



PRECISION GUIDED THERAPY

**\*\*\*\* URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION \*\*\*\***

Re: **Volcano s5 and CORE Series** with system software versions 3.3, and 3.4 (with and without iFR<sup>®</sup> Scout technology) and v3.4 software kits

June 22, 2015

Dear Volcano Customer:

Volcano Corporation is initiating a voluntary Field Corrective Action because a software issue has been identified with the FFR/iFR modality. This software issue impacts **s5/s5i/CORE/CORE Mobile** systems with system software versions 3.3, and 3.4 (with and without iFR<sup>®</sup> Scout technology) and v3.4 software kits.

When using the FFR/ iFR modalities there are occasional circumstances when the aortic pressure (Pa) on the Volcano system should be manually zeroed. This is the case if the Pa displayed on the Volcano system  $\neq$  the Pa displayed on the hemo-system. In the majority of cases there is no need to zero Pa.

With this software issue, we have discovered very specific workflow scenarios where the Aortic pressure (Pa) offset used in the FFR/iFR modalities will be lost or reset to 0 mmHg. This issue will lead to an inaccurately calculated FFR or iFR value. Should this occur, a clinician may rely on an inaccurate value in diagnosing a patient's condition. If the Pa was not zeroed as part of the workflow, the software issue has no impact on the FFR/ iFR values or on the patient.

The risk of a misdiagnosis is remote; however, if zeroing Pa is warranted, as described in the FFR Option Operator's Manual, performance of this product cannot be assured until the software update is provided. A Volcano Representative will contact you to schedule a correction to the software in the next few weeks. In the meantime, please review the attached Technical Service Bulletin for additional information regarding this issue as well as what you can do to potentially avoid this issue from occurring. If after reviewing the attached document you should have additional questions, contact Volcano Customer Service at (800) 228-4728, option 4 to speak with a Volcano representative.

Please complete, sign, and return the attached form indicating that you received this 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, we appreciate your partnership and your continued support.

Sincerely,



Lisa M. Quaglia  
AVP, Regulatory Affairs and Quality Compliance

**CUSTOMER RETURN FORM**

**Volcano s5/CORE Pa Zero Issue**

**Hospital Name:** \_\_\_\_\_

**Hospital Address:** \_\_\_\_\_

**Contact Email:** \_\_\_\_\_

**Contact Phone:** \_\_\_\_\_

**Instructions:**

1. Complete the information below.
2. Fax completed form to Volcano Customer Service at (916) 638-8812.

\_\_\_\_\_ NO, I do not have any Volcano s5/s5i/CORE/CORE Mobile systems with software versions 3.3, and 3.4 (with and without iFR® Scout technology).

\_\_\_\_\_ YES, I have Volcano s5/s5i/CORE/CORE Mobile systems with system software versions 3.3, and 3.4 (with and without iFR® Scout technology). Please contact me to arrange for an update to my software.

| <b>Completed By:</b> | <b>Name</b> | <b>Signature</b> | <b>Date</b> |
|----------------------|-------------|------------------|-------------|
|                      |             |                  |             |

**Upon completion, please return form to Volcano Customer Service by Fax (916) 638-8812. Questions? Please call (800) 228-4728, option 4.**