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BULLETIN

(Northern Ireland Version)

Blood Pressure Measurement Devices - Mercury and Non-mercury



HEALTH ESTATES

ESTATE POLICY

*An Executive Agency of the Department of
Health, Social Services and Public Safety*

*Áisíneacht Feidhmeannach don Roinn Sláinte,
Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

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The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

The Medical Devices Agency is an Executive Agency of the Department of Health



The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving Medical Devices and equipment used in Health and Personal Social Services in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient or user injury. NIAIC has direct links with MDA who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland. NIAIC also disseminates safety information in Northern Ireland, including information provided by MDA.

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety.

CONTENTS

1. SCOPE	4
2. SUMMARY	4
3. CURRENT POSITION OF MERCURY DEVICES IN THE UK AND EUROPE	5
4. BLOOD PRESSURE MEASUREMENT EQUIPMENT AVAILABLE.....	5
5. SOURCES OF ERROR AND OTHER ISSUES.....	8
Manual	8
Automated.....	8
Manual and Automated.....	8
6. PURCHASE, TRAINING AND MAINTENANCE	9
7. MERCURY ISSUES.....	10
8. BIBLIOGRAPHY	11

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1. SCOPE

The purpose of this document is to provide information and guidance to all involved with the use, purchase and management of non-invasive blood pressure measurement devices. This document reviews the current situation regarding the use of mercury, and the issues associated with electronic blood pressure measuring devices, which should ensure the most appropriate technology is selected for use.

2. SUMMARY

The measurement of blood pressure is important in the monitoring of a wide range of clinical conditions. The mercury sphygmomanometer is currently seen as the "gold standard" and is often used as a reference for determining the accuracy of automated devices. However, such devices are not without problems and their long-term future is uncertain due to a number of environmental concerns.

Although at present no ban has been imposed on the use of medical devices containing mercury in the UK, it is recommended that consideration is given to the selection of mercury-free products when the opportunity arises.

The automatic-cycling non-invasive blood pressure (NIBP) monitor, although designed for clinical use, is an expensive alternative. However, provided that accuracy can be assured, it may have a useful role throughout a healthcare facility.

The low-cost automated NIBP device, although originally designed for home use, is now being increasingly purchased for clinical practice, particularly those devices that have been validated against clinical trial protocols. It is expected that in time, the reliability of these products will improve, leading to an increase in user confidence and 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; the pros and cons of the different devices; and ensure that these products deliver the performance required for the optimal management of the patient conditions being investigated.

3. CURRENT POSITION OF MERCURY DEVICES IN THE UK AND EUROPE

Mercury-in-glass thermometers and mercury sphygmomanometers have served the medical profession well over the last 100 years. However, environmental concerns regarding mercury mean the long-term future for these devices is now uncertain. These concerns have led to the imposition of bans in some European countries.

Although at present no ban has been imposed on the use of medical devices containing mercury in the UK, it is possible that this may change in the future. The introduction of the Control Of Substances Hazardous to Health (COSHH) Regulations (Northern Ireland) has resulted in a decline in the use of these medical devices. It is therefore recommended that consideration is given to the selection of mercury-free products when the opportunity arises.

4. BLOOD PRESSURE MEASUREMENT EQUIPMENT AVAILABLE

- Mercury Sphygmomanometer - This includes a mercury manometer, an upper arm cuff, a hand inflation bulb with a pressure control valve and requires the use of a stethoscope to listen to the Korotkoff sounds. Relies on the auscultatory technique.
- Aneroid Sphygmomanometer - As for a mercury sphygmomanometer, except an aneroid gauge replaces the mercury manometer. The aneroid gauge may be desk mounted or attached to the hand bulb. Relies on the auscultatory technique.
- Semi-automated Device - This includes an electronic monitor with a pressure sensor, a digital display, an upper arm cuff and a hand bulb. The pressure is raised manually using the hand bulb. The device automatically deflates the cuff and displays the systolic and diastolic values. Pulse rate may also be displayed. Battery powered. Uses the oscillometric technique.
- Automated 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, about 30 mmHg above the predicted systolic reading. On operation of the start button the device automatically inflates and deflates the cuff and displays the systolic and diastolic values. Pulse rate may also be displayed. Devices may

also have a memory facility that stores the last measurement or up to 10 or more previous readings. Battery powered. Uses the oscillometric technique.

- Wrist Device - This includes an electronic monitor with a pressure sensor, an electrically driven pump and a wrist cuff, or the device itself may be attached to the wrist. Function is similar to the automated device above. Battery powered. Uses the oscillometric technique.
- 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.
- Automatic-cycling Non-Invasive Blood Pressure (NIBP) Monitor – This is a more sophisticated version of the automated device above, with the addition of an automatic-cycling facility to record the patient's blood pressure at set time intervals. There may also be an option to measure temperature or SpO₂. Alarm limits can usually be set to alert nursing staff when one or more patient functions have exceeded the limits. Mains and battery powered. Uses the oscillometric technique.
- 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 over a 24-hour period during normal activities and stores the data for future analysis. Battery powered. Uses auscultatory and oscillometric techniques.

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 and diastolic blood pressure.

Manufacturers develop their own algorithms by studying a population group and may validate the stated accuracy by performing a clinical trial in accordance with one of the protocols referenced in Section 8.2.2. The American and German protocols allow validation of the test device against either intra-arterial measurements or non-invasive measurements. The British Hypertension Society protocol only specifies non-invasive methods, i.e. comparison with a mercury sphygmomanometer.

There are other methods of blood pressure measurement, but these are not commonly available. They may include palpatory, infrasound, ultrasound, volume oscillometric, vascular unloading, arterial tonometry, pulse-wave velocity and plethysmographic methods.

Generic types of equipment available

Equipment	Advantages	Disadvantages
Mercury Sphygmomanometer Price £35 to £45	"Gold standard", transportable, well understood by users, can be used on most patients.	Contains toxic substance leading to maintenance problems, although safe in normal use. Can be prone to observer bias.
Aneroid Sphygmomanometer Price £25 to £55	Mercury-free, easily transported, well understood by users, easy to check calibration, can be used on most patients.	Can be prone to observer bias. Wear and mechanical shock to mechanism may result in incorrect readings. Requires regular calibration check.
Semi-automated and Automated Device Price £50 to £140.	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. May be difficult to calibrate. Some cuffs cannot be washed or decontaminated.
Wrist Device Price £80 to £120	As above, with increased patient comfort.	As above. Readings are dependent on the relative positioning of the wrist to the heart.
Finger Device Price £100 to £120	As above.	As above. May not be suitable for patients with narrow or cold fingers.
Automatic-cycling Non-Invasive Blood Pressure Monitor Price £2,000 to £3,000.	Mercury-free, no observer bias, transportable, easy to use, designed for clinical use, may have motion artefact rejection.	Cost is likely to restrict acceptability as a direct replacement for the mercury sphygmomanometer for all applications.
Ambulatory Blood Pressure Monitor Price £1,000 to £2,000	Mercury-free, lightweight, compact, designed for clinical use, records 24-hour blood pressure trend.	Cost and function is likely to restrict acceptability as a direct replacement for the mercury sphygmomanometer for all applications.

5. SOURCES OF ERROR AND OTHER ISSUES

Manual

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

However, formal training in blood pressure measurement can improve this situation, and 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. Concern has been expressed that the skills for manual techniques may be lost by those clinical staff using automated devices.

Automated

Users should be aware that for patients experiencing muscle tremors, abnormal heart rhythms, weak pulse or low blood pressure due to shock, some automated blood pressure devices may fail to obtain a reading or may give unreliable results.

Differences in blood pressure readings can occur between products validated by reference to intra-arterial measurements and with those validated by non-invasive measurements.

Manual and automated

Incorrect cuff size is a major source of error for both automated blood pressure measuring devices and mechanical sphygmomanometers. An under-sized cuff tends to over-estimate blood pressure, while an over-sized cuff may under-estimate.

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.

Other problems such as ulnar nerve palsy and venous haemostasis, 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.

Inadequate or infrequent servicing of equipment can lead to error. Equipment calibration should be checked in accordance with the manufacturers instructions.

6. PURCHASE, TRAINING AND MAINTENANCE

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

Purchasers will be aware that blood pressure monitors for clinical use should be CE marked to show compliance with the Medical Devices Directive 93/42/EEC. This CE mark will be accompanied by the number of the Notified Body involved in the conformity assessment. However, some blood pressure monitors are supplied as an aid to exercise or diet programmes and may not be classified as medical devices. These may be CE marked against another Directive, such as EMC 89/336/EEC and are not recommended for clinical use.

When new medical devices are introduced it is important that 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 Device Bulletin DB 9904(NI).

All blood pressure measuring equipment should be regularly maintained and calibrated in accordance with the manufacturer's instructions. However, it should be noted that those originally designed for home-use may be difficult to calibrate without returning to the supplier.

7. MERCURY ISSUES

Environmental concerns arise from the fact that once mercury is released into the environment it can accumulate and possibly contaminate the food chain. Direct exposure to mercury is also a health risk via inhalation of vapour and absorption through the skin.

The Health and Safety Executive (HSE) first issued the Regulations for the Control of Substances Hazardous to Health COSHH in 1990 (last updated in 2000). They have also produced several guidance documents in order to protect personnel and limit the amount of mercury reaching the environment (EH 17 & MS 12). Occupational Exposure Limits are now contained within EH40/99.

The COSHH Regulations provide a comprehensive and systematic approach to the control of hazardous substances at work and require employers to: (a) assess risks to health arising from exposure to hazardous substances; (b) prevent or adequately control exposure; (c) ensure control measures are used, maintained, examined and tested; (d) in some instances monitor exposure and carry out appropriate health surveillance; (e) inform, instruct and train employees.

For medical devices containing mercury the question needs to be asked, “are these products needed?” If the answer is yes, then control measures should be implemented and staff should 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.

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 of 0.025 mg/m³ (EH40/99). This resulted in a decision being made to replace mercury sphygmomanometers throughout the hospital.

8. BIBLIOGRAPHY

8.1 Health and Safety Executive documents (available from HMSO)

- a) EH 17 (Revised) Mercury and its inorganic divalent compounds 1996.
- b) MS12 (Revised) Mercury – medical guidance notes 1996.
- c) Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000 (General COSHH and Carcinogens and Biological agents Approved Codes Of Practice.)
- d) EH40/99 Occupational Exposure Limits, 1999.

8.2 Standards (available from BSI)

- a) EN 60601-1 Medical Electrical Equipment, General requirements for safety.
- b) EN 60601-1-2 Medical Electrical Equipment, Electromagnetic compatibility.
- c) EN 60601-2-30 Medical Electrical Equipment, Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment.
- d) EN 1060-1 Non-invasive sphygmomanometers, General requirements.
- e) EN 1060-2 Non-invasive sphygmomanometers, Supplementary requirements for mechanical sphygmomanometers.
- f) EN 1060-3 Non-invasive sphygmomanometers, Supplementary requirements for electro-mechanical blood pressure measuring systems.

8.2.1 Accuracy

- a) EN 1060-1 states that the limit of error of the cuff pressure indication shall be ± 3 mmHg.
- b) EN 1060-3 states the overall system accuracy values shall apply: maximum mean error of measurement ± 5 mmHg, maximum experimental standard deviation 8 mmHg.

8.2.2 Clinical trial protocols

EN 1060-3 Annex A recommends a clinical investigation to demonstrate compliance and refers to three protocols.

- a) The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. Journal of Hypertension 1993, 11 (Suppl 2): S43-S62, O'Brien E. et al.
- b) E DIN 58130 : 1995, Non-invasive sphygmomanometers - Clinical investigation.
- c) ANSI/AAMI SP10, American National Standard for electronic or automated sphygmomanometer 1992 (Currently under revision).

**8.3 MDA/Health
Estates
Publications**

SAB (93) 41. Mercury contamination of baby incubators: The need for vigilance.

Device Bulletin DB9904 (NI) July 1999 – Medical Device and Equipment Management for Hospital and Community-based Organisations.

Device Bulletin DB9904(NI) Supplement 1, – Checks and tests for newly-delivered medical devices.

Safety Action Notice June 1998, SAN (NI) 98/32 – Mercury Sphygmomanometer: Yamasu desk models UN600 and UN605P, mercury leakage and possible sluggish performance.

**8.4 DHSSPS
Publications**

Clinical Resource Efficiency Support Team (CREST), Equipment Evaluation - User survey of Non-Invasive Blood Pressure Monitoring, February 1995

DISTRIBUTION

This Device Bulletin should be brought to the attention of managers and staff in all hospitals, healthcare establishments, the community and others who are involved in Equipment Management.

This Device Bulletin should also be brought to the attention of liaison officers, risk managers, medical and nursing directors, medical equipment managers, clinical engineering staff, midwifery local supervising officers, general practitioners, practice nurses, purchasers and staff responsible for medical equipment use in the community.

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