





TEST REPORT MEDICAL ELECTRICAL EQUIPMENT

Equipment / Product	Power supplies for medical electric equipment	
Name and address of the applicant	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 U.S.A.	
Name and address of the manufacturer	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 U.S.A.	
Name and address of the factory	See Page 2.	
Trade mark	 GlobTek, Inc.	
Model/type	GT500148-12, GT500148-15, GT500148-24	
Rating and principal characteristics	Input voltage 100-240 V~, 50/60 Hz, 1.0 A max; Class I. See Page 2 for output ratings.	
Serial no	Prototypes	
Tested in the period, dates	November 2000	
Tested according to	IEC 60601-1 (2 ed. 1988) + Amend. 1 (1991) + Amend. 2 (1995) + Corrigendum (June 1995) MEDICAL ELECTRICAL EQUIPMENT - Part 1: General requirements for safety	
Result of testing	The equipment complies with the above mentioned standards.	
The test results relate only to the sample(s) tested.		
Name and address of the testing laboratory	 P.O. BOX 73 BLINDERN N - 0314 OSLO, NORWAY	Telephone (+47) 22 96 03 30 Fax (+47) 22 96 05 50
Tested by	 signature Vegard Andersen	3 November 2000 date
Verified by	 signature Frank Skarpsno	3 November 2000 date
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Verdicts are placed in the column to the right.: P = Pass, F = Fail, N = Not applicable, — = Considered/Information.

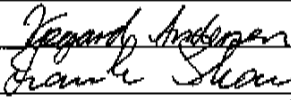

Due to Nemko's computerised handling of test reports the layout of this form is modified compared to the original TRF published by EMEDCA; 1992-12-01. The content fully covers the original TRF.

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Issue Nemko 97-09-05

DESCRIPTION OF EQUIPMENT UNDER TEST:		
<p>Equipment is a combined battery charger and DC power supply. Universal supply voltage, 100 to 240 VAC. The last two numbers of the model number represent the output voltage.</p> <p>All three types are the identical, except for the components controlling the output voltage.</p>		
Model	Rating	
GT500148-24	24 VDC output, 2,1 A maximum	
GT500148-15	15 VDC output, 3,3 A maximum	
GT500148-12	12 VDC output, 4,0 A maximum	
NAME AND ADDRESS OF PRODUCTION-SITES (FACTORIES):		
<p>GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 U.S.A.</p>		
INFORMATION ABOUT THE STANDARDS / DOCUMENTS CONSIDERED:		
<p>EN 60601-1 (1990) + A1 (1993) + A2 (1995) + A13 (1996) + Corrigenda (July 1994).</p>		
<p>EMC standard : Manufacturer has self declared.</p>		
TESTED ACCORDING TO NATIONAL REQUIREMENTS FOR THE FOLLOWING COUNTRIES:		
<p>Tested according to Australian, Canadian and US deviations as the deviations are listed in the CB Bulletin of March 1999.</p>		
LIST OF APPENDIXES / ENCLOSURES TO THE TEST REPORT:		
<p>See page 3.</p>		
SUMMARY OF TESTING		
<p>As the equipment is not intended to be connected to the patient and does not have any patient applied parts, it is not marked with the type B applied part symbol.</p> <p>Nevertheless, the product complies with the requirements for type B applied part concerning protection against electric shock</p>		
Clause	Remarks	Information/Comments
6.1 L3	Symbol for protection against electric shock:	Not applicable. No applied part.
36	IEC 60601-1-2 (1993)	Manufacturer has self declared.

LIST OF ATTACHMENTS PROVIDING FURTHER INFORMATION ON THE EQUIPMENT TESTED AND THE TEST METHODS		
The following attachments are added to this TRF or kept in file at the Testing Station 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:	<i>Kept in file at Nemko.</i>	ATT. No.: <i>Not attached</i>
List of worksheets which describe measurement procedures or test methods where practicable:		
Document title/identification:	<i>Kept in file at Nemko.</i>	ATT. No.: <i>Not attached</i>
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:	<i>See summary of testing in this report.</i>	ATT. No.: <i>Not attached</i>
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:	<i>Kept in file at Nemko</i>	ATT. No.: <i>Not attached</i>
Description of safety systems (specifying for example safety circuits, redundant circuits, double circuits, hardware/software safety measures, temperature controls, etc.):		
Document title/identification:	<i>Kept in file at Nemko</i>	ATT. No.: <i>Not attached</i>

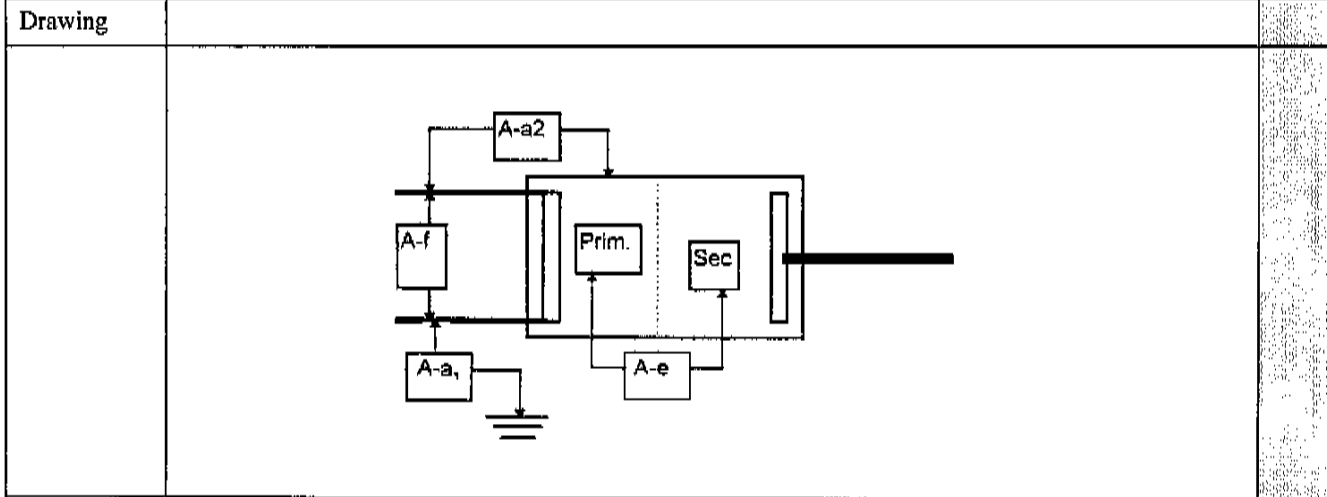
PERSONNEL - INITIALS USED THROUGHOUT THIS TRF		
Initials:	Full name:	Signatures:
VA	<i>Vegard Andersen</i>	
FSk	<i>Frank Skarpsno</i>	
	This Part 1 TRF contains 60 pages, numbered from 1 to 60 .	
	This TRF contains Australian deviations. Attachment no. 1 .	
	This TRF contains Canadian deviations. Attachment no. 2 .	
	This TRF contains US deviations. Attachment no. 3 .	
	This TRF contains photographs. Attachment no. 4 .	

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 fore- seen and which is not connected with its intended application in NORMAL CONDITION and in S.F.C.	<i>The equipment causes no hazards when used according to the manufacturers instructions.</i>	P
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.	<i>No alternative construction.</i>	N

5	CLASSIFICATION		
5.1	Type of protection against electric shock.	<i>Class I equipment.</i>	P
5.2	Degree of protection against electric shock.	<i>As the equipment is not intended to be connected to the patient and does not have any patient applied parts, it is not be marked with the type B applied part symbol. Nevertheless, the product complies with the requirements for type B applied part concerning protection against electric shock.</i>	N
5.3	Classification of the equipment against ingress of liquids.	<i>Ordinary equipment.</i>	P
5.5	Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	<i>The equipment is not an AP or APG category equipment.</i>	N
5.6	Mode of operation.	<i>Continuous operation.</i>	P

INSULATION DIAGRAM

Protection against electric shock - Block diagram of system *Refer to table below..*

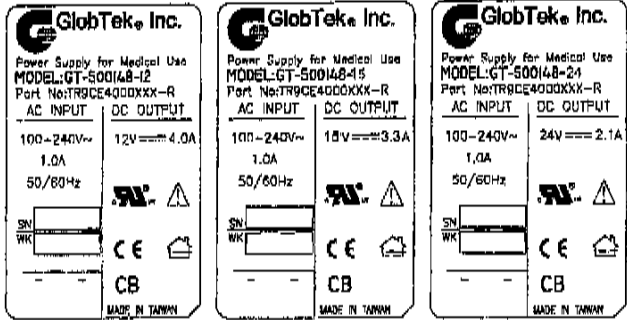





Comments

TABLE TO INSULATION DIAGRAM ABOVE

Distance (Test Refer to 20.1 + 20.2)	Insulation type Basic/Supplement/ Double/Reinforced Insulation	Maximum circuit voltage	Required distances (mm)		Dielectric strength test voltage Refer to 20.3
			Clearance	Creepage	
A-a ₁	Basic	250 VAC.	2.5 mm	4.0 mm	1 500 VAC.
A-a ₂	Double/Reinforce.	250 VAC.	5.0 mm	8.0 mm	4000 VAC.
A-e	Double/Reinforce.	250 VAC.	5.0 mm	8.0 mm	4000 VAC.
A-f	Basic	250 VAC.	1.6 mm	3.0 mm	1 500 VAC.

Comments Note to table V in A2 used for the calculation of working voltage.

6	IDENTIFICATION, MARKING AND DOCUMENTS			
6.1	Marking on the outside			
6.1 a	Markings of Mains operated EQUIPMENT			P
6.1 b	Markings of Internally Powered EQUIPMENT	Not applicable. Not a internally powered equipment.		N
6.1 c	Markings of EQUIPMENT supplied from a specified power supply	Not applicable. Not for connection to a specified power supply.		N
6.1 d	Minimum requirements if limited space for marking	Not applicable. Not limited space for marking.		N
6.1 e	Name and/or trademark of the manufacturer or supplier			P
6.1 f	Model or type reference	GT500148-12, GT500148-15, GT500148-24		P
6.1 g	Rated supply voltage(s) or voltage range(s) Number of phases Type of current	100 - 240 V ~ Single phase a.c. max. 1.0		P
6.1 h	Rated frequency or rated frequency range(s) in Hz	50 / 60Hz		P
6.1 j	Rated power input (VA, W or A)	Max. 1.0		P
6.1 k	Power output of auxiliary mains socket outlets	Not applicable. No auxiliary mains socket outlets.		N
6.1 l	Class II symbol	Not applicable. Not of class II.		N
6.1 m	Symbol for degree of protection with respect to harmful ingress of water according to EN 60529 (IPX0 not required to be marked)	Ordinary equipment (IP 20). No marking required.		N
6.1 n	Symbol for protection against electric shock:	Not applicable. No applied part.		N
6.1 o	Mode of operation (if no marking, suitable for continuous operation)	Continuous operation.		P
6.1 p	Types and rating of external accessible fuses	Not applicable. No external fuses.		N
6.1 q	Rated output voltage and current or power, output frequency (where applicable)	GT500148-12 : 12VDC, 4,0A GT500148-15 : 15VDC, 3,3A GT500148-24 : 24VDC, 2,1A		P
6.1 r	Symbol for physiological effect(s):	Not applicable. No physiological effect.		N
6.1 s	Anaesthetic-proof symbol:	Not of category AP or APG.		N

6.1 s	High voltage symbol:	<i>Not applicable. No parts with a voltage over 1 000 VAC or over 1 500 VDC or 1 500 V peak value.</i>	N
6.1 t	Special cooling requirements	<i>Not applicable. No special cooling requirements.</i>	N
6.1 u)	Limited mechanical stability	<i>Not applicable. No limited mechanical stability.</i>	N
6.1 v	Protective packing requirement(s). Marking(s) for unpacking safety hazard(s)	<i>Not applicable. No protective packing requirement.</i>	N
6.1 y	Earth terminals:	<i>Not applicable.</i>	N
6.1 z	Removable protective means	<i>Not applicable. No removable protective means.</i>	N
	Durability of markings	<i>Tested with a cloth of rack soaked with, in turn, water, methylated spirit and isopropyl alcohol. The sample label withstood the test.</i>	P
6.2	Marking on the inside		
6.2 a	Marking clearly legible	<i>Fuse T 3,15A / 250V</i>	P
	Nominal supply voltage of permanently installed equipment marked inside or outside of equipment	<i>Not applicable.</i>	N
6.2 b	Maximum power loading of heating elements or lamp holders for heating lamps clearly and indelibly marked near or in the heater	<i>Not applicable.</i>	N
	Heating elements or lamp holders for heating lamps not intended to be changed by operator and which can be changed only with the use of a tool, have at least an identifying marking referring to information stated in the accompanying documents	<i>Not applicable.</i>	N
6.2 c	High voltage parts:	<i>Not applicable. No parts with a voltage over 1 000 VAC or over 1 500 VDC or 1 500 V peak value.</i>	N
6.2 d	Type of battery and mode of insertion (if applicable) marked (see Sub-clause 56.7 b)	<i>Not applicable. No use of battery.</i>	N
	Batteries not intended be changed by operator and which can be changed only with use of tool have at least marking referring to information in accompanying documents	<i>Not applicable. See above.</i>	N
6.2 e	Fuse type and rating or reference stated	<i>Fuse: T3,15A 250 V.</i>	P
6.2 f	Protective earth terminal marked 	<i>Ground connection point on PWB is marked.</i>	P
6.2 g	Functional earth terminal marked 	<i>Not applicable. No functional ground.</i>	N
6.2 h	Terminals for supply neutral conductor in permanently installed equipment marked (N)	<i>Not applicable. No permanently installed equipment.</i>	N
6.2 j	Markings required in Sub-clause 6.2 f, h, k and l	<i>Not applicable. No marking required.</i>	N

6.2 k	The supply connections are clearly marked adjacent to the terminals or in accompanying documents (for small equipment)	<i>Not applicable. Appliance inlet.</i>	N
6.2 l	Statement for suitable wiring materials (at temperatures over 75°C) locates at or near the point of the supply connections and is clearly discernible after connection	<i>Not applicable. No temp. over 75°C. No user changeable internal wires.</i>	N
6.2 n	Capacitors and/or circuit parts are marked as required in Sub-clause 15 c	<i>Not applicable. Marking not required.</i>	N
6.3	Marking of controls and instruments		
6.3 a	Mains switch clearly identified. "On" and "off" positions marked or otherwise indicated	<i>Green lamp indication. Detachable power cord used as disconnect device.</i>	P
6.3 b	Adequate indications of different positions of controls and other switches	<i>Not applicable. No controls or switches.</i>	N
6.3 c	Adequate indication of the direction of setting devices if change of setting of a control could cause a safety hazard	<i>Not applicable. No controls or switches.</i>	N
6.3 f	Functions of operator controls and indicators identified	<i>Not applicable. No controls or switches.</i>	N
6.3 g	Numeric indications of parameters are in SI units according to ISO 1000. Units outside the International System as specified	<i>Not applicable. No controls or switches.</i>	N
6.4	Symbols		
6.4 a	Marking symbols compliance with appendix D, where applicable	<i>Not applicable. No marking symbols.</i>	N
6.4 b	Symbols for controls and performance conform to IEC 878, where applicable	<i>Not applicable.</i>	N
	Durability of marking symbols	<i>Tested in Clause 6.1.</i>	P
6.5	Colours of insulation of conductors		
6.5 a	Protective earth conductor has green/yellow insulation	<i>All internal earth wiring is green / yellow.</i>	P
6.5 b	All insulations of internal protective earth conductors are green/yellow, at least at the terminations of the conductors		P
6.5 c	Only protective earth-, functional earth-, potential equalisation and inside earthing conductors (cf. 6.5 b) are green/yellow	<i>No other wiring has green or yellow sleeving.</i>	P
6.5 d	Colour of neutral conductor: light blue according to IEC 227 or 245	<i>Not applicable. No use of neutral conductor in equipment.</i>	N
6.5 e	Colours of phase conductors in power supply cord according to IEC 227 or 245	<i>User manual instructs user to only use approved detachable cord.</i>	N

6.5 f	Additional protective earthing in multi-conductor cords are marked green/yellow at the ends of the additional conductors	<i>Not applicable.</i>	N
6.6	Identification of medical gas cylinders and connections		
6.6 a	Identification of content in accordance with ISO/R32	<i>Not applicable. No use of medical gas cylinders</i>	N
6.6 b	Identification of connection point that errors are avoided when a replacement is made	<i>Not applicable.</i>	N
6.7	Indicator lights and push-buttons		
6.7 a	Colour red only used for warning of danger or/and need for urgent action. Dot-matrix/alphanumeric displays not considered to be indicator lights	<i>Not applicable. No use of colour red.</i>	N
6.7 b	Colours of unilluminated push-buttons. Colour red only used in case of emergency	<i>Not applicable. No push-buttons used.</i>	N
Location	Meaning of indicator lights	Illuminated push-button (see IEC 73)	Colour
<i>Front</i>	<i>Ready for action</i>	—	<i>Green</i>
6.8	Accompanying documents		
6.8.1	Equipment is accompanied at least by		
	- instructions for use	<i>User and Operating Manual</i>	P
	- technical description	<i>Technical and Service Manual</i>	P
	- an address to which the user can refer	<i>In both the above mentioned booklets</i>	P
	All applicable classifications specified in Clause 5 are included in instructions for use and technical description	<i>In both the above mentioned booklets</i>	P
	markings in Sub-clause 6.1 included in accompanying documents if not permanently affixed to equipment		P
	Warning statements and explanations of warning symbols are provided in accompanying documents		P
	Language of accompanying documents	<i>English. Will be in the language required for the market where the equipment is intended to be sold.</i>	P
6.8.2	Instructions for use		
6.8.2 a	General information		
	Necessary information to operate the equipment		P
	Explanation of the function of controls, displays and signals	<i>Not applicable. No controls on equipment.</i>	N
	Sequence of operation		P
	Connection and disconnection of detachable parts and accessories	<i>Not applicable. No detachable parts and accessories.</i>	N

	Replacement of material which is consumed during operation	<i>Not applicable. No consummation of materials.</i>	N
	Indications of recognised accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	<i>Not applicable. See above.</i>	N
	Cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	<i>Not applicable.</i>	N
	Information about safe performance of routine maintenance	<i>Not applicable.</i>	N
	Information about preventive inspection and maintenance to be performed by other persons	<i>Not applicable. No need for preventive inspection.</i>	N
	Meanings of figures, symbols, warning statements and abbreviations on equipment explained in the instructions for use	<i>Not applicable. Self explaining.</i>	N
	Instruction for use states the function and intended application of equipment		P
	Instructions for use provide user with information regarding potential electromagnetic or interference and advice how to avoid such interference	<i>Not applicable. No electromagnetic interference.</i>	N
6.8.2 c	Signal output and signal input parts		
	Signal output or signal input parts intended only for connection to specified equipment stated in instruction for use	<i>No SIP or SOP parts</i>	N
6.8.2 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 given in instruction for use	<i>Not applicable.</i>	N
6.8.2 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	<i>Not applicable. No additional power source.</i>	N
	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 shall be operated from its internal electrical power source	<i>Not applicable. See above.</i>	N
6.8.2 f	Removal of primary batteries (i.e. not rechargeable batteries);		

	Instruction for use contains a warning to remove batteries if equipment is not likely to be used for some time ,unless no risk of safety hazard	<i>Not applicable. No use of batteries.</i>	N
6.8.2 g	Rechargeable batteries:		
	Instructions to ensure safe use and adequate maintenance	<i>Not applicable. See above.</i>	N
6.8.2 h	Equipment with a specified power supply or battery charger:		
	Instructions for use identify power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	<i>Not applicable.</i>	N
6.8.2 j	Instructions for use identify risks associated with disposal of waste, residues etc. and of equipment/accessories at end of their lives. Further it provides advice on minimising these risks	<i>Not applicable. No waste.</i>	N
6.8.3	Technical description		
6.8.3 a	General		
	Technical description provides all data essential for safe operation including data in Sub-clause 6.1 and all characteristics of the equipment	<i>The Technical and Service Manual is well written and contains all necessary information required.</i>	P
	A statement whether particular measures or particular conditions are to be observed for installing equipment and bringing equipment into use	<i>Not applicable.</i>	N
6.8.3 b	Replacement of fuses and other parts :		
	Required type and rating of fuses utilised in the mains supply circuit external to permanently installed equipment	<i>Not applicable.</i>	N
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	<i>Not applicable. No interchangeable or detachable parts.</i>	N
6.8.3 c	Circuit diagrams, component part lists, etc.:		
	The technical description contains a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc. in order to assist user in case of necessary reparations		P
6.8.3 d	Environmental conditions for transport and storage:		

	The technical description contains a specification of the permissible environmental conditions for transport and storage	<i>Not applicable. No requirements for environmental conditions for transport and storage.</i>	N
	The above said specification also repeated on the outside of the packaging	<i>Not applicable. See above.</i>	N

7 POWER INPUT						
7.1	Steady state current or power input does not exceed the marked rating by more than specified					
	Equipment:	N-3636, N-2859, N-1704				
	Initials Tester / Date:	VA / November 2000				
	GT500148-12 50 Hz supply	Power input: 100-240VAC, max. 1.0 A				P
Power input	Function	$U_{nlower} = 90 \text{ V}$	$U_N = 100 \text{ V}$	$U_N = 240 \text{ V}$	$U_{Nupper} = 264 \text{ V}$	
Input current	Normal operation (A)	1,179	1,044	0,413	0,368	
	Standby (A)	0,035	0,036	0,050	0,050	
Input power	Normal operation (W)	59,6	59	57	58	
Input power	Normal operation (VA)	104	104	100	94	
Power factor	cos ϕ	0,566	0,550	0,58	0,600	
	GT500148-24 60 Hz supply	Power input: 100-240VAC, max. 1.0 A				P
Power input	Function	$U_{nlower} = 90 \text{ V}$	$U_N = 100 \text{ V}$	$U_N = 240 \text{ V}$	$U_{Nupper} = 264 \text{ V}$	
Input current	Normal operation (A)	1,070	0,970	0,530	0,500	
	Standby (A)	0,053	0,050	0,080	0,090	
Input power	Normal operation (W)	59,4	59	57	57	
Input power	Normal operation (VA)	94,8	97	127	132	
Power factor	cos ϕ	0,606	0,600	0,450	0,440	
	GT500148-15 50 Hz supply	Power input: 100-240VAC, max. 1.0 A				P
Power input	Function	$U_{nlower} = 90 \text{ V}$	$U_N = 100 \text{ V}$	$U_N = 240 \text{ V}$	$U_{Nupper} = 264 \text{ V}$	
Input current	Normal operation (A)	1,120	1,000	0,422	0,356	
	Standby (A)	0,028	0,027	0,046	0,049	
Input power	Normal operation (W)	58	59	56	56	
Input power	Normal operation (VA)	100	100	105	94	
Power factor	cos ϕ	0,580	0,588	0,535	0,593	

	GT500148-15 60 Hz supply	<i>Power input: 100-240VAC, max. 1.0 A</i>				P
Power input	Function	$U_{Nlower} = 90\text{ V}$	$U_N = 100\text{ V}$	$U_N = 240\text{ V}$	$U_{Nupper} = 264\text{ V}$	
Input current	Normal operation (A)	1,100	0,953	0,530	0,483	
	Standby (A)	0,040	-	0,060	0,070	
Input power	Normal operation (W)	58	58	56	56	
Input power	Normal operation (VA)	94	95	125	124	
Power factor	$\cos \varphi$	0,605	0,615	0,447	0,448	
	GT500148-12 50 Hz supply	<i>Power input: 100-240VAC, max. 1.0 A</i>				P
Power input	Function	$U_{Nlower} = 90\text{ V}$	$U_N = 100\text{ V}$	$U_N = 240\text{ V}$	$U_{Nupper} = 264\text{ V}$	
Input current	Normal operation (A)	1,100	1,000	0,427	0,358	
	Standby (A)	0,030	0,030	0,051	0,055	
Input power	Normal operation (W)	59	58	56	56	
Input power	Normal operation (VA)	98	101	100	95	
Power factor	$\cos \varphi$	0,594	0,577	0,550	0,586	
	GT500148-12 60 Hz supply	<i>Power input: 100-240VAC, max. 1.0 A</i>				P
Power input	Function	$U_{Nlower} = 90\text{ V}$	$U_N = 100\text{ V}$	$U_N = 240\text{ V}$	$U_{Nupper} = 264\text{ V}$	
Input current	Normal operation (A)	1,000	0,953	0,512	0,470	
	Standby (A)	0,040	-	0,065	0,075	
Input power	Normal operation (W)	59	58	57	57	
Input power	Normal operation (VA)	92	95	125	125	
Power factor	$\cos \varphi$	0,630	0,62	0,452	0,452	

10	ENVIRONMENTAL CONDITIONS		
10.1	Equipment capable, while packed for transport and storage, of being exposed to environmental conditions as stated by manufacturer (see 6.8.3 d)	<i>Considered OK.</i>	P
10.2	Operation of equipment according to specified environment and power supply	<i>Considered OK.</i>	P

13	GENERAL		
	Equipment so designed that risk of electric shock obviated as far as practicable (requirements as given in section three)	<i>Considered OK.</i>	P

14	REQUIREMENTS RELATED TO CLASSIFICATION		
14.1	Class I equipment		
14.1 a	Parts with Double Insulation	<i>Plastic enclosure and transformer, equivalent to DI/RI.</i>	P
	Parts with Reinforced Insulation	<i>Plastic enclosure and transformer, equivalent to DI/RI.</i>	P
	Parts with SELV-Voltage		N
	Parts with Protective Impedance	<i>Not applicable.</i>	N
14.1 b	If the mains part of equipment specified for an external d.c. power source is isolated from accessible conductive parts by basic insulation only, a separate protective earth conductor is provided	<i>Not applicable. For connection to a ac power supply.</i>	N
14.2	Class II equipment		
14.2 a	Class II equipment is of one of the following types:	<i>Not applicable. Class I.</i>	N
14.2 b	If equipment is fitted with a device for changing over from class I to class II protection, the following requirements are fulfilled:	<i>Not applicable.</i>	N
	The change-over device indicates the selected class clearly	<i>Not applicable.</i>	N
	A tool for change-over is necessary	<i>Not applicable.</i>	N
	The equipment complies with all requirements for the selected class at any given time	<i>Not applicable.</i>	N
	Class II position: The device interrupts the connection of protective earth conductor to equipment or changes it into functional earth conductor (compliance with 18.2)	<i>Not applicable.</i>	N
14.2 c	Class II equipment provided with functional earth connections (cf. Sub-clause 18 k and l)	<i>Not applicable.</i>	N
14.4	Class I and II equipment		
14.4 a	Equipment is provided with an additional protection according to the requirements of Class I or Class II equipment	<i>Not applicable. Not provided.</i>	N
14.4 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)	<i>Not applicable. No external d.c. power source.</i>	N
14.5	Internally powered equipment		
14.5 b	Equipment also having means of connection to supply mains complies also with requirements for Class I or II while so connected	<i>Not applicable. Not an internally powered equipment.</i>	N

14.6	Types B, BF and CF applied parts		
14.6 c	Applied parts suitable for direct cardiac application are of type CF	<i>Not applicable. No applied parts.</i>	N

15	LIMITATION OF VOLTAGE AND/OR ENERGY										
15 b	Equipment with mains plug so designed that the voltage 1 sec. after disconnection does not exceed 60 V		<i>See table below</i>								P
	Interference suppression capacitors		<i>C1 and C4 between lines C2 and C44 between N and PE</i>								—
	Capacitance between each line and protective earth. Measured value										N
	Equipment:		N2843								
	Initials Tester / Date:		VA / November 2000								
	Maximum residual voltage in the mains plug 1 second after disconnection (measured in the least favourable position of the on-off switch, if any):										
	Remark: pins 1 and 2 are Line and Neutral supply pins. Note! PE is equal to enclosure.										
Measurement no.	1	2	2	4	5	6	7	8	9	10	
Voltage between pins 1 and 2 (Limit 60 V)	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	
Voltage between pin 1 and PE (Limit 60 V)	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	
Voltage between pin 2 and PE (Limit 60 V)	<10	<10	<10	<10	<10	<10	<10	<10	<10	<10	
15 c	Accessible live parts of capacitors or related circuits having a residual voltage above 60 V does not have a residual energy above 2 mJ (see 15 c below)		<i>Not applicable. No parts with a voltage above 60 V.</i>								N
	A non-automatic discharging device is included and marked		<i>Not applicable.</i>								N
	Equipment:										
	Initials Tester / Date:										
Capacitor and its location	Working voltage (V)		Capacitance value (mF)			Residual voltage (V)		Residual energy (mJ)			
16	ENCLOSURES AND PROTECTIVE COVERS										
16 a	Protection against contact with live parts.		<i>Plastic enclosure: File no. E 12 15 62 Polyphenylen Oxide (PPHOX) Noryl, SE 100 series. Min thickness 2.3, Flammability UL 94V-1</i>								P
	- and with parts which can become live in single fault conditions		<i>Not applicable. No parts can become live in single fault condition.</i>								N

	Instruction for use instructs operator not to touch such parts and the patient simultaneously	<i>Not applicable. No use for such instruction.</i>		N
	Equipment:			
	Initials Tester / Date:			
Location of opening		Test result (finger, pin, hook)		
<i>No holes in enclosure.</i>		<i>Pass</i>		
16 b	Check of openings in top covers with the vertical suspended test rod	<i>Not applicable. No openings.</i>		N
16 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 max. 0,2 ohms or the separation from live parts complies with 17 g	<i>Not applicable.</i>		N
16 d	Protection of contact with internal parts of the equipment with a circuit voltage exceeding 25 VAC or 60 VDC which cannot be disconnected from the supply by external mains switch or plug device	<i>Not applicable. External plug disconnects all parts.</i>		N
	Equipment:	N-2843		
	Initials Tester / Date:	VA / November 2000		
Location of part		Covering	Warning notice	Remarks
<i>Output plug</i>				<i>Maximum 24 VDC.</i>
16 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	<i>Only with the aid of a tool.</i>		P
16 f	Live parts are inaccessible to the test rod through openings for adjustment of pre-set controls	<i>Not applicable. No openings for adjustment of pre-set controls.</i>		N

17	SEPARATION			
17 a	Separation method of the applied part from live parts so that allowable leakage currents are not exceeded	<i>Not applicable. No applied part.</i>		
17 a 1	Basic insulation - applied part earthed	<i>Not applicable.</i>		N
17 a 2	By protectively earthed conductive part (e.g. screen)	<i>Not applicable.</i>		N
17 a 3	By separate earthed intermediate circuit	<i>Not applicable.</i>		N
17 a 4	By double or reinforced insulation	<i>Not applicable.</i>		N
17 a 5	By protective impedances limiting current to applied part	<i>Not applicable.</i>		N

17 a 6	Other method, e.g. specified in particular standard	<i>Not applicable.</i>			N
	Equipment:				
	Initials Tester / Date:				
	Additional leakage current test in single fault conditions				
Fault condition (description)	Earth leakage current	Enclosure leakage current	Patient leakage current	Patient auxiliary current	
17 c	There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed	<i>Not applicable.</i>			N
17 d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I equipment)	<i>Not applicable.</i>			N
	Adequate isolation of accessible metal parts from motor shaft				—
	Rated motor voltage				—
	Test voltage				—
	Air clearances/creepage distances (mm)/(mm)				—
17 g	Separation method of accessible parts other than applied parts from live parts so that allowable leakage currents are not exceeded				
17 g 1	Basic insulation - accessible part earthed	<i>Not applicable. No accessible part earthed. Plastic enclosure.</i>			N
17 g 2	By protectively earthed conductive part (e.g. screen)	<i>Not applicable. See above.</i>			N
17 g 3	By separate earthed intermediate circuit	<i>Not applicable. Class I equipment</i>			N
17 g 4	By double or reinforced insulation	<i>Plastic enclosure and transformer withstood dielectric strength test.</i>			P
17 g 5	By protective impedances limiting current to accessible part	<i>Not applicable. See above.</i>			N
	Leakage currents measurements, when required				—
17 h	Adequate arrangements used to isolate defibrillation-proof applied parts from other parts	<i>Not applicable. No defibrillation-proof applied parts.</i>			N
	Impulse voltage tests				—
	Peak voltage between Y1 and Y2 does not exceed 1 V				—
	After recovery time equipment continues to perform its intended function				—

18		PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION			
18 a	Sufficiently low impedance to the protective earth terminal(18 f and 18 g)	See below.			P
18 b	Suitable connection between protective earth terminal and protective conductor in the installation (18 f)	Not applicable. See above.			N
18 e	Means for connection of potentially equalisation conductor complies with specified requirements	Not applicable. No connection of potentially equalization conductor.			N
	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 equalisation conductor				—
	- connection is marked with symbol				—
18 f	Impedance of protective earthing system: Impedance between any accessible metal part and: 1) protective earth terminal (PE) (requirement: R max. 0.1 Ohm), 2) protective earth contact in appliance inlet (requirement: R max. 0.1 Ohm), 3) protective earth contact in the mains plug Test equipment: See attached list. (requirement: R max. 0,2 Ohm), are tabled below:	1) Not applicable. Appliance inlet used. 2) 0.86 V needed to get 30 A between inlet and the bonding point furthestmost from inlet. 30A used instead of 25 to comply with Canadian deviations. 3) Not applicable. Appliance inlet used.			P
	Equipment:				
	Initials Tester / Date:	VA / November 2000			
Accessible part and its location		R (Ohm) measured against (numbers see above)			
		1 PE	2 inlet	3 plug	
Appliance inlet to PWB.			0.030Ω		
18 g	If the impedance of protective earth connections other than in 18 f exceeds 0.1 Ohm, the allowable value of the enclosure leakage current is not exceeded in single fault condition	Not Applicable.			N
18 k	Functional earth terminals are not used to provide protective earthing	Not applicable. No use of functional earth terminal.			N
18 l	For Class II equipment with isolated internal screens and with a power supply cord:	Not applicable. No use of internal screens.			N

	- the third conductor is used only as functional earth of these screens and is coloured green/yellow		N
	- insulation of such screens and all internal wiring connected to them is double insulation or reinforced insulation (see also 20.3)		N
	- marking of functional earth terminal is distinguished from protective earth terminal and is explained in accompanying documents		N
	Test of insulation (see Clause 20)		N

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENTS AUXILIARY CURRENTS			
19.1	General requirements (tests see 19.4)			
19.1 g	Equipment with multiple patient connections: Patient leakage current and patient auxiliary current do not exceed allowable values while one or more patient connections are disconnected from the patient or disconnected from the patient and earthed	<i>Not applicable. No multiple patient connections.</i>		N
19.2	Single fault conditions (tests see 19.4)			
19.3	Allowable values (see 19.4)			
19.4	Tests before humidity preconditioning treatment			<i>See comment below.</i>
	Equipment:	N2239, N2718, N2266, N3171		
	Initials Tester / Date:	VA / November 2000		
		In normal condition		In single fault condition
Type of leakage current	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)
Earth leakage current	500	80	1000	180
Enclosure leakage current	100	7	500	47
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—
P.l.c. (110 % of the mains voltage on the signal input part or signal output part)	—	—	B: 5000 BF, CF: —	—
P.l.c. (110 % of mains voltage on the applied part)	—	—	B: — BF: 5000 CF: 50	—
Patient auxiliary current, a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—
Patient auxiliary current, d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—
Comments	<i>The listed values are the maximum values.</i>			

19.4	Tests after humidity preconditioning treatment			
	Equipment:	N2239, N2718, N2266, N3171		
	Initials Tester / Date:	VA / November 2000.		
Type of leakage current	In normal condition		In single fault condition	
	Allowed value (μA)	Measured max. value (μA)	Allowed value (μA)	Measured max. value (μA)
Earth leakage current	500	80	1000	180
Enclosure leakage current	100	7	500	47
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—
P.l.c. (110 % of the mains voltage on the signal input part or signal output part)	—	—	B: 5000 BF, CF: —	—
P.l.c. (110 % of mains voltage on the applied part)	—	—	B: — BF: 5000 CF: 50	—
Patient auxiliary current, a.c. :	B, BF: 100 CF: 10	—	B, BF: 500 CF: 50	—
Patient auxiliary current, d.c. :	B, BF: 10 CF: 10	—	B, BF: 50 CF: 50	—
Comments	<i>The listed values are the maximum values.</i>			

20 DIELECTRIC STRENGTH (at operating temperature)					
Overall compliance with Clause 20					P
Equipment:			<i>High voltage supply : N1979</i>		
Initials Tester / Date:			<i>VA / November 2000</i>		
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations
All equipment types	A-a ₁		250 VAC	1 500 VAC	
	A-a ₂		250 VAC	4000 VAC	
	A-e		250 VAC	4000 VAC	
	A-f		250 VAC	1 500 VAC	
*) IEC 60601-1 does not require to measure this					

20 DIELECTRIC STRENGTH (after humidity preconditioning treatment)					
Overall compliance with Clause 20					P
Equipment:			<i>Humidity room : N3205 High voltage supply : N601</i>		
Initials Tester / Date:			<i>VA / November 2000</i>		
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations
All equipment types	A-a ₁		250 VAC	1 500 VAC	
	A-a ₂		250 VAC	4000 VAC	
	A-e		250 VAC	4000 VAC	
	A-f		250 VAC	1 500 VAC	
*) IEC 60601-1 does not require to measure this					

21 MECHANICAL STRENGTH			
21 a	Rigidity of enclosure (45 N test force)	<i>Tested with 45 N. No damage to enclosure parts.</i>	P
21 b	Strength of enclosure part and any component thereon (Impact hammer test, 0.5 J).	<i>No damage resulting in a safety hazard.</i>	P
21 c	On portable equipment carrying handles or grips withstand the requirements of the loading test. (Test force four times the weight of equipment)	<i>Not applicable. Not portable equipment.</i>	N
21.3	No damage to parts of patient support and/or immobilisation system after the loading test (1350 N and 2700 N tests)	<i>Not applicable. Equipment is not intended to support patient.</i>	N

	The test force for foot rests and chairs shall be twice the specified maximum load or, if not specified, the test force shall be 2,7 kN. The test force shall be distributed over an area of 0,1 m ² surface for 1 minute.	<i>Not applicable. See above.</i>	N
21.5	Hand-held equipment or equipment parts are safe after drop test (dropping height 1 m)	<i>Not applicable. Not hand-held equipment.</i>	N
21.6 a	Portable and mobile equipment is able to withstand rough handling.	<i>Equipment withstands rough handling.</i>	P
21.6 b	Propel test of mobile equipment (performed 20 times). Equipment complies with requirements of this standard.	<i>Not applicable. See above.</i>	N

22	MOVING PARTS		
22.2 a	Moving parts of transportable equipment are provided with guards which form an integral part of the equipment	<i>Not applicable. No moving parts.</i>	N
22.2 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	<i>Not applicable. See above.</i>	N
22.3	Cords (ropes), chains and bands are confined so they cannot run off or jump out of their guiding devices	<i>Not applicable.</i>	N
	Other means used to prevent a safety hazard		N
	Mechanical safeguard means are removable only with a tool		N
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation of the control	<i>Not applicable. No such parts.</i>	N
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	<i>Not applicable. No such parts.</i>	N
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	<i>Not applicable.</i>	N
	The means for emergency switching are readily identifiable and accessible and do not introduce a further safety hazard		N
	Current breaking capability		N

	Means for stopping of movements operate as a result of one single action		N
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23	SURFACES, CORNERS AND EDGES		
	There are no rough surfaces, sharp corners, flange or frame edges and burrs which may cause injury or damage	<i>The edges are well rounded.</i>	P

24	STABILITY IN NORMAL USE		
24.1	Equipment does not overbalance, when tilted through an angle of 10°	<i>Tested.</i>	P
24.3	If equipment overbalances when tilted 10°, it does not overbalance when tilted:	<i>Not applicable. Equipment does not overbalance.</i>	N
	- 5° in any position of normal use, excluding transport		N
	- 10° in the condition specified for transport		N
	The equipment carries a warning notice for transport		N
24.6 a	Equipment or its parts with a mass of more than 20 kg:	<i>Not applicable. Below 20 kg.</i>	N
	- is provided with handling devices (grips etc.)		N
	- is provided with handling instructions for lifting and assembling		N
24.6 b	Portable equipment with a mass of more than 20 kg carrying handle(s) suitably placed that equipment may be carried by 2 or more persons	<i>Not applicable. See above.</i>	N

25	EXPELLED PARTS		
25.1	Protective means are provided where expelled parts of the equipment could constitute a safety hazard	<i>Not applicable. No expelled parts.</i>	N
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	<i>Not applicable. No use of display tubes.</i>	N
	Certificate of the test provided		N

26	VIBRATION AND NOISE	
		<i>No general requirement.</i>

27	PNEUMATIC AND HYDRAULIC POWER	
		<i>No general requirement.</i>

28	SUSPENDED MASSES		
28.3	Suspension systems with safety devices:	<i>Not applicable. No suspended masses.</i>	N
	Suspension systems include a safety device with adequate safety factors to protect user or patient from hazards		N
	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		N
28.4	Suspension systems of metal without safety devices:	<i>Not applicable. See above.</i>	N
	The construction of the suspension complies with:		N
28.4 1	The TOTAL LOAD does not exceed the SAFE WORKING LOAD	<i>Not applicable.</i>	N
28.4 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	<i>Not applicable.</i>	N
28.4 3	Where impairment by wear, corrosion, material fatigue is expected, the SAFETY FACTOR is not less than 8	<i>Not applicable. See above.</i>	N
28.4 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	<i>Not applicable.</i>	N
28.4 5	Sheaves, sprockets, band wheels 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	<i>Not applicable.</i>	N
28.5	Dynamic loads:	<i>No general requirement.</i>	

29	X-RADIATION		
29.1	Diagnostic X-ray equipment, see IEC 601-1-3. Radiotherapy equipment, see relevant Particular standard	<i>Not applicable. No x-radiation.</i>	N
29.2	For equipment not intended to produce X-radiation for diagnostic and therapeutic purposes, ionising radiation emitted by vacuum tubes excited by voltages exceeding 5 kV does not produce an exposure exceeding 130 nC/kg (0.5 mR)	<i>Not applicable. See above.</i>	N
30	ALPHA, BETA, GAMMA, NEUTRON RADIATION AND OTHER PARTICLE RADIATION		
		<i>No general requirement.</i>	
31	MICROWAVE RADIATION		
		<i>No general requirement.</i>	
32	LIGHT RADIATION (INCLUDING LASERS)		
		<i>No general requirement.</i>	
33	INFRA-RED RADIATION		
		<i>No general requirement.</i>	
34	ULTRAVIOLET RADIATION		
		<i>No general requirement.</i>	
35	ACOUSTICAL ENERGY (INCLUDING ULTRA-SONICS)		
		<i>No general requirement.</i>	
36	ELECTROMAGNETIC COMPATIBILITY		
	IEC 60601-1-2 (1993)	<i>Manufacturer has self declared.</i>	
37 - 41	REQUIREMENTS FOR CATEGORY AP AND APG EQUIPMENT		
	See additional test report form.	<i>Not applicable.</i>	N

42		EXCESSIVE TEMPERATURES			
Ambient temperature during measurements:		See tables below.			
Humidity:		45% RH			
Atmospheric pressure:		1020hP			
Equipment:		Humidity : N2531 Pressure : N2842			
Initials Tester / Date:		VA / November 2000			
42.1 - 42.2		Determination of the temperature with thermocouples:			P
Equipment:		N2366			
Initials Tester / Date:		VA / November 2000			
Quantity	Rated	Frequency	Used	Frequency	
Supply voltage, V	100-240VAC	50/60Hz	90, 240, 264 VAC	50/60Hz	
Output power, VA	48	—	48	—	
Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Model GT500148-12	
1. Ambient, T = 23,5° C	—	—	—		
2. Transformer	70	110	130	Class B insulation. Tab Xa	
4. Enclosure	25	65	85	Tab. Xa	
5. PWB	26	66	-	UL 94V-0	
6. Appliance inlet	23	63	85	Tab. Xa	
7. Power output cord	15	55	85	Tab. Xa	
8. Ground cord inside	25	65	105	Tab. Xa	
9. MOV1	36	76	85	Tab. Xa	
10. TH1	28	68	85	Tab. Xa	
11. Q1	65	105	150	Tab. Xa	
12. L1	58	98	105	Tab. Xa	
13. DB1	59	99	150	Tab. Xa	
14. D12	65	105	150	Tab. Xa	
15. D15	65	105	150	Tab. Xa	
16. C9	57	97	105	Tab. Xa	
17. C25	64	104	105	Tab. Xa	
18. C27	64	104	105	Tab. Xa	
19. C29	64	104	105	Tab. Xa	
Quantity	Rated	Frequency	Used	Frequency	
Supply voltage, V	100-240VAC	50/60Hz	90, 240, 264 VAC	50/60Hz	
Output power, VA	48	—	48	—	

Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Model GT500148-15
1. Ambient, T = 23,5° C	—	—	—	
2. Transformer	69	109	130	Class B insulation. Tab Xa
4. Enclosure	25	65	85	Tab. Xa
5. PWB	26	66	-	UL 94V-0
6. Appliance inlet	24	643	85	Tab. Xa
7. Power output cord	13	53	85	Tab. Xa
8. Ground cord inside	22	62	105	Tab. Xa
9. MOV1	35	75	85	Tab. Xa
10. TH1	26	66	85	Tab. Xa
11. Q1	63	103	150	Tab. Xa
12. L1	57	97	105	Tab. Xa
13. DB1	58	98	150	Tab. Xa
14. D12	64	104	150	Tab. Xa
15. D15	64	104	150	Tab. Xa
16. C9	57	97	105	Tab. Xa
17. C25	62	102	105	Tab. Xa
18. C27	63	103	105	Tab. Xa
19. C29	64	104	105	Tab. Xa
Quantity	Rated	Frequency	Used	Frequency
Supply voltage, V	100-240VAC	50/60Hz	90, 240, 264 VAC	50/60Hz
Output power, VA	48	—	48	—
Measuring point	Measured temp. Δt (°K)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks Model GT500148-24
1. Ambient, T = 23,5° C	—	—	—	
2. Transformer	70	110	130	Class B insulation. Tab Xa
4. Enclosure	25	65	85	Tab. Xa
5. PWB	26	66	-	UL 94V-0
6. Appliance inlet	23	63	85	Tab. Xa
7. Power output cord	15	55	85	Tab. Xa
8. Ground cord inside	25	65	105	Tab. Xa
9. MOV1	36	76	85	Tab. Xa
10. TH1	28	68	85	Tab. Xa
11. Q1	65	105	150	Tab. Xa
12. L1	58	98	105	Tab. Xa
13. DB1	59	99	150	Tab. Xa
14. D12	65	105	150	Tab. Xa

15. D15	65	105	150	Tab. Xa				
16. C9	57	97	105	Tab. Xa				
17. C25	64	104	105	Tab. Xa				
18. C27	64	104	105	Tab. Xa				
19. C29	64	104	105	Tab. Xa				
Comments	According to IEC 60601-1 clause 42.1, table Xa and Xb, 40°C or 25°C is added to the temperature rise for determination of the final temperature T.							
	Temperature rise is measured at 90, 240 and 264 VAC, at both 50 and 60 Hz. Electronic load used to simulate resistance. Only maximum temperatures from these 6 tests on each model is listed.							
42.1 - 42.2	Determination of the temperature rise of copper windings by the resistance method: $\Delta t = \frac{R_2 - R_1}{R_1} (234.5 + t_1) - (t_2 - t_1)$		Not applicable. Switch mode designed transformer is used, (switch mode construction with electrical protection in event of short-circuit or overload).			N		
	Equipment:							
	Initials Tester / Date:							
Quantity	Rated		Used in tests		Remarks			
Supply voltage, V								
Supply power, VA	—		—					
Output power, VA	—		—					
Winding	R ₁ (Ω)	R ₂ (Ω)	Room temperature		Final temperature		Allowed T (°C)	Remarks
			t ₁ (°C)	t ₂ (°C)	Δt (°K)	T (°C)		
Comments	According to IEC 60601-1 clause 42.1, table Xa and Xb, 40°C or 25°C is added to the temperature rise for determination of the final temperature T.							
42.3	Surface temperatures of applied parts not intended to supply heat to a patient do not exceed 41°C		Not applicable. No applied parts.			N		
42.5	Guards for preventing contact with hot accessible surfaces are removable only with the aid of a tool		Not applicable. No accessible hot surfaces.			N		

43	FIRE PREVENTION		
43.1	Strength and rigidity of the equipment are sufficient to avoid fire hazards (see 21)	The equipment is well constructed with regard to avoid fire hazard.	P
43.2	Oxygen enriched atmospheres:	No general requirement.	

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION AND COMPATIBILITY		
44.2	Overflow		
	Equipment containing a liquid reservoir:	<i>Not applicable. No use of liquid reservoir.</i>	N
	- The equipment is electrically safe after 15% overfill steadily over a period of 1 min		N
	- Transportable equipment is electrically safe after additionally having been tilted through 15° in least favourable direction(s) (if necessary with refilling)		N
	No signs of wetting of uninsulated live parts		N
	Dielectric strength test (if deemed necessary)		N
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 for approximately 15 s from a height of max. 5 cm)	<i>Not applicable.</i>	N
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). Equipment shall be so constructed that liquid which might escape in a single fault condition does not cause a safety hazard(see also Sub-clause *52.4.1)	<i>Not applicable.</i>	N
44.5	Humidity		
	Checked by the pre-conditioning treatment and tests (see 4.10)	<i>48 hours.</i>	P
44.6	Ingress of liquids		
	Equipment checked by relevant tests of IEC 529	<i>Not applicable. IP20.</i>	N
	Equipment withstands dielectric strength test in Clause 20.		N
	Water, if entered equipment, has no harmful effect, in particular there is no trace of water on insulation for which creepage distances are specified		N

44.7	Cleaning, sterilisation and disinfection		
	Equipment/equipment parts capable of withstanding cleaning, sterilisation or disinfection likely to be encountered in normal use or specified by the manufacturer	<i>Not applicable. See Sub-clause 6.8.2 d.</i>	N
	Test with saturated steam at 134 degrees C+4 for 20 cycles, each of 20 min duration		—
	Method specified by the manufacturer in instructions for use		—
	Safety of the equipment not impaired by the test. No appreciable signs of deterioration. Dielectric strength test specified in Clause 20. withstood.		—
44.8	Compatibility with substances used with the equipment:	<i>No general requirement</i>	

45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		
45.2	Pressure vessel with a pressure volume greater than 200 kPa x l, and pressure greater than 50 kPa, withstands the hydraulic test pressure.	<i>Not applicable. No such parts.</i>	N
	Hydraulic test pressure: (The test pressure shall be maximum permissible working pressure multiplied by a factor obtained from Fig. 38).		N
45.3	The maximum pressure to which a part can be subjected in normal condition and single fault condition does not exceed the maximum permissible working pressure for the part	<i>Not applicable.</i>	N
	The used maximum pressure is the highest of the following:		N
45.3 a	Rated maximum supply pressure from an external source	<i>Not applicable.</i>	N
45.3 b	Pressure setting of a pressure relief device provided as part of the assembly	<i>Not applicable.</i>	N
45.3 c	Maximum pressure that can be developed by an air compressor that is part of the assembly, unless the pressure is limited by a pressure-relief device	<i>Not applicable.</i>	N
45.7	Equipment incorporates pressure-relief device(s) where excessive pressure could occur	<i>Not applicable.</i>	N
	If yes, it complies with all the following requirements:		N

45.7 a	Connected as close as possible to the pressure vessel or parts of system it is intended to protect	<i>Not applicable.</i>	N
45.7 b	Readily accessible for inspection, maintenance and repair	<i>Not applicable.</i>	N
45.7 c	Not capable of being adjusted or rendered inoperative without a tool	<i>Not applicable.</i>	N
45.7 d	Its discharge opening located and directed so, that released materials is not directed towards any person	<i>Not applicable.</i>	N
45.7 e	Operation of device does not deposit material on parts causing possible safety hazard	<i>Not applicable.</i>	N
45.7 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	<i>Not applicable.</i>	N
45.7 g	No shut-off valve between the pressure-relief device and the parts it is intended to protect	<i>Not applicable.</i>	N
45.7 h	Minimum number of cycles of operation is 100 000, except for bursting disks	<i>Not applicable.</i>	N

46	HUMAN ERRORS		
		<i>No general requirement.</i>	

47	ELECTROSTATIC DISCHARGES		
		<i>No general requirement.</i>	

48	BIOCOMPATIBILITY		
	Equipment parts and accessories intended to come into contact with biological tissues, cells or body fluids assessed and documented as given in ISO 10993-1. Inspection of information provided by manufacturer.	<i>No parts of the equipment or accessories are intended to come into contact with biological tissues, cells or body fluids.</i>	N

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	<i>Not applicable. No use of automatically resetting thermal cut-outs and overcurrent releases</i>	N

49.2	Interruption and restoration of the power supply do not result in hazards	<i>No hazards.</i>	P
49.3	Means are provided for removal of mechanical constraints on patients in case of a supply mains failure	<i>Not applicable. Not provided.</i>	N

50	MARKING OF CONTROLS AND INSTRUMENTS		
50.1		<i>See Sub-clause 6.3.</i>	

51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.1	Intentional exceeding of safety limits.	<i>No general requirement (cf. Appendix A, Sub-clause A2)</i>	
51.2	Indication of parameters relevant to safety.	<i>No general requirement (cf. Appendix A, Sub-clause A2)</i>	
51.3	Reliability of components.	<i>See Sub-clause 3.6 f.</i>	
51.4	Equipment providing both low- and high-intensity outputs. Minimised possibility of high intensity output being selected accidentally	<i>Not applicable. No such output.</i>	N
51.5	Incorrect output.	<i>No general requirement</i>	

52	ABNORMAL OPERATION AND FAULT CONDITIONS		
52.1	Equipment shall be so designed and manufactured that even in single fault condition no safety hazard as described under Sub-clause 52.4 exists (see 3.1 and 13)		P
52.1	Safety of equipment incorporating programmable electronic systems (PES) conforms to the rules of future IEC 601-1-4	<i>The equipment does not include programmable electronic subsystems as specified in IEC 60601-1-4, 1996</i>	N
52.5.1	Overloading of mains supply transformers	<i>See Sub-clause 57.9.</i>	—
52.5.2	Failure of thermostats	<i>Not applicable. No use of thermostats.</i>	N
52.5.3	Short-circuiting one part of a double insulation	<i>Short-circuiting of capacitors between primary and secondary side, forming part of double insulation. No hazard observed.</i>	P
	Capacitors short-circuited one at a time	<i>C8, C9, C44</i>	
Comments	Earth leakage measurement is not applicable according to IEC 60601-1 clause 19, note 1 to table IV.		
52.5.4	Interruption of the protective earth conductor (tests as described in Sub-clause 19.4)	<i>No hazard</i>	P
52.5.5	Impairment of cooling. Temperatures do not exceed 1.7 times values of Clause 42, Tables Xa and Xb, minus 17.5 degrees C.	<i>Not applicable. No cooling requirements.</i>	N

52.5.6	Locking of moving parts (see also 52.5.8)	<i>Not applicable. No moving parts.</i>							N
52.5.7	Interruption and short-circuiting of motor capacitors (see also 52.5.8)	<i>Not applicable. No motor capacitors.</i>							N
Equipment:									
Initials Tester / Date:									
Capacitor and winding	Short circuit	Open circuit	R ₁ (Ω)	R ₂ (Ω)	t ₁ (°C)	t ₂ (°C)	Δt (°K)	Final t (°C)	
Comments									
52.5.8	Additional tests for motor operated equipment:	<i>Not applicable. No use of motors.</i>							N
52.5.9	Failure of components (refer to Table in Clause 56)	<i>See table below.</i>							P
	X1 and X2 capacitors between parts of opposite polarity in the mains part and complying with IEC 60384-14 exempted from this requirement	<i>X capacitors comply with IEC60384-14 and/or EN132400.</i>							
52.5.10	Overload								
52.5.10 a	Equipment with heating elements:	<i>Not applicable. No heating elements.</i>							N
52.5.10 a 1	Thermostatically controlled equipment (see 52.5.10.c and d)								—
52.5.10 a 2	Equipment with heating elements with short-time rating (see 52.5.10.c and e)								—
52.5.10 a 3	Other equipment with heating elements (see 52.5.10.c)								—
52.5.10 b	Equipment having motors, which are a part of equipment (see 52.5.5 - 52.5.8 and 52.5.10.f - 52.5.10.h)	<i>Not applicable. No motors.</i>							N
52.5.10 b 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)								—
52.5.10 b 2	Mention for example safety hazards according to 3.1 and 13 and 52.4								—
Test No from 52.5	Applied single fault condition (refer to 52.5) 1)	Observed result (e.g. hazards which arise or not) 2)							
	<i>Short circuiting of secondary side of transformer</i>	<i>No hazard.</i>							
	<i>Short circuiting of the output</i>	<i>No hazard, output voltages drops. Primary side current regulators works.</i>							
	<i>C2 short circuited</i>	<i>No hazard.</i>							
	<i>C23 short circuited</i>	<i>No hazard.</i>							
	<i>C27 short circuited</i>	<i>No hazard.</i>							

	<i>C44 short circuited</i>	<i>No hazard.</i>	
	<i>C8 short circuited</i>	<i>No hazard.</i>	
	<i>C9 short circuited</i>	<i>Fuse F1 blows. No hazard.</i>	
	<i>D15 short circuited</i>	<i>No hazard.</i>	
	<i>DB 1 short circuited from ac to + pin</i>	<i>Fuse F1 and F2 blows. No hazard.</i>	
	<i>IC1 short circuited between pin 1 and 2 (C13)</i>	<i>No hazard.</i>	
	<i>IC1 short circuited between pin 4 and 5 (C11)</i>	<i>No hazard.</i>	
	<i>IC1 short circuited between pin 4 and 7 (C12)</i>	<i>No hazard.</i>	
	<i>IC1 short circuited between pin 4 and 8 (R15)</i>	<i>No hazard.</i>	
	<i>IC2 short circuited</i>	<i>No hazard, output voltages drops. Primary side current regulators works.</i>	
	<i>IC6 short circuited</i>	<i>No hazard, output voltages drops. Primary side current regulators works.</i>	
	<i>Q1 short circuited between pin D and S</i>	<i>No hazard.</i>	
	<i>R54 short circuited</i>	<i>No hazard, output voltages drops. Primary side current regulators works.</i>	

53	ENVIRONMENTAL TESTS		
		<i>See Sub-clause 4.10 and Clause 10.</i>	

54	CONSTRUCTIONAL REQUIREMENTS - GENERAL		
		<i>See Clause 55 to 59.</i>	

55	ENCLOSURES AND COVERS		
		<i>See Clause 16, 21 and 24.</i>	

56 COMPONENTS AND GENERAL ASSEMBLY - LIST OF CRITICAL COMPONENT PARTS			
Code	Approved by	Manufacturer, Type number, Nominal ratings	Location
PWB	UL	MK UL listed. 123220(S) UL 94V-0 ES49XXXXY 31289, A-0173	PWB
Mains transformer	Tested in applicance.	Hitron HES49-XXXXY transformer 100 - 240 VAC, 0,53 - 0,22 A, 52,63 VA 50 W secondary output	T1
Mains transformer insulation system	UL	File no. E 15 18 49 R 120 E, Class B.	T1
Smoothing Capacitor		10 μ F 400V 105 $^{\circ}$ C 100 μ F 400V 105 $^{\circ}$ C	C6 C9
Interference suppression capacitor	UL/cUL, VDE, Nemko	Cheng Tung 0,33 μ F 300 V CTX series	C1, C4
Ceramic Disc Capacitors	UL, VDE	Matsushita type RS, NS or AM or TDK type CS or Murita type KC or Pan Overseas type AC or Roederstein type WKO or Success type SB or SF	C2:1000pF 250V C44:1000pF 250V C7:220pF 250V C8: 470pF 250V
Varistor	UL	Walsin Tech, 470V 20J VZ 7D 471K Centra Sc 470V 30J CNR 7D 471K Ceramate 470V 30J GNR 7D 471K Marcon 470V 20J TNR 9G 471K Centra Sc 470V 30J CNR 471K Ishizuka 470V 20J Z7d 471K	MOV1 (Connected line to line after fuse).
Bridge Diode		4A, 800 V	DB1
Thermistor	UL	Thinking, 10 Ω 2A SCK 102	TH1
Photo-coupler	UL	Sharp PC 123 FY2, Viso 5kVac/min	IC2, IC6
Fuse	UL, VDE, Semko	Wickmann T3,15A, 250V p/n 19372 (TR5-T)	F1, F2
Internal ground wire	CSA, UL	AWM VW-1 Pacific TEW FTI LL30062 105 $^{\circ}$ C 600V 18 AWG	PWB
Inlet	UL, CSA, VDE, Nemko	Supercom 10A 250V type SC8-R	P1
Diode Bridge 12 V		Shindengen Electric mfg co Ltd Rating 10A 60V	D12 and D15
Diode Bridge 15 V		Shindengen Electric mfg co Ltd Rating 10A 90V	D12 and D15
Diode Bridge 24 V		Nihon Inter Electronics Rating 10A 200V	D12 and D15

Enclosure material		UL File no. E 12 15 62 Polyphenylen Oxide (PPHOX) Noryl, SE 100 series. Min thickness 2.3, Flammability UL 94V-1	Enclosure
Empty slot		Not used in equipment even though it is marked on schematics.	Q4
Empty slot		Not used in equipment even though it is marked on schematics.	R48

56.1	General	Marking of components (refer to Table in Clause 56)	
56.1 b	Component markings are according with conditions of use	The components are used according to their ratings. All components in the mains part and applied part are marked or otherwise identified regarding their ratings.	P
56.1 d	Fixing of components.	The movement of components is prevented.	P
56.1 f	Fixing of wiring.	Conductors and connectors are adequately secured and insulated. Accidental detachment does not result in a safety hazard.	P
56.3	Connections - general		
56.3 a	Incorrect interconnection of accessible connectors is prevented where a hazard may be caused	Not applicable. No such connections.	N
	Accessible parts are separated from live parts (see 17 g)	Not applicable.	N
	Plugs for connection of patient circuit cannot be connected to other outlets	Not applicable. No plugs for connection of patient circuit.	N
	Medical gas connections are not interchangeable (see Sub-clause 6.6 and ISO R407)	Not applicable. No medical gas connections.	N
56.3 b	Accessible conductive parts are prevented from becoming live when connection between different part of the equipment is broken	Not applicable. No accessible conductive parts.	N
56.3 c	Connectors having conductive connection to patient are constructed so that no conductive connection of the connector remote from patient can contact earth or hazardous voltages	Not applicable. No connection to patient.	N
	Test with flat conductive surface	Not applicable. No conductive surface.	N
	Test with straight unjointed test finger	Not applicable.	N
	Test if able to be plugged into a mains socket	Not applicable.	N

56.4	Connections of capacitors		
	Capacitors not connected between live parts and non- protectively earthed accessible conductive parts	<i>Not applicable. No such connection.</i>	N
	Capacitors between the mains part and earthed accessible parts, comply with IEC 60384-14 or equivalent	<i>Y-capacitors comply with IEC 60384-14 and/or EN132400.</i>	P
	The enclosure of capacitors are not secured directly to non-protectively earthed accessible metal parts	<i>Not applicable.</i>	N
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	<i>Not applicable. No such connection.</i>	N
56.5	Protective devices		
	Protective devices which operate by producing a short circuit which results in operation of an overcurrent protection device in supply mains system not used (see also 59.3)	<i>Not applicable. No protective devices which operate by producing a short circuit.</i>	N
56.6	Temperature and overload control devices		
56.6 a	Thermal cut-outs which require soldering to reset are not used	<i>Not applicable. No thermal cut-outs.</i>	N
	Thermal safety devices are provided to prevent temperature limits being exceeded		—
	An independent non-self resetting thermal cut-out is provided where the failure of a thermostat may cause a hazard		—
	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 could present a safety hazard	<i>No use of audible alarm.</i>	—
	Test of thermal cut-outs and overcurrent releases		—
	Heated liquid containers are protected against dangerous overheating when container is empty		—
56.6 b	Means provided for varying the temperature setting of thermostats, the temperature setting is clearly indicated		—
	The operating temperature of thermal cut-outs is clearly indicated		—
56.7	Batteries		
56.7 a 1	Adequately ventilation	<i>Not applicable. No use of batteries.</i>	N

56.7 a 2	Accidental short-circuiting is prevented (Note! Lithium batteries)	<i>Not applicable. See above.</i>		N
56.7 b	Incorrect polarity of connection prevented (Note! Lithium batteries) 1) Establish whether there is a possibility of making an incorrect battery connection. 2) Where such a possibility exists, establishing the effect of an incorrect battery connection.	<i>Not applicable.</i>		N
	Type of battery is clearly marked (see also 6.2 d)	<i>Not applicable. See above.</i>		N
56.7 c	Battery state.	<i>No general requirement.</i>		N
56.8	Indicators			
	Unless indication is otherwise apparent to the operator from normal operating position, indicator lights are provided:	<i>Green lamp indicator.</i>		P
	- to indicate that equipment is energised	<i>See Sub-clause 6.3 a.</i>		P
	- to indicate the operation of non-luminous heaters	<i>Not applicable. No non-luminous heaters.</i>		N
	- to indicate when output exists if a safety hazard could result	<i>Not applicable. See Sub-clause 6.7.</i>		N
	Charging mode is visibly indicated to the operator	<i>Green lamp indicator.</i>		P
56.10	Actuating parts of controls			
56.10 a	Accessible parts of electrical controls comply with requirements in Sub-clause 16 c	<i>Not applicable. No accessible parts of electrical controls.</i>		N
56.10 b	Fixing, prevention of maladjustments:			N
	Actuating parts are adequately secured to prevent them working loose during normal use			N
	Controls are secured to prevent movement relative to scale marking			N
	Detachable indicating devices are prevented from incorrect connection without the use of a tool			N
	Equipment:			
	Initials Tester / Date:			
Rotating controls	Gripping diameter of the knob (mm)	Test torque (Nm)	Remarks	
Pull controls	Axial pull, test force (Nm)		Remarks	

56.10 c	Stops of adequate mechanical strength are provided on rotating or movable parts of controls, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a safety hazard	<i>Not applicable. No mechanical strength are provided on rotating or movable parts of controls.</i>	N
	Manual torque test		N
	Axial pull test		N
56.11	Cord connected hand-held and foot-operated control devices		
56.11 a	Voltage on cord connected control devices do not exceed 25 VAC or 60 VDC or peak value	<i>Not applicable. No cord connected hand-held and foot-operated control devices.</i>	N
	Circuits isolated from mains part (see 17 g)		N
56.11 b	Hand-held control devices: No safety hazard as a result of the free fall test (Sub-clause 21.5)		N
	Foot-operated control devices able to support the weight of an adult human being. Test with an actuating force of 1350 N over an area of 625 mm ² . No damage to the device resulting in a safety hazard.		N
56.11 c	Hand-held and foot-operated control devices do not change their control setting when inadvertently placed in abnormal position		N
56.11 d	IP-classification of foot-operated control device at least IPX1		N
	Electrical switching parts specified for use in operating rooms at least IPX8		N
56.11 e	Provided with adequate means of anchoring as for power supply cords (see test of 57.4).		N

57	MAINS PARTS, COMPONENTS AND LAY-OUT		
57.1	Isolation from supply mains		
57.1 a	Means of isolation:		P
	The equipment has means for simultaneous disconnection of all supply poles	<i>Mains plug used as disconnecting device from the mains.</i>	P
	Means for disconnection incorporated in equipment	<i>Not applicable. No means for disconnection incorporated.</i>	N
	External means for disconnection are specified in accompanying documents	<i>Not applicable. No external means for disconnection are specified.</i>	N

57.1 d	Switches for mains disconnection comply with creepage distance and air clearances (IEC 328 , replaced by IEC 1058-1)	<i>Not applicable. No use of switches for mains disconnection.</i>	N
57.1 f	Mains switches are not incorporated in power supply cord or flexible leads	<i>Not applicable. See above.</i>	N
57.1 g	The directions of movement of actuators of mains switches comply with IEC 447	<i>No switch.</i>	N
57.1 h	Suitable plug device used to isolate the non-permanently installed equipment from the supply mains		P
57.1 m	Fuses and semiconductor devices are not used as isolating devices	<i>Not applicable.</i>	N
57.2	Mains connectors , appliance inlets and the like		
57.2 e	Auxiliary mains sockets outlets:	<i>Not applicable. No auxiliary mains sockets outlet.</i>	N
	- cannot accept a mains plug (does not apply to emergency trolleys)		N
	Number of socket-outlets on emergency trolleys are limited to maximum 4.		N
	- and they are properly marked		N
57.3	Power supply cords		
57.3 a	Equipment not provided with more than one connection to supply mains	<i>Only one appliance inlet used.</i>	P
	Alternative connections to a different supply system do not cause safety hazards when more than one connection is made simultaneously	<i>Not applicable.</i>	N
	Mains plug not fitted with more than one power supply cord	<i>Not applicable. Single appliance inlet used</i>	N
	Equipment not intended to be permanently connected to fixed wiring is provided with either a power supply cord or an appliance inlet	<i>Power supply cord.</i>	P
57.3 b	Power supply cords not less robust than ordinary flexible cord, designation 53 of IEC 245 or IEC 227	<i>Not applicable. No cord supplied with equipment. User manual instructs user to only use approved detachable power cord.</i>	—
	PVC insulated power supply cords not used for equipment having external metal parts exceeding 75°C , unless cord rated for the temperature measured	<i>Not applicable. No cord supplied with equipment. User manual instructs user to only use approved detachable power cord.</i>	—
57.3 c	Cross-sectional area of power supply cords (see Table XV)	<i>Not applicable. No cord supplied with equipment. User manual instructs user to only use approved detachable power cord.</i>	—
	Equipment:		
	Initials Tester / Date:		
57.3 d	Stranded conductors fixed by any clamping means or screws are not soldered	<i>Not applicable.</i>	N
57.4	Connection of Power Supply Cords		

57.4 a	Cords anchorages:	<i>Not applicable. Not used.</i>	N
	The equipment or its mains connectors incorporate a cable anchoring device to relieve strain on conductors and prevent abrasion of covering (no knots etc.)		N
	The construction and materials of the cord anchorages are made of insulating material or insulated from unearthed accessible metal parts by supplementary insulation,		N
	or having an insulating lining complying with the requirements for basic insulation fixed to the cord anchorage if an insulation fault on power supply cord could make accessible parts live		N
	Clamping screws do not bear directly on the cord insulation		N
	Screws associated with cable replacement are not used to fix other components		N
	Conductors so arranged that if the cord anchorage fails no strain on protective earth conductor occurs as long as phase conductors are in contact with their terminals		N
	Pull test 25 times		N
	Torque test for 1 min		N
	After the tests, the cord sheath has not been longitudinally displaced by more than 2 mm and the conductor ends have not moved over a distance of more than 1 mm from their normally connected position		N
	Creepage distances and air clearances are not reduced below the values specified in Sub-clause 57.10.		N
	Not possible to push the cord into equipment to such an extent that the cord, or internal parts of the equipment, could be damaged		N
57.4 b	For other than stationary equipment, the power supply cord is adequately protected against excessive bending by means of a cord guard of insulating material	<i>Not applicable. No cord supplied with equipment. User manual instructs user to only use approved detachable power cord.</i>	N
	Alternatively shaped opening for the power supply cord		N
	Bending test:		N
	Flexing test (if guards fail the dimensional test) (see IEC 335-1 AM 6:1988, Sub-clause 25.10)		N

	Results of flexing test:		N
	Percent of broken conductor strands:		N
57.4 c	There is sufficient space inside the equipment to allow the supply cable conductors to be introduced and connected	<i>Appliance inlet and detachable power cord.</i>	N
	Any covers can be fitted without risk of damage to the conductors or their insulation		N
	It is possible to check that conductors are correctly connected before the cover is fitted		N
57.5	Mains Terminal Devices and wiring of mains part		
57.5 a	Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts, soldering, clamping, crimping of conductors or equally effective methods	<i>Not applicable. No cord supplied with equipment. User manual instructs user to only use approved detachable power cord.</i>	N
	Reliance not placed upon terminals alone to maintain conductors in position, unless barriers are provided		N
	Terminals of components used for external conductors comply with specified requirements and are properly marked (see 6.2 h, j and k)		N
	Screws and nuts which clamp external conductors are not used to fix any other component (other than internal conductors unlikely to be displaced)		N
	Barriers provided		N
57.5 b	Terminals including any protective earth terminal are closely grouped to allow easy connection	<i>Not applicable. No such terminals.</i>	N
	Protective earth conductor, see 58		N
	Marking of mains terminals, see 6.2		N
	Mains terminal devices are inaccessible without the use of a tool		N
	Mains terminal devices are so located or shielded that there is no risk of accidental contact between live parts and accessible conductive parts		N
	- and for class II equipment between live parts and conductive parts separated from accessible parts by supplementary insulation only		N
	Single strand of wire (8 mm). Test result:		N

57.5 c	Tightening or loosening of clamping means of conductors does not subject internal wiring to stress	<i>Not applicable. Appliance inlet. Tightening or loosening of clamping means of conductors does not subject internal wiring to stress.</i>	N
	- does not reduce creepage distances and air clearances below allowable values		N
	Cross-sectional area of the conductor used in the fastening and loosening test:	<i>Instruction for use instructs user to only use approved power cord.</i>	P
57.5 d	Effective connection to mains terminals does not require special preparation of cables		P
	Conductors are not damaged or displaced when tightening or loosening of clamping screws or nuts		P
57.5 e	Fixing of wiring	<i>See Sub-clause 56.1 f.</i>	P
57.6	Mains Fuses and Over-current Releases		
	List of fuses and over-current releases: See table at the beginning of Clause 56 in this TRF		P
	There are fuses or over-current releases in each supply lead for class I equipment and class II equipment having a functional earth according to Sub-clause 18.1		P
	There is at least one mains fuse for other single phase class II equipment	<i>Class I.</i>	N
	A protective earth conductor is not fused		P
	No fuse is fitted in neutral conductor of permanently installed equipment	<i>Pluggable Type A.</i>	P
57.8	Wiring of Mains Part		
57.8 a	The insulation of an individual conductor is at least equivalent to that required by IEC 227 or 245 (otherwise the conductor is considered bare)	<i>Not applicable. No internal wiring.</i>	N
	- dielectric strength test of 2000 V for 1 min		—
57.8 b	The cross-sectional area of internal wiring between the mains terminal and protective devices is not less than minimum required for the power supply cord. Measured area: (see Sub-clause 57.3 c)	<i>Not applicable. No internal wiring.</i>	N
	Equipment:		
	Initials Tester / Date:		
	The cross-sectional area of other wiring in the mains part and sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard in case of possible fault currents	<i>Not applicable. See above.</i>	N
	In case of doubt concerning adequacy of incorporated overcurrent protection connecting test performed. No safety hazard arises		—
57.9	Mains supply transformers (refer to table below)	<i>See list of components</i>	

57.9.1	Insulation of mains supply transformers protected against overheating in event of short-circuit or overload (see 57.9.1 a and b)	<i>Switch mode designed transformer is used, (switch mode construction with electrical protection in short-circuit or overload condition).</i>					P
	External protective devices connected such that failure of components cannot render the protective devices inoperative	See above.					P
57.9.1 a	Short-circuit test(s) at 90 to 110 percent of rated supply voltage / voltage range	<i>Primary side current regulator cuts off. No hazard.</i>					P
57.9.1 b	Overload						
	Tests under the conditions specified in Clause 42 until steady thermal conditions are obtained. Results: See table below.	See test below.					P
	Loading of a section or winding of the transformer:	<i>Transformer is regulated by current regulators on primary side. This will cut off the current when the secondary side output resistance is too low.</i>					P
	Supply voltage:	264 V					
	Equipment:	N3103					
	Initials Tester / Date:	VA/November 2000					
<p><i>For switch mode power supplies:</i> A resistor connected directly across secondary winding at 110% of normal load, input 264 VAC; resistance decrease to just before foldback. Output load used was electric resistor with automatic regulation of the resistance to keep current at a preset level. The power in a SMPS is limited by current regulators on primary side.</p> <p><i>Results:</i> No excessive temperature rises were observed after 2.5 hours. Maximum temperature was measured to 130 °C Maximum secondary output current is 5A with 15AVC. Minimum resistance before primary current regulators are activated: 17Ω. (short circuiting resistance lowered as close to cut off as possible.) Dielectric test was conducted at 4000VAC for one min. No breakdown.</p>							
57.9.2	Dielectric strength of electrical insulation between turns and layers	<i>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.</i>					
	Insulation between turns and layers, test performed according to 57.9.2:	<i>Not applicable. Not a relevant test for switch mode power supply.</i>					N
	Voltage used in test:						
	Frequency used in test:						
57.9.4	Construction						
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)	
T1	Hitron See clause 56.	50VA	B	250VAC max. primary side 4A max. secondary side		Not applicable.	
*) A construction diagram has to be added to this test report for each transformer mentioned above.							

Insulation between	Ref. voltage (V)	Air clearance (mm)		Creepage distance (mm)		Notes
		Required	Measured	Required	Measured	
Primary 1 - Primary 1	250	2.4	5.0	4.0	5.0	Parts other than windings
Primary 1 - Primary 2	<250	1.6	3.0	3.0	3.0	
Primary 2 - Primary 2	<250	1.6	3.0	3.0	3.0	
Primary 1 - Secondary 1	250	5.0	14.0	8.0	15.0	
Primary 1 - Secondary 2	250	5.0	14.0	8.0	15.0	
Primary 2 - Secondary 1	250	5.0	14.0	8.0	15.0	
Primary 2 - Secondary 2	250	5.0	14.0	8.0	15.0	
Primary 1 - Primary 1	250	2.4	6.0	4.0	6.0	Windings
Primary 1 - Primary 2	<250	1.6	3.0	3.0	3.0	
Primary 2 - Primary 2	<250	1.6	3.0	3.0	3.0	
Primary 1 - Secondary 1	250	5.0	9.2	8.0	9.2	
Primary 1 - Secondary 2	250	5.0	9.2	8.0	9.2	
Primary 2 - Secondary 1	250	5.0	9.2	8.0	9.2	
Primary 2 - Secondary 2	250	5.0	9.2	8.0	9.2	
Primary 1 - Core	250	2.5	4.6	4.0	4.6	
Primary 2 - Core	250	2.5	4.6	4.0	4.6	
Secondary 1 - Core	250	2.5	4.6	4.0	4.6	
Secondary 2 - Core	250	2.5	4.6	4.0	4.6	
Comments						
57.9.4 a	One of the following methods is used to separate primary from secondary and patient connected windings:		One bobbin with concentric windings separated by double or reinforced insulation. TIW is used.			P
57.9.4 c	Means are provided to prevent displacement of end turns					P
57.9.4 d	An earthed screen has a minimum overlap of 3 mm and a width at least equal to the axial length of the primary winding		Not applicable. No earthed screen used.			N

57.9.4 e	The insulation between the primary and secondary winding in reinforced or double insulated transformers consists of:	<i>Triple insulated wiring (TIW) used in transformer.</i>					P
	number of insulation layer(s):	<i>3 layer</i>					P
	total thickness	<i>0.02 mm</i>					P
	combination of two layers withstands dielectric strength test for reinforced insulation	<i>Test voltage 4178 V</i>					P
57.9.4 f	The creepage distances between the primary and secondary windings comply with requirements for reinforced insulation, with specified allowances	<i>See Sub-clause 57.9.4 e, no allowances needed..</i>					P
	mm at location:						—
	Notes:						—
57.9.4 g	For toroidal transformers:						
	the exit of wires from internal windings is provided with double sleeving complying with requirements for double insulation	<i>Not applicable. No toroidal transformers</i>					N
	its total thickness is at least 0.3 mm extending at least 20 mm outside the winding. Measured thickness:						—
57.10	Creepage distances and air clearance						
57.10 a	Values (refer to table)						
	Creepage distances and air clearances comply at least with the values of Table XVI						P
	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	<i>Not applicable. No slot insulation of motors.</i>					N
	Creepage distances and air clearances between defibrillation proof applied parts and other parts are not less than 4 mm	<i>Not applicable. No applied parts.</i>					N
	Insulation between	Ref. voltage (V)	Air clearance (mm)		Creepage distance (mm)		Notes
			Required	Measured	Required	Measured	
Equivalent to basic insulation between parts of opposite polarity	A - f	250	1.6	8.0	3.0	8.0	
Basic or supplementary insulation	A - a ₁	250	2.5	4.0	4.0	4.0	
Double insulation or reinforced insulation	A - a ₂	250	5.0	9.0	8.0	9.2	
	A - e	250	250	9.0	8.0	9.2	
Comments							
57.10 b	Statements , test specifications etc. observed						
57.10 d	Statements regarding measurement of creepage distances and clearances observed						

58		PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS	
58.1	Clamping means of the protective earth terminal for fixed supply conductors or power supply cords comply with requirements of Sub-clause 57.5 c:		P
	Not possible to loosen the clamping means without use of a tool	<i>A tool is needed.</i>	P
	Screws for internal protective earth connections are covered or protected against loosening from outside	<i>Not applicable. Only soldered earth connections.</i>	N
58.2	Internal protective earthing connections by means of screw, soldering, crimping, wrapping, welding or a reliable pressure contact	<i>Soldering used.</i>	P
58.3	Not used (see 57.5 b)		
58.7	Where an appliance inlet is used for the supply connection, its earth pin is regarded as the protective earth terminal	<i>Approved appliance inlet and mains connector used. See clause 56.</i>	P
58.8	The protective earth terminal is not used for connection between different parts or fixing of any component not related to protective or functional earthing	<i>Not applicable.</i>	N
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	<i>Approved appliance inlet and mains connector used. See clause 56.</i>	P

59		CONSTRUCTION AND LAYOUT	
59.1	Internal wiring		
	Fixing of wiring in the applied part and the mains part, see Sub-clause 56.1 f	<i>Not applicable. No internal wiring</i>	N
59.1 a	Internal cables and wiring:		
	- are protected against contact with moving parts and friction with sharp corners and edges	<i>Not applicable. No internal cables and wiring.</i>	N
	- are protected by additional fixed sleeving or similar means, if there is movement relative to metal parts where it is in direct contact with metal parts	<i>Not applicable. No protected by additional fixed sleeving or similar means.</i>	N
	- and wiring, cord forms or components are not likely to be damaged by opening or assembling the equipment or opening or closing of inspection doors	<i>Not applicable. No wiring, cord forms or components are likely to be damaged by opening or assembling the equipment.</i>	N
59.1 b	The bending radius of cables and cable forms is at least 5 times the outer diameter of the lead	<i>Not applicable. No bending radius of cables.</i>	N
59.1 c	Insulation:		

	- insulating sleeving is adequately secured. It can only be removed by breaking or cutting or is secured at both ends	<i>Not applicable. No insulating sleeving.</i>	N
	Sheath of a flexible cord used as supplementary insulation inside equipment is not subject to undue mechanical or thermal stresses and its insulation properties are at least as specified in IEC 227 or 245	<i>Not applicable. No sheath of a flexible cord used.</i>	N
	- insulated conductors, which are subject to temperatures greater than 70°C, have an insulation of heat-resistant material	<i>Not applicable.</i>	N
	Dielectric strength test of insulation of 2000 V for 1 min		—
59.1 d	Aluminium wires below 16 mm ² cross-section are not used	<i>Not applicable. No use of aluminum wires.</i>	N
59.1 e	Separation of circuits (see Clause 17)		
59.1 f	Connecting cords between equipment parts (e.g. parts of an x-ray or patient monitoring installation or a data-processing installation or combinations) are considered belonging to equipment and subject to requirements of this standard	<i>Not applicable. No connecting cords between equipment parts.</i>	N
59.2	Insulation		
59.2 b	Insulation characteristics, mechanical strength and resistance to heat and fire is retained. Result of the ball-pressure test:	<i>Test of enclosure parts. Temperature of ball 75 °C. Test of parts supporting bare mains parts. Temperature of ball 125 °C See table below.</i>	P
	Equipment	<i>Measure instrument: N- 3011</i>	
	Tester	<i>VA / November 2000</i>	
Part	Temperature (°C)	Time (h)	Result (mm)
Appliance inlet	125°C	1	0.8
Enclosure	75°C	1	1.0
Bobbin of T1	125°C	1	0.7
59.2 c	Insulation is not likely to be impaired by deposition of dirt or dust resulting from wear of parts within the equipment such that creepage distances and clearances are reduced below specified values		P
	Ceramic materials and the like specified in this sub-clause are not used as supplementary or reinforced insulation	<i>Not applicable. No use of ceramic materials.</i>	N
	Rubber materials used as supplementary insulation in class II equipment are resistant to ageing (oxygen test) and arranged and dimensioned adequately	<i>Not applicable. No rubber materials used.</i>	N
	Creepage distances are not reduced below values specified in 57.10 despite any cracks in such insulation	<i>Not applicable.</i>	N

	Insulating materials in which heating elements are embedded are not used as reinforced insulation	<i>Not applicable. No heating elements.</i>	N
59.3	Excessive current and voltage protection		
	See Sub-clause 57.6. An internal electrical power source in equipment is provided with an appropriately rated device to protect against fire hazards. Protective means used. Inspection of design data	<i>Not applicable. No internal electrical power source.</i>	N
	Fuse elements replaceable without opening the enclosure are fully enclosed in a fuseholder and fuse replacement does not cause safety hazard. Test with standard test finger.	<i>Not applicable. Fuse element replacement requires the use of a tool.</i>	N
	Live parts of fuseholders are shielded to prevent electric shock when replacing fuses (if replaceable without the use of a tool)	<i>Not applicable. See above.</i>	N
	Protective devices between an F-type applied part and the enclosure do not operate below 500 V r.m.s.	<i>Not applicable.</i>	N
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	<i>Not applicable. No use of oil containers.</i>	N
	Oil containers in mobile equipment are sealed to prevent loss of oil during transport	<i>Not applicable. See above.</i>	N
	An oil level indicator is provided on partially sealed oil-filled equipment or parts. Inspection of equipment and technical description , and by manual test	<i>Not applicable. See above.</i>	N

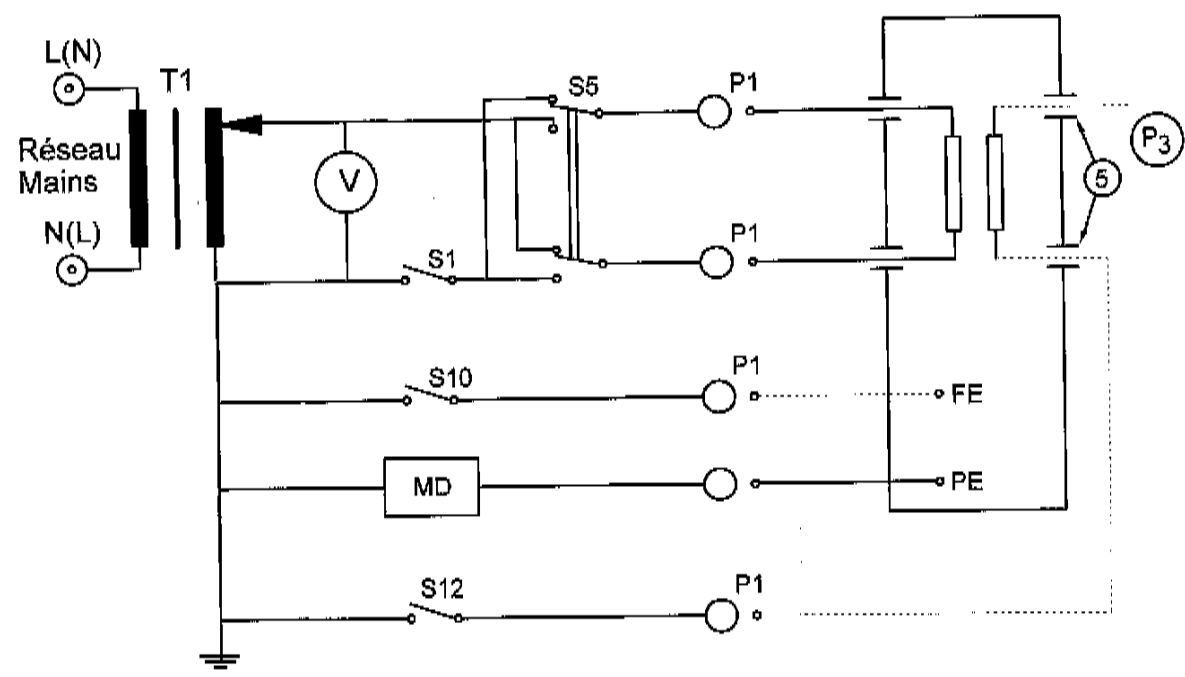
19.4 f APPENDIX 1

Fig. 16 in IEC 601-1

Measurement of the earth leakage current

FOR MAINS OPERATED EQUIPMENT

P



(Measuring supply circuit with one side of the supply mains at approximately earth potential (fig. 10)).

Switch positions	NC (S1 = 1)		SFC (S1 = 0)		Additional SFC* (see Clause 17.a)* (S1 = 1)	
	Measured (µA)		Measured (µA)		Measured (µA)	
S5	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
1	80	80	180	180	—	—
0	80	80	180	180	—	—

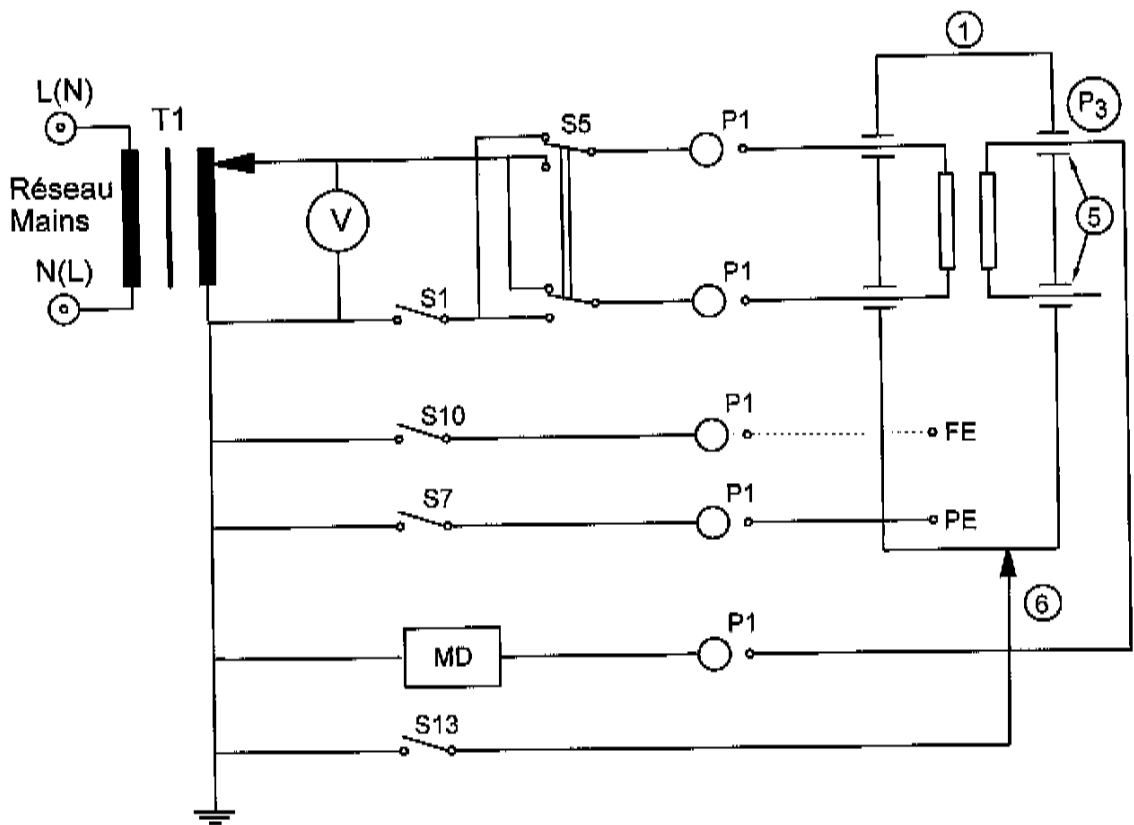
¹ and ² = Before and after humidity preconditioning treatment.

Note:	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above	Additional SFC not used for measuring earth leakage current.
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19.4 g	APPENDIX 2		
Fig. 18 in IEC 601-1	Measurement of the enclosure leakage current	FOR INTERNALLY POWERED EQUIPMENT	N
<p>See fig. 18 on previous page. Using MD2 between different parts of the enclosure.</p>			
<p>Normal Condition Measured (μA)</p>			
Before ¹		After ²	
Comments :			
¹ and ² = Before and after humidity preconditioning treatment.			

19.4 h APPENDIX 3

Fig. 20 in IEC 601-1 Measurement of the patient leakage current FOR MAINS OPERATED EQUIPMENT **N**



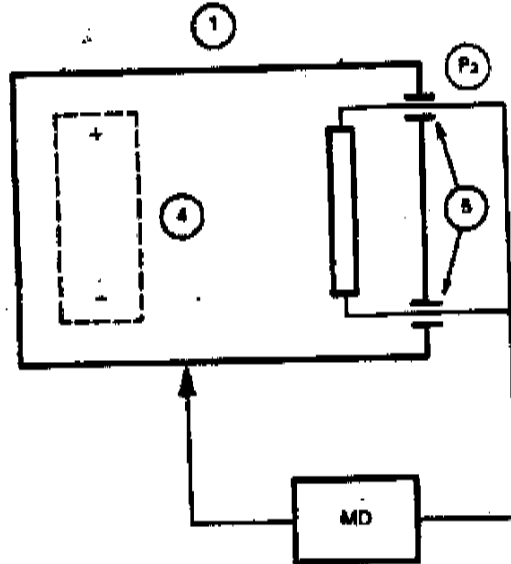
Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
		Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
S5	S10	—	—	—	—	—	—	—	—
1	1	—	—	—	—	—	—	—	—
1	0	—	—	—	—	—	—	—	—
0	1	—	—	—	—	—	—	—	—
0	0	—	—	—	—	—	—	—	—

¹ and ² = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above
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19.4 h APPENDIX 3

Fig. 23 in IEC 601-1 Measurement of the patient leakage current **FOR INTERNALLY POWERED EQUIPMENT** **N**



Normal Condition
Measured (μA)

Before¹

After²

Comments :

¹ and ² = Before and after humidity preconditioning treatment.

19.4 h2

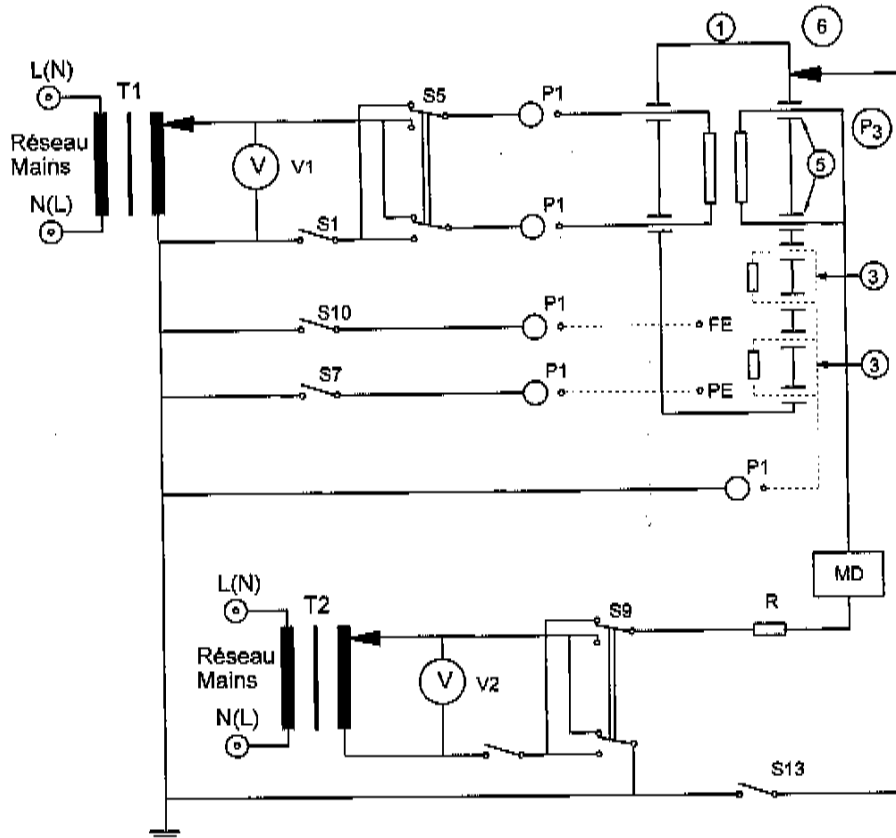
APPENDIX 4

Fig. 21 in IEC 601-1

Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part

FOR MAINS OPERATED EQUIPMENT

N



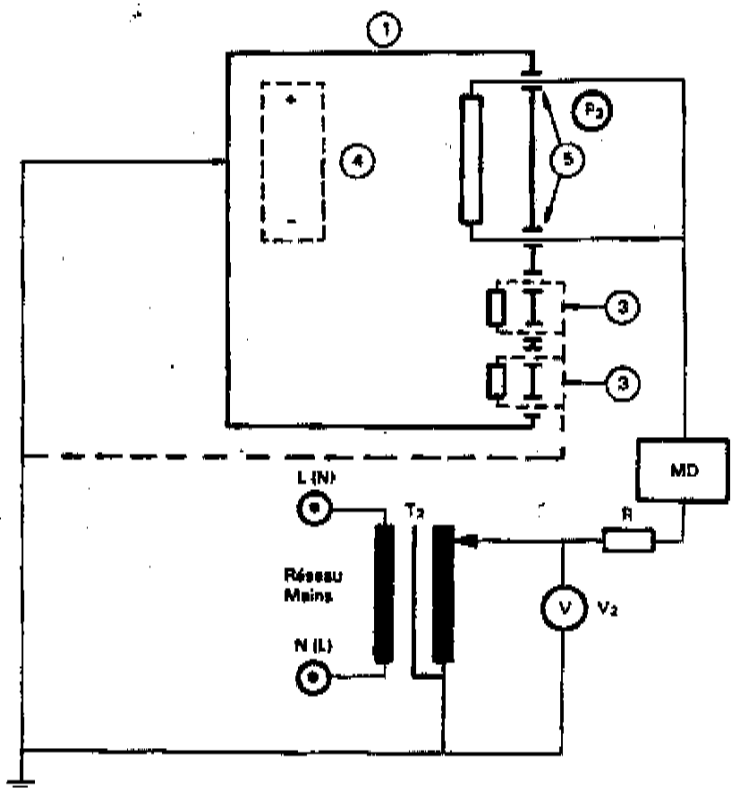
Switch position			Measured μA	
S5	S10	S13	Before ¹	After ²
1	1	1	—	—
1	1	0	—	—
1	0	1	—	—
1	0	0	—	—
0	1	1	—	—
0	1	0	—	—
0	0	1	—	—
0	0	0	—	—

¹ and ² = Before and after humidity preconditioning treatment.

Note: S7 not used for Class II equipment NC = Normal Conditions 1 = Switch Closed
 SFC = Single Fault Condition 0 = Switch Open

19.4 h2 APPENDIX 4

Fig. 24 in IEC 601-1 Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part **FOR INTERNALLY POWERED EQUIPMENT** N



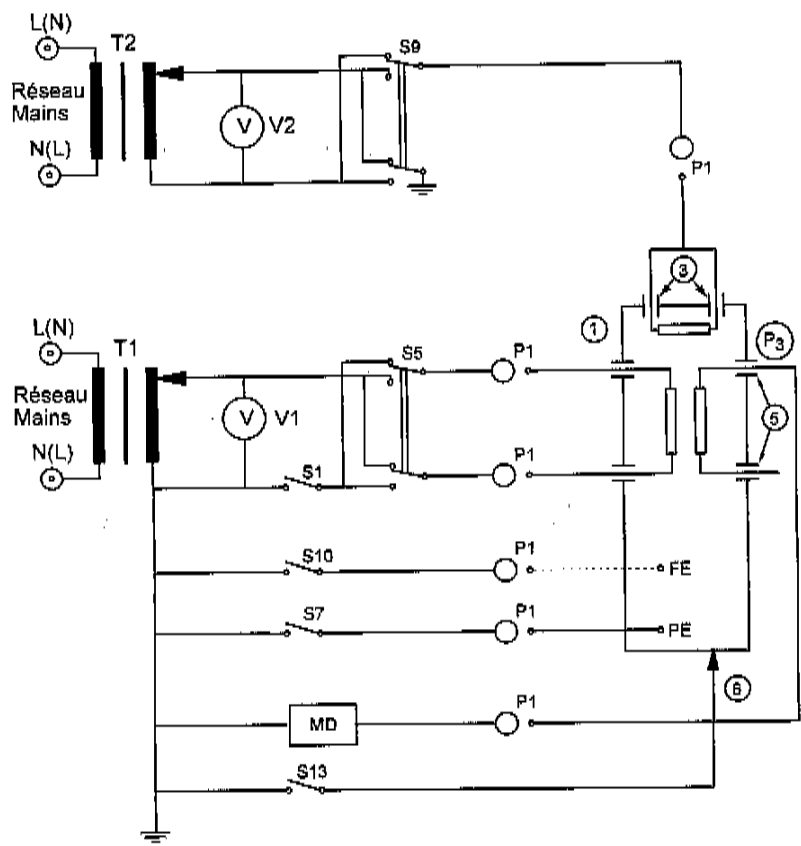
Single Fault Condition
Measured (μA)

Before ¹	After ²

Comments :

¹ and ² = Before and after humidity preconditioning treatment.

19.4 h3	APPENDIX 5		
Fig. 22 in IEC 601-1	Measurement of the patient leakage current with mains voltage on a signal input or signal output part	FOR MAINS OPERATED EQUIPMENT	N

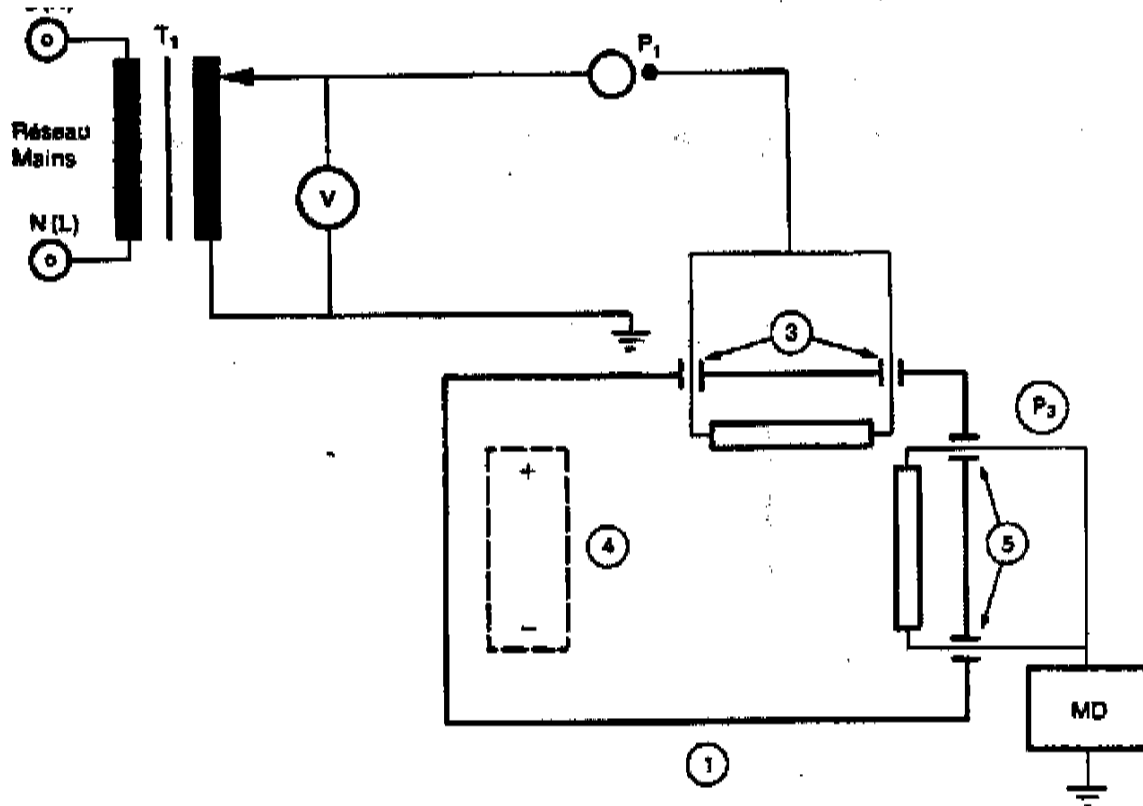


SS	Switch position		Measured μ A	
	S10	S13	Before ¹	After ²
1	1	1	—	—
1	1	0	—	—
1	0	1	—	—
1	0	0	—	—
0	1	1	—	—
0	1	0	—	—
0	0	1	—	—
0	0	0	—	—

¹ and ² = Before and after humidity preconditioning treatment.

Note: S7 not used for Class II equipment NC = Normal Conditions 1 = Switch Closed
 SFC = Single Fault Condition 0 = Switch Open

19.4 h3	APPENDIX 5		
Fig. 25 in IEC 601-1	Measurement of the patient leakage current with mains voltage on a signal input or signal output part	FOR INTERNALLY POWERED EQUIPMENT	N



Single Fault Condition
Measured (μA)

Before¹

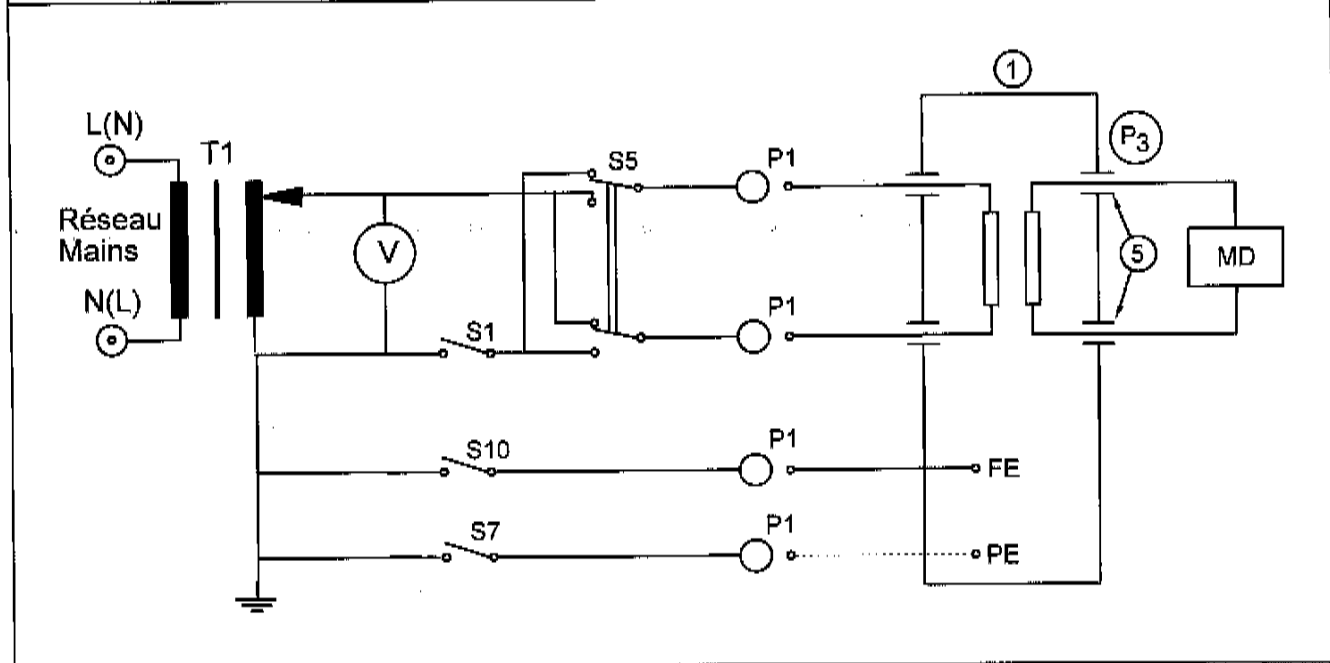
After²

Comments :

¹ and ² = Before and after humidity preconditioning treatment.

19.4 j **APPENDIX 6**

Fig. 26 in IEC 601-1 Measurement of the patient auxiliary current **FOR MAINS OPERATED EQUIPMENT** **N**



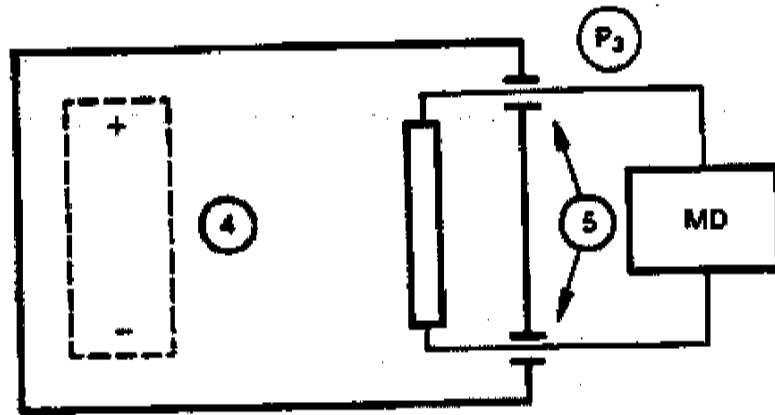
Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
		Before ¹	After ²	Before ¹	After ²	Before ¹	After ²	Before ¹	After ²
S5	S10	—	—	—	—	—	—	—	—
1	1	—	—	—	—	—	—	—	—
1	0	—	—	—	—	—	—	—	—
0	1	—	—	—	—	—	—	—	—
0	0	—	—	—	—	—	—	—	—

¹ and ² = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above
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19.4 j **APPENDIX 6**

Fig. 27 in IEC 601-1	Measurement of the patient auxiliary current	<i>FOR INTERNALLY POWERED EQUIPMENT</i>	N
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Normal Condition
Measured (μA)

Before ¹	After ²

Comments :

¹ and ² = Before and after humidity preconditioning treatment.