



Animas, 50-100 Holmers Farm Way, High Wycombe, Bucks HP12 4DP
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Email: AnimasUK@its.jnj.com Website: www.animascorp.co.uk

Technical Support and Supplies Freephone: UK 0800 055 6606 IRELAND 1800 812 715

May 29th, 2015

URGENT FIELD SAFETY NOTICE

Important Information for Patients with Animas® 2020 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 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 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 these pumps with confidence until that date.

We are requesting that all patients with an Animas® 2020 or IR 1200 insulin pump contact Animas as soon as possible to arrange for the return of their pump to Animas and, if eligible, receive an Animas® Vibe™ replacement pump at no cost.

To contact Animas regarding your Animas® 2020 or IR 1200 insulin pump, please download and complete this [form](#) and return it via:

Email: animasUK@its.jnj.com

Fax: +44 (0) 1494 658751

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.

Please return this [form](#) even if you no longer use or have your Animas® 2020 or IR 1200 Insulin Pump so that we can update our records.

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

Should you have any questions or concerns, please contact us at 0800 055 6606 (UK) or 1800 812 715 (Ireland). Thank you for your cooperation and support.

Sincerely,
Animas Customer Service



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

Do you currently have an Animas® Vibe™ 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 Customer Service at 0800 055 6606 (UK) or 1800 812 715 (Ireland) 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) _____



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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 is disposed of appropriately.

Please return this completed form via: Email: animasUK@its.jnj.com

Fax: +44 (0) 1494 658751

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.