
Urgent Field Safety Notice

KODAK DirectView DR 7500 System

Carestream Health FSCA MA-2014-013

Device inspection

Date: 11 July 2014

Attention: Potential for DR 7500 Beta Assembly (x-ray tube and collimator) to fall from the Overhead Tube Crane (OTC) telescope.

Details on affected devices:

- KODAK DirectView DR 7500 System (all units)

Description of the problem:

Through post-market surveillance, Carestream Health has identified an issue at a customer site where the DR 7500 Beta Assembly (x-ray tube and collimator) had fallen from the Overhead Tube Crane (OTC) telescope while a patient was lying on the table for an examination. The DR 7500 Beta Assembly fell onto the patient and this resulted in injuries to this person. It has been determined that the cause of this issue was an improperly assembled part which holds the Beta Assembly to the OTC telescope. This was a single event and no other complaints of this type have been received since the device was introduced into commercial distribution in 2005.

Action taken by the manufacturer:

A qualified service representative will visit each customer site and inspect the DR 7500 System to determine whether there is an issue with this assembly and if necessary, repair the part. We expect this action to be completed within 4 weeks.

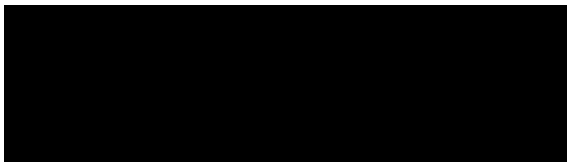
Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, please call your local Service Support number.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Sincerely,



Director, International Regulatory Affairs
Carestream Health, Inc.
150 Verona Street
Rochester New York 14608
USA