

URGENT FIELD SAFETY NOTICE

January 24th 2013

Important Information about your Animas[®] 2020 Insulin Pump

Dear Valued Animas Pump User:

Animas is dedicated to supporting our pump users with high quality products and service. As part of that commitment, we contact you whenever we have urgent information about our products.

We have identified two issues that affect your Animas[®] 2020 Insulin Pump:

- 1) Animas has identified a component issue affecting a small supply of our Animas[®] 2020 insulin pumps. We are therefore issuing a recall for these pumps.

We are reaching out to you today because our records indicate your Animas[®] 2020 insulin pump is included in this recall. Animas will send you a replacement pump, along with instructions for returning your current pump to us. In the meantime, we want to make sure you are aware of these issues.

About the Component Issue

The component issue may trigger your pump to sound a false alarm or warning related to one of the following:

- “Loss of prime”
- “Occlusion”
- “No Cartridge detected”

If you receive any of these alarms, the pump may then prompt you to complete the rewind, load and prime sequence to clear this alarm. **Failure to follow the pump’s safety instructions and disconnect your infusion set from your body during the “rewind, load and prime” steps can lead to unintended delivery of insulin, placing you in danger of potential serious health risks.**

There is **NO SAFETY RISK** associated with this component issue, as long as you follow the safety instructions in your Animas Owner’s Booklet and ALWAYS disconnect the infusion set from your body when:

- Rewinding the motor
- Loading the cartridge
- Priming the infusion set

Please note the unintended delivery of insulin does not occur during basal and bolus insulin delivery.

Scheduling your Pump Replacement

Due to the component issue, we will replace your Animas[®] 2020 insulin pump at no charge. **Please contact our support team who will discuss the replacement of your new pump with you. They can be contacted on (UK) 0800 032 0990 or (IRELAND) 1800 812 715 TBC during the hours of 9am to**

5pm, Monday - Friday. It may take up to three months before you can expect to receive your replacement pump, depending on where you reside.

Animas is discontinuing the Animas[®] 2020 insulin pump and therefore will be replacing it with our newest insulin pump, the Animas[®] Vibe™. Your existing Animas warranty policy will remain the same. The Animas[®] Vibe™ provides the additional option of Continuous Glucose Monitoring. However, Continuous Glucose Monitoring with the Animas Vibe™ insulin pump is only approved for people aged 18 years and older. We will provide detailed information and training on the insulin pump with your pump shipment.

In the meantime, you may continue using your current Animas[®] 2020 pump while you await the delivery of your new pump, as long as you follow your User's Guide instructions, pay attention to all pump warnings and **NEVER rewind the pump motor, load the insulin cartridge, or prime your infusion set while the pump is connected to your body.**

- 2) The second issue is a software limitation affecting the Animas[®] 2020 insulin pump that will impact its ability to function after December 31, 2015. After this date, the pump will no longer deliver insulin and will generate a Call Service Alarm. The end of use date is not currently included in our product labelling.

If you have any technical questions about either of these issues or if you want to report a concern, please contact our Customer Technical Support Centre at 0800 055 6606 (UK) or 1800 812 715 (IRELAND). We also have notified your healthcare professional regarding these issues.

We appreciate your time and attention to this important notification, and continued trust in Animas. We look forward to hearing from you.

Sincerely,

Animas UK & Ireland