BS 5724 : Part 1 : 1989
IEC 601-1 : 1988

British Standard

Medical electrical equipment

Part 1. General requirements for safety

Appareils électromédicaux
Partie 1. Règles générales de sécurité

Elektromedizinische Geräte
Teil 1. Allgemeine Sicherheitsanforderungen

BSI STANDARDS

National foreword

This Part of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee and is identical with IEC 601-1 'Medical electrical equipment, Part 1 : 1988 General requirements for safety', prepared by Technical Committee TC 62 Electrical Equipment in Medical Practice of the International Electrotechnical Commission (IEC). The associated CENELEC harmonization document is HD 395.1 and this will be updated in due course.

The differences between this British Standard and the 1979 edition are predominantly to remove anomalies and ambiguities and include editorial clarifications of meaning. Numerous technical changes have also been made, e.g. the provisions for isolation from the mains of patient and operator in clause **17** have been changed; the requirement for provision of an additional protective earth conductor in clause **18***(h)* has been deleted; and the provisions for mains supply transformers have been revised and transferred from appendix J to **57.9**.

In order to give manufacturers time to clear stocks of equipment complying with BS 5724 : Part 1 : 1979, and to allow time for the Particular Standards which refer to it to be revised, it is intended that the two editions be in effect simutaneously for a period. This period is expected to be the longer of either two years or the period to the date of the final revisions of the Particular Standards by the IEC and by the UK technical committees. At the end of this period BS 5724 : Part 1 : 1979 will be withdrawn.

NOTE. Upon publication of this revision, BSI Sales Department will respond to purchase orders for BS 5724 : Part 1 by supplying copies of the 1989 edition. Copies of the 1979 edition may be obtained by quoting the number 'BS 5724 : Part 1/79'.

This Part of BS 5724 (hereinafter called the General Standard) specifies safety requirements that are generally applicable to medical electrical equipment. For particular types of equipment, these requirements are supplemented or modified by the requirements of Particular Standards which have been issued as additional Sections of this standard, many of them corresponding to Particular Standards in the series IEC 601-2. Where Particular Standards exist, this General Standard should not be used alone. Special care is required in applying this General Standard alone to equipment for which no Particular Standard has yet been published.

An index to this General Standard has been added as national appendix A and it has been proposed to IEC that such an index should be included in future editions of IEC 601-1.

NOTE. If marking with this British Standard is used, attention is drawn to the following:

Marking BS 5724 : Part 1 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is therefore solely the responsibility of the person making the claim. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

In this General Standard the following print types are used to differentiate between requirements, test specifications and explanatory matter.

Requirements: in roman type

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

Test procedures: in italic type.

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

For the purposes of this British Standard, any references to IEC page numbers in the text 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 corrresponding 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, Linford Wood, Milton Keynes, MK14 6LE.

BSI

Amendment No. 1
published and effective from 21 December 1990
to BS 5724 : Part 1 : 1989

Medical electrical equipment
Part 1. General requirements for safety

Revised text

AMD 6715
December 1990

Front and back covers

In the top right-hand corner of the front cover and twice on the back cover, immediately below 'IEC 601 – 1 : 1988' insert 'EN 60601 – 1 : 1990'.

AMD 6715
December 1990

National foreword

At the end of paragraph 1 insert the following new paragraph.

'In 1990 the European Committee for Electrotechnical Standardization (CENELEC) accepted IEC 601 – 1 : 1988 as European Standard EN 60601 – 1.'.

AMD 6715
December 1990

New EN title page and brief history

Immediately after the national foreword, insert the attached new EN title page and brief history page.

AMD 6715
December 1990

New annex ZA

Immediately after appendix L insert the new Annex ZA.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1

August 1990

UDC 615.84:614.8

Descriptors: Medical electrical equipment, definitions, requirements, testing, construction, safety, symbols

English version

Medical electrical equipment
Part 1: General requirements for safety

(IEC 601-1:1988)

Appareils électromédicaux
Première partie: Règles générales de sécurité
(CEI 601-1:1988)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
(IEC 601-1:1988)

This European Standard was approved by CENELEC on 11 June 1990.
CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue Bréderode 2, B-1000 Brussels

Brief history

The CENELEC Questionnaire Procedure, performed for finding out whether or not IEC 601-1:1988 could be accepted without textual changes, has shown that no CENELEC common modifications were necessary for the acceptance as a European Standard. The Reference Document was submitted to the CENELEC members for formal vote and acceptance.

The text of the International Standard IEC 601-1:1988 was approved by CENELEC on the 11th of June 1990 as a European Standard.

The following dates were fixed:

Latest date of announcement of the EN at national level (doa) : 1990-09-01

Date of latest publication of a new harmonized standard (dop) : 1991-01-01

Date of withdrawal of conflicting national standards (dow) : 1991-01-01

For products which have complied with HD 395 S2:1988 before 1991-01-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1996-01-01.

Annex ZA (normative) lists the IEC, ISO and other publications quoted in this Standard and the corresponding CENELEC standard.

Endorsement notice

The text of the International Standard IEC 601-1:1988 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD

When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	*Date*	*Title*	*EN/HD*	*Date*
65 (mod)	1985	Safety requirements for mains operated electronic and related apparatus for household and similar general use. Fifth edition 1985, incorporating Amendment No. 1 (1978) Amendment No. 2 (1981).	HD 195 S6	1989
68-2-2	1974	Basic environmental testing procedures. Part 2-2: Test B, Dry heat.	HD 323.2.2 S1	1988
73	1984	Colours of indicator lights and push-buttons.	HD 354 S2	1987
79	–	Electrical apparatus for explosive gas atmospheres.	–	
79-2	1983	Electrical apparatus for explosive gas atmospheres. Part 2: Electrical apparatus - type of protection "p".		
79-5:	1967	Electrical apparatus for explosive gas atmospheres. Part 5: Sand-filled apparatus.		
79-6	1968	Electrical apparatus for explosive gas atmospheres. Part 6: Oil-immersed apparatus.		
85	1984	Thermal evaluation and classification of electrical insulation.	HD 566 S1	1990
112	1979	Method for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions.	HD 214 S2	1980
127	1974	Cartridge fuse-links for miniature fuses.	HD 109 S3	1983
227 (mod)	–	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V. Amendment No. 1 (1985).	HD 21	–
241	1968	Fuses for domestic and similar purposes.	–	
245 (mod)	–	Rubber insulated cables of rated voltages up to and including 450/750 V.	HD 22	–
245-4 (mod)	1980	Rubber insulating cables of rated voltages up to and including 450/750 V. Part 4: Cords and flexible cords.	HD 22.4 S2	1982
252	1975	A.C. motor capacitors.	–	
309	–	Plugs, socket-outlets and couplers for industrial purposes.	HD 196	–
320 (mod)	1981	Appliance couplers for household and similar general purposes.	EN 60320-1	1987
328	1972	Switches for appliances.	–	
355-1	1970	Safety of household and similar electrical appliances. Part 1: General requirements.	–	
336	1982	Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use.	HD 509 S1	1988
348	1978	Safety requirements for electronic measuring apparatus.	HD 401 S1	1980
364-4-41	1982	Electrical installations of buildings. Part 4: Protection for safety. Chapter 41: Protection against electric shock.	HD 384.4.41 S1	–
384-14	1981	Fixed capacitors for use in electronic equipment. Part 14: Sectional specification: Fixed capacitors for radio interference suppression. Selection of methods of test and general requirements.		
417	–	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	HD 243	–

IEC Publication	*Date*	*Title*	*EN/HD*	*Date*
445	1973	Identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notation.	HD 241 S2	1981
447	1974	Standard directions of movement for actuators which control the operation of electrical apparatus.	HD 331 S1	1977
513	1976	Basic aspects of the safety philosophy of electrical equipment used in medical practice.	–	
529	1976	Classification of degrees of protection provided by enclosures.	HD 365 S3	1985
536	1976	Classification of electrical and electronic equipment with regard to protection against electric shock.	HD 366 S1	1977
601-1	1977	Safety of medical electrical equipment. Part 1: General requirements. First edition 1977. Amendment No. 1 (1984)	HD 395 S2	1988
664	1980	Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment.	–	
695	–	Fire hazard testing.	HD 444	–
707	1981	Methods of test for the determination of the flammability of solid electrical insulating materials when exposed to an igniting source.	HD 441 S1	1983
742 (mod)	1983	Isolating transformers and safety isolating transformers: Requirements.	EN 60742	1989
878	1988	Graphical symbols for electrical equipment in medical practice.		

ISO Publication		
ISO 32	1977	Gas cylinders for medical use – Marking for identification of content.
ISO 407	1983	Small medical gas cylinders – Yoke-type vale connections.
ISO 471	1983	Rubber – Standard temperatures, humidities and times for the conditioning and testing of test pieces.
ISO 780	1985	Packaging – Pictorial marking for handling of goods.
ISO 1853	1975	Conducting and antistatic rubbers – Measurement of resistivity.
ISO 2878	1987	Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance.
ISO 2882	1979	Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits.
ISO 8185	1988	Humidifiers for medical use – Safety requirements.

Cross-references

International standard *Normative references*	Corresponding British Standard
IEC 68-2-2 : 1974	BS 2011 Basic environmental testing procedures Part 2.1B : 1977 Tests B. Dry heat (Identical)
IEC 127 : 1974	BS 4265 : 1977 Specification for cartridge fuse links for miniature fuses (Identical)
IEC 320 : 1981	BS 4491 : 1989 Specification for appliance couplers for household and similar general purposes (Technically equivalent)
IEC 384-14 : 1981	BS 6201 Fixed capacitors for use in electronic equipment Part 3 : 1982 Specification for fixed capacitors for radio interference suppression. Selection of methods of test and general requirements (Identical)
IEC 417 : 1973	BS 6217 : 1981 Guide to graphical symbols for use on electrical equipment (Identical)
IEC 445 : 1973	BS 5559 : 1978 Specification for identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notation (Identical)
IEC 447 : 1974	BS 6013 : 1980 Specification for standard directions of movement for actuators which control the operation of electrical apparatus (Identical)
IEC 529 : 1976	BS 5490 : 1977 Specification for classification of degrees of protection provided by enclosures (Identical)
ISO 32 : 1977	BS 1319 : 1976 Specification for medical gas cylinders, valves and yoke connections (Technically equivalent)
ISO 471 : 1983	BS 903 Methods of testing vulcanized rubber Part A35 : 1985 Temperatures, humidities and times for conditioning and testing of test pieces (Identical)
ISO 780 : 1985	BS 2770 : 1986 Specification for pictorial marking of handling instructions for goods in transit (Identical)

The Technical Committee has reviewed the provisions of the following international standards to which normative references have been made in the text and for which there are no corresponding British Standards and has decided that they are acceptable for use with this standard: IEC 65 : 1985, IEC 79-2 : 1983, IEC 79-5 : 1967, IEC 79-6 : 1968, IEC 227 + AMD No. 1 : 1985, IEC 241 : 1968, *IEC 245-4 : 1980, IEC 252 : 1975, IEC 328 : 1972, ISO 1853 : 1975, ISO 2878 : 1987, ISO 2882 : 1979(1984).

*Appears as 'IEC 245' in clauses **6.5***(a)* and **57.3***(b)*.

International standard	Corresponding British Standard
Informative references	
IEC 73 : 1984	BS 4099 Colours of indicator lights and push-buttons, annunciators and digital readouts Part 1 : 1986 Specification for colours of indicator lights and push-buttons (Identical)
IEC 85 : 1984	BS 2757 : 1986 Method for determining the thermal classification of electrical insulation (Identical)
IEC 112 : 1979	BS 5901 : 1980 Method of test for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions (Identical)
IEC 335-1 : 1970	BS 3456 Specification for safety of household and similar electrical appliances Part 101 : 1987 General requirements (Technically equivalent)
IEC 536 : 1976	BS 2754 : 1976 Memorandum. Construction of electrical equipment for protection against electric shock (Technically equivalent)
IEC 664 : 1980	PD 6499 : 1981 Guide to insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment (Identical) BS 6458 Fire hazard testing for electrotechnical products
IEC 695-2-1 : 1980	Section 2.1 : 1984 Glow-wire test (Identical)
IEC 695-2-2 : 1980	Section 2.2 : 1984 Needle-flame test (Identical)
IEC 695-2-3 : 1984	Section 2.3 : 1985 Bad-connection test with heaters (Identical)
IEC 707 : 1981	BS 6334 : 1983 Methods of test for the determination of the flammability of solid electrical insulating materials when exposed to an igniting source (Identical)
ISO 407 : 1983	BS 1319 : 1976 Specification for medical gas cylinders, valves and yoke connections (Technically equivalent)
ISO 8185 : 1988	BS 5724 Medical electrical equipment Section 2.24 : 1989 Particular requirements for the safety of humidifiers for medical use (Identical)
EN 29001 : 1987	BS 5750 Quality systems Part 1 : 1987 Specification for design/development, production installation and servicing. (Identical)

The Technical Committee has reviewed the provisions of the following international standards to which informative references have been made in the text and for which there are no corresponding British Standard and has decided that they are acceptable for use with this standard: IEC 364-4-41 : 1982, IEC 513 : 1976, IEC 742 : 1983, IEC 878 : 1988.

Textual errors. When adopting the text of the international standard, the textual errors given below were discovered. They have been marked in the text and have been reported to the IEC in a proposal to amend the text of the international standard.

The references to IEC 309 and IEC 336 appear in appendix L in error; they appear in the 1979 edition of IEC 601-1 and do not now appear in the text of the 1988 edition.

The reference to IEC 348 is a similar error; the reference in appendix A2 (clause 1) to the scope of IEC SC 66E should be to IEC 1010*.

The reference to 'IEC 355-1' in appendix L should be read as 'IEC 335-1'.

*In preparation, provisional title, 'Safety of electrical measuring, control and laboratory equipment'.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification for product conformity with this British Standard, based on testing and continuing surveillance which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

Alternatively, users of this British Standard may wish to consider the desirability of assessment and registration of a supplier's quality systems against the appropriate Part of BS 5750 by a third party certification body.

Compliance with a British Standard does not of itself confer immunity from legal obligations. Attention is drawn to the following.

(a) The provisions of the Health and Safety at Work Act etc. 1974 in respect of the safety of maintenance engineers who may work on equipment with certain safety covers removed (see clause **3.1**).

(b) Current UK legislation contained in the Factories Act 1961 and in the Mines and Quarries Act 1954 (see clause **45.2**).

(c) UK legislation concerning radio interference limits. Requirements for electromagnetic compatability are found in clause **36** of the relevant Particular Standards. Such legislation is, in general, based on CISPR Recommendations including CISPR 11 : 1975 Limits and methods of measurement of radio interference characteristics of industrial scientific and medical radio frequency equipment (excluding surgical diathermy equipment) obtainable from BSI, Overseas Sales Department, Linford Wood, Milton Keynes, MK14 6LE.

(d) Statutory Instrument 1988, No 1586 which embodies the directive 84/539/EEC, the latter proscribing the refusal by member states to allow the import of electrical medical equipment which complies with the requirements of IEC 601-1. A further EEC directive covering electrical medical equipment which was in preparation in 1988 is expected to make mandatory reference to a quality system based on EN 29001. Such a quality system (provisional title 'Guide to the application of quality systems for the manufacture of energized medical devices') was also in preparation by CENELEC in 1988.

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MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

SECTION ONE – GENERAL

*1. Scope and object

1.1 *Scope*

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

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

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

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

1.2 *Object*

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

*1.3 *Particular Standards*

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

1.4 *Environmental conditions*

See Section Two.

2. Terminology and definitions †

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

- Where the terms "voltage" and "current" are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.
- The auxiliary verb:
  - "shall" means that compliance with a requirement or a test is mandatory for compliance with this Standard;
  - "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this Standard;
  - "may" is used to describe a permissible way to achieve compliance with a requirement or test.

2.1 *EQUIPMENT parts, auxiliaries and ACCESSORIES*

2.1.1 *ACCESS COVER*

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

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

2.1.2 *ACCESSIBLE METAL PART*

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

2.1.3 *ACCESSORY*

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

2.1.4 *ACCOMPANYING DOCUMENTS*

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

2.1.5 *APPLIED PART*

Entirety of all parts of 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 OPERATOR as an APPLIED PART.

For some EQUIPMENT, an F-TYPE 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 (see Sub-clause 2.1.7 and Figure 1).

2.1.6 *ENCLOSURE*

Exterior surface of EQUIPMENT including:

- all ACCESSIBLE METAL PARTS, knobs, grips and the like;
- accessible shafts;
- for the purpose of tests, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material.

2.1.7 *F-TYPE ISOLATED (FLOATING) APPLIED PART (hereinafter referred to as F-TYPE APPLIED PART)*

APPLIED PART isolated from all other parts of the EQUIPMENT to such a degree that the PATIENT LEAKAGE CURRENT allowable in SINGLE FAULT CONDITION is not exceeded when a voltage equal to 1.1 times the highest RATED MAINS VOLTAGE is applied between the APPLIED PART and earth.

2.1.8 Not used.

2.1.9 *INTERNAL ELECTRICAL POWER SOURCE*

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

2.1.10 *LIVE*

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

2.1.11 Not used.

2.1.12 *MAINS PART*

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

2.1.13 Not used.

2.1.14 Not used.

2.1.15 *PATIENT CIRCUIT*

Electrical circuit of which the PATIENT forms a part.

2.1.16 Not used.

2.1.17 *PROTECTIVE COVER*

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

2.1.18 *SIGNAL INPUT PART*

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

2.1.19 *SIGNAL OUTPUT PART*

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

2.1.20 Not used.

2.1.21 *SUPPLY EQUIPMENT*

Equipment which supplies electrical power to one or more items of EQUIPMENT.

2.1.22 *ACCESSIBLE PART*

Part of EQUIPMENT which can be touched without the use of a TOOL.

2.2 *EQUIPMENT types (classification)*

2.2.1 Not used.

2.2.2 *CATEGORY AP EQUIPMENT*

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

2.2.3 *CATEGORY APG EQUIPMENT*

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

2.2.4 *CLASS I EQUIPMENT*

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

2.2.5 *CLASS II EQUIPMENT*

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

2.2.6 Not used.

2.2.7 *DIRECT CARDIAC APPLICATION*

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

2.2.8 Not used.

2.2.9 *DRIP-PROOF EQUIPMENT*

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

2.2.10 Not used.

2.2.11 *EQUIPMENT (see Sub-clause 2.2.15)*

2.2.12 *FIXED EQUIPMENT*

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

2.2.13 *HAND-HELD EQUIPMENT*

EQUIPMENT intended to be supported by the hand during NORMAL USE.

2.2.14 Not used.

2.2.15 *MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT)*

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

2.2.16 *MOBILE EQUIPMENT*

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

2.2.17 *PERMANENTLY INSTALLED EQUIPMENT*

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

2.2.18 *PORTABLE EQUIPMENT*

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

2.2.19 Not used.

2.2.20 *SPLASH-PROOF EQUIPMENT*

EQUIPMENT provided with an ENCLOSURE preventing entry of such an amount of liquid, splashed from any direction, as 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 Not used.

2.2.23 *TRANSPORTABLE EQUIPMENT*

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

Examples: MOBILE EQUIPMENT and PORTABLE EQUIPMENT.

*2.2.24 *TYPE B EQUIPMENT*

EQUIPMENT providing a particular degree of protection against electric shock, particularly regarding:

— allowable LEAKAGE CURRENT;

— reliability of the protective earth connection (if present).

2.2.25 *TYPE BF EQUIPMENT*

TYPE B EQUIPMENT with an F-TYPE APPLIED PART.

*2.2.26 *TYPE CF EQUIPMENT*

EQUIPMENT providing a degree of protection higher than that for TYPE BF EQUIPMENT against electric shock particularly regarding allowable LEAKAGE CURRENTS, and having an F-TYPE APPLIED PART.

2.2.27 Not used.

2.2.28 *WATERTIGHT EQUIPMENT*

EQUIPMENT provided with an ENCLOSURE which, when the ENCLOSURE is immersed in water under specified conditions, prevents entry of an amount of water to areas where its presence could cause a SAFETY HAZARD (see Sub-clause 44.6).

2.2.29 *INTERNALLY POWERED EQUIPMENT*

EQUIPMENT able to operate from an INTERNAL ELECTRICAL POWER SOURCE.

2.3 *Insulation*

2.3.1 *AIR CLEARANCE*

Shortest path in air between two conductive parts.

*2.3.2 *BASIC INSULATION*

Insulation applied to LIVE parts to provide basic protection against electric shock.

2.3.3 *CREEPAGE DISTANCE*

Shortest path along the surface of insulating material between two conductive parts.

*2.3.4 *DOUBLE INSULATION*

Insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION.

2.3.5 Not used.

2.3.6 Not used.

*2.3.7 *REINFORCED INSULATION*

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

2.3.8 *SUPPLEMENTARY INSULATION*

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

2.4 *Voltages*

2.4.1 *HIGH VOLTAGE*

Any voltage over 1 000 V a.c. or over 1 500 V d.c. or 1 500 V peak value.

2.4.2 *MAINS VOLTAGE*

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

*2.4.3 *SAFETY EXTRA-LOW VOLTAGE (SELV)*

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

2.5 *Currents*

2.5.1 *EARTH LEAKAGE CURRENT*

Current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR.

2.5.2 *ENCLOSURE LEAKAGE CURRENT*

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

2.5.3 *LEAKAGE CURRENT*

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

*2.5.4 *PATIENT AUXILIARY CURRENT*

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

2.5.5 Not used.

2.5.6 *PATIENT LEAKAGE CURRENT*

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

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

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

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

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

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 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.

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

7.2 Not used.

SECTION TWO — ENVIRONMENTAL CONDITIONS

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

*8. Basic safety categories

The content of Clause 8 of the first edition has now been transferred to Appendix A1.2.

9. Removable protective means

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

10. Environmental conditions

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

10.1 *Transport and storage*

Unless otherwise stated by the manufacturer, EQUIPMENT shall be capable, while packed for transport or storage, of being exposed for a period not exceeding 15 weeks to environmental conditions not outside the following ranges:

a) an ambient temperature range of −40 °C to +70 °C;

b) a relative humidity range of 10% to 100%, including condensation;

c) an atmospheric pressure range of 500 hPa to 1 060 hPa.

See also Sub-clause 6.1 *v)*.

10.2 *Operation*

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

*10.2.1 *Environment*

a) An ambient temperature range of +10 °C to +40 °C.

b) A relative humidity range of 30% to 75%.

c) An atmospheric pressure range of 700 hPa to 1 060 hPa.

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

*10.2.2 *Power supply*

a) EQUIPMENT shall be suitable for a power supply having:

— a RATED voltage not exceeding:

- 250 V for HAND-HELD EQUIPMENT;
- 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for EQUIPMENT with a RATED apparent power input of up to 4 kVA;
- 500 V for all other EQUIPMENT;

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

— voltage fluctuation not exceeding ±10% of the NOMINAL voltage except momentary fluctuations exceeding −10% and of a duration of less than 1 s, for example those occurring at irregular intervals caused by operation of X-ray generators or similar EQUIPMENT;

— no voltage in excess of the NOMINAL value +10% between any of the conductors of the system or between any of these conductors and earth;

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

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, unless stated otherwise;

A polyphase 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 polyphase 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 exceeds 5% of the magnitude of the positive sequence current components;

— a frequency of not more than 1 kHz;

— a frequency which deviates not more than 1 Hz from the NOMINAL value up to 100 Hz and not more than 1% from the NOMINAL value from 100 Hz to 1 kHz;

— the protective measures as described in IEC Publication 364.

b) An INTERNAL ELECTRICAL POWER SOURCE, if replaceable, shall be specified by the manufacturer.

Compliance with the conditions of Clause 10 is checked by application of the tests of this Standard.

11. Not used.

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

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13. General

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

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

14. Requirements related to classification

14.1 *CLASS I EQUIPMENT*

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

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

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

14.2 *CLASS II EQUIPMENT*

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

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

1) insulation-enclosed CLASS II EQUIPMENT:

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

2) metal-enclosed CLASS II EQUIPMENT:

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

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

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

- the change-over device shall clearly indicate the selected Class;
- for change-over the use of a TOOL shall be necessary;
- the EQUIPMENT shall comply with the whole range of requirements for the Class selected at any given time;
- in the CLASS II position the device shall interrupt the connection of the PROTECTIVE EARTH CONDUCTOR to EQUIPMENT or change it into a FUNCTIONAL EARTH CONDUCTOR, complying with the requirements of Clause 18.

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

14.3 Not used.

*14.4 *CLASS I and CLASS II EQUIPMENT*

a) In addition to BASIC INSULATION, EQUIPMENT shall be provided with an additional protection according to the requirements of CLASS I or CLASS II EQUIPMENT (see Figures 2 and 3).

b) In EQUIPMENT specified for power supply from an external d.c. power source (for example, for use in ambulances), no SAFETY HAZARD shall develop when a connection with the wrong polarity is made.

14.5 *INTERNALLY POWERED EQUIPMENT*

a) INTERNALLY POWERED EQUIPMENT having a means of connection to a SUPPLY MAINS, shall have dual classification (e.g. CLASS I EQUIPMENT, INTERNALLY POWERED EQUIPMENT).

b) INTERNALLY POWERED EQUIPMENT intended for connection to a SUPPLY MAINS shall comply with the requirements for CLASS I or CLASS II EQUIPMENT while so connected.

14.6 *TYPES B, BF and CF EQUIPMENT*

a) Not used.

b) Not used.

c) EQUIPMENT or EQUIPMENT parts intended for DIRECT CARDIAC APPLICATION shall be of TYPE CF.

d) EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more APPLIED PARTS of TYPE CF EQUIPMENT may have one or more additional APPLIED PARTS of TYPE B or TYPE BF EQUIPMENT which may be applied simultaneously if the requirements of Subclause 6.1 *l)* for such EQUIPMENT have been met.

A similar requirement applies to EQUIPMENT with a mixture of TYPE B and TYPE BF APPLIED PARTS.

14.7 Not used.

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

15. Limitation of voltage and/or energy

a) Not used.

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

Compliance is checked by the following test:

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

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

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

The measured voltages shall not exceed 60 V.

The test shall be performed ten times.

The test between lines and ENCLOSURE shall not be performed if interference suppression capacitors are used with a capacitance between each line and earth of less than 3000 pF for RATED voltages up to and including 250 V or 5000 pF for RATED voltages up to and including 125 V.

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

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

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

Compliance is checked by the following test:

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

*16. **ENCLOSURES and PROTECTIVE COVERS**

a) EQUIPMENT shall be so constructed and enclosed that there is adequate protection against contact with LIVE parts, and with parts which can become LIVE in the event of failure of BASIC INSULATION.

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

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

This requirement shall be applied taking into account that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Excluded are:

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

   Examples which are applicable are:

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

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

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

   Compliance is checked by inspection and:

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

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

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

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

g) Not used.

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

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

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

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

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

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

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

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

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

Additionally EQUIPMENT and/or its circuits are examined to determine whether the limitation of LEAKAGE CURRENTS and/or PATIENT AUXILIARY CURRENT to the prescribed values is dependent on the insulating properties of junctions in semiconductor devices which are

interposed between the APPLIED PART and the MAINS PART; the APPLIED PART and other LIVE parts and for F-TYPE APPLIED PARTS between the APPLIED PART and earthed parts.

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

b) Not used.

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

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

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

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

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

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

e) Not used.

f) Not used.

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

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

1) The ACCESSIBLE PART is separated from LIVE parts by BASIC INSULATION only, but PROTECTIVELY EARTHED.

2) The ACCESSIBLE PART is separated from LIVE parts by a PROTECTIVELY EARTHED metal part, which may be a fully enclosing conductive screen.

3) The ACCESSIBLE PART is not PROTECTIVELY EARTHED but is separated from LIVE parts by an intermediate PROTECTIVELY EARTHED circuit which in the event of any insulation failure cannot produce an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.

4) The ACCESSIBLE PART is separated from LIVE parts by DOUBLE or REINFORCED INSULATION.

5) Impedances of components prevent the flow to the ACCESSIBLE PART of an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.

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

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

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

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

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

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

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

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

18. **Protective earthing, functional earthing and potential equalization**

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

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

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

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

c) Not used.

d) Not used.

e) If EQUIPMENT is provided with a means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR this connection shall comply with the following requirements:

- be readily accessible;
- accidental disconnection is prevented in NORMAL USE;
- the conductor can be detached without the use of a TOOL;
- the POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR;
- the connection means shall be marked with Symbol 9, Table DI.

Compliance is checked by inspection.

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

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

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

Compliance is checked by the following test:

A current not less than 10 A and not exceeding 25 A from current source with a frequency of 50 or 60 Hz with a no-load voltage not exceeding 6 V is passed for at least 5 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each ACCESSIBLE METAL PART which could become LIVE in case of failure in BASIC INSULATION.

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

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

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

h) Not used.

j) Not used.

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

Compliance is checked by inspection.

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

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

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

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

19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

19.1 *General requirements*

a) The electrical insulation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the specified values.

b) The specified values of the continuous EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:

— Both at operating temperature and following the humidity preconditioning treatment, as described in Sub-clauses 4.10 and 19.4.

— In NORMAL CONDITION and in the specified SINGLE FAULT CONDITIONS (see Sub-clause 19.2).

— With EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position.

— With the highest RATED supply frequency.

— With a supply equal to 110% of the highest RATED MAINS VOLTAGE.

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

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

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

**d)* The measurement of the ENCLOSURE LEAKAGE CURRENT of CLASS I EQUIPMENT shall only be performed:

— to earth from each part, if present, of the ENCLOSURE not PROTECTIVELY EARTHED;

— between parts, if present, of the ENCLOSURE not PROTECTIVELY EARTHED.

e) The PATIENT LEAKAGE CURRENT shall be measured (see Appendix K):

— in TYPE B EQUIPMENT, from all PATIENT connections connected together or with APPLIED PARTS loaded according to the manufacturer's instructions;

— in TYPE BF EQUIPMENT, from and to all PATIENT connections of a single function of the APPLIED PART connected together or with APPLIED PARTS loaded according to the manufacturer's instructions;

— in TYPE CF EQUIPMENT, from and to every PATIENT connection in turn.

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

f) The PATIENT AUXILIARY CURRENT shall be measured between any single PATIENT connection and all other PATIENT connections connected together.

*19.2 *SINGLE FAULT CONDITIONS*

a) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured under the following SINGLE FAULT CONDITIONS:

— the interruption of each supply conductor one at a time;

— the interruption of a PROTECTIVE EARTH CONDUCTOR (not applicable in the case of EARTH LEAKAGE CURRENT). Not to be investigated if a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR is specified;

— see also Sub-clauses 17*a)* and 17*g)*.

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

— a voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART, not PROTECTIVELY EARTHED.

This requirement shall not apply where:

1) the SIGNAL INPUT or SIGNAL OUTPUT PARTS are designated by the manufacturer for exclusive connection to EQUIPMENT which complies with requirements specified in the ACCOMPANYING DOCUMENTS for such EQUIPMENT;

2) for EQUIPMENT of TYPE B, unless inspection of the circuits and physical arrangement shows a SAFETY HAZARD exists;

3) for EQUIPMENT of TYPES CF and BF.

— A voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between any F-TYPE APPLIED PART and earth.

— A voltage equal to 110% of the highest RATED MAINS VOLTAGE applied betwwen earth and any ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED.

This requirement does not apply:

1) for EQUIPMENT of TYPE B, unless inspection of the circuits and physical arrangement shows that a SAFETY HAZARD exists;

2) for EQUIPMENT of TYPES CF and BF.

c) Additionally, the ENCLOSURE LEAKAGE CURRENT shall be measured with a voltage equal to 110% of the highest RATED MAINS VOLTAGE, applied between earth and any SIGNAL INPUT or SIGNAL OUTPUT PART, not PROTECTIVELY EARTHED.

This requirement is not applied where the SIGNAL INPUT or SIGNAL OUTPUT PARTS are designated by the manufacturer for exclusive connection to EQUIPMENT which complies with requirements specified in the ACCOMPANYING DOCUMENTS for such EQUIPMENT.

*19.3 *Allowable values*

a) The allowable values of the continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table IV for d.c. and a.c. and composite waveforms with frequencies up to and including 1 kHz. Unless stated otherwise values may be d.c. or r.m.s.

b) For frequencies above 1 kHz, the allowable values according to Table IV shall be multiplied by the numerical value of the frequency in kilohertz.

However, the results of the multiplication shall not exceed 10 mA. See also Subclause 19.4*e)*.

c) Not used.

d) Not used.

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

TABLE IV

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

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

N.C.: NORMAL CONDITION
S.F.C.: SINGLE FAULT CONDITION

Notes on Table IV

1) The only SINGLE FAULT-CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time (see Sub-clause 19.2*a)* and Figure 16).

2) EQUIPMENT which has no PROTECTIVELY EARTHED ACCESSIBLE PARTS and no means for the protective earthing of other EQUIPMENT and which complies with the requirements for the ENCLOSURE LEAKAGE CURRENT and for the PATIENT LEAKAGE CURRENT (if applicable).

Example:

Some computers with a screened MAINS PART.

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

Examples of such EQUIPMENT are:

- Major components of an X-ray installation such as the X-ray generator, the examination or treatment table.
- EQUIPMENT with mineral insulated heaters.
- EQUIPMENT with an EARTH LEAKAGE CURRENT higher than stated in Table IV, first line, which is due to compliance with requirements for radio-interference suppression.

4) MOBILE X-ray EQUIPMENT and MOBILE EQUIPMENT with mineral insulation.

19.4 *Tests*

a) General

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

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

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

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

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

2) *EQUIPMENT is connected to a supply with a voltage equal to 110% of the highest RATED MAINS VOLTAGE.*

3) *Three-phase EQUIPMENT which is also suitable for single-phase supply is tested as single-phase EQUIPMENT with the three sections connected in parallel.*

4) *Where examination of the circuit arrangement and the arrangement of components and material of EQUIPMENT shows no possibility of any SAFETY HAZARD, the number of tests may be reduced.*

5) *Not used.*

**b) Measuring supply circuits*

1) *EQUIPMENT specified for connection to a SUPPLY MAINS which is approximately at earth potential on one side and EQUIPMENT for which the nature of the power supply is not specified, is connected to a circuit as shown in Figure 10.*

2) *EQUIPMENT specified for connection to a SUPPLY MAINS of which the voltages between the lines and the neutral are approximately equal and in opposition, is connected to a circuit as shown in Figure 11.*

3) *Polyphase or single-phase EQUIPMENT, specified for connection to a polyphase (for example, three-phase) SUPPLY MAINS, is connected to one of the circuits as shown in Figures 12 and 13.*

4) *EQUIPMENT specified for use with a specified CLASS I single-phase power supply, is connected to a circuit as shown in Figure 14.*

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

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

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

c) Connection of the EQUIPMENT to the measuring supply circuit

1) *EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.*

2) *EQUIPMENT provided with an APPLIANCE INLET is tested while connected via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified by the manufacturer.*

3) *EQUIPMENT specified to be PERMANENTLY INSTALLED is tested while connected to the measuring supply circuit via the shortest possible connection.*

**d) Measuring arrangement*

1) *It is recommended to position the measuring supply circuit and the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise*

in the following sub-clauses) to avoid placing the EQUIPMENT on or near a large earthed metal surface.

2) However, external parts of the APPLIED PART, including PATIENT cords (when present), shall be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.

e) Measuring device (MD)

1) The measuring device shall load the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately 1 000 Ω for d.c. and a.c. and for composite waveforms with frequencies up to and including 1 MHz.

2) The evaluation of current or current components according to Sub-clauses 19.3a) and b) is obtained automatically if a measuring device according to Figure 15 or a similar circuit with the same frequency characteristic is used. This allows measurement of the total effect of all frequencies with a single instrument.

If currents or current components with frequencies exceeding 1 kHz and a value exceeding 10 mA are likely to occur, these shall be measured by other appropriate means.

3) The deviation of the frequency characteristic of Figure 15 from the ideal curve following from the requirement of Sub-clause 19.3b) (at 1 kHz about 3 dB), is disregarded.

** 4) The measuring instrument as shown in Figure 15 shall have an impedance of approximately 1 MΩ or more for frequencies from d.c. up to and including 1 MHz. It shall indicate the true r.m.s. value of the voltage across the measuring impedance being d.c. or a.c. or a composite waveform having components with frequencies from d.c. up to and including 1 MHz, with an indicating error not exceeding ±5% of the indicated value.*

The scale may indicate the current through the measuring device including automatic evaluation of components with frequencies above 1 kHz so as to enable direct comparison of the reading with Table IV.

The requirements for percentage-indicating error and for calibration may be limited to frequency range with an upper limit lower than 1 MHz if it can be proven (for example, by the use of an oscilloscope) that frequencies above such an upper limit do not occur in the measured current.

f) Measurement of the EARTH LEAKAGE CURRENT

1) CLASS I EQUIPMENT, with or without an APPLIED PART, is tested according to Figure 16, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

2) EQUIPMENT specified for use with a specified CLASS I single-phase power supply is tested according to Figure 17, using the measuring supply circuit of Figure 14. If the EQUIPMENT is PROTECTIVELY EARTHED, the measurement with MD2 shall also be performed.

g) Measurement ot the ENCLOSURE LEAKAGE CURRENT

1) CLASS I EQUIPMENT, with or without an APPLIED PART, is tested according to Figure 18, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

Measure with MD1 between earth and each part of the ENCLOSURE which is not PROTECTIVELY EARTHED.

Measure with MD2 between parts of the ENCLOSURE which are not PROTECTIVELY EARTHED.

2) *CLASS II EQUIPMENT, with or without an APPLIED PART, is tested according to Figure 18 using one of the measuring supply circuits of Figures 10, 11, 12 or 13 as relevant, but without the protective earth connection and S_7.*

Measure with MD1 between the ENCLOSURE and earth or between each part of the ENCLOSURE if more than one is present.

Measure with MD2 between parts of the ENCLOSURE or between any two ENCLOSURES if more than one is present.

3) *EQUIPMENT specified for connection to an SELV-source and INTERNALLY POWERED EQUIPMENT are tested for ENCLOSURE LEAKAGE CURRENT flowing between different parts of the ENCLOSURE (measuring device applied as MD2 in Figure 18).*

4) *EQUIPMENT, with or without an APPLIED PART, specified for use with a specified CLASS I single-phase power supply is tested according to Figure 19, using the measuring supply circuit of Figure 14.*

EQUIPMENT, with or without an APPLIED PART, specified for use with a specified CLASS II single-phase power supply shall be tested according to Figure 19 using the measuring supply circuit of Figure 14, but without the protective earth connection(s) and S_8.

The protective earth connection(s) to EQUIPMENT and S_8 are used only when the EQUIPMENT itself is of CLASS I.

Test a CLASS I power supply and/or CLASS I EQUIPMENT connected to it, as mentioned under "CLASS I EQUIPMENT" (see Sub-clause 19.4g)1)).

Test a CLASS II power supply and EQUIPMENT not being CLASS I, connected to it, as mentioned under "CLASS II EQUIPMENT" (see Sub-clause 19.4g) 2)).

5) *If EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm × 10 cm shall be applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.*

To achieve this, it may be pressed against the insulating material with a pressure of approximately 0.5 N/cm^2.

The metal foil is shifted, if possible, to determine the highest value of the ENCLOSURE LEAKAGE CURRENT. Care shall be taken that the metal foil does not touch any metal parts of the ENCLOSURE which are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE which are not PROTECTIVELY EARTHED may be covered partly or totally by the metal foil.

Where it is intended to measure the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION, the metal foil may be arranged to contact the metal part of the ENCLOSURE.

Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR may be larger than that of a normal hand, the size of the foil is increased corresponding to the area of contact.

6) If applicable, the measurements according to Sub-clause 17g) are performed in addition to those mentioned above.

**h) Measurement of the PATIENT LEAKAGE CURRENT*

For connections to the APPLIED PART(S) see Sub-clause 19.1e) and Appendix K.

1) CLASS I EQUIPMENT with an APPLIED PART is tested according to Figure 20, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

2) CLASS I EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 21, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

SIGNAL INPUT and SIGNAL OUTPUT PARTS shall, if not already permanently earthed in the EQUIPMENT, be connected to earth.

The value of the voltage to be set at the transformer T_2 in Figure 21 shall be equal to 110% of the highest RATED MAINS VOLTAGE of the EQUIPMENT.

3) CLASS I EQUIPMENT with an APPLIED PART and a SIGNAL INPUT and/or SIGNAL OUTPUT PART, is, when required (see Sub-clause 19.2b)), additionally tested according to Figure 22, using one of the measuring supply circuits of Figures 10, 11, 12 or 13, as relevant.

The value of the voltage set at the transformer T_2 shall be equal to 110% of the highest RATED MAINS VOLTAGE of the EQUIPMENT. The SIGNAL INPUT and SIGNAL OUTPUT PART is short-circuited unless a load is prescribed by the manufacturer, in which case the test voltage is applied in turn to all poles of the SIGNAL INPUT and SIGNAL OUTPUT PART.

4) CLASS II EQUIPMENT is tested as CLASS I EQUIPMENT mentioned in tests 1) to 3) above, but disregarding the protective earth connection(s) and S_7.

The PATIENT LEAKAGE CURRENT of CLASS II EQUIPMENT with an F-TYPE APPLIED PART and an external voltage on the APPLIED PART is measured with the metal ENCLOSURE (if present) connected to earth.

In the case of CLASS II EQUIPMENT with an ENCLOSURE made of insulating material, it is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE.

5) EQUIPMENT with an APPLIED PART, specified for use with a specified single-phase power supply, is tested using the measuring supply circuit of Figure 14, but disregarding the protective earth connection(s) and S_8 if the specified single-phase power supply is of CLASS II.

- *If EQUIPMENT itself is of CLASS I, it is tested as CLASS I EQUIPMENT mentioned in test 1) above.*
- *If EQUIPMENT itself is of CLASS II, it is tested as CLASS II EQUIPMENT mentioned in test 4) above.*
- *If the specified single-phase power supply is of CLASS I only S_8 shall be opened (SINGLE FAULT CONDITION) and closed during the measurement, while S_1, S_2, S_3 and S_{10} (when present) are closed.*

6) INTERNALLY POWERED EQUIPMENT is tested according to Figure 23.

Where the ENCLOSURE is made of insulating material, metal foil as described in Sub-clause 19.4g) 5) shall be applied.

7) *INTERNALLY POWERED EQUIPMENT provided with an F-TYPE APPLIED PART is additionally tested according to Figure 24. The value of the voltage to be set at the transformer T_2 shall be 250 V at the supply frequency (see Sub-clause 19.1b)).*

For this test a metal ENCLOSURE of EQUIPMENT and the SIGNAL INPUT and SIGNAL OUTPUT PART is connected to earth.

An ENCLOSURE made of insulating material is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE.

8) *INTERNALLY POWERED EQUIPMENT provided with an APPLIED PART and a SIGNAL INPUT and/or SIGNAL OUTPUT PART is, if applicable according to Sub-clause 19.2b), additionally tested according to Figure 25. The value of the voltage to be set at the transformer T_1 shall be 250 V at the supply frequency (see Sub-clause 19.1b)).*

For this test EQUIPMENT is positioned as in NORMAL USE as indicated in Sub-clause 19.4d) or as indicated in Sub-clause 19.4h) 7), whichever is less favourable.

9) *An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under Sub-clause 19.4g) 5). Alternatively a saline solution may be used in which the APPLIED PART is immersed.*

Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm × 10 cm, the size of the foil is increased to correspond to the area of contact.

10) *If loading of the APPLIED PART is specified by the manufacturer, the measuring device is connected in turn to all poles of the load (APPLIED PART).*

11) *If applicable, the measurements according to Sub-clause 17a) are performed in addition to those mentioned above.*

j) *Measurement of the PATIENT AUXILIARY CURRENT*

For connections to the APPLIED PART(S) see Sub-clause 19.1e) and Appendix K.

1) *CLASS I EQUIPMENT with an APPLIED PART is tested according to Figure 26, using one of the relevant measuring supply circuits of Figures 10, 11, 12 or 13.*

2) *CLASS II EQUIPMENT with an APPLIED PART is tested as CLASS I EQUIPMENT mentioned above, but disregarding the protective earth connection(s) and S_7.*

3) *EQUIPMENT with an APPLIED PART, and specified for use with a specified single-phase power supply is tested using the measuring supply circuit of Figure 14, but disregarding the protective earth connection and S_8, if the specified single-phase power supply is of CLASS II.*

If EQUIPMENT itself is of CLASS I, it is tested as CLASS I EQUIPMENT mentioned under paragraph 1).

If EQUIPMENT itself is of CLASS II, it is tested as CLASS II EQUIPMENT mentioned under paragraph 2).

If the specified single-phase power supply is of CLASS I,

- *S_8 shall be opened (SINGLE FAULT CONDITION) and S_1, S_2 and S_3 shall be closed;*

- *Additionally S_8 shall be closed and S_1, S_2 or S_3 shall be opened in turn (SINGLE FAULT CONDITION).*

  During the three measurement procedures described above S_5 and S_{10} shall be set in all possible combinations of positions.

4) INTERNALLY POWERED EQUIPMENT is tested according to Figure 27.

20. Dielectric strength

Only insulation with a safety function need be subject to testing.

20.1 *General requirements for all types of EQUIPMENT*

The dielectric strength shall be tested (see also Appendix E):

A-a_1 Between LIVE parts and ACCESSIBLE METAL PARTS which are PROTECTIVELY EARTHED.

This insulation shall be BASIC INSULATION.

A-a_2 Between LIVE parts and parts of the ENCLOSURE not PROTECTIVELY EARTHED.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

A-b Between LIVE parts and conductive parts isolated from the LIVE parts by BASIC INSULATION forming part of DOUBLE INSULATION.

This insulation shall be BASIC INSULATION.

A-c Between the ENCLOSURE and conductive parts isolated from LIVE parts by BASIC INSULATION forming part of DOUBLE INSULATION.

This insulation shall be SUPPLEMENTARY INSULATION.

A-d Not used.

A-e Between LIVE parts not being parts of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS and SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS not PROTECTIVELY EARTHED.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

Separation shall be achieved by one of the methods indicated in Items *g)* 1 to 5 of Clause 17.

No separate investigation is needed if the voltages appearing on the SIGNAL INPUT PART (SIP) and/or SIGNAL OUTPUT PART (SOP) in NORMAL and SINGLE FAULT CONDITIONS do not exceed SAFETY EXTRA LOW VOLTAGE.

A-f Between parts of opposite polarity of the MAINS PART.

This insulation shall be BASIC INSULATION.

The electrical insulation of parts A-f shall be investigated only if, after inspection of insulation quantities and sizes, including CREEPAGE DISTANCES and AIR CLEARANCES according to Sub-clause 57.10, no complete compliance can be established.

If separation of circuits or protection of components, necessary for the investigation of parts A-f, is not possible without damage to EQUIPMENT, the manufacturer and the testing laboratory shall make an agreement as to any other method possible to fulfil the purpose of this investigation.

A-g Between a metal ENCLOSURE (or cover) lined internally with insulating material and a metal foil applied for testing purposes in contact with the interior surface of the lining. Such a lining may be applied where the distance, measured through the lining, between a LIVE PART and the ENCLOSURE (or cover) is less than the AIR CLEARANCE required according to Sub-clause 57.10.

Where the ENCLOSURE (or cover) is PROTECTIVELY EARTHED, the required AIR CLEARANCE is that for BASIC INSULATION and the lining shall be treated as such.

Where the ENCLOSURE (or cover) is not PROTECTIVELY EARTHED, the required AIR CLEARANCE is that for REINFORCED INSULATION.

If the distance between the LIVE PART and the interior surface of the lining is not less than the AIR CLEARANCE required for BASIC INSULATION, that distance shall be treated as BASIC INSULATION. The lining shall then be treated as SUPPLEMENTARY INSULATION.

Where the distance, as described before, is less than that required for BASIC INSULATION, the lining shall be treated as REINFORCED INSULATION.

A-h Not used.

A-j Between ACCESSIBLE PARTS not PROTECTIVELY EARTHED and likely to become LIVE in the event of failure of the insulation of the POWER SUPPLY CORD, and either metal foil wrapped around the POWER SUPPLY CORD inside inlet bushings, cord guards, cord anchorages and the like, or a metal rod having the same diameter as the POWER SUPPLY CORD, inserted in its place.

This insulation shall be SUPPLEMENTARY INSULATION.

A-k Between, in turn, a SIGNAL INPUT PART, A SIGNAL OUTPUT PART and ACCESSIBLE PARTS not PROTECTIVELY EARTHED.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

This insulation need not be investigated separately if at least one of the following conditions is satisfied:

a) The voltages appearing on the SIGNAL INPUT PART or SIGNAL OUTPUT PART in NORMAL USE do not exceed SAFETY EXTRA LOW VOLTAGE.

b) The LEAKAGE CURRENTS do not exceed the allowable values in SINGLE FAULT CONDITION in the event of any single component failure in the SIGNAL INPUT or SIGNAL OUTPUT PARTS.

c) The SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS are PROTECTIVELY EARTHED or separated from ACCESSIBLE PARTS by any of the means as described in Sub-clause 17*g)*.

d) The SIGNAL INPUT or SIGNAL OUTPUT PARTS are designated by the manufacturer for exclusive connection to EQUIPMENT which complies with requirements specified in the ACCOMPANYING DOCUMENTS for such EQUIPMENT.

20.2 *Requirements for EQUIPMENT with an APPLIED PART*

For EQUIPMENT with an APPLIED PART, the dielectric strength shall also be tested (see also Appendix E):

B-a Between the APPLIED PART (PATIENT CIRCUIT) and LIVE parts.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

This insulation need not be investigated separately if the parts in question are effectively separated as described in Sub-clause 17*a)* 1), 2) or 3). In this case the test is replaced by the tests of B-c and B-d.

Where the total separation between the APPLIED part and the LIVE part consists of more than one circuit insulation, possibly of circuits with a substantially different operating voltage, care shall be taken that each part of the separation means is stressed with the proper test voltage derived from the relevant reference voltage. This may mean that the test B-a may have to be replaced by two or more tests on separate parts of the separation means.

B-b Between parts of the APPLIED PART and/or between APPLIED PARTS.

See Particular Standards.

B-c Between the APPLIED PART and parts not PROTECTIVELY EARTHED which are isolated from LIVE parts by BASIC INSULATION only.

This insulation shall be SUPPLEMENTARY INSULATION.

This insulation need not be investigated separately if the parts in question are effectively separated as described in Sub-clause 17*a)* 1), 2) or 3).

B-d Between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE including SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS. See also Sub-clauses 20.3 and 20.4*j)*.

This insulation shall be BASIC INSULATION. See also B-e.

B-e Between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE where the F-TYPE APPLIED PART contains voltages stressing the insulation to the ENCLOSURE in NORMAL USE including earthing of any part of the APPLIED PART.

This insulation shall be DOUBLE INSULATION or REINFORCED INSULATION.

B-f Not used (see B-a).

*20.3 *Values of test voltages*

The dielectric strength of the electrical insulation at operating temperature as well as following the humidity preconditioning treatment and after any required sterilization procedure, if applicable (see Sub-clause 44.7), shall be sufficient to withstand the test voltages as specified in Table V.

The reference voltage *(U)* as used in Table V is the voltage to which the relevant insulation is subjected in NORMAL USE and at RATED supply voltage or a voltage as specified by the manufacturer, whichever is the greater.

The reference voltage *(U)* for each part of a DOUBLE INSULATION is equal to the voltage to which that DOUBLE INSULATION is subjected in NORMAL USE, NORMAL CONDITION and RATED supply voltage, the EQUIPMENT being energized at the voltage defined in the preceding paragraph.

For reference voltages *(U)* involving an APPLIED PART not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.

For insulation between two isolated parts or between an isolated part and an earthed part, the reference voltage (*U*) is equal to the arithmetic sum of the highest voltages between any two points within both parts.

The reference voltage *(U)* between an F-TYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART.

However, the reference voltage *(U)* shall be not less than the highest RATED supply voltage or for polyphase EQUIPMENT, the phase to neutral supply voltage or for INTERNALLY POWERED EQUIPMENT 250 V.

TABLE V

Test voltages

Insulation to be tested	Test voltages for reference voltage U(V)					
	$U \leq 50$	$50 < U \leq 150$	$150 < U \leq 250$	$250 < U \leq 1000$	$1000 < U \leq 10000$	$10000 < U$
BASIC INSULATION	500	1000	1500	$2U+1000$	$U+2000$	[1]
SUPPLEMENTARY INSULATION	500	2000	2500	$2U+2000$	$U+3000$	[1]
REINFORCED and DOUBLE INSULATION	500	3000	4000	$2(2U+1500)$	$2(U+2500)$	[1]

[1] If necessary, to be prescribed by Particular Standards.

Note. — Tables VI and VII, not used.

20.4 *Tests*

*a) *The test voltage for single-phase EQUIPMENT and for three-phase EQUIPMENT (to be tested as single-phase EQUIPMENT) shall be applied to the insulation parts as described in Sub-clauses 20.1 and 20.2 for 1 min and according to Table V:*

- *immediately after warming up to operating temperature and de-energizing the EQUIPMENT with an incorporated mains switch closed, or*
- *for heating elements after warming up to operating temperature and keeping the EQUIPMENT in operation by application of the circuit of Figure 28, and*
- *immediately after the humidity preconditioning treatment (as described in Sub-clause 4.10) with the EQUIPMENT de-energized during the test and kept in the humidity cabinet, and*
- *after any required sterilization procedure (see Sub-clause 44.7) with the EQUIPMENT de-energized.*

Initially, not more than half the prescribed voltage shall be applied, then it shall be gradually raised over a period of 10 s to the full value, which shall be maintained for 1 min, after which it shall be gradually lowered over a period of 10 s to less than half the full value.

*b) *The test voltage shall have a waveform and frequency such that the dielectric stress on the insulation is at least equal to that which would occur if the waveform and the frequency of the test voltage were equal to those of the voltage applied to the various parts in NORMAL USE.*

c) Not used.

d) Not used.

e) Not used.

f) During the test, no flashover or breakdown shall occur. Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower

value, which must be higher, however, than the reference voltage (U) and provided that the discharges do not provoke a drop in test voltage.

**g) Care is taken that the voltage applied to a REINFORCED INSULATION does not overstress BASIC INSULATION or SUPPLEMENTARY INSULATION in the EQUIPMENT.*

h) Where metal foil is applied this is done according to Sub-clause 19.4g) 5).

Care is taken that the metal foil is positioned in such a manner that flashover does not occur at the edges of insulation linings. If applicable, the metal foil is moved so as to test all parts of the surface.

**j) Power-consuming voltage-limiting devices, in parallel with an insulation to be tested, are disconnected from the earthed side of the circuit.*

Lamps, electronic tubes, semiconductors or other automatic regulating devices may be removed or rendered inoperative if necessary to carry out the test.

Protective devices connected between the F-TYPE APPLIED PART and the ENCLOSURE are disconnected if they would become operative at the test voltage or below (see Sub-clause 59.3).

k) With the exception of the tests on the insulations described in Sub-clauses 20.1 A-b, 20.1 A-f, 20.1 A-g, 20.1 A-j and 20.2 B-b, the terminals of the MAINS PART, SIGNAL INPUT PART, SIGNAL OUTPUT PART and the APPLIED PART (if applicable) respectively are short-circuited during the test.

l) In the case of motors provided with capacitors where a resonance voltage U_c may occur between the point where a winding and a capacitor are connected together on the one hand and any terminal for external conductors on the other hand, a test voltage equal to 2 U_c + 1 000 V shall be applied between the point where the winding and the capacitor are connected together and the ENCLOSURE or conductive parts separated from LIVE parts by BASIC INSULATION only.

During the test, parts not mentioned above are disconnected and the capacitor shall be short-circuited.

SECTION FOUR — PROTECTION AGAINST MECHANICAL HAZARDS

21. Mechanical strength

General

For general requirements on design and manufacture of EQUIPMENT see Clauses 3 and 54.

ENCLOSURES including any ACCESS COVERS forming part of them, with all components thereon, shall have sufficient strength and rigidity.

Compliance is checked by application of the following tests:

a) The rigidity of an ENCLOSURE or an ENCLOSURE part, and of any component thereon, is tested by application of an inward directed force of 45 N applied over an area of 625 mm² anywhere on the surface.

There shall not be any appreciable damage or reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in Sub-clause 57.10.

b) The strength of an ENCLOSURE or an ENCLOSURE part, and of any component thereon, is tested by application of blows with an impact energy of 0.5 J ± 0.05 J by means of the spring-operated impact test apparatus shown and described in Appendix G.

The release mechanism springs are adjusted so that they exert just sufficient pressure to keep the release jaws in the engaged position.

The test apparatus is cocked by pulling the cocking knob until the release jaws engage with the groove in the hammer shaft. The blows are applied by pushing the release cone against the sample in a direction perpendicular to the surface at the point to be tested.

The pressure is slowly increased so that the cone moves back until it is in contact with the release bars, which then move to operate the release mechanism and allow the hammer to strike.

The EQUIPMENT shall be rigidly supported and three blows shall be applied to every point of the ENCLOSURE that is likely to be weak. The blows shall also be applied to handles, levers, knobs, displays and the like, and to signal lamps and their covers, but only if the lamps or covers protrude from the ENCLOSURE by more than 10 mm or if their surface area exceeds 4 cm^2. Lamps within EQUIPMENT and their covers are tested only if they are likely to be damaged in NORMAL USE.

After the test, any damage sustained shall produce no SAFETY HAZARD; in particular, LIVE parts shall not have become accessible so as to cause non-compliance with the requirements of Section Three, Clause 44 and Sub-clause 57.10. If, as a result of the preceding test, the integrity of SUPPLEMENTARY or REINFORCED INSULATION is in doubt, the relevant insulation only (not the rest of the EQUIPMENT) shall be subjected to a dielectric strength test as specified in Clause 20.

Damage to the finish, small dents which do not reduce CREEPAGE DISTANCES and AIR CLEARANCES below the values specified in Sub-clause 57.10 and small chips which do not adversely affect the protection against electrical shock or moisture shall be ignored.

Cracks not visible to the naked eye and surface cracks in fibre reinforced mouldings and the like shall be ignored.

If a decorative cover is backed by an inner cover, fracture of the decorative cover shall be ignored if the inner cover withstands the test after removal of the decorative cover.

c) Carrying handles or grips furnished on PORTABLE EQUIPMENT shall withstand loading as described in the following test.

The handle and its means of attachment are subjected to a force equal to four times the weight of the EQUIPMENT.

The force is applied uniformly over a 7 cm length of the handle at the centre, without clamping, started at zero and gradually increased so that the test value will be attained in 5 s to 10 s and maintained for a period of 1 min.

If more than one handle is furnished on the EQUIPMENT, the force shall be distributed between the handles. The distribution of forces shall be determined by measuring the percentage of the EQUIPMENT mass sustained by each handle with the EQUIPMENT in the normal carrying position. If the EQUIPMENT is furnished with more than one handle but so designed that it may readily be carried by only one handle, each handle shall be capable of sustaining the total force. The handles shall not break loose from the EQUIPMENT and there shall not be any permanent distortion, cracking or other evidence of failure.

21.1 Not used.

21.2 Not used.

21.3 EQUIPMENT parts serving for support and/or immobilization of PATIENTS shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental loosening of fixings.

Supporting parts for adult human PATIENTS shall be designed for a PATIENT having a mass of 135 kg (normal load).

Where manufacturers specify particular applications, such as paediatric use, the normal load shall be reduced.

Where breakdown of a PATIENT support constitutes a SAFETY HAZARD, the requirements of Clause 28 shall apply.

Compliance is checked by the following test:

A PATIENT support system shall be positioned horizontally and in the least favourable position consistent with the instructions for use and loaded with weight distributed evenly over the support surface, including any side rails. The weight shall be applied gradually to the system until the required load is in place.

During the test structural members not considered part of the system under test may be provided with additional support.

The weight shall be equal to the required SAFETY FACTOR (see Clause 28) times the specified normal load. Where no normal load is specified, a weight that exerts a force of 1.35 kN shall be considered the normal load for the test. The full load shall act on the support system for a period of 1 min.

There shall be no damage to parts of the support system such as chains, clamps, cords, cord terminations and connections, belts, axles, pulleys and the like that affect protection against a SAFETY HAZARD.

The support system shall be in equilibrium within 1 min after the application of the full test load.

Foot rests and chairs shall be tested by the same procedure, but the test shall be twice the specified maximum normal load or, if such a load is not specified, the test force shall be 2.7 kN. The test force shall be evenly distributed over an area of 0.1 m^2 surface area for one minute.

At the completion of the test foot, rests and chairs shall show no damage resulting in a SAFETY HAZARD.

21.4 Not used.

*21.5 EQUIPMENT or EQUIPMENT parts which are hand held during NORMAL USE shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface.

Compliance is checked by the following test:

The sample to be tested shall be allowed to fall freely once from each of three different starting attitudes from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood > 700 kg/m^3) which lies flat on a rigid base (concrete block).

After the test EQUIPMENT shall comply with the requirements of this Standard.

*21.6 PORTABLE and MOBILE EQUIPMENT shall withstand the stresses caused by rough handling.

Compliance is checked by the following test:

EQUIPMENT is lifted to a height as indicated in Table VIII above a 50 mm thick hardwood board (see Sub-clause 21.5).

The dimension of the board shall be at least 1.5 times that of the EQUIPMENT and it shall lie flat on a rigid (concrete) base. The EQUIPMENT is dropped three times from each attitude in which it may be placed in NORMAL USE.

TABLE VIII

Drop height

Mass of EQUIPMENT (kg)	Drop height (cm)
Up to and including 10	5
More than 10 up to and including 50	3
More than 50	2

After the test EQUIPMENT shall comply with the requirements of this Standard.

*22. **Moving parts**

22.1 Not used.

22.2 Moving parts which do not need to be exposed for the operation of EQUIPMENT and which, if exposed, constitute a SAFETY HAZARD shall:

a) in the case of TRANSPORTABLE EQUIPMENT, be provided with adequate guards which shall form an integral part of the EQUIPMENT, or

b) in the case of STATIONARY EQUIPMENT, be similarly guarded unless installation instructions provided by the manufacturer in the technical description require that such guarding or equivalent protection will be separately provided.

Compliance is checked by inspection of the accessibility of moving parts and the adequacy of possible protective measures, either forming an integral part of EQUIPMENT or being provided during installation of STATIONARY EQUIPMENT (see installation instructions).

22.3 Cords (ropes), chains and bands shall either be confined so that they cannot run off or jump out of their guiding devices, or a SAFETY HAZARD shall be prevented by other means. Mechanical means applied for this purpose shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

22.4 Movements of EQUIPMENT or EQUIPMENT parts which may cause physical injury to the PATIENT shall be possible only by the continuous activation of the control by the OPERATOR of these EQUIPMENT parts.

Compliance is checked by inspection.

22.5 Not used.

22.6 Parts subject to mechanical wear likely to result in a SAFETY HAZARD shall be accessible for inspection.

Compliance is checked by inspection.

22.7 — If an electrically produced mechanical movement could cause a SAFETY HAZARD, readily identifiable and accessible means shall be provided for emergency switching of the relevant part of EQUIPMENT.

Such means shall only be recognized as a SAFETY DEVICE if the emergency situation becomes obvious to the OPERATOR and his reaction time is taken into account.

- Operation of an emergency switching or stopping means shall not introduce a further SAFETY HAZARD nor interfere with the complete operation necessary to remove the original SAFETY HAZARD.
- Devices for emergency stopping shall be able to break the full load current of the relevant circuit, taking into account possible stalled motor currents and the like.

- Means for stopping of movements shall operate as a result of one single action.

Compliance is checked by inspection.

23. **Surfaces, corners and edges**

Rough surfaces, sharp corners and edges which may cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection.

24. **Stability in NORMAL USE**

24.1 EQUIPMENT shall either not overbalance during NORMAL USE when tilted through an angle of 10°, or shall satisfy the requirements of Sub-clause 24.3.

24.2 Not used.

24.3 If EQUIPMENT overbalances when tilted through an angle of 10°, all the following requirements shall be met:

- EQUIPMENT shall not overbalance when tilted through an angle of 5° in any position of NORMAL USE, excluding transport.
- EQUIPMENT shall carry a warning notice stating that transport should only be undertaken in a certain position which shall be clearly described in the instructions for use or illustrated on the EQUIPMENT.
- In the position specified for transport, EQUIPMENT shall not overbalance when tilted to an angle of 10°.

Compliance is checked by application of the following tests, during which EQUIPMENT shall not overbalance.

a) EQUIPMENT is provided with all specified connection leads: the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favourable combination of possible detachable parts and ACCESSORIES.

EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.

The connection leads shall be laid down on the inclined plane (see tests b) and c)) in the position most unfavourable for stability.

b) If no special transport position with increased stability is specified, EQUIPMENT is placed in any possible position of NORMAL USE on a plane inclined at an angle of 10° to the horizontal plane.

If castors are present, they shall be temporarily fixed in their most disadvantageous position.

Doors and drawers and the like shall be placed in the most disadvantageous position.

c) If a special transport position with increased stability is specified and marked on EQUIPMENT, it is tested as described in the preceding sub-clause, but only in the prescribed transport position on a plane inclined at an angle of 10°.

Furthermore, such EQUIPMENT shall be tested in any possible position of NORMAL USE as described in this sub-clause, but the angle of inclination shall be restricted to 5°.

d) EQUIPMENT having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.

24.4 Not used.

24.5 Not used.

24.6 *Grips and other handling devices*

a) EQUIPMENT or EQUIPMENT parts with a mass of more than 20 kg and which need(s) to be handled in NORMAL USE shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where EQUIPMENT can be lifted safely or how it should be handled during assembly.

Where the method of handling is obvious and no SAFETY HAZARDS can develop when this is done, no particular construction or instruction is required.

Compliance is checked by weighing (if necessary) and by inspection of EQUIPMENT and/or the ACCOMPANYING DOCUMENTS.

b) EQUIPMENT specified by the manufacturer as PORTABLE EQUIPMENT with a mass of more than 20 kg shall have (a) carrying-handle(s) suitably placed which enable(s) the EQUIPMENT to be carried by two or more persons.

Compliance is checked by weighing (if necessary) and by carrying.

25. Expelled parts

25.1 Where expelled parts could constitute a SAFETY HAZARD protective means shall be provided.

Compliance is checked by inspection for the presence of protective means.

25.2 A graphical display vacuum tube whose maximum face dimension exceeds 16 cm shall either be intrinsically safe with respect to effects of implosion and to mechanical impact, or the ENCLOSURE of the EQUIPMENT shall provide adequate protection against the effects of an implosion of the tube.

A non-intrinsically safe tube shall be provided with an effective protective screen which cannot be removed without the use of a TOOL; if a separate screen of glass is used, it shall not be in direct contact with the surface of the tube.

The tube shall be tested as specified in IEC Publication 65, unless a certificate of the testing is provided.

*26. Vibration and noise

Not used.

27. Pneumatic and hydraulic power

Under consideration.

28. Suspended masses

28.1 *General*

The following requirements concern EQUIPMENT parts suspending masses (including PATIENTS), where a mechanical defect of the means of suspension could constitute a SAFETY HAZARD.

Any moving part shall also comply with the requirements of Clause 22.

28.2 Not used.

28.3 *Suspension system with SAFETY DEVICES*

— Where the integrity of a suspension depends on parts, such as springs, which may, due to their manufacturing process, have hidden defects, or on parts having SAFETY FACTORS not complying with Sub-clause 28.4, a SAFETY DEVICE shall be provided, unless excess travel in the event of breakdown is limited.

— The SAFETY DEVICE shall have SAFETY FACTORS complying with Sub-clause 28.4.2.

— If EQUIPMENT can still be used after failure of suspension means and activation of a SAFETY DEVICE (for example a secondary rope), it shall become obvious to the OPERATOR that the SAFETY DEVICE has been activated.

28.4 *Suspension systems of metal without SAFETY DEVICES*

If a SAFETY DEVICE is not provided, the construction of the suspension shall comply with the following requirements:

1) The TOTAL LOAD shall not exceed the SAFE WORKING LOAD.

2) Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the SAFETY FACTOR of all supporting parts shall not be less than 4.

3) Where impairment by wear, corrosion, material fatigue or ageing is expected, relevant supporting parts shall have a SAFETY FACTOR not less than 8.

4) Where metal having a specific elongation at break of less than 5% is used in supporting components, the SAFETY FACTORS, as given in 2) and 3) above shall be multiplied by 1.5.

5) Sheaves, sprockets, bandwheels and guides shall be so designed and constructed that the SAFETY FACTORS of this sub-clause of the suspension system shall be maintained for a specified minimum life till replacement of the ropes, chains and bands.

Compliance with the requirements of Sub-clauses 28.3 and 28.4 is checked by inspection of the design data and any maintenance instructions.

*28.5 *DYNAMIC LOADS*

Not used.

28.6 Not used.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

General

Radiation from MEDICAL ELECTRICAL EQUIPMENT intended for application to PATIENTS for diagnostic or therapeutic purpose under medical supervision may exceed limits normally acceptable for the population as a whole.

Adequate provisions shall be made to protect the PATIENT, OPERATOR and other persons and sensitive devices in the vicinity of the EQUIPMENT from unwanted or excessive radiation from the EQUIPMENT.

Limits for EQUIPMENT intended to produce radiation for diagnostic or therapeutic purpose are specified in Particular Standards.

Requirements and tests will be found in Clauses 29 to 36.

29. **X-Radiation**

29.1 Not used.

29.2 For EQUIPMENT not intended to produce X-radiation for diagnostic and therapeutic purposes, ionizing radiation emitted by vacuum tubes excited by voltages exceeding 5 kV shall not produce an exposure exceeding 130 nC/kg (0.5 mR) in 1 h at a distance of 5 cm from any accessible surface of the EQUIPMENT.

Compliance is checked by measurements of exposure or exposure rate with a radiation detector suitable for the energy of the emitted radiation. In order to average the exposure of narrow beams over the appropriate area, the detector shall have an entry window with an area of approximately 10 cm².

The relevant HIGH VOLTAGE source(s) in the EQUIPMENT is (are) set to the least favourable value so as to produce the maximum X-radiation emission by adjustment of internal and external means provided for such purpose.

Single failures of components causing the least favourable situation are provoked in turn.

Detailed requirements concerning failure of components may be specified in Particular Standards.

30. **Alpha, beta, gamma, neutron radiation and other particle radiation**

Under consideration.

31. **Microwave radiation**

Under consideration.

32. **Light radiation (including lasers)**

Under consideration.

33. **Infra-red radiation**

Under consideration.

34. **Ultraviolet radiation**

Under consideration.

35. **Acoustical energy (including ultra-sonics)**

Under consideration.

36. **Electromagnetic compatibility**

Under consideration.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

Note. – This clause has been re-written and re-numbered.

37. Locations and basic requirements

37.1 Not used.

37.2 Not used.

37.3 Not used.

37.4 Not used.

37.5 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

Where a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs because of a leakage or discharge of a FLAMMABLE ANAESTHETIC WITH OXYGEN OR NITROUS OXIDE from an ENCLOSURE, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm from such a point. The location of such a volume and the duration of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR (including a flammable mixture of desinfection or cleaning agent with air) depends on local circumstances.

37.6 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

A FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE may be contained in a completely or partly enclosed EQUIPMENT part and in the PATIENT'S respiratory tract. Such a mixture is considered to propagate to a distance of 5 cm from an ENCLOSURE part where leakage or discharge occurs.

37.7 EQUIPMENT or parts thereof specified for use in a location defined in Sub-clause 37.5 shall be CATEGORY AP or APG EQUIPMENT and shall comply with the requirements of Clauses 39 and 40.

37.8 EQUIPMENT or parts thereof specified for use in a location defined in Sub-clause 37.6 shall be CATEGORY APG EQUIPMENT and shall comply with the requirements of Clauses 39 and 41.

Parts of CATEGORY APG EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs shall be CATEGORY AP or APG EQUIPMENT and shall comply with the requirements of Clauses 38, 39 and 40.

Compliance with the requirements of Sub-clauses 37.7 and 37.8 is checked by inspection and by the appropriate tests of Clauses 39, 40 and 41.

These tests shall be made after applicable tests according to Sub-clause 44.7.

38. Marking, ACCOMPANYING DOCUMENTS

38.1 Not used.

38.2 CATEGORY APG EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters "APG", permanently affixed and clearly legible (see Appendix D and Clause 6). The length of the green-coloured band shall be at least 4 cm. The sizes of the marking shall be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

38.3 Not used.

38.4 CATEGORY AP EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters "AP", permanently affixed and clearly legible (see Appendix D and Clause 6).

The size of the marking shall be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

38.5 The marking according to Sub-clauses 38.2 and 38.4 shall be present on the major part of the EQUIPMENT if this part is AP or APG. It need not be repeated on detachable parts which can only be used together with the marked EQUIPMENT.

38.6 ACCOMPANYING DOCUMENTS shall contain an indication for the USER enabling him to distinguish the parts of EQUIPMENT (see Sub-clause 38.7) that are categorized AP and APG.

Compliance is checked by inspection (see Sub-clause 6.8).

38.7 On EQUIPMENT in which only certain EQUIPMENT parts are CATEGORY AP or CATEGORY APG, the marking shall clearly indicate which parts are CATEGORY AP or CATEGORY APG.

Compliance is checked by inspection.

38.8 Not used.

39. Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

39.1 *Electrical connections*

a) CREEPAGE DISTANCES and AIR CLEARANCES between the connection points of POWER SUPPLY CORDS shall be according to Sub-clause 57.10, Table XVI, values for SUPPLEMENTARY INSULATION.

b) Connections, except those in the circuits described in Sub-clauses 40.3 and 41.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection and/or disconnection can be performed only with the use of a TOOL.

c) CATEGORY AP EQUIPMENT and CATEGORY APG EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of Sub-clauses 40.3 or 41.3.

Compliance is checked by inspection and/or measurement.

39.2 *Construction details*

a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.

Compliance is checked by inspection.

b) To avoid the likelihood of arcing and sparking due to foreign objects penetrating the ENCLOSURE:

— top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob;

— openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented;

— openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.

Compliance is checked by means of a cylindrical test rod of 4 mm diameter for side-covers and 12 mm diameter for base plates. The test rod shall not enter the ENCLOSURE *when applied in all possible directions without appreciable force.*

c) Where BASIC INSULATION of electrical conductors may contact a part containing a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or ignitable gases alone or oxygen, a short circuit of these conductors or a short circuit of one conductor to a conductive part containing the gas or mixture shall not result in loss of integrity of such a part or result in an inadmissible temperature or in a SAFETY HAZARD in such a part (see Sub-clause 41.3*a)*).

Compliance is checked by inspection. In case of doubt, a short-circuit test (without explosive gases) shall be performed and the temperature in the relevant part shall be measured if possible. The short-circuit test need not be performed if the product of the open-circuit voltage in volts and the short-circuit current in amperes does not exceed 10.

39.3 *Prevention of electrostatic charges*

a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG EQUIPMENT by a combination of appropriate measures such as:

- the use of antistatic materials with a limited electrical resistance as specified in Sub-clause 39.3*b)*, and
- provision of electrically conductive paths from EQUIPMENT or EQUIPMENT parts to a conductive floor or to the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room.

b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO Standard 2882.

Compliance with the allowable resistance limits given in ISO 2882 is checked by measurements according to ISO 471, ISO 1853 and ISO 2878.

39.3 *c)* to *j)* Not used.

39.4 *Corona*

Parts and components of EQUIPMENT operating at more than 2000 V a.c. or more than 2400 V d.c. which are not included in ENCLOSURES in compliance with Sub-clauses 40.4 or 40.5 shall be so designed that corona cannot be produced.

Compliance is checked by inspection and measurement.

40. Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof

40.1 *General*

EQUIPMENT, EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.

EQUIPMENT, EQUIPMENT parts or components complying with one of the Sub-clauses 40.2 to 40.5 are considered to comply with the requirement of this sub-clause.

EQUIPMENT, EQUIPMENT parts or components complying with the requirements of IEC Publication 79 for pressurized enclosures (79-2), for sandfilled enclosures (79-5) or for

oil-immersed equipment (79-6) as well as with the requirements of this Standard (excluding those of Sub-clauses 40.2 to 40.5), are considered to comply with the requirements for CATEGORY AP EQUIPMENT.

40.2 *Temperature limits*

EQUIPMENT, EQUIPMENT parts or components not producing sparks and not producing operating temperatures of surfaces, in contact with gas mixtures in NORMAL USE and NORMAL CONDITION, exceeding 150 °C in case of restricted vertical air circulation by convection, or exceeding 200 °C in case of unrestricted vertical air circulation, if measured at an ambient temperature of 25 °C, are considered to comply with the requirements of Sub-clause 40.1.

The operating temperatures are measured during the tests mentioned in Section Seven.

*40.3 *Low-energy circuits*

EQUIPMENT, EQUIPMENT parts or components which may produce sparks in NORMAL USE and NORMAL CONDITION of the EQUIPMENT (for example, switches, relays, plug connections which can be detached without the use of a TOOL, including connections inside EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of Sub-clause 40.2 and additionally the voltage U_{max} and the current I_{max} which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} shall comply with the following:

$U_{max} \leqslant U_{zR}$ with a given current I_{zR}, see Figure 29, and

$U_{max} \leqslant U_{zC}$ with a given capacitance C_{max}, see Figure 30, and

$I_{max} \leqslant I_{zR}$ with a given voltage U_{zR}, see Figure 29, and

$I_{max} \leqslant I_{zL}$ with a given inductance L_{max} and a $U_{max} \leqslant 24$ V, see Figure 31.

— The graphs of Figures 29, 30 and 31 have been obtained with the test apparatus according to Appendix F with the most readily flammable mixtures or ether vapour with air (ether volume percentage 4.3 ± 0.2%) for an ignition probability (without safety factor) of 10^{-3}.

— Extrapolation of the graph of Figure 29 is allowed for combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leqslant 50$ W.

Extrapolation for voltages of more than 42 V is not valid.

— Extrapolation of the graph of Figure 30 is allowed for combinations of capacitances and corresponding voltages within the limitations:

$$\frac{C}{2} U^2 \leqslant 1.2 \text{ mJ}$$

Extrapolation for voltages of more than 242 V is not valid.

If the equivalent resistance R is less than 8000 Ω, U_{max} is additionally determined with the actual resistance R.

— Extrapolation of the graph of Figure 31 is allowed for combinations of currents and corresponding inductances within the limitations

$$\frac{L}{2} I^2 \leqslant 0.3 \text{ mJ}$$

Extrapolation for inductances larger than 900 mH is not valid.

— Voltage U_{max} is taken as the highest supply voltage occurring in the circuit under investigation with the sparking contact open, taking into account the MAINS VOLTAGE variations required in Sub-clause 10.2.2.

- Current I_{max} is taken as the highest current flowing in the circuit under investigation with the sparking contact closed, taking into account the MAINS VOLTAGE variations required in Sub-clause 10.2.2.
- Capacitance C_{max} and inductance L_{max} are taken as the values which occur at the component under investigation which produces sparks in the EQUIPMENT.
- If the circuit is supplied with a.c., the peak value is taken into account.
- If the circuit is complicated and consists of more than one capacitance, inductance and resistance, or a combination thereof, an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and additionally the equivalent U_{max} and I_{max}, either as d.c. values or as a.c. peak values.

Compliance is checked either by temperature measurement and determination of U_{max}, I_{max}, L_{max} and C_{max} and application of Figures 29, 30 and 31, or by examination of the design data.

*40.4 *External ventilation with internal overpressure*

Where EQUIPMENT, EQUIPMENT parts or components are enclosed in an enclosure with external ventilation by means of internal overpressure the following requirements shall apply:

a) FLAMMABLE ANESTHETIC MIXTURES WITH AIR which might have penetrated into the enclosure of EQUIPMENT or of an EQUIPMENT part shall be removed by ventilation before the EQUIPMENT or EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the EQUIPMENT or the EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen).

b) The overpressure inside the enclosure shall be at least 0.75 hPa in NORMAL CONDITION. The overpressure shall be maintained at the site of potential ignition even if the air or inert gas can escape through openings in the enclosure which are necessary for the normal operation of EQUIPMENT or of EQUIPMENT parts.

Energizing EQUIPMENT shall only be possible after the required minimum overpressure has been present for a time sufficient to ventilate the relevant enclosure so that the displaced volume of air or of inert gas is at least five times the volume of the enclosure. (However, EQUIPMENT may be energized at any time or repeatedly if the overpressure is continuously present.)

c) If the overpressure drops below 0.5 hPa during operation, ignition sources shall be de-energized automatically by means which either shall be located in a place where the requirements and tests of Clause 40 do not apply, or comply with the requirements of Clause 40.

d) The external surface of the enclosure in which the internal overpressure is maintained shall not attain in NORMAL CONDITION and NORMAL USE an operating temperature exceeding 150 °C, measured in an ambient temperature of 25 °C.

Compliance with the requirements of Sub-clauses 40.4a) to 40.4d) is checked by temperature, pressure and flow measurements and inspection of the pressure monitoring device.

40.5 *Enclosures with restricted breathing*

Where EQUIPMENT, EQUIPMENT parts or components are enclosed in an enclosure with restricted breathing the following requirements shall apply:

*a) Enclosures with restricted breathing shall be so designed that the formation of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR inside the enclosure does not occur whilst the enclosure is surrounded by a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of a high concentration for a period of at least 30 min but without any pressure difference to the space inside the enclosure.

b) If the required tightness is obtained by gaskets and/or sealing, the material used shall therefore be resistant to ageing.

Compliance is checked by application of test B-b of IEC Publication 68-2-2, Clause 15, temperature 70 °C ± 2 °C, duration 96 h.

c) If the enclosure contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending and/or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see Sub-clause 57.4*a*)).

Compliance with the requirements of Sub-clauses 40.5a), 40.5b) and 40.5c) is checked by application of the following tests:

After completion of the test of Sub-clause 40.5b) if relevant, an internal overpressure of 4 hPa is created and 30 pulls of the value shown in Table IX are applied to each flexible cord alternately in the axial direction of the cord inlet and in the least favourable perpendicular direction, each pull without jerks and of 1 s duration. At the end of the test the overpressure shall not be reduced to less than 2 hPa.

TABLE IX

Gas-tightness of cord inlets

Mass of EQUIPMENT (kg)	Pull (N)
Up to and including 1	30
Over 1 up to and including 4	60
Over 4	100

When the enclosure of EQUIPMENT parts or components is sealed or gas-tight and no doubt exists that the enclosure complies with the aforementioned requirement, the enclosure is tested by inspection only.

The operating temperature of the external surface of the enclosure shall not exceed 150 °C measured at an ambient temperature of 25 °C. The steady state operating temperature of the enclosure shall also be measured.

41. Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof

41.1 *General*

EQUIPMENT, EQUIPMENT parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH OXYGEN OR NITROUS OXIDE. This requirement applies both in NORMAL USE and in the event of any applicable SINGLE FAULT CONDITION, as described in Sub-clause 3.6.

EQUIPMENT, EQUIPMENT parts or components which do not comply with the requirements of Sub-clauses 41.3 are tested by a continuous operation test over a period of 10 min in an ether/oxygen mixture (ether volume percentage 12.2% ± 0.4%) after the terminal steady state condition has been attained, but not longer than 3 h after switching on.

*41.2 *Power supply*

Parts or components of CATEGORY APG EQUIPMENT which operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source which is isolated from earth by at least BASIC INSULATION and from LIVE parts by DOUBLE or REINFORCED INSULATION.

Compliance is checked by inspection of circuit diagrams and measurement.

*41.3 *Temperatures and low-energy circuits*

EQUIPMENT, and EQUIPMENT parts or components are considered to comply with the requirements of Sub-clause 41.1 without being tested according to Sub-clause 41.1 if, in NORMAL USE, NORMAL CONDITION and SINGLE FAULT CONDITIONS (see Sub-clause 3.6):

a) no sparks are produced and no temperatures exceeding 90 °C occur, or

b) a temperature limit of 90 °C is not exceeded, EQUIPMENT or EQUIPMENT parts contain components which may produce sparks in NORMAL USE, NORMAL CONDITION and applicable SINGLE FAULT CONDITIONS, but the voltage U_{max} and the current I_{max} which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max}, comply with the following:

$U_{max} \leqslant U_{zR}$ with a given I_{zR}, see Figure 32, and
$U_{max} \leqslant U_{zC}$ with given C_{max}, see Figure 33, as well as
$I_{max} \leqslant I_{zR}$ with a given voltage U_{zR}, see Figure 32, and
$I_{max} \leqslant I_{zL}$ with a given inductance L_{max} and $U_{max} \leqslant 24$ V, see Figure 34.

— The graphs in Figures 32, 33 and 34 have been obtained with the test apparatus according to Appendix F with the most readily flammable mixture of ether vapour with oxygen (ether volume percentage 12.2 ± 0.4%) for an ignition probability of 10^{-3}. The maximum allowable values of I_{zR} (Figure 32), U_{zC} (Figure 33) and I_{zL} (Figure 34) include a safety factor 1.5.

— Extrapolation of the curves of Figures 32, 33 and 34 is limited to the areas indicated.

— Voltage U_{max} is taken as the highest no-load voltage occurring in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in Sub-clause 10.2.2.

— Current I_{max} is taken as the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in Sub-clause 10.2.2.

— Capacitance C_{max} and inductance L_{max} are taken as values which occur in the relevant circuit.

— If the equivalent resistance R in Figure 33 is less than 8000 Ω, U_{max} is additionally determined with the actual resistance R.

— If the circuit is supplied with a.c., the peak value is taken into account.

— If the circuit is complicated and consists of more than one capacitance, inductance and resistance or a combination thereof an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and, additionally, the equivalent U_{max} and I_{max} either as d.c. values or a.c. peak values.

— If the energy produced in an inductance and/or capacitance in a circuit is limited by voltage-limiting and/or current-limiting devices preventing the limits of Figures 32 and/or 33 and/or 34 being exceeded, two independent components shall be applied, so

that the required limitation of voltage and/or current is obtained even in the case of a first fault (short circuit or open circuit) in one of these components.

This requirement does not apply to transformers designed and made according to this Standard and to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in the event of rupture.

Compliance is checked by inspection, temperature measurements, comparison with design data and/or by measurement of U_{max}, I_{max}, R, L_{max} and C_{max} and using Figures 32, 33 and 34.

41.4 *Heating elements*

EQUIPMENT, EQUIPMENT parts and components which heat a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be provided with a non-SELF-RESETTING THERMAL CUT-OUT, as an additional protection against overheating.

Compliance is checked by the corresponding test of Sub-clause 56.6a).

The current-carrying part of the heating element shall not be in direct contact with the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

Compliance is checked by inspection.

*41.5 *Humidifiers*

In the water-bath of "air over water" humidifiers, the location considered as hazardous because of a possible ignition of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE is limited to a distance of 1 cm below the water surface where the temperature of the heating element can exceed 90 °C and the heating element is automatically switched off if the water-level drops below 1 cm above the heating element.

This reduction to 1 cm does not apply if any other components producing sparks or temperatures above 90 °C are within 5 cm around the volume of the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

Compliance is checked by inspection and measurement.

SECTION SEVEN — PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42. Excessive temperatures

*42.1 EQUIPMENT parts having a safety function and their environment shall not attain temperatures exceeding the values given in Table Xa during NORMAL USE and NORMAL CONDITION over the range of ambient temperatures specified in Sub-clause 10.2.1.

TABLE Xa

Allowable maximum temperatures[1)]

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
— of Class A material[2), 3)]	105
— of Class B Bateriak[2), 3)]	130
— of Class E material[2), 3)]	120
— of Class F material[2), 3)]	155
— of Class H material[2), 3)]	180
Air adjacent to switches and THERMOSTATS with *T* marking[4), 5)]	*T*
Natural rubber or polyvinyl chloride insulation of internal and external wiring and flexible cords with *T* marking[4), 6)]	*T*
Motor capacitors with marking of maximum operating temperature *(tc)*	*tc*-10
Parts in contact with oil having a flash-point of *t*°C	*t*-25
Batteries (INTERNAL ELECTRICAL POWER SOURCE)	[7)]
Parts accessible without the use of a TOOL, except for heaters and their guards, lamps, and handles held in NORMAL USE by the OPERATOR	85
Accessible surfaces of handles, knobs, grips and the like of all EQUIPMENT, which in NORMAL USE are continuously held by the OPERATOR:	
— of metal	55
— of porcelain or vitreous material	65
— of moulded material, rubber or wood	75
Accessible surfaces of handles, knobs, grips and the like, which in NORMAL USE are held by the OPERATOR for short periods only (for example, switches):	
— of metal	60
— of porcelain or vitreous material	70
— of moulded material, rubber or wood	85
EQUIPMENT parts which may in NORMAL USE have a brief contact with a PATIENT	50

See explanations on pages 145 and 147

*42.2 EQUIPMENT parts and their environment shall not attain temperatures exceeding the values as given in Table Xb when the EQUIPMENT is operated during NORMAL USE and under NORMAL CONDITIONS at an ambient temperature of 25 °C.

TABLE Xb

Allowable maximum temperatures[1)]

Parts	Maximum temperature °C
Pins of APPLIANCE INLETS:	
— for hot conditions[8)]	155
— for other conditions	65
All terminals for external conductors (see Sub-clause 57.5)[9)]	85
Air adjacent to switches, THEROMSTATS without *T* marking[4)]	55
Natural rubber or polyvinyl chloride insulation of internal and external wiring and flexible cords:	
— if flexing of wiring occurs or is likely	60
— if flexing does not occur or is unlikely	75
Natural rubber used for parts, the deterioration of which could have an effect on safety:	
— when used as SUPPLEMENTARY or REINFORCED INSULATION	60
— in other cases	75
Cord sheaths used as SUPPLEMENTARY INSULATION	60
Material used as electrical insulation other than for wires or windings:	
— impregnated or varnished textile, paper or press board:	95
— laminated bonded with:	
. melamine-formaldehyde, phenol-formaldehyde or phenol-furfural resins	110
. urea-formaldehyde resin	90
— mouldings of:	
. phenol-formaldehyde with cellulose fillers	110
. phenol-formaldehyde with mineral fillers	125
. melamine-formaldehyde	100
. urea-formaldehyde	90
— thermoplastic material[10)]	
— polyester with glass-fibre reinforcement	135
— silicone rubber and the like[11)]	
— polytetrafluorethylene	290
— pure mica and tightly sintered ceramic material when such products are used as SUPPLEMENTARY or REINFORCED INSULATION	425
— other materials[13)]	
Materials used as thermal insulation and in contact with hot metal:	
— laminates bonded with:	
. melamine-formaldehyde, phenol-formaldehyde or phenol-furfural resins	200
. urea-formaldehyde resin	175
— mouldings of:	
. phenol-formaldehyde with cellulose fillers	200
. phenol-formaldehyde with mineral fillers	225
. melamine-formaldehyde	175
. urea-formaldehyde	175
— other materials[13)]	
Wood in general[12)]	90
Electrolytic capacitors, without a marking for *tc*	65
Other capacitors, without a marking for *tc*	90
Supports, walls, ceiling and floor of the test corner as described in the test of Sub-clause 42.3	90

Explanations for Tables Xa and Xb:

1) It is recognized that higher maximum temperatures may be allowed for insulating materials under insulating oil and in the absence of air or oxygen.

2) The classification is in accordance with IEC Publication 85.

Examples of Class A material are:

— impregnated cotton, silk, artificial silk and paper; enamels based on oleo- or polyamide resins.

Examples of Class B material are:

— glass fibre, melamine and phenol-formaldehyde resins.

Examples of Class E material are:

— mouldings with cellulose fillers, cotton fabric laminates and paper laminates, bonded with melamine-formaldehyde, phenol-formaldehyde or phenol-furfural resins;

— cross-linked polyester, cellulose triacetate films, polyethylene terephthalate films;

— varnished polyethylene terephthalate textile bonded with oil-modified alkyd resin varnish;

— enamels based on polyvinylformal, polyurethane or epoxy resins.

Examples of Class F material are:

— glass fibre;

— varnished glass, fibre textile, built-up mica (with or without supporting material), the foregoing impreganted or bonded with alkyd epoxy, cross-linked polyester and polyurethane resins with superior thermal stability or silicone-alkyd resins.

Examples of Class H material are:

— glass fibre;

— varnished glass fibre impregnated or bonded with appropriate silicone resins or silicone elastomer;

— built-up mica (with or without supporting materials), glass fibre laminates, the foregoing impregnated or bonded with appropriate silicone resins.

3) Motors are required to be marked with their insulation classes or certified by the manufacturer. Totally enclosed motors with insulation Class A, B, E, F and H may have maximum temperature values as indicated, plus 5 °C.

4) *T* signifies the maximum operating temperature.

5) If so requested by the EQUIPMENT manufacturer switches and THERMOSTATS marked with the letter *T* followed by the value of the temperature limit are considered as being not marked. In this case Table Xb applies.

6) This limit will only become applicable when IEC standards for high temperature wires and flexible cords are available.

7) The operating temperature of an INTERNAL ELECTRICAL POWER SOURCE shall not attain a value which causes a SAFETY HAZARD.
Such a value shall be established by consultation with the supplier of the INTERNAL ELECTRICAL POWER SOURCE.

8) The possibility of reducing the maximum temperature of the pins of APPLIANCE INLETS for hot conditions is under consideration. See also IEC Publication 320.

9) Terminals of TRANSPORTABLE or HAND-HELD EQUIPMENT are excluded.

10) There is no specific limit for thermoplastic material which, however, must comply with the requirements for resistance to heat, fire or tracking, for which purpose the maximum temperature must be determined.

11) As specified by the supplier of the material.

12) The limit is concerned with the deterioration of wood and does not take into account deterioration of surface finishes.

13) Electrical or thermal insulating materials other than those given in Tables Xa and Xb may be used, subject to the production of evidence from the manufacturer of the suitability of such materials for their intended use.

42.3 APPLIED PARTS of EQUIPMENT not intended to supply heat to a PATIENT shall not have surface temperatures exceeding 41 °C.

Compliance with the requirements of Sub-clauses 42.1 to 42.3 is checked by operation of EQUIPMENT and temperature measurements as follows:

1) Positioning and cooling

— *Heating EQUIPMENT is placed in a test corner. The test corner consists of two walls at right angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner shall be at least 115% of the linear dimensions of the EQUIPMENT under test.*

The EQUIPMENT is positioned in the test corner as follows:

a) EQUIPMENT normally used on a floor or a table is placed as near to the walls as possible, provided that the manufacturer has not given special instructions concerning its use.

b) EQUIPMENT normally fixed to a wall is mounted on one of the walls, as near to the other wall and to the floor or ceiling as is likely to occur in NORMAL USE, provided the manufacturer has not given special instructions concerning the installation.

c) EQUIPMENT normally fixed to a ceiling is fixed to the ceiling as near to the walls as is likely to occur in NORMAL USE, provided the manufacturer has not given special instructions concerning its installation.

d) Other EQUIPMENT shall be tested in the position of NORMAL USE.

e) HAND-HELD EQUIPMENT is suspended in its normal position, in still air.

f) EQUIPMENT intended for installation in a cabinet or wall is built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.

– *Generally EQUIPMENT under test is operated at the prevailing ambient temperature, the value of which is measured. If the ambient temperature changes during the test, such a change shall be noted. Where doubts exist concerning the effectiveness of cooling means the test may have to be conducted at the ambient temperature which represents the least favourable condition, provided that this temperature is within the ambient temperature range specified in Sub-clause 10.2 of this Standard. If cooling liquid is used during the test the conditions of Sub-clause 10.2 shall apply.*

2) Supply

— *EQUIPMENT having heating elements is operated as in NORMAL USE, with all heating elements energized unless prevented by switching interlocks, the supply voltage being equal to 110% of the maximum RATED voltage.*

— *Motor operated EQUIPMENT is operated under normal load and normal DUTY CYCLE and the least favourable voltage between 90% of the minimum RATED voltage and 110% of the maximum RATED voltage.*

— *Combined heating and motor operated and other EQUIPMENT shall be tested both at 110% of the maximum RATED voltage and at 90% of the minimum RATED voltage.*

3) DUTY CYCLE

The EQUIPMENT is operated:

— *for the RATED operating time for EQUIPMENT for SHORT-TIME OPERATION;*

— *over consecutive cycles of operation until thermal-equilibrium conditions are established for EQUIPMENT for INTERMITTENT OPERATION, the "ON" and "OFF" periods being the RATED "ON" and "OFF" periods;*

— *for EQUIPMENT for CONTINUOUS OPERATION*

a) until the temperature measured according to test 4) described below does not increase in 1 h by more than 2 °C;

b) for 2.5 h, whichever is shorter.

4) Temperature measurement

The temperature of windings is determined by the resistance method unless the windings are non-uniform or severe complications are involved in making the necessary connections for the resistance measurement.

In this case the measurement is made by devices so chosen and positioned that they have a negligible effect on the temperature of the part under test.

Devices used for determining the temperature of surfaces of walls, ceiling and floor of the test corner shall be embedded in the surfaces or attached to the back of small blackened disks of copper or brass, 15 mm in diameter and 1 mm thick, which are flush with the surfaces.

As far as possible, EQUIPMENT is positioned so that parts likely to attain the highest temperatures touch the disks.

The value of the temperature rise of a copper winding is calculated from the formula:

$$\Delta t = \frac{R_2 - R_1}{R_1}(234.5 + t_1) - (t_2 - t_1)$$

where:

Δt *is the temperature rise in °C*
R_1 *is the resistance at the beginning of the test in Ω*
R_2 *is the resistance at the end of the test in Ω*
t_1 *is the room temperature at the beginning of the test in °C*
t_2 *is the room temperature at the end of the test in °C*

At the beginning of the test, windings are to be at room temperature. It is recommended that the resistance of windings at the end of the test be determined by taking resistance measurements as soon as possible after switching off, and then at short intervals so that a curve of resistance against time can be plotted for ascertaining the resistance at the instant of switching off.

The temperature of electrical insulation, other than that of windings, is determined on the surface of the insulation at places where failure could cause a short circuit, contact between LIVE parts and ACCESSIBLE METAL PARTS, bridging of insulation or reduction of CREEPAGE DISTANCES or AIR CLEARANCES below the values specified in Sub-clause 57.10.

The point of separation of cores of a multicore cord and where insulated wires enter lampholders are examples of places where temperatures may have to be measured.

5) Test criteria

During the test THERMAL CUT-OUTS shall not be de-activated and shall not operate. At the end of the test the maximum temperature of the parts listed in Table Xa is determined taking into account the ambient temperature of the test environment, the temperature of the parts tested and the ambient temperature range specified in Sub-clause 10.2.

For the EQUIPMENT parts listed in Table Xb the temperatures measured during the test shall, if necessary, be corrected to determine the values which would correspond to operation at an ambient temperature of 25 °C.

42.4 Not used.

42.5 *Guards*

Guards intended to prevent contact with hot accessible surfaces shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

43. Fire prevention

EQUIPMENT shall have the strength and rigidity necessary to avoid a fire hazard which may occur as a result of a total or partial collapse caused by the abuses to which it is liable to be subjected in NORMAL USE.

Compliance is checked by the mechanical strength test for enclosures (see Clause 21).

44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

44.1 *General*

The construction of EQUIPMENT shall ensure a sufficient degree of protection against SAFETY HAZARDS caused by overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection.

44.2 *Overflow*

If EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet electrical safety insulation which is liable to be adversely affected by such a liquid, nor shall a SAFETY HAZARD be created. Unless restricted by a marking or by the instructions for use, no SAFETY HAZARDS shall develop if TRANSPORTABLE EQUIPMENT is tilted through an angle of 15°.

Compliance is checked by filling the liquid reservoir completely and subsequently adding a further quantity equal to 15% of the capacity of the reservoir which is poured in steadily over a period of 1 min.

TRANSPORTABLE EQUIPMENT is subsequently tilted through an angle of 15° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.

After these procedures, EQUIPMENT shall show no signs of wetting of uninsulated LIVE parts or electrical insulation of parts which may cause a SAFETY HAZARD. For electrical insulation in case of doubt the EQUIPMENT shall be subjected to the dielectric strength test as described in Clause 20.

44.3 *Spillage*

EQUIPMENT requiring the use of liquids in NORMAL USE shall be so constructed that spillage does not wet parts which may cause a SAFETY HAZARD.

Compliance is checked by the following test:

The EQUIPMENT is positioned as in NORMAL USE. A quantity of 200 ml of water is poured steadily on an arbitrary point on the top surface of the EQUIPMENT. See also Sub-clause 4.6a).

After the test, the EQUIPMENT shall comply with the requirements of this Standard.

44.4 *Leakage*

EQUIPMENT shall be so constructed that liquid which might escape in a SINGLE FAULT CONDITION does not wet parts which may cause a SAFETY HAZARD.

Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.

Compliance is checked by the following test:

By means of a pipette, drops of water shall be applied to couplings, to seals and to hoses which might rupture, moving parts being in operation or at rest, whichever is least favourable.

After these procedures, the EQUIPMENT shall show no signs of wetting of electrical insulation which is liable to be adversely affected by such a liquid. In case of doubt, it shall be subjected to the dielectric strength test as described in Clause 20.

44.5 *Humidity*

EQUIPMENT, including any detachable parts, shall be sufficiently proofed against the effects of humidity to which it is liable to be subjected in NORMAL USE.

Compliance is checked by the preconditioning treatment and tests (see Sub-clause 4.10).

44.6 *Ingress of liquids*

ENCLOSURES designed to give a specified degree of protection against harmful ingress of water shall provide this protection in accordance with the classification of IEC Publication 529.

Compliance is checked by the following tests:

- *DRIP-PROOF EQUIPMENT is checked by the test prescribed for the second characteristic numeral 1 of IEC Publication 529.*
- *SPLASH-PROOF EQUIPMENT is checked by the test prescribed for the second characteristic numeral 4 of IEC Publication 529.*
- *For WATERTIGHT EQUIPMENT, the test conditions shall be specified by Particular Safety Standards but they shall not be less severe than those prescribed in IEC Publication 529 for the second characteristic numeral 7.*

Except for WATERTIGHT EQUIPMENT, EQUIPMENT shall withstand the dielectric strength test specified in Clause 20. Inspection shall show that water which may have entered EQUIPMENT can have no harmful effect; in particular, there shall be no trace of water on insulation for which CREEPAGE DISTANCES are specified in Sub-clause 57.10.

44.7 *Cleaning, sterilization and disinfection*

For EQUIPMENT parts which come in contact with the PATIENT in NORMAL USE, see Sub-clause 6.8.2*d)*.

EQUIPMENT or EQUIPMENT parts, including APPLIED PARTS and parts into which PATIENTS may exhale, shall be capable of withstanding without damage or deterioration of safety provisions the cleaning, sterilization or disinfection processes which are likely to be encountered in NORMAL USE or which are specified by the manufacturer in the instructions for use.

Should the instructions for use restrict cleaning, sterilization or desinfection to specific methods for the EQUIPMENT as a whole or for parts of it, then only these specified methods shall be applied. See also Sub-clause 6.8.2*d)*.

Compliance is checked by sterilizing or disinfecting the EQUIPMENT or EQUIPMENT parts 20 times in accordance with the methods specified. If no special method of sterilization or disinfection is specified, the test is made with saturated steam at 134 °C ± 4 °C for 20 cycles, each of 20 min duration (with intervals until EQUIPMENT has cooled to room temperature). There shall be no appreciable signs of deterioration. At the end of the treatment and after an adequate cooling and drying period, EQUIPMENT or parts of it shall withstand the dielectric strength test specified in Clause 20.

*45. **Pressure vessels and parts subject to PRESSURE**

The requirements of this clause apply to vessels and parts subject to PRESSURE, the rupture of which could cause a SAFETY HAZARD.

45.1 Not used.

*45.2 If a pressure vessel is not covered by a national regulation, with or without an inspection procedure, and has a PRESSURE × volume content greater than 200 kPa/l, and PRESSURE greater than 50 kPa, it shall withstand the HYDRAULIC TEST PRESSURE.

Compliance is checked by the following tests:

Where the test PRESSURE for the EQUIPMENT is not specified by an existing National Standard for the part concerned, the test PRESSURE shall be the MAXIMUM PERMISSIBLE WORKING PRESSURE multiplied by a factor obtained from Figure 38.

The PRESSURE is raised gradually to the specified test value and shall be held at that value for 1 min. The sample shall not burst nor suffer from permanent (plastic) deformation nor leak. Leakage at a gasket during this test is not considered to constitute failure unless it occurs at a PRESSURE below 40% of the required test value, or below the MAXIMUM PERMISSIBLE WORKING PRESSURE, whichever is greater.

No leakage is allowed for pressure vessels intended for toxic, flammable or otherwise hazardous substances.

Where pipework and fittings (e.g. of steel and copper) made to relevant National Standards are provided, these may be considered to have adequate strength.

Where unmarked pressure vessels and pipes cannot be hydraulically tested, integrity shall be verified by other suitable tests, e.g. pneumatic using suitable media, at the same test PRESSURE as for the hydraulic test.

*45.3 The maximum PRESSURE to which a part can be subjected in normal or abnormal operation shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part.

The maximum PRESSURE in use shall be considered to be whichever is the highest of the following:

a) the RATED maximum supply PRESSURE from an external source;

b) the PRESSURE setting of a pressure-relief device provided as part of the assembly;

c) the maximum PRESSURE that can be developed by an air compressor that is part of the assembly, unless the PRESSURE is limited by a pressure-relief device.

Compliance is checked by inspection.

45.4 Not used.

45.5 Not used.

45.6 Not used.

45.7 EQUIPMENT shall incorporate pressure-relief device(s) where excessive pressure could otherwise occur.

A pressure-relief device shall comply with all of the following requirements:

a) it shall be connected as close as possible to the pressure vessel or parts of the system that it is intended to protect;

b) it shall be so installed that it is readily accessible for inspection, maintenance and repair;

c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;

d) it shall have its discharge opening so located and directed that the released material is not directed towards any person;

e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts which may cause a SAFETY HAZARD;

f) it shall be of adequate discharge capacity to ensure that the PRESSURE will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10% in the event of a failure in the control of the supply PRESSURE;

g) there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect;

h) the minimum number of cycles of operation shall be 100000, except for bursting disks.

Compliance is checked by inspection and functional test.

The control device responsible for limiting the PRESSURE in the vessel shall be capable of performing under RATED load for 100000 cycles of operation and shall prevent the PRESSURE from exceeding 90% of the setting of the pressure-relief device under any condition of NORMAL USE.

45.8 Not used.

45.9 Not used.

45.10 Not used.

*46. **Human errors**

Not used.

47. **Electrostatic charges**

Not used.

*48. **Materials in APPLIED PARTS in contact with the body of the PATIENT**

Not used.

49. **Interruption of the power supply**

49.1 THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used if they may cause a SAFETY HAZARD by such resetting.

Compliance is checked by a functional test.

*49.2 EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a SAFETY HAZARD other than interruption of its intended function.

Compliance is checked by interruption and restoration of relevant power supplies.

49.3 Means shall be provided to allow the mechanical constraints on a PATIENT to be removed in the event of failure of the SUPPLY MAINS.

Compliance is checked by functional testing.

49.4 Not used.

SECTION EIGHT — ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50. Accuracy of operating data

50.1 *Marking of controls and instruments*

Not used. See Sub-clause 6.3.

50.2 *Accuracy of controls and instruments*

Not used.

51. Protection against hazardous output

51.1 *Intentional exceeding of safety limits*

If the control range of EQUIPMENT is such that the delivered output in a part of the range considerably differs from the output which is regarded as non-hazardous, means shall be provided which prevent such a setting or which indicate to the OPERATOR (for example by means of an apparent additional resistance when the control is set or the bypassing of an interlock or by an additional special or audible signal) that the selected setting is in excess of a safety limit.

This requirement shall apply only where Particular Standards specify safe output levels.

Compliance is checked by inspection.

51.2 *Indication of parameters relevant to safety*

Any EQUIPMENT delivering energy or substances to a PATIENT shall indicate the possible hazardous output, preferably as a pre-indication, e.g. energy, rate or volume.

This requirement shall apply only where Particular Standards specify it.

Compliance is checked by inspection.

51.3 *Reliability of components*

Not used (see also Sub-clause 3.6*f*)).

51.4 *Accidental selection of excessive output values*

Where EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, appropriate steps shall be taken to minimize the possibility of a high intensity output being selected accidentally e.g. interlocks in order to achieve deliberate action, separated output terminals.

Compliance is checked by inspection.

SECTION NINE — ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

Note. — The content of this Section has been augmented and rearranged, to include a wider range of hazards and their possible causes.

52. Abnormal operation and fault conditions

52.1 EQUIPMENT shall be so designed and manufactured that even in SINGLE FAULT CONDITION no SAFETY HAZARD exists (see Sub-clause 3.1 and Clause 13).

It is assumed that EQUIPMENT is operated according to the conditions of NORMAL USE, unless specified otherwise in the following tests.

Compliance is fulfilled if:

The introduction of any of the SINGLE FAULT CONDITIONS described in Sub-clause 52.5, one at a time, does not lead directly to any of the SAFETY HAZARDS described in Sub-clause 52.4.

52.2 Not used.

52.3 Not used.

52.4 The following SAFETY HAZARDS shall be taken into consideration:

*52.4.1 — emission of flames, molten metal, poisonous or ignitable gas in hazardous quantities;

— deformation of ENCLOSURES to such an extent that compliance with this Standard is impaired;

— temperatures exceeding the maximum values shown in Table XII during the tests of Sub-clauses 52.5.10*d)* through 52.5.10*h)*. These temperatures apply for an ambient temperature of 25 °C.

TABLE XI

Maximum temperatures under fault conditions

Parts	Maximum temperatures °C
Walls, ceiling and floor of the test corner[1)]	175
Supply cord[1)]	175
SUPPLEMENTARY and REINFORCED INSULATION other than thermoplastic materials	1.5 times the values shown in Table Xb minus 12.5 °C

[1)] For motor operated EQUIPMENT without heaters, these temperature measurements are not made.

Temperatures shall be measured as prescribed in Sub-clause 42.3 *4)*.

The requirements of Sub-clause 52.1 and the corresponding tests shall not be applied to components the construction or the supply circuit of which limits the power dissipation in SINGLE FAULT CONDITION to 15 W or less.

After the test of Sub-clauses 52.5.10*d)* through 52.5.10*h)*, the insulation between the MAINS PART and the ENCLOSURE, when cooled down to approximately room temperature, shall withstand relevant dielectric strength tests.

However the tests according to this sub-clause shall be performed in the sequence indicated in Appendix C (C23, C25, C26, C27).

For SUPPLEMENTARY and REINFORCED INSULATION of thermoplastic materials, the ball-pressure test specified in Sub-clause 59.2*b)* is carried out at a temperature 25 °C higher than that measured during these tests.

For EQUIPMENT which is immersed in, or filled with, conducting liquid in NORMAL USE, the sample is immersed in or filled with the conducting liquid or water, as appropriate, for 24 h before the dielectric strength test is made.

After the tests of this section THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.

52.4.2 — Exceeding of the limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION as indicated in Sub-clause 19.3, Table IV;

— Exceeding of the voltage limits in case of a SINGLE FAULT CONDITION (in a BASIC INSULATION) for the parts indicated in Sub-clause 16*a)* 5).

52.4.3 Starting, interrupting or locking of movements, particularly for EQUIPMENT (parts) supporting, lifting or moving masses (including PATIENTS) and suspension systems of masses in the vicinity of PATIENTS. See also Clauses 21, 22 and 49.

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

During the insertion of only one fault at a time, AIR CLEARANCES and CREEPAGE DISTANCES for which requirements are specified in this Standard but are less than the specified value shall be short-circuited simultaneously or consecutively in a combination which produces the less favourable result. See also Sub-clauses 17*a)* and 17*g).*

52.5.1 Overloading of mains supply transformers in EQUIPMENT

Tests are described in Sub-clause 57.9.

52.5.2 Failure of THERMOSTATS

THERMOSTATS are short-circuited or interrupted, whichever is less favourable. See also Sub-clauses 52.5.10 and 56.6 for overloading situations.

52.5.3 Short-circuiting of either constituent part of a DOUBLE INSULATION

Each constituent part of a DOUBLE INSULATION is short-circuited independently.

52.5.4 Interruption of the PROTECTIVE EARTH CONDUCTOR

Tests are described in Sub-clause 19.4.

52.5.5 Impairment of cooling

Contrary to possible statements in the instructions for use impairments of cooling which may occur in practice are simulated, for example:

— *single ventilation fans are locked consecutively;*

— *ventilation through openings in top and sides is impaired by,*
  - *covering of openings in the top of the ENCLOSURE, or*
  - *positioning of EQUIPMENT against walls;*

— *blocking of filters is simulated;*

— *the flow of a cooling agent is interrupted.*

Temperatures shall not exceed 1.7 times the values of Clause 42, Tables Xa and Xb, minus 17.5 °C. Test conditions of Clause 42 are applied as far as possible.

52.5.6 Locking of moving parts

Moving parts are locked if EQUIPMENT:

— *has accessible moving parts liable to be jammed, or*

— *is liable to be operated while unattended (this includes EQUIPMENT which is automatically or remotely controlled), or*

— *has one or more motors with a locked rotor torque smaller than the full load torque.*

If EQUIPMENT has more than one moving part as described above, only one part at a time is locked. For further test requirements see Sub-clause 52.5.8.

*52.5.7 Interruption and short-circuiting of motor capacitors

Motors with a capacitor in the circuit of an auxiliary winding are operated with a locked rotor, with the capacitor short-circuited or open-circuited in turn.

The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC Publication 252 and EQUIPMENT is not intended for unattended use (including automatic or remote control).

For further tests, see Sub-clause 52.5.8.

*52.5.8 Additional tests for motor operated EQUIPMENT

For every test in the SINGLE FAULT CONDITION of Sub-clauses 52.5.6 and 52.5.7, taking into account the exemptions stated in Sub-clause 52.4.1, motor-operated EQUIPMENT shall be operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:

a) 30 s for:

- *HAND-HELD EQUIPMENT,*
- *EQUIPMENT which has to be kept switched on by hand,*
- *EQUIPMENT which has to be kept under physical load by hand;*

b) 5 min for other EQUIPMENT not intended for unattended use;

c) for the maximum period of a timer, if such a device terminates the operation, for EQUIPMENT not listed under a) or b);

d) as long as necessary, to establish steady thermal conditions for all the remaining EQUIPMENT.

Note. — EQUIPMENT which is automatically or remotely controlled is regarded as EQUIPMENT for unattended use.

Temperatures of windings are determined at the end of the specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices and the like.

Temperatures are measured as specified in Sub-clause 42.3 4).

Temperatures shall not exceed the limits of Table XI.

TABLE XII

Temperature limits of motor windings, in °C

Type of EQUIPMENT	Insulation class				
	Class A	Class B	Class E	Class F	Class H
EQUIPMENT provided with a timer and not intended for unattended use and EQUIPMENT to be operated for 30 s or 5 min	200	225	215	240	260
Other EQUIPMENT					
— if impedance-protected	150	175	165	190	210
— if protected by protection devices which operate during the first hour, maximum value	200	225	215	240	260
— after the first hour, maximum value	175	200	190	215	235
— after the first hour, arithmetic average	150	175	165	190	210

52.5.9 *Failure of components*

Failure of one component at a time, which failure could cause a SAFETY HAZARD as mentioned in Sub-clause 52.4, is simulated.

This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION.

52.5.10 *Overload*

a) EQUIPMENT having heating elements is checked for compliance as follows:

1) for thermostatically controlled EQUIPMENT having heating elements, which is intended for built-in or for unattended operation, or which has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT: by the tests of Sub-clauses 52.5.10c) and 52.5.10d);

2) for EQUIPMENT having heating elements with short-time rating: by the tests of Sub-clauses 52.5.10c) and 52.5.10e);

3) for other EQUIPMENT having heating elements: by the test of Sub-clause 52.5.10c).

If more than one of the tests is applicable to the same EQUIPMENT, these tests shall be made consecutively.

If, in any of the tests, a non-SELF-RESETTING THERMAL CUT-OUT operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted before steady conditions are established without the possibility of automatic restoration, the heating period is ended. However, if the interruption is due to the rupture of a heating element or of an intentionally weak part, the test shall be repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample does not in itself entail a failure to comply. Both samples shall comply with the conditions specified in Sub-clause 52.4.1.

b) EQUIPMENT having motors is checked for compliance as follows:

1) for the motor part of the EQUIPMENT, by the tests of Sub-clauses 52.5.5 through 52.5.8 and 52.5.10f) through 52.5.10h), as applicable;

2) for EQUIPMENT containing motors as well as heating parts, the tests shall be performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition;

3) if more than one of the tests is applicable for the same EQUIPMENT, these tests are made consecutively.

c) EQUIPMENT having heating elements is tested under the conditions specified in Clause 42, but without adequate heat discharge, the supply voltage being 90% or 110% of the RATED supply voltage, whichever is the least favourable.

If a non-SELF-RESETTING THERMAL CUT-OUT operates, or if the current is otherwise interrupted without the possibility of automatic restoration before steady thermal conditions are established, the operating period is ended. If interruption of the current does not occur, EQUIPMENT shall be switched off as soon as steady thermal conditions are established and shall be allowed to cool to approximately room temperature.

For EQUIPMENT with short-time rating, the duration of the test shall be equal to the RATED operating time.

d) Heating parts of EQUIPMENT are tested under all of the following conditions:

1) as specified in Clause 42;

2) with the EQUIPMENT operated in NORMAL CONDITION;

3) with a supply voltage being 110% of the RATED supply voltage;

4) disabling any control which serves to limit the temperature required in Section Seven, except a THERMAL CUT-OUT;

5) if the EQUIPMENT is provided with more than one control, they are disabled in turn.

e) Heating parts of EQUIPMENT are additionally tested under all of the following conditions:

1) as specified in Clause 42;

2) with the EQUIPMENT operated in NORMAL CONDITION;

3) with a supply voltage being 110% of the RATED supply voltage;

4) without any control which serves to limit the temperature required in Section Seven disabled;

5) until steady thermal conditions are established, irrespective of the RATED operating time.

f) Motors are checked for running overload protection if they are:

1) intended to be remotely controlled or automatically controlled, or

2) liable to be operated continuously whilst unattended,

by operating EQUIPMENT under normal load conditions at RATED voltage or at the maximum of the RATED voltage range, until steady thermal conditions are achieved (see Section Seven).

The load is then increased so that the current is increased in appropriate steps, the supply voltage being maintained at its original value.

When steady thermal conditions are established, the load is again increased. The load is thus progressively increased in appropriate steps until the overload protection operates, or until no further temperature rise is noted.

The motor winding temperature is determined during each steady period and the maximum value recorded shall not exceed:

Insulation class	A	B	E	F	H
Maximum temperature °C	140	165	155	180	200

If the load cannot be changed in appropriate steps in EQUIPMENT, the motor is removed from the EQUIPMENT in order to perform the test.

g) EQUIPMENT rated for SHORT-TIME or INTERMITTENT OPERATION other than:

- *HAND-HELD EQUIPMENT;*
- *EQUIPMENT which has to be kept switched on by hand;*
- *EQUIPMENT which has to be kept under physical load by hand;*
- *EQUIPMENT with a timer and a back-up system;*

is operated under normal load and at RATED voltage or at the upper limit of the RATED voltage range until steady thermal conditions are established, or until the protective device operates.

Motor winding temperatures are determined when steady thermal conditions are established or immediately before the operation of the protective device and shall not exceed the values specified in Sub-clause 52.5.8.

If in NORMAL USE a load-reducing device in EQUIPMENT operates, the test is continued with EQUIPMENT running idle.

h) EQUIPMENT with three-phase motors is operated with normal load, connected to a three-phase (SUPPLY MAINS) with one phase disconnected. Periods of operation shall be according to Sub-clause 52.5.8.

53. **ENVIRONMENTAL TESTS**

See Sub-clause 4.10 and Clause 10.

SECTION TEN — CONSTRUCTIONAL REQUIREMENTS

*54. **General**

The following requirements in Section Ten specify details of the electrical and mechanical construction insofar as the safety of EQUIPMENT is concerned.

The aim is to specify requirements in such a manner as to allow manufacturers the widest possible choice in design and construction.

As allowed in Sub-clause 3.4, a manufacturer may make use of materials and constructions differing from those detailed in this Section, if an equivalent degree of safety is obtained. The requirements of this Section are considered as not more than one means of achieving the required degree of safety and the term "shall", where used, should be understood accordingly.

*54.1 *Arrangements of functions*

Not used.

*54.2 *Serviceability*

Not used.

*54.3 *Inadvertent changing of settings*

Not used.

55. ENCLOSURES and covers

Not used. See Clauses 16, 21 and 24.

*55.1 *Materials*

Not used.

*55.2 *Mechanical strength*

Not used.

55.3 *ACCESS COVERS*

Not used.

55.4 *Grips and other handling devices*

Not used. Moved to Sub-clauses 21*c)* and 24.6.

56. Components and general assembly

56.1 *General*

a) Not used.

b) *Marking of components*

Ratings of components shall not conflict with the conditions of use in EQUIPMENT.

All components in the MAINS PART and in the APPLIED PART shall be marked or otherwise identified so that their ratings can be ascertained.

The markings may be integral with the parts themselves, or made available by reference to construction drawings, parts lists, or in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ratings of components to ascertain that no conflict exists with the condition of use in EQUIPMENT.

c) *Supporting of components*

Not used.

d) *Component fixing*

Components, the unwanted movement of which could result in a SAFETY HAZARD, shall be mounted securely to prevent such movement.

Compliance is checked by inspection.

e) *Resistance of components to vibration.*

Not used.

f) *Fixing of wiring*

Conductors and connectors shall be so secured and/or insulated that accidental detachment shall not result in a SAFETY HAZARD. They are not considered to be adequately secured if on breaking free at their joint and moving about their support point they are capable of touching circuit points giving rise to a SAFETY HAZARD.

One instance of breaking free shall be considered to be a SINGLE FAULT CONDITION.

Compliance is checked by inspection.

56.2 *Screws and nuts*

Not used.

56.3 *Connections – General*

For connections and connectors in the MAINS PART see Sub-clauses 57.2 and 57.5.

a) Construction of connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where a SAFETY HAZARD may be caused.

- Connectors shall comply with Sub-clause 17*g)*.
- Plugs for connection of PATIENT CIRCUIT leads shall be so designed that they cannot be connected to other outlets on the same EQUIPMENT intended for other functions, unless it can be proven that no SAFETY HAZARD can result.
- Medical gas connections on EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also Sub-clause 6.6 and ISO Recommendation R407.

Compliance is checked by inspection, if possible by interchanging of connections, to establish the absence of a SAFETY HAZARD (LEAKAGE CURRENT exceeding the values in NORMAL CONDITION, movement, temperature, radiation, etc.).

b) Connections between different parts of EQUIPMENT. See also Clause 58.

Detachable flexible cords used for interconnection of different parts of EQUIPMENT shall be provided with means for connection such that ACCESSIBLE METAL PARTS cannot become LIVE when a connection is loosened or broken due to the disengagement of one of the connecting means.

Compliance is checked by inspection and measurement and, if necessary, by a test with the standard test finger according to Sub-clause 16a).

*56.4 *Connections of capacitors*

- Capacitors shall not be connected between LIVE parts and non-PROTECTIVELY EARTHED ACCESSIBLE PARTS where the failure of such a capacitor could result in ACCESSIBLE PARTS becoming LIVE.
- Capacitors connected directly between the MAINS PART and PROTECTIVELY EARTHED ACCESSIBLE METAL PARTS shall comply with the requirements of IEC Publication 384-14 or equivalent.
- The ENCLOSURE of capacitors connected to the MAINS PART and providing only BASIC INSULATION shall not be secured directly to non-PROTECTIVELY EARTHED ACCESSIBLE METAL PARTS.
- Capacitors or other spark-suppression devices shall not be connected between the contacts of THERMAL CUT-OUTS.

Compliance is checked by inspection.

56.5 *Protective devices*

EQUIPMENT shall not be fitted with protective devices which cause disconnection of the EQUIPMENT from the SUPPLY MAINS by producing a short-circuit which results in operation of an overcurrent protection device. See also Sub-clause 59.3.

Compliance is checked by inspection.

56.6 *Temperature and overload control devices*

a) Application

— THERMAL CUT-OUTS with a safety function which have to be reset by a soldering operation which may affect the operating value shall not be fitted in EQUIPMENT.

— Thermal safety devices shall be provided where necessary to prevent operating temperatures exceeding the limits specified in Section Nine and in Sub-clause 57.9.

— Where a failure of a THERMOSTAT could constitute a SAFETY HAZARD an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device but shall be within the safe temperature limit for its intended function.

— Where the consequent loss of function of EQUIPMENT caused by operation of a THERMAL CUT-OUT presents a SAFETY HAZARD, an audible warning shall be given.

Compliance is checked by inspection and, if applicable, by the following tests:

Thermal safety devices may be tested separately from EQUIPMENT.

THERMAL CUT-OUTS and OVER-CURRENT RELEASES shall be tested by operating the EQUIPMENT under the conditions described in Section Nine.

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES shall be caused to operate 200 times.

Non-self resetting OVER-CURRENT RELEASES shall be caused to operate 10 times.

During the tests, forced cooling and resting periods may be introduced to prevent damage to the EQUIPMENT. After the tests, the samples shall show no damage impairing their further use.

EQUIPMENT which incorporates a fluid filled container having heating facilities shall be provided with a safety device to safeguard against overheating in the event of the heater being switched on with the container empty, if dangerous overheating can occur in the absence of fluid.

Compliance is checked by operating the relevant EQUIPMENT with an empty container. No overheating shall occur which causes damage to the EQUIPMENT resulting in a SAFETY HAZARD.

b) Allowable temperature range

— Where means are provided for varying the temperature setting of THERMOSTATS, the temperature range shall not exceed substantially that which is necessary for the proper functioning of EQUIPMENT and the temperature setting shall be clearly indicated.

— The operating temperature of THERMAL CUT-OUTS shall be clearly indicated.

Compliance is checked by inspection.

56.7 *INTERNAL ELECTRICAL POWER SOURCE*

a) Housing

Housings containing batteries from which gases can escape during charging or discharging shall be ventilated to minimize the risk of accumulation and ignition.

Battery compartments shall be designed to prevent the risk of accidentally short-circuiting the battery where such short circuits could result in a SAFETY HAZARD.

Compliance is checked by inspection.

b) Connection

If a SAFETY HAZARD might develop by the incorrect connection or replacement of a battery, EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also Sub-clause 6.2*d)*.

Compliance is checked by:

1) Establishing the possibility of making an incorrect battery connection.

2) Where this possibility exists, establishing the effect of an incorrect battery connection.

56.8 *Indicators*

Unless indication is otherwise apparent to the OPERATOR, indicator lights shall be provided:

— To indicate that EQUIPMENT is energized.

— On EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operative if a SAFETY HAZARD could result.

This does not apply to heated stylus-pens for recording purposes.

— To indicate that an output exists where an inadvertent or prolonged operation of the output circuit could constitute a SAFETY HAZARD.

Colours of indicator lights are described in Sub-clause 6.7.

In EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE the charging mode shall be visibly indicated to the OPERATOR.

Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

56.9 *Pre-set controls*

Not used.

56.10 *Actuating parts of controls*

a) Protection against electric shock

ACCESSIBLE PARTS of electrical controls shall comply with the requirements of Sub-clause 16*c)*.

b) Fixing, prevention of maladjustment

— All actuating parts shall be so secured that they cannot be pulled off or work loose during NORMAL USE.

— Controls, the adjustment of which can present a SAFETY HAZARD to the PATIENT or OPERATOR while EQUIPMENT is in use, shall be so secured that the indication of any scale always corresponds with the position of the control.

The indication in this case refers to "On" or "Off" position, scale markings or other indications of position.

— Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL.

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table XIII shall be applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test shall be repeated 10 times.

The knob shall not rotate with respect to the shaft.

If an axial pull is likely to be applied in NORMAL USE, compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

TABLE XIII

Test torques for rotating controls

Gripping diameter of control knob (mm)	Torque (Nm)
10≤d<23	1.0
23≤d<31	1.8
31≤d<41	2.0
41≤d<56	4.0
56≤d≤70	5.0

c) Limitation of movement

Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a SAFETY HAZARD and to prevent damage to wiring. See also Sub-clause 6.3*c)*.

Compliance is checked by inspection and manual tests. For rotating controls the torques as shown in Table XIII shall be applied for not less than 2 s in each direction alternately. The test shall be repeated 10 times.

No SAFETY HAZARD shall develop if an axial pull is likely to be applied in NORMAL USE. Compliance shall be checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

56.11 *Cord-connected hand-held and foot-operated control devices*

a) Limitation of operating voltages

Hand-held and foot-operated control devices and associated connection cords shall contain only conductors and components operating at voltages not exceeding 25 V a.c. or 60 V d.c. or peak value in circuits isolated from the MAINS PART by one of the means specified in Sub-clause 17*g)*.

Compliance is checked by inspection and, if necessary, voltage measurements.

b) Mechanical strength

- Hand-held control devices shall comply with the requirement and test of Sub-clause 21.5.
- Foot-operated control devices shall be able to support the weight of an adult human being.

Compliance is checked by application in the position of NORMAL USE of an actuating force of 1 350 N for 1 min. There shall be no damage to the device resulting in a SAFETY HAZARD.

c) Inadvertent operation

Hand-held and foot-operated control devices shall not change their control setting when inadvertently placed in an abnormal position.

Compliance is checked by turning the device in all possible abnormal positions and placing it as such on a supporting surface. There shall not be any inadvertent change of control setting resulting in a SAFETY HAZARD.

d) Entry of liquids

— Foot-operated control devices shall be drip-proof.

Compliance is checked as described in Sub-clause 44.6 for DRIP-PROOF EQUIPMENT.

— The electrical switching parts of foot-operated control devices of EQUIPMENT, specified by the manufacturer for use in operating rooms, shall be of watertight construction.

Compliance is checked as described in Sub-clause 44.6 for WATERTIGHT EQUIPMENT.

e) Connection cords

The connection and anchorage of a flexible cord to a hand-held or foot-operated control device at the entry point to the control device shall comply with the requirements specified for flexible supply cords in Sub-clause 57.4.

Compliance is checked by performance of the tests of Sub-clause 57.4.

57. MAINS PARTS, components and layout

57.1 *Isolation from the SUPPLY MAINS*

a) Isolation

— EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously. This isolation shall include each LIVE supply conductor, except that PERMANENTLY INSTALLED EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device which does not interrupt the neutral conductor, but only if local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed extra-low voltage.

— Means for isolation shall either be incorporated in EQUIPMENT or, if external, shall be specified in the ACCOMPANYING DOCUMENTS (see Sub-clause 6.8.3).

b) Not used.

c) Not used. See Sub-clause 57.1 *a).*

d) Switches that are used to comply with Sub-clause 57.1 *a)* shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC Publication 328.

e) Not used.

f) Mains switches shall not be incorporated in a POWER SUPPLY CORD or any other external flexible lead.

g) The directions of movement of the actuators of switches that are used to comply with Sub-clause 57.1 *a)* shall comply with IEC Publication 447.

h) In non-PERMANENTLY INSTALLED EQUIPMENT a suitable plug device used to isolate EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of Sub-clause 57.1 *a).*

APPLIANCE COUPLERS and flexible cords with MAINS PLUGS are suitable plug devices.

j) Not used. See Sub-clause 57.1 *a)*.

k) Not used.

l) Not used.

m) Fuses and semiconductor devices shall not be used as isolating devices in the sense of this sub-clause.

Compliance is checked by inspection.

Table XIV. Not used.

57.2 *MAINS CONNECTORS, APPLIANCE INLETS and the like*

a) Not used.

b) Not used.

c) Not used.

d) Not used.

**e)* AUXILIARY MAINS SOCKET OUTLETS on non-PERMANENTLY INSTALLED EQUIPMENT, intended for the provision of mains supply to other EQUIPMENT, or to separated parts of EQUIPMENT shall be of a type that cannot accept a MAINS PLUG. See also Sub-clause 56.3.

This requirement does not apply to EMERGENCY TROLLEYS.

Such AUXILIAIRY MAINS SOCKET OUTLETS shall be properly marked (see Sub-clause 6.1 *k)*.

Compliance is checked by inspection.

f) Not used.

57.3 *POWER-SUPPLY CORDS*

a) Application

— EQUIPMENT shall not be provided with more than one connection to a particular SUPPLY MAINS.

— If a facility for alternative connection to a different supply system, e.g. external battery, is provided no SAFETY HAZARD shall occur when more than one connection is made simultaneously.

— MAINS PLUGS shall not be fitted with more than one POWER SUPPLY CORD.

— EQUIPMENT which is not intended to be permanentely connected to fixed wiring shall be provided with either a POWER SUPPLY CORD or an APPLIANCE INLET.

Compliance is checked by inspection.

b) Types

POWER SUPPLY CORDS shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC Publication 245, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC Publication 227, designation 53).

Polyvinyl chloride insulated POWER SUPPLY CORDS shall not be used for EQUIPMENT having external metal parts with a temperature exceeding 75 °C and which may be touched in NORMAL USE by the cord, unless it is RATED for that temperature (see also Table Xb).

Compliance is checked by inspection and measurement.

c) Cross-sectional area of conductors

The NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS shall be not less than that shown in Table XV.

Compliance is checked by inspection.

TABLE XV

NOMINAL cross-sectional area of POWER SUPPLY CORDS

RATED current of EQUIPMENT (A)	NOMINAL cross-sectional area (mm^2 Cu)
Up to and including 6	0.75
over 6 up to and including 10	1
over 10 up to and including 16	1.5
over 16 up to and including 25	2.5
over 25 up to and including 32	4
over 32 up to and including 40	6
over 40 up to and including 63	10

d) Preparation of conductors

Stranded conductors shall not be soldered if fixed by any clamping means.

Compliance is checked by inspection.

57.4 *Connection of POWER SUPPLY CORDS*

a) Cord anchorages

— EQUIPMENT and MAINS CONNECTORS provided with POWER SUPPLY CORDS shall have cord anchorages such that the conductors are relieved from strain, including twisting, where they are connected within the EQUIPMENT and within the MAINS CONNECTOR and the insulation of the conductors is protected from abrasion.

Strain relief methods, such as tying the cord into a knot or tying the ends with string, shall not be used.

— Cord anchorages of POWER SUPPLY CORDS shall be made:

1) of insulating material, or
2) of metal, insulated from ACCESSIBLE CONDUCTIVE PARTS not PROTECTIVELY EARTHED by SUPPLEMENTARY INSULATION, or
3) of metal provided with an insulating lining, if otherwise a total insulation failure of the POWER SUPPLY CORD could render LIVE ACCESSIBLE CONDUCTIVE PARTS not PROTECTIVELY EARTHED. This lining shall be fixed to the cord anchorage, unless it is a flexible bushing which forms part of the cord guard specified in this sub-clause, and shall comply with the requirements for BASIC INSULATION.

— Cord anchorages of POWER SUPPLY CORDS shall be so designed that the cord is not clamped by a screw which bears directly on the cord insulation.

— Screws, if any, which have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.

— Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.

Compliance is checked by inspection and by the following tests:

EQUIPMENT, if designed for a POWER SUPPLY CORD, is tested with the cord supplied by the manufacturer.

The POWER SUPPLY CORD conductors should, if possible, be disconnected from the mains terminals or from the MAINS CONNECTOR of the EQUIPMENT.

The cord shall be subjected 25 times to a pull on the sheath of the value shown in Table XVIII. The pulls shall be applied in the most unfavourable direction without jerks, each time for 1 s.

Immediately afterwards, the cord shall be subjected for 1 min to a torque of the value shown in Table XVIII.

Note. — Table XVII not used. Table XVI incorporates (see Sub-clause 57.10*a)*) Tables XVI and XVII of the first edition.

TABLE XVIII

Testing of cord anchorages

Mass of EQUIPMENT (kg)	Pull (N)	Torque (Nm)
Up to and including 1	30	0.1
over 1 up to and including 4	60	0.25
over 4	100	0.35

After the tests, the cord sheath shall not have been longitudinally displaced by more than 2 mm and the conductor ends shall not have moved over a distance of more than 1 mm from their normally connected position.

CREEPAGE DISTANCES and AIR CLEARANCES shall not be reduced below the values specified in Sub-clause 57.10.

For the measurement of the longitudinal displacement, a mark shall be made on the cord sheath while it is subjected to the first pull, at a distance of approximately 2 cm from the cord anchorage or other suitable point between the cord anchorage and the test apparatus.

This displacement of the mark on the cord sheath in relation to the cord anchorage or other point shall be measured while the cord is subjected to the last pull.

It shall not be possible to push the cord into EQUIPMENT to such an extent that the cord, or internal parts of the EQUIPMENT, could be damaged.

b) Cord guards

POWER SUPPLY CORDS of other than STATIONARY EQUIPMENT shall be protected against excessive bending at the inlet opening of EQUIPMENT by means of a cord guard of insulating material.

Alternatively, an opening in EQUIPMENT shall be so shaped that the applied supply cord, even if not provided with a guard, passes the following flexing test.

Compliance is checked by inspection, by measurement and by the following test(s):

EQUIPMENT designed for a POWER SUPPLY CORD is fitted with a cord guard or opening and the POWER SUPPLY CORD shall have an exposed length of approximately 100 mm. The EQUIPMENT is so held that the axis of the cord guard, where the cord leaves it, projects upward at an angle of 45° to the horizontal when the cord is free from stress.

A mass equal to 10 D^2 g is then attached to the free end of the cord, D being the overall diameter, in millimetres, or, for flat cords, the minor overall dimensions of the POWER SUPPLY CORD delivered with the EQUIPMENT.

If the cord guard is temperature sensitive, the test is made at 23 °C ± 2 °C.

Flat cords are bent in a direction perpendicular to the plane containing the axis of the cores.

Immediately after the mass has been attached, the curvature of the cord shall nowhere be less than 1.5 D, being checked by a cylindrical rod with a diameter of 1.5 D.

Guards which fail the above dimensional test shall pass the following test:

A sample of the guard, together with the cord delivered with the EQUIPMENT, is to be subjected to 5000 cycles of flexing. The guard is mounted in the EQUIPMENT with a 60 cm to 100 cm length of cord. With the EQUIPMENT held stationary, the guard is flexed by moving the cord back and forth in a plane through an angle of approximately 180°.

After the test, the cord shall not have worked loose and neither the cord anchorage nor the cord shall show appreciable damage, except that not more than 10% of the total number of conductor strands may have been broken.

c) Accessibility of the connection

The space inside EQUIPMENT designed for fixed wiring or a rewirable POWER SUPPLY CORD shall be adequate to allow conductors to be easily introduced and connected, and covers, if any, to be fitted without risk of damage to the conductors or their insulation. It shall be possible to check that the conductors are correctly connected and positioned before the cover is fitted.

Compliance is checked by inspection and by an installation test.

57.5 *MAINS TERMINAL DEVICES and wiring of MAINS PART*

**a) General requirements for MAINS TERMINAL DEVICES*

EQUIPMENT intended to be permanently connected to fixed wiring and EQUIPMENT intended to be connected by means of rewirable non-detachable POWER SUPPLY CORDS shall be provided with MAINS TERMINAL DEVICES in which connection shall be made by means of screws, nuts or equally effective methods.

Reliance shall not be placed upon the terminals alone to maintain the conductors in position, unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES between LIVE parts and other conductive parts cannot be reduced to less than the values specified in Sub-clause 57.10, should the conductor break away.

Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of this sub-clause and are properly marked according to Sub-clauses 6.2*h), j)* and *k).*

Screws and nuts which clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.

Compliance is checked by inspection.

b) Arrangement of MAINS TERMINAL DEVICES

— For EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or flexible supply cords, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.

— For details of PROTECTIVE EARTH CONDUCTOR connections see Clause 58.

— For marking of MAINS TERMINAL DEVICES see Sub-clause 6.2.

— MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL, even if their LIVE parts are not accessible.

Compliance is checked by inspection.

— MAINS TERMINAL DEVICES shall be so located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact between LIVE parts and ACCESSIBLE PARTS and, for CLASS II EQUIPMENT, between LIVE parts and conductive parts separated from ACCESSIBLE PARTS by SUPPLEMENTARY INSULATION only.

Compliance is checked by inspection and, in case of doubt, by the following test:

The end of a flexible conductor having the NOMINAL cross-sectional area specified in Sub-clause 57.3c) (Table XV) is stripped of its insulation for a length of 8 mm.

A single wire of the stranded conductor is left free and the rest of the conductor is secured to the terminal.

The free wire is bent in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.

The free wire of a conductor connected to a LIVE terminal shall not come into contact with any ACCESSIBLE PARTS or parts connected to ACCESSIBLE PARTS, or, for CLASS II EQUIPMENT, parts which are separated from ACCESSIBLE PARTS by SUPPLEMENTARY INSULATION only.

The free wire of a conductor connected to a PROTECTIVE EARTH TERMINAL shall not come into contact with any LIVE part (see Sub-clause 57.5a)).

c) Fixing of mains terminals

Terminals of EQUIPMENT shall be so fixed that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and CREEPAGE DISTANCES and AIR CLEARANCES are not reduced below the values specified in Sub-clause 57.10.

Compliance is checked by inspection and by measurement after fastening and loosening a conductor of the largest cross-sectional area specified 10 times.

**d) Connections to mains terminals*

— For EQUIPMENT with rewirable flexible cords to be connected by clamping means the cord terminals shall not require special preparation of the conductor in order to effect correct connection, and they shall be so designed or placed that the conductor is not damaged and cannot slip out when the clamping screws or nuts are tightened.

— For further requirements limiting conductor preparation in POWER SUPPLY CORDS and DETACHABLE POWER SUPPLY CORDS see Sub-clause 57.3*d)*.

Compliance is checked by inspection of the terminals and of the conductors after the test of Sub-clause 57.5c).

e) Fixing of wiring

Not used. See Sub-clause 56.1*f)*.

57.6 *Mains fuses and OVER-CURRENT RELEASES*

Fuses or OVER-CURRENT RELEASES shall be provided in each supply lead for CLASS I EQUIPMENT and for CLASS II EQUIPMENT having a functional earth according to Sub-clause 18*l)* and in at least one supply lead for other single-phase CLASS II EQUIPMENT.

The current rating of mains fuses and OVER-CURRENT RELEASES shall be such that they reliably carry the normal operating current and shall not be greater than the current rating of any component in the mains circuit carrying the mains supply current.

— A PROTECTIVE EARTH CONDUCTOR shall not be fused.

— For PERMANENTLY INSTALLED EQUIPMENT the neutral conductor shall not be fused.

Compliance is checked by inspection.

*57.7 *Location of interference suppressors in the MAINS PART*

Not used.

57.8 *Wiring of the MAINS PART*

a) Insulation

If the insulation of an individual conductor in the MAINS PART is not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC Publications 227 or 245, that conductor shall be considered to be a bare conductor.

Compliance is established by checking the insulation of conductors in the MAINS PART.

b) Cross-section

— Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in Sub-clause 57.3*c)*.

Compliance is checked by inspection.

— The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits shall be sufficient to prevent any fire hazard in case of possible fault currents.

If any doubt exists concerning the adequacy of incorporated overcurrent protection, compliance is checked by connecting the EQUIPMENT to a specified SUPPLY MAINS from which the most unfavourable short-circuit current expected can be drawn in the event of a fault in the MAINS PART.

Subsequently, a fault in a single insulation in the MAINS PART is simulated so that the fault current is the least favourable. No SAFETY HAZARD shall arise.

*57.9 *Mains supply transformers*

Mains supply transformers shall comply with the following requirements:

57.9.1 *Overheating*

— Mains supply transformers used in MEDICAL ELECTRICAL EQUIPMENT shall be protected against overheating of BASIC INSULATION, SUPPLEMENTARY INSULATION and REINFORCED INSULATION in the event of short-circuit or overload on any output winding.

Compliance is checked by the tests described in Sub-clauses 57.9.1a) and 57.9.1b).

— Where protective devices external to the transformer or transformer ENCLOSURE provide the protection against overheating e.g. fuses, OVERCURRENT RELEASES, THERMAL CUT-OUTS, these devices shall be connected in such a way that failure of any component other than wiring interposed between the protective devices and the transformer cannot render the protective devices inoperative.

Compliance is checked by inspection.

TABLE XIX

Maximum allowable temperatures at 25 °C ambient temperature of mains supply transformer windings under overload and short-circuit conditions

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
— of Class A material	150
— of Class B material	175
— of Class E material	165
— of Class F material	190
— of Class H material	210

a) Short-circuit

Compliance is checked by application of the following tests under the conditions specified in Clause 42:

— *Mains supply transformers provided with a protective device for limitation of the winding temperatures are connected to a supply voltage which is maintained between 90% and 110% of the RATED supply voltage or between 90% and 110% of the lowest value of the RATED supply voltage range, whichever is the least favourable. Each secondary winding is short-circuited in turn, all other windings, except the primary winding, being loaded as in NORMAL USE.*

Any protective device for a secondary winding shall be operative.

The protective device shall operate before the maximum temperatures of Table XIX are exceeded.

Where a primary protective device does not operate, the maximum temperatures of Table XIX shall not be exceeded in steady thermal condition.

b) Overload

Mains supply transformers including their protective devices, if any, are tested in conditions of normal operation:

- under the conditions specified in Clause 42 until steady thermal conditions are obtained;
- the supply voltage being maintained at 90% or 110% of RATED supply voltage or at 110% of the highest value of the RATED supply voltage range, whichever is the least favourable;
- the tests are made on each winding or section in turn, the other windings or sections being loaded as in the relevant EQUIPMENT in NORMAL USE;
- the section or winding of the transformer under overload is loaded as follows:

  - Mains supply transformers having fuses in accordance with IEC Publications 127 and 241 as protective devices, are loaded for 30 min and 1 h respectively, so that the test current in the fused circuit is in accordance with Table XX with the fuses replaced by links of negligible impedance.

  - Mains supply transformers having fuses deviating from IEC Publications 127 and 241 as protective devices, are loaded for 30 min so that the test current in the fused circuit is as high as possible according to the characteristics supplied by the fuse manufacturer, but does not cause the fuse to operate. The fuses shall be replaced by links of negligible impedance.

TABLE XX

Test current for mains supply transformers

Marked value of RATED current of protecting fuse-link (A)	Ratio between test current and RATED current of the fuse-link
Up to and including 4	2.1
over 4 up to and including 10	1.9
over 10 up to and including 25	1.75
over 25	1.6

- *If the current under short-circuit condition is smaller than the test current specified in Items a) and b), the transformer section or winding is short-circuited until steady thermal condition is attained.*
- *Mains supply transformers having THERMAL CUT-OUTS as protective devices are loaded so that the current through the transformer section or winding is the maximum which does not cause the cut-out to operate, the test being continued until steady thermal condition is attained.*
- *Mains supply transformers having OVERCURRENT RELEASES as protective devices are loaded to 95% of the tripping current of the release until steady thermal condition is attained.*
- *On mains supply transformers not provided with a protective device for limitation of the winding temperature, the output terminals of the secondary winding or of a section of*

such a winding which gives the least favourable results shall be short-circuited. The test shall be continued until steady thermal condition is attained.

For the purpose of these tests, the tripping current is for:

- *an OVERCURRENT RELEASE without time-delay: the lowest current which causes the release to operate;*
- *an OVERCURRENT RELEASE with delay: the current which causes the release, starting from room temperature, to operate with maximum delay or after 1 h, whichever is the shorter period.*

During the tests, the temperature shall not exceed the value given in Table XIX.

57.9.2 *Dielectric strength*

The electrical insulation between the primary winding and other windings, screens and the core of a mains supply transformer is presumed to have been investigated by the dielectric strength tests performed on the assembled EQUIPMENT as described in Clause 20. They shall not be repeated.

The dielectric strength of the electrical insulation between turns and layers of the primary and secondary windings of a mains supply transformer shall be such that after the humidity preconditioning treatment (see Sub-clause 4.10) it passes the following tests:

— *Transformers not having any winding with a RATED voltage exceeding 500 V are tested with a voltage across the winding of five times the RATED voltage or five times the upper limit of the RATED voltage range of that winding and a frequency not less than five times the RATED frequency.*

— *Transformers having any winding with a RATED voltage exceeding 500 V are tested with a voltage across that winding of twice the RATED voltage or twice the upper limit of the RATED voltage range of that winding and a frequency not less than twice the RATED frequency.*

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer shall be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the voltage specified in Sub-clause 20.3, Table V, BASIC INSULATION, if the RATED voltage of such a winding is considered as reference voltage U. If this should occur, the test voltage on the primary winding shall be reduced accordingly. The test frequency may be adapted to produce in the core approximately the magnetic induction present in NORMAL USE.

— *Three-phase transformers may be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.*

— *The value of the test voltage with respect to the core and to any screen between primary and secondary windings shall be in accordance with the specification of the relevant transformer. If the primary winding has an identified connection point for the neutral of the SUPPLY MAINS such a point shall be connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit. To simulate this the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to the identified connection point.*

If such a connection point has not been identified, each side of the primary winding in turn shall be connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit.

To simulate this, the core (and screen) shall be connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

— *During the test, all windings not intended for connection to the SUPPLY MAINS shall be left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with a*

point nearly at earth potential shall have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit.

To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings.

- *Initially not more than half the prescribed voltage shall be applied, then it shall be raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage shall be reduced rapidly and switched off.*
- *Tests are not conducted at resonant frequencies.*
- *During the test, no flashover or breakdown of any part of the insulation shall occur. There shall be no detectable deterioration of the transformer after the test.*

Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, that this value is higher than the reference voltage (U) and that the discharges do not provoke a drop in test voltage.

57.9.3 *Housing*

Not used.

57.9.4 *Construction*

a) The separation of primary and secondary windings having a CONDUCTIVE CONNECTION to APPLIED PARTS or to ACCESSIBLE METAL PARTS not PROTECTIVELY EARTHED shall be achieved by one of the following methods:

- wound on separate bobbins or formers;
- wound on one bobbin or former with an imperforate insulating partition between windings;
- wound on one bobbin or former with concentric windings and having an imperforate protective copper screen with a thickness of not less than 0.13 mm;
- concentrically wound on one bobbin with windings separated by DOUBLE or REINFORCED INSULATION.

Compliance is checked by inspection.

b) Not used.

c) Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.

d) If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.

e) In transformers with REINFORCED INSULATION or DOUBLE INSULATION the insulation between the primary and secondary winding shall consist of:

- one insulation layer having a thickness of at least 1 mm, or
- at least two insulation layers with a total thickness of not less than 0.3 mm, or
- three layers provided that each combination of two layers can withstand the dielectric strength test for REINFORCED INSULATION.

f) For transformers complying with Sub-clause 57.9.4*a)* the CREEPAGE DISTANCES between the primary and secondary windings shall comply with the requirements for REINFORCED INSULATION (A–e, Table XX, Sub-clause 57.10) with the following allowances:

— enamel or lacquer of winding wires are considered as contributing 1 mm each to these CREEPAGE DISTANCES.

— CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:

· either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

· or the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.

— CREEPAGE DISTANCES within moulded transformers are considered not to exist if it can be shown that no gas bubbles are present and the thickness of the insulation between enamelled or lacquered primary and secondary windings is at least 1 mm for reference voltages U not exceeding 250 V and increased proportionally for higher reference voltages.

g) The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for DOUBLE INSULATION and having a total wall thickness of at least 0.3 mm, extending at least 20 mm outside the winding.

Compliance with the requirements of Sub-clauses 57.9.4c) through 57.9.4g) is checked by inspection.

57.10 *CREEPAGE DISTANCES and AIR CLEARANCES*

**a) Values*

— CREEPAGE DISTANCES and AIR CLEARANCES shall comply with at least the values of Table XVI.

For a number of insulations Sub-clauses 20.1 and 20.2 apply.

— The value of the reference voltage (U) is as given in Sub-clause 20.3. In case the reference voltage has a value between those given in Table XVI, the higher of the two values shall be applied.

Values for reference voltages above 1 000 V a.c. or 1 200 V d.c. are under consideration.

— For slot insulation of motors a reduction to 50% of the values of Table XVI for CREEPAGE DISTANCES shall be allowed, with a minimum of 2 mm at 250 V.

**b) Application*

— For insulation in the MAINS PART between parts of opposite polarity (see Sub-clause 20.1 A-f) the minimum CREEPAGE DISTANCES and AIR CLEARANCES are not required if short-circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not produce a SAFETY HAZARD.

Operation of a protective device shall not be considered as a SAFETY HAZARD.

— The contribution to the CREEPAGE DISTANCES of any groove or air gap less than 1 mm wide shall be limited to its width (see Figures 39 through 47).

The AIR CLEARANCES required between LIVE parts shall not apply to the air gap between the switching contacts of THERMOSTATS, THERMAL CUT-OUTS, OVER-CURRENT RELEASES, switches of microgap construction and the like, or to the air gap

between the current-carrying parts of such devices where the clearance varies with the movement of the contacts and where adequacy of ratings has been proved.

— When assessing CREEPAGE DISTANCES and AIR CLEARANCES, the effect of insulating linings of metal ENCLOSURES or covers shall be taken into consideration.

If the insulation on a conductor is not at least electrically equivalent to that of the individual conductors of flexible cords, that conductor shall be considered to be a bare conductor and the insulation thickness shall be regarded as an AIR CLEARANCE. See also Sub-clause 57.8*a)*.

— AIR CLEARANCE alone is only acceptable for isolation between LIVE parts and APPLIED PARTS and ACCESSIBLE PARTS not PROTECTIVELY EARTHED if the relative positioning is such that the relevant parts are rigid and located by mouldings or the design is otherwise such that there is no likelihood of a distance being reduced by deformation or movement of the parts.

Where limited movement of one of the relevant parts is normal or likely, this shall be taken into account when computing the minimum clearance.

**c)* Not used.

**d) Measurement of CREEPAGE DISTANCES and AIR CLEARANCES*

Compliance is checked by measurement taking into account the rules in Figures 39 through 47.

For EQUIPMENT provided with an APPLIANCE INLET, the measurements are made with an appropriate connector inserted. For other EQUIPMENT incorporating POWER SUPPLY CORDS, they are made with supply conductors of the largest cross-sectional area specified and also without conductors.

Movable parts are placed in the least favourable position; nuts and screws with non-circular heads are tightened in the least favourable position.

AIR CLEARANCES and CREEPAGE DISTANCES between terminals and ACCESSIBLE PARTS are also measured with the screws or nuts unscrewed as far as possible, and the AIR CLEARANCES shall then be not less than 50% of the values shown in Table XVI.

CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts of insulating material are measured to metal foil in contact with the accessible surface. For the purpose of this sub-clause accessible surfaces of insulating material are treated as though they were covered with a layer of metal foil, foil being stretched across any openings, but pressed into corners with the standard test finger of Figure 7.

If necessary, a force is applied to any point on bare conductors and to the outside of metal ENCLOSURES in an endeavour to reduce the CREEPAGE DISTANCES and AIR CLEARANCES while taking the measurements.

The force is applied by means of a standard test finger having a tip as shown in Figure 7 and having a value of:

2 N for bare conductors;
30 N for ENCLOSURES.

TABLE XVI

CREEPAGE DISTANCES and AIR CLEARANCES in millimetres[1)]

	d.c. voltage	15	34	75	150	300	450	600	800	900	1200	
	a.c. voltage	12	30	60	125	250	380	500	660	750	1000	
BASIC INSULATION between parts of opposite polarity	A-f	0.4	0.5	0.7	1	1.6	2.4	3	4	4.5	6	AIR CLEARANCES
		0.8	1	1.3	2	3	4	5.5	7	8	11	CREEPAGE DISTANCES
BASIC INSULATION OR SUPPLEMENTARY INSULATION	A-a1, A-b A-c, A-j	0.8	1	1.2	1.6	2.5	3.5	4.5	6	6.5	9	AIR CLEARANCES
	B-d, B-c	1.7	2	2.3	3	4	6	8	10.5	12	16	CREEPAGE DISTANCES
DOUBLE INSULATION OR REINFORCED INSULATION	A-a2 A-e, A-k	1.6	2	2.4	3.2	5	7	9	12	13	18	AIR CLEARANCES
	B-a, B-e	3.4	4	4.6	6	8	12	16	21	24	32	CREEPAGE DISTANCES

[1)] This table replaces Tables XVI and XVII of the first edition.

58. Protective earthing — Terminals and connections

58.1 The clamping means of the PROTECTIVE EARTH TERMINAL for fixed supply conductors or POWER SUPPLY CORDS shall comply with the requirements of Sub-clause 57.5*c)*. It shall not be possible to loosen it without the aid of a TOOL. Screws for internal protective earthing connections shall be completely covered or protected against inadvertent loosening from the outside of EQUIPMENT.

58.2 For internal protective earthing connections, clamping by means of a screw, soldering, crimping, wrapping, welding or a reliable pressure contact are allowed.

58.3 Not used. See Sub-clause 57.5*b)*.

58.4 Not used.

58.5 Not used.

58.6 Not used.

58.7 Where an APPLIANCE INLET forms the supply connection to EQUIPMENT, the earth pin of the APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.

58.8 The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.

58.9 *Protective earth connection*

Where the connection between mains supply conductors and EQUIPMENT or between separated parts of EQUIPMENT which can be operated by the OPERATOR is made via a plug and

socket device, the protective earth connection shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are connected to protective earth. See also Sub-clauses 57.1, 57.2 and 57.3.

Compliance with the requirements of Clause 58 is checked by inspection of materials and construction, by manual tests and by the test of Sub-clause 57.5.

59. Construction and layout

59.1 *Internal wiring*

For fixing of wiring in the APPLIED PART and the MAINS PART, see Sub-clause 56.1*f*).

a) Mechanical protection

— Cables and wiring shall be adequately protected against contact with a moving part or from friction at edges or sharp corners, if there is a relative movement between the part and cords or wiring.

— Wiring having BASIC INSULATION only shall be protected by additional fixed sleeving or by other similar means where it is in direct contact with metal parts and where such wiring is subject to a relative movement in NORMAL USE during which it is in direct contact with metal parts.

— EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged in the normal process of assembly or replacement of covers or the opening or closing of inspection doors.

Compliance is checked by inspection and, where appropriate, by manual test.

b) Bending

Guiding rollers of leads shall be constructed in such a manner that movable leads in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned.

Compliance is checked by inspection and measurement of the relevant dimensions.

c) Insulation

— If insulating sleeving is needed on internal wiring, it shall be adequately secured. Sleeving is regarded as adequately secured if it can only be removed by breaking or cutting or if it is secured at both ends.

— Inside EQUIPMENT the sheath of a flexible cord shall be used as SUPPLEMENTARY INSULATION only where it is not subject to undue mechanical or thermal stresses and if its insulation properties are not less than those specified in IEC Publications 227 or 245.

— Insulated conductors which in NORMAL USE are subject to temperatures exceeding 75 °C shall have an insulation of heat-resistant material if compliance with this Standard is likely to be impaired by deterioration of the insulation.

Compliance is checked by inspection and, if necessary, by special tests. Temperatures shall be determined as indicated in Clause 42.

d) Materials

Aluminium wires of less than 16 mm^2 cross-section shall not be used.

Compliance is checked by inspection.

*e) *Separation of circuits*

Not used. See Clause 17.

f) *Applicable requirements*

Connecting cords between EQUIPMENT parts, e.g. parts of an X-ray installation or a PATIENT monitoring installation or a data-processing installation or combinations thereof shall be considered as belonging to the EQUIPMENT and not be subject to requirements for wiring of electrical installations (in hospitals or otherwise).

Compliance is checked by application of the relevant tests of this Standard.

59.2 *Insulation*

This sub-clause refers to parts of EQUIPMENT other than wire insulation which is covered in Sub-clause 59.1 *c).*

a) *Fixing*

Not used.

*b) *Mechanical strength and resistance to heat and fire*

The insulating characteristics, mechanical strength and resistance to heat and fire shall be retained by all types of insulation, including insulating partition walls, even in the case of extended use.

Compliance is established by inspection and, if necessary, in conjunction with the following tests:

— *resistance to moisture, etc. (see Clause 44);*

— *dielectric strength (see Clause 20);*

— *mechanical strength (see Clause 21).*

Resistance to heat is established by the following tests which need not be performed if satisfactory evidence of compliance is provided:

1) *For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could influence the safety of the EQUIPMENT, by the ball-pressure test:*

ENCLOSURES and other external parts of insulating material, except the insulation of flexible cords, are subjected to a ball-pressure test using the test apparatus shown in Figure 48. The surface of the part to be tested is placed in the horizontal position and a steel ball of 5 mm diameter is pressed against the surface with a force of 20 N. The test is made in a heating cabinet at a temperature of 75 °C ± 2 °C or at a temperature of 40 °C ± 2 °C plus the temperature rise of the relevant part of insulating material measured during the test of Clause 42, whichever is the higher.

The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. It shall be not greater than 2 mm. The test is not made on parts of ceramic material.

2) *For parts of insulating material which support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the EQUIPMENT, by the ball-pressure test:*

A test is made as described in Item 1), but at a temperature of 125 °C ± 2 °C or at a temperature of 40 °C ± 2 °C plus the temperature rise which was determined during the test of Clause 42 of the relevant part, whichever is the higher.

The test is not made on parts of ceramic material, insulating parts of commutators, brush-caps and the like, on coil formers not used as REINFORCED INSULATION and the insulation of cords.

Note. — For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also Sub-clause 52.4.1.

c) Protection

BASIC INSULATION, SUPPLEMENTARY INSULATION and REINFORCED INSULATION shall be so designed or protected that they are not likely to be impaired by deposition of dirt or by dust resulting from wear of parts within the EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in Sub-clause 57.10.

Ceramic material not tightly sintered, and the like, and beads alone shall not be used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION.

Parts of natural or synthetic rubber used as SUPPLEMENTARY INSULATION in CLASS II EQUIPMENT shall be resistant to ageing and be so arranged and dimensioned that CREEPAGE DISTANCES are not reduced below the values specified in Sub-clause 57.10 whatever cracks may occur.

Insulating material in which heating conductors are embedded shall be considered as BASIC INSULATION and shall not be used as REINFORCED INSULATION.

Compliance is checked by inspection, by measurement and for rubber by the following test:

Parts of rubber are aged in an atmosphere of oxygen under pressure. The samples are suspended freely in an oxygen cylinder, the effective capacity of the cylinder is at least ten times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97% pure, to a pressure of 210 ± 7 N/cm².

The samples are kept in the cylinder at a temperature of 70 °C ± 2 °C for 96 h. Immediately afterwards, they are taken out of the cylinder and left at room temperature for at least 16 h. After the test, the samples are examined and shall show no crack visible to the naked eye.

59.3 *Excessive current and voltage protection*

— See Sub-clause 57.6.

— An INTERNAL ELECTRICAL POWER SOURCE in EQUIPMENT shall be provided with an appropriately RATED device for protection against fire hazard caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components may give rise to the occurrence of a fire hazard in case of a short circuit.

Test under consideration.

— Fuse elements replaceable without opening the ENCLOSURE of the EQUIPMENT shall be fully enclosed in a fuseholder. When fuse replacement can be carried out without the use of a TOOL, uninsulated LIVE parts associated with the fuseholder shall be shielded to enable fuse replacement without a SAFETY HAZARD.

Compliance is checked by inspection and by the use of the standard test finger.

— Protective devices connected between an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.

Compliance is checked by testing the operating voltage of the protective devices.

— For THERMAL CUT-OUTS and OVER-CURRENT RELEASES see Sub-clause 56.6*a)*.

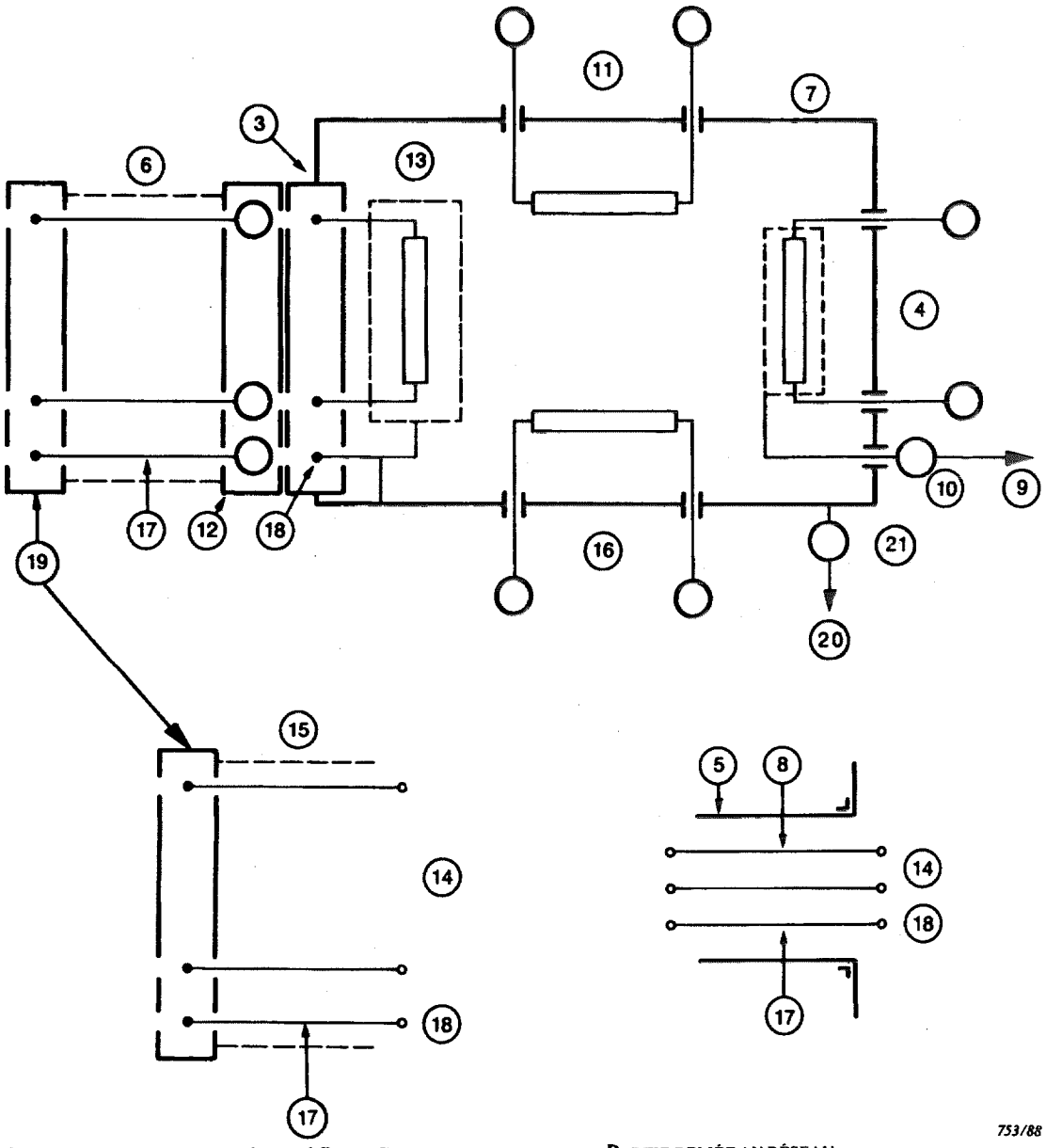
59.4 *Oil containers*

— Oil containers in PORTABLE EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.

Oil containers in MOBILE EQUIPMENT shall be sealed to prevent the loss of oil during transport but may be fitted with a pressure-release device which can operate during NORMAL USE.

— Partially sealed oil-filled EQUIPMENT or EQUIPMENT parts shall be provided with means for checking the oil level.

Compliance is checked by inspection of EQUIPMENT, technical description and by manual test.



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③ SOCLE DE CONNECTEUR (voir aussi figure 5)
APPLIANCE INLET (see also Figure 5)

④ PARTIE APPLIQUÉE
APPLIED PART

⑤ Traversée
Conduit

⑥ CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE
DETACHABLE POWER SUPPLY CORD

⑦ ENVELOPPE
ENCLOSURE

⑧ Câblage fixé à demeure
Fixed wiring

⑨ CONDUCTEUR DE TERRE FONCTIONNELLE
FUNCTIONAL EARTH CONDUCTOR

⑩ BORNE DE TERRE FONCTIONNELLE
FUNCTIONAL EARTH TERMINAL

⑪ ENTRÉE DE SIGNAL
SIGNAL INPUT PART

⑫ PRISE RÉSEAU
MAINS CONNECTOR

⑬ PARTIE RELIÉE AU RÉSEAU
MAINS PART

⑭ DISPOSITIF DE RACCORDEMENT AU RESEAU
MAINS TERMINAL DEVICE

⑮ CÂBLE D'ALIMENTATION
POWER SUPPLY CORD

⑯ SORTIE DE SIGNAL
SIGNAL OUTPUT PART

⑰ CONDUCTEUR DE PROTECTION
PROTECTIVE EARTH CONDUCTOR

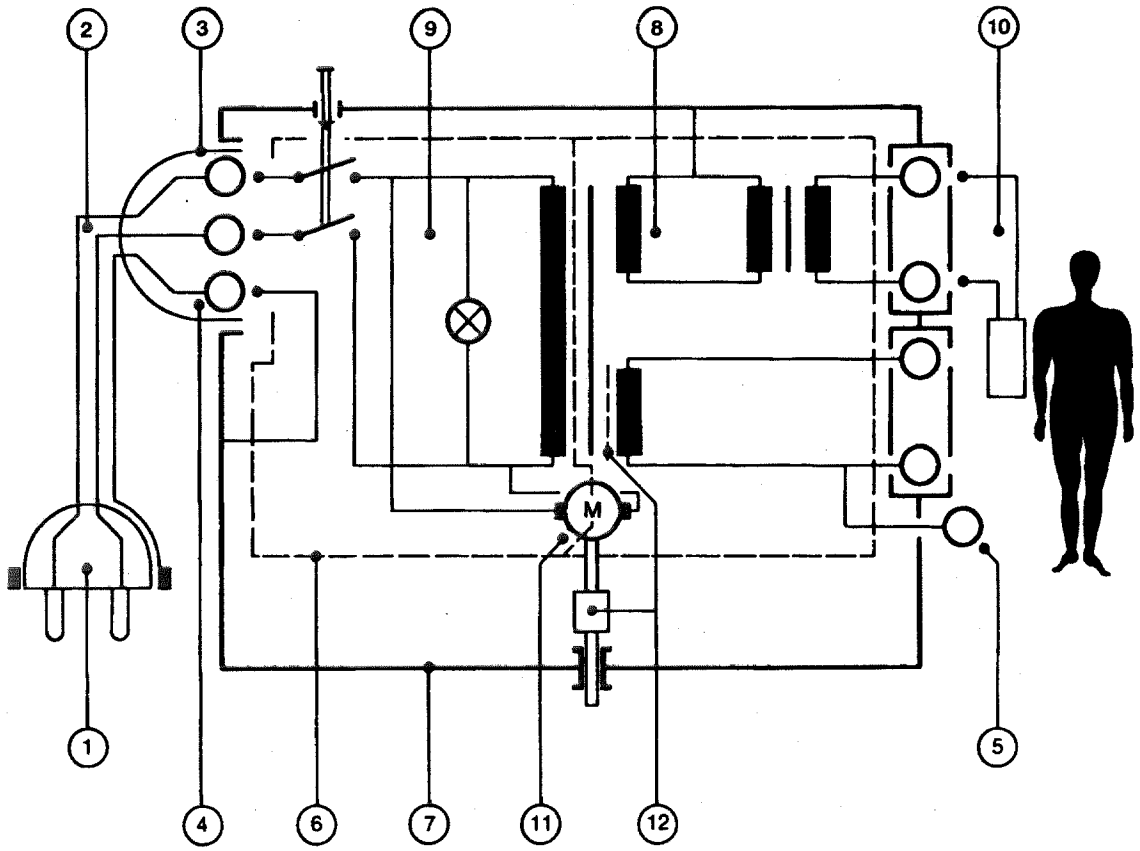
⑱ BORNE DE TERRE DE PROTECTION
PROTECTIVE EARTH TERMINAL

⑲ FICHE RÉSEAU
MAINS PLUG

⑳ CONDUCTEUR D'ÉGALISATION DES POTENTIELS
POTENTIAL EQUALIZATION CONDUCTOR

㉑ Moyen de raccordement d'un CONDUCTEUR D'ÉGALISATION DES POTENTIELS
Means for the connection of a POTENTIAL EQUALIZATION CONNECTOR

FIG. 1. — Exemple des conducteurs et des bornes définis (voir article 2).
Example of the defined terminals and conductors (see Clause 2).



① Fiche avec contact de mise à la terre de protection
Plug with protective earthing contact

② CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE
DETACHABLE POWER SUPPLY CORD

③ CONNECTEUR
APPLIANCE COUPLER

④ Contact et broche de mise à la terre de protection
Protective earth contact and pin

⑤ BORNE DE TERRE FONCTIONNELLE
FUNCTIONAL EARTH TERMINAL

⑥ ISOLATION PRINCIPALE
BASIC INSULATION

⑦ ENVELOPPE
ENCLOSURE

⑧ Circuit intermédiaire
Intermediate circuit

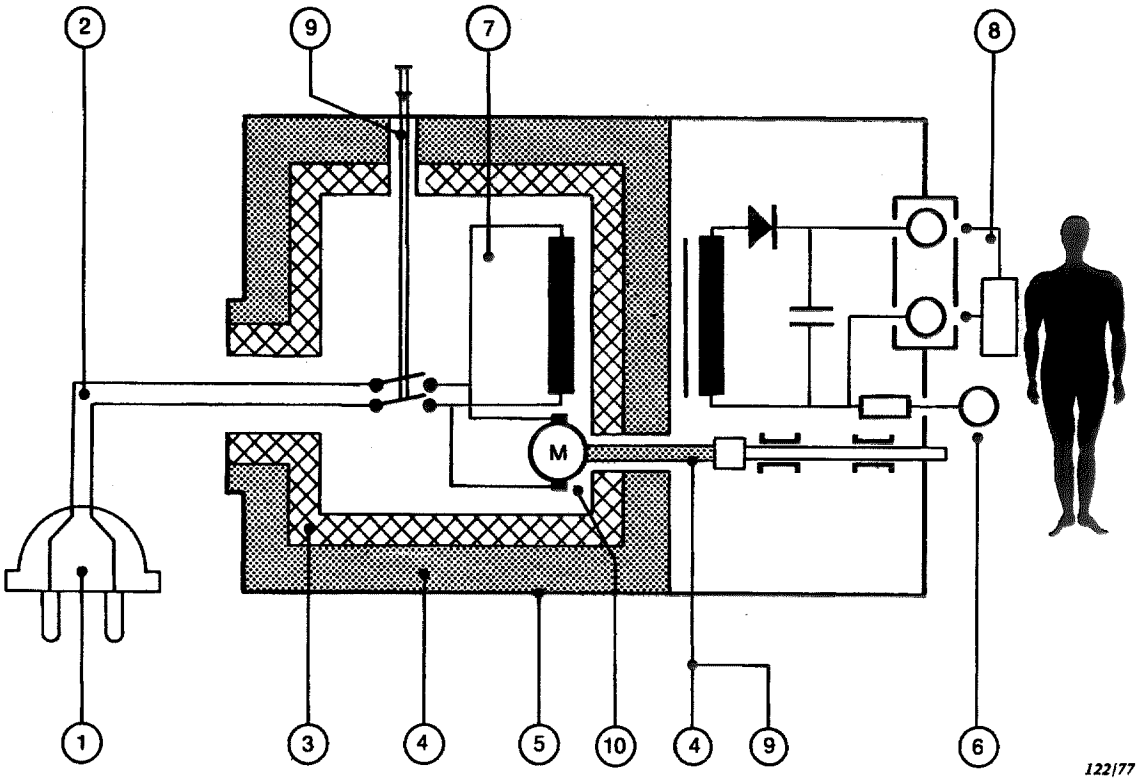
⑨ PARTIE RELIÉE AU RÉSEAU
MAINS PART

⑩ PARTIE APPLIQUÉE
APPLIED PART

⑪ Moteur à arbre accessible
Motor with accessible shaft

⑫ ISOLATION SUPPLÉMENTAIRE ou écran mis à la terre de protection
SUPPLEMENTARY INSULATION or protectively earthed screen

FIG. 2. — Exemple d'un APPAREIL DE LA CLASSE I (voir paragraphe 2.2.4).
Example of a CLASS I EQUIPMENT (see Sub-clause 2.2.4).



① FICHE RÉSEAU
MAINS PLUG

② CÂBLE D'ALIMENTATION
POWER SUPPLY CORD

③ ISOLATION PRINCIPALE
BASIC INSULATION

④ ISOLATION SUPPLÉMENTAIRE
SUPPLEMENTARY INSULATION

⑤ ENVELOPPE
ENCLOSURE

⑥ BORNE DE TERRE FONCTIONNELLE
FUNCTIONAL EARTH TERMINAL

⑦ PARTIE RELIÉE AU RÉSEAU
MAINS PART

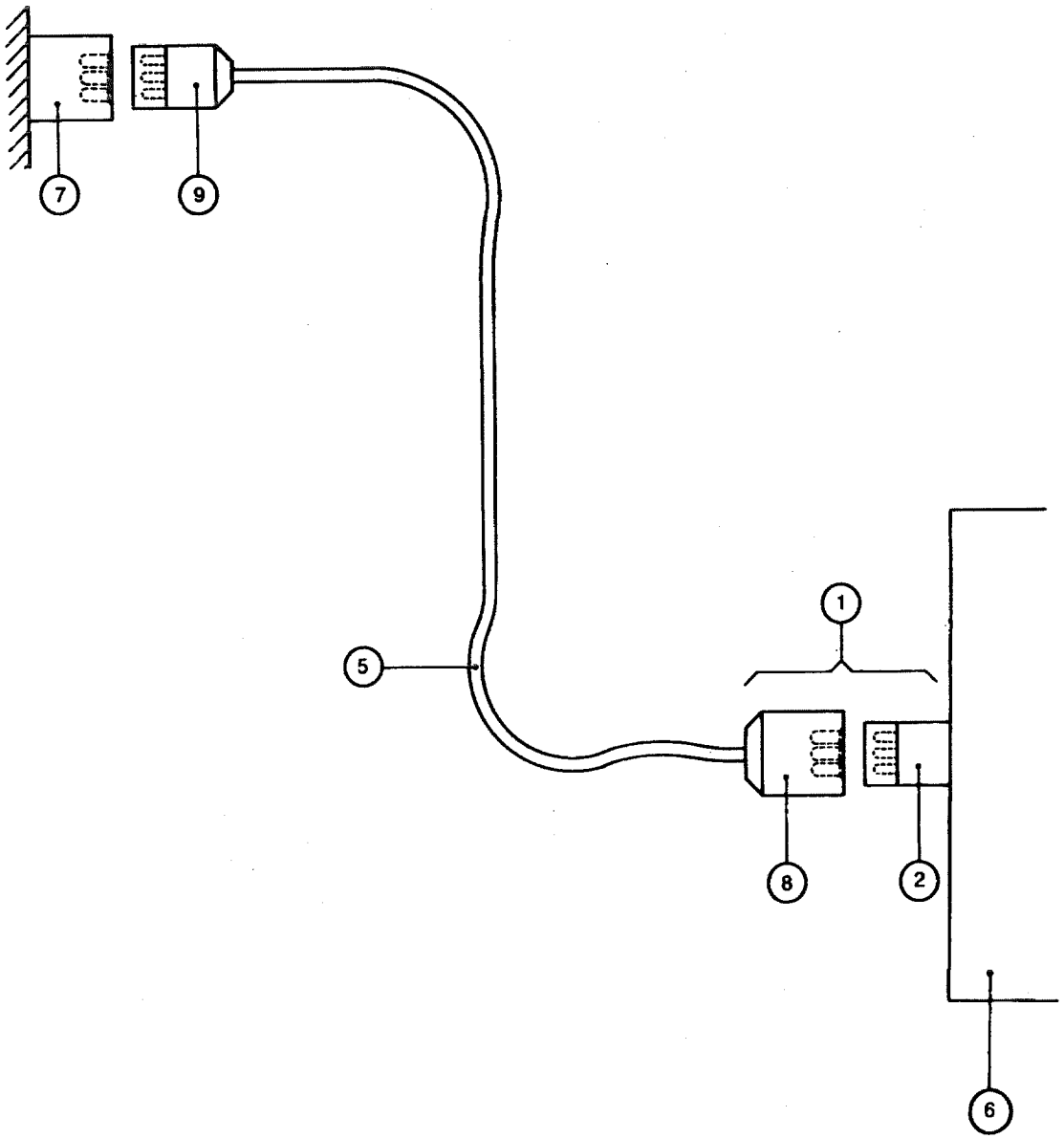
⑧ PARTIE APPLIQUÉE
APPLIED PART

⑨ ISOLATION RENFORCÉE
REINFORCED INSULATION

⑩ Moteur à arbre accessible
Motor with accessible shaft

FIG. 3. — Exemple d'un APPAREIL DE LA CLASSE II à enveloppe métallique (voir paragraphe 2.2.5).
Example of a metal-enclosed CLASS II EQUIPMENT (see Sub-clause 2.2.5).

FIG. 4. — Non utilisé.
Not used.



① CONNECTEUR
APPLIANCE COUPLER

② SOCLE DE CONNECTEUR
APPLIANCE INLET

⑤ CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE
DETACHABLE POWER SUPPLY CORD

⑥ APPAREIL
EQUIPMENT

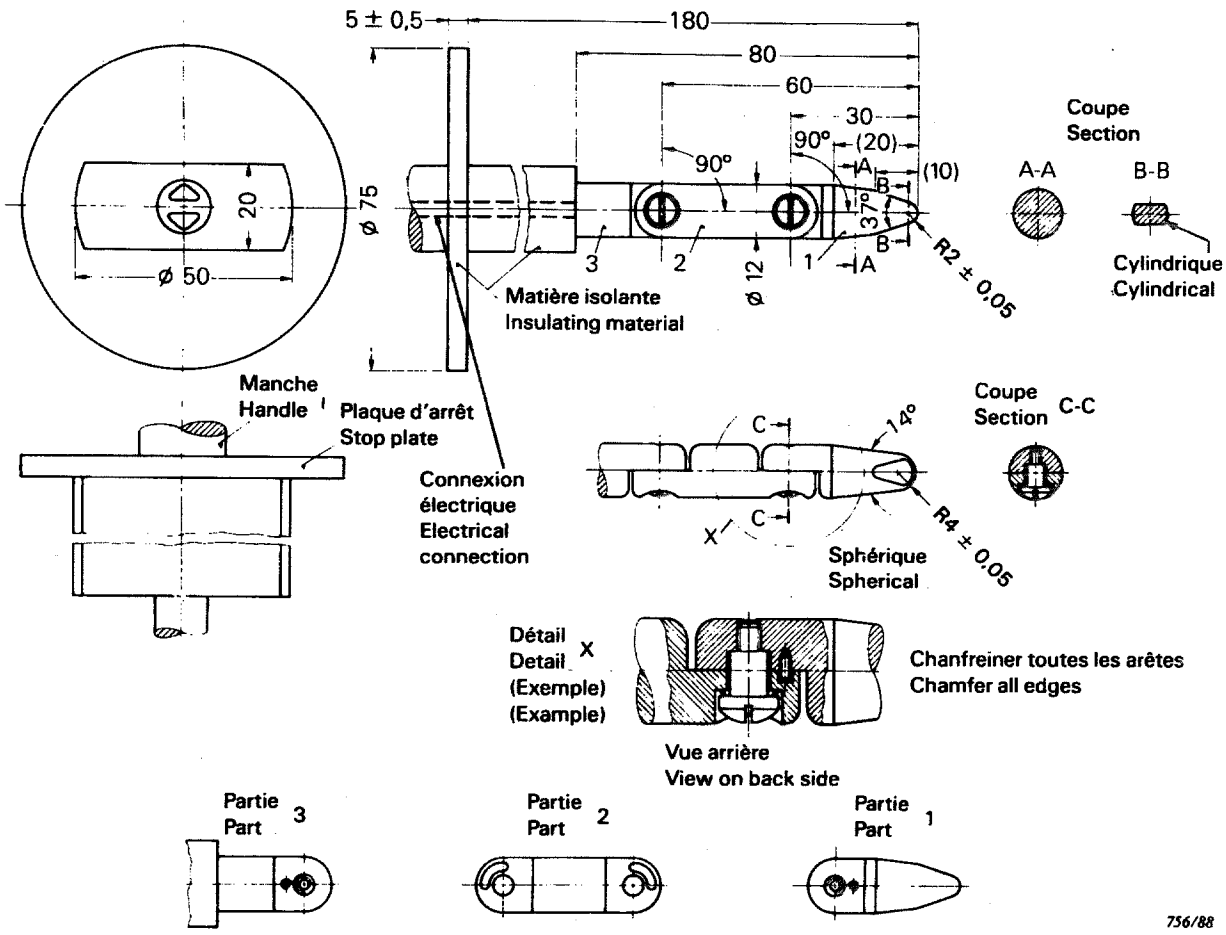
⑦ SOCLE FIXE DE PRISE DE COURANT RÉSEAU
FIXED MAINS SOCKET-OUTLET

⑧ PRISE RÉSEAU
MAINS CONNECTOR

⑨ FICHE RÉSEAU
MAINS PLUG

FIG. 5. — Raccordement au réseau non fixé à demeure (voir article 2).
Detachable mains connection (see Clause 2).

FIG. 6. — Non utilisé.
Not used.



Dimensions linéaires en millimètres

Tolérances des dimensions sans indication de tolérance:

Sur les angles: $^{+\ 0}_{-10°}$

Sur les dimensions: Jusqu'à 25 mm: $^{+0}_{-0,05}$

Au-dessus de 25 mm: ± 0,2

Matériau des parties 1, 2 et 3: métal (par exemple, acier traité à chaud)

Les deux articulations du doigt peuvent être pliées sous un angle $90^{+10°}_{0}$ mais dans une seule et même direction.

L'emploi de la solution pointe-rainure n'est qu'une des solutions possibles pour limiter l'angle de pliage à 90°. Pour cette raison, les dimensions et tolérances de ces détails ne sont pas indiquées sur le dessin. La conception réelle doit assurer un angle de pliage de 90°, avec une tolérance de 0 à +10°.

Linear dimensions in millimetres

Tolerances on dimensions without specific tolerance:

on angles: $^{+\ 0}_{-10°}$

on linear dimensions: up to 25 mm: $^{+0}_{-0.05}$

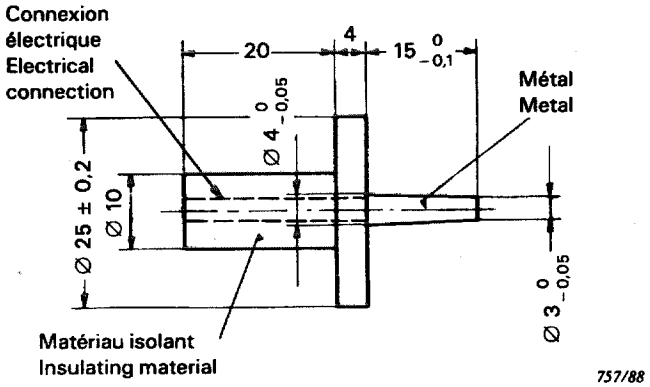
over 25 mm: ± 0.2

Material of parts 1, 2 and 3 metal (e.g. heat-treated steel)

Both joints of this finger may be bent through an angle of $90^{+10°}_{0}$ but in one and the same direction only.

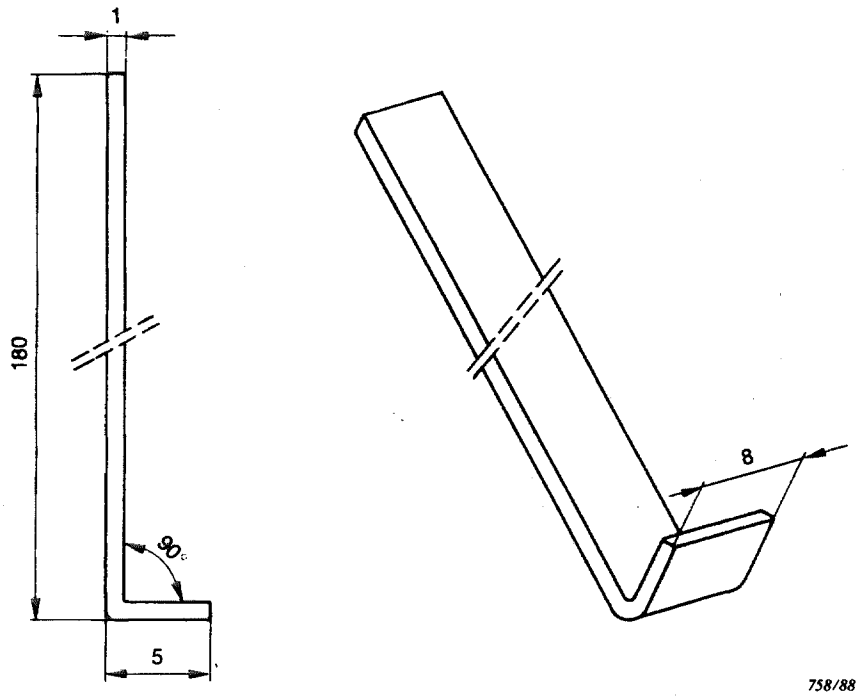
Using the pin and groove solutions is only one of the possible approaches in order to limit the bending angle to 90°. For this reason dimensions and tolerances of these details are not given in the drawing. The actual design must ensure a 90° bending angle with a 0 to +10° tolerance.

FIG. 7. — Doigt d'épreuve normalisé (voir article 16).
Standard test finger (see Clause 16).



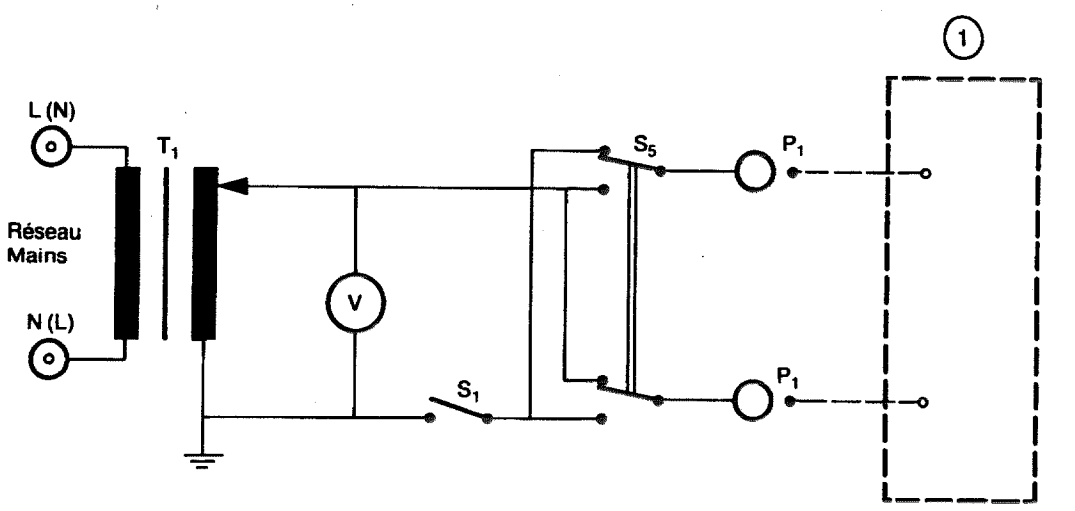
Dimensions en millimètres
Dimensions in millimetres

FIG. 8. — Broche d'essai (voir article 16).
Test pin (see Clause 16).



Dimensions en millimètres, matériau: acier
Dimensions in millimetres, material: steel

FIG. 9. — Crochet d'essai (voir article 16).
Test hook (see Clause 16).



Voir légendes page 243 See legends page 243

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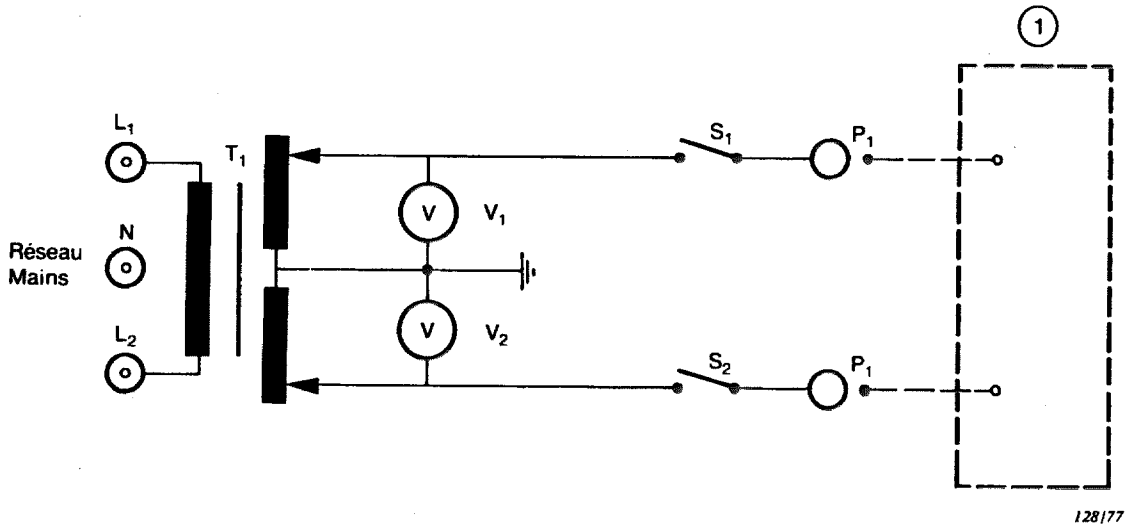
FIG. 10. — Circuit d'alimentation de mesure ayant un côté du RÉSEAU D'ALIMENTATION approximativement au potentiel de la terre (voir paragraphe 19.4*b*)).
Measuring supply circuit with one side of the SUPPLY MAINS at (approximately) earth voltage (see Sub-clause 19.4*b*)).



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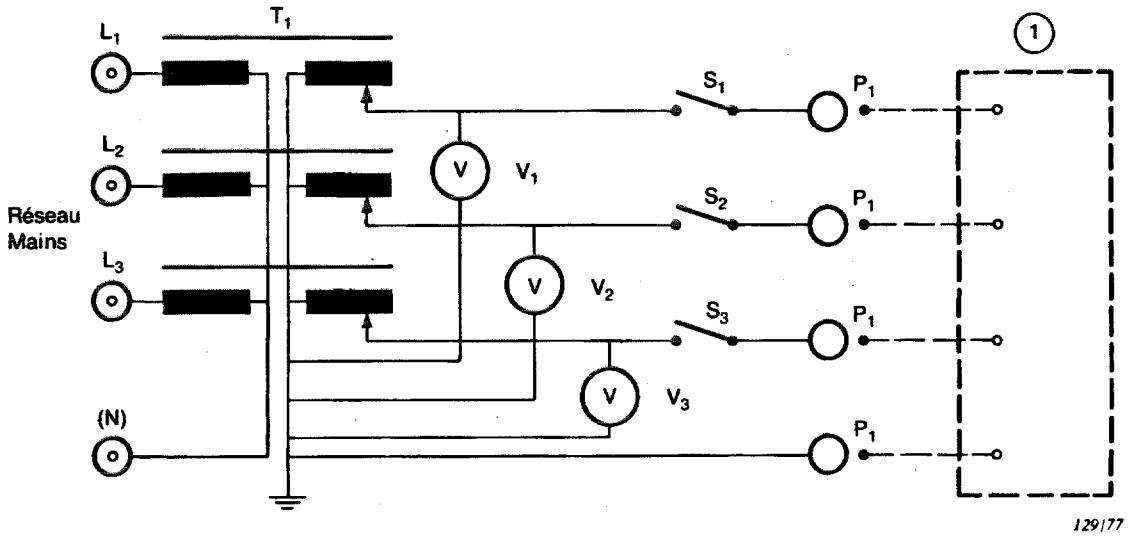
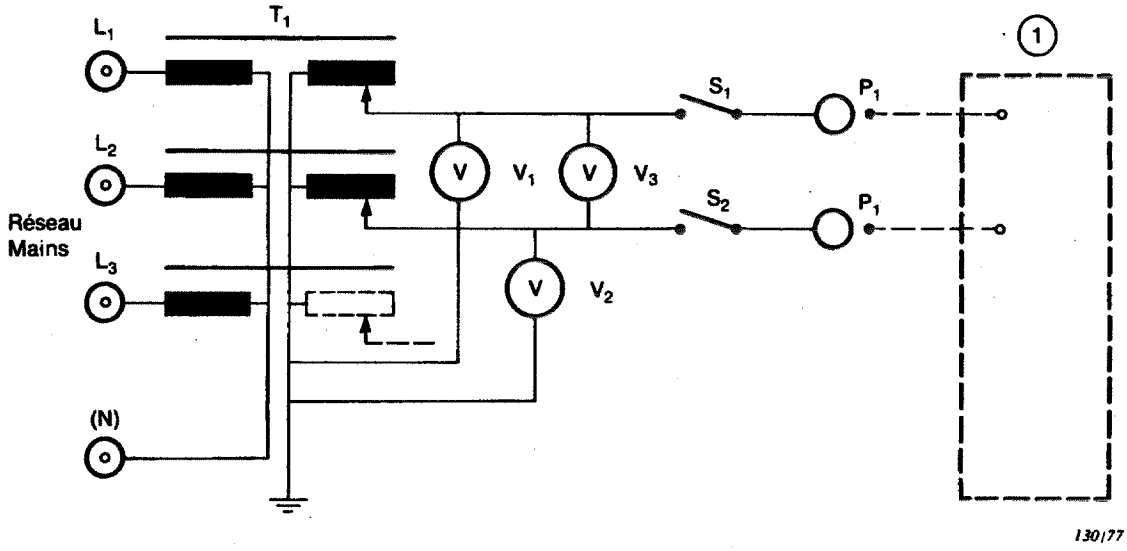
Voir légendes page 243 See legends page 243

FIG. 11. — Circuit d'alimentation de mesure avec le RÉSEAU D'ALIMENTATION approximativement symétrique par rapport à la terre (voir paragraphe 19.4*b*)).
Measuring supply circuit with the SUPPLY MAINS approximately symmetrical to earth (see Sub-clause 19.4*b*)).



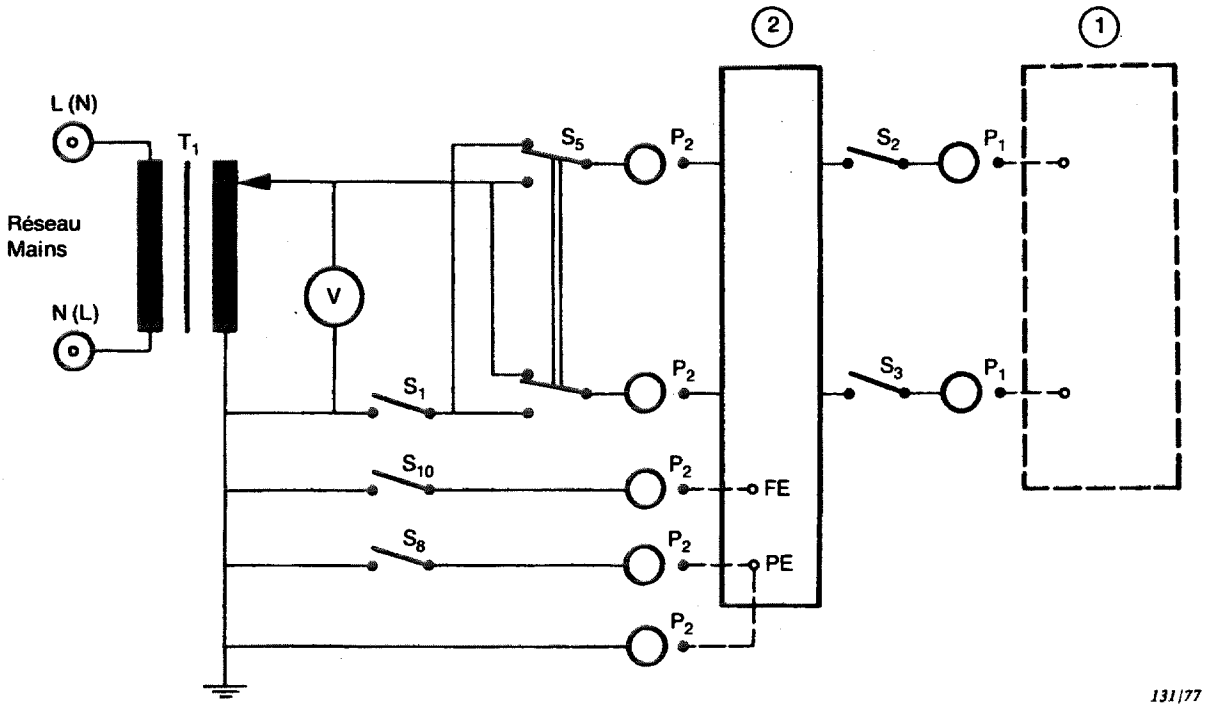
Voir légendes page 243 See legends page 243

FIG. 12. — Circuit d'alimentation de mesure pour un APPAREIL polyphasé spécifié pour être alimenté par un réseau polyphasé (voir paragraphe 19.4*b*)).
Measuring supply circuit for polyphase EQUIPMENT specified for connection to a polyphase SUPPLY MAINS (see Sub-clause 19.4*b*)).



Voir légendes page 243 See legends page 243

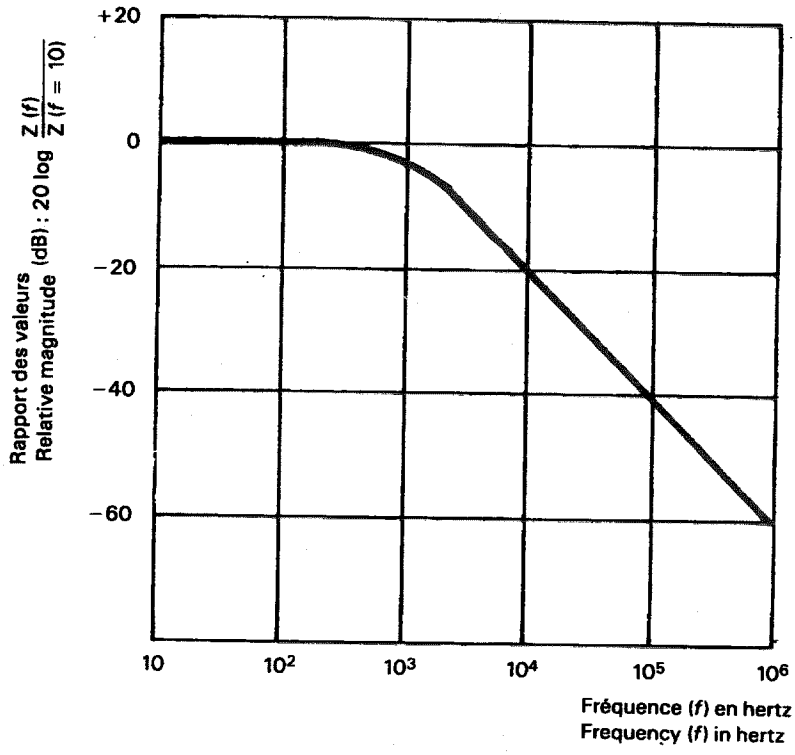
FIG. 13. — Circuit d'alimentation de mesure pour un APPAREIL monophasé, spécifié pour être alimenté par un réseau polyphasé (voir paragraphe 19.4*b*)).
Measuring supply circuit for single-phase EQUIPMENT specified for connection to a polyphase SUPPLY MAINS (see Sub-clause 19.4*b*)).

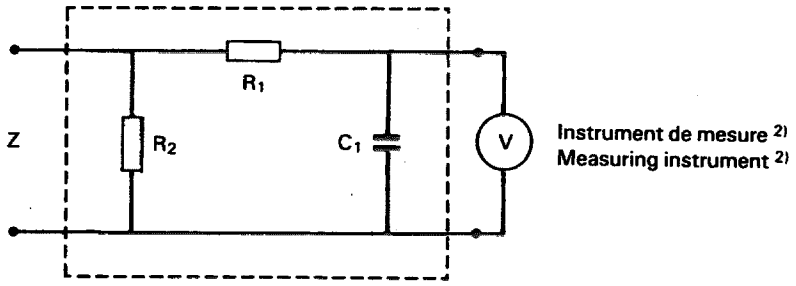


Voir légendes page 243 See legends page 243

FIG. 14. — Circuit d'alimentation de mesure pour: soit un APPAREIL alimenté par une source monophasée spécifiée de la CLASSE I, soit un APPAREIL alimenté par une source monophasée spécifiée de la CLASSE II n'utilisant pas dans ce cas la liaison de terre de protection et S_8 (voir paragraphe 19.4*b*)).

Measuring supply circuit for either EQUIPMENT supplied from a specified class I single-phase power supply or for EQUIPMENT supplied from a specified class II single-phase power supply, not using in this case the protective earth connection and S_8 (see Sub-clause 19.4*b*)).





$R_1 = 10\,k\Omega \pm 5\%$ [1]
$R_2 = 1\,k\Omega \pm 1\%$ [1]
$C_1 = 0.015\,\mu F \pm 5\%$ [1]

[1] Composants non inductifs
Non-inductive components
[2] Impédance ≫ impédance de mesure Z
Impedance ≫ measuring impedance Z

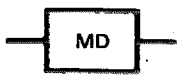


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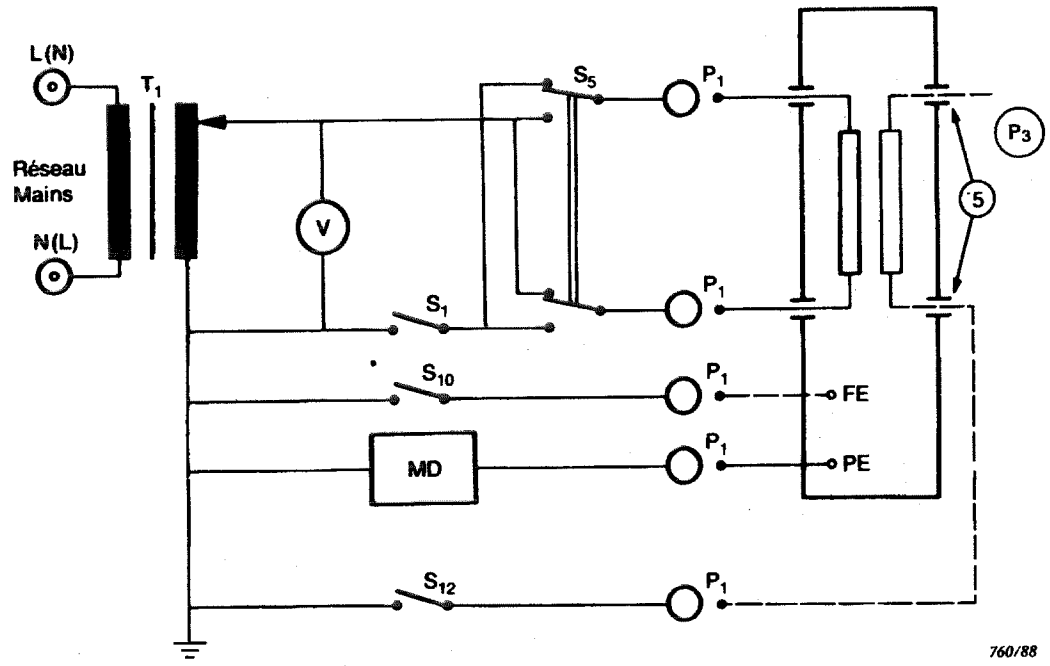
Schéma équivalent au schéma ci-dessus dans les figures ci-après.
Equivalent to the above in subsequent figures.

FIG. 15. — Exemple d'un dispositif de mesure et de sa caractéristique de fréquence (voir paragraphe 19.4*e*)).
Example of a measuring device and its frequency characteristic (see Sub-clause 19.4*e*)).



Voir légendes page 243

See legends page 243

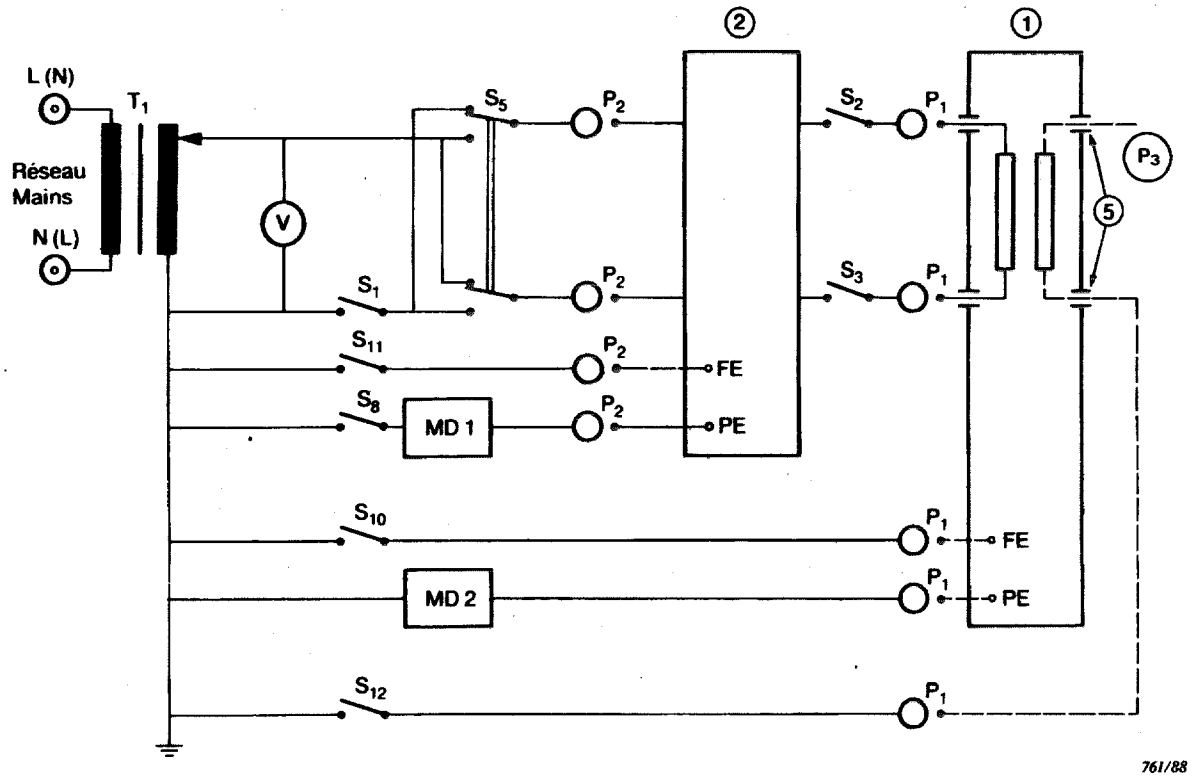
Mesure dans toutes les combinaisons possibles des positions de S_5, S_{10} et de S_{12} avec:

S_1 fermé (CONDITION NORMALE), et
S_1 ouvert (CONDITION DE PREMIER DÉFAUT)
et pour les mesurages selon le paragraphe 19.4*a)*, tableau IV, notes 1 à 4 inclus
S_1 ouvert (CONDITION DE PREMIER DÉFAUT)

Measure in all possible combinations of positions of S_5, S_{10} and S_{12} with:

S_1 closed (NORMAL CONDITION), and
S_1 open (SINGLE FAULT CONDITION)
and for measurement in accordance with Sub-clause 19.4*a)*, Table IV, notes 1 up to and including 4
S_1 open (SINGLE FAULT CONDITION)

FIG. 16. — Circuit de mesure pour le COURANT DE FUITE À LA TERRE d'un APPAREIL DE LA CLASSE I, avec ou sans PARTIE APPLIQUÉE (voir paragraphe 19.4*f)* et notes du tableau IV).
Exemple avec le circuit d'alimentation de mesure de la figure 10.
Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I EQUIPMENT, with or without APPLIED PART (see Sub-clause 19.4*f)* and notes to Table IV).
Example with the measuring supply circuit of Figure 10.



Voir légendes page 243

See legends page 243

Mesure avec MD1 et MD2, avec S_8 fermé et S_1, S_2, S_3 fermés et dans toutes les combinaisons possibles des positions de S_5 et de S_{10}, S_{11} et S_{12} (CONDITION NORMALE).

Mesure avec MD2, avec S_8 ouvert (CONDITION DE PREMIER DÉFAUT) si l'alimentation spécifiée est PROTÉGÉE PAR MISE À LA TERRE et avec S_1, S_2 et S_3 fermés dans toutes les combinaisons possibles des positions de S_5 et de S_{10}, S_{11} et S_{12}.

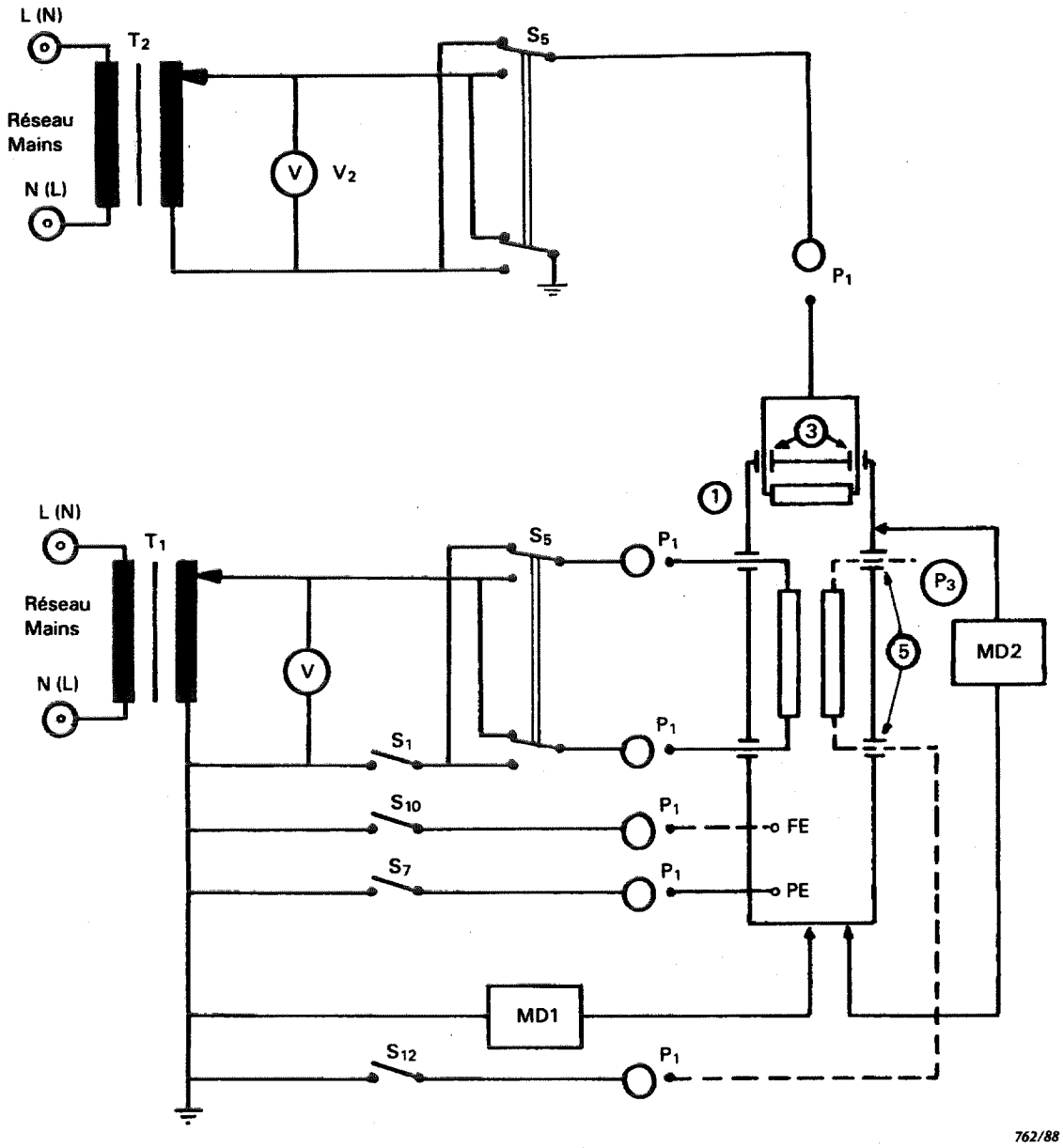
En outre, avec S_8 fermé et un des interrupteurs S_1, S_2, S_3 ouvert à tour de rôle (CONDITION DE PREMIER DÉFAUT), mais seulement pour les mesurages selon les notes du tableau IV.

Measure with MD1 and MD2 with S_8 closed and S_1, S_2 and S_3 closed and under all possible combinations of positions of S_5, S_{10} and S_{12} (NORMAL CONDITION).

Measure with MD2 with S_8 open (SINGLE FAULT CONDITION), if the specified power supply is PROTECTIVELY EARTHED and with S_1, S_2 and S_3 closed under all possible combinations of positions of S_5, S_{10} and S_{12}.

Additionally, with S_8 closed and one of the switches S_1, S_2 or S_3 opened in turn (SINGLE FAULT CONDITION) but only for measurements in accordance with notes to Table IV.

FIG. 17. — Circuit de mesure du COURANT DE FUITE À LA TERRE d'un APPAREIL, avec ou sans PARTIE APPLIQUÉE, spécifié pour l'utilisation avec une alimentation monophasée spécifiée de la CLASSE I, utilisant le circuit d'alimentation de mesure de la figure 14 (voir paragraphe 19.4*f*) et les notes du tableau IV).
Measuring circuit for the EARTH LEAKAGE CURRENT of EQUIPMENT, with or without APPLIED PART, specified for use with a specified class I single-phase power supply using the measuring supply circuit of Figure 14 (see Sub-clause 19.4*f*) and notes of Table IV).



Voir légendes page 243

See legends page 243

Mesure (avec S_7 fermé en CLASSE I) dans toutes les combinaisons possibles des positions de S_1 et S_5 et de S_9, S_{10} et S_{12}. S_1 ouvert est une CONDITION DE PREMIER DÉFAUT.

CLASSE I seulement:

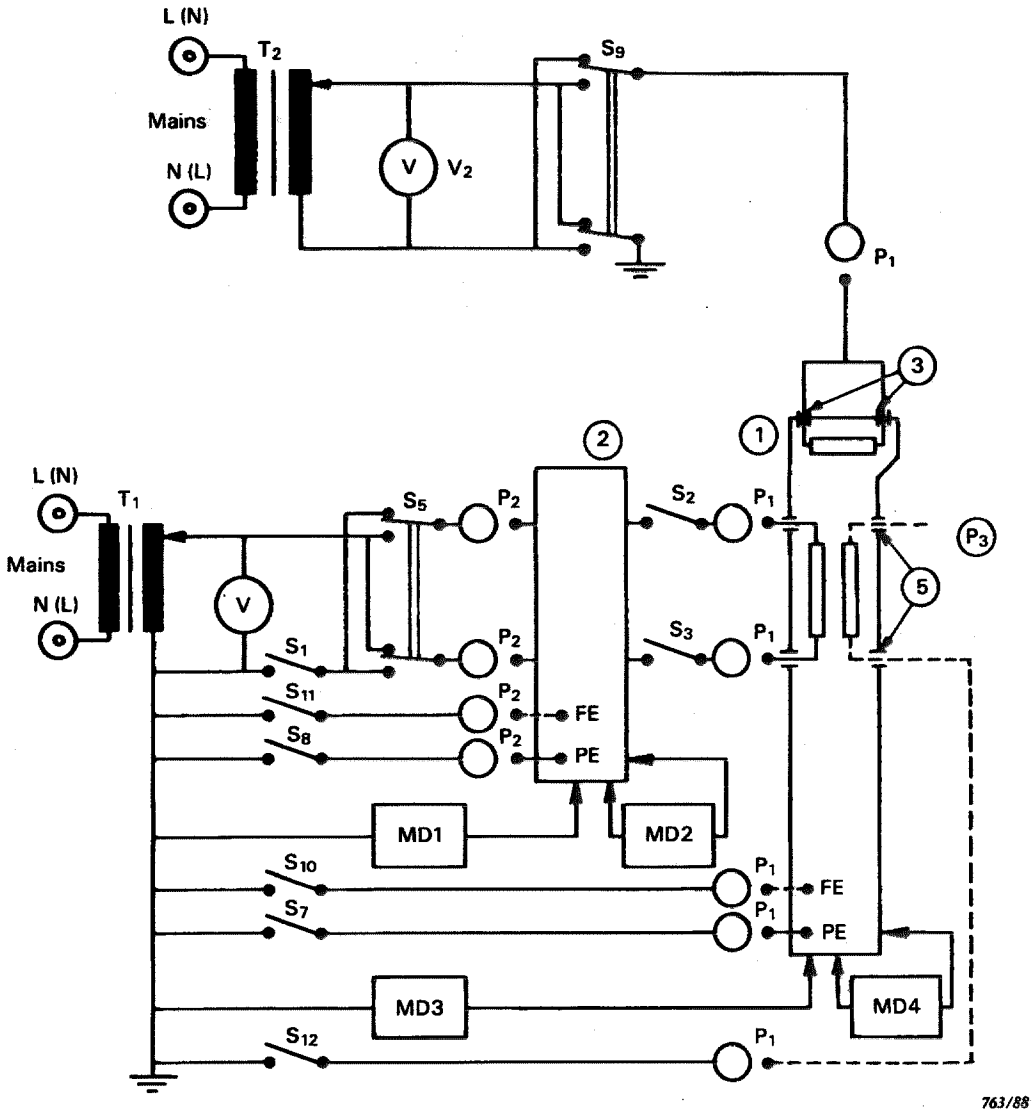
Mesure avec S_7 ouvert (CONDITION DE PREMIER DÉFAUT) et avec S_1 fermé, dans toutes les combinaisons possibles des positions de S_5 et de S_9, S_{10} et S_{12}.

Measure (with S_7 closed if CLASS I EQUIPMENT) under all possible combinations of positions of S_1, S_5, S_9, S_{10} and S_{12}. S_1 open is SINGLE FAULT CONDITION.

CLASS I only:

Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, S_9, S_{10} and S_{12}.

FIG. 18. — Circuit de mesure du COURANT DE FUITE À TRAVERS L'ENVELOPPE. Pour les APPAREILS DE LA CLASSE II la liaison de terre de protection et S_7 ne sont pas utilisés.
Exemple avec le circuit d'alimentation de mesure de la figure 10 (voir paragraphe 19.4*g*)).
Measuring circuit for the ENCLOSURE LEAKAGE CURRENT. For CLASS II EQUIPMENT the protective earth connection and S_7 are not used.
Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*g*).



See legends page 243

Measure with MD1 and MD2 (with S_8 closed if specified power supply is of class I) under all possible combinations of positions of S_1, S_5, S_9 and S_{11}. S_1 open is SINGLE FAULT CONDITION.

Specified power supply of class I only:
Measure with MD1 and MD2 with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, S_9 and S_{11}.

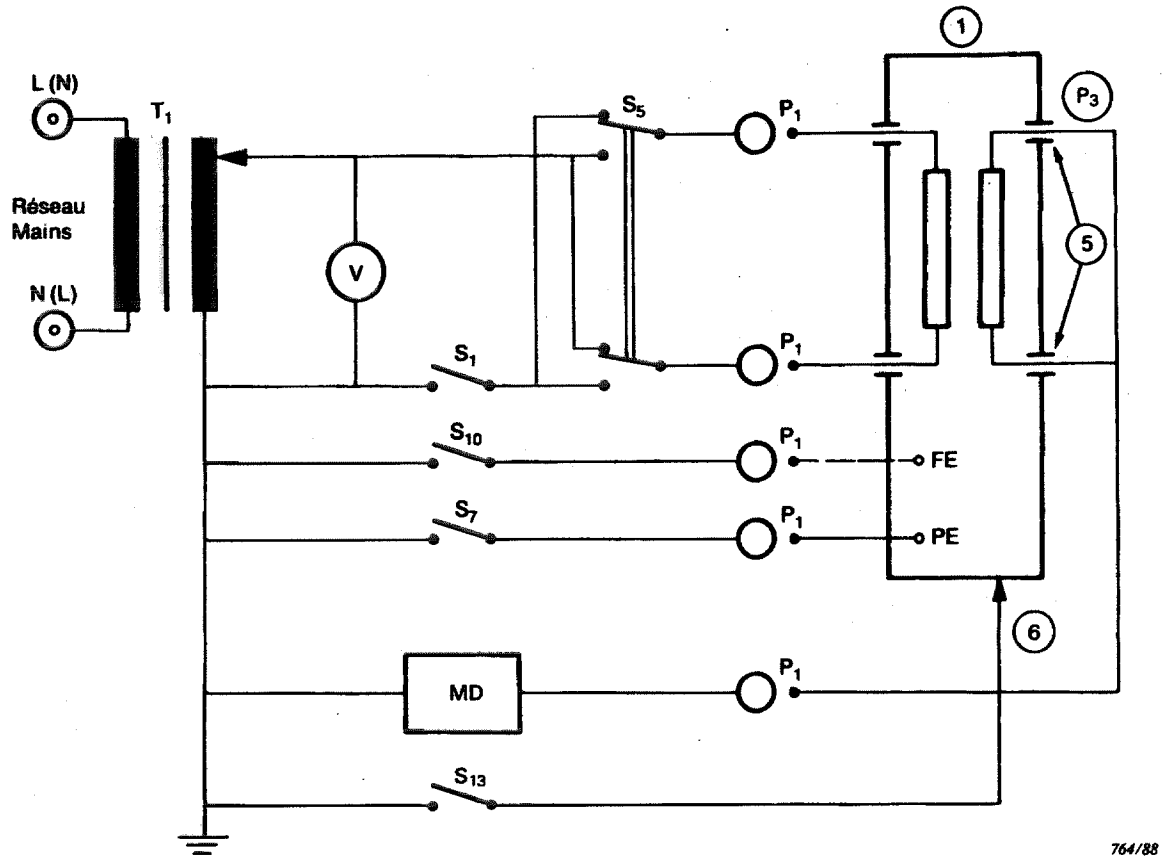
Measure with MD3 and MD4 (with S_7 closed if the EQUIPMENT itself is of CLASS I and with S_8 closed if the specified power supply is of class I) with:

- S_1, S_2 and S_3 closed (NORMAL CONDITION), and
- S_1 or S_2 or S_3 open (SINGLE FAULT CONDITION) under all possible combinations of positions of S_5 and of S_9, S_{10}, S_{11} and S_{12}.

Measure with MD3 and MD4 with either (SINGLE FAULT CONDITION):

- S_7 open (when the EQUIPMENT is of CLASS I) or
- S_8 open (when the specified power supply is of class I) and with S_1, S_2 and S_3 closed under all possible combinations of positions of S_5 and of S_9, S_{10}, S_{11} and S_{12}.

FIG. 19. — Measuring circuit for the ENCLOSURE LEAKAGE CURRENT of EQUIPMENT with or without APPLIED PART, intended only for use with a specified single-phase power supply. For a specified single-phase supply circuit of Class II, the protective earth connection and S_7 are not used. Example with measuring supply circuit of Figure 14 (see Subclause 19.4g)).



Voir légendes page 243

See legends page 243

Mesure (avec S_7 fermé en CLASSE I) dans toutes les combinaisons possibles des positions des S_1 et de S_5 et de S_{10}.

S_1 ouvert est une CONDITION DE PREMIER DÉFAUT.

CLASSE I seulement:
Effectuer, si possible, l'essai du paragraphe 17*a)* (CONDITION DE PREMIER DÉFAUT).

Measure avec S_7 ouvert (CONDITION DE PREMIER DÉFAUT) et avec S_1 fermé, dans toutes les combinaisons possibles des positions de S_5 et de S_{10} et S_{13}.

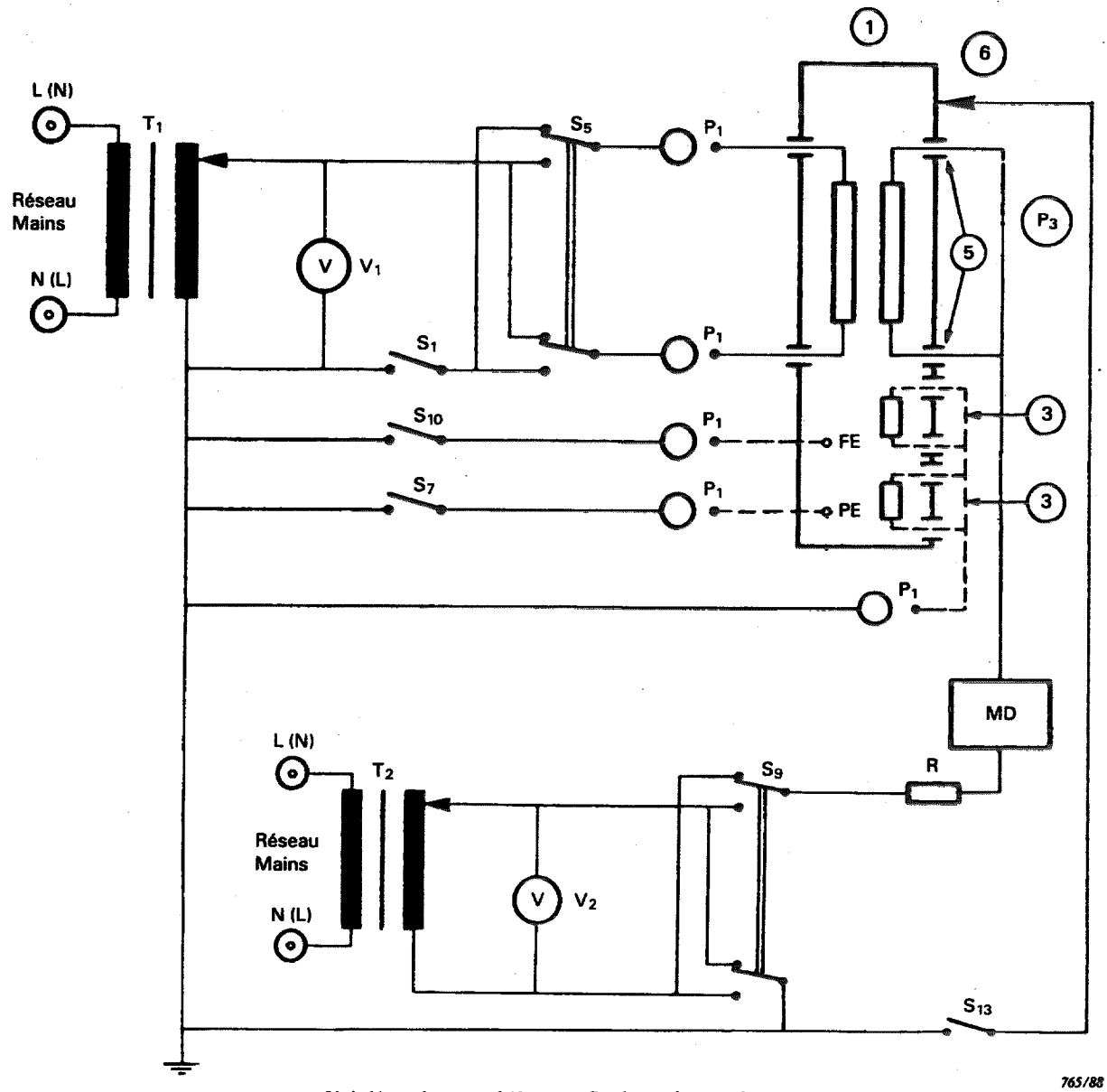
Measure (with S_7 closed if CLASS I) under all possible combinations of positions of S_1, S_5 and of S_{10}.

S_1 open is SINGLE FAULT CONDITION.

CLASS I only:
Perform, if applicable, the test of Sub-clause 17*a)* (SINGLE FAULT CONDITION).

Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, S_{10} and S_{13}.

FIG. 20. — Circuit de mesure du COURANT DE FUITE PATIENT d'une PARTIE APPLIQUÉE vers la terre.
Pour les APPAREILS DE LA CLASSE II la mise à la terre de protection et S_7 ne sont pas utilisés.
Exemple avec le circuit d'alimentation de mesure de la figure 10 (voir paragraphe 19.4*h)*).
Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth.
For CLASS II EQUIPMENT, the protective earth connection and S_7 are not used.
Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*h)*).

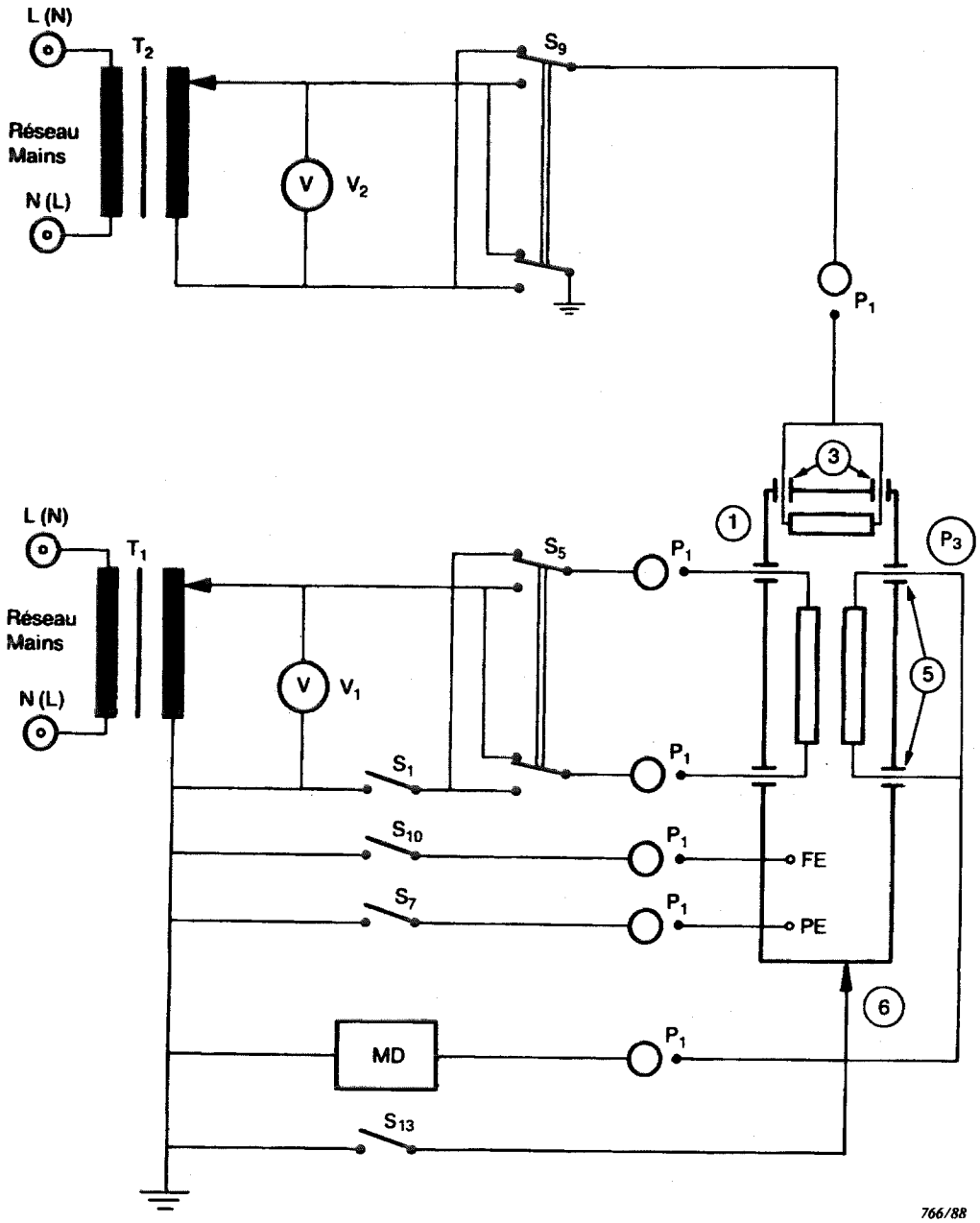


Voir légendes page 243 See legends page 243

Mesure (avec S_7 fermé en CLASSE I) avec S_1 fermé dans toutes les combinaisons possibles des positions de S_5, S_9, S_{10} et de S_{13} (CONDITION DE PREMIER DÉFAUT).

Measure (with S_7 closed, if CLASS I EQUIPMENT) with S_1 closed under all possible combinations of positions of S_5, S_9, S_{10} and S_{13} (SINGLE FAULT CONDITION).

FIG. 21. — Circuit de mesure du COURANT DE FUITE PATIENT via une PARTIE APPLIQUÉE DU TYPE F vers la terre dû à une tension externe sur la PARTIE APPLIQUÉE.
Pour les APPAREILS DE LA CLASSE II la mise à la terre de protection et S_7 ne sont pas utilisés.
Exemple avec le circuit d'alimentation de mesure de la figure 10 (voir paragraphe 19.4*h*)).
Measuring circuit for the PATIENT LEAKAGE CURRENT via an F-TYPE APPLIED PART to earth caused by an external voltage on the APPLIED PART.
For CLASS II EQUIPMENT the protective earth connection and S_7 are not used.
Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*h*)).



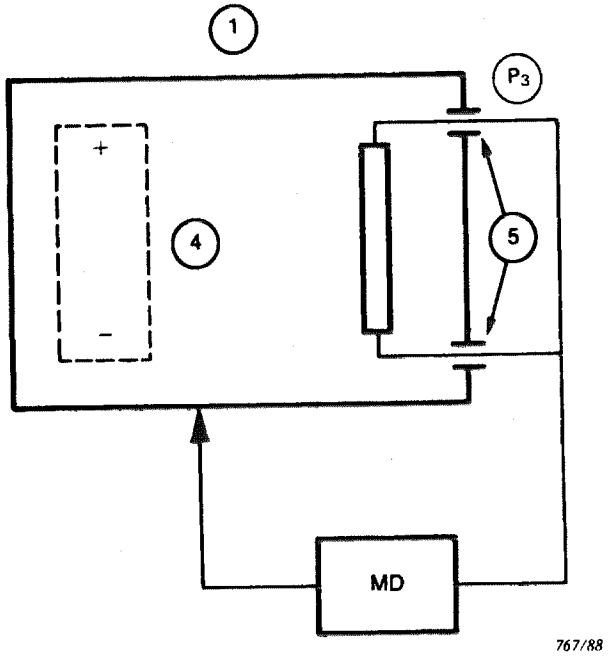
Voir légendes page 243

See legends page 243

Mesure (avec S_7 fermé en CLASSE I) avec S_1 fermé dans toutes les combinaisons possibles des positions de S_5 et S_9, S_{10} et de S_{13} (CONDITION DE PREMIER DÉFAUT)

Measure (with S_7 closed, if CLASS I) with S_1 closed under all possible combinations of positions of S_5 and S_9, S_{10} and S_{13} (SINGLE FAULT CONDITION).

FIG. 22. — Circuit de mesure du COURANT DE FUITE PATIENT provenant de la PARTIE APPLIQUÉE vers la terre dû à une tension externe sur une ENTRÉE ou SORTIE (DE SIGNAL).
Pour les APPAREILS DE LA CLASSE II, la mise à la terre de protection et S_7 ne sont pas utilisés.
Exemple avec le circuit d'alimentation de la figure 10 (voir paragraphe 19.4*h*)).
Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth caused by an external voltage on a SIGNAL INPUT or a SIGNAL OUTPUT PART.
For CLASS II EQUIPMENT the protective earth connection and S_7 are not used.
Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*h*)).



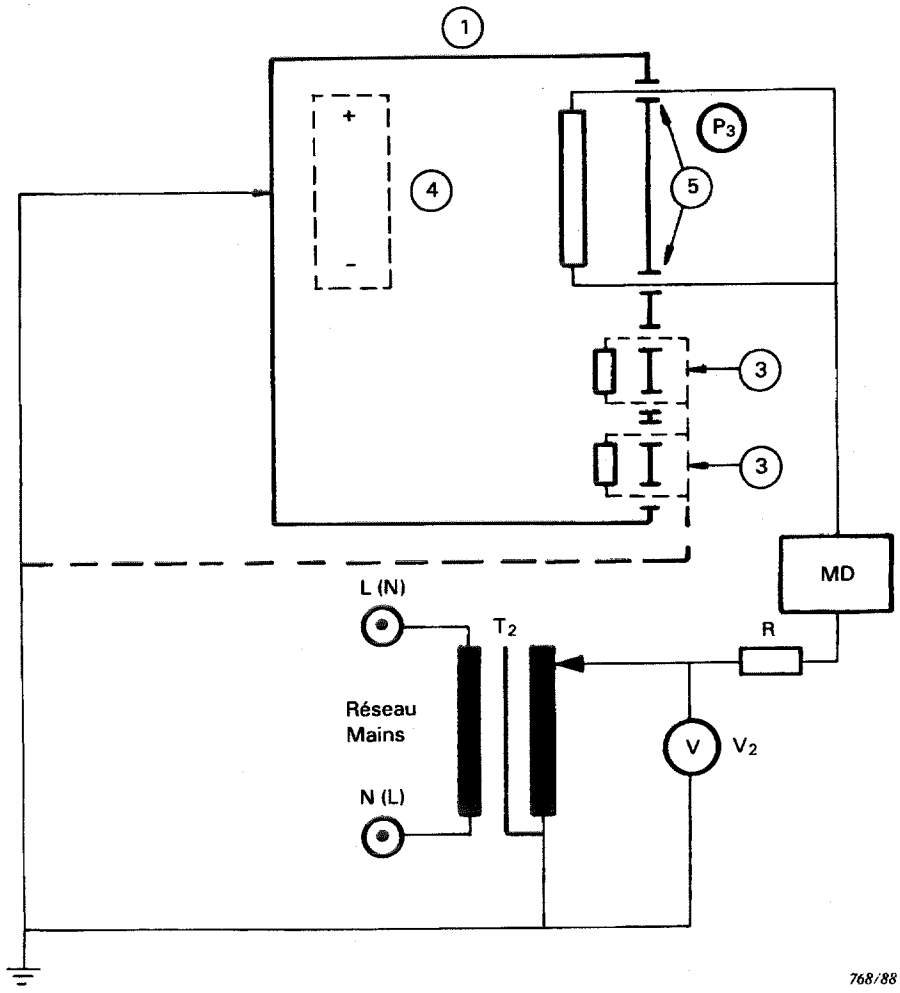
Voir légendes page 243

See legends page 243

Mesure entre la PARTIE APPLIQUÉE et l'ENVELOPPE (CONDITION NORMALE). Effectuer, si applicable, l'essai du paragraphe 17*a*).

Measure between the APPLIED PART and the ENCLOSURE (NORMAL CONDITION). Perform, if applicable, the test of Sub-clause 17*a*).

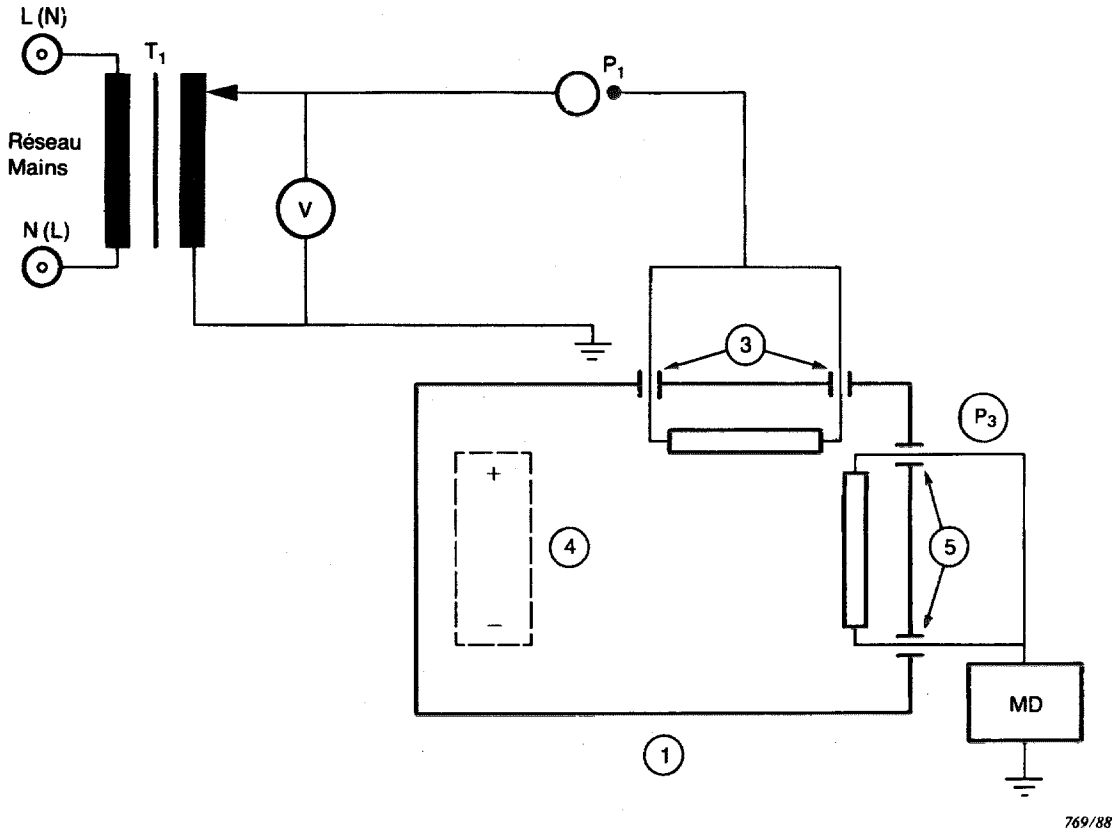
FIG. 23. — Circuit de mesure du COURANT DE FUITE PATIENT provenant d'une PARTIE APPLIQUÉE vers l'ENVELOPPE d'un APPAREIL À SOURCE ÉLECTRIQUE INTERNE (voir paragraphe 19.4*h*)).
Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to the ENCLOSURE of INTERNALLY POWERED EQUIPMENT (see Sub-clause 19.4*h*)).



Voir légendes page 243 See legends page 243

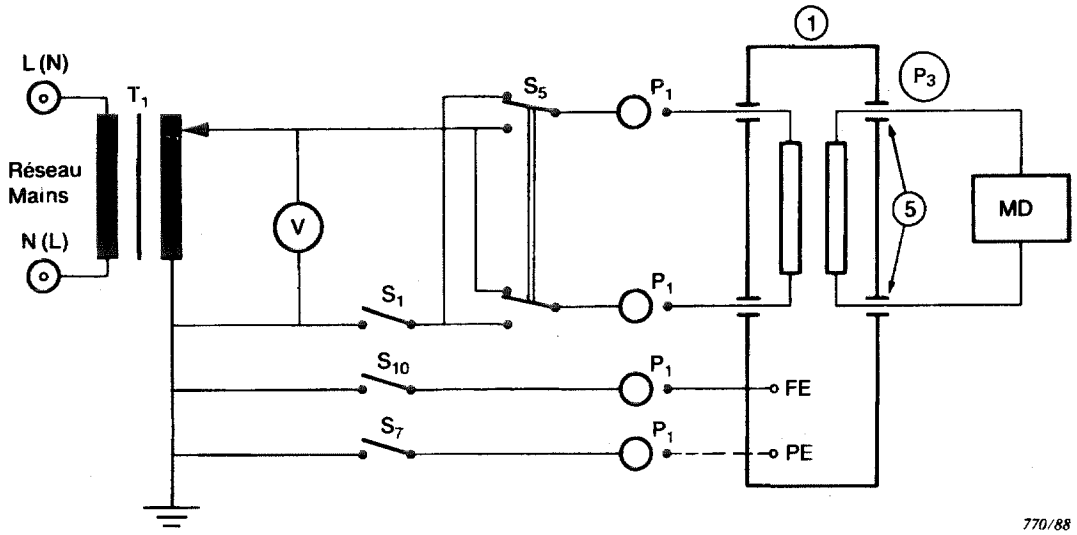
FIG. 24. — Circuit de mesure du COURANT DE FUITE PATIENT s'écoulant par une PARTIE APPLIQUÉE DU TYPE F vers l'ENVELOPPE d'un APPAREIL À SOURCE ÉLECTRIQUE INTERNE (voir paragraphe 19.4*h*)).

Measuring circuit for the PATIENT LEAKAGE CURRENT via an F-TYPE APPLIED PART to the ENCLOSURE of INTERNALLY POWERED EQUIPMENT (see Sub-clause 19.4*h*)).



Voir légendes page 243 See legends page 243

FIG. 25. — Circuit de mesure du COURANT DE FUITE PATIENT d'une PARTIE APPLIQUÉE vers la terre, d'un APPAREIL À SOURCE ÉLECTRIQUE INTERNE dû à une tension externe sur une ENTRÉE ou SORTIE (DE SIGNAL) (voir paragraphe 19.4*h*)).
Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED EQUIPMENT, caused by an external voltage on a SIGNAL INPUT OR SIGNAL OUTPUT PART (see Sub-clause 19.4*h*)).

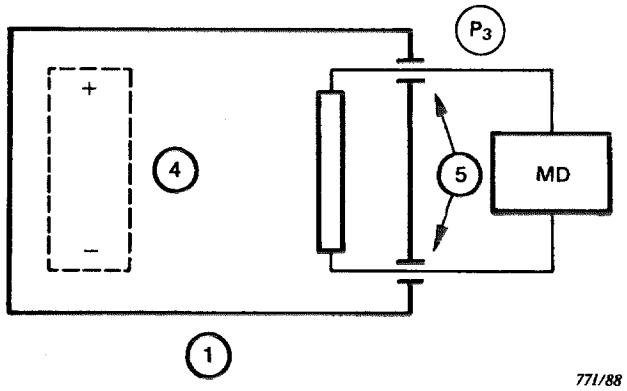


Voir légendes page 243 See legends page 243

Mesure (avec S_7 fermé en CLASSE I) dans toutes les combinaisons possibles des positions de S_1 et S_5 et de S_{10}.
S_1 ouvert est une CONDITION DE PREMIER DÉFAUT.
CLASSE I seulement:
Mesure avec S_7 ouvert (CONDITION DE PREMIER DÉFAUT) et avec S_1 fermé, dans toutes les combinaisons possibles des positions de S_5 et de S_{10}.

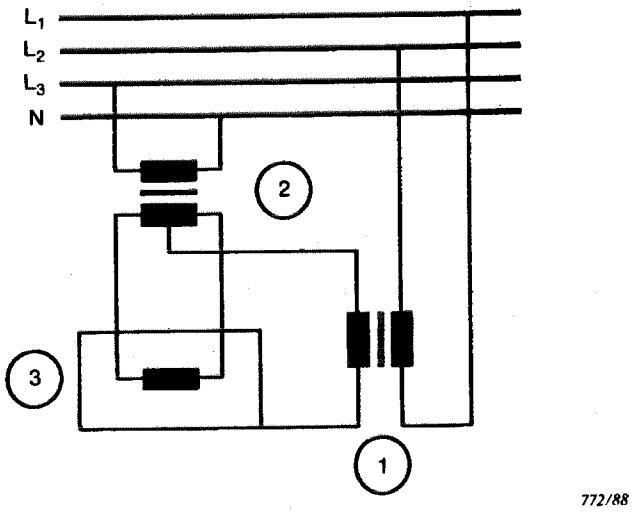
Measure (with S_7 closed if CLASS I) under all possible combinations of positions of S_1, S_5 and S_{10}.
S_1 open is SINGLE FAULT CONDITION.
CLASS I only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5 and S_{10}.

FIG. 26. — Circuit de mesure du COURANT AUXILIAIRE PATIENT.
Pour les APPAREILS DE LA CLASSE II la mise à la terre de protection et S_7 ne sont pas utilisés.
Exemple avec le circuit d'alimentation de mesure de la figure 10 (voir paragraphe 19.4*j*)).
Measuring circuit for the PATIENT AUXILIARY CURRENT.
For CLASS II EQUIPMENT, the protective earth connection and S_7 are not used.
Example with the measuring supply circuit of Figure 10 (see Sub-clause 19.4*j*)).



Voir légendes ci-contre See legends page opposite

FIG. 27. — Circuit de mesure du COURANT AUXILIAIRE PATIENT d'un APPAREIL À SOURCE ÉLECTRIQUE INTERNE (voir paragraphe 19.4*j*)).
Measuring circuit for the PATIENT AUXILIARY CURRENT of INTERNALLY POWERED EQUIPMENT (see Sub-clause 19.4*j*)).



① Transformateur d'essai
Test transformer

② Transformateur de séparation
Isolating transformer

③ APPAREIL
EQUIPMENT

FIG. 28. — Exemple d'un circuit pour l'essai de tension de tenue à la température de fonctionnement pour des éléments chauffants (voir paragraphe 20.4).
Example of a circuit for dielectric strength test at operating temperature for heating elements (see Sub-clause 20.4).

Légendes relatives aux symboles des figures 10 à 27

①	ENVELOPPE D'APPAREIL
②	Alimentation spécifiée
③	ENTRÉE OU SORTIE (DE SIGNAL) court-circuitée ou chargée
④	SOURCE ÉLECTRIQUE INTERNE
⑤	PARTIE APPLIQUÉE
⑥	PARTIE MÉTALLIQUE ACCESSIBLE n'étant pas une PARTIE APPLIQUÉE et non PROTÉGÉE PAR MISE À LA TERRE
T_1, T_2	Transformateurs de séparation monophasé, biphasé, polyphasé ayant une puissance suffisante et une tension secondaire réglable
V (1, 2, 3)	Voltmètres indiquant la valeur efficace, en utilisant le cas échéant et si possible un seul appareil avec un commutateur
S_1, S_2, S_3	Interrupteurs monopolaires simulant la coupure sur un conducteur d'alimentation (CONDITION DE PREMIER DÉFAUT)
S_5, S_9	Inverseurs de polarité de la TENSION RÉSEAU
S_7, S_8	Interrupteurs monopolaires simulant la coupure d'un unique CONDUCTEUR DE PROTECTION (CONDITION DE PREMIER DÉFAUT)
S_{10}, S_{11}	Interrupteurs pour le raccordement d'une BORNE DE TERRE FONCTIONNELLE au point de mise à la terre du circuit d'alimentation de mesure
S_{12}	Interrupteur pour le raccordement de la PARTIE APPLIQUÉE DU TYPE F au point de mise à la terre du circuit d'alimentation de mesure
S_{13}	Interrupteur pour mise à la terre d'une PARTIE MÉTALLIQUE ACCESSIBLE n'étant pas une PARTIE APPLIQUÉE et non PROTÉGÉ PAR MISE À LA TERRE
P_1	Socles, fiches ou bornes pour le raccordement de l'APPAREIL
P_2	Socles, fiches ou bornes pour le raccordement de la source d'alimentation spécifiée
P_3	Socles, fiches ou bornes pour le raccordement au PATIENT
MD	Dispositif de mesure (voir figure 15)
FE	BORNE DE TERRE FONCTIONNELLE
PE	BORNE DE TERRE DE PROTECTION
----	Raccordement optionnel.

Legends of symbols for Figures 10 to 27

①	EQUIPMENT ENCLOSURE
②	Specified power supply
③	SIGNAL INPUT or SIGNAL OUTPUT PART short-circuited or loaded
④	INTERNAL ELECTRICAL POWER SOURCE
⑤	APPLIED PART
⑥	ACCESSIBLE METAL PART not being an APPLIED PART and not PROTECTIVELY EARTHED
T_1, T_2	Single-, double-, polyphase isolation transformers with sufficient power rating and adjustable output voltage
V (1, 2, 3)	Voltmeters indicating r.m.s. value, using, if relevant and possible, one meter with a commutator switch
S_1, S_2, S_3	Single-pole switches, simulating the interruption of a power supply conductor (SINGLE FAULT CONDITION)
S_5, S_9	Commutator switches to reverse the polarity of the MAINS VOLTAGE
S_7, S_8	Single-pole switches, simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR (SINGLE FAULT CONDITION)
S_{10}, S_{11}	Switches for connecting a FUNCTIONAL EARTH TERMINAL to the earthed point of the measuring supply circuit
S_{12}	Switch for connecting an F-TYPE APPLIED PART to the earthed point of the measuring supply circuit
S_{13}	Switch for connecting to earth an ACCESSIBLE METAL PART not being an APPLIED PART and not PROTECTIVELY EARTHED
P_1	Sockets, plugs or terminals for the supply connection of the EQUIPMENT
P_2	Sockets, plugs or terminals for the connection to a specified power supply
P_3	Sockets, plugs or terminals for the PATIENT connections
MD	Measuring device (see Figure 15)
FE	FUNCTIONAL EARTH TERMINAL
PE	PROTECTIVE EARTH TERMINAL
----	Optional connection.

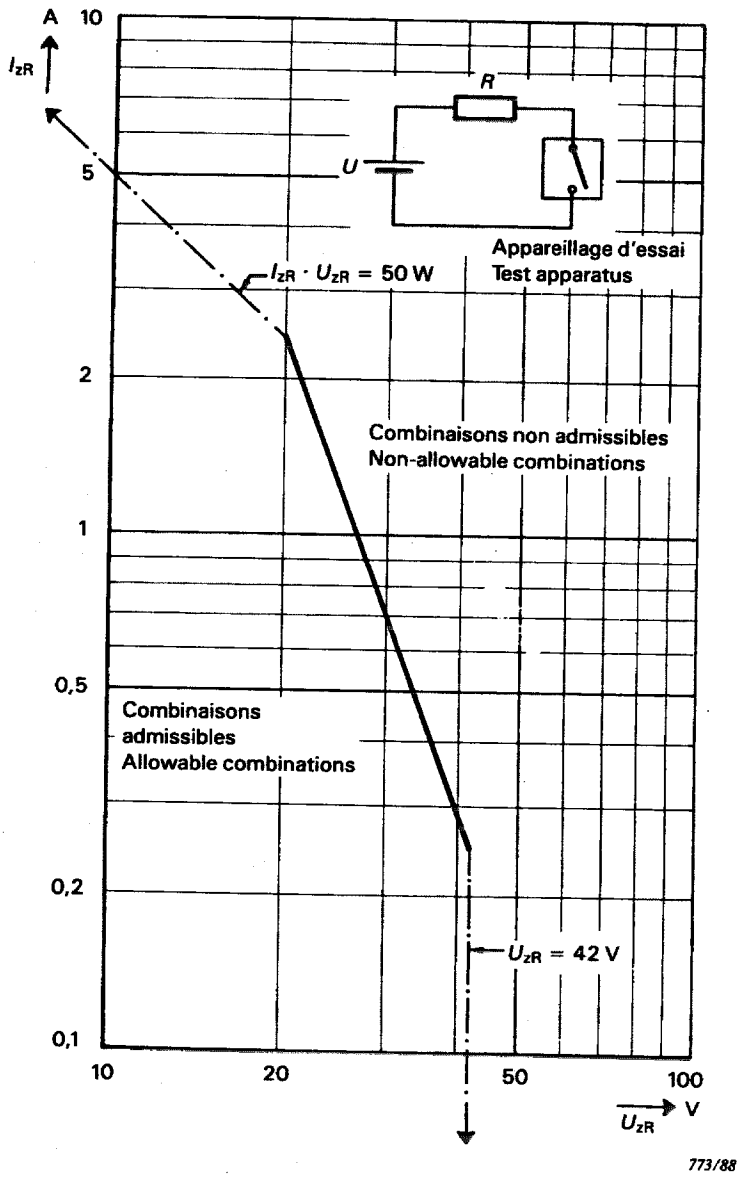
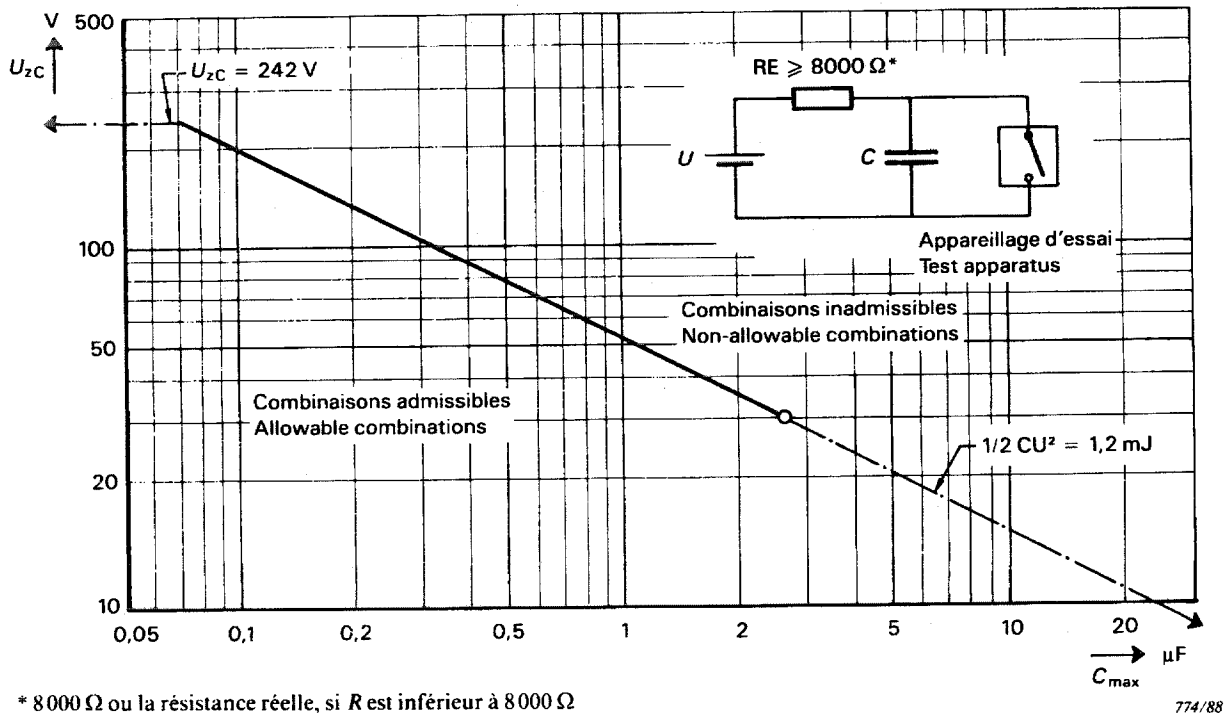


FIG. 29. — Courant maximal admissible I_{zR} en fonction de la tension maximale admissible U_{zR}, mesuré dans un circuit purement résistif dans le mélange le plus facilement inflammable de vapeur d'éther et d'air (voir paragraphe 40.3).
Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR} measured in a purely resistive circuit with the most readily flammable mixture of ether vapour with air (see Sub-clause 40.3).



* 8000 Ω ou la résistance réelle, si R est inférieur à 8000 Ω
* 8000 Ω or the actual resistance, if R is less than 8000 Ω

FIG. 30. — Tension maximale admissible U_{zC} en fonction de la capacité C_{max}, mesurée dans un circuit capacitif dans le mélange le plus facilement inflammable de vapeur d'éther et d'air (voir paragraphe 40.3).
Maximum allowable voltage U_{zC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most readily flammable mixture of ether vapour with air (see Sub-clause 40.3).

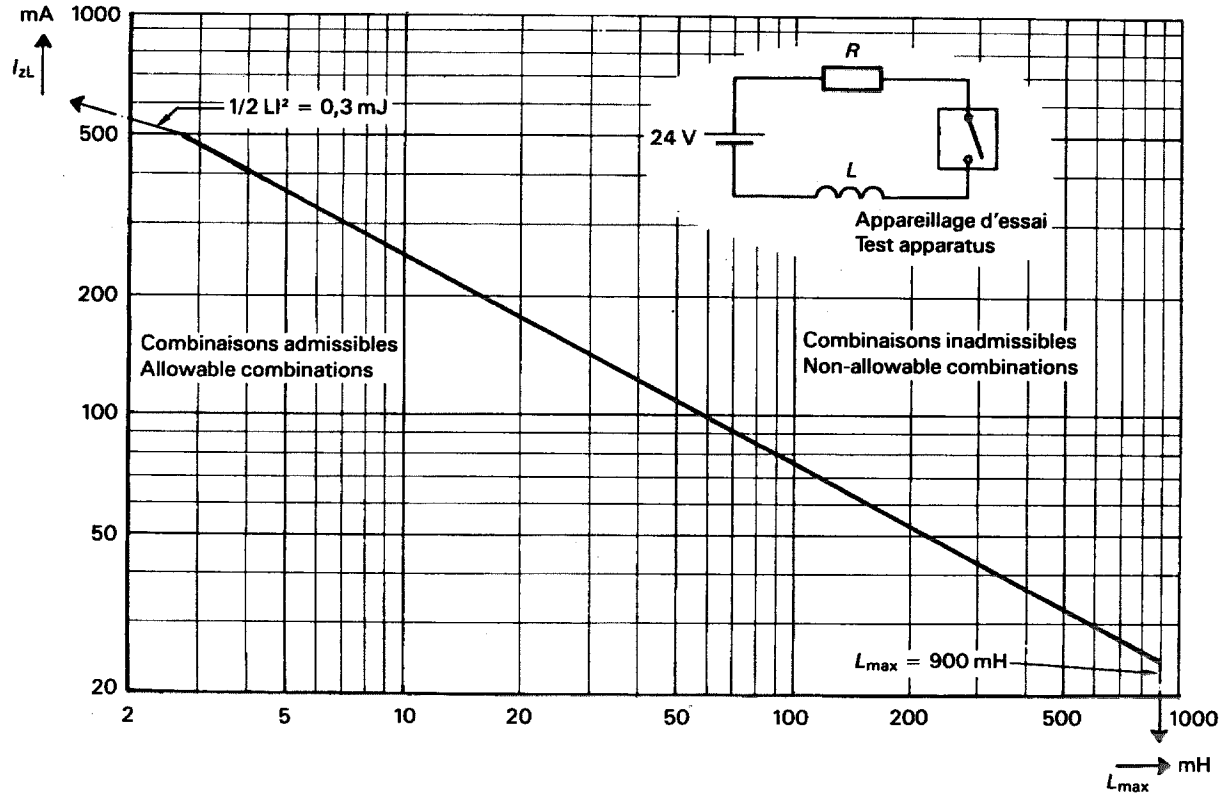


FIG. 31. — Courant maximal admissible I_{zL} en fonction de l'inductance L_{max}, mesuré dans un circuit inductif dans le mélange le plus facilement inflammable de vapeur d'éther et d'air (voir paragraphe 40.3).
Maximum allowable current I_{zL} as a function of the inductance L_{max}, measured in an inductive circuit with the most readily flammable mixture of ether vapour with air (see Sub-clause 40.3).

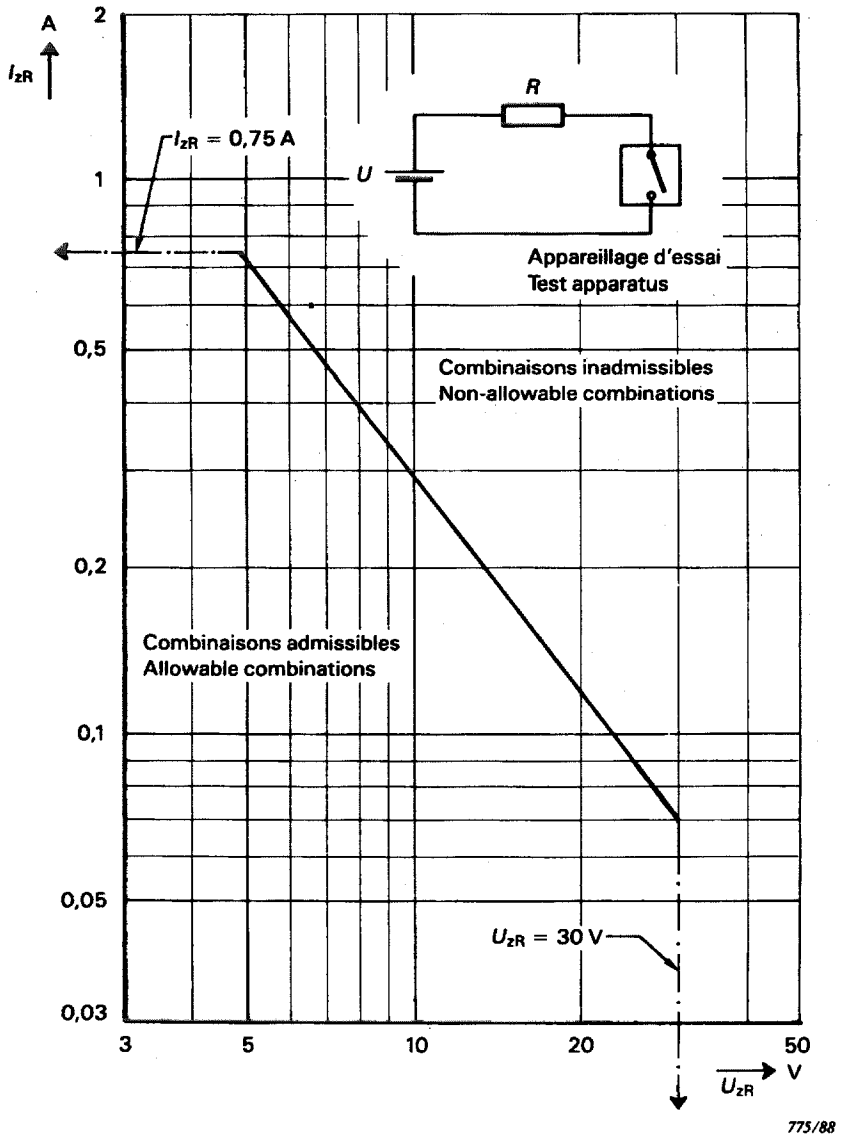
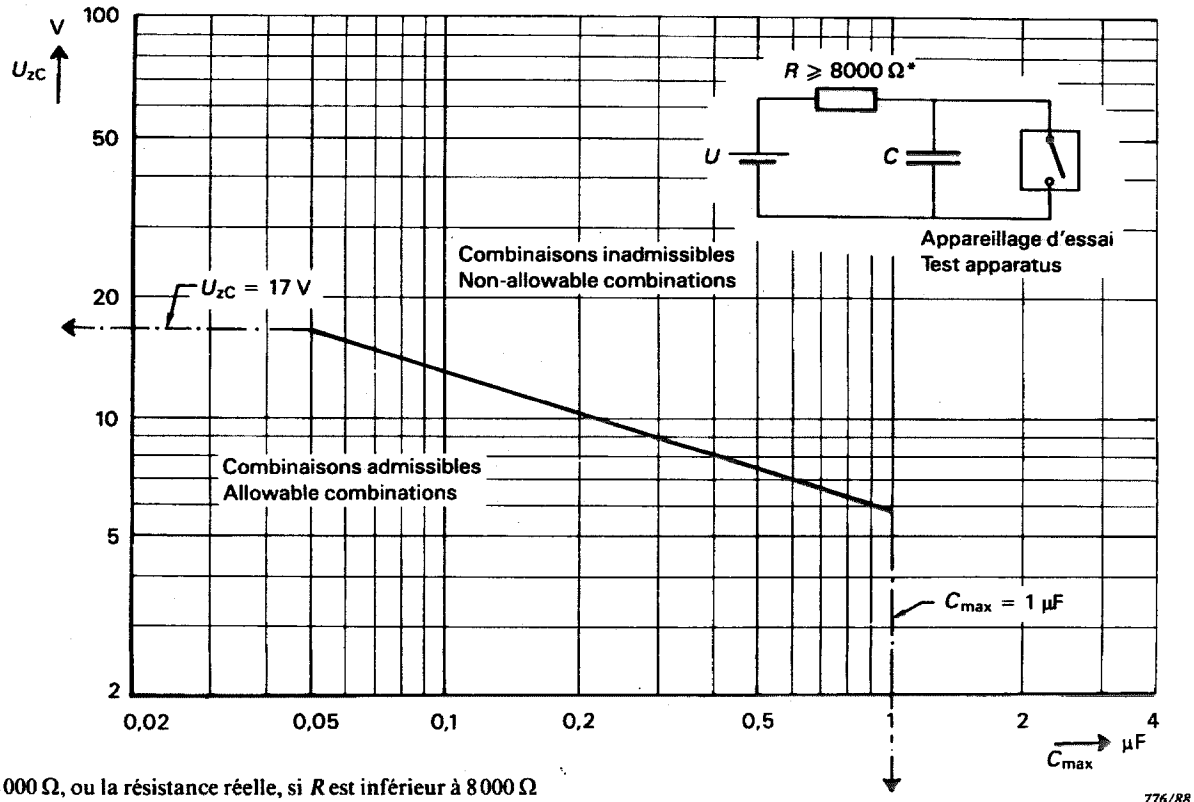


FIG. 32. — Courant maximal admissible I_{zR} en fonction de la tension maximale admissible U_{zR}, mesuré dans un circuit purement résistif dans le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène (voir paragraphe 41.3).
Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR}, measured in a purely resistive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).



* 8000 Ω, ou la résistance réelle, si R est inférieur à 8000 Ω
* 8000 Ω, or the actual resistance, if R is less than 8000 Ω

FIG. 33. — Tension maximale admissible U_{zC} en fonction de la capacité C_{max}, mesurée dans un circuit capacitif dans le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène (voir paragraphe 41.3).
Maximum allowable voltage U_{zC} as a function of the capacity C_{max}, measured in a capacitive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).

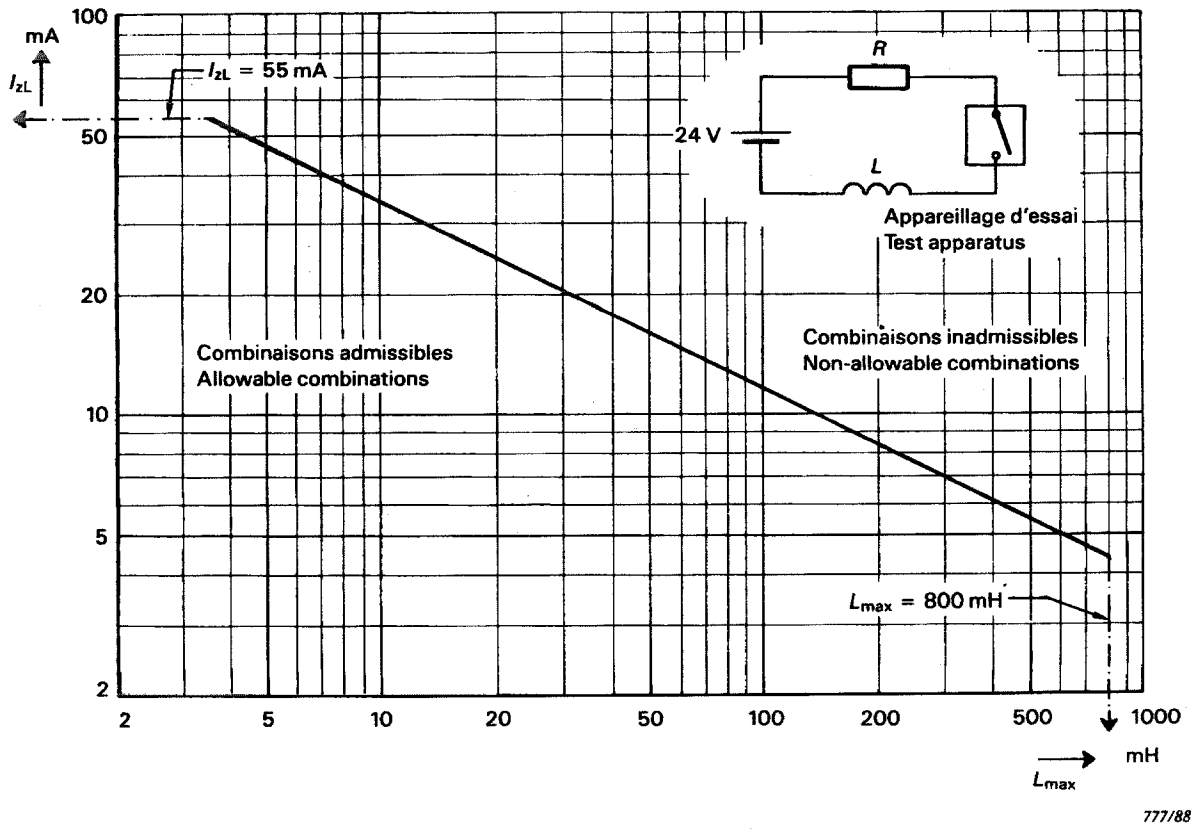


FIG. 34. — Courant maximal admissible I_{zL} en fonction de l'inductance L_{max}, mesuré dans un circuit inductif dans le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène (voir paragraphe 41.3).
Maximum allowable current I_{zL} as a function of the inductance L_{max}, measured in an inductive circuit with the most readily flammable mixture of ether vapour with oxygen (see Sub-clause 41.3).

FIG. 35. — Non utilisé.
FIG. 36. — Not used.
FIG. 37. —

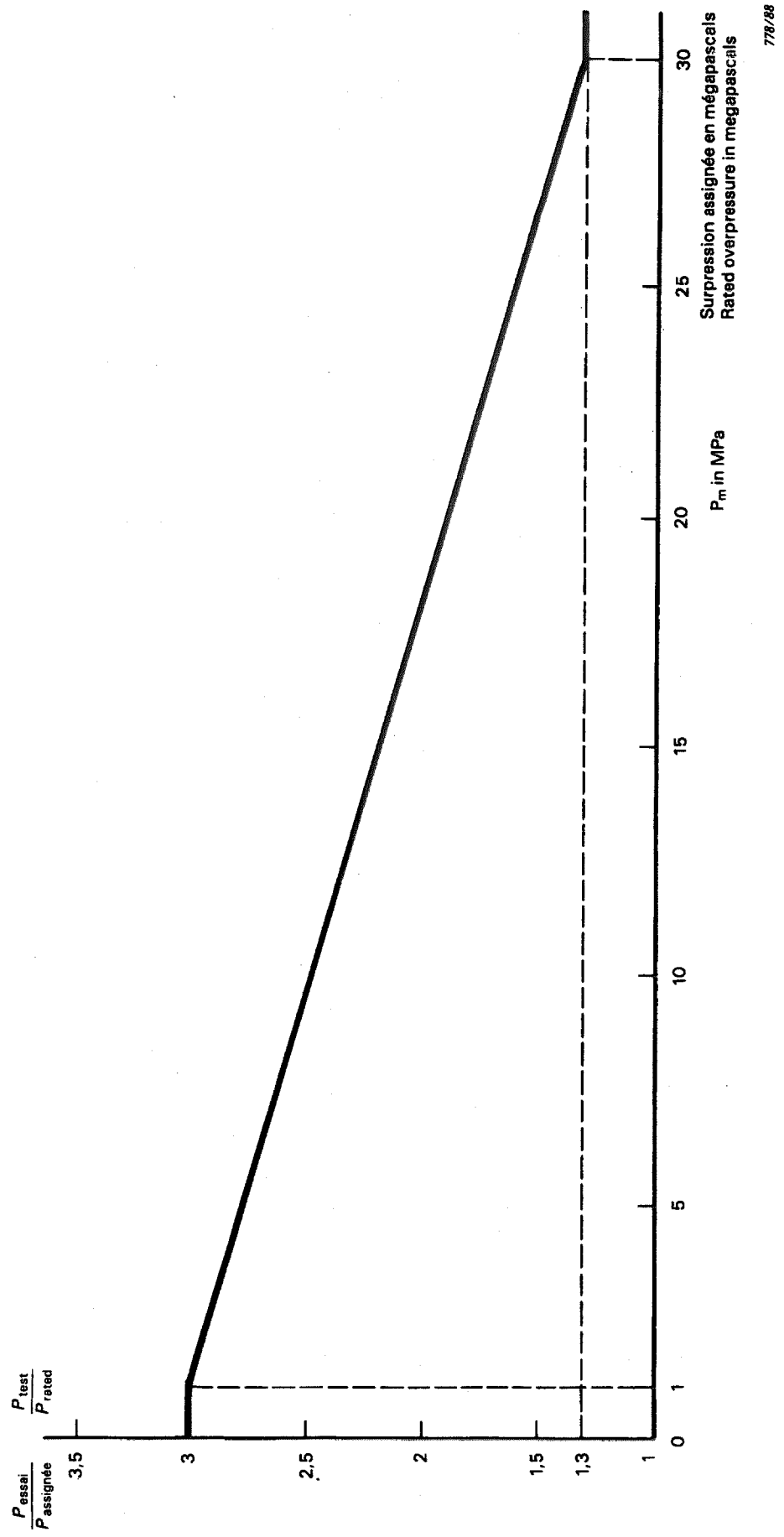
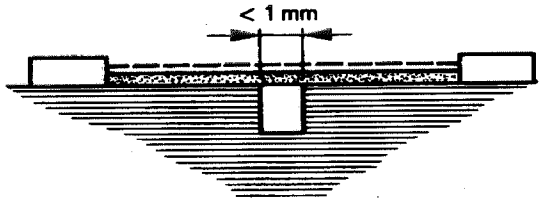


FIG. 38. — Rapport entre la PRESSION D'ESSAI HYDRAULIQUE et la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT (voir paragraphe 45.2).
Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE (see Sub-clause 45.2).



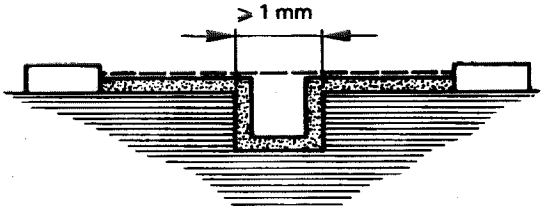
Condition: Le cheminement considéré comprend une encoche à flancs parallèles ou convergents, de profondeur quelconque et de largeur inférieure à 1 mm.

Règle: La LIGNE DE FUITE et la DISTANCE DANS L'AIR sont mesurées en ligne droite au-dessus de l'encoche, comme indiqué dans la figure.

Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than 1 mm.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

FIG. 39. — Exemple nº 1 (voir paragraphe 57.10).
Example 1 (see Sub-clause 57.10).



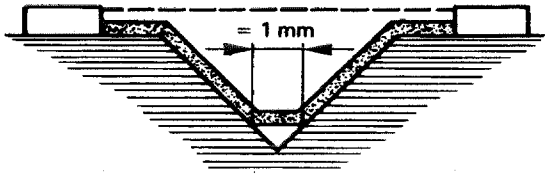
Condition: Le cheminement considéré comprend une encoche à flancs parallèles de profondeur quelconque et de largeur égale ou supérieure à 1 mm.

Règle: La DISTANCE DANS L'AIR est «la distance en ligne droite». Le cheminement de fuite longe le profil de l'encoche.

Condition: Path under consideration includes a parallel-sided groove of any depth and equal to or more than 1 mm.

Rule: AIR CLEARANCE is the "line of sight" distance. Creepage path follows the contour of the groove.

FIG. 40. — Exemple nº 2 (voir paragraphe 57.10).
Example 2 (see Sub-clause 57.10).



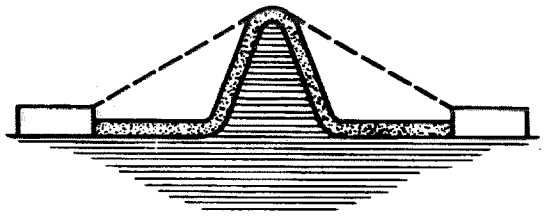
Condition: Le cheminement considéré comprend une encoche en V dont la largeur est supérieure à 1 mm.

Règle: La DISTANCE DANS L'AIR est «la distance en ligne droite». Le cheminement de fuite longe le profil de l'encoche, mais «court-circuite» le bas de l'encoche par un tronçon de 1 mm.

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

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

FIG. 41. — Exemple nº 3 (voir paragraphe 57.10).
Example 3 (see Sub-clause 57.10).



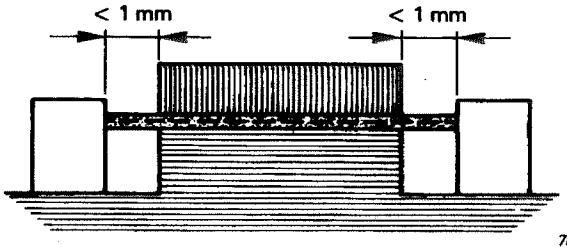
Condition: Le cheminement considéré comprend une nervure.

Règle: La DISTANCE DANS L'AIR est le cheminement dans l'air le plus court par-dessus le sommet de la nervure. Le cheminement de fuite longe le profil de la nervure.

Condition: Path under consideration includes a rib.

Rule: AIR CLEARANCE is the shortest direct air path over the top of the rib. Creepage path follows the contour of the rib.

FIG. 42. — Exemple nº 4 (voir paragraphe 57.10).
Example 4 (see Sub-clause 57.10).



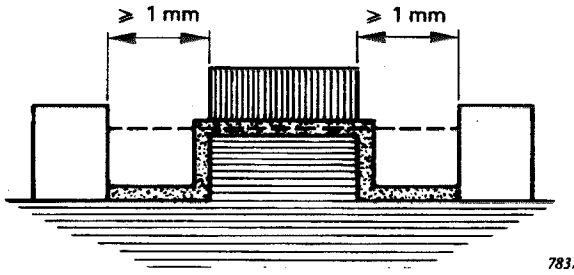
Condition: Le cheminement considéré comprend un joint non collé avec des encoches de largeur inférieure à 1 mm de chaque côté.

Règle: Le cheminement de la LIGNE DE FUITE et de la DISTANCE DANS L'AIR est «la distance en ligne droite» indiquée ci-dessus.

Condition: Path under consideration includes an uncemented joint with grooves less than 1 mm wide on each side.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE path is the "line of sight" distance shown.

FIG. 43. — Exemple nº 5 (voir paragraphe 57.10).
Example 5 (see Sub-clause 57.10).



Condition: Le cheminement considéré comprend un joint non collé avec des encoches de largeur égale ou supérieure à 1 mm de chaque côté.

Règle: La DISTANCE DANS L'AIR est «la distance en ligne droite». Le cheminement de fuite longe le profil des encoches.

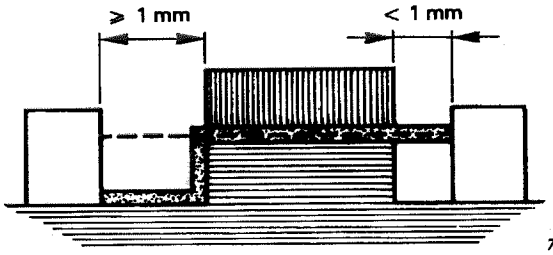
Condition: Path under consideration includes an uncemented joint with grooves equal to or more than 1 mm wide on each side.

Rule: AIR CLEARANCE is the "line of sight" distance. Creepage path follows the contour of the grooves.

FIG. 44. — Exemple nº 6 (voir paragraphe 57.10).
Example 6 (see Sub-clause 57.10).

DISTANCE DANS L'AIR
AIR CLEARANCE

LIGNE DE FUITE
CREEPAGE DISTANCE



Condition: Le cheminement considéré comprend un joint non collé avec, d'un côté, une encoche de largeur inférieure à 1 mm et, de l'autre côté, une encoche de largeur égale ou supérieure à 1 mm.

Règle: Les DISTANCE DANS L'AIR et les LIGNES DE FUITE sont indiquées dans la figure.

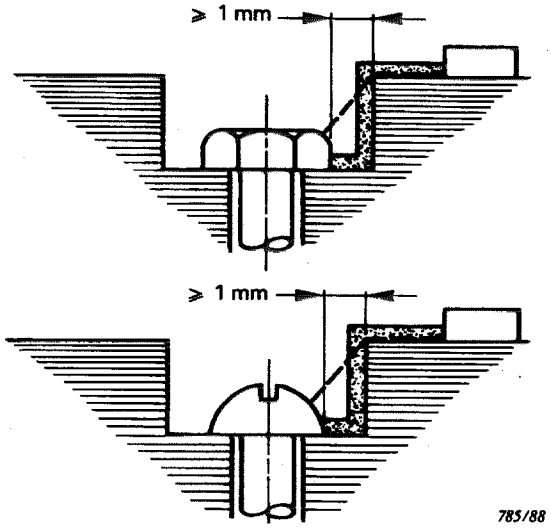
Condition: Path under consideration includes an uncemented joint with a groove on one side less than 1 mm wide and the groove on the other side equal to or more than 1 mm wide.

Rule: AIR CLEARANCES and CREEPAGE DISTANCES are as shown.

FIG. 45. — Exemple nº 7 (voir paragraphe 57.10).
Example 7 (see Sub-clause 57.10).

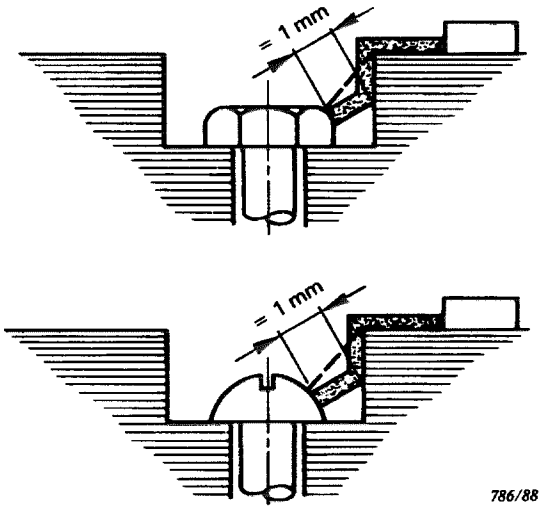
DISTANCE DANS L'AIR
AIR CLEARANCE

LIGNE DE FUITE
CREEPAGE DISTANCE



L'intervalle entre la tête de la vis et la paroi du logement est assez large pour être compté.
Gap between head of screw and wall of recess wide enough to be taken into account.

FIG. 46. — Exemple nº 8 (voir paragraphe 57.10).
Example 8 (see Sub-Clause 57.10).



L'intervalle entre la tête de la vis et la paroi du logement est trop faible pour être compté.
Le mesurage de la LIGNE DE FUITE s'effectue entre la vis et la paroi quand la distance est égale à 1 mm.
Gap between head of screw and wall of recess too narrow to be taken into account.
Measurement of CREEPAGE DISTANCE is from screw to wall when the distance is equal to 1 mm.

FIG. 47. — Exemple nº 9 (voir paragraphe 57.10).
Example 9 (see Sub-clause 57.10).

DISTANCE DANS L'AIR
AIR CLEARANCE

LIGNE DE FUITE
CREEPAGE DISTANCE

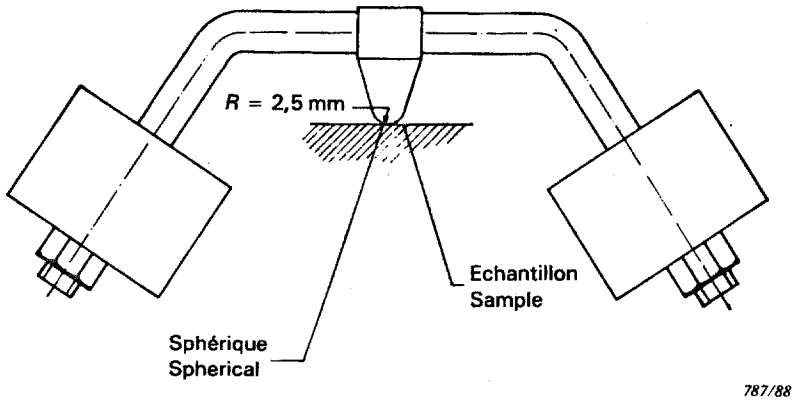


FIG. 48. — Appareillage pour l'essai à la bille (voir paragraphe 59.2*b*)).
Ball-pressure test apparatus (see Sub-clause 59.2*b*)).

FIG. 49. — Non utilisé.
Not used.

Légendes relatives aux figures 39 à 47 (voir paragraphe 57.10)

1) Les méthodes suivantes de mesure des LIGNES DE FUITE et des DISTANCES DANS L'AIR sont utilisées pour l'interprétation des prescriptions de la présente Norme.
Les méthodes ne font pas de distinction entre intervalles ou encoches ou entre types d'isolation.
On part des hypothèses suivantes:
a) Une encoche transversale peut avoir des flancs parallèles, convergents ou divergents.
b) Tout coin dont l'angle d'ouverture est inférieur à 80° peut être considéré comme mis en dérivation par un tronçon isolant de 1 mm placé dans la position la plus défavorable (voir figure 41).
c) Lorsque la distance au sommet d'une encoche est égale ou supérieure à 1 mm, il n'y a pas de LIGNES DE FUITE à travers l'espace dans l'air (voir figure 40).
d) Les LIGNES DE FUITE et DISTANCES DANS L'AIR mesurées entre des parties mobiles l'une par rapport à l'autre sont évaluées lorsque ces parties se trouvent dans leurs positions les plus défavorables.
e) La LIGNE DE FUITE évaluée n'est jamais inférieure à la DISTANCE DANS L'AIR mesurée.
f) Un intervalle d'air de moins de 1 mm de large n'est pas pris en considération pour l'évaluation de la DISTANCE totale DANS L'AIR (voir figure 39 à 47).

2) Les parties SOUS TENSION, simplement vernies, émaillées ou oxydées, sont considérées comme des parties SOUS TENSION nues. Des revêtements en matériau isolant, cependant, peuvent être considérés comme constituant une isolation, si le revêtement est équivalent à une feuille en matériau isolant d'une épaisseur égale eu égard à ses propriétés électriques, thermiques ou mécaniques.

3) Si les LIGNES DE FUITE et DISTANCES DANS L'AIR sont interrompues par des parties conductrices flottantes. La somme des sections ne doit pas être inférieure à la valeur minimale spécifiée donnée au tableau XVI. Les distances inférieures à 1 mm ne sont pas prises en considération. Si la tension de référence est supérieure à 1000 V, il faut faire attention à la division des tensions par les capacités.

4) S'il y a des encoches transversales par rapport à la LIGNE DE FUITE, la paroi de l'encoche n'est comptée comme LIGNE DE FUITE que si la largeur de l'encoche est supérieure à 1 mm (voir figure 40). Dans tous les autres cas l'encoche est négligée.

5) Dans le cas de nervures encastrées ou placées sur un isolant, la LIGNE DE FUITE ne doit être mesurée en passant par dessus la nervure, que si celle-ci est fixée par collage, cimentage ou soudure de telle sorte que ni la poussière ni l'humidité ne puissent pénétrer dans l'encoche ou dans le joint.

6) Des intervalles étroits ayant la même direction qu'un éventuel cheminement de fuite et n'ayant que quelques dixièmes de 1 mm de large devraient être évités autant que possible, car la poussière et l'humidité peuvent s'y déposer.

Legends to Figures 39 to 47 (see Sub-clause 57.10)

1) The following methods for determination of CREEPAGE DISTANCES and AIR CLEARANCES shall be used in interpreting the requirements of this Standard.
The methods do not differentiate between gaps and grooves nor between types of insulation.
The following assumptions are made:
a) A transverse groove may have parallel, converging or diverging sides.
b) Any corner with included angle less than 80° may be assumed to be bridged with an insulating link of 1 mm moved into the least favourable position (see Figure 41).
c) Where the distance across the top of a groove is 1 mm or more, no CREEPAGE DISTANCE exists across the air space (see Figure 40).
d) CREEPAGE DISTANCES and AIR CLEARANCES measured between parts moving relative to each other are considered in their least favourable position.
e) Computed CREEPAGE DISTANCE is never less than measured AIR CLEARANCE.
f) Any air gap less than 1 mm wide is ignored in computing the total AIR CLEARANCE (see Figures 39 to 47).

2) LIVE parts which are varnished, enamelled or oxidized only are considered to be bare LIVE parts. Coverings of any insulating material, however, may be considered as insulation, if the covering is equivalent to a foil of insulating material of equal thickness with respect to its electrical, thermal and mechanical properties.

3) If CREEPAGE DISTANCES or AIR CLEARANCES are interrupted by a floating conductive part, the sum of the sections shall be not less than the minimum specified value given in Table XVI. Distances less than 1 mm are not taken into consideration. If the reference voltage is above 1000 V, attention should be paid to the voltage division by the capacitances.

4) If there are grooves transverse to the CREEPAGE DISTANCE, the wall of the groove is counted as CREEPAGE DISTANCE only if the width of the groove is more than 1 mm (see Figure 40). In all other cases the groove is neglected.

5) In the case of barriers placed on the surface of insulation or held in a recess, the CREEPAGE DISTANCE may be measured over the barrier only if the latter is so fixed that dust and moisture cannot penetrate into the joint or recess.

6) Narrow gaps, running into the direction of a possible creepage path and being some tenths of 1 mm wide only, should be avoided as far as possible, for dirt and moisture may deposit there.

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APPENDIX A

GENERAL GUIDANCE AND RATIONALE*

A1. General Guidance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The total safety of EQUIPMENT may consist of:

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

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

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

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

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

Reference to other publications is only made if such publications are of a general nature, that is, not restricted to particular equipment types (see References, page 343). In other cases requirements and tests have been adopted unmodified or slightly modified, without quoting the source.

A1.2 *Guidance to the second edition*

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

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

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

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

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

A new defined concept PROTECTIVELY EARTHED has been introduced.

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

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

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

The requirements for the separation between an APPLIED PART and LIVE parts were also applied to the separation between ACCESSIBLE PARTS and LIVE parts (see Clause 17). The PATIENT currents allowed where CREEPAGE DISTANCE and AIR CLEARANCES are less than the values in Sub-clause 57,10 were changed from the values for SINGLE FAULT CONDITION to those for NORMAL CONDITION.

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

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

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

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

The allowable ENCLOSURE LEAKAGE CURRENT for TYPE CF EQUIPMENT in NORMAL CONDITION was changed from 0.01 mA to 0.1 mA.

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

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

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

Clause 20 was rearranged in a number of ways:

- The requirements for the insulation between the MAINS PART and other parts were extended to include all LIVE parts, but restricted to cases where a SAFETY HAZARD would develop.
- For each particular insulation a statement was added to clarify that such insulation would be BASIC, SUPPLEMENTARY, DOUBLE or REINFORCED INSULATION.
- As a result all references to the Class of EQUIPMENT (I, II, INTERNALLY POWERED) could be deleted and Tables V, VI and VII replaced by one new much simplified Table V. Test voltages for reference voltages of more than 10000 V were referred to Particular Standards.
- The insulation between an F-TYPE APPLIED PART and the BODY of the EQUIPMENT was reviewed to distinguish the case where such an APPLIED PART would contain voltages which would make the PATIENT LIVE when the insulation would become defective (see new categories B-d and B-e).
- Sub-clauses 20.1, 20.2, 20.3 and 20.4 were rearranged to include exclusively all statements pertaining to their titles.
- The new version of Clause 20 has led to an important simplification of Sub-clause 57.10 in Section Ten (AIR CLEARANCES and CREEPAGE DISTANCES).

A1.3 *Protection against electric shock hazards*

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

- prevention of contact between the body of the PATIENT, the OPERATOR, or a third person and parts which are LIVE or may become LIVE in the case of an insulation failure, by means of enclosing, guarding or mounting in inaccessible locations;
- restriction of voltages on or currents from parts which may be touched intentionally or unintentionally by the PATIENT, the OPERATOR or a third person. These voltages or currents may be present during NORMAL USE or may appear in SINGLE FAULT CONDITION.

Generally, this protection is obtained by a combination of:

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

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

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

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the EQUIPMENT, leads to a 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.

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

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

The requirements for LEAKAGE CURRENT were formulated taking into account:

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

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

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

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

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

A1.4 *Protection against mechanical hazards*

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

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

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

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

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

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

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

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

A1.5.1 Radiation from MEDICAL ELECTRICAL EQUIPMENT may occur in all forms known in physics. Safety requirements are concerned with unwanted radiation. Protective measures are necessary for EQUIPMENT and for the environment and methods for determining levels of radiation must be standardized.

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

Their evaluation is possible only by adequate study of operating methods and duration of operation of EQUIPMENT and positioning of 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.

A1.5.2 High frequency radiation above 0.15 MHz is normally directly harmful only if produced at substantial energy levels, 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 CISPR publications.

The sensitivity of EQUIPMENT to external interference (electromagnetic field, perturbations of the supply voltage) is under consideration.

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

A1.6.1 *Applicability*

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

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

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

In high voltage parts sparks may be caused by corona. Static discharges may cause sparks.

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

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

A1.6.2 *Industrial equipment and components*

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

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

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

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

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

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

A1.6.3 *Requirements for MEDICAL ELECTRICAL EQUIPMENT*

The location of flammable anaesthetic mixtures is described:

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

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

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

The requirements, limits and tests of this section are based on the results of statistical considerations obtained from experiments with the most readily flammable mixtures of ether vapour with air and with oxygen, using the test apparatus described in Appendix F. This is

justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

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

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

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

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

A1.7 *Protection against excessive temperatures and other safety hazards*

— *Temperatures (see Clause 42)*

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

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

For PATIENT contact, special temperature limits have been set.

— *Preventing fire hazard (Clause 43)*

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

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

— *Pressure vessels (Clause 45)*

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

— *Interruption of the power supply (Clause 49)*

Interruption of the power supply may cause a SAFETY HAZARD.

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

IEC Publication 601-1 is the guideline for all Particular Standards and must therefore contain some requirements of a more general character in order to serve this purpose. So it is necessary to have some generally formulated requirements in Section Eight.

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

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

A1.9 *Abnormal operation and fault conditions causing electric shock, overheating and/or mechanical damage; environmental tests*

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

A2. Rationale to particular clauses and sub-clauses

Clause 1

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

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

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

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

Sub-clause 1.3

A Particular Standard may state:

— clauses of the General Standard which apply without amendment;

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

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

— any additional clauses or sub-clauses.

A Particular Standard may contain:

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

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

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

d) accuracy of working data;

e) extension of environmental conditions.

Sub-clause 2.2.24

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

Sub-clause 2.2.26

TYPE CF EQUIPMENT is primarily intended for DIRECT CARDIAC APPLICATION.

Sub-clause 2.3.2

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

Sub-clause 2.3.4

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

Sub-clause 2.3.7

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

Sub-clause 2.4.3

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

Sub-clause 2.5.4

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

Sub-clause 2.7.6

Cord sets are covered by IEC Publication 320.

Sub-clause 2.11.2

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

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

Sub-clause 2.12.2

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

Sub-clause 3.6

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

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

This condition can only be relied upon if either:

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

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

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

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

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

a) REINFORCED or DOUBLE INSULATION;

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

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

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

Sub-clause 3.6c)

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

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

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

Clause 4

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

Sub-clause 4.1

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

Such measures may take the form of:

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

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

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

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

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

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

Suggested test parameters could be leakage current and dielectric strength.

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

Sub-clause 4.3

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

Sub-clause 4.8

The aim is to verify that EQUIPMENT is operating properly.

Sub-clause 4.10

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

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

b) According to Sub-clause 2.2.28, the ENCLOSURE of WATER-TIGHT EQUIPMENT prevents, under stated conditions, the entry of an amount of water where its presence could cause a SAFETY HAZARD.

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

c) To prevent condensation when EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet must be equal to or slightly lower than the temperature of the EQUIPMENT when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of +20°C to +32°C and then "stabilized" at the initial value. Although the effect of the cabinet temperature on the degree of absorption of humidity is recognized, it is felt that the reproducibility of test results is not impaired substantially and the cost-reducing effect is considerable.

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

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

Clause 5

EQUIPMENT may have a multiple classification.

Sub-clause 5.1

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

Sub-clause 6.1f)

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it may possible not denote the exaxt 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.

Sub-clause 6.1z)

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

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

C_2H_8O (MW60.1) — Propanol. Isopropyl alcohol. A clear colourless liquid with a characteristic odour, mixable with water and with alcohol. It has a relative density of about 0.785, boiling-point 81 °C to 83 °C.

Sub-clause 6.7

For colours of indicator lights see also IEC Publication 73.

Sub-clause 6.8.1

The subject of languages used in markings and in ACCOMPANYING DOCUMENTS cannot be solved by IEC. Even a requirement that identifications and ACCOMPANYING DOCUMENTS have to be in the national languages cannot be upheld worldwide.

Sub-clause 6.8.2b)

Responsibility of the manufacturer

The instructions for use may 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, readjustments, modifications or repairs are carried out by persons authorized by him,
- the electrical installation of the relevant room complies with the appropriate requirements, and
- the EQUIPMENT is used in accordance with the instructions for use.

Sub-clause 10.2.1

These environmental conditions are based on the conditions in buildings without air-conditioning in climates where the ambient temperature occasionally reaches +40 °C.

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

Sub-clause 10.2.2

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

In this Standard such effects are covered in a number of safety tests.

According to Fortescue's theorem any unbalanced polyphase system can be resolved in three balanced systems of phases:

a) a system of so-called positive sequence components of equal magnitude and phase angle, but having the opposite phase sequence as the original system;

b) a system of so-called negative sequence components of equal magnitude and phase angle, but having the same phase sequence as the original system;

c) a system of so-called zero sequence components of equal magnitude, no mutual phase angle (in phase) and no phase sequence (stationary vectors). Systems without a neutral conductor cannot have zero sequence current components.

The zero sequence current can be determined as the sum of the three phase currents divided by three.

Thus the neutral current is three times the zero sequence current.

Literature: — Elements of Power Systems Analysis
W.D. Stevenson, jr.
McGraw Hill (page 272)

— IEEE Vol 37 Part II (1918)
page 1329

Modern Power Systems
Neuenswonder
page 183, Measurement of Zero Sequence.

Sub-clause 14.1b)

EQUIPMENT, specified for an external d.c. power source (e.g. for use in an ambulance), has to satisfy all requirements for CLASS I or CLASS II EQUIPMENT.

Sub-clause 14.4

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

Clause 16

ENCLOSURES and PROTECTIVE COVERS are intended to provide protection for human beings against contact with parts that are LIVE or may become LIVE after a single failure of protective insulation. They may, at the same time, provide protection against other hazards (mechanical, thermal, chemical, etc.).

"Accidental contact" means that parts are touched in NORMAL USE by a human being, without the aid of a TOOL and without appreciable force.

Except in special cases, such as PATIENT supports and waterbeds, contact with EQUIPMENT is supposed to be made with:

— one hand, simulated by a metal foil of 10 cm × 20 cm (or less if the total EQUIPMENT is smaller);

— one finger, straight or bent in a natural position, simulated by a test finger provided with a stop plate;

— a pencil or pen, held in a hand, simulated by a guided test pin;

— a necklace or similar pendant, simulated by a metal rod suspended over openings in a top cover;

— a screwdriver for adjustment of a preset control by the USER, simulated by an inserted metal rod;

— an edge or slit that can be pulled outward allowing subsequent entry of a finger, simulated by a combination of test hook and test finger.

Other devices are not permitted unless they are necessary for the compliance check.

Sub-clause 16a) 5)

This sub-clause is also intended to cover those cases where EQUIPMENT is remotely controlled by means of a hand-held control box, usually connected to the mainframe of the EQUIPMENT by means of a multiconductor flexible cable.

Usually control circuits are operated at extra-low voltage or even at SAFETY EXTRA-LOW VOLTAGE. Control currents and cross-sections of conductors are usually small.

Protective earthing of the ENCLOSURE of the control box would not be very effective (high resistance).

DOUBLE INSULATION would consume a lot of space and weight and control switches and push buttons of miniature size would not be available with REINFORCED INSULATION.

Where it is unlikely in NORMAL USE that the control box and a PATIENT are touched simultaneously, the control box may be made with BASIC INSULATION only, with a metal ENCLOSURE or an ENCLOSURE made of insulating material.

The insulation may be designed for extra-low voltage.

Sub-clause 16c)

The compliance test for the protective earthing of ACCESSIBLE METAL PARTS of EQUIPMENT (Sub-clause 18*l)* is conducted with a current between 10 A and 25 A provided by a source with a sufficiently low voltage (not exceeding 6 V). The current is maintained for at least 5 s. The reasons for these requirements are that the connection can only perform its protective function if it is able to carry the fault current resulting from a failure in BASIC INSULATION.

Such a current is assumed to have sufficient amplitude to cause operation of protective devices in the electrical installation (fuses, circuit-breakers, earth leakage circuit-breakers and the like) in a reasonably short time.

The minimum time required for the test current is intended to reveal any overheating of parts of the connection due to thin wiring or a bad contact. Such a "weak spot" may not be discovered by resistance measurement alone.

Where conductive parts of actuating mechanism of electrical controls are PROTECTIVELY EARTHED the required maximum resistance is 0.2 Ω, the minimum test current is 1 A, the maximum source voltage is 50 V and there is no minimum time other than the time needed for reading the test instruments.

This relaxation is justified because:

a) Where actuating mechanisms are fragile and not able to carry a test current of 10 A to 25 A, they are usually part of a secondary circuit and the fault current through the connection will be limited.

b) In connection with this, maximum resistance may be raised because it forms a smaller fraction of the total fault circuit impedance. The source voltage and testing time are less critical, a burn-out of the protective connection is unlikely.

Sub-clause 16d)

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

Clause 17

Air may form part or all of the BASIC INSULATION and/or SUPPLEMENTARY INSULATION.

Sub-clause 18a)

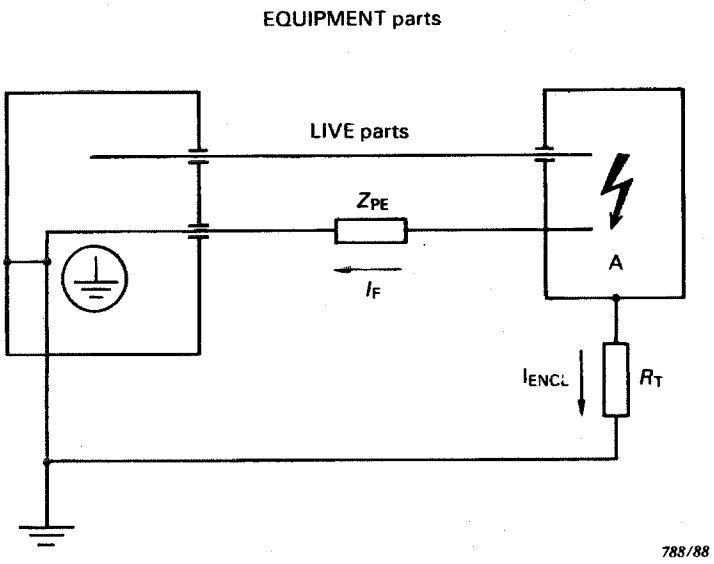
Generally, ACCESSIBLE CONDUCTIVE PARTS of CLASS I EQUIPMENT shall be connected permanently and with sufficiently low impedance to the PROTECTIVE EARTH TERMINAL.

However, CLASS I EQUIPMENT may contain ACCESSIBLE PARTS which are so separated from the MAINS PART that, in NORMAL CONDITION and SINGLE FAULT CONDITION of the insulation of the MAINS PART or of the protective earthing, the LEAKAGE CURRENT from these ACCESSIBLE PARTS to earth does not exceed the value of Table IV (see Clause 19).

In this case, these ACCESSIBLE PARTS need not be connected to a PROTECTIVE EARTH TERMINAL but they may be connected to, for example, a FUNCTIONAL EARTH TERMINAL, or they may be left floating.

The separation of ACCESSIBLE METAL PARTS from the MAINS PART may be obtained by DOUBLE INSULATION, by metallic screening or by a PROTECTIVELY EARTHED ACCESSIBLE METAL PART or a PROTECTIVELY EARTHED secondary circuit, separating the ACCESSIBLE METAL PARTS completely from the MAINS PART.

Metal parts behind a decorative cover, which does not comply with the mechanical strength test, are regarded as ACCESSIBLE METAL PARTS.



Legend

A = Short circuiting between two parts.

Z_{PE} = Impedance of protective earth connection in ohms (exceeding 0.1 Ω).

I_F = Maximum continuous prospective fault current in amperes in the protective earthing connection caused by a single failure of the insulation to earth.

I_{ENCL} = Allowable value of the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION.

R_T = Test resistance (1 Ω).

The fault current may be limited to a relatively low value, because of inherent impedance or the characteristic of the power source, for example where the power system is not connected to earth or connected to it via a high impedance.

In such cases the cross-section of the protective earthing connection may be determined primarily by mechanical considerations.

Sub-clause 19.1d)

The ENCLOSURE LEAKAGE CURRENT of CLASS I EQUIPMENT from PROTECTIVELY EARTHED parts is negligible in NORMAL CONDITION.

Sub-clause 19.2a)

The breakdown of BASIC INSULATION in CLASS I EQUIPMENT is not generally regarded as a SINGLE FAULT CONDITION as the LEAKAGE CURRENTS in this case cannot be kept within allowable limits (Table IV) during the time before a fuse, or OVER-CURRENT RELEASE operates. Exceptionally, LEAKAGE CURRENTS are measured during short-circuiting BASIC INSULATION in cases where there are doubts concerning the effectiveness of protective earth connections inside the EQUIPMENT (see Sub-clauses 17*a)* and 17*g)*).

Sub-clause 19.3 and Table IV

Allowable values of continuous LEAKAGE and PATIENT AUXILIARY CURRENTS for a.c. and d.c. composite waveforms with frequencies up to and including 1 kHz.

- In general the risk of ventricular fibrillation or pump failure increases with the value or duration, up to a few seconds, of the current passing through the heart. Some areas of the heart are more sensitive than others. That is, a current that causes ventricular fibrillation when applied to one part of the heart may have no effect when applied to another part of the heart.
- The risk is highest and approximately equal for frequencies in the 10 to 200 Hz range. It is lower, by a factor of nearly 5, at d.c. and by approximately 1.5 at 1 kHz. Beyond 1 kHz, the risk decreases rapidly.[1] The values in Table IV cover the range from d.c. to 1 kHz. SUPPLY MAINS frequencies of 50 and 60 Hz are in the range of highest risk.

- Although as a general rule requirements in a General Standard are less restrictive than the requirements in Particular Standards, some of the allowable values in Table IV have been set at such a value that:
  a) the majority of EQUIPMENT types can comply, and
  b) they can be applied to most EQUIPMENT types (existing or future) for which no Particular Standards exist.

EARTH LEAKAGE CURRENT

- The allowable values for EARTH LEAKAGE CURRENT are not critical and have been chosen to avoid any significant increase in the currents flowing through the protective earthing system of the installation.
- In Note 2) to Table IV is stated under which conditions higher EARTH LEAKAGE CURRENTS are allowed if internal conductive parts are not accessible.

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[1] See references page 299.

— In Note 3) to Table IV is stated that EQUIPMENT with a fixed and permanently installed PROTECTIVE EARTH CONDUCTOR may have higher allowable EARTH LEAKAGE CURRENTS as the accidental interruption of the PROTECTIVE EARTH CONDUCTOR is very unlikely.

ENCLOSURE LEAKAGE CURRENT

The limits are based on the following considerations:

a) The ENCLOSURE LEAKAGE CURRENT of TYPE CF EQUIPMENT in NORMAL CONDITION was raised to the same level as for TYPES B, BF EQUIPMENT because such EQUIPMENT may be used simultaneously on a PATIENT.

b) The ENCLOSURE LEAKAGE CURRENT may flow through the PATIENT to earth. In the case of TYPE B EQUIPMENT via the APPLIED PART and in the case of TYPE BF and CF EQUIPMENT by indirect contact with the ENCLOSURE via the OPERATOR.

The current density created at the heart by current entering the chest is 50 $\mu A/mm^2$ per ampere.[8] The current density at the heart for 500 μA (maximum allowable value in SINGLE FAULT CONDITION) entering the chest is 0.025 $\mu A/mm^2$, well below the level of concern.

c) The probability of the ENCLOSURE LEAKAGE CURRENT flowing through the heart and causing ventricular fibrillation or pump failure.

ENCLOSURE LEAKAGE CURRENT could conceivably reach an intracardiac site if careless procedures are used in handling intracardiac conductors or fluid filled catheters. Such devices should always be handled with great care and always with dry rubber gloves.

The probability of a direct contact between an intracardiac device and an EQUIPMENT ENCLOSURE is considered to be very low, perhaps 1 in 100 procedures. The probability of an indirect contact via the medical staff is considered to be somewhat higher, say 1 in 10 procedures. The maximum allowable LEAKAGE CURRENT in NORMAL CONDITION is 100 μA which itself has a probability of inducing ventricular fibrillation of 0.05. If the probability of indirect contact is 0.1 then the overall probability is 0.005. Although this probability would appear undesirably high, it should be recalled that with correct handling of the intracardiac device this probability can be reduced to that for mechanical stimulation alone, 0.001.

The probability of the ENCLOSURE LEAKAGE CURRENT rising to the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) is considered to be 0.1 in departments with poor maintenance procedures. The probability of this current causing ventricular fibrillation is taken as 1. The probability of accidental contact directly with the ENCLOSURE is, as above, considered as 0.01, giving an overall probability of 0.001, equal to the mechanical stimulation alone probability.

The probability of ENCLOSURE LEAKAGE CURRENT at the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) being conducted to an intracardiac device via the medical staff is 0.01 (0.1 for the SINGLE FAULT CONDITION, 0.1 for accidental contact). Since the probability of this current causing ventricular fibrillation is 1, the overall proba-

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[8] See references page 299.

bility is also 0.01. Again this probability is high; however it can be brought down to the mechanical stimulation alone probability of 0.001 by adequate procedures.

d) The probability of the ENCLOSURE LEAKAGE CURRENT being perceptible to the PATIENT.

The probability of 500 μA being perceptible is 0.01 for men and 0.014 for women when using grip electrodes with intact skin.[1,2] There is a higher perceptibility for current passing through mucous membranes or skin punctures.[2] Since distribution is normal[1], there will be a probability that some PATIENTS will perceive very small currents. One person is reported to have sensed 4 μA passing through a mucous membrane.[2]

ENCLOSURE LEAKAGE CURRENT for TYPE B, BF and CF EQUIPMENT is made equal because all types of EQUIPMENT may be used simultaneously on a PATIENT.

PATIENT LEAKAGE CURRENT

The allowable value of PATIENT LEAKAGE CURRENT for TYPE CF EQUIPMENT in NORMAL CONDITION is 10 μA which has a probability of 0.002 for causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site.

Even with zero current, it has been observed that mechanical irritation can produce ventricular fibrillation.[4] A limit of 10 μA is readily achievable and does not significantly increase the risk of ventricular fibrillation during intracardiac procedures.

The 50 μA maximum allowed in SINGLE FAULT CONDITION for TYPE CF EQUIPMENT is based on a value of current which has been found, under clinical conditions, to have a very low probability of causing ventricular fibrillation or interference with the pumping action of the heart.

For catheters 1.25–2 mm diameter likely to contact the myocardium, the probability of 50 μA causing ventricular fibrillation is near 0.01 (see Figure A1 and its explanation). Small cross-section area (0.22 mm^2 and 0.93 mm^2) catheters used in angiography have higher probabilities of causing ventricular fibrillation or pump failure if placed directly on sensitive areas of the heart.

The overall probability of ventricular fibrillation being caused by PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION is 0.001 (0.1 for probability of SINGLE FAULT CONDITION, 0.01 probability of 50 μA causing ventricular fibrillation) equal to the probability for mechanical stimulation alone.

The 50 μA current allowed in SINGLE FAULT CONDITION is not likely to result in a current density sufficient to stimulate neuromuscular tissues nor, if d.c., cause necrosis.

For TYPE B and TYPE BF EQUIPMENT where the maximum allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION is 500 μA, the same rationale applies as that for ENCLOSURE LEAKAGE CURRENT since this current will not flow directly to the heart.

[1, 2, 4] See references page 299.

The probability of MAINS VOLTAGE appearing on the PATIENT is considered to be extremely low. For this to happen the following faults must have occurred:

a) failure of PROTECTIVE EARTHING of CLASS I EQUIPMENT (probability of 0.1);

b) a fault in BASIC INSULATION. The probability, based on experience, is less than 0.01.

This gives an overall probability of 0.001 of MAINS VOLTAGE appearing on the PATIENT.

For TYPE CF EQUIPMENT the PATIENT LEAKAGE CURRENT will be limited to 50 μA, no worse than the previously discussed SINGLE FAULT CONDITION.

For TYPE BF EQUIPMENT the maximum PATIENT LEAKAGE CURRENT under these conditions is 5 mA. Even this value entering the chest would produce only a current density at the heart of 0.25 $\mu A/mm^2$. This current would be very perceptible to the PATIENT, however the probability of its occurrence is very low.

PATIENT AUXILIARY CURRENT

The allowable values for PATIENT AUXILIARY CURRENT are for EQUIPMENT such as impedance plethysmographs, these apply to currents having a frequency not less than 0.1 Hz. Lower values are given for d.c. to prevent tissue necrosis with long-term application.