

IEC 601-1 2nd EDITION 1988 MEDICAL
ELECTRICAL EQUIPMENT
PART 1: GENERAL REQUIREMENTS FOR SAFETY

Clause No.	Description, Requirements	Compliance OK N/A Fail			Results, Observations, Notes/Comments
6	Identification, marking and documents	/			
6.1	Marking on the outside of equipment or equipment parts	/			
6.1e)	Manufacturers or suppliers name and/or trademark	/			
6.11)	Model or type reference	I'			
6.1g)	Rated Voltage range to which equipment may be connected		I'		
	Number of phases		/		
	Type of current		I		
6.1h)	Rated. supply frequency in Hz		/		
6.1j)	Power input (VA, W or A)		I		
6.1k)	Power output of auxiliary mains socket outlets		/		
6.11)	Class II symbol		I		Not applicable to component.
	Symbol for degree of protection provided by enclosure e.g. IPX1, IPX4 or IPX7		I		Not applicable to component.
	Symbol for protection against electric shock		I		Not applicable to component.
6.11m)	Mode of operation (if no marking, suitable for continuous operation)		I		Suitable for continuous operation.
6.1n)	Types and ratings of external accessible fuses		I		No fuses.
6.1p)	Rated output voltage and current or power output and frequency		~/		Signal level outputs.
6.1q)	Physiological effects (symbols and warning statements)	I			Risk of burn or death if swallowed marking.
6.1r)	Category AP/APG equipment (clause 38)				Not applicable to component.
6.1s)	High Voltage symbol		I		Not a high voltage component.

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6.1t)	Special cooling requirements		I		
6.1u)	Limited mechanical stability		I		
6.1v)	Protective packaging markings		I		Info needed.
6.1y)	Potenti-1 equalization conductor terminal				
6.1z	Functional Earth Terminal		/		
	Durability test of markings	I			
6.2	Marking on the inside of equipment or equipment parts		I		No markings within the equipment.
6.2a)	Is nominal supply voltage or voltage range of permanently installed equipment?				
6.2b)	Is maximum power loading of heating elements or holders for heating lamps		/		No heating lamps.
6.2c)	High voltage parts		if		No high voltage parts.
6.2d)	Type of battery, polarity and mode of insertion		I		No batteries.
6.2e)	Fuses, type and rating or reference		I		No fuses.
6.2f)	Protective earth terminal		I		No protective earth.
6.2g)	Functional earth terminal		I		No functional earth terminal.
6.2h)	Supply neutral conductor in permanently installed equipment		I		No neutral conductor.
6.2j)	Are markings on or near electrical connection points no: affixed to parts which have to be removed to make the connection?		I		
6.2k)	Are they visible after connection		/		
	Are the supply connections clearly marked adjacent to the terminals. For small equipment description in accompanying document;?		I		No safety hazard involved if terminals are misconnected.
Clause No.	Description, Requirements	Compliance OKN/A Fail			Results, Observations, Notes/Comments
6.21)	Is the equipment marked with the following statement (if at any point within a terminal box or wiring compartment intended for connection of the power supply conductors attains a temperature of more than 75°C during the normal temperature test): 'For supply connections, use wiring materials suitable for at least ?		I		
6.3	Marking of controls and instruments		I		No mains switch on component.
6.3a)	Is the mains switch clearly identified? Markings of the positions of the mains switch				
6.3b)	Is indication of different positions of control devices and different positions of switches on equipment (where patient hazard is possible) ?		I		No controls on component.

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6.3c)	Indication of the direction of setting devices if safety hazard to the patient possible				
6.30	Are controls and indicators with safety functions, e.g. alarms, identified?				
6.4	<i>Symbols</i>				
6.4a)	Compliance with appendix D, where applicable?				
6.4b)	Do the symbols for controls and performance conform to IEC publication 878?				
6.5 6.5a)	Colors of insulation of conductors Is the protective earth conductor green/yellow throughout its length?				
6.5b)	Is insulation of internal conductors, which connect accessible metal parts to the protective earth terminal green/yellow?				
6.5c)	Are only protective earth or potential equalization conductors green/yellow? (see 6.51) and 18 for exceptions)				
6.5d)	Is the neutral conductor in the supply cord light blue?				

Clause No.	Description, Requirements	Compliance OK/N/A/Fail			Results, Observations, Notes/Comments
6.5e)	Are the colors of conductors in the power supply cord in accordance with IEC227 and IEC 245?		/		No power supply conductor on component.
6.51)	Is the multi-conductor to Potential Equalization connection 0.1?		I		No bonding conductors.
	Is the end of the multi conductor colored or marked green/yellow?		I		No bonding conductors.
6.6	Identification of medical gas cylinders and connections		I		Component not composed of gas cylinders.
6.6a)	Are these in compliance with ISO/R32?				
6.6b)	Is the point of connection of gas cylinders so identified that errors are avoided when a replacement is made?		I		Component not composed of gas cylinders.
6.7	Indicator lights and push buttons Colored according to Table III?		I		No indicator lights.
6.7a)	Red		/		No indicator lights.
	Yellow		I		No indicator lights.
	Green		I		No indicator lights.
6.7b)	Color red only used for emergency push buttons?		I		No indicator lights.
6.8	Accompanying documents				
~	Are instructions for use delivered with the product?				
	Is a technical description included with the equipment?				
	Is a reference address provided				
	Are warning statements and symbols explained in the accompanying documents?				
	Is the language of the accompanying documents suitable for the destination country?				

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6.8.2 6.8.2a)	<i>Instructions for use</i> Do the instructions for use contain an explanation of the controls, displays and signals, sequence of operation, connection and disconnection of detachable parts and replacement of material(s) which is consumed during operation?			I	Info needed
	A description of the accessories?			I	No accessories.
	A description of device labelling?			I	
	Information on maintenance, cleaning and preventative inspections?			I	Does not apply to component evaluation.
6.8.2c)	Specified connection of equipment to SIP/SOP?			if	Does not apply to component evaluation.
6.8.2d)	Parts in contact with patient:			J	
	Cleaning method			f	
	disinfection method			I	
	sterilization method			I	
6.8.2e)	Warning as to the necessity for periodical checking or replacement of additional or internal power source if not automatically maintained in a fully usable condition?			I	
6.8.2i)	Warning to the user to remove batteries when not in use or if the equipment is not to be used for some time?.			I	No batteries.
6.8.2g)	Use and maintenance of rechargeable batteries?			I	No batteries.
6.8.2h) 6.8.3 6.8.3a) 6.8.3b) 6.8.3c)	Identification of appropriate power supplies or battery chargers?				No power supply required.
	<i>Technical description</i> Performance data and characteristics details to enable safe operation?				
	Particular measures or conditions for installation of the equipment?			I	
	Instructions for replacement of interchangeable and/or detachable parts (e.g. fuses in permanently installed equipment)?				No replaceable parts.
	(Only for parts which are designated to be replaced). Has a statement of availability been made for: Circuit diagrams?			I	No replaceable parts.

Clause No.	Description, Requirements	Compliance Results, Observations, Notes/Comments OKN/A Fail		
	Description of function?		I	
	Service and calibration instructions		I	
6.8.3d)	Are any restricted environmental conditions for transport and storage specified?			Verify
7. 7.1a)	Power Input Power consumed mainly by electric motor(s): Allowed deviation: +25% (rated input ≤ 100 W or 100 VA) +15% (rated input > 100W or 100 VA)		I	No power input. Rated Value: Measured value:

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7. ib)	Power consumed mainly by other components: Allowed deviation: +15% (rated input ≤ 100 W or 100 VA) +10% (rated input < 100W or 100 VA)		I	Rated Value: Measured value:
10. 10.1	Environmental Conditions Is equipment capable of, while packed for transport or storage, of being exposed for a period not exceeding 15 weeks to environmental conditions not outside of the following ranges:	I		
10.1.a)	Ambient temperature range of -40°C to +70°C	I		
10.1.b)	Relative humidity range of 10% to 100%, including condensation.	I		
10.1.c)	Atmospheric pressure range of 500hPa to 1060hPa.	I		
10.2.1	Environmental requirements for test conditions.	I		
10.2.2	Power Supply Power supply voltages and frequency.	I		No power supply required.
14. 14.1 14. ib)	Requirements related to classification <i>Class I equipment</i> If the mains part of equipment specified for an external d.c. power source is isolated from accessible conductive parts by basic insulation only, is a separate protective earth conductor provided?	I		Not class I equipment.
14.2 14.2a)	<i>Class II equipment</i> Insulation enclosed?	I		Component is SELV.
	Metal enclosed?			
	Combination of above?			
Clause No.	Description, Requirements	Compliance OK? ~ / A Fail		Results, Observations, Notes/Comments
14.2b)	Is there a device for changing over from class to class II protection? If yes, are all following requirements fulfilled: Clear indication of the selected class? Use of a tool is necessary for change over In class II position, is PE connection interrupted or changed into a functional earth connection?		I	No device for converting from class II to Class I.
	Compliance of the equipment with the requirements of the selected class given at any time?		I	
14.4 14.4a)	<i>Class I and II equipment</i> Is the equipment provided with an additional protection according to the requirements of class I or class II equipment	I		SELV.
14.4b)	Equipment for connection to external d.c. power supplies: Does no hazard arise if the supply polarity is reversed?		I	
14.5 14.5a)	Internally powered equipment Is equipment with internal power source with		I	No means for connection to a supply mains.

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	means of connection to a supply mains dual classified?				
~i4.5b)	Does the equipment intended <i>for</i> connection to a supply mains comply with the requirements for class I or II equipment while so connected?		/		No means for connection to a supply mains.
14.6 14.6c)	<i>Type B, BF and C'F equipment</i> Is the equipment intended for direct cardiac application type CF?		I		Not intended for direct cardiac application.
14.6d)	Does equipment with applied parts of type CF and type B or BF comply with the requirements of 6.11?		/		No applied parts.
IS. 15.b)	Limitation of voltage <i>and/or</i> energy Are residual voltages between supply plug pins and between supply pin and enclosure after is _ 60 V?		I		Component not intended to be connected to the supply mains.
Clause No.	Description, Requirements	Compliance OKN/A Fail	Results, Observations, Notes/Comments		

Retention of charge in capacitor. Residual voltage: _ 60 V?

Residual energy: _ 2 mJ?	I		Component not intended to be connected to the supply mains.
Endosures and Protective Covers	I		Does not apply to component. Operates at SELV.
Protection against accidental contact with live parts and parts which can become live in the event of failure of basic insulation?			
Are openings in top covers of so enclosure positione or dimensioned that accessibility to d live parts is prevented rod)? (test			Does not apply to component. Operates at SELV.
Do conductive parts of actuating mechanisms of electrical controls which are accessible, after the removal of handles, knobs and levers, have either a resistance _ 0.2 to protective earth or does separation from live parts comply with clause 17g?	I		No accessible conductive parts.
Are internal parts of the equipment with a circuit voltage exceeding 25 VAC or 60 VDC , which cannot be disconnected from the supply, protected against contact even after opening of the enclosure?	I		No circuits over 25 VAC or 60 VDC.
OR			
Are protective enclosures removable only with the aid of a tool?	I		Protective covers are not removable.
Is there an automatic device which disconnects live parts from the supply when the enclosure is opened?.	/ accessible		No live parts accessible.
Are live parts inaccessible to the test rod through openings for adjustment of pre-set controls?			No openings.
Separation	I		Separated from mains part or other live parts (please specify):
<i>Separation method of the applied part from live pans:</i>			No applied parts. Components are not hand held.

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Are allowable leakage currents exceeded?				
Basic insulation		I		No applied parts. Components are not hand held.
Applied part protectively earthed?				
By protectively earthed conductive part (e.g. screen)?		/		No applied parts. Components are not hand held.

Clause No.	Description, Requirements	Compliance OKN/A Fail			Results, Observations, Notes/Comments			
17.a)3)	By separate earthed intermediate circuit?		I		No applied parts.			
17.a)4)	By double or reinforced insulation?		I		No applied parts.			
17.a)5)	By protective impedances limiting current to applied part?		I		No applied parts.			
17.a)	Other method; e.g. specified in particular standard		I		Dei~i~ Faul~ Cc~ditic~i	Strth Leakage Cuncn~	Enc1~urc Le~ka~c Cur,~	Pat~t Lca~cigc Cwyet,t
	Additional leakage current tests in single fault conditions (see clause 19.4)							
17.c)	Is there no connection between applied parts and accessible conductive parts, which are not protectively earthed?		I		No applied parts.			
17.d)	Supplementary insulation between hand-held flexible shafts and motor parts (class 1)		I		Not a hand held component. No motors.			
	Rated motor voltage:		I		V			
	Test voltage:		I		V			
	Adequate mechanical strength:		I					
	Air clearances/creepage distances:		I		minI mm			
17.g)	Separation methods of accessible parts (other than applied parts) from live parts in normal and single fault condition: (Allowable leakage currents are not exceeded)	I			Component operates as a SELV.			
	1. Basic insulation accessible part protectively earthed?		I		Component operates as a SELV.			
	2. By protectively earthed conductive part (e.g. a screen)		I		Component operates as a SELV.			
	3. By separate earthed intermediate circuit?		I		Component operates as a SELV.			
	4. By double or reinforced insulation?		I		Component operates as a SELV.			
	5. By protective impedances limiting current to the accessible part?		I		Component operates as a SELV.			
18.	Protective earthing, functional earthing and potential equalization		I		Not a class I type of equipment.			
18.a)	Are accessible parts of class I equipment which are separated from live parts by basic insulation, connected by a sufficiently low impedance to the protective earth conductor?							
Clause No.	Description, Requirements	Compliance OKN/A Fail			Results, Observations, Notes/Comments			
18.b)	Is the protective earth terminal suitable for connection to the protective earth conductor of the power system?		I		No protective earth terminal.			
18.e) ~	If the equipment is provided with means for the connection of a potential equalization conductor, does this connection comply with the following requirements:		/		No potential equalization conductors.			

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	The connection is readily accessible?					
	Accidental disconnection is prevented in normal use?		I			
	The conductor can be detached without the use of a tool?		I			
	Power supply cord does not incorporate a potential equalization conductor?		I			
	Connection is marked with symbol 9 of table DI?		I			
18.0	Impedance of protective earthing system Is the impedance ≤ 0.1 between the PE terminal and any other earthed part where a flexible supply cord is not used or where a detachable supply cord is used OR is the impedance ≤ 0.2 between the protective earth terminal in the mains plug and any other earthed part where a non-detachable supply cord is used?		I		No protective earth terminal.	
	Measurement between any accessible part and:				Measurement	Requirement
	Protective Earth Terminal		I		No protective earth.	0.1
	– Appliance inlet		I		No appliance inlet.	0.1
	Mains plug		I		No mains plug.	0.2
18.g)	If the impedance of protective earth connections other than in 18.1) exceeds 0.1, does the continuous fault current to an accessible part not exceed the allowable value of the enclosure leakage current in single fault condition?		I		No protective earth.	
18.k)	Are functional earth terminals not used to provide functional earthing?		I		No protective earth.	

Clause No.	Description, Requirements	Compliance OK/N/A/Fail	Results, Observations, Notes/Comments
18.1)	For class II equipment with isolated internal screens and with power supply cord (three conductors):	I	No power supply cord.
	Is the third conductor only used as functional earth of these screens, and is it colored green/yellow?	I	No power supply cord.
	Is the insulation of these screens, and all internal wiring connected to them, double or reinforced insulated?	I	No power supply cord.
	Is the marking of the functional earth terminals distinguished from protective earth terminal and is it noted in the accompanying documents?	/	No power supply cord.
19.	Earth Continuity, Earth Leakage Currents, and Insulation Resistance	I	Result
	Protective Earth Continuity	I	No protective earth.
INSULATION POTENTIAL 500 Volts dc			Limit(s)
	Insulation Resistance Mains F1 to Case	I	>50M
	Insulation Resistance Mains F2 to Case	I	> 50M
	Insulation between mains & Applied Parts	I	> SOM
	insulation between Applied Parts and Case	I	> SOM
Earth Leakage Current			
	Earth leakage Current SFC; Open Supply	I	A 1000 A

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Earth leakage Current Normal Condition		I		A	500 A
Earth leakage Current SFC; Open Supply Mains reversed		I		A	1000 A
Earth leakage Current Normal; Mains reversed		I		A	500 A

ENCLOSURE LEAKAGE CURRENT

Enclosure Leakage Current SFC; Open Supply

I

A

Enclosure Leakage Current Normal Condition		/		A	100 A
Enclosure Leakage Current SFC; Open Circuit Earth		I		A	500 A

Enclosure Leakage Current SFC; Open Supply, Mains Reversed

500A

I

A

500A

Earth, Mains Rev

Clause No.	Description, Requirements	Compliance OKN/A Fail	Results, Observations, Notes/Comments
	Enclosure Leakage Current Normal Condition; Mains Reversed	I	A 100 A
	Enclosure Leakage Current SFC; Open Circuit Earth Mains Rev	I	A 500 A

PATIENT LEAKAGE CURRENT

Patient Leakage Current SFC; Open Supply	I	A	
Patient Leakage Current Normal Condition	/	A	500 A
Patient Leakage Current SFC; Open Circuit Earth	I	A	100 A
Patient Leakage Current SFC; Open Supply, Mains Reversed	I	A	500 A
Patient Leakage Current Normal Condition, Mains Reversed	/	A	100 A
Patient Leakage Current SFC; Open Circuit Earth, Mains Rev	I	A	500 A
Patient Leakage Current; Mains on Applied Part	I	A	5000 A
Patient Leakage Current; Mains on Applied Part Mains Rev	I	A	5000 A

PATIENT AUXILIARY CURRENT

Patient Auxiliary Current SFC; Open Supply

I

A

500A

Patient Auxiliary Current Normal Condition	I		
Patient Auxiliary Current SFC; Open Circuit Earth	I	A	10 A
Patient Auxiliary Current SFC; Open Supply, Mains Reversed	I	A	500 A
Patient Auxiliary Current Normal Condition, Mains Reversed	I	A	10 A

A

500A

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Clause No.	Description, Requirements	Compliance OKN/A Fail	Results, Observations, Notes/Comments
20	Dielectric strength (prior to humidity preconditioning)	I	Exception applies: insulation is not a safety

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						function.	
Equipment	Insulation under test	Reference Voltage [V]				Test voltage [VI]	Observations
All types	A-al ~b.i.)			<i>I</i>			
	A-a2 (d.i. or r.i.)			/			
	A-b (b.i.)			<i>I</i>			
	A-c(s.i.)			<i>I</i>			
	A-e (d.i. or r.i.)			<i>I</i>			
	A-f (b.i.)			/			
	A-g (b.i. or r.i.)			/			
	A-j (s.i.)			<i>I</i>			
	A-k (d.i. or r.i.)			<i>I</i>			
Types with applied part	B-a (d.i or r.i.)			<i>I</i>			
	B-b see particular standard			<i>I</i>			
	B-c (s.i.)			<i>I</i>			
	B-d (b.i.)			<i>I</i>			
	b-e (d.i. or ri.)			<i>I</i>			
	Overall compliance with clause 20? b.i. = basic insulation d.i. = double insulation r.i. = reinforced insulation s.i. = supplementary insulation				<i>I</i>		
Note							
Clause No.	Description, Requirements		Compliance 0KM/A Fail		Results, Observations, Notes/Comments		
20	Dielectric strength (prior to humidity preconditioning)			<i>I</i>			
Equipment	insulation under test	Reference Voltage I[VI				Test voltage [VI]	Observations
All types	A-al (b.i.)			/			
	A-a2 (d.i. or r.i.)			/			
	A-b(b.i.)			<i>I</i>			
	A-c(s.i.)			/			
	A-e (d.i. or r.i.)			/			
	A-f(b.i.)			<i>I</i>			
	A-g (b.i. or r.i.)			<i>I</i>			
	A-j (s.i.)			<i>I</i>			
	A-k (d.i. or r.i.)			<i>I</i>			
Types with applied part	B-a (d.i or r.i.)		<i>I</i>	<i>I</i>			
	B-b see particular standard						
	B-c (s.i.)			<i>I</i>			
	B-d (b.i.)			<i>I</i>			

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b-e (d.i. or r.i.)			I			
Overall compliance with clause 20?			I			

Note

b.i. = basic insulation d.i. = double insulation r.i. = reinforced insulation s.i. = supplementary insulation

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21.	Mechanical Strength Are enclosures, including any access covers forming part of them, of sufficient strength and rigidity?	I			Polymeric enclosure is suitable for intended application.
21.3	Is there no damage to parts of patient support and/or immobilization system after loading test (1.35 Kn and 2.7 Kn)?		I		No patient immobilization components.
21.5	Are hand held equipment or equipment parts safe after drop test (drop height 1 m)?		I		Not hand held during normal use.
21.6	Is portable and mobile equipment able to withstand rough handling?	I			Components are able to withstand a drop from 5cm onto a hardwood floor.
22.	Moving Parts		I		No moving parts.
22.2a)	Are moving parts provided with guards which form an integral part of the equipment (transportable equipment)?		I		
22.2b)	Are moving parts provided with similar guards as above unless it is evident that equivalent protection will be separately provided during installation (stationary equipment)?		I		No moving parts.
22.3	Are cords, chains, belts, etc. so confined that they cannot run off or jump out of their guiding devices?		I		No moving parts.
	Are guides or other safeguards removable only with the use of a tool?		I		No moving parts.
22.4	Are dangerous movements of equipment parts, which may cause physical injury to the patient only possible under the control of the operator?		I		No moving parts.
22.6	Are parts of equipment subject to mechanical wear accessible for inspection?		I		No moving parts.
22.7	Is there a means for emergency switching off a relevant part, to remove an unexpected safety hazard caused by an electrically produced mechanical movement?		I		No moving parts.
	Is the means of emergency switching readily identifiable and accessible and does it not introduce a further safety hazard?		I		No moving parts.
	Are the devices for emergency stopping able to break the full load current?		/		No moving parts.

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22.7cont	Does means for stopping of movements operate as the result of one single action?		I		No moving parts.
23.	Surfaces, Corners and Edges Is the equipment free from sharp edges, corners and burrs?	I			
24.	Stability in Normal Use	I			
24.1	Does the equipment not overbalance when tilted through an angle of 100 in normal use?				
24.3	if the equipment overbalances when tilted through 100, does it meet the following requirements: does the equipment not overbalance when tilted through 50 in any position of normal use?		I		
	does the equipment carry a warning notice for transport?		I		
	Does the equipment not overbalance when tilted through 100 in the position specified for transport?		I		
24.6	Grips and orher handling devices		I		No grips or handling devices.
24.6a)	Equipment or its parts with a mass of more than 20 Kg: is it provided with suitable handling devices?				
	Is it provided with handling instructions for lifting and assembling?		I		No grips or handling devices.
24.6b)	Portable equipment with a mass of more than 20 Kg:		I		No more than 20 Kg.
25.	does it have carrying handles, which are suitably place so that the equipment can be carried by 2 or more persons?				
25.1					
25.2					
~	Expelled Parts		I		No expelled parts.
	Are protective means provided where expelled parts of the equipment could constitute a safety hazard?				
	Is a graphical display vacuum tube with a diameter of 16 cm or larger intrinsically safe with respect to effects of implosion and mechanical impact? OR		I		No graphical displays.

lause No .	Description, Requirements	Compliance 0KM/A Fail	Results, Observations, Notes/Comments
	Does the enclosure provide an adequate protection against implosion?	/	No implosion hazard.
28 .	Suspended Masses	/	No suspended masses.
28.3	Suspension systems with safety devices Do suspension systems with safety devices with adequate safety factors protect the		

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	user or patient from hazards? If so, is it obvious to the user when the safety device comes into operation?			
28.4	Suspension systems of material without safety devices		I	No suspended masses. ~
	1. Does the total load not exceed the safe working load?			
	2. Where supporting characteristics are not impaired by wear, corrosion, material fatigue or ageing, is the safety factor of supporting parts not less than 4?		I	No suspended masses.
	3. Where impairment by wear, corrosion, material fatigue or ageing is expected, do the relevant supporting parts have a safety factor not less than 8?		I	No suspended masses.
	4. Where metal with a specific elongation at break of less than 5% is used, do supporting parts have safety factors as in 2 and 3. above multiplied by 1.5?		I	No suspended masses.
	5. Are sheaves, sprockets, bandwheels and guides so designed that the safety factors of these subclauses are maintained for a specific minimum life till replacement of the ropes, chains and bands?		I	No suspended masses.
29	X-radiation	-	I	No X-radiation
29.2	Have precautions been taken to protect the user/patient from harmful extraneous radiation from the equipment?			

38. Marking, Accompanying Documents

38.2

Is APG equipment marked prominently with a green band imprinted with the characters "APG~ (see Appendix DII)?

I

If this marking is impossible, is the relevant information given in the instructions for use?

I

38.4	Is AP equipment marked prominently with a green circle imprinted with the characters "AP" (see appendix DII)?	I
	If this marking is impossible, is the relevant information given in the instructions for use?	I
38.5	Is the above marking (38.2 and 38.4) present on the major part of the equipment?	
38.6	Do the accompanying documents contain an indication to distinguish the parts of the equipment which are AP and APG?	I

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1: GENERAL REQUIREMENTS FOR SAFETY			
Clause	Description, Requirements	Compliance	Results, Observations, Notes/Comments
	cont Ionizing radiation emitted by the equipment (other than X-ray equipment) utilizing vacuum tubes excited by voltages exceeding 5 KV: Allowed value: 130 nC/Kg = 0.5 mR in 1 hour at a distance of 5 cm from the equipment.	I	No X-radiation.
	Alpha, beta, gamma, neutron, radiation and other particle radiation (under consideration)	I	No X-radiation.
	Microwave radiation (under consideration)	I	
	Light radiation (including lasers)		
	– Infra red radiation (under consideration)	I	
	Ultraviolet radiation (under consideration)	I	
	Acoustic energy (including ultrasonics) (under consideration)	I	
	Electromagnetic compatibility JEC 62A(CO)41	I	
	Locations and basic requirements <i>Flammable anaesthetic mixture with air</i>	I	No flammable anaesthetic mixtures with air.
	<i>Flammable anaesthetic mixture with oxygen or nitrous oxide</i>	I	Flammable anaesthetic mixture with oxygen or nitrous oxide
	Are equipment or parts of the equipment, which are used in a location defined in 37.5, AP or APG equipment?	I	

Clause No.	Description, Requirements	Compliance	Results, Observations, Notes/Comments
38.7	Where only parts of the equipment are AP or APG, are the relevant parts clearly marked?	I	Not AP or APG equipment.
39.	Common requirements for Category AP and Category APG equipment.	I	Not AP or APG equipment.
39. 1a)	Are creepage distances and clearances between the connection points of power supply cords as required (57.10 table XVI)?		
39. 1b)	Are connections prevented from accidental disconnection or only removable with the use of a tool (except circuits complying with 40.3 and 41.3)?	I	Not AP or APG equipment.
39. 1c)	Is category AP and APG equipment not provided with a detachable supply cord? (except circuits complying with 40.3 and 41.3)		Not AP or APO equipment.
39.2	<i>Construction details</i>	I	Not AP or APG equipment.
39.2a)	Are covers for protection against penetration of gasses only removable with the use of a tool?		
39.2b)	Do openings in covers meet the following requirements:	I	Not AP or APG equipment.
	1. Openings for control elements in the top cover are fully covered by the control knobs?		
	2. In the sides they do not allow penetration from a > 4mm test rod?	I	Not AP or APG equipment. Not A? or APG equipment.
	3. In the base plate they do not allow penetration from a > 12 mm test rod?	I	

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³ 9.2c)	Are inadmissible temperatures or safety hazards due to a conductor short circuit to a conductive part, which contains flammable anaesthetic gas, prevented?		I	Not AP or APG equipment.
³ 9.3 ³ 9.3a)	<i>Prevention of electrostatic charges</i> Have measures been taken to prevent electrostatic charges by providing leakage paths to earth or by the use of anti static materials?		I	Not AP or APG equipment.
39.3b)	Do the electrical resistance limits of anaesthetic tubes, mattresses and pads, castor tires and other anti static materials comply with ISO standard 2882?		I	Not A? or APG equipment.
Clause No .	Description, Requirements	Compliance	0KM/A Fail	Results, Observations, Notes/Comments
39.4	Corona Are parts of equipment operating at more than 2000 V a.c. or 2400 V d.c., which are not included in an enclosure, so designed that corona cannot be produced?		I	Not A? or APG equipment.
40. 40.1	Requirements and Tests for Category A? Equipment, parts and components thereof Does equipment or equipment parts not ignite flammable anaesthetic mixtures with air in normal use and normal condition?		I	Does not apply to component evaluation. Must be investigated in final assembly.
40.2	Temperature limits Does equipment, producing no sparks, remain under the following surface temperatures, where vertical air circulation is: 1. restricted .150°C? 2. unrestricted .200°C?		I	Does not apply to component evaluation. Must be investigated in final assembly.
		/		Does not apply to component evaluation. Must be investigated in final assembly.
40.3	Low energy circuits Does equipment which may produce sparks in normal use comply with: 1. temperature requirements and 2. requirements of U, I, L and C?		I	Component does not produce sparks in normal use.
40.4 ⁴ O.4a)	External ventilation with internal overpressure Are flammable anaesthetic mixtures with air removed by ventilation before the equipment is energized? Is the penetration of such mixtures prevented by maintenance of overpressure within the equipment, by means of air not containing flammable gases?		I	Does not apply to component evaluation. Must be investigated in final assembly.
		I		Does not apply to component evaluation. Must be investigated in final assembly.
40.4b)	Is the ventilating gas in the enclosure at an overpressure of at least 0.75 hPa? Is the energizing of equipment only possible if the required minimum overpressure has been present, so that the displaced volume is at least 5 times the volume of the enclosure?		I	
⁴ O.4c)	Is the equipment provided with a pressure sensor to detect and to de-energize ignition sources when the		I	

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i~	overpressure drops below 0.5 hPa?				
Clause No.	Description, Requirements	Compliance	Results, Observations, Notes/Comments 0KM/A Fail		
42.	Excessive Temperatures	/	Does not apply to component evaluation. Must be investigated in final assembly.		
42.1	Do equipment parts having a safety function and their environment not attain temperatures exceeding the values in Table Xa during normal use/normal condition over the range of ambient temperatures specified in 10.2.1?				
	Measuring point	I	Measured	AllowedT[°C]	T[°C]
42.2	Do equipment parts and their environment not attain temperatures exceeding the values given in Table Xb during normal use/normal condition at an ambient temperature of 25°C?	I			
	Measuring point		Measured T[°C]	Allowed T[°C]	
Clause No.	Description, Requirements	Compliance 0KM/A Fail		Results, Observations, Notes/Comments	
42.2 cont	Determination of the temperature rise of copper motor windings by the resistance method:		I	Insulation class:	
	~t= (R2-R1/R1)x(234.5 + ti) + (t2-tl)			Room temperature: ti =	
	Overall compliance with clause 42?			Room temperature: t2 =	
	Motor Details:				
	Manufacturer:				
	Part or Model No:				
	Rated Voltage:				
	Rated Current:				
	No. of Phases:				
	RPM Specified: HP:				
	Motor Capacitor Ratings (if applicable)				
	Manufacturer:				
	Part or Model No:				
	Rated Voltage:				
	Capacitance:				
	Construction Details:				
	TEMPERATURE RISE OF MOTOR WINDINGS BY CHANGE OF RESISTANCE METHOD				
	R1WI=	1=	A	R2WI=	~T=____ or
	R1W2=	1='	A	R2W2=	~T=____ OC,
	Ri W3 =	I =	A	R2 W3=	~T=____
	Ri W4 =	I	A	R2 W4=	=*T=____
	R1W5=	1=	A	R2WS=	=~T=____
	R1W6=	1=	A	R2W6=	*T=____
	R1W7=	1=	A	R2W7=	~*T=____
	R1W8=	1=	A	R2W8=	~T=____ °C
42.3	Surface temperatures				
	Are surface temperatures of applied parts, which are not intended to supply heat, not higher than 41°C?				
	Does not apply to component evaluation. Must be investigated in final assembly.				
43.	Fire Prevention	I			

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43.1	Does equipment have the strength and rigidity necessary to avoid fire hazards (see clause 21) ?			
44.	Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization and Disinfection		I	No liquid reservoirs.
44.2	Overflow If equipment contains a liquid reservoir: a) is the equipment electrically safe in the event of 15% overfill? b) as for (a) and tilted through 15° for transportable equipment?		I	No liquid reservoirs.
44.3	<i>Spillage</i> Does spillage not wet parts, which may cause a safety hazard? Test: A quantity of 200 ml of water is poured steadily on an arbitrary point on the top surface of the equipment for 15 seconds.		I	No liquids.
44.4 44.5	<i>Leakage</i> Does liquid, which escapes in single fault condition, not wet parts, which may cause a safety hazard? Test: By means of a pipette, drops of water are applied to couplings, which might rupture. <i>Humidity</i> Is the equipment sufficiently proofed against the effects of humidity: Compliance is checked by preconditioning treatment		I	No liquids. _Not adversely affected by humidity.

Compliance
OKM/A Fail
42.5

I

Results, Observations, Notes/Comments

Does not apply to component evaluation. Must be investigated in final assembly.

Guards

Are guards provided where there are hot accessible surfaces?

Are guards removable only with a tool

I

Does not apply to component evaluation.

Ingress of liquids

Is protection against harmful ingress of liquids
in accordance with IEC publication 529?

Drip-proof equipment test?

Splash-proof equipment test?

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_____ Watertight equipment test?

44.7 Cleaning, Sterilization and disinfection
Sterilization or disinfection method specified
by the manufacturer:

b) does the equipment satisfy the
requirements of the dielectric strength
test?

45. Pressure vessels subject to pressure

45.2 Is the equipment covered under the inspection
procedures of a national regulation?

If yes, test 45.3 are not required.

Does the maximum pressure to which a part can be subjected in normal and abnormal operation not
exceed the maximum permissible working pressure for the part? The used maximum pressure is the
highest of

_____ the following:

⁴S.3a) Rated maximum supply pressure from the
external source

45.3b) The pressure setting of a pressure-relief
_____ device provided as part of the assembly

Clause

No.

44.6

Description, Requirements

I

Compliance Results, Observations, Notes/Comments OKM/A Fail

Does not apply to component evaluation.

I

I

I

I

Test 20 cycles?	I
No sterilization or disinfection method is specified:	/
Test conditions: Steam 134 ± 4°C, 2 bar, 20 cycles, 20 mm duration each	I
After the above specified methods:	I
a) are there any signs of deterioration?	

I

45.3

Not a pressure vessel.

I

I

45. 3c)

/

I

The maximum pressure which can be developed by an air compressor that is part of the assembly, unless the
pressure is limited by a pressure relief device

I

No air compressors.

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Clause No.	Description, Requirements	Compliance OKM/A Fail	Results, Observations, Notes/Comments
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45.7	Are pressure relief devices (where fitted):		I		No pressure vessels.
45.7a)	Located as close to the pressure vessel or parts of the system they are intended to protect?				
45.7b)	Accessible for repairs, inspection and maintenance?		I		
45.7c)	Cannot be adjusted or rendered inoperative without the use of a tool?		I		
45.7d)	Is the discharge opening so located and directed that the released material is not directed towards any person?		I		
45.7e)	Is the discharge opening so located and directed that operation of the device will not deposit material on parts causing possible safety hazards?		I		
45.70	Is there an adequate discharge capacity?		I		
^{45.7g)}	Is there no shut-off valve between a pressure relief and the part that it is intended to protect?		I		
45.7h)	Minimum number of cycles of operation of safety device: 100,000		I		
49.	Interruption of the power supply		I		Does not apply to component evaluation.
49.1	If thermal cut—outs and overcurrent releases with automatic resetting are used, do they not cause a safety hazard by such resetting?				
49.2	Does interruption and restoration of the power supply cause no hazards?		I		
49.3	Are means provided for the removal of mechanical constraints on patients in the event of a supply mains failure?		I		Not a patient applied device.
51.	Protection against hazardous output <i>Intentional exceeding of safety limits</i>		I		Does not apply to component.
51.1	Are means provided which prevent or indicate to the operator that the selected setting is in excess of a safety limit?				
51.2	<i>Indication of parameters relevant to safety</i> Does equipment delivering energy or substances to patients indicate a hazardous output?		I		Component does not deliver substances or energy to patient.
~					

Clause	Description, Requirements	Compliance OK/M/A Fail	Results, Observations; Notes/Comments
	<i>Accidental selection of excessive output values</i>	I	Not a therapeutic piece of equipment.
	In therapeutic equipment providing low and high outputs, are means providing to avoid the accidental selection of high output?		
	Abnormal Operation and Fault Conditions I		
	Is the equipment so designed and manufactured that in single fault condition, no safety hazards exist? (see clause 3.1 and clause 13)		
	The following safety hazards shall be taken into consideration:		
1	Emission of flames, molten metal, poisonous or		

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ignitable gas in hazardous quantities.					
deformation of the enclosure					
temperatures exceeding the maximum values shown in table XII					
Exceeding the limits for leakage current in single fault condition.					
exceeding the voltage limits in the case of single fault condition (for basic insulation)					
Starting, interrupting or locking of movements					
Single fault conditions					
1 Overloading of mains supply transformers in equipment (test see clause 57.9)					
Failure of thermostats (see clause 52.5. 10 and 56.6)				<i>I</i>	No thermostats.
Short circuiting of either constituent part of a double insulation					
Interruption of the protective earth conductor					
Impairment of cooling					
Locking of moving parts (see clause 52.5.8)	/	No moving parts.			

Clause No.	Description, Requirements					Compliance 0KM/A Fail		Results, Observations; Nctes/Comments							
52.5.7	Interruption and short circuiting of motor capacitors (see clause 52.5.8)						I		No motors or capacitor motors.						
	Capacitor and Winding	Short Circuit	Open Circuit					Ri	R2	ti	t2	t	Final Temp		
52.5.8	Additional tests for motor operated equipment Do the temperatures not exceed the limits of table XI and XII?						I		Duration of test: mmVoltage: VFinal temperature of winding:						
52.5.9	Failure of components						I								
52.5.10 ~ _	Overload						I								
	a) Equipment with heating elements						I		No heating elements.						
	1. Thermostats (see clause 52.5. lOc and 52.5. lOd)														
	2. Equipment with heating elements with short time rating (see clause 52.5. lOc and 52.5. lOe)						I								
	3. other equipment (see clause 52.5. lOc)						I								
	b) Equipment with motors						I								
	1. Motor is part of equipment (see 52.5.5 through 52.5.8 and 52.5. lOf through 52.5. lOh)														
	2. Equipment containing motors as well as heating parts						I								
	3.If more than one of the tests is applicable for the same equipment, these tests are made consecutively						I								
	c) Equipment having heating elements						I		No heating elements.						
d) Heating parts of equipment						I									
e) Heating parts of equipment (part 2)						/									

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0	Motors with overload protection	I		
g)	Equipment rated for short-time or intermittent operation	I		

Clause No.	Description, Requirements	Compliance OKM/A Fail			
	h) Equipment for three phase motors	I	1'		No motors. _____
56.	Components and General Assembly				
56.1	Is the constructional data form with a list of critical parts available? (mains part and applied part)				
56. ib)	Marking of components	I			
	Do the ratings of components not conflict with the conditions of use?				
56.1d)	Component fixing		I		Does not apply to component evaluation.
	Is unwanted movement of components prevented?				
56.10	Fixing of wiring		I		Does not apply to component evaluation.
	Are conductors and connectors so secured that accidental detachment cannot result in a safety hazard?				
56.3	connections . General		/		No accessible connectors.
56.3a)	Is incorrect interconnection of accessible connectors prevented where a hazard may be caused (electrical, hydraulic & pneumatic)?				
	Are accessible parts separated from live parts? (see 17g)		I		
	Can plugs for connection of patient circuit leads not be connected to other outlets?		I		No interconnecting plugs.
	Are medical gas connections not interchangeable?		I		No gas connections.
56.3b)	Are accessible conductive parts prevented from becoming live when connection between different parts of the equipment is broken?		I		No accessible conductive parts.
56.4	Connection of capacitors				
	Are capacitors not connected between live parts and non-protectively earthed accessible parts?				
	Do capacitors connected between the mains part and protectively earthed accessible parts comply with IEC 384-14?		/		No capacitors across terminals.
	Are enclosures of capacitors provided only with basic insulation not secured to non-protectively earthed accessible parts?		I		No capacitors.

95

1

Clause No.	Description, Requirements	Compliance OKM/A Fail		Results, Observations, Notes/Comments
56.4 cont	Are capacitors not connected between thermal cut-out terminals?	I		No capacitors.
56.5	Protective devices Are protective devices to disconnect the supply mains which operates by producing a short circuit	I		No protective devices. Does not apply to component evaluation.

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	which results in operation of an overcurrent device not used?		
56.6	<i>Temperature and overload control devices</i>	I	No temperature or control devices. Does not apply to component evaluation.
56.6a)	Application Are thermal cut-outs which require soldering to reset not used?		
	Are thermal safety devices provided to prevent operating temperatures exceeding the specified limits? (see 57.9)	I	No thermal safety devices. Does not apply to component evaluation.
	Is an independent non-self-resetting thermal cut-out provided where the failure of a thermostat may cause a hazard?	I	No thermal cut outs. Does not apply to component evaluation.
	Does the operating temperature of the above thermal cut-out lie between the upper limit of the first thermostat and the safe limit for function?	I	No thermal cut outs. Does not apply to component evaluation.
	Is there an audible alarm where loss of function could present a safety hazard?	/	No temperature or control devices. Does not apply to component evaluation.
	Are heated liquid containers protected against dangerous overheating when empty?	I	No heated liquid containers.
56.ob)	Is the adjustment range of thermostats not much greater than required for equipment function?	I	No temperature or control devices. Does not apply to component evaluation.
	Is the temperature setting clearly indicated?	I	
	Is the operating temperature of thermal cut-outs clearly indicated?	I	
Clause No.	Description, Requirements	Compliance OKM/A Fail	Results, Observations, Notes/Comments
56.7	<i>Intern-al electrical power source</i> Housing	I	No batteries.
56.7a)	Are housings containing batteries: Adequately ventilated?		
	constructed to prevent accidental short circuiting of the batteries?	I	No batteries.
56.7b)	Connection	I	No batteries.
	Is the equipment fitted with means to prevent incorrect polarity of connection?		
56.8	<i>Indicators</i> Unless indication is provided by other means, are indicator lamps used:	I	Does not apply to component evaluation.
	to indicate that equipment is energized?		
	to indicate the operation of non-luminous heaters?	I	Does not apply to component evaluation.
	to indicate when outputs are energized? (required only where a safety hazard could result)	I	Does not apply to component evaluation.
	Is a charging mode provided and is it visibly indicated to the operator?	I	Does not apply to component evaluation.
56.10	<i>Actuating parts of controls</i>	I	No controls. Does not apply to component evaluation.
56. 10a)	Protection against electric shock Do accessible parts of electrical controls comply with the requirements of		

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	16c)?	
56. 10b)	Fixing, prevention of maladjustment Are all actuating parts so secured that they cannot be pulled off or work loose?	I
	Are controls so secured that the indication of any scale always corresponded with the position of the control?	I
	Is an incorrect connection of an indicating device prevented by an adequate construction, if it can be separated without the use of a tool?	I

No controls. Does not apply to component evaluation.
No controls. Does not apply to component evaluation.
No controls. Does not apply to component evaluation.

Clause Description, Requirements No.
Rotating Controls

56.11b) Gripping diameter of the knob [mm]
Mechanical strength
Do hand-held control devices comply with the requirements of **21.5?**

Are foot operated control devices able to withstand the weight of a human being? (1.35 Kn for 1 minute)

Are foot-operated controls drip-proof?

Are electrical switching parts of foot-operated control devices in operating rooms of watertight construction?

I

No control devices.

56. 10b)

cont.

Test Torque [Nm]

Compliance Results, Observations, Notes/Comments OK/M/A Fail

10 d 23	1.0	/
23 d 31	1.8	/
31 d 41	2.0	I
41 d 56	4.0	/
56 d 70	5.0	I
Axial Pull	Test Force	I
~	60 N	

Med-anicai Cctnp~n~s

100 N

I

56. 10c)	Limitation of movement Are steps provided to prevent an unexpected change from maximum to minimum or vice-versa and to prevent damage to wiring?	I
56.11	<i>cord connected hand held and foot-operated control devices</i>	I
56.11a)	Limitation of operating voltage Do operating voltages of cord connected control switches not exceed 25 v a.c. or 60 V d.c (see clause 17g)	

No control devices. Does not apply to component evaluation.

Measured voltage: V

I No control devices.

I No control devices.

56.1 ic) Inadvertent operation

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Do control devices not change their control ____ setting in abnormal position?

56.1ld) Entry of liquids

I No control devices.

I No control devices.

Clause No.	Description, Requirements	Compliance	0KM/A Fail	Results, Observations, Notes/Comments
56.1 le)	Connection cords Does the connection and anchorage of flexible cord to control devices comply with the requirements of 57.4?	I		No connection cords.
57. 57.1	Mains Parts, Components and Layout Isolation from the supply mains Isolation	I		Does not apply to component evaluation.
57.1a)	Does the equipment have means for simultaneous disconnection of all supply poles?			
	Means for isolation: incorporated in the equipment?	I		Does not apply to component evaluation.
	external (specified in accompanying documents)?	I		Does not apply to component evaluation.
57. id)	Does any switch fitted to comply with the clause 57.1a) above meet the requirements of IEC 328?	I		No switches. Does not apply to component evaluation.
57.10	Are mains switches not incorporated in flexible mains leads?	I		No switches. Does not apply to component evaluation.
57. ig)	Are directions of movement of actuators of switches in accordance with JEC 447?	I		No switches. Does not apply to component evaluation.
57. lh	If there is a suitable plug device to isolate a non-permanently installed equipment from the supply mains, does it comply with 571.a)?	I		No switches. Does not apply to component evaluation.
57. im)	Are fuses and semiconductor devices not used as isolating devices?	I		No fuses or semiconductor devices.
57.2 57.2e)	Mains connectors, appliance inlets and the like Are auxiliary mains socket outlets of a type that cannot accept a mains plug? (see 56.3). Are they properly marked?	I		Not a mains operated appliance.
57.3 57.3a)	Power supply cords Is the equipment not provided with more than one connection to a particular supply mains?	I		Not a mains operated appliance.
	Does no hazard result if more than one connection is made simultaneously?	I		Not a mains operated appliance.
	Is the mains plug not fitted with more than one power supply cord?	I		Not a mains operated appliance.

Clause Notes/Comments	Description, Requirements	Compliance	Results, Observations,
No.		0KM/A Fail	
57.3q) Is the equipment provided with a power apply to		I	No supply cord. Does not
contsupply cord or with an appliance inlet?			component evaluation.
57.3b) Types		I	No supply cord. Does not
apply to			component evaluation.
	Do power supply cords comply with IEC 245 designation 53 or with IEC 227 designation 53?		
	Are polyvinyl chloride insulated power supply	I	No supply cord.

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Does not apply to

cords not used where external metal parts with
a temperature exceeding 75°C exist?

component evaluation.

3c)
min²Cu

Cross-sectional area of conductors

I

Area:

Do supply conductors comply with the cross
sectional areas in table XV?

57.3d)
apply to

Preparation of conductors

I

No supply cord. Does not

Are stranded conductors of cables fixed by
any clamping means but not soldered?

component evaluation.

57.4
apply to

Connection of Power Supply Cords

I

No supply cord. Does not

Chord anchorages

component evaluation.

Does equipment and mains connectors provided with power supply cords have cord anchorages?
Are the cord anchorages made of:

/

No supply cord. Does not

apply to

component evaluation.

1. Insulating material OR
2. Metal insulated by supplementary
insulation from accessible conductive
parts non-protectively earthed?
3. Metal provided with an insulated
lining?

/

I

Do clamping screws not bear directly on the
cord insulation?

I

Do screws operated when replacing the power
component other than parts of the cord anchorage?

I supply cord not serve to fix any

Are conductors of the power supply cord so
the protective earth conductor is not subject to
strain?

I arranged, that if the cord anchorage fails,

Clause	Description, Requirements	Compliance OK/M/A Fail	
Cord guards		I	No supply cord. Does not apply to component evaluation.
For other than stationary equipment, is the flexible supply cable adequately protected against excessive bending?			
Is an opening in equipment so shaped that the applied supply cord (even if not provided with guards) passes the flexing test (clause 57.4b)?			No supply cord. Does not apply to component evaluation.
Accessibility of the connection Is there sufficient space inside the equipment to allow the supply cable conductors to be introduced and connected?		I	Does not apply to component evaluation.
Can any covers be fitted without risk of damage to the conductors or their insulation?		I	Does not apply to component evaluation.
Is it possible to check that conductors are correctly connected and positioned before the cover is fitted?		I	Does not apply to component evaluation.
Mains Terminal Devices and Wiring of Mains Part		I	Not a mains connected appliance. Does not apply to component evaluation.

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Is mains connected equipment other than that fitted with a detachable supply cord provided with mains terminals where connections are made with screws, nuts etc.?			
Is a barrier provided to prevent a reduction of the values of creepage distances and air clearances between live parts and other conductive parts, should the conductor break away? (see 57.10)	<i>I</i>		Not a mains connected appliance. Does not apply to component evaluation.
Are the screws and nuts not used to secure other components (other than internal conductors likely to be displaced)?	<i>I</i>		Does not apply to component evaluation.
Arrangement of mains terminal devices Are terminals including any protective earth terminal closely grouped as to allow easy connection? Protective earth conductor, see clause 58. Marking of mains terminal, see clause 6.2.	<i>I</i>		Not a mains connected appliance. Does not apply to component evaluation.
Are they inaccessible without the use of a tool?			Not a mains connected appliance. Does not apply to component evaluation.

Mains Fuses **and** Overcurrent Releases

List of fuses and overcurrent releases:

Device, type and rating

Are there fuses or overcurrent releases in each supply lead for class I equipment and for class II equipment having a functional earth (according to 18.1)?

I

Does not apply to component evaluation.

Clause No.	Description, Requirements	Compliance 0KM/A Fail	
57.5b) continued	Are mains terminal devices so located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact between live parts and accessible parts and, for class II equipment, between live parts and conductive parts separated from accessible parts by supplementary insulation only?	<i>I</i>	
57.5c)	Fixing of mains terminals Does tightening or loosening of clamping means of conductor not: 1. Subject internal wiring to stress? 2. Reduce creepage distances and air clearances below allowable limits? Cross sectional area of the conductor used in the test:	<i>I</i> <i>I</i> <i>I</i>	Not a mains connected appliance. Does not apply to component evaluation.
57.5d)	Connections to mains terminals Does effective connection to mains terminals not require special preparation of conductors (also see clause 57.3d)? Are conductors not damaged or displaced by	<i>I</i> <i>I</i>	Not a mains connected appliance. Does not apply to component evaluation.
			Does not apply to component

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	tightening or loosening of clamping screws or nuts?	
--	---	--

evaluation.

~7.6

I Does not apply to component evaluation.

Location in the circuitry

Maths supply transformers

List of mains supply transformers:

Clause No.	Description, Requirements	Compliance OKM/A Fail			Results, Observations, Notes/Conunents
57.6 cont	Is the current rating of maths fuses and overcurrent releases such that they reliably carry the normal operating current and not greater then the current rating of any component in the mains circuit carrying the mains supply current?		I		Does not apply to component evaluation.
	Is the protective earth conductor not fused?				Does
	Is no fuse fitted in the neutral conductor of permanently installed equipment?		I		not apply to component evaluation. Does not apply to component evaluation.
57.8	<i>Wiring of mains part</i>		I		No mains wiring. Does not apply to component evaluation.
...I. 8a)	Insulation				
57.8b)	If insulation of an individual conductor is not at least equivalent to that required by IEC 227 or IEC 245, that conductor is considered as bare.				
	Cross section				Measured area: — mmi ² Cu
	Is the cross sectional area of wiring between the maths terminal and fuse sufficient to prevent any fire hazard in case of fault currents (see clause 57.3c)?				
	Is the cross section of other wiring and PC board tracks in the maths part adequate to prevent a fire hazard in the event of a fault?				

57.9

57.9 Type of transformer:

continued

57.9.1 Overheating

Are mains supply transformers protected against overheating of basic insulation, supplementary insulation and reinforced insulation in the event of short circuit or overload on any output winding?

Are protective devices external to the transformer or its enclosure provided against overheating connected in such a way that failure of any component other than wiring interposed between the protective device and the transformer cannot render the protective device inoperative?

Test under conditions specified in clause 42.

until steady thermal conditions are obtained.

e) Overcurrent releases

l) Protective device not provided for limitation of the winding

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temperature?

Compliance Results, Observations,
Notes/Comments 0KM/A Fail
/ What current was used as the

basis for the

overload test?

A

I If the secondary outputs are

shorted in turn,

does a fuse rupture? If so

which fuse

ruptured? or

Is there another means for
prevention of
overheating?

If none of the above, the
transformer must
be considered a failure

I

57.9.lb) Overload

S ⁷ .9.la)	Short circuit Conditions specified in clause 42.	I
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I Does not apply to component

evaluation.

Loading of a section or each winding in turn of the transformer:	I	Does not apply to component evaluation.
a) With fuses which comply with IEC 127 and IEC 241?	I	
b) With fuses which deviate from IEC 127 and IEC 241?	/	
c) Short circuit current is smaller than test current?	I	
d) Thermal cut-outs?	I	

I

I

NOTES ON FAILURES

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Clause No.	Description, Requirements	Compliance 0KM/A Fail	Results, Observations, Notes/Comments
57.9b) cont	Determination of the temperature rise of Transformer copper windings by the resistance method: $At = (R_2 - R_1 / R_1) \times (2345 + t_1) + (t_2 - 1)$ Overall compliance with clause 42?	I	Insulation class: Room temperature: $t_i =$ Room temperature: $t_2 =$ $t =$ °C

R1W1=	1=	A	R2W1=	=~T=	
R1W2=	1=	A	R2W2=	°~T=	
R1W3=	1=	A	R2W3=	=~T=	
R1W4r=	1=	A	R2W4=	~T=	°C
R1W5=	1=	A	R2W5=	=T=	°C
R1W6=	1=	A	R2W6=	=~T=	°C
R1W7=	1=	A	R2W7=	=~T=	°C
RIW8=	1=				

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57.9.4e) Does reinforced or double insulation between the primary and secondary winding consist of:
One insulation layer having a thickness of at least 1 mm? OR

Two insulation layers with a total thickness of not less than 0.3 mm? OR

Three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation?

I
No transformers. **No** transformer
No transformers.

Clause No.	Description, Requirements	Compliance OKN/AFajl	Results, Observations, Notes/Comments
57.9.2	Dielectric Strength Are the requirements of clause 20 fulfilled? (if yes, they shall not be repeated!)	I /	Does not apply to component evaluation. No transformers.
	Do electrical insulations between turns and layers pass the test of 57.9.2 after the humidity pre-conditioning treatment?	I	Test voltage: vTest
57.9.4 S7.9.4a)	Construction Methods used for separation: Separate bobbins or formers?	I	frequency: Hz
	One bobbin or former with imperforate partition between windings?	I	No transformers.
	One bobbin or former with concentric windings and having an imperforate protective copper screen with a thickness not less than 0.13 mm?	I	No transformers.
	One bobbin with concentric windthgs separated by double or reinforced insulation?	I	No transformers.
57.9.4c)	Are means provided to prevent displacement of end turns?	I	No transformers.
57.9.4d)	Protective earthed screen with one turn:	I	No transformers.
	Does the screen overlap at least 3 mm?	I	No
	Is the width of the screen at least equal to the axial winding length of the primary winding?	I	transformers.
			No transformers.

I

No transformers.

Do creepage distances between the primary and secondary windings comply with the requirements for reinforced insulation?

I

Clause No.	Description, Requirements	Compliance OKM/A Fail	Results, Observations, Notes!Comments
57.9.4g)	Are the exit of the wires from the internal windings of toroidal transformers provided with	I	No transformers.

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	double sleeving complying with the requirements of double insulation?								
	Is the total thickness at least 0.3 mm, extending at least 20 mm outside the winding?		I					Measured thickness: mm	Measured length: mm
57.10	Creepage distances and air clearances		I					Component produces a 4-20 millivolt potential. Creepage and clearance distances are adequate for intended application.	
57.10a)	Do creepage distances and air clearances comply with the values in table XVI?		I					Component produces a 4-20 millivolt potential.	
~	Are creepage distances for slot insulation of motors at least 50% of the values of table XVI with a minimum of 2 mm at ~OV?		I					Not a mains supplied component.	
	For insulation in the mains part between parts of opposite polarity the minimum creepage distances and air clearances are not required if short-circuit of the creepage distances and air clearances in turn does not produce a safety hazard.		I						
Insulation between		Reference voltage [V]	I					Air clearance [mm]	Creepage distance [mm]
Basic ~ bctwcc~pstt,o(cpc~ itc po1in~y	A-f							Required	Measured
Buicot '~'~Y issuistion									
~	A-al								
	A-b								
	A-c								
	A-j								
	B-c								
	B-d								
Rcurforcc4 UtMtrialics,	A-a2								
	A-e								
	A-k								
	B-a		I						
~	B-e								
	Overall compliance with S7. 10a)?								

Clause No.	Description,	Requirements	Compliance 0KM/A Fail	Results, Observations, Notes/Comments
58.	Protective earthing connections	-Terminals and	I	No protective earthing required, Not a maths operated component.
58.1	Does the protective means comply with 57.5c)?	earth terminal clamping the requirements of		No protective earthing required.
	Is it not possible to of a tool?	loosen it without the use	/	

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58.7	Are screws for internal connections completely against inadvertent of the equipment?	protective earth covered or protected loosening from the outside		No protective earthing required.
58.8	Is the earth pin of the as the protective inlet forms the supply equipment?	appliance inlet regarded terminal, where an appliance connection to	<i>I</i>	No protective earthing required. Not a mains operated component.
58.9	Is the protective earth the mechanical parts of the equipment component not related or functional earthing?	terminal not used for connection between different or the fixing of any to protective earthing	<i>I</i>	No protective earthing required. Not a mains operated component.
59.	<i>Protective earth connection</i> ~ Is the protective earth and interrupted after are made or interrupted, between mains supply equipment is made via device? (see also 57.1, 57.2 & 57.3)	connection made before the supply connections where the connection conductors and a plug and socket	<i>I</i>	No protective earthing required. Not a mains operated component.
59.1	Construction and layout Internal wiring Mechanical protection Are internal cables and wires protected from: 1. Contact moving parts? sharp edges, with2. Friction with burs or corners? 3. Is wiring basic insulation having additional sleeving, if provided relative to metal with there is is in direct contact with movement parts where it them?		/	Does not apply to component evaluation. Does not apply to component evaluation. Does not apply to component evaluation.

Are internal cables and wires and components not likely to be damaged by opening or assembling equipment?

Bending

Is the bending radius of cables and cable forms at least 5 times the outer diameter of the lead?

Can insulating sleeving only be removed by breaking or cutting or is it secured at both ends?
Are aluminum wires of less than 16 mm² cross section not used?

Applicable requirements

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Are connecting cords between equipment parts (e.g. parts of an X-ray patient monitoring installation or a data processing installation or combinations) considered belonging to equipment and not be subject to requirements for wiring of electrical installations?

Insulation

Mechanical strength and resistance to heat and fire

Does insulation comply with the requirement

Moisture resistance? (see clause 44) Dielectric strength? (see clause 21)

The following tests need not be carried out where evidence of compliance is provided:

1. Ball pressure test?

2. Do parts of insulation material supporting parts at mains voltage satisfy the requirements of the ball pressure test at a temperature of

125°C

Does not apply to component evaluation.

Ball pressure test temp: – Does not apply to component evaluation.

Does not apply to component evaluation.

58.1 cont

Description, Requirements

Date: 11/08/95

59.1b)

I

Compliance Results, Observations, Notes/Comments

0KM/A Fail

Does not apply to component evaluation.

59.1c)

I

Insulation

Does not apply to component evaluation.

/

No sleeving.

Does the sheath of a flexible cord comply with the requirements of IEC 227 and IEC 245, if it is used as supplementary insulation?	I	No flexible cords.
--	----------	--------------------

59.1d)

Do insulated conductors, which are subject to temperatures greater than 75°C, have an insulation of heat resistant material?

Materials

I

Does not apply to component evaluation.

I

No aluminum wires.

I

Does not apply to component evaluation.

59.10

59.2

59.2b)

of:

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Does not apply to component evaluation.

Does not apply to component evaluation.

Clause No.	Description, Requirements	Compliance	0KM/A Fail	Results, Observations, Notes/Comments
59.2c) ~	<i>Protection</i> Is insulation not likely to be impaired by deposition of dirt or dust resulting from wear of parts within the equipment?	<i>I</i>		Does not apply to component evaluation.
	Are ceramic materials, not tightly sintered, not used as supplementary or reinforced insulation?	<i>I</i>		No ceramic materials.
	Are rubber materials used as supplementary insulation in class II equipment resistant to ageing? (oxygen test 59.2c)	<i>I</i>		No rubber materials used for supplementary insulation.
	Are creepage distances not reduced below those specified in 56.10 despite any cracks in such insulation?	<i>I</i>		Does not apply to component evaluation.
	Are insulation materials in which heating conductors are embedded not used as reinforced insulation?	<i>I</i>		No heating conductors.
59.3	Excessive current and voltage protection Has an internal electrical power source in equipment an appropriately rated device to protect against fire hazards? (test under consideration)	<i>I</i>		Does not apply to component evaluation.
	Are fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder?	<i>I</i> - <i>I</i>		No fuses. Does not apply to component evaluation.
	Are live parts of fuseholders shielded to prevent electric shock when replacing fuses? (if replaceable without the use of a tool)			No fuseholders. Does not apply to component evaluation.
	Do protective devices between isolated applied part and the enclosure not operate below 500 V RMS?	<i>I</i>		No protective devices. Does not apply to component evaluation.
59.4	Oil containers Are oil containers in portable equipment adequately sealed to prevent oil loss in any position and does the oil container design allow for the expansion of oil?	/		No oil containers.
	Are oil containers in mobile equipment sealed to prevent loss of oil during transport? (a pressure release device may be fitted)	<i>I</i>		No oil containers.
	Is an oil level indicator provided on partially sealed oil filled components?	<i>I</i>		No oil containers.