



****** URGENT FIELD SAFETY NOTICE ******

Re: **Volcano s5, s5i, CORE and CORE Mobile systems** with software versions v3.2.x, v3.3, and v3.4

May 6, 2016

Dear Volcano Customer:

Volcano Corporation is initiating a voluntary Field Corrective Action because an issue has been identified with software versions v3.2.x, v3.3, and v3.4 that run on the s5/s5i/CORE/CORE Mobile systems ("Impacted Systems"). This voluntary recall only affects Impacted Systems.

Volcano Corporation has become aware of a system incompatibility issue between Impacted Systems and hospital network scans. In specific circumstances, an Impacted System will encounter unexpected data from the hospital network and the system will need to be manually rebooted. This condition can occur at any time, including in the middle of a patient procedure.

The system incompatibility issue occurs when hospital staff scan their networks for potential security vulnerabilities. When the Impacted System receives such data, a message is displayed that indicates an unexpected condition has occurred and requires the user to select the "Ok" button. When the "Ok" button is selected, the application will shut down leaving a screen with the Volcano logo on the system display. Once this occurs, the user will be required to manually reboot the system. If this issue occurs during an active procedure, a reboot would result in a delay in the procedure and/or abandonment of the use of IVUS and FFR/iFR functionality in the procedure.

The above-described scenario is consistent with the complaint reports Volcano has received; however, there are other potential consequences which can occur depending upon the modality in use at the time the Impacted System encounters the incompatibility issue. For all potential consequences on the Impacted Systems, refer to the attached Technical Service Bulletin (see Attachment 1.)

If you have an Impacted System but it is not connected to a network, this issue does not affect your system. Additionally, if network scans are not performed, this issue does not affect your system.

If you have an Impacted System that is connected to a network and staff performs network scans while the Impacted System is in operation, this issue does affect you and the circumstances exist for a manual reboot to occur during an active procedure. To avoid this, the following corrections must promptly be taken:

1. Disconnect your Impacted Systems from the facilities network. If you need to reconnect it while not being used in a procedure, make sure it is disconnected again before starting any procedure;
OR
2. Do not permit your staff to perform network scans while the Impacted Systems are in operation.



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Please complete, sign, and return the attached form indicating that you received this Field Corrective Action notification.

We recognize the inconvenience this may cause you, your staff, and your patients. However, this action reflects Volcano Corporation's commitment to patient safety and high quality standards.

Please ensure that a copy of this Field Corrective Action is provided to all personnel within your organization who handle these products. Thank you for your prompt attention to this important matter. On behalf of Volcano Corporation, we appreciate your partnership and your continued support.

Sincerely,

A handwritten signature in blue ink, appearing to read "Peter Dekempeneer".

Peter Dekempeneer
QA/RA Manager



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