

**Urgent Field Safety Notice**  
**SynchroMed® II Implantable Infusion Pump**  
**Models 8637-20,8637-40**  
 Recall

October 2019

Medtronic reference: FA889

Dear Healthcare Professional,

This letter is to inform you that Medtronic is voluntarily retrieving specific SynchroMed® II Implantable Drug Infusion Pumps, Models 8637-20 and 8637-40, after investigating complaints related to permanent motor stall. This recall is being conducted due to the potential for the presence of a foreign particle inside the pump motor assembly which could interfere with motor gear rotation and lead to a permanent motor stall. The source of the foreign particle has been identified and eliminated.

**Issue Description**

A permanent pump motor stall will result in cessation of drug infusion therapy which may result in return of underlying symptoms and/or withdrawal symptoms. For patients receiving intrathecal baclofen therapy, there exists the risk for Baclofen Withdrawal Syndrome, which can lead to a life-threatening condition. As of 30-SEP-2019, Medtronic has confirmed five (5) reports of early permanent motor stall due to the presence of foreign particles from a manufacturing process. Of the five events, two (2) were identified prior to implant; the other three (3) occurred within 5 months of implant. In each case, the pump alarm functioned properly.

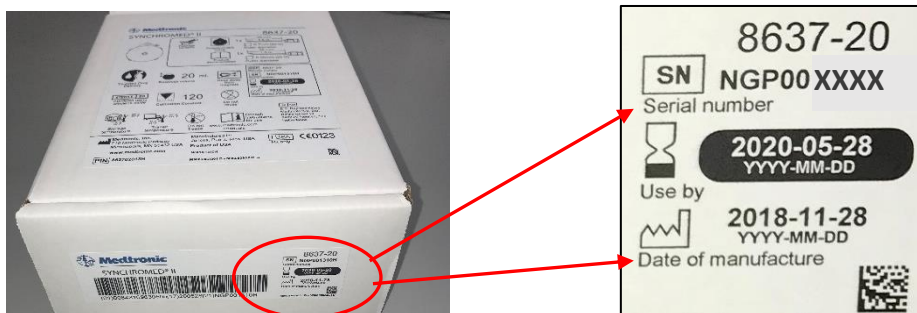
Medtronic is **not** recommending prophylactic replacement of potentially affected SynchroMed II pumps, due to the low observed occurrence of motor stall from this issue, the presence of pump alarms, and the risks associated with replacement surgery.

**Product Scope**

Refer to Appendix A for a listing of all device serial numbers potentially affected by this recall that, according to our records, are in your inventory. Additionally, you can verify whether your unused inventory is affected by this recall using a serial number lookup tool located at this Medtronic website: <http://mdt20-05fp.medtronic.com/>

**Pump Identification**

The SynchroMed II pumps that are affected and in scope of this recall can be identified by the serial number and date of manufacture on the box label, as shown below.



*Note: All affected devices fall within a manufacture date range of 04-MAY-2018 through 05-APRIL-2019(2018-05-04 to 2019-04-05), however not all serial numbers within this date range are affected.*

**Actions**

Using the enclosed Appendix, A and/or serial number lookup website:

- Identify and quarantine all unused affected product in your inventory.
- Return all unused affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary

This notice needs to be forwarded to all those who need to be aware within your organization and to any organization where the affected product may have been transferred. This information will also be available on Medtronic's website at [www.medtronic.com/tddproductadvisories](http://www.medtronic.com/tddproductadvisories).

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

We appreciate your assistance and regret the inconvenience this causes you. If you have questions or require assistance, please contact your Medtronic Field Representative.

Sincerely,

Ziad Kassir  
Business Manager, Pain, APS

**Enclosure:** Appendix A

Appendix A. Serial number list :

<b>Product/Model number</b>	<b>Serial number</b>
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV650397H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV650373H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV650356H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV650318H
PUMP 8637-40 SYNCHROMED II L105	NGV611400H
PUMP 8637-40 SYNCHROMED II L105	NGV611371H
PUMP 8637-40 SYNCHROMED II L105	NGV611330H
PUMP 8637-40 SYNCHROMED II L105	NGV611320H
PUMP 8637-40 SYNCHROMED II L105	NGV611180H
PUMP 8637-40 SYNCHROMED II L105	NGV611161H
PUMP 8637-40 SYNCHROMED II L105	NGV611136H
PUMP 8637-40 SYNCHROMED II L105	NGV611133H
PUMP 8637-40 SYNCHROMED II L105	NGV611127H
PUMP 8637-40 SYNCHROMED II L105	NGV611125H
PUMP 8637-40 SYNCHROMED II L105	NGV611113H
PUMP 8637-40 SYNCHROMED II L105	NGV611103H
PUMP 8637-40 SYNCHROMED II L105	NGV611090H
PUMP 8637-40 SYNCHROMED II L105	NGV611087H
PUMP 8637-40 SYNCHROMED II L105	NGV611082H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV003498H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV003443H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV002008H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV002006H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV002005H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV002003H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV001997H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV001665H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV001644H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV001640H
PUMP 8637-40 SYNCHROMED II L088 E-MANUAL	NGV001465H
PUMP 8637-20 SYNCHROMED II L105	NGP615505H

PUMP 8637-20 SYNCHROMED II L105	NGP615491H
PUMP 8637-20 SYNCHROMED II L105	NGP615490H
PUMP 8637-20 SYNCHROMED II L105	NGP615488H
PUMP 8637-20 SYNCHROMED II L105	NGP615487H
PUMP 8637-20 SYNCHROMED II L105	NGP615479H
PUMP 8637-20 SYNCHROMED II L105	NGP615475H
PUMP 8637-20 SYNCHROMED II L105	NGP612852H
PUMP 8637-20 SYNCHROMED II L105	NGP612849H
PUMP 8637-20 SYNCHROMED II L105	NGP612848H
PUMP 8637-20 SYNCHROMED II L105	NGP612844H
PUMP 8637-20 SYNCHROMED II L105	NGP612841H
PUMP 8637-20 SYNCHROMED II L105	NGP612839H
PUMP 8637-20 SYNCHROMED II L105	NGP612837H
PUMP 8637-20 SYNCHROMED II L105	NGP612835H
PUMP 8637-20 SYNCHROMED II L105	NGP612834H
PUMP 8637-20 SYNCHROMED II L088 E-MANUAL	NGP002152H
PUMP 8637-20 SYNCHROMED II L088 E-MANUAL	NGP002078H
PUMP 8637-20 SYNCHROMED II L088 E-MANUAL	NGP002076H
PUMP 8637-20 SYNCHROMED II L088 E-MANUAL	NGP002056H
PUMP 8637-20 SYNCHROMED II L088 E-MANUAL	NGP002048H
PUMP 8637-20 SYNCHROMED II L088 E-MANUAL	NGP002030H