AS/NZS 3200.1.1:1995
IEC 601-1-1:1992

Australian/New Zealand Standard

Approval and test specification—Medical electrical equipment

Part 1.1: General requirements for safety—Collateral Standard: Safety requirements for medical electrical systems

[IEC title: Medical electrical equipment
Part 1: General requirements for safety
1. Collateral Standard:
Safety requirements for medical electrical systems]

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/15, Medical Electrical Equipment—General Safety Systems. It was approved on behalf of the Council of Standards Australia on 17 March 1995 and on behalf of the Council of Standards New Zealand on 6 March 1995. It was published on 5 July 1995.

The following interests are represented on Committee HT/15:

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Australian and New Zealand College of Anaesthetists
Australian Federation for Medical and Biological Engineering
Australian Private Hospitals Association
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This Standard was issued in draft form for comment as DR 94303.

Australian/New Zealand Standard

Approval and test specification—Medical electrical equipment

Part 1.1: General requirements for safety—Collateral Standard: Safety requirements for medical electrical systems

PUBLISHED JOINTLY BY:

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Homebush NSW 2140 Australia

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Level 10, Radio New Zealand House,
155 The Terrace,
Wellington 6001 New Zealand

ISBN 0 7262 9762 3

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/15 on Medical Electrical Equipment—General Safety Aspects, as a Joint Standard.

It is based on and includes the full text of IEC 601-1-1:1992 *Medical electrical equipment* Part 1.1: *General requirements for safety—Collateral Standard—Safety requirements for medical electrical systems.*

This Standard includes IEC Amendment 1:1995. An Australian/New Zealand Appendix ZZ has been added to the Standard. Those Clauses affected by the Appendix are marked with marginal bars.

This Standard is one of a series of Approval and Test Specifications issued by Standards Australia and Standards New Zealand for various categories of medical equipment. It is supplementary to AS 3200.1: (NZS 6150) 1990, *Approval and test specification—Medical electrical equipment,* Part 1—*General requirements for safety.*

The international Standard IEC 601-1-1 modifies and supplements the corresponding Clauses of IEC 601-1: 1988, *Medical electrical equipment,* Part 1: *General requirements for safety* which has been adopted as AS 3200.1 (NZS 6150) hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

IEC 601-1-1 is a Collateral Standard. Collateral Standards specify safety requirements for groups of equipment (for example, radiology equipment) or for a characteristic common to all medical electrical equipment not covered by the General Standard.

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

(i) Requirements, compliance with which can be tested and definitions . . . . . in large roman type

(ii) Explanations, advice, introductions, general statements, exceptions and references . . . in smaller roman type

(iii) Headings of sub-clauses and text specifications . . . . . *in italic type*

(iv) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index . . . . . IN SMALL CAPITALS

* An asterisk is placed before each Clause for which rationale is included in Annex AAA.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover and title page.

For the purpose of this Standard, the IEC text should be modified as follows:

(a) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the word ‘this International Standard’ wherever they appear.

(b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

(c) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS/NZS	
50 (826)	International Electrotechnical Vocabulary Chapter 826: Electrical installations of buildings	1852.826	Electrical installation of buildings

IEC		AS/NZS	
65	Safety requirements for mains operated electronic and related apparatus for household and similar general use	3250	Approval and test specification—Mains operated electronic and related equipment for household and similar general use
335	Safety of household and similar electrical appliances	3300	Approval and test specification—General requirements for household and similar electrical appliances
348	Safety requirements for electronic measuring apparatus	—	
414	Safety requirements for indicating and recording electrical measuring instruments and their accessories	—	
820	Electrical safety of laser equipment and installations	—	
950	Safety of information technology equipment, including electrical business equipment	3260	Approval and test specification— Safety of information technology equipment including electrical business equipment
1010	Safety requirements for electrical equipment for measurement, control, and laboratory use	—	
1010-1	Part 1: General requirements		
ISO		—	
7767	Oxygen analyzers for monitoring patient breathing mixtures—Safety requirements		
8185	Humidifiers for medical use—Safety requirements	—	
8359	Oxygen concentrators for medical use—Safety requirements	3200.2.2000	Oxygen concentrators for individual patient use

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

CONTENTS

SECTION 1: GENERAL

Page

Clause

1 Scope and object . . . 1
1.201 Scope . . . 1
2 Terminology and definitions . . . 1
2.201 COUPLING . . . 1
2.202 INDIRECT CONTACT . . . 1
2.203 MEDICAL ELECTRICAL SYSTEM . . . 1
2.204 PATIENT ENVIRONMENT . . . 1
2.205 SEPARATION DEVICE . . . 1
2.206 MULTIPLE PORTABLE SOCKET-OUTLET . . . 2
3 General requirements . . . 2
3.201 General requirements for the SYSTEM . . . 2
4 General requirements for tests . . . 2
4.201 General requirements for tests for the SYSTEM . . . 2
6 Identification, marking and documents . . . 3
6.1.201 Marking . . . 3
6.8.201 ACCOMPANYING DOCUMENTS . . . 3

SECTION 2: ENVIRONMENTAL CONDITIONS

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

16 Enclosures and protective covers . . . 3
16.201 ENCLOSURES . . . 3
17 Separation . . . 4
17.201 Electrical separation . . . 4
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS . . . 5
19.201 LEAKAGE CURRENTS . . . 5
19.201.1 ENCLOSURE LEAKAGE CURRENT . . . 5
19.201.2 PATIENT LEAKAGE CURRENT . . . 5
19.201.3 Connection of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS . . . 5

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

22 Moving parts . . . 5
22.7.201 Protective means . . . 5

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

Clause		*Page*
43.201	Fire prevention	6
44.7.201	Cleaning, sterilization and disinfection	6
49.201	Interruption of the power supply	6

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

56.3.201	Connections	6
57.2	MAINS CONNECTORS, APPLIANCE INLETS AND THE LIKE	7
57.2.201	MULTIPLE PORTABLE SOCKET-OUTLET	7
57.10	CREEPAGE DISTANCES AND AIR CLEARANCES	7
57.10.201	SEPARATION DEVICE	7
58.201	PROTECTIVE EARTH CONDUCTOR	7
59.201	Protection of wiring	7

FIGURES

201	PATIENT ENVIRONMENT	8
202	Symbol 14, table D1, appendix D of IEC 601-1	8

ANNEXES

AAA	General guidance and rationale	9
BBB	Examples of combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment	13
CCC	Normative references	18
DDD	Bibliography	19
EEE	Requirements for MULTIPLE PORTABLE SOCKET-OUTLETS	20
FFF	Examples of application of MULTIPLE PORTABLE SOCKET-OUTLETS	22

APPENDIX

ZZ	Variations to this standard applicable in Australia and New Zealand	24

First published as AS/NZS 3200.1.1:1995.
Incorporating:
Amdt 1—1997

AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment

Part 1.1:
General requirements for safety—Collateral Standard—Safety requirements for medical electrical systems

SECTION 1: GENERAL

1 Scope and object

*1201 *Scope*

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.203. It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

NOTE — It is presumed that the party assembling or modifying the MEDICAL ELECTRICAL SYSTEMS will take the necessary steps to assure compliance with this standard.

2 Terminology and definitions

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 **COUPLING:** All functional connections between different items of equipment.

2.202 **INDIRECT CONTACT:** Contact of persons or livestock with exposed conductive parts which have become live under fault conditions (IEV 826-03-06).

*2.203 **MEDICAL ELECTRICAL SYSTEM** (hereinafter referred to as a **SYSTEM**): Combination of either more than one item of MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL EQUIPMENT and other non-medical electrical equipment having a specified function and inter-connected by:

- COUPLING, and/or
- a MULTIPLE PORTABLE SOCKET-OUTLET.

NOTE - The SYSTEM includes those accessories which are needed for operating the SYSTEM and are to be specified by the manufacturer.

(See also examples given in annexes BBB and FFF.)

*2.204 **PATIENT ENVIRONMENT:** Any volume in which intentional or unintentional contact between PATIENT and parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur (see for illustration figure 201).

2.205 **SEPARATION DEVICE:** A component or arrangement of components with a SIGNAL INPUT PART and SIGNAL OUTPUT PART that prevents for safety reasons a transfer of unwanted voltage or current between parts of a SYSTEM.

*2.206 *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.

3 General requirements

3.201 *General requirements for the SYSTEM*

A SYSTEM after installation or subsequent modification shall not cause a SAFETY HAZARD for the PATIENT, the OPERATOR or surroundings.

A SYSTEM as a whole shall provide:

- within the PATIENT ENVIRONMENT the same level of safety as MEDICAL ELECTRICAL EQUIPMENT complying with IEC 601-1, 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 subclauses 3.201.1, 3.201.2 and 3.201.3 are met.

3.201.1 MEDICAL ELECTRICAL EQUIPMENT shall comply with the general safety requirements according to IEC 601-1 and its relevant particular standards (see current IEC catalogue).

Compliance is checked by inspection of appropriate documents or certificates.

*3.201.2 Non-medical electrical equipment shall comply with IEC and ISO safety standards that are relevant for the equipment in question. See also annex DDD: Bibliography.

Equipment of class 0 shall not be used in a SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

*3.201.3 COUPLING of equipment in a SYSTEM shall not result in a safety level for the PATIENT that is inferior to the level given in IEC 601-1.

3.201.4 A SYSTEM using equipment, components or forms of construction different from those detailed in relevant standards as mentioned in subclauses 3.201.1 and 3.201.2 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

4 General requirements for tests

*4.201 *General requirements for tests for the SYSTEM*

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

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

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

- *Safety tests, on individual equipment of the SYSTEM, already carried out to the relevant standards used, shall not be repeated.*

- *Tests shall be carried out:*

  - *in NORMAL CONDITION unless otherwise specified in this standard, and*

  - *under operating conditions as specified by the manufacturer of the SYSTEM.*

6 Identification, marking and documents

6.1.201 *Marking*

Where in the ACCOMPANYING DOCUMENTS a warning is given related to a particular SAFETY HAZARD from a non-medical electrical equipment, symbol 14, table DI, appendix D of IEC 601-1 (see figure 202) shall be provided on that particular non-medical electrical equipment or on a particular part of that equipment.

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.

*6.8.201 *Accompanying documents*

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

NOTE - It is the responsibility of the assembler of a SYSTEM (including a modified SYSTEM), that it is accompanied by documents containing all the data necessary for safe and reliable use.

These documents shall include:

a) The ACCOMPANYING DOCUMENTS for each item of MEDICAL ELECTRICAL EQUIPMENT (see 6.8 of IEC 601-1).

b) The accompanying 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 safely 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;

- the maximum permitted load for any MULTIPLE PORTABLE SOCKET-OUTLET(S);

- an instruction that MULTIPLE PORTABLE SOCKET-OUTLETS provided with the SYSTEM shall only be used for powering equipment which forms 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 SYSTEM is 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.

Compliance is checked by inspection.

SECTION 2: ENVIRONMENTAL CONDITIONS

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

16 **ENCLOSURES and PROTECTIVE COVERS**

16.201 *ENCLOSURES*

Within the PATIENT ENVIRONMENT parts of non-medical electrical equipment which, 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 subclauses 17 g) 1) to 5) of IEC 601-1.

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

Compliance is checked by inspection.

17 Separation

*17.201 *Electrical separation*

If the allowable values of LEAKAGE CURRENTS can be exceeded — caused by conductive connections between different items of equipment of a SYSTEM and other systems, e.g. a luminous call 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.

NOTE - SEPARATION DEVICES may be insulating or may be voltage or current limiting. If safety measures incorporating an insulating SEPARATION DEVICE are applied, such a SEPARATION DEVICE will have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES appropriate to the highest voltage occurring during a fault at the point of electrical separation.

For the SEPARATION DEVICES involved, compliance with the requirements of this subclause shall be checked as follows:

The insulating SEPARATION DEVICES shall withstand a dielectric strength test according to clause 20 of IEC 601-1 between their SIGNAL INPUT PART and their SIGNAL OUTPUT PART. The terminals of each of these parts are connected together during the test.

The test voltage is chosen from clause 20, table V, for BASIC INSULATION.

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.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

*19.201 *LEAKAGE CURRENTS*

19.201.1 *ENCLOSURE LEAKAGE CURRENT*

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

In the event of the interruption of any non-permanently installed protective earth conductor the allowable ENCLOSURE LEAKAGE CURRENT from or between parts of a SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0,5 mA. If the SYSTEM includes a MULTIPLE PORTABLE SOCKET-OUTLET the ENCLOSURE LEAKAGE CURRENT shall also be measured from parts which are in NORMAL CONDITION protectively earthed.

19.201.2 *PATIENT LEAKAGE CURRENT*

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

Compliance with the requirements of subclauses 19.201.1 and 19.201.2 is checked by inspection and measurement of LEAKAGE CURRENTS using a device according to IEC 601-1, subclause 19.4 e).

19.201.3 *Connection of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS (see also annex BBB)*

If compliance of the MEDICAL ELECTRICAL EQUIPMENT with subclause 19.2 b) first dash and/or 19.2 c) of IEC 601-1 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:

- either to such equipment which, if CLASS I, is connected to the common PROTECTIVE EARTH of the SYSTEM,
- or to a SEPARATION DEVICE.

Compliance is checked by inspection.

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

22 Moving parts

22.7.201 *Protective means*

When in a SYSTEM, movement of equipment or equipment parts may cause a SAFETY HAZARD, the SYSTEM shall be provided with a protective means e.g. an emergency stopping device, in accordance with subclause 22.7 of IEC 601-1.

Compliance is checked by inspection and tests.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

NOTE - See subclause 44.7.201.

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

*43.201 *Fire prevention*

44.7.201 *Cleaning, sterilization and disinfection*

SYSTEMS should be installed in such a way that the USER is able to carry out the necessary cleaning, and where applicable the sterilization and disinfection measures as specified in the ACCOMPANYING DOCUMENTS. National authorities may require the use of certain sterilization or disinfection methods and measures for protection against hazards of ignition of flammable anaesthetic mixtures.

*49.201 *Interruption of the power supply*

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

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

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

56.3.201 *Connections*

Plugs for connection of PATIENT CIRCUIT leads shall be so designed that they cannot be connected to other outlets on the same SYSTEM, unless it can be proven that no SAFETY HAZARD can result.

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

57.2 *MAINS CONNECTORS, APPLIANCE INLETS and the like*

*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 at least a separating transformer.

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

Compliance is checked by inspection.

57.10 *CREEPAGE DISTANCES AND AIR CLEARANCES*

57.10.201 *SEPARATION DEVICE*

The SEPARATION DEVICE shall have CREEPAGE DISTANCES and AIR CLEARANCE according to table 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.

Table 1 - CREEPAGE DISTANCES and CLEARANCES in millimetres

U	DC voltage	15	36	75	150	300	450	600	800	900	1 200	
	AC voltage	12	30	60	125	250	400	500	660	750	1 000	
SEPARATION DEVICE		0,8	1	1,2	1,6	2,5	3,5	4,5	6	6,5	9	AIR CLEARANCES
		1,7	2	2,3	3	4	6	8	10,5	12	16	CREEPAGE DISTANCES

NOTE - The reference for this table is IEC 601-1, and amendments 1 and 2, table XVI for BASIC INSULATION or SUPPLEMENTARY INSULATION.

Compliance is checked by inspection.

*58.201 *PROTECTIVE EARTH CONDUCTOR*

The PROTECTIVE EARTH CONDUCTOR connection shall be made in such a way that the removal of any single item of equipment in the SYSTEM will not interrupt the PROTECTIVE EARTH CONDUCTOR connection to any part of the SYSTEM, without at the same time disconnecting the supply of electric energy from that part.

Outside the equipment the PROTECTIVE EARTH CONDUCTOR shall be routed together with the mains supply conductor.

Compliance is checked by inspection.

59.201 *Protection of wiring*

Conductors which connect different items of equipment within a SYSTEM shall be protected against the effects of short-circuiting and overload and be protected against mechanical damage.

Compliance is checked by inspection.

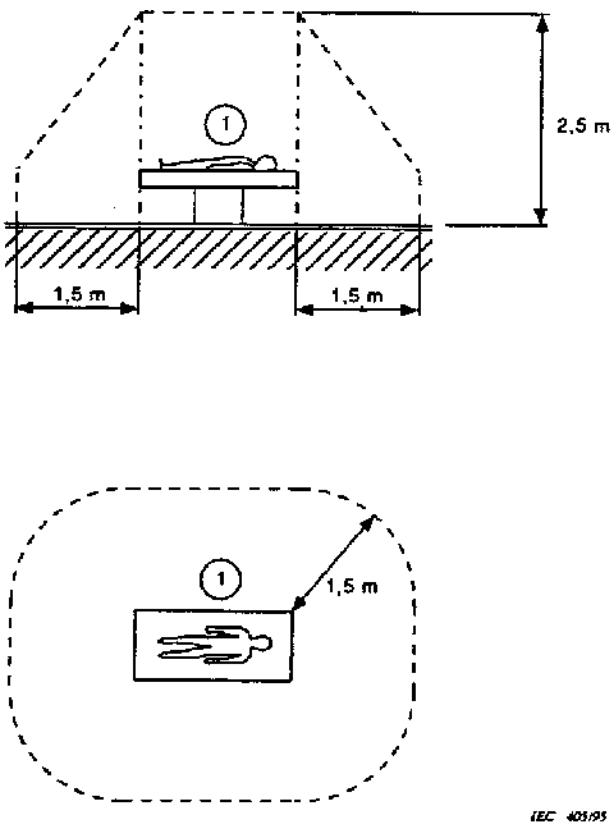


Figure 201 — Example of PATIENT ENVIRONMENT

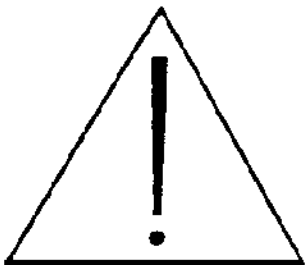


Figure 202 — Symbol 14, table D1, appendix D of IEC 601-1;
Attention, consult accompanying documents.

Annex AAA
(informative)

General guidance and rationale

Subclause 1.201 Scope

This standard is intended to be used by manufacturers who assemble and offer for sale a combination of electrical equipment which includes one or more items of MEDICAL ELECTRICAL EQUIPMENT.

This standard is also intended to be used by hospital personnel who assemble similar systems. In this case, engineering expertise in the application of the electrical equipment design standards may be required to ensure that the SYSTEM complies with all requirements of this standard.

The application and rapid development of modern electronic and biomedical technologies in medical practice have already led to a situation that instead of a single item of MEDICAL ELECTRICAL EQUIPMENT, rather complex and extensive SYSTEMS of electrical equipment are applied for the diagnosis, therapy or monitoring of PATIENTS.

More and more such SYSTEMS comprise equipment, originally manufactured for use in different specific application fields (not necessarily medical) that are connected with each other in a direct or indirect way.

Thus MEDICAL ELECTRICAL EQUIPMENT complying with IEC 601-1 may be connected with other non-medical electrical equipment.

The latter equipment may, each individually, fully meet the requirements as mentioned in safety standards applicable in their specific application field. Often they do not comply with the safety requirements for MEDICAL ELECTRICAL EQUIPMENT and may influence the safety of the whole SYSTEM.

The electrical equipment may be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is carried out.

Within a medically used room electrical equipment may be placed inside an area that is defined as a PATIENT ENVIRONMENT or outside this area.

There are two situations possible in medical practice:

Situation a)

Simultaneously operated MEDICAL ELECTRICAL EQUIPMENT, i.e. different equipment connected at the same time to a PATIENT but not connected to each other. Such equipment can influence each other e.g. high frequency surgical equipment in the operating theatre may influence PATIENT monitoring.

This situation can possibly be covered by an advice in the instructions for use. This standard does not apply to this situation.

Situation b)

SYSTEMS, consisting of MEDICAL ELECTRICAL EQUIPMENT and possibly also non-medical electrical equipment, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a PATIENT. Examples: SYSTEMS for diagnostic X-ray examination, endoscopes

with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed tomography or magnetic resonance imaging.

The various parts of such a SYSTEM may be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room or may extend beyond its boundaries and be located in a non-medically used room containing e.g. electrical power distribution or data processing equipment.

This situation is covered in this standard, the requirements of which have to describe the necessary safety measures and tests.

Subclause 2.203 MEDICAL ELECTRICAL SYSTEM

Rationale to allow in a SYSTEM a MULTIPLE PORTABLE SOCKET-OUTLET:

Interconnections to supply mains of a MULTIPLE PORTABLE SOCKET-OUTLET are subject to certain conditions in order to minimize the impairment of the safety level of IEC 601-1.

This means that such MULTIPLE PORTABLE SOCKET-OUTLETS shall be constructed to comply with the requirements which apply to EQUIPMENT according to IEC 601-1; therefore an additional subclause 57.2.201 is incorporated in this collateral standard.

IEC 884-1 has been taken into account.

Subclause 2.204 PATIENT ENVIRONMENT

Such a volume is an environment in which medical diagnosis, monitoring or treatment is carried out. It is very difficult to attach unique dimensions to a volume of the PATIENT ENVIRONMENT.

It is difficult to attach unique dimensions to the PATIENT ENVIRONMENT.

In practice a distance of 2,5 m above the floor on which the medical personnel stand and a horizontal distance of 1,5 m have justified themselves as indicative of the dimensions of the PATIENT ENVIRONMENT (see figure 201).

Subclause 2.206 MULTIPLE PORTABLE SOCKET-OUTLETS

The definition is derived from IEC 884-1.

MULTIPLE PORTABLE SOCKET-OUTLETS are necessary and offer advantages as well as disadvantages, which have to be investigated in order to establish a balance.

The use of MULTIPLE PORTABLE SOCKET-OUTLETS should be avoided as far as possible for the following reasons:

- combined EARTH LEAKAGE CURRENTS may result in:
  - excessive EARTH LEAKAGE CURRENT in NORMAL CONDITION,
  - excessive ENCLOSURE LEAKAGE CURRENT in the SINGLE FAULT CONDITION of a broken common protective earth;
- availability of the SUPPLY MAINS depends on the reliability of a single FIXED MAINS SOCKET-OUTLET;
- a complete interruption of power is possible and may provoke a longer set-up time to reactivate the complete SYSTEM;
- only one (less reliable) protective earth connection is provided;

- the protective earth resistance is increased.

MULTIPLE PORTABLE SOCKET-OUTLETS may be necessary for the following reasons:

- to minimize the number of power supply cords lying on the floor;

- to allow all the equipment necessary for proper treatment or diagnosis to be used despite an insufficient number of FIXED MAINS SOCKET-OUTLETS;

- to improve mobility with all equipment on one trolley;

- to reduce potential differences within the protective earth wiring to below those which occur in some fixed installations.

However, the optimum solution is to install an adequate number of FIXED MAINS SOCKET-OUTLETS according to appropriate installation rules.

Subclause 3.201.2

Class 0 equipment is equipment in which protection against electric shock relies upon basic insulation; this implies that there are no means for the connection of accessible conductive parts, if any, to the protective conductor in the fixed wiring of the installation, reliance in the event of a failure of the basic insulation being placed upon the environment.

Subclause 3.201.3

Safety after COUPLING is maintained when the SIGNAL INPUT PART and SIGNAL OUTPUT PART of the MEDICAL ELECTRICAL EQUIPMENT are in accordance with the requirements of IEC 601-1 by:

- measures that are built-in within the EQUIPMENT;

- SEPARATION DEVICES provided as ACCESSORIES of the EQUIPMENT (see sub-clause 17.201);

- SEPARATION DEVICES provided as accessories of the SYSTEM.

Subclause 4.201 General requirements for tests for the SYSTEM

This standard may be used in a hospital environment where the conditions for tests as described in IEC 601-1 cannot easily be reproduced.

Subclause 6.8.201 Accompanying documents

ACCOMPANYING DOCUMENTS of a SYSTEM intended for DIRECT CARDIAC APPLICATION should provide data on such items as:

- use of rubber gloves;

- use of stop-cocks made of insulating material;

- minimum distances between PATIENT and equipment being part of the SYSTEM (PATIENT ENVIRONMENT);

- instructions about how to use the MEDICAL ELECTRICAL EQUIPMENT in the typical medical application e.g. use of a catheter.

To judge safety, particular attention should be paid to the different levels of hazards when within the PATIENT ENVIRONMENT electrodes or other sensors are used externally and internally to the body including direct connection to the heart.

Possible connections to the heart of a PATIENT should be kept isolated from the equipment.

The warning not to place MULTIPLE PORTABLE SOCKET-OUTLETS on the floor is necessary in order to prevent the likelihood of the ingress of liquids and to prevent mechanical damage.

Furthermore, measures should be taken to ensure that, when assembling or modifying a SYSTEM incorporating MULTIPLE PORTABLE SOCKET-OUTLETS, these are mounted in such a way as to prevent ingress of liquids and to avoid mechanical damage during NORMAL USE and transportation.

Subclause 17.201 Electrical separation

The safety of some MEDICAL ELECTRICAL EQUIPMENT depends on the precondition that the SIGNAL INPUT PART or the SIGNAL OUTPUT PART is connected only to equipment which is specified for this purpose. The reason is that LEAKAGE CURRENTS may be increased by unwanted currents flowing through signal cables.

Hazardous situations may occur if the SIGNAL INPUT PART or SIGNAL OUTPUT PART of MEDICAL ELECTRICAL EQUIPMENT are connected to equipment outside the medically used room, possibly in another building and therefore connected to another mains supply branch circuit.

A SEPARATION DEVICE included in the interconnecting signal cables prevents a hazard to the PATIENT or OPERATOR. It should be placed as near as practicable to the MEDICAL ELECTRICAL EQUIPMENT. Additionally the inclusion of the SEPARATION DEVICE helps to avoid hazards through malfunction of equipment caused by unwanted currents flowing through the signal cables.

The requirements for such a SEPARATION DEVICE depend also on the configuration of the protection types of equipment used in a SYSTEM.

Compliance of voltage and current limiting devices with the requirements of this subclause is under consideration.

Subclause 19.201 LEAKAGE CURRENTS

- Some non-medical equipment may be allowed by the relevant standards to have ENCLOSURE LEAKAGE CURRENTS higher than limits required by this standard. These are acceptable outside the PATIENT ENVIRONMENT.

  If such equipment is to be used within the PATIENT ENVIRONMENT appropriate measures are needed to reduce the ENCLOSURE LEAKAGE CURRENTS. Such measures may include:

  - additional PROTECTIVELY EARTHED parts, or
  - potential equalization (see note), or
  - a separating transformer, or
  - an additional non-conductive ENCLOSURE.

  NOTE - For DIRECT CARDIAC APPLICATIONS and the application of invasive (surgical) techniques, measures should be taken to bring metal parts and/or extraneous conductive parts, that can be touched, on equal or almost equal potential. Such equipotential measures are desirable to safeguard the PATIENT against currents which can arise because of potential differences between the parts mentioned above.

- For the moment, the only aspect of COUPLING which is considered is the connection of SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS. Also the only possible effect on the safety level which is considered is an increase in the voltage on or current from the ENCLOSURE or an APPLIED PART.

IEC 601-1 does not address the possible effect on PATIENT LEAKAGE CURRENT or ENCLOSURE LEAKAGE CURRENT of the voltages which are normally present on a SIGNAL INPUT PART or a SIGNAL OUTPUT PART, in either NORMAL CONDITION or SINGLE FAULT CONDITION of the MEDICAL ELECTRICAL EQUIPMENT.

For example, consider a MEDICAL ELECTRICAL EQUIPMENT which just complies with the limit of 5 mA with 110 % of 250 V applied to a SIGNAL INPUT PART or a SIGNAL OUTPUT PART (SINGLE FAULT CONDITION). Assuming linearity, this will exceed the NORMAL CONDITION limit of 0,1 mA if any voltage above 5,5 V is applied to the SIGNAL INPUT PART or a SIGNAL OUTPUT PART.

Subclauses 19.201.1 and 19.201.2 of this standard therefore specify additional requirements.

Subclause 43.201 Fire prevention

At the installation of a SYSTEM architectural measures for protection against fire hazards should be maintained.

The installation of electrical parts in hollow spaces, vertical shafts and ventilation of air-handling ducts should be so made that the possible spread of fire or products of combustion will not be substantially increased.

Openings around electrical penetrations through fire-resistance rated walls, partitions, floors or ceilings should be fireproof using approved methods to maintain the fire-testing rating.

Subclause 49.201 Interruption of power supply

Attention is paid to the effect of a power interruption concerning unwanted movements, removal of compression forces and removal of PATIENTS from a hazardous position.

Subclause 57.2.201 MAINS CONNECTIONS, APPLIANCE INLETS and the like

The inaccessibility is required to impede the connection of other equipment which could cause excessive ENCLOSURE LEAKAGE CURRENTS.

Subclause 58.201 PROTECTIVE EARTH CONDUCTOR

Within the PATIENT ENVIRONMENT it is important to limit potential differences between different parts of a SYSTEM, and an adequate connection with a protective earthing system plays an important role in limiting that potential difference. It is therefore important to prevent interruption of that protective means to any part of the SYSTEM.

Annex BBB
(informative)

Examples of combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment

BBB.1 Introduction

A summary is given of situations that may occur when different equipment combinations are used in different medical environments. To keep this summary surveyable no more than two items of equipment (A and B) are used per situation.

By assuming that both equipment A and B can either be IEC 601-1 TYPE B, TYPE BF, TYPE CF EQUIPMENT or non-medical electrical equipment according to other IEC or ISO standards, all practicable situations can be simulated. Where some combinations do not make sense or are already covered by others, only the most meaningful or the worst combinations (from a safety point of view) are presented.

BBB.2 Localities in a medical environment

The following localities are foreseen (see also Figure BBB.201):

- the PATIENT ENVIRONMENT as part of a medically used room;
- the remaining part of the medically used room (not including the PATIENT ENVIRONMENT);
- the non-medically used room (a room not designed for medical treatment, like an office or a room for storage purposes).

To each locality a PROTECTIVE EARTH (PE) can be dedicated.

NOTE - A potential difference (*V*) can exist between the PROTECTIVE EARTH TERMINALS in different localities. In case of an interruption of a PROTECTIVE EARTH CONNECTION (fault condition) for an equipment in the PATIENT ENVIRONMENT this potential difference may appear on the ENCLOSURE of the equipment causing a SAFETY HAZARD for the OPERATOR or for the PATIENT if the OPERATOR simultaneously touches the equipment and the PATIENT, or for the PATIENT if the equipment is of TYPE B.

If the electrical installation incorporates equipotential bonding, the potential difference (*V*) may be negligible.

BBB.3 Basic principles

- PATIENTS should only be connected to MEDICAL ELECTRICAL EQUIPMENT complying with IEC 601-1. Other equipment should comply with relevant IEC or ISO Standards.
- In fault condition the allowable ENCLOSURE LEAKAGE CURRENT is 0,5 mA.

BBB.4 Assumptions on EQUIPMENT

a) All EQUIPMENT complying with IEC XXX and placed in the PATIENT ENVIRONMENT need measures to limit the ENCLOSURE LEAKAGE CURRENT to a value not exceeding 0,5 mA in fault condition.

b) EQUIPMENT complying with IEC 601-1 and of TYPE B **without** PATIENT connection only need measures as in item 4 a) above when connected to IEC XXX EQUIPMENT or to EQUIPMENT outside the medically used rooms.

c) EQUIPMENT complying with IEC 601-1 and of TYPE B **with** PATIENT connection may not provide sufficient protection for high signal levels on the SIGNAL INPUT PART or SIGNAL OUTPUT PART when the protective earth connection is interrupted. In this case additional earthing or a SEPARATION DEVICE will be required when connected to IEC XXX EQUIPMENT or to EQUIPMENT outside the medically used rooms.

NOTE - Though this may look like a double fault condition and therefore should not be applicable for EQUIPMENT complying with IEC 601-1, it is considered to be a realistic probability when such EQUIPMENT is connected to IEC XXX EQUIPMENT.

d) TYPE BF or TYPE CF EQUIPMENT provide sufficient protection for the PATIENT connection but need measures as in 4a) above when connected to IEC XXX EQUIPMENT or to EQUIPMENT outside the medically used room (see also 4b)).

e) For TYPE CF EQUIPMENT the maximal ENCLOSURE LEAKAGE CURRENT has the same value as for TYPE B and TYPE BF: not exceeding 0,5 mA in fault condition. This follows IEC 601-1.

BBB.5 Equipment codes

IEC 601/B = IEC 601-1 EQUIPMENT of TYPE B **with** PATIENT connection.

IEC 601/F = IEC 601-1 EQUIPMENT of TYPE BF or TYPE CF (or TYPE B **without** PATIENT connection).

IEC 601/x = IEC 601-1 EQUIPMENT of TYPE B or TYPE BF or TYPE CF.

IEC XXX = Equipment complying with e.g. IEC 348, IEC 950, etc.

BBB.6 Codes assigned to feasible solutions

Code P

Provide additional protective earthing (if one protective earth connection fails, a second protective earth connection is available)or one protective earth connection may be permanently installed and permanently connected.

NOTE - Equipment modification may be required.

Code Q

Limit the ENCLOSURE LEAKAGE CURRENT to a value not exceeding 0,5 mA by using an additional separating transformer.

NOTE - No equipment modification is required.

Code R

Limit the ENCLOSURE LEAKAGE CURRENT to a value not exceeding 0,5 mA by using a floating power supply.

NOTE - May be difficult to realize and control.

Code S

Apply SEPARATION DEVICE.

Code OK

No additional measures required.

Example: Two equipment are placed within the PATIENT ENVIRONMENT (see situation No. 2 in figure BBB.201).

There are three possibilities designated as 2a, 2b and 2c:

2a: Both equipment A and B comply with IEC 601-1: no problems exist.

2b: Equipment A complies with IEC 601-1 and is of TYPE BF or TYPE CF (or TYPE B **without** PATIENT connection) and equipment B complies with IEC XXX:

only the ENCLOSURE LEAKAGE CURRENT of equipment B has to be limited to a value not exceeding 0,5 mA. This can be realized by one of the feasible solutions *P*, *Q* or *R*.

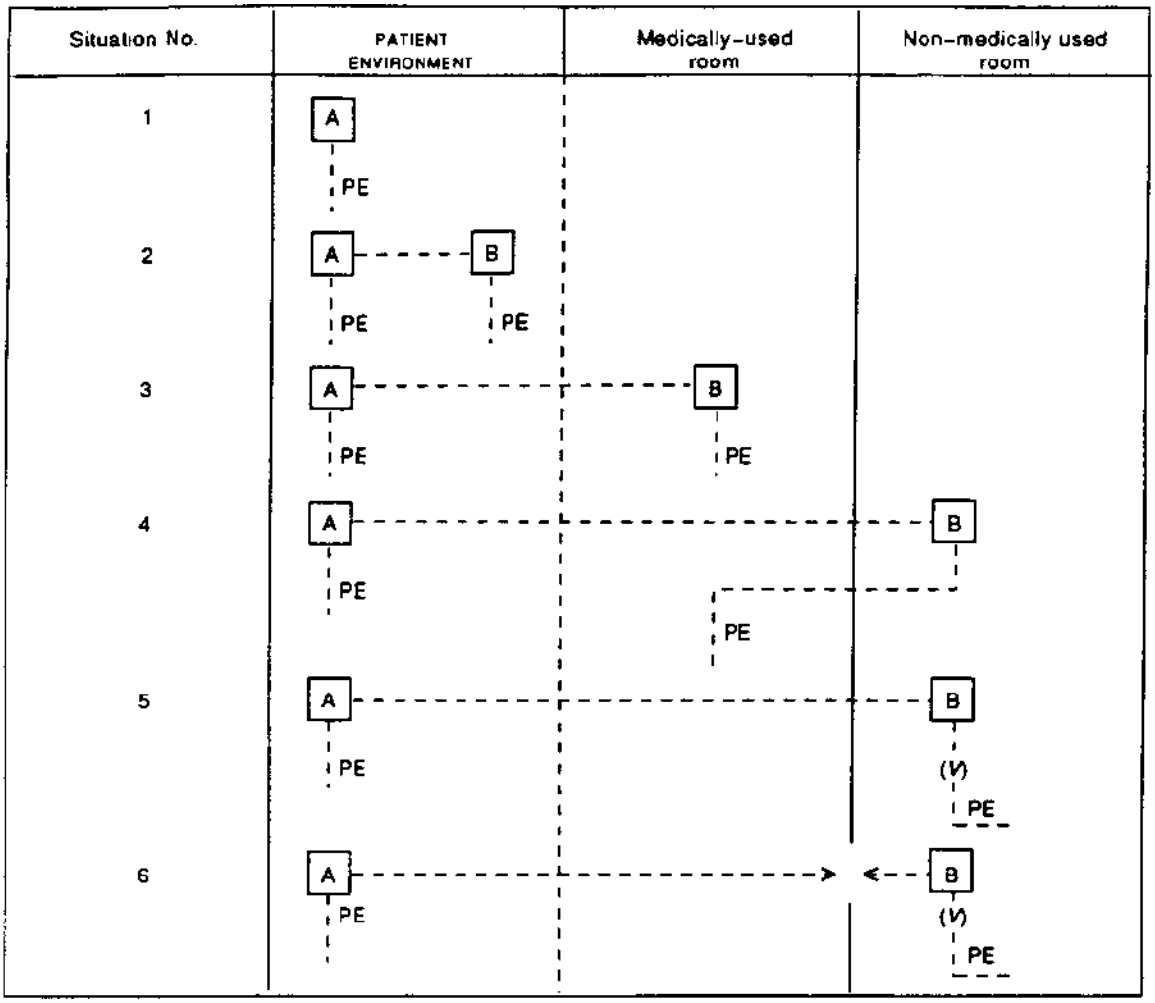
2c: Equipment A complies with IEC 601-1 and is of TYPE B **with** PATIENT connection and equipment B complies with IEC XXX:

equipment A requires extra protective earthing to protect the PATIENT connection while equipment B needs the same measures as described for 2b.

BBB.7 Summary of situations

Situation No.	Equipment A	Equipment B	Solution
1	IEC 601/X		*OK*
1a	IEC XXX		*OK*, if ENCLOSURE LEAKAGE CURRENT is less than 0,5 mA. If the ENCLOSURE LEAKAGE CURRENT is more than 0,5 mA: Solution Q (Separating transformers).
2a	IEC 601/X	IEC 601/B	*OK*
2b	IEC 601/F	IEC XXX	for B any one of *P*, *Q*, *R*
2c	IEC 601/B	IEC XXX	for A solution *P* for B any one of *P*, *Q*, *R*
3a	IEC 601/X	IEC 601/B	*OK*
3b	IEC 601/F	IEC XXX	*OK*
3c	IEC 601/B	IEC XXX	for A solution *P*
4	see 3a, 3b, 3c		
5a	IEC 601/X	IEC 601/B	for A solution *P* or *S* (groundloop possible)
5b	IEC 601/X	IEC XXX	for A solution *P* or *S* (groundloop possible)
6a	IEC 601/X	IEC 601/X	*OK* (with *S*)
6b	IEC 601/X	IEC XXX	*OK* (with *S*)

(*P*: additional protective earth)
(*Q*: additional separating transformer)
(*R*: floating power supply)
(*S*: separation)



Legend:

(*V*) = Potential difference between different localities.

> < = SEPARATION DEVICE

PE = Protective earth.

Figure BBB.201 — Combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment

Annex CCC
(normative)

Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 83: 1975, *Plugs and socket-outlets for domestic and similar general use — Standards* Amendment No. 1 (1979)

IEC 601-1: 1988, *Medical electrical equipment— Part 1: General requirements for safety.*

IEC 601-1: Amendment No. 1: 1991.

IEC 601-2-....: 19..., *Medical electrical equipment — Part 2: Particular requirements for the safety of ...*

IEC 884-1: 1994, *Plugs and socket-outlets for household and similar purposes — Part 1: General requirements*

IEC 989: 1991, *Separating transformers, autotransformers, variable transformers and reactors*

NOTES

1 For informative references see annex DDD, Bibliography.

2 For equipment and SYSTEMS, the electrical installation in a medical establishment is an important aspect to consider. In some countries rules are followed.

3 The normative references are only applicable for those parts of the SYSTEM which are MEDICAL ELECTRICAL EQUIPMENT.

Annex DDD
(informative)

Bibliography

IEC 50(826): 1990, *International Electrotechnical Vocabulary — Chapter 826: Electrical installations of buildings.*

IEC 65: 1985, *Safety requirements for mains operated electronic and related apparatus for household and similar general use.*

IEC 335, *Safety of household and similar electrical appliances.*

IEC 348: 1978, *Safety requirements for electronic measuring apparatus.*

IEC 414: 1973, *Safety requirements for indicating and recording electrical measuring instruments and their accessories.*

IEC 820: 1986, *Electrical safety of laser equipment and installations.*

IEC 950: 1986, *Safety of information technology equipment including electrical business equipment.*

IEC 1010-1: 1990, *Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements.*

ISO 7767: 1988, *Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements.*

ISO 8185: 1988, *Humidifiers for medical use — Safety requirements.*

ISO 8359: 1988, *Oxygen concentrators for medical use — Safety requirements.*

Annex EEE
(normative)

Requirements for MULTIPLE PORTABLE SOCKET-OUTLETS

EEE.1 MULTIPLE PORTABLE SOCKET-OUTLETS with separating transformers

The separating transformer shall comply with the requirements of IEC 989, with exemption from maximum rated output power (1 kVA) and degree of protection (IPX4).

NOTES

1 DOUBLE OR REINFORCED INSULATION is not required because the ENCLOSURE LEAKAGE CURRENT of the SYSTEM is less than 0,5 mA in SINGLE FAULT CONDITION.

2 The total impedance of the protective earth path for a SYSTEM may be up to 0,4 Ω or higher if the conditions of 18 *g)* of IEC 601-1, are satisfied.

- The transformer assembly shall be of class I.

NOTE 3 - This requirement is necessary in order to provide connected equipment with a protective earth connection.

- If necessary the transformer assembly shall have a specified degree of protection against ingress of water as detailed in the current edition of IEC 529.

- the rated output power limit of 1 kVA for the transformer specified in IEC 989 does not apply.

NOTE 4 - Limitation of output power is not explained in IEC 989 and the rated output power is also defined by the fuse in the installation and by the used allowable power supply cable. However the characteristics of the transformer shall be carefully selected, taking into account the variations in the load current of the SYSTEM to ensure that the supply voltage to the various items of the SYSTEM remains within the limits specified in 10.2.2 of IEC 601-1.

- In additionalto the requirements of IEC 989, the transformer assembly shall be marked according to the requirements of 6.1 and 6.2 of IEC 601-1.

- The MULTIPLE PORTABLE SOCKET-OUTLET shall be permanently connected to the transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept mains plugs according to IEC 83 (see annex FFF).

NOTE 5 - Isolation monitoring of the separating transformer is not necessary. SINGLE FAULT CONDITION can be detected during routine maintenance and double fault condition is of no concern. The transformer construction with protectively earthed centre tapped secondary winding is allowed, but not required.

- The MULTIPLE PORTABLE SOCKET-OUTLET shall be marked with symbol 14 of table DI, appendix D of IEC 601-1.

Compliance is checked by inspected and as described in the relevant subclauses of IEC 601-1.

EEE.2 MULTIPLE PORTABLE SOCKET-OUTLETS without separating transformers

The MULTIPLE PORTABLE SOCKET-OUTLETS shall comply with IEC 884-1, and as follows:

- CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 57.10 of IEC 601-1.

- The MULTIPLE PORTABLE SOCKET-OUTLETS shall be of class I and the protective earth conductor shall be connected to the earthing contacts in the output sockets.

NOTE - The total impedance of the protective earth path for a SYSTEM may be up to 0,4 Ω or higher if the conditions of 18 *g)* of IEC 601-1, are satisfied.

- Protective earthing terminals and protective earthing connections shall comply with clause 58 of IEC 601-1.

- ENCLOSURES shall comply with clause 16 of IEC 601-1.

- MAINS TERMINAL DEVICES and wiring, if applicable, shall comply with 57.5 of IEC 601-1.

- Ratings of components shall not conflict with the conditions of use (see 56.1 *b)* of IEC 601-1).

- Requirements for connections as described in 56.3 of IEC 601-1 shall be fulfilled.

- Requirements for the power supply cords as described in 57.3 and 57.4 of IEC 601-1, shall be fulfilled.

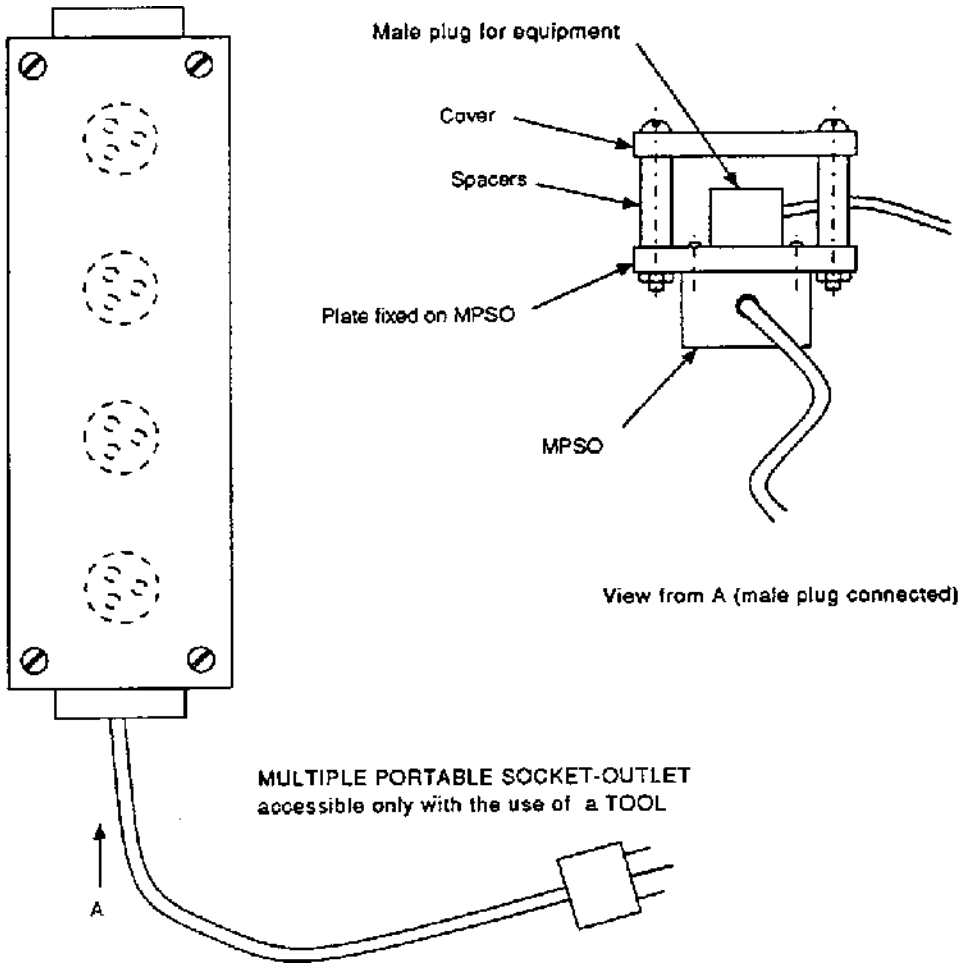
- Protective earthing shall be according to clause 18 of IEC 601-1.

- The MULTIPLE PORTABLE SOCKET-OUTLET shall be marked with symbol 14 of table DI, appendix D of IEC 601-1.

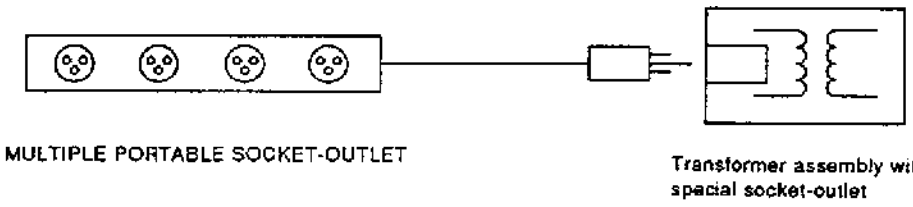
Compliance is checked by inspection and as described in the relevant subclauses of IEC 601-1.

Annex FFF
(informative)

Examples of application of MULTIPLE PORTABLE SOCKET-OUTLETS



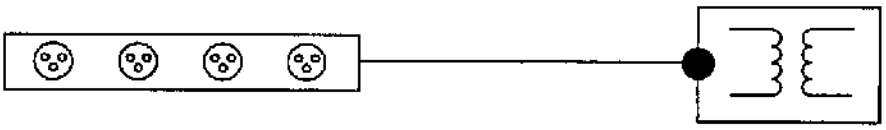
CEI/IEC 406/95



MULTIPLE PORTABLE SOCKET-OUTLET

Transformer assembly with spacial socket-outlet

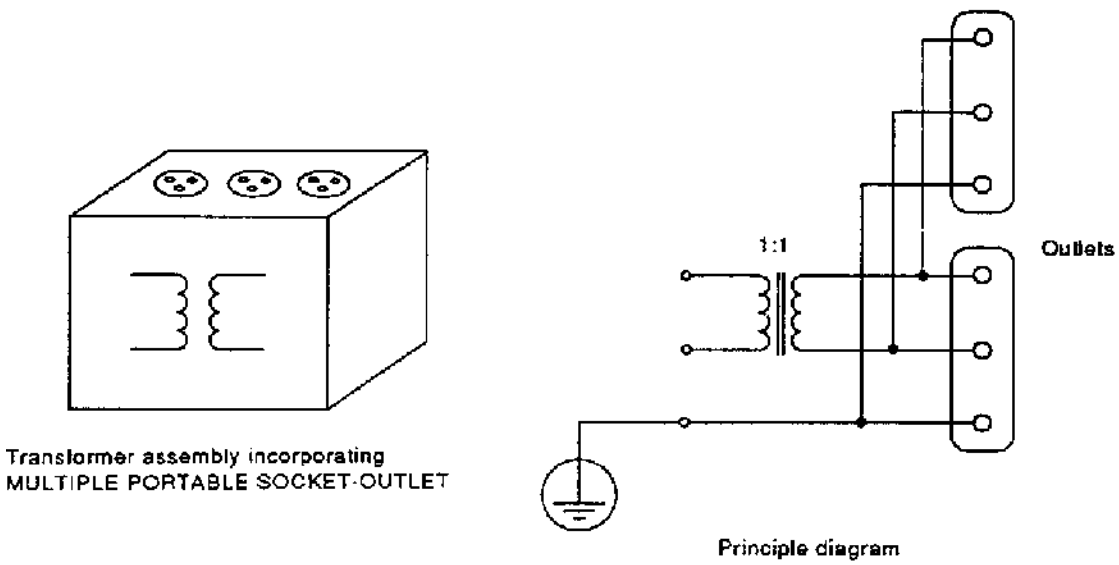
CEI-IEC 407/95



MULTIPLE PORTABLE SOCKET-OUTLET

Transformer assembly with permanently connected MULTIPLE PORTABLE SOCKET-OUTLET

CEI-IEC 408/95



Transformer assembly incorporating MULTIPLE PORTABLE SOCKET-OUTLET

Principle diagram

CEI-IEC 409/95

APPENDIX ZZ

VARIATIONS TO THIS STANDARD APPLICABLE IN AUSTRALIA AND NEW ZEALAND

(Normative)

Clause 6.8.201(c)	Fifth dash—*replace* 'shall' with 'should'. Eighth dash—*replace* 'via a MULTIPLE PORTABLE SOCKET OUTLET with a separating transformer' with 'via a MULTIPLE PORTABLE SOCKET OUTLET with an isolated supply of electricity or a socket-outlet protected by a Type 1 residual current device.' **RATIONALE:** Unlike most IEC countries, Australian mains supply wiring conforms to a single national standard, and the wiring of Medical Treatment areas is further specified in accordance with AS 3003, which has been in force since 1976. This Standard does not allow the presence of unprotected outlets in the PATIENT ENVIRONMENT.
Clause 57.2.201	*Replace* the Clause with 'The MULTIPLE PORTABLE SOCKET-OUTLET, which shall comply with AS/NZS 3105, *Approval and test specification—Electrical portable outlet devices*, shall be supplied with electricity from a Type 1 residual current device or by an isolated supply of electricity. Unused socket-outlets not required for the system should be protected against inadvertent use by a cover or other effective method of protection.'
Clause 19.201.1	Not relevant to Australian and New Zealand requirements.
Annex EEE	Not relevant to Australian and New Zealand requirements.
Annex FFF	Not relevant to Australian and New Zealand requirements.

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