

Urgent Field Safety Notice

SynchroMed® II Implantable Infusion Pump Design Enhancements Models 8637-20, 8637-40 Device Retrieval

1 March 2016

Medtronic reference: FA696

Dear Customer,

Medtronic has incorporated enhancements to the SynchroMed® II pump which decrease the potential for internal electrical shorting and motor corrosion that can cause loss of therapy. With this communication, there is no new information to share regarding the safety or performance of the SynchroMed II pump. These enhancements are part of Medtronic's ongoing activities around monitoring and improving upon device performance. All SynchroMed II pumps are now being manufactured with these changes.

This letter is to inform you that your Medtronic Representative will review your inventory and retrieve any unused SynchroMed II pumps that were manufactured prior to the design changes mentioned above. For your information, SynchroMed II pumps manufactured prior to the design changes can be identified based on Use By date as shown below:

Any pump with a Use By date **on or before** 14/May/2017 was manufactured **prior to** design changes.

SynchroMed II -- Shelf Box Side Label



Use By Date

Information regarding internal electrical shorting and motor corrosion has been communicated previously in field safety notifications issued by Medtronic in November 2012 (Medtronic ref. FA553) and May 2013 (Medtronic ref. FA574). This information can be found under the advisory sections for chronic pain and severe spasticity therapy at professional.medtronic.com.

Medtronic has notified the Competent Authority of your country of this action.

If you have any questions related to the retrieval of SynchroMed II pumps manufactured prior to the design changes, please contact your Medtronic representative directly or via Tel No. +353 1511 1400. We appreciate your assistance with this matter and apologize for the disruption and inconvenience. We remain committed to providing you with the highest quality products and services.

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland