Carestream

Carestream Health, Inc.
150 Verona Street
Rochester, NY 14608

Date: March 15, 2019

URGENT: MEDICAL DEVICE CORRECTION

To: Director of Radiology, Chief Radiology Administrator and OnSight 3D Extremity System Administrators

Cc: Chairman Medical Board and/or Head of Department

This is to inform you of a product recall involving the OnSight 3D Extremity System.

Description of the Problem:
If the need arises to reassign a parent volume along with its companion volume to a different patient – the parent volume will be transferred but the companion will remain in the original patient's exam.

Risk to Health:
The result of this incomplete reassignment is that the companion volume will remain in a different patient's exam and is not representative of that patient. The risk occurs if this non-relevant companion volume alone is used to diagnose the patient.

There is no risk to the patient that the parent volume was reassigned to as the only impact is a missing companion volume that can be easily regenerated from the parent if needed.

Action to be Taken:
Carestream has created a software update for the OnSight 3D Extremity System to eliminate the potential for this problem to occur. Carestream's representative will contact you to schedule a convenient date and time within the next 6 months to install the software update. In the meantime, please use extreme caution to ensure proper reassignment of both parent and companion volumes whenever reassignment to a different patient is required.

If you have any questions or concerns, please contact the Carestream Customer Care Center in the U.S. at 1-800-328-2910, available 7 days per week on a 24 hour basis. Outside of the U.S., please call your local Carestream Service support number.

If you have distributed the device outside your facility, please alert your customer(s) of this field correction and contact the Carestream Customer Care Center as instructed above.

This Field Corrective Action is being made with the knowledge of the US Food and Drug Administration. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA in the U.S.:

- Online at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
- Call FDA at 1-800-FDA-1088 (1-800-332-1088)

We regret any inconvenience this may have caused to your operations.

Martin S. Pesce, RT

[redacted]

OnSight 3D Extremity System Product Line Manager
Carestream Health, Inc.