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

To the person in charge of Service for the unit where the DRX Ascend/ Q-Rad System is distributed.

July 25, 2018

Ref: SEIMENS Healthineers: SIEMENS 3D-Top or 3DV lifting column.

(URGENT) SAFETY ADVISORY NOTICE / (URGENT) FIELD SAFETY NOTICE

Important safety information for customers regarding a field corrective action notified to Carestream Health Inc. By SIEMENS Healthineers:

To all users of the System **DRX Ascend/Q-Rad System**
Cc: Chairman Medical Board and relevant HODs
Re: Potential malfunction of the SIEMENS 3D-Top or 3DV lifting column.

Dear Customer,

This letter is to inform you of a potential issue we have been made aware of by SIEMENS which may if not remediated lead to the possible hazard to persons associated with the operation of the following product **SIEMENS 3D-Top or 3DV lifting column,** which is integrated with the: **Carestream DRX Ascend with /Q-Rad Systems with Ceiling Mounted Tube Support (RS-590 or RS-580)** used in your facilities. This affects any of the serial numbers indicated in the attached acknowledgment receipt form.

What is the Problem?

In rare cases of insufficient maintenance or high clinical workload, the Primary steel cable of the ceiling stand, which is designed to take the load, could break without triggering the safety lock and this could lead to overloading the safety cable which is not designed for continuous load and ongoing movement under load. This may lead to mechanical fatigue and cause the arm to drop down during patient positioning.

What are the Possible Risks to Health?

Patients and users may be seriously injured.

What steps must be taken?

Retrofit kits are available for installation to avoid risk to patients and users. If you have questions or need assistance, please use the referenced contact information.

Are there interim steps to reduce risk before the Retrofit Kit is installed?

The retrofit kit is intended to fully address the problem. However, until the retrofit kit is installed, we strongly recommend against performing up/down movements of the lifting column directly above the patient. Instead, the vertical movement should be completed beside the patient and then the system should be moved horizontally to the patient.

Dissemination of the content of this notice

SIEMENS have requested that Carestream Heath Inc. ensure that all those who have the affected product, including any others who may need to be informed, receive the safety relevant information provided with this notice and comply with the recommendations herein.

Retention

Please ensure that this Safety Notice is appropriately retained in your product related records. Please keep this information, at minimum, until retrofit kits have been installed at all of your customer sites.

Complete and Return Form

Please complete the attached acknowledgement form to document retrofit kits ordered from Carestream Health Inc. and/or installed. If you have not, to date, ordered and or installed the retrofit kits, this information also needs to be filled out. Please complete the applicable portions of the form and send it back to the email addresses stated on the acknowledgement form.

Please note that the relevant Regulators /National Competent Authorities will be informed directly of this notice by SIEMENS.

We appreciate your immediate attention to this very important safety matter.

Sincerely,

[redacted]

Steven J. Romocki | Worldwide Product Line Manager
Global X-ray Solutions

[redacted]