AS EN 1060.3—2004
EN 1060-3:1997

Australian Standard™

Non-invasive sphygmomanometers

Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

STANDARDS AUSTRALIA

This Australian Standard was prepared by Committee HE-022, Sphygmomanometers. It was approved on behalf of the Council of Standards Australia on 18 December 2003 and published on 26 February 2004.

The following are represented on Committee HE-022:

Australian Nursing Federation

College of Biomedical Engineering

Commonwealth Department of Veterans Affairs

Department of Human Services (South Australia)

Health Department of Western Australia

Institute of Hospital Engineering Australia

Medical Industry Association of Australia Inc

National Heart Foundation of Australia

National Standards Commission

NSW Health Department

Queensland Health

Royal Australasian College of Physicians

Royal Australian College of General Practitioners

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Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-022, Sphygmomanometers. 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.

This Standard is identical with and has been reproduced from EN 1060-3:1997, *Non-invasive sphygmomanometers—Part 3: Supplementary requirements for electromechanical blood pressure measuring systems*.

The objective of this Standard is to specify performance, efficiency and safety requirements for electromechanical blood pressure measuring systems that, by means of an inflatable cuff are used for non-invasive measurements of arterial blood pressure at the upper arm, the wrist and the thigh. It also specifies requirements for their accessories and gives test methods.

The term 'informative' has been used to define the application of the annex to which it applies. An informative annex is only for information and guidance.

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'.

(c) A full point substitutes for a comma when referring to a decimal marker.

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

*Reference to European Standard**		*Australian or Australian/New Zealand Standard*	
EN		AS EN	
1060	Non-invasive sphygmomanometers	1060	Non-invasive sphygmomanometers
1060-1	Part 1: General requirements	1060.1	Part 1: General requirements
1060-2	Part 2: Supplementary requirements for mechanical sphygmomanometers	1060.2	Part 2: Supplementary requirements for mechanical sphygmomanometers
		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1	Part 1.0: General requirements for safety—Parent Standard
60601-1-2	Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests
60601-2-30	Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment	3200.2.30	Part 2.30: Particular requirements for safety—Automatic cycling non-invasive blood pressure monitoring equipment

* Any European Standard not listed has not been adopted as an Australian or Australian/New Zealand Standard.

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AUSTRALIAN STANDARD

Non-invasive sphygmomanometers

Part 3:

Supplementary requirements for electromechanical blood pressure measuring systems

1 Scope

This Part of EN 1060 specifies performance, efficiency and safety requirements for electro-mechanical blood pressure measuring systems that, by means of an inflatable cuff are used for non-invasive measurements of arterial blood pressure at the upper arm, the wrist and the thigh. It also specifies requirements for their accessories and gives test methods.

This Part of EN 1060 applies to electro-mechanical blood pressure measuring systems in which the cuff pressure is measured electronically, but in which the blood pressure can be determined either manually with the aid of a stethoscope or automatically.

Additional safety requirements for automatic cycling indirect blood pressure monitoring equipment are specified in EN 60601-2-30: 1995.

This Part of EN 1060 is to be used in conjunction with EN 1060-1.

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 any 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 475	Medical devices - Electrically generated alarm signals
EN 1060-1: 1995	Non-invasive sphygmomanometers - Part 1: General requirements
EN 1060-2: 1995	Non-invasive sphygmomanometers - Part 2: Supplementary requirements for mechanical sphygmomanometers
EN 60601-1: 1990	Medical electrical equipment - Part 1: General requirements for safety
EN 60601-1-2: 1993	Medical electrical equipment - Part 1: General requirements for safety; Collateral Standard - Electromagnetic compatibility - Requirements and tests