



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

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

March 26, 2019

Dear Valued Customer:

Philips Volcano is initiating a voluntary field corrective action to address an interoperability issue that affects **Volcano s5, 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
807300001	Volcano Imaging System s5	
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	
435-0602.48	FFR v2.5 Software Kit	

Note: There are other identifiers and/or lots affected globally. Please verify with product owner if in doubt.



Philips Volcano

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If the calibrated HMS AO and Volcano Pa values have a misalignment greater than +/- 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.

Sincerely,



Peter Dekempeneer
Quality Assurance Manager IGT-D International

Cc: Chairman Medical Board and relevant Head of Departments



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