PART VIII

MAMMOGRAPHIC SYSTEMS

FORM FDA 3070

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ROUTINE COMPLIANCE TESTING

MAMMOGRAPHIC SYSTEMS

(Test Procedure MAA - Use Form FDA 3070)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to any mobile or stationary special purpose mammographic x-ray system.

1.2 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 section why this was skipped; and continue on with the next appropriate section.

2.0 PRETEST CHECKLIST

2.1 Turn on the main power to the x-ray system and have it oriented for a craniocaudal view (i.e., x-ray beam in a direction from the head to the feet).

2.2 Connect the 6-cm^3 ionization chamber to the electrometer. 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 reading should be less than 4 mR/min. If it is not, the instrument may be defective and the CDRH should be contacted.

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

2.4 Enter the five digits, which appear preprinted on the General Information Test Record, and a unique letter designator, in the appropriate block on each page of the Mammographic Systems Field Test Record.

2.5 Verify that the assembler's report, FDA 2579, is correctly prepared. If it is not, write the correct information above the incorrect information.

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

2.7 Check the certification status of each component to determine if the components are: certified without a variance (C), certified with a variance (V), not certified (N), or not present (X). Record this data at item 2.

2.8 Determine the image receptor size most commonly used with the system. Select the correct cone or aperture for this image receptor.

2.9 (a) If the SID is adjustable, adjust it to the maximum for which the above beam-limiting device - image receptor combination is designated. Record the SID at item 3.

(b) If the SID is fixed, record the design SID at item 3.

2.10 Record at item 4, whether or not the beam-limiting device was manufactured after October 1977.

2.11 If possible, have the x-ray technician retract to remove from the x-ray beam any existing breast compression device.

CATION: 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 to 1,800 heat units.

3.0 BEAM QUALITY

Test Setup (see figures on test record)

Note: If a BENT test stand is available, complete steps a), b), and c). If not, then place the electrometer directly on the image receptor support device (IRSD) and skip to step d).

a) Place the BENT test stand on the image receptor support deviation (IRSD).

b) Secure the 6-cm^3 ion chamber to the BENT test stand.

c) Center the ion chamber and test stand in the x-ray field using the alignment means provided on the system and secure with tape.

CAUTION: Be sure not to disturb the ionization chamber position during the following exposures. Most of these systems have a severe x-ray field intensity gradient (heel effect), so that chamber movement between exposures may substantially affect the readings.

d) Place the cardboard support over the ion chamber such that the chamber is centered in the cardboard support.

e) If the maximum operable kVp control setting is less than 50, set 1.5 mm of aluminum on the cardboard support.

f) If the maximum operable kVp control setting is between 50 and 70, set 3.0 mm of aluminum on the cardboard support.

Test Procedure

3.1 Whenever a manual mode of operation for exposure termination (manually set time or mAs) is provided, select this mode of operation over the automatic control mode (phototimer). Record the mode of operation used during testing at item 5.

3.2 (a) If the maximum operable kVp control setting is less than 50, set the kVp to the maximum value. Record at item 6.

(b) If the maximum operable kVp control setting is 50 or greater, set the kVp to a value between 50 and 60. Record at item 6.

3.3 (a) If testing in the phototimed mode, select a commonly used value of tube current and record at item 7. Leave items 8 and 9 blank.

(b) If independently selectable, choose a combination of tube current and exposure time not to exceed the anode's heat loading specifications. Record at item 7 and 8. Leave item 9 blank.

(c) If only the mAs is selectable, choose a value not to exceed the anode's heat loading specifications. Record at item 9. Leave items 7 and 8 blank.

3.4 If the capability is provided for adjustment of the filtration present in the useful beam, adjust for the minimum filtration that will allow an exposure. Be sure that the compression device is in the x-ray beam.

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

MANUALLY SET TIMER OR mAs MODE

3.6 Make an exposure and record the reading (exclusive of the minus sign) and the corresponding aluminum thickness at item 10.

3.7 (a) If the kVp setting is less than 50, place aluminum on top of the cardboard support to obtain totals of 1.0, 0.75, 0.5, and 0.25 mm. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

(b) If the kVp setting is 50 or greater, place aluminum on top of the cardboard support to obtain totals of 2.0, 1.5, 1.0 and 0.5 mm. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

3.8 Skip to 3.11

PHOTOTIMER MODE

3.9 Make an exposure and record the reading (exclusive of the minus sign) and the corresponding aluminum thickness at item 10.

3.10 (a) If the kVp setting is less than 50, transpose aluminum from the top of the cardboard support to the cardboard support to the bottom such that totals of 1.0, 0.75, 0.5, and 0.25 mm end up between the source and ion chamber. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

(b) If the kVp setting is 50 or greater, transpose aluminum from the top of the cardboard support to the bottom such that totals of 2.0, 1.5, 1.0, and 0.5 mm end up between the source and ion chamber. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

3.11 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.

3.12 Are the technique factors visible at the operator's position? Record at item 16.

3.13 Is exposure terminated after a preset time interval, preset mAs, preset number of pulses, or preset radiation exposure? Record at item 17.

NOTE: The intent of this question is to identify conditions that pose an imminent 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.

4.0 REPRODUCIBILITY AND LINEARITY

Test Setup (same as BEAM QUALITY without cardboard support or Al filters)

Test Procedure

4.1 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.

4.2 If phototiming has been selected, place an aluminum filter with a nominal thickness of 2 mm on the test stand so as to cover the entire sensitive area of the phototimer detector.

4.3 (a) If the system is single-phase, set the x-ray monitor Pulse Fraction Threshold

to 0.2 and record this number at item 18.

(b) If the system is three-phase, set the x-ray monitor Pulse Fraction Threshold to 0.5 and record this number at item 18.

4.4 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.

4.5 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 19. Switch the mode selector to PULSE DURATION and record this time reading at item 20. DO NOT reset the x-ray monitor.

NOTE: If testing in the phototimed mode, the exposure item recorded by the x-ray monitor should be greater than 0.1 and less then 1.0 seconds. If the exposure time is outside this range, adjust the aluminum attenuator thickness accordingly, verify its placement, and repeat steps 4.4 and 4.5.

4.6 (a) Make three additional exposures with the exposure readings being recorded at items 21, 23, and 25 and the time readings at items 22, 24, and 26. 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 27, 29, 31, 35, and 37, and the time readings at items 28, 30, 32, 34, 36, and 38.

4.7 If testing in the phototimed mode, or if the system either does not allow specific selection of tube current, or it only mAs is selectable, then omit steps 4.8 through 4.11 and enter an asterisk in the first column of item 39 on the Field Test Record, and state in Remarks than mA is fixed, mAs is selected, or the system is phototimed only.

4.8 (a) If tube selection is in fixed stations, select an adjacent tube current station and record the indicated value at item 39.

(b) If the 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, and record at item 39.

4.9 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 4.10 and 4.11. However, if the kVp cannot be compensated back to its original setting, enter an "*" in the first column of item 40, skip steps 4.10 and 4.11 and state in the Remarks that the kVp could not be compensated.

4.10 Make an exposure at the selected technique factors. Record this reading at item 40.

4.11 While varying technique factors between each measurement as described is step 4.1, make three additional exposures. Record the exposure readings at items 41, 42, and 43. It is not necessary to reset the x-ray monitor between exposures.

5.0 X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

Test Setup

a. Remove all equipment from the image receptor support device (IRSD).

b. Have the x-ray technique position an image receptor for an exposure using the alignment means provided (e.g., lightfield, cassette guides, and so forth). The developed image will be used to evaluate the x-ray field alignment.

c. Place two plastic cassettes containing direct print paper in an overlapping pattern over the image receptor such that the cassettes extend at least 2 inches beyond three edges of the image receptor. These edges should correspond to the chest wall and adjacent side wall edges (see Figure 1).

d. Place metal markers on top of the plastic cassettes to identify the patient side or chest wall edge of the image receptor.

e. Place the slide assembly on top of the plastic cassettes, grid side down, and align one long edge with the chest wall edge of the image receptor (See c., Figure 1).

f. Set the electrometer on the IRSD. Position the ion chamber in the center of the image receptor.

Test Procedure

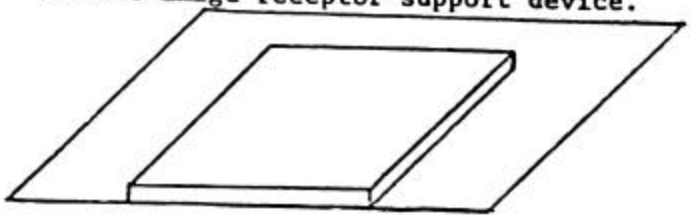
5.1 Maintain the technique factors used for beam quality testing. If photo timing has been selected, retain the aluminum filter used in reproducibility testing.

5.2 Set the function selector on the x-ray monitor to EXPOSURE. Make an exposure and check the reading. Make any additional exposures needed to obtain 3 R at the ion chamber.

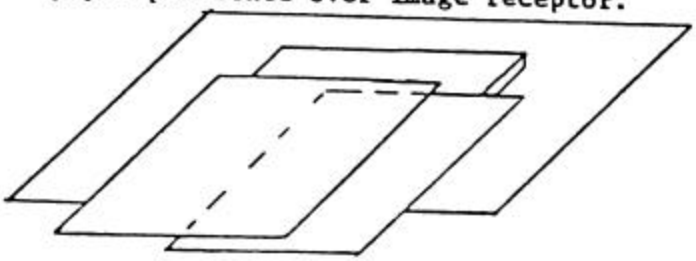
5.3 Have the technician process the mammographic image receptor.

5.4 Develop the direct print paper in each cassette. (Refer to page LINA-1 for proper development technique.)

a) Image receptor positioned for an exposure on the image receptor support device.



b) Two plastic cassettes with direct print paper positoned over image receptor.



c) Slide assembly, grid side down, positioned over the plastic cassettes.

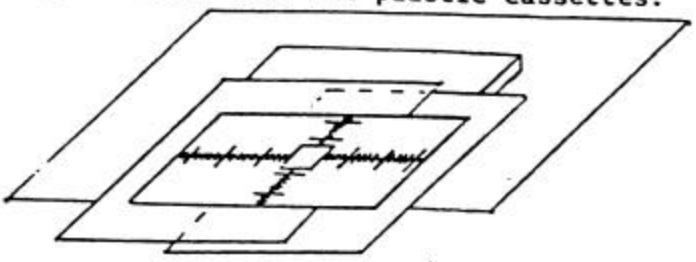


FIGURE 1.

5.5 Refer to the developed mammographic image obtained from the technician. Using this image and the direct print paper images, reconstruct the geometric relationship in effect during the exposure.

> NOTE: The metal marker images identify the chest wall edge of the image receptor. The other edges are identified with respect to this edge as right and left edges (see Figure 2).

5.6 Measure to the nearest millimeter, the maximum x-ray field excess at the chest, right and left edges of the image receptor. The measurement direction should be perpendicular to the image receptor edges. Record the results at items 44, 45, and 46. For any edge where the x-ray field is smaller than the image receptor, record 0.00 at the corresponding item number. Figure 3 shows an example where the x-ray field excess occurs only at the chest wall edge.

6.0 ILLUMINANCE OF LIGHT LOCALIZER

6.1 If the SID is variable, set the diagnostic source assembly to a source to detector distance of 39.25 inches (100 cm or the maximum SID whichever is less). Open the beam-limiting device to the indicated image receptor size.

6.2 Set the photometer on the cassette holder. (Refer to page PHOTO-1 for proper use of the photometer.) Turn on the localizer. At or near the center of one quadrant of the light file, 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. Record this illuminance in the REMARKS section.

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

6.3 Repeat the measurements at or near the center of the other three quadrants of the light field and record in the REMARKS section in the following format (example):

ILLUM 17 + 18.15 + 16 + 15.4 = 16.6 fc

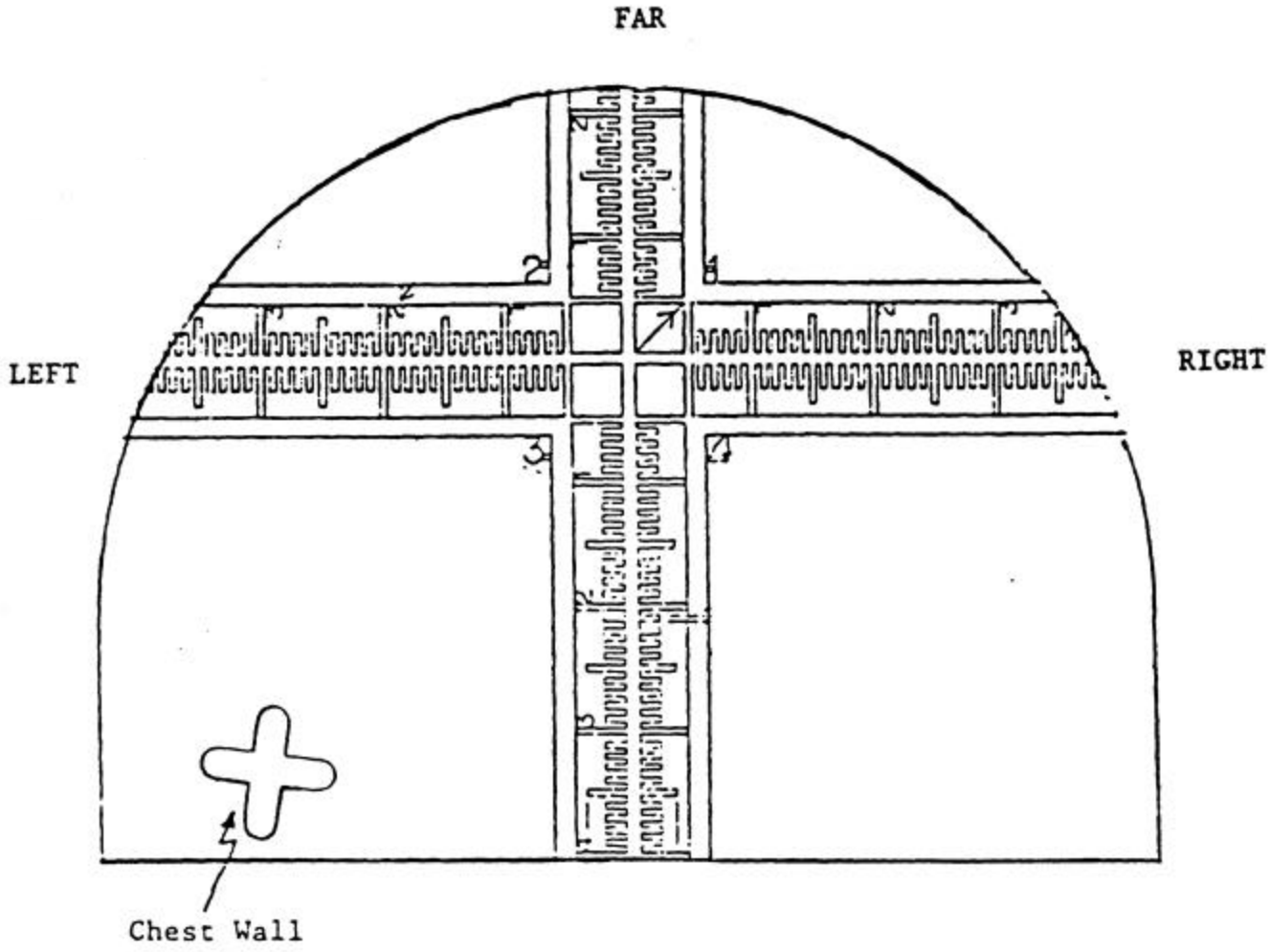


FIGURE 2.

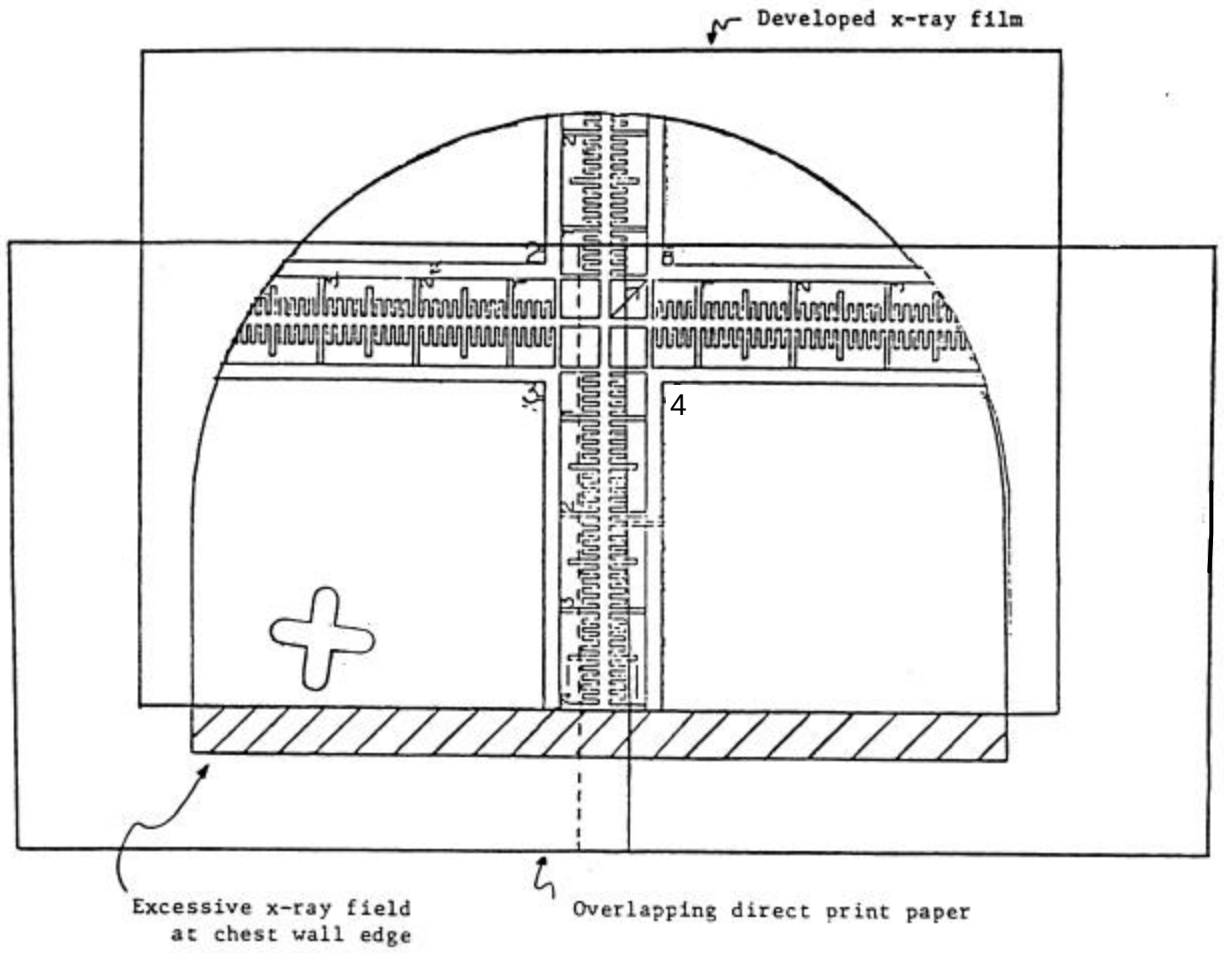

Developed x-ray film
4
Excessive x-ray field
at chest wall edge
Overlapping direct print paper

FIGURE 3

MAMMOGRAPHIC SYSTEMS

FILED TEST RECORD EDIT CHECKS

(Test Procedure MAA - Use Form FDA 3070)

Verify that:

1. SID has been entered at data item 3.

2. If data item 5 is marked "P," the exposure times at data items 20, 22, 24, and 26 are greater than 100 milliseconds.

3. If data item 6 (kVp) is less than 50, the aluminum filters used at data items 10 through 14 correspond to 1.5, 1.0, 0.75, and 0.25 mm, respectively.

4. If data items 6 (kVp) is between 50 and 70 kVp, the aluminum filters used at data items 10 through 14 correspond to 3.0, 2.0, 1.5, 1.0, and 0.5 mm, respectively.

5. If the difference between any two of data items 19, 21, 23, and 25 is greater than 10 percent of the largest value, an additional 6 exposures have been entered for reproducibility at data items 27 through 38.

6. If data item 5 is marked "P," data is not present at data items 39 through 43.

CALCULATION TECHNIQUES

MAMMOGRAPHIC SYSTEMS

(Test Procedure MAA - Form FDA 3070)

A. REPRODUCIBILITY AND LINEARITY

1. Refer to data items 19, 21, 23, and 25 of the Field Test Record. Calculate the average exposure $\overline{E_1}$, as follows:

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

where the X_i 's are the data items referred to above. Record the value of $\overline{E_1}$ at Result 1. If item exposure measurements have been taken, data items 19, 21, 23, 27, 29, 31, 33, 35, and 37 would be used in the calculation and n=10 in the equation.

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

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

where the X_i s are the data items 19, 21, 23, and 25. Record the value of C_1 at Result 2. If ten exposure measurements have been taken, data items 19, 21, 23, 25, 27, 29, 31, 33, 35, and 37 would be used in the calculation and n=10 in the equation.

> NOTE: If testing in the phototimed mode, or if the system either does not allow specific selection of tube current, or if only mAs is selectable, skip the following calculations.

3. Refer to data items 7, 8, and 9 of the Field Test Record and compute the mAs, if data item 9 is blank, by multiplying data item 7 by data item 8. If data item 8 is given as pulses, convert to time in seconds by dividing the pulses by 120. The average exposure rate per mAs, $\overline{X_1}$, is given by:

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

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

4. Refer to data items 40, 41, 42, and 43 of Field Test Record and calculate the average exposure, $\overline{E_2}$, as follows:

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

where the X_i's are the data items 40, 41, 42, and 43. Record $\overline{E_2}$ at Result 4.

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

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

where the X_i's are the data items 40, 41, 42, and 43. Record the value of C_2 at Result 5.

6. Refer to data items 8 and 39 of Filed Test Record and compute the mAs by multiplying data item 39 by data item 8. If data item 8 is given as pulses convert to time in seconds by dividing the pulses by 120. The average exposure rate per mAs, $\overline{X}_2$ is given by:

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

Record the value of $\overline{X}_2$ at Result 6.

7. Refer to Results 3 and 6 and calculate the coefficient of linearity, L, by:

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

where $\overline{X}_1$ and $\overline{X}_2$ are the average exposure per mAs recorded at Results 3 and 6. Record at Result 7.

B. <u>BEAM QUALITY</u>

1. Refer to data items 10 through 14 on the Field Test Record and convert to normalized exposure ratios by dividing each of them by Results 8 through 12, respectively. Plot the six normalized exposure ratios on semilog paper, with the corresponding thickness of aluminum absorber along the linear axis. Draw a smooth curve fit to the six points and determine the half-value layer (HVL) as that thickness of aluminum absorber which would yield a normalized exposure ratio of 0.50. Record the HVL and selected kVp (data item 6 on the Field Test Record) at Result 13.

2. Refer to Table 1 and determine the minimum acceptable HVL for the indicated kVp. Record the minimum acceptable HVL at Result 14.

Table 1. Minimum acceptable HVL

kVp	HVL	kVp	HVL
20	0.20	41	0.41
21	0.21	42	0.42
22	0.22	43	0.43
23	0.23	44	0.44
24	0.24	45	0.46
25	0.25	46	0.47
26	0.26	47	0.48
27	0.27	48	0.49
28	0.28	49	0.50
29	0.29	50	1.20
30	0.30	51	1.21
31	0.31	52	1.22
32	0.32	53	1.23
33	0.33	54	1.24
34	0.34	55	1.25
35	0.35	56	1.26
36	0.36	57	1.27
37	0.37	58	1.28
38	0.38	59	1.29
39	0.39	60	1.30

C, TIMER ACCURACY

1. Refer to data item 8 on the Field Test Record, if this item is blank, omit the timer accuracy computation. Otherwise, record data item 8 on the Field Test Record at Result 15 on the Results Record (i.e., indicate time setting), and, if necessary, convert to time in seconds by dividing by 120. Refer to data items 20, 22, 24, and 26 (28, 30, 32, 34, 36, 38) on the Field Test Record and choose the one value that has the largest deviation from the indicated time setting. Calculate this deviation as the absolute value of the measured time subtracted from the indicated time. Record that deviation at Result 16.

2. Calculate the percent timer inaccuracy as follows:

   Percent Timer Inaccuracy = (Maximum deviation/Indicated time setting) x 100.

   Record the percent timer inaccuracy at Result 17.

D. X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

1. Refer to data item 3 on the Field Test Record. If necessary, convert data item 3 (SID) to centimeters by multiplying by 2.54. Record the SID at Result 18.

2. Refer to data items 44, 45, and 46 on the Field Test Record. Calculate the x-ray field excess in percent SID as follows:

x-ray field excess in percent SID = (data items 44, 45, or 46/SID) x 100.

Record the x-ray field excess in percent SID at Result 19.

3. Refer to data item 4 on the Field Test Record and record at Result 20. If "yes", the x-ray field may not exceed the image receptor, except at the chest wall edge.

RESULTS RECORD

MAMMOGRAPHIC SYSTEMS

(Test Procedure MAA - Form FDA 3070)

FIELD TEST
SERIAL NO._____

REPRODUCIBILITY AND LINEARITY

1. Average Exposure, $\overline{E}_1$= _____ mR
2. Coefficient of Variation, C_1 = _____
3. Average Exposure Ratio, $\overline{X}_1$ = _____ mR/mAs
4. Average Exposure, $\overline{E}_2$ = _____ mR
5. Coefficient of Variation, C_2 = _____
6. Average Exposure Ratio, $\overline{X}_2$ = _____ mR/mAs
7. Coefficient of Linearity, L = _____

BEAM QUALITY

8. N_5 = _____ at _____ mm Al
9. N_4 = _____ at _____ mm Al
10. N_3 = _____ at _____ mm Al
11. N_2 = _____ at _____ mm Al
12. N_1 = _____ at _____ mm Al

No. = 1.000 at 0 mm Al

13. HVL = _____ mm Al at _____ kVp
14. Minimum Acceptable HVL = _____ mm Al

TIMER ACCURACY

15. Indicated Time Setting = _____ sec.
16. Maximum Deviation from Indicated Setting = _____ sec.
17. Percent Timer Inaccuracy = _____ %

X-RAY FIELD RECEPTOR ALIGNMENT

18. SID = _____ cm.

19. X-ray field excess in percent SID. _____ _____ _____ cm
chest right left

20. Beam Limiting device manufactured after October 1977: yes no (circle)

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

MAMMOGRAPHIC 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.

FIELD TEST SERIAL NO. *(1-8)*: MA

REGIONAL REVIEW (NAME)

CARD NO. *(9-10)*

Test Procedure

1. MA [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

[14] Beam Limiting Device
[15] Image Receptor Support Device
[16] Tube Housing Assembly
[17] High Voltage Generator
[18] X-ray Controls
[19] Other *(Specify in Remarks)*

10

Source-to-Image Receptor Distance

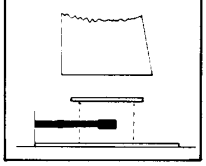
3. [20–22] in OR [23–26] cm

Date of Manufacture

4. Beam limiting device manufactured after October 1977 [27] Y–YES N–NO

Test Setup

MDH (Pulse Exposure)
mm Al
over 50 kV - 3.0
below 50 kV-1.5



Technique Factors

5. Timer mode of operation during testing [31]
M–manually set time or mAs P–phototimer

6. [28–30] kVp
7. [32–34] mA
8. [35–38] sec OR [39–41] pulses
9. [42–44] mAs

If max kV is below 50, select max value. If max kV is above 50, select a value between 50 and 60.

11

Beam Quality

		over 50 kV	below 50 kV
10.	[11–15] mR @ [16–17] mm Al	3.0 mm	1.5 mm
11.	[18–22] mR @ [23–24] mm Al	2.0 mm	1.0 mm
12.	[26–30] mR @ [31–33] mm Al	1.5 mm	0.75 mm
13.	[35–39] mR @ [40–41] mm Al	1.0 mm	0.5 mm
14.	[42–46] mR @ [47–49] mm Al	0.5 mm	0.25 mm

15. Warning Label Present [25] Y–YES N–NO

16. Technique Factors Indicated
Before Exposure [34] Y–YES N–NO

17. Exposure Terminated After Preset Time Interval, Preset mAs, Or Preset Number of Pulses [50] Y–YES N–NO

Reproducibility

12

18. Threshold Setting [0] . [11]

19. [12–16] mR
21. [21–25] mR
23. [30–34] mR
25. [39–43]

If any of items 19, 21, 23, or 25 differ by more than 10 percent of the largest value, provide additional data at items 27 to 38.

20. [17–20] msec
22. [26–29] msec
24. [35–38] msec
26. [44–47]

FORM FDA 3070 (10/80)

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

MOBILE 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): MR

REGIONAL REVIEW (NAME)

Reproducibility (Continued)

22. ____.____ mR (29 33)
24. ____.____ mR (38 42)
26. ____.____ mR (47 51)
28. ____.____ mR (56 60)
30. ____.____ mR (65 69)
32. ____.____ mR (11 15)

Data here, if any of items 14, 16, 18 and 20 differ by more than 10 percent of the largest value.

23. ____ msec (34 37)
25. ____ msec (43 46)
27. ____ msec (52 55)
29. ____ msec (61 64)
31. ____ msec (70 73)
33. ____ msec (16 19)

Linearity

34. ____ mA (20 22)

If change in mA causes a kVp shift, readjust kVp (if possible) to value selected at item 4 above.

35. ____.____ mR (29 33)
36. ____.____ mR (37 41)
37. ____.____ mR (45 49)
38. ____.____ mR (50 54)

Illuminance (uncorrected; SID = 42.5" (106 cm))

39. ____ (total) − ____ (ambient) = ____.____ fc (23 28)
40. ____ (total) − ____ (ambient) = ____.____ fc (26 28)
41. ____ (total) − ____ (ambient) = ____.____ fc (34 36)
42. ____ (total) − ____ (ambient) = ____.____ fc (42 44)

X-Ray Field/Light Field Alignment:

43. Length Misalignment ____.____ cm (55 56)
44. Width Misalignment ____.____ cm (57 58)

Minimum Source To Skin Distance

45. Outside Separation of Image of Focal Spot Strips ____.____ cm (59 61)

Standby Radiation: (Capacitor discharge equipment only)

46. ____.____ mR (62 66)
47. ____ min (67) ____ sec (68 69)

REMARKS

CHECK IF CONTINUATION SHEET USED

FORM FDA 2783 (10/80)

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