
Urgent Field Safety Notice

**Merge Eye Station and Eye Care PACS
2016-044
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 a potential issue preventing image acquisition or image import. This issue was reported by one customer whose configuration allowed sharing a database between an outdated version and new version of WinStation Manager (WSM). An additional symptom involved the software to prevent opening Merge capture session.

Use of this product may delay patient treatment and/or diagnosis.

Action to be taken by the user:

Currently there are no instructions for action to be taken by the customer/user.

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: Compatibility Issue

Recall # 2016-044

YOUR RESPONSE TO THIS NOTIFICATION IS REQUIRED

Currently, there aren't containment instructions required by the customer/user.

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