****** IMPORTANT FIELD CORRECTIVE ACTION ******

Re: Volcano s5/s5i™ Family Software Version 3.2.1 / 3.2.2

August 30, 2012

Dear Sir, Madame:

We are writing to inform you of an extremely remote event that may occur when using the Volcano s5/s5i™ Imaging System when running either software version 3.2.1 or 3.2.2. Under very specific and remote conditions, two software display errors may occur in the 3.2.X Intravascular Ultrasound (IVUS) software when used with Digital IVUS Catheters (except PV .018 and PV 8.2) and the Rotational Revolution® 45 MHz Catheter. The software display errors do not occur in the Digital IVUS Catheters if the normal (default) of 10mm Field of View (FOV) is used and in the Revolution Catheter if the system default of 8 mm FOV is used. If the software errors occur, the display will be shifted to a different FOV and will differ from the angiographic data. If the user fails to compare the displayed data to the angiographic data as required by the Instructions for Use (IFU), the issue may be overlooked, leading to a possible error in vessel sizing with a moderate potential for restenosis or the potential placement of an additional stent. The In-Line Digital (ILD) measurements, VH® IVUS, ChromaFlo® and Fractional Flow Reserve (FFR) measurements are **not** affected.

Volcano is developing a software patch to address the errors. We will begin deployment of the patch in August 2012. Our records indicate that your facility has a Volcano s5/s5i™ Imaging System that is running either version 3.2.1 or 3.2.2 of Volcano's software. Your system(s) will be updated by a Volcano representative at no cost to you.

In the interim, the enclosed White Paper explains in detail the nature of the errors and how to avoid them. Please ensure that the enclosed White Paper is circulated to the appropriate users and administrators in your facility. Contact your Volcano sales representative if you have any questions, or call our technical support group at the contact information below.

We are notifying the appropriate Regulatory Authorities of this voluntary field corrective action. We regret the inconvenience. On behalf of Volcano, we appreciate your partnership and your continued support.

Sincerely,

[redacted]

Director Operations

Contact information:

Please contact your local Volcano Corporation sales representative or:

Volcano Technical Service

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August 2012

TWO POTENTIAL SOFTWARE ERRORS

AFFECTING DIGITAL AND ROTATIONAL IVUS CATHETERS:

INTERIM AVOIDANCE PENDING SOFTWARE PATCH

This document discusses the software display errors that can occur in Volcano s5/s5i™ Imaging System when running either version 3.2.1 or 3.2.2 of Volcano's software. These software errors will cause the display to be shifted to a different Field of View (FOV) which if encountered will differ from the angiography values. In the discussion below, we describe the potential errors, the remote set of conditions that must be met for the errors to occur, and how to recognize when the errors have occurred. We also describe how to avoid the errors. You should institute these error avoidance steps until the permanent software patch is installed.

Please note that the In-Line Digital (ILD) measurements, VH® IVUS, ChromaFlo® and Fractional Flow Reserve (FFR) measurements are not affected by this display error. However, once the errors have occurred any images captured in a Video Loop or Still Frame cannot be corrected but they can be detected.

1. DIGITAL IVUS CATHETER ERROR

A software display issue may occur if the user changes the normal (default) FOV to another setting in addition to a unique sequence of events occurring. This may lead to the graticules FOV display to revert back to the default setting but does not affect the gray scale image quality. It has been reported twice from the field and in each case was immediately detected by the user.

This issue can occur when the following IVUS catheters are used:

Digital IVUS Catheters:

Eagle Eye® Gold
Eagle Eye® Platinum
PV .014 (for Japan only)
VIBE® RX Vascular Imaging Balloon Catheter

Under What Conditions Can the Error Occur?

Very specific conditions in the workflow need to occur in the following order for this error to occur:

1. A change in the "Field of View" to a diameter other than the default 10mm; **AND**
2. An interruption of the signal between the catheter and the system that is less than five (5) seconds in duration; **AND**
3. User then selects the "Adjust Image" screen or pushes either the NearVu button or ChromaFlo button.

A signal interrupt is introduced through a loose or damaged connector. A loose cable connection is quickly and easily avoided by ensuring a tight fit between the cables and the devices to which they are connected. It should also be noted that a signal interrupt of five (5) seconds or longer will cause the system to go to a "No Catheter" mode which will result in the system correcting itself.

How To Avoid The Error

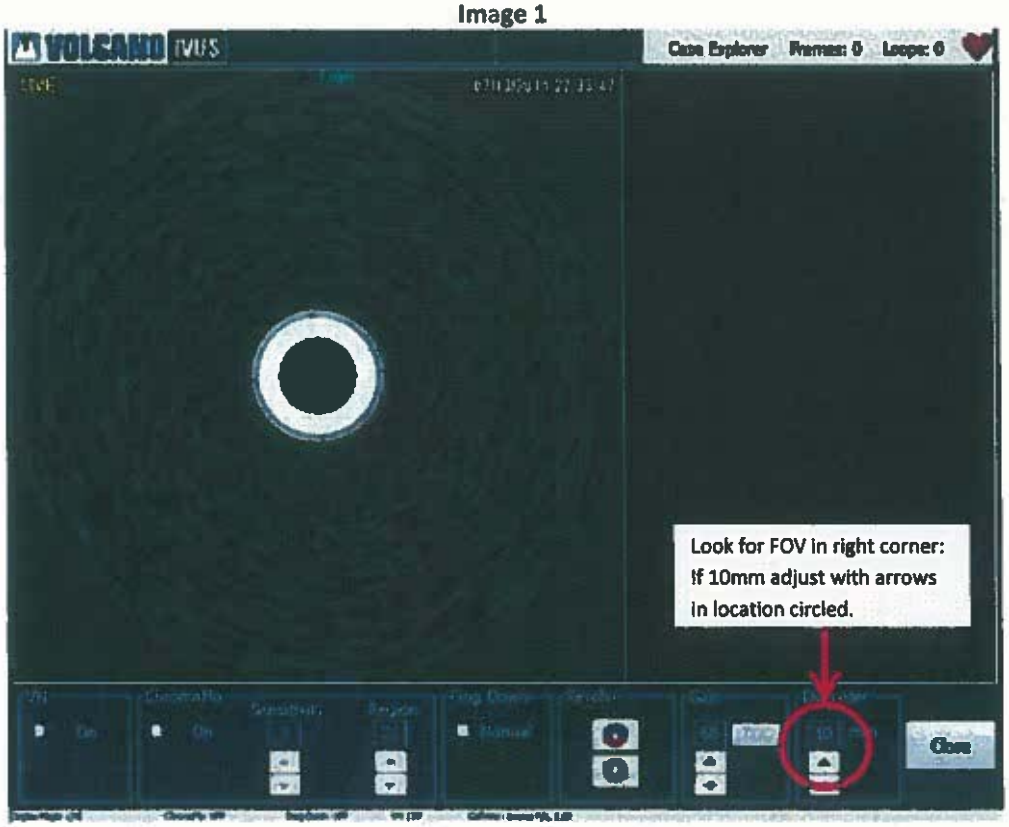
If you do not change the FOV from the normal (default) 10mm diameter, the error cannot occur. If possible, you should only use normal (default) FOV until the software patch is deployed.

In addition if you only use gray scale for review of the vessel, the image quality is not affected; whereas drawing borders and graticules are affected.

If you must change the FOV, follow these steps:

- Verify the FOV setting on the Adjust Image screen. (Refer to Image 1).
- If the system indicates 10mm, simply adjust using the up arrow or the down arrow to the desired FOV before recording.
- Confirm your measurements with those images acquired by angiography as directed by the Instructions for Use.

Image 1



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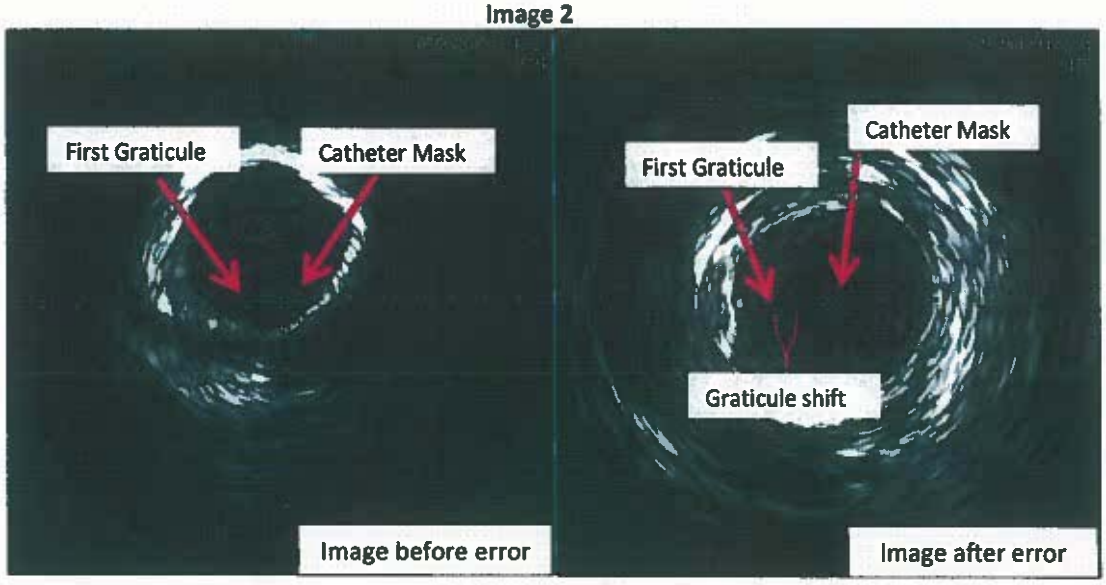
How to Detect the Error

Pay attention to the following indicators as this error is easily detected by the following visual cues. Please refer to Image 2 which shows how easily the issue can be detected.

- The graticules shift from the defined FOV back to the normal (default) FOV.
- The first graticules from the center are not aligned with the edge of the catheter mask.

Once the errors have occurred any images captured in a Video Loop or Still Frame cannot be corrected. Affected Video Loops or Still frames can be detected by verifying whether the first graticules are aligned with the edge of the catheter mask (Refer to Image 2).

Image 2



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2. ROTATIONAL IVUS CATHETER ERROR

We have identified a similar error with our Rotational IVUS catheter. This only occurs under very specific conditions which manifests into easily identifiable visual cues. It has been reported once from the field and was immediately detected by the user.

This issue can appear only with the Revolution® 45MHz IVUS Imaging Catheter.

Under What Conditions Can the Error Occur?

Very specific conditions in the workflow will need to have occurred to observe this error:

1. Image with a Revolution catheter and a PIMr 1.5; **AND**
2. User then selects a Field of View (FOV) other than the system default of 8mm diameter; **AND**
3. The PIMr then experiences an over spin/overcurrent condition caused by the catheter rotation stalling briefly for less than two (2) seconds leading to the PIMr resetting itself.

Rotational stalls can occur if there is pressure applied to the catheter connection or rotational resistance is encountered during imaging. A stall of two (2) seconds or longer will cause the system to go into a "Catheter Fault" error which will result in the system correcting itself.

How To Avoid The Error

If you do not change the FOV from the system default 8mm diameter, the error cannot occur. If possible, you should only use 8mm FOV until the software patch is deployed.

If you must change the FOV and you believe an error has occurred (see section below for detection of the error) then disconnect the PIMr, reconnect it and re-image. Per normal practice, confirm your measurements with those images acquired by angiography as directed by the Instructions for Use.

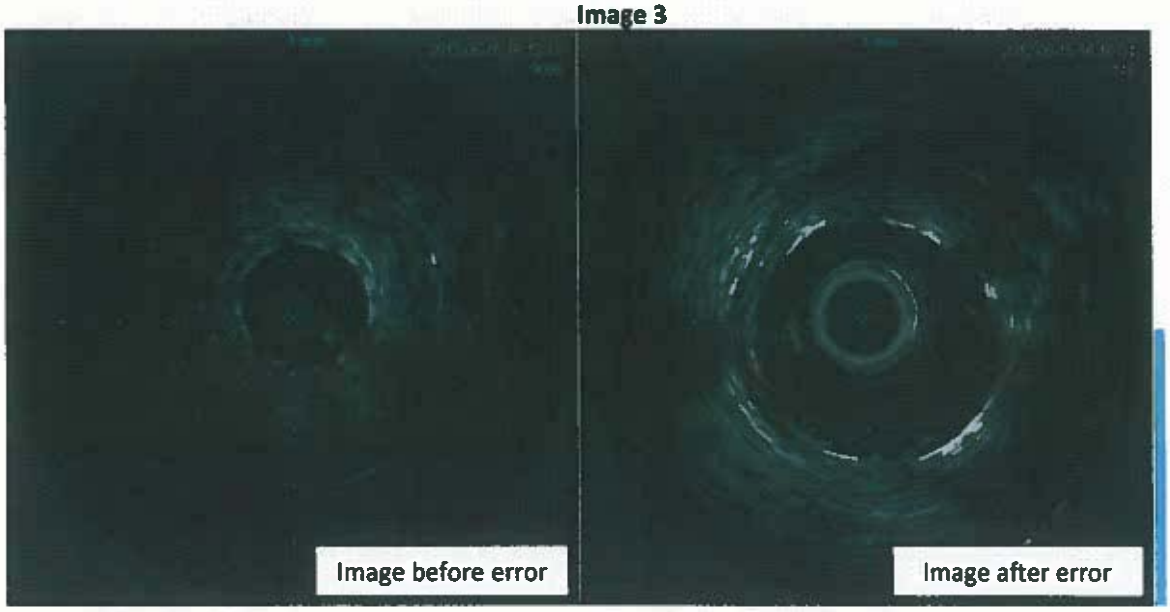
How to Detect the Error

Pay attention to the following indicators as this error is easily detected by one or all of the following visual cues. Please refer to Image 3 which shows how the easily the issue can be detected.

- The quality of the image is significantly brighter from previous recordings and you will not be able to modify this image by adjusting the gain.
- The Catheter mask (center of the tomographic display) will increase in size by 1.5x and will have an unnatural appearance (i.e. no blood speckle).
- The image has a zoomed in appearance and becomes more obvious as the FOV increases beyond 10mm.
- The PIMr reset will cause the LED lights to turn off and on providing the users who work with the PIMr a visual cue that the PIMr is resetting.

The images below were taken at the same point in the vessel; the correct image identified as "Image before error" is displayed on the left and the Incorrect image identified as "Image after the error" is displayed on the right.

Image 3



Once the errors have occurred any images captured in a Video Loop or Still Frame cannot be corrected. Affected Video Loops or Still frames can be detected by verifying whether the presence of a white ring as shown in the right hand picture of Image 3.