

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.