Carestream

Urgent Field Safety Notice
OnSight 3D Extremity System
Carestream Health FSCA MA-2018-014 - Device modification

Date: 3-May-2019

Attention: Potential malfunction of the **OnSight 3D Extremity System** exists where a parent volume is reassigned, along with its companion volume, to a different patient.

Details on affected devices:
OnSight 3D Extremity System (Serial Number Range 10013 - 20022).

Description of the problem:
If the need arises to reassign a parent volume (parent CT image) along with its companion volume (enhanced version of the parent CT image) from patient A to patient B, the parent volume will be transferred from patient A to patient B, but the companion volume may remain in the original (patient A) exam. A reassignment of the volumes to a different patient is usually required in situations where the users failed to identify the correct patient prior to initiating the procedure.
A risk of misdiagnosis exists if the non-relevant companion volume alone is used to diagnose patient A.
There is no risk to patient B as the only impact is a missing companion volume that can be easily regenerated from the transferred parent volume, if needed.

Advice to users:
As a precautionary measure before the execution of the correction, Carestream Health strongly advise users to:

- Follow good patient identification protocols in order to reduce the need to reassign volumes to a different patient (user error in identifying the correct patient prior to initiating the procedure is the typical cause for the need to reassign both the parent and companion volumes from patient A to patient B).
- Check proper reassignment of both parent and companion volumes whenever reassignment to a different patient is required.

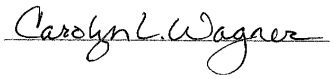
Please complete and send the attached confirmation form back to us within 5 working days.

Action taken by the manufacturer:
A Carestream Service Engineer or Carestream Health Authorized Service Representative will contact you to schedule a convenient date and time within the next 6 months to update the software.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

The undersigned confirms that this Field Safety Corrective Action has been notified to the appropriate Regulatory Agency. If you have any questions, please call your local Service Support number.

We regret any inconvenience this may cause to your operation.



Carolyn L. Wagner - Director
Regulatory Affairs Clearance & Surveillance

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FSCA Appendix – Notification Acknowledgement

Please read and complete all information below and send this form back to the following mail box within 5 working days: postmarketra@carestream.com. Thank you.

I hereby acknowledge receipt of the Field Safety Notice related to the following Field Safety Corrective Action:

OnSight 3D Extremity System
Carestream Health FSCA MA-2018-014 - Device modification
Potential malfunction of the **OnSight 3D Extremity System** exists where a parent volume is reassigned, along with its companion volume, to a different patient.

I certify that the users/departments are aware of the advices given in the Field Safety Notice.

Comments (optional): _____

_____

_____

Device Serial Number: _____

Name of the site: _____

Address of the site: _____

_____

Country: _____

Name of the person: _____

Title of the person: _____

Signature: _____

Date: _____