

Safety Notice

Medical Devices



IRISH MEDICINES BOARD

Paradigm Insulin Infusion Pump

Priority 2 – Warning



IMB Safety Notice: SN2014(20)

Issue Date: 24 April 2014

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
Medtronic MINIMED	V20262

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.

ACTION OR RECOMMENDATIONS

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.

TARGET GROUPS

All Hospital Staff	High Dependency Units
All Nursing Home Staff	Hospital Managers
A&E Departments	Hospital Pharmacists
Ambulance Service	Intensive Care Units
Cardiology Departments	IV Nurse Specialists
Cardiothoracic Departments	Maternity Units
Carers	Midwifery Departments
Chief Executive Officers	Neonatology Departments
Clinical Directors	Nursing Managers
Day Surgery Units	Nursing staff
Emergency Medical Technicians	Obstetrics and Gynaecology Departments
Diabetic Clinics/ outpatients	Oncology Nurse Specialists
Diabetic nurse specialists	Paediatric Departments
Diabetic departments	Paramedics
Endocrinology units	Peritoneal Dialysis Units
Endocrinology Consultants	Purchasing / Procurement / Material Managers
Gastroenterology Departments	Renal Medicines Departments
General Practitioners	Resuscitation Officers
General Public	Risk Managers
Haemodialysis Units	Supplies Managers
Healthcare professionals who use these devices	Theatre Managers and nurses
Healthcare professionals managing patients who use these devices	Urology Departments

BACKGROUND

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.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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
Website: N/A

IMB CONTACT INFORMATION

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
Website: www.imb.ie