

URGENT: FIELD SAFETY NOTICE

Merge FSN # 2016-074

Dear eFilm Workstation/eFilm Lite User,

This is to inform you of a product field safety corrective action involving:

Product: eFilm Workstation/eFilm Lite versions 2.1, 2.1.2, 3.0, 3.1, 3.3.5, 3.4, 4.0, 4.0.1, 4.0.2, 4.0.3 and 4.1. Merge began shipping this product in December 2007.

- Note: You can find the version of your software by opening eFilm Workstation/eFilm Lite, then navigating to the Help/About screen where the version and build number are shown.

Issue: This issue happens for RF projection images [the 12 DICOM SOP classes below]. If user measures on RF image, "cal" (Calibration) is not displayed and measurement is not correct. The "cal" label is not displayed on the projection images after calibration is performed which should be present if the measurement is presented based on Pixel Spacing.

Measurements are incorrect because eFilm is using the imager pixel spacing DICOM tag, but it should be using the pixel spacing tag if the value for pixel spacing is present and is differing from imager pixel spacing tag.

Based on industry practice for projection images, if both the imager pixel spacing and pixel spacing attributes are present and differ, the pixel spacing attribute should be used and the "cal" (for calibrated) label should be displayed.

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1.2.840.10008.5.1.4.1.1.1.1.1.1//Digital X-Ray - For Processing
1.2.840.10008.5.1.4.1.1.1.2.1//Digital Mammography X-Ray - For Processing
1.2.840.10008.5.1.4.1.1.1.3//Digital Intra-oral X-Ray - For Presentation
1.2.840.10008.5.1.4.1.1.1.3.1//Digital Intra-oral X-Ray - For Processing
1.2.840.10008.5.1.4.1.1.12.1.1//Enhanced XA Image Storage
1.2.840.10008.5.1.4.1.1.12.2//X-Ray Radiofluoroscopic Image Storage
1.2.840.10008.5.1.4.1.1.12.2.1//Enhanced XRF Image Storage
1.2.840.10008.5.1.4.1.1.7//Secondary Capture Image Storage
1.2.840.10008.5.1.4.1.1.7.1//Multi-frame Single Bit Secondary Capture
1.2.840.10008.5.1.4.1.1.7.2 //Multi-frame Grayscale Byte Capture
1.2.840.10008.5.1.4.1.1.7.3//Multi-frame Grayscale Word
1.2.840.10008.5.1.4.1.1.7.4//Multi-frame True Color Secondary Capture
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www.merge.com

Potential Harm: Use of this product may result in incorrect measurements on projection images of the SOP classes listed above and the imager pixel spacing DICOM tag and the pixel spacing tag. A user will likely be able to notice that the measurements are not as expected.

Potential health consequence for this issue includes delay in patient care and/or change in recommendation for treatment.

Actions by Merge: Merge has a released fix for this issue.

The fix remedies this issue as well as provides additional improvements. The software can be downloaded from our web site.

In order to obtain the updated version of the software, users must have an active support agreement in place to receive updates and 24/7 support.

Actions by Customer: You must discontinue using eFilm Workstation/eFilm Lite for viewing of projection images for the affected SOP classes listed above until the upgrade is installed and in use.

Your response is required within 15 days of receipt of this notification.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (if appropriate)

Please transfer this notice to other organisations on which this action has an impact. (if appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

If you have any additional questions, please send an email to intlrec@us.ibm.com.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency



Mike Diedrick
Vice President of Quality and Regulatory Affairs

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YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

Workaround: You must discontinue using eFilm Workstation/eFilm Lite for viewing of projection images for the affected SOP classes listed above until the upgrade is installed and in use.

A response is required **15 calendar days** after receipt of this field safety corrective action letter.

1. I have read and understand the field safety corrective action instructions provided in this letter Yes No
2. Did you ever receive shipment of eFilm Workstation/eFilm Lite?
If no, please sign and return. Yes No
3. Do you have eFilm Workstation/eFilm Lite at your facility?
If no, please sign and return. Yes No
If yes, please record version(s): _____
4. Will you discontinue use of the feature as requested? Yes No
If no, please state why: _____
5. Are you interested in accepting the fix? Yes No
If no (declining the fix), please state why: _____
6. Have you received any reports of injury or illness related to this product issue? Yes No
If yes, please explain: _____

Company Representative:

First Name

Last Name

Organization Name

Email Address

Telephone Number

Signature

Date