

**Notice Information: - Advisory  
28 August 2012**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

a) Target Audience:

Diabetes clinics/outpatients  
Diabetes nurse specialists  
Endocrinology units  
Medical directors  
Outpatient clinics  
Paediatricians  
Pharmacists  
Risk managers  
Supplies managers  
Community nurses  
General practitioners  
Private medical practitioners  
Practice nurses  
School nurses  
Clinics  
Hospitals  
Nursing Homes  
Community Care Managers  
Community Therapists  
Carers

Please bring this safety notice to the attention of all who need to be aware of it.

### Part 3. Problem/Issue

a) Problem/Issue:

There is a risk of compromised insulin delivery whereby keypad buttons become unresponsive. The issue can arise due to wear and tear of keypads on the insulin pump, or sticking of keypad buttons.

## Part 4. Background Information

a) Background Information:

Animas Corporation has received an increase in complaints relating to the durability of insulin pump keypads. Over time, tearing and peeling of the keypad buttons can occur. Keypad buttons can also stick and become unresponsive. An average time to failure of approximately 18 months was reported by the manufacturer.

Animas Corporation has a new keypad design which is incorporated into all pumps distributed post February 2012. Newer keypad designs are not affected by this problem. Animas Corporation has provided the attached Patient Notification to affected customers providing information.

The Irish Medicines Board (IMB) is issuing this Safety Notice to ensure all Animas Insulin Pump users are aware of the issue.

## Part 5. Action to be taken

a) Action to be taken:

1. Ensure that all pump users are aware of the information provided in the attached Field Safety Notice (FSN) issued recently by Animas.
2. Pump users experiencing problems with their device or experiencing keypad issues are encouraged to contact Animas without delay to arrange for a replacement as outlined in the FSN.
3. Pump users are encouraged to report any issues with pump keypad both to Animas and to the IMB using the contact details provided below.

## Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Animas Corporation

Animas UK & Ireland

Telephone: 1800 812 715

E-mail: [AnimasUK@its.jnj.com](mailto:AnimasUK@its.jnj.com) or via the website at:  
[www.animascorp.co.uk/contact-us](http://www.animascorp.co.uk/contact-us)

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://www.imb.ie)

[Please click here to view a PDF Version of this Safety Notice](#)

[Please click her to view a copy of the Field Safety Notice](#)