



## 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

Medtronic Reference: FA606

17 March 2014

Dear Healthcare Professional:

We are sending this letter to you and your patients to reinforce important information regarding the safe use of Medtronic insulin pumps and to provide a product update. Medtronic is informing directly your patients, no action is required from your side.

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).

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.

Sincerely,

Medtronic Diabetes

Enclosure: Dear Pump User Letter



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### Recommendations for scrolling when selecting insulin delivery amounts

Medtronic Reference: FA606

17 March 2014

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.

Sincerely,

Medtronic Diabetes

Enclosure: Dear Pump User Letter

## 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 March 2014

Medtronic reference: FA606

Dear Distributor Partner:

Medtronic is sending customers a letter to reinforce Important Information regarding the safe use of Medtronic insulin pumps. 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.

This communication 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.

#### ACTION:

- 1) Please take the time to review the safety information in this letter.
- 2) Please compile your own customer mailing list i.e. Healthcare Professionals (HCP), Certified Product Trainers (CPT) and Pump Users who are impacted (see affected pump models above).
- 3) Please use the attached letters to notify on and no sooner than March 18, 2014.

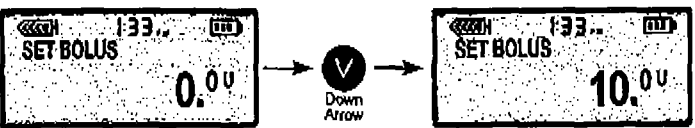
#### How can this accidental programming occur?

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 'SET BOLUS' screen. It starts with a screen showing '0.0U' and ends with a screen showing '10.0U'. An arrow labeled 'Down Arrow' points from the first screen to the second.

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 customers 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?**

Pump users should always ensure the Max Bolus and Max Basal safety limits are programmed in the insulin pump according to the customer's personal insulin needs. The customer's healthcare professional will help determine the settings that are right for the customer. See the User Guide for instructions on how to program these settings.

**What action does the user need to take?**

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

You are required to notify all customers of the Impacted models on and no sooner than **March 18, 2014.**

For all Paradigm insulin infusion pumps that you have supplied, please confirm you contacted all customers (three attempts being the gold standard). When the mailing is completed please provide the Field Action Confirmation Sheet.

In the event you have not provided these devices directly to pump user or HCP but to another distributor, please forward this information to said distributor so they may comply with this requirement.

Thank you in advance for your cooperation. If you have any additional questions, please do not hesitate to contact us.

Sincerely,

Medtronic Diabetes

**Enclosures**

- Dear Paradigm Pump User Letter
- Dear HCP Letter V1 to be used to inform HCP when you informed pump users directly (direct sales model)
- Dear HCP Letter V2 to be used to request HCP to inform pump users
- Field Action Confirmation Sheet