

Urgent Field Safety Notice

Merge Eye Station Excessive Electrical Output

20 December 2018
Field Action #2018-001

Dear Director of Ophthalmic Imaging/IT Manager,

Merge Healthcare has recently become aware of a safety issue affecting the hardware associated with Merge Eye Station.

Certain configurations of Merge Eye Station hardware may result in electrical output that exceeds the allowable limits for medical devices. Leakage current was found to exceed allowable limits in earth leakage current, touch current in a single fault condition (of open ground) and patient leakage current in a single fault condition (of open ground).

Merge Healthcare has not received any reports of serious injury or death related to this issue.

Safety Instructions:

Merge Healthcare recommends that you immediately cease use of all Eye Station hardware. A hardware correction is planned to prevent excessive leakage current and will be provided free of charge. A Merge Healthcare representative will contact you to schedule the correction once the modification is available.

Please ensure all potential users of Merge Eye Station have received this notice.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions regarding this notice, please contact customer support at Eyecaresupport@us.ibm.com or 877-741-5369.

The undersigned confirms that this notice has been sent to the appropriate regulatory agency.

Sincerely,



Ms. Margaret Mucha
Senior Leader, Quality Assurance and Regulatory Affairs