

August 13, 2012

## URGENT DEVICE CORRECTION

### Re: Potential Error in Values for Calcium Scoring When Restoring Snapshots

Dear Customer:

Vital Images has found two potential errors in calcium score values in restored snapshots of studies generated through use of Vitrea or Vitrea Enterprise Suite. This issue affects **Version 3.1 of Vitrea fX; Version 5.2 of Vitrea; Versions 6.0, 6.1 and 6.2 of Vitrea and Vitrea fX; and Versions 1.3, 6.0, 6.1 and 6.2 of Vitrea Enterprise Suite**; and all updates to those versions. If the calcium score in the restored snapshot is relied upon, less-healthy vessels may be incorrectly considered as healthy, which may lead to different treatment paths than would otherwise be followed. We are providing a software update (patch) for these issues and will contact you to upgrade your systems.

You are receiving this letter because your institution was eligible to receive one of the affected versions.

The first error can be avoided if a user follows either of the following recommended workflows: (1) using the "manual" method and not selecting "Interpolate;" or (2) selecting "Interpolate" after drawing all contours. The second error can be avoided by using the "manual" method and not using "Interpolate."

The first error occurs during the following specific workflow in the calcium scoring application when a user:

- draws multiple contours in the selected vessel,
- selects the "Interpolate" button,
- draws one or more additional contours, but does not select the "Interpolate" button,
- takes a snapshot, and
- restores that snapshot.

Upon restoring the snapshot, the color tinting and calcium score reflect only the drawn contours, while the formerly interpolated regions are excluded from the color tinting and the resulting calcium score. Because of the loss of interpolation between the drawn contours, the displayed value after snapshot restore will be lower than the original snapshot, unless no calcium was present in the interpolated regions. Review of the contours shown upon restoring a snapshot will show the loss of the interpolation.

To resolve the first issue, Vital Images has generated a software update that performs two functions. First, when a user selects "Interpolate" while drawing contours and then draws additional contours and does not select "Interpolate" before attempting to take a snapshot, an on-screen dialogue box notifies the user that all contours have not been interpolated and requires all contours to be interpolated before taking the snapshot. Additionally, when a user restores a snapshot, an on-screen dialogue box notifies the user to review and confirm all contours in the restored snapshot.

The second error occurs when, after restoring a snapshot of a calcium score image that used interpolation, a user draws additional contours. When the new contours are drawn, the interpolation between all drawn contours becomes lost and the resulting calcium score value accounts only for the drawn contours. To obtain

the correct calcium score after drawing new contours on a restored image that was generated through interpolation, the user will need to again select “Interpolate.”

To resolve the second issue, users need to select “Interpolate” after drawing additional contours in order to obtain correct calcium scores after drawing additional contours on restored snapshots. All contours will then be interpolated. Additionally, the software update retains the calcium score values for the interpolated regions, even if the user draws additional contours.

Please immediately inform all potential users of these issues and the two alternative workflows that will prevent the first issue. You will be contacted to arrange for installation of the software update.

Direct customers of Vital Images should contact Vital Images Customer Support with any questions at 1-800-208-3005 or send an e-mail to [support@vitalimages.com](mailto:support@vitalimages.com). If you acquired the software through a reseller, you should contact your reseller.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jim Litterer', with a stylized flourish at the end.

Jim Litterer  
Vice President, Operations  
Vital Images, Inc.

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