



URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

March 26, 2010

**Important Information about the Animas® 2020 Insulin Pump
and the Animas® IR1200 Insulin Pump**

Dear Animas Parent or Caregiver:

Animas is dedicated to supporting pumpers with quality customer service and products. As part of that commitment, we reach out whenever we have urgent information about our products.

We have learned of several cases in which pumpers have accidentally delivered excessive insulin when they ignored pump warnings and did not disconnect from their infusion set before loading the pump cartridge. In each of these cases, the pump had been damaged. Because of this damage, the pump delivered the entire cartridge of insulin during the “load cartridge” step of the priming sequence.

Failure to follow safety instructions and disconnect your infusion set from your child’s body during the “rewind, load and prime” steps can lead to unintended delivery of insulin. This can cause serious injury or death.

This warning is in your User Guide and was part of your child’s pump training. The pump also warns you to disconnect before these steps (see below). **NEVER IGNORE THESE WARNINGS.**

REWIND MOTOR	PRIME
Disconnect infusion set from your body!	Be sure set is disconnected from your body. Then select Continue.
Go Rewind	Insulin: 200U
Cancel	Continue Cancel

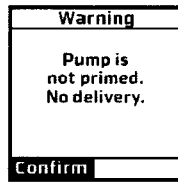
There is NO SAFETY RISK from this condition if your child ALWAYS disconnects the infusion set from his or her body when:

- rewinding the motor
- loading the cartridge
- priming the infusion set tubing
- tightening the cartridge cap

Please note, this issue does NOT occur during basal and bolus insulin delivery.

How Will I Know if My Child’s Pump is Affected?

- If you see a pump warning message that says: “No Cartridge Detected. Deliveries Disabled” after the “Load Cartridge” step; or
- If you see repeated “no prime” warnings (see below) that are **not related** to an occlusion alarm, auto-off alarm or loose cartridge cap; or



- In some cases, you may also notice that the pump's screen is hard to read or goes blank.

If you notice any of these things, contact Animas Customer Support at UK 0800 055 6606 or Ireland 1800 812 715. As always, if you need immediate medical attention call your healthcare professional or 999.

What do I do now?

The key things to remember are:

- Follow your User Guide instructions
- Pay attention to all pump warnings
- NEVER rewind the pump motor, load the insulin cartridge, or prime your infusion set while your child is connected

Should you have any questions or concerns, please call the Animas Customer Support Department. A trained healthcare professional will take your call at UK 0800 055 6606 or Ireland 1800 812 715. If you are travelling outside of the U.K. or Ireland, please call +44 800 055 6606, option 1.

We have also sent a letter to your child's healthcare professional to inform them of this issue.

Sincerely,

Animas UK/Ireland