

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/23

Issued: 14<sup>th</sup> March 2007

For:

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



**HEALTH ESTATES**

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	Section								
<p><b>Medical Device/Equipment:</b> Single-use capillary blood sampling device: Unistik 3 Normal, Unistik 3 Comfort and Unistik 3 Neonatal &amp; Laboratory devices. Manufactured by Owen Mumford. Product codes AT1002, AT1042 and AT1052.</p>	▶ ①								
<p><b>Problem:</b> Potential for needlestick injury to users and damage to a patient's sampling site due to a manufacturing fault. The manufacturer recalled five batches of these products that were distributed during the period 06 September to 07 November 2006.</p>	▶ ②								
<p><b>Action by:</b> All healthcare and care workers involved in the purchase, supply, distribution or use of these devices.</p>	▶ ③								
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Ensure that all relevant staff are aware of this recall.</li> <li>• Stop using product from the affected batches.</li> <li>• Identify, remove from the supply chain and quarantine all stock from the affected batches.</li> <li>• Contact Owen Mumford to arrange the return and replacement of devices from the affected batches.</li> </ul>	▶ ④								
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practices	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
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<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p><b>Feedback Requirements to NIAIC</b> None required.</p>	▶ ⑦								

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

## 1. DEVICE/EQUIPMENT:

These products are disposable single-use lancing systems used for taking samples of capillary blood. Details of the product, product codes and batch numbers of recalled devices are given below.

Product	Manufacturer product code	Batch numbers
Unistik 3 Normal Box of 100	AT1002	A4494 A4495
Unistik 3 Comfort Box of 100	AT1042	A4432 A4568
Unistik 3 Neonatal & Laboratory Box of 100	AT1052	A4457

## 2. PROBLEM:

Owen Mumford has identified a manufacturing fault affecting the batches listed above. These batches were distributed between 06 September and 07 November 2006. The fault can result in failure of the needle to retract fully after firing, leading to the risk of a needlestick injury to users or damage to a patient's sampling site.

The manufacturer issued a recall letter to users on 13 November 2006. Due to the nature of the risk to patient and user the MHRA has issued this Medical Device Alert to support the manufacturer's recall action. It will also help to ensure that, in the unlikely event that any product from the relevant batches is still in circulation, it is returned either directly to the manufacturer or your normal supplier.

## 3. ACTION BY:

All healthcare and care workers involved in the purchase, supply, distribution or use of these devices.

## 4. ACTION:

- Ensure that all relevant staff are aware of this recall.
- Stop using product from the affected batches.
- Identify, remove from the supply chain and quarantine all stock from the affected batches.
- Contact Owen Mumford to arrange the return and replacement of devices from the affected batches.

## 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:

- A&E departments
- Adult intensive care units
- All wards
- Ambulance services directors
- Anti-coagulation clinics
- Clinical governance leads
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Endocrinology, directors of
- Intensive care units
- Intensive care, directors of
- Maternity units
- Medical directors
- Microbiologists
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Nursing executive directors
- Obstetricians
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- Directors of public health
- District nurses
- Equipment libraries and stores
- Health visitors
- Infection control nurses
- Minor injury units

- Equipment stores
- General surgical units, directors of
- Health and safety managers
- Hospital pharmacies
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Infection control nurses
- Infection prevention and control directors
- Obstetrics and gynaecology departments
- Obstetrics departments
- Occupational health departments
- Outpatient clinics
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatrics departments
- Paramedics
- Pharmacists
- Phlebotomists
- Point of care testing co-ordinators
- Occupational health departments
- Practice managers
- Practice nurses
- Residential special schools
- School nurses
- Walk-in centres
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers

## 6. CONTACTS:

Enquires to manufacturer should be addressed to:

Michelle Grant  
 Customer Technical Support Coordinator  
 Owen Mumford Ltd  
 Brook Hill  
 Woodstock  
 Oxfordshire OX20 1TU  
 Tel: 01993 812 021  
 Fax: 01993 813 466

E-mail: [michell.grant@owenmumford.co.uk](mailto:michell.grant@owenmumford.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2007/23 and be addressed to:

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

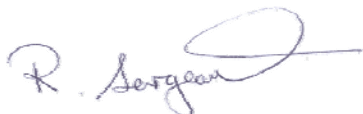
Tel: 028 9052 3868

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)2006/01. 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*