

Medical Device Safety Notification
SynchroMed® II Implantable Drug Infusion Pump Design Change
Model Numbers 8637-20, 8637-40

January 2017

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 in initial production. To ensure your patients have access to uninterrupted therapy, pumps manufactured prior to this latest change will remain available subject to certain requirements and conditions. Once there is sufficient inventory of the pumps with the new design, we will no longer distribute pumps manufactured prior to this change.

Actions

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).

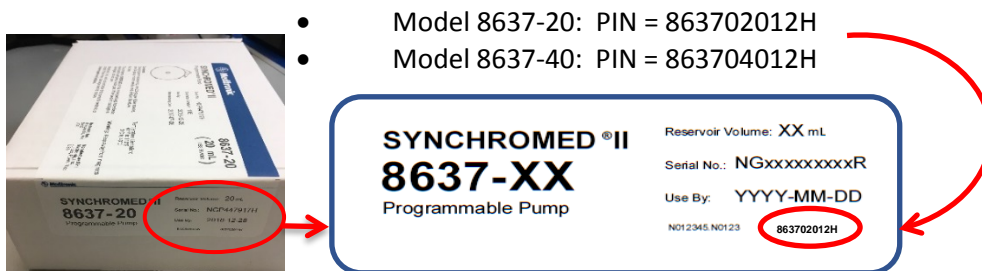
² Survivability = [1] – [cumulative probability of non-recoverable motor stall at six years post-implant].

Please respond to Medtronic confirming that you have received this notification by completing and returning the enclosed physician confirmation form.

Pump Identification

For your information, within the USA, SynchroMed II pumps manufactured **prior to the incorporation of this design change** can be identified by the Product Identification Numbers (PIN) ending in “12H” as shown below:

Location of the Product Identification Number for pumps manufactured prior to incorporation of this 2017 design change



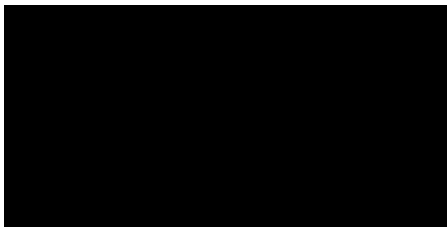
Additional Information

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. This site also provides access to our November 2012 safety notification titled *Use of Unapproved Drugs with the SynchroMed II Implantable Infusion Pump*.

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. Physicians with device related questions can contact Technical Services at 1-800-707-0933 weekdays 7am-6pm CT. We appreciate your assistance with this matter and apologize for any disruption or inconvenience.

Yours Sincerely,



Shirley Loh
Marketing Director

Enclosure
Appendix 1: Physician Confirmation Form

cc Chairman Medical Board and relevant Head of Departments

Appendix 1: PHYSICIAN / HCP REPLY FORM

Important information regarding SynchroMed® II Implantable Drug Infusion Pump Design Change

December 2017

Dear Physician / Healthcare Professional,

According to our records, you are currently the managing physician for patients implanted with SynchroMed® II Implantable Drug Infusion Pump.

Medtronic requires confirmation that you have received and understand the attached information regarding the SynchroMed® II Implantable Drug Infusion Pump device correction.

Confirm physician name (please print)

Facility Name and Stamp (please print)

Physician signature and stamp

Date

Please sign and date this form and return it to Medtronic immediately, providing any corrections to your contact information. Thank you.

Return this form (keep a copy for your records) to:

POSTAL MAIL:

Medtronic International Ltd., 49 Changi South Avenue 2, Singapore 486056

FAX:

+65 6776 6355