

Urgent Field Safety Notice
SynchroMed® II Implantable Drug Infusion Pump
 Design Change of Model Numbers 8637-20 and 8637-40

November 2017

Medtronic reference: FA794

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic has received approval to implement a design change to the SynchroMed® II implantable drug infusion pump that reduces the likelihood for non-recoverable motor stall, which can cause loss of therapy. For pumps manufactured prior to this design change, analysis of our post-market data¹ estimates the pump survivability specific to non-recoverable motor stall at six years post-implant to be 97.3%² for pumps exposed to on-label drugs and 91.1%² for pumps exposed to off-label drugs. This is detailed in the table below:

Pump Survivability Specific to Non-Recoverable Motor Stall

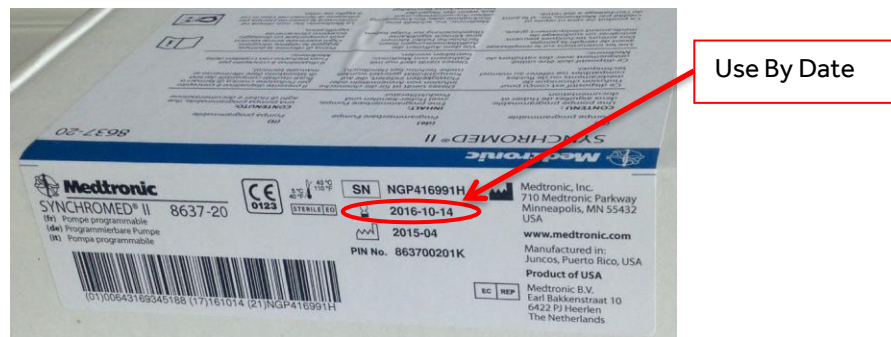
	Years Post-Implant					
	1	2	3	4	5	6
On-Label drugs	>99%			98.8%	97.8%	97.3%
Off-Label drugs				98.1%	95.4%	91.1%

The most common contributing factor to motor stall is shaft wear and this is observed in 59% of SynchroMed II pumps returned and analyzed for motor stall. Engineering testing estimates that this new design change addresses over 99% of shaft wear and will decrease the occurrence of motor stall.

Medtronic recommends the SynchroMed II infusion system be used according to approved product labeling. Reliability for SynchroMed II pumps used with off-label drugs will still be lower than pumps used with on-label drugs, regardless of indication.

All SynchroMed II pumps are now manufactured with the new design change, although there are limited quantities of these new devices available. To ensure your patients have access to uninterrupted therapy, pumps manufactured prior to this latest change will remain available. Once there is sufficient inventory of the pumps with the new design, we will no longer distribute pumps manufactured prior to this change.

Pump Identification: in Europe, Middle East, Africa, Latin America and India any pump with a Use By Date **on or before** 2018-12-31 was manufactured **prior to** design change. An image of the Shelf Box Side Label of the SynchroMed II is shown below.



¹ Post market surveillance data for this analysis used 8,204 SynchroMed II pumps enrolled through April 30, 2017 in Medtronic’s prospective, long-term multi-center registry study (PSR).

² Survivability = [1] – [cumulative probability of non-recoverable motor stall at six years post-implant].



Additional Information

Implementation of this change completes a series of three design improvements that address contributing factors of motor stall. Medtronic initiated distribution of SynchroMed II pumps with the first two design changes in January 2016. These design changes addressed motor corrosion of the drive gear and internal electrical shorting, observed in 2% and 14% respectively, of pumps returned and analyzed for motor stalls. Engineering testing estimates that these design changes address over 93% of corrosion of the drive gear and over 96% of internal shorting.

The use of off-label drugs is known to reduce pump reliability, as published in our Product Performance Report, which can be found at medtronic.com/advisories.

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

Please share this notification with others in your organization as appropriate. In case of any questions related to this Urgent Field Safety Notice Update, contact your Medtronic Representative at.

Medtronic is committed to patient safety and continues to actively monitor performance of the SynchroMed System through our extensive patient registry, which includes over 8.200 SynchroMed II pumps at 64 centers through April 30, 2017.

Sincerely,
Medtronic