

Urgent: Medical Device Safety Notification **InterStim™ Therapy Programmer Compatibility**

May 2019

Dear Health Care Provider,

This letter is to notify you of the potential for an unexpected increase in stimulation during InterStim programming with the A510 Clinician Application (on Medtronic's smart programmer). This issue may occur during device programming, which is performed by the healthcare professional in a clinical setting. Included in this notification are steps that can be taken to prevent the issue which you may have previously been made aware of via your Medtronic sales associate.

Background on Issue:

The issue occurs when enabling a new program on an InterStim implantable neurostimulator (INS) with the A510 Clinician Application if the InterStim INS has previously been interrogated or programmed with an N'Vision™ Clinician programmer (8840). This issue can result in the InterStim INS amplitude increasing from 0 volts immediately to the amplitude upper limit, rather than increasing in 0.05 – 0.5 volt increments. This has been reported while using the InterStim smart programmer handset with communicator and A510 Clinician Application (Models TH90G01 and TH90GFA). The A510 Clinician Application programming guide does not describe the use of both the smart programmer and legacy programmers, such as the N'Vision Clinician programmer, on the same INS.

The patient risk associated with this issue is temporary pain that subsides when the stimulation is stopped by the clinician (using the "Stop Therapy" button on the programmer screen). The temporary pain is due to the sudden stimulation at the maximum available amplitude setting rather than an increase in stimulation of 0.05-0.5volt increments.

Since January 2019, Medtronic has received ten (10) reports of amplitude increasing to maximum while using the smart programmer. During these events, patients have reported sudden painful stimulation that was immediately resolved when the onscreen "Stop Therapy" button was pressed by the clinician performing the programming.

Recommendation:

Avoid programming using the A510 Clinician Application on an InterStim INS that has previously been interrogated or programmed using the N'Vision Clinician programmer. See Figure 1 for images of both the N'Vision Clinician programmer and the smart programmer.

- Only use the N'Vision Clinician programmer to program InterStim INSs that are managed with iCon™ (Model 3037) patient programmers.
- Only use the smart programmer to program InterStim INSs that are managed with smart programmers.
- If the N'Vision Clinician programmer was used on an InterStim INS prior to using a smart programmer on the same INS, ensure that the maximum amplitude limit for all programs is either OFF or has a specific value set. Guidance for setting the amplitude limit can be found in the A510 Clinician App for Sacral Neuromodulation Therapy Clinician Programming Guide located on emanuals.medtronic.com.

If the issue is encountered and the amplitude increases to an undesired value, press the “Stop Therapy” button on the screen to immediately stop therapy. To complete programming and therapy adjustments, ensure that the maximum amplitude limit for all programs is either OFF or has a specific value set. At this point, amplitude can be increased at the expected interval.



N'Vision Clinician Programmer
Model 8840



Smart programmer handset with communicator
Models TH90G01 and TH90GFA

Figure 1 – InterStim therapy clinician programmers

Action Required:

Please sign and return the enclosed response form to acknowledge that you have read and understand this letter. Retain a copy of this letter and completed response form for your records.

Additional Information:

We appreciate your assistance with this matter and 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 related to this issue, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CDT. Please report any malfunction or adverse event related to a Medtronic product to Medtronic Neuromodulation Technical Services and to FDA's MedWatch Program (www.fda.gov/medwatch).

Sincerely,

Vice President Quality & Regulatory