FLUOROSCAN InSight®-FD

InSight® 2 Mini C-arm Imaging System Technical Reference Manual

MAN-04849 Revision 003

HOLOGIC®

InSight® 2

Mini C-arm Imaging System

Technical Reference Manual

Part Number: MAN-04849
Revision 003
July 2021

HOLOGIC®

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Customer Support

Toll Free in USA: +1.800.321.4659

Email: SkeletalHealth.Support@hologic.com

In Europe, South America, or Asia, contact your local dealer or distributor.

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1 Product Specifications

1.1 Power Requirements

Table 1 Power Requirements

Parameter	Value
AC Input Voltage	Nominal 100/120/220/230/240 VAC selectable, Single Phase
Wattage	750 watts maximum
AC Input Frequency	Nominal 50/60 Hz
Power Failure Protection	Images software protected

1.2 Environmental Requirements

Table 2

Parameter	Value
Temperature Range (Operating)	+15.5 °C to +32 °C (+60 °F to +90 °F)
Temperature Range (Storage)	-20 °C to +50 °C (-4 °F to +122 °F)
Relative Humidity (Operating)	20 – 80% non-condensing
Relative Humidity (Storage and Transport)	20 – 85% non-condensing
Atmospheric Pressure	500 – 1060 hPa (375 - 795 mm Hg)

1.3 Weights/Dimensions

Table 3 Weights/Dimensions

Height	65 in. (165.1 cm)
Width	35 in. (88.9 cm)
Depth	35 in. (88.9 cm)
Weight	500 lb (227 kg)

1.4 Space Requirements

Table 4 Space Requirements

Required Floor Space:	5 ft x 6.6 ft (1.5 m x 2.0 m)
Door Size	30 in. (88.9 cm) minimum
Ground Clearance:	3.875 in. (9.8 cm) minimum
Floor Capacity	151.1 lb/ft^2 (737.2 kg/m^2)

1.5 X-Ray Specifications

Table 5 X-Ray Specifications

Source - Image receptor distance	44 cm (17.5")
X-ray source	Grounded tungsten anode X-ray tube with custom designed high voltage generator
X-ray tube window	0.005 inch (0.127 mm) Beryllium
Beam filtration	Stainless steel and copper with aluminum equivalence ≥ 2.7 mm
Focal spot	0.045 mm (0.0018 in.) @ 7.5 watts
Field of View (FOV)	Operator selectable collimation of 4 in. or 6 in. diameter (10.16 cm or 15.24 cm) FOV at the plane of the image intensifier.
Rated peak tube potential	75 kVp
Tube kVp range	40 to 75 kVp
Tube current range	0.020 to 0.100 mA
Accuracy of displayed values for kV/mA	kVp ± 5% of displayed value mA ± 8% ≤0.035 mA of displayed value mA ± 5% >0.035 mA of displayed value
Maximun Duty cycle at 75 kVp/0.100 mA	50%

1.6 Performance

Table 6 Performance

Parameter	Value
Acquisition Frame Rate	Non-cine recording 30 FPS Cine recording 25 FPS
Fluoroscopic Time Alarm Range	15 seconds – 5 minutes, adjustable in 15 second increments (default is 5 minutes)
Image Storage Capacity	10000 Images (maximum)
Cine Loop Capacity	40 minutes maximum
Laser Alignment Guide Timeout	60 seconds (press and release) No timeout (press and hold for 2 seconds)

1.7 Imaging Specifications

Table 7 Imaging Specifications

Image intensifier	High sensitivity Cesium Iodide
C-arm dimensions	Source to detector distance: 17.5 in. (44 cm) Free space: 14 in. (36 cm) Depth of arc: 14 in. (36 cm)
Image processing	Digital, with up to 32 frames of video averaging and last frame freeze
Video system	24 in. (61 cm) LED touch screen monitor with a native resolution of 1920 x 1200 and an aspect ratio of 16:10. Solid state video camera HDMI output
Resolution (using Nuclear Associates test tool 07-539, located at the minimum SSD in normal (6 in. mode)	7.0 lp/mm, minimum
Contrast (using Nuclear Associates test tool 07-647, located at the surface of the image intensifier housing in normal (6 in. mode)	Must resolve, at minimum, 30# mesh At least 3 of 4 low contrast masses (2,4,6,8 mm) visible Low contrast inserts in both monitor adjustment squares visible
Brightness	On first use, a warning will be displayed if the saved physician preference for brightness is below the value (20) specified in the <low_brightness_threshold> system configuration field

1.8 Laser Performance Specifications

Table 8 Laser Performance Specifications

Parameter	Condition	Value
Laser Power	Device on	IEC Class 1
Laser Wavelength	Device on	635 nm
Projected Line Width	At image intensifier surface	0.05 ± 0.03 in.
Projected Line Length	At center of image intensifier surface	7.00 ± 0.50 in.
Line Intersection Location Accuracy	At center of image intensifier surface	± 0.125 in.
Auto-off delay Auto-off disabled	Press and release Press and hold for 2 seconds	Off in 60.0 ± 2.0 seconds Laser remains on until turned off (press again)
Input Power Voltage	N/A	5.00 ± 0.25 volts
Input Power Current	Device off	10 mA, max.
Input Power Current	Device on	100 mA, max.

2 Equipment Classification

InSight 2 is classified* as follows:

Table 9 Equipment Classification

Type of protection against electric shock	CLASS 1
Degree of protection against electric shock	TYPE B
Laser per IEC-60825-1	CLASS 1
Degree of protection against harmful ingress of water	IPXO
Mode of operation	Continuous Operation

InSight 2 is also classified* as:

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

* Medical Electrical Equipment - UL 60601-1

2 InSight 2 Entrance Exposure Rate Data

Typical entrance exposure rates, measured at a point in center of image intensifier, 2 cm above surface of the housing.

Table 10 Entrance Exposure Rates — Standard Mode

kV	µA	µGy/s
43	30	3.22
44	34	3.86
45	38	4.65
46	42	5.47
47	44	6.18
48	46	6.81
49	52	8.05
50	56	9.14
51	58	9.98
52	60	10.87
53	62	11.70
54	64	12.69
55	66	13.61
56	68	14.71
57	70	15.64
58	72	16.77
59	74	17.85
60	76	19.08
61	78	20.22
62	80	21.51
63	82	22.75
64	84	24.05
65	86	25.36
66	88	26.77
67	90	28.20

Table 10 Entrance Exposure Rates — Standard Mode

kV	µA	µGy/s
68	92	29.61
69	94	31.32
70	96	32.73
71	99	34.73
72	100	35.84
73	100	36.70
74	100	37.70
75	100	38.41

3 Entrance Exposure Rate Data, Auto Mode

Typical entrance exposure rates with Auto kV/mA ON.

Table 11 Typical Entrance Exposure Rates

6 inch mode	8.9 µGy/s
4 inch mode	9.6 µGy/s

Measured using RTI Barracuda dosimeter with Multi-Purpose Detector, positioned 2 cm above input surface of the image intensifier housing. There is no additional attenuation of the x-ray beam between the source and the dosimeter detector (open beam).

3.1 Scatter Radiation Survey

Table 12 Scatter Radiation Survey

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.075	0.079	0.086	0.093	0.018
40	0.025	0.025	0.032	0.046	0.018
60	0.014	0.007	0.014	0.032	0.001
80	0.003	0.003	0.009	0.025	N/A
100	0.003	0.003	0.006	0.01	N/A

Table 13 Air Kerma (mGy/h) Rate Parallel to Cathode - Anode Axisusing ANSI Knee Phantom; 75 kVp@ 0.100 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.432	0.428	0.378	0.306	0.057
40	0.158	0.144	0.133	0.122	0.032
60	0.057	0.068	0.07	0.068	0.01
80	0.036	0.046	0.043	0.043	N/A
100	0.025	0.028	0.029	0.025	N/A

Table 14 Air Kerma (mGy/h) Rate Perpendicular to Cathode - Anode Axisusing ANSI Knee Phantom; 65 kVp@ 0.088 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.064	0.05	0.075	0.09	0.025
40	0.025	0.032	0.029	0.046	0.003
60	0.039	0.028	0.024	0.032	0.003
80	0.032	0.018	0.014	0.025	N/A
100	0.021	0.007	0.003	0.003	N/A

Table 15 Air Kerma (mGy/h) Rate Perpendicular to Cathode - Anode Axisusing ANSI Knee Phantom; 75 kVp@ 0.100 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.345	0.53	0.381	0.298	0.1
40	0.136	0.115	0.14	0.122	0.028
60	0.086	0.093	0.068	0.064	0.018
80	0.061	0.046	0.043	0.036	N/A
100	0.043	0.028	0.025	0.018	N/A

Table 16 Air Kerma (mGy/h) Rate Parallel to Cathode - Anode Axisusing Anthropomorphic Hand Phantom; 50 kVp@ 0.058 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.324	0.21	0.172	0.176	0.046
40	0.129	0.09	0.064	0.079	0.014
60	0.064	0.046	0.036	0.05	0.021
80	0.057	0.032	0.021	0.021	N/A
100	0.032	0.021	0.014	0.014	N/A

Table 17 Air Kerma (mGy/h) Rate Parallel to Cathode - Anode Axis using Anthropomorphic Hand Phantom; 75 kVp@ 0.100 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.507	0.352	0.356	0.266	0.072
40	0.212	0.144	0.111	0.111	0.028
60	0.1	0.079	0.061	0.064	0.025
80	0.072	0.05	0.036	0.032	N/A
100	0.043	0.032	0.025	0.021	N/A

Table 18 Air Kerma (mGy/h) Rate Perpendicular to Cathode - Anode Axis using Anthropomorphic Hand Phantom; 50 kVp@ 0.058 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.324	0.18	0.198	0.187	0.068
40	0.126	0.118	0.075	0.09	0.018
60	0.05	0.07	0.039	0.05	0.007
80	0.028	0.036	0.025	0.025	N/A
100	0.021	0.025	0.014	0.014	N/A

Table 19 Air Kerma (mGy/h) Rate Perpendicular to Cathode - Anode Axisusing Anthropomorphic Hand Phantom; 75 kVp@ 0.100 mA

Distance (cm)	45° mGy/h	22.5° mGy/h	0° mGy/h	-22.5° mGy/h	-45° mGy/h
20	0.507	0.295	0.345	0.28	0.104
40	0.198	0.194	0.129	0.126	0.032
60	0.082	0.118	0.068	0.068	0.014
80	0.079	0.057	0.039	0.039	N/A
100	0.054	0.036	0.025	0.021	N/A

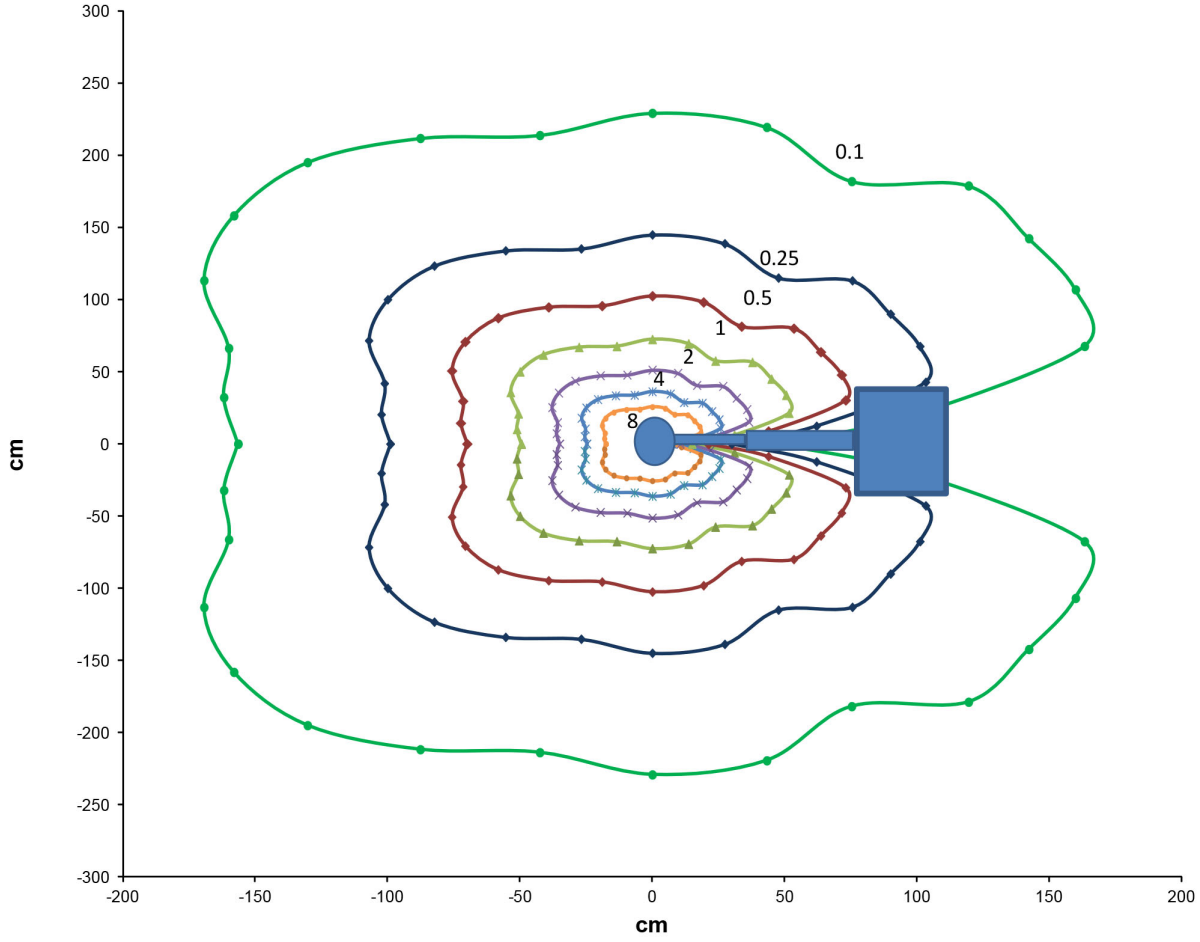
4 Iso-Exposure Rates

Scatter radiation measurements around the Fluoroscan InSight 2 Mini C-arm were made with a hand phantom and a foot phantom placed on the imaging assembly as scatter sources.

Figure 1 Phantom Positioning

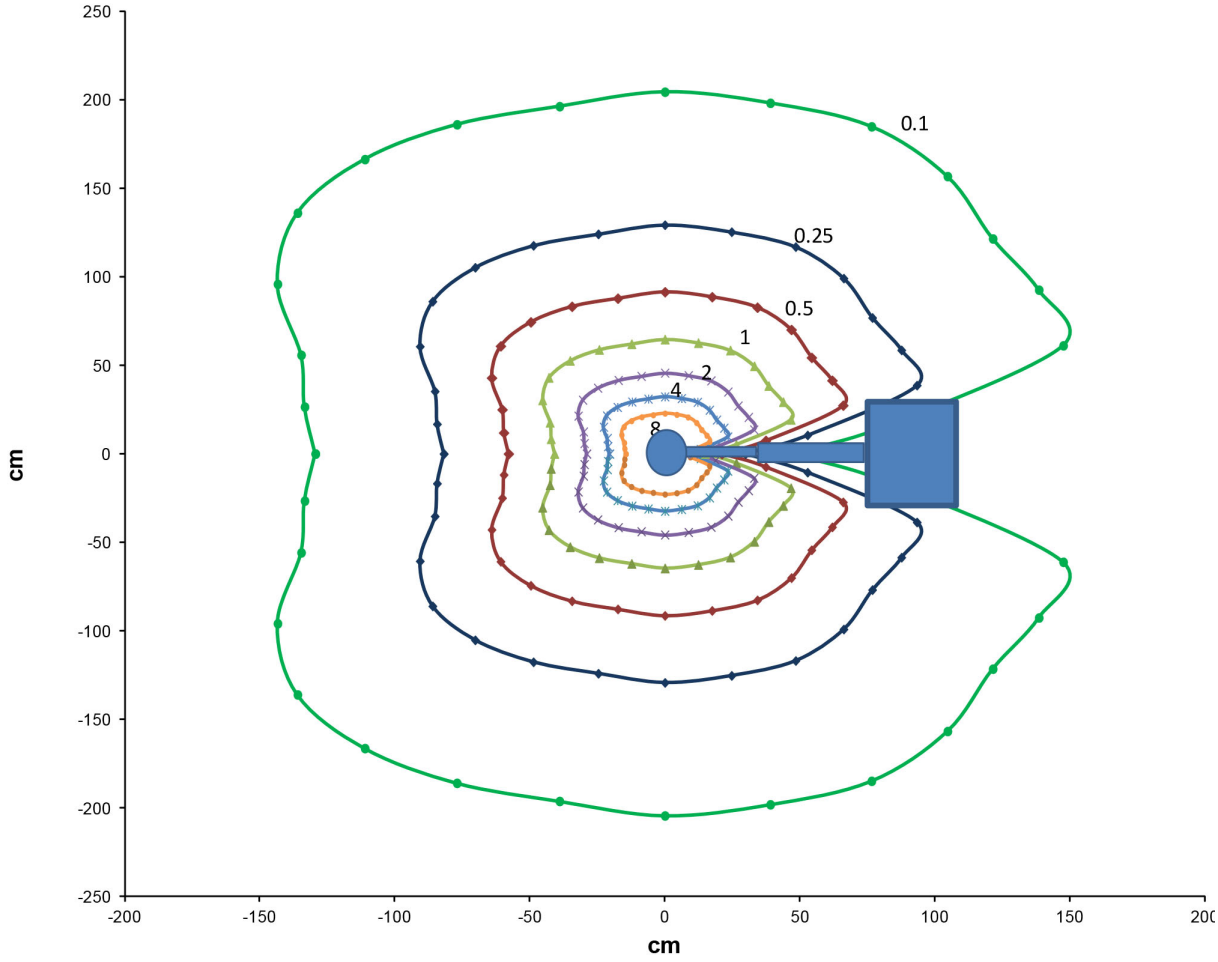
Phantom	Hand
Field	Full
Mode	Auto IQ
Technique	Kv 53
	mA 0.099

Figure 2 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



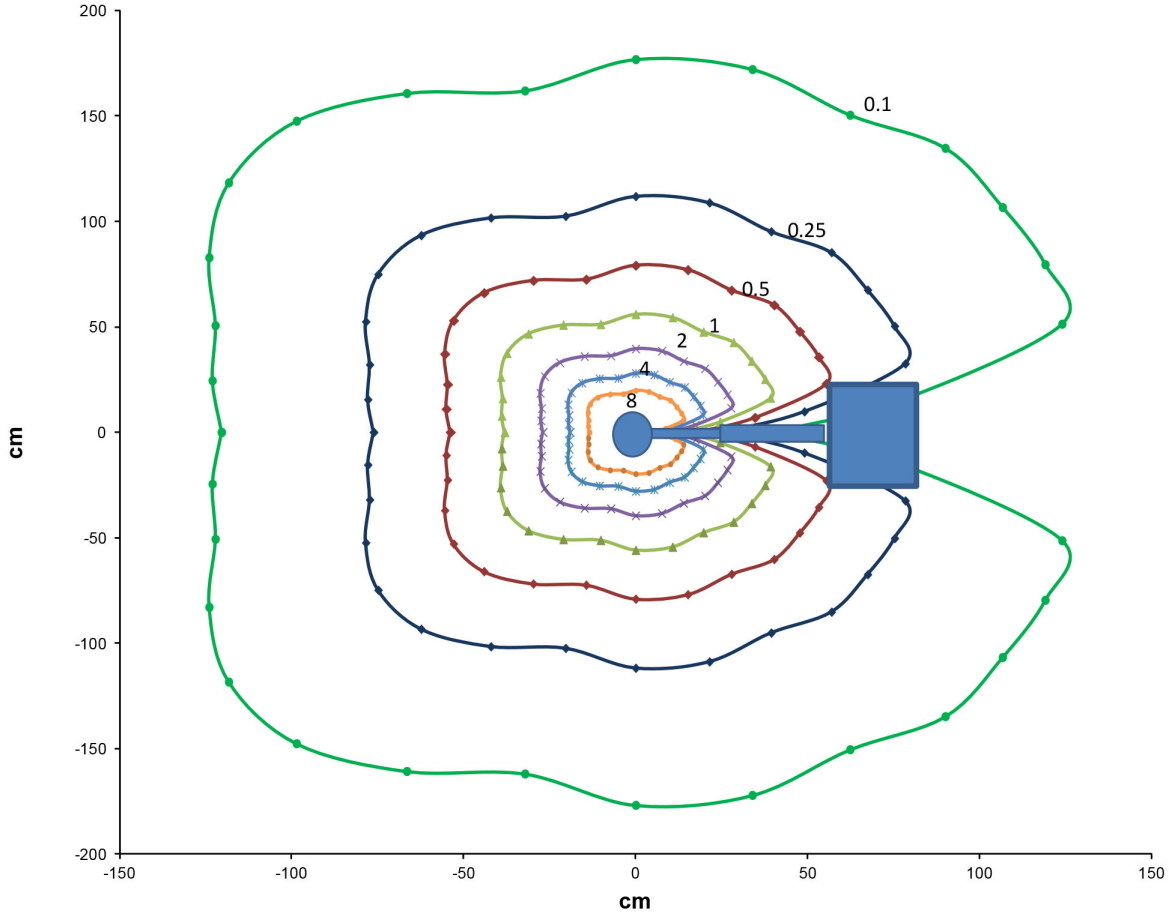
Phantom	Hand
Field	Limited
Mode	Auto IQ
Technique	kV 54
	mA 0.098

Figure 3 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



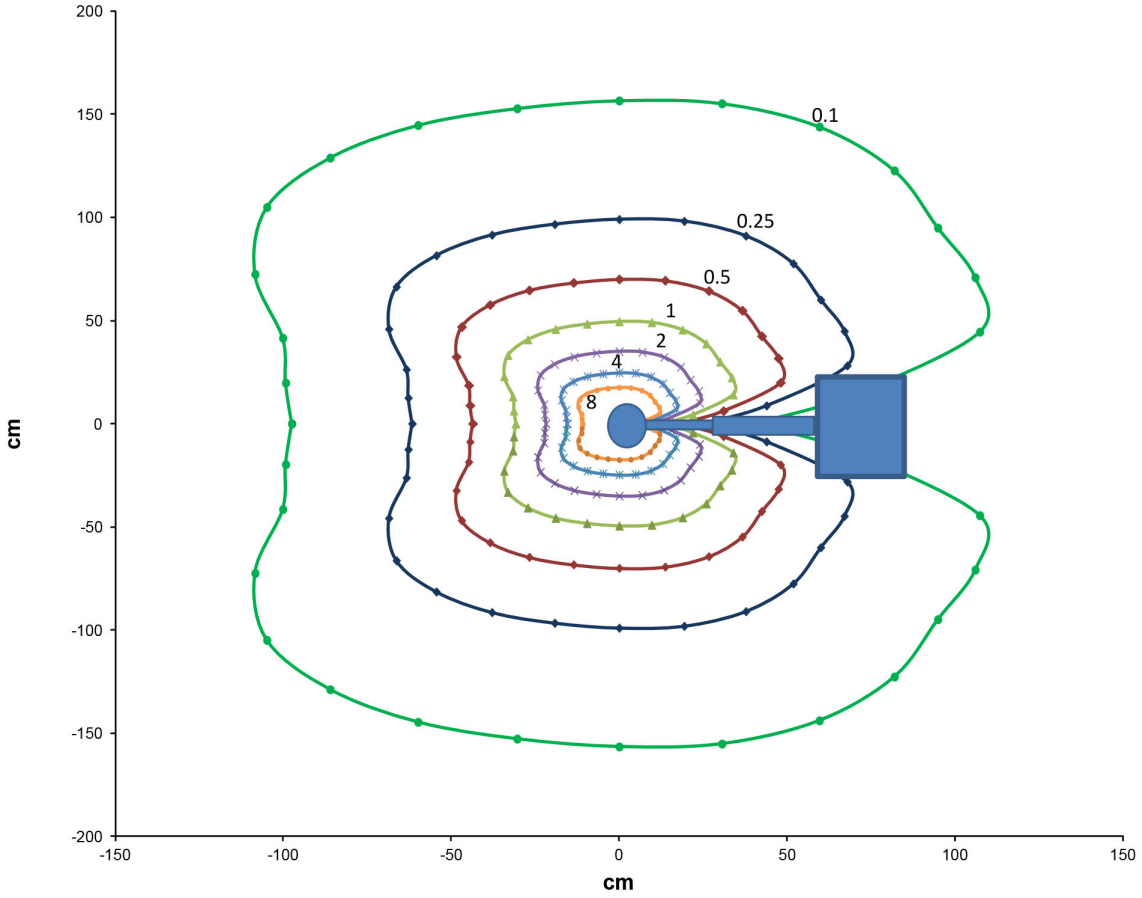
Phantom	Hand
Field	Full
Mode	Auto
Technique	kV 52
	mA 0.060

Figure 4 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



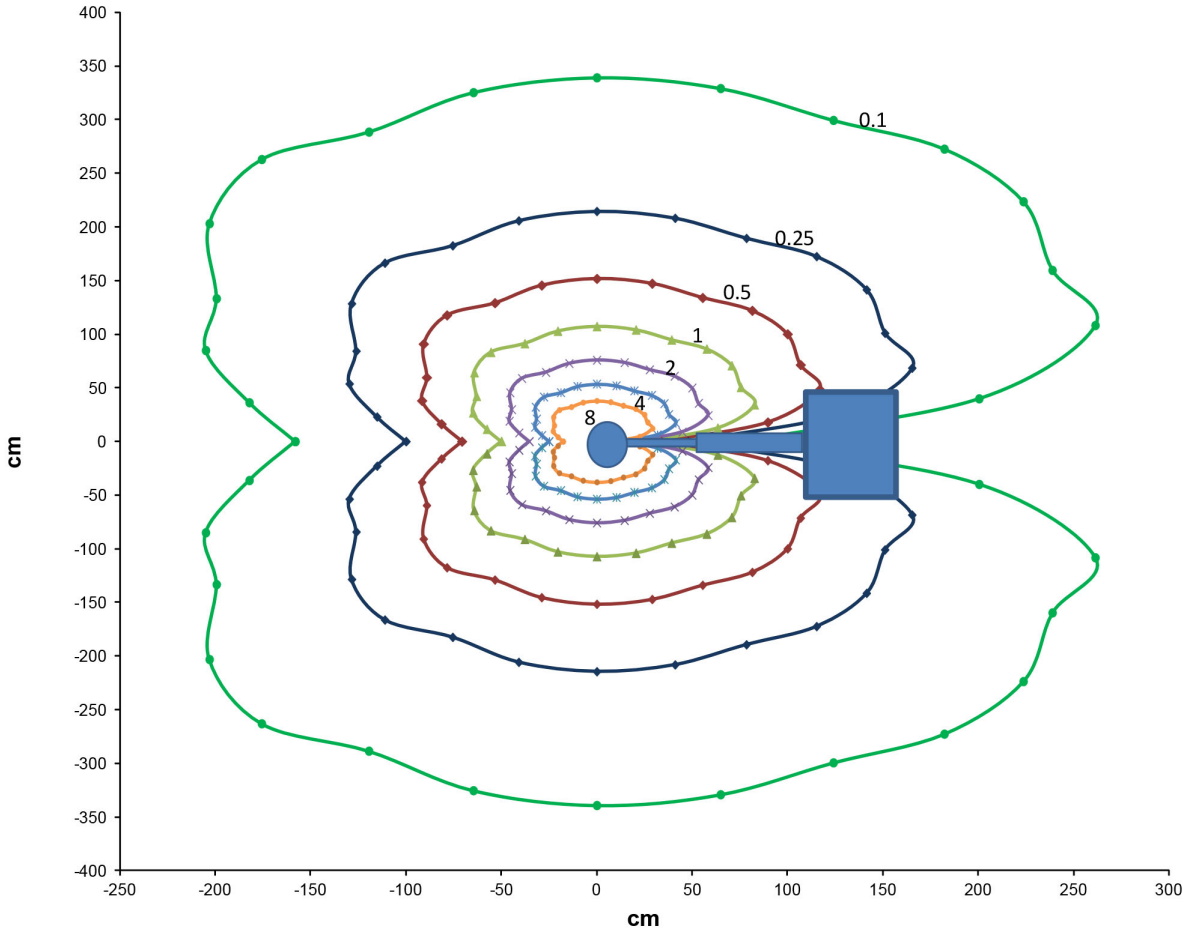
Phantom	Hand
Field	Limited
Mode	Auto
Technique	kV 54
	mA 0.058

Figure 5 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



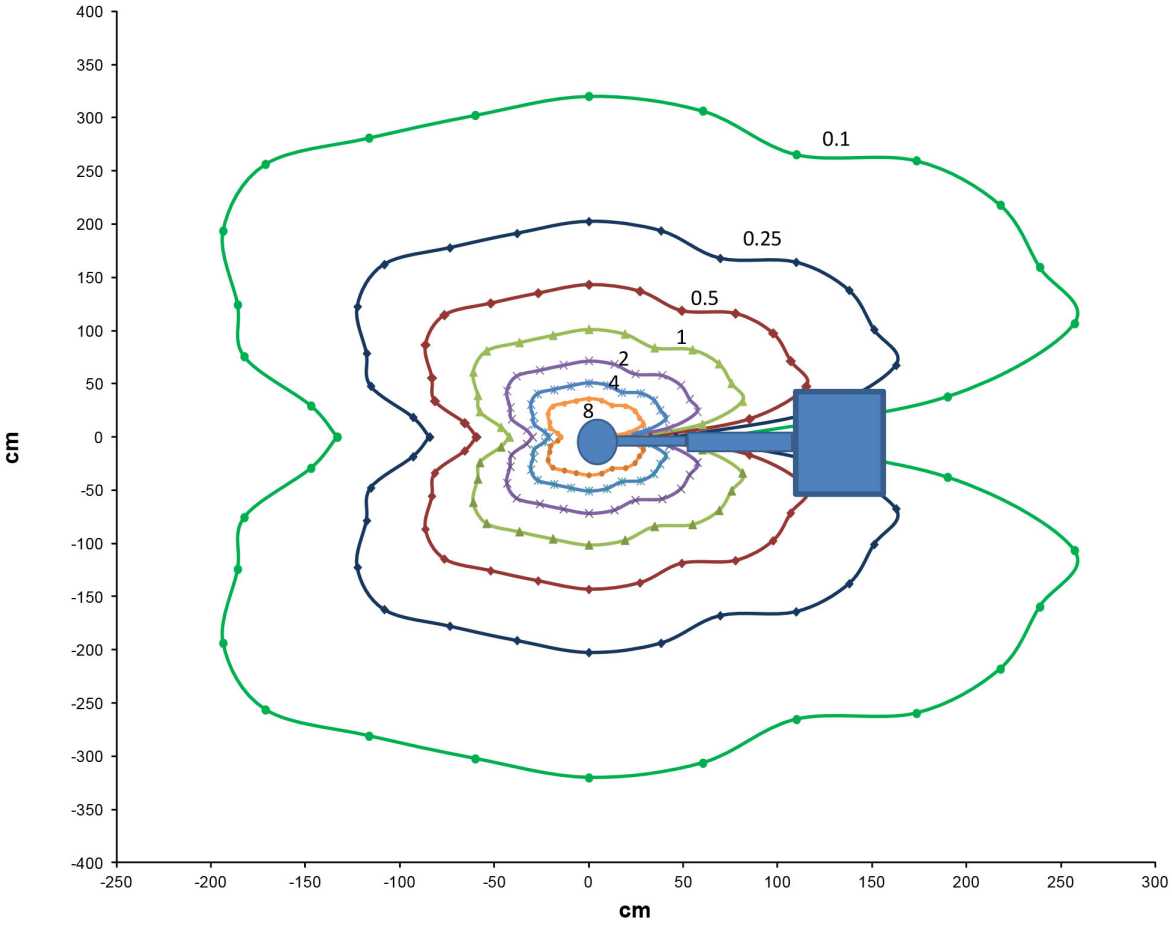
Phantom	Foot
Field	Full
Mode	Auto IQ
Technique -	kV 56
	mA 0.099

Figure 6 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



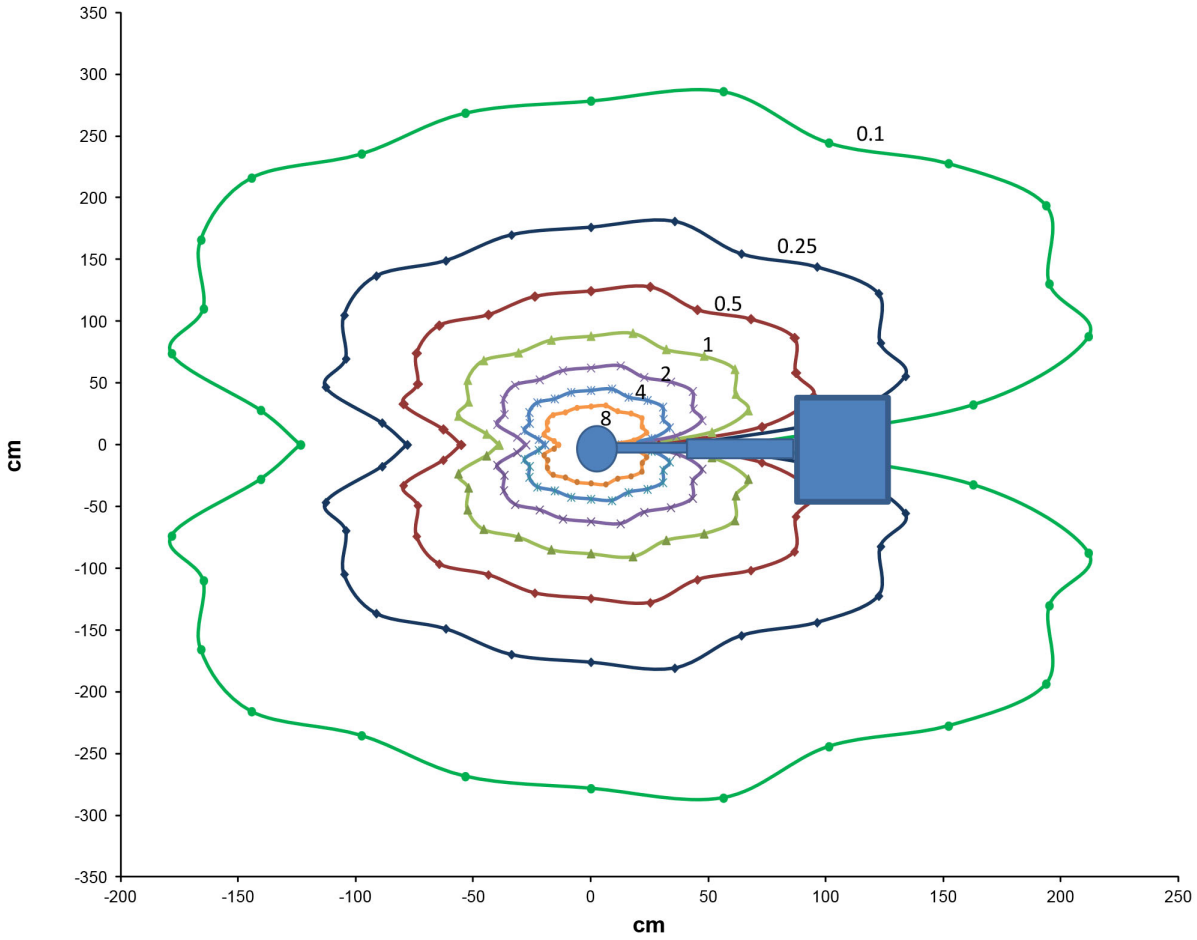
Phantom	Foot
Field	Limited
Mode	Auto IQ
Technique	kV 58
	mA 0.099

Figure 7 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



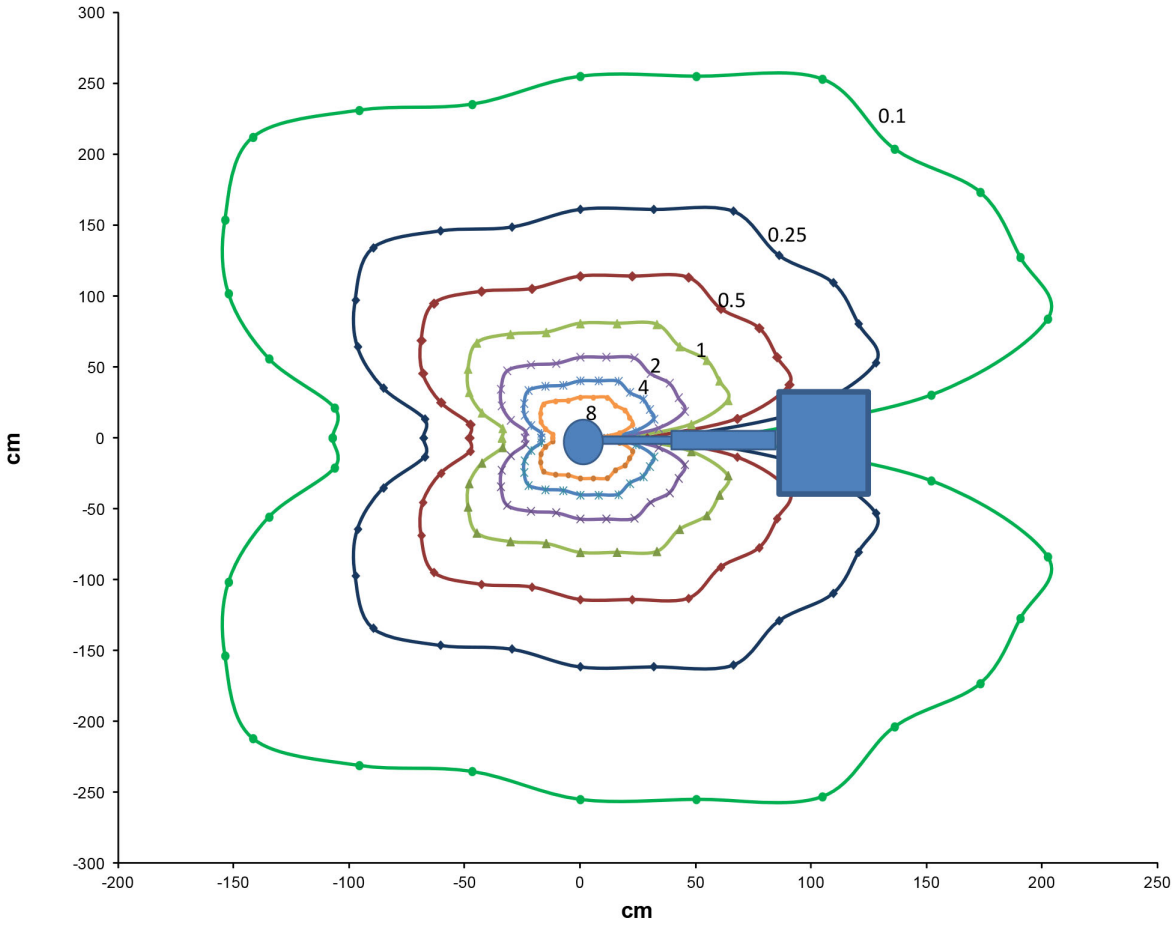
Phantom	Foot
Field	Full
Mode	Auto
Technique	kV 55
	mA 0.066

Figure 8 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



Phantom	Foot
Field	Limited
Mode	Auto
Technique	kV 58
	mA 0.066

Figure 9 Contours: 0.1, 0.25, 0.5, 1, 2, 4 and 8 mR/h



5 Symbols

	Dangerous voltage		Caution
	Type B applied part		X-ray filtration
	Warning: Electricity		AC Voltage
	Time delay fuse		Protective earth (ground)
	Earth (ground)		Equipotentiality
	USB connector		Electrostatic sensitive device
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.		Computer On/Standby switch
	Rear wheels free to move in all directions		Rear wheels move forward and back only
	Locking, general		Manufacturer
	Date of Manufacture		Authorized representatives in the European Community
	Radiation of laser apparatus		X-ray source emitting

	Store		Print
	Increase or decrease kV/mA		Rotate image
	Cycle through the noise suppression settings		Serial number
	Catalogue number		No pushing
	ISO 7010-M002, Refer to instruction manual/ booklet.		

6 InSight 2 System Labels

6.1 System Main Label

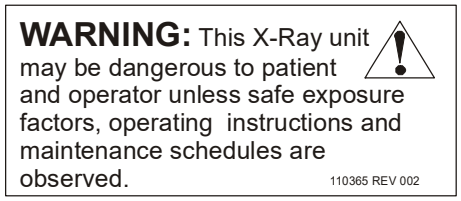
The System Main Label is on the back of the base cabinet.

Figure 10 System Main Label

6.2 X-Ray System Warning Label

The X-Ray System Warning Label is on the front of the base cabinet below the Computer On/Standby switch.

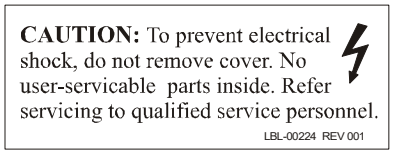
Figure 11 X-Ray System Warning Label



6.3 Electric Shock Warning Label

The Electric Shock Warning Label is located near the fasteners for panels covering high voltage components.

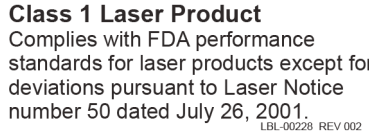
Figure 12 Electric Shock Warning Label



6.4 Class 1 Laper Product Label

Class 1 Laser Product complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice number 50 dated July 26, 2001.

Figure 13 Class 1 Laser Product Label



6.5 Caution on Incline Label

The Caution on Incline Label is on the back of the unit, above the handle.

Figure 14 Caution on Incline Label

6.6 Transport Label

The Transport Label is on the back of the unit, above the handle.

Figure 15 Transport Label

6.7 X-Ray Controller Compliance Label

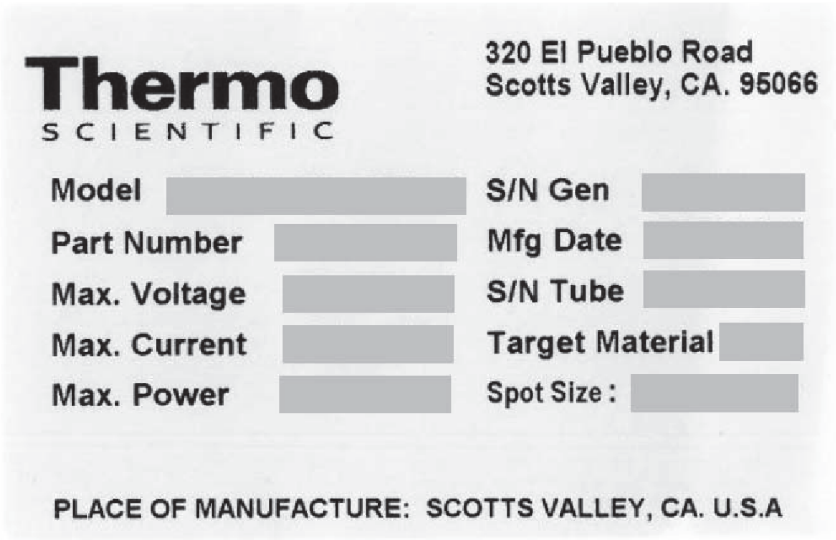
The X-Ray Controller Compliance Label (Figure 16) is on the X-Ray Controller assembly and on the back of the base cabinet.

Figure 16 X-Ray Controller Compliance Label

6.8 X-Ray Source Compliance Label

The X-Ray Source Compliance Label is on the X-Ray source module and on the back of the base cabinet.

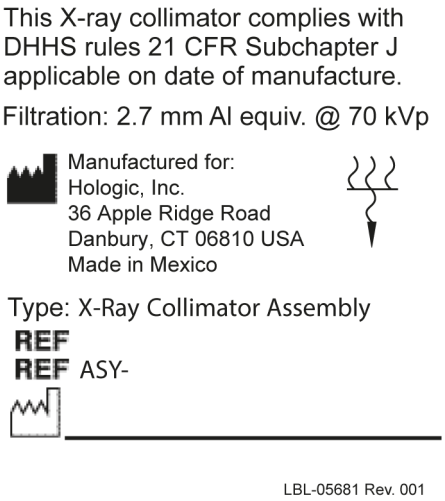
Figure 17 X-Ray Source Compliance Label



6.9 Collimator Compliance Label

The Collimator Compliance Label is on the X-Ray source module (near the collimator assembly).

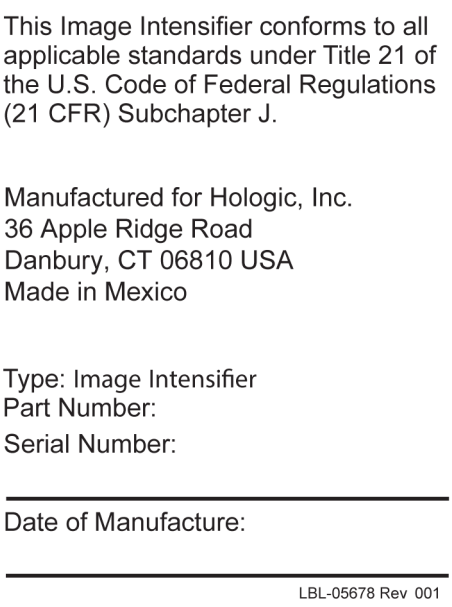
Figure 18 Collimator Compliance Label



6.10 Image Intensifier Compliance Label

The Image Intensifier Compliance Label is on the back of the Radiological Imaging Unit cover.

Figure 19 Image Intensifier Compliance Label



6.11 C-Arm Compliance Label

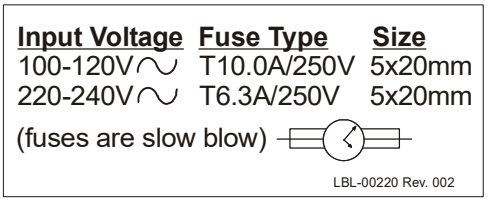
The C-Arm Compliance Label is on the bottom of the High Voltage Power Supply cover.

Figure 20 C-Arm Compliance Label

6.12 AC Input Power Fuse Label

The AC Input Power Fuse Label is on the back of the base cabinet near the AC power connector.

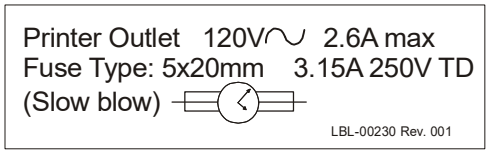
Figure 21 AC Input Power Fuse Label



6.13 Printer Fuse Label

The Printer Fuse Label is located at the back of the printer compartment near the printer outlet.

Figure 22 Printer Fuse Label



6.14 Explosion Risk Label

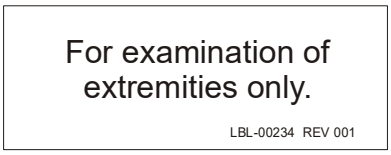
The Explosion Risk Label is located on the back of the base cabinet.

Figure 23 Explosion Risk Label

6.15 Extremities Only Label

The Extremities Only Label is located on the back of the base cabinet.

Figure 24 Extremities Only Label



6.16 No Pushing Warning Label

The No Push Warning Label is located on the back of the base cabinet.

Figure 25 No Pushing Warning Label*

*Do not push the system with the casters locked or obstructed and the C-arm extended.

6.17 ISO 7010-M002 Label

Figure 26 ISO 7010-M002 Label

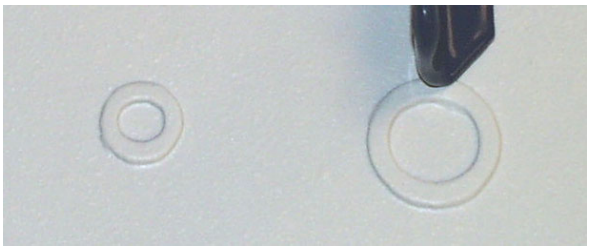
The ISO 7010-M002 Label, refer to instruction manual/booklet, is located on the back of the base cabinet.

Note *On ME Equipment "Follow instructions for use."*

6.18 Field of View

Field of View is represented by raised circles rectangles on the underside of the High Voltage Power Supply. When the Field of View selection lever is positioned at the large rectangle full field of view is selected. When the Field of View selection lever is positioned at the small rectangle reduced field of view is selected.

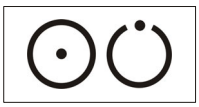
Figure 27 Field of View



6.19 Computer On/Standby Label

The Computer On/Standby Label is on the front of the base cabinet above the Computer On/Standby switch.

Figure 28 Computer On/Standby Label



6.20 Ground Labels

Each system grounding point, depending upon type of ground, has one of the Ground Labels shown below.

Figure 29 Ground Labels

Earth (ground)

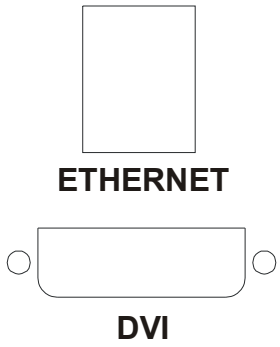
Protective earth (ground

Equipotentiality

6.21 Back Panel Labels

The Ethernet and DVI labels are located in the middle of the system back panel below their respective connectors.

Figure 30 Back Panel Labels



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