

IMPORTANT MEDICAL DEVICE SAFETY INFORMATION

March 13, 2014

Dear Medtronic Insulin Pump User:

We are sending you this letter to reinforce important information regarding the safe use of your Medtronic insulin pump and to provide an important product update.



1. Insulin delivery programming through the Main Menu

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 hypoglycemia.

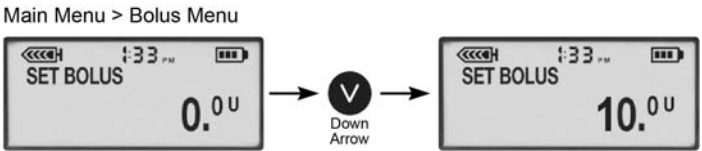
With your health as our top priority, please take the time to review the safety information in this letter which applies to the following Medtronic insulin pump models:

- **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, and MMT-723K
- **MiniMed 530G:** MMT-551 and MMT-751

How can this accidental programming occur?

When using the Express Bolus button  to deliver a bolus, the down arrow  will scroll to 0.0 units and stop.

However, **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.)	

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 you determine the settings that are right for you. (See the User Guide for instructions on how to program these settings, which can also be found at www.medtronicdiabetes.com, navigate to Support> Settings & Features.)

What action do I need to take?

- a) 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.
- b) Always **confirm the insulin dose flashing on the display is correct before pressing ACT to start delivery.**
- c) Make sure your Max Bolus and Max Basal settings are programmed according to your personal insulin needs, per your healthcare professional's instructions.

2. Pump button (keypad) update

Based on feedback we've received from our customers we have made improvements to the pump buttons (keypad) and the adhesive which are designed to reduce button error alarms and improve button response. These improvements are being incorporated into the manufacturing of insulin pumps in the coming months.

What action do I need to take?

No action is needed on your part. If you notice issues with cracks in your keypad, lifting edges, buttons that are not responding, or have any other concerns with your keypad please contact the 24-Hour Helpline at 866-222-7304 for a replacement.

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 letter please do not hesitate to contact the 24-Hour Helpline at 866-222-7304.

You can always report a concern to the FDA's MedWatch Adverse Event Reporting program:

Online at: <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>

Report by telephone: 1.800.FDA.1088

Fax report: 1.800.FDA.0178

We appreciate your time and attention to this important notification.

Sincerely,

Vice President, Quality
Medtronic Diabetes