



URGENT: INSULIN PUMP RECALL

January 3, 2013

Important Information about your Animas® 2020 Insulin Pump

Dear 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 impact your Animas® 2020 Insulin Pump:

- 1) Animas has identified a component issue impacting 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 Product Fulfillment Center at 877-280-2339 between the hours of 6 a.m. and 12 a.m. EST to schedule shipment of your replacement pump.**



Animas recently discontinued the Animas® 2020 insulin pump, and therefore we will be replacing it with a OneTouch® Ping® Glucose Management System, which includes an insulin pump and a glucose meter that can also act as a remote controller of the pump. The OneTouch® Ping® insulin pump has very similar features to the Animas® 2020 insulin pump you were originally trained on and are currently using. Therefore, additional training may not be required. To familiarize yourself with the meter-remote and overall system features, please watch the enclosed Orientation DVD and read the enclosed Owner's Booklet and "Upgrading to the OneTouch® Ping®" Reference Sheet before using your OneTouch® Ping® system.

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 labeling.

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 Center at **866-793-5253**. We also have notified your healthcare provider regarding these issues.

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

Sincerely,

Animas Corporation