AS/NZS IEC 60601.2.25:2016
IEC 60601-2-25, Ed. 2.0 (2011)

AS/NZS IEC 60601.2.25:2016

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.25: Particular requirements for the basic safety and essential performance of electrocardiographs

STANDARDS Australia

STANDARDS® NEW ZEALAND PAEREWA AOTEAROA

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 20 May 2016 and by the New Zealand Standards Approval Board on 20 April 2016.
This Standard was published on 2 June 2016.

The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering, Engineers Australia
Department of Defence
Engineers Australia
Medical Technology Association of Australia
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
Therapeutic Goods Administration
Wairarapa District Health Board
Waitemata District Health Board
Worksafe New Zealand

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.saiglobal.com or Standards New Zealand web site at www.standards.govt.nz and looking up the relevant Standard in the on-line catalogue.

For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of Standards Australia or the New Zealand Standards Executive at the address shown on the back cover.

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.25:2015.

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.25: Particular requirements for the basic safety and essential performance of electrocardiographs

Originally in Australia as AS 3201.3—1971.
Previous and first New Zealand edition AS/NZS 3200.2.25:1993.
Jointly revised and redesignated as AS/NZS IEC 60601.2.25:2016.

Jointly published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001 and by Standards New Zealand, PO Box 10729, Wellington 6011.

ISBN 978 1 76035 502 9

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.25:1993, *Approval and test specification—Medical electrical equipment,* Part 2.25: *Particular requirements for safety—Electrocardiographs*.

The objective of this Standard is to establish particular requirements for basic safety and essential performance of electrocardiographs, which are defined as equipment and associated lead wires and electrodes intended for the production of ECG reports for diagnostic purposes.

The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1, *Medical electrical equipment*, Part 1: *General requirements for basic safety and essential performance*. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015.

This Standard is identical with, and has been reproduced from, IEC 60601-2-25, Ed. 2.0 (2011), *Medical electrical equipment*, Part 2-25: *Particular requirements for the basic safety and essential performance of electrocardiographs*.

As this Standard is reproduced from an International Standard, a full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS IEC	
60601	Medical electrical equipment	60601	Medical electrical equipment
60601-2-2	Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	60601.2.2	Part 2.2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

CONTENTS

Page

Page

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

This particular standard now includes the contents of the particular standard IEC 60601-2-51: *Medical electrical equipment – Part 2-51: Particular requirements for the safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs.*

Updating the particular standards to refer to the third edition of the general standard provided the opportunity to merge the first editions of IEC 60601-2-25 and IEC 60601-2-51 into one standard. Reformatting and technical changes were both made.

The requirements of this particular standard take priority over those of the general standard.

A "General guidance and rationale" for the more important requirements of this particular standard is included in Annex AA. Knowledge of the reasons for these requirements will not only facilitate proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this standard.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.25:
Particular requirements for the basic safety and essential performance of electrocardiographs

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHS as defined in 201.3.63 intended by themselves or as a part of an ME SYSTEM, for the production of ECG REPORTS for diagnostic purposes, hereinafter referred to as ME EQUIPMENT.

Not included within the scope of this particular standard are:

a) the part of ME EQUIPMENT that provides vectorcardiographic loops;

b) ambulatory electrocardiographic ME EQUIPMENT covered by IEC 60601-2-47 where not intended for obtaining ECG REPORTS for diagnostic purposes;

c) cardiac monitors covered by IEC 60601-2-27 where not intended for obtaining ECG REPORTS for diagnostic purposes.

NOTE 1 For example. ME EQUIPMENT includes:

a) direct-writing ELECTROCARDIOGRAPHS;

b) other ME EQUIPMENT that produce ECG REPORTS for diagnostic purposes, e.g. patient monitors, defibrillators, exercise testing devices;

c) ELECTROCARDIOGRAPHS having a display that is remote from the PATIENT (e.g. via phone lines, networks or storage media). These ME EQUIPMENT or ME SYSTEMS are within the scope of this particular standard excluding transmission media.

NOTE 2 ME EQUIPMENT that provide selection between diagnostic and monitoring functions shall meet the requirements of the appropriate standard when configured for that function.

ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment or physician's office, such as in ambulances and air transport, shall comply with this particular standard. Additional standards may apply to ME EQUIPMENT for those environments of use.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHS as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

---

1 The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*