MHRA

Medicines and Healthcare products Regulatory Agency

Medical Device **ALERT**

Ref. MDA/2005/069
Issued: 13 December 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	

	Further Information
DEVICE: Blood pressure monitors and sphygmomanometers.	
PROBLEM: The Committee on Blood Pressure Monitoring in Clinical Practice was established by the Chief Medical Officer to address concerns regarding the use of mercury sphygmomanometers and the accuracy of alternatives.	►
ACTION BY: All those who purchase, use and maintain blood pressure measuring equipment.	
ACTION: Users need to be aware of the conclusions and recommendations of this committee, which are of great importance to both primary and secondary healthcare. The full report is published on MHRA's website: www.mhra.gov.uk See annex for summary of recommendations.	►
DISTRIBUTED to: NHS Trusts (England) – Chief Executives***** Commission for Social Care Inspection (CSCI) – Headquarters Healthcare Commission (CHAI) – Headquarters Primary Care Trusts (England) – Chief Executives***** Social Services (England) – Directors***** ***** via CE Bulletin	►
CONTACTS: Details of contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	►
ANNEX: Summary of recommendations.	►

► Further information supplied in the following pages.

The full text of this notice is on our website: **http://www.mhra.gov.uk**

PROBLEM:

The Committee's remit was: 'To evaluate whether mercury sphygmomanometers should continue to be used or removed from the clinical environment: and to consider the alternative to mercury devices and the evidence regarding their accuracy'.

ACTION:

ACTION DEADLINES FOR THE SAFETY ALERT BROADCAST SYSTEM (SABS)

Trust managers should ensure that measures to implement the 'Actions' specified above are planned and completed in line with the following SABS deadlines.

Deadline (Action underway): 13 June 2006	**Deadline (Action complete): 13 December 2007**
Action plan to be agreed and actions started.	All actions to be completed.

Further information about SABS can be found at www.info.doh.gov.uk/sar/cmopatie.nsf

DISTRIBUTION:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

TRUSTS to:

- Liaison officers (for onward distribution)
- Accident & emergency departments
- Adult & paediatric intensive care units
- All wards (medical and nursing staff)
- Clinical governance leads
- EBME (medical electronics)
- Health & safety officers
- Medical directors
- Nursing executive directors
- Purchasing departments
- Risk managers
- Theatre managers

PRIMARY CARE TRUSTS to:

- Liaison officers (for onward distribution)
- Clinical governance leads
- Community hospitals
- Directors of public health
- District nurses
- General dental practitioners
- Health visitors
- Lead nurses
- Practice managers
- Practice nurses
- Prison healthcare managers

SOCIAL SERVICES to:

- Liaison officers (for onward distribution)
- Care at home staff
- Day centres

COMMISSION FOR SOCIAL CARE INSPECTION (CSCI) to:

- Headquarters (for onward distribution)
- Care homes providing nursing care
- Care homes providing personal care
- Domiciliary care providers

HEALTHCARE COMMISSION (CHAI) to:

- Headquarters (for onward distribution)
- Clinics
- Hospices
- Hospitals in the independent sector
- Mental health hospitals
- Private medical practitioners

CONTACTS:

Enquiries should quote reference number **20030131.018-16 or SZT/001/001/385** and be addressed to:

Technical aspects:
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Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

HOW TO REPORT ADVERSE INCIDENTS

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (http://www.mhra.gov.uk).

Alternatively, further information and printed incident report forms are available from:
MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk
(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: http://www.mhra.gov.uk

Summary of recommendations from page 2 of 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 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.