

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/009

Issued: 28<sup>th</sup> February 2008

For:

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



**HEALTH ESTATES**

creating healing environments

	Section								
<p><b>Medical Device/Equipment:</b> Blood coagulation test. SmartCheck INR system manufactured by Unipath Ltd.</p>	▶ ①								
<p><b>Problem:</b> Risk of inaccurate results leading to incorrect dosing of anticoagulant therapy. (see Appendix)</p>	▶ ②								
<p><b>Action by:</b> General practitioners; Practice managers; Directors of pathology; Head of haematology department; Point of care test (POCT) coordinators.</p>	▶ ③								
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Stop using the SmartCheck INR system.</li> <li>• Quarantine and return affected meters to Unipath Ltd.</li> <li>• Destroy consumables, test strips, control pack and carry cases for all affected devices.</li> <li>• Review patient results in parallel with the patient's target therapeutic INR range and the associated anticoagulant dose.</li> <li>• Recall patients whose last dose adjustments were made using the SmartCheck INR system and retest using another method.</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 Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <p><b>For onward distribution see Section 5</b></p>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
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<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p>									
<p><b>Acknowledge Receipt of Alert:</b> 6<sup>th</sup> March 2008</p>	<p><b>Action Under Way:</b> 6<sup>th</sup> March 2008</p>	<p><b>Action Complete:</b> 28<sup>th</sup> March 2008</p>	▶ ⑦						

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

## 1. DEVICE/EQUIPMENT:

The SmartCheck INR system measures the prothrombin time (PT) and expresses this as an international normalised ratio (INR).

These meters are used at the point of care by GPs and other healthcare professionals to monitor patients taking blood thinning medication (anticoagulation therapy such as warfarin).

The test measures how long the blood takes to clot and is important in patients with a high risk of forming blood clots including those with artificial heart valves, irregular heart rhythms or a history of recurrent blood clots.

- SmartCheck INR POC meter pack product code 506602.
- SmartCheck INR POC test strip pack x50 product code 506604.
- SmartCheck INR POC controls pack product code 506606.
- SmartCheck INR POC carry case pack product code 506607.

## 2. PROBLEM:

Although there have been no reported adverse incidents associated with this device, the company has decided to recall SmartCheck INR meters on the basis of a clinical study in which the performance of the device did not meet its labelled claims and there may be a risk of incorrect results. Incorrect results could lead to a prescription for anticoagulant therapy that is too high (with a risk of bleeding) or too low (with a risk of blood clots).

## 3. ACTION BY:

- General practitioners
- Practice managers
- Directors of pathology
- Head of haematology department
- Point of care test (POCT) coordinators.

## 4. ACTION:

- Stop using the SmartCheck INR system.
- Quarantine and return affected meters to Unipath Ltd.
- Destroy consumables, test strips, control pack and carry cases for all affected devices.
- Review patient results in parallel with the patient's target therapeutic INR range and the associated anticoagulant dose.
- Recall patients whose last dose adjustments were made using the SmartCheck INR system and retest using another method.

## 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:

- Anti-coagulation clinics
- Biomedical science departments
- Cardiology, directors of
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Haematologists
- Health and safety managers
- Medical directors
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Supplies managers
- Independent Health and Social Care Providers – Private Hospitals, Clinics, Residential and Nursing Homes through RQIA
- Community nurses
- General practitioners
- Out of Hour walk-in centres
- Practice managers
- Practice nurses

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mrs Candice Pell  
Unipath Limited  
Priory Business Park  
Bedford  
MK44 3UP  
United Kingdom

Tel: 01234 835 811

Fax: 01234 835 003

E-mail: [product.support@invmed.com](mailto:product.support@invmed.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/009 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)

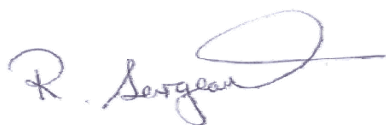
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

**Acknowledge Receipt of Alert:**  
6<sup>th</sup> March 2008

**Action Under Way:**  
6<sup>th</sup> March 2008

**Action Complete:**  
28<sup>th</sup> March 2008



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)2007/01. 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*

# Appendix to MDEA(NI)2008/009

R2008-01

UK

## Urgent Field Safety Notice

UNIPATH

Priory Business Park, Bedford MK44 3UP, UK  
t: +44 (0)1234 835000 f: +44 (0)1234 835001

**Product:** SmartCheck INR system  
**FSCA ID:** R2008-01  
**Action:** Field Safety Corrective Action (FSCA)  
Return of SmartCheck INR Meter to Manufacturer  
Destruction of SmartCheck INR Consumables

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**Date:** 18<sup>th</sup> February 2008

**Attention:** Healthcare Professionals

### Details on Affected Device:

SmartCheck INR POC Meter Pack Product Code 506602  
SmartCheck INR POC Test Strip Pack x50 Product Code 506604  
SmartCheck INR POC Controls Pack Product Code 506606  
SmartCheck INR POC Carry Case Pack Product Code 506607

POC = Point of Care

### Description of the problem:

Unipath Limited are implementing a Field Safety Corrective Action for the SmartCheck INR system. The FSCA is to request the return of the SmartCheck INR Meters product code 506602. The FSCA requires the return of all meters for the product codes listed above and also destruction of the consumable product codes listed above (test strips, control packs and carry cases).

Following completion of a clinical study, a report was issued to Unipath Limited which states that the lots used in the study did not produce equivalent performance to the claims documented in the product labelling. Unipath Limited are concerned with the potential non-conformance of production material to the documented product label claims and feel that FSCA is the most appropriate route to reduce the risk of an adverse event occurring with the product.

Based on the findings in the clinical study, it is thought that patients may be at risk of being prescribed a lower than required oral anticoagulant therapy (OAT) dose by their Healthcare Professional.

The product is used in a Point of Care setting only.

### **Risk to Patients Monitored Using SmartCheck Devices**

The potential risks associated with incorrect results obtained with the SmartCheck INR System would be either under or over medicating with Oral Anticoagulant Therapy (OAT). The risk of under medication may increase the risk of recurrent thrombosis or embolism and therefore could lead to serious deterioration in health or potentially death. Administering a higher than required oral anticoagulant therapy (OAT) dose may increase the risk of spontaneous bleeding. Again, this could lead to serious deterioration in health or potentially death.

## Appendix to MDEA(NI)2008/009

R2008-01

UK

UNIPATH

Priory Business Park, Bedford MK44 3UP, UK  
t:+44 (0)1234 835000 f:+44 (0)1234 835001

**Advice on action to be taken by the user:**

Please cease using the SmartCheck INR System with immediate effect and return the Meter to Unipath Limited, Priory Business Park, Bedford, MK44 3UP, United Kingdom. Double bag each Meter using the two resealable bags provided then place inside the pre-paid labelled padded envelope. It would be greatly appreciated if this could be completed as soon as possible but no later than 25<sup>th</sup> February 2008.

All consumables, that is, test strips, control packs and carry cases (product codes listed above) should be destroyed. If destruction is not a feasible option for your facility then please return the consumables to Unipath Limited, Priory Business Park, Bedford, MK44 3UP, United Kingdom. It would be greatly appreciated if this could be completed as soon as possible but no later than 25<sup>th</sup> February 2008.

Please confirm the quantities of both Meters and consumables that you currently hold by completion of the Faxback Form. Also confirm return of meters and destruction of consumables via the Faxback Form. Fax the Faxback Form for the attention of Mr Mark Gittins, VP IMI Corporate Regulatory Affairs to Unipath Limited at +44 (0)1234 835003.

**Recommended Patient Follow-Up**

It is recommended that Healthcare Professionals complete testing by another method if they have not already done so. Review the patient's therapeutic range and the associated OAT dose.

**Transmission of this Field Safety Notice: if appropriate**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please inform Unipath Limited of any affected devices that have been transferred to other organisations immediately. In addition, transfer this field safety notice to other organisations on which this action has an impact if appropriate.

## Appendix to MDEA(NI)2008/009

R2008-01

UK

UNIPATH

Priory Business Park, Bedford MK44 3UP, UK  
t: +44 (0)1234 835000 f: +44 (0)1234 835001

**Contact Reference Person:**

Mrs Candice Pell  
Unipath Limited  
Priory Business Park  
Bedford, MK44 3UP  
United Kingdom

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E-mail: [product.support@invmed.com](mailto:product.support@invmed.com)

Tel No: +44 (0)1234 835811

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.



Mark Gittins  
VP IMI Corporate Regulatory Affairs

# Appendix to MDEA(NI)2008/009

R2008-01

UK

Recall ref \_\_\_\_\_  
(Unipath use only)

FAX Back Form

**UNIPATH**

**Please complete this form and fax back to:-**

Priory Business Park, Bedford MK44 3UP, UK  
t: +44 (0)1234 835000 f: +44 (0)1234 835001

**Company:** Unipath Limited

**Contact Name:** Mr Mark Gittins (VP IMI Corporate Regulatory Affairs)

**Fax No:** +44 (0)1234 835003

**Postal Address:** Unipath Limited  
Priory Business Park  
Bedford  
MK44 3UP  
United Kingdom

**Subject:** Field Safety Corrective Action for SmartCheck INR System  
Product Codes: 506602, 506604, 506606, 506607

Please complete the information below and return to the fax number above.

**Contact Name:** \_\_\_\_\_ **Tel No:** \_\_\_\_\_

**Company:** \_\_\_\_\_

We do / do not\* have any stock which is subject to this Field Safety Corrective Action (\*Delete as appropriate).

Product	Quantity	Please replace (✓)	Do not replace (✓)
SmartCheck Meter			

Component	Product code	No of Meters for Return	Returned to Unipath Limited
Meters	506602		YES / NO*

\* Delete as appropriate

Component	Product Code	Lot Numbers	Action
Test Strips	506604		Destroyed / No Stock / Other*
Control Packs	506606		Destroyed / No Stock / Other*
Carry Case	506607	N/A	Destroyed / No Stock / Other*

\* Other \_\_\_\_\_

By signing this document I certify that this material has been disposed of in full and request credit to the value of the purchase price.

**Signed:** \_\_\_\_\_ **Date:** \_\_\_\_\_