

**URGENT FIELD SAFETY NOTICE**

April XX, 2015

**Important Information For Patients With Animas® 2020 and IR 1200 Insulin Pumps  
Who Also 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 use 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.**

According to our records, you have an Animas® Vibe™ and, our records show that you did not return your Animas® 2020 or IR 1200 insulin pump. We recommend that the Animas® 2020 or IR 1200 insulin pump be returned as soon as possible to ensure it is removed from service prior to the end of service life.

- **How to return your Animas® 2020 or IR 1200 insulin pump:** Included in this notification are insulin pump return instructions and a pre-paid envelope.
- **If you still have the Animas® 2020 or IR 1200 insulin pump in your possession,** but do not want to return the pump for disposal, please complete the accompanying form and return in the postage paid envelop so we can update the pump record(s) on your account. If you prefer, you can use an alternative method to return it as indicated in the form itself.
- **If you no longer have the Animas® 2020 or IR 1200 insulin pump in your possession,** please complete the accompanying form and return in the postage paid envelop so we can close outstanding records on your account. If you prefer, you can use an alternative method to return it as indicated in the form itself.

We would appreciate your timely response to this notification – even if you believe you received this notice in error or no longer have your Animas® 2020 or IR 1200 insulin pump.

**On Animas Letterhead**

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

Should you have any questions or concerns, please contact us. Thank you for choosing Animas as your partner in pump therapy.

Sincerely,

XX

Animas Corporation

**Animas® 2020 or IR 1200 Insulin Pump Return Form**

Please provide the following information to return 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

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 XXX-XXX-XXXX, and we will help you to locate it. 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 accompanying postage-paid envelope.**

Alternatively you may return this form by

Email XXXXXXXXXXXXXXXXX

Fax XXXXXXXXXXXXXXXXX

**URGENT FIELD SAFETY NOTICE**

April XX, 2015

**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 use 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.

**OnAnimas Letterhead**

Should you have any questions or concerns, please contact us at **XX**. Thank you for choosing Animas as your partner in pump therapy.

Sincerely,

**XX** Animas Corporation

**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 XXX-XXX-XXXX, 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.

**On Distributor Letterhead**

**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 XXXXXXXXXXXXXXXX

Fax XXXXXXXXXXXXXXXX