

## **Urgent Field Safety Notice**

### **MiniMed™ 640G Insulin Infusion Pump**

#### **Power Error 25**

February 2017

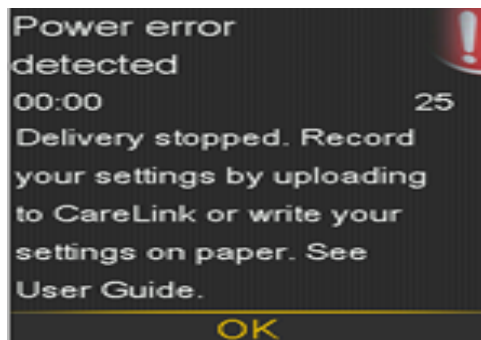
Medtronic reference: FA749

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 your patients' MiniMed 640G insulin pump.

#### **Issue:**

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



Medtronic has identified the specific pumps potentially associated with this issue and has determined that your facility has received one or more potentially affected pumps, see attached. **Because Medtronic does not have your patients' records on file, we ask you to inform patients who use a potentially affected 640G pump using the enclosed letter.**

In the event you are contacted by a patient who has experienced a power error 25, please advise the patient to contact Medtronic for assistance.

It is important to note that only 640G pumps on software version 2.6 are potentially affected by this issue. Patients who have a 640G pump with software version 2.9 are not impacted by this issue and don't need to be notified.

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

The safety of your patients and their complete satisfaction are our first priority and we appreciate your time and attention to this important notification. Please contact our Customer Support team directly on tel.no. 015111 444 if you have any questions.

Sincerely,



Keith Taverner

Regulatory Affairs Manager UK & Ireland.