

Australian Standard™

Non-invasive sphygmomanometers

**Part 3: Supplementary requirements for
electromechanical blood pressure
measuring systems**



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
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This Standard was issued in draft form for comment as DR 03495.

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Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

First published as AS EN 1060.3—2004.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5732 4

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:

<i>Reference to European Standard*</i>		<i>Australian or Australian/New Zealand Standard</i>	
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

EN 60601-2-30: 1995 Medical electrical equipment -
 Part 2: Particular requirements for the safety of automatic
 cycling indirect blood pressure monitoring equipment.

3 Definitions

For the purposes of this European Standard, the definitions in EN 1060-1: 1995, EN 1060-2: 1995, EN 60601-1: 1990 and EN 60601-2-30: 1995 apply, together with the following:

3.1 auscultatory method: Technique whereby sounds (known as Korotkov sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with systolic and the disappearance of sounds with diastolic blood pressure.

3.2 electro-mechanical blood pressure measuring system: System that consists of:

- a) at least one cuff, which is connected to the pneumatic system;
- b) at least one electro-mechanical transducer to measure cuff pressure;
- c) at least one measured value display;
- d) if needed, signal inputs and outputs.

3.3 electro-mechanical pressure transducer: Component that transforms pressure signals into electrical signals.

3.4 oscillometric method: Method wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced.

NOTE: During the inflation and deflation of the cuff small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses.

These oscillations, which first increase and then decrease, are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm. It is possible to carry out the measurement during the inflation phase.

3.5 zero setting: Procedure that corrects a deviation of the pressure reading to 0 mmHg at atmospheric pressure (gauge pressure: 0 mmHg).

3.6 patient simulator: Device for simulating the oscillometric cuff pulses and/or auscultatory sounds during inflation and deflation.

NOTE: This device is not used for testing accuracy but is required in assessing stability of performance.

4 Cuff

Clause 4 of EN 1060-1: 1995 shall apply.

5 Display

Clause 5 of EN 1060-1: 1995 shall apply.

6 Units

Clause 6 of EN 1060-1: 1995 shall apply.

7 Requirements

7.1 General

Equipment or parts thereof, using materials or having forms of construction different from those detailed in this Part of EN 1060, shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

7.2 Limits of the error of the cuff pressure indication

7.1.1 of EN 1060-1: 1995 shall apply.

7.3 Effect of voltage variations of the power source variations

7.3.1 Internal electrical power source

- a) Blood pressure measuring systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 of EN 60601-2-30: 1995;
- b) Changes of the voltage within the working range determined in 8.2.1 shall not influence the cuff pressure reading and the result of the blood pressure measurement;
- c) Outside of the working range, no cuff pressure reading and no result of the blood pressure measurement shall be displayed.

Testing shall be carried out in accordance with 8.2.1 and 8.3.1.

7.3.2 External electrical power source

- a) Blood pressure measuring systems in which the cuff pressure is generated by an electrical pump shall comply with 49.3 and 49.101 of EN 60601-2-30: 1995;
- b) Changes of the voltage within the working range specified by the manufacturer (see 9.2) shall not influence the cuff pressure reading and the result of the blood pressure measurement.

Testing shall be carried out in accordance with 8.2.2 and 8.3.2 (alternating current) or 8.2.3 and 8.3.3 (direct current).

- c) Incorrect values resulting from voltage variations outside the limits given in 7.3.2 b) shall not be displayed.

Testing shall be carried out in accordance with 8.2.4 (alternating current) or 8.2.5 (direct current).

7.4 Pneumatic system

7.4.1 Air leakage

Air leakage shall not exceed a pressure drop of 6 mmHg/min (0,8 kPa/min).

For those devices in which the blood pressure is determined manually with the aid of a stethoscope the air leakage shall not exceed a pressure drop of 4 mmHg/min (0,5 kPa/min). Testing shall be carried out in accordance with 8.4.

7.4.2 Pressure reducing system for devices using the auscultatory method

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 2 mmHg/s to 3 mmHg/s (0,3 kPa/s to 0,4 kPa/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of between 2 mmHg/pulse and 3 mmHg/pulse (0,3 kPa/pulse and 0,4 kPa/pulse) shall be maintained.

NOTE: Manually operated deflation valves should be easily adjustable to these values.

Testing shall be carried out in accordance with 8.5.

7.4.3 Rapid exhaust

During the rapid exhaust of the pneumatic system with fully opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg (34,7 kPa to 2,0 kPa) shall not exceed 10 s.

For blood pressure measuring systems having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 150 mmHg to 5 mmHg (20,0 kPa to 0,7 kPa) during the rapid exhaust of the pneumatic system with fully opened valve shall not exceed 5 s.

Testing shall be carried out in accordance with 8.6.

7.4.4 Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 mmHg (0 kPa) shall exist and be displayed thereafter.

Devices performing zero setting only immediately after switching on, shall switch off automatically before the drift of the pressure transducer and the analog signal processing exceeds 1 mmHg (0,1 kPa).

Testing shall be carried out in accordance with 8.7 and 8.8.

7.5 Environmental performance

7.5.1 Storage

Blood pressure measuring systems shall maintain the requirements specified in this Part of EN 1060 after storage for 24 h at a temperature of - 5 °C and for 24 h at a temperature of + 50 °C and a Relative Humidity of 85 % (non-condensing).

Testing shall be carried out at environmental conditions (see subclause 7.1.1 of EN 1060-1: 1995) in accordance with 8.1 of EN 1060-1: 1995 after the test sample has been placed for 24 h at a temperature of - 5 °C and immediately afterwards for 24 h at a temperature of + 50 °C in a climatic chamber.

NOTE: Integrated multiparameter monitors may contain components which can be damaged during storage. The general temperature range in EN 1060-1: 1995 has therefore been reduced.

7.5.2 Temperature, relative humidity

7.1.2.2 of EN 1060-1: 1995 shall apply.

The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and Relative Humidity specified in 7.1.2.2 of EN 1060-1: 1995.

Testing shall be carried out in accordance with 8.9.

7.5.3 Electromagnetic compatibility

Either:

- a) Electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement, or;
- b) if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

Testing shall be carried out in accordance with EN 60601-1-2: 1993.

7.6 Stability of the cuff pressure indication

The change of the cuff pressure indication shall not be more than 3 mmHg (0,4 kPa) throughout the pressure range after 10 000 simulated measurement cycles.

Testing shall be carried out in accordance with 8.10.