

Medical Device Alert

Ref: MDA/2012/046 Issued: 16 July 2012 at 15:30

Device

Non CE-marked portable dental X-ray units.

Including the Tianjie Dental 'Falcon'.



Problem

Testing by the Health Protection Agency (HPA) has revealed that the Tianjie Dental Falcon device lacks sufficient shielding in the X-ray tube, which could give rise to high patient doses and under typical high radiographic workloads result in operator doses in excess of the Ionising Radiation Regulations 1999 annual dose limits. This could give rise to adverse health effects caused by radiation.

The Tianjie Dental Falcon is not CE-marked as a medical device.

Action by

Dentists, Medical Physics Departments

Action

- Identify and stop using this and similar non CE-marked devices.
- Replace the device with a suitable CE-marked alternative.
- Be aware of the NRPB (HPA) [Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment](#) or the [Medical & Dental Guidance Notes](#) published by IPEM.
- Be aware of the general requirement to consult a suitable radiation protection adviser with regard to the use of X-ray equipment.
- Be aware of [MHRA advice on the use of non-CE marked devices](#).
- Report any suspected devices to [MHRA Adverse Incident Centre](#).

CAS deadlines

Action underway: 23 July 2012

Action complete: 06 August 2012

Contact

Manufacturer

Lin Lin
Zhengzhou Tianjie Electronic Equipment Co

Tel: +86 371 67934274

Fax: +86 371 67375396

Email: linzseason@gmail.com

Device

The Tianjie Dental Falcon portable X-ray unit is not CE-marked as a medical device and was purchased on eBay. It is identical in appearance to a number of other non CE-marked devices that are available on the internet:



Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Health and Safety Executive
- Primary care 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:

- Dental Hospitals
- Dentists
- Orthodontists
- Medical physics departments
- Radiographer superintendents
- Radiographers
- Radiologists
- EBME Departments
- Supplies departments

Primary care trusts

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

- Community dental practices
- Directors of public health
- General dental practitioners
- Maintenance staff

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Dental Practices

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

Manufacturer

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/046** or **2012/006/025/081/008**

Technical aspects

David Grainger or Paul Sandhu
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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Fax: 020 8754 3965

Email: david.grainger@mhra.gsi.gov.uk
paul.sandhu@mhra.gsi.gov.uk

Clinical aspects

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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

Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB
Tel: 0131 275 7575 Fax: 0131 314 0722
Email: nss.irc@nhs.net
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk

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Appendix



Health Protection Agency

Centre for Radiation, Chemical
and Environmental Hazards

Hospital Lane, Cookridge
Leeds LS16 6RW

Tel: +44 (0) 113 267 9041
Fax: +44 (0) 113 261 3190
www.hpa.org.uk/radiation

21 June 2012

Tianjie Dental 'Falcon' hand held X-ray set imported from China: Summary of HPA radiation protection assessment results

HPA's Dental X-ray Protection Service (DXPS) has recently obtained an example of a hand held dental X-ray unit available for purchase in the UK via the eBay website. There are other X-ray units of identical appearance being sold under different names on the internet. This particular unit was sold from China and was priced at £205, a fraction of the cost of other dental hand held X-ray sets available for sale in the UK, which can be over £4,000. The unit is not CE marked and there was no identifiable information provided about the supplier or manufacturer. DXPS is aware of one UK dentist who has purchased this type of X-ray set and has received several other enquiries from dentists who are considering purchasing one. The X-ray set obtained is pictured below.



The operating potential and tube current are fixed and exposure times are selected on the control panel. Times can be selected between 0.1 and 9.9 seconds, in 0.1 second increments. X-ray exposures are triggered by either pressing an exposure button on the control panel or on the X-ray tube, or by using the remote exposure switch. The X-ray tube can be attached to a tripod if required but is intended to be used held in the hands.

DXPS has made an assessment of the operating parameters of the X-ray set and measurements of scattered and leakage radiation at positions representative of the operator's hand and body position when holding the X-ray set in the hands. **These results give cause for concern** and are summarised overleaf.

Maximum dose at the operator body position for a typical exposure ¹ :	5.6 µGy
Maximum dose at the operator hand position for the same exposure:	7592 µGy
Assessed operating potential:	49 kVp
Focal spot to end of cone distance:	100 mm
Beam size:	55 mm circular²

These operating parameters do not meet the requirements specified in the Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment and the measurements of scattered and leakage radiation raise serious concerns (see below).

Potential annual doses to operator

Assuming a simple relationship that 1 Gy is equivalent to 1 Sv, potential doses to the operator can be estimated. If the operator was to use this X-ray set under a typical heavy workload of 100 exposures per week for 50 weeks of the year, using a 3 second exposure time, potential doses could be up to **40 Sv** (equivalent dose) to the hands and **30 mSv** (effective dose) to the body.

Potential dose to the patient

The patient is exposed to significant leakage radiation, resulting in a Dose Area Product (DAP) almost ten times greater than it would be if the X-ray tube was adequately shielded and the X-ray beam was collimated to just the primary X-ray beam.

Conclusion

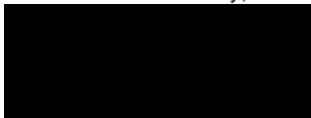
The example tested demonstrates a number of serious deficiencies, the most worrying of which is a lack of sufficient shielding in the X-ray tube which could (under circumstances of high but realistic radiographic workloads) give rise to operator doses in excess of the IRR99 annual dose limits and could even lead to localised deterministic effects. The X-ray set also fails to meet a number of the standards recommended in the Dental GNs, and is not CE marked. In addition, an assessment conducted by HPA CRCE's Technology Development Group concluded that the X-ray unit did not meet the expected standards of construction and electrical safety.

HPA recommends that regulators give consideration to prohibiting the use of this model of X-ray unit. Furthermore, professional bodies within the dental community may wish to inform potential users of the risks of using this X-ray unit.

If you would like further information, or a copy of the full report on this X-ray set, please contact either:

Andrew Gulson andrew.gulson@hpa.org.uk or John Holroyd john.holroyd@hpa.org.uk

Yours sincerely,



DXPS Group Leader
 @hpa.org.uk

¹ An exposure time of 3 seconds was chosen. This gave a dose of 1.9 mGy at the end of the director cone (100 mm from the X-ray focal spot). This is actually a lower dose than that likely to be required to obtain good quality radiographs with either film or digital imaging systems given the operating parameters of this X-ray set.

² Due to the deficiency in shielding of the X-ray tube and director cone a significantly larger X-ray beam was apparent. The dose in the 'outer' X-ray beam was measured to be approximately half that in the primary beam and the total size of the beam was measured to be 225 mm in diameter.