

# Medical Device Alert

Ref: MDA/2013/064 Issued: 14 August 2013 at 14:30

## Device

Home use blood glucose test strips.

GlucoMen LX Sensor blood glucose test strips 50 count (product code 38877), used with the GlucoMen LX and GlucoMen LX PLUS meter manufactured by Menarini. Lot 3212214249, expiry date 31-08-2014 and lot 3212219249, expiry date 31-08-2014.

Problem	Action
<p>Affected lots have been contaminated during manufacture, and may give an overestimation of blood glucose levels, potentially resulting in inappropriate insulin administration.</p> <p>The manufacturer distributed the affected lots in the UK via wholesale outlets during October and November 2012. The product may, however, still remain with users or pharmacies.</p> <p>There is currently no evidence that UK patients have been affected.</p>	<ul style="list-style-type: none"> <li>• Identify and quarantine affected lots.</li> <li>• Identify patients using these meters and advise them that they should return and not use strips from the affected lots.</li> <li>• Ensure that users who return strips from the affected lots can continue to monitor their blood glucose.</li> <li>• Contact Menarini to arrange the return of any strips from the affected lots.</li> </ul>
Action by	
Healthcare personnel managing patients who use these devices.	
CAS deadlines	Contact
<p>Action underway: 21 August 2013</p> <p>Action complete: 29 August 2013</p> <p><b>Note:</b> These deadlines are for the removal of unused affected devices.</p>	<p><b>Manufacturer</b> Tony Jones A.Menarini Diagnostics Tel: 0118 944 4100 Email: <a href="mailto:tony.jones@menarinidiag.co.uk">tony.jones@menarinidiag.co.uk</a></p>

## Device

Illustration of tub, containing 50 test strips



## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- Directors of public health
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Public Health England (for information)
- Social services in England (directors)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.

Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Ambulance services directors
- Ambulance staff
- Chief pharmacists
- Clinical biochemistry leads
- Clinical governance leads
- Community children's nurses
- Community diabetes specialist nurses
- Community nurses
- Community Pharmacies
- Consultant Clinical Biochemists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Minor injury units
- NHS walk-in centres
- Paediatrics departments
- Paramedics

- Pathology Directors
- Pharmaceutical advisors
- Pharmacists
- Point Of Care Testing Managers
- Purchasing managers
- Risk managers
- School nurses
- Supplies managers
- Walk-in centres

## **Public Health England**

Directors for onward distribution to:

- Risk manager
- Safety officers

## **NHS England area teams**

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- Practice managers
- Practice nurses

## **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Directors of public health
- In-house residential care homes

## **Independent distribution**

### **Establishments registered with the Care Quality Commission (CQC) (England only)**

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

### **Establishments registered with OFSTED**

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Tony Jones  
A.Menarini Diagnostics  
Wharfedale Road  
Winnersh  
Wokingham  
Berkshire  
RG41 5RA

Tel: 0118 944 4100

Email: [tony.jones@menarinidiag.co.uk](mailto:tony.jones@menarinidiag.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/064** or **2013/007/019/081/020**

### Technical aspects

Bina Mackenzie or Anthony Llewellyn  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7229 / 6792

Fax: 020 8754 3965

Email: [bina.mackenzie@mhra.gsi.gov.uk](mailto:bina.mackenzie@mhra.gsi.gov.uk)  
[anthony.llewellyn@mhra.gsi.gov.uk](mailto:anthony.llewellyn@mhra.gsi.gov.uk)

### Clinical aspects

For clinical aspects please contact the clinical team.

Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7032 / 7248

Fax: 020 8754 3965

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

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

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)