

AS/NZS 3200.2.25:1993  
IEC 601-2-25:1993

## Australian/New Zealand Standard

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

### **Part 2.25: Particular requirements for safety—Electrocardiographs**

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

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**AS/NZS 3200.2.25:1993**

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 Department of Health, New South Wales  
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### **Approval and test specification— Medical electrical equipment**

### **Part 2.25: Particular requirements for safety—Electrocardiographs**

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PREFACE

This Standard is issued as a joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand. It was prepared by the Joint Australia/New Zealand Standards Committee HT/20 on Cardiac Equipment and Patient Monitoring Equipment on behalf of the Multitechnics Standards Policy Board. The Standard is technically equivalent to IEC 601-2-25, *Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs*.

The Standard is one of a series of Approval and Test Specifications issued by Standards Australia/Standards New Zealand for individual items of medical electrical equipment. It is supplementary to AS/NZS 3200.1—1990, *Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety*. Only safety matters and closely aligned conditions are covered by this series. In some instances, however, these are more stringent than for most electrical appliances because of the additional requirements necessary to ensure the safety of the patient, and because of the environmental conditions, e.g. high humidity and hazardous locations, in which some equipment is likely to be used.

The International Standard IEC 601-2-25 modifies and supplements the corresponding clauses of IEC 601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety*, second edition. The second edition has been adopted as Joint Standard AS/NZS 3200.1—1990, *Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

The clauses of this Particular Standard supplement or modify the corresponding clauses in the General Standard. As stated in Clause 1.3 of the General Standard, the requirements of a Particular Standard take priority, where appropriate, over those of the General Standard. Where the reference in the text of this Standard indicates an ‘amendment’, ‘addition’ or ‘replacement’ of the relevant requirements, tests or explanatory notes of AS/NZS 3200.1—1990, these changes are made to the relevant text which then becomes part of the Standard.

Sub-clauses and figures which are additional to the General Standard are numbered starting from 101; additional appendices are indicated by a sequence of double capitals e.g., AA), BB), . . . and additional items are denoted by an aa), bb), . . . sequence.

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 deviations.

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

- (a) Requirements, compliance with which can be tested and definitions . . . . . in roman type.
  - (b) Explanations, advice, introductions, general statements, exceptions and references . . . . . in smaller roman type.
  - (c) Headings of sub-clauses and test specifications . . . . . in italic type.
  - (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 located beside each clause for which rationale is included in Annex AA.

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## STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

**Australian/New Zealand Standard****Approval and test specification—Medical electrical equipment****Part 2.25: Particular requirements for safety—Electrocardiographs****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 Particular International Standard specifies the particular safety requirements for ELECTROCARDIOGRAPHS as defined in 2.102, intended for the production of detachable ELECTROCARDIOGRAMS for diagnostic purposes. It also applies to vector-cardiographs and EQUIPMENT for stress testing.

This Particular Standard covers minimum safety requirements.

Special requirements concerning use in ambulances, phono-cardiographs, cardiographic monitors, polygraphs, telemetering, special tests (for example, His bundle electrocardiographs), etc. are not covered by this Particular Standard.

EQUIPMENT with microelectrodes used directly in the fibres of the heart muscle is also excluded.

**1.2 Object***Replacement:*

The object of this Particular International Standard is to establish particular requirements for the safety of ELECTROCARDIOGRAPHS as defined in 2.102.

**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)".

## 2

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 appendices 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.

## 2 Terminology and definitions

This clause of the General Standard applies except as follows:

### *Additional definitions:*

#### 2.101 *ELECTROCARDIOGRAM (ECG)*

Visible record of heart action potentials.

#### 2.102 *ELECTROCARDIOGRAPH (ecg)*

MEDICAL ELECTRICAL EQUIPMENT and associated ELECTRODES intended for the production of detachable ELECTROCARDIOGRAMS for diagnostic purposes.

#### 2.103 *LEAD(S)*

ELECTRODE combination used for a certain ECG recording.

#### 2.104 *ELECTRODE*

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

## 3

2.105 *LEAD SELECTOR*

System to select certain LEADS and TEST.

2.106 *MULTICHANNEL ELECTROCARDIOGRAPH*

EQUIPMENT for the simultaneous recording of several ecg LEADS.

This EQUIPMENT may also provide facilities for phonocardiography and pulse recording etc.

2.107 *NEUTRAL ELECTRODE*

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

2.108 *NORMAL SENSITIVITY*

SENSITIVITY of 10 mm/mV.

2.109 *PATIENT CABLE*

Multiwire cable and associated connector(s) to connect the ELECTRODES to the ELECTROCARDIOGRAPH.

2.110 *SENSITIVITY*

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

2.111 *SINGLE CHANNEL ELECTROCARDIOGRAPH*

EQUIPMENT for the recording of one ecg LEAD at a time.

2.112 *STANDARDIZATION VOLTAGE*

Voltage step recorded for amplitude calibration purposes.

2.113 *TEST*

Facility enabling the STANDARDIZATION VOLTAGE or zero voltage to be recorded in place of the ELECTROCARDIOGRAM.

## 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 and 51.101 of this Particular Standard shall be carried out in that order prior to the LEAKAGE CURRENT and dielectric strength tests of clauses C24 and C25 of Appendix C of the General Standard.

**5 Classification**

This clause of the General Standard applies except as follows:

**5.6 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****1) Classification***Addition:*

The ELECTROCARDIOGRAPH and parts thereof that are specified as being protected against the effects of defibrillation shall be marked with one of the symbols as appropriate, given in Appendix D of this Particular Standard. (See also 17.101 and 51.101.)

**6.8.2 Instructions for use***Additional item:*

aa) Advice shall be given on the following:

- 1) The procedures necessary for safe operation, drawing attention in the case of TYPE B ELECTROCARDIOGRAPHS to the safety hazards which may occur as a result of an inadequate electrical installation.
- 2) The type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR.
- 3) That conductive parts of ELECTRODES and associated connectors for TYPE BF or CF ELECTROCARDIOGRAPHS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.
- 4) The specification (and type number, if necessary) of the PATIENT CABLE which needs to be used to provide protection against the effect of the discharge of a cardiac defibrillator and against high-frequency burns.
- 5) If the ELECTROCARDIOGRAPH is provided with protective means against burns of the PATIENT when used with high-frequency (HF) surgical equipment, this shall be

## 5

drawn to the attention of the OPERATOR. If no such means are incorporated, advice shall be given regarding the location of the ECG ELECTRODES to reduce the hazard of burns in the event of a defect in the HF surgical neutral electrode connection.

- 6) The choice and application of ELECTRODES.
- 7) The suitability of the ELECTROCARDIOGRAPH for DIRECT CARDIAC APPLICATION.
- 8) The possible hazard caused by the summation of LEAKAGE CURRENTS when several EQUIPMENTS are interconnected.
- 9) Any safety hazard due to the operation of a cardiac pacemaker or other electrical stimulators.
- 10)\* Instructions for regular testing of the ELECTROCARDIOGRAPH and the PATIENT CABLE.
- 11) The precautions to be taken when a defibrillator is used on a PATIENT.
- 12) The means of indicating an inoperative ELECTROCARDIOGRAPH (see 51.103 of this Particular Standard).

## SECTION TWO – ENVIRONMENTAL CONDITIONS

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

**10 Environmental conditions**

This clause of the General Standard applies except as follows:

**10.2.1 b)\* Replacement:**

Relative humidity between 25 % and 95 % (without condensation).

## SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

**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) to d) mentioned below shall be so designed that during the discharge of a cardiac defibrillator to a PATIENT connected to the ELECTRODES, hazardous electrical energies are excluded from the following: