Urgent Field Safety Notice (FSN)
I-View® Contrast Enhanced Digital Mammography (CEDM)
Product Code - ASY-08109

Hologic FSCA Ref: FA-00056

Attention of:

This letter is to inform you of an urgent field safety notice (FSN) and product correction involving the above mentioned software product – associated with Mammography systems.

We are notifying you because you have purchased I-View® Contrast Enhanced Digital Mammography. To ensure visibility of the contrast, the system needs to be recalibrated. We have initiated this FSN and will implement a voluntary field correction to recalibrate the system.

The I-View imaging software is an optional product/upgrade that can be added to any Selenia Dimensions and 3Dimensions Mammography system. I-View® enables Contrast Enhanced Digital Mammography (CEDM). This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion in breast tissue.

This FSN and product correction has been initiated due to a calibration issue that could impact contrast enhancement throughout the subtracted image. This may have an impact on contrast uptake visibility throughout the subtracted image.

There have been reports that, ***at the time a contrast enhanced digital mammography exam was conducted, it was not possible to visualize contrast uptake in the subtracted images.***
We have investigated these reports and identified a software calibration issue. This issue causes the system to be too dependent on swirl phantom patterns for correct calibration. This impact is system-dependent and detectable when imaging is used to confirm contrast uptake. The image quality for an improperly calibrated system is readily apparent and differs significantly from standard quality.

Our Health Risk Assessment indicates that this failure could potentially lead to misdiagnosis if the clinicians don't identify that the images are not of acceptable diagnostic quality. The probability of this risk has been calculated to be around 1 in 20,000 mammography procedures.

We wanted to notify you that Hologic is aware of the issue, has a resolution in process, and is working to deploy field service engineers to your site to recalibrate the system as quickly as possible. We anticipate field service availability for this action starting promptly. At that time, ***Hologic will contact you to begin scheduling appointments for a field service engineer to recalibrate your system for contrast enhanced digital mammography.***

At this time, please only use I-View for patients with known lesions. Please ensure images are of acceptable diagnostic quality. If I-View images are of acceptable diagnostic quality they may continue to be used for diagnostic purposes. If I-View images are not of acceptable diagnostic quality please consider the use of an alternative diagnostic work up.

Please note, this issue does not impact on any other Mammography mode or procedure that may be performed.

At Hologic, we are committed to continually evaluating and improving the quality and reliability of our products. If you have any questions, please do not hesitate to reach out to your local representative Andreas Kristensen at +45 70212870 / +45 30266824 or mail to andreas.kristensen@trompmedical.dk.

The Competent (Regulatory) Authority of your country has been informed about this communication

This notice needs to be passed on all personnel who need to be made aware of this issue - within your organization or to any organization where the potentially affected devices have been transferred.

Respectfully Regards,

Hologic NV
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