AS/NZS 3200.2.38:2007

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.38: Particular requirements for safety—Electrically and manually operated medical beds for adult use (IEC 60601-2-38, Ed.1.0(1996) MOD)

STANDARDS Australia

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-027, Hospital Beds. It was approved on behalf of the Council of Standards Australia on 20 September 2007 and on behalf of the Council of Standards New Zealand on 2 November 2007.
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The following are represented on Committee HE-027:

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Australian Chamber of Commerce and Industry
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Australian Nursing Federation
Consumers Federation of Australia
Department of Health, S.A.
Furnishing Industry Association of Australia
Human Factors and Ergonomics Society of Australia
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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.

This Standard was issued in draft form for comment as DR 05036.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-027, Hospital Beds to supersede AS/NZS 3200.2.38:1997, *Approval and test specification—Medical electrical equipment,* Part 2.38: *Particular requirements for safety—Electrically operated hospital beds.*

The objective of this revision is to incorporate IEC Amendment No. 1:1999, which includes safety requirements for side rails and prevention of entrapment, and to introduce variations for Australian/New Zealand use.

The principal differences between this Standard and the 1997 edition are as follows:

(a) Mechanical bed requirements have been included.

(b) Emergency back rest requirements have been specified.

(c) Tests for side rail safety and patient entrapment have been included.

This Standard is an adoption with national modifications and has been reproduced from IEC 60601-2-38, Ed.1.0(1996), *Medical electrical equipment – Part 2-38: Particular requirements for the safety of electrically operated hospital beds*, incorporating its Amendment 1:1999, and has been varied as indicated to take account of Australian/New Zealand conditions.

Variations to IEC 60601-2-38, Ed.1.0(1996) are indicated at the appropriate places throughout this Standard. Strikethrough (~~example~~) identifies IEC text, tables and figures which, for the purposes of this Australian/New Zealand Standard, are deleted. Where text, tables or figures are added, each is set in its proper place and identified by shading (example). Added figures are not themselves shaded, but are identified by a shaded border.

National variations for use in Australia and New Zealand are listed also in Appendix ZZ, for easy reference. Appendix ZA contains additional references.

IEC 60601-2-38 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.

As this Standard is 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) A full point should be substituted for a comma when referring to a decimal marker.

In this Standard, the following print types are used:

(A) Requirements, compliance with which can be tested and definitions: in arial type.

(B) Test specifications: *in italic type*.

(C) Notes, explanations, advice, introductions, general statements, exceptions and references: in smaller arial type.

(D) Terms defined in Clause 2 of the Parent Standard, AS/NZS 3200.1.0 or this Particular Standard: SMALL CAPITALS.

An asterisk (*) is placed before each clause for which rationale is included in Annex AA.

The terms 'normative' and 'informative' are used to define the application of the annex or appendix to which they apply. A normative annex or appendix is an integral part of a standard, whereas an informative annex or appendix is only for information and guidance.

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Any table, figure or text of the international standard that is struck through is not part of this standard. Any Australian/New Zealand table, figure or text that is added is part of this standard and is identified by shading.

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 Standard specifies requirements for the design, manufacture and safety of electrically operated and manually operated medical beds, herein referred to as BED, as defined in 2.2.101, for general adult use in a range of health and community care environments. It applies to beds in general use in a full range of environments where patients or residents may be cared for, or supervised by, health care professionals.

~~This Particular Standard specifies requirements for safety of ELECTRICALLY OPERATED HOSPITAL BEDS, hereinafter referred to as BED, as defined in 2.2.101.~~

1.2 Object

Replacement:

The object of this Particular Standard for BEDS is to keep the SAFETY HAZARDS to PATIENTS, OPERATORS, and the environment as low as possible, and to describe tests to verify that these requirements are attained.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2 and IEC 60601-1-1: 1992, *Medical electrical equipment – Part 1 : General requirements for safety – 1. Collateral Standard: Safety requirements for medical electrical systems.*

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 60601-1-1 as the "Collateral Standard".

The term "this Standard" covers the Particular Standard, used together with the General Standard and any Collateral Standards.