Medtronic
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www.medtronic.com

URGENT: MEDICAL DEVICE CORRECTION

Model 8637 SynchroMed™ II

MRI Guidelines for the SynchroMed Infusion System

21 November 2023 | 07:51 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

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 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 1, 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.

Patient Management Recommendations:

- Upon completion of an MRI scan, interrogate the pump with the Clinician Programmer 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 Confirmation Form enclosed with this letter, acknowledging that you have received this information.

Additional Information:

Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to your local Medtronic field representative.

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 local Medtronic field representative or rs.seaandfmplusfca@medtronic.com.

Sincerely,

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 21 November 2023 | 07:51 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director
Mainland and Island Southeast Asia

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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Physician Confirmation Form

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MRI Guidelines for the SynchroMed Infusion System

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately

Customer Contact Details		Medtronic Contact Details
Distributor / Hospital / Clinic / Physician / Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

By signing this form, I confirm that I have read the Urgent Medical Device Correction Notification Letter, dated 21 November 2023 | 07:51 SGT **from Medtronic regarding Medtronic regarding MRI Guidelines for the SynchroMed Infusion System and taken appropriate action. For questions, contact your local Medtronic field representative. Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic field representative.**

Note: The addressee may continue to receive reminders of this notice until a response is received.

Name (print): _____ Signature: _____ Stamp: _____ Date: DD MMM YYYY