
Urgent Field Safety Notice

**CARESTREAM DRX-1 System Battery
FSCA VIG-1317307-2012-00008
Device Modification or Replacement**

Date: 18 JUNE 2012

Attention: **Potential DRX-1 detector lithium-ion battery overheating**

Details on affected devices:

CARESTREAM DRX-1 System Batteries manufactured before June 2012. These batteries are used in the Carestream DRX-1 and DRX-1C System Detector used in the CARESTREAM DRX-1 System.

Description of the problem and action to be taken:

The purpose of this letter is to advise you that Carestream Health is performing a field evaluation and possible replacement of Carestream DRX-1 System batteries manufactured before June 2012.

Two occurrences of lithium-ion battery overheating have come to our attention out of the over 11,000 DRX-1 detector lithium-ion batteries in use. The overheating caused the plastic battery casing of the DRX-1 detector to melt which can cause burns or other injury.

To address this issue, we have created a field evaluation and modification kit. Service personnel will evaluate all batteries in use. Immediately upon evaluation batteries will either be modified (a change to battery configuration values) or replaced at no charge.

Your local service representative will contact you to schedule the evaluation.

As a reminder, please handle batteries in accordance with the instructions found in the CARESTREAM DRX-1 System Battery User's Guide at all times. Additionally, to minimize the risk of overheating, batteries should be fully charged prior to storage.

Transmission of this Field Safety Notice:

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



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

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