

URGENT MEDICAL DEVICE CORRECTION

SynchroMed® II Implantable Drug Infusion Pump Audible Alarm

Dear Healthcare Professional,

The purpose of this letter is to provide you with important information regarding a potential malfunction of the critical and non-critical audible alarms of a finite subset of Model 8637-20 and 8637-40 SynchroMed® II implantable drug pumps (based on serial number). The cause of this issue has been addressed, and therefore only products identified by this notification are potentially affected.

Nature of the Device Issue:

The SynchroMed II pump sounds an alarm when critical and certain noncritical pump events occur. This audible alarm functionality is confirmed for each pump during the manufacturing process and is operational at that time. However, it has been identified that some pumps may have a damaged component that could result in a subsequent failure of the alarm to sound. Otherwise, the pump operates as intended. If the audible alarm fails to sound, any event that triggers the alarm function is time-stamped and logged in the device Event Log for subsequent review. The event will also be visually displayed on the Model 8840 Clinician Programmer and on the Model 8835 Personal Therapy Manager (myPTM®) following interrogation.

Scope and Likelihood of the Issue:

Medtronic has performed analysis which indicates the potential for this issue to result in latent audible alarm failure is approximately 0.3%. As of April 14, 2015, Medtronic has received no complaints of audible alarm failure due to this issue and is not aware of any occurrences of patient injury related to this issue.

The enclosed *Physician Patient Detail Report* identifies your patients who, according to our records, are implanted with a pump from the potentially affected population, which was manufactured from December 2014 to February 2015. The following website may also be used to identify (based on pump serial number) whether a specific SynchroMed II pump is potentially affected by this audible alarm issue: <http://synchromed2alarm.medtronic.com>

The potential for patient injury exists if the pump ceases to deliver therapy due to alarm events, such as empty drug reservoir, and the audible alarm ceases to function and therapy cessation goes unnoticed due to the lack of audible alarm sound. Alarm conditions include: low or empty drug reservoir; pump end-of-service; pump motor stall; pump is stopped for longer than 48 hours; and critical pump memory error.

Recommendations:

Medtronic does not recommend prophylactic replacement of SynchroMed II pumps, due to the estimated low probability of audible alarm failure as compared to the risks associated with pump replacement surgery. However, consideration should be given to individual patient medical needs.

Please refer to the patient management recommendations below for the patients identified on your enclosed *Physician Patient Detail Report*.

Patient Management Recommendations:

- For those patients with a potentially affected pump, explain to the patient and include a copy of this notification in the patient's medical record so that other healthcare professionals who may treat the patient will be aware of this information.

- Consider reviewing pump event logs at each visit to identify any alarm events.
- Consider conducting an alarm test at each visit to confirm the pump alarm remains audible.
- If the alarm does not sound, contact Medtronic Technical Services for assistance in trouble shooting the alarm test results. If it is confirmed that the alarm does not sound, consider whether pump replacement would be most beneficial for that patient.
- Reinforce with patients and caregivers information on the signs and symptoms of drug withdrawal due to therapy cessation, and the importance of contacting their provider immediately if these signs or symptoms are experienced.
- Inform patients about the importance of keeping their pump refill appointments and remind them as necessary.

Additional Information:

The US Food and Drug Administration (FDA) has been made aware of this SynchroMed II pump issue. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services, at 1-800-707-0933 available weekdays from 7am – 6pm Central Time, and to FDA's MedWatch Program (www.fda.gov/medwatch).

We value your partnership in infusion therapy and apologize for the disruption and inconvenience caused by this issue. We are committed to continuing to improve our product performance to enable you to manage your patients in a safe and effective manner.

Sincerely,

Michael Crader
Vice President Quality
Medtronic Neuromodulation

Enclosures:

Physician Confirmation Form & Reply Envelope

Physician Patient Detail Report

Instructions to initiate an Alarm Test on the 8840 Clinician Programmer

Instructions to review Event Logs on the 8840 Clinician Programmer