

Medtronic

Urgent Field Safety Notice Pump Motor Issue with the MiniMed® 640G System Recall

September 2015

Medtronic reference: FA680

Dear Healthcare Professional:

Medtronic has become aware of an issue potentially affecting specific MiniMed 640G insulin pumps. The pump drive motors may experience a malfunction, which would result in a pump error message alarm notifying the pump user that insulin is no longer being delivered. Medtronic has identified the cause of the issue and it has been corrected in the current manufacturing of the MiniMed 640G. Through September 22 there have been no reported failures from customers as a result of this issue.

Medtronic has identified the specific pumps potentially associated with this issue and has determined that one or more of your patients may have an affected pump. Therefore we are proactively replacing those patient's pumps.

A notification letter explaining the issue will be sent with the replacement pump and packaging to return affected pumps to us.

Please make sure your patients who receive a new pump and notification letter switch over to the replacement pump and return the old pump to us as quickly as possible. Please also work with your patients to put the appropriate settings into their replacement pump.

If you have a patient with a MiniMed 640G insulin pump who did not receive a replacement pump and notification, this means their pump is not affected by this motor issue, and they can continue using their insulin pump.

Pump versions related to this report notification:

- MiniMed 640G insulin pump (MMT-1711 & MMT-1712)
Note: This recall does not affect other MiniMed pump models.

Instructions to return affected MiniMed 640G insulin pump:

If there any affected pumps in your hospital inventory or retrieved from patients, please return these to Medtronic using the included pre-paid packaging.

Please contact our Customer Support team if you have any questions.

Medtronic is committed to keeping you and your patients informed of issues and solutions concerning our products and services.

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

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

Sincerely,

Appendix 1: Patient Letter

Medtronic

Pump Motor Issue with the MiniMed® 640G System

September 2015

Medtronic reference: FA680

Dear Valued Customer:

Medtronic has become aware of an issue potentially affecting specific MiniMed 640G insulin pumps. The pump drive motors may experience a malfunction, which would result in a pump error message alarm notifying you that insulin is no longer being delivered. Medtronic has identified the cause of the issue and it has been corrected in the current manufacturing of the MiniMed 640G. Through September 22 there have been no reported failures from customers as a result of this issue.

Medtronic has determined that your pump may be affected. Therefore we are proactively replacing your pump with the enclosed replacement pump.

Please work with your healthcare professional to put your settings into your new pump. Medtronic encourages you to switch over to the replacement pump and return the old pump to us as quickly as possible, to avoid the potential for interrupted therapy.

Pump versions affected by this recall:

- MiniMed 640G insulin pump (MMT-1711 & MMT-1712)
Note: This recall does not affect other MiniMed pump models.

Return of the affected MiniMed 640G insulin pump:

After successfully programming your replacement 640G pump, return your affected pump to Medtronic using the included pre-paid packaging.

Please contact our Customer Support team if you have any questions. Your healthcare professional has been informed of this situation and can also provide guidance.

Medtronic is committed to keeping you and your healthcare professional informed of issues and solutions concerning our products and services.

We appreciate your time and attention to this important update and apologize for any inconvenience this exchange may cause you. We are pleased to be a partner in your diabetes management.

Sincerely,