



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

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

April 29, 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.



Philips Volcano

Philips Volcano, 3721 Valley Centre Drive, Suite 500, San Diego, CA 92130 USA
www.volcanocorp.com, Tel 800 228 4728, Fax 916 638 8812
324-1300.11/004





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.



Philips Volcano

Philips Volcano, 3721 Valley Centre Drive, Suite 500, San Diego, CA 92130 USA
www.volcanocorp.com, Tel 800 228 4728, Fax 916 638 8812
324-1300.11/004





CUSTOMER RETURN FORM

**Volcano s5/s5i/CORE/CORE Mobile systems with Software versions v3.2.x, v3.3, and v3.4;
System Incompatibility Issue**

Hospital Name: _____

Hospital Country: _____

Hospital Address: _____

Contact Email: _____

Contact Phone: _____

Instructions:

1. Complete the information below.
2. Fax completed form to Volcano Customer Service at (see list below) or email to vefsca@volcanocorp.com.

Sweden	+46850127334
Norway	+4785228735
Denmark	+4569802402
Poland	+48123841700
Italy	+390459971861
Spain	+34935207112
France	+33153010911
Germany	+493221122683167
Austria	+43125367227262

Switzerland	+41225948163
Greece	+302112686696
Cyprus	+302112686696
Belgium	+3227065758
The Netherlands & Luxemburg	+31205248304 +35224611375
UK	+442030700489
All other countries	+3226791079

☐ NO, I do not have any Volcano s5/s5i/CORE/CORE Mobile systems with software versions v3.2.x, v3.3, or v3.4.

☐ YES, I have Volcano s5/s5i/CORE/CORE Mobile systems with system software versions v3.2.x, v3.3, or v3.4.

☐ This issue does not affect my System for the reasons described in the Volcano Field Corrective Action notification; or

☐ I acknowledge my System is affected and will implement the identified corrections to avoid the occurrence of this issue.

Completed By: Name	Signature	Date

Upon completion, please return form to Volcano Customer Service by Fax or email vefsca@volcanocorp.com.

Questions? Please call +32 2 713 18 20.



Philips Volcano

Philips Volcano, 3721 Valley Centre Drive, Suite 500, San Diego, CA 92130 USA
www.volcanocorp.com, Tel 800 228 4728, Fax 916 638 8812
324-1300.11/004

