTM348-12-1200D	113mA	116mA	P
GTM3T35-12-250D	35mA	34mA	P
GTM3T41-24-300D	58mA	60mA	P
GTM3T57-12-1500D	139mA	142mA	P
GTM335-12-250D	40mA (4.8W)	6W	P
GTM341-12-700D	95mA (11.4W)	16W	P
GTM348-48-250D	160mA (19.2W)	20W	P
GTN357-12-1500D	250mA (30W)	32W	P

Attachment 4

Dielectric Strength

Note: A mixture of 120 volt and 230 volt models tested

Selected units tested to represent entire range as evidenced below

Model No	A-a1	Test voltage	A-a2 I/P to Enclosure	Test voltage	A-a2 I/P to O/P	Test voltage
GTM341-3-1300	N/A	N/A	100mA	3000VAC	200mA	3000VAC
GTM348-3-1500	100mA	1000VAC	100mA	3000VAC	200mA	3000VAC
GTM357-3-2500	N/A	N/A	250mA	3000VAC	400mA	3000VAC
GTM3T57-3-2500	N/A	N/A	300mA	4000VAC	500mA	4000VAC
GTM348-3-1500	100mA	1000VAC	100mA	3000VAC	200mA	3000VAC
GTM335-3 500	N/A	N/A	100mA	3000VAC	200mA	3000VAC
GTM3T35-12-250	N/A	N/A	300mA	4000VAC	400mA	4000VAC
GTM348-12-100	100mA	1000VAC	100mA	3000VAC	200mA	3000VAC
GTM3T41-24-300	N/A	N/A	300mA	4000VAC	500mA	4000VAC
GTM3T48-48-200	N/A	N/A	250mA	4000VAC	450mA	4000VAC
GTM348-48-250	100mA	1000VAC	300mA	3000VAC	400mA	3000VAC
GTM357-48-350	N/A	N/A	300mA	3000VAC	400mA	3000VAC

Test equipment:

4010, 4076

Attachment 5

Sample selection

The following testing for excessive temperatures and transformer short circuit and overload has been performed on selected samples from the range covered (see Attachment 2). The samples have been selected across the range and to represent the worst case for each of the core sizes by selecting the devices that develop the maximum power in the secondary circuit.

For transformer short circuit and overload tests the input voltage was held at rated voltage -10% .

No significant difference in results was expected for rated voltage $+10\%$.

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM335-12-250D

Input Voltage: $120 \times 110\% = 132\text{VAC}$

Input Current: 38mA

Load current: 250mA

Duration of test: 2.5 hours

Protection: 100mA primary fuse 115°C secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	63.7	77.9
Surface of secondary winding	61.1	75.3
Surface of capacitor	51.6	65.8
Enclosure top	35.8	50.1
Ambient	25.8	N/A

Attachment 5

Input Voltage: 120x90% = 108VAC
 Input Current: 42mA
 Load current: 250mA
 Duration of test: 3 hours
 Protection: 100mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	52.9	70.4
Surface of secondary winding	50.4	67.9
Surface of capacitor	44.4	61.9
Enclosure top	31.9	49.4
Ambient	22.5	N/A

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 120x90% = 108VAC
 Result of short circuit: Primary fuse opens
 Overload current reqd: 2.1X100mA = 210mA
 Overload used: Short circuit (gives rise to 140mA in primary)
 Duration of test: Approx 5 minutes until primary thermal cut-out opens
 Protection: 100mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	91.9	110.1
Surface of secondary winding	85.3	103.5
Surface of capacitor	68.3	86.5
Enclosure top	35.1	53.3
Ambient	21.8	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 5

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM341-12-700D

Input Voltage: 120x110% = 132 VAC
 Input Current: 95mA
 Load current: 700mA
 Duration of test: 2.5 hours
 Protection: 375mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	85.9	100.1
Surface of secondary winding	94.9	109.3
Surface of capacitor	67.8	82.0
Enclosure top	34.1	48.3
Ambient	25.8	N/A

Input Voltage: 120x90% = 108 VAC
 Input Current: 103mA
 Load current: 700mA
 Duration of test: 3 hours
 Protection: 375mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	68.0	82.2
Surface of secondary winding	74.4	88.6
Surface of capacitor	57.5	71.7
Enclosure top	30.3	44.5
Ambient	22.3	N/A

Attachment 5

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 120x90% = 108 VAC
 Result of short circuit: Primary fuse opens
 Overload current reqd: 2.1x375mA = 787.5mA
 Overload used: Short circuit (gives rise to 470mA in primary)
 Duration of test: Approx 6 minutes until thermal cut out opens
 Protection: 375mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	105.2	121.9
Surface of secondary winding	116.3	133.0
Surface of capacitor	81.1	97.8
Enclosure top	29.2	45.9
Ambient	23.3	N/A

Test Equipment used: 4039, 4023, 4025, 4096, 4027, 4062

Attachment 5

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM348-48-250D

Input Voltage: 120x110% = 132VAC
 Input Current: 160mA
 Load current: 250mA
 Duration of test: 2.5 hours
 Protection: 500mA primary fuse, 130oC primary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	67.2	83.9
Surface of secondary winding	80.5	97.2
Surface of capacitor	47.1	63.8
Enclosure top	45.3	62.0
Ambient	23.3	N/A

Input Voltage: 120x90% = 108VAC
 Input Current: 154mA
 Load current: 250mA
 Duration of test: 1.5 hours
 Protection: 500mA primary fuse 130oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	68.6	84.8
Surface of secondary winding	79.2	95.4
Surface of capacitor	47.4	63.6
Enclosure top	46.8	63.0
Ambient	23.8	N/A

Attachment 5

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 120x90% = 108VAC
 Result of short circuit: Primary fuse opens
 Overload current reqd: 2.1x500mA = 1050mA
 Overload used: Short circuit (gives rise to 623mA in primary and 1400mA in secondary)
 Duration of test: Approx 3 minutes until primary thermal cut-out opens
 Protection: 500mA primary fuse 130oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	83.6	100.4
Surface of secondary winding	118.3	135.1
Surface of capacitor	47.7	64.5
Enclosure top	39.8	56.6
Ambient	23.2	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 5**Clause 42 – Excessive Temperatures****Normal conditions****Model: GTM357-12-1500D**

Input Voltage: 120x110% = 132VAC
 Input Current: 250mA
 Load current: 1500mA
 Duration of test: 2.5 hours
 Protection: 500mA primary fuse, 130oC primary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	83.6	100.3
Surface of secondary winding	95.7	112.4
Surface of capacitor	65.1	81.8
Enclosure top	54.0	70.7
Ambient	23.3	N/A

Input Voltage: 120x90% = 108VAC
 Input Current: 248mA
 Load current: 1500mA
 Duration of test: 1.5 hours
 Protection: 500mA primary fuse 130oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	82.7	98.9
Surface of secondary winding	94.4	110.6
Surface of capacitor	65.4	81.6
Enclosure top	61.4	77.6
Ambient	23.8	N/A

Attachment 5

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 120x90% = 108VAC
 Result of short circuit: Primary fuse opens
 Overload current reqd: 2.1x500mA = 1050mA
 Overload used: Short circuit (gives rise to 1050mA in primary and 8.4A in secondary)
 Duration of test: 5 minutes until primary thermal cut-out opens
 Protection: 500mA primary fuse 130oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	113.2	129.8
Surface of secondary winding	109.0	125.6
Surface of capacitor	64.2	80.8
Enclosure top	45.8	62.4
Ambient	23.4	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 5

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM3T35-12-250D

Input Voltage: 230x110% = 253VAC
 Input Current: 35mA
 Load current: 250mA
 Duration of test: 2.5 hours
 Protection: 100mA primary fuse, 115oC primary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	61.9	78.0
Surface of secondary winding	82.2	98.3
Surface of capacitor	64.7	80.8
Enclosure top	41.9	21.0
Ambient	23.9	N/A

Input Voltage: 230x90% = 207VAC
 Input Current: 34mA
 Load current: 250mA
 Duration of test: 1.5 hours
 Protection: 100mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	48.3	64.2
Surface of secondary winding	61.6	77.5
Surface of capacitor	50.7	66.6
Enclosure top	34.1	50.0
Ambient	24.1	N/A

Attachment 5

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 230x90% = 207VAC
 Result of short circuit: Primary fuse opens
 Overload current reqd: $2.1 \times 100\text{mA} = 210\text{mA}$
 Overload used: Short circuit (gives rise to 125mA in primary)
 Duration of test: 2.5 minutes until primary thermal cut-out opens
 Protection: 100mA primary fuse 115°C secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	105.3	121.4
Surface of secondary winding	114.2	130.3
Surface of capacitor	56.2	72.3
Enclosure top	38.6	24.7
Ambient	23.9	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 5

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM3T41-24-300D

Input Voltage: 230x110% = 253VAC

Input Current: 58mA

Load current: 300mA

Duration of test: 2.5 hours

Protection: 150mA primary fuse, 115oC primary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	79.6	95.7
Surface of secondary winding	84.9	101.0
Surface of capacitor	59.4	75.5
Enclosure top	24.2	40.3
Ambient	23.9	N/A

Input Voltage: 320x90% = 207VAC

Input Current: 62mA

Load current: 250mA

Duration of test: 1.5 hours

Protection: 150mA primary fuse 115oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	66.8	82.7
Surface of secondary winding	71.1	87.6
Surface of capacitor	52.7	68.6
Enclosure top	24.2	41.1
Ambient	24.1	N/A

Attachment 5**Clause 57.9 – Transformer short Circuit and overload**

Input Voltage: 230x90% = 207VAC
 Result of short circuit: Primary fuse opens
 Overload current reqd: 2.1x150mA = 315mA
 Overload used: Short circuit (gives rise to 250mA in primary)
 Duration of test: Approx 3 minutes until primary thermal cut-out opens
 Protection: 150mA primary fuse 115°C primary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	107.2	123.3
Surface of secondary winding	121.1	137.2
Surface of capacitor	61.6	77.7
Enclosure top	24.5	40.6
Ambient	23.9	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 5

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM3T48-12-1200D

Input Voltage: 230x110% = 253VAC
 Input Current: 113mA
 Load current: 1200mA
 Duration of test: 3 hours
 Protection: 500mA primary fuse 130°C secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	88.1	103.8
Surface of secondary winding	90.6	106.3
Surface of capacitor	73.6	89.3
Enclosure top	45.8	61.5
Ambient	24.3	N/A

Input Voltage: 230x90% = 207VAC
 Input Current: 119mA
 Load current: 1200mA
 Duration of test: 2 hours
 Protection: 500mA primary fuse 130°C secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	76.1	92.2
Surface of secondary winding	78.7	94.8
Surface of capacitor	66.3	82.4
Enclosure top	41.3	57.4
Ambient	23.9	N/A

Attachment 5

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 230x90% = 207VAC
 Result of short circuit: Primary fuse does not open
 Overload current reqd: 2.1x500mA = 1050mA
 Overload used: Short circuit (gives rise to 335mA in primary and 5A in secondary)
 Duration of test: Approx 2 minutes until 130°C thermal cut-out opens
 Protection: 500mA primary fuse 130oC secondary thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	104.7	122.3
Surface of secondary winding	110.9	128.5
Surface of capacitor	73.4	91.0
Enclosure top	43.7	61.3
Ambient	22.4	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 5

Clause 42 – Excessive Temperatures

Normal conditions

Model: GTM3T57-12-1500D

Input Voltage: 230x110% = 253VAC
 Input Current: 139mA
 Load current: 1500mA
 Duration of test: 3 hours
 Protection: 500mA primary fuse, 5.0A secondary fuse and
 130oC thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	89.2	104.9
Surface of secondary winding	86.5	102.2
Surface of capacitor	64.9	80.6
Enclosure top	45.1	60.8
Ambient	24.3	N/A

Input Voltage: 230x90% = 207VAC
 Input Current: 119mA
 Load current: 1500mA
 Duration of test: 2 hours
 Protection: 500mA primary fuse, 5.0A secondary fuse and
 130oC thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	79.5	97.7
Surface of secondary winding	77.6	95.8
Surface of capacitor	60.9	79.1
Enclosure top	41.7	59.9
Ambient	21.8	N/A

Attachment 5

Clause 57.9 – Transformer short Circuit and overload

Input Voltage: 230x90% = 207VAC
 Result of short circuit: Primary fuse does not open
 Overload current reqd: 2.1x500mA = 1050mA or 2.1x5A =10.5A
 Overload used: Short circuit (gives rise to 530mA in primary and 8.6A in secondary)
 Duration of test: Approx 2 minutes until primary thermal cut-out opens
 Protection: 500mA primary fuse, 5.0A secondary fuse and 130oC thermal cut-out

Thermocouple placement	Maximum Temperature	T compensated
Surface of primary winding	113.2	129.8
Surface of secondary winding	109.1	125.7
Surface of capacitor	64.2	80.8
Enclosure top	45.8	62.4
Ambient	23.4	N/A

Test Equipment used:

4039, 4023, 4025, 4096, 4027, 4062

Attachment 6

Critical components list

Component Type	Manufacturer	Model, current rating, power rating, voltage rating, insulation class	Test Mark
Enclosure	GE Plastics Americas	ABS Type KJW – 94V-0 (85°C)	E121562(R)
Transformer bobbin	DuPont DE	Nylon 66 101L – 94V-2 (125°C)	E41938
Windings	Menours & CO 1. Chuen Yin Wire Co 2. Feng Ching Metal Corp Jiuh Fu Copper Wire Co	Polyurethane enameled copper wire (2UEW) (120°C)	1. E15709 2. E17329 3. E169290(S)
Thermal fuse	Aupo Electronics Ltd	#A2 (115°C) #A5 (130°C)	E140487
PC Board	1. Shenzen Weijie electric circuit 2. Technology Limited 3. Golden Glorious Industries	“W2” Type 1.6mm thickness – 94V-0 “T2” Type 1.6mm thickness – 94V-0 “CY ₂ ” Type 1.6 mm thickness – 94V-0	E162665 E154355 E112804(S)
Fuse	Walter Electronic Co. Ltd	250VAC 100mA to 500mA 125VAC 5A	E56092(M) LR41870
Input cord	1. Yung Li Co. Ltd 2. Kenic Electric Mfg Co. Ltd 3. Dong Guan Appollo Wire & cable	VDE approved 0.75mm ² x 2 conductor HO3VVH2-F – 1830mm +150(-50)mm	Q90096 Q97182 113067
Output cord	4. Techpoint Electric Wire & Cable Co.Ltd 5. Dong Guan gumeetal Electric wire and Cable Factory 6. Zhe Jiang You Qing Xin Ya Radio Factory 7. Leader Electric Wire & Cable Co. Ltd	AWG #18 x 2C SPT-1 1830mm-150(-50)	E174881 E204204 E170689 E154283

Attachment 7

Creepage and Clearance

230V Model	A-f		A-a1		A-a2		Pri-Sec	
	CL	CR	CL	CR	CL	CR	CL	CR
GTM3T41-24-300D	2.2	4.5	N/A	N/A	11.7	11.7	10.5	15.0
GTM3T48-12-1200D	2.2	5.0	N/A	N/A	11.2	11.2	9.0	9.0
GTM3T57-48-350D	2.2	2.2	N/A	N/A	13.0	13.0	9.0	9.0
GTM3T35-12-250D	2.3	2.3	N/A	N/A	12.5	12.5	8.5	8.5

Requirements:

A-f – 1.6mm air clearance 3.0mm creepage

A-a1 – 2.5mm air clearance 4.0mm creepage

A-a2 – 5.0mm air clearance 8.0mm creepage

Pri-Sec - 5.0mm air clearance 8.0mm creepage

120V Model	A-f		A-a1		A-a2		Pri-Sec	
	CL	CR	CL	CR	CL	CR	CL	CR
GTM348-12-1000D	4.8	4.8	6.5	6.5	6.5	6.5	10.0	10.0
GTM357-48-350D	2.2	2.2	N/A	N/A	11.6	11.6	11.0	11.0
GTM335-12-250D	2.3	2.3	N/A	N/A	9.2	9.2	8.5	8.5
GTM341-12-700D	9.0	9.0	N/A	N/A	13.0	13.0	7.8	7.8

Requirements:

A-f – 1.0mm air clearance 2.0mm creepage

A-a1 – 1.6mm air clearance 3.0mm creepage

A-a2 – 3.20mm air clearance 6.0mm creepage

Pri-Sec - 3.20mm air clearance 6.0mm creepage

Test Equipment:

4099

File: E
Unit:
Tested By:

UL Project:
Reference No.:
Reviewed By:

Page:1 of 1
Date:

Attachment 8

North American Deviations (Supplement to CB Report):

U.S. - UL 2601-1, 2nd Edition / Can.- CAN/CSA C22.2 No. 601.1-M90

Clause	Requirement	Comments	Result
			P-Pass F-Fail N/A
U.S. 3.100	Component Requirements: <u>The Following Must be UL Components:</u> - Printing wiring boards (>15W sfc) - Lithium battery - Optical isolators (>15W sfc) - Wiring and Tubing (>15W sfc) - CRT's > 5 inches (12.7 cm)	See UL Description Report See Appendix 6	P
U.S. Exception 3.100.1	Power Measurements: Record Circuits Measured / Voltage, VA, A or W. <u>Circuit Location</u> <u>V</u> <u>A</u> <u>W/VA</u> No such exemptions declared * Note areas < 15 W. Measurements made after 5 sec.		N/A

File: E
Unit:
Tested By:

UL Project:
Reference No.:
Reviewed By:

Page:2 of 2
Date:

Attachment 8

North American Deviations (Supplement to CB Report):

U.S. - UL 2601-1, 2nd Edition / Can.- CAN/CSA C22.2 No. 601.1-M90

Clause	Requirement	Comments	Result
U.S. 3.101	Primary Circuit Components: - In addition to Compliance with this basic standard (IEC 601-1), primary circuit components up to an Isolating Transformer meet nationally recognized standards (such as ANSI/UL or internationally harmonized component standards). See Supplement A of UL 2601-1 for component list.	See UL Description Report See Appendix 6	P
CAN. 6	Markings: Are Safety Instructions on Equipment and in Accompanying Documents in English and French.	English only supplied	Open
U.S. 6	Markings: Signal words (CAUTION, DANGER, WARNING) Letter height min. 2.8 mm Letter height min. 1.6 mm of other words. Good contrast of letters? X-ray warning statement? Particular factory marking? Multiple voltage information?	_____ mm 1.6 mm on GTM335 and GTM3T35 (smallest)	N/A P P N/A N/A N/A
CAN. 6.1z)	Marking Durability: Methylated Spirits consists of the following: Ethanol 90.0%, Methanol 9.5%, <u>Pyridine 0.5%</u>	Solution not available	Open
U.S. 6.2 1)	Wiring compartment marking permanently connected equipment above 60°C?		N/A

File: E
Unit:
Tested By:

UL Project:
Reference No.:
Reviewed By:

Page:3 of 3
Date:

Attachment 8

North American Deviations (Supplement to CB Report):

U.S. - UL 2601-1, 2nd Edition / Can.- CAN/CSA C22.2 No. 601.1-M90

Clause	Requirement	Comments	Result
U.S. 6.6a)	Gas Cylinders if color coding, is it in accordance with the color coding requirements of ANSI/NFPA 99 ? See also sub-clause 56.3a.	No gas Cylinders	N/A
U.S. 14	Fixed and Permanently Installed Equipment: - Class 1 equipment	Class ____	N/A
U.S. 18 m/n	X-ray Equipment: - Protectively grounded enclosure for high voltage parts. - high voltage shielded cable?		N/A
U.S. 19	Enclosure leakage current: - at highest rated voltage 120V/240V measured. * Note - Measured from Earthed Conductive Enclosures and Non-conductive Enclosures!	Measured: Max.5.7 uA	P
U.S. 22	End Stop Test: <u>Note Conditions of Tests Below:</u> <u>Location</u> <u>Manual/Motorized</u> <u>1st. Device</u> <u>2nd Device</u> <u>Cycles</u> <u>No such controls</u> _____ _____ _____ _____ _____		N/A

File: E
Unit:
Tested By:

UL Project:
Reference No.:
Reviewed By:

Page:4 of 4
Date:

Attachment 8**North American Deviations (Supplement to CB Report):**

U.S. - UL 2601-1, 2nd Edition / Can.- CAN/CSA C22.2 No. 601.1-M90

Clause	Requirement	Comments	Result
U.S. 22.7	Emergency switch off requirements - Color red - Shall be maintain the off condition - Readily accessible	Color ____	N/A
U.S. 28.3	Suspension System: - with safety devices (Tested @ 4X) Warning Marking - See Attachment ____	Normal Load: Test Load:	N/A
U.S. 28.4	Suspension System: - without safety devices (Tested @ 8X) (Need 1.5 times load production testing).	Normal Load: Test Load:	N/A
U.S. 400	Oxygen - Barrier - Ventilation - No source of ignition		N/A
U.S. 42	Excessive Temperatures (UL 1446) - Insulation system class A (max. 105°C in N.C. based on 40 °C ambient). * Note - If normal condition temperatures exceeded Insulation Class A limits, a UL Recognized Insulation System (OBJY2) is mandatory.	T = ____ °C Class E used	N/A

File: E
Unit:
Tested By:

UL Project:
Reference No.:
Reviewed By:

Page:6 of 6
Date:

Attachment 8**North American Deviations (Supplement to CB Report):**

U.S. - UL 2601-1, 2nd Edition / Can.- CAN/CSA C22.2 No. 601.1-M90

Clause	Requirement	Comments	Result
U.S. 57	Mains Parts Permanently Installed: NEC, ANSI/NFPA 70, field wiring provision Wiring Method: <u>Terminal Block for Field Wiring</u> or, <u>§ 57.5.</u>		N/A
U.S. 57.2 CAN. 57.2(g)	Hospital Grade Plug for Class 1 Equipment: - Hospital grade plug marking or tag - X-ray unit rated ____A, plug rated ____A		N/A
U.S. 57.3 CAN. 57.3(b)	Power Supply Cord: Type SJ, or SV for light duty (0.5kg) devices. - Subjected to oil? - Min. 18 AWG?	Where fitted VDE approved Type S____ (See PIDF App. A for Cord types) 0.75mm ²	P
U.S. 57.5	Mains Terminal Devices: - 152 mm free length of the lead. - Wiring terminates in inaccessible enclosure?	Not re- wireable	N/A
U.S. 57.9.1	Transformer Short Circuit / Overload: - Electronic circuit: three times. - Short circuit: PTC is left in -> ultimate results. - Overload: PTC does not switch, -> ultimate results.	Primary fuses and thermal cut- outs	N/A
U.S. 58.2	Internal PE Connection: - Mechanical secure as well as being soldered. - Independent of all other connections.		N/A

File: E
Unit:
Tested By:

UL Project:
Reference No.:
Reviewed By:

Page:7 of 7
Date:

Attachment 8

North American Deviations (Supplement to CB Report):

U.S. - UL 2601-1, 2nd Edition / Can.- CAN/CSA C22.2 No. 601.1-M90

Clause	Requirement	Comments	Result
U.S. 59.1 CAN. 59.1	Connection Cords: Meets NEC (NFPA 70) requirements. Meets Canadian Electrical Code (CEC), Part 1.	Style No. _____, ____ V, ____ °C, or; Cable Type _____ (i.e. <i>SJT</i>)	Open
CAN. 60	Test for Defibrillator-Protected Equipment of Types BF and CF: - Marked with Symbols 02-04 or 02-06 (IEC 878) - Min. 4 mm creepage and clearance spacings between isolated and non-isolated parts. - Isolates Patient from other parts of Equipment during defibrillator application to Patient. - Testing to Figure 50. Data Attached in Attachment Nr. _____ - Voltage Measured Between Y1 and Y2: _____ V (Less than 1 V represents <100 µC charge).	Symbol: Creepage: ____ mm Clearance: ____ mm Leakage Current measured from: Enclosure _____ µA SIF/SOPS _____ µA Non-conductive enclosure _____ µA	N/A
U.S. 600	Separate Power Units: - Packed with equipment or, - Reference label on equipment or Accompanying Documents?		N/A
U.S. 600.2	Direct Plug-in Requirements: - Complies with required sections of UL 1310. - See Attachment _____ for Test Data.	See clients information	P