

AS/NZS 3200.1.0:1998

Australian/New Zealand Standard™

Medical electrical equipment

**Part 1.0: General requirements
for safety—Parent Standard**

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AS/NZS 3200.1.0:1998

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 Australasian Society for Ultrasound in Medicine
 Australian Dental Association
 Australian Institute of Radiography
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AS/NZS 3200.1.0:1998

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Medical electrical equipment

Part 1.0: General requirements for safety—Parent Standard

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PREFACE

This Standard is issued by Committee HE/3, Medical Electrical Equipment as a Joint Australian/New Zealand Standard to supersede AS 3200.1.0—1990/NZS 6150:1990, which now becomes AS/NZS 3200.1.0, *Medical electrical equipment, Part 1.0: Particular requirements for safety—Parent Standard*.

This General Standard is based on and reproduced from IEC 60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety*, including Amendment 1:1991, Amendment 2:1995 and Corrigendum:1995, and also includes a ZZ appendix for variations applicable in Australia and New Zealand. The amendments to IEC 60601-1 are indicated with a marginal bar against the relevant clause, note, table or figure. The General Standard is the Parent Standard for a series of Standards on the safety of electrical equipment.

This General Standard (AS/NZS 3200.1.0) details electrical safety requirements for all types of medical electrical equipment. A Particular Standard (the AS/NZS 3200.2.XX series) details additional safety requirements for a related group of medical electrical devices. A Collateral Standard (the AS/NZS 3200.1.XX series) details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

In the text of this Standard, the following print types are used.

- (a) Requirements, compliance with which can be tested and definitions
..... in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
..... in smaller roman type
- (c) Headings of sub-clauses and text specifications in italic type
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

* An asterisk is placed before each Clause for which rationale is included in Appendix A.

The objective of this revision is to incorporate AS 3200.1.0, Amendment 1:1992, Amendment 2:1995 and Amendment 3:1998 as a consolidated Joint Australian/New Zealand Standard. The title has been changed but the requirements are unchanged apart from being presented differently for the convenience of the reader.

This Standard requires reference to IEC, ISO and Australian/New Zealand Standards. These are listed in Appendix L.

IEC has decided to apply a new numbering system, the 60000 series, to all its existing and future publications, including amendments to existing Standards. As a consequence, IEC has modified the bibliographic references in its databases to accord with the new numbering system. All IEC publications issued since the beginning of 1997 will carry references in terms of the 60000 series numbering. Publications printed earlier than 1997 will continue to carry the old series of numbers. For example, a reference to the IEC 60598 series of Standards will be to IEC 598 if the current edition of the Standard was printed prior to 1997.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian and New Zealand Standard
Medical electrical equipment

Part 1.0: General requirements for safety—Parent Standard

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.

1.2 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.

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.

† The defined terms are alphabetically listed in the Index on page 348.

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.

2.1.19 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 1000 V a.c. or over 1500 V d.c. or 1500 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 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 Subclause 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).

2.11 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.

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);
- i) leakage of liquid (see Sub-clause 44.4).
- 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.

***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 1 is recognized.

TABLE 1 – 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.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 $\pm 1\%$ 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.

(See also addition to corresponding rationale.)

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 $93\% \pm 3\%$. 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 $+20^{\circ}\text{C}$ to $+32^{\circ}\text{C}$. Before being placed in the humidity cabinet, EQUIPMENT shall be brought to a temperature between t and $t + 4^{\circ}\text{C}$, 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 6.11)).

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.

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 6.1a))	INTERNALLY POWERED EQUIPMENT (See Sub-clauses 6.1b) and 14.5)	EQUIPMENT supplied from a specified power source (see Sub-clause 6.1c))
6.1e)	Indication of origin	x	x	x
6.1f)	MODEL OR TYPE REFERENCE	x	x	x
6.1g)	Connection to the supply	x ²⁾	—	—
6.1h)	Supply frequency (Hz)	x ²⁾	—	—
6.1j)	Power input	x ²⁾	—	—
6.1k)	Mains power output	x ¹⁾	—	—
6.1l)	Classification	x ¹⁾	x ¹⁾	x ¹⁾
6.1m)	Mode of operation	x ¹⁾	x ¹⁾	x ¹⁾
6.1n)	Fuses	x ¹⁾	x ¹⁾	x ¹⁾
6.1p)	Output	x ¹⁾	x ¹⁾	x ¹⁾
6.1q)	Physiological effects	x ¹⁾	x ¹⁾	x ¹⁾
6.1r)	CATEGORY AP/APG EQUIPMENT	x ¹⁾	x ¹⁾	x ¹⁾
6.1s)	HIGH VOLTAGE TERMINAL DEVICE	x ¹⁾	x ¹⁾	x ¹⁾
6.1t)	Cooling conditions	x ¹⁾	x ¹⁾	x ¹⁾
6.1u)	Mechanical stability	x ¹⁾	x ¹⁾	x ¹⁾
6.1v)	Protective packing	x ¹⁾	x ¹⁾	x ¹⁾
6.1y)	Earth terminals	x ¹⁾	x ¹⁾	x ¹⁾
6.1z)	Remove 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 6.2a).

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 6.1e), 6.1f) and 6.1g) (not for PERMANENTLY INSTALLED EQUIPMENT), 6.1l) and 6.1q) (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking is practicable, all information shall be included in the ACCOMPANYING DOCUMENTS.

e) Indication of origin

The name and/or trade-mark of the manufacturer or supplier claiming that the EQUIPMENT complies with this Standard.

f) MODEL OR TYPE REFERENCEg) 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 $\pm 10\%$ 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.
- 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 6.8.3d) and 10.1 and ISO Publication R780).

Where premature unpacking of EQUIPMENT or EQUIPMENT parts may result in a SAFETY HAZARD, the packing shall be appropriately marked.

The packaging of EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile.

*w) Not used.**x) Not used.**y) Earth terminals*

— A terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR shall be marked with Symbol 9 of Table DI of Appendix D (see Sub-clause 18e)).

— A FUNCTIONAL EARTH TERMINAL shall be marked with Symbol 7 of Table DI of Appendix D.

***z) Removable protective means**

If EQUIPMENT has alternative applications which require the removal of a protective means to utilize a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided (see also Sub-clause 6.8).

Compliance with the requirements of Sub-clause 6.1 is checked as follows:

- *Inspect the presence of required markings on the outside of EQUIPMENT.*
- *Test the durability of markings.*

For determination of durability, markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol.

Markings shall be clearly legible after all the tests of this Standard have been performed (see Appendix C, Item C36). Adhesive labels shall not have worked loose or become curled at the edges.

When evaluating durability, the effect of NORMAL USE on markings is also to be taken into account.

6.2 Marking on the inside of EQUIPMENT or EQUIPMENT parts

- a) Marking on the inside of EQUIPMENT or EQUIPMENT parts shall be “clearly legible” as defined in Sub-clause 6.1. Concerning permanent affixation, it shall not be subjected to the rubbing test of Sub-clause 6.1.

The NOMINAL supply voltage or voltage range to which PERMANENTLY INSTALLED EQUIPMENT can be connected may be marked on the inside or the outside of EQUIPMENT, preferably adjacent to the supply connection terminals.

- b) The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be clearly and indelibly marked near the heater or in the heater itself.

For heating elements or lampholders designed for use with heating lamps not intended to be changed by the OPERATOR and which can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

- c) The presence of HIGH VOLTAGE parts shall be marked with the symbol “dangerous voltage” (see Appendix D, Table DII, Symbol 6).

- d) The type of battery and the mode of insertion (if applicable) shall be marked (see Sub-clause 56.7b)).

For batteries not intended to be changed by the OPERATOR and which can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

- *e) Fuses accessible only with the aid of a TOOL shall be identified either by type and rating next to the fuse, or by at least a reference, for example, the diagram number which can be associated with the technical description in which the type and rating shall be stated.

- f) PROTECTIVE EARTH TERMINALS shall be marked with the prescribed symbol (see Appendix D, Table DI, Symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC Publication 320.

- g) FUNCTIONAL EARTH TERMINALS shall be marked with the prescribed symbol (see Appendix D, Table DI, Symbol 7).

- h) Terminals which are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED EQUIPMENT shall be marked with the prescribed symbol (see Appendix D, Table DI, Symbol 8).

- j) Markings required in Sub-clauses 6.2f), h), k) and l) on or near electrical connection points shall not be affixed to parts which have to be removed to make the connection.

They shall remain visible after the connection has been made.

Markings on or near terminals shall comply with IEC Publication 445.

- k) The correct method of connection of the supply conductors shall be marked clearly with terminal marking which should be affixed adjacent to the terminals, unless no SAFETY HAZARD can develop if connections are interchanged.

If EQUIPMENT is so small that the terminal marking cannot be affixed, it may be included in the ACCOMPANYING DOCUMENTS. If marking for connection to a three-phase supply is necessary, it shall be according to IEC Publication 445.

- l) If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for permanently connected EQUIPMENT (including such conductors themselves), attains a temperature of more than 75°C during the normal temperature test, EQUIPMENT shall be marked with the following or any equivalent statement:

“For supply connections, use wiring materials suitable for at least ... °C”.

This statement shall be located at or near the point where the supply connections are to be made and shall be clearly discernible after the connections have been made.

- m) Not used.
n) Capacitors and/or the connected circuit parts shall be marked as required in Subclause 15c).

Compliance with the requirements of Sub-clause 6.2 is checked by application of the tests and criteria as described in Sub-clause 6.1, except the rubbing test.

6.3 Marking of controls and instruments

- a) A mains switch shall be clearly identified. “ON” and “OFF” positions shall be marked according to the relevant symbols of Appendix D (Symbols 15 and 16 of Table DI), or indicated by an adjacent indicator light or other unambiguous means.
- b) Different positions of control devices and different positions of switches on EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by means of Symbols 17 and 18 of Table DI.
- c) If in NORMAL USE the change of setting of a control could cause a SAFETY HAZARD to the PATIENT, such controls shall be provided with either:
- an associated indicating device, e.g. instruments or scale, or
 - an indication of the direction in which the magnitude of the function changes. See also Sub-clause 56.10c).
- d) Not used.
- e) Not used.
- f) The functions of OPERATOR controls and indicators shall be identified.
- g) Numeric indications of parameters shall be in SI units according to ISO 1000 with the following additions:

Units outside the International System, which can be used on EQUIPMENT:

- Plane angle units:
 - revolution,
 - grade,
 - degree,
 - minute of angle,
 - second of angle;
- Time units:
 - minute,
 - hour,
 - day;
- Energy unit:
 - electronvolt;
- Pressure of blood and other body fluids:
 - millimetre of mercury.

Compliance with the requirements of Sub-clause 6.3 is checked by inspection and application of the durability test of 6.1.

6.4 Symbols

- a) Symbols used for marking according to Sub-clauses 6.1 to 6.3 shall conform to Appendix D, where applicable. See also Sub-clause 6.1*q*).
- b) Symbols used for controls and performance shall conform to IEC Publication 878, where applicable.

Compliance is checked by inspection and application of the durability test of 6.1.

6.5 Colours of the insulation of conductors

- a) A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.
- b) Any insulation on conductors inside EQUIPMENT which connect ACCESSIBLE METAL PARTS or other PROTECTIVELY EARTHED parts with a protective function to the PROTECTIVE EARTH TERMINAL shall be identified by the colours green and yellow at least at the termination of the conductors.
- c) Identification by green and yellow insulation shall only be used for:
 - PROTECTIVE EARTH CONDUCTORS (see Sub-clause 18*b*));
 - Conductors as specified in Sub-clause 6.5*b*));
 - POTENTIAL EQUALIZATION CONDUCTORS (see Sub-clause 18*e*));
 - Functional earth conductors as specified in Sub-clause 18*f*).
- d) Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured "light blue" as specified in IEC Publication 227 (Amendment No.1) or in IEC Publication 245.
- e) Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC Publication 227 (Amendment No. 1) or with IEC Publication 245.
- f) Where a multi-conductor cord is used between EQUIPMENT parts and the maximum allowed resistance of the protective earth connection would be exceeded if only the green and yellow coloured conductor were used, other conductors of the same cord may be connected in parallel with the green and yellow conductor, provided that the ends of such additional conductors are marked green and yellow.

Compliance with the requirements of Sub-clause 6.5 is checked by inspection.

6.6 Identification of medical gas cylinders and connections

- a) Identification of the content of gas cylinders used in medical practice as a part of electrical EQUIPMENT shall be in accordance with ISO Recommendation ISO/R 32. See also Sub-clause 56.3*a*).
- b) The point of connection of gas cylinders shall be so identified on EQUIPMENT that errors are avoided when a replacement is made.

Compliance with the requirements of Sub-clause 6.6 is checked by inspection of the identification of the content, and the point of connection of gas cylinders.

*6.7 Indicators lights and push-buttons

- a) Colours of indicator lights

On EQUIPMENT the colour red shall be used exclusively to indicate a warning of danger and/or a need for urgent action.

Dot-matrix and other alphanumeric displays are not considered to be indicator lights.

TABLE III

*Recommended colours of indicator lights and their meaning
for EQUIPMENT*

Colour	Meaning
Yellow	Caution or attention required
Green	Ready for action
Any other colour	Meaning other than that of red or yellow

b) Colours of unilluminated push-buttons

The colour red shall be used only for the push-button by which a function is interrupted in case of emergency.

*c) Not used.**d) Non used.*

Compliance with the requirements of Sub-clause 6.7 is checked by inspection (see also Subclause 56.8).

6.8 ACCOMPANYING DOCUMENTS***6.8.1 General**

EQUIPMENT shall be accompanied by documents containing at least instructions for use, a technical description and an address to which the USER can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a component part of EQUIPMENT.

All applicable classifications specified in Clause 5 shall be included in both the instructions for use and the technical description, if separable.

All markings specified in Sub-clause 6.1 shall be included in full in the ACCOMPANYING DOCUMENTS if they have not been permanently affixed to EQUIPMENT by the manufacturer. See also Sub-clause 6.1d).

Warning statements and the explanation of warning symbols (marked on the EQUIPMENT) shall be provided in the ACCOMPANYING DOCUMENTS.

6.8.2 Instructions for use***a) General information**

- Instructions for use shall state the function and intended application of the EQUIPMENT.
- Instructions for use shall contain all information necessary to operate the EQUIPMENT in accordance with its specification. This shall include explanation of the function of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and ACCESSORIES, replacement of material which is consumed during operation.
- Instructions for use shall provide the USER or OPERATOR with information regarding potential electromagnetic or other interference between the EQUIPMENT and other devices together with advice regarding avoidance of such interference.
- Instructions for use shall include indications on recognized ACCESSORIES, detachable parts and materials, if the use of other parts or materials can degrade minimum safety.
- Instructions for use shall instruct the USER or OPERATOR in sufficient detail concerning cleaning, preventive inspection and maintenance to be performed by him, including the frequency of such maintenance.

Such instructions shall provide information for the safe performance of routine maintenance.

Additionally, instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by other persons, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.

- The meaning of figures, symbols, warning statements and abbreviations on EQUIPMENT shall be explained in the instructions for use.

**b) Responsibility of the manufacturer*

Not used (see Appendix A).

c) SIGNAL OUTPUT and SIGNAL INPUT PARTS

If a SIGNAL OUTPUT or SIGNAL INPUT PART is intended only for connection to specified EQUIPMENT complying with the requirements of this Standard, this shall be stated in the instructions for use (see Sub-clauses 19.2b) and 19.2c)).

d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT

For EQUIPMENT parts which come into contact with the PATIENT during NORMAL USE, instructions for use shall contain details about cleaning or disinfection or sterilization methods that may be used (see also Sub-clause 44.7) or, where necessary, identify suitable sterilization agents, and list the temperature, pressure, humidity and time limits which such EQUIPMENT parts can tolerate.

e) Mains operated EQUIPMENT with additional power source

Instructions for use of mains operated EQUIPMENT containing an additional power source not automatically maintained in a fully usable condition shall contain a warning statement referring to the necessity for periodical checking or replacement of such an additional power source. If CLASS I EQUIPMENT is specified for operation connected to a SUPPLY MAINS and alternatively using an INTERNAL ELECTRICAL POWER SOURCE, instructions for use shall contain a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, EQUIPMENT shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.

f) Removal of primary batteries

Instructions for use of EQUIPMENT containing primary batteries shall contain a warning to remove these batteries if EQUIPMENT is not likely to be used for some time, unless there is no risk of a SAFETY HAZARD arising.

g) Rechargeable batteries

Instructions for use of EQUIPMENT containing rechargeable batteries shall contain instructions to ensure safe use and adequate maintenance.

h) EQUIPMENT with a specified power supply or battery charger

Instructions for use shall identify power supplies or battery chargers necessary to ensure compliance with the requirements of this Standard.

j) Environmental protection

Instructions for use shall:

- identify any risks associated with the disposal of waste products, residues, etc. and of the EQUIPMENT and ACCESSORIES at the end of their useful lives;
- provide advice on minimizing these risks.

6.8.3 Technical description**a) General**

The technical description shall provide all data, which is essential for safe operation. This shall include:

- data mentioned in subclause 6.1;
- all characteristics of the EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found.

In addition to details required to be included in instructions for use, the technical description shall state whether particular measures or particular conditions are to be observed for installing EQUIPMENT and bringing EQUIPMENT into use.

b) Replacement of fuses and other parts

- If the type and rating of fuses utilized in the mains supply circuit external to PERMANENTLY INSTALLED EQUIPMENT is not apparent from the information concerning RATED current and mode of operation of EQUIPMENT, the required type and rating of fuses shall be indicated in at least the technical description.
- The technical description shall contain instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during NORMAL USE.

c) Circuit diagrams, component part lists, etc.

The technical description shall contain a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the USER'S appropriately qualified technical personnel to repair those parts of EQUIPMENT which are designated by the manufacturer as repairable.

d) Environmental conditions for transport and storage

The technical description shall contain a specification of the permissible environmental conditions for transport and storage which shall be repeated on the outside of the packaging of the EQUIPMENT (see Sub-clause 6.1v)).

6.8.4 Not used.

6.8.5 Not used.

Compliance with the requirements of Sub-clause 6.8 is checked by inspection of the ACCOMPANYING DOCUMENTS.

7. Power input

7.1 The steady state current or power input of EQUIPMENT at RATED voltage, steady state operating temperature, and at operational settings specified by the manufacturer shall not exceed the marked rating as required by Sub-clause 6.1j) by more than:

- a) for EQUIPMENT with a power input mainly caused by electric motor drive(s):
 - +25% for a RATED input power up to and including 100 W or 100 VA;
 - +15% for a RATED input power over 100 W or 100 VA;
- b) for other EQUIPMENT :
 - +15% for a RATED input power up to and including 100 W or 100 VA;
 - +10% for a RATED input power over 100 W or 100 VA.

Compliance with the requirements of Sub-clause 7.1 is checked by inspection and by the following tests:

- *EQUIPMENT shall be operated as specified in the instructions for use until the input has reached a stable value.*

Current or power input shall be measured and compared with markings or the contents of the ACCOMPANYING DOCUMENTS.

Measured values shall not exceed the limits required in this clause.

- *For EQUIPMENT marked with one or more RATED voltage ranges the test is made at both upper and lower limits of the ranges, unless the marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is made at a voltage equal to the mean value of that range.*
- *The steady state current shall be measured with a true r.m.s reading instrument, for example, a thermal instrument.*

Power input, if expressed in volt-amperes, shall either be measured with a voltampere meter or be determined as the product of the steady state current (measured as described above) and the supply voltage.

7.2 Not used

SECTION TWO — ENVIRONMENTAL CONDITIONS

Note. — This Section replaces the former Section Two: "Safety requirements", of the first edition.

*8. Basic safety categories

The content of Clause 8 of the first edition has now been transferred to Appendix A1.1.

9. Removable protective means

Not used. Replaced by Sub-clause 6.1z).

10. Environmental conditions

The former title of this clause "Special environmental conditions" and the corresponding text are not used.

10.1 Transport and storage

EQUIPMENT shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer (see 6.8.3 d)).

10.2 Operation

EQUIPMENT shall comply with all the requirements of this Standard when operated in NORMAL USE under the least favourable combination of the following conditions:

***10.2.1 Environment (see also 4.5).**

- a) An ambient temperature range of +10°C to +40°C.
- b) A relative humidity range of 30% to 75%.
- c) An atmospheric pressure range of 700 hPa to 1 060 hPa.
- d) A temperature of the water at the inlet of water-cooled EQUIPMENT not higher than 25°C.

***10.2.2 Power Supply**

- a) EQUIPMENT shall be suitable for a power supply having:
 - a RATED voltage not exceeding:
 - 250 V for HAND-HELD EQUIPMENT;
 - 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for EQUIPMENT with a RATED apparent power input of up to 4 kVA;
 - 500 V for all other EQUIPMENT;
 - a sufficiently low internal impedance (as may be required by a Particular Standard);
 - voltage fluctuation not exceeding $\pm 10\%$ of the NOMINAL voltage except momentary fluctuations exceeding -10% and of a duration of less than 1 s, for example those occurring at irregular intervals caused by operation of X-ray generators or similar EQUIPMENT;
 - no voltage in excess of the NOMINAL value $+10\%$ between any of the conductors of the system or between any of these conductors and earth;
 - voltages which are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;
 - a frequency of not more than 1 kHz;
 - a frequency which deviates not more than 1 Hz from the NOMINAL value up to 100 Hz and not more than 1% from the NOMINAL value from 100 Hz to 1 kHz;
 - the protective measures as described in IEC Publication 364.
- b) An INTERNAL ELECTRICAL POWER SOURCE, if replaceable, shall be specified by the manufacturer.

Compliance with the conditions of 10.2 is checked by application of the tests of this Standard.

11. Not used.

12. Not used. Transferred to Sub-clause 3.6.

SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13. General

EQUIPMENT shall be so designed that the risk of electric shock in NORMAL USE and in SINGLE FAULT CONDITION is obviated as far as practicable.

Compliance is considered to be fulfilled if EQUIPMENT meets the relevant requirements of this section.

14. Requirements related to classification

14.1 CLASS I EQUIPMENT

a) CLASS I EQUIPMENT may have parts with DOUBLE INSULATION or REINFORCED INSULATION or parts operating at SAFETY EXTRA-LOW VOLTAGE or ACCESSIBLE PARTS protected by protective impedance in cases where conductive parts of an electrical circuit have to be accessible to enable EQUIPMENT to function.

*b) If the isolation of the MAINS PART from ACCESSIBLE METAL PARTS of EQUIPMENT specified for an external d.c. power source is accomplished by BASIC INSULATION only, a separate PROTECTIVE EARTH CONDUCTOR shall be provided.

14.2 CLASS II EQUIPMENT

a) CLASS II EQUIPMENT shall be one of the following types:

1) insulation-enclosed CLASS II EQUIPMENT:

EQUIPMENT having a durable and substantially continuous ENCLOSURE of insulating material which envelops all conductive parts with the exception of small parts, such as name-plates, screws and rivets, which are isolated from LIVE parts by insulation at least equivalent to REINFORCED INSULATION. The ENCLOSURE of insulation-enclosed CLASS II EQUIPMENT may form a part or the whole of the SUPPLEMENTARY INSULATION;

2) metal-enclosed CLASS II EQUIPMENT :

EQUIPMENT having a substantially continuous conductive ENCLOSURE in which DOUBLE INSULATION is used throughout the MAINS PARTS (except for those parts where REINFORCED INSULATION is used, because the application of DOUBLE INSULATION is manifestly impracticable);

3) EQUIPMENT which is a combination of types 1) and 2) above.

b) If EQUIPMENT is fitted with a device for changing over from CLASS I TO CLASS II protection, all of the following requirements shall be fulfilled:

— the change-over device shall clearly indicate the selected Class;

— for change-over the use of a TOOL shall be necessary;

— the EQUIPMENT shall comply with the whole range of requirements for the Class selected at any given time;

— in the CLASS II position the device shall interrupt the connection of the PROTECTIVE EARTH CONDUCTOR TO EQUIPMENT or change it into a FUNCTIONAL EARTH CONDUCTOR, complying with the requirements of Clause 18.

c) CLASS II EQUIPMENT may be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also Sub-clauses 18k) and l).

14.3 Not used.

14.4 *CLASS I and CLASS II EQUIPMENT*

- a) In addition to BASIC INSULATION, EQUIPMENT shall be provided with an additional protection according to the requirements of CLASS I OR CLASS II EQUIPMENT (see Figures 2 and 3).
- b) In EQUIPMENT specified for power supply from an external d.c. power source (for example, for use in ambulances), no SAFETY HAZARD shall develop when a connection with the wrong polarity is made.

14.5 *INTERNALLY POWERED EQUIPMENT*

- a) Not used.
- *b) INTERNALLY POWERED EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I or CLASS II EQUIPMENT while so connected, and with the requirements for INTERNALLY POWERED EQUIPMENT while not so connected.

*14.6 *TYPES B, BF AND CF APPLIED PARTS*

- a) Not used.
- b) Not used
- c) APPLIED PARTS which are specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION shall be TYPE CF.
- d) Not used.

14.7 Not used.

Compliance with the requirements of Clause 14 is checked by inspection and relevant tests.

15. **Limitation of voltage and/or energy**

- a) Not used.
- b) EQUIPMENT intended to be connected to the SUPPLY MAINS by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the supply pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V.

Compliance is checked by the following test:

EQUIPMENT is operated at RATED voltage or at the upper limit of the RATED voltage range.

EQUIPMENT is disconnected from the SUPPLY MAINS by means of the plug with the EQUIPMENT mains switch in the "On" or "Off" position whichever is least favourable.

The voltage between the pins of the plug and between either pin and the ENCLOSURE is measured 1 s after disconnection with an instrument the internal impedance of which does not affect the test.

The measured voltages shall not exceed 60 V.

The test shall be performed ten times.

The test between lines and ENCLOSURE shall not be performed if interference suppression capacitors are used with a capacitance between each line and earth of less than 3 000 pF for RATED voltages up to and including 250 V or 5 000 pF for RATED voltages up to and including 125 V.

The test between lines shall not be performed if interference suppression capacitors less than or equal to 0.1 μ F are connected between them.

- c) *LIVE parts of capacitors or circuit parts connected to them, which become accessible after EQUIPMENT has been de-energized and ACCESS COVERS as present in NORMAL USE have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V, or, if this value is exceeded, shall not have a residual energy exceeding 2 mJ.*

If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device which is included and which permits manual discharging is acceptable. The capacitor(s) and/or the connected circuitry shall then be marked.

Compliance is checked by the following test:

EQUIPMENT is operated at RATED voltage and then de-energized. Any ACCESS COVERS as at present in NORMAL USE are removed as quickly as normally possible. Immediately thereafter, the residual voltage on any accessible capacitors or circuit parts shall be measured and the retained energy calculated. If a non-automatic discharging device is specified by the manufacturer, its inclusion and marking shall be ascertained by inspection.

***16. ENCLOSURES and PROTECTIVE COVERS**

- a) EQUIPMENT shall be so constructed and enclosed that there is protection against contact with LIVE parts, and with parts which can become LIVE in SINGLE FAULT CONDITIONS.

This requirement applies for all positions of EQUIPMENT when it is operated as in NORMAL USE, even after opening of lids and doors and removal of parts without the use of a TOOL or according to the instructions for use.

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

This requirement shall be applied taking into account that:

- 1) It does not apply to LIVE parts of electrodes in general in the APPLIED PART of EQUIPMENT, in so far as they are necessarily connected directly or indirectly to the body of the PATIENT during NORMAL USE.
- 2) Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds which may replasticeze at temperatures to be expected during operation (including sterilization), shall not be regarded as enclosures providing protection against contact with LIVE parts.
- 3) Not used.
- 4) Not used.
- *5) Where the occurrence of a CONDUCTIVE CONNECTION, either directly or through the body of the OPERATOR, between a part accessible without the use of a TOOL and a PATIENT is impossible in NORMAL USE, such a part may assume, in case of a fault in its BASIC INSULATION, a voltage to earth not exceeding 25 V a.c. or 60 V. d.c.

Instructions for use shall instruct the OPERATOR not to touch such a part and the PATIENT simultaneously.

Compliance with the requirements of Sub-clause 16a) is checked by inspection and by a test with the standard test finger shown in Figure 7, applied in a bent or straight position. In addition openings in EQUIPMENT, other than those giving access to LIVE parts in plugs, connectors and socket outlets, are tested with the test pin shown in Figure 8.

The standard test finger and the test pin are applied without appreciable force in every possible position, except that EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 40 kg shall not be tilted. EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, shall be tested in its final mounting position.

Openings preventing the entry of the standard test finger of Figure 7 shall be mechanically tested by means of a straight unjointed test finger of the same dimensions, which shall be applied with a force of 30 N. If this finger enters, the test with the standard test finger of Figure 7 shall be repeated, the finger being pushed through the opening if necessary.

It shall not be possible to touch with the standard test finger or the test pin BASIC INSULATION, bare LIVE parts or LIVE parts protected only by lacquer, enamel, ordinary paper, cotton, oxide film, beads or sealing compound, or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

For signalling contact with LIVE parts, the use of a lamp and a test voltage of at least 40 V is recommended.

EQUIPMENT openings shall be mechanically tested by means of the test-hook (see Figure 9), if the hook can be inserted.

The test-hook is inserted in all openings in question and is subsequently pulled with a force of 20 N for 10 s and in a direction substantially perpendicular to the surface in which the relevant opening is present. No LIVE parts shall become accessible and the CREEPAGE DISTANCE and AIR CLEARANCES of LIVE parts shall not be reduced below the values as specified in Sub-clause 57.10.

Compliance is checked using the standard test finger and by inspection.

- b) Any opening in a top cover of an ENCLOSURE shall be so positioned or dimensioned that accessibility of LIVE parts by means of a freely and vertically suspended test rod with a diameter of 4 mm and a length of 100 mm, penetrating up to its length, is prevented.

Compliance is checked in NORMAL USE by inserting through the holes a metal test rod with a diameter of 4 mm and a length of 100 mm. The test rod is suspended freely and vertically, the penetration being limited to its length. The test rod shall not become LIVE and shall not touch BASIC INSULATION or any parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

- *c) Conductive parts of actuating mechanisms of electrical controls which are accessible after the removal of handles, knobs, levers and the like shall either:

— have a resistance of not more than 0.2Ω to the PROTECTIVE EARTH TERMINAL of the EQUIPMENT when measured with a test voltage of not more than 50 V a.c. open circuit and a test current not less than 1 A, or

— shall be separated from LIVE parts by one of the means described in Sub-clause 17g).

The requirements of this sub-clause do not apply to controls in secondary circuits which are isolated from the MAINS PART by at least BASIC INSULATION and having RATED circuit voltages not exceeding 25 V a.c. or up to and including 60 V d.c. or peak value. In these cases shafts and the like may be isolated from parts of the circuit by BASIC INSULATION only.

Compliance is checked by calculation of the resistance from current and voltage drop. It shall not exceed the required value. Alternatively, the presence of adequate separation shall be confirmed by inspection.

- *d) Parts within the ENCLOSURE of EQUIPMENT with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by an external mains switch or a plug device that is accessible at all times (for example, in circuits for room lighting, remote control of the main switch etc.) shall be protected against contact even after opening of the ENCLOSURE (for example, for the purpose of maintenance) by additional coverings or, in the case of a spatially separated arrangement, shall be marked clearly as "LIVE".

Compliance is checked by inspection of the required covers or warning notice (if present) and, if necessary, by application of the standard test finger of Figure 7.

- *e) ENCLOSURES protecting against contact with LIVE parts shall be removable only with the aid of a TOOL or, alternatively, an automatic device shall make these parts not LIVE, when the ENCLOSURE is opened or removed.

Excluded are:

- 1) ENCLOSURES or EQUIPMENT parts removable without the use of a TOOL and allowing the OPERATOR in NORMAL USE to have access to LIVE parts operating at a voltage not exceeding 25 V a.c. or 60 V d.c. or peak value supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in Sub-clauses 17g)1) to 5).

Examples which are applicable are:

- covers of illuminated push-buttons;
- covers of indicator lamps;
- covers over recorder pens;
- plug-in modules;
- covers or battery compartments.

- 2) Lampholders allowing access to LIVE parts after removal of the lamp.

In such a case instructions for use shall instruct the OPERATOR not to touch such a part and the PATIENT simultaneously.

Compliance is checked by inspection and:

- *by measurement of the effectiveness of an automatic switching off or discharging device;*
- *by measurement of the voltage of LIVE parts accessible with the standard test finger of Figure 7.*

- f) Openings for the adjustment of pre-set controls which may be adjusted by the USER in NORMAL USE by using a TOOL shall be so designed that the TOOL used for adjustment is

not able to touch inside the opening BASIC INSULATION or any LIVE parts or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

Compliance is checked by inspection and by insertion through the opening of a metal test rod with a diameter of 4 mm and a length of 100 mm, in every possible position, in case of doubt with a force of 10 N. The rod shall not contact BASIC INSULATION or any LIVE parts or parts not PROTECTIVELY EARTHED and separated from the MAINS PART by BASIC INSULATION only.

g) Not used.

***17. Separation** (Previous title: Insulation and protective impedances)

- a) APPLIED PARTS shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see Sub-clause 3.6), in such a way that allowable LEAKAGE CURRENTS (see Clause 19) are not exceeded.

This requirement may be fulfilled by one of the following methods:

- 1) The APPLIED PART is separated from LIVE parts by BASIC INSULATION only, but PROTECTIVELY EARTHED and the APPLIED PART has such a low internal impedance to earth that LEAKAGE CURRENTS do not exceed the allowable values in NORMAL CONDITION and SINGLE FAULT CONDITION.
- 2) The APPLIED PART is separated from LIVE parts by a PROTECTIVELY EARTHED metal part, which may be a fully enclosing metal screen.
- 3) The APPLIED PART is not PROTECTIVELY EARTHED but is separated from LIVE parts by an intermediate PROTECTIVELY EARTHED circuit which, in the event of any insulation failure, cannot produce a LEAKAGE CURRENT to the APPLIED PART exceeding the allowable value.
- 4) The APPLIED PART is separated from LIVE parts by DOUBLE or REINFORCED INSULATION.
- 5) Impedances of components prevent the flow to the APPLIED PART of a PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT exceeding the allowable values.

Compliance with Sub-clause 17a) is checked by inspection and measurement.

If the CREEPAGE DISTANCE and/or AIR CLEARANCE between the APPLIED PART and LIVE parts does not comply with the requirements of Sub-clause 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited.

The PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured as described in Sub-clause 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.

If inspection of the APPLIED PART in Item 1) and of the PROTECTIVELY EARTHED metal part in Item 2) and of the intermediate circuit in Item 3) gives rise to doubts concerning the effectiveness of the separation under SINGLE FAULT CONDITION, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured after short-circuiting of the insulation between LIVE parts and the APPLIED PART (Item 17 a) 1) above), between LIVE parts and the metal part (item 17 a) 2) above) or between LIVE parts and the intermediate circuit (item 17 a) 3) above).

Transient currents occurring during the first 50 ms following the short-circuit shall be disregarded. After 50 ms, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall not exceed the allowable value for SINGLE FAULT CONDITION.

Additionally EQUIPMENT and/or its circuits are examined to determine whether the limitation of LEAKAGE CURRENTS and/or PATIENT AUXILIARY CURRENT to the prescribed values is dependent on the insulating properties of junctions in semiconductor devices which are interposed between the APPLIED PART and the MAINS PART; the APPLIED PART and other LIVE parts and for F-TYPE APPLIED PARTS between the APPLIED PART and earthed parts.

In the event that such semiconductor devices are so identified, they shall be short-circuited to simulate a break-down of the critical junction, one at a time, to establish that the allowable LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT for SINGLE FAULT CONDITION are not exceeded.

- b) Not used.
- c) An APPLIED PART shall have no CONDUCTIVE CONNECTION to ACCESSIBLE METAL PARTS which are not PROTECTIVELY EARTHED.

Compliance is checked by inspection and the LEAKAGE CURRENT test of Sub-clause 19.4.

- d) Hand-held flexible shafts of CLASS I EQUIPMENT shall be isolated from the motor shaft by SUPPLEMENTARY INSULATION.

ACCESSIBLE METAL PARTS driven by an electric motor of CLASS I protection and which during NORMAL USE are likely to come into direct contact with an OPERATOR or PATIENT, and which cannot be PROTECTIVELY EARTHED, shall be isolated from the motor shaft by at least SUPPLEMENTARY INSULATION capable of withstanding the dielectric strength test appropriate to the RATED voltage of the motor and having adequate mechanical strength.

Compliance is checked by inspection and test of the insulation between hand-held flexible shafts and/or driven ACCESSIBLE METAL PARTS OF CLASS I EQUIPMENT and the motor shafts. The test specified for SUPPLEMENTARY INSULATION (see Sub-clause 20.4) shall be applied.

Compliance with the requirements for CREEPAGE DISTANCES and AIR CLEARANCES is checked additionally (see Sub-clause 57.10).

- e) Not used.
- f) Not used.
- g) ACCESSIBLE PARTS not being an APPLIED PART shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see Sub-clause 3.6) in such a way that allowable LEAKAGE CURRENTS are not exceeded (see Clause 19).

This requirement may be fulfilled by one of the following methods:

- 1) The ACCESSIBLE PART is separated from LIVE parts by BASIC INSULATION only, but PROTECTIVELY EARTHED.
- 2) The ACCESSIBLE PART is separated from LIVE parts by a PROTECTIVELY EARTHED metal part, which may be a fully enclosing conductive screen.
- 3) The ACCESSIBLE PART is not PROTECTIVELY EARTHED but is separated from LIVE parts by an intermediate PROTECTIVELY EARTHED circuit which in the event of any insulation failure cannot produce an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.
- 4) The ACCESSIBLE PART is separated from LIVE parts by DOUBLE or REINFORCED INSULATION.
- 5) Impedances of components prevent the flow to the ACCESSIBLE PART of an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.

Compliance is checked by inspection of the required separation in order to find out where an insulation failure might cause a SAFETY HAZARD.

If the CREEPAGE DISTANCE and/or AIR CLEARANCE between an ACCESSIBLE PART and LIVE parts does not comply with the requirements of Sub-clause 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited.

The ENCLOSURE LEAKAGE CURRENT shall subsequently be measured as described in Sub-clause 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.

If inspection of the PROTECTIVELY EARTHED metal part in item 17 g) 2) or of the intermediate circuit in item 17 g) 3) gives rise to doubt concerning the effectiveness of the separation under SINGLE FAULT CONDITION the ENCLOSURE LEAKAGE CURRENT shall be measured by short-circuiting the insulation between LIVE parts and the metal part (item 17 g) 2) above) or between LIVE parts and the intermediate circuit (item 17 g) 3) above).

Transient currents occurring during the first 50 ms following the application of the short-circuit shall be disregarded.

After 50 ms, the ENCLOSURE LEAKAGE CURRENT shall not exceed the allowable value for SINGLE FAULT CONDITION.

Additionally EQUIPMENT and/or its circuits shall be examined to determine if the limitation of LEAKAGE CURRENTS and/or PATIENT AUXILIARY CURRENTS to the prescribed values is dependent on the insulating properties of junctions in semiconductor devices which are interposed between the ACCESSIBLE PART and LIVE parts.

In the event that such semiconductor devices are so identified, they shall be short-circuited to simulate a break-down of the critical junction, one at a time, to establish that the allowable LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS for SINGLE FAULT CONDITION are not exceeded.

**h) Arrangement used to isolate DEFIBRILLATION-PROOF APPLIED PARTS from other parts shall be so designed that:*

- during a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION-PROOF APPLIED PART, hazardous electrical energies do not appear on:
 - the ENCLOSURE, including the outer surfaces of accessible leads and connectors,
 - any SIGNAL INPUT PART,
 - any SIGNAL OUTPUT PART,
 - metal foil for test on which the EQUIPMENT is placed and which has an area at least equal to the base of the EQUIPMENT,
- after exposure to the defibrillation voltage, the EQUIPMENT, after any necessary time of recovery stated in the ACCOMPANYING DOCUMENTS, shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

Compliance is checked by the following impulse voltage tests:

- (Common-mode test) *The EQUIPMENT is connected to the test circuit shown in figure 50. The test voltage is applied to all the PATIENT CONNECTIONS connected together and isolated from earth;*
- (Differential-mode test) *The EQUIPMENT is connected to the test circuit shown in figure 51. The test voltage is applied to each PATIENT CONNECTION in turn with all the remaining PATIENT CONNECTIONS being connected to earth.*

Note. — The differential-mode test is not used when the APPLIED PART consists of a single PATIENT CONNECTION.

During each test:

- *the PROTECTIVE EARTH CONDUCTOR of CLASS I EQUIPMENT is connected to earth. CLASS I EQUIPMENT which is capable of operation without a SUPPLY MAINS, e.g. having an internal battery, is tested again without the protective earth connection;*
- *the EQUIPMENT shall not be energized;*
- *insulating surfaces of APPLIED PARTS are covered with metal foil or immersed in a saline solution as specified in 19.4 h) 9);*
- *any connection to a FUNCTIONAL EARTH TERMINAL is removed; where a part is internally connected to earth for functional purposes, either such a connection shall be considered a protective earth connection and shall comply with the requirements of clause 18, or it shall be removed for the purpose of the present text;*

- *parts specified in the first dash of this subclause that are not PROTECTIVELY EARTHED are connected to an oscilloscope.*

After the operation of S, the peak voltage between the points Y1 and Y2 shall not exceed 1 V.

Each test is repeated with V_T reversed.

After any necessary time of recovery, stated in the ACCOMPANYING DOCUMENTS, the EQUIPMENT shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

18. Protective earthing, functional earthing and potential equalization

- *a) ACCESSIBLE PARTS of CLASS I EQUIPMENT separated from LIVE parts by BASIC INSULATION shall be connected by sufficiently low impedance to the PROTECTIVE EARTH TERMINAL. See also Sub-clause 17g).

Compliance is checked by inspection and the tests of Sub-clauses 18f) and 18g).

- b) The PROTECTIVE EARTH TERMINAL shall be suitable for connection to the protective conductor in the installation either by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR. For constructional requirements for the earth connection see Clause 58.

Compliance is checked by inspection (see Sub-clause 18f)).

- c) Not used.
- d) Not used.
- e) If EQUIPMENT is provided with a means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR this connection shall comply with the following requirements:
 - be readily accessible;
 - accidental disconnection is prevented in NORMAL USE;
 - the conductor can be detached without the use of a TOOL;
 - the POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR;
 - the connection means shall be marked with Symbol 9, Table DI.

Compliance is checked by inspection.

- f) For EQUIPMENT without a POWER SUPPLY CORD the impedance between the PROTECTIVE EARTH TERMINAL and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0.1 Ω .

For EQUIPMENT with an APPLIANCE INLET the impedance between the protective earth contact in the APPLIANCE INLET and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0.1 Ω .

For EQUIPMENT with a non-detachable POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any ACCESSIBLE METAL PART which is PROTECTIVELY EARTHED shall not exceed 0.2 Ω .

Compliance is checked by the following test:

A current of 25A or 1,5 times the rated current of the EQUIPMENT, whichever is greater ($\pm 10\%$), from current source with a frequency of 50 Hz or 60 Hz with a no-load voltage not exceeding 6 V is passed for 5 s to 10 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each ACCESSIBLE METAL PART which could become LIVE in case of failure in BASIC INSULATION.

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. It shall not exceed the values indicated in this sub-clause.

- *g) The impedance of protective earth connections other than those described in Sub-clause 18f) is allowed to exceed 0.1 Ω if the continuous fault current to an ACCESSIBLE PART in case of failure in BASIC INSULATION of such a part or of a component connected to such a part is limited to such an extent that the allowable value of the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION is not exceeded.

Compliance is checked by inspection and measurement of the ENCLOSURE LEAKAGE CURRENT in a SINGLE FAULT CONDITION. See also Sub-clause 17g).

h) Not used.

j) Not used.

k) FUNCTIONAL EARTH TERMINALS shall not be used to provide protective earthing.

Compliance is checked by inspection.

- l) If CLASS II EQUIPMENT with isolated internal screens is supplied with a POWER SUPPLY CORD having three conductors, the third conductor (connected to the protective earth contact of the MAINS PLUG) shall be used only as functional earth for these screens and shall be coloured green and yellow.

The insulation of such internal screens and all internal wiring connected to them shall be DOUBLE INSULATION or REINFORCED INSULATION.

In such case the FUNCTIONAL EARTH TERMINAL of such EQUIPMENT shall be marked so as to distinguish it from a PROTECTIVE EARTH TERMINAL and additionally there shall be an explanation in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and measurement. The insulation shall be tested as described in Clause 20.

19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

19.1 General requirements

- a) The electrical insulation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the specified values.
- b) The specified values of the continuous EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:

- Both at operating temperature and following the humidity preconditioning treatment, as described in Sub-clauses 4.10 and 19.4.
- In NORMAL CONDITION and in the specified SINGLE FAULT CONDITIONS (see Sub-clause 19.2).
- With EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position.
- With the highest RATED supply frequency.
- With a supply equal to 110% of the highest RATED MAINS VOLTAGE.

The measured values shall not exceed the allowable values given in Sub-clause 19.3.

- c) EQUIPMENT specified for connection to a SELV source can only comply with the requirements of this Standard if such a source complies with this Standard and if the EQUIPMENT, tested in combination with such a source, complies with the requirements for allowable LEAKAGE CURRENTS.

Such EQUIPMENT and INTERNALLY POWERED EQUIPMENT shall be investigated for ENCLOSURE LEAKAGE CURRENT but only as far as described in Sub-clause 19.4g)3).

- *d) The measurement of the ENCLOSURE LEAKAGE CURRENT of CLASS I EQUIPMENT shall only be performed:
- to earth from each part, if present, of the ENCLOSURE not PROTECTIVELY EARTHED;
 - between parts, if present, of the ENCLOSURE not PROTECTIVELY EARTHED.
- e) The PATIENT LEAKAGE CURRENT shall be measured (see Appendix K):
- in TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected together or with APPLIED PARTS loaded according to the manufacturer's instructions;
 - in TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function of the APPLIED PART connected together or with APPLIED PARTS loaded according to the manufacturer's instructions;
 - in TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.

If the manufacturer specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT cord and electrodes), the PATIENT LEAKAGE CURRENT measurements shall be made with the least favourable specified detachable part.

- f) The PATIENT AUXILIARY CURRENT shall be measured between any single PATIENT connection and all other PATIENT connections connected together.
- g) EQUIPMENT with multiple PATIENT CONNECTIONS shall be investigated to ensure that, under NORMAL CONDITIONS, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values while one or more PATIENT CONNECTIONS are:
- disconnected from the PATIENT; and
 - disconnected from the PATIENT and earthed.

Testing shall be carried out if an examination of the EQUIPMENT circuit indicates that the PATIENT LEAKAGE CURRENT or the PATIENT AUXILIARY CURRENT may increase to excessive levels under the above conditions, and actual measurements should be limited to a representative number of combinations.

19.2 SINGLE FAULT CONDITIONS

- *a) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured under the following SINGLE FAULT CONDITIONS:
- the interruption of each supply conductor one at a time;
 - the interruption of a PROTECTIVE EARTH CONDUCTOR (not applicable in the case of EARTH LEAKAGE CURRENT). Not to be investigated if a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR is specified;
 - see also Sub-clause 17a) and 17g).

- b) Additionally the PATIENT LEAKAGE CURRENT shall be measured under the following SINGLE FAULT CONDITIONS :

- a voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART.

This requirement shall not apply in the following cases:

- the SIGNAL INPUT PART(S) or SIGNAL OUTPUT PART(S) are designated by the manufacturer for connection to EQUIPMENT in situations where a risk of external voltage does not exist (see IEC 601-1-1).
 - for TYPE B APPLIED PARTS, unless inspection of the circuits and physical arrangement shows that a SAFETY HAZARD exists;
 - for F-TYPE APPLIED PARTS.
- A voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between any F-TYPE APPLIED PART and earth.
 - A voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between earth and any ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED.

This requirement does not apply:

- for TYPE B APPLIED PARTS, unless inspection of the circuits and physical arrangement shows that a SAFETY HAZARD exists;
- for F-TYPE APPLIED PARTS.

- c) Additionally, the ENCLOSURE LEAKAGE CURRENT shall be measured with a voltage equal to 110% of the highest RATED MAINS VOLTAGE, applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART.

This requirement is only applied where the SIGNAL INPUT PART(S) or SIGNAL OUTPUT PART(S) are designated by the manufacturer for connection to EQUIPMENT in situations where a risk of external voltage exists (see IEC 601-1-1).

*19.3 Allowable values

- a) The allowable values of the continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table IV for d.c. and a.c. and composite waveforms. Unless stated otherwise values may be d.c. or r.m.s.
- b) The allowable values stated in table IV apply to currents flowing through the network of figure 15 and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in figure 15).

Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION.

- c) Not used.
- d) Not used.
- e) Not used, but see Notes 3) and 4) of Table IV.

TABLE IV

**Allowable values of continuous LEAKAGE and PATIENT AUXILIARY CURRENTS , in milliamperes*

Current	Type B		Type BF		Type CF	
	N.C.	S.F.C.	N.C.	S.F.C.	N.C.	S.F.C.
EARTH LEAKAGE CURRENT general	0.5	1 ¹⁾	0.5	1 ¹⁾	0.5	1 ¹⁾
EARTH LEAKAGE CURRENT for EQUIPMENT according to notes ²⁾ and ⁴⁾	2.5	5 ¹⁾	2.5	5 ¹⁾	2.5	5 ¹⁾
EARTH LEAKAGE CURRENT for EQUIPMENT according to note ³⁾	5	10 ¹⁾	5	10 ¹⁾	5	10 ¹⁾
ENCLOSURE LEAKAGE CURRENT	0.1	0.5	0.1	0.5	0.1	0.5
PATIENT LEAKAGE CURRENT d.c. according to note 5) a.c.	0.01	0.05	0.01	0.05	0.01	0.05
	0.1	0.5	0.1	0.5	0.01	0.05
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the SIGNAL INPUT PART or SIGNAL OUTPUT PART)	—	5	—	—	—	—
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)	—	—	—	5	—	0.05
PATIENT AUXILIARY CURRENT d.c. (according to note 5) a.c.	0.01	0.05	0.01	0.05	0.01	0.05
	0.1	0.5	0.1	0.5	0.01	0.05

N.C.: NORMAL CONDITION

S.F.C.: SINGLE FAULT CONDITION

Notes on Table IV

- 1) The only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time (see sub-clause 19.2a) and Figure 16).
- 2) EQUIPMENT which has no PROTECTIVELY EARTHED ACCESSIBLE PARTS and no means for the protective earthing of other EQUIPMENT and which complies with the requirements for the ENCLOSURE LEAKAGE CURRENT and for the PATIENT LEAKAGE CURRENT (if applicable).

Example:

Some computers with a screened MAINS PART.

- 3) EQUIPMENT specified to be permanently installed with a PROTECTIVE EARTH CONDUCTOR which is electrically so connected that the connection can only be loosened with the aid of a TOOL, and which is so fastened or otherwise so secured mechanically at a specific location that it can only be moved after the use of a TOOL.

Examples of such EQUIPMENT are:

- Major components of an X-ray installation such as the X-ray generator, the examination or treatment table.
 - EQUIPMENT with mineral insulated heaters.
 - EQUIPMENT with an EARTH LEAKAGE CURRENT higher than stated in Table IV, first line, which is due to compliance with requirements for radio-interference suppression.
- 4) MOBILE X-ray EQUIPMENT and MOBILE EQUIPMENT with mineral insulation.
 - 5) The maximum values for the the a.c. component of the PATIENT LEAKAGE CURRENT and of the PATIENT AUXILIARY CURRENT specified in table IV refer to the a.c. only component of the currents.

19.4 Tests

*a) General

- 1) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured:

— after the EQUIPMENT has been brought up to operating temperature in accordance with the requirements of Section Seven, and

— after the humidity preconditioning treatment as described in Sub-clause 4.10.

The measurements shall be carried out with the EQUIPMENT located in an environment with a temperature approximately equal to t where t is the temperature of the humidity cabinet and a relative humidity between 45% and 65% and shall commence 1 h after the end of the humidity preconditioning treatment.

The measurements which do not energize the EQUIPMENT shall be made first.

- 2) EQUIPMENT is connected to a supply with a voltage equal to 110% of the highest RATED MAINS VOLTAGE.
- 3) Three-phase EQUIPMENT which is also suitable for single-phase supply is tested as single-phase EQUIPMENT with the three sections connected in parallel.
- 4) Where examination of the circuit arrangement and the arrangement of components and material of EQUIPMENT shows no possibility of any SAFETY HAZARD, the number of tests may be reduced.
- 5) Not used.

**b) Measuring supply circuits*

- 1) EQUIPMENT specified for connection to a SUPPLY MAINS which is approximately at earth potential on one side and EQUIPMENT for which the nature of the power supply is not specified, is connected to a circuit as shown in Figure 10.
- 2) EQUIPMENT specified for connection to a SUPPLY MAINS of which the voltages between the lines and the neutral are approximately equal and in opposition, is connected to a circuit as shown in Figure 11.
- 3) Polyphase or single-phase EQUIPMENT, specified for connection to a polyphase (for example, three-phase) SUPPLY MAINS, is connected to one of the circuits as shown in Figures 12 and 13.
- 4) EQUIPMENT specified for use with a specified CLASS I single-phase power supply, is connected to a circuit as shown in Figure 14.

The switch S_8 shall be opened and closed in turn during the tests.

However, if the specified power supply has a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR, the switch S_8 shall be left closed during tests.

- 5) EQUIPMENT specified for use with a specified CLASS II single-phase power supply is connected to a circuit as shown in Figure 14, not using the protective earth connection S_8 .

c) Connection of the EQUIPMENT to the measuring supply circuit

- 1) EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.
- 2) EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified by the manufacturer.
- 3) EQUIPMENT specified to be PERMANENTLY INSTALLED is tested while connected to the measuring supply circuit via the shortest possible connection.

**d) Measuring arrangement*

- 1) It is recommended to position the measuring supply circuit and the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following sub-clauses) to avoid placing the EQUIPMENT on or near a large earthed metal surface.