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 *(NAME)*

Card No. *(9-10)*

Test Procedure: 1. CF *(11-13)*

2. System Type [ ] *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 V--Certified with a Variance
N--Not Certified X--Not Present or not applicable

[ ] *17* Tub 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)*	

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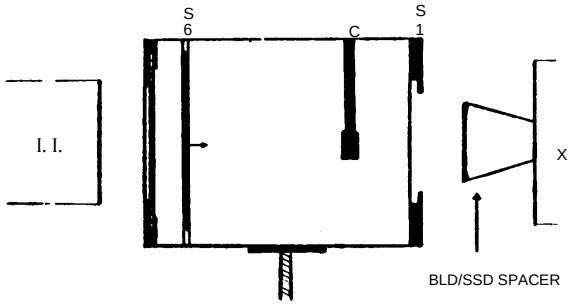
Initial Set-up (Fluoroscopic Mode) And Surveyor Protection Test

MDH (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

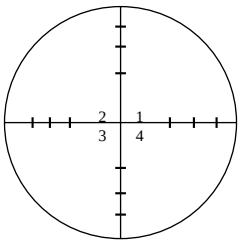


	Image Dimension	X-ray Field Dimension
1/4	8. [ ][ ] . [ ] *27 29* in	12. [ ][ ] . [ ] *30 32* cm
2/1	9. [ ][ ] . [ ] *33 35* in	13. [ ][ ] . [ ] *36 38* cm
3/2	10. [ ][ ] . [ ] *39 41* in	14. [ ][ ] . [ ] *42 44* cm
4/3	11. [ ][ ] . [ ] *45 47* in	15. [ ][ ] . [ ] *48 50* cm

NO MAGNIFICATION

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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 ___ . ___ cm (11, 13)

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

Minimum Fluoro Field Size

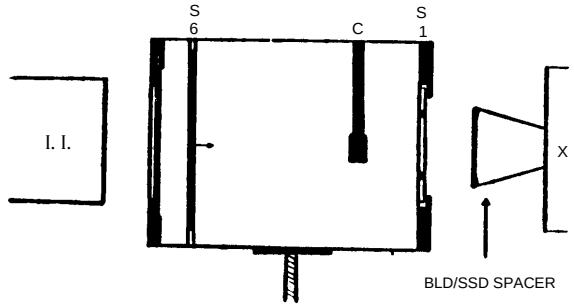
29. X-ray field Image length ___ . ___ cm (17, 19)

30. X-ray field Image width ___ . ___ cm (20, 22)

31. Field Shape ___ (23) 1--Circular 2--Rectangular

11

Entrance Exposure rate: (BLD fully open, no magnification)



MDH (Exposure rate)

32. Fluoroscopic Technique Factor Control Type ___ (24)

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

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--N/A				
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--N/A				

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Source -- Image Distance and Minimum Source to Skin Distance

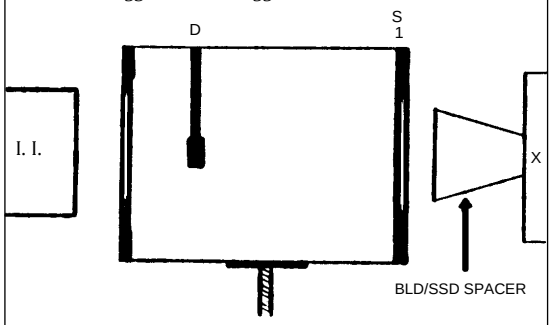
43. Distance from face of SSD spacer (or from face of BLD if spacer is not present) to top of brass strips [47] . [49] cm

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

11

Beam Quality

47. [53][55] kVp



MDH (Pulse Exposure 4.5mm Al

46. [56][58] mR @ 4.5 mm Al

48. [62][64] mR @ 3.5 mm Al

50. [68][70] mR @ 2.5 mm Al

52. [74][76] mR @ 1.5 mm Al

54. [11][13] mR @ 0.0 mm Al

47. [59] . [61] sec

49. [65] . [67] sec

51. [71] . [73] sec

53. [77] . [79] sec

55. [14] . [16] sec

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

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 fluorographic camera provided)

58. Spot-film length [19] . [21] cm

59. Spot-film width [22] . [24] cm

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

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

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

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

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

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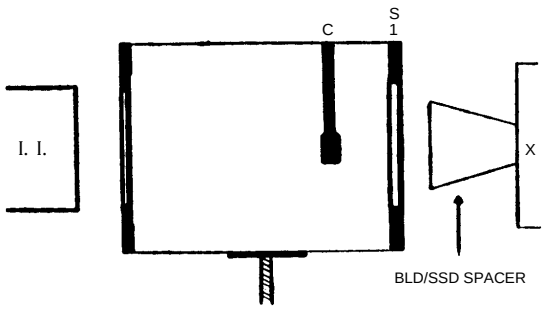
47 . 49 cm

Spot-Film Reproducibility and Linearity



65. MDH Threshold Setting. 0.5-3 phase, 0.2-1 phase: 6 . 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)

Reproducibility (no Al in beam)

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

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

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 test stand (24 . 26) cm

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

96. Width (31 . 33) cm

REMARKS