

# Dental Handheld X-ray Systems

PROPOSED REVISIONS TO 4732.XXXX, 2.0

## **4732.#### DENTAL HANDHELD X-RAY SYSTEMS.**

Subpart 1. **Applicability.** A registrant's x-ray system used for dental handheld imaging must meet the requirements of Minnesota Statutes, section 144.1215 and the applicable performance standards in Code of Federal Regulations, title 21, section 1020.30 to 1020.40, or successor requirements.

**Commented [JC1]:** Based on existing parts 4732.0880 and 4732.0890.

## X-ray Equipment

Subp. 2. **X-ray beam alignment.** A registrant is responsible for the x-ray beam alignment provisions of this subpart.

A. A handheld dental 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.

**Commented [JC2]:** Replaces existing 4732.0800, subp. 5. (GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Diagnostic radiographic systems designed for one image receptor size.)  
Consistent with *SSRCR, Part F, p. 51.*  
Item A – 21 CFR 1020.31(i)(1)  
Item B – 21 CFR 1020.31(f)(1)(i)

Subp. 3. **Support of tube housing assembly and position-indicating device.** A registrant using a dental handheld x-ray system is responsible for the requirements of this subpart. The tube housing assembly and the position-indicating device must be:

**Commented [JC3]:** Adding "assembly" to "tube housing".  
Consistent with *SSRCR* and *Definitions*.

- A. stable during the exposure;
- B. designed to operate while handheld; and
- C. held by the tube housing support or by the handle.

**Commented [JC(4)]:** See Minn Stat. § 144.1215

Subp. 4. Radiation exposure control. A registrant is responsible for the radiation exposure control provisions of this subpart.

- A. An x-ray control must:
  - (1) be incorporated into each x-ray system so that an exposure can be terminated by a qualified operator at any time; and
  - (2) be of the continuous pressure type.
  - (3) must bear the warning statement under 21 CFR 1020 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.", or successor requirements.

**Commented [JC5]:** 1. Adding "by a qualified operator". Specifies who is doing the action and consistent with both SSRCC and Michigan administrative code.  
2. Adding subitem 2 – consistent with both SSRCC and Michigan administrative code.

**Commented [JC6]:** From 4732.0800, subp. 2, item D. (GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)  
No change.

Subp. 5. Beam-on indicators. A registrant is responsible for the beam-on indicator requirements of this subpart.

- A. A visual indication that is observable at or from a qualified operator's protected position whenever x-rays are produced; and
- B. a signal that is audible to the qualified operator that the exposure has terminated.

**Commented [JC(7)]:** From 4732.0800, subp. 2, Items C & F. (GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.) No changes. Consistent with SSRCC, Part F, p. 50.

Subp. 6. Technique factors. A registrant is responsible for the technique factor provisions of this subpart.

**Commented [JC(8)]:** Specifying provisions for technique factors that were not part of 4732.0800, subp. 2. (GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)  
From SSRCC, Part F, p. 50

- A. The technique factors on manual and automatic exposure control x-ray systems must be:
  - (1) indicated; and
  - (2) visible to a qualified operator before the exposure begins.

**Commented [JC(9)]:** From *SSRCR, Part F, p. 50* Consistent with FDA 1020.31 (a) and Texas Administrative Code

- B. The requirements of item A may be met by permanent markings on dental handheld x-ray systems that have fixed technique factors.

**Commented [JC(10)]:** From *SSRCR, Part F, p. 50* Consistent with FDA, TX, and SSRCR, p. F 24.

- C. An electronic or written chart must be available at the control panel. The chart must identify the kVp, mA, time, and image receptor used for:

**Commented [JC(11)]:** Based on a sample technique chart in Texas guidance, Appendix C, and [American Dental Association and FDA recommendations for Technique Chart/Protocols](#).

- (1) anterior region, posterior region, and bitewing; and
- (2) adult and pediatric.

**Subp. 7. Equipment performance evaluation; testing requirements; frequency. A**

registrant using a dental handheld x-ray system is responsible for the equipment performance evaluation testing requirements under subparts 7 to 11.

**Commented [JC(12)]:** Based on part 4732.1100, subparts 1, 2, and 11 - **INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.**

- A. A registrant must have equipment performance evaluation testing performed over all clinical ranges used by the registrant.
- B. Initial equipment performance evaluation testing must be performed at installation before first patient use.
- C. Periodic equipment performance evaluation testing must be performed at intervals not to exceed 24 months (730 calendar days) from the date of the previous equipment performance evaluation. A registrant may have a grace period of 30 calendar days to comply with the periodic equipment performance evaluation testing interval requirement under this item.

**Commented [JC(13)]:** Based on 4732.1100, subpart 1, Item B, and combines subp. 2 (Frequency of tests.)

D. Equipment performance evaluation testing must be performed by a qualified service provider.

E. If a registrant's dental handheld x-ray system fails to meet any of the equipment performance evaluation testing under subparts 8 to 11, then a registrant must:

(1) not use the dental handheld x-ray system; and

(2) have a qualified service provider calibrate the dental handheld x-ray system so that the operating parameter complies with this part.

**Commented [JC(14)]:** Based on existing 4732.1100, subpart 1, Item A. MDH intends to require a comparable qualified service provider requirement to calibrate equipment into proper working condition as specified in item F.

**Commented [JC(15)]:** From 4732.0520, subp. 1, item E.

**Subp. 8. Equipment performance evaluation; filtration (half-value layer) test.**

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

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

**Commented [JC(16)]:** From 4732.0800, subp. 6 (GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Beam quality, half-value layer)

<u>Design operating range (kVp)</u>	<u>Measured kVp</u>	<u>Half-value layer</u>	
		<u>(millimeter of aluminum)</u>	<u>Specified Dental Systems</u>
<u>Below 50</u>	<u>30</u>	<u>0.3</u>	<u>1.5</u>
	<u>40</u>	<u>0.4</u>	<u>1.5</u>
	<u>50</u>	<u>0.5</u>	<u>1.5</u>
<u>51-70</u>	<u>51</u>	<u>1.2</u>	<u>1.5</u>
	<u>60</u>	<u>1.3</u>	<u>1.5</u>
	<u>70</u>	<u>1.5</u>	<u>1.5</u>
<u>Above 70</u>	<u>71</u>	<u>2.1 [2.5]</u>	<u>2.1</u>

<u>80</u>	<u>2.3 [2.9]</u>	<u>2.3</u>
<u>90</u>	<u>2.5 [3.2]</u>	<u>2.5</u>
<u>100</u>	<u>2.7 [3.6]</u>	<u>2.7</u>
<u>110</u>	<u>3.0 [3.9]</u>	<u>3.0</u>
<u>120</u>	<u>3.2 [4.3]</u>	<u>3.2</u>
<u>130</u>	<u>3.5 [4.7]</u>	<u>3.5</u>
<u>140</u>	<u>3.8 [5.0]</u>	<u>3.8</u>
<u>150</u>	<u>4.1 [5.4]</u>	<u>4.1</u>

\*X-ray systems manufactured before June 10, 2006, are not in brackets. X-ray systems manufactured on or after this date are in brackets.

C. To determine a half-value layer at a kVp (x-ray tube potential) that is not listed under item C, a qualified service provider must:

- (1) make a linear interpolation or extrapolation; and
- (2) include this determination in the calibration report under part

4732.####.

**Commented [JC(17)]:** MDH intends to update the internal reference to the proposed equivalent of part 4732.0280 - SERVICE PROVIDER'S RESPONSIBILITY.

D. All dental handheld x-ray systems must have a minimum half-value layer not less than 1.5 millimeters of aluminum.

E. For capacitor energy storage equipment, compliance with the requirements of this subpart must be determined 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.

**Commented [JC(18)]:** MDH to ask Qualified Service Provider focus group if items E and F are relevant.

F. The half-value layer of the useful beam must be measured with all the materials in the beam that normally are present between the source and the patient.

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.

**Commented [JC(19)]:** HVL definition is consistent with SSRCR.

**Subp. 9. Equipment performance evaluation; timer test.**

- A. The accuracy of the timer must meet the manufacturer's specifications.
- B. The manufacturer specifications required under item A must be available for:
  - (1) use by a qualified service provider; and
  - (2) review by the commissioner at the time of inspection.
- C. If manufacturer's specifications under item B are not available, the timer accuracy must be  $\pm 10$  percent of the indicated time with testing performed at 0.5 second.
- D. Means must be provided to terminate the exposure at:
  - (1) a preset time interval;
  - (2) a preset product of current and time;
  - (3) a preset number of pulses; or
  - (4) a preset radiation exposure to the image receptor.

**Commented [JC(20)]:** Based on Texas §289.232(i)(6) (H) (p. 65). This also the same as FDA (21 CFR 1020.31(a) (2). Reviewed UT, IN, FL, CO, NC, TX

E. It must not be possible to make an exposure when the timer is set to a "zero" or "off" position, if either position is provided.

**Subp. 10. Equipment performance evaluation; kVp accuracy test.**

- A. A registrant's dental handheld x-ray system must meet manufacturer's specifications for the kilovolt peak.
- B. The manufacturer specifications required under items A and must be available for:
  - (1) use by a qualified service provider; and
  - (2) review by the commissioner at the time of inspection.
- C. If the manufacturer's specifications under item B are not available, then the indicated kilovolt peak of a registrant's dental intraoral x-ray system must be accurate to within ±10% of the indicated setting(s).

**Commented [JC(21)]:** Based on Texas administrative code: §289.232(i)(6)(J) (p. 65).

**Subp. 11. Equipment performance evaluation; exposure output reproducibility test.**

When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems must be less than or equal to 5%.

**Commented [JC(22)]:** Reviewed comparable provisions from the following states: TX, IA, ME, NC.

## Shielding

**Subp. 12. Shielding requirements.** A registrant operating a dental handheld x-ray system must:

- A. maintain the dose levels so that they do not exceed the limits under parts 4732.#### to 4732.####;

**Commented [JC(23)]:** Proposed 4732.0365, subp. 1 Proposed 4732.0365, subp. 2, items A & B Consistent with SSRCR

**Commented [JC(24)]:** MDH intends to update the internal reference to the proposed equivalent of parts 4732.0410 – 4732.0430 - DOSE LEVELS.

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

C. provide protective barriers that are at least 6.5 feet (2 meters) in height or maintain at least 6 feet (1.8 meters) distance from the x-ray operator and the patient.

**Commented [JC25]:** Consistent with SSRCR

**Subp. 13. Shielding plan exemption.** A registrant with only a handheld dental intraoral x-ray system is exempt from the shielding plan requirements under part 4732.####.

**Commented [JC(26):** From:4732.0220, subp. 4 (GENERAL REQUIREMENTS FOR ALL FACILITIES; Exemption.)

**Commented [JC(27):** MDH intends to update the internal reference to the proposed equivalent of part 4732.0360.

## Conditions of Operation

**Subp. 14. Prohibited uses.** A registrant must not be exposed to the useful beam except for healing arts purposes. [Deliberate] exposure is prohibited for:

A. training;

B. demonstration; or

C. other non-healing arts purposes.

**Commented [JC(28):** Replaces 4732.0305, subp. 1, item A (Prohibited Uses). Based on *SSRCR Part F, p. 18*. Will move this to General Requirements for all registrants.

**Commented [JC(29):** MDH intends to require a comparable qualified service provider requirement.

**Subp. 15. Ordering of diagnostic radiographic examinations.** A registrant is exempt from the requirements of part 4732.#### if:

A. the registrant has a written procedure for ordering dental examinations;

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

C. the written procedure is available and on site for review by the commissioner.

**Commented [JC(30):** Contains revisions to part 4732.0560, subpart 3, suggested by Board of Dentistry and agreed upon by Dental Focus Group.

**Commented [JC(31):** MDH intends to update the internal reference to the proposed equivalent of part 4732.0560

**(ORDERING OF DIAGNOSTIC RADIOGRAPHIC OR THERAPEUTIC PROCEDURE)**



Subp. 16. Handheld x-ray system; off-site use. A registrant must document the date and location of a registrant’s qualified operator’s use of a handheld x-ray system when used off-site.

Subp. 17. Qualified operator protection. A registrant is responsible for the qualified operator protection requirements in this subpart.

A. A qualified operator must:

(1) remain behind a protective barrier; or

(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. A registrant must have a lead apron available for use by an x-ray operator or a patient.

Subp. 18. Safety controls. A registrant is responsible for the safety controls in this subpart.

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

B. Intraoral image receptor 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.

**Commented [JC(32)]:** 1. 2m or 6.5 ft is SSR. We are staying with 6 feet.  
2. Replacing “x-ray tube” with “tube housing assembly”

**Commented [JC(33)]:** From - Proposed 4732.0365, subp. 3, Item C. No changes.

**Commented [JC(34)]:** From - Proposed 4732.0365, subp. 3, Item C. No changes.  
From 4732.0880, subp. 2, item A (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

**Commented [JC(35)]:** From 4732.0880, subp. 2, item A (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

**Commented [JC(36)]:** From - 4732.0880, subp. 2, item B (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

D. A dental handheld x-ray system must not be operated in a hallway, waiting room, or other common area.

**Commented [JC(37)]:** Based on Iowa Administrative Code

F. A qualified operator must use a tube stand if the qualified operator is unable to hold a dental handheld x-ray system without any motion during a patient examination.

For purposes of this subpart, a tube stand is an apparatus designed to support the x-ray tube during the performance of x-ray examination. A tube stand includes various forms of suspension and vary from a table top stand, a mobile floor stand, or an overhead ceiling mounting.

**Subp. 19. Film processing; dental registrants.**

A. A registrant using a dental handheld x-ray system with an analog image receptor must:

(1) use only E-speed or F-speed film;

(2) have equipment for processing that meet the requirements of this subpart;

(3) use a dental radiographic normalizing and monitoring device, also referred to as a Crabtree device, when processing intraoral images. The film must be between 0.75 and 1.05 O.D. (optical density), or follow the Crabtree device manufacturer's recommendations;

(4) perform processing quality control testing daily before diagnostic films are processed; and

(5) document the results of processing quality control testing daily.

B. For manual processing of analog images, a registrant must:

(1) develop film according to the time-temperature relationships recommended by the film and chemistry manufacturers; or

(2) maintain the temperature of solutions in the tanks within the range of 60 degrees Fahrenheit to 80 degrees Fahrenheit (15.6 degrees Celsius to 26.7 degrees Celsius) according to the following time-temperature chart:

Time-Temperature Chart

<u>Thermometer</u>	<u>Reading</u>	<u>Thermometer</u>	<u>Reading</u>	<u>Minimum</u> <u>Developing</u> <u>Time</u>	<u>(Minutes)</u>
<u>Celsius</u>		<u>Degrees</u>	<u>Fahrenheit</u>	<u>Degrees</u>	
<u>26.7</u>			<u>80</u>		<u>2</u>
<u>26.1</u>			<u>79</u>		<u>2</u>
<u>25.6</u>			<u>78</u>		<u>2-1/2</u>
<u>25.0</u>			<u>77</u>		<u>2-1/2</u>
<u>24.4</u>			<u>76</u>		<u>3</u>
<u>23.9</u>			<u>75</u>		<u>3</u>
<u>23.3</u>			<u>74</u>		<u>3-1/2</u>
<u>22.8</u>			<u>73</u>		<u>3-1/2</u>
<u>22.2</u>			<u>72</u>		<u>4</u>
<u>21.7</u>			<u>71</u>		<u>4</u>
<u>21.1</u>			<u>70</u>		<u>4-1/2</u>
<u>20.6</u>			<u>69</u>		<u>4-1/2</u>
<u>20.0</u>			<u>68</u>		<u>5</u>
<u>19.4</u>			<u>67</u>		<u>5-1/2</u>
<u>18.9</u>			<u>66</u>		<u>5-1/2</u>
<u>18.3</u>			<u>65</u>		<u>6</u>
<u>17.8</u>			<u>64</u>		<u>6-1/2</u>

<u>Thermometer</u>	<u>Reading</u>	<u>Thermometer</u>	<u>Reading</u>	<u>Minimum Developing Time</u>
<u>Celsius</u>	<u>Degrees</u>	<u>Fahrenheit</u>	<u>Degrees</u>	<u>(Minutes)</u>
<u>17.2</u>		<u>63</u>		<u>7</u>
<u>16.7</u>		<u>62</u>		<u>8</u>
<u>16.1</u>		<u>61</u>		<u>8-1/2</u>
<u>15.6</u>		<u>60</u>		<u>9-1/2</u>

(3) use a thermometer-to verify the actual temperature of the developer;

(4) use a timer for accurate development time;

(5) document daily the developer temperature before first patient use.

(6) maintain a copy of the film or developer manufacturer's  
recommendations for a qualified operator; and

(7) have the manufacturer's recommendations under subitem (6)  
available at the time of inspection by the commissioner.

C. For automatic processing of analog images, a registrant must:

(1) develop films according to the time-temperature relationship  
recommended by the film and chemistry manufacturer;

(2) use a thermometer to verify that the developer temperatures fall  
within manufacturer's specifications.

(3) document the developer temperature before first patient use:

(a) weekly when the processor has a digital read-out or ready  
light; or

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*09/29/2017*

*This document may be made accessible upon request to [xrayrules@state.mn.us](mailto:xrayrules@state.mn.us).*

(b) daily when the processor does not have a digital read-out or ready light.

(4) maintain a copy of the film and developer manufacturer's recommendations for a qualified operator; and

(5) have the manufacturer's recommendations under subitem (4) available at the time of inspection by the commissioner.

D. A registrant processing intraoral images with a manual or an automatic process must:

(1) verify that the amount of fog for a two-minute fog test does not allow visualization of the outline of a coin on the intraoral film; and

(2) perform a two-minute fog test at six month intervals.

Subp. 20. Digital imaging. A registrant using a digital imaging receptor must:

A. comply with the quality control recommendations provided by the digital imaging receptor manufacturer; and

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

(1) use by a qualified operator; and

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

Subp. 21. Storage; notification in event of theft or loss.

A. 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).

B. A registrant must develop and implement written procedures for storage and security of a handheld x-ray system to prevent unauthorized use or removal when the handheld x-ray system is not under the control and constant surveillance of a qualified operator or a registrant.

C. A registrant must notify the commissioner of the theft or loss of a dental handheld intraoral x-ray system according to part 4732.####.

Subp. 21. Records.

**Commented [JC(38)]:** Based on Ohio administrative code.

**Commented [JC(39)]:** Timeframe and method of notifying the commissioner to be part of internal reference.

**Commented [JC(40)]:** MDH intends to update the internal reference to 4732.0600 - **REPORTS OF THEFT OR LOSS OF RADIATION-PRODUCING EQUIPMENT.**

**Commented [JC(41)]:** There will be one Records provisions in a General Requirements part that is applicable to all registrants.