

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/91

Issued: 14<sup>th</sup> December 2005

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section										
<b>Medical Device/Equipment:</b> Blood pressure monitors and sphygmomanometers.	▶ ①										
<b>Problem:</b> 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.	▶ ②										
<b>Action by:</b> All those who purchase, use and maintain blood pressure measuring equipment.	▶ ③										
<b>Action:</b> 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: <a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a> See annex for summary of recommendations.	▶ ④										
<b>Distributed by NIAIC to:</b> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>GP Practices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>General Dental Practitioners</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td>Community Pharmacists</td> </tr> <tr> <td></td> <td>Hospices</td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	GP Practices	Chief Executive of each Agency	General Dental Practitioners	NIAIC Liaison Officers	Community Pharmacists		Hospices	▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners										
Chief Executive of each HSS Trust	GP Practices										
Chief Executive of each Agency	General Dental Practitioners										
NIAIC Liaison Officers	Community Pharmacists										
	Hospices										
<b>Contacts</b> Details of NIAIC contacts.	▶ ⑥										
<b>ANNEX:</b> Summary of recommendations.	▶ ⑦										

**This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>**

## 1. DEVICE/EQUIPMENT:

Blood pressure monitors and sphygmomanometers.

## 2. 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'.

## 3. ACTION BY:

All those who purchase, use and maintain blood pressure measuring equipment.

## 4. 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 NIAIC's website with this alert at: [www.dhsspsni.gov.uk/niaic/mdea.asp](http://www.dhsspsni.gov.uk/niaic/mdea.asp)

See annex for summary of recommendations.

## 5. ONWARD DISTRIBUTION TO:

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

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- EBME (Medical Electronics)
- Estates Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Practice Managers and Nurses
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- All Wards (Medical and Nursing Staff)
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Adult & Paediatric Intensive Care
- Resuscitation Officers
- Day Procedure Units
- District Nurses

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2005/91 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

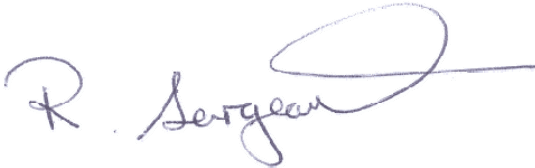
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None required.



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2005/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

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

## **ANNEXE to MDEA(NI)2005/91**

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.