



InSight® FD Mini C-arm Imaging System User Guide

MAN-10192-001 Revision 003

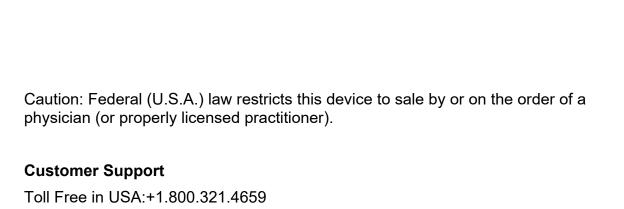




User Guide

Part Number MAN-10192-001 Revision 003 July 2025





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

Email: SkeletalHealth.Support@hologic.com

© 2025 Hologic, Inc. Printed in the USA. This manual was originally written in English.

Hologic, Fluoroscan, InSight, MegaView, and associated logos are trademarks and/or registered trademarks of Hologic, Inc., and/or its subsidiaries in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners.

This product may be protected by one or more U.S. or foreign patents as identified at www.Hologic.com/patent-information.

Table of Contents

Lis	st of Figures	ix
Lis	st of Tables	xi
1: I:	Indications for Use	1
1.1	Essential Performance	
1.2	Warranty Statement	
1.3	Product Complaints	
1.4	User Profiles	
	1.4.1 Education	
	1.4.2 Knowledge	3
	1.4.3 Experience	
	1.4.4 Permissible impairments	
2: R	Radiation Safety	5
2.1	General	
2.2	Radiation Dose and Dose Rate	
2.3	X-ray Shielding	5
3: F	Regulations for X-ray Equipment	7
3.1	United States Federal and State Regulations	
3.2	Compliance	
4: E	EMI	9
5: C	Cybersecurity	11
6: A	Accessories	13
7: V	Where to Obtain Copies of the Manuals	15
8: T	Terms and Definitions	17
9: I	InSight FD System Labels	19
9.1	System Main Label	
9.2	X-ray System Warning Label	
9.3	Electric Shock Warning Label	
9.4	No Pushing Warning Label	
9.5	ISO 7010-M002 Label	21
9.6	Field of View	22
	9.6.1 Symbols	22

10: 5	Safety Hazards	25
10.1	Radiation Safety	25
10.2	Electrical Safety	25
10.3	Overbalance Hazard	26
10.4	Imaging Function Loss	26
10.5	Unauthorized Modifications to X-ray Tube	26
10.6	Electrical Fire	27
10.7	Explosion Hazard	27
10.8	Footswitch Safety	27
10.9	Collision Hazard	28
10.10	Cleaning Safety	28
10.11	1 Device Safety	29
10.12	2 Electrosurgical Device	29
10.13	3 Tripping	29
10.14	4 Pinching Hazards	30
10.15	5 Damaged Power Cord	30
10.16	6 Obstructed View	30
11: 5	System Components	31
12: (Controls and Indicators	33
12.1	X-ray Head Control Panel	
12.2	Keyboard Controls	35
13: I	InSight FD 20 cm SSD Cone Installation Instructions	37
	Installation Procedure	
14: F	Footswitch Functions	41
14.1	Acquire an X-ray Image	42
14.2	Display a MegaView Image	
14.3	Tag an Image	
14.4	Save an Image	
14.5	Print an Image	
	0	
14.7	Wireless Footswitch Battery Replacement	
14.8	Wireless Footswitch Transmitter/Receiver Pairing	
14.9	Wired Footswitch Connection	
15: U	Using the System	47
15.1	Moving the System	47
15.2	Adjusting the C-arm	
15.3	Sterile C-arm Drape	
15.4	*	
15.5	Powering Down the System	

16: (Configuring the Application	53
16.1	System Configuration User Interface	53
16.2	System	54
16.3	DICOM Send Options	56
	16.3.1 DICOM Print Options	59
16.4	Worklist Configuration	61
	16.4.1 Users	63
16.5	Physician Preferences	64
16.6	Physician Preferences — Image Acquisition	65
16.7	Physician Preferences — Image Processing	67
16.8	Physician Preferences — Image Management	
16.9	Administrative Settings Page	70
17: U	Using the Application	71
17.1	Patient Positioning	71
17.2	Main Screen	71
17.3	X-ray Head Control Panel	76
	17.3.1 Image Acquisition Session	78
	17.3.2 Image Acquisition Screen	79
	17.3.3 Filmstrip Symbols	82
	17.3.4 Select Reference Images Window	
17.4	Review Images Session	89
	17.4.1 Select Study for Review Window	
	17.4.2 Review Screen	91
17.5	Maintaining Patient Study Records	
	17.5.1 Update Patient Study Information Window	
17.6	1 0	
	17.6.1 Export from Review Images Screen	
17.7	1 0	
17.8	Worklist Entry	
	17.8.1 Option 1 Tools Submenu	
	17.8.2 Option 2 Patient Information Screen	
	Delete Images	
17.10) View DICOM Queue Window	105
18: 9	System Maintenance	106
18.1	System Backup	
18.2	System Recover	106
18.3	Cleaning	106
	18.3.1 Recommended Disinfectants	107
18.4	Preventive Maintenance	107
18.5	Troubleshooting	107
18.6	Disposal	107

List of Figures

Figure 1: InSight FD Mini C-arm	1
Figure 2: System Main Label	19
Figure 3: X-ray System Warning	20
Figure 4: Electric Shock Warning	20
Figure 5: No Pushing Warning Label	21
Figure 6: ISO 7010-M002 Label	21
Figure 7: Field of View	22
Figure 8: Rotate the C-arm	38
Figure 9: Align the Cone	38
Figure 10: Opening on Cover for Cone	39
Figure 11: Wireless Footswitch	
Figure 12: Footswitch Storage	
Figure 13: Footswitch in Bracket	47
Figure 14: Keyboard in Down Position	48
Figure 15: C-arm in Transport Position	
Figure 16: Rear Casters	49
Figure 17: Adjusting the C-arm	50
Figure 18: Sterile C-arm Drape	51
Figure 19: System Configuration Menu	54
Figure 20: System	54
Figure 21: DICOM Send Options	56
Figure 22: DICOM Print Options	59
Figure 23: Worklist Configuration	
Figure 24: Users	63
Figure 25: Physician Preferences — Image Acquisition	65
Figure 26: Physician Preferences — Image Processing	67
Figure 27: Physician Preferences — Image Management	69
Figure 28: Main Screen	71
Figure 29: System Configuration Menu	72
Figure 30: Tools Menu	74
Figure 31: Select or Enter Patient Window	78
Figure 32: Image Acquisition Screen	79
Figure 33: Image Effects Menu	
Figure 34: Filmstrip Symbols	82
Figure 35: Configure Image Area Menu	83
Figure 36: Image Acquisition Screen Buttons	
Figure 37: Select Reference Images Window	
Figure 38: Study for Review	
Figure 39: Review Images Screen	
Figure 40: Patient Details	
Figure 41: VISTA Details	93

InSight FD Mini C-arm User Guide List of Figures

Figure 42: Enhanced Displayed Image Screen	94
Figure 43: Update Patient Study Information Window	95
Figure 44: Review Images Screen	96
Figure 45: Export Images Panel	97
Figure 46: Tool Menu Export	97
Figure 47: Export Images	98
Figure 48: Tools Menu	100
Figure 49: Import Images Window	100
Figure 50: Delete Images	102
Figure 51: Image Selected for Deletion	103
Figure 52: View DICOM Queue	105

List of Tables

Γable 2: Symbols 18 Γable 3: Symbols 22 Γable 4: X-ray Head Control Panel 33 Γable 5: Keyboard Controls 35 Γable 6: Parts List 37 Γable 7: Footswitch Pedal Functions 41 Γable 8: Conditioning Schedule 52 Γable 9: System Configuration User Interface 53 Γable 10: System Page 55 Γable 11: DICOM Send Options Page 57 Γable 12: DICOM Send Options Page, Button Functions 58
Γable 4: X-ray Head Control Panel33Γable 5: Keyboard Controls35Γable 6: Parts List37Γable 7: Footswitch Pedal Functions41Γable 8: Conditioning Schedule52Γable 9: System Configuration User Interface53Γable 10: System Page55Γable 11: DICOM Send Options Page57
Γable 5: Keyboard Controls 35 Γable 6: Parts List 37 Γable 7: Footswitch Pedal Functions 41 Γable 8: Conditioning Schedule 52 Γable 9: System Configuration User Interface 53 Γable 10: System Page 55 Γable 11: DICOM Send Options Page 57
Γable 6: Parts List37Γable 7: Footswitch Pedal Functions41Γable 8: Conditioning Schedule52Γable 9: System Configuration User Interface53Γable 10: System Page55Γable 11: DICOM Send Options Page57
Γable 7: Footswitch Pedal Functions41Γable 8: Conditioning Schedule52Γable 9: System Configuration User Interface53Γable 10: System Page55Γable 11: DICOM Send Options Page57
Γable 8: Conditioning Schedule52Γable 9: System Configuration User Interface53Γable 10: System Page55Γable 11: DICOM Send Options Page57
Γable 9: System Configuration User Interface53Γable 10: System Page55Γable 11: DICOM Send Options Page57
Гable 10: System Page
Гable 11: DICOM Send Options Page57
Table 12: DICOM Send Options Page, Button Functions
tubic 12. 2 1001/1 certa options 1 ago, 2 accord 1 arrestories
Table 13: DICOM Print Options Page, Section/Field Descriptions60
Table 14: DICOM Print Options Page, Button Functions60
Table 15: Worklist Configuration, Section Descriptions62
Table 16: Worklist Configuration, Button Functions62
Table 17: Users Page, Section/Field Descriptions63
Гable 18: Users Page, Button Functions
Table 19: Physician Preferences, Section/Field Descriptions64
Гable 20: Physician Preferences, Button Functions64
Table 21: Physician Preferences, Image Acquisition Tab, Section/Field Descriptions66
Table 22: Physician Preferences, Image Processing Tab, Section/Field Descriptions
Fable 23: Physician Preferences, Image Management Tab, Section/Field Descriptions69
Гable 24: Administrative Settings, Section Descriptions70
Гable 25: Administrative Settings, Button Functions70
Table 26: Main Screen Options
Гable 27: System Configuration Menu73
Гable 28: Tools Menu
Гable 29: X-ray Head Control Panel76
Table 30: Select or Enter Patient Window, Section/Field Descriptions
Гable 31: Select or Enter Patient Window, Button Functions
Table 32: Image Acquisition Screen80
Гable 33: Image Effects Menu81
Гable 34: Filmstrip Symbols82
Гable 35: Configure Image Area Menu83
Гable 36: Image Acquisition Screen, Button Functions84
Гаble 37: Tool Set
Гable 38: Select Reference Images Window, Section Descriptions88
Table 39: Select Reference Images Window, Button Functions89
Гable 40: Select Study for Review Window, Section/Field Descriptions90
Table 41: Select Study for Review Window, Button Functions90

InSight FD Mini C-arm User Guide List of Tables

Table 42: Review Screen, Button Functions	91
Table 43: Detailed Image Viewing Screen, Button Functions	94
Table 44: Update Patient/Study Information Window, Section Descriptions	95
Table 45: Update Patient/Study Information Window, Button Functions	96
Table 46: Export Window, Section Descriptions	98
Table 47: Export Window, Button Functions	99
Table 48: Import Window, Section Descriptions	101
Table 49: Import Window, Button Functions	101
Table 50: Delete Images Window, Section Descriptions	104
Table 51: Delete Images Window, Button Functions	104
Table 52: Queue Window, Section Description and Button Functions	105
Table 53: Recommended Wipes	107
Table 54: Recommended Chemicals	107

Chapter 1 Indications for Use

The InSight® FD System is a Mini C-arm Fluoroscopic Imaging System designed to provide physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations.

Intended Use:

RONLY

Caution: United States federal law restricts this device to sale by or on the order of a physician.



Figure 1: InSight FD Mini C-arm

1.1 Essential Performance

The Insight FD System is a mobile fluoroscopic mini C-arm system that provides fluoroscopic images safely and effectively during diagnostic, treatment, and surgical procedures of patient's extremities.

1.2 Warranty Statement

US Sales only: Hologic's sales terms and conditions for US customers can be found at the following URL: https://www.hologic.com/hologic-sales-terms-conditions.

For all other customers, please contact your local sales representative for any applicable warranty information.

1.3 Product Complaints

Report any complaints or problems regarding the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to a Hologic Authorized Representative and Competent authority of the respective member state or country.

The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

1.4 User Profiles

It is anticipated that InSight Flat Detector users may include nurses both sterile and nonsterile, radiological or other technicians, doctors or surgeons with minimal training in fluoroscopic procedures.

1.4.1 Education

- Minimum of an associate degree or equivalent radiation technology certificate program
- No maximum

1.4.2 Knowledge

• Minimum

Read and understand the InSight Flat Detector User's Manual Basic knowledge of computers

• No maximum

1.4.3 Experience

- Minimum
 - No other special experience is needed
- No maximum

1.4.4 Permissible impairments

- Mild reading vision impairment or vision corrected to log MAR 0.2 (6/10 or 20/32)
- Average degree of aging-related short term memory
- Impaired by 40% resulting in 60% of normal hearing at 500 Hz to 2 kHz

Chapter 2 Radiation Safety

Improper imaging procedures or the failure to observe radiation safety and technique factor recommendations could result in increased exposure. It is the operator's responsibility to observe all safety procedures and to keep radiation exposures As Low As Reasonably Achievable (ALARA) and to comply with all national, state and local regulatory requirements.

Hologic recommends that all members of the operating staff wear a radiation monitoring device. This is usually a film badge or TLD (thermoluminescent dosimetry) dosimeter which will record any radiation dose over a specific period of time. The physician should wear a ring badge to record any exposure to his/her hands.

2.1 General

A fluoroscopic device emits a continuous beam of X-rays in order to view an object in real-time.

Primary radiation is present in the space between the X-ray source and the detector screen. The operator should never place his/her own hands in the beam.

Secondary radiation or X-ray scatter is caused by X-rays that do not fully penetrate the object placed in the primary beam. X-ray scatter has considerably less energy than the primary beam and is absorbed by other objects in the immediate area. The amount of scatter depends upon the power setting used, the density and proximity of the body part to the beam, and the length of exposure time.

2.2 Radiation Dose and Dose Rate

Radiation received by each kilogram of a patient's body is called *dose*. *Dose rate* refers to the dose received per unit time.

Distance from the X-ray source reduces dose to both the patient and the operator. For example, at maximum output the dose is 2.6 mGy/minute at the image receptor and 45 mGy/minute at the Tube Housing exit port, or 17 times greater _ than the dose at the image receptor. This higher value is known as the *maximum Entrance Exposure Rate* (EER).

Scattered radiation decreases with the square of the distance in exactly the same way as noted previously for X-rays in the primary beam. However, as the dose rate is much less, scatter is usually expressed in mR/hour (1 mR = 0.01 mGy).

Dose and scatter data for the InSight FD system is available from Hologic upon request.

2.3 X-ray Shielding

The scattered radiation from the InSight FD system is low compared to many other radiological devices, and the requirement to wear protective lead aprons and/or attenuating gloves is governed by applicable facility policy. Also many states, provinces, countries, and individual institutions may require persons in the same room with any operating fluoroscopic device to wear lead aprons. The strict observation of safe operating practices and the use of minimal fluoroscopic times is the key to reducing human exposure.

Chapter 3 Regulations for X-ray Equipment

3.1 United States Federal and State Regulations

InSight FD Mini C-arm Imaging Systems conform to the United States Code of Federal Regulations, 21 CFR 1020.32 "Performance Standards for Ionizing Radiation Emitting Products: Fluoroscopic Equipment." However, additional state regulations may apply to X-ray products. This may require notifying your state regulatory agency about your installation and/or operator training and certification.

It is the responsibility of the user to contact the applicable state radiation control agency to verify that your installation is in compliance with regulations in your state governing installation and use of X-ray equipment.

The InSight FD Mini C-arm Imaging System complies with 21CFR Subchapter J.

The InSight FD Mini C-arm Imaging System is intended for special surgical applications that would be prohibited at the Source to Skin Distances (SSD) specified in 21CFR 1020.32 (g) but are permitted under 21CFR 1020.32 (g) (2). The SSD is 10 cm minimum.

3.2 Compliance

InSight FD Mini C-arm Imaging Systems comply with the requirements of IEC 60601-1. The InSight FD Mini C-arm Imaging Systems comply with the following IEC standards:

IEC/EN 60601-1:2005 + IEC 60601-2-28:2010 IEC 60601-2-54:2009 + A1: 201
A1:2012
IEC 60601-1-2:2014 IEC 60601-1-3:2008 + A1: CAN/CSA-C22.2 No.60601-1:08
2013

The classification of the Insight FD Mini C-arm Imaging Systems under this specification is Class 1, Type B.

Chapter 4 EMI

This instrument is designed to be compatible with the electromagnetic environments specified in IEC60601-1-2 and will operate satisfactorily when placed in an environment that includes other equipment complying with that standard. If equipment that is not electromagnetically compatible is placed into the environment where the InSight FD Mini C-arm System is used, the InSight FD Mini C-arm System or the non-compliant equipment may malfunction or exhibit other anomalous behavior. Consult the appropriate field service engineer.

Chapter 5 Cybersecurity

Hologic continuously tests the current state of computer and network security to examine possible security problems. When necessary, Hologic provides the updates to the product.

Please refer to the following documents for Cybersecurity information:

- MAN-00734 InSight Cybersecurity Best Practices
- MAN-00664 Insight Cyber-Security Product Report

These documents are available on the Hologic, Inc. website at:

http://www.hologic.com/support/fluoroscan-mini-c-arm

Chapter 6 Accessories

This instrument is supplied with hardware and software accessories that are needed for safe and reliable operation. Additional accessories may be used to perform optional procedures. Do not use any accessories with this instrument other than those approved by Hologic.

Chapter 7 Where to Obtain Copies of the Manuals

To obtain a PDF file of the User Guide or Service Manual, go to the support pages at www.Hologic.com

Adobe Acrobat Reader version 5.0 or higher is required to view the PDF file.

To order printed manuals, contact Hologic Customer Support.

Toll Free in USA: +1.800.321.4659

Email: <u>SkeletalHealth.Support@hologic.com</u>

For support in Europe, South America, or Asia, contact your local dealer or distributor.

Chapter 8 Terms and Definitions

Table 1: Terms and Definitions

Term	Definition
AC	Alternating Current
AKR	Air Kerma, X-ray dose rate displayed in the units of mGy/min on InSight systems
ALARA	As Low As Reasonably Achievable Every reasonable effort to maintain exposures to ionizing radiation as low as practical
Annotations	Graphic or text marks on an image to show an area of interest.
С-ЕСНО	Confirms network connection to PACS.
CMOS	Complementary metal-oxide-semiconductor
DAP	Dose Area Product (cGy*·cm² or mGY* cm²)
DICOM	Digital Imaging and Communications in Medicine
EER	Entrance Exposure Rate
Last Image Hold	Whenever X-rays are being generated, the yellow X-ray light is ON, and the monitor displays the real time fluoroscopic image.
	When X-rays are terminated, the image displayed is the Last Image Hold (LIH) and the yellow X-ray light is OFF.
	This image is visible until the user replaces it with one from the filmstrip or activates another X-ray exposure
Noise	Light and dark areas (speckle) that are not part of the patient anatomy
PACS	Picture Archiving and Communications System A computer and network system that transmits and archives digital medical images.
ROI	Region of Interest
SMPTE	Test pattern for evaluating the quality of video displays produced by the Society of Motion Picture & Television Engineers
SSD	Solid-state Drive A solid-state storage device that uses integrated circuit assemblies as memory to store data persistently.
TLD	Thermoluminescent Dosimetry, a method of measuring cumulative X-ray radiation exposure over time.

Table 2: Symbols

Symbol	Definition
\triangle	Note identifying recommended actions or additional information.
\triangle	Caution Procedures that you must follow to avoid compromising processes, prevent damage to equipment, loss of data, damage to files in software applications, or minor injury.
<u> </u>	Warning Procedures that you must follow to prevent death or serious injury.

Chapter 9 InSight FD System Labels

9.1 System Main Label

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

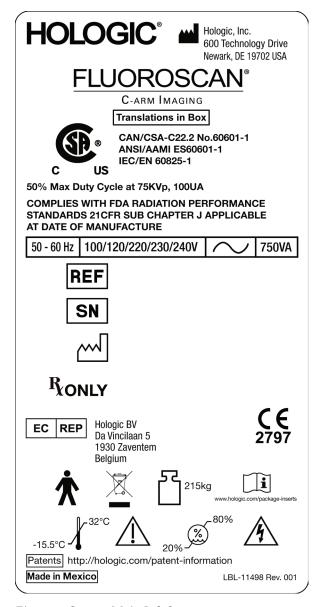


Figure 2: System Main Label

^{*} Additional labeling information is available in MAN-09975.

9.2 X-ray System Warning Label

The X-ray System Warning Label is on the left side of the base cabinet opposite the DVD player.

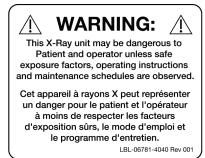


Figure 3: X-ray System Warning

9.3 Electric Shock Warning Label

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



Figure 4: Electric Shock Warning

9.4 No Pushing Warning Label

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



Figure 5: No Pushing Warning Label

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

9.5 ISO 7010-M002 Label



Figure 6: ISO 7010-M002 Label

For information on the ISO 7010-M002 Label, refer to instruction manual or 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..."

The above definition aligns well with the definition for medical electrical devices in the European Medical Device Directive.

9.6 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 limited field of view is selected.



Figure 7: Field of View

9.6.1 Symbols

Table 3: Symbols

© us	CSA listed device	\triangle	Caution
À	Warning: Electricity	222	Radiation Filter
	Ionized radiation emitted when X-ray beam is energized		Caution: Radiation
2	X-ray source assembly	?	Alternating current
†	Type B applied part		Protective earth (ground)

Table 3: Symbols

<u></u>	Earth (ground)	Å	Equipotentiality
	Fuse		Electrostatic sensitive device
•	USB connector	%	Humidity limitation
1	Temperature limit	C	Computer Standby switch
\odot	Computer On switch		Manufacturer
	Date of Manufacture	EC REP	Authorized representatives in the European Community
	Equipment to be disposed in compliance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment.	SN	Serial number
REF	Catalog number	57	Combined weight of the equipment and its safe working load
	Follow instructions for use		No pushing
CE	CE mark		Compliant to AS/NZS 4268 for short range radio equipment, Australian Standard AS/NZS 4417.1, and AS/NZS 4417.2.
	Caution — X-Rays Attention — Rayons X (Canada)		

Chapter 10 Safety Hazards

The following section itemizes various safety hazards. Each hazard is cross referenced with the respective cause and proper course of action.

10.1 Radiation Safety

Cause



Warning:

This system produces ionizing radiation and may be dangerous to patients and operators unless the safety and operating instructions in this manual are followed.

Course of Action

Although operating this system can result in low scatter radiation levels, it is recommended that protective X-ray clothing be worn and radiation safety precautions be observed when operating the system.

Operators should avoid placing their hands or any part of their bodies in the path of the X-ray beam. When making X-ray exposures, place the anatomy close to the CMOS detector for the best image quality and to reduce exposure to radiation. An alarm sounds after every five minutes of accumulated exposure time.

10.2 Electrical Safety

Cause



Warning:

Electrical circuits inside the system can cause serious injury or death. This system operates on high voltages. High voltages are at the following locations: X-ray tube: 75,000 Volts.

Course of Action

Safety covers have been designed for this system to mitigate the hazards caused by electrical circuits and high voltages. Never remove the covers or operate the system while the covers are off. If any cover is off, request service before using the system.



Warning:

Unplugging the power cord from the wall is the only way to disconnect main power from this system.

10.3 Overbalance Hazard

Cause

Placing too much weight on the C-arm CMOS detector may cause the system to overbalance. The amount of weight that the CMOS detector can support is highly variable, depending on the position of the flex-arm, C-arm, and other factors. This hazard is greatest when the flex-arm is extended and moved to the far left or right of the system.

Course of Action

If weight is to be applied to the C-arm CMOS detector, caution must be used to prevent the device from becoming unstable.



Note

Do not place the full weight of the lower extremity directly on the CMOS detector.

Do not attempt to move the system from the left or right side or by pushing on the system C-arm or the mast when the casters are locked or obstructed.

10.4 Imaging Function Loss

Cause

Detector damage from surgical tools (such as drills coming into contact with the detector surface)

Course of Action



Caution

Do not use the C-arm CMOS detector as a working surface.

10.5 Unauthorized Modifications to X-ray Tube

Cause



Warning:

Never remove the housing around the X-ray tube or make any changes to the X-ray tube.

When the product leaves the manufacturing plant and at the time of installation, the X-ray source and assembly meet the requirements of 21 CFR 1020.30-32. Any unapproved change to the system could cause death, injury or expensive damage to the equipment, and could void the service agreement.

Course of Action

Do not make any changes to the X-ray tube. Contact a Hologic Representative to replace the X-ray tube.

10.6 Electrical Fire

Cause

Fire from any source.

Course of Action

If there is a fire in the area, and it is safe to do so, turn the system off and unplug the power cord from the wall outlet.

Do not touch a system that is on fire. Leave the area. Only use fire extinguishers approved for electrical fires

10.7 Explosion Hazard

Cause

The system is not designed for use in explosive atmosphere (for example, in the presence of a flammable anesthetics mixture with air or oxygen or nitrous oxide).

Course of Action

If an abnormal condition occurs, such as the room filling with flammable gas, take steps to prevent the gas from contacting the equipment.

Follow these guidelines:

- Do not turn the system ON or OFF, or unplug it from an AC power receptacle.
- Do not operate any other electrically powered equipment.
- Evacuate the area immediately. Ventilate the area with fresh air.
- Avoid operating any automated (electrically operated) doors or windows.
- Contact your local fire department.

10.8 Footswitch Safety

Cause

The footswitch can be damaged by falling objects, being rolled over by the system wheels, and if it is dropped.

Course of Action

Remain aware of the footswitch at all times during operation and transport to avoid these hazards.

10.9 Collision Hazard

Cause

If improperly moved or if the wheel brakes are not used correctly, the system could roll out of control. If the articulating flex arm is not locked in place during transport, the C-arm could swing out of control and cause injury to the patient or medical personnel.

Course of Action



Warning:

Use caution when moving the system on an incline.

Do not move the system on an incline greater than ten degrees. One person can move the system easily on a level surface.

Always lock the wheel brakes before procedures. Never leave the system unattended on an incline greater than five degrees. Always lock the flex arm after changing the position of the C-arm.

10.10 Cleaning Safety

Cause

Almost any liquid spilled into electronic equipment automatically becomes a conductor of electricity.

Course of Action

This system is not waterproof. If liquid is spilled on the system, turn the system off immediately. Do not turn the system on until the liquid has dried completely. Do not splash or spray cleaning solution on the system. Clean exterior surfaces of the InSight FD Console, the flex-arm, and the C-arm with a soft cloth or disposable lint-free tissue moistened with water, isopropanol or methanol. Wipe surfaces; do not scrub.

For additional details on disinfectants, refer to section <u>Recommended Disinfectants</u> on page <u>107</u>.

10.11 Device Safety

Cause



Warning:

Injury could result if unapproved devices are connected to the system.

Certain devices were tested for use with the InSight FD System, use only these or compatible devices.

Course of Action

Do not connect any devices to the system other than those described in this manual. Internally connected devices should be installed only by persons trained in the servicing of this system.

10.12 Electrosurgical Device

Cause

This system is shielded from electrical discharges. However, there is still a possibility that an electrosurgical device discharged directly into the system could adversely affect system operation. In addition, shielding might not always protect the system from the amount of energy produced by a spark-gap type device.

Course of Action

If a strong electrosurgical surge causes the system to malfunction:

- 1. Turn the system off.
- 2. Wait five seconds.
- 3. Turn the system on.

If the problem persists after resetting the system twice, request service.

10.13 Tripping

Cause



Warning:

Cables and cords can pose a tripping hazard.

Course of Action

Position cords safely out of the way. When not in use, wind cords securely around the cord management plates.

10.14 Pinching Hazards

Cause



Warning:

Movement of the monitor arm poses a potential pinching hazard. The monitor arm may contact the Flex arm, C-arm, or handle.

Course of Action

Place hands and fingers in a safe position when repositioning the monitor arm. Avoid placing hands and fingers in joints and system pivot points.

10.15 Damaged Power Cord

Cause

A damaged power cord can be an electrical shock hazard.

Course of Action

Make sure that the power cord for the InSight FD Mini-C-arm is in good condition. When disconnecting the console from power, always grasp the plug at the insertion point and pull lightly. NEVER pull on the cord to unplug the unit.

10.16 Obstructed View

Cause



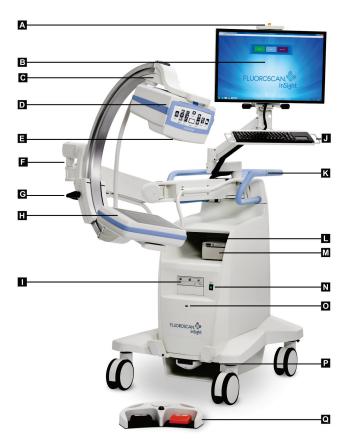
Warning:

The system may hinder visibility to surgical workspace.

Course of Action

It is best to move system away from the surgical site after imaging.

Chapter 11 System Components



A	X-ray ON light	J	Keyboard with integrated pointing device
В	Touch screen monitor	K	C-arm retainer clamp placement line
С	C-arm retainer	L	Image printer shelf
D	X-ray head	M	Printer
E	Collimation switch	N	Computer On/Standby switch
F	Flex-arm	О	USB port
G	C-arm	P	Front-facing storage tray and wireless footswitch receiver
Н	CMOS Detector	Q	Wireless footswitch
I	Optical Drive (CD/DVD RW recorder)		

Chapter 12 Controls and Indicators

12.1 X-ray Head Control Panel

Table 4: X-ray Head Control Panel

Symbol	Label	Function
	Save	Saves selected images or cine loop to the record of the patient. If the number of stored images or minutes of cine loop exceeds the storage limit, a message displays.
	Rotate	Rotates the image clockwise or counterclockwise. Press once to rotate 10 degrees. Hold for continuous rotation.
+	B/C	Allows adjustment of image brightness and contrast.
	X-ray	Acquires an X-ray exposure. Press switch once to actuate X-rays. A yellow indicator light located on top of the monitor shows that X-rays are being produced. When the yellow indicator light is OFF, the monitor displays the image captured at the end of the X-ray exposure - sometimes referred to as the last image hold.
*	Laser	Turns on the Positional Laser ^{1.}
	Noise Suppression	Cycles through the Noise suppression settings during image acquisition. Refer to the table <i>Physician Preferences, Image Processing Tab, Section/Field Descriptions</i> in section <i>Physician Preferences — Image Processing</i> on page <u>67</u> .

Table 4: X-ray Head Control Panel

Symbol	Label	Function
kV/mA	kV/mA	Increases or decreases technique factors based on selected mode. Refer to the table <i>Physician Preferences, Image Processing Tab, Section/Field Descriptions</i> in section <i>Physician Preferences — Image Acquisition</i> on page 65. Note Pressing both the up and down power buttons at the same time returns the system to Auto Power mode.
Continuo and the m When the switch, th displayed Snapshot		Acquisition Mode Selection cycles through: Continuous ² – When the user activates X-ray, the yellow X-ray light is ON and the monitor displays continuous real-time X-ray images. When the user deactivates X-rays by releasing the foot pedal or tube head switch, the yellow X-ray light turns OFF, and the last image hold is displayed (that is, what is on-screen when the X-rays have stopped). Snapshot ² – When X-rays are activated, the device acquires a last image hold only. The X-ray dose used for the last image hold depends on the
		settings for X-ray mode technique factor and noise suppression. The exposure terminates when the user terminates the X-rays.
		Cine Record – Records the real time fluoroscopy images acquired into a cine loop.

¹ Press and hold the Laser button for 10 seconds to enable the positional laser to stay on. This option will reset when the system is powered off. ² Continuous and/or Snapshot mode may be disabled. Refer to the section <u>Physician Preferences</u> on page <u>64</u>

12.2 Keyboard Controls

The keyboard is directly mounted to the monitor mount and has handles for easy rotation and repositioning the monitor during use

Table 5: Keyboard Controls

Icon	Function Key	Function
?	F1	Displays help window.
i	F2	Displays the Patient Information window in Image Acquisition session.
•		Displays the Select Study for Review window in Review session.
ЯК	F3	Flips image horizontally.
C	F4	Rotates image 10 degrees clockwise.
Shift C	Shift-F4	Rotates image 10 degrees counterclockwise.
44	F5	Decreases kV/mA if simultaneous is on or decreases kV if simultaneous is OFF.
•		Pressing this key puts the system into manual mode.
Shift	Shift-F5	Decreases mA if simultaneous is OFF.
Shift		Pressing this key puts the system into manual mode.
*	F6	Increases kV/mA if simultaneous is on or increases kV if simultaneous is OFF.
		Pressing this key puts the system into manual mode.
Shift	Shift-F6	Increases mA if simultaneous is OFF.
Shift		Pressing this key puts the system into manual mode.
ı	F7	Resets fluoro alarm timer.
	F8	Saves the current image to the patient's record.
	F9	Prints the current image to the local printer.
	F10	Toggles Play back of a recorded cine loop ON/OFF.
₽ 5	F11	Restores physician's defaults.

Table 5: Keyboard Controls

Icon	Function Key	Function	
Shift 5	Shift-F11	Returns the system to Auto Power mode.	
	F12	Cycles through the Noise suppression settings that will be used during imag acquisition. The noise suppression settings are off, low, medium, high, auto and ultra.	
		Noise suppression off or low has less image blur due to motion, but the im will have significant noise (i.e., speckle).	
		Higher noise suppression (medium, high or ultra) reduces speckle by averaging more frames in the displayed image. The high and ultra noise suppression settings should be used when there is no motion of the anatomy and image clarity is needed.	
		Auto noise suppression varies the noise suppression between low, medium and high, depending on the motion detected by the imaging algorithm.	

Chapter 13 InSight FD 20 cm SSD Cone Installation Instructions

Installing the InSight™ FD 20 cm SSD Cone requires:

- aligning the SSD Cone, and
- snapping the cone into the cover.

The estimated time to perform this procedure is five (5) minutes.

Table 6: Parts List

Part Number	Description	
ASY-10630	0630 Kit, SSD 20 cm, Insight FD	
FAB-08816	Cone, SSD, FD	
MME-01738	Push-in Plug, 8 mm ID, 12 mm Head	

13.1 Installation Procedure

- 1. Exit the InSight application.
- 2. Turn off the system.
- 3. Disconnect mains power by unplugging the AC line cord.
- 4. Rotate the C-arm, as shown in the following figure, to position the source for easy access.



Figure 8: Rotate the C-arm

- 5. Align the slots in the cone with the opening in the cover as shown in the following figure.
- 6. Using your fingers to adjust the feet on the bottom of the cone, insert the cone into the openings (3) on the bottom of the tube head cover.



Figure 9: Align the Cone

7. Snap the SSD Cone into place.



Note

Push-in plugs (MME-01738) can be mounted in the cover openings when the SSD Cone is not used.



Error! Reference source not found. Opening on Cover for Cone

- 8. Rotate the C-arm to a working position.
- 9. Connect the AC line cord.
- 10. Turn on power to the system.
- 11. Log in to the InSight application.
- 12. Check that the system operates properly.

Chapter 14 Footswitch Functions

The footswitch can be used for quick access to several software functions.



Figure 11: Wireless Footswitch

Table 7: Footswitch Pedal Functions

Ref	Icon	Pedal	Function
1		Save / Tag	Save or Tag images
2		MegaView™ Image and/or Print	User Configurable: ■ In Perform Mode, you can toggle between standard view and full-screen view (MegaView™ Image) ■ Print images

Table 7: Footswitch Pedal Functions

Ref	Icon	Pedal	Function
3		X-ray	Take X-ray
4	(((•)))	Receiver	RF Receiver
5		Pairing Button	Footswitch
6		Pairing Button	Receiver



Note

The receiver must be turned ON to use the footswitch functions.

Specific footswitch functions must be enabled in the Physician's Preferences window options:

- Tag References from Footswitch
- Toggle Full Screen View from Print Footswitch

14.1 Acquire an X-ray Image

- 1. To acquire an image, press the **X-ray** pedal **(3)**.
- 2. Press again to take subsequent images.

14.2 Display a MegaView Image

When in Perform Mode, press and release **MegaView Image and/or Print (2)** to toggle between Standard and Full-Screen View.

From the Image Acquisition Screen, or the Enhanced View screen, double-click on a **Megaview** image to zoom in on the image.

- 1. Select **Review** to open the scanned image.
- 2. Double-click on the image to open the image in **Megaview** mode.

14.3 Tag an Image

To mark an acquired image as a reference image, press and release Save or Tag (1) once.

14.4 Save an Image

1. To save the image and deselect as a reference, press and release **Save** or **Tag (1)** a second time.

2. To save the image and mark as a reference, press and release **Save** or **Tag (1)** a third time.

14.5 Print an Image



Note

The printer has a separate power button. Be sure to power up the printer before attempting to print images from the system.

To print an image, press and hold MegaView Image and/or Print (2).

14.6 Footswitch Storage

When not in use, store the footswitch in the bracket at the front of the system, as shown in the following figure.



Figure 12: Footswitch Storage



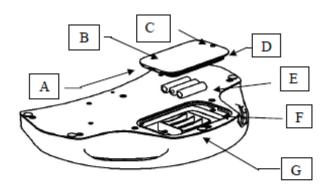
Warning:

Position the footswitch and power cords to prevent accidental tripping.

14.7 Wireless Footswitch Battery Replacement

Footswitch receiver will display red LED and emit intermitting audio beep when battery power is low.

Footswitch requires three (3) AA alkaline batteries.



Name	Description
A	2X Locking Tabs
В	Battery Cover
С	Slotted drive ¼ turn fastener
D	O-Ring seal
E	3X "AA" Alkaline batteries
F	Recessed area for cover removal. Gently pry with flat tip devise to remove cover
G	3X Battery polarity indicator on bottom face of holder

14.8 Wireless Footswitch Transmitter/Receiver Pairing



Note

Only transmitters and receivers of the same manufacturer and type (single, twin, triple, etc.) can be paired.



Note

Any failed pairing attempt will leave the footswitch or receiver unpaired.

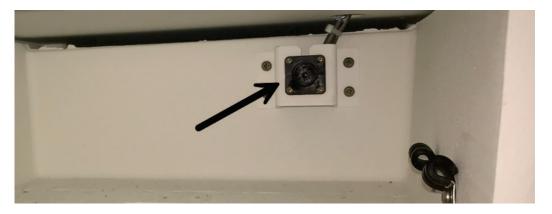
To pair footswitch to the receiver:

- 1. Make sure the InSight FD system is on.
- 2. Move the footswitch within 6 feet of the receiver during the entire pairing procedure.

- 3. Tilt the footswitch vertically or upside down.
- 4. Press and hold both pairing pushbuttons at the same time for at least 3 seconds but no more than 6 seconds, then release both pushbuttons at the same time. The receiver status LED will turn Green to indicate the pairing sequence has been initiated. If not, wait at least 30 seconds before repeating this step.
- 5. If the LED turns Green, un-tilt the footswitch and wait for the pairing sequence to complete in approximately 5-8 seconds. Receiver will beep 3 times if pairing was successful or 1 time if unsuccessful. Receiver status LED will turn BLUE if pairing was successful or flash RED if unsuccessful.
- 6. Repeat the above steps as necessary.

14.9 Wired Footswitch Connection

A setup procedure is not required for a wired footswitch to function if connected to the system. The wired footswitch connection to the system is in the same location as the wireless receiver connection located at the back of the storage cavity at the bottom of the system.





Warning:

Position the footswitch and power cords to prevent accidental tripping.

Chapter 15 Using the System



Note

InSight FD operators should read the Radiation Safety section before operating the system.

15.1 Moving the System



Warning:

Before moving the system, the flex-arm and C-arm must be in the locked storage position to prevent overbalancing.

- 1. Ensure that the system is powered off. See section <u>Powering Down the System</u> on page <u>52</u>.
- 2. Unplug the power cord and wrap it around the cord guides on the back of the cabinet.
- 3. Place the foot switch in the footswitch bracket, as shown in the figure that follows.



Figure 13: Footswitch in Bracket

4. Using the cutout on the mount, flip the monitor forward and down, as shown in the figure that follows.

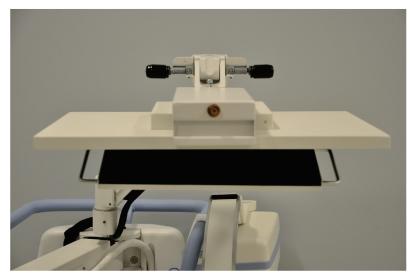


Figure 14: Keyboard in Down Position

- 5. Push the C-arm down to align the C-arm clamp with the handle.
- 6. Swing the arm to the right side of the machine.
- 7. Align the C-arm clamp to the front side of the black indicator line on the handle to prevent damage to the detector during transport.

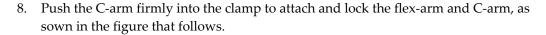




Figure 15: C-arm in Transport Position

9. Lock the rear casters to prevent the system from moving. The swiveling angle of the rear casters can be locked to prevent lateral movement of the system or unlocked to allow lateral movement.



Rear Wheels Locked



Back Only



Rear Wheels Move Forward and Rear Wheels Free to Move in **All Directions**







Figure 16: Rear Casters

15.2 Adjusting the C-arm



Caution

When moving the arm of the system, it may collide with the system itself or surrounding equipment. Collisions may cause damage to the system or other equipment.

Turn the flex-arm lock counterclockwise to loosen; then adjust the flex-arm height.

To reposition the C-arm:

- 1. Turn the C-arm lock to loosen.
- 2. Roll the arm to the desired position.
- 3. Turn to lock the arm in place.

The locking lever can also be positioned between open and locked to provide various levels of resistance to arm roll.



Caution

When casters are in the locked position or obstructed, do not attempt to move the system from the left or right side or by pushing on the system C-arm or the mast.



Figure 17: Adjusting the C-arm

15.3 Sterile C-arm Drape

Before using the InSight FD Mini C-arm in the operating room, fit the C-arm with a sterile drape. Small labels on the drape indicate how to fit the drape to the X-ray head and to the CMOS detector.



Note

After use, dispose of sterile C-arm drape properly in a biohazard container.



Caution

Contamination of the sterile field may occur when moving the system. This may occur when the C-arm is draped



Caution

If the drape becomes damaged during application or from use, dispose of the damaged drape and fit a new sterile drape to the system.

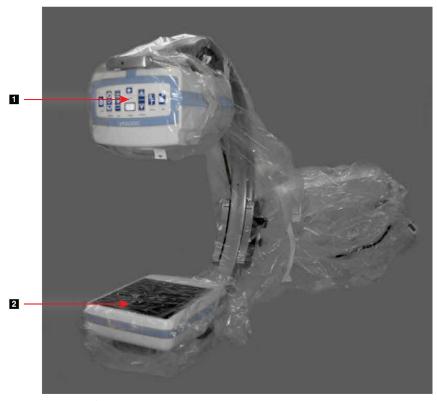


Figure 18: Sterile C-arm Drape

- 1. X-ray Head
- 2. Detector

15.4 Powering Up the System



Warning:

The InSight FD system operates on standard 115 Volt, 60 Hz AC power for United States, Japanese and Canadian models, 230 Volt, 60 Hz AC, and 240 volt, 50 Hz AC power for other export models.

- The system should only be plugged into a properly grounded three-wire wall outlet.
- Never cut the third (grounding) pin from the power cord to plug the unit into an ungrounded two wire outlet. Never use a three wire-to-two wire adapter.

The system should be at ambient room temperature.

The power cord must be plugged into a standard single-phase three-wire grounded outlet. A special dedicated outlet is not required.

To power up the system, press the **Computer On/Standby** switch. InSight FD will prompt the user to log in.

If the system has been off for more than two weeks, use the following source conditioning procedure to safeguard and prolong the life of the X-ray source:

Step	kV	mA	Minimum Time
1	40	0.05	2 minutes
2	50	0.10	2 minutes
3	60	0.10	2 minutes
4	70	0.10	3 minutes
5	75	0.10	3 minutes

Table 8: Conditioning Schedule



Caution

The system must warm up for FOUR MINUTES before generating X-rays. Failure to provide adequate warm up could result in damage to the system.

15.5 Powering Down the System



Caution

Be sure to save images before shutdown.

To close the application and place the system in standby:

- From the **InSight FD Main Screen** select the **Shut Down** button.
- From the **Exit** Menu on the **InSight FD Main Screen**, select **Exit** before unplugging the power cord.

Chapter 16 Configuring the Application

16.1 System Configuration User Interface

System configuration user interface consists of a multiple-page tab-selected window. Each tab displays a page of configuration data.

Four buttons display at the bottom of the window that are independent of the selected page:

Table 9: System Configuration User Interface

Button	Function
OK	Saves data for all System Configuration pages and closes the window.
Apply	Saves data for the currently selected System Configuration page.
Cancel	Closes the window without saving any data.
Help	Displays help for the selected page.

16.2 System

From the **System Configuration** Menu on the **Main Screen**, the **System** page is accessible. Refer to the following two figures.

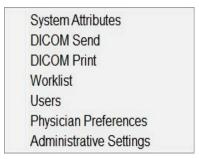


Figure 19: System Configuration Menu

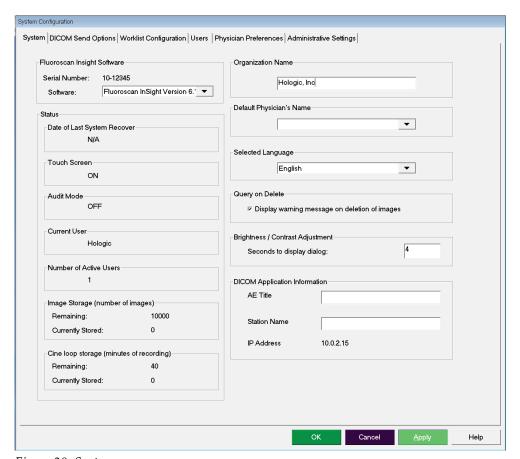


Figure 20: System

Table 10: System Page

Section/Field	Description	
InSight FD	InSight FD system serial number.	
Software	Dropdown list to display installed software and version.	
Serial Number		
Software		
Status	Displays the current settings for:	
Date of Last System Recover	Date application settings and configuration data were recovered from backup media.	
Touch Screen	Enabled/Disabled.	
Audit Mode	On/Off.	
Number of Active Users	Number of active registered users allowed to log into the system.	
Image Storage (number of images)	Maximum number of images* that can be stored on the system and the number currently stored.	
Cine Loop Storage (minutes of recording)	Maximum minutes of recording that can be stored on the system and the minutes currently stored.	
Organization Name	Administrator can enter name.	
Default Physician's Name	Select default physician to be used by the application.	
Selected Language	Select language to be used by the application.	
Selected DAP Units	Select DAP units to be used by the application (cGY* cm² or mGy* cm²)	
Query on Delete	Administrator can select to display warning message when deleting images.	
Brightness/Contrast Adjustment	Sets the amount of time (from 1 to 60 seconds) that the Brightness/Contrast adjustment dialog will be displayed.	
DICOM Application Information	AE Title and Station Name for the application. IP Address displays the network address assigned to the system the application is running on.	
	Station Name allows multiple systems to use the same AE Title. It is to Standard Resolution images. High Resolution images require more storage space.	

16.3 DICOM Send Options

The DICOM Send Options menu is available from **System Configuration** Menu on the **Main Screen**. Refer to the System Configuration Menu in section <u>System</u> on page <u>54</u>.

Connect an ethernet cable to the system prior to executing the following steps.

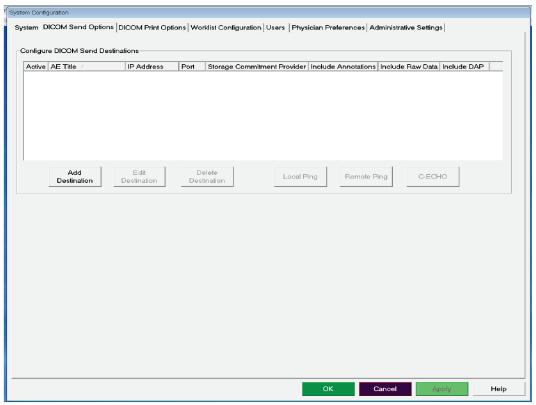


Figure 21: DICOM Send Options

Table 11: DICOM Send Options Page

Section/Field	Description
Configure DICOM Send Destinations	Selection list of DICOM Send destinations configured on the system and six function buttons.
	When checked, the Active column check box enables destination for use.
Add/Edit Destination	Entry/edit fields to identify a DICOM Send destination, three check boxes, and two function buttons.
AE Title	Destination's Application Entity Title.
Host Name or IP Address	Destination's Name or IP address.
Port	Destination's Port number.
Use as Storage Commitment Provider	When checked, indicates the destination is committed to storing information sent to it.
	During a normal shut down, if any DICOM Commit queue entries are greater than 7 days old, a message box appears indicating: <i>DICOM Storage</i> Commitment Queue contains entries older than 7 days. DO you want to delete them?
Include Raw Data	When checked, indicates studies sent to the destination shall include the raw data.
Include DAP Report	When checked, indicates that the corresponding DAP Reports for the selected studies shall also be sent to the destination.
Include Radiation Dose Structured Report	When checked, indicates that the corresponding Radiation Dose Structured Reports for the selected studies shall also be sent to the destination.
Include Annotations	When checked, includes annotations with exported images. Method of inclusion choices are:
	Embedded - Annotations are embedded into the bitmap image.
	As Overlay -Annotations are included as a DICOM overlay.
	As annotation files - Annotations are included as a separate file.

InSight FD Mini C-arm User Guide Chapter 16: Configuring the Application

Table 12: DICOM Send Options Page, Button Functions

Button	Function	
Add Destination	Adds a DICOM Send destination to the system.	
Edit Destination	Edits selected destination information.	
Delete Destination	Deletes selected destinations from the system.	
Local Ping	Confirms connection to the local network.	
Remote Ping	Confirms network connection to the selected destination.	
С-ЕСНО	Confirms network connection to PACS.	
OK	Updates the selection list with new or updated information and checks the destination's Active check box.	
Cancel	Ignores all edits and hides the Add/Edit Destination section.	

16.3.1 DICOM Print Options

Available from **System Configuration Menu** on the **Main** Screen. Refer to the System Configuration Menu in section <u>System</u> on page <u>54</u>.

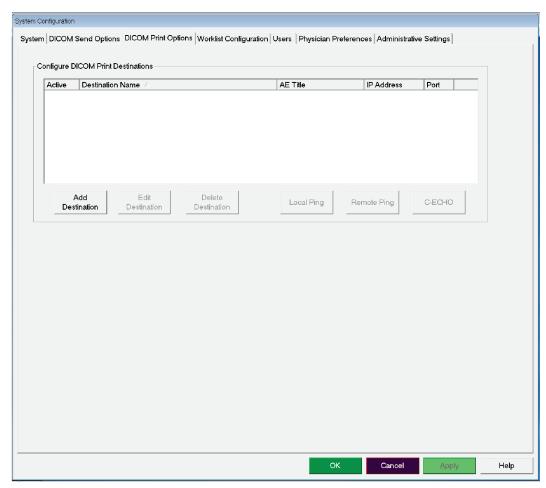


Figure 22: DICOM Print Options

Table 13: DICOM Print Options Page, Section/Field Descriptions

Section/Field	Description
Configure DICOM Print Destinations	Selection list of DICOM Print destinations configured on the system and six function buttons. When checked, the Active column check box enables destination for use.
Add/Edit Destination	Entry/edit fields to identify a DICOM Print destination, a section for entering and selecting print parameters, and two function buttons.
AE Title	Destination's Application Entity title.
Host Name or IP Address	Destination's Name or IP address.
Port	Destination's Port number.
Destination Name	Name for destination (allows a single destination to be configured in multiple ways).
Print Parameters	
Number of Copies	Enter number of copies to print.
Image Display Format	Select (row and column) from dropdown list.
Orientation	Select image layout (Portrait or Landscape).
Film Size	Select from dropdown list.
Medium Type	Select from dropdown list.
Decimate/Crop Behavior	Select from dropdown list.

Table 14: DICOM Print Options Page, Button Functions

Button	Function
Add Destination	Adds a DICOM Print destination to the system.
Edit Destination	Edits selected destination information.
Delete Destination	Deletes selected destinations from the system.
Local Ping	Confirms connection to the local network.
Remote Ping	Confirms network connection to the selected destination.
С-ЕСНО	Confirms network connection to PACS.
OK	Updates the selection list with new or updated information and checks the destination's Active check box.
Cancel	Ignores all edits and hides the Add/Edit Destination section.

16.4 Worklist Configuration

Available from **System Configuration** Menu on the **Main Screen**. Refer to the System Configuration Menu in section <u>System</u> on page <u>54</u>.

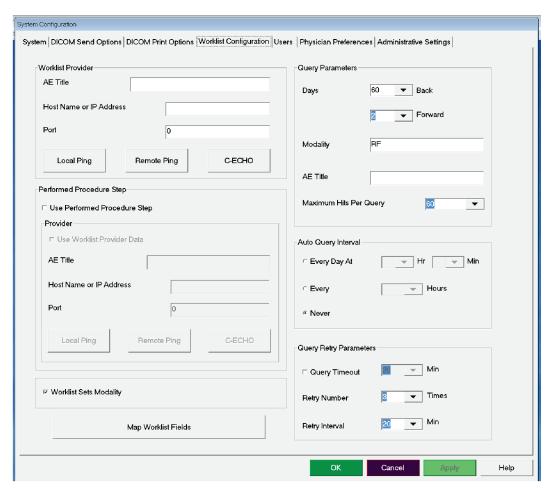


Figure 23: Worklist Configuration

Table 15: Worklist Configuration, Section Descriptions

Section/Field	Description
Worklist Provider	Identifies the system to access for the Worklist by providing entry fields for the provider's AE Title, Host Name or IP Address, and Port.
Use Performed Procedure Step	When checked, DICOM Modality Performed Procedure Step shall be performed when required.
Provider	Allows the user to access a system other than the one identified in the Worklist Provider section.
	When <i>Use Worklist Provider Data</i> is selected AE Title, Host Name or IP Address, and Port fields are automatically populated with data identical to the contents of the corresponding fields in the Worklist Provider section. When cleared, the fields can be populated by the user.
Query Parameters	Provides entry fields to identify:
	Requesting system (AE Title)
	Type of worklist being requested (Modality)
	Range of days to query
	Maximum number of scheduled patient examinations to include in the worklist
Auto Query Interval	Specifies if automatic queries are to be performed and how often.
Query Retry Parameters	Specifies if queries are to time out after a specific time (Query Timeout check box and Min selection), and number of times to retry and time intervals.
Worklist sets Modality	When selected, Modality is set by the Worklist.

Table 16: Worklist Configuration, Button Functions

Button	Function
Map Worklist Fields	Displays Map Worklist Keys window. Administrators can map InSight FD data fields to Worklist provider data fields.
Local Ping	Confirms connection to the local network and display the results.
Remote Ping	Confirms network connection to the Worklist Provider or Provider system.
С-ЕСНО	Confirms network connection to the PACS.

16.4.1 Users

Available from **System Configuration Menu** on the **Main Screen**. Refer to the System Configuration Menu in section *System* on page <u>54</u>.

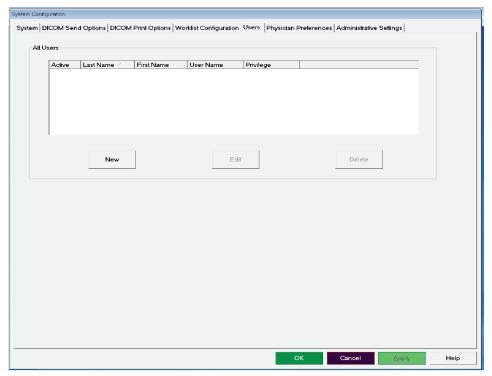


Figure 24: Users

Table 17: Users Page, Section/Field Descriptions

Section/Field	Description
All Users	Displays selection list of registered system users. When checked, the Active column check box allows user to log into the system.
Add/Edit User	Administrator entry/edit fields for user's actual name, login username, login password, and privilege.

Table 18: Users Page, Button Functions

Button	Function
New	Adds new users to the system.
Edit	Edits selected user information.
Delete	Deletes the selected user from the system.
OK	Updates the user list.
Cancel	Ignores all edits and removes the Add/Edit User section.

16.5 Physician Preferences

Available from **System Configuration Men**u on the **Main Screen**. Refer to the System Configuration Menu in section *System* on page <u>54</u>.

Table 19: Physician Preferences, Section/Field Descriptions

Section/Field	Description
Set System Defaults or Physician Defaults	Select system defaults to be used for visiting physician. Select physician defaults to set defaults for a selected physician.
Select Physician to set details for	Selection list of all physicians registered on the system, entry fields for physician's name, and two buttons (Add Physician and Delete Physician).

Table 20: Physician Preferences, Button Functions

Button	Function
Add Physician	Adds the physician's name and default preferences to the system.
Delete Physician	Deletes the selected physician from the system.
Reset Defaults	Resets all the preference settings to the factory defaults if editing system defaults, or to the system defaults if editing physician preferences. If system defaults have not yet been saved, all settings are reset to the factory defaults.
Save	Saves the preference settings for the System Defaults or for the selected physician.

16.6 Physician Preferences — Image Acquisition

Displays the current default preference settings for the system or the selected physician. Settings can be customized by an administrator.

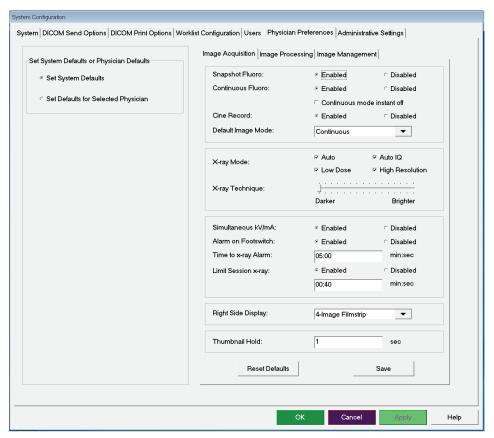


Figure 25: Physician Preferences — Image Acquisition

Table 21: Physician Preferences, Image Acquisition Tab, Section/Field Descriptions

Section/Field	Description
Snapshot Fluoro	Enables/disables Snapshot image acquisition mode.
Continuous Fluoro	Enables/disables Continuous image acquisition mode.
Default Image Mode	Selects initial image mode setting for Image Acquisition screen.
X-ray Mode	Selects active X-ray modes. Choose from Auto, Auto IQ, Low Dose, and High Resolution. One of Auto, Auto IQ, or Low Dose must be enabled, or the system will enable Auto mode. The system default enables all modes.
X-ray Technique	Slider control with 15 selectable settings from "Darker" to "Brighter" for preferred selection of the kVp and mA under automatic exposure control. Changing this value to "Darker"/"Brighter" will marginally decrease/increase the kVp and mA chosen by the automatic exposure control and, as a consequence, the corresponding dose to the patient.
Simultaneous kV/mA	When enabled, kV / mA goes up/down together to the next dose curve pair when manually adjusting X-ray power. When disabled, kV and mA can be adjusted independently.
Alarm on Footswitch	Enables or disables setting of the alarm to sound when the X-ray footswitch is depressed or released.
Time to X-ray Alarm	Sets when the alarm will sound based on the accumulated X-ray exposure time. Maximum value is 5 minutes.
Limit Session X-ray	Sets a limit* to the cumulative X-ray exposure time. Within 30 seconds of the set limit (maximum value is 10 minutes), a warning appears in the upper right corner of the screen. If you do not extend the session, you will be warned to extend or end the session.
Right Side Display	Selects initial filmstrip/tools area setting for Image Acquisition screen.
Thumbnail Hold	Determines the time a thumbnail image is displayed after the acquisition ends.
*The X-ray is disabled after the x-	ray exposure time has reached the limit. A User must exit a session and re-enter o continue.

16.7 Physician Preferences — Image Processing

Displays the current default preference settings for the system or the selected physician. Settings can be customized by an administrator.

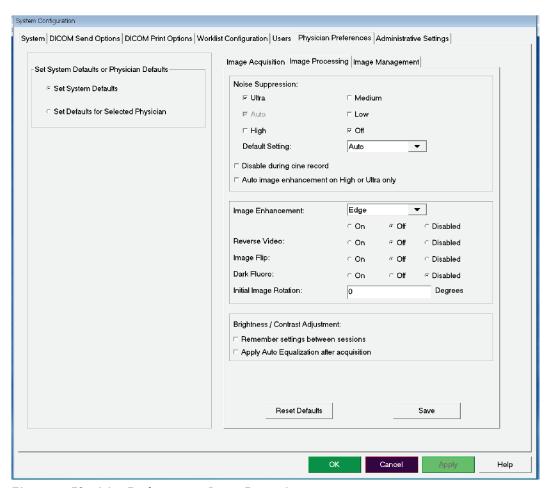


Figure 26: Physician Preferences — Image Processing

Table 22: Physician Preferences, Image Processing Tab, Section/Field Descriptions

Section/Field	Description
Noise Suppression	Cycles through the Noise Suppression settings that will be used during image acquisition.
	The noise suppression settings are Off , Low , Medium , High , Auto and Ultra .
	Noise suppression OFF or Low has less image blur due to motion, but the image will have significant noise (such as speckle).
	Higher noise suppression (Medium , High or Ultra) reduces speckle by averaging more frames in the displayed image. The High and Ultra noise suppression settings should be used when there is no motion of the anatomy and image clarity is needed.
	Auto noise suppression varies the noise suppression between Low , Medium and High , depending on the motion detected by the imaging algorithm.
	Disable during cine record - When selected, disables noise suppression when cine recording.
	Auto edge enhancement on High or Ultra only - When checked, image enhancement occurs only when noise suppression is set to High or Ultra .
	Default Setting defines the initial noise suppression for an image acquisition session. Select Ultra , Auto , High , Medium , Low , or Off from the dropdown list.
Image Enhancement	Select Edge or Sharpen from the dropdown list. Edge enhancement increases visualization between bone and soft tissue in the image. Sharpening enhancement increases visualization of fine detail. On/Off or Disabled affects the "image effects settings" in the Image Acquisition screen.
Reverse Video	Select On/Off or Disabled , which affects the "image effects settings" in the Image Acquisition screen.
Image Flip	Select On/Off or Disabled , which affects the "image effects settings" in the Image Acquisition screen.
Dark Fluoro	Select On/Off or Disabled , which affects the "image effects settings" in the Image Acquisition screen.
Initial Image Rotation	Enter number of degrees to automatically rotate an image while it is being acquired. Enter a negative number for counterclockwise rotation
Brightness/Contrast Adjustment	Remember settings between sessions - When selected, maintains Brightness/Contrast settings for subsequent images.
	Apply Auto Equalization after acquisition - When selected, applies Auto Equalization to the image to optimize contras

16.8 Physician Preferences — Image Management

Displays the current default preference settings for the system or the selected physician. Settings can be customized by an administrator.

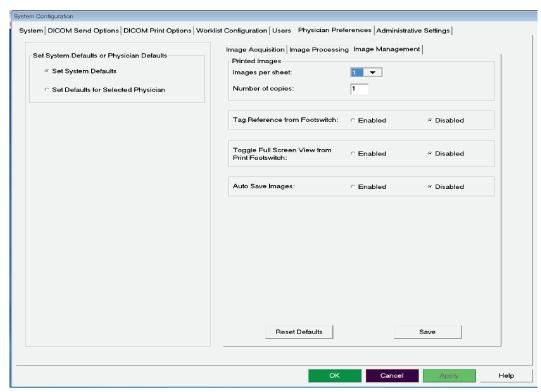


Figure 27: Physician Preferences — Image Management

Table 23: Physician Preferences, Image Management Tab, Section/Field Descriptions

Section/Field	Description
Printed Images	Select Number of Images per sheet and Number of copies to print.
Tag Reference from Footswitch	When Enabled: Press the Save footswitch once to tag the image as a reference image. Press Save a second time to save the image and remove the reference tag. Press Save a third time to re-tag the image as a reference image. When Disabled: Press the Save footswitch once to save the image (does not tag the image as a reference image).
Autosave Images	To automatically save scanned images during a session, select Enabled to activate Autosave Images *.
*If Alarm on Footswitch is enal	bled, a tone for X-ray ON will sound followed by the tone indicating that an image has been saved.

16.9 Administrative Settings Page

Available from System Configuration Menu on the Main Screen

Table 24: Administrative Settings, Section Descriptions

Section/Field	Description
Log Files	Selection list of all log files.
Set Level of Detail	Administrators can set System Error log level of detail to Error Only or Error and Operations.
Audit Mode	Administrators can set on or off.
Enable Touch Screen	Administrators can enable or disable.
Automatic Image	Select Delete at the following limits to:
Deletion	Establish the number of images at which a deletion prompt is displayed and the number of images to be deleted
	and
	Establish the number of cine minutes at which a deletion prompt is displayed and the number of cine minutes to be deleted.
	Prior to deletion, the system displays the number of studies required to achieve the desired number of images, or cine minute, deletions.
Last System Backup	Displays date of last system configuration and calibration backup.
	Display warning if last backup is older than days
	When selected, upon starting the application the system will display a warning message when the last backup is older than the given number of days.
System Shutdown	Administrators can select or clear.
	When selected, the full system shuts down (default setting).
	When cleared, only the InSight FD application shuts down.

Table 25: Administrative Settings, Button Functions

Button	Function
Configure	Displays the Level of Detail section.
Accept Change	Changes the detail level for System Error log to that selected by Error Only or Error and Operations button. Hides the Set Level of Detail section.

Chapter 17 Using the Application

You can select buttons, menus, menu functions, icons, and position the insertion cursor in fields by:

- Positioning the cursor on the respective item and clicking the left mouse button, or
- Touching the item on the touch screen if enabled.

The main screen appears if **Audit Mode** is on. If Audit mode is off, the **Image Acquisition** screen is displayed.

17.1 Patient Positioning

Place anatomy of the patient on the detector in the desired position. Use the positional lasers for more precise positioning if needed.

17.2 Main Screen



Figure 28: Main Screen

Table 26: Main Screen Options

1	System Configuration Menu. Refer to the table System Configuration Menu in the section <u>Main</u> <u>Screen</u> on page <u>71</u> .
2	Tools Menu. Refer to the table Tools Menu in the section <u>Main Screen</u> on page <u>71</u> .
3	About
	Displays InSight FD application's version number, serial number, and copyright data.
4	Exit Menu. Allows the user to log out or exit the application.
5	Perform . Starts an image acquisition session. Refer to section <u>X-ray Head Control Panel</u> on page <u>33</u> .
6	Review. Starts an image review session. Refer to the section <u>Review Screen</u> on page <u>91</u>
7	Shutdown. Exits application and shuts down the system.
8	Minimize the screen
9	Maximize the screen.
10	Close the Application screen.

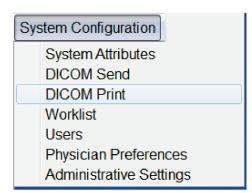


Figure 29: System Configuration Menu

Table 27: System Configuration Menu

Function	Description
System Attributes	Administrators can enter organization name, select default physician's name to be used by the application, select default language, enter DICOM application information and check if warning message should display when deleting images.
	All users can view system information. See section <u>System</u> on page <u>54</u> .
DICOM Send	Present if the DICOM Send option is installed.
	Administrators can add, edit, delete, and activate/deactivate Send destinations.
	All users can view the list of destinations, view destination information, and ping destinations. See section <u>DICOM Send Options</u> on page <u>56</u> .
DICOM Print	Present if the DICOM Print option is installed.
	Administrators can add, edit, delete, and activate/deactivate Print destinations.
	All users can view the list of destinations, view destination information, and ping destinations. See section <u>DICOM Send Options</u> on page <u>56</u> .
Worklist	Present if the Worklist options is installed.
	Administrators can add and configure a source.
	All users can view the source information and ping the source. See section <i>Worklist Configuration</i> on page <u>61</u> .
Users	User privileges within InSight FD are managed by Windows user accounts. Administrators can:
	Add new user mappings
	Edit existing user data, status (active/inactive) and privilege settings
	Delete user mapping.
	All users can view the list of users registered on the system. See section <u>DICOM</u> <u>Print Options</u> on page <u>59</u> .
Physician Preferences	Administrators can maintain a list of registered physicians and edit default preferences.
	All users can view the list of physicians registered on the system and view the default preferences for each physician. See section <u>Worklist Configuration</u> on page <u>61</u>
Administrative Settings	Administrators can change the System/Error log level of detail, turn audit mode on or off, enable or disable the touch screen, view the date of the last system configuration backup, and turn on or off the feature to shut down the system upon application shutdown.
	All users can view log file statistics and the data maintained by administrators. See section <u>Administrative Settings Page</u> on page <u>70</u> .

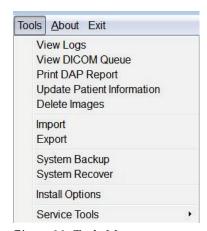
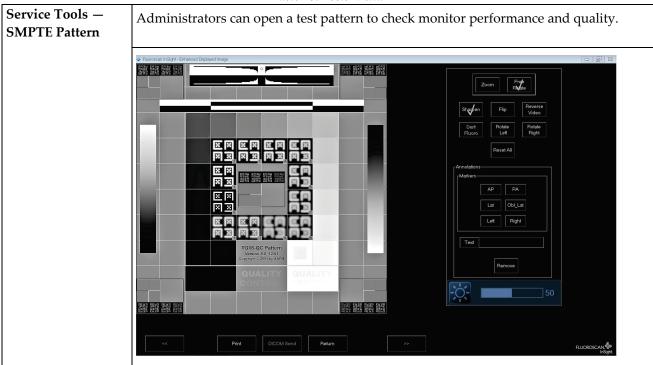


Figure 30: Tools Menu

Table 28: Tools Menu

Function	Description		
View Logs	View, print, export and in some cases edit various log files the application maintains.		
View DICOM Queue	Present if the DICOM Send option is installed. View status of DICOM Send requests, and retry or delete selected requests. See section <u>View DICOM Queue Window</u> on page <u>105</u> .		
Print DAP Report	Display and print the Dose Area Product report. Note Select DICOM Send, on the DAP Report display screen, to send the DAP Report to a DICOM destination. Include DAP Report must be selected to include the DAP Report with sent images. Otherwise, only the image will be sent.		
Update Patient Information	Administrators can update patient information for a selected patient study. See section <i>Update Patient Study Information Window</i> on page <u>95</u> .		
Worklist Entry	Allows configuration of a Worklist without a server connection. See section <u>Worklist Entry</u> on page <u>101</u> .		
Delete Images	Administrators can delete selected images from the system. See section <u>Delete Images</u> on page <u>102</u> .		
Import	Import selected images into the system from removable media. See section <u>Import Images</u> <u>Window</u> on page <u>100</u> .		
Export	Export selected images from the system to removable media, as shown in the figure Export Images in section <i>Export from Review Images Screen</i> on page <u>96</u> .		
System Backup	Backup system configuration and calibration data to external media.		
System Recover	Administrators can restore system configuration and calibration data from external media.		
Install Options	Administrators can install application software options.		

Table 28: Tools Menu



X-ray Head Control Panel 17.3

Table 29: X-ray Head Control Panel

Symbol	Label	Function
	Save	Saves selected images or cine loop to the record of the patient. If the number of stored images or minutes of cine loop exceeds the storage limit, a message displays.
	Rotate	Rotates the image clockwise or counterclockwise. Press once to rotate 10 degrees. Hold for continuous rotation.
+ •••	B/C	Allows adjustment of image brightness and contrast.
	X-ray	Acquires an X-ray exposure. Press switch once to actuate X-rays. A yellow indicator light located on top of the monitor shows that X-rays are being produced. When the yellow indicator light is OFF, the monitor displays the image captured at the end of the X-ray exposure - sometimes referred to as the last image hold.
*	Laser	Turns on the Positional Laser ^{1.}
	Noise Suppression	Cycles through the Noise suppression settings during image acquisition. Refer to the table <i>Physician Preferences, Image Processing Tab, Section/Field Descriptions</i> in section <i>Physician Preferences — Image Processing</i> on page <u>67</u> .

Table 29: X-ray Head Control Panel

Symbol	Label	Function	
kV/mA	kV/mA	Increases or decreases technique factors based on selected mode. Refer to the table <i>Physician Preferences, Image Processing Tab, Section/Field Descriptions</i> in section <i>Physician Preferences — Image Acquisition</i> on page 65. Note Pressing both the up and down power buttons at the same time returns the system to Auto Power mode.	
	Mode	Acquisition Mode Selection cycles through: Continuous² – When the user activates X-ray, the yellow X-ray light is ON and the monitor displays continuous real-time X-ray images. When the user deactivates X-rays by releasing the foot pedal or tube head switch, the yellow X-ray light turns OFF, and the last image hold is displayed (that is, what is on-screen when the X-rays have stopped). Snapshot² – When X-rays are activated, the device acquires a last image hold only. The X-ray dose used for the last image hold depends on the settings for X-ray mode technique factor and noise suppression. The exposure terminates when the user terminates the X-rays. Cine Record – Records the real time fluoroscopy images acquired into a	
		cine loop.	

¹ Press and hold the Laser button for 10 seconds to enable the positional laser to stay on. This option will reset when the system is powered off. ²Continuous and/or Snapshot mode may be disabled. Refer to the section <u>Physician Preferences</u> on page <u>64</u>

17.3.1 Image Acquisition Session

Select or Enter Patient Window

Available from Main Screen by clicking **Perform**, from the Image Acquisition screen by clicking **Update Patient**, and from the Review screen during an image acquisition session by clicking **Update Patient**.

If patient information is not entered prior to acquiring images the images will be associated with a temporary patient record (Temp Temp).

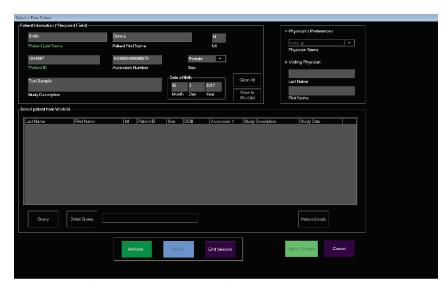


Figure 31: Select or Enter Patient Window

Table 30: Select or Enter Patient Window, Section/Field Descriptions

Section/Field	Function	
Patient Information	Identifies the current patient. Data is either entered by the user or filled in when a paties selected from the "Select Patient from" selection list. Select Clear All to clear Patien Information fields.	
Physician's Preferences	Selection button and dropdown selection list of physicians registered on the system.	
Visiting Physician	Selection button and entry fields for physician's name to be used when a physician is not registered on the system.	

Table 31: Select or Enter Patient Window, Button Functions

Button	Function	
Clear All	Clears Patient Information fields	
Perform	Displays the Image Acquisition screen	
Review	Displays the Review screen	
Save To Worklist	Manually add Worklist entry for this patient.	
End Session	Terminates the entry of Patient Information and leaves the Select or Enter Patient screen	
Apply Changes	Enters changes without leaving the Select or Enter Patient screen	
Cancel	Cancel the entry of Patient Information without leaving Select or Enter Patient screen	

17.3.2 Image Acquisition Screen

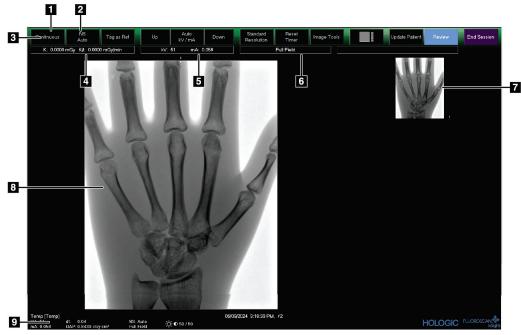


Figure 32: Image Acquisition Screen

Table 32: Image Acquisition Screen

1	Image Effects Menu. Refer to the following table, Image Effects Menu.
2	Configure Image Area Menu. Refer to the table <i>Configure Image Area Menu</i> in section <i>Filmstrip Symbols</i> on page <u>82</u> .
3	Function Buttons. Refer to the table <i>Image Acquisition Screen, Button Functions</i> in section <i>Filmstrip Symbols</i> on page <u>82</u> .
4	Displays AKR and cumulative air kerma while the X-ray tube is active. Air kerma is calculated at 2 cm above the entrance to the CMOS detector.
5	Displays current power settings.
6	Displays collimation mode. Limited Field magnifies a small area. Full field displays a large area. You can cycle through fields by moving the collimation switch. The collimation switch is underneath the X-ray head. Refer to section <i>System Components</i> on page <u>31</u> .
7	Filmstrip/Tools Area. For descriptions of the Tool Set, refer to the table <i>Tool Set</i> , in section <i>Filmstrip Symbols</i> on page <u>82</u> .
8	Image Area*
9	Displays cumulative DAP
	the X-ray light is on and x-rays are being generated, the displayed image is the live fluoroscopic image. When the X-ray has terminated, the image becomes the ge hold except when cine mode is active.

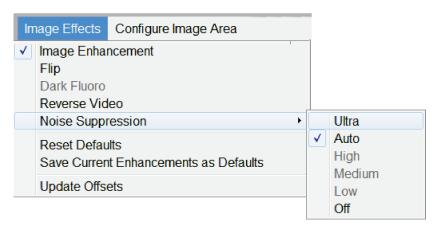


Figure 33: Image Effects Menu

Table 33: Image Effects Menu

Function	Description	
Image Enhancement*	* Images enhanced according to edge and sharpening configurations set in the Image Enhancement field in the table, <i>Update Patient/Study Information Window, Section Descriptions</i> , in section <i>Update Patient Study Information Window</i> on page <u>95</u> .	
Flip*	Images are flipped before being viewed by the user.	
Dark Fluoro*	Images have their white image pixels changed to black.	
Reverse Video*	Images are changed to a negative (blacks go to white; whites go to black).	
Noise Suppression	Selects noise suppression level. Selections are Ultra , Auto , High , Medium , Low and Off . Refer to the section <i>Physician Preferences</i> on page <u>64</u> for default setting.	
Reset Defaults	Resets the image enhancements, flip, dark fluoro, reverse video, and noise suppression settings to the default settings specified by the current physician's preferences settings, or the system default preferences settings in the event of a visiting physician.	
Save Current Enhancements as Defaults	Enabled if the selected physician is registered on the system. Saves the current image effect settings as the selected physician's preference settings.	
Update Offsets	Updates the offsets for Flat Field correction.	
* May be disabled or initially checked or unchecked. See the section <u>Physician Preferences</u> on page <u>64</u>		

17.3.3 Filmstrip Symbols

The following symbols appear on a filmstrip/thumbnail image in InSight software.

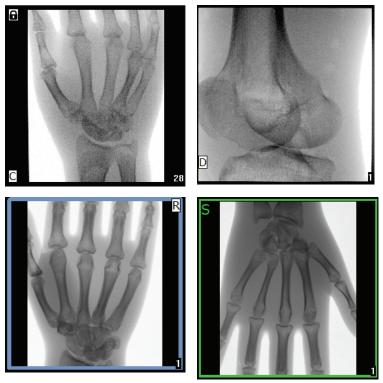


Figure 34: Filmstrip Symbols

Table 34: Filmstrip Symbols

Indicator	Identifies
С	Cine Loop
D	DICOM Storage Commit
R	Reference Image
s	Saved (identified by green outline around the image)
⊕	Locked image (cannot be deleted)

^{*}The lock icon is visible from the Review screen, and selecting the box under lock icon column. The study and images in that study will become locked.

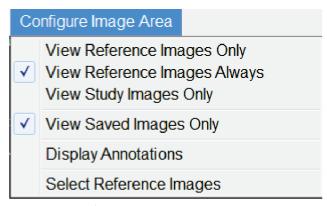


Figure 35: Configure Image Area Menu

Table 35: Configure Image Area Menu

Function	Description	
View Reference Images Only	Only images tagged as reference images are displayed in the filmstrip. This includes images tagged as reference during the current session and/or reference images selected from previous studies for the current patient.	
View Reference Images Always	Images tagged as reference always display at the top of the filmstrip followed by reference images selected from previous studies for the current patient, followed by non-reference images acquired in the current session in reverse order.	
View Study Images Only	Only images (reference and non-reference) acquired in the current session are displayed in the filmstrip.	
View Saved Images	Select View Saved Images from the Configure System Images Menu to display only saved images in the Filmstrip.	
Display Annotations	Displays annotations on the image displaying in the live image area.	
Select Reference Images	Displays the Select Reference Images window allowing users to select images from any current patient study residing on the system. Selected images are put into the filmstrip following any reference images acquired during the current session unless View Study Images Only is chemically the current session unless View Study Images Only in the current session unless View Study Images Only in the current session unless View Study Images Only in the current session unless View Study Images Only in the current session unless View Study Images Only in the current session unl	



Figure 36: Image Acquisition Screen Buttons

Table 36: Image Acquisition Screen, Button Functions

Button	Image	Function
Acquisition Mode Selection	Snapshot	Cycles through: Continuous — Displays continuous images when X-rays are actuated. Snapshot — Captures and displays one image when X-rays are actuated. Cine Record — Gathers all images acquired into a cine loop. Continuous and/or Snapshot mode may be disabled. Refer to
		the section <u>Physician Preferences</u> on page <u>64</u> .
NS (Noise Suppression)	NS Auto	Cycles through the levels selected during configuration. Refer to the table Physician Preferences, Section/Field Descriptions in section <i>Physician Preferences</i> on page <u>64</u> . Select Ultra to acquire images for very still anatomy. Image processing for Ultra level imaging averages frames at High noise suppression.
Tag as Ref	Tag as Ref	Marks the image as a reference image for the current session or unmarks a marked image.
Up	Up	Increases the kV and/or mA incrementally by one.

Table 36: Image Acquisition Screen, Button Functions

Button	Image	Function
X-ray Power Adjustment	Auto kV / mA	Cycles through: Auto Modes
Selection Auto kV/mA Auto IQ kV/mA Manual kV/mA Manual kV Manual mA Low Dose		Auto kV/mA — automatically adjusts kV/mA. Auto IQ kV/mA — automatically adjusts kV/mA. Select Auto IQ mode to acquire an enhanced image with improved clarity and less noise. Using Auto IQ mode increases the X-ray dose to the patient. Use Auto IQ when enhanced clarity is required in accordance with ALARA. Low Dose Modes Low Dose — automatically adjusts kV/mA.
		Select Low Dose mode to acquire images at a lower dose but with increased susceptibility to motion blur. Manual Modes
		Manual kV/mA — allows the user to manually increase or decrease kV/mA when simultaneous kV/mA¹ is enabled.
		Manual kV — allows the user to manually increase or decrease the kV when simultaneous kV/mA^{1} is disabled.
		Manual mA — allows the user to manually increase or decrease the mA when simultaneous kV/mA¹ is disabled.
Up	Up	Increases the kV and/or mA incrementally by one.
Down	Down	Decreases the kV and/or mA incrementally by one.
Resolution Mode	High Resolution	Select the Resolution Mode button to toggle between High Resolution Mode ² and Standard Resolution.
Reset Timer	Reset Timer	Resets the X-ray warning timer to zero and turns off the audible alarm.
Image Tools	Image Tools	Shows or hides the tool set in the Filmstrip/Tools area.

Table 36: Image Acquisition Screen, Button Functions

Button	Image	Function	
Format Toggle		Selects current image size and number of thumbnail images that display in the filmstrip area.	
			one filmstrip image.
			two filmstrip images.
			three filmstrip images.
			four filmstrip images.
Update Patient	Update Patient	Returns to	the Select or Enter Patient window.
Review	Review	Displays th	e Review Images screen.
End Session	End Session	Ends the cu	urrent patient's acquisition session. Returns to the n.

¹Refer to the Section <u>Physician Preferences</u> on page <u>64</u> for enabling or disabling simultaneous kV/mA.

²High-Resolution Mode captures more detail at a higher dose than Standard-Resolution Mode but is more susceptible to motion blur. Use the Zoom tool to view fine detail in High Resolution images.

Table 37: Tool Set

Button	Function
Zoom	Magnifies the current image two times. The magnified image can be panned by dragging with the mouse or touchscreen to see a different area of the image. Pinch to Zoom allows use of the touchscreen to magnify and contract the image — pinching outwards enables the zoom while pinching inwards contracts the image to normal size.
Free Rotate	Allows image to be freely rotated using the mouse or touch screen.
Enhance *	Applies/removes image enhancement to/from the image according to Image Enhancement settings selected in the previous table, <i>Image Acquisition Screen</i> , <i>Button Functions</i> .
Flip *	Flips/unflips the image horizontally about the center.
Reverse Video *	Applies/removes reverse video (blacks go to white; whites go to black) to/from the image.
Dark Fluoro *	Applies/removes dark fluoro (white image pixels change to black) to the image.
Rotate Left	Rotates the image in 10 degrees increments counterclockwise.
Rotate Right	Rotates the image in 10 degrees increments clockwise.
Reset All	Resets all image processing on the image to the last saved state of the image.
Annotations	Contains function buttons and a field that allows the user to add markers or text to the image or remove selected markers or text from the image. Annotations can be moved and/or removed using the mouse or touch screen. To remove an annotation, select the annotation, select Delete . Annotations include: AP, PA, Lat, Obl_Lat, Left, Right, Text (Places the text in the text edit box on the image).
Brightness/Contrast *This button may be configured	Allows adjustment of brightness and contrast of the selected image. 50 on, off, or disabled. Refer to the Section Physician Preferences on page 64

17.3.4 Select Reference Images Window

Available from the **Image Acquisition** screen by selecting **Select Reference Images** from the **Configure Image Area** Menu.

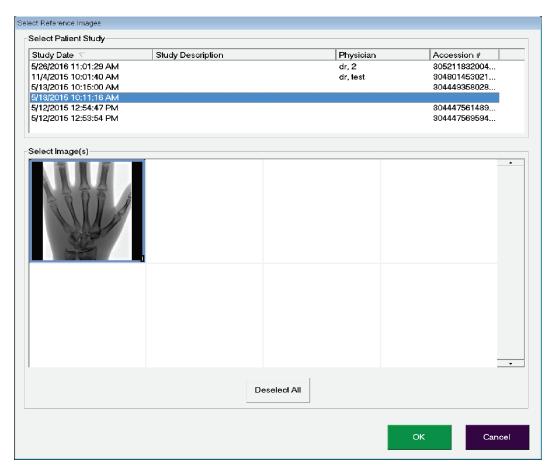


Figure 37: Select Reference Images Window

Table 38: Select Reference Images Window, Section Descriptions

Section	Description
Select Patient Study	Selection list of prior studies for the current patient stored on the system. The selection list can be sorted on any column by clicking in the respective column label. The entry field label in the Find section changes to correspond to the selected sort column.
Select Image(s)	A selection list of thumbnail images contained in the selected patient/study file. Selected images are highlighted. Multiple images can be selected. All images can be selected/unselected by clicking Select All or Deselect All . A scroll bar is displayed if the filmstrip layout does not show all images.

Table 39: Select Reference Images Window, Button Functions

Button	Function
Select All/Deselect All	Selects or deselects all images in the image selection list.
ОК	Returns all selected images to the Image Acquisition screen's filmstrip unless View Study Images Only is checked in the Configure Image Area Menu.
Cancel	Closes the window without returning any images to the Image Acquisition screen.

17.4 Review Images Session

17.4.1 Select Study for Review Window

Available from Main Screen by clicking **Review** and from the Review screen during a review session by clicking **Select Patient**.



Note

On a wide-screen monitor, when a single study is selected, images appear top to bottom in a single column on the right side of the monitor screen.

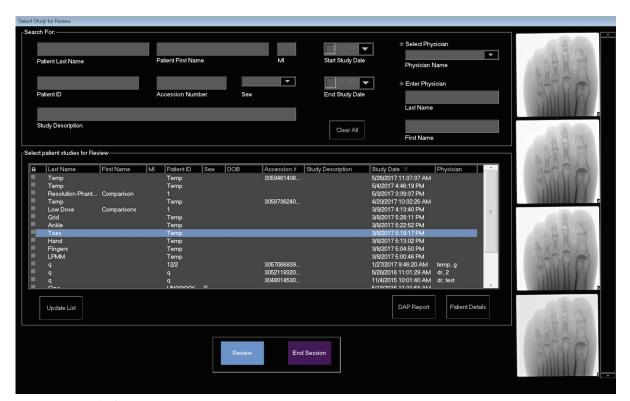


Figure 38: Study for Review

Table 40: Select Study for Review Window, Section/Field Descriptions

Section/Field	Description
Search For	Search criteria entry fields. To use Start Study and/or End Study Dates as a search criteria, the check box must be checked. The respective check box can be checked by clicking in the box, typing a date in the date field, or selecting a date from the calendar page that appears when clicking the down arrow.
Select Physician	Selection button and dropdown selection list of physicians registered on the system.
Enter Physician	Selection button and two entry fields for physician's name. Use when a physician's name is not registered on the system.
Select Patient Studies for Review	Selection list of all patient/study records on the system. Selection list can be filtered by completing one or more fields in the "Search For" section and clicking Update List . The selection list can be sorted on any column by clicking in the respective column label. One or more studies can be selected.

Table 41: Select Study for Review Window, Button Functions

Button	Function	
Clear All	Clears all entries in the Search For section.	
Update List	Updates the <i>Select Patient Studies for Review</i> selection list using criteria contained in the <i>Search For</i> section to limit the list. If all <i>Search For</i> parameters are empty, a list of all studies on the system is retrieved.	
DAP Report	Displays the DAP report for the selected patient. Note Select DICOM Send, on the DAP Report display screen, to send the DAP Report to a DICOM destination. Include DAP Report must be selected to include the DAP Report with sent images. Otherwise, only the image will be sent.	
Patient Details	Enabled when only one study is selected. Displays patient information.	
Review	Displays the Review screen. At least one study must be selected to enable the Review button.	
End Session	Terminates the review session.	

17.4.2 Review Screen

Available from the Select Study for Review window, and from the Image Acquisition screen by clicking **Review**.



Figure 39: Review Images Screen

Table 42: Review Screen, Button Functions

Button	Function	
Display Mode	Determine how images are displayed.	
Selection		Displays one row of two images.
		Displays two rows of four images.
		Displays three rows of six images.
Select Studies	Selects studies for review.	
Display/Print Annotations	Displays or prints annotations on the displayed image.	
Display Saved Images Only	Visible only during acquisition session. Displays only saved images.	
Select/Deselect All	Toggles between:	
	Select All - Selects all unselected images.	
	Deselect	All - Deselects all selected images.
Full View	Displays the selected image in the section <u>Enhanced Displayed Image Screen</u> on page <u>94</u> .	

Table 42: Review Screen, Button Functions

Button	Function	
Save	Saves selected images or cine loop to the patient's record. If the number of stored images or minutes of cine loop exceed the storage limit, a message is displayed.	
Delete	Deletes the selected images. If the system setting <i>Query on Delete</i> is enabled, the user is asked to confirm the deletion. Select Yes to confirm; No to cancel the deletion.	
Export	Copies the selected image(s) or cine loop to removable media. Patient information will be removed from images when <i>De-Identify Patient Information</i> is selected.	
Print	Prints the selected image(s) to the local printer. Images will be printed with annotations when <i>Display/Print Annotations</i> is checked. Patient information will be removed from images when <i>De-Identify Patient Information</i> is selected.	
DICOM Print	Sends the selected images to a DICOM node printer for printing. Images will be printed with annotations when <i>Display/Print Annotations</i> is checked. Patient information will be removed from images when <i>De-Identify Patient Information</i> is selected.	
DICOM Send	Sends the selected image(s) to a DICOM Send node. Patient information will be removed from images when <i>De-Identify Patient Information</i> is selected.	
View Queue	Displays the status of all DICOM Send requests. Refer to section <u>View DICOM</u> <u>Queue Window</u> on page <u>105</u> .	
Patient Details	Displays patient information. Select Additional Details to reveal Vista Dialog. See the figure, <i>VISTA Details</i> in the section <u>Review Screen</u> on page <u>91</u> .	
DAP Report	Displays the DAP report for the selected patient. Note Select DICOM Send, on the DAP Report display screen, to send the DAP Report to a DICOM destination.	
De-Identify Patient Information	Omits protected patient health information details related to specific patients.	
Update Patient / Select Study	In an acquisition session, returns to the Select or Enter Patient window to view or update patient information. In a review session, returns to the <i>Select Patient for Review</i> window to select a different patient study.	
Perform	Visible only in an acquisition session.	
End Session	Returns to the image acquisition screen. Terminates the current session.	

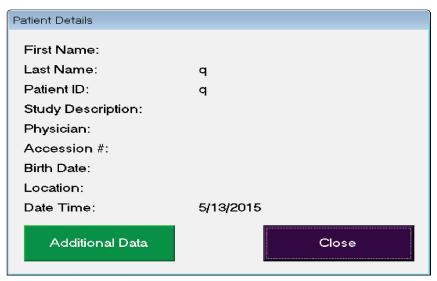


Figure 40: Patient Details

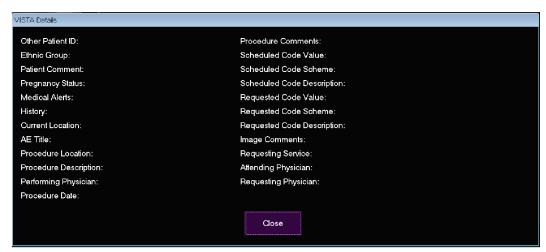


Figure 41: VISTA Details

Enhanced Displayed Image Screen

Available from the Review Images screen by selecting one image and selecting **Full View**, or by double-clicking an image.



Figure 42: Enhanced Displayed Image Screen

The tool set is identical to those described in the table, *Tool Set* in section *Filmstrip Symbols* on page <u>82</u>.

Table 43: Detailed Image Viewing Screen, Button Functions

Button	Function
<< (Previous Image)	Displays the previous image.
Print	Prints a copy of the image.
Delete	Deletes the image currently being displayed. If the system setting <i>Query on Delete</i> is enabled, the user is asked to confirm the deletion. Select Yes to confirm; No to cancel the deletion.
Return	Returns to the Review screen.
>> (Next Image)	Displays the next image.

17.5 Maintaining Patient Study Records

17.5.1 Update Patient Study Information Window

Available to administrators from the Tools Menu on the Main Screen.

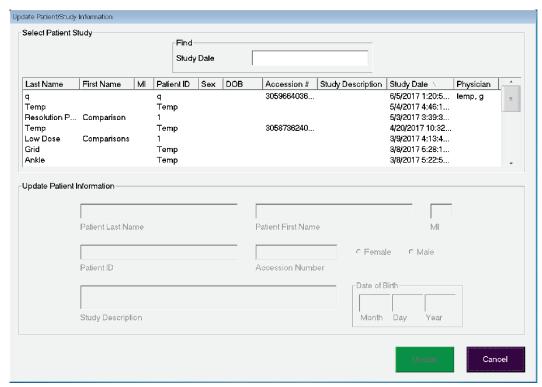


Figure 43: Update Patient Study Information Window

Table 44: Update Patient/Study Information Window, Section Descriptions

Section	Description	
Select Patient Study	Selection list of all patient/study records on the system and a search criteria section (Find).	
	The selection list can be sorted on any column by clicking in the respective column label.	
	The entry field label in the Find section changes to correspond to the selected sort column.	
Find	Use to quickly locate a patient/study.	
Update Patient Information	Displays information from the selected patient/study record.	

Table 45: Update Patient/Study Information Window, Button Functions

Button	Function	
Update	Updates the patient information on all images in the selected study.	
	Note The Auto-Accession number is associated with a specific patient. It does not change when patient information is updated.	
Cancel	Closes the window without updating and returns to the main screen.	

17.6 Export Images

Available from the **Tools Menu** on the **Main Screen** and from the **Review Images** Screen.

17.6.1 Export from Review Images Screen

A USB device may be used for export. Insert a USB device into the USB port of the system before executing the following steps.

- 1. From the **Review Images Screen** in section <u>Export from Review Images Screen</u> on page <u>96</u>, select images for export.
- 2. Select **Export** to open the **Export Images Panel** in section <u>Export from Review</u> <u>Images Screen</u> on page <u>96</u>.
- 3. Select the options for export: File Type and/or Annotations
- 4. Select Export.

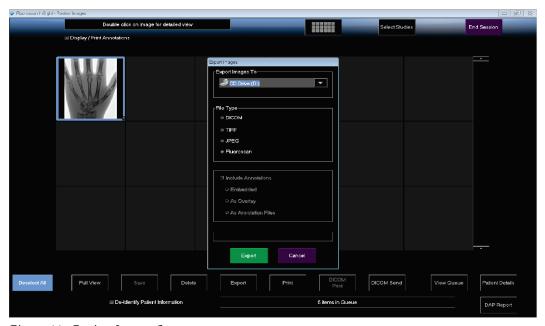


Figure 44: Review Images Screen

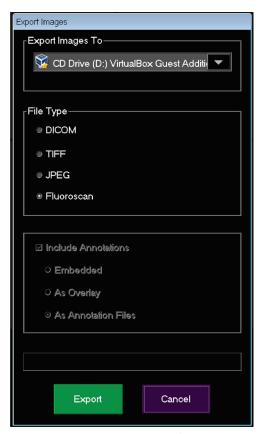


Figure 45: Export Images Panel

Export Using the Tools Menu

1. From the **Tools** Menu, select **Export**. Refer to the following figure.

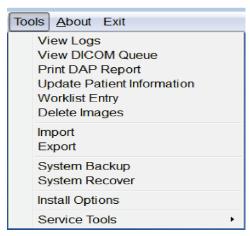


Figure 46: Tool Menu Export

- 2. Select **Export** to open the **Export Images** Window.
- 3. In the **Export Images** window, select the studies from which files will be exported. Refer to the following figure.

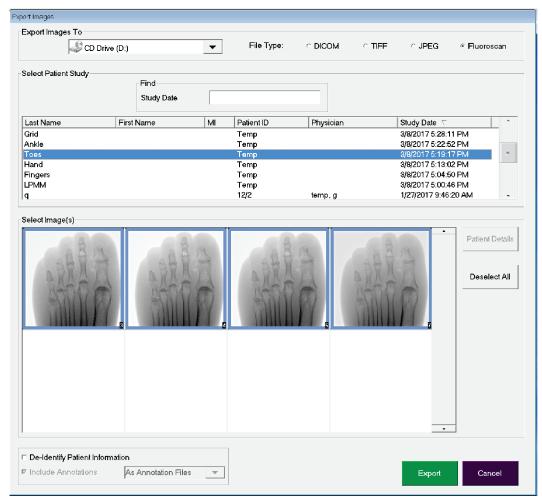


Figure 47: Export Images

- 4. Select **Export** to open the **Export Images** Window.
- 5. Select the images and options for the export:
 - a. Select the images for export.
 - b. Specify the location to which the files will be exported.
 - c. Select the File Type.
 - d. De-identify Patient Information.
 - e. Annotations
- 6. Select Export.

Table 46: Export Window, Section Descriptions

Section	Description
	Selection list of removable media devices currently available to the system. Other Locations allows the user to browse for a folder on the system or network.

Table 46: Export Window, Section Descriptions

Section	Description					
File Type	File format selection.					
Select Patient Study	Selection list of all patient/study records on the system and a search criteria section (Find).					
	The selection list can be sorted on any column by clicking in the respective column label. The entry field label in the Find section changes to correspond to the selected sort column.					
	One or more studies can be selected. When one study is selected, all images in the study display in the Select Image(s) section. When multiple studies are selected, images are not displayed.					
Find	Use to quickly locate a patient/study.					
Select Image(s)	Images are displayed when one patient/study is selected.					
	Images are not displayed when multiple studies are selected.					
	A selection list of thumbnail images contained in the selected patient/study file.					
	Selected images are highlighted. Multiple images can be selected. All images can be selected/cleared by clicking Select All or Deselect All .					
De-Identify Patient Information	When selected, removes patient identification data from images being exported.					
Include Annotations	When checked, includes annotations with exported images. Method of inclusion choices are:					
	Embedded - Annotations are embedded into the bitmap image.					
	As Overlay - Annotations are included as a DICOM overlay.					
	As annotation files - Annotations are included as a separate file.					

Table 47: Export Window, Button Functions

Button	Function				
Patient Details	Enabled when only one image is selected.				
	Displays patient information.				
Select All/Deselect All	Selects or clears all images in the image selection list.				
Export	Exports the selected images to the selected media device in the selected format. When more than one study is selected, copies all images in each study. <i>Images are not deleted from the system</i> .				
Cancel	Closes the window without exporting images and returns to the main screen.				

17.7 Import Images Window

A USB device may be used for import. Insert a USB device into the USB port of the system before importing images.

Available from **Tools** Menu on the **Main Screen**. Refer to the following figure.



Figure 48: Tools Menu

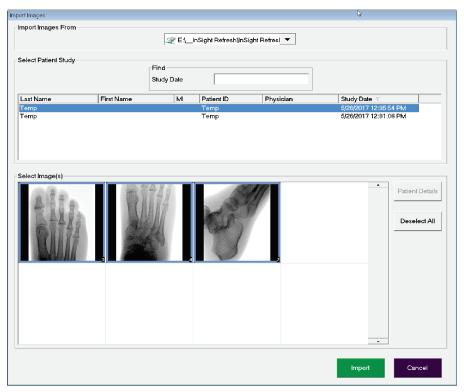


Figure 49: Import Images Window

Table 48: Import Window, Section Descriptions

Section	Description			
Import Images from	Selection list of removable media devices currently available to the system. Other Locations allows the user to browse for a folder on the system or network.			
Select Patient Study	Selection list of all patient/study records on the selected media and a search criteria section (Find).			
	The selection list can be sorted on any column by clicking in the respective column label. The entry field label in the Find section changes to correspond to the selected sort column.			
	One or more studies can be selected. When one study is selected, all images in the study display in the Select Image(s) section. When multiple studies are selected, images are not displayed.			
Find	Use to quickly locate a patient/study.			
Select Image(s)	Images are displayed when one patient/study is selected. Images are not displayed when multiple studies are selected. A selection list of thumbnail images contained in the selected patient/study file. The selected images are highlighted. Multiple images can be selected. All images can be selected/cleared by clicking Select All or Deselect All.			

Table 49: Import Window, Button Functions

Button	Function				
Patient Details	Enabled when only one image is selected.				
	Displays patient information.				
Select All/Deselect All	Selects or clears all images in the image selection list.				
Import	Imports the selected images into the system.				
Cancel	Closes the window without importing images and returns to the main screen.				

17.8 Worklist Entry

Worklist Entry allows configuration of a Worklist without a server connection.

17.8.1 Option 1 Tools Submenu

- 1. Select **Tools**.
- 2. Select Worklist Entry.
- 3. Enter **Patient Information**.
- 4. Select **Add** to enter patient information to **Worklist**.

17.8.2 Option 2 Patient Information Screen

- 1. After patient data has been entered on the Patient Information screen, select **Save to Worklist**. Refer to the figure <u>Select or Enter Patient Window</u> on page <u>78</u>.
- 2. Select **OK**.

17.9 Delete Images

Available to administrators from the *Tools Menu* on the **Main Screen**.

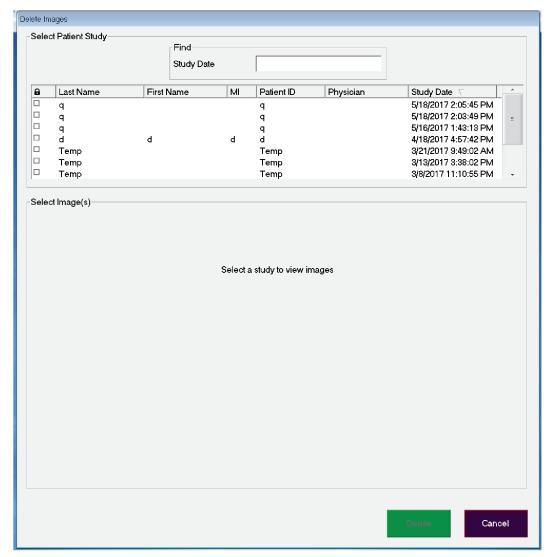


Figure 50: Delete Images

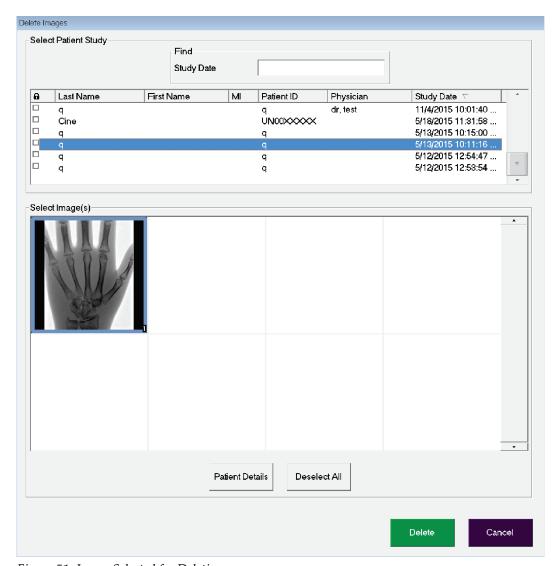


Figure 51: Image Selected for Deletion

Table 50: Delete Images Window, Section Descriptions

Section	Description			
Select Patient Study	Selection list of all patient/study records on the system and a search criteria section (Find).			
	The selection list can be sorted on any column by clicking in the respective column label. The entry field label in the Find section changes to correspond to the selected sort column.			
	One or more studies can be selected. When one study is selected, all images in the study display in the Select Image(s) section. When multiple studies are selected, images are not displayed.			
Find	Use to quickly locate a patient/study.			
Select Image(s)	Images are displayed when one patient/study is selected. Images are not displayed when multiple studies are selected. A selection list of thumbnail images contained in the selected patient/study file. Selected images are highlighted. Multiple images can be selected. All images can be selected/cleared by clicking Select All or Deselect All.			

Table 51: Delete Images Window, Button Functions

Button	Function				
Patient Details	Enabled when only one image is selected.				
	Displays patient information.				
Select All/Deselect All	Selects or clears all images in the image selection list.				
Delete	Deletes the images selected in the image selection list from the InSight FD system. When more than one study is selected, deletes all images in each study. If the system setting Query on Delete is enabled, the user is asked to confirm the deletion. Select Yes to confirm; No to cancel the deletion.				
Cancel	Closes the window without deleting images and returns to the main screen.				

17.10 View DICOM Queue Window

Available from the **Tools Menu** and from the **Review Images** screen.

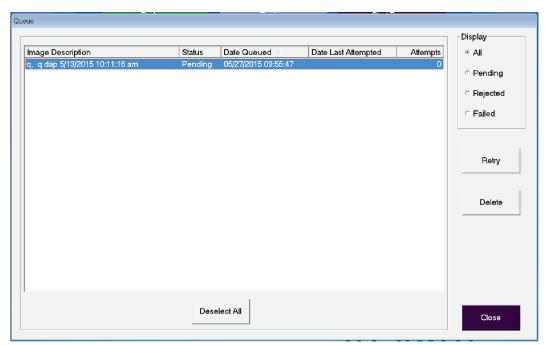


Figure 52: View DICOM Queue

Table 52: Queue Window, Section Description and Button Functions

Section/Button	Description/Function				
DICOM Queue List	Selection list of queue request information that can be filtered.				
Display	Filters the selection list depending on the selected radio button.				
Select All/Deselect All	Selects or clears all DICOM requests listed in the Queue List.				
Delete	Deletes the selected DICOM request(s).				
Retry	System tries to send the selected DICOM request(s) again.				
OK	Closes the <i>Queue</i> window and returns to the previous screen (<i>Main</i> Screen or <i>Review Images</i> screen).				

Chapter 18 System Maintenance

18.1 System Backup

Any user can backup system configuration and calibration data to a selected removable media device by selecting **System Backup** from the *Tools Menu* on the *Main Screen*.

18.2 System Recover

Administrators can restore system configuration and calibration data from a selected removable media device by selecting **System Recover** from the *Tools Menu* on the *Main Screen*.

18.3 Cleaning

Exterior surfaces of the InSight FD Mini C-arm should be cleaned once a week and any time after a surface has become soiled. Clean exterior surfaces of the cabinet, the flex-arm and the C-arm with a soft cloth or disposable lint-free tissue moistened with water, isopropanol or methanol. Disinfect using a 10% bleach solution. Wipe surfaces do not scrub. A commercial glass cleaner may be used to clean the monitor's touch screen.



Warning:

Disconnect the equipment from the AC Power Source before applying any cleaners or disinfectants to the system.

18.3.1 Recommended Disinfectants

Table 53: Recommended Wipes

Cleaner
PDI Super Sani-Cloth Germicidal Disposable Wipes
PDI Sani-Cloth plus Germicidal Disposable Cloth

Table 54: Recommended Chemicals

Base Type	Typical Products		
Chlorine (maximum 10% solution)	Clorox, Nolvasan		
Formaldehyde	Formaldehyde solution 37%, Vinco, Formaldegen		
Glutaraldehyde	Aldacide 200, Lysoform, Wavicide		
Phenol family	Lysol I.C., Beaucoup, Magna Clean, Tek-Trol		
Alcohol	CaviCide, Isopropyl Alcohol, Medicide		
Oxidizing	Hydrogen Peroxide 3% Solution, Lifeguard Series		
Quaternary Ammonium	Roccal-D, Bactosep, Parvosol		
Soap and Water			

18.4 Preventive Maintenance

Hologic recommends that preventative maintenance be performed by authorized service personnel at least once a year.

18.5 Troubleshooting

For assistance with the proper operation of your equipment, contact Hologic Customer Support.

Toll Free in USA: +1.800.321.4659

Email: <u>SkeletalHealth.Support@hologic.com</u>

18.6 Disposal



Equipment to be disposed in compliance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).

physician preferences • 64 Index system • 54 user interface • 53 Α worklist • 61 continuous • 34 Accessories controls • 33 hardware • 13 cord • 25, 27, 29, 30, 37, 39, 47, 52 operation • 13 customer support • 15, 107 software • 13 Cybersecurity acquisition • 33, 36, 66, 68, 72, 76, 78, 86, 91, 92 best practices • 11 add/edit • 57, 58, 60, 63 product report • 11 Administrative Settings accept change • 70 D audit mode • 70 automatic image deletion • 70 defaults • 35, 64 configure • 70 detector • 5, 25, 26, 48, 51, 71, 80 enable touch screen • 70 DICOM • vii, ix-xi, 17, 55-60, 62, 73, 74, 82, 90, last system backup • 70 92, 99, 105 log files • 70 dose • v, 5, 17, 57, 66, 74, 85 set level of detail • 70 dosimeter • 5 system shutdown • 70 drape • 51 administrator • 55, 63 ALARA • 5, 17, 85 E alarm • 25, 35, 66, 85 electromagnetic • 9 annotations • 17, 57, 83, 87, 91, 92, 96, 98, 99 emergency • 1 auto query interval • 62 EMI • 9 enhanced view • 42 B essential performance • 2 battery replacement • vi, 44 brightness/contrast • 55, 68, 87 F buttons • 34, 53, 57, 60, 64, 71, 77, 87 field of view • v, ix, 22 field service • 9 \mathbf{C} flat detector • 2, 3 caution • 1, 18, 22, 23, 26, 50-52 Fluoroscopic Imaging System • 1 CD/DVD • 31 footswitch • 41 cine record • 34 **Footswitch Functions** compliance • 7 wired footswitch • 45 computer • 23, 31, 52 wireless footswitch • 44 conditioning • 52 X-ray Head Control Panel Functions cone • 37, 38 rotate images • 33 configuring the application • 53 auto power mode • 36

administrative settings • 70

DICOM Send Options • 56

displays help window • 35

flips image horizontally • 35

laser • 33 plugs • 39 mode • 34 printer • 31 product complaints • 2 noise suppression • 36 noise suppression • 33 provider • 57, 62 patient information • 35 rotates image clockwise • 35 Q rotates image counterclockwise • 35 query • 55, 62, 92, 94, 104 save images • 33 R Ι radiation • 2, 5, 7, 17, 22, 25 IEC standards • 7 rear casters • 49 image acquisition screen • 42 receiver • 31, 42, 44, 45 images • 2, 17, 33, 34, 41-43, 52, 55, 57, 68-70, 73, regulations for x-ray equipment • 7 74, 76-78, 82-92, 96-101, 104 regulatory requirements • 5 indications for use • v, 1 reports • 57 indicators • 33 installation • 37 S intended use • 1 Safety K cleaning • 28 collision • 28 keyboard • vi, ix, xi, 31, 35, 48 device • 29 kV/mA • 34, 35, 66, 77, 85, 86 electrical • 25 electrosurgical • 29 L explosion • 27 LED • 44, 45 imaging • 26 obstructed view • 30 overbalance • 26 M pinching • 30 MegaView • vi, 41-43 power cord • 30 menu • 56, 71 tripping • 29 Mini C-arm • ix, 1, 7, 9, 51, 106 unauthorized modifications • 26 models • 52 security • 11 monitor • 17, 30, 33-35, 48, 75-77, 89, 106 snapshot • 34 software • 55 N SSD cone • 37 status • 55 network • 11, 17, 55, 58, 60, 62, 98, 101 storage • vi, ix, 43, 55, 57, 82 note • 18, 21, 26, 34, 39, 42-44, 47, 51, 74, 77, 89, storage tray • 31 90, 92, 96 study • vii, ix-xii, 35, 74, 81, 83, 88-92, 95, 96, 99, 101, 104 P symbols • v, vii-xi, 18, 22, 80, 82, 94 system • 31 PACS • 17, 58, 60, 62 **System Components** patient • 2 collimation switch • 31 pedal • 34, 42, 77 flex-arm • 31

ping • 58, 60, 62

InSight FD Mini C-arm User Guide

Index

touch screen monitor • 31 optical drive • 31 usb port • 31 system labels • 19

System Maintenance backup • 106 cleaning • 106 disposal •107 preventive •107 recover • 106 troubleshooting • 107

T

terms and definitions • 17 tools • ix-xi, 72, 74, 95-97, 100, 102, 105, 106 transmitters and receivers • 44

U

user profiles • 2
education • 2
experience • 3
knowledge • 3
permissible impairments • 3
Using the Application
delete images • 102
DICOM queue • 105

export images • 96 import images • 100 main screen • 71 patient positioning • 71 patient study records • 95 review images • 89 worklist entry • 101 Using the System adjusting the c-arm • 50 moving • 47 sterile c-arm drap • 51 powering down • 52 powering up • 52

\mathbf{V}

video • 68, 81, 87 VISTA • ix, 92, 93

\mathbf{W}

warning • v, ix, 18, 20-22, 25, 26, 28-30, 43, 45, 47, 52, 106
warranty statement • 2
where to obtain copies of the manuals • 15
window • 35, 42, 53, 62, 83, 86, 89, 91, 92, 96, 97, 99, 101, 104, 105
worklist • vii, ix, xi, 61, 62, 73, 74, 79, 101, 102

HOLOGIC®



Hologic Inc 600 Technology Drive Newark, DE 19702 USA 1.800.447.1856

Australian Sponsor Hologic (Australia & New Zealand) Pty Ltd. Level 3, Suite 302 2 Lyon Park Road

Macquarie Park NSW 2113

Australia 1.800.264.073



Hologic BV

Da Vincilaan 5 1930 Zaventem Belgium

Tel: +32 2 711 46 80 Fax: +32 2 725 20 87

