Medtronic, Inc.
18000 Devonshire St.
Northridge, CA 91325
www.medtronicdiabetes.com

Urgent Field Safety Notification

MiniMed™ 600 Series Insulin Infusion Pump

Temporary Unresponsive Keypad

Affecting MiniMed 630G and MiniMed 670G systems in the US

February 13, 2018

Dear Valued Clinician:

We are writing to inform you of a rare and temporary condition in which the keypad buttons on your patients' MiniMed™ 600 series insulin 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 600-series insulin pump, as well.

How does the keypad become temporarily unresponsive?
Keypad buttons on the MiniMed™ 600 series 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 patients notice the keypad buttons are difficult to press down*, the pump will continue to deliver basal insulin. They 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). Patients 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 FAQ and a copy of the patient letter at http://www.medtronicdiabetes.com/notice6.

940M17013-012 09Feb2018

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The Medtronic 24-Hour Helpline is also available to answer patient questions at 1-888-204-7616.

Note: *This only applies to MiniMed™ 600 series insulin pumps. The MiniMed™ Paradigm insulin pumps are not affected by this condition.*
You can report a concern to the FDA's MedWatch Adverse Event Reporting program, online at:
http://www.fda.gov/safety/medwatch/howtoreport/
Report by telephone: 1-800-FDA-1088/Fax report: 1-800-FDA-0178.

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

Sincerely,

James Dabbs
Vice President, Quality Assurance
Medtronic Diabetes

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