

May 29, 2015

URGENT FIELD SAFETY NOTICE

Important Information For Patients With Animas® 2020 and IR 1200 Insulin Pumps Who Do Not Have an Animas® Vibe™ Insulin Pump

Dear Animas Pump User:

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

In December 2012, we notified patients of an end of service life date issue that will affect the Animas® 2020 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.
- **Animas 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, and patients can continue to use their pumps with confidence until that date.

According to our records, you have an Animas® 2020 or IR 1200 insulin pump that has not been replaced by another Animas product. We are requesting that you contact Animas as soon as possible to discuss replacement options.

How to contact Animas regarding your Animas® 2020 or IR 1200 insulin pump

Complete the accompanying form and return it using the enclosed postage paid envelope. If you prefer, you can use an alternative method to return it as indicated in the form itself.

Upon receipt of this form, Animas will contact you regarding replacement options for your Animas® 2020 or IR 1200 pump. Please allow 8 – 10 weeks for a reply.

If you are not using your Animas® 2020 or IR 1200 Insulin Pump or no longer have it, please return the accompany form so that we can arrange for return of your unused pump or update our records.

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

We would appreciate your timely response to this notification to ensure there is no impact on your Animas insulin pump therapy.

Should you have any questions or concerns, please contact us at 0800 055 6606 (UK) or 1800 812 715 (IE). Thank you for choosing Animas as your partner in pump therapy.

Sincerely,



Tina Williams
Operations Manager
Animas UK and Ireland

Animas[®] 2020 or IR 1200 Insulin Pump Return Form

Please provide the following information regarding your Animas[®] 2020 or IR 1200 insulin pump:

Patient/Guardian First Name: _____

Patient/Guardian Last Name: _____

Patient/Guardian Address: _____

Patient/Guardian Telephone Number: _____

Patient/Guardian E-mail (optional): _____

Preferred method of contact (Circle one)

Mail

E-mail

Telephone

Do you still have your Animas[®] 2020 or IR 1200 Insulin Pump? Yes No

Do you still use your Animas[®] 2020 or IR 1200 Insulin Pump? Yes No

Please list the serial number of your Animas[®] 2020 or IR 1200 Insulin Pump. If you are not able to locate your pump's serial number, please call our Customer Service at 0800 055 6606 (UK) or 1800 812 715 (IE), and we will help you to locate it.

Serial SN: _____

Will you return your Animas[®] 2020 or IR 1200 insulin pump Yes No

If you will not return your Animas[®] 2020 or IR 1200 insulin pump please indicate the reason below:

I no longer have the pump, the pump was lost or disposed of

I am unable or unwilling to return the pump

Other (Explain) _____

Please note: Animas recommends you return your Animas[®] 2020 or IR 1200 Insulin Pump before January 1, 2016 to ensure it is removed from service prior to the end of service life date and disposed appropriately.

Please return this form, even if you do not want to return your pump, in the Postage Paid envelope provided with this letter.

Alternatively you may return this form by

Email: animasUK@its.jnj.com

Fax: +44 (0) 1494 658 751

We take your privacy seriously. The information provided by you will be held by **Animas®** to assist with the return and replacement of **Animas® 2020 or IR 1200 Insulin Pump**. We will only use your personal data in accordance with the Data Protection Act 1998. Limited personnel will access your information for data management purposes; it will not be given to other parties unless required by law. **Animas®** apply adequate privacy safeguards to protect your personal information when it is processed in the US where different data protection rules apply. You have the right to access the data that we hold and to request that any incorrect data be amended. Please contact us on the details provided if you require any further information.