User Manual

For

Pulmonary CT Imaging Auxiliary Diagnosis Software

File No.: YZ-GC-010-B0（03）

Beijing Yizhun Medical AI Technology Co. ,Ltd.

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Any user must read this manual before using the products of our company. This manual exposes the operating steps that must be read carefully. Improper use might endanger equipment or persons. Our company will not undertake the responsibility for the safety, reliability and performance if equipment is used improperly. Our company will not offer complimentary service for misused equipment.

Our company has the right to revise any content in this manual without notice and has no obligation to update either hardware or software of the ventilator described herein to the user or owner.

Manufacturer's Responsibility

Our company is responsible for the security, reliability and functions of our product, only when the following requirements are strictly adhered to:

1) Only individuals authorized by our company may perform installation, adjustments and

repairs.

2) Necessary working environment must be in accordance with the national standards, professional standards and the requirements listed in this manual.

3) Equipment must be used as instructed in this manual.

Warning for use

Welcome to use our products!

In order to use this product correctly and effectively, please read these user manual carefully and completely before using the product for the first time.

User must fully understand and strictly comply with this manual in using this product.

This product is only for intended use as described in the operating instructions.

Only specially trained service professionals are authorized to perform the installation and

service of the product.

Any questions in using process, please contact with us. We will provide you with warm service.

Table of Contents

1. Specification

Product name：Pulmonary CT Imaging Auxiliary Diagnosis Software
Model：LCI ADS
Software version：V2

2. Overview

The lung CT image aided diagnosis software includes image examination, aided diagnosis tasks, user management, user group management .

3. Structure

The storage medium of this product is a CD, which is composed of a server and a client, including image loading module, image display module, aided diagnosis module and aided analysis module, etc.

4. Intended Use

The device is intended for image display, data measurement, data retrieval, automatic marking and intelligent analysis of lung nodule position of lung CT images under the DICOM3.0 standard protocol to assist clinical diagnosis.

5. Working Principle

The product is based on the DICOM3.0 standard medical image data provided by CT equipment, and uses deep learning technology to automatically detect lung nodules to assist doctors to improve the efficiency of image reading.

6. **Intended use environment**

The software is expected to be used in radiology departments of various hospitals and related departments that need to combine chest CT for clinical diagnosis.

7. Medical indication or condition

Pulmonary CT imaging auxiliary diagnosis software is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during the review of CT examinations of the chest on an asymptomatic population.Pulmonary CT imaging auxiliary diagnosis software requires that both lungs be in the field of view. Pulmonary CT imaging auxiliary diagnosis software provides adjunctive information and is not intended to be used without the original CT series.

8. **Contraindication**

This software processes CT image data and does not directly touch the human body, so there are no contraindications.

9. Intended users

Medical staff with professional knowledge who have undergone professional training related to this software before using this software.

10. Intended patients

Adult patients (age≥18 years old) who need and are suitable for chest CT scan.

11. **Intended clinical performance and expected clinical benefits**

Intended clinical performances of this product are listed in below;

Clinical performance	Requirements
Recall rate (nodule-based sensitivity)	The overall recall rate is no less than 90%.
Classification accuracy	Classification accuracy of nodule type is no less than 50%.
Mean measure deviation	Mean measure deviation (MAE) of nodule long diameter is no more than 1.5 mm.

The clinical benefits to be expected are:

- Detecting pulmonary nodules automatically with high accuracy
- Classify pulmonary nodules correctly
- Measure the size of pulmonary nodules correctly
- Assist the doctors to make diagnosis and improve doctor's ability of detecting pulmonary nodules.
- Quickly detect and reduce the reading time of doctor

12. **Installation and Use**

The software installation and verification process is carried out by professionals trained by our company.

13. Warning Information

Expert knowledge required by the user to use and operate the software:

a) Received professional use and operation training of this product;

b) Have a doctor's practice certificate.

c) Capability to read lung CT images and diagnose lung nodules.

⚠ When the users use the software to assist in the diagnosis of lung nodules, they must also refer to the unlabeled original CT image.

⚠ This device is only an auxiliary diagnosis software, and the automatic diagnosis result of this software cannot be used as the only basis for the diagnosis of lung nodules. The diagnosis result should be made by the user instead of the software.

⚠ The device can only be used to assist in the diagnosis of lung nodules.

⚠ The input data of this device should be chest CT image complying with DICOM3.0 standard protocol.

⚠ Users are not allowed to modify the program directly.

⚠ Use restrictions:

1) The maximum number of characters allowed in the key field "Patient Name" is 64 bit.
2) The maximum number of characters allowed in the key field "Patient ID" is 64bit.
3) The maximum number of characters allowed in the key field "Device Type" is 32bit.
4) The maximum number of characters allowed in the key field "Access Number" is 32bit.
5) The maximum number of characters allowed in the key field "Task ID" is 18bit, and it must be number
6) The maximum number of characters allowed in the key field "Check UID" is 128 bit.
7) The maximum number of characters allowed in the key field "Check No." is 12 bit.
8) The maximum number of characters allowed in the key field "number of labels" is 3 bit.
9) The number of words in the editorial report should be less than or equal to 16777215.
10) Threshold for tiny nodules (the length of the nodule, in mm) range: 0＜threshold ≤30
11) The exposure parameters of CT equipment meet: tube voltage 70kV~140kV, tube current 10mA~400mA combination.

⚠ Waste after use, such as CDs, CD boxes, etc., should be disposed of in accordance with relevant local environmental protection laws and regulations.

14. **Residual risks and undesirable side-effects**

• Miss diagnosis or over diagnosis may happen. Although the software has been proved to have good detection, classification and measurement performance, miss diagnosis or over diagnosis may still occur in rare case. This device is only auxiliary diagnosis software, and the diagnosis result should be made by the user instead of the software.

• Temporary delay diagnosis caused by device malfunction or inadequate operation may happen if the device is not installed, used, or maintained according to the instruction of the user manual.

• Divulgence of patient data caused by cybersecurity issues may happen if not follow the instruction of this user manual, or when some unknown threats happen.

15. System Function and Performance

15.1. Login

Enter the correct user name and password, log into the software and enter the main interface.

15.2. Check the image (auto import)

1) Check retrieval

Query imported examinations by patient ID, name, and examination time.

2) Check list

Display patient name, patient ID, patient age, patient gender, equipment type, examination time, examination equipment, report status.

3)Operation function

a: Report: prepare report

b: Video: view video

c: Delete: delete the image (only the administrator has this function)

d: Details: display detailed patient information.

15.3. Upload images manually

Images can be uploaded manually from the local.

15.4. Review images

1) Three-dimensional function:

a: The doctor can view images from the axial, sagittal, and coronal positions. And can also click the "VR" button to view the three-dimensional volume reconstruction (VR);

b: Drag the VR button into the view, the corresponding view will display a partial 3D image, and the center of the image corresponds to the position of the MPR front sight;

c: Length measurement;

d: Clear the length measurement mark;

e: Support MPR, MIP and MinIP mode views;

f: In the partial 3D view, the left mouse button rotates, the mouse wheel zooms, and the right mouse button adjusts the transparency;

g: Basic settings: window position linkage, display pointer and pointer control;

h: Drag the axis under the image to flip.

2) Overturn the picture

Overturn the picture by scrolling with the mouse.

3) Window adjustment

Adjust the window width and window level.

4) Move

Move the image as a whole.

5) Zoom

Zoom the image.

6) Layout

Display images in follow-up, 1×1, 1×2, 2×1, 2×2, three-view, and 3×2 layout.

7) Magnifier

Zoom in on the image.

8) Reset

Restore the initial state of the image.

9) Play

Play the video dynamically.

10) Hidden mark

Hidden the mark frame on the image, which is convenient for the doctor to read the initial image.

11) Edit mode

Open the edit mode, the doctor can modify the position and size of the software's automatic mark.

12) Add marker

The doctor manually adds markers to the lung nodules that are missed after being automatically marked by the software.

13) System setting function

a: Basic settings

Including the default window width and window level, the threshold of tiny nodules and the theme color settings;

b: Button setting

Window adjustment shortcut key setting, refresh the browser to take effect after the setting is over.

14) Aided analysis of lung nodules

a: Automatically mark the position of lung nodules;

b: Automatic detection and manual modification of the long diameter of lung nodules;

c: Display the location list of lung nodules;

d: Cancel/Select the check box on the right, the image will automatically cancel/mark the position of the corresponding lung nodule.

15) Full screen function

Click the "full screen" button in normal mode to switch to full screen mode; Click the "exit full screen" button in full screen mode to switch back to normal mode.

16) List mode

The details of the detected lung nodules are displayed in the form of a list.

17) Follow-up mode:

Nodules can be automatically registered for multiple examinations of the same patient at different time, and the growth curve and CT value change curve can be drawn to contrast changes in length, diameter, volume, and properties.

15.5. Aided diagnosis tasks

1) Browse all tasks, display task ID, examination number, patient ID, task status, calculation time, and delete tasks (only the administrator has this permission), image and recalculate operations.

2) Browse the follow-up information, display the follow-up number, patient ID, patient name, task status, calculation time, and delete tasks (only the administrator has this permission), image and recalculate operations.

16. System operating environment

1) Recommended server configuration

Hardware Configuration

CPU：Intel(R) Core(TM) i7-8700K CPU @ 3.70GHz and above

RAM：64GB and above

Hard disk：4TB and above

Graphics card：Nvidia GTX 1080Ti and above

Web environment: 100MB and above

Network card：100/1000 Base TX

Software configuration：

Operation system：Ubuntu 16.04

Database：MySQL 5.7 and its compatible version

Plug-in：JDK1.8 and its compatible version，Python3.6 and its compatible version，Pytorch1.0 and its compatible version，opencv3.4 and its compatible version，pydicom1.2 and its compatible version，SimpleITK 1.1 and its compatible version

2) Client(PC) recommended configuration requirements

Hardware Configuration：

CPU：Intel(R) Core(TM) i5-7400K CPU @ 3.00GHz and above

RAM：8 GB and above

Hard disk：256GB and above

Network card：100Base TX

Monitor display resolution： 1920 x 1080 and above

Web environment：LAN, network bandwidth is greater than or equal to 2MB and above

Software configuration：

Browser：Chrome 78.0 and its compatible version

Operating system: Windows 7 and its compatible version

17. Client system

Open the chrome browser, enter the IP address such as: http://10.2.112.96:8080/, and click the "Enter" key, as shown in Figure 1.

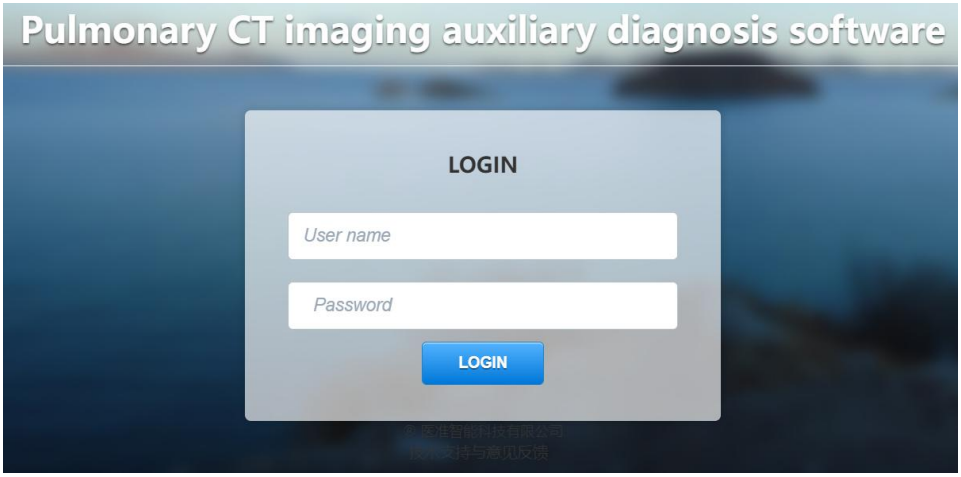


Figure 1

Enter the correct user name and password, and click the "Login" button to enter the user interface, as shown in Figure 2.

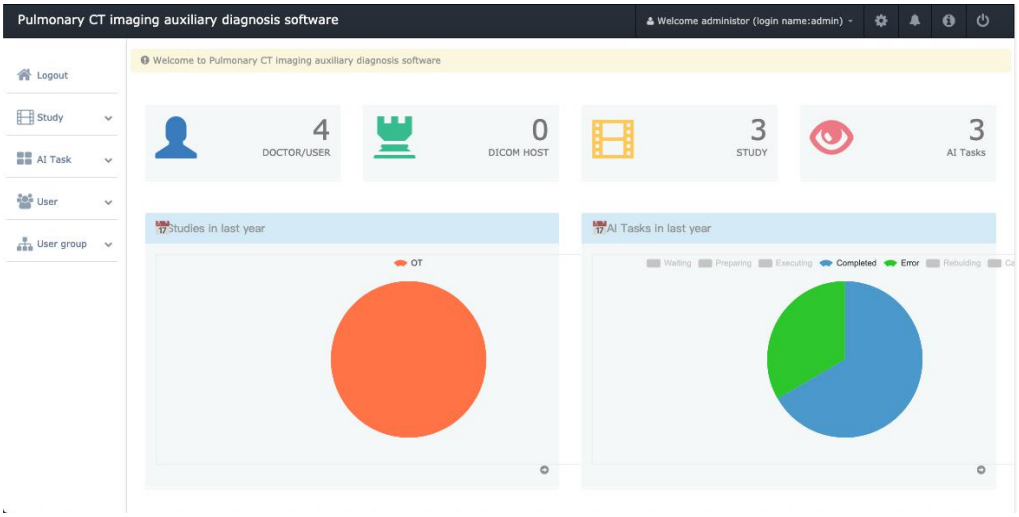


Figure 2

18. Check the image (auto import)

18.1. Overview

This chapter mainly introduces the examination retrieval, examination list and operation functions.

18.2. Operation method

18.2.1. Examination search

Query imported examinations by patient ID, name, and examination time, as shown in Figure 3:

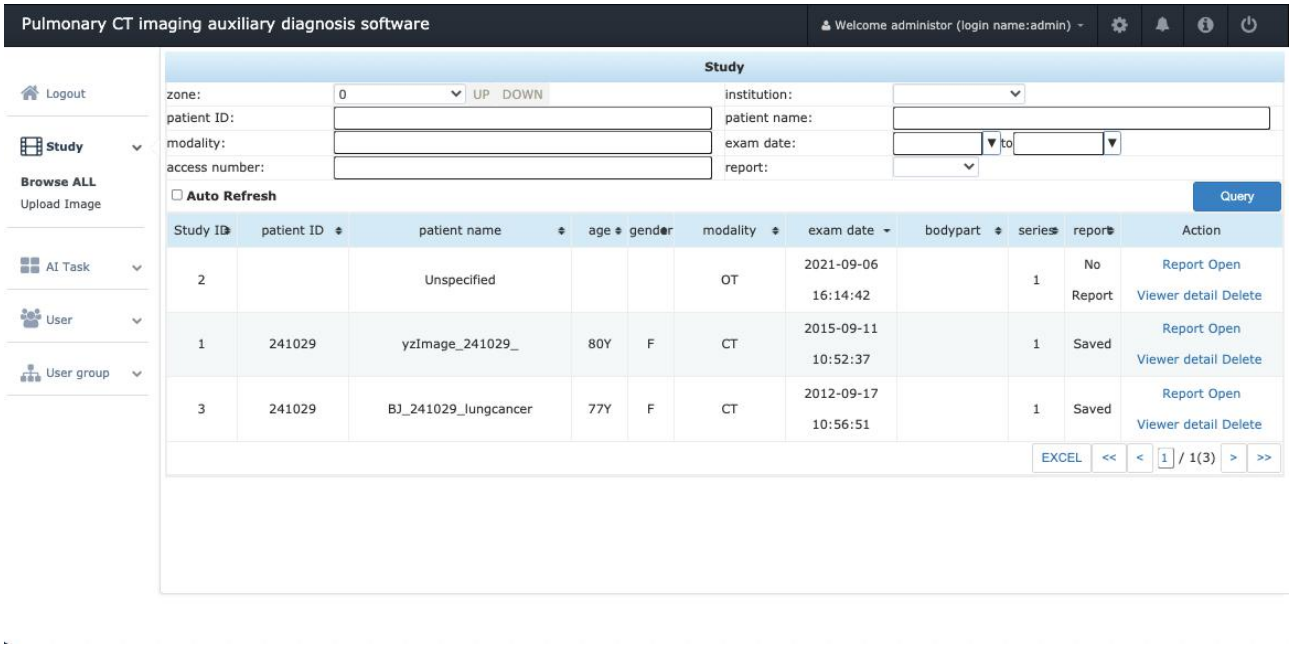


Figure 3

18.2.2. Examination list and operation function

The examination list displays the patient's name, patient ID, patient age, patient gender, equipment type, examination time, examination equipment and report status. It is available to write reports, view images, delete the images (only the administrator has this function) and display patient detailed information. As shown in Figure 4:

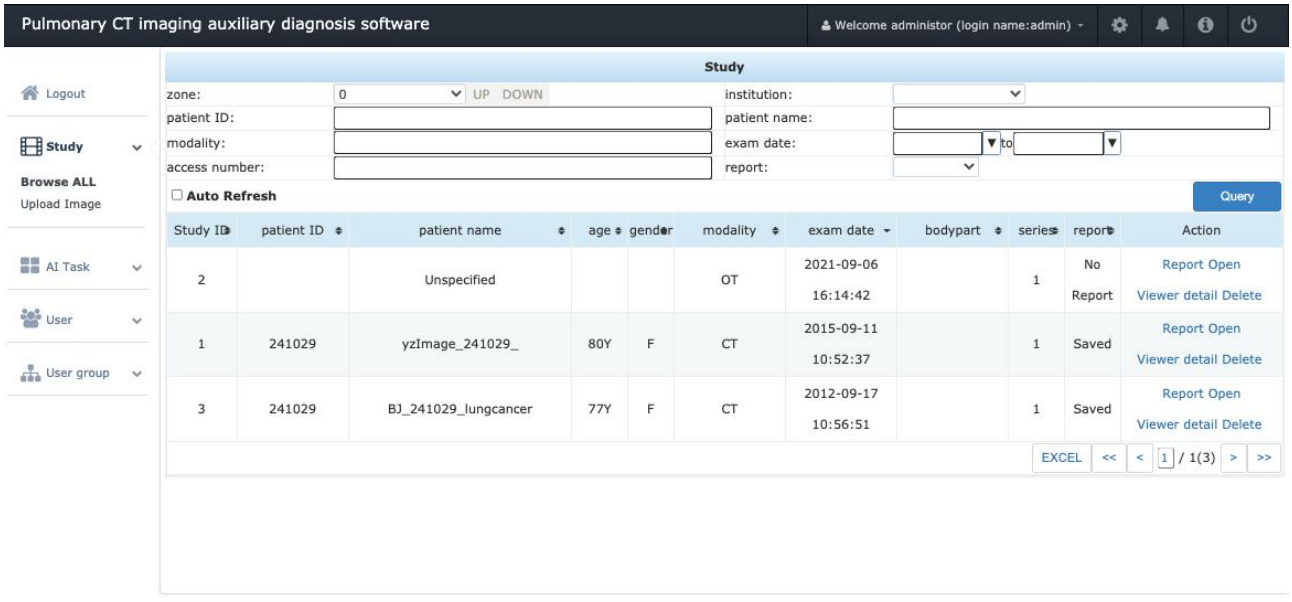


Figure 4

18.2.3. Upload images manually

Images can be uploaded manually from the local, as shown in Figure 5:

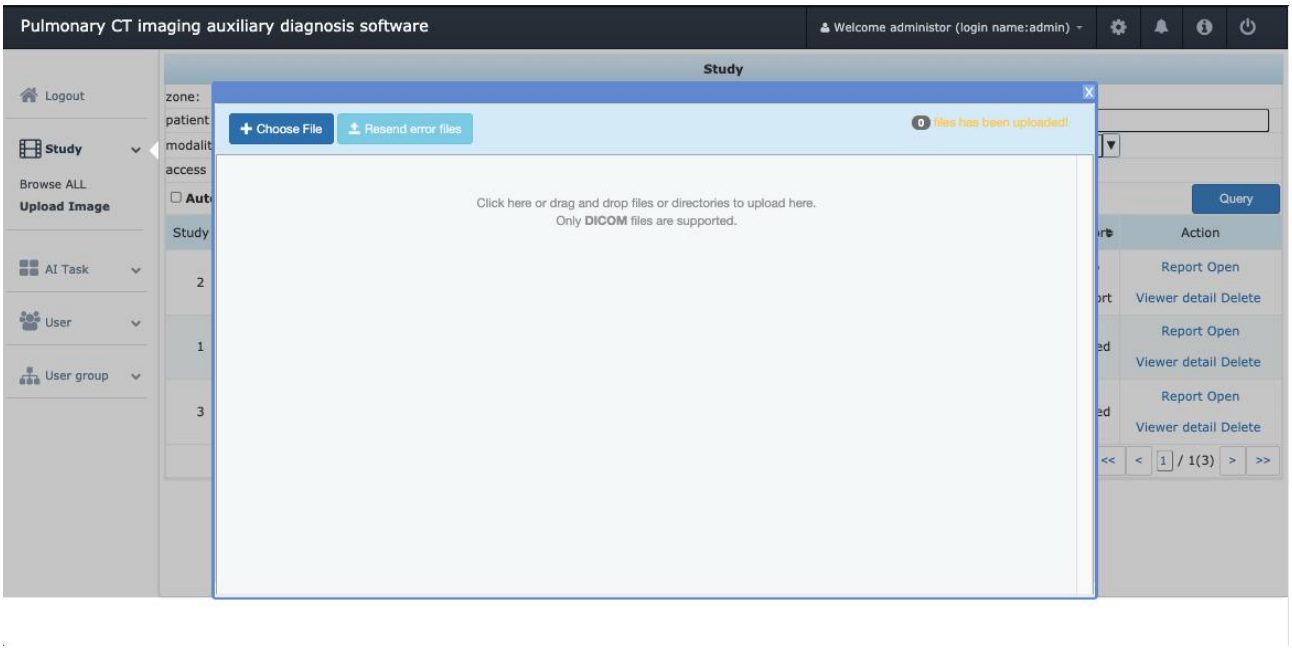


Figure 5

19. View images

19.1. Overview

This chapter focuses on the product's 3D reconstruction, image flipping, window adjustment, movement, zooming, layout, magnifying glass, reset, playback, hide mark, edit mode and add mark functions.

19.2. Operation method

Refer to the image viewing function interface diagram, as shown in Figure 6:

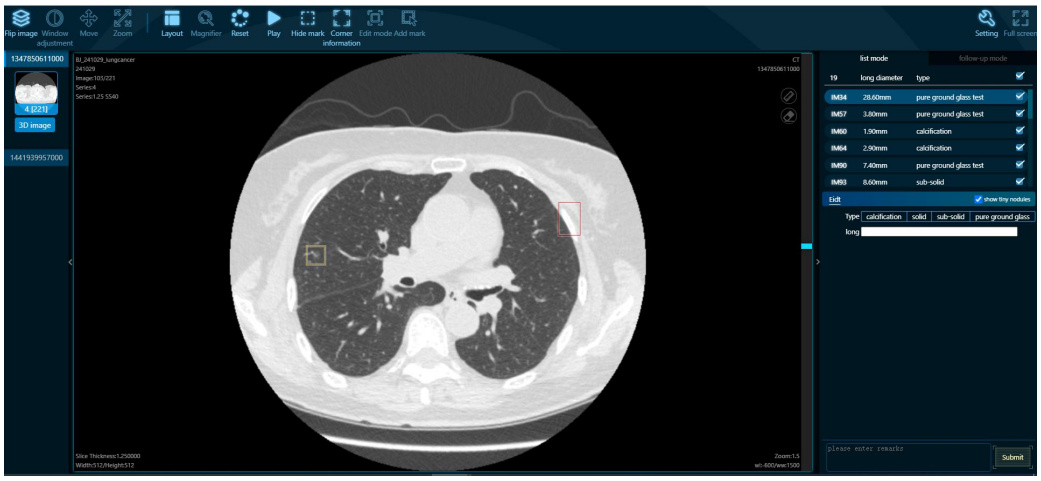


Figure 6

19.2.1. Three-dimensional function

19.2.1.1. Axial position, sagittal position, crown position, detailed mode

a: Click to construct 3D, doctors can view the images from the axial, sagittal, coronal, and detailed mode, or click the "VR" button to view the three-dimension volume reconstruction (VR) as shown in Figure 7.

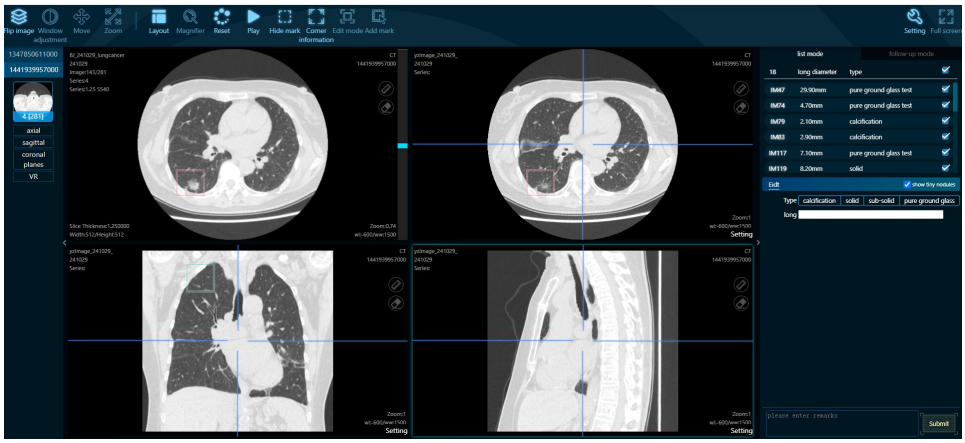


Figure 7

b: Click the button and drag it into the view, the corresponding view will display a partial 3D image, and the center of the image corresponds to the position of the MPR front sight. As shown in Figure 8.

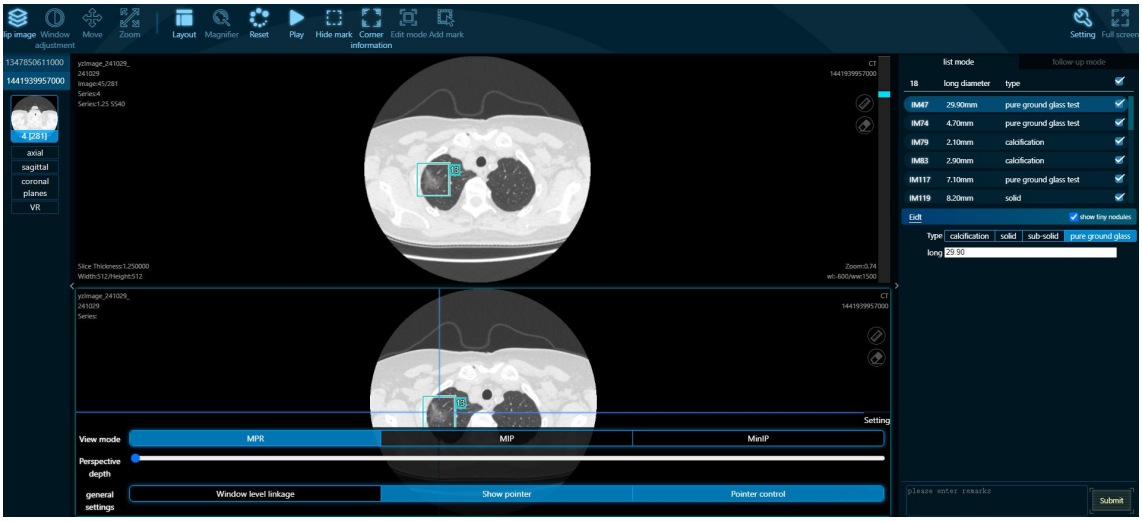


Figure 8

19.2.1.2. Length measurement

Click  button to view the distance between two points on the image. As shown in Figure 9.

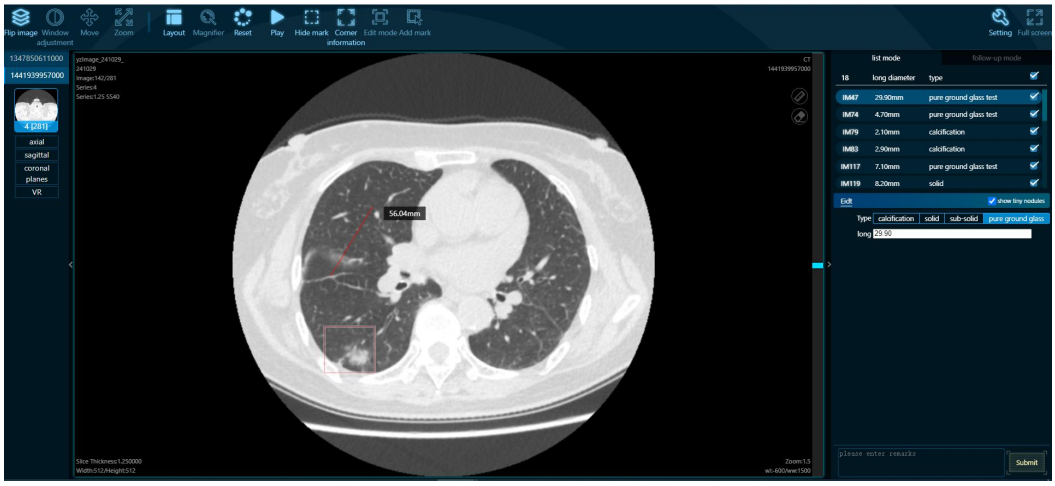
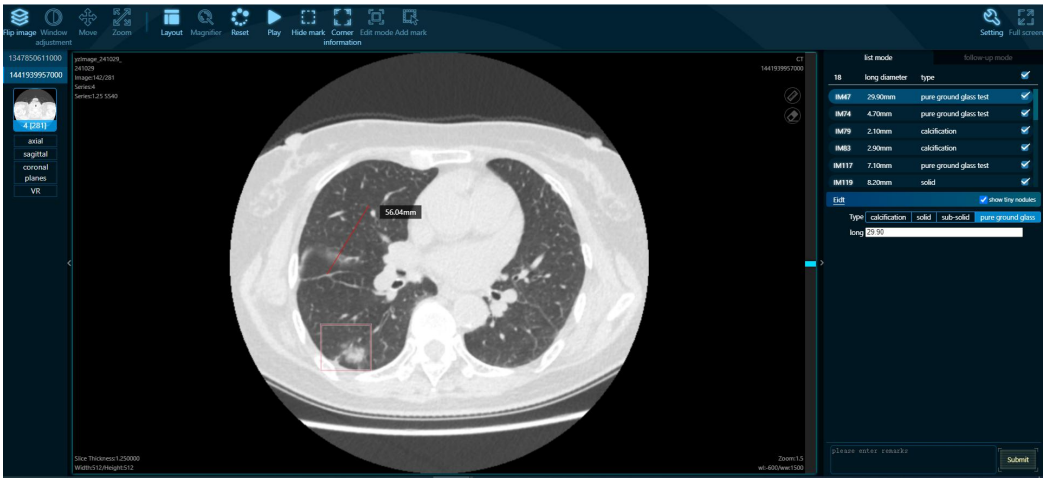


Figure 9

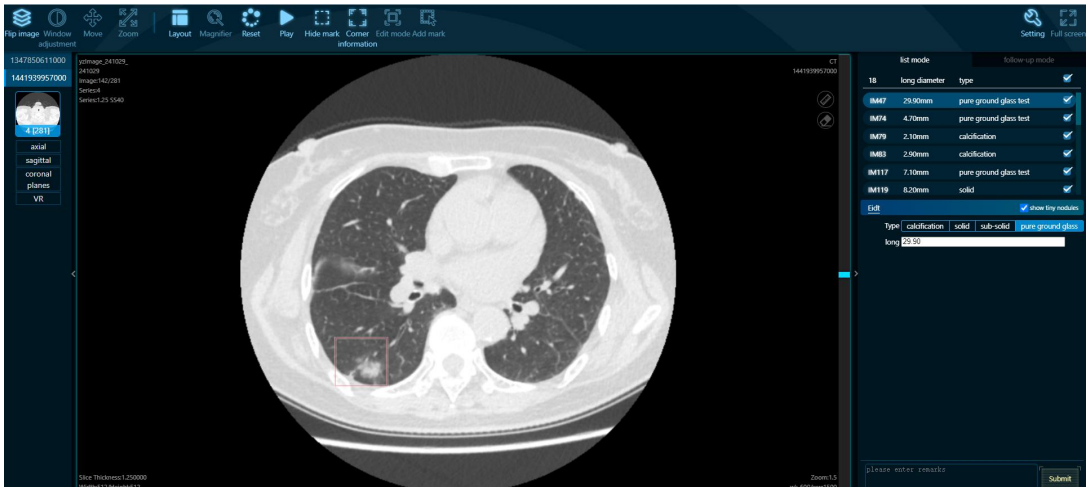
Note: When performing the "manual measurement" operation, the length measurement error under normal conditions should not exceed ±1mm. In order to reduce the error caused by the operation, the CT image should be enlarged to a reasonable multiple when performing the "length measurement".

19.2.1.3. Clear length measurement mark

Click  button to delete the marked line segment of the distance measurement on the image. As shown in Figure 10.



View before marking

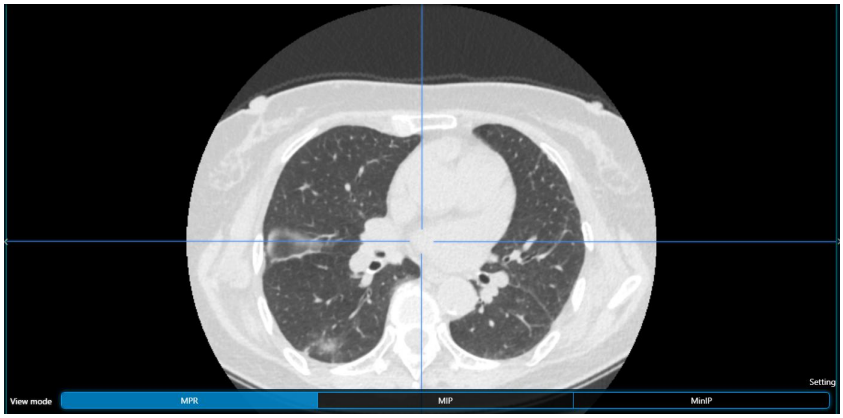


View after the mark is cleared

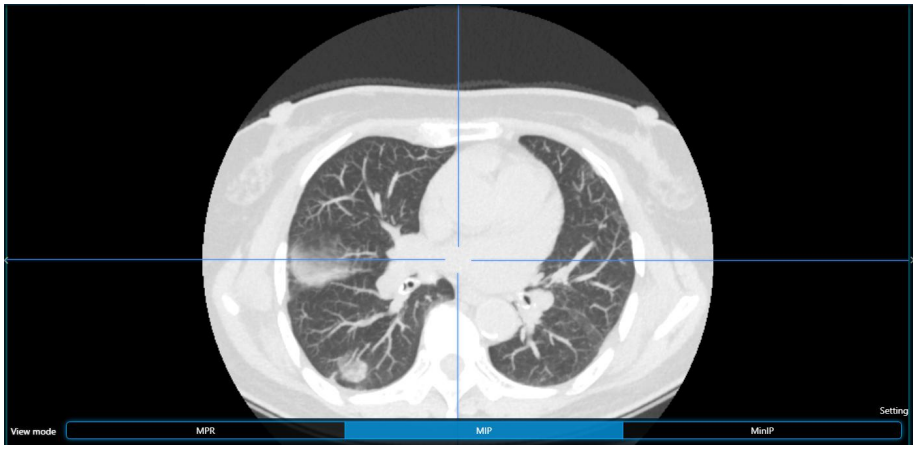
Figure 10

19.2.1.4. MPR、MIP and MinIP mode view

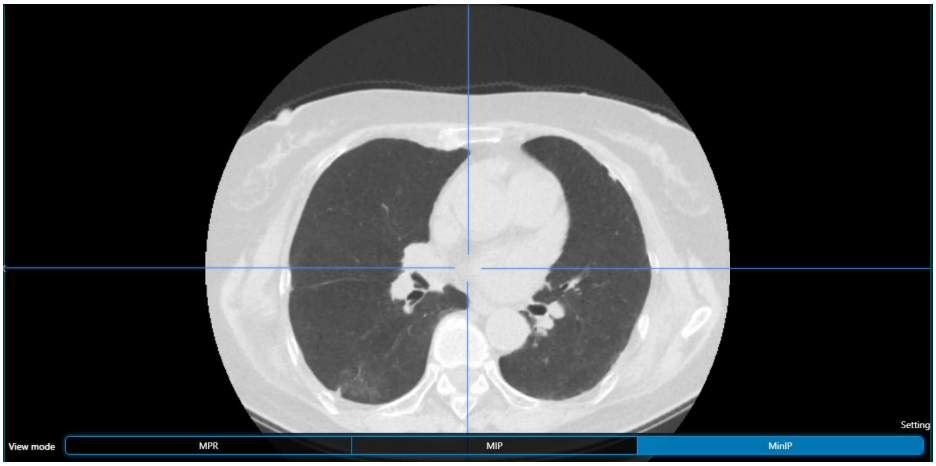
Click the Setting button in lower right corner of the 3D image. It can be viewed in MPR, MIP and MinIP modes, as shown in Figure 11.



MPR



MIP

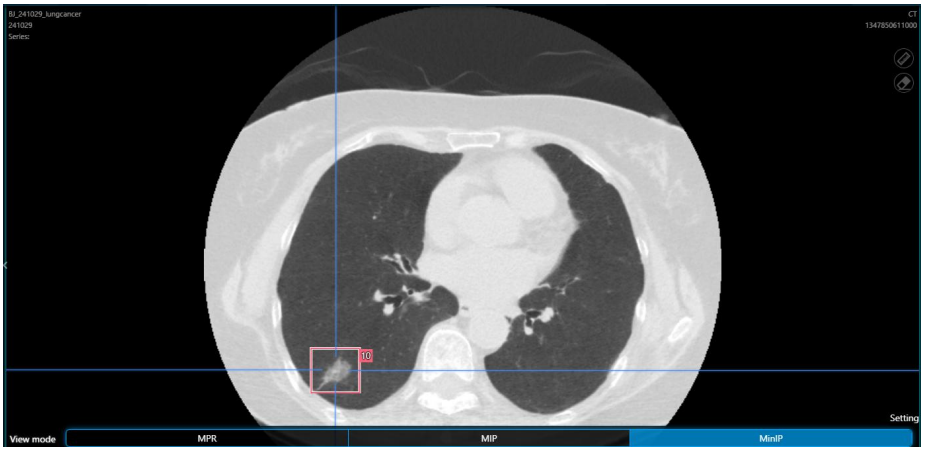


MinIP

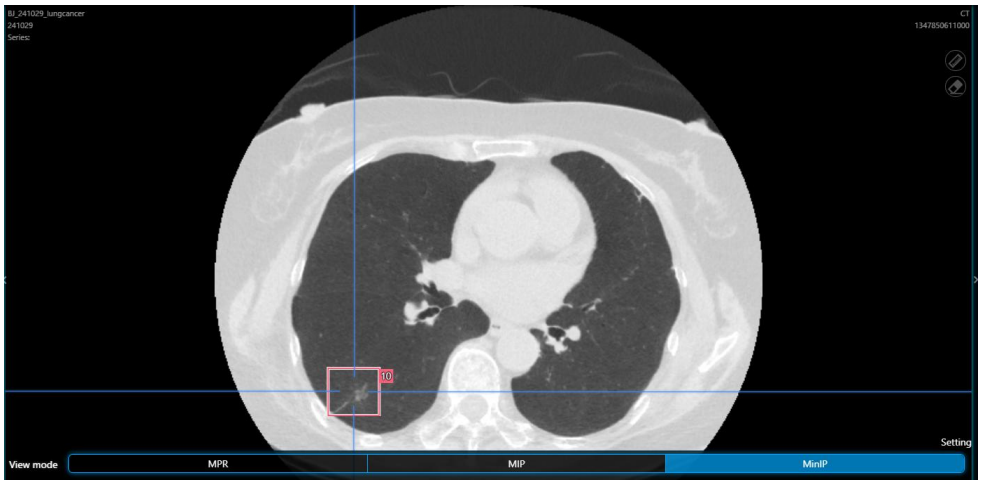
Figure 11

19.2.1.5. Transparency

In the partial 3D view, the left mouse button rotates, the mouse wheel zooms, and the right mouse button adjusts the transparency, as shown in Figure 12.



Initial transparency



After adjusting the transparency

Figure 12

19.2.1.6. Basic settings

Click Setting button, it can set the window position linkage, display pointer and pointer control, as shown in Figure 13.

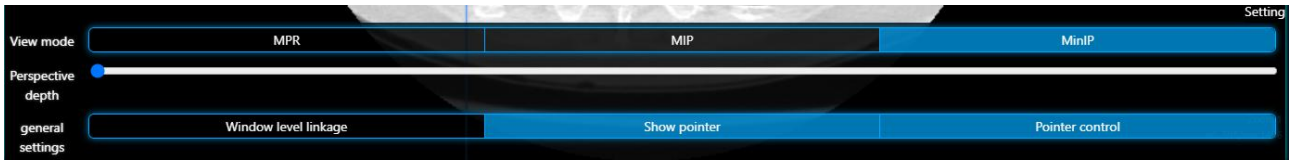


Figure 13

19.2.2. Turnover the picture

Click Flip image button, and use the mouse to scroll and slide to browse the CT images.

19.2.3. Window adjustment

Click Window adjustment button to adjust the window width and position, as shown in Figure 14:

Figure 14

19.2.4. Movement

Click Move button, and use the mouse to move the CT image in the display interface.

19.2.5. Zooming

Click Zoom button to perform the image reduction operation.

19.2.6. Layout

Click 

button to display images through follow-up, 1×1, 1×2, 2×1, 2×2, three-view, 3×2 mode, etc. As shown in Figure 15.

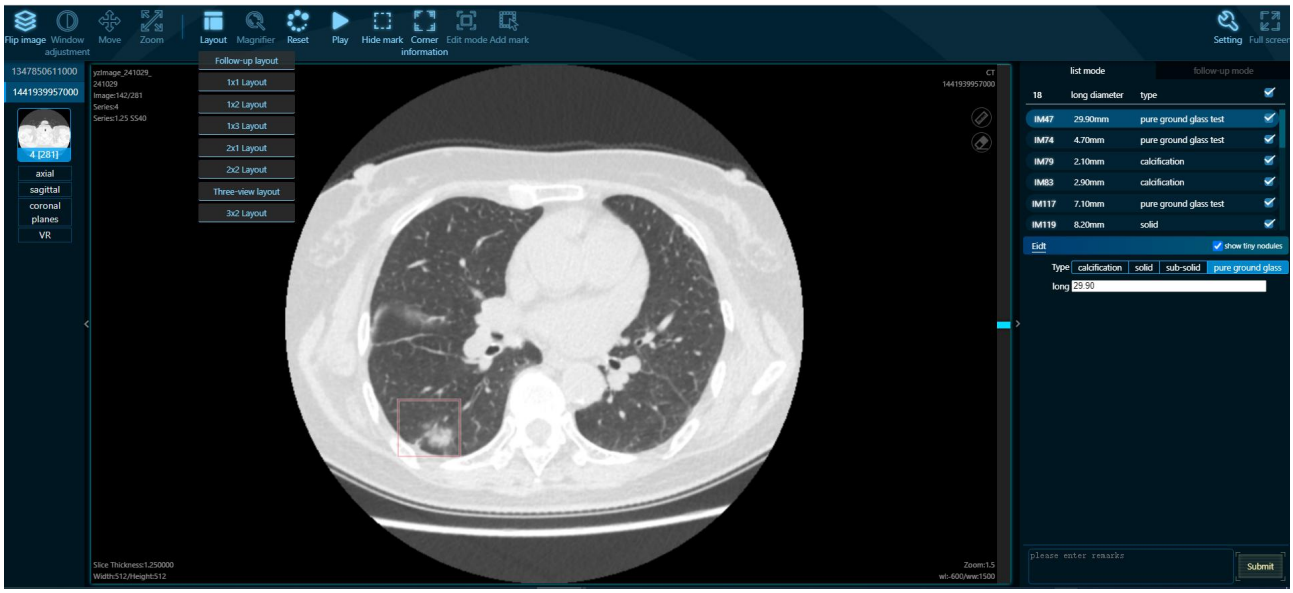


Figure 15

19.2.7. Magnifying glass

Click 

button to enlarge the image.

19.2.8. Reset

Click 

button to restore the initial state of the image.

19.2.9. Play

Click 

button to play the image dynamically.

19.2.10. Hide mark

Click 

button to hide mark frame on the image which is convenient for the doctor to read the initial image.

19.2.11. Edit mode

Click 

button by doctors to modify the position and size of the automatic mark by the software.

19.2.12. Add mark

Click  button, the doctor can manually adds marks to the lung nodules that are missed after being automatically marked by the software.

19.2.13. System settings

Click  button, and it can make basic settings (including the default window width and window level, the threshold of small nodules and the theme color settings) and key settings (window adjustment shortcut key settings which will take effect after the setting is refreshed), as shown in Figure 16.

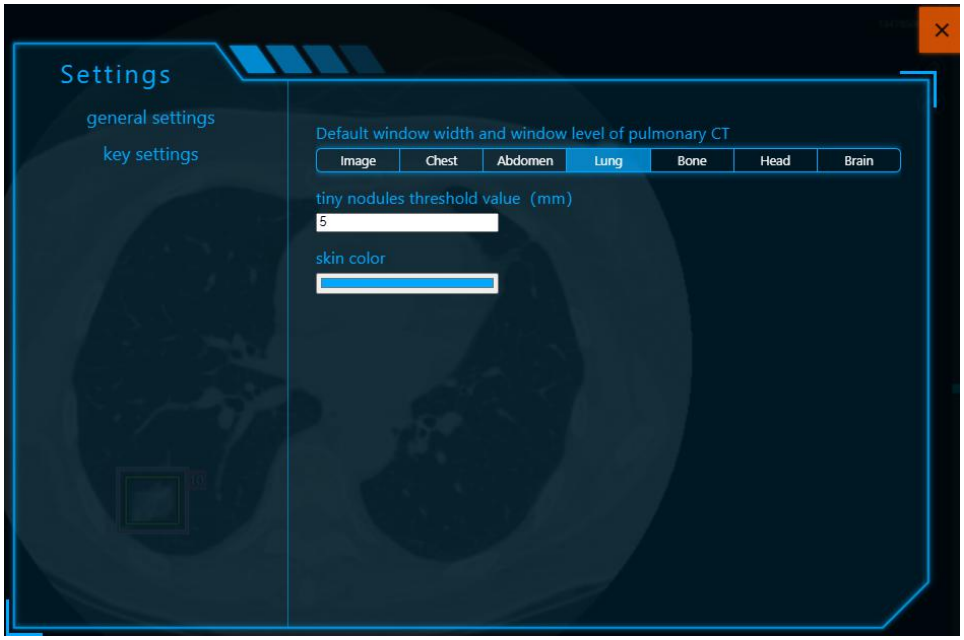


Figure 16

19.2.14. Aided analysis of lung nodules

Click the list mode, the software can automatically complete the following functions (as shown in Figure 17):

1) Automatically mark the position of lung nodules;

2) Automatic detection and manual modification of the pulmonary nodule's longest diameter and type;

3) Display the location list of lung nodules;

4)Cancel/select the check box on the right, the image will automatically cancel/mark the position of the corresponding lung nodule.

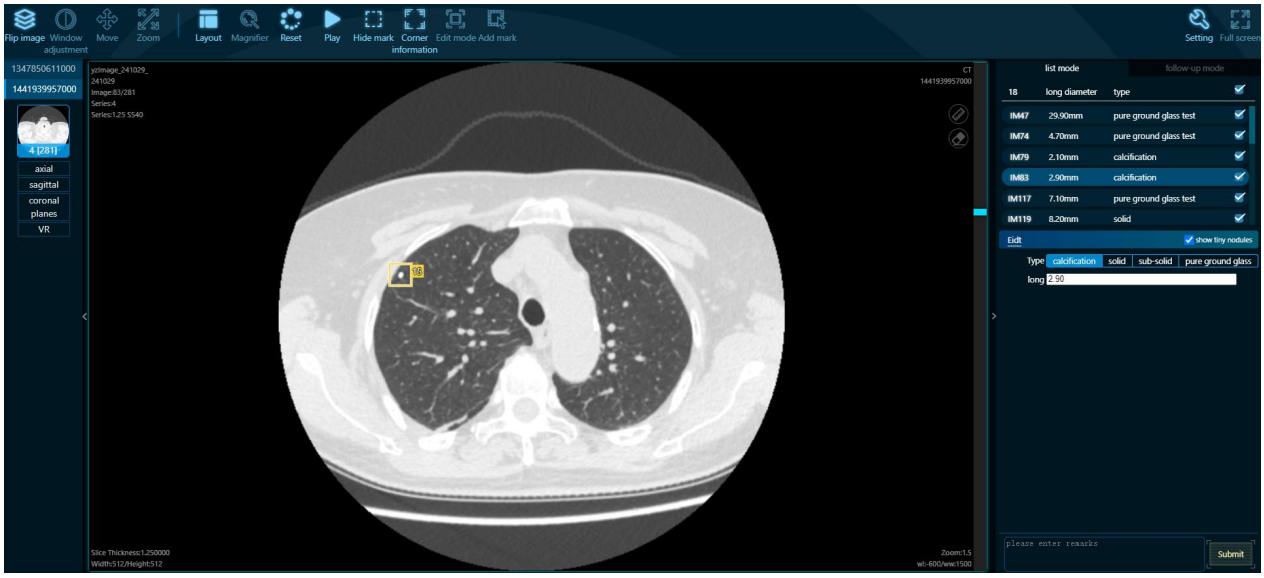


Figure 17

19.2.15. Full screen function

Click the "full screen" button in normal mode to switch to full screen mode; Click the "exit full screen" button in full screen mode to switch back to normal mode.

19.2.16. List mode

The details of the detected lung nodules are displayed in the form of a list.

19.2.17. Follow-up mode

Click 

button, the doctor can automatically analyze the size changes of the lung nodules at the same position in any number of examinations and generate a graph of changes, as shown in Figure 18.

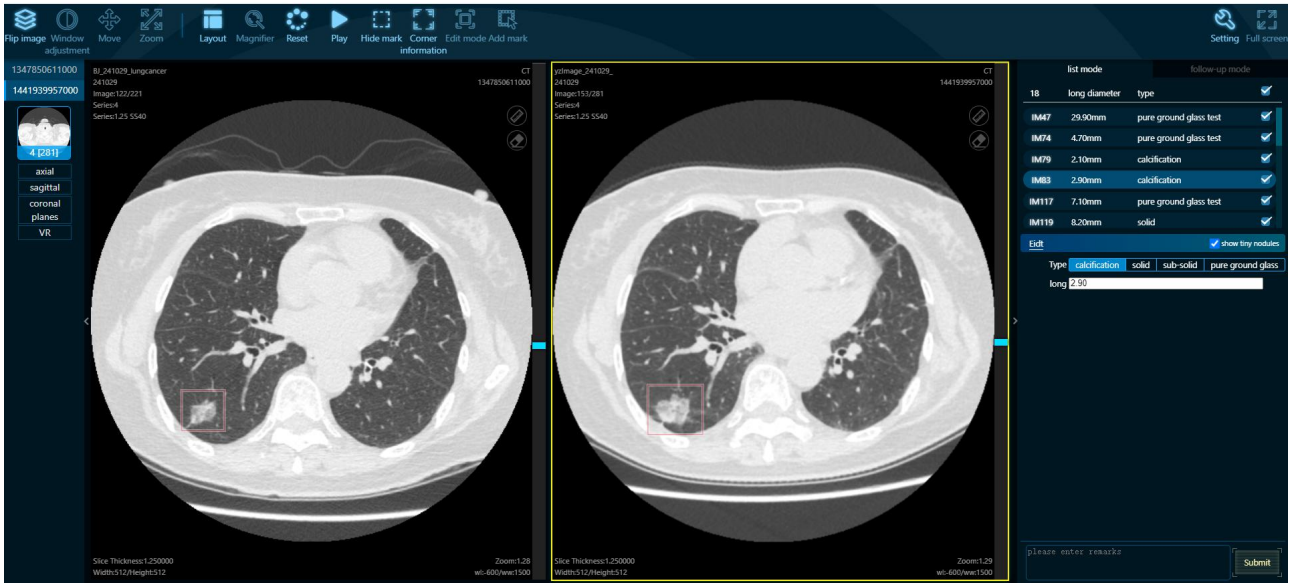


Figure 18

19.3. Aided diagnosis tasks

19.3.1. Overview

This chapter mainly describes the functions of browsing all tasks and browsing follow-up information in aided diagnosis tasks.

19.3.2. Operation method

19.3.2.1. Browse all tasks

Click‘AI Task’ button, and then click ‘Browse All’ button to browse all tasks, it can display task ID, examination number, patient ID, task status, calculation time, and can also delete, image and recalculate the task at the same time.

As shown in Figure 19.

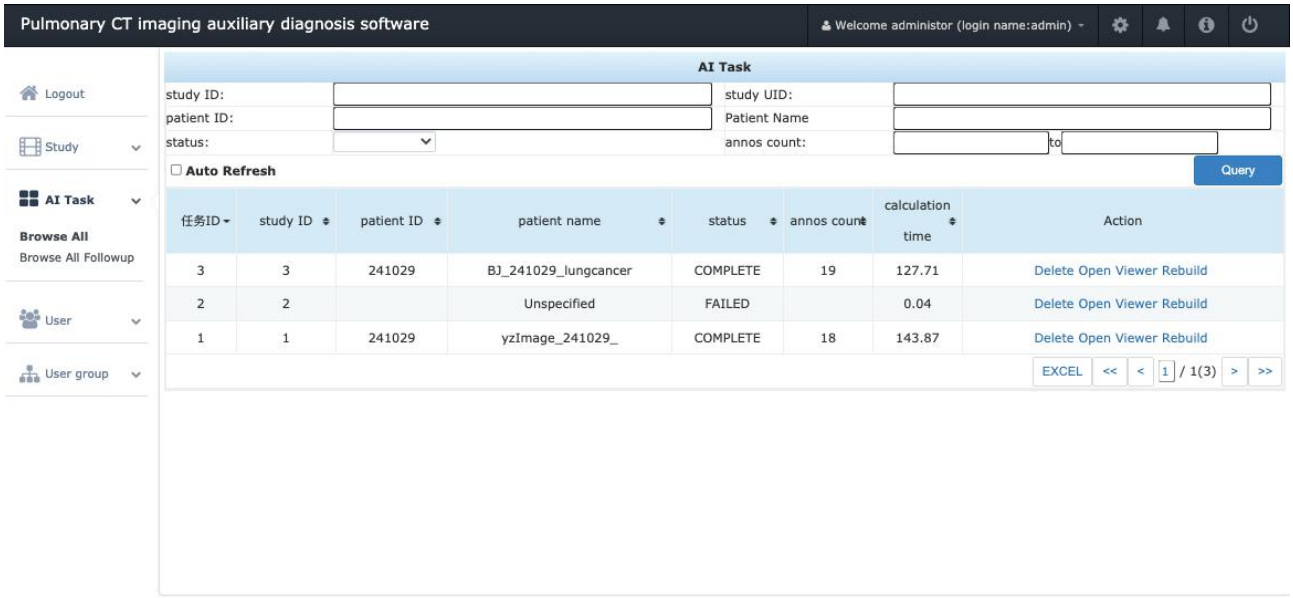


Figure 19

19.3.2.2. Browse the follow-up information function

As shown in Figure 20.

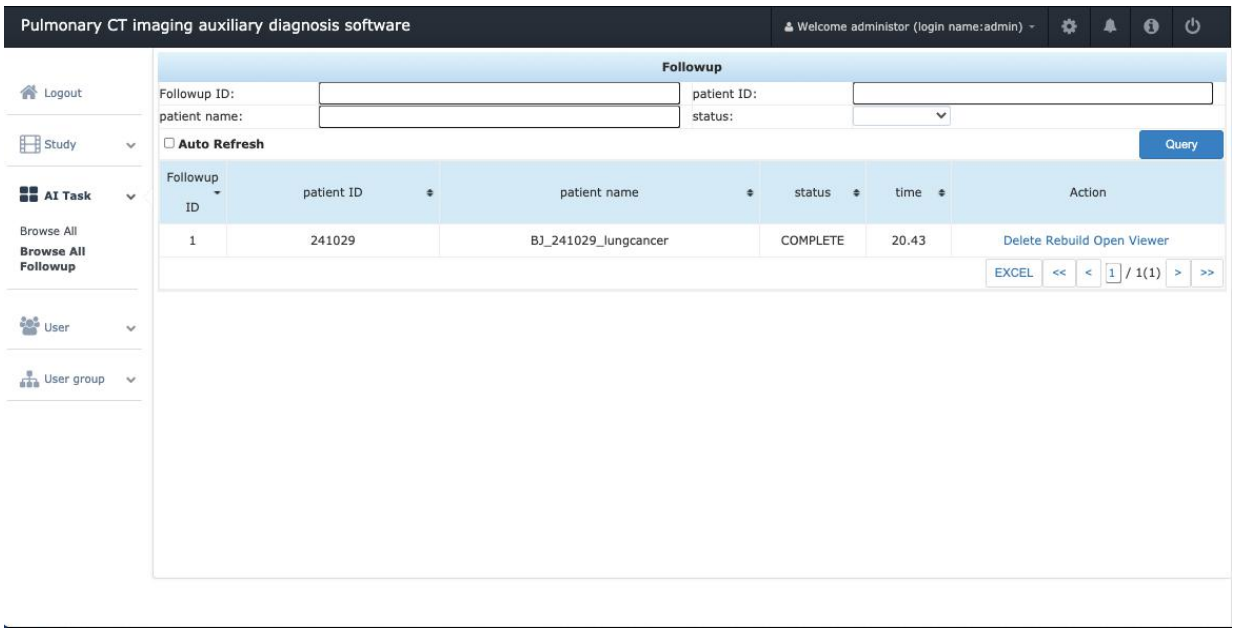


Figure 20

19.4. User Management

19.4.1. Overview

This chapter mainly introduces the related functions of user management (only administrator users have this authority), which include creating new users, browsing users and changing passwords.

19.4.2. Operation method

19.4.2.1. Create user

Click ‘User’ button, then click ‘Create user’ button, it can enter the user login account, user name, password, regional organization, organization direct users, contact information and user grouping relationship, as shown in Figure 21.

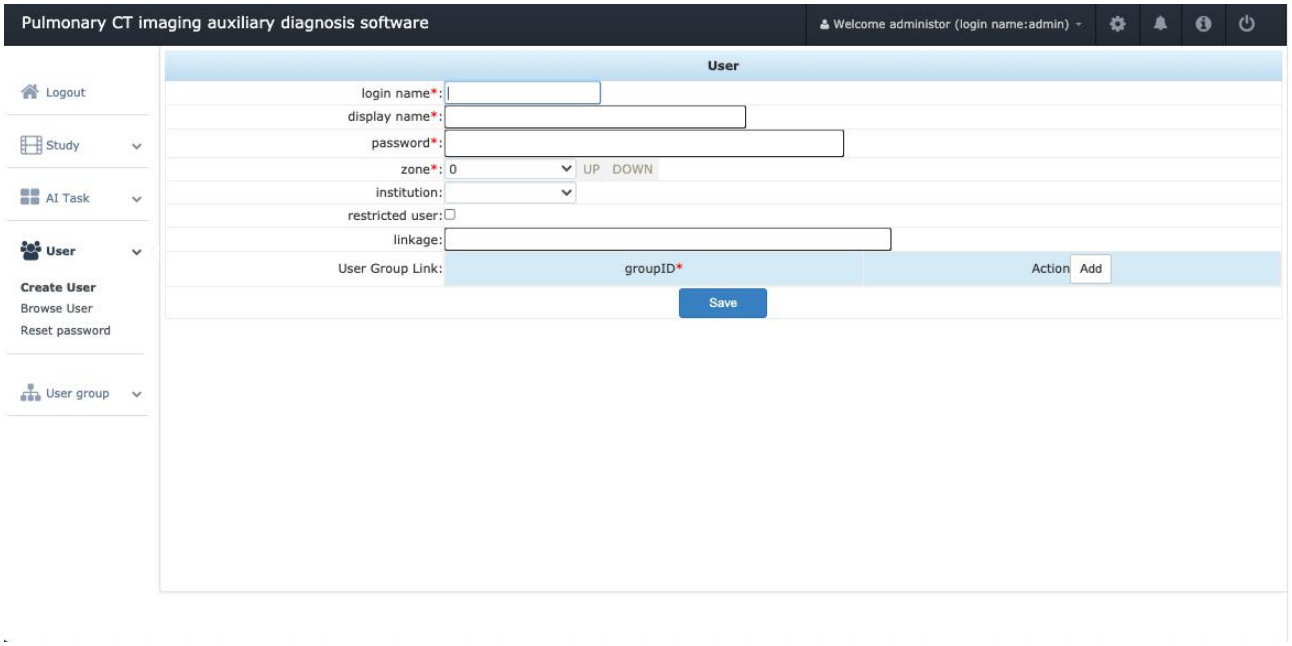


Figure 21

19.4.2.2. Browse users

Click ‘User’ botton, then click ‘Browse user’ button to browse user information. As shown in Figure 22.

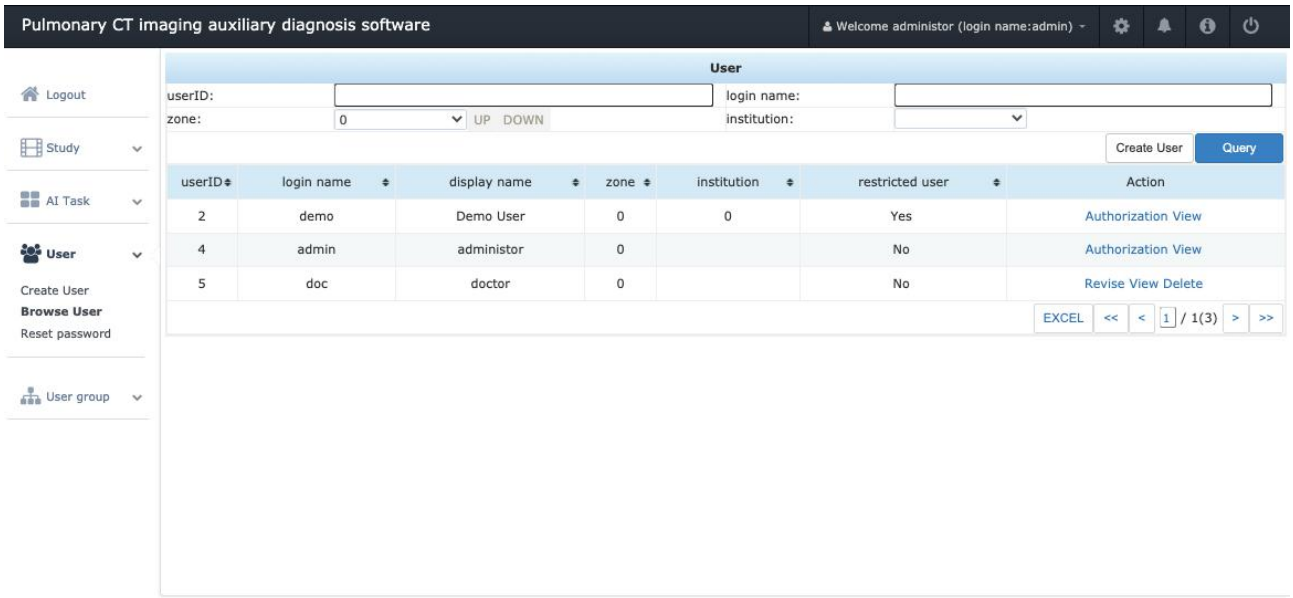


Figure 22

19.4.2.3. Change password

Click ‘User’ botton ,then click ‘ Reset password’ button, it can enter the old password, new password, repeat new password and contact information. As shown in Figure 23.

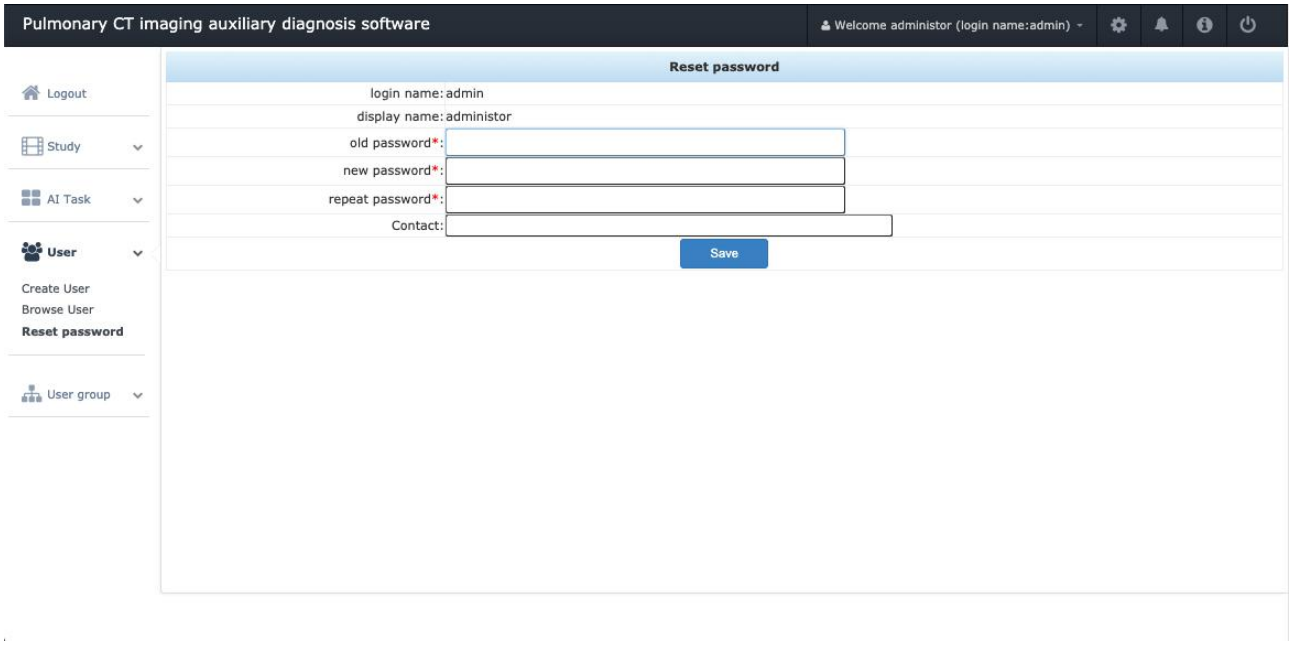


Figure 23

19.5. User group management

19.5.1. Overview

This chapter mainly introduces the related functions of user group management (only administrator users have this permission), which include creating a new user group and browsing user groups.

19.5.2. Operation method

19.5.2.1. Create user group

Click ‘User group’ button, then click ‘Create User Group’ button, it can fill in the user group name, user group description, sharing level, allowed operations and data permission authorization. As shown in Figure 24.

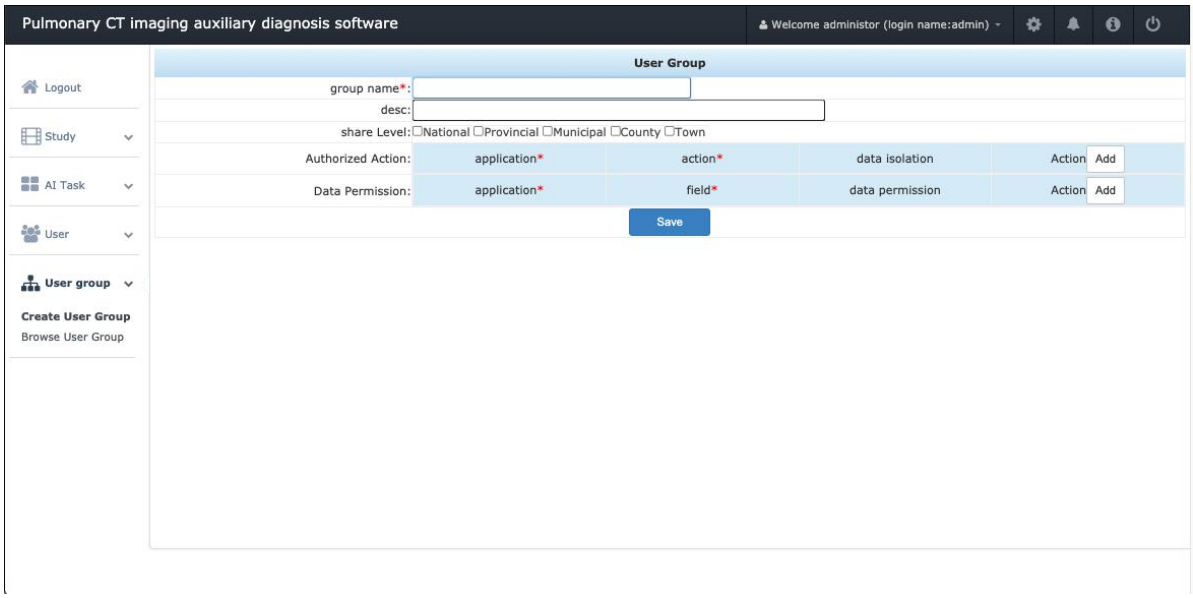


Figure 24

19.5.2.2. Browse user groups

Click ‘User group’ button, then click ‘Browse User Group’ button, it can fill in the number and create user name and user group name. As shown in Figure 25.

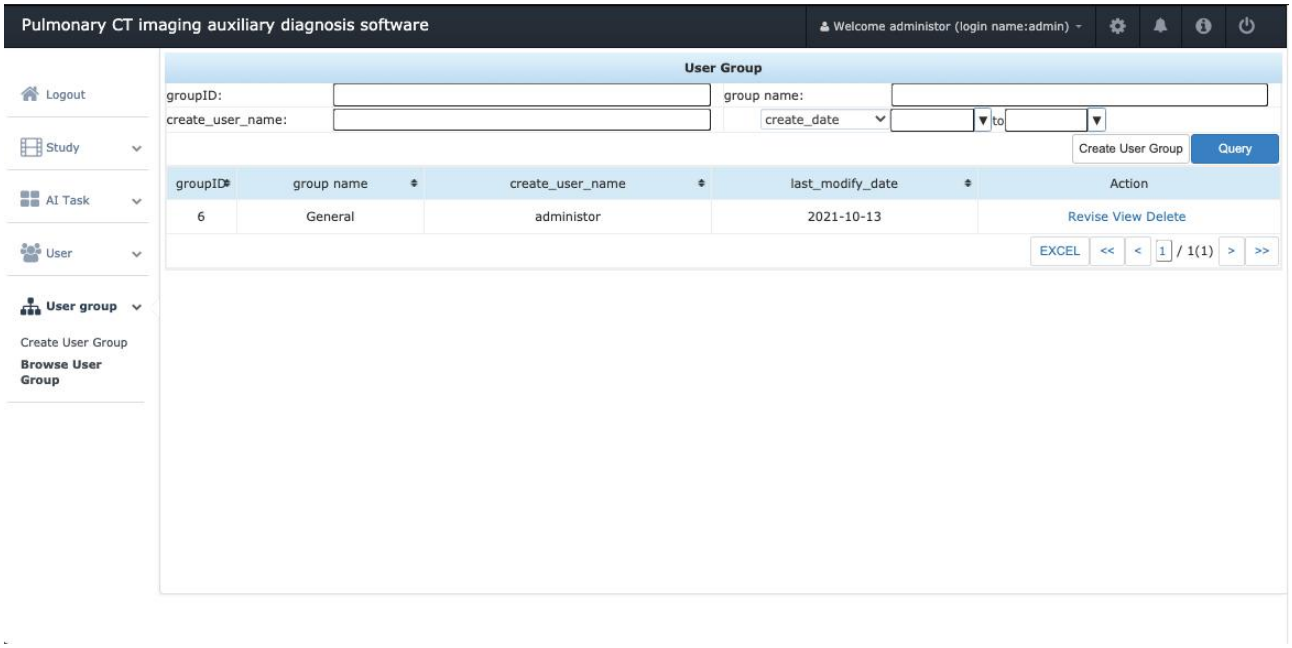


Figure 25

20. Maintenance

This product is maintained by Beijing Yizhun Medical AI Technology Co., Ltd. or its designated after-sales service organization.

21. Storage Condition

Transportation conditions and methods:

The CD burning software should be placed in a CD box, and there should be no heavy objects accumulated on it during transportation.

Storage conditions:

The CD burning software should be placed in a CD box, and the storage environment temperature is -20℃～+55℃, the relative humidity is 20%-80%, and there is no corrosive gas.

It is forbidden to expose the CD to sunlight or ultraviolet light for a long time, and the CD should be kept away from dirt or foreign objects.

22. Production Date and Service Life

Production date: See the CD label for details.

Use period: The use period is 5 years if the version has not been upgraded.

23. Product and Manufacturer's Information

23.1. Registrant

Name：Beijing Yizhun Medical AI Technology Co. ,Ltd.

Address：Room 1202,1203, 12th Floor, Zhizhen Tower,Building A, No.7, Zhichun Road, Haidian District, 100191 Beijing,China.

23.2. Manufacturer

Name：Beijing Yizhun Medical AI Technology Co. ,Ltd.

Address：Room 1202,1203, 12th Floor, Zhizhen Tower,Building A, No.7, Zhichun Road, Haidian District, 100191 Beijing,China.

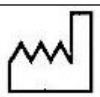
23.3. After-Sales Organization

Tel.：010-86393784
Service：Beijing Yizhun Medical AI Technology Co. ,Ltd.

24. List of Complete Parts

CD box ×1, CD labeling ×1, user manual ×1.

25. Symbols

No.	Symbol	Meaning	No.	Symbol	Meaning
1		Manufacturer	**8**		Consult instructions for use or consult electronic instructions for use
2		Production date	**9**		Caution
3		Temperature limit	**10**		Humidity range
4		Fragile, handle with care	**11**		Keep dry
5		CE Mark And Identification Number Of Notified Body	**12**		Authorized representative in the European Community/European Union
6		Medical device	**13**		Model number
7		Country of manufacture	**14**		Unique device identifier

26. Safety Statement

Software safety requirements statement:

In order to ensure the safety of the pulmonary CT imaging auxiliary diagnosis software, the machine (including server and client) where the software is installed must be installed with network security software. It is recommended to use security software (Kaspersky), which is not compatible with 360 anti-virus software. In addition, in order to ensure the normal operation of the system, please do not install other irrelevant software, such as game software, on the machine where this software is installed.

Data security requirements statement:

Since the pulmonary CT imaging auxiliary diagnosis software is installed on a third-party server, it is medically necessary for the software to operate normally under encountering the data damage or loss caused by natural and human factors such as hardware damage, server infection with Trojan horse virus and artificial attack on the server. Our company will actively cooperate with customers to restore the system, but we will not bear any responsibility for the damage or loss of data.

Hardware safety requirements statement:

Ensuring the safety of the computer information system equipment itself and the physical environment of the area where the equipment is located is the prerequisite and foundation for the safety of the computer information system. The hospital is requested to formulate hardware management specifications in accordance with the "User Safety Management Instruction Manual" compiled by our company. Due to the security issues of the hardware equipment of the information system (including the security of the equipment itself, unauthorized access, and carrying in and out) and the security of the physical environment where the information system is located (including the computer-related equipment and other media in the protected area are subject to earthquakes, Floods, fires, thunder and lightning and other environmental accidents and surrounding environmental factors), causing damage to the software system and data damage or loss, our company will actively cooperate with customers to restore the system, but we will not have any responsibility for the damaged or lost data.

CT equipment used in conjunction with this software should comply with corresponding safety guidelines.

27. Data and equipment (system) interface

The software makes access requests through the TCP/IP protocol, and the image data transmission is through the DICOM3.0 protocol.

The data storage format for image data is stored locally in dcm format, and other patient data is stored in MySQL 5.7 database

28. Requirements for user access control

1) The software is accessed through user name and password.

2) Users are mainly divided into two categories which include administrators and ordinary users. Administrator users have the rights to delete images, delete aided diagnosis tasks, user management and user group management, while ordinary users do not have the above rights.

29. Software environment (including system software, support software, application software) and security software update requirements

The security software that can be used with this product are:

Server side: Ubuntu firewall

Client: Kaspersky, 360 Security Guard Enterprise Edition, Windows Firewall, Kaspersky software is recommended.

When the user uses the recommended security software to update, it will have no impact on the software environment (including system software, supporting software, and application software), and no manual settings are required.

30. Supporting hardware and software

The operation of the software depends on the computer tomography (CT) imaging equipment that meets the DICOM3.0 standard.

31. Critical flaws

Under certain improper operations, there may be some data loss or software deadlock situations.

32. Copyright Protection Technology

The software is protected by copyright through the license authorization file.

The software obtains the network card ID and encrypts the ID to generate a machine code. The user sends this machine code to the manufacturer to generate a license.dat file. Place the license.dat file in the specified file directory on the server, and the software can be authorized for use.

33. Conditions that affect performance efficiency

Conditions that affect performance efficiency include the internet speed, the browser and the computer memory.

34. Methods to prevent user misoperation

Use the message prompt box to prevent user deleting information by mistake.

35. Handling method for user interface error

When the software encounters a network error, it will ensure that the currently saved data will not be lost and will not affect other functions.

36. Efficiency

Under the recommended configuration environment and the maximum concurrent number, the lung CT image (image size ≤512K) transmission time (referring to the client downloading images from the server) is less than 10 seconds, and the time for automatically marking the location of lung nodules is less than 60 seconds while processing lung CT image sequences (less than 1000 pieces).

37. Maximum concurrent number

The maximum number of concurrent users is 64, and the number of patients is unlimited.

38. Data backup

This system and the hospital's existing PACS and other systems independently store copies of data and serve as backups for each other.

39. Software uninstallation method and precautions

Uninstallation method: Please contact after-sales technicians to uninstall.

Do not uninstall the software arbitrarily to avoid causing system instability.

40. User login system compatibility

Win7 system, XP system, Win10 system

41. Reliability

1) Function: When the input information is wrong, the software will pop up a prompt box. When importing non-CT image data, the software will prompt an upload error. When the network connection is disconnected, the software will prompt the network interruption.

2) Data backup and recovery: It can realize the backup and recovery of image data stored on disk through copying, and realize the backup and recovery of other patient data through MySQL database management tool or command line.

3) After the server is down and restarted, the program runs normally and the data is not lost.

42. Risk resistance

1) This product can limit the operation rights of users of different levels by managing user group access rights. Administrator users have the rights to delete images, delete aided diagnosis tasks, manage user and user group. Ordinary users do not have such rights.

2) If the authorized user modifies the result of the aided diagnosis analysis tasks, there will be a message indicating that the software calculation result has been changed. If the modification is an incorrect operation, the task can be recalculated.

43. Software language

Users of this software are required to have normal keyboard operation ability and be able to correctly recognize English.

44. Collection equipment requirements

- Acquisition equipment parameters and configuration:

Slice thickness and layer spacing	The recommended diagnostic slice thickness range is 0.50-1.25mm. In order to facilitate computer-aided detection and volume analysis, for conventional and enhanced scanning, slice thickness no greater than 1 mm can be reconstructed continuously without interval. For slice thickness greater than 1 mm, the reconstruction interval can select the 50% to 80% thickness of the collimation slice. For low-dose CT, if the reconstructed slice thickness is no greater than 0.625 mm, reconstruction can be without interval. If the reconstructed slice thickness is between 0.625 and 1.25 mm, the reconstruction interval is no greater than 80% of the slice thickness.It is recommended that the image slice thickness does not exceed 2mm.
Equipment manufacturer	Including but not limited to common manufacturers such as GE, Philips, Siemens, Canon (Toshiba), United Imaging, Neusoft and domestic and foreign manufacturers with medical device registration certificates, which must comply with the DICOM3.0 protocol standard data.
Detector	Row 16-320
Scan parameters	Combination of tube voltage (70～140kV) and tube current (10～400mA).
Radiation dose	0.4～8mSv; Other units such as mAs and mGy can also be used to describe the dose. It is recommended to turn on the “dose report” function when scanning so that the dose report automatically generated by the machine can be routinely stored.

Window width and level	Recommended lung window (window level, -700～-600HU; window width, 1500～1600HU). Mediastinal window (window level, 30～70HU; window width, 350～400HU). Other window widths and window levels can be used for auxiliary reading images such as bone windows.
Reconstruction method	The standard algorithm or combination the lung algorithm and the standard algorithm are used for reconstruction at the same time. The thin-slice reconstruction algorithm is recommended to use soft tissue algorithm or lung algorithm.
Display method	It is recommended to use multi-plane reconstruction (MPR) and maximum intensity projection (MIP) to read images. MPR displays the morphological characteristics of lung nodules in multiaspect.

- CT image quality requirements:

The image can clearly display and distinguish the anatomical structure of the lung field and the mediastinal soft tissue. The lung texture in the lung window display mode is clear, and the small blood vessels within 1 cm from the pleura can be displayed. The image in the mediastinal window display mode can see large blood vessels in the mediastinum. The structure is clear and there is a sharp interface with the surrounding fat. The cortical bone and trabecular bone of the bones of the chest wall can be clearly displayed in the bone window display mode.

- The high resolution of the thin-slice reconstruction image can clearly distinguish the secondary lung lobule structure and the interlobular pleura.
- There is a clear contrast between the lesion and the surrounding structure which can be clearly identified and meet the needs of imaging diagnosis.
- No obvious motion artifacts and external metal artifacts. And can meet the requirements of routine diagnosis.
- For thick-slice images, the slice thickness and spacing should not be greater than 2mm.

45. Guidance of electronic user manual

Electronic user manual download site:

http://www.yizhun-ai.com/en/instruction

If you cannot download it on the website, please contact the manufacturer:

Tel: 010-86393784，400-680-1280

Mail:media@yizhun-ai.com

Note:

When the manufacturer’s user manual is updated, it will be uploaded timely. For it is difficult to trace to every end user to inform the change, we advise the customer to browse and check it regularly.

46. Cybersecurity

Cybersecurity capabilities	No.	Predictable events and sequences of events	Adoption of control measures
Automatic logout (ALOF)	W1	The client computer sits idle for a period of time and is abused by other users.	After 30 minutes of no-operation through the UI, or if the correct password cannot be provided for the operation, the login will be logged out.
Audit control (AUDT)	W2	Inability to record and track access, modification, and deletion of health data	The server will record the login and data access of all users.
Authorization (AUTH)	W3	The intended user role does not match the data permissions.	It can only be within the scope of authorization for software classifies,operations, and personnel access.
Security Feature Configuration (CNFS)	W4	The local IT administrator does not use the product's cybersecurity capabilities.	System administrators can configure product security functions through specific commands or operation interfaces; Security features can be configured and changed, and security group rules can be set as needed.
Health data identity information removal (DIDT)	W5	Patient identification information was leaked in plaintext.	The software considers the function of hiding health information when designing
Data Backup and Disaster Recovery (DTBK)	W6	After the system fails, the health data cannot be restored.	The server can backup the data within the agreed time, and data backup and disaster recovery can be carried out by means of configuring disk arrays to avoid data loss due to damage to individual hard disks. At the same time, the software operation interface should support users to carry out data import, and data that has been lost can be imported into the system again through the operation of data import for recovery.
Health Data Integrity and Authenticity (IGAU)	W7	Health data has been tampered with.	The software should consider the source of the received data. The data source can be verified according to the DICOM 3.0 communication protocol. Data that does not meet the DICOM3.0 communication protocol cannot be accepted by the software system. Even tampering cannot be transmitted successfully.

Malware Detection and Protection (MLDP)	W8	Unable to detect malware and unauthorized software that interacts with the product.	Server side: the designated service organization will regularly maintain the server side (cleaning cache, virus checking and killing, etc.). Client side: It is recommended that users use anti-virus software for garbage cleaning and virus scanning, etc.
Network Node Authentication (NAUT)	W9	Unable to recognize device account.	When using the software, users should be advised to properly control the network nodes: ensure that the network nodes that are not in use are closed, and that the normally used network nodes are bound to the corresponding hardware, and then bound with the specific responsible person to ensure this network Security configuration.
Personnel identification (PAUT)	W10	Cannot control and monitor network access and activity.	Authorized users of the software can only obtain a unique user name and password. Identity verification is required when logging in to the software. After the verification is successful, they can log in to the software for subsequent operations.
Physical lock (PLOK)	W11	Ensure that data stored on the product or medium is secure and that the level of security is commensurate with the sensitivity and volume of the data.	Hospital has unified physical lock management for all product servers and client computers. The servers are deployed in the hospital's server room, and visitors to the server room should go through an application and approval process. There is a dedicated person on duty to control, identify and record the personnel entering; Fix the equipment and set up obvious marks that are not easy to remove to ensure that the server is anti-theft and anti-destroy.
Systems and Applications Hardening (SAHD)	W12	Possible computer viruses on the client side compromise the security of data on the server side.	Under normal use, the configuration information related to the required network security protection should be strictly and correctly determined, including: communication ports, access rights of accessible accounts, access time, etc. Avoid too much configuration, which brings hidden risks to the use of the software; too little configuration, the software cannot be used properly. Timely remediation of security vulnerabilities as reported by users.
Security Guidance (SGUD)	W13	Incorrect user operation	Provide the relevant instruction manuals and professional training to the users of the products to ensure that they are clear about

			the operation and use of the software.
Health Data Storage Confidentiality (STCF)	W14	Server-side health data is illegally intercepted or downloaded during user access links.	Encrypted access control to the database of medical data stored by the system. Clients wanting to access health data must pass authentication to protect data security.
Transmission Confidentiality (TXCF)	W15	Patient health data is stolen during network transmission.	The data exchange outside the software system should follow TCP/IP protocol to ensure the security of data transmission. The data transmission of the software should be strictly in accordance with the DICOM 3.0 communication protocol, which is a point-to-point transmission method and can ensure the security of transmission. The client side can use antivirus software to confirm the environmental security of the client side when accessing the software system.
Transmission Integrity (TXIG)	W16	Incomplete data information during network transmission of patient health data.	-The data exchange outside the software system should follow TCP/IP protocol to ensure the security of data transmission. -There are progress bar prompts during the transfer. -The server side accepts data in strict accordance with the DICOM 3.0 communication protocol so that the integrity of the data can be guaranteed. In the client side access, if the image is uploaded manually (DICOM data), an incomplete image will be displayed if the transmitted data is incomplete, and the user can determine whether this is caused by a bad network status and can choose to re-upload the data.

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CE 2797 CE mark in this manual apply only to product with CE mark.

Pulmonary CT Imaging Auxiliary Diagnosis Software User Manual

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Beijing Yizhun Medical AI Technology Co. ,Ltd.