AS EN 1060.1—2002
EN 1060-1:1995

Australian Standard™

Non-invasive sphygmomanometers

Part 1: General requirements

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PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-022 on Sphygmomanometers.

This Standard is identical with and has been reproduced from EN 1060-1:1995, *Non-invasive sphygmomanometers — Part 1: General requirements*.

The objective of this Standard is to specify requirements for non-invasive sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the International Standards referenced herein:

Reference to International Standard or other publication		*Equivalent Australian/New Zealand Standard*	
IEC		AS/NZS	
60601-1	Medical electrical equipment: Part 1: General requirements for safety	3200.1.0	Medical electrical equipment — Part 1.0: General requirements for safety — Parent Standard

As this Standard is reproduced from a European Standard, the following applies:

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

(b) In the source text 'this European Standard' should read 'this Australian Standard'.

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AUSTRALIAN STANDARD

Non-invasive sphygmomanometers

Part 1: General requirements

1 Scope

This Part of this European Standard specifies general requirements for non-invasive sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

It specifies performance, efficiency, mechanical and electrical safety requirements for these devices and gives test methods.

NOTE: This standard recommends that Luer lock connectors should not be used with these devices.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 60601-1: 1988	Medical electrical equipment - Part 1: General requirements for safety
EN 980[1)]	Terminology, symbols and information provided with medical devices; Graphical symbols for use in the labelling of medical devices
EN 1041[1)]	Terminology, symbols and information provided with medical devices; Information supplied by the manufacturer with medical devices

3 Definitions

For the purposes of this Part of EN 1060, the following definitions apply.

3.1 bladder: Inflatable component of the cuff.

3.2 blood pressure: Pressure in the arterial system of the body.

[1)] In preparation.

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