

Specification for

# **Aneroid and mercury non-automated sphygmomanometers**

## Committees responsible for this British Standard

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Association of Anaesthetists of Great Britain and Ireland  
Association of Manufacturers of Domestic Electrical Appliances  
British Association of Critical Care Nurses  
British Hypertension Society  
British Laboratory Ware Association  
British Medical Association  
British Surgical Trades Association  
Department of Health  
Electro Medical Trade Association Limited  
Institute of Physical Sciences in Medicine  
Joint Committee of Professional Nursing, Midwifery and Health Visiting Associations (England)  
Medical Research Council  
National Blood Transfusion Service  
Royal College of General Practitioners  
Royal College of Physicians of London

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# Contents

|                                                                                                       | Page               |
|-------------------------------------------------------------------------------------------------------|--------------------|
| Committees responsible                                                                                | Inside front cover |
| Foreword                                                                                              | 2                  |
| <b>Specification</b>                                                                                  |                    |
| <b>Section 1. General</b>                                                                             |                    |
| 1 Scope                                                                                               | 4                  |
| 2 Definitions                                                                                         | 4                  |
| 3 Description                                                                                         | 4                  |
| 4 General performance                                                                                 | 4                  |
| 5 Environmental performance                                                                           | 5                  |
| 6 Occluding cuffs                                                                                     | 5                  |
| 7 Inflation and pressure control system                                                               | 6                  |
| 8 Marking and accompanying documents                                                                  | 7                  |
| <b>Section 2. Mercury manometers</b>                                                                  |                    |
| 9 Manometer tube                                                                                      | 9                  |
| 10 Mercury                                                                                            | 9                  |
| 11 Protection from loss of mercury                                                                    | 9                  |
| 12 Mercury column response                                                                            | 9                  |
| <b>Section 3. Aneroid manometers</b>                                                                  |                    |
| 13 Dial scale                                                                                         | 10                 |
| 14 Cursor or pointer                                                                                  | 10                 |
| 15 External adjustment                                                                                | 10                 |
| 16 Pointer response                                                                                   | 10                 |
| <b>Appendices</b>                                                                                     |                    |
| A Conversion of pressures                                                                             | 11                 |
| B Assessment of sphygmomanometer general performance                                                  | 11                 |
| C Assessment of durability and air leakage                                                            | 12                 |
| D Drop test                                                                                           | 13                 |
| E Assessment of cuff closure performance and durability                                               | 13                 |
| F Assessment of inflation and deflation controls                                                      | 13                 |
| G Advice to be included in the instructions accompanying a sphygmomanometer using a mercury manometer | 14                 |
| H Guidance on the use of sphygmomanometers                                                            | 15                 |
| J Guidance on the measurement of blood pressure in children                                           | 16                 |
| K Information to be supplied by the purchaser                                                         | 16                 |
| L Bibliography                                                                                        | 16                 |
| <b>Tables</b>                                                                                         |                    |
| 1 Dimensions of occluding cuffs                                                                       | 6                  |
| 2 Approximate conversion of pressures                                                                 | 11                 |
| <b>Figure</b>                                                                                         |                    |
| 1 Diagram of the occluding cuff                                                                       | 6                  |

## Foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It constitutes a combined revision of BS 2743 : 1956 and BS 2744 : 1956 which are withdrawn.

The first editions of BS 2743 'Specification for sphygmomanometers. Aneroid type' and BS 2744 'Specification for sphygmomanometers. Mercury type' specified the essential design requirements for each type of device. Because of this emphasis on design, these standards have proved restrictive towards the development of newer sphygmomanometers that could take advantage of modern technology and modern materials. In addition, medical evidence has indicated the importance of the bladder size in the occluding cuff if reliable and accurate measurements of arterial blood pressure are to be obtained. This revision, therefore, mainly specifies performance requirements and only where it is considered critical are design criteria specified.

The Technical Committee responsible for the preparation of this standard recommends that, for efficient clinical practice and treatment of patients, the scale on sphygmomanometers should be graduated in millimetres of mercury (mmHg), although for research and other purposes it acknowledges that a scale calibrated in kilopascals (kPa) may be required. Thus this standard specifies sphygmomanometers graduated with either scale but does not permit the use of dual scale sphygmomanometers because of the likelihood of confusion and consequent errors in diagnosis. Replies to a questionnaire sent to Regional Health Authorities supported this view.

It is expected that mmHg will continue as the most common unit for blood pressure measurement for many years to come but, as the use of the kilopascal (kPa) is specified as an alternative in this standard, for convenience appendix A provides means for readily converting data between the two units.

NOTE. There is a general movement towards the use of SI units wherever possible, and this is enforced in many instances by EEC Directive 80/181/EEC. Nevertheless, because misunderstandings could result if scales of sphygmomanometers were graduated in kilopascals instead of the established mmHg and because these misunderstandings could lead to potentially hazardous diagnoses (e.g. in detecting hypertension), Directive 85/1/EEC specifically permits the use of millimetres of mercury for the measurement of blood pressure.

This standard does not specify the design of the occluding cuffs except the dimensions which are considered essential for accurate measurement of blood pressure<sup>1)</sup>.

In the preparation of this standard, the Committee was assisted by the following, particularly with regard to sizes of occluding cuffs:

- (a) the 'Recommendations for Human Blood Pressure Determination by Sphygmomanometers' published by the American Heart Association in 1967 and in 1981;
- (b) the American national standard for non-automated sphygmomanometers, ANSI/AAMI SP9-1985, and the Australian standard for sphygmomanometers, AS 3655; and
- (c) the recommendations of the British Hypertension Society.

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<sup>1)</sup> It should be noted that the dimensions of the cuffs specified in this standard differ from those required by BS 7088 which specifies pneumatic tourniquet equipment. This is because the cuffs specified in BS 7088 serve a different purpose and their requirements are more critical.

As a consequence, and principally following the recommendations of the British Hypertension Society, this standard specifies only three sizes of cuff, for adults, children and small children respectively (see table 1). It is believed that this range covers the majority of patients aged 1 year or above (see appendix J). The cuff for use with adults has a wider range than hitherto and hence has been designated 'Adult (wide range)' to differentiate it from existing adult cuffs.

Because of the known hazards associated with mercury, the standard draws particular attention to the need for the user when handling mercury sphygmomanometers to be made aware of these hazards, the need for care during use, and the steps to be taken after any spillage of mercury. In addition, the manufacturer should be aware of Section 6 of the Health and Safety at Work etc. Act 1974. (See appendix G.)

The standard does not specify a carrying case as the specification encompasses both wall-mounted and portable instruments.

A standard for semi-automated sphygmomanometers is being considered and a specification for fully automated sphygmomanometers is in preparation.

**Product certification.** Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

Alternatively users of this British Standard may wish to consider the desirability of assessment and registration of a supplier's quality systems against the appropriate Part of BS 5750 by a third party certification body.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

## Section 1. General

### 1 Scope

This British Standard specifies requirements for aneroid and mercury type non-automated sphygmomanometers to be used with occluding cuffs for the indirect measurement of arterial blood pressures in the range 0 mmHg to at least 260 mmHg, or 0 kPa to at least 35 kPa. It specifies manometers graduated either in millimetres of mercury (mmHg) or in kilopascals (kPa) but not both (see note 1). Data for conversion between mmHg and kPa are given in appendix A. This standard also specifies requirements for occluding cuffs (see note 2), including the inflatable bladder, the inflation device and the connecting tubing.

NOTE 1. The purchaser should state in his enquiry or order whether an aneroid or mercury manometer is to be supplied and whether it is to be graduated in mmHg or kPa (see appendix K).

NOTE 2. The purchaser should state in his enquiry or order the number and size of the occluding cuffs to be supplied with the manometer unit (see appendix K).

Marking requirements and details to be included in accompanying documents are also specified.

This standard is not applicable to automated or semi-automated sphygmomanometers.

NOTE 3. The titles of the publications referred to in this standard are listed on the inside back cover.

NOTE 4. The titles of other publications of relevance to this standard are listed in appendix L for information.

### 2 Definitions

For the purposes of this British Standard, the following definitions apply.

#### 2.1 cuff

The component of the sphygmomanometer (comprising a bladder and a sleeve) which is firmly wrapped around the patient's limb.

#### 2.2 bladder

The inflatable component of a cuff, which is enclosed by and detachable from the sleeve.

#### 2.3 sleeve

The essentially inelastic part of a cuff which at one end encloses the bladder and which, when wrapped around a limb, enables the bladder to be held firmly against the limb.

NOTE. The end of the sleeve distant from the bladder may be provided with a touch-and-close or similar fastener.

#### 2.4 bandage sleeve

A sleeve which is not provided with a fastener (see note to 2.3) and which is secured around the limb of the patient by tucking in the end distant from the bladder.

### 3 Description

A sphygmomanometer shall comprise the following components:

- (a) *Manometer*, operating either on the aneroid principle or by use of a column of mercury, to indicate the pressure in the cuff;
- (b) *Cuff*;
- (c) *System or device*, for inflating the bladder;
- (d) *Connecting tubing*, incorporating detachable connectors;
- (e) *Valve(s)*, for pressure control.

NOTE. A sphygmomanometer should be supplied either in a container or with a system by which the components can be supported relative to each other.

### 4 General performance

#### 4.1 General

All tests specified in clauses 4 to 7 and, where appropriate, clauses 9 to 16, shall be carried out on a single instrument and its components.

#### 4.2 Access to the pressure sensitive element (opening)

There shall be an opening between the pressure sensitive element and the atmosphere such that the sphygmomanometer complies with either clause 12 in the case of an instrument with a mercury manometer, or clause 16 in the case of an instrument with an aneroid manometer.

#### 4.3 Indicated pressure measurement range

4.3.1 The manometer shall indicate the measured pressure either in millimetres of mercury ('mmHg scale') or in kilopascals ('kPa scale') (see foreword).

NOTE. The conversion of pressure measurements in mmHg to the equivalent SI unit, kPa, is given in appendix A for information.

4.3.2 The manometer shall indicate pressures either within the scale range 0 mmHg to at least 260 mmHg or within the scale range 0 kPa to at least 35 kPa.

For those sphygmomanometers that use a mercury manometer in which the zero position is offset or is obscured from the user (see note), the scale of the manometer shall extend to 300 mmHg (mmHg scale) or 40 kPa (kPa scale).

NOTE. These latter sphygmomanometers are more commonly required for research purposes.