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Medtronic

Urgent Field Safety Notice

Verify™ External Neurostimulator (Model 3531)

Battery Replacement Guidance for Sacral Neuromodulation

May 2016

Medtronic reference: FA710

Dear Healthcare Professional,

The purpose of this letter is to reinforce the direction provided within the patient labeling which states:

"Do not replace the external neurostimulator batteries by yourself. Call your clinician."

Medtronic recently sent you a guidance document titled "Verify Evaluation System Step by Step Guide" that incorrectly indicated batteries could be replaced by the patient. To ensure continued delivery of stimulation therapy, battery replacement should be done under the supervision of a healthcare professional. Correct instructions for use can be found in the product labeling provided with the product. Medtronic has not received any complaints related to this issue.

Action required by Healthcare Professional:
Delete electronic files of the affected guide that you have may stored on your computer. In addition request that all individuals to whom you potentially provided the Verify Step-by-Step guide delete electronic files of the affected guide they may have stored on their computers and ensure these individuals are aware that if the ENS batteries deplete during a test stimulation period, they should contact their clinician.

Additional Information:
The Competent Authority of your country has been notified of this action.

If you have questions regarding Sacral Neuromodulation therapy, the Verify™ Evaluation System, or current labeling, please contact your sales representative directly or via Tel. No. 01923 212213

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland