CE 0344

Digital Intraoral X-ray Sensor
i-Sensor H1 / i-Sensor H2
User's Manual

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Before operating, please read this user manual and pay attention to all safety precautions.

Please ensure that this user's manual is properly maintained so that it can be accessed at any time (reserve).

Please use it correctly on the basis of full understanding of the content.

Guilin Woodpecker Medical Instrument Co., Ltd.

To Customers

Congratulations on your purchase of the Digital Intraoral X-ray Sensor i-Sensor H1/ i-Sensor H2 which is manufactured by Guilin Woodpecker Medical Instrument Co., Ltd.

Woodpecker is a high-tech enterprise researching, developing, producing and selling dental products. It owns a sound quality control system. To ensure that you use the equipment correctly and safely, please read the full text of the instruction manual carefully before use.

Caring for your environment

This symbol indicates that this product is not to be disposed of with your residential or commercial waste.

Recycling Equipment

Please do not dispose of this product with your residential or commercial waste. Improper handling of this type of waste could have a negative impact on health and on the environment. Some countries or regions, such as the European Union, have set up systems to collect and recycle electrical or electronic waste items. Contact your local authorities for information about practices established in your region. If collection systems are not available, call Customer Service for assistance.

Disclaimer

Woodpecker shall not be liable to the purchaser of this product or third parties for any damage, loss, or injury incurred by purchaser or third parties as a result of fire, earthquake, any accident, misuse or abuse of this product.
Woodpecker shall not be liable to any damage, loss, or injury arising from unauthorized modifications, repairs, or alterations to this product or failure to strictly comply with Woodpecker's operating and maintenance instructions.
Woodpecker shall not be liable for any damage or loss arising from the use of any options or consumable products other than those dedicated as Original Products by Woodpecker Technology.
Information regarding specification, compositions, and appearance of this product is subject to change without prior notice.

Copyright

Symbols and Conventions

The following symbols and conventions are used throughout the user guide.

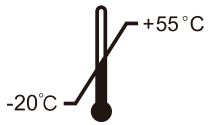
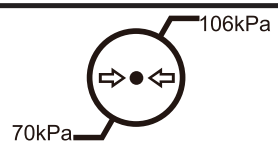
⚠ WARNING	This symbol is used to identify conditions under which improper use of the product may cause death or serious personal injury.

⚠ CAUTION	This notice is used to identify conditions under which improper use of the product may cause minor personal injury.
CAUTION	This notice is used to identify conditions under which improper use of the product may cause property damage.
 Prohibited	This is used to indicate a prohibited operation.
	This is used to indicate an action that must be performed.
 Important	This is used to indicate important operations and restrictions.
 Information	This is used to indicate operations for reference and complementary information.

Labels and markings on the equipment

The contents of the labels and markings on i-Sensor H1 / i-Sensor H2 product are indicated below: i-Sensor H1 / i-Sensor H2

Symbol	Guide
	Caution: please refer to the instructions in the user manual.
SN	This symbol is used to identify the manufacture's series number which is after, below or adjacent to the symbol.
CE 0344	CE Mark
	This symbol is used to indicate the name and address of the manufacturer.
EC REP	Authorized Representative in the EUROPEAN COMMUNITY
	This symbol is used to indicate consultation of the user guide for general information.
	Safety Signs: please refer to the user guide for safety instructions.
	Type BF applied part
IP68	IP Grade of the sensor

Symbol	Guide
	Package symbol, fragile, handle with care
	Package symbol, keep away from rain
	Package symbol, the package shall be stored, transported, and handled within temperature limits.
	Humidity limitation
	Temperature limitation
	Intended for a single use
	The date of manufacture
	Do not use if package is damaged

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1 SAFETY INFORMATION

1.1 Safety precautions

Follow these safeguards and properly use the equipment to prevent injury and damage to any equipment/data.

WARNING	
Installation and environment of use  Prohibited	• Do not use or store the equipment near flammable chemicals such as alcohol, thinner, benzene, etc. • If chemicals are spilled or evaporate, it may result in fire or product damage through contact with electric parts inside the equipment. • Do not connect the equipment with anything other than specified. • Doing so may result in personal injury or product damage. • Do not install or use in the following environment, or it may cause fire, personal. injury or product damage: Facilities near water sources In direct sunlight Close to air condition or ventilation Dusty to a heat source as a heater In a salty or acidic environment Ice or condensation In the environment easy to vibrate

WARNING	
Handling  	Never disassemble or modify the equipment. No modification of this equipment is allowed. • Follow the below instructions to prevent damage to the sensor and cable Do not twist, bend, pull and pinch the cable strongly Do not strike or drop the equipment. Do not touch the pin of the usb connector Do not put the equipment and pointed objects together.
When a problem occurs	Please unplug the usb connector when a problem happened and contact the supplier or local dealer: • When there is smoke, an odd smell or abnormal sound. • When liquid has been spilled into the equipment or a metal object has entered through an opening. • When the equipment has been dropped and damaged.
Maintenance and inspection 	Before operation every day, the following contents of the product should be routinely • checked to ensure that the product can operate correctly, safely and effectively • Check the sensor and cable for any damage or abnormal conditions. Do not use if damaged • Check that the PC and software are working properly. The software can log in normally.

CAUTION	
Hygienic protection and Maintenance 	• Hygienic protection The sensor should be covered with hygiene bag when you apply the sensor to a patient Note that a hygiene bag whose is single use only. Please use the bag provided by the manufacturer. Use a hygiene bag whose size fit the size of the sensor. • Maintenance Pay special attention to avoid the risk of damage when cleaning the sensor. The sensor should be cleaned frequently. a. Wet the soft cloth completely with purified water, and wipe the test sample surface thoroughly for 3 times. After each wipe, replace the clean soft cloth. If there are still visible stains, wipe repeatedly until there are no visible stains. b. Wet the clean soft cloth completely with 80% isopropyl alcohol, wipe the surface of the sensor and the front 40cm USB cable for 5 times. Wipe for 30 s each time. c. Wet the clean soft cloth completely with sterile water, wipe the surface of the test sample thoroughly for 5 times. Wipe for 30 s each time, to remove the residual disinfectant on the surface. d. Use a dry water absorbent sterile cloth to wipe off the residual water on the test sample. Note Do not immerse the sensor in disinfectants or any other chemicals Do not sterilize the product by heating, autoclaving or UV Please check whether the USB connector is dry or clean before connecting the USB connector

CAUTION	
	No valuable clinical obtained after exposure due to operational reasons or failure of the device The sensor performance was abnormal, no valuable clinical images obtained after exposure due to the interference of the equipment which is not conforming to IEC60601-1-2standard.
⚠ CAUTION	The sensor is used in conjunction with the registered x-ray machine. Installation and software operation of this product, please refer to the product user's manual. For the other operation, please refer to the operation manual of the x-ray machine.
	Any serious incident that has occurred in relation to the device should be reported to manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.2 Notes for Using

When using the equipment, take the following precautions. Otherwise, problems may occur and the equipment may not function correctly.

When a serious incident occurs, should be reported to manufacturer and competent authority as soon as possible.

Before using

• Please check whether the USB connector is dry or clean before connecting the USB connector

• Please hold the control box of the USB when plugging the USB connector, do

not touch the pin of USB connector

During using

• Do not move the USB connector during the use of the sensor

• When the sensor is working, the temperature of the sensor will increase. Please pay attention to the temperature of the sensor to avoid the risk of injury.

During exposure

• Do not move the power or Ethernet Cables during exposure, or it may cause image noise or artifacts, even incorrect images.

After using

• After the USB port is pulled out, please take care of the USB connector to avoid the risk of damage.

• The sensor should be stored in a place free of chemicals or gases and free from adverse factors such as pressure, direct sunlight, dust, oxides or sulfides.

• When the sensor is out of using, it is recommended to put it into the product package box, to avoid damage.

1.3 Storage and Operation Environment

Only in the professional medical environment and its condition:

	Temperature	Humidity	Barometric pressure
Operation	10~35°C	20~90% RH	700~1060mbar
Storage	-20~55°C	10~93% RH	

2 General Introduction

2.1 Intended use

Digital Intraoral X-ray Sensor, models i-Sensor H1 and i-Sensor H2, are intended to be used by a professional dentist. The sensor (located in the patient's mouth just like a silver film) captures the X- rays produced by the generator. Then it transmits this data to the computer to display the X-ray image on the screen.

NOTE

This manual contains information about i-Sensor H1/ i-Sensor H2. All users should read and understand this manual before using the product. All information in this manual, including illustrations, is based on the device prototype. If the device does not contain these contents, they will not apply to this device. The intended patient populations of i-Sensor H1/ i-Sensor H2 are patients who need to take dental film.

2.2 Component of the imaging sensor

The component of Digital Intraoral X-ray Sensor are sensor and Ai-Dental software.

2.2.1 IMAGE ACQUISITION WORKSTATION

The Ai-Dental software is used to acquire and display the image, patient management, examination management, image storage and image printing administration.

Note: See Chapter 3 for a detailed description of the Ai-Dental software.

2.2.2 SENSOR

The sensor i-Sensor H1/ i-Sensor H2 is a digital size-1/ size-2 intraoral sensor. It features a 20 µm pixel pitch CMOS sensor with directly deposited CsI:Tl scintillator which ensures optimal resolution. Made from a strong sealed Kevlar shell, the sensor has an ergonomic design with smooth edges, rounded corners, and a flexible cable for maximum patient comfort. An easy to use hi-speed direct USB interface enables a simple connection to a PC without need for an additional control box. The optional intra-oral software application makes it easy to acquire, enhance, analyze, view and share images from the i-Sensor H1/ i-Sensor H2 sensor.

i-Sensor H1

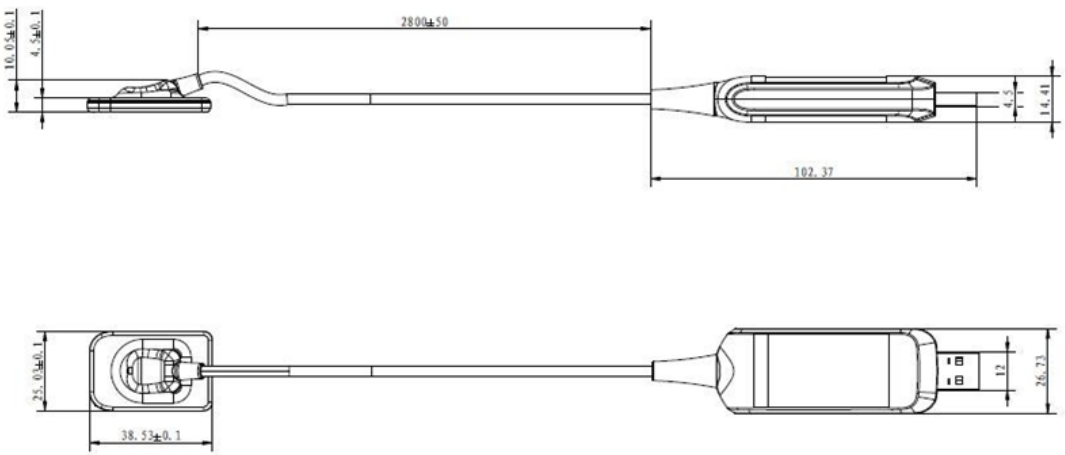


Fig.1-1 i-Sensor H1 outline(unit: mm)

i-Sensor H2

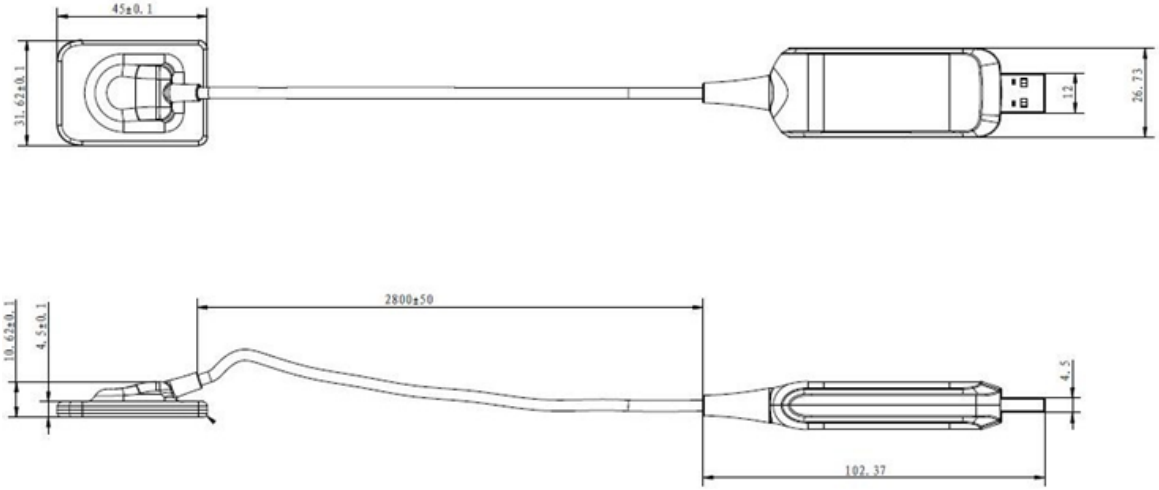


Fig.1-1 i-Sensor H2 outline(unit: mm)

Main Characteristics

CMOS detector technology
Standard Size 1 accommodate children and adults
Slim, rounded corner and smooth edge
Direct USB connectivity
AED trigger, fast and easy workflow
Durable material and components
Friendly software user interface

Technical Specification

Item	Detailed information
Purpose	Intro-oral X-Ray sensor
Largest pixel matrix	1000×1500(H1)/1300×1800(H2)
Effective imaging area	20×30(H1)/26×36(H2)
Average Pixel pitch	20μm
Scintillation Screen	CsI
Sensor size	38.5mm×25mm×4.5mm(H1)/40.0×31.0×4.5mm(H2)
Spatial resolution	Theoretical resolution: 25lp/mm Real resolution: ≥12lp/mm
Ingress Protection	IP68
Length of cable	2.8m
Interface	Direct USB, USB2.0
Power	2.5W

Software version: Firmware program version: V1.0.0;
Ai-Dental Software version: V1.0.0.

2.3 Operation Environment

PC configuration standard:

Windows®:	Configuration

Operating system	Windows® 7 or above
Processor	Intel® Core 4
Memory	8 GB or above
Hard disk	500 GB or above
USB port	4 high-speed USB 2.0 ports
Display board	NVIDIA GT710
USB chip	Intel or NEC® / RENESAS®
Display resolution	1920 x 1080 or above

PC connected to the sensor must be approved by local authorities: for example, by IEC (CE certification), UL/CSA approval.

PC connected to the sensor must be supported work in an altitude less than 3000m

The component, such as PC, connected to the i-sensor H1 / H2 shall not be placed in the patient environment and shall comply with IEC 60601-1-1 (EN60601-1-1). The minimum horizontal distance between the patient and these components is 1.5 m. The minimum vertical distance between the patient and these components is 2.5 m. The operator should not to touch parts which are not comply with IEC 60601-1 and the patient simultaneously.

In order to prevent the computer from being powered off during shooting and unable to complete normal shooting, desktop PCs need to be equipped with

uninterruptible power supply (UPS) to avoid the harm of secondary X-ray exposure to patients.

Compatible X-ray generator

The compatible X-ray source voltage of the sensor is 60-70kV and 1-8mA.

2.4 Cybersecurity related instructions

2.4.1 Operating environment

(1) Recommended hardware/software configuration

Perform hardware/software configuration in accordance with 2.3 PC configuration requirements.

(2) Network conditions

Network environment: With a local area network, the client and server are in the same local area network.

2.4.2 Security Software

Ai-Dental software supports universal security software, and the security software should be an effective version that can ensure the safety of the computer system.

2.4.3 Data and equipment (system) interface

Transmission protocol: USB2.0 interface serial communication

Storage format: Images can be stored in dcm, png, jpg, jpeg, bmp, dcm.

2.4.4 User access control mechanism

When the software starts to log in, it needs to identify and verify the identity of

the logged-in user (at least the user name and password need to be checked) to obtain different permissions. The authority is divided into administrators, ordinary users, etc. The administrator has the authority to add new users, and all users have the authority to add, modify, and access patient data.

2.4.5 Software environment and relevant requirements for security software updates When the software environment and security software are updated, it will not affect the security of Ai-Dental software.

2.5 European authorized representative

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

2.6 Fixed bracket installation

The sensor fixing bracket is fixed on a flat wall by two screws. When the sensor is in an idle state, install it on the fixing bracket, as shown in the figure.

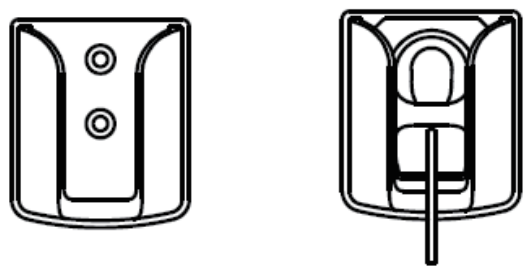


Figure 1-2

2.7 Accessories of this device

No.	Accessories	Quantity
1	U disk	1 pcs
2	Disposable protective bag	1 box
3	Sensor silicone sleeve	1 pcs

• See the packing list for other accessories of this device.

• The disposable protective bag meets the requirements of biocompatibility. To ensure the safety of the product, it is recommended to use a disposable protective bag specially designed for the i-Sensor series sensor.

3 Operating instructions

3.1 Software installation

3.1.1 Double-click the installation program, as shown in Figure 2:

Figure 2

3.1.2 Select “Setup Language”, as shown in Figure 3:

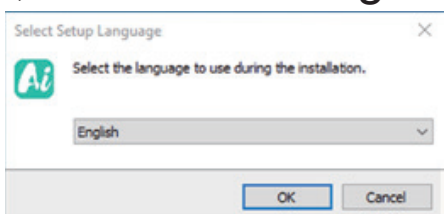


Figure 3

3.1.3 After the installation program is started, click the “Browse” button to select

the installation path. After the path is selected, click the “Next” button, as shown in Figure 4:

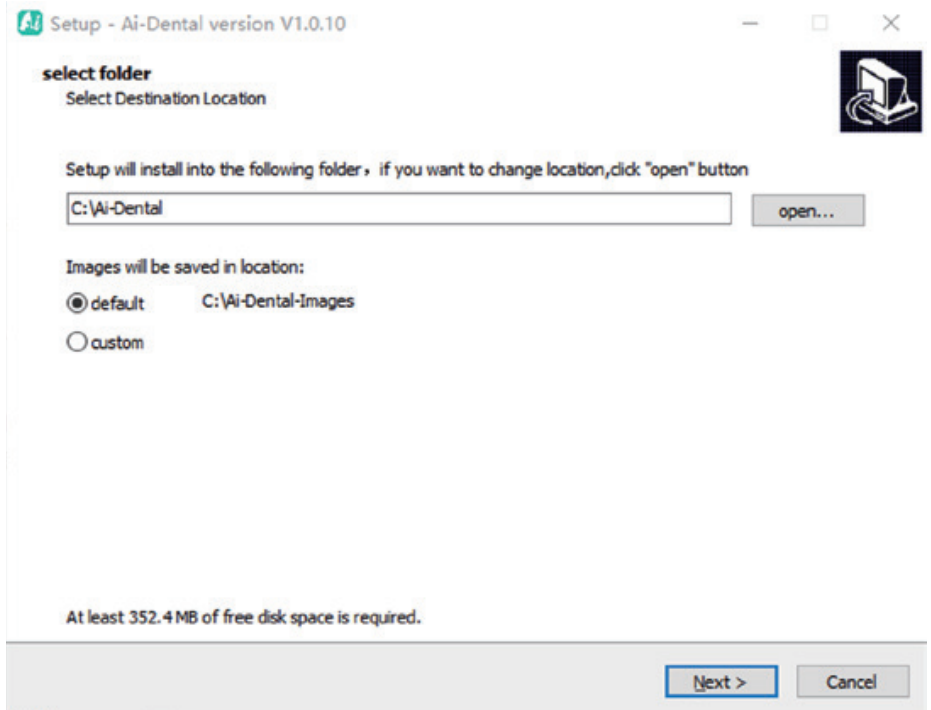


Figure 4

3.1.4 Read the software license agreement, agree to this agreement and click “I accept the agreement”, click Next to continue installation, disagree with this agreement and click “I do not accept the agreement” to exit the installation program, as shown in Figure 5.

Figure 5

3.1.5 Select components. The user selects the corresponding component as needed, and then click the “Next” button, as shown in Figure 6:

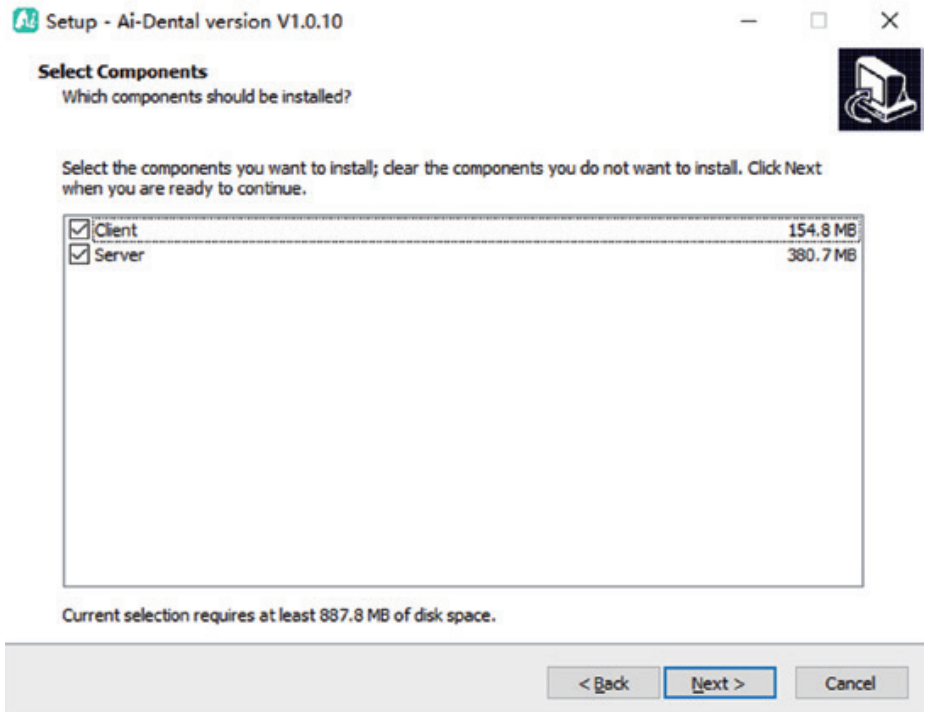


Figure 6

3.1.6 Set whether to create a desktop shortcut and server auto start, click the “Next” button after completion, as shown in Figure 7:

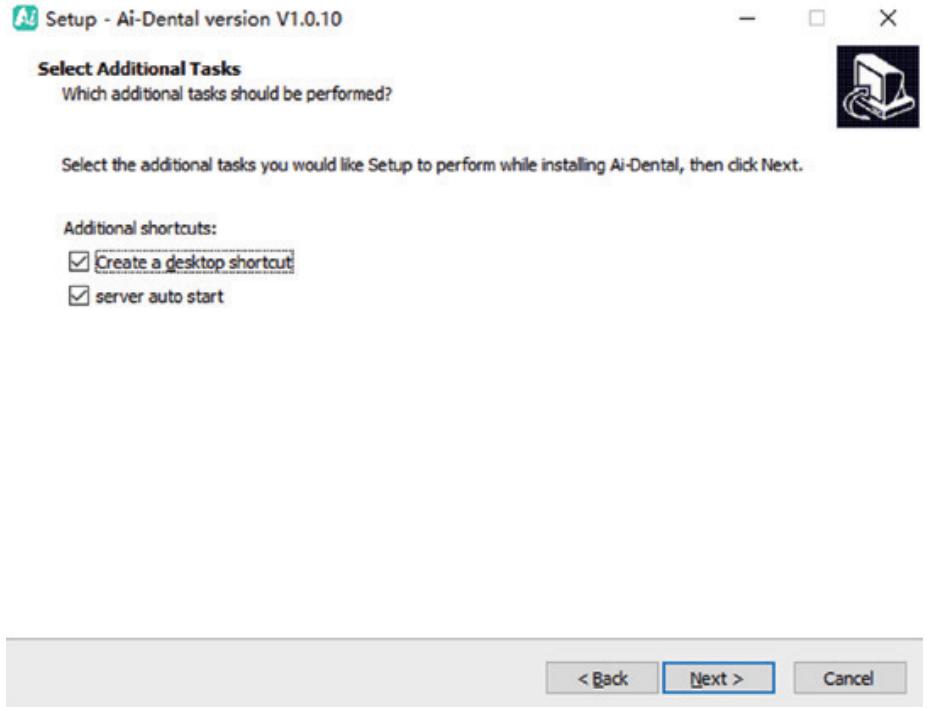


Figure 7

3.1.7 Click the “Install” button to start the installation, as shown in Figure 8:

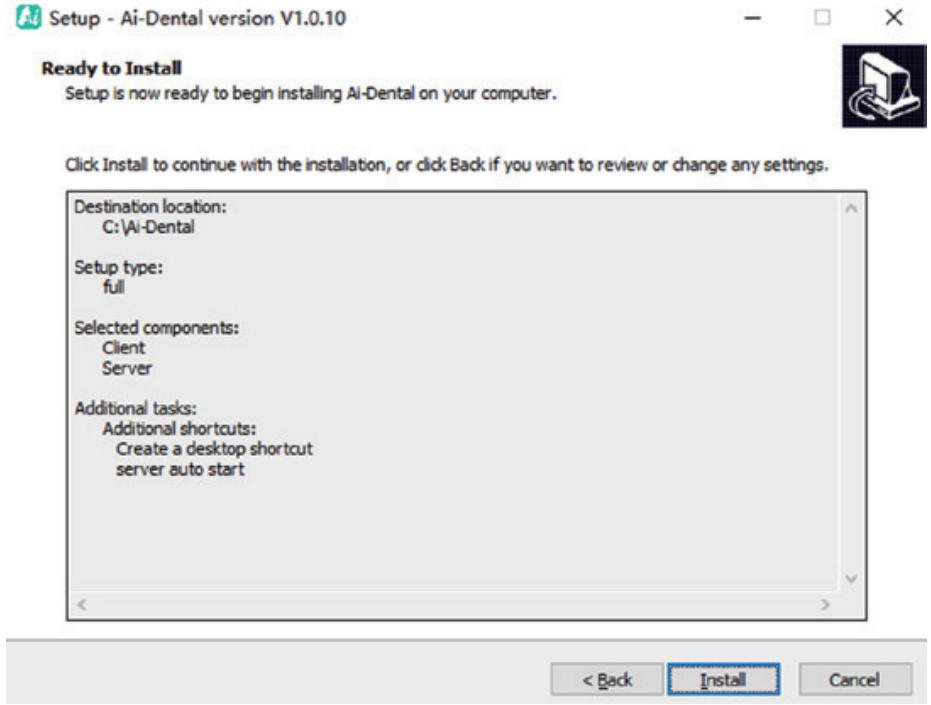


Figure 8

3.1.8 After the “Install” button is clicked, the program starts to install. The user just waits for the installation to complete, as shown in Figure 9:

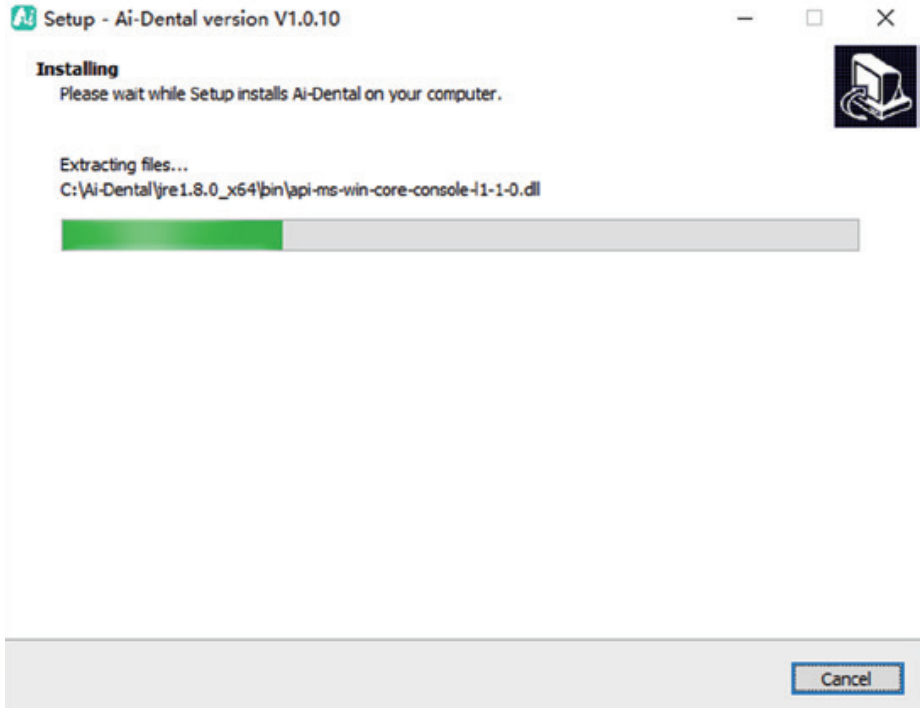


Figure 9

3.1.9 After the software is installed, click the “Finish” button, as shown in Figure 10:

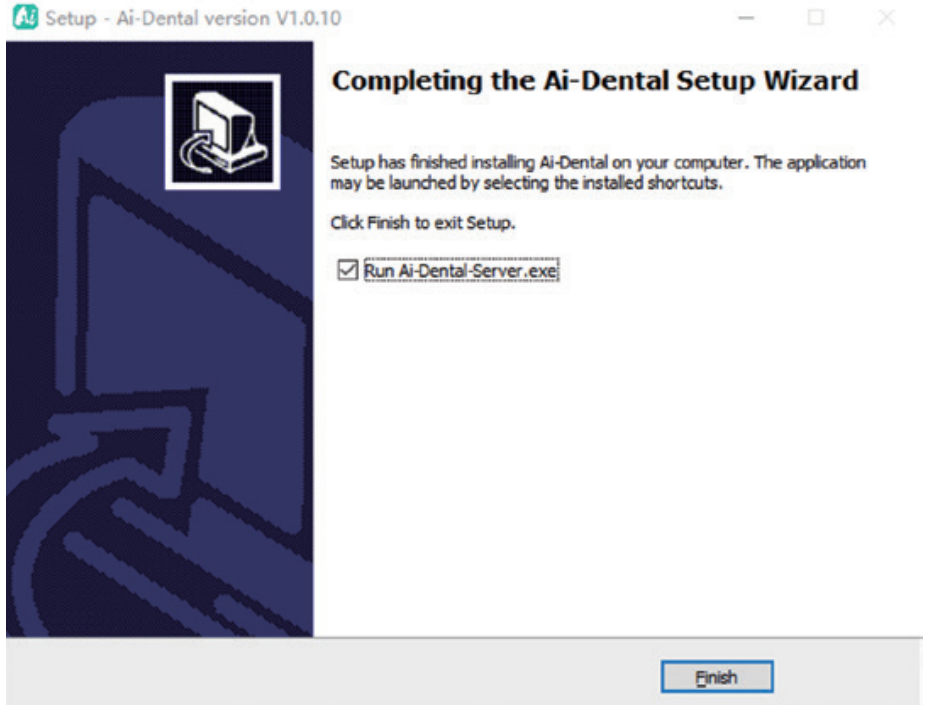


Figure 10

3.2 Shooting preparation

(1) Turn on the PC with the image software installed, and start the image processing software.

(2) Connect the USB interface of the sensor directly to the USB interface of the PC.

(3) Start the supporting dental X-ray radiation device and set the shooting parameters.

(4) Put the sensor on the silicone sleeve, then put on the disposable protective

bag, and place the sensor in the patient's mouth parallel to the long axis of the teeth, so that the effective surface of the sensor is against the teeth.

(5) Move the dental X-ray radiation device to the patient's head. Determine the position of the cone of the radiation device perpendicular to the sensor. Press the switch of the radiation device.

(6) When the exposure is completed, the imaging software downloads the X-ray image to the screen for display.

3.3 Use of disposable protective bags

In order to ensure the greatest degree of hygiene and safety for patients, the sensor must be covered with a disposable protective bag. Pay attention to the following points during operation:

(1) Put on gloves and place a disposable protective bag;

(2) Replace the disposable protective bag every time you complete a shooting;

(3) Put the disposable protective bag in a dry and clean place;

(4) The used disposable protective bags should be disposed of together with other organisms and wastes with potential infection hazards;

(5) It is best to use a disposable protective bag specially designed for the digital intraoral X- ray sensor.

3.4 Software Interface

3.4.1 Login module

Double-click “Ai-Dental-Server” to start the server. After the server is started successfully (as shown in Figure 11), double-click “Ai-Dental-Client” to start the software and enter the software login interface (as shown in Figure 12). Enter the user name and password, and click the “Login” button to log in to the main interface, as shown in Figure 13.

The first time you use the software, you don’t have a user name and password, as shown in Figure 14. Click “Sign up for free” to register the administrator, as shown in Figure 15. Enter user name, password, confirm password, and other information to register successfully. Enter the user name and password in the login interface to log in to the main interface of the software. The administrator account has user management functions such as New User, Delete User, Modify User and Search User. Ordinary users do not have user management functions. For details.

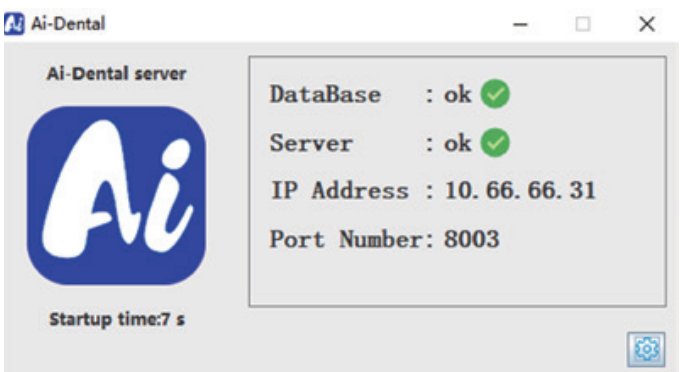


Figure 11

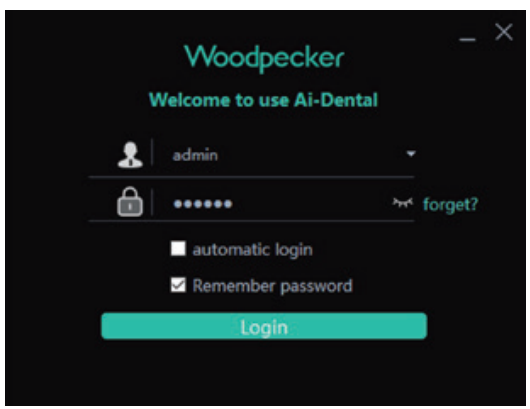


Figure 12

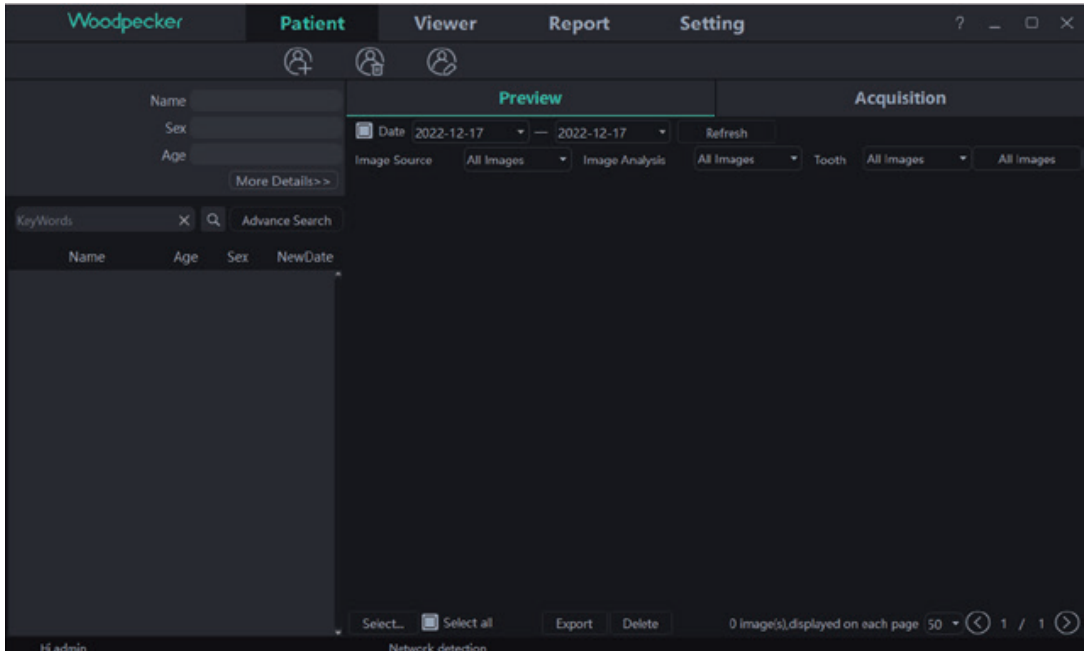


Figure 13

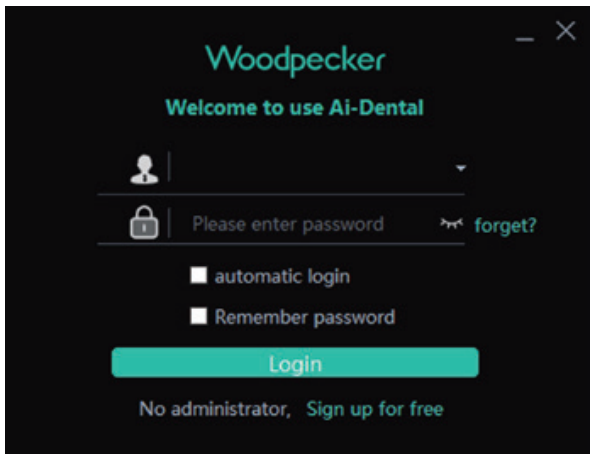


Figure 14

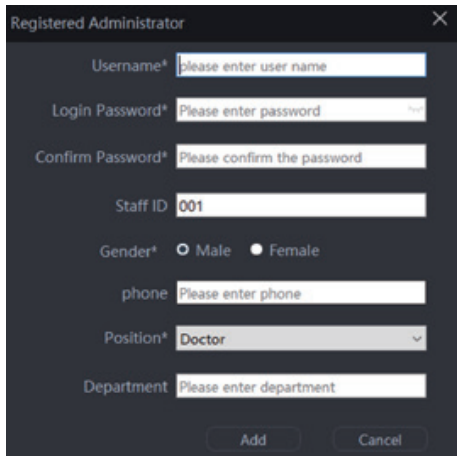


Figure 15

3.4.2 Patient module

Click the “Patient” button to enter the patient module.

1. Add, delete, modify and query patients

The patient toolbar is as shown in Figure 16. Click the “Add Patient” button to enter the information, click “OK” and a patient can be added, as shown in Figure 17. If you need to modify the patient information, click the “Modify Patient” button to modify the patient information. Click “Modify” and the modification can be successful, as shown in Figure 18. If you need to delete a patient, click the “Delete Patient” button and click “OK” after 3 seconds, as shown in Figure 19.

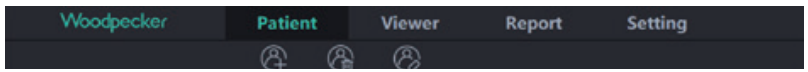


Figure 16

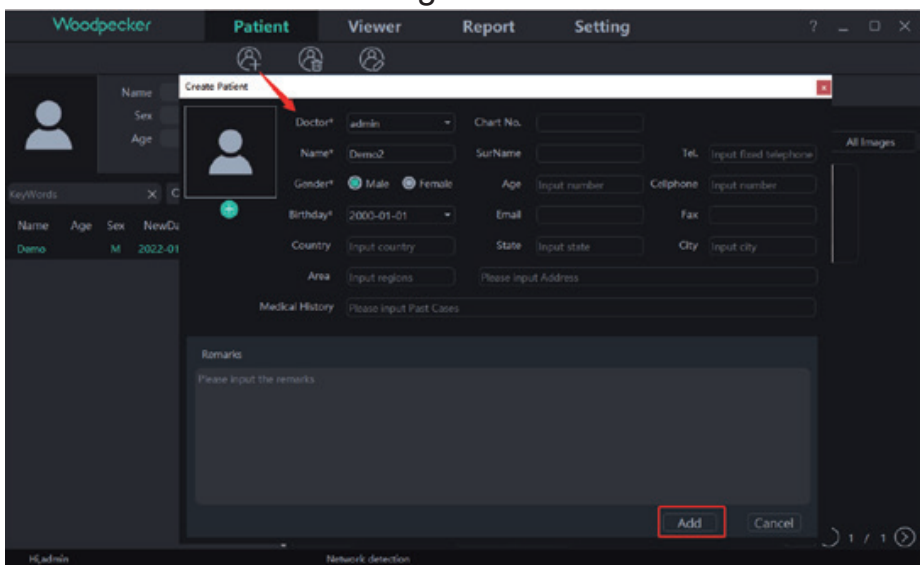


Figure 17

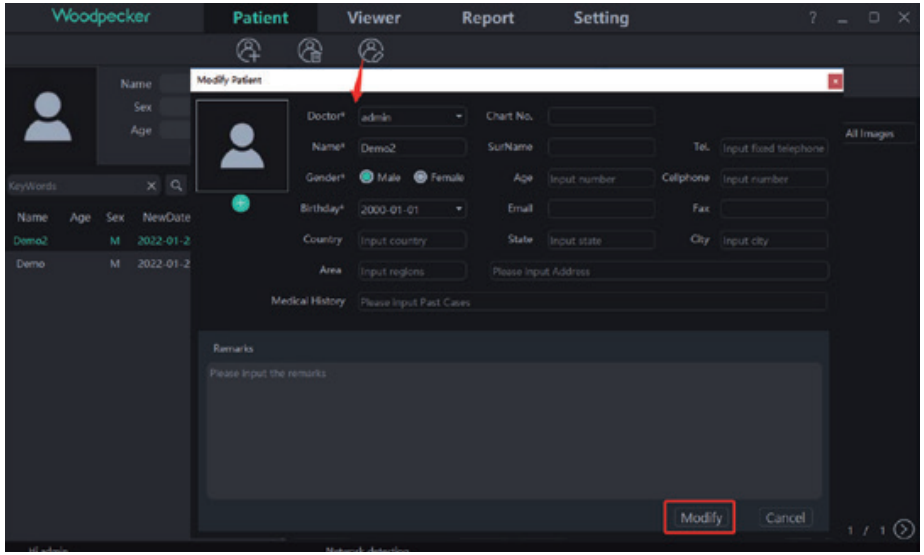


Figure 18

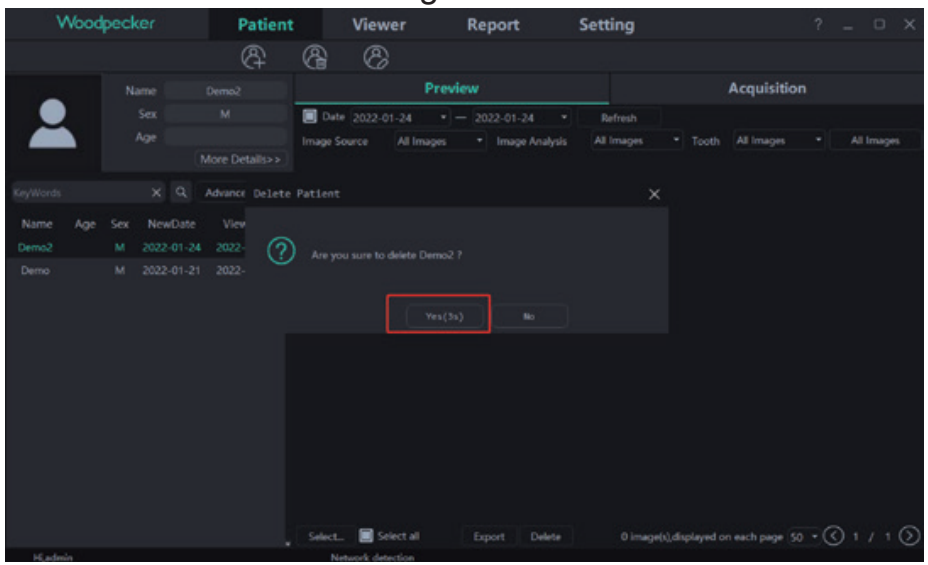


Figure 19

Select the patient in the patient list, as shown in Figure 20. The patient

information is displayed on the patient information interface. Click “More Details” to view detailed patient information. Enter patient information in the search bar. Click “Advance Search”, enter or select information such as New Date, Age, Sex, and Doctor, and click the search button to query the specified patient. If you only want to view the patients created by the current user, select “Current User” in the Doctor option, as shown in Figure 21.

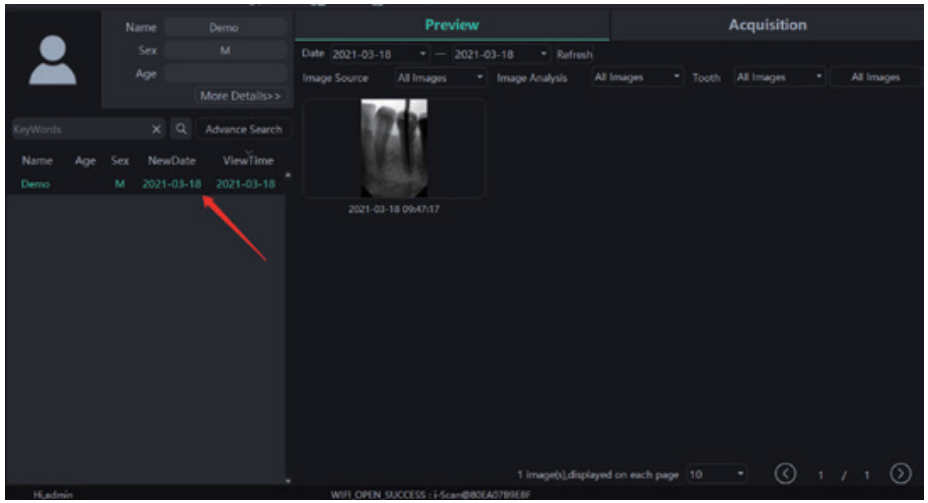


Figure 20

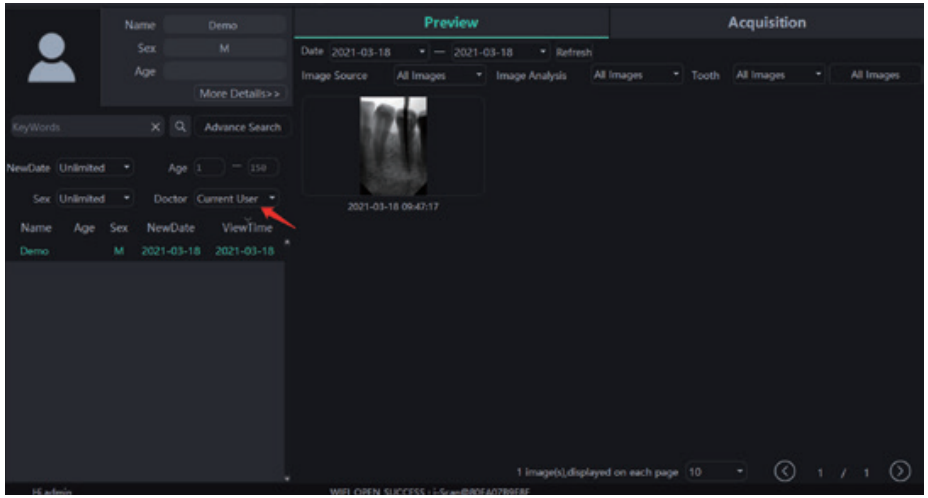


Figure 21

2. Image acquisition

Click the “Acquisition” button to enter the image acquisition interface.

a) Connect the sensor device to the computer USB interface, and select the “Sensor” device type in area 1, as shown in Figure 22. Click “Open”, the device will enter the acquisition state, and start to acquire images. At this time, the sensor serial number is displayed in the software status bar of area 2, as shown in Figure 22. When the sensor is used for the first time, the user will be prompted “Whether to download the calibration file through the network”. Click “Yes” to start the download; click “No”, the user will be prompted “Whether to manually import the calibration file”. Click “Yes” to select the calibration file to import. Generally, the image acquired by the sensor will be better after the calibration file is selected, as shown in Figures 23, 24.

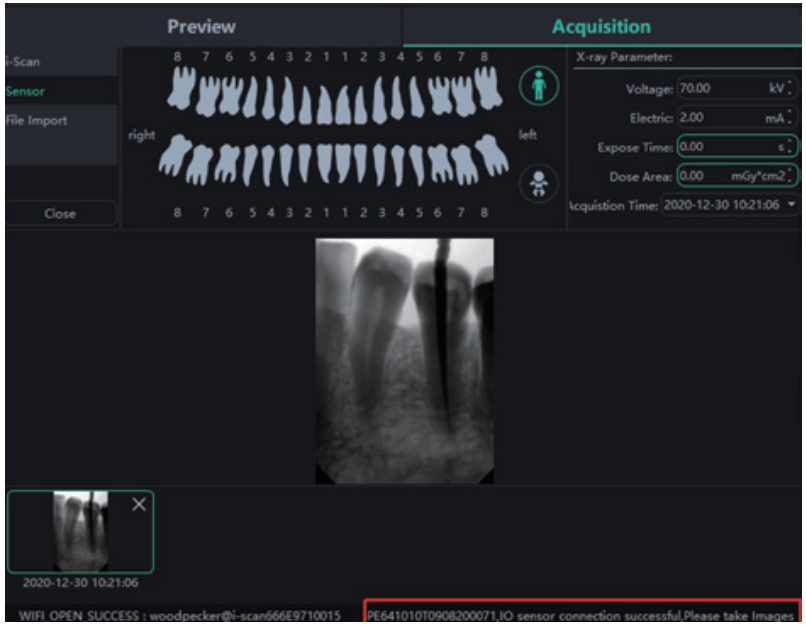


Figure 22

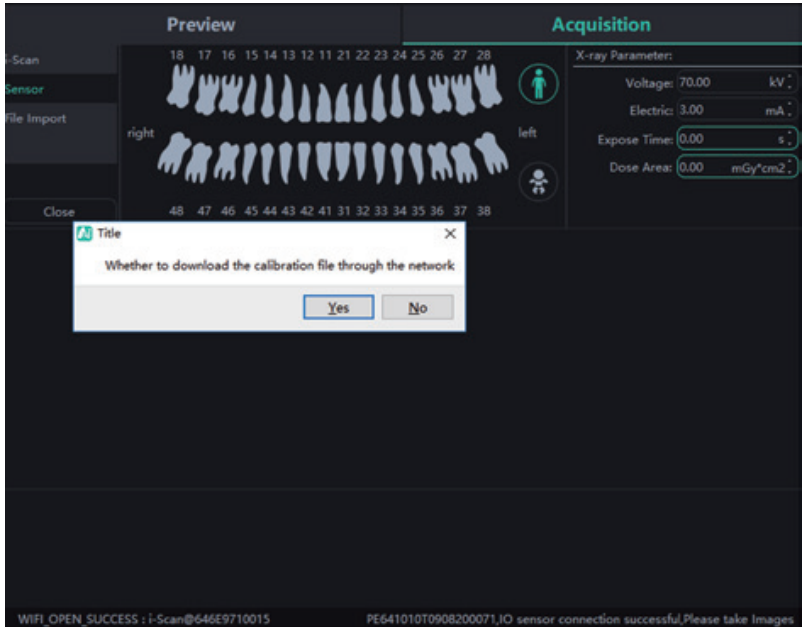


Figure 23

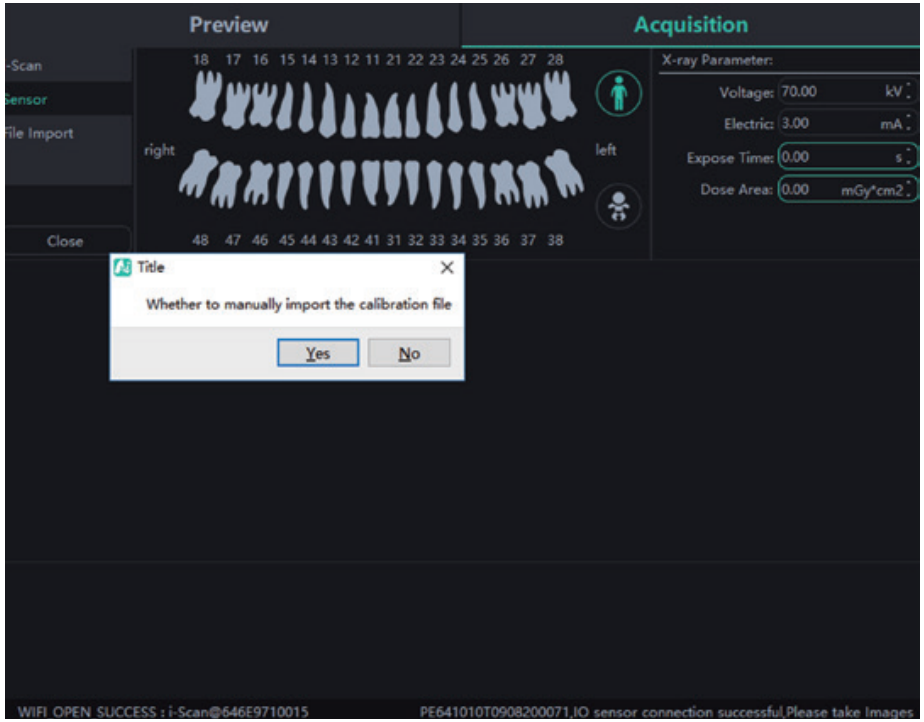


Figure 24

b) Importing files. After entering the software, click the “Acquisition” button. Select the “File Import” device type and click “Import” to enter the image selection interface. The software supports the import of images in PNG, JPG, JPEG, BMP, DCM and other formats, as shown in Figure 25. After selecting the image, click “OK” to enter the “Import image” interface, as shown in Figure 26. You can select the target patient and shooting time for each image, and click “OK” to save the image to the specified patient.

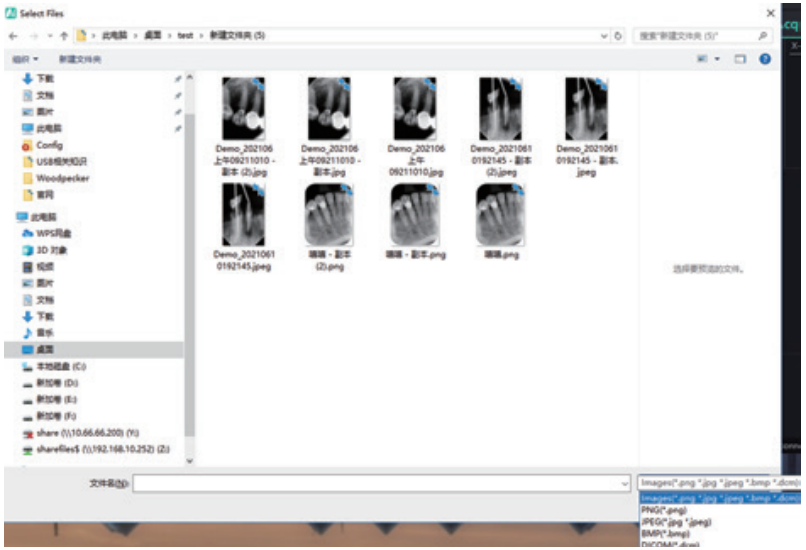


Figure 25

Figure 26

c) When the software is used for the first time, the user will be prompted to set the relevant parameters of the clinic's X-ray source. X-ray sources are divided into power frequency, medium frequency and high frequency. Select AC (Alternating Current mode) for power frequency and DC (Direct Current mode) for medium and high frequency. Triggerthreshold is the X-ray dose trigger threshold. The voltage and current are set according to the X-ray source parameters, as shown in Figure 27:

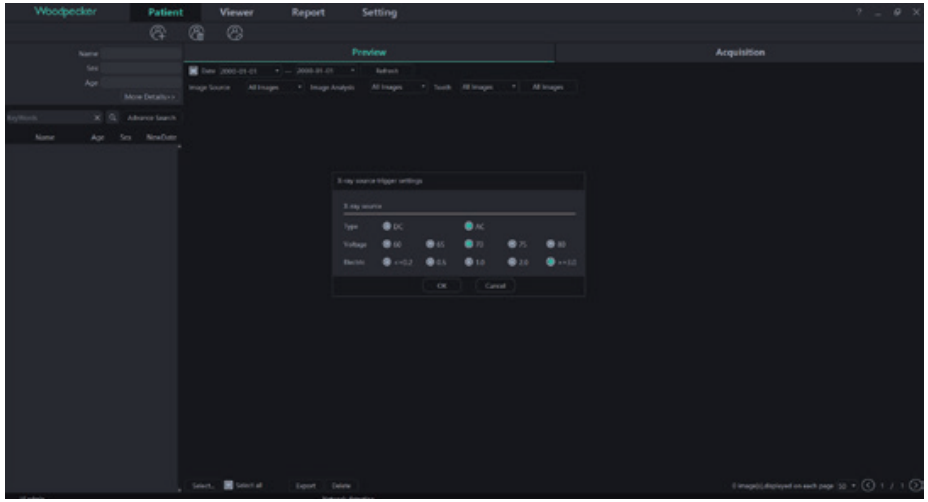


Figure 27

d) During the acquisition, problems such as network instability may be encountered, resulting in the failure of image saving. In this case, there is an image saving failure mark in the lower right corner of the image. Right-click the image and it can be exported to local and saved again, as shown in Figure 28 and Figure 29.

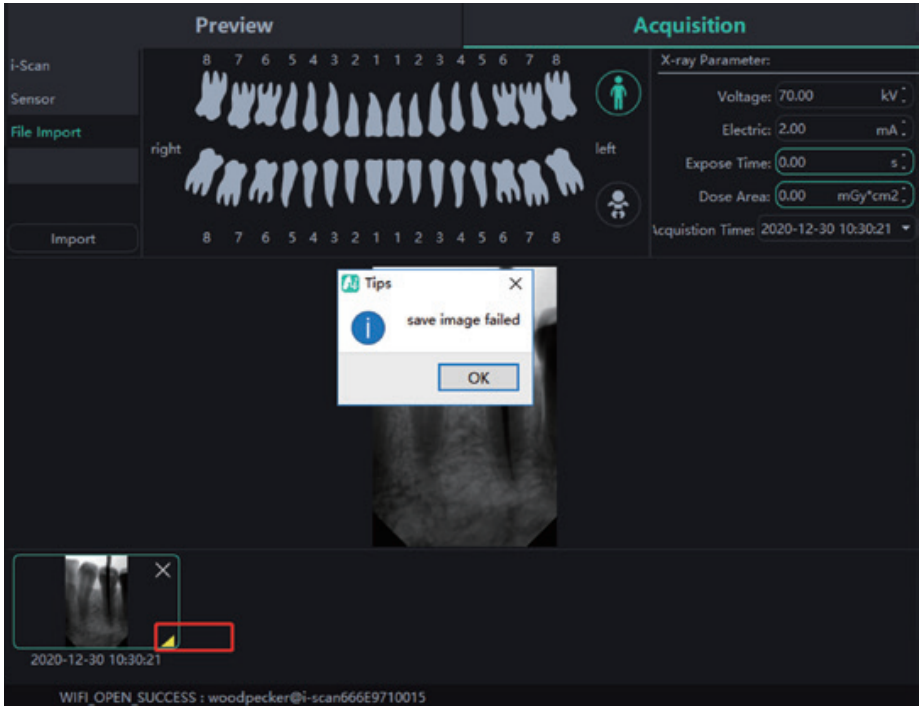


Figure 28

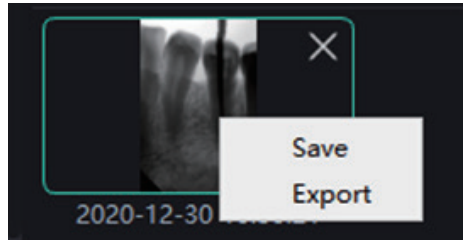


Figure 29

3. Image preview

Click the “Preview” button to view acquired images. Select an image, right-click and select “Export” to export the image to the local. Select “Information” to view the information of the image. Select “Delete” to delete the image after the user confirms to delete. Double-click the image to enter the diagnosis interface. If you want to delete or export multiple images, you can click “Select...” to select the images you want and then export or delete them. As is shown in Figure 30,31:

The image preview interface has filter image functions such as Date, Image Source, Image Analysis, Tooth Profile, All images, etc. Click the “Refresh” button, and the software will synchronize the latest image data of the patient and display it in the image list.

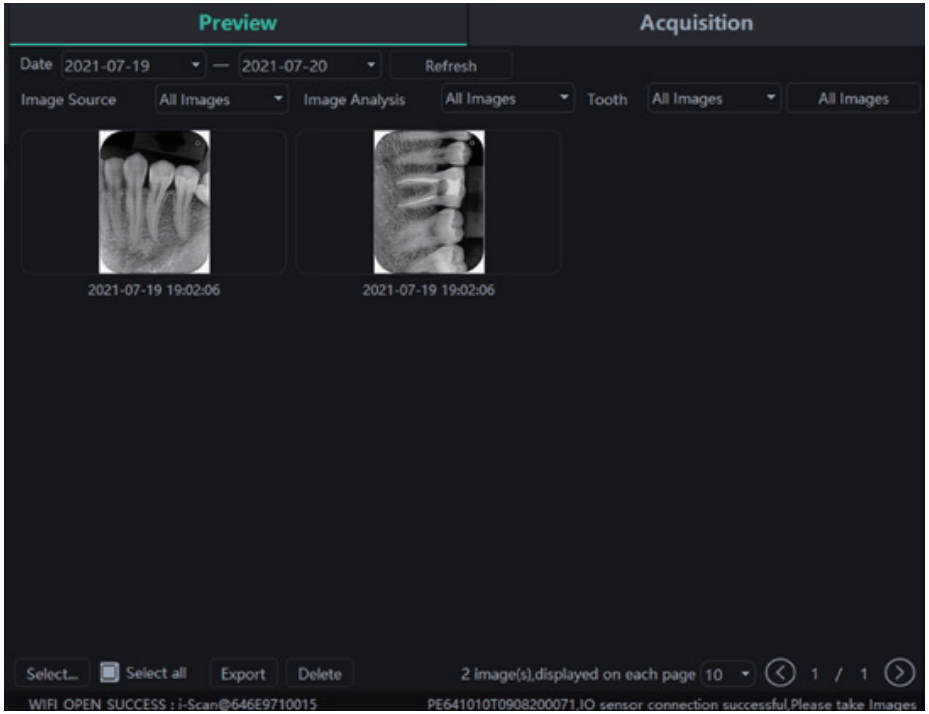


Figure 30

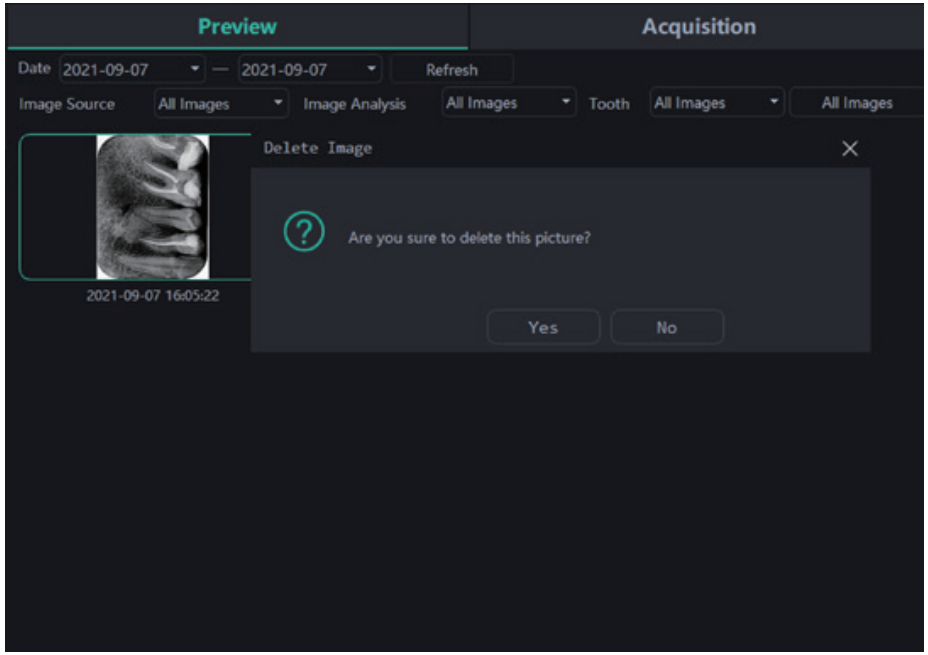


Figure 31

3.4.3 Diagnosis module

Click the “Diagnosis” button to enter the diagnosis module.

Click the image on the left to select an image to be processed. There are image processing tools on the right side of the diagnosis interface, such as Display, Image Correction, Measuring, View, Enhance, Sharpening, Histogram, Annotation, etc. Hover the mouse arrow over the image processing function, and the corresponding image processing function description will be displayed. Select the image processing tool and adjust the image quality to a satisfactory level. In the Enhance, click the “HD” button and the image will be enhanced.

Click the “HD” button again to cancel the enhancement.
Use image processing tools to adjust image quality. Click the “Add Temporary State” button to save the image quality at this time. Select the temporary state in the drop-down box to reproduce the image.
There are delete, export, and image information functions above the processed image. These functions are similar to the corresponding functions of the patient module. When multiple images are selected for processing, click the “Clear” button to close them all.
Move the mouse wheel up and down to zoom in and out of the image. Hold down the right button and move the mouse up to increase contrast, move down to decrease contrast, move left to decrease brightness, and move right to increase brightness.
Select an image, and click the linear measurement icon (or angle measurement icon) in the Measuring. Click the left mouse button to form the starting point and move the mouse. Click the left mouse button again to form the end point and right-click the end point to end the measurement. The measurement line will be displayed on the image, and meanwhile the corresponding annotation of the measurement line will be displayed in the Annotation, as shown in Figure 32:
For images acquired by File Import, TWAIN, etc., the measured value may be inaccurate, and can be calibrated through the calibration function. Select the measurement line, enter the actual length of the measurement line in the

Measuring, and click the “Modify” button to perform calibration.

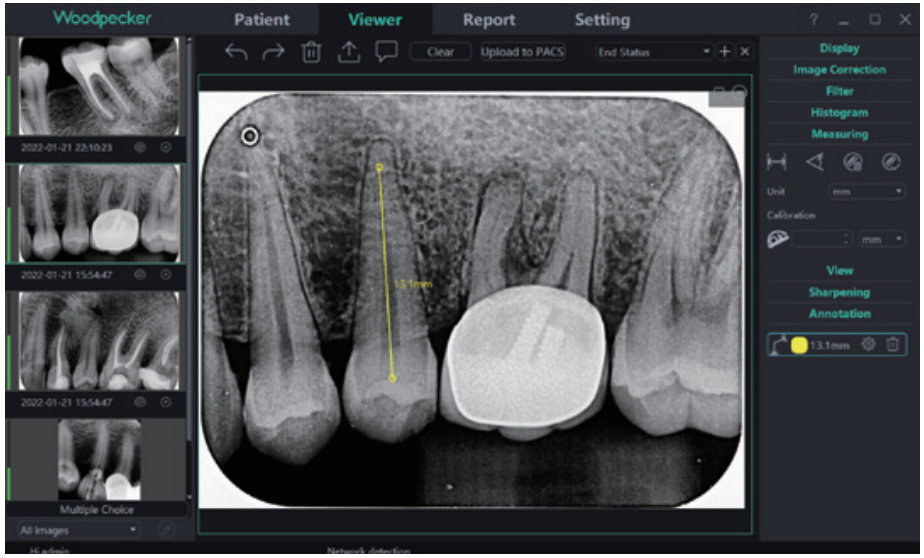
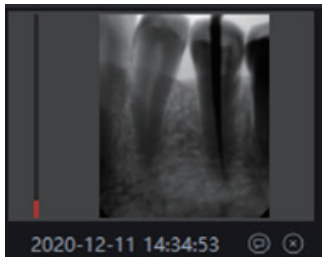


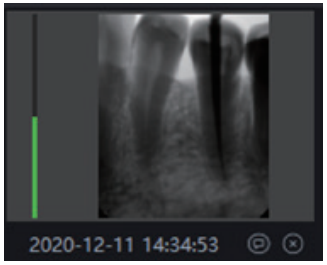
Figure 32

The dose of the image taken by digital intraoral X-ray sensor will be displayed on the left color column in the preview image on the left side of the diagnostic module. Red column indicates that the dose is too low; orange and relatively low column indicates that the dose is relatively low; green column indicates that the dose is appropriate; orange and relatively high column indicates that the dose is relatively high; red column indicates that the dose is too high, as shown in Figure 33:

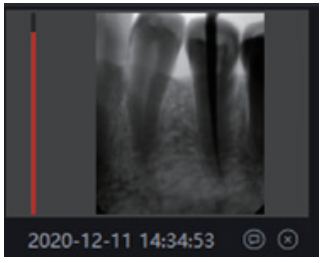


(1)Too low dose

(2)Relatively low dose



(3)Appropriate dose



(4)Too high dose

Figure 33

Image processing function list

	Adapt to window		Zooming to 100%
	Forward rotation 90°		Reverse rotation 90°
	Left and right reverse		Up and down reverse

	Brightness		Contrast
	Gamma		Pseudo-color
	Reverse		Intra-oral Caries
	Intra-oral High Definition		Intra-oral Fine
	Straight line measurement		Angle measurement
	Delete measurement		Scale
	Calibration line		Flash lamp
	Magnifying lens		Contour enhancement
	Relief		

3.4.4 Report module

Click the “Report” button to enter the report module. Click the “New Report” button to create a new report template. Drag an image from the left to the image box, and enter the diagnosis result in the text box, etc. If you need more pages,

click “Add Page”, and a page will be added to the report. After writing the report, click the “Save to Server” button to save the report to the server. When you want to view the report, click “Open Report”, select the report you want, and click “Open” to view. Click the “Export to PDF” button to export the report to the local. As is shown in Figure 34:

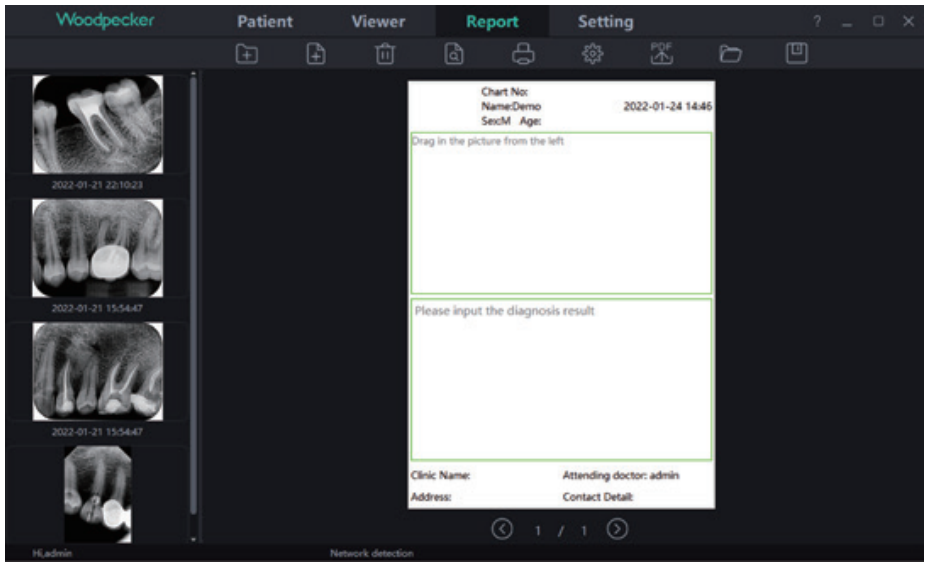


Figure 34

3.4.5 Setting module

Click the “Setting” button to enter the setting module.

1) Basic setting

Click the “Basic Setting” button to enter the basic setting page. Click the “Sign Out” button to return to the login interface. Click the language drop-down box to select the software language. Click the tooth profile drop-down box and select

the tooth profile number. As is shown in Figure 35:

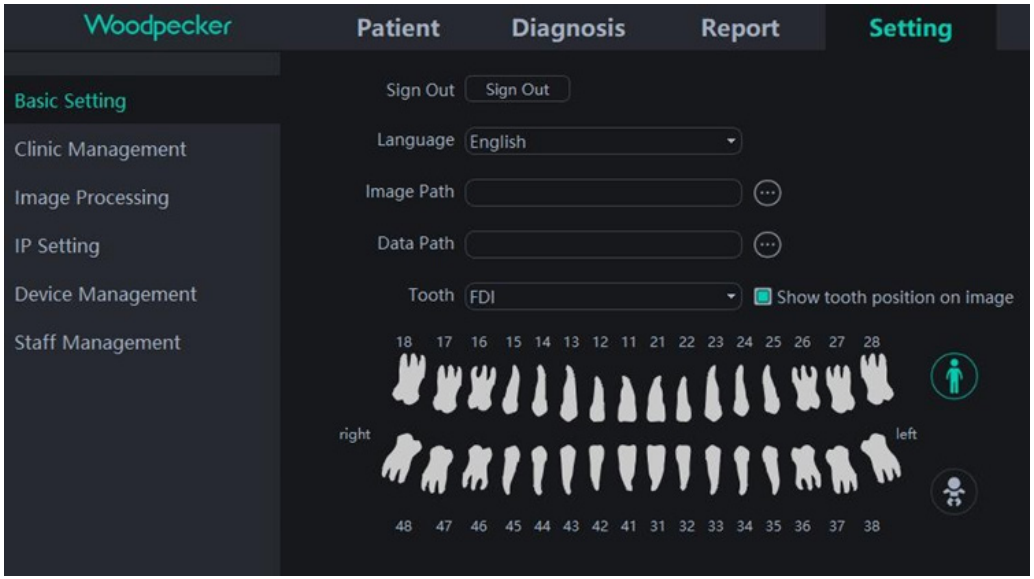


Figure 35

2) Clinic management

Click the “Clinic Management” to enter the clinic management interface and enter the clinic information, as shown in Figure 36:

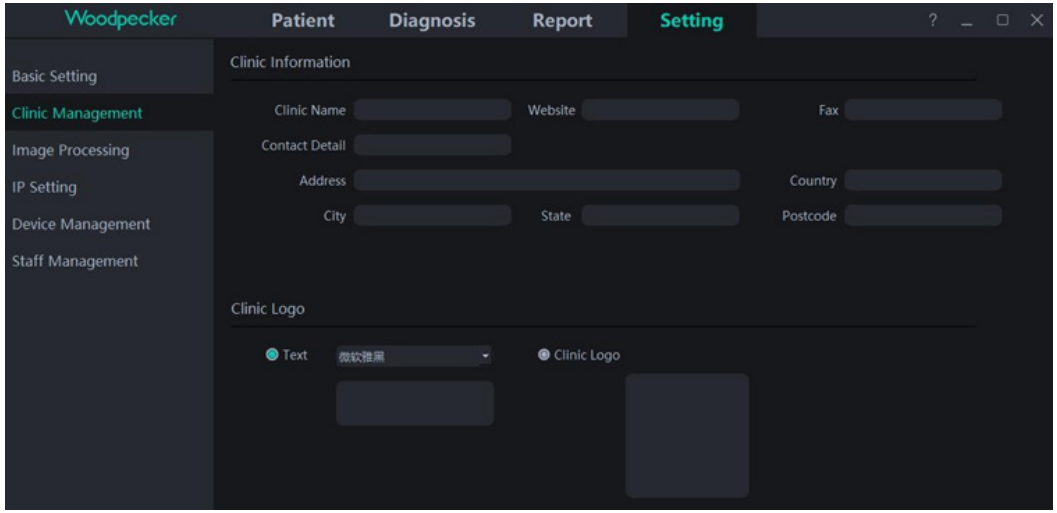


Figure 36

3) Image processing

Click the “Image Processing” button to enter the image processing interface. Select the HD checkbox, select “HD”, and the acquired image will be initialized and HD processed automatically. Select “Fine” and the acquired image will automatically undergo initialization and fine processing.

Click the “Setting” button to set the initial color of the measurement line of the diagnostic module. As is shown in Figure 37:

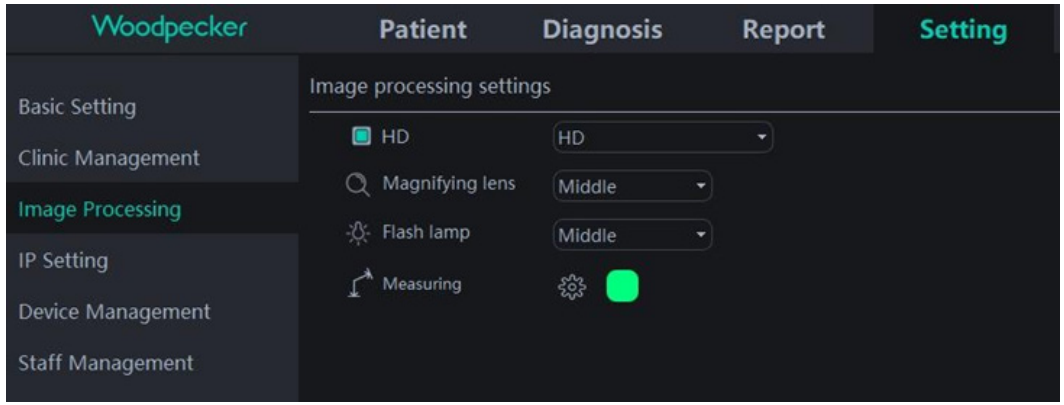


Figure 37

4) IP setting

Click the “IP Setting” button to enter the IP setting interface. Enter the IP address and port number. Click “Connection Test” to view the test result. Click “Modify” to switch the connected server, and the software need restarting at this time. As is shown in Figure 38:

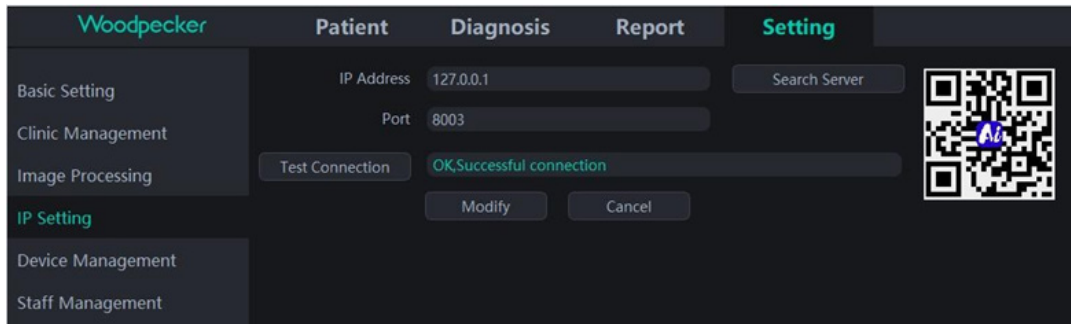


Figure 38

5) Device management

Click the “Device Management” button to enter the device management

interface, as shown in Figure 39:

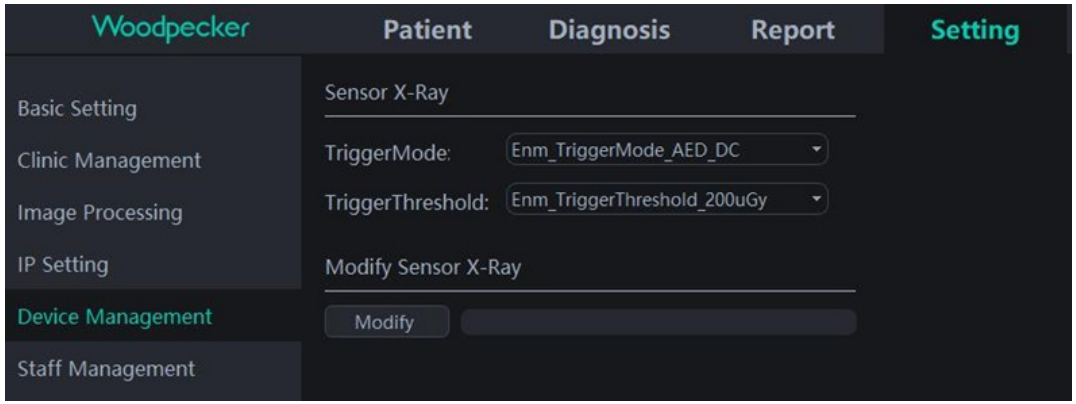


Figure 39

Before using this function, you need to determine whether the sensor is successfully connected and whether “IO sensor connection successful, Please take images” is displayed in the lower right corner. If it does not appear, please go to the acquisition interface in the patient interface to connect the sensor. As is shown in Figure 40:

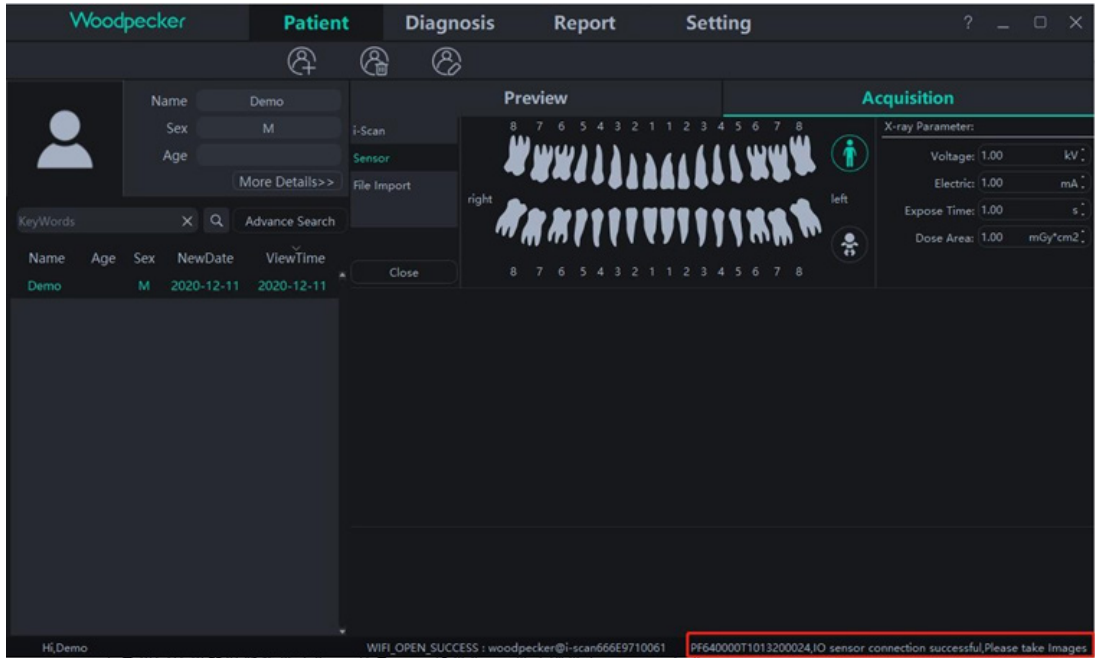


Figure 40

After the connection is successful, return to the device management interface in the setting interface to set the sensor parameters. Before setting new parameters, first determine whether the X-ray trigger mode is AC or DC. If it is DC mode, set “TriggerMode” to “Enm_TriggerMode_AED_DC”,and “TriggerThreshold” to “Enm_TriggerThreshold_50uGy”; if it is AC mode, set“TriggerMode”to“Enm_TriggerMode_AED_AC”,and “TriggerThreshold” to “Enm_TriggerThreshold_50uGy”. Then click “Modify” and “Ok”, Setup succeeded” will be displayed after the modification is successful. As is shown in Figure 41:

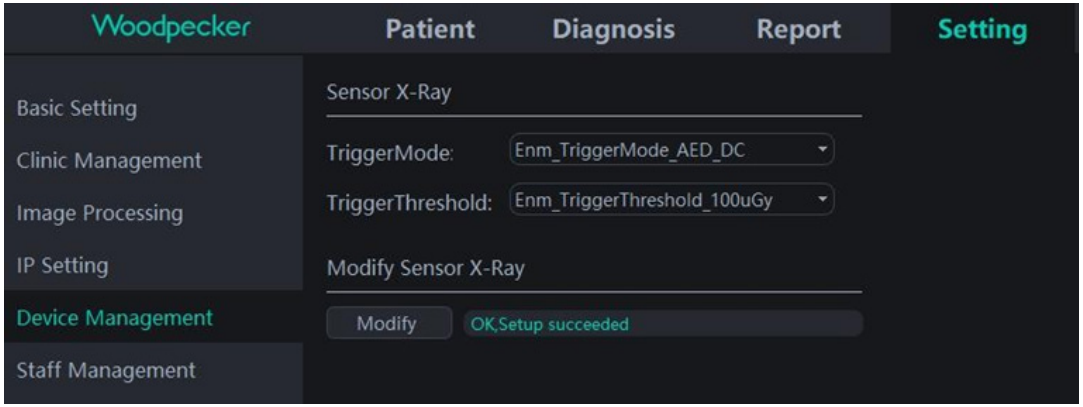


Figure 41

If there is no picture during the shooting process, the exposure time can be appropriately adjusted to re-expose. If the picture still cannot be produced, set “TriggerThreshold” to “Enm_TriggerThreshold_100uGy” or “Enm_TriggerThreshold_200uGy” for re-exposure. If the picture still cannot be produced, please contact the relevant personnel.

Note: If incorrect parameter settings are made or the sensor is not connected, “Sorry, Setup failed” will appear and the previous parameters will be displayed, as shown in Figure 42:

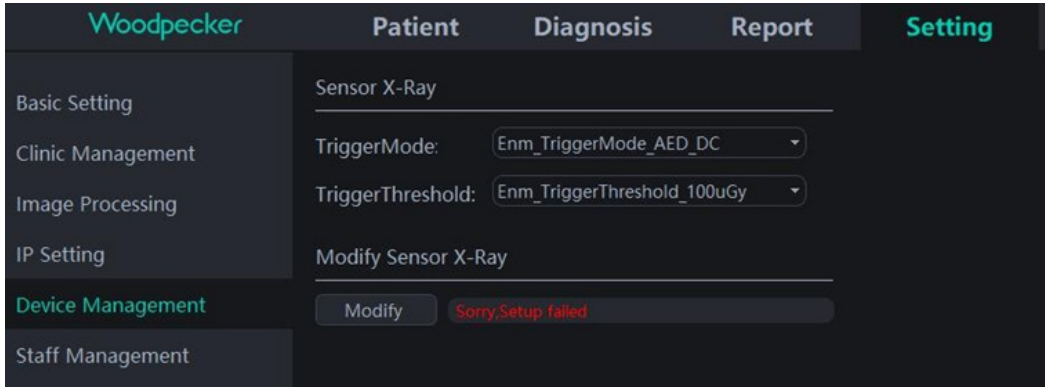


Figure 42

6) Staff Management

Only when the administrator account is logged in to the software, there will be a “Staff Management” button in the setting module. Click the “Staff Management” button to enter the staff management interface, as shown in Figure 43.

The staff management interface has the functions of New User, Delete User, Modify User and Search User. Click the New User and enter the User Name, Login Password, Confirm Password and other information, as shown in Figure 44. Enter the user name in the search bar to query the specified user. Double click the staff information bar to query the details of the user.

When the administrator forgets the login password, open the server interface. Click the “Setting” button -> click “Password” -> check “Show password”, you can view the administrator password, as shown in Figure 45. If an ordinary user forgets the login password, double-click the staff information bar, and the staff information interface will pop up. Press and hold the password viewing button,

the login password input box will display the staff's password, as shown in Figure 46. The problem of forgetting the password can also be solved by changing the staff's password.

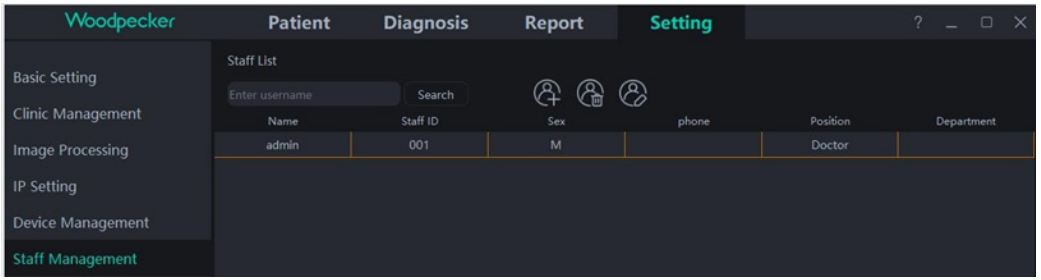


Figure 43

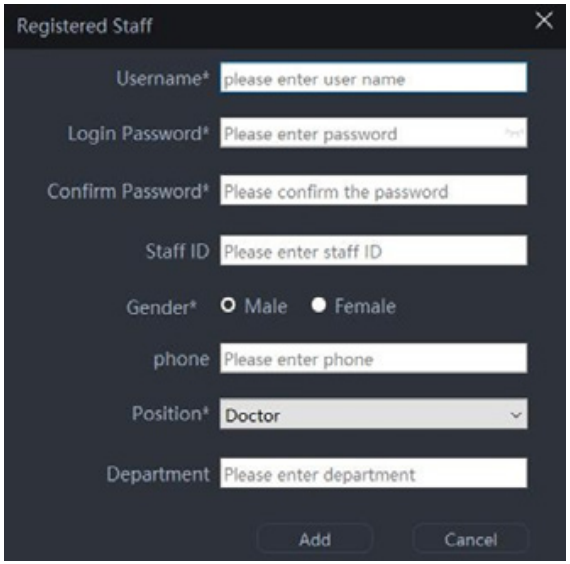


Figure 44

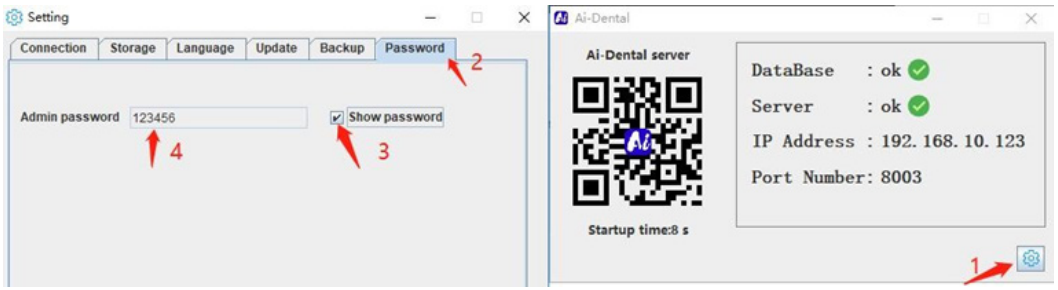


Figure 45

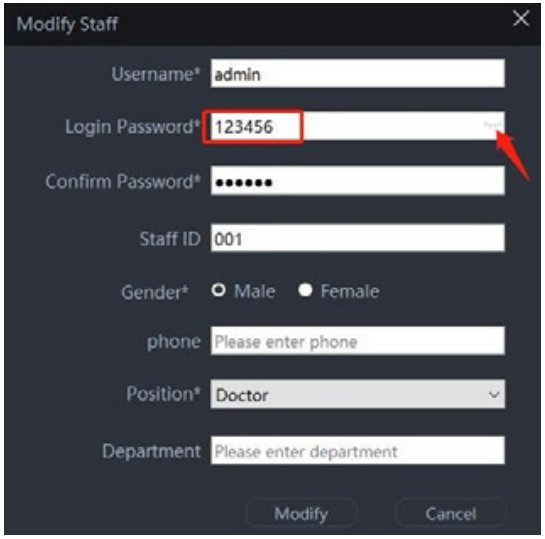


Figure 46

3.4.5 Help document

Log in to the main interface of the software and click “?” on the upper right corner. There are online help documents such as Ai-Dental manual, App Manual, i-Scan Manual, FAQ, etc. In addition, “About Ai-Dental” can be clicked to check the software version. As is shown in Figure 47:

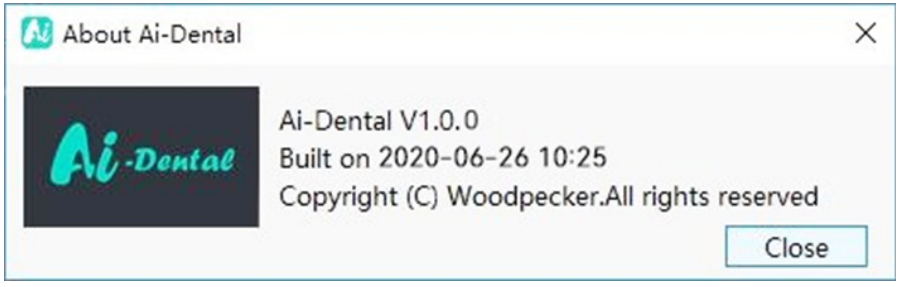


Figure 47

3.5 Software upgrade

The software has an automatic upgrade function. If the Ai-Dental server is installed on the computer and the software can be upgraded, there will be a pop-up window indicating whether to upgrade. Click “Yes”, as shown in Figure 48. After the upgrade is completed, click “Finish”, as shown in Figure 49. After started, all clients connected to the server will receive the upgrade countdown 10s. The software will automatically close after 10s, and start to upgrade. Click “No”, the software will not be upgraded temporarily.

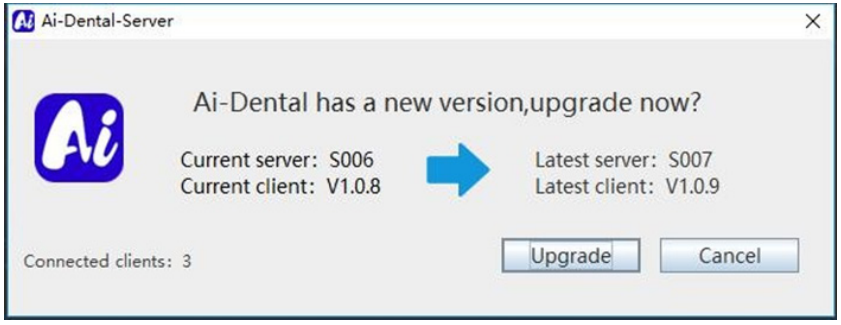


Figure 48

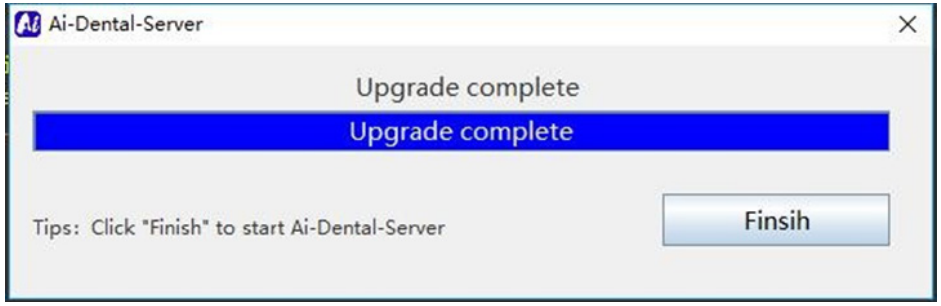


Figure 49

3.6 Software exit and shutdown safely

(1) Software exit safely

Ai-Dental software has a safe logout function. The user switches to the "Settings" interface, then clicks "Basic Settings" to enter the basic settings interface, and clicks the "Exit" button to return to the login interface. If you want to enter the system again, you need to log in again. When the user clicks the "Logout" button, the software background will clear the login information, release the session state, prevent third parties from using the background session state to obtain user data, and protect data security.

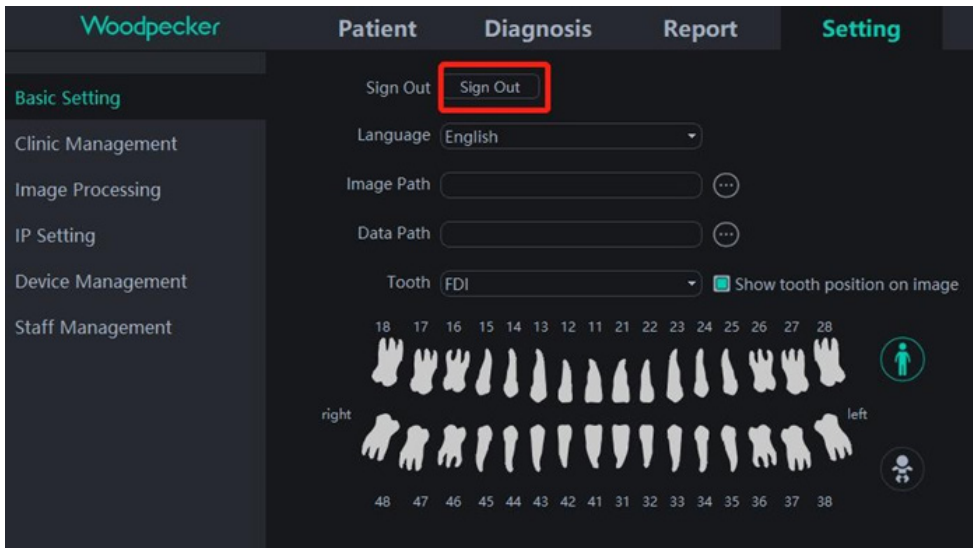


Figure 50

(2) Click the "Close Software" button in the upper right corner of the software interface, and a dialog box "Are you sure to close the software?" will pop up.

Click the "Yes" button to clear the session status and exit the software. If you want to enter the system again, you need to log in again.

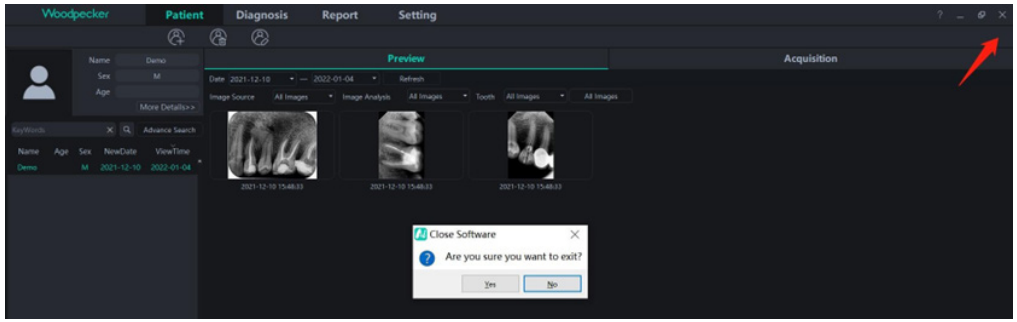


Figure 51

3.7 Exception handling

(1) In case of unclear image, please adjust the exposure time first. If repeated adjustment of the exposure time is invalid, you can go to the software “Setting” -> “Device Management” to set the sensor parameters.

(2) During the use of the software, when the server is unavailable due to some reasons, the software will enter the server disconnect interface, as shown in Figure 50. At this time, the user can check whether the network is normal or restart the server.

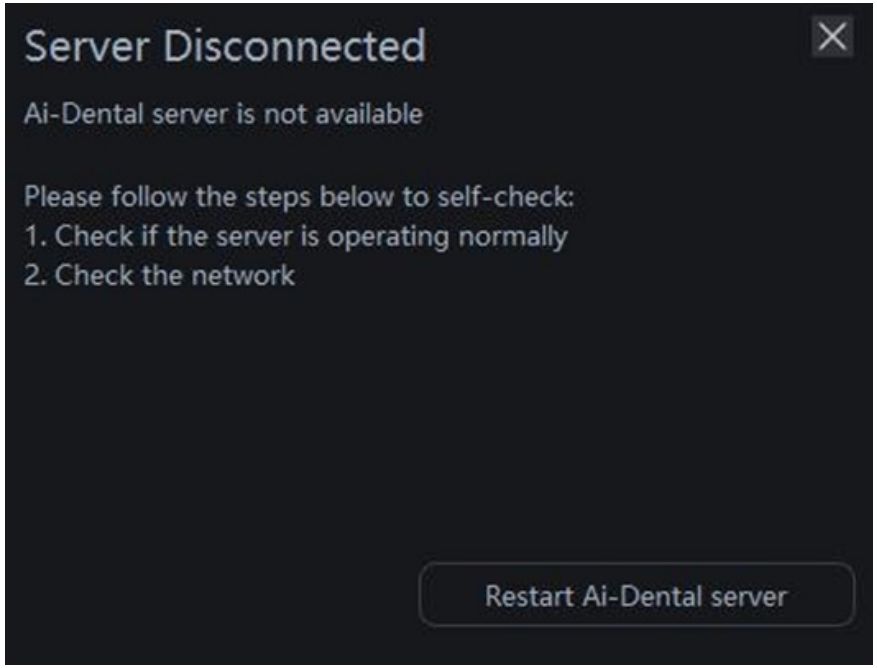


Figure 52

4 Troubleshooting

4.1 Quick troubleshooting

The following table lists the problem, cause and corrective action.

Problem	Cause	Correction action
Failure to connect sensor	Can not find device	No sensor connection The USB connector is damage Re-plug the USB connector Change the USB port and re-plug Check the cable and sensor for damage or other abnormallities
No image display	No sensor connection Sensor or cable is damged X-ray dose is too low Exposure time is too short	Check the sensor and cable Increase the distance between tube and sensor Increase mA Increase exposure time Replug the sensor and try again
Image from x-ray exposure is pale and grainy	The sensor is moving during exposure X-ray is instability The imaging surfaceofsensor is not facing the x-ray device	Fix the sensor before exposure Check the x-ray machine Check the sensor position

⚠ If the problem still exists, please contact your local Product Distributor.

Product regulatory information includes safety, EMC and other related regulation requirements of the product and its accessories.

5 Standards and Specifications

5.1 Medical Equipment Safety Standards

• Medical equipment classification

Protection type against electrical shock	Externally powered equipment, using DC power supply
Protection degree against electrical shock	With type BF applied part BF
Protection degree against water penetration	IP68 (intraoral sensor part) IPX0 (control box)
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in situation with flammable anesthetic mixture with air, oxygen or nitrous oxide Not suitable for use in oxygen-rich situation
Both i-Sensor H1/ i-Sensor H2 are only one power supply and signal input and output part, both the power and signal via a USB port to connect to a PC.	

• Safety standards reference

Digital Intraoral X-ray Sensor safety standards cover the sensor, charger, battery pack and other accessories.

IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012)	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance

EN 60601-1:2006+A11:2011+A1:2013+A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601- 1:2005/(R)2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CAN/CSA-C22.2 No.60601-1:14	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
KS C IEC 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
IEC 60601-2-65:2012+A1:2017	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
CAN/CSA-C22.2 NO. 60601-1-6:11+A1:2015	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability

KS C IEC 60601-1-6:2011	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
EN 60601-1-6:2010+A1:2015	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic disturbances– Requirements and tests
EN 62304:2006/AC:2008	Medical device software – Software life-cycle processes
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
ISO 15223-1:2016	Medical devices-symbols to be used with medical device labels, labeling and information to be supplied–Part1:General requirements

5.2 Guidance and manufacture's declaration for EMC

EMI Compliance Table

• Emissions

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment

EMS Compliance Table 6. EMS

• Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Near fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table “Near fields from RF wireless communications equipment”
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

• Near fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

- Input a.c. power port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

• Recommended separation distances between portable or mobile RF communication device and sensor

Recommended separation distances between portable and mobile RF communications equipment and the sensor			
The sensor is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the sensor as recommended below, according to the maximum output power of the communicationsequipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter(m)		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,7GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3

10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.
NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 3 Portable and mobile RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the sensor.

• Cable provided for EMC

Cable	Recommended length	Shield/Unshielded	Number	Cable classification
DC power and signal cable	< 3m	Unshielded	1 piece	DC power and SIP/SOP

• Electromagnetic Compatibility (EMC)

The i-Sensor H1/ i-Sensor H2 Digital Intraoral X-ray Sensor need special precautions regarding EMC, and should be installed by authorized personnel and follow EMC guidance in the user manual. The i-Sensor series product when in use may interfere with portable and mobile RF communication devices such

as mobile (cellular) telephones. Electromagnetic interference may result in incorrect operation of the system and a potentially dangerous situation.

The i-Sensor series Digital Intraoral X-ray Sensor should not be stacked with or adjacent to other devices. If inevitable, verify the detector.

The i-Sensor series Digital Intraoral X-ray Sensor conforms to this EN60601-1-2:2015 standard on both immunity and emissions.

Accessories, transmitters and cables other than those specified by the user manual or sold together with product may result in increased emissions or decreased immunity of the detector.

5.3 Environmental Directive

Europe WEEE directive ROHS(2011/65/EU)

PFOS legislation(No.757/2010) REACH legislation(No.1907/2006)

Cadmium legislation (Controlled substance: Annex XVII)

REACH legislation (No.1907/2006) (SVHC: Annex XVII)

EU Packaging Directive(94/62/EC)

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Website: http://www.glwoodpecker.com
EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

Digital Intraoral X-ray Imaging System

Name of Customer		**(Return to Manufacturer)**
Tel		
Address Details		
Postal Code		
Model		
Product No.		
Purchase Date		
Contact Person		
Date	**Maintenance Record/Repairer**	

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Fax: +86-773-5822450
E-mail: woodpecker@glwoodpecker.com, sales@glwoodpecker.com
Website: http://www.glwoodpecker.com

Distributor:

Seal

Cut along the dashed line

Warranty Instruction

1. Period validity:

Since the date of sales ,the main unit can enjoy warranty for 24 months with warranty card.

2. Range of warranty:

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

3. The following are beyond our warranty:

a. The damage caused by disobeying the operation instruction or lack of the needed condition.

b. The damage caused by unsuitable operation or disassembly without authorization.

c. The damage caused by unadvisable transportation or preservation.

d. There isn’t the seal of distributor or the warranty card isn’t filled in completed.

Digital Intraoral X-ray Imaging System

Name of Customer		(For Distributor)
Tel		
Address Details		Guilin Woodpecker Medical Instrument Co., Ltd. Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China Europe Sales Dept. Tel: +86-773-5873196, +86-773-2125222 North America, South America & Oceania Sales Dept. Tel:+86-773-5873198, +86-773-2125123 Asia & Africa Sales Dept. Tel:+86-773-5855350, +86-773-2125896 Fax: +86-773-5822450 E-mail: woodpecker@glwoodpecker.com, sales@glwoodpecker.com Website: http://www.glwoodpecker.com
Postal Code		
Model		Distributor: Seal
Product No.		
Purchase Date		
Contact Person		
Date	Maintenance Record/Repairer	

Cut along the dashed line

Warranty Instruction

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