

Medical Device Alert

Ref: MDA/2013/003 Issued: 22 January 2013 at 14:00

Device

Ambulatory insulin infusion pumps.

Manufactured by Animas.

Animas IR1200, Animas IR1250 and Animas 2020.

All serial numbers.



Problem	Action
<p>The pumps will only operate until 31 December 2015 due to a software problem.</p> <p>From 01 January 2016 the pumps will not deliver insulin and will generate a call service alarm.</p> <p>The manufacturer has stated that this software issue will not affect pumps prior to 01 January 2016.</p> <p>Further information is available in the manufacturer's Field Safety Notice (FSN) dated 12 November 2012.</p>	<ul style="list-style-type: none"> Identify affected devices. Ensure that staff and patients who are affected are aware of this problem. Contact the manufacturer to arrange for replacement pumps. Please note that they will only be providing free-of-charge replacements for pumps that are within warranty. Ensure that all affected pumps are replaced before 31 December 2015.
<h3>Action by</h3> <ul style="list-style-type: none"> Diabetes departments Pharmacists Those involved in the procurement, supply and use of this device. 	
<h3>CAS deadlines</h3>	<h3>Contact</h3>
<p>Action underway: 19 February 2013</p> <p>Action complete: 22 July 2013</p> <p>Note: These deadlines are for systems to be in place to ensure the replacement of affected pumps by 31/12/15.</p>	<p>Manufacturer Animas Corporation Animas UK & Ireland Tel: 0800 055 6606 Email: AnimasUK@its.jnj.com</p>

Device

Animas no longer distributes the IR1200, IR1250 or the 2020 models in the UK. Affected pumps will be replaced with a different model of Animas insulin infusion pump. Animas will be providing training on the use of the replacement pumps.

The manufacturer considers pumps that are outside the warranty period to have exceeded their expected life, and so will only be providing free-of-charge replacements for pumps that are still within warranty on 31 December 2015.

Please note that all IR1200 and IR1250 pumps will be out of warranty by 31 December 2015.

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)
- 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:

- Clinical governance leads
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetologists
- EBME departments
- Endocrinology units
- Endocrinology, directors of
- Health and safety managers
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Medical libraries
- Nursing executive directors
- Outpatient clinics
- Paediatricians
- Pharmacists
- Risk managers
- Supplies managers

Primary care trusts

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

- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community pharmacists
- District nurses
- General practitioners
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- In-house residential care homes

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care
- Care homes providing personal care
- Clinics
- Hospitals in the independent sector
- 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

Manufacturer

Animas Corporation
Animas UK & Ireland
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4DP

Tel: 0800 055 6606

Email: AnimasUK@its.jnj.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/003** or **2012/010/019/081/023**

Technical aspects

Sharon Knight and Enitan Taiwo
Medicines & Healthcare products Regulatory Agency, Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7202/7122 Fax: 020 8754 3965

Email: sharon.knight@mhra.gsi.gov.uk
enitan.taiwo@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge
Medicines & Healthcare products Regulatory Agency, Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128 Fax: 020 8754 3965

Email: mark.grumbridge@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
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.irc@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

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