PART XI

HEAD AND NECK RADIOGRAPHIC SYSTEMS

FORM FD 3297

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ROUTINE COMPLIANCE TESTING

HEAD AND NECK RADIOGRAPHIC SYSTEMS

(Test Procedure HNA - Use Form FDA 3297)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to stationary radiographic x-ray systems specifically designed for head and neck radiography. It applies to systems operating at fixed as well as variable SID's and that are equipped with either fixed aperture, manual, or positive beam-limiting devices.

1.2 Unless otherwise instructed, when a step or entire section of the procedure is skipped, enter an asterisk in the first data item of that section, explain in the "Remarks" why this was skipped, and continue on with the next appropriate section.

2.0 PRETEST CHECKLIST

2.1 Turn on the power on the x-ray system.

2.2 Set the x-ray monitor mode selector switch to EXPOSURE RATE and the function selector switch to MEASURE. Allow the electronics 10 seconds to stabilize. After 10 seconds, the exposure rate should be less than 4 mR/min. If it is not, the instrument may be defective and you should contact NCDRH for guidance.

2.3 If not already done, complete the general information field test record.

2.4 Record the five digits that appear preprinted on the general information field test record, and a unique letter designator, in the appropriate block on each page of the Head and Neck Radiographic Systems field test record.

2.5 Record the code for the appropriate test procedure at item 1.

2.6 Indicate the certification status of each component at item 2.

3.0 INITIAL SETUP

3.1 Rotate the tubehead and image receptor support to a horizontal position (central axis of x-ray beam is horizontal). If the tubehead and/or the cassette holder provides angulation, be sure that the system is adjusted so that the cassette holder is aligned perpendicular to the beam axis.

> NOTE: For systems with stepless adjustment collimators, and either fixed or variable SID, the survey can be performed with the x-ray system in a vertical configuration and the test stand sitting on the cassette holder provided the following precautions are observed:

a. The cassette holder device is sturdy enough to support the weight of the test

stand.

b. The light field can be adjusted so that it passes through the opening in the top of the test stand while still wide enough to image the focal-spot assembly and also "fit" on the direct-print paper in the slide assembly.

c. If the SID is variable, it is adjusted to an SID that is numerically indicated on the beam-limiting device as called for in step 3.4, and this indicated SID is recorded at data item 3.

d. The distance from the base of the stand to the front panel of the cassette holder is recorded as 000.0 cm at data item 42.

3.2 Remove any head constraint or support devices attached to the cassette holder.

3.3 If the system does not have stepless adjustment collimation but uses cones or fixed apertures instead, select a collimator according to the following:

a. For an SID of 40 inches or greater, use a collimator with an indicated field size no larger than 10" x 12".

b. For an SID of less than 40 inches, use a collimator with an indicated field size no larger than 8" x 10".

3.4 If the SID is adjustable, adjust it to the maximum for which the collimator selected in 3.3 is designed, or if the collimator is stepless, adjust the SID to one that is numerically indicated on the beam-limiting device. Record the indicated SID at item 3. If the SID is fixed and not indicated, look in the user's manual.

3.5 Place a loaded film cassette into the cassette holder. If film is not available, use direct-print paper in the following manner: precisely center and tape a plastic cassette containing a piece of direct-print paper onto an empty film cassette selected for the survey. Insert the film cassette into the cassette holder.

NOTE: If the film cassette with the plastic cassette attached will not slide into the cassette holder because it is too thick, remove the plastic cassette from the film cassette, and reattach it (precisely centered) to the front plate of the cassette holder.

3.6 Set up test stand and equipment as follows (see figure on test record):

a. Mount the test stand onto the tripod so that the MDH holes are on top.

b. Position the test stand and tripod assembly so that the stand is centered in the x-ray beam axis with the base of the test stand towards the image receptor.

NOTE: On some systems such as Continental X-Ray Corporation's Compere

with a fixed SID and fixed aperture cone length, the space between the end of the cone and the image receptor is not enough for the test stand to fit lengthwise. For such systems, see page HN-12 for the appropriate test setup and procedure.

c. For systems with stepless adjustment collimation, the test stand can be positioned at any point along the x-ray beam axis provided that the "top" of the stand is not closer than 12 inches from the source.

d. For systems with cones or fixed apertures, in order to image both brass strips of the focal-spot assembly, move the test stand and tripod assembly so that the top of the stand is as close as possible to the end of the cone or beam-limiting device, but no closer than 12 inches from the source.

NOTE: On those systems which have long cones or large fixed aperture collimators, the distance from the source to the end of the collimator will often be greater than 12 inches, thus the test stand should be positioned against the end of the collimator. On short cone systems or systems with small fixed aperture collimators, the distance between the source and the end of the collimator is less than 12 inches, so that the test stand must be positioned a few inches from the end of the collimator to ensure that it is at least 12 inches from the source.

e. Insert the slide assembly, grid side towards the BLD, into slot 6 of the test stand.

f. Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly.

g. Position the 6 cm^3 chamber in hole "D" of the test stand and secure with the retaining ring.

h. Insert the focal-spot assembly, brass side towards the BLD, into slot 1 of the test stand.

3.7 If the system has stepless adjustment collimation with light localizer, perform the following additional steps:

a. Turn on the light localizer to ensure that it is operable. If it is not, explain in the "Remarks" section and skip sections 9.0, 10.0, 11.0, and 13.0.

b. Center the test stand by centering the light field on the slide assembly grid. A piece of white paper in the slide assembly makes visualization of the light field easier during setup.

c. Adjust the beam-limiting device so that the light field is approximately 4" x 6" at the slide assembly with the longer dimension parallel to the long

dimension of the slide assembly. Using a piece of white paper, at the "top" of the test stand, check all edges of the light field against those of the opening in the top of the test stand to make sure that the light field is not shielded by the stand and passes through the opening in the top of the test stand.

d. Be sure that both brass strip images from the focal-spot assembly can be seen within the light field at the slide assembly.

e. Define the edges of the light field on the slide assembly grid by placing the metal marker strips so that the outside edge of the marker is along the inside edge of the light field and one end of the marker is along the central line of the grid. Avoid disturbing the slide assembly or the test stand.

3.8 Place 4.5 mm of aluminum on "top" of the focal-spot assembly.

4.0 BEAM QUALITY

4.1 Whenever a manual mode of operation for exposure termination (Manually set time or mAs) is provided, select this mode of operation over the automatic mode (phototimer). Record the mode of operation used during testing at item 4.

4.2 Select a commonly used technique in the above 70 kVp range. Record the selected kVp at item 5.

4.3 a. If independently selectable, choose values of tube current and exposure time commonly used, and record at items 6 and 7. Leave item 8 blank.

b. If only mAs is selectable, choose a value commonly used, and record at item 8. Leave items 6 and 7 blank.

4.4 If testing in the phototimed mode, select a commonly used value of tube current (or the fixed value if mA is fixed) and record at item 6. Leave item 7 and 8 blank.

4.5 Set the x-ray monitor to PULSE EXPOSURE and the function selector to MEASURE. The display should indicate -0.00. If any other reading is present, reset the monitor by switching the function selector to HOLD and then back to MEASURE.

CAUTION: Consult the system's duty cycle information and anode cooling curves to ensure that the following series of exposure will not exceed the manufacturer's anode heat loading specifications. If 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 to 1800 heat units.

NOTE: If a loaded film cassette is used at step 3.5, make an exposure at the selected techniques. Have the film processed, and if a readable image is not obtained at these technique factors, adjust the technique factors appropriately and repeat the exposure with another film. Set the developed film aside for later determination of the centers alignment and continue with the next step.

MANUALLY SET TIMER OR mAs MODE

4.6 Make an exposure and record the reading (without the minus sign) at item 9.

4.7 Remove successive aluminum filters to obtain totals of 3.5, 2.5, and 1.5 mm, and make an exposure for each total. Record the exposure readings at items 10, 11, and 12.

4.8 Skip to 4.11.

PHOTOTIMER MODE

4.9 Make an exposure and record the reading (without the minus sign) at item 9.

NOTE: For the reproducibility test in the next section (5.0), the exposure time must be equal to or greater than 100 milliseconds. Therefore, switch the x-ray monitor mode selector to PULSE DURATION and ensure that the exposure time is at least 100 msec. If it is not, reduce the tube potential to increase the exposure time above the minimum value, and repeat the test exposure. Correct items 5 and 9 if necessary.

4.10 Transpose successive aluminum filters from the "top" of the stand to slot 7 such that the totals of 3.5, 2.5, and 1.5 mm remain at the "top" and make an exposure for each total. Record the readings at items 10, 11, and 12.

4.11 Are the technique factors indicated before the exposure? Record at item 13.

4.12 Is the exposure terminated after a preset time interval, preset mAs, or preset radiation exposure to the image receptor? Record at item 14.

NOTE: The intent of this question is to identify conditions that pose an eminent radiation hazard; e.g., a system which, upon activation of exposure, not one but repeated exposures occur, or termination of exposure occurs only upon release of the exposure switch.

4.13 Is there a warning label as prescribed in 21 CFR 1020.30(j) present on the control panel containing the main power switch? Record at item 15.

5.0 REPRODUCIBILITY LINEARITY

Test Setup Same as BEAM QUALITY except all aluminum filters removed unless testing in phototimer mode, then all aluminum filters transposed to slot 7.

Test Procedure

5.1 Maintain the technique factors used for beam quality testing. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

NOTE: The adjustment of all variable controls for technique factors to alternate settings and then back to the test setting is only applicable to equipment manufactured after September 5, 1978.

5.2 a. If the system is single-phase, set the x-ray monitor Pulse Fraction Threshold to 0.2 and record this number at item 16.

b. If the system is three-phase, set the x-ray monitor Pulse Fraction Threshold to 0.5 and record this number at item 16.

5.3 Set the x-ray monitor mode selector to PULSE EXPOSURE and the function selector to MEASURE. The display should indicate -0.00. If any other reading is present, reset the monitor by switching the function selector to HOLD and then back to MEASURE.

5.4 Make an exposure. DO NOT record the resultant reading. Without resetting the x-ray monitor, make another exposure. The reading will now have no minus sign present. Record the exposure reading at item 17. Switch the mode selector to PULSE DURATION and record the time reading at item 18. DO NOT reset the x-ray monitor.

5.5 a. Make three additional exposures with the exposure readings being recorded at items 19, 21, and 23, and the time readings at items 20, 22, and 24 DO NOT reset the x-ray monitor.

b. If any two exposure readings differ by more than 10 percent of the higher exposure reading, make an additional 6 exposures. Record the exposure readings at items 25, 27, 29, 31, 33, and 35, and the time readings at item 26, 28, 30, 32, 34, and 36.

5.6 If testing in the phototimed mode, or if the system was manufactured before May 1994 and the system either does not allow specific selection of tube current, or if only mAs is selectable, then omit steps 5.7 through 5.10 and enter an asterisk in the first column of item 37 on the Field Test Record, and state in Remarks, that mA is fixed, mAs is selected, or the system is phototimed only.

5.7 Use step (a) for systems manufactured before May 1994 and step (b) for systems manufactured on or after May 1994.

(a) (1) If tube current selection is in fixed stations, select an adjacent tube current

station and record the indicated value at item 37.

(2) If tube current selection is continuous (i.e., not in discrete steps), select a second tube current not differing from the first by more than a factor of 2. Record at item 37.

(b)(1) If tube current or mAs is in fixed steps, select an adjacent setting and record the mAs product at item 37.

(2) If the tube current or mAs is continuous (i.e. not in discrete steps), select a second setting not differing from the first by more than a factor of 2, and record the mAs product at item 37.

5.8 The change in tube current may cause a change in the indicated tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with steps 5.9 and 5.10. However, if the kVp cannot be compensated back to its original setting, enter an asterisk in the first column of item 38, skip steps 5.9 and 5.10 and state in the Remarks that kVp could not be compensated.

5.9 Make an exposure at the selected technique factors. Record the reading at item 38.

5.10 While varying technique factors between each measurement as described in step 5.1, make three additional exposures. Record the exposure readings at items 39, 40, and 41. It is not necessary to reset the x-ray monitor between exposures.

5.11 Sum the exposures entered on the test record. If the sum is 1 R or greater, the direct-print paper in the slide assembly should provide a satisfactory image. Make additional exposures, if required, to obtain at least 1 R to the ion chamber.

5.12 Remove the cassette from the slide assembly and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique). If a readable image has not been obtained, a new cassette with fresh direct-print paper should be inserted and exposed with sufficient radiation to produce an image.

6.0 ADDITIONAL EXPOSURES TO CASSETTE HOLDER

If you use a plastic cassette containing direct-print paper instead of film (step 3.5), a total exposure of 6 to 8 R to the ion chamber when testing at 48" SID, or 3 to 4 R when testing at 40" SID is necessary to provide a readable image on the direct-print paper. If the total exposure to the ion chamber (step 5.11) is greater than 6 R (3 R for 40" SID) skip to step 6.2. However, if the total exposure to the ion chamber is less than 6 R (3 R for 40" SID), perform step 6.1.

NOTE: If the survey is being performed with the x-ray system in a vertical configuration with the test stand sitting on the cassette holder, the required exposure to the chamber is reduced to approximately 2 to 3 R.

6.1 Make additional exposures as required to obtain at least 6 R (3 R for 40" SID) to the ion chamber. Check the anode cooling curves to ensure that the rated anode limits are not exceeded.

6.2 Remove the cassette and develop the direct-print paper as before.

7.0 SID DETERMINATION

7.1 With the test stand still in position, measure to the nearest millimeter the distance from the base of the test stand to the front panel of the cassette holder. Record at item 42. If the cassette holder does not have a front panel, then load a film cassette into the holder and measure the distance from the base of the test stand to the film cassette. Record this distance at item 42, record 00.0 at item 43, and skip steps 7.2 and 7.3.

7.2 Place a film cassette into the cassette holder.

7.3 Measure to the nearest millimeter the distance from the film cassette to the plane of the face of the cassette holder and record at item 43.

7.4 Take the developed direct-print paper that had been in the slide assembly and was developed in step 5.12, and while viewing the radiographic image, locate the outside edges of the image of the focal-spot assembly. Measure the minimum separation of the outside edges to the nearest millimeter and record at item 44.

7.5 Remove the test stand and other test equipment, but do not disassemble the tripod and test stand if the system has positive beam-limitation as it will be used later to test the PBL operation.

8.0 X-RAY FIELD/INDICATED FIELD SIZE COMPARISON (Fixed Collimation Only)

If the system being tested uses cones or fixed aperture collimation, complete the steps in this section and skip sections 9.0, 10.0, 11.0, and 13.0. If the system being tested has stepless adjustment collimation, skip this section.

8.1 Record the field size dimensions indicated on the cone or fixed aperture selected in step 3.3 at items 45 and 46.

8.2 Take the developed direct-print paper that had been in the slide assembly and reconstruct the outline of the x-ray field using a straight edge and pencil or pen.

8.3 Measure to the nearest millimeter the dimensions of the x-ray field image on the direct-print paper. Record the dimensions at items 47 and 48.

9.0 ACTUAL VERSUS INDICATED FIELD SIZE

9.1 Does the beam-limiting device numerically indicate the field size at the SID at which the diagnostic source assembly is set? Record at item 49.

9.2 Being careful not to change the SID previously set in step 3.4, select the largest film cassette available for the system, and insert it into the cassette holder.

9.3 Manually adjust the beam-limiting device for an indicated field size, but smaller than the selected film cassette. Record the indicated field size at items 50 and 51.

9.4 Turn on the light localizer and measure to the nearest millimeter the dimensions of the light field at the surface of the film cassette (or the surface of the front panel if the cassette holder has a front panel). Record the dimensions at items 52 and 53.

10.0 ILLUMINANCE OF LIGHT LOCALIZER

10.1 If the SID is variable, set it so that the source assembly is at a distance of 42.5 inches (108 cm) from the front panel of the cassette holder (or film plane if there is no front panel) or to the maximum SID, whichever is less. Turn on the light localizer and open the BLD to an approximate field size of 10" x 10".

10.2 Set the photometer against the front panel (or film cassette if there is no front panel) and hold into place. (Refer to page PHOTO-1 for proper use of the photometer). At or near the center of one quadrant of the light field, determine the illuminance by subtracting the ambient light level from the corresponding light level when the light localizer is engaged. Do not move the photometer between measurements, and be careful not to cover or shade the detector element with your hand or body. Record this illuminance at item 54.

> NOTE: Do not apply the correction factor provided on the photometer to any of the measurements. The recorded illuminance values must be uncorrected.

10.3 Repeat the measurement at or near the center of the other three quadrants of the light field and record at items 55, 56, and 57.

11.0 X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

11.1 Take the direct-print paper that had been in the slide assembly and reconstruct the outline of the x-ray field using a straight edge and pencil or pen.

11.2 Reconstruct the image of the metal markers to their actual size (usually 0.5" x 1.5").

11.3 Measure the dimensions of the x-ray field image on the direct-print paper to the nearest millimeter. Record the x-ray field dimensions at items 58 and 59.

11.4 Measure the light field dimensions by measuring the distance from the outside edges

of the image of the marker strips which define the edge of the light field in each direction. Record the light field dimensions at items 60 and 61.

11.5 Measure the distance from the outside edges of the marker strips to the outline of the x-ray field in the horizontal direction. Sum the two distances for the total horizontal misalignment. Record at item 62.

11.6 Determine the total vertical misalignment in the same manner as the total horizontal misalignment is determined in step 11.5. Record at item 63.

12.0 X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

12.1 Still referring to the direct-print paper from the slide assembly, draw diagonals from opposite corners of the x-ray field image to define the center of the field.

12.2 Make note of the center location in reference to the grid image.

12.3 Refer now to the x-ray film or direct-print paper that was positioned at the cassette holder (step 3.5). Draw diagonals from opposite corners of the film or direct-print paper to define the center.

12.4 From the noted center location from step 12.2, transcribe this center mark to the same geometrical location on the film (or direct-print paper) form the cassette holder. Use the grid image on the film to ascertain the proper location.

12.5 Measure to the nearest millimeter the misalignment between the center of the x-ray field and the center of the film (or direct-print paper) and record at item 64.

13.0 PBL X-RAY FIELD IMAGE RECEPTOR SIZE COMPARISON

13.1 If the system has positive beam-limitation operation, complete this section (13.0), otherwise enter an asterisk in the first data block of item 65 and leave items 66 through 78 blank.

13.2 Select a commonly used size cassette. Record the film dimensions of the cassette at items 65 and 66.

13.3 Place the cassette into the cassette holder. Select two SID's at which the PBL sensors operate.

13.4 Set the source assembly to the shorter of the selected SID's and lock it into place. Make an exposure to ensure that the system operates at this SID. If an exposure is not possible, move to an SID at which an exposure may be made. Record this indicated SID at item 67.

13.5 Record at item 68 the type of PBL. Either the PBL system automatically adjusts the x-ray field when the cassette is inserted, or the PBL system prevents production of x-rays until manual adjustments are made.

13.6 Determine if the PBL is functioning as intended.

a. If an automatic PBL, does the unit automatically adjust field size?

NOTE: Since PBL devices by definition must be positive beam-limiting, the following has been useful in testing the PBL operation:

1. Partially withdraw the film cassette, putting the system into the "bypass" or manual mode.

2. Manually open the collimator blades fully.

3. Turn on the light localizer.

4. Reinsert the film cassette.

5. Watch the image of the light field to see if it adjusts down.

b. If a manual PBL, does it prevent the production of x-rays until manual adjustment are made?

Record at item 69. If the PBL is not functioning according to its intended design, skip over the rest of this section and explain in the Remarks.

13.7 Position the test stand and tripod assembly in the x-ray beam with the base of the stand towards the beam-limiting device. Tape a plastic cassette flat against the base of the stand with its long axis parallel with the longer dimension of the film cassette in the cassette holder.

13.8 Turn on the light localizer and move the test stand towards or away from the BLD until the light field "fits" completely within the edges of the plastic cassette.

13.9 Measure to the nearest millimeter the distance from the film cassette to the plastic cassette. Record this dimension at item 70.

13.10 Turn on the light localizer, and being careful not to disturb the test stand, measure to the nearest millimeter the dimensions of the light field at the plastic cassette. Record the light field dimensions at items 71 and 72.

13.11 Set the source assembly to the second (longer) SID and lock it into place. After ensuring that an exposure can be made at this SID, repeat step 13.10. Record the indicated SID at item 73 and the light field dimensions at items 74 and 75.

13.12 Turn on the light localizer and close the beam-limiting device to the smallest field possible. Is it possible to manually adjust the x-ray field size smaller than the image receptor? Record at item 76.

13.13 With the x-ray field size adjusted to a size smaller than the image receptor, remove the film cassette and insert one of a different size, or the same one rotated 90º. Does the beam-limiting device return to positive beam-limitation? Record at item 77.

13.14 If possible, move the source assembly to an SID greater then 36" where the PBL system is not intended to operate. Attempt to make an exposure. Is x-ray production prevented at SID's where operation is not intended? Record at item 78.

SUPPLEMENT FOR COMPERE AND SIMILAR SYSTEMS

For systems that have a fixed SID and fixed aperture cone length in which the space between the end of the cone and the image receptor is not enough for the test stand to fit lengthwise, use the following procedure:

1. If not already done, complete steps 2.1 through 3.6a. of the main procedure except choose the smallest collimator available at step 3.3b.

   NOTE: If the smallest collimator available is not less than 8" x 10", then film is required at step 3.5. The film size must be larger than the indicated field size of the selected collimator.

2. Change the code at data item 1 from "A" to "B".

3. Position the test stand and tripod assembly in the x-ray beam axis such that the long axis of the stand is perpendicular to the x-ray beam axis (the stand is sideways in the beam).

4. Mount the 6 cm^3 chamber in either hole "C" or hole "D" such that the chamber can be positioned in the x-ray beam.

5. Using masking tape, tape 4.5 mm of aluminum onto the test stand between the 6 cm^3 chamber and the beam-limitation device.

   NOTE: This configuration will require the aluminum filters to be suspended in the test stand between the top and bottom surfaces, and for phototimed only systems, will require transposing the filters to the opposite side when performing the radiation measurements. Be sure that the test stand is positioned close enough to the end of the beam-limiting device so that the x-ray beam will not be larger than the aluminum filters.

6. Complete sections 4.0 (BEAM QUALITY), 5.0 (REPRODUCIBILITY AND LINEARITY), and 6.0 (ADDITIONAL EXPOSURES TO CASSETTE HOLDER) of the main procedure, except skip steps 5.11 and 5.12 since there will not be plastic cassette or slide assembly in the test stand.

7. Remove the test stand and other test equipment.

8. If the plastic cassette was taped to the front panel of the cassette holder instead of to an empty film cassette (step 3.5 of the main procedure), then measure to the nearest millimeter the distance from the front panel to the film cassette and record at item 43. Otherwise, record 00.0 at item 43.

9. Leave items 42 and 44 blank.

10. Record the indicated field size dimensions of the selected collimator (step #1 above) at items 45 and 46.

11. If direct-print paper was used instead of film at step 3.5, reconstruct the outline of the x-ray field on the developed paper using a straight edge and pencil or pen.

12. Measure to the nearest millimeter the dimensions of the x-ray field image on the film (or direct-print paper). Record the dimensions at item 47 and 48.

13. Draw diagonals from opposite corners of the x-ray field image to define the center of the field. Likewise, draw diagonals from opposite corners of the film (direct-print paper) to define the center of the film.

14. Measure to the nearest millimeter the misalignment between the center of the x-ray field and the center of the film (direct-print paper). Record at item 64.

15. Leave all other items blank.

HEAD AND NECK RADIOGRAPHIC SYSTEMS

FIELD TEST RECORD EDIT CHECKS

(Test Procedure HNA - Form FDA 3297)

Verify that:

1. The certification status of each component is indicated at data item 2.

2. The kVp at data item 5 is in the above 70 kVp range.

3. The mA at data item 6 does not equal the mA in data item 37, and the two mA settings do not differ by more than a factor of two.

4. If values of mA and time are entered at data items 6 and 7, the space for the mAs value (item 8) is blank. Likewise, if a value is given for mAs at data item 8, items 6 and 7 are blank.

5. The exposure values for beam quality increase sequentially from data item 9 to data item 12.

6. The x-ray monitor threshold setting is recorded at data item 16.

7. For reproducibility, if only four values are entered (data items 17 through 24), no two exposures differ by more than 10 percent of the highest value.

8. If data item 4 is marked "P", the exposure times at data items 18, 20 ,22, and 24 are greater than 100 milliseconds.

9. If data item 4 is marked "P", data is not present at data items 37 through 41.

10. If data item 45 is less than data item 46, then data item 47 is less than data item 48, or vice versa.

11. The total horizontal misalignment (data item 62) is at least as great as the difference between the x-ray field horizontal dimension (data item 58) and the light field horizontal dimension (data item 60). If this is not the case, check the direct-print paper to verify the figures. Repeat for the vertical measurements.

12. A standard size cassette was used for PBL sizing.

13. If the control was manufactured on or after May 1994 then data entered at item 37 is mAs product (mA x s) and not just mA.

CALCULATION TECHNIQUE

HEAD AND NECK RADIOGRAPHIC SYSTEMS

(Test Procedure HNA - Form FDA 3297)

A. REPRODUCIBILITY

1. Refer to data items 17, 19, 21, and 23 of the Field Test Record. (Also use data items 25, 27, 29, 31, 33, and 35 if ten exposures were made for reproducibility).

   a. Using the following equation, substituting n=4 or n=10, as appropriate calculate the average exposure, $\overline{E_1}$:

   $$\overline{E_1} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

   Record the value of $\overline{E_1}$ at Result 1.

   b. Calculate the coefficient of variation, C_1, as follows:

   $$C_1 = \frac{1}{\overline{E_1}}\left(\sum_{i\text{-}1}^{n}\left(X_i - \overline{E_1}\right)^2/(n-1)\right)^{1/2}$$

   where n=4 or n=10, depending on the number of exposures.

   Record the value of C_1 at Result 2.

2. Refer to data items 6, 7, and 8 on the Field Test Record and compute the mAs. This may be given as a selected technique factor, or must be calculated as a product of the exposure time and the tube current.

3. Calculate the average exposure per mAs, $\overline{X_1}$, as follows:

   $$\overline{X_1} = \overline{E_1} / mAs_1$$

   Record the value of $\overline{X_1}$ at Result 3.

4. Refer to data items 38 to 41, calculating the average exposure, $\overline{E_2}$, as follows:

   $$\overline{E_2} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

   Record the value of $\overline{E_2}$ at Result 4.

5. Calculate the coefficient of variation, C_2, as follows:

   $$C_2 = \frac{1}{\overline{E_2}}\left(\sum_{i\text{-}1}^{n}\left(X_i - \overline{E_2}\right)^2/(n-1)\right)^{1/2}$$

   Record the value of C_2 at Result 5.

6. For controls manufactured before May 1994 refer to data items 7 and 37 on the Field Test Record and compute the mAs by multiplying the exposure time in 7 by the tube current in 37. For controls manufactured on or after May 1994, data item 37 should be in mAs units already.

Calculate the average exposure per mAs, $\overline{X_2}$, as follows:

$$\overline{X_2} = \overline{E_2} / mAs_2$$

Record the value of $\overline{X_2}$ at result 6.

B. LINEARITY

Refer to Results 3 and 6. Calculate the coefficient of linearity, L, as follows:

$$L = \frac{\left|\overline{X_1} - \overline{X_2}\right|}{(\overline{X_1} + \overline{X_2})}$$

Where $\overline{X_1}$ and $\overline{X_2}$ are the average exposures per mAs. Record the value of L at Result 7.

C. BEAM QUALITY

1. Refer to data items 9 to 12 and convert to normalized exposures by dividing each item by $\overline{E_1}$ (Result 1). Record the normalized exposures at the indicated locations; Results 8 through 11.

2. On semi-log paper, plot the five normalized exposures along the logarithmic scale with the corresponding thickness of aluminum attenuators along the linear axis. Draw a smooth curve fit to the points and determine the observed half-value layer (HVL) as that thickness of added aluminum which would yield a normalized exposure of 0.50. Record the observed HVL and selected kVp (data item 5) at Result 12.

3. To determine the actual HVL, corrections for geometry effects and energy dependence must be made. For testing with the MDH x-ray monitor:

   Actual HVL = (0.923 x Observed HVL) + 0.165

   This equation does not represent a universal correction to the observed HVL. The equation is only applicable to observed HVL's in the vicinity of the limits specified in the x-ray performance standard. For extremely large observed HVL's the equation underestimates the actual HVL. The intent of the equation is to enable accurate compliance determinations for x-ray beams with marginal observed HVL's. Record the value of the actual HVL and the selected kVp (data item 5) at Result 13.

D. TIMER ACCURACY

1. Refer to the time setting of data item 7, and if left blank, omit the timer accuracy calculation. Otherwise, record it at Result 14 as the indicated time setting.

2. Refer to data items 18, 20, 22, and 24, and if ten exposures were made, to data items 26, 28 30, 32, 34, and 36 also. Choose the one value which has the maximum deviation from the indicated time setting. Calculate the maximum deviation as the absolute value of the measured time from the indicated time. Record the deviation at Result 15.

3. Calculate the timer inaccuracy as follows:

$$\text{percent timer inaccuracy} = \frac{\text{maximum deviation x 100}}{\text{indicated timer setting}}$$

Record the percent timer inaccuracy at Result 16.

E. SID DETERMINATION

1. Refer to data items 42, 43, and 44 on the Field Test Record.

Calculate the SID as follows:

$$\text{SID} = \left(\frac{224.47}{\text{Item 44} - 6.35}\right) + 39.92 + \text{Item 42} + \text{Item 43}$$

Record the SID at Result 17.

F. X-RAY FIELD/INDICATED FIELD SIZE COMPARISON (Fixed Collimation Only)

1. Refer to data items 45 and 46 on the Field Test Record and record at Results 18 and 19. Convert any item given in inches to centimeters prior to recording on the results record.

2. Refer to data items 44, 47, and 48 and calculate the x-ray field size at the image receptor:

$$\text{Calculated horizontal dimension} = \text{Item 47 x SID x} \frac{(\text{Item 44} - 6.35)}{\text{Item 44 x 35.35}}$$

$$\text{Calculated vertical dimension} = \text{Item 48 x SID x} \frac{(\text{Item 44} - 6.35)}{\text{Item 44 x 35.35}}$$

Record these values at Result 20 and 21.

3. Calculate the horizontal and vertical differences and percent differences:

Horizontal difference = Result 18 - Result 20

Vertical difference = Result 19 - Result 21

Record at Results 22 and 23, respectively.

If Result 22 is negative, calculate the percent difference:

$$\text{Percent horizontal difference} = \left| \frac{\text{Result 22 x 100}}{\text{SID}} \right|$$

Record at Result 24. (If Result 22 is positive, record 0.00 at Result 24).

If Result 23 is negative, calculate the percent difference:

$$\text{Percent vertical difference} = \left| \frac{\text{Result 23 x 100}}{\text{SID}} \right|$$

Record at Result 25. (If Result 23 is positive, record 0.00 at Result 25).

G. X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

1. Refer to data items 62 and 63 and record at Result 26 and 27.

2. Determine the distance from the source to the center of the light field as follows:

   SID' = (Result 17 - data item 42 - data item 43 - 4.6) cm

   Record SID' at Result 28.

3. Calculate the misalignment as a percent of the SID':

   $$\text{Percent horizontal misalignment} = \frac{\text{Result 26 x 100}}{\text{SID}'}$$

   $$\text{Percent vertical misalignment} = \frac{\text{Result 27 x 100}}{\text{SID}'}$$

   Record the percent horizontal and vertical misalignments at Results 29 and 30, respectively.

4. Refer to data items 58 through 61 and calculate the horizontal correction factor (HCF) and the vertical correction factor (VCF) as follows:

   HCF = data item 58/data item 60

   VCF = data item 59/data item 61

   Record the HCF at Result 31 and the VCF at Result 32.

H. X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

1. Refer to data item 64 on the Field Test Record and record at Result 33.

2. Calculate the centers misalignment as a percent of the SID (Result 17):

$$\text{Percent centers misalignment} = \frac{\text{Result 33 x 100}}{\text{Result 17}}$$

Record the percent centers misalignment at Result 34.

I. ACTUAL VERSUS INDICATED FIELD SIZE

1. Refer to data items 50 and 51, the indicated field horizontal and vertical dimensions. Convert to centimeters, if necessary, before recording at Results 35 and 36.

2. Refer to data items 52 and 53 and calculate the x-ray field horizontal and vertical dimensions as follows:

$$\text{CHD} = \text{HCF x data item 52 x } \left(\frac{\text{Result 17}}{\text{Result 17 - data item 43}}\right)$$

$$\text{CVD} = \text{VCF x data item 53 x } \left(\frac{\text{Result 17}}{\text{Result 17 - data item 43}}\right)$$

Record at Results 37 and 38.

3. Calculate the horizontal and vertical differences and the percent differences:

Horizontal difference = CHD - Result 35

Vertical difference = CVD - Result 36

$$\text{Percent difference (horizontal)} = \frac{\text{horizontal difference x 100}}{\text{Result 17}}$$

$$\text{Percent difference (vertial)} = \frac{\text{vertical difference x 100}}{\text{Result 17}}$$

Record at Results 39-42.

J. ILLUMINANCE OF LIGHT LOCALIZER

Refer to data items 54, 55, 56, and 57. If the SID has been set to 108 cm or it is fixed at less than 108 cm, calculate the average illuminance value by summing the four values and dividing by four. Record at Result 43. If the SID is fixed at greater than 108 cm (Result 17), calculate the average illuminance as follows:

$$\text{Average illuminance} = \frac{(\text{SID - data item 43})^2}{(108)^2} x \frac{(\text{data items } 54 + 55 + 56 + 57)}{4}$$

Record at Result 43.

K. PBL X-RAY FIELD/IMAGE RECEPTOR SIZE COMPARISON

1. Refer to data items 65, 66, and 67 and record at Results 44-46. Convert any item given in inches to centimeters prior to recording on the results record.

2. Refer to data items 70, 71, and 72 and calculate the horizontal and vertical x-ray field dimensions:

$$CAH = HCF \text{ x data item } 71 \text{ x } (\frac{ISID}{ISID - \text{data item } 70})$$

$$CAV = VCF \text{ x data item } 72 \text{ x } (\frac{ISID}{ISID - \text{data item } 70})$$

where the ISID is Result 46.

Record at Results 47 and 48.

3. Calculate the horizontal and vertical differences, the percent differences, and the sum of percent horizontal and vertical differences:

Horizontal difference = CAH - Result 44

Vertical difference = CAV - Result 45

$$\% \text{ Horizontal difference} = \frac{\text{Horizontal difference x } 100}{\text{Result } 46}$$

$$\% \text{ Vertical difference} = \frac{\text{Vertical difference x } 100}{\text{Result } 46}$$

$$\text{Sum of \% differences} = \left|(\% \text{ horizontal difference})\right| + \left|(\% \text{ vertical difference})\right|$$

Record at Results 49-53.

4. Refer to data item 73 and, if necessary, convert into centimeters before recording at Result 54.

5. Refer to data items 74 and 75 and repeat the calculations of step 2 and 3 using the ISID of Result 54. Record at Results 55-61.

SUPPLEMENTARY CALCULATION TECHNIQUE

FOR

"COMPERE TYPE" SYSTEMS

(Test procedure HNB - Form FDA ----)

Use the main calculation technique for reproducibility, linearity, beam quality, and timer accuracy, recording the values as appropriate at Result 1 through 16.

ACTUAL VERSUS INDICATED FIELD SIZE COMPARISON

1. Refer to data items 45 and 46 on the Field Test Record and record at Results 18 and 19. Convert any items given in inches to centimeters prior to recording on the results record.

2. Refer to data items 3, 43, 47, and 48 and calculate the x-ray field size at the image receptor:

$$\text{Calculate horizontal dimension} = \text{data item 47} \times \frac{\text{data item 3}}{\text{data item 3} - \text{data item 43}}$$

$$\text{Calculate vertical dimension} = \text{data item 48} \times \frac{\text{data item 3}}{\text{data item 3} - \text{data item 43}}$$

   Record these values at Results 20 and 21.

3. Calculate the horizontal and vertical differences and percent differences:

   Horizontal difference = Result 18 - Result 20

   Vertical difference = Result 19 - Result 21

   Record at Results 22 and 23, respectively.

   If Result 22 is negative, calculate the percent difference:

$$\text{Percent horizontal difference} = \left| \frac{\text{Resutl 22} \times 100}{\text{data item 3}} \right|$$

   Record at Result 24. (If Result 22 is positive, record 0.00 at Result 24).
   If Result 23 is negative, calculate the percent difference:

$$\text{Percent ve rtical difference} = \left| \frac{\text{Resutl 23} \times 100}{\text{data item 3}} \right|$$

   Record at Result 25. (If Result 23 is positive, record 0.00 at Result 25).

X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

1. Refer to data item 64 on the Field Test Record and record at Result 33.

2. Calculate the centers misalignment as a percent of the SID (data item 3):

$$\text{Percent centers misalignment} = \left| \frac{\text{Resutl 33 x 100center}}{\text{data item 3}} \right|$$

Record the percent centers misalignment at Result 34.

RESULTS RECORD

HEAD AND NECK RADIOGRAPHIC SYSTEMS

(Test Procedure HNA - Form FDA 3297)

Field Test
Serial No._____

REPRODUCIBILITY AND LINEARITY

1. Average exposure, $\overline{E}_1$= _____mR
2. Coefficient of variation, C_1 = _____
3. Average exposure/mAs, $\overline{X}_1$= _____ mR/mAs
4. Average exposure, $\overline{E}_2$ = _____ mR
5. Coefficient of variation, C_2 = _____
6. Average exposure/mAs $\overline{X}_2$= _____ mR/mAs
7. Coefficient of linearity, L = _____

BEAM QUALITY

Normalized Exposure:

8. N_4 = _____ at 4.5 mm Al
9. N_3 = _____ at 3.5 mm Al
10. N_2 = _____ at 2.5 mm Al
11. N_1 = _____ at 1.5 mm Al

    N_0 = 1.00 at 0.00 mm Al

12. Observed HVL = _____ mm Al at _____ kVp
13. Actual HVL = _____ mm Al at _____ kVp

TIMER ACCURACY

14. Indicated time setting = _____ seconds
15. Maximum deviation from indicated setting = _____ seconds
16. Percent timer inaccuracy = _____ percent

SID DETERMINATION

17. Measured SID = _____ cm

X-RAY FIELD/INDICATED FIELD SIZE COMPARISON (Fixed Collimation Only)

18. Indicated field size horizontal dimension = _____ cm

19. Indicated field size vertical dimension = _____ cm

20. Calculated horizontal dimension = _____ cm

21. Calculated vertical dimension = _____ cm

22. Horizontal difference = _____ cm

23. Vertical difference = _____ cm

24. Percent horizontal difference = _____ percent

25. Percent vertical difference = _____ percent

X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

26. Total horizontal misalignment = _____ cm

27. Total vertical misalignment = _____ cm

28. SID' = _____ cm

29. Percent horizontal misalignment = _____ percent

30. Percent vertical misalignment = _____ percent

31. HCF = _____

32. VCF = _____

X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

33. Centers misalignment = _____ cm

34. Percent centers misalignment = _____ percent

ACTUAL VERSUS INDICATED FIELD SIZE

35. Indicated field horizontal dimension = _____ cm

36. Indicated field vertical dimension = _____ cm

37. CHD = _____ cm

38. CVD = _____ cm

39. Horizontal difference = _____ cm

40. Vertical difference = _____ cm

41. Percent difference (horizontal) = _____ percent

42. Percent difference (vertical) = _____ percent

ILLUMINANCE OF LIGHT LOCALIZER

43. Average illuminance = _____ footcandles

PBL X-RAY FIELD/IMAGE RECEPTOR SIZE COMPARISON

44. Horizontal film dimension = _____ cm

45. Vertical film dimension = _____ cm

46. Indicated SID (ISID) = _____ cm

47. CAH = _____ cm

48. CAV = _____ cm

49. Horizontal difference = _____ cm

50. Vertical difference = _____ cm

51. Percent horizontal difference = _____ percent

52. Percent vertical difference = _____ percent

53. Sum percent horizontal and vertical differences = _____ percent

54. Indicated SID (ISID) = _____ cm

55. CAH = _____ cm

56. CAV = _____ cm

57. Horizontal difference = _____ cm

58. Vertical difference = _____ cm

59. Percent horizontal difference = _____ percent

60. Percent vertical difference = _____ percent

61. Sum percent horizontal and vertical difference = _____ percent

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

HEAD AND NECK RADIOGRAPHIC SYSTEMS FIELD TEST RECORD

(Use Form FDA 2782, Field Test Record Continuation, if more space is needed.)

Print Legibly. Use Black Ball Point Pen. Enter One Character Per Box. Do Not Write in Shaded Area.

FIELD TEST SERIAL NO. *(1-8)*
HN
REGIONAL REVIEW *(NAME)*

Card No. *(9-10)* **10**

Test Procedure
1. HN ____ *11 13*

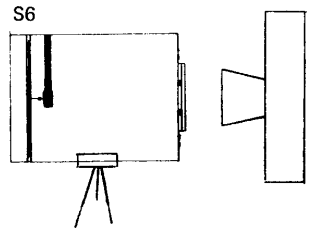
Component Certification Information
2. Indicate the status of each as follows:

C—Certified
V—Certified with a Variance
N—Not Certified
X—Not Present or Not Applicable

____ *14* Beam Limiting Device
____ *15* High Voltage Generator
____ *16* Cassette Holder
____ *17* Tube Housing Assembly
____ *18* Tube Housing Assembly With Beam Limiting Device
____ *19* Other *(Specify)*
____ *20* X-ray Control

3. Indicated Source To Image Distance *(SID)* ____ . ____ inches *21 23* OR ____ . ____ cm *24 27*

Test Setup



MDH *(Pulse Exposure)*
4.5 mm Al

Technique Factors
4. Timer mode of operation during testing ____ *28*
M—manually set time or mAs
P—phototimer
5. ____ kVp *29 31*
6. ____ mA *32 34*
7. ____ . ____ sec OR ____ pulses *35 38 39 41*
8. ____ mAs *42 44*

Beam Quality
9. ____ . ____ mR @ 4.5 mm Al *45 49*
10. ____ . ____ mR @ 3.5 mm Al *50 54*
11. ____ . ____ mR @ 2.5 mm Al *55 59*
12. ____ . ____ mR @ 1.5 mm Al *60 64*

11

13. Techinque Factors indicated Before Exposure ____ *11* Y—YES N—NO
14. Exposure Terminated After Preset Time Interval, Preset mAs, Or Preset Radiation Exposure To Image Receptor ____ *12* Y—YES N—NO
15. Warning Label Present ____ *13* Y—YES N—NO
16. MDH Threshould Setting, 0.5-3 phase, 0.2—1 phase 0 . ____ *14*

Reproducibility
17. ____ . ____ mR *15 19*
18. ____ msec *20 23*
19. ____ . ____ mR *24 28*
20. ____ msec *29 32*
21. ____ . ____ mR *33 37*
22. ____ msec *38 41*
23. ____ . ____ mR *42 46*
24. ____ msec *47 50*

FORM FDA 3297 (4/84)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
HEAD AND NECK RADIOGRAPHIC SYSTEMS
FIELD TEST RECORD
(Use Form FDA 2782, Field Test Record Continuation, if more space is need)

Print Legibly. Use Black Ball Point Pen. Enter One Character Per Box. Do Not Write in Shaded Area

FIELD TEST SERIAL NO. *(1-8)*
HN
REGIONAL REVIEW *(NAME)*

11

Reproducibility (Continued)

25. ___ . ___ mR (51, 55)	Data Here If Any Two Of Items 17, 19, 21, And 23 Differ By More Than 10 Percent Of Largest Value	26. ___ msec (56, 59)	
27. ___ . ___ mR (60, 64)		28. ___ msec (65, 68)	
29. ___ . ___ mR (69, 73)		30. ___ msec (74, 77)	
31. ___ . ___ mR (11, 15)		32. ___ msec (16, 19)	
33. ___ . ___ mR (20, 24)		34. ___ msec (25, 28)	
35. ___ . ___ mR (29, 33)		36. ___ msec (34, 37)	

12

Linearity

37. ___ mA (38, 40)
If Change in mA Causes a kVp Shift, Readjust kVp Setting to Value Selected at Item 5 Above

38. ___ . ___ mR (41, 45)
39. ___ . ___ mR (46, 50)
40. ___ . ___ mR (51, 55)
41. ___ . ___ mR (56, 60)

42. Distance from Base of Test Stand To Face of Cassette Holder ___ . ___ cm (61, 64)
43. Distance from Face of Cassette Holder to Image Receptor ___ . ___ cm (65, 67)
44. Outside Separation of Image of Focal Spot Strips ___ . ___ cm (68, 70)

X-Ray Field/Indicated Field Size Comparison (Fixed Collimation Only)

45. Indicated Field Size Horizontal Dimension ___ . ___ inches (11, 13) OR ___ . ___ cm (14, 16)
46. Indicated Field Size Vertical Dimension ___ . ___ inches (17, 19) ___ . ___ cm (20, 22)
47. X–Ray Field Image Horizontal Dimension ___ . ___ cm (23, 25)
48. X–Ray Field Image Vertical Dimension ___ . ___ cm (26, 28)

13

Actual Versus Indicated Field Size

49. Beam Limiting Device Numerically indicates Field Size ___ Y–YES N–NO (29)
50. Indicated Field Horizontal Dimension ___ . ___ inches (30, 32) OR ___ . ___ cm (33, 35)
51. Indicated Field Vertical Dimension ___ . ___ inches (36, 38) OR ___ . ___ cm (39, 41)
52. Light Field Horizontal Dimension ___ . ___ cm (42, 44)
53. Light Field Vertical Dimension ___ . ___ cm (45, 47)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

HEAD AND NECK RADIOGRAPHIC SYSTEMS
FIELD TEST RECORD
(Use Form FDA 2782, Field Test Record Continuation, if more space is needed.)

Print legibly. Use Black Ball Point Pen. Enter One Character Per Box. Do Not Write in Shaded Area.

FIELD TEST SERIAL NO. *(1-8)*
HN
REGIONAL REVIEW *(NAME)*

13

Illuminance

54. ____ total ____ ambient = [48] . [50] fc

55. ____ total ____ ambient = [51] . [53] fc

56. ____ total ____ ambient = [54] . [56] fc

57. ____ total ____ ambient = [57] . [59] fc

X-Ray Field/Light Field Alignment and Size Comparison

58. X-Ray Field Horizontal Dimension [60] . [62] cm

59. X-Ray Field Vertical Dimension [63] . [65] cm

60. Light Field Horizontal Dimension [66] . [68] cm

61. Light Field Vertical Dimension [69] . [71] cm

62. Horizontal Misalignment [72] . [73] cm

63. Vertical Misalignment [74] . [75] cm

14

X-Ray Field/Image Receptor Centers Comparison

64. Centers Misalignment [11] . [12] cm

PBL X-Ray Field/ Image Receptor Size Comparison

65. Horizontal Film Dimension [13] . [15] Inches OR [16] . [18] cm

66. Vertical Film Dimension [19] . [21] Inches OR [22] . [24] cm

67. Indicated SID [25] . [27] inches OR [28] . [31] cm

68. Type of Positive Beam Limitation *(PBL)*
A. Automatically Adjusts X-ray Field
B. Prevents Production of X-rays Until Manual Adjustments are Made
[32]

69. Is the PBL Currently Operating in Conformance with its Design [33] Y—YES N—NO

70. Distance from Film Cassette to Plastic Cassette [34] . [37] cm

71. Light Field Horizontal Dimension [38] . [40] cm

72. Light Field Vertical Dimension [41] . [43] cm

73. Indicated SID [44] . [46] inches OR [47] . [50] cm

74. Light Field Horizontal Dimension [51] . [53] cm

75. Light Field Vertical Dimension [54] . [56] cm

PBL Operation

76. In PBL Mode, Adjustment Possible To Field Size Smaller Than Image Receptor [57] Y—YES N—NO

77. Automatic Return To PBL When Image Receptor is Changed [58] Y—YES N—NO

78. X-ray Production Prevented At SID's Where Operation Is Not Intended [59] Y—YES N—NO

REMARKS