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Australian Standard®

Sphygmomanometers

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SPHYGMOMANOMETERS (Manual or Electronic) NSC 6515]

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The following interests are represented on Committee MD/12:

Australian Medical Association
Australian Medical Devices and Diagnostics Association
Commonwealth and State Departments of Health
Department of Veterans' Affairs
Government Supply Department, N.S.W.
Institution of Biomedical Engineering (Australia)
Institute of Hospital Engineering, Australia
National Heart Foundation of Australia
National Standards Commission
Royal Australasian College of Physicians
Royal Australian College of General Practitioners
Royal Australian Nursing Federation

Additional interests participating in the preparation of this Standard:

Manufacturers
Hospital scientists and engineers

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PREFACE

This Standard was prepared by the Association's Committee on Sphygmomanometers, under the direction of the Medical Materials and Equipment Standards Board, in response to a request by the Commonwealth Department of Community Services and Health.

In the preparation of this Standard account as been taken of ANSI/AAMI SP9—1985, *Non-automated sphygmomanometers*, and ANSI/AAMI SP10—1987, *Electronic or automated sphygmomanometers*, and this is acknowledged.

CONTENTS

FOREWORD

Sphygmomanometers are among the most frequently used clinical measuring devices and are extensively used in monitoring blood pressure and the treatment of blood pressure abnormalities. Additionally, they influence life and death decisions in critical care. Increasingly, sphygmomanometers make use of microcomputers and other novel features and are being utilised by patients themselves at home and in public places with little expert supervision.

This Standard aims to assure that sphygmomanometers are capable of a maintained high order of accuracy in the hands of the average trained observer.

A basic sub-division into manual, semi-automated and automated devices is used in this Standard, and features which appear to cover virtually all types of instrument in current use are dealt with. New features appearing with advancing technology could be readily accommodated because of the modular layout.

It is acknowledged that in clinical medicine blood pressure is usually measured in mmHg, but to encourage the use of SI units (kPa) both units are referred to in this Standard. The Standard requires that blood pressure measuring instruments be marked in 'mmHg', and in 'kPa'. In order to minimize the chance of error, the Standard requires that the units should be inscribed in different colours with equal prominence given to both. For digital displays the two units need not be displayed simultaneously, but they should be clearly differentiated.

While the Standard makes provision for all the commonly used sphygmomanometers, it is possible that the accelerating pace of electronic development will lead to new instruments with features not addressed by this Standard.

STANDARDS AUSTRALIA

Australian Standard
Sphygmomanometers

1 SCOPE. This Standard specifies requirements for manual, semi-automated and automated devices for indirect measurement of arterial blood pressure.

The Standard applies to liquid manometer, mechanical gauge, oscillotonometer or electro-manometer sphygmomanometers used in conjunction with a stethoscope or other methods for the detection and display of pulsations, flow or sounds in connection with the measurement, display or recording of blood pressure by electronic means, regardless of whether they have an automatic inflation system.

Safety aspects of the instruments and their servicing and maintenance are also dealt with.

The Standard does not apply to invasive devices such as those used for the direct measurement of blood pressure, nor does it apply to the non-invasive determination of blood pressure during exercise.

NOTE: Specialized instruments, such as the population of new ambulatory blood pressure recorders, the London School of Hygiene (LSH), or the random zero machines (RZM) and devices based on the vascular unloading principle combined with plethysmography may require additional consideration, as these research-based instruments are not completely covered by this Standard.

2 APPLICATION. The requirements of this Standard may be read in conjunction with, but do not take precedence over, any Statutory Regulations that may apply in any area.

3 REFERENCED DOCUMENTS. The following documents are referred to in this Standard:

AS
2901 Medical devices—Characteristics of audible and visible alarm signals

3200 Electromedical equipment—General requirements

4 DEFINITIONS. For the purpose of this Standard, the definitions below apply:

4.1 Sphygmomanometer—an instrument for the indirect (non-invasive) measurement of arterial blood pressure.

NOTE: Such an instrument would typically include a manometer or other pressure sensing device, inflation system and occluding cuff with bladder that is used in conjunction with a method of detection of Korotkoff sounds, pulsation or arterial wall movement.

4.2 Cuff—that component of the sphygmomanometer which in operation is applied to a limb of the subject whose arterial blood pressure is to be measured. The cuff consists of an inflatable section which may be integral to it or be a separate bladder enclosed by an inelastic sleeve with fastening mechanism.

NOTE: The definition for the term 'Cuff', refers generally and inclusively to that part of the device which is applied to a limb. This meaning can be adopted effectively by also describing the component parts of the 'cuff', e.g. the bladder and sleeve. 'Bladder' and 'sleeve' do not require definition since these terms are self descriptive of the cuff components to which they are applied, particularly when the adjectives 'inflatable' and 'inelastic' are used.

4.3 Manual device—an aneroid, mercury gravity or electronic transducer/display sphygmomanometer used in conjunction with a stethoscope or with other manual methods for detecting Korotkoff sounds, arterial wall movement, pulsation or blood flow.

4.4 Semi-automated device—a sphygmomanometer with an in-built method of detection of Korotkoff sounds, arterial wall movement, pulsation, or blood flow which may alert the user, typically by sound or visual indication when to take a reading of its pressure display. The device may have either an automatic cuff inflation and deflation system or an automatic detection system.

4.5 Fully automated device—a sphygmomanometer with an in-built method of detection of Korotkoff sounds, arterial wall movement, pulsation, or blood flow and an automatic inflation and deflation system which, once activated, measures and displays blood pressure without further user intervention.

4.6 Audible alarm—any alert tone generation intended to attract attention.

5 DESCRIPTION OF SPHYGMOMANOMETER. The sphygmomanometer may contain some or all of the following components:

(a) Manometer (tube, reservoir, trap, scale plate).
(b) Valves.
(c) Cuff.
(d) Tubing.
(e) Inflating and deflating system.
(f) Transducer(s).
(g) Signal processing.
(h) Display.
(i) Hard copy device.
(j) Alarm system.

6 GENERAL REQUIREMENTS.

6.1 Environmental performance and stability.

6.1.1 *Operating conditions*. The performance of the device, when set up in its normal operating configuration, shall be such that it complies with Clause 6.2.4, after stabilization for 2 h and whilst maintained at each of the following conditions:

(a) A temperature of not less than 34°C with a relative humidity of not less than 85 percent.
(b) Atmospheric pressure in the range 85 kPa to 100 kPa.

NOTE: This is considered equivalent to an altitude of –50 m to 1500 m, relative to sea level.