



URGENT FIELD SAFETY NOTICE

InterStim[®], InterStim[®] II, Itrel[®]3 and Enterra[®]

Impact of Cycling Feature on Device Battery Longevity

9 January 2015

Medtronic Reference: FA639

Dear Healthcare Professional,

This letter is to notify you of updates to labeling related to the cycling feature in some Neurostimulation devices used for sacral nerve stimulation, gastric electrical stimulation and spinal cord stimulation. Current labeling indicates the use of cycling improves device longevity under every programming scenario; however, enabling cycling at certain parameter settings may decrease the device battery longevity. Further, anytime cycling is enabled, longevity estimation displayed on the N'Vision[®] Clinician Programmer (Model 8840) may not be accurate. There is no impact from this issue to therapy delivered or battery level notifications (i.e. LOW/EOL/EOS¹).

Issue Description:

Cycling is a programmable feature which allows the stimulation output of a device to toggle on and off based on programmed settings. Cycling is enabled, adjusted, and viewed by the N'Vision Clinician Programmer. Current labeling and the N'Vision Clinician Programmer provide longevity estimates which may not accurately account for the impact of cycling on device longevity under all programming scenarios.

Occurrence:

Medtronic has not received any complaints that have been confirmed to be the result of this issue. The potential hazard would be premature battery depletion requiring an earlier than anticipated device replacement.

Labeling Update:

References to the use of cycling for improved battery longevity, when compared to continuous mode, are not accurate for every combination of programmable parameters. If cycling is being used solely to improve device battery longevity, the information below should be considered.

InterStim (Model 3023), InterStim II (Model 3058), and Itrel 3 (Model 7425)

For patients with cycling enabled and pulse amplitudes greater than or equal to 1 Volt, the following cycling intervals may improve device battery longevity when compared to programming in continuous mode:

- Cycling intervals greater than or equal to 2 seconds ON and greater than or equal to 2 seconds OFF, without SoftStart/Stop[™] enabled

OR

- Cycling intervals greater than or equal to 60 seconds ON and greater than or equal to 60 seconds OFF, with SoftStart/Stop enabled and programmed at greater than or equal to 4 seconds

¹ EOS – End of Service, EOL – End of Life.



NOTE: Cycling at intervals less than those noted above with pulse amplitudes less than or equal to 1 Volt, may result in reduced device battery longevity, when compared to continuous mode. Anytime cycling is enabled, the longevity estimate provided by labeling and the N'Vision Clinician Programmer may not be accurate.

Enterra (Model 3116)

At the nominal settings there is no negative impact to battery longevity when compared to programming in continuous mode. Anytime cycling is enabled, the longevity estimate provided by the N'Vision Clinician Programmer may not be accurate.

Additional Information:

The Competent Authority of your country has been notified of this issue.

We appreciate your assistance with this matter and apologize for the inconvenience.

If you have questions, please contact your Medtronic sales representative at **-Gulf Medical 00 966 (2) 651 2828**

Sincerely,

Ayman Doughan
Neuro Modulation Business Manager,
Middle East and Africa