RESULTS RECORD

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure CFR - Form FDA 3260)

Source to Image Distance

1. Y = _____ cm.
2. Fluoroscopic SID = _____ cm.
3. Minimum SSD = _____ cm.

Fluoroscopic X-Ray Field/Image Receptor Alignment

4. Misalignment 1/4 = _____ cm.
5. Misalignment 2/1 = _____ cm.
6. Misalignment 3/2 = _____ cm.
7. Misalignment 4/3 = _____ cm.
8. SID' = _____ cm.
9. (1/4 + 3/2) misalignment = _____ cm.
10. Percent (1/4 + 3/2) misalignment = _____ cm.
11. (2/1 + 4/3) misalignment = _____ cm.
12. Percent (2/1 + 4/3) misalignment = _____ percent.
13. Total misalignment = _____ cm.
14. Percent total misalignment = _____ percent.
15. Misalignment 1/4 = _____ cm.
16. Misalignment 2/1 = _____ cm.
17. Misalignment 3/2 = _____ cm.
18. Mi-alignment 4/3 = _____ cm.
19. SID' = _____ cm.
20. (1/4 + 3/2) misalignment = _____ cm.
21. Percent (1/4 + 3/2) misalignment = _____ percent.
22. (2/1 + 4/3) misalignment = _____ cm.

45. R_1 = _____ mR/s at 1.5 mm Al.

46. R_0 = _____ mR/s at 0.0 mm Al.

Normalized Exposure Rate

47. N_4 = _____ at 4.5 mm Al.

48. N_3 = _____ at 3.5 mm Al.

49. N_2 = _____ at 2.5 mm Al.

50. N_1 = _____ at 1.5 mm Al.

N_0 = 1.0 at 0.0 mm Al.

51. HVL_{obs} = _____ mm Al at _____ kVp.

52. Actual HVL = _____ mm Al at _____ kVp.

Spot-Film Reproducibility and Linearity

53. Average exposure, $\bar{E}_1$, = _____ mR.

54. Coefficient of variation, C_1, = _____.

55. Average exposure/mAs, $\bar{X}_1$, = _____ mR/mAs.

56. Average exposure, $\bar{E}_2$, = _____ mR.

57. Coefficient of variation, C_2, = _____.

58. Average exposure/mAs $\bar{X}_2$, = _____ mR/mAs.

59. Coefficient of linearity, L, = _____.

X-Ray Field/Spot-Film Size Comparison

60. Spot-Film SID _____ cm.

61. CL = _____ cm.

62. CW = _____ cm.

63. ΔL = _____ cm.

64. ΔW= _____ cm.

65. Percent ΔL = _____ percent.

66. Percent ΔW = _____ percent.

67. Percent ΔL + percent ΔW = _____ percent.

45. R_1 = _____ mR/s at 1.5 mm Al.

46. R_0 = _____ mR/s at 0.0 mm Al.

Normalized Exposure Rate

47. N_4 = _____ at 4.5 mm Al.

48. N_3 = _____ at 3.5 mm Al.

49. N_2 = _____ at 2.5 mm Al.

50. N_1 = _____ at 1.5 mm Al.

N_0 = 1.0 at 0.0 mm Al.

51. HVL_{obs} = _____ mm Al at _____ kVp.

52. Actual HVL = _____ mm Al at _____ kVp.

Spot-Film Reproducibility and Linearity

53. Average exposure, $\bar{E}_1$, = _____ mR.

54. Coefficient of variation, C_1, = _____.

55. Average exposure/mAs, $\bar{X}_1$, = _____ mR/mAs.

56. Average exposure, $\bar{E}_2$, = _____ mR.

57. Coefficient of variation, C_2, = _____.

58. Average exposure/mAs $\bar{X}_2$, = _____ mR/mAs.

59. Coefficient of linearity, L, = _____.

X-Ray Field/Spot-Film Size Comparison

60. Spot-Film SID _____ cm.

61. CL = _____ cm.

62. CW = _____ cm.

63. ΔL = _____ cm.

64. ΔW= _____ cm.

65. Percent ΔL = _____ percent.

66. Percent ΔW = _____ percent.

67. Percent ΔL + percent ΔW = _____ percent.

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

C-ARM FLUOROSCOPIC AND SPOT-FILM 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)* CF

REGIONAL REVIEW *(NASIZ)*

Card No. *(9-10)*

Test Procedure: 1. CF A

2. System Type [M] *14* M—Mobile S—Stationary

Beam Limiting Device Information

3. BLD Manufactured after 5/22/79 [ ] *15* Y—yes N—no

4. BLD type [ ] *16* 1—Fixed Aperture 2—Stepless

Component Certification Information

5. Indicate the Status of Each as Follows:

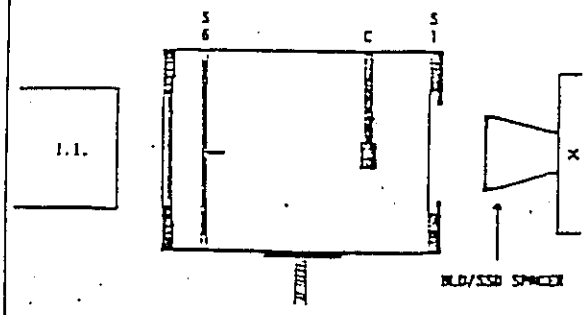
C—Certified
N—Not Certified
V—Certified with a Variance
X—Not Present or not applicable

[ ] *17* Tube Housing Assembly
[ ] *18* X-Ray Control
[ ] *19* Spot Film Device *(after 4/77)*
[ ] *20* Beam Limiting Device
[ ] *21* High Voltage Generator
[ ] *22* Fluoroscopic Imaging Assembly *(before 4/77)*
[ ] *23* Table
[ ] *24* Image Intensifier *(after 4/77)*

10

Initial Setup (Fluoroscopic Mode) And Surveyor Protection Test

MOH(Exposure)



6. System Hazardous [ ] *25* Y—yes N—no

If yes, describe hazard in Remarks and discontinue testing

7. Warning Label Present [ ] *26* Y—yes N—no

Fluoroscopic X-ray Field/Image Receptor Alignment

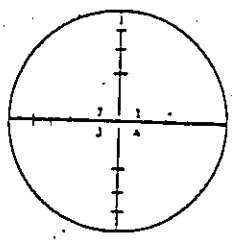


	Image Dimension	X-ray Field Dimension
1/4	8. [ ] *27* × [ ] *29* in	12. [ ] *30* × [ ] *32* cm
2/1	9. [ ] *33* × [ ] *35* in	13. [ ] *36* × [ ] *38* cm
3/2	10. [ ] *39* [ ] *41* in	14. [ ] *42* × [ ] *44* cm
4/3	11. [ ] *45* × [ ] *47* in	15. [ ] *48* × [ ] *50* cm

NO MAGNIFICATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
C-ARM FLUOROSCOPIC AND SPOT-FILM 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.

CF
REGIONAL REVIEW (NAME)

10

Fluoroscopic X-ray Field/Image Receptor Alignment

	Image Dimension	X-ray Field Dimension
1/4	16. ___ . ___ in (51, 53)	20. ___ . ___ cm (54, 56)
2/1	17. ___ . ___ in (57, 59)	21. ___ . ___ cm (60, 62)
3/2	18. ___ . ___ in (63, 65)	22. ___ . ___ cm (66, 68)
4/3	19. ___ . ___ in (69, 71)	23. ___ . ___ cm (72, 74)

24. Visible Area: ___ (75) 1—Circular 2—Rectangular

25. Tube Potential and Current Continuously Indicated During Exposure ___ (76) Y—yes N—no

26. Maximum Cumulative Setting for Fluoro Timer is 5 minutes or less ___ (77) Y—yes N—no

Primary Protective Barrier/X-ray Field Size Comparison

27. Diameter of the Image Intensifier Housing ___ (11) : ___ (13) cm

28. Distance from face of I.I. to base of stand ___ (14) . ___ (16) cm

Minimum Fluoro Field Size

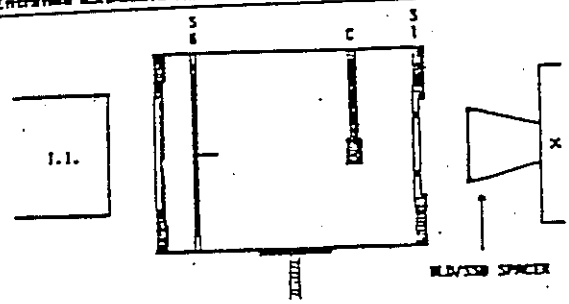
29. X-ray field image length ___ (17) . ___ (19) cm

30. X-ray field image width: ___ (20) . ___ (22) cm

31. Field Shape: 2 (23) 1—Circular 2—Rectangular

11

Entrance Exposure Rate (BLD fully open, no magnification)



32. Fluoroscopic Technique Factor Control Type ___ (24)

M—Manual Only
A—Automatic Only
B—Both Manual and Automatic

MDH (Exposure rate)

MANUAL

33. ___ (25) ___ (27) kVp

34. ___ (28) ___ (29) mA

35. ___ (30) . ___ (33) R/min

36. Is a high level control present? ___ (34) Y—YES N—NO

37. Continuous Audible Signal Upon Activation of High Level Control ___ (35) Y—YES N—NO X—

AUTO

38. ___ (36) ___ (38) kVp

39. ___ (39) . ___ (40) mA

40. ___ (41) . ___ (44) R/min

41. Is a high level control present? ___ (45) Y—YES N—NO

42. Continuous Audible Signal Upon Activation of High Level Control ___ (46) Y—YES N—NO X

PAGE 2 OF 4

FORM FDA 2260 (9/82)

9/30/

CF-30

PART X

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS
FIELD TEST RECORD
(Use Form FDA 3252, 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)
CF

REGIONAL REVIEW (NAME)

11

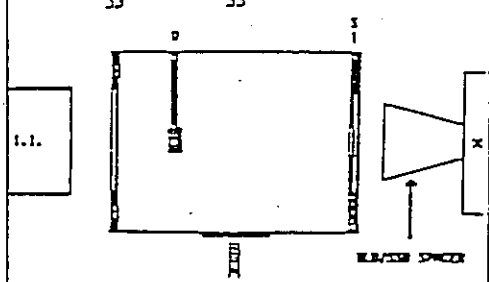
Source — Image Distance and Minimum Source to Skin Distance

43. Distance from face of SSD spacer (or from face of BLD if spacer is not present) to top of brass strips [ ] . [ ] cm (47, 49)

44. Outside Separation of Image of Focal Spot Strips [ ] . [ ] cm (50, 52)

Beam Quality

45 [ ] kVp (53, 55)



MDH (Pulse Exposure 4.5mm Al)

46. [ ] mR @ 4.5 mm Al (56, 58) — 47. [ ] . [ ] mR (59, 61)

48. [ ] mR @ 3.5 mm Al (62, 64) — 49. [ ] . [ ] mR (65, 67)

50. [ ] mR @ 2.5 mm Al (68, 70) — 51. [ ] . [ ] mR (71, 73)

52. [ ] mR @ 1.5 mm Al (74, 76) — 53. [ ] . [ ] mR (77, 79)

54. [ ] mR @ 0.0 mm Al (11, 13) — 55. [ ] . [ ] mR (14, 16)

56. At End of Present Cumulative Time Interval Either Continuous Audible Signal and /or Termination of X-rays [ ] Y-YES N-NO (17)

12

Spot-film Mode

57. Type of spot-film device [ ] (18)
1. Clip-on cassette holder
2. Cut-film changer
3. N/A (only a fluoroscopic camera provided)

58. Spot-film length [ ] . [ ] cm (19, 21)

59. Spot-film width [ ] . [ ] cm (22, 24)

60. Technique factors fixed or selectable indicated before exposure [ ] Y-yes N-no (25)

61. A visible beam-on indication during exposure [ ] Y-yes N-no (26)

62. An audible indication of exposure termination [ ] Y-yes N-no (27)

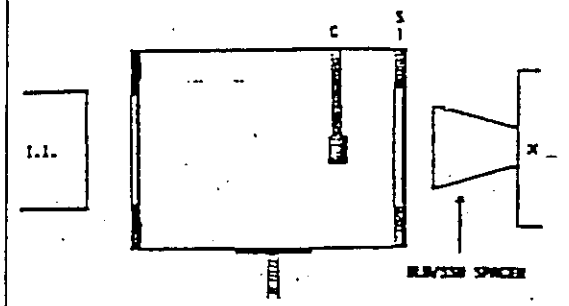
63. Exposure terminated at a present time or mAs [ ] Y-yes N-no (28)

64. Means provided for maintaining the fluoro field size during spot-filming [ ] Y-yes N-no (29)

X-N/A

12

Spot-Film Reproducibility and Linearity



65. MDH Threshold Setting, 0.5-3 phase, 0.2-1 phase ___ . ___ (30)

66. Generator Type ___ (31) 1-single phase 3-three phase

67. Technique Factors
___ kVp (32 34) ___ mAs (35 37)
___ mA (38 40) ___ . ___ sec. (41 43)

13

Reproducibility (no Al in beam)

68. ___ (44) . ___ (48) mR	69. ___ (49 51) mas	78. ___ (52) . ___ (56) mR	79. ___ (57 59) mas
70. ___ (60q) . ___ (64) mR	71. ___ (65 67) mas	80. ___ (68) . ___ (72) mR	81. ___ (73 75) mas
72. ___ (11) . ___ (15) mR	73. ___ (16 18) mas	82. ___ (19) . ___ (23) mR	83. ___ (24 26) mas
74. ___ (27) . ___ (31) mR	75. ___ (32 34) mas	84. ___ (32) . ___ (34) mR	85. ___ (40 42) mas
76. ___ (43) . ___ (47) mR	77. ___ (48 50) mas	86. ___ (51) . ___ (55) mR	87. ___ (56 58) mas

Linearity

88. ___ (59 62) mA

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

89. ___ (63) . ___ (67) mR

90. ___ (68) . ___ (72) mR

91. ___ (11) . ___ (15) mR

92. ___ (16) . ___ (20) mR

14

X-ray Field/Spot-film Size Comparison

93. Distance from the spot-film plane to the SSD spacer (or from face of BLD if spacer is not present) ___ (21) . ___ (23) cm

94. Distance from Image Receptor to bottom of table stand ___ (24) . ___ (26) cm

95. Length ___ (28) . ___ (30) cm (For circular field enter diameter twice)

96. Width ___ (31) . ___ (33) cm

REMARKS