TrueView 100 Pro

Specimen Radiography System

User Manual

P000007 V4.0

0.1 Product Introduction

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

The TrueView 100 Pro and QuadraView 100 are both In Vitro Diagnostic Medical Device.

The software name is “TrueView 100 Pro Software”.

0.2 Manufacturer Information

Company name:	CompAI Healthcare (Shenzhen) Co., ltd
Registered address:	No.323, 3/F, Comprehensive Xinxing Phase I, No.1, Haihong Road, Fubao Community, Fubao Street, Futian District, Shenzhen, P.R. China
Manufacturer:	CompAI Healthcare (Suzhou) Co., ltd
Manufacture address:	Room 3A05, Building 2, No.8 Changting Road, High-tech Zone, Suzhou, Jiangsu, P.R. China
After-sales Service:	CompAI Healthcare (Suzhou) Co., ltd
Telephone:	(+86) 0512-67236750

0.3 Conformance Standards

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

- According to REGULATION (EU) 2017/746, the equipment is Class A,

  Equipment is In Vitro Diagnostic Medical Device.

- 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 regulatory requirement:

- 21 CFR 1020.40 Cabinet x-ray systems

  International Electrotechnical Commission (IEC).

- 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

- EN 61326-1 Electrical l Equipment for Measurement, Control, and Laboratory Use – EMC Requirements, General Requirements

- EN 61326-2-6 Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-6: Particular requirements for in vitro diagnostic (IVD) medical equipment

- IEC62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

- IEC 62304 Medical device software - Software life cycle processes.

- International Organization of Standards (ISO)

  Canadian Standards Association (CSA).

- CSA 22.2, 61010-1-12 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements.

- CSA 22.2, 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 22.2, 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

- COUNCIL REGULATION (EU) 2017/746
  the CE label affixed to the product testifies compliance to the regulation.

0.4 Attention

1) This manual is for TureView 100 Pro.

   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.

   Keep this manual with the equipment at all times. Periodically review the procedures for operation and safety precautions.

2) This product must be maintained regularly, and faulty products cannot be used. If components are damaged, lost, deformed or contaminated, they should be replaced immediately.

3) When repair or replacement is needed, please contact the service department of CompAI Healthcare. Only the qualified person authorizes to repair the system. Do not make any changes to this product without permission.

4) If the product malfunctions due to improper use, incorrect maintenance, improper repair, or replacement of components by unqualified persons, the owner of the product shall bear full responsibility.

5)

Caution: United States Federal law restricts medical devices to sale by or on the order of a physician.

Outside the United States, check out any local legal restrictions that may apply.

6) Do not use incompatible disinfectants, cleanser, etc.

7) Any serious incident occurring shall be reported to the manufacturer and the competent authority in which the user and/or the patient is established.

8) When using or placing this equipment, make sure that the casters have been locked to avoid this equipment sliding.

9) It is strictly forbidden to place other objects on the console.

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

11) When pushing this equipment, it is recommended that two people should move one behind the other to avoid the equipment tipping over or hitting others.

12) When it is necessary to dispose of this equipment or any accessories, follow all the precautions. Do not dispose of this equipment or accessories without consulting our company. For more information, please contact the manufacturer's authorized representatives.

0.5 Revision History

Version	Date	Description
V1.0	2020-05-20	Initial Release
V2.0	2020-11-10	Update some software function’s description
V3.0	2021-03-09	Update registered address and product labels
V4.0	2021-07-06	Update 1.12 and 5.2.6 about specimen holder and features

Table of Contents

0.1 Product Introduction 1
0.2 Manufacturer Information 2
0.3 Conformance Standards 3
0.4 Attention 5
0.5 Revision History 7
Table of Contents 8
1. System Overview 13
1.1 Product Description 13
1.2 Intended Use of the Product 15
1.3 Contraindication 15
1.4 Compatibility 15
1.5 Product Operation Principle 15
1.6 Product Function and Features 16
1.7 Product Service Life 16
1.8 Product Label 16
1.9 Peripheral 21
1.10 Safety Interlock of the System 22
1.11 Specimen Tray 22
1.12 Specimen Container 23

1.12.1 Assembly Steps: 23

1.12.2 Specimen Container Function 25

1.12.3 Method of Use 25

1.12.4 Attention Points 27

1.12.5 Specimen Holder Specifications 28

2. Safe and Effective Use 29

2.1 Environment Conditions 29

2.1.1 Environment Conditions for System 29

2.1.2 Environment Conditions for Specimen Container 29

2.2 Protection against X-ray Radiation 30

2.3 Protection against the Risk of Electric Shock 30

2.4 Protection of Equipment 31

2.5 Precautions for Operation 32

2.5.1 Check before Use 32

2.5.2 Special Instructions for Operation 33

2.5.3 Shutdown 36

2.5.4 Noise 36

2.6 System Defect and Limitation 36

2.7 System Maintenance 36

2.8 Decommissioning and Resuming Use 36

2.9 Environmental Protection 37

2.9.1 About the Disposal of Waste Electronic Articles 37

2.9.2 Insulating Oil 37

3. Installation and Configuration 38

3.1 Installation Preparation 38

3.2 Installation Process 38
3.3 System Configuration 40
4. Control System Operation 52
4.1 Control System Function Keys and Indicators 52
4.2 System Startup Process 54
4.3 System Shutdown Procedure 58
5. Software Operation 59
5.1 General Layout of Interface 59
5.1.1 Login 60
5.1.2 Touchscreen General Layout 63
5.1.3 System Monitor General Layout 72
5.2 Utilities 73
5.2.1 General 74
5.2.2 User Management 76
5.2.3 Exposure Settings 83
5.2.4 Connectivity 83
5.2.5 Miscellaneous 87
5.2.6 About 96
5.3 Home 97
5.3.1 New Patient 98
5.3.2 Worklist 99
5.3.3 Review 100
5.4 Imaging 103
5.4.1 Exposure 103

5.5 Tools 107

5.5.1 Window Level..... 109

5.5.2 Zoom In/Out..... 111

5.5.3 Magnifier 114

5.5.4 Calcification..... 115

5.5.5 Ruler..... 116

5.5.6 Arrow..... 118

5.5.7 Annotation..... 119

5.5.8 Ellipse 121

5.5.9 Layout 123

5.5.10 Next Screen..... 123

5.5.11 Show Info..... 124

5.5.12 Invert..... 125

5.5.13 Sharpen 126

5.5.14 Fit to Image..... 126

5.5.15 Fit to Window 127

5.5.16 Rotate 90° 128

5.5.17 Mirror..... 128

5.5.18 Flip..... 130

5.5.19 Free Rotate..... 131

5.5.20 Image Note..... 132

5.5.21 Functional Icons of the Touchscreen 132

6. System Maintenance..... 137

6.1 System Maintenance 137

6.1.1 Daily Inspection and Maintenance..... 137

6.1.2 Periodic Check and Calibration 138

6.1.3 Event-triggered Calibration 138
6.1.4 Barcode Scanner Maintenance and Repair 139
6.1.5 Replace the Power Socket Fuse 139
6.1.6 Charging the battery 141
6.2 Cleaning 142
6.2.1 Cleaning the System Cover 143
6.2.2 Cleaning System Monitor 143
6.2.3 Cleaning Touchscreen and Touchpad 144
6.2.4 Cleaning Imaging Cabinet 144
6.2.5 Cleaning Specimen Tray 145
6.2.6 Inspecting the System 145
7. Appendix I Technical Specifications 146
8. Appendix II Electromagnetic Compatibility 148

1. System Overview

1.1 Product Description

The TrueView 100 Pro is a self-contained, direct digital imaging system for imaging surgical and biopsy specimens. The TrueView 100 Pro 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:

- The surgical suite
- The stereotactic biopsy suite
- The pathology lab

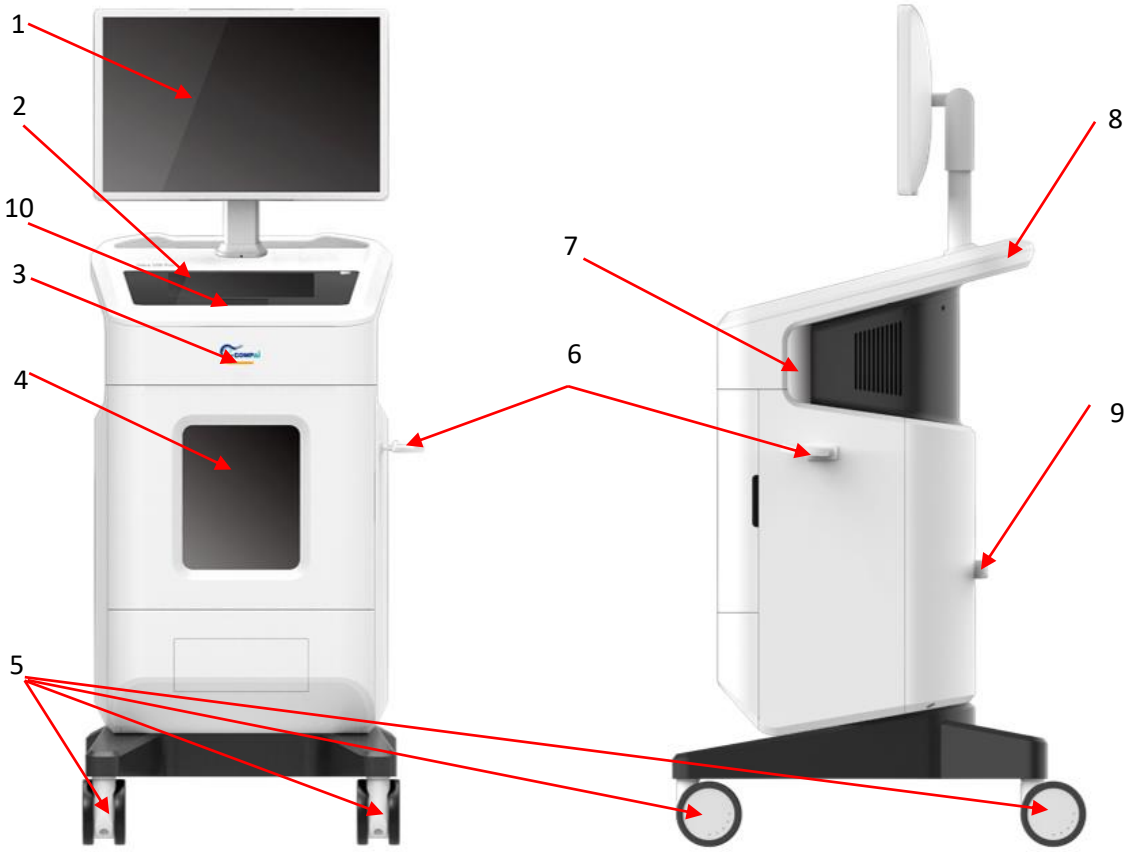


Figure1. system overview

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 Intended Use of the Product

The TrueView 100 Pro is intended to provide digital X-ray images of surgical and core biopsy specimens from various anatomical regions in order to rapidly verify that the correct tissue has been excised during the biopsy procedure.

Verifying in the same room where the procedure is performed or nearby improves workflow, thus reducing the time patient needs for examination.

The intended user of this system should be limited to professionals, including surgeons, pathologists or nurses in the operating room.

1.3 Contraindication

There is no contraindication.

1.4 Compatibility

The system's data interaction is through the network and USB port. Data of patient can be interacted with the hospital DICOM server through the network and with external storage media (USB disk) through the USB port. Device data can only be interacted with external storage media (USB disk) through the USB port. Network interaction supports wired and wireless (WIFI protocol (802.11) and complies with standard DICOM3.0 protocol. USB port is compatible with USB2.0.

1.5 Product Operation Principle

The TrueView 100 Pro has one physical imaging methods: X-ray photography. In terms of X-ray photography, use a fixed focal source distance (the distance from the focus of the X-ray tube to the active array of the flat-panel detector), and use computer control software to control the pathological specimens

placed on the bracket of the specimen detection cabinet in the imaging area to perform X-ray photography, save the obtained digital image data, and display the image directly in the designated area of the display screen.

1.6 Product Function and Features

The main functions of the system are as follows：

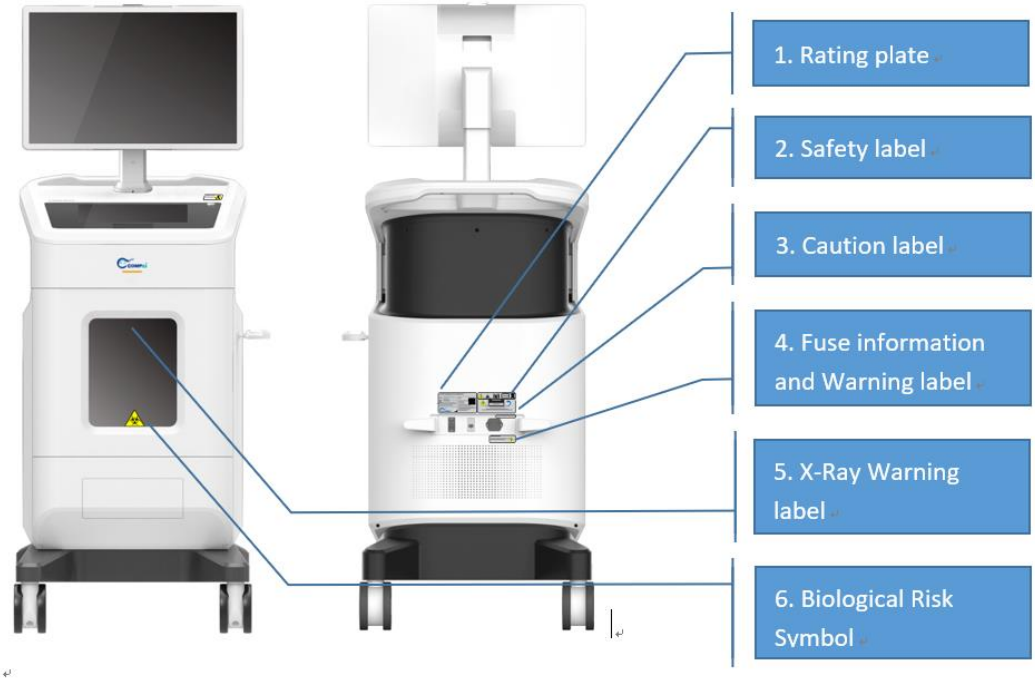
1) X-ray digital image acquisition function, including automatic and manual modes;
2) Auto detect magnification ratio based on specimen position
3) Highlight suspected calcification
4) X-ray exposure parameters default-setting;
5) DICOM protocol supporting;
6) Image analysis tools
7) Barcode scanner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

1.7 Product Service Life

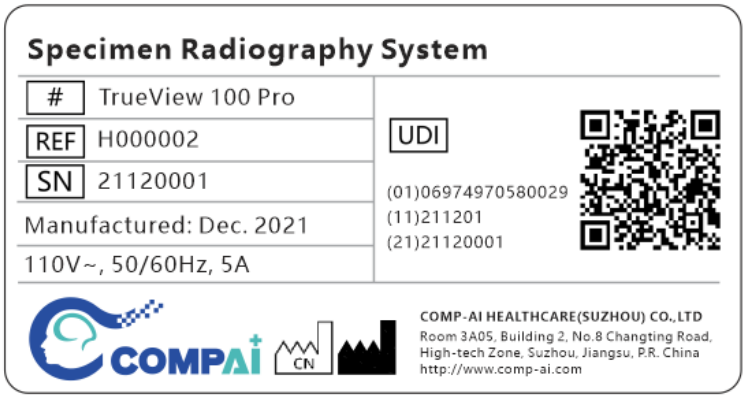
Under the conditions of correct use, maintenance and storage, the product service life is 10 years from the date of delivery.

1.8 Product Label

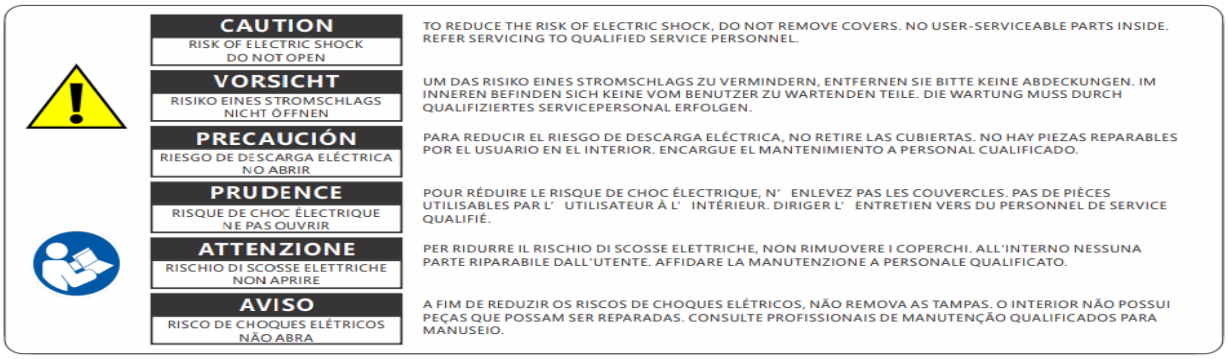
a） Overview:



- Rating plate

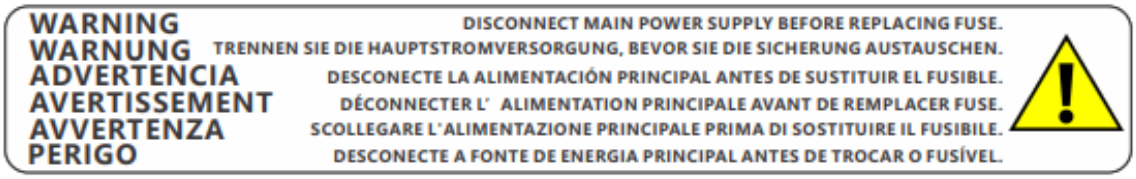


- Caution Label

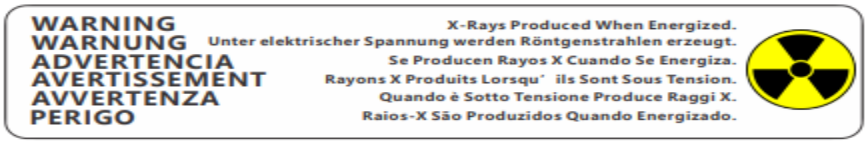


- Safety and Importer information Label

- Fuse information and Warning label



- X-Ray Warning label



- Biological Risk Symbol

b） 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		United States Federal law restricts medical devices to sale by or on the order of a physician	Above the switch button
7		Attention static sensitive devices	Above the switch button
8		Warning：Recommended two persons to move the system during the long distance to avoid the System tilt down.	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
12	110V~, 50/60Hz, 2.5A	Power Conditions	Above the switch button

Table 1.1 Description of graphic symbols

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

Warning: Failure to pay attention to or avoid this condition will cause personal injury or serious damage to this equipment or data.

1) Do not connect other (non-system component) equipment or components to the system to make them parts of the system without permission.
2) No other (non-system part) removable socket (MPSO) or extension cord should be connected to the system.
3) In order to enable users to obtain the best intended use, it is recommended to refer to the steps specified in the installation program for system when installing.

1.9 Peripheral

Three recommended peripherals for TrueView 100 Pro:

Name	Manufacture	Type	Use instruction
Barcode Scanner	Honeywell	Xenon 1900	Refer to 3.3.5
Wireless card	Tenda	U12	Refer to 5.2.4.2
Specimen container	CompAI Healthcare	H000005	Refer to1.12

Table 1.2 peripheral list

1.10 Safety Interlock of the System

The system provides the following safety interlock through hardware and software to ensure safe use:

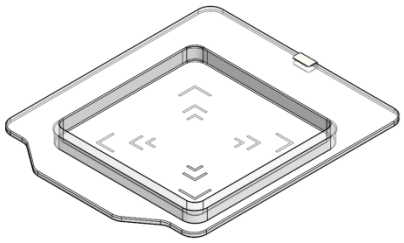
a） Safety interlock with cabinet door: when the cabinet door is open, the system cannot perform exposure operation; if the cabinet door is accidentally opened during exposure, the system immediately interrupts the exposure process；

b） X-ray image operation confirmation prompt: due to the need to emit X-rays during the imaging process, the software has designed a prompt box to confirm the X-ray beaming operation. The software will pop up a confirmation prompt box, which can only be exited after confirming the information.

1.11 Specimen Tray

Specimen tray is intended to place the specimen.

The system provides three slots corresponding to different imaging magnifications (1.0x, 1.5x, 2.0x) from bottom to top. The innermost marker line corresponds to magnification 2.0, the middle marker line corresponds to 1.5, and the outermost marker line corresponds to 1.0.



NOTE: ***It's not recommended to place the specimen on the tray directly. The specimen should be collected by the specimen collection bag first, and then***

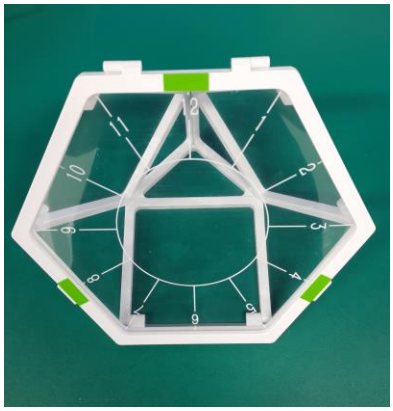
be put on the specimen tray, to avoid the Biological Risk.

NOTE: ***Wrapping tray and putting them into the cabinet may affect the identification of magnification. It is not recommended to put the tray into the cabinet after wrapping.***

1.12 Specimen Container

The QuadraView 100, as an accessory, is designed for the TrueView 100 Pro. The QuadraView 100 is intended to fix specimen and achieve Multi-angle X-Ray photography.

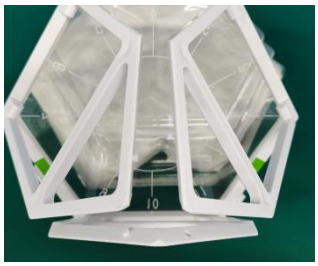
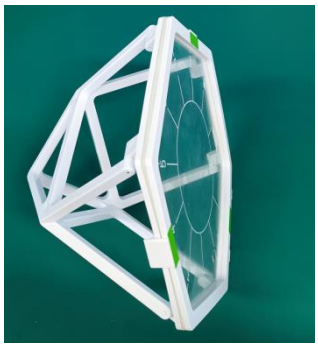
It's a disposable accessory.

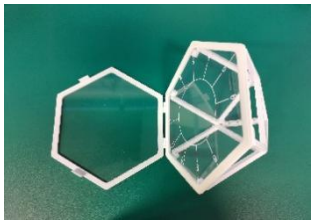
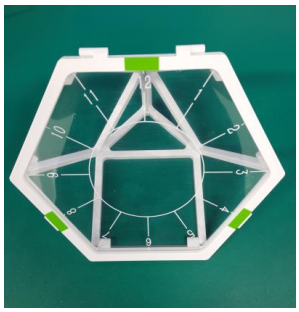


QuadraView 100

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 on the specimen tray, it supports:

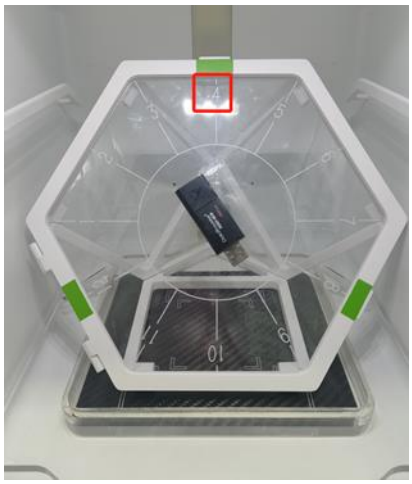
- To obtain multi-angle image.
- To calculate the distance from the calcification, point to the incisal edge
- To locate the position of the tumor specimen to avoid blindly expanding the scope of surgical resection
- To assist the pathology department in locating the specimen

1.12.3 Method of Use

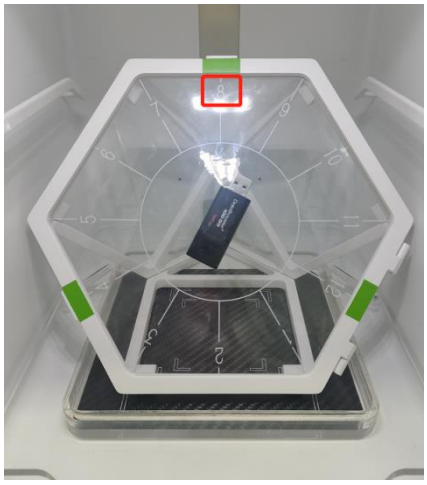
After the specimen container is assembled, open the buckle, put the specimen into the specimen bag between the film and the cover, close the buckle, and finally put the specimen container on the tray.

There are four ways to put the specimen container on the tray as follow:

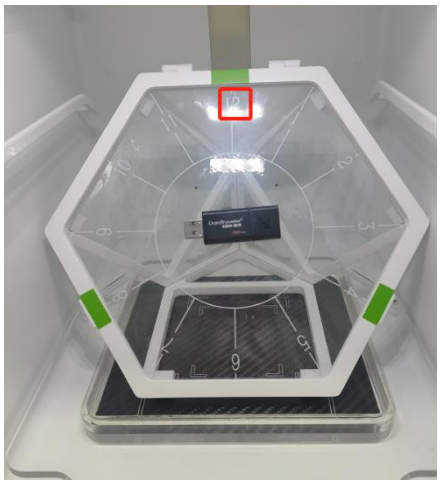
1) The number 4 marked on the specimen container is directly above, as shown in the figure below:



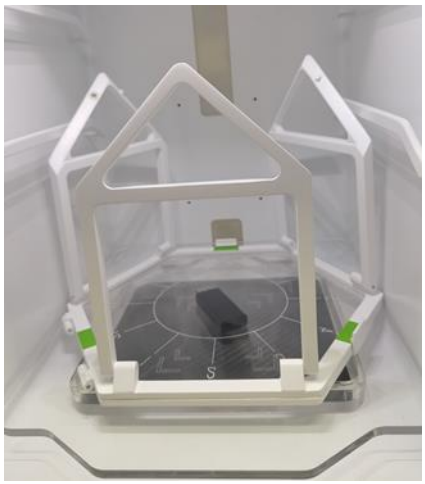
2) The number 8 marked on the specimen container is directly above, as shown in the figure below:



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 on the specimen tray, as shown in the figure below:



1.12.4 Attention Points

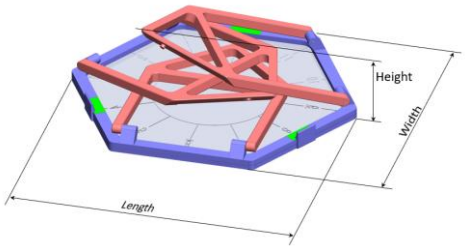
1) When using the specimen container, put the specimen into the specimen bag first and then put the specimen bag into the container to avoid tissue dropping into the cabinet, or accidentally dropping the tissue, causing the tissue to be contaminated.
2) There may be microbial residue after using the specimen holder. Please treat it as medical waste after use.
3) The imaging area is the center circle marked on the cover of specimen holder.

4) The maximum weight which the holder can clamp is 0.20kg.

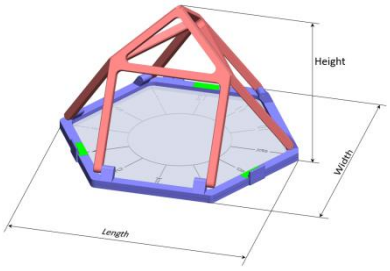
5) The quality guarantee period of specimen container is 2 years.

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 manufacture of this system provides effective protective measures to ensure the safety and effectiveness of product use that the system will not cause any harm under normal use.

Before putting this system into use, users should carefully read and understand this user manual. Operation and maintenance of the product should be in strict accordance with the provisions of this manual during the life cycle of the product.

The company shall not be liable for any harm caused by the user due to incorrect operation, unauthorized modification, or failure to properly maintain the equipment according to the requirements of this manual.

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 °C	-10℃– +60℃	-10℃– +60℃
Humidity	30%- 80% non-condensing	10% – 90%	10% – 90%
Pressure	70 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 °C	-10℃– +55℃	-10℃– +55℃
Humidity	35%- 80% non-condensing	10% – 90%	10% – 90%
Pressure	70 kPa – 106kPa	70 kPa – 106kPa	70 Pa – 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 100 Pro meets IEC60601-2-091 Clause 12.101.1's requirements. 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 you need.***

Please strictly observe the radiation protection regulations and the relevant requirements of this manual, otherwise it will cause harm to the operator!

The operation and maintenance personnel of this system should be properly trained. It is believed that all operating and maintenance personnel authorized to use and maintain the system should be aware of the dangers of X-rays and have received sufficient training to master the relevant knowledge.

2.3 Protection against the Risk of Electric Shock

After the system is powered on, the equipment components carry dangerous voltage, so improper use and maintenance may cause electric shock

It is strictly forbidden to disassemble the protective shells of equipment components while the power is on, nor to power on the system after removing the protective shells of equipment components to avoid the risk of electric shock.

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

Use a damp cloth that does not drip as much as possible to clean the inside of the imaging cabinet. When cleaning the surface of the equipment parts, liquids should be prevented from entering the equipment parts, so as not to cause electric shock and affect the basic performance of the product.

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 damage to 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） Because 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 Precautions for Operation

2.5.1 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, you 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 100 Pro software to verify:

- Whether the system can normally complete exposure 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 about 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.

2.5.2 Special Instructions for Operation

a） Precautions for Clinical Application

During clinical use, specimens cannot be placed directly on the specimen tray or specimen container. 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 container.

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 overheated, 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.

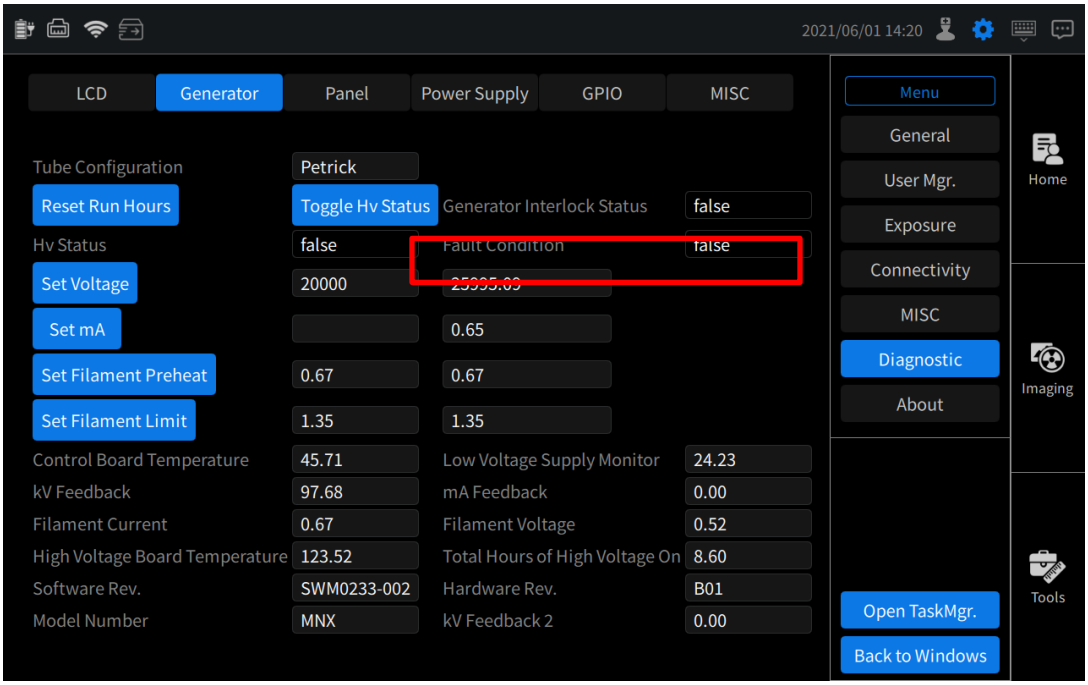


Figure 2.1 Related parameters and status feedback of the generator

At this time, 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 you find that the device emits smoke or fire during use, immediately turn off the device power button, unplug the network power cable, and turn off the UPS power supply (see 4.1.3 for details).

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.

2.5.3 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.

2.5.4 Noise

The noise-producing parts of this system are speakers and UPS power supply fans.

If you hear abnormal sounds from the speakers or UPS power supply fan, immediately turn off the power button of the device and contact the manufacturer for troubleshooting.

2.6 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.

2.7 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.

2.8 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.

2.9 Environmental Protection

2.9.1 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.

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

2.9.2 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 handled 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: 110V±10%

   Input Power: not less than 500W

   Frequency: 50/60 Hz

2) Floor Space Preparation

The minimum floor space should be prepared: 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 for satisfying the use.

3) Temporary installation area condition

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

NOTE: ***TrueView 100 Pro 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. If any accident caused by it, the violators would be held legally liable.

3.3 System Configuration

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

3.3.1 System Self-Check

As soon as the system is powered on, the operating system will automatically run the special software for this system to perform initial connection checks on the hardware. The touch screen and the system monitor will simultaneously show whether the hardware link status is normal.

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.

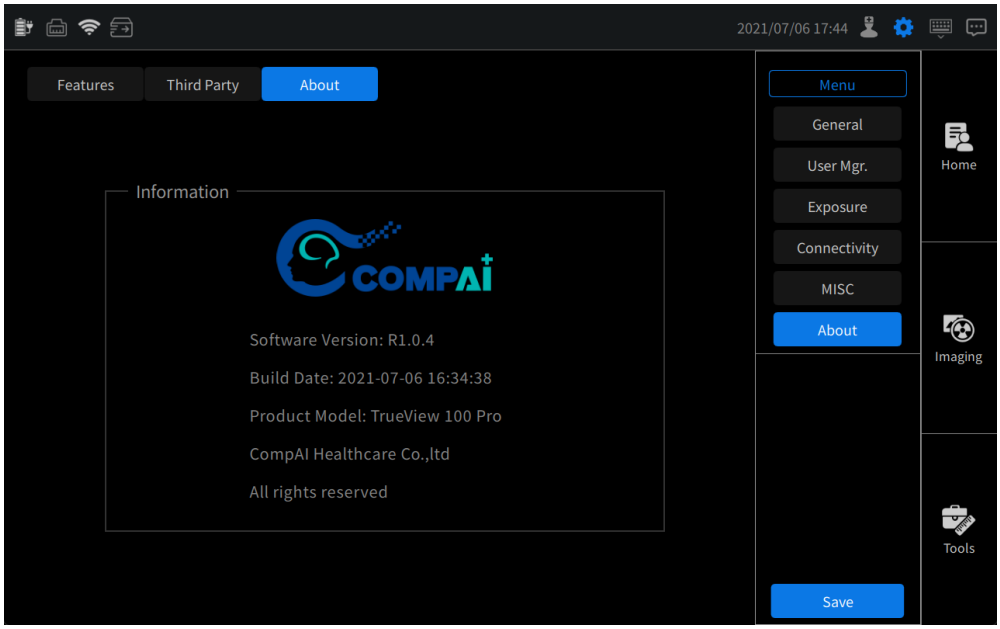


Figure 3.3- 1 The system information page

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. It is recommended to add

them one by one for the convenience of functional key management in the future)，see Figure 3.3-2。

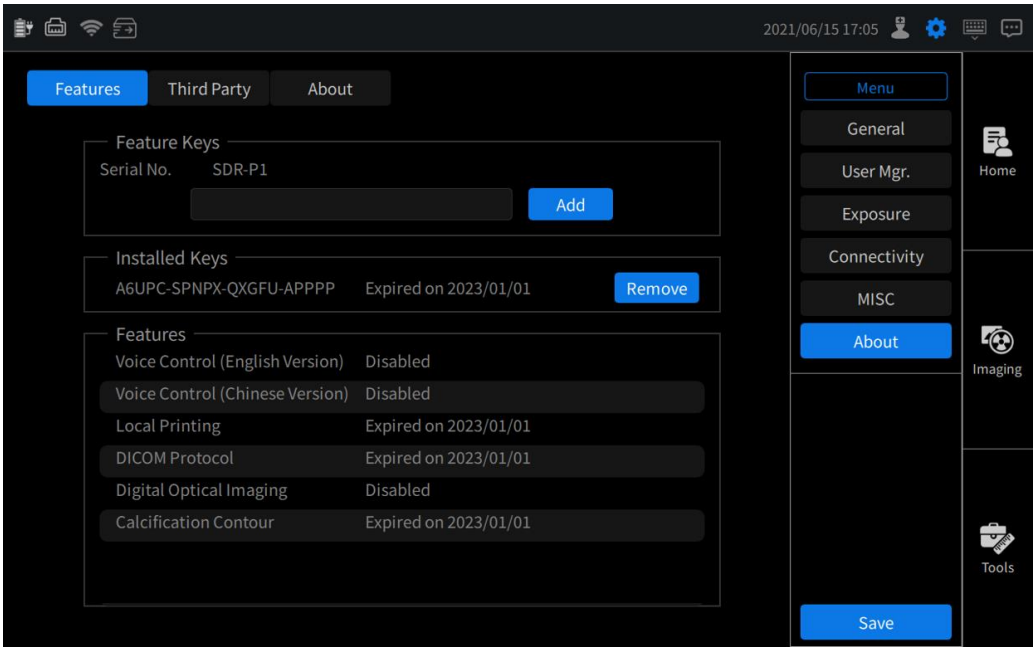


Figure 3.3- 2 The system function options page

3.3.3 System 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.

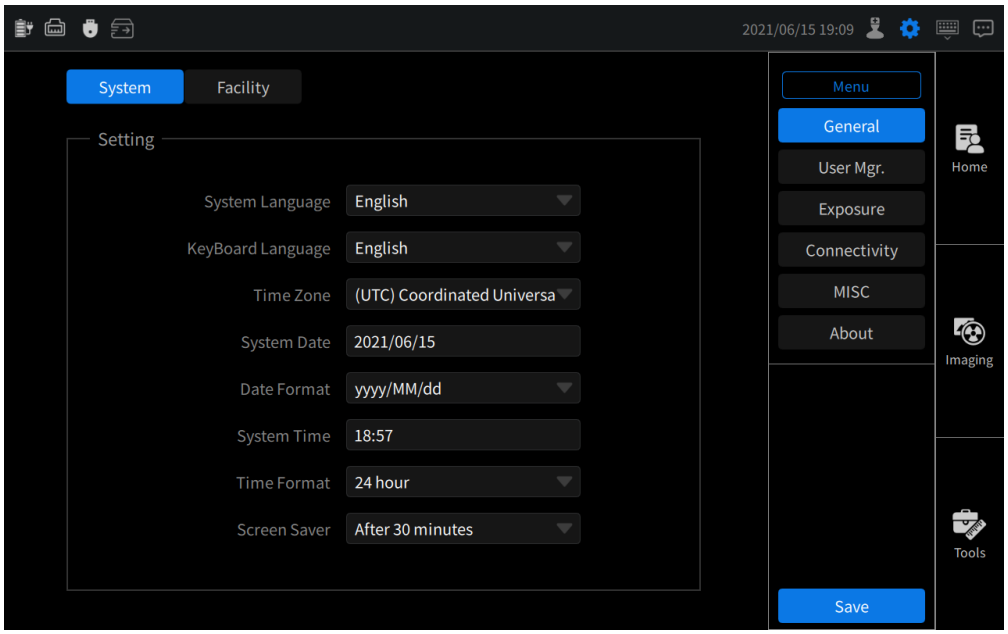


Figure 3.3- 3 The general settings page

- System Language: Set system language to English or Chinese;
- 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, 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.

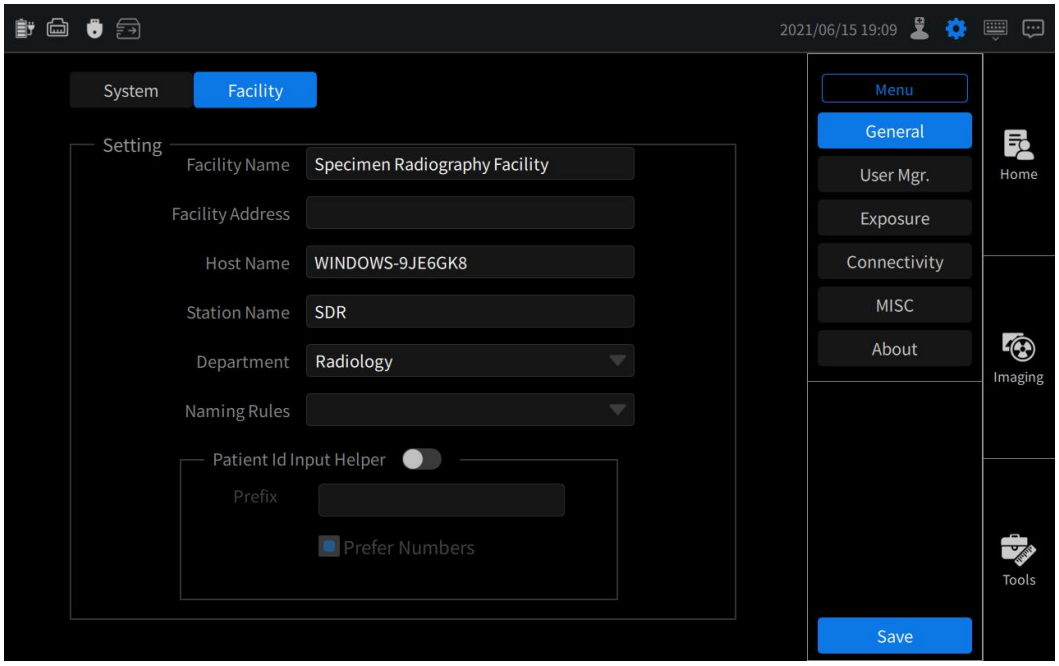


Figure 3.3- 4 The general facility settings page

- Facility Name: Set the facility name; ***Note: Only the ADM user authorizes 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 click the "Connectivity" button. The connectivity setting page (see Figure 3.3-5) is shown as follow.

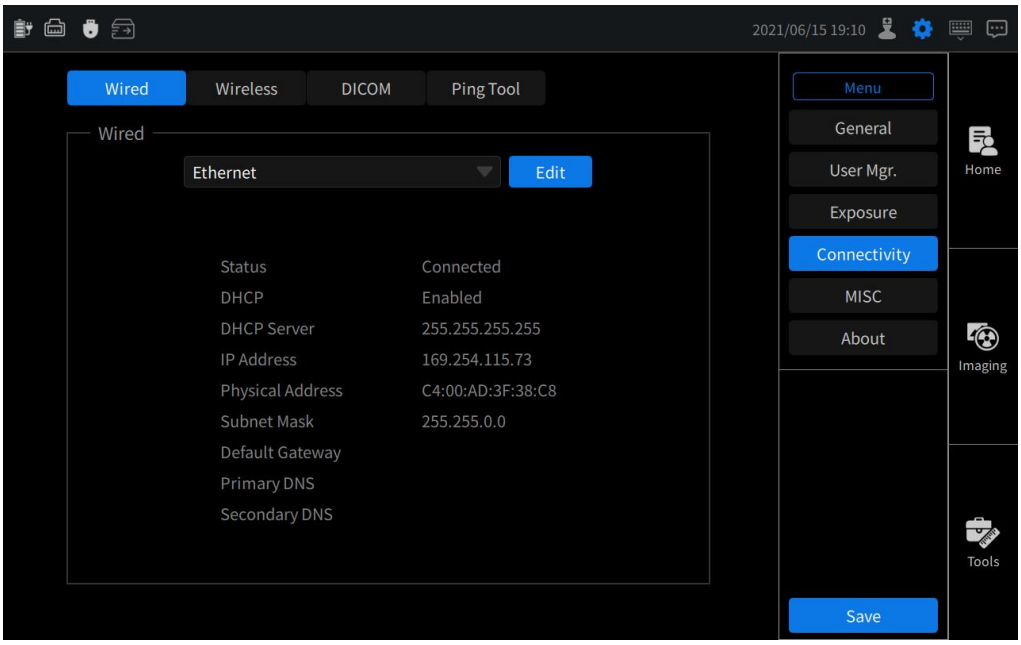


Figure 3.3- 5 The connectivity setting page

a） Wired Network

Plug the network cable into the network port behind the device. Click “Wired” button, check IP address and connection status, and current wired network information will be displayed on the touchscreen. The default wired setting is DHCP (Figure3.3-6 as follow). If you need to configure another network, you can click the “Edit” button and then choose "Manual" to connect the network (Figure 3.3-7 as follow).

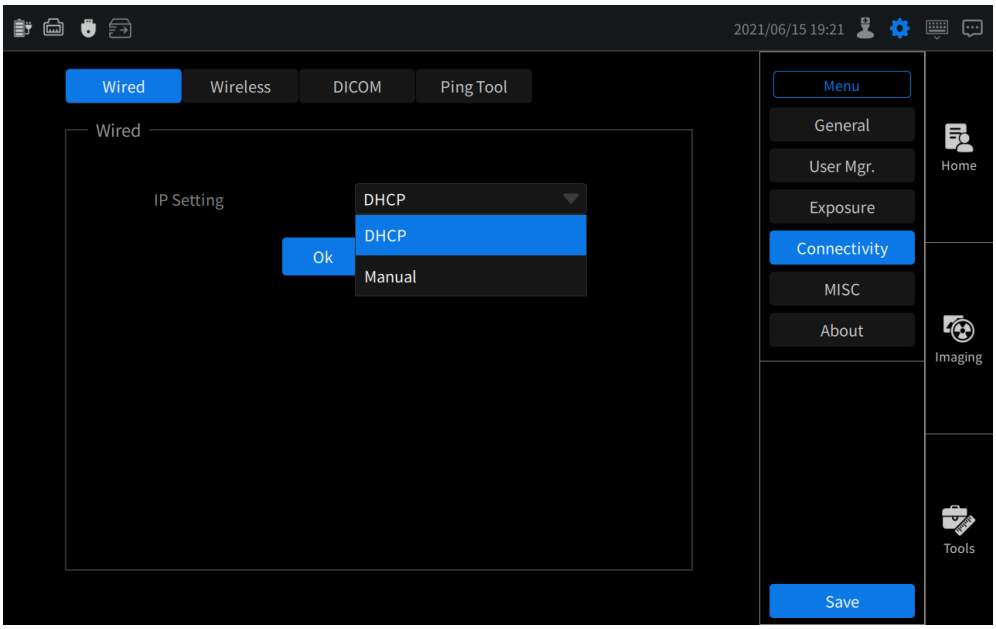


Figure 3.3- 6 The wired network connection page for DHCP

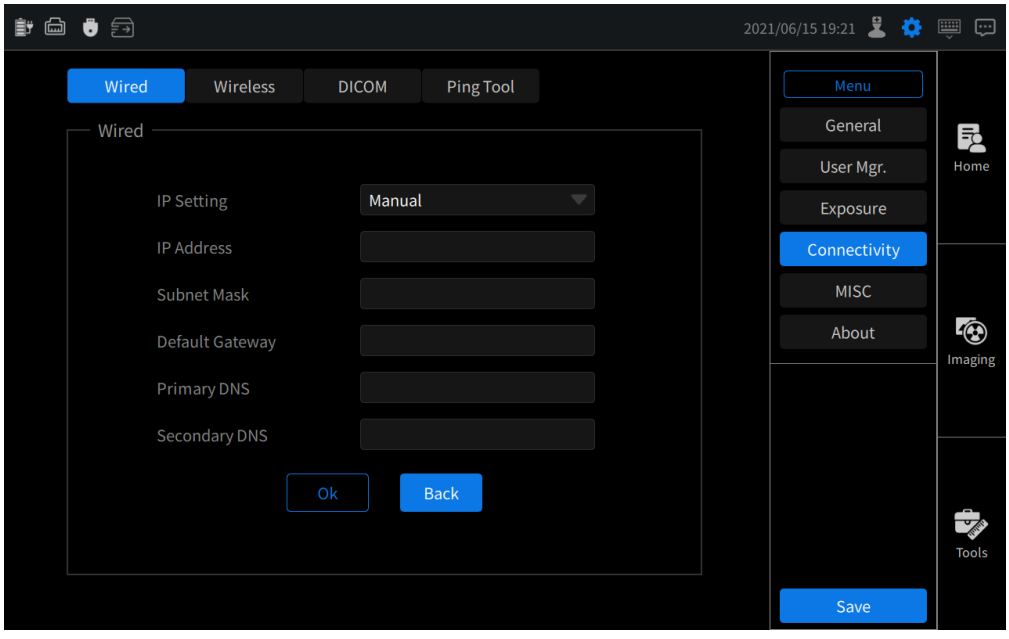


Figure 3.3- 7 The wired network connection page for Manual

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.

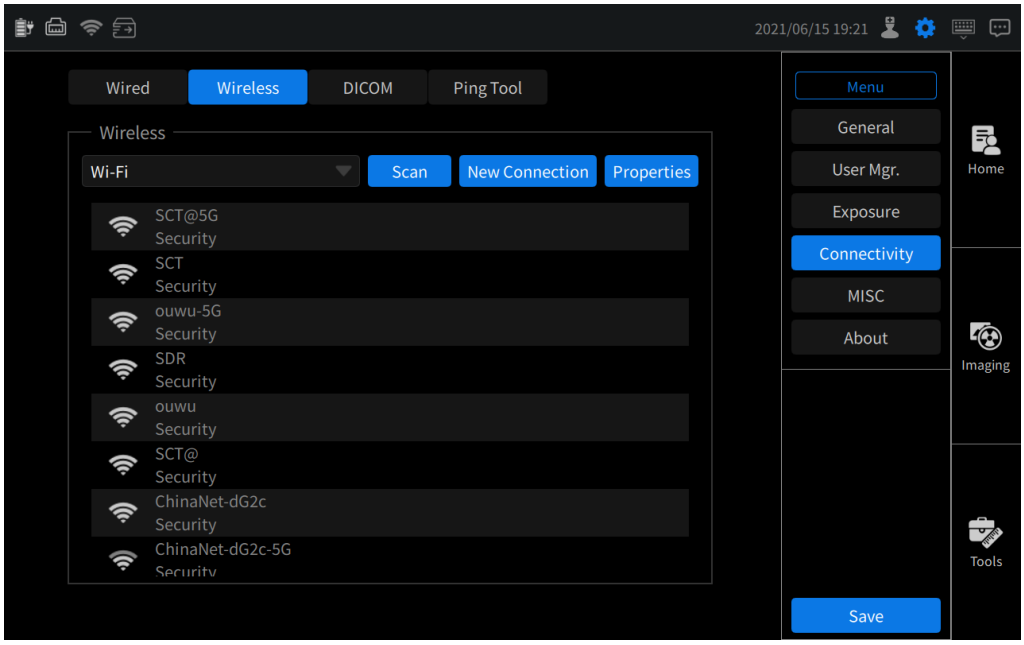


Figure 3.3- 8 The Wireless function page

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

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

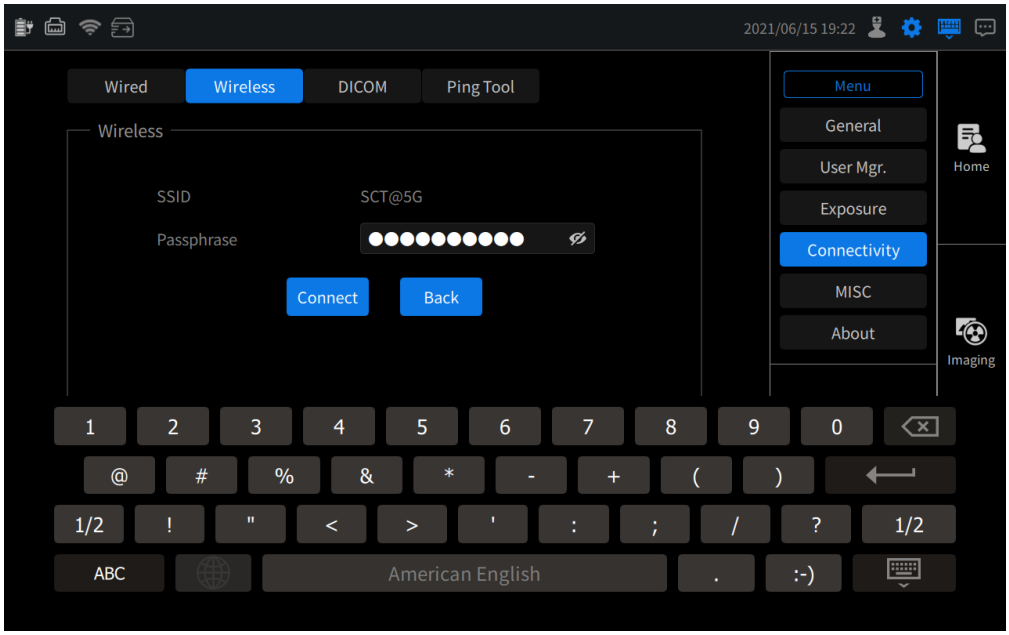


Figure 3.3- 9 The wireless network connects

c） DICOM

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

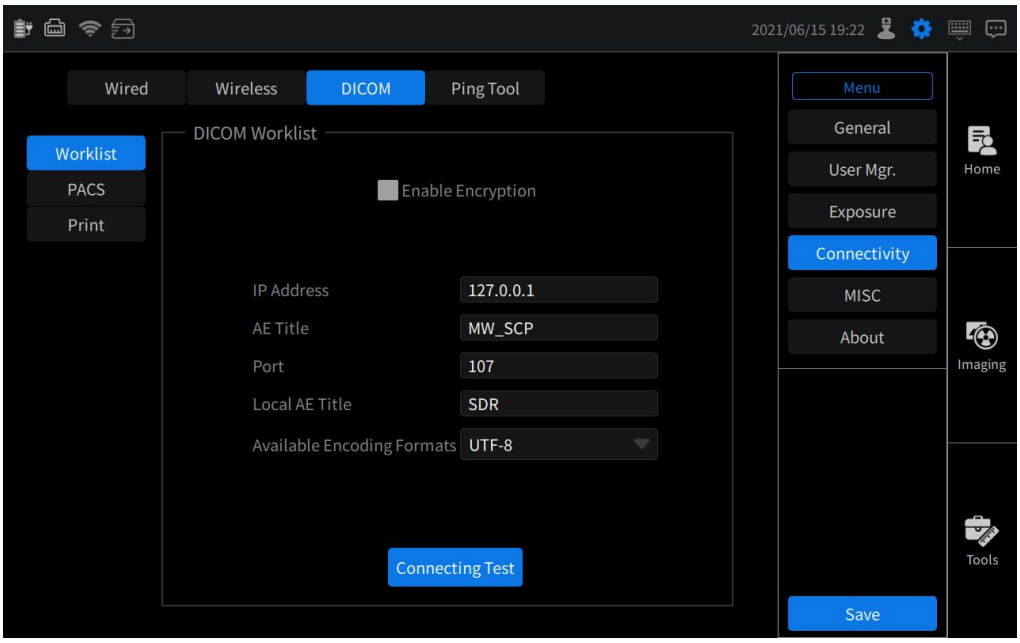


Figure 3.3- 10 The DICOM configuration page

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 and DICOM print connection 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.

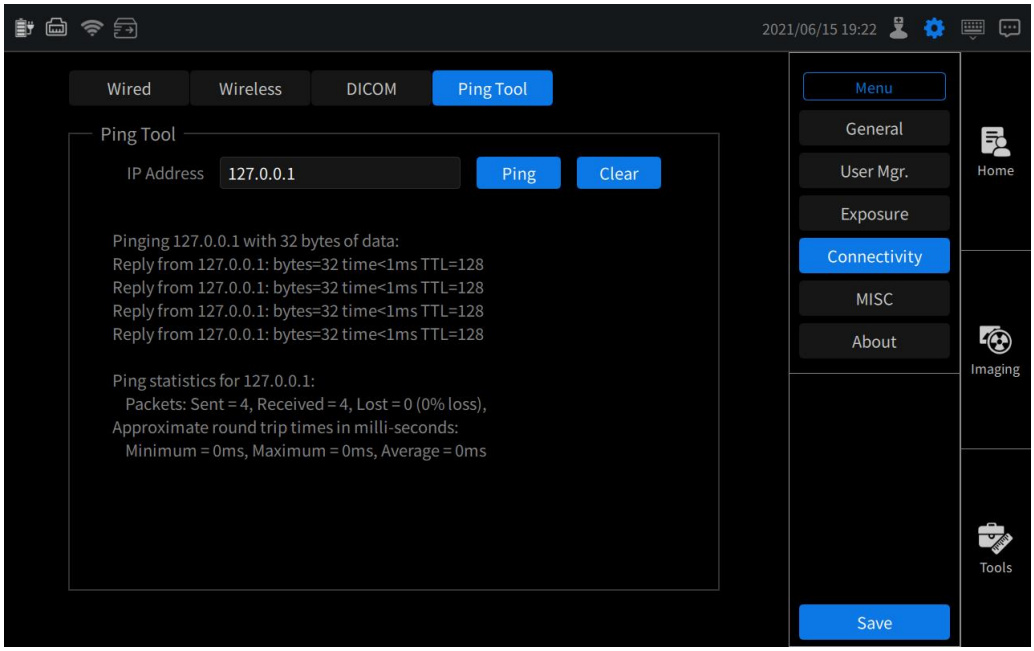


Figure 3.3- 11 The Ping Tool function page

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 .

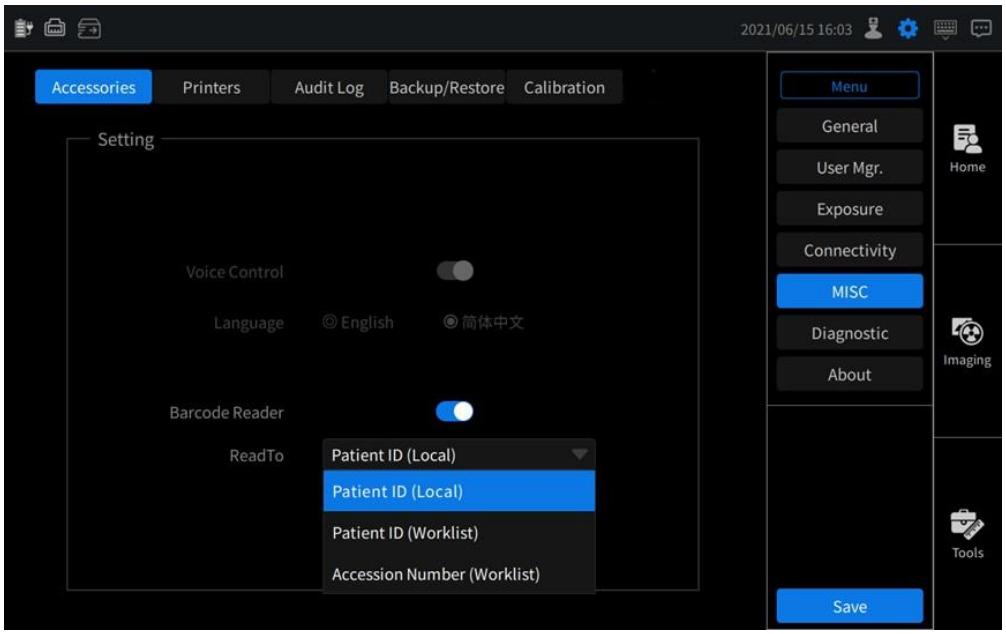


Figure 3.3- 12 The Barcode reader setting page

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.

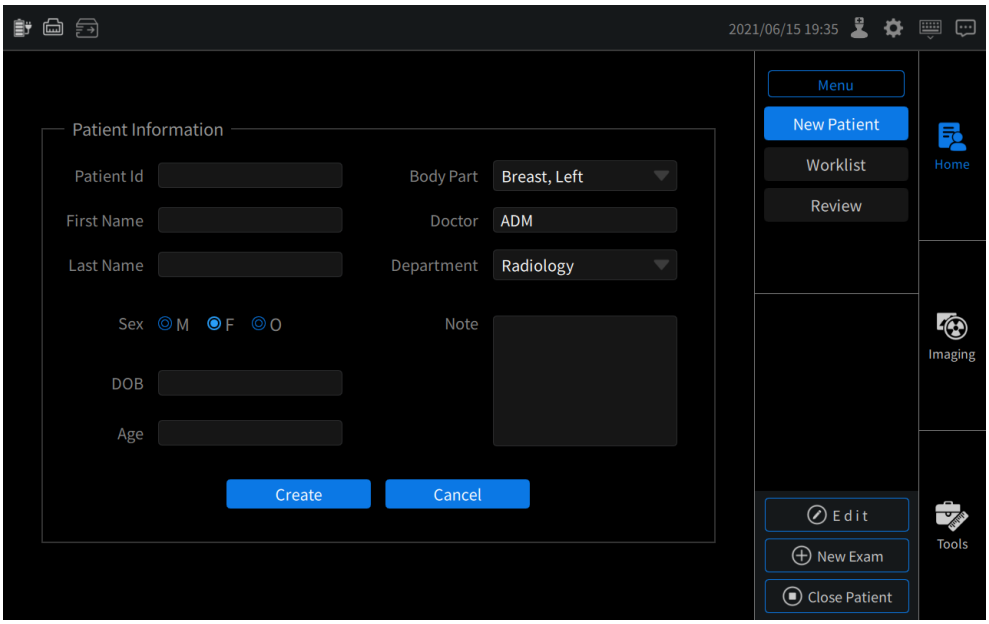


Figure 3.3- 13 The patient ID input via the Barcode reader as a New Patient

Set the DICOM worklist connection configuration 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 and scan the code with a barcode reader as shown in Figure3.3-14.

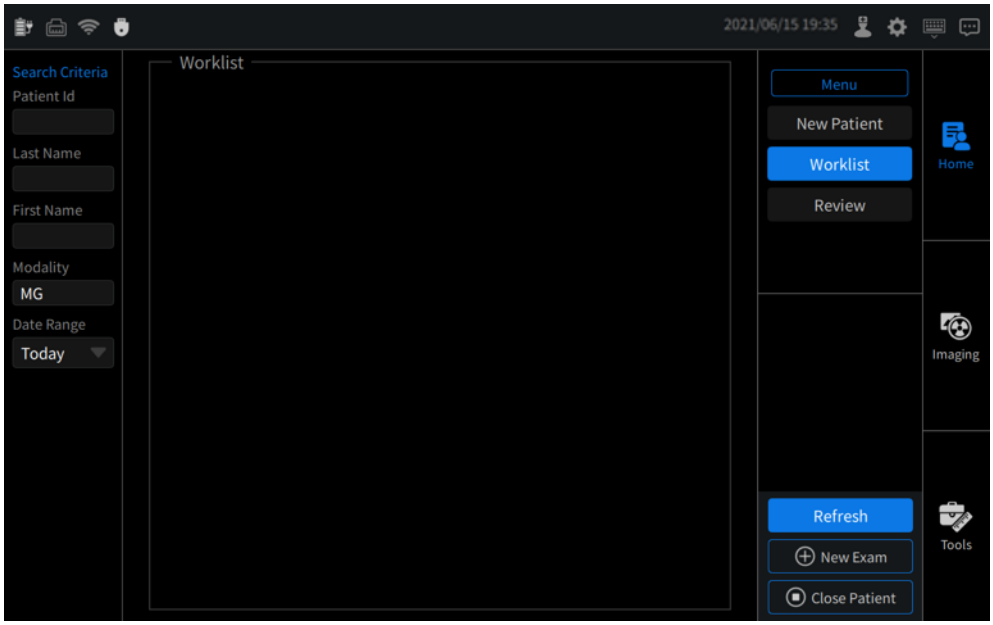


Figure 3.3- 14 The patient ID input via the barcode reader as Worklist

4. Control System Operation

In the entire procedure of using this system, it is necessary to initialize hardware devices including high-voltage generators and flat panel detectors before completing the entire procedure through the coordination of software and hardware. The system can automatically control the high-voltage generator, X-ray tube and X-ray flat panel detector through software, and display the important information to the user.

This chapter mainly introduces the operation rules and precautions of the control system and its 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.

4.1.3 UPS button and indicator

There are five buttons on the operation panel of UPS power supply, only  button namely "Power On / OFF" needs user action.

Figure 4. 5 Operation panel of UPS power supply.

When you need to manually start the UPS, press the "Power On / OFF" button and hold on for one minute then release. ***Note: When the device is shipped from the factory, it has been set to the software command startup mode, so there is no need to press this button again.*** When the sample imaging system application software is started, it will automatically wake up the UPS.

When you need to manually turn off the UPS, please press and hold the "Power On / OFF" button. When you hear the continuous sound of "Drip", release the button immediately. ***Note: You should release the button in time, because after the sound of "drip" is terminated, releasing the button will fail to power off the UPS.***

4.2 System Startup Process

4.2.1 Check before Starting

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

- The equipment covering should be properly tightened and placed in a normal position, with the

appearance not being damaged;

- The cables should be connected normally, and their appearance should not be damaged;
- The mechanical devices should be properly tightened and their 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

After checking that everything is normal, turn on the system as follows:

a) Turn on the System

Press the power button, and the system is powered on. After starting, the system monitor and touchscreen will display the software operating system login interface.

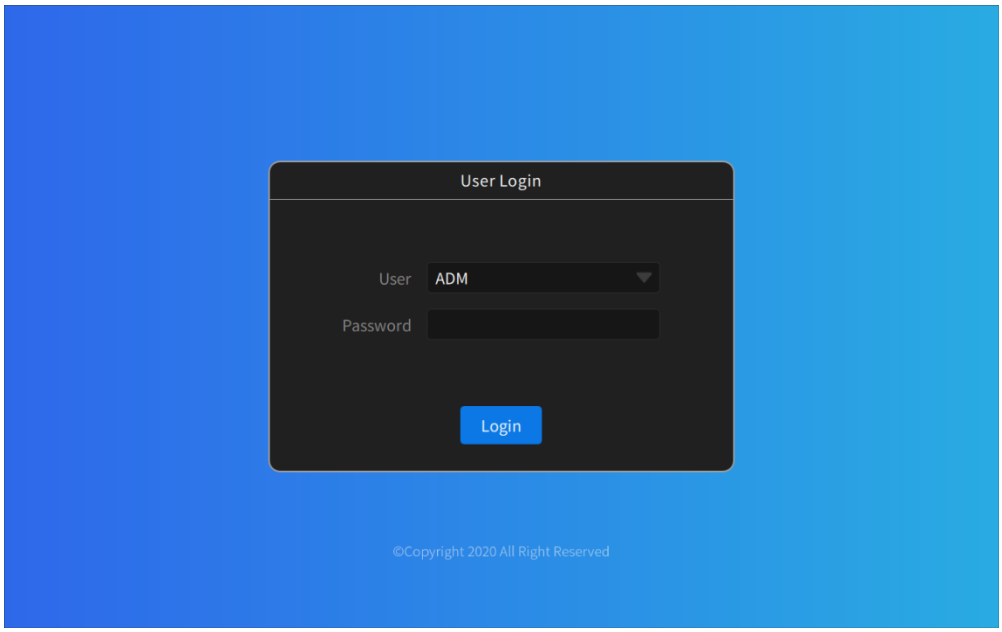


Figure 4. 6 Software login interface screens

NOTE: If the user logs in too fast after startup, "Panel is connecting" may appear in the imaging page. After a few seconds, it will automatically connect successfully.

b) Software for TrueView 100 Pro Started

The special software for this system is automatically started by the operating system.

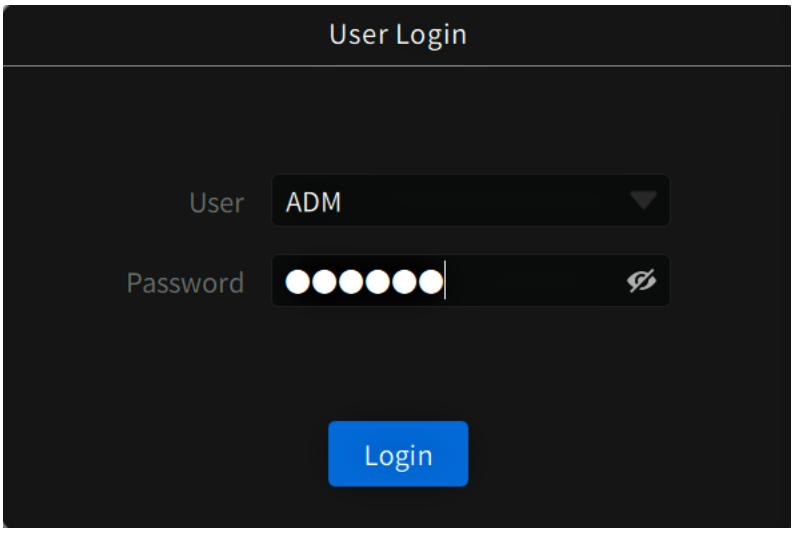


Figure 4. 7 Login interface

c) Status on the Software Interface

——Red bar means error, indicating that the system is detecting an error.

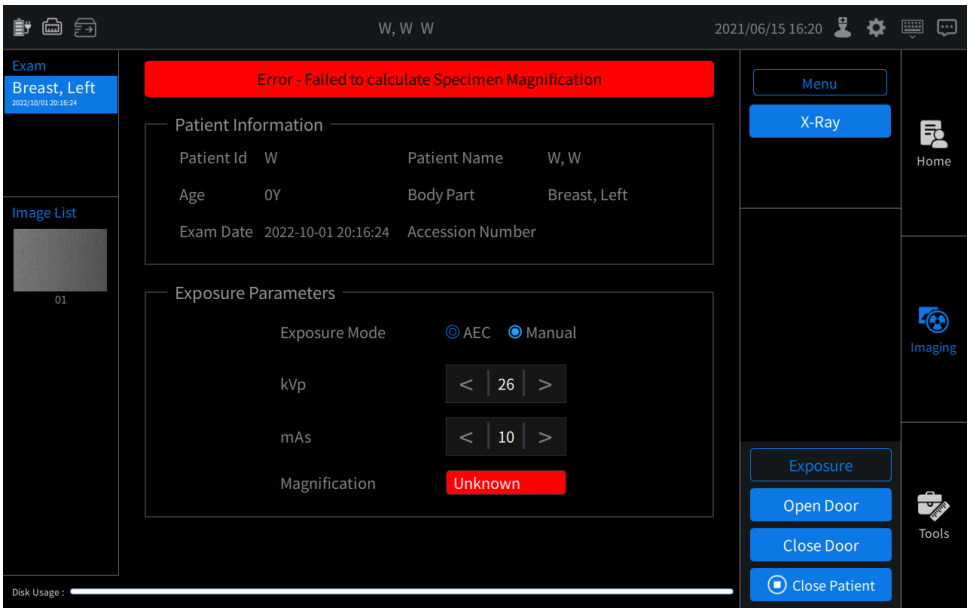


Figure 4. 8 The system detects an error.

——Yellow bar means warning, indicating that system is not ready for exposure.

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

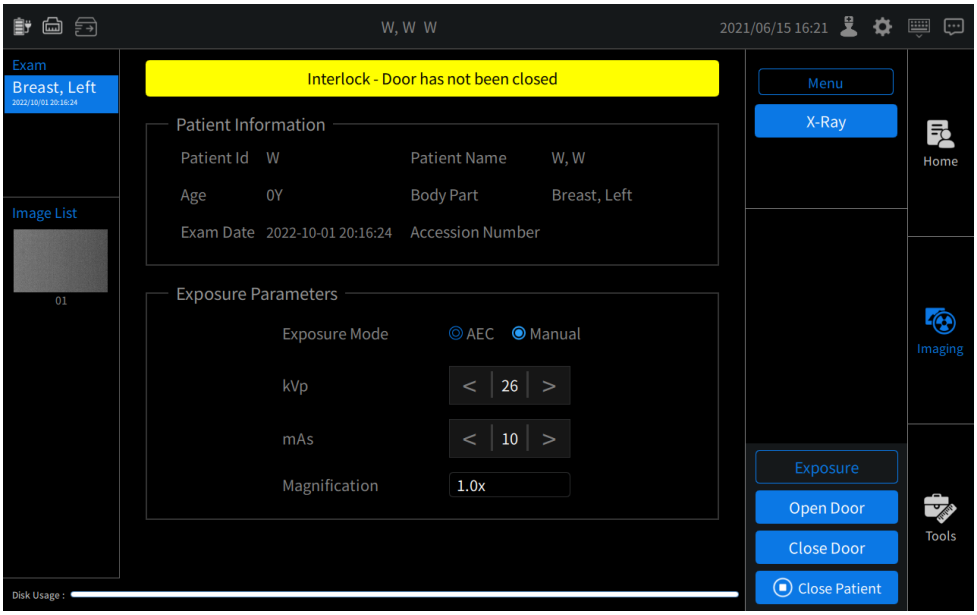


Figure 4. 9 X-ray cabinet door has not been closed.

——Green bar means ready, indicating that exposure can be used for image acquisition.

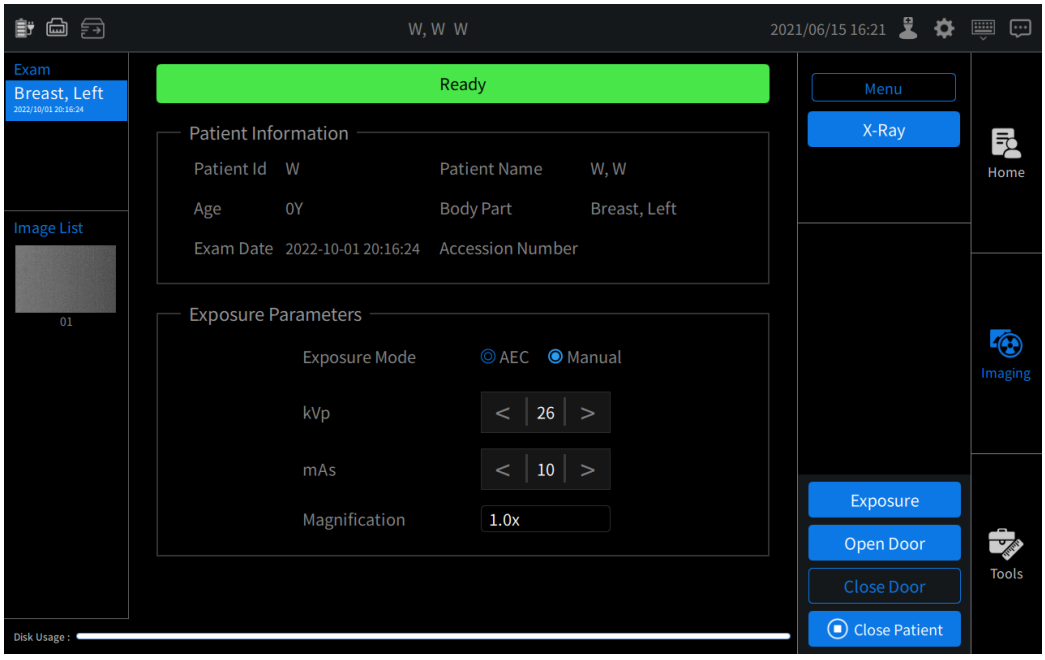


Figure 4. 10 X-ray system ready indicator.

4.3 System Shutdown Procedure

To shut down the system, follow these steps:

a) Turn off the System

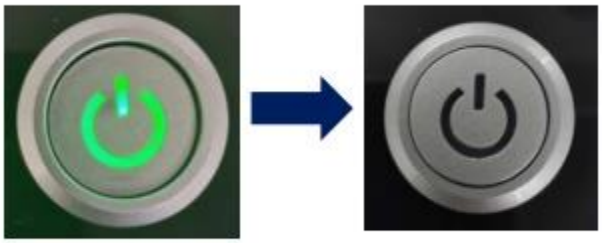


Figure 4. 11 Power button

Press the power button, then release it, and set it to the OFF position.

The software for this system exits. When it exits, it will automatically shut down the control computer and other components. ***Note: It is better to restart the system after it has been turned off for 5 seconds.***

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 100 Pro will be performed by using the touchpad, the touchscreen, and the monitor as seen in Figure5.1(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 100 Pro software has two primary user interfaces. The touchscreen allows users to select icons, buttons, and provides an interface of a keyboard to enter textual information. The touchpad can be used to select icons and buttons visible on the screen.

The first step to get into the software requires the user to login in.

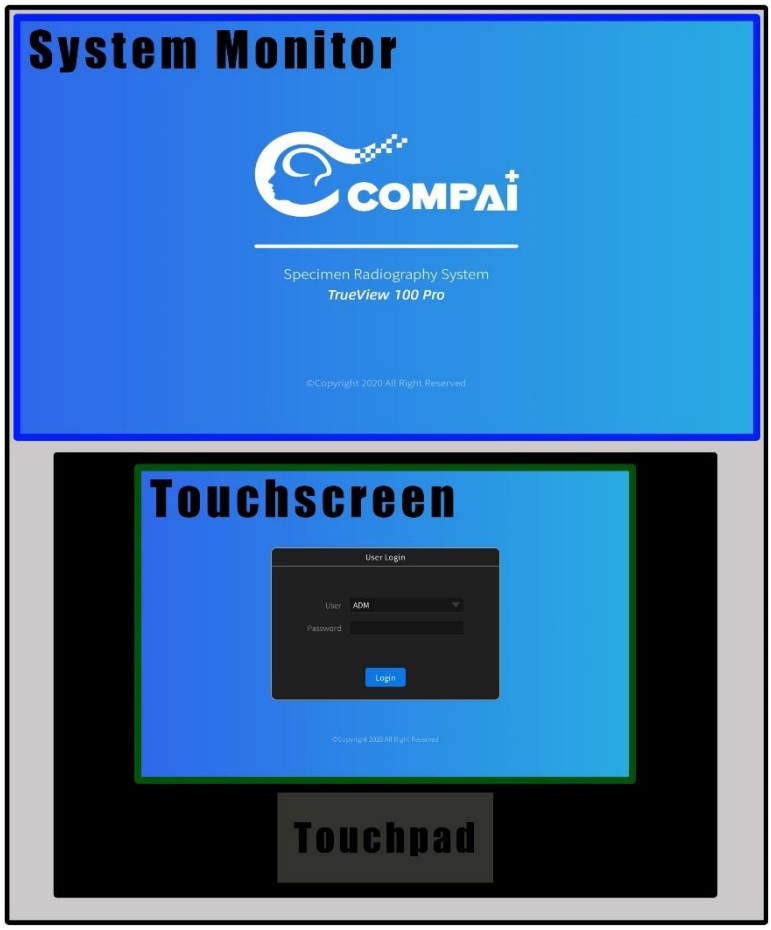


Figure5. 1 TrueView 100 Pro login in screens on the system monitor and the touchscreen.

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

5.1.1 Login

The system divides users into three levels according to the user's role. Accordingly, the user selects the appropriate user role for the use case they need to accomplish, and logs into the system. ***ADM*** is the administrative user for the system; ***Specimen*** represents the clinical users; and ***Service*** is only for factory authorized technicians. There will only be one ***ADM*** user and one ***Service*** user for the system; However,

there can be many ***Specimen*** users as needed. Figure 5.2 shows the three default users and an additional Specimen user on the user pull down menu of the login screen. ***Note: Since the Service user is only for factory authorized technicians, its functionality will not be covered in this manual.***

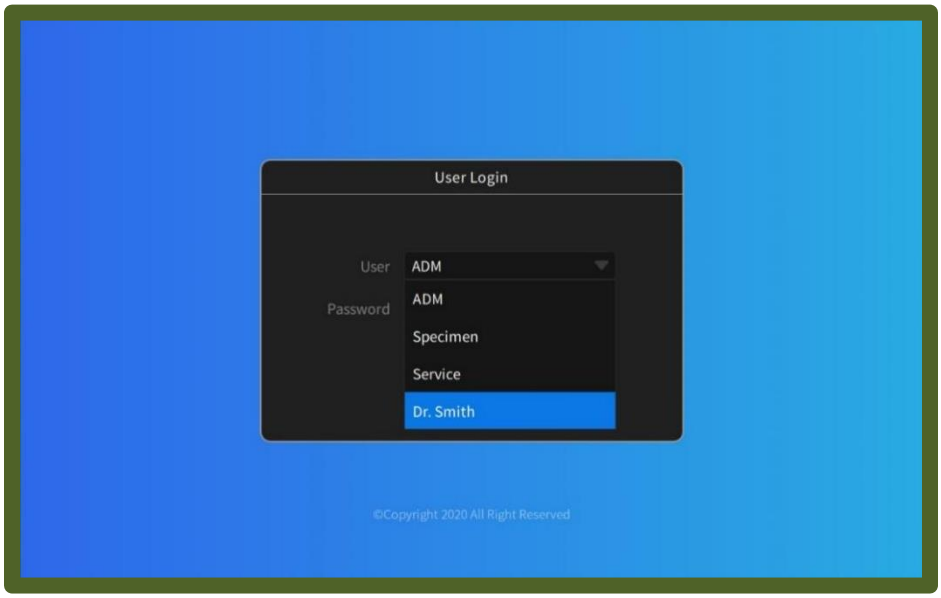


Figure5. 2 TrueView 100 Pro login screen with user pulldown menu shown.

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 entered values, 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.

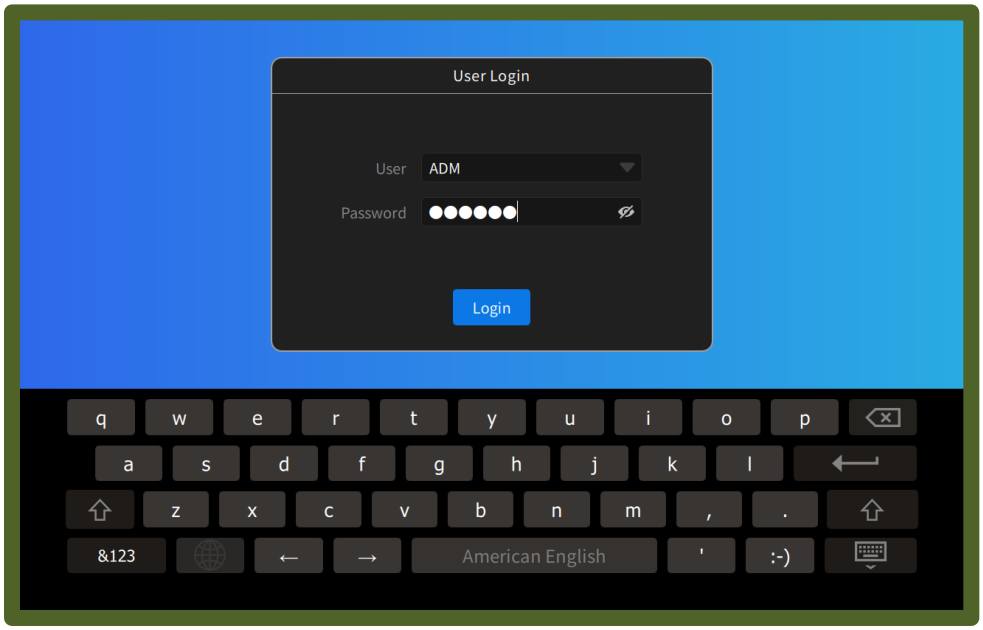


Figure5. 3 Password input

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

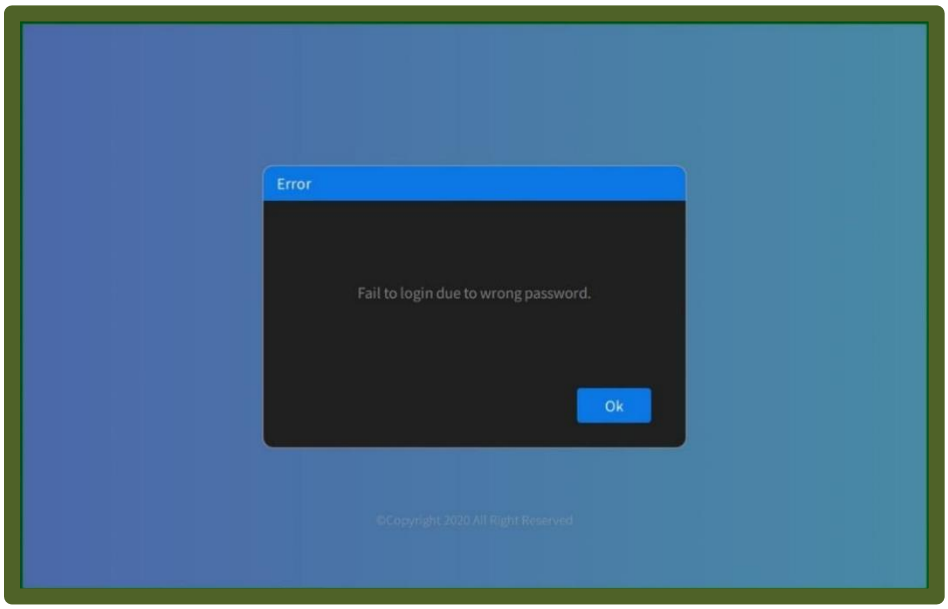


Figure5. 4 Failure to login due to wrong password error message

After the initial user of the system logging on successfully, the system will display the default Home menu and system monitor screens. If a previous user has used the system and then logged out, the system will return to the screens visible when the previous user logged out. A user may logout of the current session by selecting the user icon from the system information ribbon on the touchscreen (see 5.1.2.1.2 User Icons of the system information ribbon).

Caution: Don't share the password with others, especially the ADM password, to avoid possible data leakage or other cybersecurity issues.

5.1.2 Touchscreen General Layout

Following the initial user login of the TrueView 100 Pro system, the user will be presented with the screens seen in Figure 5. 5.

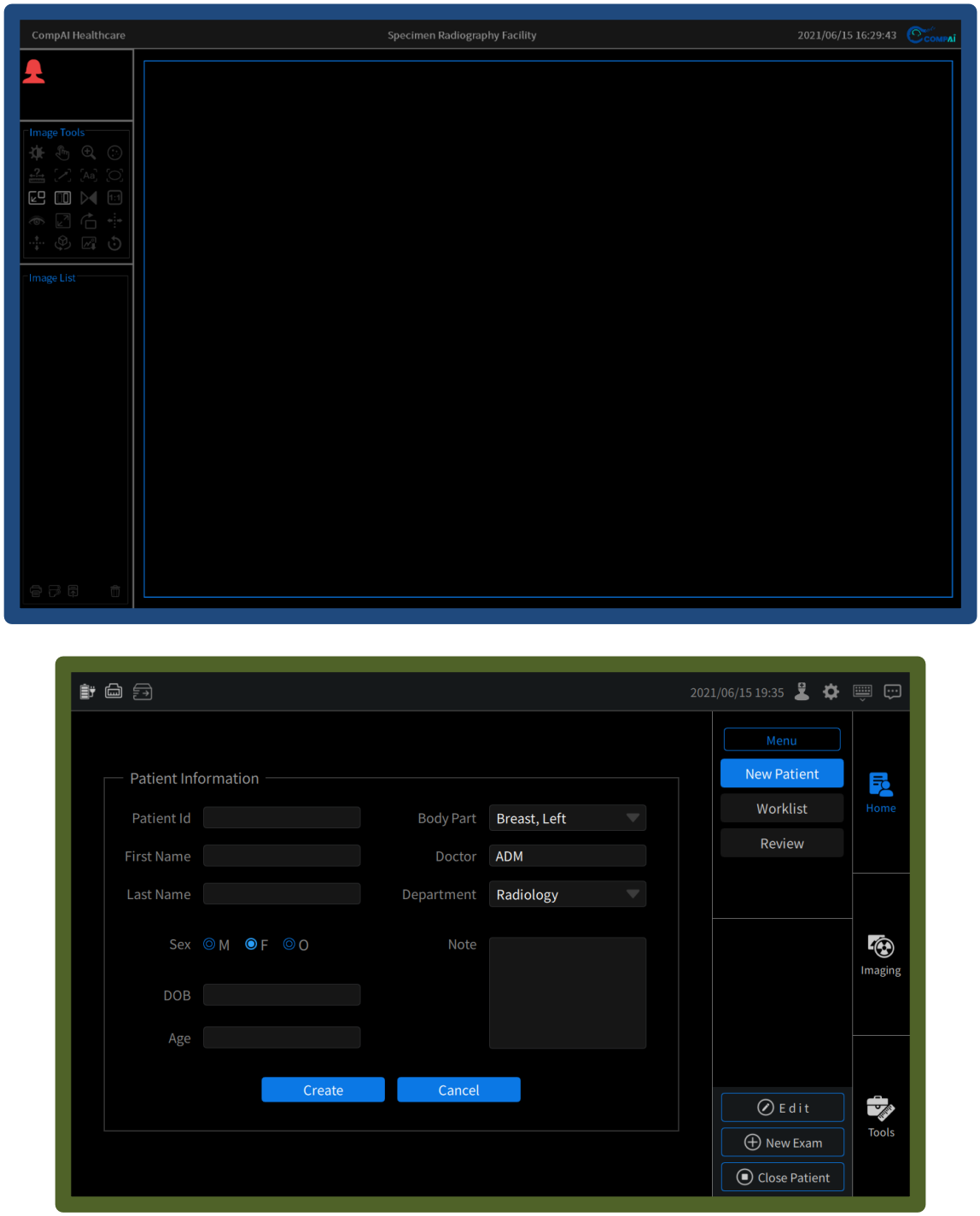


Figure5. 5 Default display configuration of the system monitor (upper) and touchscreen (lower) of the TrueView 100 Pro software following initial login.

The touchscreen seen in 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 (Figure5.14); and the system workspace (Figure5.8).

5.1.2.1 System Information Ribbon

The system information ribbon (Figure5.6) displays the system status icons on the left (see Figure5.7), 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 in the right (see Figure5.9).

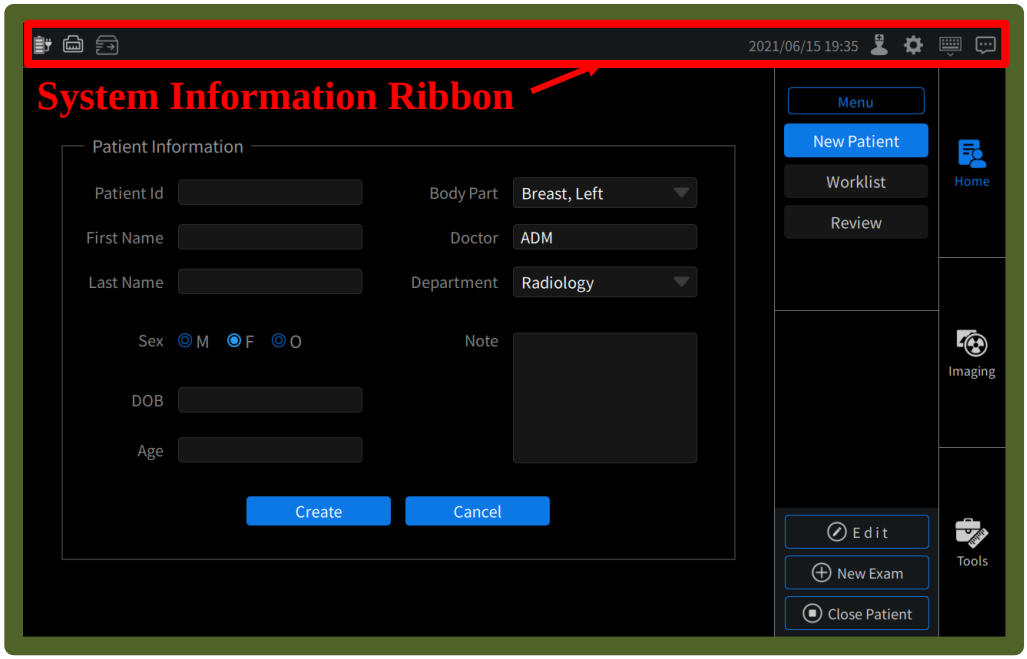


Figure5. 6 System information ribbon of the touchscreen indicated by the red border.

5.1.2.1.1 System Status Overview

The user can select any of the system status icons seen in Figure5.7 to display the system status overview screen. Figure5.8 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 status, network status, safely eject a removable storage device, and review the details of the

DICOM spooler queue. 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, thus the user may return to their previous system workspace screen by selecting any of the status overview icons of the system information ribbon.

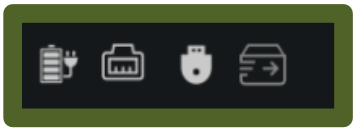


Figure5. 7 Example of system status overview icons.

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.

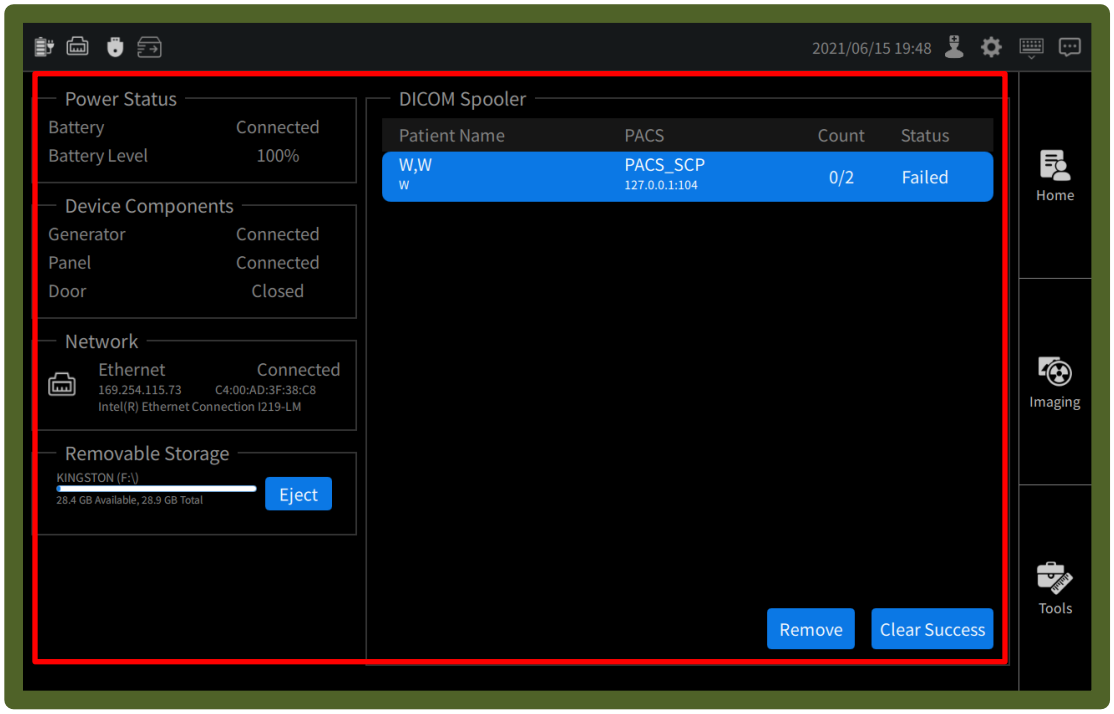


Figure5. 8 Example of a system status overview screen appearing in the system workspace (system workspace indicated with a red border) when any one of the system status icons on the system information ribbon is selected.

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 (Figure5.9). ***Note: to adjust the date and time and set the formatting see section5.2.1.*** 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.

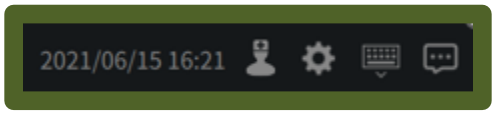


Figure5. 9 Individual selectable icons on the upper right of the touchscreen.

5.1.2.1.2 User Icon of the System Information Ribbon

From left to right on the selectable icons of Figure5.9, the first icon represents the user. Use the touchscreen or the touchpad to select this icon to logout as the current user. Figure5.10 shows the touchscreen display following the selection of 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 was unintended, the user may 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 Figure5.10).

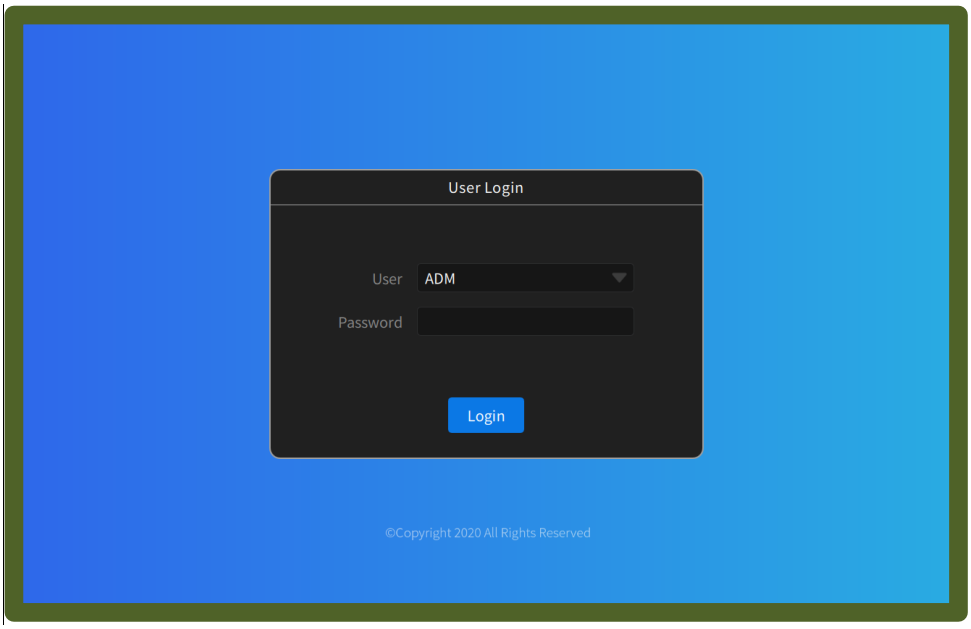


Figure5. 10 Interface on the touchscreen after selecting the user icon from the system information ribbon.

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 and opens the utilities page in the system workspace (see Figure5.11). The utilities page provides the user access to the configurable parameters of the TrueView 100 Pro system. Some system parameters require administrative authority to configure. A detailed discussion of the configuration options for the Utilities menu items can be found in section 5.2 Utilities.

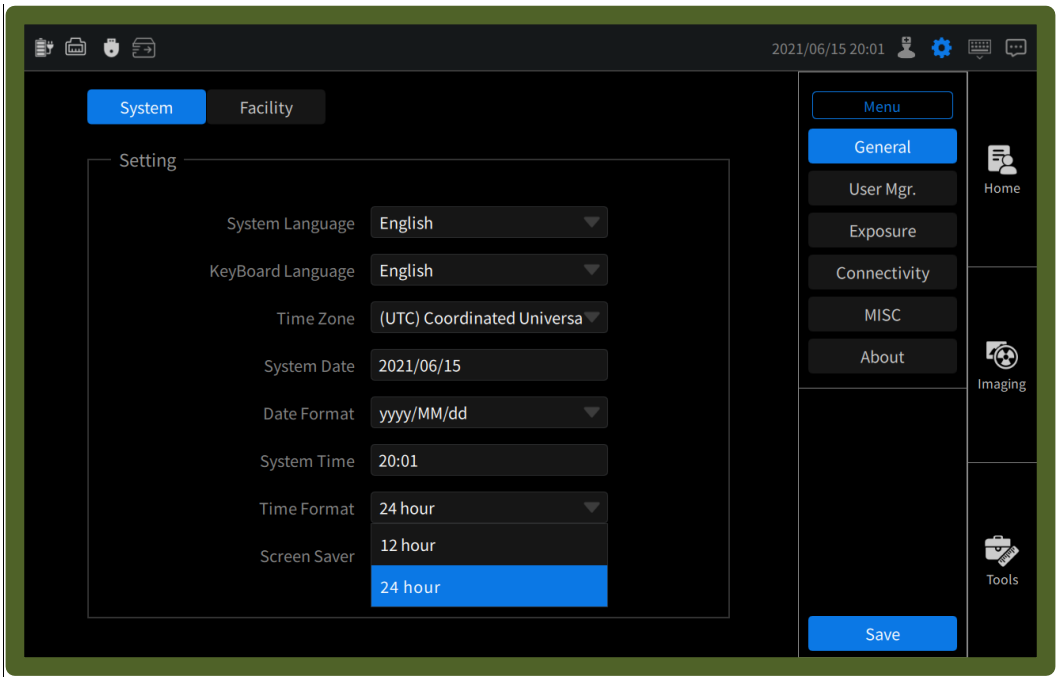


Figure5. 11 The utilities page displayed in the system workspace when the gear icon of the system information ribbon is selected.

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 will 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 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. Figure5.12 shows an example of the system status messages overview in the system workspace. The user may use the history pulldown menu to configure the number of messages displayed in the screen. 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.

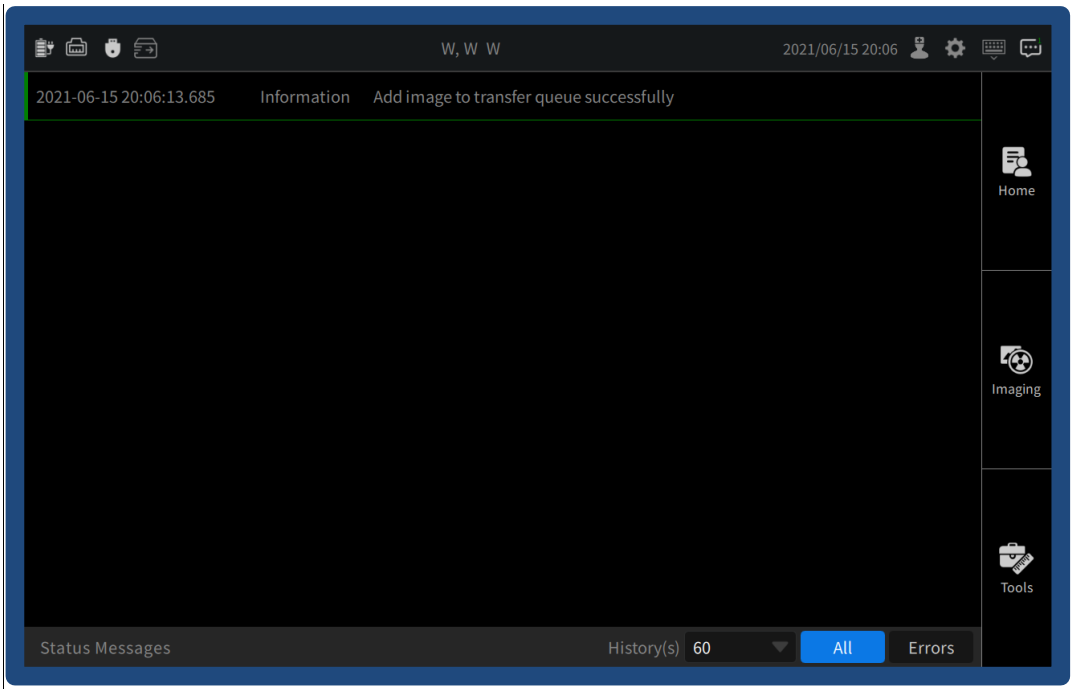


Figure5. 12 The System Status Messages page is accessed by selecting the message bubble icon of the system information ribbon.

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 (Figure5.13). 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.

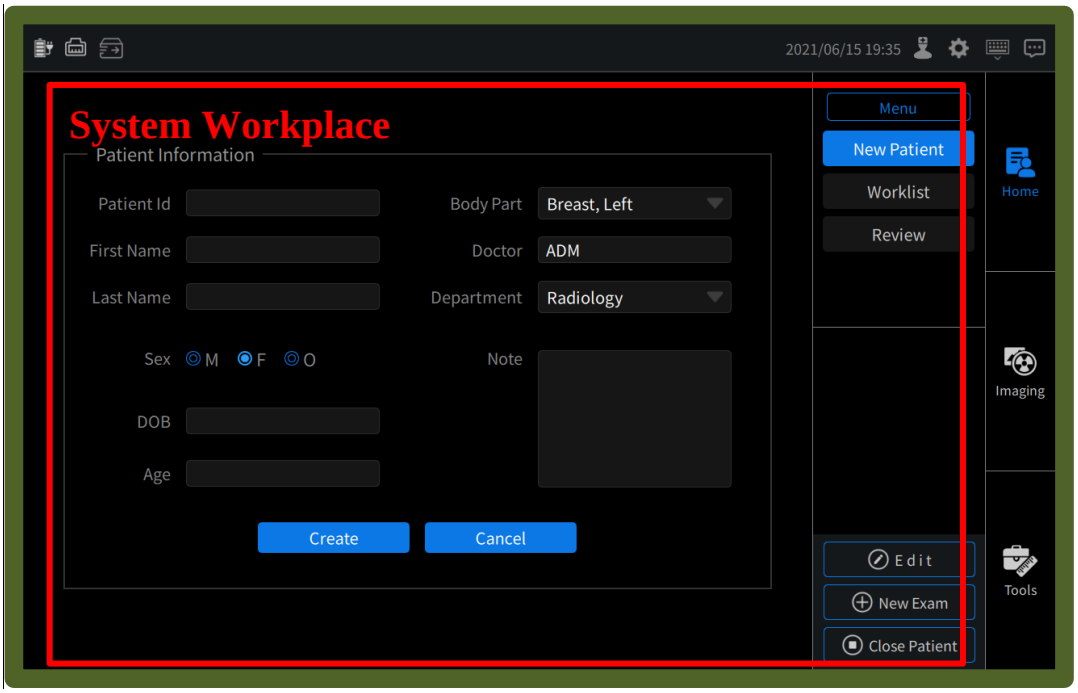


Figure5. 13 The dynamically set system workspace area of the touchscreen.

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 workflow steps for any specimen analysis will follow the system workflow icons visible on the right side of the touchscreen (Figure5.14).

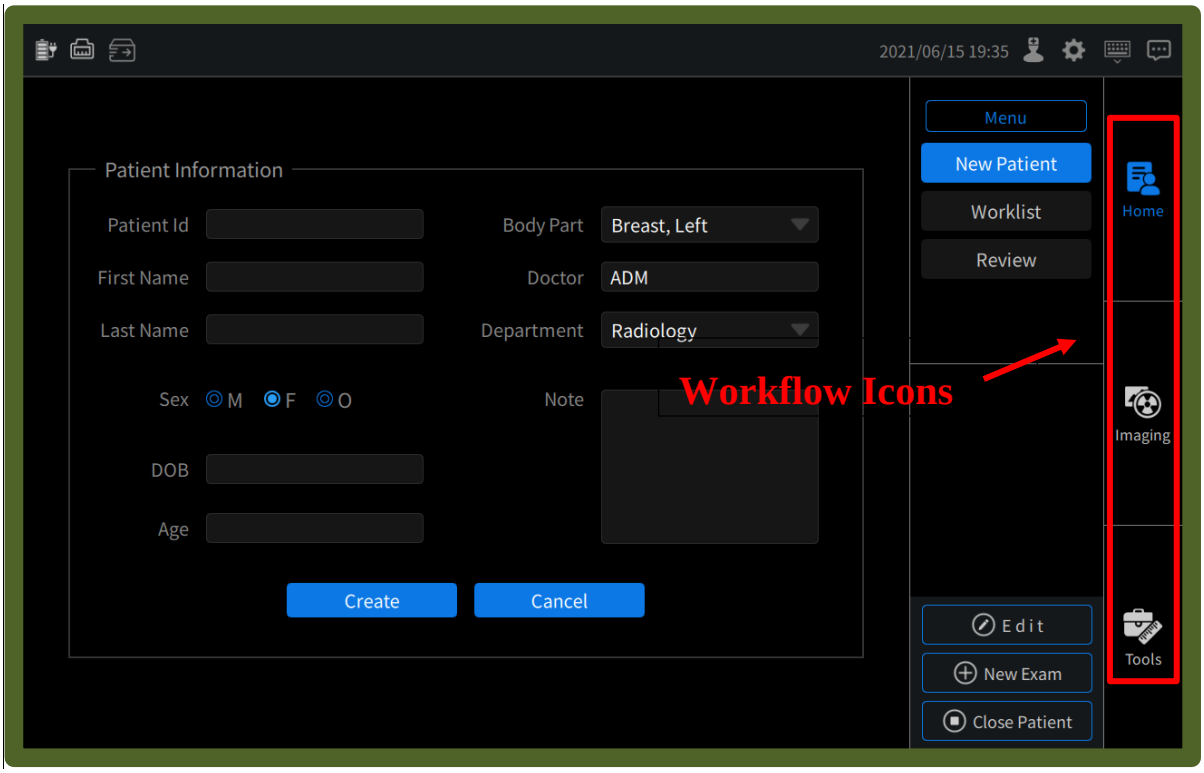


Figure5. 14 Workflow icons of the touchscreen.

These icons, their respective menu items, and the functionality available to the user will be the focus of sections5.3, 5.4, and 5.5.

5.1.3 System Monitor General Layout

The upper screen shown in the general layout (Figure5.5) 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 Figure5.15). 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 print, PACS store, and image delete functions of the Image list area are enabled, they will display a blue background (see5.5.22).

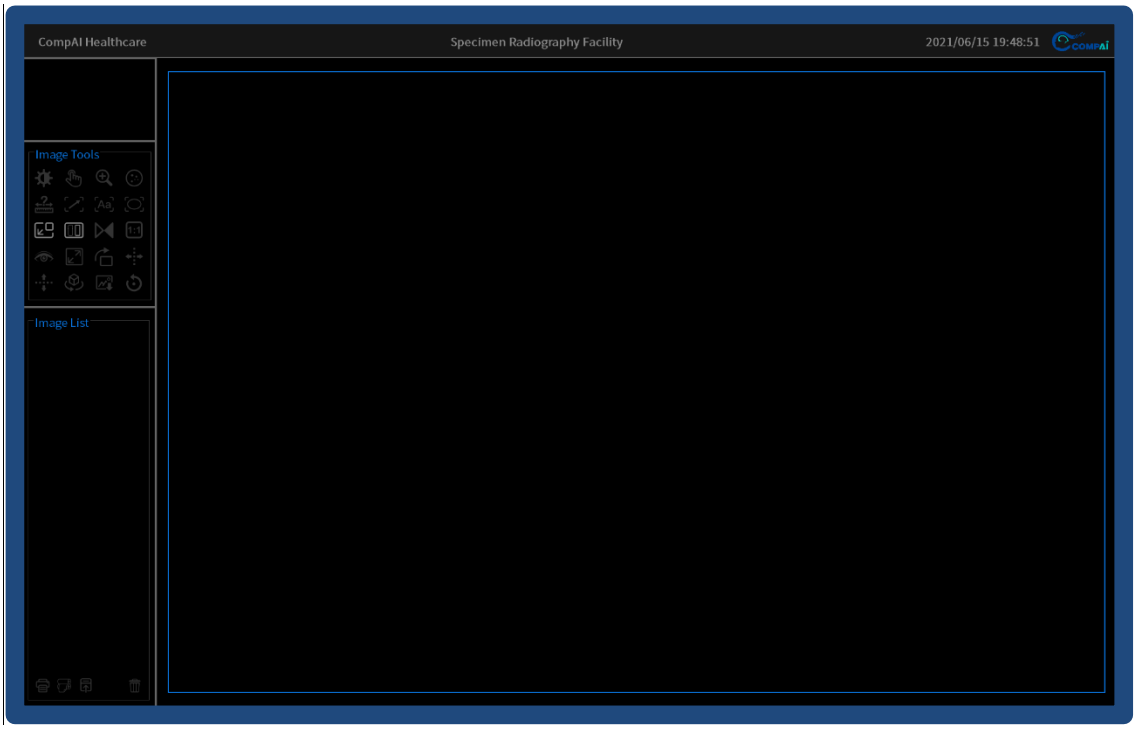


Figure5. 15 System monitor with Image tools highlighted by yellow border and configured for single image display. Only the "Layout" and "Next Screen" icons are enabled.

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

Click the “Utilities” button, the general settings page will be displayed by default (Figure5.16).

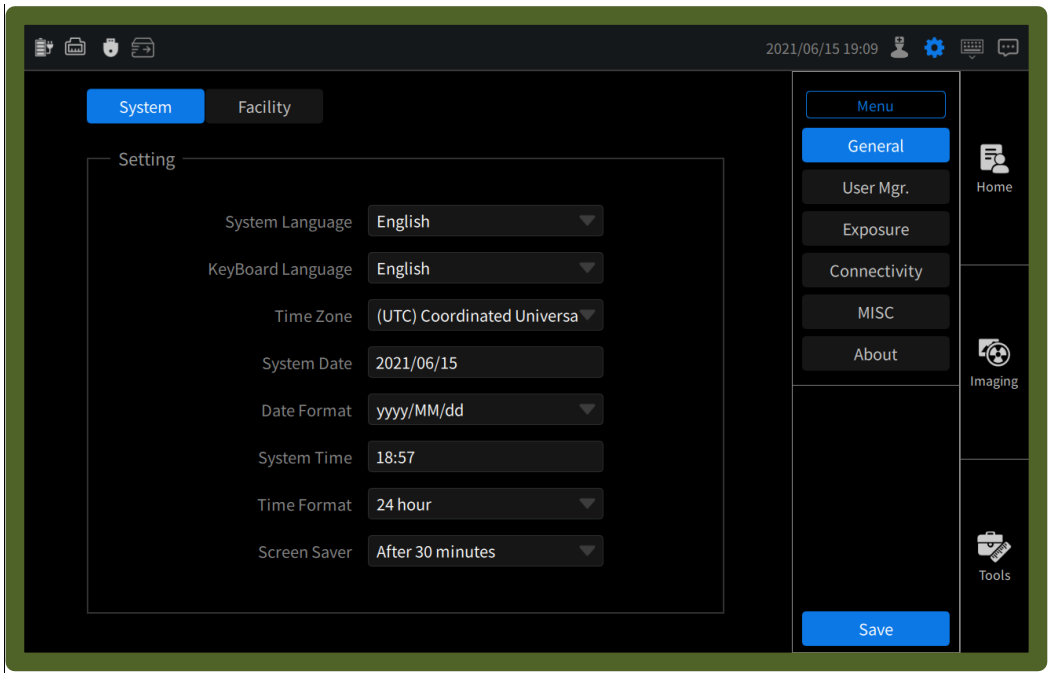


Figure5. 16 The default view of the utilities page in the system workspace opens with the General settings selection from the utilities menu.

The general settings allow the authorized user to set the 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, 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 format, 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. Figure5.17) or the scroll wheel (e.g. Figure5.18) 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.

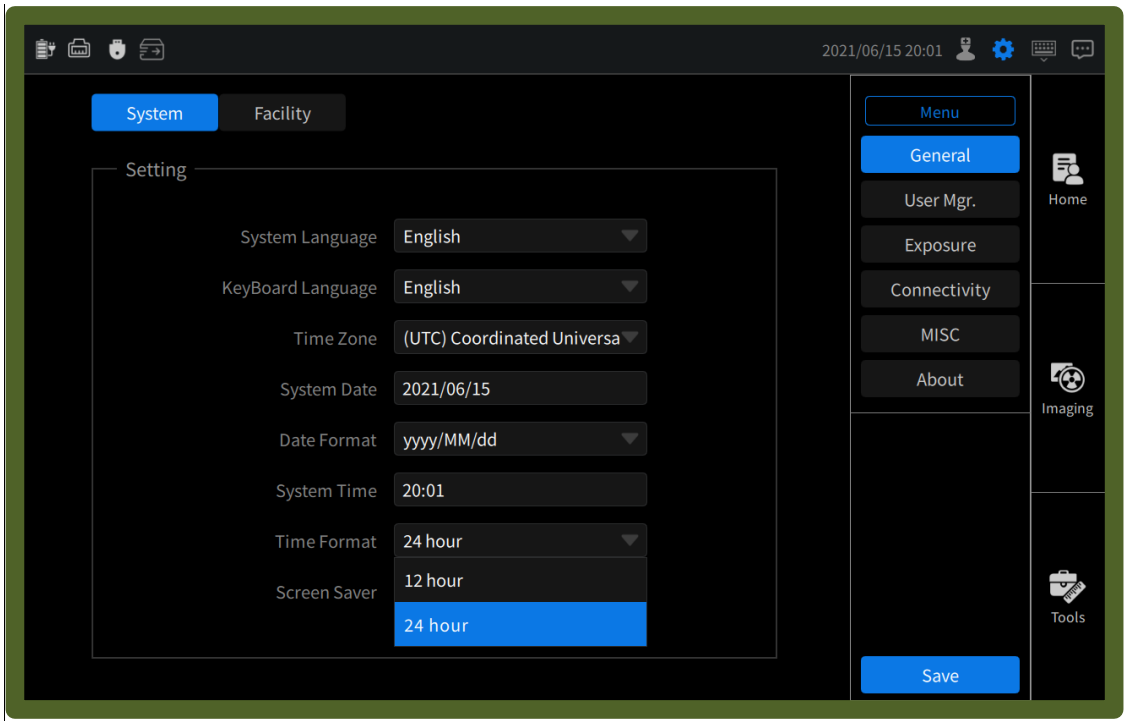


Figure5. 17 Pulldown menu of the configurable time format value.

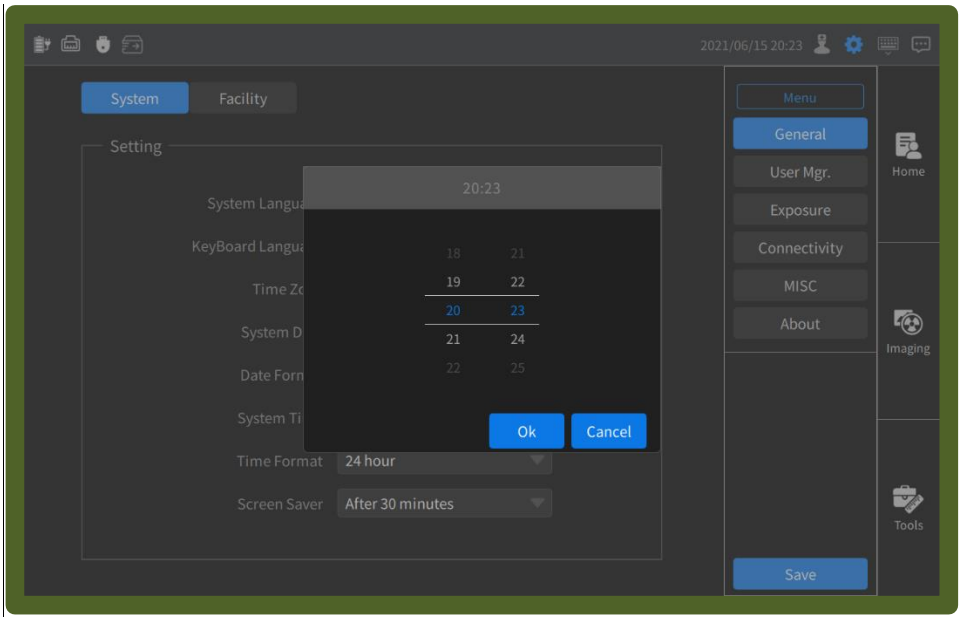


Figure5. 18 Scroll wheel interface for the configurable current date.

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 (Figure5.19).

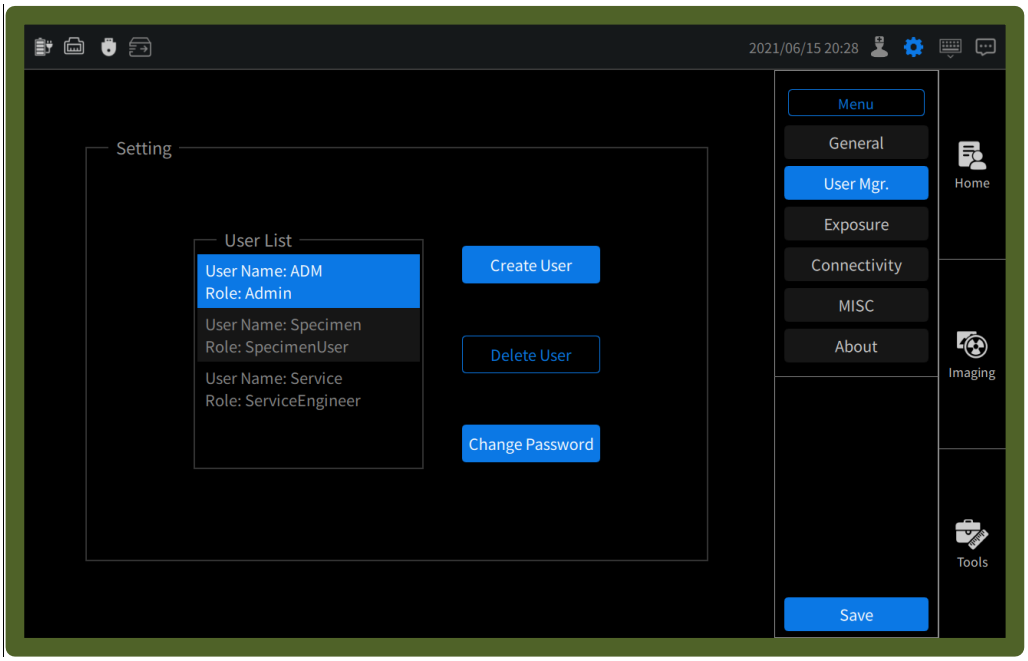


Figure5. 19 When logging in as the ADM user, select the User Mgr. menu item and then select the “Create User” button to create a new clinical user.

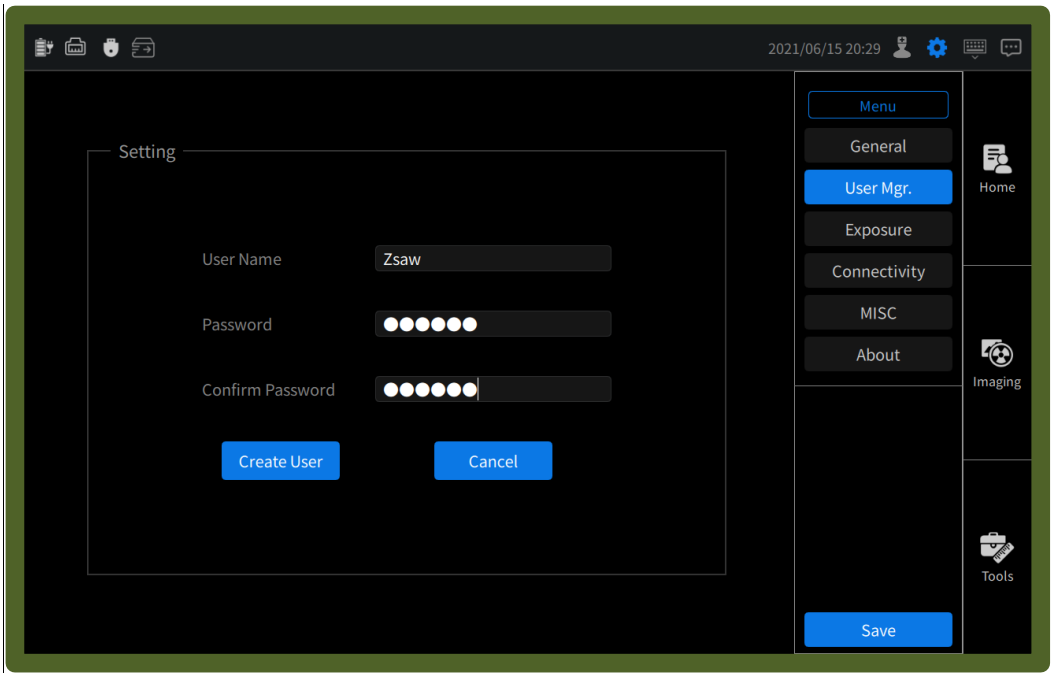


Figure5. 20 Using the touchscreen keyboard, the ADM user enters the new clinical user's username and password and then selects the Create User button.

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 (Figure5.21) acknowledging the creation of the new user. After clicking "Ok" in the confirmation window, the new user's name will appear in the user list.

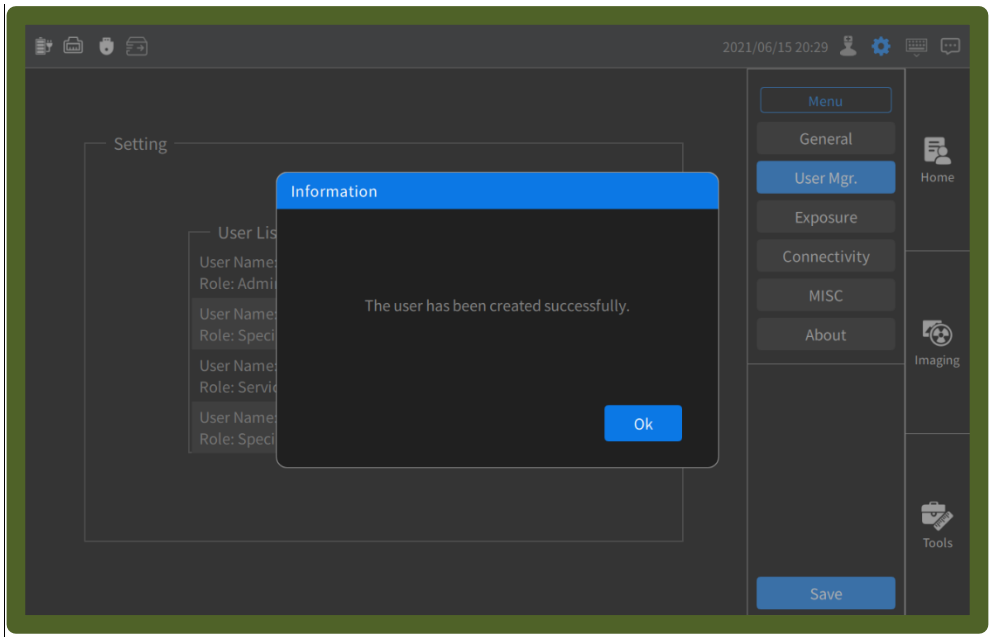


Figure5. 21 System acknowledgment of the creation of the new clinical user.

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 (Figure5.22) and then the system will display a message that the action has been successful (Figure5.23).

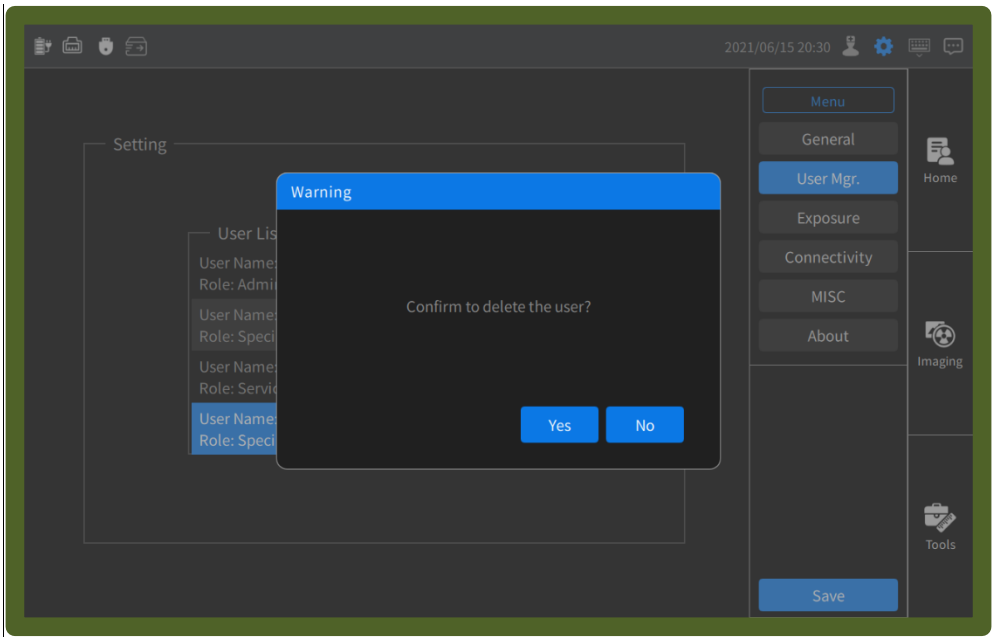


Figure5. 22 Confirm user deletion.

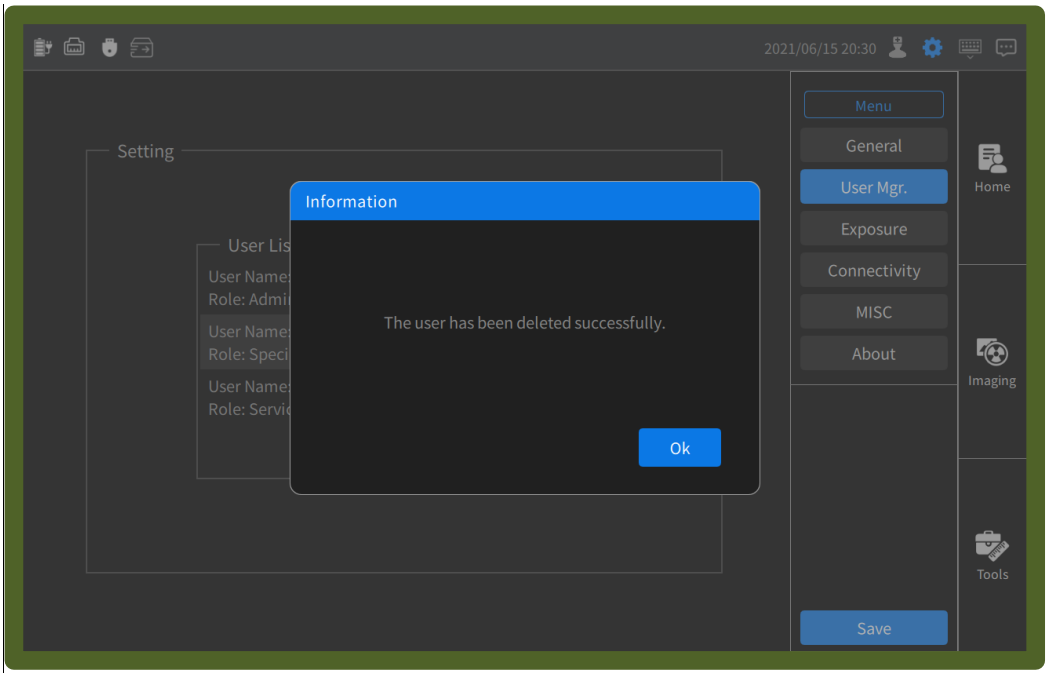


Figure5. 23 System acknowledgment of user deletion.

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 (Figure5.24).

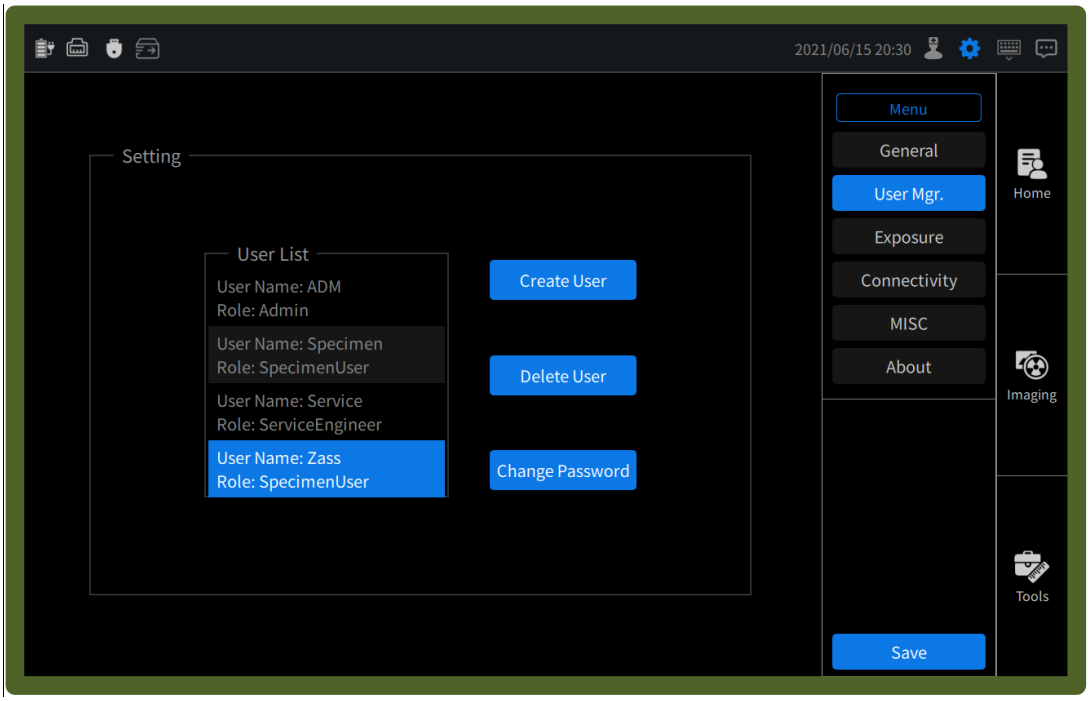


Figure5. 24 As the ADM user, select a new clinical username from the user list and push the Change password button to initiate the change password workflow.

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 (Figure5.25). 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 (Figure5.26).

If logging in as a clinical user, the user management page will have only one function available, the change password function (Figure5.27). 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.

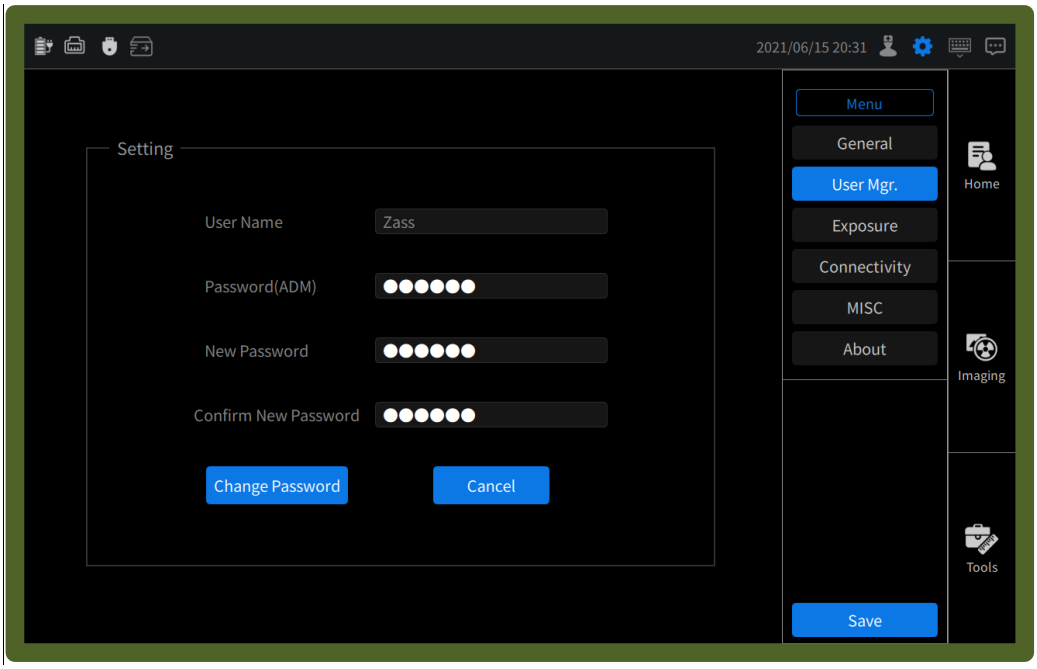


Figure5. 25 ***ADM*** user change clinical user password workflow.

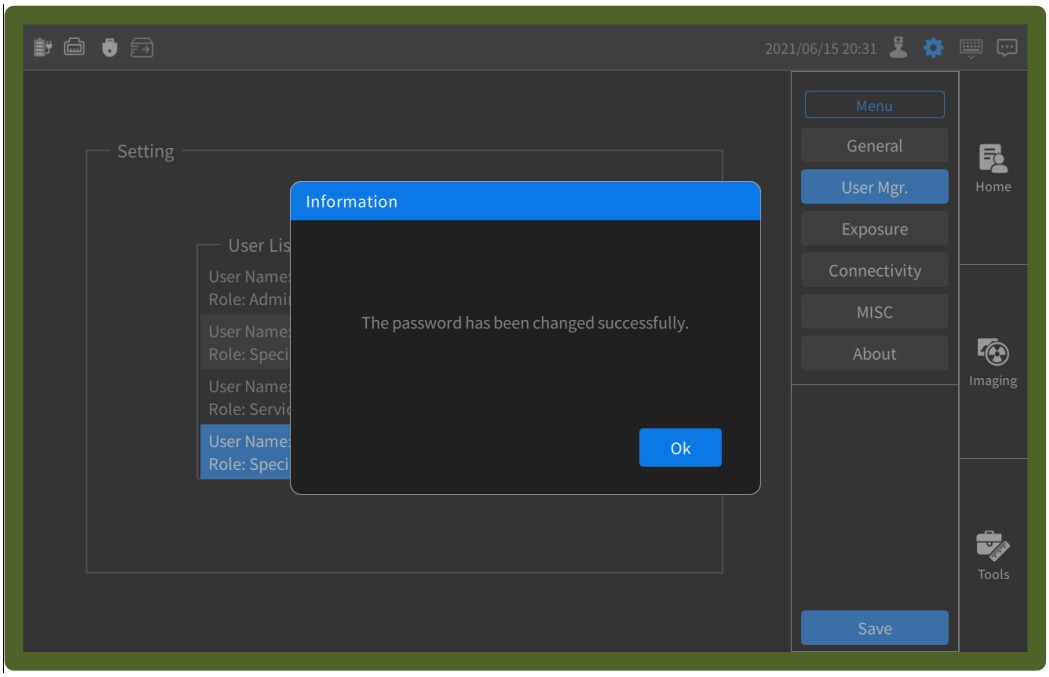


Figure5. 26 System confirmation that the user password has been changed successfully.

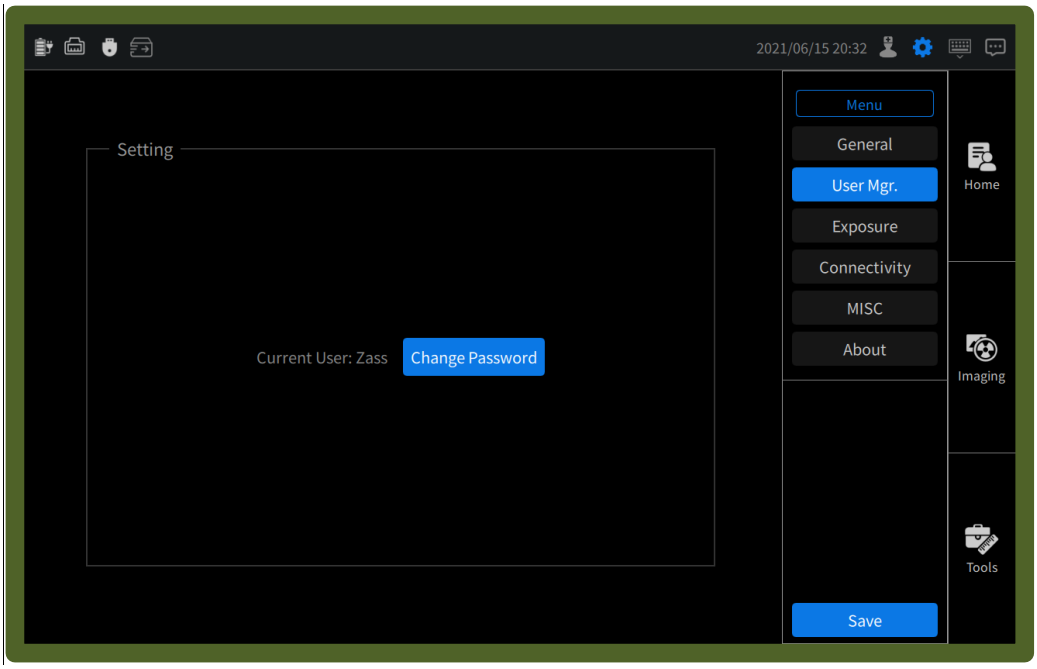


Figure5. 27 Change password as a clinical user.

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. Figure5.28 shows the options available to 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.

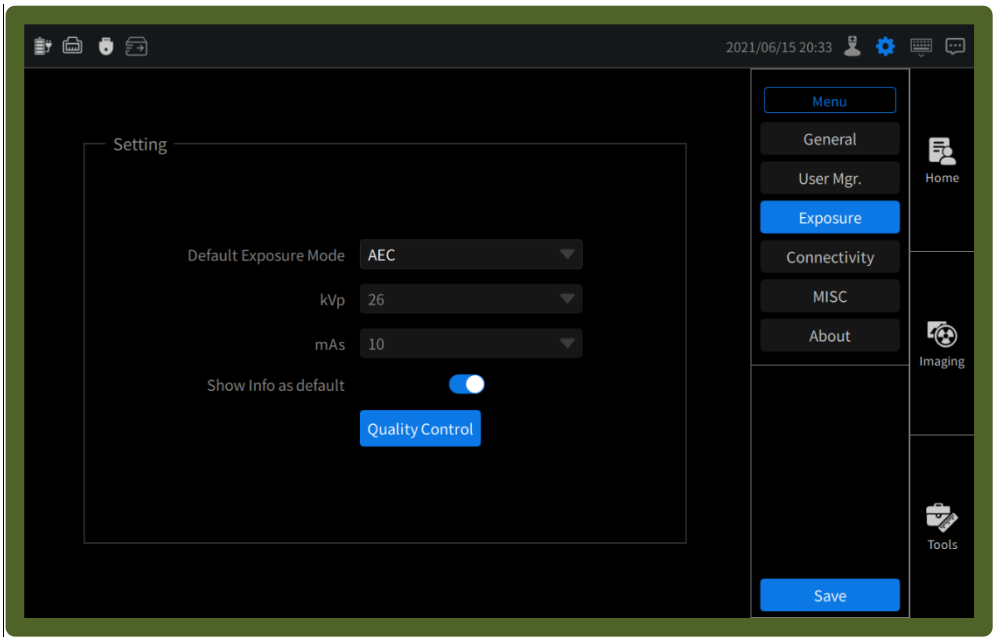


Figure5. 28 Exposure setting interface

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 and whether shows information as default.

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 that 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).

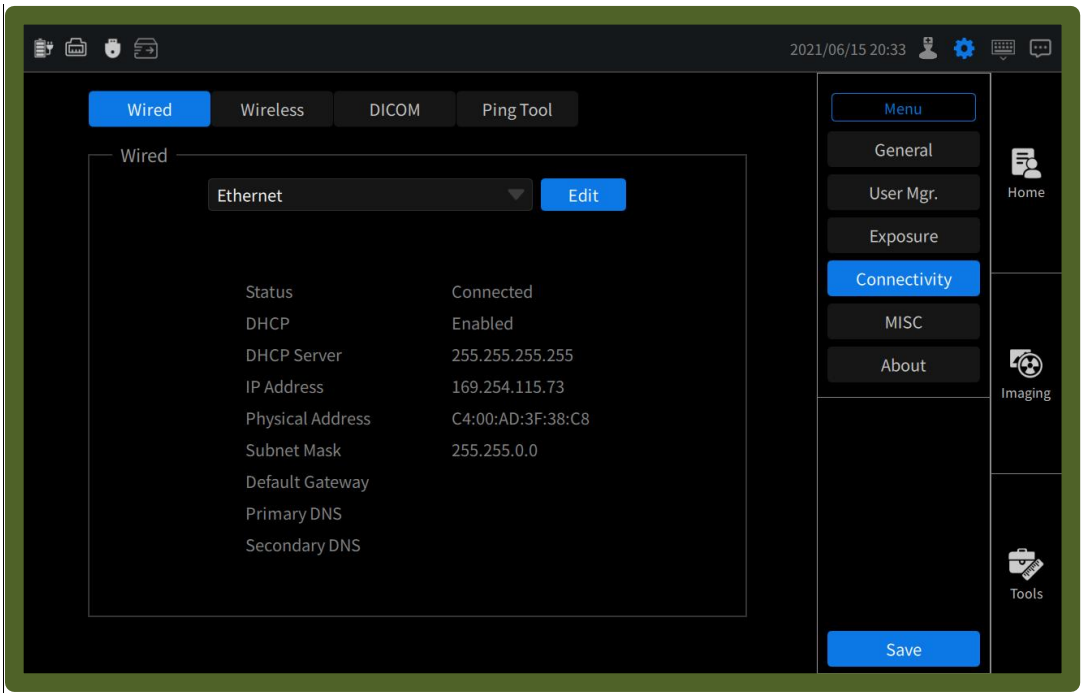


Figure5. 29 The Wired page of the connectivity menu item of the utilities page in the system workspace.

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 (Figure5.30) after the USB wireless card is connected.

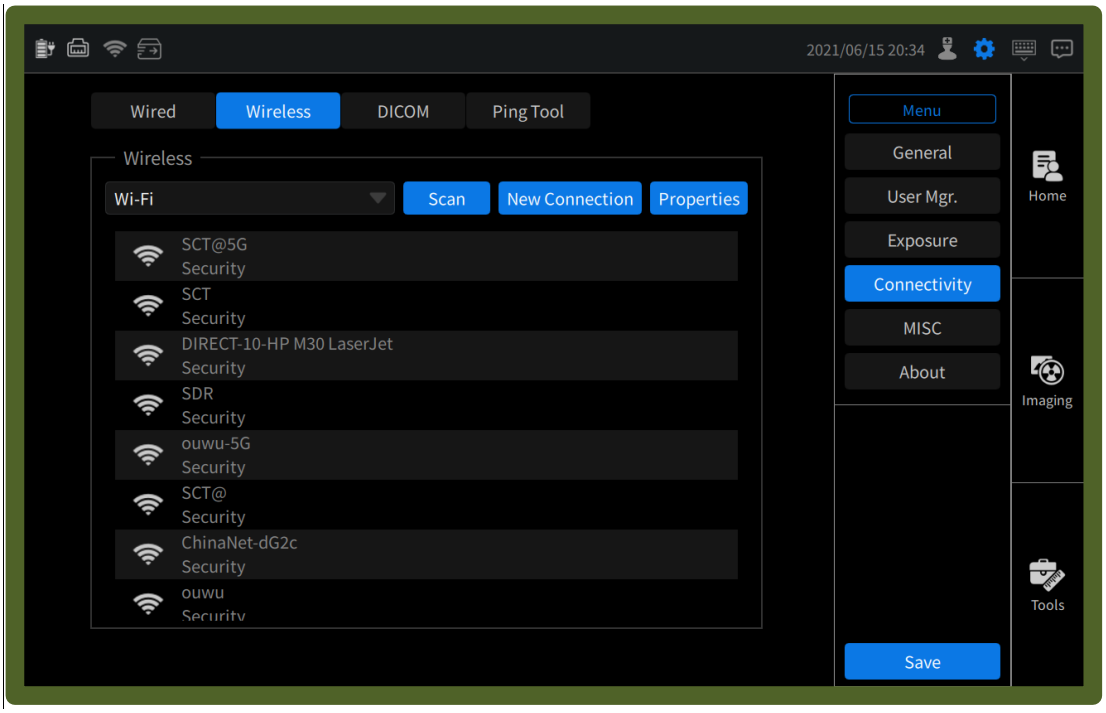


Figure5. 30 The wireless page of the connectivity menu item of the utilities page in the system workspace.

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, PACS Image storage and DICOM print connectivity. If any of the connecting tests fail, contact the ***ADM*** user to configure the IP Address, AE title, and Port for each connection. Figure5.31 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 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.

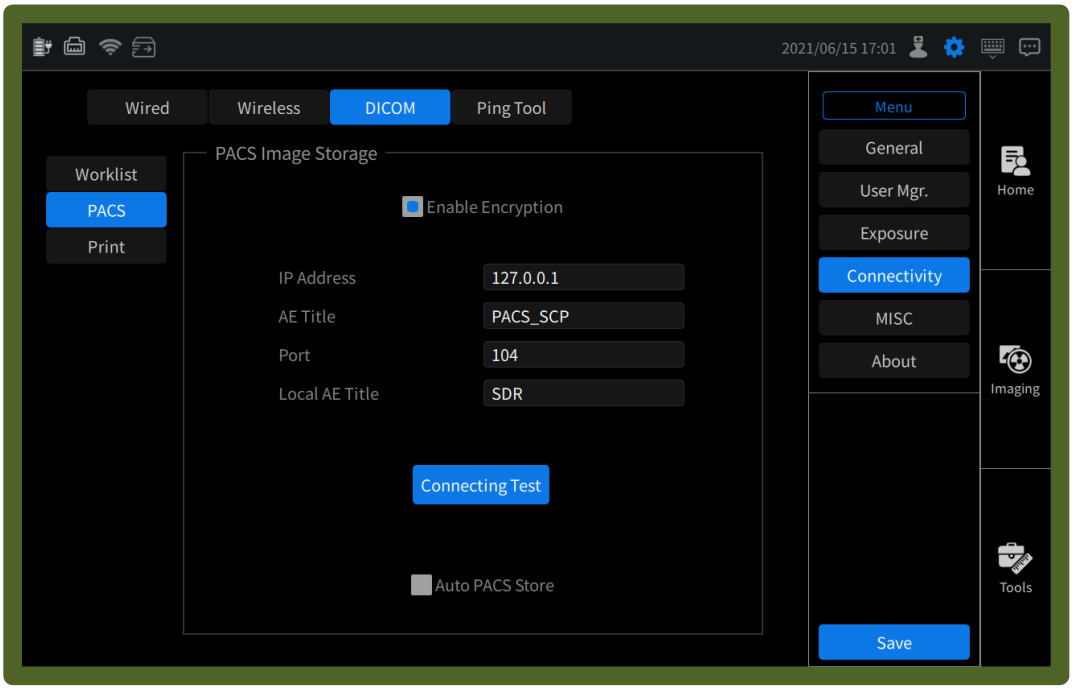


Figure5. 31 The PACS Image Storage configuration and test page of the connectivity menu item of the utilities page in the system workspace. The Auto PACS store feature is enabled in this view, as indicated by the blue circle in the radio button at the bottom.

The operation procedure of the DICOM worklist and DICOM print pages 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 barcode reader, and to configure the “ReadTo” parameter of the barcode reader workflow (Figure5.32).

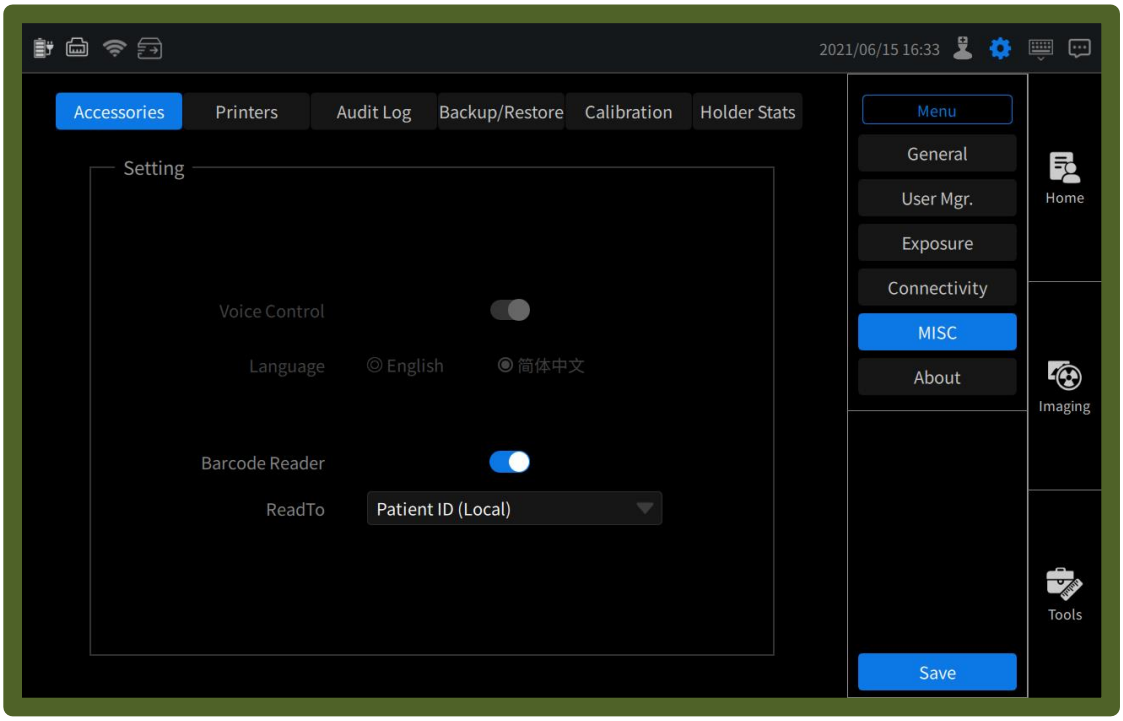


Figure5. 32 The Accessories page of the MISC menu item of the utilities page in the system workspace.

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

5.2.5.2 Printer

Local printer can be scanned and added on the printer page. If the network connects successfully, click the "Add" button and then click the "Scan" button to select the corresponding printer and click “Add”, as

shown in Figure 5.33. The recommended printer model is shown in the following link: https://support.hp.com/us-en/document/c04324001.

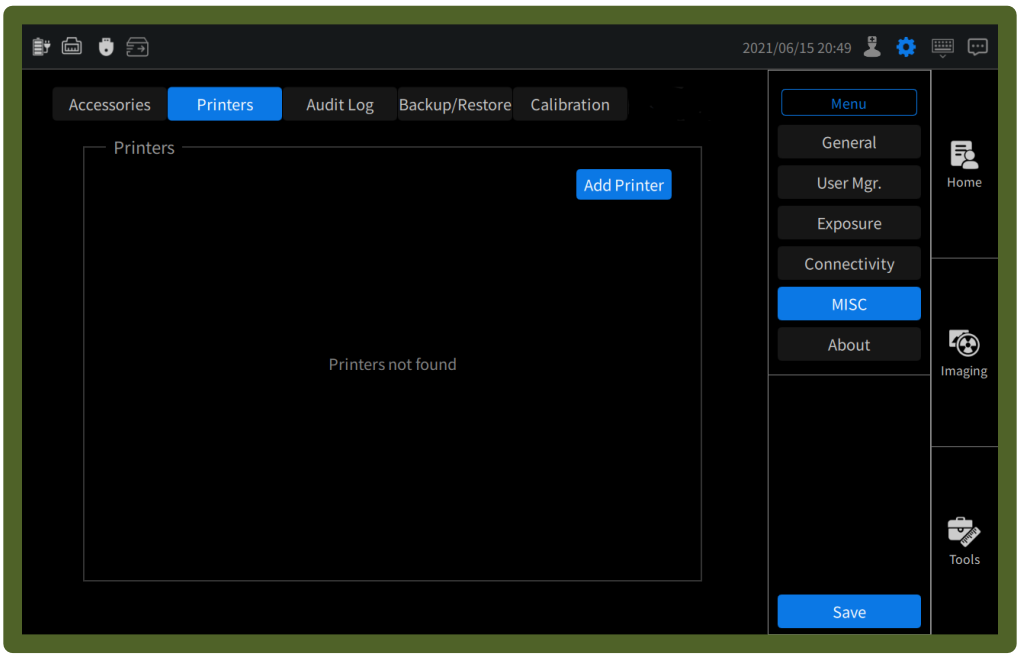


Figure5. 33 The Pinter page of the MISC menu item of the utilities page in the system workspace. ***NOTE: only the ADM user will see the Backup/Restore and Calibration pages.***

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 Figure5.34)

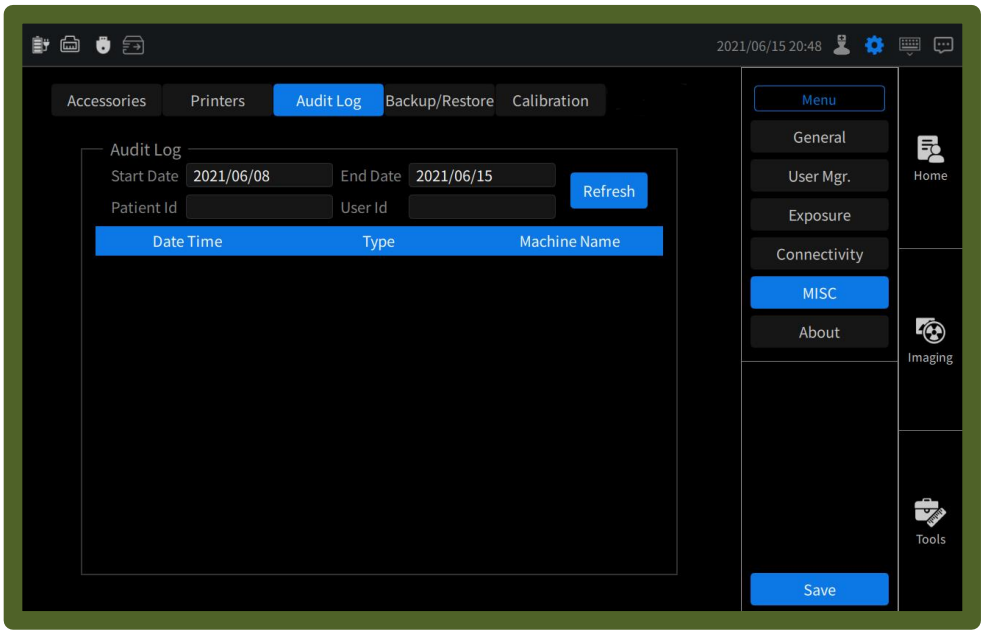


Figure5. 34 The Audit Log page of the MISC menu item of the utilities page in the system workspace.

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 Figure5.35).

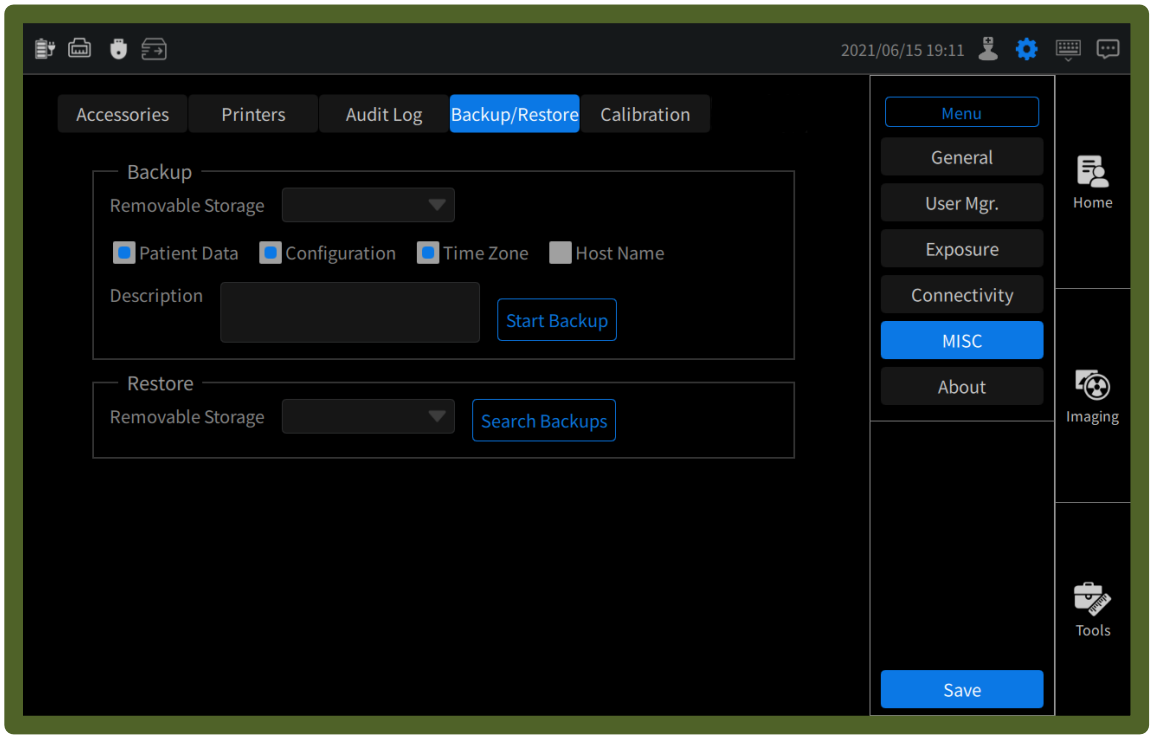


Figure5. 35 The Backup/Restore page of the MISC menu item of the utilities page in the system workspace.

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 Figure5.36). At the start of the procedure, the table shows the calibration steps and indicates 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 Figure5.37). This procedure can take several minutes, and the tube calibration progress status will be displayed in the system workspace (see Figure5.38) 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, contact your service representative.

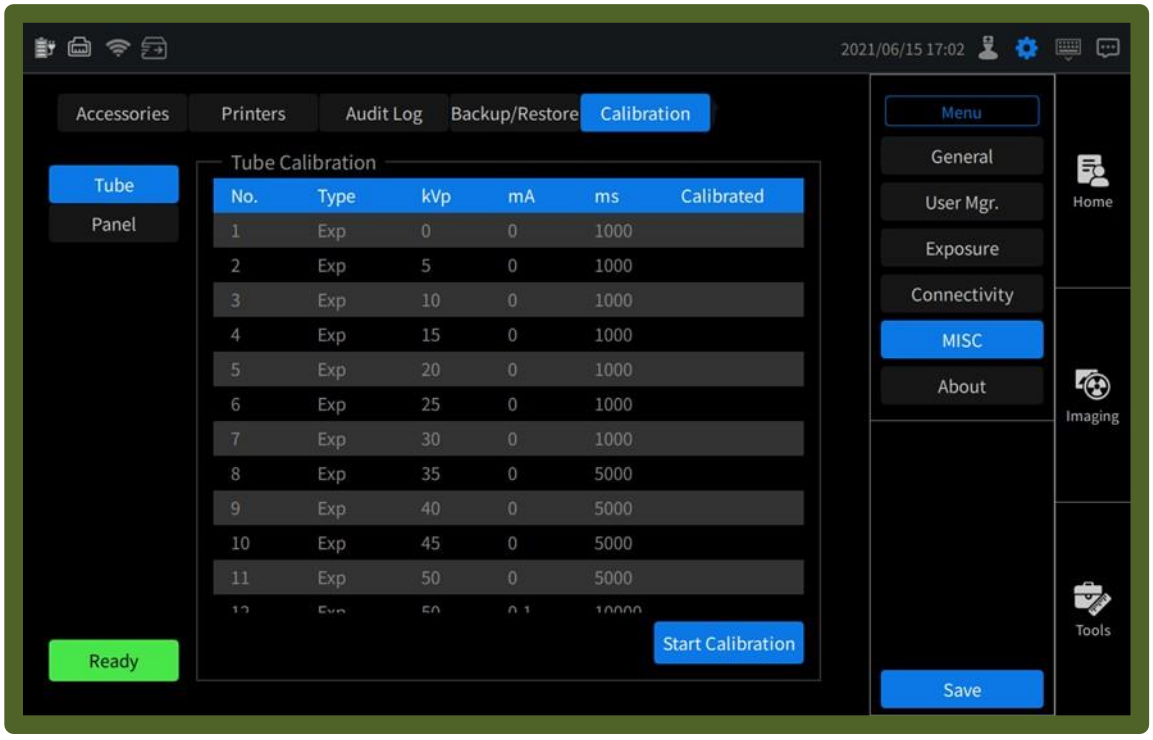


Figure5. 36 The tube calibration page of the MISC menu item of the utilities page in the system workspace.

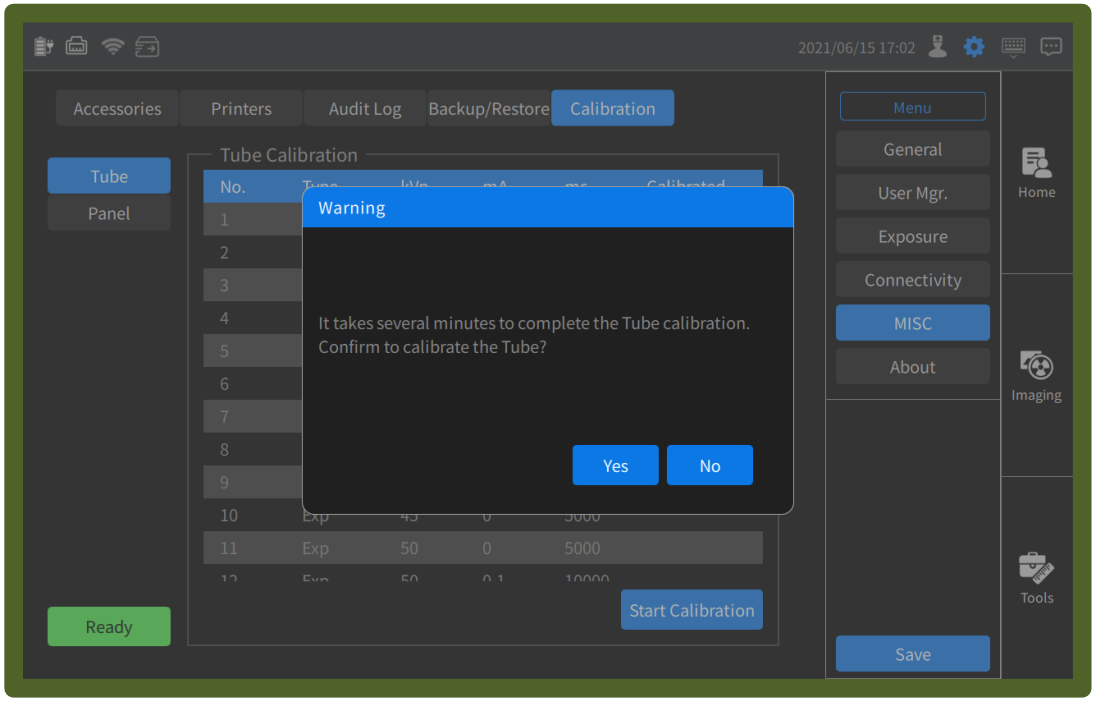


Figure5. 37 Warning that the system requires several minutes to complete the tube calibration. User is required to confirm before the calibration proceeds.

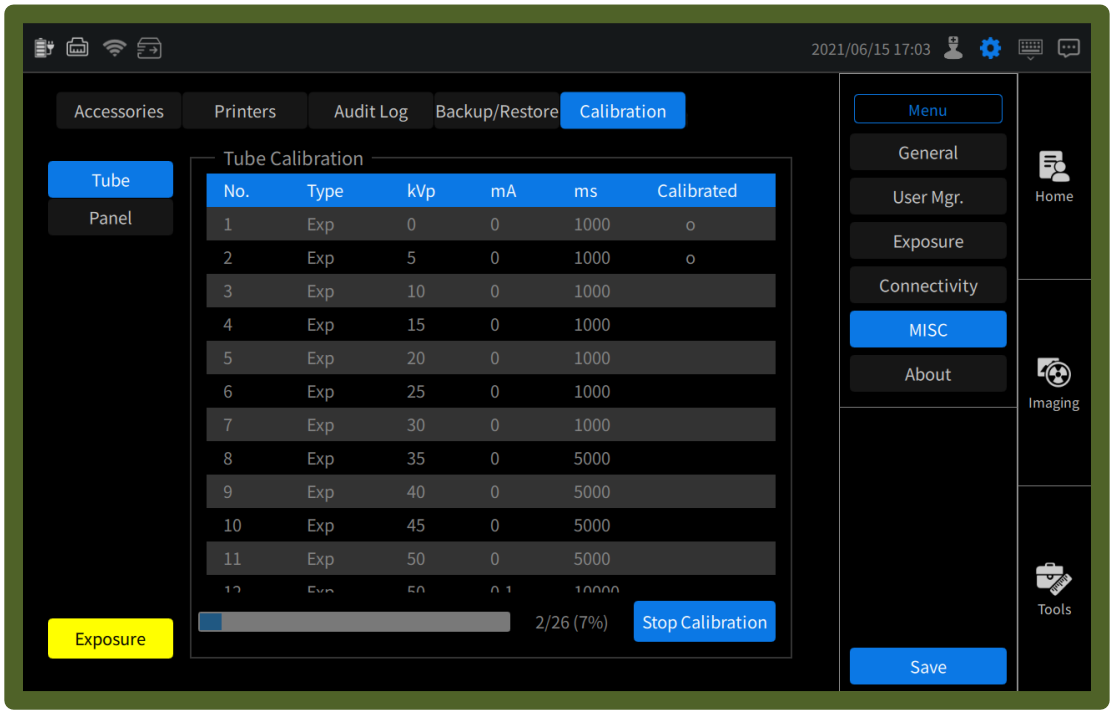


Figure5. 38 Tube calibration progress display indicates the current calibration number and percentage completion.

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 Figure5.39). 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 performing 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.

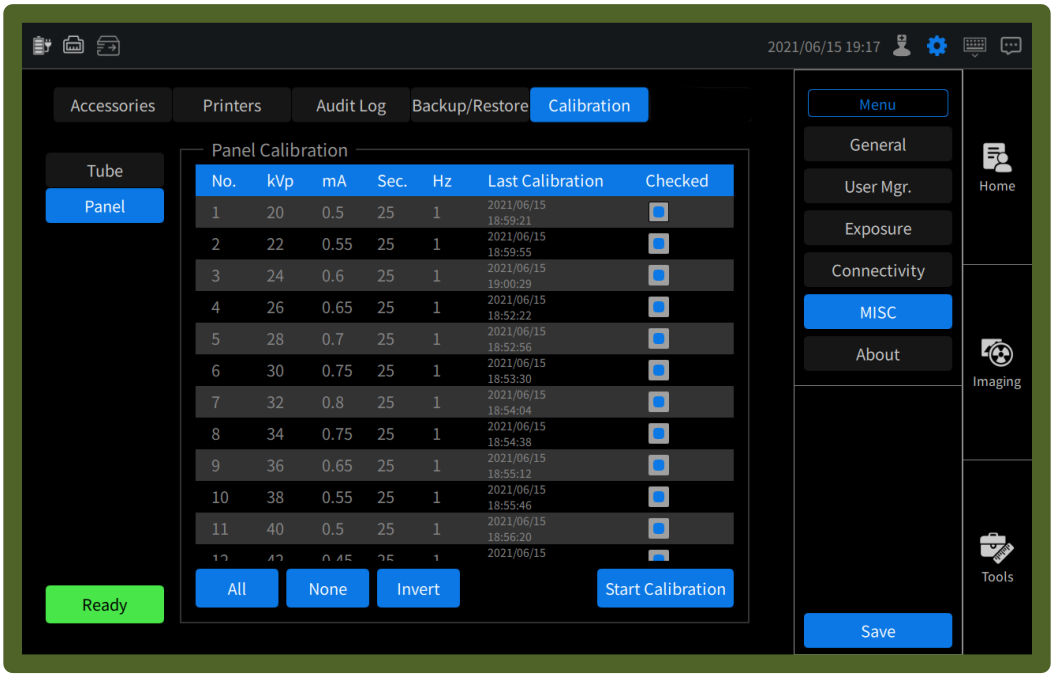


Figure5. 39 The Panel calibration page of the MISC menu item of the utilities page in the system workspace. In this configuration, all the panel calibration steps have been selected and the system is ready to start the calibration.

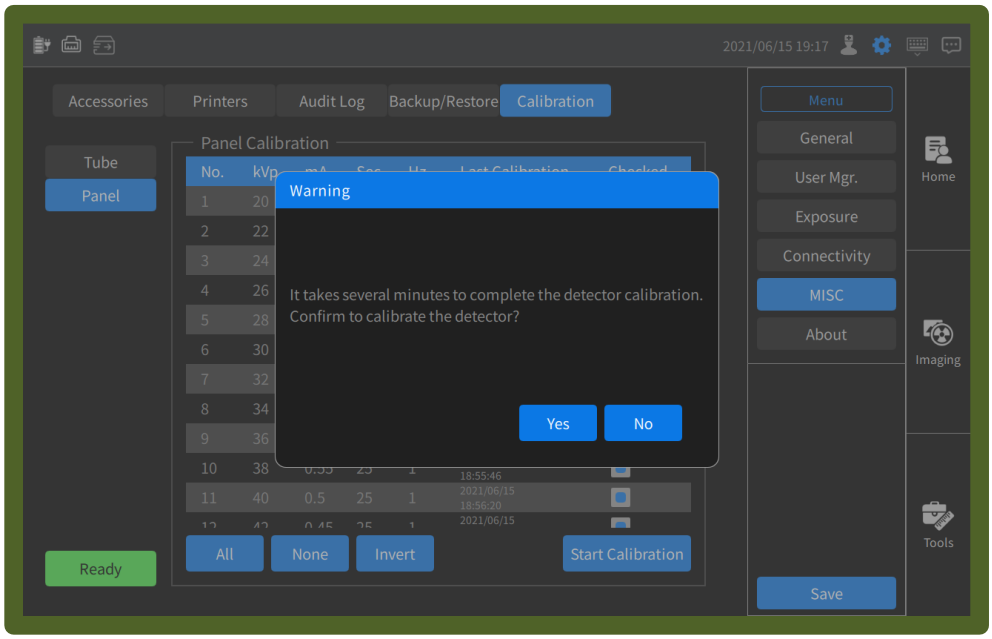


Figure5. 40 Panel calibration and dialog box of warning confirmation.

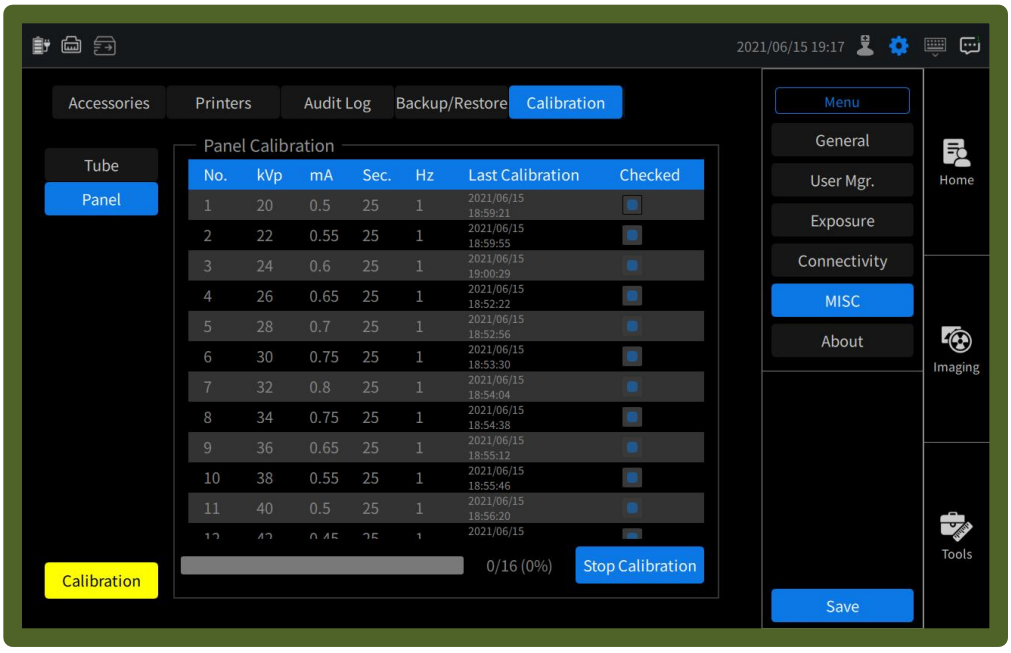


Figure5. 41 Panel calibration procedure

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.

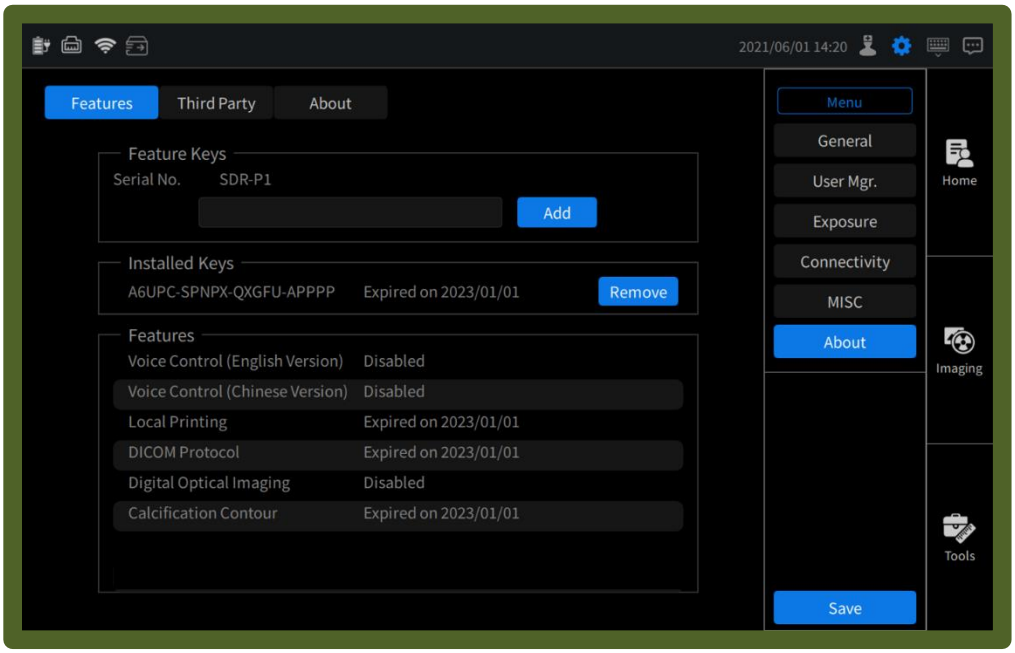


Figure5. 42 The About menu item of the utility's workspace provides the setting of features

5.2.6.2 About

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

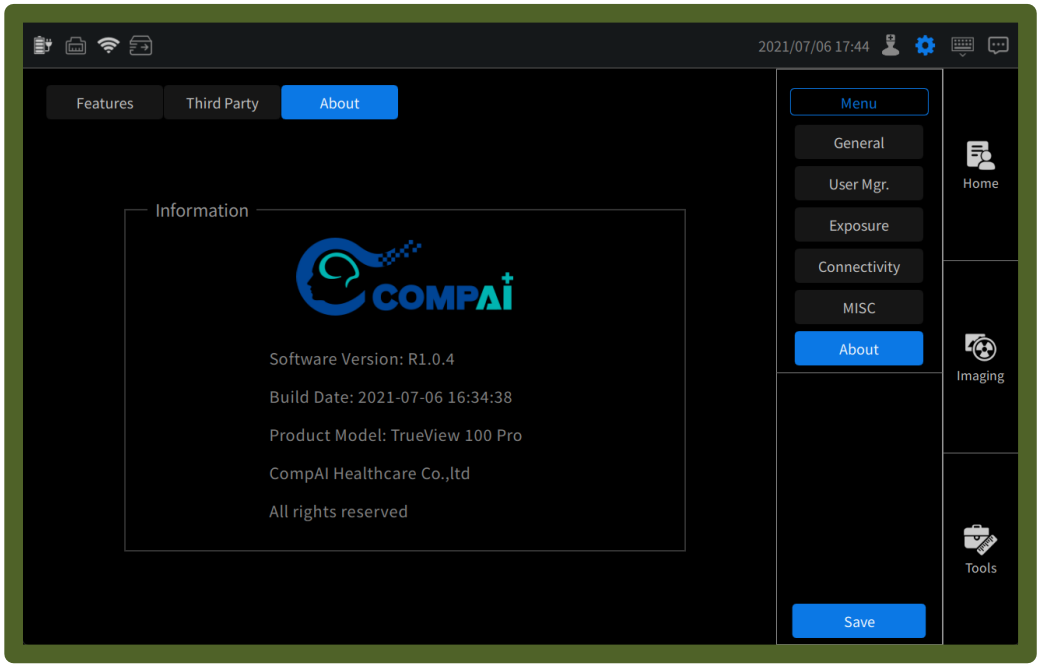


Figure5. 43 The About menu item of the utilities workspace.

5.3 Home

The menu options of the Home workspace on the touchscreen allows the user to create a new patient, see the worklist, or review an existing patient. In figure 5.44, 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), or Review (5.3.3) from the list of menu items.

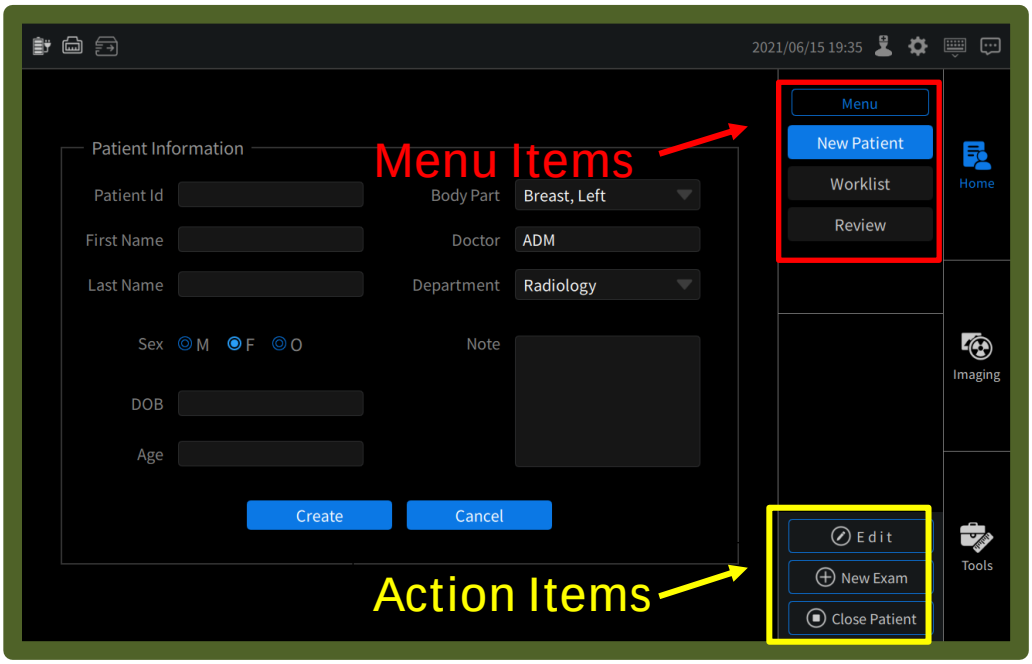


Figure5. 44 Menu and Action items on the initial login Home screen.

Figure 5.44 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 5.46.

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 (Figure5.45). 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.

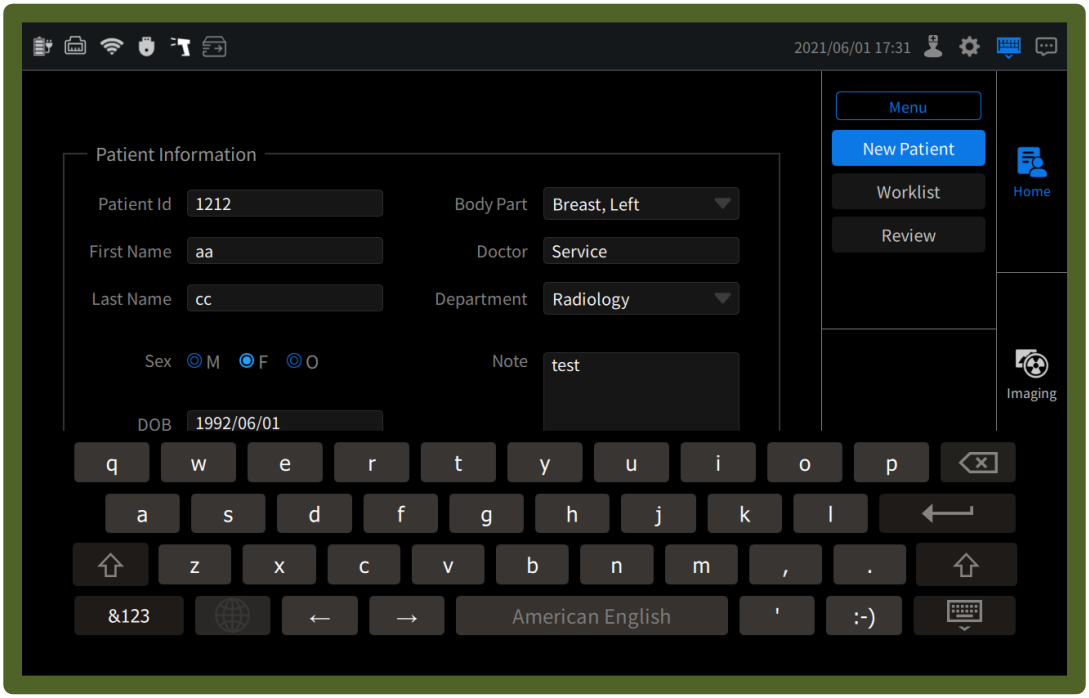


Figure5. 45 Create a new patient workspace.

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 of the Home workspace allows users to search for scheduled patient and select patients for imaging. If the worklist is empty, then select the “Refresh” action item to repopulate the worklist in the server. If the Refresh fails, then contact the ***ADM*** to configure the DICOM worklist connectivity (5.2.4 Connectivity). Figure 5.46 shows the action items of the worklist menu item on the home workspace. In the worklist, the user can select a patient from it and then select the “New Exam” action item to open the imaging menu.

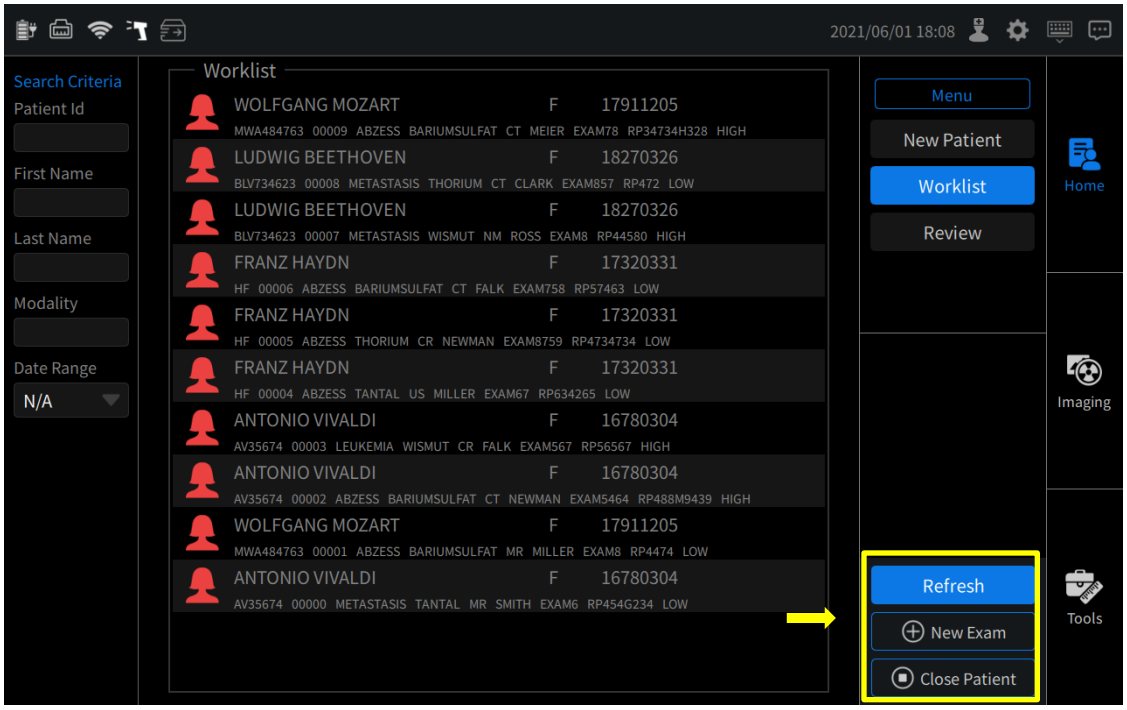


Figure5. 46 Action items of the worklist.

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

5.3.3 Review

The last menu item on the Home workspace is the Review menu item (Figure 5.47). This function allows the user to choose an existing patient from the patient list and then choose from several action items. 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.

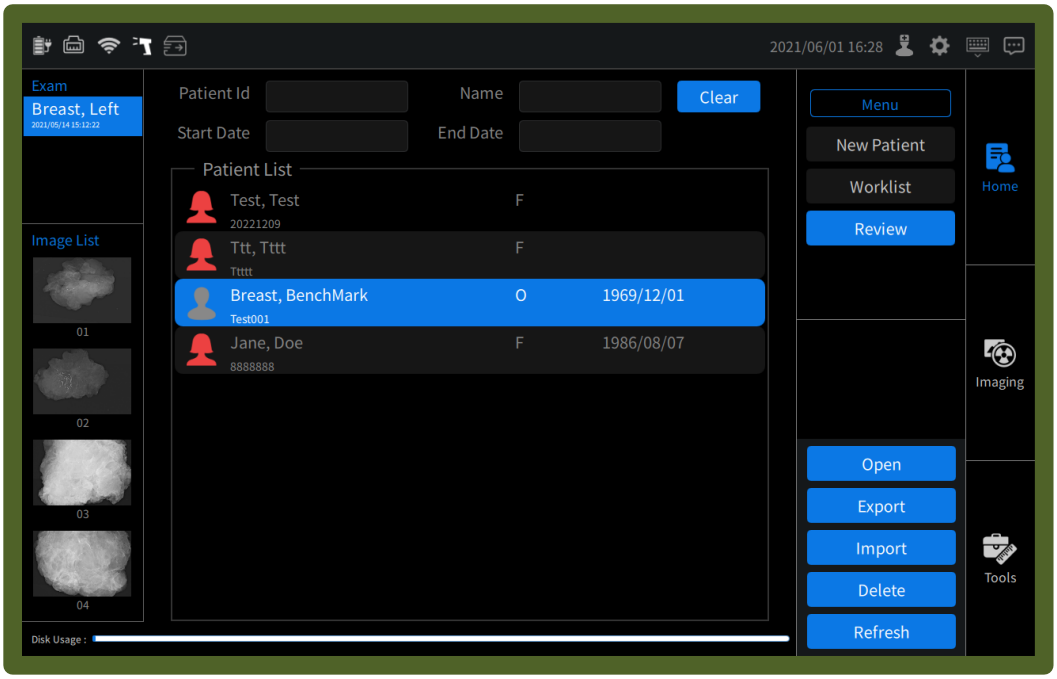


Figure5. 47 The Review menu item of the Home workspace for the ADM user.

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 5.48).

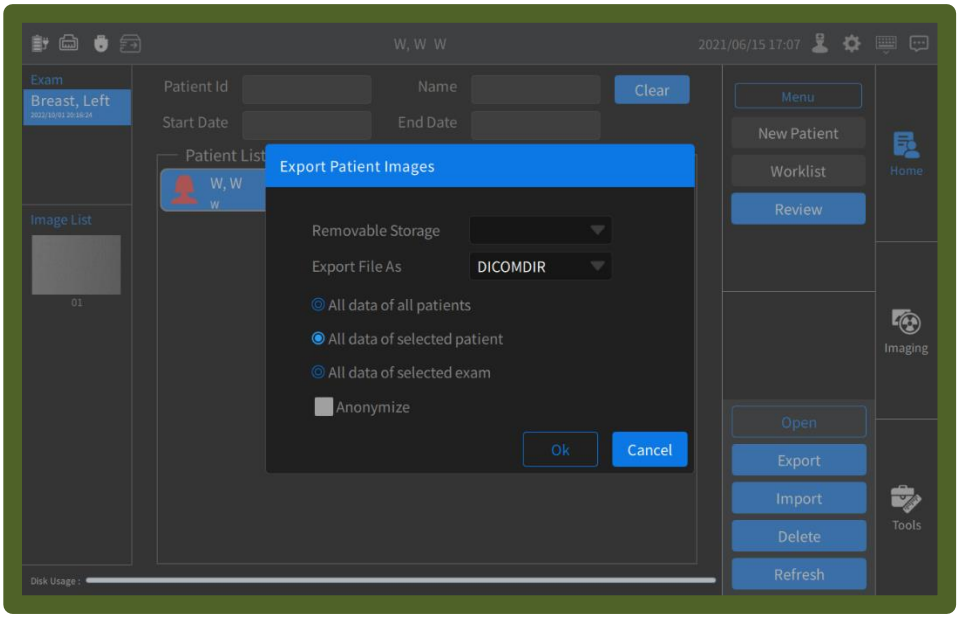


Figure5. 48 Export patient in the Review menu item on the home workspace.

(Only accessible to the ***ADM*** user)

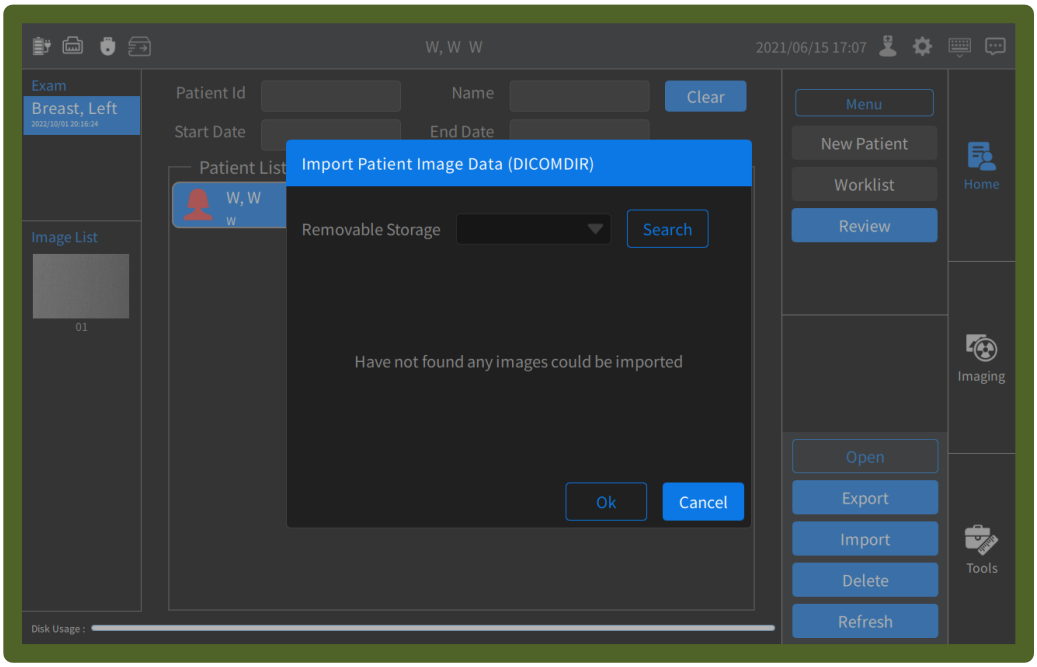


Figure5. 49 Import patient image data from the review menu of the home workspace (only accessible to the ***ADM*** user).

The “Import” action item allows the ***ADM*** user to import patient image data from a removable storage device (Figure 5.49).

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

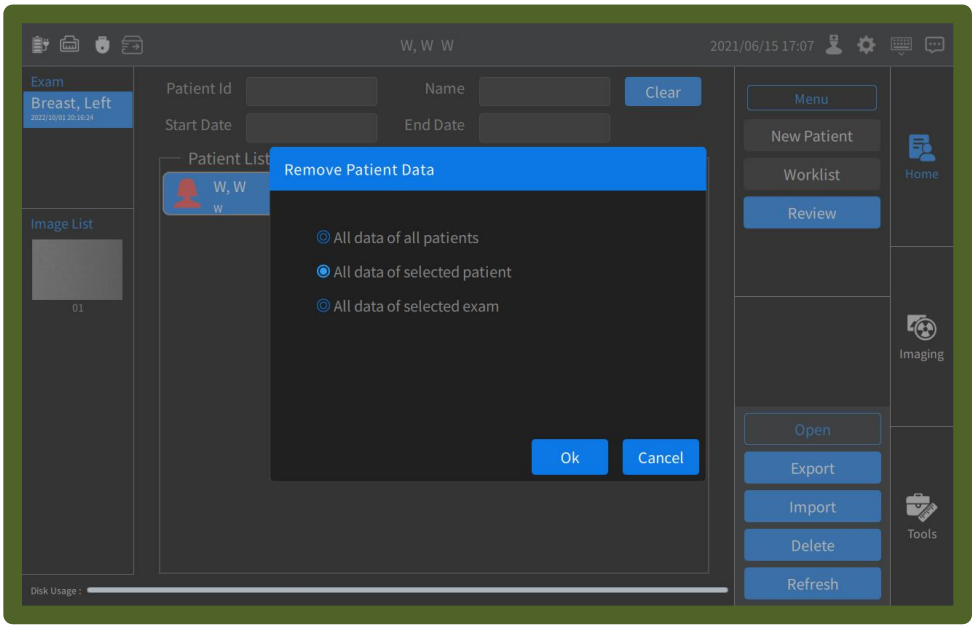


Figure5.50 The Delete action item of the Review menu on the Home workspace.

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 5.51 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 parameters come from the Exposure menu of the Utilities workspace (5.2.3 Exposure Settings); However, the user can change the exposure settings 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 to have 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 parameter 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 the user to confirm before imaging the specimen, select the “Ok” button in the confirmation window to proceed with imaging (Figure 5.52).

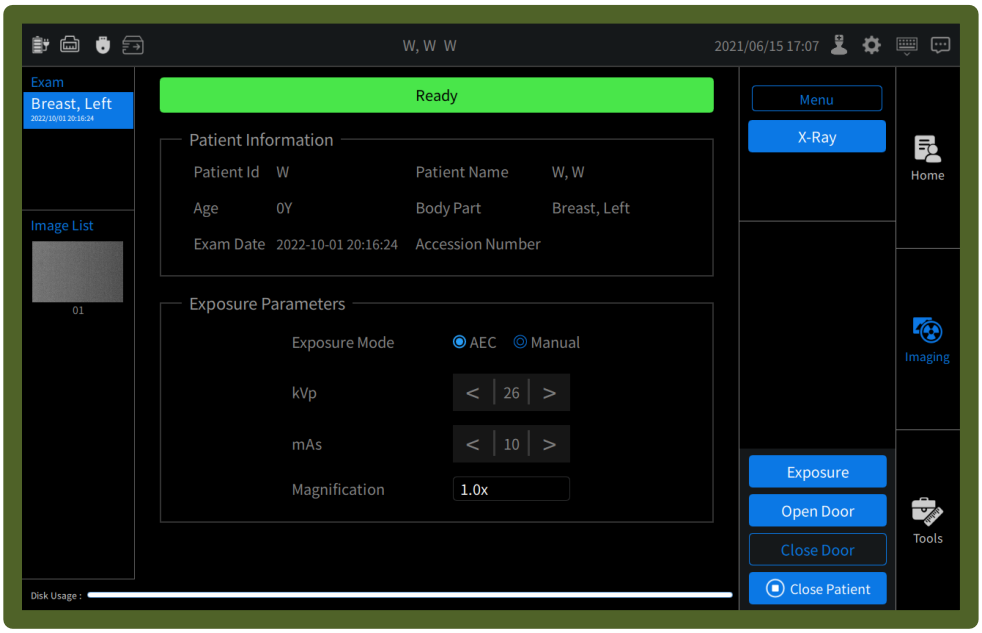


Figure5. 51 The open patient information, the exposure parameters, the exam type, and the current image list in the workplace.

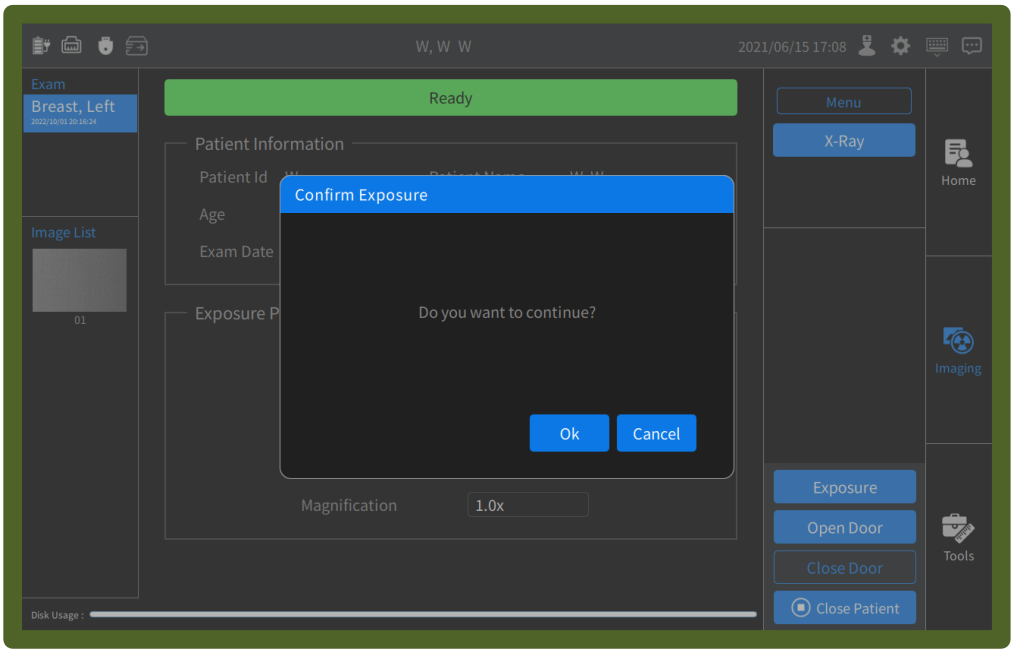


Figure5. 52 Exposure confirmation on the Imaging workspace.

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 5.53). Wait several seconds for the system to capture the X-ray image, or select the “Cancel” button to stop the imaging if needed.

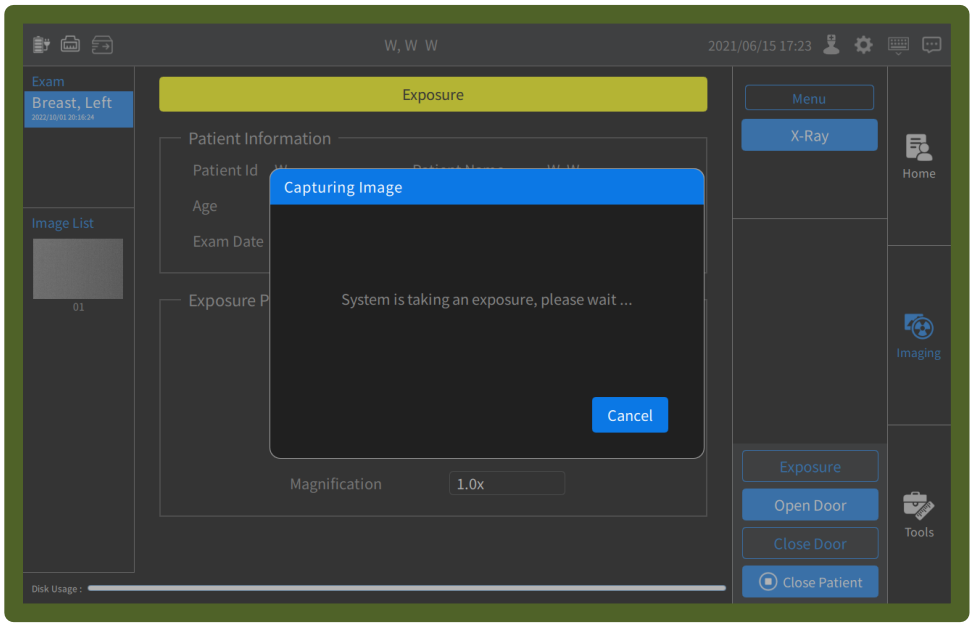


Figure5. 53 The system is capturing an image screen. If there is a need to stop the imaging before it is completed, select the cancel button from the capturing image dialog box.

After the image acquisition is completed, the system will switch to the Tools workspace for image analysis. If you want to take another image, simply return to the Imaging workspace to continue imaging. The user may simply choose that patient, and if Auto PACS store has been enabled (see Figure5.31), then all images will be automatically sent to the DICOM server.

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 5.54) and the system monitor (seen with the blue border in Figure 5.54). 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 5.54 (in the single image configuration) displays the patient information, twenty selectable Image tools, a scrolling image list, and three functional icons (Print, PACS Store, and Delete Image).

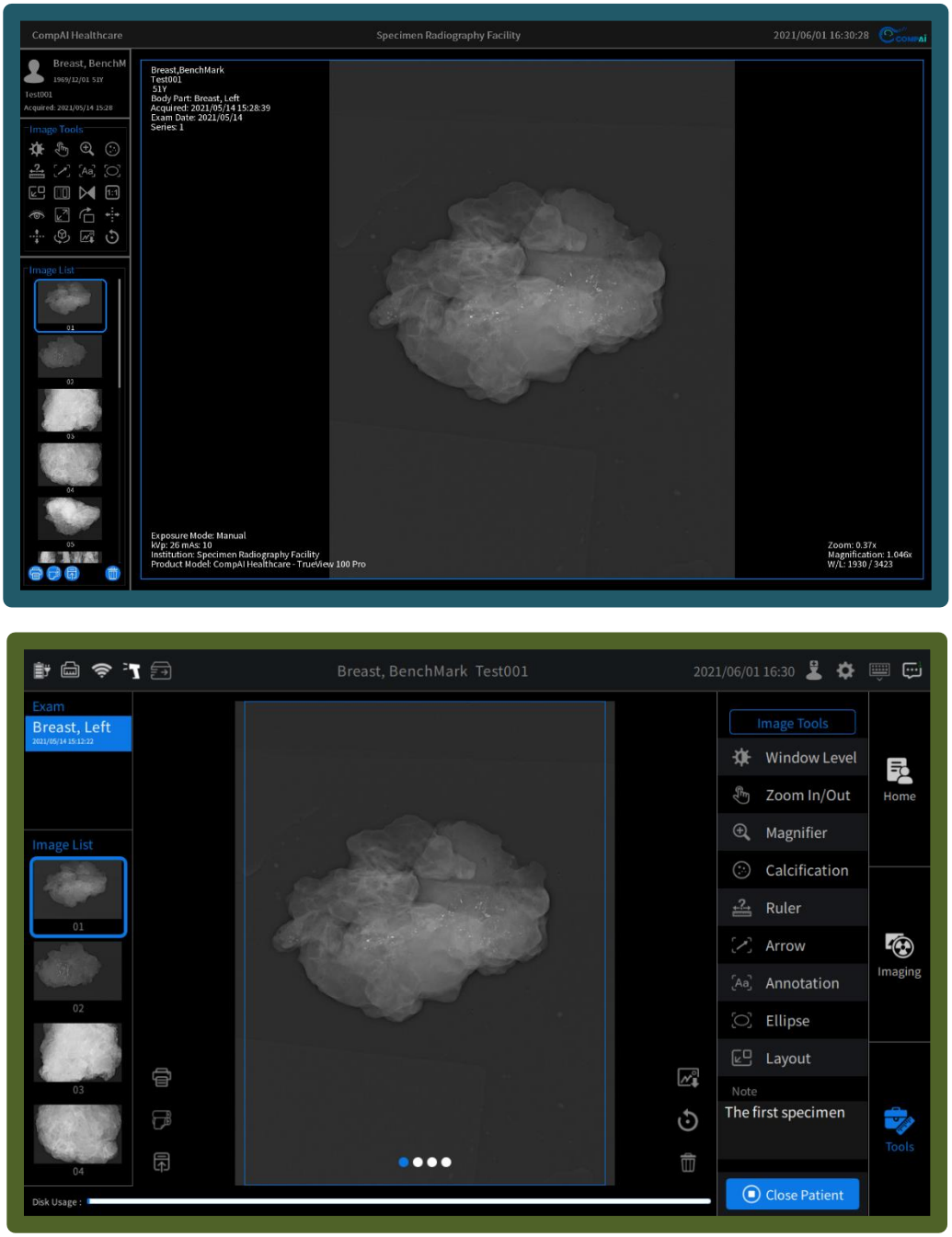


Figure5. 54 The system monitor in the single image configuration (blue border), and the touchscreen (green border) for the Tools workspace with an image selected from the Image list.

Figure 5.54 also shows the twenty image tools accessible from the scrolling image tools menu of the touchscreen, with five 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. As the same functionality of the image list is found on the image list of the touchscreen, 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 5.55 shows the user interface in the touchscreen when the Window Level tool is 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.

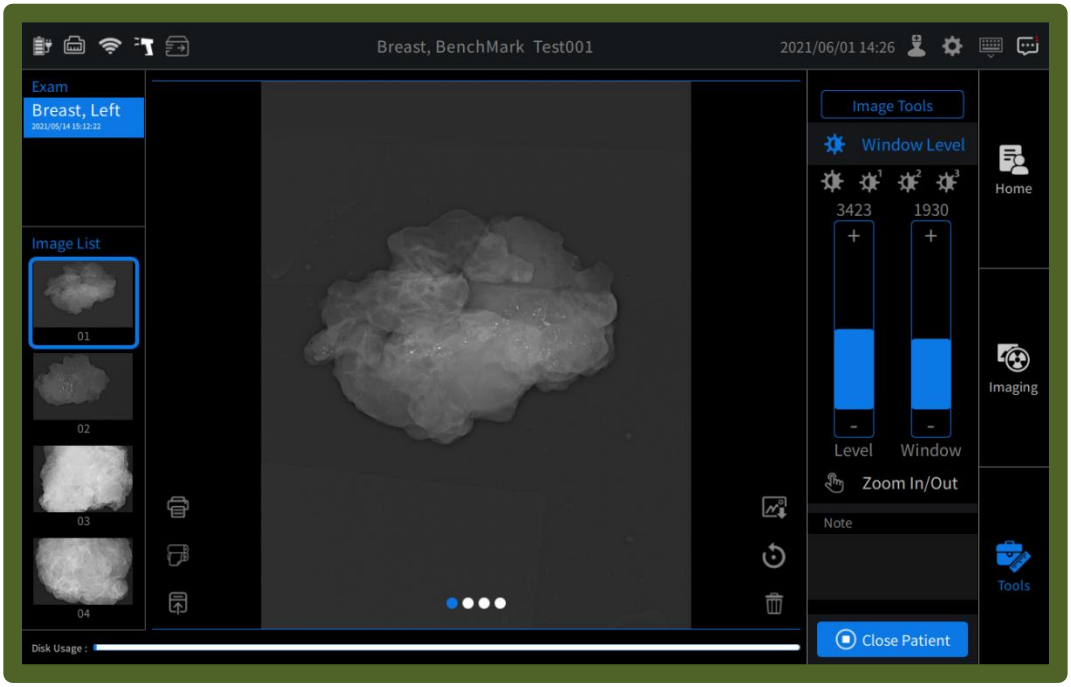
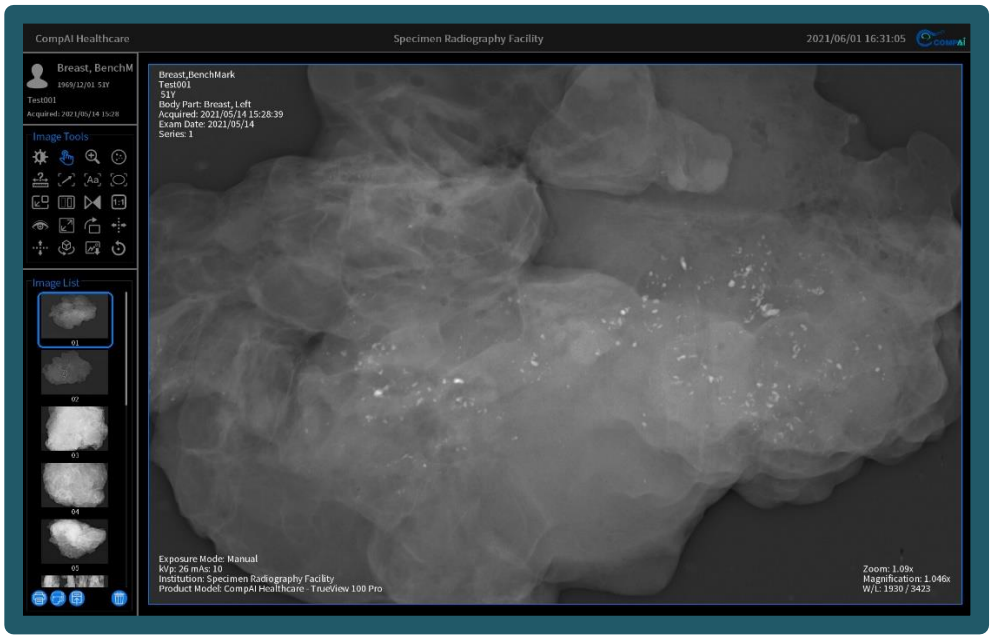


Figure5. 55 Window Level tool interface on the touchscreen of the Tools workspace.

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 individually 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.



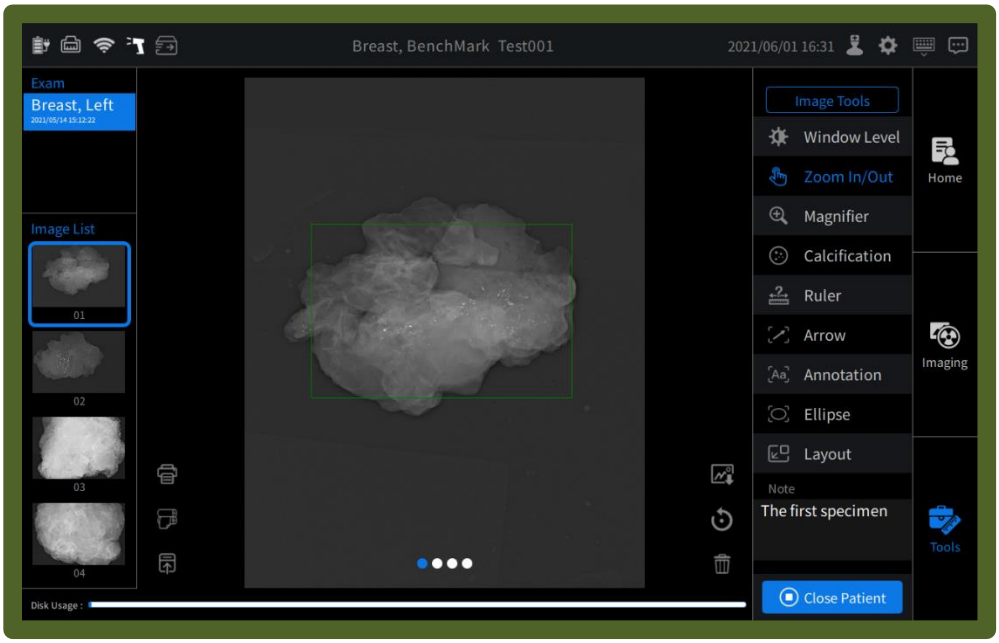


Figure5. 56 The selected image on the system monitor and touchscreen when expanding two fingers to zoom in the image

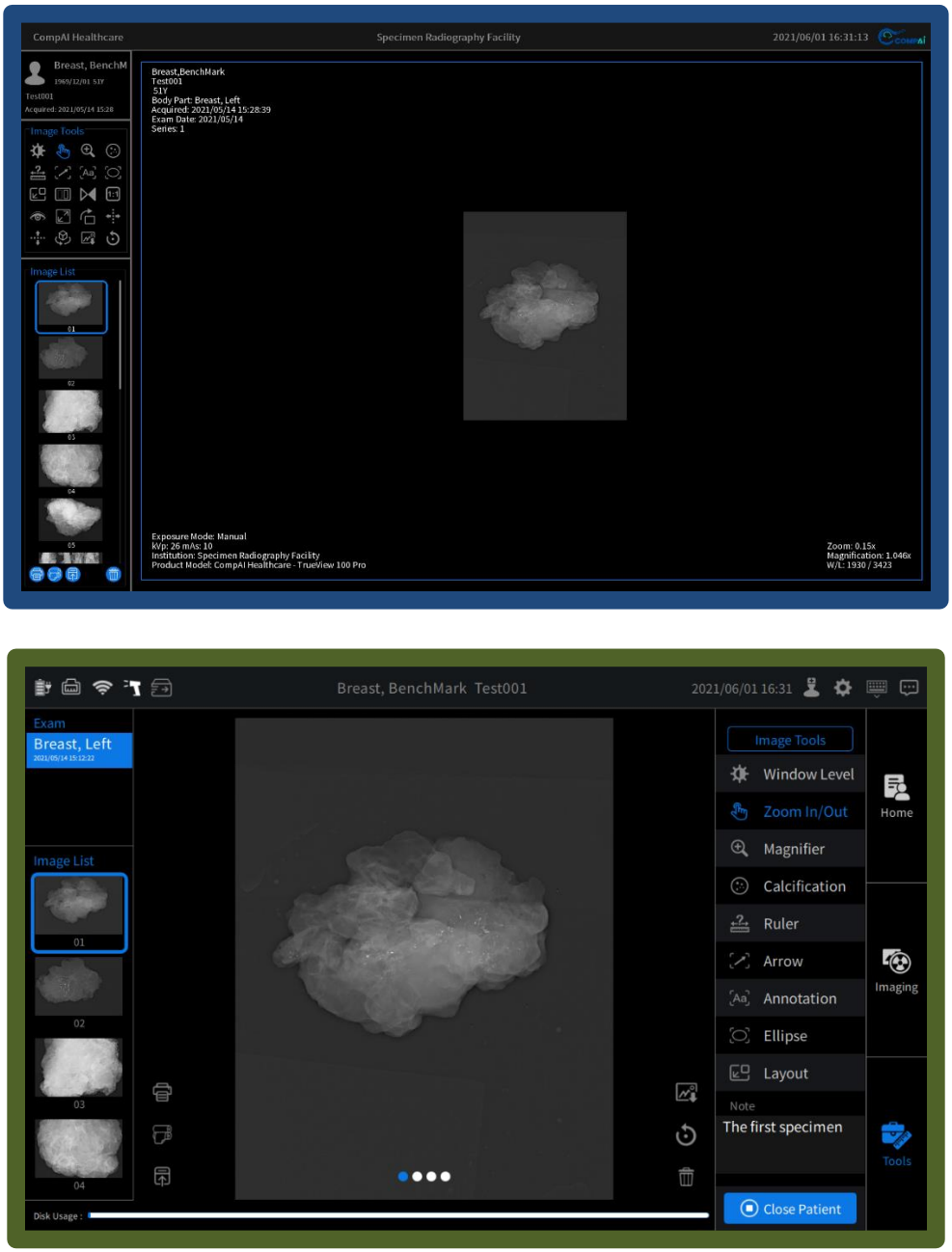


Figure 5. 57 The selected image on the system monitor and touchscreen when pinching two fingers to zoom out the image.

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.

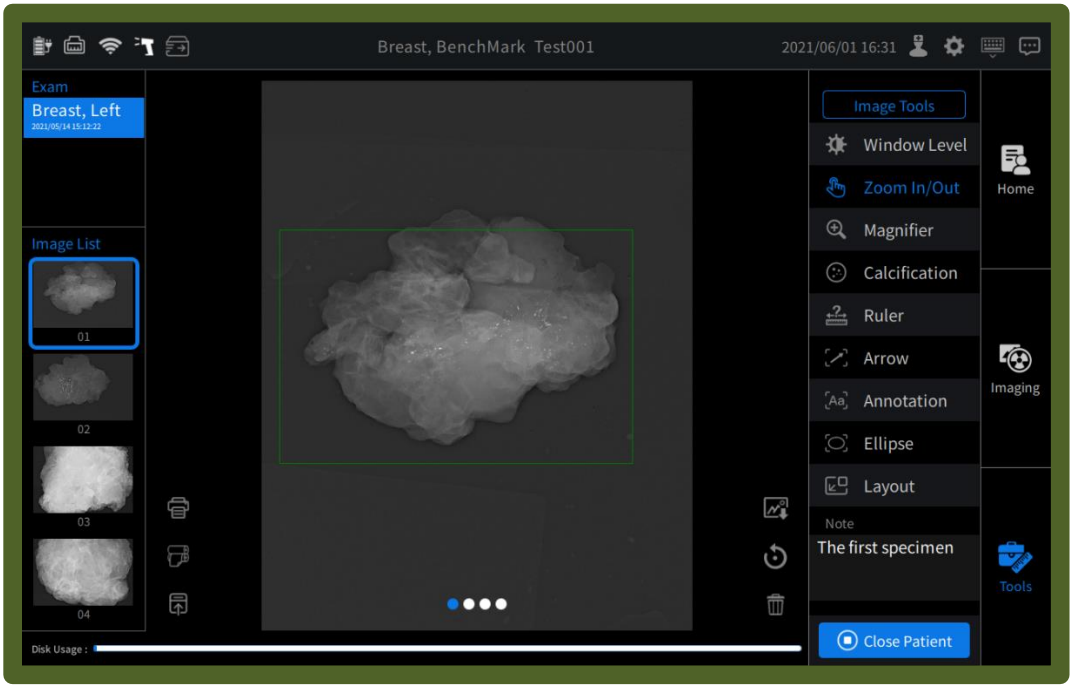


Figure 5. 58 The blue square turns green and it can be dragged around

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 5.59 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.

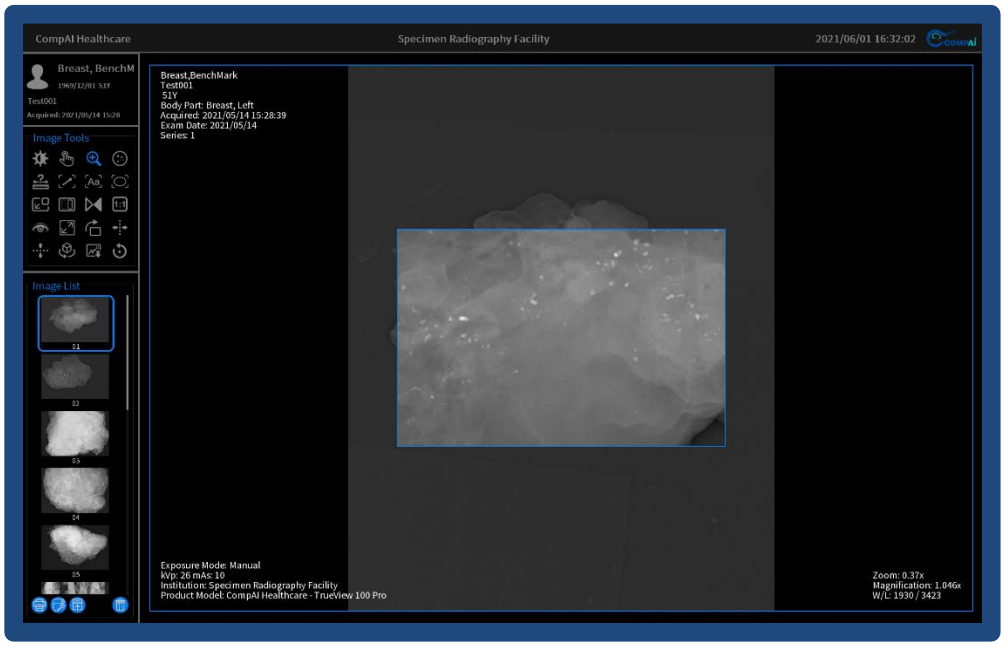


Figure5. 59 Magnifier tool interface on the system monitor.

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, its function is only available on the system monitor. This tool will identify likely calcifications in the specimen image by drawing a clearly visible red box around the suspected calcification. The calcification indicators will remain visible while the tool is enabled and can be used in conjunction with other image tools. The user can select the Calcification button to toggle the functionality on or off.

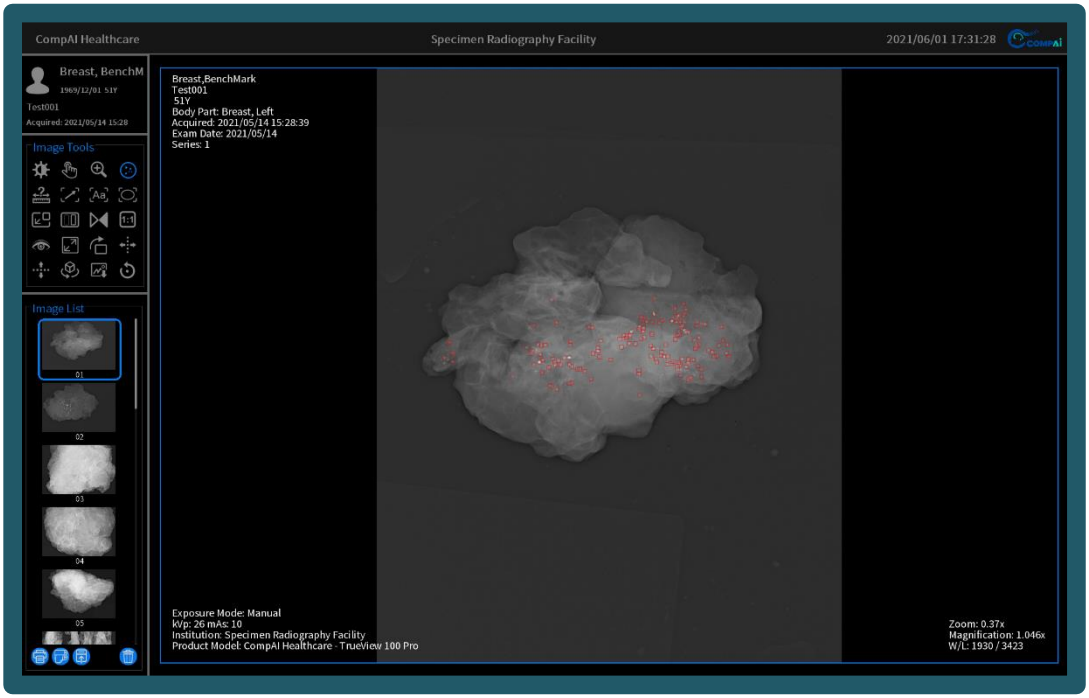


Figure5. 60 Calcification tool interface on the system monitor.

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, 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.

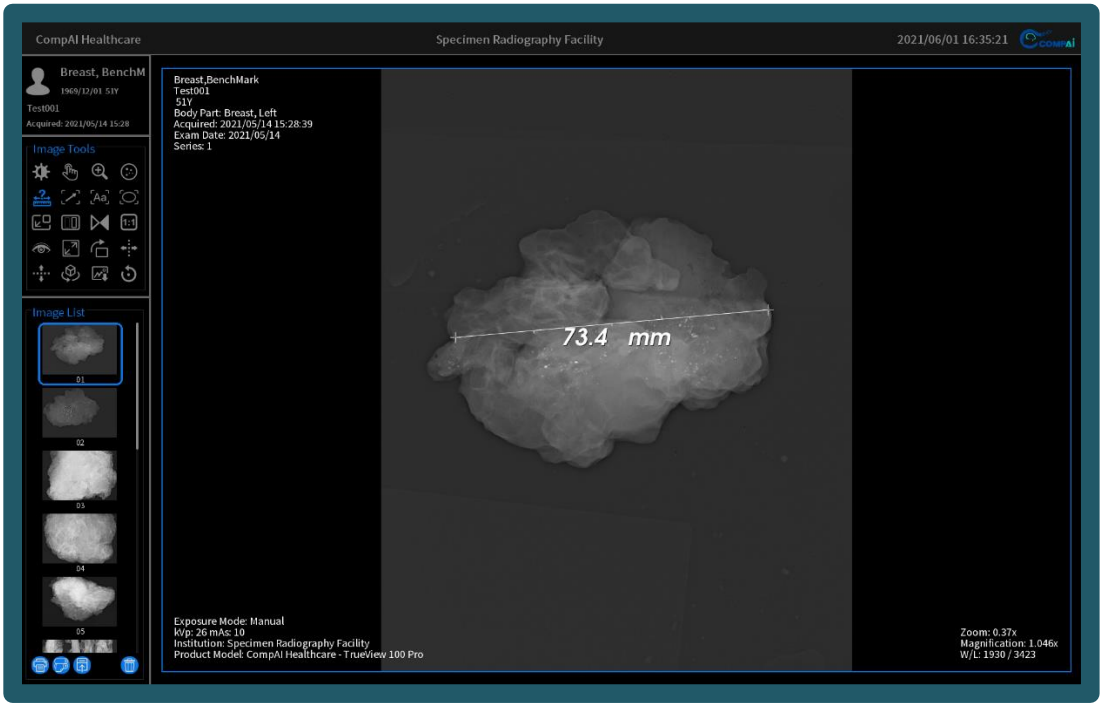


Figure5. 61 Ruler tool interface on the system monitor.

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.

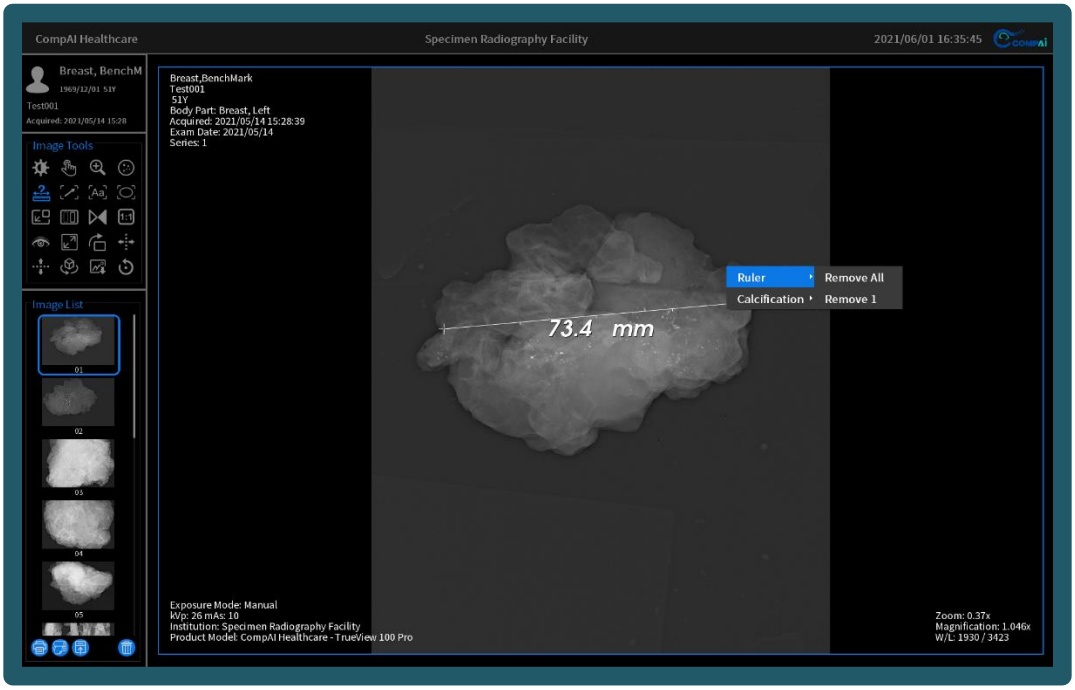


Figure5. 62 Remove option interface on the system monitor.

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.

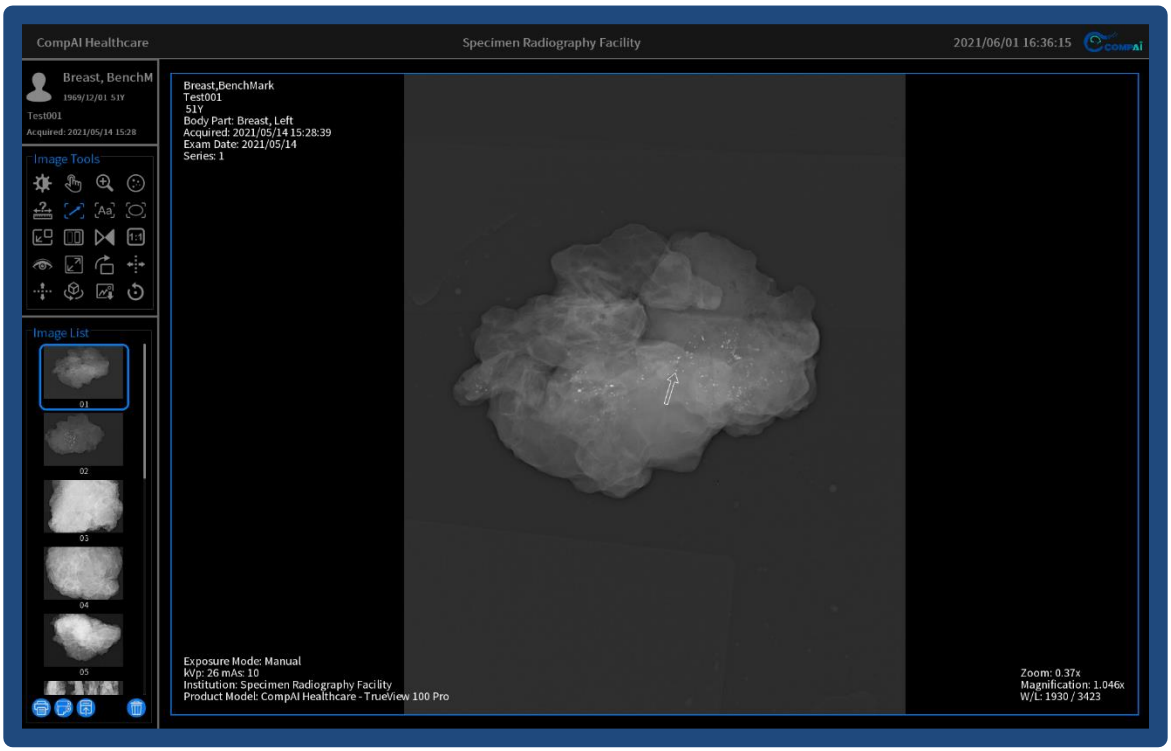


Figure5. 63 Arrow tool interface on the system monitor in the two-image display layout.

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 the options or one single option (similar to Figure 5.62 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 display 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 image 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 5.62 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.

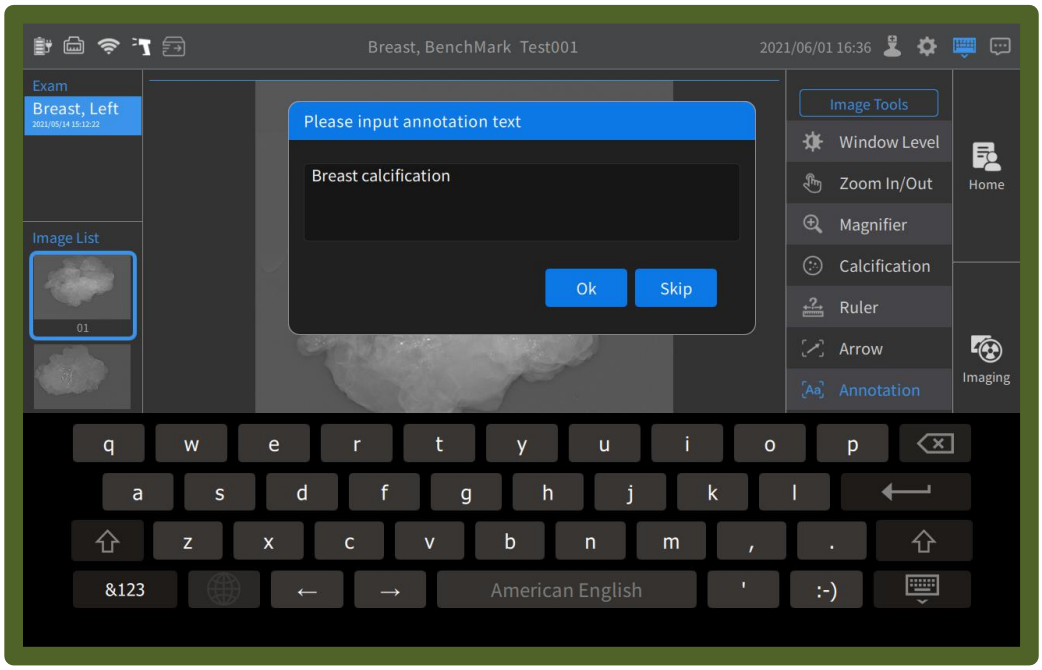


Figure5. 64 Annotation tool interface on the touchscreen of the Tools workspace.

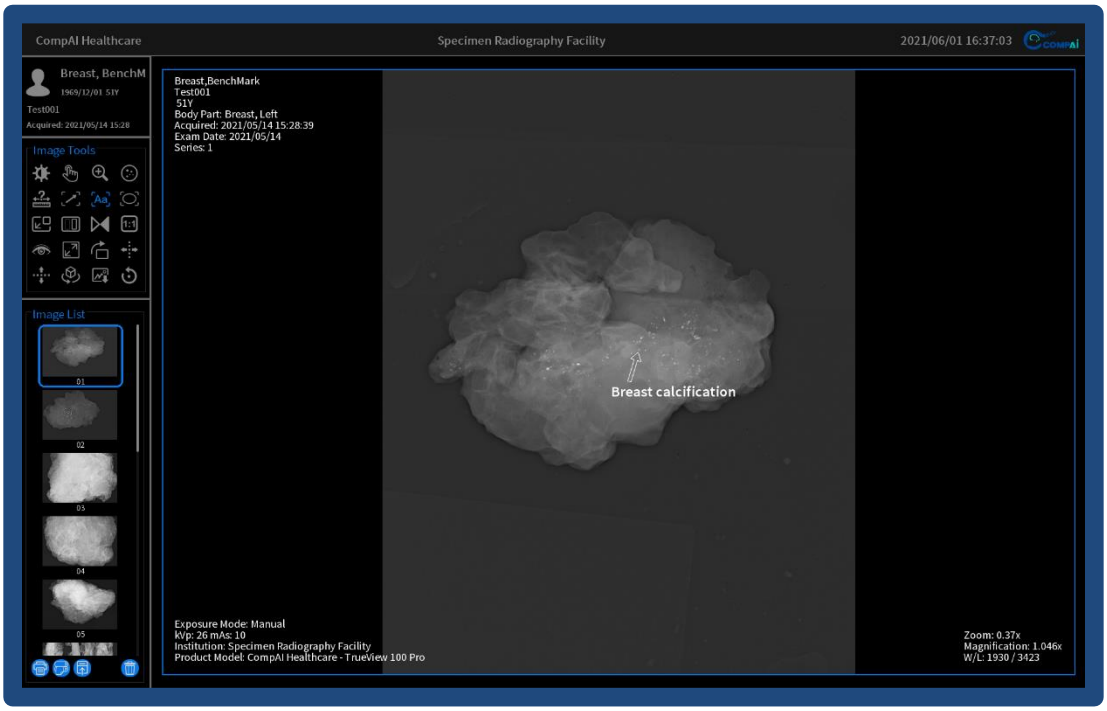


Figure5. 65 Annotation interface on the system monitor.

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.

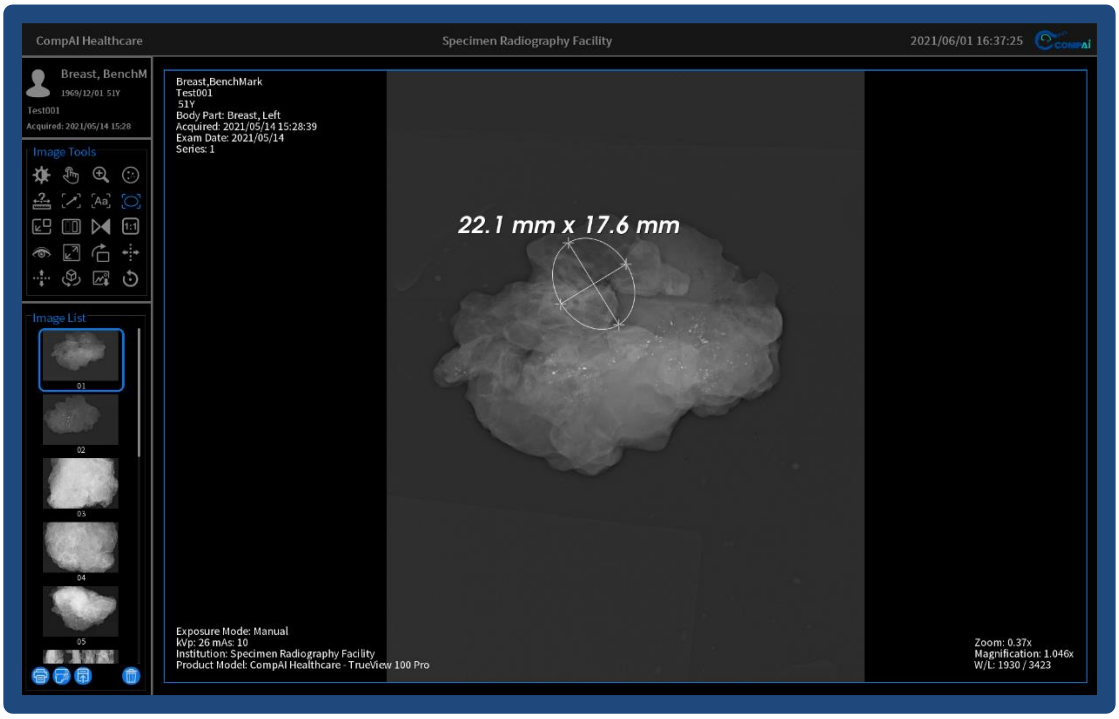


Figure5. 66 Ellipse interface on the system monitor.

The ellipse can be edited, rotated, and moved by using the touchpad. To change an axis length, hover 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.

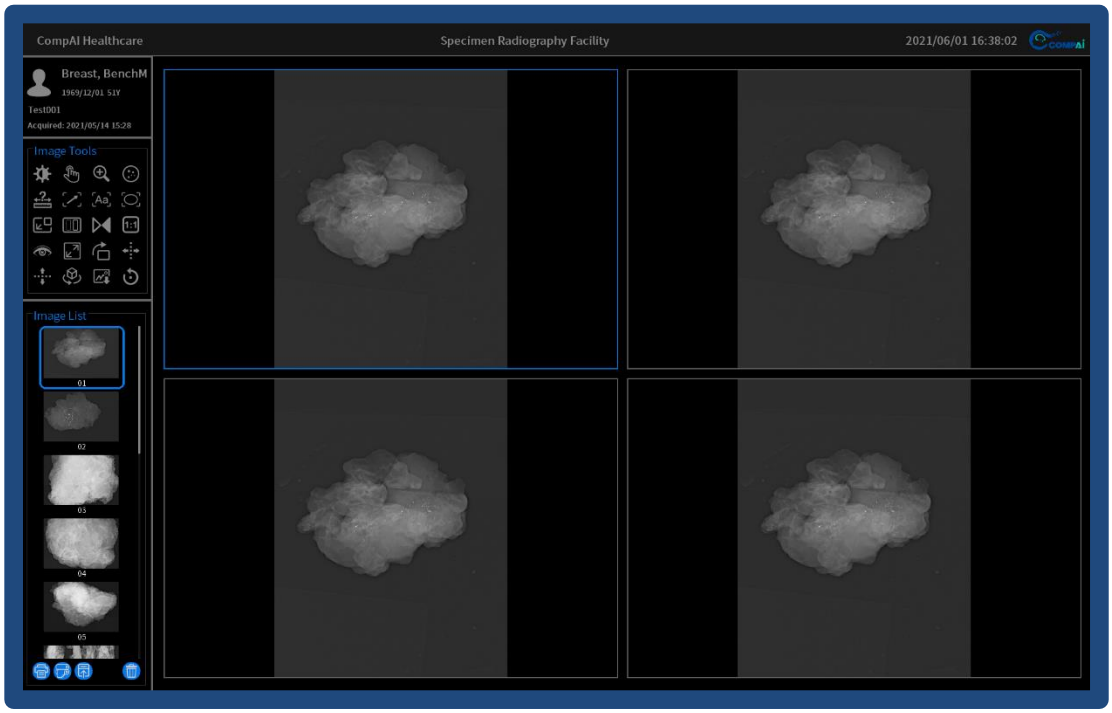


Figure5. 67 Layout interface on the system monitor in the four-image display layout.

5.5.10 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.

5.5.11 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.

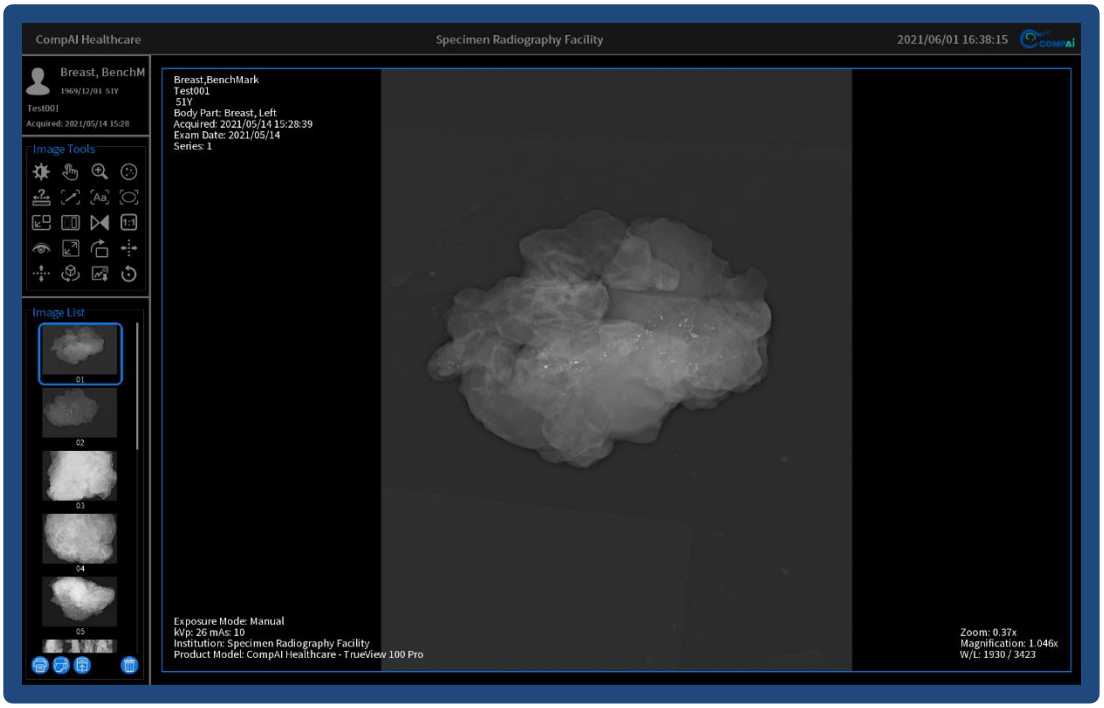


Figure5. 68 Show Info interface on the system monitor.

5.5.12 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.

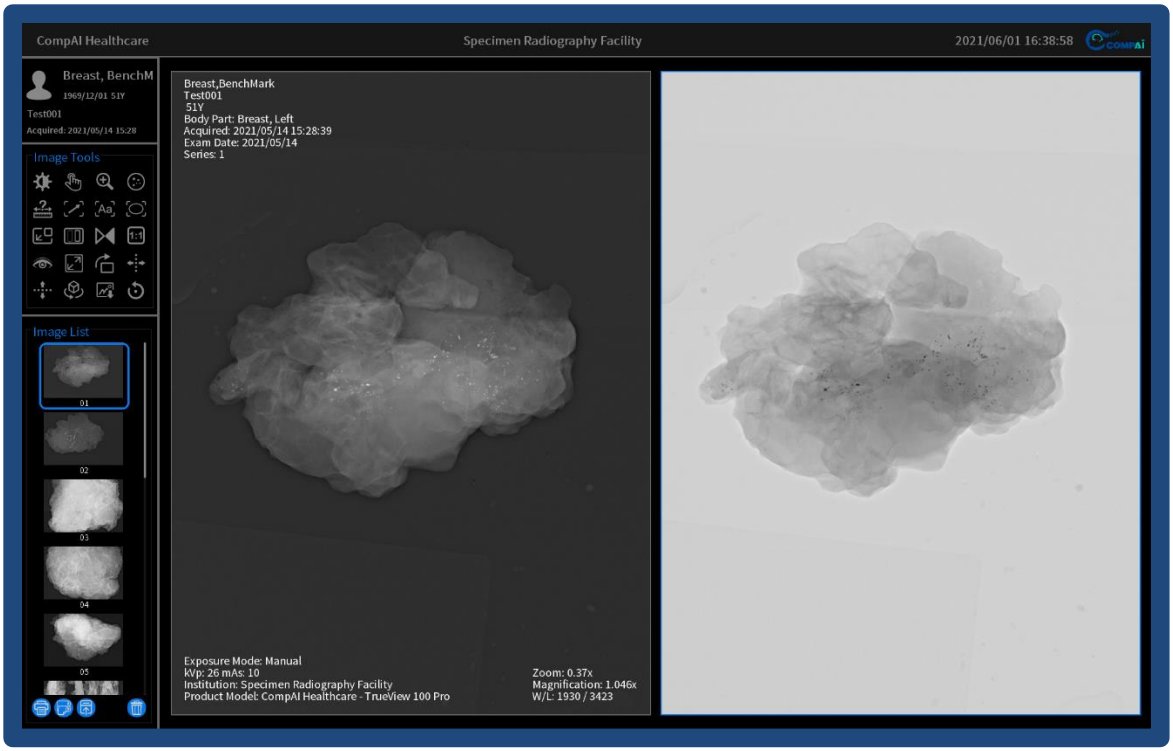


Figure5. 69 Invert interface on the system monitor in the two-image display layout.

5.5.13 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.

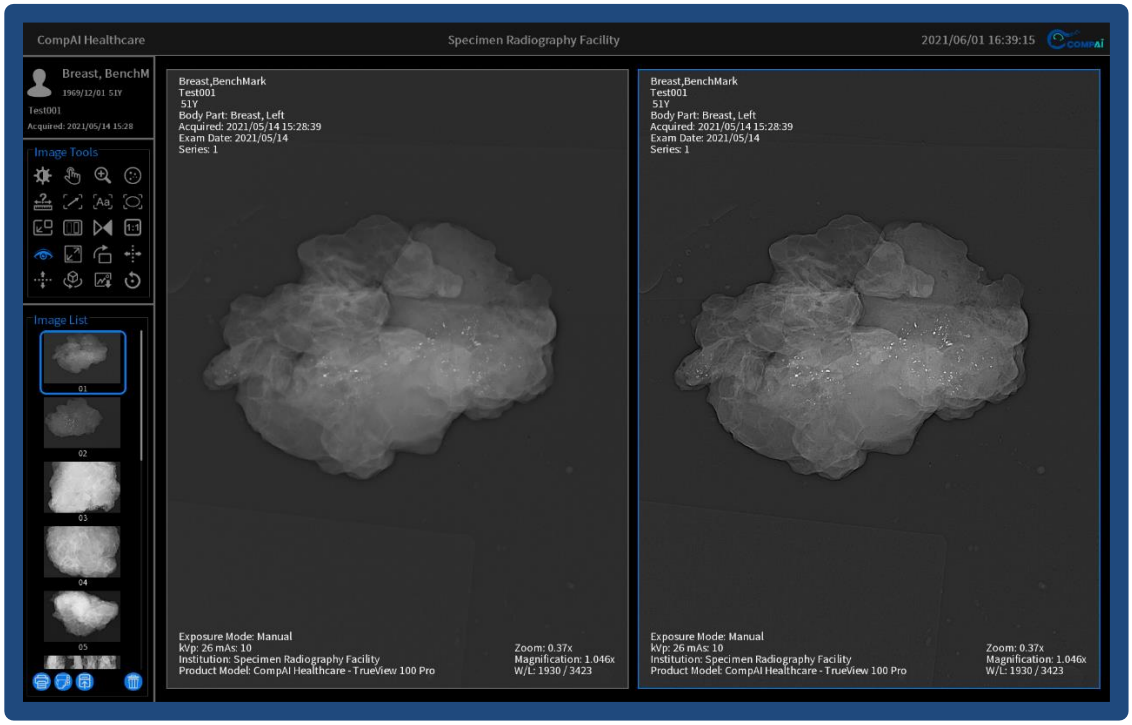


Figure5. 70 Sharpen tool interface on the system monitor in the two-image display layout.

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.

5.5.14 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.

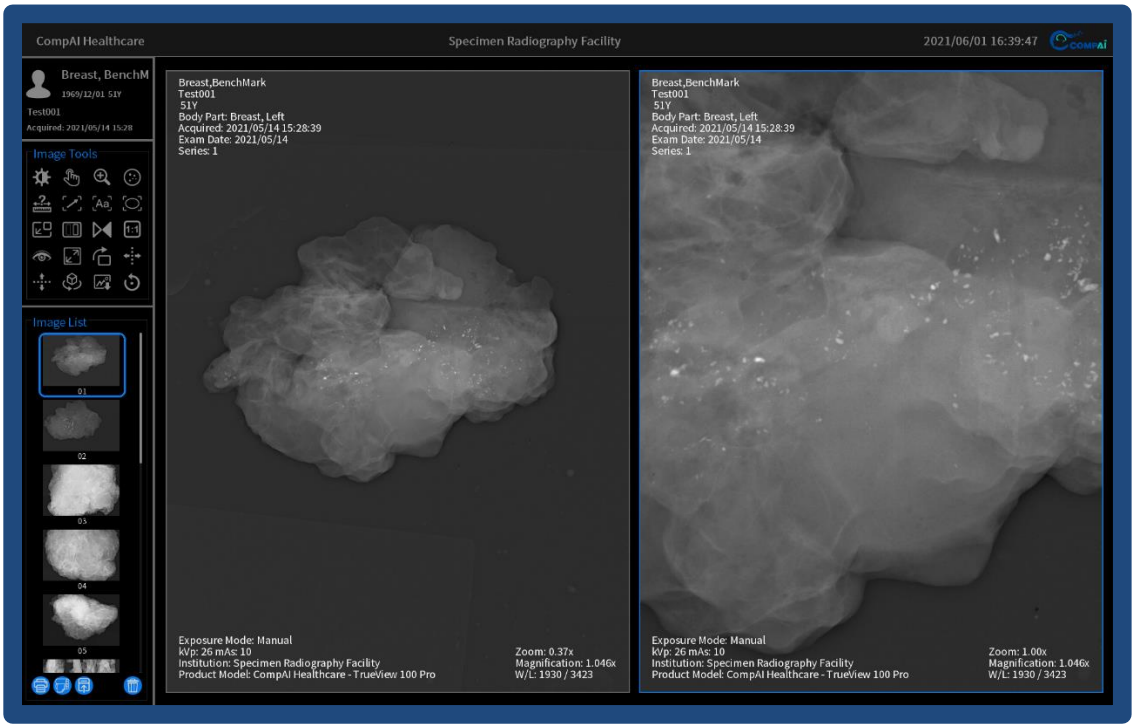


Figure5. 71 Fit to Image interface on the system monitor in the two-image display layout.

5.5.15 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.

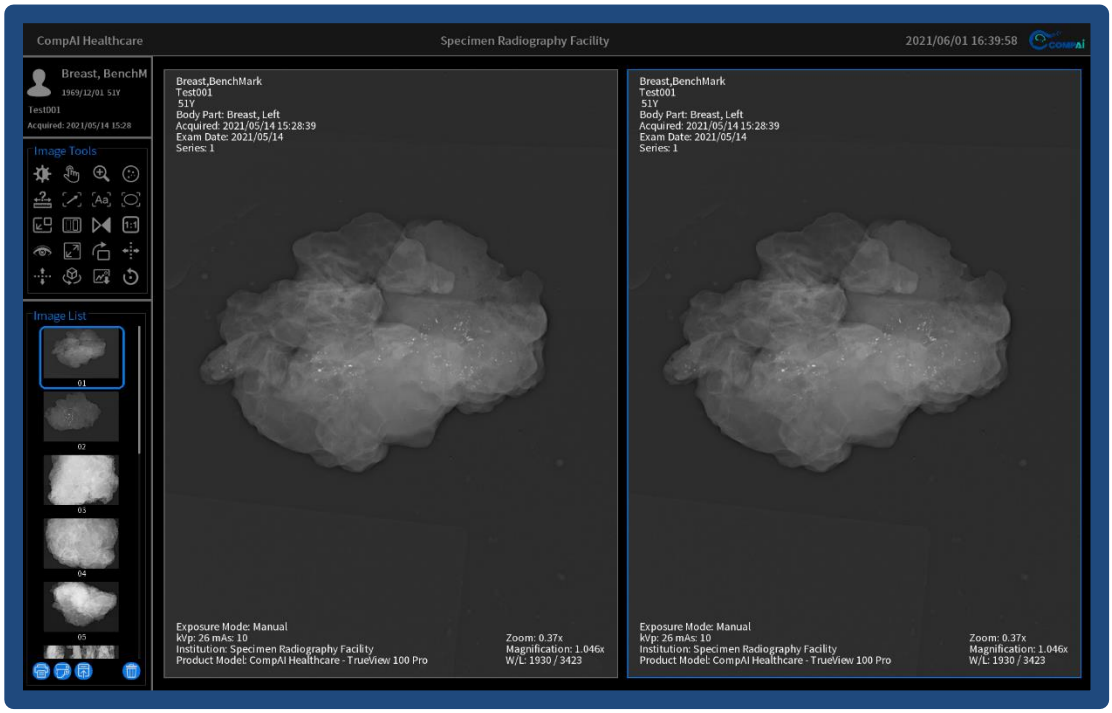


Figure5. 72 Fit to Window interface on the system monitor in the two-image display layout.

5.5.16 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.

5.5.17 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.

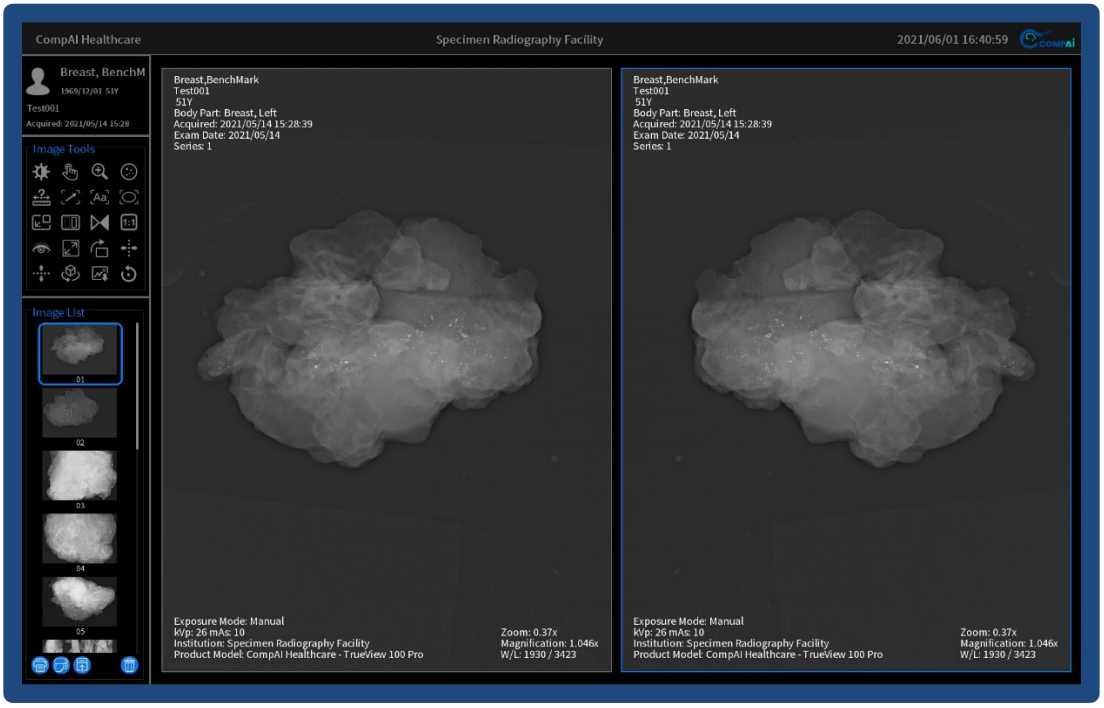


Figure5. 73 Mirror interface on the system monitor in the two-image display layout.

5.5.18 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 horizontal axis (i.e. top to bottom). Any previous annotations, measurements, and identified calcifications will display properly in conjunction with this tool.

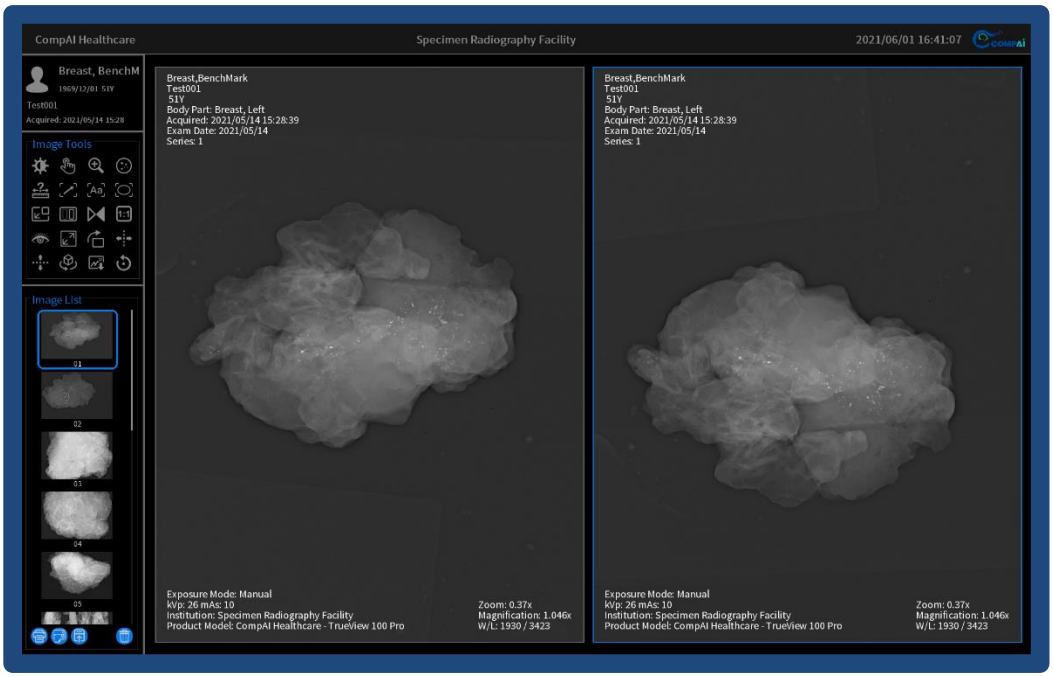


Figure5. 74 Flip interface on the system monitor in the two-image display layout.

5.5.19 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, press and hold on the touchpad to rotate 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.

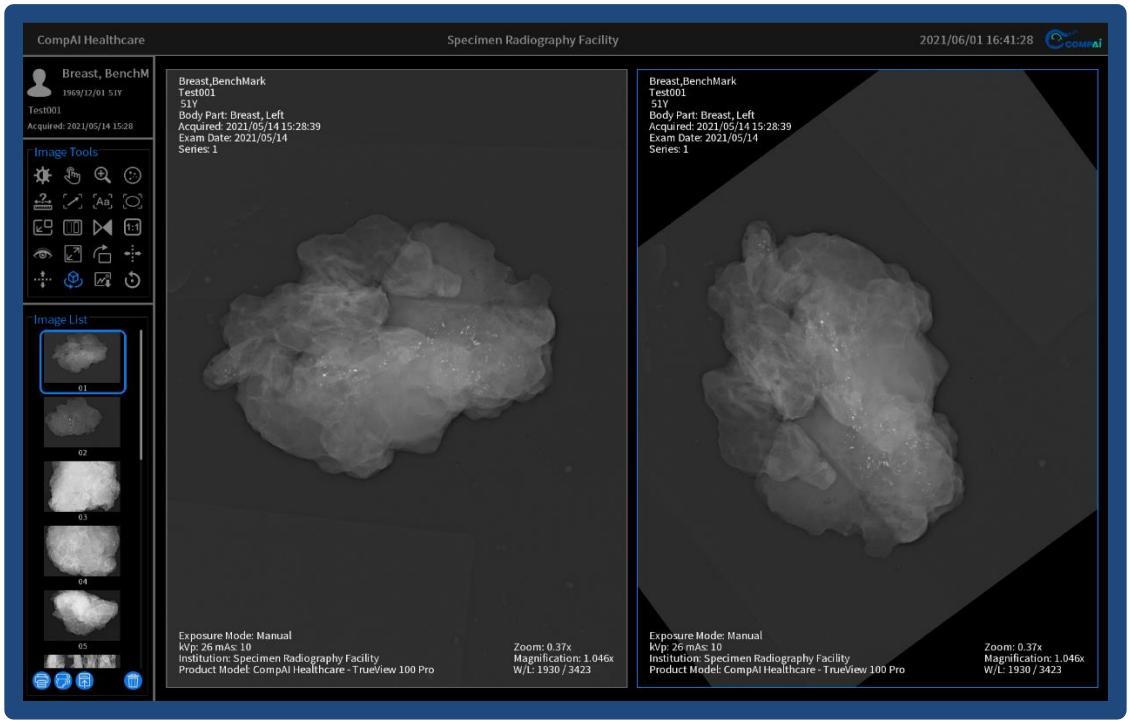


Figure5. 75 Free rotate interface on the system monitor in the two-image display layout.

5.5.20 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.

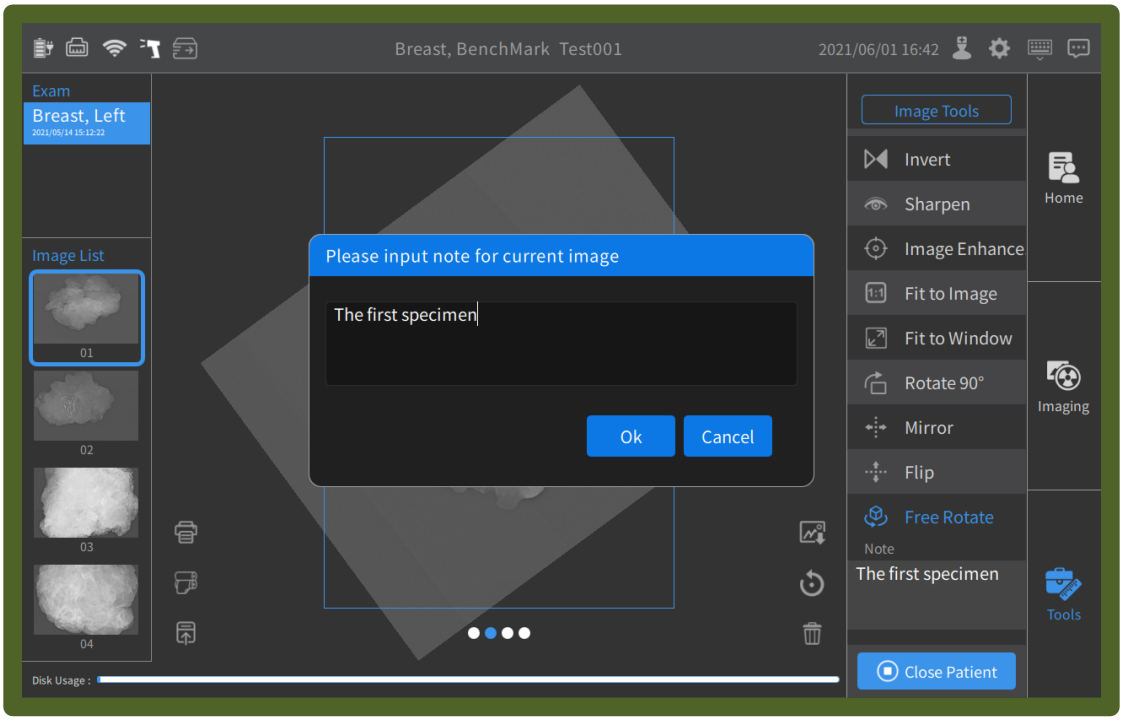


Figure5. 76 Image note tool interface on the touchscreen of the Tools workspace.

5.5.21 Functional Icons of the Touchscreen

The functional icons of the touchscreen are 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 touchscreen.

5.5.22.1 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. Local printing means to select the local printer that has been added successfully to print on A4 paper, as shown in Figure 5.77 below.

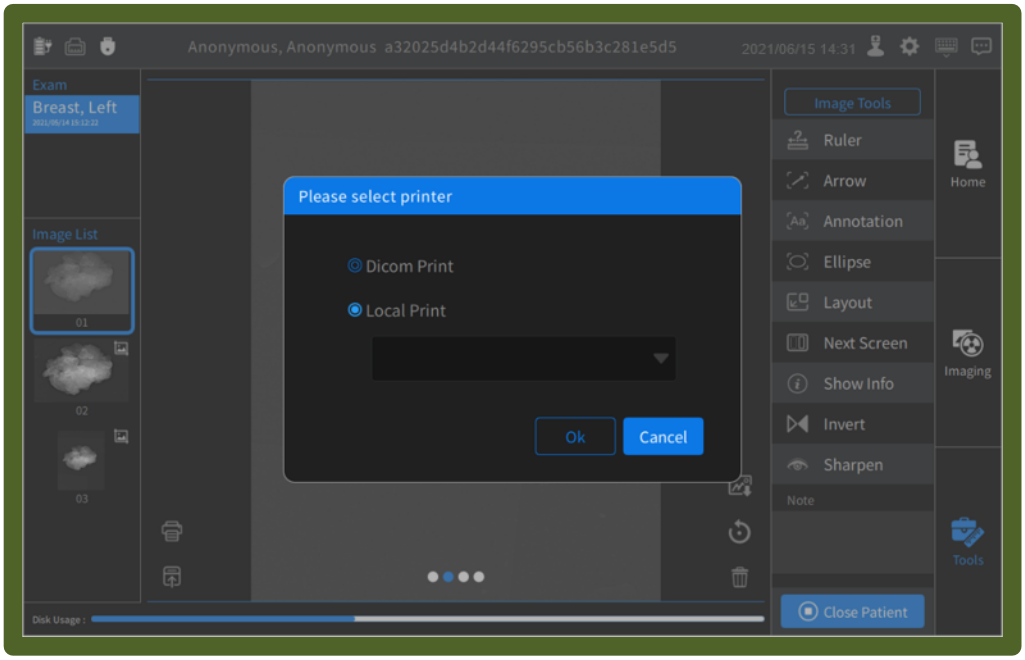


Figure5. 77 Select print mode

5.5.22.2 PACS Store

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

5.5.22.3 Save Image

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

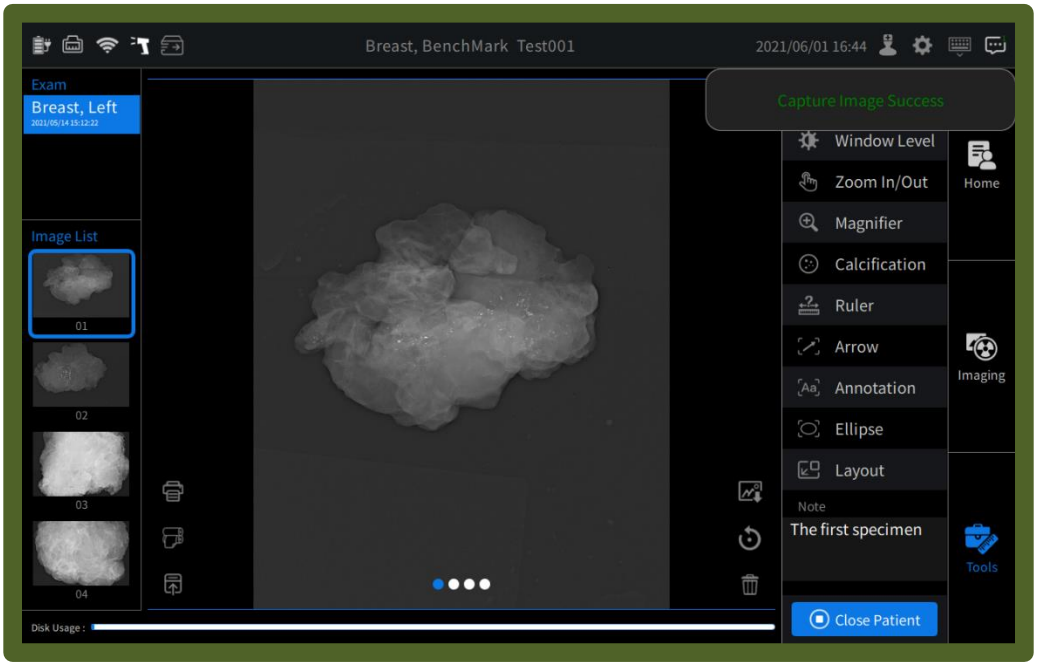


Figure5. 78 Save active window as image.

5.5.22.4 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 5.5.22.3)

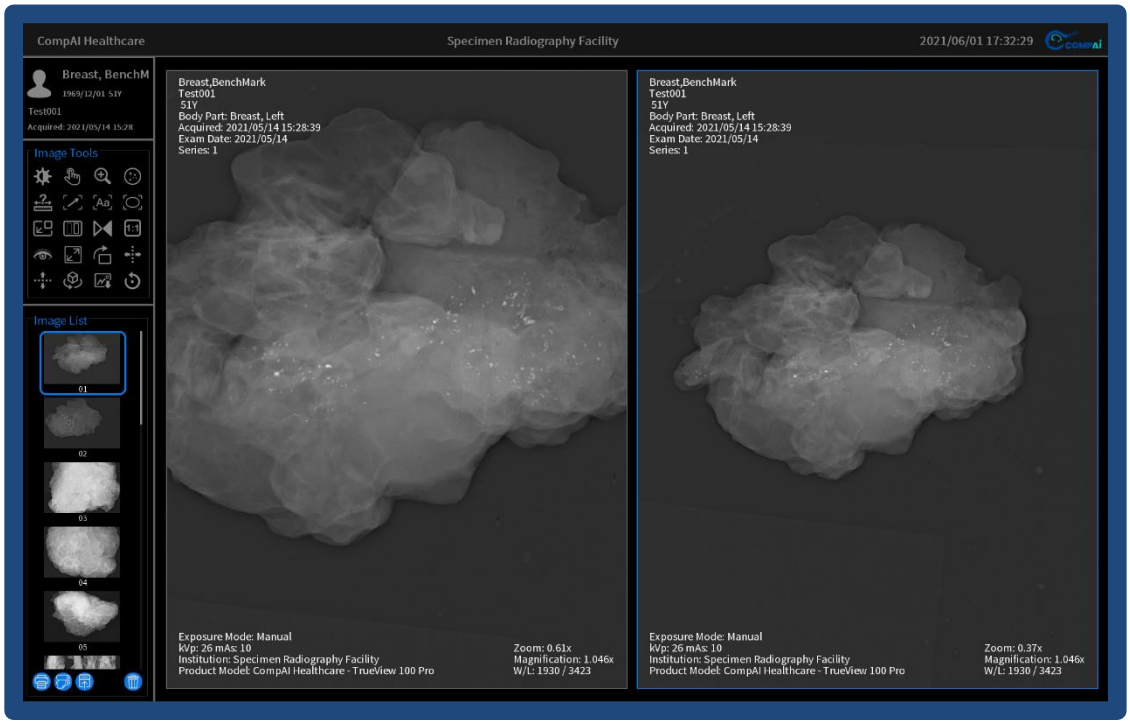


Figure5. 79 Reset image in active window.

5.5.22.5 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 .

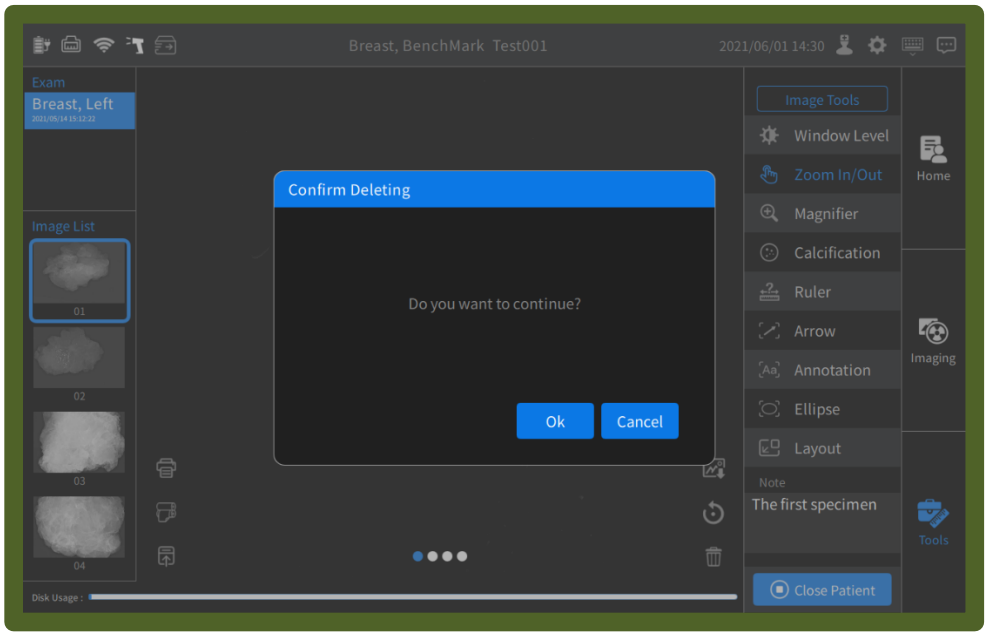


Figure5. 80 Confirm deleting image in active window

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 the 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 Effective Use.

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 includes 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 their connecting devices 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 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 Make the new fuse lay flat in the drawer.

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

Figure 6. 4 Closed the drawer

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

6.1.6 Charging the battery

To charge the UPS, plug the power plug into the socket. The first button of the information display bar represents the status of UPS, display icon  for charging, display icon  for charging completed, display icon  indicates that the battery is discharging. Click the charging icon to check the battery status of UPS and its current power, as shown in Figure 6.5, when the power is lower than the rated value, the system will give a prompt to user. when the power is too low, the system will shut down automatically. ***Note: The UPS is automatically charging after startup.***

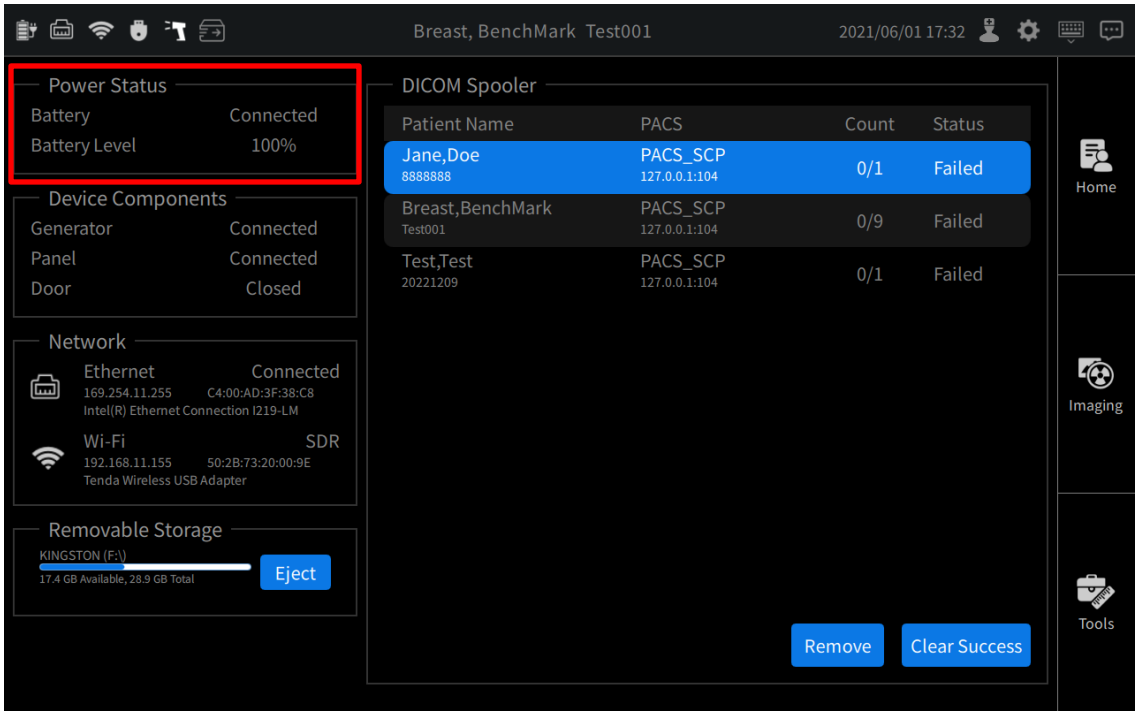


Figure 6. 5 Charging the battery

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

Before 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 system monitor, 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 control panel, 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.

7. Appendix I Technical Specifications

The system technical specifications are as follows:

Digital Image Receptor Specifications	Value	Units
Active Imaging Area Size	11.4×14.6	cm
Pixel Size	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)	127	μm

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

Power Conditions:	Value	Units
Input Voltage	110±10%	VAC
Input Power	500	Wat
Frequency	50/60	Hz

Environment Conditions:	Value	
Operation:		
Temperature:	+10℃– +40℃；	
Humidity:	30% – 80%；	
Atmospheric pressure	70 kPa – 106kPa	
Storage and transport:		
Temperature	-10℃– +60℃；	
Humidity	10% – 90%；	

Atmospheric pressure	70 kPa – 106kPa	

Physical Specifications	Value	Units
Dimensions	≤60×72×162	cm
Weight	168	kg
Monitor	24.1	inch

System Performance Specifications	Description
Time to Preview	<20 seconds of AEC mode
Spatial Resolution	>7lp/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.

8. 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	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 55011:2009+A1:2010**	Pass
Radiated emission	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 55011: 2009+A1:2010**	Pass
Harmonic of current	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-3-2: 2006+A1:2009+A2:200**	Pass
Flicker	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-3-3: 2008**	Pass
ESD immunity	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-4-2:2009**	Pass
Radiated EM field immunity	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-4-3:2006 +A1:2008+A2:2010**	Pass
EFT immunity	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-4-4:2004 +A1:2010**	Pass
Surge immunity	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-4-5:2006**	Pass
Inject current immunity	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-4-6: 2009**	Pass
Power frequency magnetic field immunity	**EN 61326-1: 2013, EN 61326-2-6 Reference: EN 61000-4-8:2010**	Pass
Voltage dips and interruption	**EN 61326-1: 2013, EN 61326-2-6**	Pass

immunity	**Reference: EN 61000-4-11: 2004**	

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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