
Urgent Field Safety Notice
DRX-Revolution Mobile X-Ray System
Carestream Health FSCA MA-2017-008
Device inspection

Date: 29 May 2017

Attention: Potential risk of separation of the tube and yoke assembly of the device

Details on affected devices: DRX-Revolution Mobile X-Ray System

Description of the problem:

Carestream Health has identified an issue with the DRX-Revolution Mobile X-Ray System that could result in separation of the tube and yoke assembly. Carestream found a single device where four screws in the assembly were not applied in the manufacturing process. Carestream considers it unlikely there are other DRX-Revolution Mobile X-Ray Systems where this step was missed. There was no injury associated with this failure however, if the tube falls and makes contact with a person, injury may occur.



Action taken by the manufacturer:

Carestream considers it unlikely that any other devices would have missed this manufacturing step and therefore have these screws missing. However, all units will be checked within 12 months as a precaution. A Carestream authorized service representative will contact you to inspect and if necessary correct your unit(s).

Advice to users:

In the meantime, the users can check that the 4 screws are on place and the DRX-Revolution can be used normally. In case the screws were to be missing, the device should be removed from use and a service call placed to Carestream (or local dealer) without any delay.

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

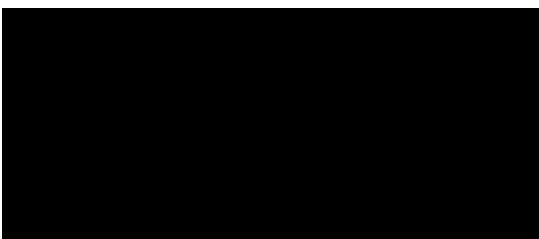
Transmission of this Field Safety Notice:

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.

We regret any inconvenience this may cause to your operation.





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:

Carestream Health FSCA MA-2017-008 – Device inspection
DRX-Revolution Mobile X-Ray System
Potential risk of separation of the tube and yoke assembly of the device

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: _____