

19<sup>th</sup> September 2016

## Urgent Field Safety Notice

### Animas<sup>®</sup> Vibe<sup>®</sup> Insulin Pump

Dear Valued Animas pump user,

We would like to reiterate some important information regarding the safe use of the Animas<sup>®</sup> Vibe<sup>®</sup> Insulin Pump due to an increased number of complaints regarding an issue with the battery compartment.

#### Description of problems:

If the pump experiences an impact or the battery cap is attached too tightly, there is the possibility that a crack may appear around the battery casing area of the pump.

#### Risk to health:

Cracks or damage to the pump may impact the battery contact and/or the waterproof feature of your pump, with the possibility to compromise the battery contacts and therefore the full pump functionality, including pumps alerts.

#### Recommended Customer Action:

Please refer to the following warning and recommendations already included in your owner's booklet

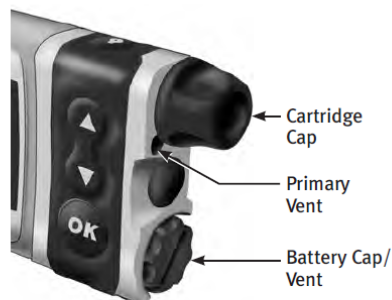
#### ***General Wear and Tear***

If you drop your pump or it has been hit against something hard, inspect it to be sure it is still working properly. Check that the display screen is working and clear, that the cartridge cap, battery cap and infusion set are properly in place. Check for leaks around the cartridge by wrapping a piece of tissue around the connection area. Cracks, chips or damage to your pump may impact the battery contact and/or the waterproof feature of your pump. Call Customer Support or your local Animas distributor (see page 187) if you identify or suspect your pump is damaged. They will help determine if your pump should be replaced.

- **Prior to replacing the battery cap, make sure the o-ring fits securely and is not damaged. A damaged o-ring may impact the battery contact and/or the waterproof feature of your pump. See Chapter 3 in Section I.**

#### **Battery Cap/Vent**

This cap unscrews easily with a coin to replace and secure your battery. There is an o-ring around the cap, which prevents water from entering the pump. The battery cap also is equipped with a built-in vent to allow air to enter your pump to maintain pressurization but prevent water from entering. Be careful not to over tighten the battery cap. See Chapter 3 in Section I.



#### **Primary Vent**

This vent is part of the redundant vent safety system, which allows air inside your pump to maintain equalized pressure but prevents water from getting inside.

**⚠ WARNING: Under no circumstances should you introduce any kind of sharp object into the vent openings. Doing so will compromise your pump's waterproof capabilities. If at any time you suspect the vent openings are clogged, replace the battery cap.**

## Care and Maintenance of your Animas® Vibe™ Insulin Pump

### The Vents

Your pump features a redundant Vent Safety System. Vents serve two purposes. First, they allow air to enter and exit your pump so that pressure is equalized under a variety of environmental circumstances, such as changes in altitude. Second, the vents are backed by a special membrane, which keeps water from entering your pump.

### Battery Cap with O-ring and Vent

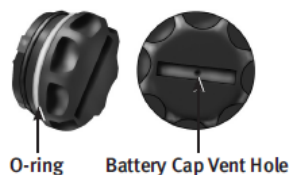
Your battery cap contains an o-ring and vent. The vent is a tiny hole backed by a membrane, which allows air to pass through but prevents water from entering. The o-ring helps to keep your pump waterproof. It is recommended that you change the battery cap/vent every six months. If you work in a dusty environment such as a construction site, mill, cement factory, etc., or if you are a frequent swimmer, you should change your battery cap every 3 months. You can contact your local Animas distributor to order an extra battery cap. See the Patient ID Card included with your Animas® Vibe™ Insulin Pump for contact information for your local Animas distributor.



**⚠ WARNING:** Under no circumstances should you introduce any kind of sharp object into the vent openings to clean them. Doing so could compromise your pump's waterproof capabilities. If at any time you suspect the vent opening is clogged, replace the battery cap.

1. Disconnect from infusion site.
2. Use a coin to unscrew the battery cap with a counter-clockwise motion.
3. Check your battery cap for damage such as cracks or missing threads, and be sure the colored o-ring fits securely and is not torn or damaged.
4. Check the vent hole on the top of the battery cap to be sure it is clear of debris. This vent maintains pressurization while preventing water from entering the compartment.

**NOTE:** The battery cap should be replaced every six months, or sooner if the o-ring or cap is damaged or the vent is clogged. See *Chapter 12 in Section I*.



Please check your Animas® Vibe® battery compartment to ensure that it is not cracked. We recommend that you continue to inspect your pump on a regular basis and that you inspect and replace your battery cap as instructed in different sections in the Owner's Booklet. Please contact Animas Technical Support at 0800 055 6606 (UK) or 1800 812 715(IE) **option 2** if you have any concerns or questions.

Your Competent Authority has been informed about this Field Safety Notice.

Thanks for your attention

Best Regards

Animas UK & Ireland