UL 60601-1

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Medical Electrical Equipment, Part 1: General Requirements for Safety

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UL Standard for Safety for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 60601-1

First Edition, Dated April 25, 2003

Revisions: This Standard contains revisions through and including April 26, 2006.

Summary of Topics

These editorial revisions to UL 60601-1 replace all references to UL 1020, the Standard for Thermal Cutoffs for Use in Electrical Appliances and Components, with reference to UL 60691, the Standard for Thermal-Links – Requirements and Application Guide. UL 1020 was withdrawn and superseded by UL 60691.

Announcement Bulletin(s): This Standard contains the announcement bulletin(s) dated July 16, 1997, May 10, 1999 and June 16, 2000. The announcement bulletin is located at the end of the Standard (after the adoption bulletin(s)).

UL Standards for Safety are developed and maintained in the Standard Generalized Markup Language (SGML). SGML -- an international standard (ISO 8879-1986) -- is a descriptive markup language that describes a document's structure and purpose, rather than its physical appearance on a page. Due to formatting differences resulting from the use of UL's new electronic publishing system, please note that additional pages (on which no requirements have been changed) may be included in revision pages due to relocation of existing text and reformatting of the Standard.

Text that has been changed in any manner is marked with a vertical line in the margin. Changes in requirements are marked with a vertical line in the margin and are followed by an effective date note indicating the date of publication or the date on which the changed requirement becomes effective.

The revisions dated April 26, 2006 include a reprinted title page (page1) for this Standard.

The revisions dated April 26, 2006 editorially replace all references to UL 1020 with the reference to UL 60691.

The UL Foreword is no longer located within the UL Standard. For information concerning the use and application of the requirements contained in this Standard, the current version of the UL Foreword is located on ULStandardsInfoNet at: http://ulstandardsinfonet.ul.com/ulforeword.html

The master for this Standard at UL's Northbrook Office is the official document insofar as it relates to a UL service and the compliance of a product with respect to the requirements for that product and service, or if there are questions regarding the accuracy of this Standard.

Revisions of UL Standards for Safety are issued from time to time. A UL Standard for Safety is current only if it incorporates the most recently adopted revisions.

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The requirements in this Standard are now in effect, except for those paragraphs, sections, tables, figures, and/or other elements of the Standard having future effective dates as indicated in the preface. The prior text for requirements that have been revised and that have a future effective date are located after the Standard, and are preceded by a ″SUPERSEDED REQUIREMENTS″ notice.

New product submittals made prior to a specified future effective date will be judged under all of the requirements in this Standard including those requirements with a specified future effective date, unless the applicant specifically requests that the product be judged under the current requirements. However, if the applicant elects this option, it should be noted that compliance with all the requirements in this Standard will be required as a condition of continued Listing, Recognition, Classification and Follow-Up Services after the effective date, and understanding of this should be signified in writing.

This Standard consists of pages dated as shown in the following checklist:

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UL 60601-1

Medical Electrical Equipment, Part 1: General Requirements for Safety

Prior to the first edition of UL 60601-1, the requirements for the products covered by this Standard were included in UL 2601-1. This Standard replaces UL 2601-1.

First Edition

April 25, 2003

An effective date included as a note immediately following certain requirements is one established by Underwriters Laboratories Inc.

Revisions of this Standard will be made by issuing revised or additional pages bearing their date of issue. A UL Standard is current only if it incorporates the most recently adopted revisions, all of which are itemized on the transmittal notice that accompanies the latest set of revised requirements.

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UL INTRODUCTION

This is an explanation of the intended implementation of Particular and Collateral Requirements associated with product evaluation using this standard. For continuity some of the introductory information from IEC 60601-1 is repeated here.

PARTICULAR STANDARDS:

UL 60601-1 contains requirements for safety which are generally applicable to all medical electrical equipment. For certain types of equipment, these requirements are to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Requirements exist, the General Standard should not be used alone. Special care is required in applying the General Standard to equipment for which no Particular Standard exists.

COLLATERAL STANDARDS:

When the equipment falls within the scope of one or more Collateral Standards, such standard(s) may, optionally, also be used.

Note – Where any of these (Collateral and Particular) standards are not yet published by UL, then the corresponding IEC Publications are used.

Preface (UL)

This UL Standard is based on IEC Publication 60601-1: Second Edition – Medical Electrical Equipment, Part 1: General Requirements for Safety, as revised by Amendments 1 and 2. IEC publication 60601-1 is copyrighted by the IEC.

The text, figures and tables of IEC Publication Medical Electrical Equipment, Part 1: General Requirements for Safety, IEC 60601-1 copyright 1988 as amended in 1991 and 1995, are used in this Standard with the consent of the IEC and the American National Standards Institute (ANSI). The IEC copyrighted material has been reproduced with permission from ANSI. ANSI should be contacted regarding the reproduction of any portion of the IEC material. The IEC Foreword and Introduction are not a part of the requirements of this Standard but are included for information purposes only. Copies of IEC Publication 60601-1 may be purchased from ANSI, 11 West 42nd Street, New York, New York, 10036, (212) 642-4900.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

UL Effective Date

As of June 30, 2003, all products Listed by UL must comply with the requirements in this Standard except for Clause 6.3 (g), which is effective February 6, 2004.

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NATIONAL DIFFERENCES

GENERAL

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

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

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

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

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

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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

It forms the second edition of IEC Publication 601-1 (1977), entitled “Safety of medical electrical equipment, Part 1: General requirements”.

The text of this Standard is based on the following documents:

Six Months’ Rule	Report on Voting	Two Months’ Procedure	Report on Voting
62A(CO)24	62A(CO)25	62A(CO)27	62A(CO)33

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

Amendment 1 has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

Six Months’ Rule	Report on Voting
62A(CO)36	62A(CO)39

Full information on the voting for the approval of this amendment can be found in the Voting Report indicated in the above table.

Amendment 2 has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

DIS	Report on voting
62A(CO)45	62A/181/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The list of IEC, ISO and other publications quoted in this Standard will be found in Appendix L.

In this Standard, the following print types are used:

Requirements, compliance with which can be tested and definitions: in roman type.

Explanations, advice, introductions, general statements, exceptions and references: in smaller roman type.

Test specifications and headings of sub-clauses: in italic type.

TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: SMALL CAPITALS

* Rationale (Appendix A).

DV.1 DE *Addition:*

The numbering system in the standard uses a space instead of a comma to indicate thousands and uses a comma instead of a period to indicate a decimal point. For example, 1 000 means 1,000 and 1,01 means 1.01.

DV.2 DE *Addition:*

Due to pagination differences, references to page numbers in the IEC text have been modified to reference the correct information.

DV.3 DE *Modification of the print types:*

Notes have been added to requirements that have corresponding rationales located in Appendix A and Annex DVC.

INTRODUCTION

Amendment 1 contains a first series of revisions to IEC Publication 601-1 (second edition, 1988): Medical electrical equipment, Part 1: General requirements for safety.

Aware of the need and the urgency for a General Standard covering electromedical EQUIPMENT, the majority of National Committees voted in 1977 in favour of the first edition of IEC 601-1, based on a draft which at the time represented a first approach to the problem.

The extent of the scope, the complexity of the EQUIPMENT concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, had required years of effort in order to prepare that first Standard, which served as a universal reference since its publication.

However, its frequent application revealed room for improvement, and careful work of revision subsequently undertaken and continued over a number of years resulted in the second edition (1988). The present publication contains further modifications.

The General Standard contains requirements of safety which are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of EQUIPMENT, these requirements are supplemented or modified by the special requirements of a Particular Standard. Where Particular Standards exist, the General Standard should not be used alone. Special care is required in applying the General Standard to EQUIPMENT for which no Particular Standard exists.

In some countries EQUIPMENT may only be certified as complying with the Standard if either a Particular Standard or an authorized document based on the General Standard is available, stating which clauses are applicable for the EQUIPMENT concerned.

Amendment 2 contains a second series of revisions to IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*.

It is intended to facilitate interpretation and application of the General Standard. It also identifies additional aspects of safety which were not previously covered. Significant changes include the following:

– APPLIED PARTS are now identified by requirements covering the possibility of physical contact with the PATIENT during NORMAL USE, without electrical considerations; individual PATIENT CONNECTIONS are then defined by requirements concerning electrical contact with the PATIENT during NORMAL USE;

– classification of the degree of protection against electric shock (TYPES CF/BF/B) is not related any more to the word EQUIPMENT but now clearly relates to individual APPLIED PARTS; it is more logical because the degree of protection is determined in fact by that of the APPLIED PART; this means no extra requirements and tests but more differentiation and clarification of the required actions;

– general requirements are included for EQUIPMENT in which the APPLIED PART is marked as providing protection against the discharge voltage from a defibrillator and for which there is no Particular Standard;

– limits for the d.c. component of PATIENT LEAKAGE CURRENT are included to align with the requirement for PATIENT AUXILIARY CURRENT;

– clarification concerning the degree of protection against ingress of liquids by using IP Code, as detailed in the basic safety publication IEC 529 is an improvement;

– the term ″not used″, which was introduced in the second edition of IEC 601-1, is replaced, where applicable, by the wording ″no general requirement″ in order to avoid misunderstanding; this means that a Particular Standard may specify requirements if it is deemed necessary;

– references to existing IEC Collateral Standards 601-1-1, 601-1-2, 601-1-3 and future IEC 601-1-4 (see Appendix L), are included;

– additional requirements are included regarding the information which must be supplied by the manufacturer in order to improve the international acceptance of symbols and units and to provide more information about the intended use of the EQUIPMENT; the latter is becoming necessary due to the relation with performance safety aspects;

– some requirements and test methods have been aligned with other existing IEC standards;

– a number of accidents having being reported due to USER error during the use of biopotential connectors (as electrodes having attached leads terminating in 2 mm exposed metal pin connectors), some additional requirements have been introduced to prevent the recurrence of such accidents whatever the type of EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety

SECTION ONE – GENERAL

1 *Scope and object

*See rationale for 1

1.1 *Scope*

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

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

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

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

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

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

*See rationale for 1.1DV

1.2 *Object*

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

1.3 ***Particular Standards***

A Particular Standard takes priority over this General Standard.

*See rationale for 1.3

1.4 *Environmental conditions*

See Section Two.

1.5 *Collateral Standards*

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

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

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

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

2 Terminology and definitions[+]

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

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

– The auxiliary verb:

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

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

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

[+]The defined terms are alphabetically listed in the Index.

2.1 *EQUIPMENT parts, auxiliaries and ACCESSORIES*

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

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

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

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

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

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

– can be brought into contact with the PATIENT; or

– needs to be touched by the PATIENT.

*See rationale for 2.1.5

2.1.6 ENCLOSURE: Exterior surface of EQUIPMENT including:

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

– accessible shafts;

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

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

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

2.1.8 Not used.

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

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

2.1.11 Not used.

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

2.1.13 Not used.

2.1.14 Not used.

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

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

*See rationale for 2.1.15

2.1.16 Not used.

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

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

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

2.1.20 Not used.

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

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

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

*See rationale for 2.1.23

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

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

*See rationale for 2.1.24

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

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

*See rationale for 2.1.25

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

*See rationale for 2.1.26

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

*See rationale for 2.1.27

2.2 *EQUIPMENT types (classification)*

2.2.1 Not used.

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

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

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

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

2.2.6 Not used.

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

2.2.8 Not used.

2.2.9 Not used.

2.2.10 Not used.

2.2.11 EQUIPMENT (see Sub-clause 2.2.15)

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

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

2.2.14 Not used.

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

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

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

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

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

2.2.19 Not used.

2.2.20 Not used.

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

2.2.22 Not used.

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

Examples: MOBILE EQUIPMENT and PORTABLE EQUIPMENT.

2.2.24 Not used.

2.2.25 Not used.

2.2.26 Not used.

2.2.27 Not used.

2.2.28 Not used.

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

2.3 *Insulation*

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

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

*See rationale for 2.3.2

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.

*See rationale for 2.3.4

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.

*See rationale for 2.3.7

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.

*See rationale for 2.4.3

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.

*See rationale for 2.5.4

2.5.5 Not used.

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

2.6 *Earth terminals and conductors*

2.6.1 Not used.

2.6.2 Not used.

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

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

*See rationale for 2.6.4

2.6.5 Not used.

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

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

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

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

2.7 *Electrical connection (devices)*

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

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

2.7.3 Not used.

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

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

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

*See rationale for 2.7.6

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

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

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

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

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

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

2.7.13 Not used.

2.7.14 Not used.

2.7.15 Not used.

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

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

2.8 *Transformers*

2.8.1 Not used.

2.8.2 Not used.

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

2.8.4 Not used.

2.8.5 Not used.

2.8.6 Not used.

2.9 *Controls and limiting devices*

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

2.9.2 Not used.

2.9.3 Not used.

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

2.9.5 Not used.

2.9.6 Not used.

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

2.9.8 Not used.

2.9.9 Not used.

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

2.9.11 Not used.

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

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

2.10 *Operation of* EQUIPMENT

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

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

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

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

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

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

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

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

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

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

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

2.10.12DV DR *Addition:*

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

*See rationale for 2.10.12DV

2.10.13DV DR *Addition:*

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

*See rationale for 2.10.13DV

2.11 *Mechanical safety*

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

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

*See rationale for 2.11.2

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

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

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

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

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

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

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

2.12 *Miscellaneous*

2.12.1 Not used.

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

*See rationale for 2.12.2

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

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

2.12.5 Not used.

2.12.6 Not used.

2.12.7 Not used.

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

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

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

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

2.12.11 Not used.

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

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

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

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

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

2.12.17 OPERATOR: Person handling EQUIPMENT.

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

2.12.19DV D2 *Addition:*

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

2.12.20DV D2 *Addition:*

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

*See rationale for 2.12.20DV

2.12.21DV D2 *Addition:*

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

3 General requirements

3.1 EQUIPMENT shall, when transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, cause no SAFETY HAZARD which could reasonably be foreseen and which is not connected with its intended application, in NORMAL CONDITION and in SINGLE FAULT CONDITION.

3.2 Not used.

3.3 Not used.

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

3.5 Not used.

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

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

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

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

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

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

f) leakage of liquid (see subclause 44.4)

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

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

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

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

*See rationale for 3.6

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

a) total electrical breakdown of a DOUBLE INSULATION;

b) electrical breakdown of a REINFORCED INSULATION;

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

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

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

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

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

*See rationale for 3.10DV

3.10DV.1 Components

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

a) Printed wiring boards

b) Lithium batteries

c) Optical isolators

d) Wiring and tubing

e) CRTs > 5 inches

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

3.10DV.2 Primary circuit components

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

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

4 *General requirements for tests

*See rationale for 4

4.1 ***Tests***

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

*See rationale for 4.1

4.2 *Repetition of tests*

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

4.3 ***Number of samples***

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

Exceptionally, an additional sample may be required.

*See rationale for 4.3

4.4 *Components*

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

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

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

4.5 *Ambient temperature, humidity, atmospheric PRESSURE*

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

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

Table I
Specified atmospheric conditions

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

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

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

4.6 *Other conditions*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4.8 ***Preconditioning**

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

*See rationale for 4.8

4.9 *Repairs and modifications*

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

4.10 ***Humidity preconditioning treatment**

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

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

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

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

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

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

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

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

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

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

*See rationale for 4.10

4.11 *Sequence*

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

5 *Classification

*See rationale for 5

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

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

a) EQUIPMENT energized from an external electrical power source:

– CLASS I EQUIPMENT;

– CLASS II EQUIPMENT.

b) INTERNALLY POWERED EQUIPMENT.

*See rationale for 5.1

5.2 According to the degree of protection against electric shock:

– TYPE B APPLIED PART;

– TYPE BF APPLIED PART;

– TYPE CF APPLIED PART.

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

5.4 According to the method(s) of sterilization or disinfection recommended by the manufacturer.

5.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

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

– CATEGORY AP EQUIPMENT;

– CATEGORY APG EQUIPMENT.

5.6 According to the mode of operation:

– CONTINUOUS OPERATION;

– SHORT-TIME OPERATION;

– INTERMITTENT OPERATION;

– CONTINUOUS OPERATION WITH SHORT-TIME LOADING;

– CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

5.7 Not used.

5.8 Not used.

6 Identification, marking and documents

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

– Permanently affixed:

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

– Clearly legible:

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

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

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

– Major part:

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

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

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

*See rationale for 6DV

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

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

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

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

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

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

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

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

a) Mains operated EQUIPMENT

Mains operated EQUIPMENT, including separable components thereof which have a MAINS PART, shall be provided at least with ″permanently affixed″ and ″clearly legible″ markings on the ″major part″ of EQUIPMENT as described in Table II, Column 3.

b) INTERNALLY POWERED EQUIPMENT

INTERNALLY POWERED EQUIPMENT shall be provided at least with the following ″permanently affixed″ and ″clearly legible″ markings on the ″major part″ of EQUIPMENT as described in Table II, Column 4.

c) EQUIPMENT supplied from a specified power supply

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

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

Table II
Marking on the outside of EQUIPMENT

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

x Marking required.
[1)] If applicable.
[2)] Not for PERMANENTLY INSTALLED EQUIPMENT if marked on the inside. See also Sub-clause 6.2*a)*.

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

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

e) Indication of origin

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

**f) MODEL OR TYPE REFERENCE*

g) Connection to the supply

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

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

h) Supply frequency

RATED frequency or RATED frequency range in hertz.

j) Power input (see Clause 7)

The RATED input shall be given in amperes or volt-amperes or in watts where the power factor exceeds 0,9.

In the case of EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of the range or ranges, if the range(s) is/are greater than ±10% of the mean value of the given range.

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

If the rating of EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the marking shall include both long-time and the most relevant momentary volt-ampere rating, each plainly identified and indicated in the ACCOMPANYING DOCUMENTS.

The marked input of EQUIPMENT provided with means for the connection of supply conductors of other EQUIPMENT shall include the RATED (and marked) output of such means.

k) Mains power output

AUXILIARY MAINS SOCKET OUTLET(S) of EQUIPMENT shall be marked with the maximum allowed output.

l) Classification

– The symbol for CLASS II EQUIPMENT, if relevant (see Appendix D, Table DI, Symbol 10).

– A symbol, using the letters IP, followed by X and the relevant characteristic numeral (1 to 8) of IEC Publication 529, according to the degree of protection provided by the ENCLOSURE with respect to harmful ingress of water.

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

– A symbol indicating the type of APPLIED PART according to the degree of protection against electric shock for TYPE B, TYPE BF and TYPE CF APPLIED PARTS (see Appendix D, table DII, symbols 1, 2 and 3).

For clear differentiation with symbol 2, symbol 1 shall not be applied in such a way as to give the impression of being inscribed within a square.

If the EQUIPMENT has more than one APPLIED PART with different degrees of protection, the relevant symbols shall be clearly marked on such APPLIED PARTS, or on or near relevant outlets (connection points).

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

– If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, the symbol 14 in Appendix D, table DI, shall be marked near the relevant outlet.

No Text on This Page

m) Mode of operation

If no marking is provided, EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION.

**n) Fuses*

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

p) Output

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

– Output frequency (where applicable).

q) Physiological effects (symbols and warning statements)

EQUIPMENT producing physiological effects which may cause danger to the PATIENT and/or OPERATOR shall bear a suitable symbol concerning the relevant hazard. The symbol shall appear in a prominent location so that it will be clearly visible after the EQUIPMENT has been installed.

If applicable, symbols for particular hazards, as adopted by ISO or IEC Publication 417, shall be used. For non-ionizing radiation (for example, high-power microwaves), Symbol 8 of Table DII of Appendix D shall be used.

For other hazards, where no specific symbol is available, Symbol 14 of Table DI of Appendix D shall be used.

r) CATEGORY AP/APG EQUIPMENT

For requirements on marking, see Clause 38.

s) HIGH VOLTAGE TERMINAL DEVICES

HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a TOOL shall be marked with the symbol ″dangerous voltage″ (see Appendix D, Table DII, Symbol 6).

t) Cooling conditions

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

u) Mechanical stability

For requirements on EQUIPMENT with a limited stability, see Clause 24.

v) Protective packing

If special measures have to be taken during transport or storage, the packing shall be marked accordingly (see Sub-clauses 6.8.3*d)* and 10.1 and ISO Publication R780).

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

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

w) Not used.

x) Not used.

y) Earth terminals

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

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

**z) Removable protective means*

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

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

– Inspect the presence of required markings on the outside of EQUIPMENT.

– Test the durability of markings.

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

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

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

*See rationale for 6.1

6.2 *Marking on the inside of* EQUIPMENT *or* EQUIPMENT *parts*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

m) Not used.

n) Capacitors and/or the connected circuit parts shall be marked as required in Sub-clause 15*c)*.

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

*See rationale for 6.2

6.2DV D2 *Modification of item l) in 6.2:*

Replace 75°C by 60°C.

*See rationale for 6.2DV

6.3 *Marking of controls and instruments*

a) A mains switch shall be clearly identified. ″ON″ and ″OFF″ positions shall be marked according to the relevant symbols of Appendix D (Symbols 15 and 16 of Table DI), or indicated by an adjacent indicator light or other unambiguous means.

b) Different positions of control devices and different positions of switches on EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by means of Symbols 17 and 18 of Table DI.

c) If in NORMAL USE the change of setting of a control could cause a SAFETY HAZARD to the PATIENT, such controls shall be provided with either:

– an associated indicating device, e.g. instruments or scale, or

– an indication of the direction in which the magnitude of the function changes. See also Sub-clause 56.10*c)*.

d) Not used.

e) Not used.

f) The functions of OPERATOR controls and indicators shall be identified.

g) Numeric indications of parameters shall be in SI units according to ISO 1000 with the following additions:

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

– Plane angle units:

• revolution,

• grade,

• degree,

• minute of angle,

• second of angle;

– Time units:

• minute,

• hour,

• day;

– Energy unit:

• electronvolt;

– PRESSURE of blood and other body fluids:

• millimetre of mercury.

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

6.4 ***Symbols***

a) Symbols used for marking according to Sub-clauses 6.1 to 6.3 shall conform to Appendix D, where applicable. See also Sub-clause 6.1*q)*.

b) Symbols used for controls and performance shall conform to IEC Publication 878, where applicable.

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

*See rationale for 6.4

6.5 *Colours of the insulation of conductors*

a) A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.

b) Any insulation on conductors inside EQUIPMENT which connect ACCESSIBLE METAL PARTS or other PROTECTIVELY EARTHED parts with a protective function to the PROTECTIVE EARTH TERMINAL shall be identified by the colours green and yellow at least at the termination of the conductors.

c) Identification by green and yellow insulation shall only be used for:

– PROTECTIVE EARTH CONDUCTORS (see Sub-clause 18*b)*);

– Conductors as specified in Sub-clause 6.5*b)*;

– POTENTIAL EQUALIZATION CONDUCTORS (see Sub-clause 18 *e)*);

– FUNCTIONAL EARTH CONDUCTORS as specified in Sub-clause 18 *l)*.

d) Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured "light blue" as specified in IEC Publication 227 (Amendment No. 1) or in IEC Publication 245.

e) Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC Publication 227 (Amendment No. 1) or with IEC Publication 245.

f) Where a multi-conductor cord is used between EQUIPMENT parts and the maximum allowed resistance of the protective earth connection would be exceeded if only the green and yellow coloured conductor were used, other conductors of the same cord may be connected in parallel with the green and yellow conductor, provided that the ends of such additional conductors are marked green and yellow.

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

6.6 *Identification of medical gas cylinders and connections*

a) Identification of the content of gas cylinders used in medical practice as a part of electrical EQUIPMENT shall be in accordance with ISO Recommendation ISO/R 32. See also Sub-clause 56.3*a)*.

b) The point of connection of gas cylinders shall be so identified on EQUIPMENT that errors are avoided when a replacement is made.

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

6.6DV DR *Modification of 6.6 by replacing item (a) with the following:*

a) Identification of the content of gas cylinders used in medical practice as part of electrical EQUIPMENT, if accomplished through color coding, shall be in accordance with the color coding requirements of the Standard for Health Care Facilities, ANSI/NFPA 99. See also sub-clause 56.3(a).

*See rationale for 6.6DV

6.7 ***Indicator lights and push-buttons***

a) Colours of indicator lights

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

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

Table III
Recommended colours of indicator lights and their meaning for EQUIPMENT

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

b) Colours of unilluminated push-buttons

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

c) Not used.

d) Not used.

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

*See rationale for 6.7

6.8 *ACCOMPANYING DOCUMENTS*

6.8DV D2 *Modification of 6.8 by adding the following:*

Cord-connected EQUIPMENT shall be provided with instructions to indicate the type of attachment plug that should be used for connection to the alternate voltage.

6.8.1 **General*

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

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

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

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

*See rationale for 6.8.1

6.8.2 *Instructions for use*

**a) General information*

– Instructions for use shall state the function and intended application of the EQUIPMENT.

– Instructions for use shall contain all information necessary to operate the EQUIPMENT in accordance with its specification. This shall include explanation of the function of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and ACCESSORIES, replacement of material which is consumed during operation.

– Instructions for use shall provide the USER or OPERATOR with information regarding potential electromagnetic or other interference between the EQUIPMENT and other devices together with advice regarding avoidance of such interference.

– Instructions for use shall include indications on recognized ACCESSORIES, detachable parts and materials, if the use of other parts or materials can degrade minimum safety.

– Instructions for use shall instruct the USER or OPERATOR in sufficient detail concerning cleaning, preventive inspection and maintenance to be performed by him, including the frequency of such maintenance.

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

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

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

*b) *Responsibility of the manufacturer*

Not used (see Appendix A).

c) *SIGNAL OUTPUT and SIGNAL INPUT PARTS*

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

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

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

e) Mains operated EQUIPMENT with additional power source

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

f) Removal of primary batteries

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

g) Rechargeable batteries

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

h) EQUIPMENT with a specified power supply or battery charger

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

j) Environmental protection

Instructions for use shall:

– identify any risks associated with the disposal of waste products, residues, etc. and of the EQUIPMENT and ACCESSORIES at the end of their useful lives;

– provide advice on minimizing these risks.

*See rationale for 6.8.2

6.8.3 *Technical description*

**a) General*

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

– data mentioned in subclause 6.1;

– all characteristics of the EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found.

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

b) Replacement of fuses and other parts

– If the type and rating of fuses utilized in the mains supply circuit external to PERMANENTLY INSTALLED EQUIPMENT is not apparent from the information concerning RATED current and mode of operation of EQUIPMENT, the required type and rating of fuses shall be indicated in at least the technical description.

– The technical description shall contain instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during NORMAL USE.

c) Circuit diagrams, component part lists, etc.

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

d) Environmental conditions for transport and storage

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

*See rationale for 6.8.3

6.8.4 Not used.