

Medical electrical equipment —

Part 1: Specification for general safety requirements

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- British Electrical and Allied Manufacturers' Association (BEAMA)
- British Electrotechnical Approvals Board
- British Railways Board
- Consumer Standards Advisory Committee of BSI
- Department of Health and Social Security*
- Department of Prices and Consumer Protection
- Electricity Supply Industry in England and Wales
- Electronic Engineering Association
- Institution of Electrical Engineers
- Ministry of Defence*
- United Kingdom Medical Equipment Industries Group*

The organizations marked with an asterisk in the above list, together with the following, were directly represented on the committee entrusted with the preparation of this British Standard:

- Association of X-ray Equipment Manufacturers
- Bath Institute of Medical Engineering
- British Institute of Radiology
- British Medical Association
- British Surgical Trades Association Incorporated
- Electro Medical Trade Association Limited
- Hospital Physicists Association
- Institute of Hospital Engineering
- National Radiological Protection Board
- Royal College of Physicians of London
- Royal College of Surgeons of England
- Scientific Instrument Manufacturers' Association
- Scottish Health Services
- The College of Radiographers

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Publications referred to	Inside back cover

Foreword

This British Standard has been prepared under the direction of the Light Electrical Engineering Standards Committee and is technically identical, except where indicated by margin marks as explained below, with IEC 601-1 “*Safety of medical electrical equipment, Part 1: General requirements*” published by the International Electrotechnical Commission (IEC).

This British Standard specifies safety requirements that are generally applicable to medical electrical equipment. For particular types of equipment, these requirements will be supplemented or modified by the requirements of particular standards which will be issued as additional Parts to this standard. Where particular standards exist, this general standard should not be used alone. Special care is required in applying this standard alone to equipment for which no particular standard has yet been published.

Terminology and conventions. In order to expedite publication and for ease of reproduction the text of IEC 601-1 has been used as the basis of this British Standard. As a result some terminology and certain conventions are not identical with these used in British Standards. In particular the following print types are used.

Requirements: in roman type.

Explanations, advice, introductions, general statements, exceptions and reference: in small roman type.

Test specifications: in *italic type*.

Terms used throughout the standard that have been defined in clause 2: small capitals.

Where it has been necessary to amend the IEC text the revised text has been indicated by a vertical line in the margin and the IEC text which it has replaced is given in Appendix M.

It will be noted that where italic type is used for test specifications the S.I. unit symbols, e.g. V (volts), mm (millimetres) have been set in italic type instead of roman type as required by convention.

On pages 43, 44, 45 and 46 italic type has been used for symbols referring to apparatus or components (e.g. *MD1*, *MD2*, *S₁*, *S₂*) which, by convention, should be in roman type.

Textual references to page numbers are to the IEC page numbers; for the purposes of this British Standard these page references should be ignored.

References to IEC and ISO (International Organization for Standardization) publications are to be read as references to the corresponding British Standards listed below. Where there is no corresponding British Standard, reference should be made to the IEC standard quoted. Appendix L lists the dates and titles of the International Standards. Copies of these standards may be obtained from British Standards Institution, Overseas Sales Department, Newton House, 101 Pentonville Road, London N1 9ND.

International Standard	Corresponding British Standard
IEC 34-9:1972	BS 4999 <i>General requirements for rotating electrical machines</i> — Part 51:1973 <i>Noise levels</i> (Identical)
IEC 65:1976	BS 415:1972 <i>Safety requirements for mains-operated household sound and vision equipment</i> (Identical)
IEC 68-2-2:1974	BS 2011 <i>Basic environmental testing procedures</i> Part 2.1B:1977 <i>Test B. Dry heat</i> (Identical)

International Standard	Corresponding British Standard
IEC 73:1975	BS 4099 <i>Specification for colours of indicator lights, push buttons, annunciators and digital readouts</i> Part 1:1976 <i>Colours of indicator lights and push buttons</i> (Identical)
IEC 85:1957	BS 2757:1956 <i>Classification of insulating materials for electrical machinery and apparatus on the basis of thermal stability in service</i> (Identical)
IEC 127:1974	BS 4265:1977 <i>Specification for cartridge fuse links for miniature fuses</i> (Identical)
IEC 161:1965	BS 2135:1966 <i>Capacitors for radio interference suppression</i> (Technically equivalent)
IEC 227:1967	BS 6500:1975 <i>Insulated flexible cords</i> (Technically equivalent)
IEC 227:1967 (code designation IEC 53)	BS 6500:1975 <i>Insulated flexible cords</i> (code designation <i>HO5 VVH2-F</i> or <i>HO5 VV-F</i>)
IEC 241:1968	BS 1361:1971 <i>Cartridge fuses for a.c. circuits in domestic and similar premises</i> (Technically equivalent)
IEC 245:1967	BS 6500:1975 <i>Insulated flexible cords</i> (Technically equivalent)
IEC 245:1967 (code designation IEC 53)	BS 6500:1975 <i>Insulated flexible cords</i> (code designation <i>HO5 RR-F</i>)
IEC 252:1975	BS 5267:1976 <i>Capacitors for single phase a.c. motors</i> (Technically equivalent)
IEC 278:1968 (subclause 5.4.1)	BS 4308:1968 <i>Documents supplied with electronic measuring instruments</i> [subclause 5.5 1] (Identical)
IEC 309:1969	BS 4343:1968 <i>Industrial plugs, socket-outlets and couplers for a.c. and d.c. supplies</i> (Identical)
IEC 309A:1973	No equivalent British Standard
IEC 320:1970	BS 4491:1969 <i>Appliance couplers for household and similar general purposes</i> (Technically equivalent)
IEC 328:1972	BS 3955 <i>Electrical controls for domestic appliances</i> Part 3:1972 <i>General and specific requirements</i> (Technically equivalent)
IEC 335-1:1976	BS 3456 <i>Specification for safety of household electrical appliances</i> Part 101:1978 <i>General requirements</i> (Technically equivalent)
IEC 348:1971	BS 4743:1971 <i>Safety requirements of electronic measuring apparatus</i> (Technically equivalent)

International Standard	Corresponding British Standard
IEC 380:1977	BS 3861 <i>Electrical safety of office machines</i> Part 1:1965 <i>General requirements and tests for earthed equipment</i> Part 2:1968 <i>Requirements and tests for machines presenting special hazards</i> Part 3:1970 <i>General requirements and tests for double insulated and all insulated equipment</i> (Technically equivalent)
IEC 407:1973	No equivalent British Standard
IEC 414:1973	BS 5458:1977 <i>Specification for safety requirements for indicating and recording electrical measuring instruments and their accessories</i> (Identical)
IEC 417:1973	No equivalent British Standard
IEC 445:1973	BS 5559:1978 <i>Specification for identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notation</i> (Identical)
IEC 447:1974	No equivalent British Standard
IEC 513:1976	No equivalent British Standard
IEC 536:1976	BS 2754:1976 <i>Memorandum. Construction of electrical equipment for protection against electric shock</i> (Technically equivalent)
ISO R32	BS 1319C:1976 <i>Chart of colours for the identification of the contents of medical gas cylinders</i> (Technically equivalent)
ISO R407	BS 1319:1976 <i>Specification for medical gas cylinders, valves and yoke connections</i> (Technically equivalent)

NOTE In the above list, the relationship between an International Standard and its corresponding British Standard is given by the words "Identical" or "Technically equivalent" immediately after the title of the British Standard.

For the purposes of this standard, the words "Identical" and "Technically equivalent" refer to that part of the text of the British Standard which is directly relevant for the implementation of this standard.

The technical committee has reviewed the provisions of the IEC Publications for which there is no equivalent British Standard and has decided that they are acceptable for use in conjunction with this standard.

Textual errors. When the text of the International Standard was adopted, the printing errors, listed below, were noticed. They have been corrected in this British Standard and have been reported to IEC in a proposal to amend the text of the International Standard.

Page 69, clause 44.3 "LIVE PARTS of electrical insulation" has been deleted and replaced by "LIVE PARTS or electrical insulation".

Page 70, line 17. "5 Nm" has been deleted and replaced by "5 N m".

Page 79, clause 55.3, line 2 "replacement purpose and they shall be fixed" has been deleted and replaced by "replacement purpose they shall be fixed".

Page 85, Table XIII "(Nm)" has been deleted and replaced by "(N m)".

Page 152, line 8. "rev/min" has been deleted and replaced by "r/min".

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to xii, pages 1 to 204, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Introduction

A complete safety philosophy can be found in IEC Publication 513.

MEDICAL ELECTRICAL EQUIPMENT may expose PATIENT, USER and surroundings to a number of potential hazards of the following nature:

- a) energies delivered to the PATIENT or USER in NORMAL USE;
- b) energies delivered to the PATIENT or USER in fault condition;
- c) absence of function in life-supporting EQUIPMENT;
- d) absence of function or interruption of non-repeatable examinations or treatments;
- e) human errors during operation of EQUIPMENT.

The energy delivered may be electrical (considered to include electromagnetic radiation and accelerated atomic particles), mechanical, thermal (temperatures and fire) or chemical. High-frequency interference may be a hazard if it leads to false signals or disturbance of automatic processes.

Some of these hazards are, of course, also present in electrical EQUIPMENT other than that used in medical practice. However, in the preparation of the present standard the following additional conditions have been taken into account:

- a) The inability of PATIENT or USER to detect the presence of certain potential hazards, such as ionizing or high-frequency radiation.
- b) Absence of normal reactions of the PATIENT (ill, unconscious, anaesthetized, secured to table, etc.).
- c) Absence of normal protection to currents provided by the normal skin if this is penetrated or treated especially to obtain a low skin-resistance.
- d) Support or replacement of vital body functions may depend on the reliability of EQUIPMENT.
- e) The simultaneous connection to the PATIENT of more than one piece of MAINS-OPERATED EQUIPMENT.
- f) Combination of high-power EQUIPMENT and sensitive low-signal EQUIPMENT, often in *ad hoc* combinations.
- g) The application of electrical circuits directly to the human body, either through contacts to the skin and/or through the insertion of probes into internal organs.
- h) Environmental conditions, particularly in operating theatres, may present a combination of humidity, moisture and/or fire or explosion hazards caused by anaesthetic media and cleaning agents.

Generally, the precautions adopted shall provide adequate protection without an undesirable restriction of normal function.

Adequate protection of the USER, PATIENT and environment is obtained by precautions:

- a) in the MEDICAL ELECTRICAL EQUIPMENT itself, as indicated in this standard;
- b) in the installation provided in medically used rooms;
- c) in the application of the EQUIPMENT.

The safety requirements in these areas should be harmonized as far as is practicable.

If the intended protection as previously specified cannot be fully realized, safety shall be provided in the following sequence of priority:

- a) as part of the EQUIPMENT and the installation;
- b) by additional measures in environment and/or application;
- c) by restriction of conditions of operation.

Generally failure of a single component of a protective system shall not cause a hazard. This may be prevented either by sound engineering or by application of redundancy or by protective devices of a mechanical or electrical nature. It is assumed that the SINGLE FAULT CONDITION becomes obvious to the USER either by an unmistakable and clearly discernible signal indicating a condition of failure or by a periodic inspection procedure by which this failure can be discovered. However, in this respect, some engineering principles, for example DOUBLE or REINFORCED INSULATION are considered not subject to the recommendation of a SINGLE FAULT CONDITION indication.

The expression "sound engineering" does not refer only to the use of good electrical and mechanical design but includes knowledge of the method of production of the relevant component and of the environmental conditions present during manufacture, transport, storage and use.

Generally it is presumed that MEDICAL ELECTRICAL EQUIPMENT is operated under the jurisdiction of qualified or licensed persons, according to the instructions for use and with the skill required for the particular medical application.

This Standard contains requirements and test methods which have been adopted (sometimes slightly modified) from other IEC publications. Reference to other Publications has only been made if they are of general nature, for example, mains switches.

Protection against electric shock hazards

The problem of protection against electric shocks is treated in this Standard more extensively than in IEC Publication 335, particularly by using new guidelines.

The sensitivity of the human or animal body for electric currents, depending upon the degree and nature of contact with the EQUIPMENT, leads to a new classification of EQUIPMENT according to the degree and quality of protection. This is described in terms of the maximum allowable LEAKAGE CURRENT (TYPES B, BF and CF EQUIPMENT). TYPES B and BF EQUIPMENT are suitable for applications involving external or internal contact with the PATIENT excluding the heart. TYPE CF EQUIPMENT is suitable for DIRECT CARDIAC APPLICATION. The above classification shall be used not only to describe requirements in this Standard, but also to establish harmonization with an Application Code, in which it may be stated that EQUIPMENT in a certain application or environment shall comply with a certain minimum classification.

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

Nevertheless, engineers should be provided with data, enabling them to design EQUIPMENT, so for the time being the requirements specified represent what is considered reasonably safe. The requirements for LEAKAGE CURRENT were formulated taking into account the following considerations:

- a) that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters;
- b) that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, and
- c) that values for NORMAL CONDITION are necessary to create a safe condition in all situations by providing a sufficiently high safety factor with respect to SINGLE FAULT CONDITIONS.

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

Protection against mechanical hazards

— Mechanical hazards (see Section 4)

Some MEDICAL ELECTRICAL EQUIPMENT is used to support the PATIENT or heavy pieces of EQUIPMENT surrounding him. Safety in this case is provided by static and dynamic mechanical strength, and protection against mechanical failures by the incorporation of redundancy or the provision of safety catches. Protection is also provided against injuries caused by moving parts. Attention is required concerning the effect of a power interruption or failure, for example, unwanted movements, the removal of compression forces and the liberation of the PATIENT from uncomfortable positions.

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

— Noise

In factories and workshops, excessive noise may cause fatigue or even damage to hearing. Limits are described in ISO Standards. In medically used rooms, very much lower limits are required for the comfort of PATIENTS and the medical personnel. Formulation of such limits for EQUIPMENT is being studied but may prove to be difficult, because the actual effect is strongly influenced by the acoustical properties of the room, the insulation between rooms and inter-action of EQUIPMENT parts.

Protection against unwanted or excessive radiation (see Section 5)

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

These limits for EQUIPMENT may of course be exceeded for intended application, where the medical supervisor takes the responsibility. For ionizing radiation the IEC Requirements generally comply with ICRP Recommendations¹⁾, their purpose is to provide data which are immediately usable by designer and USER. Their evaluation is possible only by adequate study of operating methods and times of EQUIPMENT and positioning of USER and assistants, because application of worst case conditions would give rise to situations which might hamper proper diagnosis or treatment.

Recent ICRP Publications also instruct the USER in methods for the restriction of intentional irradiation. Neutron-therapy is being studied for medical application and protection requirements.

High frequency radiation above 0.15 MHz upwards is normally directly harmful only if produced in substantial quantities, for example, by diathermy and surgical EQUIPMENT. However, this radiation may, even when produced at fairly low energy levels, influence the function of sensitive electronic devices and cause interference in radio and television reception.

Constructional requirements can hardly be given, but limits and measuring methods have been described in C.I.S.P.R. Publications, which will be reissued as C.I.S.P.R. manuals for specific groups of EQUIPMENT.

The sensitivity of EQUIPMENT for external interference (electro-magnetic field, perturbations of the supply voltage) is a subject of study.

Protection against the hazards of explosions in medically used rooms (see Section 6)

Protection against excessive temperatures, fire and other hazards (see Section 7)

— Temperatures

Temperature limits are required for almost all types of electrical EQUIPMENT with the purpose of preventing rapid ageing of insulation and unpleasant experiences where EQUIPMENT is touched or manipulated.

PATIENTS may have to be touching EQUIPMENT parts for prolonged periods, EQUIPMENT parts may be inserted into body cavities, usually temporarily but sometimes permanently.

For these situations, special temperature limits have been set.

— Fire hazard

Except for anaesthesia-EQUIPMENT and hyperbaric oxygen EQUIPMENT and some laboratory EQUIPMENT the fire hazard of MEDICAL ELECTRICAL EQUIPMENT is not subject to special requirements. The normal limits for operating temperatures and requirements for overload protection are applicable. EQUIPMENT enclosures must be so designed that molten metal, burning insulation and the like cannot fall out.

— Environment

Contrary to what is often assumed, MEDICAL ELECTRICAL EQUIPMENT is often used in a hostile environment. In case of emergency, EQUIPMENT is carried or wheeled on trolleys over doorsteps and into elevators and subjected to bumps and vibration. Such conditions may in fact typify NORMAL USE for some EQUIPMENT.

In operating theatres, where EQUIPMENT is often grouped closely around the operating table, EQUIPMENT may in NORMAL USE be subjected to the spillage of conductive fluids or in case of emergency to rough handling. To specify the robustness required, EQUIPMENT is required to withstand a combination of environmental tests of a climatic and mechanical nature and of overload conditions, taking into account where and how the EQUIPMENT is intended to be used, for example, PORTABLE or wheeled EQUIPMENT for outdoor use, for use in ambulances or vans, in the operating room, etc.

A number of clauses dealing with complicated and/or special problems are under consideration.

¹⁾ Obtainable from Pergamon Press Ltd., Headington Hill Hall, Oxford.

Section 1. General

1 Scope and object

1.1 Scope

This Standard applies to MEDICAL ELECTRICAL EQUIPMENT intended for use by or under the supervision of qualified personnel in the PATIENT ENVIRONMENT, or related to the PATIENT in such a way that the safety of persons or animals in that environment is directly affected.

This Standard specifies requirements for the transport, storage, installation, use and maintenance of such EQUIPMENT under the environmental conditions specified in Sub-clause 1.4 or by the manufacturer or as prescribed in Particular Standards.

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

Dangers resulting from the physiological effects produced by the intended function of EQUIPMENT covered by this Standard are not considered.

A (non-exhaustive) survey of MEDICAL ELECTRICAL EQUIPMENT is given in Appendix A.

1.2 Object

The object of this Standard is to establish requirements for a satisfactory level of safety for MEDICAL ELECTRICAL EQUIPMENT used in the PATIENT ENVIRONMENT and to serve as the basis for the safety requirements of Particular Standards for individual EQUIPMENT.

1.3 Particular Standards

A requirement of a Particular Standard takes priority over a requirement of this General Standard.

A Particular Standard shall state at least:

- the Clauses or Sub-clauses (or parts of them) of the General Standard which are not applicable;
- the Clauses or Sub-clauses (or parts of them) of the General Standard which have been modified;
- any additional Clauses or Sub-clauses.

A Particular Standard may contain:

- a) requirements which result in an increased degree of safety;
- b) requirements which may be less stringent than the requirements in this General Standard if the latter cannot be maintained, because of, for example, the power output of the EQUIPMENT;
- c) requirements concerning additional safety measures required externally to the EQUIPMENT, if the unconditional safety defined in Clause 8 is not obtained (see Clauses 8 and 10);
- d) requirements concerning restriction of conditions for safe operation, if the conditional safety described in Clause 8 is not obtained (see Clauses 8 and 11);
- e) requirements concerning performance, reliability, interfaces etc.;
- f) accuracy of working data.

1.4 Environmental conditions

a) *Transport and Storage*

The requirements of this Standard apply:

- 1) to MEDICAL ELECTRICAL EQUIPMENT which is capable of being transported and stored under environmental conditions not exceeding those specified by the manufacturer;
- 2) in the absence of such specifications, to MEDICAL ELECTRICAL EQUIPMENT which, while packed for transport and storage, is capable of being exposed for a period not exceeding 15 weeks to environmental conditions not exceeding the following:
 - a) an ambient temperature between -40°C and $+70^{\circ}\text{C}$,
 - b) a relative humidity between 10 % and 100 %,
 - c) an atmospheric pressure between 500 millibar²⁾ and 1 060 millibar.

If the period of transportation and storage of such EQUIPMENT exceeds 15 weeks, environmental conditions as specified in Sub-clause 1.4 b) apply.

²⁾ 1 mbar = 10^2N/m^2 = 100 Pa

b) *Operation*

The requirements of this Standard apply to MEDICAL ELECTRICAL EQUIPMENT which is specified for NORMAL USE under the following conditions:

1) *Environment*

- a) an ambient temperature between + 10 °C and + 40 °C

NOTE The upper limit of the ambient temperature range is based on the environmental conditions in buildings without air-conditioning in climates where the ambient temperature occasionally reaches 40 °C.

- b) a relative humidity between 30 % and 75 %.

- c) an atmospheric pressure between 700 mbar and 1 060 mbar.

The EQUIPMENT covered by this Standard may not be suitable for use in pressure chambers.

- d) a temperature of the water at the inlet of water cooled EQUIPMENT not higher than 25 °C.

Cooling water is assumed to be drinking-water.

2) *Power supply*

- a) A SUPPLY MAINS having:

— A RATED voltage not exceeding:

- 250 V for HAND-HELD EQUIPMENT,
- 250 V single-phase or 500 V poly-phase for EQUIPMENT with a RATED power input of up to 4 kVA,
- 500 V for all other EQUIPMENT with the restriction that the voltage to earth within the MAINS PART shall not exceed 300 V;

— a sufficiently low internal impedance (as may be required by a Particular Standard);

— voltage fluctuations generally not exceeding – 10 % and + 10 % of the nominal voltage, not including short-time fluctuations (for example, duration less than 1 second) at irregular intervals such as caused by operation of X-ray generators or similar EQUIPMENT;

— voltages which are practically sinusoidal and forming a practically symmetrical supply system in case of poly-phase supply;

— a frequency of not more than 1 kHz;

— a frequency which does not deviate more than 1 Hz from the nominal value up to 100 Hz and 1 % from 100 Hz to 1 kHz;

— the protective measures described in the “Regulations for the Electrical Equipment of³⁾ Buildings”, published by the Institution of Electrical Engineers.

If a nominal voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 5 % of the peak value of the ideal waveform.

A poly-phase voltage system is considered to be symmetrical if neither the magnitude of its negative sequence components nor the magnitude of its zero sequence components exceeds 2 % of the magnitude of its positive sequence components.

A poly-phase supply system is considered to be symmetrical if, when supplied from a symmetrical voltage system, the resulting current system is symmetrical. That is, the magnitude of neither the negative sequence current components nor the zero sequence current components exceed 5 % of the magnitude of the positive sequence current components.

- b) An INTERNAL ELECTRICAL POWER SOURCE as specified by the manufacturer.

2 Terminology and definitions

See also the Index.

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

Where the terms “voltage” and “current” are used, they imply the r.m.s. values of an alternating, direct or composite voltage or current.

In this Standard, the auxiliary verb:

- “shall” implies that compliance with a requirement or a test is mandatory for compliance with the Standard;

³⁾ See Appendix M.

— “should” implies that compliance with a requirement or test is strongly recommended but is not mandatory for compliance with the Standard;

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

These implications are under consideration.

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

2.1.1

ACCESS COVER

part of an enclosure or guard providing the possibility of access to EQUIPMENT parts for the purpose of adjustment, inspection, replacement or repair

2.1.2

ACCESSIBLE CONDUCTIVE PART

conductive part of EQUIPMENT which may be touched by USER or PATIENT without the use of a TOOL

2.1.3

ACCESSORY

an 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 pertinent functions

2.1.4

ACCOMPANYING DOCUMENTS

documents accompanying EQUIPMENT or an ACCESSORY and containing all important information for the USER and installer or assembler of the EQUIPMENT, particularly regarding safety

2.1.5

APPLIED PART

the entirety of all parts of the EQUIPMENT including the PATIENT leads which come intentionally into contact with the PATIENT to be examined or treated. For some EQUIPMENT, Particular Standards may consider parts in contact with the USER as an APPLIED PART (see Figure 1, page 99)

For some EQUIPMENT, an isolated (floating) APPLIED PART extends as seen from the PATIENT into the EQUIPMENT to the point(s) where the prescribed insulation and/or PROTECTIVE IMPEDANCE is completed.

2.1.6

BODY OF THE EQUIPMENT

the enclosure of the EQUIPMENT including:

- all ACCESSIBLE CONDUCTIVE PARTS, knobs, handles, grips and the like;
- accessible shafts;
- for the purpose of tests, metal foil not larger than 20 cm × 10 cm, applied in contact with all accessible surfaces of insulating material.

2.1.7

F-TYPE ISOLATED (FLOATING) APPLIED PART

APPLIED PART isolated from all other parts of the EQUIPMENT to such a degree that the allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITIONS is not exceeded when 1.1 times the highest rated MAINS VOLTAGE is applied between the APPLIED PART and earth

2.1.8

INPUT PART

the entirety of all parts of CLASS III EQUIPMENT intended for connection to MEDICAL SAFETY EXTRA-LOW VOLTAGE with a special plug

2.1.9

INTERNAL ELECTRICAL POWER SOURCE

power source intended to provide the electrical power necessary and sufficient to operate EQUIPMENT and which is incorporated in that EQUIPMENT

2.1.10**LIVE**

the state of a part, under NORMAL or SINGLE FAULT CONDITION, which, when the part is contacted, can cause a current exceeding the ALLOWABLE LEAKAGE CURRENT under NORMAL CONDITION, as described 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**LIVE PARTS**

parts which are LIVE under NORMAL CONDITION

- LIVE PARTS may be part of the MAINS PART or of an internal circuit or of the APPLIED PART (PATIENT CIRCUIT).
- LIVE PARTS include the neutral conductor and all conductive parts connected to it.
- LIVE PARTS exclude the PROTECTIVE EARTH CONDUCTOR and all conductive parts connected to it.

2.1.12**MAINS PART**

entirety of all parts of the 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, page 99)

2.1.13**MODULAR SYSTEM**

EQUIPMENT system in which several EQUIPMENT functions have been designed according to a common principle concerning, for example, dimensions, connection means and display

2.1.14**OUTPUT PART**

the entirety of all parts of CLASS III EQUIPMENT intended for external connection excluding the INPUT PART and the APPLIED PART

2.1.15**PATIENT CIRCUIT**

electrical circuit of which the PATIENT forms a part

2.1.16**PLUG-IN MODULE**

EQUIPMENT part being part of a MODULAR SYSTEM and intended to be connected by a plug-in arrangement and to be inserted or removed by the USER

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, for example, for display, recording or data processing (see Figure 1, page 99)

2.1.19**SIGNAL OUTPUT PART**

part of EQUIPMENT, not being an APPLIED PART, intended to deliver output signal voltages or currents, for example, for display, recording or data processing (see Figure 1)

2.1.20**SUPPLY CIRCUIT**

circuit from which the EQUIPMENT receives the energy necessary for its function

2.1.21**SUPPLY EQUIPMENT**

EQUIPMENT which supplies electrical power to one or more pieces of EQUIPMENT

2.2 EQUIPMENT types (classification)**2.2.1****AMBULANCE or VEHICLE USED EQUIPMENT**

EQUIPMENT specially designed for application or transport in vehicles or in or on trolleys (carts)

2.2.2**ANAESTHETIC-PROOF EQUIPMENT (AP)**

see Sub-clause 38.3

2.2.3**ANAESTHETIC-PROOF CATEGORY G EQUIPMENT (APG)**

see Sub-clause 38.1

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 such a way that means are provided for the connection of ACCESSIBLE CONDUCTIVE PARTS to the PROTECTIVE (EARTH) CONDUCTOR in the fixed wiring of the installation in such a way that ACCESSIBLE CONDUCTIVE PARTS cannot become LIVE in the event of a failure of the BASIC INSULATION

For an example, see Figure 2, page 100.

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

For an example, see Figure 3, page 101.

2.2.6**CLASS III EQUIPMENT**

EQUIPMENT in which protection against electric shock relies on supply at safety extra-low voltage (SELV) and in which voltages higher than those of SELV are not generated

For an example, see Figure 4, page 102.

2.2.7**DIRECT CARDIAC APPLICATION**

the use of EQUIPMENT which may come in direct CONDUCTIVE CONNECTION to the PATIENT's heart

2.2.8**DISINFECTABLE EQUIPMENT**

EQUIPMENT of which the satisfactory operation and safety is not impaired when the EQUIPMENT is disinfected by means prescribed in the instructions for use or indicated on the EQUIPMENT

2.2.9**DRIP-PROOF EQUIPMENT**

EQUIPMENT provided with an enclosure preventing entry of such an amount of falling liquid which might interfere with the satisfactory and safe operation of the EQUIPMENT (see Sub-clause 44.6)

2.2.10**ENCLOSED MEDICAL GAS SYSTEM**

see Sub-clause 37.1

2.2.11

EQUIPMENT

a single, self-contained unit or a combination of units (for example, in a rack or in or on a trolley) and provided with not more than one connection to the SUPPLY MAINS

2.2.12

FIXED EQUIPMENT

EQUIPMENT which is fastened or otherwise secured at a specific location in a building or a vehicle

2.2.13

HAND-HELD EQUIPMENT

EQUIPMENT intended to be supported by the hand during NORMAL USE

2.2.14

MAINS OPERATED

condition of EQUIPMENT indicating that it is operated when connected to a SUPPLY MAINS or is intended for such a connection

2.2.15

MEDICAL ELECTRICAL EQUIPMENT

electrical EQUIPMENT specified for use in the PATIENT environment and related in such a way to the PATIENT that the PATIENT's safety can be influenced

For examples, see Appendix A.

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 by means of PERMANENT CONNECTIONS

2.2.18

PORTABLE EQUIPMENT

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

2.2.19

RESTRICTED MOVABLE EQUIPMENT

EQUIPMENT movable within a course or area restricted by means of, for example, rails, guides, pivots, etc.

2.2.20

SPLASH-PROOF EQUIPMENT

EQUIPMENT provided with an enclosure preventing entry of such an amount of liquid, splashed from any direction, which might interfere with the satisfactory and safe operation of the EQUIPMENT (see Sub-clause 44.6)

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

STERILIZABLE EQUIPMENT (parts)

EQUIPMENT (parts) of which the satisfactory operation and safety is not impaired when it is sterilized as prescribed in the instructions for use or as indicated on the EQUIPMENT

2.2.23**TRANSPORTABLE EQUIPMENT**

EQUIPMENT which is intended to be easily moved from one place to another whether or not connected to the supply and without an appreciable restriction of range

Examples: MOBILE EQUIPMENT and PORTABLE EQUIPMENT.

2.2.24**TYPE B EQUIPMENT**

CLASS I, II or III EQUIPMENT or EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE providing an adequate degree of protection against electric shock particularly regarding:

- allowable LEAKAGE CURRENTS;
- reliability of the protective earth connection (if present).

TYPE B EQUIPMENT is, for example, suitable for intentional external and internal application to the PATIENT, excluding DIRECT CARDIAC APPLICATION.

2.2.25**TYPE BF EQUIPMENT**

TYPE B EQUIPMENT with an F-TYPE ISOLATED (FLOATING) APPLIED PART

2.2.26**TYPE CF EQUIPMENT**

CLASS I OR II EQUIPMENT or EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, providing a high degree of protection against electric shock particularly regarding allowable LEAKAGE CURRENTS, and having an F-TYPE ISOLATED (FLOATING) APPLIED PART

TYPE CF EQUIPMENT is primarily intended for DIRECT CARDIAC APPLICATION.

2.2.27**TYPE H EQUIPMENT**

CLASS I, II or III EQUIPMENT or EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE providing a degree of protection against electric shock comparable to that of household and similar electrical EQUIPMENT complying with the relevant IEC Standards

2.2.28**WATERTIGHT EQUIPMENT**

EQUIPMENT provided with an enclosure which, when the enclosure is immersed in water under stated conditions, prevents entry of an amount of water to areas where its presence could cause a hazard

2.3 Insulation**2.3.1****AIR CLEARANCE**

the 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

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

2.3.3**CREEPAGE DISTANCE**

the 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**OPERATIONAL INSULATION**

insulation between LIVE PARTS which have a potential difference between them and which is necessary for the normal functioning of the EQUIPMENT

2.3.6**PROTECTIVE IMPEDANCE**

component or assembly of components the impedance, construction and reliability of which are such that it may be connected between LIVE PARTS or parts which may become LIVE under SINGLE FAULT CONDITIONS and ACCESSIBLE CONDUCTIVE PARTS or APPLIED PARTS without giving rise to electric shock

2.3.7**REINFORCED INSULATION**

a 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

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

2.3.8**SUPPLEMENTARY INSULATION (protective 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 (potential difference)**

any voltage (potential difference) over 1 000 V a.c. or over 1 500 V d.c. or 1 500 V peak value

2.4.2**MAINS VOLTAGE**

voltage between two different line conductors of a poly-phase system of a SUPPLY MAINS or the voltage between the line conductor and the neutral conductor of a single-phase system of a SUPPLY MAINS

2.4.3**MEDICAL SAFETY EXTRA-LOW VOLTAGE (MSELV)**

a voltage which does not exceed a nominal value of 24 V a.c. or up to and including 50 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 MEDICAL SAFETY EXTRA-LOW VOLTAGE TRANSFORMER or by a convertor with separate windings

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 part of the enclosure, 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**

non-functional current through or across an insulation. 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 amplifiers, currents used in impedance plethysmography

2.5.5**PATIENT FUNCTIONAL CURRENT**

current flowing in the PATIENT in NORMAL USE between parts of the APPLIED PART and intended to produce a physiological effect, for example, currents necessary for nerve and muscle stimulation, cardiac pacing, defibrillation, high-frequency surgical procedures

2.5.6**PATIENT LEAKAGE CURRENT**

current flowing from the APPLIED PART via the PATIENT to earth (excluding any PATIENT FUNCTIONAL CURRENT) or flowing from the PATIENT via an F-TYPE ISOLATED (FLOATING) 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****ADDITIONAL PROTECTIVE EARTH CONDUCTOR**

conductor to be connected between an ADDITIONAL PROTECTIVE EARTH TERMINAL and an external protective system (see Figure 1, page 99)

2.6.2**ADDITIONAL PROTECTIVE EARTH TERMINAL**

a PROTECTIVE EARTH TERMINAL provided in addition to the normal PROTECTIVE EARTH TERMINAL for the purpose of providing facilities for protection against electric shock in case of SINGLE FAULT CONDITION of the normal PROTECTIVE EARTH CONDUCTOR (see Figure 1)

2.6.3**FUNCTIONAL EARTH CONDUCTOR**

conductor (intended 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**PATIENT CENTRE EQUIPOTENTIAL POINT**

under consideration

2.6.6**POTENTIAL EQUALIZATION CONDUCTOR**

CONDUCTIVE CONNECTION between extraneous conductive parts and/or the EQUIPMENT specified in sub-clause 18 e) and a potential equalization busbar

2.6.7**PROTECTIVE EARTH CONDUCTOR**

conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system (see Figure 1, page 99)

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)

2.7 Connection (devices)**2.7.1****APPLIANCE COUPLER**

a means enabling the connection at will, of a flexible cable or cord to EQUIPMENT (see Figure 5, page 103). It consists of two parts: a MAINS CONNECTOR and an APPLIANCE INLET

2.7.2**APPLIANCE INLET**

that part of an APPLIANCE COUPLER incorporated in or fixed to the EQUIPMENT (see Figure 1 and Figure 5)

2.7.3**AUXILIARY MAINS PLUG**

part integral with, or intended to be attached to, a flexible cable or cord of EQUIPMENT or of an EQUIPMENT part to be inserted into an AUXILIARY MAINS SOCKET OUTLET

2.7.4**AUXILIARY MAINS SOCKET OUTLET**

a socket outlet with MAINS VOLTAGE on EQUIPMENT intended for provision of mains supply to other EQUIPMENT or to other separate parts of EQUIPMENT

2.7.5**CONDUCTIVE CONNECTION**

a connection through which a current may flow exceeding the allowable LEAKAGE CURRENT

2.7.6**DETACHABLE CORD**

a flexible supply cord connected to the EQUIPMENT with an APPLIANCE COUPLER (see Figure 5 and sub-clause 57.3)

2.7.7**EXTERNAL TERMINAL DEVICE**

TERMINAL DEVICE by which the electrical connection to other EQUIPMENT is made

2.7.8**FIXED MAINS SOCKET OUTLET**

mains socket outlet installed in a fixed wiring system in a building or a vehicle (see Figure 5)

2.7.9**INTERCONNECTION TERMINAL DEVICE**

TERMINAL DEVICE by which internal connections within the 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 the flexible cable or 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 Figure 1, Figure 5, pages 99 and 103, and sub-clause 57.2)

2.7.11**MAINS PLUG**

part integral with or intended to be attached to a flexible cable or 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**NON-REWIRABLE, NON-DETACHABLE CORD**

a flexible supply cord permanently attached to a piece of EQUIPMENT and not intended to be replaced

2.7.14**PERMANENT CONNECTION**

connection that can be loosened or tightened only with the aid of a TOOL

2.7.15**REWIRABLE NON-DETACHABLE CORD**

flexible supply cord where the method of attachment to the EQUIPMENT is designed to permit replacement with the use of a TOOL

2.7.16**TERMINAL DEVICE**

part of EQUIPMENT by which electrical connection is made; it may contain several individual contacts

2.8 Transformers**2.8.1****INHERENTLY SHORT-CIRCUIT PROOF TRANSFORMER**

SHORT-CIRCUIT PROOF TRANSFORMER without any external or internal device for automatically opening the input circuit or the output circuit when the transformer is overloaded or when its output terminals are short-circuited

2.8.2**MEDICAL ISOLATING TRANSFORMER**

electrical EQUIPMENT used in medical practice intended to supply isolated power to MEDICAL ELECTRICAL EQUIPMENT in order to minimize the likelihood of discontinuity of supply in case of a failure to earth in the isolated power source or in one of the other EQUIPMENT connected to it

For requirements and tests, see Appendix K.

2.8.3**MEDICAL 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 MEDICAL SAFETY EXTRA-LOW VOLTAGE circuits

2.8.4**NON-INHERENTLY SHORT-CIRCUIT PROOF TRANSFORMER**

SHORT-CIRCUIT PROOF TRANSFORMER which incorporates a PROTECTIVE DEVICE, such as a fuse, an OVERLOAD RELEASE or a THERMAL CUT-OUT which is intended to protect the transformer against overheating in case of overloading or short-circuiting

2.8.5**NON-SHORT-CIRCUIT PROOF TRANSFORMER**

transformer intended to be protected against excessive temperature in case of overloading or short-circuiting by means of a PROTECTIVE DEVICE which is not incorporated in the transformer

2.8.6**SHORT-CIRCUIT PROOF TRANSFORMER**

transformer of which the temperature does not exceed specified limits when it is overloaded or short-circuited. It may be INHERENTLY or NON-INHERENTLY SHORT-CIRCUIT PROOF

2.9 Controls and limiting devices**2.9.1****ADJUSTABLE SETTING (of a control or limiting device)**

setting which can be altered by the USER without the use of a TOOL

2.9.2**CIRCUIT-BREAKER**

a CIRCUIT-BREAKER denotes a switching device capable of making, carrying and breaking currents under normal circuit conditions and also making, carrying for a specified time and breaking currents under specified abnormal circuit conditions

2.9.3

ELECTRICAL SAFETY DEVICE

any device such as an interlock which removes the voltage from LIVE PARTS which become accessible when the enclosure is opened (for example, SAFETY SWITCHES, earthing switches and isolating switches)

2.9.4

FIXED SETTING (of a control or limiting device)

setting which is not intended to be altered by the USER and which can only be altered by means of a TOOL

2.9.5

MECHANICAL SAFETY DEVICE

any device which is destined for protection against mechanical hazards by a direct mechanical action

2.9.6

NON-SELF-RESETTING THERMAL CUT-OUT

THERMAL CUT-OUT which requires resetting either manually or by the use of a TOOL or by replacement of a part, in order to restore the current

2.9.7

OVER-CURRENT RELEASE

an OVER-CURRENT RELEASE denotes a release which causes a CIRCUIT-BREAKER to open with or without delay, when the current in the release exceeds a predetermined value

2.9.8

PROTECTIVE DEVICE

an automatic control device which senses a specified parameter (or parameters) and is specifically designed to protect the persons, EQUIPMENT or environment against those hazards which could arise should the sensed parameter assume a value outside the limits within which safe operation is ensured

2.9.9

SAFETY SWITCH

any switch incorporated in the EQUIPMENT for safety purposes

2.9.10

SELF-RESETTING THERMAL CUT-OUT

THERMAL CUT-OUT which automatically restores the current after the relevant part of the EQUIPMENT has cooled down sufficiently

2.9.11

TEMPERATURE SWITCH

temperature sensing device, the operating temperature of which may be either fixed or adjustable and which is intended to operate during the normal operating cycle of EQUIPMENT by opening or closing a circuit when the temperature of the EQUIPMENT or of parts of it reaches a predetermined value. It does not make the reverse operation during subsequent parts of the normal operating cycle

Resetting before the start of a normal operating cycle may be either manual or automatic.

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 operating temperature setting cannot be altered by the USER (see definition of SELF-RESETTING THERMAL CUT-OUT and NON-SELF-RESETTING THERMAL CUT-OUT)

2.9.13

THERMOSTAT

device which is sensitive to temperature and is intended to keep the temperature of EQUIPMENT or of parts of it within required limits

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 rise 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 to attain 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 rise 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 hazards are intact

2.10.8

NORMAL USE

operation, including stand-by, according to the instructions for use or for the obvious intended purpose

2.10.9

PROPERLY INSTALLED

condition in which at least the relevant instructions concerning installation given by the manufacturer in⁴⁾ 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 rise being exceeded, the intervals between each period of operation being sufficient to allow the EQUIPMENT to cool down to room temperature

⁴⁾ See Appendix M.

2.10.11**SINGLE FAULT CONDITION**

condition in which a single means for protection against hazards is defective or a single abnormal hazardous condition is present (see Clause 12)

2.11**Mechanical safety**

terms, see Clause 28

2.12 Miscellaneous**2.12.1****COEFFICIENT OF VARIATION**

the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{S}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{\frac{1}{2}}$$

where:

S = estimated standard deviation of the population

$\bar{X}$ = mean value of observations in sample

X_i = i th observation in sample

n = number of observations in sample

2.12.2**MODEL OR TYPE REFERENCE (type number)**

a combination of figures or letters or of both used to identify a certain model of a particular item of *EQUIPMENT*

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

2.12.3**NOMINAL (value)**

that 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**

any living being (person or animal) subjected to medical investigation or treatment

2.12.5**PATIENT ENVIRONMENT**

any area up to 2.5 m distance from the intended location of the PATIENT in which intentional or unintentional contact between PATIENT and EQUIPMENT or some other person touching the EQUIPMENT can occur

2.12.6**PER CENT AVERAGE ERROR**

the per cent ratio of the difference between a pre-set or pre-indicated value and the mean value of a population of observations to the pre-set or indicated value

the following formula may be used:

$$PAE = \frac{X_p - \bar{X}}{X_p} \cdot 100 (\%)$$

where:

PAE = PER CENT AVERAGE ERROR of the population

$\bar{X}$ = mean value of observations in sample

X_p = pre-set or pre-indicated value

2.12.7

PETROLEUM SPIRIT (petroleum ether)

a liquid complying with the following specification:

Bromine number: not greater than 1.0

Distillation range: not less than 90 %, should distill between 60 °C and 80 °C.

Weight at 20 °C: 0.665 g to 0.675 g/ml.

Very flammable.

2.12.8

RATED (VALUE)

value assigned to electrical EQUIPMENT by the manufacturer

2.12.9

SERIAL NUMBER

a number and/or other designation used to identify a particular piece of a certain model of EQUIPMENT

2.12.10

SUPPLY MAINS

any permanently installed power source, which is not used exclusively to supply EQUIPMENT which is within the scope of this Standard

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

2.12.11

SURGICAL SPIRIT

flammable liquid mixture (see "Martindale — The Extra Pharmacopoeia"⁵⁾)

2.12.12

TOOL

any extra-corporeal object which may be used to secure or release fasteners or to make adjustments

2.12.13

USER

a person utilizing or operating EQUIPMENT

3 General requirements

Because of the wide range of MEDICAL ELECTRICAL EQUIPMENT covered in this Standard, it is not possible to specify the permissible effects on performance by MAINS VOLTAGE and frequency fluctuations on each particular type of EQUIPMENT.

This should be covered in Particular Standards.

However, in this Standard the effects of the MAINS VOLTAGE and frequency fluctuations are included in a number of safety tests.

3.1 EQUIPMENT shall be so designed, constructed and manufactured that, when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, it causes no danger which could reasonably be foreseen other than that connected with its intended application for diagnostic or therapeutic purposes, to the USER, to the PATIENT or to the surroundings IN NORMAL USE and in SINGLE FAULT CONDITION.

⁵⁾ Published by Pharmaceutical Press, 1 Lambeth High Street, London SE1 (ISBN 0 853 69078 2).

3.2 EQUIPMENT of TYPE B, BF and CF shall comply with all applicable requirements of this Standard. Compliance is considered to be fulfilled if all relevant tests of this Standard are passed successfully.

EQUIPMENT should be made and finished with a degree of uniformity and grade of workmanship complying with the appropriate requirements of this Standard and generally accepted principles of sound and safe practice.

3.3 Diagnostic, therapeutic, life supporting or PATIENT handling EQUIPMENT can be either TYPE B, BF or CF but not TYPE H EQUIPMENT.

TYPE H EQUIPMENT shall comply with the requirements of the relevant IEC Publication; but shall not be Class 0 or 0I.

Such relevant IEC Publications are (including supplements and amendments) for example:

Publication 65: *Safety Requirements for Mains Operated Electronic and Related Apparatus for Household and Similar General Use.*

Publication 335: *Safety of Household and Similar Electrical Appliances.*

Publication 348: *Safety Requirements for Electronic Measuring Apparatus.*

Publication 380: *Safety of Electrically Energized Office Machines*

Publication 414: *Safety Requirements for Indicating and Recording Electrical Measuring Instruments and Their Accessories.*

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.

3.5 *Compliance with the requirements of Sub-clauses 3.2 to 3.4 shall be checked by inspection and by performance of the relevant tests described in this Standard.*

4 General requirements for tests

In this Standard, a number of test requirements are stated in order to establish that an adequate standard of safety is maintained even under SINGLE FAULT CONDITIONS. However, in many cases inspection of the EQUIPMENT circuit arrangement or of the construction used may show that a safety hazard under NORMAL or SINGLE FAULT CONDITIONS is unlikely to occur, in which case some tests need not be carried out.

For example, in a typical MEDICAL ELECTRICAL EQUIPMENT there may be hundreds of separate pieces of insulation in some of which a failure would not produce a safety hazard to PATIENT, USER or surroundings, even though causing a deterioration or failure of the performance of the EQUIPMENT.

Only insulation the failure of which under NORMAL or SINGLE FAULT CONDITIONS could produce a hazard need be subject to testing. Inspection of other (safety) insulation may show that it is obviously functioning within allowable limits and detailed testing would be unnecessarily time-consuming and expensive.

4.1 Type tests and routine tests

a) Type tests

Except as specified in Sub-clause 4.1 b), all tests described in this Standard are type tests.

b) Routine tests

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

Although a detailed specification of such measures cannot be given, some guidance concerning routine testing or sample testing for compliance with a number of safety requirements is given in Appendix B.

Further routine tests or sample tests may be described by Particular Standards.

4.2 Repetition of tests

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

4.3 Number of samples

Where possible, all type tests are made on one representative sample of the item being tested.

In some cases, for example, to dismantle a CLASS II EQUIPMENT for the tests, an additional sample may be required.

If the EQUIPMENT is designed for different supply voltages, for both a.c. and d.c., for different speeds, etc., more than one 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 while the EQUIPMENT is on test and shall satisfy the appropriate section of this Standard. The rating of such components shall be checked.

Where a component or EQUIPMENT part has specified ratings exceeding that appropriate to its use in the EQUIPMENT, it does not have to be tested for such a wider range, unless called for by Particular Standards.

4.5 Ambient temperature, humidity, atmospheric pressure

a) *After the EQUIPMENT to be tested has been set up for NORMAL USE (according to Sub-clause 4.8), tests are carried out under normal operating conditions at:*

- an ambient temperature within the range of 15 °C to 35 °C;*
- a relative humidity within the range of 45 % to 75 %;*
- an atmospheric pressure within the range of 860 mbar to 1 060 mbar (645 mm Hg to 795 mm Hg).*

For reference tests (if the results are dependent on the ambient condition), three sets of specified atmospheric conditions are recognized and it is recommended that only one of these be used for any particular application (see Table I).

Table I — Specified atmospheric conditions

	<i>a</i>	<i>b</i>	<i>c</i>
Temperature (°C)	20 ± 2	23 ± 2	27 ± 2
Relative humidity (%)	65 ± 5	50 ± 5	65 ± 5
Atmospheric pressure	860 mbar to 1 060 mbar (645 mm Hg to 795 mm Hg)		

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

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

d) *Where necessary, Particular Standards may require tests at other temperatures.*

4.6 Other conditions

a) *Unless otherwise specified, the 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 USER 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.*

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

In the context of this Standard the voltage of the SUPPLY MAINS may be subject to fluctuations. These fluctuations are not included in the concept “RATED”.

a) *Where the 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 shall be according to Sub-clause 1.4 b) 2). Any test voltage below 1 000 V a.c. or 1 500 V d.c. or 1 500 V peak value shall not differ by more than 2 % from the prescribed value.

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

These requirements shall be met at the moment of measuring.

- b) *EQUIPMENT for a.c. only shall be tested with a.c. at RATED frequency (if marked) ± 1 Hz, between 0 and 100 Hz and ± 1 % above 100 Hz. EQUIPMENT marked with a RATED frequency range shall be tested at the least favourable frequency within that range.*
- c) *EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., shall be tested in conditions (described in Sub-clause 4.6) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current.*
- d) *EQUIPMENT for d.c. only shall be tested with d.c.; the possible influence of polarity on the operation of the EQUIPMENT shall be taken into consideration, according to the instructions for use.*
- e) *Unless otherwise specified by this Standard or by a Particular Standard, EQUIPMENT shall be tested at the least favourable RATED voltage within the relevant range. It may be necessary to perform some of the tests more than once in order to establish the least favourable voltage.*
- f) *EQUIPMENT for which alternative ACCESSORIES or heating elements are available shall be tested with those accessories or elements which give the least favourable conditions, provided that the accessories or elements used are within the manufacturer's specification of the EQUIPMENT.*
- g) *EQUIPMENT specified for use in combination with a prescribed type of power supply, for example, regarding voltages, capacitances, insulating resistances respectively to earth, etc., shall be tested in combination with such a prescribed power supply.*
- h) *The measurements 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, the 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. The aim is to verify that it is operating properly.

4.9 Repairs and modifications

- a) *No repairs or modifications, unless required by the normal course of the test, should be made to the EQUIPMENT during the tests.*
- b) *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 upon making all the necessary repairs or modifications after which only relevant tests shall be repeated.*

4.10 Moisture preconditioning treatment

As preconditioning for the tests of Sub-clauses 19.4 and 20.4, the EQUIPMENT is subjected to the following test:

a) Severity

Upper temperature: 40 °C.

Number of cycles: 1.

b) Preconditioning procedure

The EQUIPMENT shall be set up complete (or where necessary in parts). PROTECTIVE COVERS, used during transport and storage, and ACCESS COVERS shall be removed. Parts which can be removed without the use of a TOOL shall be removed but shall be treated simultaneously with the major part.

Doors and drawers which can be opened without a TOOL shall be opened.

c) Description of the stabilizing period and preconditioning cycle (see Figure 6, page 104).

The temperature of the specimen shall be stabilized at 25 ± 3 °C either:

- 1) *by placing the specimen in a separate chamber before introducing it into the test chamber;*

or:

- 2) *by adjusting the temperature of the test chamber to 25 ± 3 °C after the introduction of the specimen and maintaining it at this level until the specimen attains temperature stability.*

During the stabilization of temperature by either method, the relative humidity shall be within the limits prescribed for standard atmospheric conditions for testing. During the final hour, with the specimen in the test chamber, the relative humidity shall be increased to not less than 95 % at an ambient temperature of 25 ± 3 °C.

For drying, the EQUIPMENT may be transferred to another room or may remain in the humidity room. In both cases the humidity and temperature shall be adjusted.

The EQUIPMENT shall be dried for at least 12 hours at $30 \pm 2^\circ\text{C}$ and from 28 % to 32 % relative humidity.

d) Measurements

After the treatment, the EQUIPMENT is re-assembled, if necessary, and tests according to Sub-clauses 19.4 and 20.4 are carried out.

4.11 Sequence

Tests should be carried out in the sequence given in Appendix C, unless otherwise specified by Particular Standards.

5 Classification

Particular Standards should state which Type and which Class applies to the EQUIPMENT. MEDICAL ELECTRICAL EQUIPMENT may be classified as follows:

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;
- CLASS III EQUIPMENT.

b) EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE (for example, a battery), see Sub-clause 14.5.

5.2 According to the degree of protection against electric shock:

- TYPE B EQUIPMENT;
- TYPE BF EQUIPMENT;
- TYPE CF EQUIPMENT.

5.3 According to the degree of protection against ingress of liquids:

- ordinary EQUIPMENT (enclosed EQUIPMENT without protection against ingress of liquids);
- DRIP-PROOF EQUIPMENT;
- SPLASH-PROOF EQUIPMENT;
- WATERTIGHT EQUIPMENT.

5.4 According to the method(s) of sterilization or disinfection allowed by the manufacturer:

- gas STERILIZABLE EQUIPMENT (or parts);
- autoclavable EQUIPMENT (or parts);
- DISINFECTABLE EQUIPMENT (or parts);
- radiation STERILIZABLE EQUIPMENT (or parts);
- ultra-sonic STERILIZABLE EQUIPMENT (or parts);
- liquid STERILIZABLE EQUIPMENT (or parts);
- (further indications under consideration).

5.5 According to the degree of safety of application in the presence of flammable anaesthetics and/or flammable cleaning agents:

- EQUIPMENT for use in environments where no flammable anaesthetics and/or flammable cleaning agents are present;
- ANAESTHETIC PROOF EQUIPMENT;
- ANAESTHETIC PROOF CATEGORY G 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 According to the degree of electrical connection between EQUIPMENT and PATIENT:

- EQUIPMENT without an APPLIED PART, for example, ultra-violet, infra-red EQUIPMENT;
- EQUIPMENT with an APPLIED PART but not specifically designed for applications where a functional CONDUCTIVE CONNECTION to the PATIENT is made, for example, ultra-sonic EQUIPMENT, shortwave diathermy EQUIPMENT, X-ray tables, dental chairs, ergometers, etc.;

- EQUIPMENT with an APPLIED PART, specifically designed for applications where a CONDUCTIVE CONNECTION is made to the PATIENT, but not directly to the heart, for example, stimulation EQUIPMENT, h.f. surgery EQUIPMENT, electrocardiographs for external application, etc.;
- EQUIPMENT with an APPLIED PART and specifically designed for applications where a CONDUCTIVE CONNECTION directly to the heart is made, for example, blood pressure measuring EQUIPMENT with an intracardiac transducer, external pacemakers, electrocardiographs for DIRECT CARDIAC APPLICATION, etc.;
- EQUIPMENT without an APPLIED PART in CONDUCTIVE CONNECTION with the PATIENT, but specifically designed for applications where an electrical or mechanical connection is made with EQUIPMENT having an APPLIED PART with a CONDUCTIVE CONNECTION to the PATIENT, for example, computers, displays, recorders, etc.

5.8 Marking or identification of classification are described in Clause 6.

6 Identification, marking and documents

For the purpose of this clause, the following definitions apply:

- “Permanently affixed” means removable with a TOOL only or by appreciable force and able to withstand the effects of temperature, moisture (water and alcohol), fumes and rubbing in NORMAL USE, etc.
- “Clearly legible” means:
 - a) for warning statements, instructive statements or drawings: affixed in a prominent location and legible with normal vision from a distance which normally may exist between the statement or symbol and (the) observer(s) for whom the statement is intended.
 - b) for FIXED EQUIPMENT: discernible when the EQUIPMENT is mounted in its position of NORMAL USE.
 - c) for TRANSPORTABLE EQUIPMENT and for STATIONARY NON-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” of the EQUIPMENT means for warning statements:
 - a) on or near the control panel or on or near a relevant part:
 - b) 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 part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point.

6.1 *Marking on the outside of MAINS OPERATED EQUIPMENT or EQUIPMENT parts and on the outside of EQUIPMENT or EQUIPMENT parts without direct SUPPLY MAINS connection, including EQUIPMENT supplied by an INTERNAL ELECTRICAL POWER SOURCE (see also Clause 11).*

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 outside of the “major part” of the EQUIPMENT as described in Table II, Column 3.

b) EQUIPMENT supplied from an INTERNAL ELECTRICAL POWER SOURCE

EQUIPMENT intended to be supplied from an INTERNAL ELECTRICAL POWER SOURCE shall at least be provided with the following “permanently affixed” and “clearly legible” markings on the “major part” of the EQUIPMENT as described in Table II, Column 4.

c) EQUIPMENT supplied from a specified power supply

EQUIPMENT intended to be supplied from a specified power supply (other than the SUPPLY MAINS and isolated from it), which is or is not part of the EQUIPMENT model or type shall be provided minimally with the following “permanently affixed” and “clearly legible” markings on the outside of the EQUIPMENT as described in Table II, Column 5.

If the specified power supply is not part of the EQUIPMENT model or type, the instructions for use of the EQUIPMENT shall additionally establish reference to the model or type of such a specified power supply. If safety aspects are involved, the model or type of such a specified power supply shall be permanently marked on the outside of the EQUIPMENT and included in the instructions for use.

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

If the size of the EQUIPMENT specified in Sub-clause 6.1 or the nature of its enclosure does not allow affixation of all specified markings, then at least the markings as indicated in Sub-clauses 6.1 e), 6.1 f) and 6.1 g) (not for PERMANENTLY INSTALLED EQUIPMENT), 6.1 l) and 6.1 q) (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking is practicable, all information shall be included in the ACCOMPANYING DOCUMENTS.

Parts of EQUIPMENT which are subject to deterioration during NORMAL USE and are interchangeable, should bear inscriptions in accordance with the above, in so far as these parts significantly affect the safety characteristics of the EQUIPMENT within the meaning of this Standard.

Table II — Marking on the outside of EQUIPMENT

Requirements as specified in Sub-clauses	Subject	MAINS OPERATED EQUIPMENT [see Sub-clause 6.1 a)]	EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE [see Sub-clause 6.1 b)]	EQUIPMENT supplied from a specified power source [see Sub-clause 6.1 c)]
6.1 e)	Indication of origin	×	×	×
6.1 f)	MODEL OR TYPE REFERENCE	×	×	×
6.1 g)	Connection to the supply	× ^b	—	—
6.1 h)	Supply frequency (Hz)	× ^b	—	—
6.1 j)	Power input	× ^b	—	—
6.1 k)	Mains power output	× ^a	—	—
6.1 l)	Classification	× ^a	× ^a	× ^a
6.1 m)	Mode of operation	× ^a	× ^a	× ^a
6.1 n)	Fuses	× ^a	× ^a	× ^a
6.1 p)	Output	× ^a	× ^a	× ^a
6.1 q)	Physiological effects	× ^a	× ^a	× ^a
6.1 r)	ANAESTHETIC PROOF EQUIPMENT	× ^a	× ^a	× ^a
6.1 s)	HIGH VOLTAGE TERMINAL DEVICE	× ^a	× ^a	× ^a
6.1 t)	Cooling conditions	× ^a	× ^a	× ^a
6.1 u)	Mechanical stability	× ^a	× ^a	× ^a
6.1 v)	Protective packing	×	×	×
6.1 w)	ADDITIONAL PROTECTIVE EARTH CONDUCTOR	× ^a	—	—
^a If applicable ^b For non-PERMANENTLY INSTALLED EQUIPMENT only. For other EQUIPMENT, see also Sub-clause 6.2 a).				

e) *Indication of origin*

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

f) *MODEL OR TYPE REFERENCE*

This is to identify the relationship between possibly separated parts of EQUIPMENT and their or its ACCOMPANYING DOCUMENTS.

By means of the MODEL OR TYPE REFERENCE, if necessary with an added SERIAL NUMBER, the manufacturer, assembler or importer shall be able to indicate, if required, exactly and verifiably, the date of manufacture, assembly or importation within five years after these events.

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

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

g) *Connection to the supply*

— The RATED supply voltage(s) or voltage range(s) to which the EQUIPMENT may be connected.

— Nature of supply, for example, number of phases (except for single-phase supply) and type of current.

The symbol for the type of current shall be affixed directly behind the RATED voltage. For RATED voltage and RATED current, numerical details are sufficient if the numerical value for the RATED current is in front of or over that for the RATED voltage and separated from the latter by a fraction stroke.

Example: 16 A/220 V ~ or $\frac{16 \text{ A}}{220 \text{ V}} \sim$

— Connection point for the PROTECTIVE EARTH CONDUCTOR shall be marked with the prescribed symbol (see Appendix D, Table D.I, symbol 6).

— FUNCTIONAL EARTH TERMINALS shall be marked with the prescribed symbol (see Appendix D, Table D.I, symbol 7).

h) *Supply frequency (in hertz)*

RATED frequency or RATED frequency range(s).

j) *Power input (see Clause 7)*

The input shall be RATED in amperes or the input may be expressed in volt-amperes or 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*

— A symbol for CLASS II EQUIPMENT, if relevant (see Appendix D, Table D.I, symbol 10).

— A symbol according to the type of protection against moisture, if relevant (see Appendix D, Table D.I, symbols 11, 12 or 13).

— A symbol indicating the type of EQUIPMENT according to the degree of protection against electric shock as classified in Sub-clause 5.2 for TYPE B, BF and CF EQUIPMENT (see Appendix D, Table D.II, symbols 1, 2 and 3).

If EQUIPMENT has more than one APPLIED PART with different degrees of protection (according to Sub-clause 5.2), the relevant symbols shall be clearly marked on such APPLIED PARTS or on or near relevant outlets (connection points). Such EQUIPMENT shall have no further type mark (see also Sub-clauses 14.4 and 19.3).

m) *Mode of operation*

— If no marking is provided, the EQUIPMENT is assumed to be designed for CONTINUOUS OPERATION.

— If a marking is provided, various ways are possible of which examples are given below. In all cases, an explanation of the meaning of the abbreviations, figures or symbols which may be used shall be given in the instructions for use [see Sub-clause 6.8.2 a)].

Examples of markings for mode of operation:

“cont”: CONTINUOUS OPERATION permitted;

“int” or “int’t”: intermittent — details regarding operating and resting times shall be given;

“10 min/15 min”: maximum operating time and minimum resting time for a single cycle.

n) *Fuses*

The type and rating of fuses accessible from the outside of the EQUIPMENT shall be marked adjacent to the fuse-holder.

p) *Output*

— The RATED output voltage and current or power (where applicable).

— The output frequency (where applicable).

q) *Physiological effects (symbols and warning statements)*

EQUIPMENT producing physiological effects which may cause danger to the PATIENT and/or the USER should bear a suitable symbol concerning the relevant hazard. The symbol should 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, shall be used. For non-ionizing radiation (for example, high-power microwaves), the symbol 8 of Table D.II of Appendix D shall be used.

For other hazards, the symbol 14 of Table D.I of Appendix D shall be used. The meaning of the symbol shall be explained in the instructions for use. Additionally, a warning statement may be allowed (see also Sub-clause 6.8.1).

The text of such a warning statement may be laid down in Particular Standards for such EQUIPMENT which produces special physiological effects.

r) *ANAESTHETIC-PROOF EQUIPMENT*

For requirements on marking, see Section 6.

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 "HIGH VOLTAGE" (see Appendix D, Table D.II, symbol 6).

t) *Cooling conditions*

Requirements for cooling provisions to EQUIPMENT (for example, supply of water or air) shall be marked (see Particular Standards).

u) *Mechanical stability*

EQUIPMENT with a limited stability shall be provided with a warning note and further markings as described in Clause 24. An indication shall be given in the ACCOMPANYING DOCUMENTS.

v) *Protective packing*

If special measures have to be taken during transport or storage, the packing shall be marked accordingly [see Sub-clause 1.4 a) 1)].

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

w) *ADDITIONAL PROTECTIVE EARTH CONDUCTOR*

If the EQUIPMENT is to be provided with an ADDITIONAL PROTECTIVE EARTH CONDUCTOR, the EQUIPMENT shall be marked with symbol 7, Table D.II of Appendix D [see Sub-clauses 18 d) and 19.3 e)].

x) *Compliance with the requirements of Sub-clause 6.1 shall be checked as follows:*

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

For determination of durability, the markings are rubbed by hand, without undue pressure first for 15 s with a cloth rag soaked with SURGICAL SPIRIT and then for 15 s with a cloth rag soaked with PETROLEUM SPIRIT.

Markings shall be "clearly legible" after all the tests of this Standard have been performed.

Adhesive labels should not have worked loose or become curled at the edges.

When evaluating durability, the effect of NORMAL USE on the markings shall also 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 x). 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 the 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 indicated near the heater or on the name-plate of the EQUIPMENT.

c) HIGH-VOLTAGE parts of EQUIPMENT shall be marked with the symbol "HIGH VOLTAGE" (see Appendix D, Table D.II, symbol 6).

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

e) Fuses not accessible from the outside of the EQUIPMENT without the use of a TOOL shall be identified either by type and rating next to the fuse-holder, or by at least a reference, for example, a diagram number which can be associated with the technical description.

f) Connection points for the PROTECTIVE EARTH CONDUCTOR shall be marked with the prescribed symbol (see Appendix D, Table D.I, symbol 6).

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

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

j) The markings required in Sub-clause 6.2 shall be affixed only on or near parts which need not be removed to make the connection. They shall remain visible after the connection has been made. Marking of 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 hazard can develop if connections are interchanged.

If the 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 rise of more than 35 °C during the normal temperature test, the EQUIPMENT shall be marked:

- For supply connections, use wiring materials suitable for at least . . . °C, or
- with an equivalent statement.

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

6.3 Marking of controls

a) The mains switch shall be clearly identified. The “ON” and “OFF” positions shall be marked according to the relevant symbols of Appendix D (symbols 15 and 16 of Table D.I), or indicated by an adjacent indicator lamp or other unambiguous means.

b) On all EQUIPMENT, the different positions of regulating devices and the different positions of switches shall be indicated by figures, letters or other visual means.

The “OFF” position shall not be indicated by words only.

If symbols are used for indicating the different positions, the “OFF” position shall be indicated by the relevant symbol of Appendix D (symbol 15 of Table D.I). A position for a greater output shall be indicated by a figure or symbol other than 0.

If symbols only are used, their meaning shall be explained in the instructions for use.

c) In the case of setting devices which may be adjusted to different values during operation, the direction in which the effect or magnitude changes shall be indicated. This may be omitted only if the value of the set magnitude is discernible from indicating devices (instruments, scales, etc.) and if no hazard to the PATIENT can occur if the value is changed in the wrong direction.

d) Switches or setting devices should be arranged, grouped or marked in such a manner that it may be clearly recognized which function they switch or set.

The marking should be understandable without knowledge of languages, national standards and the like, for example, by self-evident symbols.

e) *Compliance with the requirements of Sub-clause 6.3 shall be checked by inspection.*

6.4 Symbols

a) Symbols used for marking according to Sub-clauses 6.1 to 6.3 shall be in accordance with Appendix D.

b) Symbols for controls and performance shall be in accordance with applicable IEC Publications (in preparation).

c) *Compliance with the requirements of Sub-clause 6.4 shall be checked by comparison with the symbols in the applicable IEC Publication.*

6.5 Colours of the insulation of conductors

- a) PROTECTIVE EARTH CONDUCTORS in supply cables or cords intended to be connected to the PROTECTED⁶⁾ EARTH TERMINAL of CLASS I EQUIPMENT shall be coloured green/yellow.
- b) The insulation of protective earth conductors inside EQUIPMENT shall be coloured green/yellow.
- c) The colour combination (green/yellow) shall only be used for identification of PROTECTIVE EARTH CONDUCTORS or POTENTIAL EQUALIZATION CONDUCTORS [see sub-clause 18 e)].
- d) Conductors in flexible supply cables or cords intended to be connected to the neutral conductor of the⁶⁾ supply system shall be coloured blue as specified in BS 6500.
- e) Conductors in two-core and three-core flexible supply cables or cords intended to be connected to the line conductor of the supply shall be coloured brown as specified in BS 6500. Conductors in flexible supply cables or cords for connection to three-phase supplies shall be coloured in accordance with the requirements of BS 6500.
- f) Where a multi-conductor cable is used between EQUIPMENT parts and the maximum allowed resistance of the protective earth connection would be exceeded if only the green/yellow coloured conductor were used, other conductors of the same cable may be connected in parallel with the green/yellow conductor, provided that the ends of such additional conductors are marked green/yellow.
- g) *Compliance with the requirements of Sub-clause 6.5 shall be checked by inspection.*

6.6 Identification of medical gas cylinders and connections

- a) The 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 46.7).
- b) The point of connection of gas cylinders shall be so identified on EQUIPMENT that errors are avoided when a replacement is made.
- c) *Compliance with the requirements of Sub-clause 6.6 shall be checked by inspection of the identification of the content and the point of connection of gas cylinders.*

6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Colours of indicator lights should as far as possible comply with ISO and IEC Standards, for example IEC Publication 73). In medical practice the meaning and application of the colours red and yellow should be as indicated in Table III.

Table III — Colours of indicator lights and their meaning for MEDICAL ELECTRICAL EQUIPMENT

Colour	Meaning
Red	Warning of danger, urgent action required
Yellow	Caution or attention required
Green	Ready for action
Any other colour	Any meaning other than that of red or yellow

Further explanations and typical applications of these colours may be provided by Particular Standards.

Dot-matrix and other alpha-numeric displays are not considered to be indicator lights. If more than one lamp of one colour is used, the function of the lamps should be marked, unless the function is obvious.

b) Colours of unilluminated push-buttons

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

c) Colours of illuminated push-buttons

See IEC Publication 73.

- d) *Compliance with the requirements of Sub-clause 6.7 b) and 6.7 c) shall be checked by inspection. (See also Sub-clause 56.8)*

⁶⁾ See Appendix M.

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 the EQUIPMENT.

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

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

6.8.2 Instructions for use

a) General information

— The instructions for use shall contain all information necessary to operate the EQUIPMENT in accordance with its specification and — as far as relevant — without exceeding general safety limits. This shall include explanation of the function of controls, displays and signals, the sequence of operation (if relevant) and of symbols used on or near control parts, connection and disconnection of detachable parts and ACCESSORIES, replacement of material which is consumed during operation.

— The instructions for use shall include indication of recognized ACCESSORIES, detachable parts and materials, if the use of other parts or materials can degrade minimum safety.

— If malfunction of any part of the EQUIPMENT can cause a hazard and such malfunction can be detected by the absence of normal displays or signals or by abnormal readings of displays or combinations of displayed data, the instructions for use should mention this and require discontinuation of operation and subsequent repair and/or recalibration.

— The instructions for use shall instruct, (if necessary to ensure safety, reliability and proper performance) the USER in sufficient detail concerning preventive inspection and maintenance to be performed by him, including the frequency of such maintenance.

Additionally, the instructions for use shall mention the parts on which preventive inspection and maintenance shall be performed by other persons, taking into account what is presumed in Sub-clause 6.8.2 b), including the periods to be applied, but not necessarily including details about the actual performance of such maintenance. Such detailed information shall, if practicable, be included in the technical description. See also Clause 12 (SINGLE FAULT CONDITIONS).

The EQUIPMENT should, if its size permits, be provided with a holder for the instructions for use. If this is not possible, the instructions for use should be supplied in a permanent protective cover that is suitable for hanging where visible.

b) Responsibility of the manufacturer

The instructions for use should contain a statement saying that the manufacturer, assembler, installer or importer considers himself responsible for the effects on safety, reliability and performance of the EQUIPMENT only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by him, and
 - the electrical installation of the relevant room complies with the "Regulations for the electrical equipment of buildings"
- PUBLISHED BY THE INSTITUTION OF ELECTRICAL ENGINEERS.
- the EQUIPMENT is used in accordance with the instructions for use.

c) MAINS VOLTAGE on the SIGNAL OUTPUT or SIGNAL INPUT PART

If the application of a voltage equal to 110 % of the highest RATED MAINS VOLTAGE to a SIGNAL OUTPUT or SIGNAL INPUT PART would be destructive without impairing the safety of USER or PATIENT, as verified by the test of Sub-clause 19.4 h), the maximum voltage that can be applied shall be stated in the instructions for use.

d) Parts in contact with the PATIENT

For EQUIPMENT parts which come into contact with the PATIENT during NORMAL USE, the instructions for use shall contain details about the 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 the 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, the instructions for use shall contain a statement saying that the EQUIPMENT shall, where the integrity of the PROTECTIVE EARTH CONDUCTOR arrangement is in doubt, 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 the EQUIPMENT is not likely to be used for some time.

g) *Rechargeable batteries*

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

6.8.3 *Technical description*

a) *General*

The technical description shall provide all data including those mentioned in Sub-clause 6.1 and, additionally, all characteristics (or an indication where they may be found) in so far as they may be considered to be essential for safe operation.

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

For example, particular attention may be necessary where racks are built into walls.

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 the EQUIPMENT, the required type and rating of the fuses shall be indicated at least in the technical description.

— The technical description shall contain instructions for the replacement of interchangeable and/or detachable parts which are subject to deterioration during NORMAL USE [see Sub-clause 6.1 d)].

c) *Circuit diagrams, component part lists, etc.*

The technical description shall contain a statement that the supplier will make available on request such 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 the EQUIPMENT which are classified by the manufacturer as repairable.

d) *Restricted ambient temperature limits*

If the full range of ambient temperatures, as mentioned in Sub-clause 1.4 b) is not permitted by the manufacturer or supplier of the EQUIPMENT, the restricted limits of ambient temperature shall be stated in the technical description.

6.8.4 *Test requirements*

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

6.8.5 *Reference to ACCOMPANYING DOCUMENTS*

Other clauses and sub-clauses in which requirements concerning the contents of ACCOMPANYING DOCUMENTS are given:

EQUIPMENT supplied from a specified power supply: 6.1 e).

Physiological effects (Symbols and warning statements): 6.1 q).

Removable protective means: 9.

Disconnection from the SUPPLY MAINS: 15 b).

For connection to SIGNAL INPUT or SIGNAL OUTPUT PART 19.2 b).

Transport stability: 24.3.

Classification, marking and ACCOMPANYING DOCUMENTS of ANAESTHETIC-PROOF EQUIPMENT: 38.

Overflow: 44.2.

Cleaning, sterilization and disinfection: 44.7.

Grips and other handling devices: **55.4 a)**.
 Switches for separation from the SUPPLY MAINS: **57.1**
 Oil containers: **59.4**.

7 Power input

7.1 The steady state current and optionally the power consumption 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 **6.1 j)** by more than:

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

7.2 The current or power consumption of heating elements in COLD CONDITION shall not be more than 120 % of the marked rating unless a greater deviation is allowed already according to Sub-clause **7.1**.

7.3 *Compliance with the requirements of Sub-clauses 7.1 and 7.2 shall be checked by inspection and by the following tests:*

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

The current or power consumption shall be measured and compared with the markings or the content of the ACCOMPANYING DOCUMENTS.

The measured values shall not exceed the limits required in Sub-clause 7.1.

- b) *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 the 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.*

- c) *The steady state current shall be measured with a true r.m.s. reading instrument, for example, a thermal instrument.*

The power consumption, if expressed in voltamperes, shall either be measured with a volt-ampere meter or be determined as the product of the steady state current (measured as described before) and the supply voltage.

Section 2. Safety requirements

Introduction

This section contains the primary requirements regarding the protection of life and property:

- protection against electric shock hazards (see Section 3);
- protection against mechanical hazards (see Section 4);
- protection against hazards from unwanted or excessive radiation (see Section 5);
- protection against the hazards of explosions in medically used rooms (see Section 6);
- protection against excessive temperatures, fire and other hazards, such as human errors (see Section 7);
- protection against incorrect output and accuracy of operating data (see Section 8).

8 Basic safety categories

The following categories of safety for the PATIENT, USER and environment are recognized and should be applied in the order given below:

- *unconditional safety*

EQUIPMENT is so designed that all means to exclude hazards are incorporated;

- *conditional safety*

if unconditional safety is not realizable, special external protective means are applied;

- *descriptive safety*

if conditional safety does not lead to the intended results, the conditions under which safe operation is possible are to be defined. Descriptive safety may include indications applying to transport, positioning, mounting, connection and putting into operation and the observance of certain rules applying to application, replacement and maintenance.

9 Removable protective means

If the 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 access to the function is no longer needed. The instructions for use shall also carry a similar notice.

Protective means should be incorporated as far as possible in the basic design of EQUIPMENT.

Compliance shall be checked by inspection of the instructions for use (see Sub-clause 6.8).

10 Special environmental conditions

Where EQUIPMENT has been specified by the manufacturer for use in environmental or operational conditions differing from those indicated in this Standard, additional safety measures may have to be applied. However, the basic requirements of this Standard shall always be fulfilled within the environmental and operational conditions specified by the manufacturer.

Special conditions may prevail, for example:

- in environments with an explosion hazard;
- at unusual high or low temperatures;
- at abnormal humidity;
- at unusual chemical or physical stresses;
- in oxygen-enriched environments;
- at atmospheric air pressures exceeding the limits of the scope of this Standard [Sub-clause 1.4 b)].

11 Special measures with respect to safety

EQUIPMENT may be exempted from some safety requirements of this Standard if special safety measures are applied which are independent of the nature and function of the EQUIPMENT, for example:

- use in locations with restricted access;
- restriction of use to a limited category of persons familiar with the special hazards associated with the proper use of the EQUIPMENT and with the necessary or suitable measures which can be applied to avoid or restrict these hazards (for example, in laboratories, testing stations, etc.).

In such cases, the EQUIPMENT shall be marked to indicate the safety features which are absent.

Compliance shall be checked by inspection

12 SINGLE FAULT CONDITION

A SINGLE FAULT CONDITION should become obvious to the USER, either by an unmistakable and clearly discernible signal or it should be detectable by periodic inspection.

The following SINGLE FAULT CONDITIONS are the subject of specific requirements or tests:

- the interruption of one PROTECTIVE EARTH CONDUCTOR;
- the appearance of an external voltage in an APPLIED PART or in a SIGNAL INPUT or SIGNAL OUTPUT PART;
- the interruption of one supply conductor of the EQUIPMENT;
- leakage of an ENCLOSED MEDICAL GAS SYSTEM;
- short-circuiting of either of the constituent parts of a DOUBLE INSULATION;
- short-circuiting of the insulation between the APPLIED PART and LIVE PARTS in case the CREEPAGE DISTANCE and AIR CLEARANCE of such insulation is not in accordance with the values required in Sub-clause 57.10;
- faults of components the failure of which may result in a safety hazard (see Particular Standards);
- failure of a mechanical part affecting the safety of EQUIPMENT (see Section 4).

The following are not regarded as SINGLE FAULT CONDITIONS:

- a total breakdown of a DOUBLE or REINFORCED INSULATION;
- earthing of the PATIENT;
- interruption of a PROTECTIVE EARTH CONDUCTOR of EQUIPMENT with a fixed and permanently installed MAINS PART.

If a single means for protection fails because of a defect in another single means for protection, the two failures are regarded as one SINGLE FAULT CONDITION.

Section 3. 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 the EQUIPMENT meets the relevant requirements of this section.

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

- prevention of contact between the body of the PATIENT, the USER or a third person and parts which are LIVE or may become LIVE in the case of an insulation failure by means of enclosing, guarding or mounting in inaccessible locations;
- restriction of voltages on or currents from parts which may be touched intentionally or unintentionally by the PATIENT, the USER or a third person.

These voltages or currents may be present during NORMAL USE or may appear in SINGLE FAULT CONDITION.

Generally, this is obtained by a combination of:

- limitation of voltage and/or current, or earthing (see Clauses 15 and 18);
- enclosing and/or guarding of LIVE PARTS (see Clause 16);
- insulation of adequate quality and construction (see Clause 17).

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

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

14 Requirements related to classification

14.1 CLASS I EQUIPMENT

In addition to the information given in Sub-clause 2.2.4, the following may apply:

- a) For EQUIPMENT intended for use with a non-detachable flexible cord or cable the additional safety precaution includes a PROTECTIVE EARTH CONDUCTOR as part of the flexible cord or cable and a MAINS PLUG with earthing contact.
- b) External SUPPLY MAINS includes an external battery or an external convertor.
- c) The connection to the PROTECTIVE EARTH CONDUCTOR is regarded as an additional safety precaution against electric shock hazard.
- d) For EQUIPMENT intended for use with a DETACHABLE CORD the additional safety precaution includes an APPLIANCE INLET with earthing contact.
- e) For EQUIPMENT intended for PERMANENT INSTALLATION the additional safety precaution includes a terminal for protective earthing.
- f) CLASS I EQUIPMENT may have parts with DOUBLE INSULATION or REINFORCED INSULATION or parts operating at safety extra-low voltage or at MEDICAL 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 the EQUIPMENT to function.

14.2 CLASS II EQUIPMENT

In addition to the information given in Sub-clause 2.2.5, the following may apply:

- a) CLASS II EQUIPMENT may 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 PART (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 the types 1) and 2).
- b) In so far as it is essential for its functioning the EQUIPMENT may be fitted with a device for changing over from Class I to Class II protection if all of the following requirements are fulfilled:
 - the change-over device clearly indicates the selected class;
 - for change-over, the use of a TOOL is necessary;
 - the EQUIPMENT complies with the whole range of requirements for the class selected at any given time;
 - in Class II position, the device interrupts the connection of the PROTECTIVE EARTH CONDUCTOR to the EQUIPMENT.
- c) CLASS II EQUIPMENT for use in medical practice may be provided with a FUNCTIONAL EARTH TERMINAL or contact or a FUNCTIONAL EARTH CONDUCTOR for earthing of the PATIENT CIRCUIT or screens. The required protection against electric shocks shall in no way depend on this functional earthing being present.

d) In CLASS II EQUIPMENT, capacitors shall not be connected between parts which carry MAINS VOLTAGE and ACCESSIBLE CONDUCTIVE PARTS, nor shall the conductive enclosure of such capacitors or an enclosure of such capacitors made of insulating material and providing only BASIC INSULATION, be secured directly to ACCESSIBLE CONDUCTIVE PARTS.

e) CLASS II EQUIPMENT may have parts operating at MEDICAL SAFETY EXTRA-LOW VOLTAGE.

f) In certain special cases, such as the signal terminals of electronic EQUIPMENT, PROTECTIVE IMPEDANCE may be used in CLASS II EQUIPMENT if this technique may be included without detriment to the safety level.

g) Metal-encased CLASS II EQUIPMENT may be provided with means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR to the enclosure.

14.3 CLASS III EQUIPMENT

In addition to the information given in Sub-clause 2.2.6, the following may apply:

a) FOR MEDICAL CLASS III EQUIPMENT the safety extra-low voltage shall be restricted to MEDICAL SAFETY EXTRA-LOW VOLTAGE (MESLV).

b) CLASS III EQUIPMENT should not be provided with means for the connection of a PROTECTIVE EARTH CONDUCTOR.

c) Metal-encased CLASS III EQUIPMENT may be provided with means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR to the enclosure.

d) The combination of isolated supply and the restricted voltage is regarded as an additional protective measure against electric shock hazard.

e) CLASS III EQUIPMENT may be provided with means for connection to earth for functional (as distinct from protective) purposes.

14.4 CLASS I, II AND III EQUIPMENT

a) For protection against electric shock, at least the MAINS PART of EQUIPMENT shall be provided in addition to the BASIC INSULATION with an additional protection according to the requirements of CLASS I, II or III EQUIPMENT (see Figure 2, Figure 3 and Figure 4, pages 100, 101 and 102).

b) In the case of EQUIPMENT specified for power supply from an external d.c. power source (for example, for use in ambulances), no hazard to PATIENT, USER or EQUIPMENT shall develop when a connection with the wrong polarity is made.

The MAINS PART shall be isolated from ACCESSIBLE CONDUCTIVE PARTS. If this isolation is accomplished by BASIC INSULATION only, then, in addition to the conductors for connection to the battery system, a separate PROTECTIVE EARTH CONDUCTOR shall be provided.

14.5 EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE

EQUIPMENT shall be recognized as such only if either no external connections to the INTERNAL ELECTRICAL POWER SOURCE are provided or electrical connection to the INTERNAL ELECTRICAL POWER SOURCE (for example, a rechargeable battery) can be made only after physical and electrical separation of the INTERNAL ELECTRICAL POWER SOURCE and a possible charging device from the remainder of the EQUIPMENT.

[See Sub-clause 5.1 b)].

If the above requirements cannot be met, the EQUIPMENT shall be classified as Class I, II or III.

14.6 TYPES B, BF AND CF EQUIPMENT

a) EQUIPMENT without an APPLIED PART shall be of Type B.

b) EQUIPMENT having an APPLIED PART with or without an intentional electrical path to the PATIENT shall be of Type B, BF or CF.

c) EQUIPMENT or EQUIPMENT parts, specifically designed for applications where a CONDUCTIVE CONNECTION directly to the heart is established shall be of Type CF.

Such EQUIPMENT may either be MAINS OPERATED, and in this case it shall be of protection CLASS I or II, or it may derive its power supply from an INTERNAL ELECTRICAL POWER SOURCE.

d) EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more APPLIED PARTS of Type CF may have one or more additional APPLIED PARTS of B or BF which may be applied simultaneously if the requirements of Sub-clauses 6.1 l) and 19.3 for such EQUIPMENT have been met.

A similar ruling applies to EQUIPMENT with a mixture of Type B and Type BF APPLIED PARTS.

14.7 Test specification

Compliance with the requirements of Clause 14 shall be checked by inspection.

15 Limitation of voltage and/or current

a) Circuits in a MEDICAL SAFETY EXTRA-LOW VOLTAGE part shall not be connected to circuits with voltages above MEDICAL SAFETY EXTRA-LOW VOLTAGE. All insulation in a MEDICAL SAFETY EXTRA-LOW VOLTAGE part shall be designed for a test voltage (according to Clause 20) of 500 V.

Compliance shall be checked by inspection or measurement of circuit voltages.

b) EQUIPMENT intended to be connected to the supply 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 or between either supply pin and BODY OF THE EQUIPMENT does not exceed 50 V.

This requirement also applies if the instructions for use, requiring the EQUIPMENT to be switched off before disconnection of the plug, are disregarded.

Compliance shall be checked by the following test:

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

The EQUIPMENT is not switched off by means of its own mains switch, but the EQUIPMENT is disconnected from the SUPPLY MAINS by means of the plug.

The voltage between the pins of the plug and between the pins and the BODY OF THE EQUIPMENT is measured 1 s after disconnection with an instrument of which the internal impedance does not affect the test. The measured voltages shall not exceed 50 V.

The test shall be performed ten times.

This test need not be performed if interference suppression capacitors are used with a capacitance between each line and protective earth of less than 3 000 pF for RATED voltages at 50 Hz up to 250 V or 5 000 pF for RATED voltages at 60 Hz up to 125 V.

c) Capacitors or circuit parts connected to them, which become accessible after EQUIPMENT has been de-energized and ACCESS COVERS have been removed immediately thereafter, shall not have a residual voltage exceeding 50 V, or, if this value is exceeded, shall not have a residual energy exceeding 2 mJ.

Discharging of capacitors may be effected by arrangement of circuits or by a discharging device which is actuated by removal of a cover.

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.

The efficacy of any automatic discharging device shall be determined by the following test. The EQUIPMENT is operated at RATED voltage and then de-energized and any ACCESS COVERS at once removed. Immediately afterwards, 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 adequate protection against accidental contact with LIVE PARTS and, for CLASS II EQUIPMENT, with conductive parts separated from LIVE PARTS by BASIC INSULATION only. This requirement applies for all positions of the EQUIPMENT when it is wired and operated as in NORMAL USE, even after opening of lids and doors which can be opened without the use of a TOOL and removal of detachable parts. During the insertion or removal of lamps, protection against accidental 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 re plasticize at temperatures to be expected during operation (including sterilization) shall not be regarded as enclosures providing protection against accidental contact with LIVE PARTS.
- 3) Outer enclosures shall have only openings which are indispensable for the use and functioning of the EQUIPMENT.
- 4) If a manufacturer instructs the USER to remove or to replace a part during NORMAL USE, such a part is regarded as a detachable part even if a TOOL has to be used for its removal.

5) Parts accessible without the use of a TOOL may present in case of a first fault in A BASIC INSULATION on an accessible conductive surface a voltage difference to earth not exceeding 24 V a.c. or 50 V d.c. but restricted to those cases where the occurrence of a CONDUCTIVE CONNECTION between such a part and a PATIENT is unlikely (possibly to be specified further by Particular Standards).

Compliance shall be checked by inspection and by a test with the standard test finger shown in Figure 7, page 105, applied in a bent or straight position. In addition, openings in CLASS II EQUIPMENT and openings in CLASS I EQUIPMENT, other than those in metal parts connected to the PROTECTIVE EARTH TERMINAL or earthing contact, and other than those giving access to LIVE PARTS in plugs, connectors and socket outlets, are tested with the test pin shown in Figure 8, page 105. 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 bare LIVE PARTS or LIVE PARTS protected only by lacquer, enamel, ordinary paper, cotton, oxide film, beads or sealing compound.

In addition, for CLASS II EQUIPMENT. It shall not be possible to much bare LIVE PARTS with the test pin as shown in Figure 8, or to touch conductive parts separated from the MAINS PART by BASIC INSULATION only with the standard test finger as shown in Figure 7.

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, page 106) if the hook can be inserted. The test-hook is applied to all points in question and is 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 accessible parts shall become LIVE and the CREEPAGE DISTANCES and air CLEARANCES of MAINS PARTS shall not be reduced below the values as specified in Sub-clause 57.10.

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.

Ventilation holes may need to be covered with a suitable gauze as a protection against the entry of insects. If gauze is applied attention should be paid to the possibility that the cooling of the EQUIPMENT may be impaired by the deposition of dirt on the gauze.

Compliance shall be checked in operational condition 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 any conductive parts of CLASS II EQUIPMENT separated from the MAINS PART by BASIC INSULATION only.

c) Shafts of actuating parts which are accessible after the removal of handles, knobs, levers and the like shall not be LIVE [see also Sub-clause 56.10 a)].

Compliance shall be checked by inspection and, if necessary, by measurement.

d) Parts within the enclosure of EQUIPMENT with a circuit voltage exceeding 24 V 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, brush-holder of motors, etc.) shall be protected against accidental 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 still be marked clearly as "LIVE".

The use of the symbol 14, Table D.I. "Attention, consult ACCOMPANYING DOCUMENTS" of Appendix D is not sufficient. A warning notice on the outside of the EQUIPMENT may be sufficient.

Details concerning this warning notice are under consideration.

Compliance shall be 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, page 105.

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 USER in NORMAL USE to have occasional access to LIVE PARTS operating at a voltage not exceeding 24 V a.c. or 50 V d.c. supplied from a source which is electrically separated from the SUPPLY MAINS.

Examples which are applicable are:

- covers of illuminated push-buttons;
- covers of indicator lamps;
- covers over recorder pens;
- PLUG-IN MODULES;
- covers of battery compartments.

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

Compliance shall be 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.*

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 any LIVE PARTS or conductive parts of CLASS II EQUIPMENT separated from the MAINS PART by BASIC INSULATION only.

Compliance shall be 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 any LIVE PARTS or conductive parts of CLASS II EQUIPMENT separated from the MAINS PART by BASIC INSULATION only.

g) EQUIPMENT shall be so constructed as to prevent the penetration from the table or floor of foreign objects which might have an adverse effect on the safety of the EQUIPMENT. If an enclosure has openings in the bottom surface, all LIVE PARTS shall be at least at a distance of 6 mm from the supporting surface, measured vertically through any opening.

This requirement is satisfied:

- 1) for EQUIPMENT intended to be placed on a table, if the EQUIPMENT is provided with legs at least 10 mm high;
- 2) for EQUIPMENT intended to be placed on the floor if the legs of the EQUIPMENT are at least 20 mm high.

Compliance shall be checked by inspection and measurement.

17 Insulation and PROTECTIVE IMPEDANCES

a) An APPLIED PART shall be separated from LIVE PARTS of the EQUIPMENT, particularly from the MAINS PART. Deterioration of parts by use and ageing shall be taken into account. In case of a SINGLE FAULT CONDITION or in case of defects of thermionic valves and/or semiconductors, wire rupture or disconnection of a component in other parts, the APPLIED PARTS shall not produce a PATIENT LEAKAGE CURRENT exceeding the allowable value for SINGLE FAULT CONDITION (see Table IV).

This requirement can generally 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 that LEAKAGE CURRENTS flowing to the APPLIED PART from other parts are diverted to earth.
- 2) The APPLIED PART is separated from LIVE PARTS by a protectively earthed conductive part, which may be a fully enclosing conductive screen.
- 3) The APPLIED PART is not connected to protective earth but is separated from LIVE PARTS by a protectively earthed intermediate circuit which cannot produce excessive LEAKAGE CURRENT to the APPLIED PART.
- 4) The APPLIED PART is separated from LIVE PARTS by DOUBLE or REINFORCED INSULATION.
- 5) PROTECTIVE IMPEDANCES prevent the flow of a current exceeding the prescribed permissible value to the APPLIED PART.

Particular Standards may describe other methods of separation.