



Urgent Field Safety Notice

SynchroMed[®] II Implantable Drug Infusion Pump Potential for Audible Alarm to Cease Functioning Patient Management Recommendations

23 April 2015

Medtronic reference: FA649 Phase II

Dear Healthcare Professional/Risk Manager,

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), which were manufactured between December 2014 and February 2015. 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.

Our records indicate that your facility has received one or more SynchroMed II pumps from the potentially affected population of devices. The Risk/Inventory Manager of your hospital was informed about this issue as well and has been requested to return unused affected devices to Medtronic.

The following website may 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 implanted with a potentially affected device.



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 is still audible.
- If the alarm does not sound, contact your Medtronic representative 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.

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

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,

Enclosures:

Instructions to initiate an Alarm Test on the 8840 Clinician Programmer

Instructions to review Event Logs on the 8840 Clinician Programmer



Urgent Field Safety Notice **Updated Scope**

SynchroMed® II Implantable Drug Infusion Pump Potential for Audible Alarm to Cease Functioning

23 April 2015

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Dear Customer/Risk Manager,

This is a follow-up to the Medtronic Neuromodulation Field Safety Notice (FSN) titled "*Urgent field Safety Notice – SynchroMed® II Implantable Drug Infusion Pump – Potential for Audible Alarm to Cease Functioning*" sent on xx April 2015. This FSN was related to a voluntary removal of a finite subset of Model 8637-20 and 8637-40 SynchroMed® II implantable drug pumps due to potential for the audible alarm to cease functioning. You received this initial FSN because our records identified that potential affected devices were shipped to your facility and you were requested to return remaining unused affected devices to Medtronic.

Further analysis of the issue by Medtronic has now concluded that the pump serial numbers that were shipped to your facility are not affected by this issue. As a result, no additional actions are necessary at your facility.

In case you shared information regarding a pending communication with HCP's related to patients implanted with an affected device, please inform them that affected devices were not shipped to your facility, and therefore there is no impact to their patients.

The following website may 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>

We apologize for any inconvenience this issue has caused you. If you have any questions, please contact your Medtronic representative at <xxxxxx>.

Sincerely,



Urgent Field Safety Notice **Updated Scope**

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This is a follow-up to the Medtronic Neuromodulation Field Safety Notice (FSN) titled "*Urgent field Safety Notice – SynchroMed® II Implantable Drug Infusion Pump – Potential for Audible Alarm to Cease Functioning*" sent on xx April 2015. This FSN was related to a voluntary removal of a finite subset of Model 8637-20 and 8637-40 SynchroMed® II implantable drug pumps due to potential for the audible alarm to cease functioning. You received this initial FSN because our records identified that potential affected devices were shipped to your facility and you were requested to return remaining unused affected devices to Medtronic.

We acknowledge that the devices returned by your facility have been received by Medtronic.

Further analysis of the issue by Medtronic has now concluded that the pump serial numbers that were implanted at your facility are not affected by this issue. As a result, no additional actions are necessary at your facility.

In case you shared information regarding a pending communication with HCP's related to patients implanted with an affected device, please inform them that affected devices were not implanted at your facility, and therefore there is no impact to their patients.

The following website may 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>

We apologize for any inconvenience this issue has caused you. If you have any questions, please contact your Medtronic representative at <xxxxxx>.

Sincerely,

Instructions to Review Event Logs on the 8840 Clinician Programmer



SynchroMed® II Infusion Systems


The Event Log records conditions in the pump and is used to:

- Log system data
- Diagnose pump status
- Alert or call attention

The following excerpt from the Model 8840/8870 N'Vision Programming Guide for SynchroMed® II infusion systems explains how to review event logs.

◆ *To view event logs*

1. Select the TOOL KIT screen tab ()
2. Select the EVENT LOG sub tab ()
3. If event logs have not been read from the pump during the current programming session, position the programming head over the pump, then select the GET LOGS button (Figure 56).
4. Select the events to be viewed from the Event Log Filter drop-down list (Figure 56).

Note: Event Logs can also be printed by selecting the PRINTER button () on the title bar, then selecting the Logs option to create a Print report.

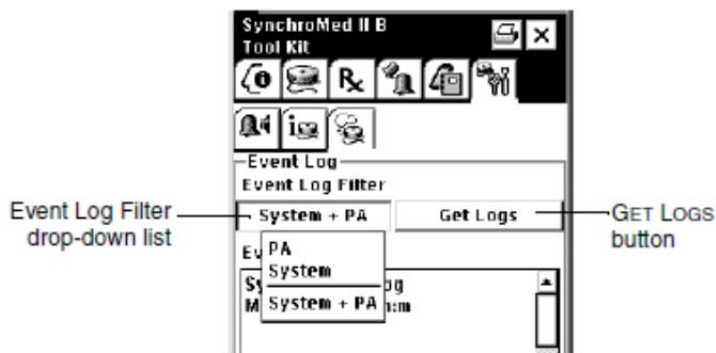


Figure 56. Viewing event logs.

Instructions to initiate an Alarm Test on the 8840 Clinician Programmer



SynchroMed® II Infusion Systems

The pump sounds an alarm when certain critical and noncritical pump events occur.

Alarm Type	Alarm Sound	Alarm Meaning	Available Intervals
Critical	Two tone 3 second duration	Imminent termination of therapy; immediate physician attention is needed	Default interval: 1 hour 10 minute increments from 10 minutes to 2 hours
Non-Critical	Single tone 1 second duration	Physician attention is needed	Default interval: 1 hour 1 hour increments from 1 to 6 hours

The following excerpt from the Model 8840/8870 N'Vision Programming Guide for SynchroMed® II infusion systems explains how to initiate an alarm test.

◆ **To initiate an alarm test**

1. Select the TOOL KIT screen tab (.
2. Select the ALARM TEST sub tab (.
3. Select the NONCRITICAL ALARM TEST button or CRITICAL ALARM TEST button (Figure 53).

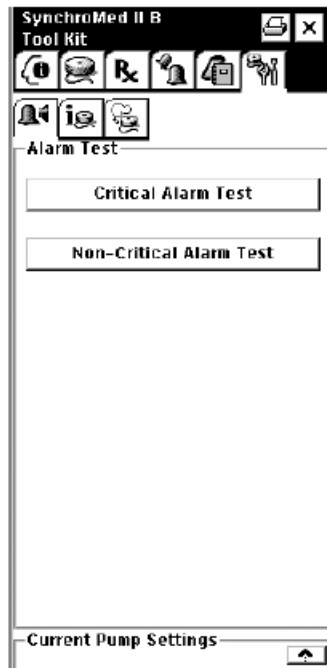


Figure 53. Testing alarms.

4. When the Alarm Test dialog box appears, position the programming head over the pump.
5. Hold the programming head steady over the pump, then press the PROGRAMMING key or select the OK button.
6. Once telemetry is successfully completed, the Telemetry Complete message appears. The programmer sounds a finished tone. Within seconds of the finished tone, the pump sounds the requested alarm.
7. Select the OK button.