Hand-held Dental X-ray Systems Revision

**4732.### HAND-HELD DENTAL INTRAORAL X-RAY SYSTEMS.**

Subpart 1. **Applicability.** A registrant's hand-held intraoral x-ray system must meet the requirements of Minnesota Statutes, section 144.1215, this chapter, and must:

A. meet nationally recognized standards such as Code of Federal Regulations, title 21, sections 1020, or successor requirements; or

B. meet the manufacturer’s specifications; and

C. follow calibration testing under subpart 8.

**X-ray Equipment**

**Subp. 2. Beam quality; half-value layer.**

A. The half-value layer of the useful beam for a given kVp must not be less than the values shown in item C.

B. If it is necessary to determine a half-value layer at a kVp that is not listed under item C, then a service provider must:

1. make a linear interpolation or extrapolation; and

2. include the determination in the calibration report under part 4732.0280.
For purposes of this subpart, half-value layer means the thickness of a specified material that absorbs the beam of radiation to such an extent that the exposure rate is reduced to one-half of its original value. The contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is considered excluded.

C. Values for half-value layer of useful beam for x-ray tube:

<table>
<thead>
<tr>
<th>Design operating range (kVp)</th>
<th>Measured kVp</th>
<th>Half-value layer (millimeter of aluminum)</th>
<th>Specified Dental Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Other x-ray Systems*</td>
<td></td>
</tr>
<tr>
<td>Below 50</td>
<td>30</td>
<td>0.3</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>0.4</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>0.5</td>
<td>1.5</td>
</tr>
<tr>
<td>51-70</td>
<td>51</td>
<td>1.2</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Above 70</td>
<td>71</td>
<td>2.1 [2.5]</td>
<td>2.1</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>2.3 [2.9]</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>2.5 [3.2]</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>2.7 [3.6]</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td>110</td>
<td>3.0 [3.9]</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>120</td>
<td>3.2 [4.3]</td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>130</td>
<td>3.5 [4.7]</td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td>140</td>
<td>3.8 [5.0]</td>
<td>3.8</td>
</tr>
<tr>
<td></td>
<td>150</td>
<td>4.1 [5.4]</td>
<td>4.1</td>
</tr>
</tbody>
</table>

*Systems manufactured after June 10, 2006, are in brackets. All other systems were manufactured before June 10, 2006.

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B. All hand-held dental intraoral x-ray systems must have a minimum half-value layer not less than 1.5 millimeters aluminum.

C. For capacitor energy storage equipment, compliance with the requirements of this subpart must be determined [by a service provider] with the capacitors fully charged and with a technique that discharges at least half of the energy stored in the capacitors, half of the maximum milliampere-second.

D. The half-value layer of the useful beam must be measured [by a service provider] with all the materials in the beam that normally are present between the source and the patient.

Subp. 3. X-ray beam alignment. A registrant is responsible for the x-ray beam alignment provisions of this subpart.

A. A hand-held x-ray system designed for use with an intraoral image receptor must limit the source-to-skin distance (SSD) to not less than 18 centimeters.

B. The x-ray field at the minimum source-to-skin distance must be contained in a circle in which the diameter does not exceed 7 centimeters.

Subp. 4. Mechanical support of tube housing assembly and position-indicating device. A registrant using a hand-held dental x-ray system is responsible for the requirements of this subpart. The tube housing assembly and the position-indicating device must be:

A. stable before the exposure is initiated and during the exposure;

B designed to operate while hand-held; and

C. may be held by the tube housing support or by the handle.

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**Subp. 5. Radiation exposure control.** A registrant is responsible for the radiation exposure control provisions of this subpart.

A. The x-ray control switch must:
   
   (1) have a circuit-closing contact that requires a deliberate action and continuous pressure by an x-ray operator to complete the exposure; and
   
   (2) be able to terminate the exposure at a preset time or interval.

B. The hand-held dental intraoral dental x-ray system must bear the warning statement which is legible and accessible to view: "WARNING This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

**Subp. 6. Beam-on indicators.** A registrant is responsible for the beam-on indicator provisions of this subpart.

A. A visual indication that is observable at or from the x-ray operator’s protected position whenever x-rays are produced; and

B. a signal that is audible to the x-ray operator that the exposure has terminated.

**Subp. 7. Technique factors.** A registrant is responsible for the technique factor provisions of this subpart.

A. The technique factors on a hand-held x-ray system must be indicated and visible to an x-ray operator before the exposure begins.

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B. If automatic exposure controls are used, the technique factors that are set before the exposure must be indicated and visible to an x-ray operator.

C. The requirements of items A and B may be met by permanent markings on intraoral dental x-ray systems that have fixed technique factors.

D. The technique chart used for all radiographic exposures must meet the requirements under part 4732.0550.

Subp. 8. Calibrations. A registrant using a handheld dental intraoral x-ray system is responsible for the calibration testing requirements of this subpart. Calibration testing must be performed:

A. at the time of installation before first use;

B. over all clinical ranges used by the registrant; and

C. at intervals not to exceed 24 months (730 calendar days) from the date of prior calibration testing.

D. A registrant may have a grace period of 30 calendar days to comply with calibration testing under this subpart. A registrant is in violation of item C if the calibration testing interval exceeds 760 calendar days.

E. CALIBRATION PERFORMANCE CRITERIA.

<table>
<thead>
<tr>
<th>TEST TYPE</th>
<th>MINIMUM PERFORMANCE CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Filtration (HVL)</td>
<td>Meet requirements in subpart 2</td>
</tr>
</tbody>
</table>

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(2) Timer reproducibility ± 10% of indicated timer setting

(3) kVp accuracy ± 5% of indicated kVp for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer’s specified limits

(4) Exposure output reproducibility Coefficient of variation < 5%

(5) Dental mA linearity ± 10% over the clinical range

A service provider must make adjustments to the handheld dental intraoral x-ray system to meet the requirements under with subpart 1.

Shielding

Subp. 9. Shielding requirements. A registrant operating an intraoral hand-held dental x-ray system must:

A. maintain the dose levels so that they do not exceed the limits under parts 4732.0410 to 4732.0430;

B. meet the requirements under Minnesota Statutes, section 144.1215, subdivision 2, paragraph (a)(2); and

Commented [JC21]: Based on existing 4732.1100, subpart 1, Item A

Commented [JC22]: Proposed 4732.0365, subp. 1 Proposed 4732.0365, subp. 2, Items A & B Consistent with SSRCR

Commented [JC23]: MDH will update the internal references to these DOSE LEVELS provisions.

Commented [JC24]: See Laws 2017, Chapter 6, Article 10, Section 58

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C. provide protective barriers that are at least 2 meters (6.5 feet) in height or maintain at least 6 feet (1.8 meters) distance from adjacent room or area.

Subp. 10. Shielding exemption. A registrant with only an intraoral hand-held dental x-ray system and complies with subpart 9 is exempt from the requirements under part 4732.0000.

4732.0000.

Conditions of Operation

Subp. 11. Prohibited uses. An individual must not be exposed to the useful beam except for healing arts purposes. Deliberate exposure is prohibited for:

A. training;

B. demonstration;

C. or other non-healing arts purposes.

Subp. 12. Ordering of diagnostic radiographic examinations. A registrant is exempt from the provisions of part 4732.0560 if the registrant has a written procedure for ordering dental examinations that:

A. is authorized and signed by a dentist who is licensed under Minnesota Statutes, chapter 150A; and

B. uses evidence-based radiological guidelines for patients that include one or more of the following:

(1) type and frequency of examination;

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(2) risk for oral disease;

(3) age of patient; and

(4) stage of dental development.

**Subp. 13. Utilization data.** A registrant performing hand-held dental imaging examinations must maintain utilization data, in electronic or written form, including:

A. a patient identifier;

B. the type of examination;

C. the date the examination was performed;

D. the x-ray operator who is operating the x-ray system;

E. the name of all individuals who remain in the room during an x-ray examination; and

F. the name of all student externs if the registrant is an externship site under part 4732.0590.

**Subp. 14. Operator protection.** A registrant is responsible for the operator protection requirements in this subpart.

A. Occupational staff must not hold an image receptor in place by using their fingers.

B. An x-ray operator must:

   (1) remain behind a protective barrier; or

Commented [JC]: Will move to General Requirements part.

Commented [JC]: MDH will update this internal reference to 4732.0590 - INDIVIDUALS OPERATING X-RAY EQUIPMENT DURING TRAINING.

Commented [JC]: From - 4732.0880, subp. 2, item B (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)
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(2) be at least six feet (or 1.8 meters) from the patient and the tube housing assembly; and

(3) not be in the path of the primary beam during an exposure.

c. Except for the patient, all individuals who remain in the room during an x-ray exposure must be protected by a minimum of 0.50 millimeter lead equivalent personal protective equipment.

Subp. 15. Safety controls. A registrant is responsible for the safety control provisions in this subpart.

A. The useful beam must be limited to the patient’s area of clinical interest.

B. Intraoral film holders and bite blocks must be used except when endodontic procedures do not permit.

C. Occupational staff must not hold an image receptor in place by using their fingers.

D. A registrant must store an intraoral handheld dental x-ray system when not in use according to Minnesota Statutes, section 144.1215, subdivision 2, paragraph [d].

E. A registrant must notify the commissioner of the theft or loss of a dental hand-held intraoral x-ray system according to 4732.0600.

Subp. 16. Quality control procedures. A registrant using a digital imaging receptor must:

Commented [JC34]: 1. 2m or 6.5 ft is SSRCR. We are staying with 6 feet.
2. Replacing “x-ray tube” with “tube housing assembly”

Commented [JC35]: From - Proposed 4732.0365, subp. 3, Item C. No changes.

Commented [JC36]: From - Proposed 4732.0365, subp. 1

Commented [JC37]: From - Proposed 4732.0365, subp. 3, Item C. No changes.

Commented [JC38]: From 4732.0880, subp. 2, item A (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

Commented [JC39]: From - 4732.0880, subp. 2, item B (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

Commented [JC40]: See Laws 2017, Chapter 6, Article 10, Section 58

Commented [JC41]: MDH will update the internal reference to 4732.0600 - REPORTS OF THEFT OR LOSS OF RADIATION-PRODUCING EQUIPMENT.
A. comply with the quality control recommendations provided by the digital imaging receptor manufacturer;

B. maintain quality control recommendations, tests, and evaluations for:

(1) use by an x-ray operator; and

(2) review by the commissioner at the time of inspection.

Subp. #. Records.

Commented [JC(42)]: There will one Records provision for all registrants.