

URGENT: FIELD CORRECTIVE ACTION
MiniMed™ 640G Insulin Infusion Pump
Power Error 25

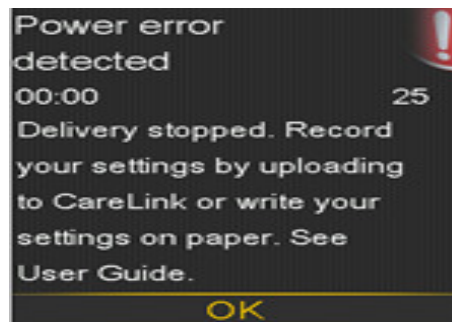
XX February 2017

Dear Healthcare Professional:

Medtronic is committed to keeping you and your patients informed of potential issues and associated solutions related to our products and services. The purpose of this letter is to inform you of an issue potentially affecting the MiniMed 640G insulin pump.

Issue:

Medtronic has identified a software issue that could prevent the internal battery of the pump from charging. Should this software issue occur, an alarm is triggered and you will see the following message displayed on the pump screen:



Medtronic has identified the specific pumps potentially affected by this issue and have determined that one or more of your patients may be affected. Therefore we are proactively sending a communication to those patients to have them contact the Medtronic Helpline if they receive a Power Error 25 alarm. Please make sure your patients who receive the notification letter contact the Medtronic HelpLine if they experience a Power Error 25 alarm. If you have a patient with a MiniMed 640G insulin pump who did not receive a notification, this means their pump does not contain the software issue.

Please contact our Customer Support team at 1800 777 808 if you have any questions.

We appreciate your time and attention to this important notification and we apologize for the disruption.

The safety of your patients and their complete satisfaction are our first priority and we appreciate your time and attention to this important notification

Sincerely,

Manish Kapoor
Regional Business Director
Medtronic Diabetes

Enclosed: Physician/HCP Reply Form