

## URGENT FIELD SAFETY NOTICE

September XX, 2008

## Information Regarding Use of the Animas<sup>™</sup> 2020 and IR 1200 Insulin Pump

## Dear Valued Customer:

Animas Corporation has become aware that some battery caps that are currently being used on the Animas<sup>TM</sup> 2020 and IR1200 insulin pumps are not maintaining contact with the pump's battery compartment. You have been identified as having received a battery cap or a pump with a battery cap that may potentially have this issue.

If the cap loses contact with the battery compartment, the pump will temporarily lose power. If this occurs, the pump will give a beep to let you know it has restarted and you will see the verify screen. If you do not confirm the verify screen the pump will begin to alarm within three minutes and the alarms will escalate to the loudest audible setting and vibration alert within an hour.

You will not receive insulin until you complete the following:

- Disconnect from the pump at your skin site
- Confirm that the information on the verify screen is correct
- Complete the rewind, load, and prime steps by carefully following the instructions in your Animas User Guide
- Reconnect to the pump at your skin site

In order to ensure the safe operation of the pump, and avoid any potential power loss related to this battery cap issue, complete the following steps:

- Immediately replace the battery cap on your Animas insulin pump with the battery cap enclosed with this letter. Follow the instructions in your Animas User Guide for changing the battery (Chapter 5).
- Discard the battery cap you remove from the pump and do not use it.
- If you received a pump kit with a spare battery cap, discard the spare battery cap and do not use it. An extra spare battery cap was provided with this letter.
- Complete and return the Response Form enclosed with this notification.

If you have any questions regarding this communication please contact you local distributor by calling the number located on the back of your pump.

Animas is dedicated to ensuring the highest level of customer support and continues to work to deliver the highest level of quality to our customers. Thank you for your support in this matter.