Medical Device Alert

Ref: MDA/2013/017 Issued: 26 March 2013 at 14:30

Device

Infusion pump: Alaris® GP volumetric pump

Product refs: 80063UN01, 80263UN01, 80263UN01-G, 9002MED01, 9002MED01-G

Manufactured by CareFusion.

All serial numbers are affected.

Problem

Risk of embolism.

The pump produces small air bubbles (less than 50µl) which are too small to trigger either the 50-500µl air-in-line alarm set by the user, or the 1ml over a rolling 15 minutes alarm.

Action by

All medical, nursing and technical staff involved in the use of these devices.

Action

Identify affected devices.

Ensure members of staff are aware of the advice detailed in the manufacturer's Field Safety Notice. In particular, CareFusion recommends the use of an air venting filter on the infusion set for the following patient groups:

- patients with atrial septal defects*
- neonates
- where multiple infusions are being administered simultaneously.

Where a filter cannot be used, consider using an anti-siphon valve on the infusion set.

Be aware of additional advice issued by CareFusion – see appendix.

* up to 20% of the population may have a patent foramen ovale, which may be undetected.

CAS deadlines

Action underway: 04 April 2013

Action complete: 16 April 2013

Note: These deadlines are for systems to be in place to identify devices and to be aware of the advice contained in the FSN.

Contact

Manufacturer

Sue Briggs

CareFusion UK

Tel: 0800 917 8776 Customer Care

Email: UK-sutomer-service@carefusion.com

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care 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 clinical departments
- All wards
- Anaesthetists
- Biomedical engineering staff
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment stores
- Health and safety managers
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Paediatricians
- Paediatric nurse specialists
- Risk managers
- Special care baby units
- Supplies managers
- Theatres

Primary care trusts

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

- Community hospitals
- Equipment libraries and stores
- Hospital at home
- Palliative care teams

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
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

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

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/017** or **2012/011/013/291/010**

Technical 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

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
Health Facilities Scotland
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/

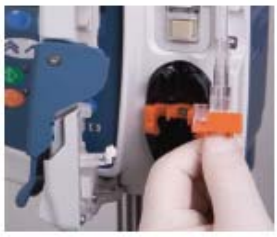
Wales

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

Appendix



Introduction

This document has been developed as an aid to support good clinical practices in reducing potential problems with air in line alarms.*

Volumetric infusion pumps typically have 2 types of air in line alarm:

- Single bubble alarm
- Bubble accumulator alarm

Depending on the specifications and configuration of the infusion pump one or both of the alarm types may be available.

Air in the line is measured in microlitres, and the alarm limits are therefore set in microlitres (100 microlitres = 0.1ml).

Managing Air-in-line Alarms

Clinical Practices

Single bubble alarm

The single bubble alarm can be configured to alarm at detected bubble sizes from 50 to 500 microlitres.

The air-in-line alarms will be triggered when a single bubble of a specific size e.g. 100 microlitres passes the air detector. The pump will stop infusing, and the user will need to investigate and then make a decision to either allow the air bubble to infuse into the patient or clear the air from the infusion set before restarting the infusion.

Bubble accumulator alarm

This works on a cumulative effect. Detectable bubble volumes will be cumulated and size measured as they pass the air-in-line detector until they reach a specific volume of air e.g. 1ml in a 15 minute time window.

When this air volume is reached the pump will alarm and stop infusing. This may lead to some confusion as the user will most likely not see a large bubble that they think caused the pump to alarm and may treat it as a nuisance alarm.

CareFusion

Tips to help manage and reduce air-in-line issues*

Prime the line slowly.

Priming is the most common cause of air-in-line problems. The faster the line is primed the more air bubbles are generated in the line. However, if the line is primed slowly it will reduce fluid turbulence and the majority of the air will be removed from the set. Spending extra time priming the set slowly will save a significant amount of time attending to air-in-line alarms.

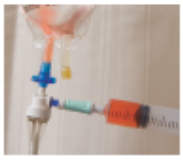
Load set into pump as per Directions for Use

Raising the height of the fluid container above the pump (it should be at least 30cm above the pump) and positioning the pump at the level of the patient may reduce the formation of bubbles in the solution by increasing the pressure of the fluid in the line.

Allowing medication that has been refrigerated to reach room temperature and tapping the bag prior to priming the line.

This will allow any gas bubbles that have been generated during the change in temperature to be removed from the fluid and not enter the IV infusion set.

Note: Not all infusions can be allowed to come to room temperature. Please refer to your Pharmacy department.

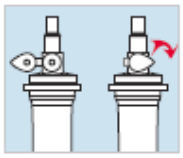


Vigorous shaking or mixing of intraveneous fluids may encourage the formation of air bubbles in some types of infusions.

Follow drug manufacturer's directions for use when mixing or compounding intravenous infusions. Gentle introduction of additional intravenous fluids will reduce turbulence and therefore the formation of foam and air bubbles.

Ensuring the drip chamber is always filled to the mark or least half-full if there is no mark.

When the fluid bag empties the fluid level in the chamber drops. This can result in air being drawn down with fluid. If the fluid level in the chamber is always returned to half full when a new bag is put up the risk of air in the line is reduced.



Confirming that the air inlet is shut.

If you are not infusing from a glass bottle or semi-rigid container the air inlet on the drip chamber needs to be closed.

Air may become trapped in the ports and in-line filters during priming of the infusion set and then become dislodged during an infusion.

For ADULT patients: invert and tap the port(s)/valve(s) while priming. For PAEDIATRIC patients: once the set is primed attach a syringe and aspirate air through the port(s)/valve(s). In-line filters should be primed in the vertical position (inlet port up). DO NOT INVERT THE FILTER TO PRIME UNLESS SPECIFIED. Refer to filter directions for use.

Attach an anti-siphon valve (ASV) to male luer on the pump set.

Fitting an ASV to an infusion set will increase the downstream pressure in the pump set. As a result the likelihood of the fluid degassing will be reduced.

Note: Remove the anti-siphon valve to use the infusion set for gravity infusions

*This tip sheet is not intended to be the comprehensive instructions for the set-up and operation of any of the Alaris® Volumetric Pumps. For complete pump information, refer to the Alaris® Volumetric Pump Directions for Use of the specific pump you are using. Prior to use all persons operating any Alaris® pump should consult the Directions for Use for that pump.

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