



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

February 2018

Medtronic reference: FA767

Dear Distribution, Service Provider,

We are writing to inform you of a rare and temporary condition in which the keypad buttons on 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 ask that you read the important information below to help you understand when this situation might happen, how it can be resolved and what action we require you to take.

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 action do I need to take?

Inform the customers to whom you have provided MiniMed 640G pumps of this notification using the attached patient or HCP letter.

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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 at <XXXX>.

Sincerely,

Country/BU manager

Enclosures:

1: Pump User Letter

2: HCP Letter V2