



May 27, 2015

WHAT HAS HAPPEN ED

Neuro Kinetics was informed of one instance of an 1-Portal NOTC system in which the 1-Portal chair spontaneously rotated after an 'Error' message was displayed at start-up and was followed by user attempts to circumvent the 'Error' message. No adverse events are related to this occurrence.

WHAT WE HAVE LEARNED

Neuro Kinetics' investigation of this event identified that a configuration file read by the VEST software at start-up was corrupted resulting in an 'Error' message. If the user ignores the 'Error' message and continues to press the 'Seatin g' or 'Testing' position buttons the chair may rotate. [NOTE: This same 'Error' message can appear with the 1-Portal VNG. There are no safety issues with the VNG as there is no chair component in the VNG system.] Our investigation has concluded that the possibility of a similar malfunction is remote.



IMPLEMENTATION AND CORRECTIVE ACTION

Neuro Kinetics is supplying a Launcher Utility designed to add an extra layer of safety and protection to your Neuro Kinetics 1-Portal® device. Installing this utility will cause the software to check to see that the system configuration is valid before starting VEST, as well as ensuring that the system is properly shut down in the event VEST closes unexpectedly.

Enclosed is a field correction CD that provides the following three items:

1. Launcher Utility to install and run on your VEST™ PC.
2. Unique confirmation number which proves that the utility has been successfully installed and offers evidence for your business records and ours.
3. Electronic version of an updated user's manual.

We request that you take immediate action using the step-by-step directions attached to this form. The software application includes an installer that directs the user through the installation process, which should take less than five minutes.

Please also save and/or print the updated user manual in your desired location.

To conclude the process you must do one of the following after installation of the software:

1. Write in the confirmation number displayed on your screen on the sheet provided and send it to PJ Musick by fax (412-963-6722) OR
2. Email the confirmation number displayed on your screen to:
pmusick@neurokinetics.com

If you need assistance with the software installation or have questions please call PJ Musick (primary contact), Vince Kytka or Rich Mosovsky at (412) 963-6649.

NOTE: Please install and run the utility and provide the confirmation number to NKI by **June 19, 2015**.

We will do all we can to help you. The quality, safety and reliability of our equipment have been, and remain, our top priorities. We apologize for any inconvenience this may cause you and thank you for your patience and cooperation.