

URGENT FIELD SAFETY NOTICE

Activa® PC, Activa® PC+S, Activa® RC, Activa® SC, all Restore® devices (including SureScan®), PrimeADVANCED®, PrimeADVANCED® SureScan® MRI and Itrel® 4

Labeling Update on Device Longevity and Recharge Interval with Cycling Feature Enabled

Medtronic Reference: FA593

17 February 2014

Dear Healthcare Professional,

This letter is to notify you of corrections to labeling related to the cycling feature in some neurostimulation devices used for deep brain stimulation (DBS), peripheral nerve stimulation (PNS) and spinal cord stimulation (SCS). Current labeling indicates the use of cycling improves device longevity and recharge interval under all programming scenarios; however, enabling cycling at certain parameter settings may decrease the recharge interval for rechargeable devices and the device longevity of non-rechargeable devices. Furthermore, longevity calculations for non-rechargeable devices during SCS trialing with cycling enabled as calculated on the N'Vision® Clinician Programmer may not be accurate.

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 can only be enabled, adjusted and viewed by the N'Vision Clinician Programmer. Current labeling provides calculations which may not accurately account for the impact of cycling on device longevity or recharge interval under all programming scenarios.

Note: Elective Replacement Indicator (ERI) and End of Service (EOS) notifications will occur accurately, as designed, upon interrogation by the patient programmer, recharger and/or N'Vision Clinician Programmer.

Occurrence:

For the neurostimulation devices identified above, only those with cycling enabled have the potential to be affected by this issue. Since the release of the first Restore device in 2005, Medtronic has received 4 complaints all of which were associated with SCS therapy. In these cases, the outcome was premature battery depletion necessitating surgical intervention.

Recommendations:

- If you have patients with cycling enabled or wish to use cycling, use the updated calculations and graphs available online at professional.medtronic.com/cycling to assess the impact of cycling on device longevity. Medtronic will update the product labeling in the second half of 2014.
- Remind your patients to continue to check their battery status. Instructions on how to check battery status can be found in the patient programmer or recharger system manual.
- Pain Stimulation Trialing Only: The cycling feature should not be enabled on the External Neurostimulator (ENS) when estimating device longevity because the resulting longevity estimate for non-rechargeable devices may not provide accurate information.



Additional Information:

Medtronic has notified the Competent Authority of your country of this field safety corrective action. Please share this notification with others in your organization as appropriate.

We are committed to continuing to improve our product performance and services to enable you to manage your patients in a safe and effective manner.

If you have questions, please contact your Medtronic sales representative at: Gulf Medical
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Sincerely,

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