Medtronic

Urgent Field Safety Notice

Model 8637 SynchroMed™ II

MRI Guidelines for the SynchroMed Infusion System

November 2023

Medtronic Reference: FA1367

EU Manufacturer Single Registration Number (SRN): SRN US-MF-000019977

Dear Healthcare Professional,

The purpose of this letter is to communicate the need to interrogate the SynchroMed II™ pump following Magnetic Resonance Imaging (MRI).

Issue Description:

The *MRI Guidelines Instructions for Use for Medtronic Model 8637 Implantable Infusion Systems* (MRI Guidelines) indicate that during normal operations, the magnetic field of the MRI scanner will temporarily stop the rotor of the SynchroMed II pump motor and suspend drug infusion for the duration of the MRI exposure. The pump should resume normal operation upon termination of MRI exposure.

Medtronic recently identified that if the SynchroMed II pump switches into telemetry mode due to electromagnetic interference (EMI) from an MRI scan, *while the pump is sounding an alarm*, the pump will **not resume** drug delivery after leaving the MRI magnetic field, which is inconsistent with the current labeling. In this case, drug delivery will only resume after performing a post-MRI pump interrogation with the Clinician Programmer (or Personal Therapy Manager) which will end telemetry mode.

If the SynchroMed II pump does not resume drug delivery after leaving the MRI magnetic field, patients may experience a return of underlying symptoms (i.e., pain or spasticity) due to loss of therapy, potentially requiring outpatient or inpatient management, and in severe cases (i.e., baclofen withdrawal), life-threatening or fatal withdrawal symptoms could occur.

From January 01 2019 through October 18 2023, Medtronic has received a total of 13 complaints related to this issue. The complaints reported non-serious underdose symptoms (i.e., withdrawal or return of symptoms) when a follow-up interrogation was not performed post-MRI. After the pump was interrogated, the issue was resolved, and therapy resumed.

Refer to Appendix 1 for product scope.

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Patient Management Recommendations:

- Upon completion of an MRI scan, interrogate the pump with the Clinician Programmer (or Personal Therapy Manager) to end telemetry mode and resume drug delivery.
- Consult the MRI Guidelines for additional information on MRI preparation and post-examination review, and motor stall recovery timing (see MRI Guidelines at www.manuals.medtronic.com).
- Remind your patients about the importance of interrogating the SynchroMed II pump after an MRI to ensure continuation of therapy.
- Educate patients, caregivers, and family members to recognize the signs and symptoms associated with intrathecal drug therapy underdose or withdrawal. Patients receiving intrathecal baclofen therapy (e.g., Lioresal Intrathecal) are at higher risk for adverse events, as baclofen withdrawal can lead to a life-threatening condition if not treated promptly and effectively.

Customer Required Actions:

- Share this notice with all those who need to be aware of this issue within your organization and maintain a copy of this notice in your records.
- Please complete and return the Customer Acknowledgment Form enclosed with this letter, acknowledging that you have received this information.

Additional Information:

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,
Medtronic

Enclosures:

- Appendix 1: Product Scope
- Customer Acknowledgment Form

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Appendix 1: Product Scope

Product Number/ CFN	UDI-Device Identifier (GTIN/UPN)
PUMP 8637-20 SYNCHROMED II (8637-20)	00613994518781, 00643169100831, 00643169345188, 00643169345195, 00643169345201, 00643169384101, 00643169384118, 00643169384125, 00643169384132, 00643169384149, 00643169384156, 00643169384163, 00643169508149, 00643169530119, 00643169630505, 00643169700901, 00643169700918, 00643169700925, 00643169700932, 00643169700949, 00643169700956, 00643169700963, 00643169700970, 00643169700987, 00643169700994, 00643169732247, 00643169732254, 00643169732261, 00643169732278, 00643169732285, 00643169732292, 00643169732308, 00643169732315, 00643169732322, 00643169732339, 00643169984219, 00643169999831, 00643169999848, 00643169999855, 00643169999862, 00643169999879, 00643169999886, 00643169999893, 00643169999909, 00643169999923, 00763000018733, 00763000018757, 00763000080600, 00763000122669, 00763000122676, 00763000122683, 00763000122690, 00763000122706, 00763000122720, 00763000122737, 00763000122744, 00763000122843, 00763000421731, 00763000421748, 00763000421755, 00763000421762, 00763000421779, 00763000421786, 00763000421793, 00763000421809, 00763000421816, 00763000421915, 00763000422608, 00763000604219, 00763000634094, 00763000689582, 00763000689599, 00763000689605, 00763000689612, 00763000689629, 00763000689636, 00763000689643, 00763000689667, 00763000689674, 00763000689681
PUMP 8637-40 SYNCHROMED II (8637-40)	00613994483195, 00643169100824, 00643169345218, 00643169345225, 00643169345232, 00643169384170, 00643169384187, 00643169384194, 00643169384200, 00643169384217, 00643169384224, 00643169384231, 00643169508156, 00643169530126, 00643169630512, 00643169701007, 00643169701014, 00643169701021, 00643169701038, 00643169701045, 00643169701052, 00643169701069, 00643169701076, 00643169701083, 00643169701090, 00643169732346, 00643169732353, 00643169732360, 00643169732377, 00643169732384, 00643169732391, 00643169732407, 00643169732414, 00643169732421, 00643169732438, 00643169984226, 00643169999930, 00643169999947, 00643169999954, 00643169999961, 00643169999978, 00643169999985, 00763000000004, 00763000000011, 00763000000028, 00763000000035, 00763000018740, 00763000018764, 00763000080747, 00763000122751, 00763000122768, 00763000122775, 00763000122782, 00763000122799, 00763000122805, 00763000122812, 00763000122829, 00763000122836, 00763000122850, 00763000421823, 00763000421830, 00763000421847, 00763000421854, 00763000421861, 00763000421878, 00763000421885, 00763000421892, 00763000421908, 00763000421922, 00763000422615, 00763000604202, 00763000634100, 00763000689476, 00763000689483, 00763000689490, 00763000689506, 00763000689513, 00763000689520, 00763000689537, 00763000689551, 00763000689568, 00763000689575

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FA1367 Customer Acknowledgement Form - Response is required

SynchroMed™ II MRI Guideline Update

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____Zip Code:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the notification regarding the use of the **SynchroMed™ II** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed **SynchroMed™ II** as required.

_____	_____	_____
Name: (print)	Signature:	Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO: rs.dusregulatory@medtronic.com