

URGENT – FIELD SAFETY NOTICE

25th Sept 2012

Important Safety Information about Animas® Insulin Pumps

Dear Valued Animas Pump User:

We recently sent you a letter, notifying you of improvements we have made to our Animas insulin pump keypads, which includes the OK button, Up Arrow/ Down Arrow buttons, and the Contrast button. The purpose of this letter is to provide further information and clarification on this issue, and to ensure you are taking every step necessary to evaluate your keypad for gradual wear or damage.

What is the issue?

Our previous keypads 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 Animas pump and also keypad buttons sticking. Both issues can result in a loss of keypad button functionality.

What are the health and safety risks that may result?

If your keypad is worn or damaged, the buttons may not respond to your commands. This could prevent you from performing basic functions, such as bolus dose settings, bolus confirmation, accessing your pump's history record. If you are unable to use the pump properly, it could result in serious hypoglycemic or hyperglycemic events. In the event that you experience any difficulty with the pump, please call the Animas customer service line at UK 0800 055 6606 or Ireland 1800 812 715. Should you at any time have any concerns related to your health condition or treatment needs please seek medical attention.

What action should I take?

Please immediately examine your insulin pump keypad for wear or damage, and ensure your buttons are functioning as intended. If you are not confident examining the pump, please have your pump inspected by a Healthcare Professional or Service Provider at the earliest opportunity. You should continue to inspect your pump's keypad and buttons on a regular basis, and contact your healthcare professional and Animas Customer Support with any concerns or questions. You should always have a back up delivery system in place in the event of device failure.

What should I do if I notice a keypad problem?

It is important for you to call us immediately if you see keypad damage or notice your buttons are not responding as intended. Please contact Animas Customer Support UK 0800 055 6606 or Ireland 1800 812 715. A trained healthcare professional is available 24 hours a day.

If you have a confirmed issue related to your keypad and are covered by the Animas warranty, Animas will replace your pump at no charge. As explained in your insulin pump Owner's Booklet, Animas provides a warranty for a period of four years from the date of purchase in most cases.

Which Animas pump models are affected by this keypad issue?

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

- Animas® IR 1200
- Animas® IR 1250 (1200 plus)
- Animas® 2020
- OneTouch® Ping® Glucose Management System (*only available in Canada and U.S.*)
- Animas® Vibe™ (*only available in Europe*)

All pumps manufactured by Animas after Feb. 1, 2012, include an improved keypad design.

We appreciate your attention to this issue and are committed to ensuring your health and safety are never compromised.

Sincerely,

Animas Corporation