Medical Device Alert

Action

Ref: MDA/2009/052 Issued: 05 August 2009 at 10:00

Device

IVD INSTRUMENTATION: DS2 automated microplate processing system.

Manufactured by Dynex Technologies.

DS2 units with serial numbers less than 1DSA-0309 e.g 1DSA-0308, 1DSA-0307 etc.

Problem

Delay in reporting of laboratory results, which may lead to a delay in treatment or diagnosis.

Action by

All affected DS2 users

CAS deadlines

Action underway: 02 September 2009

Action complete: 01 October 2009

Action

1. Contact your local distributor to arrange for a retrofit upgrade. Where communication problems are suspected, the upgrade should take place as soon as possible. Where no communication problems are evident the upgrade can take place at the next service visit.
2. Ensure an alternative method of screening is available until the upgrade is complete.

Contact

Manufacturer
Mr Dale Morgan
Dynex Technologies UK.

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Link to full Medical Device Alert

Device

All DS2 units with serial numbers less than 1DSA-0309 must be upgraded by fitting a USB Grounding Mask. This has already been installed on the following units:
1DSA0309-1DSA0311 (inclusive)
1DSA0314-1DSA0316 (inclusive)
1DSA0319 and all higher units.

The device has been sold by the following distributors in UK - Inverness Medical UK; Launch Diagnostics UK; Instrumentation Laboratory UK Ltd and previously by Binding Site UK.

Problem

Following a confirmed customer complaint of sporadic communication errors, the DS2 may experience a floating ground at the USB port .This may introduce spurious electronic noise to USB communications that may result in the loss of communication, requiring a reboot of the system. The communication failure may stop a test run before completion, leading to delayed test results.

Dynex Technologies has informed the MHRA that all instruments with affected serial numbers will require a retrofit upgrade. This upgrade should occur immediately for units exhibiting communication problems or by the next service visit for other units. The retrofit involves the implementation of a small metal frame fitted to the USB port, which will eliminate the possibility of improper grounding.

Distribution

This MDA has been distributed to:
- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- Health Protection Agency (HPA) (Directors)
- NHS Boards in Scotland (Chief Executives)
- OFSTED (Directors of Children's Services)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

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

Trusts to:

CAS liaison officers for onward distribution to all relevant staff including:
- Biochemists
- Biomedical scientists
- Clinical governance leads
- Clinical pathologists
- Haematologists
- Medical directors
- Purchasing managers
- Risk managers
- Supplies managers
- Virologists

Care Quality Commission (CQC) to:

The MHRA considers this information to be important to:
- Clinics
- Hospitals in the independent sector

Health Protection Agency to:

Directors for onward distribution to:
- Laboratory managers
- Regional microbiologists
- Risk manager
- Safety officers

Change of address or removal from address list for Care Quality Commission:
National Contact Centre
Care Quality Commission
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 03000 61 61 61

E-mail: enquiries@cqc.org.uk

Contacts

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Distributors
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Kelvin Close
Birchwood Science Park
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WA3 7PB

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Stockport
SK7 5BW

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/052** or **MHRA 2008/011/004/061/001.**

Technical aspects
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Clinical aspects
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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

Enquiries in Northern Ireland should be addressed to:

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

Tel: 02890 523 704
Fax: 02890 523 900

E-mail: 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 https://sabs.dhsspsni.gov.uk

Scotland

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

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

E-mail: iric@shs.csa.scot.nhs.uk

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

Wales

Enquiries in Wales should be addressed to:

Dr Jane Ludlow
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff
CF10 3NQ

Tel: 029 2082 3505 / 3922

E-mail: Haz-Aic@wales.gsi.gov.uk