Carestream

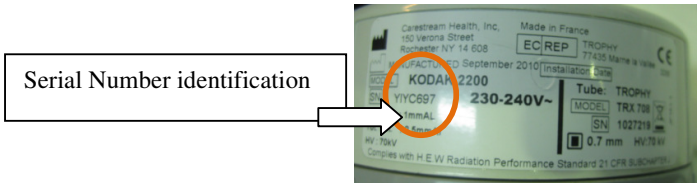
Urgent Field Safety Notice

Kodak 2100 and Kodak 2200 Intraoral X-Ray Systems
FSCA MA-2013-0037
Device modification

Date: 5 February 2014

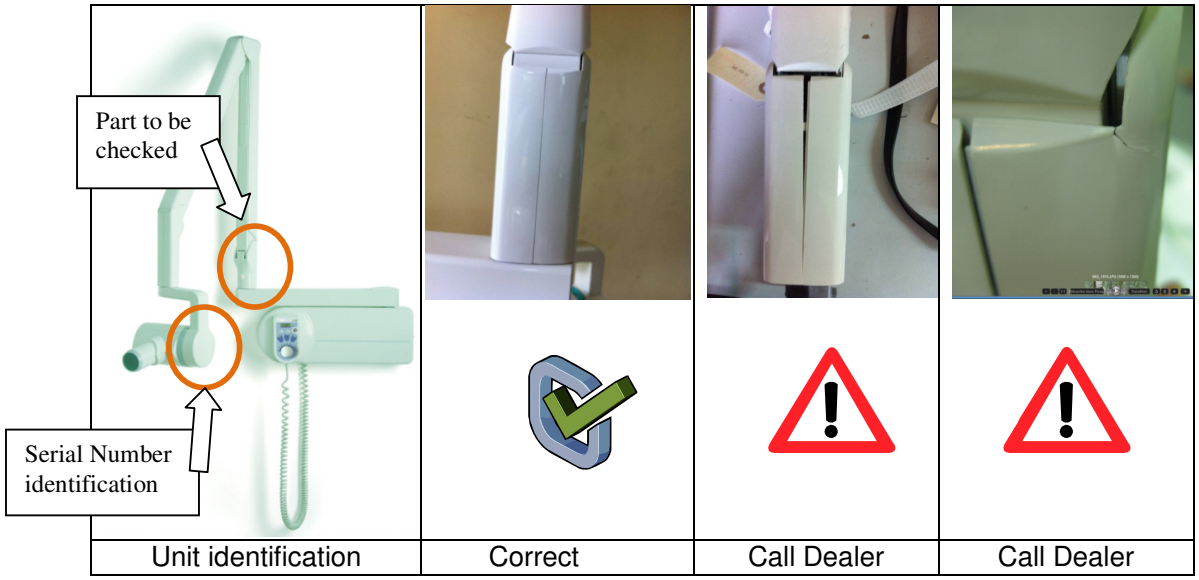
Attention: **Potential for early failure of Kodak 2100 and Kodak 2200 scissor arm bracket joint.**

Details on affected devices:
Kodak 2100 and Kodak 2200 Intraoral Dental X-Ray Systems, wall mounted models with serial numbers starting WE, WF, WG, WH, WI, WJ, WK, WL, XA, XB, XC, XD, XE, XF, XG, XH, XI, XJ, XK, XL, YA, YB, YC, YD and ceiling mounted models with serial numbers starting WE, WF, WG, WH, WI, WJ, WK, WL, XA, XB, XC, XD, XE, XF, XG, XH, XI, XJ, XK, XL, YA, YB, YC, YD, YE, YF, YG, YH, YI, YJ, YK.



Description of the problem:
Carestream has identified a problem in the manufacturing process during the above period which could result in the early failure of the scissor arm to bracket connection. The failure is not immediate and normally is visible to the user before the arm can fall. Should the arm fall, there is a risk of injury by impact to patient or user.

Advice to users:
Carestream recommends that users make regular inspections of their units using the pictures below, to ensure the arm has not failed. A service engineer from your dealer will visit to make a detailed inspection and a modification to rectify the problem. If the unit shows early signs of failure at inspection, please stop using it and call your dealer immediately.



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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 a modification added to each unit.

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

Robert C Meagher
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