

URGENT MEDICAL DEVICE SAFETY INFORMATION - Medtronic Insulin Pumps

The following warning and information applies to MMT-511, MMT-512/712/712E, MMT-515/715, MMT-522/522K/722/722K, MMT-523/523K/723/723K, and MMT-551/751 model insulin pump models.

Medtronic is conducting a voluntary recall to notify users of a button pressing error that can result in unintended insulin delivery and is reinforcing important information regarding the safe use of your Medtronic insulin pump.

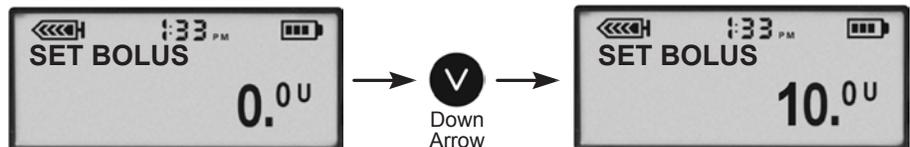
Medtronic has received reports regarding users who have accidentally programmed the pump to deliver the maximum bolus amount, including one incident that resulted in severe hypoglycemia.

All insulin delivery settings that are programmed through the Main Menu (specifically, manual bolus, basal and temporary basal) can be inadvertently changed by pressing the down arrow button to scroll down from 0.0 units for bolus/basal or 0% (for temp basal deliveries), to the programmed maximum insulin dose. This may result in an accidental delivery of your maximum allowed insulin dose.

Bolus Example

A single press of the down arrow button moves the bolus amount from 0.0 units to 10.0 units (which is the default Max Bolus setting.)

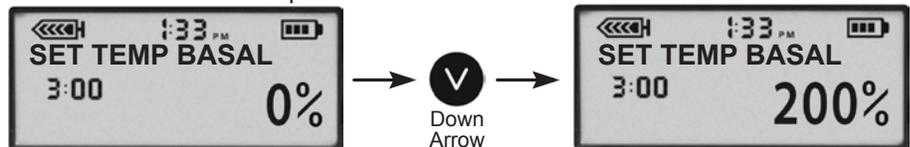
Main Menu > Bolus Menu



Temp Basal % Example

A single press of the down arrow button moves the temp basal amount from 0% to 200% (which is the highest temp basal rate.)

Main Menu > Basal > Temp Basal



Accidental delivery of your maximum allowed dose could cause hypoglycemia (low blood sugar). Symptoms of low blood sugar may include trembling, excessive sweating, weakness, hunger, confusion, and headache. Severe low blood sugar with loss of consciousness, seizure, or death may occur.

If you realize you have accidentally delivered an insulin dose that is higher than intended, you should call your healthcare professional immediately.

If the unintended delivery is still under way, manually suspend the pump to stop the delivery. Check the status screen to see how much insulin dose was delivered. If the delivered amount did not exceed your intended insulin dose, you can resume the pump delivery by following the User Guide.

Note: this accidental programming cannot occur when using the Express Bolus button to program a bolus. When using the Express Bolus button  to deliver a bolus, pressing the down arrow  will scroll down to 0.0 and stop.

What action do I need to take?

1. When programming insulin doses through the Main Menu, pay close attention because scrolling down allows the insulin dose displayed on the screen to go from 0.0 units (or 0%) to the maximum programmed insulin dose.
2. Always **confirm that the insulin dose flashing on the display is correct before pressing ACT to start delivery.**
3. Always ensure the Max Bolus and Max Basal safety limits programmed in your pump are set according to your personal insulin needs.
4. If you would prefer a pump without the scroll around feature, you can call Medtronic to exchange your pump.

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 regarding this or any other matter regarding your Medtronic pump, please do not hesitate to contact the 24 Hour HelpLine at 1-866-222-7304.

