Medical Device Alert

Ref: MDA/2013/062 Issued: 08 August 2013 at 12:00

Device

Infusion pumps: Alaris® GP, GP Guardrails®, GP Plus and GP Plus Guardrails

Manufactured by CareFusion.

Specific serial numbers are affected.

Problem

Risk of interruption to therapy.

A fault with the front and rear bearings of the pump's stepper motor may cause the pump to stall during an infusion. The pump stops, alarms and displays a 'DRV1' or 'DRV2' error on the screen.

Replacement of the motors will begin in September 2013.

CareFusion issued a Field Safety Notice (FSN) in May 2013.

Action by

Risk managers, clinical and biomedical personnel who use, maintain, and are responsible for these pumps.

Action

- Identify affected pumps.
- Consider using an alternative pump, particularly if an interruption to an infusion could compromise patient safety.
- If an alternative pump is not available, follow the advice in the manufacturer's instructions for use. In particular if a 'DRV1 or DRV2' error is displayed, immediately remove the pump from use and contact CareFusion.
- Return completed verification form in the FSN to CareFusion.
- When available, ensure the stepper motors are replaced.

CAS deadlines

Action underway: 22 August 2013

Action complete: 06 September 2013

Note: These deadlines are for systems to be in place to identify pumps and to arrange for motor replacements.

Contact

CareFusion UK Ltd
Customer Care

Tel: 0800 917 8776

Email: G-Bas-Customer-Service@carefusion.com

Device

General purpose volumetric infusion pumps intended for acute and sub-acute applications.

Product codes: 80263UN01, 80263UN01-G, 9002MED01, 9002MED01-G.

The serial numbers of affected pumps are specific to each customer.
Contact your local biomedical engineering department to obtain this list or contact CareFusion directly to determine which pumps are affected.
The serial number is printed on the back of each pump.

The MHRA does **not** possess a list of affected serial numbers.

Problem

The motor stall condition may occur during start-up (immediately after the start key is pressed) or during an infusion, which may result in the early termination of an infusion. Early termination of an infusion could require intervention especially if critical drugs are being administered.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- 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 (for information)
- NHS trusts in England (chief executives)

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:

- A&E departments
- Adult intensive care units
- All wards
- All clinical areas
- Anaesthesia, directors of
- Biomedical engineering staff
- Clinical governance leads
- Community hospitals

- EBME departments
- Equipment libraries
- Health and safety managers
- In-house maintenance staff
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Outpatient departments
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Supplies managers
- Theatres

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

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 and requesting this facility.

Contacts

Sue Briggs
Customer Care
CareFusion UK Ltd
Basingstoke
RG22 4BS
Tel: 0800 917 8776
Email: G-Bas-Customer-Service@carefusion.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/062** or **2013/006/007/291/002.**

Technical aspects
Enitan Taiwo and Roopa Prabhakar
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
Tel: 020 3080 7122 / 7293 Fax: 020 8754 3965
Email: enitan.taiwo@mhra.gsi.gov.uk
roopa.prabhakar@mhra.gsi.gov.uk

Clinical aspects
Jonathan Plumb
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
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Email: jonathan.plumb@mhra.gsi.gov.uk

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

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.iric@nhs.net

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

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