FLUOROSCAN InSight™ FD

RM InSight™ FD Mini C-arm Technical Reference Manual

MAN-09975 Revision 001

HOLOGIC®

RM InSight™ FD

Mini C-arm Imaging System

Technical Reference Manual

Part Number MAN-09975
Revision 001
July 2023

HOLOGIC®

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

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1 Product Specifications

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
Power Cord Length	20 ft (6 m)

Table 2 Environmental Requirements

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)

Table 3 Weights/Dimensions

Height	66 in. (168 cm)
Width	28 in. (71 cm)
Depth	32 in. (81 cm)
Weight	475 lb (215 kg)

Table 4 Space Requirements

Required Floor Space:	5 ft x 6.6 ft (1.5 m x 2.0 m)
Door Size	32 in. (81.2 cm) minimum
Ground Clearance:	3.875 in. (9.8 cm) minimum
Floor Capacity	151.1 lb/ft^2 (737.2 kg/m^2)
Arm Length	51.8 in. (132 cm) fully extended from the pivot to mid point of detector

Table 5 X-ray Specifications

Source - Image receptor distance	44 cm (17.5 in.)
X-ray source	Grounded tungsten anode X-ray tube with custom designed high voltage generator
X-ray tube window	0.005 in. (0.127 mm) Beryllium
Beam filtration	Aluminum with minimum thickness 3.0 mm
Focal spot	0.045 mm (0.0018 in.) @ 7.5 watts
Field of View (FOV)	Operator selectable collimation of Limited Field or Full Field. Limited Field uses a 4.4 in. x 4.4 in. collimation mode, which magnifies a small area. Full Field uses a 5.7 in. x 4.5 in. collimation mode, which displays large area.
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%
Maximum Output	0.100 mA @75 kVp

Table 6 Performance

Parameter	Value
Acquisition Frame Rate	Standard Resolution image / Cine 30 FPS High Resolution image* and Low Dose image / Cine are approximately 50% of the Standard Resolution image rate. *Cine recording not available in High resolution mode
Fluoroscopic Time Alarm Range	15 seconds – 5 minutes, adjustable in 15 second increments (default is 5 minutes)
Image Storage Capacity	10000 Images (maximum)* *Fewer images can be stored at high resolution mode
Cine Loop Capacity	40 minutes maximum
Laser Alignment Guide Timeout	60 seconds (press and release) No timeout (press and hold for 2 seconds)

Table 7 Imaging Specifications

Parameter	Value
CMOS detector	75 micron pixel array 2k x 1.5k resolution Full +/-90 degree rotation Auto-tracking collimation
C-arm dimensions	Source to detector distance: 17.5 in. (44 cm) Free space: 13.5 in. (34.3 cm) Depth of arc: 20 in. (50.6 cm) Orbital rotation: 120 degrees Horizontal travel: 23 degrees Vertical travel: 23 in. (58 cm) Pivot rotation: 380 degrees Panning motion: 320 degrees
Image processing	Digital, with up to 32 frames of video averaging and last frame freeze 16-bit image processing
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 (Full Field) mode)	7.0 lp/mm, minimum

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 CMOS detector surface	0.05 ± 0.03 in.
Projected Line Length	At center of CMOS detector surface	7.00 ± 0.50 in.
Line Intersection Location Accuracy	At center of CMOS detector 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	0.010 mA, max.
Input Power Current	Device on	0.100 mA, max.
Maximum Output	Device on	0.20 mW
Pulse Duration	Device on	CW (Continuous Wave)

The InSight™ FD Mini C-arm Imaging System 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

The RM InSight FD Mini C-arm Imaging System 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 FD Entrance Exposure Rate Data

Typical entrance exposure rates, measured at a point in center of the CMOS detector, 5 cm above surface of the detector.

Technique Controls:

- Patient Entry Air Kerma Rate (AKR) and Exposure Rate
- kVp and mA
- FS to AK reference location: 40 cm
- Measurements made at 5cm above IA

Table 8 Mode: Auto, Standard Dose

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.056	0.493	0.056
Limited			50	0.058	0.502	0.057
Full	19 mm Al	Average	63	0.084	1.338	0.152
Limited			64	0.086	1.429	0.162
Full	2 mm Pb	Maximum	74	0.099	2.067	0.235
Limited			74	0.099	2.186	0.248

Table 9 Mode: Auto, High Resolution

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.099	0.879	0.100
Limited			50	0.099	0.915	0.104
Full	19 mm Al	Average	67	0.099	1.832	0.208
Limited			68	0.099	1.882	0.214
Full	2 mm Pb	Maximum	74	0.097	2.210	0.251
Limited			74	0.099	2.210	0.259

Table 10 Mode: Auto IQ, Standard Dose

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.094	0.839	0.095
Limited			49	0.094	0.823	0.094
Full	19 mm Al	Average	67	0.099	1.833	0.208
Limited			67	0.099	1.823	0.207
Full	2 mm Pb	Maximum	74	0.099	2.218	0.252
Limited			74	0.099	2.196	0.250

Table 11 Mode: Auto, Low Dose

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.022	0.193	0.022
Limited			50	0.023	0.207	0.024
Full	19 mm Al	Average	63	0.033	0.524	0.060
Limited			64	0.034	0.565	0.064
Full	2 mm Pb	Maximum	74	0.040	0.868	0.099
Limited			74	0.040	0.865	0.098

Table 12 Mode: Cine Record, Auto

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.056	0.491	0.056
Limited			49	0.056	0.488	0.056
Full	19 mm Al	Average	63	0.084	1.329	0.151
Limited			64	0.086	1.430	0.163
Full	2 mm Pb	Maximum	74	0.099	2.196	0.250
Limited			74	0.099	2.209	0.251

Table 13 Mode: Cine Record, Auto IQ

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.094	0.835	0.095
Limited			49	0.094	0.830	0.094
Full	19 mm Al	Average	67	0.099	1.790	0.203
Limited			67	0.099	1.822	0.207
Full	2 mm Pb	Maximum	74	0.099	2.185	0.248
Limited			74	0.099	2.173	0.247

Table 14 Mode: Cine Record, Low Dose

Field Size	Phantom	Patient Size	kVp	mA	Measured Values	
					Converted to mGy/min at AK Ref Pt.	Exposure R/min
Full	3.3 mm Al	Small	49	0.022	0.196	0.022
Limited			49	0.023	0.212	0.024
Full	19 mm Al	Average	63	0.033	0.514	0.058
Limited			64	0.034	0.564	0.064
Full	2 mm Pb	Maximum	74	0.040	0.855	0.097
Limited			74	0.040	0.858	0.097

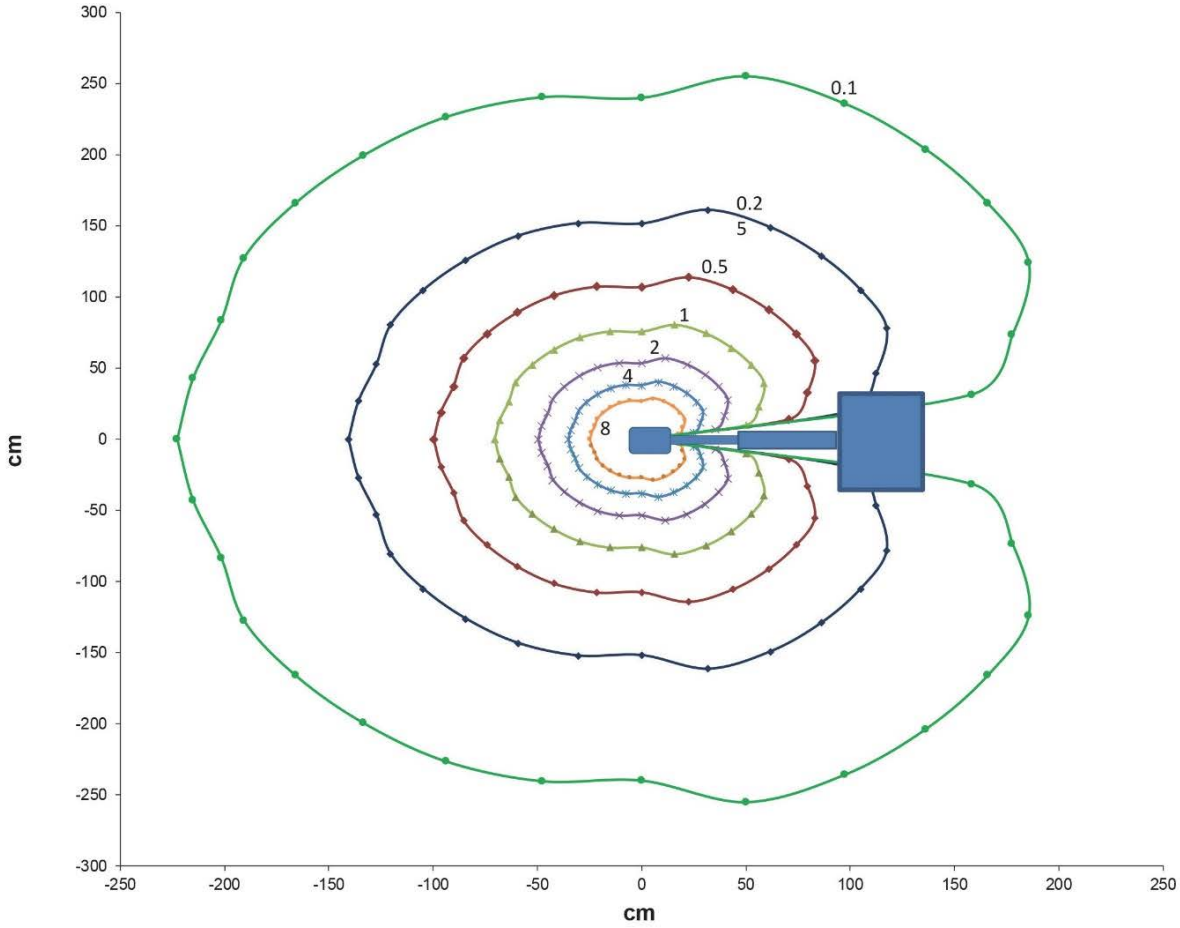
3 Iso-Exposure Rates

Scatter radiation measurements around the Fluoroscan InSight FD 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

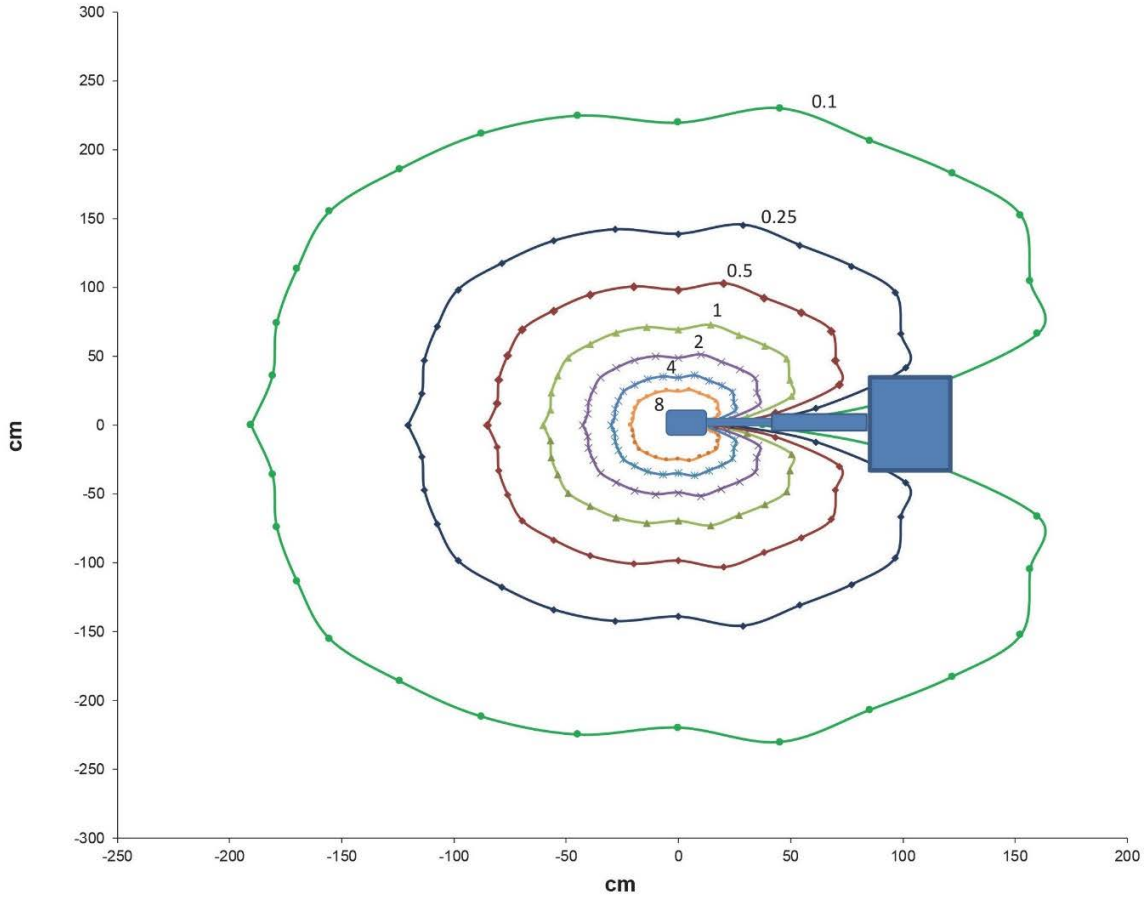
Phantom	Hand
Field	Full
Mode	Auto, Hi Res
Technique	kV 52
	mA 0.099

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



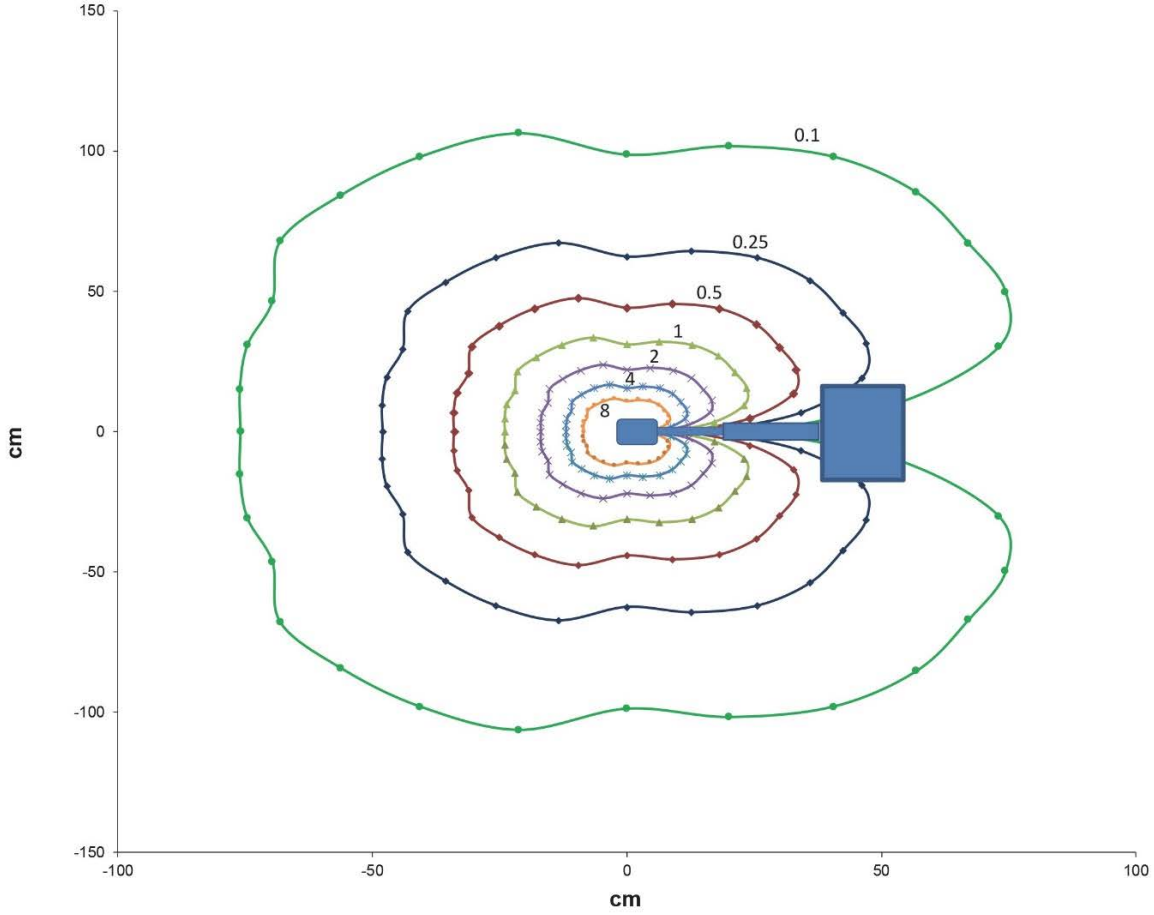
Phantom	Hand
Field	Limited
Mode	Auto, Hi Res
Technique	kV 51
	mA 0.99

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



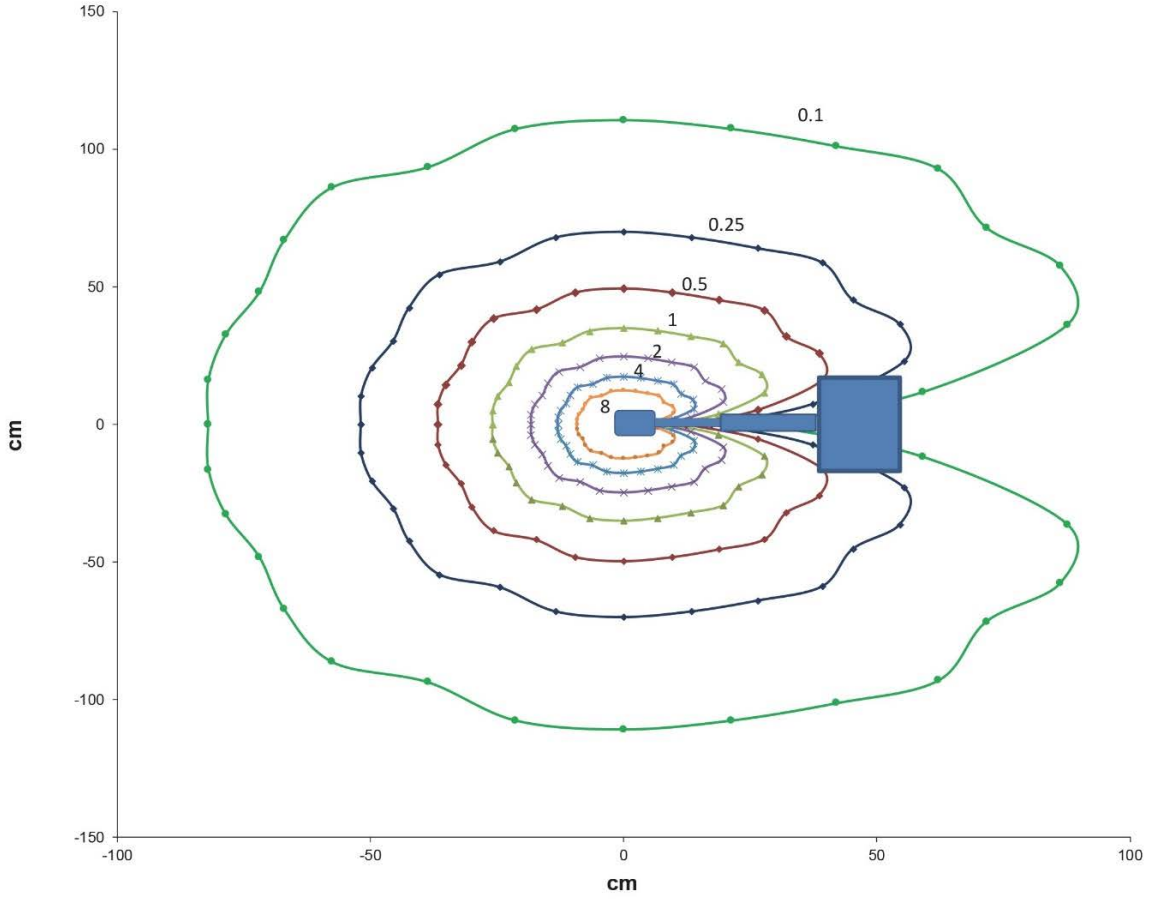
Phantom	Hand
Field	Full
Mode	Low Dose, Std
Technique	kV 51
	mA 0.024

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



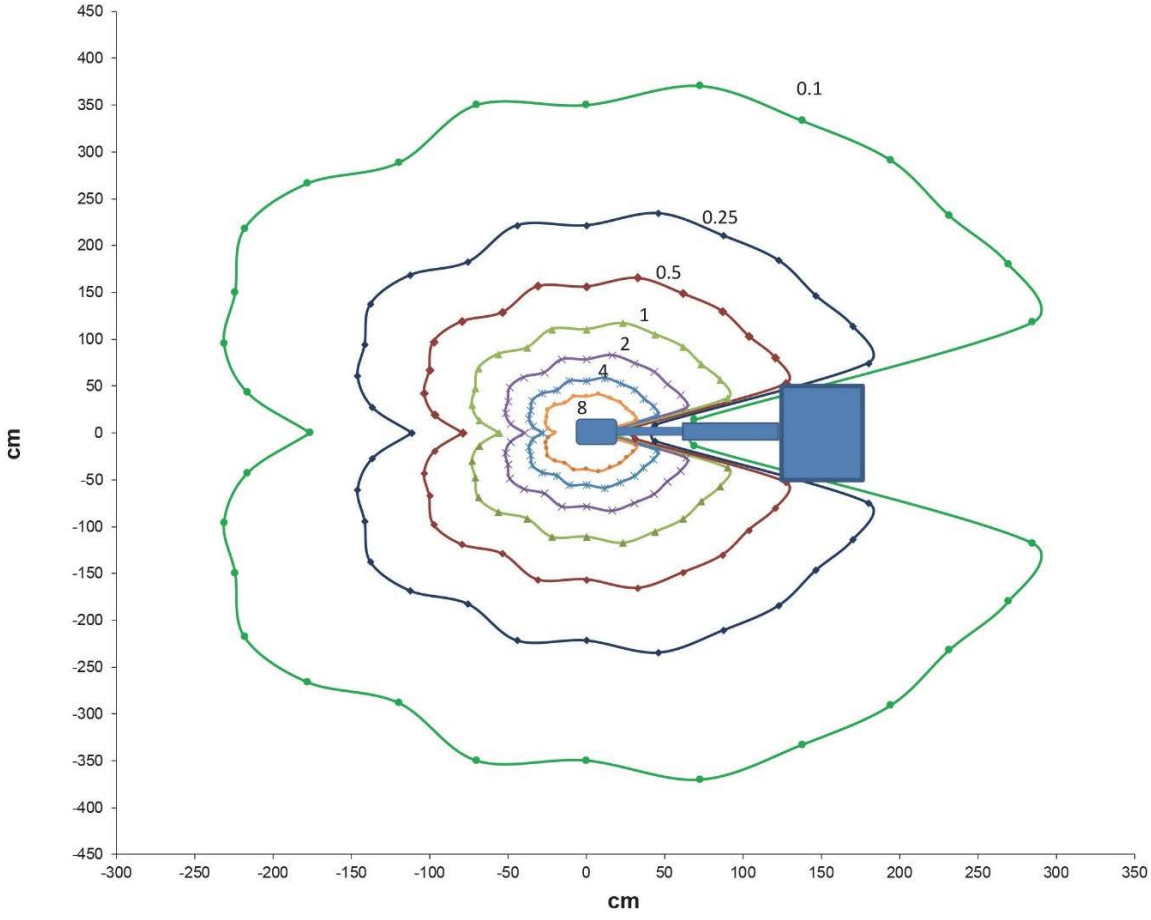
Phantom	Hand
Field	Limited
Mode	Low Dose, Std
Technique	kV 51
	mA 0.024

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



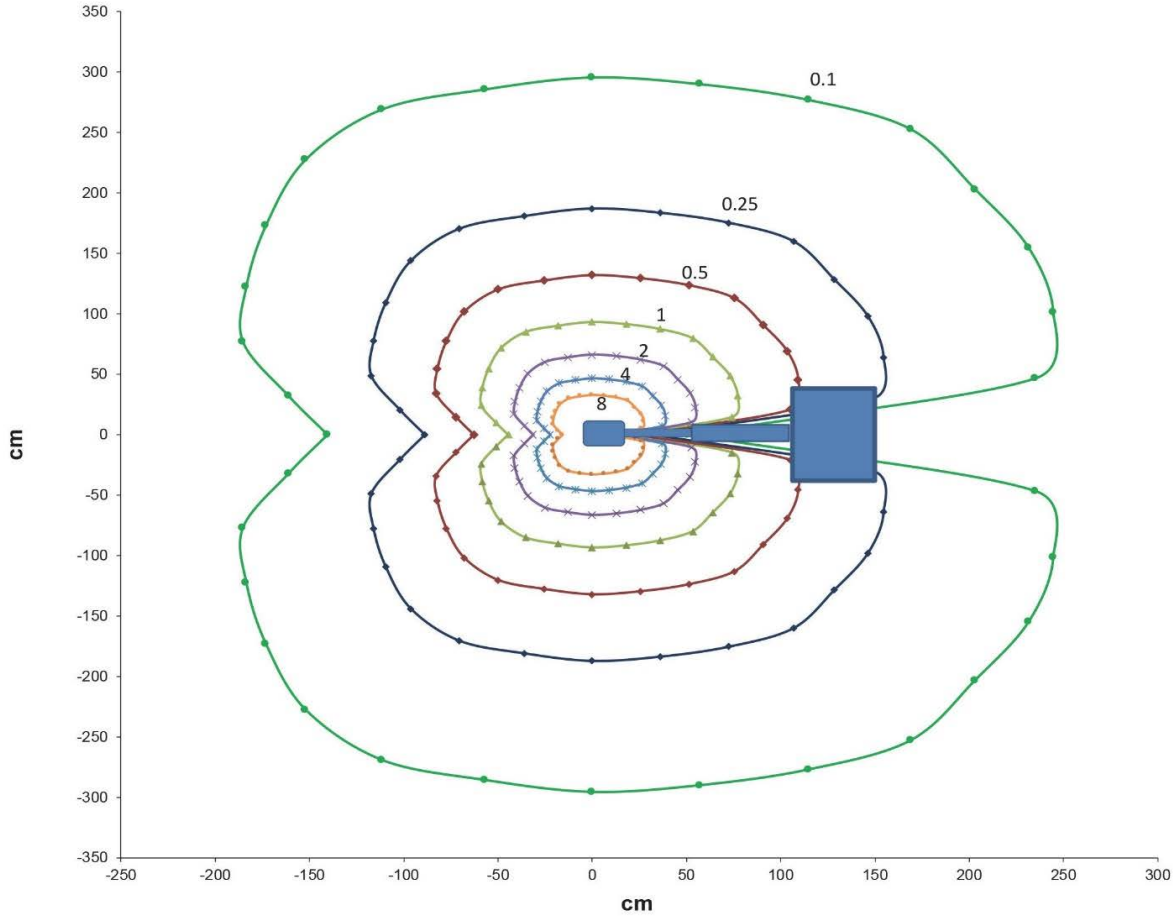
Phantom	Foot
Field	Full
Mode	Auto, Hi Res
Technique	kV 53
	mA 0.099

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



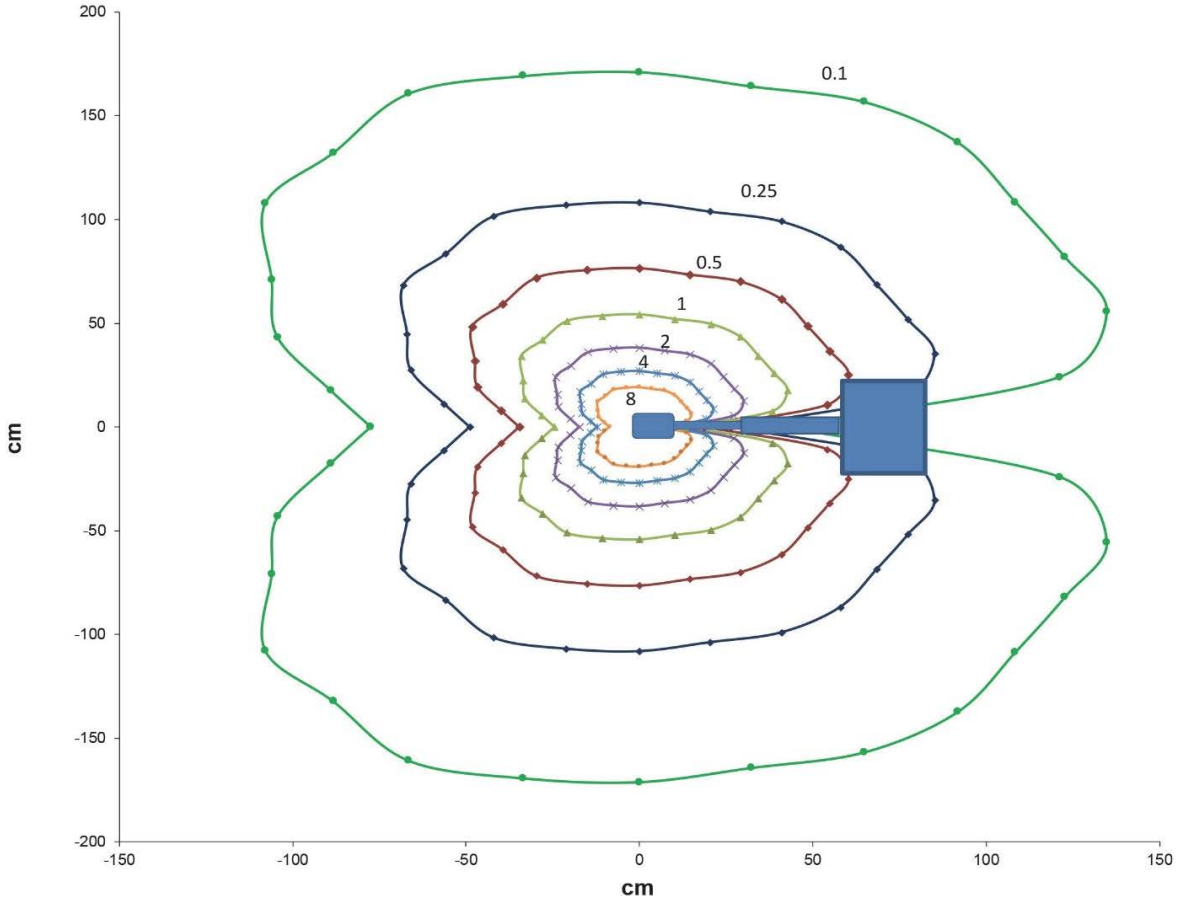
Phantom	Foot
Field	Limited
Mode	Auto, Hi Res
Technique	kV 54
	mA 0.099

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



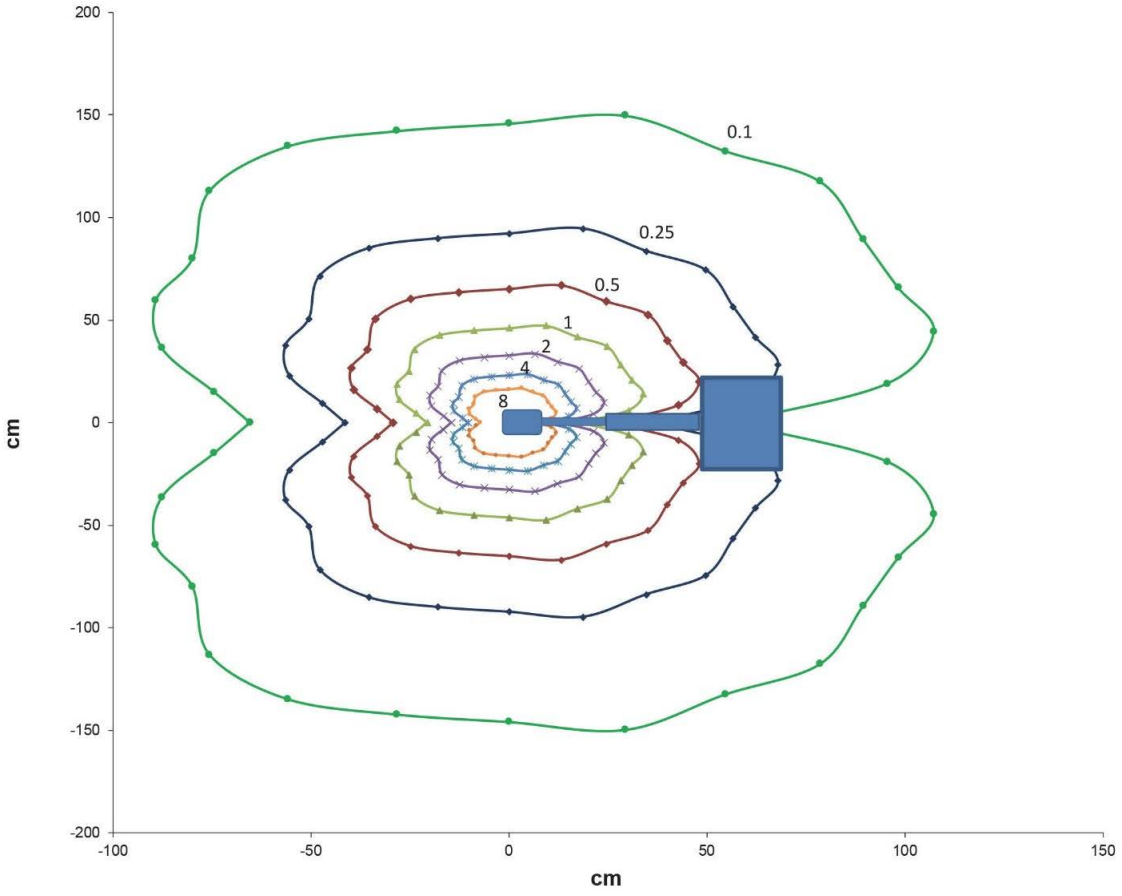
Phantom	Foot
Field	Full
Mode	Low Dose, Std
Technique	kV 54
	mA 0.026

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



Phantom	Foot
Field	Limited
Mode	Low Dose, Std
Technique	kV 53
	mA 0.025

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

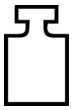


4 Symbols

Table 15 Symbols

	CSA listed device		Caution
	Warning: Electricity		Radiation Filter
	X-ray source assembly		Alternating current
	Type B applied part		Protective earth (ground)
	Earth (ground)		Equipotentiality
	Fuse		Electrostatic sensitive device
	USB connector		Humidity limitation
	Temperature limit		Computer Standby switch
	Computer On switch		Manufacturer
	Equipment to be disposed in compliance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment.	EC REP	Authorized representatives in the European Community

Table 15 Symbols

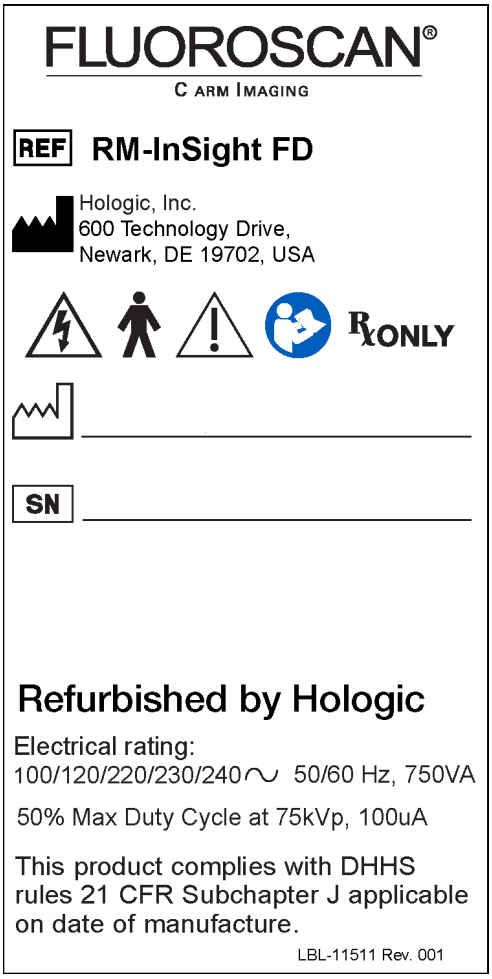
	Date of Manufacture		Serial number
	Catalog number		Combined weight of the equipment and its safe working load
	Follow instructions for use		

5 InSight FD System Labels

5.1 Manufacturer Serial Number Label

The Manufacturer Serial Number Label is on the back of the base cabinet.

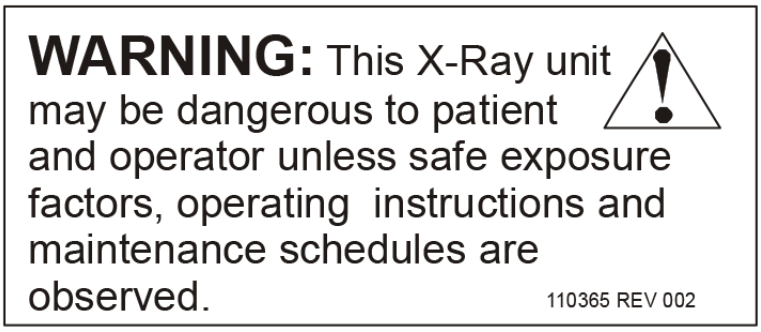
Figure 10 System Main Label



5.2 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.

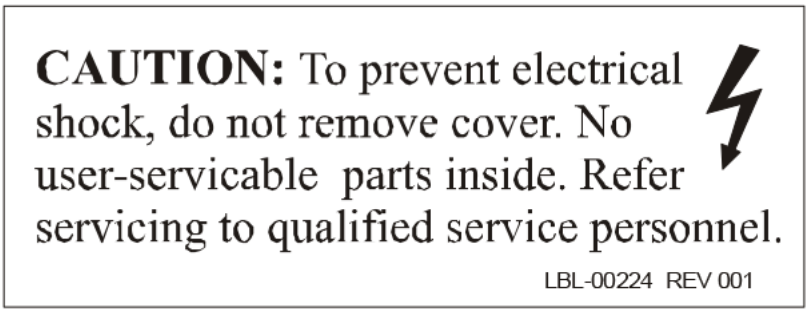
Figure 11 X-ray System Warning Label



5.3 Electric Shock Caution/Danger Label

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

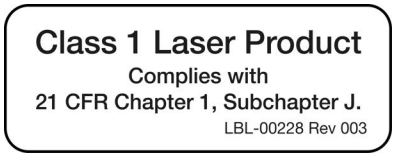
Figure 12 Electric Shock Warning Label.



5.4 Class 1 Laser 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



5.5 Caution on Incline Label

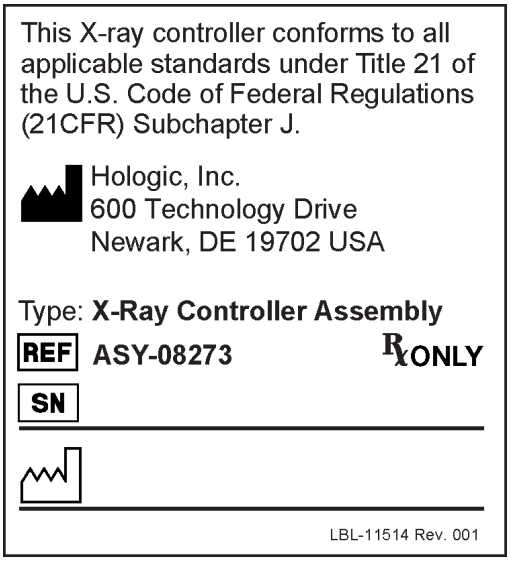
The Caution on Incline Label is on the back of the unit, above the handle.

Figure 14 Caution on Incline Label

5.6 X-ray Controller Compliance Label

The X-ray Controller Compliance Label is on the X-ray Controller assembly and on the back of the base cabinet.

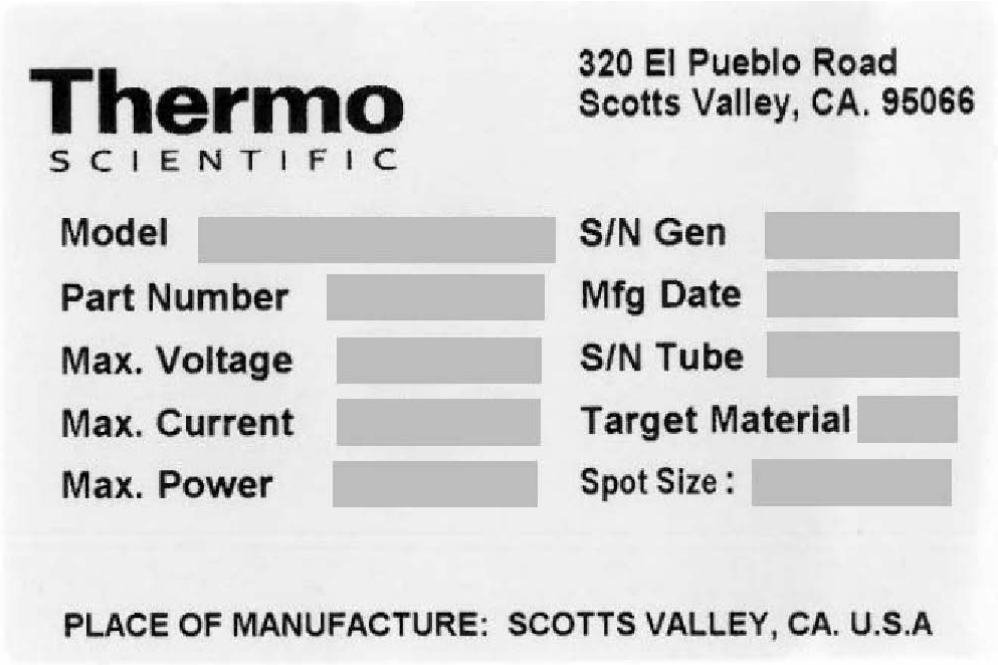
Figure 15 X-ray Controller Compliance Label



5.7 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.

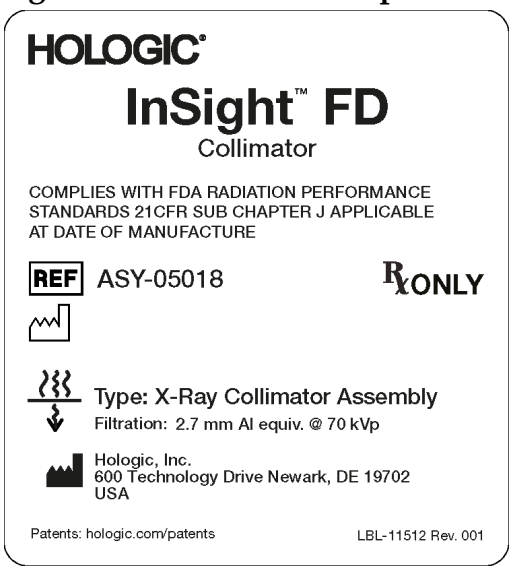
Figure 16 X-ray Source Compliance Label



5.8 Collimator Compliance Label

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

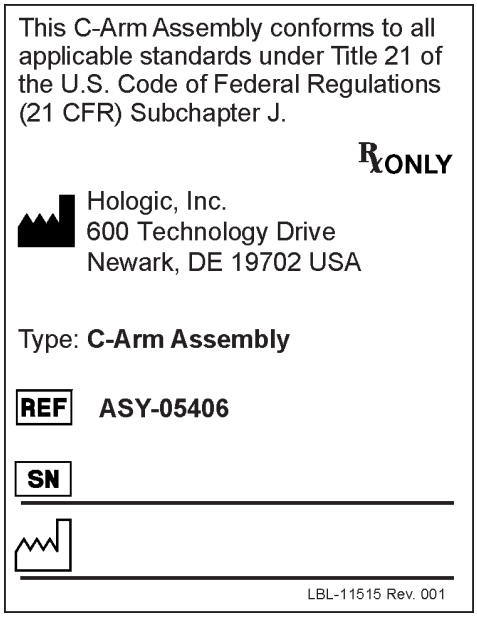
Figure 17 Collimator Compliance Label



5.9 C-arm Compliance Label

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

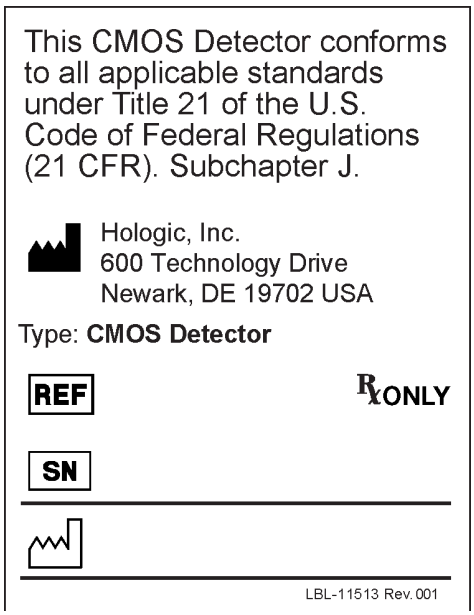
Figure 18 C-arm Compliance Label



5.10 CMOS Detector Compliance Label

The detector compliance label is on the C-Arm, outside of the detector cover.

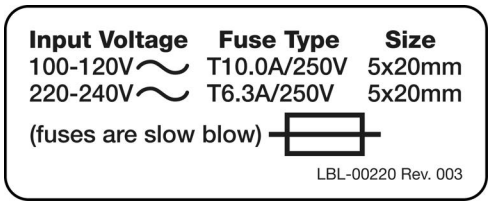
Figure 19 CMOS Detector Compliance Label



5.11 AC Input Power Fuse Label

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

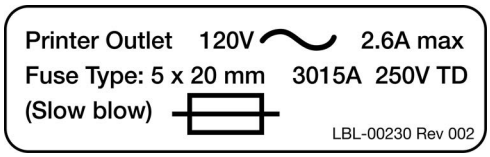
Figure 20 Input Power Fuse Label



5.12 Printer Fuse Label

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

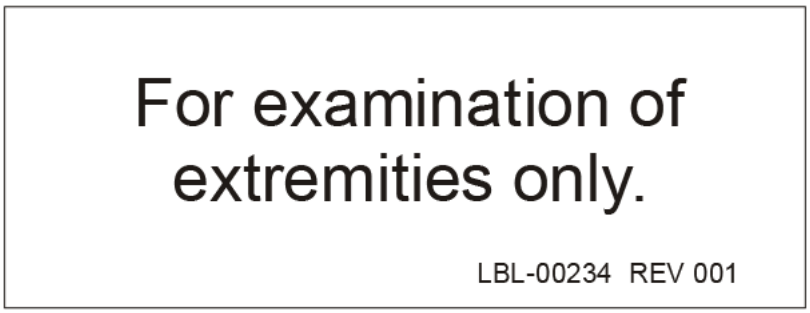
Figure 21 Printer Fuse Label



5.13 Extremities Only Label

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

Figure 22 Extremities Only Label



5.14 ISO 7010-M002 Label

Figure 23 ISO 7010-M002 Label

The ISO 7010-M002 Label: refer to instruction manual/booklet.

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

**ME EQUIPMENT is equipment*

1. *provided with not more than one connection to a particular SUPPLY MAINS; and*
2. *intended by its MANUFACTURER to be used:*
   a. *in the diagnosis, treatment or monitoring of a PATIENT; or*
   b. *for compensation or alleviation of disease, injury or disability.*

having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT…".

5.15 Field of View

Field of View is represented by raised 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 24 Field of View

5.16 Computer On/Standby Label

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

Figure 25 Computer On/Standby Label

5.17 Ground Labels

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

Figure 26 Ground Labels

Earth (ground)

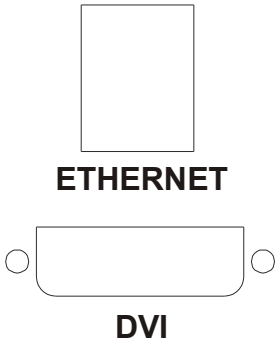
Protective earth (ground)

Equipotentiality

5.18 Back Panel Labels

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

Figure 27 Back Panel Labels



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