IEC 60601-1-1

Edition 2.0 2000-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems

Appareils électromédicaux –
Partie 1-1: Règles générales de sécurité – Norme collatérale: Règles de sécurité pour systèmes électromédicaux

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a world-wide organisation for standardisation comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardisation in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organisations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organisation for Standardisation (ISO) in accordance with conditions determined by agreement between the two organisations.
2) 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.
3) They have the form of recommendations for international use published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-1-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of 60601-1-1 cancels and replaces the first edition published in 1992 and its amendment 1(1995) and constitutes a technical revision.

This second edition is a Collateral Standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety,* hereinafter referred to as the General Standard, and is the first of a series of Collateral Standards amplifying the General Standard.

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

FDIS	Report on voting
62A/312/FDIS	62A/318/RVD

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

In the 60601 series of publications, Collateral Standards specify general requirements for safety applicable to

– a group of MEDICAL ELECTRICAL EQUIPMENT (for example, radiological equipment);
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (for example, electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc.

In this Collateral Standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: in roman type;
– explanations, advice, general statements, exceptions and references: in smaller roman type;
– *test specifications: in italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) at the left margin of a clause or subclause indicates the presence of additional information.

Annexes AAA, BBB, DDD and FFF are for information only.

Annexes CCC and EEE form an integral part of this Collateral Standard.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

– reconfirmed;
– withdrawn;
– replaced by a revised edition, or
– amended.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems

SECTION ONE — GENERAL

1 Scope and object

*1.201 Scope

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.201. It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

2 Terminology and definitions

In this Collateral Standard, terms printed in small capitals are used in accordance with their definitions in IEC 60601-1.

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

For the purpose of this standard the following additional definitions apply:

2.201
MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as SYSTEM)
combination of items of equipment, at least one of which must be MEDICAL ELECTRICAL EQUIPMENT and inter-connected by FUNCTIONAL CONNECTION or use of a MULTIPLE PORTABLE SOCKET-OUTLET

NOTE Equipment, when mentioned in connection with a SYSTEM, should be taken to include EQUIPMENT. (See also examples given in annexes BBB and FFF.)

***2.202**
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between PATIENT and parts of the SYSTEM or between PATIENT and other persons touching parts of the SYSTEM (see figure 201)

***2.203**
SEPARATION DEVICE
a component or arrangement of components with input parts and output parts that, for safety reasons, prevent a transfer of unwanted voltage or current between parts of a SYSTEM

***2.204**
MULTIPLE PORTABLE SOCKET-OUTLET
a combination of two or more socket-outlets intended to be connected to, or integral with, flexible cables or cords, and which can easily be moved from one place to another while connected to the supply

NOTE A MULTIPLE PORTABLE SOCKET-OUTLET may be a separate item or an integral part of medical or non-medical equipment

***2.205**
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals and/or power and/or substances

3 General requirements

*3.201 General requirements for the SYSTEM

After installation or subsequent modification, a SYSTEM shall not cause a SAFETY HAZARD.

A SYSTEM shall provide:

– within the PATIENT ENVIRONMENT, a level of safety comparable to that provided by MEDICAL ELECTRICAL EQUIPMENT complying with IEC 60601-1, and

– outside the PATIENT ENVIRONMENT, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

Compliance is considered to exist if the requirements of 3.201.1, 3.201.2, 3.201.3 and 3.201.4 are met. A SYSTEM incorporating equipment or parts, which use materials or have forms of construction different from those detailed in relevant standards as mentioned in 3.201.1 and 3.201.2, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

3.201.1 MEDICAL ELECTRICAL EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT shall comply with the requirements of IEC 60601-1 and its relevant particular standards.

Compliance is checked by inspection of appropriate documents or certificates.

3.201.2 Non-medical electrical equipment

Non-medical electrical equipment shall comply with IEC and ISO safety standards that are relevant to that equipment. See also annex DDD.

Equipment in which protection against electric shock relies on BASIC INSULATION only shall not be used in a SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

*3.201.3. Specified power supply

A specified power supply according to 10.2.2.201 shall be in accordance with IEC 60601-1 or shall demonstrate an equivalent degree of safety.

NOTE The party assembling or modifying the SYSTEM should calculate the power consumption of the SYSTEM, make sure that this consumption is consistent with the power that the MULTIPLE PORTABLE SOCKET-OUTLET(S) can support and document it.

Compliance is checked by inspection of appropriate documents or certificates.

***3.201.4. SYSTEM**

After installation or subsequent modification, the SYSTEM shall be in compliance with the requirements of this Collateral Standard.

Compliance is checked by inspection, by testing or by analysis, as specified in the relevant subclause.

Only hazards arising from the interconnection of various equipment to constitute a SYSTEM shall be considered.

Safety tests which have already been carried out on individual equipment of the SYSTEM according to relevant standards shall not be repeated.

Tests shall be carried out:

- *in NORMAL CONDITION unless otherwise specified in this standard, and*
- *under the operating conditions specified by the manufacturer of the SYSTEM.*

6 Identification, marking and documents

***6.8.201 ACCOMPANYING DOCUMENTS of a SYSTEM**

A SYSTEM (including a modified SYSTEM) shall be accompanied by documents containing all the data necessary for safe and intended use.

These documents shall include:

a) the ACCOMPANYING DOCUMENTS for each item of MEDICAL ELECTRICAL EQUIPMENT (see 6.8 of IEC 60601-1);

b) the equivalent documents for each item of non-medical electrical equipment;

c) the following information:

- instructions for cleaning and, where applicable, sterilizing and disinfecting each item of equipment forming part of the SYSTEM;
- additional safety measures which should be applied, during installation of the SYSTEM;
- which parts of the SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures which should be applied during preventive maintenance;
- a warning that MULTIPLE PORTABLE SOCKET-OUTLETS shall not be placed on the floor;
- a warning that an additional MULTIPLE PORTABLE SOCKET-OUTLET or extension cord shall not be connected to the system;
- a warning not to connect items which are not specified as part of the SYSTEM;
- the maximum permitted load for any MULTIPLE PORTABLE SOCKET-OUTLET(S) used with the SYSTEM;
- an instruction that MULTIPLE PORTABLE SOCKET-OUTLETS provided with the SYSTEM shall only be used for supplying power to equipment which is intended to form part of the SYSTEM;
- an explanation of the risks of connecting a non-medical electrical equipment, which has been supplied as a part of the SYSTEM, directly to the wall outlet when the non-medical equipment is intended to be supplied via a MULTIPLE PORTABLE SOCKET-OUTLET with a separating transformer;

– an explanation of the risks of connecting electrical equipment, which has not been supplied as a part of the SYSTEM, to the MULTIPLE PORTABLE SOCKET-OUTLET;

– any restrictions in the environmental conditions to ensure safety (see clause 10 of the General Standard);

– instructions to the OPERATOR not to touch parts referred to in 16.201 and the PATIENT simultaneously;

d) advice to

– the installer, recommending that the SYSTEM be installed in a way that enables the USER to achieve optimal use, and

– the USER, to carry out all cleaning, adjustment, sterilization and disinfection procedures specified herein.

Compliance is checked by inspection.

SECTION TWO — ENVIRONMENTAL CONDITIONS

10 Environmental conditions

*10.2.2.201 Power supply

A power supply from another equipment for EQUIPMENT in a SYSTEM shall be specified by the manufacturer.

SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

16 ENCLOSURES and PROTECTIVE COVERS

16.201 ENCLOSURES

Parts of non-medical electrical equipment in the PATIENT ENVIRONMENT that, after removal of covers, connectors, etc., without the use of a TOOL, may be contacted by the OPERATOR during routine maintenance, calibration, etc., shall operate 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 17 *g)* 1) to 5) of IEC 60601-1.

Compliance is checked by inspection.

17 Separation

*17.201 Electrical separation

If the allowable values of LEAKAGE CURRENTS can be exceeded – caused by FUNCTIONAL CONNECTION between different items of equipment of a SYSTEM and other systems, for example, an emergency calling system or a data processing system – then safety measures incorporating a SEPARATION DEVICE shall be applied.

Such safety measures provide suitable electrical separation between the equipment and/or between the SYSTEM and other systems and shall have the dielectric strength, CREEPAGE

DISTANCES and AIR CLEARANCES appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.

Compliance is checked as follows:

The SEPARATION DEVICE shall withstand the dielectric strength test for BASIC INSULATION according to clause 20 of IEC 60601-1 between input parts and output parts. The terminals of each of these parts are connected together during the test.

The test voltage is chosen from table V of IEC 60601-1.

The reference voltage (U) is the highest RATED supply voltage or, for polyphase equipment, the phase-to-neutral supply voltage. For INTERNALLY POWERED EQUIPMENT, U is 250 V a.c.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

*19.201 LEAKAGE CURRENTS

19.201.1 ENCLOSURE LEAKAGE CURRENT

In NORMAL CONDITION, the ENCLOSURE LEAKAGE CURRENT from or between parts of the SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0,1 mA.

NOTE For the purpose of this standard, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be ENCLOSURE LEAKAGE CURRENT.

In the event of the interruption of any non-permanently installed PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of a MULTIPLE PORTABLE SOCKET-OUTLET or of an equipment, the ENCLOSURE LEAKAGE CURRENT from or between parts of a SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0,5 mA.

If the SYSTEM or part of the SYSTEM is supplied from a MULTIPLE PORTABLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE PORTABLE SOCKET-OUTLET shall not exceed 0,5 mA.

19.201.2 PATIENT LEAKAGE CURRENT

In NORMAL CONDITION, the PATIENT LEAKAGE CURRENT shall not exceed 0,1 mA for TYPE B and BF APPLIED PARTS and 0,01 mA for TYPE CF APPLIED PARTS.

Compliance with the requirements of 19.201.1 and 19.201.2 is checked by inspection and measurement of LEAKAGE CURRENTS using a measuring device as specified in 19.4e) of IEC 60601-1.

19.201.3 Connection of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS

If compliance of the MEDICAL ELECTRICAL EQUIPMENT with 19.2 *b)* first dash and/or 19.2 *c)* of IEC 60601-1 is achieved by specifying that the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART is for exclusive connection to equipment as specified in the ACCOMPANYING DOCUMENTS, then the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART shall be connected to the specified equipment. However, for CLASS I EQUIPMENT, if the specified equipment is not connected to the common protective earth of the SYSTEM, then a SEPARATION DEVICE shall be used (see situation 3 of table BBB.201).

Compliance is checked by inspection.

SECTION FOUR — PROTECTION AGAINST MECHANICAL HAZARDS

22 Moving parts

22.7.201 Protective means

When movement of parts of a SYSTEM can cause a SAFETY HAZARD, the SYSTEM shall be provided with a protective means, for example, an emergency stopping device, in accordance with 22.7 of IEC 60601-1.

Compliance is checked by inspection.

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

NOTE See 44.7.201
.

SECTION SEVEN — PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

*44.7.201 Cleaning, sterilization and disinfection

See informative note in annex AAA.

49 Interruption of the power supply

*49.201 Interruption of the power supply

A SYSTEM shall be so designed that an interruption and restoration of the power supply to any EQUIPMENT or non-medical equipment of the SYSTEM shall not result in a SAFETY HAZARD other than interruption or cessation of its intended function.

Compliance is checked by interruption and restoration of relevant power supplies one at a time.

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

SECTION NINE — ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

52 Abnormal operation and fault conditions

52.1.201

NOTE Requirements for prevention of functional hazards arising from programmable electrical medical systems are specified in IEC 60601-1-4. Attention should be paid to the possible impact of, for example, telematics.

SECTION TEN — CONSTRUCTIONAL REQUIREMENTS

56 Components and general assembly

56.3.201 Connections

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 can be caused.

– Connectors shall comply with 17 *g)* of the General Standard.
– Plugs for connection of PATIENT CIRCUIT leads shall be so designed that they cannot be connected to other outlets of the same SYSTEM, which are likely to be located in the PATIENT ENVIRONMENT, unless it can be proven that no SAFETY HAZARD can result.

Compliance is checked by inspection, if possible by interchanging connectors, to establish the absence of a SAFETY HAZARD (LEAKAGE CURRENT exceeding the values in NORMAL CONDITION, movement, temperature, radiation, etc.).

57 MAINS PARTS, components and layout

57.2 MAINS CONNECTORS, APPLIANCE INLETS and the like

NOTE The MAINS CONNECTOR is not required to be fixed since the intent is to prevent unintentional connection of other equipment which may adversely effect the safety of the system. Reassignment of system wiring is a dangerous practice and beyond the scope of this Collateral Standard. Warnings are already provided in 6.8.201.

*57.2.201 MULTIPLE PORTABLE SOCKET-OUTLET

Connection of equipment used in medical practice to a MULTIPLE PORTABLE SOCKET-OUTLET shall only be possible by using a TOOL, or the MULTIPLE PORTABLE SOCKET-OUTLET shall be supplied via a separating transformer.

Compliance is checked by inspection.

The separating transformer and the MULTIPLE PORTABLE SOCKET-OUTLET shall comply with the requirements as given in annex EEE.