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

GENERAL INFORMATION 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)**
GI 50324

REGIONAL REVIEW (NAME)

Card No. (9-10)

Facility Identification

01 Name **(11-80)**

02 Street Address **(11-80)**

03 City **(11-73)** | State Code (74 75) | Zip Code (76 80)

04 Room Number **(11-37)** | Person Interviewed **(38-56)** | Telephone Number (57 59) (60 66)

Surveyor Information

05 Name *(Last, First, Middle Initial)* **(11-67)**

Signature

Accomp. Agency (68 69) | Accomp. District (70 72)

FDA Region (73 74) | Date *(Mo/Day/Yr)* (75 80)

Survey Information

Purpose of Survey (11)
I – Initial Survey
R – Resurvey
C – Compliance F/U
A – Audit
H – HIA

Assembler Report Nos. *(Letter included)* (12 18) (19 25) (26 32)

Installation Date (33) Mo/Day/Yr (34 38)

Previous FTRs *(5 or 6 digit number)* (39 44) (45 50)

System Information

06 Certification Status (57)
C – System Fully Certified
M – Mixed Certified/Non-Certified
V – Fully Certified With Variance
N – Fully Non-Certified

Control Manufacturer | Control Serial No. (52 63) | Date of Mfr. *(Mo/Yr)* (64 67)

Control Model No. | Mfr Code (68 71) | Unique ID (72 77)

System Maintenance

Is a maintenance schedule designed for compliance being followed? (78)

Is the maintenance schedule available for review? (79)

Y – Yes
N – No
X – Unknown

Who does the compliance maintenance? (80)
M – Mfr Rep
P – Private
I – In House
N – Not Done
X – Unknown

Instrumentation

MDH Serial No. (11 14) | Digiphot Serial No. (15 19)

Number of Each Form Attached

07

(19) AR	(20) DR	(21)
(22) AF	(23) MA	(24)
(25) UF	(26) KV	(27)
(28) MR	(29)	(30)

Assembler Data

Company

Street Address

City | State

Home District (31 33) | Assembler Code *(Central File No.)* (34 40)

FORM FDA 3071 (10/80)

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

UNDERTABLE X-RAY SOURCE FLOUROSCOPIC 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)

UF

REGIONAL REVIEW (NAME)

Card No. (9-10)

Test Procedure

1. UF (11-13)

Beam Limiting Device Information

2. Manufacturer — Mfr Code (14-17)

3. Model No. — Unique ID (18-23)

Component Certification Information

4. Indicate the Status of Each as Follows:

C – Certified
N – Not Certified
V Certified with a Variance
X – Not Present

- (24) Tube Housing Assembly
- (25) X-Ray Control
- (26) Spot Film Device *(after 4/77)*
- (27) Beam Limiting Device
- (28) High Voltage Generator
- (29) Fluoroscopic Imaging Assembly *(before 4/77)*
- (30) Table
- (31) Image Intensifier *(after 4/77)*

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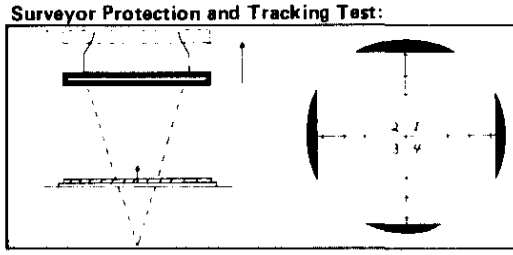
Interlock Test

5. X-Ray Production Prevention When Image Receptor Not in Position to Intercept Beam (32) Y – YES N – NO X – UNTESTED

Surveyor Protection and Tracking Test:



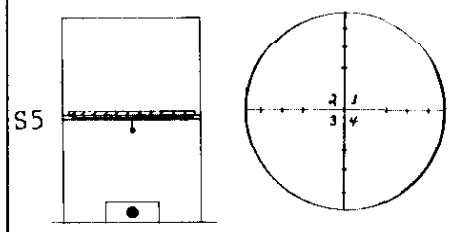
6. System Hazardous (33) Y – YES N – NO

If yes, describe hazard in Remarks and discontinue testing.

7. Beam Limiting Device Tracks Image Receptor Properly (34) Y – YES N – NO

X-Ray Field/Image Receptor Alignment

MDH (Exposure)



Insert Loaded Plastic Casette After Centering Test Stand.

	Image Dimension		X-Ray Field Dimension
1/4	8. (35) • (37) in.	Image Intensifier Positioned at Worst Case SID. Data Here Only if Answer to Tracking Question (#7) is "NO". Otherwise Proceed with Data at 16-23.	12. (38) • (40) cm
2/1	9. (41) • (43) in.		13. (44) • (46) cm
3/2	10. (47) • (49) in.		14. (50) • (52) cm
4/3	11. (53) • (55) in.		15. (56) • (58) cm
1/4	16. (11) • (13) in	Only Part of Test That Requires Magnification Mode. Take Out of This Mode After Completing the Test.	20. (14) • (16) cm
2/1	17. (17) • (19) in.		21. (20) • (22) cm
3/2	18. (24) • (26) in.		22. (27) • (29) cm
4/3	19. (31) • (33) in.		23. (34) • (36) cm

24. Tube Potential and Current Continuously Indicated During Exposure (23) Y – YES N – NO

11

25. Warning Label Present (30) Y – YES N – NO

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UNDER TABLE X-RAY SOURCE
FLUOROSCOPIC AND SPOT FILM SYSTEMS
FIELD TEST RECORD

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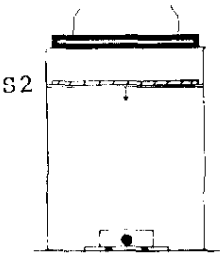
FIELD TEST SERIAL NO. (1-6)
UF

REGIONAL REVIEW (NAME)

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



MDH (Exposure rate)

26. Fluoroscopic Technique Factor Control Type [37] M–Manual Only A–Automatic Only B–Both Manual And Automatic

AUTO
27. [38–40] kVp
28. [41] . [42] mA
29. [43] . [45] R/min
30. Is a high level control present? [47] Y–YES N–NO
31. Continuous Audible Signal Upon Activation of High Level Control [48] Y–YES N–NO X–N/A

11

MANUAL
32. [49–51] kVp
33. [52] . [53] mA
34. [54] . [57] R/min
35. Is a high level control present? [58] Y–YES N–NO
36. Continuous Audible Signal Upon Activation of High Level Control [59] Y–YES N–NO X–N/A

Primary Barrier Transmission:

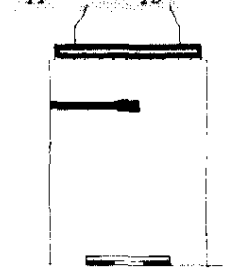
37. [60–62] kVp
38. [63] . [64] mA
39. [65] . [68] R/min
40. [69] . [72] mR
41. [73] . [75] sec

Copper appropriate for selected kVp: greater than 125 kV-0.12"; 100 to 125 kV-0.1"; 99 kV or less – 0.08".

min SSD:

42. Outside Separation of Image of Focal Spot Strips [76] . [78] cm

Beam Quality:



43. [11–13] kVp

MDH (Pulse Exposure) 4.5 mm Al

44. [14–16] mR @ 4.5 mm Al
45. [17] . [19] sec
46. [20–22] mR @ 3.5 mm Al
47. [23] . [25] sec
48. [26–28] mR @ 2.5 mm Al
49. [29] . [31] sec
50. [32–34] mR @ 1.5 mm Al
51. [35] . [37] sec
52. [38–40] mR @ 0.0 mm Al
53. [41] . [43] sec

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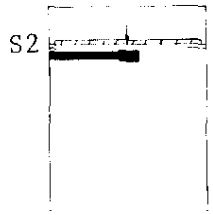
54. At End of Preset Cumulative Time Interval Either Continuous Audible Signal and/or Termination of X-rays [44] Y–YES N–NO

Spot-Film Reproducibility and X-ray Field/Image Receptor Size Comparison:

MDH (Pulse Exposure)



55. Type of Spot Film Exposure Timer [46] M–Manually Set Timer or mAs Selector only B–Both Manually Set Timer or mAs Selector and Phototimer P–Phototimer Only

56. MDH Threshold Setting [0] . [46]

Technique Factors

57. [47–49] kVp
58. [50–52] mA
59. [53] . [55] sec
60. [56–58] mAs

61. Film Dimension Along Table [59] . [61] in OR [62] . [64] cm
62. Film Dimension Across Table [68] . [70] in OR [71] . [73] cm
63. Image Along Table [65] . [67] cm
64. Image Across Table [74] . [76] cm
65. Distance From Table Top to Spot Film Plane [77] . [79] cm

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FLUOROSCOPIC AND SPOT FILM SYSTEMS
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UF

REGIONAL REVIEW (NAME)

Spot-Film Continued:

13

66. ___ . ___ mR (11–15)	67. ___ msec (16–18)	76. ___ . ___ mR (19–23)	77. ___ msec (24–26)
68. ___ . ___ mR (27–31)	69. ___ msec (32–34)	78. ___ . ___ mR (35–39)	79. ___ msec (40–42)
70. ___ . ___ mR (43–47)	71. ___ msec (48–50)	80. ___ . ___ mR (51–55)	81. ___ msec (56–58)
72. ___ . ___ mR (59–63)	73. ___ msec (64–66)	82. ___ . ___ mR (67–71)	83. ___ msec (72–74)
74. ___ . ___ mR (11–15)	75. ___ msec (16–18)	84. ___ . ___ mR (19–23)	85. ___ msec (24–26)

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86. Technique Factors fixed or selectable Indicated Before Exposure ___ (27) Y YES N NO

87. Exposure Terminated After Preset Time Interval, Preset mAs, Preset Number of Pulses, Or Preset Radiation Exposure To Image Receptor ___ (28) Y--YES N NO

REMARKS