

AS/NZS 3200.2.27:1996
IEC 601-2-27:1994

Australian/New Zealand Standard[®]

**Approval and test specification—
Medical electrical equipment**

**Part 2.27: Particular requirements
for safety—Electrocardiographic
monitoring equipment**

[IEC title: Medical electrical equipment, Part 2: Particular requirements
for the safety of electrocardiographic monitoring equipment]

STANDARDS AUSTRALIA



STANDARDS NEW ZEALAND



Documents

Document Sharing Hub

AS/NZS 3200.2.27:1996

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/20, Cardiac Equipment and Patient Monitoring Equipment. It was approved on behalf of the Council of Standards Australia on 27 June 1996 and on behalf of the Council of Standards New Zealand on 1 July 1996. It was published on 5 September 1996.

The following interests are represented on Committee HT/20:

Australian and New Zealand College of Anaesthetists
Australian Federation for Medical and Biological Engineering
Australian Society of Anaesthetists
Canterbury Area Health Board, New Zealand
College of Biomedical Engineering, Australia
Department of Health, New South Wales
Department of Human Services and Health, Australia
Health Industry Suppliers Association of New Zealand
Medical Industry Association of Australia
Ministry of Commerce, New Zealand
Ministry of Health, New Zealand
Public Works Department, New South Wales
Royal Australian College of Physicians

Review of Standards. To keep abreast of progress in industry, Joint Australian/New Zealand Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto.

Full details of all Joint Standards and related publications will be found in the Standards Australia and Standards New Zealand Catalogue of Publications; this information is supplemented each month by the magazines 'The Australian Standard' and 'Standards New Zealand', which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.

Suggestions for improvements to Joint Standards, addressed to the head office of either Standards Australia or Standards New Zealand, are welcomed. Notification of any inaccuracy or ambiguity found in a Joint Australian/New Zealand Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

AS/NZS 3200.2.27:1996

Australian/New Zealand Standard[®]

**Approval and test specification—
Medical electrical equipment**

**Part 2.27: Particular requirements
for safety—Electrocardiographic
monitoring equipment**

PUBLISHED JOINTLY BY:

STANDARDS AUSTRALIA
1 The Crescent,
Homebush NSW 2140 Australia

STANDARDS NEW ZEALAND
Level 10, Standards House,
155 The Terrace,
Wellington 6001 New Zealand

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/20 on Cardiac Equipment and Patient Monitoring Equipment, as a Joint Standard.

This Standard is technically equivalent to and has been reproduced from IEC 601-2-27:1994, *Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment*.

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 601-2-27 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.

To accommodate Australian/New Zealand conditions and well-accepted safety practices, where the Australian/New Zealand requirements differ from the IEC specifications a marginal bar is placed alongside the altered IEC text, and Appendix ZZ details the rationale for the variations.

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

- (a) Requirements, compliance with which can be tested, and definitions in large roman type.
- (b) Explanations, advice, introductions, general statements, exceptions and references in smaller roman type.
- (c) Headings of sub-clauses and text specifications in italic.
- (d) 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 Appendix AA.

Under arrangements made between Standards Australia/Standards New Zealand and the 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:

- (i) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (ii) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

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

CONTENTS

Page

SECTION ONE – GENERAL

1	Scope and object	1
2	Terminology and definitions	2
4	General requirements for tests	3
5	Classification	3
6	Identification, marking and documents	3

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

14	Requirements related to classification	4
17	Separation	5
19	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	5
20	Dielectric strength	6

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21	Mechanical strength	6
----	---------------------------	---

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED
OR EXCESSIVE RADIATION

34	Ultraviolet radiation	7
----	-----------------------------	---

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

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES
AND OTHER SAFETY HAZARDS

42	Excessive temperatures	7
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	7

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

51 Protection against hazardous output 8

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS,
ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

56 Components and general assembly 11

57 MAINS PARTS, components and layout 12

Figures 13

Appendix D – Symbols on markings 18

Appendix ZZ – Variations to IEC 601-2-27 for application in Australia and New Zealand 25

Annex AA – General guidance and rationale 19

First published as AS/NZS 3200.2.27:1996.

© Copyright – STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Users of Standards are reminded that copyright subsists in all Standards Australia and Standards New Zealand publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia or Standards New Zealand may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia or Standards New Zealand. Permission may be conditional on an appropriate royalty payment. Australian requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia. New Zealand requests should be directed to Standards New Zealand.

Up to 10 percent of the technical content pages of a Standard may be copied for use exclusively in-house by purchasers of the Standard without payment of a royalty or advice to Standards Australia or Standards New Zealand.

Inclusion of copyright material in computer software programs is also permitted without royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia or Standards New Zealand at any time.

AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment**Part 2.27:****Particular requirements for safety—Electrocardiographic monitoring equipment**

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1* Scope*Addition:*

This Standard specifies the particular safety requirements for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 2.101 and hereinafter also referred to as EQUIPMENT.

Telemetry monitors, ambulatory ("Holter") monitors and other recording devices are outside the scope of this Particular Standard.

1.2 Object*Replacement:*

The object of this Particular Standard is to specify particular requirements for the safety of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT as defined in 2.101.

1.3 Particular Standards*Addition:*

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*.

For brevity Part 1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s).

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

3 Terminology and definitions

This clause of the General Standard applies, except as follows:

Additional definitions:

2.101 *ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT*

EQUIPMENT and associated ELECTRODES for the monitoring and/or recording of heart action potentials and displaying the resultant data locally and/or transmitting to a central station.

2.102 *LEAD(S) (ECG)*

ELECTRODE combination used for a certain ECG recording.

2.103 *ELECTRODE*

Conductor attached to a specified part of the body to detect heart action voltages in combination with another ELECTRODE or ELECTRODES.

2.104 *LEAD SELECTOR*

System to select LEADS.

2.105 *NEUTRAL ELECTRODE*

Reference point for differential amplifiers and/or interference suppression circuits, not forming part of any ECG LEAD.

2.106 *SENSITIVITY (ECG)*

Ratio of the amplitude of a displayed signal to the amplitude of the signal producing it, expressed in mm/mV.

4 General requirements for tests

This clause of the General Standard applies, except as follows:

4.11* *Sequence*

Amendment:

Tests called for in 17.101, 51.101 and 51.102 of this Particular Standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in clauses C24 and C25 of Appendix C of the General Standard.

5 Classification

This clause of the General Standard applies, except as follows:

5.2 According to the degree of protection against electric shock:

Amendment:

Delete Type B and BF EQUIPMENT.

5.6 According to the mode of operation:

Amendment:

Delete all but CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard applies, except as follows:

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

Addition:

aa) Parts of an ECG MONITORING EQUIPMENT (for example, PATIENT cables) specified as being protected against the effects of defibrillation shall be marked with the symbol given in Appendix D (addition to table DII) of this Particular Standard.

6.8.2 *Instructions for use*

Addition:

aa) Advice shall be given on the following:

- 1) That conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.

- 2) The type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR.
- 3) The specification (or type-number) of ACCESSORIES such as patient cables which shall be used in order to provide defibrillation protection (see 17.101 and 51.101, 51.102 and 51.103) and protection against high frequency burns, and any precautions to be taken when a defibrillator is used on a PATIENT.
- 4) If parts of the ECG MONITORING EQUIPMENT are provided with protective means against burning of the PATIENT when used with high frequency (HF) surgical equipment, this shall be drawn to the attention of the OPERATOR. If no such means are incorporated, advice shall be given regarding the location of the ELECTRODES and leads etc, to reduce the hazard of burns in the event of a defect in the HF surgical neutral electrode connection.
- 5) The choice and application of ELECTRODES (see 51.102 and 51.103).
- 6) Any possible hazard caused by the summation of LEAKAGE CURRENTS when several items of EQUIPMENT are interconnected.
- 7) Any safety hazard due to the simultaneous use of other PATIENT-connected EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators.
- 8)* The need for regular testing of the EQUIPMENT and ACCESSORIES.
- 9) The means of indicating an inoperative ECG MONITORING EQUIPMENT (see 51.103).
- 10) If indication of the heart-rate may be adversely affected by the operation of cardiac pacemaker pulses or by cardiac arrhythmias.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

14 Requirements related to classification

This clause of the General Standard applies, except as follows:

14.6* TYPES B, BF and CF EQUIPMENT

Replacement:

The EQUIPMENT shall be of TYPE CF.

17 Separation

This clause of the General Standard applies, except as follows:

Addition:

17.101* *Protection against the effects of a cardiac defibrillator discharge*

Arrangements used to isolate any ELECTRODES from parts a), b), c) and d) mentioned below shall be so designed that during the discharge of a defibrillator to a PATIENT connected to the ELECTRODES, hazardous electrical energies are excluded from the following:

- a) the ENCLOSURE;
- b) any SIGNAL INPUT PART;
- c) any SIGNAL OUTPUT PART;
- d) metal foil on which the EQUIPMENT is placed and which has an area at least equal to the base of the EQUIPMENT. (CLASS I and CLASS II, and INTERNALLY POWERED EQUIPMENT.)

The above-mentioned requirement is met when, after operation of S_1 (see figure 101), the peak voltage between the points Y_1 and Y_2 does not exceed 1 V.

The EQUIPMENT shall not be energized for this test.

CLASS I EQUIPMENT shall be tested while connected to the PROTECTIVE EARTH TERMINAL.

CLASS I EQUIPMENT which is capable of operation without a SUPPLY MAINS, for example, one having an internal battery, shall also be tested with no connexion to the PROTECTIVE EARTH TERMINAL. Any connection to a FUNCTIONAL EARTH TERMINAL shall be removed.

Repeat the test with V_1 reversed.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies, except as follows:

19.3* *Allowable values*

Addition:

aa) For ECG MONITORING EQUIPMENT having a FUNCTIONAL EARTH TERMINAL, the PATIENT LEAKAGE CURRENT flowing from the APPLIED PART to earth shall be no greater than 0,05 mA, when a voltage equal to 110 % of the highest RATED MAINS VOLTAGE is applied between the FUNCTIONAL EARTH TERMINAL and earth.

This test is not performed when the FUNCTIONAL EARTH TERMINAL is connected directly to the PROTECTIVE EARTH TERMINAL inside the EQUIPMENT.

Compliance is checked by measurement according to figures 102 and 103.