PART VII

PEAK KILOVOLTAGE DETERMIINATION RADIOGRAPHIC SYSTEMS

FORM FDA 3068

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ROUTINE COMPLIANCE TESTING

PEAK KILOVOLTAGE DETERMINATION

RADIOGRAPHIC SYSTEMS

(Test Procedure KVA - Use Form FDA 3068)

1.0 GENERAL GUIDANCE

1.1 This kVp test procedure is applicable to single and three phase, stationary and mobile radiographic, medical and dental x-ray equipment with a tungsten target. It is not applicable to capacitor discharge or fluoroscopic x-ray equipment.

1.2 The kVp test procedure is intended to be performed in conjunction with an Abovetable Radiographic (ARA), Mobile Radiographic (MRA), or Dental Radiographic (DRA) Field Test.

1.3 This test is only valid for reproducible systems. If it is suspected that the system under test has a reproducibility noncompliance, this test should not be performed.

1.4 Record the five digits, which appear preprinted on the general information test record, into the box in the upper right hand corner of the peak kilovoltage determination test record. Since this test is performed in conjunction with abovetable radiographic, dental radiographs, or mobile radiographic tests, add the same letter designator as on the radiographic test record. Thus, test records for an abovetable radiographic/undertable fluoroscopic system would be identified as follows: "GI12345" - general information; "AR12345A" - radiographic; "KV12345A" - peak kilovoltage; and "UF12345B" - fluoroscopic.

1.5 Connect the 6-cm^3 ionization chamber to the electrometer. Set the x-ray monitor mode selector to EXPOSURE RATE and the function selector to MEASURE. Allow the electronics 10 seconds to stabilize. After 10 seconds, the exposure rate reading should be less than 4 mR/min. If it is not, the instrument may be defective and CDRH should be contacted.

2.0 TEST SETUP

2.1 Attach the spacer assembly, positioned out of the beam, to the top of the test stand. Insert the beam-defining assembly, lead side up, into Slot 1 of the test stand.

2.2 (a) Non-Dental Equipment: Using the light localizer, center the test stand underneath the source assembly. Lower the source assembly until the face of the beam-limiting device is in firm contact with the spacer assembly. Lock the vertical movement. Turn on the light localizer and adjust the beam-limiting device such that the visually defined field is approximately 3" x 3" at the beam-defining assembly. The field should be centered on the 2" x 2" aperture of the beam-defining assembly.

(b) If the filtration present in the useful beam is adjustable, adjust to the value used during the radiographic field test.

2.3 Dental Equipment: Center the tube head above the beam-defining assembly so that the PID is pointing downward approximately 3 inches (height of spacer assembly) above and perpendicular to the beam-defining assembly. For kVp setting of 70 kVp or lower, center a total of 3.5 mm of aluminum on the beam-defining assembly. Tape the aluminum in place. For 90 kVp, fixed, omit the 3.5 mm of Al.

2.4 Insert the 6-m^3 ion chamber through the top mounting hole of the test stand, and set the x-ray monitor mode selector to EXPOSURE and the function selector to HOLD.

3.0 COPPER TRANSMISSION DATA

3.1 Enter the code for the appropriate test procedure at item 1.

3.2 Non-Dental Equipment: The kVp setting tested must be in the range of 71-90 kVp, and must be identical to the kVp used during beam quality measurements. Record at item 2.

3.3 Dental Equipment: The kVp setting must be 70 kVp or lower when there is a range of kVp settings available. Record at Item 2.

3.4 (a) If independently selectable, choose values of tube current and exposure time that will result in at least 100 mR at the chamber position when there is no copper absorber in the beam (3.5 mm of aluminum for dental equipment tested at 70 kVp or lower). To accomplish this condition, a test exposure as described in step 3.5 may be required. Record tube current and exposure time at items 3 and 4. Leave item 5 blank.

(b) If only mAs is selectable, choose a value that will result in a least 100 mR at the chamber position when there is no copper absorber in the beam (3.5 mm of aluminum for dental equipment tested at 70 kVp or lower). To accomplish this condition, a test exposure as described in step 3.5 may be required. Record the mAs at item 5. Leave items 3 and 4 blank.

3.5 The x-ray monitor display should read 0.00. If any other display is present, reset the instrument by switching the function selector to MEASURE and then back to HOLD. Make an exposure at the selected technique factors as soon as possible after switching the function selector to MEASURE. Since there is a slow upward drift in the exposure value in MEASURE, switch back to HOLD as soon as possible after exposure and record the exposure reading at item 6.

3.6 Consult Table 1 (kVp versus copper absorber thickness) for the appropriate thickness of copper absorbers for completing the test. If the kVp setting selected for the test is not provided as part of Table 1, select the closest kVp in the table and the associated thickness of copper absorbers.

Table 1. Copper absorber thickness to be used at each data item number during the test procedure as a function of equipment type and kVp setting.

		Copper Thickness (mm)			
	kVp	Item 7	Item 8	Item 9	Item 10
Dental:	65	0.46	0.87	1.00	1.26
	70	0.46	0.87	1.00	1.54
	90	0.80	1.26	2.00	2.54
Non-Dental:	71	0.46	0.87	1.00	1.67
	80	0.54	1.00	1.33	2.13
	90	0.67	1.33	1.67	2.67

NOTE: Six copper sheets are included in the test kit, with approximate thickness in millimeters of 0.13 (2 each), 0.33, 0.54, 1.0, and 2.0 - the exact thickness of each sheet is stamped on the sheet. Using various combinations of these thickness, total copper thickness millimeters of approximately 0.13, 0.26, 0.33, 0.46, 0.54, 0.67, 0.80, 0.87, 1.0, 1.16, 1.26, 1.33, 1.46, 1.54, 1.67, 1.80, 1.87, 2.0, 2.13, 2.26, 2.33, and 2.46 can be achieved.

3.7 Center the copper absorber(s) corresponding to the smallest thickness (item 7) on the beam-defining assembly.

3.8 Set the x-ray monitor back to MEASURE. As soon as possible after switching the function selector to MEASURE, make an exposure.

3.9 Switch back to HOLD as soon as possible after the exposure and record the exposure reading and selected copper thickness at item 7.

CAUTION: Consult the system's duty cycle information and anode cooling curves to ensure that the following series of exposures will not exceed the manufacturer's anode heat loading specifications. If the proper cooling time between exposures cannot be determined, use the following guidance:

a. Rotating anode tubes: Wait 60 seconds after every accumulated 5,000 heat units loading of the anode.

b. Stationary anode tubes: Wait 30 seconds between exposures of less than 900 heat units and 60 seconds between exposures of 900 of 1800 heat units.

3.10 Repeat the procedure of steps 3.8 and 3.9 for each thickness of copper absorber with the largest thickness last. Record the exposure reading and the selected copper thickness at items 8, 9, and 10, respectively.

Note: For the last copper thickness, quickly check that the resultant exposure value is less than 2 percent of the 0.0-mm Cu exposure; i.e., data item 6. If it is not, repeat the last exposure with sufficient copper to satisfy this condition.