



Urgent Field Safety Notice
MiniMed™ 640G Insulin Infusion Pump
Temporary Unresponsive Keypad

May 2017

Medtronic reference: FA767

Dear Physician, Healthcare Professional,

We are writing to inform you of a rare and temporary condition in which the keypad buttons on your patients' MiniMed™ 640G Insulin Infusion Pump may become temporarily stuck, and the keypad becomes unresponsive. This is a **field safety notification** and patients **do not** need to return or replace their pump. We do ask that you read the important information below to help you understand when this situation might happen, and how it can be resolved. We are proactively providing this information to patients who currently have a 640G insulin pump, as well.

How does the keypad become temporarily unresponsive?

Keypad buttons on the MiniMed 640G insulin pumps may become temporarily unresponsive when the atmospheric pressure around the pump increases or decreases rapidly. This would most likely happen when traveling in an airplane during take-off or landing. If this happens, in most cases a patient may not even notice because the pump will resolve this on its own.

How will patients notice if this happens to their pump?

During this temporary situation, a button may be too difficult to press down or a button can look like it is pressed and stuck in that position.

- *If a patient notices the keypad buttons are difficult to press down, the pump will continue to deliver basal insulin. The patient may not be able to program a bolus or suspend delivery as the buttons temporarily will not press down, but this will resolve on its own, usually within 30 minutes.*
- *If a button is stuck in a pressed position, after three (3) minutes a "Stuck Button" alarm is triggered which suspends insulin delivery (including basal). The patient may not be able to clear the alarm as the keypad is unresponsive. In the rare situation where this continues for more than ten (10) minutes, the pump will begin to siren.*

Once the alarm is triggered and insulin is suspended, patients will be unable to program a bolus or resume insulin delivery until the alarm is cleared.

What should patients do if this happens to their pump?

If patients experience this keypad condition and want to resolve it immediately to bolus or clear the alarm, they have to *remove the battery cap from the pump and then place it back on.*

PLEASE NOTE: Patients should have a fresh new AA battery available in case their pump prompts to insert a new battery.

What if I have more questions?

If you have other questions or concerns, you can find an addendum with FAQ attached to the pump user letter.

Note: *The MiniMed™ Paradigm insulin pumps are not affected by this condition.*



The Competent Authority of your country has been notified of this action.

Medtronic considers patient safety and customer satisfaction our primary priorities. We appreciate your time and attention in reading this important notification. In case of any questions contact your Medtronic representative.

Sincerely,

Enclosures:

Pump User Letter



Urgent Field Safety Notice

MiniMed™ 640G Insulin Infusion Pump

Temporary Unresponsive Keypad

May 2017

Medtronic reference: FA767

Dear pump user,

We are writing to inform you of a rare and temporary condition in which the keypad buttons on your MiniMed™ 640G Insulin Infusion Pump may become temporarily stuck, and the keypad becomes unresponsive. This is a **field safety notification** and you **do not** need to return or replace your pump. We do ask that you read the important information below to help you understand when this situation might happen and how to resolve it.

How does the keypad become temporarily unresponsive?

Keypad buttons on the MiniMed 640G insulin pumps may become temporarily unresponsive when the atmospheric pressure around the pump increases or decreases rapidly. This would most likely happen when traveling in an airplane during take-off or landing. If this happens, in most cases you may not even notice because the pump will resolve this on its own.

How will I notice if this happens to my pump?

During this temporary situation, a button may be too difficult to press down or a button can look like it is pressed and stuck in that position.

- *If you notice the keypad buttons are difficult to press down, the pump will continue to deliver your basal insulin. You may not be able to program a bolus or suspend delivery as the buttons temporarily will not press down, but this will resolve on its own, usually within 30 minutes.*
- *If a button is stuck in a pressed position, after three (3) minutes a "Stuck Button" alarm is triggered which suspends insulin delivery (including basal). You may not be able to clear the alarm as the keypad is unresponsive. In the rare situation where this continues for more than ten (10) minutes, the pump will begin to siren.*

Once the alarm is triggered and insulin is suspended, you will be unable to program a bolus or resume insulin delivery until the alarm is cleared.

What should I do if this happens to my pump?

If you experience this keypad condition, and want to resolve it immediately to bolus or clear the alarm, *remove the battery cap from the pump and then place it back on.*

PLEASE NOTE: You should have a fresh new AA battery available in case your pump prompts you to insert a new battery.

What if I have more questions?

If you have other questions or concerns, you can find an addendum with FAQ attached to this letter.

You can also always reach the Medtronic 24-Hour HelpLine at <XXXXX>



Note: The MiniMed™ Paradigm insulin pumps are not affected by this condition.

Medtronic considers patient safety and customer satisfaction our primary priorities. We appreciate your time and attention in reading this important notification.

Sincerely,

Addendum: Frequently Asked Questions

Q. IS THIS A RECALL?

No, you are not required to return your pump.

Q. DOES MY PUMP REQUIRE REPLACEMENT IF THIS HAPPENS?

No, you do not have to replace your pump unless the removing and replacing the battery cap does not fix the problem. If this does not relieve the pressure and the keypad is not functioning as normal then please call your local HelpLine to trouble shoot and find out what next steps should be taken.

Q. WHAT CAN I DO TO RESOLVE THIS SITUATION IF IT HAPPENS TO MY PUMP?

The easiest thing to do if you are not experiencing a "Stuck Button" alarm is to wait for the pump to resolve the issue on its own. However, we realize that you may want to quickly get your pump back to a normal state so the quickest solution is to remove the battery cap and put it back on the pump.

Q. IS THERE SOMETHING I CAN DO WHILE FLYING TO AVOID THIS SITUATION FROM HAPPENING?

This is a very rare and temporary condition so we do not expect this to occur. However, if you wish to avoid this completely while in flight, you should temporarily remove the battery cap during take-off and landing and only place it back on after your flight has leveled in altitude.

Remember: It is recommended to have extra batteries and a backup therapy particularly when you travel in the unlikely event that your pump is unavailable.

Q. HOW COMMON IS THIS PROBLEM AND WHAT ARE MY CHANCES OF THIS HAPPENING WHEN TRAVELING IN AN AIRPLANE?

This is a rare situation and we do not expect this to happen in most cases. However, because of the potential therapy interruption and simple solution, we have chosen to make our patients aware of this condition.

Remember: It is recommended to have extra batteries and a backup therapy particularly when you travel in the unlikely event that your pump is unavailable.



Q. ARE THERE ANY PRECAUTIONS I CAN TAKE NOW TO HELP PREVENT THIS?

The best action for ensuring therapy is not or is minimally interrupted for this situation is to:

- a) Always carry a fresh new AA battery for the pump
- b) Always carry an HCP prescribed back up therapy in the unlikely event the pump is not available

Q. WILL MY PUMP STOP DELIVERING INSULIN IF THIS ISSUE OCCURS?

Your pump will only stop delivering insulin if *a button is stuck in a pressed position* for three (3) minutes and a "Stuck Button" alarm is triggered **which suspends insulin**.

In the case where the keypad buttons are difficult to press down, your insulin delivery will not be interrupted.

Q. DOES THIS AFFECT THE PRESSURE IN THE RESERVOIR COMPARTMENT, AS WELL?

No, the p-cap feature on the reservoir allows the insulin reservoir compartment to equalize pressure faster than the rest of the body of the pump. Therefore, the delivery of insulin will continue as usual unless the pump keypad is stuck and alarming.

Q. WHAT DO I DO IF THIS DOES NOT FIX THE PROBLEM?

If removing and replacing the battery cap does not improve the keypad responsiveness, then please call your local HelpLine.