Appendix A Results of Tests on Hand-held Dental X-ray Equipment conducted by PHE

A1 Summary of models tested by PHE

Table A1 lists the models of hand-held X-ray equipment that have been tested by PHE and summarises their main features. The tests were either conducted on behalf of suppliers prior to sale or for type testing purposes, or were annual routine tests undertaken on behalf of dental practices. The models have been anonymised for the purposes of this report.

The test results for the Tianjie Dental 'Falcon' are not included here as they were published in summary form in an MHRA medical device alert*. Furthermore, the device is not CE marked, so is not considered to be legitimately available in the UK.

Table A1: Main features of hand-held models tested by PHE

Specification/description	Model A (Nomad)	Model B	Model C	Model D	Model E (Rextar X)
Operating potential (kV)	60	60	60	60	70
Tube current (mA)	2.5	2.0	2.0	2.0	2.0
Exposure time range (seconds)	0.02–1.00	0.01–2.00	0.03–2.00	0.05–1.35	0.01–1.30
Dose rate at end of cone (mGy/s)	3.41	2.38	Not specified	4.90	3.37
Backscatter shield provided?	Yes	No	No	Yes	Yes
Focus to skin distance (mm)	200	200	100	120	205
Beam size: diameter (mm) or width (mm) x height (mm)	34 x 46	60	65	60	35 x 43
Total filtration (mm Al)	1.5	1.8	2.0	1.5	1.5
'Power on' light provided?	Yes	Yes	Yes	Yes	Yes
'X-rays on' light provided?	Yes	Yes	Yes	Yes	Yes
'X-rays on' audible signal provided?	Yes	Yes	Yes	Yes	Yes
Automatic power down/control timeout?	Yes	No	Yes	Yes	Yes

* MHRA (2012). Medical Device Alert: Non CE-marked portable dental X-ray units including the Tianjie Dental 'Falcon' (MDA/2012/046). London, Medicines and Healthcare Products Regulatory Agency. Available at http://webarchive.nationalarchives.gov.uk/20141205150130/http://mhra.gov.uk/publications/safetywarnings/medicaldevicealerts/con173752 (accessed 18/06/2015).

A2 Results of tests conducted by PHE

Table A2 summarises the estimated annual absorbed doses to the operator's body and hands arising from use of the models in Table A1. The estimated doses are based on measurements of absorbed doses taken at positions in a vertical plane 0.50 m behind the hand-held unit, and at positions representative of the operator's hands, and an assumed workload of 100 radiographs a week for 50 weeks a year. Again, the models have been anonymised for the purposes of this report, and the test results for the Tianjie Dental 'Falcon' are not included.

Table A2: Results of tests on hand-held models conducted by PHE

Feature	Model A (Nomad)	Model B	Model C	Model D	Model E (RextarX)
PHE recommended exposure time for adult mandibular molar radiograph using speed group F film (s)	0.40	0.61	0.29	0.40	0.26
Patient entrance dose corresponding to above exposure time (mGy)	1.17	1.45	1.10	1.93	0.86
Absorbed dose per 0.50 s exposure at operator's body position (nGy)	73	122	461	73	27
Absorbed dose per 0.50 s exposure at operator's hand position (nGy)	160	1,800	10,800	1,700	70
Estimated annual dose at operator's body position (mGy)*	0.10	0.70	1.3	0.30	0.07
Estimated annual dose at operator's hand position (mGy)*	0.62	10.9	31.0	6.80	0.20

* For comparison with the dose constraints recommended in Section 3.2, measurements reported using the quantity air kerma (in units of mGy) are unlikely to underestimate the effective or equivalent dose (in units of mSv).

A2.1 Summary of test results

Models A, D and E complied with the dose constraints recommended in Section 3.3 of the main text. These models were provided with a backscatter shield. It is likely that model B would also have complied if it were fitted with a backscatter shield.

However, models C and D had a focus-to-skin distance (fsd) which was less than the minimum value of 200 mm recommended for equipment operating at 60 kV or above. Use of a longer spacer cone providing an fsd of 200 mm would reduce the patient entrance dose necessary for a radiograph of adequate diagnostic quality, with a proportionate reduction in the annual doses to the operator's body and hands.

In the case of model C this would not be sufficient to meet the recommended constraints on effective and equivalent dose. Model C was supplied with a circular collimator of stated diameter 65 mm, which exceeds the maximum recommended value of 63 mm. However, the X-ray beam at the end of the spacer cone was measured to be 57 mm in diameter.

In the case of model D, provision of an fsd of 200 mm would also have the desirable effect of reducing the patient entrance dose to below the current national diagnostic reference level of 1.7 mGy and increasing the size of the protected zone.