Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

Date: December 29, 2016

URGENT: MEDICAL DEVICE CORRECTION

To: Director of Radiology, Chief Radiology Administrator and Administrators for Carestream DRX-Revolution Mobile X-Ray System

This is to inform you of a product recall involving:

DRX-Revolution Mobile X-Ray System

Serial Numbers: Worldwide except China: 101 – 2545

China Only: 800101 – 800468

Description of the Problem:
Carestream Health has identified an issue with the DRX-Revolution Mobile X-Ray System that could result in unintended motion. Carestream's investigation found that the pivot screws in the drive handle can back out and interfere with the driving mechanism. The backed out screw can interfere with operator control of the DRX Revolution and result in unintended motion. The investigation revealed that thread locking compound applied in the manufacturing process to secure this screw was not always applied as it should. To date, Carestream has found only a single system where this failure has occurred, there was no resulting injury, but the problem could manifest in additional units over the life of the device.

Action to be Taken:

Carestream will replace the pivot screws on a visit to each site for all potentially affected systems.

Carestream has fully assessed the identified risk, and based on the time to failure will replace the affected pivot screws on all customer units within 12 months; prioritizing based on time in service. The DRX Revolution can be used normally until the correction is made. Carestream recommends that routine user inspections of drive operation of the DRX Revolution are continued, and should any part show a visual problem or fail to operate as expected, the device should be removed from use and a service call placed to Carestream, or your dealer.

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 Service support number.

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

This Field Corrective Action is being made with the knowledge of the Unites States Food and Drug Administration. Adverse reactions or quality problems experienced with the use of the 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

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

Andrew Hartmann
GM Carestream Health