

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

17th 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.

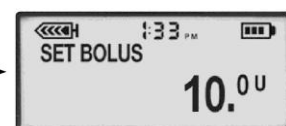
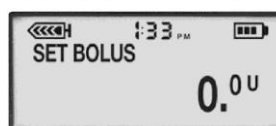
How can this accidental programming occur?



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

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 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 Competent Authority of your country 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,



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Enclosure: Dear Pump User Letter