

**Notice Information: - Warning  
24 April 2014**

**Part 1. Product Information**

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

**Part 2. Target Audience**

a) Target Audience:

All Hospital Staff  
All Nursing Home Staff  
A&E Departments  
Ambulance Service  
Cardiology Departments  
Cardiothoracic Departments  
Carers  
Chief Executive Officers  
Clinical Directors  
Day Surgery Units  
Emergency Medical Technicians  
Diabetic Clinics/ outpatients  
Diabetic nurse specialists  
Diabetic departments  
Endocrinology units  
Endocrinology Consultants  
Gastroenterology Departments  
General Practitioners  
General Public  
Haemodialysis Units  
Healthcare professionals who use these devices  
Healthcare professionals managing patients who use these devices  
High Dependency Units  
Hospital Managers  
Hospital Pharmacists  
Intensive Care Units   IV Nurse Specialists   Maternity Units   Midwifery Department

Intensive Care Units  
IV Nurse Specialists  
Maternity Units  
Midwifery Departments  
Neonatology Departments  
Nursing Managers  
Nursing staff  
Obstetrics and Gynaecology Departments  
Oncology Nurse Specialists  
Paediatric Departments  
Paramedics  
Peritoneal Dialysis Units  
Purchasing / Procurement / Material Managers  
Renal Medicines Departments  
Resuscitation Officers  
Risk Managers  
Supplies Managers  
Theatre Managers and nurses  
Urology Departments

### Part 3. Problem/Issue

a) Problem/Issue:

Medtronic has received a number of reports regarding users who have accidentally programmed the pump to deliver the maximum bolus amount, including one incident that resulted in severe hypoglycaemia.

All insulin delivery programmed through the Main Menu will allow the down arrow button to scroll from 0.0 units to the programmed maximum bolus insulin dose.

## Part 4. Background Information

a) Background Information:

This action applies to Paradigm Pump models MMT-511, MMT-512, MMT-712, MMT-712E, MMT-515, MMT-715, MMT-522, MMT-522K, MMT-722, MMT-722K, MMT-523, MMT-523K, MMT-723, MMT-723K, MMT-554, and MMT-754.

When using the Express Bolus button to deliver a bolus, the down arrow will scroll to 0.0 units and stop.

Because accidental button pressing errors may occur, it is important that patients always confirm the insulin dose flashing on the display is correct before pressing ACT to start delivery.

The IMB is working with Medtronic and the HSE to ensure awareness of this issue.

## Part 5. Action to be taken

a) Action to be taken:

The IMB advise that users:

(1) Follow the instructions outlined by the manufacturer in the field safety notice (FSN) attached.

(2) When programming insulin doses through the Main Menu, pay close attention because scrolling down allows the dose displayed on the screen to go from 0.0 units to the maximum programmed insulin dose.

(3) Always confirm the insulin dose flashing on the display is correct before pressing ACT to start delivery.

(4) The Max Bolus and Max Basal safety limits should be programmed in your patients' pumps according to their individual insulin needs.

(5) Forward this IMB Safety Notice to all those within your organisation that need to be aware of this information. Please also pass this Safety Notice and the attached FSN on to any end users or organisations where these devices may have been distributed.

## Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Medtronic MINIMED

18000 Devonshire Street

CA 91325 -1219

Northridge

USA

Telephone: +1 818 576 5555

Fax: +1 818 365 2246

E-mail: N/A

Website: N/A

Enquiries to the distributor should be addressed to:

Medtronic Limited

Building 9 Croxley Green Business Park

WD18 8WW

Watford

United Kingdom

Telephone: +44 1923 212213

Fax: N/A

E-mail: [vigilance.eu@medtronic.com](mailto:vigilance.eu@medtronic.com)

Website: N/A

#### IMB CONTACT INFORMATION

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

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

Irish Medicines Board

Human Products Monitoring

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 here to view a copy of FSN 1](#)

[Please click here to view a copy of FSN 2](#)