

URGENT: Medical Device Recall Notification

Pump Motor Issue Report Notification with the MiniMed® 640G System

September XX, 2015

Dear Valued Customer:

Medtronic is committed to keeping you and your healthcare professional informed of issues and solutions concerning our products and services. 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. To date, 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 this enclosed replacement pump, to eliminate the risk of this potential motor issue. Please work with your healthcare professional to put your settings into your new pump. Medtronic has also included pre-paid packaging to return your current pump to us. 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 of therapy interruption.

Pump versions related to this report notification:

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

Instructions to return your affected MiniMed 640G insulin pump:

XXXXXXXX – [Will be specific to each local market and will be filled in during localization process of letters]

This is a product recall and exchange of the MiniMed 640G insulin pump.

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

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,

Insert local regional leader name>
Insert local regional leader title>
Medtronic Diabetes