

18<sup>th</sup> March 2014

Medtronic Reference: FA606

Dear Medtronic Insulin Pump User:

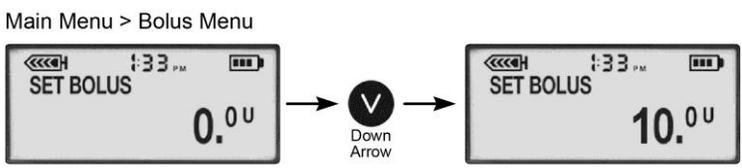
With your health as our top priority, please take the time to review the safety information in this letter which applies to the following Medtronic insulin pump models:

- **Paradigm:** 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.

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

### How can this accidental programming occur?

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

**Bolus Example through the Main Menu**  
A single press of the down arrow button will move the bolus from 0.0 units to the programmed Max Bolus (The default Max Bolus is 10.0 units).  
Main Menu > Bolus Menu  


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 you always **confirm the insulin dose flashing on the display is correct before pressing ACT to start delivery.**

### What Safety Settings will minimize the risk of an accidental programming error?

Always ensure the Max Bolus and Max Basal safety limits are programmed in your pump according to your personal insulin needs. Your healthcare professional will help determine appropriate settings for you. See the User Guide or second page of this letter for instructions on how to program these settings.

### What action do I need to take?

1. Pay close attention when programming insulin doses through the Main Menu, because scrolling down allows the dose displayed on the screen to go from 0.0 units to the maximum programmed insulin dose.
2. Always **confirm the correct insulin dose is flashing on the display before pressing ACT to start delivery.**

3. Verify your Max Bolus and Max Basal settings are programmed according to your personal insulin needs, per your healthcare professional's instructions.

**To set the maximum bolus limit:**

The Maximum bolus (Max bolus) is a safety feature that limits the amount of insulin that can be delivered in a single bolus. It is important to discuss this feature with your healthcare professional to determine your Max bolus amount.

Go to the MAX BOLUS SETUP screen.

**For Paradigm MMT-523/MMT-723/MMT-523K/MMT-723K and MMT-554/MMT-754 (Veo):**

- 1 **Main > Bolus > Bolus Setup > Max Bolus**
- 2 Set your Max bolus limit and press **ACT**
- 3 Your Max bolus is set. Exit the menus

**All other Paradigm Pump models:**

- 1 **Main > Bolus > Max Bolus**
- 2 Set your Max bolus limit and press **ACT**
- 3 Your Max bolus is set. Exit the menus

**Setting the Max basal rate:**

It is important to determine your Max basal rates with your healthcare professional. This safety feature will not allow you to program any basal rates, including patterns and temporary basal rates that are greater than the Max basal rate.

Go to the MAX BASAL RATE screen.

**For Paradigm MMT-523/MMT-723/MMT-523K/MMT-723K and MMT-554/MMT-754 (Veo):**

- 1 **Main > Basal > Basal Setup > Max Basal Rate**
- 2 Change the rate and press **ACT**
- 3 Your Max basal rate is now set. Exit the menus

**All other Paradigm Pump models:**

- 1 **Main > Basal > Max Basal Rate**
- 2 Change the rate and press **ACT**
- 3 Your Max basal rate is now set. Exit the menus

Medtronic is committed to keeping you and your healthcare professional informed of issues and solutions concerning our products and services. Should you have any questions about this or any other matter regarding your Medtronic pump, please do not hesitate to contact the 24-Hour Helpline on +44 (0)1923 212213.

We appreciate your time and attention to this important notification.

Yours sincerely,



David G Dunham BSc, PhD  
Regulatory Affairs & Quality Manager – UK & Ireland

## Urgent Field Safety Notice

**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.**

### Recommendations for scrolling when selecting insulin delivery amounts

17<sup>th</sup> March 2014

Medtronic Reference: FA606

Dear Healthcare Professional:

We are sending this letter to reinforce important information regarding the safe use of Medtronic insulin pumps and to provide a product update. Medtronic is informing directly patients for which we have contact details. **Because Medtronic does not have your patients' records on file, we kindly ask you to inform Paradigm pump users using the enclosed letter.**

Medtronic has received a small 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.

With your patient's health as our top priority, please take the time to review the safety information in this letter which applies to the following Medtronic insulin pump models:

- **Paradigm:** 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.

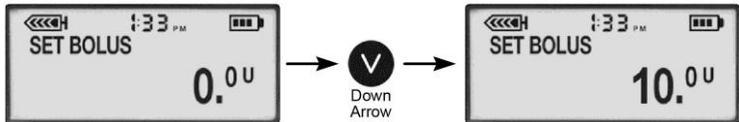
### How can this accidental programming occur?

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

#### Bolus Example through the Main Menu

Main Menu > Bolus Menu

A single press of the down arrow button will move the bolus from 0.0 units to the programmed Max Bolus (The default Max Bolus is 10.0 units).



The diagram illustrates the process of scrolling through the bolus amount. It starts with a screen showing 'SET BOLUS' and '0.0 u'. An arrow points to a circular button with a downward-pointing arrow, labeled 'Down Arrow'. Another arrow points to a second screen showing 'SET BOLUS' and '10.0 u'.

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.**

**What Safety Settings will minimize the risk of an accidental programming error?**

The Max Bolus and Max Basal safety limits should be programmed in your patients' pumps according to their individual insulin needs. See the User Guide for instructions on how to program these settings.

**What action do I need to reinforce with my patients?**

1. 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.
2. Always **confirm the insulin dose flashing on the display is correct before pressing ACT to start delivery.**
3. Make sure the Max Bolus and Max Basal settings are programmed according to individual insulin needs.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of this action. This notice needs to be passed on all those who need to be aware within your organization.

We appreciate your time and attention to this important notification. A copy of the pump user letter is also included for your reference.

Yours sincerely,



David G Dunham BSc, PhD  
Regulatory Affairs & Quality Manager – UK & Ireland

Enclosure: Dear Pump User Letter