

Urgent Field Safety Notice **MiniMed™ 640G Insulin Infusion Pump** **Power Error 25**

February 2017

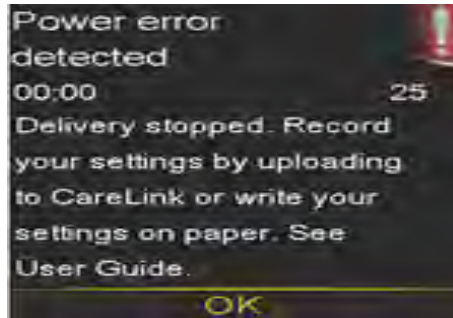
Medtronic reference: FA749

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 one or more of your patients has a potentially affected pump. Therefore we are sending a communication (see attached) to those patients to have them contact the Medtronic Helpline if they receive a power error 25 alarm.

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 will not 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 at XXXXXXXX if you have any questions.

Sincerely,

Urgent Field Safety Notice MiniMed™ 640G Insulin Infusion Pump Power Error 25

February 2017

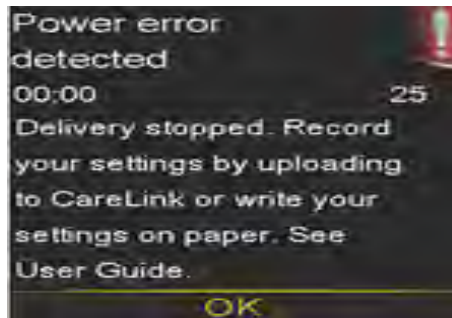
Medtronic reference: FA749

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 at XXXXXXXX if you have any questions.

Sincerely,

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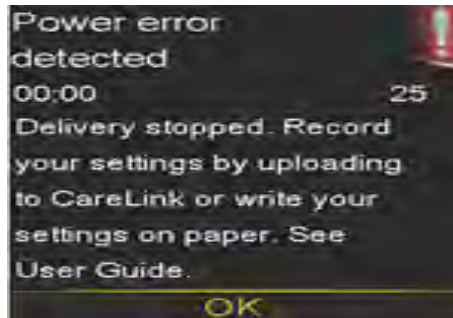
Medtronic reference: FA749

Dear Distribution Partner/ Service Provider,

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.

What action do I need to take?

- Inform the customers to whom you have provided potentially affected pumps of this notification using the attached patient or HCP 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 at **XXXXXXXX** if you have any questions.

Sincerely,



MiniMed™ 640G Insulin Infusion Pump Power Error 25

February 2017

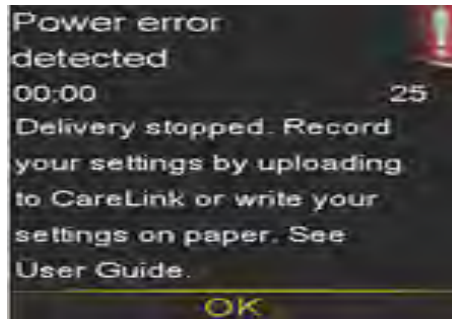
Medtronic reference: FA749

Dear pump user,

Medtronic is committed to keeping you and your healthcare professional 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 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 you will see the following message displayed on the pump screen:



If you experience this alarm and see the "Power error detected" message on your pump accompanied by the number "25", contact the Medtronic HelpLine at **XXXXXX** for assistance with troubleshooting the error.

Recommendations:

1. If you see a power error 25 alarm, contact Medtronic's Helpline at **XXXXXXXX**.
2. The Helpline will assist you in troubleshooting the alarm and determining next steps, including the potential replacement of your pump.
3. Should you have any questions or concerns regarding this issue please do not hesitate to contact Medtronic HelpLine at **XXXXXXXX** or your healthcare professional.

Your safety and complete satisfaction are our first priority and we appreciate your time and attention to this important notification.

Sincerely,