



URGENT MEDICAL DEVICE CORRECTION

May 26, 2015

Important Information about Animas® 2020, IR 1250 or 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 would like to inform you that we are notifying 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. Patients 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, patients using a data management software program with their pump 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.

While we stopped actively marketing these products several years ago (IR 1200 in 2004, IR 1250 in 2007 and Animas 2020 in 2008) as newer products were introduced, we remain committed to contacting all known owners of these products directly. We also ask for your assistance in contacting your patients who may have an Animas® 2020, IR 1250 or IR 1200 insulin pump to request their return to Animas as quickly as possible and to discuss potential replacement options.

Samples of the notifications we are sending to patients are attached for your reference.

Please share this information with your patients who may still have an Animas® 2020, IR 1250 or IR 1200 insulin pump, regardless of whether they have also transitioned to another pump insulin pump or are no longer using a pump. Ask them to contact Animas to learn how to return their pump and to discuss potential replacement options:

Animas Web site: www.animas.com/calreplacement

Animas Customer Service: 1-866-545-3831

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



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 call Animas Customer Service at 1-866-545-3831.

Thank you for your cooperation and continued support of Animas.

Sincerely,

Animas Corporation

Attachments:

Patient letters with forms



URGENT MEDICAL DEVICE CORRECTION

May 26, 2015

Important Information about Your Animas® 2020, IR 1250 or IR 1200 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 using Animas® 2020, IR 1250 and IR 1200 insulin pumps that their pumps have an end of service life date, 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.

According to our records, you have an Animas® Vibe™ or OneTouch® Ping® insulin pump. However, our records show that you did not return your Animas® 2020, IR 1250 or IR 1200 insulin pump. We recommend that the Animas® 2020, IR 1250 or IR 1200 insulin pump be returned to Animas for disposal to ensure it is removed from use prior to the end of service life date.

- **How to return your Animas® 2020, IR 1250 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, IR 1250 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 envelope so we can update the pump record(s) on your account.

OR

Enter the information on the Animas Web site: www.animas.com/calreplacement



- **If you no longer have the Animas® 2020, IR 1250 or IR 1200 insulin pump in your possession,** please complete the accompanying form and return it in the postage paid envelope so we can close outstanding records on your account.

We appreciate your timely response to this notification. Should you have any questions or concerns, please contact us at 1-866-545-3831. Thank you for choosing Animas as your partner in pump therapy.

Sincerely,

Animas Corporation



Animas® 2020, IR 1250 or IR 1200 Insulin Pump Return Form

Please provide the following information regarding your Animas® 2020, IR 1250 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 if required (Circle one)

Mail

E-mail

Telephone

Do you still have your Animas® 2020, IR 1250 or IR 1200 Insulin Pump? Yes No

Do you still use your Animas® 2020, IR 1250 or IR 1200 Insulin Pump? Yes No

Would you be willing to have Animas dispose of your unused pump? Yes No

Please list the serial number of your Animas® 2020, IR 1250 or IR 1200 Insulin Pump. Call 1-866-545-3831 if you have trouble locating the serial number.

Serial Number:

If you will not return your Animas® 2020, IR 1250 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, IR 1250 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 form, even if you do not want to return your pump, in the accompanying postage-paid envelope.



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May 26, 2015

Important Information about Your Animas® 2020, IR 1250 or IR 1200 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 using the Animas® 2020, IR 1250 and IR 1200 insulin pumps that their pumps have an end of service life date 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.

According to our records, you have an Animas® 2020, IR 1250 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 potential replacement options.

How to contact Animas regarding your Animas® 2020, IR 1250 or IR 1200 insulin pump

Complete the accompanying form and return it using the enclosed postage paid envelope.

OR

Enter the information on the Animas Web site: www.animas.com/calreplacement

Upon receipt of this information, Animas will contact you regarding replacement options for your Animas® 2020, IR 1250 or IR 1200 pump. Please allow 8 -10 weeks for reply from Animas.

If you are not using your Animas® 2020, IR 1250 or IR 1200 Insulin Pump or no longer have it, please return the accompanying form so that we can arrange for the return of your unused pump or update our records.



We appreciate your timely response to this notification. **Please be assured that this issue does not affect the operation of these pumps prior to January 1, 2016.**

Should you have any questions or concerns, please contact us at 1-866-545-3831. Thank you for choosing Animas as your partner in pump therapy.

Sincerely,

Animas Corporation



Animas® 2020, IR 1250 or IR 1200 Insulin Pump Form

Please provide the following information regarding your **Animas® 2020, IR 1250 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, IR 1250 or IR 1200 Insulin Pump? Yes No

Do you still use your Animas® 2020, IR 1250 or IR 1200 Insulin Pump? Yes No

Would you be willing to have Animas dispose of your unused pump? Yes No

Please list the serial number of your Animas® 2020, IR 1250 or IR 1200 Insulin Pump. Call 1-866-545-3831 if you have trouble locating the serial number.

Serial Number:

If you will not return your Animas® 2020, IR 1250 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, IR 1250 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.