
Urgent Field Safety Notice

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

Date: July 13, 2016

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 **within 15 days** of receipt of this notification.

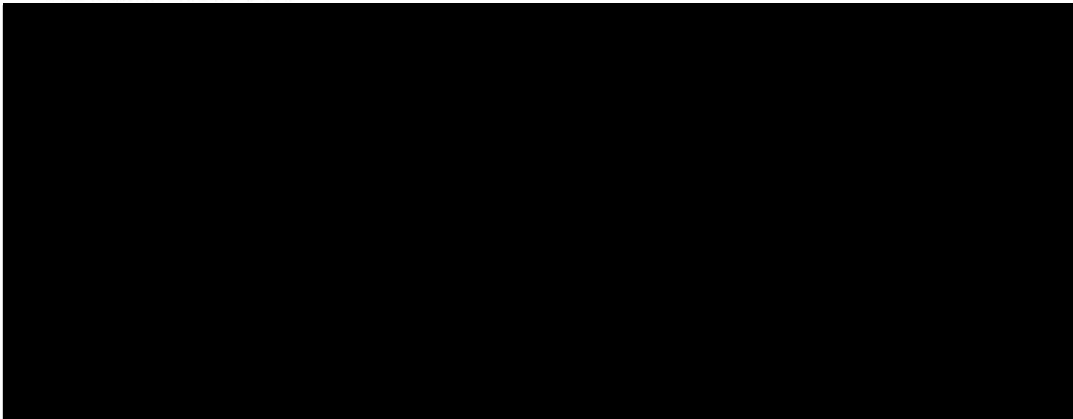
Transmission of this Field Safety Notice: (if appropriate)

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:



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 **within 15 Days** of receipt of this notification.

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|--|------------------------------|-----------------------------|
| 1. I have read and understand the recall instructions provided in this letter | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Did you ever receive shipment of Merge Eye Care PACS and/or Merge Eye Station? (If no, please sign and return) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Do you have Merge Eye Care PACS and/or Merge Eye Station at your facility? (If no, please sign and return)
If yes, please record version(s): _____ | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Do you understand the workaround?
If no, please state why: _____ | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Have you received any reports of injury or illness related to this product issue?
If yes, please explain: _____ | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Company Representative:

First Name

Last Name

Organization Name

Email Address

Telephone Number

Signature

Date