

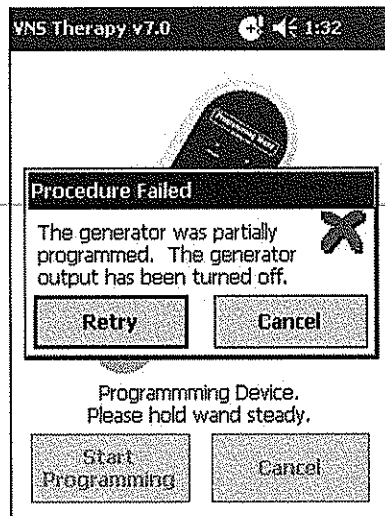


Important Safety Alert 4/09/07 – 3rd Notice

VNS Therapy™ Programming Software 8.0 milliamp Anomaly

Cyberonics, Inc. is notifying VNS Therapy practitioners of an anomaly associated with the Model 250 programming software used to program the implanted VNS Therapy generator. Through reports from field experience, Cyberonics has become aware of a rare event in which patients' VNS Therapy generators were inadvertently programmed to 8.0 milliamps (mA). The event has been observed in only six patients from among over 45,000 patients implanted with the VNS Therapy System. Five of the six patients reported experiencing pain, and one of these patients also reported coughing and shortness of breath during the stimulation; the sixth patient was asymptomatic. This programming event may occur with all Models 100 and 101 NCP Pulse Generators, and Model 102 and 102R VNS Therapy Pulse Generators, using any version of software on the programming system. This letter addresses the circumstances under which the event can occur, and the steps you should take to avoid its occurrence.

The event can occur if there is an interruption of communication during a programming parameter change sequence. An interruption of communication prompts a pop-up instruction screen requesting the user to "Retry" or "Cancel."



If the retry button is pushed within two seconds of the communication error, the software code sent to the generator can, on rare occasions, cause the generator to be programmed to 8.0 mA.

