Clause	Description	Result	Verdict
3.	**General requirements**		
	EQUIPMENT shall, when transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, cause no SAFETY HAZARD which could reasonably be foreseen and which is not connected with its intended application, in NORMAL CONDITION and in SINGLE FAULT CONDITION.		
5.	**Classification**		
	EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in clause 6.		
5.1	According to the type of protection against electric shock		
5.2	According to the degree of protection against electric shock		
5.3	According to the degree of protection against ingress of water as detailed in current edition of IEC 529 (see 6.1l)		
5.4	According to the method(s) of sterilization or disinfection recommended by the manufacturer		
5.5	According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE		
5.6	According to the mode of operation		
5.7	Not used.		
5.8	Not used.		
6.	Identification, marking and documents		

Clause	Description	Result	Verdict
6.1	Marking on the outside of EQUIPMENT or EQUIPMENT parts a) Mains operated EQUIPMENT Mains operation EQUIPMENT, including separable components thereof which have a MAINS PART, shall be provided at last with "permanently affixed" and "clearly legible" markings on the "major part" of EQUIPMENT as described in Table II, Column 3.		
	b) INTERNALLY POWERED EQUIPMENT INTERNALLY POWERED EQUIPMENT shall be provided at least with the following "permanently affixed" and "clearly legible" markings on the "major part" of EQUIPMENT as described in Table II, Column 4.		
	c) EQUIPMENT supplied from a specified power supply EQUIPMENT intended to be supplied from a specified power supply (other than the SUPPLY MAINS and isolated from it), which is or is not part of the EQUIPMENT model or type shall be provided minimally with the following "permanently affixed" and "clearly legible" markings on the outside of the equipment as described in Table II, Column 5. If the specified power supply is not part of the EQUIPMENT model or type, the instructions for use of the EQUIPMENT shall additionally establish reference to the model or type of such a specified power supply. If safety aspects are involved, the model or type of such a specified power supply shall be permanently marked on the outside of the EQUIPMENT and included in the instructions for use.		
	d) Minimum requirements for marking on EQUIPMENT and on interchangeable parts If the size of the EQUIPMENT specified in subclause 6.1 or the nature of its ENCLOSURE does not allow affixation of all specified markings, then at least the markings as indicated in subclauses 6.1d), 6.1f) and 6.1g) (not for PERMANENTLY INSTALLED EQUIPMENT), 6.1l) and 6.1q) (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking is practicable, all information shall be included in the ACCOMPANYING DOCUMENTS.		
	e) Indication of origin The name and/or trademark of the manufacturer or supplier claiming that the EQUIPMENT complies with this standard.		
	f) MODEL OR TYPE REFERENCE		

Clause	Description	Result	Verdict
6.1	g) Connection to the supply – The RATED supply voltage(s) or voltage range(s) to which EQUIPMENT may be connected. – Nature of supply, for example, number of phases (except for single-phase supply) and type of current.		
	h) Supply frequency RATED frequency or RATED frequency range in hertz.		
	j) Power input (see clause 7) The RATED input shall be given in amperes or volt-amperes or in watts where the power factor exceeds 0.9. In the case of EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of the range or ranges, if the range(s) is/are greater than ± 10 % of the mean value of the given range. If the rating of EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the marking shall include both long-time and the most relevant momentary volt-ampere rating, each plainly identified and indicated in the ACCOMPANYING DOCUMENTS. The marked input of EQUIPMENT provided with means for the connection of supply conductors of other EQUIPMENT shall include the RATED (and marked) output of such means.		
	k) Mains power output AUXILIARY MAINS SOCKET OUTLET(S) of EQUIPMENT shall be marked with the maximum allowed output.		

Clause	Description	Result	Verdict
6.1	l) Classification – The symbol for CLASS II EQUIPMENT, if relevant (see appendix D, table DI, symbol 10). – A symbol, using the letters IP, followed by X and the relevant characteristic numeral (1 to 8) of IEC Publication 529, according to the degree of protection provided by the ENCLOSURE with respect to harmful ingress of water. – A symbol indicating the type of APPLIED PART according to the degree of protection against electric shock for TYPE B, TYPE BF and TYPE CF APPLIED PARTS (see appendix D, table DII, symbols 1, 2 and 3). For clear differentiation with symbol 2, symbol 1 shall not be applied in such a way as to give the impression of being inscribed within a square. DEFIBRILLATION–PROOF APPLIED PARTS shall be marked with the relevant symbols (see appendix D, table DII, symbols 9, 10 and 11). If the EQUIPMENT has more than one APPLIED PART with different degrees of protection, the relevant symbols shall be clearly marked on such APPLIED PARTS, or on or near relevant outlets (connection points). – If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, the symbol 14 in appendix D, table DI, shall be marked near the relevant outlet.		
	m) Mode of operation If no marking is provided, EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION.		
	n) Fuses The type and rating of fuses accessible from the outside of EQUIPMENT shall be marked adjacent to the fuse-holder.		
	p) Output – RATED output voltage and current or power (where applicable). – Output frequency (where applicable).		

Clause	Description	Result	Verdict
6.1	q) Physiological effects (symbols and warning statements) EQUIPMENT producing physiological effects which may cause danger to the PATIENT and/or OPERATOR shall bear a suitable symbol concerning the relevant hazard. The symbol shall appear in a prominent location so that it will be clearly visible after the EQUIPMENT has been installed. If applicable, symbols for particular hazards, as adopted in ISO or IEC Publication 417, shall be used. For non-ionizing radiation (for example, high-power microwaves), symbols 8 of table DII of appendix D shall be used. For other hazards, where no specific symbol is available, symbol 14 of table DI of Appendix D shall be used.		
	r) CATEGORY AP/APG EQUIPMENT For requirements on marking, see clause 38.		
	s) HIGH VOLTAGE TERMINAL DEVICES HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a tool shall be marked with the symbol "dangerous voltage" (see appendix D, table DII, symbol 6).		
	t) Cooling conditions Requirements for cooling provisions for EQUIPMENT (for example, supply of water or air) shall be marked.		
	u) Mechanical stability For requirements on EQUIPMENT with a limited stability, see clause 24.		
	v) Protective packing If special measures have to be taken during transport or storage, the packing shall be marked accordingly (see subclause 6.8.3d) and 10.1 and ISO Publication R780). Where premature unpacking of EQUIPMENT or EQUIPMENT parts may result in a SAFETY HAZARD, the packing shall be appropriately marked. The packaging of EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile.		
	w) Not used.		
	x) Not used.		

Clause	Description	Result	Verdict
	y) Earth terminals – A terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR shall be marked with symbol 9 of table DI of appendix D (see subclause 18e) – A FUNCTIONAL EARTH TERMINAL shall be marked with symbol 7 of table DI of appendix D.		
	z) Removable protection means If EQUIPMENT has alternative applications which require the removal of a protective means to utilize a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided (see also subclause 6.8). Markings shall be clearly legible after all the tests of this standard have been performed (see appendix C, Item C36). Adhesive labels shall not have worked loose or become curled at the edges.		
6.2	Marking on the inside of EQUIPMENT or EQUIPMENT parts a) Marking on the inside of EQUIPMENT or EQUIPMENT parts shall be "clearly legible" as defined in subclause 6.1. Concerning permanent affixation, it shall not be subjected to the rubbing test of subclause 6.1).		
	b) The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be clearly and indelibly marked near the heater or in the heater itself.		
	c) The presence of HIGH VOLTAGE parts shall be marked with the symbol "dangerous voltage" (see appendix D, table DII, symbol 6).		
	d) The type of battery and the mode of insertion (if applicable) shall be marked (see subclause 56.7b).		
	e) Fuses accessible only with the aid of a TOOL shall be identified either by type and rating next to the fuse, or by at least a reference, for example, the diagram number which can be associated with the technical description in which the type and rating shall be stated.		
	f) PROTECTIVE EARTH TERMINALS shall be marked with the prescribed symbol (see appendix D, table DI, symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an appliance inlet according to IEC Publication 320.		
	g) FUNCTIONAL EARTH TERMINALS shall be marked with the prescribed symbol (see appendix D, table IDI, symbol 7).		

Clause	Description	Result	Verdict
	h) Terminals which are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED EQUIPMENT shall be marked with the prescribed symbol (see appendix D, table DI, symbol 8).		
	j) Markings required in subclauses 6.2f), h), k) and l) on or near electrical connection points shall not be affixed to parts which have to be removed to make the connection. They shall remain visible after the connection has been made. Markings on or near terminals shall comply with IEC Publication 445.		
	k) The correct method of connection of the supply conductors shall be marked clearly with terminal marking which should be affixed adjacent to the terminals, unless no SAFETY HAZARD can develop if connections are interchanged. If EQUIPMENT is so small than the terminal marking cannot be affixed, it may be included in the ACCOMPANYING DOCUMENTS. If marking for connection to a three-phase supply is necessary, it shall be according to IEC Publication 445.		
	l) If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for permanently connected EQUIPMENT (including such conductors themselves), attains a temperature of more than 75 °C during the normal temperature test, EQUIPMENT shall be marked with an appropriate statement. This statement shall be located at or near the point where the supply connections are to be made and shall be clearly discernable after the connections have been made.		
	m) Not used.		
	n) Capacitors and/or the connected circuit parts shall be marked as required in subclause 15c).		
6.3	Marking of controls and instruments a) A mains switch shall be clearly identified. "ON" and "OFF" positions shall be marked according to the relevant symbols of appendix D (symbols 15 and 16 of table DI), or indicated by an adjacent indicator light or other unambiguous means.		
	b) Different positions of control devices and different positions of switches on EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by means of symbols 17 and 118 of table DI.		

Clause	Description	Result	Verdict
	c) If in NORMAL USE the change of setting of a control could cause a SAFETY HAZARD to the PATIENT, such controls shall be provided with either: – an associated indicating device, e.g. instruments or scale, or – an indication of the direction in which the magnitude of the function changes. See also subclause 56.10c).		
	d) Not used.		-
	e) Not used		-
	f) The functions of OPERATOR controls and indicators shall be identified.		
	g) Numeric indications of parameters shall be in SI units according to ISO 1000 with the specified additions.		
6.4	Symbols a) Symbols used for marking according to subclauses 6.1 to 6.3 shall conform to appendix D, where applicable. See also subclause 6.1q).		
	b) Symbols used for controls and performance shall conform to IEC Publication 878, where applicable.		
6.5	Colours of the insulation of conductors a) A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.		
	b) Any insulation on conductors inside equipment which connect ACCESSIBLE METAL PARTS or other PROTECTIVELY EARTHED parts with a protective function to the PROTECTIVE EARTH TERMINAL shall be identified by the colours green and yellow at least at the termination of the conductors.		
	c) Identification by green and yellow insulation shall only be used for: – PROTECTIVE EARTH CONDUCTORS (see subclause 18b)); – Conductors as specified in subclause 6.5b)); – POTENTIAL EQUALIZATION CONDUCTORS (see subclause 18e)); – Functional earth conductors as specified in subclause 18l).		
	d) Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured "light blue" as specified in IEC Publication 227 (Amendment No. 1) or in IEC Publication 245.		

Clause	Description	Result	Verdict
	e) Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC Publication 227 (Amendment No. 1) or with IEC Publication 245.	no power supply cord	
	f) Where a multi-conductor cord is used between EQUIPMENT parts and the maximum allowed resistance of the protective earth connection would be exceeded if only the green and yellow coloured conductor were used, other conductor of the same cord may be connected in parallel with the green and yellow conductor, provided that the ends of such additional conductors are marked green and yellow.		
6.6	Identification of medical gas cylinders and connections a) Identification of the content of gas cylinders used in medical practice as a part of electrical EQUIPMENT shall be in accordance with ISO Recommendation ISO/R 32. See also subclause 56.3a).		
	b) The point of connection of gas cylinder shall be so identified on EQUIPMENT that errors are avoided when a replacement is made.		
6.7	Indicator lights and push-buttons a) Colours of indicator lights On EQUIPMENT the colour red shall be used exclusively to indicate a warning of danger and/or a need for urgent action.		
	b) Colours of unilluminated push-buttons The colour red shall be used only for the push-button by which a function is interrupted in case of emergency.		
	c) Not used.		
	d) Not used.		
6.8	ACCOMPANYING DOCUMENTS		

Clause	Description	Result	Verdict
6.8.1	General EQUIPMENT shall be accompanied by documents containing at least instructions for use, a technical description and an address to which the USER can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a component part of EQUIPMENT. All applicable classifications specified in clause 5 shall be included in both the instructions for use and the technical description, if separable. All markings specified in subclause 6.1 shall be included in full in the ACCOMPANYING DOCUMENTS if they have not been permanently affixed to EQUIPMENT by the manufacturer. See also subclause 6.1d). Warning statements and the explanation of warning symbols (marked on the EQUIPMENT) shall be provided in the ACCOMPANYING DOCUMENTS.		

Clause	Description	Result	Verdict
6.8.2	Instructions for use – shall state the function and intended application of the EQUIPMENT. – shall contain all information necessary to operate the EQUIPMENT in accordance with its specification. This shall include explanation of the function of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and ACCESSORIES, replacement of material which is consumed during operation. – shall provide the USER or OPERATOR with information regarding potential electromagnetic or other interference between the EQUIPMENT and other devices together with advice regarding avoidance of such interference. – shall include indications or recognized ACCESSORIES, detachable parts and materials, if the use of other parts or materials can degrade minimum safety. – shall instruct the USER or OPERATOR in sufficient detail concerning cleaning, preventive inspection and maintenance to be performed by him, including the frequency of such maintenance. Such instructions shall provide information for the safe performance of routine maintenance. Additionally, instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by other persons, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance. – The meaning of figures, symbols, warning statements and abbreviations on EQUIPMENT shall be explained in the instructions for use.		
	b) Responsibility of the manufacturer (Not used)		
	c) SIGNAL OUTPUT and SIGNAL INPUT PARTS If a SIGNAL OUTPUT or SIGNAL INPUT PART is intended only for connection to specified EQUIPMENT complying with the requirements of this standard, this shall be stated in the instructions for use (see subclauses 19.2b) and 19.2c)).		

Clause	Description	Result	Verdict
	d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT For EQUIPMENT parts which come into contact with the PATIENT during NORMAL USE, instructions for use shall contain details about cleaning or disinfection or sterilization methods that may be used (see also subclause 44.7) or, where necessary, identify suitable sterilization agents, and list the temperature, pressure, humidity and time limits which such EQUIPMENT parts can tolerate.		
	e) Mains operated EQUIPMENT with additional power source Instructions for use of mains operated EQUIPMENT containing an additional power source not automatically maintained in a fully usable condition shall contain a warning statement referring to the necessity for periodical checking or replacement of such an additional power source. If CLASS I EQUIPMENT is specified for operation connected to a SUPPLY MAINS and alternatively using an INTERNAL ELECTRICAL POWER SOURCE, instructions for use shall contain 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.		
	f) Removal of primary batteries Instructions for use of EQUIPMENT containing primary batteries shall contain a warning to remove these batteries if equipment is not likely to be used for some time, unless there is no risk of a SAFETY HAZARD arising.		
	g) Rechargeable batteries Instructions for use of EQUIPMENT containing rechargeable batteries shall contain instructions to ensure safe use and adequate maintenance.		
	h) EQUIPMENT with a specified power supply or battery charger Instructions for use shall identify power supplies or battery chargers necessary to ensure compliance with the requirements of this Standard.		

Clause	Description	Result	Verdict
	j) .Environmental protection Instructions for use shall: – identify any risks associated with the disposal of waste products, residues, etc. and of the EQUIPMENT and ACCESSORIES at the end of their useful lives; – provide advice on minimizing these risks.		
6.8.3	Technical description a) The technical description shall provide all data, which is essential for safe operation. This shall include: – data mentioned in subclause 6.1. – all characteristics of the EQUIPMENT, including range(s) accuracy, and precision of the displayed values or an indication where they can be found. In addition to details required to be included in instructions for use, the technical description shall state whether particular measures or particular conditions are to be observed for installing EQUIPMENT and bringing EQUIPMENT into use.		
	b) Replacement of fuses and other parts – If the type and rating of fuses utilized in the mains supply circuit external to PERMANENTLY INSTALLED EQUIPMENT is not apparent from the information concerning RATED current and mode of operation of EQUIPMENT, the required type and rating of fuses shall be indicated in at least the technical description. – The technical description shall contain instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during the NORMAL USE.		
	c) Circuit diagrams, component part lists, etc. The technical description shall contain a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the USER's appropriately qualified technical personnel to repair those parts of EQUIPMENT which are designated by the manufacturer as repairable.		
	d) Environmental conditions for transport and storage The technical description shall contain a specification of the permissible environmental conditions for transport and storage which shall be repeated on the outside of the packaging of the EQUIPMENT (see subclause 6.1v)).		

Clause	Description	Result	Verdict
6.8.4	Not used.		-
6.8.5	Not used.		-
7.	**Power input**		
7.1	The steady state current or power input of EQUIPMENT at RATED voltage steady state operating temperature, and at operational settings specified by the manufacturer shall not exceed the marked rating as required by subclause 6.1j) by more than: a) for EQUIPMENT with a power input mainly caused by electric motor drive(s): + 25 % for a RATED input power up to and including 100 W or 100 VA; + 15 % for a RATED input power over 100 W or 100 VA.		
	b) for other EQUIPMENT: + 15 % for a RATED input power up to and including 100 W or 100 VA; + 10 % for a RATED input power over 100 W or 100 VA.		
7.2	Not used.		-
	SECTION TWO – ENVIRONMENTAL CONDITIONS		
8.	**Basic safety categories** (Transferred to Appendix 1.1)		-
9.	**Removable protective means** (Not used. Replaced by subclause 6.1z))		-
10.	**Environmental conditions**		
10.1	Transport and storage EQUIPMENT shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer (see 6.3.8d))		
10.2	Operation EQUIPMENT shall comply with all the requirements of this standard when operated in NORMAL USE under the least favourable combination of the following conditions:		
10.2.1	Environment (see also 4.5) a) An ambient temperature range of +10 °C to +40 °C. b) A relative humidity range of 30 % to 75 %. c) An atmospheric pressure range of 700 hPa to 1 060 hPa. d) A temperature of the water at the inlet of water-cooled EQUIPMENT not higher than 25 °C.		

Clause	Description	Result	Verdict
10.2.2	Power supply a) EQUIPMENT shall be suitable for a power supply having: – a RATED voltage not exceeding: • 250 V for HAND-HELD EQUIPMENT; • 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for EQUIPMENT with a RATED apparent power input of up to 4 kVA; • 500 V for all other EQUIPMENT; – a sufficiently low internal impedance (as may be required by a particular standard); – voltage fluctuation not exceeding ± 10 % of the NOMINAL voltage except momentary fluctuations exceeding – 10 % and of a duration of less than 1 s, for example those occurring at irregular intervals caused by operation of X-ray generators or similar EQUIPMENT; – no voltage in excess of the NOMINAL value + 10 % between any of the conductors of the system or between any of these conductors and earth; – voltages which are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply; – a frequency of not more than 1 kHz; – a frequency which deviates not more than 1 Hz from the NOMINAL value up to 100 Hz and not more than 1 % from the NOMINAL value from 100 Hz to 1 kHz; – the protective measures as described in IEC Publication 364.		
	b) An INTERNAL ELECTRICAL POWER SOURCE, if replaceable, shall be specified by the manufacturer.		
11.	Not used.		-
12.	Not used.		-
	SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS		
13.	General		
	EQUIPMENT shall be so designed that the risk of electric shock in NORMAL USE and in SINGLE FAULT CONDITION is obviated as far as practicable.		

Clause	Description	Result	Verdict
14.	**Requirements related to classification**		
14.1	CLASS I EQUIPMENT a) CLASS I EQUIPMENT may have parts with DOUBLE INSULATION or REINFORCED INSULATION or parts operating at SAFETY EXTRA-LOW VOLTAGE or ACCESSIBLE PARTS protected by protective impedance in cases where conductive parts of an electrical circuit have to be accessible to enable EQUIPMENT to function. b) If the isolation of the MAINS PART from ACCESSIBLE METAL PARTS of EQUIPMENT specified for an external d.c. power source is accomplished by BASIC INSULATION only, a separate PROTECTIVE EARTH CONDUCTOR shall be provided.		
14.2	CLASS II EQUIPMENT a) CLASS II EQUIPMENT shall be one of the following types: 1) insulation-enclosed CLASS II EQUIPMENT 2) metal-enclosed CLASS II EQUIPMENT; 3) EQUIPMENT which is a combination of types 1) and 2) above.		
	b) If EQUIPMENT is fitted with a device for changing over from CLASS I to CLASS II protection, all of the following requirements shall be fulfilled: – the change-over device shall clearly indicate the selected class; – for change-over the use of a TOOL shall be necessary; – the EQUIPMENT shall comply with the whole range of requirements for the class selected at any given time; – in the CLASS II position the device shall interrupt the connection of the PROTECTIVE EARTH CONDUCTOR to EQUIPMENT or change it into a FUNCTIONAL EARTH CONDUCTOR, complying with the requirements of class 18.		
	c) CLASS II EQUIPMENT may be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also Sub-clauses 18 k) and l).		
14.3	Not used.		-

Clause	Description	Result	Verdict
14.4	CLASS I and CLASS II EQUIPMENT a) In addition to BASIC INSULATION, EQUIPMENT shall be provided with an additional protection according to the requirements of CLASS I or CLASS II EQUIPMENT (see figures 2 and 3):		
	b) In EQUIPMENT specified for power supply from an external d.c. power source (for example, for use in ambulances), no SAFETY HAZARD shall develop when a connection with the wrong polarity is made.		
14.5	INTERNALLY POWERED EQUIPMENT a) Not used.		-
	b) INTERNALLY POWERED EQUIPMENT having a means for connection to a SUPPLY MAINS shall comply with the requirements for class I or class II equipment while so connected, and with the requirements for INTERNALLY POWERED EQUIPMENT while not so connected.		
14.6	TYPES B, BF and CF EQUIPMENT a) Not used.		-
	b) Not used.		-
	c) APPLIED PARTS which are specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATIONS shall be TYPE CF.		
14.7	Not used.		-
15.	Limitation of voltage and/or energy		
	a) Not used.		-
	b) EQUIPMENT intended to be connected to the SUPPLY MAINS by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the supply pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V.		
	c) LIVE parts of capacitors or circuit parts connected to them, which become accessible after EQUIPMENT has been de-energized and ACCESS COVERS as present in NORMAL USE have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V, or, if this value is exceeded, shall not have a residual energy exceeding 2 mJ. If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device which is included and which permits manual discharging is acceptable. The capacitor(s) and/or the connected circuitry shall then be marked.		

Clause	Description	Result	Verdict
16.	ENCLOSURES and PROTECTIVE COVERS		
	a) EQUIPMENT shall be constructed and enclosed that there is adequate protection against contact with LIVE parts, and with parts which can become LIVE in SINGLE FAULT CONDITIONS.		
	b) Any opening in a top cover of an ENCLOSURE shall be so positioned or dimensioned that accessibility of LIVE parts by means of a freely and vertically suspended test rod with a diameter of 4 mm and a length of 100 mm, penetrating up to its length, is prevented.		
	c) Conductive parts of actuating mechanisms of electrical controls which are accessible after the removal of handles, knobs, levers and the like shall either: – have a resistance of not more than 0,2 Ω to the PROTECTIVE EARTH TERMINAL of the EQUIPMENT which measured with a test voltage of not more than 50 V a.c. open circuit and a test current not less than 1 A, or – shall be separated from LIVE parts by one of the means described in subclause 17g).		
	d) Parts within the ENCLOSURE of EQUIPMENT with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by an external mains switch or a plug device that is accessible at all times (for example, in circuits for room lighting, remote control of the main switch etc.) shall be protected against contact even after opening of the ENCLOSURE (for example, for the purpose of maintenance) by additional coverings or, in the case of a spatially separated arrangement, shall be marked clearly as "LIVE".		
	e) ENCLOSURES protecting against contact with LIVE parts shall be removable only with the aid of a TOOL or, alternatively, an automatic device shall make these parts not LIVE, when the ENCLOSURE is opened or removed.		
	f) Openings for the adjustment of preset controls which may be adjusted by the USER in NORMAL USE by using a TOOL shall be so designed that the TOOL used for adjustment is not able to touch inside the opening BASIC INSULATION or any LIVE parts or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.		
	g) Not used.		-
17.	Separation		

Clause	Description	Result	Verdict
	a) APPLIED PARTS shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see subclause 3.6), in such a way that allowable LEAKAGE CURRENTS (see Clause 19) are not exceeded.		I
	b) Not used.		-
	c) An APPLIED PART shall have no CONDUCTIVE CONNECTION to ACCESSIBLE METAL PARTS which are not PROTECTIVELY EARTHED.		
	d) Hand-held flexible shafts of CLASS I EQUIPMENT shall be isolated from the motor shaft by SUPPLEMENTARY INSULATION. ACCESSIBLE METAL PARTS driven by an electric motor of CLASS I protection and which during NORMAL USE are likely to come into direct contact with an OPERATOR or PATIENT, and which cannot be PROTECTIVELY EARTHED, shall be isolated from the motor shaft by at least SUPPLEMENTARY INSULATION capable of withstanding the dielectric strength test appropriate to the RATED voltage of the motor and having adequate mechanical strength.		
	e) Not used.		-
	f) Not used.		-
	g) ACCESSIBLE PARTS not being an APPLIED PART shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see subclause 3.6) in such a way that allowable LEAKAGE CURRENTS are not exceeded (see clause 19).		
	h) Arrangements used to isolate DEFIBRILLATION-PROOF APPLIED PARTS from other parts shall be designed that: - during a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION-PROOF APPLIED PART, hazardous electrical energies do not appear on: * the ENCLOSURE, including the outer surfaces of accessible leads and connectors, * any SIGNAL INPUT PART, * any SIGNAL OUTPUT PART, * metal foil for test on which the EQUIPMENT is placed and which has an area of at least equal to the base of the EQUIPMENT, - after exposure to the defibrillation voltage, the EQUIPMENT, after any necessary time of recovery stated in the ACCOMPANYING DOCUMENTS, shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.		I

Clause	Description	Result	Verdict
18.	**Protective earthing, functional earthing and potential equalization**		
	a) ACCESSIBLE PARTS of CLASS I EQUIPMENT separated from LIVE parts by BASIC INSULATION shall be connected by sufficiently low impedance to the PROTECTIVE EARTH TERMINAL. See also subclause 17g).		
	b) The PROTECTIVE EARTH TERMINAL shall be suitable for connection to the protective conductor in the installation either by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR. For constructional requirements for the earth connection see clause 58.		
	c) Not used.		-
	d) Not used.		-
	e) If EQUIPMENT is provided with a means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR this connection shall comply with the following requirements: – be readily accessible; – accidental disconnection is prevented in NORMAL USE; – the conductor can be detached without the use of a TOOL; – the POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR; – the connection means shall be marked with symbol 9, table DI.		
	f) For EQUIPMENT without a POWER SUPPLY CORD the impedance between the PROTECTIVE EARTH TERMINAL and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0,1 Ω. For EQUIPMENT with an APPLIANCE INLET the impedance between the protective earth contact in the APPLIANCE INLET and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0,1 Ω. For EQUIPMENT with a non-detachable POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0,2 Ω.		

Clause	Description	Result	Verdict
	g) The impedance of protective earth connections other than those described in subclause 18f) is allowed to exceed 0,1 Ω if the continuous fault current to an ACCESSIBLE PART in case of failure in BASIC INSULATION of such a part or of a component connected to such a part is limited to such an extent that the allowable value of the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION is not exceeded.		
	h) Not used.		-
	j) Not used.		-
	k) FUNCTIONAL EARTH TERMINALS shall not be used to provide protective earthing.		
	l) If CLASS II EQUIPMENT with isolated internal screens is supplied with a POWER SUPPLY CORD having three conductors, the third conductor (connected to the protective earth contact of the MAINS PLUG) shall be used only a functional earth for these screens and shall be coloured green and yellow. The insulation of such internal screens and all internal wiring connected to them shall be DOUBLE INSULATION or REINFORCED INSULATION. In such case the FUNCTIONAL EARTH TERMINAL of such EQUIPMENT shall be marked so as to distinguish it from a PROTECTIVE EARTH TERMINAL and additionally there shall be an explanation in the ACCOMPANYING DOCUMENTS.		
19.	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		
19.1	General requirements a) The electrical insulation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the specified values.		

Clause	Description	Result	Verdict
	b) The specified values of the continuous EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions: – Both at operating temperature and following the humidity preconditioning treatment, as described in subclause 4.10 and 19.4. – In NORMAL CONDITION and in the specified SINGLE FAULT CONDITIONS (see subclause 19.2). – With EQUIPMENT energized stand-by condition and fully operating and with any switch in the MAINS PART in any position. – With the highest RATED supply frequency. – With a supply equal to 110 % of the highest RATED MAINS VOLTAGE. The measured values shall not exceed the allowable values given in subclause 19.3.		
	c) EQUIPMENT specified for connection to a SELV source can only comply with the requirements of this standard if such a source complies with this standard and if the EQUIPMENT, tested in combination with such a source, complies with the requirements for allowable LEAKAGE CURRENTS. Such EQUIPMENT and INTERNALLY POWERED EQUIPMENT shall be investigated for ENCLOSURE LEAKAGE CURRENT but only as far as described in subclause 19.4g)3).		
	d) The measurement of the ENCLOSURE LEAKAGE CURRENT of CLASS I EQUIPMENT shall only be performed: – to earth from each part, if present, of the ENCLOSURE not PROTECTIVELY EARTHED; – between parts, if present, of the ENCLOSURE not PROTECTIVELY EARTHED.		

Clause	Description	Result	Verdict
	e) The PATIENT LEAKAGE CURRENT shall be measured (see appendix K): – in TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected together or with APPLIED PARTS loaded according to the manufacturer's instructions; – in TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function of the APPLIED PART connected together or with APPLIED PARTS loaded according to the manufacturer's instructions; – in TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn. If the manufacturer specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT cord and electrodes), the PATIENT LEAKAGE CURRENT measurements shall be made with the least favourable specified detachable part. If the manufacturer specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT cord and electrodes), the PATIENT LEAKAGE CURRENT measurements shall be made with the least favourable specified detachable part.		
	f) The PATIENT AUXILIARY CURRENT shall be measured between any single PATIENT connection and all other PATIENT connections connected together.		
	g) EQUIPMENT with multiple PATIENT CONNECTIONS shall be investigated to ensure that, under NORMAL CONDITIONS, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values while one or more PATIENT CONNECTIONS are: - disconnected from the PATIENT; and - disconnected from the PATIENT and earthed.		
19.2	SINGLE FAULT CONDITIONS a) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured under the following SINGLE FAULT CONDITIONS: – the interruption of each supply conductor one at a time; – the interruption of a PROTECTIVE EARTH CONDUCTOR (not applicable in the case of EARTH LEAKAGE CURRENT). Not to be investigated if a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR is specified; – see also subclause 17a) and 17g).		

Clause	Description	Result	Verdict
	b) Additionally the PATIENT LEAKAGE CURRENT shall be measured under the following SINGLE FAULT CONDITIONS: – a voltage equal to 110 % of the highest RATED MAINS VOLTAGE applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART. – a voltage equal to 110 % of the highest RATED MAINS VOLTAGE applied between any F-TYPE APPLIED PART and earth. – a voltage equal to 110 % of the highest RATED MAINS VOLTAGE applied between earth and any ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED.		
	c) Additionally, the ENCLOSURE LEAKAGE CURRENT shall be measured with a voltage equal to 110 % of the highest RATED MAINS VOLTAGE, applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART. This requirement is not applied where the SIGNAL INPUT PART(S) or SIGNAL OUTPUT PART(S) are designated by the manufacturer for connection to EQUIPMENT in situations where a risk of external voltage exists (see IEC 601-1-1)		
19.3	Allowable values a) The allowable values of the continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in table IV for d.c. and a.c. and composite waveforms. Unless stated otherwise values may be d.c. or r.m.s.		
	b) The allowable values stated in table IV apply to currents flowing through the network of figure 15 and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in figure 15). Additionally, regardless of waveform or frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION in SINGLE FAULT CONDITION.		
	c) Not used.		-
	d) Not used.		-
	e) Not used, but see Notes 3) and 4) of Table IV.		-
19.4	The tests are described in this subclause.		-
20.	Dielectric strength		
20.1	General requirements for all types of EQUIPMENT The dielectric strength shall be tested (see also appendix E):		-

Clause	Description	Result	Verdict
	A-a_1 Between LIVE parts and ACCESSIBLE METAL PARTS which are PROTECTIVELY EARTHED. This insulation shall be BASIC INSULATION.		
	A-a_2 Between LIVE parts and parts of the ENCLOSURE not PROTECTIVELY EARTHED. This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.		
	A-b Between LIVE parts and conductive parts isolated from the LIVE parts by BASIC INSULATION forming part of DOUBLE INSULATION. This insulation shall be BASIC INSULATION.		
	A-c Between the ENCLOSURE and conductive parts isolated from LIVE parts by BASIC INSULATION forming part of DOUBLE INSULATION. This insulation shall be SUPPLEMENTARY INSULATION.		
	A-d Not used.		-
	A-e Between LIVE parts not being parts of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS and SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS not PROTECTIVELY EARTHED.		
	A-f Between parts of opposite polarity of the MAINS PART. This insulation shall be equivalent to BASIC INSULATION. The electrical insulation of parts A-f shall be investigated only if, after inspection of insulation quantities and sizes, including CREEPAGE DISTANCES and AIR CLEARANCES according to subclause 57.10, no complete compliance can be established. If separation of circuits or protection of components, necessary for the investigation of parts A-f, is not possible without damage to EQUIPMENT, the manufacturer and the testing laboratory shall make an agreement as to any other method possible to fulfil the purpose of this investigation.		
	A-g Between a metal ENCLOSURE (or cover) lined internally with insulating material and a metal foil applied for testing purposes in contact with the interior surface of the lining. Such a lining may be applied where the distance, measured through the lining, between a LIVE PART and the ENCLOSURE (or cover) is less than the AIR CLEARANCE required according to subclause 57.10.		
	A-h Not used.		-

Clause	Description	Result	Verdict
	A-j Between ACCESSIBLE PARTS not PROTECTIVELY EARTHED and likely to become LIVE in the event of failure of the insulation of the POWER SUPPLY CORD, and either metal foil wrapped around the POWER SUPPLY CORD inside inlet bushings, cord guards, cord anchorages and the like, or a metal rod having the same diameter as the POWER SUPPLY CORD, inserted in its place. This insulation shall be SUPPLEMENTARY INSULATION.		
	A-k Between, in turn, a SIGNAL INPUT PART, a SIGNAL OUTPUT PART and ACCESSIBLE PARTS not PROTECTIVELY EARTHED. This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION. This insulation need not be investigated separately if at least one of the following conditions is satisfied: a) The voltages appearing on the SIGNAL INPUT PART or SIGNAL OUTPUT PART in NORMAL USE do not exceed SAFETY EXTRA LOW VOLTAGE. b) The LEAKAGE CURRENTS do not exceed the allowable values in SINGLE FAULT CONDITION in the event of any single component failure in the SIGNAL INPUT or SIGNAL OUTPUT PARTS. c) The parts in question are effectively separated by a PROTECTIVELY EARTHED shielding of by a PROTECTIVELY EARTHED intermediate circuit. d) The SIGNAL INPUT or SIGNAL OUTPUT PARTS are designated by the manufacturer for connection to EQUIPMENT in situations where no risk of external voltage exists (see IEC 601-1-1).		
20.2	Requirements for equipment with an APPLIED PART For EQUIPMENT with an APPLIED PART, the dielectric strength shall also be tested (see also appendix E):		
	B-a Between the APPLIED PART (PATIENT CIRCUIT) and LIVE parts. This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.		
	B-b Between parts of the APPLIED PART and/or between APPLIED PARTS. See particular standards.		

Clause	Description	Result	Verdict
	B-c Between the APPLIED PART and parts not PROTECTIVELY EARTHED which are isolated from LIVE parts by BASIC INSULATION only. This insulation shall be SUPPLEMENTARY INSULATION.		
	B-d Between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE including SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS. See also subclauses 20.3 and 20.4j). This insulation shall be BASIC INSULATION. See also B-e.		
	B-e Between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE where the F-TYPE APPLIED PART contains voltages stressing the insulation to the ENCLOSURE in NORMAL USE including earthing of any part of the APPLIED PART. This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.		
	B-f Not used.		-
20.3	Values of test voltages are specified in this subclause.		-
20.4	The tests are descibed in this subclause.		-
	SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS		
21.	**Mechanical strength**		
	General ENCLOSURES including any ACCESS COVERS forming part of them, with all components thereon, shall have sufficient strength and rigidity.		
21.1	Not used.		-
21.2	Not used.		-
21.3	EQUIPMENT parts serving for support and/or immobilization of PATIENTS shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental loosening of fixings. Supporting parts for adult human PATIENTS shall be designed for a PATIENT having a mass of 135 kg (normal load). Where breakdown of a PATIENT support constitutes a SAFETY HAZARD, the requirements of clause 28 shall apply.		
21.4	Not used.		-

Clause	Description	Result	Verdict
21.5	EQUIPMENT or EQUIPMENT parts which are hand held during NORMAL USE shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface.		
21.6	PORTABLE and MOBILE EQUIPMENT shall be capable of withstanding the stresses caused by rough handling.		
22.	Moving parts		
22.1	Not used.		-
22.2	Moving parts which do not need to be exposed for the operation of EQUIPMENT and which, if exposed, constitute a SAFETY HAZARD shall: a) in the case of TRANSPORTABLE EQUIPMENT, be provided with adequate guards which shall form an integral part of the EQUIPMENT, or		
	b) in the case of STATIONARY EQUIPMENT, be similarly guarded unless installation instructions provided by the manufacturer in the technical description require that such guarding or equivalent protection will be separately provided.		
22.3	Cord (ropes), chains and bands shall either be confined so that they cannot run off or jump out of their guiding devices, or a SAFETY HAZARD shall be prevented by other means. Mechanical means applied for this purpose shall be removable only with the aid of a tool.		
22.4	Movements of EQUIPMENT or EQUIPMENT parts which may cause physical injury to the PATIENT shall be possible only by the continuous activation of the control by the operator of these EQUIPMENT parts.		
22.5	Not used.		-
22.6	Parts subject to mechanical wear likely to result in a SAFETY HAZARD shall be accessible for inspection.		
22.5	Not used.		-
22.6	Part subject to mechanical wear likely to result in a SAFETY HAZARD shall be accessible for inspection.		

Clause	Description	Result	Verdict
22.7	– If an electrically produced mechanical movement could cause a SAFETY HAZARD, readily identifiable and accessible means shall be provided for emergency switching of the relevant part of EQUIPMENT. – Operation of an emergency switching or stopping means shall not introduce a further SAFETY HAZARD nor interfere with the complete operation necessary to remove the original SAFETY HAZARD. – Devices for emergency stopping shall be able to break the full load current of the relevant circuit, taking into account possible stalled motor currents and the like. – Means for stopping of movements shall operate as a result of one single action.		
23.	Surfaces, corners and edges		
	Rough surfaces, sharp corners and edges which may cause injury or damage shall be avoided or covered.		
24.	Stability in normal use		
24.1	EQUIPMENT shall either not overbalance during NORMAL USE when tilted through an angle of 10°, or shall satisfy the requirements of subclause 24.3.		
24.2	Not used.		-
24.3	If EQUIPMENT overbalances when tilted through an angle of 10°, all the following requirements shall be met: – EQUIPMENT shall not overbalance when tilted through an angle of 5° in any position of NORMAL USE, excluding transport. – EQUIPMENT shall carry a warning notice stating that transport should only be undertaken in a certain position which shall be clearly described in the instructions for use or illustrated on the EQUIPMENT. – In the position specified for transport, EQUIPMENT shall not overbalance when tilted to an angle of 10°.		
24.4	Not used.		-
24.5	Not used.		-

Clause	Description	Result	Verdict
24.6	Grips and other handling devices a) EQUIPMENT or EQUIPMENT parts with a mass of more than 20 kg and which need(s) to be handled in NORMAL USE shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where EQUIPMENT can be lifted safely or how it should be handled during assembly.		
	b) EQUIPMENT specified by the manufacturer as PORTABLE EQUIPMENT with a mass of more than 20 kg shall have (a) carrying-handle(s) suitably placed which enable(s) the EQUIPMENT to be carried by two or more persons.		
25.	Expelled parts		
25.1	Where expelled parts could constitute a SAFETY HAZARD protective means shall be provided.		
25.2	A graphical display vacuum tube whose maximum face dimension exceeds 16 cm shall either be intrinsically safe with respect to effects of implosion and to mechanical impact, or the ENCLOSURE of the EQUIPMENT shall provide adequate protection against the effects of an implosion of the tube. A non-intrinsically safe tube shall be provided with an effective protective screen which cannot be removed without the use of a TOOL; if a separate screen of glass is used, it shall not be in direct contact with the surface of the tube. The tube shall be tested as specified in IEC Publication 65, unless a certificate of the testing is provided.		
26.	Vibration and noise (No general requirement)		
27.	Pneumatic and hydraulic power (No general requirement)		
28.	Suspended masses		
28.1	General Any moving part shall also comply with the requirements of clause 22.		
28.2	Not used.		-

Clause	Description	Result	Verdict
28.3	Suspension system with SAFETY DEVICES – Where the integrity of a suspension depends on parts, such as springs, which may, due to their manufacturing process, have hidden defects, or on parts having SAFETY FACTORS not complying with subclause 28.4, a SAFETY DEVICE shall be provided, unless excess travel in the event of breakdown is limited. – The SAFETY DEVICE shall have SAFETY FACTORS complying with subclause 28.4.2. – If EQUIPMENT can still be used after failure of suspension means and activation of a SAFETY DEVICE (for example a secondary rope), it shall become obvious to the OPERATOR that the SAFETY DEVICE has been activated.		
28.4	Suspension systems of metal without SAFETY DEVICES If a SAFETY DEVICE is not provided, the construction of the suspension shall comply with the following requirements: 1) The TOTAL LOAD shall not exceed the SAFE WORKING LOAD. 2) Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or aging, the SAFETY FACTOR of all supporting parts shall not be less than 4. 3) Where impairment by wear, corrosion, material fatigue or aging is expected, relevant supporting parts shall have a SAFETY FACTOR not less than 8. 4) Where metal having a specific elongation at break of less than 5 % is used in supporting components, the SAFETY FACTORS, as given in 2) and 3) above shall be multiplied by 1.5. 5) Sheaves, sprockets, bandwheels and guides shall be so designed and constructed that the SAFETY FACTORS of this subclause of the suspension system shall be maintained for a specified minimum life till replacement of the ropes, chains and bands.		
28.5	Dynamic Loads (No general requirement)		-
28.6	Not used		-
	SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION		

Clause	Description	Result	Verdict
	General Adequate provisions shall be made to protect the PATIENT, OPERATOR and other persons and sensitive devices in the vicinity of the EQUIPMENT from unwanted or excessive radiation from the EQUIPMENT.		
29.	**X-Radiation**		
29.1	– For diagnostic X-ray EQUIPMENT – See IEC 601-1-3 (see appendix L); – For radiotherapy EQUIPMENT – No general requirement, see relevant particular standard.		
29.2	For EQUIPMENT not intended to produce X-radiation for diagnostic and therapeutic purposes, ionizing radiation emitted by vacuum tubes excited by voltages exceeding 5 kV shall not produce an exposure exceeding 130 nC/kg (0,5 mR) in 1 h at a distance of 5 cm from any accessible surface of the EQUIPMENT.		
30.	**Alpha, beta, gamma, neutron radiation and other particle radiation** (No general requirement)		
31.	**Microwave radiation** (No general requirement)		
32.	**Light radiation (including lasers)** (No general requirement)		
33.	**Infra-red radiation** (No general requirement)		
34.	**Ultraviolet radiation** (No general requirement)		
35.	**Acoustical energy (including ultra-sonics)** (No general requirement)		
36.	**Electromagnetic compatibility** (See IEC601-1-2 (see appendix L))		
	SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES		
37.	Locations and basic requirements		
37.1	Not used.		-
37.2	Not used.		-
37.3	Not used.		-
37.4	Not used.		-
37.5	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR A description is given.		-

Clause	Description	Result	Verdict
37.6	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE A description is given.		-
37.7	EQUIPMENT or parts thereof specified for use in a location defined in subclause 37.5 shall be CATEGORY AP or APG EQUIPMENT and shall comply with the requirements of Clauses 39 and 40.		
37.8	EQUIPMENT or parts thereof specified for use in a location defined in subclause 37.6 shall be CATEGORY APG EQUIPMENT and shall comply with the requirements of clauses 39 and 41. Parts of CATEGORY APG EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs shall be CATEGORY AP or APG EQUIPMENT and shall comply with the requirements of clauses 38, 39 and 40.		
38.	Marking, ACCOMPANYING DOCUMENTS		
38.1	Not used.		-
38.2	CATEGORY APG EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters "APG", permanently affixed and clearly legible (see appendix D and clause 6). The length of the green-coloured band shall be at least 4 cm. The sizes of the marking shall be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.		
38.3	Not used.		-
38.4	CATEGORY AP EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters "AP", permanently affixed and clearly legible (see appendix D and clause 6). The size of the marking shall be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.		
38.5	The marking according to subclauses 38.2 and 38.4 shall be present on the major part of the EQUIPMENT if this part is AP or APG.		
38.6	ACCOMPANYING DOCUMENTS shall contain an indication for the USER enabling him to distinguish the parts of EQUIPMENT (see subclause 38.7) that are categorized AP and APG.		

Clause	Description	Result	Verdict
38.7	On EQUIPMENT in which only certain equipment parts are CATEGORY AP or CATEGORY APG, the marking shall early indicate which parts are CATEGORY AP or CATEGORY APG.		
38.8	Not used.		-
39.	**Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT**		
39.1	Electrical connections a) CREEPAGE DISTANCES and AIR CLEARANCES between the connection points of POWER SUPPLY CORDS shall be according to subclause 57.10, table XVI, values for SUPPLEMENTARY INSULATION.		
	b) Connections, except those in the circuits described in subclauses 40.3 and 41.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection and/or disconnection can be performed only with the use of a TOOL.		
	c) CATEGORY AP EQUIPMENT and CATEGORY APG EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of subclauses 40.3 or 41.3.		
39.2	Construction details a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.		
	b) To avoid the likelihood of arcing and sparking due to foreign objects penetrating the ENCLOSURE. – top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob; – openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented. – openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.		
	c) Where BASIC INSULATION of electrical conductors may contact a part containing a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or ignitable gases alone or oxygen, a short circuit of these conductors or a short circuit of one conductor to a conductive part containing the gas or mixture shall not result in loss of integrity of such a part or result in an inadmissible temperature or in a SAFETY HAZARD in such a part (see subclause 41.3a)).		

Clause	Description	Result	Verdict
39.3	Prevention of electrostatic charges a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG EQUIPMENT by a combination of appropriate measures such as: – the use of antistatic materials with a limited electrical resistance as specified in subclause 39.3b), and – provision of electrically conductive paths from EQUIPMENT or EQUIPMENT parts to a conductive floor or to the protective earth system or the potential equalization system or via wheels to an antistatic floors of the medically used room.		
	b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO Standard 2882.		
39.3	c) to j) Not used.		-
39.4	Corona Parts and components of EQUIPMENT operating at more than 2 000 V a.c. or more than 2 400 V d.c. which are not included in ENCLOSURES in compliance with subclauses 40.4 or 40.5 shall be so designed that corona cannot be produced.		
40.	Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof		
40.1	General EQUIPMENT, EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.		
40.2	Temperature limits A description of temperature limits is given.		-

Clause	Description	Result	Verdict
40.3	Low-energy circuits EQUIPMENT, EQUIPMENT parts or components which may produce sparks in normal use and NORMAL CONDITION of the EQUIPMENT (for example, switches, relays, plug connections which can be detached without the use of a TOOL, including connections inside EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of subclause 40.2 and additionally the voltage U_{max} and the current I_{max} which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} shall comply with the following: $U_{max} \leq U_{zR}$ with a given current I_z, see Figure 29, and $U_{max} \leq U_{zC}$ with a given capacitance C_{max}, see Figure 30, and $I_{max} \leq U_{zR}$ with a given voltage U_{zR}, see Figure 29, and $I_{max} \leq U_{zR}$ with a given inductance L_{max} and a $U_{max} \leq 24$ V, see Figure 31.		
40.4	External ventilation with internal overpressure Where EQUIPMENT, EQUIPMENT parts or components are enclosed in an enclosure with external ventilation by means of internal overpressure the following requirements shall apply: a) FLAMMABLE ANAESTHETIC MIXTURES WITH AIR which might have penetrated into the enclosure of EQUIPMENT or of an EQUIPMENT part shall be removed by ventilation before the EQUIPMENT or EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the EQUIPMENT or the EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen).		
	b) The overpressure inside the enclosure shall be at least 0,75 hPa in NORMAL CONDITION. The overpressure shall be maintained at the site of potential ignition even if the air or inert gas can escape through openings in the enclosure which are necessary for the NORMAL OPERATION of EQUIPMENT or of EQUIPMENT parts. Energizing EQUIPMENT shall only be possible after the required minimum overpressure has been present for a time sufficient to ventilate the relevant enclosure so that the displaced column of air or of inert gas is as least five times the volume of the enclosure.		
	c) If the overpressure drops below 0,5 hPa during operation, ignition sources shall be de-energized automatically by means which either shall be located in a place where the requirements and tests of clause 40 do not apply, or comply with the requirements of clause 40.		

Clause	Description	Result	Verdict
	d) The external surface of the enclosure in which the internal overpressure is maintained shall not attain in NORMAL CONDITION and NORMAL USE an operating temperature exceeding 150 °C, measured in an ambient temperature of 25 °C.		
40.5	Enclosures with restricted breathing Where EQUIPMENT, EQUIPMENT parts or components are enclosed in an enclosure with restricted breathing the following requirements shall apply: a) Enclosures with restricted breathing shall be so designed that the formation of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR inside the enclosure does not occur whilst the enclosure is surrounded by a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of a high concentration for a period of at least 30 min but without any pressure difference to the space inside the enclosure.		
	b) If the required tightness is obtained by gaskets and/or wealing, the material used shall therefore be resistant to aging.		
	c) If the enclosure contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending and/or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see subclause 57.4a)).		
41.	**Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof**		
41.1	General EQUIPMENT, EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH OXYGEN OR NITROUS OXIDE.		
41.2	Power supply Parts of components of CATEGORY APG EQUIPMENT which operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source which is isolated from earth by at least BASIC INSULATION and from LIVE parts by DOUBLE or REINFORCED INSULATION.		
41.3	Temperatures and low-energy circuits A description of acceptable cases with data is given.		

Clause	Description	Result	Verdict
41.4	Heating elements EQUIPMENT, EQUIPMENT parts and components which heat a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be provided with a non-SELF-SETTING THERMAL CUT-OUT, as an additional protection against overheating. The current-carrying part of the heating element shall not be in direct contact with the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.		
	SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS		
42.	Excessive temperatures		
42.1	EQUIPMENT parts having a safety function and their environment shall not attain temperatures exceeding the values given in table Xa during NORMAL USE and NORMAL CONDITION however the range of ambient temperatures specified in subclause 10.2.1.		
42.2	EQUIPMENT parts and their environment shall not attain temperatures exceeding the values as given in table Xb when the EQUIPMENT is operated during NORMAL USE and under NORMAL CONDITIONS at an ambient temperature 25 °C.		
42.3	APPLIED PARTS of EQUIPMENT not intended to supply heat to a PATIENT shall not have surface temperatures exceeding 41 °C.		
42.4	Not used.		
42.5	Guards Guards intended to prevent contact with hot accessible surfaces shall be removable only with the aid of a TOOL.		
43.	Fire prevention		
43.1	Strength and rigidity EQUIPMENT shall have the strength and rigidity necessary to avoid a fire hazard which may occur as a result of a total or partial collapse caused by the abuses to which it is liable to be subjected in NORMAL USE.		
43.2	Oxygen enriched atmospheres (No general requirement)		-
44.	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility		

Clause	Description	Result	Verdict
44.1	General The construction of EQUIPMENT shall ensure a sufficient degree of protection against SAFETY HAZARDS caused by overflow, spillage leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection.		
44.2	Overflow If EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet electrical safety insulation which is liable to be adversely affected by such a liquid, nor shall a SAFETY HAZARD be created. Unless restricted by a marking or by the instructions for use, no SAFETY HAZARDS shall develop if TRANSPORTABLE EQUIPMENT is tilted through an angle of 15°.		
44.3	Spillage EQUIPMENT requiring the use of liquids in NORMAL USE shall be so constructed that spillage does not wet parts which may cause a SAFETY HAZARD.		
44.4	Leakage EQUIPMENT shall be so constructed that liquid which might escape in a SINGLE FAULT CONDITION does not cause a SAFETY HAZARD (see also subclause 52.4.1.).		I
44.5	Humidity EQUIPMENT, including any detachable parts, shall be sufficiently proofed against the effects of humidity to which it is liable to be subjected in NORMAL USE.		
44.6	Ingress of liquids ENCLOSURES designed to give a specified degree of protection against harmful ingress of water shall provide this protection in accordance with the classification of IEC publication 529.		
44.7	Cleaning, sterilization and disinfection EQUIPMENT or EQUIPMENT parts, including APPLIED PARTS and parts into which PATIENTS may exhale, shall be capable of withstanding without damage or deterioration of safety provisions the cleaning, sterilization or disinfection processes which are likely to be encountered in NORMAL USE or which are specified by the manufacturer in the instructions for use.		
44.8	Compatibility with substances used with the EQUIPMENT (No general requirement)		-
45.	Pressure vessels and parts subject to pressure		

Clause	Description	Result	Verdict
45.1	Not used.		-
45.2	If pressure vessel has a pressure greater than 200 kP x ℓ, and PRESSURE greater than 50 kPa, it shall withstand the HYDRAULIC TEST PRESSURE.		
45.3	The maximum PRESSURE to which a part can be subjected NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part.		
45.4	Not used.		-
45.5	Not used.		-
45.6	Not used.		-
45.7	EQUIPMENT shall incorporate pressure-relief device(s) where excessive pressure could otherwise occur. A pressure-relief device shall comply with all of the following requirements: a) it shall be connected as close as possible to the pressure vessel or parts of the system that it is intended to protect; b) it shall be so installed that it is readily accessible for inspection, maintenance and repair; c) it shall not be capable of being adjusted or rendered inoperative without the use of a tool; d) it shall have its discharge opening so located and directed that the released material is not directed towards any person; e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts which may cause a SAFETY HAZARD; f) if shall be of adequate discharge capacity to ensure that the PRESSURE will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply PRESSURE; g) there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protected; h) the minimum number of cycles of operation shall be 100 000, except for bursting disks.		
45.8	Not used.		-
45.9	Not used.		-
45.10	Not used.		-

Clause	Description	Result	Verdict
46.	**Human errors** (Not used)		
47.	**Electrostatic charges** (Not used)		
48	**Biocompatibility**		
	Parts of EQUIPMENT and ACCESSORIES intended to come into contact with biological tissues, cells or body fluids, shall be assessed and documented according to the guidance and principles given in ISO 10993-1.		
49.	**Interruption of the power supply**		
49.1	THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used if they may cause a SAFETY HAZARD by such resetting.		
49.2	EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a SAFETY HAZARD other than interruption of its intended function.		
49.3	Means shall be provided to allow the mechanical constraints on a PATIENT to be removed in the event of failure of the SUPPLY MAINS.		
49.4	Not used.		-
	SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT		
50.	**Accuracy of operating data**		
50.1	Marking of controls and instruments (Not used)		-
50.2	Accuracy of controls and instruments (Not used)		-
51.	**Protection against hazardous output**		
51.1	No general requirement.		-
51.2	No general requirement.		-
51.3	Reliability of components (Not used)		-
51.4	Accidental selection of excessive output values Where EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, appropriate steps shall be taken to minimize the possibility of a high intensity output being selected accidentally e.g. interlocks in order to achieve deliberate action, separated output terminals.		
51.5	Incorrect output (No general requirement)		-
	SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS		

Clause	Description	Result	Verdict
52.	Abnormal operation and fault conditions		
52.1	EQUIPMENT shall be so designed and manufactured that even in SINGLE FAULT CONDITION no SAFETY HAZARD exists (see subclause 3.1 and clause 13). Additionally the safety of EQUIPMENT incorporating programmable electronic systems is checked by applying the rules of the future IEC Collateral Standard 601-1-4 (see appendix L).		
52.2	Not used.		-
52.3	Not used.		-
52.4	SAFETY HAZARDS as described in this subclause are to be considered during testing.		-
52.5	SINGLE FAULT CONDITIONS as described in this subclause are to be considered during testing.		-
53.	Environmental tests (See subclause 4.10 and clause 10)		
	SECTION TEN – CONSTRUCTIONAL REQUIREMENT		
54.	General		
	The following requirements in section ten specify details of the electrical and mechanical construction insofar as the safety of EQUIPMENT is concerned.		-
54.1	Arrangements of functions (Not used)		-
54.2	Serviceability (Not used)		-
54.3	Inadvertent changing of settings (Not used)		-
55.	ENCLOSURES and covers (Not used)		
55.1	Materials (Not used)		-
55.2	Mechanical strength (Not used)		-
55.3	Access covers (Not used)		-
55.4	Grips and other handling devices (Not used)		-
56.	Components and general assembly		
56.1	General a) Not used.		-

Clause	Description	Result	Verdict
	b) Marking of components Ratings of components shall not conflict with the conditions of use in EQUIPMENT. All components in the MAINS PART and in the APPLIED PART shall be marked or otherwise identified so that their ratings can be ascertained.		
	c) Sorting of components (Not used)		-
	d) Component fixing Components, the unwanted movement of which could result in a SAFETY HAZARD, shall be mounted securely to prevent such movement.		
	e) Resistance of components to vibration (Not used)		-
	f) Fixing of wiring Conductors and connectors shall be so secured and/or insulated that accidental detachment shall not result in a SAFETY HAZARD.		
56.2	Screws and nuts (Not used)		-
56.3	Connections – General a) Construction of connectors Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where a SAFETY HAZARD may be caused. – Connectors shall comply with subclause 17g). – Plugs for connection of PATIENT CIRCUIT leads shall be so designed that they cannot be connected to other outlets on the same EQUIPMENT intended for other functions, unless it can be proven that no SAFETY HAZARD can result. – Medical gas connections on EQUIPMENT for different gases to be operated in normal use shall not be interchangeable.		
	b) Connections between different parts of EQUIPMENT Detachable flexible cords used for interconnection of different parts of EQUIPMENT shall be provided with means for connection such that ACCESSIBLE METAL PARTS cannot become LIVE when a connection is loosened or broken due to the disengagement of one of the connecting means.		

Clause	Description	Result	Verdict
	c) Any conductor in a lead having a CONDUCTIVE CONNECTION to a PATIENT shall be constructed in such a manner that no CONDUCTIVE CONNECTION of that part of the said connector which is remote from the PATIENT can contact earth or possibly hazardous voltages.		NA
56.4	Connections of capacitors		
	– Capacitors shall not be connected between LIVE parts and non-PROTECTIVELY EARTHED ACCESSIBLE PARTS where the failure of such a capacitor could result in ACCESSIBLE PARTS becoming LIVE.	YES	C
	– Capacitors connected directly between the MAINS PART and PROTECTIVELY EARTHED ACCESSIBLE METAL PARTS shall comply with the requirements of IEC Publication 384-14 or equivalent.	no connection to mains	NA
	– The enclosure of capacitors connected to the MAINS PART and providing only BASIC INSULATION shall not be secured directly to non-PROTECTIVELY EARTHED ACCESSIBLE METAL PARTS.		NA
	– Capacitors or other spark-suppression devices shall not be connected between the contacts of THERMAL CUT-OUTS.	no thermal cut-outs	NA
56.5	Protective devices EQUIPMENT shall not be fitted with protective devices which causes disconnection of the EQUIPMENT from the SUPPLY MAINS by producing a short-circuit which results in operation of an over current protection device.	not for connection to mains	NA

Clause	Description	Result	Verdict
56.6	Temperature and overload control devices a) Application – THERMAL CUT-OUTS with a safety function which have to be reset by a soldering operation which may affect the operating value shall not be fitted in EQUIPMENT. – Thermal safety devices shall be provided where necessary to prevent operating temperatures exceeding the limits specified in section nine and in subclause 57.9. – Where a failure of a THERMOSTAT could constitute a SAFETY HAZARD an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device but shall be within the safety temperature limit for it intended function. – Where the consequent loss of function of EQUIPMENT caused by operation of a THERMAL CUT-OUT presents a SAFETY HAZARD, an audible warning shall be given.		
	b) Temperature settings – Where means are provided for varying the temperature setting of THERMOSTATS, the temperature settings shall be clearly indicated. – The operating temperature of THERMAL CUT-OUTS shall be clearly indicated.		
56.7	Batteries a) Housing Housings containing batteries from which gases can escape during charging or discharging shall be ventilated to minimize the risk of accumulation and ignition. Battery compartments shall be designed to prevent the risk of accidentally short-circuiting the battery where such short circuits could result in a SAFETY HAZARD.		
	b) Connection If a SAFETY HAZARD might develop by the incorrect connection or replacement of a battery, EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also subclause 6.2d).		
	c) Battery state (No general requirement)		-

Clause	Description	Result	Verdict
56.8	Indicators Unless indication is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided: – To indicate that EQUIPMENT is energized (see subclause 6.3a)). – On EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operative if a SAFETY HAZARD could result. – To indicate that an output exists where an inadvertent or prolonged operation of the output circuit could constitute a SAFETY HAZARD. In EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE the charging mode shall be visibly indicated to the OPERATOR.		
56.9	Pre-set controls (Not used)		-
56.10	Actuating parts of controls a) Protection against electric shock ACCESSIBLE PARTS of electrical controls shall comply with the requirements of subclause 16c).		
	b) Fixing, prevention of maladjustment – All actuating parts shall be so secured that they cannot be pulled off or work loose during NORMAL USE. – Controls, the adjustment of which can present a SAFETY HAZARD to the PATIENT or OPERATOR while EQUIPMENT is in use, shall be so secured that the indication of any scale always corresponds with the position of the control. – Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL		
	c) Limitation of movement Stops of adequate mechanical strength shall be 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.		

Clause	Description	Result	Verdict
56.11	Cord-connected hand-held and foot-operated control devices a) Limitation of operating voltages Hand-held and foot-operated control devices and associated connection cords shall contain only conductors and components operating at voltages not exceeding 25 V a.c. or 60 V d.c. or peak value in circuits isolated from the MAINS PART by one of the means specified in subclause 17g).		
	b) Mechanical strength – Hand-held control devices shall comply with the requirement and test of subclause 21.5. – Foot-operated control devices shall be able to support the weight of an adult human being.		
	c) Inadvertent operation Hand-held and foot-operated control devices shall not change their control setting when inadvertently placed in an abnormal position.		
	d) Entry of liquids – Foot-operated control devices shall be at least IP X1 according to IEC 529. – The electrical switching parts of foot-operated control devices of equipment, specified by the manufacturer for use in operating rooms, shall be IP X8 according to IEC 529.		
	e) Connection cords The connection and anchorage of a flexible cord to a hand-held or foot-operated control device at the entry point to the control device shall comply with the requirements specified for POWER SUPPLY CORDS in subclause 57.4.		
57.	MAINS PARTS, components and layout		

Clause	Description	Result	Verdict
57.1	Isolation from the SUPPLY MAINS a) Isolation – EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously. This isolation shall include each live supply conductor, except that PERMANENTLY INSTALLED EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device which does not interrupt the neutral conductor, but only if local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed extra-low voltage. – Means for isolation shall either be incorporated in EQUIPMENT or, if external, shall be specified in the ACCOMPANYING DOCUMENTS (see subclause 6.8.3).		
	b) Not used.		-
	c) Not used.		-
	d) Switches that are used to comply with subclause 57.1a) shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC Publication 328.		
	e) Not used.		-
	f) Mains switches shall not be incorporated in a POWER SUPPLY CORD or any other external flexible lead.		
	g) The directions of movement of the actuators of switches that are used to comply with subclause 57.1a) shall comply with IEC Publication 447.		
	h) In non-PERMANENTLY INSTALLED EQUIPMENT a suitable plug device used to isolate equipment from the SUPPLY MAINS shall be considered as complying with the requirements of subclause 57.1a).		
	j) Not used.		-
	k) Not used.		-
	l) Not used.		-
	m) Fuses and semiconductor devices shall not be used as isolating devices in the sense of this subclause.		
57.2	MAINS CONNECTORS, APPLIANCE INLETS and the like a) Not used.		-
	b) Construction (No general requirement)		-
	c) Not used.		-

Clause	Description	Result	Verdict
	d) Not used.		-
	e) AUXILIARY MAINS SOCKET OUTLETS on non-PERMANENTLY INSTALLED EQUIPMENT, intended for the provision of mains supply to other EQUIPMENT, or to separated parts of EQUIPMENT shall be of a type that cannot accept a MAINS PLUG. See also subclause 56.3. These AUXILIARY MAINS SOCKET-OUTLETS shall be properly marked (see subclause 6.1k).		
	f) Not used.		-
	g) Except where a functional earth needs to be provided, CLASS I APPLIANCE INLETS shall not be used in CLASS II EQUIPMENT.		
57.3	POWER SUPPLY CORDS a) Application – EQUIPMENT shall not be provided with more than one connection to a particular SUPPLY MAINS. – If a facility for alternative connection to a different supply system, e.g. external battery, is provided no SAFETY HAZARD shall occur when more than one connection is made simultaneously. – MAINS PLUGS shall not be fitted with more than one POWER SUPPLY CORD. – EQUIPMENT which is not intended to be permanently connected to fixed wiring shall be provided with either a POWER SUPPLY CORD or an APPLIANCE INLET.		
	b) Types POWER SUPPLY CORDS shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC Publication 245, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC Publication 227, designation 53). Polyvinyl chloride insulated POWER SUPPLY CORDS shall not be used for EQUIPMENT having external metal parts with a temperature exceeding 75 °C and which may be touched in NORMAL USE by the cord, unless it is RATED for that temperature (see also table Xb).		
	c) Cross-sectional area of conductors The NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS shall be not less than that shown in table XV.		

Clause	Description	Result	Verdict
	d) Preparation of conductors Stranded conductors shall not be soldered if fixed by any clamping means.		
57.4	Connection of POWER SUPPLY CORDS a) Cord anchorages – EQUIPMENT and MAINS CONNECTORS provided with POWER SUPPLY CORDS shall have cord anchorages such that the conductors are relieved from strain, including twisting, where they are connected within the EQUIPMENT and within the MAINS CONNECTOR and the insulation of the conductors is protected from abrasion. Strain relief methods, such as tying the cord into a knot or tying the ends with string, shall not be used. – Cord anchorages of POWER SUPPLY CORDS shall be made: 1) of insulating material, or 2) of metal, insulated from conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED by SUPPLEMENTARY INSULATION, or 3) of metal provided with an insulating lining, if otherwise a total insulation failure of the POWER SUPPLY CORD could render LIVE conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED. This lining shall be fixed to the cord anchorage, unless it is a flexible bushing which forms part of the cord guard specified in this subclause, and shall comply with the requirements for BASIC INSULATION. – Cord anchorages of POWER SUPPLY CORDS shall be so designed that the cord is not clamped by a screw which bears directly on the cord insulation. – Screws, if any, which have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage. – Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.		
	b) Cord guards POWER SUPPLY CORDS of other than STATIONARY EQUIPMENT shall be protected against excessive bending at the inlet opening of EQUIPMENT by means of a cord guard of insulating material.		

Clause	Description	Result	Verdict
	c) Accessibility of the connection The space inside EQUIPMENT designed for fixed wiring or a rewirable POWER SUPPLY CORD shall be adequate to allow conductors to be easily introduced and connected, and covers, if possible to check that the conductors are correctly connected and position before the cover is fitted.		
57.5	MAINS TERMINAL DEVICES and wiring of MAINS PART a) General requirements for mains terminal devices EQUIPMENT intended to be permanently connected to fixed wiring and EQUIPMENT intended to be connected by means of rewirable non-detachable POWER SUPPLY CORDS shall be provided with MAINS TERMINAL DEVICES in which connection shall be made by means of screws, nuts, soldering, clamping, crimping of conductors or equally effective methods. Reliance shall not be placed upon the terminals alone to maintain the conductors in position, unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES between LIVE parts and other conductive parts cannot be reduced to less than the values specified in subclause 57.10, should the conductor break away. Screws and nuts which clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.		
	b) Arrangement of MAINS TERMINAL DEVICES – For EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be loosely grouped, so as to provide a convenient means of connection. – MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL, even if their LIVE parts are not accessible. – MAINS TERMINAL DEVICES shall be 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.		

Clause	Description	Result	Verdict
	c) Fixing of mains terminals Terminals of EQUIPMENT shall be so fixed that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and CREEPAGE DISTANCES and AIR CLEARANCES are not reduced below the values specified in subclause 57.10.		
	d) Connections to mains terminals – For EQUIPMENT with rewirable flexible cords to be connected by clamping means the cord terminals shall not require special preparation of the conductor in order to effect correct connection, and they be so designed or placed that the conductor is not damaged and cannot slip out when the clamping screws or nuts are tightened.		
	e) Fixing of wiring (Not used)		-
57.6	Mains fuses and OVER-CURRENT RELEASES Fuses or OVER-CURRENT RELEASES shall be provided in each supply lead for CLASS I EQUIPMENT and CLASS II EQUIPMENT having a functional earth according to subclause 18l) and in at least one supply lead for other single-phase CLASS II EQUIPMENT. The current rating of mains fuses and OVER-CURRENT RELEASES shall be such that they reliably carry the normal operating current and shall not be greater than the current rating of any component in the mains circuit carrying the mains supply current. – A PROTECTIVE EARTH CONDUCTOR shall not be fused. – For PERMANENTLY INSTALLED EQUIPMENT the neutral conductor shall not be fused.		
57.7	Location of interference suppressors in the MAINS PART (Not used)		-
57.8	Wiring of the MAINS PART a) Insulation The insulation of an individual conductor in the MAINS PART shall be at least electrically equivalent to that of the individual conductors of POWER SUPPLY CORDS a complying with IEC 227 or 245, or that conductor shall be considered to be a bare conductor.		

Clause	Description	Result	Verdict
	b) Cross-section – Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in subclause 57.3c). – The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits shall be sufficient to prevent any fire hazard in case of possible fault currents.		
57.9	Mains supply transformers Mains supply transformers shall comply with the described requirements.		
57.9.1	Overheating – Mains supply transformers used in MEDICAL ELECTRICAL EQUIPMENT shall be protected against overheating of BASIC INSULATION, SUPPLEMENTARY INSULATION and REINFORCED INSULATION in the event of short-circuit or overload on any output widening. – Where protective devices external to the transformer or transformer ENCLOSURE provide the protection against overheating e.g. fuses, OVER-CURRENT RELEASES , THERMAL CUT-OUTS, these devices shall be connected in such a way that failure of any component other than wiring interposed between the protective devices and the transformer cannot render the protective devices inoperative.		
57.9.2	Dielectric strength The dielectric strength of the electrical insulation between turns and layers of the primary and secondary windings of a mains supply transformer shall be such that after the humidity preconditioning treatment (see subclause 4.10) it passes the prescribed tests.		
57.9.3	Housing (Not used)		-

Clause	Description	Result	Verdict
57.9.4	Construction a) The separation of primary and secondary windings having a CONDUCTIVE CONNECTION to APPLIED PARTS or to ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED shall be achieved by one of the following methods: – wound on separate bobbins or formers; – wound on one bobbin or former with an imperforate insulating partition between windings; – wound on one bobbin or former with concentric windings and having an imperforate protective copper screen with a thickness of not less than 0,13 mm; – concentrically wound on one bobbin with windings separated by DOUBLE or REINFORCED INSULATION.		
	b) Not used.		-
	c) Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.		
	d) If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.		
	e) In transformers with REINFORCED INSULATION or DOUBLE INSULATION the insulation between the primary and secondary winding shall consist of: – one insulation layer having a thickness of not less than 0,3 mm, or – at least 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.		
	f) For transformers complying with subclause 57.9.4a) the CREEPAGE DISTANCES between the primary and secondary windings shall comply with the requirements for REINFORCED INSULATION (A-e, table XVI, subclause 57.10).		
	g) The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for DOUBLE INSULATION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside and winding.		

Clause	Description	Result	Verdict
57.10	CREEPAGE DISTANCES and AIR CLEARANCES a) Values – CREEPAGE DISTANCES and AIR CLEARANCES shall comply with at least the values of table XVI. – Between DEFRIBILLATION-PROOF APPLIED PARTS and other parts, CREEPAGE DISTANCES and AIR CLEARANCES shall be not less than 4 mm.		
	b) Application (... of requirement in subclause)		-
	c) Not used.		-
	d) Measurement of CREEPAGE DISTANCES and AIR CLEARANCES (A description of measurements, including special cases and a table of limits is presented.)		-
58.	Protective earthing – Terminals and connections		
58.1	The clamping means of the PROTECTIVE EARTH TERMINAL for fixing supply conductors or POWER SUPPLY CORDS shall comply with the requirements of subclause 57.5c). It shall not be possible to loosen it without the aid of a TOOL. Screws for internal protective earthing connections shall be completely covered or protected against inadvertent loosening from the outside of EQUIPMENT.		
58.2	For internal PROTECTIVE EARTHING CONNECTIONS, clamping by means of a screw, soldering, crimping, wrapping, welding or a reliable pressure contact are allowed.		
58.3	Not used.		-
58.4	Not used.		-
58.5	Not used.		-
58.6	Not used.		-
58.7	Where an APPLIANCE INLET forms the supply connection to EQUIPMENT, the earth pin of the APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.		
58.8	The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.		

Clause	Description	Result	Verdict
58.9	Protective earth connection Where the connection between mains supply conductors and EQUIPMENT or between separated parts of EQUIPMENT which can be operated by the OPERATOR is made via a plug and socket device, the protective earth connection shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are connected to protective earth.		NA
59.	**Construction and layout**		
59.1	Internal wiring a) Mechanical protection – Cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges, if there is a relative movement between the part and cords or wiring. – Wiring having BASIC INSULATION only shall be protected by additional fixed sleeving or by other similar means where it is in direct contact with metal parts and where such wiring is subject to a relative movement in NORMAL USE during which it is in direct contact with metal parts – EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged in the normal process of assembly or replacement of covers or the opening or closing of inspection doors.		
	b) Bending Guiding rollers of leads shall be constructed in such a manner that movable leads in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned.		
	c) Insulation – If insulating sleeving is needed on internal wiring, it shall be adequately secured. – Inside EQUIPMENT the sheath of a flexible cord shall be used as SUPPLEMENTARY INSULATION only where it is not subject to undue mechanical or thermal stresses and if its insulation properties are not less than those specified in IEC Publications 227 or 245. – Insulated conductors which in NORMAL USE are subject to temperatures exceeding 70 °C shall have an insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation.		

Clause	Description	Result	Verdict
	d) Materials Aluminium wires of less than 16 mm² cross-section shall not be used.		
	e) *Separation of circuits* (Not used)		-
	f) Applicable requirements Connecting cords between EQUIPMENT parts, e.g. parts of an X-ray installation or a PATIENT monitoring installation or a data-processing installation or combinations thereof shall be considered as belonging to the EQUIPMENT and not be subject to requirements for wiring of electrical installations (in hospitals or otherwise).		
59.2	Insulation a) Fixing (Not used)		
	b) Mechanical strength and resistance to heat and fire The insulating characteristics, mechanical strength and resistance to heat and fire shall be retained by all types of insulation, including insulating partition walls, even in the case of extended use.		
	c) Protection BASIC INSULATION, SUPPLEMENTARY INSULATION and REINFORCED INSULATION shall be so designed or protected that they are not likely to be impaired by deposition of dirt or by dust resulting from wear of parts within the EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in subclause 57.10. Ceramic material not tightly sintered, and the like, and beads alone shall not be used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION. Parts of natural or synthetic rubber used as SUPPLEMENTARY INSULATION in CLASS II EQUIPMENT shall be resistant to aging and be so arranged and dimensioned that CREEPAGE DISTANCES are not reduced below the values specified in subclause 57.10 whatever cracks may occur. Insulating material in which heating conductors are embedded shall be considered as BASIC INSULATION and shall not be used as REINFORCED INSULATION.		

Clause	Description	Result	Verdict
59.3	Excessive current and voltage protection		
	– An INTERNAL ELECTRICAL POWER SOURCE in EQUIPMENT shall be provided with an appropriately RATED device for protection against fire hazard caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components may give rise to the occurrence of a fire hazard in case of a short circuit.	internal fuse provided	C
	– Fuse elements replaceable without opening the ENCLOSURE of the EQUIPMENT shall be fully enclosed in a fuseholder.	inside enclosure	NA
	When fuse replacement can be carried out without the use of a TOOL, uninsulated LIVE parts associated with the fuseholder shall be shielded to enable fuse replacement without a SAFETY HAZARD.	only by tool	NA
	– Protective devices connected between an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.	no applied parts	NA
59.4	Oil containers	no oil containers	
	– Oil containers in PORTABLE EQUIPMENT shall be adequately sealed to prevent loss of oil in any position.		NA
	The container design shall allow for the expansion of the oil.		NA
	Oil containers in MOBILE EQUIPMENT shall be sealed to prevent the loss of oil during transport but may be fitted with a pressure-release device which can operate during NORMAL USE.		NA
	– Partially sealed oil-filled EQUIPMENT or EQUIPMENT parts shall be provided with means for checking the oil level.		NA