Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

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 your facility has received one or more pumps from the affected population. Please see attached list. New pumps will arrive at your facility within the next days to replace these potentially affected pumps.

Please inform the patients to whom you have provided potentially affected pumps using the attached letter and make sure that the potentially affected pumps will be replaced and returned to us as soon as possible. Please also work with your patients to put the appropriate settings into their replacement pump.

If you have previously received additional MiniMed 640G insulin pump that are not mentioned in the attached list, this means these pump are not affected by this motor issue.

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.

<u>Instructions to return affected MiniMed 640G insulin pump:</u>

Please return affected pumps in hospital inventory and received from patients to Medtronic via your Direct Field Contact.
Please contact our Customer Support team at Tel no. + 353 1 511 1400 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,
Keith Taverner
Regulatory Affairs Manager UK & Ireland
Appendix 1: Patient Letter
Appendix 2: List of affected serial numbers shipped to your facility