

Date

Address to include

### Important Information about Animas® Vibe Insulin Pump

Dear Valued Health Care Professional:

Animas takes our commitment to notify patients of issues regarding their pumps seriously. We have received complaints concerning faded, dim or discolored displays on Animas® Vibe insulin pumps manufactured prior to February 2013. The display may fade or become dim over time as a result of exposure to extremes of temperature and humidity. The purpose of this letter is to request that you to contact your patients who are still using an Animas® Vibe Insulin Pump Animas produced before February 2013.

#### **What is the issue?**

The display on the Animas® Vibe pump may fade over time, making it difficult to read the information on the screen.

#### **What are the health and safety risks that may result?**

If the display is faded dim or discolored, the patient may not be able to read the screen, which could prevent the patient from using the pump correctly.

The Owner's Booklet includes instructions for patients to contact Animas Technical Assistance if they suspect the pump has been damaged.

#### **What action should I take?**

Please do the following:

- 1) Identify patients who have been provided with affected pumps as identified on the accompanying serial number list;
- 2) Once you have identified the affected patients, please distribute the attached letter to these individuals as soon as possible;
- 3) When you have completed the mailing activity, please confirm with your Local Animas Representative that all impacted patients have been notified by identifying the pump serial numbers whose owners have been contacted
- 4) Animas will cover all the costs associated to this mailing activity.

We appreciate your prompt attention to this issue.

Sincerely,

Animas Corporation

Attachments:

- a. List of affected Animas® Vibe pumps serial numbers manufactured prior to February 2013 Vibe;
- b. Letter for patients