

Appendix



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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 circular ²

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

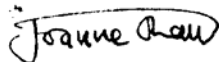
The example tested demonstrates a number of serious deficiencies, the most worrying of which is a lack of sufficient shielding in the X-ray tube which could (under circumstances of high but realistic radiographic workloads) give rise to operator doses in excess of the IRR99 annual dose limits and could 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:

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Yours sincerely,



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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.