

May 29, 2015

## URGENT FIELD SAFETY NOTICE

### Important Information about Animas<sup>®</sup> 2020 and IR 1200 Insulin Pumps

Dear Healthcare Professional:

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.

We need to inform you that we are notifying patients of an end of service life date issue that will affect the Animas<sup>®</sup> 2020 and IR 1200 insulin pumps as follows:

- **Animas<sup>®</sup> 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 1200 insulin pump:** 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.**

As our valued Partner, we ask for your assistance in informing patients with an Animas<sup>®</sup> 2020 or IR 1200 insulin pump to request their return to Animas and, if eligible, receive an **Animas<sup>®</sup> Vibe™** replacement pump at no cost. There are two types of patients who are requested to return their existing Animas<sup>®</sup> 2020 or IR 1200 insulin pump:

1. **Patients who already have an Animas<sup>®</sup> Vibe™ insulin pump but have not returned their Animas<sup>®</sup> 2020 or IR 1200 Insulin Pump** – These patients are **not eligible** to receive a free of charge Animas<sup>®</sup> Vibe™ insulin pump as a replacement. However, we ask that they return their old pump as soon possible to ensure it is removed from service prior to the end of service life date.
2. **Patients who currently are using an Animas<sup>®</sup> 2020 or IR 1200 insulin pump and have not received an Animas<sup>®</sup> Vibe™ insulin pump** – These patients **may be entitled to a free of charge Animas<sup>®</sup> Vibe™ insulin pump** as a replacement, regardless of whether the Animas<sup>®</sup> 2020 or IR 1200 insulin pump is still under warranty policy. As part of this program, we also request that they return their existing Animas<sup>®</sup> 2020 or IR 1200 insulin pump.

Please find attached the letters and relative forms prepared for these two categories of patients.

**Instructions for contacting patients about returning their Animas® 2020 and IR 1200 insulin pumps:**

1. Help us to identify all patients who have received and not returned an Animas® 2020 or IR 1200 insulin pump, including those who have subsequently received an Animas® Vibe™ insulin pump.
2. Contact your Animas Representative to support you to reach out to your patients with the attached communication to assure that each eligible patient receives one of the two enclosed letters and forms:
  - a. Patients who already have an Animas® Vibe™ insulin pump should receive the letter requesting the return of the completed form and of their Animas® 2020 or IR 1200 insulin pump.
  - b. Patients who do not have an Animas® Vibe™ insulin pump should receive the letter requesting the return of the completed form in order to discuss their potential replacement pump options and the return of their Animas® 2020 or IR 1200 insulin pump.

Animas has notified the Competent Authority in your country concerning this Field Safety Notice.

We apologize for any inconvenience this issue may cause you or the patients you serve. Should you have any questions or concerns about this communication, please do not hesitate to contact 0800 055 6606 (UK) or 1800 812 715 (IE).

Thank you for your cooperation and continued support of Animas.

Sincerely,



**Tina Williams**  
Operations Manager  
Animas UK and Ireland

Attachments:

Patient letters and forms