Cyberonics ®

Important Safety Alert – 3rd Notice

VNS Therapy™ Software Model 250 Version 7.1 Handheld Computer Screen Freeze

Cyberonics, Inc. is notifying all VNS Therapy™ practitioners of an event that can occur with the VNS Therapy™ Software used with the Model 250 Handheld Computer. The programming software is used to program implanted VNS Therapy™ pulse generators.

According to reports from the field, the **Dell X5** handheld computer screen will freeze following an interrogation. Once frozen, the handheld device becomes non-responsive to user inputs. Cyberonics' investigation concluded that this event is related to the interaction between the Microsoft® 2002 operating system and the model **Dell X5** handheld computers. This event has not been seen with other combinations of Dell models (e.g. Dell X50) or with other versions of Microsoft operating systems.

Based on the risk assessment the event will not produce a direct adverse health consequence. However, indirect adverse health consequences could result from a delay in programming tasks.
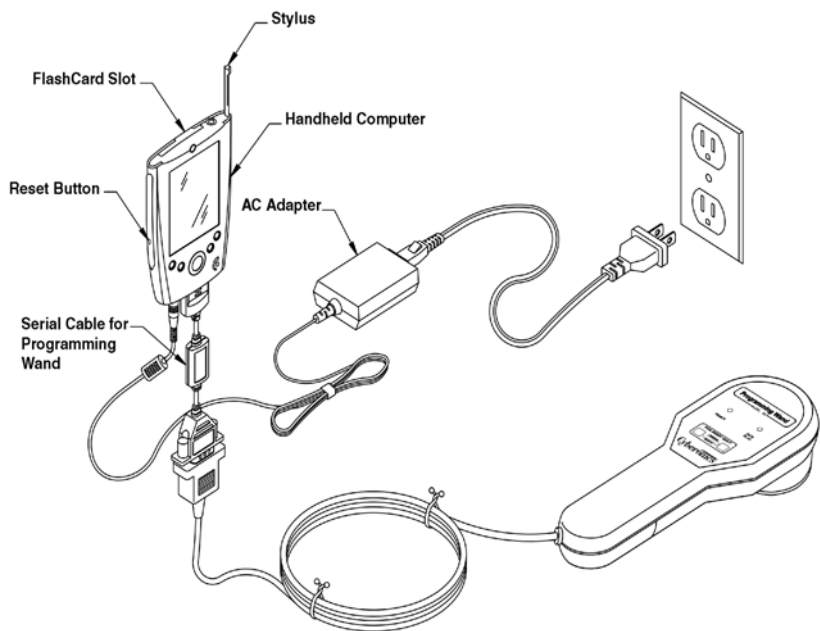
In the event that the handheld computer becomes non-responsive to a user's input due to a screen freeze, two options can be taken to resolve the issue during a programming event:

Option 1 - Reinitialize the flash memory (Recommended)
1. Remove the FlashCard for the handheld computer.
2. Allow the software to resume operation.
3. Reinsert the FlashCard into the handheld computer.
4. Continue normal use.

Option 2 – Perform a soft reset of the handheld computer
1. Press the reset button for 5 seconds.

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2. Allow the software to load
3. Continue normal use.

We have updated our labeling to include the different troubleshooting options to address screen freeze events. You can review these labeling changes at www.VNStherapy.com.

Please complete and return the enclosed receipt card as soon as possible. By returning this Effectiveness Check Card, you are acknowledging that you have read and understood this Safety Alert Letter. Returning the Effectiveness Check Card will also prevent repeat notifications of this Safety Alert.

If you need further information, please contact us at the following numbers:

United States customers may contact Clinical Technical Support at 866-882-8804 or via email at clinicaltechnicalservices@cyberonics.com

International customers may contact Clinical Technical Support at +32 - 2 - 720 95 93 or via email at europeclintechservices@cyberonics.com

The Safety Alert is being made with the knowledge of the US Food and Drug Administration.

We appreciate your assistance in this matter.

Sincerely,

Richard L. Rudolph, M.D.

Richard L. Rudolph, MD
Vice President, Clinical & Medical Affairs
and Chief Medical Officer