



Carestream Health Singapore Pte Ltd
Company Regn. No. 200701017H
315 Alexandra Road # 04-01
Sime Darby Business Centre
Singapore 159944
Tel: (65) 6501 5000 Fax: (65) 6471 2280

URGENT: MEDICAL DEVICE CORRECTION

Date: 18 May 2017

Subject Device: Carestream DRX Revolution Mobile X-Ray System

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

Cc: Chairman Medical Board and Relevant Head of Departments

This is to inform you of a Medical Device Correction involving:

Device Name:	DRX Revolution Mobile X-Ray System
Serial Numbers:	800101 - 800468
Description of 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.
Safety Impact	To date, Carestream has found only a single system where this failure has occurred and considers it unlikely that there are other DRX-Revolution Mobile X-Ray Systems where this step was missed. There was no injury associated with this failure.

Action to be applied by user	<p>The DRX Revolution can be used normally until this inspection is made.</p> <p>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 as a precaution.</p>
Actions planned by Carestream	<p>Carestream has added a verification step to the manufacturing process and will inspect each device in the field to verify that the screws are installed. If they are not installed, they will be added.</p> <p>A Carestream field engineer will contact you to schedule inspection and to confirm results.</p>
Further Information and Support	<p>If you have any questions or concerns, please contact Carestream local Service support number.</p>

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

Debra Benjamin | Worldwide Product Line manager
DMS XRS ADVANCED RADIOLOGY

Enclosed.

Notification by Carestream Health Inc.

MEDICAL DEVICE CORRECTION

ACKNOWLEDGMENT FORM

Acknowledgement of Receipt of Field Notification:

By signing below, I acknowledge that I am aware of the issue and have been informed on the recommended actions as indicated in the Notification.

Printed Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____

Contact Number: _____

Signature: _____ Date: _____