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MHRA
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Blood pressure measurement devices

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Contents

Revision history

Version	Date published	Changes
V2.3	January 2021	Updated to reflect changes due to the UK's exit from the EU
V2.2	October 2019	Section 2, paragraph 1. Section 5.1, paragraph 3. Section 6, paragraph 1. Removed reference to the medical devices directive. Amended reference to guidance on mercury.
V2.1	December 2013	New MHRA logo

1 Executive summary

The purpose of this document is to provide information and guidance to all involved with the purchase, management and use of non-invasive blood pressure measurement devices.

We review the advantages and disadvantages of mercury, aneroid, electronic manual sphygmomanometers and automated blood pressure measuring devices. This should help to ensure the most appropriate technology is selected for use.

2 Introduction

The measurement of blood pressure is important in the diagnosis and monitoring of a wide range of clinical conditions. Traditionally, blood pressure is measured non-invasively using the auscultatory technique (Korotkoff sounds) with the pressure in the cuff measured using a mercury sphygmomanometer. This consequently became, and still is recognised as, the 'gold standard'. However, environmental concerns regarding mercury mean that there is no long-term future for these devices. Those for healthcare use are no longer available for purchase in the UK from the start of 2021. It is therefore recommended that consideration be given to the selection of mercury-free products when the opportunity arises.

The cuff pressure can also be measured by an aneroid gauge or by electronic pressure transducers. However, concerns about their reliability and ability to withstand the stresses of clinical use have in the past limited their widespread acceptance. Meanwhile, automated blood pressure measurement devices, many of which use the oscillometric measurement technique, have become increasingly popular because of their ease of use. However, these automated devices have limitations of which users need to be aware.

Automated devices are currently available in four generic types:

1 Automatic-cycling non-invasive blood pressure (NIBP) monitors
These make repetitive measurements at set time intervals and often incorporate vital sign parameter alarms. They are designed for bed-side monitoring in a clinical environment and are an expensive option. However, provided accuracy can be assured, they may have a useful role throughout a healthcare facility.

2 Spot-check NIBP monitors
These make single measurements and often incorporate additional vital signs monitoring. They are designed for routine clinical assessment and are now becoming popular for clinic and general ward use.

3 Ambulatory NIBP monitoring devices
These are designed to record the patient's blood pressure at pre-defined intervals over a 24-hour period during normal activities and store the data for future analysis.

4 Automated (spot-check) NIBP monitoring devices
These make single measurements only of blood pressure. Although these were originally designed for monitoring in the home and hence were low cost, they are now being increasingly purchased for clinical practice, particularly if they have been validated against clinical trial protocols.

The falling cost of automated devices, together with the improved reliability of aneroid devices and the introduction of manual electronic sphygmomanometers, are leading to a further reduction in the use of the mercury sphygmomanometer.

It is important that health service personnel involved in purchasing or replacing blood pressure measuring devices seek, and take into account, the views of clinical and technical staff. They should also consider the pros and cons of the different devices to ensure that they choose those devices that deliver the performance required for the optimal management of the patient's clinical conditions, and are appropriate for the environment in which they are to be used.

All those who purchase, use and maintain blood pressure measuring equipment need to be aware of the conclusions and recommendations of the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice [1] (see Appendix 1 for summary).

3 Blood pressure measurement equipment

3.1 Manual auscultatory technique

The auscultatory method relies on inflating an upper arm cuff to occlude the brachial artery and then listening to the Korotkoff sounds through a stethoscope whilst the cuff is slowly deflated. The patient's systolic (phase I) and diastolic blood pressure (phase V) is recorded from the reading on the sphygmomanometer.

Devices for use with the manual auscultatory technique

- **Mercury sphygmomanometer** This includes a mercury manometer, an upper arm cuff and a hand inflation bulb with a pressure control valve; requires the use of a stethoscope to listen to the Korotkoff sounds.

- **Aneroid sphygmomanometer** As above, with an aneroid gauge replacing the mercury manometer. The aneroid gauge may be wall or desk mounted or attached to the hand bulb.

- **Electronic sphygmomanometer** As above, with a pressure sensor and electronic display replacing the mercury manometer. The display may be a numerical display or a circular or linear bar graph. Battery powered.

3.2 Automated oscillometric technique

The majority of non-invasive automated blood pressure measuring devices currently available use the oscillometric method.

The oscillometric method relies on detection of variations in pressure oscillations due to arterial wall movement beneath an occluding cuff. Empirically derived algorithms are employed, which calculate systolic, mean arterial and diastolic blood pressure.

Manufacturers develop their own algorithms by studying a population group and may have validated the stated accuracy by performing a clinical trial in accordance with one of the standards listed in section 7.2 of this document.
Note: In general, these standards/protocols allow validation of the test device against either intra-arterial measurements or non-invasive (sphygmomanometric) measurements whereas the traditional British Hypertension Society protocol only specifies comparison with a mercury sphygmomanometer.

Automated devices, generally using the oscillometric technique

- **Automated (spot-check) device**
  This includes an electronic monitor with a pressure sensor, a digital display and an upper arm cuff. An electrically-driven pump raises the pressure in the cuff. Devices may have a user-adjustable set inflation pressure or they will automatically inflate to the appropriate level, usually about 30mmHg above an estimated systolic reading. When started, the device automatically inflates, then deflates the cuff and displays the systolic and diastolic values. The majority calculate these values from data obtained during the deflation cycle, but there are some that use data from the inflation cycle. The pulse rate may also be displayed. These devices may also have a 'memory' facility which stores the last measurement and previous readings. Battery powered.

- **Wrist device**
  This includes an electronic monitor with a pressure sensor, an electrically-driven pump attached to a wrist cuff. Function is similar to the automated (spot-check) device above. Battery powered.

- **Finger device**
  This includes an electronic monitor and a finger cuff, or the device itself may be attached to the finger. Generally battery powered. Uses oscillometric, pulse-wave or plethysmographic methods for measurement.

- **Spot-check non-invasive blood pressure (NIBP) monitor**
  This is a more sophisticated version of the automated device above and is designed for routine clinical assessment. There may be an option to measure additional vital signs, such as oxygen saturation in the finger pulse (SpO_2) and body temperature. Mains and battery powered.

- **Automatic-cycling non-invasive blood pressure (NIBP) monitor**
  This is similar to the spot-check NIBP monitor, but with the addition of an automatic-cycling facility to record a patient's blood pressure at set time intervals. These are designed for bed-side monitoring in a clinical environment where repetitive monitoring of patients and an alarm function is required. These devices may incorporate the ability to measure additional vital signs. The alarm limits can usually be set to alert nursing staff when one or more of the measured patient parameters exceed the pre-set limits. Mains and battery powered.

- **Multi-parameter patient monitors**
  These are designed for use in critical care wards and operating theatres and monitor a range of vital signs including blood pressure. May be possible to communicate with a Central Monitoring Station via Ethernet or Wi-Fi.

- **Ambulatory blood pressure monitor**
  This includes an upper arm cuff and an electronic monitor with a pressure sensor and an electrically-driven pump that attaches to the patient's belt. The unit is programmed to record the patient's blood pressure at pre-defined intervals over a 24-hour period during normal activities and stores the data for future analysis. Battery powered. Uses electronic auscultatory and oscillometric techniques.

Some automated devices may use an electronic auscultatory method. These devices incorporate a microphone in the cuff and apply sound-based algorithms to calculate the systolic and diastolic blood pressure. There are alternative methods of blood pressure measurement, but these are beyond the scope of this document.

3.3 Generic types of equipment available

Equipment	Advantages	Disadvantages
Mercury sphygmomanometer	'Gold standard', portable, good reliability, can be used on most patients.	• Contains a toxic substance leading to maintenance and disposal problems. • Manual technique prone to observer bias. • Requires clinical skill to operate. • Will be unavailable for purchase in near future.
Aneroid sphygmomanometer	Mercury-free, portable, can be used on most patients.	• Wear and mechanical shock to mechanism may result in incorrect readings. • Requires regular calibration check. • Manual technique prone to observer bias. • Requires clinical skill.
Electronic sphygmomanometer	Mercury-free, portable, good reliability, can be used on most patients.	• Manual technique prone to observer bias. • Requires clinical skill.
Automated spot-check device	Mercury-free, lightweight, compact, portable, easy to use, no observer bias.	• Originally designed for home use, and may not be suitable for all patients, particularly those with arrhythmias, pre-eclampsia and certain vascular diseases. • Validation recommended*.
Wrist device	As above, with increased patient comfort.	• As for automated device above. • Readings are dependent on the relative positioning of the wrist to the heart. • Tends to be less accurate than upper arm devices.
Finger device	As above.	• As for wrist device above, although measurement more peripheral and less reliable. • May not be suitable for patients with narrow or cold fingers.
Spot-check non-invasive blood pressure monitor Automatic-cycling non-invasive blood pressure monitor	• Mercury-free, no observer bias, portable, easy to use, designed for monitoring in clinical use. • May include additional vital signs.	• May not be suitable for all patients, particularly those with arrhythmias, pre-eclampsia and certain vascular diseases. • Clinical validation recommended*.
Ambulatory blood pressure monitor	Mercury-free, lightweight, compact, designed for clinical use, records 24-hour blood pressure trend.	• Designed for ambulatory monitoring, not as a replacement for the mercury sphygmomanometer. • Clinical validation recommended*.

*Validation as described in Recommendation 5 of the Report by the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice [1].

4 Sources of error and other issues

Manual
Manual techniques may suffer from observer bias including differences of auditory acuity between observers. Digit preference is common, with observers recording a disproportionate number of readings ending in five or zero. The observer may also be influenced by the knowledge that they have of the patient, such as earlier readings, expected effect of drug therapy, gender, age, race and weight.

However, formal training in blood pressure measurement can improve this situation. At the same time the observer may obtain additional useful information about the general health of the patient, such as the regularity and strength of the pulse, skin condition and any tremors.

Automated
Users should be aware that for patients experiencing muscle tremors, abnormal heart rhythms, weak pulse or very low blood pressure due to shock, some automated blood pressure devices may fail to obtain a reading and will either indicate an error code or give unreliable results.

The accuracy in clinical diagnosis and monitoring, particularly in certain groups (e.g. those with cardiac arrhythmias, pre-eclampsia and certain vascular diseases) needs to be established through testing against clinical trial protocols.

Users should also be aware that some automated non-invasive blood pressure monitors may have been validated by reference to intra-arterial measurements. There can be differences in readings between these devices and those validated by reference to non-invasive (sphygmomanometric) measurements.

The Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice has recognised the limitations of automated oscillometric devices and has recommended that calibrated, non-mercury devices, which do not rely on oscillometry, are made available in all clinical areas [1] (recommendation 7 in appendix 1).

Concern has been expressed that the skills for manual techniques may be lost by clinical staff who use only automated devices.

Manual and automated
The blood pressure recorded using either manual or automated techniques may be influenced by behavioural factors that are related to the effects of the observer on the patient, such as ‘white-coat hypertension’.

The patient should be discouraged from talking and moving during the measurement phase as this can cause the blood pressure to vary and may interfere with the detection method.

The height of the cuff in relation to the heart affects the blood pressure measurement. If the cuff is placed above the level of the heart, then lower pressures are recorded, whilst placing the cuff below the heart leads to higher pressure readings. The limb used for the blood pressure measurement should be properly supported.

Other problems such as ulnar nerve palsy and venous haemostasis, although rare, can be caused by both automated blood pressure measuring devices and mechanical sphygmomanometers and depend on factors such as cuff placement, pressure and duration of inflation.

Readers may wish to refer to: the guidelines issued by the National Institute for Health and Clinical Excellence for the management of hypertension in adults in primary care [2]; the British Hypertension Society website [3]; ABC of Hypertension [4].

Cuff
Incorrect cuff size is a major source of error for both automated blood pressure measuring devices and manual sphygmomanometers. An under-sized cuff tends to over-estimate blood pressure, while an over-sized cuff may under-estimate. This is especially critical when measuring blood pressure in children. Cuffs should be marked to indicate the correct size for the patient's limb.

Incorrect cuff placement can also be a source of error. The cuff should be placed on the arm with the centre of the bladder over the brachial artery. Cuffs should be marked to facilitate this. Users should note that the tubing usually attaches to one end of the bladder and is therefore not a reliable indicator for positioning the cuff, particularly when using the same cuff on left and right arms.

The standard BS ISO 81060-1:2012 [5] considers the optimum bladder size to be: width 40% of limb circumference, length 80% to 100% of limb circumference at the centre of the range for each cuff size. These dimensions are subject to ongoing consideration.

Automated sphygmomanometers can be designed with different cuff dimensions. This can be of benefit when designing cuffs for obese patients. Extra long cuffs with a width of 40% of circumference are often too wide for these patients.
Note: Manufacturers need to consider the marking of these cuffs to identify the patient group and maintain clinical evidence supporting performance claims.

Accuracy
BS ISO 81060-1:2012 [5] states that for both increasing and decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0.4 kPa). This applies to the 'static calibration' of the cuff pressure in manual and automated devices.

BS ISO 81060-2:2019 [6] states for systolic and diastolic blood pressures, the mean value of the differences of the determinations shall be within or equal to ± 5 mm Hg (± 0.67 kPa), with a standard deviation not greater than 8 mm Hg (1.07 kPa).
This applies to the results from a clinical trial protocol when evaluating the accuracy of the blood pressure algorithm in a population of subjects.

5 Purchase, training, maintenance and calibration

5.1 Purchase

Staff responsible for purchasing should take into account any relevant local policy, and ensure that the product meets the requirements of clinical staff and that the accuracy is adequate for the clinical situation in which it is to be used. Relevant information should be obtained from the manufacturer before purchase, including clinical validation, standards complied with, manuals available, warranty details, availability of training for users, and maintenance contracts. It is also important to take into account total costs, including training, consumables and maintenance.

The selection of disposable or re-useable cuffs should consider the cost differentials, supply logistics, infection control and the environmental impact of disposal.

Purchasers should be aware that blood pressure monitors for clinical use should be UKCA, CE UKNI or CE marked as a medical device. As part of this process, manufacturers may use the designated standards listed under 'standards' in section 7.2 of this document. It is a requirement of these standards that clinical data is available to demonstrate the accuracy of the device. Although it is not mandatory for a device to comply with these standards, their requirements are considered to be 'state of the art'. A manufacturer will either comply with them or carry out a risk assessment to demonstrate an equivalent level of safety.

Both purchasers and staff who use these devices should be aware that recommendations have been published by the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice regarding the purchase and use of blood pressure monitors [1] (see appendix 1 for summary).

5.2 Training

When new medical devices are introduced it is important that members of staff are trained to ensure they are aware of the equipment's limitations and can recognise artefacts. General advice on the selection, purchasing, maintenance and the need for user training are given in the MHRA's publication 'Managing Medical Devices' [7].

It is also important that auscultation, as a method of determining blood pressure, is continued to be taught to healthcare workers as appropriate [see recommendation 7 in appendix 1].

5.3 Maintenance and calibration

All blood pressure measuring equipment should be regularly checked and calibrated in accordance with the manufacturer's instructions. These maintenance recommendations vary depending on the type, frequency and location of use. However, it should be noted that some of those originally designed for use in the home may be difficult to calibrate without returning to the supplier.

Cuffs and their hoses should be regularly inspected and replaced as necessary. Excessive air leakage from damaged cuffs, hoses and tubing connectors may reduce the accuracy of the readings. Both disposable (single patient use) and re-usable cuffs are available. Re-usable cuffs should be cleaned in accordance with the manufacturer's instructions, ensuring that cleaning fluid does not enter the cuff bladder or hoses.

Particular concern over the lack of maintenance of blood pressure measurement devices, both in the community and acute hospital settings, has been highlighted [8]. Faulty cuffs, hoses, aneroid gauges and mercury manometers can all lead to erroneous blood pressure measurements, with significant effects on patient care. Healthcare organisations have a responsibility to ensure that adequate maintenance arrangements are available.

The MHRA receives many enquiries relating to the frequency of calibration of aneroid gauges as this directly affects the cost of maintaining this service. Those responsible should take into account manufacturer's recommendations and type, such as hand-held, wall or desk mounted. Hand-held devices used in the community are likely to receive more shocks and drops than the other types. Those devices that incorporate anti-shock mechanisms may be more resilient to this type of wear and tear. We recommend at least annual checks or twice a year for aneroid devices.

Those operating an established calibration system can look at the calibration history of particular devices and see whether the frequency is adequate. If devices are generally found to be out of calibration then maybe the devices should be checked more frequently. However, it could be worthwhile investigating the cause to see whether the device is appropriate for the intended purpose or whether users should be taking more care.

Note: Prior to any changes being made to the calibration frequency, a rationale should be documented and agreed in accordance with local procedures.

6 Mercury

Mercury sphygmomanometers have been used by healthcare professionals over the last 100 years. However, environmental concerns regarding mercury mean that there is no long-term future for these devices. These concerns have led to the imposition of bans in some countries and can no longer be supplied to members of the public in the UK.

The current regulations are summarised below.

The Control of Substances Hazardous to Health (COSHH) Regulations [9] provide a comprehensive and systematic approach to the control of hazardous substances at work and require employers to:

- assess risks to health arising from exposure to hazardous substances
- prevent or adequately control exposure
- ensure control measures are used, maintained, examined and tested
- in some instances, monitor exposure and carry out appropriate health surveillance
- inform, instruct and train employees.

For medical devices containing mercury the question needs to be asked: are these products still required? If the answer is ‘yes’, then appropriate health and safety procedures should be implemented and mercury spillage kits should be made available. Staff should also be trained to ensure safe handling:

- during normal use and storage
- in the event of a mercury spillage
- during maintenance of mercury sphygmomanometers, if performed in-house
- in the event of mercury disposal or when a complete instrument is discarded.

This can result in extra costs associated with the use of devices containing mercury, when compared with non-mercury types. Inspection and functional checks can be easily performed, although maintenance of those parts in contact with mercury should be restricted to a suitably controlled environment.

In a particular example, a hospital’s maintenance laboratory was closed after a safety check revealed that the mercury vapour present exceeded the occupational exposure limit. This resulted in a decision being made to replace mercury sphygmomanometers throughout the hospital.

Workplace exposure limits can be found in the HSE’s publication EH40 [10].

7 References and bibliography

7.1 References

1 'Report of the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice.' June 2005.
https://webarchive.nationalarchives.gov.uk/20141204103756/http://www.mhra.gov.uk/home/groups/dts-iac/documents/committeedocument/con2022714.pdf

2 National Institute for Health and Care Excellence – Hypertension in adults: diagnosis and management. August 2019.
https://www.nice.org.uk/guidance/ng136

3 British and Irish Hypertension Society
https://bihsoc.org/resources/bp-measurement/measure-blood-pressure/

4 G Beevers, G Y H Lip, E O'Brien. ABC of Hypertension, 5th edition. BMJ Books January 2007. ISBN: 978-1-4051-3061-5

5 BS ISO 81060-1:2012 Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type

6 BS ISO 81060-2:2019 Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement.

7 Medicines and Healthcare products Regulatory Agency. Managing Medical Devices. 2015
https://www.gov.uk/government/publications/managing-medical-devices

8 Coleman AJ, Steel SD, Ashworth M, Vowler SL, Shennan A. Accuracy of the pressure scale of sphygmomanometers in clinical use within primary care. Blood Pressure Monitoring 2005 Aug:10(04): 181-8.
http://journals.lww.com/bpmonitoring/Abstract/2005/08000/Accuracy_of_the_pressure_scale_of.3.aspx

9 Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended). Statutory Instrument 2002 No. 2677. ISBN 0 11 042919 2.
http://www.opsi.gov.uk/SI/si2002/20022677.htm

10 Health and Safety Executive. EH40/2005 Workplace Exposure Limits: Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended). HSE Books, 2011. ISBN:9780717664467
http://www.hse.gov.uk/pubns/books/eh40.htm

7.2 Bibliography

Standards
Available from British Standards Institute, BSI
http://shop.bsigroup.com/Navigate-by/Standards/Standards-LP/

BS EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

BS EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

BS ISO 81060-1:2012 Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type

BS ISO 81060-2:2019 Non-invasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement.

BS EN 1060-3:1997 +A2:2009 Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

BS EN 1060-4:2004 Non-invasive sphygmomanometers – Part 4: Test procedures to determine the overall system accuracy of automated noninvasive sphygmomanometers.

Clinical validation protocols likely to have been applied to monitors designed prior to 2006:

O'Brien E, Petrie J, et al. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices: Journal of Hypertension 1993, 11 (Suppl 2): S43-S62.

E O'Brien, T Pickering, et al. Working Group on Blood Pressure Monitoring of the European Society of the Hypertension International Protocol for validation of blood pressure measuring devices in adults: Blood Pressure Monitoring 2002, 7:3-17.

Association for the Advancement of Medical Instrumentation. ANSI/AAMI SP10:2002/A1:2003 - Manual, electronic or automated sphygmomanometers. http://www.aami.org

Note: internet links correct at time of publication.

Appendix 1 Summary of recommendations from the report of the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice

Recommendation 1
While mercury sphygmomanometers continue to be used, appropriate health and safety procedures should be maintained including the availability of mercury spillage kits. When mercury is decommissioned then its disposal should be performed in compliance with the appropriate regulations.

Recommendation 2
Where aneroid gauges are used for sphygmomanometry their calibration accuracy should be regularly checked based on the manufacturer's recommendation or annually.

Recommendation 3
Where oscillometric blood pressure measurement is used, it should not be assumed that a UKCA/CE UKNI/CE marked blood pressure monitor is automatically suitable for use in the diagnosis of hypertension.

Recommendation 4
In those clinical conditions where oscillometry is inappropriate (e.g. arrhythmias, pre-eclampsia and certain vascular diseases) an alternative method of pressure measurement (auscultation, arterial cannulation) should be used.

Recommendation 5
The MHRA, in collaboration with the **Committee on Blood Pressure Monitoring in Clinical Practice** should define acceptable performance criteria against which automated non-invasive blood pressure monitors should be evaluated. Evidence for compliance with these criteria should be obtained from properly conducted clinical trials. The population characteristics for which the device has been evaluated should be specifically included.

Recommendation 6
The NHS and other healthcare sectors should only purchase devices that meet the performance criteria in recommendation 5.

Recommendation 7
Auscultation as a method of determining blood pressure should continue to be taught to healthcare workers as appropriate. Calibrated, non-mercury devices, which do not rely on oscillometry, should be made available in all clinical areas. These will be used to check oscillometric results and other non auscultatory alternative blood pressure measurement determination on individual patients. These devices should also be used in clinical conditions where these alternative methods may be inappropriate e.g. arrhythmia, pre-eclampsia or specific vascular disease