



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

Re: **Philips Volcano V2.5 FFR/iFR Software**

December 15, 2018

Dear Valued Customer:

Philips Volcano is initiating a voluntary field corrective action to address an interoperability issue that affects **Volcano s5i, CORE and CORE Mobile systems** with version 2.5 FFR/iFR software connected to the McKesson, Schwarzer, and some Philips Xper Hemodynamic Systems (HMS). Other Hemodynamic System which do not adhere to commonly used pressure calibration values (0V @ 0mmHg and 1V @ 100 mmHg) may also be impacted.

The version 2.5 FFR/iFR software is designed to calibrate with the aortic output of the Hemodynamic Monitoring System (HMS). If the HMS adheres to commonly used pressure calibration values, then the interoperability issue will not have any impact. However, if the system does not adhere to commonly used values the interoperability issue will prevent calibration of the software with an impacted HMS.

In cases where the HMS does not adhere to commonly used values, the Volcano Pa (AO) and the HMS AO may be misaligned by up to +/- 5 mm Hg. This discrepancy may lead to confusion. Philips has confirmed that the FFR/iFR normalization process ensures there is negligible impact to the FFR/iFR measurements.

You are receiving this letter because our records show you have a system with version 2.5 FFR/iFR software. The Product Numbers and Software Revision that are affected are listed below:

Product Code/ Part Number	Product Description	Software Version
807400001	Volcano Imaging System s5i	FFR/iFR version v2.5 software Distributed beginning August 7, 2017
400-0100.01, 400-0100.01-R 400-0100.07 400-0100.07-R 400-0100.08 400-0100.08-R	CORE Mobile Imaging System (120V) CORE Mobile Imaging System Refurbished CORE Mobile Imaging System (240V) CORE Mobile Imaging System Refurbished CORE Mobile Imaging System (100V) CORE Mobile Imaging System Refurbished	
400-0100.02	CORE Imaging System	



**Philips Volcano**

Philips Volcano, 2870 Kilgore Road, Rancho Cordova, CA 95640 USA  
www.volcanocorp.com, Tel 800 228 4728, Fax 916 638 8812

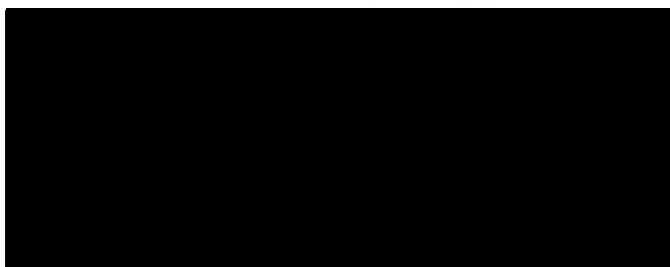




If the calibrated HMS AO and Volcano Pa values have a misalignment greater than  $\pm 3$  mmHg, contact Philips Volcano Technical support so that the system can be corrected. Additionally, a software update to FFR/iFR V2.5 will be made available in January 2019 which will resolve the interoperability issue. Once available the Philips Technical support team will deploy the update on each system to ensure no future interoperability issue will occur.

Please ensure that a copy of this letter is provided to all personnel within your organization who handle this device. We recognize the inconvenience this may cause you, your staff, and your patients. However, this action reflects Philips' commitment to high quality standards.

Thank you for your prompt attention to this important matter. On behalf of Philips, we appreciate your partnership and your continued support.



**Philips Volcano**

Philips Volcano, 2870 Kilgore Road, Rancho Cordova, CA 95670 USA  
www.volcanocorp.com, Tel 800 228 4728, Fax 916 638 8812





## CUSTOMER RETURN FORM

### Philips Volcano V2.5 FFR/iFR Software issue

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

Hospital Country: \_\_\_\_\_

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

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

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

#### Instructions:

1. Complete the information below.
2. Email the completed form to [verecall@philips.com](mailto:verecall@philips.com)

\_\_\_\_\_ NO, I do not have any Volcano s5i/CORE/CORE Mobile systems with software V2.5 FFR/iFR.

\_\_\_\_\_ YES, I have Volcano s5i/CORE/CORE Mobile systems with software V2.5 FFR/iFR and acknowledge the receipt of this notice.

Completed By:	Name	Signature	Date

Questions? Please call +32 2 713 18 20.



#### Philips Volcano

Philips Volcano, 2870 Kilgore Road, Rancho Cordova, CA 95640 USA  
www.volcanocorp.com, Tel 800 228 4728, Fax 916 638 8812





## **TSB FFR v2.5 AO Calibration Values Reset to Factory Default**

**Control #** D000259953\A

**Technical Service Bulletin Number:** D000259953\A

**Subject:** Aortic Field Calibration Values Reset to Factory Default Calibration Values with FFR 2.5 Upgrade

---

### **Product(s) Affected:**

CORE Mobile, CORE Integrated, S5ix and S5x connected to Hemodynamic Systems (HMS) that output non-standard signals. Most Hemodynamic systems generate standard signals.

### **Bulletin Distribution:**

Philips Field Service Engineers, Technical Support, and Area Managers

### **Purpose of communication:**

This TSB identifies potential situations where Aortic field calibration values are reset to Factory default calibration values. The change in calibration values can adversely affect measurements that incorporate Aortic pressure measurements, e.g., FFR and iFR. Options are presented to alleviate the loss of Aortic field calibration values.

This situation may occur only with systems where both of the following apply:

- 1) Upgraded to FFR v2.5
- 2) Utilize outputs from hemodynamic systems with analog voltage outputs that differ from the nominal calibration standard of 0.0 volt output for 0 mmHg and 1.0 volt for 100 mmHg are affected. A  $\pm 3$  mmHg offset at 0.0 mmHg or a  $\pm 3$  mmHg offset at 100 mmHg is considered within tolerance, and does not require any action to be taken. The greater the difference from the nominal standard, the larger the potential hazard.



## TSB FFR v2.5 AO Calibration Values Reset to Factory Default

Control # D000259953\A

### Description of actions:

The loss of field Aortic calibration values can be mitigated by several methods:

1. **For Integrated systems and Mobile systems not shared among multiple labs:** First, perform the normal field aortic calibration. Then follow with Factory calibration while still connected to the hemodynamic system. The Factory Calibration steps are as follows:

#### **Factory Calibration Instructions**

1. Select the Settings/Factory Tab and provide the Factory password
2. Select Aortic Calibration
3. Open the Aortic transducer to air
4. Select Set for Zero pressure
5. Select 100mmHg
6. Close the Aortic transducer and connect a syringe (or Endoflator) to the transducer
7. Using the syringe, increase the aortic pressure to 100 mmHg on the hemo system
8. Select Set
9. Select Exit Factory Mode to exit the Factory tab
10. Select FFR tab and then ensure that Pa is within 3 mmHg when HMS shows 0 mmHg and that Pa is within 3 mmHg when HMS shows 100 mmHg

By setting the factory calibration to the customer's hemodynamic system, we are ensuring that the field calibration will remain correct even when the system is rebooted. This method is not recommended for mobile systems used with multiple hemodynamic systems, see option 2.

2. **For Mobile Systems shared among multiple labs:** Contact Technical Support to order a LoMap accessory and schedule a field service visit. The LoMap supplies high level analog aortic pressure values to the system. The LoMap is designed to meet the nominal standard and will output voltages that are compatible with the Factory default values. This is recommended for mobile systems which are used with multiple hemodynamic systems.



## **TSB FFR v2.5 AO Calibration Values Reset to Factory Default**

**Control # D000259953\A**

3. **For situations where options 1 or 2 do not harmonize the IGTD System with the Hemodynamic System:** Contact Technical Support to schedule a field service visit to downgrade the FFR software revision to FFR v2.4.1. The software anomaly is not present in FFR v2.4.1. If the equipment previously required a LoMap to obtain Aortic pressure values, then the LoMap will need to be reinstalled. This strategy applies to both integrated and mobile systems.
4. **When the IGTD System is successfully harmonized with the Hemodynamic System:** fax, email, or mail the completed Data Sheet on the next page to the appropriate Technical Support/Field Service office for your region. If this form is completed using DocuSign, then no additional faxing, emailing, or mailing is required.

### **Philips Volcano Contact:**

If additional information is required, please contact:

**Philips Volcano North  
America**

2870 Kilgore Road  
Rancho Cordova, CA 95670  
United States of America  
+1 (800) 228-4728  
+1 (916) 358-8492 FAX

**Philips Volcano Europe  
BVBA/SPRL**

Excelsiorlaan 41 B-1930  
Zaventem Belgium  
+32-2-679-1075  
+32-2-679-1072 FAX

**Philips Volcano Japan Co.  
Ltd.**

Tokyo Housing Complex  
Warehouse Building B,  
2F 3-5-1 Heiwa Jima,  
Ohta-ku Tokyo 143-0006  
Japan  
+81-3-5767-7340  
+81-3-5767-7342 FAX



Dept. Responsibility: Field Service  
808383-003/LB, Template, Technical Service Bulletins  
Page 3 of 4

User is responsible for obtaining current revision prior to using this document.





## **TSB FFR v2.5 AO Calibration Values Reset to Factory Default**

**Control #** D000259953\A

### **Data Sheet**

**Hospital / Facility Name:** \_\_\_\_\_

**City:** \_\_\_\_\_

**System Serial Number:** \_\_\_\_\_

**IVUS & FFR Software Version Numbers:** \_\_\_\_\_

**Is FFR 2.5 installed?**

☐ Yes

☐ No

**Calibration Status:**

☐ Check if Pa is within 3 mmHg when HMS shows 0 mmHg

☐ Check if Pa is within 3 mmHg when HMS shows 100 mmHg

**Test Equipment**

N/A

Each section of the checklist has met acceptance criteria, actual results have coincided with the expected results, and the information contained in this document is correct.

\_\_\_\_\_  
Name (Printed)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Fax, email, or mail this completed Data Sheet to the appropriate Technical Support/Field Service office for your region. If this form is completed using DocuSign, then no additional faxing, emailing, or mailing is required.

<b>North America</b>	<b>Europe</b>	<b>Japan</b>
Philips Volcano North America 2870 Kilgore Road Rancho Cordova, CA 95670 United States of America +1 (800) 228-4728 +1 (916) 358-8492 FAX FCODocumentation@philips.com	Philips Volcano Europe BVBA/SPRL Excelsiorlaan 41 B-1930 Zaventem Belgium +32-2-679-1075 +32-2-679-1072 FAX	Philips Volcano Japan Co. Ltd. Tokyo Housing Complex Warehouse Building B, 2F 3-5-1 Heiwa Jima, Ohta-ku Tokyo 143-0006 Japan +81-3-5767-7340 +81-3-5767-7342 FAX



Dept. Responsibility: Field Service  
808383-003/LB, Template, Technical Service Bulletins  
Page 4 of 4

User is responsible for obtaining current revision prior to using this document.