

18th March 2014

Medtronic Reference: FA606

Dear Medtronic Insulin Pump User:

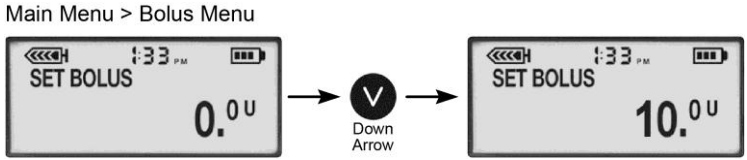
With your health as our top priority, please take the time to review the safety information in this letter which applies to the following Medtronic insulin pump models:



- **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	
<p>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).</p>	<p>Main Menu > Bolus Menu</p> 

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 +353 (0)1.5111444

We appreciate your time and attention to this important notification.

Yours sincerely,



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