

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Amendment No. 1

to

AS/NZS 3200.1.1:1995

Approval and test specification—Medical electrical equipment

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

REVISED TEXT

The 1995 edition of AS/NZS 3200.1.1 is amended as follows; the amendment(s) should be inserted in the appropriate place.

SUMMARY: This Amendment applies to the Preface, Contents, Clauses 1, 2, 4, 6, 17, 19, 57.2, 57.10, Figure 201, Annexes AAA, BBB, CCC, EEE, FFF and Appendix ZZ.

The text of this Amendment is based on and includes the full text of IEC 601-1-1 Amend.1:1995.

Published on 5 August 1997.

Approved for publication in New Zealand on behalf of the Standards Council of New Zealand on 14 April 1997.

AMDT
No. 1
AUG.
1997

Page ii Preface

- 1 *Delete* from the second paragraph 'It is identical with and has been reproduced from' and *substitute* 'It is based on and includes the full text of'.
- 2 Insert the following additional paragraph after the second paragraph:
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.
- 3 From the sentence preceded by an asterisk, *delete* 'Appendix AA' and *substitute* 'Annex AAA'.

AMDT
No. 1
AUG.
1997

Page 20 Appendix ZZ

Add the following Appendix ZZ:

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.

601-1-1 Amend. 1 © IEC:1995

Amendment 1

CONTENTS

Add, after 2.205, the title of the following new subclause:

2.206 MULTIPLE PORTABLE SOCKET-OUTLET	1
---	---

Add on page V, after 56.3.201, the titles of the following new subclauses:

57.2.201 MULTIPLE PORTABLE SOCKET-OUTLET	3
57.10.201 CREEPAGE DISTANCES and AIR CLEARANCES	4

Add the following two annexes:

EEE Requirements for MULTIPLE PORTABLE SOCKET-OUTLETS	9
FFF Examples of application of MULTIPLE PORTABLE SOCKET-OUTLETS	11

Section 1

1 Scope and object

*1.201 Scope

Replace the text of this subclause by the following:

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

*2.203 MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as a SYSTEM)

Replace the text of this subclause by the following:

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

Replace, first line, the word "area" by "volume", and add, at the end of the paragraph, "(see for illustration figure 201)".

Add the following new definition, taken and derived from IEC 884-1:

*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.

4 General requirements for tests

Add an asterisk in front of the 4.201 subclause number.

Replace the text of the last dash of the compliance text of this subclause by the following:

- 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

Replace, in the second line of the subclause, "table 1" by "table DI".

Add, before the compliance text, the following note:

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.

*6.8.201 ACCOMPANYING DOCUMENTS

Replace the title and the text of this subclause by the following:

*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 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;

- 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 3

17 Separation

Replace the last three paragraphs of the compliance text by the following:

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.

19.201.1 ENCLOSURE LEAKAGE CURRENT

Add, after the second paragraph of this subclause, the following sentence:

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.

Section 10

Add, after 56.3.201, the following new subclauses:

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 CLEARANCES 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 AIR CLEARANCES in millimetres

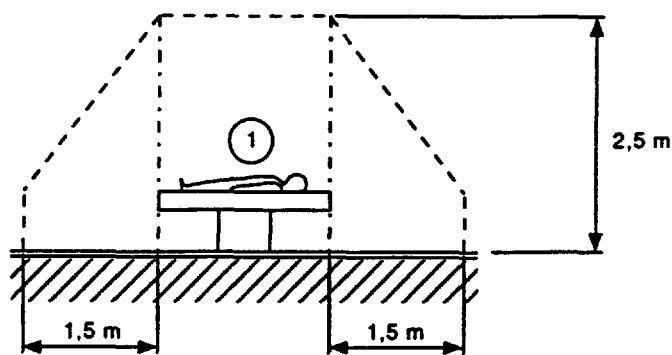
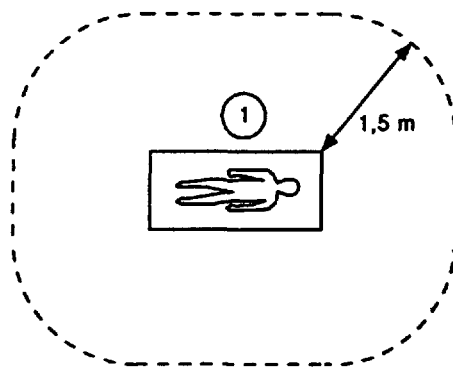
U	DC voltage	15	36	75	150	300	450	600	800	900	1 200	
	AC voltage	12	30	60	125	250	400	500	660	750	1 000	
SEPARATION DEVICE		0,8	1	1,2	1,6	2,5	3,5	4,5	6	6,5	9	AIR CLEARANCES
		1,7	2	2,3	3	4	6	8	10,5	12	16	CREEPAGE DISTANCES

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.

Figure 201

Replace the existing figure by the following new one defining a volume instead of an area.



IEC 405/95

Figure 201 – Example of PATIENT ENVIRONMENT

ANNEX AAA

Subclause 1.201 Scope

Add, at the beginning of the text, the following two paragraphs:

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.

Replace the first paragraph under the heading "Situation b)" by the following:

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.

Add, at the end of 1.201, the title and text of the following sub-clause:

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

Replace, in two places in the first paragraph, the word "an area" by "a volume".

Replace the text of the second paragraph by the following:

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).

Add the title and text of the following subclause:

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.

Add, after 3.201.3, the title and text of the following subclause:

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

Replace, in the title, "ACCOMPANYING DOCUMENTS" by "Accompanying documents".

Add, page 31, at the end of the text of this subclause, the following new paragraphs:

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 19.201 LEAKAGE CURRENTS

Replace the third dot of the second paragraph by the following:

- a separating transformer, or

Add, after 49.201, the title and text of the following subclause:

Subclause 57.2.201 MAINS CONNECTORS, APPLIANCE INLETS and the like

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

ANNEX BBB

BBB.4 Assumptions on EQUIPMENT

Add, in item c) fourth line, after "additional earthing" the words "or a SEPARATION DEVICE".

BBB.6 Codes assigned to feasible solutions

Code Q

At the end of the paragraph, page 39, replace "extra isolating transformer" by the words "additional separating transformer".

BBB.7 Summary of situations

Add, in the second line of the table, the following new elements in their respective columns:

Situation No.	Equipment A	Equipment B	Solution
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).

In the legend replace "(Q: extra isolating transformer)" by "(Q: additional separating transformer)".

ANNEX CCC – Normative references

Insert, in the existing list, the titles of the following standards:

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

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*

Add, after annex DDD, the following new annexes EEE and FFF:

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 addition to 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 inspection 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.