

URGENT: FIELD SAFETY NOTICE

Merge FSN # 2016-078

Dear Office Manager:

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

- Product:** Merge Eye Station: All versions. Merge began shipping this product in 2005.
- **Note:** You can find the version of your software in the About Box under the Help option from the main menu.
- Issue:** This field safety corrective action has been initiated due to an issue related to the potential accidental deletion of record(s) by an Eye Station user. In the current workflow, a user can select to delete a record(s). When that selection is made, a confirmation box is presented asking the user if they want to delete the record(s). The user can then either left click on "OK" or press the "enter" key to confirm the action. Currently, this confirmation defaults to "OK" or "Yes". In this workflow, a user could inadvertently hit the "enter" key, which would delete the images or procedures. Once these images or procedures are deleted, they are lost permanently with no recovery.
- Potential Harm:** Use of this product may result in permanent patient data loss with a potential impact to clinical diagnosis.
- Actions by Merge:** Merge has released a version of Eye Station with a correction for this issue. The correction we have made is to change the default choice on the confirmation box to "Cancel" or "No". In this workflow, a user who selects images or procedures to delete will have to left click on the OK or Yes in order to delete, thus confirming this is the action they wish to take. This also eliminates the potential of accidentally hitting the enter key and inadvertently performing a deletion. If the user selects images or procedure to delete, and presses the enter key, since the new default is defaulted to cancel or no, images or procedures will not be deleted.
- Actions by Customer:** It is highly recommended that the user take extreme caution while performing a delete to ensure the deletion request is a valid action.

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)

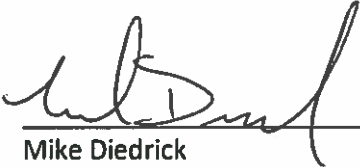
Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

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

URGENT: FIELD SAFETY NOTICE

Re: User Record Deletion

Merge FSN # 2016-078

YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

It is highly recommended that the user take extreme caution while performing a delete to ensure the deletion request is a valid action.

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 Eye Station? (If no, please sign and return) Yes No
3. Do you have Eye Station at your facility? (If no, please sign and return)
If yes, please record version(s): Yes No
4. Do you understand the workaround? 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