

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/085

Issued: 16<sup>th</sup> Oct 2007



**HEALTH ESTATES**

creating healing environments

For:

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

	Section		
<b>Medical Device/Equipment:</b> Home use blood glucose meters: Boots brand blood glucose monitoring system.	▶ ①		
<b>Problem:</b> Dropping or knocking the meter can cause display failure.	▶ ②		
<b>Action by:</b> <ul style="list-style-type: none"> <li>Pharmacists who supply these devices or the Optium Plus test strips that are used with these meters.</li> <li>Healthcare professionals who manage patients who use these devices.</li> <li>Healthcare professionals who use these devices.</li> </ul>	▶ ③		
<b>Action:</b> <ul style="list-style-type: none"> <li>Advise meter users:                             <ul style="list-style-type: none"> <li>to check the display before each reading;</li> <li>if the meter fails to display a reading return it to the supplier or contact the Boots helpline (0800 072 1230).</li> </ul> </li> <li>Cease supply of affected meters to users.</li> </ul>	▶ ④		
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">                             Chief Executive of each HSS Board                              Chief Executive of each HSS Trust                              Chief Executive of each Agency                              NIAIC Liaison Officers                         </td> <td style="width: 50%; border: none;">                             General Medical Practitioners                              Community Pharmacists                              Hospices                         </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practitioners Community Pharmacists Hospices	▶ ⑤
Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practitioners Community Pharmacists Hospices		
<b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.	▶ ⑥		
<b>Feedback Requirements to NIAIC</b> None.	▶ ⑦		

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

## 1. DEVICE/EQUIPMENT:

Boots brand blood glucose monitoring system.

Boots brand blood glucose meters use Optium Plus test strips manufactured by Abbott Diabetes Care. The performance of the test strips is not affected by this issue.

List of affected batches of monitors:

01K102C	03K108C	06K166C	07K169C	10K101C	13K102C
01K106C	04K100C	07K101C	08K107C	10K166C	13K114C
01K108C	04K102C	07K102C	09K106C	11K101C	17K127C
02K106C	04K103C	07K107C	09K107C	12K103C	18K165C
02K169C	05K108C	07K113C	09K128C	12K170C	18K180C

## 2. PROBLEM:

The manufacturer has informed the MHRA that affected meters have failed the standard 'drop test' for blood glucose meters and therefore the liquid crystal display (LCD) on some Boots brand blood glucose meters may fail if the meter is dropped or knocked. This may result in the meter either:

- failing to display the full date/time and lot number details; or
- failing to display a reading.

## 3. ACTION BY:

See below.

## 4. ACTION:

### Pharmacists supplying these devices or Optium Plus test strips

- Do not supply affected meters.
- Identify and quarantine these meters from your current stock and contact the Boots helpline (0800 072 1230).
- When you dispense test strips for use with Boots brand meters, advise the meter user:
  - before each reading to check that the display is complete in accordance with the manufacturer's instructions for use
  - that storing the meter in its wallet can help to protect it from damage if it is dropped or knocked
  - that if the meter fails to display a reading they should return it to the supplier or contact the Boots helpline (0800 072 1230).

### Healthcare professionals managing patients who use these devices

- Do not supply affected meters.
- Identify and quarantine Boots brand meters from your current stock and return to Boots.
- Identify patients who use these meters and advise the meter user:
  - before each reading to check that the display is complete, in accordance with the manufacturer's instructions for use
  - that storing the meter in its wallet can help to protect it from damage if it is dropped or knocked
  - that if the meter fails to display a reading they should return it to the supplier or contact the Boots helpline (0800 072 1230).

### Healthcare professionals who use these devices

- Before each reading check that the display is complete, in accordance with the manufacturer's instructions for use.
- If the meter fails to display a reading return it to the supplier or contact the Boots helpline (0800 072 1230).
- Consider storing the meter in its wallet to help protect it from damage if it is dropped or knocked.

## 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
- Biochemists
- Chief pharmacists
- Clinical governance leads
- Clinical pathology directors
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Hospital pharmacists
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Supplies managers
- In-house residential care homes
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Community children's nurses
- Community diabetes specialist nurses
- Community nurse managers
- District nurses
- Practice managers
- Practice nurses
- Primary care nurses
- School nurses
- Paramedics
- Point of care testing co-ordinators
- Risk managers

## 6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Kevin Linthwaite or Samantha Rising  
Boots NPI Healthcare  
D90 West First 17  
Thane Road  
Nottingham NG90 1BS

Boots helpline 0800 072 1230

E-mail: [kevin.linthwaite@boots.co.uk](mailto:kevin.linthwaite@boots.co.uk)  
[samantha.rising@boots.co.uk](mailto:samantha.rising@boots.co.uk)

Enquiries to NIAIC should quote reference number MDEA(NI)2007/085 and be addressed to:

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

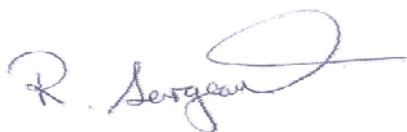
Tel: 028 9052 3868

Fax: 028 9052 3900

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

## 7. FEEDBACK:

None.



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*