May 27, 2015

URGENT FIELD SAFETY NOTICE

Important Information For Patients With Animas® 2020, IR 1250 Or IR 1200 Insulin Pumps

At Animas, we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of Animas products.

In December 2012, we notified patients of an end of service life date issue that will affect the Animas® 2020, IR 1250 and IR 1200 insulin pumps as follows:

- **Animas® 2020 insulin pump:** The pump will only operate until midnight on Dec. 31, 2015. After this date, the pump will no longer deliver insulin and will generate a "Call Service" Alarm. This end of service life date was not originally included in the product labelling.

- **IR 1250 & 1200 insulin pumps:** After midnight on Dec. 31, 2015, the pump's calendar will revert to a previous year. You will not be able to set the correct date as the pump's calendar will not recognize the year 2016 or beyond. Although the pump will continue to deliver insulin, if you are using a data management software program with your pump, you will notice inaccuracies in the reports because of the incorrect date. This end of service life date was not originally included in the product labelling.

Please be assured that this issue does not affect the operation of these pumps prior to January 1, 2016, and patients can continue to use these pumps with confidence until that date.

We are requesting that all patients with an Animas® 2020, IR 1250 or IR 1200 insulin pump contact Animas as soon as possible to arrange for the return of their pump to Animas and to discuss potential replacement options.

To contact Animas, please complete this online survey.

Upon receipt of this information, Animas will contact you to arrange the return your old Animas® 2020, IR 1250 or IR 1200 insulin pump and discuss potential replacement options. Please allow 8 – 10 weeks for a reply.

Please complete this **online survey** even if you no longer use or have your Animas® 2020, IR 1250 or IR 1200 Insulin Pump so that we can update our records.

Animas has notified the U.S. Food and Drug Administration (FDA) of this Medical Device Correction.

Should you have any questions or concerns, please contact us at 1-866-545-3831. Thank you for your cooperation and support.

Sincerely,
Animas Customer Service

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