TrueView 200 Pro-US

Specimen Radiography System

User Manual

P000220 V3.0

0.1 Product Introduction

This manual is developed by CompAI Healthcare (Suzhou) Co., ltd, for both the product specimen radiography system (TrueView 200 Pro-US) and its accessory, specimen container (QuadraView 100).

The product name is TrueView 200 Pro-US Specimen Radiography System.

0.2 Manufacturer Information

Registrant:	CompAI Healthcare (Suzhou) Co., ltd
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Manufacturer:	CompAI Healthcare (Suzhou) Co., ltd
Manufacture Address:	Room 3A05, Building 2, No.8 Changting Road, High-tech Zone, Suzhou, Jiangsu, P.R. China
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0.3 Conformance Standards

The following classifications are in accordance with the IEC/ EN/UL 61010-1:

According to IEC/EN 61010-1, IEC/EN 61010-2-101

Equipment is Class I.

According to EN55011,

Equipment is Group 1, Class A ISM Equipment.

This product complies with the following standards:

IEC/EN/UL 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements

IEC/EN/UL 61010-2-091 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-091: Particular Requirements for Cabinet X-ray Systems

IEC/EN/UL 61010-2-101 Safety requirements for electrical equipment for Measurement, Control, and Laboratory Use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

IEC 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipmentIEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

IEC 62304 Medical device software - Software life cycle processes.

CSA C22.2#61010-1-12Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements.

CSA C22.2#61010-2-091 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-091: Particular Requirements for Cabinet X-ray Systems

CSA C22.2#61010-2-101Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

0.4 Attention

1) This manual is designated for TureView 200 Pro-US.

   This manual contains necessary and sufficient information to operate the system safely.

   Read and understand all instructions in this manual before attempting to use the system.

   It is advised to retain this manual with the equipment at all time.

   Regularly review the operational procedures and safety precautions outlined within.

2) Routine maintenance of this product is essential, and any faulty products should not be used. In the event that components are damaged, lost, deformed, or contaminated, immediate replacement is necessary.

3) In cases where repair or replacement is warranted, please reach out to the service department of CompAI Healthcare. Only individuals with the appropriate qualifications are authorized to undertake repairs on the system. Any modifications to this product should not be made without prior authorization.

4) If the product malfunctions as a result of improper utilization, incorrect maintenance procedures, inadequate repairs, or component replacements performed by unqualified individuals, the owner of the product will be held entirely accountable for any resulting issues.

5)

Caution: In the United States, federal law restricts the sale of medical devices to be conducted solely by or under the order of a physician.

For locations outside the United States, it is advised to thoroughly review and adhere to any applicable local legal restrictions.

6) Avoid using disinfectants, cleansers, or any other substances that are incompatible with the equipment.

7) Any serious incidents must be promptly reported to both the manufacturer and the relevant regulatory authority in the jurisdiction where the user and/or patient is located.

8) When using or positioning this equipment, ensure that the casters are locked to prevent the equipment from sliding.

9) Placing other objects on the console is strictly prohibited.

10) Please take care to avoid pinching hands when opening and closing the cabinet door.

11) When pushing this equipment, it is recommended that two people move with one person behind the other to prevent the equipment from tipping over or colliding with others.

12) When disposing of this equipment or any accessories, adhere to all necessary precautions. Do not dispose of this equipment or its accessories without consulting our company. For further information, please reach out to the manufacturer's authorized representatives.

Table of Contents

1. System Overview

1.1 Product Description

The TrueView 200 Pro-US is a Cabinet X-ray System intended to provide the detailed radiographic imaging of small surgical excised or biopsy specimens and to further provide rapid verification that correct tissue has been excised. The TrueView 200 Pro-US includes the following major components: system monitor, touch-screen control display, and an imaging cabinet.

This all-in-one system includes shielding that is incorporated within the cabinet chamber system design, eliminating the need for separate shielding. The unit is mounted on casters for easy transportation.

This system is intended to be used in the following environments:

• Surgical suites

• Biopsy suites

• Pathology labs

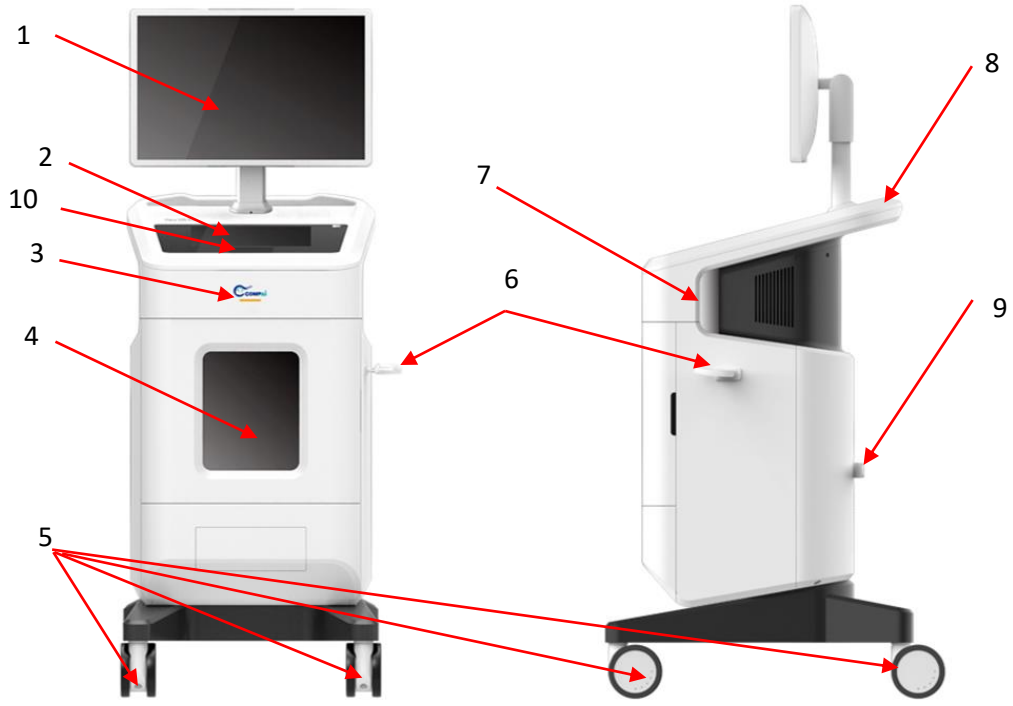


Figure1. system overview

1. System Monitor
2. Touch Screen
3. Exposure Indicator
4. Imaging Cabinet
5. Casters
6. Barcode Scanner Holder
7. Side Handle
8. Back Handle
9. Cable Hook
10. Touchpad

1.2 Intened Use of the Product

The TrueView 200Pro system is designed for use in biopsy suites, surgical suites, and pathology departments. Its primary purpose is to deliver digital X-ray images of surgical and core biopsy specimens from diverse anatomical regions, enabling swift verification of the excised tissue's accuracy during the procedure. Performing the verification in proximity to the procedure room enhances workflow, ultimately leading to a reduction in overall operative time.

This system is intended for use by professionals such as surgeons, pathologists, nurses, and surgical technologists.

1.3 Contraindication

There is no contraindication.

1.4 Compatibility

The system’s data interaction occurs through the network and USB port. Patient data can be transmitted to the hospital’s DICOM server via the network, and it can also be transferred to external storage media (USB

disk) through the USB port. Device data can only be transferred to external storage media (USB disk) through the USB port. Network interaction supports both wired and wireless (Wi-Fi protocol 802.11) and adheres to the standard DICOM 3.0 protocol. The USB port is compatible with USB 2.0.

1.5 Product Operation Principle

The TrueView 200 Pro-US has one physical imaging methods: X-ray radiography. In X-ray radiography, a fixed focal source distance is utilized (referring to the distance from the X-ray tube's focus to the active array of the flat-panel detector). The computer control software manages the process of placing pathological specimens on the bracket within the imaging area for X-ray radiography. Subsequently, the digital image data obtained is saved, and the image is displayed directly in the specified section of the display screen.

1.6 Product Function and Features

The main functions of the system are as follows：

1) X-ray digital image acquisition function, including automatic and manual modes;
2) Auto detect magnification ratio based on specimen position
3) Highlight suspected calcification
4) X-ray exposure parameters default-setting;
5) DICOM protocol supporting;
6) Image analysis tools
7) Barcode scanner support as option
8) Mobility
9) Local printing

1.7 Product Service Life

Under appropriate conditions of use, maintenance, and storage, the product has a service life of 10 years from the date of delivery.

1.8 Symbol Description

No	Symbol	Description	Location
1		Warning	Above the power input
2		Warning: electricity	Above the power input
3		Beware of ionizing radiation	Above the switch button
4		Biological Risk	A conspicuous location of cabinet door
5		Refer to instruction manual	Above the switch button
6		Attention static sensitive devices	Above the switch button
7		Warning ： Recommended two persons to move the system during the long distance to avoid the System tilt down.	Above the switch button
8		RoHS compliant	Above the switch button
9		Assembled in China	Above the switch button
10		Manufacturer	Above the switch button

11		The ETL Listing Mark	Above the switch button

Table 1.1 Description of graphic symbols

a） The warning graphic symbols used in this manual are as follow:

Warning: Failure to pay attention to or avoid this condition or situation may result in personal injury or significant damage to the equipment or data.

1) Do not connect any other (non-system component) equipment or components to the system without authorization to integrate them as part of the system.
2) Do not connect any other (non-system component) detachable socket (MPSO) or extension cord to the system.
3) To ensure users achieve the optimal intended use, it is advisable to follow the steps outlined in the system's installation program during installation.

1.9 Peripheral

Three recommended peripherals for TrueView 200 Pro-US:

Name	Manufacturer	Type	Use instruction
Barcode Scanner	Honeywell	Xenon 1900	Refer to 3.3.5
Wireless card	Tenda	U18	Refer to 5.2.4.2
Specimen Container	CompAI Healthcare	QuadraView100	Refer to1.12

Table 1.3 peripheral list

1.10 Safety Interlock of the System

The system incorporates the following safety interlocks through hardware and software to ensure safe operation:

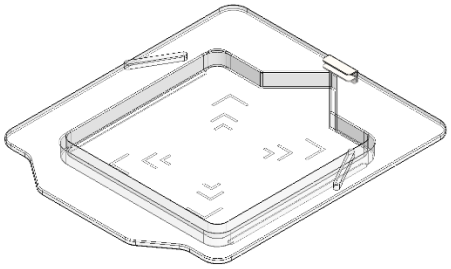
a） Safety interlock with cabinet door: When the cabinet door is open, the system is prevented from conducting exposure operations. If the cabinet door is inadvertently opened during exposure, the system promptly halts the exposure process.

b） X-ray image operation confirmation prompt: As X-rays are emitted during the imaging procedure, the software includes a prompt box to confirm the X-ray beaming operation. A confirmation prompt box is displayed by the software, requiring acknowledgment before exiting the prompt.

1.11 Specimen Tray

The specimen tray is designed for placing specimens during imaging.

The system features three slots that correspond to different imaging magnifications (1.0x, 1.5x, 2.0x) from bottom to top. The innermost marker line aligns with a magnification of 2.0x, the middle marker line corresponds to 1.5x, and the outermost marker line corresponds to 1.0x. This design allows for easy selection and positioning of the specimens according to the desired imaging magnification level.



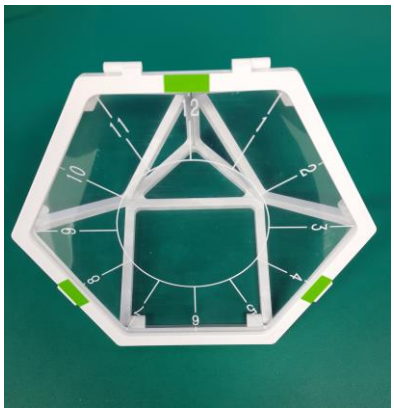
NOTE: ***It is not recommended to place specimens directly onto the specimen tray. To avoid biological risks, the specimen should first be collected using a specimen collection bag before being placed on the tray.***

NOTE: ***Wrapping the tray and placing it in the cabinet may interfere with the identification of the imaging magnification. Therefore, it is not advisable to place the tray into the cabinet after wrapping it.***

1.12 Specimen Container

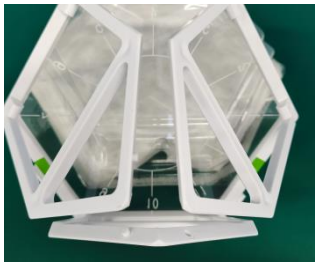
The QuadraView 100 is an accessory designed for the TrueView 200 Pro-US, serving the purpose of securely positioning specimens and facilitating multi-angle X-ray radiography.

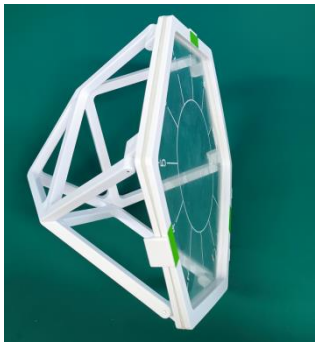
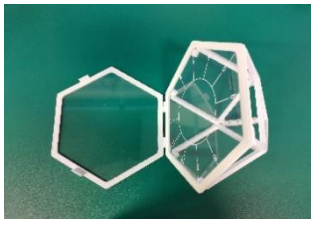
It is worth noting that the QuadraView 100 is intended as a disposable accessory.

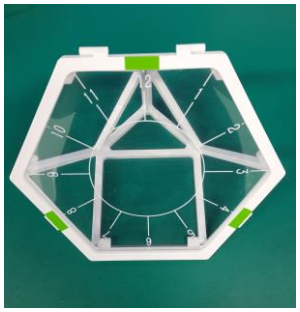


QuadraView 100

1.12.1 Assembly Steps:

	Step 1. Open the package of specimen container.
	Step 2. There is one small raised cylinder and one hole in each side of the bracket.

	Step 3. Close it and pinch it
	Step 4. Three brackets connect together.
	Step 5. Open the buckle in the left and right side
	Step 6. The specimen container is ready and the specimen can be put between the film and cover

	Step 7. Close the buckle. It’s ready for use.

1.12.2 Specimen Container Function

Put specimen into specimen container and then put the specimen container on the specimen tray, it supports:

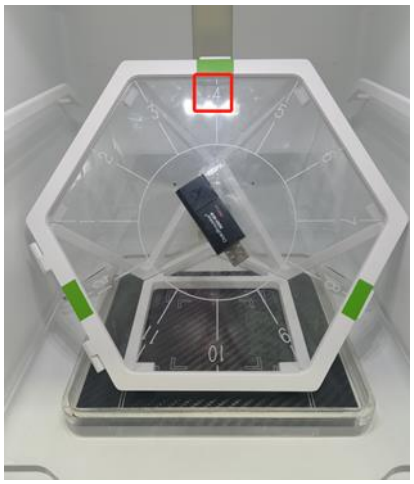
- To obtain multi-angle image.
- To calculate the distance from the calcification point to the incisal edge
- To locate the position of the tumor specimen to avoid blindly expanding the scope of surgical resection
- To assist the pathology department in locating the specimens

1.12.3 Method of Use

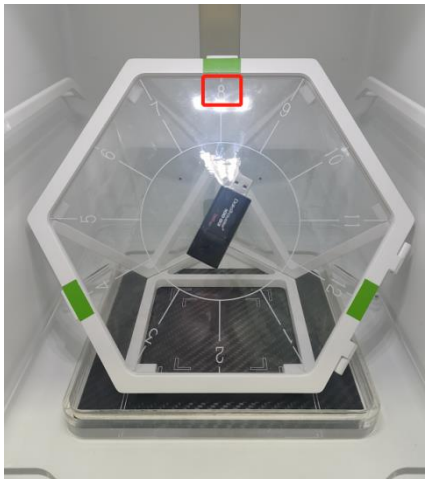
After the specimen container is assembled, open the buckle, put the specimen into the specimen bag between the film and the cover, close the buckle, and finally put the specimen container on the tray.

Four ways to put the specimen container on the tray are as follows:

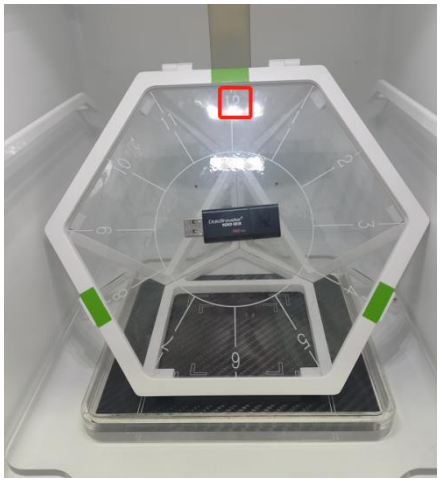
1) The number 4 marked on the specimen container is directly above, as shown in the figure below:



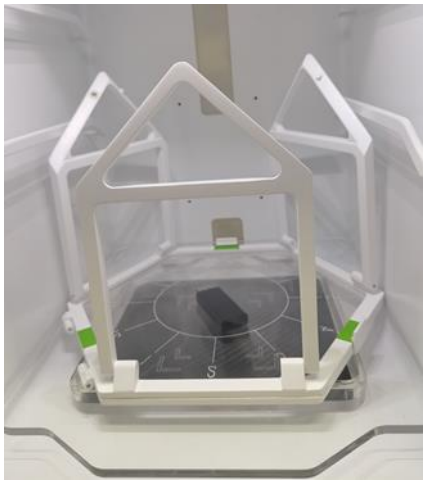
2) The number 8 marked on the specimen container is directly above, as shown in the figure below:



3) The number 12 marked on the specimen container is directly above, as shown in the figure below:



4) Open the three brackets of the specimen container and put the specimen container on the specimen tray, as shown in the figure below:

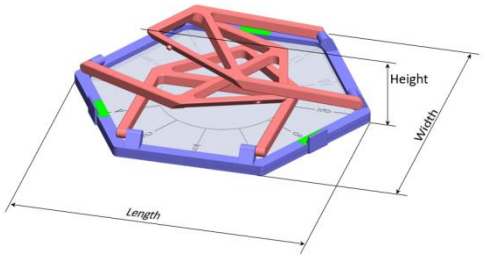


1.12.4 Attention Points

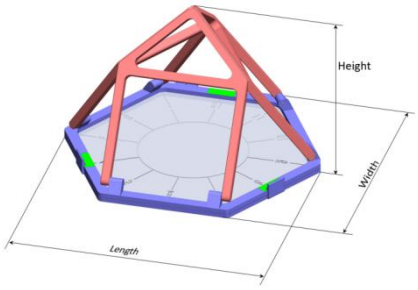
1) When using the specimen container, it is recommended to place the specimen into the specimen bag first and then insert the specimen bag into the container. This precaution helps prevent tissue from inadvertently falling into the cabinet or becoming contaminated due to accidental dropping.
2) After using the specimen holder, there may be microbial residue present. It is important to dispose of the holder as medical waste following use.
3) The imaging area is defined by the central circle marked on the cover of the specimen holder.
4) The maximum weight capacity of the holder is 0.20 kg.
5) The specimen container has a quality guarantee period of 2 years.

1.12.5 Specimen Holder Specifications

1) The net size of folded specimen holder is less than 250mm x 250mm x 100mm (length x width x height) as below:



2) The net size of open specimen holder is less than 250mm x 250mm x 200mm (length x width x height) as below:



2. Safe and Effective Use

The design and manufacturing of this system incorporate effective protective measures to ensure the safe and efficient use of the product, thereby preventing any harm under normal operating conditions.

Prior to using this system, users are strongly advised to meticulously read and comprehend both the system and its accompanying user manual. Throughout the product's lifecycle, operational procedures and maintenance should strictly adhere to the guidelines outlined in the manual.

The company will not be held liable for any harm resulting from user error, unauthorized modifications, or failure to adequately maintain the equipment in accordance with the manual's specifications.

2.1 Environment Conditions

2.1.1 Environment Conditions for System

The system should be operated, stored, or transported within the parameters as shown in the table. Either its operational environment must be constantly maintained or the system must be turned off.

	Operation	Storage	Transport
Temperature	+10℃– +40 ℃	-10℃– +55℃	-10℃– +55℃
Humidity	35%- 80% non-condensing	10% – 90%	10% – 90%
Pressure	80 kPa – 106kPa	70 kPa – 106kPa	70 kPa – 106kPa

2.1.2 Environment Conditions for Specimen Container

The container should be operated, stored, or transported within the parameters as shown in the table:

	Operation	Storage	Transport
Temperature	+10℃– +40 ℃	-10℃– +55℃	-10℃– +55℃
Humidity	35%- 80% non-condensing	10% – 90%	10% – 90%
Pressure	70 kPa – 106kPa	70 kPa – 106kPa	70 kPa – 106kPa

2.2 Protection against X-ray Radiation

This system needs to generate X-ray radiation in the process of achieving the intended use, and leakage of X-ray radiation will be dangerous to personnel. The emitted X-radiation of TrueView 200 Pro-US meets the requirements of IEC60601-2-091 Clause 12.101.1. The radiation emitted from the system did not exceed 5 μSv/h at any point 50 mm outside the external surface. The user does not need special protection under normal use..

NOTE: ***It is strictly forbidden to disassemble equipment , please contact the maintenance engineer if necessary.***

It is imperative to strictly adhere to the radiation protection regulations and the specific requirements outlined in this manual to prevent harm to the operator.

It is essential that all authorized individuals who operate and maintain the system understand the risks associated with X-rays and have acquired the necessary training to proficiently handle relevant knowledge.

2.3 Protection against the Risk of Electric Shock

Upon powering on the system, the equipment components carry hazardous voltage, and improper use or maintenance may result in electric shock.

It is strictly prohibited to dismantle the protective shells of equipment components while the power is on or to activate the system after removing these protective shells to mitigate the risk of electric shock.

It is strictly prohibited to clean the components of the equipment when the system is powered on.

When cleaning the interior of the imaging cabinet, it is advisable to use a slightly damp cloth to prevent dripping. When cleaning the equipment surfaces, precautions should be taken to prevent liquids from entering the components to avoid electric shock and preserve the product's fundamental performance.

2.4 Protection of Equipment

a） It is strictly forbidden to disassemble the shells of equipment parts such as high-voltage generators, X-ray tubes, X-ray flat panel detectors and computers without authorization to avoid the risk of electric shock;

b） It is strictly forbidden to connect other equipment to this system, or install other software into this system, so as not to cause safety hazards and affect the basic performance of the system;

c） It is strictly forbidden to hit or collide with the components of the system, and it is strictly forbidden to disassemble the mechanical connection devices of the system to avoid damaging the equipment;

d） The environmental conditions for storage and use of the system should meet the requirements specified in this manual, so as to avoid inappropriate environmental conditions affecting the basic performance of the product or leading to early failure of product functions;

e） It is strictly forbidden to modify the software and the hardware of this system, so as to avoid safety hazards affecting the basic performance of the product;

f） The X-ray flat panel detector should be properly protected. It is strictly forbidden to press or touch the imaging area of the X-ray flat panel detector with a hard object, so as to avoid damaging the X-ray flat panel imaging area leading to deterioration or loss of the basic performance of the product;

g） In any case, it is strictly forbidden to move the X-ray tube and X-ray flat panel detector. After the installation and calibration of the system is completed, the geometric parameter value is fixed, and the software configuration file is entered. Any movement to it will cause the basic performance of the product to be reduced or lost.

h） As the system is intended to be used in a hospital environment, there is no special protection for liquid entering the equipment parts. When storing, using, maintaining and cleaning the equipment, users should pay attention to avoid the liquid entering the equipment parts, so as not to cause electric shock danger and affect the basic performance of the product.

In any case, if an unexpected event mentioned in a) ~ h) occurs, please contact the manufacturer to perform professional maintenance and verification of the system.

The company shall not be liable for the losses and legal liabilities caused by users who violate the above requirements.

2.5 Information Security

The integrity and availability of the product’s cybersecurity features are taken into consideration based on the product’s intended use, environment for use, and core functionality. The following main measures (see Cybersecurity Overview for details) are required as product inputs to be controlled by design, including the identification of product inputs, and related testing processes and results, all of which are included in the design control process and currently have met the requirements. Specific design inputs, design verification and definite evidence are detailed in the Document of Risk Control Analysis.

- The system should disable unnecessary software

- The system should keep the Principle of Least Privilege
- No command-access rights
- Customization of software update method and strategy
- System integrity check
- External storage media control
- Health information control
- Backup and restore strategy
- User Access Control (UAC)
- Audit Control
- Port Access Policy
- Physical Interface Locking Policy
- Network transmission protection

2.6 Precautions for Operation

2.6.1 Check before Use

The pre-use inspection includes pre-power-on inspection, power-on process inspection, and exposure inspection, as follows:

a） Check before Starting

Before turning on the power, the user should carefully check to make sure that the device is in good condition. Do not power on the system if it is found that the device covering is removed, the cable is disconnected (including the ground wire), or the insulator is damaged.

b） Check during the Boot Process

Turn on the hardware components of the system in the order specified in the 4.2 system startup process, and check during the startup process:

- After the device is started, check whether the power indicator of the device is on;

c） Exposure Check

After the system is powered on, use the TrueView 200 Pro-US software to verify:

- Whether the system can normally complete exposure and imaging operations;
- Whether the image is blocked by foreign objects;
- Whether the image quality is clear.

NOTE: Before the exposure inspection, make sure that the cabinet door is closed.

If any problems are found during the above inspection process, trained professionals should follow the relevant instructions on system repair and maintenance in this manual to eliminate the problems before applying them to the clinic.

If the user is not competent to solve the problem, please contact the manufacturer to provide technical support.

2.6.2 Special Instructions for Operation

a） Precautions for Clinical Application

During clinical use, specimens cannot be placed directly on the specimen tray or specimen holder. Please place the clinically collected specimens in a specimen bag or container first, and then place the specimen bag or container on the specimen tray or specimen holder.

b） Prevent X-ray Tube Damage due to Overheating

In the case of frequent exposure, the X-ray tube may be damaged due to overheating and high temperature. To prevent this from happening, the manufacturer prompts:

When the system detects that the X-ray tube is overheating, the exposure operation will be prohibited.

The system monitor displays the status of the X-ray tube in real time. When the temperature reaches the critical value of the device, the software "Exposure" button will be disabled and the user will not be able to perform the exposure operation. At the same time, the Fault Condition column of the software interface will display the true status, as shown in Figure 2.1.

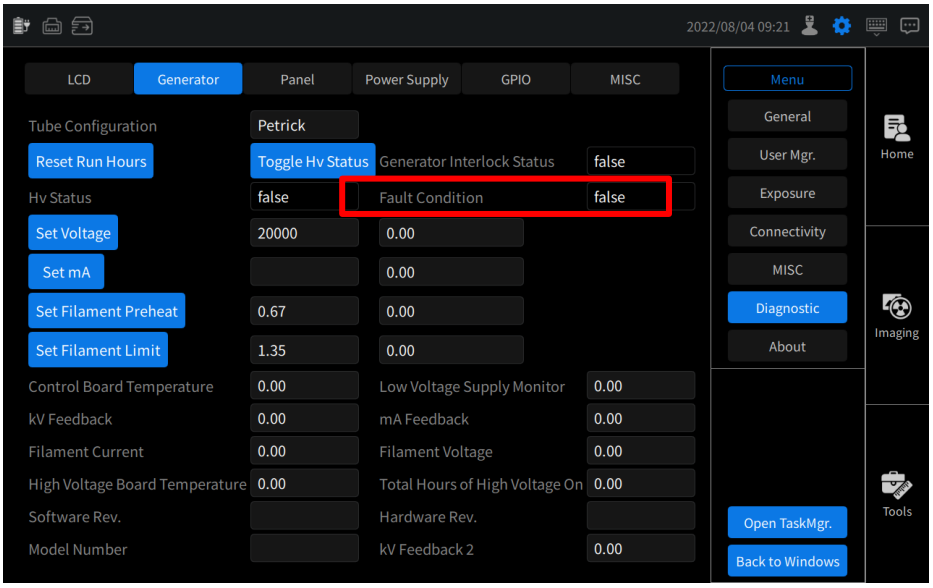


Figure 2.1 Related parameters and status feedback of the generator

At this piont, the user needs to wait for the temperature of the X-ray tube to cool down before continuing to work. The cooling time is determined by the environmental conditions. Once the system detects that the temperature of the X-ray tube drops to a normal state, the system will release the alarm and resume the working state.

c） Smoke or Fire from the Equipment

If it is found that the device emits smoke or fire during use, the user must immediately turn off the device power button and unplug the network power cable.

The sealed device must not be used. Contact the manufacturer for fault diagnosis and repair. It is strictly forbidden to turn on the device again until the fault is not resolved.

2.6.3 Shutdown

Operators should turn off the hardware components and system power before leaving work to extend the service life of the system and prevent unpredictable accidents.

For the operation sequence of shutting down the system, see 4.3 System Shutdown Process.

2.6.4 Noise

The noise-producing parts of this system are speakers. If you hear an abnormal sound from the speakers, you should immediately turn off the power button of the device and contact the manufacturer for troubleshooting.

2.7 System Defect and Limitation

As our software is based on the Windows, it is unavoidable to encounter crashes, slow response and other situations when it is unable to operate. It is recommended to restart the device by pressing the power button which can shut down and restart the system. If it fails, the user can unplug the power cord to force the system shutdown, and then restart.

2.8 System Maintenance

The safe and effective application of this system depends on the basic performance of the product. Using the product in an abnormal state of the system may cause unexpected consequences.

The user should maintain the system according to the requirements of Chapter 6 of this manual. Please contact the manufacturer for replacement of the system's accessories, and consumables.

2.9 Decommissioning and Resuming Use

When the system has been shut down for a long time, its environmental conditions should meet the storage conditions specified in this manual to ensure that the basic performance of the system is maintained.

When the period of deactivation is over three months, the system should be calibrated and maintained before resuming use.

2.10 Environmental Protection

2.10.1 About the Disposal of Waste Electronic Articles

This system contains electronic components such as electronic circuit boards and capacitors. When the service life of equipment parts or systems is over, these components or materials are harmful to the environment. Please do not dispose of these components or materials as ordinary garbage. Disposal should follow the legal requirements of the country / region where it is located.

The user can contact the manufacturer to recycle all the scrapped components and parts including electronic waste in this system, and the manufacturer will dispose of them in accordance with the regulations.

2.10.2 Insulating Oil

The X-ray tube device contains insulating oil for stable high voltage, and its sealing device is designed and manufactured to ensure that no leakage will occur under normal circumstances.

Due to the hazardous nature of insulating oil that pollutes the environment and harms human health, discarded or leaking insulating oil due to accidents should be disposed of in accordance with the regulations of the country / region where it is located.

3. Installation and Configuration

3.1 Installation Preparation

1) Power Condition Preparation

Input Voltage: 100V-240V~

Input Power: not less than 500W

Frequency: 50/60 Hz

2) Floor Space Preparation

The minimum floor space should be prepared is: 800mm (length) * 700mm (width) * 1800mm (height).

Minimum load weight: 200kg.

Due to the volume of the product itself, it is necessary for the hospital to provide the corresponding site conditions as a prerequisite.

3) Temporary Installation Area Condition

The minimum installation area should be prepared is: 3m (length) * 4m (width).

NOTE: ***TrueView 200 Pro-US is all-in-one and includes shielding that is incorporated within the cabinet chamber system design, eliminating the need for separate shielding.***

3.2 Installation Process

The total installation process should be done by qualified personnel. Process in detail can be found in the service manual.

NOTE: ***The installation of the device and software should be done by the qualified and professional person of the manufacturer.***

NOTE: ***The content of this chapter is only as the reference for the user of this system to strengthen the understanding of the structure and performance of the equipment.***

NOTE: ***Please read the manual carefully before installing.***

Unqualified personnel are prohibited from the system installation. Any accident caused by it would be investigated and affixed legal liability.

3.3 System Configuration

After the installation finished, connect the power supply and then power on the system.

3.3.1 System Self-Check

Upon powering on the system, the operating system will automatically initiate the specialized software designed for initial hardware connection checks. The touch screen and system monitor will concurrently display the status of the hardware link, indicating whether it is functioning normally.

3.3.2 System Information Check

a) Login the system (detail refer to section5.1), click the (Utility button) in the upper right corner, then click the “About” button, and the system information will be shown, see Figure 3.3- 1.

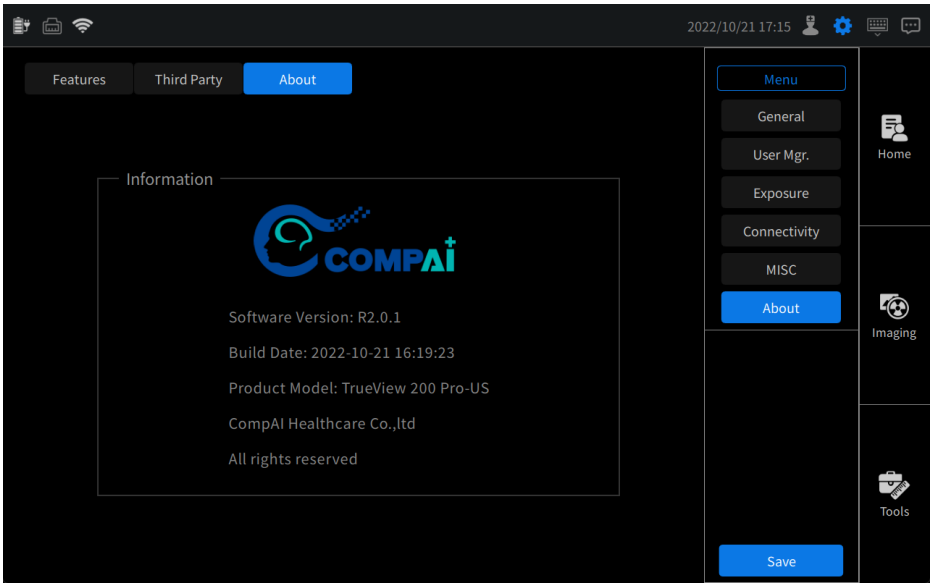


Figure 3.3- 1 The system information page

b) Check system function options, check “Features” to switch to the page, check the option keys and their validity period (Function keys can be added together or separately, but it is recommended to add them one by one for the convenience of functional key management in the future), see Figure 3.3-2.

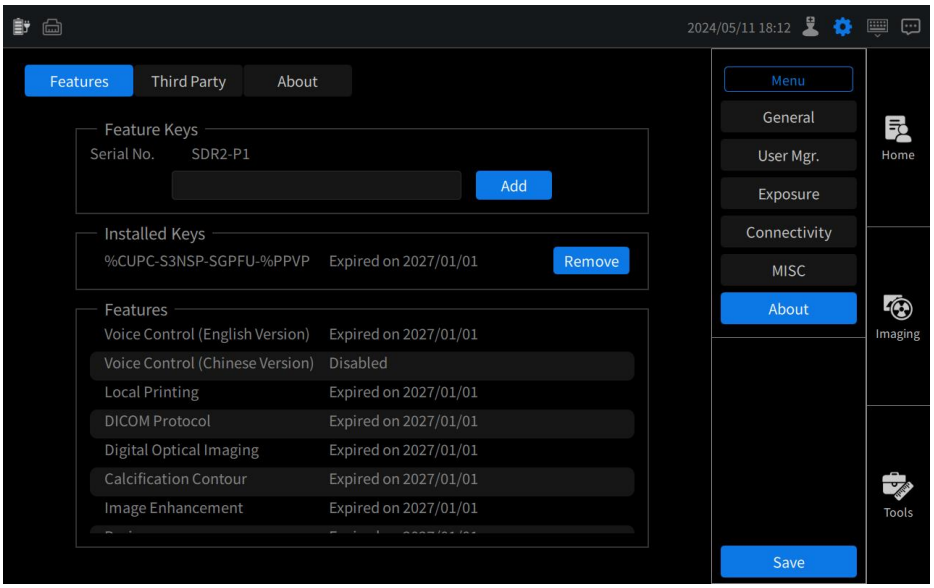


Figure 3.3- 2 The system function options page

3.3.3 General Setting

3.3.3.1 System Setting

Click  (Utility button) in the top right corner, then click the “General” button. The system setting page Figure 3.3- 3 is shown as follow.

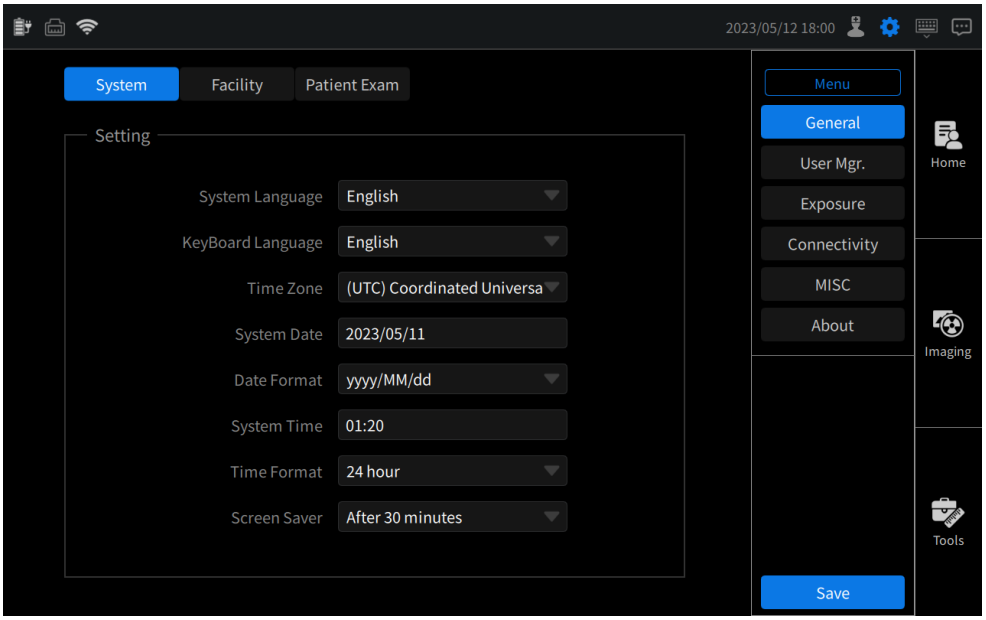


Figure 3.3- 3 The general settings page

- System Language: Set system language to English or Chinese;
- Keyboard Language: Set keyboard language;
- Time Zone: Set time zone;
- System Date: Set system date；
- Date Format: Set date format, the date format options are “dd/MM/yyyy”, “MM/dd/yyyy” and “yyyy/MM/dd”;
- System Time: Set system time；
- Time Format: Set time format, time format options are “12 hour” and “24 hour”;
- Screen Saver: Set the interval of screen saver, the interval options are "After 10 minutes", "After 30 minutes", "After 1 hour", "After 3 hours", "After 8 hours" or "Never".

After setting all items, click “Save” button. Restart the software, then the system will execute according to the current settings.

3.3.3.2 Facility Setting

Click the “Facility” button beside the “System” button. The facility setting page Figure 3.3- 4 is shown as follow.

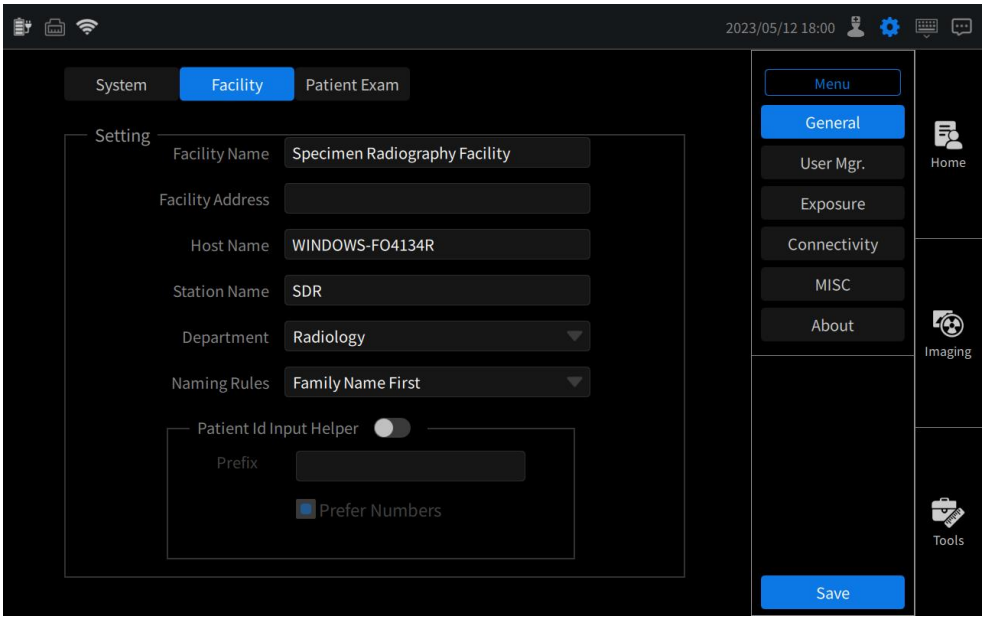


Figure 3.3- 4 The general facility settings page

- Facility Name: Set the facility name; ***Note: Only the ADM user is authorized to change the facility name***;
- Facility Address: Enter the facility address;
- Host Name: Host name is shown accordingly; it is not recommended to change host name;
- Station Name: The default station name is SDR; it is not recommended to change station name;
- Department: Set department to breast surgery, laboratory dept or radiology.

After setting all items, click “Save” button. Restart the software, the system will execute according to the current settings.

3.3.4 Connectivity Setting

Click the “Utility” button in the top right corner and then choose the “Connectivity” button. The connectivity setting page (Figure 3.3- 5) is shown as follow.

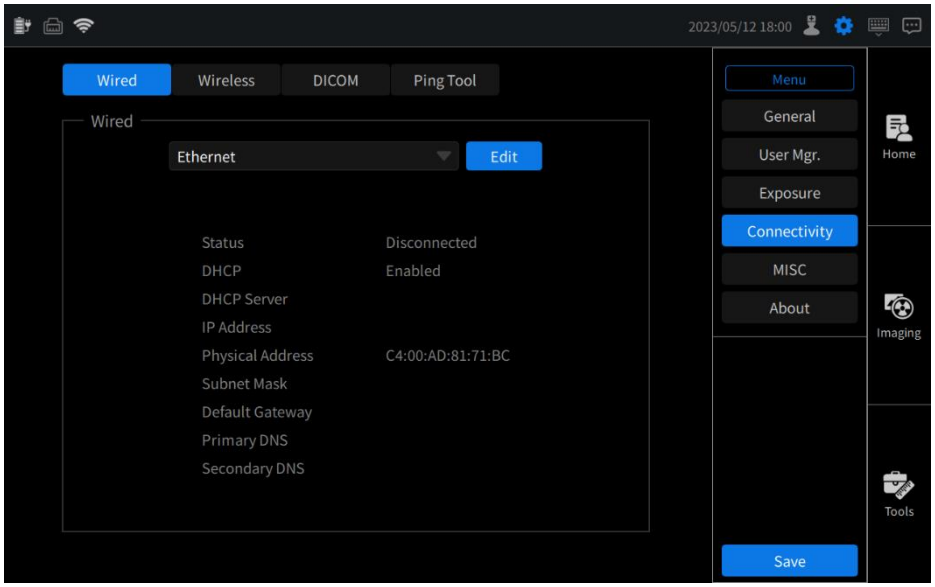


Figure 3.3- 5 The connectivity setting page

a） Wired Network

Please follow these steps to connect the device to the network:

1. Insert the network cable into the network port located at the rear of the device.

2. Click on the “Wired” button to access the network settings. Verify the IP address and connection status, which will be displayed on the touchscreen. The default wired configuration is set to DHCP (refer to Figure 3.3-6).

3. If manual network configuration is required, click on the “Edit” button and select “Manual” to establish the network connection (refer to Figure 3.3-7).

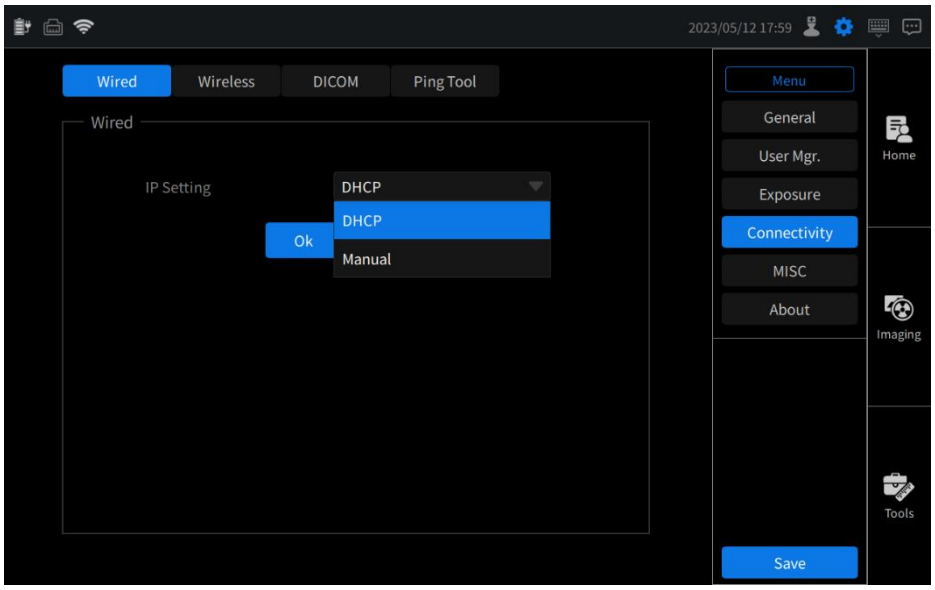


Figure 3.3- 6 The wired network connection page for DHCP

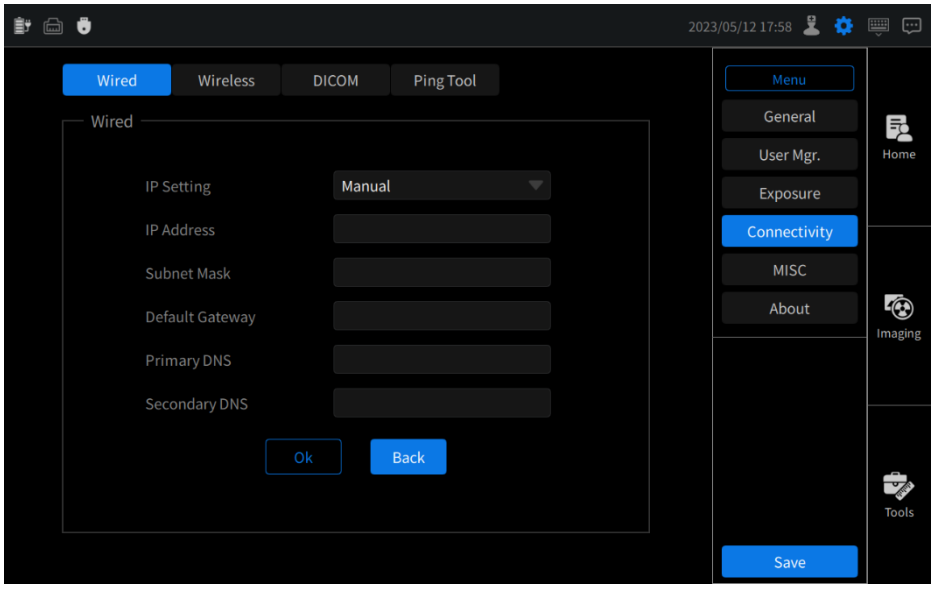


Figure 3.3- 7 The wired network connection page for Manual

b） Wireless Network

Plug the wireless card into the USB port under the monitor or behind the device, click “Wireless” button, then click “Scan” button, and then the screen will display all currently WIFI hot spots you can connect as shown in the Figure 3.3- 8.

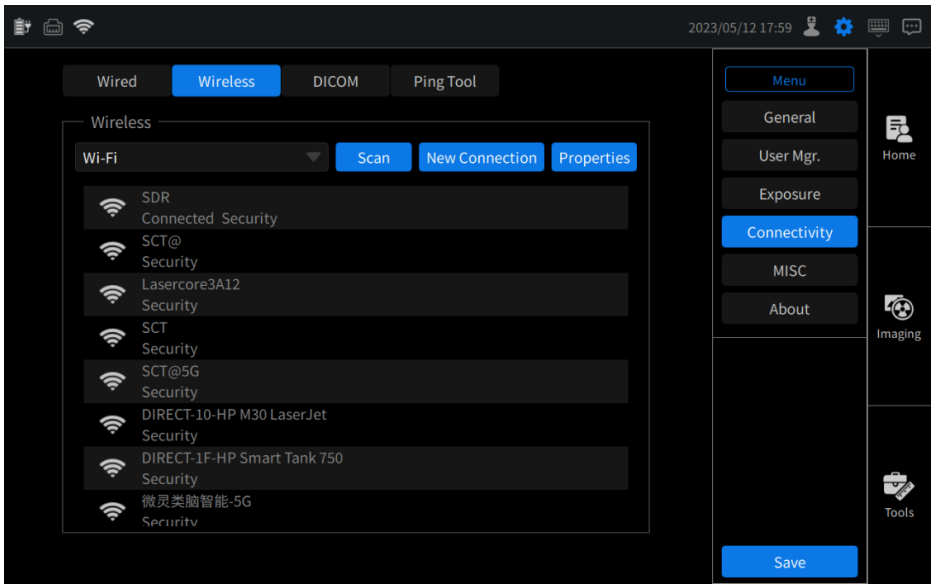


Figure 3.3- 8 The Wireless function page

Select a hot spot name, click “Connect” button, enter correct passphrase, then click “Connect” button again (see Figure 3.3- 9), and wireless network connects successfully.

Caution: Do not connect the suspicious hot spot to avoid possible data leakage or other cybersecurity issues.

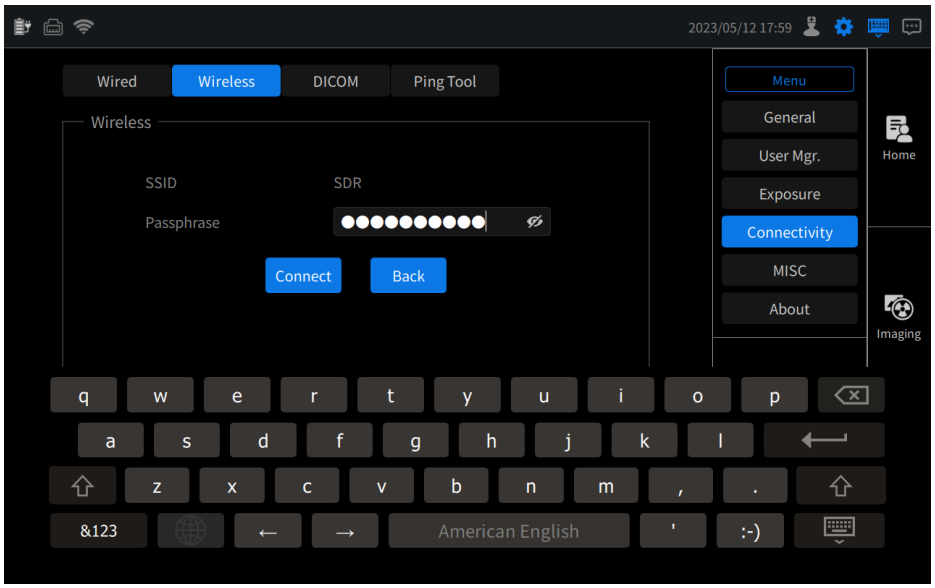


Figure 3.3- 9 The wireless network connects

c） DICOM

Click “DICOM” button, you can configure the DICOM worklist connection, MPPS connection, DICOM PACS connection, DICOM print connection, DICOM query and DICOM retrieve, the configuration page Figure 3.3- 10 as follow.

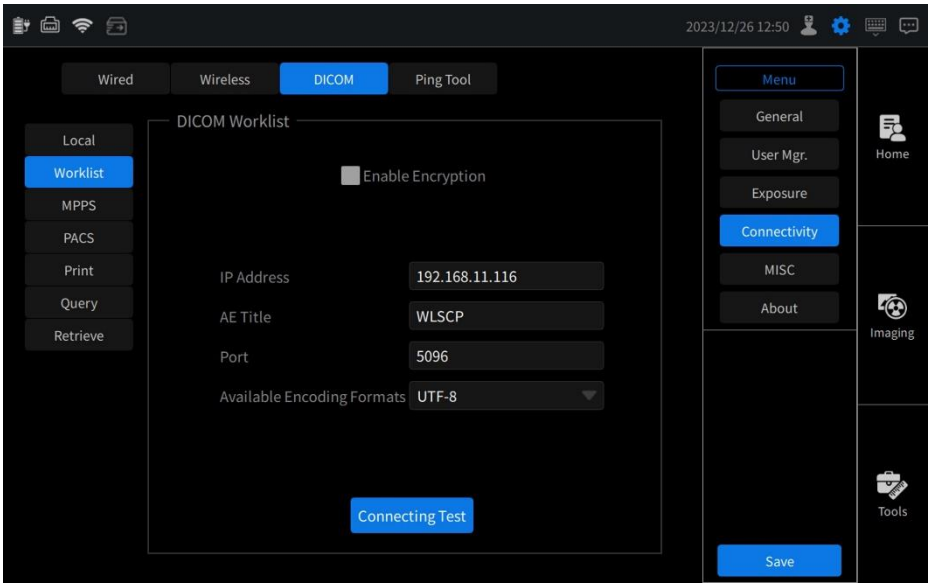


Figure 3.3- 10 The DICOM configuration page

Enter IP address, AE Title and Port number of the PACS server, and click the “Connection Test” button to check the test results. If the connection fails, you can use the Ping tool to diagnose whether the IP address is connected or not.

The operation procedure of the DICOM PACS connection, DICOM MPPS connection, DICOM print connection, DICOM query and DICOM retrieve can refer to the DICOM worklist connection.

d） Ping Tool

Enter IP address of PACS server, click “Ping” button as shown in Figure 3.3- 11, and check whether the communication between the system and the PACS computer is normal.

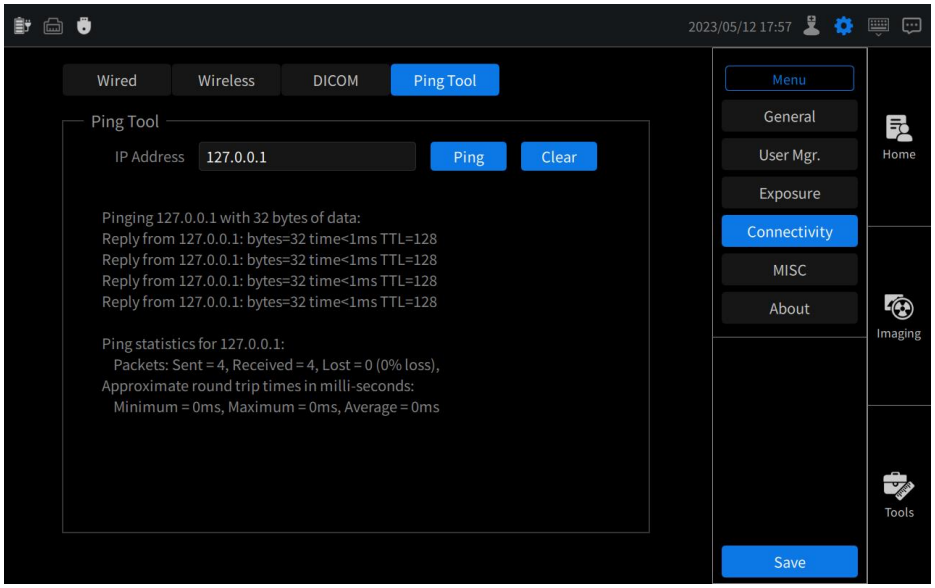


Figure 3.3- 11 The Ping Tool function page

3.3.5 Barcode Reader Settings and Use

a） Barcode Reader Settings

Click the “Utility” button in the top right corner and then click the “MISC” button. When the barcode reader is enabled, you can set the “ReadTo” as “Patient ID (Local)”, “Patient ID (Worklist)” and “Accession Number (Worklist)”, the configuration page is shown in Figure 3.3- 12.

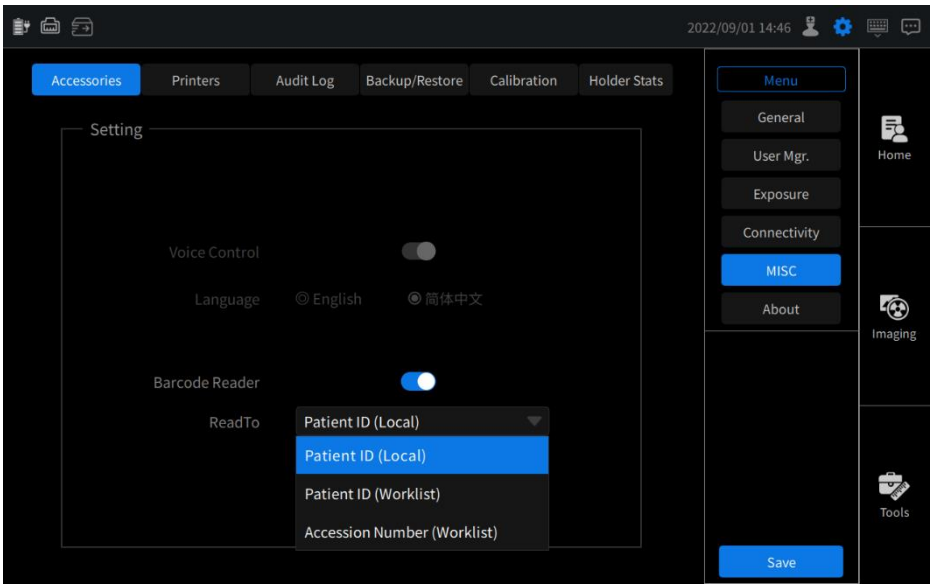


Figure 3.3- 12 The Barcode reader setting page

b） Barcode Reader Use Methods

Plug barcode reader to the system and set the “ReadTo” as “Patient ID(Local)”, enter “Home-New patient” page, click Patient Id and scan the code with a barcode reader as shown in Figure 3.3- 13.

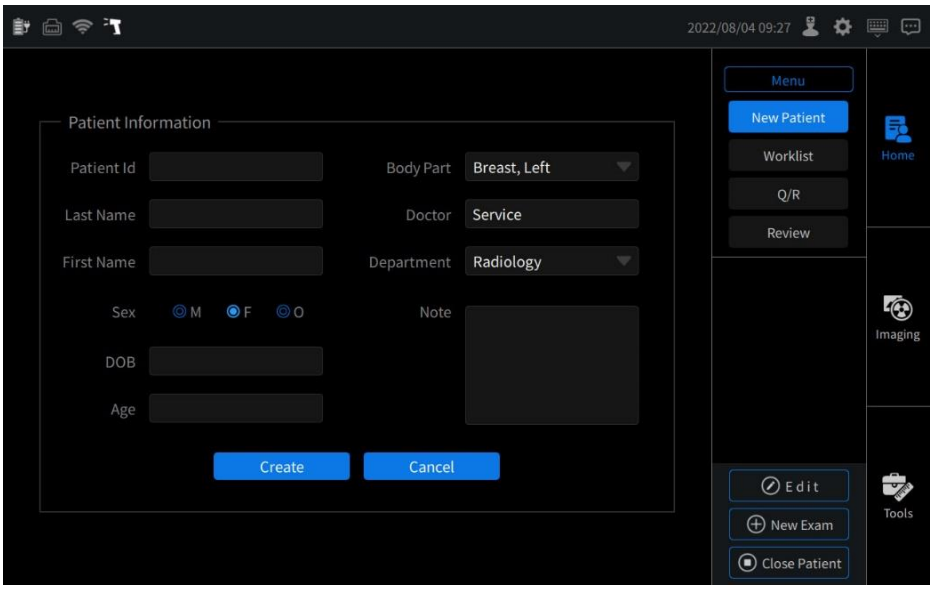


Figure 3.3- 13 The patient ID input via the Barcode reader as a New Patient

Set the DICOM worklist connection and make sure that the system is connected to the DICOM server. Plug barcode reader, set the “ReadTo” as “Patient ID(Worklist)” or “Accession Number

(Worklist)", enter "Home-worklist" page, scan the code with a barcode reader as shown in Figure 3.3-14.

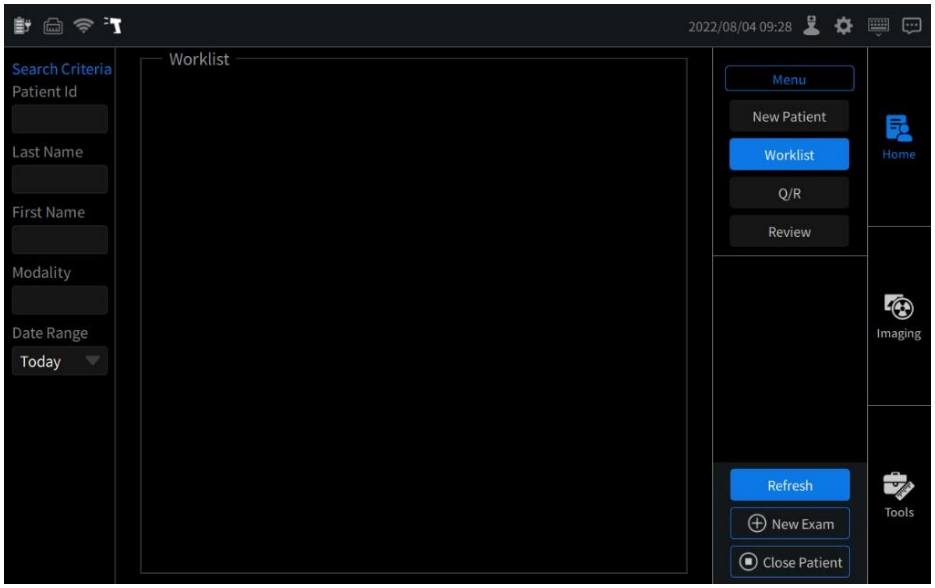


Figure 3.3- 14 The patient ID input via the Barcode reader as Worklist

4. Control System Operation

The proper functioning of this system requires the initialization of hardware devices such as high-voltage generators and flat panel detectors. This initialization process involves the seamless coordination between software and hardware components to ensure the completion of the entire procedure. Through the software, the system can effectively control the high-voltage generator, X-ray tube, and X-ray flat panel detector, while also providing important information to the user.

This chapter primarily focuses on elucidating the operation rules and precautions pertaining to the control system and its various components.

4.1 Control System Function Keys and Indicators

4.1.1 Power Button and Indicator

A physical power button is in the upper right corner of the equipment operation console, with a halo indicator in the middle. As shown below:

Figure 4. 1 Physical power button

When pressing this button, the button will be concave. After the system is normally powered on and started, the middle green halo indicator will be lit, as shown in the Figure 4. 2:

Figure 4. 2 Physical power button with green halo indicator lit

4.1.2 X-ray Exposure Indicator

An exposure indicator is set on the front panel of the device, as shown in the following figure:

Figure 4. 3 X-ray exposure indicator

As the exposure continues, the exposure indicator lights up in a yellow halo, as shown in the following figure:

Figure 4. 4 X-ray exposure indicator lit

4.2 System Startup Procedure

4.2.1 Check before Starting

Before turning on the system, make a routine check of the system:

- The electrical equipment covering should be properly tightened, placed in a normal position, with the appearance not being damaged;
- The cables should be connected normally, and its appearance should not be damaged;
- The mechanical devices should be properly tightened and its appearance should not be damaged.

When an abnormal situation occurs during the inspection, the maintenance personnel should be notified in time to avoid system failure.

4.2.2 Startup Steps

To initiate the system after confirming its readiness, follow these steps:

a) Activate the System:

Press the power button to switch on the system. Upon startup, the software operating system login interface will be displayed on both the system monitor and touchscreen.

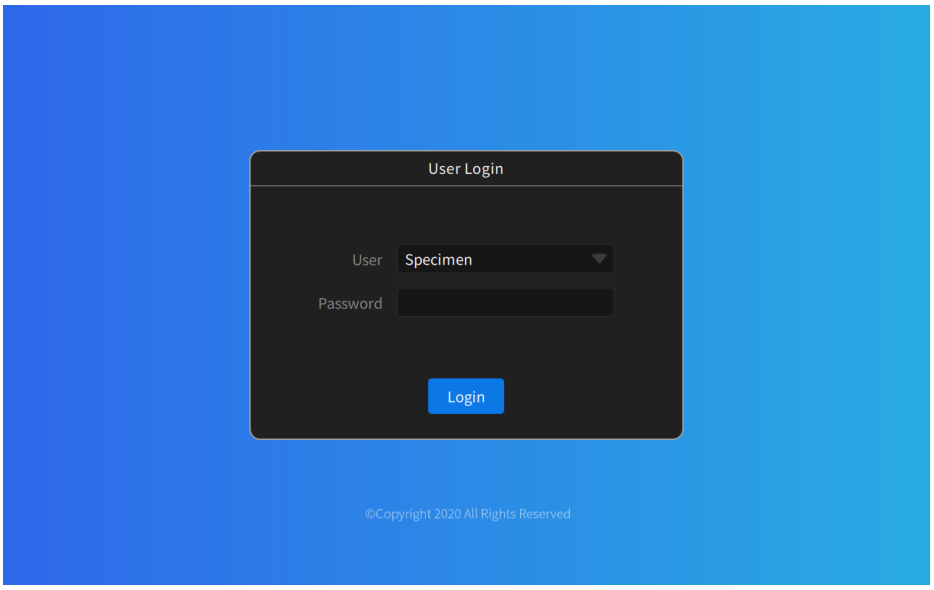


Figure 4. 5 Software login interface screens

NOTE: In the event that the user logs in quickly after system startup, the imaging page may display "Panel is connecting." After a brief delay, the connection will automatically establish successfully.

b) Software for TrueView 200 Pro-US Started

Upon system startup, the specialized software for TrueView 200 Pro-US is automatically launched by the operating system.

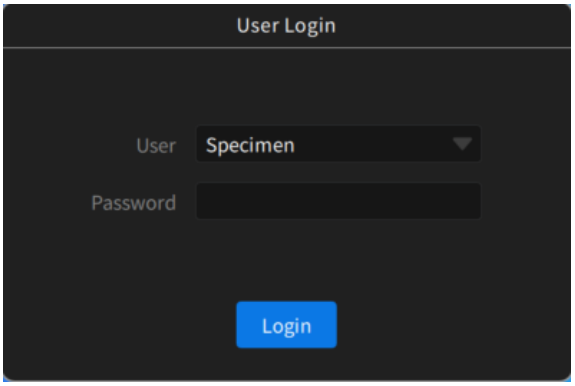


Figure 4. 6 Login interface

c) Status on the Software Interface

——A red bar signifies an error, indicating that the system has detected an error condition.

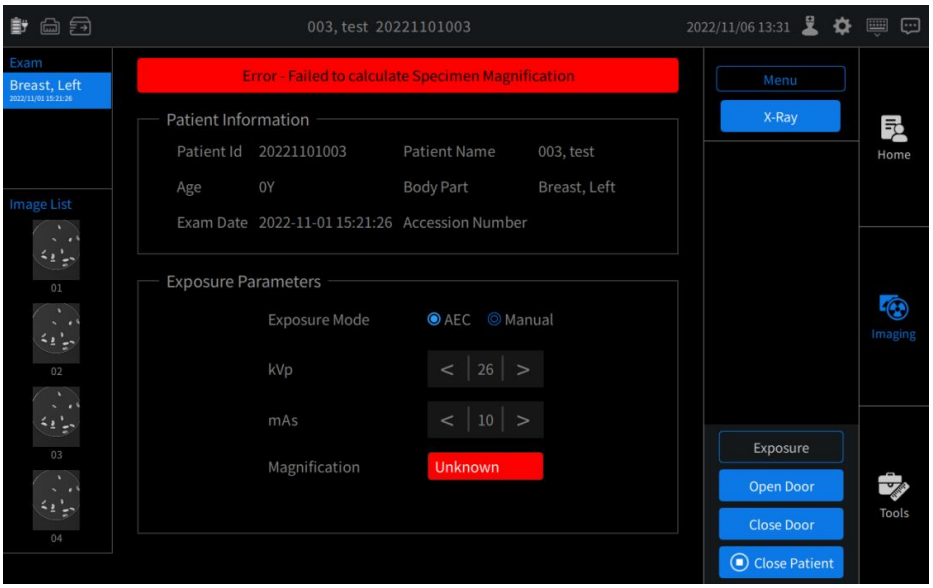


Figure 4. 7 The system is detecting an error

——A yellow bar indicates a warning, signifying that the system is not prepared for exposure.

For example, the software cannot perform exposure because cabinet door is open.

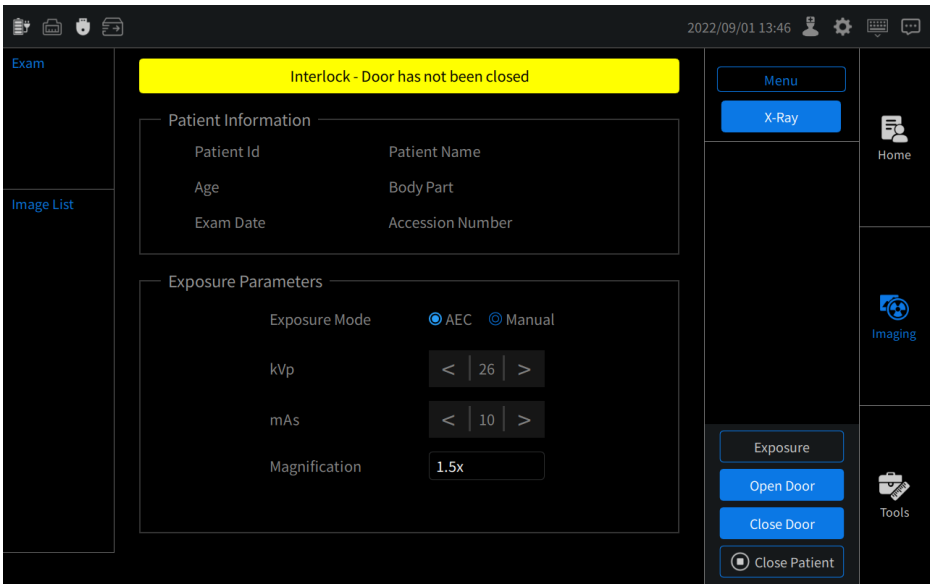


Figure 4. 8 X-ray cabinet door has not been closed

——A green bar signifies that the system is ready, indicating that exposure can be utilized for image acquisition.

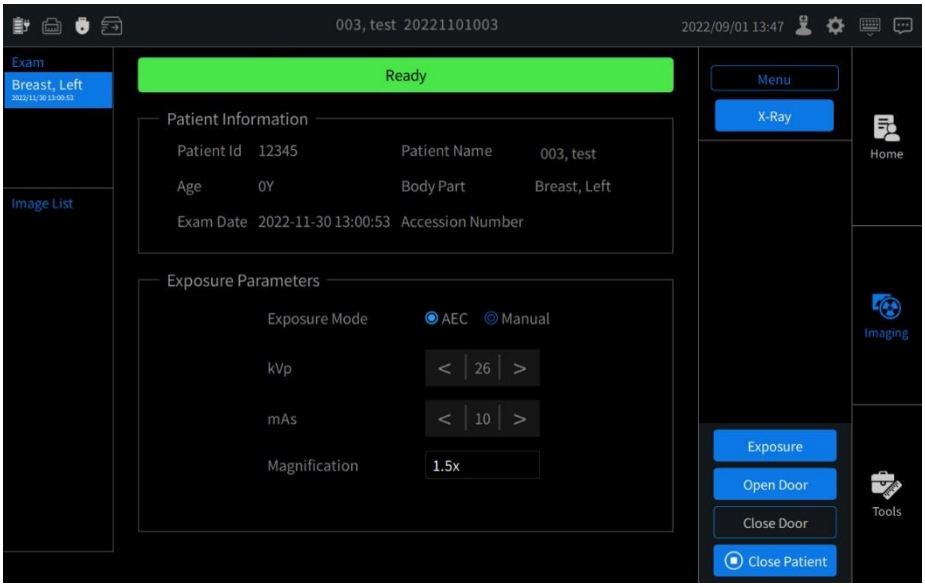


Figure 4. 9 X-ray system ready indicator

4.3 System Shutdown Procedure

To shut down the system, follow these steps:

a) Turn off the System

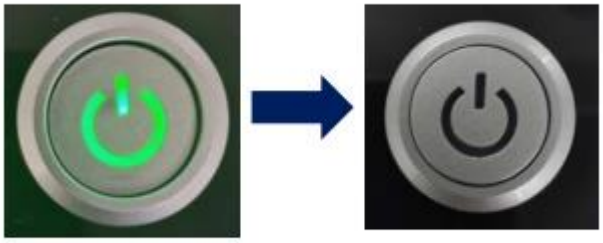


Figure 4. 10 Power button

To power down the system, follow these steps:

1. Press the power button and then release it.
2. Set the power button to the OFF position.
3. The software for the system will exit, initiating an automatic shutdown of the control computer and other components. ***Note: It is advisable to wait for at least 5 seconds before restarting the system after it has been powered off.***

5. Software Operation

After the system starts normally (see 4.2.2), the user login interface will be automatically displayed on the touchscreen. The software operation of the TrueView 200 Pro-US will be performed by using the touchpad, the touchscreen, and the monitor as seen in Figure 5. 1 (Note: For this chapter, screen shots with a green border represent the touchscreen, while those with the blue border are for the system monitor.).

5.1 General Layout of Interface

The TrueView 200 Pro-US software features two primary user interfaces. The touchscreen enables users to select icons, buttons, and provides a virtual keyboard interface for entering textual information. Additionally, the touchpad allows for the selection of icons and buttons displayed on the screen.

The initial step to access the software involves the user logging in.

Figure 5. 1 TrueView 200 Pro-US login in screens on the system monitor and the touchscreen

This document will use the convention that screens with a blue border are displayed on the system monitor, while screens with a green border are on the touchscreen.

5.1.1 Login

The system categorizes users into three levels based on their roles. Users are required to select the appropriate user role corresponding to the task they intend to perform and then proceed with logging into the system. The ADM user assumes the administrative role within the system, Specimen users represent clinical users, and Service users are exclusively designated for factory authorized technicians. Each system will have one ADM user and one Service user, while the number of Specimen users can vary as needed. In

Figure 5.2, the default users - ADM, Specimen, and an additional Specimen user - are displayed in the user pull-down menu on the login screen. ***It is important to note that the Service user's functionalities, reserved for factory authorized technicians, are not covered in this manual.***

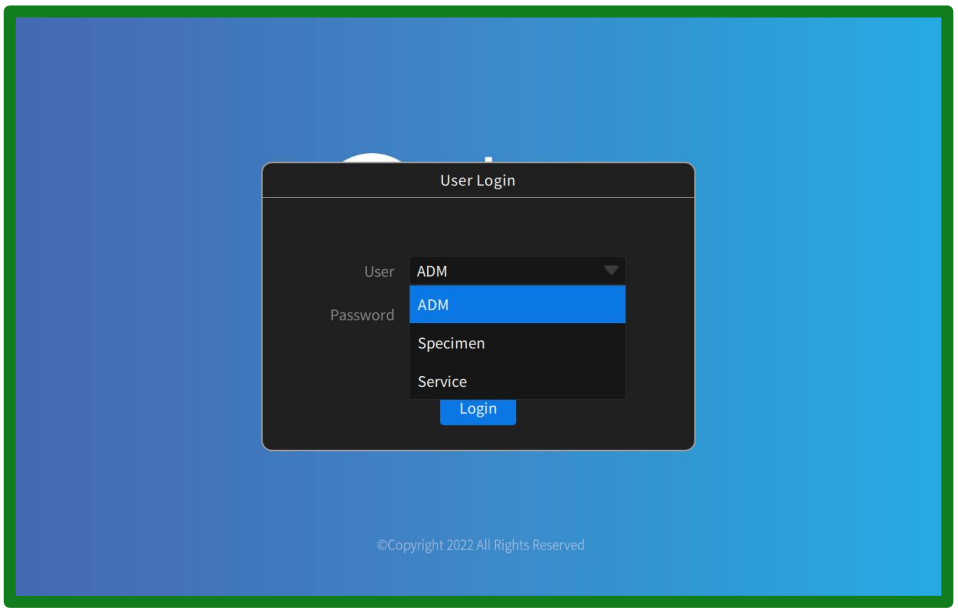


Figure 5. 2 TrueView 200 Pro-US login screen with user pulldown menu shown

To Login:

1. Use the touchpad or the touchscreen to select the pull-down menu of users, and then select the appropriate user for the planned task.

2. Use the touchpad or the touchscreen and select the Password text input box. A blinking cursor will appear in the text box, and the touchscreen will display a keyboard for the user to enter the password (see Figure 5.3).

3. Use the touchpad or the touchscreen to select the “Login” button and the system will display the home screen on the touchscreen and the image review interface on the system monitor.

If the wrong password is entered, a message indicating failure to login in due to error password will appear (see Figure 5. 4). Use the touchpad or the touchscreen to select “OK” button to return to the login interface. Make sure that you have selected the correct user and that the correct password has been entered. Passwords are case sensitive, and if there is any question about the values entered, then select the Display

Password icon at the right side of the text box to show the entered values. If the correct values are entered and the login still fails, then contact the administrative user to reset the password.

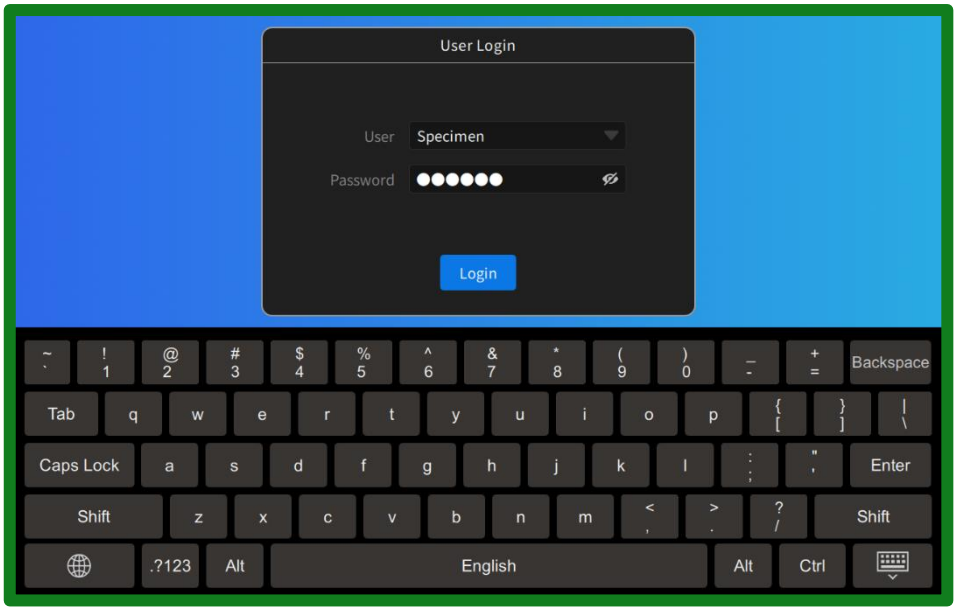


Figure 5. 3 Password input

Use the touchscreen keyboard to enter the user password and then select the “Login” button to complete the login procedure.

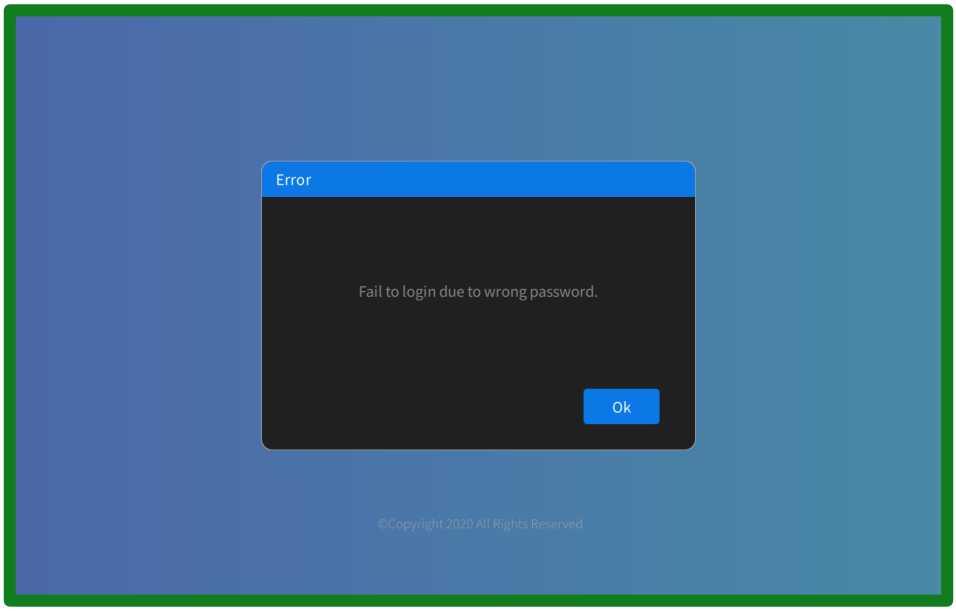


Figure 5. 4 Failure to login due to wrong password error message

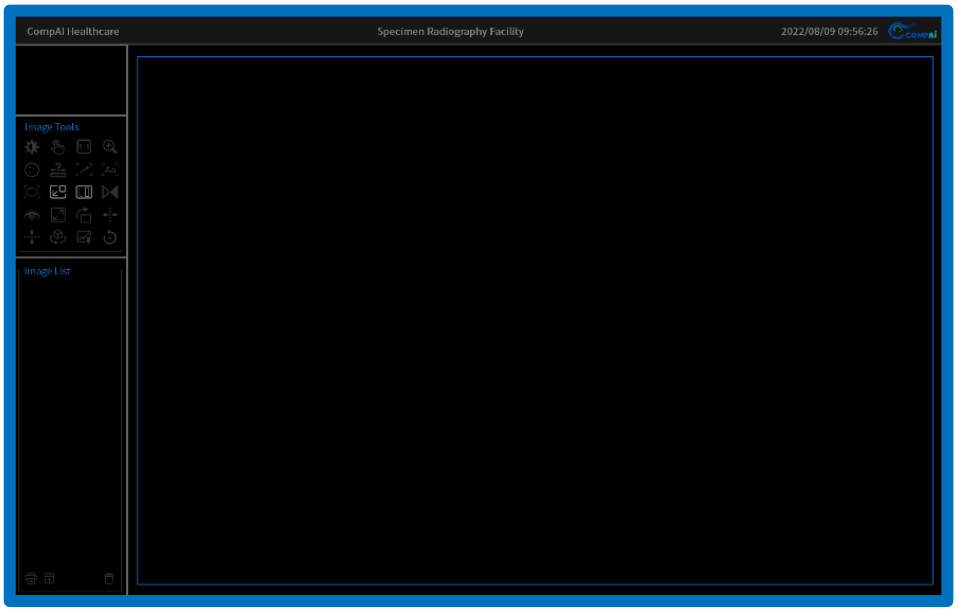
Upon successful login by the initial user, the system will present the default Home menu and system monitor screens. If a previous user had utilized the system and subsequently logged out, the system will restore the screens to the state at the time of the previous user's logout.

To conclude a session, a user can log out by selecting the user icon from the system information ribbon displayed on the touchscreen (refer to section 5.1.2.1.2 User Icon)

Caution: It is crucial not to disclose passwords to others, particularly the ADM password, to prevent potential data breaches or cybersecurity concerns.

5.1.2 Touchscreen General Layout

Following the initial user login of the system, the user will be presented the screens seen in Figure 5. 5.



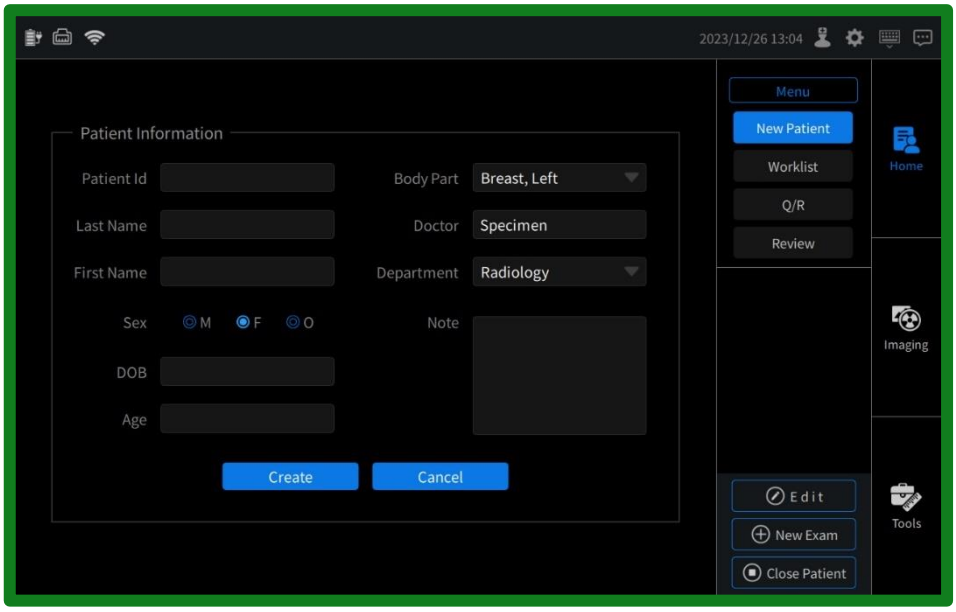


Figure 5. 5 Default display configuration of the system monitor (upper) and touchscreen (lower) of the software following initial login

The touchscreen seen Figure 5. 5 maintains the same general layout for all software operations of the system, except for user login. This layout is characterized by three distinct regions of the touchscreen: The system information ribbon (Figure 5. 6); the common workflow icons (Figure 5.14); and the system workspace (Figure 5. 8).

5.1.2.1 System Information Ribbon

The system information ribbon (see Figure 5. 6) displays the system status icons on the left (see Figure 5. 7), the currently open patient's name and ID in the middle (this area is blank if no patient is selected), and the time/date display and functional icons on the right (see Figure 5. 9).

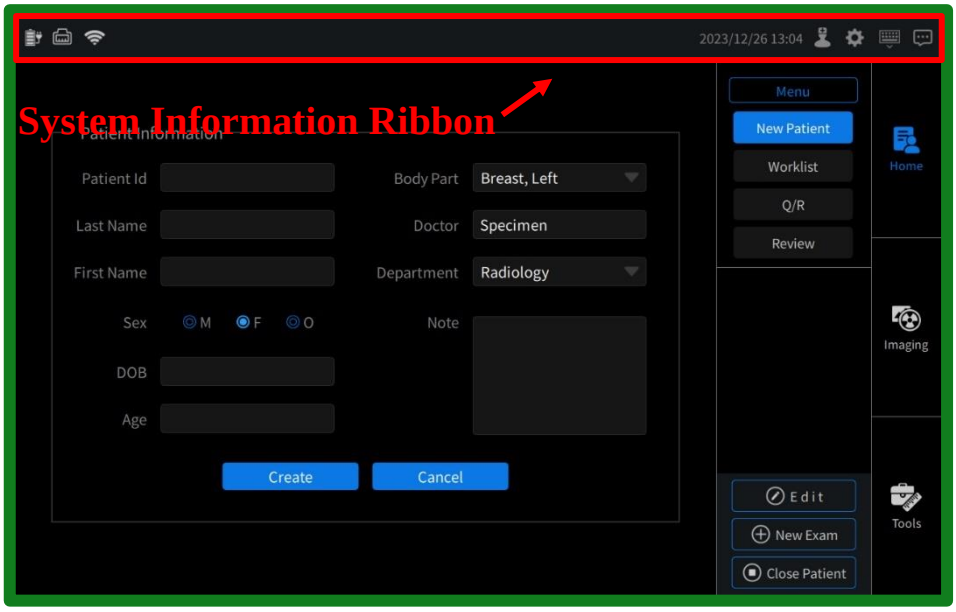


Figure 5. 6 System information ribbon of the touchscreen indicated by the red border

5.1.2.1.1 System Status Overview

The user can select any of the system status icons seen in Figure 5. 7 to display the system status overview screen. Figure 5. 8 highlights the system workspace with a red border, and shows an example of a system status overview screen in the system workspace. The user can review the status of the system power, driver component, network, safely ejecting a removable storage device, and review the details of the DICOM spooler queue. Since the system status icons of the system information ribbon act as a toggle between the current system workspace screen and the system status overview screen, the user can return to their previous system workspace screen by selecting any of the status overview icons of the system information ribbon.

Figure 5. 7 Example of system status overview icons

This display can change depending on the overall configuration of the system, but selecting any one of the icons in this area will bring up the system status overview page on the touchscreen.

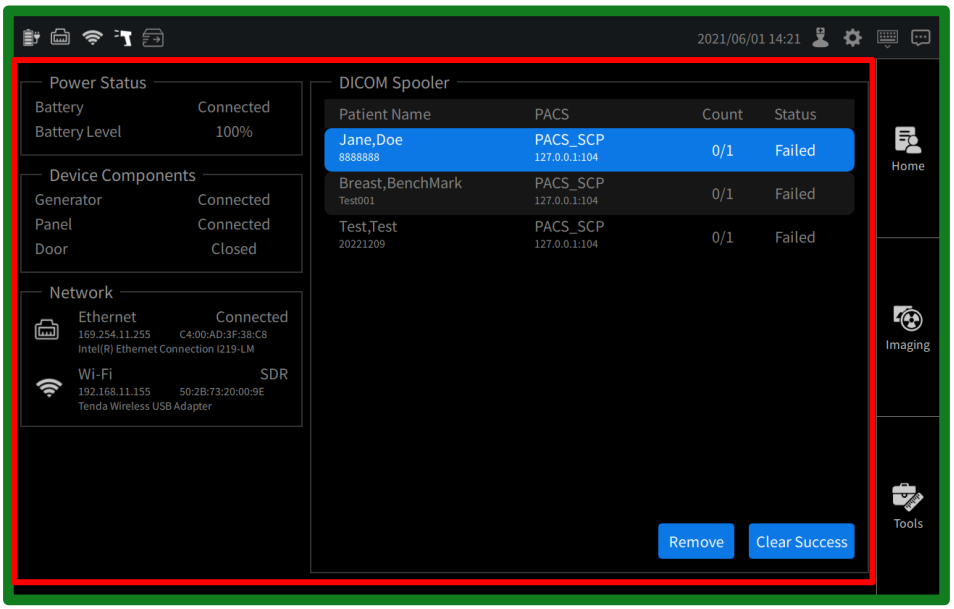


Figure 5. 8 Example of a system status overview screen appearing in the system workspace (system workspace indicated with a red border) when any one of the system status icons on the system information ribbon is selected.

The center of the system information ribbon will display the open patient's last name, first name, and patient I.D. ***Note: This area will be blank if no patient is currently open.***

The right side of the system information ribbon displays the current date and time and four functional icons (Figure 5. 9). ***Note: to adjust the date and time and set the format, see section 5.2.1.*** The four functional icons allow the user to access the login screen, the utilities menu, bring up the touchscreen keyboard, and check system status messages.

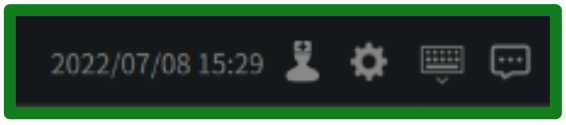
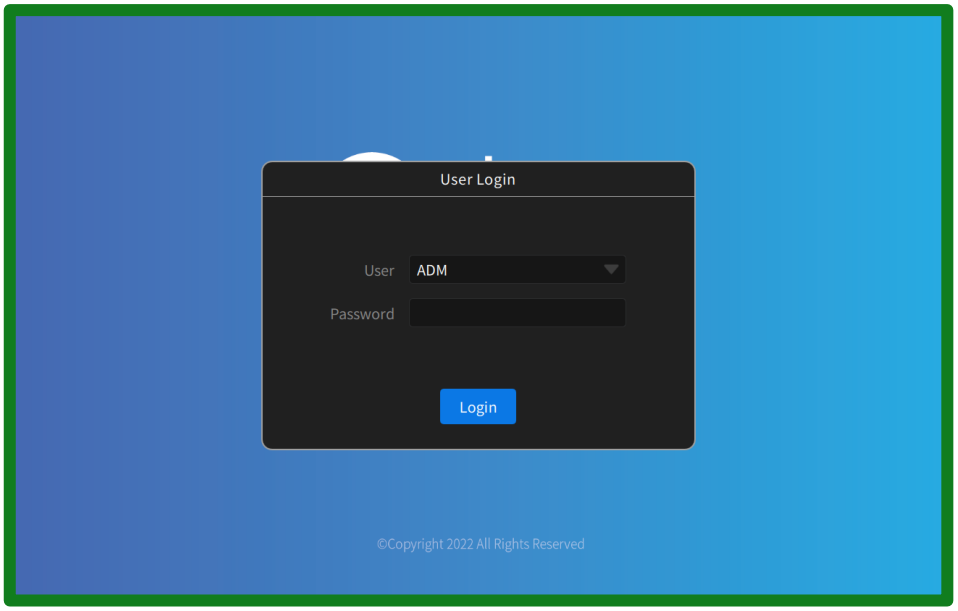


Figure 5. 9 Individual selectable icons on the upper right of the touchscreen

5.1.2.1.2 User Icon of the System Information Ribbon

From left to right on the selectable icons seen in Figure 5. 9, the first icon represents the user. Use the touchscreen or the touchpad to select this icon to logout as the current user. Figure 5. 10 shows the interface

on the touchscreen after selecting the user icon from the system information ribbon. The user is prompted to select either the “Logout” or “Exit” button from the “User Login” dialog box. If the selection of the user icon from the system information ribbon is unintended, the user can select the “Exit” button and return to the previous screen to continue working, without logging out. If the user chooses to logout, then the system is ready for the next user to login (see Figure 5. 10).



7.65

Figure 5. 10 Interface on the touchscreen after selecting the user icon from the system information ribbon

5.1.2.1.3 Utilities Icon of the System Information Ribbon

The next selectable icon on the system information ribbon is the gear icon which can open the utilities page in the system workspace. The utilities page provides the user access to the configurable parameters of the system. Some system parameters require administrative authority to configure. A detailed information about of the configuration options for the Utilities menu items can be found in section 5.2 Utilities.

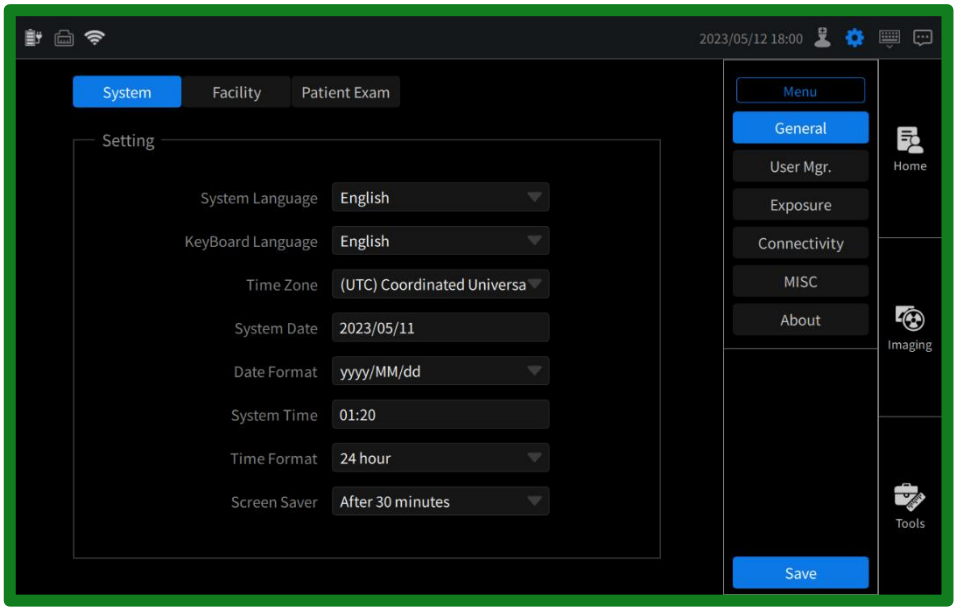


Figure 5. 11 The utilities page displayed in the system workspace when the gear icon of the system information ribbon is selected

5.1.2.1.4 Keyboard Icon of the System Information Ribbon

The next selectable icon of the system information ribbon is the touchscreen keyboard icon. By selecting this icon, the user can have access to the touchscreen keyboard. Whenever the user selects a text input box, the touchscreen keyboard will automatically appear, and the icon will change from white to blue. The touchscreen keyboard functionality is limited to entering information into text boxes. Manually selecting the touchscreen keyboard will not offer any additional functions to the user, since the touchscreen keyboard can only be used in conjunction with a text input box.

5.1.2.1.5 Message Bubble Icon of the System Information Ribbon

The last selectable icon of the system information ribbon is the message bubble icon that toggles the system workspace between the current page and the system status messages overview. Figure 5. 12 shows an example of the system status messages overview in the system workspace. The user can use the history pulldown menu to configure the number of messages displayed. The user can also choose whether to display

all system messages or only error messages by selecting the corresponding button to the right of the history menu.

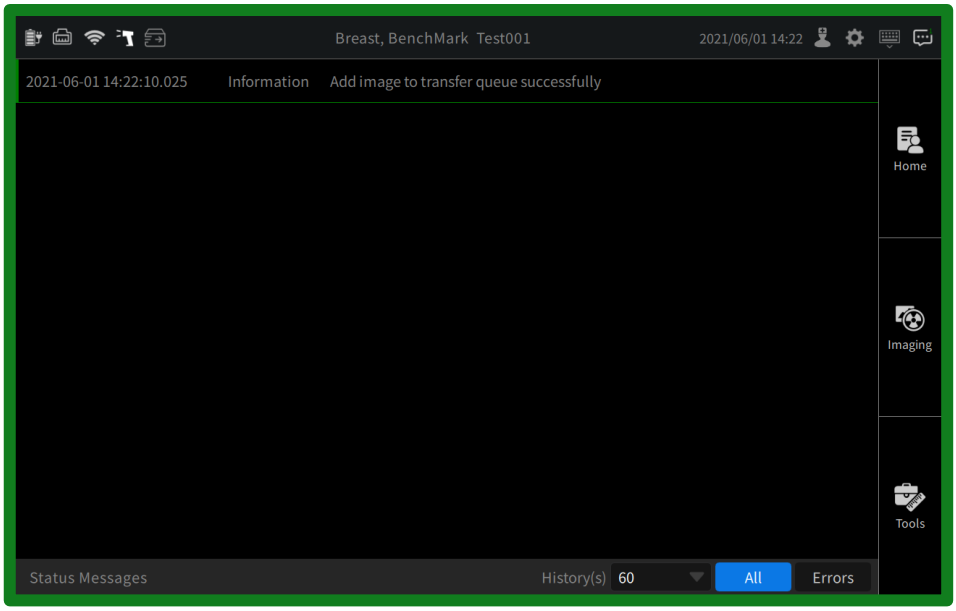


Figure 5. 12 The System Status Messages page is accessed by selecting the message bubble icon of the system information ribbon.

5.1.2.2 System Workspace

The system workspace area of the touchscreen display is a dynamic interface that changes depending on the selected icon or menu item (Figure 5. 13). In contrast, the system information ribbon and the system workflow icons remain basically unchanged while the user is logging in and using the system. The individual icons of the system status overview icons of the system information ribbon will change depending on the exact hardware configuration of the system.

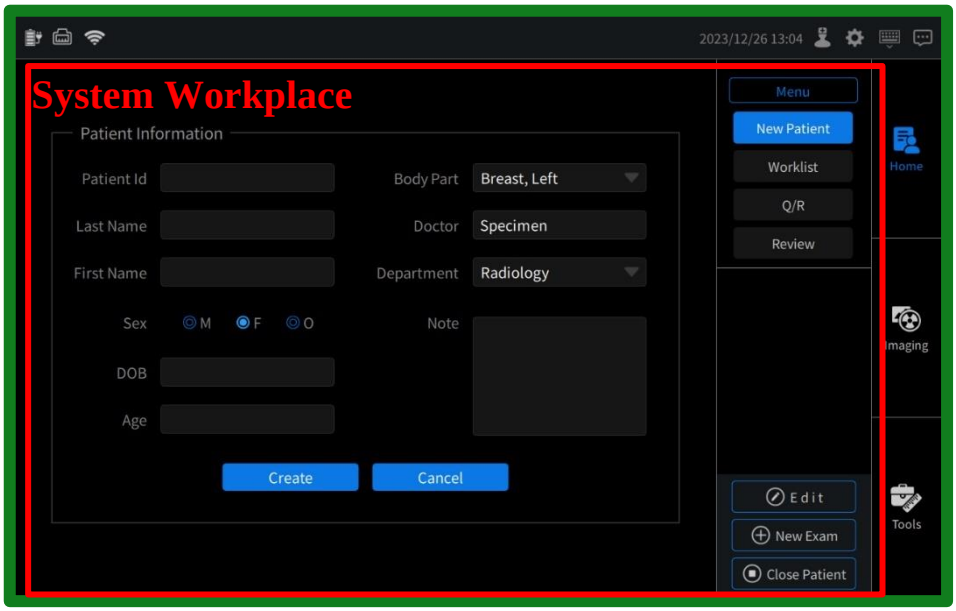


Figure 5. 13 The dynamically set system workspace area of the touchscreen

The individual screens displayed in the system workspace will be detailed in the following sections of this software operation guide.

5.1.2.3 System Workflow Icons

The major steps for any specimen analysis will follow the system workflow icons visible on the right side of the touchscreen (Figure 5. 14).

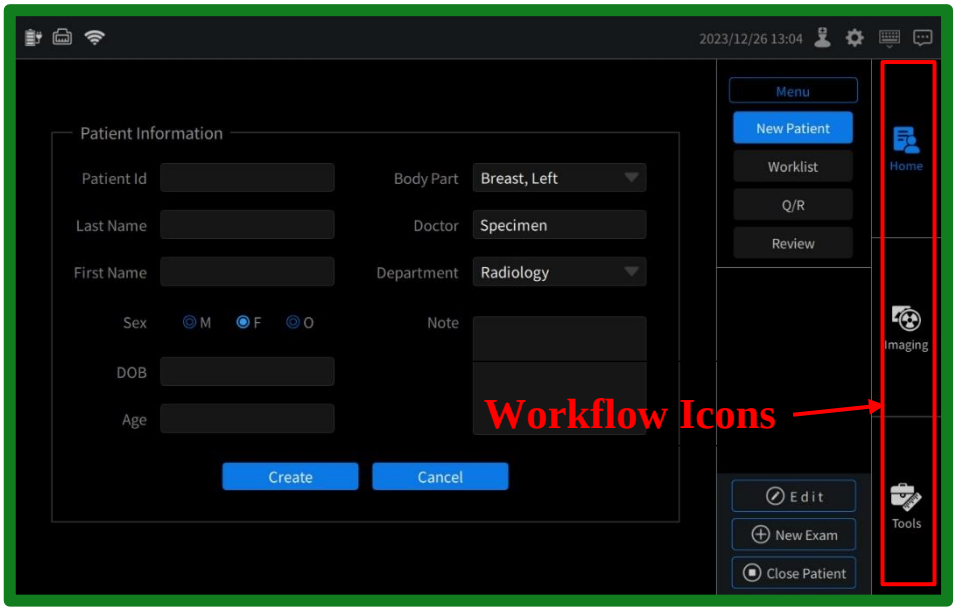


Figure 5. 14 Workflow icons of the touchscreen

These icons, their respective menu items, and the functionality available to the user are individually described in detail in sections 5.3, 5.4, and 5.5.

5.1.3 System Monitor General Layout

The upper screen shown in the general layout (Figure 5. 5) is the system monitor for image analysis.

Since there are no images to review upon initial login, the system monitor has only two active icons in the Image Tools area (see Figure 5. 15). The “Layout” icon changes the number of image display windows on the system monitor. The system monitor can display one, two, or four images; however, the touchscreen will only display the single currently selected image. Users can assign up to four images from a patient’s image list to the four active windows. The user can then change the currently selected image by using the “Next Screen” tool to cycle through any of the four images in the four active windows for review, and select the active window by using the toggle active window icon, or by using the touchpad to move the cursor to the desired image window on the system monitor and then to select it. The other image tool functions are only available when an image has been selected. When the DICOM print, PACS store, and image delete functions of the Image list area are enabled, they will display a blue background (see 5.5.23).

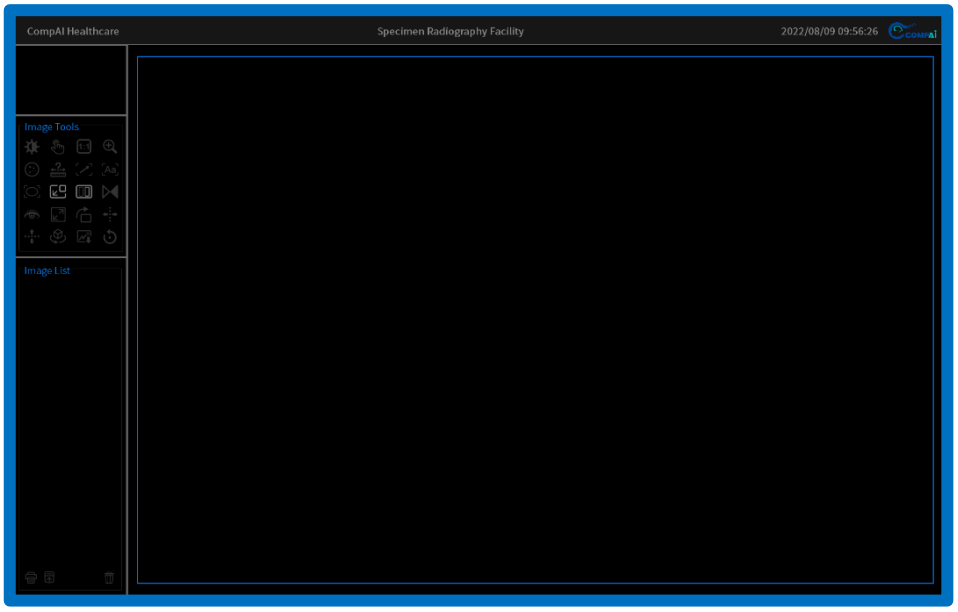


Figure 5. 15 System monitor with Image tools highlighted by yellow border and configured for single image display. Only the “Layout” and “Next Screen” icons are enabled.

A detailed review of the menu items and functionality available to the user of the software is provided in the following sections.

5.2 Utilities

The gear icon of the system information ribbon is the link to the utilities page. This section details the menu items and functionality available to the user when accessing the utilities page. The utilities page will be visible in the system workspace area on the touchscreen.

From the home screen, select the gear icon to open the utilities screen. In this section, the six menu items of the utilities page in the system workspace will be reviewed.

5.2.1 General

Clicking the “Utilities” button, the general settings page will be displayed by default (Figure 5. 16).

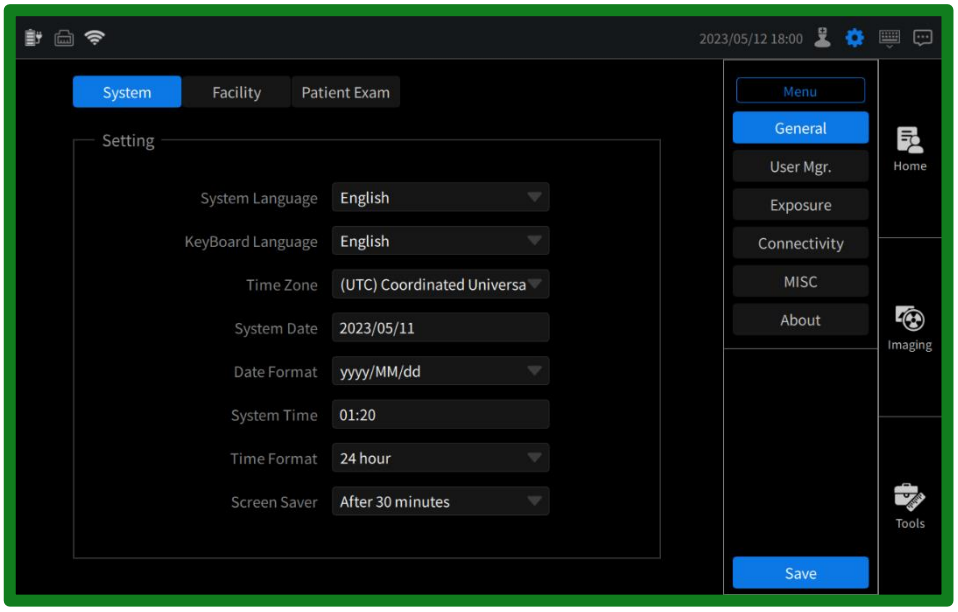


Figure 5. 16 The default view of the utilities page in the system workspace opens with the General settings selection from the utilities menu.

The general settings allow the user to set system and facility information. The facility information includes facility name, facility address, host name, station name, department and patient id input helper; system information includes system language, keyboard language, time zone, system date, date format, system time, time format, and the screen saver activation time. ***Note: only the ADM user can change the Facility Name.***

The current date and time are displayed on the system information ribbon. To change the values or formats, use the touchscreen or touchpad to select the configurable item that is to be changed and then select from the pulldown menu values (e.g. Figure 5. 17) or the scroll wheel (e.g. Figure 5. 18) to set the desired values. To change any of the other values or formats, just select the current value in the box and enter the new desired value or format from the available values. Values are either entered by using the touchscreen keyboard, the scroll wheel, or from a selection in a pulldown menu.

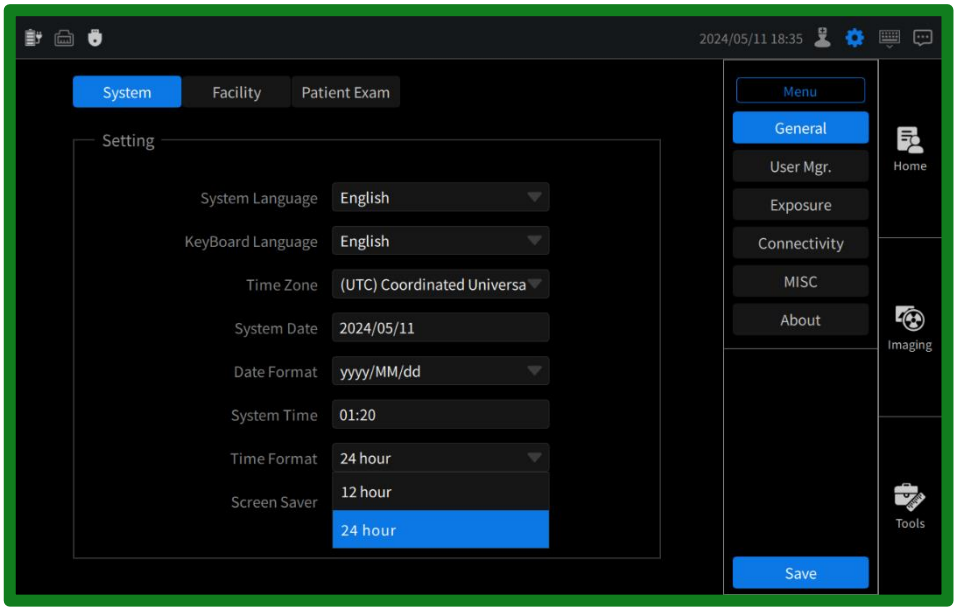


Figure 5. 17 Pulldown menu of the configurable time format value

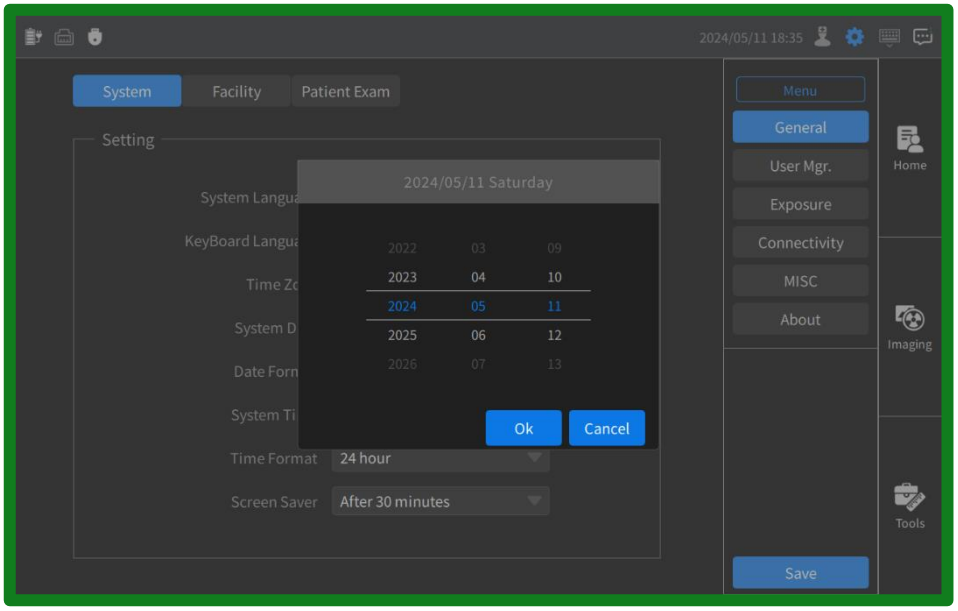


Figure 5. 18 Scroll wheel interface for the configurable current date

The facility settings allow an authorized user to set the facility name, facility address, and department. As the host name is shown accordingly and the default station name is SDR, it is not recommended to change them. ***Note: only the ADM user can change the Facility Name.***

5.2.2 User Management

The ***ADM*** user can create new clinical users, delete old clinical users, and change the password for all clinical users and for the ***ADM*** user. A clinical user only has the authority to change his own current password.

5.2.2.1 Create / Delete User Account as ***ADM*** User

When logged in as the ***ADM*** user, the User Mgr. menu item of the utilities page allows you to create a new clinical user (Figure 5. 19).

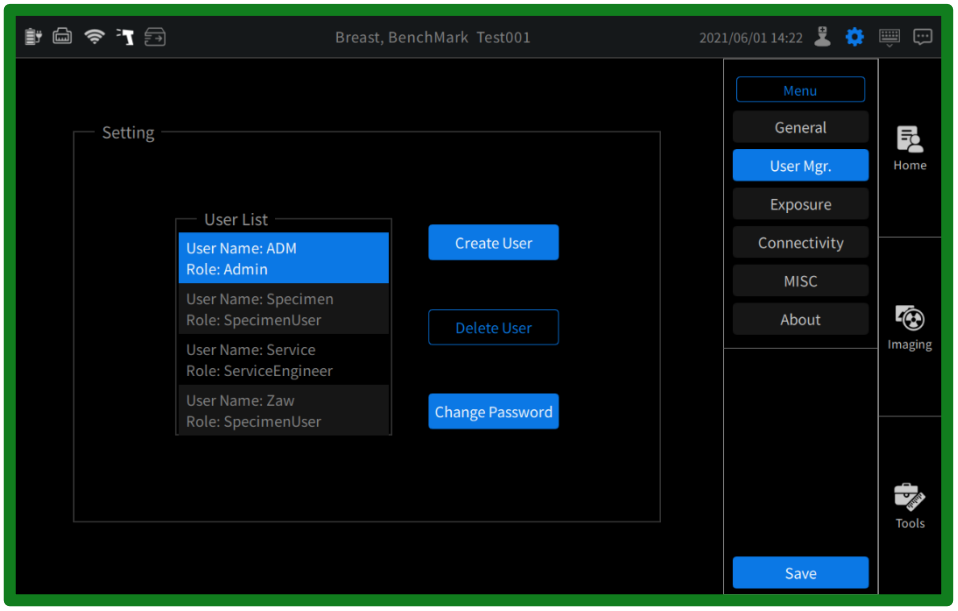


Figure 5. 19 When logging in as the ADM user, select the User Mgr. menu item and then select the “Create User” button to create a new clinical user.

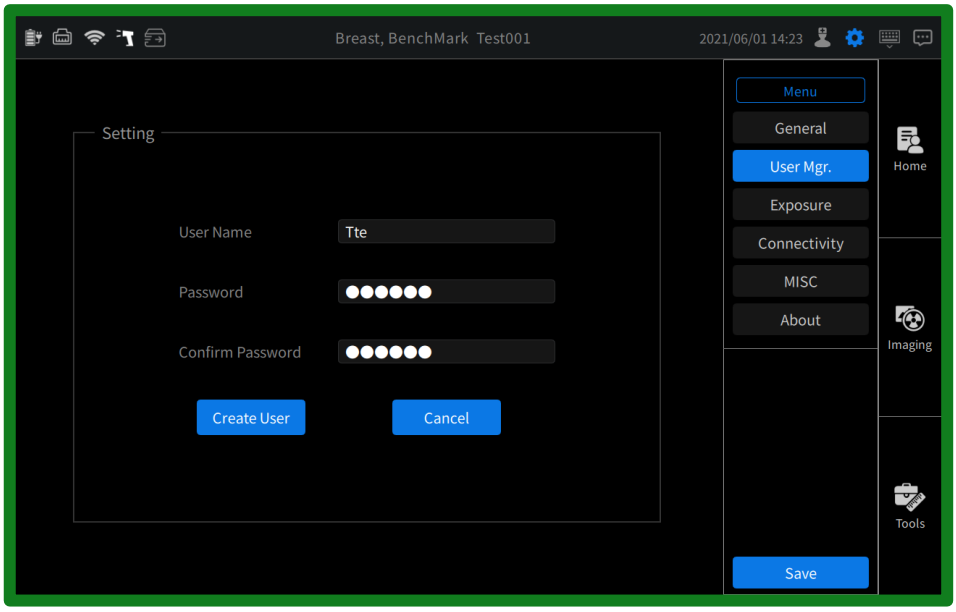


Figure 5. 20 Using the touchscreen keyboard, the ADM user enters the new clinical user's username and password and then selects the Create User button.

After entering the new user's name and password, select the "Create User" button to create the new user. The system will display a confirmation message (Figure 5. 21) acknowledging the creation of the new user. After hitting "Ok" in the confirmation window, the new user's name will appear in the user list.

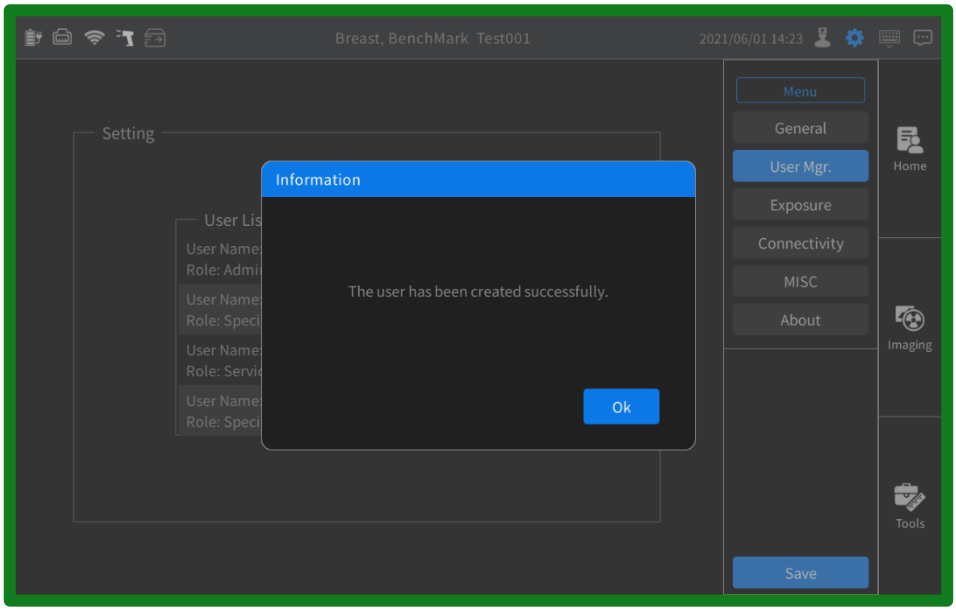


Figure 5. 21 System acknowledgment of the creation of the new clinical user

5.2.2.2 Delete Clinical User Account as ***ADM*** User

The ***ADM*** user can delete any new clinical user account, but cannot delete the three default users: ***ADM, Specimen***, or ***Service***. To delete any clinical account other than the ***Specimen*** account, select the user from the user list and then select the Delete User button (the user must log in as the ***ADM*** user).

Once the "Delete User" button is pressed, confirm the action (Figure 5. 22) and then the system will display a message that the action has been successful (Figure 5. 23).

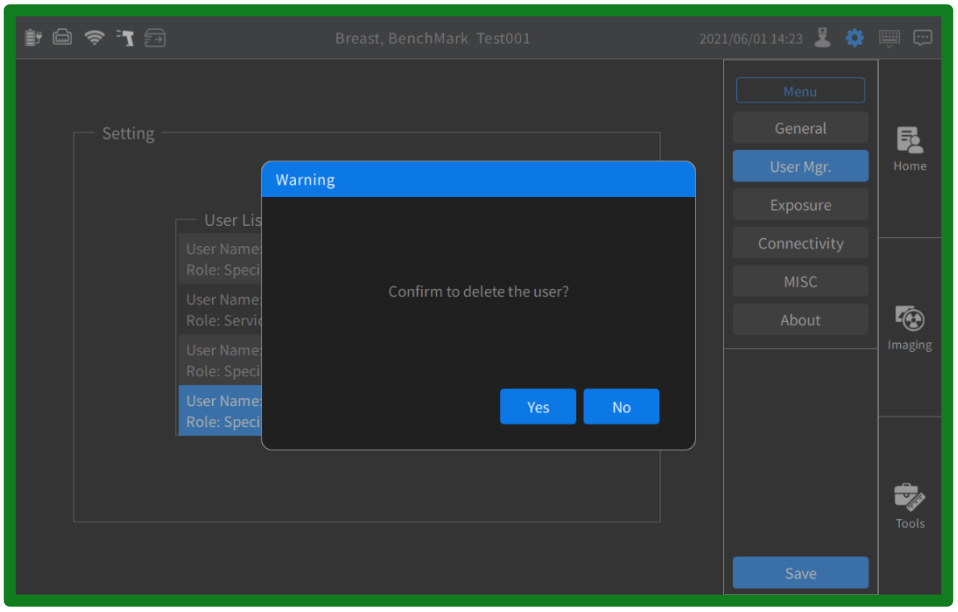


Figure 5. 22 Confirm user deletion.

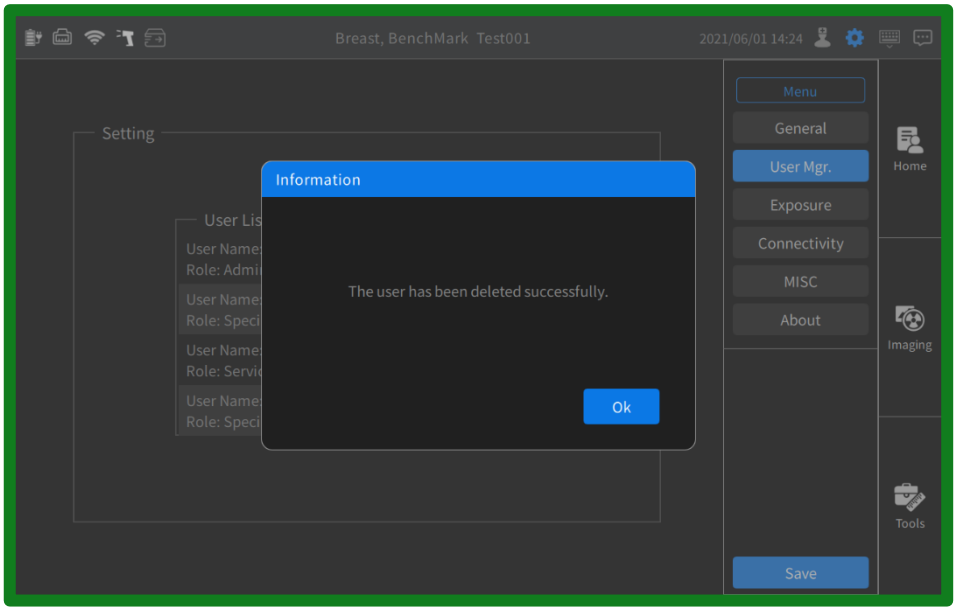


Figure 5. 23 System acknowledgment of user deletion.

5.2.2.3 Change User Password

The ***ADM*** user can change any clinical user password and the ***ADM*** user password from the user management page of the Utilities workspace. A clinical user can only change his own password from the user management page, but the process is the same.

As the ***ADM*** user, select the clinical users name from the user list and then press the “Change Password” button (Figure 5. 24).

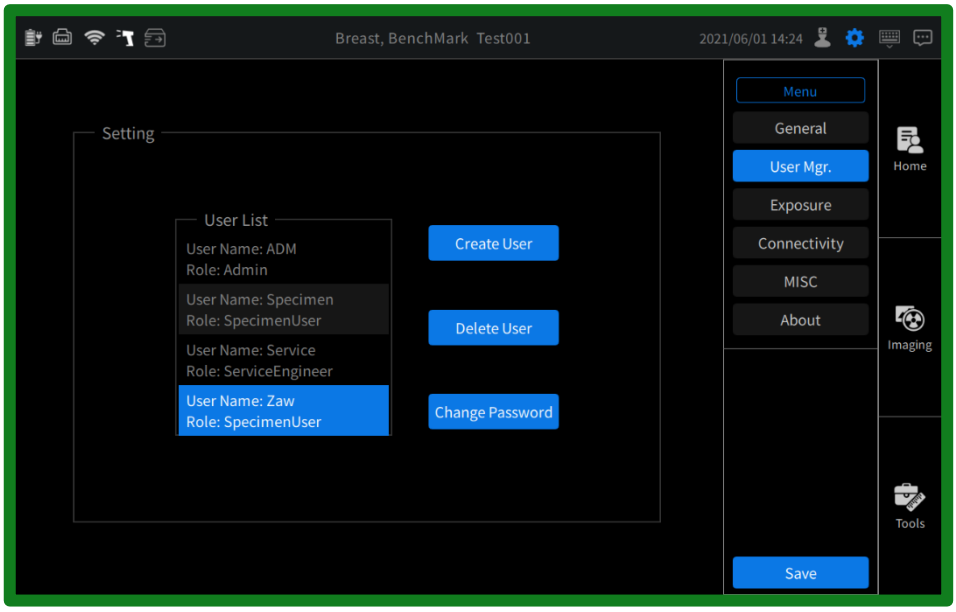


Figure 5. 24 As the ADM user, select a new clinical username from the user list and push the Change password button to initiate the change password workflow.

The ***ADM*** user is then required to enter the current ***ADM*** password as well as the new password for the clinical user and re-enter the new password to ensure it is correct (Figure 5. 25). Click the "Change Password" button and, if the new password and the confirmed password match, then the system will confirm that the password has been changed (Figure 5. 26).

If logging in as a clinical user, the user management page will have only one function available, the change password function (Figure 5. 27). The procedure is basically the same as when the ***ADM*** changes the password. The clinical user must first enter the current password before changing a new password. Select the "Change password" button, and as long as the new password and the confirmed password have been matched, then the system will confirm the action has been successful.

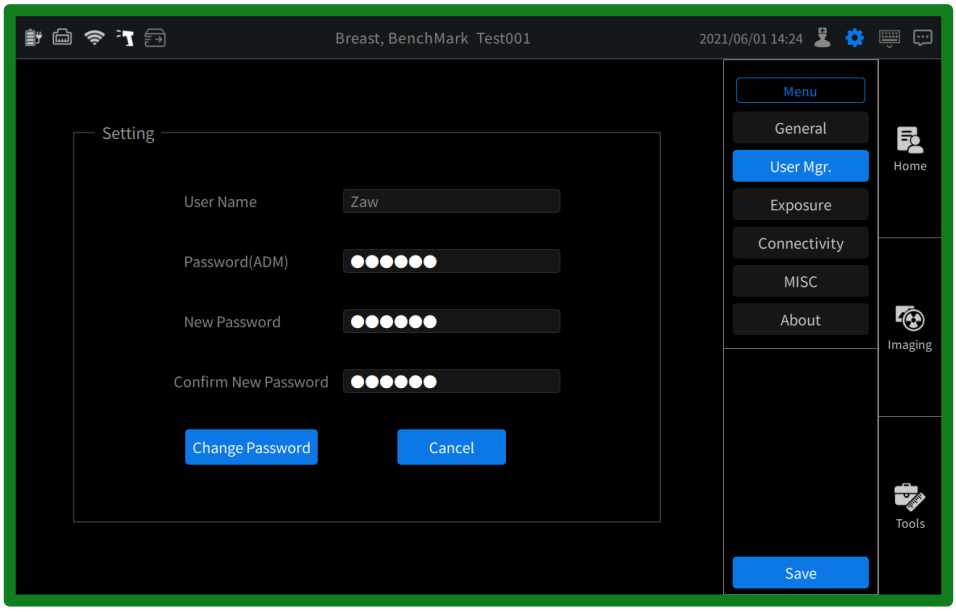


Figure 5. 25 ADM user change clinical user password workflow

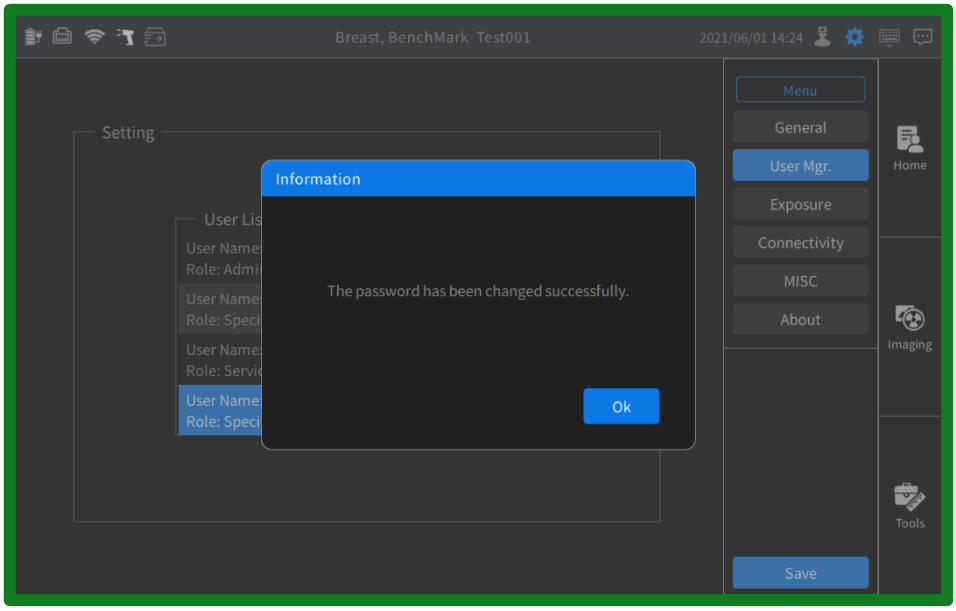


Figure 5. 26 System confirmation that the user password has been changed successfully

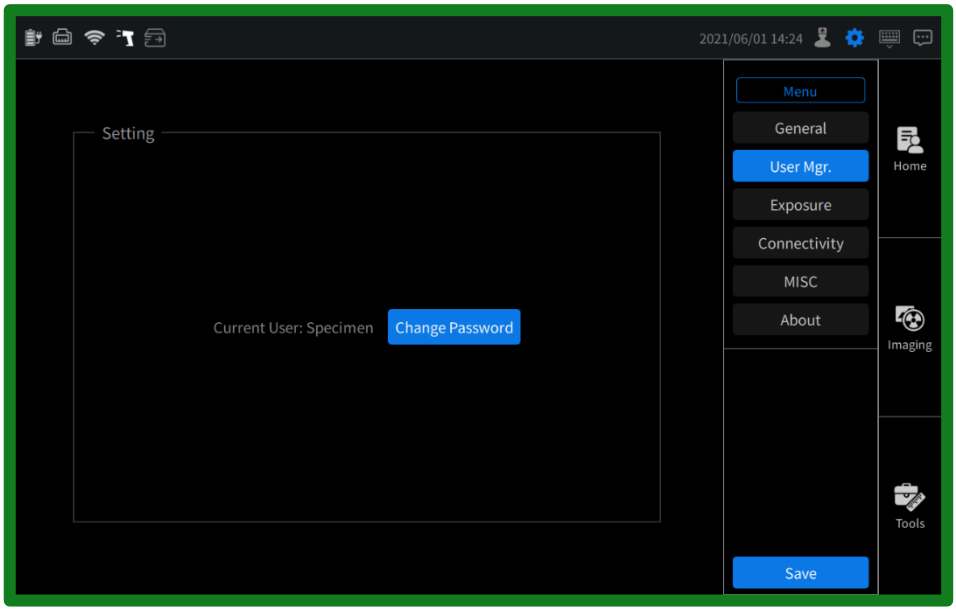


Figure 5. 27 Change password as a clinical user

5.2.3 Exposure Settings

The exposure menu item of the utilities page in the system workspace allows the user to set the default exposure parameters for the Imaging workflow. Figure 5. 28 shows the options available for the default exposure settings. As for exposure mode, the user may choose automatic exposure control (AEC) or manual exposure control for specimen imaging. The user can also set the default tube voltage between 20kVp to 50kVp, and the default tube current between 5mAs to 20mAs.

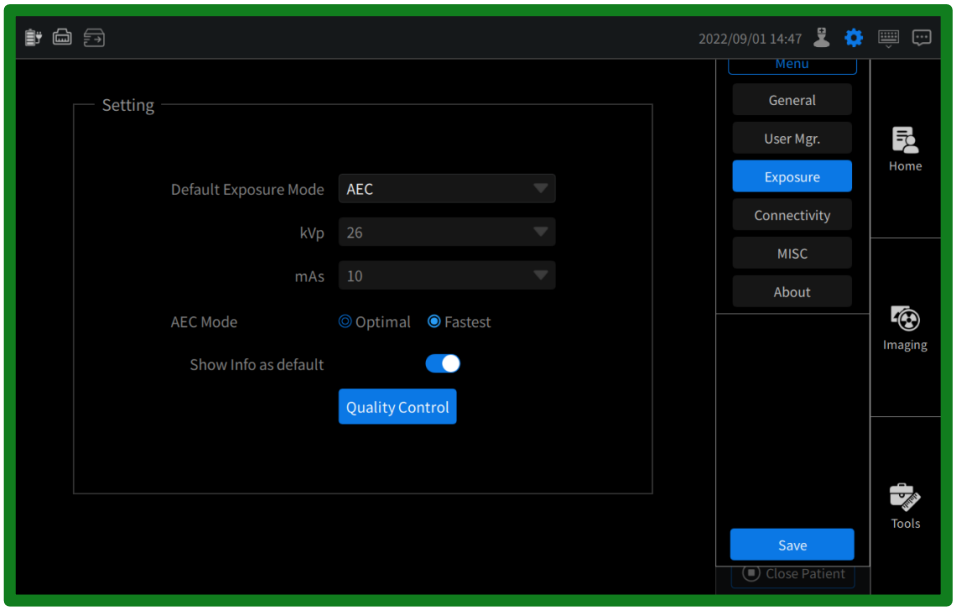


Figure 5. 28 Exposure setting interface

The exposure menu item of the utilities page in the system workspace allows the user to set the default exposure mode, the default values for the voltage and current for the X-ray tube, whether shows information as default.

The user can click the “Quality Control” button, and a patient called Quality Control will be automatically established where the user can capture image to check image quality.

5.2.4 Connectivity

The connectivity menu item of the utilities page in the system workspace provides the user the functionality to manage the connectivity of the system. Besides the DICOM connectivity properties only available to the ***ADM*** user, the clinical user has access to most of the functionality as the same as the ***ADM*** user to check the system connectivity status.

NOTE: The subnetwork segment is used by the hospital cannot be the same as that was used by the panel. At present, the panel subnetwork segment is 172.16.8.x. If the segments collide, please contact The CompAI Healthcare operation and maintenance personnel to reset the panel IP address.

5.2.4.1 Wired

If the user selects the Wired page, the status of the Ethernet connection is displayed (Figure 5. 29).

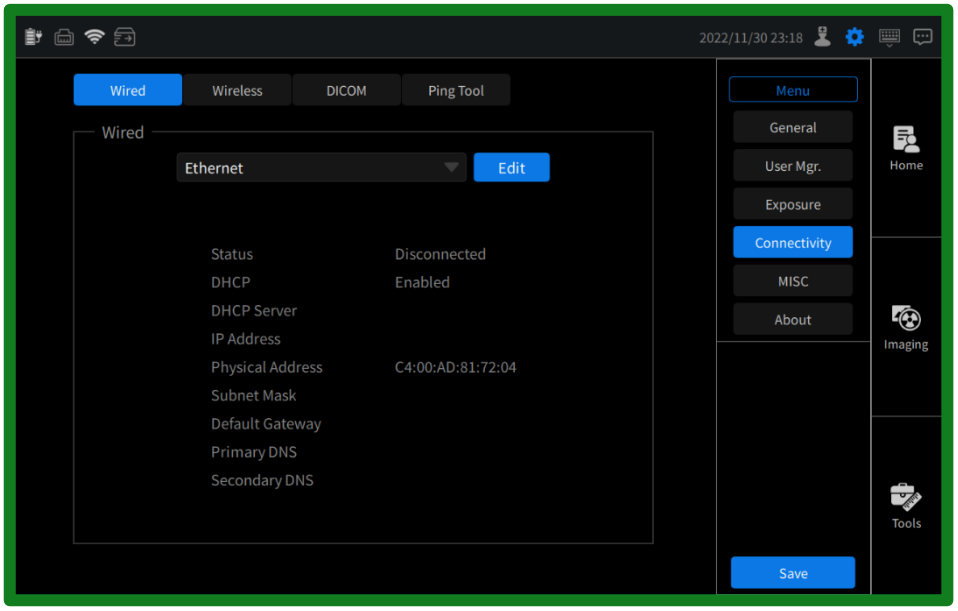


Figure 5. 29 The Wired page of the connectivity menu item of the utilities page in the system workspace.

5.2.4.2 Wireless

The wireless page of the connectivity menu item of the utilities page in the system workspace allows the user to scan available networks, create a new connection, and to check the properties of the currently connected wi-fi network (Figure 5. 30) after the USB wireless card is connected.

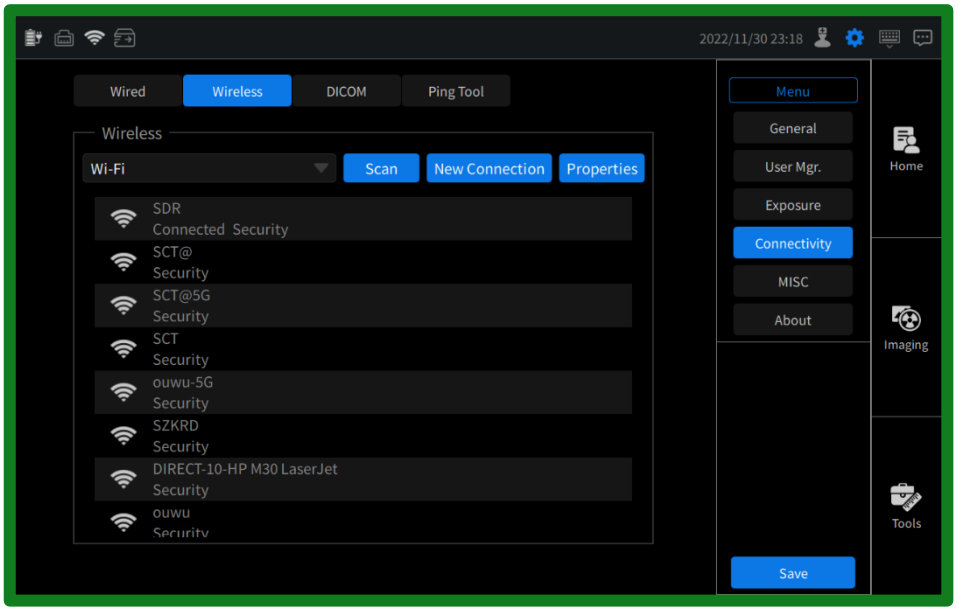


Figure 5. 30 The wireless page of the connectivity menu item of the utilities page in the system workspace.

5.2.4.3 DICOM

The DICOM page of the connectivity menu item of the utilities page in the system workspace allows the clinical user to test the DICOM worklist, MPPS, PACS Image storage, DICOM print connectivity, DICOM query and DICOM retrieve. If any of the connecting tests fail, contact the ***ADM*** user to configure the IP Address, AE title, and Port for each connection. Figure 5. 31 shows the PACS Image storage page with auto PACS store enabled. If Auto PACS store is enabled, then when the user closes a patient by selecting the “Close Patient” button, the system will send all the images taken during the exam to the DICOM server automatically. A blue circle will be visible in the radio button to the left of Auto PACS store when this feature is selected. The user can select the radio button to toggle this feature on and off.

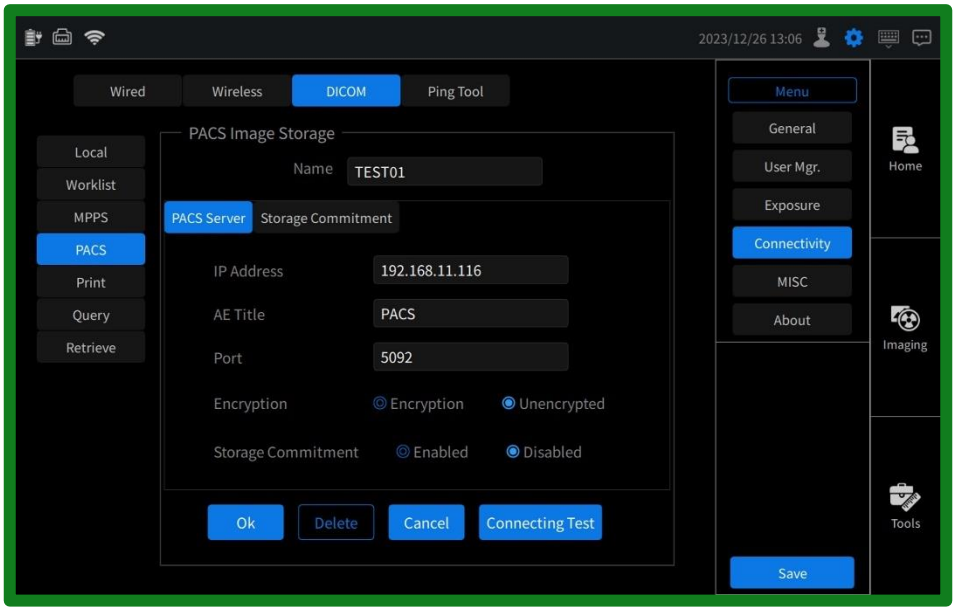


Figure 5. 31 The PACS Image Storage configuration and test page of the connectivity menu item of the utilities page in the system workspace. The Auto PACS store feature is enabled in this view, as indicated by the blue circle in the radio button at the bottom.

The operation procedure of the DICOM worklist, DICOM MPPS, DICOM print pages, DICOM query and DICOM retrieve can refer to that of the PACS Image Storage page.

5.2.4.4 Ping Tool

The Ping Tool page of the connectivity menu item of the utilities page in the system workspace allows the user to “ping” an IP Address.

5.2.5 Miscellaneous

The miscellaneous menu item of the utilities page in the system workspace provides the user access to the accessories and audit log pages. The ***ADM*** user will have access to two additional pages, the Backup/Restore and Calibration pages.

5.2.5.1 Accessories

The accessories page allows the user to enable the barcode reader, and to configure the “ReadTo” parameter of the barcode reader workflow (Figure 5. 32).

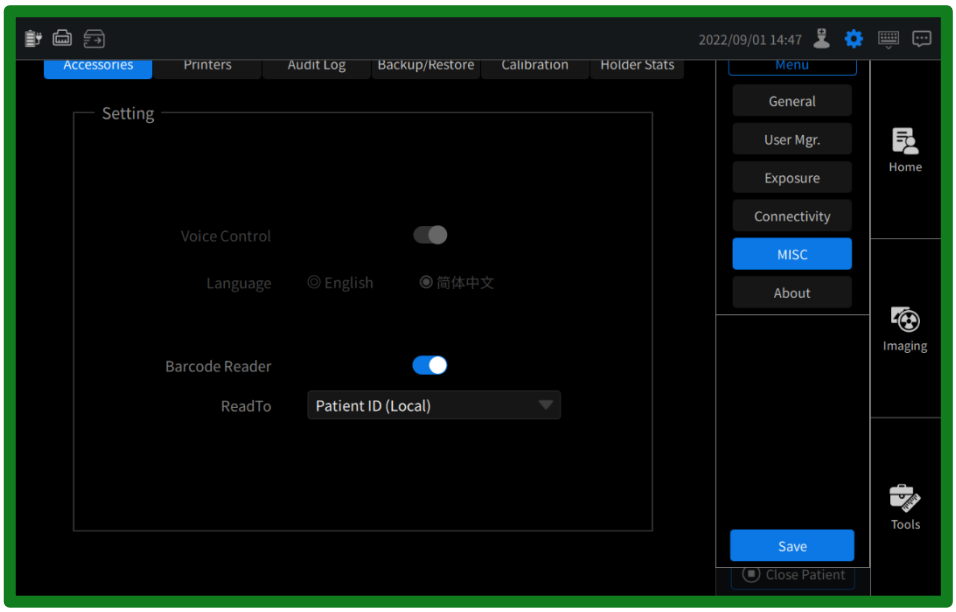


Figure 5. 32 The Accessories page of the MISC menu item of the utilities page in the system workspace

NOTE: Only the ADM user will see the Backup/Restore and Calibration pages.

5.2.5.2 Printer

Local printers can be scanned and added on the printer page. If the network connection is successful, click the “Add" button and then click the “Scan" button to select the corresponding printer and click “Add", as shown in Figure 5.33.

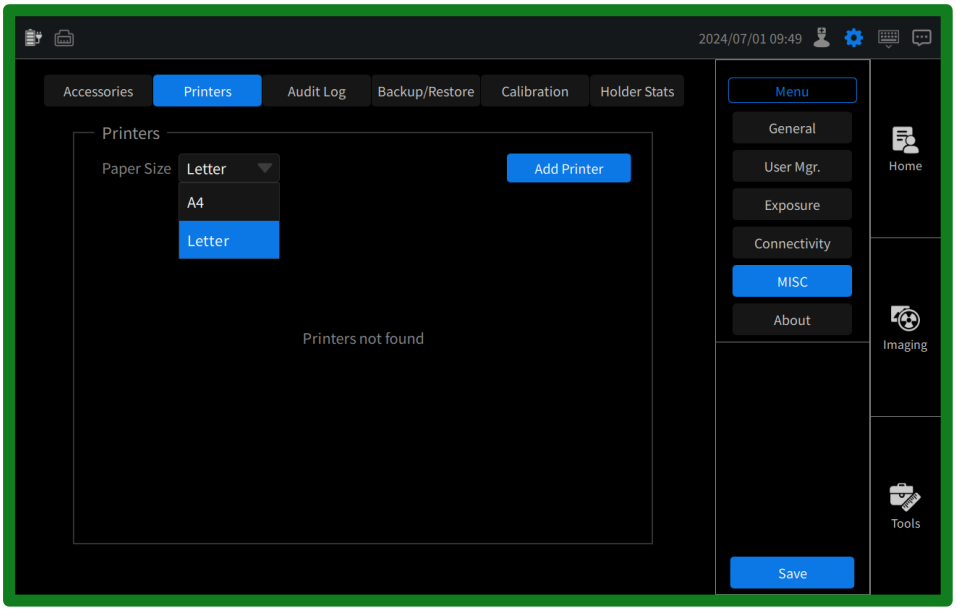


Figure 5. 33 The Pinter page of the MISC menu item of the utilities page in the system workspace

NOTE: Only the ADM user will see the Backup/Restore and Calibration pages.

Alternatively, you can directly connect the printer to the device using the data cable that comes with the printer. After a successful connection, set the paper size. Recommended printer models are listed below.

HP Laser Jet Pro MFP M30w
HP Smart Tank 755
Laser Jet Pro MFP M227sdn

5.2.5.3 Audit Log

The Audit Log page allows the user to search the audit log by date, patient ID, or user ID (see Figure 5. 34).

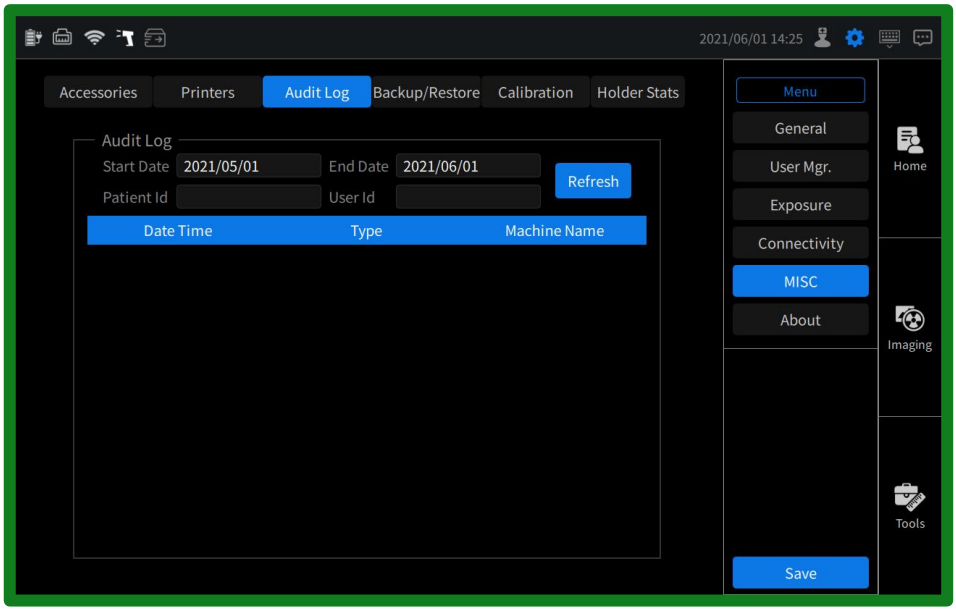


Figure 5. 34 The Audit Log page of the MISC menu item of the utilities page in the system workspace

NOTE: Only the ADM user will see the Backup/Restore and Calibration pages.

If the user is logging in as the ADM user, then the miscellaneous menu item also provides access to the Backup/Restore and Calibration pages.

5.2.5.4 Backup/Restore

The Backup/Restore page of the MISC menu item of the utilities page in the system workspace allows the ADM user to start a backup or restore from a previous backup (see Figure 5. 35).

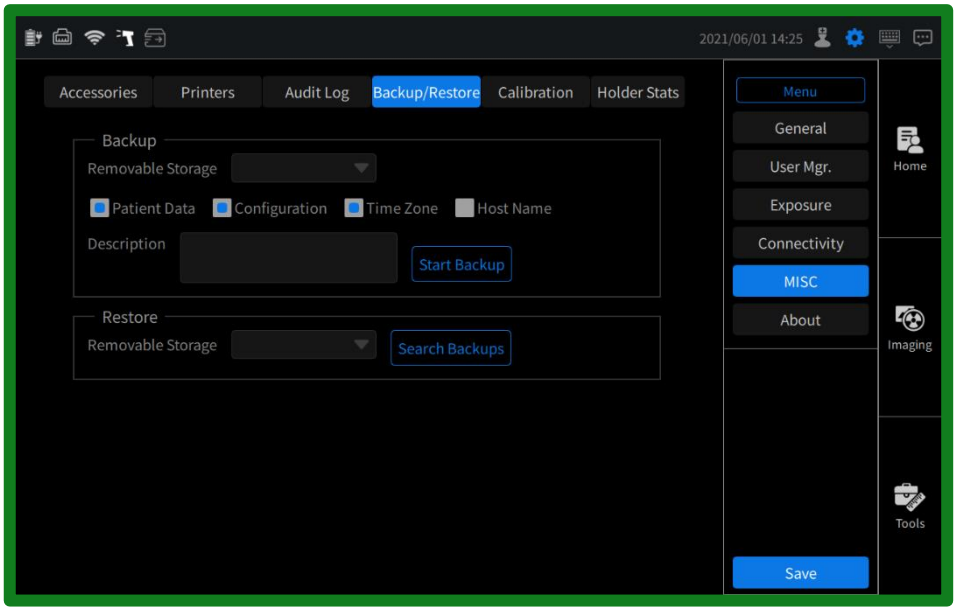


Figure 5. 35 The Backup/Restore page of the MISC menu item of the utilities page in the system workspace

Note: only the ADM user will see the Backup/Restore and Calibration pages.

5.2.5.5 Calibration

5.2.5.5.1 Tube Calibration

The tube calibration page of the MISC menu item of the utilities page in the system workspace allows the ***ADM*** user to perform the tube calibration procedure (see Figure 5. 36). At the start of the procedure, the table shows the calibration steps and indicate if any of the steps has been previously calibrated. A circle will appear in the calibration column if the step has been successfully completed. ***Note: Use an empty tray without screen printing for calibration.***

It should be noted that the calibration status will revert to “un-calibrated” (i.e. no circle displayed) when the system is rebooted. However, the tube calibration data is stored, and latest calibration data is used even if the indication in the calibrated column does not show the circle. The ***ADM*** user is recommended to update the tube calibration data once every six months.

Once the “Start Calibration” button has been selected, the system will require a confirmation from the user to start the calibration (see Figure 5. 37). This procedure can take several minutes, and the tube calibration progress status will be displayed in the system workspace (see Figure 5. 38). Once the calibration is completed”, the tube calibration table will show if all the calibration steps completed successfully. If any of the tube calibration steps fails to calibrate, contact your service representative.

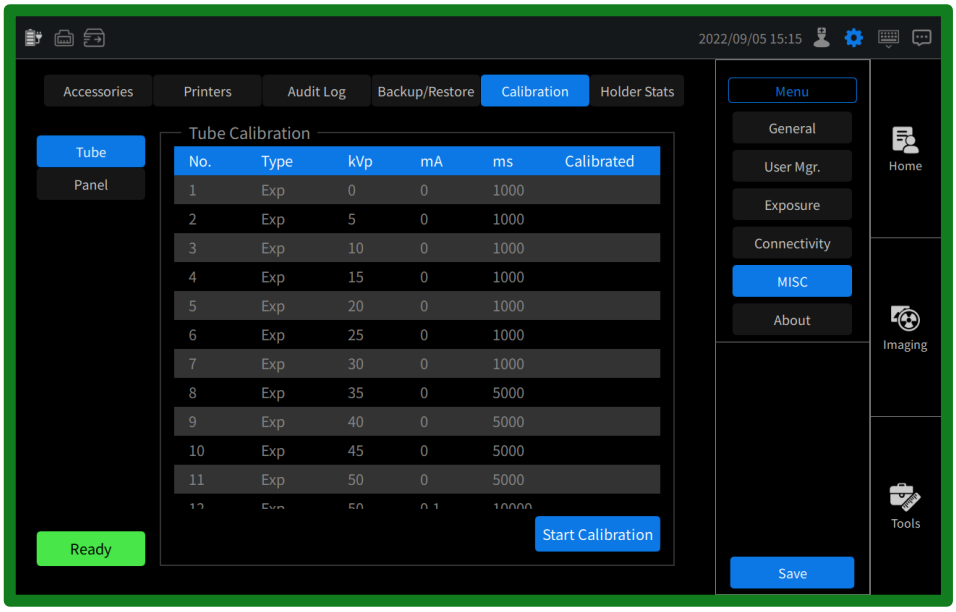


Figure 5. 36 The tube calibration page of the MISC menu item of the utilities page in the system workspace

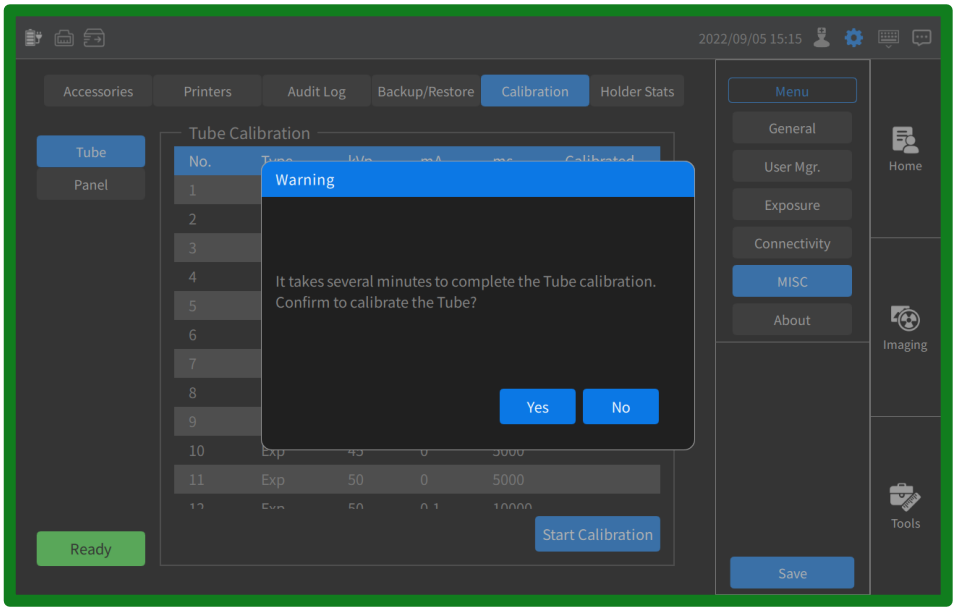


Figure 5. 37 Warning that the system requires several minutes to complete the tube calibration

User is required to confirm before the calibration proceeds.

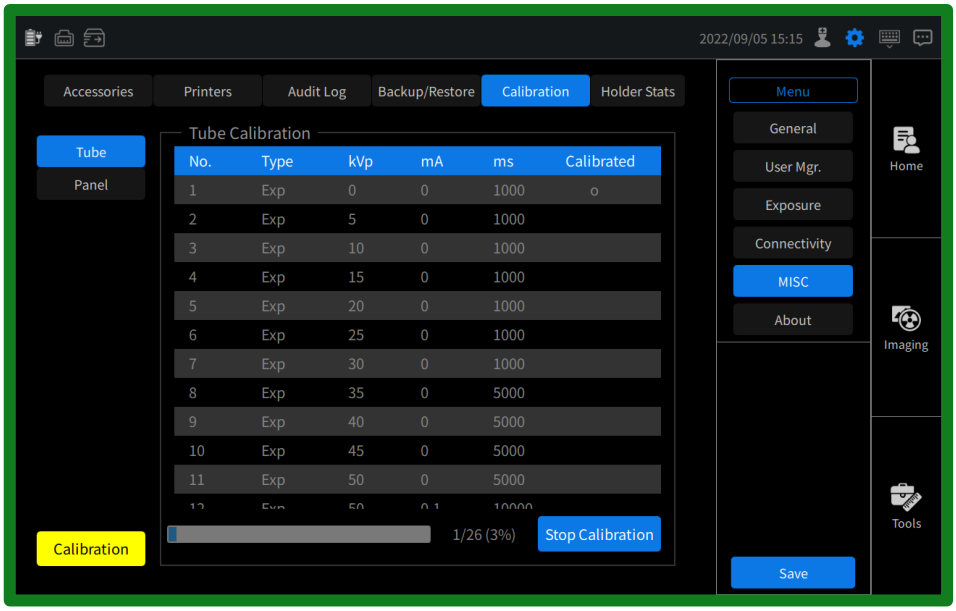


Figure 5. 38 Tube calibration progress display indicates the current calibration number and percentage completion

5.2.5.5.2 Panel Calibration

The panel calibration page of the MISC menu item of the utilities page in the system workspace allows the ***ADM*** user to perform the panel calibration procedure (see Figure 5. 39). At the start of the procedure, the table shows the calibration steps and indicates if any has been previously calibrated. A date and time will appear in the Last Calibration column if the step has been successfully completed. ***Note: Use an empty tray without screen printing when running the panel calibration procedure.***

The first step of the panel calibration is the dark field calibration that is performed every time a panel calibration is performed. However, the user may select any number of the subsequent calibration steps as needed. The system saves the panel calibration data, and uses the latest calibration data when taking images. The panel calibration table will maintain that latest list of calibration data, even if the system is rebooted.

Once the “Start Calibration” button has been selected, the system will require a confirmation from the user to start the calibration (see Figure 5.40). This procedure can take several minutes, and the panel calibration progress status will be displayed in the system workspace (see Figure 5.41). Once completed, the panel calibration table will show if all the calibration steps completed successfully by displaying the current date and time in the last calibration column. If any of the panel calibration steps failed, contact your service representative.

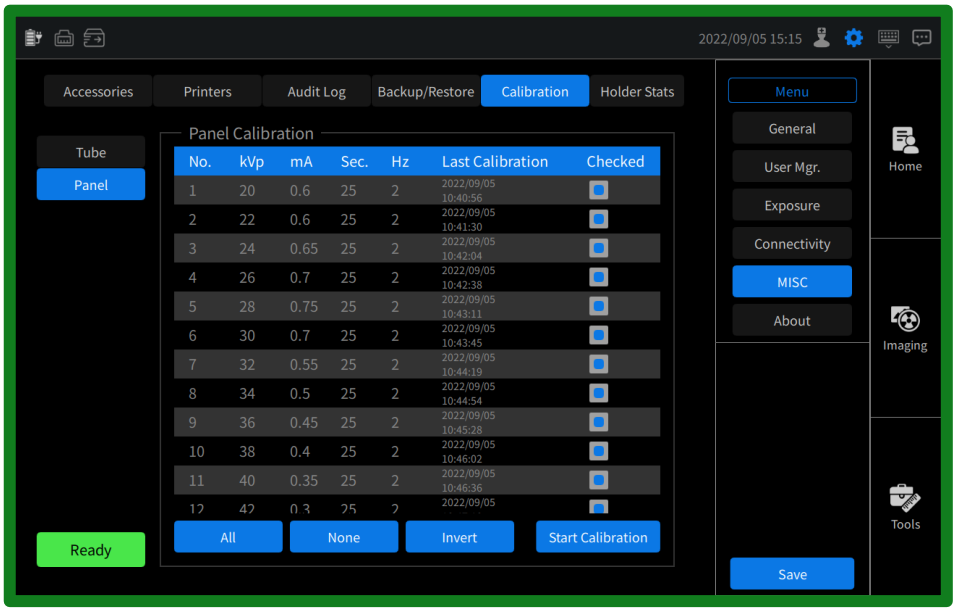


Figure 5. 39 The Panel calibration page of the MISC menu item of the utilities page in the system workspace.

In this configuration, all the calibration steps have been selected and the system is ready to start the calibration.

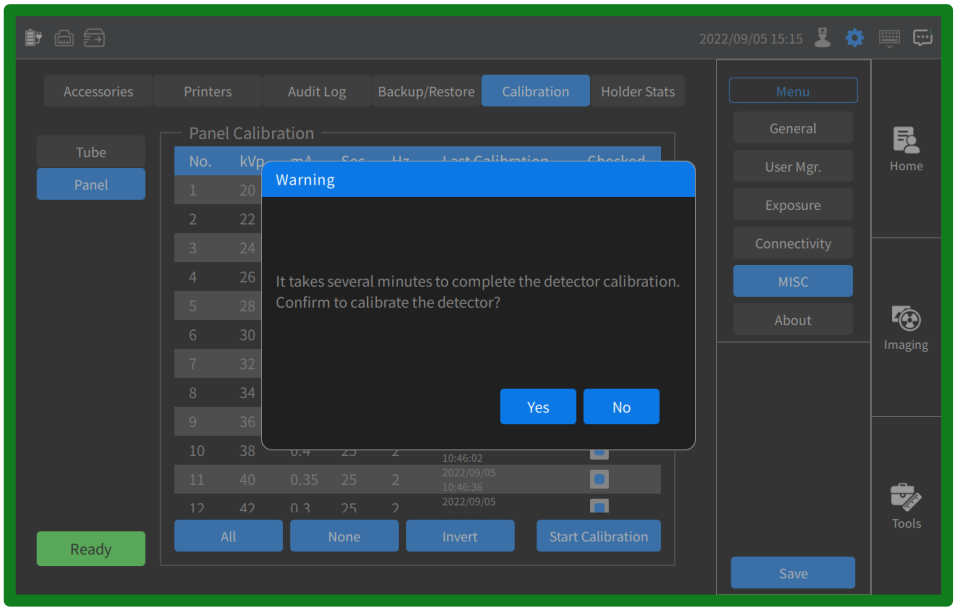


Figure 5. 40 Panel calibration and a dilog box of warning information

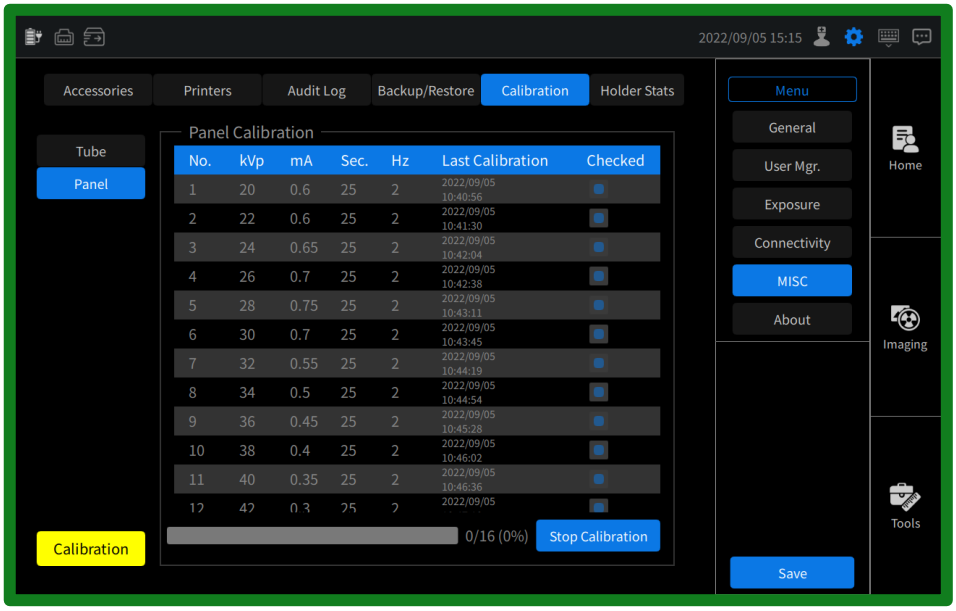


Figure 5. 41 Panel calibration procedure

5.2.5.6 Holder Stats

The user can check how many specimen containers are used (see Figure 5.42) and select from the pulldown menu (see Figure 5.43) to refresh the data.

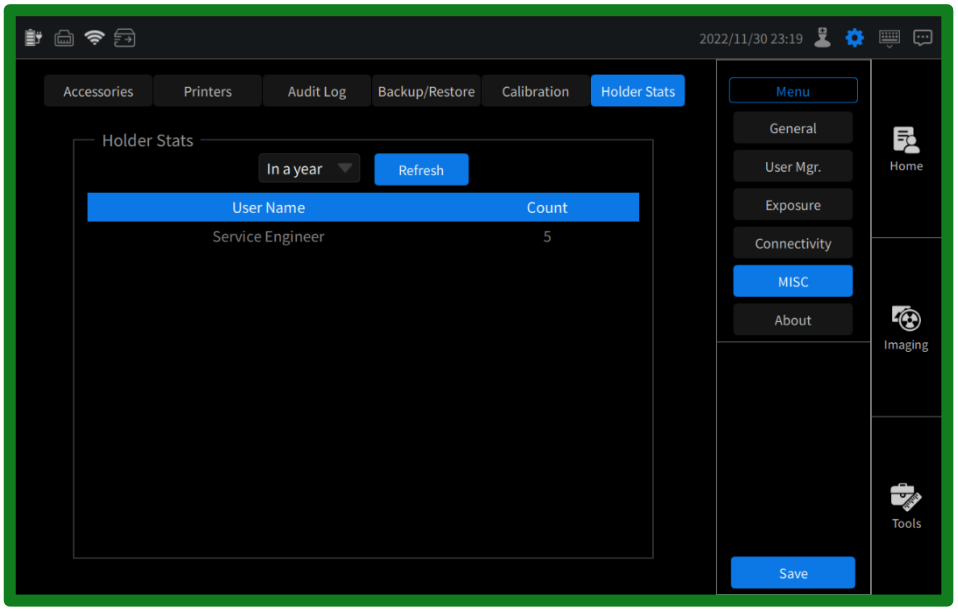


Figure 5.42 Holder Stats

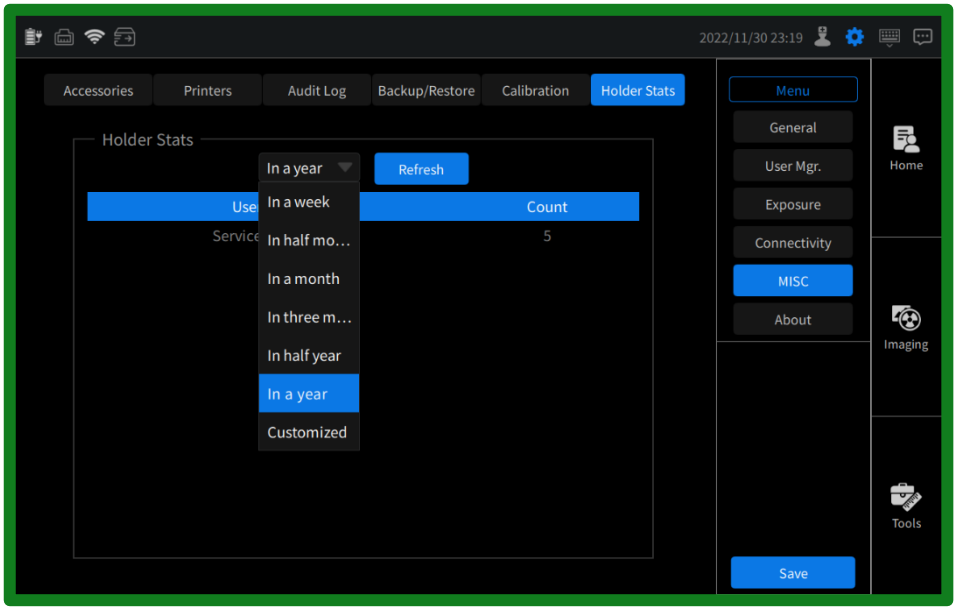


Figure 5.43 Select from the pulldown menu

5.2.6 About

The About menu item on the utility's workspace provides user the setting of function option and the software version, build date, product model for the system.

5.2.6.1 Features

ADM user can add and delete feature keys (They will be available for purchase separately) in the Features page, as shown in the figure below

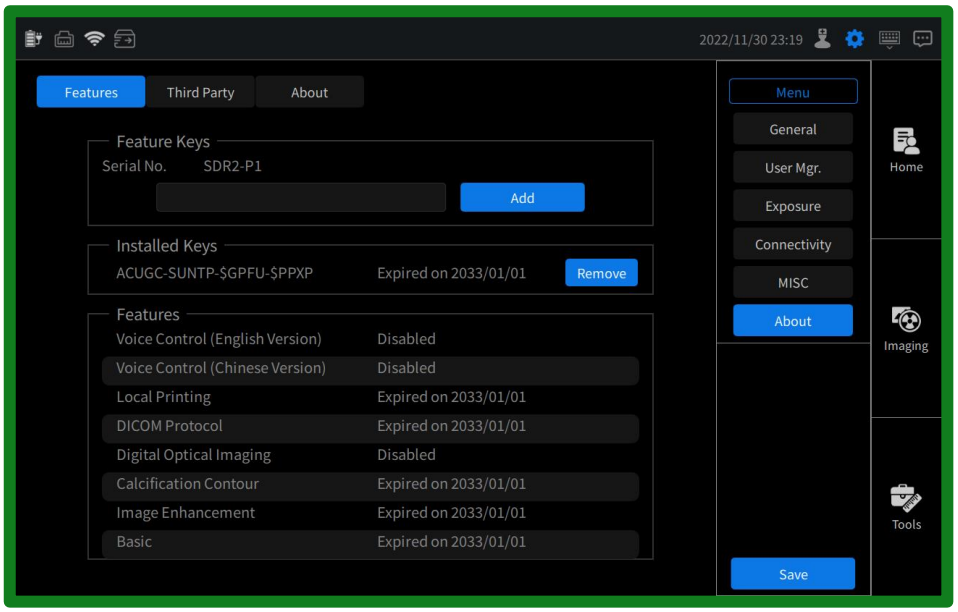


Figure 5. 44 The About menu item of the utility's workspace provides the setting of features

5.2.6.2 About

Users can check version information on the page, such as software version, build date, product model and so on.

Figure 5. 45 The About menu item of the utility's workspace provides software and product information

5.3 Home

The menu options of the Home workspace on the touchscreen allows the user to create a new patient, see the worklist, query and retrieve, or review an existing patient. In Figure 5.46, the red arrow and red border indicate the location of the menu items in the workspace. The currently selected menu item of the Home workspace will have a blue background and white text. The menu items with white text and grey background are available for selection. By using the touchscreen or the touchpad, the user can select New Patient (5.3.1), Worklist (5.3.2), Q/R (5.3.3) or Review (5.3.4) from the list of menu items.

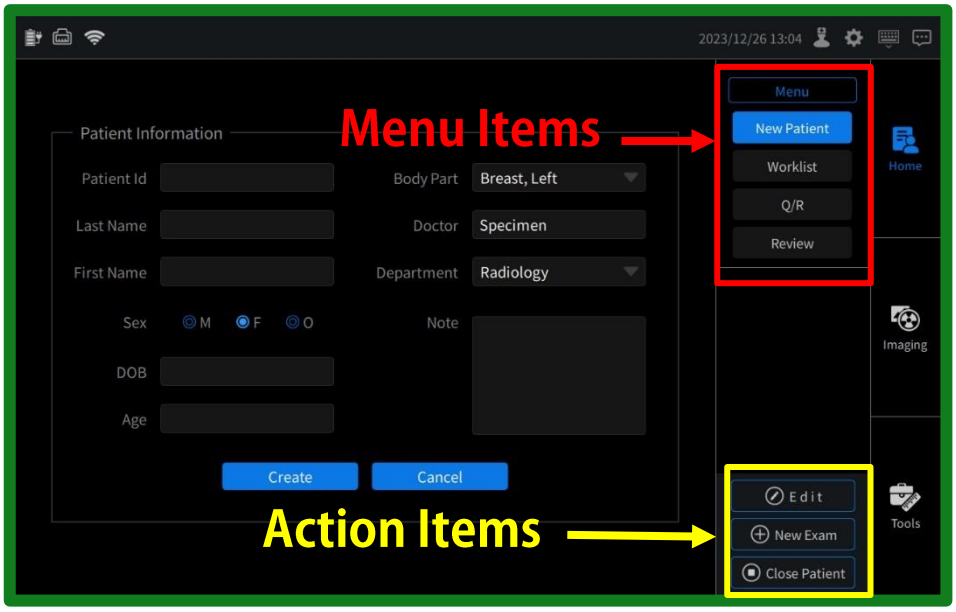


Figure 5. 46 Menu and Action items on the initial login Home screen

Figure 5.46 also indicates the location of the action items with a yellow arrow and border in the Home workspace. Action items with a solid blue background are enabled, while those with only a blue border are not currently enabled. An example of action items that are enabled can be seen in the Worklist screen in Figure 5.48.

The user can create a new patient, pull a scheduled patient from the worklist, or review the existing patient from the patient list.

5.3.1 New Patient

To create a new patient, simply enter the patient information into the corresponding text boxes by using the touchscreen keyboard (Figure 5.47). The system will display a message if any required information is left blank. Once the patient has been created, the patient will appear on the patient list. The patient list is accessible from the Review menu item of the Home workspace.

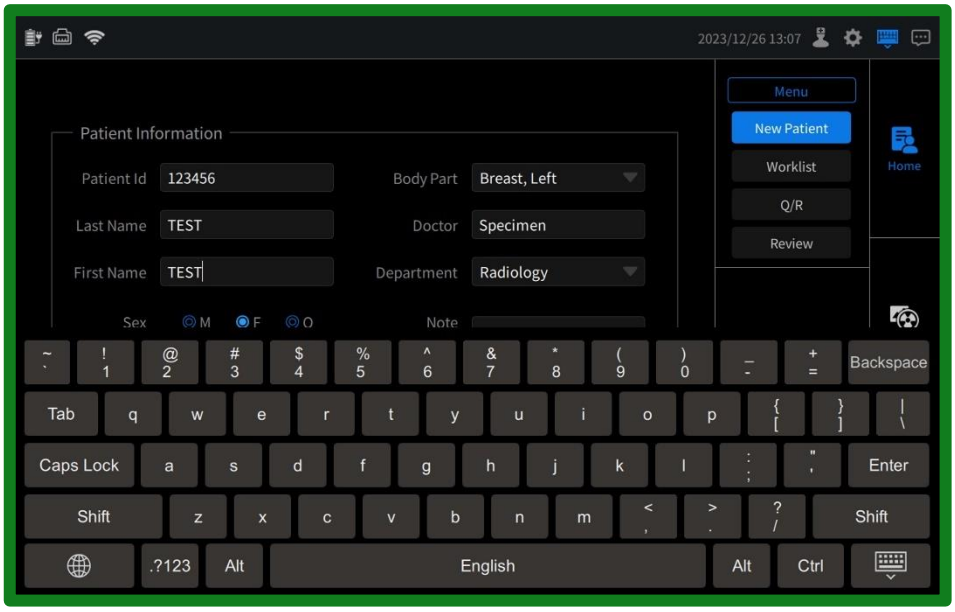


Figure 5.47 Create a new patient workspace

Enter the patient information into the corresponding text box and then select the “Create” button at the bottom of the workspace.

5.3.2 Worklist

The Worklist menu item within the home workspace permits users to search for scheduled patients and select patients for imaging purposes. If the worklist appears empty, users can initiate the "Refresh" action item to repopulate the worklist from the server. In the event that the refresh process encounters an issue, users should contact the ADM to configure the DICOM worklist connectivity (refer to section 5.2.4 Connectivity). Figure 5.48 illustrates the action items available within the worklist menu on the home workspace.

Within the worklist, users have ability to select a patient and subsequently use the "New Exam" action item to access the imaging menu.

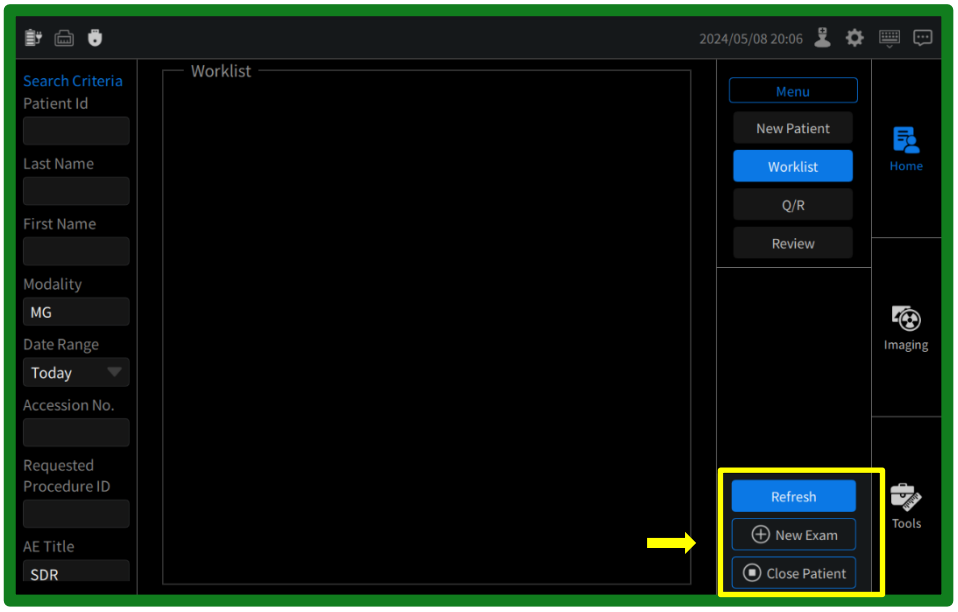


Figure 5.48 Action items of the worklist

The “Refresh” and “New Exam” action items are enabled, and thus with a solid blue background. The “Close Patient” action item is not enabled, and thus with a blue border and a dark grey background.

5.3.3 Q/R

The Q/R menu item of the home workplace allows the user to query and retrieve the patient information and image information from the DICOM server. If the Q/R list is empty, click the “Query” button to retrieve patient information from the server and select the “Retrieve” button to retrieve patient image information (Figure5. 49).

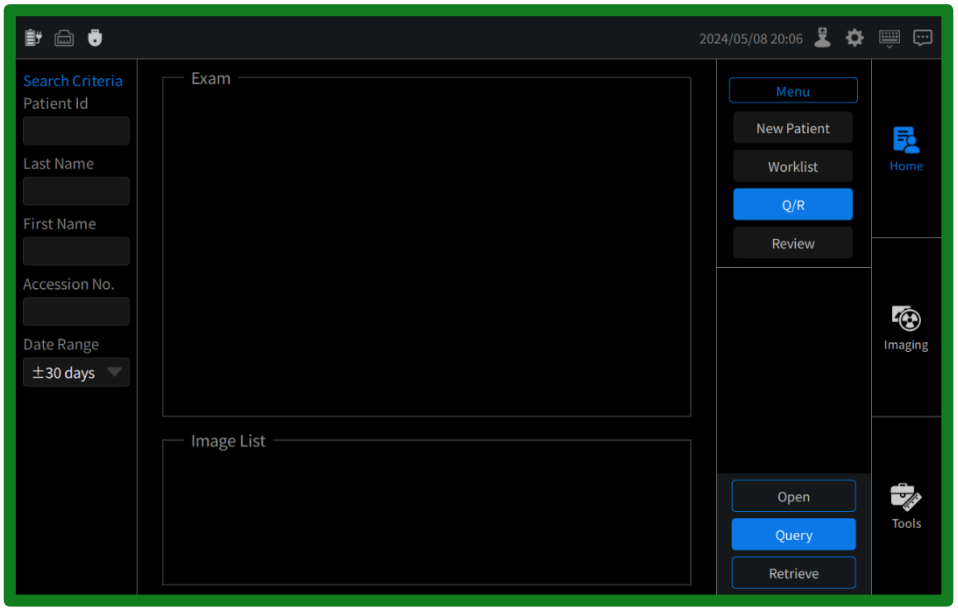


Figure 5.49 Retrieve the patient information

5.3.4 Review

The last menu item on the Home workspace is the Review menu item (Figure 5.50). This function allows the user to choose an existing patient from the patient list and then choose from several actions. The ***ADM*** user has access to the full list of action items, while a clinical user can only Open, Delete, or Refresh the patient list.

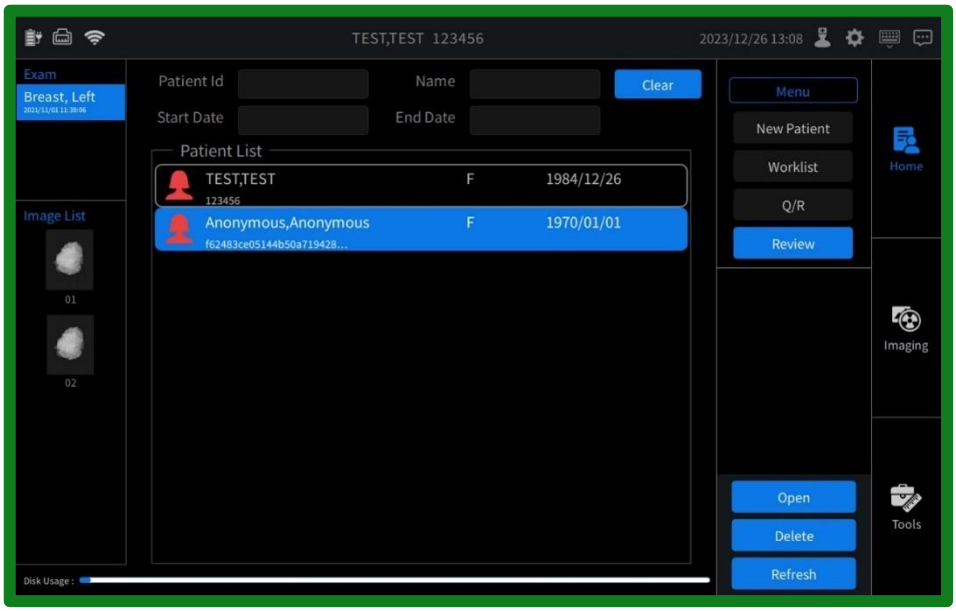


Figure 5.50 The Review menu item of the Home workspace for the ADM user

The “Open” action will take the user to the imaging workspace, but the user can also choose the Tools workspace if they just want to review previous specimen images.

The “Export” action item allows the ***ADM*** user to export patient data and to configure the file format. Choose the removable storage device to store the files, and the scope of the data the user wishes to export (Figure 5.51).

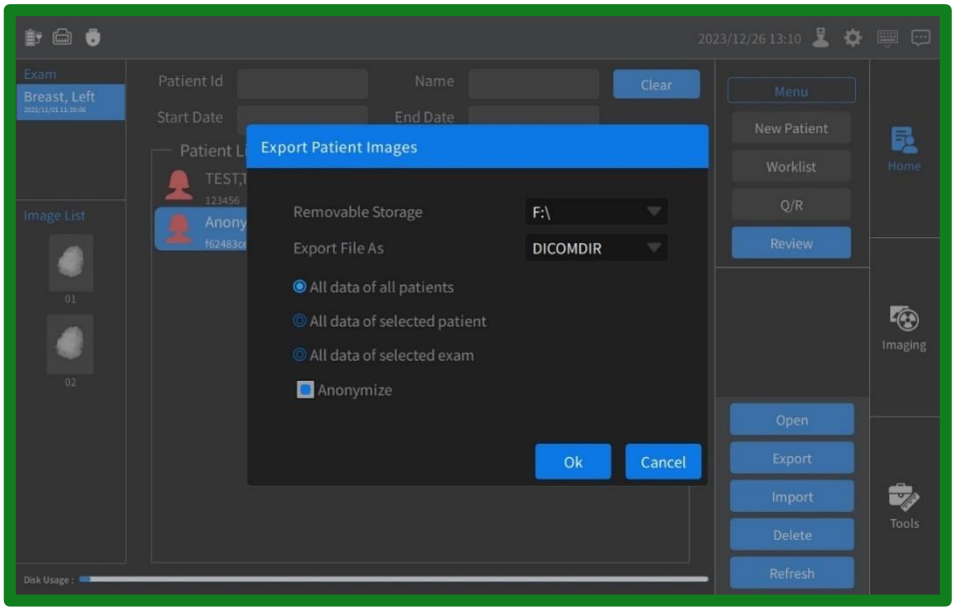


Figure 5.51 Export patient images in the Review menu item on the home workspace (only accessible to the ADM user)

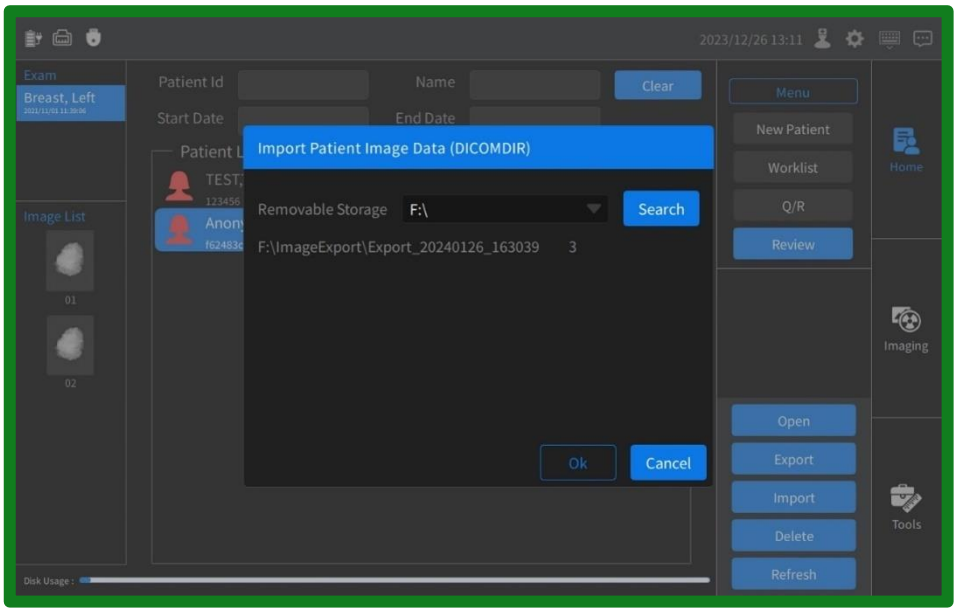


Figure 5.52 Import patient image data from the review menu of the home workspace (only accessible to the ADM user)

The “Import” action item allows the ***ADM*** user to import patient image data from a removable storage device (Figure 5.52).

The ***ADM*** or clinical user can remove patient data by selecting the “Delete” action item of the Review menu in the Home workspace.

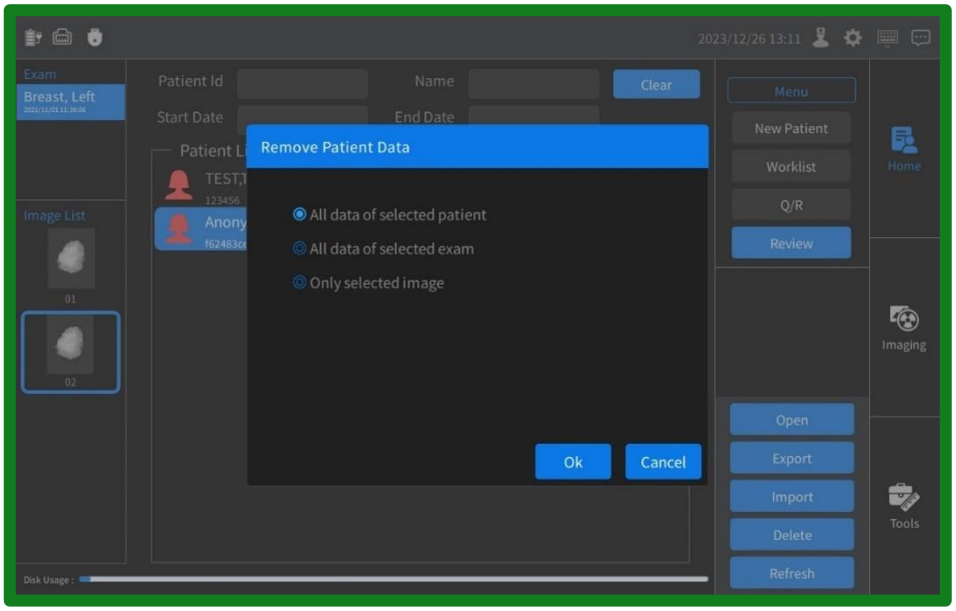


Figure 5.53 The Delete action item of the Review menu on the Home workspace

5.4 Imaging

The imaging workspace has only one menu item, so the only options for the user are the action items.

5.4.1. Exposure

Figure 5.54 shows the X-Ray menu of the Imaging workspace. The user will see the current patient’s information, the configurable exposure settings, the exam type, and the image list. The default values of the exposure settings come from the Exposure menu of the Utilities workspace (5.2.3 Exposure Settings); However, the user can change the exposure parameters for the current specimen images here on the imaging workspace. The user can set the tube voltage between 20kVp to 50kVp, and the tube current between 5mAs to 20mAs. The values will be used as the default values for the next specimen.

The user can choose the AEC exposure mode in the imaging workspace to automatically configure the exposure parameters. In this mode, the user does not need to set specific values for the kVp and mAs.

The magnification parameter is automatically determined by the system depending on the sample tray location in the specimen test cabinet. Use the “Open Door” and “Close Door” action items to open and close the specimen test cabinet door. Move the specimen tray to the appropriate level in the test cabinet to achieve the desired imaging magnification. The application software will display the current magnification according to the location of the specimen tray in the test cabinet rack. There are three positions in the test cabinet rack corresponding to magnification values of 1.0x, 1.5x and 2.0x.

With the exposure parameters set appropriately for imaging, the cabinet door closed, and the system displaying the ready message in the Imaging workspace, select the Exposure action item for exposure and imaging. As the system requires a confirmation before imaging the specimen, select the “Ok” button in the confirmation window to procedure with imaging (Figure 5.55).

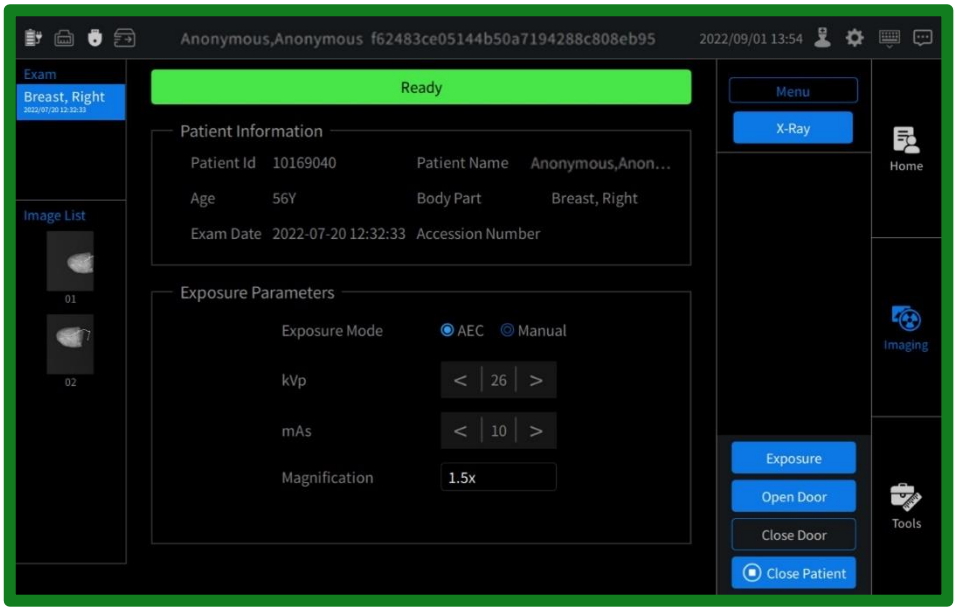


Figure 5.54 The open patient information, the exposure parameters, the exam type, and the current image list in the workplace.

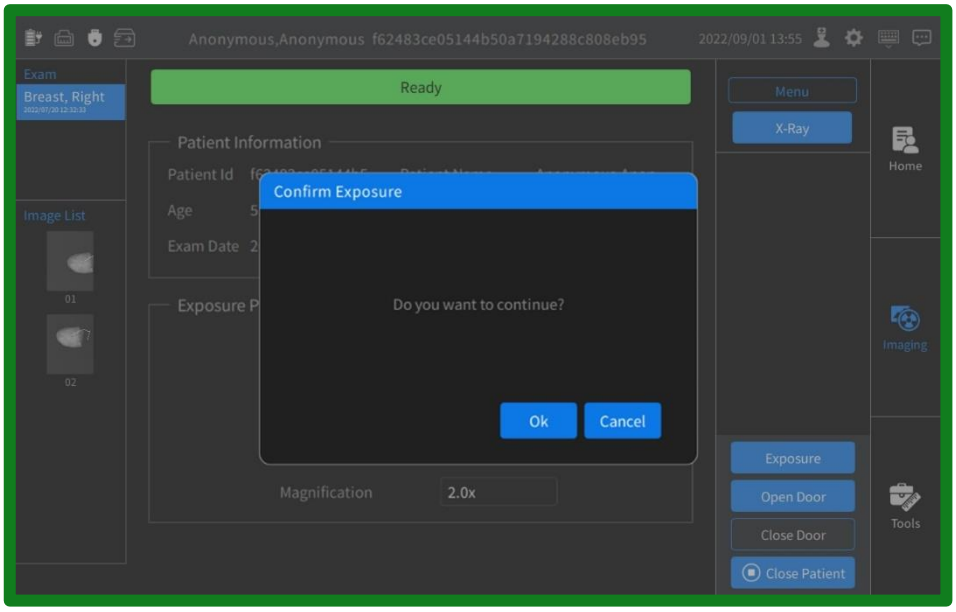


Figure 5.55 Exposure confirmation on the Imaging workspace

After clicking the “OK” button, a pop-up message appears in the screen while the system is proceeding with the imaging of the specimen (Figure 5.56). Wait several seconds for the system to capture the X-ray image, or select the “Cancel” button to stop the imaging if needed.

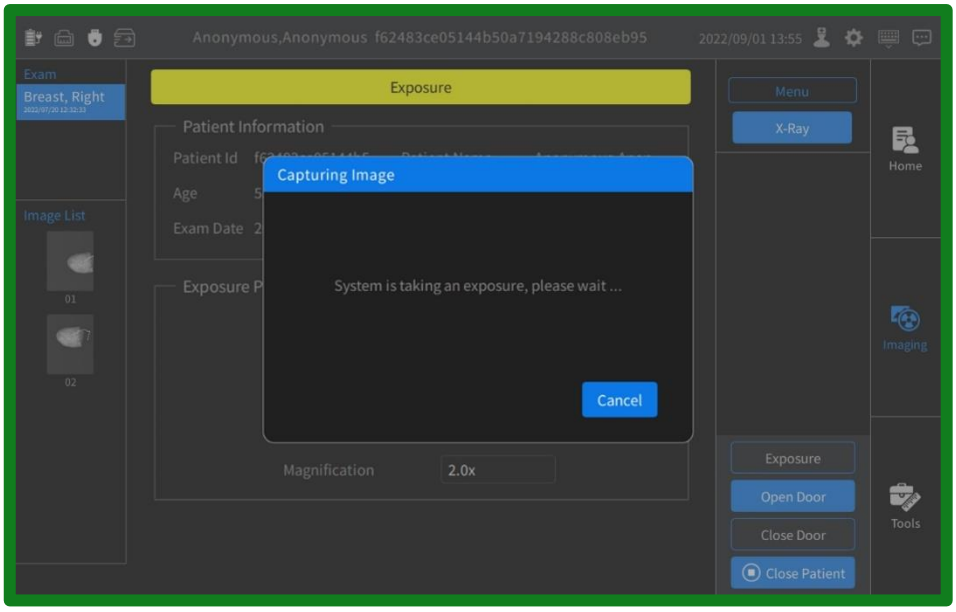


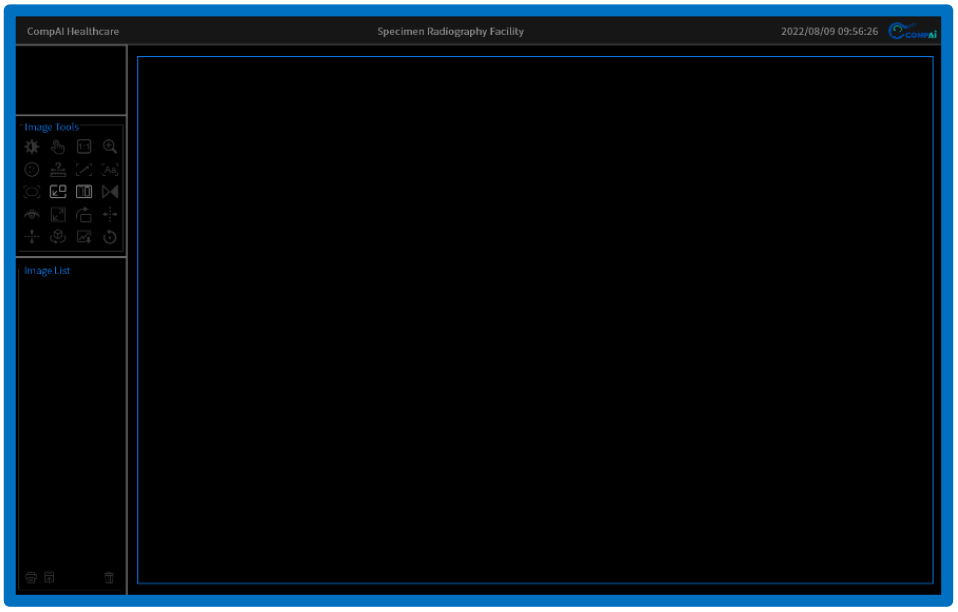
Figure 5. 56 The system is capturing an image screen. If there is a need to stop imaging before it is completed, select the cancel button from the capturing image dialog box.

5.5 Tools

When the exposure is completed, the system will jump to the Tools workspace and the newly taken image of the specimen will automatically be displayed on the touchscreen and simultaneously on the system monitor.

The Tools workspace utilizes both the touchscreen (seen with the green border in Figure 5.57) and the system monitor (seen with the blue border in Figure 5.57). This dual screen workspace provides the user access to the image list and the image tools for required image analysis. The system monitor will display the patient information and currently selected image information in the top left of the display. The touchscreen will display the exam information in the top left of the system workspace.

The system monitor seen in Figure 5.57 (in the single image configuration) displays the patient information, twenty selectable Image tools, a scrolling image list, and three functional icons (DICOM print, PACS network store, and image deletion).



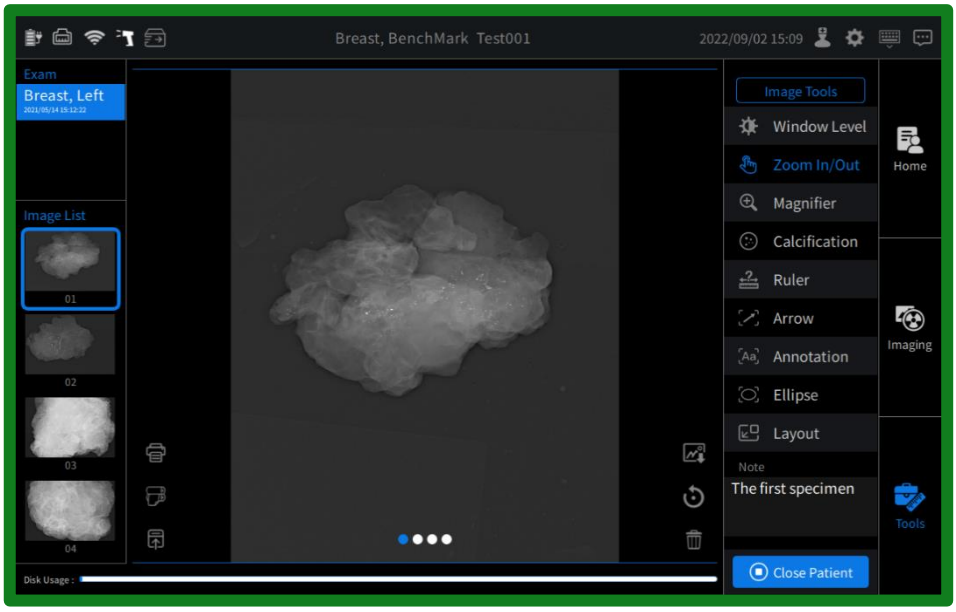


Figure 5. 57 The system monitor in the single image configuration (blue border), and the touchscreen (green border) for the Tools workspace with an image selected from the Image list.

Figure 5.57 also shows the twenty-two image tools accessible from the scrolling image tools menu of the touchscreen, with six functional icons in the image window. The system monitor provides the same access to all image tools and functional icons as the touchscreen, except for the show info image tool which is exclusive on the image tools list of the touchscreen.

The image list on the bottom left of both the system monitor and the touchscreen shows a scroll bar when the number of images exceeds the display space of the image list (the number of images displayed at once on the image list is up to four). The user can use the touchpad to select any of the visible images on the system monitor image list, or single-click and hold on the scroll bar with the touchpad to drag the list up or down. The user can also move the cursor onto the image list on the system monitor and use two fingers on the touchpad to scroll the image list. The same functionality of the image list is found on the image list of the touchscreen. However, the user can also touch the touchscreen image list to scroll and select images.

5.5.1. Window Level

The Window Level image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. The interface for the Window Level tool is different in the two screens. Figure 5.58 shows the user interface in the touchscreen when the Window Level tool selected. The user can select one of the four preset window and level values by choosing the corresponding icons. Alternatively, the user can also use sliders on the touchscreen to change the “Window” and “Level” values.

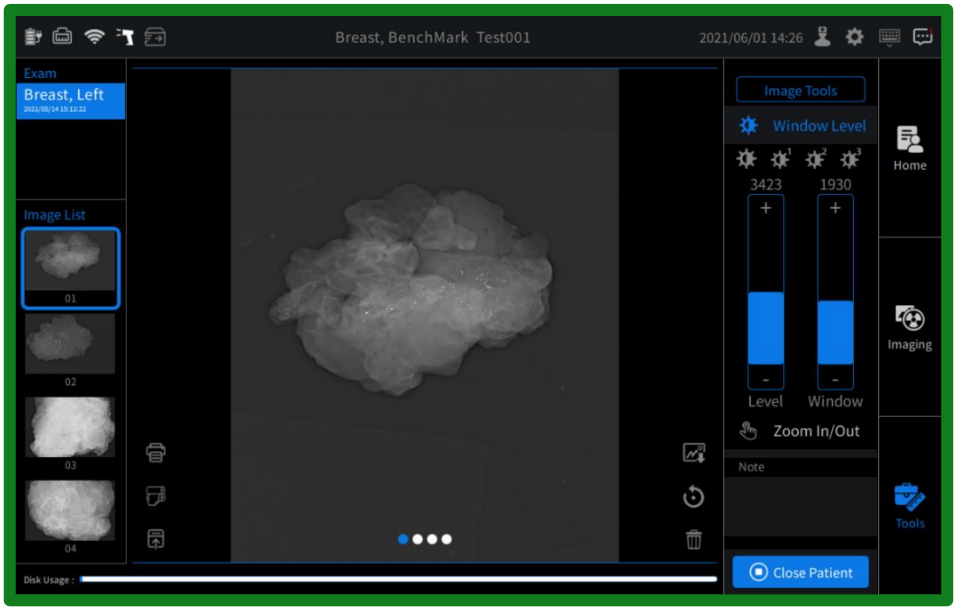
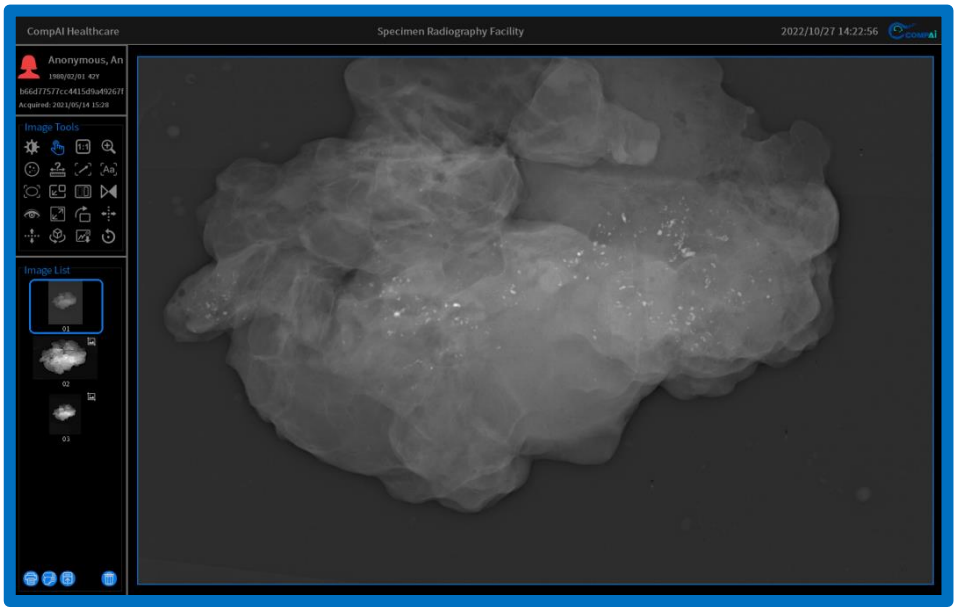


Figure 5. 58 Window Level tool interface on the touchscreen

The user can move the pointer within the selected image on the system monitor, and then by pressing and holding it on the system monitor the user may change the “Window” value by sliding left or right, and the “Level” value by sliding up or down.

5.5.2. Zoom In/Out

The Zoom In/Out image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. The interface for the Zoom In/Out tool is different in the two screens. Figure 5.59 and Figure 5.60 respectively show the selected image in the system monitor and touchscreen when the Zoom In/Out image tool is selected. With the pointer on the image in the touchscreen, the user can pinch two fingers on the touchscreen or the touchpad to decrease the image size on the system monitor. The touchscreen will display a blue square to indicate the visible area of the system monitor. Whereas pinching will cause the blue square to increase in size, by expanding two fingers on the touchscreen or touchpad the blue square will decrease in size. A smaller blue square will have the effect of making anything inside appear larger on the system monitor.



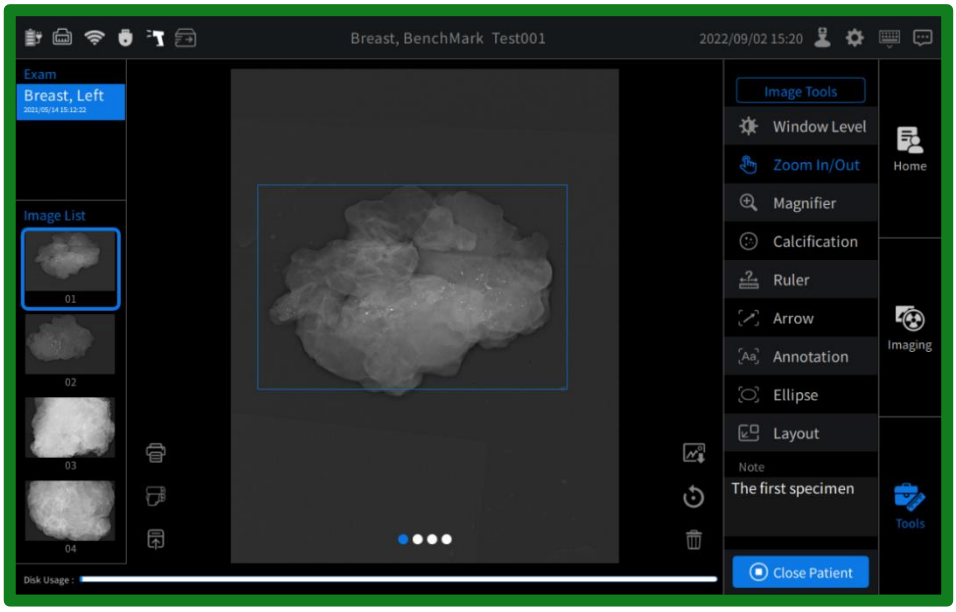
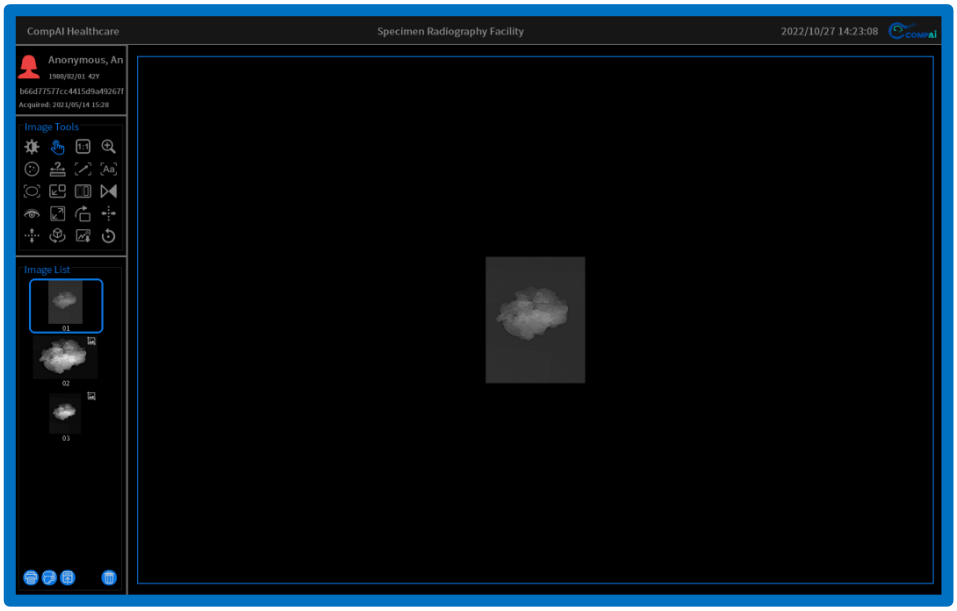


Figure 5. 59 The selected image on the system monitor and touchscreen when expanding two fingers to zoom in the image



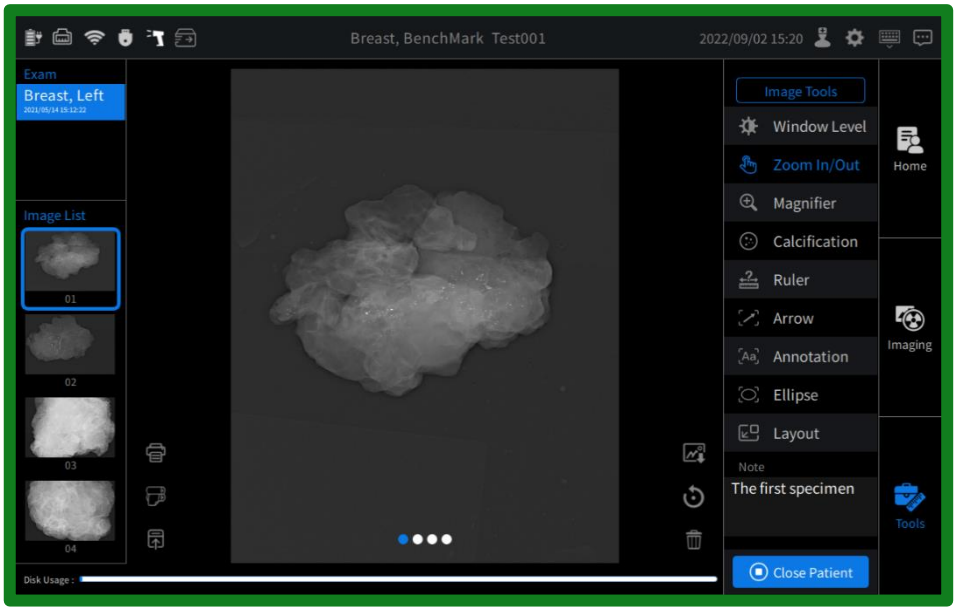


Figure 5. 60 The selected image on the system monitor and touchscreen when pinching two fingers to zoom out the image

The user can also use one finger to push and hold the touchpad while the pointer is on the touchscreen to drag the square around when the blue square turns green. The system monitor will display whatever is inside the square. If the pointer is on the system monitor image, the same action will have the same effect.

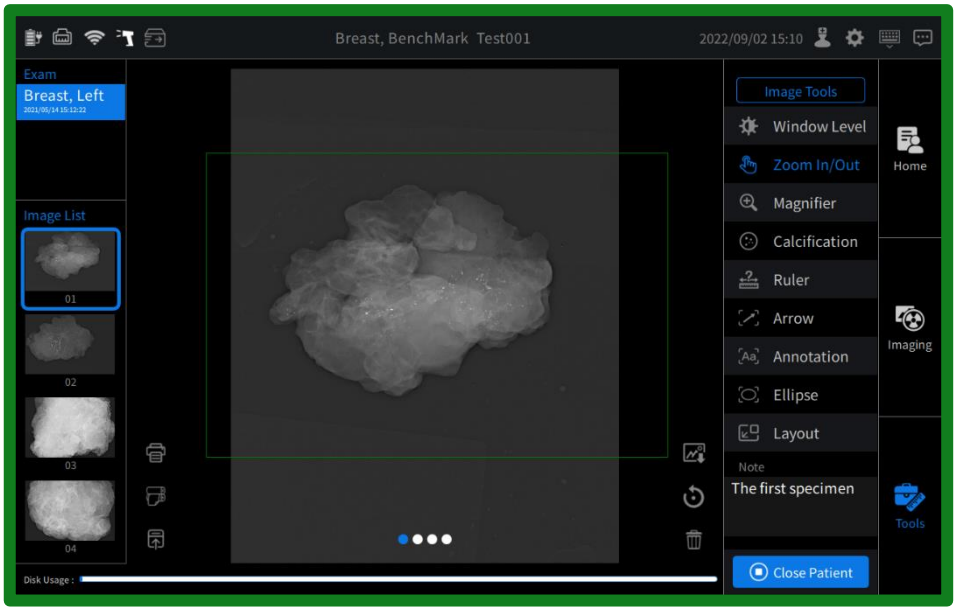


Figure 5. 61 The blue square turns green and it can be dragged around

5.5.3. Magnifier

The Magnifier image tool can be selected from the touchscreen image tools list or from the system monitor image tools list. However, its function is only available on the system monitor. Figure 5.62 shows the active square with blue border visible on the system monitor that can be moved by the touchpad. And the square will display the image with a fixed 2x magnification.

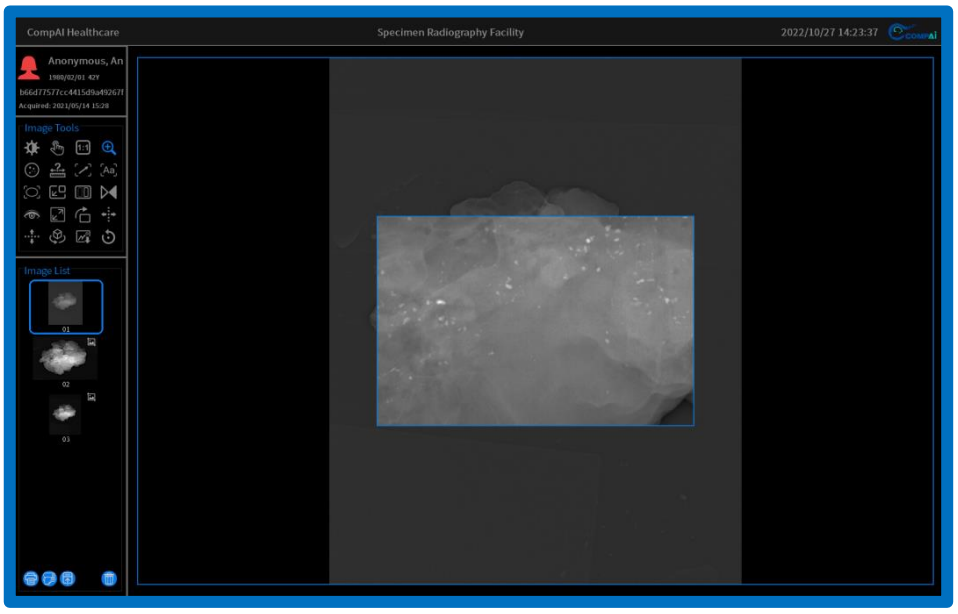


Figure 5. 62 Magnifier tool interface on the system monitor

Since the Magnifier image tool can be used in conjunction with other image tools, the user can simply select the Magnifier image tool to toggle it on or off.

5.5.4. Calcification

The Calcification image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, the its function is only available on the system monitor. This tool will identify likely calcifications in the image of specimen by drawing a clearly visible red box around the suspected calcification or smudging red over the calcification. When the tool is enabled, the calcification

indicators will remain visible and this tool can be used in conjunction with other image tools. The user can select the Calcification button to toggle the functionality on or off.

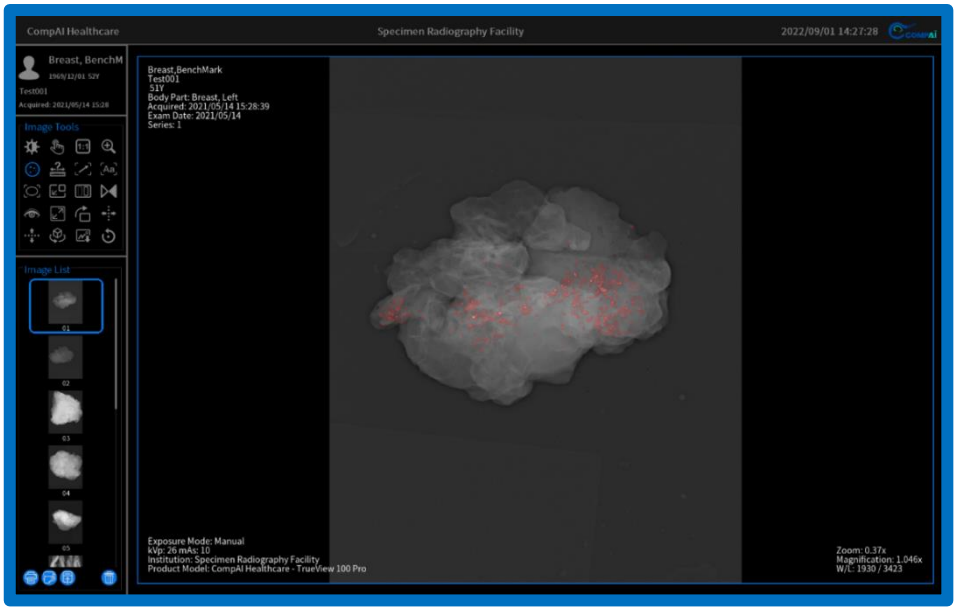


Figure 5. 63 Calcification tool interface on the system monitor

5.5.5. Ruler

The Ruler image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, the its function is only available on the system monitor. With the pointer in the image window of the system monitor, use the touchpad to move the pointer to the location you want to begin measuring. A single press of the touchscreen will enable the ruler. Then use the touchpad to move the pointer to the second location of the measurement and again press the touchpad. And the straight line between the two locations as well as the length will be displayed on the image in the system monitor.

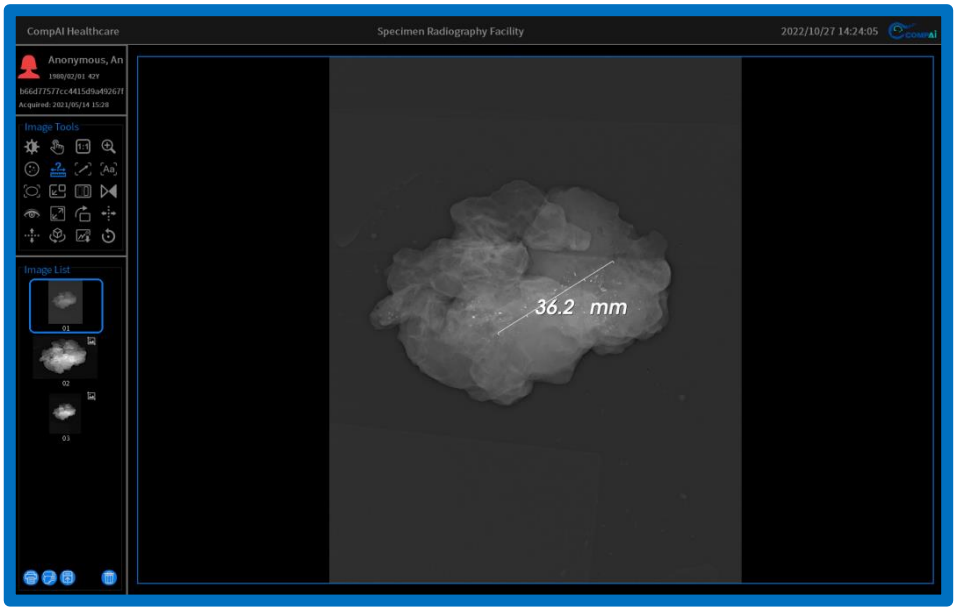


Figure 5. 64 Ruler tool interface on the system monitor

Either endpoint of the measurement can be adjusted by hovering the pointer over the location. The pointer will change into a hand icon. Simply select and hold on the touchpad to drag the point around. The length is calculated based on the original image, and will not be influenced by any image tools. The measurements can be erased together or one-by-one by right-selecting on the touchpad while the pointer is on the image on the system monitor, selecting the ruler option and then choose to remove all the options or one single option.

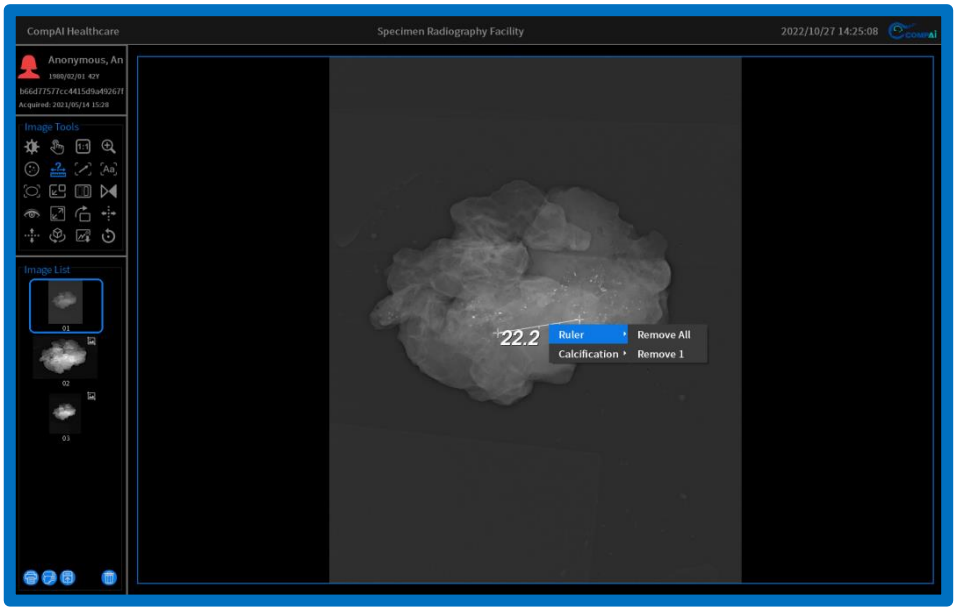


Figure 5. 65 Remove option interface on the system monitor

5.5.6. Arrow

The Arrow image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, its function is only available on the system monitor. With the pointer in the image window of the system monitor, use the touchpad to move the pointer to location you want for the tip of the arrow. A single press of the touchscreen will place the arrow tip at your current location. Now use the touchpad to rotate the arrow around to the desired orientation. Another press of the touchpad will fix the arrow in place. The user may add as many arrows as desired to the image in the active window.

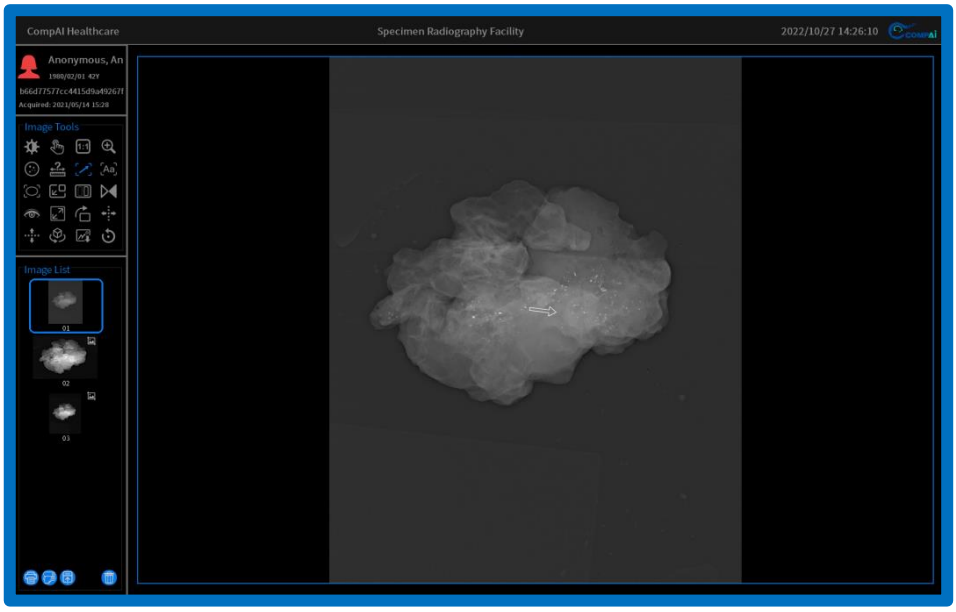


Figure 5. 66 Arrow tool interface on the system monitor

The arrows can be erased together or one-by-one by right-selecting on the touchpad while the pointer is on the image on the system monitor, selecting the arrow option and then choose to remove all option or one single option (similar to Figure 5.65 for the ruler).

5.5.7. Annotation

The Annotation image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, its function is only available on the system monitor. When the tool is selected, a text input window will appear. Enter the text you wish to have displayed on the image and then select “Ok”. If the text on the image is not displayed in the desired location, hover the pointer over the text until the icon change to a four-pointed arrow. Simply select and hold on the touchpad to drag the text around the images and release the touchpad when the text is in the desired position.

The annotation can be erased together or one-by-one by right-selecting on the touchpad while the pointer is on the image on the system monitor, select the annotation option and then choose to remove all the options or one single option (similar to Figure 5.65 for the ruler). Further annotations can be added to

the image by selecting the annotation icon again, or by right-selecting the touchpad, selecting the annotation option, and then selecting the new option.

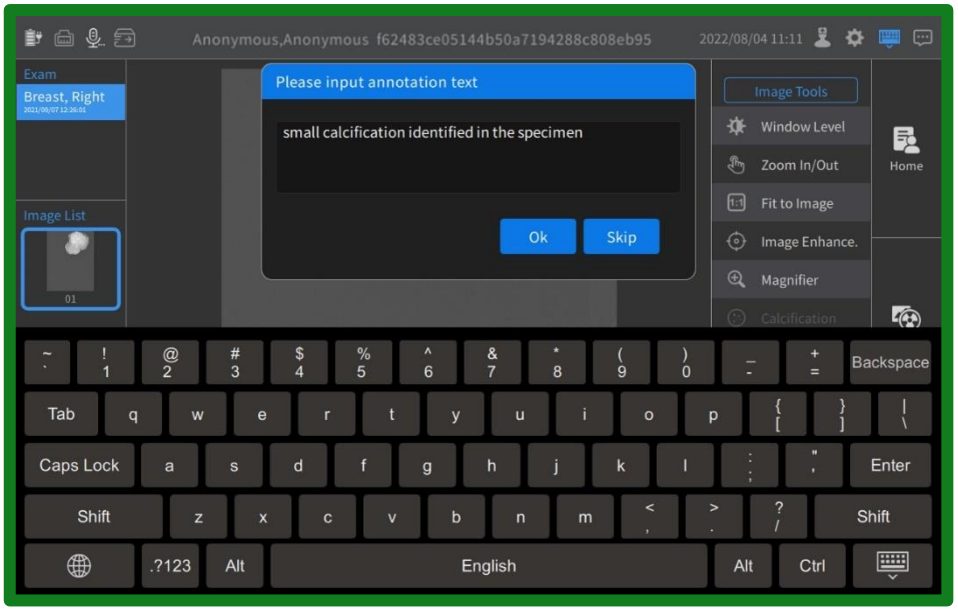


Figure 5. 67 Annotation tool interface on the touchscreen of the Tools workspace

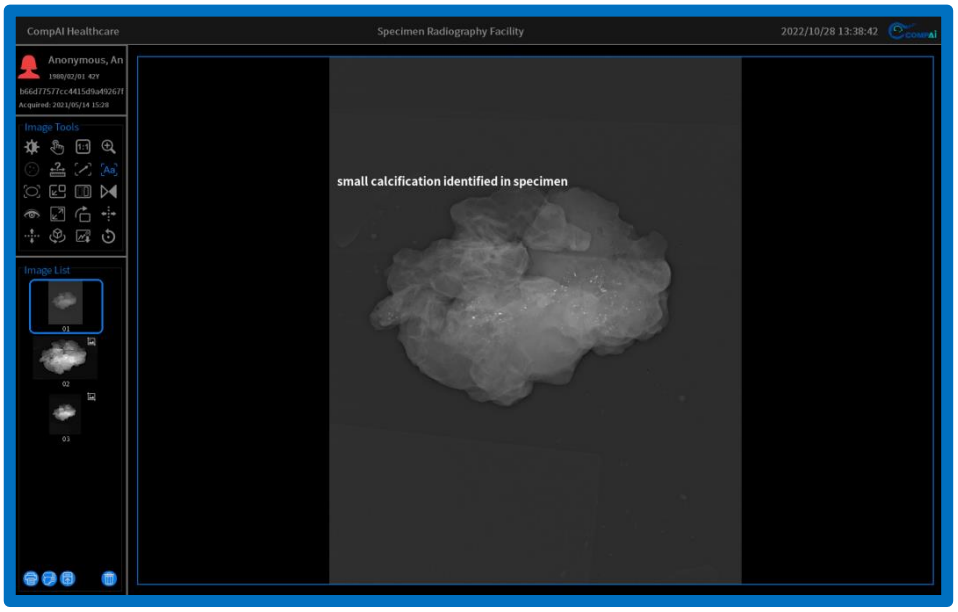


Figure 5. 68 Annotation interface on the system monitor

5.5.8. Ellipse

The Ellipse image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, its function is only available on the system monitor. With the pointer in the image window of the system monitor, use the touchpad to move the pointer to location you want to begin measuring the first axis of the ellipse. A single press of the touchscreen will fix the first point of the ellipse axis. Now use the touchpad to move the pointer to the second point of the ellipse axis and again press the touchpad again. With the first axis of the ellipse set, use the touchpad to move the point and set the second axis of the ellipse. Once the second axis is at the desired length, press the touchpad again to finish drawing the ellipse. The parameters of the ellipse will be displayed on the image in the system monitor.

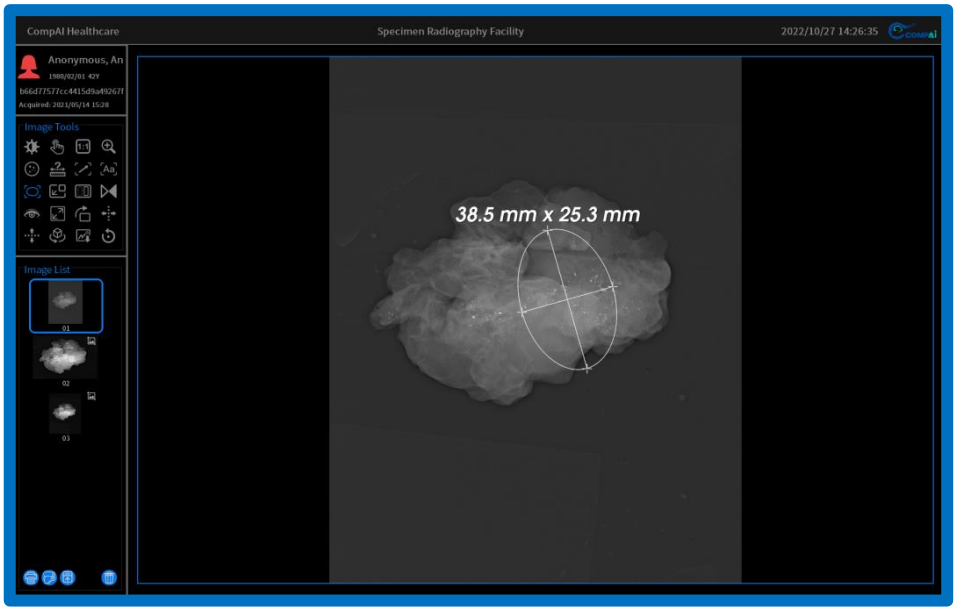


Figure 5. 69 Ellipse interface on the system monitor

The ellipse can be edited, rotated, and moved by using the touchpad. To change an axis length, however the point over either end of the axis until a double arrow appears. Press and hold the touchpad, and then drag the axis to the desired length. To rotate the ellipse, hover the pointer near any endpoint until the icon changes to a hand. Press and hold the touchpad, and then drag the ellipse to rotate it to the desired orientation. To displace the ellipse in either the x or y direction, hover the pointer over the center of the ellipse until a four-pointer arrow appears. Press and hold the touchpad, and then drag the ellipse until it is in the desired position.

The ellipse can be erased together or one-by-one by right-selecting on the touchpad while the pointer is on the image on the system monitor, selecting the ellipse option and then choose to remove all the options or one single option.

5.5.9. Layout

The Layout image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. Selecting this icon will cycle the number of displayed images on the system monitor between one, two, or four images. Although several images can be displayed on the system monitor simultaneously, only the active window (the one with the blue border) can be affected by the image tools. The active window on the system monitor can be changed with the next screen image tool, by using the touchpad to select and image on the system monitor, or changing the active image on the touchscreen.

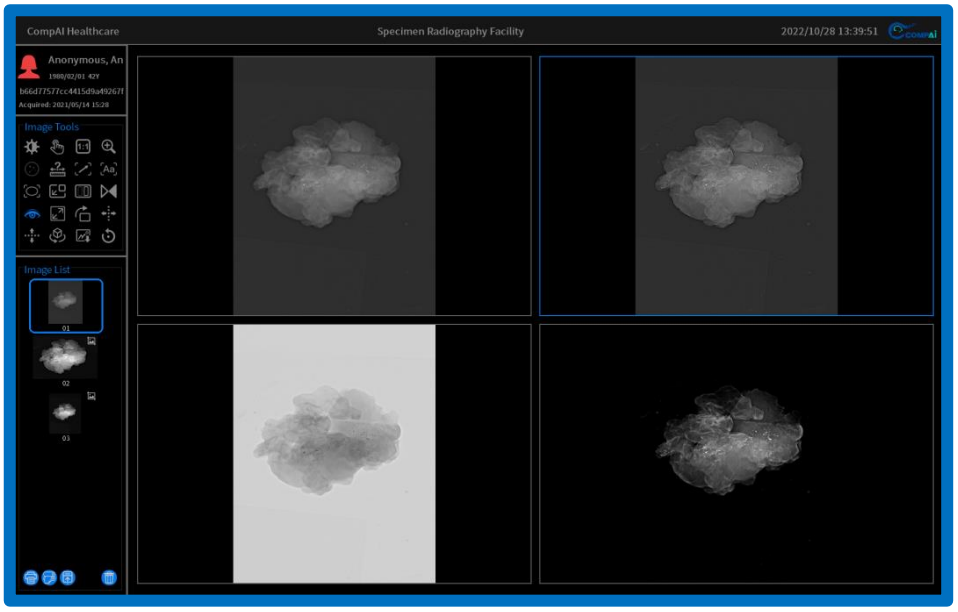


Figure 5. 70 Layout interface on the system monitor in the four-image display layout

5.5.10. Image Enhancement

The Image Enhancement image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. This tool is intended to improve the contrast of the image.

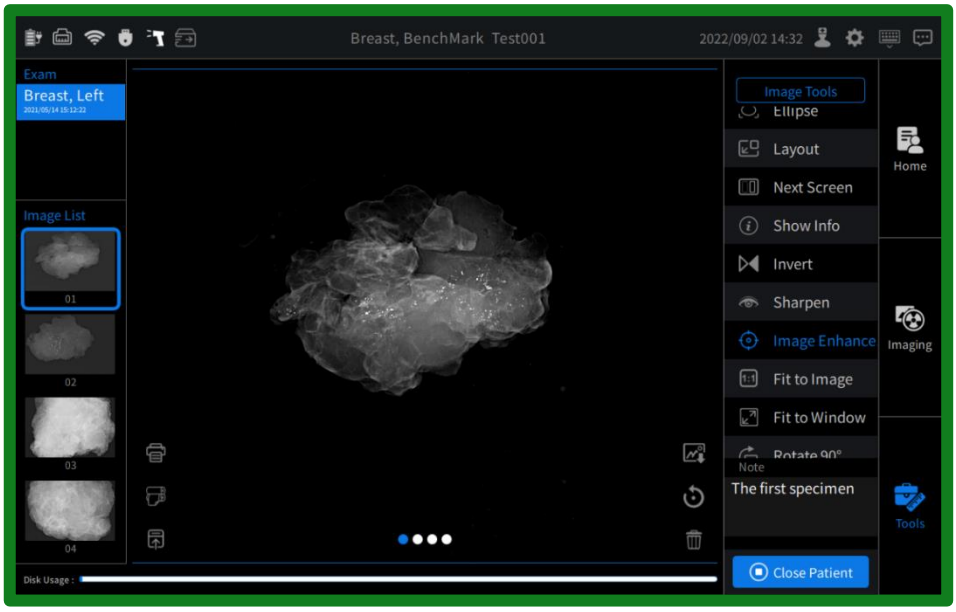


Figure 5. 71 Image Enhancement interface on the touchscreen

5.5.11. Next Screen

The Next Screen image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. Selecting this icon will sequentially change the active window on both the system monitor and the touchscreen.

5.5.12. Show Info

The Show Info image tool is only accessible via the touchscreen image tools list. Selecting this icon will toggle between displaying the image information on the image in the active window of the system monitor.

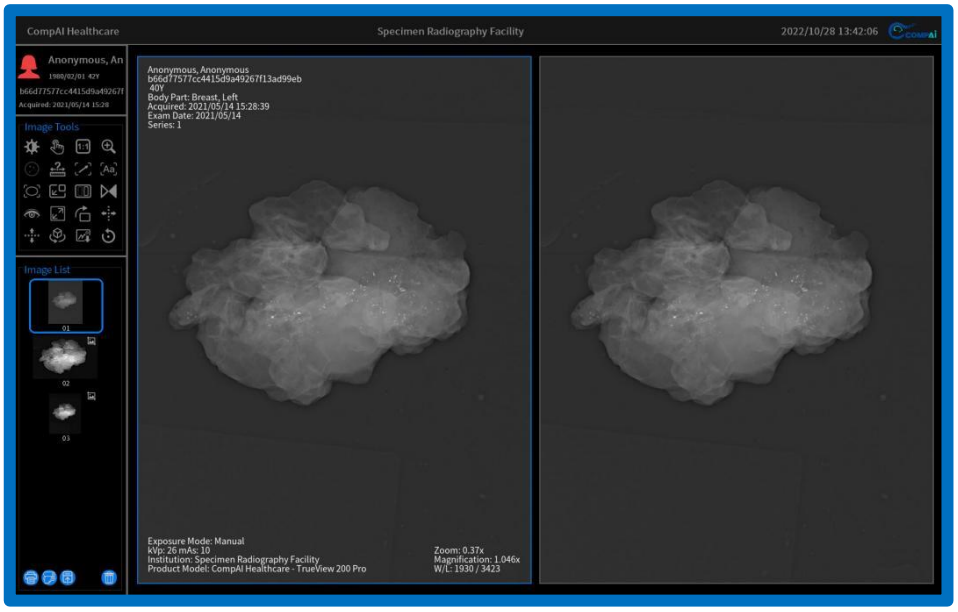


Figure 5. 72 Show Info interface on the system monitor in the two-image display layout

5.5.13. Invert

The Invert image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. Selecting this icon will invert the grayscale values of the image in the active window. This will not change the color of any annotation, image information, ruler, ellipse, or arrow drawn on the image, as all those objects will remain white. If the calcification feature is enabled, any calcification identified will still be displayed with a red border.

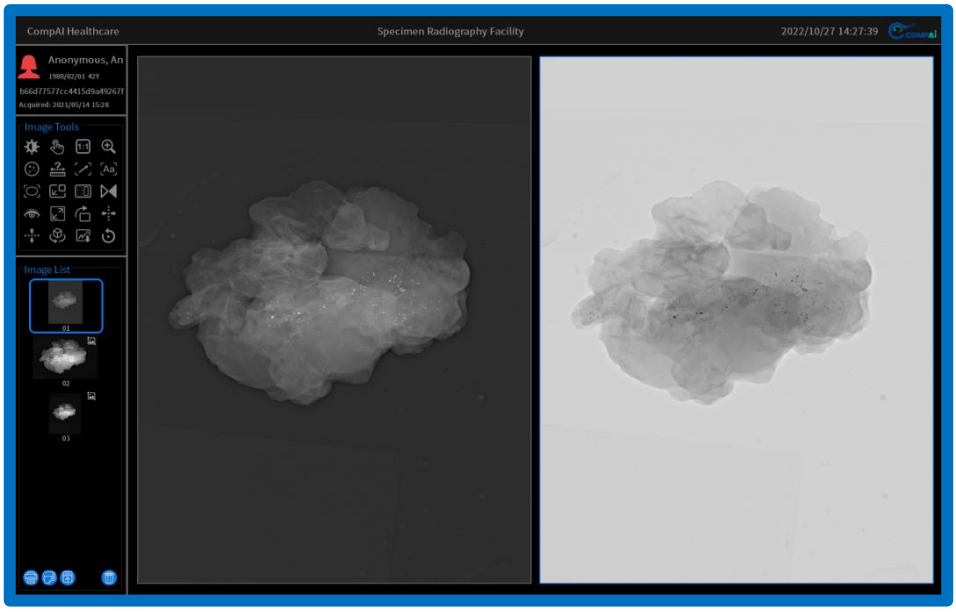


Figure 5. 73 Invert interface on the system monitor in the two-image display layout

5.5.14. Sharpen

The Sharpen image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, only the touchscreen interface will allow the user to apply sharpening to the image in the active window. REF shows the pre-set image sharpening levels that can be applied to the image in the active window.

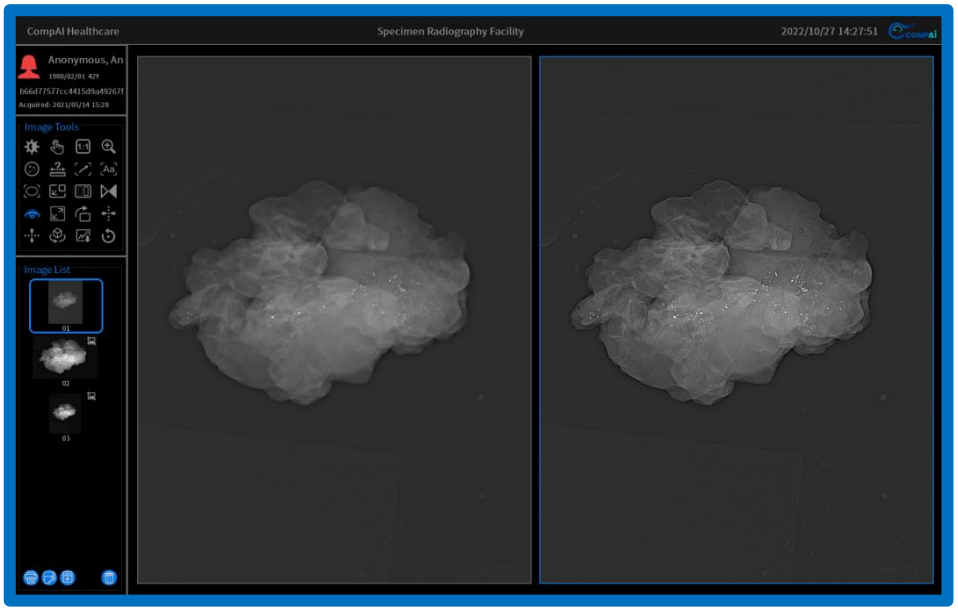


Figure 5. 74 Sharpen tool interface on the system monitor in the two-image display layout

If the user moves the pointer within the selected image window of the system monitor, then by pressing and holding on the system monitor the user may change the sharpen level by sliding left or right.

5.5.15. Fit to Image

The Fit to Image tool changes the region of interest on the touchscreen to reflect the native resolution of the imaging panel. This will effectively zoom in on the image as viewed by the system monitor.

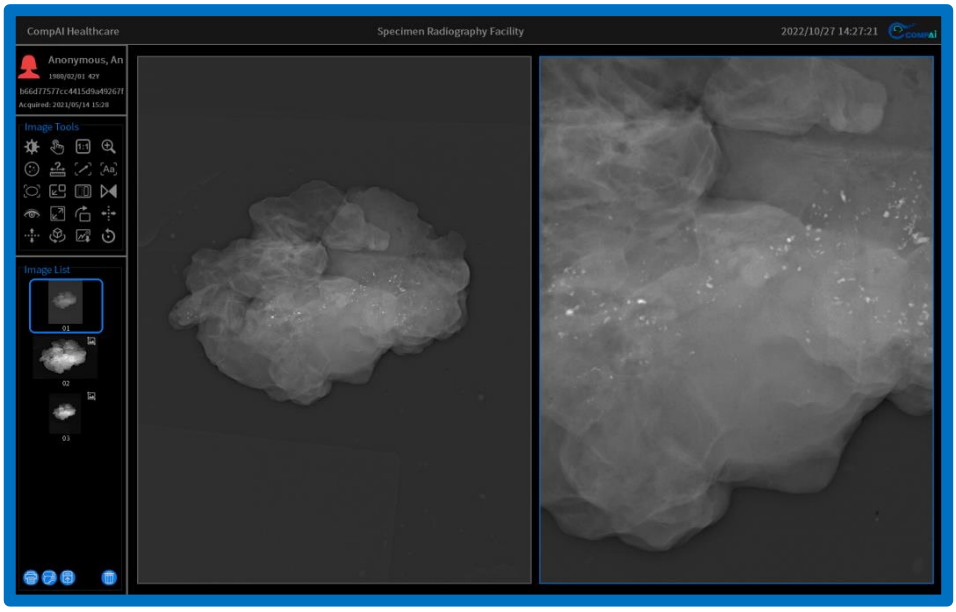


Figure 5. 75 Fit to Image interface on the system monitor in the two-image display layout

5.5.16. Fit to Window

The Fit to Window image tool changes the region of interest on the touchscreen so that the entire image is displayed on the system monitor. This will appear to zoom out on the image as viewed by the system monitor.

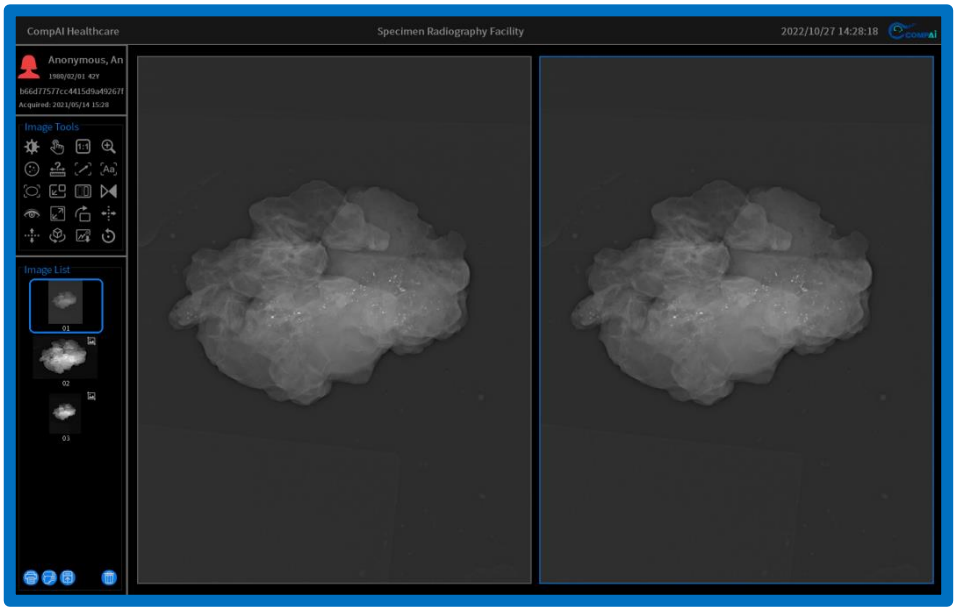


Figure 5. 76 Fit to Window interface on the system monitor in the two-image display layout

5.5.17. Fit to Specimen

The Fit to Specimen image tool makes the image with original size be displayed on the screen.

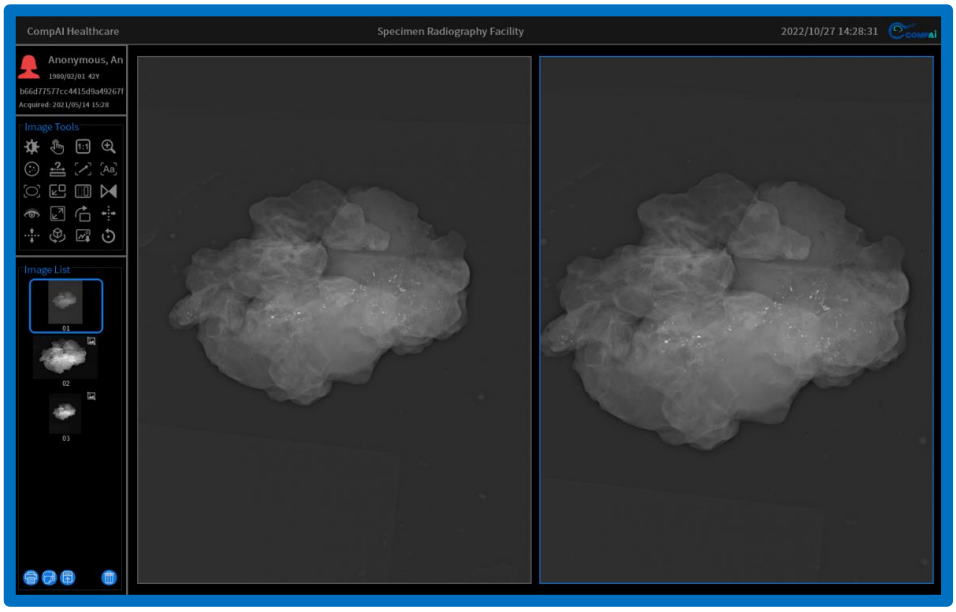


Figure 5. 77 Fit to Specimen interface on the system monitor in the two-image display layout

5.5.18. Rotate 90°

The Rotate 90° image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. Selecting this icon will cycle the image orientation in the active window by 90°. Any previous annotations, measurements, and identified calcifications will display properly in conjunction with this tool.

5.5.19. Mirror

The Mirror image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. Selecting this icon will mirror the image in the active window about the vertical axis (i.e. left to right). Any previous annotations, measurements, and identified calcifications will display properly in conjunction with this tool.

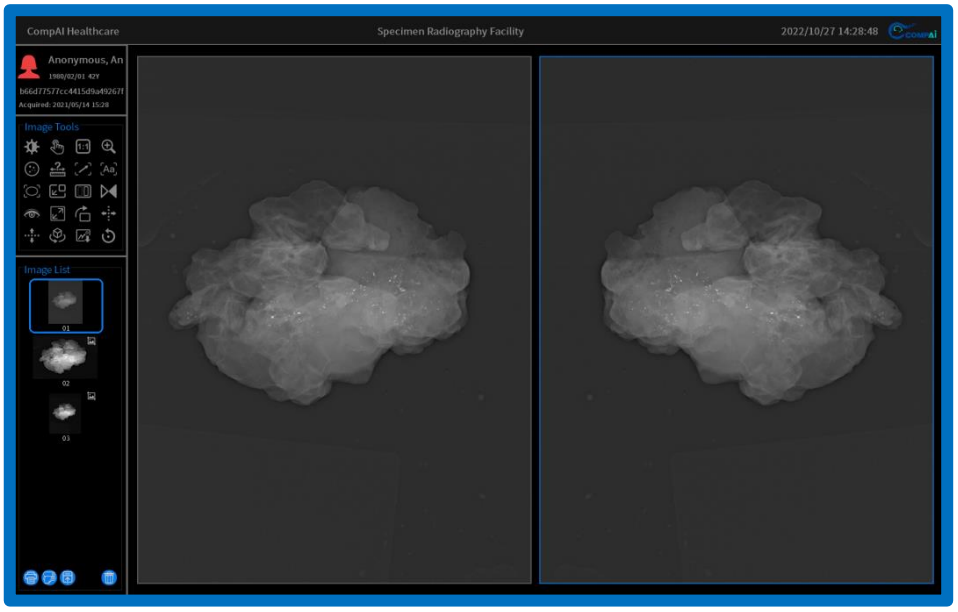


Figure 5. 78 Mirror interface on the system monitor in the two-image display layout

5.5.20. Flip

The Flip image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. Selecting this icon will mirror the image in the active window about the horizontal1 axis (i.e. top to bottom). Any previous annotations, measurements, and identified calcifications will display properly in conjunction with this tool.

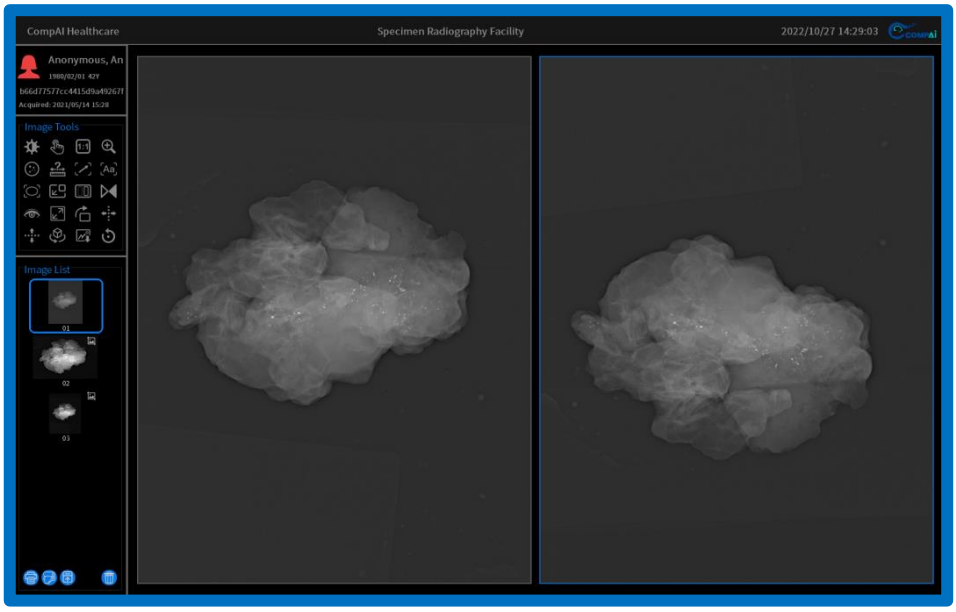


Figure 5. 79 Flip interface on the system monitor in the two-image display layout

5.5.21. Free Rotate

The Free Rotate image tool can be accessed from the touchscreen image tools list or from the system monitor image tools list. However, its function is only available on the system monitor. With the pointer in the image window of the system monitor, use the press and hold on the touchpad to rotate the display about the center of the image. Any previous annotations, measurements, and identified calcifications will display properly in conjunction with this tool. However, any previous displacement of the image will be overridden by the rotation. If you want to center the newly rotated image, then use the zoom in/out image tool after the free rotation to adjust the image location in the display window.

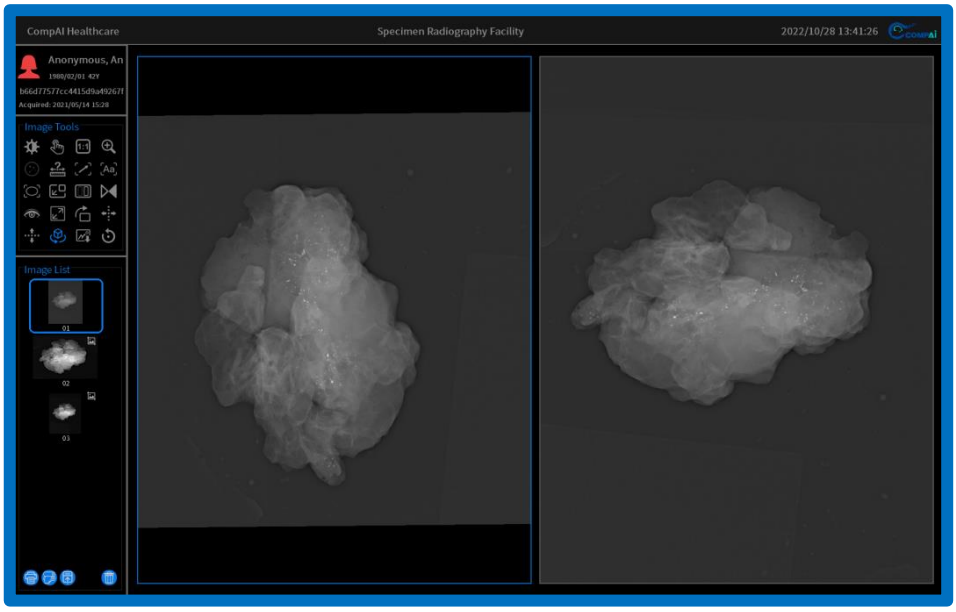


Figure 5. 80 Free rotate interface on the system monitor in the two-image display layout

5.5.22. Image Note

The user can add a note to an individual image within the current exam. Select the text box at the bottom of the image tools list in the system workspace of the touchscreen and the keyboard will appear. Enter the desired text and then select the OK button to add your text to the image in the active window.

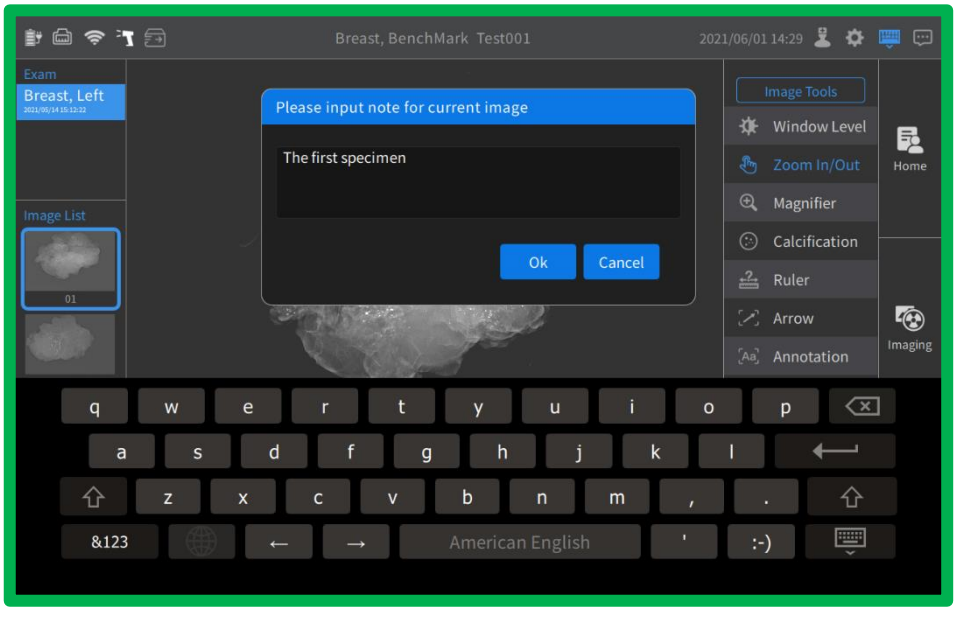


Figure 5. 81 Image note tool interface on the touchscreen of the Tools workspace

5.5.23. Functional Icons of the Touchscreen

The functional icons of the touchscreen are Local Print, DICOM Print, PACS Store, Save Image, Reset, and Delete Image. The “Save Image” and the “Reset” are Image tools on the system monitor, but they are also available in the touchscreen.

5.5.23.1. Local Print

There are two ways of printing, namely DICOM printing and Local printing. Local printing means to select the local printer that has been added successfully to print on A4 paper. Besides, the user can also select which image to be printed and make notes, as shown in Figure 5.82 below.

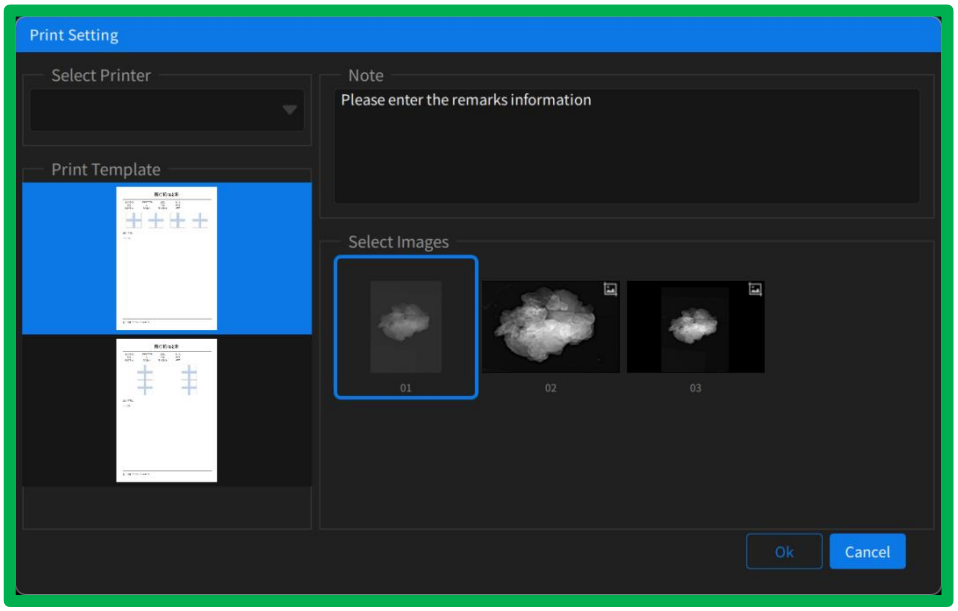


Figure 5. 82 Select image to print

5.5.23.2. DICOM Print

There are two ways of printing, namely DICOM printing and local printing. DICOM printing is to send the image in the active window to DICOM printer.

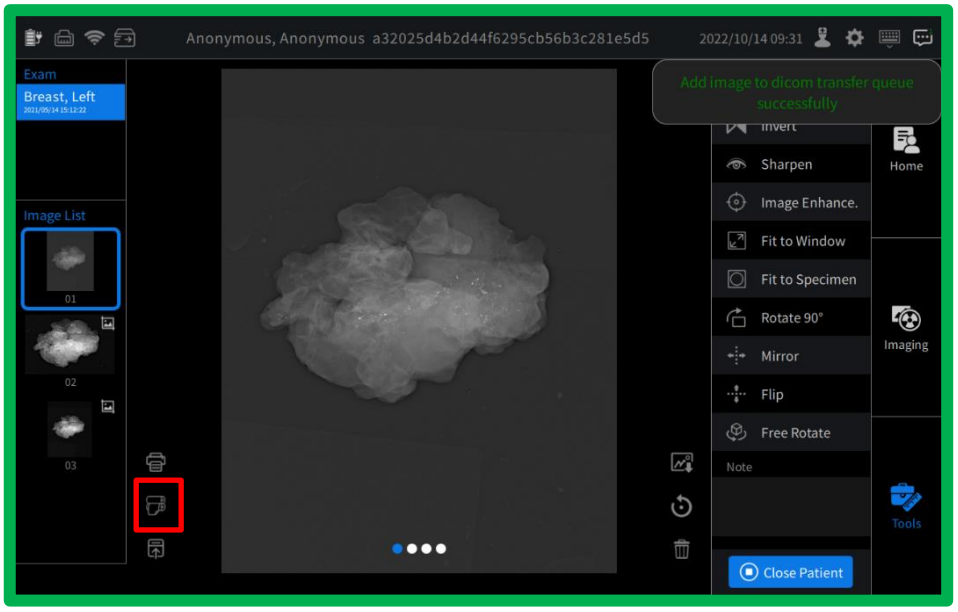


Figure 5.83 Add image to dicom transfer queue successfully

5.5.23.3. PACS Store

The PACS Store functional icon adds the image in the active window to PACS store server queue to be saved on the PACS server.

5.5.23.4. Save Image

The Save Image functional icon saves the image in the active window as a jpeg and adds it to the Image list.

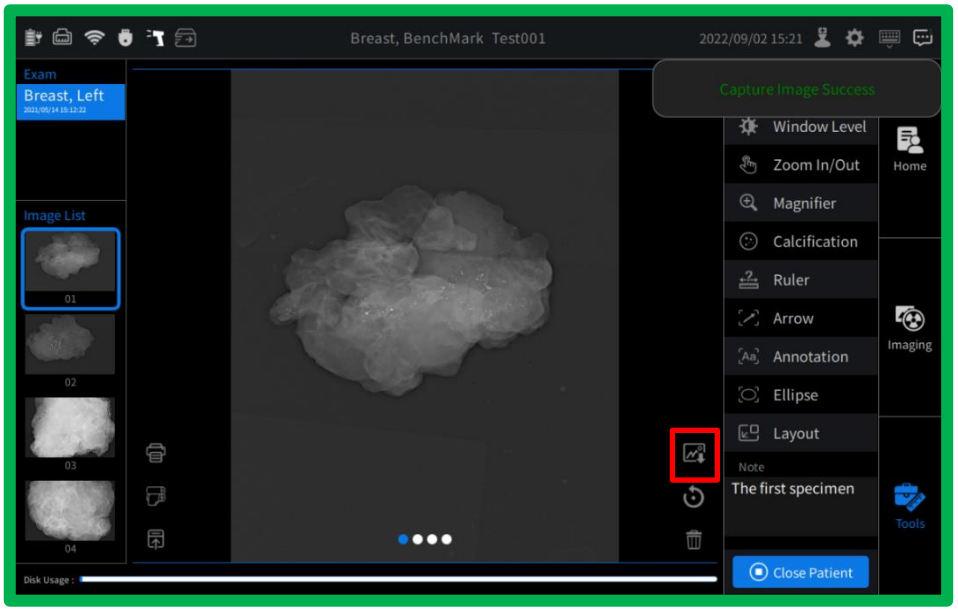


Figure 5. 84 Save active window as image

5.5.23.5. Reset

The Reset functional icon reverts the image in the active window to the original image. However, this feature is only available for original x-rays of the specimen. This feature has no impact on images created with the “Save Image” (see 5.5.23.4).

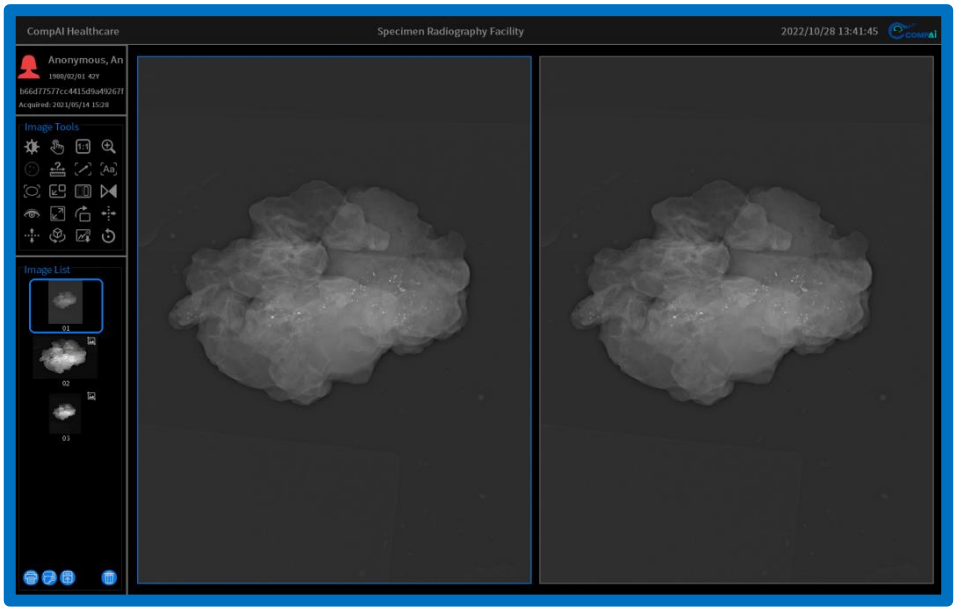


Figure 5. 85 Reset image in active window

5.5.23.6. Delete Image

The Delete Image functional icon deletes the image in the active window from the image list. After clicking this button, a dialog box will pop up requiring the user to confirm deleting before the action is taken.

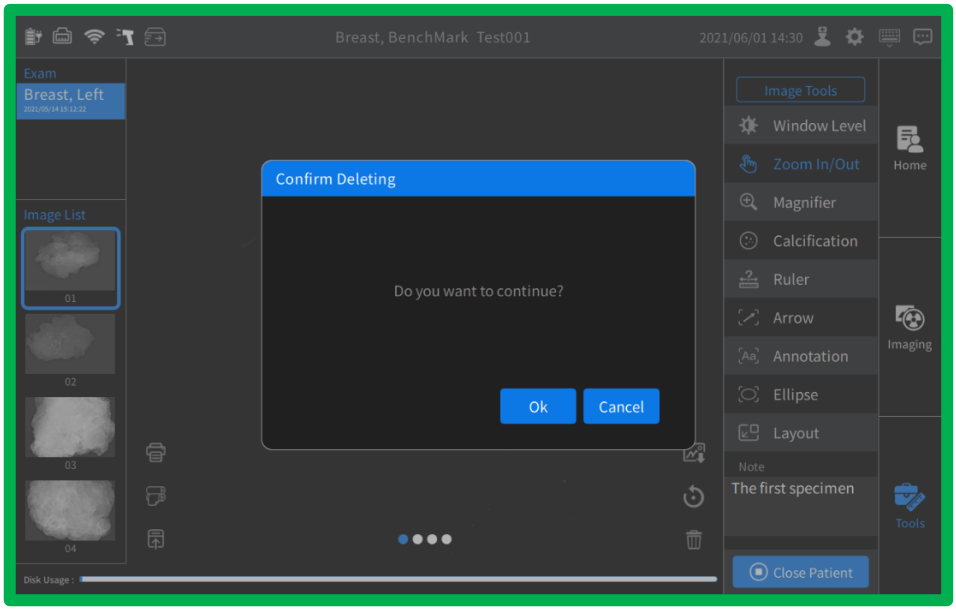


Figure 5. 86 Confirm deleting the image in active window

6. System Maintenance

The safe and effective application of this system depends on the basic performance of the product. Using the product in an abnormal state of the system may cause unexpected consequences.

In order to ensure that the intended use and purpose can be achieved safely and effectively, the user should maintain this system according to the requirements and methods of this chapter during the life cycle of this system.

When the system fails during operation, the user personnel who have received special training and are competent for system detection and maintenance can perform general simple detection and maintenance according to the instructions in this chapter. However, the user is not authorized to change the system software, hardware, or adjust the imaging geometry of the system and if the abnormal situation found by the user involves these aspects, please contact the manufacturer for technical support.

When users maintain the system according to the requirements of this chapter, they should strictly abide by the relevant requirements and warnings of Chapter 2 Safety and Liability Precautions.

6.1 System Maintenance

6.1.1 Daily Inspection and Maintenance

a） Daily Inspection

Check the device status before using the device every day, and confirm that the device is in good condition before positioning. The contents of the inspection include those described in 2.4.1:

- The appearance of the equipment components is intact without having been moved, and disassembled as well as covering other objects;
- The power cable is not disconnected and the insulation is not damaged;

- No foreign objects block the X-ray path;
- After the power is turned on, the power indicator is normal.

b） Daily Maintenance

- Ensure that the system's operating environment meets the requirements of this manual;
- Keep the surface of the device clean, especially the surface of the X-ray flat panel detector and tray.
- When the system is turned off, clean the surface of the device by using a soft dry cloth or a wringed wet cloth to remove dust and dirt.

6.1.2 Periodic Check and Calibration

The periodic inspections of the system include semi-annual inspection and annual inspection:

a） Semi-annual Inspection

Under normal use, qualified personnel should calibrate the system's imaging components once every six months.

b） Annual Inspection

Under normal use, qualified personnel should perform paired verification of the high-voltage generator and X-ray tube once a year, and then use a fixed die body to check the image quality. When the test result shows that the image quality does not meet the specified requirements, the user should contact the manufacturer in time to resolve.

6.1.3 Event-triggered Calibration

When the following situations occur, the user should check the system in time and do not continue to use the system until the verification is completed:

a） Severe impact on X-ray tube, X-ray flat panel detector or its connecting device may cause these components to move;

b） The imaging components of this system have been replaced or repaired.

Please contact the manufacturer in time to verify the system.

6.1.4 Barcode Scanner Maintenance and Repair

a） Recommended Maintenance Method for Barcode Scanner

Please follow the following guidelines to keep the barcode scanner of the barcode verification system working in good condition:

Usually, the barcode scanner is placed on the side bracket of the device and can be removed when needed. Use USB to connect the barcode scanner to the device host to ensure that barcode data is transmitted to the system.

b） Recommended Care for Wireless Barcode Scanner

Follow the instructions and pay attention to the warnings.

- Clean the outer surface of the scanner and scan the window regularly to ensure optimal operation.

6.1.5 Replace the Power Socket Fuse

This system must use a ceramic or glass fuse with a length of 20±0.5mm, a rated current of 10A, and a fast-blow type.

The fuse of the power socket must be replaced after ensuring that the device is shut down and the power cord is disconnected from the power supply.

a) Use a tool to push out against the notch of the power socket to expose the drawer where the fuse is placed

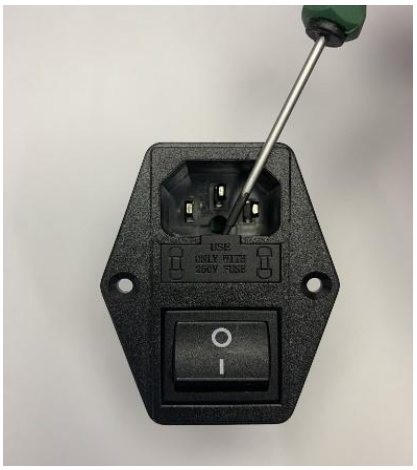


Figure 6. 1 Use a tool to push out the power socket

b) You can use a tool to gently lift the fuse from the square opening under the drawer, and then take it out by hand.

Figure 6. 2 Use a tool to gently lift the fuse

c) Put the new fuse in and make it lay flat in the drawer.

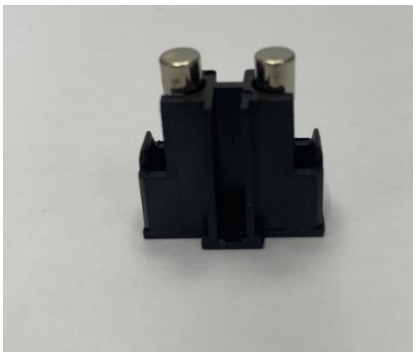


Figure 6. 3 Put the new fuse in

Figure 6. 4 Make the new fuse lay flat in the drawer

d) Push the drawer with both hands until all closed.

Figure 6. 5 Closed the drawer

e) Reconnect the power cord to the power socket, and then connect to the power supply.

6.2 Cleaning

Weekly care and maintenance of the system is recommended to ensure safe and proper function. Clean the following:

- Imaging cabinet
- LCD Monitor
- Operator control panel

Cleaning the system

Prior to cleaning any components of the system:

- Turn off the system power. Disconnect the power cord.
- Make sure to follow the cleaning procedures and use the cleaners mentioned in this manual.

6.2.1 Cleaning the System Cover

To clean the system cover:

a) Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soapy water or 75% alcohol.

NOTE: ***The cloth should be damp, not dripping wet.***

b) Wipe down the top, front, back, and both sides of the system cover about 5 minutes. Be careful with the output and input ports of the system and do not allow anything especially liquid to enter into the ports.

c) Wipe off excess cleaners.

NOTE: ***Do not spray any liquid directly into the unit.***

6.2.2 Cleaning System Monitor

To clean the system monitor:

a) Use a sponge, cleaning cloth or soft fabric and slightly moisten the approved medical device cleaning product to clean the display.

Read and follow all the instructions on the cleaning product label.

If a cleaning product is not sure for use, please use water.

b) Do not use below cleaners:

- Alcohol
- Strong alkali water, strong solvent
- Acid
- Fluorine-containing cleaners
- Ammonia containing detergent
- Scrub cleaner
- Steel wool
- Frosted sponge
- Scraper
- Steel wire cloth

NOTE: ***When cleaning the screen, make sure not to damage or scratch the front glass or LCD. Pay attention to rings and other ornaments, and avoid excessive force on the front glass or LCD.***

NOTE: ***Do not smear or spray the liquid directly on the display, otherwise it may cause damage to the internal electronic components. Instead, the cleaning cloth should be wet with liquid for use.***

6.2.3 Cleaning Touchscreen and Touchpad

To clean the Control Panel:

a) Use a soft, folded cloth. Gently Wipe the touch screen, touch pad, and control panel surface about 2 minutes.

b) If you're not sure if you can use a cleaning product, use water or soapy water.

NOTE: ***When cleaning the screen, make sure not to damage or scratch the front glass or LCD. Pay attention to rings and other ornaments, and avoid excessive force on the front glass or LCD.***

NOTE: ***Do not smear or spray the liquid directly on the display, otherwise it may cause damage to the internal electronic components. Instead, the cleaning cloth should be wet with liquid for use.***

6.2.4 Cleaning Imaging Cabinet

To clean the imaging cabinet:

a) Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive hydrogen peroxide solution.

NOTE: ***The cloth should be damp, not dripping wet.***

b) Wipe down the top, front, back, and both sides of the imaging cabinet about 5 minutes.

Wipe down the specimen tray about 5 minutes.

c) Wipe off excess cleaners.

NOTE: ***Do not spray any liquid directly into the unit. Do not disassemble the device covering or cables when cleaning the device; do not collide with or move the X-ray tube and X-ray flat panel detector; it is strictly forbidden to clean the surface of the device by spraying with a cleaning liquid.***

6.2.5 Cleaning Specimen Tray

Cleaning specimen tray:

a) Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soapy water or 75% alcohol.

NOTE: ***The cloth should be damp, not dripping wet.***

b) Clean the tray before each operation to ensure that the tray is free of impurities and foreign objects.

6.2.6 Inspecting the System

After cleaning, inspect the system, and if any dirty is founded, please repeat above steps.

After cleaning，inspect the system, and if any cracks appear in the shell, please contact the service.

Appendix I Technical Specifications

The system technical specifications are as follows:

Digital Image Receptor Specifications	Value	Units
Active Imaging Area Size	12.0 x 14.0/11.4 x 14.6	cm
Pixel Size	50.0/49.5	μm
Digitization for Output Image	14	bit

X-ray Source Specifications	Value	Units
Energy Range	20-50	kV
Tube Current	0~1	mA
Focal Spot Size	50	μm
Filtration (beryllium)	100	μm

- The X-ray tube target material is tungsten.
- Support continuous exposure mode.

Power Conditions:	Value	Units
Input Voltage	100V-240V~（±10%）	V
Input Current	2.5	A
Frequency	50/60	Hz

Environment Conditions:	Value	
Operation:		
Temperature:	+10℃– +40℃；	
Humidity:	35% – 80%；	
Atmospheric pressure	80 kPa – 106kPa	
Storage and transport:		
Temperature	-10℃– +55℃；	
Humidity	10% – 90%；	
Atmospheric pressure	70 kPa – 106kPa	
Pollution Degree	2	

Physical Specifications	Value	Units
Dimensions	60×72×162	cm
Weight	120	kg
Monitor	24.1	inch

System Performance Specifications	Description
Hard Disk	SSD≥500GB
Operation Interface	Multi-touch screen, virtual keyboard, touchpad
Time to Preview	<20 seconds of AEC mode
Spatial Resolution	≥10lp/mm
Magnification	Specimen tray positions(auto-sensed) at 1.0X,1.5X and 2.0X
Exposure Mode	AEC or Manual
Operating System	Windows 10

- System determines optimum kV and mAs in AEC mode.
- Users manually selects kV and mAs in manual mode.

Appendix II Electromagnetic Compatibility

This system is not intended to transmit energy to patients in the form of radio frequency electromagnetics, and is expected to be installed in a typical medical environment and used by professional medical personnel.

Test Item	Standard	Result
Conducted disturbance voltage at mains ports	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Radiated emission	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Harmonic of current	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Flicker	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
ESD immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Radiated EM field immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
EFT immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Surge immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Inject current immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Power frequency magnetic field immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass
Voltage dips and interruption immunity	**IEC 61326-1:2020** **IEC 61326-2-6:2020**	Pass

It is forbidden to use the device near strong radiation sources, otherwise it may interfere with the normal operation of the device.

When the device is used in a dry environment, especially in the presence of artificial materials (artificial fabrics, carpets, etc.), it may cause destructive electrostatic discharge, resulting in erroneous conclusions.

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