Medical Device Alert

Ref: MDA/2014/005 Issued: 24 February 2014 at 12:00

Device

Intra-oral dental X-ray units:
Kodak 2100 and Kodak 2200 (wall and ceiling mounted)

Manufactured by Carestream Health

Models released for sale from May 2008 to April 2010, serial numbers as identified in the FSN.

Problem

Risk of injury if the joint between the scissor arm and bracket fails.

This joint could fail prematurely due to a manufacturing problem during the period from May 2008 to April 2010.

Action by

Dentists.
Community dental practices.
General dental practitioners.

Action

- Identify affected devices using the guidance in the manufacturer's Field Safety Notice (FSN).
- Inspect the units using the pictures in the FSN, to ensure the arm has not failed.
- If the unit shows signs of failure, stop using it and call your dealer immediately.
- All systems need to be inspected even if they don't show signs of failure.
- Contact your dealer to arrange a service engineer visit.

CAS deadlines

Action underway: 10 March 2014

Action complete: 24 March 2014

Note: These deadlines are for systems to be in place to identify affected units and plan any appropriate actions

Contact

Carestream Health
Carestream Dental Technical support team
Tel: 00 800 4567 7654
Email: europedental@carestream.com

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Community dental practices
- Dental departments
- Dental nurses
- Dentists
- In-house maintenance staff
- Maxillofacial departments
- Medical physics departments
- Oral surgeons
- Radiographer superintendents
- Radiology departments
- Radiology directors

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General dental practitioners

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Clinics
- General dental practices
- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Carestream Health
Carestream Dental Technical support team
Tel: 00 800 4567 7654
Email: europedental@carestream.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/005** or **2014/001/013/081/022**

Technical aspects
David Grainger or Ian Sealey
Medicines and Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7199 / 6691
Fax: 020 8754 3965

Email: david.grainger@mhra.gsi.gov.uk
ian.sealey@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines and Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: mark.grumbridge@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6, Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 5801

Email: Haz-Aic@wales.gsi.gov.uk