AS EN 1060.2—2002
EN 1060-2:1995

Australian Standard™

Non-invasive sphygmomanometers

Part 2: Supplementary requirements for mechanical sphygmomanometers

Standards Australia

This Australian Standard was prepared by Committee HE-022, Sphygmomanometers. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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Commonwealth Department of Veterans' Affairs
Department of Human Services (South Australia)
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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 1060-2:1995, *Non-invasive sphygmomanometers — Part 2: Supplementary requirements for mechanical sphygmomanometers.*

The objective of this Standard is to specify performance, efficiency and mechanical and electrical safety requirements, including test methods, 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.

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.

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AUSTRALIAN STANDARD

Non-invasive sphygmomanometers

Part 2: Supplementary requirements for mechanical sphygmomanometers

1 Scope

This part of EN 1060, in conjunction with EN 1060-1:1995, specifies performance, efficiency and mechanical and electrical safety requirements, including test methods, for non-invasive mechanical sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

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 1060-1: 1995: Non-invasive sphygmomanometers - Part 1: General requirements

EN 980[1)] Terminology, symbols and information provided with medical devices; Graphical symbols for use in the labelling of medical devices

3 Definitions

For the purposes of this Part of EN 1060, the definitions in EN 1060-1 : 1995 together with the following apply,

3.1 mechanical sphygmomanometer: Sphygmomanometer which uses either a mercury or an aneroid manometer or other mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.

NOTE: Components of these devices are manometer, cuff, valve for deflation (often in combination with rapid exhaust valve), hand pump or electro-mechanical pump and connection hoses. These devices may also contain electro-mechanical components for pressure control.

[1)] In preparation