
Urgent Field Safety Notice

**CS 8100 and CS 8100 3D
FSCA MA-2014-023
Device inspection**

Date: 5th January 2015

Attention: **Potential for CS 8100 and CS 8100 3D heads to descend unexpectedly**

Details on affected devices:

On devices manufactured between June 2012 and September 2014.

Description of the problem:

Carestream has identified a problem in the manufacturing process during the above period which could result in the head unit descending unexpectedly and contacting the patient. The issue was found at an installation and nobody was injured, however, to ensure devices are not affected and will perform as designed through their expected life, a Field Safety Corrective Action has been started.

Advice to users:

Carestream recommends that users continue to use device normally and take no additional action.

Action taken by the manufacturer:

Carestream is performing a Field Safety Corrective Action to have each unit within the affected period inspected on site by an engineer and if needed, a repair made. Given the risk of immediate failure is low, it's expected the inspection will be completed over the next 12 months.

Transmission of this Field Safety Notice:

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

If you have any questions, please call your Dealer.

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



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