References

1. MR Conditional: If the patient is implanted with a Medtronic SynchroMed II or SynchroMed III pump, MRI examinations of the entire body may be safely performed under the following conditions:

   - *1.5-Tesla (T) and 3-T horizontal cylindrical system for hydrogen imaging*
   - *Radio-frequency (RF) coil: Any type*
   - *Maximum spatial field gradient of 19T/m (1900 gauss/cm)*
   - *Maximum gradient slew rate: 200 T/m/s or less per axis*
   - *Maximum RF field intensity: First Level Controlled Operating Mode*
   - *Active scan time: The risk of heating increases for active torso scanning durations over 30 minutes*

   SynchroMed II and SynchroMed III pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

2. SynchroMed II pumps only: This will address the potential for the unlikely event that electromagnetic interference from the MRI scan causes a change to "safe state", the pump will automatically switch to minimum rate mode (infusion at 0.006 mL/day). The pump must be reprogrammed with a clinician programmer in order for proper infusion to resume.

3. 8637 SynchroMed II pumps only: Potential for delay in logging motor stall events
   In some cases, electromagnetic interference (EMI) from an MRI scan can interfere with normal event logging. If this occurs, it may cause the pump to switch into the telemetry mode. "Telemetry mode" is a state in which the pump is able to communicate with the clinician programmer. While in this state, the pump infuses normally; however, some error logging and the audible alarm for motor stall are suspended. If the pump switches into telemetry mode due to EMI, the pump resumes drug delivery after leaving the MRI magnetic field; however, pump motor stall and motor stall recovery detection function is not active until the post-MRI pump interrogation ends telemetry mode (refer to "Post- MRI examination review"). Due to this issue, if the interrogation is not performed upon completion of the MRI scan or shortly thereafter, review of the pump logs may indicate that the pump ceased drug delivery for an extended period of time, when in fact it had recovered normally. In this scenario, you may receive an erroneous "stopped pump period may exceed tube set" error message.

   Note: *In some cases, the SynchroMed II pump event log may not register motor stall recovery until after the pump has been interrogated a second time due to the effect of electromagnetic interference on the pump.*

4. SynchroMed II and SynchroMed III pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

SynchroMed™ Drug Infusion System
Brief Statement

This material should not be considered the exclusive source of information; it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events. For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI. If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. Medtronic products placed on European markets bear the CE mark and the UKCA mark (if applicable). For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

If you have any questions specific to the medicinal product that you are using this device to administer, please contact the Marketing Authorisation Holder.

When ITB is mentioned, we are considering Intrathecal baclofen (an anti-spastic) administered by an intrathecal drug delivery pump therapy. Medtronic provides only the intrathecal drug delivery pump and the catheter; the intrathecal baclofen, morphine or ziconotide is provided to the relevant healthcare professional by an external company.

Contact

Contact & Support:
For more information or to access the latest MRI labeling:
www.medtronic.com/mri

Additional Resources:

- SynchroMed™ II & III MRI Technical Manuals
- Clinician Programming Guide
- Intrathecal Drug Labeling

SynchroMed™ II & III MRI Guidelines

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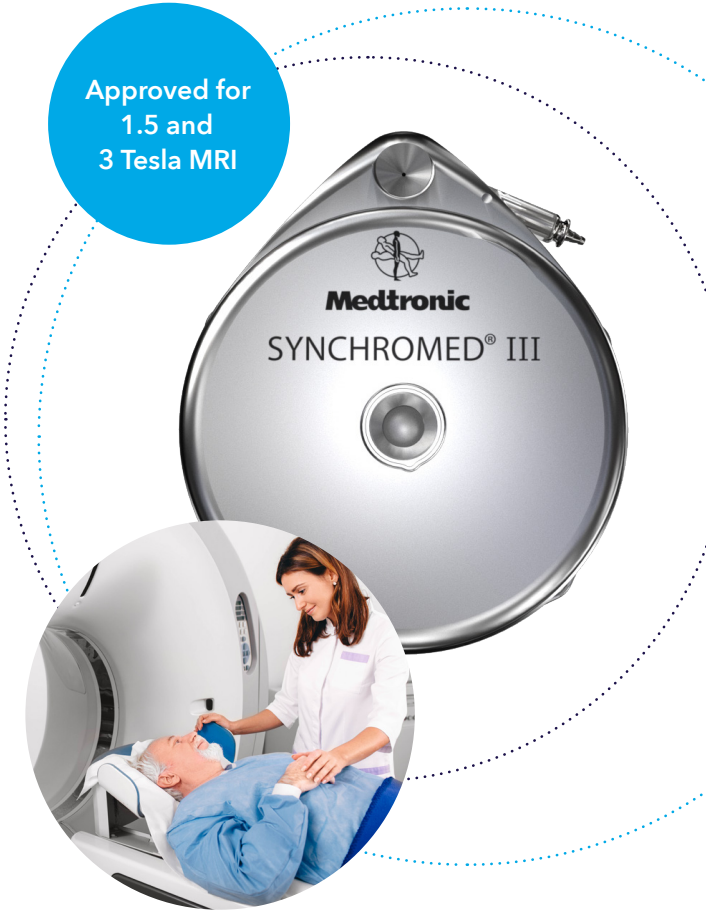
Medtronic
Engineering the extraordinary

SynchroMed™ II & III

Infusion System

MRI Safety Guide

Guidance for MRI procedures involving patients with implanted SynchroMed™ infusion pumps.



Convenience for you and your patient

1.5 and 3-Tesla MRI Approval for SynchroMed™ II & III Infusion System

During the MRI

- The MRI's magnetic field will temporarily stop the pump rotor, pausing drug delivery.
- Infusion should automatically resume once the MRI scan is complete.

Safety Considerations, Clinical Warnings & Key Notes:

- Avoid scanning for longer than 30 minutes over the torso to minimize risk of tissue heating.
- Patients may feel:
  - *A slight tugging sensation at the pump site (due to static magnetic field)*
  - *Peripheral nerve stimulation (due to gradient magnetic fields)*
  - *If the patient experiences discomfort or stimulation, stop the MRI scan and adjust the scan parameters to reduce the potential for nerve stimulation.*
- Motor Stall Risk:
  - *Detection of stall recovery will typically occur within 20 minutes of MRI completion (for pumps delivering ≥ 0.048 mL/day, delaying infusion restart for up to 24 hours.*
- Orientation Matters:[4]
  - *If the pump is aligned 90° to the MRI z-axis, there is a risk of permanent motor stall.*
- Critical Therapy Alert:
  - *Patients on intrathecal baclofen are at increased risk.*
  - *Baclofen withdrawal can be life-threatening – monitor closely.*

How to perform MRI in a patient with an implanted SynchroMed™ II & III pump

Before 1.5 or 3 Tesla MRI[1]

- Determine if the patient can safely be deprived of drug delivery during the MRI procedure.
- If not, arrange for medical supervision and/or alternative drug delivery during the scan.
- Stopping the pump is not recommended.
  - *Use of "stopped pump mode" may delay detection of a motor stall.*
- Ensure that a recording of the current infusion parameters is available in case reprogramming is needed after the MRI.[2]

After 1.5 or 3-Tesla MRI

- All pumps **must be interrogated** to confirm proper pump functioning.[3]
- When a motor stall occurred during the MRI:
  - *It will be recorded in the pump event log which will appear within the 20 minute period from the MRI exposure*
  - *An audible alarm will sound **within 20 minutes***
  - *Detection of stall recovery will typically occur within 20 minutes of MRI completion (for pumps delivering ≥ 0.048 mL/day) delaying infusion restart for up to 24 hours*
- A second interrogation may be needed in some cases to detect Motor Stall Recovery.
- If the SynchroMed™ II pump entered "safe state" due to MRI exposure:
  - *The pump must be reprogrammed to resume infusion. magnetic fields)*