AS/NZS 3200.2.26:2005
IEC 60601-2-26:2002

AS/NZS 3200.2.26:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.26: Particular requirements for safety—Electroencephalographs

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 31 August 2005 and on behalf of the Council of Standards New Zealand on 9 September 2005.
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The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Ageing
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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 either Standards Australia or Standards New Zealand at the address shown on the back cover.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment to supersede AS/NZS 3200.2.26:1995, *Approval and test specification—Medical electrical equipment,* Part 2.26: *Particular requirements for safety—Electroencephalographs.*

The objective of this revision is to adopt the 2002 edition of IEC 60601-2-26 which updates requirements for the safety of electroencephalographs.

This Particular Standard has been reproduced from, and is identical to, IEC 60601-2-26:2002, *Medical electrical equipment,* Part 2.26: *Particular requirements for the safety of electroencephalographs,* which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment*, Part 1: *General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998, *Medical electrical equipment,* Part 1.0: *General requirements for safety—Parent Standard* and is hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

The General Standard details electrical safety requirements for the design and manufacture of medical electrical equipment which makes physical or electrical contact with the patient. A Particular Standard details additional safety requirements for a medical device, or related group of medical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

It is recommended that, to interpret a Particular Standard or a Collateral Standard, a copy of the General Standard should be readily available.

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) Notes, explanations, advice, introductions, general statements, exceptions and references ..... in smaller roman type

(c) Test specifications.....*in italic type*

(d) Terms defined in Clause 2 of the General Standard or this Particular Standard ....IN SMALL CAPITALS

As this publication has been reproduced from an International Standard, the following modifications apply:

(i) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(ii) The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.

(iii) The substitution of a full point (.) for a comma (,) where it appears as a decimal marker.

Some pages of the original, which relate to IEC administrative matters, do not appear in this version.

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 an ‘informative’ appendix or annex is only for information and guidance.

References to international Standards should be replaced by reference to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-2	Part 1-2: Collateral Standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: Collateral Standard: Electromagnetic compatibility—Requirements and tests
60601-1-4	Part 1-4: Collateral Standard: Programmable electrical medical systems	3200.1.4	Part 1.4: Collateral Standard: Programmable electrical medical systems

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SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTRODUCTION

This Particular Standard concerns the safety of electroencephalographs. It amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety*, including its Amendment 1 (1991) and Amendment 2 (1995), hereinafter referred to as the General Standard.

A "General guidance and rationale" for the requirements of this Particular Standard is included in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the 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.

An asterisk (*) by a clause or subclause number indicates that explanatory notes are given in Annex AA of this Particular Standard.

AUSTRALIAN/NEW ZEALAND STANDARD

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SECTION ONE – GENERAL

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

1 Scope and object

*1.1 Scope

Addition:

This Particular Standard specifies the particular safety requirements for ELECTRO-ENCEPHALOGRAPHS as defined in 2.2.103 and also referred to as EQUIPMENT.

The special requirements for other equipment also used in electroencephalography are not covered by this standard, for example:

- cerebral function monitors;
- phono-photic stimulators;
- electroencephalographic telemetry;
- EEG data storage and retrieval;
- EQUIPMENT particularly intended for monitoring during electro-convulsive therapy;
- ambulatory electroencephalographic recorders.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular requirements for the safety of ELECTROENCEPHALOGRAPHS.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements IEC 60601-1 (1988*): Medical electrical equipment – Part 1: General requirements for safety* as amended by its Amendment 1 (1991) and Amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-2 and IEC 60601-1-4 as the “Collateral Standards”.

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