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NZEC 12:1993

NEW ZEALAND ELECTRICAL CODE OF PRACTICE

for

ELECTRICAL INSTALLATIONS

**THE SAFE USE OF ELECTRICITY IN MEDICAL LOCATIONS AND
ASSOCIATED AREAS**

Issued by the Office of
The Chief Electrical Inspector,
Energy and Resources Division, Ministry of Commerce

THE ELECTRICITY ACT 1992

APPROVAL OF ELECTRICAL CODE OF PRACTICE

FOR

ELECTRICAL INSTALLATIONS

THE SAFE USE OF ELECTRICITY IN

MEDICAL LOCATIONS AND ASSOCIATED AREAS

Pursuant to Section 36 of the Electricity Act 1992 ("the Act")

On the 1st day of February 1993, the Secretary of Commerce issued the Electrical Code of Practice for Electrical Installations, the Safe use of Electricity in Medical Locations and Associated Areas ("the Code")

On the 4th day of February 1993, pursuant to Section 38 of the Act the Secretary published in the Gazette a notice of intention to apply to me for approval of the code, and there has been consultations with such persons (or their representatives) as will be affected by the Code and they have had the opportunity to consider possible effects and comment on those effects.

I have considered the comments concerning those effects and where necessary amendments were made to the Code.

Therefore Pursuant to Section 38 of the Act, I, John Luxton, Minister of Energy, have this day approved the Code as attached to this approval, which Code shall come into force on the 1st day of April 1993.

Dated this 18th day of March 1993.

John Luxton
Minister of Energy.

COMMITTEE REPRESENTATION

This Code of Practice was prepared by the Ministry of Commerce, Chief Electrical Inspector's Office with reference to the following organisations:

Electrical Contractors' Association of NZ Inc.
Electrical Supply Engineers' Association of NZ Inc.
New Zealand Electrical Institute
Electrical Inspectors' Association
Institution of Professional Engineers of New Zealand

REVIEW

This Code of Practice will be revised as occasions arise. Suggestions for improvement of this Code are welcome. They should be sent to the Chief Electrical Inspector's Office, Ministry of Commerce, P O Box 1473, WELLINGTON.

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INTRODUCTION

This code of practice is intended to provide guidance on acceptable methods for determining the safe supply of electricity for patient treatment purposes.

ELECTRICAL INSTALLATIONS, THE SAFE USE OF ELECTRICITY IN MEDICAL LOCATIONS AND ASSOCIATED AREAS

SECTION 1

SCOPE, APPLICATION, REFERENCED DOCUMENTS, INTERPRETATIONS, GLOSSARY AND NUMBERING

1.1 SCOPE

This Code of Practice sets out the requirements of electrical installations for supply of electricity to patient treatment areas, including hospitals, private clinics, medical and dental practices, and dedicated medical areas in other places. The Code also sets requirements for medical electrical appliances.

1.2 APPLICATION

In this Code, particular requirements are given for:

- (a) The supply of electricity to fittings and appliances used in patient treatment areas.
- (b) Fixed wiring installations in patient treatment areas.
- (c) Electrical fittings and appliances used in patient treatment areas.
- (d) Maintenance of installations and fittings and appliances associated with patient areas.
- (e) Training on the use of medical electrical appliances associated with patient areas.
- (f) Inspection and certification of installations associated with patient areas.
- (g) Periodic reinspection of installations and appliances associated with patient areas.

1.3 REFERENCED DOCUMENTS

AS 2500 - Guide to the safe use of electricity in patient care.
AS 3003 - Electrical installations - Patient treatment areas in hospitals.
AS 3009 - Electrical installations - Emergency power supplies in hospitals.
AS 3013 - Electrical installations - Wiring systems for specific applications.
AS 3190 - Approval and test specification - Residual current devices (current-operated earth-leakage devices).
AS 3551 - Acceptance testing and in-service testing - Electromedical Equipment.

1.4 INTERPRETATIONS

In this Code, unless the context otherwise requires:

- 1.4.1 Applied part - means entirety of all parts of fittings and appliances including the patient leads which come intentionally into contact with the patient to be examined or treated.
- 1.4.2 Body Protected Electrical Areas - means a location where applied parts of electrical fittings and appliances is intended to be used, but not for intracardiac procedures.
- 1.4.3 Cardiac Protected Electrical Areas - means a location where medical electrical fittings and appliances for intracardiac procedures is intended to be used.
- 1.4.4 Distribution switchboard - means a switchboard which has no link between neutral and earth.
- 1.4.5 Electrical equipment - means electrical fittings and appliances.
- 1.4.6 Electrical Installation:
- (a) Means all fittings:
 - (i) that form part of such a system for conveying electricity; and
 - (ii) that form part of such a system at any point from the point of supply to a consumer to any point from which electricity conveyed through that system may be consumed; and
 - (b) Includes any fittings that are used, or designed or intended for use, by any person, in or in connection with the generation of electricity for that person's use and not for supply to any other person; but
 - (c) Does not include any electrical appliance.
- 1.4.7 General Purpose Outlet (GPO) - means a low voltage socket-outlet having a rating of 10 A and which is designed to accommodate a 10 A three-pin flat-pin plug.
- 1.4.8 Linked busbar switchboard - means a switchboard which has a removable link between earth and neutral for the purpose of returning earth fault currents to the supply neutral.
- 1.4.9 Main switchboard - means in respect of an electrical installation, that switchboard which provides the greatest degree of control of the supply of electricity to that installation.
- 1.4.10 Mains - means those fittings forming part of an electrical installation that are used for the supply of electricity to the main switchboard of that installation.

- 1.4.11 MEN switchboard - means a switchboard which has a connection to an earth electrode via an earthing lead, and a connection between earth and neutral made by a removable link, for the purposes of an MEN system.
- 1.4.12 Medical electrical fittings and appliances - means electrical (including battery supplied) fittings and appliances provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient.
- 1.4.13 Mobile fittings and appliances - means transportable fittings and appliances intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.
- 1.4.14 Patient treatment area - means a location intended for accommodation of patients for purposes of diagnoses, treatment and care.
- 1.4.15 Patient circuit - means an electrical circuit of which the patient forms a part.
- 1.4.16 Patient location - means any intended location of the bed, table or seating arrangement for a patient, whether or not occupied by the patient.
Where the location of a patient undergoing a medical electrical procedure is likely to vary for different occasions, e.g. in some operating theatres, the patient location extends to the entire room. This includes locations for incubators or cribs in delivery suites.
- 1.4.17 Prospective touch voltage - means the highest touch voltage liable to appear in the event of a fault of negligible impedance in the electrical installation.
- 1.4.18 Verification dossier - means a set of documents showing the correctness by examination demonstration for the compliance of electrical appliances and fittings.

1.5 GLOSSARY OF ABBREVIATIONS USED IN THIS CODE

| | |
|-----|-------------------------|
| AS | Australian Standard |
| mm | Millimetres |
| rms | Root-mean-square |
| RCD | Residual current device |
| LIM | Line isolation monitor |

1.6 NUMBERING SYSTEM OF THIS CODE

- 1.6.1 Sections are numbered from 1 to 10.
- 1.6.2 Subsections are numbered by one full stop between two numbers. (eg:1.6).
- 1.6.3 Clauses are numbered by two full stops between three numbers. (eg:4.18.3).
- 1.6.4 Subclauses are numbered by three full stops between four numbers. (eg:3.2.1.1).
- 1.6.5 Paragraphs contain numbering punctuated by one or more full stops together with a parenthesised letter.
- 1.6.6 Subparagraphs are represented by lower case roman numerals enclosed in parenthesis following paragraphs.

SECTION 2

DISTRIBUTION AND CONTROL

2.1 MEN SWITCHBOARDS

- 2.1.1 For the purposes of this Code; MEN switchboards of an electrical installation shall:
- (a) Be supplied with electricity from an electricity supply system, a generator, or another MEN switchboard;
 - (b) Have a connection to the earth electrode made to the earth busbar;
 - (c) Have a removable link between the earth continuity busbar and the neutral busbar; and
 - (d) Not be supplied from either a linked busbar or distribution switchboard.
- 2.1.2 MEN switchboards may:
- (a) Have an earth continuity conductor linking its earth continuity busbar with the earth continuity busbar of the switchboard from which that MEN switchboard derives a supply of electricity; and
 - (b) For the purposes of equipotential bonding, have conductive parts which have an electrical path to earth connected to the earth continuity busbar.

2.2 LINKED BUSBAR SWITCHBOARDS

- 2.2.1 Linked busbar switchboards of an electrical installation shall:
- (a) Not be supplied from a distribution switchboard;
 - (b) Have an earth continuity conductor linking its earth continuity busbar with the earth continuity busbar of the switchboard from which that linked busbar switchboard derives a supply of electricity;
 - (c) Have a removable link between the earth continuity busbar and the neutral busbar; and
 - (d) Not supply an MEN or distribution switchboard.
- 2.2.2 Linked busbar switchboards may, for the purposes of equipotential bonding, have conductive parts which have an electrical path to earth, connected to the earth continuity busbar.

2.3 DISTRIBUTION SWITCHBOARDS

- 2.3.1 Distribution switchboards of an electrical installation shall:
- (a) Not be supplied from a linked busbar switchboard;
 - (b) Have an earth continuity conductor linking its earth continuity busbar with the earth continuity busbar of the switchboard from which that distribution switchboard derives a supply of electricity;

- (c) Not be supplied with electricity from more than one switchboard (this does not prevent the total segregation of a single physical switchboard assembly into two separate sections); and
- (d) Not supply a main or linked busbar switchboard; and
- (e) Not have a link between any neutral and earth conductors.

2.3.2 Distribution switchboards may, for the purposes of equipotential bonding, have conductive parts which have an electrical path to earth connected to the earth continuity busbar.

2.4 SWITCHBOARDS INSTALLED PRIOR TO 1 APRIL 1994

2.4.1 Any switchboard installed prior to 1 April 1994 in which the connection to the mass of earth is made onto the supply neutral is deemed to be in conformity with these requirements and is deemed to constitute a MEN Switchboard.

2.5 SUPPLY TO INSTALLATIONS CONTAINING PATIENT TREATMENT AREAS

2.5.1 All installations containing patient treatment areas supplied with electricity from an MEN system shall have a MEN Switchboard.

2.5.2 In every installation containing a patient treatment area supplied with electricity from an MEN system, the switchboard electrically closest to the point of supply shall be a MEN Switchboard.

2.5.3 Any installation containing a patient treatment area supplied with electricity from an MEN system may include any number of MEN, Linked busbar or Distribution Switchboards in accordance with the limitations applying to the interconnection of such switchboards.

2.5.4 The characteristics of the protective devices, the earthing arrangements for the installation, and the relevant impedances of any submain feeding a distribution switchboard shall be coordinated so that during an earth fault the simultaneous voltages between accessible exposed conductive parts occurring anywhere in the installation shall be of a magnitude and duration as not to cause danger.

2.5.4.1 This is deemed to be met when the earth fault loop impedance of every circuit of the installation or part of installation is such that disconnection occurs within 0.4 of a second and the prospective touch voltage does not exceed 50 volts.

2.6 SUPPLY TO CARDIAC PROTECTED PATIENT TREATMENT AREAS

- 2.6.1 A Distribution Switchboard may be used in an installation for the supply of electricity to a patient treatment area provided that:
- a) The installation contains only one MEN Switchboard; and,
 - b) The installation does not contain any Linked busbar Switchboards.
- 2.6.2 A Distribution Switchboard may be used in a sub-installation for the supply of electricity to a patient treatment area provided that:
- a) The sub-installation is supplied, within an installation, from an individual electricity supply to which only one MEN Switchboard is connected; and,
 - b) That MEN Switchboard is the Main Switchboard for the sub-installation ; and,
 - c) The installation does not contain any Linked busbar Switchboards.
- 2.6.3 A Distribution Switchboard may be used in an installation for the supply of electricity to a patient treatment area provided that any conductive parts connected to the earth continuity bus bar for the purposes of equipotential bonding do not have an electrical path to earth which is shared with that of any other switchboard within the installation of which that Distribution Switchboard forms a part.
- 2.6.4 Where a distribution switchboard supplies a protected area, only those subcircuits and earth bonding conductors installed for that area shall be connected to that distribution switchboard.
- 2.6.5 A MEN switchboard may be used for the supply of electricity to a patient treatment area provided that:
- a) The installation contains only one MEN Switchboard; and,
 - b) The installation does not contain any Linked busbar Switchboards.
- 2.6.6 A Linked busbar switchboard shall not be used for the supply of electricity to any patient treatment area.
- 2.6.7 Where unregistered persons have access to switchboards, overcurrent protection shall be by a suitably rated circuit breakers.
- 2.6.8 All earthing continuity conductors shall be of high grade conductivity copper.

SECTION 3

FIXED WIRING INSTALLATIONS IN PATIENT TREATMENT AREAS

3.1 GENERAL

- 3.1.1 The electrical installation associated with patient treatment areas shall be to the requirements of AS 3003:1985 as modified by Appendix A of this Code.
- 3.1.2 Body Protected and Cardiac Protected electrical areas shall be indicated and marked by the use of area designation labels.
- 3.1.3 The supply to appliances used for patient treatment in areas outside a normal patient treatment area shall be in accordance with the requirements for body-protected areas. Such treatments include haemodialysis treatments, dental procedures, etc.

3.2 ELECTRICAL CABLES

Where security of supply is deemed essential, cables used to supply these services shall comply with WS4X for submains and WS1X for other cables to the requirements of AS 3013, unless the cable is installed in an area which is protected by sprinklers.

3.3 SUPPLEMENTARY EQUIPOTENTIAL BONDING

- 3.3.1 Supplementary equipotential bonding shall be carried out in accordance with AS 3003 as amended by Appendix A of this Code.
- 3.3.2 Equipotential bonding conductors shall be insulated and the colour of the insulation shall be green or a combination of green and yellow.
- 3.3.3 The earth continuity conductor from the equipotential bus to the supply switchboard shall be appropriately labelled at the supply switchboard.
- 3.3.4 The total current carried by a piped service shall not exceed 10 amperes in a cardiac protected area. This may be controlled by the installation of isolation devices.

SECTION 4**INSTALLATION OF FITTINGS AND APPLIANCES****4.1 GENERAL**

- 4.1.1 Where inflammable gases are present or likely to be used on a regular basis, electrical fittings and appliances shall not be installed less than 500 mm from the floor.
- 4.1.2 Socket-outlets provided for dedicated cleaning appliances in cardiac protected locations shall be a non standard 3 pin socket-outlet protected by an RCD. The outlet shall be marked "cleaning purposes only".
- 4.1.3 The number and disposition of socket-outlets at a patient location shall be such as to alleviate the need for the use of cord extension sets and adaptors.
- 4.1.4 Where the room is under positive pressure from ventilation or air-conditioning systems, the use of dust proof socket-outlets shall be used or means employed to minimize the effects of dust contamination of contact surfaces.
- 4.1.5 Where the use of a plug in extra low voltage "power pack" medical fittings and appliances requires a greater spacing of general purpose socket-outlets, a horizontal spacing of no less than 65 mm shall apply to all socket-outlets.

SECTION 5**EMERGENCY SUPPLIES****5.1 GENERAL**

- 5.1.1 Installations, fittings and appliances associated with emergency supply of electricity to patient treatment areas shall be in accordance with AS 3009.

SECTION 6**EXAMINATION, TESTING AND CERTIFICATION****6.1 GENERAL**

- 6.1.1 The examination, testing and certification of installations and fittings for the supply of electricity to patient treatment areas shall be in accordance with the requirements of Appendix K of AS 3003, as amended by Appendix A of this Code.
- 6.1.2 Certification shall not be issued for any installations or fittings for the supply of electricity to patient treatment areas that do not meet the requirements of this Section.

6.2 DOCUMENTATION

To ensure that the electrical installation of patient care areas complies with the certification documents, records shall be kept and made available for inspection and maintenance. This can be achieved by the following methods:

- 6.2.1 Plans of the electrical installation together with records, drawings, wiring diagrams and modifications, as well as instructions for operation and maintenance, shall be prepared and be readily available.
- 6.2.2 Drawings and wiring diagrams shall contain a list of all symbols used and their meanings.
- 6.2.3 The documents shall include:
- (a) Block diagrams showing the distribution systems of the normal power supply and power supply for safety services in a single-line representation. These diagrams shall contain information on the location of the switchboards within the building;
 - (b) Block diagrams showing switchgear and control gear and switchboards in a single-line representation;
 - (c) Schematic diagrams of controls;
 - (d) Instructions for operation and maintenance of storage batteries and power sources for safety services;
 - (e) Lists of loads permanently connected to the power supply for safety services indicating the normal currents and, in the case of motor-operated loads, the starting currents;
 - (f) A logbook containing a record of all tests and inspections which require to be completed prior to commissioning.

SECTION 7**INSPECTION, TESTING AND CERTIFICATION****7.1 GENERAL**

- 7.1.1 The inspection, testing and certification of installations and fittings for the supply of electricity to patient treatment areas shall:
- (a) Verify that the examination, testing and certification in accordance with Section 6 has been carried out;
 - (b) Verify that the documentation in accordance with Section 6 has been completed;
 - (c) Verify by testing, the operation of all RCDs and LIMs for the supply of electricity to patient treatment areas are in accordance with the requirements of this Code;
 - (d) Verify that all area designation labels and switchboard labelling have been installed in accordance with the requirements of this Code.
- 7.1.2 The inspecting person shall not certify any installations or fittings for the supply of electricity to patient treatment areas that do not meet the requirements of this Section.

SECTION 8

MEDICAL ELECTRICAL APPLIANCES

8.1 GENERAL

- 8.1.1 Electrical appliances used for medical electrical procedures shall comply with one of the Standards listed in the First Schedule to this Code except that NZS 6200 may only be applied where no applicable particular Standard is listed in the Schedule.
- 8.1.2 Medical electrical appliances shall undergo acceptance testing to the requirements of AS 3551:1988, acceptance testing and in-service testing - Electromedical Equipment.
- 8.1.3 Documentation showing compliance with an electrical safety standard shall be recorded in a verification dossier.

SECTION 9

MAINTENANCE

9.1 GENERAL

- 9.1.1 This section sets the requirements for maintenance which are applicable to patient treatment areas and medical electrical fittings and appliances. Although this Code cites AS 3003 as the Standard for new installations and alterations, the need for continuous maintenance of safety standards of existing installations and fittings and appliances is recognized. This section shall also apply to all existing patient treatment areas where Body Type or Cardiac Type patient procedures are carried out.
- 9.1.2 Each installation shall have a responsible person; having appropriate knowledge and experience and holding a relevant electrical/electronic qualifications, to be responsible for the implementation and updating of a system of inspection, testing and maintenance.
- 9.1.3 Regular inspection procedures, by properly trained personnel, shall be established for fittings and appliances maintenance programmes and area maintenance programmes.
- 9.1.4 Routine test results shall be recorded in the verification dossier for the fittings and appliances and be made available if required.
- 9.1.5 The general condition of all fittings and appliances shall be noted periodically and appropriate remedial measures taken where required. Care shall be taken to ensure that the remedial measures adopted maintain the integrity of the type of protection provided for the fittings and appliances.
- 9.1.6 Repair or modification to electrical appliances and fittings shall ensure that the electrical appliances and fittings comply to the standard for that apparatus before use.

9.2 FAULT REPORTING

- 9.2.1 All faults with medical electrical fittings and appliances shall be reported to a responsible person via an established procedure.
- 9.2.2 All patient-care staff shall be provided with, or have access to, a fault report book or other means which ensure that fault reports are transmitted, permanently recorded and acted upon.
- 9.2.3 Staff should be encouraged to report all electrical faults, however minor, to responsible person so that remedial action may be taken.
- 9.2.4 Immediately fittings and appliances has been detected as faulty, it shall be

disconnected from the supply, removed from use, and have attached a warning notice against further use.

9.2.5 It is recommended that the warning notice:

- (a) Be readily available and attachable;
- (b) Include provision for description of fault symptoms; and
- (c) Be prominent in its design, e.g. "fault tag".

9.2.6 All incidents involving fittings and appliances failure and/or injury to staff or patients shall be reported, with a suitable file being established to enable regular and coordinated review of hospital safety programmes.

SECTION 10

PERIODIC REINSPECTION

10.1 ELECTRICAL INSTALLATIONS AND FITTINGS

- 10.1.1 Electrical installations and fittings shall be retested and verified by the use of the test sheets of AS 3003 Appendix K as amended by Appendix A of this Code or equivalent.
- 10.1.2 Test results shall be held in a verification dossier for the installations and fittings being tested and made available to the inspecting authority.
- 10.1.3 Electrical installations and fittings in Cardiac and Body Protected Areas of hospitals shall be retested at intervals determined by their normal usage, but shall not exceed the intervals as follows:

| Item | Type of inspection / test | Period between tests |
|---|---|----------------------|
| Socket-outlets and switches | Visual (external) examination | 1 month |
| Basic operation of RCD's and LIM | Integral test facility, e.g. test button to be activated | 1 month |
| Performance of RCD's and LIM | Measurement of speed of operation and sensitivity | 6 months |
| Earthing facilities, including loose or faulty socket-outlet contacts | Detailed visual examination and measurement of continuity | 12 months |

10.2 MEDICAL ELECTRICAL APPLIANCES

- 10.2.1 Medical electrical appliances shall be tested to verify their electrical safety by the applicable tests of AS 3551 as amended by Appendix B of this Code.
- 10.2.1.1 In no case shall these tests be more stringent than the applicable tests of AS 3200.1.
- 10.2.1.2 Test results shall be held in the verification dossier for the medical electrical appliances being tested and be made available to the inspecting authority.

10.2.2 Medical electrical appliances shall be retested at intervals determined by their location or area of use, or by manufacturers instructions, but in no case shall the intervals exceed the following unless the period has been determined by a recognised quality assurance system under the responsibility of a competent person:

| Type of appliances | Period between tests |
|--|----------------------|
| Appliances in general areas | 6 months |
| Appliances used in cardiac-type and body-type procedures | 3 months |
| Appliances in constant use subject to possible mechanical damage | 3 months |

10.2.3 Retesting results of medical electrical appliances shall be recorded into the verification dossier for the appliances

10.3 CERTIFICATION

10.3.1 Certificates of reinspection of installations associated with patient treatment areas shall only be issued by persons holding a registration as an electrical inspector and having a valid practising certificate.

10.3.2 Certificates of reinspection of installations associated with patient treatment areas shall be valid for a period of 4 years.

10.3.3 The issuing person shall complete testing and examination in accordance with the requirements of this section. The issuing person may issue a certificate (referred to as a "Certificate of Reinspection") to the client whose installation associated with a patient treatment area meets the requirements of Section 6. The certificate issued in accordance with this section shall be in the Form prescribed in Appendix A of this Code.

10.3.4 The person issuing the certificate shall:

- a) Give a copy to the applicant;
- b) Either retain a copy of the certificate for a period not less than 4 years or supply a copy to the Secretary of Commerce.

SECTION 11

TRAINING

11.1 GENERAL

- 11.1.1 All patient care staff involved in the supervision of patients undergoing medical electrical procedures shall take part in in-service training for the correct and safe use of fittings and appliances.
Such training shall occur at intervals not exceeding 12 months.
Specific training shall be given (to relevant staff) at the introduction of new fittings and appliances or procedures.
- 11.1.2 All persons involved in the maintenance and testing of medical electrical installations, fittings and appliances, both at the time of commissioning and on-going, shall take part in in-service training of the correct maintenance and testing procedures. Such training shall occur at intervals not exceeding 12 months.
- 11.1.3 AS 2500 "Guide to the Safe use of Electricity in Patient Care", may be used as a training document for electrical safety in medical areas to meet the requirements of above.

APPENDIX A

AMENDMENT TO AS 3003

- 1 Where text in the standard reads "plug-socket" replace with "GPO".
- 2 Clause 1.3 Reference Documents add: "VDE 0664-1985: 10 mA residual current-operated protection devices; residual current-operated circuit breakers rated up to 500V ac and up to 63 A."
- 3 Clause 1.3 reference Documents. Replace reference to AS 3200 with "AS 3200.1/NZS 6150-Approval and test specification-Medical electrical equipment. Part 1 General requirements".
- 4 Clause 1.4.6.2, Delete references to "Class A, or Class B patient-circuit", and replace with "Clause 2.1.7 for F-type, Clause 2.2.24 to 26 for Type B, BF and CF equipment, in accordance with AS 3200.1/NZS 6150.
- 5 Clause 1.4.17, Delete reference "0.5.73", and replace with "0.5.70".
- 6 Clause 1.4.18, Delete the text, and replace with "Outlet-general purpose (GPO)-see definition 0.5.66 in AS 3000".
- 7 Clauses 2.2.1 and 2.2.2, delete "and medium voltage".
- 8 Clause 2.6.1(a) Add after core balance devices, "or VDE 0664 10 mA earth leakage

core balance devices".

- 9 Clause 2.6.3, delete the word "shall" and replace with the word "should".
- 10 Clause 3.2.3.2, add after "AS 3127" with the words "or AS 3180".
- 11 Clause 3.3.2, delete the words "and medium voltage".
- 12 Clause 3.6.1(a) Add after core balance devices, "or VDE 0664 10 mA earth leakage core balance devices".

APPENDIX B

AMENDMENT TO AS 3551

- 1 Clause 1.4, Referenced documents. Add "AS 3200.1/NZS 6150, Approval and test specification - Medical Electrical Equipment. Part 1, General requirements for safety.
- 2 Appendix B and Appendix G of AS 3551 are replaced with Patient Auxiliary Current Tests to diagram on page 190 of AS 3200.1/NZS 6150, "Examples for the connection of the applied part for measurement of the patient auxiliary current", diagram for Type B, BF, CF equipment (This is reproduced in this Appendix).
- 3 Test results on page 46, Table IV of AS 3200.1/NZS 6150. (This is reproduced in Appendix B of this standard).

Patient Auxiliary Circuit Test (for acceptance testing only).

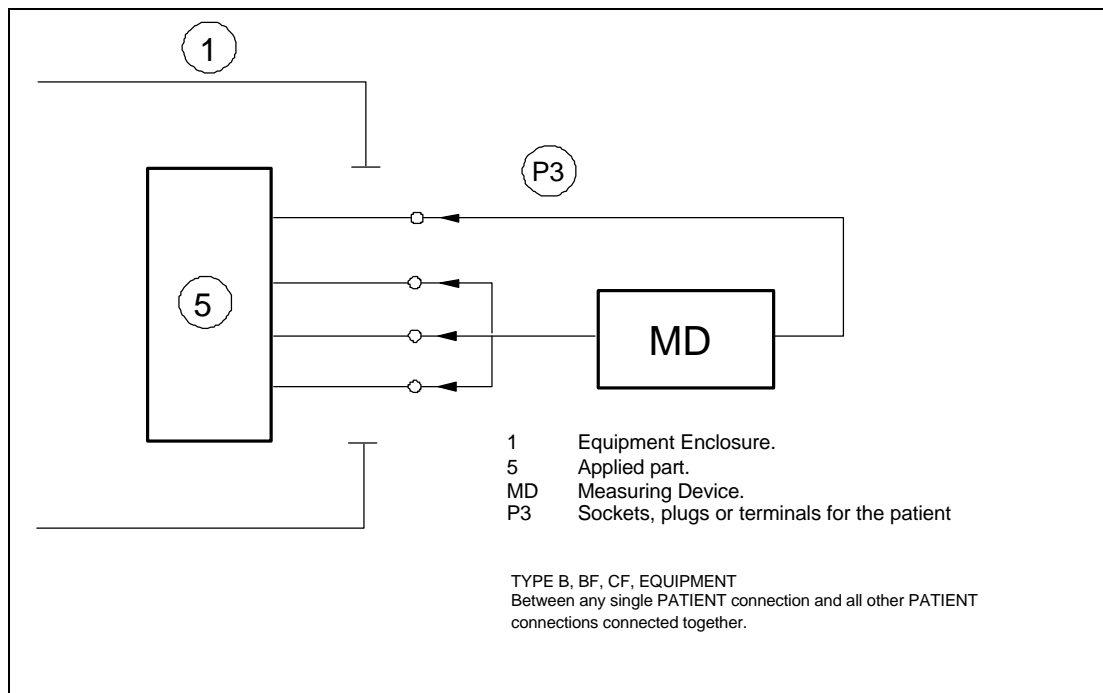


Figure 1 Patient Auxiliary Current

TABLE 1

** Allowable values of continuous LEAKAGE and Patient AUXILIARY CURRENTS,
in milliamperes*

| Current | Type B | | Type BF | | Type CF | | |
|--|--------|------------------|---------|------------------|---------|------------------|------|
| | N.C. | S.F.C. | N.C. | S.F.C. | N.C. | S.F.C. | |
| Earth leakage current general | 0.5 | 1 ¹⁾ | 0.5 | 1 ¹⁾ | 0.5 | 1 ¹⁾ | |
| Earth leakage current for equipment according to notes ²⁾ and ⁴⁾ | 2.5 | 5 ¹⁾ | 2.5 | 5 ¹⁾ | 2.5 | 5 ¹⁾ | |
| Earth leakage current for equipment according to note ³⁾ | 5 | 10 ¹⁾ | 5 | 10 ¹⁾ | 5 | 10 ¹⁾ | |
| Enclosure leakage current | 0.1 | 0.5 | 0.1 | 0.5 | 0.1 | 0.5 | |
| Patient leakage current | 0.1 | 0.5 | 0.1 | 0.5 | 0.01 | 0.05 | |
| Patient leakage current (MAINS VOLTAGE on the SIGNAL INPUT PART OR SIGNAL OUTPUT PART) | - | 5 | - | - | - | - | |
| Patient leakage current (MAINS VOLTAGE on the APPLIED PART) | - | - | - | 5 | - | 0.05 | |
| * Patient auxiliary current | d.c. | 0.01 | 0.05 | 0.01 | 0.05 | 0.01 | 0.05 |
| | a.c. | 0.1 | 0.5 | 0.1 | 0.5 | 0.01 | 0.05 |

Notes on Table 1

N.C.: Normal Condition
S.F.C.: Single Fault Condition

- 1 The only single fault condition for the earth leakage current is the interruption of one supply conductor at a time (see Sub-clause 19.2 (a) and figure 16 of AS 3200.1).
- 2 Equipment which has no protectively earthed accessible parts and no means for the protective earthing of other equipment and which complies with the requirements for the enclosure leakage current and for the patient leakage current (if applicable).

Example: Some computers with a screened mains part.

- 3 Equipment specified to be permanently installed with a protective earth conductor which is electrically so connected that the connection can only be loosened with the aid of a tool and which is so fastened or otherwise so secured mechanically at a specific location that it can only be moved after the use of a tool.

Examples of such equipment are:

- Major components of an X-ray installation such as the X-ray generator, the examination or treatment table.
 - Equipment with mineral insulated heaters.
 - Equipment with an earth leakage current higher than stated in table IV, first line, which is due to compliance with requirements for radio-interference suppression.
- 4 Mobile x-ray equipment and mobile equipment with mineral insulation.
 - 5 Appendix C of AS 3551, delete from Table C1 "Cord connected fittings and appliances with "Type CF" mark on rating plate, and test figures".
 - 6 Appendix D of AS 3551, delete from Table D1 "Cord connected equipment with "Type CF" mark on rating plate, and test figures".
 - 7 Appendix E of AS 3551, delete and replace with "Patient Circuit Current Test".

Patient Circuit Current Test

Note: (Figure 2 Reproduced from page 125 of AS 3200.1)

Patient- circuit current is the current which flows between any patient connection of the patient-circuit and any other patient connection or earth.

When tested in accordance with the circuit in Figure 2, the maximum values of patient circuit current recorded shall not exceed the appropriate limits specified in Table 4.2. Patient-circuit current measured here is the total patient-circuit current (i.e. measured with all patient connections of a patient-circuit bonded together). AS 3200.1 defines test protocols that measure both patient leakage current and patient auxiliary current. This test determines the combination of both currents.

NOTES:

- 1 This test does not attempt to check the patient-circuit current under the comprehensive test combinations specified in the AS 3200.1 series for 'type approval' testing. The tests in this standard are fewer and are specified to check that equipment which has been type approved has not been degraded by faulty manufacture or transport damage.
- 2 A true r.m.s. reading meter with sensitivity characteristics complying with those specified in AS 3200.1, Clause 19.4 (e), Measuring Devices (MD), is required.

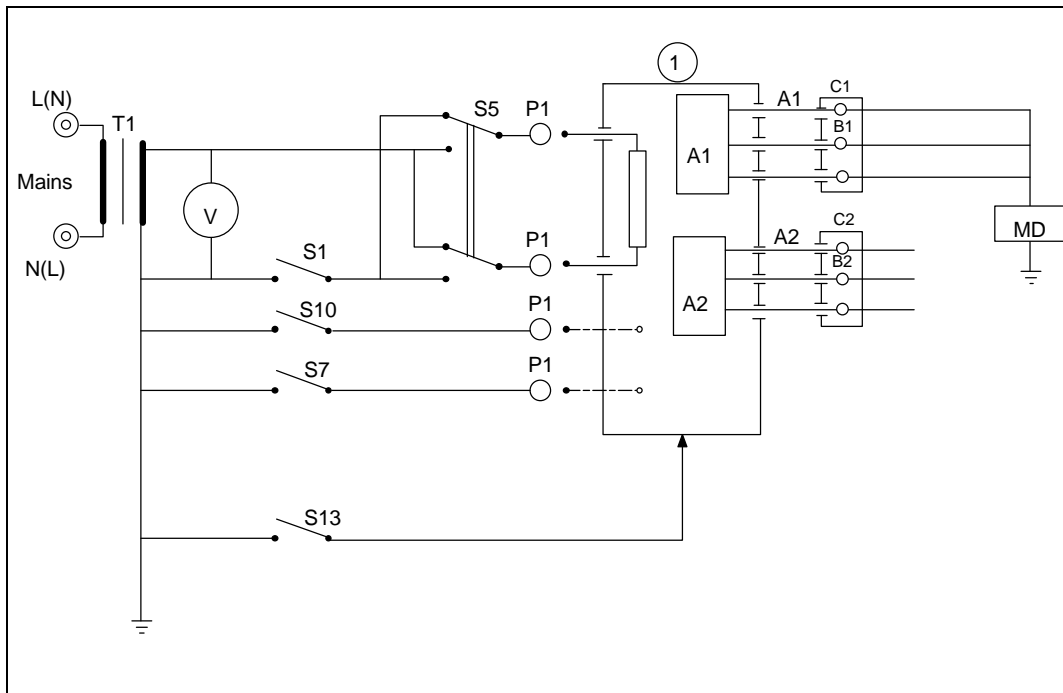


Figure 2 Measurement of Patient Circuit Current

KEY

- 1 Equipment enclosure.
- T1 Single or polyphase isolation transformers with sufficient power rating and adjustable output voltage.
- V Voltmeter indicating r.m.s value, using, if relevant and possible, one meter with a commutator switch.
- S1 Single-pole switches, simulating the interruption of a power supply conductor (single fault condition).
- S5 Commutator switches to reverse the polarity of the mains voltage.
- S7 Single-pole switches, simulating the interruption of a single protective earth conductor (single fault condition).
- S10 Switches for connecting a functional earth terminal to the earthed point of the measuring supply circuit.
- S13 Switch for connecting to earth an accessible metal part not being an applied part and not protectively earthed.
- P1 Sockets, plugs or terminals for the supply connection of the equipment.
- MD Measuring device.
- FE Functional earth terminal.
- PE Protective earth terminal.
- Optional connection.
- A1 Patient circuit.
- A2 Other patient circuit.
- B1 Patient connection(s).

- B2 Other patient connections.
 C1 Applied part.
 C2 Other applied part.

The patient-circuit current should be measured under the following conditions, in turn:

- (a) With the supply conductors connected in the correct polarity, including the earth, if any.
 (b) With the earth conductor open-circuited at the mains plug*.
 (c) With the neutral open-circuited at the mains plug*.

* Testing under these conditions is only applicable to equipment intended for connection by means of a flexible supply cord.

TABLE 2
MAXIMUM PERMISSIBLE PATIENT CIRCUIT CURRENT FOR APPLIANCES
CONNECTED BY FLEXIBLE CORD

| Patient Circuit | Normal Condition (all appliances) | Neutral conductor Interrupted | Earth conductor * Interrupted |
|-------------------|--------------------------------------|----------------------------------|----------------------------------|
| Cardiac-prot (CF) | 20 μ A | 20 μ A | 100 μ A |
| Body-prot (BF) | 200 μ A | 200 μ A | 1000 μ A |
| Unprotected (B) | 200 μ A | 200 μ A | 1000 μ A |

APPENDIX C

CERTIFICATE OF REINSPECTION

(Please print)

IDENTIFICATION OF INSTALLATION :.....

LOCATION OF INSTALLATION :.....

NAME OF INSPECTOR & REG. NUMBER :.....

DATE OF EXAMINATION :.....

I hereby certify that the examination and testing of the above installation has been carried out in accordance with Section 10 of ECP 12, and that the installation meets the requirements for the issue of a certificate of reinspection.

Signed by: (Inspector).

FIRST SCHEDULE**STANDARDS SET AND ENDORSED UNDER THIS CODE**

AS 1169-1982 Minimizing of combustion hazards arising from the medical use of Flammable Anaesthetic Agents.

AS 1319-1983 (including Amendment 1) - Safety signs for the occupational environment.

AS 2120.1-1992 Medical Suction Equipment (Part 1: Electrically powered suction equipment).

AS 2901-1986 Medical devices - Characteristics of audible and visible alarm signals.

AS 3190-1990 Approval and test specification - Residual current devices (current-operated earth-leakage devices).

AS 3200.1-1990/NZS 6150-1990 (Including amendment 1) Approval and test specification- Electro-medical equipment (Part 1, General requirements for safety).

AS 3200.2.2-1992 Approval and test specification - Medical electrical equipment. (Part 2.2, Particular requirements for safety - High frequency surgical equipment).

AS 3200.2.3-1992 Approval and test specifications - Medical electrical equipment. (Part 2.3, Particular requirements for safety - Short-wave therapy equipment).

AS 3200.2.5-1992 Approval and test specification - Medical electrical equipment. (Part 2.5, Particular requirements for safety - Ultrasonic therapy equipment).

AS 3200.2.6-1992 Approval and test specification - Medical electrical equipment. (Part 2.6, Particular requirements for safety - Microwave therapy equipment).

AS 2300.2.14-1992 Approval and test specification - Medical electrical equipment. (Part 2.14, Particular requirements for safety - Electroconvulsive therapy equipment).

AS 3200.2.18-1992 Approval and test specification - Medical electrical equipment. (Part 2.18, Particular requirements for safety - Endoscopic equipment).

AS 3200.2.19-1992 Approval and test specification - Medical electrical equipment. (Part 2.19, Particular requirements for safety - Baby incubators (nursing))

AS 3200.2.20-1992 Approval and test specification - Medical electrical equipment. (Part 2.20, Particular requirements for safety - Baby incubators (transport)).

AS 3200.2.200-1992 Approval and test specification - Medical electrical equipment. (Part 2.200, Particular requirements for safety - Oxygen concentrators for individual patient use).

AS 3201.2-1971 Approval and test specification for electro-medical equipment (Part 2, Electrically heated incubators for babies).

AS 3203-1981 Approval and test specification for electrocardiographs.

AS 3204-1981 Approval and test specification for cardiac defibrillators.

AS 3205-1985 Approval and test specification - Dental and mobile diagnostic x-ray equipment.

AS 3208-1988 Approval and test specification - Transformers in electro-medical equipment.

NZS/AS 3209-1986 Approval and test specification - Short-wave therapy equipment.

NZS/AS 3210-1986 Approval and test specification - Microwave therapy equipment.

NZS/AS 3211-1986 Approval and test specification - Ultrasonic therapy equipment.