

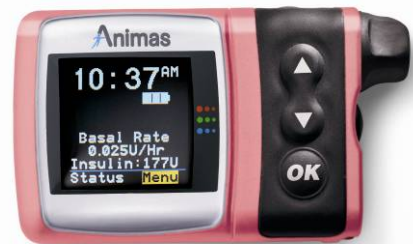
Medical Device Alert

Ref: MDA/2012/059 Issued: 22 August 2012 at 11:30

Device

Animas ambulatory insulin infusion pumps.

Animas[®] IR 1200
 Animas[®] 2020
 One Touch[®] Ping[®] Glucose management system
 Animas[®] Vibe[™]



Example of one of the models affected.

Problem

Risk of compromised insulin therapy due to failure of the buttons caused by keypad wear.

Action

Check the list of serial numbers affected in the [Animas UK document](#).

Ensure that patients using the pump are aware of:

- the potential for buttons to fail.
- the need to examine the keypad regularly for signs of wear, such as peeling or tearing of the keypad edge from the pump.
- the need to have a back-up insulin delivery method available at all times.

Action by

- Diabetes departments.
- Pharmacists.
- Those involved in procurement, supply and use of this device.

- Patients and healthcare providers should refer to the updated Animas patient information in the appendix.
- Patients who identify problems with, or have concerns about, their pump's keypad should contact their health care provider and Animas customer technical support.
- Report any problems with the pump to the MHRA.

CAS deadlines

Action underway: 12 September 2012
 Action complete: 03 October 2012

Note: These deadlines are for users and patients to be aware of the problem.

Contact

Manufacturer
 Animas Corporation
 Animas UK & Ireland
 Tel: 0800 055 6606
 Email: AnimasUK@its.jnj.com

Device

Devices distributed before February 2012 and which do not contain the revised keypad are affected.

Problem

The manufacturer has noted an increase in customer complaints regarding the durability of the insulin pump keypad. Deterioration has led to the coating tearing and the edge of the keypad peeling away from the pump. There are also reports of the keys becoming unresponsive or sticking. Animas has consequently redesigned the keypad to improve durability.

The manufacturer has found that the average time to failure is 18 months.

Animas distributed a [Patient notification letter](#) on the 16 July 2012 (see appendix). There is updated information on their website, <http://animascorp.co.uk/importantproductnews>.

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 (adults)
- Care homes providing personal care (adults)
- 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/2012/059** or **2012/007/013/081/020**

Technical aspects

Enitan Taiwo and Nicole Small
Medicines & Healthcare products Regulatory Agency
Floor 4
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Fax: 020 8754 3965

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nicole.small@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge
Medicines & Healthcare products Regulatory Agency
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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-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

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Addressees may take copies for distribution within their own organisations

Appendix

Important Information about your Animas® Insulin Pump

Animas relies on input from healthcare professionals and patients to continually improve our products. Based on such feedback, we recently improved the durability of the insulin pump keypad, which includes the OK button, Up Arrow / Down Arrow buttons, and the Contrast button.

Our previous keypads and all other components in our insulin pumps were designed and manufactured to withstand wear under normal use and conditions. However, some patients experienced gradual wear of their insulin pump keypad that led to damage, such as tearing or peeling of the keypad's edge from the pump.

We recently sent a letter to patients who have insulin pumps with the previous keypad component and instructed them to examine their keypad for this type of wear or damage. We informed them that the buttons may not respond as intended if the keypad is worn or damaged.

If they see any damage or have issues with their insulin pump keypad, patients are instructed to contact Animas through our website, at www.animascorp.co.uk/contact-us, Animas Customer Technical Support at (UK) 0800 055 6606 (Ireland) 1800 182 715 or the phone number provided on the back of the insulin pump. Animas carefully investigates all complaints related to the insulin pump. If pump users have a confirmed issue related to the keypad and they are covered by the Animas warranty, Animas will replace the pump at no charge. As explained in our insulin pump Owner's Booklet, Animas provides a warranty for a period of four years from the date of purchase in most cases.

Out-of-warranty patients should contact their Healthcare Professional to review options.

We encourage patients with questions or concerns to contact Animas Customer Support at (UK) 0800 055 6606 (Ireland) 1800 182 715. A trained healthcare professional is available 24 hours a day.

FREQUENTLY ASKED QUESTIONS:

Which Animas pump models are affected by this issue?

Animas pumps made prior to February 2012 may be affected, including:

- Animas® IR1200
- Animas® IR 1250 (1200 plus)
- Animas® 2020
- OneTouch® Ping® Glucose Management System
- Animas® Vibe™ (*only available in Europe*)

Note: The improved keypad design was incorporated in phases between September 2011 and February 2012; some pumps made during this time received the improved keypad design and are not affected so patients with unaffected keypads were not notified.

How will I know my pump is affected?

A pump affected by this issue is easily identifiable. You will notice your keypad is worn through or damaged, and exhibits issues like tearing or peeling of the keypad's edge from the pump.

How do I find out if my pump or my patient's pump has the new keypad?

You can contact Animas through our website, at www.animascorp.co.uk/contact-us, Animas Customer Technical Support at (UK) 0800 055 6606 (Ireland) 1800 182 715 or the phone number provided on the back of the insulin pump to obtain this information. A representative can assist you.

My pump is out-of-warranty. What should I do if my pump exhibits this type of wear or damage?

Out-of-warranty patients should contact their Healthcare Professional to review options.

Are patients who experience keypad issues at a health or safety risk?

Our previous keypads and all other components in our insulin pumps were designed and manufactured to withstand wear under normal use and conditions. However, some patients experienced gradual wear of their insulin pump keypad that led to damage, such as tearing or peeling of the keypad's edge from the pump.

We have determined through an intensive investigation that the previous keypad does not pose a serious safety or efficacy risk to patients. However, please be aware that the buttons may not respond as intended if the keypad is worn through or damaged. This could possibly result in unexpected high or low blood glucose.

What changes did Animas make to the keypad?

In reviewing patient feedback, we recently saw an opportunity to improve the durability of our insulin pump keypad, which includes the OK button, Up Arrow / Down Arrow buttons, and the Contrast button. In the spirit of continuous improvement, we therefore engaged a new keypad supplier who now provides Animas with the keypad components included in our current models.

Are all your insulin pumps now manufactured with the new keypad improvements?

Yes.

Will you be issuing a recall for Animas insulin pumps, given this issue?

This is a Field Notification, meaning that we are proactively notifying patients, healthcare professionals and our distributors about the keypad design enhancement. We are not removing and replacing Animas insulin pumps with the previous keypad component in the hands of patients but are making warranty replacements if there is confirmed wear or damage that led to issues like tearing or peeling edges.

Given this issue, is it safe to continue using my pump or should I get a new pump from Animas?

There is no need for you to return your pump unless gradual wear on the keypad has led to damage, like tearing or peeling of the keypad's edge from the pump. However, as explained in your Owner's Booklet, the warranty does not extend to any damage as a result of negligence, misuse or abuse of your pump by the user or any other third person. Inspecting your insulin pump for any signs of damage should always be considered a routine activity for any pump user.

The keypad on my pump is in great condition. Is there anything I can do to protect my pump or keypad from damage?

As with any equipment, care should be taken to protect the pump. Animas offers several products that can assist you in caring for your pump, including lens film protectors, skins, and other protective cases. Contact our Reorders department or visit our website to order these items.

Will my healthcare professional be notified?

Yes, Animas sent notifications to healthcare professionals who have a patient on an Animas pump that was manufactured with the previous keypad component. The letters were posted via Royal Mail on July 16.

What should patients do if they have questions?

Should you have any questions or concerns, please contact Animas through our website, at www.animascorp.co.uk/contact-us, Animas Customer Technical Support at (UK) 0800 055 6606 (Ireland) 1800 182 715 or the phone number provided on the back of your insulin pump.