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DRAFT STANDARD - Medical Electrical Equipment, Part 1: General Requirements for Safety

NATIONAL DIFFERENCES

GENERAL

National Differences from the text of International Electrotechnical Commission (IEC) Publication 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety, copyright 1988 as amended in 1991 and 1995 are indicated by notations (differences) and are presented in bold text.

There are five types of National Differences as noted below. The difference type is noted on the first line of the National Difference in the standard. The standard may not include all types of these National Differences.

DR – These are National Differences based on the **National Electrical Code (NEC)** and **other U.S. Regulatory Requirements**.

D1 – These are National Differences which are based on **basic safety principles and requirements**, elimination of which would compromise safety for U.S. consumers and users of products.

D2 – These are National Differences based on **safety practices**. These are differences for IEC requirements that may be acceptable, but adopting the IEC requirements would require considerable retesting or redesign on the manufacturer's part.

DC – These are National Differences based on the **component standards** and will not be deleted until a particular component standard is harmonized with the IEC component standard.

DE – These are National Differences based on **editorial comments or corrections**.

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety

SECTION ONE – GENERAL

1 *Scope and object

1.1 *Scope*

This Standard applies to the safety of MEDICAL ELECTRICAL EQUIPMENT (as defined in Sub-clause 2.2.15).

Although this Standard is primarily concerned with safety, it contains some requirements regarding reliable operation where this is connected with safety.

SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

Appendices in this Standard are not mandatory unless made so by an explicit statement in the main text.

1.1DV D2 ***Replacement of the third paragraph of 1.1 with the following:***

SAFETY HAZARDS resulting from intended physiological function of EQUIPMENT covered by this Standard are not considered. These requirements do not contemplate the investigation of protection against ionizing radiation or radioactive isotopes. Such EQUIPMENT is subject to Federal radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.

1.2 *Object*

The object of this Standard is to specify general requirements for the safety of MEDICAL ELECTRICAL EQUIPMENT and to serve as the basis for the safety requirements of Particular Standards.

**1.3 ***Particular Standards*

A Particular Standard takes priority over this General Standard.

1.4 *Environmental conditions*

See Section Two.

1.5 *Collateral Standards*

In the IEC 601 series, Collateral Standards specify general requirements for safety applicable to:

– a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. electromagnetic compatibility).

If a Collateral Standard applies to a Particular Standard, then the Particular Standard takes priority over the Collateral Standard.

2 Terminology and definitions+

For the purpose of this Standard, the following shall apply:

– Where the terms ″voltage″ and ″current″ are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.

– The auxiliary verb:

• “shall” means that compliance with a requirement or a test is mandatory for compliance with this Standard;

• “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this Standard;

• “may” is used to describe a permissible way to achieve compliance with a requirement or test.

+The defined terms are alphabetically listed in the Index.

2.1 *EQUIPMENT parts, auxiliaries and ACCESSORIES*

2.1.1 ACCESS COVER: Part of an ENCLOSURE or guard providing the possibility of access to EQUIPMENT parts for the purpose of adjustment, inspection, replacement or repair.

2.1.2 ACCESSIBLE METAL PART: Metal part of EQUIPMENT which can be touched without the use of a TOOL. See also Sub-clause 2.1.22.

2.1.3 ACCESSORY: Optional component necessary and/or suitable to be used with EQUIPMENT in order to enable, facilitate or improve the intended use of EQUIPMENT or to integrate additional functions.

2.1.4 ACCOMPANYING DOCUMENTS: Documents accompanying EQUIPMENT or an ACCESSORY and containing all important information for the USER, OPERATOR, installer or assembler of EQUIPMENT, particularly regarding safety.

2.1.5 *APPLIED PART: A part of the EQUIPMENT which in NORMAL USE:

– necessarily comes into physical contact with the PATIENT for the EQUIPMENT to perform its function; or

– can be brought into contact with the PATIENT; or

– needs to be touched by the PATIENT.

2.1.6 ENCLOSURE: Exterior surface of EQUIPMENT including:

– all ACCESSIBLE METAL PARTS, knobs, grips and the like;

– accessible shafts;

– for the purpose of tests, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material.

2.1.7 F-TYPE ISOLATED (FLOATING) APPLIED PART (hereinafter referred to as F-TYPE APPLIED PART): APPLIED PART isolated from other parts of the EQUIPMENT to such a degree that no current higher than the PATIENT LEAKAGE CURRENT allowable in SINGLE FAULT CONDITION flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the APPLIED PART and earth.

F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

2.1.8 Not used.

2.1.9 INTERNAL ELECTRICAL POWER SOURCE: Power source intended to provide the electrical power necessary to operate EQUIPMENT and which is incorporated in that EQUIPMENT.

2.1.10 LIVE: State of a part which, when connection is made to that part, can cause a current exceeding the allowable LEAKAGE CURRENT (specified in Sub-clause 19.3) for the part concerned to flow from that part to earth or from that part to an ACCESSIBLE PART of the same EQUIPMENT.

2.1.11 Not used.

2.1.12 MAINS PART: Entirety of all parts of EQUIPMENT intended to have a CONDUCTIVE CONNECTION with the SUPPLY MAINS. For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 1).

2.1.13 Not used.

2.1.14 Not used.

2.1.15 *PATIENT CIRCUIT: Any electrical circuit which contains one or more PATIENT CONNECTIONS.

PATIENT CIRCUITS include all conductive parts which are not insulated from the PATIENT CONNECTIONS to the extent necessary to comply with the dielectric strength requirements (see clause 20) or which are not separated from the PATIENT CONNECTIONS to the extent necessary to comply with the CREEPAGE DISTANCE and AIR CLEARANCE requirements (see 57.10).

2.1.16 Not used.

2.1.17 PROTECTIVE COVER: Part of an ENCLOSURE or guard provided to prevent accidental access to parts which might be hazardous if contacted.

2.1.18 SIGNAL INPUT PART: Part of EQUIPMENT, not being an APPLIED PART, intended to receive input signal voltages or currents from other EQUIPMENT, for example, for display, recording or data processing (see Figure 1).

2.1.19 SIGNAL OUTPUT PART: Part of EQUIPMENT, not being an APPLIED PART, intended to deliver output signal voltages or currents to other EQUIPMENT, for example, for display, recording or data processing (see Figure 1).

2.1.20 Not used.

2.1.21 SUPPLY EQUIPMENT: EQUIPMENT which supplies electrical power to one or more items of EQUIPMENT.

2.1.22 ACCESSIBLE PART: Part of EQUIPMENT which can be touched without the use of a TOOL.

2.1.23 *PATIENT CONNECTION: Every individual part of the APPLIED PART through which current can flow between the PATIENT and the EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

2.1.24 *TYPE B APPLIED PART: APPLIED PART complying with the specified requirements of this Standard to provide protection against electric shock, particularly regarding allowable LEAKAGE CURRENT and marked with symbol 1, table DII, of Appendix D.

NOTE – TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

2.1.25 *TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of this Standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS and marked with symbol 2, table DII, of Appendix D.

NOTE – TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

2.1.26 *TYPE CF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of this Standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS and marked with symbol 3, table DII, of Appendix D.

2.1.27 *DEFIBRILLATION-PROOF APPLIED PART: APPLIED PART having protection against the effects of a discharge of a cardiac defibrillator to the PATIENT.

2.2 *EQUIPMENT types (classification)*

2.2.1 Not used.

2.2.2 CATEGORY AP EQUIPMENT: EQUIPMENT or EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR.

2.2.3 CATEGORY APG EQUIPMENT: EQUIPMENT or EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

2.2.4 CLASS I EQUIPMENT: EQUIPMENT in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for the connection of the EQUIPMENT to the PROTECTIVE EARTH CONDUCTOR in the fixed wiring of the installation in such a way that ACCESSIBLE METAL PARTS cannot become LIVE in the event of a failure of the BASIC INSULATION (see Figure 2).

2.2.5 CLASS II EQUIPMENT: EQUIPMENT in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions (see Figure 3).

2.2.6 Not used.

2.2.7 DIRECT CARDIAC APPLICATION: Use of APPLIED PART which may come in direct CONDUCTIVE CONNECTION to the PATIENT'S heart.

2.2.8 Not used.

2.2.9 Not used.

2.2.10 Not used.

2.2.11 EQUIPMENT (see Sub-clause 2.2.15)

2.2.12 FIXED EQUIPMENT: EQUIPMENT which is fastened or otherwise secured at a specific location in a building or a vehicle and can only be detached by means of a TOOL.

2.2.13 HAND-HELD EQUIPMENT: EQUIPMENT intended to be supported by the hand during NORMAL USE.

2.2.14 Not used.

2.2.15 MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT): Electrical EQUIPMENT, provided with not more than one connection to a particular SUPPLY MAINS and intended to diagnose, treat, or monitor the PATIENT under medical supervision and which makes physical or electrical contact with the PATIENT and/or transfers energy to or from the PATIENT and/or detects such energy transfer to or from the PATIENT.

The EQUIPMENT includes those ACCESSORIES as defined by the manufacturer which are necessary to enable the NORMAL USE of the EQUIPMENT.

2.2.16 MOBILE EQUIPMENT: TRANSPORTABLE EQUIPMENT intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

2.2.17 PERMANENTLY INSTALLED EQUIPMENT: EQUIPMENT that is electrically connected to the SUPPLY MAINS by means of a permanent connection which can only be detached by the use of a TOOL.

2.2.18 PORTABLE EQUIPMENT: TRANSPORTABLE EQUIPMENT intended to be moved from one location to another while used or between periods of use while being carried by one or more persons.

2.2.19 Not used.

2.2.20 Not used.

2.2.21 STATIONARY EQUIPMENT: Either FIXED EQUIPMENT or EQUIPMENT which is not intended to be moved from one place to another.

2.2.22 Not used.

2.2.23 TRANSPORTABLE EQUIPMENT: EQUIPMENT which is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range.

Examples: MOBILE EQUIPMENT and PORTABLE EQUIPMENT.

2.2.24 Not used.

2.2.25 Not used.

2.2.26 Not used.

2.2.27 Not used.

2.2.28 Not used.

2.2.29 INTERNALLY POWERED EQUIPMENT: EQUIPMENT able to operate from an INTERNAL ELECTRICAL POWER SOURCE.

2.3 *Insulation*

2.3.1 AIR CLEARANCE: Shortest path in air between two conductive parts.

2.3.2 *BASIC INSULATION: Insulation applied to LIVE parts to provide basic protection against electric shock.

2.3.3 CREEPAGE DISTANCE: Shortest path along the surface of insulating material between two conductive parts.

2.3.4 *DOUBLE INSULATION: Insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION.

2.3.5 Not used.

2.3.6 Not used.

2.3.7 *REINFORCED INSULATION: Single insulation system applied to LIVE parts which provides a degree of protection against electric shock equivalent to DOUBLE INSULATION under the conditions specified in this Standard.

2.3.8 SUPPLEMENTARY INSULATION: Independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION.

2.4 *Voltages*

2.4.1 HIGH VOLTAGE: Any voltage over 1 000 V a.c. or over 1 500 V d.c. or 1 500 V peak value.

2.4.2 MAINS VOLTAGE: Voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system.

2.4.3 *SAFETY EXTRA-LOW VOLTAGE (SELV): Voltage which does not exceed a NOMINAL value of 25 V a.c. or 60 V d.c. at RATED supply voltage on the transformer or converter, between conductors in an earth-free circuit which is isolated from the SUPPLY MAINS by a SAFETY EXTRA-LOW VOLTAGE TRANSFORMER or by a device with an equivalent separation.

2.5 *Currents*

2.5.1 EARTH LEAKAGE CURRENT: Current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR.

2.5.2 ENCLOSURE LEAKAGE CURRENT: Current flowing from the ENCLOSURE or from parts thereof, excluding APPLIED PARTS, accessible to the OPERATOR or PATIENT in NORMAL USE, through an external CONDUCTIVE CONNECTION other than the PROTECTIVE EARTH CONDUCTOR to earth or to another part of the ENCLOSURE.

2.5.3 LEAKAGE CURRENT: Current that is not functional. The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, ENCLOSURE LEAKAGE CURRENT and PATIENT LEAKAGE CURRENT.

2.5.4 *PATIENT AUXILIARY CURRENT: Current flowing in the PATIENT in NORMAL USE between parts of the APPLIED PART and not intended to produce a physiological effect, for example, bias current of an amplifier, current used in impedance plethysmography.

2.5.5 Not used.

2.5.6 PATIENT LEAKAGE CURRENT: Current flowing from the APPLIED PART via the PATIENT to earth or flowing from the PATIENT via an F-TYPE APPLIED PART to earth originating from the unintended appearance of a voltage from an external source on the PATIENT.

2.6 *Earth terminals and conductors*

2.6.1 Not used.

2.6.2 Not used.

2.6.3 FUNCTIONAL EARTH CONDUCTOR: Conductor to be connected to a FUNCTIONAL EARTH TERMINAL (see Figure 1).

2.6.4 *FUNCTIONAL EARTH TERMINAL: Terminal directly connected to a point of a measuring supply or control circuit or to a screening part which is intended to be earthed for functional purposes (see Figure 1).

2.6.5 Not used.

2.6.6 POTENTIAL EQUALIZATION CONDUCTOR: Conductor providing a connection between EQUIPMENT and the potential equalization busbar of the electrical installation.

2.6.7 PROTECTIVE EARTH CONDUCTOR: Conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system (see Figure 1).

2.6.8 PROTECTIVE EARTH TERMINAL: Terminal connected to conductive parts of CLASS I EQUIPMENT for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR (see Figure 1).

2.6.9 PROTECTIVELY EARTHED: Connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this Standard.

2.7 *Electrical connection (devices)*

2.7.1 APPLIANCE COUPLER: Means enabling the connection of a flexible cord to EQUIPMENT without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET (see Figure 5).

2.7.2 APPLIANCE INLET: Part of an APPLIANCE COUPLER incorporated in or fixed to EQUIPMENT (see Figures 1 and 5).

2.7.3 Not used.

2.7.4 AUXILIARY MAINS SOCKET-OUTLET: Socket-outlet with MAINS VOLTAGE on EQUIPMENT, accessible without the use of a TOOL and intended for provision of mains supply to other EQUIPMENT or to other separate parts of the EQUIPMENT.

2.7.5 CONDUCTIVE CONNECTION: Connection through which a current can flow exceeding the allowable LEAKAGE CURRENT.

2.7.6 *DETACHABLE POWER SUPPLY CORD: Flexible cord intended to be connected to EQUIPMENT by means of a suitable APPLIANCE COUPLER (see Figures 1, 2 and 5 and Sub-clause 57.3).

2.7.7 EXTERNAL TERMINAL DEVICE: TERMINAL DEVICE by which electrical connection to other EQUIPMENT is made.

2.7.8 FIXED MAINS SOCKET-OUTLET: Mains socket-outlet installed in a fixed wiring system in a building or a vehicle (see Figure 5).

2.7.9 INTERCONNECTION TERMINAL DEVICE: TERMINAL DEVICE by which internal connections within EQUIPMENT or between EQUIPMENT parts are made.

2.7.10 MAINS CONNECTOR: Part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord which is intended to be connected to the SUPPLY MAINS. A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of EQUIPMENT (see Figures 1 and 5 and Sub-clause 57.2).

2.7.11 MAINS PLUG: Part integral with or intended to be attached to a POWER SUPPLY CORD of EQUIPMENT, to be inserted into a FIXED MAINS SOCKET OUTLET (see Figure 5).

2.7.12 MAINS TERMINAL DEVICE: TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made (see Figure 1).

2.7.13 Not used.

2.7.14 Not used.

2.7.15 Not used.

2.7.16 TERMINAL DEVICE: Part of EQUIPMENT by which electrical connection is made; it may contain several individual contacts.

2.7.17 POWER SUPPLY CORD: Flexible cord, fixed to or assembled with EQUIPMENT for mains supply purposes.

2.8 *Transformers*

2.8.1 Not used.

2.8.2 Not used.

2.8.3 SAFETY EXTRA-LOW VOLTAGE TRANSFORMER: Transformer with an output-winding which is electrically separated from earth and the body of the transformer by at least BASIC INSULATION and which is electrically separated from the input-winding by an insulation at least equivalent to DOUBLE INSULATION or REINFORCED INSULATION and which is designed to supply SAFETY EXTRA-LOW VOLTAGE circuits.

2.8.4 Not used.

2.8.5 Not used.

2.8.6 Not used.

2.9 *Controls and limiting devices*

2.9.1 ADJUSTABLE SETTING (of a control or limiting device): Setting which can be altered by the OPERATOR without the use of a TOOL.

2.9.2 Not used.

2.9.3 Not used.

2.9.4 FIXED SETTING (of a control or limiting device): Setting not intended to be altered by the OPERATOR and which can only be altered by means of a TOOL.

2.9.5 Not used.

2.9.6 Not used.

2.9.7 OVER-CURRENT RELEASE: Protective device which causes a circuit to open with or without delay, when the current in the device exceeds a predetermined value.

2.9.8 Not used.

2.9.9 Not used.

2.9.10 SELF-RESETTING THERMAL CUT-OUT: THERMAL CUT-OUT which automatically restores the current after the relevant part of EQUIPMENT has cooled.

2.9.11 Not used.

2.9.12 THERMAL CUT-OUT: Device which, during abnormal operation, limits the temperature of EQUIPMENT or of parts of it, by automatically opening the circuit or by reducing the current, and which is so constructed that its setting cannot be altered by the OPERATOR.

2.9.13 THERMOSTAT: A temperature sensing control, which is intended to keep a temperature between two particular values under normal operating conditions and which may have provision for setting by the OPERATOR.

2.10 *Operation of* EQUIPMENT

2.10.1 COLD CONDITION: The condition obtained if EQUIPMENT is de-energized for a sufficiently long time to attain the ambient temperature.

2.10.2 CONTINUOUS OPERATION: Operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.

2.10.3 CONTINUOUS OPERATION WITH INTERMITTENT LOADING: Operation in which EQUIPMENT is connected continuously to the SUPPLY MAINS. The stated permissible loading time is so short that the long term on-load operating temperature is not attained. The ensuing interval in loading is, however, not sufficiently long for cooling down to the long term no-load operating temperature.

2.10.4 CONTINUOUS OPERATION WITH SHORT-TIME LOADING: Operation in which EQUIPMENT is connected continuously to the SUPPLY MAINS. The stated permissible loading time is so short that the long term on-load operating temperature is not attained. The ensuing interval is, however, sufficiently long for cooling down to the long term no-load operating temperature.

2.10.5 DUTY CYCLE: Ratio of the operating time to the sum of the operating time and the ensuing interval. In the case of operating times and intervals of varying duration, it is calculated as a mean value over a sufficiently long time.

2.10.6 INTERMITTENT OPERATION: Operation in a series of specified identical cycles, each cycle being composed of a period of operation under normal load, without the specified limits of temperature being exceeded, followed by a rest period with the EQUIPMENT running idle or switched off.

2.10.7 NORMAL CONDITION: Condition in which all means provided for protection against SAFETY HAZARDS are intact.

2.10.8 NORMAL USE: Operation, including routine inspection and adjustments by the OPERATOR, and stand-by, according to the instructions for use.

2.10.9 PROPERLY INSTALLED: Condition in which at least the relevant instructions concerning installation given by the manufacturer in the ACCOMPANYING DOCUMENTS are observed.

2.10.10 SHORT-TIME OPERATION: Operation under normal load for a specified period, starting from COLD CONDITION without the specified limits of temperature being exceeded, the intervals between each period of operation being sufficient to allow the EQUIPMENT to cool down to COLD CONDITION.

2.10.11 SINGLE FAULT CONDITION: Condition in which a single means for protection against a SAFETY HAZARD in EQUIPMENT is defective or a single external abnormal condition is present (see Sub-clause 3.6).

2.10.12DV DR *Addition:*

X-RAY INSTALLATIONS (LONG-TIME RATING): A rating based on an operating interval of 5 minutes or longer.

2.10.13DV DR *Addition:*

X-RAY INSTALLATIONS (MOMENTARY RATING): A rating based on an operating interval that does not exceed 5 seconds.

2.11 *Mechanical safety*

2.11.1 HYDRAULIC TEST PRESSURE: PRESSURE applied to test a vessel or part of it for compliance with Clause 45.

2.11.2 *MAXIMUM PERMISSIBLE WORKING PRESSURE: PRESSURE specified by the manufacturer or by the inspection authority or competent person(s) in the report of the most recent examination.

2.11.3 MINIMUM BREAKING LOAD: Maximum load where Hooke's Law is applicable.

2.11.4 PRESSURE (overpressure): Pressure above atmospheric (gauge pressure).

2.11.5 SAFE WORKING LOAD: Maximum load on an EQUIPMENT or EQUIPMENT part that can be permitted according to a declaration of the supplier of such an EQUIPMENT or EQUIPMENT part if his instructions for installation and use are followed.

2.11.6 SAFETY DEVICE: Means which protect the PATIENT and/or OPERATOR from a hazardous force due to excessive travel or from the fall of a suspended mass in the event of failure of a means of suspension.

2.11.7 STATIC LOAD: Maximum loading of a part excluding any loading caused by acceleration or deceleration of masses. Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility shall be considered.

2.11.8 SAFETY FACTOR: The ratio between the MINIMUM BREAKING LOAD and SAFE WORKING LOAD.

2.11.9 TOTAL LOAD: Sum of the STATIC LOAD and the forces caused by acceleration and deceleration occurring in NORMAL CONDITION.

2.12 *Miscellaneous*

2.12.1 Not used.

2.12.2 *MODEL OR TYPE REFERENCE (type number): Combination of figures, letters or both used to identify a particular model of EQUIPMENT.

2.12.3 NOMINAL (value): Value quoted for reference purposes which is subject to agreed tolerances, for example, NOMINAL MAINS VOLTAGE, NOMINAL diameter of a screw.

2.12.4 PATIENT: Living being (person or animal) undergoing medical or dental investigation or treatment.

2.12.5 Not used.

2.12.6 Not used.

2.12.7 Not used.

2.12.8 RATED (value): Value assigned by the manufacturer to a quantity characteristic of the EQUIPMENT.

2.12.9 SERIAL NUMBER: Number and/or other designation used to identify an individual unit of a certain model of EQUIPMENT.

2.12.10 SUPPLY MAINS: Permanently installed power source which may also be used to supply electrical apparatus that is outside the scope of this Standard.

This also includes permanently installed battery systems in ambulances and the like.

2.12.11 Not used.

2.12.12 TOOL: Extra-corporeal object which may be used to secure or release fasteners or to make adjustments.

2.12.13 USER: Authority responsible for the use and maintenance of EQUIPMENT.

2.12.14 EMERGENCY TROLLEY: Wheeled trolley intended to support and convey life-supporting and resuscitation EQUIPMENT for cardio-respiratory emergencies.

2.12.15 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR: Mixture of a flammable anaesthetic vapour with air in such a concentration that ignition may occur under specified conditions. A mixture of the vapour of a flammable disinfection or cleaning agent with air may be treated as a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR subject to national or local regulations.

2.12.16 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE: Mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition may occur under specified conditions.

2.12.17 OPERATOR: Person handling EQUIPMENT.

2.12.18 SAFETY HAZARD: Potentially detrimental effect on the PATIENT, other persons, animals, or the surroundings, arising directly from EQUIPMENT.

2.12.19DV D2 *Addition:*

PATIENT CARE EQUIPMENT: EQUIPMENT intended for use in or likely to be used in the PATIENT VICINITY.

2.12.20DV D2 *Addition:*

PATIENT VICINITY: In areas in which PATIENTS are normally cared for, the PATIENT VICINITY is the space with surfaces likely to be contacted by the PATIENT or an attendant who can touch the PATIENT. This encloses a space within the room 1,83 m (6 feet) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2,29 m (7-1/2 feet) above the floor.

2.12.21DV D2 *Addition:*

INTERNATIONALLY HARMONIZED COMPONENT STANDARD: A standard satisfying U.S. national and international safety concerns and may include national differences (exceptions) which modify the requirements of the relevant internationally recognized safety standard, (such as an IEC/ISO standard). When necessary, due to national safety concerns, the national differences may include the unique U.S. national safety, regulatory, and legal requirements taken from the relevant nationally recognized safety standard (such as an ANSI/UL standard).

3 General requirements

3.1 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.

3.2 Not used.

3.3 Not used.

3.4 EQUIPMENT or parts thereof, using materials or having forms of construction different from those detailed in this Standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained. See also Clause 54.

3.5 Not used.

3.6 *The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests in this Standard:

a) interruption of a PROTECTIVE EARTH CONDUCTOR (see Section Three);

b) interruption of one supply conductor (see Section Three);

*c) appearance of an external voltage on an F-TYPE APPLIED PART (see Section Three);

d) appearance of an external voltage on SIGNAL INPUT or on a SIGNAL OUTPUT PART (see Section Three);

e) leakage of the ENCLOSURE of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (see Section Six);

f) leakage of liquid (see subclause 44.4)

g) failure of an electrical component which might cause a SAFETY HAZARD (see Section Nine);

h) failure of mechanical parts which might cause a SAFETY HAZARD (see Section Four);

j) failure of temperature limiting devices (see Section Seven).

Where a SINGLE FAULT CONDITION results unavoidably in another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

3.7 The following phenomena are considered by this Standard as unlikely to occur:

a) total electrical breakdown of a DOUBLE INSULATION;

b) electrical breakdown of a REINFORCED INSULATION;

c) interruption of a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR.

3.8 Earthing of a PATIENT is considered as a NORMAL CONDITION.

3.9 Unless otherwise specified in the instructions for use, EQUIPMENT shall not be required to withstand the effects of operation under separate dust covers or sterile covers (see Sub-clause 52.5.5).

Compliance with the requirements of this clause is considered to exist when the criteria of the relevant inspections and tests in this Standard are achieved.

3.10DV D2 *Addition of 3.10DV.1 – 3.10DV.3:*

3.10DV.1 Components

3.10DV.1.1 In addition to compliance with this standard, the following components shall meet nationally recognized standards (such as ANSI/UL standards) or INTERNATIONALLY HARMONIZED COMPONENT STANDARDS:

a) Printed wiring boards

b) Lithium batteries

c) Optical isolators

d) Wiring and tubing

e) CRTs > 5 inches

Items a), c), and d) are exempt from this requirement if they are connected totally in an SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a SAFETY HAZARD.

3.10DV.2 Primary circuit components

3.10DV.2.1 In addition to compliance with this basic standard, components in the primary circuit up to the isolation transformer shall meet nationally recognized standards (such as ANSI/UL standards) or INTERNATIONALLY HARMONIZED COMPONENT STANDARDS.

3.10DV.3 Annex DVA tabulates UL component Standards covering components as specified in subclauses 3.10DV.1 and 3.10DV.2.

4 *General requirements for tests

**4.1 ***Tests*

Tests described in this Standard are type tests. Only insulation, components and constructional features the failure of which could produce in NORMAL CONDITION or SINGLE FAULT CONDITION a SAFETY HAZARD shall be tested.

4.2 *Repetition of tests*

Unless otherwise specified in this Standard, tests shall not be repeated. This applies particularly to the dielectric strength tests, which are made only at the manufacturer's site or in test laboratories.

4.3 ***** *Number of samples*

Type tests are made on one representative sample of the item being tested.

Exceptionally, an additional sample may be required.

4.4 *Components*

All components, the failure of which could cause a SAFETY HAZARD, shall be capable of withstanding the stresses encountered in the EQUIPMENT in NORMAL USE and shall satisfy the appropriate section of this Standard.

Compliance of the rating of such components with conditions of use is checked by inspection.

A component or EQUIPMENT part which has specified ratings exceeding that of its appropriate use in EQUIPMENT does not have to be tested for such a wider range (see also Sub-clause 56.1).

4.5 *Ambient temperature, humidity, atmospheric PRESSURE*

a) After the EQUIPMENT to be tested has been set up for NORMAL USE (according to 4.8) tests are carried out within the range of environmental conditions specified in 10.2.1, unless otherwise specified by the manufacturer.

For reference tests (if the results are dependent on the ambient condition) one set of atmospheric conditions specified in table I is recognized.

Table I
Specified atmospheric conditions

Temperature (°C)	*23 ± 2*
Relative humidity (%)	*60 ± 15*
Atmospheric PRESSURE	*860 hPa to 1 060 hPa* *(645 mm Hg to 795 mm Hg)*

b) EQUIPMENT shall be shielded from other influences (for example, draughts), which might affect the validity of the tests.

c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.

4.6 *Other conditions*

a) Unless otherwise specified in this Standard, EQUIPMENT is to be tested under the least favourable specified working conditions, but in accordance with the instructions for use.

b) EQUIPMENT having operating values which can be adjusted or controlled by the OPERATOR shall be adjusted during the tests to values least favourable for the relevant test, but in accordance with the instructions for use.

c) If the test results are influenced by the inlet PRESSURE and flow or chemical composition of the cooling liquid, the test shall be carried out within the limits for these conditions as prescribed in the technical description.

d) During any test under SINGLE FAULT CONDITION, one fault only at a time shall be applied (see Sub-clause 3.6).

e) Where cooling water is required, potable water shall be used.

4.7 *Supply and test voltages, type of current, nature of supply, frequency*

In the context of this Standard the MAINS VOLTAGE may be subject to fluctuations; these fluctuations are ignored for the purposes of the term "RATED".

a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations shall be taken into account.

The waveform of a supply voltage during tests shall be according to Sub-clause 10.2.2a).

Any test voltage below 1 000 V a.c. or 1 500 V d.c. or 1 500 V peak value shall not differ by more than 2% from the prescribed value. Any test voltage at and above 1 000 V a.c. or 1 500 V d.c. or 1 500 V peak value shall not differ by more than 3% from the prescribed value.

b) EQUIPMENT for a.c. only shall be tested with a.c. at RATED frequency (if marked) ±1 Hz between 0 and 100 Hz and ±1% above 100 Hz. EQUIPMENT marked with a RATED frequency range shall be tested at the least favourable frequency within that range.

c) EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., shall be tested in conditions (described in Sub-clause 4.6) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current.

d) EQUIPMENT for d.c. only shall be tested with d.c.; the possible influence of polarity on the operation of the EQUIPMENT shall be taken into consideration, according to the instructions for use.

e) Unless otherwise specified by this Standard or by a Particular Standard, EQUIPMENT shall be tested at the least favourable RATED voltage within the relevant range. It may be necessary to perform some of the tests more than once in order to establish the least favourable voltage.

f) EQUIPMENT for which alternative ACCESSORIES or components specified by the manufacturer are available shall be tested with those ACCESSORIES or components which give the least favourable conditions.

g) EQUIPMENT intended for use with a specified power supply, for example regarding voltages, capacitances, insulation resistances respectively to earth, etc., shall be tested with such a specified power supply.

h) Measurement of voltages and currents shall be carried out with instruments which do not appreciably affect the magnitude of the values to be measured.

4.8 ***Preconditioning**

Before testing is started, EQUIPMENT shall be kept in the testing location unoperated for at least 24 h. Before the actual series of tests, it is operated as far as is necessary for the tests at RATED voltage, in accordance with the instructions for use.

4.9 *Repairs and modifications*

In the event of the necessity for repairs or modifications after a failure or a likelihood of future failure during the sequence of tests, the testing laboratory and the supplier may agree either upon the presentation of a new sample on which all tests shall be carried out again or preferably, upon making all the necessary repairs or modifications after which only relevant tests shall be repeated.

4.10 ***Humidity preconditioning treatment**

Prior to the tests of 19.4 and 20.4, all EQUIPMENT not being IPX8, (see IEC 529, protected against the effects of continuous immersion in water) or EQUIPMENT parts shall be subjected to a humidity preconditioning treatment.

EQUIPMENT or EQUIPMENT parts shall be set up complete (or where necessary in parts). Covers used during transport and storage shall be detached.

This test shall be applied only to those EQUIPMENT parts likely to create a SAFETY HAZARD when influenced by the climatic conditions that are simulated by the test.

Parts which can be detached without the use of a TOOL shall be detached but shall be treated simultaneously with the major part.

Doors, drawers and ACCESS COVERS which can be opened or detached without the use of a TOOL shall be opened and detached.

The humidity preconditioning treatment shall be performed in a humidity cabinet containing air with a relative humidity of 93% ± 3%. The temperature of the air in the cabinet, at all places where EQUIPMENT can be located, shall be maintained within 2°C of any convenient value t in the range of +20°C to +32°C. Before being placed in the humidity cabinet, EQUIPMENT shall be brought to a temperature between t and t + 4°C, and kept at this temperature for at least 4 h before the humidity treatment.

EQUIPMENT and EQUIPMENT parts shall be kept in the humidity cabinet for:

– 2 days (48 h) for EQUIPMENT RATED IPX0 (non-protected);

– 7 days (168 h) for EQUIPMENT RATED IPX1 to IPX8.

After the treatment, the EQUIPMENT is reassembled, if necessary.

4.11 *Sequence*

It is recommended that all tests be performed in the sequence as given in Appendix C. The tests numbered C23 to C29 shall be performed in the specified sequence.

5 *Classification

EQUIPMENT and its APPLIED PARTS shall be classified by marking and/or identification as described in Clause 6. This includes:

5.1 *According to the type of protection against electric shock:

a) EQUIPMENT energized from an external electrical power source:

– CLASS I EQUIPMENT;

– CLASS II EQUIPMENT.

b) INTERNALLY POWERED EQUIPMENT.

5.2 According to the degree of protection against electric shock:

– TYPE B APPLIED PART;

– TYPE BF APPLIED PART;

– TYPE CF APPLIED PART.

5.3 According to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1 *l)*).

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:

– EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE;

– CATEGORY AP EQUIPMENT;

– CATEGORY APG EQUIPMENT.

5.6 According to the mode of operation:

– CONTINUOUS OPERATION;

– SHORT-TIME OPERATION;

– INTERMITTENT OPERATION;

– CONTINUOUS OPERATION WITH SHORT-TIME LOADING;

– CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

5.7 Not used.

5.8 Not used.

6 Identification, marking and documents

For the purpose of this clause the following meanings shall apply to identification and marking:

– Permanently affixed:

Removable with a TOOL only or by appreciable force and capable of complying with the requirements of Sub-clause 6.1.

– Clearly legible:

• for warning statements, instructive statements or drawings: affixed in a prominent location and legible with normal vision from the OPERATOR'S position.

• for FIXED EQUIPMENT: discernible when the EQUIPMENT is mounted in its position of NORMAL USE.

• for TRANSPORTABLE EQUIPMENT and for STATIONARY EQUIPMENT which is not FIXED EQUIPMENT: discernible in NORMAL USE or after dislodging the EQUIPMENT from a wall against which it has been positioned or after turning the EQUIPMENT from its position of NORMAL USE and in the case of dismountable rack units, after their removal from the rack.

– Major part:

• for warning statements on outside or inside surfaces of the EQUIPMENT: on or near the control panel or on or near a relevant part.

• for MODEL OR TYPE REFERENCE and all markings referring to the SUPPLY MAINS (power input, voltage, current, frequency, classification, mode of operation, etc.): usually on the outside of the part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point.

6DV D2 *Modification of 6 by adding 6DV.1 – 6DV.4:*

6DV.1 The text of the marking prefaced with an upper case signal word ″CAUTION″, ″WARNING″, or ″DANGER″, shall consist of upper and lower case letters, in English, that comply with the following:

a) All words comprising the text of the marking, excluding the signal word, shall be in letters not less than 1,6 mm (1/16 inch) high, based upon upper case,

b) The signal word shall be in letters at least 2,8 mm (7/64 inch),

c) The letters shall be in contrast color to the background. Letters that are raised or indented and do not have a contrasting color to the background are not acceptable.

6DV.2 EQUIPMENT capable of emitting ionizing radiation shall bear a warning statement concerning the risk of injury to persons from X-radiation. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: ″WARNING: This X-ray unit may be dangerous to PATIENT and OPERATOR unless safe exposure factors and operating instructions are observed.″

6DV.3 When a manufacturer produces or assembles EQUIPMENT at more than one factory, the EQUIPMENT shall have a distinctive marking – which may be in code – by means of which it may be identified as the product of a particular factory.

6DV.4 Multiple-voltage EQUIPMENT intended for permanent connection to the branch circuit shall be marked to indicate the particular voltage for which it is connected when shipped from the factory. The marking may be in the form of a paper tag or any other nonpermanent material.

6.1 *Marking on the outside of EQUIPMENT or EQUIPMENT parts*

a) Mains operated EQUIPMENT

Mains operated EQUIPMENT, including separable components thereof which have a MAINS PART, shall be provided at least 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.

Table II
Marking on the outside of EQUIPMENT

Requirements as specified in Sub-clauses	Subject	Mains operated EQUIPMENT (see Sub-clause 6.1*a)*)	INTERNALLY POWERED EQUIPMENT (see Sub-clauses 6.1*b)* and 14.5)	EQUIPMENT supplied from a specified power source (see Sub-clause 6.1*c)*)
6.1*e)*	Indication of origin	x	x	x
6.1*f)*	MODEL OR TYPE REFERENCE	x	x	x
6.1*g)*	Connection to the supply	x[2)]	–	–
6.1*h)*	Supply frequency (Hz)	x[2)]	–	–
6.1*j)*	Power input	x[2)]	–	–
6.1*k)*	Mains power output	x[1)]	–	–
6.1*l)*	Classification	x[1)]	x[1)]	x[1)]
6.1*m)*	Mode of operation	x[1)]	x[1)]	x[1)]
6.1*n)*	Fuses	x[1)]	x[1)]	x[1)]
6.1*p)*	Output	x[1)]	x[1)]	x[1)]
6.1*q)*	Physiological effects	x[1)]	x[1)]	x[1)]
6.1*r)*	CATEGORY AP/APG EQUIPMENT	x[1)]	x[1)]	x[1)]
6.1*s)*	HIGH VOLTAGE TERMINAL DEVICE	x[1)]	x[1)]	x[1)]
6.1*t)*	Cooling conditions	x[1)]	x[1)]	x[1)]
6.1*u)*	Mechanical stability	x[1)]	x[1)]	x[1)]
6.1*v)*	Protective packing	x[1)]	x[1)]	x[1)]
6.1*y)*	Earth terminals	x[1)]	x[1)]	x[1)]
6.1*z)*	Removable protective means	x[1)]	x[1)]	x[1)]

x Marking required.

[1)] If applicable.

[2)] Not for PERMANENTLY INSTALLED EQUIPMENT if marked on the inside. See also Sub-clause 6.2*a)*.

d) Minimum requirements for marking on EQUIPMENT and on interchangeable parts

If the size of the EQUIPMENT specified in Sub-clause 6.1 or the nature of its ENCLOSURE does not allow affixation of all specified markings, then at least the markings as indicated in Sub-clauses 6.1*e)*, 6.1*f)* and 6.1*g)* (not for PERMANENTLY INSTALLED EQUIPMENT), 6.1*l)* and 6.1*q)* (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 trade-mark of the manufacturer or supplier claiming that the EQUIPMENT complies with this Standard.

**f) MODEL OR TYPE REFERENCE*

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.

In the case of range limits which do not differ by more than 10% from the mean value, marking of the input at the mean value of the range is sufficient.

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.

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.

NOTE – EQUIPMENT of IPXO classification is not required to be marked as such.

– 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.

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).

DEFIBRILLATION-PROOF APPLIED PARTS shall be marked with the relevant symbols (see Appendix D, table DII, symbols 9, 10 and 11).

– 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).

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 by ISO or IEC Publication 417, shall be used. For non-ionizing radiation (for example, high-power microwaves), Symbol 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 Sub-clauses 6.8.3*d)* and 10.1 and ISO Publication R780).

Figure 33 – Maximum allowable voltage U_{zC} as a function of the capacity C_{max}, measured in a capacitive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).

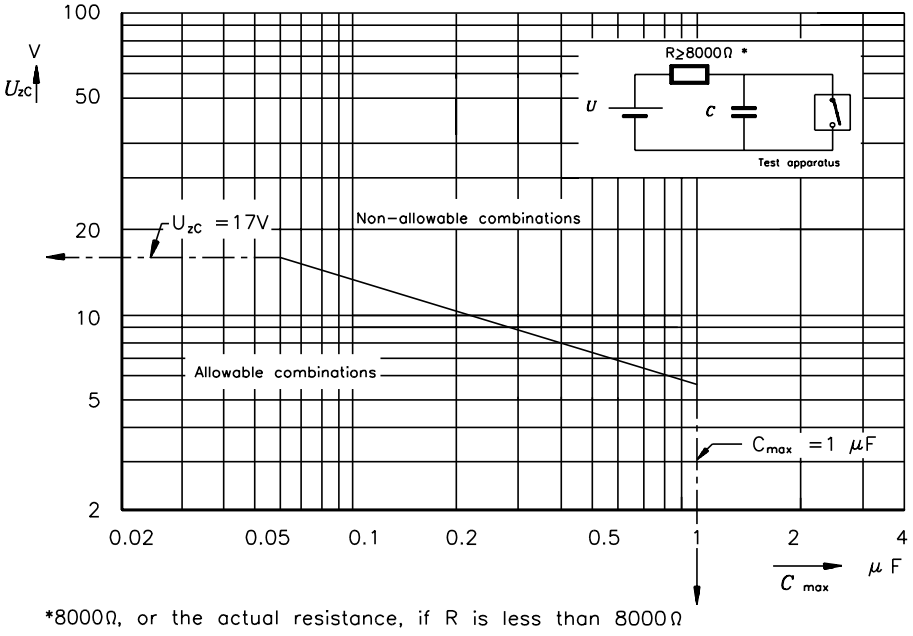

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Figure 34 – Maximum allowable current I_{zL} as a function of the inductance L_{max}, measured in an inductive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).

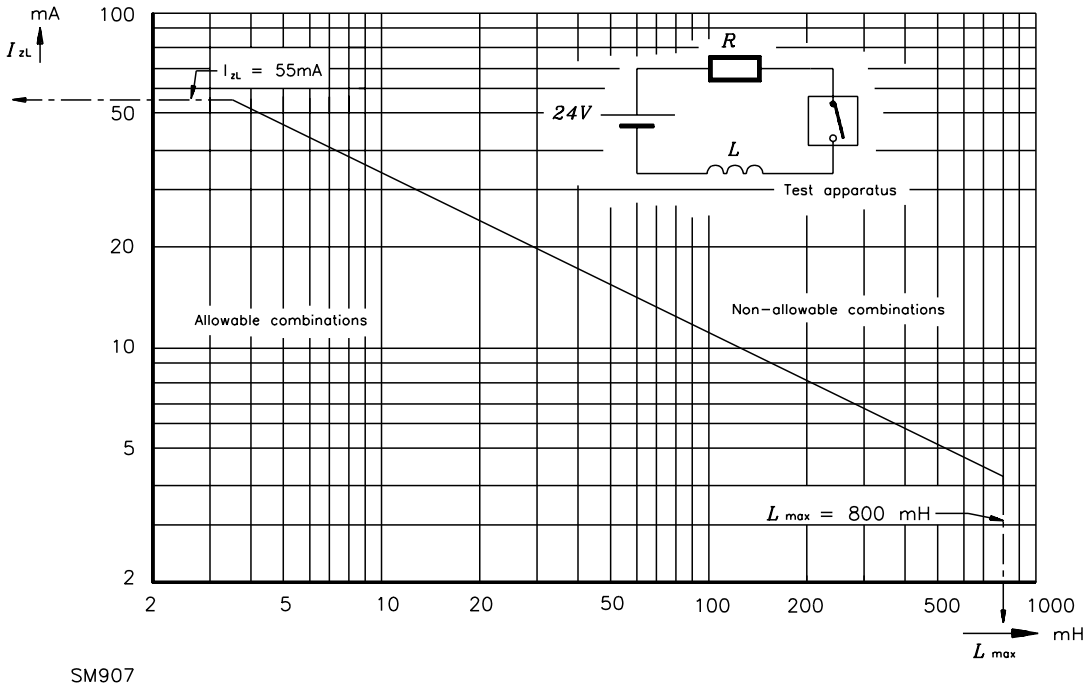

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Figure 35 – Not used.

Figure 36 – Not used.

Figure 37 – Not used.

Figure 38 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE (see Sub-clause 45.2).

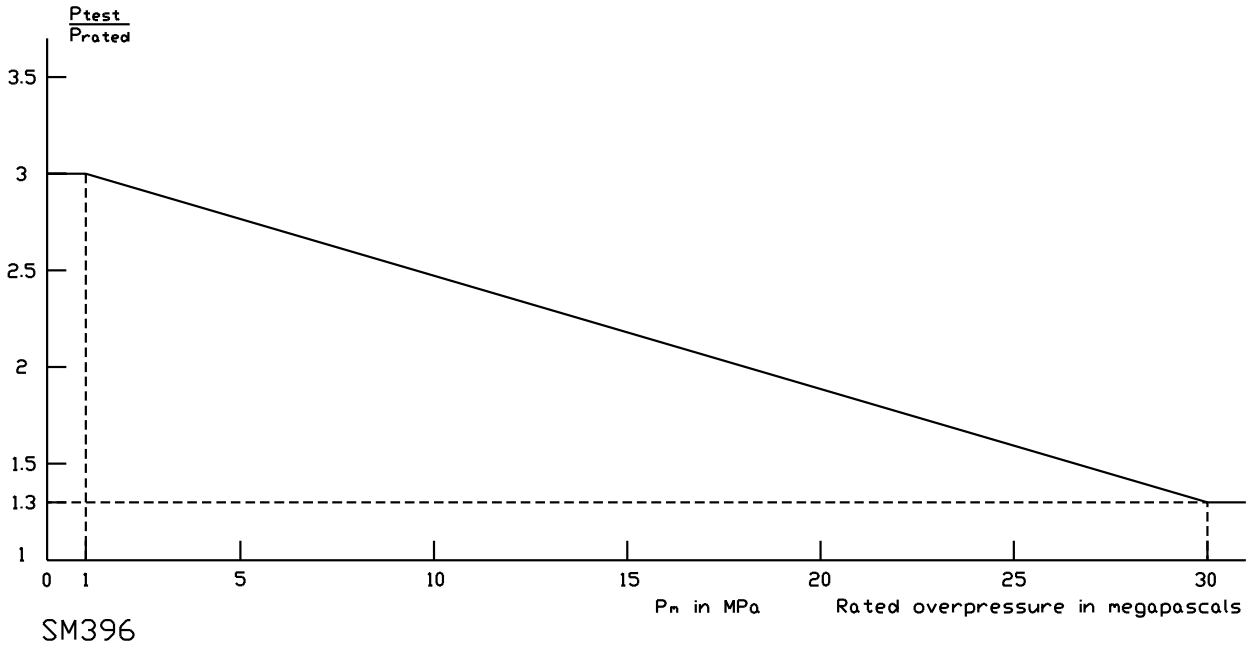
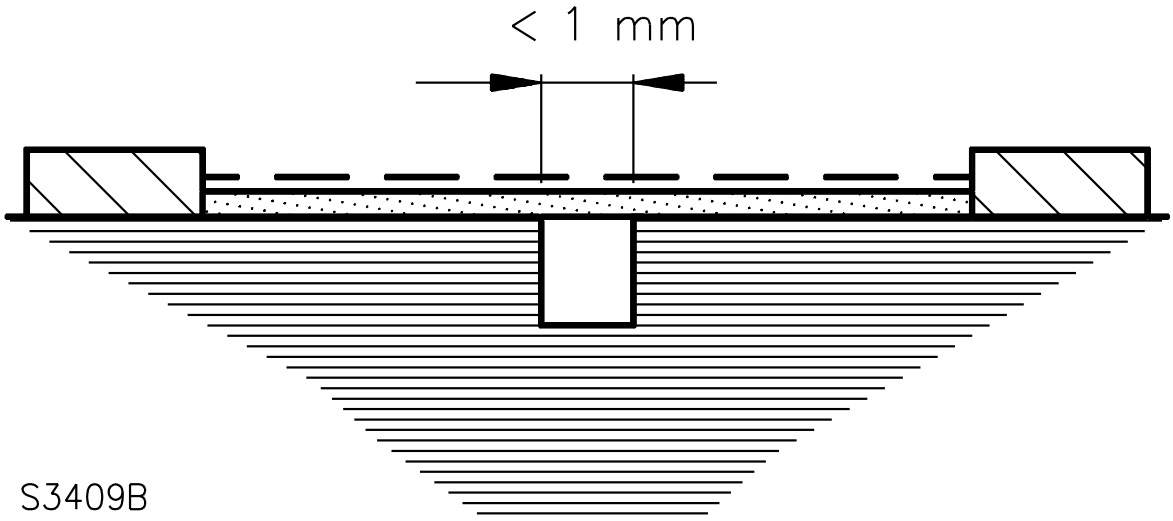
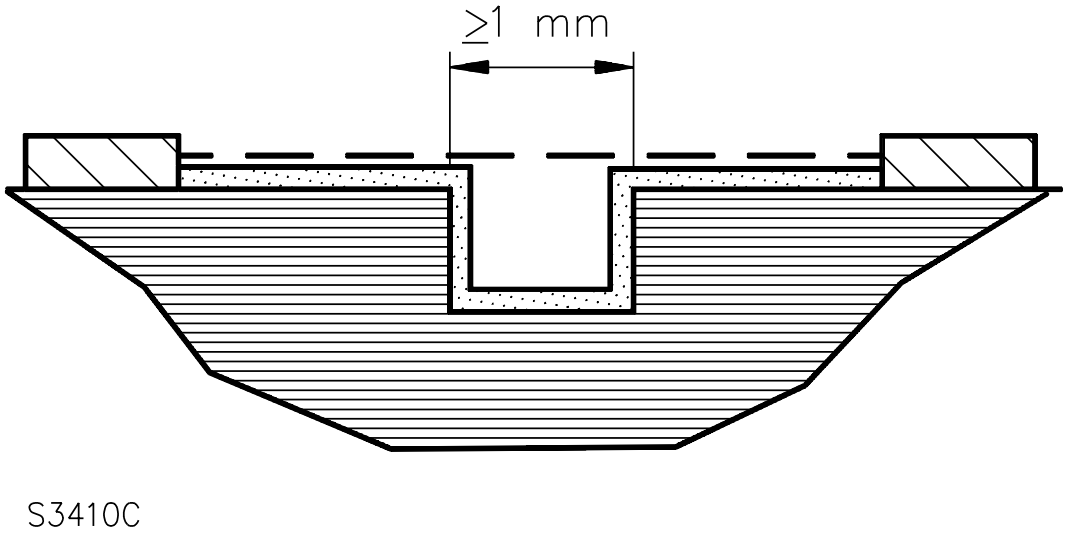


Figure 39 – Example 1 (see Sub-clause 57.10).



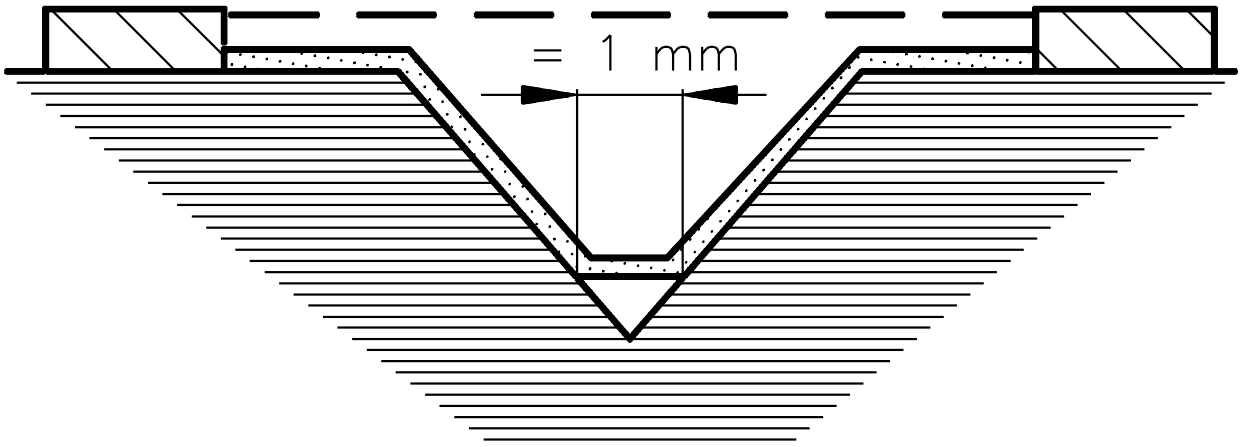
Condition:	Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than 1 mm.
Rule:	CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

Figure 40 – Example 2 (see Sub-clause 57.10).



Condition:	Path under consideration includes a parallel-sided groove of any depth and equal to or more than 1 mm.
Rule:	AIR CLEARANCE is the “line of sight” distance. Creepage path follows the contour of the groove.

Figure 41 – Example 3 (see Sub-clause 57.10).



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Condition: Path under consideration includes a V-shaped groove with a width greater than 1 mm.

Rule: AIR CLEARANCE is the “line of sight” distance. Creepage path follows the contour of the groove but “short-circuits” the bottom of the groove by a 1 mm link.

AIR CLEARANCE CREEPAGE DISTANCE

S3409C

APPENDIX A
GENERAL GUIDANCE AND RATIONALE*

A1 General Guidance

This general safety Standard for MEDICAL ELECTRICAL EQUIPMENT is necessary because of the particular relationship of such EQUIPMENT to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:

a) The inability of PATIENT or OPERATOR to detect the presence of certain potential hazards, such as ionizing or high-frequency radiation.

b) Absence of normal reactions of the PATIENT who may be ill, unconscious, anaesthetized, immobilized, etc.

c) Absence of normal protection to currents provided by the PATIENT'S skin, if this is penetrated or treated to obtain a low skin-resistance.

d) Support or replacement of vital body functions may depend on the reliability of EQUIPMENT.

e) The simultaneous connection to the PATIENT of more than one piece of EQUIPMENT.

f) Combination of high-power EQUIPMENT and sensitive low-signal EQUIPMENT often in ad hoc combinations.

g) The application of electrical circuits directly to the human body, either through contacts to the skin and/or through the insertion of probes into internal organs.

h) Environmental conditions, particularly in operating theatres, may present a combination of humidity, moisture and/or fire or explosion hazards caused by air, oxygen or nitrous oxide combined with anaesthetic media and cleaning agents.

*In the first edition Appendix A was entitled "Survey of medical electrical equipment." It has been deleted and replaced by the present appendix.

A1.1 Safety of MEDICAL ELECTRICAL EQUIPMENT, as described in IEC Publication 513, is part of the total safety situation, comprising safety of EQUIPMENT, safety of the installation in medically used rooms of medical establishments and safety of application.

Safety of EQUIPMENT is required for NORMAL USE and NORMAL CONDITION and for SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a safety aspect for life-supporting EQUIPMENT and where interruption of an examination or treatment is considered as a SAFETY HAZARD for the PATIENT.

Adequate construction and lay-out which serve to prevent human errors are regarded as safety aspects.

Safety precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function.

Generally it is presumed that EQUIPMENT is operated under the jurisdiction of qualified or licensed persons, that the OPERATOR has the skill required for a particular medical application and that he acts according to the instructions for use.

The total safety of EQUIPMENT may consist of:

– Protective precautions incorporated in the EQUIPMENT (unconditional safety).

– Additional protective precautions, such as the use of shields or protective clothing (conditional safety).

– Restriction in the instructions for use concerning transport, mounting and/or positioning, connection, putting in service, operation and the position of the OPERATOR and his assistants in relation to the EQUIPMENT during use (descriptive safety).

Generally, safety precautions are presumed to be applied in the order as described here. They may be attained by sound engineering (which includes knowledge of methods of production and environmental conditions during manufacture, transport, storage and use), by application of redundancy and/or by protective devices of a mechanical or electrical nature.

Reference to other publications is only made if such publications are of a general nature, that is, not restricted to particular EQUIPMENT types (see References in Appendix L). In other cases requirements and tests have been adopted unmodified or slightly modified, without quoting the source.

A1.2 *Guidance to the second edition*

In this second edition a number of clauses and sub-clauses from the first edition have been deleted as, e.g., when no test requirements are available or when it is indicated ″under consideration″.

In order to indicate the relevant subject the title is kept, so that Particular Standards may refer to this sub-clause.

The paragraphs concerning the content of Particular Standards have been moved from Clause 1 to this Appendix (A2 Sub-clause 1.3).

Specifications of environmental conditions formerly in Sub-clause 1.4 now appear as a requirement for EQUIPMENT in Clause 10, where it is stated that compliance with these requirements for operation is considered to have been checked by application of the test of this Standard.

The new specification of the scope (Sub-clause 1.1) refers to a new definition of MEDICAL ELECTRICAL EQUIPMENT which is considered to be more appropriate and more practical (see Sub-clause 2.2.15).

A new defined concept PROTECTIVELY EARTHED has been introduced.

The term SAFETY HAZARD and its definition will simplify referencing in the standard itself (see Sub-clause 2.12.18).

The standard now distinguishes between an OPERATOR of EQUIPMENT and a USER, who may be considered responsible for its proper application and maintenance (see Sub-clauses 2.12.17 and 2.12.13).

The sequence of Sub-clauses of Clause 14 was rationalized. Paragraphs which had been derived from IEC Publication 536 (1976) and which were of descriptive nature have been deleted.

The requirements for the separation between an APPLIED PART and LIVE parts were also applied to the separation between ACCESSIBLE PARTS and LIVE parts (see Clause 17). The PATIENT currents allowed where CREEPAGE DISTANCE and AIR CLEARANCES are less than the values in Sub-clause 57.10 were changed from the values for SINGLE FAULT CONDITION to those for NORMAL CONDITION.

The requirement in Sub-clause 18*e)* for a facility for connection of a POTENTIAL EQUALIZATION CONDUCTOR was withdrawn and replaced with requirements for the construction of such a connection if provided.

All references to an additional PROTECTIVE EARTH CONDUCTOR were deleted, because the protective function of such a conductor was no longer recognized.

The sequence of sub-clauses of Clause 18 was rationalized.

An appendix was added illustrating the connection of the APPLIED PART for measurement of the PATIENT LEAKAGE CURRENT and of the PATIENT AUXILIARY CURRENT (see Appendix K and Sub-clause 19.1*e)*).

The allowable ENCLOSURE LEAKAGE CURRENT for EQUIPMENT with a TYPE CF APPLIED PART in NORMAL CONDITION was changed from 0,01 mA to 0,1 mA.

EQUIPMENT with a high EARTH LEAKAGE CURRENT due to compliance with requirements for radio-interference suppression was recognized.

Sub-clauses 19.4*a)* and 20.4*a)* were changed.

A true r.m.s. meter was recognized as a suitable instrument for LEAKAGE CURRENT measurements.

Clause 20 was rearranged in a number of ways:

– The requirements for the insulation between the MAINS PART and other parts were extended to include all LIVE parts, but restricted to cases where a SAFETY HAZARD would develop.

– For each particular insulation a statement was added to clarify that such insulation would be BASIC, SUPPLEMENTARY, DOUBLE or REINFORCED INSULATION.

– As a result all references to the Class of EQUIPMENT (I, II, INTERNALLY POWERED) could be deleted and Tables V, VI and VII replaced by one new much simplified Table V. Test voltages for reference voltages of more than 10 000 V were referred to Particular Standards.

– The insulation between an F-TYPE APPLIED PART and the ENCLOSURE of the EQUIPMENT was reviewed to distinguish the case where such an APPLIED PART would contain voltages which would make the PATIENT LIVE when the insulation would become defective (see new categories B-d and B-e).

– Sub-clauses 20.1, 20.2, 20.3 and 20.4 were rearranged to include exclusively all statements pertaining to their titles.

– The new version of Clause 20 has led to an important simplification of Sub-clause 57.10 in Section Ten (AIR CLEARANCES and CREEPAGE DISTANCES).

A1.3 *Protection against electric shock hazards*

Protection against electric shocks caused by currents not resulting from the specified physical phenomena of EQUIPMENT may be obtained by a combination of the following measures:

– prevention of contact between the body of the PATIENT, the OPERATOR, or a third person and parts which are LIVE or may become LIVE in the case of an insulation failure, by means of enclosing, guarding or mounting in inaccessible locations;

– restriction of voltages on or currents from parts which may be touched intentionally or unintentionally by the PATIENT, the OPERATOR or a third person. These voltages or currents may be present during NORMAL USE or may appear in SINGLE FAULT CONDITION.

Generally, this protection is obtained by a combination of:

– limitation of voltage and/or energy, or protective earthing (see Clauses 15 and 18);

– enclosing and/or guarding of LIVE parts (see Clause 16);

– insulation of adequate quality and construction (see Clause 17).

The value of electric current flowing in the human or animal body which may cause a certain degree of stimulation varies from individual to individual, according to the way in which the connection to the body is made and according to the frequency of the current applied and its duration.

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation. For currents of medium or high frequency, the risk of electric shock is less or negligible, but the risk of burning remains.

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the EQUIPMENT, leads to a system of classification reflecting the degree and quality of protection provided by the APPLIED PARTS (classified as TYPES B, BF and CF APPLIED PARTS). TYPES B and BF APPLIED PARTS are generally suitable for applications involving external or internal contact with the PATIENT, excluding the heart. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATIONS.

In conjunction with this classification, the requirements for allowable LEAKAGE CURRENT have been formulated. The absence of sufficient scientific data concerning the sensitivity of the human heart for currents causing ventricular fibrillation still presents a problem.

Nevertheless, engineers are provided with data enabling them to design EQUIPMENT; so, for the time being, the requirements represent what is considered reasonably safe.

The requirements for LEAKAGE CURRENT were formulated taking into account:

a) that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters;

b) that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, and

c) that values for NORMAL CONDITION are necessary to create a safe condition in all situations by providing a sufficiently high SAFETY FACTOR with respect to SINGLE FAULT CONDITIONS.

The measurement of LEAKAGE CURRENTS has been described in a way which enables the use of simple instruments, avoiding different interpretations of a given case and indicating possibilities for periodic checking by the USER (to be described in the Application Code).

The dielectric strength requirements are included to check the quality of the insulation material used at different places in the EQUIPMENT.

A1.4 *Protection against mechanical hazards*

Requirements in Section Four are divided into one part describing SAFETY HAZARDS caused by damage or deterioration of EQUIPMENT (mechanical strength) and several parts describing hazards of a mechanical nature caused by EQUIPMENT (injury by moving parts, by rough surfaces, by sharp edges and corners, by instability, by expelled parts, by vibration and noise and by breakdown of PATIENT supports and of suspension means for EQUIPMENT parts).

EQUIPMENT may become unsafe because of parts damaged or deteriorated by mechanical stresses such as blows, PRESSURES, shocks, vibration, by ingress of solid particles, dust, fluids and moisture and aggressive gases, by thermal and dynamic stresses, by corrosion, by loosening of fastenings of a moving part or a suspended mass and by radiation.

Effects of mechanical overloads, material failure or wear can be avoided by:

– means which interrupt or render non-hazardous the operation or the energy-supply (for example, fuses, PRESSURE valves) as soon as overloading occurs;

– means which guard against or catch flying or falling parts (caused by material failures, wear or overload) which may constitute a SAFETY HAZARD.

Protection against breakdown of PATIENT supports and suspensions can be provided by redundancy or the provision of safety catches.

EQUIPMENT parts which are intended to be held in the hand or positioned on a bed must be sufficiently robust to withstand a fall. They may be subject to vibration and shocks, not only when transported but also when used in vehicles.

A1.5 *Protection against hazards from unwanted or excessive radiation*

Radiation from MEDICAL ELECTRICAL EQUIPMENT may occur in all forms known in physics. Safety requirements are concerned with unwanted radiation. Protective measures are necessary for EQUIPMENT and for the environment and methods for determining levels of radiation must be standardized.

Limits for EQUIPMENT may have to be exceeded for the intended application, where the medical supervisor takes the responsibility. For ionizing radiation IEC requirements generally comply with ICRP Recommendations. Their purpose is to provide data which are immediately usable by designer and USER.

Their evaluation is possible only by adequate study of operating methods and duration of operation of EQUIPMENT and positioning of OPERATOR and assistants, because application of worst case conditions would give rise to situations which might hamper proper diagnosis or treatment.

Recent ICRP publications also instruct the OPERATOR in methods for the restriction of intentional irradiation.

A1.6 *Protection against hazards of ignition of flammable anaesthetic mixtures*

A1.6.1 *Applicability*

Where EQUIPMENT is used in areas in which flammable anaesthetics and/or flammable agents for disinfection and/or skin cleaning are applied, an explosion risk may exist if such anaesthetics or agents are mixed with air, or with oxygen or nitrous oxide.

Ignition of such a mixture may be caused by sparks or by contact with parts having a high surface temperature.

Sparks may be caused where electrical circuits are opened or closed by operation of switches, connectors, fuses or OVER-CURRENT RELEASES and the like.

In HIGH VOLTAGE parts sparks may be caused by corona. Static discharges may cause sparks.

The probability of ignition of such anaesthetic mixtures depends on their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures and the energy of sparking.

The hazard caused by an ignition depends on the location and on the relative quantity of the mixture.

A1.6.2 *Industrial EQUIPMENT and components*

The constructional requirements of IEC Publication 79 are generally not appropriate for MEDICAL ELECTRICAL EQUIPMENT for several reasons:

a) they lead to constructions of a size, weight or design which are not applicable for medical reasons and/or which may not be sterilizable;

b) some constructions allow an explosion inside an ENCLOSURE, but prevent propagation outside it. Such a construction which may be inherently safe would be unacceptable in an operating theatre where continuity of operation of EQUIPMENT is essential;

c) industrial requirements were made for flammable agents mixed with air. They cannot be applied to mixtures with oxygen or nitrous oxide used in medical practice;

d) in medical practice flammable anaesthetic mixtures occur only in relatively small quantities.

However some of the constructions described in IEC Publication 79 are acceptable for CATEGORY AP EQUIPMENT (see Sub-clause 40.1).

A1.6.3 *Requirements for MEDICAL ELECTRICAL EQUIPMENT*

The location of flammable anaesthetic mixtures is described:

– as much as necessary for the construction of EQUIPMENT in Clause 37 of this Standard, as minimum for specified conditions of exhaust and absorption;

– as much as necessary for the allocation of EQUIPMENT and the construction of the electrical installation in IEC Publication 364.

That standard additionally provides information on flammable concentrations of a number of flammable agents, their usual application concentrations, ignition temperatures, lowest ignition energy and flash-points. Requirements for ventilation and exhaust of areas, maintenance of a minimum relative humidity and permission to use certain EQUIPMENT types in certain areas may be subject to local (hospital) or national and possibly legal regulations.

The requirements, limits and tests of this section are based on the results of statistical considerations obtained from experiments with the most readily flammable mixtures of ether vapour with air and with oxygen, using the test apparatus described in Appendix F. This is justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

Where temperatures or circuit parameters of EQUIPMENT used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR exceed allowable limits and sparking cannot be avoided the relevant parts and circuits can be enclosed in ENCLOSURES with pressurized inert gas or clean air or in ENCLOSURES with restricted breathing.

ENCLOSURES with restricted breathing delay the build-up of an ignitable concentration. They are recognized because it is assumed that a period in which EQUIPMENT is used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR is followed by a period of ventilation during which such a concentration will disappear.

For EQUIPMENT containing or used in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, requirements, limits and tests are far more stringent.

Requirements apply not only to NORMAL CONDITION but, additionally, in the SINGLE FAULT CONDITION, as indicated in Sub-clause 3.6. Only two exemptions from an actual ignition test are recognized, these being either the absence of sparks and limited temperature or limited temperature and restricted circuit parameters.

A1.7 *Protection against excessive temperatures and other SAFETY HAZARDS*

– Temperatures (see Clause 42)

Temperature limits are required to prevent hazards for almost all types of electrical EQUIPMENT with the purpose of preventing rapid ageing of insulation and discomfort where EQUIPMENT is touched or manipulated, or injuries where PATIENTS may contact EQUIPMENT parts.

EQUIPMENT parts may be inserted into body cavities, usually temporarily but sometimes permanently.

For PATIENT contact, special temperature limits have been set.

– Preventing fire hazard (see clause 43)

Except for CATEGORY AP and CATEGORY APG EQUIPMENT prevention of the fire hazard of MEDICAL ELECTRICAL EQUIPMENT may be subject to requirements in Particular Standards.

The normal limits for operating temperatures and requirements for overload protection are applicable.

– PRESSURE vessels (see clause 45)

Attention is drawn to the requirements dealing with PRESSURE vessels and parts subject to PRESSURE, where no local regulations are available.

– Interruption of the power supply (see clause 49)

Interruption of the power supply may cause a SAFETY HAZARD.

A1.8 *Accuracy of operating data and protection against incorrect output*

IEC Publication 60601-1 is the guideline for all Particular Standards and must therefore contain some requirements of a more general character in order to serve this purpose. So it is necessary to have some generally formulated requirements in Section Eight.

It is also, for the time being, and for several reasons, impossible to provide standards, even urgently needed, for a number of kinds of MEDICAL ELECTRICAL EQUIPMENT.

Standardization bodies, including those outside IEC, have taken over the system of this IEC Publication in order to have an unique system of standards. In such cases it is most important to give a guideline in this section as a help towards ″functional″ PATIENT safety.

A1.9 *Abnormal operation and fault conditions; environmental tests*

EQUIPMENT or parts of EQUIPMENT may cause, due to abnormal operation, excessive temperatures or other SAFETY HAZARDS. Therefore these abnormal operations or fault conditions must be investigated.

A1.10 *APPLIED PARTS and ENCLOSURES – General*

Parts which are intended to contact PATIENTS can present greater hazards than other parts of the ENCLOSURE, and these APPLIED PARTS are therefore subject to more stringent requirements, for example, for temperature limits and (according to classification B/BF/CF) for LEAKAGE CURRENT.

NOTE – Other ACCESSIBLE PARTS of the ENCLOSURES of MEDICAL ELECTRICAL EQUIPMENT are subject to tests which are more demanding than those for ENCLOSURES of other kinds of EQUIPMENT, because the PATIENT may touch them, or the OPERATOR may touch them and the PATIENT simultaneously.

In order to determine which requirements apply, it is necessary to distinguish between APPLIED PARTS and parts which are simply considered as the ENCLOSURE. However there can be difficulties in doing this, especially with parts which can be expected to contact the PATIENT on some occasions but do not have to do so for the EQUIPMENT to perform its function.

The distinction between ENCLOSURES and APPLIED PARTS is made according to two criteria. Firstly, if contact is essential for the NORMAL USE of the EQUIPMENT, the part is subject to the requirements for APPLIED PARTS.

If contact is incidental to the functioning of the EQUIPMENT, the part is categorized according to whether contact results from deliberate action by the PATIENT or by the OPERATOR. Where contact is incidental and results from action by the PATIENT, the PATIENT is in most respects no more at risk than any other person, so the requirements for ENCLOSURES are sufficient.

In order to assess which parts are APPLIED PARTS, PATIENT CONNECTIONS and PATIENT CIRCUITS, the following process is employed in the order shown:

a) Determine whether the EQUIPMENT has an APPLIED PART and if it has, identify the extent of the APPLIED PART (these decisions being based on non-electrical considerations).

b) If there is no APPLIED PART, there are no PATIENT CONNECTION(S) or PATIENT CIRCUIT(S).

c) If there is an APPLIED PART, there may be one or more PATIENT CONNECTION(S). Where a conductive part of the APPLIED PART is not in direct contact with the PATIENT, but is not isolated and current can flow through such a part to or from the PATIENT, it is to be treated as an individual PATIENT CONNECTION.

d) The PATIENT CIRCUIT then consists of these PATIENT CONNECTION(S) and any other conductive parts from which they are inadequately insulated/segregated.

NOTE – Relevant separation requirements are those which relate to APPLIED PARTS and are necessary to comply with the dielectric strength tests in clause 20, and the CREEPAGE DISTANCE and AIR CLEARANCE requirements in subclause 57.10.

A2 Rationale to particular clauses and sub-clauses

Clause

1 Particular Standards can in further sub-clauses specify the particular subject and it should be quite clear as to what is being referred to in the General Standard and in the Particular Standard.

Only such laboratory EQUIPMENT is included in the scope of this Standard which is related to the PATIENT in such a way that the PATIENT'S safety can be influenced.

Laboratory EQUIPMENT within the scope of IEC SC 66E is not covered by this Standard.

Combinations of EQUIPMENT developed by the USER may not conform to this Standard even if they are composed of EQUIPMENT that, taken separately, satisfy the requirements of this Standard.

Sub-clause

1.3 A Particular Standard may state:

– clauses of the General Standard which apply without amendment;

– clauses or sub-clauses (or parts of them) of the General Standard which do not apply;

– clauses or sub-clauses (or parts of them) of the General Standard which are replaced by a clause or a sub-clause in a Particular Standard;

– any additional clauses or sub-clauses.

A Particular Standard may contain:

a) requirements which result in an increased degree of safety;

b) requirements which may be less stringent than the requirements in this General Standard, if the latter cannot be maintained because of, for example, the power output of EQUIPMENT;

c) requirements concerning performance, reliability, interfaces, etc.;

d) accuracy of working data;

e) extension and limitation of environmental conditions.

Subclause

2.1.5 This General Standard includes a definition for APPLIED PART which, in most cases, clearly establishes which parts of the EQUIPMENT need to be treated as APPLIED PARTS and comply with more stringent requirements than those for ENCLOSURES.

Excluded are those parts which are only likely to be contacted following an unnecessary action by the PATIENT. Thus:

– An infrared therapy lamp does not have an APPLIED PART because it does not need to be brought into direct contact with the PATIENT.

– The only part of an X-ray table which is an APPLIED PART is the top on which the PATIENT lies.

– Likewise, in an MRI scanner, the only APPLIED PARTS are the table supporting the PATIENT and any other parts which must be brought into direct contact with the PATIENT.

This definition may not always clearly establish whether an individual part of a particular item of EQUIPMENT is an APPLIED PART. Such cases need to be considered on the basis of the above rationale, or by reference to the Particular Standards which should specifically identify the APPLIED PART(S) in particular types of EQUIPMENT.

Subclause

2.1.15 Where APPLIED PARTS have PATIENT CONNECTIONS, these should be adequately separated from specified LIVE parts within the EQUIPMENT and, in the case of TYPE BF and TYPE CF APPLIED PARTS, from earth. Testing of the dielectric strength of the insulation involved, and assessment of CREEPAGE DISTANCE and AIR CLEARANCE are used to verify compliance with these criteria.

The definition of the PATIENT CIRCUIT is intended to identify all the parts of the EQUIPMENT which can readily provide current to, or receive it from, the PATIENT CONNECTION(S).

For an F-TYPE APPLIED PART the PATIENT CIRCUIT extends as seen from the PATIENT into the EQUIPMENT to the point(s) where the prescribed insulation and/or protection impedance is completed.

For a TYPE B APPLIED PART, the PATIENT CIRCUIT may be connected to protective earth.

Subclause

2.1.23 One of the potential hazards associated with the application of an APPLIED PART is the fact that LEAKAGE CURRENT may flow through the PATIENT via the APPLIED PART. Particular limits are placed on the magnitude of these currents, both in the NORMAL CONDITION and in various fault conditions.

NOTE – The current which flows through the PATIENT, between various parts of the APPLIED PART, is known as PATIENT AUXILIARY CURRENT. The LEAKAGE CURRENT which flows through the PATIENT to earth is known as PATIENT LEAKAGE CURRENT.

The definition of PATIENT CONNECTION is intended to ensure the identification of each individual part of the APPLIED PART between which current may flow as PATIENT AUXILIARY CURRENT, and from which PATIENT LEAKAGE CURRENT may flow into an earthed PATIENT.

In some cases it will be necessary to carry out PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT measurements to determine which parts of the APPLIED PARTS are individual PATIENT CONNECTIONS.

PATIENT CONNECTIONS are not always accessible to touch. Any conductive parts of the APPLIED PART which come into electrical contact with the PATIENT, or which are prevented from doing so only by insulation or air gaps which do not comply with the relevant dielectric strength tests or AIR CLEARANCE and CREEPAGE DISTANCE requirements specified in this standard, are PATIENT CONNECTIONS.

Examples include the following:

– A table top supporting a PATIENT is an APPLIED PART. Sheets do not provide adequate insulation and the conductive parts of the table top would therefore be classified as PATIENT CONNECTIONS.

– The administration set or needle of an infusion controller is an APPLIED PART. Conductive parts of the controller separated from the (potentially conducting) fluid column by inadequate insulation would be PATIENT CONNECTIONS.

Where an APPLIED PART has a surface of insulating material, subclause 19.4 *h) 9)* specifies that it is tested using foil or saline solution. This is then considered as a PATIENT CONNECTION.

Subclause

2.1.24 TYPE B APPLIED PARTS provide the lowest degree of PATIENT protection of all the types of APPLIED PART and are not suitable for DIRECT CARDIAC APPLICATION.

Subclause

2.1.25 TYPE BF APPLIED PARTS provide a degree of PATIENT protection higher than provided by TYPE B APPLIED PARTS. This degree of protection is achieved by isolation from earthed parts and other ACCESSIBLE PARTS of the EQUIPMENT, thus limiting the magnitude of current that would flow through the PATIENT in the event of the PATIENT contacting other LIVE EQUIPMENT.

However, TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

Subclause

2.1.26 TYPE CF APPLIED PARTS provide the highest degree of PATIENT protection. This degree of protection is achieved by increased isolation from earthed parts and other ACCESSIBLE PARTS of the EQUIPMENT, further limiting the magnitude of possible current flow through the PATIENT. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION.

Subclause

2.1.27 A DEFIBRILLATION-PROOF APPLIED PART is protected only against discharges of defibrillators designed in accordance with IEC 601-2-4. Sometimes defibrillators of other construction are used in hospitals, e.g. defibrillators with higher voltages and pulses. Such defibrillators may also damage DEFIBRILLATION-PROOF APPLIED PARTS.

Sub-clause

2.3.2 This definition does not necessarily include insulation used exclusively for functional purposes.

Sub-clause

2.3.4 BASIC INSULATION and SUPPLEMENTARY INSULATION can, if required, be tested separately.

Sub-clause

2.3.7 The term ″insulation system″ does not imply that the insulation must be one homogeneous piece. It may comprise several layers which cannot be tested separately as SUPPLEMENTARY or BASIC INSULATION.

Sub-clause

2.4.3 This definition is based on IEC Publications 364-4-41 and 536.

Sub-clause

2.5.4 This is distinct from what was formerly referred to as ″PATIENT functional current″ which is intended to produce a physiological effect, for example, current necessary for nerve and muscle stimulation, cardiac pacing, defibrillation, high-frequency surgical procedures.

Subclause

2.6.4 In MEDICAL ELECTRICAL EQUIPMENT functional earth connections may be made by means of a FUNCTIONAL EARTH TERMINAL which is accessible to the OPERATOR. Alternatively this Standard also allows a functional earth connection for CLASS II EQUIPMENT via a green and yellow conductor in a POWER SUPPLY CORD. In this case the parts concerned have to be insulated from ACCESSIBLE PARTS (see subclause 18 *l)*).

Sub-clause

2.7.6 Cord sets are covered by IEC Publication 320.

Sub-clause

2.11.2 The MAXIMUM PERMISSIBLE WORKING PRESSURE is decided by a competent person, taking into account the original design specification, the manufacturer's rating, the current condition of the vessel and the circumstances of use.

In some countries, the figure may be reduced from time to time.

Sub-clause

2.12.2 The MODEL OR TYPE REFERENCE is intended to establish its relationship to commercial and technical publications, to ACCOMPANYING DOCUMENTS and between separable parts of EQUIPMENT.

Sub-clause

3.6 As stated in Sub-clause 3.1 EQUIPMENT is required to remain safe in SINGLE FAULT CONDITION. Thus one fault of a single protective means is allowed.

The probability of simultaneous occurrence of two single faults is considered small enough to be negligible.

This condition can only be relied upon if either:

a) the probability of a single fault is small, because of sufficient design reserve, or the presence of a double protection prevents the development of a first single fault, or

b) a single fault causes operation of a SAFETY DEVICE (e.g. a fuse, OVER-CURRENT RELEASE, safety catch, etc.) which prevents occurrence of a SAFETY HAZARD, or

c) a single fault is discovered by an unmistakable and clearly discernible signal which becomes obvious to the OPERATOR, or

d) a single fault is discovered and remedied by periodic inspection and maintenance which is prescribed in the instructions for use.

Non-exclusive examples of the categories *a)* to *d)* are:

a) REINFORCED or DOUBLE INSULATION;

b) CLASS I EQUIPMENT in case of a fault in BASIC INSULATION;

c) Abnormal indications of displays, defect in a redundant suspension cord causing excessive noise or friction;

d) Deterioration of a flexible protective earth connection which is moved in NORMAL USE.

Sub-clause

3.6 c)

The appearance of an external voltage on an F-TYPE APPLIED PART (which may be conductively connected to a SIGNAL INPUT PART or to a SIGNAL OUTPUT PART) would have to be caused by a double failure of protective means in other EQUIPMENT, simultaneously connected to the PATIENT and complying with this Standard, or by a single failure of protective means in EQUIPMENT not complying with this Standard. As such this condition is very unlikely in good medical practice.

However, since the main safety feature of EQUIPMENT with an F-TYPE APPLIED PART is that the PATIENT is not earthed by the connection to the EQUIPMENT, the electrical separation of an F-TYPE APPLIED PART from earth must have a minimum quality. This is assured by the requirement that, even if a hypothetical voltage of supply frequency and equal to the highest supply voltage to earth present in the PATIENT'S environment would appear on the APPLIED PART, the limit for the PATIENT LEAKAGE CURRENT would not be exceeded.

In this hypothetical case the PATIENT is supposed not to be connected to the APPLIED PART.

Clause

4 In EQUIPMENT there may be many pieces of insulation, components (electrical and mechanical) and constructional features in which a failure would not produce a SAFETY HAZARD to PATIENT, OPERATOR or surroundings, even though causing a deterioration in or a failure of performance of EQUIPMENT.

Sub-clause

4.1 In order to ensure that every individually produced item of EQUIPMENT conforms to this Standard, the manufacturer and/or installer should carry out such measures during manufacture and/or installation assembly as to ensure that each item satisfies all requirements even if it is not completely tested individually during manufacture or installation.

Such measures may take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests may not be identical with type tests, but may be adapted to manufacturing conditions and possibly invoking less risk for the quality of the insulation or other characteristics important for safety.

Production tests would, of course, be restricted to setting (possibly derived from type tests) which would provoke the worst case situation.

Depending upon the nature of EQUIPMENT, production methods and/or tests may concern critical insulation of the MAINS PART, of the APPLIED PART and the insulation and/or the separation between these parts.

Suggested test parameters could be LEAKAGE CURRENT and dielectric strength.

Where applicable, the continuity of protective earthing may be a major test parameter.

Sub-clause

4.3 Whether a sample is representative is decided by the test laboratory and the manufacturer.

Sub-clause

4.8 The aim is to verify that EQUIPMENT is operating properly.

Sub-clause

4.10

a) The humidity preconditioning treatment and subsequent tests of MEDICAL ELECTRICAL EQUIPMENT are often performed in laboratories suitable for treatment and tests for household and similar electrical appliances.

To avoid unnecessary investments and costs for such laboratories, preconditioning treatments and tests should be aligned as far as is feasible.

b) According to IEC 529, the ENCLOSURE of EQUIPMENT RATED IPX8 prevents, under stated conditions, the entry of an amount of water where its presence could cause a SAFETY HAZARD.

The test condition as well as the acceptable amount and location of water are to be defined in Particular Standards. If no ingress of water is tolerated (sealed ENCLOSURES) the application of the humidity preconditioning treatment is inappropriate.

Parts sensitive to humidity, normally used in controlled environments and which do not influence safety, need not be subjected to this test. Examples are: high-density storage media in computer-based systems, disc and tape drives, etc.

c) To prevent condensation when EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet must be equal to or slightly lower than the temperature of the EQUIPMENT when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of +20°C to +32°C and then ″stabilized″ at the initial

value. Although the effect of the cabinet temperature on the degree of absorption of humidity is recognized, it is felt that the reproducibility of test results is not impaired substantially and the cost-reducing effect is considerable.

d) DRIP-PROOF EQUIPMENT and SPLASH-PROOF EQUIPMENT may be used in an environment where the humidity is higher than the humidity of the environment in which ordinary EQUIPMENT is used.

Therefore such EQUIPMENT is kept in the humidity cabinet for 7 days (see Sub-clause 4.10, 7th paragraph).

Clause

5 EQUIPMENT may have a multiple classification.

Sub-clause

5.1 The safety of Class III EQUIPMENT is critically dependent on the installation and on other Class III EQUIPMENT connected thereto. These factors are outside the control of the OPERATOR and this is considered to be unacceptable for MEDICAL ELECTRICAL EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure safety of the PATIENT. For these reasons this Standard does not recognize Class III EQUIPMENT in this second edition.

Sub-clause

6.1 f)

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it may possible not denote the exact construction, including the applied components and materials. If this is required, the MODEL OR TYPE REFERENCE may have to be supplemented by a SERIAL NUMBER. The SERIAL NUMBER may also be used for other purposes.

Indication of a manufacturing series only may not be sufficient if local requirements require individual identification.

Subclause

6.1 n)

For fuses in accordance with IEC 127, the marking of the type and rating should be in accordance thereto. Examples of marking: T 315L or T 315mAL, F 1,25H or F 1,25AH.

Sub-clause

6.1 z)

The rubbing test is performed with distilled water, methylated spirit and isopropyl alcohol.

Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms:

C_3H_8O (MW60.1) – Propanol. Isopropyl alcohol. A clear colourless liquid with a characteristic odour, mixable with water and with alcohol. It has a relative density of 0,785 at 20 °C, boiling point 82,5 °C at 1013 hPa.