
Urgent Field Safety Notice

Merge Eye Care PACS and Merge Eye Station 2016-061 Field Safety Corrective Action

Date:

Attention: Ophthalmology Manager

Details on affected devices:

- Merge Eye Care PACS, all versions

- Merge Eye Station, all versions

Description of the problem:

This notice has been issued due to potential loss of data when an anti-virus program scans Eye Station (ES) or Eye Care PACS (ECP). During a scan, the anti-virus program may detect a newly captured image to be an unwanted file and delete the image permanently.

Use of this product with anti-virus program that is not configured properly may result in permanent data loss which could lead to misdiagnosis/treatment.

Action to be taken by the user:

- Be aware of the following workaround:

When configuring an anti-virus product, ensure folders containing patient images are excluded from the scan.

- Merge is not taking further action to correct this issue. Please be aware of this possible behaviour and insure that all readers are appropriately instructed.

- **YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED**

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

Your response is required no later than **DATE**.

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 recall@merge.com

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

Mike Diedrick
Vice President of Quality and Regulatory Affairs

URGENT: MEDICAL DEVICE RECALL

Re: Eye Care Anti-Virus Setup

Recall # 2016-061

YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

Be aware of the following workaround:

When configuring an anti-virus product, ensure folders containing patient images are excluded from the scan.

Please respond no later than **DATE**.

1. I have read and understand the recall instructions provided in this letter Yes No
2. Did you ever receive shipment of Merge Eye Care PACS and/or Merge Eye Station? (If no, please sign and return) Yes No
3. Do you have Merge Eye Care PACS and/or Merge Eye Station at your facility? (If no, please sign and return) Yes No
If yes, please record version(s): _____
4. Do you understand the workaround? Yes No
If no, please state why: _____
5. 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