URGENT: MEDICAL DEVICE RECALL

October 12, 2016
Recall # 2016-074
Dear eFilm Workstation/eFilm Lite User,

This is to inform you of a product recall 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 pacing 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.

1.2.840.10008.5.1.4.1.1.1.1.1//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
1.2.840.10008.5.1.4.1.1.12.1.1.1//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
1.2.840.10008.5.1.4.1.1.1.7//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
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.

Containment by the Customer / User: 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 an in use.

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: YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

Please reply using the enclosed form and the return addressed envelope.

A response is required 15 calendar days after receipt of this recall letter.

Please ensure that all users of the product are provided with this notification. Your assistance is appreciated and necessary to prevent patient harm.

If you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Merge Healthcare is committed to improve efficiencies and enhancing the quality of healthcare worldwide. If you have any additional questions, please send an email to recall@merge.com.

This recall is being made with the knowledge of the Food and Drug Administration.

Mike Diedrick
Vice President of Quality and Regulatory Affairs

Enclosure: Customer response form
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YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

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 an in use.

A response is required 15 calendar days after receipt of this recall letter.

1. I have read and understand the recall 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.
   If yes, please record version(s):

4. Will you discontinue use of the feature as requested?
   If no, please state why:

   □ Yes   □ No

5. Are you interested in accepting the fix?
   If no (declining the fix), please state why:

6. Have you received any reports of injury or illness related to this product issue?
   If yes, please explain:

   □ Yes   □ No

Company Representative:

First Name          Last Name

Organization Name

Email Address      Telephone Number

Signature           Date

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